AMRAD Medical

Helianthus

PRODUCT DATA

Helianthus is a complete digital mammography system optimized for 2D image acquisition.

It is composed of:

- Mammography Unit with isocentric C-Arm, integrated high voltage generator, biangular X-ray tube and full field digital detector;
- Integrated or separated Acquisition Work Station (AWS)

CLASSIFICATION (IEC 60601-1/A1)

Protection against electric shock	Class I, with type B applied parts
Applied parts	• Compression paddles • Magnification device
Protection degree according to IEC 529	IP X0 (Mammo Unit), IP X2 (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

POWER SUPPLY

Line voltage	115/220/230/240 Vac ±10% 50/60 Hz
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 installed (IEC 60601-1)
Wall connection	20 A Thermal-magnetic circuit breaker (40 A Thermal-magnetic circuit breaker in 115 Vac option)
Mains resistance	<0,50 Ω

EMERGENCY STOPS

Number and type	Two red push buttons on both sides of mammography unit. One red push button on optional separate AWS
Function	To switch off totally the power of mammo unit except PC and logic interfaces (Safety to close/save studies and switch off the unit)

ENVIRONMENT PROTECTION AND WASTE DISPOSAL

System contains in some of its parts and subassemblies, solid and liquid substances that must be disposed only by designated companies according to local laws	
Tube assembly	Beryllium, glass, dielectric oil (PCB free), other metals and plastic
H.V. transformer	Dielectric oil (PCB free), plastic, copper and other metals
Other subassemblies	Plastic, other metals, electronic components, glass, epoxy printed circuits, amorphous selenium

ENVIRONMENTAL CONDITIONS (with a-Se Detector)

Mammography Unit Transit/Delivery and Storage Conditions	Temperature: -20° C ÷ +70° C Relative humidity: 10% ÷ 90% Barometric pressure: 700 hPa ÷ 1060 hPa
Detector conditions during: • Transfer to transport terminal • Destination terminal Custom Clearance period • Door delivery • Storage conditions • Mammo unit switched off	Temperature: +5 °C ÷ +40 °C Relative humidity: 10% ÷ 90% Barometric pressure: 700 hPa÷ 1060 hPa
Detector conditions during: • International air transport Note: detector packed in the original crate	Temperature: -20 °C ÷ +60 °C (24 h) Relative humidity: 10% ÷ 90% Barometric pressure: 700 hPa ÷ 1060 hPa
Operating conditions • Mammo unit switched on	Temperature: +20° C ÷ +25° C Relative humidity: 30% ÷ 75% Barometric pressure: 700 hPa ÷ 1060 hPa
Detector maximum rate of temperature change	10 °C in 20 min
Heat dissipated in max load condition of 35 kV 500 mAs (1 shot every 5 minutes)	316 kCal/h

ISOCENTRIC C-ARM

F.D.D. (Focus Detector Distance)/S.I.D.	66 cm
Motorized Movements	Rotation and vertical translation
C- Arm rotation range	±180° (CW, CCW continuous to any position)
Rotation speed	20°/s with acceleration and deceleration ramp for smooth operation
C-Arm vertical range (Floor-Potter Bucky table)	From 54 to 145 cm (travel of 91 cm)
Vertical movement speed	5 cm/s
Projection Preset positions	N° 7 Programmable projections (0°, -45°, +45°, -90°, +90°, -135°, +135°)

CONTROL SWITCHES

Number and Type	Three multiswitches (five push-buttons): two on both sides of C-Arm and one on top of X-Ray tube cover
Control Actions	Vertical movement of C-Arm, Continuous rotation of C-Arm, Switch-on of collimation light

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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÷49 kV
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 (allowed)
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

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X-RAY TUBE (IAE XM1016 T)

Anode rotation speed	3,000 rpm @50 Hz (10,000 rpm @50 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	500 kHU (375 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	0.1 x 0.1 mm (Small Focus)/0.3 x 0.3 mm (Large Focus
Power (Nominal Anode Input Power)	1400 W (Small)/5900 W (Large) (3000 rpm) 2400 W (Small)/9600 W (Large) (10000 rpm opt.)
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 and 80 mA Small focus: 49 kV and 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: 145 mA and 32 kV Small focus: 65 mA and 35 kV
Corresponding 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)	Large focus: 32 kV*145 mA=4640 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 lowestresulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8 mAs (using 20 mm PMMA phantom)
X-Ray Window	0.5 mm Beryllium
Housing X-Ray protection	≥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 CPU control	Upper limit temperature 65° outside tube assembly. HU and °C display available in technical menu.

FILTERS	
50 µm Rhodium (Rh)	0.51 mm Al eq. 28 kV (measured with Tungsten target)
50 µm Silver (Ag)	0.54 mm Al eq. 28 kV (measured with Tungsten target)
300 µm Copper (Cu) (optional, predisposition for future Dual Energy implementation)	3.85 mm Al eq. 49 kV (measured with Tungsten target)

AUTOMATIC COLLIMATION DEVICE	
Type	Automatic recognition of compression paddle format and position. The operator can switch from automatic to manual collimation mode
Light source	LED (Risk Group 1 at 50 cm - Low Risk -according to IEC 62471)
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
Image 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 2D exam

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DIGITAL FLAT PANEL DETECTOR

Detector technology	Amorphous Selenium (a-Se)
Selenium thickness	200 µm
Case dimensions	35.9x34.6 cm (24x30 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 differenceof around 4-5 degrees with respect to the ambient temperature
Digitalization type	Logarithmic
Pixel dimension	85 x 85 µm
Active area	23.9 x 30.5 cm (24x30 cm format)
Image matrix	2816 x 3584
~~Image~~ depth	16 bit
Fill factor	88 % geometric
MTF (Modulation Transfer Function)	>95% @ 1 lp/mm >50% @ 5,8 lp/mm
DQE (Detector Quantum Efficiency) for an exposure of 28 kV	>70% @ 1 lp/mm >20% @ 5,8 lp/mm
Resolution	5.9 lp/mm (Nyquist)
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 "EUREF")	0.05
Reconstruction time from last exposure (Model 020 BR3D CIRS phantom, 50 mm thickness)	2 s ± 20% (in 2D mode)
Time to display the image on the AWS from last exposure (Model 020 BR3D CIRS phantom, 50 mm thickness)	5.5 s ± 20% (in 2D mode)

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"SensROI" 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)	Automatically selected in function of employed compression paddle

"POEt" POST-PROCESSING ALGORITHM

Type	Specific for mammography to optimize the quality of acquired images
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
Images compression format	JPEG LOSSLESS (JL), JPEG 2000 LOSSLESS (J2L)
Images saving/export format	DICOM FOR PROCESSING FFDM

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GRID	
Type	Linear, vibrating
Interspace Material	Carbon Based Polymer
Ratio	6:1
Lines/cm	36
Contrast factor	1.54

DEVICE FOR GEOMETRIC MAGNIFICATION (optional)	
Type	Gridless, interchangeable with Potter-Bucky
Magnification Ratio	x1.5/ x 1.8/x2
Small Focus Selection	Automatic once fitted

IMAGE QUALITY	
Spatial resolution	Conformity with: "European Guidelines for Quality Assurance inmammography screening", Fourth edition and with "Recommended specifications" for QualityAssurance in mammography of American College of Radiology

DOSE CALCULATOR	
Method of Calculation	Average Glandular Dose (AGD) according to:"D.R. Dance et al."
Data visualization (mGy)	On Acquisition Work Station (AWS)
Method of recording	Image Header (DICOM)
AGD with a 4 cm PMMA phantom (2D)	1.40 mGy
Dose limits	According to European Protocol for Dosimetry and EUREF protocol

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"Smart µPress" COMPRESSION SYSTEM

Compression paddle movement	Motor driven or manual with fine adjustment
Standard compression paddles	24x30 cm for normal breasts 18x24 cm with lateral shifting for small breasts
Optional compression paddles	9x21 cm for magnification Φ7,5 cm spot for magnification 9x9 cm squared for magnification 18x24 cm with Φ7,5 cm spot for contact examination 18x24 cm with 9x9 cm spot for contact examination 10x24 cm for axillary examination 10x24 cm for prosthesis examination
Compression paddle holder	Fast mechanical unlock by rotating knob Right 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 range	Adjustable from 70 to 200 N
Compression force displayed	Effective applied force with 1 N resolution
Compression thickness accuracy	±1 mm
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 release after exposure	Selectable from control panel
Compression paddle aluminium equivalence	< 0.2 mm Al (0.135 mm Al≈30 kV)

ROTATING CONTROLLERS FOR COMPRESSION WITH FINE ADJUSTMENT

Number and type	Two rotating wheels with central push-button on both sides of C-Arm

TOUCHSCREEN COLOR DISPLAYS

Number and type	Two LED backlight touchscreens on both sides of C-Arm
Screen size (aspect ratio) and resolution	7" (4:3) - 640x480
Displayed parameters	Compression force, compressed breast thickness, patient name, projection angle, breast laterality, ACR code, collimation format, magnification factor

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FOOT-CONTROLS

Number and type	One with four pedals and one push-button 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
Protection degree according to IEC 529	IP X2

ANTI-X PROTECTIVE BARRIER (OPTIONAL)

Type	Half transparent screen (metallic lower part and transparent upper part)
Pb equivalence	> 0.34 mm @ 35 kV/0.26 mm @ 49 kV (IEC (thickness of 20 mm) > 0.5 mm up to 150 kV (optional) (thickness of 11 mm)
Dimensions	773 x 2100 x 505 mm

CALCULATOR (Integrated in Mammo Unit)

Operating System	Windows 10 IoT Enterprise
CPU	Intel Core i5-6500 (Quad Core) 3.2 GHz
RAM	
HDD	128 GB SSD for Operating System, DMD Acquisition Software and DMD Toolkit Software (256 GB SSD opt.) 1 TB SATA for images storage (~ 25000 images) (2TB SATA opt.)
Pointing and selection device	Keyboard with integrated touchpad
CD/DVD Recorder	24x
USB port	1 (3.1)
Power pack	250 W

2 MP (standard), 3 or 5 MP (optional) COLOR MONITOR

Technology	TFT color LCD
Screen size (aspect ratio) and resolution	24" (2 MP), 21,3" (3 MP), 21,3" (5 MP) 1920 x 1200 (2 MP), 2048 x 1536 (3 MP), 2800 x 2100 (5 MP)
Viewing angle	178° (horizontal and vertical)
Response time	7 ms (2 MP), 20 ms (3 MP), 12,5 ms (5 MP)
Brightness	600 cd/m² max - 350 cd/m² DICOM calibrated (2 MP) 900 cd/m² max - 500 cd/m² DICOM calibrated (3 MP) 1000 cd/m² max - 500 cd/m² DICOM calibrated (5 MP)
Contrast ratio	1000:1 typical (2 MP), 1400:1 typical (3 and 5 MP)

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CALCULATOR (Separated Acquisition Workstation)

Operating System	Windows 10 IoT Enterprise
CPU	Intel Core i5-6500 (Quad Core) 3,2 GHz
RAM	8 GB
HDD	128 GB SSD for Operating System, DMD Acquisition Software and DMD Toolkit Software (256 GB SSD opt.) 1 TB SATA for images storage (~25000 images)(2TB SATA opt.)
Power pack	250 W

CONSOLLE WITH TRANSPARENT ANTI-X PROTECTION BARRIER

Pb equivalence	> 0.34 mm @ 35 kV/0,26 mm @ 49 kV (IEC (thickness of 20 mm) > 0.5 mm up to 150 kV (optional) (thickness of 11
Pointing and selection device	Touchscreen 15" color display and mouse or trackball
CD/DVD Recorder	24x
USB port	1 (3.1)
Dimensions	857 x 2003 x 640 mm
Weight	90 kg (0.34 mm Pb eq), 56 kg (0.50 mm Pb eq)

TOUCH SCREEN COLOR DISPLAY

Technology	Capacitive LCD screen
Screen size (aspect ratio) and resolution	15" (4:3) - 1024x768
Viewing angle	160° horizontal/150° vertical
Brightness	300 nits
Contrast ratio	800:1

2 MP (standard), 3 or 5 MP (optional) COLOR MONITOR

Technology	TFT color LCD
Screen size (aspect ratio) and resolution	24" (2 MP), 21.3" (3 MP), 21.3" (5 MP) 1920 x 1200 (2 MP), 2048x1536 (3 MP), 2800x2100 (5 MP)
Viewing angle	178° (horizontal and vertical)
Response time	7 ms (2 MP), 20 ms (3 MP), 12,5 ms (5 MP)
Brightness	600 cd/m^2 max - 350 cd/m^2 DICOM calibrated (2 MP) 900 cd/m^2 max - 500 cd/m^2 DICOM calibrated (3 MP) 1000 cd/m^2 max - 500 cd/m^2 DICOM calibrated (5 MP)
Contrast ratio	1000:1 typical (2 MP), 1400:1 typical (3 and 5 MP)

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LITR068-0124