Digital Mammography

Mammograph FFDM C +

Product Data

The new **Mammograph FFDM C +** platform has been engineered to meet all diagnostic requests, to allow the radiologist to use the latest digital mammography imaging methods.

Mammograph FFDM C + is suitable for 2D image acquisition; it is not upgradable, but it can be integrated with a wide range of accessories with unmatched performance-price specs.

It produces digital mammographic images of the breast for diagnosis of breast cancer. Its intended use is for two-dimensional diagnosis and screening.

This mammo unit is totally microprocessor controlled and its high-performance compactness make it particularly suitable for installations in very narrow environments.

This new unit is composed of

- Mammography Unit with tube stand with fully motorized isocentric C-Arm and 7" touch screen colour display on both sides of C-Arm for any operation;
- Image acquisition station with integrated X-Ray control;
- A digital flat field detector;
- Viewing and Reporting Diagnostic station (optional).

The digital Mammograph is equipped with **high frequency X-ray generator (7,4 kW)**, Tungsten X-ray tube with 2 focal spots and predisposed for many image formats, up to 24x30 cm.

Breast image acquisition is based on Indirect Conversion flat field Detector, featuring Amorphous Silicon (a-Si) technology, or, optionally, on Direct Conversion Full Field Flat Panel Detector featuring Amorphous Selenium (a-Se) technology.

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.

Post-processing algorithm specific for mammography optimizes the quality of acquired images that, once displayed, can be manipulated in terms of visualization as contrast, sharpness, zoom etc.

The mammography system, connected to the PACS, allows opening a study from the Worklist (remotely generated); closing the study, the acquired images and all exam parameters are sent to the PACS, synchronized with the Worklist and stored on the appropriate server of the RIS.

Mammograph FFDM C + is a "Standalone" equipment solution, an optional review station may be provided on request to examine and review acquired images.

MAIN CHARACTERISTICS

X-RAY TUBE WITH BIANGULAR TUNGSTEN ANODE

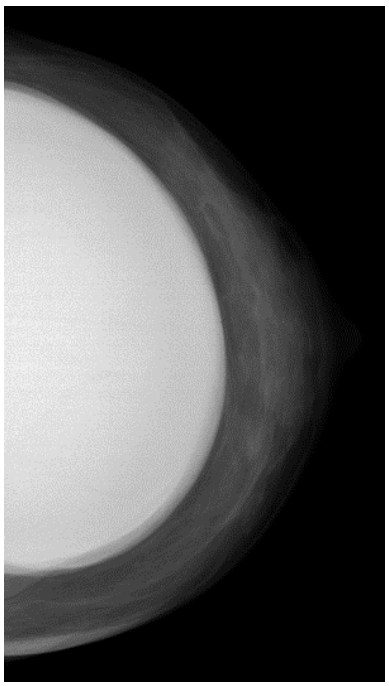
Biangular anode reduces exposition times and consequently the risk of useless movements, so to obtain a best quality of mammographic images.

Tungsten anode together with Rhodium and Silver filters represents in digital mammography the optimal combination for the best image quality in two-dimensional exams.

Tungsten/Rhodium combination allows obtaining the minimum dose and the best quality image over all ranges of breast density.
Tungsten/Silver combination allows a further dose reduction (around 20%) for high-density breasts.
Tungsten/Copper (optional) predisposition for future Dual Energy implementation.

ENHANCEMENT ALGORITHM FOR MAMMOGRAPHIC IMAGES

Mammograph FFDM C + enhancement algorithm is specific for mammography to optimize the quality of acquired images.
This software processes acquired RAW images and displays them in "For Presentation" format to enhance breast tissue structures and reduce the noise.



Customizations of this algorithm are possible with dedicated filters for geometric magnification and in case of prosthesis, metallic clips, and surgical markers, clusters of microcalcifications, breast specimens and surgical anatomical parts.

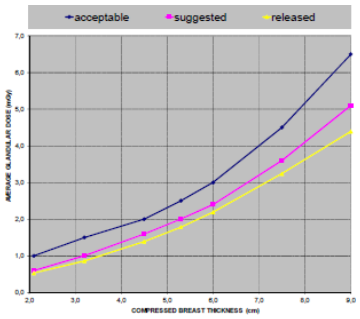
DOUBLE MODALITY FOR AUTOMATIC EXPOSURE CONTROL

PRE mode : tissue composition based. Parameters are evaluated by short X-ray exposure (1 mAs minimum) by reading a mosaic of 96 sensitive areas (ROI), automatically selected in function of breast size and projection
FAST mode: compressed breast thickness based. This modality can be used in special cases with breast implants and surgical metal aspects.

MAIN CHARACTERISTICS

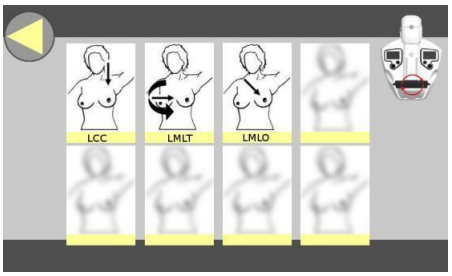
AVERAGE GHIANDOLAR DOSE

Mammograph FFDM C + has a tool for calculating and displaying the Average Ghiandolar Dose. Dose value, in mGy (or µSv), is displayed after every exposure on the acquisition workstation. It is also stored on the image DICOM header.



AUTOMATIC IMAGE TAGGING AND ACR TOUCHSCREEN DISPLAY

ACR code is a standard created by the American College of Radiology (ACR) to identify laterality, view, operative technique and other information on the mammographic image.
It is associated to each image basing on DICOM standard.
Operator can associate codes that are not automatically set by the mammographic system, by means the two backlighted resistive 7" touch screens on both sides of C-Arm.
These displays clearly visualize Compression force, compressed breast thickness, patient name, projection angle, breast laterality, ACR code, collimation format, magnification factor.



COMPRESSION SYSTEM

For motorized compression, a dedicated microprocessor-controlled function automatically adapts compression force to breast density.
Compressor descending speed decreases as soon as a specific distance from the supporting surface is reached.

Once in contact with breast the compressor briefly stops and starts to increase compression force. Basing on breast density the microprocessor controlled system evaluates if reaching the selected force value or if stopping the compression at 100 N.

TECHNICAL SPECIFICATIONS: MAMMOGRAPHY UNIT	
ISOCENTRIC C-ARM	
S.I.D	66 cm
Rotation	± 180° with disk brake
Motorized Movements	Vertical movement Rotation (*)
Motorized rotation (*)	± 180° (CW, CCW continuous to any position)
Rotation speed	≈15°/s with acceleration and deceleration ramp for smooth operation
Projection Preset positions	N° 5 Programmable projections (LAT, OBL, CC, OBL, LAT)
Rotation angle display	On control panel and on auxiliary display (ACR)
Range of Vertical Movement (from Floor)	From 54 to 145 cm (travel of 91 cm)
Speed of Vertical Movement	5 cm/s
EMERGENCY STOPS	
Number and Type	Two red push-buttons on both sides of mammography unit. One red push-button on optional Acquisition Workstation.
Function	To Switch totally off the mammography System except except PC and logic interfaces (Safety to close/save studies and switch off the unit).
CONTROL SWITCHES	
Number and Type	Three multiswitches (five push-buttons): Two on both sides of C-Arm and one on tip of X-Ray tube cover
Control Actions	Vertical movement of C-Arm Continous rotation of C-Arm (with motorized option) Switch-on of collimation light
TOUCH SCREEN COLOUR DISPLAYS	
Number and type	Two LED backlighted resistive touch screens on both sides of C-Arm
Screen Size (aspect ratio)	7" (4:3) - 640x480
Information	Compression force, compressed breast thickness, patient name, projection angle, breast laterality, ACR code, collimation format, magnification factor
FOOT-CONTROLS	
Number and Type	One with two pedals and one push-button Two with two pedals and one push-button (*) One with four pedals and one push-button (*) Two with four pedals and one push-button (*)
Control actions	Vertical movement of compression Paddle Motor driven compression unlock
Protection degree according to IEC 529	IP X2

(*) Optional

TECHNICAL SPECIFICATIONS: MAMMOGRAPHY UNIT	
COMPRESSION SYSTEM	
Compression paddle movement	Motor driven or manual with fine adjustment by double rotating controller
Compression paddles	24x30 cm shifted for normal breasts 18x24 cm with lateral shifting for small breasts
Compression paddles (*)	9x21 cm for magnification 18x24 cm with Φ7,5 cm spot for contact examination Φ7,5 cm spot for magnification 18x24 cm with holes for 2D biopsy 10x24 cm for auxiliary examination
Compression Paddle Holder	Fast mechanical unlock with rotating knob. Right lock warning LED
Maximum free space available between Com pression Plate and top cover of Potter-Bucky	18,2 cm with shifted compression paddles In Magnification Mode with specific compression paddle: x1,5 = 18,3 cm x1,8 = 12,3 cm x2 = 8,3 cm
Compression breast thickness display	Compression breast thickness displayed in mm (±1 mm resolution)
Compression Force	Range 0-200; Adjustable Range from 70 to 200 N (1 N resolution)
Compression Force Display	Effective applied force with 1 N resolution
Compression paddle descent speed	4 cm/s at start. Proportionally decreasing during breast compression.
Maximum Compression Force Safety device	Triple safety device: electronic, electro-mechanical, mechanical.
Soft compression paddle release after exposure	Selectable from control panel
Compression paddle aluminium equiv.	< 0.2 mm Al (0.135 mm Al≈30 kV)
ROTATING CONTROLLERS FOR MANUAL COMPRESSION	
Number and type	Two rotating wheels with central push-button on both sides of C-Arm

(*) Optional

TECHNICAL SPECIFICATIONS

X-RAY TUBE

Model	IAE XM1016 T
Anode rotation speed	3.000 gg/min - 10.000 gg/min (*)
Target material	Tungsten Focal track: RT (Tungsten+Rhenium) Bulk: TZM (Molibdenum+Titanium+Zirconium)
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)	Large Focus : 49 kV ; 80 mA Small Focus: 49 kV; 42 mA
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)	Large Focus: 35 kV; 135 mA Small Focus: 35 kV; 65 mA
Corresponding combination of X-Ray Tube Voltage and X-Ray Tube Current which results in Highest Electric Output Power (IEC 60601-2-45:201.7.9.2.1.c)	Large Focus: 35 kV * 135 mA= 4725 W Small Focus: 42 kV * 55 mA= 2310 W
Lowest current time product (IEC 60601-2-45:201.7.9.2.1.f)	1 mAs for both operation modes
For Mammographic X-Ray Equipment provided with automatic Exposure Control controlling Loading Time, shortest Loading Time and/or the lowest resulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8 mAs (using 20 mm PMMA phantom)
Anode Heat Storage Capacity	300 kHU
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	500 kHU
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	8 cm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1 x 0,1 mm (small focus) - 0,3 x 0,3 mm (large focus)
Power (Nominal Anode Input Power)	P_{max} (small focus) = 2,4 kW - P_{max} (large focus) = 9,6 kW

TECHNICAL SPECIFICATIONS	
X-RAY TUBE	
X-Ray Window	0,5 mm Be
Housing X-Ray protection	≥0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
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
Filters	50 µm Silver (Ag) 50 µm Rhodium (Rh)
Filter selection mode	Manual or Automatic
COLLIMATOR	
Light source	LED (Risk Group 1 - Low Risk - according to IEC 62471)
Type	Automatic recognition of compression paddle format and position
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 function
Formats	24x30 cm 18x24 cm 14x30 cm 12x30 cm 11x30 cm 10x24 cm 11x14 cm 9x13 cm 8x11 cm 7x7 cm
Protection of examination field	Protective screen to keep patient's face out of X-ray beam during bidimensional exams.

TECHNICAL SPECIFICATIONS	
X-RAY GENERATOR	
Inverter Frequency	50 kHz
Ripple Frequency/Amplitude	100 kHz < 2%
Generator Output Power	7,4 kW (@37 kW)
kV range	20÷35 kV 20 - 49 kV (*) Resolution: 0,5 kV (manual and automatic). Precision: ±1%. Repeatability: ±0,1%.
kV display	XX,X kV (3 digits)
mA Range	20-250 mA
mAs range	1 - 640 mAs Resolution : 0,1 mAs (automatic)
mAs values (R'20)	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
AUTOMATIC EXPOSURE CONTROL	
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
Sensitive area (only for PRE mode)	Mosaic of 96 areas of detector automatically selected in function of breast size and projection
DOSE CALCULATOR	
Method of Calculation	Average Glandular Dose (AGD) according to: "D.R. Dance et al."
Data visualization (mGy)	On Acquisition Work Station
Method of recording	Image Header (DICOM)
AGD with a 4 cm PMMA phantom (only for 2D acquisition)	1,4 mGy
Dose limits	According to European Protocol for Dosimetry and EUREF protocol
DEVICE FOR GEOMETRIC MAGNIFICATION (*)	
Type	Gridless interchangeable with potter-bucky
Magnification ratio (variable)	x1,5 / x1,8/ x2
Small focus selection	Automatic once fitted
GRID	
Type	Linear, Vibrating
Ratio	6:1
Lines/cm	36

(*) Optional

TECHNICAL SPECIFICATIONS

DIGITAL IMAGING SYSTEM

DIGITAL FLAT PANEL DETECTOR	**Amorphous Silicon detector (a-Si)**	**Amorphous Selenium (a-Se)**(*)
Type	Indirect conversion digital detector	Direct conversion digital detector
Technology	(a-Si) TFT Array + Pin photodiode Amorphous Silicon	Amorphous selenium (a-Se)
Scintillator	CsI	-
Format (ISO 4090)	24 x 30 cm	
Case dimensions	35,9 x 34,6 cm	
Image matrix	2816 x 3584	
Active Area	23,9 x 30,5 cm	
Image depth	16 bit	
Pixel Pitch	85x85 µm	
Top Cover	Carbon fiber 0.1 mm Al equivalent	
Cooling method	Air + Fan (integrated)	
Fill factor	80%, geometric	88%, geometric
DQE (typ.)	45% (@ 1 lp/mm for 28 kV exposure) 10% (@ 5,8 lp/mm for 28 kV exposure)	> 50% (@ 1 lp/mm for 28 kV exposure) > 20% (@ 5,8 lp/mm for 28 kV exposure)
MTF	>75% @ 1 lp/mm >10% @ 5,8 lp/mm	>90% @ 1 lp/mm >60% @ 5 lp/mm
Spatial resolution	5,9 lp/mm	
Reconstruction time from last exposure	<15 s	
Time between two images acquisition	<15 s	

(*) Optional

TECHNICAL SPECIFICATIONS

ACQUISITION WORKSTATION (AWS)

SOFTWARE	
Image Display Time on Acquisition Station	< 15 s
Time Between Two Consecutive Images Acquisition	< 15 s
POST-PROCESSING ALGORITHM: Type	Specific for mammography to optimize the quality of acquired images
POST-PROCESSING ALGORITHM: Description	Processing of acquired RAW images and display in "For Presentation" format to enhance breast tissue structures and reduce the noise
Dedicated filters	For geometric magnification and in case of prosthesis, metallic clips, surgical markers, clusters of microcalcifications, breast specimens and surgical anatomical parts
Post processing	Zoom, Pan/Scroll, Lente, Window/Level, Contrast, Histo, Restore original, AOI operations, Anchor Point, Measures, Lens .
Quality check	Tool for periodic calibration and quality check according to EUREF protocols (March 2014).
Images compression format	JPEG LOSSLESS (JL) - JPEG 2000 LOSSLESS (J2L)
Images saving/export format	DICOM FOR PROCESSING FFDM

NETWORKING

DICOM Functions	
DICOM Storage (SCU)	Send Image to PACS
DICOM Modality worklist (SCU)	Interface with HIS / RIS with auto refresh option
DICOM Print (SCU)	Support DICOM printers
Dicom Storage Commitment (SC)	Yes (*). Send commitment status
Dicom Modality Performed Procedure Step (MPPS)	Yes (*). Send the status of exams to HIS / RIS
DICOM Structured Dose Report	Yes (*). To exchange structured data produced in the course of image acquisition or post-processing

(*) Optional

TECHNICAL SPECIFICATIONS

INTEGRATED ACQUISITION WORKSTATION (AWS)

AWS PERSONAL COMPUTER (integrated in mammo unit)			
Hard-disk	128 GB SSD: Hard disk for Operative System, System, DMD Acquisition Software and DMD Toolkit Software: SATA 1 TB: Hard disk for image storage - SATA 1 TB: additional hard disk for image storage (*)		
Processor	Intel		
RAM	16 GB		
CD/DVD	External DVD recorder USB 3.0		
Operative system	Windows Embedded standard 7		
Network	100/1000 MB/s		
UPS	Yes (*). Emergency power unit system (650 VA) that grants for safe and controlled switch off preventing any data loss or damage.		
Image storage capacity	~25.000 images (no compression) for 1 TB hard-disk.		
MONITOR	**2 MP**	**3 MP (*)**	**5 MP (*)**
Type	TFT Color LCD		
Size	24''	21,3"	21,3"
Recommended resolution	1900 x 1200 pixel	2048 x 1536 pixel	2800x 2100
Contrast	1000:1 tip.	1400:1	1400:1
Max brightness	600 cd/m^2	900 cd/ m^2	1000 cd/ m^2
Viewing Angle	178° H/V		

(*) Optional

TECHNICAL SPECIFICATIONS

SEPARATE ACQUISITION WORKSTATION (AWS) (*)

TOUCH SCREEN COLOUR DISPLAY (*)	
Technology	Active matrix TFT LCD
Screen Size (aspect ratio)	15" (4:3)
Display Resolution (pixels)	1024x768
Colours	16,2 million with dithering
Brightness	300 cd/m^2
Contrast ratio	800:1 max
Viewing Angle	160° H / 150° V
POINTING AND SELECTION DEVICE (*)	
Type	Trackball with scroll ring and four customizable buttons
Technology	Optical tracking
ANTI-X PROTECTIVE BARRIER	
Type	Integrated
Pb equivalence	> 0,34 mm @ 35 kV/0,26 mm @ 49 kV (IEC 60601-2-45) (thickness of 2 cm) > 0,5 mm up to 150 kV (thickness of 1,1 cm)
Dimensions	85,7 x 200,3 x 64 cm
Glass thickness	• 1,1 cm (*) • 2 cm

(*) Optional

TECHNICAL SPECIFICATIONS

REVIEW STATION (*)

HARDWARE

Type	Allows operator to review positioning, anatomy, annotations and exposure factors through means of a mammography review software with unlimited number of dedicated protocols allowing operator to create tailor made review workflows.
Hard-disk	2x1 TB SATA (7.000 rpm)
Processor	Intel Xeon Quad Core 3,00 GHz 10 MB cache
RAM	8 GB DDRIII-1600 MHz
Dedicated track-ball	For fast access to main reviewig functions
CD/DVD	8x SATA DVD +/-RW DL
Operative system	Windows 7 Professional 64-bit
Graphic card	ATI MED X 3900 (very high resolution display system) NVIDIA Quadro (colour service monitor)
UPS	650 VA
Image storage capacity	~25.000+25.000 images
Software	Dedicated mammography image review software with processing and reporting tools, dedicated views and protocols and FULL DICOM package
FULL DICOM features	Yes, FULL DICOM package including the possibility to import via Query Retrieve any type of exam (Ultrasound, MRI, CT) via DICOM from other medical devices or PACS
Post Processing features	Windowing, Zoom, Magnifying glass, Color inversion, Vertical and horizontal panning, annotations, Mosaic view, quadrant view, measurements, Image rotating, Tabar viewing system, Password protection for individual operators, image export in JPEG format
Additional dedicated keypad	Yes
CAD (Computed Aided Diagnosys)	CAD algorithm is capable of identifying different injuries distinguishing them with different symbols in dependence of their nature (mass, micro calcifications). Algorithm takes detection experience from a database of more than 10.000 clinical cases with correspondent findings in different breast views. CAD software supports output to PACS via DICOM.

MONITOR	2 MP (colour service monitor)	2 x 5 MP (very high resolution) (*)
Use	For Patient and Exam management with network connections	For Mammography Diagnosys
Type	COLOR LED	Monochrome, LCD Panel (IPS)
Size	21,5" (16:9)	21.3"
Recommended resolution	1920 x 1080 pixel	2048x2560 pixel
Contrast	1000:1	1200:1
Brightness	200 cd/m^2	1200 cd/m^2 max
Flicker free	Yes	Yes
Antiglare	Yes	Yes
QA/QC diagnostics	--	Yes

(*) Optional

TECHNICAL SPECIFICATIONS

INSTALLATION DATA

Power supply	115/220/230/240 Vac ±10% 50/60 Hz (115 Vac ±10% 50/60 Hz (*))
Dimensions (MAMMOGRAPH UNIT) Weight (MAMMOGRAPH UNIT)	Dimensions: 73 x 69 x 199,8 cm Weight: 300 kg
Dimensions (ACQUISITION STATION) Weight (ACQUISITION STATION)	Dimensions: 85,7 x 53 x 200,3 cm Weight: 90 kg (0,34mm Eq.Pb, thickness 20mm) - 56 kg (0,50mm Eq. Pb thickness 11mm)

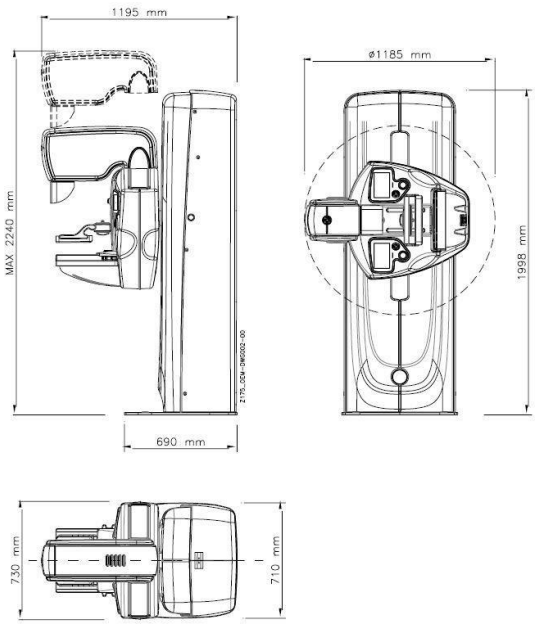
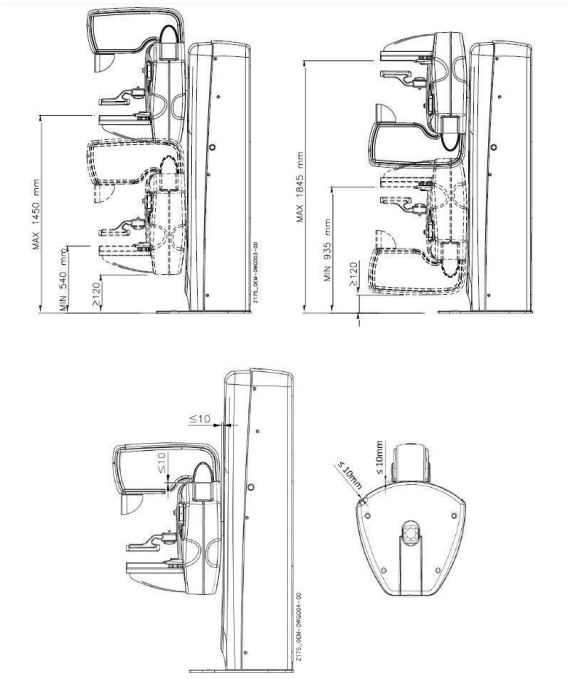
ENVIRONMENTAL CONDITIONS

OPERATING	MAMMOGRAPHIC UNIT	a-Se DETECTOR	a-Si DETECTOR
Temperature Humidity Atmospheric Pressure	+20°C ÷ +70°C 10% ÷ 90% 500 mbar ÷ 1060 mbar	+20°C ÷ +25°C 30% ÷ 75% 540 mbar ÷ 1060 mbar	5°C ÷ +40°C 30% ÷ 85% 540 mbar ÷ 1060 mbar
TRANSPORT AND STORAGE	MAMMOGRAPHIC UNIT	a-Se DETECTOR	a-Si DETECTOR
Temperature Humidity Atmospheric Pressure	+20°C ÷ +70°C 10% ÷ 90% 500 mbar ÷ 1060 mbar	+5°C ÷ +40°C 10% ÷ 90% 540 mbar ÷ 1060 mbar	-15°C ÷ +65°C 10% ÷ 85% 540 mbar ÷ 1060 mbar

(*) Optional

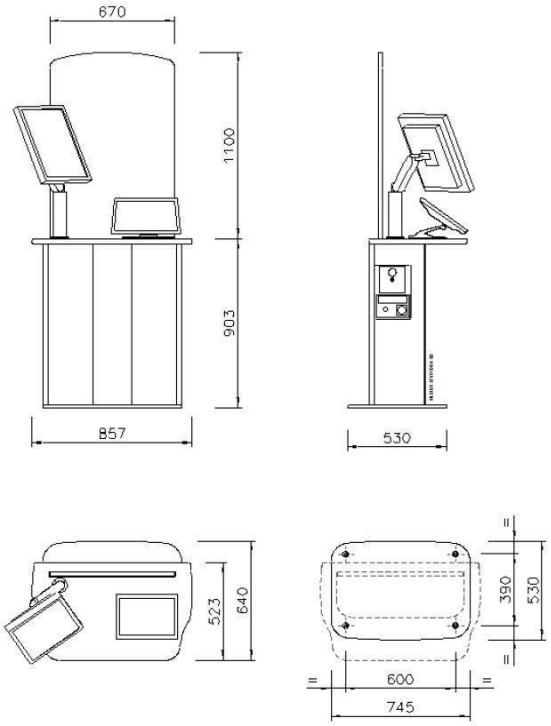
SIZE AND DIMENSIONS

MAMMOGRAPH FFDM C +

FRONT VIEW		
LATERAL VIEW		

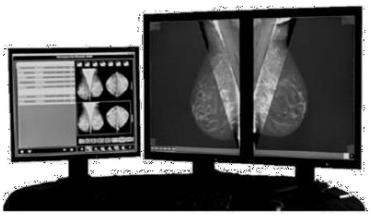
SIZE AND DIMENSIONS

ACQUISITION STATION

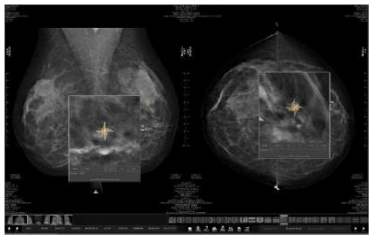
FRONT VIEW		

ACCESSORIES

WORKSTATION FOR EXAM REVIEW AND SCREENING (*)

Expert viewing methodology (TABAR's systematic viewing masks) and comparison between images to enhance perception of subtle abnormalities		

COMPUTER AIDED DETECTION (CAD) MAMMOGRAPHY SYSTEM (*)

This tool helps the operator to identify and distinguish breast injuries. It is based on a wide database of clinical cases previously analysed by radiology experts helps the operator to identify and distinguish breast injuries.		

(*) Optional

INSTALLATION AND WARRANTY

INSTALLATION

Only authorized technical personnel that has been appropriately trained by ITALRAY can install Italray Digital Mammographs. Upon request, ITALRAY Installation Office can prepare system installation layouts (including eventual construction/electrical)

WARRANTY

ITALRAY guarantees its products for one year from the delivery date. ITALRAY can offer to its customers a wide range of service plans that will perfectly fit all needs and preferences

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Your X-ray Solution

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