

Serena Bright Datasheet

CESM Guided Biopsy for Senographe Pristina



GE imagination at work

Indications for Use

The **Serena Bright** option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images acquired with **Contrast Enhanced Spectral Mammography (CESM)** under the same breast compression

This information provides guidance for a variety of minimally invasive or interventional procedures in the breast such as vacuum assisted biopsy, core biopsy, pre-surgical localization (e.g. hookwire), and fine needle aspirations (FNA)

CESM-Biopsy application is indicated for patients with suspicious lesions only seen with certainty when imaged with a contrast agent or that do not have a definite correlate on mammography or ultrasound

Ergonomics

Pristina Serena adapts to the patient, not the patient to the system

Gantry rotation position during biopsy	Any angle between -90° and $+90^{\circ}$
Distance between detector and the edge of the breast support	The short distance (<5 mm) between detector and the edge of the breast support facilitate biopsies of lesions located close to chest wall
Tube Parking position	Tube can be parked angulated at -33° and $+33^{\circ}$ to allow easy access to the breast during the biopsy procedure. It increases visibility of the workspace and provides complete access during the biopsy procedure while reducing physical strain of the radiologist
Access to lesion above the compression plate	Lesions located up to 1cm above the paddle aperture can be biopsied
Flexibility of the biopsy approach vertical or horizontal	<ul style="list-style-type: none"> A simple pivot changes between horizontal and vertical approaches with the same arm, removing the need for a mechanical horizontal set-up thereby saving time. The ability to easily change the biopsy device orientation without decompressing the patient may accelerate the exam.
Breast spacer	The breast spacer is 20mm in thickness which provides an increase accessibility for thin breasts with the horizontal approach.
Breast support thickness	Different compressed breast thicknesses as well as patients with varying health concerns (Wheelchair, Kyphosis, ...) can be biopsied with either needle approach
Acoustic noise of the system	The near silence of Pristina and its biopsy positioner provides a calm environment to the patient.
Remote angulation	Remote angulation reduces technologist workflow during the procedure, reducing exam time
Laser light	A laser light is included to serve as a guidance aid for an accurate anesthesia injection
Touchscreen display	Designed to operate intuitively in the 3 axes for targeting (X,Y,Z), the touchscreen may be placed on either side of the Serena system to match the work space of the technologist/radiologist during the biopsy exam

Technical information

System angulation for Xray Acquisition	<ul style="list-style-type: none"> 0° for CESM or 2D scout view -15° and $+15^{\circ}$ for CESM or 2D pairs 25° sweep for a 3D acquisition
Field Of View	2 choices of FOV for Scout: standard 12x11cm and Large 15x18cm designed for easy patient positioning. A larger FOV potentially reduces exam time by reducing retakes due to repositioning
Needle axis tilt	The 10-degree tilt provides optimal IQ in the vertical approach
Biopsy window Size	50 x 40 mm
Exposure parameters selection (track, filter, kV, mAs)	2 Modes available: Automatic or Manual

Radiation dose of a CESM-Biopsy exposure	Average dose for a CESM-biopsy compared to a 2D guided biopsy is no more than +20% for an average breast
Time to display the Image	Time to display the Recombined image is <10sec
Image Size	<ul style="list-style-type: none"> Scout view: 120x110mm or 150x180mm Stereotaxy views: 110x 90 mm
Serena Accuracy	The Pristina Serena accuracy is +/- 1 mm on each axis (X, Y and Z independently)
DICOM Connectivity	Leverages Senographe Pristina DICOM platform
Printing	Available in manual mode
System Weight	Less than 12kg. The technologist easily maneuvers Serena as needed using the dedicated rolling table
Procedure time	<ul style="list-style-type: none"> The user can acquire the triplet of images allowing first targeting in less than 5min A biopsy procedure can be performed in less than 15min * <p>* As determined in GE internal workflow study</p>

User Interface

Target management	Multiple targets can be defined in the breast
Pre/Post fire Checks	Display on the same screen of pre-fire and post-fire images
Easy Targeting Interface	Critical targeting tools available on screen for fast and accurate targeting
Image display	Possibility to magnify, invert the image, modify window width or window level.
Biopsy Device Management	<ul style="list-style-type: none"> Ability to select from a comprehensive biopsy device database Biopsy device drop down menu can be organized to the user preferences
Programmable needle length	Up to 180 mm

Equipment

Standard configuration	<ul style="list-style-type: none"> Biopsy positioner and Touchscreen Display Calibration kit Generic Vertical and Horizontal Support for Core Biopsy, FNA, Hookwire 2 Compression paddle Arms (left and right) 2 Set of biopsy plates (with and without aperture) 8 Vertical and 4 horizontal Needle guide supports for Core Biopsy Laser guide Table Stand
VAD adaptors Pristina Biopsy is fully compatible with biopsy devices commonly available in the market	<ul style="list-style-type: none"> Mammotome Revolve Mammotome ST Encor Enspire Eviva ATEC (Suros)
CB adaptors	<ul style="list-style-type: none"> Bard Magnum Bard Vacora
Compatible needle guides	<ul style="list-style-type: none"> Sterilizable metal needle guides with retaining catch Sterilizable metal needle guides without retaining catch Sterile plastic needle guides Sterile plastic needle guides with slot for wire positioning
Ultra DBI table	The Ultra DBI™ maximizes department space by incorporating seated and decubitus stereotactic breast biopsy, as well as mammography into one bariatric capable platform, increasing throughput and increasing continuity of care. Refer to dedicated datasheet for more information
Multi Gantry installation	Pristina Serena can be licenced to operate on up to 5 Senographe Pristina gantries which adds flexibility to a department

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**Serena Bright it is not available in all countries.
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Data subject to change.

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