GE Healthcare





TAVI Analysis

Automated segmentation & pre-procedure planning software for transcatheter aortic valve implantation.

Transcatheter Aortic Valve Implantation (TAVI) or Replacement (TAVR) is a procedure for select patients with severe symptomatic aortic stenosis (narrowing of the aortic valve opening). TAVI/TAVR is performed on a beating heart and a replacement valve is delivered via a catheter.

CT provides important information that is important for successful TAVI/TAVR procedures. CT is used to help determine aortic annulus size, to guide selection of appropriate valve, provide dimensions of the entire aorta, help determine the access path for the catheter and give guidance for Carm angulation for deployment of the device.

GE's TAVI Analysis software provides a streamlined, guided workflow to enable efficient, consistent work-ups of your TAVI studies with connectivity directly to the interventional suite.

Overview

TAVI Analysis is a post-processing software package for the Advantage Workstation (AW) and AW Server platforms. It is a planning tool used for TAVI/TAVR procedures. It automatically segments the aorta and displays the aortic valve in multiple views for quick and easy measurements of the annulus. TAVI Analysis provides guided workflow and semi-automated tools to help evaluate appropriate access pathways and can communicate directly with the interventional suite.



Hiahliahts

- Automated Aortic segmentation displayed to highlight calcific areas.
- Guided workflow for complete pre-procedure planning measurements.
- Wizard panel for valve measurements used for sizing requirements.
- Perpendicular view demonstrates working angles for valve deployment.
- Auto bone segmentation
- Fast centerline tracking to subclavian and femoral arteries.
- Lumen and curved views showing entire vascular tree.
- Quantification wizard panel.
- Intuitive and easily accessible tools
- Connectivity to the interventional suite





Features

- One comprehensive workflow for valve measurements and access path measurements.
- Automatic segmentation of transparent volume rendered model of the aorta with calcifications highlighted
- Auto orientation to aortic valve plane.
- Intuitive workflow for acquiring measurements for aortic valve sizing
- Summary table automatically populates as measurements are placed.
- Easily generate a report with measurements and associated images for efficient communication with Heart Team.
- One click perpendicular view provides guidance for C-arm angulation for deployment of device.
- Automatic bone segmentation for the chest, abdomen and pelvis.
- Real time vessel tracking provides fast centerline detection based on a single start point.
- Guided vessel tracking tools allow for easy access planning for all transcatheter approaches:
- Peripheral artery measurements automatically sent to summary table to allow easy exporting and report generation.
- Save State and send to the Cath lab for sharing access to models and measurements.

Indications for Use

TAVI Analysis for CT

TAVI Analysis is intended to provide an optimized non-invasive application to analyze vascular anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

TAVI Analysis is a post processing application option for the Advantage Workstation (AW) platform, CT Scanner or PACS stations, which can be used in the analysis of 2D and 3D CT Angiography images/data derived from DICOM 3.0 compliant CT scans for the purpose of cardiovascular and vascular disease assessment. This software is designed to support the physician in assessment of stenosis analysis, pre/post stent planning and directional vessel tortuosity visualization.

TAVI Analysis automatic visualization tools provide the users with the capabilities to facilitate segmentation of bony structures for accurate identification of the vessels. Once vessels are visualized, tools are available for sizing the vessel, analyzing calcified and non-calcified plaque to determine the densities of plaque within a coronary artery, measure areas of abnormalities within a vessel. TAVI Analysis for X-Ray

TAVI Analysis is a software post processing option for the Advantage Workstation (AW) Platform, which can be used in the analysis of the 3D angiography data. It provides a number of display, measurement and batch filming/archive features and will aid Physicians in studying user selected vessels for stenosis analysis, pre & post stent planning, and directional vessel tortuosity visualization.

System Requirements Minimum platform release:

TAVI Analysis option can be installed on GE's AW workstation or AW Server with VolumeShare 7 or later software

 VesselIQ Xpress with Autobone are pre-requisites for TAVI Analysis

Compatible hardware:

• Z800, Z820, Z440 (and later)

• AW Server 3.1 and above (recommended monitor resolution is up too dual 2MP (1600 x 1200) or a single 3MP (1536 x 2048)

Regulatory Compliance

This product complies with the European CE marking regulation following Medical Devices Directive: Directive 93/42/EEC.

Features Detail

Valve Definition

• The TAVI protocol allows users to select single or multiple cardiac phases.

• Automatic segmentation of aorta and auto detection of valve plane with double oblique tool.



- Analyze, trace and edit annulus contour. Available annulus measurements include:
 - o Minimum diameter
 - $_{\circ}$ Maximum diameter
 - o Perimeter
 - o Area
 - Equiv. diameter based on perimeter and area

• Ability to define minimum and maximum diameters above the annulus along the length of the aorta.



- Aortic measurement tools provide: • Minimum and Maximum
 - diameters above annulus • Left Ventricular Outflow Tract
 - (LVOT)
 - Ostia HeightsSinus diameters
- One click perpendicular view demonstrates working angles for valve deployment in the cath lab.
- Measurements are auto populated into the summary table for easy viewing and export into a report.



Aorta Analysis

- Automatic bone segmentation and real time vessel tracking.
- Guided vessel tracking tools allow for easy access planning for all transcatheter approaches:
 - Subclavian Artery
 - Femoral Artery
 - Apical Approach



- Quantification view has dedicated tools capable of doing measurements for stenosis, aneurysms, 3D angles and distance measurements.
- Predefined measurements list provides a template for a standard order and location from which to place all measurements.



• Peripheral artery measurements automatically sent to summary table to allow easy exporting.



 Summary table converts to PDF format for a simple and concise way to share measurements and images with heart team for planning discussions.

Procedure Preparation

- Provides valve measurements, perpendicular view and gantry angulation in the cath lab to prepare for TAVI/TAVR procedure.
- Direct communication with Heart Vision software for easy transition from planning to guidance.
- 3D and calcium overlay VR models to aide in visualization during procedure.



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