

STERNMED[®]



Xenox S200

Full field digital mammography system



www.sternmed.de

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The Xenox S200 is an advanced full field digital mammography system, can be configured for any type of digital mammography exam including Tomosynthesis, upgradeable with stereotactic biopsy techniques in Tomo and contrast mammography. The motorised Iso-centric C-Arm assures accurate and fast workflow.





FEATURES

- CsI Indirect Conversion detector 24 x 30 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
- Two 7 inch LED backlight touch screen color displays on both sides of C-arm
- 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 specific for Tomo exams (24 x 30 cm format)
- Compression paddle descent speed proportionally decreasing compressing the breast for a gentle compression
- "Smart μ Press" compression system
- 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 3 MP)
- 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 FEATURES

DIGITAL BREAST TOMOSYNTHESIS

DBT is a further evolution of digital mammography in which a series of low-dose projection images of the breast are obtained at different tube angles.

- 50° wide-angle Tomosynthesis
- 3D breast representing
- Better radiological interpretation, in particular in dense sinuses and multifocal lesions by reducing overlapping and enhancing detail

It can lead to better breast cancer detection and fewer false-positive recalls compared to digital mammography.

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.

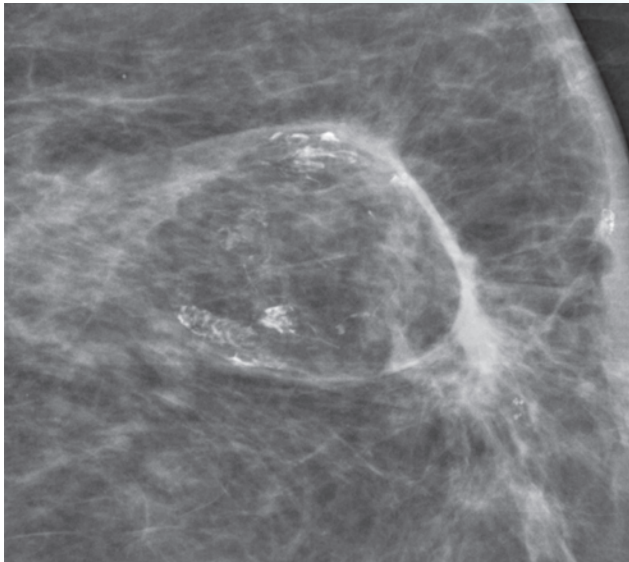
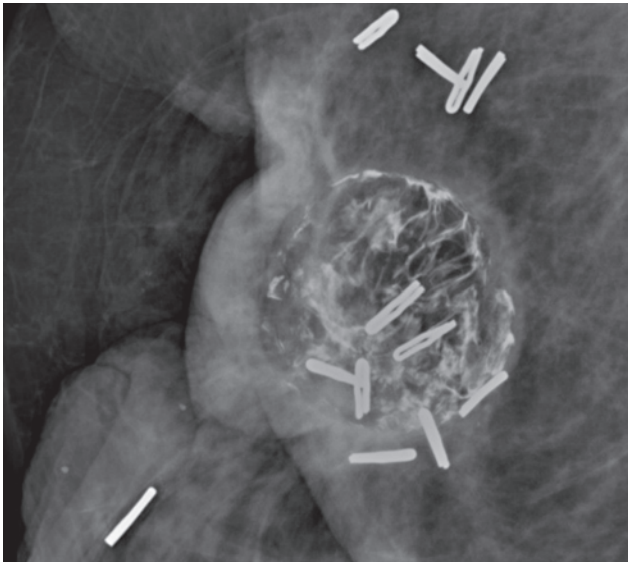
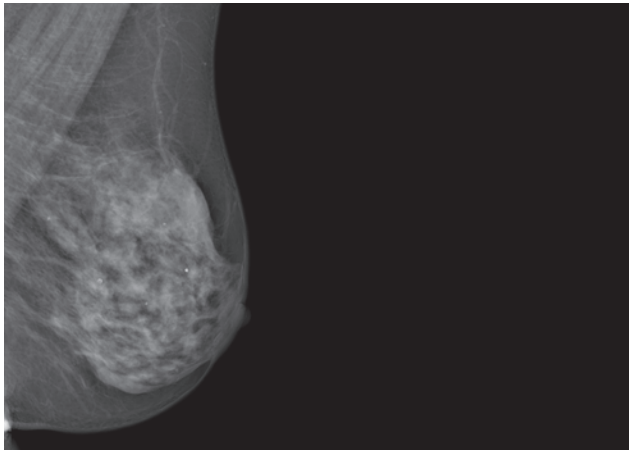
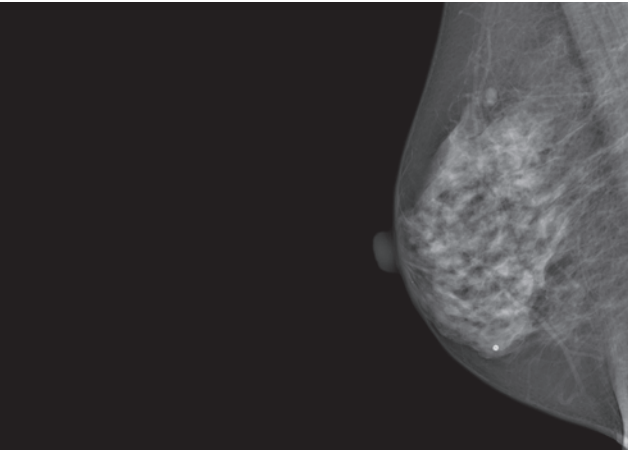
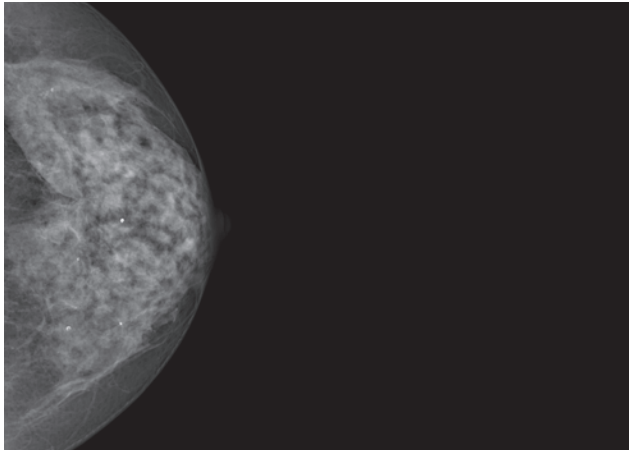
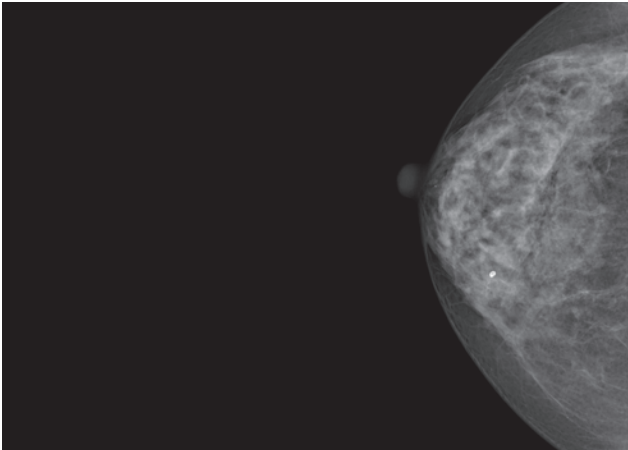
STEREOTACTIC BIOPSY

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.

„SMART μPRESS“ COMPRESSION SYSTEM

The „SMART μPRESS“ 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.

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	115/220/230/240 Vac, Momentary: 85/45/43/41 A , Long-time: 2.5/1.3/1.2/1.2 A
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	7,4 kW (@ 37 kV)
kV range	20/35 kV (20/49 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	60 kHU/min (750 W)
Dissipation Rate	
X-Ray Tube Assembly Heat	500 kHU (375 kJ)
Storage Capacity	
X-Ray Tube Assembly Heat	108 HU/s (80 W)
Dissipation Rate	
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	0,1 x 0,1 mm (Small) 0,3 x 0,3 mm (Large)
Power (Nominal Anode Input Power)	1400 W (Small) - 5900 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)	49 kV; 80 mA (@ 0,3 mm) 49 kV; 42 mA (@ 0,1 mm) In Tomo (opt.): 35 kV; 200 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)	35 kV; 135 mA (@ 0,3 mm) 35 kV; 65 mA (@ 0,1 mm) In Tomo (opt.): 35 kV; 200 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)	35 kV x 135 mA = 4725 W (@ 0,3 mm) 42 kV x 55 mA = 2310 W (@ 0,1 mm) In Tomo: 35 kV x 200 mA=7.000W
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 - 49 kV

TECHNICAL SPECIFICATIONS

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STANDARD X-RAY TUBE (IAE XM1016 T)

X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	$\geq 0,5$ mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 60522:1999-02
HVL measured at 28 kV	$> 0,5$ mm Al equivalent
Total filtration at 28 kV	$> 0,5$ mm Al

TUBE ASSEMBLY THERMAL OVERLOAD PROTECTION

With active temperature sensor under main	Upper limit temperature 65° outside tube assembly. HU and °C display
CPU control	available in technical menu

FILTERS

Rhodium (50 µm thickness)	0,51 mm Al eq @ 28 kV, measured with W target
Silver (50 µm thickness)	0,54 mm Al eq. @ 28 kV, measured with W target

AUTOMATIC COLLIMATOR

Light source	LED (Risk Group 2 at 20 cm- according to IEC62471), (Risk Group 1 at 50 cm - Low Risk - according to IEC62471)
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.
Image Formats	24 x 30 cm, 18 x 24, 14 x 30, 12 x 30, 11 x 30, 10 x 24, 11 x 14, 9 x 13, 8 x 11, for biopsy 7 x 7, 8 x 5/7 x 5, Tomo trapezoidal dynamic
Protection of examination field	Polycarbonate screen to keep patient's face out of X-ray beam

LATERAL CONTROL PANEL

Position	Double
Technology	Microprocessor controlled with unique safety features, all functions under active operator control
Display Type	GRAPHIC LCD (240 x 128 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. Selectable service functions on LCD

Diagnostic functions	Display for hardware testing of each specific board with input status display, single status display and ON/OFF function
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DIGITAL FLAT PANEL DETECTOR

Detector Technology	(a-Si) TFT Array + Pin photodiode Amorphous Silicon Amorphous Selenium (a-Se). (Selenium thickness: 200 µm)
Case Dimensions	35,9 x 34,6 cm (24 x 30 cm format)
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	85 x 85 µm
Active Area	23,9 x 30,5 cm
Image Matrix	2816 x 3584 = 10092544
Image Depth	16 bit
Image Size	~ 20 MB
Fill Factor	> 88 % geometric
MTF (Modulation Transfer Function)	90% @ 1 lp/mm > 40 % @ 5,8 lp/mm
DQE (Detector Quantum Efficiency)	50% @ 1 lp/mm > 20 % @ 5,8 lp/mm
Nyquist Frequency	5,9 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
Tomo acquisition time	10 s (15°), 12 s (24°), 30 s (50°)
Reconstruction time from last exposure	< 4 s in 2D mode
Time to display image on the AWS from last exposure	< 5 s in 2D mode
	Tomo 9 s (15°), 10 s (24°), 11 s (50°)
	Tomo 19 s (15°), 20 s (24°), 30 s (50°)
GRID	
Type	Linear, vibrating
Interspace Material	Carbon Based Polymer (2D), Graphite (TOMO)
Ratio	6:1 (2D), 5:1 (TOMO)
Lines/cm	36 (2D), 102 (TOMO)
Contrast factor	1,54 (2D), 1,3 (TOMO)

TECHNICAL SPECIFICATIONS

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AUTOMATIC EXPOSURE CONTROL AND DOSE CALCULATION

Controlled parameters	Auto kV / Auto mAs (Zero Point Mode) Manual kV / Auto mAs (One Point Mode)
Auto parameters selection criteria	Dual mode: PRE and FAST PRE: tissue composition based (parameters evaluated by short X-Ray exposure) FAST: compressed breast thickness based
Method of Calculation	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	1,40 mGy (2D), 1,6 mGy (15° TOMO), 2,20 mGy (24° TOMO), 2,30 mGy (50° TOMO)
Dose limits	According to European Protocol for Dosimetry and EUREF protocol

C-ARM

F.D.D. (Focus Detector Distance)/S.I.D.	66 cm
Motorized movements	+/- 15° Rotation and vertical
C-Arm rotation range	+/-180° (CW, CCW continuous to any position)
Projection Preset positions	N° 7 Programmable (0°, -45°, +45°, -90°, +90°, -135°, +135°)
Speed of Rotation	20 °/s with acceleration and deceleration ramp
Display of angle rotation	On Control Panel On Auxiliary Display
Range of Vertical Movement	From 54 to 145 cm (travel of 91 cm)
Tomosynthesis scan angles	± 7,5° (15°), ± 12° (24°), ± 25° (50°)
Speed of Vertical Movement	5 cm/s

TOUCHSCREEN COLOR DISPLAYS

Display Type	Two LED backlight touchscreens on both sides of C-Arm
Screen size (aspect ratio) and resolution	7" (4:3) - 640 x 480
Displayed parameters	Compression force, compressed breast thickness, patient name, projection angle, breast laterality, ACR code, collimation format, magnification factor.

„INTELLIGENT COMP“ COMPRESSION SYSTEM

Compression Paddle Movement	Motor driven or manual with fine adjustment by double rotating controller
Standard Compression Paddles	24 x 30 cm shifted for large breasts 18 x 24 cm shifted for normal breasts
Optional Compression Paddles	24 x 30 cm for tomo exams, 9 x 21 cm for magnification, Ø 7,5 cm spot for magnification, 9 x 9 cm squared for magnification, 18 x 24 cm with Ø 7,5 cm spot for contact examination, 18 x 24 cm with 9 x 9 cm spot for contact examination, 18 x 24 cm with holes for 2D biopsy, 10 x 24 cm for axillary examination 10 x 24 cm for prosthesis examination
Compression Paddle Holder	Fast mechanical unlock by rotating knob and lock warning LED
Maximum free space available between compression paddle and top cover of Potter Bucky or magnification device	182 mm with shifted compression paddles, In magnification mode with specific compression paddle: 183 mm @ 1,5x/123 mm @ 1,8x/83 mm @ 2x
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
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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 C-Arm Vertical movement of compression Paddle, Motor driven compression unlock

ACQUISITION WORKSTATION

CONSOLE WITH TRANSPARENT ANTI-X PROTECTION BARRIER

Type	Integrated
Pb equivalence	> 0,34 mm @ 35 kV/0,26 mm @ 49 kV (IEC 60601-2-45), (thickness of 20 mm), > 0,5 mm up to 150 kV (optional)
Dimensions	857 x 2003 x 640 mm
Glass thickness	11 mm

COMPUTER

Operating System	Windows 10 IoT Enterprise
CPU	Intel Core i5-6500 (Quad Core) 3.2 GHz
RAM	8 GB (2D), 16 GB (TOMO)
HDD (removable)	128 GB SSD for Operating System, DMD Acquisition Software and DMD Toolkit Software (256 GB SSD optional), 1 TB SATA for images storage (~ 25.000 images) (2 TB SATA optional)
DVD Recorder	24x
Power Pack	250 W
UPS (Uninterruptible Power Supply)	Integrated UPS (24 Vdc), 5±10 minutes typically

STANDARD 2 MP COLOUR MONITOR

Technology	TFT LCD IPS
Screen Size (diagonal)	24"
Display Resolution (pixels)	1.920 x 1.200
Viewing Angle	178° horizontal and vertical
Response Time	7 ms
Brightness	600 cd/m ² max - 350 cd/m ² DICOM
Contrast Ratio	1000:1 typical

OPTIONAL 3 MP COLOUR MONITOR

Technology	TFT LCD IPS
Screen Size (diagonal)	21,3" (541 mm)
Display Resolution (pixels)	2048 x 1536
Viewing Angle	178° horizontal and vertical
Response Time	20 ms
Brightness	900 cd/m ² max - 500 cd/m ² DICOM calibrated
Contrast Ratio	1.400:1 typical

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

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 µm
Viewing Angle	90° vertical/65° horizontal
Response Time	5 ms
Brightness	200 cd/m ² typical
Contrast Ratio	1000:1 typical

OPTIONAL 5 MP COLOUR MONITOR

Technology	TFT color LCD
Screen Size	21,3" (541 mm)
Display Resolution (pixels)	2800 x 2100
Viewing Angle	178°
Response Time	12.5 ms
Brightness	1.000 cd/m ² max - 500 cd/m ² DICOM calibrated
Contrast Ratio	1400:1 typical

ENVIRONMENTAL CONDITIONS (with a-Se Detector)

Operating conditions (24 h)	Temperature: +20 °C ÷ +25 °C Relative humidity: 30% ÷ 75% Barometric pressure: 700 hPa ÷ 1060 hPa
Heat dissipated in max load condition of 35 kV 500 mAs (1 shot every 5 minutes)	316 kCal/h

MAMMOGRAPHY VIEWING WORKSTATION

CLASSIFICATION (IEC 60601-1)

Protection against electric shock	Class I, with type B applied parts; including: - Potter-Bucky/Biopsy device carbon fiber - Compression paddles - Magnification device
Protection degree according to IEC 529 standard	IP X0 (Mammo Unit), IIPX2 (Foot-controls)
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[®]

SternMed GmbH
Schubertstrasse 31
88214 Ravensburg - Germany

Tel: +49 751 35 978 0
Fax: +49 751 35 978 105

email@sternmed.de

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