IBS GROUPE

STERNMED®

Xenox S100

Mammography system

www.sternmed.de

STERNMED®

Xenox S100

Mammography system

The Xenox S100 is a versatile analog mammography system with an iso-centric c-arm and superb image quality. It allows all breast projections without moving the patient and without adjusting the height of the C-Arm.

It is upgradeable with a 3D stereotactic biopsy device. In this case, the C-Arm positioning for biopsy views (+/-15°) is motorized and selectable when the 3D device is inserted.

FEATURES

- Equipped with two red push-buttons on both sides of mammography unit for Emergency Stops
- H.V. generator with kV closed loop and line Feed forward compensation
- LATERAL CONTROL PANEL On preferred side of mammography unit
- Microprocessor controlled technology with unique safety features
- All functions under active operator control
- Dedicated serial Port for Film ID Flasher or Dose Label Printer
- Alarm messages In several languages selectable
- Serial /USB port for Calibration and service laptop with dedicated software
- Special features Last 1300 exposure memory.
- 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.
- Statistics function like as average dose, amount of exposures for every kV value, amount of exposure
- 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
- Cassette Compatibility with all the most common models with window
- Cassette Detector Switch With alarm in different languages to avoid double exposure or exposure without cassette
- Top Cover Carbon fiber
- Film Markers integrated with two ID labels wheels
- Optional device for geometric magnification
- Automatic exposure control
- Auto parameters selection criteria selected in function of effective breast density evaluated by pre-exposure
- Programmable with PC independently for all the operative techniques available
- A.E.C. self test procedure included in control panel functions
- Dose calculator
- Iso-centric c-arm
- Display of angle rotation on control panel and auxiliary display
- Compression paddle movement motor driven or manual with fine adjustment by double rotating controller
- Compression paddle descent speed proportionally decreasing compressing the breast and customizable according to three curves
- Maximum Compression Force Safety Device
- Compression paddle release after exposure selectable from control panel, automatic or manual for bidimensional biopsy
- Auxiliary display position on basis of mammography unit indicating the information about compression force c-arm rotation angle compressed breast thickness
- Foot-controls for motorized compression with two pedals and push-button control actions for vertical movement of compression paddle and motor driven compression unlock
- Optional multifunction foot-controls with four pedals and one push-button control actions for vertical movement of c-arm, vertical movement of compression paddle, motor driven compression unlock

A WIDE RANGE OF ACCESSORIES

POTTER-BUCKY
There are two different tables (18x24 or 24x30 cm format) with carbon fiber grid, complete of ID labels. Tables are perfectly interchangeable.

COLLIMATION PLATES
For each table size or for magnification technique are available appropriate magnetic collimation plates. Theshape of collimation plate is studied to avoid wrong insertion.

AUTOMATIC COLLIMATOR
XENOX S100 can be provided with an automatic collimator. In this case, the mammography unit is able to detect the table size (18x24 or 24x30 cm) and to select automatically the proper collimation field.

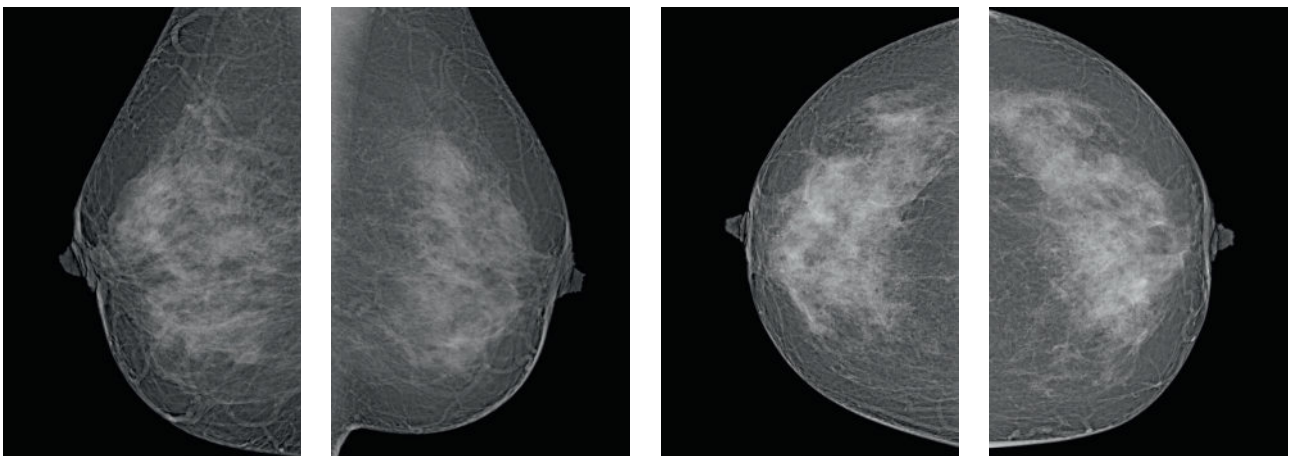
FULLY MOTORIZED C-ARM
XENOX S100 is optionally supplied with motorized rotation of C-Arm (pre-selectable and fine adjustment angles).

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.

ANTI-X PROTECTIVE BARRIERS
To obtain the maximum protection against stray radiation are optionally available two different kinds of stand-alone anti-X protective barriers. X-ray attenuation exceeds the IEC 60601-2-45 specifications.
The XENOX S100 in ISO-Centric version is fitted with an 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 S100 is upgradeable with stereotactic biopsy device ISO-Centric 3D.

ISO-CENTRIC 3D
The ISO-Centric 3D device represents a reliable add-on solution for performing stereotactic biopsies supporting film-screen or digital cassette. An easy and quick move upgrades the XENOX S100 ISO-Centric 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

EXCELLENT CLINICAL IMAGES



OUTSTANDING

HIGH PERFORMANCE
XENOX S100 is the state-of-the-art in analogue breast imaging providing the best patient care at the most efficient cost.

It is a completely independent mammo¬graphy unit allowing clinicians to obtain high quality images while expediting patient throughput.

It is suitable both for all the in depth studies of the breast 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.

„INTELIGENT COMP" - COMPRESSION SYSTEM
The cutting-edge „INTELIGENT COMP„ 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.

Displays located above the rotary controls allow viewing the set compression force and that actually applied, and the thickness of the compressed breast. This data is also shown on the control panel of the mammography unit and optionally on an auxiliary display placed frontally on the bottom of the unit.

The „ INTELIGENT COMP „ system is equipped with a triple protection device (electronic, electromechanical, mechanical) on the maximum compression force ensuring complete patient safety.

„ULTIMATE" SOFTWARE
Really innovative is the XENOX S100's intelligent and microprocessor controlled automatic exposure device enhanced by the „ULTIMATE" software.

This standard feature makes the mammography system's calibration incredibly rapid and simple (CR included). O.D. linearity exceeds QA protocols. Film and CR operations are also guaranteed by means of special AEC characteristics.

CONTROL PANEL
A LCD graphic display shows exposure parameters, alarm messages and many other data like the Average Glandular Dose (AGD) calculated after each exposure and the HU level of tube assembly.

TUBES AND FILTERS
The XENOX S100 in standard version is supplied with a X-Ray tube with Molybdenum anode and Molybdenum filter.

Different X-Ray tubes can be chosen:
- With biangular anode (10°/16°)
- High speed tube (9.000 rpm)
- With bimetallic anode (Mo/W)

As option is available an automatic filter Rhodium/ Molybdenum to obtain a superior penetration of dense breast tissue.

TECHNICAL SPECIFICATIONS
Xenox S100 | SternMed Mammography system

POWER SUPPLY	
Line voltage	220/230/240 Vac +/-10% 50/60 Hz
Power	6.6 kVA (0.5 kVA stand-by)
Current absorption	30 A peak
Number of phases	1 or 2 configurable
Connection	Permanently installed (IEC 601-1)
Wall connection	20 A fuse or Thermal-magnetic circuit breaker
Maximum apparent resistance	0.50 Q
EMERGENCY STOPS	
Function	To switch totally off the Mammography Unit
Number and Type	Two red push-buttons on both sides of mammography unit
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)
Nominal electric power (IEC 601-2-45 par. 6.8.2-4)	4.2 kW=140 mA*30 kV (3 s)
kV range	20 / 35 kV (20/40 kV optional)
kV resolution (Man & Auto mode)	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 601-2-45 par. 6.8.2-5)	1 mAs
mAs maximum value	640 mAs
mAs resolution (Automatic)	0,1 mAs
mAs values in accordance with R'20 series	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 13, 16, 20, 25, 32, 40, 50, 63, 80, 100, 130, 160, 180, 200, 250, 320, 400, 500, 640
mAs range	Small focus: 1/200 mAs (from 20 to 30 kV) 1/180 mAs (from 31 to 35 kV) Large focus: 1/640 mAs (from 20 to 30 kV) 1/500 mAs (from 31 to 35 kV)
mAs range (High Speed Starter option)	Small focus: 1/200 mAs (from 20 to 24 kV) 1/250 mAs (from 25 to 30 kV) 1/200 mAs (from 31 to 35 kV) Large focus: 1/640 mAs (from 20 to 30 kV) 1/500 mAs (from 31 to 35 kV)
mAs display	XXX,X mAs (4 digits)
Exposure Time	0.02 / 9 s (Automatically selected in function of selected mAs)
Safety timer	10 s
STANDARD X-RAY TUBE (IAE XM12)	
Anode rotation speed	3000 rpm (standard) - 10000 rpm (optional)
Target material	Molybdenum
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	12,5°
Anode Disc Diameter	80 mm
Focal spots	2
Focal spot size according to IEC 336	0,1x0,1 mm (Small) 0,3x0,3 mm (Large)
Power	1150 W (Small)-4800 W (Large) (3000 rpm) 2000 W (Small)-9000 W (Large) (10000 rpm)
Nominal X-Ray Tube Voltage	40 kV
Highest X-ray Tube Current available at 35 kV	20 mA (Small)-100 mA (Large)
(IEC 601-2-45 par. 6.8.2-1)	(3000 rpm) 40 mA (Small)-130 mA (Large)
Highest X-Ray Tube Current	(10000 rpm) 22 mA (Small)-100 mA (Large) (3000 rpm) 40 mA (Small)-135 mA (Large) (10000 rpm)
Highest X-Ray Tube Voltage available at 100 mA	40 kV*
(IEC 601-2-45 par. 6.8.2-2)	*40 kV version
Combination of X-Ray Tube Voltage and X-Ray Tube	35 kV*100 mA=3500 W (3000 rpm)
Current which results in the highest electric output power (IEC 601-2-45 par. 6.8.2-3)	35 kV*130 mA=4550 W (10000 rpm)
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

TECHNICAL SPECIFICATIONS
Xenox S100 | SternMed Mammography system

FILTER	
Filter materials	Molybdenum (Mo) std/Rhodium (Rh) opt
Method of filter selection	Manual or Automatic
Filter properties	Molybdenum (30 pm thickness) 0,38 mm Al eq @ 28 kV, measured with Mo target Rhodium (25 pm thickness) 0,62 mm Al eq. @ 28 kV, measured with Mo target

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

OPTIONAL X-RAY TUBE (IAE XM1016 T)	
Anode rotation speed	3000 rpm (standard) - 10000 rpm (optional)
Target material	Tungsten Focal track: RT (W+Re)/ Bulk: TZM (Mo+Ti+Zr)
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
Anode Disc Diameter	Focus)
Focal spots	80 mm
Focal spot size according to IEC 336	2 0,1x0,1 mm (Small) 0,3x0,3 mm
Power	(Large) 1400 W (Small)-5600 W (Large) (3000 rpm) 2400 W (Small)-9600
Nominal X-Ray Tube Voltage	W (Large) (10000 rpm)
Highest X-ray Tube Current available at 35 kV (IEC 601-2-45 par. 6.8.2-1)	49 kV 30 mA (Small)-90 mA (Large)
Highest X-Ray Tube Current	44 mA (Small)-135 mA (Large) (3000 rpm) 44 mA (Small)-135 mA (Large) (10000 rpm)
Highest X-Ray Tube Voltage available at 100 mA (IEC 601-2-45 par. 6.8.2-2)	40 kV* *40 kV version
Combination of X-Ray Tube Voltage and X-Ray Tube Current which results in the highest electric output power (IEC 601-2-45 par. 6.8.2-3)	35 kV*90 mA=3150 W (3000 rpm) 35 kV*135 mA=4725 W (10000 rpm)

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

FILTER	
Filter material	Rhodium (Rh)
Filter properties	50 pm thickness 0,51 mm Al eq. @ 28 kV, measured with W target

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

COLLIMATOR	
Light source	LED (Class 1 Device-320 pW power)
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 601-1-3
Mirror	with automatic out of field function
Standard collimation plate	18x24 cm
Optional collimation plates	24x30 cm 0 14 cm for magnification
Optional automatic collimator	18x24 cm/24x30 cm
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
Technology	Microprocessor controlled with unique safety features exceeding IEC 601-1-4, all functions under active operator control
Display	GRAPHIC LCD Display 240x128 dots
Alarm messages	In several languages selectable
Port for Film ID Flasher or Dose Label Printer	Dedicated serial port
Calibration and service Serial port/USB	For service laptop with dedicated software

TECHNICAL SPECIFICATIONS
Xenox S100 | SternMed Mammography system

LATERAL CONTROL PANEL	
Special features	Last 1300 exposure memory. 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.
Statistics function	Average dose, amount of exposures for every kV value, amount of exposure
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
POTTER-BUCKY	
Formats	18x24 cm (standard) 24x30 cm (optional)
Cassette Compatibility	All the most common models with window
Cassette Detector Switch	With alarm in different languages to avoid double exposure or exposure without cassette
Top Cover	Carbon fiber
Aluminum Equivalence	0.1 mm Al (carbon fiber) 0.3 mm Al (carbon fiber and grid)
Film Markers	Integrated with two ID labels wheels
Test with NORMI Phantom	Typical 3.5 balls
GRID	
Type	Linear, vibrating
Interspace Material	Carbon Based Polymer
Bucky factor	1.96
Ratio	5:1
Lines/cm	36
Contrast factor	1.47
OPTIONAL DEVICE FOR GEOMETRIC MAGNIFICATION	
Format	18 x 24 cm
Type	Gridless, interchangeable with Potter-Bucky
Magnification Ratio	x1,5 and x2
Small Focus Selection	Automatic once fitted

AUTOMATIC EXPOSURE CONTROL	
Controlled parameters	Auto kV / Auto mAs (Zero Point Mode) Manual kV / Auto mAs (One Point Mode)
Auto parameters selection criteria	Selected in function of effective breast density evaluated by pre-exposure
Nominal shortest Irradiation Time (IEC 601-2-45 par. 6.8.2-6)	10 ms limited to pre-exposure with alarms for detector Saturation or Overexposed
Auto kV range	Function of selected technique (STD-HC-LD) and Anode/Filter combination
Manual density control	11 steps 0 +/- 5 Programmable with PC independently for all the operative techniques available
Film Screen combinations	13 programmable settings for film/screen use
CR combinations	3 programmable settings for CR use
O.D. linearity over 2 to 6 cm of Plexiglas	Better than +/- 0.1 of O.D. (after field calibration)
Reference O.D.	Programmable during installation
CR dose limits	Programmable during installation
A.E.C. short time stability measured over 10 exposures taken at 28 kV 50 mAs	<3%
Detector	Solid state (9 active sensors)
Detector Positions	3 fields electronically selectable
Erratic exposure protection	Detector Saturation or Excessive Breast Density For both cases Dose Released < 1 mAs
Test Phantom	3x2 cm + 1 cm + 0.5 cm of Plexiglas for calibration and daily Self Test Procedure
A.E.C. Self Test Procedure	Included in control panel functions
Average Glandular Dose measured in ACR method (4.5 cm phantom of 50% glandular tissue and 50% adipose tissue exposure taken with 28 kV)	< 3 mGy

TECHNICAL SPECIFICATIONS
Xenox S100 | SternMed Mammography system

DOSE CALCULATOR	
Method of Calculation	Average Glandular Dose (AGD) according to: „D.R. Dance et al."
Data visualization (mGy)	On display of Control Panel and on Label Printer Data memory with average dose value on 1300 exposition to evaluate released dose
Dose Rate (28 kV-80 mAs)	36,63 R/min without Compression Plate 29,80 R/min with Compression Plate

ISO-CENTRIC C-ARM	
F.D.D. (Focus Detector Distance)/S.I.D.	65 cm
Movements	Vertical (motorized) Rotation (manual or optionally motorized) +/- 15° Rotation (only with BYM 3D)
Range of Vertical Movement (from Floor)	From 75 to 160 cm (travel of 85 cm)
Range of C-Arm Rotation	+/-180° Manual with disk brake (standard) CW, CCW continuous motorization (optional)
Projection Preset positions	Mechanical reference notches 45° each for easy positioning (standard) N° 5 (LAT, OBL, CC, OBL, LAT) programmable projections (optional)
Speed of C-Arm Rotation in motorized version	90°/8 s with acceleration and deceleration ramp for smooth operation
Display of angle rotation	On Control Panel On Auxiliary Display

„INTELIGENT COMP" COMPRESSION SYSTEM	
Compression Paddle Movement	Motor driven or manual with fine adjustment by double rotating controller
Standard Compression Paddle	18x24 cm shifted for normal breasts
Optional Compression Paddles	24x30 cm shifted for large breasts 0 7,5 cm straight for magnification 0 7,5 cm shifted 10x24 cm shifted 9x21 cm straight 18x24 cm shifted for bidimensional biopsy
Compression Paddle Holder	Fast mechanical unlock
Maximum free space available between Compression Paddle and breast support	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	Proportionally decreasing compressing the breast and customizable according to three curves
Maximum Compression Force Safety Device	Triple: electronic, electro-mechanical, mechanical
Compression paddle release after exposure	Selectable from control panel, automatic or manual for bidimensional biopsy
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

AUXILIARY DISPLAY	
Position	On basis of mammography unit
Display Type	3 rows (7 segments)
Information	Compression force C-Arm rotation angle Compressed breast thickness

FOOT-CONTROLS FOR MOTORIZED COMPRESSION	
Number and Type	One with two pedals and push-button
Control Actions	Vertical movement of Compression Paddle Motor driven compression unlock

OPTIONAL MULTIFUNCTION FOOT-CONTROLS	
Number and Type	One with four pedals and one push-button
Control Actions	Vertical movement of C-Arm Vertical movement of Compression Paddle Motor driven compression unlock

OPTIONAL ANTI-X PROTECTION BARRIER	
Pb equivalence	> 0,34 mm (at 35 kV)
Dimensions	770x2100x510 mm (half transparent screen) or 840x2100x490 mm (full transparent screen)
Glass thickness	20 mm

TECHNICAL SPECIFICATIONS
Xenox S100 | SternMed Mammography system

ENVIRONMENTAL CONDITIONS	
Storage and delivery conditions (packed)	Temperature - 20° C / + 70° C Relative humidity 10% / 90% Barometric pressure 500 hPa/1060 hPa (24 h)
Operating conditions	Temperature + 10° C / + 40° C Relative humidity 30% / 75% Barometric pressure 700 hPa/1060 hPa (24 h)
Protection degree according to standard IEC 529	IP 10
Heat dissipated in max load condition of 35 kV 500 mAs (1 shot every 5 minutes)	264 kCal/h
CLASSIFICATION (IEC 601-1)	
Protection against electric shock	Class I, with type B applied parts
Protection against harmful ingress of water	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