

Mammograph



PRODUCT DATA

Product data

Mammograph – Rev.3 (April 2015)

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DESCRIPTION

Mammograph is Italray's new mammography unit: the innovative mammograph for traditional analogue imaging, which grants high productivity and superb image quality to clinical operator, not disregarding, at the same time, patient care and advantageous costs.

For its versatility, Mammograph is suitable both for deep breast research and for screening programs, without missing out result accuracy.

Efficiency increase of Radiology Dept. and improvement in patient care standards, are the immediate outcomes of working with Mammograph, which is the best synthesis of imaging excellent technology and a successful design made of modern and ergonomic layouts.

Mammograph is a column stand with C-arm, equipped with: high frequency X-ray generator (Frequency: 100 KHz – Power: 5 KW), Molybdenum X-ray tube with 2 focal spots (0,1 and 0,3 mm), with Molybdenum filter, and predisposed for the following formats: either 18x24 cm or 24x30 cm; Quality and diagnostic content of image are improved with a particular compression device, softly curved and with smooth lines that grants for higher patient comfort and that can be both motor and manually driven.

The optional version of Mammograph with Isocentric C-arm can be used for stereo biopsy together with the proper device SBD (Stereotactic Biopsy device).

In detail, the main features of this new Mammograph, involve:

- **Device symmetry that assure both easier operator access to the console, and the complete control of patient during the examination, by operator,**
- **Compression system, both manual and motorized, with safe un-lock and the visualization of compression parameters on both displays**
- **Automatic exposure control AEC**
- **Control panel with graphic display of: exposure parameters, alarm messages, Average Glandular Dose (AGD), HU level of the tube, ...**
- **Integrated auxiliary display for: C-arm rotation angle, compression thickness and compression force**
- **Small and modern new foot pedals with a central button to control immediate release of compressor**

- New compression system "SmartµPress" with following main features:
 - Easy calibration procedure
 - 2-way compression mode; motorized, by means of foot pedals, manual with sharp compression force regulation by means of double knobs on both sides of C-arm
 - Compression force automatically set basing on breast density (measured by a microprocessor controlled dedicated sensor)
 - Decreasing descent speed during compression with personalized slope basing on 3 different profiles.

About options:

- Isocentric C-arm that allows all breast projections without moving the patient and without adjusting the C-arm height.
- Stereotactic biopsy function that can be carried out by means of SBD device. SBD is available only in presence of the Isocentric C-arm: this introduces the possibility to direct the needle on any direction, with the motorized rotation (+/-15°) of the arm totally controlled by the external Mammograph console.
- Anti-X protective barriers for operator safety.
- The magnification device (MAG. Factor: 1,5x or 2x) gridless and with automatic selection of small focus.
- X-ray tube with biangular anode (6°/10°).
- High speed X-ray tube
- X-ray tube with bimetallic anode (Mo/W)
- Rhodium filter (for a deep penetration of breast tissues).
- Removable Potter Bucky that can fit cassettes with 18x24 cm format.
- Multifunctional 2 pairs foot pedals to control both compressor release and C-arm vertical movement.

TECHNICAL SPECIFICATIONS:

POWER SUPPLY	
Line voltage	220/230/240Vac 10% 50/60Hz
Power	6.6 kVA (0.5 kVA stand-by)
Current absorption	30 A

ENVIRONMENTAL CONDITIONS	
Storage and delivery conditions	Temperature: -20° C / + 70° C Relative humidity: 10% / 90% Barometric pressure: 700 hPa/1060 hPa
Operating conditions	Temperature: +10° C / + 40° C Relative humidity: 30% / 75% Barometric pressure 700 hPa/1060 hPa
Protection degree according to standard IEC 529	IP 10
Heat dissipated in max load condition of 35 kV 300 mAs (1 shot every 5 minutes)	264 kCal/h

ENVIRONMENT PROTECTION AND WASTE DISPOSAL	
Device contains in some of its parts and subassemblies, solid and liquid substances that must be disposed only by designated companies according to local laws. More specifically, device contains:	
Tube assembly	Beryllium, lead, glass, dielectric oil (PCB free), other metals and plastic.
H.V. transformer	Dielectric oil (PCB free), plastic, copper other metals
Other subassemblies	Plastic, other metals, electronic components glass-epoxy printed circuits

H.V.GENERATOR	
Output Frequency	100 KHz
Power	5 KW
Nominal power (IEC 60601-2-45)	4.2 kW=140 mA*30 kV (3 s)
kV range	20 / 35 kV (20/40 kV opt.)
kV resolution (Man Et Auto mode)	Man Et Auto mode, 0.5 KV
kV precision	± 1 %
kV repeatability	± 0.1 %
KV display	XX.X kV (3 digits)
Minimum mAs	1 mAs
Maximum mAs	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 display	XXX.X mAs (4 digits)
Exposure Time	Automatically selected in function of selected mAs (max. 8 s)
Safety timer	10 s

STANDARD X-RAY TUBE ASSEMBLY (I.A.E. XM12I)	
Anode rotation speed	3000 rpm 50 Hz 10000 rpm 150 Hz (optional)
Target material	Molybdenum
Maximum Anode Heat Content	300 kHU (225 kJ)
Maximum X-Ray Tube Assembly Heat Content	425 kHU (320 kJ)
Housing continuous Heat Dissipation	108 HU/s (80 W)
Cooling method	Free air convection
Anode Disc Target Angle	12.5°
Anode Disc Diameter	80 mm
Focal spot (spot size according to IEC 336)	0.1x0.1 mm (small focus) 0.3x0.3 mm (large focus)
Power	4800 W (l.f.) 1150 W (s.f.) (@3000 rpm) 9000 W (l.f.) 2000 W (s.f.) (@10000 rpm)
Nominal X-Ray Tube Voltage range	20/35 kV (20/40 kV opt.)
Highest X-Ray Tube Current	Large focus:
Highest X-ray Tube Voltage available at 100 mA (IEC 60601-2-45 par. 201.7.9.2.1.b)	100 mA @ 35 kV (80 mA @ 40 kV opz.) @3000 rpm 130 mA @ 35 kV (80 mA @ 40 kV opz.) @10000 rpm
Combination of X-Ray Tube Voltage and X-Ray Tube Current which results in the highest electric output power (IEC 60601-2-45 par. 201.7.9.2.1.c)	Large focus. 35 kV*100 mA=3500 W (80 mA*40 kV=3200 W opz.) @3000 rpm 35 kV*130 mA=4550 W (80 mA*40 kV=3200 W opz.) @10000 rpm
Filter	30 µm Molybdenum - 25 µm Rhodium (opt.)
Inherent filtration	0.0 mm Al IEC 522/1976
HVL measured at 28 kV	>0.3 mm Al equiv.
Total filtration	>0.5 mm Al
Tube assembly thermal overload protection	Upper limit temperature 65° outside tube assembly (active temperature sensor). HU and °C display available in technical menu

OPTIONAL X-RAY TUBE ASSEMBLY (IAE XM1016)	
Anode rotation speed	3000 rpm 50 Hz 10000 rpm 150 Hz (optional)
Target material	Molybdenum
Maximum Anode Heat Content	300 kHU (225 kJ)
Maximum X-Ray Tube Assembly Heat Content	425 kHU (320 kJ)
Housing continuous Heat Dissipation	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 spot (spot size according to IEC 336)	0.1x0.1 mm (small focus) 0.3x0.3 mm (large focus)
Power	2900 W (l.f.) 700 W (s.f.) (@3000 rpm) 4900 W (l.f.) 1350 W (s.f.) (@10000 rpm)
Nominal X-Ray Tube Voltage range	20/35 kV (20/40 kV opt.)
Highest X-Ray Tube Current Highest X-ray Tube Voltage available at 100 mA (IEC 60601-2-45 par. 201.7.9.2.1.b)	Large focus: 60 mA @3000 rpm 80 mA @10000 rpm
Combination of X-Ray Tube Voltage and X-Ray Tube Current which results in the highest electric output power (IEC 60601-2-45 par. 201.7.9.2.1.c)	Large focus. 30 kV*90 mA=2700 W (@3000 rpm) 30 kV* 130 mA= 3900 W (@10000 rpm)
Filter	30 µm Molybdenum – 25 µm Rhodium (opt.)
Inherent filtration	0.0 mm Al IEC 522/1976
HVL measured at 28 kV	>0.3 mm Al equiv.
Total filtration	>0.5 mm Al
Tube assembly thermal overload protection	Upper limit temperature 65° outside tube assembly (active temperature sensor). HU and °C display available in technical menu

OPTIONAL X-RAY TUBE ASSEMBLY (IAE XM1016 T)	
Anode rotation speed	3000 rpm 50 Hz 10000 rpm 150 Hz (optional)
Target material	RT (Tungsten+Rhenium) TZM (Molybdenum+Titanium+Zirconium)
Maximum Anode Heat Content	300 kHU (225 kJ)
Maximum X-Ray Tube Assembly Heat Content	425 kHU (320 kJ)
Housing continuous Heat Dissipation	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 spot (spot size according to IEC 336)	0.1x0.1 mm (small focus) 0.3x0.3 mm (large focus)
Power	5600 W (l.f.) 1400 W (s.f.) (@3000 rpm) 9600 W (l.f.) 2500 W (s.f.) (@10000 rpm)
Nominal X-Ray Tube Voltage range	20/35 kV (20/40 kV opt.)
Highest X-Ray Tube Current Highest X-ray Tube Voltage available at 100 mA (IEC 60601-2-45 par. 201.7.9.2.1.b)	Large focus: 90 mA @3000 rpm 90 mA @10000 rpm
Combination of X-Ray Tube Voltage and X-Ray Tube Current which results in the highest electric output power (IEC 60601-2-45 par. 201.7.9.2.1.c)	Large focus. 35 kV*90 mA=3150 W (@3000 rpm) 35 kV*90 mA=3150 W (@10000 rpm)
Filter	50 µm Rhodium
Inherent filtration	0.0 mm Al IEC 522/1976
HVL measured at 28 kV	>0.3 mm Al equiv.
Total filtration	>0.5 mm Al
Tube assembly thermal overload protection	Upper limit temperature 65° outside tube assembly (active temperature sensor). HU and °C display available in technical menu

OPTIONAL X-RAY TUBE ASSEMBLY (VARIAN M113)	
Anode rotation speed	3000 rpm 50 Hz
Target material	Molybdenum
Maximum Anode Heat Content	300 kHU (225 kJ)
Maximum X-Ray Tube Assembly Heat Content	500 kHU (376 kJ)
Housing continuous Heat Dissipation	135 HU/s (100 W)
Cooling method	free air convection
Anode Disc Target Angle	10° (small focus)/16° (large focus)
Anode Disc Diameter	77 mm
Focal spots (spot size according to IEC 336)	0.1x0.1 mm (small focus) - 0.3x0.3 mm (large focus)
Power	800W (s.f.) - 3600 W (l.f.)
Nominal X-Ray Tube Voltage	20/35 kV (20/40 kV opt.)
Highest X-Ray Tube Current	Large focus: 60 mA
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)	Large focus: 30 kV*90 mA=2700 W
Filter	30 µm Molybdenum - 25 µm Rhodium (opt.)
Inherent filtration	0,0mm Al IEC 522/1976
HVL measured at 28kV	>0,3 mm Al equiv.
Total filtration	>0.5mm Al
Tube assembly thermal overload protection	Upper limit temperature 65° outside tube assembly (microprocessor controlled temperature sensor). HU and °C display available in technical menu

OPTIONAL X-RAY TUBE ASSEMBLY (VARIAN M113T)	
Anode rotation speed	3000 rpm 50 Hz
Target material	Tungsten
Maximum Anode Heat Content	300 kHU (225 kJ)
Maximum X-Ray Tube Assembly Heat Content	500 kHU (376 kJ)
Housing continuous Heat Dissipation	135 HU/s (100 W)
Cooling method	free air convection
Anode Disc Target Angle	10° (small focus)/16° (large focus)
Anode Disc Diameter	77 mm
Focal spots (spot size according to IEC 336)	0.1x0.1 mm (small focus) - 0.3x0.3 mm (large focus)
Power	1400 W (s.f.) - 5900 W (l.f.)
Nominal X-Ray Tube Voltage	20/35 kV (20/40 kV opt.)
Highest X-Ray Tube Current	Large focus: 90 mA
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)	Large focus: 35 kV*90 mA=3150 W
Filter	50 µm Rhodium
Inherent filtration	0,0mm Al IEC 522/1976
HVL measured at 28kV	>0,3 mm Al equiv.
Total filtration	>0.5mm Al
Tube assembly thermal overload protection	Upper limit temperature 65° outside tube assembly (microprocessor controlled temperature sensor). HU and °C display available in technical menu

AUTOMATIC EXPOSURE CONTROL A.E.C.	
Controlled parameters	(ZERO POINT mode) Auto kV / Auto mAs, Automatic (ONE POINT mode) Man. kV / Auto mAs, Semi-Automatic
Auto parameters selection criteria	Selected in function of effective BREAST DENSITY evaluated by pre-exposure ≤ 10 ms
Auto KV range	Function of the selected technique (standard- high contrast-low dose), the Anode/Filter combination
Manual density control	11 steps, 0 ± 5 (programmable with PC independently for all the operative techniques available)
Optical Density	Linear over 2 to 6 cm of Plexiglas $\pm 0,1$ of O.D. (after field calibration).
Reference O.D.	Programmable during installation
Film/Screen combination	16 film/screen fully programmable (3 dedicated for CR use)
Detector	PHTM 9000 Solid state (9 active sensors)
Detector positions	3 fields electronically selectable
Erratic exposure protection	Detector saturation 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 procedures
AEC, 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	< 2 mGy

IMAGE QUALITY	
Spatial Resolution	Conformity with: " <i>European Guidelines for quality assurance in mammography screening</i> ", third edition, and with " <i>Recommended specifications</i> " for Quality assurance in mammography of American College of Radiology

MAGNIFICATION	
Type	Gridless. Interchangeable with Potter-Bucky
Top Cover	Carbon Fiber 0.1 mm Al eq.
Magnification ratio	x1,5 / x2 (variable) oer x1.8 (fixed)

NON ISOCENTRIC C-ARM	
F.F.D.	65 cm
Manual Rotation	+/- 180° with disk brake
Motorized Rotation (opt.)	±180° (90°/8 s with acceleration and deceleration ramp for smooth operation)
Projection Preset positions	Mechanical reference notches 45°each for easy positioning (Manual Rotation) Programmable projections LAT, OBL, CC, OBL, LAT and CW, CCW continuous rotation to any position over +/-180° (Motorized rotation)
Vertical movement with respect to Breast support (C-ARM in vertical position)	428 mm to 1278 mm (motorized)
Protection of examination field	Removable polycarbonate screen
Weight	286 kg

ISOCENTRIC C-ARM	
F.F.D.	65 cm
Manual Rotation	±180° with disk brake (± 35° with the C-Arm in lowest position)
Motorized Rotation (opt.)	±180° (90°/8 s with acceleration and deceleration ramp for smooth operation)
Rotation for biopsy projections	Motorized ±15° microprocessor controlled
Projection Preset positions	Mechanical reference notches 45°each for easy positioning (Manual Rotation) Programmable projections LAT, OBL, CC, OBL, LAT and CW, CCW continuous rotation to any position over +/-180° (Motorized rotation)
Vertical movement with respect to Breast support (C-ARM in vertical position)	747 mm (923 mm with C-ARM in caudocranial position) to 1597 mm (motorized)
Protection of examination field	Removable polycarbonate screen
Weight	330 kg

COLLIMATOR	
Light source	LED (Class 1 Device-320 µW power)
Light beam	Automatic switch ON 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 function
Collimation Plates (std)	18x24 cm removable
Collimation Plates (opt)	24x30 cm removable, Ø 14 cm removable
Automatic Collimators (standard with Bimetallic X-Ray Tube, otherwise optional)	18x24 cm, 24x30 cm
Protection of examination field	Polycarbonate screen to keep patient's face out of X-ray beam

"SMART μPRESS" COMPRESSION SYSTEM	
Compression plate movement	Motor driven or manual with fine adjustment by rotating controller
Compression Plates (std)	18x24 shifted
Compression Plates (opt)	\emptyset 7.5 cm spot, 24x30 cm shifted, 10x24 cm shifted, 9x21 cm straight, \emptyset 7.5 cm shifted, 18x24 cm shifted for bidimensional biopsy
Maximum free space available between Compression Plate and image receptor	325 mm with shifted Compression Plates In Magnification Mode (straight compression plate) MAG. x1.5 = 231 mm MAG. x2 = 131 mm;
Compression Thickness Display	Displayed in mm
Compression Force Adjustment	Adjustable from 70 to 200 N
Maximum Compression Force Safety	Triple safety device: electronic, electro-mechanical, mechanical
Compression Holder	Fast mechanical unlock
Compression plate release after exposure	Selectable from control panel, automatic or manual for 2D biopsy
Compression plate aluminium equiv.	Less than 0.2 mm Al (0.135 mm Al 30 kV)
Special function for 0 compression force for oncology procedures	

POTTER BUCKY AND GRID	
Cassette size	18x24 cm (std.) 24x30 cm (opt.)
Top Cover	Carbon Fiber
Grid type	Linear, vibrating
Bucky factor (grid)	1,96
Ratio	5:1
Lines/cm	36
Contrast factor	1.47
Cassette detector switch	With alarm in different languages to avoid double exposure or exposure without cassette

DOSE CALCULATOR	
Method of calculation	Average Glandular Dose (AGD)
Data visualization	mGy on display, label printer and data memory with average dose value on 1300 exposition to evaluate released dose
Dose rate	36,63 R/min without Compression Plate 29,80 R/min with Compression Plate

CONTROL PANEL	
Position	On preferred side of mammographic unit (on request)
Technology	Microprocessor controlled with unique safety, all functions under active operator control.
Display	GRAPHIC LCD Display 240x128 dots
Alarm Messages	In several languages selectable (voice optional)
Serial port for Film ID Flasher or Dose Label Printer	Dedicated for Film Labelling device (200 characters printed on film) or Adhesive Labels with Dose
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 in every test technique
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

AUXILIARY DISPLAY	
Position	Frontally at the base of mammography unit
Display type	3 rows 7 segments
Information	C-arm rotation angle Compression thickness Compression force

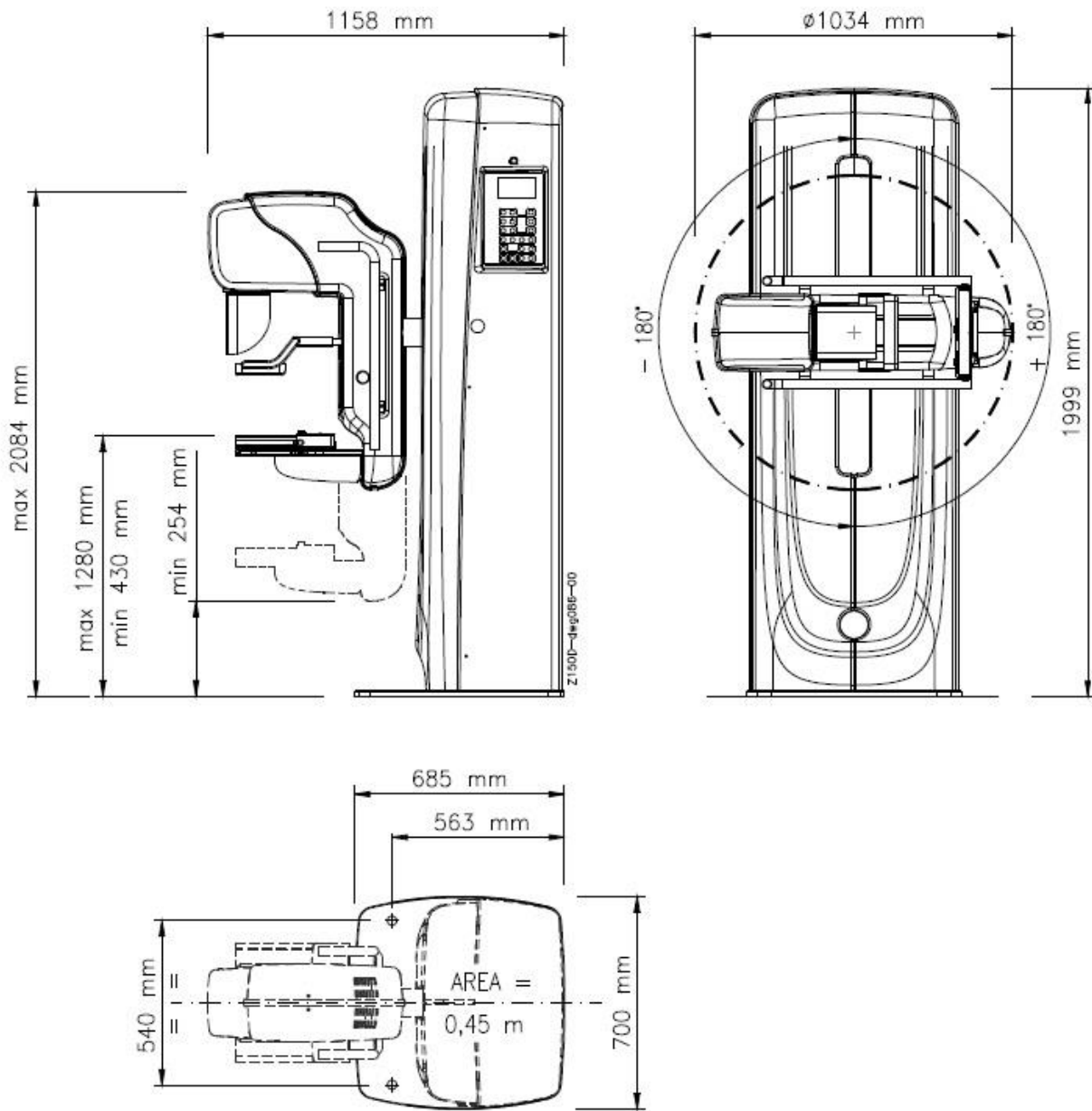
FOOT CONTROLS FOR MOTOR DRIVEN COMPRESSION	
Number and type (standard)	One pair with push-button for motor driven compression unlock
Number and type (optional)	Second pair with push-button for motor driven compression unlock or Multifunction foot-controls (compression, c-Arm vertical movement)

EMERGENCY STOP/SHUTDOWN SWITCHES	
Red push-button	On both sides to switch the unit totally off

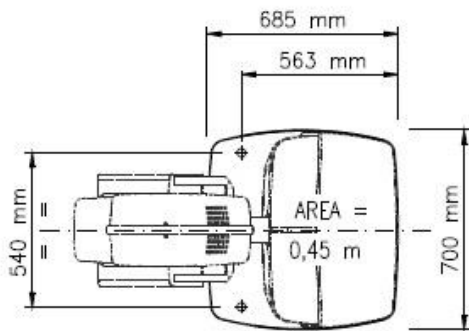
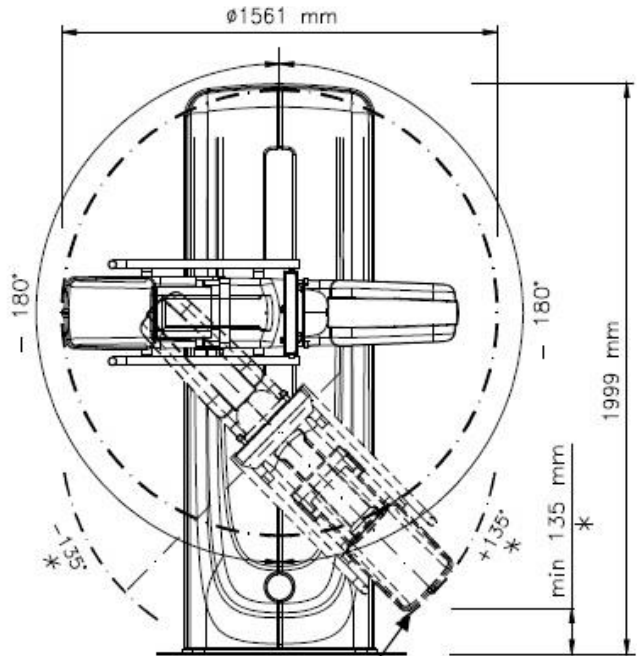
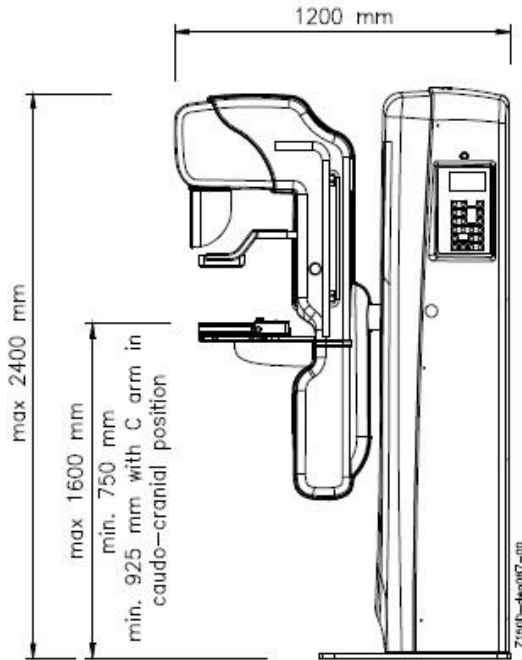
MAIN OPTIONS	
Stand-alone anti-X transparent protective barrier (optional)	Pb equivalence: > 0.34 mm @35 kV
SBD (for Isocentric C-Arm configuration)	SBD stereo biopsy device with 3 cone collimators manually interchangeable for 18x24 cm films. Compression thickness shown at display.

SIZE AND DIMENSIONS

Mammograph



Mammograph with Isocentric "C" arm



(*) When the distance of the C-Arm lower edge from the floor is ≤ 135 mm the rotation range is limited at $\pm 135^\circ$ to avoid crushing of the patient feet

CLASSIFICATION

Mammograph has been designed, built and tested accordingly to European directives: 93/42 CEE, 89/336 CEE.

This device is a Class 2 b device, by the EEC 93/42 and a Class I type B by the CEI EN 60601-1.

ITALRAY is certified according to international standards: UNI EN ISO 9001:2008 (certificate n° CERT-10119-2002-AQ-FLR-SINCERT) and UNI EN ISO 13485:2012 (certificate CERT-03181-98-AQ-IND-SINCERT) by Det Norske Veritas (DNV).

NOTE:

SBD is a device having its own CE certificate according to Medical Device Directive 93/42/CE and not conditioning X-Ray emission.

INSTALLATION AND WARRANTY

Mammograph device can be installed in pre-existing diagnostic room or in a new room, only by our technician staff or by authorized technical personnel that has been appropriately trained by ITALRAY.

Italray technical staff can provide the best position plan of Mammograph. Upon request, ITALRAY Installation Office can prepare installation layouts (including eventual construction and electrical). ITALRAY can offer to its customers a wide range of service plans that will perfectly fit customer needs and preferences.

Because of the peculiar technology of digital flat panel detector, system warranty has to be cancelled whenever there is an abnormal functioning due to detector operating use out of the suggested temperature limits.

PACKING AND TRANSPORT

Mammograph can be packed in two different ways.

- *For sea transport:* wooden case with barrier bag.
- *For normal transport:* wooden case.

Device or configurations can change without notice



Via Del Parlamento Europeo 9/D 50018 Scandicci (Firenze)
tel. +39/055/7228511 fax. +39/055/7228512

website: www.italray.it - e-mail info@italray.it