GE Healthcare

Marquette™ 12SL™ ECG Analysis Program

Physician's Guide

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Publication Information

The information in this manual only applies to 12SL version 23. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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A	3 April 2015	Internal release.
B	13 July 2015	Customer release.
C	29 March 2019	Updated for new findings.

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http://apps.gehealthcare.com/servlet/ClientServlet?REQ=Enter+Documentation+Library, and click **Cardiology**. To access Original Equipment Manufacturer OEM) documents, go to the device manufacturer's website.

Intended Audience

This manual is intended for qualified health care professionals using the 12SL ECG Analysis Program. It may also be useful for those who are not responsible for interpreting 12-lead ECGs but want to learn more about the capabilities and limitations of this medical device. See Contents for more details.

Manual Purpose: Ancillary Documentation, Product Labeling

GE's Marquette 12SL ECG Analysis Program is a prescriptive class II medical device, cleared by the Food and Drug Administration (FDA). The 12SL program does not directly acquire the ECG signal. It is used as a component in devices such as electrocardiographs, which digitize the analog ECG, and in computer systems, which receive digital 12-lead ECGs from other sources so that an initial ECG interpretation can be generated by 12SL for review and correction by a physician.

The International Electrotechnical Commission (IEC) requires manufacturers to disclose the performance of ECG analysis programs used in diagnostic electrocardiographs. "The intent is that this performance information be readily available to customers who want to know the information. The intent is not to require expansion of OPERATOR documentation to include this performance information. This information may be disclosed in one of the documents that are created and made generally available by the manufacturer of an ELECTROCARDIOGRAPH. Examples of these documents are physician's guides and technical notes, in addition to the OPERATOR's guide."[1]

This *12SL Physician's Guide* is not an operator manual. It is ancillary to the operator's manual and is considered product labeling. What the FDA terms "product labeling" extends beyond what is printed on the medical device or in an operator manual. It is brochures or any material regarding the product. If a manufacturer discloses the accuracy of the program in its Physician's Guide, it needs evidence to support it.

Intended Use of Computerized ECG

Computerized electrocardiography has been in existence since the late 1950's.[2, 3] Despite its widespread use,[4] there is little written that directly addresses the intent of computerized electrocardiography.

The pioneers of this technology had motivations which ranged from the esoteric - like demonstrating that a computer could mimic human intelligence - to the basic need of recording artifact free tracings.[5] Some of the favorable developments which resulted from the evolution of this technology were hardly imagined at its inception. For example, computerized ECG has been shown to reduce the cost of managing ECG services, especially as the volume of ECGs that need to be interpreted increases.[6] A major reason for this is that it reduces "analysis time by up to 24% to 28% for experienced readers."[7]

It should be made clear that a computerized analysis of the ECG is not a substitute for human interpretation. Statements of accuracy need to be viewed from a statistical perspective. Although accuracy levels may be high, outliers can and will exist. A computer does not have the ability to include the entire clinical picture of the patient. A person with organic heart disease can exhibit an ECG within normal limits. In a study of 391,208 patients with acute myocardial infarction, the initial ECG obtained in the emergency department was normal in 30,759.[8] Conversely, a normal individual can have an abnormal appearing ECG.[9, 10] The ECG must always be reviewed by a physician in the context of the patient and acted upon with sound clinical judgement.

Intended Use of 12SL Program as Registered with FDA (as recorded in 510k# K141963, cleared July 2014)

The 12SL ECG Analysis Program assists the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. The interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patients' homes.

The ACS Tool option is intended for adult patient populations who are suspected clinically to have acute coronary syndrome.

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Introduction

The Marquette™ 12SL™ Program: A Brief History

The Marquette™ 12SL™ program has been in existence since 1980. It was the first commercially available program to analyze all 12 leads simultaneously recorded for the entire 10-seconds of the diagnostic resting ECG. In 1982, the 12SL program was embedded into a computerized electrocardiograph known as the MAC-II. It was the first of its kind, generating a 12 lead interpretation at the bedside in less than 10 seconds.[11]

Since then, GE Healthcare has continued to evolve the Marquette™ 12SL™ program. The Marquette™ 12SL™ program has been validated on a variety of platforms beyond the diagnostic electrocardiograph, including bedside monitors, stress-testing systems, pre-hospital defibrillators, Holter recorders, and PC-based systems.

ECG Analysis/12SL Timeline

1980 – 12SL™ program introduced on MUSE™ system[11]

1982 – Incorporated into a computerized electrocardiograph: MAC-II™[11, 12]

1984 – 12SL™ Serial Comparison program[13]

1986 – Automated testing of 12SL using non-ECG, gold-standard databases[14]

1987 – Pediatric analysis, based on Davignon tables, incorporated into 12SL[15]

1988 – Analysis of extra leads, generating vector loops at an electrocardiograph[16]

1989 – Recognition of ST-elevated acute myocardial infarction (MI) in prehospital setting[17]

1991 – 12SL™ in a pre-hospital defibrillator equipped with 12-lead ECG[18]

1992 – 500 samples per second analysis, compression and storage[19]

1993 – 12SL™ in a bedside monitor, equipped with 12-lead ECG[20]

1995 – ACI-TIPI integrated into 12SL for prediction of acute cardiac ischemia[21]

1997 – Automated QT dispersion and T-wave principal component analysis.[22]

1998 – ECG Research Workstations for systematic assessment of ECG measurements[23-25]

1999 – MacRhythm: 12SL™ incorporates asynchronous P wave detector based on QRS subtraction[26]

2000 – Gender specific acute MI criteria[27]

2001 – Improved pacemaker detection using ECG acquired at 4,000 samples per second (SPS)[28]

2002 – 12SL™ in a Holter recorder, equipped with 12 lead ECG[29-31]

2003 – New 12SL™ QT algorithm,[25] validated by core lab on more than 40,000 ECGs[32]

2004 – Pattern recognition of noise via Hook-up Advisor™ tied to interpretation performance[33]

2005 – 12SL™ cleared for measurement and trending of 12-lead ambulatory recordings[34]

2006 – Recognition of acute right ventricular infarction via analysis of V4R[35]

2010 – Detection of biventricular and low energy artificial pacing on data acquired at 75K SPS[36]

2011 – Acute coronary syndrome tool based on the use of a neural network[37]

2012 – T-wave morphology measures related to hERG channel block[38-46]

2014 – Detection of left ventricular hypertrophy (LVH) in accordance with ACC recommendation[47]

2015 – Detection of Brugada Type 1 pattern in accordance with ESC guideline[48]

2017 – Combined LVH criteria improves prediction of stroke, myocardial infarction, etc.[49]

Hazard Information

The terms Danger, Warning, and Caution are used throughout this manual to point out hazards, and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance.

Hazard is defined as a source of potential injury to a person.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

Additional safety messages that provide appropriate safe operation information may be found throughout this manual.

WARNING:
INTERPRETATION HAZARD
12SL analyses should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and or invasive tests.
12SL analyses must be reviewed by a qualified physician.

Prescription Device

CAUTION:
United States federal law restricts this device to sale by, or on the order of, a physician.

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An Overview of 12SL in Two Parts

To show an overview of the Marquette 12SL ECG Analysis Program, we can follow the same steps the software uses to analyze an ECG. Start with acquisition, followed by detection, measurement, etc. Often, a physician wants to know the clinical evidence regarding the performance of the program, not the steps it took to analyze the ECG. Consequently, this manual is divided into two parts:

Part I: Criteria and Methodology

Part II: Statement of Validation and Accuracy

A side-effect of approaching this from both perspectives is that portions of the document will appear redundant. Whenever Part-II happens to cover the same topic as Part-I, the emphasis will not be on the "how", but rather, "how well" the program performed the task. Given there are over a hundred peer-reviewed scientific articles about 12SL, there are well over a hundred pages of performance metrics that must be presented in a series of tables using a format defined by the IEC. The approach of dividing the ***12SL Physician's Guide*** into two parts allows the guide to be used as a reference manual. Instead of having to read the ***12SL Physician's Guide*** from cover-to-cover, you should be able to find the information you need using the table of contents and the hyperlinks provided throughout the document.

Part I: Criteria and Methodology

Digitization of the Analog ECG

Simultaneous 12-Lead Acquisition

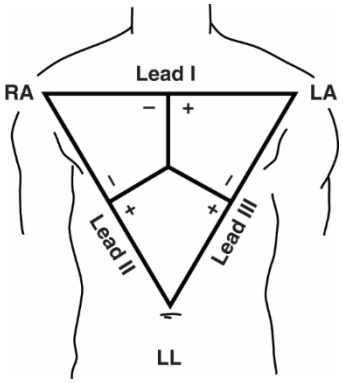
In 1979, GE Healthcare introduced simultaneous recording of 12 leads so that the computer could use all signals from all 12 leads to properly detect and classify each QRS complex.[11, 12] The Common Standards for Electrocardiography independently verified the advantage of this technique:

> *"Conclusion: The simultaneous recording and analysis of all 12 standard leads…is certainly an improvement over the conventional recording of three leads at a time. Similarly…multi-lead programs proved to be more stable than those obtained by conventional programs analyzing three leads at a time…"*[50]

Although the 12SL program can be used in a variety of ECG devices, the 12SL program only analyzes data simultaneous recorded for 10 seconds from at least 12 leads. Eight of the leads are acquired directly (I, II, and V1 through V6). The remaining four are derived via Einthoven's law (III) and Goldberger's equations (aVR, aVL, and aVF):

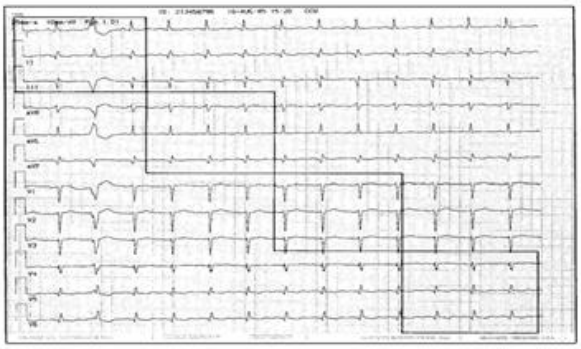
- III = II - I
- aVR = -(I + II)/2
- aVL = I - II/2
- aVF = II - I/2

Because of the inherent relationship of the standard limb leads to each other, Einthoven stated that at any given instant during the cardiac cycle, the sum of the potentials of leads I and III equals the potential of lead II. Similarly, Goldberger said that the sum of the three augmented leads at any instant in time equals zero (aVR + aVL + aVF = 0).



Most formats show only a portion of the 12-lead, 10-second data. An example of this is the standard 12-lead presentation which displays only 2.5 seconds from each of the 4 lead groups. Regardless of the data that you see, the complete data is always acquired. This is used by the 12SL analysis program for precise waveform measurement. It also allows you to choose from a multiple set of formats for accurate rhythm and contour diagnosis.

This ability to acquire all leads simultaneously complies with the American Heart Association recommendations.[51]



Sampling Rate

All resting electrocardiographs currently sold by GE Healthcare, analyze the waveform at a minimum of 500 samples per second (SPS). In some GE Healthcare resting electrocardiographs, the ECG is sampled at a much higher rate, such as 4,000 SPS. This is referred to as over-sampling and it used by the device to generate an average, cleaner signal at 500 SPS. Specifications for electrocardiographs, across the industry, often cite the raw sample rate (e.g. 4K SPS or higher) without clarifying that the ECG analysis and measurement software executes on data with a lower sample rate. Current guidelines for resting ECG analysis cite 500 SPS,[52] which is the minimum sample rate executed by 12SL. In some GE Healthcare electrocardiographs, the 12SL program can be configured to analyze the ECG at 1,000 SPS.

Before the physiological data is sampled, analog filtering is applied. These filters attenuate high-frequency electrical noise that is not part of the physiological signal. If these analog filters were not present in the device, high-frequency signals could be digitized by the device and appear as low frequency noise, inter-mixed with the physiological cardiac signal. To eliminate this possible source of contamination, GE Healthcare applies an analog filter, known as an anti-aliasing filter.

To detect high-frequency artifacts generated by electronic cardiac implants, GE Healthcare developed a patented[53, 54] high-bandwidth acquisition system that runs in parallel with the acquisition system for the physiological signal.[55-57] In some systems available from GE Healthcare there are two parallel digital data streams for analysis: one at 2K SPS (for the physiological signal from 0.04 to 250Hz), the other at 75K SPS (for pacemaker detection from 22 to 11KHz). The pacemaker channel is analyzed at 75K SPS.

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Hookup Advisor™

Operator manuals exist for all GE Healthcare devices that acquire ECGs. These manuals specify proper electrode positions and patient preparation for obtaining a quality ECG. The following serves as a reminder to physicians and administrators the importance of quality control. This is especially true given how ECG services are often dispersed throughout the hospital, diminishing the role of the "Heart Station" in setting acceptable standards.

GE Healthcare's Hookup Advisor™ scores the 12-lead ECG for signal quality and encapsulates this information with the ECG before it is sent to the MUSE system. From there, analytical tools available on the MUSE system can be used to determine the origin of poor-quality ECGs so that corrective action can be taken.

Hookup Advisor provides real-time feedback to the person acquiring the ECG. Hookup Advisor statements appear only on the screen during ECG acquisition on cardiographs that have the Hookup Advisor turned on. These statements never appear in an original interpretation.

Methodology Based on Pattern Recognition, Not Skin Impedance

As opposed to measuring skin impedance, which has been found to be poorly correlated with signal quality,[58] Hookup Advisor uses pattern recognition on ECGs manually scored by cardiologists for acceptable quality. After such training, automated quality scores generated by Hookup Advisor have been found to be predictive of the accuracy of automated interval measurements as well as rhythm interpretations.[33, 59] See graphs of reported performance metrics for Hookup Advisor in Part II.

Proper Electrode Placement for Diagnostic Resting ECG

In addition to artifacts, incorrect placement of electrodes can have a negative impact on the diagnostic value of the ECG. Although a limb-lead reversal has the most pronounced effect, a study of 150 subjects found that moving limb electrodes onto the torso shifted the P/QRS/T axis rightward and eliminated approximately 50% of significant Q-waves in cases of an old inferior infarction.[60]

Although less obvious than a limb lead reversal, swapping chest electrodes is a common cause of poor R-wave progression and false positive interpretations of anterior-septal infarction.[61] In a study of 60 patients with known cardiac disease, ECG morphology changes became evident when chest electrodes were moved beyond 2 cm from their proper location, with V2 being the most sensitive to displacement errors.[62]

Electrode Placement: Continuous Monitoring versus Diagnostic 12-lead ECG

In some monitoring environments, all 6 chest leads are applied with the result being that continuous 12-lead ECGs can be acquired by the monitor. Under this circumstance, the limb leads are usually put back on the torso using the Mason-Likar or Lund positions.[63] As already stated, this results in QRS axis changes and, in some case, the elimination of significant Q-waves in inferior leads. This practice is done to reduce noise and the tangling of lead wires since

in the monitored patient has been shown to be beneficial for capturing transient ST/T wave changes due to acute ischemia,[64, 65] T-wave alternans,[66] complex drug-induced T-wave changes[67, 68] or transient arrhythmias that need to be effectively localized for ablation.[69]

To reduce the confusion resulting from leaving the limb-leads on the torso, some institutions use the following techniques:

- Identify 12-leads coming from bedside monitors using a torso configuration for the limb-leads.
- Do not continuously send 12-leads to the MUSE system - instead, sequester the 12-leads in the monitoring environment that come from continuous acquisition.
- Send only 12-leads from the monitor that reflect an important change or only send those when the frontal plane configuration of the electrodes has been returned to the limbs.

Consistency of Serial ECGs

Even when the skin is marked as to where to place chest electrodes for repeat ECGs for serial analysis, normal day-to-day variation is considerable, especially with respect to QRS voltage measurement in the precordial leads.[70-72] Nevertheless, an undisciplined approach to recording ECGs increases the variability of ECG measurements and interpretive findings by both the computer and physician.[73, 74] This is unfortunate, given the growing evidence that serial ECG measurements can be predictive of heart failure or other serious clinical conditions.[75-78]

In conclusion, studies have shown a significant incidence of limb lead reversal and wide variability in chest electrode placement, even among experienced ECG technicians.[79, 80] Training in proper lead positioning has demonstrated a reduction in these errors.[81] Periodic retraining should be routine for all personnel who are responsible for the recording of ECGs as recommended in clinical guidelines.[82]

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Pacemaker Detection and Annotation

Over the last decade, there has been a significant increase in permanent pacemaker implantation as well as advancements in pacemaker technology.

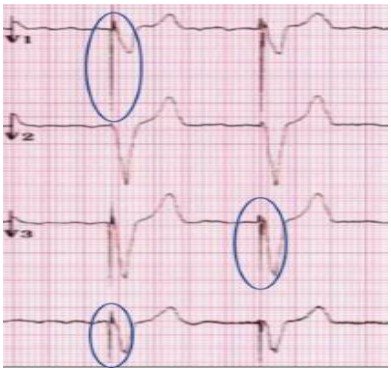
A worldwide survey found that virtually all countries showed increases in the number of pacemaker implants.[83] More specifically, the United States "had the largest number of cardiac pacemaker implants (225,567) and Germany the highest new implants per million population (927)."[83]

With regards to technological advancements of artificial pacing, consider the following:

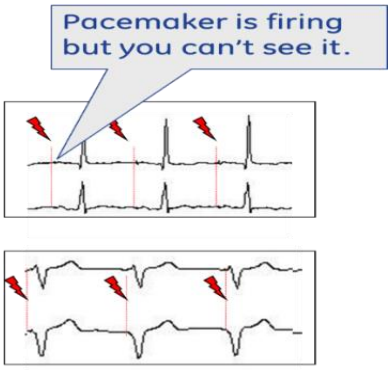
- Artificial stimulation used to be confined to a single location: the apex of the right ventricle. Fast forward to the advent of cardiac resynchronization therapy (CRT) and artificial stimulations occurring in the right atrium as well as the right and left ventricle. Now optimum resynchronization therapy is being explored via multipoint pacing of the left ventricle.[84]
- Lead wires used to only support unipolar pacing. Now even bipolar pacing is being replaced by leadless pacing.[85]
- Pacemaker pulses observed at the body surface were so large, standards had to be developed to make monitoring manufacturers avoid falsely detecting them as QRS complexes.[86] Now, they "are often too small to be recognized on the standard ECG."[51]
- The minimum timing intervals between artificial stimuli was relatively fixed and certainly greater than 100ms. Now these are configurable and the interval so small, multiple pulses can appear as single artifact on the surface ECG.[87]

Examples of Artificial Pacing, Then and Now

Older Pacing Technology



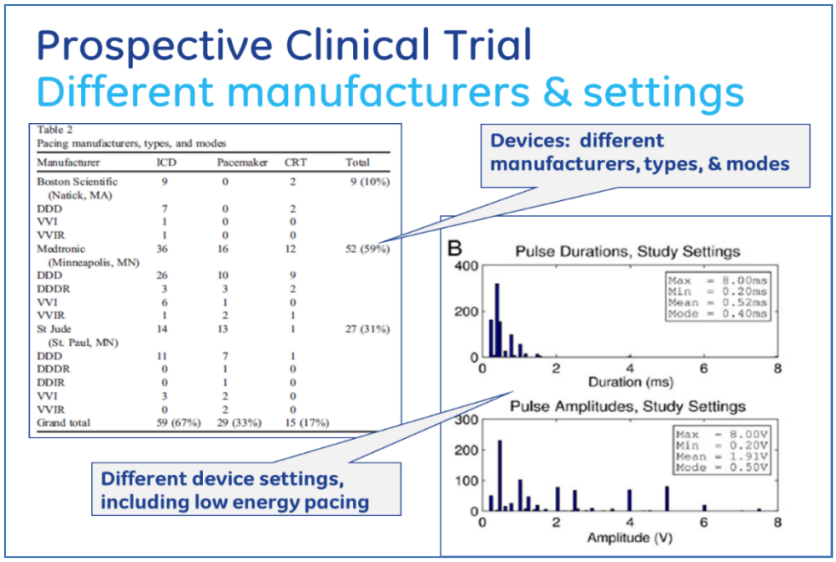
Contemporary Artificial Pacing



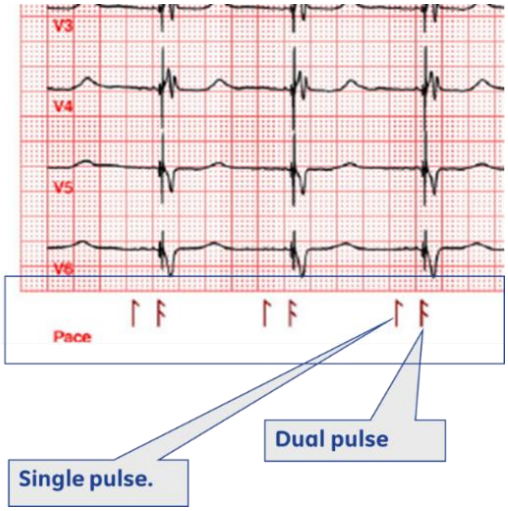
All of this makes the interpretation of the paced ECG difficult and given it has been reported that roughly 10% of in-hospital ECGs are paced,[88] it has become a significant challenge for both the computer[89] and human reader.[85, 90] To combat this, GE Healthcare (Milwaukee, WI) developed a new high-bandwidth acquisition system to detect artificial stimuli that runs in parallel with the acquisition system for the physiological signal. There are two parallel digital data streams for analysis: one at 2K SPS (the physiological signal from 0.04 to 250Hz), the other at 75K SPS (the pacemaker detector channel from 22 to 11KHz).

The pacemaker channel is analyzed at 75K SPS. By sampling the high-frequency spectrum, the challenge is to discriminate the electrical stimuli generated by the artificial pacemaker versus other high-frequency noise unrelated to pacing the heart, such as a left ventricular assist device (LVAD), pacemaker programmer or electro-static discharge.

In 2010, this system was prospectively evaluated on patients with implanted pacemakers (different vendors at different settings) and challenged with differing levels of noise.



The sensitivity for the detection of artificial pacing exceeded 99% while the positive predictive value remained at 100% regardless of the level of noise.[36] This system can detect pulses as small as .5mV and 0.2ms, which is several times more sensitive than the AAMI standard of 2mV and 0.5ms, and provides pacemaker annotations, including indications of biventricular pacing. In accordance with AHA/ACC/HRS recommendations, these annotations are supplied separately from the waveform in a "single row of the standard output tracing."[51]



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Signal Conditioning and Removal of Noise

In the presence of noise, both physicians and computers make frequent mistakes.[91] If there is a way to remove noise from the signal without reducing the clinical value of the ECG, it should be pursued. This is known as signal conditioning, done by removing signals that exhibit characteristics which could not possibly be generated by the heart.

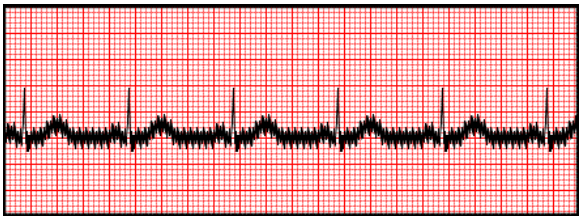
Fortunately, the characteristics of the P-QRS-T have been well studied and there is plenty of documentation as to the limitation of which frequencies can be generated by the heart.[1, 52, 86, 92, 93] Frequencies below 0.67Hz cannot be generated by the heart. If the recorded signal exhibits a waveform below 0.67Hz, it is not of cardiac origin.[94] Frequencies above 20Hz only occur during a QRS complex and only for a brief period of time (<20ms), such as during the onset, peak or notch of a QRS.[95] The duration of a QRS complex resulting from an intact conduction system can be no more than 140ms long.[96] As a result, a complex that is longer than 200ms which contains frequent, high-frequency components (>20Hz) cannot come from the heart; it is more likely due to electrode motion artifact.

The signal conditioning and removal of noise performed in conjunction with 12SL, includes the following topics:

- Removal of AC interference
- Removal of baseline wander
- Removal of high frequency artifact
- Upper cut-off frequency

Removal of AC Interference

A good example of a signal that has a characteristic which could not be generated by the heart is the signal that results from the radiated or conducted energy of wires or devices powered by alternating current (AC). As opposed to the QRS complex, AC interference is continuous and sinusoidal.



GE Healthcare electrocardiographs have a configurable setting for the removal of AC interference. The setting - either 50 or 60 cycles per second (Hz) - should match the line/mains frequency of the power grid where the electrocardiograph is operating. This allows the system to select a filter that specifically targets that frequency.

A filter that attempts to eliminate a single frequency from the spectrum of frequencies is often referred to as a "notch filter". Notch filter used in GE Healthcare's electrocardiographs does more than simply attenuate either 50 or 60Hz. It locks onto the artifact and measures its amplitude as well as shape. Instead of

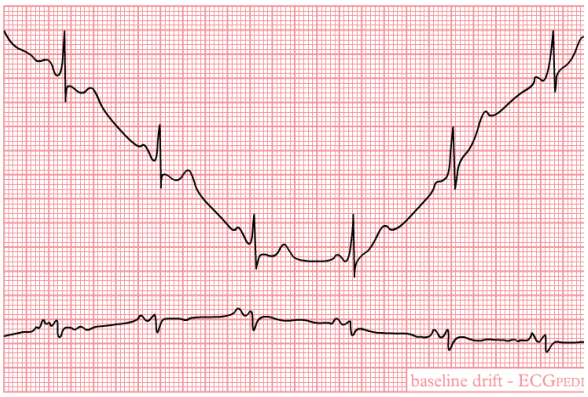
eliminating either 50 or 60Hz, the system forms a model of the noise and then subtracts it from the raw waveform.[97]

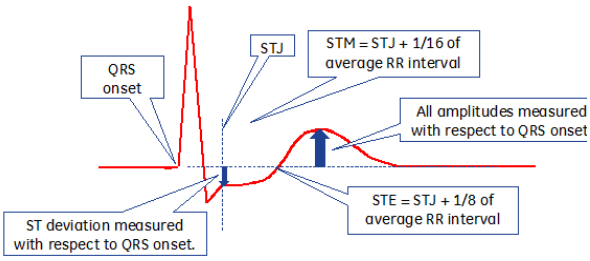
There a couple of advantages to an adaptive AC interference notch filter. First, the filter attenuates the signal at just the right amount – no more, no less. Secondly, because the filter is synched up with the AC interference, it does not attenuate the naturally occurring transient 50/60 Hz frequencies that reside within the QRS complex. This is because the model of the artifact only adapts to a continuous 50/60Hz signal, not a transient signal.

Removal of Baseline Wander

Baseline wander can be due to respiration, perspiration, body movements, loose electrodes, dry electrodes or the lack of using Ag/AgCl electrodes versus other electrode designs.[98] Measuring the ECG can be challenging in the presence of such artifact. In fact, if the baseline is wandering so much the signal does not remain on the page or saturates an amplifier, measurement of the ECG is not possible.

Even in mild cases of baseline wander, the assessment of the ST-segment deviation from the raw ECG will be compromised since its amplitude should be measured in relation to QRS onset. A representative complex generated from this data is not immune to the problem. It will incorporate the amplitude variation occurring across each QRS complex. This will be particularly noticeable in the ST- segment of the representative complex. The slope of the ST segment will be a composite of the wandering baseline immediately following each QRS.





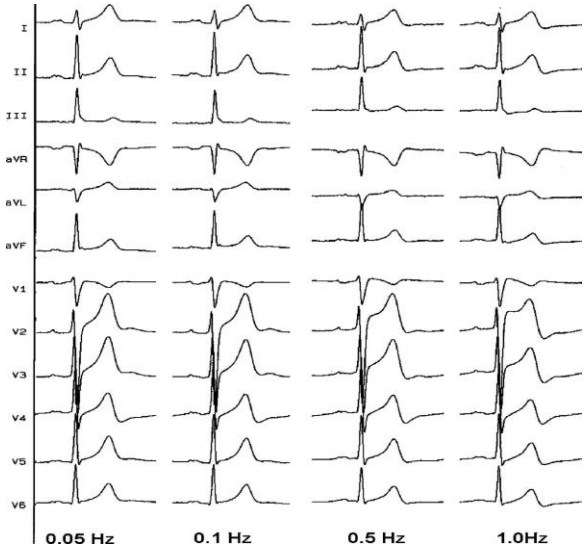
Baseline wander is a low frequency signal. Filters that remove low frequencies are referred to as high-pass filters since they pass along higher frequencies yet leave behind lower frequencies.

To deploy a high-pass filter, it is important to know the lowest possible frequency generated by the heart so that it will remain untouched by the filter. This can be determined via the heart rate. If the heart rate is 60 beats per minute (bpm), the lowest possible frequency is 1 cycle per second or 1Hz. "Heart rates below 40 bpm (0.67 Hz) are uncommon in practice."[51] The 2007 ACC/AHA recommendations for standardization of the ECG stipulate that frequencies below 0.67Hz can safely be removed from the ECG.[51]

Not all high pass filters are alike. Some not only attenuate low frequencies but shift them in time versus the high frequency components of the signal. This is known as phase distortion.

Following is an example of the use of a high pass filter that exhibits phase distortion.[99] As the filter setting progressively goes beyond 0.05Hz, the ST segment becomes so distorted it appears to be an ST-elevated acute myocardial infarction (STEMI). While using a high pass filter with phase distortion, the only way to preserve the ST segment is to use a less aggressive filter setting (≤.05Hz.). This comes at the expense of not correcting the baseline.

Example of ST-Segment Distortion Due to High-Pass Filter from the Literature.[99]



With the advent of digital sampling and storage of the ECG, high-pass filters can be designed so that they have zero phase distortion (ZPD). The use of a ZPD high-pass filter at a setting of 0.67Hz can "correct baseline drift while preserving the fidelity of the ST-segment."[51]

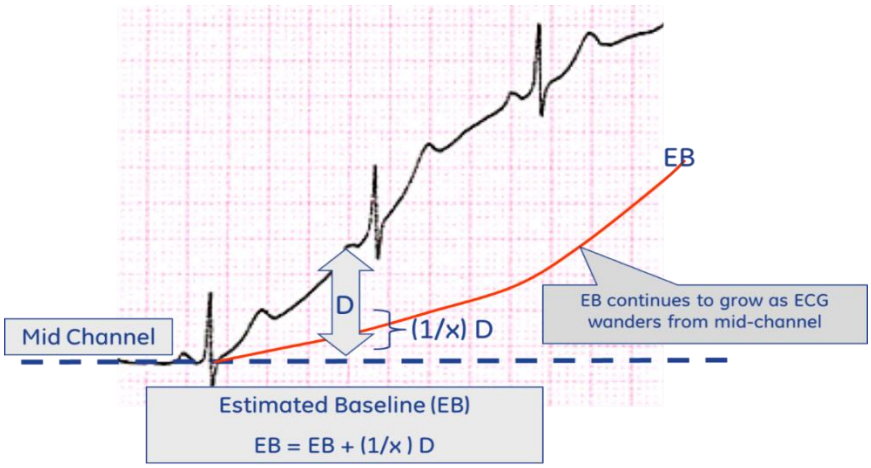
Since the introduction of the 12SL program, a ZPD high pass-filter (≤0.32Hz) has been used to remove baseline sway. Baseline wander is aggressively removed from the 12-lead report without ST-segment distortion. The representative complex generated by 12SL reveals a ST-segment not contaminated by baseline wander. Until recently, real-time rhythm strips were another matter.

Not until the advent of the MAC VU360 or MAC 2000 has it been possible to use a ZPD high pass filter when acquiring and printing continuous rhythm strips. Via these newer products, the ST segment on a continuous rhythm strip will be the same as the ST-segment on the 12-lead report, even at the most aggressive filter setting, which on the MAC VU360 is 0.56Hz. This means anyone printing a rhythm strip does not have to be trained to properly contend with the tradeoff of selecting the appropriate filter setting to either preserve the ST-segment with a lower setting (≤0.05Hz), or remove the baseline sway via a higher setting (>0.05Hz). With these newer products, the high-pass filter setting can be set once and behave the same way for both the rhythm and 12-lead report without ST-segment distortion.

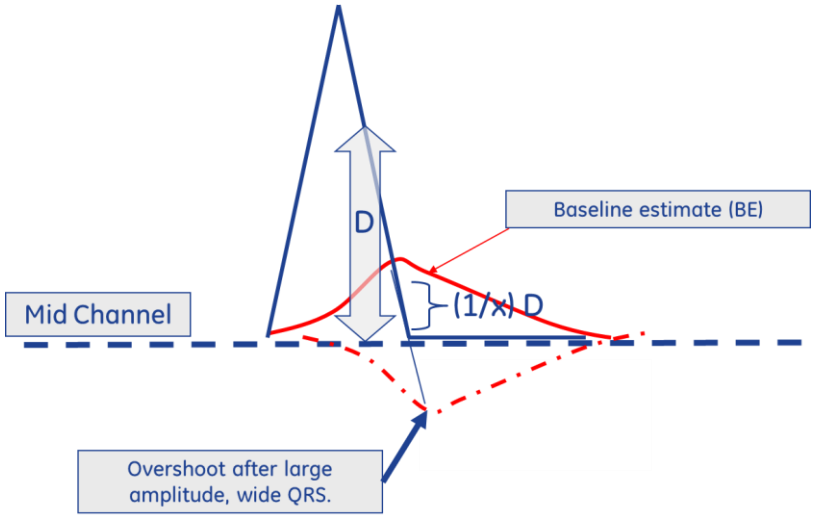
ZPD is an important advancement now available when printing a rhythm strip. Consider that a study conducted in an emergency department found, that as opposed to the 12-lead ECG reports, 93% of rhythm tracings had clinically significant alterations that could be construed as an acute coronary syndrome (ACS) due to the use of a baseline roll filter without ZPD at a setting of 0.5Hz.[100] ZPD on both the rhythm and 12-lead report eliminates this confusion.

The following four diagrams are useful for describing what changed in GE Healthcare's high-pass filter design. The first diagram portrays a high-pass filter that continuously corrects the baseline in real-time as the signal is acquired. The second diagram shows the ST-segment distortion that results when such a filter encounters a QRS complex that is either tall or long. The third diagram shows how 12SL can do the same operation without ST-segment distortion, because the system can correct the entire recording in both directions. The final diagram shows a high pass filter that utilizes digital rhythm. It digitizes the rhythm for a couple of seconds before correcting the waveform. In the latter case, the system can use the samples before and after the point where it corrects the baseline.

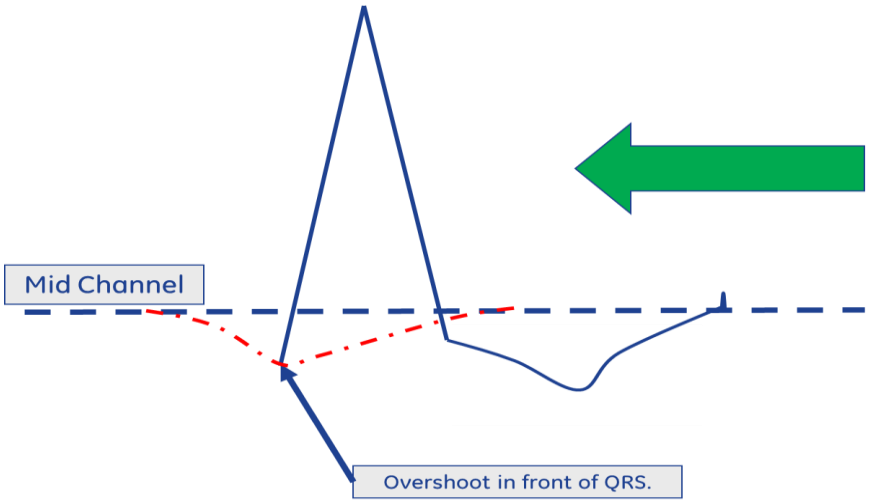
More precisely, the first diagram shows the computer estimating the baseline sway and then subtracting it from the incoming signal. In real-time, the amplitude of each sample is measured relative to the middle of the channel. The estimate of the baseline sway is determined by having a running tally of a fraction of these amplitudes. That fraction becomes larger as the high-pass filter setting increases.



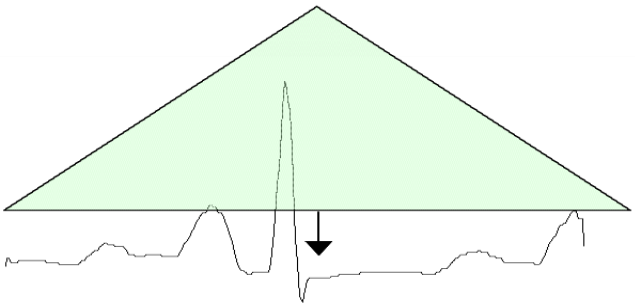
Unfortunately, this filter cannot discriminate between a large or wide QRS complex versus baseline sway. See figure below. The filter can be unduly influenced by the QRS, resulting in an overshoot immediately after the QRS. This effect is apparent in the ECG presented above. Note that those leads with the largest QRS complex (such as V2) have the greatest distortion while those leads exhibiting a smaller QRS complex (such as aVL) have almost no ST-segment distortion. When using a filter of this type, the distortion from the ST segment can only be eliminated using a filter setting of 0.05Hz, but the baseline wander will not be removed.



The 12SL program has always been able to remove low frequencies (i.e., < 0.32Hz) without ST-segment distortion. It does this by running this same filter, forwards and backwards, over the entire 10 seconds. In this way, both sides of the QRS are similarly impacted and the ST is no longer depressed in relation to QRS onset.



The MAC VU 360 and MAC 2000 have obsoleted this approach. Instead, the correction of each sample point is based on a weighted average of the samples before and after it.



To accomplish this on a scrolling rhythm strip, the signal must be digitized and buffered for a couple seconds before it is displayed. This 2 second delay enables the filter to aggressively correct the baseline without ST-segment distortion.

To keep abreast of the ACC/AHA recommendations, which relaxed the high-pass filter setting from 0.05Hz to 0.67Hz for filters capable of ZPD, IEC/AAMI issued new performance standards for the low frequency response of diagnostic electrocardiographs.[92] This includes a simple test which can be performed by a biomedical engineer to evaluate the low-frequency response of any electrocardiograph and determine whether it uses a high-pass filter with ZPD. A 3mV, 100ms square wave fed into an electrocardiograph should not result in an artifact that exceeds 100µV; otherwise the user must select a lower filter setting (0.05Hz) to preserve the ST segment.

Removal of High-frequency Artifact

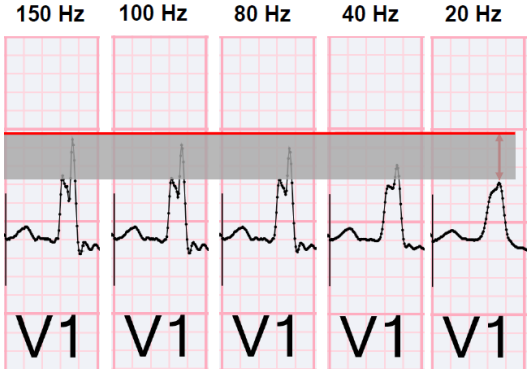
Electrocardiographs have various low-pass filter settings, including 40Hz, 100Hz, or 150Hz. The lower the filter setting, the more aggressively the filter removes high frequency signals, which includes noise due to muscle tremor, electrode-motion artifact, etc. These low-pass filters also operate on the entire ECG signal and attenuate all high-frequency elements of the ECG signal, such as the QRS complex and pacemaker artifacts. To consistently measure the resting ECG and capture the proper QRS amplitude, the 12SL program always analyzes the ECG at the AHA / AAMI recommended full bandwidth of 150Hz,[52, 93] regardless of the low-pass filter setting. These settings are sometimes referred to as “writer settings”, since they do not affect the ECG interpretation.

It should be noted, that all filter settings travel with the ECG. That is, the MUSE system can be configured to either portray the ECG signal as it was acquired at the electrocardiograph or at another specified filter

setting. Over-reliance on aggressive, low-pass filtering implies that the 12SL program is subjected to more high-frequency noise than the physician sees in a filtered ECG tracing.

Using an aggressive low-pass filter has significant consequences especially when comparing ECGs. The following is an example of an ECG waveform that is low pass filtered at different settings, all the way down to 20Hz.

Lead V1 in Presence of RBBB at Different Low-Pass Filter Settings



Notice that the most peaked aspects of the QRS complex are more attenuated by filtering. This is because the peaked components of the waveform contain the highest frequencies. Regardless of the filter setting, the shape and duration of the QRS complex indicates right bundle branch block (RBBB). Comparing any of these complexes could lead to the erroneous conclusion that a clinically significant change has taken place when, in fact, the "change" is due to filtering.

Upper Cut-off Frequency

The ACC/AHA/HRS recommendations for standardization of the ECG states that "to measure routine durations and amplitudes accurately in adults, adolescents, and children, an upper frequency cutoff of at least 150 Hz is required."[51] The ACC/AHA/HRS recommendation discusses a 250Hz cutoff for infants in relation to research performed in 2001 which reported higher QRS amplitudes at a bandwidth of 330 Hz in children.[101] Yet, in 2008, this same researcher found no clinical benefit in measuring the QRS amplitude at a cutoff frequency of 250 versus 150Hz.[102]

Extending the cutoff frequency from the required 150Hz to 250Hz, will generate more noise and increase the amplitude of the QRS.* It does not impact the amplitudes of the P or T-wave. The only value of measuring QRS amplitude is for the diagnosis of ventricular hypertrophy. When evaluating these higher QRS amplitudes versus ultrasound, Rijnbeek discovered for the detection of hypertrophy the "sensitivity decreased slightly (from 20% to 17%) while the specificity improved (from 88%–92% to 94%–100%)."[102] Even when applying customized criteria for hypertrophy, extending the cutoff frequency from the required 150Hz to 250Hz generated no clinical benefit.

It is important to consider that along with a higher cutoff frequency comes noise.[51] Despite the significant reduction in QRS amplitude, many users opt for applying a cut-off frequency at 40Hz to obtain the cleanest signal possible and yet still be able to identify rhythm as well as other contour-based diagnostic findings besides hypertrophy.[103]

* A higher cut-off frequency will also increase the amplitude of a pacemaker spike. In accordance with AHA/ACC/HRS recommendations, pacemaker annotations are supplied separately from the waveform in a "single row of the standard output tracing."

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Detection and Measurement

QRS Detection

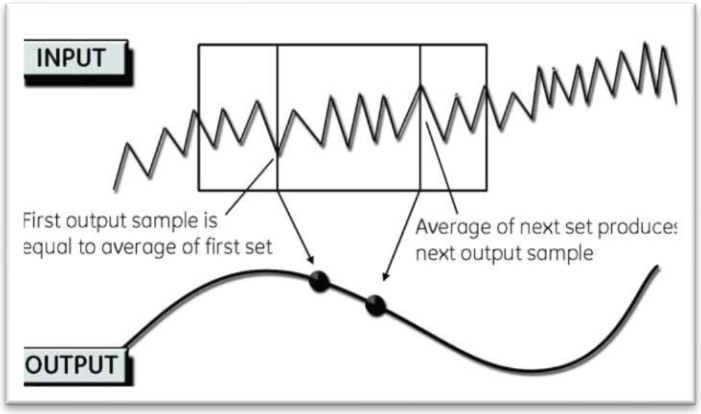
The first step in computerized ECG analysis is the identification of each QRS complex. This step is vital. If it is done incorrectly, all subsequent steps in the analysis will be in error. Since all 12 leads are available to the 12SL program, correct identification is maximized. Even when individual leads have low voltage complexes, the program can use all signals from all leads to properly identify each QRS.

Before the QRS detector can scan the signal data for something that resembles a QRS, it must first remove any pacemaker artifact. This is because pacemaker signals can be large in amplitude and they could fool the detector. The program identifies pacemaker artifact through two independent methods. Separately, the 12SL analysis program identifies pacemaker artifact in the ECG data by finding large amplitude spikes (greater than 1000 µV) or lower amplitude spikes (greater than 250 µV) that pass further scrutiny, so as not to be deceived by muscle artifact. Regardless of how the spikes are detected, the 12SL program remembers their height and position and then removes them. When the program is finished, it replaces these spikes.

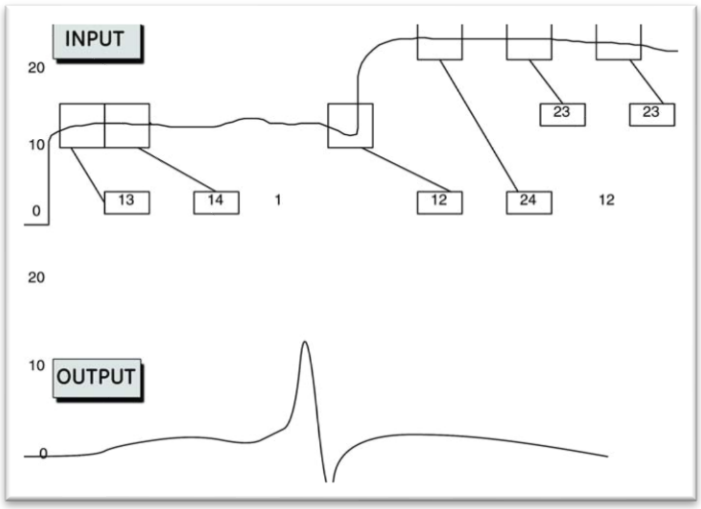
After the pacemaker spikes are removed, the QRS detector filters the data. It attenuates both low frequency and high frequency waves, leaving untouched the mid-band frequencies that are usually evident in the QRS.

This may sound complicated, but it is ultimately reduced to the adding and subtracting of samples. High frequencies are attenuated by adding samples together while low frequencies are attenuated by subtracting samples. See the following examples.

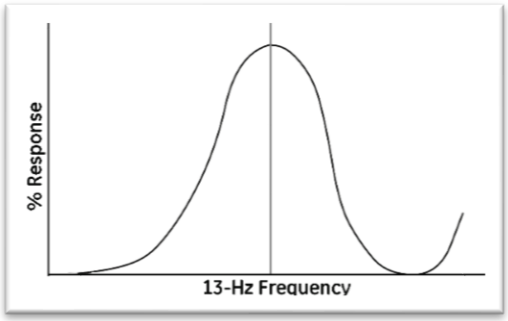
Reduce High Frequencies by Adding



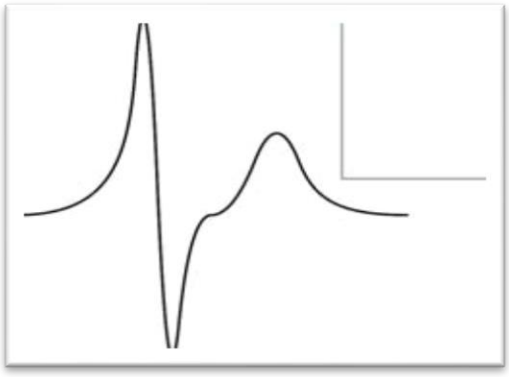
Eliminate Low Frequencies by Subtracting



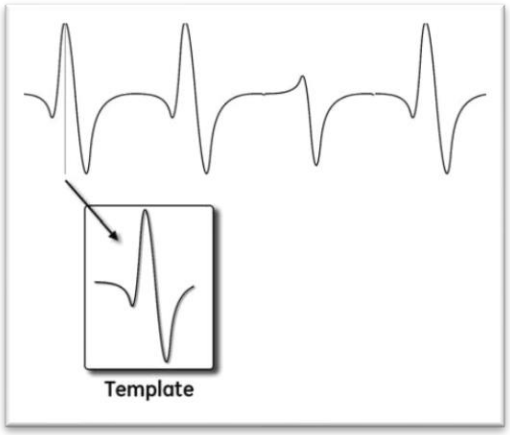
This filter makes the QRS detector more resilient in the presence of noise. It also decreases the probability of a false detection due to T waves. Following is a diagram of the frequency response of the QRS detector.



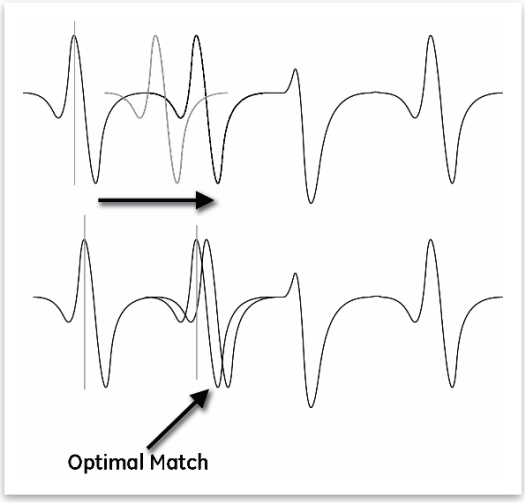
The output of this filter is summed across all 12 leads. Once the summed output crosses a specific threshold, a QRS is detected. To avoid the following T wave, the threshold is increased for a short period of time (200 ms).



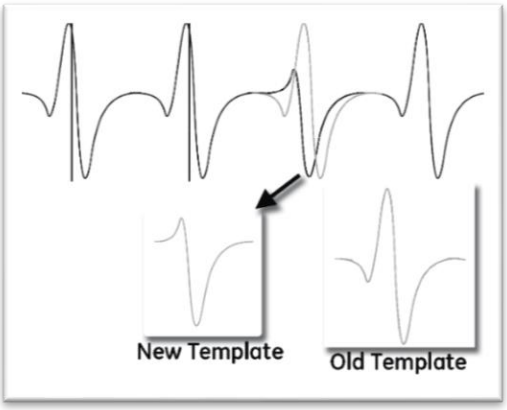
Once a QRS is detected, the 12SL analysis program makes a template of it for each lead.



From this point on, the QRS detector looks for the same shape. If it finds a match, the program classifies it as another QRS detection and slides the waveforms past one another looking for the optimal match. This sample time will be used later when we form a composite cycle.



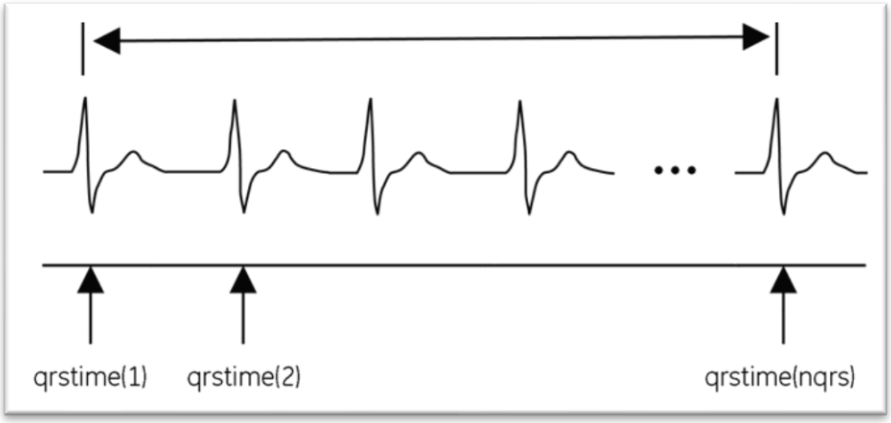
If the filter output exceeds thresholds, but there is no match, it is assumed that a different beat type has been detected and an additional set of lead templates is made for further matching tests.



In summary, the QRS detector uses filter and template matching techniques to both detect and group, by shape, the QRS complexes which occur in the ECG record. The QRS detector also defines the points in the ECG record that can be used to align in time, with maximum correlation, the respective beats of a beat type.

Ventricular Rate Calculation – Average RR

After the QRS complexes have been detected, the ventricular rate is computed by counting the number of beats detected and dividing by the time difference between the first and last beats.



(number of QRSs - 1) beats
rate = 60000 msec/min*
(time difference between first and last QRS) msec

The number of R-R intervals (number of QRS complexes minus one) is divided by the time difference between the first and last beats, and the result is converted to units of beats per minute.

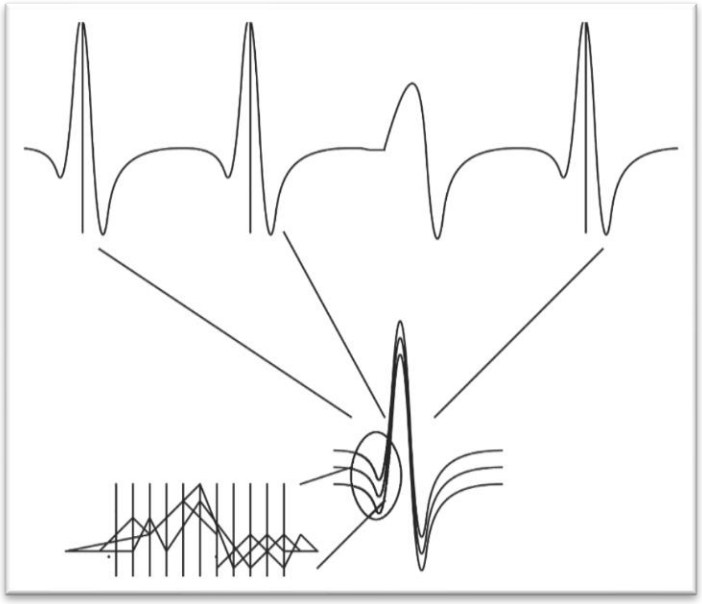
NOTE: For interpretation of Sinus bradycardia, Sinus rhythm, or Sinus tachycardia atrial rate is used, not the ventricular rate. The atrial rate is determined from the P wave detections. The atrial rate will equal the ventricular rate for most ECGs. I n cases of 2nd or 3rd degree AV blocks, for example, the atrial rate may legitimately differ from the ventricular rate.

Median Formation

Before any further signal processing takes place, the 12SL program must determine which beat type will be used for the morphology measurements. The 12SL program uses the RR intervals and the location of any pacer spikes to decide which beat type has the highest level of origin in the conduction system. This selection is not dependent upon the number of beats per beat type. The beat type which is most informative for analysis is the one sought after and any beat type with three or more complexes can qualify.

The beat type considered to be most informative of normal conduction is often referred to as the "primary beat type" or "dominant beat." Later in this guide you will see the rhythm criteria refer to "a normally shaped beat." This is a QRS complex with the same shape as the primary beat.

After a primary beat type has been chosen, each of its associated beats is used in generating a *representative (median) complex* for each lead. This is done using the sample times that were generated by the QRS detector. These times not only indicate the occurrence of a QRS, but they also indicate when the QRSs for a specific beat type are optimally matched. The representative complex is then generated with the median voltages from this aligned group of beats; that is, it is formed by taking, at each sample time, the middle voltage of the superimposed beats.



This process has several advantages. As opposed to other analysis programs, the alignment is done in all channels simultaneously. The problem of reconciling data from different lead groups is eliminated. This technique is excellent for diminishing noise. A median is better than an average. It disregards the contributions that could be made by outliers. The net result is the most artifact-free picture of the electromotive forces generated by the heart cycle.

Consider, for example, the following set of five voltages, which may be the voltages at the same point in the cardiac cycle of five beats of the primary beat type. The median is defined as the value at which half of the samples are above this value and half of the samples are below this value. For this example, the median is 10 (two samples are greater than 10 and two samples are less than 10). The average is 26. The average was greatly biased by the outlier value of 100, whereas the outlier did not unduly bias the median.

Median

0	5	10	15	100	Median is 10

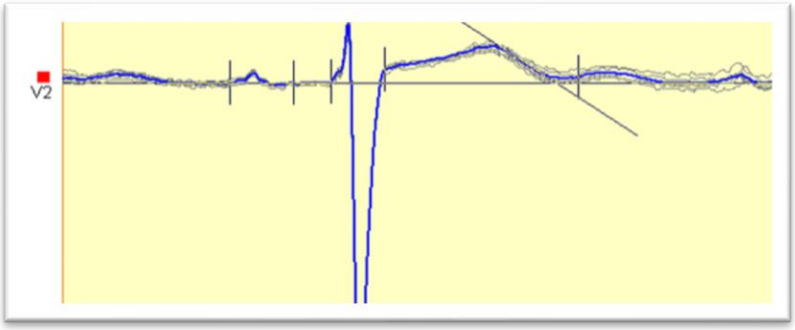
Average

0	5	10	15	100	Median is 26

Starting with 12SL version 22, ECG data acquired at 1,000 samples per second (SPS) can be analyzed at 1,000 SPS. Under this circumstance, 12SL generates an additional copy of the signal data at 500 SPS. QRS detection times are determined with the data at 500 SPS. 12SL then generates two sets of medians. One at 1,000 SPS; the other at 500 SPS. The medians at 1,000 SPS are formed first using the same principles as defined above. The medians at 500 SPS are formed by decimating (that is, averaging) the 1,000 SPS data down to 500 SPS.

Global Onsets/Offsets and Intervals

At this point, the median for the primary cycle has been established for each of the 12 leads. Since all leads were sampled and time aligned synchronously, the median complexes are also synchronous. Since noise has been eliminated, the accuracy of the identification of wave onset/ offset has been increased and the process simplified.



The onsets and offsets of the P, QRS, and T are found in a specific order. QRS onset is detected first because it is the easiest to find; the slope change is usually very rapid and in great contrast to the other slopes in the median. This is followed by QRS offset and T offset. Next, the representative complex is searched for a P wave. P waves will be found in the representative complex only if P waves are present and are synchronous with the QRS complexes. For example, junctional rhythms may not have a P wave and the P waves of Mobitz I (Wenckebach) second degree AV block will not have a constant PR interval and are asynchronous with QRS complexes. Finally, if a P wave is found, the onset and offset of the P wave are delineated.

When data has been acquired at 1,000 SPS, all onsets/offsets are still calculated at 500 SPS. This is done by using the additional set of medians that were formed at 500 SPS.

The onsets and offsets are determined by an analysis of the simultaneous slopes in all 12 leads. Onsets are defined as the earliest deflection in any lead, and offsets are defined as the latest deflection in any lead. The *QRS duration* is measured from the earliest onset in any lead to the latest deflection in any lead. Similarly, the QT interval is measured from the earliest detection of depolarization in any lead to the latest detection of repolarization in any lead. The PR interval is measured from the earliest detection of atrial depolarization in any lead to the earliest detection of ventricular depolarization in any lead (the QRS onset). A PR interval is reported only if synchronous P waves are detected (for example, P waves are detected and have a constant PR interval for each beat).

QT Correction Formulas

The QT interval is corrected for heart rate (QTc). The correction of QT based on heart rate is a large area of study. Not everyone agrees that Bazett should be used exclusively for calculating the corrected QT. At higher heart rates (HR > 100), Bazett has been criticized for being too sensitive. For these reasons, the 12SL program now supports the Bazett, Fridericia, and Framingham correction formulas.

$$\text{QTc (Bazett)} = \frac{QT}{\sqrt{RR}}$$

$$\text{QTc (Fridericia)} = \frac{QT}{\sqrt[3]{RR}}$$

$$\text{QTc (Framingham)} = \text{QT} + 0.154\ (1 - \text{RR})$$

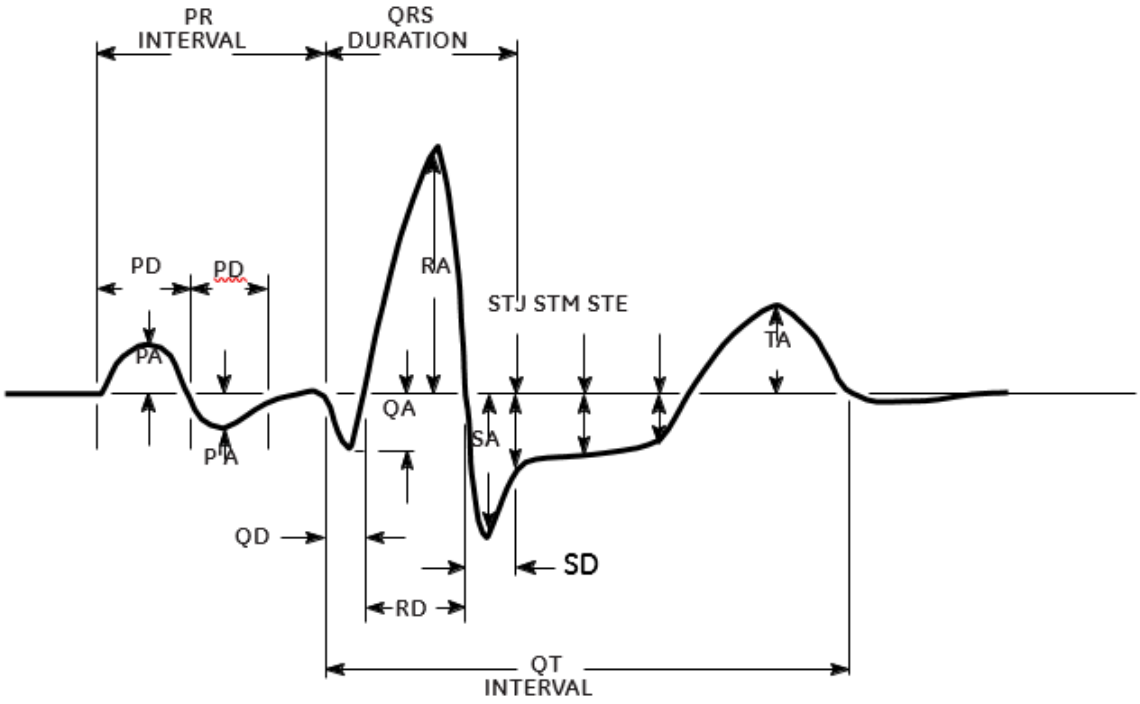
In all three formulas, QT and QTc are in milliseconds. RR is the average RR interval across the 10 second ECG. RR values in these formulas are in seconds.

NOTE: QTc will equal the QT interval for a heart rate of 60 bpm.
Not all products will display Fridericia or Framingham QTc.
Unless otherwise denoted on the ECG report, the reported QTc is the Bazett-corrected value.

Wave Measurement – Basis for Measurement Matrix

After the P, QRS, and T complexes have been demarcated in the median complex, the waves for each complex are identified. This is done separately for each lead. The program finds the points at which the signal crosses the baseline within each complex. If the crossing points define a wave that has an area greater than or equal 160µV-ms, the wave is considered significant. If the area is less than this value, the program considers the wave to be insignificant, and it will not label it as a separate wave.

The measurement matrix contains the amplitudes (with respect to QRS onset) and durations of all of these individual waves.

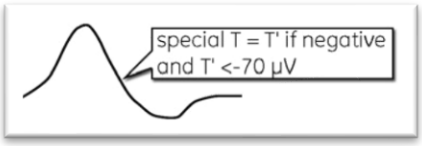


The median complex is shifted so that the voltage at the QRS onset is 0 by definition. All amplitudes and ST levels are voltages in µV with respect to the voltage at the QRS onset. The P, P', T, and T' amplitudes and the STJ, STM, and STE voltages may be positive or negative values, depending on whether the values are greater than or less than 0. Because the Q, S, and S' waves are always defined as negative deflections, their amplitudes are represented as positive values with the implicit understanding that they are negative deflections.

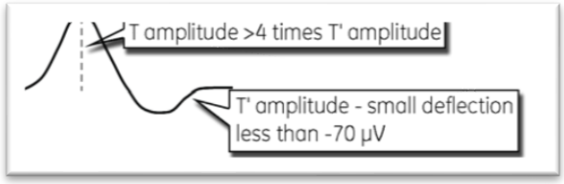
STJ is defined as the ST level (with respect to QRS onset) at the QRS offset (commonly referred to as the "J point"). STM is the ST level at the QRS offset plus 1/16 of the average RR interval. STE is the ST level at the QRS offset plus 1/8 of the average RR interval.

In addition to the individual wave durations and amplitudes defined on in the previous paragraph, the following quantities are also defined for each lead:

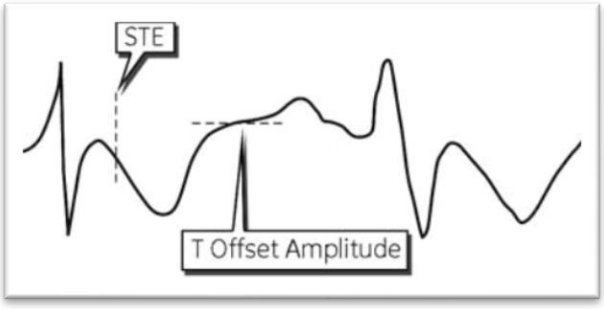
Maximum R amplitude	Maximum of the R or R' This is the maximum positive deflection.
Maximum S amplitude	Maximum of the Q, S, or S' This is the maximum negative deflection. (a positive value)
QRS balance	Maximum R amplitude – maximum S amplitude Will be positive if the QRS is predominately positive. Will be negative if the QRS is predominately negative. This is sometimes also referred to as "QRS amplitude" within this document.
QRS deflection	Maximum R amplitude + maximum S amplitude The maximum peak-to-peak deflection.
Minimum ST amplitude	Minimum of STJ or STM
Special T amplitude	Minimum of either T amplitude or T amplitude–STE This value reflects the T amplitude without ST segment effects. If the T' amplitude is negative, then the special T amplitude = T' amplitude If T amplitude >-70 µV and T' amplitude is 4 times greater than the T amplitude and the T' amplitude is positive, the special T amplitude is = T' amplitude



There is an exception to this if the T' is a small deflection. Specifically, if the wave is less than 70 µV and the positive wave is at least 4 times bigger than the negative deflection, it ignores the small negative deflection.

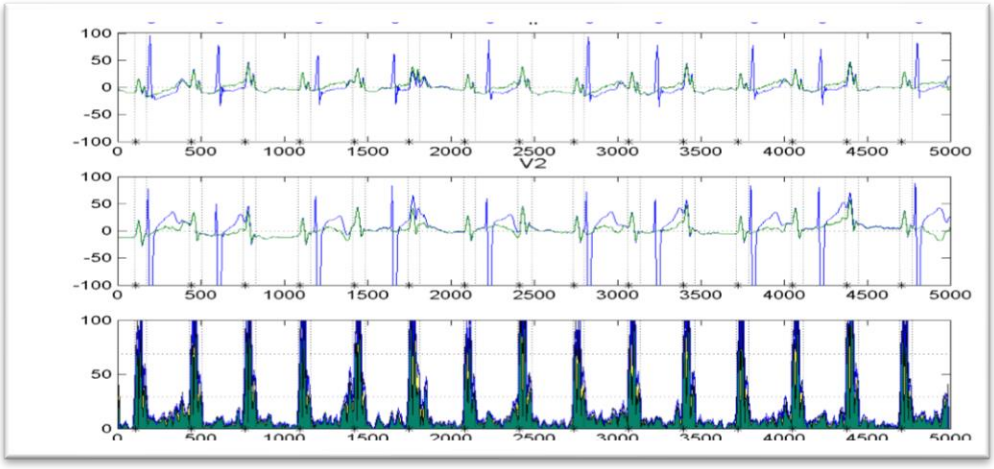


If T' = 0 and T amplitude is negative, then special T amplitude = minimum of either, minimum of T amplitude, or T amplitude – STE, or T amplitude – amplitude at T offset.

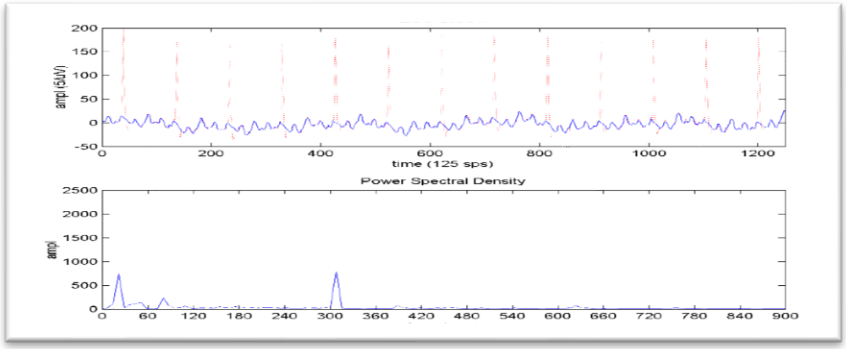


P Wave Detection

In addition to P wave detection in the median complex, the raw rhythm data is also analyzed for atrial activity following the QRS detection and median formation. All leads are first examined for the greatest probability of proper P wave detection. One of leads I and II is selected and one precordial lead (V1 - V6) is selected. The QRST portion of the median complexes of the two selected leads are subtracted from the corresponding QRST locations in the rhythm data as previously explained in the literature.[26, 104-106] Then, atrial waves (P, fibrillatory, or flutter waves) are detected from a composite signal of the two leads using a threshold based on the maximum values in the regions between the QRS complexes. Onsets and offsets of the detected atrial waves are delineated using a second threshold based on the baseline activity. Each detected atrial wave is assigned a confidence score based on how closely its measurements resemble those of most of the detected waves. Next, contextual analysis is applied to the measurements of the detected atrial waves, their confidence scores, and their temporal relations to each other and to QRS complexes. This is intended to exclude erroneously detected P waves and to perform a second search, using lower thresholds, for P waves that are suspected to be missing.



Mac Rhythm, the rhythm analysis component of 12SL, uses a QRST subtraction method to precisely locate P waves within the T waves for accurate rhythm interpretation. In addition to traditional time-domain criteria, a power spectral density provides improved sensitivity for detection of atrial flutter.



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Criteria – Rules for Interpretation

The intent of this section is to provide the criteria, that is the rules, which the 12SL program uses to interpret the ECG. A pediatric or an adult interpretation is available with the 12SL program If an age of less than 16 years is entered, the program employs pediatric as opposed to adult criteria. Age can also adjust thresholds within these two main bodies of criteria, as in the characterization of left ventricular hypertrophy. If age is not entered, the program enters a default adult age.

Age is used by the rhythm criteria but in very limited ways; for example, age is used to define normal sinus rates for pediatric ages. The rhythm criteria for both pediatric and adult analysis is presented as a single unit.

Morphology analysis cannot be presented as a single unit since a pediatric interpretation is not possible through simple adjustments of adult thresholds. A whole other approach is required. The morphology criteria for pediatrics and adults are presented separately, with the adult criteria presented first.

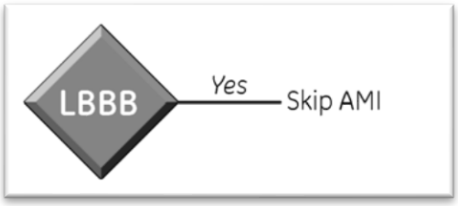
Rules for interpreting the ECG can be quite complex. This manual presents an overview of each unit before delving into the details. The hyperlinks presented below will allow you to skip to the section you are interested in finding.

Overview of Rhythm Criteria – Both Pediatric and Adult,33
Detailed Criteria for Predominant Rhythms – Both Adult and Pediatric,34
Detailed Criteria for Rhythm Modifiers,38
Overview of Adult Contour Criteria,47
Adult Contour Criteria Details,66
Pediatric Contour Criteria,105
Pediatric Contour Criteria Details,122

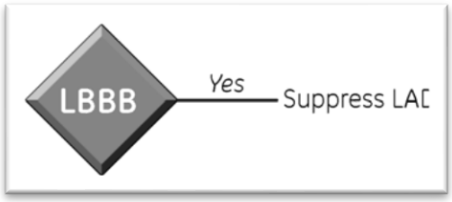
The following figures and flow-chart symbols are intended to facilitate the use of this guide:

- The flow of the program can be comprehended by viewing the drawings from top to bottom.
- The logic symbols are used to indicate tests that cause the program to proceed forward or to suppress statements that the program has already made. For example:

Proceed forward:

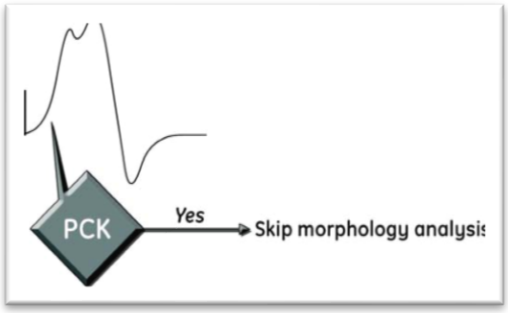


Suppress statement:



Most of the acronyms are obvious, but if they are not, consult the statement library acronyms in the appendix.

Rhythm criteria are presented first. This sequence is required because information regarding the rhythm is needed before a proper morphology interpretation can take place. For example, an artificially paced ventricular rhythm is not analyzed for myocardial infarction, etc.



Overview of Rhythm Criteria – Both Pediatric and Adult

The rhythm criteria first determine the origin of the predominant rhythm in the 10 seconds of analyzed data. The program chooses from the following major categories:

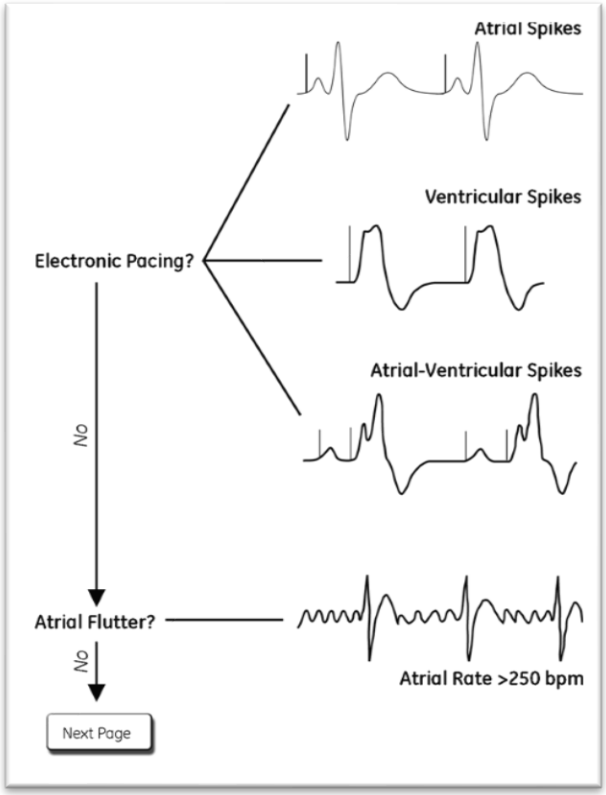
- Electronic artificial pacing
- Atrial flutter
- Ectopic atrial rhythm
- Sinus rhythm
- Junctional rhythm
- Atrial fibrillation

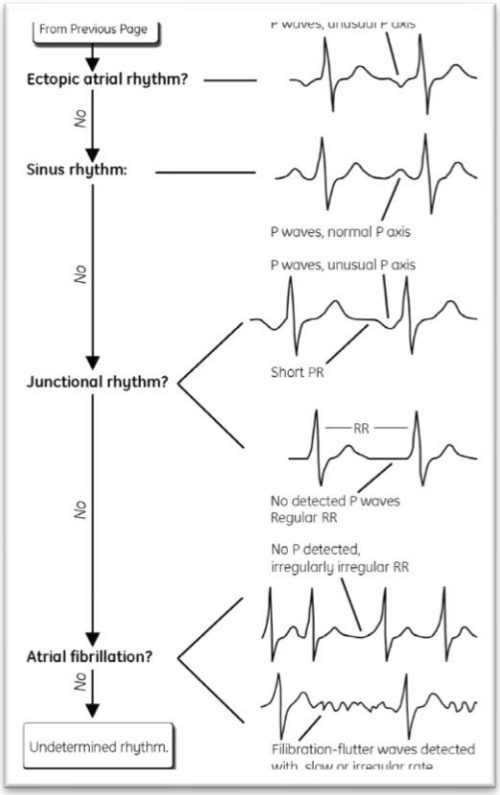
A set of statements exists for each of these categories; for example, sinus rhythm includes sinus tachycardia, normal sinus rhythm, sinus bradycardia, and marked sinus bradycardia. See details under Detailed Criteria for Predominant Rhythms – Both Adult and Pediatric.

If the program is not able to choose a rhythm that is described by one of the above categories, it defaults to the undetermined rhythm category. This category includes such statements as wide QRS tachycardia and supra-ventricular tachycardia; these describe the overall rhythm but refrain from defining the mechanism. If the rhythm cannot be labeled by these descriptive statements, the program states "Undetermined Rhythm."

After the program states the predominant rhythm, several rhythm modifier statements can be appended for abnormalities of conduction and/or ectopy. Some of the modifier statements are only used for specific rhythms. For example, the statement "with rapid ventricular response" is used only in conjunction with atrial fibrillation.

The following figure portrays in simplified graphical form the criteria for the predominant rhythms. Notice that if the program does not find a match in the first six categories, it defaults to the undetermined rhythm category. Since the use of the rhythm modifiers are dependent upon the stated predominate rhythm, the document will first describe the criteria that is used for determining the predominant rhythm. See Detailed Criteria for Rhythm Modifiers.





Detailed Criteria for Predominant Rhythms – Both Adult and Pediatric

There are seven categories of predominant rhythm statements.

Electronic Artificial Pacing,34
Atrial Flutter,35
Ectopic Atrial Rhythm,35
Sinus Rhythm,36
Junctional Rhythm,36
Atrial Fibrillation,37
Undetermined Rhythm,37

Each of these categories is presented with its associated statements. Each statement is shown in its actual wording, followed by the statement acronym, and any specific criteria associated with that statement. For statements that further define the rhythm, see Detailed Criteria for Rhythm Modifiers.

Electronic Artificial Pacing

This category requires that the predominant rhythm (i.e., the dominant beats) be artificially paced. The following statements are included in this category; they delineate the origin of the artificial pacing.

Rhythm Statement	*Acronym*	*Description*
Atrial-paced rhythm	APR	Pace spikes in front of P waves, where P waves are synchronous with QRS complexes.
Ventricular-paced rhythm	VPR	Pace spikes in front of QRS complexes and either no organized atrial activity or atrial activity asynchronous to the QRS complex.

Rhythm Statement	*Acronym*	*Description*
Atrial-sensed ventricular-paced rhythm	ASVPR	Pace spikes in front of QRS complexes which follow non-paced, organized atrial activity (for example, sinus or ectopic atrial rhythm)
AV dual-paced rhythm	AVDPR	Pace spikes in front of the P waves and the QRS complexes.

Although not "rhythm" statements per se, the following statements may be made regarding detected pace spikes. The generation of both of the following statements will depend on the specific product and version used in the acquisition of the ECG. Not all products or versions will make these statements.

Rhythm Statement	*Acronym*	*Description*
*** Suspect unspecified pacemaker failure	**PMFAIL**	Requires that less than half of the detected pace spikes are associated with P waves or QRS complexes. This was only implemented in 12SL v22. This test has since been retired.
Bi-ventricular pacemaker detected	**BIVPCK**	Requires at least 50% more ventricular spikes detected than ventricular- paced beats.

Atrial Flutter

Rhythm Statement	*Acronym*	*Description*
Atrial Flutter	**FLUT**	The program must detect an atrial rate from 200 to 350 bpm for adults, and 300 to 350 bpm for pediatrics.

Ectopic Atrial Rhythm

This category is chosen if a P wave, with an abnormal axis, is found before the primary beats. Specifically, this category requires:

- Rigidly coupled P wave detected for primary beat, and
- No flutter or second-degree AV block
- P axis less than -30 or greater than 120. (For pediatrics, P axis less than -20 or greater than 100.)

For adults the ectopic atrial rhythm statements are rate dependent.

Rhythm Statement	*Acronym*	*Description*
Unusual P axis, possible ectopic atrial bradycardia	**EABRAD**	Requires atrial rate less than 60 bpm.
Unusual P axis, possible ectopic atrial rhythm	**EAR**	Requires atrial rate from 60 to 100 bpm
Unusual P axis, possible ectopic atrial tachycardia	**EATACH**	Requires atrial rate greater than 100 bpm. For pediatrics, the ectopic atrial rhythm statements are dependent on both rate and origin of impulse. If low right atrial rhythm is stated, the P axis is greater than 100 degrees. A left atrial rhythm is stated if the P axis is less than -20. Rate thresholds are age dependent. • Low Right Atrial Bradycardia — RABRAD • Low Right Atrial Tachycardia — RATACH • Left Atrial Bradycardia — LABRAD • Left Atrial Tachycardia — LATACH • Low Right Atrial Rhythm — RAR • Left Atrial Rhythm — LAR

Sinus Rhythm

This category requires the program to detect P waves with a normal axis. Specifically, it requires.

- Rigidly coupled P wave detected for primary beat
- Normal P axis
- P waves detected at a regular rate and not associated with primary beat.

Sinus rhythm statements are rate and age dependent. *Marked Sinus Bradycardia* is stated for both adults and pediatrics at a rate below 45 bpm.

The determination of sinus bradycardia, sinus rhythm, or sinus tachycardia is based on the atrial rate, not the ventricular rate. This is because it is the atrial rate that reflects the rate of the sinus node. While these two rates will be identical for the majority of sinus rhythms, they may differ in cases such as 2nd or 3rd degree AV block. For example, an ECG with complete heart block and an atrial (sinus) rate of 115 bpm and a ventricular rate of 55 beats per minute would be interpreted as Sinus tachycardia with complete heart block even though the ventricular response might normally be thought of as bradycardia.

Rhythm Statement	***Acronym***	***Description***
Sinus bradycardia	**SBRAD**	Requires atrial rate from 45 to 59 bpm.
Normal sinus rhythm	**NSR**	Requires atrial rate from 60 to 100 bpm and no rhythm modifiers appended or only with sinus arrhythmia appended.
Sinus rhythm	**SRTH**	Requires atrial rate from 60 to 100 bpm and any rhythm modifiers appended beyond with sinus arrhythmia.
Sinus tachycardia	**STACH**	Requires atrial rate over 100 bpm.
Marked sinus bradycardia	**MSBRAD**	Requires atrial rate less than 45 bpm.

Junctional Rhythm

Two sets of criteria are used for this category. One set of criteria is applicable to those junctional rhythms that have a P wave which precedes the QRS. The other criteria is for when the P wave is submerged in the QRS or T. If the P wave precedes the QRS, it must be ectopic in shape with a short PR interval. Pediatric patients exhibit shorter time intervals before the onset of ventricular activation. As a result, they rarely exhibit AV nodal rhythms with a short PR interval. Pediatric analysis leaves this rhythm categorized as ectopic atrial rhythm.

Specifically, if P waves are visible before the QRS then the criteria require:

- Rigidly coupled P wave detected for primary beats
- No flutter or second-degree AV block
- PR interval less than 140 ms
- P wave axis outside of -60 to 240 degrees
- An adult age

The statements for these criteria are rate dependent.

Rhythm Statement	**Acronym**	**Description**
Unusual P axis and short PR, probable junctional bradycardia	JBRAD	Requires ventricular rate less than 50 bpm.
Unusual P axis and short PR, probable junctional rhythm	JR	Requires ventricular rate from 50 to 75 bpm.
Unusual P axis and short PR, probable junctional tachycardia	JTACH	Requires ventricular rate greater than 75 bpm. If P waves are not visible, then the program requires a very regular, narrow QRS rhythm. Specifically:

Rhythm Statement	Acronym	Description
		No P waves found A regular RR interval (a range of RR intervals that is less than 10% of the average RR interval) A narrow primary beat (<120 ms for QRS duration for adults, for pediatrics refer to Appendix C: Pediatric Tables. A ventricular rate less than 90 bpm Junctional rhythm statements are rate dependent. The rate thresholds are the same for both pediatric and adult analyses.
Junctional bradycardia	JUNBRAD	Requires rate less than 45 bpm.
Junctional rhythm	JUNCT-R	Requires rate from 45 to 65 bpm.
Accelerated	ACCEL	This statement precedes Junctional Rhythm when the rate is greater than 65 bpm.

Atrial Fibrillation

If none of the other aforementioned categories has been chosen, the program tests for atrial fibrillation. The program looks for an irregular rhythm or fibrillatory waves in the presence of a slow heart rate. Specifically, it requires test 1 or test 2 to be true.

Test 1 requires:

- An irregularly irregular rhythm (range of RR intervals more than 15% of the average RR interval and RR intervals not organized)
- No regular atrial rhythm detected.

Test 2 requires an atrial rate >400.

Only one statement is generated for this category. The rhythm can be further defined by rhythm modifier statements.

Rhythm Statement	*Acronym*	*Description*
Atrial Fibrillation	**AFID**	Atrial fibrillation occurs so rarely in pediatric individuals that the program requires an adult age for this diagnosis.

Undetermined Rhythm

This category is chosen if none of the other previously mentioned categories fits the description of the measurements extracted from the ECG. Some descriptive statements can be issued from this category without specifying the mechanism.

Rhythm Statement	*Acronym*	*Description*
Idioventricular Rhythm	**IVR**	Requires: • A slow ventricular rate (≤ 40 bmp for adult and pediatric). • A wide QRS (QRS duration > 120 ms; refer to Appendix C for pediatric ages). A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).
Wide QRS Rhythm	**WQR**	Requires: • Ventricular rate between 40 and 120 bpm; refer to Appendix C: Pediatric Tables for pediatric upper rate limit. • A wide QRS (QRS duration > 120 ms; refer to Appendix C: Pediatric Tables for pediatric ages).

Rhythm Statement	*Acronym*	*Description*
		• A regular heart rate (the range of RR intervals is less than 20% of the average RR interval).
Wide QRS Tachycardia	**WQTACH**	Requires: • A fast ventricular rate (>120 bpm; refer to Appendix C: Pediatric Tables). • A wide QRS (QRS duration > 120 ms; refer to to Appendix C: Pediatric Tables for pediatric ages). • A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).
Supraventricular Tachycardia	**SVT**	Requires: • A fast ventricular rate (>140 bpm; >220 bpm for pediatric). • A narrow QRS (QRS duration <120 ms; refer to Appendix C for pediatric). • A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).
Narrow QRS Tachycardia	**NQTACH**	Requires: • Pediatric age. • Same criteria as described for supraventricular tachycardia but allows rates below 220 bpm that are still above the fast heart rate for age.
Undetermined Rhythm	**UR**	If the criteria cannot be met for these descriptive statements, then the program will state *Undetermined rhythm*.

Detailed Criteria for Rhythm Modifiers

Rhythm modifiers may be added to the predominant rhythm statement. Rhythm modifiers are grouped into the following categories:

- Sinus arrhythmia (e.g., with marked sinus arrhythmia)
- Irregular rhythm (e.g., with undetermined rhythm irregularity)
- PR interval (e.g., with 1st degree AV block)
- AV block (e.g., with complete heart block)
- Ectopy (e.g., with premature ventricular complexes)
- Paced complexes (e.g., with occasional ventricular-paced complexes)

The rhythm modifiers that may be added to the rhythm statement are dependent on the predominant rhythm. Following is a list of the predominant rhythms and the applicable rhythm modifier categories, as well as a more complete description of each rhythm modifier category, including the specific statements that may be made.

Rhythm Modifier Categories for Each Predominant Rhythm

The following table lists the rhythm modifier categories for each predominant rhythm.

Predominant Rhythm	*Modifier Categories*
Sinus Rhythm	• Sinus arrhythmia • PR interval • AV block • Ectopy

Predominant Rhythm	*Modifier Categories*
Ectopic Atrial Rhythm including Junctional Rhythm with P waves preceding QRS	• Irregular rhythm • AV block • Ectopy
Atrial Fibrillation, Atrial Flutter	• AV block (tailored for fibrillation/flutter) • Ectopy (tailored for fibrillation/flutter) • Paced complexes
Junctional and other rhythms with no distinct P waves preceding QRS (e.g., WQRS, IVR)	• Ectopy • Paced complexes
Electronic Artificially Paced Rhythm	• PR interval • AV block (tailored for paced rhythms) • Ectopy • Paced complexes

Rhythm Modifiers by Modifier Category

Some rhythm modifier categories are tailored for specific predominant rhythms to make them more appropriate for that rhythm. For example, ectopy can occur with atrial fibrillation or flutter, but the origin of it is harder to define. That is why atrial fibrillation and atrial flutter have a tailored set of ectopy statements. This section covers the details for the following rhythm modifiers:

- Sinus Arrhythmia,39
- Irregular Rhythm,39
- PR Interval,40
- AV Block,40
- Ectopy,43
- Paced Complexes,46

Sinus Arrhythmia

Predominant rhythm: *Sinus*

Requires a rigidly coupled P wave detected for the primary beat and no premature supraventricular beats (normal shape but without P wave) or premature ectopic beats (shape other than primary beat).

Sinus arrhythmia is stated if the range of RR intervals exceeds a particular limit. The limits are much higher for the pediatric population, which has much more sinus arrhythmia. Specifically:

Statement	*Acronym*	*Description*
with sinus arrhythmia	**SAR**	Requires range of RR intervals 20 to 39% (greater than 40% for pediatrics) of average RR interval.
with marked sinus arrhythmia	**MSAR**	Requires range of RR intervals 40% or greater of average RR interval (not used for pediatric ages).

Irregular Rhythm

Predominant rhythm: *Ectopic atrial*, *junctional (with P waves)*

This category is analogous to the sinus arrhythmia category for sinus rhythms. If the program did not detect any ectopy and if the rhythm is irregular, the program will describe the condition with the following statements.

Statement	*Acronym*	*Description*
with undetermined rhythm irregularity	**IRREG**	Requires adult age and range of RR intervals greater than 20% of average RR interval. This statement will not appear if screening criteria is turned on. See for more information.
Irregular	**IRR**	Requires pediatric age and range of RR intervals greater than 20% of average RR interval. In this case, this statement is prefixed to the existing rhythm statement, for example, "Irregular right atrial rhythm".

PR Interval

Predominant rhythm: *Sinus, paced*

The modifiers that can be added for sinus rhythms are different than those for paced rhythms as indicated below.

Statement	*Acronym*	*Description*
with short PR	**SPR**	Requires sinus rhythm and PR interval 110 ms or less (for pediatrics, it must be less than the 2nd percentile for age. Refer to Appendix C: Pediatric Tables for pediatric threshold). Is not made if WPW is detected.
with 1st degree AV block	**FAV**	Requires sinus rhythm and PR interval of 210 ms or longer (for pediatrics, it is the 98th percentile plus 20 ms; refer to Appendix C for pediatric threshold).
with prolonged AV conduction	**PROAV**	Requires any paced rhythm and PR interval of 210 ms or longer (for pediatrics, it is the 98th percentile plus 20 ms; refer to Appendix C for pediatric threshold).

AV Block

Predominant rhythm: *Sinus*, *ectopic atrial*, *junctional* (with P waves)

This section lists the statements that express 2nd and 3rd degree AV block.

Statement	*Acronym*	*Description*
with 2nd degree AV block (Mobitz I)	**MBZI**	Requires: • At least one beat that follows an RR interval which is longer than 1.4 times the longer of the previous RR or the median RR. • No rigidly coupled P wave for this beat. • Two P waves preceding that beat. • PR interval for this beat is shorter than average. • This beat follows a normally shaped beat.
with 2nd degree AV block (Mobitz II)	**MBZII**	Requires: • Two or more P waves preceding a beat. • This beat follows a normally shaped beat • that beat follows an RR interval which is longer than one of the following: • 2.2 times the longer of the previous RR or the median RR • 1.8 times the longer of the previous RR or the median RR and there is a rigidly coupled P wave for this beat.

Statement	*Acronym*	*Description*
with 2:1 AV conduction	**W2TI**	For MBZI and MBZII This statement will not appear if screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity, for more information. Requires: • Synchronous blocked P wave identified in the median complex in addition to synchronous conducted P wave. • Pattern of blocked P, conducted P, blocked P, conducted P detected somewhere in the rhythm analysis
with 2nd degree AV block	**SAV**	Requires: • Rigidly coupled P wave detected for primary beats. • Atrial rate less than 200 bpm. • The atrial rate is less than 10 bpm different than twice the ventricular rate.
with 2:1 AV conduction	**W2T1**	For **SAV** Requires: • Synchronous blocked P wave identified in the median complex in addition to synchronous conducted P wave. • Pattern of blocked P, conducted P, blocked P, conducted P detected somewhere in the rhythm analysis. • Atrial rate is within 5 bpm of 2 times the ventricular rate.
with 3:1 AV conduction	**W3T1**	For SAV Require atrial rate is within 10 bpm of 3 times the ventricular rate.
with 4:1 AV conduction	**W4T1**	For SAV Requires atrial rate is within 15 bpm of 4 times the ventricular rate.
with complete heart block	**CHB**	Requires: • No AV Block (Mobitz I or II). • Regular atrial rhythm detected. • No rigidly coupled P wave detected for primary beats. • Atrial rate more than 6 bpm faster than ventricular rate • One of the following: • PR variance greater than 200 ms. • Atrial rate more than 25 bpm faster than ventricular rate.
with AV dissociation	**AVDIS**	Requires: • No AV Block (Mobitz I or II). • No flutter. • Regular atrial rhythm detected. • No rigidly coupled P wave detected for primary beats. • One of the following:

Statement	Acronym	Description
		• Atrial rate more than 25 bpm faster than ventricular rate. • PR variance greater than 200 ms. If complete heart block or with AV dissociation is stated, then additional statements regarding the ventricular activity will follow. The presence of an atrioventricular dyssynchrony requires that both the atrial and the ventricular activity be specified. The ventricular activity will be stated as one of the otherwise predominant rhythm statements of: *Junctional rhythm*, *Junctional bradycardia*, *Ideoventricular rhythm*, *Wide QRS rhythm*, or *Wide QRS tachycardia*.

AV Block (tailored for Atrial Fibrillation)

Predominant rhythm: Atrial fibrillation

Statement	Acronym	Description
with rapid ventricular response	**RVR**	Requires ventricular rate higher than 100 bpm. This statement will not appear if screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.
with slow ventricular response	**SVR**	Requires ventricular rate lower than 60 bpm. This statement will not appear if screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.

with a competing junctional pacemaker	**CJP**	Requires:
		• No electronic pacer spikes detected.
		• One of the following:
		  ○ Range of RR intervals less than 5% of average RR.
		  ○ the 3 longest RR intervals are longer than 800 ms and within 40 ms of each other.
		This statement will not appear if screening criteria is turned on.
		See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.

AV Block (tailored for Atrial Flutter)

Predominant rhythm: *Atrial flutter*

Statement	Acronym	Description
with variable AV block	**VAVB**	Requires range of RR intervals is 10% or more of the average RR interval.
with 2:1 AV conduction	**W2T1**	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 2 times the ventricular rate. This statement will not appear if screening criteria is turned on.

Statement	Acronym	Description
		See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.
with 3:1 AV conduction	**W3T1**	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 3 times the ventricular rate. This statement will not appear if screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.
with 4:1 AV conduction	**W4T1**	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 4 times the ventricular rate. This statement will not appear if screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.
with 5:1 AV conduction	**W5T1**	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 5 times the ventricular rate. This statement will not appear if screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.

AV Block (Tailored for Paced Rhythms)

Predominant rhythm: *Paced*

If the predominant rhythm is ventricular-paced and not atrial-sensed or - paced, the program continues to look for P waves. If P waves are asynchronous with ventricular pacing and with a regular P-P interval, then the program will prefix the *Ventricular-paced rhythm* statement with *Sinus rhythm with complete heart block*.

Ectopy

Predominant rhythm: *Sinus*, *ectopic atrial*, *junctional* (with or without P waves), *paced*

The ectopy group contains statements that pertain to premature beats, fusion beats, or escape beats.

Modifiers that are associated with premature beats are always preceded by a phrase that indicates how often the beats occur. Specifically:

Statement	Acronym	Description
with occasional	**OCC**	Requires 1 or 2 beats.
with frequent	**FREQ**	Requires greater than 2 beats. If ectopic shaped beats appear as at least one consecutive pair, then not only is the frequency of the beats commented on, but the consecutive nature of the beats is also indicated.

Statement	*Acronym*	*Description*

and consecutive	**CSEC**	Requires:
		• At least one pair or beats.
		• These beats are either
		  ○ Separated by less than 600 ms for rates lower than 85 bpm.
		  ○ At least 100 ms premature for rates over 85 bpm.

Following are the various premature beat modifier statements that follow the previous prefixes.

Statement	*Acronym*	*Description*
premature supraventricular complexes	**PSVC**	Requires: • No AV block, Mobitz I or II. • No AV dissociation. • At least one QRS that is premature, normally shaped. • No P wave found before this QRS.
premature atrial complexes	**PAC**	Requires: • No AV block, Mobitz I or II. • No AV dissociation. • At least one QRS that is premature, normally shaped. • A P wave found preceding this QRS
premature ventricular complexes	**PVC**	Requires: • At least one QRS that is premature, ectopic shaped • Has a QRS duration greater than 120 ms (for pediatrics, wide for age; refer to Appendix C: Pediatric Tables). • No fusion beats detected.

in a pattern of bigeminy	**BIGEM**	Requires:
		• A strict 10-second pattern of alternating premature and not premature beats.
		• One of the following:
		  ○ At least one QRS that is premature, ectopic shaped.
		  ○ At least one premature atrial or supraventricular beat.

Statements that specifically deal with fusion beats or escape beats are not conjugated with the phrase *With Occasional* etc. These statements are as follows:

Statement	*Acronym*	*Description*
fusion complexes	**$SFUS**	Requires QRS complex that is different from dominant beat type and is not premature and not late.
with junctional escape complexes	**JESC**	Requires: • No AV block, Mobitz I or II. • No AV dissociation. • At least one QRS that is premature, normally shaped. • A P wave found preceding this QRS

Statement	*Acronym*	*Description*
premature ventricular complexes	**PVC**	Requires: • No AV block, Mobitz I or II. • At least one beat that follows an RR interval which is longer than 1.4 times the longer of the previous RR or the median RR. • No P wave preceding that beat. • Follows a normally shaped beat
with ventricular escape complexes	**VESC**	Requires: • At least one beat that is ectopic shaped. • Has a QRS duration greater than 120 ms, (for pediatrics, wide for age; refer to Appendix C: Pediatric Tables). • Follows an RR interval of more than 1200 ms. • Follows a normally shaped beat.
with fusion or intermittent ventricular pre-excitation (WPW)	**ALTWPW**	Requires: • Fusion beats. • No premature ectopic shaped beats. • Delta waves in three or more leads of the fusion beat. A fusion beat requires: • A QRS that is not premature but ectopic shaped. • Not the first QRS of the 10 second strip • Within 100 ms of the expected RR interval
with retrograde conduction	**RETC**	Requires: • Junctional bradycardia, junctional rhythm, or accelerated junctional rhythm stated. • No AV dissociation or complete heart block. • Regular atrial rhythm detected. • Number of P waves detected < number of QRSs plus 5 • Short RP interval. This statement will not appear if screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity, for more information.

Ectopy (Tailored for Atrial Fibrillation / Atrial Flutter)

Predominant rhythm: Atrial fibrillation, atrial flutter

In the presence of atrial fibrillation or atrial flutter, it is difficult to define the origin of ectopic shaped beats. The following statement is used in most instances of ectopy.

Statement	*Acronym*	*Description*
with premature ventricular or aberrantly conducted complexes	**ABER**	Requires any complexes that are of a different morphology than the dominant beat shape, unless they are otherwise classified as ventricular escape or paced.
with ventricular escape complexes	**VESC**	Requires: • At least one beat that is ectopic shaped. • Has a QRS duration greater than 120 ms, (for pediatrics, wide for age; refer to Appendix C: Pediatric Tables) • Follows an RR interval of more than 1200 ms.

Statement	Acronym	Description
		• Follows a normally shaped beat.

Paced Complexes

Predominant rhythm: *any*

With the exception of *intrinsic complexes*, all of the statements in this category will be preceded by "*with occasional*" or "*with frequent*".

Statement	Acronym	Description
atrial-paced complexes	**APCX**	Requires atrial-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not Atrial-paced rhythm.
ventricular-paced complexes	**VPCX**	Requires ventricular-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not Ventricular- paced rhythm.
AV dual-paced complexes	**AVPCX**	Requires AV dual-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not AV dual- paced rhythm.
atrial-sensed ventricular-paced complexes	**ASVPCX**	Requires atrial-sensed ventricular-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not Atrial-sensed ventricular-paced rhythm. **NOTE:** No more than one of the previous four statements will be made. If there are multiple paced beat types, only the most frequently occurring will be commented on.
sinus complexes	**SCX**	Requires predominant rhythm of paced and QRS complexes of a normal morphology with normal P waves.
supraventricular complexes	**SVCZ**	Requires: predominant rhythm of paced and QRS complexes of a normal morphology but with abnormal or no P waves. **NOTE:** No more than one of the previous two statements will be made. If there are both sinus and supraventricular complexes, only the most frequently occurring will be commented on.
with intrinsic complexes	**WITH + INTRIN**	Requires predominant rhythm of paced, non-paced QRS complexes of morphology different from the dominant beat type, and no other statements from either this section or regarding ectopy are made.

Overview of Adult Contour Criteria

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The morphology interpretation consists of two separate bodies of criteria: one for adults, the other for pediatrics. If an adult age is entered (16 years or older) or if no age is entered, an adult analysis is performed.

The 12SL analysis program has adult age and gender-specific contour criteria. These criteria are invoked if an adult age is entered and if the patient's sex is entered. If age and sex are not entered, 12SL returns to conventional criteria.

The categories of abnormalities that the program always examines for are listed in the following table. This outline is expanded upon in succeeding figures which describe, in very simplistic terms, the basic flow and logic of the program. Note that the order of the steps is important since information obtained from tests, performed earlier in the sequence, are applied to subsequent tests.

Following the presentation of the basic flow of the program are more detailed explanations of each step. See Adult Contour Criteria Details. This includes specific thresholds, sample tracings, and additional figures. This section will provide details regarding criteria, as opposed to revealing the overall approach used by the program to interpret the morphology.

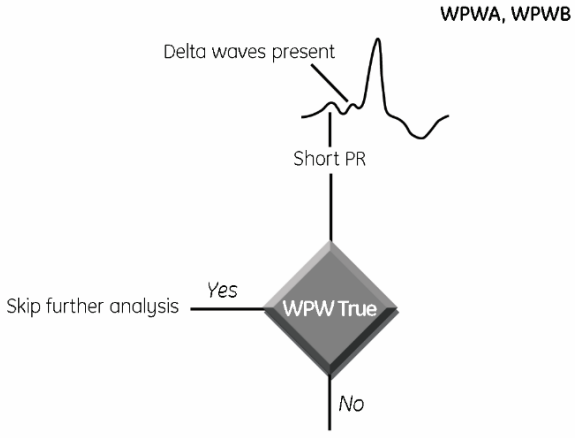
Adult Contour Criteria Summary

Major Category	*Subcategory*	*Acronyms/Statements*
Wolff-Parkinson-White		WPWA WPWB
Atrial Hypertrophy		RAE, Right Atrial Enlargement LAE, Left Atrial Enlargement BAE, Biatrial Enlargement
QRS Abnormalities	Low Voltage QRS Pulmonary Disease Pattern QRS Axis	LOWV PULD RAD, Right Axis Deviation LAD, Left Axis Deviation RSAD, Right Superior Axis Deviation
	Brugada Conduction Abnormalities	BRUG1, Brugada Pattern, type 1 RBBB, Right Bundle Branch Block LBBB, Left Bundle Branch Block IRBBB, Incomplete Right Bundle Branch Block ILBBB, Incomplete Left Bundle Branch Block RSR, RSR Pattern In V1 IVCB, Intraventricular Conduction Block

Major Category	*Subcategory*	*Acronyms/Statements*
		IVCD, Intraventricular Conduction Delay AFB, Left Anterior Fascicular Block PFB, Left Posterior Fascicular Block
	Ventricular Hypertrophy	LVH, Left Ventricular Hypertrophy RVH, Right Ventricular Hypertrophy BIVH, Biventricular Hypertrophy RVE+, Plus Right Ventricular Hypertrophy QRSW, With QRS Widening
	Infarction	MI, Myocardial Infarction AMI, Anterior SMI, Septal LMI, Lateral IMI, Inferior PXT, With Posterior Extension
ST Abnormalities—QRS Related	ST + T abnormality with Ventricular Hypertrophy Dating Infarcts	2ST, With Repolarization Abnormality AC, Possibly Acute AU, Age Undetermined
ST Elevation Abnormalities	Epicardial Injury	INJ, Injury SINJ, Septal AINJ, Anterior LINJ, Lateral IINJ, Inferior
	Pericarditis	PCARD, Acute Pericarditis
	Early Repolarization Undefined ST Elevation	REPOL, Early Repolarization
	ST Elevation	STEL, ST Elevation Consider Early Repolarization, Injury or Acute Pericarditis
	Nonspecific	NST, Nonspecific ST Abnormality
ST Depression Abnormalities	Subendocardial Injury	SBINJ, Subendocardial Injury SSBINJ, Septal ASBINJ, Anterior LSBINJ, Lateral ISBINJ, Inferior STDEP, ST Depression, Consider Subendocardial Injury JST, Junctional ST Depression Probably Abnormal JSTN, Junctional ST Depression, Probably Normal NST, Nonspecific ST Abnormality
	Undefined ST Depression	STDEP, ST Depression, Consider Subendocardial Injury NST, Nonspecific ST Abnormality
	Junctional ST Depression	JST, Junctional ST Depression Probably Abnormal JSTN, Junctional ST Depression, Probably Normal

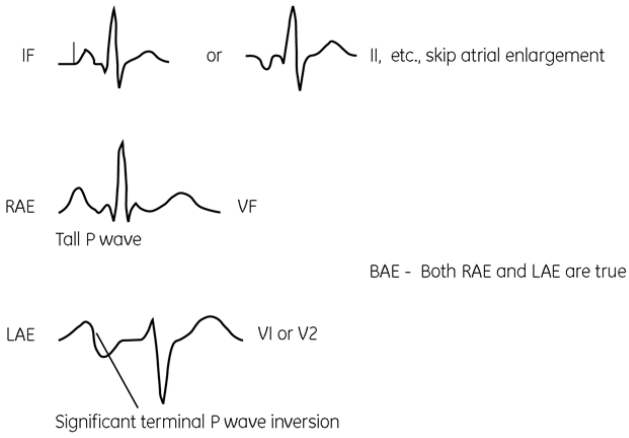
Major Category	*Subcategory*	*Acronyms/Statements*
	Nonspecific	NST, Nonspecific ST Abnormality
T Wave Abnormalities	Ischemia	T Ischemia AT, Anterior IT, Inferior LT, Lateral MT, Marked Ischemia MAT, Anterior MIT, Inferior MLT, Lateral
	Nonspecific QRS-T Angle	NT, Nonspecific T Wave Abnormality AQRST, Abnormal QRS-T Angle, Consider Primary T Wave Abnormality
	QT Interval	LNGQT, Prolonged QT

Wolff-Parkinson-White

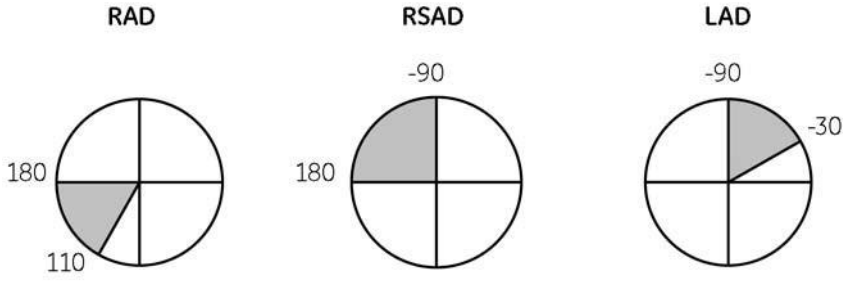


Atrial Enlargement

Skip the test if it is not a sinus rhythm.

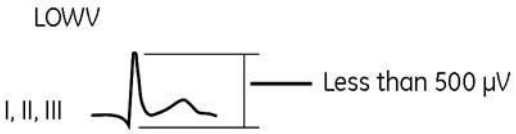


QRS Axis



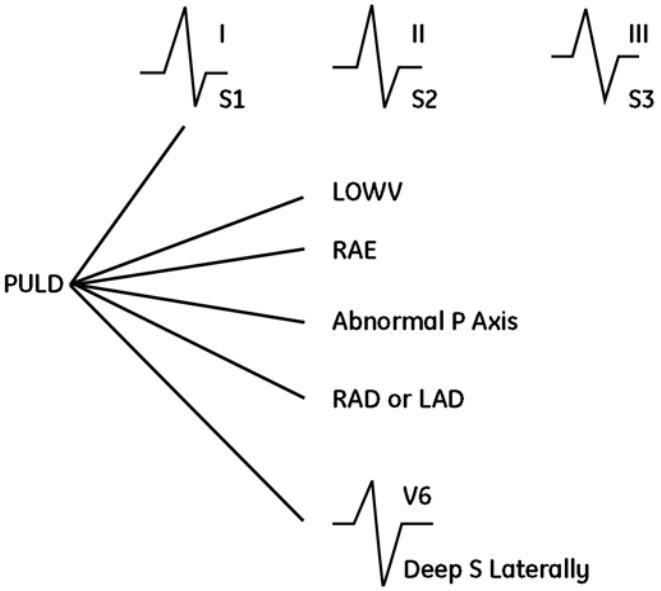
Low Voltage QRS

Standard requirement of limb leads less than 500 µV. If horizontal plane exhibits low voltage and the limb lead have voltage close to the standard requirement, state *low voltage QRS*.

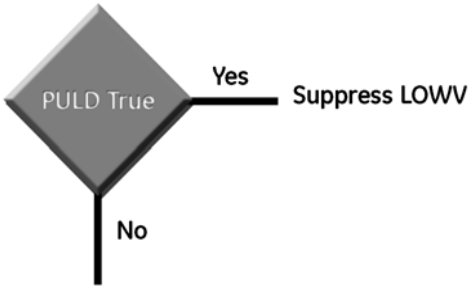


Pulmonary Disease Pattern

PULD — check for several attributes, states if at least a few are present.

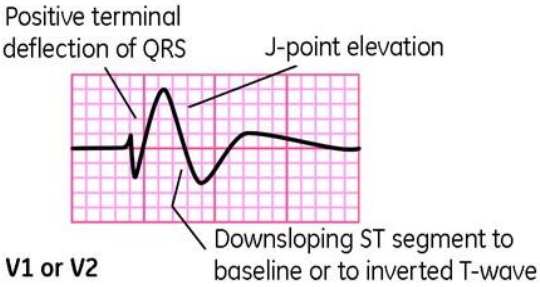


If **PULD** is true, do not redundantly state *LOWV*.



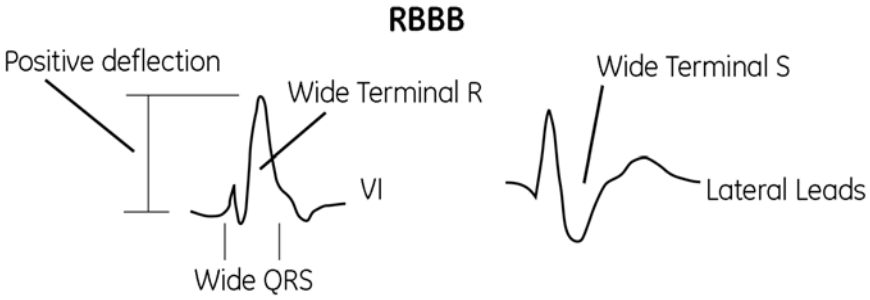
Brugada

If Brugada pattern found in V1 or V2, and RBBB and anterior injury ruled out, state *Brugada*.



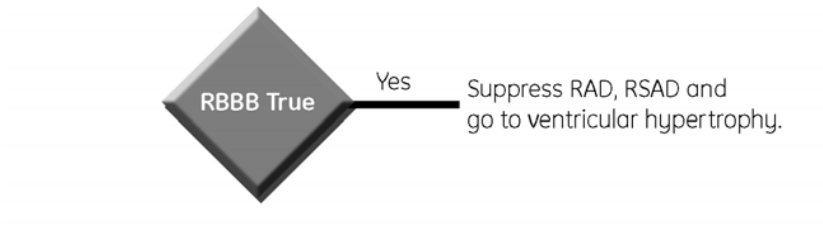
Conduction Abnormalities

Major Blocks

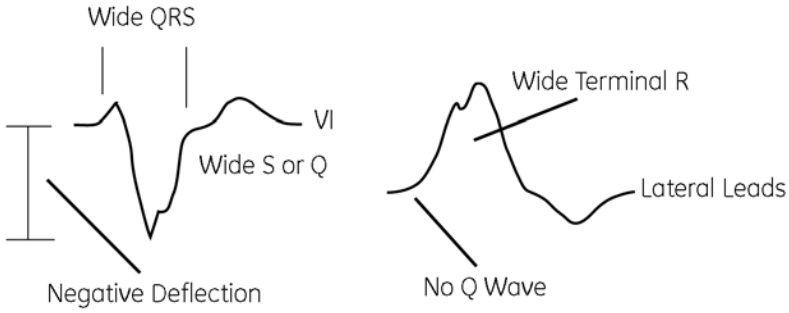


If **RBBB** is true, suppress **RAD** and **RSAD**.

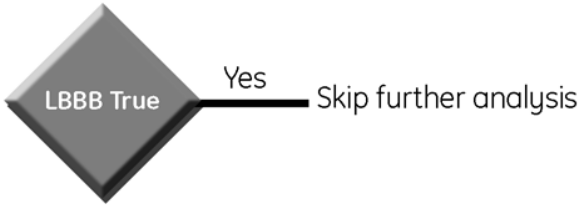
If **RBBB** is true, skip further conduction tests and go to ventricular hypertrophy tests.



LBBB

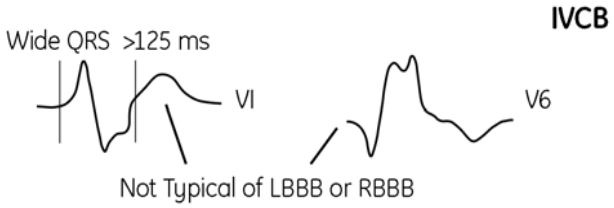


If **LBBB** is true, skip further analysis.

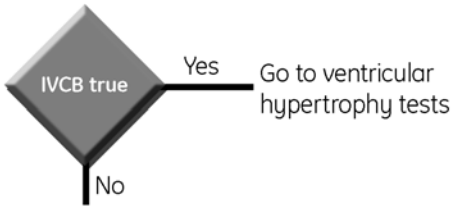


If **QRS** is wide and not **RBBB** or **LBBB**, state **IVCB**.

IVCB

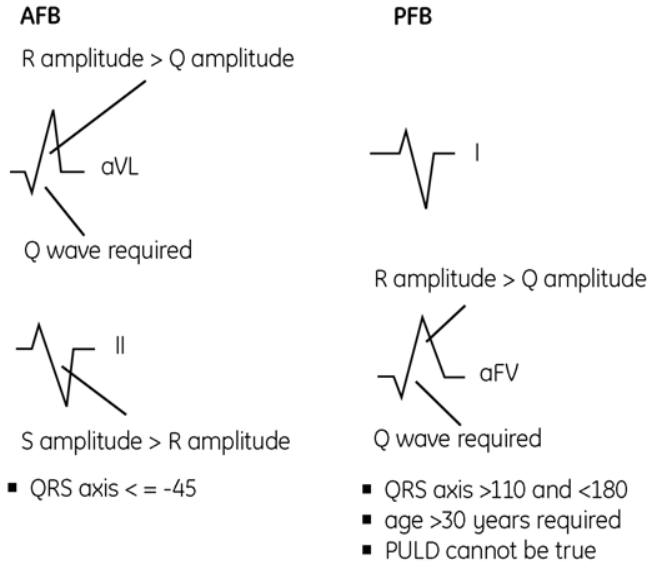


If IVCB is true, go to ventricular hypertrophy tests. If not true, test for incomplete blocks.

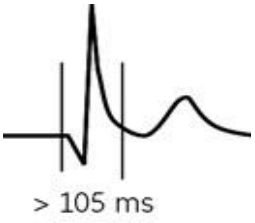


Incomplete Blocks

Hemiblocks



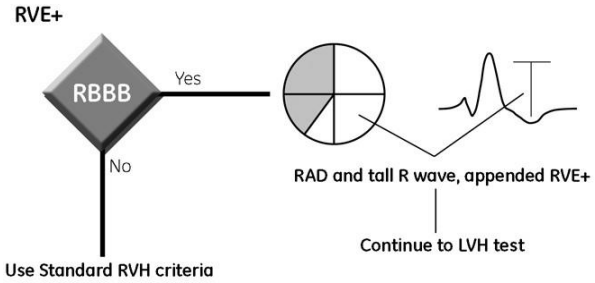
- If **AFB** is true, suppress **ILBBB** and **LAD**. If **PFB** is true, suppress **RAD**.
- If *RBBB* is also true, append *BIFB*.
- *IVCD* - If no conduction abnormality is stated and QRS duration is greater than 105 ms, state *IVCD*.

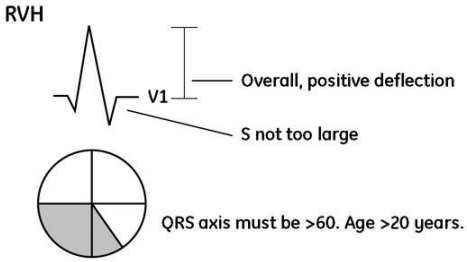


Ventricular Hypertrophies

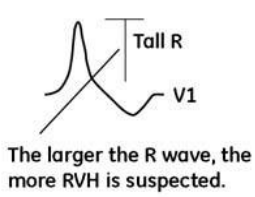
Right Ventricular Hypertrophy

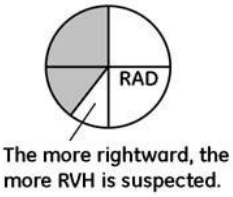
If *RBBB* is true, use a separate set of criteria for *RVH*.

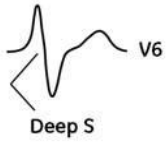




If these conditions exist, the program looks for other characteristics. If at least a few of these exist, it states **RVH**.

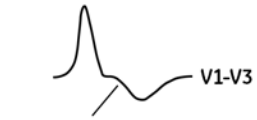


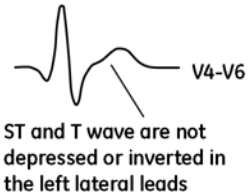




RVH-2ST

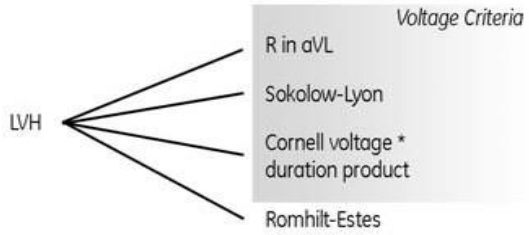
If the program finds a repolarization abnormality that is also indicative of RVH, it will upgrade any RVH call to *right ventricular hypertrophy with repolarization abnormality*.





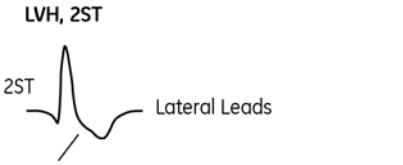
Left Ventricular Hypertrophy

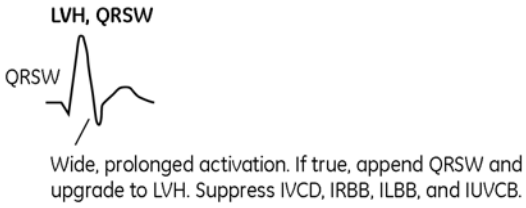
The 12SL program incorporates four commonly used LVH criteria from the literature.



If one or more of the voltage criteria tests are positive, one of the LVH voltage criteria statements are made. The specific voltage criteria statement depends on the number of positive voltage criteria tests.

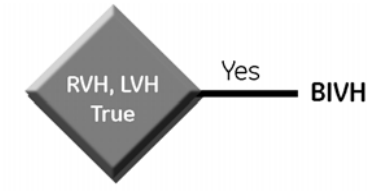
The program makes the stronger statement *Left ventricular hypertrophy* without the phrase *voltage criteria* if the Romhilt-Estes test is positive or if any of the voltage criteria tests are true and the program finds additional indications of hypertrophy, namely repolarization changes, widened QRS, or left atrial enlargement.



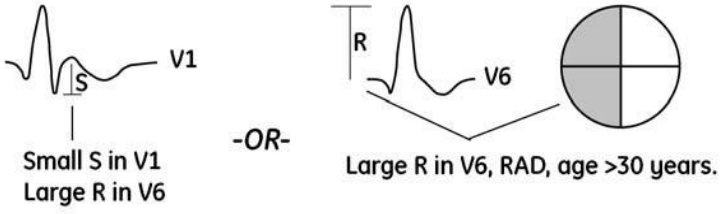


Biventricular Hypertrophy

If both *RVH* and *LVH* are true, then state *BVH*.



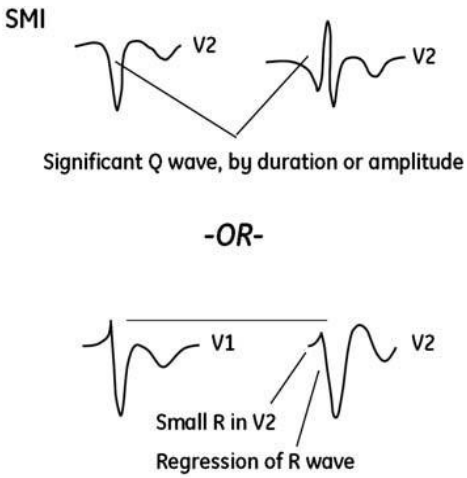
It is also possible to call *BIVH* based upon other tests.



If *BIVH* is stated, the program will not also state *LVH* and/or *RVH*.

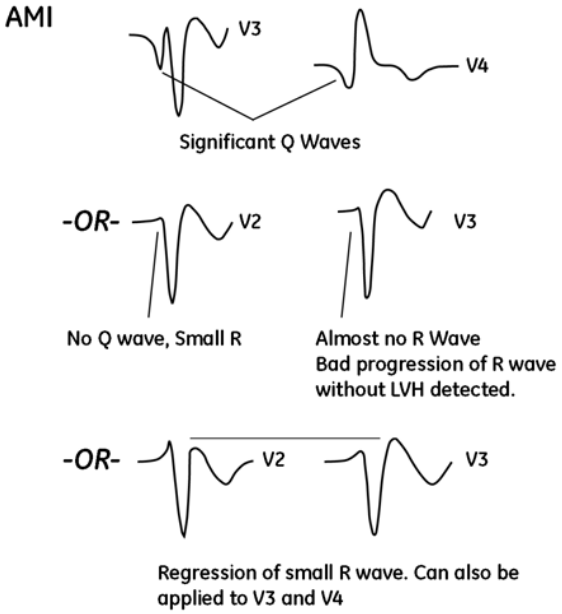
Infarction

Septal Myocardial Infarction



Degree of confidence is based on repolarization. If the ST is elevated, with terminal or complete T wave in version, SMI is stated without qualification, otherwise it is preceded by *cannot rule out*.

Anterior Myocardial Infarction

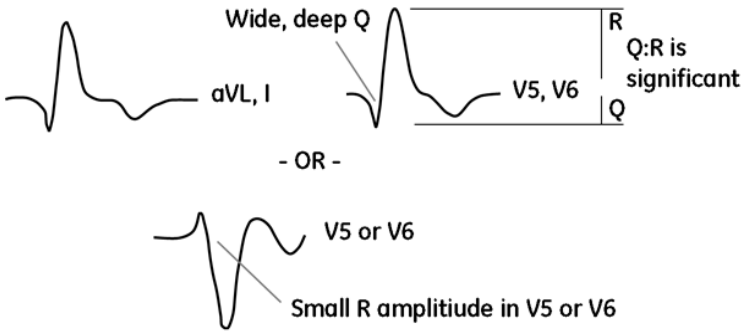


Narrow and shallow Q waves will be qualified as *cannot rule out* or *possible*.

Lateral Myocardial Infarction

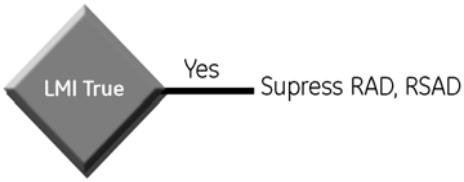
LMI

At least two lateral leads have wide and deep Q waves that have significant Q:R ratios.

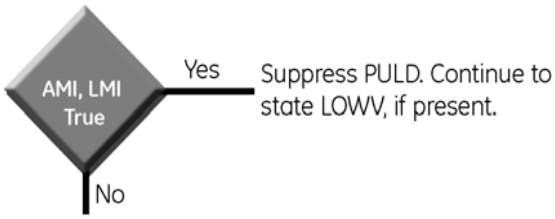


If the criteria detected significant Q waves, it states an unqualified *LMI*; otherwise it would prefix *possible*.

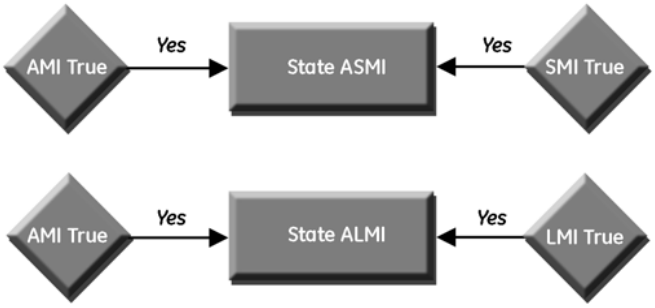
If *LMI* is true, suppress statements concerning right axis deviation (*RAD*, *RSAD*).



If *AMI* or *LMI* is true, the program will suppress *PULD*.



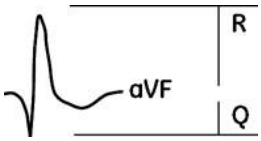
At this point the program will issue conjunctions of the different MIs it detected in the horizontal plane. For example:



Inferior Myocardial Infarction

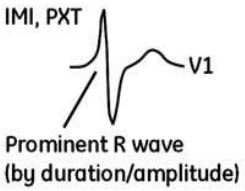
Acronym: *IMI*

Significant Q:R ratio is the main component of this test.

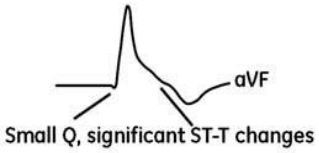


The significance of the Q:R ratio is evaluated in conjunction with other parameters, namely: Q amplitude, Q duration, QRS axis, and presence of Q in lead II.

If the *IMI* is true, then inspect posterior involvement.



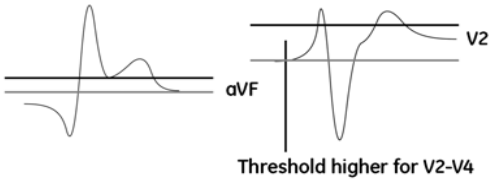
The qualification of the infarct is based upon the QRS and repolarization. Small Qs in aVF will be qualified as cannot rule out or possible unless there are ST-T changes commensurate with infarction.



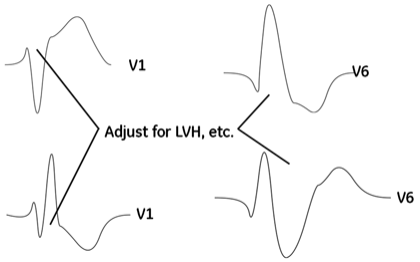
ST Elevation Abnormalities

Epicardial Injury

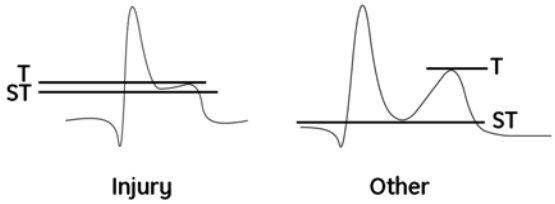
All leads are inspected for ST elevation. Anteroseptal leads are tested with a higher threshold than the other leads.



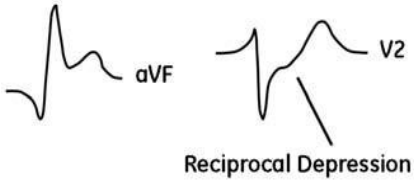
The thresholds are also adjusted for repolarization abnormalities that can occur with *LVH* and/or conduction abnormalities.



If any lead is over threshold, the program then applies several additional tests. As the ST:T ratio gets larger, the program considers the character of the *STT* to be more like injury.

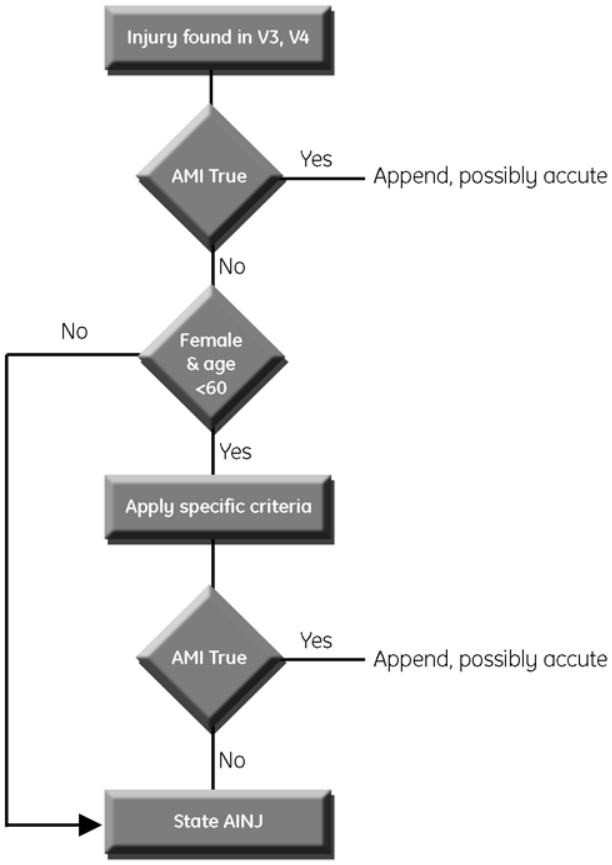


All leads on the opposite side of the ST vector are analyzed for reciprocal depression. If present, the ST elevation is considered more like injury.

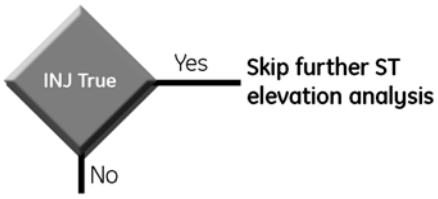


These three items: degree of ST elevation, ST:T ratio, and reciprocal changes are used for stating injury.

Injury is stated for those lead groups where it is most pronounced. If an MI has already been cited for that lead group, then the program does not state injury, it qualifies the MI as acute.



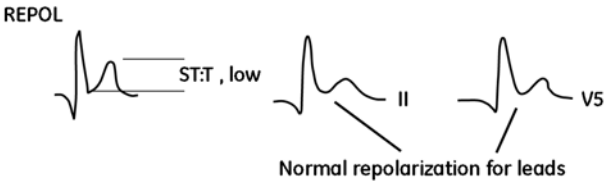
If injury has been stated, do no further analysis of ST elevation abnormalities.



The program has three choices
(1) pericarditis,
(2) early repolarization, or
(3) unknown origin.

Early Repolarization

Early repolarization is stated if the ST:T ratio is low and the repolarization character appears normal (that is, T waves are upright in appropriate leads and ST aligned



Acute Pericarditis

Pericarditis has similar criteria to early repolarization except more ST elevation is required.

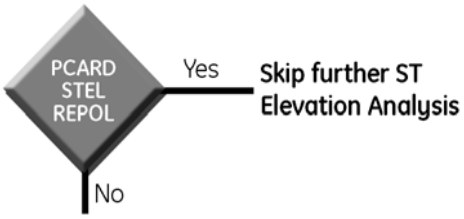
ST Elevation, Mechanism Unknown

If pericarditis or early repolarization cannot be stated, the program identifies the ST elevation and suggests the three aforementioned mechanisms.

Acronym: *STEL*

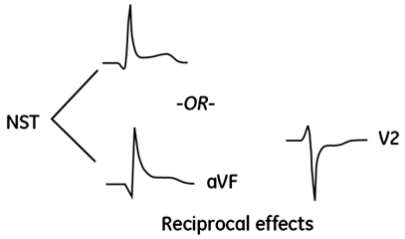
ST elevation, consider early repolarization, pericarditis, or injury

If *PCARD*, *REPOL*, or *STEL* is stated, skip further ST elevation analysis.



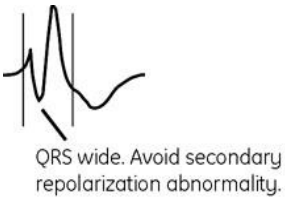
Nonspecific ST Abnormalities

Nonspecific ST elevation abnormality is detected using the same methods as outlined above. The difference is that the threshold for elevation is twice as sensitive. The program only states the elevation as a nonspecific abnormality if it has characteristics that meet the criteria outlined for injury.



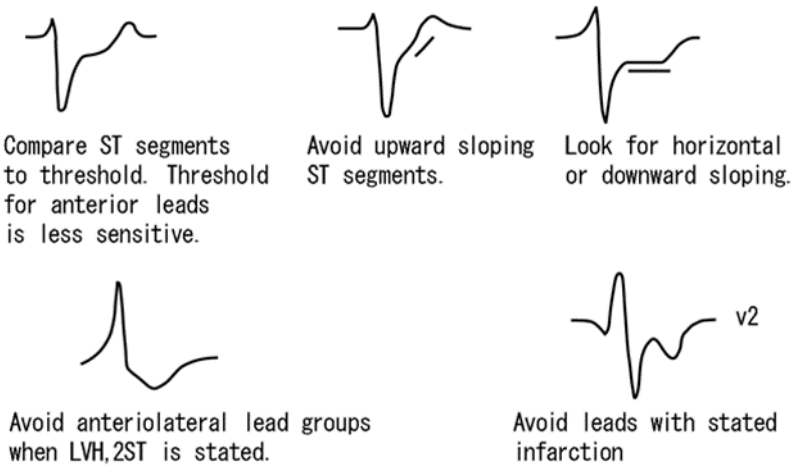
ST Depression Abnormalities

If the QRS is wide, do not test for ST depression abnormalities.

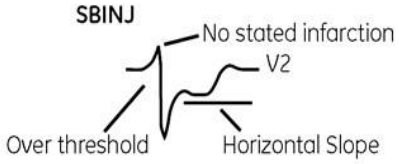


If injury has been called and the ST elevation is larger than the depression, do not test for any ST depression abnormality.

Subendocardial Injury

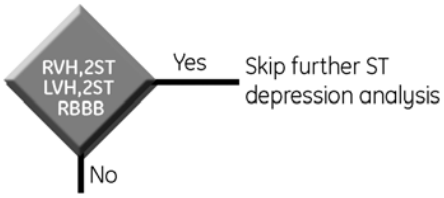


If all of these items are true, call *subendocardial injury*.

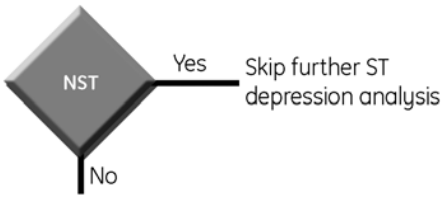


If subendocardial injury is true, skip further analysis.

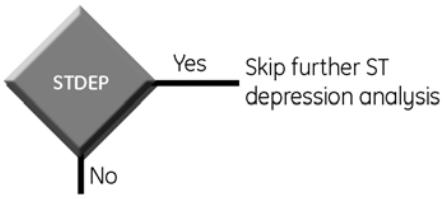
If any repolarization abnormality has been stated, in association with hypertrophy, do no further ST depression analysis. Avoid *RBBB*.



If a nonspecific ST elevation abnormality has already been found from ST elevation, test ST depression analysis.

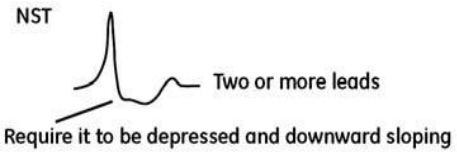


Now analyze ST segments as was done for *SUBNJ*, only with more sensitivity. If true, state *ST depression, consider subendocardial injury (STDEP)*. Also skip further ST depression analysis.



Nonspecific ST Abnormality

Analyze the ST segment with even more sensitivity.



If this occurs in at least two leads, state *NST*.

Junctional ST Depression

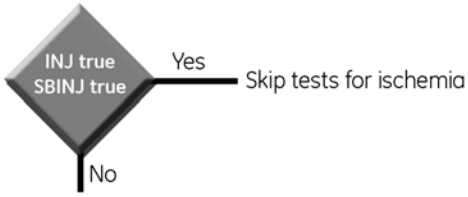
If true, state: *Junctional ST depression, probably normal*.

If true, state: Junctional ST depression, probably abnormal.

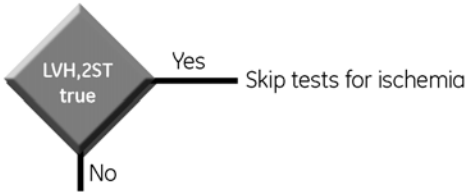
T Wave Abnormalities

Ischemia

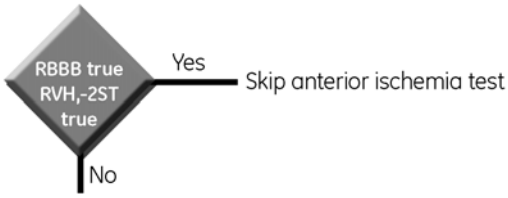
If any injury statement has been made, do not test for ischemia.



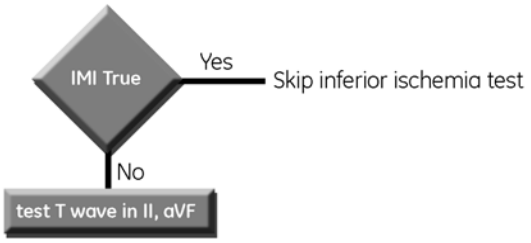
Likewise, if *LVH with repolarization abnormality* is stated, do not test for ischemia.

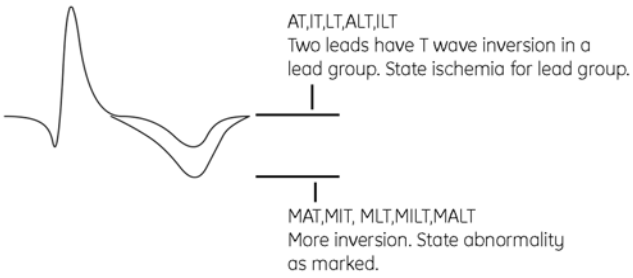


Additional restrictions are applied to anterior leads in order to avoid calling anterior ischemia in the presence of *RBBB* or *RVH,-2ST*.

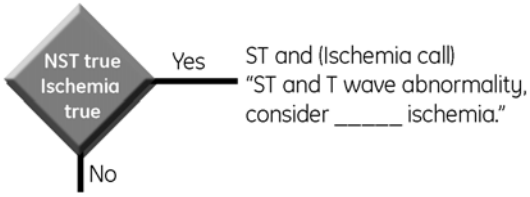


T wave abnormalities are also not tested in lead groups where infarction is stated.

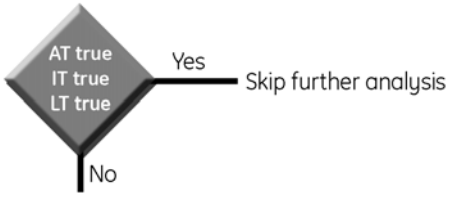




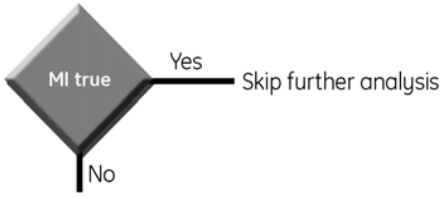
If ischemia is stated and a nonspecific ST abnormality was previously detected, make one statement as opposed to two.



If ischemia is called, skip further analysis of T waves.



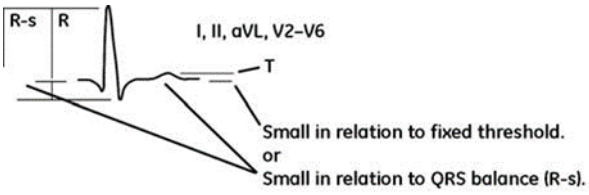
If infarction is present, skip further analysis of T waves.



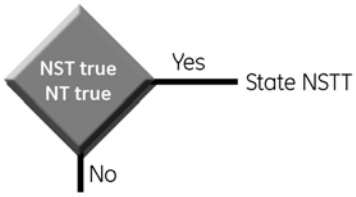
Nonspecific T Wave Abnormality

Acronym: *NT*

Small T waves or shallow T wave inversion are found in at least two leads.



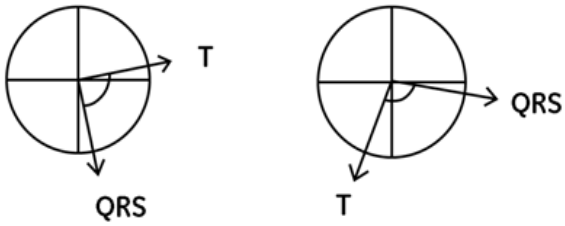
If a nonspecific ST abnormality is found in conjunction with NT, then make one statement as opposed to two.



Abnormal QRS-T Angle

Acronym: AQRST

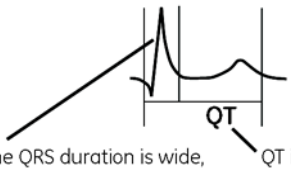
Do not test for abnormal QRS-T angle if any other T wave abnormality has already been stated.



Abnormal T axis
and
Abnormally large QRS-T angle

Prolonged QT

QT interval is corrected for rate using the Bazett, Fridericia, or Framingham formula. (See Global Onsets/Offsets and Intervals for more information about formulas for QT correction.) As the ventricular rate increases, the corrected QT increases.



If the QRS duration is wide, or if a major conduction block is indicated, skip prolonged QT analysis

QT interval is measured across all 12 leads from earliest onset to latest offset.

LNGQT -- If QTc is at least 460 ms and rate <120 bpm, state LNGQT.

Adult Contour Criteria Details

The details for adult contour criteria are presented under the following headings:

Suspect Arm Lead Electrode Reversal,66
WPW,66
Atrial Enlargement,67
Frontal Plane Axis Deviation,68
Low Voltage and Lung Disease,69
Brugada,70
Conduction Defects,71
Nonspecific Intraventricular Conduction Block,75
Ventricular Hypertrophy,75
Infarction,79
ST Abnormality (Elevation),90
ST Abnormality (Depression),97
T Wave Abnormality,100
Acute MI,104

Suspect Arm Lead Electrode Reversal

Stop test if ventricular pacemaker.

Statement is made if:

either	QRS axis is between 90 and 270 degrees
and	P axis is between 90 and 210 degrees
or	QRS axis is between 130 and 270 degrees
and	P axis is not measurable
and	Q amplitude >R amplitude in lead I

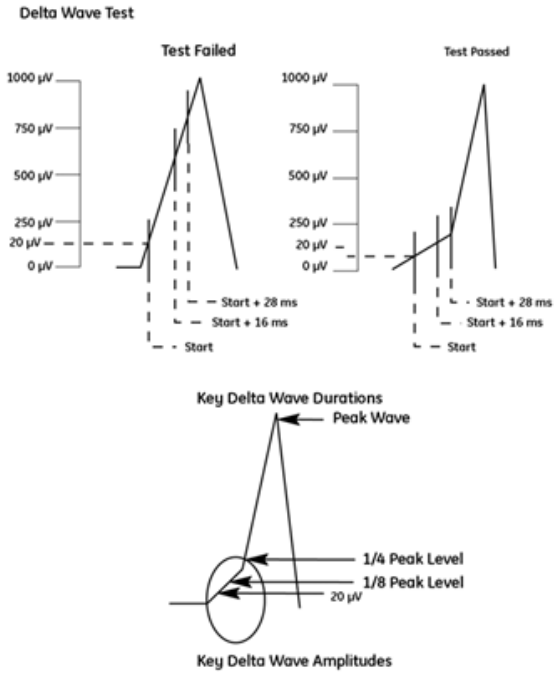
Then say suspect arm lead reversal.

WPW

Skip test WPW if:

Atrial flutter or atrial fibrillation is present

or No P wave is present.



Statement is made if:

Delta wave is present in three or more of 12 leads

and PR interval is not =0.

and P axis is >-30 degrees and <120 degrees

and P amplitude + P' amplitude in lead aVF >–50 µV

and QRS area is positive in lead V1 and PR interval <180 ms

or QRS area is positive in lead V2 and PR interval <160 ms

or QRS area is negative in lead V1 and PR interval <140 ms

If QRS area is positive (R amplitude >80% of the total deflection) in lead V1, then say: Ventricular pre-excitation, WPW pattern type A.

If QRS area is negative (S amplitude >80% of the total deflection) in lead V1, then say: Ventricular pre-excitation, WPW pattern type B.

If not, say: Wolff-Parkinson-White.

If test WPW passed, then suppress with short PR.

Atrial Enlargement

Skip all atrial enlargement tests if:

Test WPW passed

or Ventricular rate >150 bpm

or PR interval = 0

or No sinus rhythm or atrial pacemaker present.

or P axis is <0 degrees or >100 degrees.

Right Atrial Enlargement

Statement is made if:

P wave amplitude >250 µV in any lead: II, III, aVF, V1, or V2 then say *right atrial enlarge*.

Left Atrial Enlargement

Perform Test 1 on leads V1 and V2:

Test 1:

Test passes for this lead if P or P':

If	Amplitude <-100 µV
and	Duration > 60 ms
and	Area > 4000 µV* ms (one small box)
If	Test 1 passed in at least one lead
and	P or P' area of V1 > 4000 µV* ms
and	P or P' amplitude <-200 µV in V1 or V2
or	P or P' area of V1 or V2 > 4900 µV* ms
or	Test 1 passed in both leads

Then say possible left atrial enlargement.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Biatrial Enlargement

Statement is made if:

Test left atrial enlargement passed

and Test right atrial enlargement passed

Then say biatrial enlargement.

Frontal Plane Axis Deviation

Skip all frontal plane axis deviation tests if: Test *WPW passed*.

Left Axis Deviation

Statement is made if:

QRS axis between -30 and -89 degrees Then say *left axis deviation*.

Right Axis Deviation

Statement is made if:

QRS axis between 90 and 109 degrees

Then say rightward axis.*

QRS axis between 110 and 180 degrees

Then say right axis deviation.*

QRS axis between 181 and 269 degrees

Then say right superior axis deviation.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Indeterminate Axis

Statement is made if:

R amplitude minus S amplitude ≤50 µV or ≤10% of the total QRS deflection in leads I, II, and III.

Then say *indeterminate axis.*

Low Voltage and Lung Disease

Skip test low voltage and lung disease if:

Test WPW passed

or QRS duration >120 ms.

Low Voltage

Statement is made if:

QRS deflection <1000 µV in all leads

or QRS deflection <500 µV in all frontal leads

Then say low voltage QRS.

Pulmonary Disease

Statement is made by point scoring technique

Test S1, S2, and S3 pattern used 1 point

Test passed if:

R amplitude < (4 x S amplitude) in any two of leads I, II, and III

and S amplitude >200 µV with no R' in leads I, II, and III

and No R' wave is present in leads I, II, and III

or S amplitude >200 µV in leads I, II, and III

and No R' wave present in leads I, II, and III

and S amplitude in lead I >300 µV

and S amplitude in lead II >400 µV

and S amplitude in lead III >700 µV

QRS deflection <500 µV in all frontal leads 1 point

P axis >80 degrees and <270 degrees 1 point

QRS axis <–30 or >90 degrees or indetermined axis passed 1 point

R amplitude in lead V5 <S amplitude in lead V5

or R amplitude in lead V6 <S amplitude in lead V6 1 point

If cumulative points are >3 points, then say pulmonary disease pattern.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Brugada

Skip test if any of the following occur:

- QRS duration > 150 ms
- ventricular rate > 150 bpm
- running the ACS analysis option of the 12SL

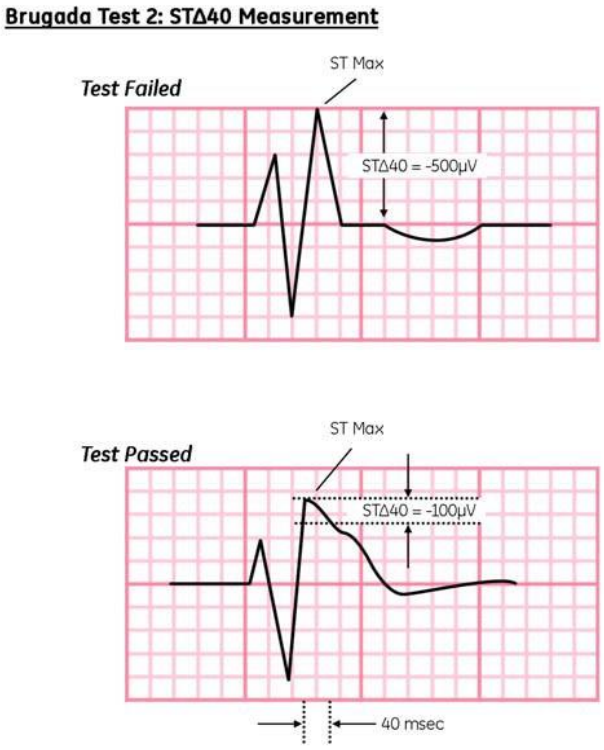
For more information, see ACI-TIPI/ACS Tool for Indicating Probability of ACS in the Symptomatic Patient.

Brugada Pattern Test

In leads V1 and V2, look for Brugada pattern (type 1).

Brugada pattern if any of the following occur:

- STJ > 200 µV
- STE < 400 µV
- STJ > STM > STE
- T-wave amplitude < 0 µV



Test 1

Test 1 looks at indicators of an acute cardiac event (such as ST elevation in leads besides V1-V3, ST depression, inverted T-waves, and Q waves) which represent a higher probability of acute MI or ischemia even though a Brugada type 1 pattern is found in lead V1 or V2.

Test 1 passes if any of the following occur:

- A minimum of STJ and STM lead V4 < 200 µV.
- For all 12 standard leads expect V1-V3, the number of leads with ST elevation (minimum of STJ and STM > 100 µV) is < 1.

- For all 12 standard leads, the number of leads with ST depression (maximum of STJ, STM, and STE <-100 µV) is < 2.
- For all 12 standard leads, ST elevation and ST depression are not both present (excluding V1-V3 for elevation, thresholds as described above).
- The number of lateral leads (V4, V5, V6, I, aVL) with inverted T waves is < 1 (T or T' amplitude <- 100 µV).
- The number of anteroseptal leads (V1-V4) with Q waves is < 2 (Q amplitude > 0 µV).

Test 2

Test 2 is used to discriminate between RBBB and Brugada pattern.

Test 2 passes if any of the following occur:

- 0 > STΔ40 > -400 µV in leads V1 and V2
- the number of lateral leads (V4, V5, V6, I, aVL) with a wide S wave (S duration ≥ 40 ms) is ≤ 3

Statement made if:

Brugada type 1 pattern is present in lead V1 or V2

- Test 1 passed
- Test 2 passed

Then say *Brugada pattern, type 1*

Conduction Defects

Skip all tests for conduction defect if Test *WPW* passed.

RSR' or QR Pattern

Skip this test if Brugada test passed.

Statement is made if in lead V1:

QRS duration > 94 ms (men)

or	>88 ms (women or unknown)
and	Q wave is >0 ms
either	
and	R wave duration >20 ms
and	R wave amplitude -STJ >200 µV
and	No S wave is present
or	R' wave duration >20 ms
and	R' wave amplitude -STJ >200 µV
and	No S' wave is present

Then say RSR' or QR pattern in V1 suggests possible right ventricular conduction delay.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Incomplete Right Bundle Branch Block

Skip test if Brugada test passed.

Statement is made if:

QRS duration is between 91 and 120 ms

and S wave duration >40 ms in any two of leads I, aVL, V4, V5, and V6

and In lead V1 or V2

either R wave duration >30 ms

and R wave amplitude >100 µV

and No S wave is present

or R' wave duration >30 ms

and R' wave amplitude >100 µV

and No S' wave is present

Then say incomplete right bundle branch block.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Incomplete Right Bundle Plus Right Ventricular Hypertrophy

Skip test if Brugada test passed.

Statement is made if:

Test for *IRBBB* passed and R or R' amplitude >1000 µV in lead V1 and QRS axis >110 degrees

Then say *incomplete right bundle branch block plus right ventricular hypertrophy*.

and Suppress *RVH*.

Right Bundle Branch Block

Skip test if test Brugada passed.

Statement is made if:

Test 1:

QRS duration >120 ms

and In any two of leads I, aVL, V4, V5, and V6, S wave duration >40 ms

and QRS area in lead V1 is positive

and No terminal S wave is present in lead V1

either

or S amplitude + minimum STJ or STM <100 µV and <R amplitude in lead V1

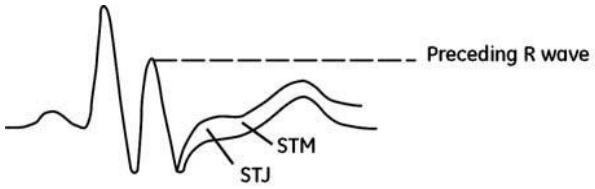
or S amplitude + minimum STJ or STM-to-R amplitude ratio <30% in lead V1

or S amplitude + minimum STJ or STM-to-R amplitude ratio <50% in lead V1

and QRS >130 ms

either

or QRS axis <100 degrees



Or if,

Test 2:

QRS duration >108 ms

and QRS area is positive in lead V1

and R or R' duration >60 ms in lead V1

and In any three of leads I, aVL, V4, V5, and V6: S wave duration >60 ms

Or if,

Test 3:

QRS duration >130 ms

and QRS area is positive in lead V2

and In two or more of leads I, aVL, V4, V5, and V6: S duration >40 ms

and R or R' wave present in lead V1 and no terminal S wave

Then say right bundle branch block.

If test RBBB passed, then suppress all right axis deviation.

RBBB Plus Right Ventricular Hypertrophy

Skip test if test Brugada passed.

Statement is made if:

Test right bundle branch block passed

and R or R' amplitude >1500 µV in lead V1

either

and QRS axis >110 degrees

Then say *right bundle branch block, plus right ventricular hypertrophy* * and suppress *right ventricular hypertrophy*.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Incomplete Left Bundle Branch Block

Statement is made if:

QRS duration >105 and <120 ms

and In leads V1 and V2, QRS amplitude is negative

and In leads V1 and V2, Q or S wave duration >80 ms

and In any two of leads I, V5, and V6, no Q wave is present

and In any two of leads I, aVL, V5, and V6, R duration >60 ms

Then say incomplete left bundle branch block.

Left Bundle Branch Block

Statement is made if:

QRS duration > 120 ms

and QRS area >1/4 of (QRS duration x maximum R amplitude) in lead I or V6. That is, the area of lead I or V6 is at least half the area of a right triangle with height h and base b.

and QRS balance is negative in leads V1 and V2

and In leads V1 and V2, Q or S duration >80 ms

and In any two of leads I, V5, and V6, no Q wave is present

and In any one of lead I, V5, or V6, R duration + R' duration >100 ms

and QRS duration >160 ms

either

or QRS duration >140 ms

and Over leads I, aVL, and V6, the sum of R duration and R' duration totals >240 ms

or QRS duration >120 ms

and Over leads I, aVL, and V6, the sum of R duration and R' duration totals >240 ms

and QRS area >1/2.5 times (QRS duration x maximum R wave amplitude) in any two of leads I, aVL, and V6

Then say left bundle branch block.

If test LBBB passed, then suppress left anterior fascicular block and left posterior fascicular block.

If *LBBB* not stated, but QRS balance is negative in lead V1, QRS duration >140 ms, and *RBBB* test did not pass, then remember this ECG has passed as complete *LBBB* for internal logic purposes. This is not printed on the analysis report, but the ECG will be treated as complete *LBBB* in the analysis program logic.

Left Anterior Fascicular Block

Statement is made if:

QRS axis is <-45 degrees and no indeterminate axis present

and R amplitude >Q amplitude in leads I and aVL

and Any Q wave is present in lead I

and either S or S' is of greater amplitude than both R and R' in lead II

Then say left anterior fascicular block.

If test left anterior fascicular block passed, then suppress all left axis deviation and ILBBB.

Left Posterior Fascicular Block

Statement is made if:

Age >30 years:

and Test S1, S2, and S3 pattern failed

and Test pulmonary disease failed

and QRS axis between 110 and 180 degrees

and Undetermined axis not present

and R amplitude >Q amplitude in leads III and aVF

and Any Q wave is present in leads III and aVF

Then say left posterior fascicular block.

If test left posterior fascicular block passed, then suppress all right axis deviation.

Bifascicular Block

Statement is made if:

Test RBBB passed

and Test left anterior fascicular block passed

or Test RBBB passed

and Test left posterior fascicular block passed

Then say bifascicular block.

Nonspecific Intraventricular Conduction Delay

Statement is made if:

QRS duration is >118 ms and <124 ms

and Tests RBBB and complete LBBB failed

and Tests IRBBB, ILBBB, fascicular blocks, and RSR failed

Then say nonspecific intraventricular conduction delay.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Nonspecific Intraventricular Conduction Block

Statement is made if:

QRS duration ≥125 ms and Test *RBBB* and *LBBB* failed

Then say *nonspecific intraventricular conduction block*.

If test nonspecific intraventricular conduction block passed, then suppress *left anterior fascicular block*, *left posterior fascicular block*, and *RSR or QR pattern*.

Ventricular Hypertrophy

Right Ventricular Hypertrophy

Skip test right ventricular hypertrophy if:

Test WPW passed

or Test Brugada passed

or Test RBBB passed

or QRS is negative in lead V1

or S amplitude >1000 µV in lead V1

QRS axis <60 degrees

Then say nonspecific intraventricular conduction delay.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Statement is made by point scoring technique:

either R or R' amplitude >500 µV in lead V1

Add one point for every 500 µV increment up to

1500 µV	1 point
QRS amplitude is negative and S amplitude >500 µV in lead V5 or V6	1 point
QRS amplitude is negative and S amplitude >500 µV in lead V5 or V6	1 point
QRS amplitude is negative and S amplitude >500 µV in lead V5 or V6	1 point
Test right atrial enlargement passed	1 point
Patient is >30 years old	1 point
Add one point for every 10 degrees increment up to maximum of 110 degrees	1 point
Test S1, S2, and S3 pattern passed	1 point

If cumulative *RVH* points are $\geq$ 3 points, then say *possible right ventricular hypertrophy*.*

If cumulative *RVH* points are $\geq$ 5 points, then say *right ventricular hypertrophy*.

Suppress *RAD, LPFB, LOWV, RSR*, and *IVCD*.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

RVH with Repolarization Abnormality

Statement is made if:

Test possible RVH passed

and	QRS duration <120 ms
and	In all leads V1, V2, and V3
either	STJ > STM or STJ > STE
or	STM or STE or T amplitude <-100 µV
and	In no more than one lead of leads V4, V5, and V6 STM or STE or T amplitude <-100 µV

Then say right ventricular hypertrophy with repolarization abnormality.

Left Ventricular Hypertrophy

The 12SL program differentiates between ECGs that meet only voltage criteria for left ventricular hypertrophy versus those that meet additional criteria for LVH and/or exhibit other abnormalities that are frequently associated with LVH. ECGs meeting these additional criteria (e.g., left atrial enlargement, wide QRS, left ventricular "strain" pattern) frequently represent a more advanced state of left ventricular hypertrophy.

The 12SL program generates four statements related to LVH. In increasing order of severity, these statements are:

- Minimal voltage criteria for LVH, may be normal variant
- Moderate voltage criteria for LVH, may be normal variant
- Voltage criteria for left ventricular hypertrophy
- Left ventricular hypertrophy

The 12SL left ventricular hypertrophy criteria incorporates four commonly used methods from the literature. These include:

- Amplitude of R wave in lead aVL [1]
- Sokolow-Lyon [1]
- Cornell Voltage*Duration Product [2, 3, 4]
- Romhilt-Estes [5]

Any of these four criteria that are positive are listed in parentheses following the LVH statement. The LVH details are as follows.

Skip test if:

Test WPW passed

or LBBB was stated

Voltage Test 1: R in aVL

Test passes if R or R' in lead aVL > 1100 µV

Voltage Test 2: Sokolow-Lyon

Calculate Sokolow-Lyon score: The maximum negative deflection in lead V1 + the greater of the maximum positive deflections in lead V5 or V6.

Test passes if Sokolow-Lyon score > 3500 µV and age ≥ 30 years

Voltage Test 3: Cornell Product

Calculate Cornell Voltage:

- The maximum negative deflection in lead V3 + the maximum positive deflection in lead aVL.

Calculate Cornell Product:

- Male: Cornell Voltage * QRS duration
- Female: (Cornell Voltage + 600 µV) * QRS duration

Test passes if Cornell Product > 244 µV * sec and age ≥ 30 years and test *RBBB* failed.

Test Romhilt-Estes

Point score method:

Condition	***Points***
Any of the following: • maximum positive deflection in I or aVL > 2000 µV • maximum negative deflection in III > 2000 µV maximum • positive deflection in V5 or V6 > 3000 µV maximum negative • deflection in V1 or V2 > 3000 µV	3
left ventricular strain pattern in one or more of V5, V6, I, or aVL	3
left atrial enlargement test passed	3
QRS axis ≤ -30	2
QRS duration ≥ 90 ms and test *RBBB* failed	1
intrinsicoid deflection in V5 or V6 ≥ 50 ms	1

Test passes if:

The voltage condition is met

and patient is male, age is 20-29 and Romhilt-Estes points > 7

or patient is male, age 30 or higher and Romhilt-Estes points > 5

or patient is female age 20 or higher and Romhilt-Estes points > 5

Test Wide QRS

Test passes if QRS duation > 115 ms and test RBBB failed.

LVH Voltage Statements

If any one of the three Voltage Tests pass, then say Minimal voltage criteria for LVH, may be normal variant.*

If any two of the three Voltage Tests pass, then say Moderate voltage criteria for LVH, may be normal variant.*

If all three of the Voltage Tests pass, then say Voltage criteria for left ventricular hypertrophy.

If the patient age is < 35 years and the LVH statement is not made (criteria below), set **Voltage Test 2** (Sokolow-Lyon) and **Voltage Test 3** (Cornell Product) to fail. In this case, an LVH Voltage statement will be made only if **Voltage Test 1** (R in aVL) passed. In other words, for ages 30-34, allow Sokolow-Lyon and Cornell Product results to be used only if other non-voltage abnormalities are present that forces the stronger LVH statement.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

LVH statement is made if:

Test *Romhilt-Estes* passes

or any one of the three *Voltage Tests* passes and either left ventricular strain pattern is present or test *LAE* passes

or any one of the three *Voltage Tests* passes and test *Possible LAE* passes and test *Wide QRS* passes

or any two of the three *Voltage Tests* pass and either test *Possible LAE* or test *Wide QRS* passes

Then say *left ventridular hypertrophy*

If LVH statement is made, the following may also be stated:

- If test Wide QRS passes, then say Left ventricular hypertrophy with QRS widening
- If left ventricular strain pattern, then say Left ventricular hypertrophy with repolarization abnormality
- If test Wide QRS passes and left ventricular strain pattern, then say Left ventricular hypertrophy with QRS widening and repolarization abnormality
- If LVH statement made and Test Wide QRS passes, then suppress IRBBB, IVCD, IVCB, and ILBBB.

If any LVH statement is made (including voltage statements), then the names of any positive tests will be listed in parentheses at the end of the statement:

- If any LVH statement is made and *Voltage Test 1* passes, then include *R in aVL* in parentheses at the end of the statement.
- If any LVH statement is made and *Voltage Test 2* passes, then include *Sokolow-Lyon* in parentheses at the end of the statement. If any LVH statement is made and *Voltage Test 3* passes, then include *Cornell Product* in parentheses at the end of the statement.

- If any LVH statement is made and test *Romhilt-Estes* passes, then include *Romhilt-Estes* in parentheses at the end of the statement.

If any LVH statement is made, then suppress *LOWV*.

Biventricular Hypertrophy

Skip test of biventricular hypertrophy if:

Test WPW passed

or If test RBBB passed

Statement is made if:

Test RVH passed and any LVH test passed

or Patient's age >30 years

and QRS axis >90 degrees

and R or R' amplitude >2600 µV in lead V5 or V6

or Q, S, and S' amplitudes <500 µV in lead V1

and R or R' amplitude >2600 µV in lead V6

Then say biventricular hypertrophy.

Suppress all LVH and RVH statements.

If test QRS widening passed, then append with QRS widening.

If test repolarization passed, then append with repolarization abnormality.

If test QRS widening and test repolarization passed, then say with QRS widening and repolarization abnormality.

Infarction

Anterior Infarction Tests

Skip tests if WPW passed or LBBB stated:

Test 1

Q duration in lead V3 >30 ms and Q amplitude is >75 µV

Test 2

Q duration in lead V4 >Q threshold duration and Q amplitude >75 µV

Establish Q duration threshold via the following criteria:

If QRS duration <120 ms

and R amplitude in lead V4 >1200 µV, then for every 100 µV over 1200 µV (from lead V4 R amplitude) add 1 ms to the default lead V4 Q duration of 30 ms up to maximum of 40 ms

or If QRS duration >120 ms

and If R amplitude in lead V4 >800 µV, then Q duration threshold in lead V4 = 35 ms

and If RS in lead V1 is present

and R duration in lead V1 >35 ms, then lead V4 duration threshold = R duration in lead V1 + 3 ms up to a maximum of 45 ms

Test 3

Q amplitude in lead V3 ≥100 µV and QRS balance is negative in lead V3.

Test 4

Q amplitude in lead V4 ≥100 µV and QRS balance is negative in lead V4.

Test 5

Q duration in leads V2 and V3 >20 ms and Q amplitude in leads V2 and V3 >200 µV.

Skip tests 6 and 7 if the QRS deflection (maximum R amplitude + maximum S amplitude) in lead V3 ≤50 µV.

Test 6

LVH is not passed and balance in leads V1 and V2 is negative

and Maximum R or R' in lead V3 <200 µV

and Maximum R amplitude in lead V3 + 25 µV <R amplitude in lead V2

and Q + R + S duration in lead V3 <50 ms

or LVH not passed and balance in leads V1 and V2 is negative

and R amplitude in lead V3 <200 µV

and R amplitude in lead V3 + 25 µV <R in lead V2

and Q + R + S duration in lead V3 >50 ms

Test 7

LVH is not passed and QRS duration <120 ms and Q amplitude in lead V2 is 0 µV

and Maximum R or R' amplitude in lead V3 <100 µV

and Q + R + S duration in lead V3 <50 ms

or LVH does not pass and QRS duration <120 ms and Q amplitude in lead V2 is 0 µV

and R amplitude in lead V3 <100 µV

and Q + R + S duration in lead V3 >50 ms

NOTE: SKIP TEST 8 IF THE QRS DEFLECTION (maximum R amplitude + maximum S amplitude) in lead V4 <50 µV.

Test 8

Q + R + S duration <50 ms

and No LVH passed

and QRS balance in leads V1 and V2 is negative.

and Maximum R amplitude in lead V4 + 25 µV <R amplitude in lead V3

or Q + R + S duration in lead V4 >50 ms

and R amplitude in lead V4 <200 µV

and R amplitude in lead V4 + 25 µV <R amplitude in lead V3

and No LVH passed

and Balance in leads V1 and V2 is negative

Cannot Rule Out Anterior Infarction

If any *AMI* tests passed, then say *cannot rule out anterior infarction.**

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Possible Anterior Infarction

Statement is made if:

Any of AMI tests passed and Low voltage did not pass and IVCB did not pass

and In lead V3 the R duration <30 ms, the Q duration = 0 ms, and the S duration >40 ms or In lead V3 the Q duration >30 ms

and In lead V4 the R duration <45 ms, the Q duration

= 0 ms, and the S duration >40 ms or In lead V4 the Q duration >35 ms

or In lead V3 the R duration <20 ms, S duration >40 ms, and Q duration = 0 ms

or In lead V3 the Q duration >35 ms

or In lead V4 the R duration <25 ms, S duration >40 ms, and Q duration = 0 ms

or In lead V4 the Q duration >40 ms

Then say possible anterior infarction.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Anterior Infarction

Statement is made if:

Any of AMI tests passed and no low voltage passed and no IVCB passed

and In lead V3 the R duration <25 ms, the Q duration = 0 ms, and the S duration >40 ms, or In lead V3 the Q duration >30 ms

and In lead V4 the R duration <30 ms, the Q duration= 0 ms, and the S duration >40 ms, or In lead V4 the Q duration >40 ms

or In lead V3 the R duration <15 ms, S duration >40 ms, and Q duration = 0 ms

or In lead V3 the Q duration >40 ms

or In lead V4 the R duration <20 ms, S duration >40 ms, and Q duration = 0 ms

or In lead V4 the Q duration >50 ms

or Any anterior injury test passed or the special T amplitude in lead V3 <-150 µV

Then say *anterior infarction*.

If LBBB statement not stated,

QRS duration >145 ms, QRS balance in lead V1 is negative, and RBBB is not stated:

and In any leads V1 through V6, the QRS balance is positive and Q duration >30 ms, Q amplitude >100 µV, and any anterior infarction test 1 through 5 passed

then If "possible anterior infarction" test passed, then state possible anterior infarction.

or If anterior infarction passed, then state anterior infarction.

Determine age of infarct:

If anterior injury is present append, *possibly acute*. Otherwise append, *age undetermined*.

Septal Infarction Tests

Skip septal infarction tests if:

Test WPW passed

or Tests complete LBBB passed

Test 1

QR is present in lead V1

and Q duration in lead V2 >30 ms

Test 2

Q duration >30 ms in lead V2

Test 3

Q amplitude >100 µV in lead V2

and QRS balance is negative in lead V2 or test RBBB passed

Test 4

If no Q present in lead V1, test if R amplitude in lead V2 <R amplitude in lead V1 by more than 50 µV, R amplitude in lead V2 <200 µV, AMI did not pass, and QRS deflection in lead V2 >50 µV

Cannot Rule Out Septal Infarct

Statement is made if any *SMI* test passed.

Then say *cannot rule out septal infarct.*[*]

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Septal Infarct

Statement is made if:

Any SMI test passed

and STM >50 µV and T and T' are negative in lead V2

either

or Test IVCB failed and LVH is not present

Then say septal infarct.

Determine age of infarct:

If anterior injury present

Then append , possibly acute.

Otherwise append , age undetermined.

Possible Lateral Infarct

If WPW, then skip all tests for lateral infarct.

Test 1

If AMI tests 1, 2, 3, 4, and 5 did not pass

and In lead V5 the Q + R + S duration <50 ms and QRS deflection >50 µV and maximum R or R' amplitude in lead V5 <100 µV

or In lead V5 the Q + R + S duration >50 ms and R amplitude <100 µV 2 points

Test 2

In lead V6 if maximum R or R' amplitude <100 µV and Q + R + S duration <50 ms and QRS deflection >50 µV

or In lead V6 if Q + R + S duration >50 ms and R amplitude <100 µV 2 points

Test 3

Test for the following conditions in leads I, V5, V6, and aVL, 1 point each lead

Q duration >25 ms Q amplitude >75 µV

5 times Q amplitude >R amplitude: when lead V5 or V6

4 times Q amplitude >R amplitude: when lead I or aVL, 1 point

If cumulative point value >2 points, then say possible lateral infarct*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Lateral Infarct

Statement is made if in two or more of leads I, aVL, V5, and V6:

Q duration >30 ms

and Q amplitude >75 µV

and 5 times Q amplitude >R amplitude in lead V5 or V6 or 4 times Q amplitude >R amplitude
in lead I or aVL

or Test for possible lateral infarction passed and test for lateral injury passed

Then say lateral infarct

If test any lateral infarct passed, then suppress all right axis deviation.

If no Q wave is present and R amplitude >200 µV in lead V3, then suppress all anterior infarct. If left anterior fascicular block is not passed, then suppress left posterior fascicular block and bifascicular block.

Determine age of infarct:

If lateral injury present

Then append, possibly acute

Otherwise append, age undetermined

Anteroseptal Infarct

Statement is made if:

Any AMI tests passed

and Any LMI test passed

Then say anterolateral infarct

If cannot rule out or possible anterior infarct passes and possible lateral infarct passes, then say possible anterolateral infarct*.

If LMI passed in the presence of cannot rule out or possible anterior infarct or if AMI passed in the presence of possible lateral infarct, then say anterolateral infarct

Suppress SMI

Suppress AMI

Suppress LMI

Suppress PULD

Suppress ILBBB

Suppress IVCD

Determine age of infarct:

If any were labeled acute, append, possibly acute

Otherwise append, age undetermined

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Anterolateral Infarct

Statement is made if:

Any AMI tests passed

and Any LMI test passed

Then say anterolateral infarct

If cannot rule out or possible anterior infarct passes and possible lateral infarct passes, then say possible anterolateral infarct*.

If LMI passed in the presence of cannot rule out or possible anterior infarct or if AMI passed in the presence of possible lateral infarct, then say anterolateral infarct

Suppress SMI

Suppress AMI

Suppress LMI

Suppress PULD

Suppress ILBBB

Suppress IVCD

Determine age of infarct:

If any were labeled acute, append, possibly acute

Otherwise append, age undetermined

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Inferior Infarct

Skip test inferior infarct if:

Test WPW passed

or LBBB printed

Inferior Infarct Tests

Test 1:

Test for normal repolarization.

Test repolarization abnormalities (refer to STELE, STDEP, and T wave abnormality details)

Normal repolarization = test 1 passes

Test 2:

Test for normal QRS and T.

If the QRS axis and T axis <30 degrees apart, use T amplitude threshold of 50 µV

else use T amplitude threshold of 100 µV

If T amplitude in leads aVF and V3 through V6 >T amplitude threshold

and Maximum ST amplitude in leads aVF and V3 through V6 >-20 µV

and Minimum ST amplitude in lead aVF <50 µV

and Minimum ST amplitude in leads V3 through V6 <200 µV

and R amplitude in lead II >500 µV and Q:R ratio in lead II <1:5 (20%)

or R amplitude in lead aVF >500 µV

and QRS balance in lead V5 is positive

and QRS axis >0 degrees

and QRS axis and T axis is <45 degrees apart

Then pass Test 2

Test 3:

Test for normal repolarization and QRS axis and duration if Test 1 passed

and QRS axis >10 degrees

and QRS duration < 120 ms

Then pass Test 3

Test 4:

Test for Q wave amplitude in lead aVF.

Skip Test 4 if test 3 failed.

Results of Test 2 are used to adjust for Q wave thresholds.

Test 2 pass uses less sensitive Q wave threshold criteria.

Test 2 fail uses more sensitive Q wave threshold criteria (in parentheses)

If QRS duration < 100 ms

and Q amplitude in lead aVF >100 µV

and Q duration >40 (30) ms in lead aVF

and Q:R duration >1:5 in lead aVF

or Q amplitude >100 µV in lead aVF

and Q duration in lead aVF >40 ms

or Q amplitude >75 µV in lead aVF

and Q duration >40 ms in lead aVF

and Q:R ratio in lead aVF >1:5

or QRS duration >100 ms and <120 ms

and Q amplitude in lead aVF >75 µV

and Q duration in lead aVF >40 (35) ms

or Q duration in lead aVF >40 (25) ms and Q:R ratio in lead aVF >1:5 (20%)

or QRS duration < 120 ms

and Q amplitude in lead aVF >200 µV

and Q duration in lead aVF >30 ms

and Q:R duration in lead aVF >1:3

Then pass Test 4.

If Test 3 passed and Test 4 failed (normal QRS axis and duration and no repolarization abnormalities and no significant Q wave in aVF), then stop and do not execute any further *IMI* tests.

Cannot Rule Out Inferior Infarct (Masked by Left Anterior Fascicular Block?)

Statement is made if:

Q duration + R duration <20 ms in lead aVF

and R amplitude in lead aVF <50 µV

and Test left anterior fascicular block passed

Then say cannot rule out inferior infarct (masked by left anterior fascicular block?) *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

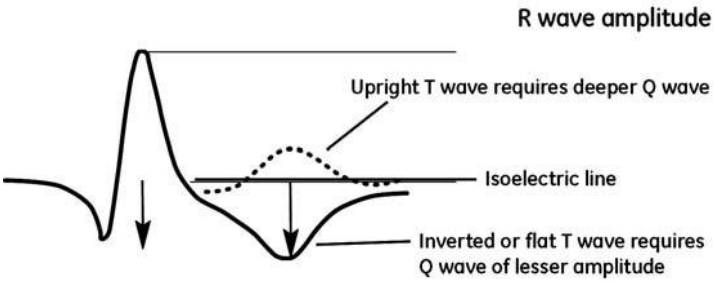
Cannot Rule Out Inferior Infarct

Statement is made if:

In lead II or aVF, Q amplitude >50 µV

and Q duration >25 ms

and Q amplitude minus the minimum of T or T' >1/5 of R amplitude



or If Q amplitude >50 µV

and Q duration >20 ms

and QRS axis <-45 degrees

either

or QRS axis >240 degrees

and Maximum R amplitude in aVF <100 µV

Then say *cannot rule out inferior infarct* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Possible Inferior Infarct

In lead II or aVF:

Q amplitude >75 µV

and Q duration >35 ms

and Q wave minus the minimum of T amplitude or T' amplitude is >1/5 R amplitude

or In lead II or aVF:

Q amplitude >75 µV

and Q duration >30 ms

and Q wave minus the minimum of T amplitude or T' amplitude is >1/4 R amplitude

or In lead II or aVF:

Q amplitude >75 µV

and Q duration >25 ms

and Q wave minus the minimum of T amplitude or T' amplitude is >1/3 R amplitude

or In lead II or aVF:

Q amplitude >75 µV

and Q duration >20 ms

and Both STJ and STM are >50 µV

and Special T amplitude <-50 µV

or In lead II or aVF:

Q amplitude >75 µV

and Q duration >20 ms

and Both STJ and STM are >100 µV

and STE + 100 µV >T amplitude

Then say possible inferior infarct*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Inferior Infarct

Determine age of infarct:

If inferior injury passed:

Then append, *possibly acute*.

Otherwise append, *age undetermined*.

Inferior-Posterior Infarct

Skip test with posterior extension if:

Test WPW passed

Statement is made if:

Any inferior infarct test passed

and No Q wave is present in leads V1 and V2

and QRS duration <120 ms

and Test complete RBBB, failed

and R duration >35 ms in leads V1 and V2,

either

and QRS balance in leads V1 and V2 is positive

or QRS balance in lead V2 is positive

and Maximum ST amplitude <-50 µV in lead V2

or R duration in lead V1 or V2 >40 ms

and R amplitude in lead V1 or V2 >200 µV

and Maximum ST amplitude in lead V1 or V2 <-100 µV

or Balance in lead V3 is positive

and Maximum ST amplitude in lead V3 <-100 µV

and Maximum ST amplitude in lead V2 <-50 µV

or Maximum ST amplitude in lead V1 <-50 µV

and Maximum ST amplitude in lead V2 <-50 µV

and Maximum ST amplitude in lead V3 <-50 µV

Then say inferior-posterior infarct.

Suppress all RVH, IRBBB, BVH, and IMI statements.

If possibly acute (see immediately below) and extra lead V4r is present, test for right ventricular involvement:

If STM in lead V4r > 100 µV

or STM in lead V4r > 50 µV and 2nd or 3rd degree AV block and STM in lead III > STM in lead II

Then append with right ventricular involvement. *

*This statement is made by version 21 or higher of the 12SL analysis program

Determine age of infarct:

If inferior injury present or maximum ST amplitude in lead V2 <-100 µV

Then append, possibly acute.

Otherwise, append, age undetermined.

Posterior Infarct

Skip test if inferior-posterior infarct or WPW passed.

Requires:

Age >30 years

and QRS duration <120 ms

and No RBBB, IRBBB, or RVH passed

Test 1

R amplitude in leads V2 and V3 >700 µV

and R amplitude in leads V2 and V3 >3 times S amplitude

Test 2

QRS balance in leads V1 and V2 is positive

or QRS balance in leads V2 and V3 is positive

Test 3

Maximum ST in lead V1 or V2 <-100 µV

Test 4

T amplitude in lead V1 or V2 is >0 µV

Test PMI 1: Test for R:S Ratio in Lead V1

If test 2 or tests 1 and 4

and If test 3 failed

and If R:S ratio in lead V1 >1:2

and R amplitude in lead V1 >100 µV

and R duration in lead V1 >20 ms

or R:S ratio >1:3 in lead V1

and R amplitude in lead V1 >100 µV

and R duration in lead V1 >40 ms

and If T amplitude in V1 >0 µV

and T amplitude in lead V2 >200 µV

and T amplitude in lead V3 >200 µV

and LVH test failed

Test PMI 2: Test True Posterior Infarct

Tests 2, 3, and 4 passed.

Statement is made if:

Test PMI 2 passed and any IMI test passed.

or PMI 1 passed, PMI 2 failed, and IMI passed.

Then say inferior-posterior infarct and suppress IMI statement.

If test PMI 2 passed and IMI failed, then say posterior infarct.

If PMI 1 passed, PMI 2 failed, and IMI failed, then say increased R/S ratio in V1, consider early transition, or posterior infarct.

Determine age of infarct if IMI and PMI or PMI is stated:

If test PMI 2 passed

and IMI is acute

or Maximum ST amplitude in lead V2 <-50 µV

Then append, possibly acute.

Otherwise append, age undetermined.

If PMI 1 or PMI 2 passed then suppress RSR' pattern statement.

ST Abnormality (Elevation)

Skip all tests for ST abnormality (elevation) if:

Test WPW passed

or Test RBBB passed and ventricular rate > 120 bpm

or Test LBBB passed

Nonspecific ST Abnormality (Elevation)

Skip test if:

Test Brugada passed

or Test RBBB passed

or Any test of infarct passed

Statement is made if:

QRS duration <120 ms

and In any 2 of leads I, II, III, aVF, and V3 through V6 STJ, STM, and STE are all >50 µV

and The slope from QRS onset to J point > slope of ST segment and T is not tall

Then say nonspecific ST abnormality

Early Repolarization Tests

Early Repolarization Test 1

Count leads from leads V1 through V6 with a QRS balance >0 in which both STJ and STM are ≥75 µV

plus The number of leads from I, II, III, aVL, and aVF with a QRS balance >0 in which ST amplitude ≥50 µV

also Compute the sum of the amplitudes of the smaller of STJ and STM for each lead which passes

Early Repolarization Test 1A

Test passes if 3 or more leads pass and the computed sum ≥ 450 µV

Early Repolarization Test 1B

Test passes if 5 or more leads pass and the computed sum ≥ 500 µV

Early Repolarization Test 2

Count the number of leads with tall T waves which passed Early Repolarization Test 1

Early Repolarization Test 3

Test passes if:

Test Early Repolarization Test 1A passes

and QTc is between 370 and 460 ms

and Test Brugada failed

and Test IRBBB failed a

and Test ILBBB failed

and Test RBBB failed

and Test RVH failed

and Test LVH failed

and All tests for infarct failed

and QRS duration <120 ms

Early Repolarization Test 4

Test passes if:

Test Early Repolarization Test 1A passes

and Test Brugada failed

and Test RBBB failed

and All tests for infarct failed

and In at least one standard lead except aVR and V1 QRS balance is positive

and minimum ST > 100 µV in limb leads or 200 µV in precordial leads

Early Repolarization Test 5

Test passes if:

For all 12 standard leads except aVR and V1

The maximum ST amplitude <-50 µV in at least 1 lead

and The maximum ST amplitude < 20 µV in at least 2 leads

or The maximum ST amplitude < 0 µV in at least 2 leads

Early Repolarization Test 6

Test passes if:

In at least one lead of I, II, aVF, and V3 through V6, the T amplitude is negative or T' amplitude < -50 µV

or In lead aVL the T or T' amplitude < -100 µV and either QRS axis < 50 degrees or in any leads II, III,

and aVF, the minimum ST amplitude > 100 µV and in lead V5 or V6 the minimum ST amplitude < 50 µV

ST Elevation, Early Repolarization, Pericarditis, or Injury

Statement is made if:

Early Repolarization Test 1A passes

and Either *Early Repolarization Test* 3 or 4 passes

and Either *Early Repolarization Test* 5 or 6 passes

Then say ST elevation, consider early repolarization, pericarditis, or injury *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

ST Elevation, Probably Due to Early Repolarization

Skip test if *Early Repolarization Test* 5 or 6 passed

Statement is made if:

Test ST elevation, consider early repolarization, pericarditis, or injury passed

and In more than half of the leads passing *Early Repolarization Test*1, T is also tall

Then say *ST elevation, probably due to early repolarization* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Early Repolarization

Skip test if:

Early Repolarization Test 5 or 6 passed or Test *Brugada* passed

Statement is made if:

Early Repolarization Test 1B passed

and T wave is tall in five or more leads (Early Repolarization Test 2)

Then say *early repolarization* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Possible Acute Pericarditis

Skip test acute pericarditis if:

Any test infarct passed

or QRS duration >120 ms

Count leads from leads I, II, and aVF in which both STJ and STM are >75 µV

plus The count of leads (V2 through V6) in which both STJ and STM are >90 µV

Statement is made if:

The total count is at least five

and In any four of leads I, II, V4, V5, and V6 T amplitude is >0 µV and STJ >1/4 of the T amplitude

and In all leads, except leads aVR and V1, both STJ and STM are >-100 µV and T amplitude >0 µV.

Then say possible acute pericarditis *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Acute Pericarditis

Statement is made if:

Possible pericarditis is made

and Count the number of leads (leads I, II, and aVF) in which both STJ and STM are ≥90 µV

plus Count the number of leads (V2 through V6) in which both STJ and STM are ≥110 µV

If count ≥5, then say *acute pericarditis*

Injury Pattern Tests

Skip test all injuries if any tests pericarditis passed (done on all 12 leads individually).

Test 1:

Inspect QRS balance:

Count the number of leads in frontal plane where QRS balance is <1000 µV and in the precordium where the QRS balance <2000 µV. Test 1 passes if count = 12.

Test 2:

Test at all 12 leads (except leads aVR and V1) for ST elevation (skip lead groups with infarct present):

If *AMI* skip leads V2, V3, and V4

If *SMI* skip lead V2.

If *IMI* skip leads II, III, and aVF

If *LMI* skip leads I, aVL, V5, and V6

For this test and subsequent tests, the parameter ST LIMIT is set for each lead:

*ST LIMIT = 200 µV unless,

If frontal lead (I, II, III, aVR, aVL, and aVF)

or If in leads V5 and V6 (R-S) ≥0 µV then = 100 µV

If lead is elevated and QRS balance is positive

or In precordial leads QRS deflection <1500 µV

or In frontal plane QRS deflection <1000 µV

or If QRS balance is negative and ratio of maximum S amplitude to QRS deflection <75%

Then Test 2 passes.

Test 3:

Look for ST elevation based on QRS duration (except leads V1 and aVR)

Skip lead groups with MI present

also Skip anterior leads if Brugada present and skip inferior leads if atrial flutter present.

*Apply ST LIMIT as above

If lead is elevated

and QRS duration is >120 but <130 ms and QRS balance is positive

and Ratio of QRS balance to QRS deflection must be >15%

or QRS duration >130 but <150 ms

and Ratio of QRS balance to QRS deflection must be >25%

or QRS duration >150 ms

and Ratio of QRS balance to QRS deflection must be >50%

or QRS duration <120 ms and QRS balance is negative or positive

and If minimum STJ and STM >100 µV in frontal leads

and If minimum STJ and STM >200 µV in precordial leads

If any of the leads meet the above criteria, then inspect further for that lead group.

*Apply ST LIMIT as above for specific lead group

If Test 1 passed

and If in precordial leads minimal STJ and STM >300 µV = set injury flag

or If in precordial leads maximum R + maximum S <1000 µV

and Minimal STJ and STM >200 µV set injury flag

or If in frontal lead minimum STJ and STM >200 µV = set injury flag

or If frontal lead maximum R + maximum S <750 µV

and Minimal STJ and STM >100 µV = set injury flag

or In any lead the minimal STJ and STM >½ T amplitude = set injury flag

else If test 2 passed

*Apply ST LIMIT as above

Test 4:

If Test 3 passed:

and If in precordial leads, STJ and STM >100 µV

or If in frontal leads, STJ and STM >50 µV

and If in elevated lead T' amplitude <-150 µV

and T' amplitude (absolute value) >1/8 of T amplitude = set injury flag

or If T amplitude is negative = set injury flag

Test 5:

If Test 1 or Test 2 passed, look for reciprocal changes:

and Excluding leads aVR and V1, count the number of leads where:

Test 5a:

Maximal STJ and STM <-100 µV in any lead

Test 5b:

Maximal STJ and STM <-50 µV in any lead

Test 5c:

Maximal STJ and STM <0 µV in any lead

and If Test 5a count >0

or Test 5b count >2

or Test 5b count >1 and Test 5c count >3 set injury flag

Test 6:

If Test 5 fails and injury flag is set:

and No MIs passed

and QRSV passed

and No LVHR present

Then state ST elevation, early repolarization, pericarditis or injury

If LVH with repolarization is present, the injury flag is clear and no statement is made.

Anterior Injury

Statement is made if:

In any lead V2, V3, or V4 criteria for ST elevation and any injury flag set

Then say *ST elevation, consider anterior injury or acute infarct*

Skip any further anterior injury tests if *Brugada* present.

If there is no evidence of *LVH*, *RBBB*, *IRBBB*, *LBBB*, *IVCB* and the QRS duration is less than 140 msec and the ventricular rate less than 100 bpm and the age of the patient is greater than or equal to 30 years old then use the following more sensitive criteria for Anterior Injury.

This Anterior Injury Criteria relies on the use of "Concomitant repolarization" information, (i.e. leads V2 - V4 are inspected for ST elevation and the inferior leads II, III, AVF are inspected for concomitant repolarization changes). The concomitant repolarization changes consist of depressed ST segments, which are weighted more heavily if they are down sloping, and T wave inversion. In these criteria the concept of setting or adapting the ST elevation thresholds based on QRS balance is used. This allows for increased sensitivity by allowing lower ST elevation thresholds to be used to call Anterior Injury but retains high specificity by requiring the presence of other repolarization changes in the inferior leads.

Inspection of the Inferior leads for repolarization changes.

T wave inversion is present if in leads II or AVF the T wave amplitude or T' amplitude is less than -100 µV.

ST depression is present if in leads II, III, AVF the STJ, STM or STE point is depressed more than -20 µV. In addition, if the ST segment is depressed and STE is depressed more than the STM point and the STM point is depressed more than the STJ point (down sloping from STJ to STM to STE) then the ST segment is considered to be "down sloping".

The ST elevation thresholds for V2, V3, and V4 are set according to the following:

If the QRS deflection (R+S) is less than or equal to 500 µV the ST threshold is 100 µV.

If the QRS deflection (R+S) is less than or equal to 1000 µV the ST threshold is 150 µV.

If the QRS deflection (R+S) is less than or equal to 1500 µV the ST threshold is 200 µV.

If the QRS deflection (R+S) is less than or equal to 2000 µV the ST threshold is 250 µV.

If the QRS deflection (R+S) is greater than 2000 µV the ST threshold is 300 µV.

If inferior ST depression and T wave inversion and down sloping ST segments are all present, then the Anterior ST elevation threshold is decreased by 25 µV.

The ST elevation in V2, V3 and V4 is established by a point scoring system. For each lead, if the minimum of the STJ and the STM point are greater than the set threshold 1 point is awarded. If two of the inferior leads have depressed and downsloping ST segments with T wave inversion an additional point is awarded. In the

case where the QRS deflection is less than 500 µV if the minimum of the STJ and the STM point is elevated by more than 200 µV an additional point is awarded. If the ST threshold is less than 250 and the minimum of the STJ and the STM point is greater than 300 µV an additional point is awarded. A single lead could accrue a maximum point score of 4.

For Anterior Injury to be called the point score for the three leads V2, V3, V4 must be greater than or equal to 2 points and at least one inferior lead must have ST depression and or T wave inversion.

For the case where a Q wave Anterior or Septal MI has been called, the MI is dated as acute if for the Anterior MI the minimum of the STJ and the STM point is greater than 200 µV and the T wave is upright (positive) and the STE point is less than the T wave amplitude in V2 or V3 or V4. For the Septal MI the same criteria is used but only for lead V2.

For the special case where there is a Q wave in V3 that is greater than 100 µV in amplitude and greater than 25 msec in duration. If the points awarded in the ST elevation section are 2 or more and the Anterior Elevation Flag is set, the Anterior MI is dated as Acute.

In addition to the previously described criteria additional Anterior injury criteria was added below and also is used when "dating" a Q wave MI as acute.

Part 1 focuses in on the ST segment in the leads V2 and V3 for ST elevation, and takes into account the T wave amplitude in the leads being inspected for elevation. This enhancement is focusing on the Septal and Antero-Septal manifestations of injury patterns. The Concomitant repolarization changes are confined to leads AVF, I, and V6 in these criteria.

Part 2 uses the ST and T wave data to "date" a Q wave MI which occurs in leads V2 – V4.

NOTE: ECGs in these criteria are included in the analysis if they have no evidence of *LVH*, *RBBB*, *IRBBB*, *LBBB*, *IVCB* and have a QRS duration less than 140 msec with a ventricular rate less than 100 bpm and the age of the patient is greater than or equal to 30 years old.

Part 1 criteria are outlined in three steps.

Step 1: Look for ST elevation in V2 and V3.

The ST elevation criteria is met if in any of V2 or V3 either the STJ point is elevated by more than 150 µV or the STM point is elevated by more than 250 µV with the requirement that the T wave amplitude in that lead be more than 1200 µV.

Step 2: Look for ST and T wave repolarization changes in leads AVF, V6, I.

The ST criteria require that the STJ point be depressed (i.e. less than 0 µV) and the STM point be depressed by more than -50 µV and the T or T' amplitude in that lead be greater than 100 µV.

Step 3: Look for large deflections in V2 and V3. If this pattern is found, then do not call Injury.

If the Maximum of either the Q wave or the S wave in leads V2 or V3 exceeds 2000 µV then no injury will be called.

If the Criteria in steps 1 and 2 are met and the criteria for step 3 is not present, then call Anterior Injury.

Part 2 of the Anterior Injury Criteria looks in detail at "dating" a Q wave Anterior Infarct as Acute.

Four ST and T wave criteria tests are applied to the leads V1 – V4.

NOTE: The following tests are performed only if the ECG shows no evidence of *LVH*, *IVCB*, *ILBBB*, *LBBB*, *IRBBB*, *RBBB*, and has a QRS duration less than 116 msec, a ventricular rate less than 100 bpm, the patients age is greater than 30 years old and the ECG shows evidence of either a non acute septal, anterior or inferior MI.

Test 1: Requires the STM point to be elevated by at least 100 µV and also requires the T amplitude be greater than 150 µV with a T' amplitude being less than -150 µV.

Test 2: Requires the STM point be elevated by at least 150 µV and also requires the T amplitude to be greater than 250 µV with a T' amplitude less than -50 µV.

Test 3: Requires the STM point to be elevated more than 250 µV and in addition requires the T amplitude to be greater than 1200 µV.

Test 4: Requires the STM point to be elevated more than 200 µV and requires the T amplitude to be greater than 500 µV and in addition requires that the T amplitude is greater than the QRS deflection in that particular lead.

If the Maximum of either the Q wave or the S wave in leads V2 or V3 exceeds 2000 µV, then no injury will be called.

If the above test is not met then if test 1 and 2 are met or test 3 and 4 are met or test 4 alone is met, then call Anterior Injury.

Lateral Injury

Statement is made if:

In any lead I, aVL, V5, or V6 criteria for ST elevation

and Injury test passed

Then say ST elevation, consider lateral injury or acute infarct

Inferior Injury

Statement is made if:

In any lead II or aVF criteria for ST elevation

and Any injury test passed

Then say ST elevation, consider inferior injury or acute infarct

If anterior injury, lateral injury, and inferior injury present, then say

ST elevation, consider anterolateral injury or acute infarct

ST elevation, consider inferior injury or acute infarct

If anterior and lateral injury present, then say ST elevation, consider anterolateral injury or acute infarct

If inferior and lateral injury present, then say ST elevation, consider inferolateral injury or acute infarct

If inferior injury present and extra lead V4r is present, test for right ventricular involvement:

If STM in lead V4r > 100 µV

or STM in lead V4r > 50 µV and 2nd or 3rd degree AV block and STM in lead III > STM in lead II

Then append with right ventricular involvement

ST Abnormality (Depression)

Skip all ST Abnormality (Depression) tests if:

Test WPW passed

or Test LBBB passed

or QRS duration >125 ms

or Heart rate >120 bpm and RBBB passed

or Acute MI or injury stated

and Maximum ST elevation is greater than maximum ST depression

Junctional ST Depression

Skip test if:

Test *LVH secondary repolarization* passed

or Test *RVH with secondary repolarization* passed

or Test *nonspecific ST abnormality (elevation)* passed

or Test *RBBB* passed

or Test *Brugada* passed

or Any acute infarct or injury test passed

or Any MI test passed

Statement is made:

If in any two of all 12 leads, except aVR STJ <-100 µV and STE $\geq$ 0

Then say *Junctional ST depression, probably normal* *

If in any two of all 12 leads, except aVT STJ <-100 µV and STE $\geq$ ½ of STJ

Then say *Junctional ST depression, probably abnormal* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Nonspecific ST Abnormality

Skip test if:

Test LVH and RVH with secondary repolarization passed

or Test nonspecific ST abnormality (elevation) passed

or Test RBBB passed

or Test Brugada passed

Statement is made if either Test 1 or Test 2 passes:

Test 1:

In any two of leads I, II, aVL, and V2 through V6:

either Minimum of STM or STE < minimum of STJ or -50 µV

or Heart rate <100 bpm

and PR interval <200 ms

and In any two of leads I, II, aVL, and V2 through V6:

Minimum of STM or STE < minimum of STJ, P onset amplitude -50 µV, or -25 µV

and T amplitude >STM +100 µV

Test 2:

In any two of leads I, II, aVL, aVF, V4, V5, and V6:

STJ <-50 µV and STE <0 µV

or STE < minimum (STJ and STM) -25 µV

If Test 1 or Test 2 passes, then say Nonspecific ST abnormality

If MI present, suppress all ST abnormality statements.

ST Depression Consider Subendocardial Injury

Skip test if:

Test *LVH* or *RVH* secondary repolarization passed

Statement is made if:

In any two of leads I, II, aVL, aVF, and V2 through V6 STJ and STM are ≤-100 µV

(If test RBBB passed, then do not test leads V2, V3, and V4)

Then say *ST depression, consider subendocardial injury* Suppress nonspecific ST statements.

Septal Subendocardial Injury

Statement is made if:

Test septal and posterior infarct failed

and In lead V1 or V2, STJ and STM are <-200 µV

Then say Marked ST abnormality, possible septal subendocardial injury

Anterior Subendocardial Injury

Statement is made if:

Test anterior and posterior infarct failed

and Tests LVH with repolarization abnormality failed

and In lead V3 or V4, STJ and STM are <-200 µV

Then say Marked ST abnormality, possible anterior subendocardial injury

Lateral Subendocardial Injury

Statement is made if:

Test lateral infarct failed

and Test LVH with repolarization abnormality (LVHR) failed

and In lead V5 or V6, STJ and STM are < -200 uV or in lead I or aVL, STJ and STM are < -100 uV

Then say Marked ST abnormality, possible lateral subendocardial injury

Inferior Subendocardial Injury

Statement is made if:

Test inferior infarct failed

and Test LVH with repolarization abnormality failed

and In lead II or aVF, STJ and STM are <-100 µV

Then say marked ST abnormality possible inferior subendocardial injury

If any tests subendocardial injury passed, then suppress nonspecific ST abnormality and junctional ST depressions.

If inferior myocardial infarction and lead III has STJ >100 µV, suppress lateral subendocardial injury statement.

If anterior and lateral subendocardial injury present but no septal subendocardial injury present, then say Marked ST abnormality possible anterolateral subendocardial injury

If inferior and lateral subendocardial injury present but no septal and no anterior subendocardial injury present, then say Marked ST abnormality possible inferolateral subendocardial injury

If septal and anterior subendocardial injury present, then say Marked ST abnormality possible anteroseptal subendocardial injury

Special LVHR and anterior subendocardial criteria if LVHR present:

- No LBBB or RBBB
- No subendocardial injury tests passed No ST elevation test passed
- No ST depression abnormalities tests passed QRS duration <150 ms
- No posterior infarct passed No acute MIs passed

Statement is made if:

In two or more of leads V2, V3, or V4

either	QRS balance is positive and ratio of maximum R amplitude to QRS deflection <75%
or	QRS balance is negative
and	Maximum ST amplitude <-100 µV and QRS balance is negative
or	Maximum ST amplitude <-100 µV and QRS balance is positive and T amplitude >0 µV
or	QRS balance is positive and maximum ST amplitude <0 µV
and	T amplitude is positive and T' = 0 and minimum ST amplitude <-150 µV

Then say Marked ST abnormality, possible anterior subendocardial injury

T Wave Abnormality

Skip test if:

Test WPW passed

or	Test LVH with repolarization abnormality passed
or	Any injury test passed
or	Test complete LBBB passed
or	Test subendocardial injury passed

Conditions for skipping test applies to all T wave tests.

Abnormal QRS-T Angle, Consider Primary T Wave Abnormality

Skip test if:

Any test infarct passed

or	Test RBBB passed
or	Test Brugada passed

Statement is made if:

QRS axis -T axis >60 degrees

and T axis <0 degrees

or QRS axis -T axis <-60 degrees

and T axis >90 degrees

Then say Abnormal QRS-T angle, consider primary T wave abnormality*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Nonspecific T Wave Abnormality

Skip test if:

Any test infarct passed or Test *RBBB* passed

or Test *Brugada* passed

For each lead to be tested:

Set test limit:

If QRS amplitude is positive, limit value is 1/20 QRS amplitude + 25 µV

or If QRS amplitude is negative, limit value is 25 µV

Lead passes test if:

Special T amplitude $\leq$ test limit

and special T amplitude <0 or T amplitude < 200 µV

Test leads as follows:

First test leads V6 to V3

If lead V3 passed test, then also test lead V2

Test leads I, II, and aVL:

If special T amplitude exceeds 150 µV, do not test that lead

For aVL, if QRS balance is negative, do not test that lead

If more than two leads pass this test, then say *Nonspecific T wave abnormality*.

Anterior Ischemia

Skip test if:

Test *Anterior MI* passed

or Test *Posterior MI* passed

or Rest *RBBB* passed

or Test *Brugada* passed

or Test *RVH with repolarization abnormality* passed

Statement is made if:

In any two of leads V2, V3, and V4, special T amplitude $\leq$-100 µV

Then say *T wave abnormality, consider anterior ischemia.*

If test nonspecific ST abnormality passed simultaneously, then prefix *ST* &.

Marked T Wave Abnormality, Consider Anterior Ischemia

Skip test if:

Test *Anterior MI* passed

or Test *Posterior MI* passed

or Rest *RBBB* passed

or Test *Brugada* passed

or Test *RVH with repolarization abnormality* passed

Statement is made if:

In two leads V2, V3, and V4, special T amplitude ≤-500 mV

Then say *Marked T wave abnormality, consider anterior ischemia*

If test nonspecific ST abnormality passed simultaneously, then prefix *ST* &.

Lateral Ischemia

Statement is made if:

Test lateral infarct failed

and In any two of leads I, aVL, V4, V5, and V6, special T amplitude <-100 µV

(Do not test aVL if QRS balance is negative.)

Then say T wave abnormality, consider lateral ischemia

If test nonspecific ST abnormality simultaneously passed, then prefix ST &

Marked T Wave Abnormality, Consider Lateral Ischemia

Statement is made if:

Test lateral infarct failed

and Any of leads I, aVL, V5, and V6, special T amplitude <-500 µV

(Do not test aVL if QRS balance is negative.)

Then say Marked T wave abnormality, consider lateral ischemia

If test nonspecific ST abnormality simultaneously passed, then prefix ST &

Anterolateral Ischemia

Statement is made if:

Test T wave abnormality, consider anterior ischemia

and Test T wave abnormality, consider lateral ischemia passed

Then say T wave abnormality, consider anterolateral ischemia

If test nonspecific ST abnormality simultaneously passed, then prefix ST &

Marked T Wave Abnormality, Consider Anterolateral Ischemia

Statement is made if:

Test T abnormality consider anterior ischemia passed

and Test marked T abnormality consider lateral ischemia passed

or Test marked T abnormality consider anterior ischemia passed

Then say Marked T wave abnormality, consider anterolateral ischemia

If test nonspecific ST abnormality simultaneously passed, then prefix ST &

T Wave Abnormality, Consider Inferior Ischemia

Statement is made if:

Any test inferior infarct failed

and Special T amplitude <-100 µV in lead II or aVF

(Test lead aVF only when QRS amplitude is positive.)

Then say T wave abnormality, consider inferior ischemia

If test nonspecific ST abnormality passed simultaneously, then prefix ST &

Marked T Wave Abnormality, Consider Inferior Ischemia

Statement is made if:

Special T amplitude $\leq$-500 µV in lead II or aVF

(Test lead aVF only when QRS amplitude is positive.)

Then say *Marked T wave abnormality, consider inferior ischemia*

If test nonspecific ST abnormality passed simultaneously, then prefix *ST* &

T Wave Abnormality, Consider Inferolateral Ischemia

Statement is made if:

Test T wave abnormality consider inferior ischemia passed

and Test T wave abnormality consider lateral ischemia passed

and Test T wave abnormality consider anterior ischemia failed

Then say T wave abnormality, consider inferolateral ischemia

If marked T wave abnormality passed with above statements, upgrade the statement to Marked T wave abnormality, consider inferolateral ischemia

If any ischemia tests pass, suppress STEREP and EREP.

If any test ischemia pass, suppress NST, STJD1, STJD2, STDIG, NT, AQRST, and STD.

Nonspecific ST and T Abnormality

Statement is made if:

Any specific ischemia tests failed

and Pericarditis test failed

and ST depression test failed

and Test nonspecific ST abnormalities passed

and Test nonspecific T abnormality passed

Then say Nonspecific ST & T abnormality

If test NSTT passed, suppress NST, STJD1, STJD2, STDIG, NT, AQRST, and STD.

Prolonged QT

The 12SL program can be configured to use Bazett, Fridericia, or Framingham QT corrections for the prolonged QT criteria. Note that not all host products support these choices. If this is not configurable on a host device, then the Bazett correction will be the default.

Skip test prolonged QT if:

Test WPW passed

or Intraventricular conduction block

or Right bundle branch block

or Left bundle branch block

or QRS duration > 120 msec

or ventricular rate > 120 bpm

or T offset confidence level is poor (i.e., score of 0 on a scale of 0 to 3)

Determine QTc threshold from the following table.

Condition	***Female ≤ 60 years, male, or unknown (in msec)***	***Female > 60 years (in msec)***
nonspecific T wave abnormality	460	470
no nonspecific T wave abnormality and no MI and no ischemia	480	490
MI or ischemia	500	510

If the test is using the Bazett-corrected QT (the default) and ventricular rate > 100 bpm, the threshold is 520 msec, independent of age, gender, or any other conditions.

Statement is made if:

QTc ≥ threshold

Then state *Prolonged QT*.

Acute MI

Statement made if:

Any injury pattern is cited

and Any MI labeled age undetermined

or Infarct statement is labeled as possibly acute.

Then say ** ** Acute MI / STEMI ** **

Consider Right Ventricular Involvement

Skip test if lead V4r present in 15-lead ECG (see test with right ventricular involvement instead).

Statement made if:

Test Acute MI passed

and Inferior injury pattern or inferior infarct labeled as possibly acute (including inferolateral injury or inferior-posterior infarct)

and STM in lead III > STM in lead II 2nd or 3rd degree AV block present

or

Then say *Consider right ventricular involvement in acute inferior infarct*

If ***ACS Tool*** is enabled, then instead say *Inferior injury pattern suggests right ventricular involvement, recommend adding leads V3r and V4r to confirm.*

Pediatric Contour Criteria

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T Wave Abnormalities,119

If an age of 15 years or less is entered, a pediatric analysis is performed.

Pediatric analysis employs a set of tables which contain the normal values for 12 different age groups. QRS duration limits are important in the diagnosis of conduction blocks. Amplitude limits are used in the diagnosis of ventricular hypertrophy. See Appendix C: Pediatric Tables.

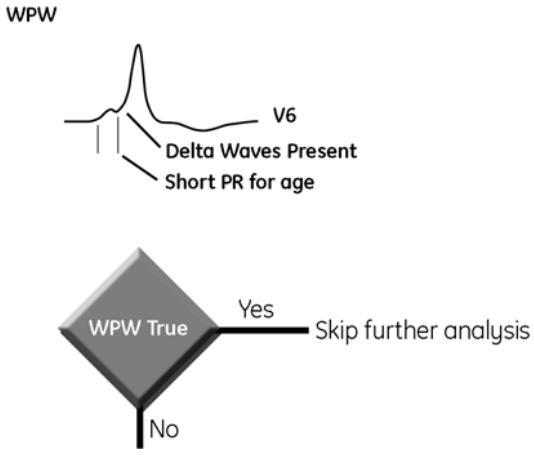
Listed below are the categories of abnormalities that the pediatric analysis program always checks for. This outline is expanded upon in succeeding figures which describe, in very simplistic terms, the basic flow and logic of the pediatric criteria. Note that the order of the steps is important since information obtained from tests performed earlier in the sequence are applied to subsequent tests. Following this outline, see Pediatric Contour Criteria Details.

Pediatric Contour Criteria Summary

Major Category	*Subcategory*	*Acronyms/Statements*
Dextrocardia		DEXTRO
Wolff-Parkinson-White		WPW
Atrial Hypertrophy		RAE, Right Atrial Enlargement LAE, Left Atrial Enlargement BAE, Biatrial Enlargement
QRS Abnormalities	Low Voltage QRS QRS Axis	LOWV RAD, Right Axis Deviation LAD, Left Axis Deviation NWA, North West Axis
	Brugada	BRUG1, Brugada Pattern, type 1 RBBB, Right Bundle Branch Block RBBRVH, Right Bundle Branch Block or Right Ventricular Hypertrophy LBBB, Left Bundle Branch Block IRBBB, Incomplete Right Bundle Branch Block
	Conduction Abnormalities	ILBBB, Incomplete Left Bundle Branch Block IVCB, Intraventricular Conduction Block IVCD, Intraventricular Conduction Delay LVH, Left Ventricular Hypertrophy

Major Category	*Subcategory*	*Acronyms/Statements*
	Ventricular Hypertrophy	RVH, Right Ventricular Hypertrophy BIVH, Biventricular Hypertrophy
	Infarction	QRSW, With QRS Widening MI, Myocardial Infarction LMI, Lateral IMI, Inferior
ST Abnormalities—QRS Related	ST + T abnormality with Ventricular Hypertrophy Dating Infarcts	2ST, With Repolarization Abnormality WSTR, With Strain Pattern AC, Possibly Acute AU, Age Undetermined
ST Elevation Abnormalities	Marked ST Elevation Pericarditis Early Repolarization Undefined ST Elevation	STELIN, ST Elevation In PCARD, Acute Pericarditis REPOL, Early Repolarization STEL, ST Elevation Probably Due to Repolarization, Injury or Acute Pericarditis
	Nonspecific	NST, Nonspecific ST Abnormality
ST Depression Abnormalities	Marked ST Depression	STDEPIN, ST Depression In
	Undefined ST Depression	STDEP, ST Depression, Consider Subendocardial Injury JST, Junctional ST Depression Probably Abnormal
	Junctional ST Depression	JSTN, Junctional ST Depression, Probably Normal
	Nonspecific	NST, Nonspecific ST Abnormality
T Wave Abnormalities	T Wave Inversion	TINVIN, T Wave Inversion In INF, Inferior Leads LAT, Lateral Leads IFLAT, Inferolateral Leads
	Nonspecific QRS-T Angle	NT, Nonspecific T Wave Abnormality NSTT, Nonspecific ST and T Wave Abnormality AQRST, Abnormal QRS-T Angle
	QT Interval	LNGQT, Prolonged QT

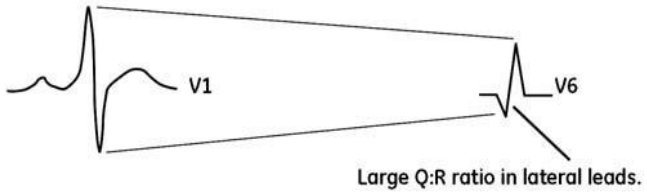
Wolff-Parkinson-White



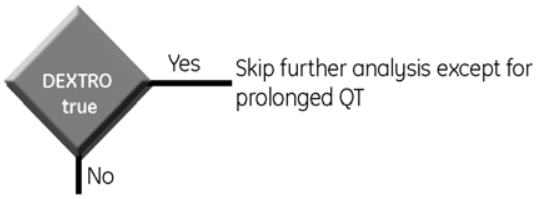
Dextrocardia

DEXTRO

QRS deflection much greater in right precordial leads as opposed to left lateral leads.

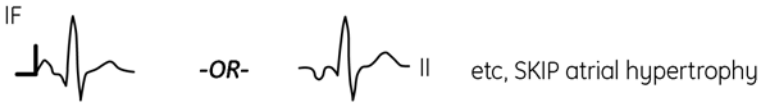


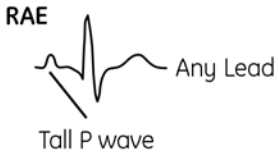
If dextrocardia is stated, do no further analysis except for prolonged QT.

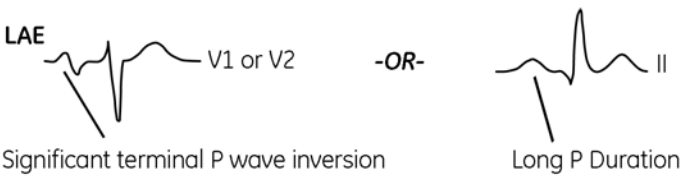


Atrial Enlargement

Skip the test if it is not a sinus rhythm.

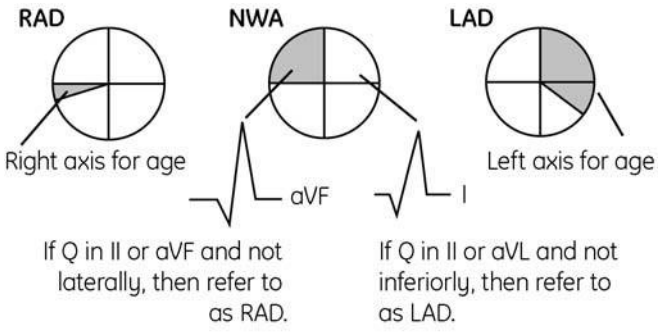




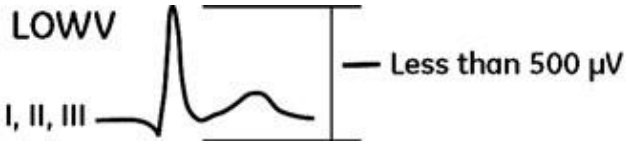


BAE
Both RAE and LAE are true.

QRS Axis

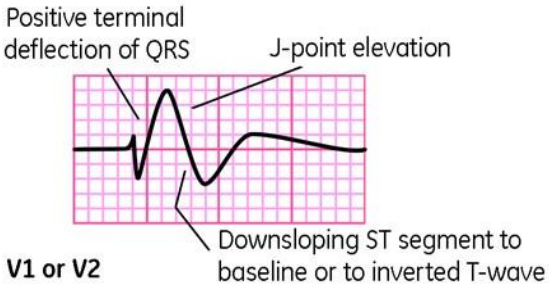


Low Voltage QRS



Standard requirement of limb leads less than 500 µV. If horizontal plane exhibits low voltage for age and the limb leads have voltage close to the standard requirement, state low voltage QRS.

Brugada



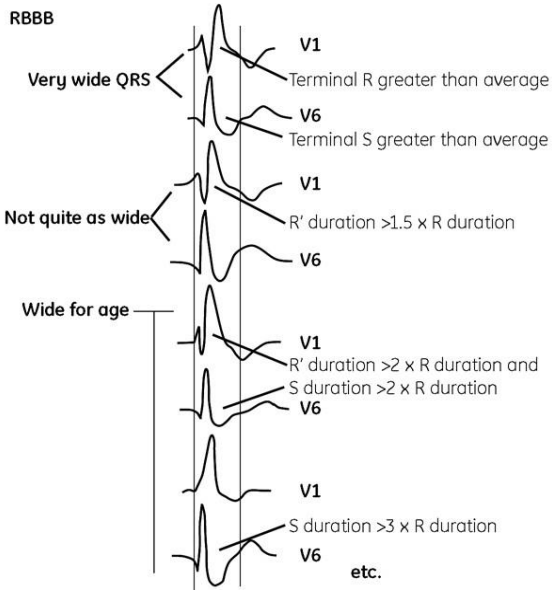
If Brugada pattern found in V1 or V2, and RBBB and anterior injury ruled out, state *Brugada*.

Conduction Abnormalities

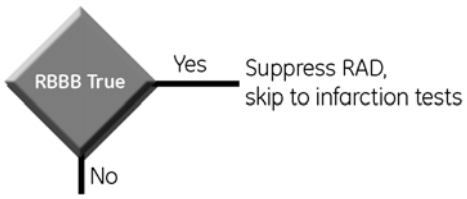
Right Bundle Branch Block

It is sometimes difficult to discriminate among *RBBB*, *RVH*, or normal variants. The pediatric criteria for *RBBB* is the most complicated of the conduction abnormalities.

If the QRS is very wide, the program tests for terminal slowing on the right. As the QRS gets narrower, the tests for terminal slowing on the right become increasingly more difficult to pass.

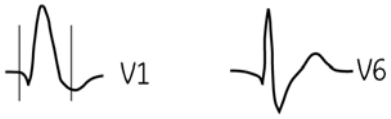


If *RBBB* is true, suppress all statements concerning right axis deviation and do not test for hypertrophy.

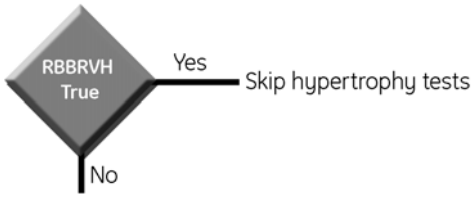


RBBRVH

If the QRS is wide for age, and it has some of the components of RBBB which do not quite meet the criteria, the program will state: "Right bundle branch block or right ventricular hypertrophy."



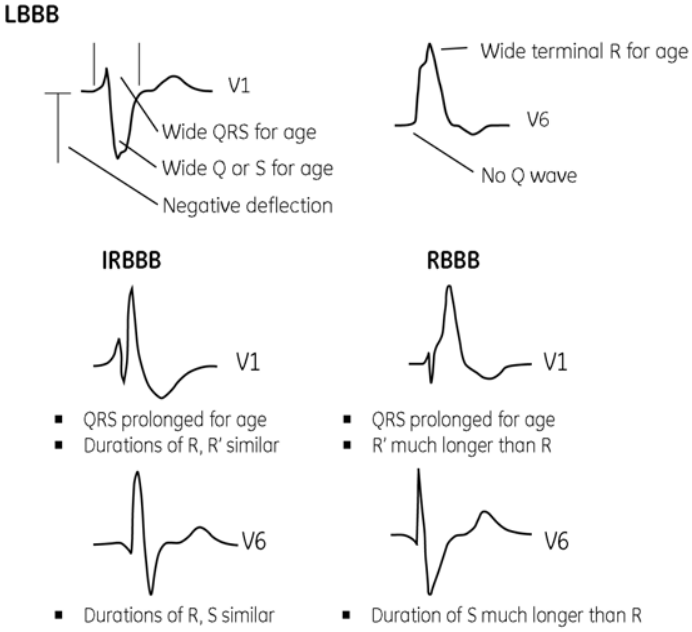
QRS is wide. Although the terminal force is towards the right, there is no evidence of terminal conduction delay. This could be due to RVH or RBBB. If RBBRVH is called, bypass hypertrophy tests.



IRBBB

IRBBB is called if the QRS has some of the attributes of RBBB, but the rightward terminal slowing is not evident enough for the criteria to state a complete block.

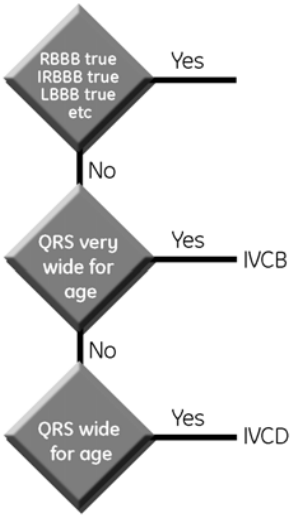
Left Bundle Branch Block



ILBBB

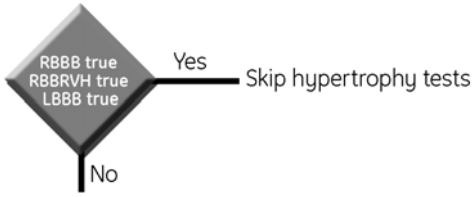
Same criteria as LBBB but QRS is slightly prolonged for age, as opposed to wide.

If a conduction abnormality has not been cited, and the QRS is wide for age, a nonspecific conduction delay or block will be cited.



Ventricular Hypertrophies

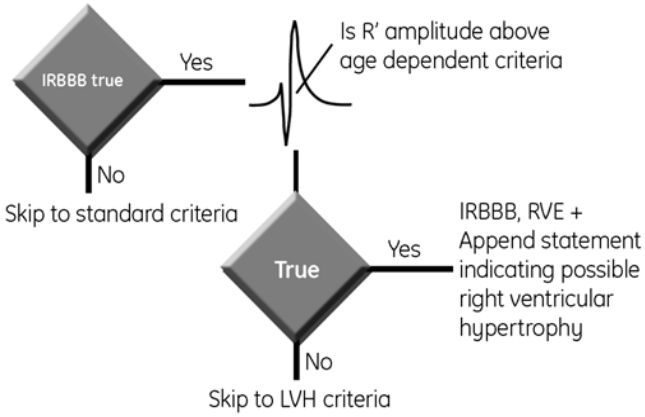
If any complete block has been stated, do not test for ventricular hypertrophy.



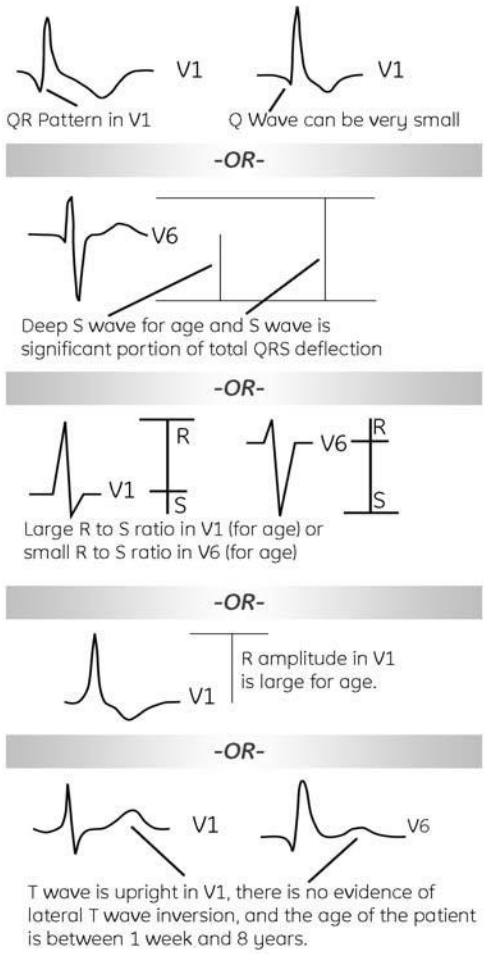
Right Ventricular Hypertrophy

RVH

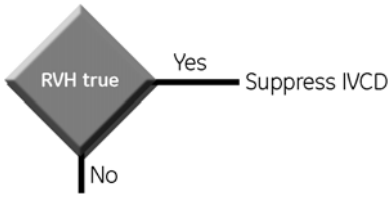
If *IRBBB* has been stated, use special criteria for *RVH*, avoid the standard criteria.



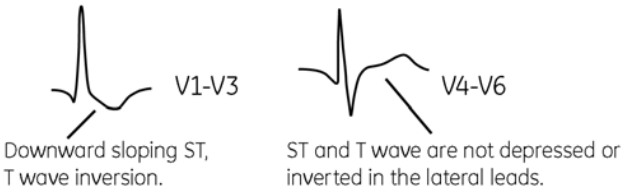
There are several ways in which *RVH* can be diagnosed via the standard criteria. Possible *RVH* is stated if any of these tests are true.



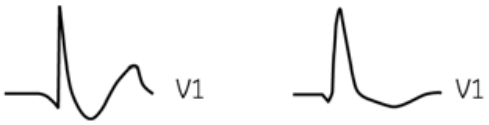
If the R amplitude in V1 is large for age, or there is a QR pattern in V1, the program states *RVH* without the prefix *possible*. If *RVH* is stated, suppress *IVCD*.



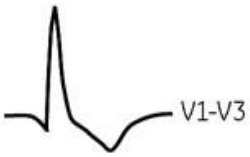
When *RVH* is stated, the repolarization of the right precordial leads is inspected.



If the ST-T meets these requirements, but is not typical of *RVH* with strain, the program will state: *With repolarization abnormality*.



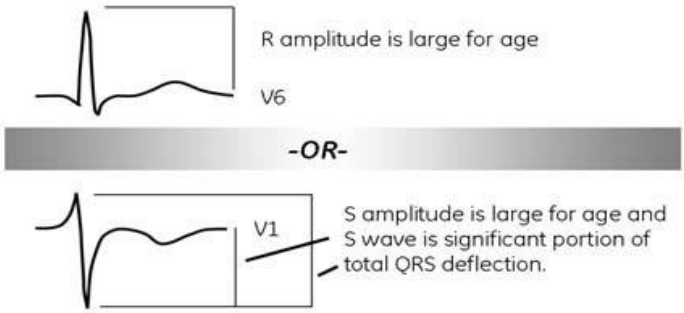
If the ST-T is typical of *RVH* with strain, the program will state: *With strain pattern.*



Left Ventricular Hypertrophy

LVH

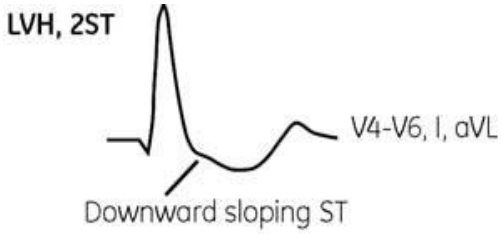
The criteria first tests the voltage in leads V1 and V6.



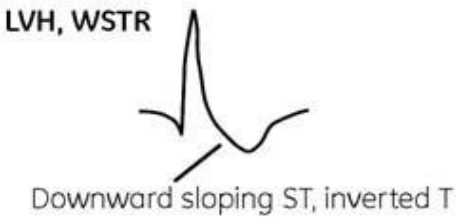
If either of these criteria are true, the program will state possible *LVH*. If the voltage significantly exceeds this criteria, the program will state *LVH* without any qualifier.

Repolarization in the lateral leads is the next item tested.

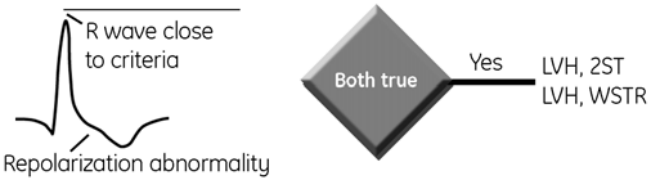
If this repolarization abnormality is found in conjunction with voltage criteria for *LVH*, the program will state: *Left ventricular hypertrophy with repolarization abnormality.*



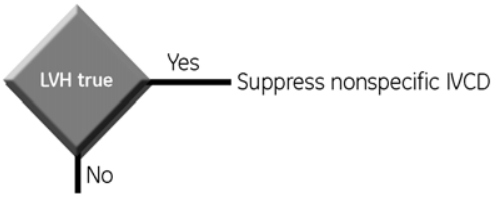
If the repolarization abnormality is more typical of a strain pattern, the program will modify the statement by using *with strain pattern*.



T wave inversion in the lateral leads is abnormal for all ages. If a repolarization abnormality is detected in the lateral leads and the ECG exhibited voltage that was close to the aforementioned criteria, the program would upgrade the diagnosis to *LVH*.



If *LVH* is cited, suppress the statement nonspecific interventricular conduction delay.

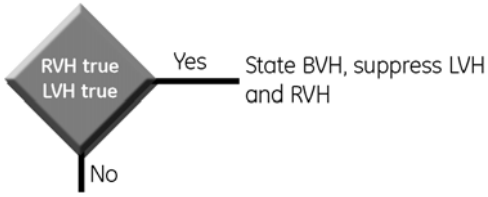


Biventricular Hypertrophy

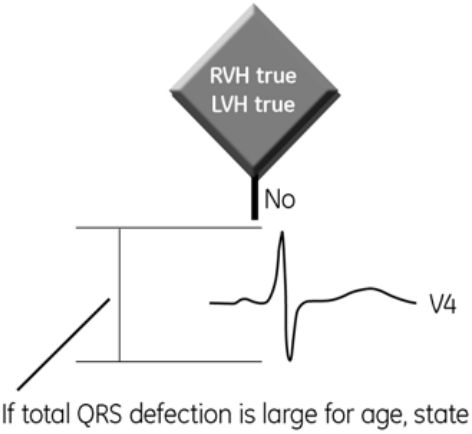
BVH

The way in which the program detects *BVH* is dependent upon what hypertrophy has already been detected by the program.

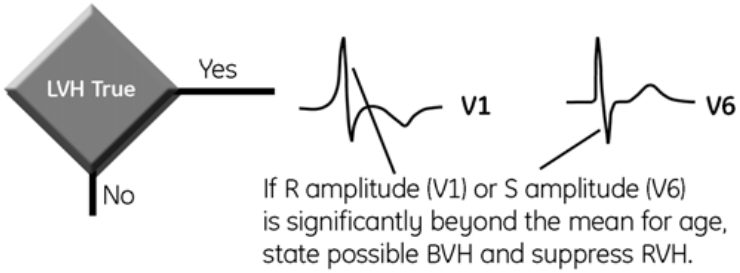
If both *LVH* and *LVH* have already been detected by the program, the program will state *LVH*.



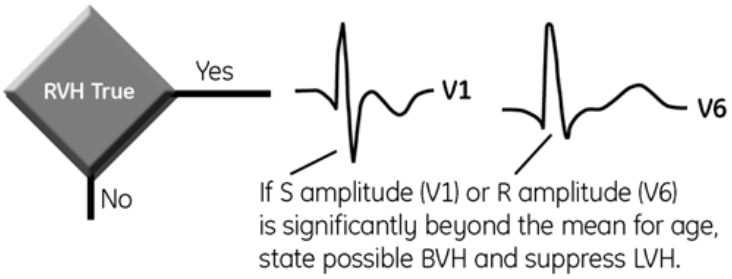
If neither *LVH* or *LVH* have been detected, then inspect mid-precordial leads.



If definite *LVH* has been detected, then see if there are some indications of *RVH*.



If definite *RVH* has been detected, then see if there are some indications of *LVH*.



Infarct

Septal Myocardial Infarct

SMI

Not diagnosed by pediatric program.

Anterior Myocardial Infarct

AMI

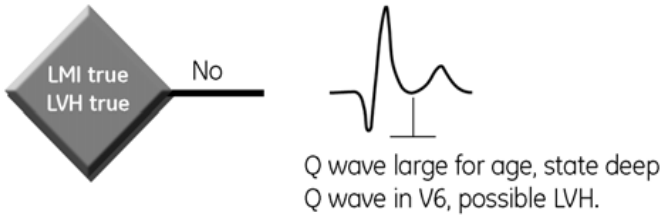
Not diagnosed by pediatric program.

Lateral Myocardial Infarct

LMI

Criteria for lateral MI is very specific. Deep, wide Q waves with a large Q:R ratio are required for diagnosis. This criteria is used to avoid the deep Q waves that occur normally in the pediatric ages.

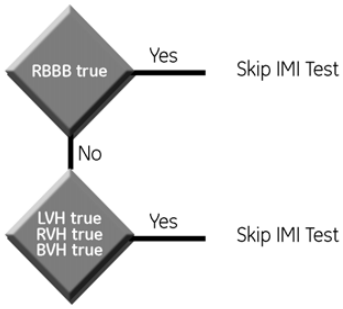
If there are deep Q waves for age, that do not meet the criteria for *LMI*, and LVH was not stated, the program will state: *Deep Q wave in V6, possible LVH*.



Inferior Myocardial Infarct

IMI

Do not execute if RBBB or any hypertrophy is detected.

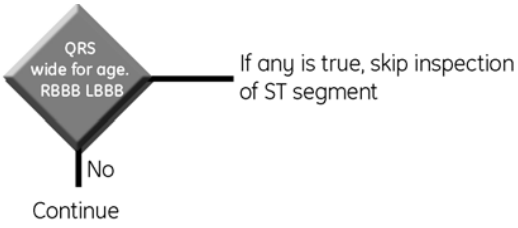


Criteria for inferior MI is very specific. Deep, wide Q waves with a large Q:R ratio are required for diagnosis. This criteria is used in order to avoid the large Q waves that occur normally in the pediatric ages.

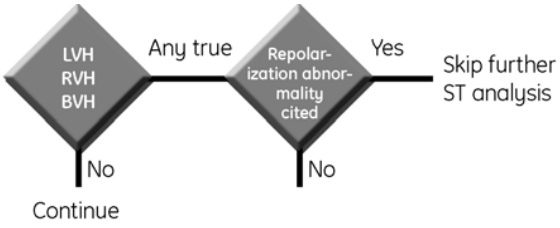
AC: Possibly acute AU: Age undetermined statements for the dating of MIs are not used by the pediatric program.

ST Abnormalities

Inspection of the ST segment is dependent upon what was found in the QRS.

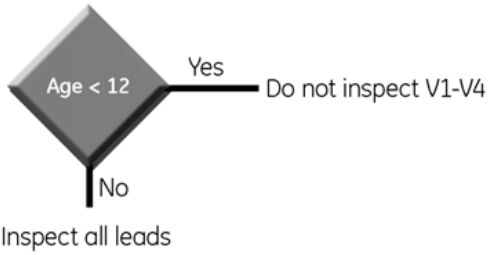


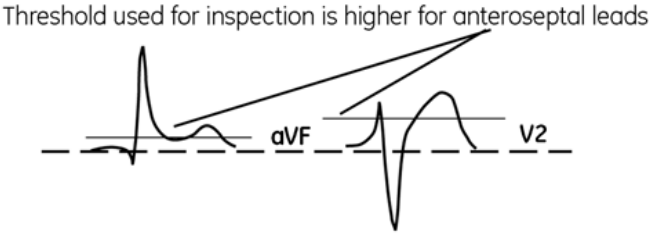
If repolarization abnormality has already been stated with *RVH*, *LVH*, or *BVH*, do not inspect the ST segment.



ST Elevation Abnormalities

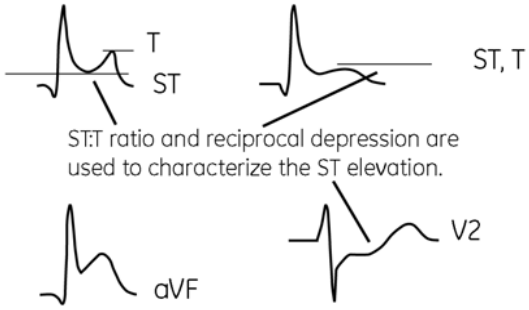
The number of leads inspected for ST elevation is dependent on age.





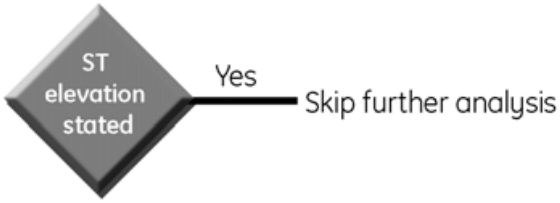
If any ST segment is over threshold, then several other tests are applied.

An injury character is suspected the larger the ST elevation and ST:T ratio. Reciprocal depression is also considered to be an indicator of injury.



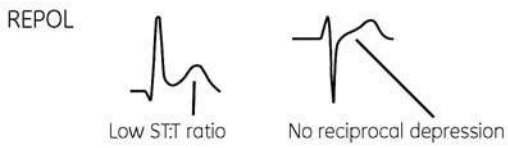
ST elevation that has an injury-like character is descriptively stated; for example: ST elevation in anterior leads.

Once it is stated, no further ST elevation analysis is done.



Early Repolarization

Early repolarization is stated if the ST elevation has low ST:T ratio and a repolarization character that appears normal (that is, T waves upright in appropriate leads and ST aligned with T).



Acute Pericarditis

Acute pericarditis has similar criteria except more ST elevation is required.

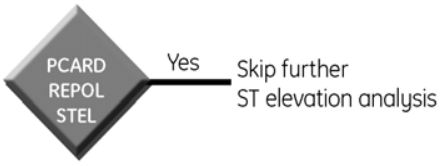
ST Elevation, Mechanism Unknown

If pericarditis or early repolarization cannot be stated, the program identifies the ST elevation and suggests the three aforementioned mechanisms.

STEL

ST elevation, consider early repolarization, pericarditis, or injury

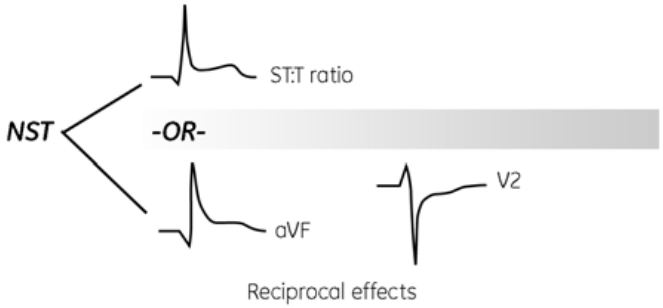
If *PCARD*, *REPOL*, or *STEL* is stated, do no further ST elevation analysis.



Nonspecific ST Elevation

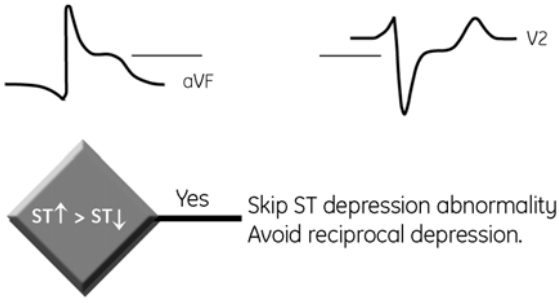
NST

Nonspecific ST elevation abnormality is detected using the same methods as outlined above. The difference is that the threshold for elevation is twice as sensitive. The program only states the elevation as a nonspecific abnormality if it has characteristics that meet the criteria outlined for injury.

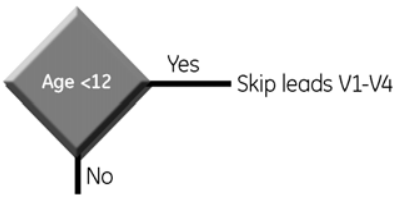


ST Depression Abnormalities

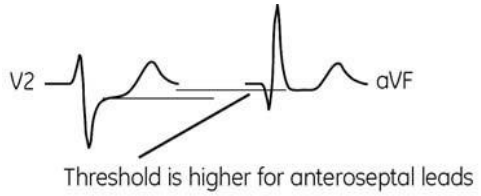
If injury has been called and the ST elevation is larger than the depression, do not test for any ST depression abnormality.



Inspect all leads for ST segment depression. The anteroseptal leads are not inspected if the age is less than 12 years.



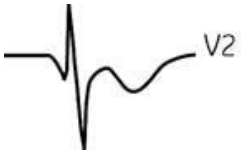
Compare ST segments to threshold. The threshold for anterior leads is less sensitive.



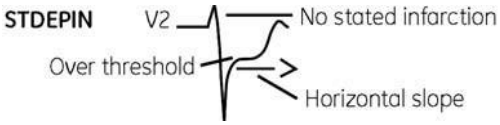
Avoid upward sloping ST segments.

Avoid anteriolateral lead groups when LVH, 2ST is stated.

Avoid leads with stated infarction.

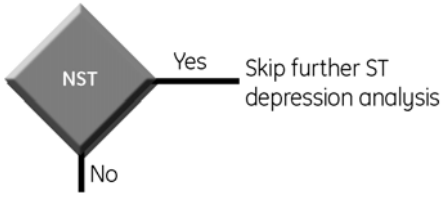


If all of these items are true, state ST depression in specific lead group.



If ST depression is true, skip further analysis.

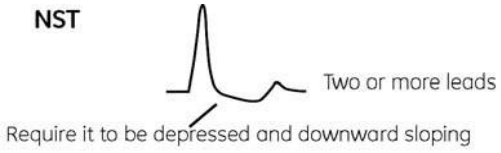
If a nonspecific ST elevation abnormality has already been found (from NST elevation tests), do no further ST depression analysis.



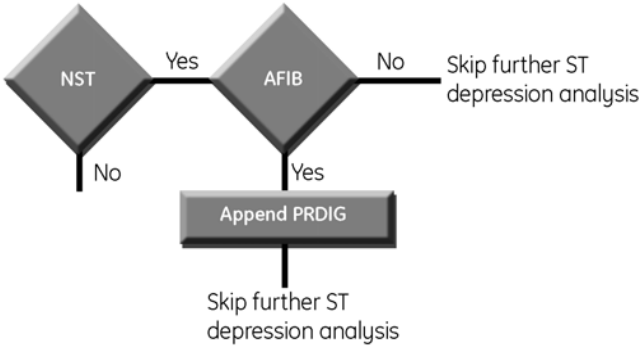
Now look for ST depression as before but with more sensitivity. If true, state *ST depression, consider subendocardial injury*. Also skip further ST depression analysis.

Nonspecific ST Abnormality

Again, analyze the ST segment with even more sensitivity.

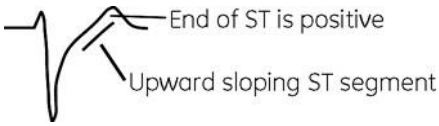


If this occurs in at least two leads, state *NST*. If atrial fibrillation is present, append *PRDIG*.



Junctional ST Depression

If true, state: *Junctional ST depression, probably normal*.



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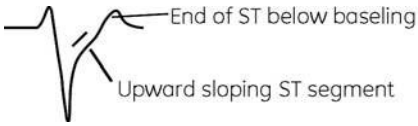
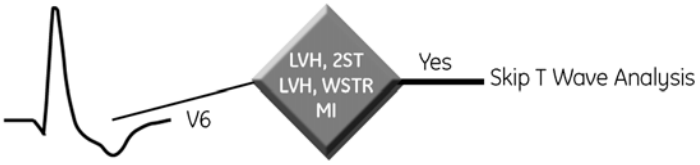
If true, state: *Junctional ST depression, probably abnormal*.



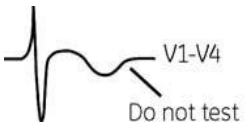
MD1306-176

T Wave Abnormalities

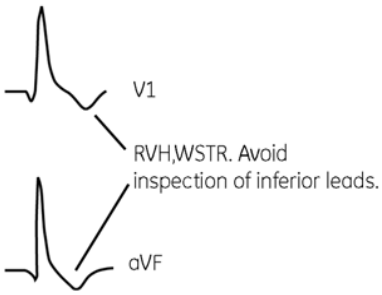
If *LVH* with a repolarization abnormality has already been stated, do not test T waves. Likewise, if an *MI* has been cited, skip T wave analysis in respective lead group.



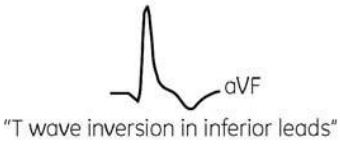
Avoid inspection of leads V1–V4. T wave inversion in this lead group is normal for age.



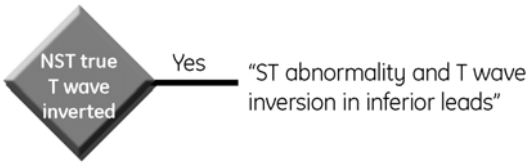
If *RVH* with strain pattern was noted, also avoid inspection of inferior leads.



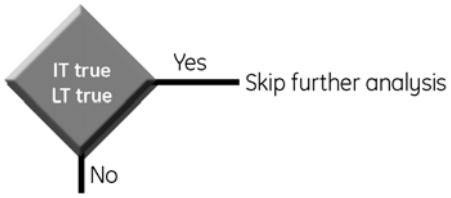
If T waves are inverted, then state descriptively as opposed to stating ischemia.



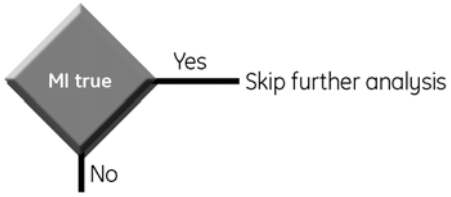
If a nonspecific ST abnormality was previously detected, make one statement as opposed to two.



If T wave inversion is stated, skip further analysis of T waves.



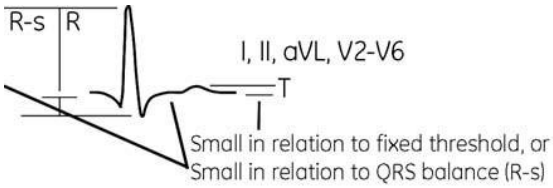
If infarction is present, skip further analysis.



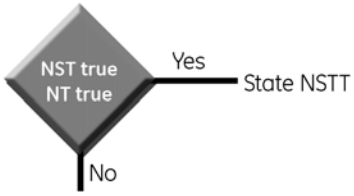
Nonspecific T Wave Abnormality

NT

Small T waves or shallow T wave inversion are found in at least two leads.



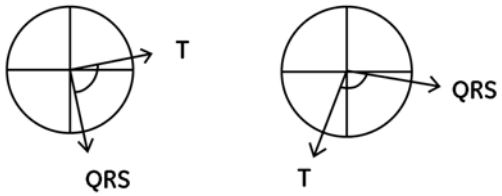
If a nonspecific ST abnormality is found in conjunction with NT, then make one statement as opposed to two.



Abnormal QRS-T Angle

AQRST

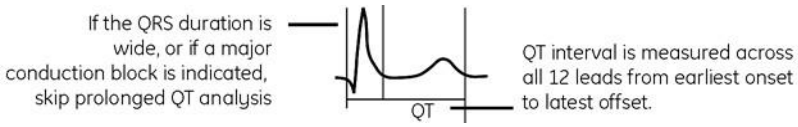
Do not test for abnormal QRS-T angle if any other T wave abnormality has already been stated.



Abnormal T axis
and
Abnormally large QRS-T angle

Prolonged QT

QT interval is corrected for rate. As the ventricular rate increases, the corrected QT increases.



LNGQT

If QTc $\geq$ 460 ms, state Borderline Prolonged QT.

If QTc $\geq$ 480 ms, state Prolonged QT.

If any hypertrophy or incomplete block is cited, append: May be secondary to QRS abnormality.

Pediatric Contour Criteria Details

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Dextrocardia,122
Atrial Enlargement,123
Frontal Plane Axis Deviation,123
Low Voltage and Lung Disease,124
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Conduction Defects,126
Ventricular Hypertrophy,132
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ST Elevation,141
ST Depression,141
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WPW

Skip test WPW if:

Atrial flutter or atrial fibrillation is present

or No P wave is present

Statement is made if:

Delta wave is present in three or more of 12 leads

and PR interval is not = 0 ms

and P axis is >-30 degrees and <120 ms

and PR interval < mean PR interval for age

or PR interval < mean PR interval for age + 25 ms

and QRS onset <12 ms after P offset

and There are >5 delta waves present

Then say *Ventricular pre excitation WPW*.

If test WPW passed, then suppress short PR and skip all other contour tests except Prolonged QT.

Dextrocardia

Skip test if WPW present

Statement is made if:

QRS deflection in lead V1 >QRS deflection in lead V5 times 1.9

and QRS deflection in lead V1 >QRS deflection in lead V6 times 1.9

and QRS duration <IVCB QRS duration for age

and In two of leads I, aVL, V5, and V6

either Q amplitude >1/4 the QRS deflection and R amplitude >100 µV

or RSR' pattern present where R amplitude <50 µV and R' amplitude >100 µV and S amplitude >1/4 the QRS deflection

Then say *dextrocardia*.

If dextrocardia present, then skip any contour tests.

Atrial Enlargement

Skip all atrial enlargement tests if:

Test WPW passed

or PR interval = 0 ms

or No sinus rhythm or atrial pacemaker present

or P axis is < the upper limit for right atrial rhythm for age

or P axis is > the upper limit for left atrial rhythm for age

Right Atrial Enlargement

Statement is made if:

P wave amplitude >250 µV in any lead

Then say *Right atrial enlargement*.

Left Atrial Enlargement

Statement is made if:

P duration in lead II >125 ms and P amplitude >100 µV

or P amplitude in lead V1 >40 ms and P' amplitude <-100 µV and P' duration >60 ms

or P amplitude in lead V1 >40 ms and P' amplitude <-125 µV and P' duration >50 ms

or P amplitude in lead V1 >40 ms and P' amplitude <-150 µV and P' duration >40 ms

Then say *Possible left atrial enlargement.**

If any test for possible LAE passed

and P' amplitude in lead V1 <-200 µV

or P duration in lead II >140 ms and P' amplitude in lead V1 <-100 µV

Then say *Left atrial enlargement*.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Biatrial Enlargement

Statement is made if:

Test left atrial enlargement passed

and Test right atrial enlargement passed

Then say *biatrial enlargement*.

Frontal Plane Axis Deviation

Skip test frontal plane axis deviation if: Test *WPW* passed and *dextrocardia* passed.

Left Axis Deviation

Statement is made if:

QRS axis is ≤LAD lower limit for age

or QRS axis is > superior NWA limit for age

and Q amplitude >40 µV in lead I or aVL

and Q amplitude ≤40 µV in leads II, III, and aVF

Then say *Left axis deviation*.

Right Axis Deviation

Statement is made if:

QRS axis is ≥RAD upper limit for age

or QRS axis is ≥NWA upper limit for age

and Q amplitude in leads I and aVL ≥40 µV

and Q amplitude in lead II, III, or aVF >40 µV

Then say *Right axis deviation*.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

North West Axis

Statement is made if:

QRS axis is > superior NWA limit for age

and Q amplitude in lead I or aVL >40 µV

and Q amplitude in lead II, III, or aVF >40 µV

or No Q wave in leads I, aVL, II, III, and aVF

Then say *North West Axis*.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Indeterminate Axis

Statement is made if:

R amplitude minus S amplitude ≤50 µV in leads I, II, and III

or The QRS balance in leads I, II, and III is <10% of the QRS deflection

Then say *Indeterminate axis*.

Low Voltage and Lung Disease

Skip test low voltage and lung disease if:

Test WPW or dextrocardia passed

or QRS duration >120 ms

Low Voltage QRS

Statement is made if:

Total QRS deflection <500 µV in all frontal leads

or QRS deflection <1500 µV in all precordial leads

and QRS deflection <1000 µV in all frontal leads

Then say *Low voltage QRS*.

Brugada

Skip test if:

QRS duration > 150 ms

or ventricular rate > 150 bpm

or age < 5 years

Brugada Pattern Test

In leads V1 and V2, look for Brugada pattern (type 1).

Brugada pattern if:

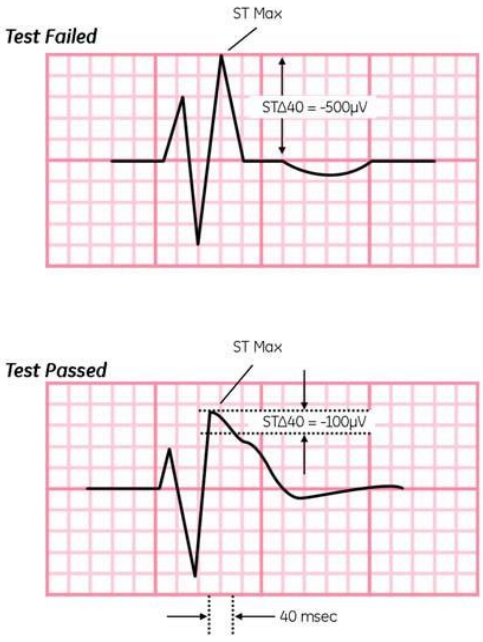
STJ > 200 µV

and STE < 400 µV

and STJ > STM > STE

and T-wave amplitude $\leq$ 0 µV

Brugada Test 2: STΔ40 Measurement



Test 1

Test 1 looks at indicators of an acute cardiac event (such as ST elevation in leads besides V1-V3, ST depression, inverted T-waves, and Q waves) which represent a higher probability of acute MI or ischemia even though a Brugada type 1 pattern is found in lead V1 or V2.

Test 1 passes if minimum of STJ and STM lead V4 < 200 µV

and for all 12 standard leads except V1-V3, the number of leads with ST elevation (minimum of STJ and STM > 100 µV) is ≤ 1

and for all 12 standard leads, the number of leads with ST depression (maximum of STJ, STM, and STE <-100 µV) is ≤ 2

and for all 12 standard leads, ST elevation and ST depression are not both present (excluding V1-V3 for elevation, thresholds as described above)

and the number of lateral leads (V4, V5, V6, I, aVL) with inverted T waves is ≤ 1 (T or T' amplitude <- 100 µV)

and the number of anteroseptal leads (V1-V4) with Q waves is ≤ 2 (Q amplitude > 0 µV)

Test 2

Test 2 is used to discriminate between RBBB and Brugada pattern.

Test 2 passes if 0 > STΔ40 > -400 µV in leads V1 and V2

or the number of lateral leads (V4, V5, V6, I, aVL) with a wide S wave (S duration ≥ 40 ms) is ≤ 3

Statement made if:

Brugada type 1 pattern is present in lead V1 or V2

and Test 1 passed

and Test 2 passed

Then say *Brugada pattern, type 1*

Conduction Defects

Skip all tests for conduction defect if: Test *WPW* or *dextrocardia* passed.

Incomplete Right Bundle Branch Block

Skip test if test *Brugada* passed.

Statement is made if:

QRS duration ≥ upper QRS duration for age 98% confidence level

and QRS area is positive in lead V1

and Test *RBBB 1* passed

and if any of the following are true:

Test 1

RBBB criteria 1-8 failed (see below criteria)

and QRS duration <90 ms

and R' amplitude in lead V1 not = 0 µV

and S' amplitude in lead V1 <100 µV

and R amplitude in lead V1 >100 µV

Test 2

RBBB criteria 1-10 failed (see below criteria)

and *IRBBB* test 1 failed

and *RBBB* test 6 failed

and R' duration in lead V1 >R duration in lead V1 times 1.3

and S duration in lead V6 >R duration in lead V6 times 1.5

and QRS duration < maximum QRS duration for age for block

and R amplitude in lead V1 >100 µV

Test 3

RBBB criteria 1-12 failed (see below criteria)

and *IRBBB* tests 1 and 2 failed

and *RBBB* test 6 failed

R amplitude in lead V1 >100 µV R' amplitude in lead V1 >100 µV S amplitude in lead V1 >100 µV

and S duration in lead V6 > maximum QRS duration for age block divided by two

and QRS duration >IVCB QRS duration for age – 20 ms

and QRS duration <IVCB QRS duration for age

Then say *Incomplete right bundle branch block*.*

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Right Bundle Branch Block Tests

Test 1

R or R' (with no S or S') is present in lead V1

Test 2

If test 1 fails:

and QRS duration > maximum QRS duration for age for block

and In any two leads I, aVL, V4, V5, and V6

S duration >1/3 QRS maximum duration for age

and QRS area in lead V1 is positive

and S amplitude + minimum STJ or STM <100 µV and <R amplitude in lead V1

or S amplitude + minimum STJ or STM to R amplitude Ratio <30% in lead V1

or S amplitude + minimum STJ or STM to R amplitude Ratio <50% in lead V1 and QRS >130 ms

or S' amplitude + minimum STJ or STM <100 µV and <R' amplitude in lead V1

or S' amplitude + minimum STJ or STM to R' amplitude Ratio <30% in lead V1

or S' amplitude + minimum STJ or STM to R' amplitude Ratio <50% in lead V1 and QRS >130 ms

Test 3

R' wave present in lead V1 with duration >40 ms

(To obtain R' duration, subtract from the measured QRS duration the Q duration + R duration + S duration + R' duration + S' duration)

Test 4

R' duration in lead V1 > duration variable lead V1 times two

and S duration in lead V6 > duration variable lead V6 times two

Duration variable lead V1 Add Q duration + R duration +

S duration in lead V1

Duration variable lead V6 Add Q duration + R duration in lead V6

Test 5A

QRS area is positive in lead V1

Notch present in lead V1 (after peak of R wave)

Notch depth ≥200 µV

Test 5B

QRS area is present in lead V1

Notch present in lead V1 (after peak of R wave)

Notch depth >100 µV

Test 6A

QRS duration <90 ms

and RBBB criteria 1-8 failed (see below criteria)

and Criteria for IRBBB test 1 failed

Test 6B

All *RBBB* criteria 1-12 failed

and *IRBBB* test failed

and *RBBB* test 6A failed

and QRS duration ≤maximum QRS duration for age for block + 20 ms

and S duration in lead V6 <R duration in lead V6 times 1.4

Right Bundle Branch Block

Skip test if test *Brugada* passed.

Statement is made if:

QRS duration > upper QRS duration for age 98% confidence level

and QRS area is positive in lead V1

and Test *RBBB* 1 passed

or Test *RBBB* 2 passed

or Test *RBBB* 3 passed

And any of the following criteria are met:

Criteria 1:

Test *RBBB* 4 passed

Criteria 2:

QRS duration ≥120 ms

and S duration in lead V6 >R duration in lead V6 times two

Criteria 3:

R' duration in lead V1 > duration variable lead V1 + 10 ms

and S duration in lead V6 >R duration in lead V6 times two

and S duration in lead V6 > duration variable lead V6 times 1.5

or Q amplitude in lead V6 <200 µV

Criteria 4:

S duration in lead V6 >R duration in lead V6 times three

or S duration in lead V5 >R duration in lead V5 times five

Criteria 5:

R' in lead V1 > duration variable in lead V1 times 1.5

and QRS duration >130 ms

Criteria 6:

R' amplitude in lead V1 = 0 µV

and S amplitude in lead I <100 µV

and RBBB test 5 passed

and S duration in lead V6 >R duration in lead V6 times two

and S duration in lead V6 > duration variable in lead V6 times 1.5

or Q amplitude in lead V6 <200 µV

Criteria 7:

R amplitude in lead V1 >100 µV

and R' amplitude in lead V1 >100 µV

and R' duration in lead V1 >R duration in lead V1 times two

and R' duration in lead V1 >R + S duration in lead V1

and S duration in lead V6 >R duration in lead V6 times two

and S duration in lead V6 > duration variable in lead V6 times 1.5

or Q amplitude in lead V6 <200 µV

Criteria 8:

QRS duration > maximum QRS duration for age for block

and S duration in lead V6 >R duration in lead V6 times 2.5

and S duration in lead V7 > duration variable in lead V6 times 1.5

Criteria 9:

QRS duration >140 ms

and At lead one lead of I, aVL, V4, V5, or V6 has

either S duration >60 ms

and R' duration in lead V6 = 0 ms

or R' duration in lead V6 not = 0 ms

and S' duration in lead V6 >60 ms

Criteria 10:

QRS duration >130 ms

and In more than one lead of I, aVL, V4, V5, and V6

either S duration >70 ms

and R' duration in lead V6 = 0 ms

or R' duration in lead V6 not = 0 ms

and S' duration in lead V6 >70 ms

Criteria 11:

IRBBB test 1 failed

and Test *RBBB* 6 passed

and Criteria 1-10 failed

and R' duration in lead V1 >R duration in lead V1 times 1.3

and S duration in lead V6 >R duration in lead V6 times 1.5

and QRS duration > maximum QRS duration for age for block

Criteria 12:

IRBBB tests 1 and 2 failed

and Test *RBBB* 6 failed

and Criteria 1-11 failed

and R amplitude in lead V1 >100 µV and R' amplitude in lead V1 >100 µV

and S amplitude in lead V1 >100 µV

and S duration in lead V6 > maximum QRS duration for age for block divided by two

and QRS duration > maximum QRS duration for age for block + 20 ms

Then say *Right bundle branch block*

If test *RBBB* passed, then suppress all right axis deviation.

Right Bundle Branch Block or Right Ventricular Hypertrophy

Skip test if test *Brugada* passed.

Statement is made if any of the following:

Test 1:

If QRS area in V1 >0 µV

and Test 1 or 2 passed

and All *RBBB* criteria 1-12 failed (see above criteria)

and All *IRBBB* tests failed

and *RBBB* test 6A failed

and *RBBB* test 6B failed

and QRS duration > maximum QRS duration for age for block + 20 ms

and S duration in lead V6 not = 0 ms

and R' not present in lead V6

Test 2:

If QRS area in V1 >0 µV

and Test 1 or 2 passed

and All *RBBB* criteria 1-12 failed (see above criteria)

and All *IRBBB* tests failed

and *RBBB* test 6A and 6B failed

and S duration in lead V6 >R duration in lead V6 + 10 ms

and *RBBB* test 5B passed

Then say *Right bundle branch block or right ventricular hypertrophy*.

If IRBBB test passed and RBBB criteria 1-12 failed, then say Incomplete right bundle branch block

If Age is <1 year

and Maximum R amplitude in V1 >1000 µV

If Age is >1 year

and Maximum R amplitude in lead V1 >1500 µV

Then say *Incomplete right bundle branch block plus right ventricular hypertrophy*.*

If any RBBB statement made, suppress any RAD statements.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Incomplete Left Bundle Branch Block

Statement is made if:

QRS duration >ILBBB QRS duration for age

and < maximum QRS duration for age for block

and In leads V1 and V2, QRS balance is negative

and In leads V1 and V2, Q or S wave duration ≥2/3 maximum QRS for age for block

and In any two of leads I, V5, and V6, no Q wave is present

and In any two of leads I, aVL, V5, and V6, ≥1/2 maximum QRS for age for block

Then say *Incomplete left bundle branch block*

If test *ILBBB* passed, then suppress leftward axis.

Left Bundle Branch Block

Statement is made if:

Two x QRS area >1/40 of (QRS duration x maximum R amplitude) in lead V1 or V6

and QRS balance is negative in leads V1 and V2

and In leads V1 and V2, Q or S duration >1/6 QRS duration for age for block

and In any two of leads I, V5, and V6, no Q wave is present

and In any one of lead I, V5, or V6, R duration + R' duration > maximum QRS duration for age for block -20 ms

and either QRS duration >maximum QRS duration for age for block times 1.3

or QRS duration >maximum QRS duration for age for block (+ 1/6 of this value)

and Over leads I, aVL, and V6 the sum of R duration

and R' duration totals > maximum QRS duration for age for block times two

or QRS duration maximum QRS duration for age for block

and Over leads I, aVL, and V6, the sum of R duration total > maximum QRS duration for age for block times two

and Five x QRS area >1/10 times (QRS duration x maximum R wave amplitude) in any two of leads I, aVL, and V6

Then say *Left bundle branch block*

*If LBBB not stated, but QRS balance is negative in lead V1, QRS duration >QRS duration for age for block (plus 1/6 of this value), then remember this ECG has passed as complete LBBB. This is not printed on the analysis report, but the ECG will be treated as complete LBBB in the analysis program logic.

Nonspecific Intraventricular Conduction Delay

Statement is made if:

QRS duration is >QRS duration for age for block minus 7 ms

and QRS duration is <QRS duration for age for block

and Tests RBBB and complete LBBB failed

and Tests IRBBB and ILBBB failed

Then say *Nonspecific intraventricular conduction delay*. *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Nonspecific Intraventricular Conduction Block

Statement is made if:

QRS duration >QRS duration for age for block

and Test RBBB and LBBB failed

Then say *Nonspecific intraventricular conduction block*.

Ventricular Hypertrophy

Right Ventricular Hypertrophy

Skip test if:

Test *WPW* passed

or Test *Dextrocardia* passed

or Test *IRBBB* passed

or Test *RBBB* passed

or Test *LBBB* passed

or Test *Brugada* passed

Statement is made if:

Maximum S or S' amplitude in lead V6 > Large S in lead V6 for age + 200 µV

and Maximum S or S' amplitude in lead V6 >1/4 QRS deflection in lead V6

or S amplitude in lead V6 not = 0 µV

and Ratio of maximum R amplitude in lead V6 to maximum S amplitude in lead V6 < low R to S Ratio in lead V6 for age

or S amplitude in lead V1 is not = 0 µV

and Maximum R amplitude to S amplitude ratio in lead V1 > high R/s ratio for age in lead V1

or Age <8 years and >0 years

and T amplitude in lead V1 >100 µV and T' amplitude in lead V1 = 0 µV

and STE in lead V6 >0 and special T amplitude in leads V5 and V6 >50 µV

or Q amplitude in lead V1 >20 µV and maximum R amplitude in lead V1 >500 µV

Then say *Possible right ventricular hypertrophy*.

Maximum R amplitude in lead V1 > large R in lead V1 for age

or Q amplitude in lead V1 >20 µV and maximum R amplitude in lead V1 >750 µV

Then say *Right ventricular hypertrophy*.

If *RVH* present, suppress *IVCD* and *LOWV*.

RVH with Repolarization Abnormality

Statement is made if:

Test RVH passed

and No IRBBB test passed

and In all leads V1, V2, and V3

either STJ >STM or STJ >STE

or STM or STE or T amplitude <-100 µV

and In no more than one lead of leads V4, V5, and V6 STM or STE or T amplitude <-100 µV

Then say *Right ventricular hypertrophy with repolarization abnormality*.

Right Ventricular Hypertrophy with Strain Pattern

Statement is made if:

In two or more leads V1, V2, and V3 the STM >STE and STE >T amplitude

and T amplitude <-200 µV

Then say *Right ventricular hypertrophy with strain pattern*.

If RVH2REP and RVHWSTER both pass, only append with strain pattern.

Left Ventricular Hypertrophy

Skip test if:

Test *WPW* dextrocardia passed or Test complete *LBBB* passed

or Test *RBBB* passed

Statement is made if:

Maximum S amplitude in lead V1 > large S in lead V1 for age

and Maximum S amplitude in lead V1 >1/4 QRS deflection in lead V1

or Maximum R amplitude in lead V6 > large R in lead V6 for age

Then say *possible left ventricular hypertrophy* *

and If test for possible LVH passed:

Maximum R amplitude in lead V6 + maximum S amplitude in lead V1 > top deflection in horizontal plane for age

or Maximum S amplitude in lead V1 > large S in lead V1 for age + 500 µV

and Maximum R amplitude in lead V6 > large R in lead V6 for age + 500 µV

Then say *Left ventricular hypertrophy*.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

With Repolarization Abnormality

Statement is made if any of leads I, aVL, V4, V5, and V6 have:

STJ >STM or STJ >STE

and STE <-50 µV

and R amplitude >1100 µV

and Possible LVH passed or LVH passed or maximum R amplitude in lead V6 > large in lead V6 for age -200 µV

Then say *left ventricular hypertrophy with repolarization abnormality*.

With Strain Pattern

Statement is made if:

Test for LVH with repolarization abnormality passed

and In at least two of leads I, aVL, V4, V5, and V6 QRS balance is positive

and STM >STE and STE >T amplitude and T amplitude <-200 µV

Then say *left ventricular hypertrophy with strain pattern*.

If any LVH passed, then suppress IVCD and LOWV.

If tests for possible LVH, LVH, or LVH2REP failed

and Q amplitude in lead V6 > the deep Q in lead V6 for age + 200 µV

Then say *Deep Q wave in lead V6, possible left ventricular hypertrophy*.

Biventricular Hypertrophy

Skip test of biventricular hypertrophy if:

Test WPW or dextrocardia passed

or If any test RBBB passed

or Test LBBB passed

Statement is made if:

Test 1:

LVH passed

and Maximum R amplitude in lead V1 > mean R amplitude in lead V1 for age + 300 µV

or Maximum S amplitude in lead V6 > mean S amplitude in lead V6 for age + 300 µ

Test 2:

LVH failed and RVH passed

and Maximum S amplitude in lead V1 > mean S amplitude in lead V1 for age + 300 µV

or Maximum R amplitude in lead V6 > mean R amplitude in lead V6 for age + 300 µV

Test 3:

LVH failed and *RVH* failed

and Lead V4 ratio of QRS deflection <35%

and Lead QRS deflection >R amplitude + S amplitude in lead V4 for age

Then say *possible biventricular hypertrophy* *

If BVH test 3 passed, then say *prominent midprecordial voltage, possible biventricular hypertrophy* *

If *LVH* and *RVH* passed and *LVH2REP* or *RVH2REP* passed, then say *BVH with secondary repolarization abnormality*.

If *LVH* and *RVH* passed and *LVHWSTR* or *RVHWSTR* passed, then say *biventricular hypertrophy with strain pattern*.

If *LVH* and *RVH* passed with no *2REP* or *WSTR*, then say *biventricular hypertrophy*.

If *BVH*, suppress *RVH* and *LVH* statements.

If *PMDPV* and possible *BVH* passed, then suppress QV6.

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Infarction

Possible Lateral Infarct

Statement is made if:

Test LBBB failed

and In at least three of leads I, aVL, V4, V5, and V6 Q amplitude >100 µV

and Q duration >24 ms

and Q/R ratio >40%

Then *say possible lateral infarct*.

Suppress QV6.

Possible Inferior Infarct

Statement is made if:

Tests for RVH, BVH, LVH, and RBBB failed

and Q duration in lead aVF >30 ms

and Q amplitude in lead aVF >100 µV

and Q/R ratio in aVF >35%

Then say *possible inferior infarct*.

Then suppress QV6.

ST Abnormality (Elevation)

Skip all ST Abnormality (Elevation) tests if:

Test WPW passed

or Test Dextrocardia passed

or Test LBBB passed

or Test RBBB passed

or QRS duration > 120 ms

or Test LVH with repolarization abnormality passed

or Test RVH with repolarization abnormality passed

Early Repolarization Tests

Early Repolarization Test 1

Count leads from leads V1 through V6 with a QRS balance > 0 in which both STJ and STM are >75 µV. If patient age < 12 years, skip leads V2 and V3.

plus The number of leads from I, II, III, aVL, and aVF with a QRS balance >0 in which ST amplitude $\geq$50 µV

also Compute the sum of the amplitudes of the smaller of STJ and STM for each lead which passes

Early Repolarization Test 1A

Test passes if 3 or more leads pass and the computed sum $\geq$ 450 µV

Early Repolarization Test 1B

Test passes if 5 or more leads pass and the computed sum $\geq$ 500 µV

Early Repolarization Test 2

Count the number of leads with tall T waves which passed *Early Repolarization Test* 1

Early Repolarization Test 3

Test passes if:

Test *Early Repolarization Test 1A* passes

and QTc is between 370 and 460 ms

and Test *Brugada* failed

and Test *IRBBB* failed

and Test *ILBBB* failed

and Test *RBBB* failed

and Test *RVH* failed

and Test *LVH* failed

and All tests for infarct failed

and QRS duration <120 ms

Early Repolarization Test 4

Test passes if:

Test *Early Repolarization Test 1A* passes

and Test *Brugada* failed and Test *RBBB* failed

and All tests for infarct failed

and In at least one standard lead except aVR and V1 (skip leads V2 and V3 if patient age < 12 years)

QRS balance is positive

and minimum ST > 100 µV in limb leads or 200 µV in precordial leads

Early Repolarization Test 5

Test passes if:

For all 12 standard leads except aVR and V1 (skip leads V2 and V3 for patient ages < 12 years)

The maximum ST amplitude <-50 µV in at least 1 lead

and The maximum ST amplitude < 20 µV in at least 2 leads

or The maximum ST amplitude < 0 µV in at least 2 leads

Early Repolarization Test 6

Test passes if:

In at least one lead of I, II, aVF, and V3 through V6, the T amplitude is negative or T' amplitude < -50 µV (skip lead V3 if patient age < 12 years)

or In lead aVL the T or T' amplitude < -100 µV and either QRS axis < 50 degrees or in any leads II, III, and aVF, the minimum ST amplitude > 100 µV and in lead V5 or V6 the minimum ST amplitude < 50 µV

ST Elevation, Early Repolarization, Pericarditis, or Injury

Statement is made if:

Early Repolarization Test 1A passed

and Either *Early Repolarization Test* 3 or 4 passes and Either *Early Repolarization Test* 5 or 6 passes

Then say *ST elevation, consider early repolarization, pericarditis, or injury* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

ST Elevation, Probably Due to Early Repolarization

Skip test if *Early Repolarization Test* 5 or 6 passed

Statement is made if:

Test ST elevation, consider early repolarization, pericarditis, or injury passed

and In more than half of the leads passing *Early Repolarization Test* 1, T is also tall

Then say *ST elevation, probably due to early repolarization* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Early Repolarization

Skip test if:

Early Repolarization Test 5 or 6 passed

or Test *Brugada* passed

Statement is made if:

Early Repolarization Test 1B passed

and T wave is tall in five or more leads (*Early Repolarization Test 2*)

Then say *early repolarization* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Possible Acute Pericarditis

Skip test acute pericarditis if:

Any test infarct passed or QRS duration >120 ms

Count leads from leads I, II, and aVF in which both STJ and STM are $\geq$75 µV

plus The count of leads (leads V2 through V6 and skip leads V2 and V3 if age <12 years) in which both STJ and STM are $\geq$90 µV

Statement is made if:

The total count is at least five

and In any of leads I, II, V4, V5, and V6 T amplitude minus the minimum (STJ or STM) is positive and STJ minus (STJ or STM) >T amplitude minus the minimum (STJ or STM)

and In all leads (other than leads aVR and V1 and skip leads V2 and V3 if age <12 years) both STJ and STM are >-100 µV or T or T'$\geq$0 µV

Then say *possible acute pericarditis* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Acute Pericarditis

Statement is made if *possible pericarditis* is made and:

The count of leads (lead I, II, or aVF) in which both STJ and STM are ≥90 µV plus the count of leads (leads V2 through V6 and skip leads V2 and V3 if age <12 years) in which both STJ and STM are ≥110 µV ≥5 µV

Then say *acute pericarditis*.

Injury Pattern Tests

Skip test all injuries if:

Any tests pericarditis passed

(Done on all 12 leads individually)

For all of the following INJURY tests, if age <12 years skip testing leads V1, V2, and V3.

Test 1:

Inspect QRS balance:

Count the number of leads in frontal plane where QRS balance is <1000 µV and in the precordium where the QRS balance <2000 µV. Test 1 passes if count = 12.

Test 2:

Test at all 12 leads (except leads aVR and V1) for ST elevation. Skip lead groups with infarct present.

For this test and subsequent tests, the parameter ST limit is set for each lead:

*ST LIMIT = 200 µV unless,

If frontal leads (I, II, III, aVR, aVL, and aVF)

or	If in leads V5 and V6 (R-S) >0 µV then = 100 µV
	If lead is elevated
and	QRS balance is positive
or	In precordial leads maximum R + maximum S <1500 µV
or	In frontal plane maximum R + maximum S <1000 µV
or	If QRS balance is negative and ratio of maximum S amplitude to maximum R + maximum S <75%
then	Test 2 passes

Test 3:

Look for ST elevation based on QRS duration (except leads V1 and aVR).

Skip lead groups with MI present

Also skip anterior leads if *Brugada* present and skip inferior leads if *atrial flutter* present.

*Apply ST LIMIT as above.

If lead is elevated

and	QRS duration is 120 to 130 ms and QRS balance is positive
and	Ratio of QRS balance to QRS deflection must be >15%
or	QRS duration >130 but <150 ms
	Ratio of QRS balance to QRS deflection must be >25%
or	QRS duration >150 ms

Ratio of QRS balance to QRS deflection must be >50%

or QRS duration <120 ms and QRS balance is negative or positive

If any of the leads meet the above criteria, then inspect further for that lead group.

*Apply ST LIMIT as above for specific lead group.

If test 1 passed

and If in precordial leads minimal STJ and STM >300 µV = set injury flag

or If in precordial leads maximum R + maximum S <1000 µV and Minimal STJ and STM >200 µV + set injury flag

or If in frontal lead minimum STJ and STM >200 µV = set injury flag

or If frontal lead maximum R + maximum S <750 µV and Minimal STJ and STM >100 µV = set injury flag

or In any lead the minimal STJ and STM >1/2 T amplitude = set injury flag

else If test 2 passed

*Apply ST LIMIT as above

and If precordial lead, ST elevation >300 µV = set injury flag

or If frontal lead, ST elevation >200 µV = set injury flag

or If in any lead, the minimal STJ and STM >1/2 T amplitude

or If in any lead T' amplitude <-150 µV

and T' amplitude (absolute value) >1/8 of T amplitude for inspected lead that is elevated

or If T amplitude is negative = set injury flag

Test 4

If test 3 passes:

and If in precordial leads, STJ and STM >100 µV

or If in frontal leads, STJ and STM >50 µV

and If in elevated lead T' amplitude <-150 µV

and T' amplitude (absolute value) >1/8 of T amplitude = set injury flag

or If T amplitude is negative = set injury flag

Test 5

If test 1 or 2 passed, look for reciprocal changes:

and Count the number of leads where:
Test 1 minimal STJ and STM <-100 µV in any lead
Test 2 minimal STJ and STM <-50 µV in any lead
Test 3 minimal STJ and STM <0 µV in any lead

and If Test 1 count >0

or If Test 2 count >2

or If Test 2 count >1 and test 3 count >3 set injury flag

Test 6

If test 5 fails and injury flag is set:

and No MIs passed

and QRSV passed

and No LVHR present

Then state *ST elevation, early repolarization, pericarditis or injury*.

If *LVH* with repolarization is present, the injury flag is clear and no statement is made.

ST Elevation

ST Elevation in Anterior Leads

Statement is made if:

In any lead V2, V3, or V4 criteria for ST elevation

and Any injury test passed

Then say *ST elevation in anterior leads*.

ST Elevation in Lateral Leads

Statement is made if:

In any lead I, aVL, V5, or V6 criteria for ST elevation

and Any Injury test passed

Then say ST elevation in lateral leads

ST Elevation in Inferior Leads

Statement is made if:

In any lead II or aVF criteria for ST elevation

and Any injury test passed

Then say *ST elevation in inferior leads*.

If anterior injury, lateral injury, and inferior injury present, then say *ST elevation in anterolateral leads ST elevation in inferior leads*.

If anterior and lateral injury present, then say *ST elevation in anterolateral leads*.

If inferior and lateral injury present, then say *ST elevation in inferolateral leads*.

ST Depression

ST Abnormality (Depression)

Skip ST abnormality (depression) if:

Test WPW or dextrocardia passed

Test LBBB passed

QRS duration >100 ms

Test RBBB passed

Test LVH2REP passed

Test RVH2REP passed

Statement is made if:

Acute MI or injury present

and Any precordial leads and acute anterior infarct present

or Anterior injury present

or Acute septal infarct present

or In lateral leads (leads I, aVL, V5 and V6) and lateral injury present or acute lateral infarct present

or In inferior leads (leads II, III, and aVF) and inferior injury present or acute inferior infarct

and If the largest of (STJ and STM minimum value greater than 0 µV) in any lead > the smallest of the absolute value of (STJ, STM, or STE maximum value <-100 µV) in any lead except lead aVR

Then SKIP ST ABNORMALITY TEST

Condition for skipping applies to all ST tests and if age <12 years skip testing leads V1, V2, and V3.

Junctional ST Depression, Probably Normal

Skip test if:

Test LVH secondary repolarization passed

or Test RVH with secondary repolarization passed

or Test nonspecific ST abnormality (elevation) passed

or Test RBBB passed

or Test Brugada passed

or Any acute infarct or injury test passed

Statement is made if:

In any two of all leads, except lead aVR, STJ <-100 µV and STE >0 µV

Then say junctional ST depression, probably normal *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Junctional ST Depression, Probably Abnormal

Skip test if:

Test LVH and RVH with secondary repolarization passed

or Test nonspecific ST abnormality (elevation) passed

or Test RBBB passed

or Test Brugada passed

or Test MI passed

Statement is made if:

STJ <-100 µV

and STE >1/2 STJ in any two of all leads except aVR

Then say *junctional ST depression, probably abnormal* *

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Nonspecific ST Abnormality

Skip test if:

Test *LVH* or *RVH* secondary repolarization passed

or Test *nonspecific ST abnormality (elevation)* passed

or Test *RBBB* passed

or Test *Brugada* passed

Statement is made if:

either In any two of leads I, II, aVL, V4, V5, and V6:
Minimum STM or STE < minimum STJ and also -50 µV

or Heart rate <100 bpm

and PR interval <200 ms

and In any two of leads I, II, aVL, and V1 through V6:
Minimum STM or STE < minimum STJ

or P onset amplitude -50 µV

or -25 µV

and T amplitude >STM +100 µV

Then say *non-specific ST abnormality*.

Skip test if:

Test LVH or RVH with secondary repolarization passed

or Test nonspecific ST abnormality (elevation) passed

or Test RBBB passed

Statement is made if in any two of leads I, II, aVL, aVF, V4, V5, and V6:

STJ <-50 µV and STE <0 µV

or STE < minimum (STJ and STM) -25 µV

Then say *nonspecific ST abnormality*.

If MI present, suppress all ST abnormality statements.

ST Depression Consider Subendocardial Injury

Skip test if:

Test *LVH* or *RVH* secondary repolarization passed

Statement is made if:

In any two of leads I, II, aVL, aVF, and V2 through V6 STJ and STM are <-100 µV (If test *RBBB* passed, then do not test leads V2, V3, and V4)

Then say *ST abnormality consider subendocardial injury*.

Suppress nonspecific ST statements.

ST Depression in Septal Leads

Statement is made if:

Test septal and posterior infarct failed

and In lead V1 or V2, STJ and STM are <-200 µV

Then say ST depression in septal leads

ST Depression in Anterior Leads

Statement is made if:

Test anterior and posterior infarct failed

and Tests LVH with repolarization abnormality failed

and In lead V3 or V4, STJ and STM are <-200 µV

Then say ST depression in anterior leads

ST Depression in Lateral Leads

Statement is made if:

Test lateral infarct failed

and Test LVH with repolarization abnormality failed

and Lead V5 or V6, STJ and STM are <200µV

and In lead I or aVL, STJ and STM are <100µV

Then say *ST depression in lateral leads*.

ST Depression in Inferior Leads

Statement is made if:

Test inferior infarct failed

and Test LVH with repolarization abnormality failed

and In lead II or aVF, STJ and STM are <-100 µV

Then say *ST depression in inferior leads*.

If any tests subendocardial injury passed, then suppress nonspecific ST abnormality, junctional ST depressions.

If inferior myocardial infarction and lead III has STJ >100 µV, suppress ST depression in lateral leads statement.

If ST depression in anterior and lateral leads present but no ST depression in septal leads present, then say *ST depression in anterolateral leads*.

If ST depression in inferior and lateral leads present but no ST depression in septal and anterior leads present, then say *ST depression in inferolateral leads*.

If ST depression in septal and anterior leads present, then say *ST depression in anteroseptal leads*.

T Wave Abnormality

Skip test if:

Test WPW or dextrocardia passed

or Test LVH with repolarization abnormality passed

or Test complete RBBB passed

or Test complete LBBB passed

Conditions for skipping test applies to all T wave tests.

Abnormal QRS-T Angle, Consider Primary T Wave Abnormality

Skip test if:

Any test infarct passed

or Test *RBBB* passed

or Test *Brugada* passed

Statement is made if:

QRS axis – T axis ≥60 degrees

and T axis <0 degrees

or QRS axis – T axis <-60 degrees

and T axis >90 degrees

Then say *abnormal QRS-T angle, consider primary T wave abnormality.*[*]

*This statement will not appear if the screening criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for information.

Nonspecific T Wave Abnormality

Skip test if:

Any test infarct passed

or Test RBBB passed

or Test Brugada passed

For age <16 years skip testing leads V1 through V4.

NONSPECIFIC T ABNORMALITY TEST

For each lead to be tested:

Set test limit

If QRS amplitude is positive, limit value Is 1/20 QRS amplitude + 25 µV

or If QRS amplitude is negative, limit value is 25 mV

Then count lead as passing test if special T Amplitude < the test limit and (special T <0 or TA <200 µV)

Test leads as follows:

First test lead V3 through V6

If lead V3 passed test, then test lead V2; then test leads I, II, and aVL

If special T amplitude exceeds 150 µV in leads I, II, and aVL do not test

and If QRS balance minus special T <0 µV in aVL, or if QRS balance is negative, do not test aVL

If more than two leads pass this test, then say *nonspecific T wave abnormality*.

T Wave Inversion in Lateral Leads

Statement is made if:

Test lateral infarct failed

and In any two of leads I, aVL, V5, and V6, special T amplitude <-100 µV

(Do not test aVL if QRS balance is negative.)

Then say *T wave inversion in lateral leads*.

If test nonspecific ST abnormality simultaneously passed, then prefix ST&.

T Wave Inversion in Inferior Leads

Statement is made if:

Any test inferior infarct failed Special T amplitude <-100 µV in lead II or aVF (Test lead aVF only when QRS amplitude is positive.)

Then say *T wave inversion in inferior leads*.

If test nonspecific ST abnormality simultaneously passed, then prefix ST&.

T Wave Inversion in Inferolateral Leads

Statement is made if:

Test T wave abnormality consider inferior ischemia passed

and Test T wave abnormality consider lateral ischemia passed

Then say *T wave inversion in inferolateral leads*.

If any T wave inversion tests pass, suppress STEREP and EREP.

If any T wave inversion tests pass, suppress NST, STJD1, STJD2, STDIG, NT, AQRST, and STD.

Nonspecific ST and T Abnormality

Statement is made if:

Any specific T wave inversion tests failed

and Pericarditis test failed

and ST depression test failed

and Test nonspecific ST abnormalities passed

and Test nonspecific T abnormality passed

Then say *nonspecific ST & T abnormality*.

If test NSTT passed, suppress NST, STJD1, STJD2, NT, AQRST, and STD.

QT Abnormalities

The 12SL program can be configured to use Bazett, Fridericia, or Framingham QT corrections for the prolonged QT criteria. Note that not all host products support these choices. If this is not configurable on a host device, then the Bazett correction will be the default.

Skip test prolonged QT if:

Test *WPW* passed

or Intraventricular conduction block or Right bundle branch block

or Left bundle branch block

or QRS duration > 120 msec

or T offset confidence level is poor (i.e., score of 0 on a scale of 0 to 3)

Determine the maximum heart rate for which statement will be made and the QTc threshold:

max HR = 1.2 * high HR for age or 180 bpm, whichever is greater QTc threshold = 460 ms

Exception: If using Bazett-corrected QT (the default) and ventricular rate > high HR for age, threshold is 500 ms.

Statement is made if:

ventricular rate $\leq$ max HR and QTc $\geq$ QTc Threshold

Then say *Prolonged QT*

If test LNGQT passed

If QTc < 480, state *Borderline Prolonged QT*

If LVH, RVH, BVH, IVCD, IRBB, or ILBB, append, *may be secondary to QRS abnormality* suppress EREP and STEREP.

Screening Criteria: Suppressed Statements, Increased Specificity

With *Screening Criteria* turned on at the electrocardiograph (also referred to as Hi-Spec, or High Specificity mode) certain lower-acuity 12SL statements are suppressed from appearing on the report. By suppressing these statements when *Screening Criteria* is turned on, 12SL is placed in a higher specificity mode; that is, fewer interpretive statements will be generated. Most statements that are suppressed are either of lower clinical acuity, such as "incomplete right bundle branch block", or represent lower confidence levels of abnormalities, such as those prefixed with "cannot rule out" or "possible".

Note that not all platforms offer the screening mode as a user-configurable choice. Screening mode is turned off by default (i.e., statements are not suppressed).

NOTE Running 12SL with the ***Screening Criteria*** turned on can affect the ECG classification. For example, an ECG with the diagnosis ***Normal sinus rhythm; Right axis deviation***, will be classified as an ***Abnormal ECG*** when ***Screening Criteria*** is off. If ***Screening Criteria*** is turned on, ***right axis deviation*** will not be stated and the ECG will be classified as a ***Normal ECG***.

Statements Suppressed when Screening Criteria Turned On

Statement Text	*Acronym*
Rhythm Statements	
... with undetermined rhythm irregularity	IRREG
... with rapid ventricular response	RVR
... with slow ventricular response	SVR
... with a competing junctional pacemaker	CJP
... with x:1 AV conduction (x=2,3,4,5)	W2T1, W3T1, W4T1, W5T1
... with retrograde conduction	RETC
... [and/with] possible premature atrial complexes with aberrant conduction	[AND/WITH] + PO + PAC + WITH + ABCOND
Axis / Voltage	
Rightward axis	RAD
Right axis deviation	RAD4
Northwest axis *	NWA
Right superior axis deviation	RAD5
Pulmonary disease pattern	PULD
Ventricular conduction	
RSR' or QR pattern in V1 suggests right ventricular conduction delay	RSR
Incomplete right bundle branch block	IRBBB
Nonspecific intraventricular conduction delay	IVCD
Hypertrophy	

Statement Text	*Acronym*
Minimal voltage criteria for LVH, may be normal variant	QRSV
Moderate voltage criteria for LVH, may be normal variant	LVH3
Possible right ventricular hypertrophy	PO + RVH
... plus right ventricular hypertrophy	RVE+
Possible left atrial enlargement	PO + LAE
Possible left ventricular hypertrophy *	PO + LVH
Deep Q wave in lead V6, possible left ventricular hypertrophy *	QV6 + PO + LVH
Possible biventricular hypertrophy *	PO + BIVH
Prominent mid-precordial voltage, possible biventricular hypertrophy *	PMDPV + PO + BIVH
Myocardial Infarction	
Cannot rule out septal infarct	CRO + SMI
Cannot rule out anteroseptal infarct	CRO + ASMI
Cannot rule out anterior infarct	CRO + AMI
Cannot rule out inferior infarct	CRO + IMI
Cannot rule out inferior infarct (masked by fascicular block?)	CRO + IMI + MAFB
Possible anteroseptal infarct	PO + ASMI
Possible anterior infarct	PO + AMI
Possible anterolateral infarct	PO + ALMI
Possible lateral infarct	PO + LMI
Possible inferior infarct	PO + IMI
ST-T	
ST elevation, consider early repolarization, pericarditis, or injury	SERYR1
ST elevation, probably due to early repolarization	SERYR2
Early repolarization	REPOL
Possible acute pericarditis	PO + PCARD
Junctional ST depression, probably normal	JSTN
Junctional ST depression, probably abnormal	JST
Abnormal QRS-T angle, consider primary T wave abnormality	QRST

*Statements marked with asterisk are statements that are only made when doing pediatric ECG analysis (age < 16 years).

ECG Classification

Unless generation of ECG Classification is suppressed in a platform's setup, each ECG is assigned one of the following classifications by the 12SL analysis program (listed in order of increasing severity):

- Normal ECG (N)
- Otherwise normal ECG (O)
- Borderline ECG (B)
- Abnormal ECG (A)

Most statements generated by 12SL have a classification associated with them. Some statements are informative only and do not have an associated classification. These are typically statements that are appended or prepended to a primary statement. The classification of each 12SL statement is given in Appendix B – "Statement Library by Number". The overall ECG classification is made based on the most severe single statement in the 12SL diagnosis.

As a very simple example, say an ECG contained the single 12SL statement: "Normal Sinus Rhythm". The classification for this statement is "N". The overall classification for this ECG would be "Normal ECG".

As another example, say 12SL generated the following statements for an ECG (the classification of each single statement is shown in parentheses):

- Sinus bradycardia (O)
- with frequent (none)
- premature ventricular complexes (O)
- in a pattern of bigeminy (O)
- Left ventricular hypertrophy (A).

In this case, the most severe single statement is "Left ventricular hypertrophy", with a classification of "A", which would result in an ECG classification of "Abnormal ECG".

Decision Support for Acute Coronary Syndromes (ACS)

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Definition of ACS:

"The term acute coronary syndrome (ACS) refers to any group of clinical symptoms compatible with acute myocardial ischemia and includes unstable angina (UA), non-ST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction (STEMI)."[107]

Requires Diagnosis by a Physician

ACS is ultimately a clinical diagnosis made by a physician. Although electrocardiography (ECG) is an essential tool for this purpose, the diagnosis of ACS should not rely solely on ECG findings. In fact, in a study of 391,208 acute myocardial infarctions (AMI), 7.9% (30,759) had a normal initial ECG.[8] In short, a normal ECG does not rule out ACS.[108] Please refer to current ACC/AHA guidelines for the latest information on the diagnosis and management of patients suspected of having an acute coronary syndrome.

> **WARNING** - INTERPRETATION HAZARD: 12SL analyses, including results from either ACI-TIPI or the ACS Tool, should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and or invasive tests.
> All reports must be reviewed by a qualified physician.
>
> **WARNING** – INTERPRETATION HAZARD: ACI-TIPI or the ACS Tool, is only intended for adults with symptoms suggestive of ACS. Applying it to all patients without symptoms will result in false-positive interpretations of the ECG as having ECG abnormalities commensurate with ACS.

First Step: Get an ECG within 10 minutes

"The standard 12-lead ECG remains the single most important diagnostic tool in the evaluation of ACS and should be performed within 10 minutes of the first contact with medical personnel."[109] A STEMI pattern is the most specific finding for ACS, especially if different from a prior ECG.[110, 111] Clinical guidelines, from across the globe, recommend time-to-treatment benchmarks for STEMI via thrombolytic (30 minutes) or emergency cardiac catheterization (90 minutes).[112, 113]

Prehospital ECG (PHECG) has been found to significantly reduce time-to-ECG and time-to-treatment. The 2015 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care states "prehospital 12-lead ECG should be acquired early for patients with possible ACS".[114] Likewise, outside the U.S., PHECG is recommended by the European Society of Cardiology (ESC),[115] backed by evidence gathered by UK's national MI registry which shows a survival advantage in STEMI and non-STEMI patients when PHECG is used.[116]

A timely ECG in the emergency department (ED) remains elusive "despite decades of quality-improvement efforts."[117] As opposed to a paramedic attending to a patient as soon as they arrive by ambulance, "the first 10 minutes of an ED visit typically consists of intake processes (registration and triage) that usually occurs well before a physician encounter."[117] In a study published in 2017 which monitored several ED's across the U.S., there was a significant percentage of STEMI cases that did not have an ECG taken within 15 minutes of

ED arrival. In fact, on average, 12.8% of all STEMI's missed the 15 minute benchmark, with the best ED at 3.4%, the worst at 32.6% and a case of one STEMI taking over 80 minutes to obtain an ECG.[117] This variation appears to be due to the screening criteria (symptoms etc.) for who should get an ECG; a broader, more inclusive set of criteria seems arranted and is under evaluation.[118]

In any case, time-to-first-ECG is so vital it is a quality and performance metric monitored by several regulatory bodies.[119-122]

Introduction: GE Healthcare's Decision Support for ACS

Since the advent of prehospital ECG for selecting candidates for thrombolytic therapy,[21, 123] GE Healthcare has been developing solutions to assist the physician in the diagnosis of ACS.

GE Healthcare's toolset for ACS includes ECG connectivity from prehospital to hospital as well as the following algorithms which are further described under the following headings:

- Automated STEMI Recognition in Prehospital or Hospital Setting via 12SL™
- ACI-TIPI/ACS Tool for Indicating Probability of ACS in the Symptomatic Patient
- Automated Serial Comparison for Detection of ECG Changes Commensurate with ACS

Before delving into this tool set, it is best to understand the challenges the healthcare system faces in assessing patients suspected of ACS. See The Challenges Associated with Diagnosing ACS.

Given the magnitude of the problem, research and development continues to be done to find new ways to deal with the challenge of ACS. This includes the use of biomarkers for accurate detection of ACS, such as use of high-sensitivity Troponin. See "ECG and the Advent of High-sensitivity Troponin."

Although the adoption of high-sensitivity Troponin is quite widespread, the knowledge regarding how to use them properly for the diagnosis and management of ACS is still unsettled and sometimes fundamentally questioned via results from recent randomized controlled trials.[124, 125] Risk stratification scores or diagnostic algorithms that include these values "has led to a constantly evolving and unquestionably chaotic scenario."[126] Regardless, it appears the ECG has a steadfast role at the extremes of the ECG patterns seen with ACS: that is, identifying patients with a STEMI in need of immediate intervention versus low-risk patients with a normal ECG that may safely benefit from an accelerated rule out protocol.[127] It is in between these extremes where further discovery will certainly take place. GE Healthcare is interested in partnerships which will tease out which computerized ECG metrics provide added value to high-sensitivity Troponin values for the diagnosis and management of ACS.

The Challenges Associated with Diagnosing ACS

Low Prevalence of ACS (≈15%) in Symptomatic Population,152
Inability to Differentiate Based on Symptoms,153
Rate of False-Negative (FN)/False-Positive (FP) in ED and Consequence of Each,154
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Top Reasons for Misdiagnosis,155

Limited Resources and Overwhelming Number of Patients Suspected of ACS

According to national health statistics for 2015, over 7 million visited the emergency department (ED) in the United States (U.S.) with the primary complaint of chest pain or related symptoms of ACS.[128] On top of that, overall ED visits are increasing at a rate of about 2.9 million visits per year (or 3.2 percent) while the number of EDs "has decreased from 4,019 to 3,833."[129] Similar trends are occurring outside the U.S., where ED visits are increasing at reported range of 3% to 7%, annually.[130-134]

Low Prevalence of ACS (≈15%) in Symptomatic Population

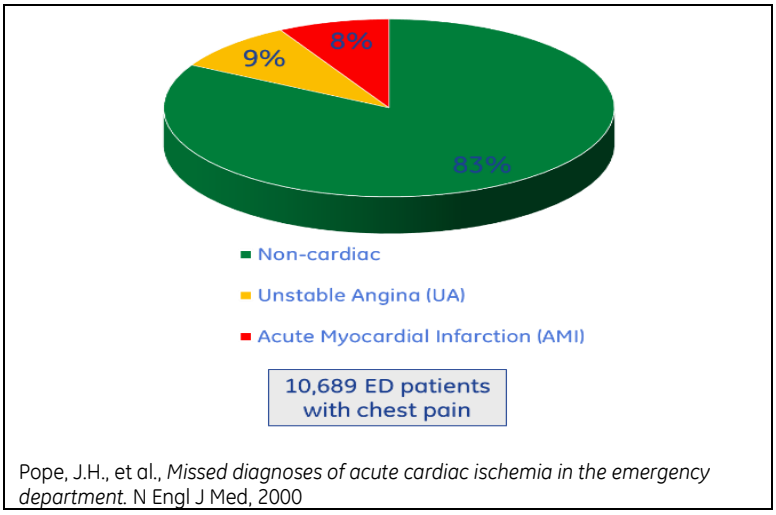
Even in the presence of chest pain, the prevalence of ACS has been found to be roughly 15%.

The reported prevalence can vary substantially based on the following factors: a.) the person performing the evaluation, b.) the location of the evaluation (e.g. office, ambulance or emergency department) and c.) whether a true-positive instance of ACS is primarily based on a blood sample versus clinical outcomes.

For example, one study reported a prevalence of 2%, another 60%, yet both stated they used similar inclusion criteria for selecting a population suspected of ACS: namely, all patients complaining of chest pain, shortness of breath, etc. It is the details of how these criteria were applied that likely accounts for the marked difference in reported prevalence.

In the case of the extremely low prevalence of 2%, 18,759 ED patients were selected based on whether their "non-processed chief complaint" matched one from a list of five preselected from data mining methods as being most predictive of acute MI.[135] At the other end of the spectrum, the prevalence of 60% was reported from a study of 511 patients who called for an ambulance due to symptoms associated with ACS, as confirmed by ambulance personnel.[136] Regardless, neither of these studies included follow-up data. There is no way to know whether either method resulted in a higher percentage of missed cases of ACS.

Unfortunately, since follow-up is time consuming and expensive, few studies have evaluated the prevalence of ACS in the admitted as well as discharged populations. One of the largest included 7 EDs that followed 10,689 ED chest-pain patient for 30 days. [137] In this case, the true-positive prevalence of ACS was found to be 17% (acute myocardial infarction 8%, unstable angina 9%) while the rate of missed cases of myocardial infarction was 2.1% (19 out of 899).



Pope, J.H., et al., *Missed diagnoses of acute cardiac ischemia in the emergency department.* N Engl J Med, 2000

In another large study published in 2018, over 48,000 ED patients suspected of ACS were followed for 1 year. Conventional serial Troponin measurements were used as a gold-standard for ACS. In this case, the prevalence of myocardial infarction or death from cardiovascular causes was 5% and unplanned hospital admission within 30 days, 18%.[124]

In any case, most studies report an incidence of ACS between 6 and 18% in chest-pain patients evaluated in the ED. [137-140] If patients in the ED were evaluated solely based on symptoms, the false positive rate would be ≈80%.

Inability to Differentiate Based on Symptoms

Signs and symptoms of ACS usually begin abruptly and include any of the following: chest pain (often described as aching, pressure, tightness or burning) which may radiate to the shoulders or arms; pain in the upper abdomen, back, neck or jaw; shortness of breath; nausea or vomiting; etc.[107] These symptoms do not effectively differentiate ACS. Indeed, in a meta-analysis of 16 studies, "it was not possible to define an important role for signs and symptoms in the diagnosis of acute myocardial infarction or acute coronary syndrome."[141] In fact, only chest-wall tenderness on palpation was found useful in ruling out ACS.[141] In conclusion, "it is well established that clinicians cannot use clinical judgment alone to determine whether an individual patient who presents to the emergency department has an acute coronary syndrome."[142] Indeed,

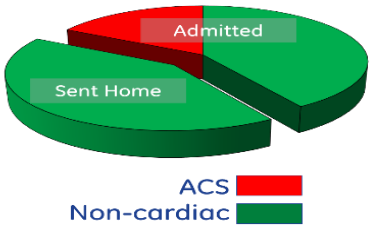
"half of all ST segment elevation myocardial infarction patients do not experience a typical episode of acute severe chest pain – the so-called 'Hollywood heart attack' – but have atypical symptoms."[133]

It is also important to know the inability to use symptoms to differentiate ACS is linked to the low prevalence of acute cardiac disease in the symptomatic population. For instance, in the aforementioned study that included 10,689 ED chest-pain patients, the percentage who identified chest pain as their chief complaint was statistically lower in those who were not found to have ACS (62%) versus those that did (88%); due to the sheer number of patients who were not found to have ACS (8,150 out 10,689) the predictive value of chest pain as a primary complaint was diminished to the point where it made little difference in the accurate diagnosis of ACS.

Rate of False-Negative (FN)/False-Positive (FP) in ED and Consequence of Each

If the initial ECG is not indicative of a STEMI, further workup is required to accurately diagnose ACS.[115, 143] After repeated testing and serial trending of ECG and/or cardiac biomarkers over several hours, more than half of patients with chest pain or other symptoms associated with ACS are diagnosed with a non-cardiac cause for their symptoms.[144] The costs for this are large and primarily due to the substantial over-admission of patients for non-cardiac conditions.[145] In rural settings, costs are compounded due to transfers to tertiary centers,[140] where approximately 20% of the transfers are reported to be a false-positive or not necessary.[146]

This diagram shows the relative proportion of noncardiac patients admitted versus sent home from the study of 10,689 chest pain patients identified in the prior figure. Notice that ACS only makes up about a third of all admitted patients.



Selker, H.P., et al., *Use of the acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI) to assist with triage of patients with chest pain or other symptoms suggestive of acute cardiac ischemia. A multicenter, controlled clinical trial.* Ann Intern Med, 1998.

There are severe consequence for a missed case of ACS, which occurs at a reported rate of 2% in the urban ED[137] and 3-5% in the rural ED.[140] A patient inadvertently sent home with an acute myocardial infarction (AMI) has a mortality rate of 16%.[147] In the U.S., complications or death due to missed cases of ACS "accounts for the highest dollar losses in emergency department malpractice cases."[148]

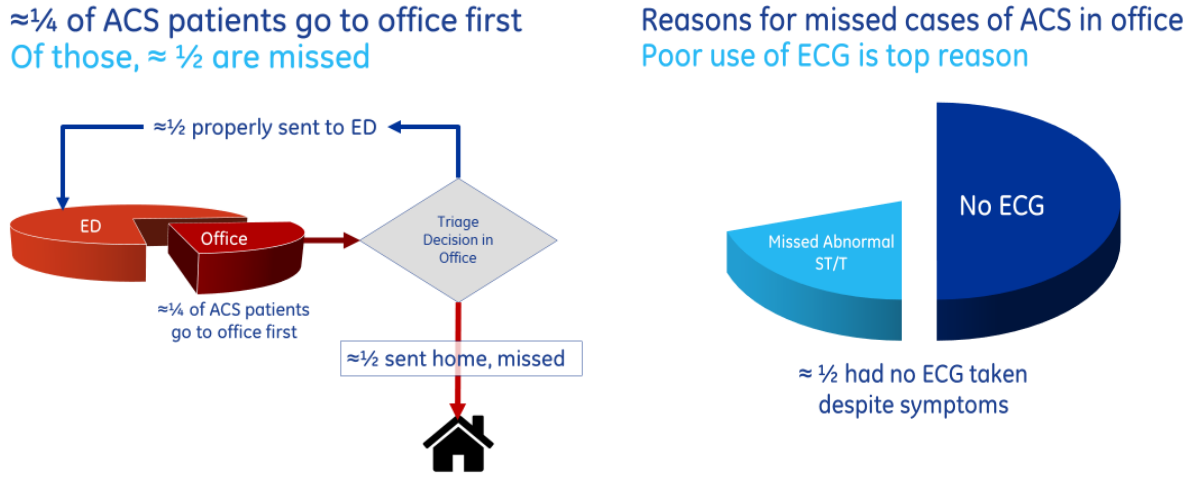
Higher FN Rate in Office

"Each year, approximately 1.5% of the population consults a primary care physician for symptoms of chest pain."[149] From an article published in 2018 on *Managing chest pain patients in general practice: an interview-based study* it is stated that "most guidelines clearly state that general practitioners (GPs) should refer every patient suspected of ACS to secondary care facilities as soon as possible" or, for the matter, "be bypassed to prevent loss of time and myocardial cell necrosis. For every chest pain patient with a life-threatening disease as ACS, GPs encounter 11 patients with chest pain of non-severe cause. Clinical judgement and triage by GPs remains inevitable to prevent unnecessary referrals …"[150] Despite this stance, GP evaluation of new-onset chest pain is occurring in the office without follow-up to ensure the FN rate approximates that seen in the ED. Given the expense and the daunting task of a follow-up study which includes hundreds of GPs and their patients, an alternative approach is to simply ask what happened before a patient showed up in the ED with an acute myocardial infarction (AMI). When this is done, the FN rate for the office appears alarmingly high.

For example, consider a study conducted in the U.S. which found that a quarter of all AMI patients went to the office first before showing up later in the ED with an AMI. In more detail, it was found for a covered population of 250,000 over a four year period, 27% of the 966 hospital admissions for AMI had primary care visits in the preceding month for symptoms suggestive of coronary disease, and 41% (106/261) of these patients were not referred for hospital care.[151] Instead of a FN rate of 2%, it is possible the FN rate for the office could be as high as 40%. Even though these patients were symptomatic when they went to the office, "half of the

patients did not have an ECG performed during the office visit, and among those who did, the ECG was not always interpreted before the patient left the office."[151]

Using a similar approach, a study conducted in Germany found "421 AMI patients, 327 (77.7%) were directly admitted to hospital after examination by the [GP] physician, whereas 94 (22.3%) were not admitted." The conclusion of the study was that missed AMI in the office setting "is a common problem."[152]



Sequist, T.D., et al., *Missed opportunities in the primary care management of early acute ischemic heart disease.* Arch Intern Med, 2006

This is a significant concern since the norm in some healthcare systems is for chest-pain patients to see their physician before calling emergency services.[134] This practice has been shown to result in significant delays in care.[133]

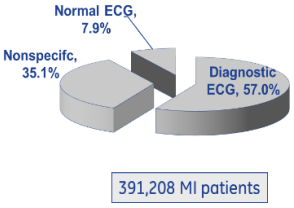
Top Reasons for Misdiagnosis

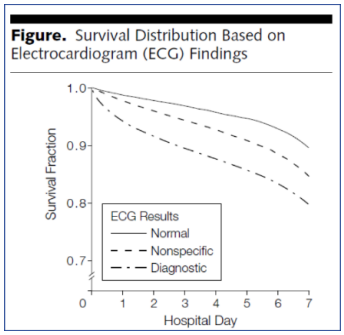
In the paper, "Missed opportunities in the primary care management of early acute ischemic heart disease",[151] half of missed cases of ACS had no ECG taken despite complaining of chest pain or other symptoms indicative of ACS.[151] See figure above.

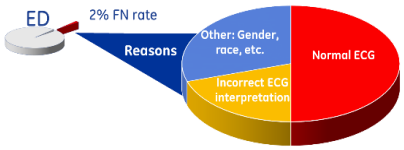
This error of omission has not been reported in any study conducted in the ED. Instead, an incorrect ECG interpretation has been cited as a top contributor to a missed case of ACS in the ED. For example, in a study that included over 10,000 ED patients suspected of ACS, investigators "found a small but important incidence of failure by the emergency department clinician to detect ST-segment elevations of 1 to 2 mm in the electrocardiograms of patients with myocardial infarction (11%). This incidence represents an important and potentially preventable contribution to the failure to admit such patients."[137]

ED physicians failed to identify "significant ST-segment depressions, ST-segment elevations, or T-wave inversions on the presenting ECG."[153] in 12% of AMI's, and these errors significantly increased the in-hospital mortality of these patients, from 4.9% to 7.9% (P=0.1).[153]

In a study of missed cases of ACS in the ED, 53% had a normal or non-diagnostic ECG.[137] Although a normal initial ECG is prognostic of a good outcome when admitted to the hospital,[8] it should not be used to exclude a diagnosis of ACS. It should be appreciated among ACS patients with normal or nonspecific initial ECGs, evidence shows that 20.1% became STEMIs.[8]







Pope, J.H., et al., *Missed diagnoses of acute cardiac ischemia in the emergency department.* N Engl J Med, 2000

Welch, R.D., et al., *Prognostic value of a normal or nonspecific initial electrocardiogram in acute myocardial infarction.* Jama, 2001.

Gender and race have also been reported to be significant factors.[137] Even if correctly diagnosed with ACS, women suffer from higher mortality rates,[154-156] which appear related to less-aggressive treatment.[157-161] Although a complex issue integral to biological differences between men and women, increased mortality in women may be due "to bias or under use of aggressive therapy".[162]

GE Healthcare's Toolset for ACS:

GE Healthcare's tool set for ACS includes the following:

- Access to a prior ECG
- Prehospital ECG connectivity
- Automated STEMI recognition in prehospital or hospital setting
- ACI-TIPI/ACS Tool for Indicating Probability of ACS in the Symptomatic Patient
- Automated serial comparison

Access to a Prior ECG via the MUSE System

Access to prior ECG has been shown to significantly reduce unnecessary admissions. Evidence for that comes from a large multi-center prospective cohort study of 5,673 patients who went to the ED complaining of symptoms commensurate with ACS. [163] Those without a cardiac condition with a prior ECG available for review were more likely to avoid CCU admission than those without prior ECGs.

This improvement was most marked in the 2,024 patients (out of 5,673) whose current ED ECG had baseline changes consistent with ACS. In this case, those not suffering from a cardiac condition were "more than twice as likely to be discharged (26% vs. 12%) and about 1.5 times as likely to avoid CCU admission (39% vs. 27% $p < 0.0001$)."[163] This reduction in unnecessary admissions was attained without a significant drop in proper admission to the hospital or to the coronary care unit (CCU) for those actually suffering from a heart attack.

Likewise, it has been found that a significant portion of false positive activations of the Cath Lab could have been avoided if the current ECG was compared with the prior ECG on file at the hospital. For example, in a study where 1,345 patients who underwent emergency cardiac catheterization, 187 (14%) were not suffering from a heart attack and did not have a blocked coronary artery.[111] Of these, most had a prior ECG that exhibited an abnormality that mimicked a heart attack. This study makes the appeal that there should be time for a obtaining a prior "ECG for comparison or the time to observe evolutionary ST-segment changes."[111]

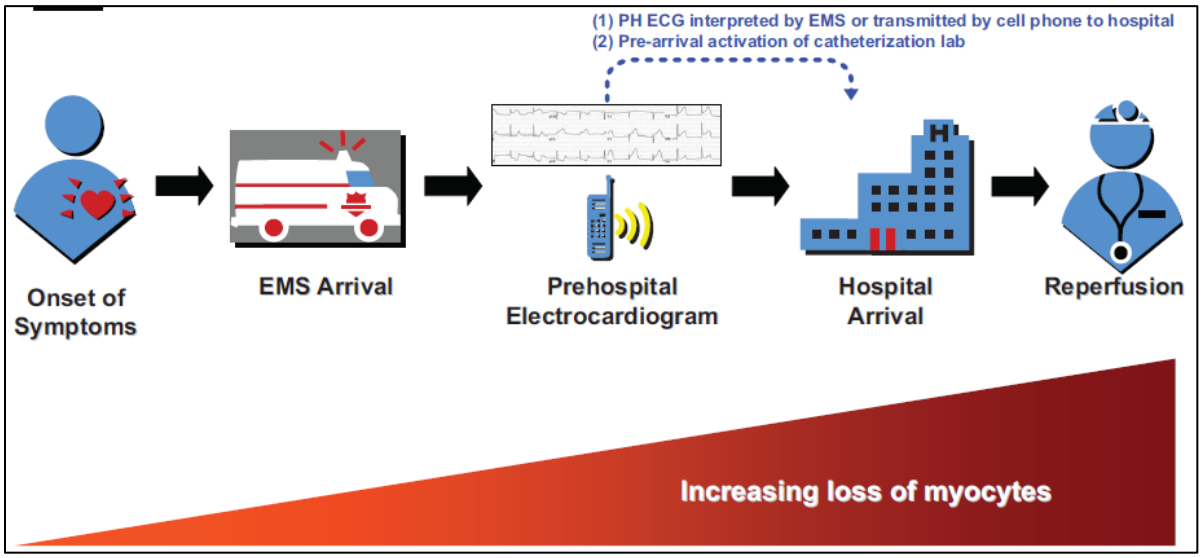
When the current ECG is negative, a significant change from a prior is predictive of poor outcome and a 2.1 times greater likelihood of intervention. This result was obtained via a year-long study at a single hospital, where 258 out of the 498 patients admitted for a heart attack had a prior ECG on file.[164] As can be expected, the prognostic value of a serial change was also present when the initial ECG in the ED was positive; in this case, the effect of the serial change was even more prognostic, resulting in more "interventions (2.0 times), complications (2.6 times), life-threatening complications (4.2 times), and acute myocardial infarctions (6.6 times)."[164]

Prehospital ECG Connectivity with the MUSE System

GE Healthcare was first to provide prehospital 12-lead ECG analysis with digital transmission to the hospital.[165, 166] Although GE Healthcare no longer manufacturers prehospital defibrillators, GE's Marquette 12SL™ program is available on prehospital defibrillators from other manufacturers. The MUSE system can acquire prehospital ECGs from any vendor using such standards as DICOM or XML.

According to an AHA scientific statement, "multiple studies have demonstrated the benefits of prehospital ECGs for decreasing door-to-drug time and door-to-balloon time in patients with STEMI. The direction and magnitude of the time savings are clinically relevant, resulting in an approximately 10-minute decrease in door-to-drug time and 15- to 20-minute decrease in door-to-balloon time. These time savings may not reflect the full potential of prehospital ECGs to decrease delays in reperfusion therapy. In fact, studies have shown further reductions in door-to-balloon time when prehospital ECGs are used to activate the catheterization laboratory while the patient is enroute to the hospital."[167]

Based on evidence published in 2018, time-to-treatment is especially important in STEMI patients experiencing cardiogenic shock. In fact, if these patients have not yet experienced a cardiac arrest, it has been found that every 10-min treatment delay results in 3.31 additional deaths for every 100 patients successfully treated in via emergency cardiac catheterization.[168] Solutions that streamline this decision process and accelerate the path to reperfusion are very important.



The figure shows a clinical workflow for a prehospital ECG from: Ting, H.H., et al., Implementation and integration of prehospital ECGs into systems of care for acute coronary syndrome: a scientific statement from the American Heart Association Interdisciplinary Council on Quality of Care and Outcomes Research, Emergency Cardiovascular Care Committee, Council on Cardiovascular Nursing, and Council on Clinical Cardiology. Circulation, 2008.

Despite the value of ambulance transport and prehospital ECG, roughly half of patients suspected of ACS delay seeking care and go to the ED on their own. This is an age-related behavior. In fact, 72% of those from ages 45 to 64 walk in to the ED.[169] This is despite public education of the value of ambulance care for chest pain.[170]

Regardless of how chest pain patients seek emergency care, it is important to consider the MUSE™ system provides connectivity with ECGs acquired in the ambulance, ED or cardiac care unit. Instead of one system for linking the ambulance to Cath Lab and another for walk-in patients, the MUSE system manages ECGs from both paths which can then be compared to any prior ECG for that patient.

Automated STEMI Recognition in Prehospital or Hospital Setting via 12SL™

GE's Marquette 12SL™ program has undergone considerable validation in both the prehospital and hospital setting. Although not as sensitive as an expert electrocardiographer for the recognition of STEMI, it is highly specific. In fact, several studies have reported that 12SL identifies STEMI with a higher predictive value than expert electrocardiographers.[123, 171, 172] In addition, it has been found useful in classifying normal versus abnormal ECGs for triage in patients with chest pain.[173]

See further details regarding these performance metrics via this hyperlink. The remainder of this section addresses how 12SL recognizes STEMI and the challenges of accurately identifying STEMI across all types of ECGs including those with left ventricular hypertrophy (LVH).

Identification of a STEMI obviously depends on the presence of significant ST elevation (STE) in the 12-lead ECG. Yet, the "definition of significant ST segment elevation varies considerably with respect to both the required minimum height (mm) of ST elevation, and the numbers of leads with ST elevation."[174]

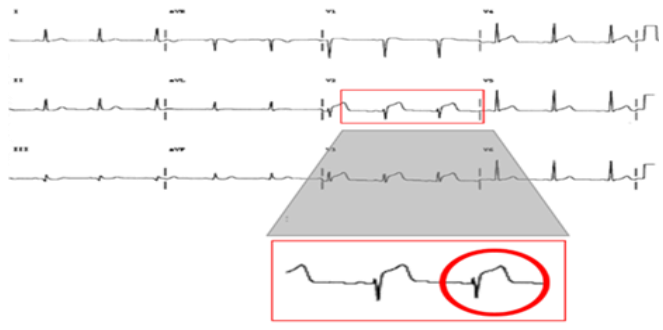
Expert electrocardiographers can identify STEMI with a high level of specificity whether they use the "conventional ST elevation criteria of 1 mm in any 2 contiguous leads"[175] or the more stringent ACC/ESC criteria which requires a 2 mm (200μV) ST deviation in leads V1-V4.[176] Specificity is unacceptably low when strictly applying these ST elevation (STE) thresholds.

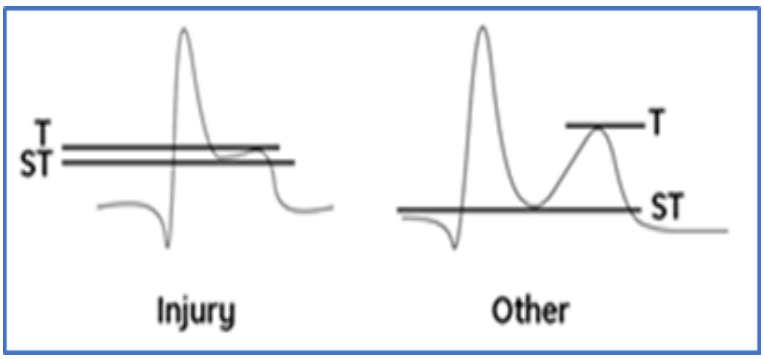
For instance, in an assessment of 6,014 healthy men enrolled in the U.S. Air Force (ages 16 to 58) it was found that "91 percent had ST segment elevation of 1 to 3 mm in one or more precordial leads."[177] In yet another, much larger prospective study, STE >0.1 mV (100μV) in at least 2 inferior or lateral leads was found in roughly half 10,957 enrolled subjects. In short, STE alone is not sufficient to accurately identify a STEMI.[178]

Isolated ST-segment elevation in the presence of AMI is "distinctly unusual".[123] There are typically other abnormalities evident in the ECG. These can occur in leads with ST-segment elevation (STE) or elsewhere in the ECG.

ST-segment Morphology

In a lead with STE, the most common pattern taught to students for discriminating STE due to STEMI is to see if the ST-segment is convex. If the ST-segment is concave or the STE is small in relation to the T-wave, the STE is likely to be normal or due to early repolarization.

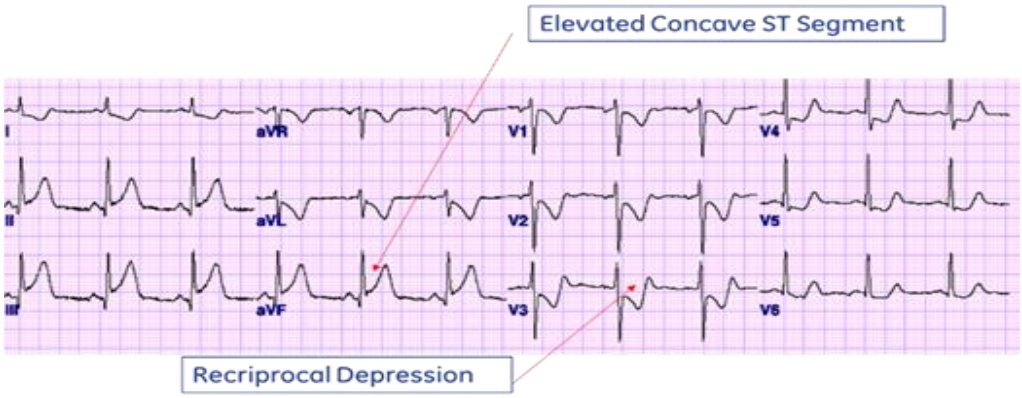




Discrimination of a STEMI based on whether the ST-segment is convex versus concave helps, but not that much. Indeed, in the first of a series of studies where PHECGs were obtained by paramedics and correlated against clinical outcomes, only half of STEMI's had convex ST segments.[17] Subsequent studies have reported similar results. Indeed, use of the "non-concave STE morphology for AMI diagnosis is not particularly helpful ..."[179]

Reciprocal Depression

Below is an example of STE which is concave. It is not early repolarization since the STE is localized to leads II, aVF & III and is accompanied by ST-depression in leads V1-V4. Instead, this is an inferior STEMI commensurate with a pattern known as "reciprocal depression".



Reciprocal depression has been noted as absent in ECGs obtained from normals.[180] Before PHECG and automated STEMI recognition based on cardiac biomarkers / clinical outcome, it was not generally appreciated how useful reciprocal depression would be for discriminating a STEMI.[17] Indeed, comparing lead-specific convex/concave criteria versus the use of reciprocal depression, "resulted in over twice the sensitivity (53%), while continuing to maintain a high rate of specificity (98%)."[17]

This same degree of improvement in performance was confirmed a few years later in several studies.[181-183] For instance, in a study of 428 PHECG chest pain patients, 29% met 1 mm (100μV) or more ST segment elevation criteria. Half of these did not have myocardial infarctions. If the 1 mm or more ST segment elevation occurred with reciprocal changes, "a positive predictive value of 94% was achieved and included 18 of the 21 (86%) myocardial infarction patients who had ST segment elevation and received thrombolytic therapy within five hours after hospital arrival." The conclusion of the study was "ST segment elevation criteria that include reciprocal changes identify patients who stand to benefit most from early interventional strategies."[183]

Reciprocal depression has also been found to be predictive of clinical outcome.[184, 185] "When concomitant ST depression is present in patients with STEMI undergoing primary PCI, less than 50% resolution of ST depression was associated with worse 90-day clinical outcomes even after accounting for the baseline risk profile, infarct location, PCI procedural outcome, and resolution of ST elevation. Although favorable outcomes are generally anticipated in patients with ST elevation resolution 50%, our data indicate that ST depression resolution adds additional important prognostic insight and deserves consideration in the management of these patients and future STEMI guidelines."[185]

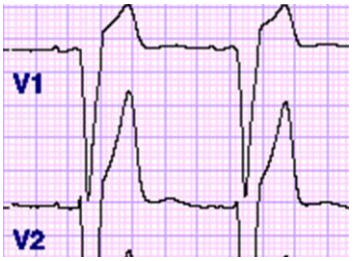
Appropriate Use of Reciprocal Depression

Reciprocal depression is an inherent characteristic of bundle branch blocks (BBB). Below is an example of a left bundle branch block (LBBB). It exhibits STE in V1-V2 and ST depression (STD) in V5-V6. In this case, the reciprocal depression is not the result of a STEMI. The STE and STD are a secondary result of the conduction abnormality.

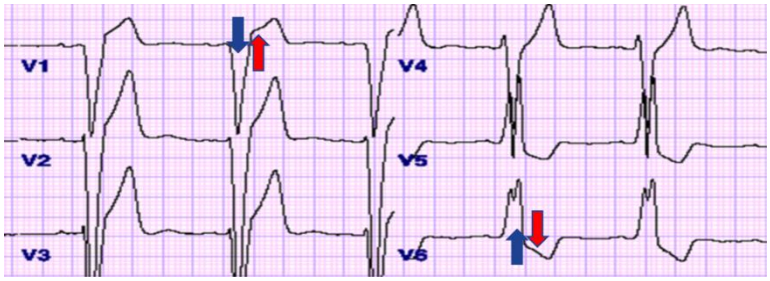
Secondary repolarization abnormalities due BBB are large and in the opposite direction of the QRS. This is because repolarization begins before the QRS has a chance to end. Consequently, there is a significant ST-segment shift at the end of the QRS. More importantly, the sequence of repolarization is altered. It begins where the conduction system was intact and follows the wave of depolarization as it spreads to the other

ventricle. This contrasts with normal repolarization which travels in the opposite direction of depolarization. In normal repolarization, the QRS and T-wave are concordant while in the case of BBB, they are 180° apart.

Although there is marked STE in V1-V2 due LBBB that could erroneously be identified as a STEMI, it is clear the STE is due to a secondary repolarization abnormality. The QRS duration is long. The depolarization (blue arrow) and repolarization (red arrow) are 180 degrees apart. Leads with a predominately positive QRS complex end up with STD and T-wave inversion and vice versa.

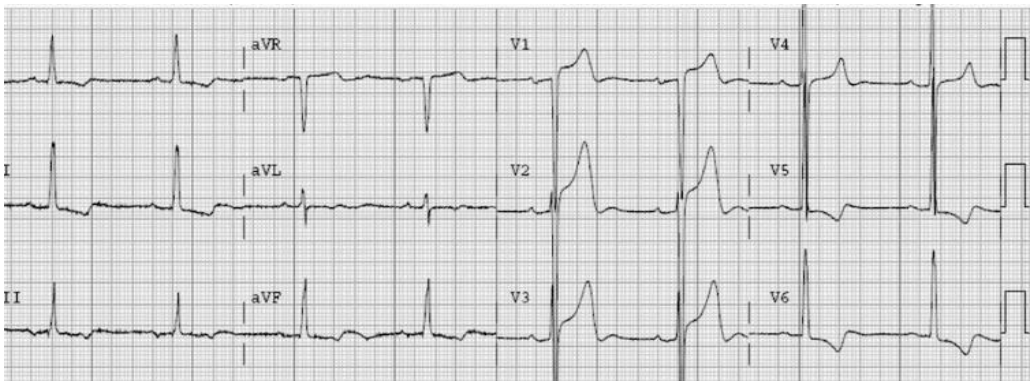


See marked STE in V1-V2



STE caused be secondary repolarization abnormality.

Likewise, in the presence of LVH, there can be significant STE in V1-V3. See example below. Although there is reciprocal depression in V5, V6 & aVL, the wave of repolarization (ST/T-wave) is in the opposite direction of depolarization (QRS). This is typical of LVH and should not be identified as a STEMI.

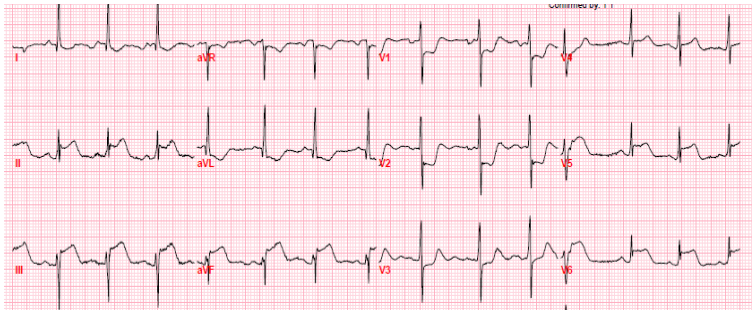


For those skilled in the art of ECG interpretation, it would seem obvious that significant STE in V1-V3 often occurs in the presence of LVH and that this finding needs to be treated with caution before identifying it as due to a STEMI. Two cardiac catheterization laboratory (CCL) registries have reported many cases of anterior STE due to LVH mistakenly identified as STEMI. In fact, it was found to be a significant contributor to a higher reported incidence of inappropriate CCL activations than expected, namely 36%[186] and 45%[187] versus the typically reported level of 15%.[111, 188] Upon closer inspection, it was found that over 30% of the inappropriate activations were due to LVH-induced anterior STE being identified as a STEMI even when 60% of these had a prior ECG exhibiting no significant change from the current ECG at the time of activation.[187]

To properly apply the clue of reciprocal depression, one must also take into account the changes in repolarization due to a conduction abnormality or hypertrophy.[182, 189] The 12SL program has rules which stipulate when it can use reciprocal depression. Although the details are provided via this hyperlink, the general approach is to evaluate whether the STE is in the opposite direction of the QRS. If it is, the program applies successively higher thresholds for identifying a STEMI based on the duration and amplitude of the QRS.

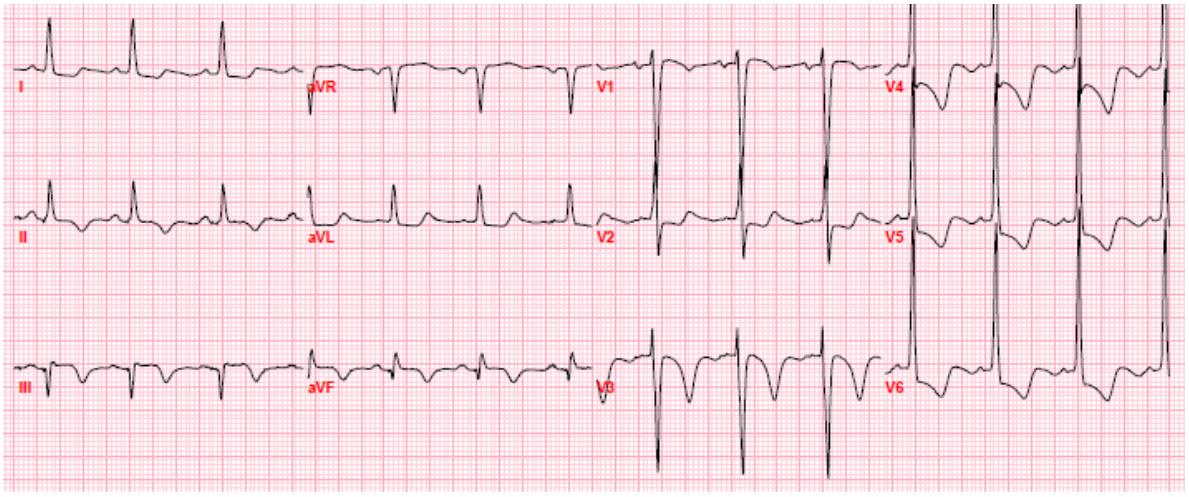
If the STE is not in the opposite direction of the QRS, the 12SL program can apply the rule of reciprocal depression liberally. As opposed to other programs which simply avoid detecting any STEMI in the presence of LVH or a conduction abnormality, these rules allow the 12SL program to go forward and detect legitimate cases of a STEMI in the presence of these QRS abnormalities. See examples below.

Due to the voltage and ST/T pattern in aVL, some programs would identify this as LVH and skip whether the ECG has evidence of a STEMI.

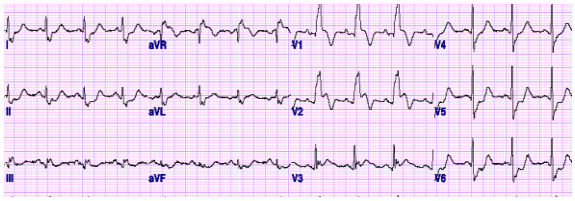


The ST/T vector is not typical of LVH; it is not 180° away from the QRS. This is an inferior-lateral STEMI with reciprocal depression evident in V1-3.

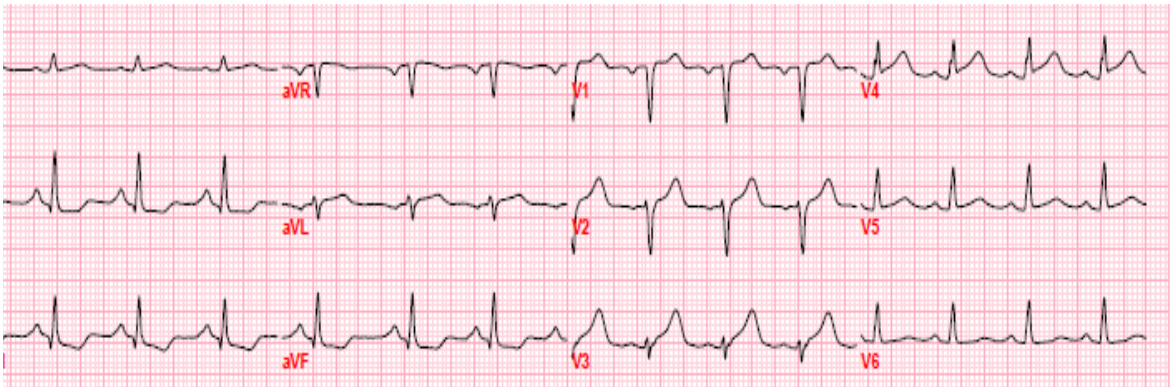
In the ECG below, some programs would not attempt analyzing this for STEMI because it meets voltage criteria for LVH and the ST/T in V5-V6 is typical of LVH. Despite the signs of LVH, this is an inferior STEMI. The STE in aVF and the STD evident in V2 is not typical of LVH. The T-wave in V3 is concordant with the QRS and atypical for LVH.



Although this is a right bundle branch block (RBBB), 12SL can identify this as STEMI because STE (in V1-2) and reciprocal depression (in V5-6) are not typical for RBBB. Likewise, LBBB can be accessed for a STEMI if there is STE in V5-V6.

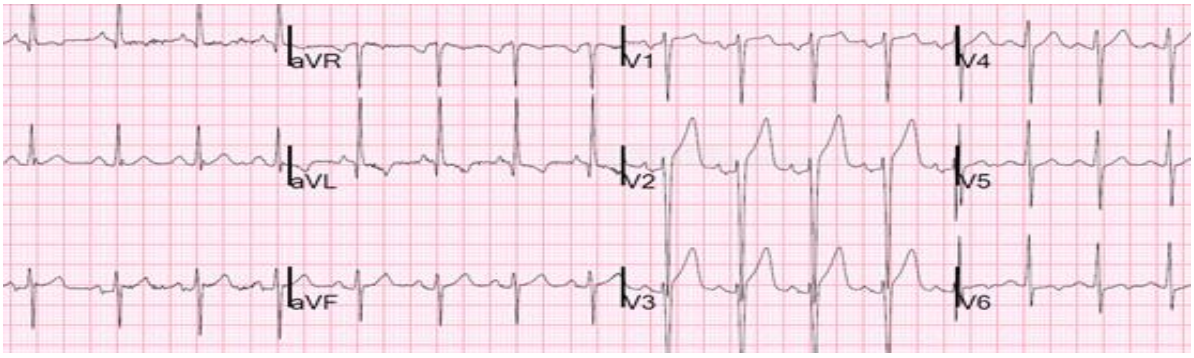


When reciprocal depression is applied correctly, smaller levels of STE can be identified as a STEMI. For instance, see the tracing below. Strictly speaking, only V4 shows STE > 100µV. Yet, given the pattern seen in the inferior leads this can be identified as an anterior STEMI.

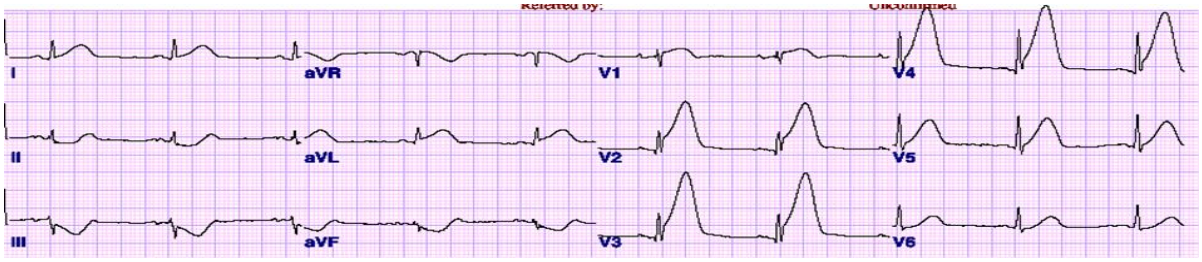


The rule of when to apply reciprocal depression can also be useful for discriminating hyperacute T-waves. See the two tracings below.

The first ECG has STE > 200µV in leads V1-V3 and large T-waves that could be mistaken as hyperacute. But the wave of repolarization is in the opposite direction of the QRS. A higher ST-segment threshold for STEMI is warranted. Any depression seen on the other side (in leads V5/6, I or aVL), should be not be construed as reciprocal depression. The pattern seen in aVL is typical of LVH. This is not a STEMI.



The second tracing has large, broad T-waves. There is significant STE in V2-V4, but it is small in relation to the T-wave amplitude. Given that the STE is in the same direction as the QRS, the ST depression in the inferior leads can be identified as reciprocal depression to an anterior STEMI.



In conclusion, identifying a STEMI is not trivial. Besides the difficulty of defining an appropriate ST-segment threshold for a STEMI, there are several common conditions that mimic, and confound STEMI recognition.[190] Although a convex elevated ST-segment is a highly specific indicator of a STEMI, it is insufficient for identifying most STEMIs. When applied under the appropriate circumstances, reciprocal depression has been shown to be a highly specific indicator of STEMI.[182]

ACI-TIPI/ACS Tool Indicating Probability of ACS in the Symptomatic Patient

The 12SL program supports two options that may assist the physician in determining the probability of a chest-pain patient having an acute coronary syndrome (ACS). Both ACI-TIPI and the ACS Tool are configurable options. To obtain a result from either tool, they must be "turned-on" when the 12SL analysis is performed. Note that not all GE Healthcare diagnostic electrocardiographs support ACI-TIPI or GE's ACS Tool.

Both ACI-TIPI and GE Healthcare's ACS Tool were developed using statistical methods applied to large databases of 12-lead ECG measurements correlated with the final clinical determination of ACS from those who entered the emergency medical system (EMS) complaining of symptoms associated with ACS. While ACI-TIPI uses a logistical regression equation, GE Healthcare's ACS Tool uses a neural network for optimum assessment of ECG patterns that have been correlated against the clinical determination of ACS.

ACI-TIPI was developed first, in the 1980's.[191] In 1996, ACI-TIPI was tested on ECGs obtained in an ambulance[21] and implemented in GE Healthcare electrocardiographs. In 1998, results of a prospective evaluation of ACI-TIPI used in GE electrocardiographs was published.[192] Results were obtained from 10 different medical centers on over 10,000 patients suspected of ACS. By turning the ACI-TIPI on, off and on again, its impact on physician decision making could be ascertained. This prospective trial demonstrated that use of ACI-TIPI by the ED physician reduced admissions by 30% without any increase incidence of missed

cases of ACS.[192] This reduction was essentially limited to centers with limited resources; if there were plenty of beds available, physicians tended to admit patients regardless of ACI-TIPI values. Since then, further studies have been published using ACI-TIPI. See these articles for more information.[193-195]

GE Healthcare's ACS Tool was developed as an evolution of ACI-TIPI based on customer feedback and preference. The difference between the ACS Tool and ACI-TIPI is more in terms of the user interface and not the statistical performance of the algorithm. These differences are listed below. The use of the ACS Tool has been shown to significantly improve the sensitivity of ED physician recognition of acute coronary syndromes without a loss of specificity.[37]

ACI-TIPI	***GE Healthcare's ACS Tool***
Two-page report. One page for the 12SL interpretation, the other for the ACI-TIPI score and reasons for score.	One-page report. Results of 12SL are fully integrated as part of the tool.
Must delineate whether chest pain is chief or secondary complaint. Report defines symptom as ""chest or left- arm pain" or "other".	No specific symptom is entered. Report simply states patient has symptoms commensurate with ACS.
On each test, ACI-TIPI states "predicted probability of acute cardiac ischemia = x%"	No probability score provided. Instead, report simply states either: ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings "*** ** CONSIDER ACUTE CORONARY SYNDROME (ACS) ** ***
Report identifies positive ECG findings	Report identifies positive ECG findings. The program also makes sure these findings are also identified in the 12SL interpretation.
ECG findings do not necessarily match what is identified by 12SL.	Fully integrated with 12SL. ECG findings match what is identified by 12SL

ACI-TIPI Methodology: Logistic Regression

The ACI-TIPI algorithm uses the following patient information in its logistic regression equation: age, gender, and most importantly, presenting symptom.

With regards to presenting symptom, ACI-TIPI requires that the operator select one of the following conditions regarding chest or left arm pain:

- Chief complaint
- Secondary complaint
- Not present

The pertinent ECG data includes:

- detection of abnormal Q-waves,
- quantification of the amount of ST segment elevation or depression, and
- quantification of the amount of T wave magnitude and polarities.

In addition, ACI-TIPI excludes from analysis the following interpretations as detected by the 12SL program: ventricular paced rhythm, left bundle branch block (LBBB), right bundle branch block (RBBB), or left ventricular hypertrophy (LVH). The equation used by ACI-TIPI to calculate the probability of acute cardiac ischemia uses similar weights for patient demographics and ECG findings. See below:

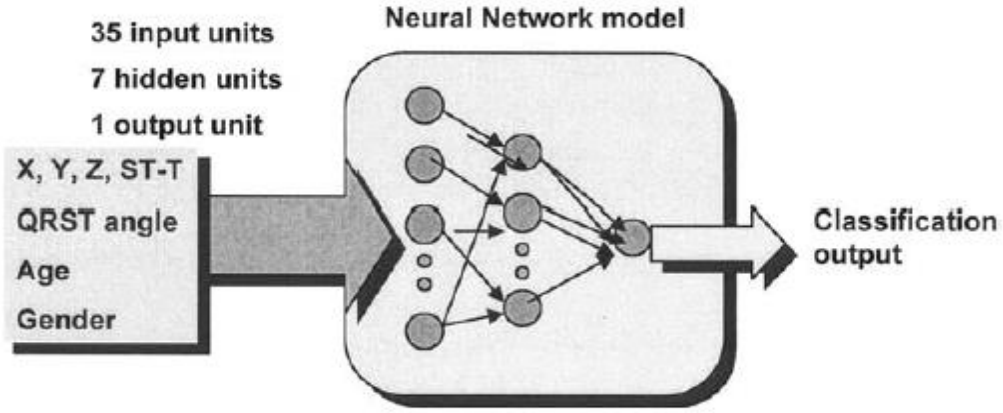
$$probability\% = 100 \times \left[1 - \frac{1}{1 + \exp(b_0 + \sum b_i x_i)}\right]$$

Variable	Coefficients (b_i)	Description	Value (X_i)
CONSTANT (b_0)	−3.933		
CPAIN	1.231	Chest or left arm pain/pressure present Otherwise	1 0
SX1CPAIN	0.882	Chest or left arm pain chief complaint Otherwise	1 0
MALESEX	0.712	Male Female	1 0
AGE	−1.441	Patient age 40 years or less Otherwise	1 0
AGE50	0.667	Patient age greater than 50 years Otherwise	1 0
SEXAGE50	−0.426	Male patient age greater than 50 years Otherwise	1 0
QWAVE	0.616	ECG Q-waves present Otherwise	1 0
STEL	1.314	ECG ST segment elevated 2 mm or more ECG ST segment elevated 1–2 mm Otherwise	2 1 0
STDEP	0.993	ECG ST segment depressed 2 mm or more ECG ST segment depressed 1–2 mm ECG ST segment depressed 0.5–1.0 mm Otherwise	2 1 0.5 0
TWEL	1.095	ECG T-waves elevated (hyperacute) Otherwise	1 0
TWINV	1.127	ECG T-waves inverted 5 mm or more ECG T-waves inverted 1–5 mm ECG T-waves flat Otherwise	2 1 0.5 0
TW1STDEP	−0.314	Both STDEP and TWINV not 0 Otherwise	1 0

NOTE: Only the largest x_i is used per variable. Electrocardiogram (ECG) findings must be present in *at least* two leads, and ST segment and T-wave changes are "normal" if secondary to right or left complete bundle branch blocks, left ventricular hypertrophy, or a paced QRS. Only one type of abnormality is coded each for ST segment and for T-wave per patient (exclusive of TW1STDEP), with elevation taking priority. Deviations are expressed in mm, using standard ECG scale of 1 mm = 0.1 mV.

ACS Tool Methodology: Neural Network

The ACS Tool uses an artificial neural network. See figure below:



Xue, J., et al., Added value of new acute coronary syndrome computer algorithm for interpretation of prehospital electrocardiograms. J Electrocardiol, 2004

Artificial neural networks are modeled after biological neural networks. A biological neural network consists of a group of neurons that interact with one another. Each neuron can be in one of two states: either firing or quiescent. Between the neurons are synapses. The synapses accumulate at varying weights the number of times they have been stimulated by a single neuron or groups of neurons. At some point, this accumulation

exceeds a threshold, resulting in the firing of the next neuron following the synapse. Similarly, the artificial neural network consists of units that are connected to one another. In this case, the configuration as to how the units are connected as well as the weights for accumulating the number of times a unit must be stimulated before it fires the next unit is automatically determined via a computer.

For an artificial neural network to be stable and robust, it must be provided plenty of examples of what it will encounter. This is true both in terms of the patterns it should properly recognize versus those patterns that may deceive it. Given too many inputs for training or too few examples of the patterns it will encounter, the neural network will not be trained properly. Instead, it will be forced to over fit the inputs it is provided to the limited answers in the truth table it was provided. In this case, when the neural network is tested on a different set of data, it will likely fail to recognize the desired pattern or, worse, identify a false positive match when it is simply an artifact.

To reduce the number of inputs that could be used for wiring the artificial neural network, GE Healthcare used derived X, Y, Z from the 12-lead ECG. This transformation was developed and testing using thousands of 12-lead ECGs that also include true Frank X, Y, Z leads.[37]

The inputs include age, gender, ST-segment/T-wave features as the spatial QRS/T angle from the derived X, Y, Z. "The hidden layer includes nonlinear function units to form the nonlinear classification boundaries. The output layer only has one unit to indicate the classification result using a continuous value range from 0 to 1 with 1 as most likely ACS, and 0 as least likely ACS."

More than 3,000 ECGs were used for training, and another 2,000 ECGs used for testing. The training set included ECG data collected from the Cardiac Care Unit (CCU) at the Mayo Clinic. All ECGs in this set included both standard 12 lead and Frank X, Y, and Z leads. The Milwaukee Chest Pain Database was used as the test set.[196]

The ACS Tool "combines a rule-based model and a data-centered model. The rule-based model used clinical criteria for ACS, while the data-centered model was a supervised artificial neural network (ANN) trained by a clinically confirmed ACS database. The results are then fused together for the final interpretation."[37]

Performance of ACI-TIPI vs GE Healthcare's ACS Tool: Comparison of ROC Curves

To compare the performance of the ACS Tool in relation to ACI-TIPI, a receiver-operator characteristic (ROC) curve analysis was performed to evaluate and compare the ability of the two methods in the discrimination between ACS and non-ACS ECGs. The Milwaukee Prehospital Chest Pain Database was used for this analysis.[196]

Milwaukee Chest Pain Database

This Milwaukee Prehospital Chest Pain Database was used only as a test database; it was not used during the development of the ACS Tool. The final patient diagnosis was determined by prehospital, emergency department, and hospital chart review by a team of trained nurse investigators and confirmed by a physician. The final diagnosis included three categories: acute MI, non-MI ACS, and non-ACS.

The final diagnosis of acute MI (STEMI or NSTEMI) was based on clinical features at presentation and throughout the hospital course, ECG findings, and results of cardiac enzyme testing according to World Health Organization criteria. The final diagnosis of non-MI ACS included new-onset angina, as well as unstable and stable angina pectoris, and was based on clinical features at presentation and throughout the patient's course, cardiac testing performed, and the treating physician's diagnosis. Patients without evidence of acute MI or myocardial ischemia (angina pectoris) were classified as non-ACS.

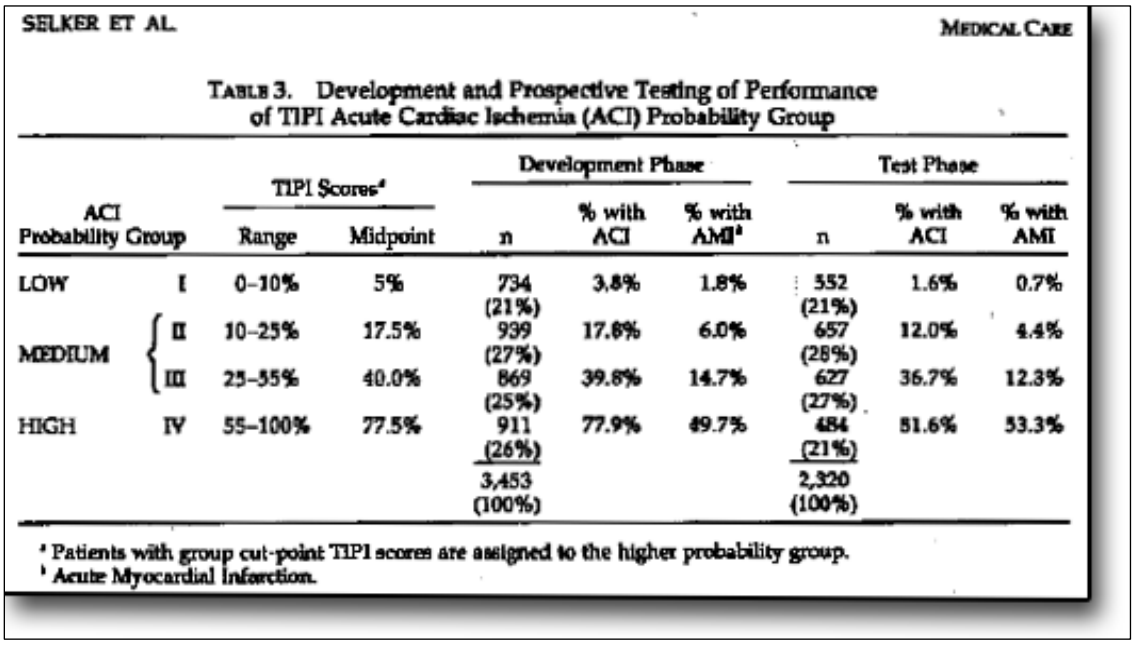
ECG exclusions included ventricular pacemaker, left bundle branch block (LBBB), heart rate > 180 bpm, and QRS duration > 160 msec. After the exclusions, this database included 2,308 ECGs including 550 with a final diagnosis of acute MI, 750 with a final diagnosis of non-MI ACS, and 1008 as non-ACS. Most of the non-ACS ECGs were abnormal ECGs, including prior MI.

ROC Curve Analysis

ROC curves were generated to assess the sensitivity and specificity at various thresholds for both the ACI-TIPI score and the ACS Tool score. That is, for a given threshold, scores above the threshold were classified as ACS and scores below the threshold were classified as non-ACS. To accomplish this, the ACI-TIPI chest pain level was set to "chief complaint" for the ACI-TIPI analysis.

The area under the ROC curve was 0.78 for the ACI-TIPI score and 0.80 for the ACS Tool score. For an ACI-TIPI threshold of 55, the sensitivity (49%) and specificity (82%). This threshold was selected due to its use as a cut-point for a high-probability of acute cardiac ischemia (ACI) group. See table below from Selker et. al.[197] In comparison, a threshold of 50 applied to the ACS Tool generated a sensitivity of 53% and a specificity of 85%. Since the ACS score is only an internal intermediate result of the ACS Tool, the overall sensitivity and specificity levels were recalculated for the final output with a sensitivity of 47.4% and specificity of 85.9%.

ACI-TIPI Thresholds vs Low, Medium and High Probability



SELKER ET AL. MEDICAL CARE

TABLE 3. Development and Prospective Testing of Performance of TIPI Acute Cardiac Ischemia (ACI) Probability Group

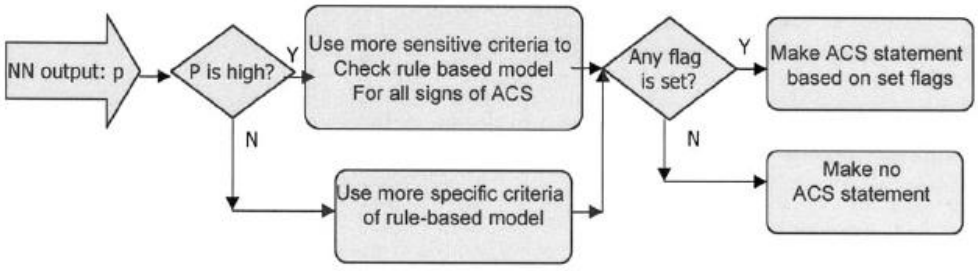
ACI Probability Group		TIPI Scores[a] Range	TIPI Scores[a] Midpoint	Development Phase n	Development Phase % with ACI	Development Phase % with AMI[b]	Test Phase n	Test Phase % with ACI	Test Phase % with AMI
LOW	I	0–10%	5%	734 (21%)	3.8%	1.8%	552 (21%)	1.6%	0.7%
MEDIUM	II	10–25%	17.5%	939 (27%)	17.8%	6.0%	657 (28%)	12.0%	4.4%
	III	25–55%	40.0%	869 (25%)	39.8%	14.7%	627 (27%)	36.7%	12.3%
HIGH	IV	55–100%	77.5%	911 (26%)	77.9%	49.7%	484 (21%)	51.6%	53.3%
				3,453 (100%)			2,320 (100%)		

[a] Patients with group cut-point TIPI scores are assigned to the higher probability group.
[b] Acute Myocardial Infarction.

Statements generated by the ACS Tool

Based on the neural network output, the ACS tool can apply more sensitive rule-based criteria. For instance, the neural network output provides an indication as to whether a T-wave inversion is due to something like LVH versus a primary repolarization abnormality.

In any case, the ACS Tool interpretation is fully integrated into the 12SL report. For a statement to be issued by the ACS tool, an acute coronary syndrome must be corroborated by rule-based ECG criteria. That is, the ACS tool cannot state "probable acute coronary syndrome" without finding additional evidence via conventional 12-lead rule-based ECG criteria.



Like any 12SL interpretation, the intended use of the tool is to assist the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician.

Unlike ACI-TIPI, ECG findings have a higher impact than patient demographics in calculating the probability of ACS. The ACS tool does not require the user to enter whether the patient has "chest or left- arm pain". Instead, when the ACS Tool is selected the ACS Tool presumes and documents that the patient has symptoms commensurate with an acute coronary syndrome (ACS). In addition, the operator is not constrained from entering further details regarding these symptoms. Such symptoms as "chest or left-arm pain" are not used as a weighted variable in the algorithm.

In addition to the statements that are routinely generated by the12SL program, the ACS Tool can state the following at the top of the ECG interpretation:

***** ** ACUTE MI / STEMI ** *****

***** ** CONSIDER ACUTE CORONARY SYNDROME (ACS) ** *****

***** ** CONSIDER ACUTE MI if LBBB is new ** *****

***** ** LBBB with primary ST/T abnormality - CONSIDER ACUTE CORONARY SYNDROME (ACS) ** *****

***** ** LBBB with primary ST elevation abnormality - CONSIDER ACUTE MI ** *****

When the tool detects STEMI or ACS, it states the ECG- based reasons for this interpretation. These reasons are placed at the end of the interpretation, following the phrase "ECG interpretation of ACS is based on presence of symptoms and".

Other than ventricular paced beats, the ACS tool will not exclude ECGs from analysis. The ACS Tool evaluates left bundle branch block (LBBB), right bundle branch block (RBBB), and left ventricular hypertrophy (LVH). It does so while considering the possibility of secondary repolarization abnormalities.

When the ACS Tool is "on" and the 12SL program detects LBBB, the LBBB is considered a significant finding. Under these circumstances the program further evaluates the ST/T of the LBBB. [17, 18] This evaluation will result in one of three statements:

***** ** Consider ACUTE MI if LBBB is new ** *****

***** ** LBBB with primary ST/T abnormality - CONSIDER ACUTE CORONARY SYNDROME (ACS) ** *****

***** ** LBBB with primary ST elevation abnormality - CONSIDER ACUTE MI ** *****

Once the ACS Tool determines that there is a high probability of ACS and the 12SL program has not detected a STEMI or LBBB, it goes back to the conventional rule-based ST/T criteria and checks the ECG again with more sensitive thresholds. If the more sensitive thresholds identify ST elevation, then adjacent leads are more closely evaluated for ST elevation while reciprocal leads are more closely evaluated for ST depression.

If the ACS Tool does not find any ST/T findings commensurate with ACS, then no finding will be indicated and no statements regarding ACS or STEMI will be made at the top of the interpretation. The ACS Tool will add the following statement to the 12SL interpretation: "ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings".

When the ACS Tool is on, the bottom of the interpretation will exhibit either of the following statements:

ECG interpretation of ACS is based on presence of symptoms and...

or

ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings

When the statement "ECG interpretation of ACS is based on presence of symptoms and..." is issued, it will be followed by the ST/T findings that resulted in the positive interpretation of ACS noted at the top of the report.

Impact of ACS Tool: Increased Accuracy of Over-reading Physician

The use of the ACS Tool interpretation on the ECG report has been shown to significantly improve the sensitivity of physician recognition of acute coronary syndromes without a loss of specificity. The "test portion of the study was conducted in 2 steps: One emergency physician and one cardiologist classified 1,902 clinically correlated out-of-hospital ECGs without seeing the interpretation statement from the algorithm into one of the following categories: acute myocardial infarction, acute ischemia, or non-ischemic. After 9 months, the same 2 physicians classified the same group of ECGs but with the interpretation statement of the algorithm printed on the tracing. The results demonstrated that with the assistance of the new algorithm, the emergency physician and cardiologist improved their sensitivity of interpreting acute myocardial infarction by 50% and 26%, respectively, without a loss of specificity. The new algorithm also improved the emergency physician's acute ischemia interpretation sensitivity by 53% and still maintained a reasonable specificity (91%). The new ACS algorithm provides added value for improving acute ischemia and infarction detection in the ED."[37] This may be important since, according to ACC/AHA guidelines, "errors in ECG interpretation [by ED physicians] can result in up to 12% of patients being categorized inappropriately, demonstrating a potential benefit of accurate computer-interpreted electrocardiography and transmission to an expert."[198]

Automated Serial Comparison Detects Changes Commensurate with ACS

ACC/AHA clinical guidelines state serial ST/T wave changes as the essential part of a serial ECG interpretation. See the following examples:

- "Transient ST-segment changes (≥0.05 mV) that develop during a symptomatic episode at rest and that resolve when the patient becomes asymptomatic strongly suggest acute ischemia."[199]
- "Dynamic ST-segment changes ±1 mm".[199]
- Isolated T-wave changes not known to be previously present.[200]
- New T-wave inversion.[201]

Some automated serial comparison programs only compare statements. Yet these guidelines do not mention changes in interpretive statements as a "significant change".

Additional ACC/AHA guidelines focus primarily on the issue of the assessment of serial ECGs in patients suspected of ACS.[200, 202, 203] This is because a significant change across serial ECGs is, in and of itself, the evidence necessary to identify a significant subset of heart attacks (see unstable angina).[202] When the initial ECG acquired in the ED is negative, it has become "common clinical practice",[199] endorsed by published clinical policy, to perform "repeat ECG or automated serial ECGs",[201] for the assessment of new-onset chest pain of unknown origin. Recent guidelines recommend that this comparison include the pre-hospital 12-lead ECG.[167]

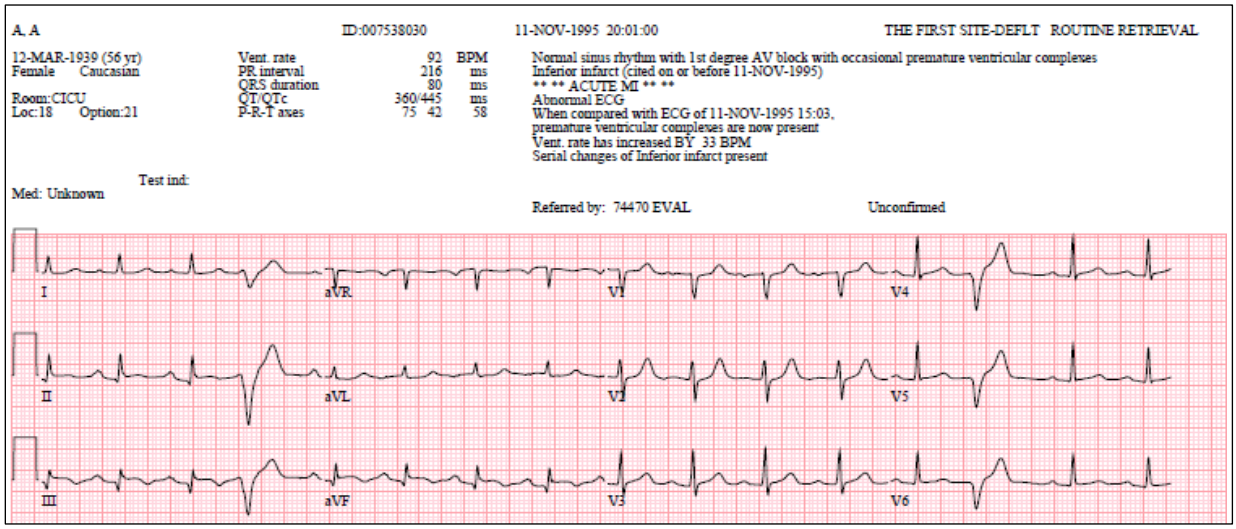
It should also be pointed out that although a significant change across serial ECGs puts a chest pain patient into a high-risk category, the converse is also true. A recent ACC/AHA practice guideline states "that patients with an unchanged ECG have a reduced risk of MI [a heart attack] and a very low risk of in-hospital life-threatening complications even in the presence of confounding ECG patterns."[200]

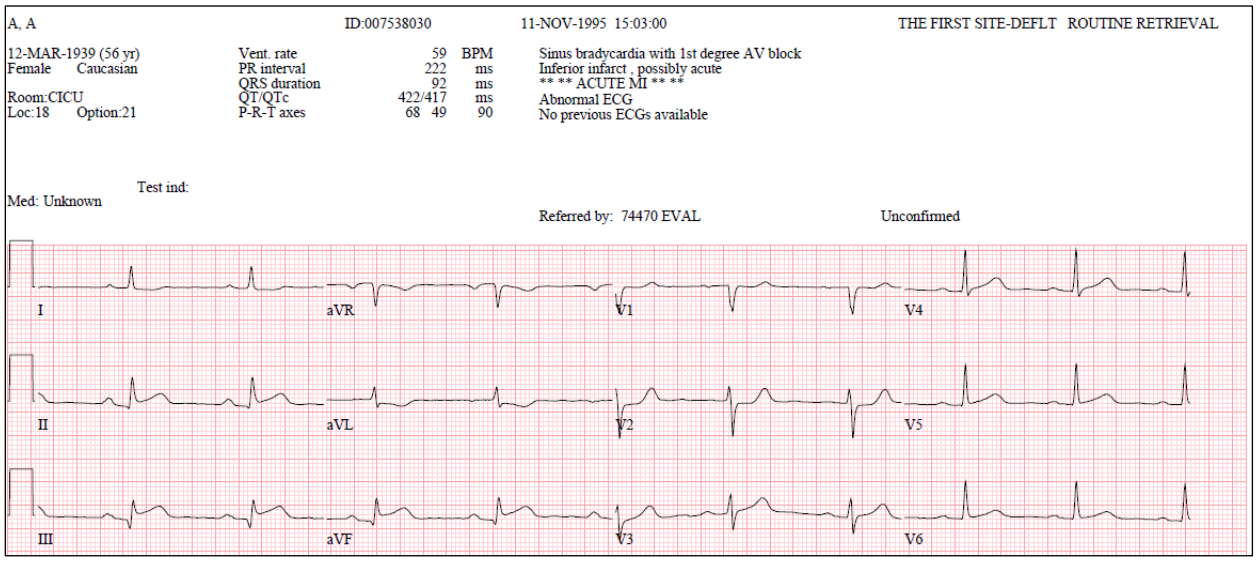
Definition of a Significant Serial Change

Normal day-to-day variation in the 12-lead ECG is considerable.[70-72, 204] Although moving an electrode by just a few millimeters can affect the reproducibility of ECG measurements, [72, 205] most of the day-to-day variation is due to changes in the position of the heart.[206, 207] That is, as the heart rotates in the chest, the electrical cardiac vector rotates with it. This will result in significant changes per lead, but the overall 12-lead ECG remains essentially the same – at least clinically. In any case, experienced electrocardiographers can discern this type of change versus that due to an acute process.

To determine whether there is a significant change in the ST/T waveform due to an acute process, other factors that can also contribute to these changes must be ruled out. This includes significant changes due to rhythm or conduction. Likewise, since a significant number of heart attacks can occur silently (i.e. without symptoms),[208] the physician must inspect the QRS complex for new Q waves that could result in sustained

changes in the ST/T that are different from normal but old, and not due to an acute process. It is only after this process is completed (that is, ruling out ST/T changes due to normal day-to-day variation or other changes due to conduction etc.) can the reader discern whether a ST/T change as outlined in the clinical guidelines is present.





Automated Serial Comparison – Detecting a Significant Change

Detailed documentation included in this guide (see here) states that GE's Marquette 12SL Serial Comparison Program[209] uses statements, measurements, *and* waveforms to compare the current and previous ECGs.

Interpretive statements guide the program as to what to more closely inspect for change. It should be clear that the program can tolerate a change in a statement that is essentially inconsequential to determining a significant change. For example, the current ECG can state incomplete right bundle branch block while the prior ECG states complete right bundle branch block. No significant change will be identified, unless it visually obvious. This is important because interpretive statements can change based on a measurement exceeding a specific threshold. As a result, interpretative statements can come and go. The real issue is whether this is a significant change.

"GE Healthcare's Marquette 12SL Serial ECG Comparison Program has been developed to emulate the techniques used by trained electrocardiographers in the comparison of serial electrocardiograms."[209]

When significant changes are detected, they are indicated using descriptive statements. For example, the program will state that the "T wave amplitude in (a specific lead group) has increased or decreased." The same is done for ST segment elevation and depression. If there is T wave inversion, the comparison will indicate the extent of any change in the T-waves by stating "T wave inversion in (specific lead group) is more evident, less evident, now evident or no longer evident." These changes can be summarized in terms of "an evolving acute myocardial infarction."

The mechanics of how this is accomplished is covered in more detail here. It may be important to know that the program uses the median complexes of both the current and previous ECG. These are superimposed upon one another by the computer and compared.[13] All measurements that are used by the 12SL program for contour analysis are regenerated and compared. Based on whether a specific abnormality was detected by the 12SL program in the current ECG, the comparison program may apply more sensitive criteria for detecting a change. For example, if the current ECG is identified as exhibiting a myocardial infarction, the program becomes more sensitive to changes commensurate to an evolving infarction. To avoid detecting a significant change in the presence of normal day-to-day variation, the program calculates spatial vectors from the 12-lead ECG. If the T-wave and QRS maintain the same spatial angle and are simply rotating in space, the program is less likely to identify a change in repolarization in a single lead.

High Sensitivity Troponin and Role of ECG

There is great excitement regarding the use of high-sensitivity Troponin as testified to by the following quote: "After decades of seeking—and failing—to safely rule out myocardial infarction with less than a 1% miss rate, we now have that capability."[210] This excitement stems from the fact that high-sensitivity Troponin can, for a large portion of chest pain patients, significantly reduce the amount of time they need to remain in the ED or hospital for evaluation.

Before the advent of high-sensitivity troponin, it was recommended that patients with chest pain who had normal clinical findings, ECG, and cardiac injury markers in the ED should have repeated testing of ECG and cardiac injury markers (Troponin) for 6 hours.[211] Results from several large studies have shown that use of high-sensitivity cardiac Troponin for this patient group can safely cut this time to less than an hour.

For instance, high-sensitivity cardiac troponin T (hs-cTnT) was used in conjunction with ECG and prospectively evaluated as part of the routine assessment of 14,636 patients suspected of ACS. The conclusion was that "all patients with chest pain who have an initial hs-cTnT level of <5 ng/l and no signs of ischemia on an ECG have a minimal risk of MI or death within 30 days, and can be safely discharged directly from the ED."[212]

In another, even larger study conducted between June 10, 2013, and March 3, 2016, 48,282 consecutive patients suspected of ACS were enrolled. Versus the conventional technique of serial testing of ECG and Troponin, "use of a high-sensitivity assay prompted reclassification of 1771 (17%) of 10,360 patients with myocardial injury or infarction, but was not associated with a lower subsequent incidence of myocardial infarction or cardiovascular death at 1 year."[124] "Although the duration of stay doubled in those reclassified by the high-sensitivity assay, it was reduced by a third across the trial population."[124]

In addition to reducing the amount of time for evaluation for low-risk chest pain patients, it fortunately does appear that use of high-sensitivity Troponin and a "1-h algorithm is associated with reduction in overall AMI diagnostic costs, provided it is carefully implemented in clinical practice."[213] Nevertheless, given that high-sensitivity Troponin will detect ever smaller levels of myocardial necrosis, it is possible that chronic diseases will impact the values obtained via high-sensitivity Troponins[125] which could have a negative impact on increasing unnecessary interventions in a population that would otherwise been left untreated - a topic currently under investigation.[144, 214, 215]

A state-of-the-art review article on the subject of the clinical use of high-sensitivity Troponin states it should not be the only factor in clinical decision making; it should only be used "in conjunction with a full clinical assessment."[127] They "should only be applied after the initial ECG has excluded ST-segment elevation myocardial infarction (STEMI) because these high-risk patients need prompt identification based on the ECG." And finally, "some rule-out strategies require a completely normal ECG to be applied; others allow also for mild and nonspecific ECG abnormalities."

ECG-based tools that perform the following functions are still vital.

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Critical Values

The Critical Values feature in a cardiograph is to provide a means to accelerate the reporting of critical test results. When a critical value or critical test result is present in the ECG, the statement "*** Critical Test Result:" followed by the type of critical values or results present in the ECG, appears as the first line of the 12SL interpretation. Depending on the cardiograph implementation, the user may also be notified by an on- screen prompt or dialog.

The Critical Values module works in conjunction with the 12SL ECG Analysis Program to identify ECGs with critical test results. It uses the outputs of the 12SL program and the user-specified thresholds and options as its input to identify the critical test results. If any critical test results are found, new statements are inserted at the beginning of 12SL interpretation.

The specific critical test results identified are:

High Heart Rate,176
Low Heart Rate,177
Long QTc,177
Arrhythmia,177
AV Block,178
ACS/Ischemia,178
ST-Elevated Myocardial Infarction (STEMI),178

Each of these notifications can be individually turned on or off. The first three (high and low HR and QTc) are based on user-specified thresholds. In addition, the high and low HR notifications are individually configurable for adults and pediatrics, each with their own user-specified thresholds. For example, high HR notifications can be turned off for pediatric patients and turned on for adults, or they can both be on, with different thresholds for each.

The following are two examples of the critical test result line in a 12SL interpretation:

*** Critical Test Result: Long QTc

*** Critical Test Result: Low HR, Arrhythmia, AV Block

Note that because the notification statements are inserted into the 12SL interpretation, these statements become part of the ECG record.

High Heart Rate

For **adults or patients with unknown age**, the High HR notification will be generated when:

- the Adult High HR notification is enabled, and
- the 12SL ventricular rate is $\geq$ the Adult High HR threshold

For **pediatric patients** (age < 16), the threshold is the maximum of the user-specified Pediatric High HR threshold and the "upper heart rate" value from the age-specific pediatric table. The notification will be generated when:

- the Pediatric High HR notification is enabled, and
- the 12SL ventricular rate is $\geq$ the threshold as described above

This strategy was implemented for pediatrics because of the very wide range of normal heart rate between neonatal and adolescent ages. A reasonable upper limit for a 1-day old neonate would miss most 15-year-olds with rates high for their age. Conversely, a reasonable upper limit for a 15-year old would result in notifications for the majority of neonates. The program will use the user-specified threshold unless that

threshold would result in a notification when the rate is within the normal limits for that patient age. In other words, the program will avoid saying "High HR" when the rhythm is "Normal sinus rhythm".

Low Heart Rate

For **adults or patients with unknown age**, the Low HR notification will be generated when:

- the High HR notification was not generated, and
- the Adult Low HR notification is enabled, and
- the 12SL ventricular rate is ≤ the Adult Low HR threshold

For **pediatric patients** (age < 16), the threshold is the minimum of the user-specified Pediatric Low HR threshold and the "lower heart rate" value from the age-specific pediatric table. The notification will be generated when:

- the High HR notification was not generated, and
- the Pediatric Low HR notification is enabled, and
- the 12SL ventricular rate is ≤ the threshold as described above

Similar to the High HR notification, the program will use the user- specified threshold unless that threshold would result in a notification when the rate is within the normal limits for that patient age; i.e., we will avoid saying "Low HR" when the rhythm is "Normal sinus rhythm".

Long QTc

The *Long QTc* notification will be generated when:

- the Long QTc notification is enabled, and
    - no LBBB, and
    - no RBBB, and
    - no ventricular pacing, and
- 12SL QRS duration ≤ 140 msec, and
- 12SL ventricular rate ≤ 140 bpm, and
- 12SL QTc is ≥ the Long QTc threshold

The QTc value used for this test will be the Bazett-corrected QT measurement unless a different correction formula for the QT tests has been selected in the device's system setup (most devices do not have this configurability). In any case, the Critical Values test will use the same QTc value as is used by 12SL for the "Prolonged QT" statement, which always defaults to the Bazett correction.

Arrhythmia

The purpose of this notification is to notify on potentially lethal arrhythmias requiring immediate intervention or at least immediate review. The inclusions for this notification include:

- 12SL statement of "Idioventricular rhythm", or
    - RR pause > 2500 msec, or
- or more consecutive PVCs (VT > 2), or
    - probable ventricular tachycardia

All of these are contingent on the arrhythmia notification being enabled.

AV Block

The AV Block notification is triggered by any of the following statements in the 12SL interpretation, contingent on the AV Block notification being enabled:

- with 2nd degree AV block (Mobitz I)
- with 2nd degree AV block (Mobitz II)
    - with 2nd degree AV block
    - with complete heart block
    - with AV dissociation

ACS/Ischemia

The ACS / Ischemia notification is triggered by the presence of either of the following statements in the 12SL interpretation, contingent on the ACS / Ischemia notification being enabled:

- ** ** LBBB with primary ST-T abnormality - Consider ACUTE CORONARY SYNDROME (ACS) ** **
- ** ** Consider ACUTE CORONARY SYNDROME (ACS) ** **

Note that these two statements are only made when the ACS option is turned on. This means that this notification will never appear unless the ACS option is on. The ACS analysis option is not available on all products.

ST-Elevated Myocardial Infarction (STEMI)

The STEMI notification is triggered by the presence of either of the following statements in the 12SL interpretation, contingent on the STEMI notification being enabled:

- ** ** ACUTE MI / STEMI ** **
- ** ** LBBB with primary ST elevation abnormality - Consider ACUTE MI ** **

Note that the second statement is only made when the ACS option is turned on. The ACS analysis option is not available on all products.

Serial Comparison

GE Healthcare's Marquette 12SL Serial ECG Comparison Program has been developed to emulate the techniques used by trained electrocardiographers in the comparison of serial electrocardiograms and is designed to take advantage of the Marquette 12SL ECG analysis program's interpretation and measurements. The Marquette 12SL ECG serial comparison program was developed to use statements, ECG measurements, and waveform comparison techniques to maximize performance and accuracy in the detection of clinically significant changes in rhythm, P, QRS, ST and T waves. The MUSE system, which stores electrocardiograms with physician edited interpretations to both individual ECGs and serial comparisons, in unison with the serial comparison program, allows for accurate and expedient processing of a patient's ECG data.

Although the 12SL analysis is completed at the cardiograph at the time of the ECG acquisition, the serial comparison analysis is done at the MUSE when the MUSE receives the ECGs. This is transparent to the electrocardiographer who reads the ECGs printed from the MUSE workstation, and because of the integration of the programs, the serial comparison interpretation is appended to the original 12SL interpretation.

Overview of Serial Comparison Analysis

Rhythm Analysis

- Dominant rhythms compared first (sinus, ventricular, atrial fibrillation, etc.) via statements
- Rhythm modifiers compared second only if dominant rhythm does not change

QRS Analysis

- QRS comparison is done via statements, measurements, and waveform analysis
- Aim is to detect changes in conduction and/or infarction
- Changes in axis and voltage (amplitude) are also detected
- Looks for the first occurrence of an infarct and labels it on the ECG
- For infarction (if acute) more sensitive criteria is used
- Time between ECGs is used to adapt criteria sensitivity

ST-T Analysis

- Looks for the presence/absence of acute infarction or ischemia
- Looks for evolution of the ST-T changes in an acute MI
- Uses MI age categories to "adapt sensitivity of detection"
- < 4 days old

NOTE: The serial comparison program looks for significant changes in the waveforms when doing the contour comparisons. It is not unusual to have an ECG that may have narrowly met the criteria for a 12SL statement and have another ECG that just missed the criteria thresholds, yet there are no significant differences in the waveforms themselves. In such a case, the first ECG would have a statement that would be absent from the second and could possibly even have a different overall ECG classification. If the serial comparison program does not discern a significant difference in the actual waveforms, it will simply state that "no significant changes have occurred."

Details of Serial Comparison Analysis

Rhythm Comparison

Rhythm comparison is done via statements. (Edited rhythm statements may be used by the program if they are from the original MUSE system library and are not user added statements or free text.) Actual Marquette 12SL program measurements are compared to assist in the detection of significant changes for first degree AV block and short PR interval. If a major rhythm change occurs, it is stated without reference to changes that occur in the rhythm modifier statements. Major rhythm changes are stated without reference to rate. For example, the statement "sinus rhythm has replaced junctional rhythm" is made instead of "sinus tachycardia has replaced unusual P axis and short PR, probable junctional bradycardia." Only when the basic rhythm is the same, does the program mention changes that occur in the rhythm modifier statements (e.g., PVCs, PACs, 1st degree AV Block, etc.).

Clustering of rhythm modifier changes is used. The program "clusters" modifier statements regarding ectopic beats as either premature ventricular or premature supraventricular. Other rhythm modifiers that are also clustered are (complete heart block and AV dissociation), (sinus pause and second-degree SA block Mobitz I and II), (second degree AV block Mobitz I and II). Certain rhythm modifier statements such as second-degree AV block, complete heart block or AV dissociation are given a higher priority than other rhythm modifier statements. For example, if the previous ECG has complete heart block and the current ECG has first degree AV block, then no statement is made about the PR interval for first degree AV block, but complete heart block is stated to be no longer present.

Rate dependent and PR interval calls are checked against the measurements before statements about change are made. Rate change statements are made at a more sensitive level if both ECGs contain electronic ventricular pacemakers. If a rhythm change (i.e. WPW or electronic pacing) results in a QRS change, the QRS-ST-T comparison is suppressed. If either of the ECGs being compared has "undetermined rhythm" then no rhythm comparison is performed.

QRS Comparison

QRS comparison uses statements, measurements and waveforms. The emphasis is in detecting conduction and infarction changes. Changes concerning axis and/or voltage are also stated but with less sensitive criteria to accommodate "normal variability" in the ECG and changes that may be caused by inaccurate and inconsistent lead placement.

When WPW is stated in either the current or the previous ECG interpretation, then further QRS and repolarization comparisons are inhibited.

For specifying a change in conduction, measurement comparison and waveform correlation are used to determine whether the change is large enough to warrant the program stating it. If a major conduction change occurs, comparison of the repolarization is suppressed (skipped) since these are considered secondary changes.

Comparison concerning infarction is the most complicated and sophisticated analysis scheme in the program. Once a statement concerning infarction occurs in either of the ECGs being compared, then parameters related to infarction along with waveform correlation techniques and measurements are used to detect "clinically significant" change. The program will also search the patient's previous records and inform the user as to when the infarction first appeared in the series of ECGs.

If both ECGs have definite evidence of infarction (or the degree of infarction evidence is unchanged, i.e. the ECG waveform data in the leads exhibiting the infarction "look very similar"), then the program states "no significant change has occurred." If a "clinically significant" waveform change is evident, then the program will state it appropriately as "(specific location) MI now present" or "criteria for (specific location) MI no longer present" or if subtle changes in the Q-waves (initial part of the QRS) have been detected, the program will state "questionable change in initial forces of (specific location)."

This approach is used until repolarization changes or injury (ST-elevation) is evident in either of the ECGs. Upon development of a significant repolarization change in the presence of myocardial infarction evidence (QRS

changes), the program becomes much more sensitive to changes in the QRS-ST-T. When there are ST-T wave changes detected by the program, the comparison becomes much more detailed. Sensitivity for detection of "clinically significant changes" changes with respect to the time difference between the two ECGs. Sensitivity and program statements will change depending on the following time differences between the acquisition dates of the ECGs: same day to 3 days, 4 days to 21 days, 22 days to 365 days and more than 365 days (1 year). When the ST-T wave changes occur within the first 3 days, the changes will be labeled as new or acute or as "serial changes of an evolving myocardial infarction." ST-T wave changes occurring between 4 days to 1 year which are becoming less severe (ST-T becoming more normal) will be described as "serial changes of myocardial infarction." If at any time the repolarization (ST-T) become more abnormal, the program will state that there are new changes present.

Repolarization Comparison

The ST segments and T waves are compared via the 12SL measurements. When significant changes are detected, they are indicated using "descriptive statements." For example, the program will state that the "T wave amplitude in (specific lead group) has increased or decreased." The same is done for ST segment elevation and depression. If there is T wave inversion, the comparison will indicate the extent of the T wave inversion by making the statement "T wave inversion in (specific lead group) is more evident, less evident, now evident or no longer evident." When the T wave abnormality is "non-specific," then the program will indicate whether the nonspecific T wave abnormality is worse or improved in (specific lead group).

Miscellaneous Comparisons/Other issues

Pediatric ECGs are not compared but the previous ECGs date and time are indicated by the program.

The Serial Comparison program tracks the length of the total interpretation. This includes the original ECG as well as the serial comparison interpretation. If more than 10 lines of text occurs and the serial comparison interpretation is more than 6 full lines of text, then the serial comparison program will suppress the comparison interpretation and simply state "significant changes have occurred." This is done to prevent the use of an additional page for the printing of the ECG.

If all previous ECGs are on an archive volume that is not "on-line" then the serial comparison program informs the user with the statement "manual comparison required data is off line and on volume#." If all previous ECGs are analog ECGs, then the program states "manual comparison required, analog tracing."

Part II: Statement of Validation and Accuracy

The following is a comprehensive disclosure of what has been reported in the literature regarding GE's Marquette 12SL™ Program. Regardless of whether the result was negative, positive or in between, it is provided here and kept current to the date of publication of this document. Topics covered under Part II include the following:

Overall Impact of Computerized ECG,182
Development and Validation Process,190
Program Structure: Measurements Before Interpretation,193
Testing of 12SL™ Measurements via Standardized Database,201
Impact of Hookup Advisor™ on Accuracy of ECG Measurements,203
Independent Evaluation of 12SL™ Measurements,205
Predictive Value/Clinical Correlation of 12SL™ Measurements,215
Accuracy of Interpretive Statements: Reported Results,225
Interpretation of Rhythm: Reported Results,227
Contour Interpretation: Reported Results,237
Overall Classification: Reported Results,259
Serial Comparison,260
Conclusion,260

Overall Impact of Computerized ECG

Approximately 10-15% of computerized ECG interpretations require some form of editing before they are deemed acceptable to a cardiologist.[216-220] There has always been a concern as to whether this technology would be misused and do more harm than good. Below are a variety of categories where the computer has been found beneficial:

Generating Final Report: Speed, Efficiency and Accuracy,183
Initial Interpretation for Physician Before Expert Review by Electrocardiographer,183
Triage, Time-to-Treatment of Chest Pain Patients,184
Identifying Normal versus Abnormal,185
Epidemiological Studies: Automated Measurements and Coding,185
Increased Error Rate in Presence of Non-Sinus Rhythms and/or Artifact,186
Clinical Impact Due to Computer Error or Inappropriate Use,186
Bibliography for this section:,187

This is followed by an assessment of when errors are most prevalent as well as the clinical impact of such errors or inappropriate use of the computerized interpretation. These include the following:

- Increased Error Rate in Presence of Non-Sinus Rhythms and/or Artifact
- Clinical Impact Due to Computer Error or Inappropriate Use

Generating Final Report: Speed, Efficiency and Accuracy

The computer provides a preliminary structured report. Since GE's Marquette12SL™ program tends to overcall, editing is streamlined by deleting or modifying the information provided. In conjunction with the 12SL™ Serial Comparison Program, the date and time of the prior ECG is automatically added to the report as well as statements regarding changes the computer considers to be significant. Even if interpretative statements differ between the current and prior ECG, the program can state, "no significant change" if it detects no significant change in the waveform.

- "The impact of computer assisted interpretation on cardiologists' readings of ECGs is demonstrably beneficial: the main empirical conclusion of this study is that, compared with conventional interpretation, the use of computer assisted interpretation of ECGs cuts physician time by an average of 28% and significantly improves the concordance' of the physician's interpretation with the expert benchmark, without increasing the false-positive rate."[221]
- "In a study of 22 cardiologists, it significantly improved the accuracy of the cardiologist's ECG interpretation (i.e., lowered false-positive and false-negative rates and increased diagnostic concordance with a recognized expert panel). While this may not affect the overall quality of patient care, it is nonetheless encouraging."[221]
- "Combined cardiologist and program results demonstrated the highest accuracy. … These findings demonstrate that the combination of expert knowledge of computer programs can, similar to panel review and group analysis in clinical practice, enhance diagnostic accuracy."[222]
- "Computer ECG systems provide a valuable function for ECG analysis, storage, retrieval, and serial comparison. The current systems can provide quality control of technician performance, acquisition equipment, and physician over reading. Its overall acceptability and clinical usefulness is documented in a clinical practice setting with a 90.4% computer-physician agreement in more than 20,000 ECGs. Computerized ECG systems have demonstrated their clinical usefulness in patient care."[216]
- "Although computer ECG analysis is still inferior to physician interpretation, it may be a useful adjunct to save physician time."[223]
- "The implementation of a digital ECG system [MUSE and 12SL] in our Children's Hospital increased the total number of ECGs officially interpreted and reported. … In addition to improving the quantity of ECGs officially interpreted, the overall quality of the ECG for interpretation was improved."[224]

Initial Interpretation for Physician Before Expert Review by Electrocardiographer

All physicians are trained in 12-lead electrocardiography. Expert electrocardiographers excel when the ECG is difficult and the interpretation complex. Physicians at the point-of-care can increase their accuracy of their interpretation by considering the patient's status and other relevant information. In fact, this is true even for a cardiologist. Consider that in a study using 12SL™, "interpretations by cardiologists as primary readers were more accurate than the interpretation provided by overreading cardiologists (94% vs 72%, $P < .001$)."[225]

- "The quality of computer-assisted ECG interpretation was comparable to that of review provided by a cardiology service. Computerized interpretation may be clinically more useful because it is immediately available."[226]

- On ECGs obtained on pediatric patients and analyzed by 12SL™ in an emergency department (ED) without immediate access to a pediatric cardiologist, "there was a significant discordance in the ECG interpretative accuracy between the ED physicians and the computer-generated report. The computer proved to be more accurate than the ED physicians in interpreting ECGs of less than critical significance. … But neither could correctly interpret even a simple majority of the most significant abnormalities. We speculate that distributing the computer-generated interpretation to the ED physicians and formal review of all ED ECGs by a skilled interpreter may decrease the number of missed diagnoses."[227]
- "In summary, this study has confirmed that junior doctors have a high error rate in reporting ECGs. Computer generated reports did not significantly improve this, even though the machine achieved a low major error rate compared with the junior doctors. Computer generated reports may have a role in prompting junior doctors to query their own ECG interpretation but should not replace experienced medical support."[228]

Triage, Time-to-Treatment of Chest Pain Patients

Several prospective clinical trials have demonstrated that prehospital ECGs can effectively be acquired by paramedics,[229] reduce time-to-treatment,[230-232] and "significantly increase the diagnostic accuracy in chest pain patients."[233] GE Healthcare was the first to introduce pre-hospital diagnostic 12 lead ECG as a small, compact unit for the ambulance that could acquire and transmit 12-lead ECGs digitally so that there would be no distortion of the ST/T waveform.[165]

Use of prehospital ECG is considered a standard-of-care. According to the ACC/AHA, prehospital ECG should widely be adopted because "prehospital ECG programs have the potential to improve the way care is delivered to patients with STEMI in the United States."[167] In this case, the paramedic is the first see the preliminary interpretation.

- Current American Heart Association guidelines recommend that paramedics perform and evaluate a prehospital ECG routinely on patients with chest pain suspected of having STEMI (Class IIa, Level of Evidence B)."[167]
- Without a computerized prehospital 12-lead ECG, it is difficult for healthcare systems to meet the time-to-treatment thresholds for STEMI issued by the Joint Commission of American Hospitals (JCAHO) as well as the Center for Medicare and Medicaid Services (CMS).[112, 234-237]
- Results of prehospital activation of the Cath Lab based on STEMI identification by 12SL™ found that prehospital diagnosis as the single most important factor in reducing the door-to-balloon time.[238]
- "A combination of prehospital automated ST-segment elevation myocardial infarction (STEMI) diagnosis [by 12SL™] and 'physician-less' cardiac Cath lab (CCL) activation was safe and effective in ensuring target door-to-balloon times in virtually all patients and resulted in an acceptable rate of inappropriate CCL activation"[172]
- "The present algorithm [12SL™] is clearly adequate for first line screening of patients with chest pain by paramedics or in the emergency department. Its sensitivity is no worse than that of the emergency physician and its specificity is superior to the trained electrocardiographer."[239]
- A total of 855 triage ECGs in the emergency department (ED) were collected over 16 weeks. "Triage ECGs identified by the computer [12SL™] as normal are unlikely to have clinical significance that would change triage care. Eliminating physician review of triage ECGs with a computer interpretation of normal may be a safe way to improve patient care by decreasing physician interruptions."[173]
- "The ED sees more than 73,000 adult patients and treats 120 STEMIs annually. … Zero control patients were incorrectly labeled 'acute MI suspected.' The specificity [of 12SL™] was 100% (100/100; 95% CI 0.96-1.0) …"[240]
- "Over a 2-year period, 1,247 ECGs acquired by primary care paramedics for suspected STEMI were collected and interpreted in real time by the GE Marquette 12SL™ ECG analysis program." "For settings with comparable ECG eligibility criteria and similarly low STEMI prevalence, our estimated

predictive values appear adequate for the implementation of a strategy to direct patients with a positive computer result to hospitals with angioplasty facilities and patients with a negative interpretation to nonspecialized centers."[171]

- "The emergency physician and cardiologist improved their sensitivity of interpreting acute myocardial infarction by 50% and 26%, respectively, without a loss of specificity. The new algorithm [12SL™, ACS tool] also improved the emergency physician's acute ischemia interpretation sensitivity by 53% and still maintained a reasonable specificity (91%)."[37]
- "Software interpretation [12SL™] of STEMI had good sensitivity and excellent specificity, and theoretically conferred a 17-minute reduction in D2D time."[241]
- This study found that serial ECGs during patient transport increased sensitivity of 12SL™ for STEMI recognition to 100%. More specifically, 325 consecutive prehospital STEMIs were retrospectively identified. "STEMI was identified on the first prehospital ECG in 275 cases, on the second ECG in 30 cases, and on the third ECG in 20 cases (cumulative percentages of 84.6%, 93.8%, and 100%, respectively). For STEMIs identified on the second or third ECG, 90% were identified within 25 minutes after the first ECG. The median times from identification of STEMI to arrival at the ED were 17.5 minutes, 11.0 minutes, and 0.7 minutes for STEMIs identified on the first, second, and third ECGs, respectively."[242]

Identifying Normal versus Abnormal

Studies have substantiated that 12SL™ has a high negative predictive value in terms of applying a classification of normal versus abnormal. There will be rare instances when 12SL™ will identify an abnormal ECG as normal. Although a normal ECG in the presence of an acute myocardial infarction is predictive of a good outcome, it is not rare; in fact, in a large pooled study of over 390,000 acute MI's, 8% of initial ECGs were normal.[8]

- The 12SL™ program "is reliable in diagnosing normality: even the disagreements are arguable. ... From a practical point of view, the eventual consensus opinion of the cardiologists was that only one tracing reported as normal by the system should have been reported as abnormal to a family doctor, resulting in a negative predictive value of 98.4%. In view of the cardiologists inter-observer variation with regard to what is normal - this may well be higher than an individual cardiologist's negative predictive value and suggests that the system examined may safely be used to exclude major abnormalities which would affect clinical management".[243]
- "A total of 39,238 electrocardiograms were reviewed ... The 12SL™ program placed the ECG into the following diagnostic classifications: normal 22%, otherwise normal 6%, borderline 5%, and abnormal 66%. The reviewing physician agreed with this classification in 96.3% of all cases ... The most striking information shows the agreement of the physicians with the computer diagnosis of an abnormal electrocardiogram in 97.7% of the 25,295 tracings. In only 204 records out of 25,987 tracings (.8%), the physicians edited a computer-called abnormal electrocardiogram and changed it to normal. In only 63 of 8,632 (.7%) tracings of which the computer called normal did the physicians edit this tracing to read abnormal."[220]
- As tested on 26,734 male and 3,737 female veterans, a classification of a normal ECG by the 12SL™ program "is associated with extremely good survival".[244]
- "Out of 2072 remaining cases, 776 (37.5%) were read [by 12SL™] as normal ... There were no discordances in the ECGs read as normal"[219]
- A study conducted in an emergency department found that using 12SL™ on pediatric patients, "the computer correctly interpreted all normal ECGs."[227]

Epidemiological Studies: Automated Measurements and Coding

Population-based research groups use 12SL™ for generating measurements since it improves their quality control, effectiveness and consistency.[245-253] This has made it possible to identify previously unknown relationships between the resting ECG and predicting such conditions as heart failure, atrial fibrillation, etc.

- Using 12SL™ measurements from 6,664 MESA study participants, prediction of heart failure was explored for those with reduced versus preserved ejection fraction (respectively, HFrEF and HFpEF). A multivariable adjusted model included computerized QRS duration, delayed intrinsicoid deflection, left-axis deviation, right-axis deviation, QT interval, ST/T-wave abnormalities, P-wave axis, QRS-T angle, etc. This study concluded "markers of ventricular repolarization and delayed ventricular activation are able to distinguish between the future risk of HFrEF and HFpEF. These findings suggest a role for ECG markers in the personalized risk assessment of heart failure subtypes."[254]
- "The Minnesota Code (MC) and Novacode (Nova) are the most widely used electrocardiographic (ECG) classification systems. … All electrocardiograms were processed in a central laboratory (Epidemiologic Cardiology Research Center, Wake Forest University, Winston-Salem, North Carolina) and were classified by the Nova and MC using the 2001 version of the GE Marquette 12SL™ program."[255] "In summary, these results show that MC and Nova are valuable classification systems for ECG myocardial infarction or ischemia with no significant gender differences for prediction of CHD events and total mortality."[255]
- By leveraging MUSE™ and the measurements generated by 12SL™, "this longitudinal observational database that contains 979,273 electrocardiograms from 461,178 patients over a 19-year study period … can provide an opportunity to study electrocardiographic changes caused by medications, disease, or other demographic variables."[256]
- "Processing for the present study utilized the 2001 version of the GE Marquette 12SL program. The repeatability of this program for coding is 100%, unlike repeatability of visual coding by trained electrocardiographers for Minnesota Code (MC) or Novacode (NC), which in turn is superior to that of repeat cardiologist reading for lesser ECG abnormalities. … The prevalence of ECG abnormalities among blacks in this younger and middle-aged biracial cohort was markedly higher than whites."[257]

Increased Error Rate in Presence of Non-Sinus Rhythms and/or Artifact

Although multiple studies have indicated the 12SL™ program is accurate when it states "normal", it is inadequate for a variety of abnormal conditions. Errors are most frequent in the presence of non-sinus rhythms and/or artifact.

- "Out of 2072 ECGs, 776 (37.5%) were normal, and 1296 (62.5%) were abnormal. … The errors [by 12SL™] in diagnosis of arrhythmia, [AV] conduction disorders and electronic pacemakers accounted for 178 cases, or 86.4% of all errors."[219]
- While using 12SL™, "sinus rhythm was correctly interpreted in 95.0% of the ECGs (1666/1753), whereas non-sinus rhythms were correctly interpreted with an accuracy of only 53.5% (192/359) (P<0.0001)."[258]
- In a study of "2,298 ECGs identified by 12SL™ as atrial fibrillation, 442 ECGs (19%) were incorrect."[91]
- Most computerized interpretation errors by 12SL™ are for rhythm interpretation, especially those with artificial pacing.[89]
- In a study that reported a sensitivity of 58% for 12SL™ STEMI recognition, "50% of the missed STEMIs were labeled as 'data quality prohibits interpretation'." [240]
- More than half of the ECGs that led to a false positive determination [by 12SL™] of atrial fibrillation exhibited "a rhythm that was irregularly irregular due to premature atrial complexes 137 patients (36%), regular sinus rhythm with marked artifact (28%), or both (11%)."[91]

Clinical Impact Due to Computer Error or Inappropriate Use

Despite the frequency of errors, there are few studies that have evaluated the clinical impact of computerized ECG interpretation errors.

- A systematic search and ongoing surveillance of MEDLINE, EMBASE and the Cochrane Controlled Register concluded, "Physicians of all specialties and levels of training, as well as computer software

for interpreting ECGs, frequently made errors in interpreting ECGs when compared to expert electrocardiographers. There was also substantial disagreement on interpretations among cardiologists. Adverse patient outcomes occurred infrequently when ECGs were incorrectly interpreted."[259]

- "Computer decision support systems can generally improve the interpretive accuracy of internal medicine residents in reading EKGs. Subjects were influenced significantly by incorrect advice, which tempers the overall usefulness of computer-generated advice."[260]
- Based on an initial false-positive interpretation of atrial fibrillation (AFIB) by 12SL™, a study was conducted of the clinical consequences of that interpretation. The study evaluated a total of 2,298 ECGs identified as AFIB. Of these, 442 (19%) were false. This led to unnecessary diagnostic testing in 90 patients (repeat ECGs in 78, cardiac ultrasound in 15, and Holter in 2). Complications due to inappropriate treatment occurred in 2 patients: 1 patient developed hematuria due to the initiation of anticoagulation, and the other patient had symptomatic bradycardia after initiation of atrioventricular nodal blocking agents. "Overreliance on computer-assisted interpretation obviously contributed to unnecessary management steps. When cardiovascular specialists were consulted, the misdiagnosis was corrected in all but 3 cases."[91]
- Door-to-balloon times were negatively impacted due to reliance on 12SL identification of STEMI. Only 12SL STEMI ECGs were immediately over-read by an emergency department physician. In 340 consecutive patients who had ECG changes which met criteria for reperfusion therapy, "92 patients were missed by computer interpretation."[261] 53% of these were identified as "myocardial infarction, age undetermined." When 12SL™ states "age undetermined", it should not imply that it is old. When 12SL identified STEMI, the culprit artery detection rate was 94.4% versus <80% for the other ECGs. Optimum screening processes in the ED for STEMI is still an area of study.[118]
- A chest-pain patient with a single ECG identified as STEMI by 12SL and later corrected by a cardiologist to state "Non-specific ST segment abnormalities" was used to evaluate care management decisions of 110 Internal and Emergency Medicine residents. Among the subgroup of residents who read the ECG as diagnostic (n = 48), residents given the erroneous interpretation were significantly more likely to recommend revascularization (54% vs. 25%, p = 0.048). [262]
- "In 97,046 study ECGs (48.2% from males), a prolonged 12SL-calculated QTc value (ie, ≥470 ms in females >60 years old, and ≥460 ms in other sex/age groups) was displayed in 16,235 (16.7%). Nonetheless, for only 7709 (47.5%) did the automated interpretation include an accompanying 'Prolonged QT' diagnostic statement. … In evaluating an adult patient whose 12SL-interpreted ECG lacks a prolonged QT diagnostic statement (assuming sinus rhythm <100 beats per minute and QRS duration <120 ms), physicians should examine the actual QTc value displayed on the report before concluding that this parameter is normal. Assessment of the clinical impact of prolonged QT diagnosis suppression by ECG waveform-based criteria is warranted."[263]

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Development and Validation Process

GE's Marquette 12SL™ program was introduced in 1980. All improvements to the program have been accomplished via a systematic, logical, controlled methodology. A major aspect of this methodology benefits from the use of stored ECGs.

The items covered for the development and validation process of 12SL include the following:

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Reanalysis of Stored ECGs

All historical ECGs analyzed by the 12SL™ program and stored on the MUSE™ system, can be re-analyzed for the purposes of validating or improving the program.[14] This is because the median QRS complex generated by the program has always been compressed and stored via a lossless Huffman encoding method.[11, 264] The first implementation of this methodology has been described in the literature,[265] was later enhanced by GE Healthcare for ECGs stored at 500 samples per second (SPS),[19] and ultimately served as the basis of a new international standard.[266] This standard includes data fidelity requirements for compressed ECGs; these requirements are surpassed by the data compression/decompression methods currently employed by GE Healthcare. For those who desire additional fidelity, GE Healthcare provides another option (known as Digital View Storage DVS), which uses lossless compression throughout the ECG.

Initiating a Change

Any change to the program requires a great deal of research. This effort can be instigated by a variety of sources:

- The constant pursuit of clinically correlated databases can yield statistics that indicate whether a change should be considered.
- New criteria published in the scientific literature can be evaluated and sometimes incorporated into the program.
- Consultations with cardiologists also stimulate investigations. This is especially true when they have stored ECGs that reveal a measurement or interpretation error.
- GE Healthcare also documents customer complaints. Although complaints can from customer interactions with service, sales or the call center, any GE Healthcare employee who is aware of a complaint must document it. The engineering department tracks these complaints. Any digital ECGs provided by a customer that exemplifies the problem can be reanalyzed to determine the source of the error. If a solution can be found without negatively impacting the rest of the program, the fix will be applied to new versions of 12SL.

Measuring the Impact: Evaluation via Library of Databases

Before a change can be instituted, it must always be evaluated in relation to the current program performance. Stored ECGs are reanalyzed and any difference due to the enhancement is scored and tracked. After this is done, the validation system automatically culls out any ECGs that scored differently between the two versions of the program. This results in an efficient method to automatically determine how a change might affect program performance.[14, 23]

Selecting an Appropriate Gold-Standard Database

In the 12SL™ Physician's guide, each 12SL™ interpretive statement has been identified as either Type A, B, or C, a classification methodology approved at the Tenth Bethesda Conference on Optimal Electrocardiography.[267]

Type A statements refer to the diagnosis of anatomic lesion or pathophysiologic state, such as myocardial infarction or hypertrophy. The accuracy of these statements can only be determined in conjunction with non-ECG evidence such as cardiac catheterization (CATH), echocardiography (ECHO), cardiac enzymes, clinical outcome, etc. These statements are evaluated with databases that have been clinically correlated with non-ECG data. The non-ECG data acts as the "gold standard".

Type B statements cover statements referring to the diagnosis of electrophysiological changes and are detected primarily by the ECG itself. This includes arrhythmias and conduction disturbances. Although intracardiac recording can be used to validate the diagnostic conclusions determined via the surface ECG, this is often not practical. As a result, a cardiologist's interpretation is used as the reference.

Type C statements refer to purely descriptive ECG features that usually cannot be documented by any other means. Examples of such statements include "non-specific ST-T abnormality" and "left axis deviation". Again, a database of ECGs with the physician's interpretation is used as the reference.

Type A Statements: Reliance on Non-ECG Correlates is Not Enough

Databases that have been correlated with non-ECG data are critical for the development and validation of Type A statements. But these databases have their limitations. Reasons include the following:

- The requirement that a non-ECG correlate must be used for validation may force the database to contain a population that is not representative of the disease in the actual clinical setting. For example, an autopsy-proven myocardial infarction (MI) database may not be indicative of what a typical MI looks like, since many patients survive an MI. Another example would be "CATH proven normals". In this case, the patient often receives the CATH because they were symptomatic, or the ECG was "abnormal". As a result, the ECGs from such a database may not be from true "normal" patients.
- Databases from most published clinical investigations have already removed the "confounding influence" of ECGs with conduction defects, artifacts, etc. This does not reflect the real world. The algorithm must operate in the presence of ischemia, conduction defects, drug effects, artifacts, etc.
- A non-ECG value may indicate the presence of an abnormality, but this does not mean that the abnormality is revealed in the surface ECG. For example, an ECG can often appear "normal" even when it is clearly established that it is from a patient with an acute myocardial infarction. It is important to not force the program to identify these ECGs as positive, if the abnormality is not revealed in the signal. Otherwise, the program will overcall the abnormality in other environments.
- The database may only contain the extreme cases of normal versus abnormal. Algorithms don't operate in a black and white world.
- And finally, non-ECG data cannot be considered perfect: every test comes with its own inherent level of inaccuracy.

Even when an abnormality can only be positively determined via a non-ECG correlate, a physician's interpretation is critical as an additional check. During development and testing, databases based on a physician's interpretation are used in conjunction with databases that have been correlated with non-ECG data.

As an additional check, GE Healthcare uses large databases that have been gathered as part of routine care. In this case, there may be little quality control of the physician interpretation. These large databases, available via a MUSE™ system, are useful for determining the rate at which a change in the program will generate a change in an interpretation across an entire institution. Reanalysis on over 100,000 ECGs can be done in a matter of minutes and it confronts the algorithm with multiple kinds of waveforms and varying

degrees of abnormality. ECGs that changed their analysis can be further investigated with either confirmation from medical records and/or another expert opinion.

Training versus Test Sets

Different databases are used for development versus validation. This precludes overtraining an algorithm so that it works beautifully on the training set but cannot be generalized across other sample sets with the same success. This is an important requirement for reliable pattern recognition.[268] In this document, all validation and reported results for interpretation performance are from independent test sets.

Porting 12SL to Multiple Platforms: Verification Process

GE's Marquette 12SL™ Program has been implemented on a variety of platforms, including Holter recorders and prehospital defibrillators. To accomplish this, the program must be completely tested in its target environment. The use of analog ECGs to test every logic path in the target environment is not feasible. Thousands of ECGs would have to be recorded and the results manually compared. A digital solution is required. GE Healthcare invented a program for this purpose, known as EZSIM (i.e. easy simulator).

EZSIM is a program that generates simulated ECGs with the intent of thoroughly exercising the 12SL program. After 12SL processes an ECG made by EZSIM, a checksum is computed across all inputs, the complete analysis output of 12SL, and many intermediate results that never get displayed on a report. Checksum mismatches indicate that 12SL produced a different output than expected on the target platform. A target implementation is only considered successful when over 70,000 ECGS have been analyzed by the target platform without any differences detected in the checksums.

ESZSIM simulates ECGs with a vast variety of shapes and rhythms, covering all categories identified by the program. Each ECG is generated algorithmically and is not restricted to 10 seconds or even 24 hours.

The simulator has two parts: the initialization routine and the running routine. The initialization routine uses about 109 random numbers to create a basic P wave pattern, a basic QRS pattern, a basic PVC pattern, a basic PP interval, an amount of PP variability, a basic PR interval, an amount and frequency of muscle tremor noise and an amount and frequency of baseline sway noise. The running routine uses up to 4 random numbers per sample to determine the noise, 3 random numbers per QRS or unconducted P-wave to determine when the next P-wave, QRS, or PVC will occur. The simulator can overlap one QRS cycle with the next so that the P-waves at higher heart rates can creep into the T-wave of the previous cycle. Types of rhythms generated by EZSIM include the following:

- unconducted P-waves
- modulated coupling intervals, P-P
- random occurrence of ectopy, blocked AV conduction
- dual synthesis of patterns allows overlap, P onto T, or R onto T
- atrial fibrillation – irregular with fibrillatory waves
- atrial flutter – fast, less irregularity, no fibrillatory waves
- ventricular tachycardia
- torsade, ventricular pattern is rotated gradually
- ventricular fibrillation
- muscle tremor noise, electrode motion noise, baseline sway

Although constructed using random numbers, these ECGs are exactly reproducible given a starting point in the random number sequence. That starting point is called the random number seed. That seed is all that is needed to reconstruct that ECG of unlimited length.

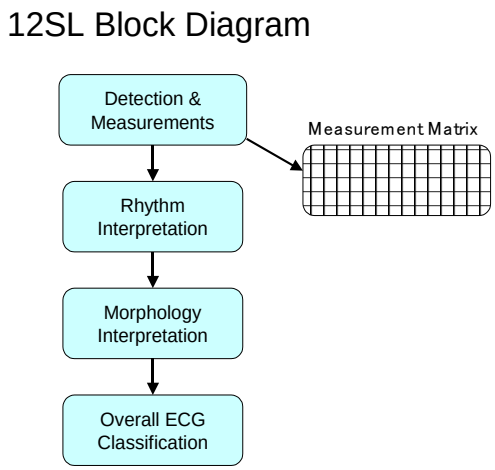
Any number can be used as the random number generator seed. All the numbers from 0 to 65535 produce different sequences of random numbers and different ECGs. The simulator algorithm is the equivalent of a

database but as opposed to conventional databases that retrieve stored ECGs, this database requires only about 3 kilobytes of code and no storage for the actual ECGs.

Program Structure: Measurements Before Interpretation

Below is a simple block diagram of GE's Marquette 12SL™ Program. Note that all the interpretative statements are generated following the measurement portion of the program.

All measurements generated by the program are stored in a measurement matrix, which are then later accessed by the interpretive portions of the program. Criteria used by the program are fully described in the 12SL™ Physician Guide: Part I – Criteria and Methodology. Note that these criteria never directly measure the ECG. The criteria use only the values from the measurement matrix. For any given ECG, the measurement matrix can be printed at the interpreting electrocardiograph or MUSE™ ECG storage system.



Since the interpretive portions of the program are based on measurements, it is critical that the ECG measurements be as robust and as accurate as possible.[269] The following sections address the necessary elements for generating quality measurements, with associated references to substantiate this quality.

The Digital ECG: Data Content and Fidelity

In addition to resting electrocardiographs, the 12SL program operates in a variety of products, from bedside monitors to prehospital defibrillators. As a result, the 12SL program has been designed to be configurable for different environments.

All 12 leads, simultaneously recorded for 10 seconds, is the minimum data set required by GE's Marquette 12SL™ Program (specifically leads I, II and V1-V6; leads III, aVR, aVL, and aVF are calculated via Einthoven's law). In some applications, the 12SL program analyzes more than 10 seconds or more than 12 leads.

In 1979, GE Healthcare introduced simultaneous recording of 12 leads so that the computer could use all signals from all 12 leads to properly detect and classify each QRS complex. The Common Standards for Electrocardiography independently verified the advantage of this technique:

> *"Conclusion: The simultaneous recording and analysis of all 12 standard leads...is certainly an improvement over the conventional recording of three leads at a time. Similarly...multi-lead programs proved to be more stable than those obtained by conventional programs analyzing three leads at a time..."[50]*

All resting electrocardiographs currently sold by GE Healthcare analyze the waveform at 500 samples per second (SPS). In some GE Healthcare resting electrocardiographs, the ECG is sampled at a much higher rate,

such as 4,000 SPS. This is referred to as over-sampling and it used by the device to generate an average, cleaner signal at 500 SPS. Specifications for electrocardiographs, across the industry, often cite the raw sample rate (e.g. 4K SPS or higher) without clarifying that the ECG analysis and measurement software executes on data with a lower sample rate. Current guidelines for resting ECG analysis cite 500 SPS,[52] which is the minimum sample rate executed by 12SL. In some GE Healthcare electrocardiographs, the 12SL program can be configured to analyze the ECG at 1K SPS.

Before the physiological data is sampled, analog filtering is applied. These filters attenuate high-frequency electrical noise that is not part of the physiological signal. If these analog filters were not present in the device, high-frequency signals could be digitized by the device and appear as low frequency noise, inter-mixed with the physiological cardiac signal. To eliminate this possible source of contamination, GE Healthcare applies an analog filter, known as an anti-aliasing filter.

Pattern Recognition of Noise/Quantifying Signal Quality

As opposed to measuring skin impedance, GE Healthcare has adopted an alternative approach for detecting signal quality, which directly analyzes the ECG signal for muscle tremor, AC power interference, electrode motion, or baseline shifts. This software algorithm for detecting these artifacts has previously been described and is referred to as Hook-up Advisor.™[33]

ECG devices often measure the impedance across the skin-electrode interface. When this impedance exceeds 600KΩ, a GE Healthcare resting electrocardiograph informs the user that a lead is off and provides no signal for that lead. The reason the device no longer provides a signal for a "lead-off" condition is because a dangling lead would result in extreme noise, obscuring the rest of the ECG report and making it difficult for both the analysis program and the human to interpret the ECG.

Throughout the ECG industry, impedance across the electrode-skin interface is often used as a surrogate for lead quality. Normal skin impedance can vary dramatically, from 10 to 300KΩ.[270] It has been shown that skin impedance has a poor correlation with the presence of artifacts. [58]

Stating there is poor signal quality below 300KΩ simply results in false-positive calls and great frustration upon the person taking the ECG. A good quality resting ECG can be obtained at an input impedance > 300KΩ.

GE Healthcare continuously analyzes the digital signal for artifacts. For instance, muscle tremor is "detected by counting the number of deflections exceeding a fixed threshold per second."[33] Powerline interference is detected by running a "frequency hunting" filter over each lead of the 10-second ECG.[271] Baseline sway is evaluated by "tracking the minimum and maximum of a low-pass filtered version of the ECG signals."[33] If the difference between these exceeds a threshold, the ECG lead is identified as being contaminated by baseline sway. Electrode noise is "determined by examining QRS complexes for false QRS detections. Individual lead energy content of the QRS, the RR intervals of QRS complexes, and a measure of the correlation of the QRS across all leads is also considered."[33] All of these methods are incorporated into a software algorithm known as Hook-up Advisor™ and its impact evaluated in the following studies.[33, 59, 272]

Hook-up Advisor™ assigns an ECG lead quality level of green, yellow, or red, which is also indicated on the user interface of the electrocardiograph. This was tested on a large database of over 120,000 ECGs. Lead quality distributions and rhythm interpretation discordance rates between the physician and GE's Marquette 12SL™ Program are reported below.

Lead quality and rhythm discordance for combined test set (N = 120,698).[33]

Lead quality	*N*	*Percent of total*	*Discordance rate*
Green	115128	95.39%	3.9%
Yellow	5170	4.28%	7.4%
Red	400	0.33%	12.1%

Overall, 95.4% of all ECGs were categorized as green (good) lead quality, 4.3% were assessed as yellow (marginal) lead quality, and 0.3% as red (poor) lead quality. As the primary rhythm from the 12SL reanalysis

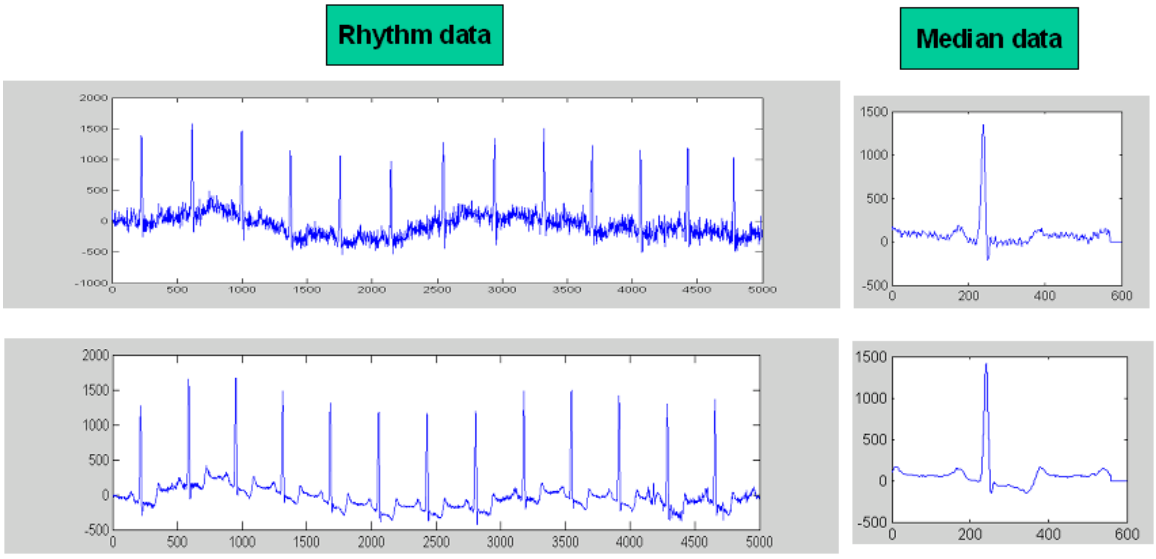
was compared to the primary rhythm in the confirmed ECG, the discordance of these two interpretations increased sharply, from 3.9% to 7.4% to 12.1% as the lead quality degraded from green to yellow to red.

Lead quality indicators can be stored on MUSE and can be used to monitor the quality of ECG acquisition across an institution.

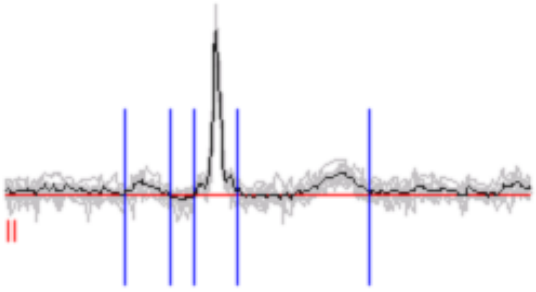
Median Beat/Signal Averaging

In addition to filtering or signal conditioning, there is another method that is employed to eliminate noise from the cardiac cycle: that is, signal averaging. Instead of analyzing the best raw QRS complex, the GE's Marquette 12SL™ Program generates a median complex. All QRSs of the same shape are aligned in time. Next, the algorithm generates a representative QRS complex from the median voltages that are found at each successive sample time. Although more complicated than creating an average, the method results in a cleaner signal than an average.

Below is an example of the formation of a median from a 12-lead Holter recording.[34]



Presented below is even a closer look at the median. It shows the median complex displayed along with the raw complexes used to form the median complex. Note the noise in the raw signal versus the median complex.



Willems et. al.,[273] independently verified the value of this technique. Without the technique, onsets and offsets were shifted outward in the presence of noise. As quoted from the literature: "Increasing levels of high-frequency noise shifted the onsets and offsets of most programs outward. Programs analyzing an averaged beat showed significantly less variability than programs, which measure every complex or a

selected beat. Based on the findings of the present study, a measurement strategy based on selective averaging is recommended for diagnostic ECG computer programs."

Results by Zywietz[274] also showed that programs analyzing an averaged beat exhibited less variability than programs that measure every complex or a selected beat. Zywietz also confirmed that median beats had less noise and generated more accurate measurements than an analysis of raw beats.[275]

Farrell[272] also demonstrated the effectiveness of the median by testing 12SL™ on 90,000 "noisy" ECGs. This test used a repeatable methodology for the creation of "noisy" ECGs, which can be applied for industry-wide assessment of robustness of computerized measurements.

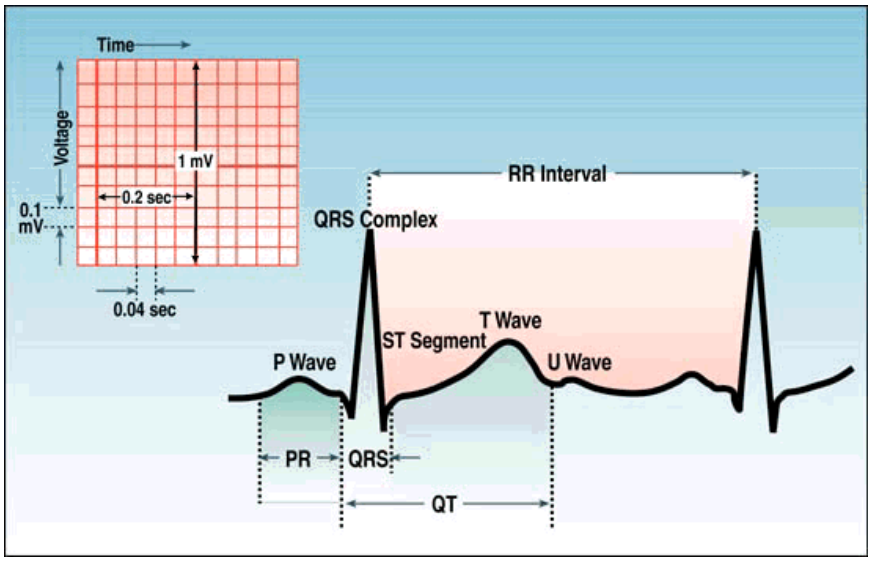
QRS Onset/Offset and Determination of Global Intervals

Good ECG measurements depend upon the proper identification of the fiducial points such as QRS onset and offset. Consistent with the signal-processing portion of the program as well as the physiological definitions for cardiac depolarization and repolarization, these fiducial points are determined by an analysis of the slopes in all 12 simultaneous leads. As a result, each fiducial point refers to the same sample-time where the median complexes are time aligned. Since these fiducial points are applied across all 12 median complexes, they are often referred to as global versus lead-specific.

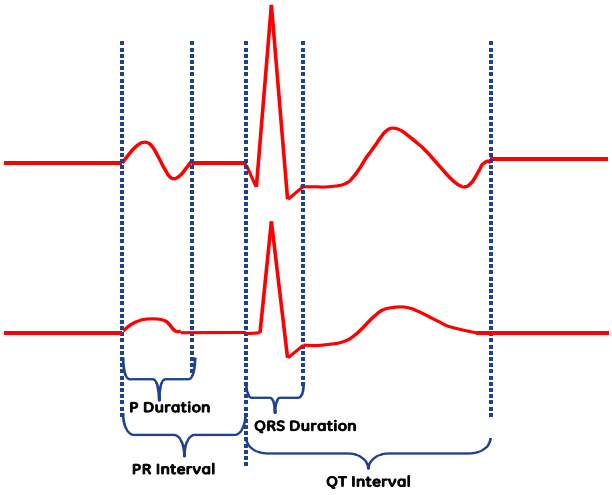
P onset and P offset are also determined via the median complexes, unless the computer detects asynchronous P wave activity or an inconsistent PR coupling interval in the rhythm data. In this case, P onset and P offset remain undefined.

As opposed to the human reader, which may only inspect the QRS duration in any single lead of the ECG, the computer measures the QRS duration as a global interval. That is, it measures the QRS duration from the earliest detection of depolarization in any lead (QRS onset) to the latest detection of depolarization in any lead (QRS offset). Similarly, the QT interval is measured as a global interval: that is, from the earliest detection of depolarization in any lead (QRS onset) to the latest detection of repolarization in any lead (T offset). See diagrams below.

Basic ECG Nomenclature



Global Fiducial Points – Across All Median Complexes



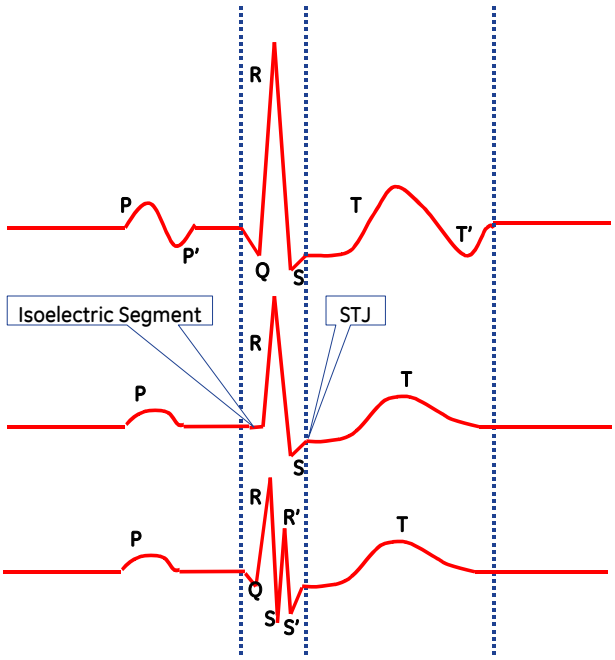
Definition and Measurement of Waves

After the global fiducial points (P onset/offset, QRS onset/offset and T offset) have been determined, the waves within each complex are measured according to published standards.[276] This is done separately for each lead. Different ECG analysis programs treat waves within the QRS complex in different ways; as a result, the IEC standard requires that this wave identification process be fully disclosed, as provided below. (See IEC 60601-2-51 clauses 50.101.2-4).[1]

Starting at QRS onset, the program finds the points at which the ECG signal crosses the baseline within each complex. If the crossing points define a wave that has an area greater than or equal to 160 µV-ms, the wave is defined as significant. If the area is less than this value, the program considers the wave to be insignificant, and it will not label it as a separate wave. Sections of the complex that do not exceed the minimum wave criteria of 160 µV-ms are combined with the adjacent significant wave.

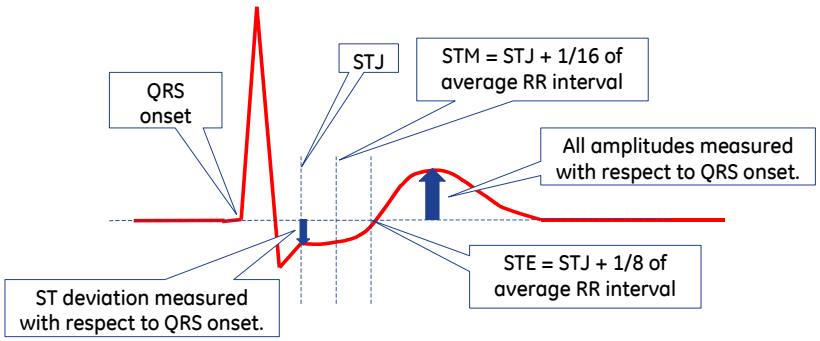
Since the wave of depolarization is a spatial entity, the onset of the wave will not be evident in all leads at the same time. Isoelectric sections starting at QRS onset of the complex are treated as part of the subsequent significant wave. Isoelectric sections at the end of the QRS will be incorporated into the preceding significant wave.

Definition of Waves Within Complex



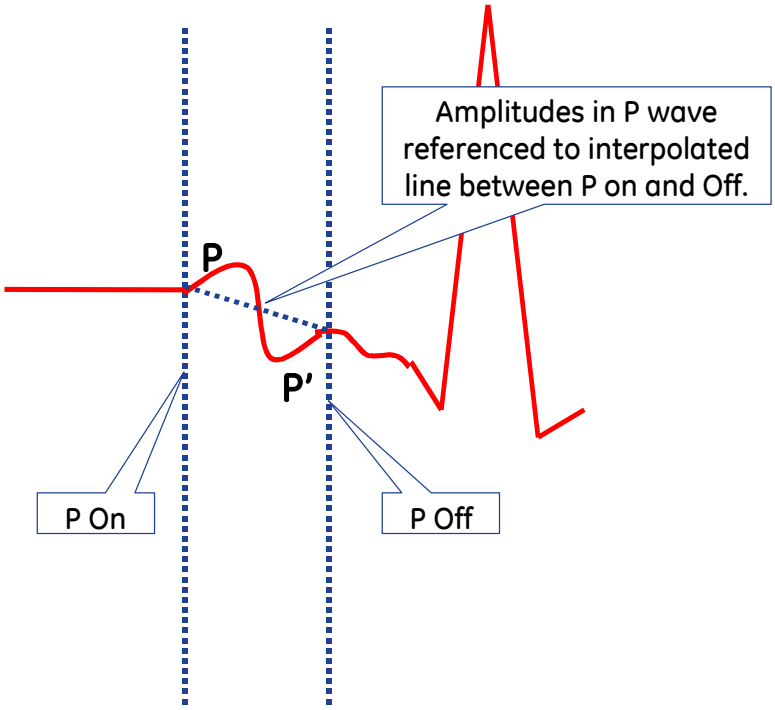
Amplitudes of significant waves within the QRS as well as the T wave are measured with respect QRS onset. Deviation of the ST segment is also measured in relation to QRS onset. STJ is defined as QRS offset. Further definition of the ST segment is defined by STM and STE, which are two additional points along the ST segment that are 1/16 and 1/8 of the average RR-interval from STJ. See diagram below.

Amplitudes of QRS and ST-T Measured in Relation to QRS onset



Amplitudes of significant waves within the P wave are measured with respect to a baseline level that is interpolated from P onset to P offset. This accommodates the phenomena of PR segment depression. See diagram below.

P amplitude adjusted for PR-segment depression



These amplitudes and durations result in a measurement matrix containing more than 800 values. Measurements are then passed onto the criteria portion of the program so that it can generate an interpretation.

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Testing of 12SL™ Measurements via Standardized Database

Common Standard for Electrocardiography (CSE)

In an effort to standardize and evaluate the performance of ECG computer measurement programs, a 12-lead ECG reference database was developed.[50] Typically referred to as the Common Standards for Electrocardiography (CSE) database,[277] it contains a set of 250 electrocardiograms (ECGs), with selected abnormalities, which were measured by five cardiologists. Attention was focused on the exact determination of the onsets and offsets of P, QRS and T waves. As quoted from the literature:

> *"The cardiologists performed their task on highly amplified, selected complexes from the library in a two-round process. With use of a modified Delphi approach, individual outlying point estimates were eliminated in four successive rounds. In this way final referee estimates were obtained that proved to be highly reproducible and precise."*[278]

All ECG waveforms in the CSE database are available to industry. Only one-half of these ECGs contain the measurements from the CSE referee committee. The other half does not contain these manual measurements. One-half has published measurements; the other half has unpublished referee measurements. As a result, the ECGs that contain the published referee measurements can be used by the industry for the self-assessment and reporting of measurement performance. The other 125 ECGs are unavailable for self-assessment.

GE's Marquette 12SL™ Program was tested using all 250 CSE ECGs (that is, including those without the published CSE measurements). This independent evaluation was done when the program only operated on data sampled at 250 SPS. The data in the CSE database was originally acquired at 500 SPS. To re-analyze this data at 250 SPS, the ECG was down-sampled to generate data at 250 SPS. The results of this independent evaluation are presented below; it includes the mean difference from the manual measurements and the standard deviation of the mean difference.

Complete CSE database evaluation, including unpublished referee annotations.[50]

Interval Measurement	*N*	*Mean difference (ms)*	*Standard Deviation (ms)*
P duration	218	-0.4	9.0
PR interval	218	-0.6	5.8
QRS duration	240	-0.6	5.4
QT interval	238	+0.9	12.2

IEC Minimum Measurement Performance Requirement

The International Electrotechnical Commission (IEC) has issued particular requirements for recording and analyzing electrocardiographs (see 60601-2-51© IEC 2003)[1] For measurement performance assessment and acceptance testing, the standard uses ECGs from the CSE database that contain the published referee measurements. As a result, this is a self-assessment, self-reporting measurement performance test.

In addition to biological ECGs, the CSE database contains analytical and calibration ECGs. These are used to evaluate the accuracy of the global interval measurements and the accuracy of amplitude and wave duration measurements within each complex of each lead. GE's Marquette 12SL program has been evaluated with these analytical and calibration ECGs. With regards to amplitude measurements, no ECGs were excluded due to fiducial point errors; the program passed all amplitude measurement requirements as defined in IEC 60601-2-51 clause 50.101.2. With regards to global interval and wave duration measurements, one ECG was excluded from QRS duration and the S duration measurements due to a QRS offset fiducial point error. All global interval measurements were within acceptable limits. For the per-lead measurements all results are reported below. No exclusions were made. All per-lead measurements were within the acceptable limits as required in IEC 60601-2-51 clause 50.101.3.1.

Results of Absolute Interval and Wave Duration Measurements for IEC

Measurement	*Mean difference (msec)*	*Standard deviation (msec)*	*Acceptable mean difference (msec)*	*Acceptable standard deviation (msec)*	*Pass / Fail*
P duration	-8.6	1.5	±10	8	**Pass**
PR interval	-6.0	1.6	±10	8	**Pass**
QRS duration	0.0	1.6	±6	5	**Pass**
QT interval	1.4	3.8	±12	10	**Pass**
Q duration	-0.8	2.8	±6	5	**Pass**
R duration	-0.7	2.2	±6	5	**Pass**
S duration	-0.9	2.7	±6	5	**Pass**

In addition to the calibration ECGs, the IEC requires testing on 100 biological ECGs from the 125 ECGs that contain the CSE measurements. In the performance reporting of the 100 ECGs, the IEC standard allows exclusion of up to four measurements with "obvious fiducial point errors". No obvious fiducial point errors were observed via GE's Marquette 12SL™ Program. No ECGs were excluded for this reason. The standard then allows exclusion of the "four largest deviations from the mean (outliers) for each measurement". As a result, the following table contains the global interval results for 96 ECGs, analyzed at 500 SPS. Included in the table are the mean difference from the CSE manual measurements, the standard deviation of the mean difference, and the IEC pass / fail criteria. The global interval measurements are well within accepted limits and pass the test. (See IEC 60601-2-51 clause 50.101.3.2).

Global Measurement Performance for IEC standard on 96 CSE Biological ECGs

Interval Measurement	*Mean difference (ms)*	*Standard Deviation (ms)*	*Acceptable mean difference*	*Acceptable standard deviation*	*Pass / Fail*
P duration	-6.7	9.0	±10	15	**Pass**
PR interval	-1.5	5.5	±10	10	**Pass**
QRS duration	-5.2	5.2	±10	10	**Pass**
QT interval	+1.0	8.9	±25	30	**Pass**

Another test includes only 10 ECGs from the CSE database that contains the published referee measurements. These 10 ECGs were analyzed by the 12SL™ program, first without noise added and then with each of the noise types specified: 25μV RMS high frequency muscle artifact noise, 50 μV peak-to-valley 60 Hz line frequency noise, and 1 mV peak-to-valley 0.3 Hz sinusoidal baseline noise.

For each noise type, the interval measurements were recorded and compared against the measurements of the noise-free ECGs. For each of the interval measurements of each noise type, the mean of the ten differences from the noise-free measurements was calculated. As specified by the IEC standard, two of the largest deviations from the mean were excluded from the final reported mean and standard deviation of the differences. (See IEC 60601-2-51 clause 50.101.4).

50.101.4 –Mean Difference from Recordings without Noise

Global Measurement	*Type of added noise*	*Mean Difference (ms)*	*Standard deviation (ms)*
P duration	high frequency	-43.5	9.9
P duration	line frequency	-2.8	6.7

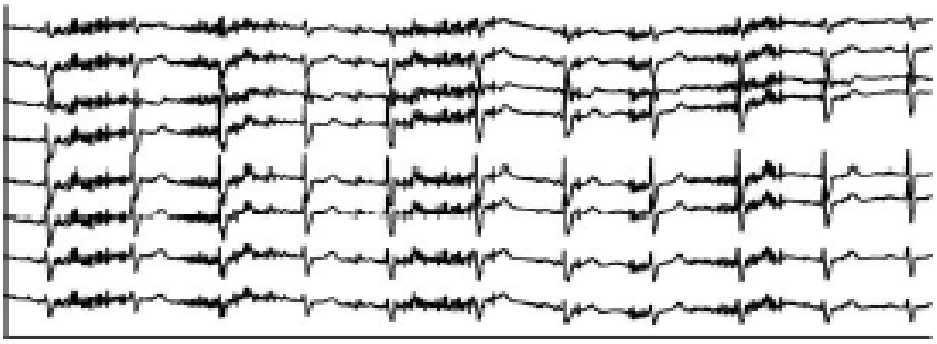
P duration	baseline	1.5	3.7
PR interval	high frequency	-18.5	11.0
PR interval	line frequency	-1.5	2.8
PR interval	baseline	0.3	1.3
QRS duration	high frequency	-7.8	2.7
QRS duration	line frequency	-1.3	4.7
QRS duration	baseline	-0.3	1.7
QT interval	high frequency	-1.3	3.2
QT interval	line frequency	1.5	3.7
QT interval	baseline	-0.3	3.5

Evaluation of 90,000 Noisy ECGs via CSE and MIT-NST Databases

The 125 ECGs of the CSE (containing the published referee measurements) were merged with records from the MIT Noise Stress Test database (MIT-NST).[279] For each CSE ECG, 720 unique noise ECGs were created, for a total of 90,000 noisy ECGs. Computerized measurements from the noisy ECGs were compared to the original ECG measurements. The repeatability of the measurements was assessed as a function of a lead quality score. Noise did not introduce any bias to the measurements, although not surprisingly, the variation of the errors increased as the lead quality degraded.[272]

Below is an example of an ECG generated by the combination of the CSE and MIT-NST databases. The MIT-NST database consists of three 30-minute 2-channel noise records and is specified for the analysis of the robustness of ambulatory ECG analysis by the AAMI standard EC38.[280] The noise recordings were made using physically active volunteers and standard ECG recorders, leads, and electrodes; the electrodes were placed on the limbs in positions in which the subjects' cardiac generated signal was not visible.

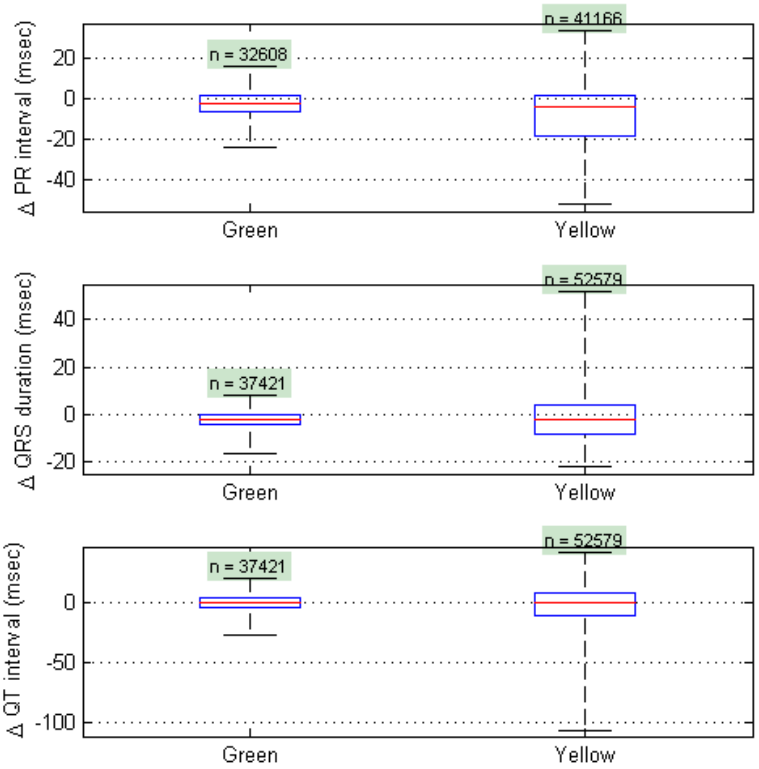
Example of CSE ECG combined with MIT-NST Record



Impact of Hookup Advisor™ on Accuracy of ECG Measurements

For each ECG, interval measurement differences versus the CSE annotations were obtained. These differences were grouped against the Hookup Advisor™ indicators[33] and the ranges of the values reported in the following figure.[272] The reported PR interval tended to shorten as the noise level increased. The mean difference of the QRS duration was relatively unaffected by noise, changing by less than 2ms. The median difference of the QT interval was 0ms for both lead quality levels, while the standard deviation (SD) of the QT differences went from 20.5 to 39ms and the interquartile range went from 8 to 18ms.

PR interval (top), QRS duration (center), and QT interval (bottom) compared to CSE



Boxes in box plots denote 25th and 75th percentiles, with 50th percentile (median) inside the box. Whiskers extend to 2.5th and 97.5th percentiles, spanning 95% of the measurement differences.

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Independent Evaluation of 12SL™ Measurements

In addition to the use of standardized databases, there have been several independent assessments of the measurements generated by GE's Marquette 12SL™ Program. These include studies conducted during routine clinical use[243, 281] versus large clinical trials or epidemiology studies.[282]

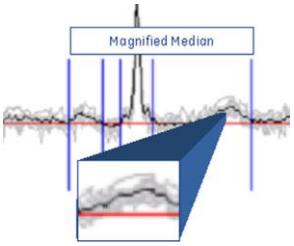
Interval Measurement Comparison Across ECG Manufacturers

A study published in *Europace* (2017),[283] found automated QRS duration (QRSd) measurements significantly differed on 76 patients depending upon which manufacturer's electrocardiograph was used. This difference occurred even when "none of the patients had variability in QRS duration and/or morphology observable at visual inspection of ECG recordings." Due to the variability of QRSd measures by the other vendor, the authors stated that "to achieve the QRSd precision comparable to that of a single GE Healthcare recording, a series of four to five ECGs would have to be recorded and QRSd averaged."[283]

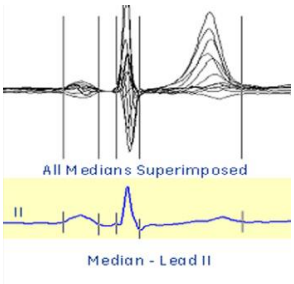
In an interval comparison study published in 2014,[284] the mean PR interval determined via Mortara on LQTS patients had a standard deviation roughly double that of the other ECG vendors.[284] "Since that publication, some algorithms have been adjusted, while other large manufacturers of automated ECGs have asked to participate in an extension of this comparison."[4] As a result, the comparative study was repeated with a different set of ECGs from LQTS patients and published in 2018.[4] In the case of Mortara, the standard deviation of the PR interval markedly improved and came into alignment with the other vendors. Unlike GE Healthcare which provided a PR interval for all the ECGs in the study (n=800), Mortara was unable to provide a PR interval in 15, Schiller 14, and MEANS (Welch Allyn) 11.[4] This study also found that "measurement differences between algorithms for QRS duration and for QT interval are larger in long QT interval subjects than in normal subjects."[4]

Measurement reproducibility is an important aspect of an ECG analysis program.[285] The Common Standards for Electrocardiography (CSE) prescribed the computerized methods used to reduce the influence of noise on measurement reproducibility.[273, 274, 286] These were found to be so critical, the AHA/ACC/HRS promulgated them in their most recent recommendation for standardization of the ECG:[51]

- "Digital electrocardiographs must provide beat alignment that allows selective averaging or formation of a representative complex with fidelity adequate for diagnostic ECG computer programs."



- "Global measurements of intervals should be obtained from time-coherent data in multiple leads to detect the earliest onset and latest offset of waveforms."



"Not all, digital electrocardiographs utilize the time coherence of simultaneously acquired representative complexes to derive "global" measurements of intervals."[*51*]

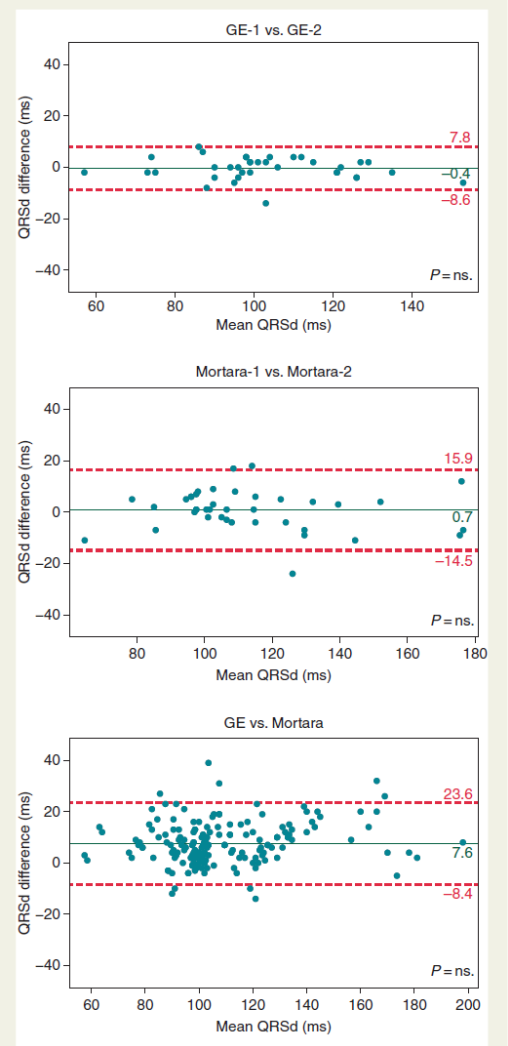
QRS Duration Reproducibility: Pair-wise Comparison to Another Vendor

"The study included randomly selected patients who were hospitalized in the department of cardiology of the University Hospital in Pilsen and had a clinical indication for a standard 12-lead ECG recording. Within a single day, they underwent separate ECG recording sessions, each with either one of the two MAC 5000 electrocardiographs (GE Medical Systems, Milwaukee, WI, USA), henceforth, GE-1 and GE-2 or one of the two Mortara ELI 350 electrocardiographs (Mortara Instrument, Inc., Milwaukee, WI, USA), henceforth Mortara-1 and Mortara-2."[283]

Below are the results of the pair-wise comparison, including intra-manufacture (first two Bland-Altman plots) and inter-manufacture (last Bland-Altman plot.) Note that there was systematic difference in QRSd of 7.6+8.1 ms with GE Healthcare being shorter than Mortara's.

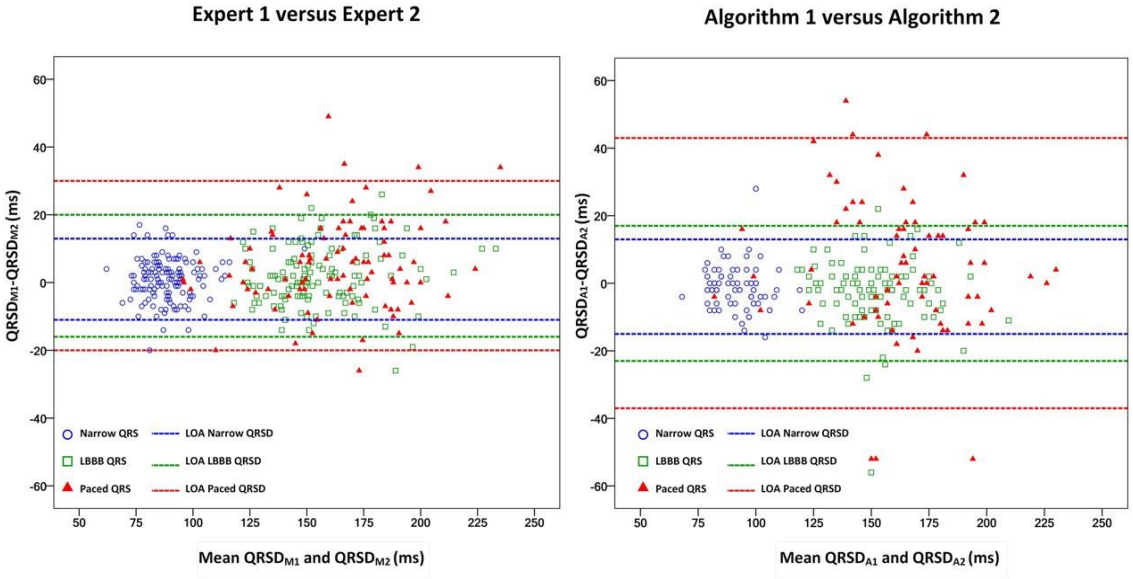
"Limited accuracy and precision of automated QRSd measurements have important clinical implications ... in risk stratification and selection of patients for specific therapies, particularly for CRT." "For the Mortara to achieve the QRSd precision comparable to that of a single GE Healthcare recording, a series of four to five ECGs would have to be recorded and QRSd averaged."[283]

Bland–Altman plots for inter-session agreement of QRSd



In another study, "QRSD was assessed in 377 digitally stored ECGs: 139 narrow QRS, 140 LBBB and 98 ventricular paced ECGs. Manual QRSD was measured as global QRSD, using digital calipers, by two independent observers. Computer-calculated QRSD was assessed by Marquette 12SL (GE Healthcare, Waukesha, WI, USA) and SEMA3 (Schiller, Baar, Switzerland)."[287]

Below are Bland-Altman plots comparing the experts to one another as well as the algorithms to one another. GE's Marquette 12SL™ program is referred to as algorithm 1 and the measurements from it as QRSDA1.



Differences among methods is insignificant when QRS's are narrow. In the presence of left bundle branch block (LBBB), small differences exist between 12SL™ and the manual readers (2 to 9 ms). In the presence of artificial pacing, the variance among all methods increases. See more details below:

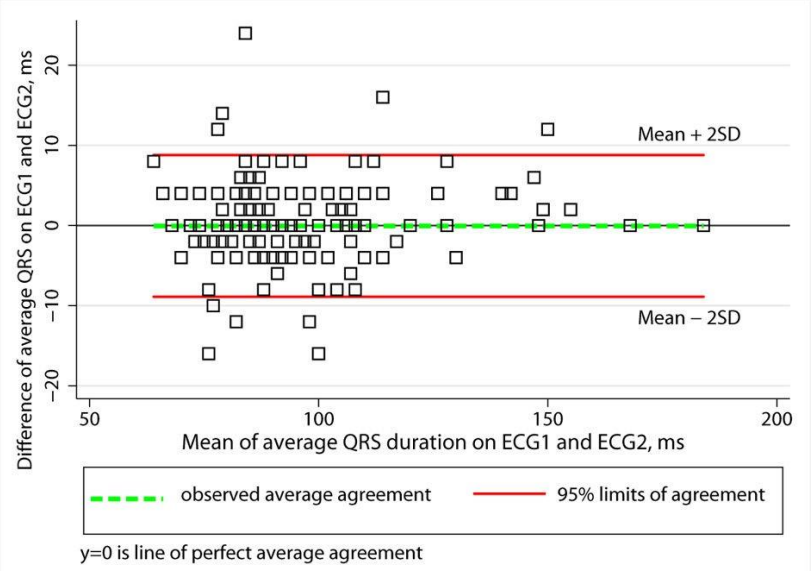
- In the presence of narrow QRS complexes, "analyzing QRSD within individual ECGs (pairwise), absolute differences in QRSD between the automated algorithms QRSDA1 versus QRSDA2 are 4 [2–9] ms (p = 0.010) and between QRSDM1 versus QRSDM2 4 [2–6] ms, p = NS. Absolute inter-manufacturer and interobserver variability were comparable in narrow QRS ECGs (4 [2–9] ms versus 4 [2–6], p=NS)."
- "Analyzing QRSD within individual LBBB ECGs (pairwise), absolute differences in QRSD between the automated algorithms QRSDA1 versus QRSDA2 are 7 [2–10] ms (p = 0.003), and between QRSDM1 versus QRSDM2 6 [3–12] ms (p = 0.006). … In LBBB ECGs, absolute inter-manufacturer and interobserver variability was comparable (7 [2–10] versus 6 [3–12] ms, p=NS). … Comparing manual versus automated QRSD measurements, absolute variability between QRSDMM and QRSDA1 was 4 [2–9] ms (p < 0.001) and between QRSDMM and QRSDA2 was 7 [3–10] ms (p = 0.044).
- In the presence of artificial ventricular pacing, variances between experts increases to 8 [4–18]ms, (p = 0.001). For manual versus automated QRSD measurements, "absolute variability between QRSDMM and QRSDA1 was 14 [7–25] ms (p = 0.005) and between QRSDMM and QRSDA2 was 14 [4–23] ms, (p = 0.001)."

Johns Hopkins ARVD/C Registry: Same-day Reproducibility

"Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) is characterized by delay in depolarization of the right ventricle, detected by prolonged terminal activation duration (TAD) in V1–V3. Manual ECG measurements have shown moderate-to-low intra- and inter-reader agreement. The goal of this study was to assess reproducibility of automated ECG measurements in the right precordial leads."[288]

"Pairs of ECGs recorded in the same day from Johns Hopkins ARVD/C Registry participants [n=247, mean age 35.2±15.6 y, 58% men, 92% whites, 11(4.5%) with definite ARVD/C] were retrospectively analyzed. ... Bland-Altman analysis revealed satisfactory reproducibility of tested parameters. V1 QRS duration bias was –0.10ms [95% limits of agreement –12.77 to 12.56ms], V2 QRS duration bias –0.09ms [–11.13 to 10.96ms]; V1 TAD bias 0.14ms [–13.23 to 13.51ms], V2 TAD bias 0.008ms [–12.42 to 12.44ms]."[288]

For global QRS duration, the following Bland-Altman diagram was provided:



Framingham Heart Study: 12SL versus Digital Calipers

The Framingham Heart Study (FHS) data repository stored on GE Healthcare's MUSE™ system includes ECGs from 1986 to 2012. For this study, ECGs were randomly selected to account for temporal changes in ECG acquisition and recording techniques. ECGs were excluded if they had a paced rhythm, atrial fibrillation, or upon review had a technically inadequate tracing. The following measures were performed manually (using digital calipers by a single reader) and automatically via 12SL™: P wave duration, P wave amplitude, PR interval, QRS duration, R wave amplitude in lead V6 and QT interval in lead V5.

This showed "excellent correlation of automated [12SL™] and digital caliper measurements of PR interval, P wave amplitude, QRS duration, QT interval and R wave amplitude. P wave duration had more limited reproducibility." This study provided FHS "with strong confidence in introducing automated measures to Framingham Heart Study data. Integrating rapidly acquired waveforms through digital ECG platforms will enhance Framingham Heart Study data acquisition, save valuable investigator time, and permit novel analyses that may guide identification of cardiovascular disease and its risk factors."[247]

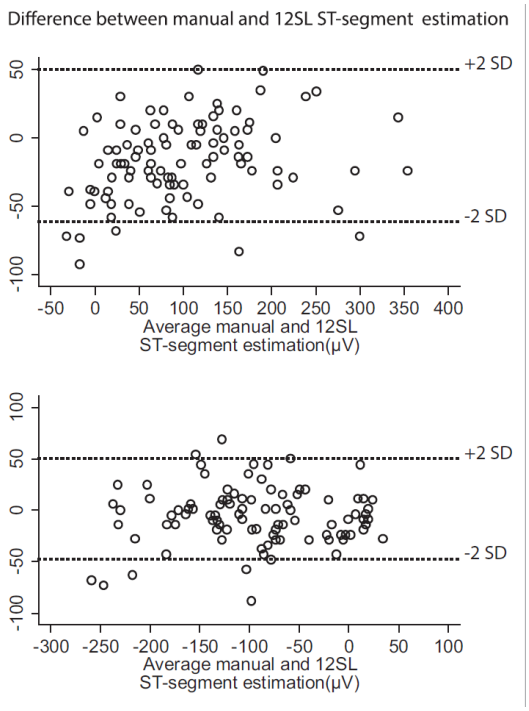
ST-segment Deviation: Automated STM versus Manual at STJ + 80ms

ST deviations were evaluated in 69 consecutive patients suspected of an acute coronary syndrome (ACS).[289] Bland-Altman analysis demonstrated clinically acceptable limits of agreement comparing measurements of the J point and the T wave, but clinically inadequate limits of agreement with respect to ST-segment deviation, between the electrocardiographer and the computer. But as quoted from the study: "The difference between these 2 methods is mainly caused by different measurement points. There is no common

agreement on what time point to use to measure ST amplitude. In this study, it was measured at 80 ms after the J point by manual measurement, while the computer selected a displacement at the midpoint of the ST segment." This 12SL measurement is known as STM, which is 1/8th of the average RR interval after the J-point. The measurement point for STM is corrected for heart rate. To get values at fixed interval from the J-point, use the expanded matrix capability available on the MUSE™ system.

In another study, "to evaluate the agreement between the 12SL algorithm and manual ST-segment measurement, a number of ECGs (N=200) were sampled."[290] In addition, "to explore the validity of the automated measurements also at the extremes of ST-segment deviations, ECGs were randomly sampled from each category of ST-deviation." The manual rater was blinded to results from the 12SL algorithm. See results of this evaluation in the figure below.

Bland Altman Results of ST deviation: 12SL Versus Manual Measurement



QT Interval

The assessment of automated QT measurements has undergone a great deal scrutiny since 2005 when the Food and Drug Administration (FDA) issued a new guidance document on the "design, conduct, analysis, and interpretation of clinical studies to assess the potential of a drug to delay cardiac repolarization."[291] An important implication of this guidance was that evaluators needed to be able to reproducibly detect a very small increase in QTc. A "through QT study" must be powered for the statistical detection of QTc interval changes that are as small as 6ms.[292] Automated measurements are desirable since they could reduce this effort.[293, 294] Measurements that are more consistent and accurate than manual measurements may result in a lower sample size and overall cost of a trial.[295]

GE Healthcare put considerable effort into improving its automated QT measurements, especially since leading investigators complained that 12SL™ was not accurate enough to eliminate manual measurement and would sometimes exhibit substantial errors in finding the end of the T-wave.[296] Fortunately, a new version of the 12SL™ program was released and evaluated by these same investigators. They found that the "accuracy of the 'new' 12SL™ algorithm is not only much greater than the accuracy previously observed with QT interval measurement by the 'old' 12SL algorithms, it also makes it feasible to use the modern equipment without any manual intervention in carefully selected parts of drug-development program."[32]

Similarly, in 2008, several cross-over, thorough-QT studies were used to evaluate the performance of GE's Marquette 12SL™ Program.[293] The variability associated with human measurements was generally 5–28% greater than that associated with automated methods. The performances of automated and human methods were comparable for demonstrating assay sensitivity in TQT studies with healthy volunteers.

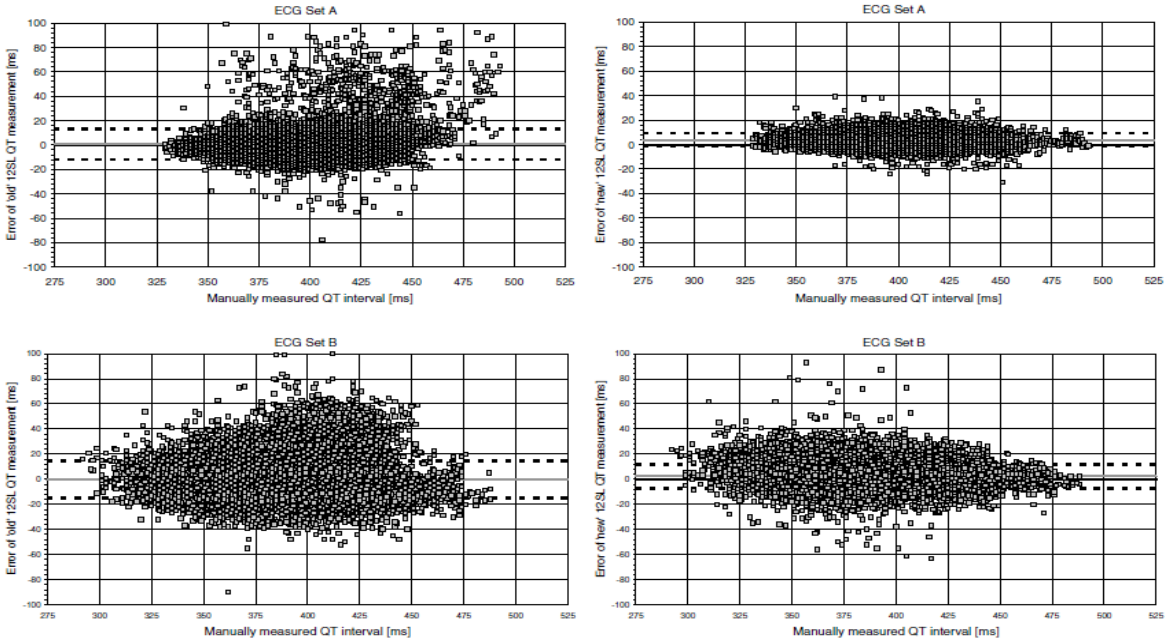
In 2006, a large independent study evaluated the new QT algorithm for 12SL™, released in 2003 and now available in all current GE Healthcare electrocardiographs. Evaluation was done on over 45,000 resting ECGs obtained from two clinical trials, labeled as set "A" and "B". Set "A" (n=15,194 ECGs) exhibited substantially better signal quality than set "B" (n=29,866 ECGs). In set A, 95.9% of ECGs were measured automatically within 10 ms of the manual measurement. In set B, 83.9% of the automated measurements were within 10ms. "The study shows that (a) compared to the "old" version of the 12SL algorithm, the QT interval measurement by the "new" version implemented in the most recent GE Healthcare ECG equipment is significantly better, and (b) the precision of automatic measurement by the 12SL algorithm is substantially dependent on the quality of processed ECG recordings."[32]

Percentages of ECGs with successful automatic QT measurement (n=45,060)[32]

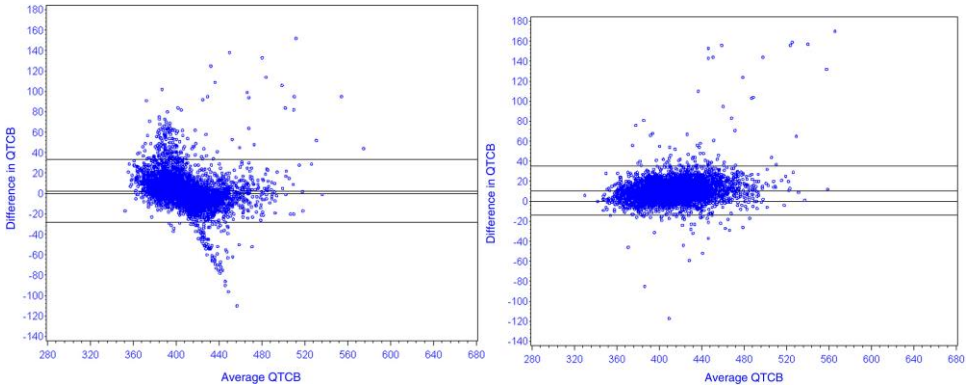
Absolute measurement error	*ECG set A*		*ECG set B*	
	"New" 12SL	*"Old" 12SL*	*"New" 12SL*	*"Old" 12SL*
≤ 5 ms	73.7	47.8	54.4	33.5
≤ 10 ms	95.9	76.6	83.9	59.5
≤ 15 ms	99.3	91.7	94.0	77.3

The table shows percentages of ECG tracings in which the error of automatic QT interval measurement was below the given threshold. For example, with a given threshold of 10ms, 95.9% of the ECGs in set A were within 10 ms of the manual measurement as opposed to only 76.6% of the ECGs with the "old" 12SL measurement algorithm.

Below are Bland-Altman plots of the older version of 12SL (on the left) versus the version of 12SL currently available GE Healthcare electrocardiographs (on the right). Clearly, the current version generates fewer errors; in fact, the agreement interval is cut in half.



Although the study by Hnatkova et. al. was large (N > 45,000), it was based on ECGs from clinical studies of normal subjects undergoing pharmaceutical testing. Tyl et. al.[297] decided there was a need to confirm these improvements on patients in a clinical environment. The two versions of 12SL were evaluated using "a total of 6,105 randomly selected electrocardiograms classified by the cardiologists as normal (4227), borderline (1254), abnormal (575), or not analyzable (49)."[297] Below are the B&A plots resulting from this study. Notice the latest version of 12SL (on the right) has the positive attribute of a narrower agreement interval versus the older version of 12SL (on the left).



Large comparative studies across the industry have demonstrated there is less agreement among ECG vendors when measuring ECGs from LQTS subjects versus normal subjects.[4, 284] It is important to know whether automated QT measurements are reliable when the QT becomes prolonged.

Fortunately, two large studies[32, 297] have evaluated the accuracy of GE's Marquette 12SL Program across a wide spectrum of QT values from 350 to 520ms and another specifically targeted the evaluation of 12SL when the QT was greater than 500ms.[298]

To assess agreement between two quantitative methods of measurement, Bland-Altman (B&A) scatter plots are recommended.[299] Each difference in milliseconds between the automated and manual QT measurement is presented on the vertical axis versus the manually measured QT along the horizontal axis.

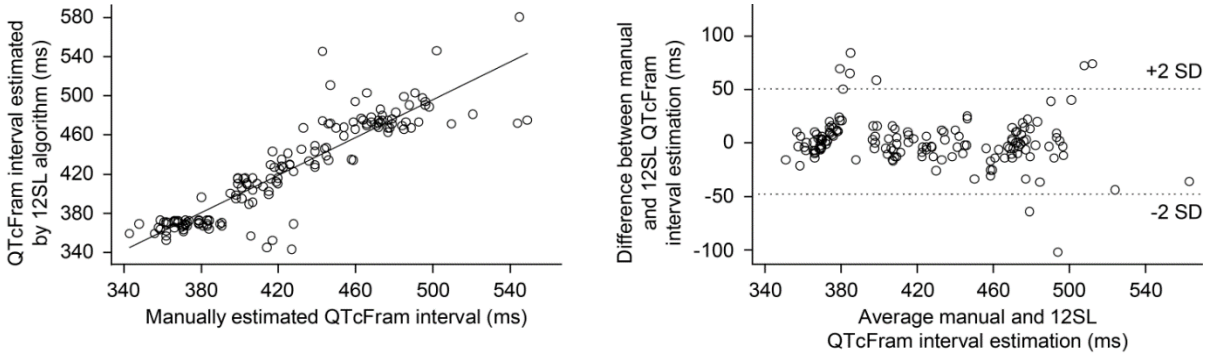
One reason B&A plots are recommended for "assessing agreement between two methods of clinical measurement"[299] is because they reveal whether there is a systematic error or difference in measurement which changes over the spectrum of measurements required for clinical assessment. In this study, the mean difference between the manual and automated measurement forms a horizontal line throughout the spectrum of measurements. There is no measurement bias or error that becomes more pronounced anywhere along the spectrum of measurements.

In addition, B&A plots provide an agreement interval (see dashed lines) which indicates where 95% of the differences between the manual and automated measurements fall. This shows that "compared to careful manual QT interval readings in recording set A, the errors of the automatic QT interval measurement were (mean ± SD) +3.95 ± 5.50ms. … In recording set B, these numbers were +2.41 ± 9.47ms."[32]

To specifically study the accuracy of automated 12SL QTc values at the extremes, and especially greater than 500ms, two large studies were performed – one from an out-of-hospital primary care population (173,529 ECGs from different patients) [300] and the other from a community hospital (225,117 ECGs from 63,286 unique patients).[301]

In the first instance, "50 ECGs were randomly sampled from the lowest 1st percentile, 100 ECGs were randomly sampled from 1st to 99th percentile, and 50 ECGs were randomly sampled from the upper 99th percentile. For all manually assessed ECGs, QTc_{Fram} intervals were measured manually in lead aVF, V2, and V5 at 10 times magnification and with the use of a digital caliper (MUSE™ Cardiology Information System, GE Healthcare, Wauwatosa, WI, USA). The mean of the manual QTc_{Fram} measurement from the three leads was used for the comparison. The manual rater (J.B.N.) was blinded to results from the 12SL algorithm. To evaluate agreement between manual and 12SL measured QTc_{Fram} intervals, results were summarized in a scatter-plot and in a Bland-Altman plot. Mean difference between manual and 12SL algorithm

measurements was calculated together with the limits of agreement (±2 standard deviations)."[300] See figures below from the supplementary material provided in this paper.

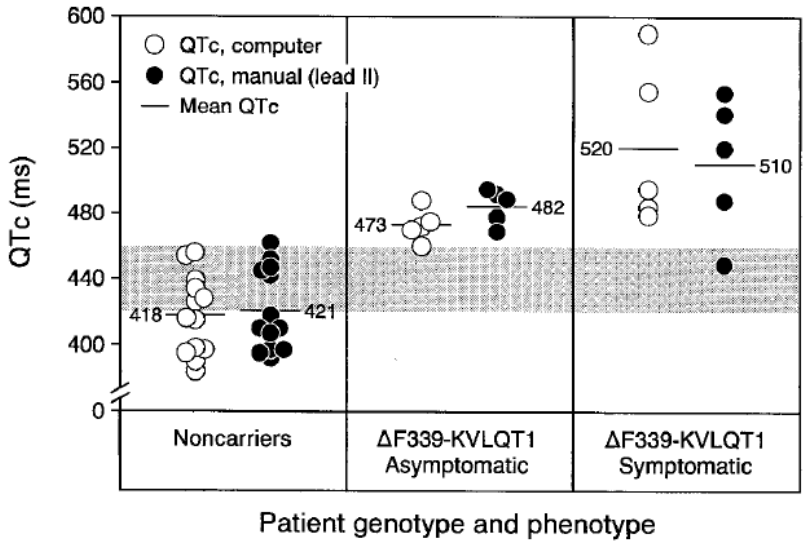


In the second instance, a GE Healthcare MUSE ECG database consisting of 225,117 ECGs from 63,286 unique patients collected over 11 years was searched using the following criteria: QTc (Bazett's formula) ≥ 500ms, QRS width ≤ 120ms, age 15 ≥ years, normal heart rate, no acute ST-elevation infarction, no atrial fibrillation, or atrial flutter. All ECGs resulting from this search were manually measured using the tangent method "in the lead showing the longest QT interval as the mean of three consecutive beats."[301] The automated QTc measurement was considered correct if it was within ± 10ms of the manual measurement, which was the case in 88% of ECGs exhibiting sinus rhythm and adequate technical quality.[298]

For QTc values ≥ 500ms, "correlation between manually and automatically measured QTc values was 0.97 (P< 0.001)."[301] This study also manually evaluated a random sample of 200 ECGs with automated QTc<500ms and found none that should have exceeded a QTc ≥ 500ms. "The manually measured median QTc was 430ms (range 339–499) vs. automatically measured median QTc 434ms (range 346–496). The correlation between the manually and the automatically measured QTc values was 0.91 (P<0.001)."[301]

In addition to these large studies, a smaller, yet important study evaluated the QTc measurement performance of 12SL versus expert cardiologists on ECG from patients who were evaluated for congenital LQTS (LQT1) with a range of QTc values from 390 to 600ms. The performance of the computer versus cardiologist measurement in lead II is presented below.

Comparison of QT measurements between cardiologist and computer in a study LQT1 patients.[302]



"Computer QTc and manual QTc (lead II) measurements. "The shaded area from 420 to 460 ms indicates the range for a 'borderline/equivocal' QTc."[302]

Several studies which exclusively evaluated 12SL,[32, 297, 298] stated there was better agreement between the automated and manual QT measurements when the ECG was of good quality. See specific details below:

- QT measurement errors (defined as > 15ms) were reduced from 8.3% to 0.7% when the ECG tracings were of high quality.[32]
- "Automated QT measurements were provided on all tracings; the readers judged some tracings as not interpretable, and QT measurements could not be performed, usually because of noisy recording or T-wave flattening."[297]
- "The biggest contributor to an incorrect QTc value was noise. In the presence of a technically inadequate ECG, the percent of ECGs where the manual and automated QTc values differed by more than 10ms was 8%."[298]

Given that ECG quality is a key requirement for quality QT measurements, it important that those acquiring ECGs leverage GE Healthcare's Hookup Advisor™ for real-time assessment and guidance regarding the quality of the waveform. In a study of 90,000 noisy ECGs, it was shown that when Hookup Advisor™ was green, the median difference was zero between the automated QT measurements by 12SL and manual measurements performed by CSE referees. The standard deviation of these differences decreased from 39 (when yellow) to 20.5ms (when green).[59]

Normals and patients with hypertrophic cardiomyopathy evaluated with the automatic QT measurements made by GE's Marquette 12SL™ Program were "more stable and reproducible than the manual measurements".[303]

The stability and consistency of the 12SL™ Program was leveraged for the measurement of QT in a large epidemiology study, because the QT variability of the 12SL Program "was smaller than that of the Dalhousie program."[304] This study derived normal limits from percentile distributions for QT as well as QT and T-wave subintervals in 22,311 participants in the Women's Health Initiative. This study advised considerable revision of the currently used limits for prolonged QT in women, with an additional race-specific adjustment in Asian women.

Similar normative values were established in another study, which was conducted on a large drug-induced trial patient population using 12SL™ Program measurements and medians, available for review by a cardiologist.[305] The analysis was performed on baseline (drug-free) ECG data. The final analysis included ECG recordings from 13,039 patients. Reference ranges from the study were stratified by important prognostic factors: age, sex, and overall ECG evaluation at baseline (normal or abnormal). From this study, proposed reference ranges were provided for patient management and data analyses in clinical drug development.

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Predictive Value/Clinical Correlation of 12SL™ Measurements

P-wave/PR interval: Predict Atrial Fibrillation, Pulmonary Death, etc.

There has been considerable interest in long PR intervals and P-wave measurements for predicting which patients will ultimately suffer from atrial fibrillation (AF). To do this, normal reference ranges also had to be established. See examples below:

- A study by Veteran Affairs Healthcare Service (VAHS) found that after "5.3 years, 1,050 (2.4%) of patients were found to have AF on subsequent ECG recordings. Several ECG characteristics, such as P-wave dispersion (the difference between the widest and narrowest P waves), premature atrial contractions, and an abnormal P axis, were predictive of AF with hazard ratio of approximately 2 after correcting for age and sex."[306] Similar findings were also found across a large primary care population (n>150,000); P-wave measures provided by 12SL "were associated with increased hazards of AF, ischemic stroke, conduction disorder, and death from all causes."[307]
- A large negative terminal P-wave in lead V1 as measured by 12SL "suggests that an underlying atrial cardiopathy may cause left atrial thrombus formation and a subsequent stroke without intervening clinically recognized atrial fibrillation."[308]
- GE's Marquette 12SL™ program was used to measure the median PR interval, maximum P-wave duration, maximum P-wave area, and P-wave terminal force on ECGs from 3,110 Framingham Heart Study (FHS) and 8,254 Atherosclerosis Risk in Communities (ARIC) participants. "Over 10-years, 217 FHS and 458 ARIC participants developed atrial fibrillation (AF). In meta-analysis, P-wave duration >120 ms was significantly associated with AF (hazard ratio [HR] 1.55, 95% CI [confidence interval] 1.29 to 1.85) compared to ≤120ms. P-wave area was marginally but not significantly related to AF (HR1.31, 95% CI 0.95 to 1.80). P-wave terminal force was strongly associated with AF in ARIC but not FHS."[245]
- To establish reference ranges of PR duration and P-wave indices in individuals free of cardiovascular disease (CVD), ECGs from the Multi-Ethnic Study of Atherosclerosis (MESA) were used. "P-wave durations and amplitudes needed to calculate p-wave indices were automatically measured with the GE Marquette 12SL program 2001 version [GE Marquette, Milwaukee, WI]. A global single measure of PR interval was calculated from the beginning of the P-wave to the beginning of the QRS."[246] In individuals free of CVD and its risk factors, there are differences by age, sex and race in the distribution of PR and P-wave indices.
- Similarly, automated 12SL™ PR interval measurements on 50,870 patients of which 5,199 developed AF over 3.72 mean years of follow-up were used to define normative values. The study settled on "a PR interval value of 200 ms as a criterion in African Americans and Hispanics for the development of AF. A value of 200 ms may be less sensitive as a predictive measure for the development of AF in African Americans compared to non-Hispanic Whites."[309]

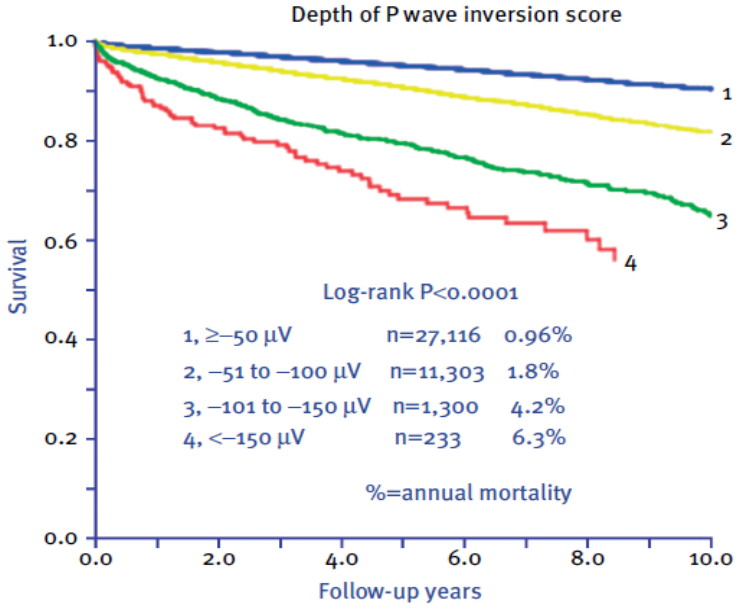
Using similar methods described above which rely on ECGs stored on a MUSE system and automated PR intervals from 12SL™, the following clinical correlates have also been established:

- Patients with genetic variants associated with AF have a longer PR Interval.[310]
- There is an "increased risk of AF for longer PR intervals for both women and men. With respect to short PR intervals, we also observed an increased risk of AF for women."[307]
- "During follow-up, we identified 34,783 deaths from all causes, 9,867 cardiovascular deaths, 9,526 cases of incident heart failure, and 1,805 pacemaker implantations. … A long PR interval conferred an increased risk of heart failure (> 200 ms; HR, 1.31; 95% CI, 1.22-1.42; P < 0.001).[311]
- An increasing PR interval conferred an increased risk of pacemaker implantation, in a dose-response manner, with the highest risk associated with a PR interval > 200 ms (HR, 3.49; 95% CI, 2.96-4.11; P < 0.001). … PR interval was significantly associated with the risk of the adverse outcomes investigated."[311]

- "Digital ECGs from 328,638 primary care patients were collected … individuals with preexcitation had higher hazards of atrial fibrillation and heart failure."[312]

In addition, the Veterans Affairs Healthcare System (VAHS) has studied pulmonary death.

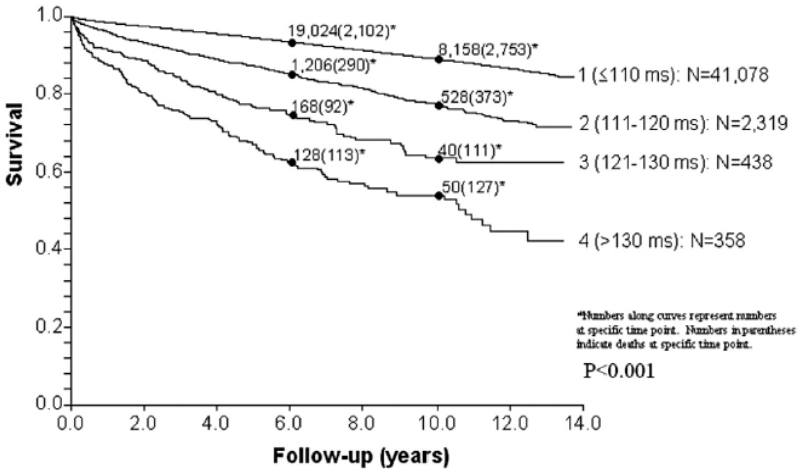
- "During a mean follow-up of 6 years there were 3,417 CV and 1,213 pulmonary deaths." P-wave amplitude in inferior leads, right axis deviation, left atrial abnormality and P-wave duration >120ms were all predictive of pulmonary death. "P-wave abnormalities are common findings that should not be ignored."[313]
- In the figure below, P-wave inversion score was evaluated against pulmonary mortality. The score was defined as the depth of P-wave (including terminal P-wave) in leads V1 or V2 (μV) of ≤ – 50 = 1; –51 to –100 = 2; –101 to –150 = 3; and < – 150 = 4. Note that although only 233 out 40,020 patients had a terminal P-wave in V1 or V2 < -150 μV, their annual mortality rate was 6.3%. "Each increment in the P-wave inversion score was associated with a 56% and 17% increase in CV and pulmonary death, respectively."[313] In a follow up study, "negative Pwaves (≤–100 μV) occurring in leads V1 or V2 with either a monophasic or biphasic pattern, and P waves with a duration of 140ms or longer, had significant associations with increased risk of CVD."[314]



QRS Duration: Selecting Candidates for CRT, etc.

Based on the QRS duration and QRS-T angle measurements made by GE's Marquette 12SL™ program, several studies have explored whether these measurements can predict death, heart failure, electrical/mechanical desynchrony or the optimum condition for cardiac resynchronization therapy.[76, 287, 315-325] Below are some quotes from the scientific literature with regards to the prognostic value of these measures:

- "Analyses were performed on the first electrocardiogram digitally recorded on 46,933 consecutive patients." Using computer generated QRS durations from 12SL™, the following conclusion was made: "QRS duration provides a simple method to stratify patients as to their risk of cardiovascular (CV) death. In a general medical sample, without BBB or paced rhythms, those with a QRS duration greater than 130 ms experience nearly twice the risk of cardiovascular death compared with those with a QRS duration of 110 ms or less. Similarly in patients with LBBB and RBBB, QRS duration greater than 150 ms is associated with greater risk of CV death."[322] See figure below:



- "The widest QRS duration on each ECG was manually measured after magnification. ... Compared with computer measurements of QRS duration, the correlation coefficient (r) was 0.95, with a SE of 0.06, p < 0.0001"[319] The longer the QRS duration, the " higher positive likelihood ratio for predicting abnormal LV EF."[319]
- "Of the 4,033 patients, 252 died during a median follow-up of 3 years. The QRS duration was univariately associated with an increased risk of death (relative risk 8.5, 95% confidence interval CI 4.4 to 16.4, p <0.0001)" ... "A QRS duration >105 ms best identified patients at increased risk. In conclusion, QRS duration is associated with an increased risk of death, even after adjustment for clinical factors, exercise capacity, left ventricular function, and exercise-induced myocardial ischemia."[323]
- "Prolonged QRS was associated with a significant increase in mortality (49.3% vs 34.0%, *P* = .0001) and sudden death (24.8% vs 17.4%, *P* = .0004)."[326]
- "A target population of 3,471 had" ... "ECG data obtained from automated sources during the first year of diagnosis. " .... "Among the heart failure population, 20.8% of the subjects had a QRS duration > 120ms. A total of 425 men (24.7%) and 296 women (16.9%) had a prolonged QRS duration (p < 0.01). There was a linear relationship between increased QRS duration and decreased ejection fraction (p < 0.01). A prolonged QRS duration of 120 to 149 ms demonstrated increased mortality at 60 months (p = 0.001), when adjusted for age, sex, and race (p = 0.001). Systolic dysfunction was associated with graded increases in mortality across ascending levels of QRS prolongation."[324]
- Obstructive sleep apnea (OSA) and prolonged QRS duration are associated with hypertension, heart failure, and sudden cardiac death. A cross-sectional study of 221 patients concluded automated "QRS duration and OSA were significantly associated."[327]

ST-segment: Left Ventricular Hypertrophy, Risk of Heart Failure, etc.

Obviously, ST segment deviation is associated acute myocardial infarction. There is a growing awareness that this measurement can be used for risk assessment in the presence of left ventricular hypertrophy or other chronic cardiovascular conditions. See examples below:

- "The predictive value of nonspecific ST depression as determined by visual and computerized [12SL™] Minnesota Code (MC) codes 4.2 or 4.3 was compared with computer-measured ST depression >or= 50 microvolts in 2,127 American Indian participants in the first Strong Heart Study examination." .... "CONCLUSIONS: Computer analysis of the ECG, using computerized MC and computer-measured ST depression, provides independent and additive risk stratification for cardiovascular and all-cause mortality, and improves risk stratification compared with visual MC."[328]
- In this study, computerized 12SL™ ST measurements were correlated with the presence of left ventricular hypertrophy (LVH). ECGs and echocardiograms (ECHO) were done on a total of 1,595

American Indian participants without evident coronary disease.[329] "The absolute magnitude of ST segment deviation above or below isoelectric baseline was measured by computer in leads V(5) and V(6), and participants were grouped according to gender-specific quartiles of maximal STdep. Left ventricular hypertrophy was defined by indexed LV mass >49.2 g/m (2.7) in men and >46.7 g/m (2.7) in women." ... "After controlling for clinical differences, increasing STdep remained strongly associated with increased prevalence of LVH (p = 0.0001). CONCLUSIONS: In the absence of evidence of coronary disease, increasing STdep in the lateral precordial leads is associated with increasing LV mass and increased prevalence of anatomic LVH."[329]

- Based on 12SL™ ST measurements from a total of 285,194 people, it was "found that ST-depressions were associated with a dose-responsive increased risk of CVD in nearly all the precordial leads. ST-elevations conferred an increased risk of CVD in women and regarding lead V1 also in men. ST-elevations in V2 to V3 were associated with a decreased risk of CVD in young men."[290] "This study also performed a validation analysis and found good agreement between manual and 12SL automated ST-segment measurements. Automated ST-segment depression in lead V6 compared with manual measurement showed a mean difference - 5.545μV (95% CI -11.07 to 0.02) with limits of agreement between -74.64 to 41.320μV."[290]
- Computerized assessment via 12SL™ of ST deviation and T-wave inversion identifies hypertensive patients at increased risk of developing congestive heart failure (CHF) and dying from it, even in the setting of aggressive blood pressure lowering.[330, 331]
- "MESA (Multi-Ethnic Study of Atherosclerosis) is a multicenter, prospective cohort of 6,441 participants (mean age, 62 years; 54% women). ... ECG interpretation was performed automatically with the GE Marquette 12SL™ program. ... ECG strain is independently associated with all-cause mortality, adverse cardiovascular events, development of LV concentric remodeling and systolic dysfunction, and myocardial scar over 10 years in multiethnic participants without past cardiovascular disease. ECG strain may be an early marker of LV structural remodeling that contributes to development of adverse cardiovascular events."[332]
- ST level was measured by 12SL in 29,281 patients. Early repolarization (ER) was defined as ST≥100μV. "Common patterns of ER without concomitant Q waves or T-wave inversion [as identified by 12SL] are not associated with increased risk of cardiovascular death; when either occurs with ER, there is a hazard ratio of 5.0 [333]

QT Interval: Overall Mortality, Sudden Cardiac Death (SCD), etc.

In addition to the question as to whether the computer can correctly measure QT, considerable study has been done to determine if a long QT interval - as measured by GE's Marquette 12SL™ Program - is predictive of poor outcome. See examples below:

- "QTc ≥ 500 ms was associated with high all-cause mortality with increased mortality in males compared with females. A new QTc mortality score [based on presence of drugs known to cause Torsade de Pointe, electrolyte abnormality, etc.] was constructed to predict mortality. Only a minority of cases with prolonged QTc > 500 ms were acknowledged in the medical records."[301]
- "86,107 ECGs were performed. ... Patients with QTc ≥ 500 ms had higher mortality than those with QTc < 500ms."[334]
- "Digital electrocardiograms from 17,529 primary care patients aged 50–90 years were collected. ... The accuracy of the personalized CVD prognosis can be improved when the QTc interval is introduced to a conventional risk model for CVD."[300]
- "Preoperative QT interval was an independent predictor of overall death and sudden cardiac death after isolated coronary bypass surgery."[335]
- "HIV+ patients have slightly but significantly longer QTc intervals compared to the general population."[336]

T-wave Morphology: Degree of IKr Block

In addition to automated QT interval measurements, GE Healthcare can quantify the shape of the T-wave in terms of the degree it is asymmetric, notched and/or flat. More specifically, this quantification is done via a product known as QT-Guard Plus, which relies on 12SL for measurement. See QT Guard Plus Physician's Guide for more details (2061747-001).

T-wave measurements available via QT Guard Plus have been correlated with many findings. See below:

- Sotalol is known for its profound effect on repolarization and its propensity to elicit Torsade de Pointes (TdP).[337] A linear combination of the T-wave shape measurements provided by GE Healthcare had a higher sensitivity than QTc to the dosage level of the drug.[38]
- "Longer T-peak to T-end interval (Tpe) implies increased risk for ventricular tachyarrhythmia (VT/VF) and mortality. ... We evaluated 305 patients with LVEF </= 35% and an implantable cardioverter-defibrillator implanted for primary prevention. ... Tpe was measured using seven different methods described in the literature, including six manual methods and the automated algorithm '12SL'. ... The automated 12SL method performs as well as any manual measurement."[338]
- "In this cohort, abnormal T wave morphology detected with the GE Healthcare QT Guard+™ accurately distinguished gene+ patients from healthy controls. This software can identify gene+ LQTS, even without QT prolongation. This may have important clinical application in ECG screening for LQTS, particularly when baseline QTc is normal."[339]
- GE Healthcare's QT dispersion and principal component analysis, have been correlated with overall mortality[244, 340-343] as well as acute ischemia.[22, 344-347]
- In an evaluation performed via the FDA, "T wave flatness, asymmetry, and the presence of notch were automatically assessed with QT Guard + (GE Healthcare, Milwaukee, WI)."[348] "T wave morphology changes are directly related to amount of hERG block; with quinidine and ranolazine, multichannel block did not prevent T wave morphology changes. A combined approach of assessing multiple ion channels, along with ECG intervals and T wave morphology may provide the greatest insight into drug-ion channel interactions and torsade de pointes risk."[348]

QRS-T Angle: Heart Failure, Mortality, etc.

QRS-T angle was first described early in the history of electrocardiography as a grave indicator.[349] Due to the difficultly of calculating it, it fell out of favor.[350] More recently, it has been confirmed to be a strong predictor of sudden cardiac death, etc.[351, 352] In any case, GE's Marquette 12SL™ Program can calculate QRS-T angle in the frontal plane or spatially. For spatial calculations, the algorithm uses a method for synthesizing XYZ that was derived from over 10,000 ECGs where both the standard scalar leads and Frank leads were simultaneously acquired for 10 seconds as described in this cited work.[37]

- "The spatial QRS-T angle, the angle between the directions of ventricular depolarization and repolarization, represents abnormal cardiac structure and electrical heterogeneities resulting in changes of the repolarization direction. Due to this, it is a strong marker of electrical instability and susceptibility to ventricular arrhythmias. ... ECGs were analyzed using the GE Marquette 12SL™ ECG Analysis Program. ... Baseline and follow-up QRS-T angle were calculated from the frontal QRS and T axis of the 12-lead surface ECG. Patients were followed for survival. A total of 2,929 heart failure (HF) patients were evaluated. Median interval between baseline ECG and follow-up ECG was 895 days, median follow-up time was 1,526 days. ... We analyzed the relation between the baseline QRS-T angle and LV systolic function. The QRS-T angle was associated with a reduction of systolic function. ... Conclusion: QRS-T angle is relatively stable in patients with HF and is a powerful predictor of outcome. Widening of the QRS-T angle has predictive value and is an ominous sign."[353]
- ECGs were analyzed with the use of the GE Marquette 12SL™ ECG Analysis Program (Marquette 12SL ECG Physician Guide). ... Frontal plane QRS-T angle was defined as the absolute value of the difference between the frontal plane QRS axis and T axis and was adjusted to an acute angle by (360°– angle) for an angle >180°. ... Patients admitted to a tertiary hospital with a clinical diagnosis of acute myocarditis were evaluated; 193 patients were included. Median follow-up was 5.7 years,

82% were male, and overall median age was 30 years (range 21–39). The most common clinical presentations were chest pain (77%) and fever (53%). … Wide QRS-T angle (≥100°) was demonstrated in 13% of the patients and was associated with an increased mortality rate compared with patients with a narrow QRS-T angle (20% vs 4%; P = .007). The rate of heart failure among patients with a wide QRS-T angle was significantly higher (36% vs 10%; P = .001). … QRS-T angle is a predictor of increased morbidity and mortality in acute myocarditis."[351]

- "During a mean follow-up of 6 years, a total of 4,127 cardiovascular deaths occurred. … Spatial QRS-T angle is a significant and independent predictor of cardiovascular mortality that provides greater prognostic discrimination than any of the commonly utilized ECG diagnostic classifications."[354]

Combining 12SL™ Measurements: Predictive Scores

One of the first and best known scores in electrocardiography is called the "Selvester Score".[355] GE Marquette was the first to computerize this score and integrate it into an electrocardiograph. Results demonstrated that it "had a high correlation with manual application (r = 0.94) and was superior regarding time, training, reader bias, reproducibility and precision of measurement."[356]

The Selvester Score primarily relies on an analysis of QRS abnormalities, especially Q waves, for the assessment of myocardial infarction (MI) size. The score was originally based on autopsy data. Other damage scores, such as Cardiac Infarction Injury Score (CIIS) [357] have focused more on acute infarction and ST/T wave changes.

In 2005, these scores (based on measurements generated by 12SL) were evaluated on 46,933 patients in relation to cardiovascular mortality.[358] During a mean follow-up of 6 years, the CIIS outperformed all other ECG classifications in determining prognosis.

Due to the reliance the Selvester score places on the subtleties of a Q-wave and, in 2012, the introduction of the third universal definition of myocardial infarction (UDMI) which incorporates Q-waves as small as 20ms in leads V2-V3 leads or Q-waves in lead I, aVL, II, or aVF that are at least 30ms wide and 100μV tall, a large study (>43,000 ECGs) was undertaken to determine the prognostic value of UDMI Q-wave criteria versus conventional Q wave criteria ≥ 40ms for the identification of prior MI. "The GE 12SL program measurements of intervals, durations, and amplitudes were used to code the presence of both UDMI and ≥40msec Q waves in all leads."[359] "The study's population were an average age of 56 (± 15) years, 90% were male, 12% were of African descent, and 74% were outpatients. There were 3,929 cardiac deaths (9.0% of the population) over a mean follow-up of 7.6 (± 3.8) years. The annual all-cause mortality was 3.3% and the annual CV mortality was 1.1%"[359] "It was found that the UDMI Q wave criteria did not outperform ≥40msec Q wave criteria with respect to predicting CV death."[359] An analysis of prior work presented in this paper found only the presence/absence of Q-waves ≥40msec as significantly associated with infarct size as determined by cardiovascular magnetic resonance (CVMR).

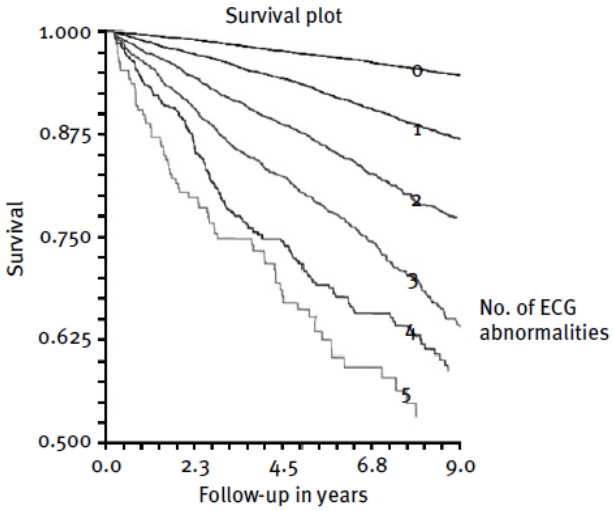
There is renewed interest in MI-sizing via ECG, since CVMR (as opposed to autopsy) provides a practical gold-standard reference for myocardial size.[360, 361] There continues to be a need for an inexpensive and accessible method for determining MI size it could have implications for finding patients which could be saved via the prophylactic use of an implantable cardiac defibrillator (ICD).[362]

Since the current method used for selecting patients for primary ICD therapy "misses ≈80% of patients who die suddenly", Strauss et. al. turned to the use of the 12-lead ECGs to test "the hypothesis that patients with elevated QRS-scores (index of myocardial scar) and wide QRS-T angles (index abnormal depolarization–repolarization relationship) would have high 1-year all-cause mortality and could be further risk stratified with clinical characteristics."[363] By leveraging MUSE, 12SL and GE Healthcare's Magellan ECG Research Workstation Software,[364] 19,750 ECGs were analyzed from patients who were not cared for in hospital areas known for a high risk of mortality (such as oncology, ICU, etc.). The study found that "QRS-scoring and QRS-T angle analysis identifies patients with high 1-year all-cause mortality and predominantly preserved left ventricular ejection fraction."[363] Based on the work published by Strauss et. al. in 2013, it appears feasible for "screening entire health system ECG databases to identify patients at increased risk of death."[363]

In addition to MI sizing, investigators with the U.S. Veteran Affairs Healthcare System (VAHS) have developed simplified predictive scores for cardiovascular mortality based on considerable study spanning more than

two decades.[365, 366] This body of work is presented in over 20 peer-reviewed articles, some including patient cohorts exceeding 40,000 U.S. veterans who have been followed for more than a decade. The first was published in 2004;[244] the most recent, fall of 2018.[314] All these studies relied upon 12SL™ measurements and GE Healthcare's MUSE™ system for data mining and export of those measurements.[244, 306, 313, 314, 322, 333, 354, 358, 359, 365-379]

In any case, their simplest approach was to just add up the number of significant abnormalities in the ECG, such as atrial fibrillation, LVH, conduction defects, Q-waves, ST-segment depression, or prolonged QT. Known as the "Simplified ECG Score", "the annual mortality rates increased proportionally with the number of ECG abnormalities. In the group with no ECG abnormalities, the annual mortality rate was 0.54%. This increased more than 10-fold in those with 5 or more abnormalities (6.7% annual mortality). After 10 y, almost 50% of the patients with an ECG score of 5 or more had died."[365] See figure below:



This could be given to primary care providers "to facilitate decision making regarding who should see a cardiologist. An elevated ECG score should heighten a physician's index of suspicion for CV risk in a patient and encourage an aggressive approach to diagnosis and patient management."[365]

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Accuracy of Interpretive Statements: Reported Results

Purpose of Reported Results: Regulatory Requirements

The Statement of Validation and Accuracy is considered official product labeling and is reviewed by the Food and Drug Administration (FDA) and the International Electrotechnical Commission (IEC). This serves as a disclosure of the accuracy of the interpretive statements generated by GE's Marquette 12SL™ Program. This contrasts with a description of how interpretive statements are generated by the program; that is the purpose of another document, known as the 12SL™ Physician's Guide: Part I – Criteria and Methodology.

In 1991, the FDA recommended that such a document as *The Statement of Validation and Accuracy* be generated for the clearance of a 1500 Series Prehospital Defibrillator[20] that incorporated GE's Marquette 12SL™ Program as the first prehospital defibrillator to provide automated analysis of the prehospital 12-lead ECG.[17] Since 1991, *The Statement of Validation and Accuracy* has periodically been updated to keep abreast of the latest scientific findings regarding the 12SL™ Program. In 2003, the IEC issued a similar request for all manufacturers of ECG analysis equipment: that is, the IEC asked the manufacturers of ECG analysis programs and equipment to report the sensitivity, specificity, and positive predictive accuracy of the interpretive statements for each of the major diagnostic categories (see 60601-2-51© IEC 2003).[1] Like the FDA, the IEC also requested that these results be published and available to the consumer. *The Statement of Validation and Accuracy* fulfills this requirement.

The 12SL™ analysis program has continually evolved since it was first introduced in 1980. Each released version of the program contains one or more changes to it and is associated with a unique version number. This number appears on the ECG report printed by the analyzing electrocardiograph. The number is also printed on each ECG from the MUSE™ system. Encoded within this number are two elements: the actual 12SL™ version number and a product specific code, which refers to the type of product used for the analysis. The 12SL™ Physician's Guide contains a table that clarifies these codes and identifies the related 12SL™ version numbers.

The 12SL™ analysis program has continually evolved since it was first introduced; only portions of the program are changed per software version. The rest of the executable is tested to ensure that it generates the same results as the last version (see above description of the development and validation process for 12SL™). Based on the 12SL™ version number, the state of revision of each portion of the program can be determined.

Scientific references and results presented in this document span a variety of dates. Portions of the program that have not been recently changed can rely on reported results that are older, and yet, remain representative of the current state of that portion of the program. Sections of the program that have recently been enhanced require more recent publications. Depending upon which portion of the program is used for a diagnostic statement, different results reported in the literature can be used to characterize the performance of that statement as long as the results were generated subsequent to any substantial change to that portion of the program. Care has been taken to ensure that results from the literature and presented in this document are representative of the current version of the 12SL™ analysis program.

Although scientific references and results presented in this document reflect the current performance of the 12SL™ Program, it would be unwise to directly extrapolate these to what will occur in a specific clinical environment. These are statistical measures, not the performance that one should expect for a single patient.

Four key accuracy measures are explained below. These are used to disclose the accuracy of the 12SL™ program in accordance with IEC requirements.

It is assumed that the true diagnosis for a patient is known (that is, the "truth"). The ECG interpretation (classification) is called a "Test". The following designations are applied to characterize the performance of a test.

- "Normal" correctly classified as "Normal" is called "True normal" (TN)
- "Normal" incorrectly classified as "Pathologic" is called "False pathologic" (FP)
- "Pathologic" incorrectly classified as "Normal" is called "False normal" (FN)
- "Pathologic" correctly classified as "Pathologic" is called "True pathologic" (TP)

Tabulation of test results

Reference	Test	
	"Normal"	"Pathologic"
"Normal"	TN	FP
"Pathologic"	FN	TP

The following equations are calculated from a two (or multi-) category test:

Sensitivity: probability that a "True pathologic" would be classified as "Pathologic"

Sensitivity = TP / (TP+FN) x 100%

Specificity: probability that a "True normal" would be classified as "Normal".

Specificity = TN / (TN+FP) x 100%

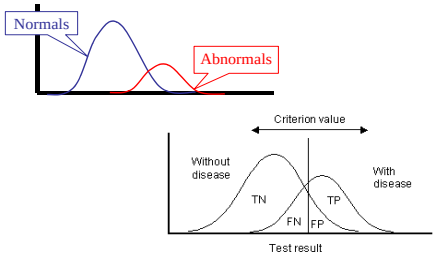
Positive predictive value (PPV): probability that a classified "Pathologic" is a "True pathologic".

PPV = TP / (TP+FP) x 100%

Negative predictive value (NPV): Probability that a classified "Normal" is a "True normal".

NPV = TN / (TN+FN) x 100%

Performance Metrics



To present performance metrics for GE's Marquette 12SL™ program, each study reported in this document uses one of the tables as presented in the following example. Note that the overall description of the study is presented in the header of the table, including the total number of ECGs for the study, the representative population or care environment where the ECGs were acquired for the study, and the independent scientific method used for verifying the disease or pathology. (See IEC 60601-2-51 clauses 50.102.3.1 and 50.102.3.2).

In the following example, 110 ECGs were collected in an emergency department from patients with chest pain of unknown origin. Each patient was tested for cardiac Troponin, a very sensitive and specific indicator of an acute myocardial infarction (AMI). Such details of the study and the method used to verify the diagnosis can be pursued via the bibliography reference associated with the title of the table. In this example, only 10 patients were positive for Troponin. As a result, under the column labeled "N", the number "10" appears in

the row labeled as acute myocardial infarction. "N" is the number of patients that have been verified for a particular diagnosis, "N" has nothing to do with number of ECGs that were positive or negative for the recognition of AMI. In this specific example, the program correctly identified 4 of the 10 patients as having an AMI. As a result, the sensitivity for the program is listed as 40%. Note: this does not necessarily mean that the program made an ECG interpretation error on the other 6 patients. It could mean that the ECG did not reveal any ST elevation. From the remaining 100 patients that were negative for Troponin, the program falsely recognized 1 as being an AMI. As a result, the specificity is listed as 99%. Since a total of 5 patients were called AMI by the program, but only 4 were correct, the positive predictive value is 80%.

Example: Study "A"[Ref A]

Representative test population:		Emergency department, patients with chest pain of unknown origin.		
Additional demographic data:		85 Men / 25 Women, ages 47- 84; Information on race is unavailable		
Total number of test ECGs:		110		
Method(s) used to verify diagnosis:		Troponin		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Acute Myocardial Infarction	10	40	99	80

Also notice that the tables indicate that this is a "test population" and that these are "test ECGs" or a validation set. This is an important distinction for the reporting of performance of the automated recognition of disease: that is, the term test ECG / validation set means that GE's Marquette 12SL™ program was not trained with the data that was collected for the study. The study provided results on a test set, not a training set. Typically, the performance of program will be worse on a test set than a training set.

The tables in this document report sensitivity, specificity, positive predictive accuracy (PPA) and, sometimes, negative predictive accuracy (NPA). Depending on the distribution and prevalence of disease in a population, a high-level of specificity may be more important than a high level of sensitivity. In the above example, there are only 10 individuals with the disease out of a population of 110. A 10-point drop in specificity would lead to many more mistakes (10% of 100 results in 10 mistakes) as opposed a 10-point drop in sensitivity (10% of 10, results in 1 mistake). It may be important to find every sick individual if a particular therapy can be applied that cures the disease but is not detrimental to the healthy individual. In this case, a high sensitivity, which typically results in a loss in specificity, may be warranted if there is no risk for treating a false positive, healthy individual. These issues are beyond the scope of this document but are discussed in the literature.[380, 381]

Interpretation of Rhythm: Reported Results

This section provides performance metrics as reported in the literature regarding rhythm interpretations generated by GE's Marquette 12SL Program. Results are reported for the following major rhythms: sinus, ectopic atrial rhythm, atrial tachycardia, atrial fibrillation, atrial flutter, junctional rhythm, and artificially paced. In addition, results are reported for the following rhythm modifiers: 1st degree AV block, 2nd AV block, 3rd AV block, and premature atrial / ventricular beats. The IEC also requires manufacturers to disclose rhythms, without reported results, due to their low rate of prevalence. (See IEC 60601-2-51 clause 50.102.4.1). For 12SL™, these include idioventricular rhythm, ventricular tachycardia, ventricular fibrillation, and wandering atrial pacemaker as well as statements regarding escape or fusion beats. Also, no reported results exist for interpretations regarding the rate or character of AV conduction during atrial fibrillation or atrial flutter.

Artificially Paced Rhythms

Several studies have evaluated the performance of GE's Marquette 12SL Program for appropriate detection and analysis of paced rhythms with and without GE Healthcare's high definition (HD) pacemaker detection technology. Regardless of whether HD technology is present, pacemaker detection is performed before any other rhythm analysis is performed.

Presented below is a comparison of pacemaker detection performance obtained during a prospective clinical trial, with and without high definition (HD) pacemaker detection technology. As opposed to other studies that have evaluated pacemaker detection performance based on what the human reader can see, the gold standard reference for measuring the accuracy of the detection was determined via information obtained from the pacemaker programmer. Notice when using HD, the sensitivity (SE) significantly increases with a 100% positive predictive value (PPV) in all recording environments.[36] With HD capability, 12SL can also state the presence of a biventricular pacing / cardiac resynchronization therapy (CRT).

Comparison of pace detection with and without HD technology[36]

All subjects		***High Definition***		***Conventional***	
Recording environment	# of ECGs	SE	PPV	SE	PPV
Baseline	88	100%	100%	76.4%	100%
Baseline + 2X settings	176	99.2%	100%	83.2%	99.9%
Extreme	352	88.7%	100%	41.5%	94.3%
Overall	528	92.4%	100%	56.0%	97.1%
CRT subjects only		***High Definition***		***Conventional***	
Recording environment	# of ECGs	SE	PPV	SE	PPV
Baseline	15	100%	100%	56.6%	100%
Baseline + 2X settings	30	98.8%	100%	69.6%	99.9%
Extreme	60	91.4%	100%	39.5%	96.1%
Non-CRT subjects only		***High Definition***		***Conventional***	
Recording environment	# of ECGs	SE	PPV	SE	PPV
Baseline	73	100%	100%	83.6%	100%
Baseline + 2X settings	146	99.3%	100%	91.1%	99.9%
Extreme	292	87.7%	100%	42.1%	93.8%

The recording environments included the following:

- "Baseline" implies routine clinical environment with patient's pacemaker settings at routine levels.
- "Baseline + 2X settings" means this is repeated at routine levels and at 2x their routine clinical levels in a pacemaker laboratory.
- "Extreme" includes 4 recordings. First the pacemaker settings are below their routine clinical settings then extreme noise is introduced into the ECG via the following three sources: turning on all 3 pacemaker programmers to generate RF noise, patient marching in place or V3 continuously tapped.

In addition to detecting biventricular pacing, 12SL version 22 and higher identifies the underlying rhythm. This is important to consider since, as reported by Guglin et. al., for ECGs with artificial pacing, "computer-drawn interpretations required revision by cardiologists in 61.3% of cases." In 18.4% of cases, a pacemaker was not detected. "The most common error in computer reading was the failure to identify an underlying rhythm."[89]

In 2001, before the advent of HD technology, 12SL was evaluated on 100 consecutive patients seen in a device clinic who were asked to participate in the study.

Evaluation of Pacemaker Detection without HD[382]

Representative test population:		Pacemaker clinic, Large hospital		
Additional demographic data:		Implanted devices included 44 single and 56 dual chamber devices (41 ICDs; 59 pacemakers; 92 bipolar leads). Pulse width settings ranged between 0.3 ms and 3.0 ms and voltage settings ranged between 0.9 and 6.0 V. Specific ages, gender and race are unavailable		
Total number of test ECGs:		372		
Method(s) used to verify diagnosis:		Patient History, Pacemaker Programmer		
Rhythm category	*N*	*Sensitivity (%)*	*Specificity (%)*	*Positive predictive value (%)*
Paced	200	87	100	100

Similarly, in 2002, a prospective trial was done at a different institution on 100 pacemaker clinic patients. ECGs

Evaluation of Pacemaker Detection without HD[383]

Representative test population:		Pacemaker clinic, Large hospital		
		Specific ages, gender and race are unavailable		
Total number of test ECGs:		389		
Method(s) used to verify diagnosis:		Patient History, Pacemaker Programmer		
Rhythm category	*N*	*Sensitivity (%)*	*Specificity (%)*	*Positive predictive value (%)*
Paced	235	87	99.4	99.5

In 2006, a large study was conducted that focused solely on pacemaker recognition and rhythm interpretation in the presence of electronic pacemakers without using HD technology. "Of the 7,834 consecutive ECGs screened, a pacemaker (PM) was identified by the computer, the cardiologists, or both in 205 ECGs. The cardiologists detected an electronic pacemaker in 201 tracings, whereas the computer detected one in 168 tracings. In 4 ECGs that were read as having an electronic pacemaker by computer, no pacemaker was present according to both cardiologists. In 164 (80.0%) of 205 ECGs, both computer and cardiologists agreed upon the presence of an electronic pacemaker. The sensitivity of recognizing a pacemaker by computer was 82.0%, and the specificity was 99.9%. In 37 cases, the algorithm failed to recognize the presence of a pacemaker. A common error was missing the ventricular spike (16 cases). Other errors included missing both the atrial and ventricular spikes (10 cases) and, rarely, the atrial spikes alone (4 cases)."[384]

Evaluation of computer analysis of pacemaker (PM) rhythms without HD[384]

Representative test population:		VA Hospital Inpatients & Outpatients		
Additional demographic data:		Specific ages, gender and race are unavailable		
Total number of test ECGs:		7834		
Method(s) used to verify diagnosis:		Confirmation by 2 cardiologists		
Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Paced ECG	205	82.0	99.9	96

The article concludes that, "automated computer ECG reading algorithms are useful tools for ECG interpretation, but they need further refinement in recognition of electronic pacemakers (PM). In 61.3% of ECGs with electronic PM, computer-drawn interpretation required revision by cardiologists. In 18.4% of cases, the ECG reading algorithm failed to recognize the presence of a PM. Misinterpretation of paced beats as intrinsic beats led to multiple secondary errors, including myocardial infarctions in varying localizations. The most common error in computer reading of ECGs with PMs is the failure to identify an underlying rhythm."[384]

Poon reported similar results for the analysis of paced tracings before the advent of HD. Quoting from the article: "The most common errors were related to interpretive statements involving patients with pacemakers: of 343 ECGs with pacemaker activity comprising 8.0% of the study ECGs, 75.2% (258/343) required revision, so that 45.7% of all inaccurate rhythm statements in this population occurred in patients with pacemakers. Overall, 13.2% (565/4297) of computer-based rhythm statements required revision, but excluding tracings with pacemakers, the revision rate was 7.8% (307/3954)."[88]

Given the need for improvement in both detection low energy artificial pacing as well as identification of underlying rhythms in the presence of artificial pacing, GE Healthcare developed and released the following:

- HD for detection of low energy pacing as well as bi-ventricular pacing.[36, 55-57]
- When HD technology is present, pacemaker annotations (including indications of biventricular pacing) are supplied at the MUSE™ system. In accordance with AHA/ACC/HRS recommendations, these annotations are supplied separately from the waveform in a "single row of the standard output tracing."[51] Some GE Healthcare electrocardiographs can supply this information, in real-time, while printing or displaying a rhythm strip.
- 12SL version 22 or higher for the detection and description of underlying rhythms in the presence of artificial pacing, regardless if HD technology is present.

Asynchronous P-Wave Detection via QRS Subtraction

Interpretation of cardiac rhythms is highly dependent on accurate detection of atrial activity. As a result, improved P wave detection has been a major pursuit of GE Healthcare.[385-387] Since 1998, a sophisticated tool, called MacRhythm, was incorporated into GE's Marquette 12SL™ Program for the detection of asynchronous P waves, hidden within the QRS or T wave.[105]

Previous versions of the program, which did not incorporate the QRS subtraction tool for P-wave detection, have been evaluated for rhythm interpretation accuracy and reported in the literature.[388, 389] The metrics in all tables presented below are from the later versions of the program, which incorporated MacRhythm.

The value of the QRS subtraction tool was prospectively tested on 10,761 ECGs.[26] Quoting from the study:

- "For three of the abnormal rhythms, namely, atrial fibrillation, junctional rhythms, and second-degree atrioventricular blocks, MAC-RHYTHM gave significantly higher sensitivity in both prospective (87.5%, 92.2%, and 80.8%, respectively) and retrospective (82.0%, 81.2%, and 79.6%

respectively) testing than the [old program] (65.0%, 39.6%, and 12.0% respectively). Similarly, for sinus rhythms, MAC-RHYTHM had significantly higher specificity (prospective, 91.0% and retrospective, 91.7%) than the [old program] (86.5%). The specificity for the abnormal rhythms remained very high with MAC-RHYTHM (prospective, 99.4% to 99.7% and retrospective, 99.1% to 99.7%) compared to the [old program] (99.0% to 99.9%)."

Prospective study using MAC-RHYTHM.[26]

Representative test population:	Hospital, all departments
Additional demographic data:	Adult population; Specific ages, gender and race are unavailable.
Total number of test ECGs:	10,761
Method(s) used to verify diagnosis:	Confirmed by experienced cardiologist.

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*NPA (%)*	*PPA (%)*
Sinus rhythms	9,324	98.7	91.0	91.5	98.6
Atral fibrillation	832	87.5	99.4	99.0	92.4
Atrial flutter	106	76.4	99.7	99.8	71.7
Junctional	64	92.2	99.5	100.0	52.7, (72.8)•
2nd-degree AV blocks	26	80.8	99.6	100.0	32.8

Since the addition of the QRS subtraction tool, several enhancements were made to the P wave detector. This included spectral analysis for the detection of atrial flutter; optimal lead selection for P wave detection; and T wave alignment to reduce subtraction artifact in the residual signals used to create a P wave detection function.[106]

As published in the literature,

> *"Performance was assessed using a test set of 69,957 confirmed ECGs from four hospitals. The rhythm interpretation in the confirmed ECG was compared to the rhythm interpretations from the previous and new versions of the program. The rate of disagreements between the confirmed rhythm and the computerized interpretation decreased from 6.9% to 4.1%. Sensitivity improved for sinus, atrial fibrillation, atrial flutter, and junctional rhythms, while specificity and positive predictive value improved for all arrhythmias."[106]*

• After excluding paced ECGs with failed pace detection.

Four hospitals, random selection of ECGs[106]

Representative test population:	Four hospitals, all departments
Additional demographic data:	Randomly selected, adult population. Specific ages, gender and race are unavailable.
Total number of test ECGs:	69,957
Method(s) used to verify diagnosis:	Routine confirmation by cardiologists

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*Positive predictive value (%)*
Sinus	62397	98.2	85.5	98.3
Atrial fibrillation	5163	89.0	99.4	91.9
Ectopic atrial rhythm	1066	35.2	99.7	63.4
No P waves	635	63.1	99.1	38.1
Atrial flutter	576	55.0	99.6	50.7
2nd/3rd degree AVB	120	49.1	99.6	18.1

Recently, Poon[88] analyzed the interpretation performance for rhythm on 3,954 non-paced ECGs analyzed by 12SL. As quoted from the literature, "Our findings differ only modestly from the corresponding performance characteristics for sinus rhythm, atrial fibrillation, and atrial flutter recently reported by Farrell et al."

Evaluation in done in 2005 at NY Presbyterian Hospital [88]

Representative test population:	University hospital
Additional demographic data:	Consecutive inpatient and outpatient ECGs over a 3-week period. Specific ages, gender and race are unavailable.
Total number of test ECGs:	4297
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

Rhythm category	*N*	*Sensitivity (%)*	*Specificity (%)*	*Positive predictive value (%)*
PRIMARY RHYTHMS				
Sinus	3579	98.7	90.1	99.0
Atrial fibrillation	250	90.8	98.9	84.7
Atrial flutter	41	61.0	99.9	83.3
Atrial tachycardia	36	2.8	99.9	25.0
RHYTHM MODIFIERS				
Premature atrial complexes	212	64.2	99.5	87.2
Premature ventricular complexes	162	82.7	99.1	80.2

In another study, a total of 2,194 consecutive ECGs from 1,856 patients were collected from a tertiary care VA Hospital from both inpatients and outpatients. The results for rhythm analysis are summarized below. Not all rhythms, for example sinus rhythms, were reported in the study.

Evaluation of rhythm analysis done in 2006 at tertiary care, VA Hospital[219]

Representative test population:	Tertiary care, VA Hospital Inpatients & Outpatients
Additional demographic data:	Age ranged from 33 to 96 years (mean 73.5). Nearly all of them (98.3%) were male. Information on race is unavailable.
Total number of test ECGs:	2194 from 1856 patients
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
PRIMARY RHYTHMS				
Atrial fibrillation	67	76.1	99.6	85.0
Atrial flutter	41	65.9	99.9	93.1
Permanent pacemaker	56	73.2	99.9	93.2
2nd degree AV block	1	100	99.7	14.3
RHYTHM MODIFIERS				
1st degree AV block	138	97.8	99.7	95.7
Premature ventricular complexes	150	94.0	99.5	94.0
Premature atrial complexes	94	66.0	99.5	86.1

In another study, ECGs were acquired from symptomatic patients with isolated pulmonary hypertension. The blinded and un-blinded cardiologist and computer program analysis agreed regarding the rate and rhythm in each case (n=64). Sinus rhythm was present in 96.9% of patients; one patient had an ectopic atrial rhythm and one had a junctional rhythm. The heart rate averaged 84.1 ± 15.5 b/min. Sinus bradycardia was present in 5, sinus tachycardia in 6, and first degree atrioventricular block in 7 patients; 2 patients had a complete right bundle branch block.[390]

ECGs from symptomatic patients with pulmonary hypertension[390]

Representative test population:	University hospital, Patients with pulmonary hypertension
Additional demographic data:	64 consecutive symptomatic patients; 12 M, 52 F, mean age 43 ± 13yr. Race is unavailable.
Total number of test ECGs:	64
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
PRIMARY RHYTHMS				

Sinus	62	100	100	100
Ectopic atrial rhythm	1	100	100	100
Junctional Rhythm	1	100	100	100
RHYTHM MODIFIERS				
1st degree AV Block	7	100	100	100
BBB	2	100	100	100

Note that the studies yield similar results, despite the different locations and environments. This increases the confidence that these results will be reproducible in other populations.

In addition to these studies, an evaluation of the clinical consequences of misdiagnosed atrial fibrillation by a computer was performed at Henry Ford Hospital in Detroit, Michigan. A total of 2298 ECGs were identified with a computerized diagnosis of atrial fibrillation by GE Marquette 12SL™ Program. Of these 2,298 ECGs, 442 (or 19%) from 382 (35%) of the 1085 patients had been incorrectly interpreted as atrial fibrillation. The paper did not report the total number of true atrial fibrillation ECGs across the entire sampled population, only the number of "true positives" and "false positives" from the computerized interpretation. Only the positive predictive value may be calculated. In 92 patients (that is, 24% of the inaccurate computerized interpretations), the physician ordering the ECG, failed to correct the inaccurate interpretation. Clinical consequences of this misdiagnosis are presented in the paper as well as in this document (see Clinical Impact due to Computer Error). The conclusion of this work is that greater efforts should be directed toward educating physicians about the electrocardiographic appearance of atrial dysrhythmias and the recognition of confounding artifacts.

Evaluation of Misdiagnosis of Atrial Fibrillation by Computer[91]

Representative test population:		Large, university hospital
Additional demographic data:		The mean age of these 382 patients was 74 ± 14 years, and 49% (n =188) were men. Only a minority of patients complained of palpitations (n=22) or dizziness (n = 44) at the time of the index ECG; the remaining patients were asymptomatic. Thirty-one percent (n = 120) of patients had a prior history of atrial fibrillation. Information on race is unavailable.
Total number of test ECGs:		2298
Method(s) used to verify diagnosis:		Patient chart and follow-up
Rhythm category	***N***	***Positive predictive value (%)***
Atrial fibrillation	2298	81.0

This value of 81% for the positive predictive accuracy for the computerized recognition of atrial fibrillation is lower but comparable to the other studies presented here. Noise in the ECG tracing is a confounding factor in this study. Note that 38% of the misinterpretations by both the computer and physician were due to artifact.[91, 391] Quality control of noise is a critical factor for proper ECG interpretations by both the physician and computer.[33, 272]

Interpretation of Rhythm in Pediatric Population

Recently, two studies have evaluated pediatric populations. The first was in an emergency department (ED); the other was across a large pediatric hospital.

In the first study, a total 294 cases were evaluated.[227] The patients ranged in age from 5 days to 21 years. The ED physicians interpreting the ECGs were directly involved in the patients' care and were familiar with the presenting complaint, past medical history, and physical examination. Physicians were allowed to use

whatever means available to aid with ECG interpretation. The physicians were blinded to the computer interpretations. The reference standard was the ECG interpretation by a pediatric electrophysiologist.

Each electrocardiographic diagnosis, as well as the ECG as a whole, was assigned to one of the following predetermined classes: I, normal sinus rhythm; II, minimal clinical significance; III, indeterminate clinical significance; IV, those of definite clinical significance.

Both the computer and ED physician correctly interpreted all normal (class I) ECGs correctly (that is, normal sinus rhythm / normal ECG). The computer correctly diagnosed class II ECGs 82% of the time as compared to 67% by the ED physicians ($p<0.001$). The computer was also significantly more accurate than the ED physicians regarding the class III diagnoses, correctly interpreting 73% compared to 30% by the physicians ($p<0.001$). Regarding the individual class IV ECG diagnoses, the ED physicians were more accurate than the computer (28% vs 14%), but this difference did not reach significance ($p>0.3$).

Pediatric rhythm interpretation resulted in most computer errors in this study. "Despite its superior ability to accurately interpret many of the simple rhythm disturbances, the computer was less accurate than the ED physicians with regards to interpreting ECGs with abnormal supra-ventricular rhythms. Specifically, the computer failed to identify all 4 ECGs with junctional rhythm, 2 of 4 with supraventricular tachycardia, and 2 with intraatrial reentry tachycardia."[227]

This study did not assess specificity. "The over interpretation of ECGs by either the computer or ED physicians was not evaluated in this study."[227] As a result, the results of this study cannot be represented in the table recommended by the IEC.[1]

The second study evaluated 56,149 pediatric ECGs.[392] From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure balanced representation in terms of age, sex, etc. This resulted in a sample size of 1,147 ECGs. The reported results for rhythm are presented below:

Evaluation of pediatric rhythm interpretation[392]

Representative test population:	Large pediatric hospital
Additional demographic data:	Median age at the time of ECG was 3.0yrs, in the heart disease group, and 6.0yrs, in the group without heart disease. Race and gender are unavailable.
Total number of test ECGs:	1,147 (sampled from 56,149)
Method(s) used to verify diagnosis:	Confirmation by 2 pediatric cardiologists

Rhythm category	*N*	*Sensitivity (%)*	*Specificity (%)*	*Positive predictive value (%)*
Sinus Rhythm in presence of Heart Disease	399	95.5	99	99
Sinus Rhythm in normal group	390	98.5	100	100
Sinus Arrhythmia in presence of Heart Disease	31	87	100	100
Sinus Arrhythmia in normal group	51	88	100	100
Sinus Rhythm with Ectopy in Heart Disease group	10	100	98.5	56
Sinus Rhythm with Ectopy in normal group	22	100	98	69

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Contour Interpretation: Reported Results

Below are the reported results for the following abnormalities:

P-wave Abnormalities,237
QRS Abnormalities,237
Repolarization Abnormalities: Reported Results,250

P-wave Abnormalities

This section provides performance metrics, as reported in the literature, for interpretation of right and left atrial abnormalities.

Evaluation of right and left atrial abnormality at tertiary care, VA Hospital[219]

Representative test population:		Tertiary care, VA Hospital Inpatients & Outpatients		
Additional demographic data:		Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.		
Total number of test ECGs:		2,194 from 1,856 patients		
Method(s) used to verify diagnosis:		Confirmation by 2 cardiologists		
P Wave Abnormality	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Right	29	100	99.9	97
Left	97	95.9	100	100

QRS Abnormalities

This section provides performance metrics, as reported in the literature, for the computerized interpretation of QRS abnormalities. These include: right bundle branch block (RBBB), left bundle branch block (LBBB), left ventricular hypertrophy (LVH), right ventricular hypertrophy (RVH) as well as healed anterior and/or inferior myocardial infarction.

The IEC also requires manufacturers to disclose those QRS abnormalities without reported results. (See IEC 60601-2-51 clause 50.102.3.1). These include the following statement categories: Wolff-Parkinson-White (WPW), QRS axis deviation abnormalities, hemi-blocks, low-voltage QRS, Brugada pattern and pulmonary disease pattern. In addition, isolated lateral or posterior myocardial infarctions have no reported results; instead, these statements are grouped with inferior or anterior myocardial infarctions.

At Mount Sinai Medical Center in New York City, over 39,000 ECGs were reviewed for computer accuracy.[220]. The cardiologist was used as the reference, since interpretative statements regarding conduction are Type B statements.

A detailed inspection of the data from the Mount Sinai study showed that the cardiologist often changed the computer diagnosis to LBBB (n=97) from another conduction abnormality already stated by the program (like ILBBB or nonspecific intraventricular conduction block). If these other conduction abnormalities were included as part of the analysis, the sensitivity would increase from 78% to 88%.

Independent Assessment of Conduction Abnormalities[220]

Representative test population:	Hospital, all departments
Additional demographic data:	Ages, gender and race are unavailable.
Total number of test ECGs:	39,000
Method(s) used to verify diagnosis:	Confirmed by cardiologists.

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
RBBB	1661	90	100	100
LBBB	860	78	100	100
LBBB (grouped w/ ILBBB, IVCB)	860	88	100	100

At the Mayo clinic, the 12SL™ program was evaluated to determine whether it could replace an ECG program, based on XYZ Leads, with the 12SL™ program, which is based on the scalar 12-lead ECG.[393] In a similar fashion as the aforementioned study, over 12,000 ECGs were evaluated at the Mayo Clinic. See table below.

Independent Assessment of Conduction Abnormalities[394]

Representative test population:	Hospital, all departments
Additional demographic data:	Ages, gender and race are unavailable.
Total number of test ECGs:	12,793
Method(s) used to verify diagnosis:	Confirmed by cardiologists.

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
RBBB	391	91	100	100
LBBB	248	87	99.9	99.9

In another study,[219] ECGs were collected in a tertiary care facility from both inpatients (36.4%), outpatients (47.6%) and in the emergency room (16.0%). There were 2,194 consecutive ECGs recorded on 1856 patients. Two cardiologists read the ECGs. Of the 2,194 tracings, 122 were excluded from analysis because of a disagreement between the cardiologists' interpretations. Out of 2072 remaining cases, 776 (37.5%) the computer interpreted as normal and 1296 as abnormal. In 206 cases, there were discordances between the computer and cardiologists' interpretation (9.9%). There were no discordances in the ECGs interpreted as normal by the computer. The discordances occurred in 15.9 % of all ECGs read as abnormal. Conduction abnormalities were also evaluated as part of this study. The results are reported below:

Independent Assessment of Conduction Abnormalities by 2 Cardiologists[219]

Representative test population:	Hospital, all departments
Additional demographic data:	Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.
Total number of test ECGs:	2072
Method(s) used to verify diagnosis:	Confirmed by 2 cardiologists.

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
RBBB	118	93.2	99.8	96.5
LBBB	33	90.9	99.9	90.9

RBBB in a pediatric population is exhibited in a narrow QRS. This diagnosis was evaluated at a pediatric hospital using 56,149 ECGs stored on a MUSE™ system. From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure a balanced representation. This resulted in a sample size of 1,147 ECGs. RBBB is a Type B statement and can be validated by a pediatric cardiologist.

Assessment of RBB in a Pediatric Population[392]

Representative test population:	Hospital, all departments
Additional demographic data:	Median age at the time of ECG was 3.0yrs, in the heart disease group, and 6.0yrs, in the group without heart disease. Race and gender are unavailable.
Total number of test ECGs:	1,147
Method(s) used to verify diagnosis:	Confirmed by 2 pediatric cardiologists.

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
RBBB	123	79.6	99.8	99

Left ventricular hypertrophy (LVH) is often assumed to be little more than a marker of hypertension. LVH can occur in the normotensive, especially in the presence of other risk factors such as diabetes.[395] More importantly, it has been found in a large survey of over 7,000 individuals that although normotensives with LVH were rare, they had similar survival rates "to hypertensive adults with LVH and lower survival rates than normotensive and hypertensive adults with no LVH."[396] Not all patients with hypertension develop LVH. Yet once it has been identified in the hypertensive patient it is, other than age, "the most potent predictor of adverse cardiovascular outcomes."[397] Guidelines for the management of arterial hypertension now recognize the substantial clinical evidence of treatment-induced reductions in LVH accompanied by a reduced incidence of cardiovascular events,[398, 399] which makes the detection of LVH "advisable not only to quantify total cardiovascular risk initially but also to monitor treatment-induced protection."[400] It has become "increasingly important to identify left ventricular hypertrophy and prescribe a combination of therapies which facilitates regression to improve patients' symptoms and prognosis."[401]

When using echocardiography (ECHO) to detect LVH, the prevalence has been found to be high in the hypertensive population - from 20 to 60% - depending upon the presence of other risk factors and the setting where the test was done.[402] A review of ECG-based LVH criteria demonstrates that the ECG detects less than half of those found positive via ECHO, leading to the conclusion that "electrocardiographic criteria should not be used to rule out left ventricular hypertrophy in patients with hypertension."[402]

The ECG continues to have an important role in care areas that neither can afford the ultrasound instrumentation nor the trained personnel to perform an accurate ECHO. Current care guidelines for the

management of arterial hypertension define LVH as detected via the ECG as sufficient evidence to require different care pathway for specific patients versus that based on blood pressure alone.[400, 403]

It should also be appreciated that ECHO and ECG measure different aspects of LVH. Although an ECHO provides a macroscopic view of the enlarged heart, it does not provide a view of the microscopic changes in the cellular substrate, which can impact conduction and repolarization.[404-406] ECHO-LVH and ECG-LVH independently predict mortality as well as other cardiovascular events, "implying that ECHO-LVH and ECG-LVH carry different prognostic information."[407] This becomes especially apparent when the disease has progressed to the point where the ECG exhibits signs of electrocardiographic "strain", which is associated with an increased risk of mortality[374] as well as developing congestive heart failure (CHF) and "dying as a result of CHF, even in the setting of aggressive blood pressure lowering."[330] Even when an ECHO is available, some have concluded that both an ECHO and ECG are necessary for a complete assessment of the risk due to LVH.[407, 408]

For identifying LVH, the latest version[⊥] of GE's Marquette 12SL program incorporates the following commonly used criteria that have been extensively validated and reported in the literature:

- Sokolow-Lyon*
- Romhilt-Estes
- Cornell Product

A systematic review of the literature before 2007,[402] identified studies that assessed these aforementioned electrocardiographic criteria in hypertensive adults against echocardiography for whom sufficient data were available for not only reporting sensitivity and specificity but the actual number of true positives (TP), false positives (FP), true negatives (TN) and false negatives (FN) . The authors evaluated the quality of these studies based on "the methods of patient selection and data collection, completeness of descriptions of index and reference tests, completeness of blinding, and the likelihood of verification bias." Studies were ranked as being of high quality if they "described the setting (for example, family physicians referring patients to the clinic); collected data prospectively, with enrolment of consecutive patients and follow-up of all patients, including those who did not have echocardiography; and provided details on echocardiography and whether the assessor of the echocardiography was unaware of the electrocardiogram result or vice versa." In accordance with IEC requirements, below are the reported results from those studies of the highest quality that included at least 250 patients and evaluated more than one of the ECG-based LVH criteria used by 12SL.

Sokolow-Lyon criteria versus ECHO (from Lee, 1992)[402]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 270 patients, mean age = 54, 69% men Prevalence of LVH = 23%		
Total number of test ECGs:		270		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 131; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	61	15	86	30

[⊥] Previous versions of the 12SL program used a modification of the Romhilt-Estes criteria

* R in aVL > 11mm should be assumed to be part of the Sokolow-Lyon criteria

Cornell Product criteria versus ECHO (from Lee, 1992)[402]

Representative test population:	Primary Care / Office setting
Additional demographic data:	Mixed black and Caucasian US population 270 patients, mean age = 54, 69% men Prevalence of LVH = 23%
Total number of test ECGs:	270
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 131; women ≥ 110

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
LVH	61	5	96	30

Romhilt Estes criteria ≥ 5 points versus ECHO (from Lee, 1992)[402]

Representative test population:	Primary Care / Office setting
Additional demographic data:	Mixed black and Caucasian US population 270 patients, mean age = 54, 69% men Prevalence of LVH = 23%
Total number of test ECGs:	270
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 131; women ≥ 110

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
LVH	61	7	97	66

Sokolow-Lyon criteria versus ECHO (from Crow, 1995)[402]

Representative test population:	Primary Care / Office setting
Additional demographic data:	Mixed black and Caucasian US population 834 patients, mean age = 55, 61% men Prevalence of LVH = 15%
Total number of test ECGs:	834
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 134; women ≥ 110

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
LVH	128	8	97	53

Cornell Product criteria versus ECHO (from Crow, 1995)[402]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 834 patients, mean age = 55, 61% men Prevalence of LVH = 15%		
Total number of test ECGs:		834		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 134; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	128	11	97	61

Romhilt-Estes ≥ 4 points versus ECHO (from Crow, 1995)[402]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 834 patients, mean age = 55, 61% men Prevalence of LVH = 15%		
Total number of test ECGs:		834		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 134; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	128	16	98	54

Sokolow-Lyon criteria versus ECHO from Verdecchia, 2000[409]

Representative test population:		Hospital / tertiary care		
Additional demographic data:		Caucasian, Italy 947 patients, mean age = 60, 59% men Prevalence of LVH = 27%		
Total number of test ECGs:		947		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 125; women ≥ 125		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	258	16	93	45

Cornell Product criteria versus ECHO from Verdecchia, 2000[409]

Representative test population:	Hospital / tertiary care
Additional demographic data:	Caucasian, Italy 947 patients, mean age = 60, 59% men Prevalence of LVH = 27%
Total number of test ECGs:	947
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 125; women ≥ 125

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
LVH	258	20	91	46

Romhilt-Estes criteria versus ECHO from Verdecchia, 2000[409]

Representative test population:	Hospital / tertiary care
Additional demographic data:	Caucasian, Italy 947 patients, mean age = 60, 59% men Prevalence of LVH = 27%
Total number of test ECGs:	947
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 125; women ≥ 125

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
LVH	258	8	97	47

Skolow-Lyon criteria versus ECHO from Salles[410]

Representative test population:	Hospital / tertiary care
Additional demographic data:	Caucasian and black, UK 471 patients, mean age = 60, 28% men Prevalence of LVH = 81%
Total number of test ECGs:	471
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 116; women ≥ 104

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
LVH	383	20	85	85

Cornell Product criteria versus ECHO from Salles[410]

Representative test population:	Hospital / tertiary care
Additional demographic data:	Caucasian and black, UK 471 patients, mean age = 60, 28% men Prevalence of LVH = 81%
Total number of test ECGs:	471
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 116; women ≥ 104

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
LVH	383	32	85	90

Subsequent to the review article published by Pewsner et al.,[402] it has been demonstrated that a composite of different voltage criteria used by 12SL™ for detecting LVH "may be a useful strategy to further increase the diagnostic ability of ECG." [411] In any case, the approach used by 12SL for the assessment of LVH conforms to the following recommendations made by the ACC:[412]

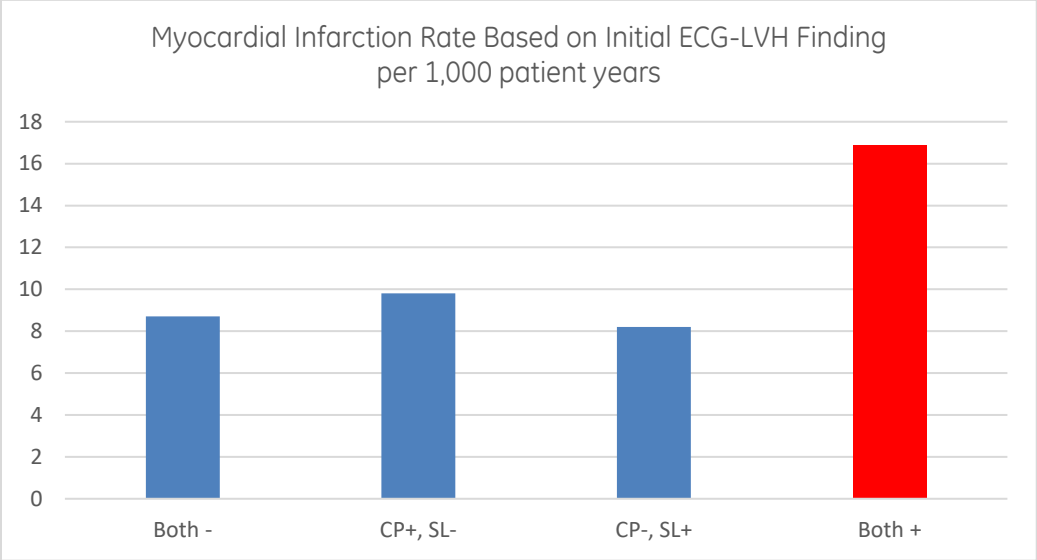
1. Interpretation of ECGs for LVH should utilize only validated criteria without deviation from the validated formulas
2. No single diagnostic criterion can be recommended for use compared with the others
3. Computer systems should utilize all criteria that are supported by valid evidence for identifying left ventricular hypertrophy.
4. Interpretations should specify which diagnostic criteria were used and which were abnormal (and thereby, by exclusion, which were examined but not found to be abnormal).

In 2017, a study by Okin et. al. found that in 9,193 patients followed 4.8±0.9 years, "persistence or development of ECG LVH by both Cornell product (CP) and Sokolow-Lyon (SL) voltage criteria during antihypertensive therapy is associated with markedly increased risks of cardiovascular end points and all-cause mortality."[49] "Compared with the absence of ECG LVH by both criteria, persistence or development of ECG LVH by both criteria entered as a time-varying covariate was associated with >3-fold increased risks of events in multivariable Cox analyses adjusting for randomized treatment, baseline risk factors, and on-treatment heart rate and systolic and diastolic blood pressures. Patients with ECG LVH by either Cornell product or Sokolow-Lyon voltage had 45% to 140% higher risks of all end points."[49]

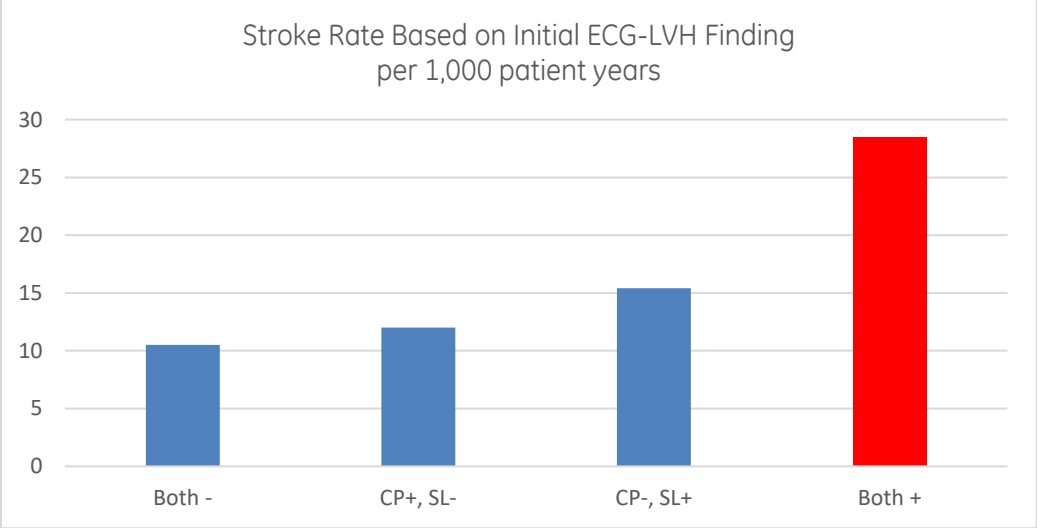
This paper by Okin et. al. also reiterated "the well-recognized limited sensitivity of any one ECG LVH criterion as compared with imaging modalities."[49] Given that serial ECG testing is inexpensive, this study suggests "that serial assessment of both CP and SL can improve risk stratification in patients with hypertension during treatment."[49]

Below, in graphical form, are some of the outcomes measured via this study. See full paper for completeness.[49]

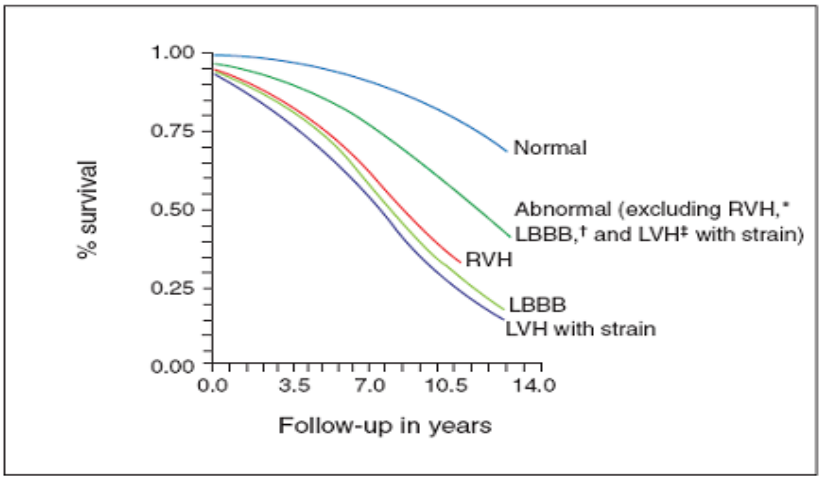
Impact of Combining Cornell and Sokolow Lyon: MI rate[49]



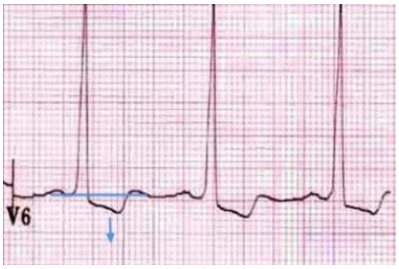
Impact of Combining Cornell and Sokolow Lyon: Stroke rate[49]



GE's Marquette 12SL™ interpretation was evaluated in terms of its prognostic value on 26,734 male and 3,737 female veterans.[244] The computerized interpretation was used without modification. Computer detected abnormalities associated with the lowest survival rates are presented below. Note that "LVH with strain" is the most predictive and that a normal ECG as defined by the 12SL program "is associated with extremely good survival".[244] This same finding was confirmed in a similar study that focused on Hispanics, although the prevalence of disease was lower."[372]



The term "LVH with strain" is an abbreviation for what the 12SL program states which is, "Left Ventricular Hypertrophy with repolarization abnormality." The correlation between LV mass and QRS voltage has been extensively studied.[413] In any case, when the QRS voltage exceeds an age-adjusted threshold, the 12SL program states "LVH". When 12SL states "LVH with strain", it means the program has identified ST/T wave changes commensurate with LVH. The figure to the right is such an example. In lead V6, the QRS voltage is large, the ST-segment is abnormal (i.e. depressed, down slopping) and the T-wave inverted - a classic example of "LVH with strain". As it turns out, it is the ECG-based characteristic referred to as "strain", which is the most predictive of a poor clinical outcome in the VA population.[374]



In 2018,[378] investigators at VAHS took the additional step of determining whether QRS voltage could distinguish between physiological and pathological hypertrophy. Physiological hypertrophy implies increased LV mass but, in this case, it is due to positive influences, such as strenuous exercise followed by rest and recovery. Pathological hypertrophy infers the ventricle has grown in an abnormal fashion due to chronic stress and no longer has the cellular structure conducive to proper function.[404] Myocardial disarray makes the ventricle unable to properly relax or contract. This becomes a vicious cycle. As the heart becomes less effective, the body sends signals to the heart to grow more. Unfortunately, since in this case the drive to grow is not followed by rest or recovery, the growth will be abnormal, resulting in myocardial disarray. Distinguishing between the two forms of LVH is important due to the frequency of athletic training that occurs in the VA population. By studying ECGs of 16,253 veterans followed a median of 17.8 years, it was found that QRS voltage does "not reflect the same pathophysiological changes, and can be due to athletic training."[378]

This is likely because the deadly changes associated with "strain" are not related to LV mass but, instead, are a reflection of the delayed conduction across the left ventricle due myocardial disarray, collagen and scar tissue that has formed as a consequence of chronic stress.[414] In any case, there is growing evidence that "ECG strain may be an early marker of LV structural remodeling that contributes to development of adverse cardiovascular events",[332] including ventricular arrhythmias and sudden cardiac death.

Right ventricular hypertrophy (RVH) is less prevalent than LVH in the adult population. In any case, a large international study evaluated program performance for hypertrophy.[218] In this study there were a total of 1220 patients, 382 controls and 838 with cardiac disorders that were collected across five European centers. ECGs showing complete Left Bundle Branch Block (LBBB), Right Bundle Branch Block (RBBB) or other major intraventricular conduction defects were excluded; otherwise there were no other criteria for excluding ECGs. A normal individual (n=286) was defined as being free of significant cardiopulmonary disease on the basis of a health screening examination (negative history, normal physical exam, normal chest X-ray) or invasive cardiac study (n=96). Invasive studies usually entailed cardiac catheterization (CATH) for atypical

chest pain or ST/T abnormalities evident at rest or during exercise. LVH or RVH was based on CATH or ECHO or both. Specific details regarding the population are contained in the article.[218]

Performance of RVH by ECG, validated by CATH and ECHO[218]

Representative test population:		5 European Academic Centers, Hospitals		
Additional demographic data:		831 men, 389 women, all white, age 52±13 years		
Total number of test ECGs:		1220		
Method(s) used to verify diagnosis:		ECHO, CATH, Clinical History		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RVH	55	29.1	100	100

In another study, patients with pulmonary hypertension due to pulmonary vascular occlusive disease were evaluated in the Pulmonary Hypertension Clinic at the University of Michigan. Each underwent a thorough history, physical exam, ECG, echocardiogram, pulmonary function testing, and right heart catheterization. Symptoms (type and duration), effort tolerance, and New York Heart Association (NYHA) functional class were recorded during the initial visit. Pulmonary hypertension was defined as a mean pulmonary artery pressure > 25 mmHg. Patients were excluded if they presented with evidence of chronic lung disease, left ventricular hypertrophy, mitral or aortic valve disease, congenital heart disease, coronary artery disease or cardiomyopathy.[390]

Performance of RAE and RVH by ECG, validated by CATH and ECHO[390]

Representative test population:		Hospital, Academic Center		
Additional demographic data:		64 consecutive symptomatic patients; 12 M, 52 F, mean age 43 ± 13yr. Race is unavailable.		
Total number of test ECGs:		64		
Method(s) used to verify diagnosis:		ECHO, CATH, Pulmonary artery pressure		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RVH	64	39.1	100	100
Right Atrial Enlargement	13	46	100	100

The blinded cardiologist and computer program diagnosed RVH in 43.8 and 39.1% of patients, respectively; this is substantially lower than the 78.1%, as determined by the un-blinded reader that was provided the age and clinical parameters (i.e. symptoms associated with possible pulmonary hypertension). Right ventricular strain was present in 71.9% of patients and was most often characterized by the blinded cardiologist and the computer program as non-specific or inferior/anterior-lateral ischemia. The most common errors by the computer and blinded cardiologist were the diagnosis of an anterior-septal infarction based on the presence of a qR in V1 (10.9%), and of an inferior-posterior myocardial infarction because of the presence of a "pathologic" Q wave in II, III and aVF associated with a prominent R in V1 (6.2%)

The study concluded that the ECG does have a high specificity for the detection of RVH in symptomatic patients with pulmonary hypertension and that correlation with the clinical parameters is essential to optimize the usefulness of the ECG. Without the clinical parameters, the computer program and blinded cardiologist often suggested myocardial infarction / ischemia.

In another study, two cardiologists were considered as the gold standard. As expected, performance metrics for the program are much higher when they are based on this human standard.

Evaluation of ventricular hypertrophy at tertiary care, VA Hospital[219]

Representative test population:	Tertiary care, VA Hospital Inpatients & Outpatients
Additional demographic data:	Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.
Total number of test ECGs:	2194 from 1856 patients
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

Hypertrophy Category	*N*	*Sensitivity (%)*	*Specificity (%)*	*Positive predictive value (%)*
Right Ventricle (RVH)	15	100	99.9	66.7

Criteria for RVH, in a pediatric patient, are defined by 16 different age categories.[415, 416] This diagnosis was evaluated at a pediatric hospital using 56,149 ECGs stored on a MUSE™ system. From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure balanced representation. This resulted in a sample size of 1,147 ECGs

Note that RVH is a Type A statement: that it typically requires non-ECG data for a reference gold-standard. In this case, the authors used the opinion of 2 pediatric cardiologists.

Assessment of RVH in a pediatric population[392]

Representative test population:	Hospital, all departments
Additional demographic data:	Median age at the time of ECG was 3.0yrs, in the heart disease group, and 6.0yrs, in the group without heart disease. Race and gender are unavailable.
Total number of test ECGs:	1,147
Method(s) used to verify diagnosis:	Confirmed by 2 pediatric cardiologists.

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
RVH	93	91.3	99.8	99

There are several independent studies that have evaluated the performance of GE's Marquette 12SL™ program to recognize healed myocardial infarction (MI).[417] The term "healed myocardial infarction" implies that this section is reporting results on the ability of the program to detect QRS abnormalities (like abnormal Q-waves) associated with necrosis. Computerized interpretation of a myocardial infarction is a Type A statement, requiring independent validation from non-ECG data.

The first series of evaluations of the 12SL™ program were done on ECGs from subjects that were selected from consecutive patients undergoing cardiac catheterization.[418, 419] The presence of an MI was determined via wall motion abnormalities associated with a 75% or greater obstruction of the relevant coronary artery. Patients with pulmonary disease, valvular disease, a history of previous MI, LV wall motion abnormalities suggesting multiple MIs, and patients with a history of previous cardiac surgery were excluded. Normals were defined as having normal LV motion and coronary arteries. This resulted in a study population of 734 patients with an MI and 406 patients defined as normal. The infarction group consisted of 84% males with an average age of 55 years. The average age of the 121 female patients was 57 years. ECGs selected for

analysis were obtained on average 3 days before the CATH in 92% of the infarction group patients. The remaining 8% were done within 30 days following the CATH procedure. The normal group consisted of 41% males with an average age of 46 years. The average age of the 238 female patients was 52 years. ECGs were obtained, on average, within 4 days before the CATH in 99% of the normal patients.

The results for the performance of the program versus CATH are presented below. Note that the physician had a similar level of sensitivity (69%) but maintained a higher level of specificity (97%).

Performance of MI: Group All Statements Indicating MI[418]

Representative test population:		Hospital		
Additional demographic data:		Specific ages, race, and gender information are unavailable.		
Total number of test ECGs:		1140		
Method(s) used to verify diagnosis:		CATH, Clinical History		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Myocardial Infarction	734	70	92	94

This same study also evaluated the performance of statements that were preceded by the modifiers "cannot rule out" and/or "possible". When these statements were not considered diagnostic for MI, the sensitivity was reduced to 54% while the specificity improved to 98%.

Performance MI Statements without Modifiers "Cannot Rule Out", "Possible"[418]

Representative test population:		Hospital		
Additional demographic data:		Specific ages, race, and gender information are unavailable.		
Total number of test ECGs:		1140		
Method(s) used to verify diagnosis:		CATH, Clinical History		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Myocardial Infarction	734	54	98	98

Using the same aforementioned source of data, an evaluation of inferior MI was conducted,[419] which demonstrated that the 12SL program had a sensitivity of 76% and a specificity of 95% while the physician had a lower sensitivity (75%) but a higher specificity (97%) than the computer.

In a separate study conducted at a Veterans Administration hospital, 137 patients were evaluated via cardiac catheterization using similar methods for data acquisition and analysis as the study but, in this case, the focus was anterior myocardial infarction. Patients who had significant valvular heart disease, left bundle branch block or paced rhythm were excluded. No attempt was made to identify and exclude patients with either left ventricular enlargement or chronic obstructive pulmonary disease, conditions that can reduce the specificity of ECG criteria for anterior myocardial infarction. All the ECGs were obtained on or near the day of each patient's catheterization. Of the 137 patients, the normal group consisted of 82 patients and the anterior MI group consisted of 55 patients. Below are the reported results for the 12SL™ program:

Performance of Anterior MI by ECG, validated by CATH[420]

Representative test population:	Veterans Administration Hospital Adult population.			
Additional demographic data:	Specific ages, race, and gender information are unavailable.			
Total number of test ECGs:	137			
Method(s) used to verify diagnosis:	CATH			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Anterior MI	55	64	99	99

Another large international study also used CATH as the reference but relied solely on the assessment of wall motion abnormalities, not including coronary obstruction. The results are presented below:

Performance of Anterior and Inferior MI by ECG, validated by CATH [218]

Representative test population:	5 European Academic Centers, Hospitals			
Additional demographic data:	831 men, 389 women, all white, age 52±13 years			
Total number of test ECGs:	1220			
Method(s) used to verify diagnosis:	CATH, wall motion studies			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Anterior MI	170	66	98	84
Inferior MI	273	65	97	86

In another, two cardiologists were defined as the standard. As expected, the performance metrics of the program are markedly higher using this human standard.

Evaluation of old infarction at tertiary care, VA Hospital[219]

Representative test population:	Tertiary care, VA Hospital Inpatients & Outpatients			
Additional demographic data:	Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.			
Total number of test ECGs:	2194 from 1856 patients			
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists			
Category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Old myocardial infarctions	399	98.8	99.5	97.4

Repolarization Abnormalities: Reported Results

Computer interpretations of a repolarization abnormality are composed of Type A and C statements. Recall that Type C statements refer to purely descriptive ECG features that usually cannot be documented by any other means. Examples of such statements include “non-specific ST-T abnormality”. This document will primarily be reporting results of the Type A statements, which are verified by non-ECG data such as cardiac enzymes, patient outcomes, etc.

The recognition of ST-elevated acute myocardial infarction (STEMI) has been a major focus of GE Healthcare. This is because the ECG is so vital in selecting an appropriate treatment path for acute myocardial infarction[198] as well as reducing time-to-treatment for STEMI.[421]

GE Healthcare was the first to introduce a pre-hospital diagnostic 12 lead ECG as a small, compact unit for the ambulance that could acquire and transmit the ECG digitally so that there would be no distortion of the ST/T waveform.[165]This led to several studies that demonstrated that a prehospital ECGs can be practically acquired,[229] significantly cuts total time-to-treatment,[230-232] and has "the potential to significantly increase the diagnostic accuracy in chest pain patients."[233]

Based on data collected from the prehospital environment,[166] GE's Marquette 12SL™ Program was modified to recognize earlier forms of STEMI, using reciprocal depression as the primary discriminating characteristic to discern STEMI versus early repolarization.[17] This approach, combined with enhancements, allowed the sensitivity to double without a loss of specificity.[422, 423] Several tests have since verified that reciprocal depression is a highly specific marker of STEMI.[183, 424, 425]

GE's Marquette 12SL™ Program (Version 14) is used in prehospital defibrillators currently offered by other vendors (Medtronic-Physio Control, Zoll).[426, 427] GE Healthcare's resting electrocardiographs use a later version that includes such features as gender and age-specific criteria for the recognition of STEMI[428] and the detection of right ventricular involvement in the presence of an acute inferior infarction.[35] As a result, the following reported results for STEMI are presented in two groups: one that applies to the results of the program in the prehospital defibrillator and one for the results of the program in GE Healthcare's resting ECG equipment. Note that both versions of the program analyze data of the same fidelity and content, generating fiducial points and medians at 500 SPS.[19]

The following series of reported results are from prehospital ECGs and are representative of version 14 of the 12SL program.

In Australia, a GE Healthcare portable prehospital electrocardiograph[429] was used for the automatic diagnosis of acute myocardial infarction via GE's Marquette 12SL™ Program. "This automated program diagnosed acute evolving Q wave myocardial infarction with 71% sensitivity and 98% specificity. Specificity was 100% when patients with a known previous Q wave myocardial infarction were excluded."[425, 430]

Results from GE Healthcare's Prehospital Electrocardiograph[425]

Representative test population:	Prehospital ECGs
Additional demographic data:	Specific ages, race, and gender information are unavailable.
Total number of test ECGs:	526
Method(s) used to verify diagnosis:	Physician interpretation, serial ECG analysis, & clinical outcome.

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
Acute MI	Unknown	71	98	Unknown
Acute MI, no previous MI	Unknown	71	100	100

As part of the NIH sponsored Myocardial Infarction Triage and Intervention (MITI) Project,[431] the 12SL™ Program accuracy for recognizing STEMI was evaluated. This was a large prehospital study (n=1,189) that acquired ECGs from patients within 6 hours of the onset of chest pain. This study used cardiac enzymes as the "gold standard". Their conclusion: "the positive predictive value of the computer- and physician-interpreted ECG was, respectively, 94% and 86% and the negative predictive value was 81% and 85%."[123]" The authors also stated: "The present algorithm is clearly adequate for first line screening of patients with chest pain by paramedics or in the emergency department. Its sensitivity is no worse than that of the emergency physician and its specificity is superior to the trained electrocardiographer." "Although more sensitive, the electrocardiographer had an overall incidence of a 5% false positive diagnosis, including a 22% incidence of false positive diagnoses in patients with isolated ST segment elevation. In contrast, the

computer was nearly perfect at excluding patients without acute myocardial infarction, but did so at the expense of diminished sensitivity." The raw numbers for algorithm performance are given in the following table.

Results from the MITI trial based on cardiac enzymes[123]

Representative test population:	Prehospital ECGs, large city
Additional demographic data:	Age 60 ± 12 years, men 66%, race unknown
Total number of test ECGs:	1,189
Method(s) used to verify diagnosis:	Cardiac Enzymes

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
Acute MI	391	52	98.5	94

The results of the MITI trial were also analyzed for the recognition of STEMI as opposed to solely using cardiac enzymes as the reference. That is, an analysis was done as to whether or not ST elevation was present along with the positive cardiac enzyme result. In this case, the program achieved a sensitivity of 71%. As stated in the literature: "The computer algorithm was developed to help differentiate early repolarization and nonspecific ECG changes from those of acute injury and, unlike the electrocardiographer, did not presume that ST elevation in a patient with chest pain was more likely than not to indicate acute infarction. Although more sensitive, the electrocardiographer has an overall incidence of 5% false positive diagnoses, including a 22% incidence of false positive diagnoses in patients with isolated ST segment elevation."[123]

Results from the MITI trial based on cardiac enzymes and presence of ST elevation[123]

Representative test population:	Prehospital ECGs, large city
Additional demographic data:	Age 60 ± 12 years, men 66%, race unknown
Total number of test ECGs:	1,189
Method(s) used to verify diagnosis:	Cardiac Enzymes and ST elevation

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
STEMI	286	71	98.5	94

In another study, clinical data and ECG findings on 264 consecutive patients admitted to a coronary care unit with suspected acute myocardial infarction were prospectively evaluated with the same portable prehospital electrocardiograph as in the aforementioned prehospital studies. Eighty-six (86) patients (32.5%) had confirmed acute infarction and of these 85% had some form of ST elevation on their initial ECG. The area under the receiver operator curve (ROC) of the interpretations made by the 12SL™ program was 83.9%.[424]

A recent survey of 365 hospitals in the United States, found that hospitals that used the results of prehospital "electrocardiography, that were called in or transmitted by emergency medical services to activate the catheterization laboratory while the patient was still enroute to the hospital, had significantly faster door-to-balloon times than did hospitals that waited for the patient to arrive before activating the catheterization laboratory (P = 0.001)."[432] This survey found that "false alarms were reported to be infrequent."[432] The authors also stated that the perception "about the number of false alarms are probably as important" in determining "whether non-cardiologists are permitted to activate the catheterization laboratory."[432]

The following series of reported results are representative of the current version of the 12SL program.

"Identified patients who presented to Emergency Departments (EDs) in Winnipeg, Manitoba, Canada from January 2015 to September 2016 who were diagnosed with STEMI and sent to the regional CCL for primary PCI. We reviewed the ECGs that triggered CCL activation and determined the sensitivity and specificity of software interpretation of the ECG (Marquette 12SL, MUSE, GE Healthcare). A third physician's blinded interpretation of the ECG was considered the "gold standard" and 95% confidence intervals were calculated using Clopper-Pearson Method. ... Conclusion: Software interpretation of STEMI conferred a potential 17-minute reduction in D2D time. The reduction was greatest in those >75 years and women, populations that have longer D2D times and worse outcomes. Further study is needed to evaluate the real-world effect of such a system in the ED."[433]

In the following study, body surface mapping (80 leads) was compared with GE's Marquette 12SL™ Program for the recognition of acute myocardial infarction on ECGs taken over a 3-month period from 103 chest-pain patients in the ED.[434] Of these, 53 had an acute myocardial infarction as defined by positive enzymes. Only 24 met ECG criteria for STEMI.

The purpose of this study was to not only detect STEMI but to detect non-ST elevated acute myocardial infarction. The motivation of the study was to reveal that body surface mapping is superior because it can detect non-ST elevated acute myocardial infarction. Note that the 12SL™ Program is designed not to detect non-ST elevated acute myocardial infarction; it will indicate ST depression or T wave inversion. Based on the severity of these abnormalities, the current program will state, "marked ST depression, consider subendocardial injury" or "marked T wave abnormality, consider ischemia". It remains controversial as to whether the ECG can diagnose non-ST elevated acute myocardial infarction: this diagnosis is currently the sole domain of cardiac enzyme data.[435]

See the reported results of this study below. The admitting physician correctly diagnosed 24 patients with AMI (sensitivity 45%, specificity 94%). Of the 24 patients correctly diagnosed, 20 received thrombolytic therapy. According to care guidelines, thrombolytic therapy should only be applied in the case of a STEMI.[198] The automated analysis program correctly diagnosed 17 patients with STEMII (sensitivity 32%, specificity 98%).

Results for STEMI Based on Cardiac Enzymes[434]

Representative test population:		Emergency Department		
Additional demographic data:		Age 64 ± 14 years, Men 74%, race unknown		
Total number of test ECGs:		103		
Method(s) used to verify diagnosis:		Cardiac Enzymes (CK-MB, Troponin)		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Acute MI	53	32	98	98

Results for STEMI based on cardiologist[434]

Representative test population:		Emergency Department		
Additional demographic data:		Age 64 ± 14 years, Men 74%, race unknown		
Total number of test ECGs:		103		
Method(s) used to verify diagnosis:		Positive for STEMI by Cardiologist		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
STEMI	24	71	98	98

In the next study, 75 electrocardiograms were interpreted. "Two criteria were compared for thrombolysis eligibility: (1) measurement of > or =1 mm ST-segment elevation in 2 contiguous leads (measured) and (2) criterion 1 plus the subjective opinion that the changes represented acute transmural injury (interpretive). The results were compared with computerized interpretations by the Marquette 12SL system."[436]

The ECGs for this study[436] were manually selected in a CCU and were roughly evenly divided among (1) normal, (2) those showing evidence of acute transmural injury, or (3) those showing other ST-segment or T-wave abnormalities (such as early repolarization, acute pericarditis, etc.) Note: this distribution of patient abnormalities is not representative of an ED, CCU or emergency medical service that typically has a much lower incidence of acute transmural injury (that is, on the order of 10-15%).[147]

This paper states that "strict reliance on measured electrocardiographic criteria alone would have resulted in overuse of thrombolysis among all 3 raters. Based on the consensus opinion, the absolute overuse of thrombolysis would have been approximately 15% (P <.0034)." In contrast, the computer had 100% specificity.

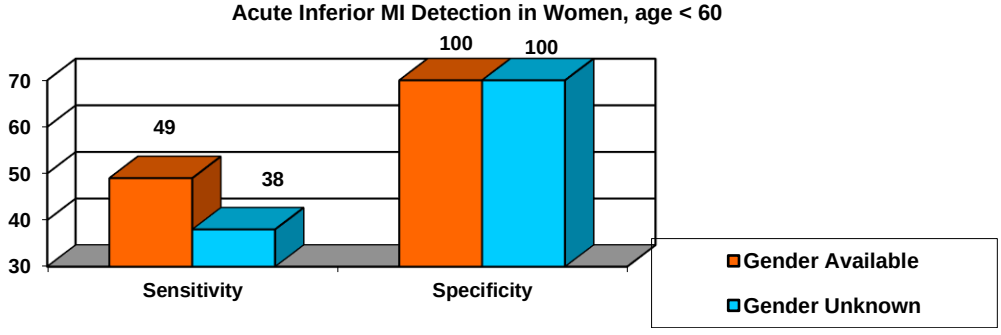
ECGs from cardiac care unit (CCU) evaluated by 3 cardiologists, consensus opinion[436]

Representative test population:	Emergency Department
Additional demographic data:	Specific ages, gender and race are unavailable.
Total number of test ECGs:	75
Method(s) used to verify diagnosis:	Consensus of 3 Cardiologists

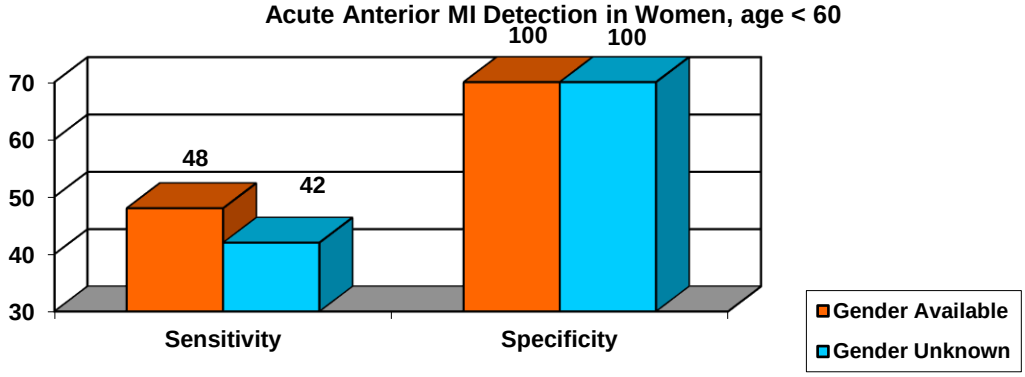
Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
TEMI	26	61.5	100	100

GE Healthcare has done considerable research in gender specific differences in the ECG. Testing was done via data collected at the Mayo Clinic and the Medical College of Wisconsin. Results of testing, and an analysis of the ECG differences based on gender, have been broken down by location of myocardial infarction: that is, anterior versus inferior.

For acute inferior MI patients under age 60, women had lower ST elevation than men (lead II STJ average: 57µV for 99 females versus 86µV for 340 males, P value <.02). The opposite was true for patients over age 60. In the older patient population, women had larger ST elevation than men (lead AVF STJ average: 130µV for 378 females versus 84µV for 522 males, P value < .04). The figure below displays a comparison of the results, between the two program versions, for the recognition of acute inferior myocardial infarction in women less than 60 years of age.[27]



For acute anterior MI patients under age 60, women had lower ST elevations than men (lead V2 STE average, 307µV for females versus 432µV for males, P value < .007). Over age 60 years, this difference becomes less pronounced (lead V2 STE average, 336µV for females versus 421µV for males, P value < .009). The figure displays a comparison of the results between the two program versions for the recognition of acute anterior myocardial infarction in women less than 60 years of age.[437]



Test results show that the program is more sensitive for the recognition of acute myocardial infarction in women less than 60 years of age. For ages 60 and over, the program performance is the same as in previously published studies.

Results for STEMI for patients with new onset chest pain of unknown origin[27, 437]

Representative test population:	Emergency Department and Prehospital / Ambulance
Additional demographic data:	Acute inferior infarct: 477 Female (99 < 60 years), 862 Male (340 < 60 years); acute anterior infarct 450 Female (64 < 60 years), 699 Male (232 < 60 years). Controls are age and gender matched patients with new onset chest pain of non-cardiac origin.
Total number of test ECGs:	3,457
Method(s) used to verify diagnosis:	Cardiac Enzymes, Clinical Outcomes

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
Acute Inferior MI	1,339	49	100	100
Acute Anterior MI	1149	48	100	100

AHA / ACC guidelines recommend that patients with inferior STEMI and hemodynamic compromise should be assessed with a right precordial lead V4r to detect ST segment elevation to screen for right ventricular (RV) infarction.[198] This is a class I recommendation, meaning that there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective. RV involvement in acute inferior infarction may be accompanied by significant hemodynamic consequences including a lowering of cardiac output and systemic blood pressure[438]. In addition, the in-hospital mortality of an acute inferior infarct is worsened when complicated by RV involvement.[439]

The 12SL ECG Analysis Program uses a threshold of 100 uV in lead V4r in interpreting all cases of right ventricular involvement, except under very specific circumstances.[35] Specifically, the program reduces the threshold to 50 uV in the presence of an acute inferior STEMI with high-degree AV block and a rightward ST vector (i.e., STE in III > II)[440-442] The prevalence of high-degree AV block (i.e., 2nd or 3rd degree AV block) in the general population is extremely rare and a person with an acute inferior STEMI and concomitant high-degree AV block is more than twice as likely to have RV involvement than not.[443]

ST elevation of 100 uV in lead V4r is a highly specific indicator of right ventricular involvement in the presence of acute inferior infarction. A threshold of 100 uV has been reported to have sensitivities of 57% - 100% and

specificities of 68% - 100%, depending on the gold standard used (post-mortem examination, hemodynamic measures, angiography, etc).[444] A threshold of 50 uV has been reported to have sensitivities of 76% - 100% and specificities of 40% - 86%, again depending on the gold standard.[444, 445] Morgera[446] analyzed both thresholds in the same study with the same patient population and reported a specificity increase from 86% to 100% as the threshold went from 50 to 100 µV, with a sensitivity decrease from 76% to 57%. One should note that the diagnostic accuracy of right ventricular involvement has not been assessed in patients with certain conditions such as chronic lung disease and pericardial disease.

Although the lower ST elevation threshold in lead V4r will increase sensitivity and decrease specificity, this decreased specificity is offset by the requirement of concomitant ST elevation in lead III exceeding ST elevation in lead II and high-degree AV block, both of which are associated with right ventricular involvement. Using only the criteria of ST in III > II, Saw[440] reported a sensitivity of 97% and a specificity of 56% for the detection of right ventricular involvement in the presence of an acute inferior infarction. The reported incidence of high degree AV block in patients with RV involvement is 43%, compared to only 13% in patients with acute inferior infarction without RV involvement.[443]

GE Healthcare developed a 16-lead ECG database in conjunction with several chest-pain centers. A total of 1,343 16-lead ECGs were acquired and analyzed from 712 chest-pain patients. Each ECG record contained the standard 12-lead ECG, simultaneously acquired with leads V4r, V7, V8, and V9. GE Healthcare, in conjunction with the contributing investigators, analyzed and reported on the characteristics of the additional leads in relation to acute myocardial infarction and outcome.[447-449] The interpretation of GE's Marquette 12SL Program was compared to patient outcomes, as registered in this 16-lead ECG database. An acute STEMI was detected in 143 ECGs. Of these, 101 were diagnosed as being an acute inferior STEMI (including inferolateral and inferior-posterior). When V4r was withheld from the analysis, "consider RVI" was stated in 84 of the 101 IMI ECGs. When V4r was included in the analysis, the "with RVI" modifier was added in 34 of the 101 IMI ECGs. With one exception, all 12-lead ECGs that stated "consider RVI" also stated "with RVI" when V4r was added.

The sensitivity of the "consider RVI" statement for predicting positive ST elevation in V4r was 97% (33 / 34), while the positive predictive accuracy was 39% (33 / 84). The result here of 34% (34 / 101) of all acute inferior STEMIs having RVI is consistent with the percentages of 30 – 50% reported in the literature.[450]

How findings are stated can have a significant impact. One good example of this is when the program states "myocardial infarction, age unknown." This occurs when the program identifies pathological Q-waves but has insufficient ST/T changes to label it as acute. In this situation, a prior ECG is most helpful.[163] Dismissing the finding as not a STEMI can delay treatment if it is a STEMI, as shown in this referenced study.[261]

ACI-TIPI[451] uses the measurements of GE's Marquette 12SL™ program. Based on the presence of pathologic Q waves and/or the presence of repolarization abnormalities, the ACI-TIPI algorithm reports the probability of acute cardiac ischemia. The logistic regression formula used by ACI-TIPI[191] was implemented in all GE electrocardiographs and tested in the emergency department (ED)[197] as well as the prehospital environment.[21]

A large prospective trial was accomplished across 10 different emergency departments, with 30-day follow-up of clinical outcomes. A total of 10, 689 patients were evaluated: 8150 were not ischemic, 673 had stable angina, and 1866 had acute cardiac ischemia (that is, unstable angina or an acute myocardial infarction. Quoting from the literature:[192]

> *"Reductions in admissions for patients without acute cardiac ischemia were greater among patients with ACI-TIPI-predicted ischemia probabilities in the lower ranges, reflecting a greater effect with stronger probabilistic advice not to admit (that is, a dose-response effect). Of note, in settings in which use of the ACI-TIPI reduced unnecessary admissions, appropriate hospital and CCU admission did not deteriorate for patients with true acute ischemia (unstable angina or acute infarction). Given these results of this "effectiveness" trial ACI-TIPI seems to be safe and effective for general use."*

ACI-TIPI had a larger impact when the attending physician was inexperienced (that is, an unsupervised resident). In this case, "use of ACI-TIPI was associated with a reduction in CCU admissions from 14% to 10%, a change of –32%(CI, –55% to 3%); a reduction in telemetry unit admissions from 39% to 31%, a change of

–20%(CI, –34% to –2%) and an increase in discharges to home from 45% to 56%, a change of 25% (CI, 8% to 45%; overall P = 0.008)."

The purpose of this study was to measure the impact of care based on whether ACI-TIPI was available or not available. Within the same ED, ACI-TIPI was available on alternate months. The effect of improved triage with ACI-TIPI was reproducible, even after the physician had several months of experience with the device.

Using two cardiologists as the reference, the following results were reported for the interpretations of ischemia by computer:

Evaluation of ST/T abnormalities stated as ischemia at tertiary care, VA Hospital[219]

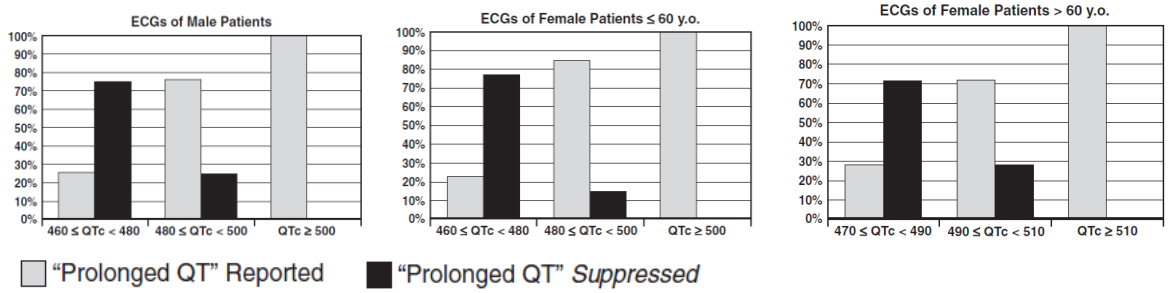
Representative test population:		Tertiary care, VA Hospital Inpatients & Outpatients		
Additional demographic data:		Age ranged from 33 to 96 years (mean 73.5). Nearly all of them (98.3%) were male. Information on race is unavailable.		
Total number of test ECGs:		2194 from 1856 patients		
Method(s) used to verify diagnosis:		Confirmation by 2 cardiologists		
ST/T Abnormality	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Ischemia	199	100	99.8	98

The diagnostic statement "Prolonged QT" is conditionally presented by 12SL even when the QTc is long (>450ms.) A study conducted by Garg et. al. evaluated the "extent to which automated censoring of a prolonged QT diagnosis occurs in large-scale clinical implementation of the 12SL program ... We observed that, of more than16,000 study ECGs for which the 12SL software calculated and displayed prolonged QTc values (≥470 ms in females >60 years old; or ≥460 ms in other sex/age groups), a prolonged QT diagnostic statement actually appeared on the computer-generated report in only 48% of these tracings, being algorithmically censored in the remaining 52% based on certain ECG waveform characteristics."[263] Gross results from this study are presented below:

Conditional presentation of "Prolonged QT" in presence of QTc > 470ms[263]

Representative test population:		Large, integrated health network		
Additional demographic data:		Majority of ECGs were from females (51.8%), and most ECGs in each sex/age group were from white patients.		
Total number of test ECGs:		97,046 ECGs from patients ≥18 years after exclusion criteria were applied: HR>100bpm or QRSD>120ms. Of these, 16,000 ECGs the 12SL program calculated and displayed prolonged QTc values (≥470 ms in females >60 years old; or ≥460 ms in other sex/age groups)		
Method(s) used to verify diagnosis:		12SL statement issued versus different QTc values, from 460 to over 500ms.		
QTC threshold & gender	***N***	***Suppressed***	***Reported***	***Percent reported***
Male 470ms ≤ QTc ≤ 500ms	3,370	1,576	1,794	53.2%
Male QTc > 500ms	997	0	997	100%
Female 480ms ≤ QTc ≤ 500ms	2,398	739	1,659	69.2%
Female > 500ms	1,301	63	1,238	95.2%

Percent of ECGs Identified as having "Prolonged QT".[263]



There are differing opinions as to when to identify "Prolonged QT". For instance, some recommend that certain populations be screened for prolonged QT, while others state this would be cost ineffective and would result in too many false positives.[10, 452-456] Some believe the statement should be issued starting at 440ms in men.[457] Others believe it only practical to begin stating it at ≥500ms, regardless of sex.[452, 458] Some insist the statement should be issued regardless of whether there is a conduction abnormality, evidence of myocardial infarction, paced rhythm, high heart rate, varying RR interval, low amplitude T-wave, poor ECG quality, etc. Others believe these conditions should preclude the statement from being issued. In any case, these tradeoffs can result in a wide swing in the prevalence of the statement "prolonged QT" in the typical hospital population, from 5 to 25%.

Using over 40,000 ECGs not analyzed by 12SL, an evaluation of cardiologists as to when they added the statement "prolonged QT" demonstrated that coexisting waveform abnormalities are considered.[459] This included bundle branch block, various ST segment or T wave abnormalities, arrhythmias, paced rhythms, myocardial ischemia or infarct. This study found that the prevalence of the statement "prolonged QT" would be 26.6% when a strict threshold of a QTc > 450ms was applied; across this same group of ECGs, cardiologists only added the statement ≈ 5% of the time.

In short, there is no easy answer as to when to state, "Prolonged QT". Apply strict thresholds below 500ms and approximately 25% of all ECGs will end up with the statement "Prolonged QT". Use higher thresholds or restrict the conditions as to when the statement is generated, then ECGs from patients known to be at risk will not have the statement "Prolonged QT" as part of their computerized interpretation. The physician needs to take an active role in evaluating the ECG and determining the appropriate level of risk. As stated in an editorial in response to the work by Garg et. al, "computerized interpretation of ECGs is a supplement not a substitute."[460]

In any case, there is a growing appreciation that QT/QTc alone is insufficient for determining risk. This is true for both congenital and drug-induced long QT syndrome (LQTS).[452, 461, 462]

The criteria used by GE's Marquette 12SL Program for when to issue "prolonged QT" has evolved. In general, thresholds for when to state it are increasing while the number of conditions that prevent the statement from being issued are being reduced. For instance, the criteria in the most recent version of the program (12SL v23), will identify prolonged QT at a faster heart rate (20 + age-adjusted threshold for sinus tachycardia). This change will address some instances in the literature that have reported that the 12SL program does not state "prolonged QT" even when the QTc>500ms, especially for pediatric patients.[227, 302]

It should also be kept in mind that a change in QTc can also be important. An increase of 60ms has been identified in an ACC/AHA consensus statement as an indicator of increased risk.[458] It is important to know that GE's 12SL Serial Comparison program will identify when there is a change in QTc greater than 50ms.

Overall Classification: Reported Results

Several studies have addressed the issue if the computer can simply classify the ECG as either normal or abnormal. The following studies reported the following:

- "the program is reliable in diagnosing normality: even the disagreements are arguable."[243]
- A total of 855 triage ECGs in the emergency department (ED) were collected over 16 weeks. "Our data suggest that triage ECGs identified by the computer as normal are unlikely to have clinical significance that would change triage care."[173]
- "From a practical point of view, the eventual consensus opinion of the cardiologists was that only one tracing reported as normal by the system should have been reported as abnormal to a family doctor, resulting in a negative predictive value of 98.4%. In view of the cardiologists inter-observer variation with regard to what is normal, this may well be higher than an individual cardiologist's negative predictive value and suggests that the system examined may safely be used to exclude major abnormalities which would affect clinical management".[243]
- "A total of 39, 238 electrocardiograms were reviewed…The program placed the ECG into the following diagnostic classifications: normal 22%, otherwise normal 6%, borderline 5%, abnormal 66%. The reviewing physician agreed with this classification in 96.3% of all cases… The most striking information shows the agreement of the physicians with the computer diagnosis of an abnormal electrocardiogram in 97.7% of the 25,295 tracings. In only 204 records out of 25,987 tracings (.8%), the physicians edited a computer-called abnormal electrocardiogram and changed it to normal. In only 63 of 8,632 (.7%) tracings of which the computer called normal did the physicians edit this tracing to read abnormal."[220]

Overall classification via large database[220]

Representative test population:	Large hospital
Additional demographic data:	Age, gender, and race information is unavailable
Total number of test ECGs:	39,238
Method(s) used to verify diagnosis:	Physician diagnosis

Verified Diagnosis	*N*	*Sensitivity (%)*	*Specificity (%)*	*PPA (%)*
Normal ECG	8,632	99.9	100	99.9
Abnormal ECG	25,987	99.9	99.9	99.9

- As tested on 26,734 male and 3,737 female veterans, a classification of a normal ECG by the 12SL program "is associated with extremely good survival".[244]
- "Three ECG computer programs-Hewlett Packard analog program (HP), Telemed analog program (T) and Marquette 12 SL digital program (MAC) were evaluated and their accuracy of ECG reading compared with the reading of 4 experienced interpreters on 140 ECGs of patients with various clinical abnormalities. Major disagreement with effect on patient management, and minor disagreement were defined at a joint session with a senior (consensus). The computers identified all normal ECGs correctly (sensitivity 100%). The percentage of major agreements (full agreements and minor disagreements) between consensus and computer was 79% for HP, 90% for T and 93% for MAC."[217]
- "A total of 2194 ECGs were included for analysis in the study. One hundred twenty-two ECGs with a disagreement between the two cardiologists were excluded from analysis. Out of 2072 remaining cases, 776 (37.5%) were read by the computer as normal" … "There were no discordances in the ECGs read as normal."[219]
- The computer correctly interpreted all normal ECGs.[227]

- "The quality of computer-assisted ECG interpretation was comparable to that of review provided by a cardiology service."[226]

Serial Comparison

The Serial Comparison program compares ECGs over time, appending interpretive statements to the report generated by GE's Marquette 12SL™ program. The Serial Comparison program is only available via the MUSE™ system and is described in the 12SL™ Physician's Guide.

The Serial Comparison program compares statements, measurements and waveforms.[13] The purpose of the program is to detect a significant clinical change and describe the change in terminology familiar to the cardiologist. Note that interpretive statements can change across serial ECGs, even though there is no significant clinical change in the ECGs. In this case, the program will not state a change.

The Serial Comparison program will compare ECGs that are analyzed by different versions of the 12SL™ program. This is because the Serial Comparison program re-analyzes historical ECGs. It compares the actual waveforms of the stored median complexes. It is critical this comparison be done on medians and fiducial point measurements generated by the same signal processing 12SL methodology, otherwise there will be a poor superimposition of the waveforms. This is important if an institution is going to compare and evaluate repolarization changes throughout the continuum of care, as recently demonstrated in a study that used 12SL measurements and waveforms to measure the potential significance of spontaneous and interventional ST-changes in patients transferred for primary percutaneous coronary intervention.[463]

GE Healthcare has developed specialized tools[65, 67, 345, 346, 464-466] for the collection, trending and comparison of serial 12-lead ECGs analyzed by the 12SL™ program for the assessment of the acute coronary syndrome patient as they migrate from the prehospital setting through to intervention and the CCU.

Conclusion

This document has presented the performance of GE's Marquette 12SL Program. The evidence came from the scientific literature and it is extensive. The gold standard data continues to be collected and the performance of the program evaluated.

Collection of data is an unending pursuit, for several reasons. The first, and most obvious, is that the program needs to be tested as improvements are made to it. Equally important, is that new gold standards become available that can fundamentally change our understanding of the ECG. Sometimes, ECG criteria that are well accepted and have been used for decades can be rejected, as recently demonstrated for atrial enlargement.[467] In addition, changes in clinical practice, can change the meaning of a gold standard, as in the case of evaluating Q-waves in an environment of aggressive treatment for STEMI. Clinical practice can also alter the use of the ECG or generate new manifestations of the ECG, as in the case of artificial pacing. The challenge is to keep abreast of these changes and, yet, have an interpretive program that is understandable to the practicing physician.

GE Healthcare is committed to continuous improvement of the program and obtaining the highest performance in the industry. GE Healthcare recognizes that data collection is key to this improvement and, as a result, collaborates across the globe with several centers in the collecting of ECGs correlated with gold standard data or other clinical input. Given the capabilities of the MUSE™ ECG storage system, most centers can investigate the performance of the program in a systematic fashion. GE Healthcare welcomes this activity and is interested in collaborating with those who are equally committed to the advancement of computerized electrocardiography. Feel free to contact us with your comments and insights. system.[244, 306, 313, 314, 322, 333, 354, 358, 359, 365-379]

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Appendices: Statement Library, Pediatric Tables, and 12SL Versions

Appendix A: Statement Library Arranged by Statement Category

Critical Values

Statement Number	*Acronym*	*Text*
1340	CRIT	*** Critical Test Result:
1342	CVHIHR	High HR
1343	CVLOHR	Low HR
1346	CVLQT	Long QTc
1360	CVSTEMI	STEMI
1361	CVACS	ACS / Ischemia
1362	CVAVB	AV Block
1363	CVARRHY	Arrhythmia

Predominant Rhythm

Sinus Rhythms

Statement Number	*Acronym*	*Text*
19	SRTH	Sinus rhythm
21	SBRAD	Sinus bradycardia
22	NSR	Normal sinus rhythm
23	STACH	Sinus tachycardia
24	MSBRAD	Marked sinus bradycardia

Atrial Rhythms

Statement Number	*Acronym*	*Text*
25	RABRAD	Low right atrial bradycardia
26	RATACH	Low right atrial tachycardia
27	LABRAD	Left atrial bradycardia
28	LATACH	Left atrial tachycardia
29	RAR	Low light atrial rhythm
30	LAR	Left atrial rhythm
61	EABRAD	Unusual P axis, possible ectopic atrial bradycardia
62	EAR	Unusual P axis, possible ectopic atrial rhythm
63	EATACH	Unusual P axis, possible ectopic atrial tachycardia
64	EARO	Ectopic atrial rhythm
161	AFIB	Atrial fibrillation
162	FLUT	Atrial flutter
164	ATAC	Atrial tachycardia
271	SVT	Supraventricular tachycardia
279	PO-ATP	Possible wandering atrial pacemaker
280	MULT-AT	Multifocal atrial tachycardia

Statement Number	Acronym	Text
288	AFL-BL	Atrial flutter with 2 to 1 block

Junctional and Ventricular Rhythms

Statement Number	Acronym	Text
34	JUNBRAD	Junctional bradycardia
41	JBRAD	Unusual P axis and short PR, probably junctional bradycardia
42	JR	Unusual P axis and short PR, probably junctional rhythm
43	JTACH	Unusual P axis and short PR, probably junctional tachycardia
238	$SIVR	Idioventricular rhythm
248	#SVTACH	Ventricular tachycardia
249	$SFIB	Ventricular fibrillation
267	JUNCT-R	Junctional rhythm
268	IDIO-R	Idioventricular rhythm with AV block
269	VENT-RTH	Ventricular rhythm
270	J-TACH	Juncational tachycardia

Rhythm of Unknown Etiology

Statement Number	Acronym	Text
235	WQTACH	Wide QRS tachycardia
236	NQTACH	Narrow QRS tachycardia
237	$SWQR	Wide QRS rhythm
265	PR-SBRAD	Probably sinus bradycardia, verify AV conduction
272	VTACH	Ventricular tachycardia (ventricular or supraventricular with aberration)
282	AV-COND	Suspect AV conduction defect
287	LHR	Low heart rate, veify AV conduction.
299	UR	Undetermined rhythm

Pacemaker

Statement Number	Acronym	Text
183	APCX	atrial-paced complexes
184	VPCX	ventricular-paced complexes
185	AVPCX	AV dual-paced complexes
186	ASVPCX	atrial-sensed ventricular-paced complexes
289	BIVPCK	Biventricular pacemaker detected
290	PCK	Electronic ventricular pacemaker
291	DPCK	Demand pacemaker, interpretation is based on intrinsic rhythm

Statement Number	Acronym	Text
292	APCK	Electronic atrial pacemaker
293	AVPCK	AV sequential or dual chamber electronic pacemaker
294	EDP	Electronic demand pacing
295	APR	Atrial-paced rhythm
296	VPR	Ventricular-paced rhythm
297	ASVPR	Atrial-sensed ventricular-paced rhythm
298	AVDPR	AV dual-paced rhythm
326	WITH-DEM	with a demand pacemaker
1669	PMFAIL	*** Suspect unspecified pacemaker failure

Rhythm Modifiers

Sinus Node

Statement Number	Acronym	Text
111	SABII	with 2nd degree SA block (Mobitz II)
112	SABI	with 2nd degree SA block (Mobitz I)
113	PAUSE	with sinus pause
187	SCX	sinus complexes
251	SAR	with sinus arrhythmia
252	MSAR	with marked sinus arrhythmia
284	SA-BLK	with SA block or transient AV block
285	SAB	with sinus arrest or transient AV block

AV Conduction

Statement Number	Acronym	Text
101	FAV	with 1st degree AV block
102	SPR	with short PR
103	MBZI	with 2nd degree AV block (Mobitz I)
104	MBZII	with 2nd degree AV block (Mobitz II)
105	SAV	with 2nd degree AV block
106	CHB	with complete heart block
107	VAVB	with variable AV block
108	AVDIS	with AV dissociation
141	W2T1	with 2:1 AV conduction
142	W3T1	with 3:1 AV conduction
143	W4T1	with 4:1 AV conduction
144	W5T1	with 5:1 AV conduction
190	PROAV	with prolonged AV conduction
245	$SRETC	with retrograde conduction
247	$SCAPTUR	sinus/atrial capture

Statement Number	Acronym	Text
278	WEKH	with Mobitz I (Wenckebach) block

Atrial Fib/Flutter

Statement Number	Acronym	Text
163	CRS	Coarse
171	RVR	with rapid ventricular response
172	SVR	with slow ventricular response
174	CJP	with a competing junctional pacemaker

Supraventricular Beats

Statement Number	Acronym	Text
188	SVCX	supraventricular complexes
189	INTRIN	intrinsic complexes
221	PSVC	premature supraventricular complexes
222	PAC	premature atrial complexes
223	PJC	premature junctional complexes

Ventricular, Aberrancy, or Fusion

Statement Number	Acronym	Text
181	ABER	with premature ventricular or aberrantly conducted complexes
231	PVC	premature ventricular complexes
232	PVCF	premature ventricular and fusion complexes
234	BIGEM	in a pattern of bigeminy
244	$SFUS	fusion complexes
246	$SABCOND	aberrant conduction
274	VENT-FUS	with ventricular fusion
277	TVT	with transient ventricular tachycardia
283	AB-VENT	with intermittent aberrant ventricular conduction

Escape

Statement Number	Acronym	Text
242	JESC	with junctional escape complexes
243	VESC	with ventricular escape complexes
275	J-ESC	with junctional escape
276	ESCBT	with escape beat

Miscellaneous

Statement Number	*Acronym*	*Text*
175	IRREG	with undetermined rhythm irregularity
211	OCC	with occasional
212	FREQ	with frequent
233	CSEC	and consecutive
241	PEC	premature ectopic complexes

QRS Axis and Voltage

Statement Number	*Acronym*	*Text*
307	DXTRO	Dextrocardia
370	LAD	Leftward axis
371	ALAD	Abnormal left axis deviation
372	LAD3	Left axis deviation
380	RAD	Rightward axis
381	ARAD	Abnormal right axis deviation
382	RSAD	Abnormal right superior axis deviation
383	RAD4	Right axis deviation
384	RAD5	Right superior axis deviation
390	INDAX	Indeterminate axis
391	NWA	Northwest axis
410	LOWV	Low voltage QRS
411	PULD	Pulmonary disease pattern

Intraventricular Conduction and Pre-excitation

Statement Number	*Acronym*	*Text*
300	WPWA	Ventricular pre-excitation, WPW pattern type A
302	WPWB	Ventricular pre-excitation, WPW pattern type B
303	ALTWPW	with fusion or intermittent ventricular pre- excitation (WPW)
304	WPW	Wolff-Parkinson-White
440	RBBB	Right bundle branch block
442	RBBRVH	Right bundle branch block -or- Right ventricular hypertrophy
445	IRBBB	Incomplete right bundle branch block
450	RSR	RSR' or QR pattern in V1 suggests right ventricular conduction delay
451	SRSRO	RSR' pattern in V1
460	LBBB	Left bundle branch block
465	ILBBB	Incomplete left bundle branch block
470	AFB	Left anterior fascicular block

Statement Number	Acronym	Text
471	PFB	Left posterior fascicular block
478	BIFB1	(RBBB and left anterior fascicular block)
479	BIFB2	(RBBB and left posterior fascicular block)
480	BIFB	*** Bifascicular block ***
481	TRIFB	Trifascicular block
482	IVCB	Nonspecific intraventricular block
487	IVCD	Nonspecific intraventricular conduction delay
782	MAFB	(masked by fascicular block?)

Chamber Hypertrophy or Enlargement

Statement Number	Acronym	Text
350	RAE	Right atrial enlargement
360	LAE	Left atrial enlargement
369	BAE	Biatrial enlargement
412	S1S2S3	S1-S2-S3 pattern, consider pulmonary disease, RVH, or normal variant
441	RVE+	, plus right ventricular hypertrophy
442	RBBRVH	Right bundle branch block -or- Right ventricular hypertrophy
520	RVH	Right ventricular hypertrophy
521	RVH-2ST	Right ventricular hypertrophy with repolarization abnormality
530	RAVL	R in AVL
531	SOKLYON	Sokolow-Lyon
532	CORNVOLT	Cornell Votage
533	CORNPROD	Cornell Product
534	ROMESTES	Romhilt-Estes
540	LVH	Voltage criteria for left ventricular hypertrophy
541	LVH2	Left ventricular hypertrophy
542	QRSV	Minimal voltage criteria for LVH, may be normal variant
543	QRSW	with QRS widening
544	2ST	with repolarization abnormality
545	QRSW-2ST	with QRS widening and repolarization abnormality
548	LVH3	Moderate voltage criteria for LVH, may be normal variant
570	BIVH	Biventricular hypertrophy
571	PMDPV	Prominent mid-precordial voltage,
968	INJONV	ST elevation, consider injury or variant associated with LVH
1084	WSTR	with strain pattern

Infarction

Statement Number	*Acronym*	*Text*
700	SMI	Septal infarct
740	AMI	Anterior infarct
760	LMI	Lateral infarct
780	IMI	Inferior infarct
795	RVI	with right ventricular involvement
800	PXT	, with posterior extension
801	IPMI	Inferior-posterior infarct
802	POSTMI	Posterior infarct
803	QESPMI	Increased R/S ratio in V1, consider early transition or posterior infarct
805	RV4R	Inferior injury pattern suggests right ventricular involvement, recommend adding leads V3r and V4r to confirm
806	CRVI	Consider right ventricular involvement in acute inferior infarct
810	ASMI	Anteroseptal infarct
820	ALMI	Anterolateral infarct
821	STEMI	** ** ACUTE MI / STEMI ** **
822	NSTEMI	** ** ACUTE MI / non-STEMI ** **
827	LBBBNEW	** ** Consider ACUTE MI if LBBB is new ** **
827	LBBBAMI	** ** LBBB with primary ST elevation abnormality - PROBABLE ACUTE MI ** **
829	ACUMI	** ** ACUTE MI ** **
830	AC	, possibly acute
831	AU	, age undetermined
832	OLD	, old
833	NEW	, new
1423	ACUT	Acute

Repolarization Abnormalities

ST Elevation

Statement Number	*Acronym*	*Text*
435	BRUG1	Brugada pattern, type 1
435	BRUG2	Brugada pattern, type 2
437	BRUG3	Brugada pattern, type 3
901	PCARD	Acute pericarditis
902	SERYR1	ST elevation, consider early repolarization, pericarditis, or injury
903	SERYR2	ST elevation, probably due to early repolarization
904	NSTE	Nonspecific ST elevation

Statement Number	Acronym	Text
963	IIOHAI	ST elevation, consider inferior injury or acute infarct
964	AIOHAI	ST elevation, consider anterior injury or acute infarct
965	LIOHAI	ST elevation, consider lateral injury or acute infarct
966	ALIHAI	ST elevation, consider anterolateral injury or acute infarct
967	ILIHAI	ST elevation, consider inferolateral injury or acute infarct
968	INJONV	ST elevation, consider injury or variant associated with LVH
1000	REPOL	Early repolarization
1083	STELIN	ST elevation in

ST Depression

Statement Number	Acronym	Text
1001	JSTN	Junctional ST depression, probably normal
1002	JST	Junctional ST depression, probably abnormal
1023	NSTD	Nonspecific ST depression
1024	STDEP2	ST depression, consider subendocardial injury
1082	STDPIN	ST depression in

Injury

Statement Number	Acronym	Text
920	SINJ	Septal injury pattern
930	AINJ	Anterior injury pattern
940	LINJ	Lateral injury pattern
950	IINJ	Inferior injury pattern
960	ASINJ	Anteroseptal injury pattern
961	ALINJ	Anterolateral injury pattern
962	ILINJ	Inferolateral injury pattern
1040	SSBINJ	Marked ST abnormality, possible septal subendocardial injury
1050	ASBINJ	Marked ST abnormality, possible anterior subendocardial injury
1060	LSBINJ	Marked ST abnormality, possible lateral subendocardial injury
1070	ISBINJ	Marked ST abnormality, possible inferior subendocardial injury
1071	MSTDIL	Marked ST abnormality, possible inferolateral subendocardial injury
1080	MSTDAS	Marked ST abnormality, possible anteroseptal subendocardial injury
1081	MSTDAL	Marked ST abnormality, possible anterolateral subendocardial injury

Other ST Effects

Statement Number	Acronym	Text
544	2ST	with repolarization abnormality
826	LBBBACS	** ** LBBB with primary ST-T abnormality - Consider ACUTE CORONARY SYNDROME (ACS) ** **
828	AIS	** ** Consider ACUTE CORONARY SYNDROME (ACS) ** **
900	NST	Nonspecific ST abnormality
1084	WSTR	with strain pattern
1100	ST&	ST &
1138	STABAND	ST abnormality and
1141	NSTT	Nonspecific ST and T wave abnormality
1460	ACSBCAUS	ECG interpretation of ACS is based on presence of symptoms and
1462	CROACS	ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings

T-Wave

Statement Number	Acronym	Text
1140	NT	Nonspecific T wave abnormality
1141	NSTT	Nonspecific ST and T wave abnormality
1141	NSTT	Nonspecific ST and T wave abnormality
1142	QRST	Abnormal QRS-T angle, consider primary T wave abnormality
1145	ILT	T wave abnormality, consider inferolateral ischemia
1150	AT	T wave abnormality, consider anterior ischemia
1151	MAT	Marked T wave abnormality, consider anterior ischemia
1160	LT	T wave abnormality, consider lateral ischemia
1161	MLT	Marked T wave abnormality, consider lateral ischemia
1170	IT	T wave abnormality, consider inferior ischemia
1171	MIT	Marked T wave abnormality, consider inferior ischemia
1172	MILT	Marked T wave abnormality, consider inferolateral ischemia
1180	ALT	T wave abnormality, consider anterolateral ischemia
1181	MALT	Marked T wave abnormality, consider anterolateral ischemia
1182	TINVIN	T wave inversion in

QT Interval

Statement Number	Acronym	Text
1139	SNDQA	, may be secondary to QRS abnormality

Statement Number	Acronym	Text
1143	LNGQT	Prolonged QT
1144	BOQTI	Borderline QT interval

Names

Measurement Names

Statement Number	Acronym	Text
100	PRINT	PR interval
322	VENT-RAT	Vent. rate
395	AXIS	QRS axis
1200	T-WAVE	T waves
1419	QRS	QRS
1420	QRS-DUR	QRS duration
1421	QRS-VOL	QRS voltage

Lead Groups

Statement Number	Acronym	Text
1450	SEP	Septal leads
1451	ANT	Anterior leads
1452	LAT	Lateral leads
1453	INF	Inferior leads
1454	POS	Posterior leads
1455	ANTSEP	Anteroseptal leads
1456	ANTLAT	Anterolateral leads
1457	INFPOS	Inferoposterior leads
1458	IFLAT	Inferolateral leads
1459	RECP	Reciprocal
1544	LD-LIMB	Limb lead

Lead Names

Statement Number	Acronym	Text
1550	LD-I	I
1551	LD-II	II
1552	LD-V1	V1
1553	LD-V2	V2
1554	LD-V3	V3
1555	LD-V4	V4
1556	LD-V5	V5
1557	LD-V6	V6
1558	LD-V7	V7

Statement Number	*Acronym*	*Text*
1559	LD-V8	V8
1560	LD-V9	V9
1562	LD-V2R	V2r
1563	LD-V3R	V3r
1564	LD-V4R	V4r
1565	LD-V5R	V5r
1566	LD-V6R	V6r
1567	LD-V7R	V7r
1568	LD-V8R	V8r
1569	LD-V9R	V9r
1570	LD-A1	A1
1571	LD-A2	A2
1572	LD-A3	A3
1573	LD-A4	A4
1574	LD-III	III
1575	LD-AVR	aVR
1576	LD-AVL	aVL
1577	LD-AVF	aVF
1579	LD-D	D
1580	LD-A	A
1581	LD-J	J
1582	LD-X	X
1583	LD-Y	Y
1584	LD-Z	Z

Electrode Names

Statement Number	*Acronym*	*Text*
1537	EL-NAP	NAP
1538	EL-NST	NST
1539	EL-NAX	NAX
1540	EL-RA	RA
1541	EL-LA	LA
1542	EL-RL	RL
1543	EL-LL	LL
1545	EL-H	H
1546	EL-E	E
1547	EL-I	I
1548	EL-M	M
1601	LD-R	R
1602	LD-L	L
1603	LD-N	N

Statement Number	Acronym	Text
1604	LD-F	F
1605	LD-C1	C1
1606	LD-C2	C2
1607	LD-C3	C3
1608	LD-C4	C4
1609	LD-C5	C5
1610	LD-C6	C6
1611	LD-C7	C7
1612	LD-C8	C8
1613	LD-C9	C9
1615	LD-C2R	C2r
1616	LD-C3R	C3r
1617	LD-C4R	C4r
1618	LD-C5R	C5r
1619	LD-C6R	C6r
1620	LD-C7R	C7r
1621	LD-C8R	C8r
1622	LD-C9R	C9r

ECG Classification

Statement Number	Acronym	Text
1684	NML	Normal ECG
1687	ABR	Otherwise normal ECG
1693	BORDE	Borderline ECG
1699	AB	Abnormal ECG

Technical Problems

Statement Number	Acronym	Text
1500	POOR	Poor data quality
1501	POWER	Powerline interference
1502	BASELINE	Baseline wander
1503	MUSCLE	Muscle tremor
1504	ELECTR	Electrode noise
1505	DISC	disconnected
1672	ARM	*** Suspect arm lead reversal, interpretation assumes no reversal
1673	QCERR	*** Poor data quality, interpretation may be adversely affected
1676	$SANLERR3	** Less than 4 QRS complexes detected, no interpretation possible **

Statement Number	Acronym	Text
1678	$SANLERR2	** No QRS complexes found, no ECG analysis possible **
1679	NSTDLDS	** Nonstandard lead placement, ECG interpretation not available **

Miscellaneous

Statement Number	Acronym	Text
2	PEDANL	** * Pediatric ECG analysis * **
5	DICTATION	Report dictated, transcription pending
20	ARAT	(Atrial rate=
31	NOPF	(no P-waves found)
32	BLKED	blocked
33	ACCEL	Accelerated
176	IRR	Irregular
177	$SWITH	with
178	$SOR	or
323	RHY	Rhythm
325	CONSEC	Consecutive
327	BASIC	Basic rhythm
843	CRI-FOR	Criteria for
845	MINI-CRIT	Minimal criteria for
846	BORD-CRIT	Borderline criteria for
1306	SUNCNF	(Unconfirmed)
1400	AND	and
1401	HOWEVER	however
1402	HWV-IT	however it
1459	RECP	Reciprocal
1510	LEAD	in lead
1511	LEADS	in leads
1665	LPAREN	(
1666	RPAREN	)
1680	PO	Possible
1682	CRO	Cannot rule out
1694	BO	Borderline

Serial Comparison

Technical

Statement Number	Acronym	Text
1301	COMPAR	When compared with ECG of
1300	NO-SERIAL	No previous ECGs available

Statement Number	Acronym	Text
1302	POOR-DAT	Poor data quality in current ECG precludes serial comparison
1303	NO-SERCMP	Serial comparison not performed, all previous tracings are of poor data quality
1304	DEMOGR	Warning: demographic data different

Rate

Statement Number	Acronym	Text
322	VENT-RAT	Vent. rate
1252	RAT-DEC	Although rate has decreased
1253	RAT-INC	Although rate has increased
1254	WITH-RATINC	with rate increase
1255	WITH-RATDEC	with rate decrease

QRS Axis

Statement Number	Acronym	Text
395	AXIS	QRS axis
396	SHFT-LFT	shifted left
397	SHFT-RGT	shifted right
842	QUE-INICHG	Questionable change in initial forces of

ST Segment

Statement Number	Acronym	Text
1104	ST-NOLDEP	ST no longer depressed in
1105	ST-LESDEP	ST less depressed in
1106	ST-MORDEP	ST more depressed in
1107	ST-NOWDEP	ST now depressed in
1108	ST-DEPREP	ST depression has replaced ST elevation in
1115	QUE-STCHG	Questionable change in ST segment
1116	ST-(INC)	Non-specific change in ST segment in
1120	ST-MORELV	ST more elevated in
1121	ST-LESELV	ST less elevated in
1122	ST-ELVPRS	ST elevation now present in
1123	ST-NOLELV	ST no longer elevated in
1124	ST-ELVREP	ST elevation has replaced ST depression in

T-Waves

Statement Number	Acronym	Text
1201	T-INC	T wave amplitude has increased in
1203	T-DEC	T wave amplitude has decreased in

Statement Number	*Acronym*	*Text*
1207	LOWT-INVT	Flat T waves have replaced inverted T waves in
1208	QUE-TCHG	Questionable change in T waves
1210	LOWT-NOL	Flat T waves no longer evident in
1211	LESS-FLTT	Fewer leads exhibit flat T waves in
1212	LOWT-NOW	Flat T waves now evident in
1213	MORE-FLTT	More leads exhibit flat T waves in
1214	NSTNL	Nonspecific T wave abnormality no longer evident in
1215	NSTNW	Nonspecific T wave abnormality now evident in
1216	NSTLS	Nonspecific T wave abnormality, improved in
1217	NSTMR	Nonspecific T wave abnormality, worse in
1218	NSTFT	Nonspecific T wave abnormality has replaced inverted T waves in
1219	NSTNF	Inverted T waves have replaced nonspecific T wave abnormality in
1220	T-INVNOW	T wave inversion now evident in
1221	T-INVMOR	T wave inversion more evident in
1222	INVT-LOWT	Inverted T waves have replaced flat T waves in
1223	T-LESINV	T wave inversion less evident in
1224	T-INVNOL	T wave inversion no longer evident in

Intervals

Statement Number	*Acronym*	*Text*
100	PRINT	PR interval
1250	QT-LONG	QT has lengthened
1251	QT-SHRT	QT has shortened
1420	QRS-DUR	QRS duration

Miscellaneous

Statement Number	*Acronym*	*Text*
840	INC-MI	Increased evidence of infarction in
844	CITED	(cited on or before
1305	NO-CHG	No significant change was found
1403	LFREQ	Less frequent
1404	MFREQ	More frequent
1405	NOLONG	is no longer
1406	NOW	is now
1407	HAS-CHG	has changed
1408	HAS-NOTCHG	has not changed
1409	ARE-NOW	are now
1410	PRESENT	present
1411	HAV-NOTCHG	have not changed

Statement Number	*Acronym*	*Text*
1412	HAV-CHG	have changed
1415	HAS-REP	has replaced
1416	HAS-INC	has increased
1417	HAS-DEC	has decreased
1418	ARE-NOL	are no longer
1422	QUE-CHG	Questionable change in
1424	EVO	Serial changes of evolving
1425	SERCHG	Serial changes of
1426	SNGCH	Significant changes have occurred

Appendix B: Statement Library Arranged by Statement Number

Code	*MUSE Acronym*	*Text - English*	*Hookup Advisor*[1]	*12SL*[2]	*Serial Comparison*[3]	*Class*[4]
1	SNF	STATEMENT NOT FOUND				N
2	PEDANL	** * Pediatric ECG analysis * **		X	X	N
3	AGSPAMI	*** Age and gender specific ECG analysis ***		X		N
4	$ACS	** Acute Cardiac Syndrome criteria **				N
5	DICTATION	Report dictated, transcription pending				N
6	$TWLVW	Leads V2, V3, V4, and V6 are interpolated		X		N
8	$VLDFMT	Waveform is valid only when viewed in 4x2.5 format with lead II as the rhythm lead				N
9	$5SECLD1	Only the first 5 seconds of lead I are valid				N
10	$RDBC1	Reserved for Database Conversion				N
11	$RDBC2	Reserved for Database Conversion				N
12	$RDBC3	Reserved for Database Conversion				N
13	$SERREM	The system removed serial comparison statements because				N
14	$NOT12SL	this ECG was not analyzed with 12SL				N
15	$NOT12SL2	the 1st previous ECG was not analyzed with 12SL				N
16	$NOT12SL3	this patient has a test analyzed with the HEART algorithm				N
19	SRTH	Sinus rhythm		X	X	N
20	ARAT	(Atrial rate=				N
21	SBRAD	Sinus bradycardia		X	X	O
22	NSR	Normal sinus rhythm		X	X	N
23	STACH	Sinus tachycardia		X	X	O
24	MSBRAD	Marked sinus bradycardia		X	X	A
25	RABRAD	Low right atrial bradycardia		X		A
26	RATACH	Low right atrial tachycardia		X		A
27	LABRAD	Left atrial bradycardia		X		A
28	LATACH	Left atrial tachycardia		X		A
29	RAR	Low right atrial rhythm		X		A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
30	LAR	Left atrial rhythm		X		A
31	NOPF	(no P-waves found)				A
32	BLKED	blocked		X		N
33	ACCEL	Accelerated		X		N
34	JUNBRAD	Junctional bradycardia		X	X	A
41	JBRAD	Unusual P axis and short PR, probable junctional bradycardia		X	X	A
42	JR	Unusual P axis and short PR, probable junctional rhythm		X	X	A
43	JTACH	Unusual P axis and short PR, probable junctional tachycardia		X	X	A
61	EABRAD	Unusual P axis, possible ectopic atrial bradycardia		X	X	A
62	EAR	Unusual P axis, possible ectopic atrial rhythm		X	X	A
63	EATACH	Unusual P axis, possible ectopic atrial tachycardia		X	X	A
64	EARO	Ectopic atrial rhythm			X	A
100	PRINT	PR interval			X	N
101	FAV	with 1st degree AV block		X	X	O
102	SPR	with short PR		X	X	O
103	MBZI	with 2nd degree AV block (Mobitz I)		X	X	A
104	MBZII	with 2nd degree AV block (Mobitz II)		X	X	A
105	SAV	with 2nd degree AV block		X	X	A
106	CHB	with complete heart block		X	X	A
107	VAVB	with variable AV block		X		A
108	AVDIS	with AV dissociation		X	X	A
111	SABII	with 2nd degree SA block (Mobitz II)			X	A
112	SABI	with 2nd degree SA block (Mobitz I)			X	A
113	PAUSE	with sinus pause			X	A
141	W2T1	with 2:1 AV conduction		X		A
142	W3T1	with 3:1 AV conduction		X		A
143	W4T1	with 4:1 AV conduction		X		A
144	W5T1	with 5:1 AV conduction		X		A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
161	AFIB	Atrial fibrillation		X	X	A
162	FLUT	Atrial flutter		X	X	A
163	CRS	Coarse				N
164	ATAC	Atrial tachycardia			X	A
171	RVR	with rapid ventricular response		X		N
172	SVR	with slow ventricular response		X		N
173	ABER2	with premature ventricular or aberrantly conducted complexes				A
174	CJP	with a competing junctional pacemaker		X	X	A
175	IRREG	with undetermined rhythm irregularity		X	X	O
176	IRR	Irregular		X		N
177	$SWITH	with		X		N
178	$SOR	or		X		N
179	$SAND	and		X		N
181	ABER	with premature ventricular or aberrantly conducted complexes		X	X	O
183	APCX	atrial-paced complexes		X	*	A
184	VPCX	ventricular-paced complexes		X	*	A
185	AVPCX	AV dual-paced complexes		X	*	A
186	ASVPCX	atrial-sensed ventricular-paced complexes		X	*	A
187	SCX	sinus complexes		X		N
188	SVCX	supraventricular complexes		X		N
189	INTRIN	intrinsic complexes		X		N
190	PROAV	with prolonged AV conduction		X		O
211	OCC	with occasional		X		N
212	FREQ	with frequent		X		N
221	PSVC	premature supraventricular complexes		X	X	O
222	PAC	premature atrial complexes		X	X	O
223	PJC	premature junctional complexes			X	O
231	PVC	premature ventricular complexes		X	X	O
232	PVCF	premature ventricular and fusion complexes			X	O

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
233	CSEC	and consecutive		X		A
234	BIGEM	in a pattern of bigeminy		X		O
235	WQTACH	Wide QRS tachycardia		X	X	A
236	NQTACH	Narrow QRS tachycardia		X		O
237	$SWQR	Wide QRS rhythm		X	X	O
238	$SIVR	Idioventricular rhythm		X	X	A
241	PEC	premature ectopic complexes			X	O
242	JESC	with junctional escape complexes		X	X	O
243	VESC	with ventricular escape complexes		X	X	O
244	$SFUS	fusion complexes		X	X	O
245	$SRETC	with retrograde conduction		X		O
246	$SABCOND	aberrant conduction		X	X	O
247	$SCAPTUR	sinus/atrial capture		X		N
248	$SVTACH	Ventricular tachycardia			X	A
249	$SVFIB	Ventricular fibrillation			X	A
251	SAR	with sinus arrhythmia		X		N
252	MSAR	with marked sinus arrhythmia		X	X	O
265	PR-SBRAD	Probable sinus bradycardia, verify AV conduction				N
266	SUP-TACH	Supraventricular tachycardia				O
267	JUNCT-R	Junctional rhythm		X	X	A
268	IDIO-R	Idioventricular rhythm with AV block				A
269	VENT-RTH	Ventricular rhythm				A
270	J-TACH	Junctional tachycardia			X	A
271	SVT	Supraventricular tachycardia		X	X	O
272	VTACH	Ventricular tachycardia (ventricular or supraventricular with aberration)				A
273	AFL	Atrial flutter			X	A
274	VENT-FUS	with ventricular fusion				O
275	J-ESC	with junctional escape				O
276	ESCBT	with escape beat				O

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
277	TVT	with transient ventricular tachycardia				O
278	WEKH	with Mobitz I (Wenckebach) block				O
279	PO-ATP	Possible wandering atrial pacemaker				O
280	MULT-AT	Multifocal atrial tachycardia				A
281	COMP-HB	Complete heart block				A
282	AV-COND	Suspect AV conduction defect				O
283	AB-VENT	with intermittent aberrant ventricular conduction				O
284	SA-BLK	with SA block or transient AV block				O
285	SAB	with sinus arrest or transient AV block				A
287	LHR	Low heart rate, verify AV conduction				O
288	AFL-BL	Atrial flutter with 2 to 1 block				A
289	BIVPCK	Biventricular pacemaker detected		X		N
290	PCK	Electronic ventricular pacemaker			X	N
291	DPCK	Demand pacemaker, interpretation is based on intrinsic rhythm			X	N
292	APCK	Electronic atrial pacemaker			X	N
293	AVPCK	AV sequential or dual chamber electronic pacemaker			X	N
294	EDP	Electronic demand pacing			X	N
295	APR	Atrial-paced rhythm		X	*	A
296	VPR	Ventricular-paced rhythm		X	*	A
297	ASVPR	Atrial-sensed ventricular-paced rhythm		X	*	A
298	AVDPR	AV dual-paced rhythm		X	*	A
299	UR	Undetermined rhythm		X	X	O
300	WPWA	Ventricular pre-excitation, WPW pattern type A		X	X	A
302	WPWB	Ventricular pre-excitation, WPW pattern type B		X	X	A
303	ALTWPW	with fusion or intermittent ventricular pre-excitation (WPW)		X	X	A
304	WPW	Wolff-Parkinson-White		X	X	A
305	CWRT	Clockwise rotation of the heart, may invalidate criteria for ventricular hypertrophy				O

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
306	CCWRT	Counter clockwise rotation of the heart, may invalidate criteria for ventricular hypertrophy				O
307	DXTRO	Dextrocardia		X		A
320	CUR-UND	Current undetermined rhythm precludes rhythm comparison, needs review			X	O
321	PRV-UND	Previous ECG has undetermined rhythm, needs review			X	O
322	VENT-RAT	Vent. rate			X	O
323	RHY	Rhythm				O
324	PRM-CON	The premature contractions				O
325	CONSEC	Consecutive				O
326	WITH-DEM	with a demand pacemaker				O
327	BASIC	Basic rhythm				O
350	RAE	Right atrial enlargement		X		B
360	LAE	Left atrial enlargement		X		B
369	BAE	Biatrial enlargement		X		A
370	LAD	Leftward axis				B
371	ALAD	Abnormal left axis deviation				A
372	LAD3	Left axis deviation		X		A
380	RAD	Rightward axis		X		B
381	ARAD	Abnormal right axis deviation				A
382	RSAD	Abnormal right superior axis deviation				A
383	RAD4	Right axis deviation		X		A
384	RAD5	Right superior axis deviation		X		A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
390	INDAX	Indeterminate axis		X		B
391	NWA	Northwest axis		X		A
395	AXIS	QRS axis			X	N
396	SHFT-LFT	shifted left			X	N
397	SHFT-RGT	shifted right			X	N
410	LOWV	Low voltage QRS		X		B
411	PULD	Pulmonary disease pattern		X		A
412	S1S2S3	S1-S2-S3 pattern, consider pulmonary disease, RVH, or normal variant				A
435	BRUG1	Brugada pattern, type 1		X		A
436	BRUG2	Brugada pattern, type 2		X		A
437	BRUG3	Brugada pattern, type 3		X		A
440	RBBB	Right bundle branch block		X	X	A
441	RVE+	, plus right ventricular hypertrophy		X		A
442	RBBRVH	Right bundle branch block -or- Right ventricular hypertrophy		X		A
445	IRBBB	Incomplete right bundle branch block		X	X	B
446	IRB-RVE	.				N
450	RSR	RSR' or QR pattern in V1 suggests right ventricular conduction delay		X	X	B
451	SRSRO	RSR' pattern in V1			X	N
460	LBBB	Left bundle branch block		X	X	A
465	ILBBB	Incomplete left bundle branch block		X	X	B
470	AFB	Left anterior fascicular block		X	X	A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
471	PFB	Left posterior fascicular block		X	X	A
478	BIFB1	(RBBB and left anterior fascicular block)			X	A
479	BIFB2	(RBBB and left posterior fascicular block)			X	A
480	BIFB	*** Bifascicular block ***		X		A
481	TRIFB	Trifascicular block				A
482	IVCB	Nonspecific intraventricular block		X	X	A
487	IVCD	Nonspecific intraventricular conduction delay		X	X	B
520	RVH	Right ventricular hypertrophy		X		A
521	RVH-2ST	Right ventricular hypertrophy with repolarization abnormality				A
530	RAVL	R in aVL		X		N
531	SOKOLYON	Sokolow-Lyon		X		N
532	CORNVOLT	Cornell Voltage		X		N
533	CORNPROD	Cornell Product		X		N
534	ROMESTES	Romhilt-Estes		X		N
540	LVH	Voltage criteria for left ventricular hypertrophy		X		A
541	LVH2	Left ventricular hypertrophy		X		A
542	QRSV	Minimal voltage criteria for LVH, may be normal variant		X		B
543	QRSW	with QRS widening		X		A
544	2ST	with repolarization abnormality		X		A
545	QRSW-2ST	with QRS widening and repolarization abnormality		X		A
548	LVH3	Moderate voltage criteria for LVH, may be normal variant		X		B

Code	*MUSE Acronym*	*Text - English*	*Hookup Advisor*[1]	*12SL*[2]	*Serial Comparison*[3]	*Class*[4]
570	BIVH	Biventricular hypertrophy		X		A
571	PMDPV	Prominent mid-precordial voltage,		X		A
572	QV6	Deep Q wave in lead V6,		X		A
573	PPV	Prominent posterior voltage				A
574	PLV	Prominent lateral voltage				A
575	QIII	Deep Q in lead III				A
700	SMI	Septal infarct		X	X	A
701	SMI-LAE	.				N
740	AMI	Anterior infarct		X	X	A
760	LMI	Lateral infarct		X	X	A
780	IMI	Inferior infarct		X	X	A
782	MAFB	(masked by fascicular block?)		X	X	N
795	RVI	with right ventricular involvement		X		A
800	PXT	, with posterior extension			X	A
801	IPMI	Inferior-posterior infarct		X	X	A
802	POSTMI	Posterior infarct		X	X	A
803	QESPMI	Increased R/S ratio in V1, consider early transition or posterior infarct		X		A
805	RV4R	Inferior injury pattern suggests right ventricular involvement, recommend adding leads V3r and V4r to confirm		X		N
806	CRVI	Consider right ventricular involvement in acute inferior infarct		X		N
810	ASMI	Anteroseptal infarct		X	X	A
820	ALMI	Anterolateral infarct		X	X	A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
821	STEMI	** ** ACUTE MI / STEMI ** **		X		A
822	NSTEMI	** ** ACUTE MI / non-STEMI ** **				A
823	LBBBNEW	** ** Consider ACUTE MI if LBBB is new ** **		X		A
826	LBBBACS	** ** LBBB with primary ST-T abnormality - Consider ACUTE CORONARY SYNDROME		X		A
827	LBBBAMI	** ** LBBB with primary ST elevation abnormality - PROBABLE ACUTE MI ** **		X		A
828	AIS	** ** Consider ACUTE CORONARY SYNDROME (ACS) ** **		X		A
829	ACUMI	** ** ACUTE MI ** **				A
830	AC	, possibly acute		X		N
831	AU	, age undetermined		X	X	N
832	OLD	, old				A
833	NEW	, new			X	A
840	INC-MI	Increased evidence of infarction in				N
841	DEC-MI	Questionable change in initial forces of				N
842	QUE- INICHG	Questionable change in initial forces of			X	N
843	CRI-FOR	Criteria for			X	N
844	CITED	(cited on or before			X	N
845	MINI-CRIT	Minimal criteria for			X	N
846	BORD-CRIT	Borderline criteria for			X	N
880	MISIZ	*** QRS contour suggests infarct size is probably				N
881	VSMA	very small				N
882	SMA	small				N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
883	MOD	moderate				N
884	LARG	large				N
885	VLAR	very large				N
900	NST	Nonspecific ST abnormality		X		A
901	PCARD	Acute pericarditis		X		A
902	SERYR1	ST elevation, consider early repolarization, pericarditis, or injury		X		A
903	SERYR2	ST elevation, probably due to early repolarization		X		B
904	NSTE	Nonspecific ST elevation				A
920	SINJ	Septal injury pattern				A
930	AINJ	Anterior injury pattern		X		A
940	LINJ	Lateral injury pattern		X		A
950	IINJ	Inferior injury pattern		X		A
960	ASINJ	Anteroseptal injury pattern				A
961	ALINJ	Anterolateral injury pattern		X		A
962	ILINJ	Inferolateral injury pattern		X		A
963	IIOHAI	ST elevation, consider inferior injury or acute infarct		X		A
964	AIOHAI	ST elevation, consider anterior injury or acute infarct		X		A
965	LIOHAI	ST elevation, consider lateral injury or acute infarct		X		A
966	ALIHAI	ST elevation, consider anterolateral injury or acute infarct		X		A
967	ILIHAI	ST elevation, consider inferolateral injury or acute infarct		X		A
968	INJONV	ST elevation, consider injury or variant associated with LVH				A
1000	REPOL	Early repolarization		X		N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1001	JSTN	Junctional ST depression, probably normal		X		B
1002	JST	Junctional ST depression, probably abnormal		X		A
1020	STDIG	ST abnormality, possible digitalis effect				A
1021	NST2	Nonspecific ST abnormality				N
1022	STDEP	ST depression, consider subendocardial injury or digitalis effect				A
1023	NSTD	Nonspecific ST depression				A
1024	STDEP2	ST depression, consider subendocardial injury		X		A
1040	SSBINJ	Marked ST abnormality, possible septal subendocardial injury		X		A
1050	ASBINJ	Marked ST abnormality, possible anterior subendocardial injury		X		A
1060	LSBINJ	Marked ST abnormality, possible lateral subendocardial injury		X		A
1070	ISBINJ	Marked ST abnormality, possible inferior subendocardial injury		X		A
1071	MSTDIL	Marked ST abnormality, possible inferolateral subendocardial injury		X		A
1080	MSTDAS	Marked ST abnormality, possible anteroseptal subendocardial injury		X		A
1081	MSTDAL	Marked ST abnormality, possible anterolateral subendocardial injury		X		A
1082	STDPIN	ST depression in		X		A
1083	STELIN	ST elevation in		X		A
1084	WSTR	with strain pattern		X		A
1100	ST&	ST &		X		A
1104	ST-NOLDEP	ST no longer depressed in			X	N
1105	ST-LESDEP	ST less depressed in			X	N
1106	ST- MORDEP	ST more depressed in			X	N
1107	ST- NOWDEP	ST now depressed in			X	N
1108	ST-DEPREP	ST depression has replaced ST elevation in			X	N
1115	QUE- STCHG	Questionable change in ST segment				N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1116	ST-(INC)	Non-specific change in ST segment in			X	N
1117	ST-(DEC)	Non-specific change in ST segment in			X	N
1120	ST-MORELV	ST more elevated in			X	N
1121	ST-LESELV	ST less elevated in			X	N
1122	ST-ELVPRS	ST elevation now present in			X	N
1123	ST-NOLELV	ST no longer elevated in			X	N
1124	ST-ELVREP	ST elevation has replaced ST depression in			X	N
1138	STABAND	ST abnormality and		X		A
1139	SNDQA	, may be secondary to QRS abnormality		X		N
1140	NT	Nonspecific T wave abnormality		X		A
1141	NSTT	Nonspecific ST and T wave abnormality		X		A
1142	QRST	Abnormal QRS-T angle, consider primary T wave abnormality		X		A
1143	LNGQT	Prolonged QT		X		A
1144	BOQTI	Borderline QT interval				A
1145	ILT	T wave abnormality, consider inferolateral ischemia		X		A
1150	AT	T wave abnormality, consider anterior ischemia		X		A
1151	MAT	Marked T wave abnormality, consider anterior ischemia		X		A
1160	LT	T wave abnormality, consider lateral ischemia		X		A
1161	MLT	Marked T wave abnormality, consider lateral ischemia		X		A
1170	IT	T wave abnormality, consider inferior ischemia		X		A
1171	MIT	Marked T wave abnormality, consider inferior ischemia		X		A
1172	MILT	Marked T wave abnormality, consider inferolateral ischemia		X		A
1180	ALT	T wave abnormality, consider anterolateral ischemia		X		A
1181	MALT	Marked T wave abnormality, consider anterolateral ischemia		X		A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1182	TINVIN	T wave inversion in		X		A
1200	T-WAVE	T waves				N
1201	T-INC	T wave amplitude has increased in			X	N
1203	T-DEC	T wave amplitude has decreased in			X	N
1207	LOWT-INVT	Flat T waves have replaced inverted T waves in				N
1208	QUE-TCHG	Questionable change in T waves				N
1210	LOWT-NOL	Flat T waves no longer evident in				N
1211	LESS-FLTT	Fewer leads exhibit flat T waves in				N
1212	LOWT-NOW	Flat T waves now evident in				N
1213	MORE-FLTT	More leads exhibit flat T waves in				N
1214	NSTNL	Nonspecific T wave abnormality no longer evident in			X	N
1215	NSTNW	Nonspecific T wave abnormality now evident in			X	N
1216	NSTLS	Nonspecific T wave abnormality, improved in			X	N
1217	NSTMR	Nonspecific T wave abnormality, worse in			X	N
1218	NSTFT	Nonspecific T wave abnormality has replaced inverted T waves in			X	N
1219	NSTNF	Inverted T waves have replaced nonspecific T wave abnormality in			X	N
1220	T-INVNOW	T wave inversion now evident in			X	N
1221	T-INVMOR	T wave inversion more evident in			X	N
1222	INVT-LOWT	Inverted T waves have replaced flat T waves in				N
1223	T-LESINV	T wave inversion less evident in			X	N
1224	T-INVNOL	T wave inversion no longer evident in			X	N
1250	QT-LONG	QT has lengthened			X	N
1251	QT-SHRT	QT has shortened			X	N
1252	RAT-DEC	Although rate has decreased				N
1253	RAT-INC	Although rate has increased				N
1254	WITH- RATINC	with rate increase				N
1255	WITH- RATDEC	with rate decrease				N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1300	NO-SERIAL	No previous ECGs available			X	N
1301	COMPAR	When compared with ECG of				N
1302	POOR-DAT	Poor data quality in current ECG precludes serial comparison				N
1303	NO- SERCMP	Serial comparison not performed, all previous tracings are of poor data quality				N
1304	DEMOGR	Warning: demographic data different				N
1305	NO-CHG	No significant change was found			X	N
1306	SUNCNF	(Unconfirmed)			X	N
1340	CRIT	*** Critical Test Result:		X		A
1342	CVHIHR	High HR		X		N
1343	CVLOHR	Low HR		X		N
1346	CVLQT	Long QTc		X		N
1360	CVSTEMI	STEMI		X		N
1361	CVACS	ACS / Ischemia		X		N
1362	CVAVB	AV Block		X		N
1363	CVARRHY	Arrhythmia		X		N
1400	AND	and				N
1401	HOWEVER	however				N
1402	HWV-IT	however it				N
1403	LFREQ	Less frequent				N
1404	MFREQ	More frequent				N
1405	NOLONG	is no longer			X	N
1406	NOW	is now			X	N
1407	HAS-CHG	has changed				N
1408	HAS- NOTCHG	has not changed			X	N
1409	ARE-NOW	are now			X	N
1410	PRESENT	present			X	N
1411	HAV- NOTCHG	have not changed				N
1412	HAV-CHG	have changed				N
1415	HAS-REP	has replaced			X	N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1416	HAS-INC	has increased			X	N
1417	HAS-DEC	has decreased			X	N
1418	ARE-NOL	are no longer			X	N
1419	QRS	QRS				N
1420	QRS-DUR	QRS duration			X	N
1421	QRS-VOL	QRS voltage			X	N
1422	QUE-CHG	Questionable change in			X	N
1423	ACUT	Acute			X	N
1424	EVO	Serial changes of evolving			X	N
1425	SERCHG	Serial changes of			X	N
1426	SNGCH	Significant changes have occurred			X	N
1427	DTOFF	Manual comparison required, data off line and on volume			X	N
1428	ANACP	Manual comparison required for analog tracing			X	N
1430	NOPHONE	Manual comparison required, cannot contact main system			X	N
1450	SEP	Septal leads		X	X	N
1451	ANT	Anterior leads		X	X	N
1452	LAT	Lateral leads		X	X	N
1453	INF	Inferior leads		X	X	N
1454	POS	Posterior leads			X	N
1455	ANTSEP	Anteroseptal leads		X	X	N
1456	ANTLAT	Anterolateral leads		X	X	N
1457	INFPOS	Inferoposterior leads			X	N
1458	IFLAT	Inferolateral leads		X		N
1459	RECP	reciprocal		X		N
1460	ACSBCAUS	ECG interpretation of ACS is based on presence of symptoms and		X		N
1462	CROACS	ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings		X		N
1500	POOR	Poor data quality	X			N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1501	POWER	Powerline interference	X			N
1502	BASELINE	Baseline wander	X			N
1503	MUSCLE	Muscle tremor	X			N
1504	ELECTR	Electrode noise	X			N
1505	DISC	disconnected	X			N
1510	LEAD	in lead	X			N
1511	LEADS	in leads	X			N
1537	EL-NAP	NAP	X			N
1538	EL-NST	NST	X			N
1539	EL-NAX	NAX	X			N
1540	EL-RA	RA	X			N
1541	EL-LA	LA	X			N
1542	EL-RL	RL	X			N
1543	EL-LL	LL	X			N
1544	LD-LIMB	Limb lead	X			N
1545	EL-H	H	X			N
1546	EL-E	E	X			N
1547	EL-I	I	X			N
1548	EL-M	M	X			N
1550	LD-I	I	X			N
1551	LD-II	II	X			N
1552	LD-V1	V1	X			N
1553	LD-V2	V2	X			N
1554	LD-V3	V3	X			N
1555	LD-V4	V4	X			N
1556	LD-V5	V5	X			N
1557	LD-V6	V6	X			N
1558	LD-V7	V7	X			N
1559	LD-V8	V8	X			N
1560	LD-V9	V9	X			N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1562	LD-V2R	V2r	X			N
1563	LD-V3R	V3r	X			N
1564	LD-V4R	V4r	X			N
1565	LD-V5R	V5r	X			N
1566	LD-V6R	V6r	X			N
1567	LD-V7R	V7r	X			N
1568	LD-V8R	V8r	X			N
1569	LD-V9R	V9r	X			N
1570	LD-A1	A1	X			N
1571	LD-A2	A2	X			N
1572	LD-A3	A3	X			N
1573	LD-A4	A4	X			N
1574	LD-III	III	X			N
1575	LD-AVR	aVR	X			N
1576	LD-AVL	aVL	X			N
1577	LD-AVF	aVF	X			N
1578	LD-MVR	mVR	X			N
1579	LD-D	D	X			N
1580	LD-A	A	X			N
1581	LD-J	J	X			N
1582	LD-X	X	X			N
1583	LD-Y	Y	X			N
1584	LD-Z	Z	X			N
1585	LD-MY	mY	X			N
1586	LD-MZ	mZ	X			N
1587	LD-CC5	CC5	X			N
1588	LD-CM5	CM5	X			N
1601	LD-R	R	X			N
1602	LD-L	L	X			N
1603	LD-N	N	X			N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1604	LD-F	F	X			N
1605	LD-C1	C1	X			N
1606	LD-C2	C2	X			N
1607	LD-C3	C3	X			N
1608	LD-C4	C4	X			N
1609	LD-C5	C5	X			N
1610	LD-C6	C6	X			N
1611	LD-C7	C7	X			N
1612	LD-C8	C8	X			N
1613	LD-C9	C9	X			N
1615	LD-C2R	C2r	X			N
1616	LD-C3R	C3r	X			N
1617	LD-C4R	C4r	X			N
1618	LD-C5R	C5r	X			N
1619	LD-C6R	C6r	X			N
1620	LD-C7R	C7r	X			N
1621	LD-C8R	C8r	X			N
1622	LD-C9R	C9r	X			N
1665	LPAREN	(		X		N
1666	RPAREN	)		X		N
1669	PMFAIL	*** Suspect unspecified pacemaker failure		X		N
1670	PDIG	, probably digitalis effect				N
1671	ODIG	or digitalis effect				N
1672	ARM	*** Suspect arm lead reversal, interpretation assumes no reversal		X		N
1673	QCERR	*** Poor data quality, interpretation may be adversely affected		X	X	N
1674	AHE	Acquisition hardware fault prevents reliable analysis, carefully check ECG record before interpreting		X		N
1675	MRR	Manual reading required due to inconsistent morphologies				N

Code	*MUSE Acronym*	*Text - English*	*Hookup Advisor*[1]	*12SL*[2]	*Serial Comparison*[3]	*Class*[4]
1676	$SANLERR3	** Less than 4 QRS complexes detected, no interpretation possible **		X	X	N
1677	$SANLERR1	*** Memory allocation failure, no ECG interpretation possible ***			X	N
1678	$SANLERR2	** No QRS complexes found, no ECG analysis possible **		X	X	N
1679	NSTDLDS	** Nonstandard lead placement, ECG interpretation not available **		X		N
1680	PO	Possible		X	X	N
1682	CRO	Cannot rule out		X		N
1683	COMMA	,		X		N
1684	NML	Normal ECG		X		N
1687	ABR	Otherwise normal ECG		X		O
1693	BORDE	Borderline ECG		X		B
1694	BO	Borderline		X		N
1699	AB	Abnormal ECG		X		A

Hookup Advisor statements appear only on the screen during ECG acquisition on cardiographs that have the Hookup Advisor™ turned on. These statements never appear in an original interpretation (but may be used when editing).

"x" in this column applies only to 12SL V22. Older versions of 12SL may make additional statements that have been deprecated (e.g., certain pacemaker statements and statements that reference digitalis effect).

"*" in this column apply only to Serial Comparison in MUSE 8.0 and higher only. Earlier versions of MUSE are not aware of these statements.

N = normal ECG or not applicable; O = otherwise normal ECG; B = borderline ECG; A = abnormal ECG

Appendix C: Pediatric Tables

The normal values included in this appendix, and used by the pediatric analysis program, are those collected and published by Davignon et al. This data is based on more than 2,000 children who were found to have a normal physical examination. The total population was divided into 12 age groups, with 7 age groups in the first year of life to reflect the greater changes in the ECG during this time.

Less Than One Day Old

Item	*Value*	*Description*
Heart Rate	154	Upper heart rate
	93	Lower heart rate
Axis Limit	187	Right axis limit
	59	Left axis limit
	N/A	Northwest axis limit
PR Interval	80	Lower PR interval
	110	Mean PR interval
	160	Upper PR interval
QRS Duration	75	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	450	Large Q amplitude for III
	200	Large Q amplitude for V6
Lead V1	500	Small R amplitude for V1
	2600	Large R amplitude for V1
	1380	Mean R amplitude for V1
	NA	Small S amplitude for V1
	2300	Large S amplitude for V1
	850	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1100	Large R amplitude for V6
	NA	Small R amplitude for V6
	420	Mean R amplitude for V6
	950	Large S amplitude for V6
	320	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2800	V6 R amplitude + V1 S amplitude in horizontal plane
	5250	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

At Least a Day Old but Not More Than 2 Days Old

Item	*Value*	*Description*
Heart Rate	159	Upper heart rate
	91	Lower heart rate
Axis Limit	187	Right axis limit
	59	Left axis limit
	N/A	Northwest axis limit
PR Interval	80	Lower PR interval
	110	Mean PR interval
	160	Upper PR interval
QRS Duration	66	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	650	Large Q amplitude for III
	250	Large Q amplitude for V6
Lead V1	500	Small R amplitude for V1
	2700	Large R amplitude for V1
	1440	Mean R amplitude for V1
	NA	Small S amplitude for V1
	2100	Large S amplitude for V1
	850	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1200	Large R amplitude for V6
	NA	Small R amplitude for V6
	450	Mean R amplitude for V6
	950	Large S amplitude for V6
	300	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2900	V6 R amplitude + V1 S amplitude in horizontal plane
	5200	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

3 to 6 Days Old

Item	*Value*	*Description*
Heart Rate	166	Upper heart rate
	91	Lower heart rate
Axis Limit	187	Right axis limit
	77	Left axis limit
	N/A	Northwest axis limit
PR Interval	70	Lower PR interval
	100	Mean PR interval
	140	Upper PR interval
QRS Duration	68	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	550	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	2400	Large R amplitude for V1
	1290	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1700	Large S amplitude for V1
	660	Mean S amplitude for V1
	0.2	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1200	Large R amplitude for V6
	50	Small R amplitude for V6
	520	Mean R amplitude for V6
	1000	Large S amplitude for V6
	350	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2450	V6 R amplitude + V1 S amplitude in horizontal plane
	4900	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

1 to 3 Weeks Old

Item	*Value*	*Description*
Heart Rate	182	Upper heart rate
	107	Lower heart rate
Axis Limit	161	Right axis limit
	65	Left axis limit
	NA	Northwest axis limit
PR Interval	70	Lower PR interval
	100	Mean PR interval
	140	Upper PR interval
QRS Duration	80	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	600	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	2100	Large R amplitude for V1
	1060	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1100	Large S amplitude for V1
	420	Mean S amplitude for V1
	1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1650	Large R amplitude for V6
	250	Small R amplitude for V6
	760	Mean R amplitude for V6
	1000	Large S amplitude for V6
	340	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2100	V6 R amplitude + V1 S amplitude in horizontal plane
	4900	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

1 to 2 Months Old

Item	*Value*	*Description*
Heart Rate	179	Upper heart rate
	121	Lower heart rate
Axis Limit	113	Right axis limit
	13	Left axis limit
	180	Northwest axis limit
PR Interval	70	Lower PR interval
	100	Mean PR interval
	130	Upper PR interval
QRS Duration	76	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	750	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	1800	Large R amplitude for V1
	950	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1200	Large S amplitude for V1
	500	Mean S amplitude for V1
	0.3	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	2150	Large R amplitude for V6
	500	Small R amplitude for V6
	1160	Mean R amplitude for V6
	650	Large S amplitude for V6
	270	Mean S amplitude for V6
	0.2	Lower R/S ratio in V6
Total Deflection	2900	V6 R amplitude + V1 S amplitude in horizontal plane
	5350	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

3 to 5 Months Old

Item	*Value*	*Description*
Heart Rate	186	Upper heart rate
	106	Lower heart rate
Axis Limit	104	Right axis limit
	7	Left axis limit
	180	Northwest axis limit
PR Interval	70	Lower PR interval
	110	Mean PR interval
	150	Upper PR interval
QRS Duration	80	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	650	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	2000	Large R amplitude for V1
	980	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1700	Large S amplitude for V1
	570	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	2250	Large R amplitude for V6
	650	Small R amplitude for V6
	1310	Mean R amplitude for V6
	1000	Large S amplitude for V6
	290	Mean S amplitude for V6
	0.2	Lower R/S ratio in V6
Total Deflection	3200	V6 R amplitude + V1 S amplitude in horizontal plane
	6150	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

6 to 11 Months Old

Item	*Value*	*Description*
Heart Rate	169	Upper heart rate
	109	Lower heart rate
Axis Limit	99	Right axis limit
	6	Left axis limit
	180	Northwest axis limit
PR Interval	70	Lower PR interval
	110	Mean PR interval
	160	Upper PR interval
QRS Duration	76	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	850	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	150	Small R amplitude for V1
	2000	Large R amplitude for V1
	940	Mean R amplitude for V1
	50	Small S amplitude for V1
	1800	Large S amplitude for V1
	640	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	3.9	Upper R/S ratio in V1
Lead V6	2250	Large R amplitude for V6
	600	Small R amplitude for V6
	1260	Mean R amplitude for V6
	700	Large S amplitude for V6
	210	Mean S amplitude for V6
	0.2	Lower R/S ratio in V6
Total Deflection	3200	V6 R amplitude + V1 S amplitude in horizontal plane
	5350	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

1 to 2 Years Old

Item	*Value*	*Description*
Heart Rate	151	Upper heart rate
	89	Lower heart rate
Axis Limit	101	Right axis limit
	7	Left axis limit
	180	Northwest axis limit
PR Interval	80	Lower PR interval
	110	Mean PR interval
	150	Upper PR interval
QRS Duration	76	98% confidence interval for QRS duration, prolonged
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	600	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	250	Small R amplitude for V1
	1700	Large R amplitude for V1
	890	Mean R amplitude for V1
	60	Small S amplitude for V1
	2100	Large S amplitude for V1
	840	Mean S amplitude for V1
	0.05	Lower R/S ratio in V1
	4.3	Upper R/S ratio in V1
Lead V6	2250	Large R amplitude for V6
	600	Small R amplitude for V6
	1330	Mean R amplitude for V6
	650	Large S amplitude for V6
	190	Mean S amplitude for V6
	0.3	Lower R/S ratio in V6
Total Deflection	3900	V6 R amplitude + V1 S amplitude in horizontal plane
	4950	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

3 to 4 Years Old

Item	*Value*	*Description*
Heart Rate	137	Upper heart rate
	73	Lower heart rate
Axis Limit	104	Right axis limit
	6	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	120	Mean PR interval
	160	Upper PR interval
QRS Duration	72	98% confidence interval for QRS duration, prolonged
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	500	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	100	Small R amplitude for V1
	1800	Large R amplitude for V1
	810	Mean R amplitude for V1
	20	Small S amplitude for V1
	2100	Large S amplitude for V1
	1020	Mean S amplitude for V1
	0.03	Lower R/S ratio in V1
	2.8	Upper R/S ratio in V1
Lead V6	2450	Large R amplitude for V6
	800	Small R amplitude for V6
	1480	Mean R amplitude for V6
	500	Large S amplitude for V6
	150	Mean S amplitude for V6
	0.6	Lower R/S ratio in V6
Total Deflection	4200	V6 R amplitude + V1 S amplitude in horizontal plane
	5350	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

5 to 7 Years Old

Item	*Value*	*Description*
Heart Rate	133	Upper heart rate
	65	Lower heart rate
Axis Limit	143	Right axis limit
	11	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	120	Mean PR interval
	160	Upper PR interval
QRS Duration	79	98% confidence interval for QRS duration, prolonged
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	400	Large Q amplitude for III
	450	Large Q amplitude for V6
Lead V1	50	Small R amplitude for V1
	1400	Large R amplitude for V1
	670	Mean R amplitude for V1
	30	Small S amplitude for V1
	2400	Large S amplitude for V1
	1200	Mean S amplitude for V1
	0.02	Lower R/S ratio in V1
	2.0	Upper R/S ratio in V1
Lead V6	2650	Large R amplitude for V6
	850	Small R amplitude for V6
	1630	Mean R amplitude for V6
	400	Large S amplitude for V6
	120	Mean S amplitude for V6
	0.9	Lower R/S ratio in V6
Total Deflection	4700	V6 R amplitude + V1 S amplitude in horizontal plane
	5400	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

8 to 11 Years Old

Item	*Value*	*Description*
Heart Rate	130	Upper heart rate
	62	Lower heart rate
Axis Limit	114	Right axis limit
	9	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	130	Mean PR interval
	170	Upper PR interval
QRS Duration	85	98% confidence interval for QRS duration, prolonged
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	300	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	30	Small R amplitude for V1
	2500	Large R amplitude for V1
	540	Mean R amplitude for V1
	30	Small S amplitude for V1
	2500	Large S amplitude for V1
	1190	Mean S amplitude for V1
	NA	Lower R/S ratio in V1
	1.8	Upper R/S ratio in V1
Lead V6	2550	Large R amplitude for V6
	900	Small R amplitude for V6
	1630	Mean R amplitude for V6
	400	Large S amplitude for V6
	100	Mean S amplitude for V6
	1.5	Lower R/S ratio in V6
Total Deflection	4550	V6 R amplitude + V1 S amplitude in horizontal plane
	5300	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

12 to 15 Years Old

Item	*Value*	*Description*
Heart Rate	119	Upper heart rate
	50	Lower heart rate
Axis Limit	130	Right axis limit
	11	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	140	Mean PR interval
	180	Upper PR interval
QRS Duration	87	98% confidence interval for QRS duration, prolonged
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	300	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	NA	Small R amplitude for V1
	1000	Large R amplitude for V1
	410	Mean R amplitude for V1
	30	Small S amplitude for V1
	2100	Large S amplitude for V1
	1080	Mean S amplitude for V1
	NA	Lower R/S ratio in V1
	1.7	Upper R/S ratio in V1
Lead V6	2300	Large R amplitude for V6
	650	Small R amplitude for V6
	1430	Mean R amplitude for V6
	400	Large S amplitude for V6
	80	Mean S amplitude for V6
	1.4	Lower R/S ratio in V6
Total Deflection	4100	V6 R amplitude + V1 S amplitude in horizontal plane
	5000	R amplitude + S amplitude in V4

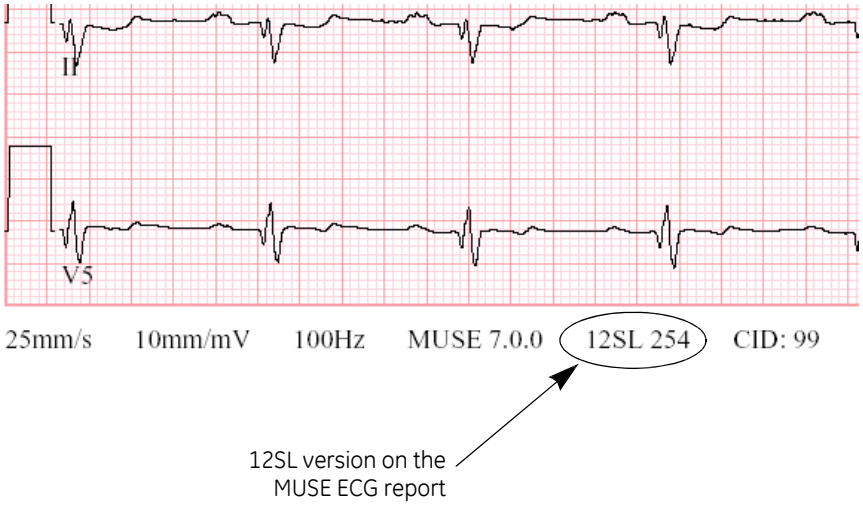
Amplitude in microvolts
Duration in milliseconds

Appendix D: 12SL Version Identification

Introduction

The 12SL analysis program has continually evolved since it was first introduced in 1980. Each released version of the program contains one or more changes to it and is associated with a unique version number.

A version number appears on the ECG report printed by an electrocardiograph or a MUSE system; encoded within this number are the actual 12SL version number and information about the specific platform on which the ECG was acquired.



Conversion Table

The following table can be used to convert the value displayed on the ECG report to the actual 12SL version number. Some values are reserved for future use. This table lists all possible values which may appear on the ECG report; not all of these values have been (or ever will be) used.

Version on Report	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*
1	14	36	2	71	reserved	106	5
2	1	37	reserved	72	4	107	reserved
3	15	38	3	73	reserved	108	6
4	2	39	reserved	74	5	109	reserved
5	reserved	40	4	75	reserved	110	7
6	3	41	reserved	76	6	111	reserved
7	reserved	42	5	77	reserved	112	8
8	4	43	reserved	78	7	113	reserved
9	reserved	44	6	79	reserved	114	9
10	5	45	reserved	80	8	115	reserved
11	reserved	46	7	81	reserved	116	10
12	6	47	reserved	82	9	117	reserved
13	reserved	48	8	83	reserved	118	11
14	7	49	reserved	84	10	119	reserved

Version on Report	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*
15	reserved	50	9	85	reserved	120	12
16	8	51	reserved	86	11	121	reserved
17	reserved	52	10	87	reserved	122	13
18	9	53	reserved	88	12	123	reserved
19	reserved	54	11	89	reserved	124	14
20	10	55	reserved	90	13	125	reserved
21	reserved	56	12	91	reserved	126	15
22	11	57	reserved	92	14	127	reserved
23	reserved	58	13	93	reserved	128	reserved
24	12	59	reserved	94	15	129	14
25	reserved	60	14	95	reserved	130	1
26	13	61	reserved	96	reserved	131	15
27	reserved	62	15	97	14	132	2
28	14	63	reserved	98	1	133	reserved
29	reserved	64	reserved	99	15	134	3
30	15	65	14	100	2	135	reserved
31	reserved	66	1	101	reserved	136	4
32	reserved	67	15	102	3	137	reserved
33	14	68	2	103	reserved	138	5
34	1	69	reserved	104	4	139	reserved
35	15	70	3	105	reserved	140	6
141	reserved	170	5	199	reserved	228	2
142	7	171	reserved	200	4	229	16
143	reserved	172	6	201	reserved	230	3
144	8	173	reserved	202	5	231	17
145	reserved	174	7	203	reserved	232	4
146	9	175	reserved	204	6	233	18
147	reserved	176	8	205	reserved	234	5
148	10	177	reserved	206	7	235	19
149	reserved	178	9	207	reserved	236	6
150	11	179	reserved	208	8	237	20
151	reserved	180	10	209	reserved	238	7
152	12	181	reserved	210	9	239	21
153	reserved	182	11	211	reserved	240	8
154	13	183	reserved	212	10	241	22
155	reserved	184	12	213	reserved	242	9
156	14	185	reserved	214	11	243	23
157	reserved	186	13	215	reserved	244	10

Version on Report	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*	*Version on Report*	*Actual 12SL version*
158	15	187	reserved	216	12	245	reserved
159	reserved	188	14	217	reserved	246	11
160	reserved	189	reserved	218	13	247	reserved
161	14	190	15	219	reserved	248	12
162	1	191	reserved	220	14	249	reserved
163	15	192	reserved	221	reserved	250	13
164	2	193	14	222	15	251	reserved
165	reserved	194	1	223	reserved	252	14
166	3	195	15	224	reserved	253	reserved
167	reserved	196	2	225	14	254	15
168	4	197	reserved	226	1	255	reserved
169	reserved	198	3	227	15		

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