

Pristina Duo™

Pristina Duo is a commercial offering of Senographe Pristina™. It 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.



Configuration

Pristina Duo is a full field digital mammography system designed to offer a comprehensive breast care solution, from first screening experience to inclusive diagnostic capabilities, with a design focused around enhancing patient throughput, increasing patient comfort and achieving clinical excellence.

Ergonomics for technologists

Re-imagined user interface

Tube Park Position to enable more space for technologists across all exam types and ease patient positioning

One touch access to preset rotation for positioning CC, MLO, LM/ML

Sliding compression paddles can move to the side of the detector for compression

Variable speed motorized gantry movements

Ergonomics and design for patient comfort

Arm rest design to ease the MLO/ML/LM positioning

Easy access patient on wheelchair, MITA compliant

Rounded edges detector for patient comfort

Off-centered FOV and paddle shift to ease positioning patient with disabilities

Smart and smooth compression with 3 speeds: the compression speeds will automatically decrease while in contact with the breast

Environmental conditions

Temperature range operating	15°C (59°F) to 30°C (86°F)
Temperature range non-operating	-5°C (-23°F) to 40°C (104°F)
Humidity range	10% to 80%
Atmospheric pressure	70 kPa to 106kPa (0 to 3000m altitude)

Technical Specifications

Detector			
Detector ready to use right after system boot.			
Detector size	24 x 29 cm		
Pixel size (pitch)	100 μm		
Acquisition dynamic range	14 bits		
Bucky front cover thickness	49mm		
Optimized room for positioning due to the bucky depth	470mm		
Image size 2D	 LFOV image size - approx. 13 MB per image Regular image size - approx. 9 MB per image 		
ACR phantom Image size DBT	Thin slices 134 MB Thick slices : 28 MB		

Patented needle structure CsI scintillator, single piece construction.

Air cooling

DQE (detective quantum efficiency) 2D/DBT

Typical DQE using the spectrum • 70% at 0.5lp/mm defined in IEC62220-1-2 at 75μGy • 64% at 2 lp/mm

MTF (Modulation Transfer Function)

Pristina Duo MTF is typically 95% at 0.5 lp/mm, 71% (+/-4%) at 2 lp/mm and 37% (+/-4%) at 4 lp/mm

System Power supply		
Input frequency	50Hz/60Hz	
Input voltage	single-phase 200-240 V~	
Boot time	2 minutes	

Grid/breast support

Universal grid compatible with 2D FFDM and DBT

Ergonomic breast support designed for patient comfort and cleanability, covering all part in contact with patient body

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 ≤ 5 mm

Grid Ratio 11 (Typical)

High voltage generator

Generator Integrated into the gantry		
Generator type	high frequency single-phase power supply	
Ripple	< 4% from peak to peak	
Generator max rating	 2 to 600 mAs (depending on track, filter and kV) this range is applicable to generator but may not be achievable at system level 22 to 49 kV, in 1 kV steps depending on track this range is achievable depending on acquisition options present on system 	
Power	5 kW max	
Generator protection	Software monitoring tube load	

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
Dissipation of heat directly i heat in tube housing	nto the air with no accumulation of
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

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 area of the breast to select the appropriate exposure parameters

The following AOP are:

· Three AOP modes for 2D FFDM

• Standard +": dose to patient

· Two AOP mode for DBT

comparable to screen/film Mammography

"Dose -": priority is given to dose reduction (not available in DBT)

"Standard": balances low noise and dose reduction

MANUAL MODE

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

Collimator	mator	
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

Dynamic collimation for DBT

Image quality

2D FFDM

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 implant.
- Automatic windowing (window level and window width)
- Other features: zoom, roaming, inversion, flip, rotation of images, window width and level setting, annotations and measurements

DBT

DBT reconstruction is based on ASIR, an iterative reconstruction scheme, that includes nonlinear processing of highly-absorbing objects, and yields improved off-plane images in terms of both in-plane and out-of-plane artifacts

Compression

Compression modes

- Motor driven compression max 20 daN
- Manual compression max 30 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

Ergonomic hand-rest

3 speed levels

Selectable automatic decompression after exposure, to minimize patient time under compression

Smooth manual compression

Gantry

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	
A set of preset position switches for positioning in CC, MLO and ML/LM		

one at each side of the tube

arm and two additional behind

Collimation buttons on the tube head for field of view size and location

Four sets of single speed switches for rotation, angulation and lift movements, with an accelerating speed profile

Automatic stop at +/- 90 degrees for lateral positions

Safety features

Gantry motions locked when compression force applied

Quality assurance

Automation of quality control tests: Flat Field, MTF, AOP, SNR

Data can be exported for data tracking (excel and pdf)

Automated Repeat and Reject Analysis for each user

QC technologist weekly 2D/3D: time 15 minutes

The Pristina Duo does not require daily calibration

Parameters display

- Tube arm support rotation angle
- · Compressed breast thickness (in mm)
- Compression force (in daN)

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Ergonomic control station

- · Controls exposure
- Provides information on system status
- Gives access to advanced parameters for system set-up

Acquisition workstation

Operating System

Suse Linux Enterprise Server (SLES) 15

• Memory: 64 GB

• 2 internal Hard disks: 1 TB disk for the system & 2D image storage + 1 TB for 3D image storage

• Ports: 4 x 1Gigabit Ethernet port

· Display port connector

Our PC P360 Ultra design includes a journaling mechanism preventing corruption of configuration files and loss of data in case of power cut. It removes the need for a dedicated UPS

2 types of display available

1MP LCD Monitor:

• Non medical grade

• 48 cm (19")

• 1280 x 1024 pixels (landscape)

• High luminance - up to 250 Cd/m2

Intel i7 8+4 cores processor workstation

· Contrast ratio: 1000.1

• Viewing angle: 178 degrees

• Mounted on a rotating arm for in-room access

3MPX LCD monitor - RX370:

· Medical grade

• High performance color IPS-TFT Color LCD

• 54 cm (21.3")

• 2048 x 1536 pixels (landscape)

• Brightness: 1100Cd/m2

• DICOM calibrated luminance: 500 Cd/m²

Contrast ratio: 1800:1
Viewing angle: 178°

• Mounted on a rotating arm for in-room access

Typical time of acquisition and display for 2D FFDM, DBT¹

		lma	aging mo	des
Parameters	Definition	2D	3D	3D+2D
3D exam Scan Angle (°)	3D angle aperture		25	25
3D exam Scan Time (sec.)	3D X-ray scan duration (pre-exposure excluded)		8.6	8.6
Cycle time X-ray end-to-system ready (sec.)	Time between X-ray end and system ready for next acquisition	3.6	2.5	3.6
Time to 2D Image view (sec.)	Time between X-ray end and 2D image display	3.3		3.6
Time to last projection display (sec.)	Time between X-ray end and last projection display		1.8	
Cycle time exposure-to-exposure time (sec.)	Time between beginning of exposure and system ready for the next exposure	8	15	19

Patient throughput

Pristina Duo supports customers with the potential to image up to 150 patients a day.²

Connectivity		User manual and technical documentation		
DICOM** 3.0 platform	 Modality Worklist User Storage Provider Storage Commitment User Query/Retrieve User Basic Grayscale Print User Verification Provider 	Quality control toolkit		
		Pair of dual foot-pedals		
		Gantry's Options		
	 DICOM-compliant CD, DVD-R/ -RW and USB Data Interchange 	19 x 23 cm sliding standard compression paddle		
Compression Formats	JPEG Lossless, JPEG 2000, JPEG LS	24 x 29 cm standard compression paddle		
Export format in 3D	вто, сто	19 x 23 cm sliding flexible compression paddle		
Export and display of DICOM Connectivity features	 Radiation Dose SR Customizable Autopush to multiple DICOM databases Autoprint Autodelete based on storage Commitment 	24 x 29 cm sliding flexible compression paddle		
		Square spot sliding compression paddle		
		10x23 Sliding Implant/Small breast compression paddle		
		Pre-surgical localization 19x23 sliding compression paddle		
		Radiation shield, integrated with control station		
Modality Perform Procedure Step User		2D cross hair		
Fully compatible with Tube Watch™ a digital twin technology to		1.5 and 1.8 magnification stands		
remotely monitor and p		Standard Face Shield		
IHE Profiles	Scheduled workflow, Mammography image, Tomosynthesis profile, Portable data for imaging, Consistent time integration, Radiation Exposure Monitoring	Universal Face Shield		
		CD, DVD-R/-RW driver		
		UPS for entire system		

Standard configuration

Motorized isocentric gantry

X-ray tube with rotating Mo/Rh anode

24 x 29 cm flat panel detector

24 x 29 cm bucky with grid

19 x 23 cm sliding standard compression paddle

24 x 29 cm standard compression paddle

Monitors

Acquisition workstation

- Control console Keyboard and mouse

UPS for entire system

Cyber-security

Seno Defense package included in the core system, available for advanced data protection, include LDAP password management

Fully compatible with Enterprise Cybersecurity

- · Centralized account management (LDAP/AD)
- Centralized Audit Trail (IHE ATNA EAT Format)

Anti-Malware McAfee Endpoint Protection (Trellix)

Cybersecurity protections configurability to integrate secured environments. (including firewall, password management, port hardening...)

Remote service

Secure connectivity to GE HealthCare Service Experts for remote diagnostic capability allowing reduced downtime

Customer-requested remote access sessions for interactive training/troubleshooting

Fully compatible with Tube Watch™ a digital twin technology to remotely monitor and predict tube failures

Pristina Duo with tomosynthesis technology

Sweep angle is 25°, with 9 projections at any gantry 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, typical DQE in 3D mode (Using the spectrum defined in IEC 62220-1-2 at 5μ Gy): Typical values are 65% at 0.5lp/mm and 57% at 2lp/mm. Measurement accuracy is +/-2%

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 tomoplanes

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

DBT planes and slabs are generated from the Pristina Duo's gantry

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

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

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

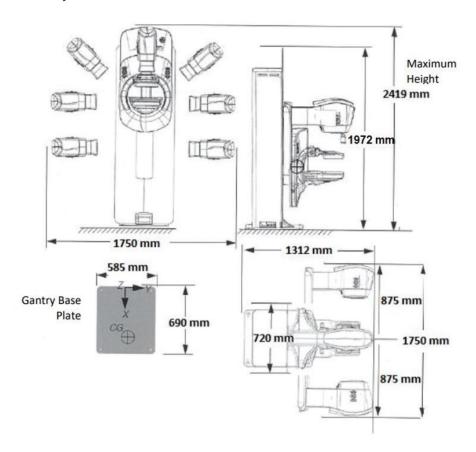
System weight and outer dimensions

Gantry: 420 kg

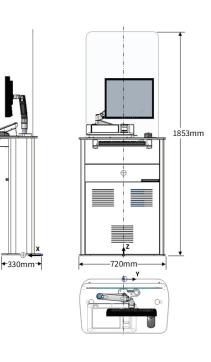
Lean control station without monitors: 90 kg

Lean control station without monitors and radshield: 75 kg

Gantry



Control station



NOTE:

Weights and dimensions may vary slightly depending on equipment configuration.

Senographe Pristina and options and iCAD are not available in all countries. Please refer to your GE Healthcare sales representative.

About GE HealthCare Technologies Inc.

GE HealthCare is a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, dedicated to providing integrated solutions, services, and data analytics to make hospitals more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 125 years, GE HealthCare is advancing personalized, connected, and compassionate care, while simplifying the patient's journey across the care pathway. Together our Imaging, Ultrasound, Patient Care Solutions, and Pharmaceutical Diagnostics businesses help improve patient care from diagnosis, to therapy, to monitoring. We are a \$19.6 billion business with approximately 51,000 colleagues working to create a world where healthcare has no limits.

Follow us on <u>LinkedIn</u>, X (formerly Twitter), and <u>Insights</u> for the latest news, or visit our website https://www.gehealthcare.com/ for more information.

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- 1. Average values based on 10 measurements in a Senographe Pristina platform system, with ACR phantom. Data on file GE HealthCare 2025. Internal Data source: DOC3101783
- 2. Analysis of 2,654 systems covering >2 million exams, Pristina Duo supports customers with the potential to image up to 150 patients a day. Results may vary according to hospital size, working days, working hours etc., there can be no guarantee that each Pristina system will achieve the same results.