



Senographe Pristina

GE imagination at work

The Senographe* Pristina is a full field digital mammography system designed to offer an extensive breast care solution with screening and diagnostic capabilities, focused on an ergonomic design for the technologist and patient comfort.

Senographe Pristina features a 24 x 29 cm detector, designed to offer full breast coverage in a single image. Smaller breasts can also be imaged in any view with paddles that can slide to both sides of the detector.

The Senographe Pristina does not require daily calibration.

Ergonomics for technologists

- Re-imagined user interface
- Park Positioning during patient positioning
- One touch access to preset rotation for positioning
- Variable speed motorized gantry movements
- Sliding compression paddles can move to the side of the detector for compression

Ergonomics and design for patient comfort

- Designed for Patient comfort
- Wheelchair access, MITA compliant
- Thinner Bucky than previous platform
- Rounded edges detector for patient comfort

Image quality

- Automatic Optimization of Parameters (AOP), selects all exposure parameters based on breast radiological properties
- Three AOP modes + 1 Automatic mode for implants
- eContrast is an image processing feature that makes automatic adjustments of brightness and contrast
- DQE at IEC 62220-2-3 equivalent spectrum, at 75 μ Gy: 70% (+/-3) at 0.5lp/mm and 64% (+/-3) at 2lp/mm

Smooth digital workflow connectivity

- Automated Quality Control
- Integrated Repeat and Reject Analysis

Technical Specifications Detector

- Detector ready to use right after system boot
- Detector size: 24 x 29 cm
- Pixel size (pitch): 100 μ m
- Acquisition dynamic range: 14 bits
- Bucky front cover thickness: 49mm
- Optimized room for positioning due to the bucky depth: 470mm

- Image size:
 - LFOV image size - approx. 13 MB per image
 - Regular image size - approx. 9 MB per image
- Patented needle structure CsI scintillator, single piece construction
- Breast support with rounded edge
- Air cooling

Tube technology

- X-Ray tube type: Artemis
- Anode target materials - Dual track: Molybdenum (Mo) enriched with Vanadium, and Rhodium (Rh)
- Four focal spots: 0.1 and 0.3 IEC on each target
- Target angle: 0 degree
- Maximal high voltage: 49 kV
- Tube current:
 - Molybdenum target:
 - 100 mA from 25 to 30 kV on large focal spot
 - 40 mA from 25 to 30 kV on small focal spot
 - Rhodium target:
 - 62 mA from 25 to 30 kV on large focal spot
 - 35 mA from 25 to 30 kV on small focal spot
- Anode size (tracks diameter): 100 mm
- Anode heat storage capacity: 250kJ (340 kHU)
- Anode maximum dissipation: 500 W (40 kHU/min)
- Max casing continuous dissipation: 150 W (12 kHU/min) at 40 °C
- Permanent filtration: 0.69 mm Beryllium
- Weight: 7 kg
- X-ray tube assembly: self-encased X-ray tube, oil-free, lead-free, air-cooled head
- Tube protection: software monitoring of tube load

Grid/breast support

- Universal grid compatible with 2D Conventional Mammography and DBT
- Ergonomic breast support designed for patient comfort and cleanability
- Motorized lock of the grid and breast support
- Breast support material: carbon fiber composite
- Optimized grid motion ensuring no grid structure visible in the image
- Detector to breast support edge-to-edge distance \leq 5 mm

Automatic exposure

Automatic Optimization of Parameters (AOP)

Fully automatic mode

- AOP is an automatic exposure system that selects all exposure parameters based on radiological density of the breast:
 - track (Mo or Rh)
 - filter (Mo or Ag)
 - kV
 - mAs
- The system identifies the densest part of the breast to select the appropriate exposure parameters
- Three AOP modes are available:
 - "Standard + ": dose to patient comparable to screen/film Mammography
 - "Dose -": priority is given to dose reduction
 - "Standard": balances low noise and dose reduction
- Automatic acquisition mode for implants

Manual mode

- Manual selection of all parameters: track, filter, kV and mAs

Collimator

- Filters: Molybdenum: 0.030 mm; Silver: 0.030 mm
- Field of View (FOV) in detector plane, in cm:
 - For standard contact views: 24 x 29 maximum FOV or 19 x 23 regular FOV, automatic adjustment depending on paddle used, breast support and gantry rotation angle
- Field of View (FOV) selection: automatic and manual
- FOV size: selected automatically based on the paddle or geometric magnification platform used, can be modified manually by using the collimation size switch on the tube head
- FOV location (left, right, center): selected automatically based on the tube arm angle, can be modified manually by using the collimation position switch on the tube head
- Compression and exposure are prevented if the FOV and compression paddle sizes or locations are not consistent
- Light centering device: a light automatically switches on when a preset position is reached, at compression start or at paddle insertion; can be turned on with the collimation switches buttons located on the tube head or on the acquisition console

Compression

- Compression modes:
 - Motor driven compression up to 20 daN
 - Manual compression up to 27 daN
- Dual foot-pedals for column height and compression adjustments
- User defined motorized compression force limit: 4 to 20 daN
- Min force for AOP: 3 daN
- Compression speed: 3 speed levels
- Selectable automatic decompression after exposure, to minimize patient time under compression

Patient Assisted Compression (PAC)

*Commercialized as *Pristina Dueta* in some countries

- Wireless and ergonomic-designed device that allows the patient to continue the compression after the technologist has positioned correctly and reached a threshold of compression
- Designed to minimize patients' perceived pain and discomfort
- Intended to be available for every patient positioning
- PAC's speed profile is similar to the technologist-controlled one

- It is always possible for the technologist to take compression control even if the patient has started self-compression
- PAC is inhibited during acquisition, the patient cannot interfere with the examination

Positioner

- Isocentric arm with motorized rotation and vertical movement
- Source to image receptor distance: 660 mm
- Floor to image receptor distance: from 65 cm to 150 cm
- Rotation angle: -180/+180 degrees
- Ergonomic hand-rest: one at each side of the tube arm and two additional behind

Safety features

- Gantry motions locked when compression force applied

User interface

- Four sets of single speed switches for rotation, angulation and lift movements, with an accelerating speed profile
- Four sets of preset position switches for positioning in CC and MLO
- Automatic stop at +/- 90 degrees for lateral positions
- Collimation buttons on the tube head for field of view size and location
- Parameters display
 - Tube arm support rotation angle
 - Compressed breast thickness (in mm)
 - Compression force (in daN)
- Ergonomic control console
 - Controls exposure
 - Provides information on system status
 - Gives access to advanced parameters for system set-up
- Patented automatic view names marking based on breast laterality
- View name can be edited while the exam is performed

Acquisition workstation

- Time to display processed image (average): 10 seconds
- Time between exposures (typical): 12 seconds
- Dose calculated and displayed on the image after every exposure (Entrance Skin Dose and Average Glandular Dose)
- Quad core Intel i5 workstation:
 - Memory: 32GB
 - Hard disk: 1 internal 250GB disk for the system
 - Hard disk: 1TB for image storage
 - Ports: 4 Gigabit Ethernet port
 - DVI Display and port connector
- 2 types of display available
 - 1MP LCD Monitor
 - 48 cm (19") medical grade
 - 1280 x 1024 pixels (landscape)
 - High luminance - up to 300 Cd/m²
 - Contrast ratio: 2000:1
 - Viewing angle: 170 degrees
 - Mounted on a rotating arm for in-room access

- Nio Color 3MP (MDNC-3421) – Barco:
 - High performance color IPS-TFT Color LCD
 - 54cm (21.3")
 - 2048 x 1536 pixels (landscape)
 - Brightness: 900 cd/m²
 - Contrast ratio: 1400:1
 - Viewing angle: 178°
 - Mounted on a rotating arm for in-room access
- Image Presentation

eContrast allows you to choose among 6 levels to better adapt to breast morphology and radiologist display preferences:

 - eContrast 1 provides a “film-like” aspect with improved visibility of the skin line
 - eContrast 2 to 4 provide increasing steps of image sharpness and contrast
 - eContrast 5 provides a high level of sharpness and contrast, with a very high level of tissue penetration
 - eContrast 6 is adapted to very dense breast or implants
 - Automatic windowing (window level and window width)
 - Other features: zoom, roaming, inversion, flip, rotation of images, window width and level setting, annotations and measurements
- In case of power failure, an Uninterruptible Power Supply (UPS) allows to close the examination without loss of information

Connectivity

- DICOM** 3.0 platform:
 - Modality Worklist User
 - Storage Provider
 - Storage Commitment User
 - Query/Retrieve User
 - Basic Grayscale Print User
 - Verification Provider
 - DICOM-compliant CD, DVD-R/-RW and USB Data Interchange
- Connectivity features: customizable Autopush to multiple DICOM databases, Autoprint, Autodelete based on Storage Commitment
- Modality Perform Procedure Step User
- Connectivity to GE Service for remote diagnostic capability
- IHE Profiles: Scheduled workflow, Mammography image, Tomosynthesis profile, Portable data for imaging, Consistent time integration

Quality assurance

- Complete quality control program
- Automation of quality control tests: Flat Field, MTF, AOP, SNR
- Test history and results can be reviewed
- Data can be exported for data tracking
- Automated Repeat and Reject Analysis

Radiation shield

- Choice between two radiation shields:
 - Integrated to the control console
 - Standalone

High voltage generator

- Generator Integrated into the gantry for room saving
- Generator type: high frequency single-phase power supply
- Ripple: < 4% from peak to peak
- Power: 5 kW max
- Generator max rating:
 - 2 to 600 mAs (depending on track, filter and kV)
 - 22 to 49 kV, in 1 kV steps depending on track
- Generator protection: software monitoring tube load

Standard configuration

- Motorized isocentric gantry
- X-ray tube with rotating Mo/Rh anode
- 24 x 29 cm flat panel detector
- Acquisition workstation
 - CD, DVD-R/-RW
 - 1MP or 3MP display
 - Control console
 - UPS
- Pair of dual foot-pedals
- Standard Face shield
- 24 x 29 cm bucky with grid
- 24 x 29 cm paddle
- Quality control toolkit
- User manual and technical documentation

Options

- 1.5 and 1.8 magnification stands
- Additional 24 x 29 cm paddle
- 19 x 23 cm sliding paddle
- 24 x 29 cm Flexible compression paddle
- 19 x 23 cm Flexible & sliding compression paddle
- 10x23 Sliding Implant/Small breast compression paddle
- Square spot sliding compression paddle
- Round spot sliding paddle
- 2D Localization 19x23 Swiss Cheese sliding compression paddle
- 2D Localization 19x23 sliding standard compression paddle
- 2D crosshair device
- X-Ray protective shield
- Bar code reader
- Printers compatibility: AGFA DRYSTAR AXYS
- Upgradable to Senographe Pristina 3D and/or SenoBright HD
- X-ray remote control hand switch
- X-ray footswitch

Senographe Pristina 3D

Senographe Pristina 3D is a three-dimensional imaging technology that uses a low dose short X-ray sweep around a compressed breast. The acquired projection images are processed electronically in order to reconstruct a 3D representation of the entire breast. This imaging technique is designed to separate the tissues and to reduce the overlapping of structures, which represents a limiting factor in standard 2D mammography.

The 3D option is available for the Senographe Pristina platform that generates 3D and 2D images.

Senographe Pristina 3D Technology

- Sweep angle is 25° with 9 projections at any rotation angle between -160°/+160°
- The “Step and Shoot” tube motion stops for each exposure to avoid image blur
- Mo and Rh tube tracks create narrow x-ray spectra, exactly where the dose efficiency is for thin (Mo) and medium and thick breasts (Rh)
- Detector: 100 microns with no binning, high DQE in 3D mode (IEC 62220-2-3, equivalent spectrum at 5μGy): 65% (+/-2) at 0.5lp/mm and 57% (+/-2) at 2lp/mm
- Automatic reconstruction of the images by using **ASIR^{DBT}** iterative algorithms
- The dose of a DBT (Digital Breast Tomosynthesis) view is designed to be equivalent to the dose of a 2D standard acquisition of the same view
- Capability to reconstruct 0.5mm or 1mm distance between tomo-planes
- 3D+2D mode allows the user to acquire in a single action a 3D sequence followed by 2D image for a given view, without releasing the compression

SenoBright HD

The SenoBright HD (Contrast Enhanced Spectral Mammography CESM) application shall enable contrast heightened breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and ultrasound exams to localize a known or suspected lesion.

Patient Comfort

- As with previous generation GE mammography systems, patients lying in a recumbent position can be examined with SenoBright HD

Ergonomics designed for technologist

- User can switch between standard mammography and Spectral Mammography mode during the same exam session
- SenoBright HD provides a timer function to both monitor and record time after injection, which is displayed as an annotated field in the images
- SenoBright HD offers Automatic Optimization of Parameters (AOP) and manual exposure modes for the dual-energy exam
- SenoBright HD will automatically acquire the Spectral Mammography images for each view with a single action of the x-ray exposure control

Technology

SenoBright HD chooses filtering materials depending on the operating mode and the exposure levels necessary. For the high-energy acquisition, a proprietary multi-layer filter is used to shape the resulting energies of the x-ray spectrum to those required to best highlight iodine.

Energy Levels

- The energy levels may vary depending on breast thickness
- 26-34 KVp for lower energy acquisition
 - 49 KVp for higher energy acquisition.

System Power supply

- Input frequency: 50Hz/60Hz
- Input voltage: single-phase 200-240 V~
- EATON UPS 5P650 650VA

System Weight

- Gantry: 420 kg
- Control Station without monitors: 160 kg

Environmental conditions

- Temperature range: 15° to 30°C
- Humidity range: 10% to 80%
- Atmospheric pressure range: 70 kPa to 106kPa (0 to 3000m altitude)

Screening Protocol

For reference, in the US a DBT screening examination may consist of one of the following combinations (CC: craniocaudal, MLO: mediolateral oblique):

- a 2D CC view and a 3D DBT MLO view, or
- a 3D DBT image set consisting of CC and MLO views, and a 2D synthesized image set consisting of CC and MLO V-Preview images.

V-Preview is the 2D synthesized image generated by GE SenoIris mammography software from GE DBT images.

Note: Breast cancer screening may be regulated by country specific rules. Please refer to competent Healthcare Authorities for guidance

Wireless Footswitch Option

The wireless footswitch is available on the Senographe Pristina platform. The footswitch includes pedals to activate lift up, lift down, compression and decompression functionalities. The communication range between the footswitch and the receiver shall be located within 1.5m radius from the gantry.

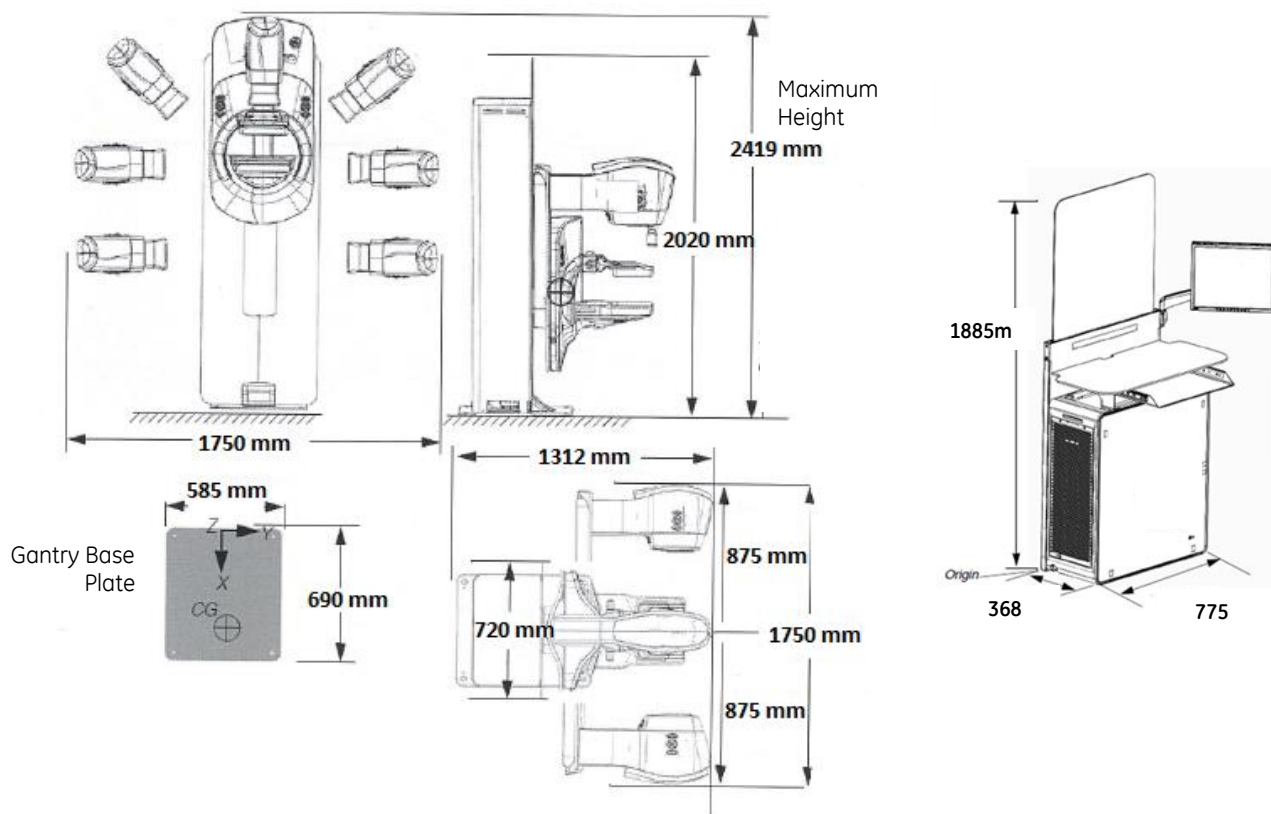
Mobile Option

A Mobile Mounting Device is available for Senographe Pristina 2D and 3D to allow its installation and transportation in a mobile unit

Workflow Options

The Senographe Pristina is compatible with iCAD Second Look (2D CAD), iCAD Tomo Detection 1.0 (3D CAD) and iCAD ProFound AI for Tomo (3D CAD)

Senographe Pristina



NOTE:

- Weights and dimensions may vary slightly depending on equipment configuration.

Senographe Pristina, PAC, Wireless footswitch, Mobiles and iCAD are not available in all countries. Please refer to your GE Healthcare sales representative.

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