IBS GROUPE

STERNMED®

Xenox S200

Full field digital mammography system

www.sternmed.de

STERNMED®

Xenox S200

Full field digital mammography system

The Xenox S200 is an advanced and reliable full field digital mammography system with image acquisition station. It is equipped with a transparent protection screen for the operator and is upgradeable with a stereotactic biopsy accessory device. The motorized +/-15° rotation of the Iso-centric C-Arm assures accurate, fast and easy workflow.

FEATURES

- CsI Indirect Conversion detector 24x30 cm format (recommended for van and hostile environment installation)
- Optional Direct conversion technology a-Se detector for excellent quality and low dose
- Automatic Collimation and filtration according to the installed compression paddle
- Iso-centric c-arm
- Fully motorized movement
- Auxiliary display showing Compression force, C-Arm rotation angle, Compressed breast thickness Laterality, Projection, ACR prefixes and suffixes

FEATURES

- OPTIONAL DEVICE FOR GEOMETRIC MAGNIFICATION with x1,5/x2 variable or x1,8 fixed
- Tube Thermal Unit display and active protection.
- H.V. generator with kV closed loop and line Feed forward compensation
- LATERAL CONTROL PANEL On preferred side of mammography unit
- FOOT-CONTROLS FOR MOTORIZED COMPRESSION OPTIONAL MULTIFUNCTION FOOT-CONTROLS
- Microprocessor controlled technology with unique safety features
- Tube Thermal Unit display and active protection
- Technical display for self-test and defective block identification, firmware release, exposure counter and last exposure time/date.
- Diagnostic functions like as Selectable service functions on LCD Display for hardware testing of each specific board with input status display, single status display and ON/OFF function
- Top Cover Carbon fiber
- Interactive microprocessor control panel with graphic display. Messages to the operator in several languages selectable during installation
- Automatic Exposure Control (AEC) select the best technique in function of effective breast density evaluated by pre-exposure
- Dose calculator
- Compression paddle movement motor driven or manual with fine adjustment by double rotating controller
- Compression paddle descent speed proportionally decreasing compressing the breast for a gentle compression
- Maximum Compression Force Safety Device
- Compression paddle release after exposure selectable from control panel, automatic or manual for bidimensional biopsy
- Acquisition console with 21,3" 2 MP COLOUR MONITOR (optional 3MP)
- Transparent anti-X protective barrier for operator (Pb equivalence>0.34 mm at 35 kV)
- FULL DICOM 3.0 MG with IHE conformity
- Patient information local Data Base with 25.000 images storage.
- QC tools based on EUREF protocol
- Optional stereotactic biopsy accessory device

OUTSTANDING

HIGH PERFORMANCE
The main target of the Xenox S200 is to obtain excellent image quality in order to allow sharp visualisation of lesions and areas of interest minimizing the dose given to the patient. It is suitable both diagnostic as well as for „screening" programs carried out always with utmost accuracy. Excellent imaging technology combined with a modern, ergonomic and winning design improves efficiency and elevates the standard of care.

EXCELLENT IMAGE QUALITY AND LOW DOSE
Xenox S200 feature the second generation of Direct conversion technology a-Se detector. It provides 85 micron pixel size chose as the best compromise between highest spatial resolution and lowest noise. The combination with the X-ray tube with Tungsten anode and Ag filter result is a significant decrease in the dose delivered to the patient.

ADVANCED AUTOMATIC EXPOSURE CONTROL
Automatic Exposure Control (AEC) with full automatic kV/mAs, manual kV/auto mAs in function of effective Breast Density evaluated by pre-exposure X-Ray pulse or breast thickness for fast operation and/or special cases with silicone prosthesis. Dose limits according to European Protocol for Dosimetry and EUREF protocol.

ERGONOMICS AND USER FRIENDLY
SternMed has payed particular attention in designing Xenox S200 in order to make it extremely easy to use for the operator and comfortable for the patient

ADVANCES DYNAMIC COLLIMATION SYSTEM
The mammography system automatically selects the proper collimation format according to the type of exam, to the format and position of the compression paddle.

MAGNIFICATION SUPPORT
A device for geometric magnification (1,5x or 2x factor) complete of cassette holder and without anti-scatter grid is optionally available. In order to reduce dose a carbon fiber free structure has been designed with automatically selected small focus once fitted.

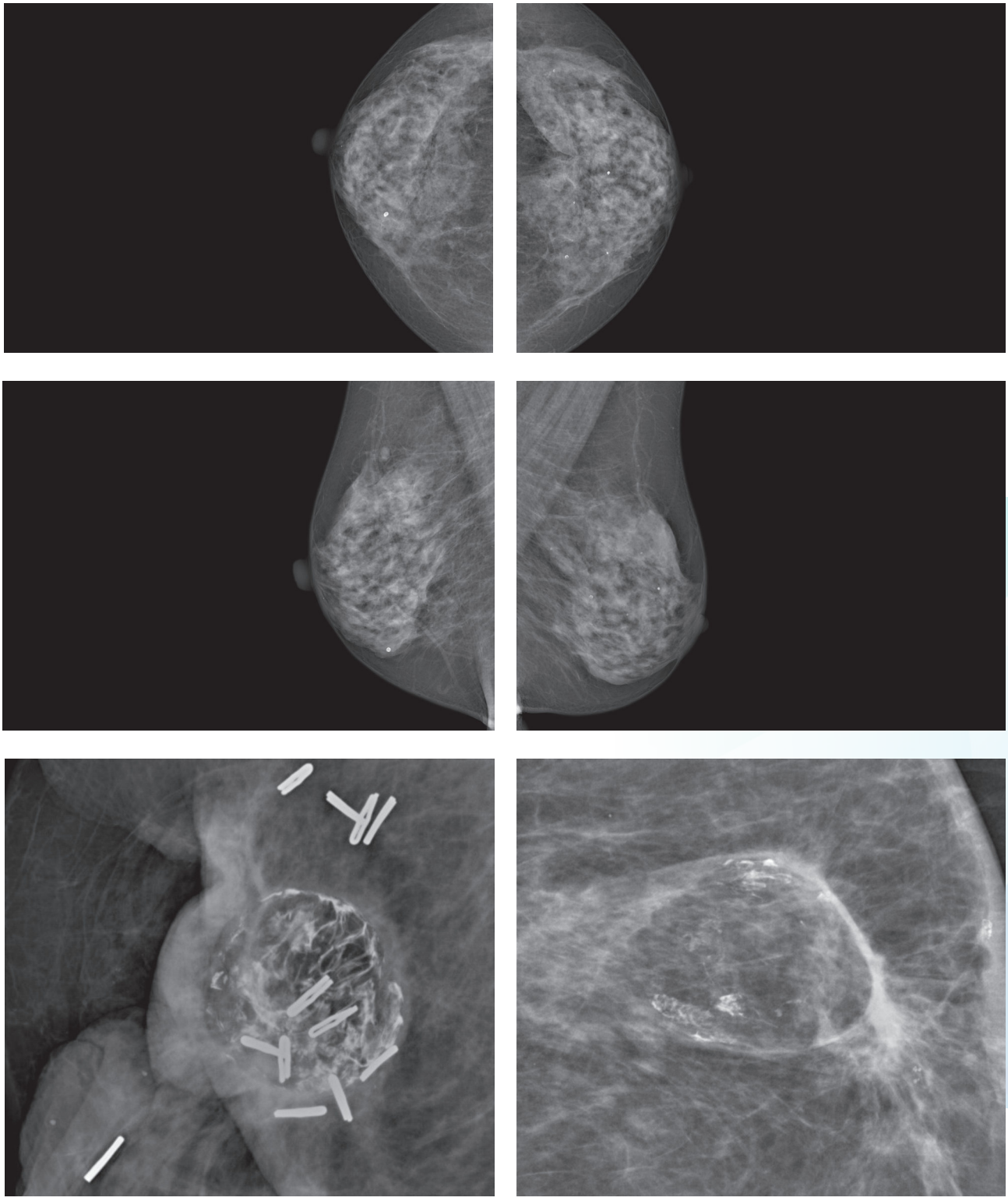
FULLY MOTORIZED ISO-CENTRIC C-ARM
XENOX S200 is supplied with motorized rotation of C-Arm (pre-selectable and fine adjustment angles). Iso-centric C-Arm that allows all breast projections without moving the patient and without adjusting height of the-Arm. The Iso-centric rotation eliminates the-Arm height adjustment when doing Cranio-Caudal and lateral projections. In this configuration the XENOX S200 is upgradeable with stereotactic biopsy device Iso-centric 3D.

STEREOTACTIC BIOPSY
The Iso-centric 3D device represents a reliable add-on solution for performing FFD stereotactic biopsies. An easy and quick move upgrades the XENOX S200 to stereotactic mode providing a comfortable working space between the tube head and the biopsy device. The motorized +/-15° rotation of the Iso-centric C-Arm assures accurate tube shift activated by means of dedicated push buttons. Lesions can be reached also in difficult positions with great precision in targeting, placing the C-Arm at the most appropriate inclination/height. Acquisition Station and includes a database for selecting needles, biopsy guns and VABs associated with the respective user selectable codes.

GENTLE AI COMPRESSION SYSTEM
The cutting-edge AI compression system, both motorized and manual, has been designed to guarantee optimal breast compression with minimal patient discomfort. In the case of motorized compression, driven by the pair of foot-controls, the exclusive microprocessor-controlled FTSE (Function of Tissue Strength Evaluation) automatically adjusts the optimal force to apply based on the specific density of the breast to be examined. The operator can also perform a manual compression with precise adjustment using two rotary controls located on C-arm.

EVERYTHING UNDER CONTROL
Displays located above the rotary controls allow viewing the set compression force and that actually applied, and the thickness of the compressed breast. Auxiliary display show all the information of the current procedure: Compression force, C-arm rotation angle, Compression breast thickness, Laterality, Projection, ACR prefixes and suffixes.

EXCELLENT CLINICAL IMAGES



TECHNICAL SPECIFICATIONS
Xenox S200 | SternMed Full field digital mammography system

POWER SUPPLY	
Line voltage	220/230/240 Vac +/-10% 50/60 Hz 115 Vac +/-10% 50/60 Hz (optional)
Power	6.6 kVA (0.5 kVA stand-by)
Current absorption	30 A peak
Number of phases	1 or 2 configurable
Connection	Permanently install. (IEC 60601-1)
Wall connection	20 A fuse or Thermal-magnetic circuit breaker (40 A fuse or Thermal-magnetic circuit breaker in 115 Vac option)
Mains resistance	<0.50 Q

EMERGENCY STOPS	
Number and Type	Two red push-buttons on both sides of mammography unit One red push-button on Acquisition Station
Function	To switch totally off the Mammography System except Digital Flat Panel Detector

X-RAY HIGH-VOLTAGE GENERATOR	
Line voltage compensation	AUTOMATIC H.V. generator with kV closed loop and line Feed forward compensation
Inverter Technology	Current fed, Mosfet bridge with output current limit capability and short circuit protection
Inverter Frequency	50 kHz
Ripple Frequency/Amplitude	100 kHz < 2%
Generator output power	5 kW (@ 35 kV)
kV range	20 / 35 kV (20 / 40 kV optional)
kV resolution (all modalities)	0,5 kV
kV precision	+/- 1%
kV repeatability	+/- 0,1%
kV risetime	<= 1.5 ms from 0 to 100%
kV display	XX,X kV (3 digits)
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1 mAs
mAs maximum value	640 mAs
mAs resolution (Automatic)	0,1 mAs
mAs values	in accordance with R'20 series (Note: values rounded down on the base of standards tolerance and series limited to 640 mAs)
mAs display	XXX,X mAs (4 digits)
Exposure Time range	0.02/ 4.7 s (640 mAs@135 mA)
	(Automatically selected in function of selected mAs)
Safety timer	10 s

Standard x-ray tube (IAE XM1016 T)	
Anode rotation speed	3000 rpm 50 Hz 10000 rpm 150 Hz (optional)
Target material	Tungsten Focal track: RT (Tungsten+Rhenium) Bulk: TZM (Molibdenum+Titanium+Zirconium)
Anode Heat Storage Capacity	300 kHU (225 kJ)
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	425 kHU (320 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	108 HU/s (80 W)
Cooling method	Free air convection
Anode Disc Target Angle	10° (Small Focus)/ 16° (Large Focus)
Anode Disc Diameter	80 mm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small) 0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	1400 W (Small) - 5600 W (Large) (3000 rpm) 2400 W (Small) - 9600 W (Large) (10000 rpm)
Nominal X-Ray Tube Voltage and Highest X-Ray Tube Current available at that voltage (IEC 60601-2-45: 201.7.9.2.1.a)	35 kV; 100 mA (@ 0,3 mm) Optional: 40 kV; 80 mA (@ 0,3 mm)
Highest X-Ray Tube Current and Highest X-Ray Tube Voltage available at that current (IEC 60601-2-45: 201.7.9.2.1.b)	34 kV; 135 mA (@ 0,3 mm) Optional: 40 kV; 80 mA (@ 0,3 mm)
Combination of X-Ray Tube Voltage and X-Ray Tube Current which results in the highest electric output power (IEC 60601-2-45: 201.7.9.2.1.c)	34 kVx135 mA=4590 W Optional: 40 kVx80 mA=3200 W
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1 mAs (for all kV values)
Range of X-Ray Tube Voltage when X-Ray Tube Voltage is controlled by AEC (IEC 60601-2-45: 201.7.9.2.1.i)	25-35 kV Optional: 25-40 kV
mAs range	1-80 mAs (from 20 to 21 kV) 1-140 mAs (from 22 to 30 kV) 1-100 mAs (from 31 to 40 kV) Large Focus: 1-320 mAs (from 20 to 24 kV) 1-400 mAs (from 25 to 27 kV) 1-640 mAs (from 28 to 30 kV) 1-560 mAs (from 31 to 34 kV) 1-320 mAs (35 kV) 1-250 mAs (from 36 to 40 kV)

TECHNICAL SPECIFICATIONS
Xenox S200 | SternMed full field digital mammography system

Standard x-ray tube (IAE XM1016 T)	
X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522/1976
HVL measured at 28 kV	>0,3 mm Al equivalent
Total filtration at 28 kV	>0,5 mm Al
TUBE ASSEMBLY THERMAL OVERLOAD PROTECTION	
With active temperature sensor under main CPU control	Upper limit temperature 65° outside tube assembly. HU and °C display available in technical. M
FILTERS	
Rhodium (50 pm thickness)	0,51 mm Al eq @ 28 kV, measured with W target
Silver (50 pm thickness)	0,55 mm Al eq. @ 28 kV, measured with W target
AUTOMATIC COLLIMATOR	
Light source	LED (Class 1 Device-320 pW)
Light beam	Switch ON by push-button or automatic when operating compression (selectable by service) Electronic timer
Light intensity	>= 150 lux
Light beam collimation accuracy	according to IEC 60601-2-45: 203.8.5.4
Mirror	with automatic out of field funct.
Formats (with device for geometric magnification)	24x30 cm and 10x14 cm for magnification
Protection of examination field	Polycarbonate screen to keep patient's face out of X-ray beam
LATERAL CONTROL PANEL	
Position	On preferred side of mammography unit (on request)
Technology	Microprocessor controlled with unique safety features, all functions under active operator control
Display Type	GRAPHIC LCD (240x128 dots)
Error messages	In several languages selectable (optionally acoustic messages available)
Special features	Tube Thermal Unit display and active protection. Technical display for self-test and defective block identification, firmware release, exposure counter and last exposure time/date.
Diagnostic functions	Selectable service functions on LCD Display for hardware testing of each specific board with input status display, single status display and ON/OFF function

DIGITAL FLAT PANEL DETECTOR	
Detector Technology	a-Si TFT Array + PIN Photodiode
Case Dimensions	35,9x34,6 cm
Top Cover	Carbon fiber 0.1 mm Al equivalent
Chest Gap	3,9 mm
Cooling Method	Air + Fan (integrated) NOTE: the detector blowers will typically create a difference of around 4-5 degrees with respect to the ambient temperature
Digitalization type	Logarithmic
Pixel Pitch	85x85 pm
Active Area	23,9x30,5 cm
Image Matrix	2816x3584=10092544
Image Depth	16 bit
Image Size	~ 20 MB
Fill Factor	>80 % geometric
MTF (Modulation Transfer Function)	85% @ 1 lp/mm 20% @ 5 lp/mm
DQE (Detector Quantum Efficiency)	50% @ 1 lp/mm 20% @ 5 lp/mm
Maximum Spatial Resolution	7 lp/mm
Nyquist Frequency	5,88 lp/mm
Signal to Noise Ratio (SNR) (with 45 mm PMMA Phantom)	15,19 (28,5 kV-10 mAs)
Ghost Image Factor (point n° 2b.2.4.5 of „European Guidelines")	0.05
Detector Read Time	< 1,1 s (24x30 cm)
Image Display Time on Acquisition Station	< 15 s
Time Between Two Images Acquisition	< 20 s
GRID	
Type	Linear, vibrating
Interspace Material	Carbon Based Polymer
Bucky factor	2,1 (W/Rh); 1,92 (W/Ag)
Ratio	6:1
Lines/cm	36
Contrast factor	1.54

TECHNICAL SPECIFICATIONS
Xenox S200 | SternMed full field digital mammography system

LINEAR, VIBRATING	
Carbon Based Polymer	Auto kV / Auto mAs (Zero Point Mode) Manual kV / Auto mAs (One Point Mode)
2,1 (W/Rh); 1,92 (W/Ag)	Dual mode: PRE and FAST PRE: tissue composition based (parameters evaluated by short X-Ray exposure) FAST: compressed breast thickness based
6:1	Mosaic of 96 areas of detector automatically selected in function of breast size and projection
1.54	Average Glandular Dose (AGD) according to: „D.R. Dance et al."
Data visualization (mGy)	On display of Control Panel/On Acquisition Station
Method of recording	Image Header (DICOM)
AGD with a 4 cm PMMA phantom	1,216 mGy
Dose Rate (28 kV-80 mAs)	36,63 R/min without Compression Plate 29,80 R/min with Compression Plate

C-ARM	
F.D.D. (Focus Detector Distance)/S.I.D.	66 cm
Manual rotation	+/-180° with disk brake
Motorized rotation (optional)	+/-180° (CW, CCW continuous to any position)
Projection Preset positions	N° 5 Programmable (LAT, OBL, CC, OBL, LAT)
Speed of Rotation	11°/s with acceleration and deceleration ramp
Display of angle rotation	On Control Panel On Auxiliary Display
Motorized Movement	Vertical
Range of Vertical Movement (from Floor)	From 43 to 128 cm (travel of 85 cm)
Speed of Vertical Movement	5 cm/s
AUXILIARY DISPLAY AND TAGGING KEYBOARD	
Display Type	3 digits (7 segments) + 18 LED
Tagging Keyboard (ACR protocol)	Ten pushbuttons: R/L laterality and prefixes/suffixes
Information	Compression force C-Arm rotation angle Compressed breast thickness Laterality, Projection, ACR prefixes and suffixes

„INTELIGENT COMP" COMPRESSION SYSTEM	
Compression Paddle Movement	Motor driven or manual with fine adjustment by double rotating controller
Standard Compression Paddles	24x30 cm shifted for large breasts 18x24 cm shifted for normal breasts
Optional Compression Paddles	18x24 cm with lateral shifting for normal breasts 9x21 cm straight for magnification 07,5 cm shifted for spot contact examination 18x24 cm shifted for bidimensional biopsy
Compression Paddle Holder	Fast mechanical unlock
Maximum free space available between Compression Plate and top cover of Potter-Bucky	325 mm with shifted Compression Paddles In Magnification Mode (straight compression paddle) MAG. X 1,5 = 231 mm MAG. X 2 = 131 mm
Compression Force	Adjustable from 70 to 200 N
Compression Force Display	Effective applied force with 1 N resolution
Compression Paddle Descent Speed	4 cm/s at the start Proportionally decreasing compressing the breast
Maximum Compression Force Safety Device	Triple: electronic, electro-mechanical, mechanical
Soft Compression paddle release after exposure	Selectable from control panel
Compression paddle aluminium equivalence	< 0.2 mm Al (0.135 mm Al~ 30 kV)
CONTROLLERS FOR MANUAL COMPRESSION	
Number and Type	Two rotating wheels with central push-button on both sides of C-Arm
FOOT-CONTROLS FOR MOTORIZED COMPRESSION	
Number and Type	Two with two pedals and push-button
Multifunction foot-controls	Two with four pedals and one push-button (optional)
Control Actions	Vertical movement of Compression Paddle Motor driven compression unlock Vertical movement of C-Arm (optional)

TECHNICAL SPECIFICATIONS Xenox S200

OPTIONAL DEVICE FOR GEOMETRIC MAGNIFICATION	
Type	Gridless, interchangeable with Potter-Bucky
Magnification Ratio	x1,5/x2 variable or x1,8 fixed
Small Focus Selection	Automatic once fitted
OPTIONAL DEVICE FOR GEOMETRIC MAGNIFICATION	
Type	Gridless, interchangeable with Potter-Bucky
Magnification Ratio	x1,5/x2 variable or x1,8 fixed
Small Focus Selection	Automatic once fitted

ACQUISITION WORKSTATION

ANTI-X PROTECTIVE BARRIER	
Type	Integrated
Pb equivalence	> 0,34 mm (@ 35 kV)
Dimensions	857x2003x640 mm
Glass thickness	20 mm
COMPUTER	
Operating System	Windows 7 Professional 64-bit
CPU	Intel Core i7 2600 3,4 GHz
RAM	8 GB DDR3-1333
HDD (removable)	n°1 TB SATA for Operating System, Acquisition Software and Toolkit Software n°1 TB SaTA for studies storage (~ 25.000 images)
DVD Recorder	48x SATA DVD +/-RW DL
Power Pack	400 W
UPS (Uninterruptible Power Supply)	650 VA
Air Flow	178 m3/h
STANDARD 2 MP COLOUR MONITOR	
Technology	TFT LCD IPS
Screen Size (diagonal)	21,3" (541 mm)
Display Resolution (pixels)	1600 x 1200
Pixel Pitch	270 pm
Viewing Angle	178° horizontal and vertical
Response Time	20 ms
Brightness	440 cd/m2 max (250 cd/m2 DICOM calibrated)
Contrast Ratio	1500:1 typical
OPTIONAL 3 MP COLOUR MONITOR	
Technology	TFT LCD IPS
Screen Size (diagonal)	21,3" (541 mm)
Display Resolution (pixels)	2048 x 1536
Pixel Pitch	212 pm
Viewing Angle	176° horizontal and vertical
Response Time	24 ms
Brightness	800 cd/m2 max (400 cd/m2 DICOM calibrated)
Contrast Ratio	750:1 typical

MAMMOGRAPHY VIEWING WORKSTATION

COMPUTER	
Operating System	Windows 7 Professional 64-bit
CPU	Intel Xeon Quad Core 3,00 GHz 10 MB cache
RAM	8 GB DDRIII-1600 MHz
HDD	2x1 TB SATA (7.000 rpm) - ~ 25.000+25.000 images
Graphic Board	ATI MED X 3900 (Very High Resolution Display System) NVIDIA Quadro NVS 310 (Colour Service Monitor)
DVD Recorder	8x SATA DVD +/-RW DL
UPS (Uninterr. Power Supply)	650 VA
COLOR SERVICE MONITOR	
Technology	LED
Screen Size (diagonal)	21,5" (16:9)
Display Resolution (pixels)	1920 x 1080
Pixel Pitch	265 pm
Viewing Angle	90° vertical/65° horizontal
Response Time	5 ms
Brightness	200 cd/m2 typical
Contrast Ratio	1000:1 typical
5 MP B/W DISPLAY	
Number	2 monitors
Technology	TFT Monochrome LCD Panel
Screen Size (diagonal)	(IPS)
Backlight	21,3" (541 mm)
Display Resolution (pixels)	LED
Pixel Pitch	2048 x 2560
Viewing Angle	165 pm
Response Time	176° horizontal and vertical
Brightness	25 ms (On/Off)
	1.200 cd/m2 (typical) 500 cd/m2
Contrast Ratio	(recommended for calibration)
ENVIRONMENTAL CONDITIONS	1.200:1
Operating conditions (24 h)	
	Temperature + 15° C / + 35° C
	Relative humidity 30%/75% Barometric pressure 700 hPa/1060
Heat dissipated in max load condition of 35 kV 500 mAs (1 shot every 5 minutes)	hPa 316 kCal/h

MAMMOGRAPHY VIEWING WORKSTATION

CLASSIFICATION (IEC 60601-1)	
Protection against electric shock	Class I, with type B applied parts
Protection degree according to IEC 529 standard	IPX0
Degree of safety in the presence of flammable anesthetics mixture with. air or with oxygen or with nitrous oxide	Not suitable for use in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide
Mode of operation	Continuous operation with intermittent loading

STERNMED®

IBS GROUPE