Chapter I:
UNIT DESCRIPTION

INTRODUCTION TO TECHNICAL MANUAL

This Technical Manual is intended to give a detailed overview for installing, starting up, testing and troubleshooting of the system. Carry out these instructions in the sequence specified in this manual. All necessary adjustments and program settings have been already performed at the factory. Only the adaptation of the device to local requirements has still to be carried out.

INTENDED USE

HELIANTHUS series is a medical device indicated to produce digital mammographic images of the breast for diagnosis of breast cancer. Its intended use is for two-dimensional diagnosis, screening, three-dimensional tomosynthesis exams or for needle localization in case of stereotactic biopsy.

PRIMARY FUNCTIONS

To finalize its intended use the medical device must perform the following principle functions:

- Exposure by means X-ray
- Move C-arm and Tube for correct positioning of the patient
- Compression of Breast in order to avoid movements artefacts and increase image quality,
- Coming into contact with Breast Tissue to perform compression

SCOPE AND INDICATIONS

The device is to be used in a radiology or clinic exam room environment in a hospital, outpatient clinic, a breast imaging center or other facilities. Mammography technologists operate the equipment for the production of mammograms. The device may also be used for quality control purposes and other clinical or research related activities by medical physicists and radiologists certified in accordance with local standards. Reading a mammogram a doctor will be looking for different types of breast changes, such as:

- small white spots called calcifications (micro/macrocalcifications),
- larger abnormal areas called masses/lumps,
- and other suspicious areas that could be signs of cancer
- X-ray pictures of each breast are taken, typically from 2 different angles.

Calcifications :

Calcifications are tiny calcium deposits within the breast tissue. They look like small white spots on a mammogram. They may or may not be caused by cancer. There are 2 types of calcifications.

Macrocalcifications:

Macrocalcifications are larger calcium deposits that are most likely due to changes caused by aging of the breast arteries, old injuries, or inflammation. These deposits are typically related to non-cancerous conditions and don't need to be checked for cancer with a biopsy. Macrocalcifications become more common as women get older (especially after age 50).

Microcalcifications:

Microcalcifications are tiny specks of calcium in the breast. When seen on a mammogram, they are more of a concern than macrocalcifications, but they don't always mean that cancer is present. The shape and layout of microcalcifications help the radiologist judge how likely it is that the change is due to cancer. In most cases, microcalcifications don't need to be checked with a biopsy. But if they have a suspicious look and pattern, a biopsy will be recommended to check for cancer.

Masses:

A mass is an area of dense breast tissue with a shape and edges that make it look different than the rest of the breast tissue. With or without calcifications, it's another important change seen on a mammogram. Masses can be many things, including cysts (non-cancerous, fluid-filled sacs) and non-cancerous solid tumors (such s fibroadenomas), but they may also be a sign of cancer. Cysts are fluid-filled sacs. Simple cysts (fluid-filled sacs with thin walls) are not cancer and don't need to be checked with a biopsy. If a mass is not a simple cyst, it's of more concern, so a biopsy might be needed to be sure it isn't cancer.

Solid masses:

can be more concerning, but most breast masses are not cancer.

A cyst and a solid mass can feel the same. They can also look the same on a mammogram. The doctor must be sure it's a cyst to know it's not cancer. To be sure, a breast ultrasound is often done because it is a better tool to see fluid-filled sacs. Another option is to use a thin, hollow needle to remove (aspirate) fluid from the area.

If a mass is not a simple cyst (that is, if it's at least partly solid, or it has other concerning features), more imaging tests might be needed to decide if it could be cancer. Some masses can be watched over time with regular mammograms or ultrasound to see if they change, but others may need to be checked with a biopsy. The size, shape, and margins (edges) of the mass can help the radiologist decide how likely it is to be cancer.

Breast density:

A mammogram report will also contains an assessment of patient's breast density. Breast density is based on how fibrous and glandular tissues are distributed in patient's breast, compared to how much of patient's breast is made up of fatty tissue. Dense breasts are not abnormal, but they are linked to a higher risk of breast cancer. Dense breast tissue can also make it harder to find cancers on a mammogram. Still, experts don't agree what other tests, if any, should be done along with mammograms in women with dense breasts who aren't otherwise at higher risk for breast cancer (based on gene mutations, breast cancer in the family, or other factors).

QUALITY CONTROLS

All quality control tests must be performed following the dedicated Quality Control Manual (MCQDM10DMD_Uxx) provided with the Mammo Unit.

TRAINING

HELIANTHUS series has not to be used by unskilled or untrained personnel. Service technicians must ensure that they receive training before to servicing HELIANTHUS series units.

Metaltronica S.p.A does not accept responsibility for injury or damage due to improper or unsafe procedures or caused by incorrect system operation.

COMPLIANCE STATEMENT

Metaltronica S.p.A declares that the medical equipment is developed following technical standards below:

IEC 60601-1 (Ed. 3.1)	Medical electrical equipment - Part.1 - General requirements for basic safety and essential performance.
IEC 60601-1-3 (Ed. 2.1)	Medical electrical equipment - Part.1 – General requirement for basic safety and essential performance – collateral standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-2 (Ed. 4)	Medical electrical equipment - Part.1-2: General requirements for basic safety and essential performance – collateral standard: Electromagnetic disturbances – requirements and tests
IEC 60601-1-6 (Ed. 3.1)	Medical electrical equipment - Part.1: General requirements for basic safety and essential performance – collateral standard: Usability

IEC 60601-2-28 (Ed. 3)	Medical electrical equipment - Part.2-28: Particular requirements for basic safety and essential performances of X-ray tube assemblies for medical diagnosis
IEC 60601-2-45 (Ed. 3.1)	Medical electrical equipment - Part.2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
IEC 62366-1 (Ed.1)	Medical devices – part.1: Application of usability engineering to medical devices
IEC 62304 (Ed.1.1)	Medical device software – Software life-cycle processes
IEC 62471 (Ed.1)	Photobiological safety of lamps and lamp systems
ISO 10993-1 (ED. 5)	Evaluation and testing within a risk management process
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes

Metaltronica S.p.A has the responsibility for safety, performance and reliability for the equipment if following provisions are observed by the user:

- Installation satisfies requirement reported into Planning Guide;
- Electrical installation meets requirement of safety and standard IEC 60364 (sec. 710)
- The equipment is used according to the current Operator manual
- The maintenance operation are performed only by authorized and trained persons
- The network and communication is installed following IEC standards
- Medical equipment shall be installed following special EMC requirements, reported into detailed paragraph “ELECTROMAGNETIC INFORMATION ACCORDING TO IEC 60601-1-2”

SAFETY SYMBOLS

WARNING

Indicates a risk of danger that may lead to death of serious physical injury.

CAUTION

Indicates a risk of danger that if disregarded leads to slight or moderate physical injury and/ or property damage.

NOTE

Should be understood as a tip. You should not observe these instructions. However, there will be advantages if you follow notes.

OTHER SYMBOLS

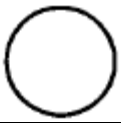
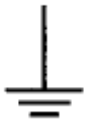
ESD

Warning symbol denoting a device's susceptibility to electrostatic discharge.

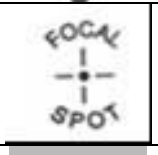
INTERNATIONAL SYMBOLS

The meaning of symbols appearing on the plate and on some components of the unit is specified in the following Table 1.

Table 1

SYMBOLS	CEI – IEC STANDARD DEFINITIONS
	ISO 7000-0434A Caution
5008 	IEC 60417-5008 “OFF” Power
5010 	IEC 60417-5010 “ON”/”OFF” (push-push)Power
5840 	IEC 60417-5840 Type B Applied Part
5032 	IEC 60417-5032 Alternating Current
5019 	IEC 60417-5019 Protective Earth (ground)
5017 	IEC 60417-5017 Earth (ground)
	ISO 15223-1 Manufacturer

	ISO 15223-1 Date of Manufacturer
	ISO 15223-1 Serial Number
	ISO 15223-1 Indicates temperature the medical device can be exposed
	ISO 7010-M002 Refer to instruction manual/booklet NOTE On ME EQUIPMENT “Follow instructions for use”
5036 	IEC 60417-5036 Dangerous Voltage
	WEEE (Waste Electrical and Electronic Equipment)
5638 	IEC 60417-5638 Emergency Stop
5326 	IEC 60417-5326 Large Focus
5325 	IEC 60417-5325 Small Focus
5384 	IEC 60417-5384 Indication of radiation field by light

5349 	IEC 60417-5349 Radiodiagnostic compression device, movement
5350 	IEC 60417-5350 Radiodiagnostic compression device, pressure applied
5351 	IEC 60417-5351 Radiodiagnostic compression device, parked
5339 	IEC 60417-5339 X-ray source assembly, emitting
5570 	IEC 60417-5570 Unlocking or Unlock
	C-arm rotation angle
	IEC 60417-5367 C-arm position
	Compressed Breast THICKNESS
	*ERROR MESSAGE*
	Focal Spot
	Xray tube label
	Z axis increase and decrease (for Biopsy device)
	***Medical Device***

	***Unique Device Identification***
	***Electronic Instruction For Use***
	Acquisition software icon (user)
	Icon to access to software maintenance tools
	Area to set or modify device users
	Access to manufacturer reserved area

ACRONYMS

Table 2

ACR:	American College of Radiology
AEC:	Automatic Exposure Control
AGD	Average Glandular Dose
AOI:	Area Of Interest
AWS	Acquisition Work Station
CB	Core Biopsy
DBT:	Digital Breast Tomosynthesis
DICOM:	Digital Imaging and Communications in Medicine
DMD	Digital Mammography Device
DME	Digital Mammography Equipment
DSP	Service display (Pop-up service window)

FFDM:	Full Field Digital Mammography
FTSE:	Function of Tissue Strength Evaluation
GUI:	Graphical User Interface
HRD	High Resolution Display (AWS)
MG	Needle Safety Margin
MMD	Manufacturer Mammography Devices
MMI:	Man-Machine Interface (it has the same meaning of GUI)
NPU	Needle Position Unit
OD	Optical density
PACS:	Picture Archiving and Communications Systems
RIS:	Radiology Information System
ROI:	Region Of Interest

TSD	Touch Screen Display (MAMMO o AWS)
UDI	Unique Device identifier

DECLARATION ACCORDING TO IEC 60601-1 STANDARD

Metaltronica S.p.A declares its responsibility concerning safety, reliability and equipment features included in this manual only if the following items are fully satisfied:

1) Installation;
   - room temperature and humidity;
   - updates;
   - recalibrations;
   - repairs and/or modifications carried out by technical personnel officially authorized from Metaltronica S.p.A.
2) Electrical pre-installation performed in the site where the system has to be put into operation, carried out according to prescription given by IEC rules concerning Medical Application.
3) Service personnel must ensure that they receive training on the mammographic unit with Metaltronica S.p.A training programs prior to service the Unit.
4) Use of the equipment according to instruction in this manual.

WARNING

Using and keeping X-Ray equipment and device must conform the local Regulations and national laws concerning Medical X-Ray handling.

NOTE

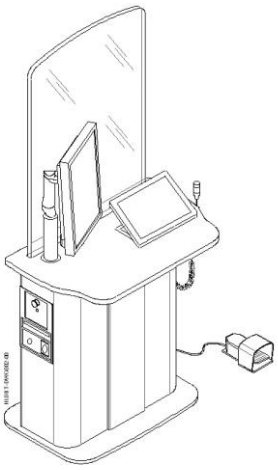
According to 2017/745 EU MDR Regulation concerning product traceability, Metaltronica S.p.A must be informed of any owner or installation address change.
Medical Devices traceability is prerequisite to assure their safety and reliability over the time.

SYSTEM CONFIGURATION

The HELIANTHUS series is a modular mammography solution optimized for digital imaging. It's composed of:

- Mammography Unit with X-ray unit, Flat filed digital detector, C-Arm also usable for Stereo biopsy in combination with SBD DMD Stereo biopsy device

- Integrated X-Ray control and image
  Acquisition Work Station (AWS) in different options;



- Components
  Please see list of Components in the Operator's manual
  Flat field digital detector is provided in two different versions:
  - Indirect Conversion Amorphous Silicon Detector (a-Si): Basic version, only for conventional mammography (2D), also usable for Stereo Biopsy with stereo biopsy device (optional) or for tomosynthesis.
  - Amorphous Selenium (a-Se): option both for conventional mammography and Tomosynthesis scan also usable for Stereo Biopsy with stereo biopsy device (optional).

SAFETY INFORMATION

CAUTION Please pay attention to the following cautions!

1. *HELIANTHUS series has not to be used by unskilled or untrained personnel. Metaltronica S.p.A does not accept responsibility for injury or damage associated with improper or unsafe system operation. The user should refer to this operator manual for HELIANTHUS series's use.*

2. *A correct use of the equipment assumes that operators (technicians and radiologists) hold the necessary technical and specialist knowledge and they have been properly trained for Good Clinical Practice.*

3. *It is supposed that the reader of this manual is used to the general operations of the windows® operating system; it is also assumed that the concepts of PACS, RIS, DICOM, server etc. are well-known.*

4. *This machine must be used only for mammography.*

5. *This machine must be used only in a controlled area inside a dedicated room provided with x-ray protection that meets local standards and regulation.*

6. *This equipment used in the presence of flammable anesthetic or enriched oxygen may cause an explosion*

7. *The equipment is classified as permanently installed according to IEC 60601-1 international standard. This means that it must be electrically connected by means of permanent connections. In particular, for the maximum electrical safety, the protective earth conductor must be fixed and permanently installed.*

8. *To guarantee the electrical insulation of the mammo unit circuits from supply mains, a locking mechanism has to be provided by the responsible organization (e.g. Thermal-magnetic circuit breaker) capable of being locked in the off position.*

9. *HELIANTHUS series can be used by all categories of patient. For disable patients (on wheel chair) be always careful to all automatic movements of c-arm (especially up/down movement).*

10. *Patients with disabilities or temporary disablement must remain seated during the positioning and the mammographic examination.*

11. *Keep away foot controls from the patient's feet and/or exam chair, especially for disable patient on wheel chair and with disability in general. Metaltronica S.p.A recommends to keep foot controls in a safe area outside the patient ambient (approximately 1,5 m, as defined by IEC 60601-1).*

12. *Before using, check always perfect state of all parts of unit.*

13. *Frequently verify the wear of the compression paddles to prevent damages as cracks and tears, and consequent risks for the patient.*

14. *Do not modify this equipment without authorization of Metaltronica S.p.A.*

15. *Use only original Components and spare parts.*

16. *Do not remove plastic coverings of mammography unit that give a protection against the electrical, thermal and mechanical hazards.*

17. *Do not insert in the x-ray beam devices other than compression paddles or magnification device.*

18. *Use lead apron for patient protection.*

19. *During x-ray emission, operator must be behind anti-X protective barrier and in a position where it is possible to watch patient and unit.*

20. *The detector has a very strict range of temperature for correct operation. It must be operated between 20° and 25 °C (for a-Se detector), between 5° and 40 (for a-Si detector)and between 10° and 40 °C (for SOLO DM detector) . Using the mammography unit outside this range can result in bad quality images.*

21. *Respect the storage conditions to avoid irreversible detector damage. Actually this component is very sensitive to the sudden changes of temperature (maximum rate of temperature change: 10°C in 20 minutes) and it must be maintained between 5° and 40°C (for a-Se detector) , between -15°C and 65°C (for a-Si detector), between -5° and 55°C (for SOLO DM).*

22. *Pay attention to the LCD monitor of mammography unit and touch screen of Acquisition Work Station (if provided) that are the most fragile parts of the device.*

23. *Use the mammography unit, the Acquisition Work Station and its software according to the instruction given in this manual. Do not try to install unauthorized software, access to operating system configuration or perform other potentially dangerous operations.*

24. *Do not use other equipment or network/data couplings (to which a signal input/output part may be connected), other than those forming part of HELIANTHUS series.*

25. *This is a medical equipment and it should not be considered to be a general-purpose computer: when operating the Acquisition Work Station, do not attempt to make any change to system software and do not use it as a personal internal PC. Any modification or attempt to modify the operating system software will make the unit unsuitable for its intended use.*

26. *If install an Anti-virus Software on the calculator where main device processes work, exclude object storage folders (C:\DMD" and "C:\UTILS) from scan by adding folders to exception on the Anti-virus software. Anti-virus protection and network security are exclusively under the responsibility of the user.*

27. *The device incorporates a LED (Risk Group 2 at 20 cm) for light beam centering device (according to IEC EN CEI 62471). Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes. This LED belongs to low risk (risk group 1 at 50 cm according to IEC EN CEI 62471)*

28. *Never leave unsolved problems that may affect the safety of the product.*

29. *The pictures present in this manual are only indicative and may be subjected to changes (for example the background color) which are not significant for the procedure described.*

30. *If mammograph is installed in a mobile environment such as a VAN or Truck, it is necessary remove any Component from unit before cruise. Lock the C-arm to the lowest position using its special support.*

ELECTROMAGNETIC INFORMATIONS ACCORDING TO IEC 60601-1-2

Basic Safety and Essential performance of medical equipment

Medical electrical equipment is safe according to IEC 60601-1. It is protected against:

- electrical hazards;
- environmental hazards;
- radiation hazards;
- thermal hazards;
- mechanical hazards;
- biological and biocompatibility hazards;
- use errors and functionality hazards;
- general hazardous outputs.

Essential performance:

- Correct functioning
- Unintended X-ray radiation

See also Operator's Manual: "Compliance statement".

Basic Safety notes for EMC

Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information provided in the accompanying documents. Portable and mobile RF communications equipment can affect medical electrical equipment.

Fixed equipment or system cabling, which cannot be removed by the user, is not listed. This cabling is part of the system and was present at all EMC-measurements. Without this cabling there is no complete functionality of the system. Medical Electrical equipment must be installed and used in an environment where radiofrequency are controlled i.e. Professional Healthcare facility environment (CISPR 11 Class A).

WARNING

The use of Components, transducers and cables other than those specified, with the exception of transducers and cables sold by Metaltronica S.p.A of the equipment or system as replacement parts for internal components, may result in increased emission or decreased immunity of the equipment or system.

WARNING

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

CAUTION

Do not use the HELIANTHUS series in electromagnetic environment in which radiated RF disturbances are not controlled.

CAUTION

It is strictly recommended to keep no closer than 0.3 m (12 inch) to any part of medical equipment (including cables) portable RF communication equipment such as antennas, mobile phones or other emitting EMC waves in order to prevent EMC interferences. If a mobile RF source emits 450 MHz or 930 MHz, keep it no closer than 0.7 m and 0.38 m, respectively.

CAUTION

This system may cause radio interference or may disrupt the operation of nearby equipment. It may necessary to take mitigation measures such as re-orienting / relocating the equipment or shielding the location.

CAUTION

If RF/EMC interferences cause essential performances lost such as incorrect functioning, incorrect display visualization or unintentional changes in operating mode, please stop immediately the exam, switch-off the unit and remove cause of interference.

EMC reference tables

Guidance and manufacturer's declaration – Electromagnetic emissions		
The HELIANTHUS series is suitable for use in the specified electromagnetic environment. The purchaser or user of the HELIANTHUS series should assure that it is used in an electromagnetic environment as described below:		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The HELIANTHUS series uses RF energy only for its internal function. Therefore, its RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The emission characteristics of HELIANTHUS series is suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measured, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	N.A.	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	

Guidance and manufacturer's declaration – Electromagnetic immunity

The HELIANTHUS series is suitable for use in the specified electromagnetic environment. The purchaser or user of the HELIANTHUS series should assure that it is used in an electromagnetic environment as described below:

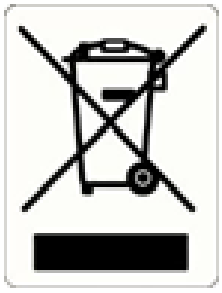
Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment
Electrostatic discharge (ESD) IEC 61000-4-2	DIRECT DISCHARGE Air discharge voltage (kV): 15, 8, 4, 2 Contact discharge voltage (kV): 8 INDIRECT DISCHARGE Contact discharge voltage (kV): 8	IEC 60601-1-2 test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 % and maximum 60% during the test.
Radiated electromagnetic field IEC 61000-4-3	3 V/m (80 MHz to 2.7 GHz)	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the EUT. including cables. Minimum distance 30 cm
Electrical fast transient/burst IEC 61000-4-4	±2 kV for input a.c. and d.c. power ports ±1 kV for signal input/output ports whose maximum cable length is more than 3m	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	INPUT POWER PORTS 0.5 and 1.0 kV (differential mode) 0.5, 1.0 and 2.0 kV (common mode) SIGNAL INPUT/OUTPUT 2.0 kV	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3V RMS (Outside ISM band) 6V RMS (Inside ISM band) Frequency range: 150 kHz to 80MHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the EUT. including cables. Minimum distance 30 cm
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	VOLTAGE DIPS 0% U_T for 0.5 cycle (at 0°,45°,90°,135°,180°,225°,270°, and 315°) 0% U_T for 1 cycle (at 0°) 70% U_T for 25 cycle (@ 50 Hz) and for 30 cycles (@ 60 Hz) (at 0°) VOLTAGE INTERRUPTIONS 0% U_T for 250 cycle (@ 50 Hz) and for 300 cycles (@ 60 Hz) (at any Sync Angle degree)	IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HELIANTHUS series requires continued operation during power mains interruptions, it is recommended that the HELIANTHUS series be powered from an uninterruptible power supply or battery.

Frequency Range and Level: proximity fields from RF wireless communication equipment		
Test Frequency (MHz)	**Modulation**	**Immunity Level (V/m)**
385	Pulse Modulation: 18Hz	27
450	Pulse Modulation: 18Hz	28
710 745 780	Pulse Modulation: 217Hz	9
810 870 930	Pulse Modulation: 18Hz	28
1720 1845 1970	Pulse Modulation: 217Hz	28
2450	Pulse Modulation: 217Hz	28
5240 5500 5785	Pulse Modulation: 217Hz	9

WEEE INFORMATIONS ACCORDING TO DIRECTIVE 2012/19/EU and 2002/96/EC (Waste Electrical and Electronic Equipment)

The following crossed-out wheeled bin symbol,



that is present on the device, means that within the European Union the product must be taken to separate collection at the product end-of life. Therefore, at the end of the life-cycle of the device, the user should deliver the device to the proper collection facilities of the Electric and Electronic Equipments. Alternatively, the user can return the device to the seller, on a one-to-one basis, as long as he is buying a new one of equivalent type and that fulfills the same functions as the old one.

Disposing of the device separately avoids possible negative consequences for the environment and health deriving from inappropriate disposal and enables the constituent materials to be recovered to obtain significant savings in energy and resources.

Who disposes any Electric and Electronic Equipment, reporting the above symbol, as unsorted municipal waste, instead of collecting it separately, incurs the administrative sanctions in accordance with law.

TECHNICAL SPECIFICATIONS

NOTE

Metaltronica S.p.A reserves the right to make further improvements while keeping main features unchanged.

CLASSIFICATION (IEC 60601-1/A1)	
Protection against electric shock	Class I, with type B applied parts
Applied parts	• Potter-Bucky/Biopsy Device carbon fiber • Compression Paddles • Magnification Device
Protection degree according to IEC 60529 and 60601-1 (Third edition)	IP X0 (Mammo Unit) where "X" means that the protection against foreign objects is not required to be specified and "0" means Not-protected against ingress of water; IP X2 (Foot Controls) where "X" means that the protection against foreign objects is not required to be specified and "2" means protected against vertically falling water drops when ENCLOSURE tilted up to 15°
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) **NOTE**: for more details about this specification, please refer to the planning guide
Mains resistance	<0.50 Ω R=0,48 Ω (@220-230-240V) R=0,13 Ω (@115V)

ENVIRONMENTAL CONDITIONS	
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	**a-Si Detector** Temperature: -15°C÷+65°C Relative humidity: 10%÷85% Barometric pressure: 700 hPa÷1060 hPa **a-Se Detector** Temperature: +5°C÷+40°C Relative humidity: 10%÷90% Barometric pressure: 700 hPa÷1060 hPa **SOLO DM Detector** Temperature: -5°C÷+55°C Relative humidity: 10%÷65% Barometric pressure: 700 hPa÷1060 hPa
Detector Conditions during: • International Air Transport Note: Detector packed in the original crate	**a-Si Detector** Temperature: -18°C÷+70°C (under 36h) Relative humidity: 10%÷85% Barometric pressure: 700 hPa÷1060 hPa **a-Se Detector** Temperature: -20°C÷+60°C (24h) Relative humidity: 10%÷90% Barometric pressure: 700 hPa÷1060 hPa **SOLO DM Detector** Temperature: -5°C÷+55°C Relative humidity: 10%÷85% Barometric pressure: 700 hPa÷1060 hPa
Operating Conditions • Mammo Unit switched on	**a-Si Detector** Temperature: +5°C÷+40°C Relative humidity: 30% to 85% Barometric pressure: 700 hPa÷1060 hPa **a-Se Detector** Temperature: +20°C÷+25°C Relative humidity: 30%÷75% Barometric pressure: 700 hPa÷1060 hPa **SOLO DM Detector** Temperature: +10°C÷+40°C Relative humidity: 10%÷65% (operating) 35%÷70% (installation/testing) 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

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 other metals
Other subassemblies	Plastic, other metals, electronic components glass-epoxy printed circuits. amorphous selenium

MAMMOGRAPHY UNIT

X-RAY HIGH VOLTAGE GENERATOR	
Line voltage compensation	AUTOMATIC High voltage 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 Rating	7,4 kW
kV range	20÷49 kV
kV resolution (Manual & 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 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 resolution (Automatic)	0,1 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

OPTIONAL X-RAY TUBE	**I.A.E. XM1016 T**
Anode rotation speed	3000 rpm (optionally 10000 rpm)
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, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	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)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA **Tomosynthesis mode:** Large focus: 49kV; 140mA
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)	**2D mode:** Large Focus: 35kV; 135mA Small Focus: 35Kv;65mA **Tomosynthesis mode:** Large Focus: 35kV; 200mA
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)	**2D mode:** Large Focus: 35kV*135mA= 4725W Small Focus: 42kV*55mA= 2310W **Tomosynthesis mode:** Large Focus: 35kV*200mA= 7000W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	**2D mode:** Large Focus: 30kV*135mA= 4050W Small Focus: 30kV*50mA= 1500W **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	**2D mode:** Large Focus: 30kV*135mA= 4050W Loading time: 4.74” Small focus 30kV*50mA= 1500W Loading time: 4.40” **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode

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)	8mAs (using 20mm PMMA phantom)
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)	20-49 kV
X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>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.

FILTER PROPERTIES	
50 μm Silver (Ag)	0.54 mm Al eq. @ 28 kV, measured with W target
50 μm Rhodium (Rh)	0.51 mm Al eq @ 28 kV, measured with W target
500 μm Aluminium (Al)	0.4 mm Al eq @ 28 kV, measured with W target
700 μm Aluminium (Al) (optional)	0.51 mm Al eq @ 28 kV, measured with W target
300 μm Copper (optional, predisposition for future Dual Energy implementation)	3.85 mm Al eq @ 49 kV, measured with W target

STANDARD X-RAY TUBE	**I.A.E. XK1016 T**
Anode rotation speed	3000 rpm (optionally 10000 rpm)
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	FORCEDair 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	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	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)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA **Tomosynthesis mode:** Large focus: 49kV; 140mA
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)	**2D mode:** Large Focus: 35kV; 135mA Small Focus: 35Kv;65mA **Tomosynthesis mode:** Large Focus: 35kV; 200mA
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)	**2D mode:** Large Focus: 35kV*135mA= 4725W Small Focus: 42kV*55mA= 2310W **Tomosynthesis mode:** Large Focus: 35kV*200mA= 7000W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	**2D mode:** Large Focus: 30kV*135mA= 4050W Small Focus: 30kV*50mA= 1500W **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	**2D mode:** Large Focus: 30kV*135mA= 4050W Loading time: 4.74” Small focus 30kV*50mA= 1500W Loading time: 4.40” **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode

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)	8mAs (using 20mm PMMA phantom)
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)	20-49 kV
X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>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.

FILTER PROPERTIES	
50 μm Silver (Ag)	0.54 mm Al eq. @ 28 kV, measured with W target
50 μm Rhodium (Rh)	0.51 mm Al eq @ 28 kV, measured with W target
500 μm Aluminium (Al) Optional	0.4 mm Al eq @ 28 kV, measured with W target
700 μm Aluminium (Al) optional	0.51 mm Al eq @ 28 kV, measured with W target
300 μm Cupper (Cu) (optional, predisposition for future Dual Energy implementation)	3.85 mm Al eq @ 49 kV, measured with W target

OPTIONAL X-RAY TUBE (ONLY FOR 2D models)	**VAREX M113T**
Anode rotation speed	3000 rpm 50 Hz
Target material	Tungsten Focal track: W-Re-Mo
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 (376 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	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	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	1400 W (Small)/5900 W (Large) (3000 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)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA **Tomosynthesis mode:** Large focus: 49kV; 140mA
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)	**2D mode:** Large Focus: 35kV; 135mA Small Focus: 35Kv;65mA **Tomosynthesis mode:** Large Focus: 35kV; 200mA
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)	**2D mode:** Large Focus: 35kV*135mA= 4725W Small Focus: 42kV*55mA= 2310W **Tomosynthesis mode:** Large Focus: 35kV*200mA= 7000W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	**2D mode:** Large Focus: 30kV*135mA= 4050W Small Focus: 30kV*50mA= 1500W **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	**2D mode:** Large Focus: 30kV*135mA= 4050W Loading time: 4.74” Small focus 30kV*50mA= 1500W Loading time: 4.40” **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode

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)	8mAs (using 20mm PMMA phantom)
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)	20-49 kV
X-Ray Window	0,63 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>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.

FILTER PROPERTIES	
50 μm Silver (Ag)	0.54 mm Al eq. @ 28 kV, measured with W target
50 μm Rhodium (Rh)	0.51 mm Al eq @ 28 kV, measured with W target
500 μm Aluminium (Al) optional	0.4 mm Al eq @ 28 kV, measured with W target
700 μm Aluminium (Al) optional	0.51 mm Al eq @ 28 kV, measured with W target
300 μm Copper (Cu) (optional, predisposition for future Dual Energy implementation)	3,85 mm Al eq @ 49 kV, measured with W target

C-ARM	
F.F.D. (Focus Detector Distance)/S.I.D. (Source to image receptor Distance)	66 cm
Motorized Movements	Vertical and rotation (optional) ±15° Rotation (only with SBD DMD)
Tomosynthesis scan angles	±7.5° (15°) ±12° (24°) ±25° (50°)
Range of vertical movement (from floor)	From 54 to 145 cm (travel of 91 cm)
Speed of vertical movement	5 cm/s
Range of C-arm rotation	±180° (CW, CCW continuous to any position)
Projection preset positions	N° 7 Programmable projections
Rotation speed	20°/s (automatic rotation); 10°/s (manual rotation) with acceleration and deceleration ramp for smooth operation
Protection of examination field	Removable polycarbonate screen

CONTROL SWITCHES	
Number and type	Three multiswitches (five push-buttons) Two on both sides of C-Arm, one on tip of X-RAY tube cover
Control actions	Vertical movement of C-Arm Continous rotation of C-Arm Switch-on of collimation light

AUTOMATIC COLLIMATION DEVICE	
Type	Automatic recognition of compression paddle format and position
Light Source	LED (Risk Group 2 at 20 cm- according to IEC EN CEI 62471) (Risk Group 1 at 50 cm - Low Risk - according to IEC EN CEI 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*	Trapezoidal dynamic for TOMO tomosynthesis 24x30 cm 18x24 cm 14x30 cm 12x30 cm 11x30 cm 10x24 cm 11x14 cm 9x13 cm 8x11 cm

	7x7 cm 8x5 cm/7x5 cm (Biopsy)
Protection of examination field	Protective screen to keep patient's face out of X-ray beam during bidimensional exams Extended protective screen to keep patient's face out of X-ray beam during tomosynthesis exams
*depending on typical configuration used	

EMERGENCY STOPS	
Number and Type	Two red push-buttons on both sides of mammography unit One red push-button on Acquisition Work Station (if in option)
Function	To Switch totally off the power of mammograph except calculator and logic interfaces (Safety to close/save studies and switch off the unit)

DIGITAL FLAT PANEL DETECTOR **AXS2430, AXS2430V2, AXS2430FDI, AXS2430FDIV2 DETECTORS**	
Detector Technology	(a-Si) TFT Array + Pin photodiode Amorphous Silicon 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 difference of around 4-5 degrees with respect to the ambient temperature.
Digitalization type	Logarithmic
Pixel dimension	85x85 μm
Pixel dimension in tomosynthesis reconstruced slices	85x85 μm (with any scan angle)
Pixel dimension in synthetic 2D images	85x85 μm
Active Area	23.9x30.5 cm (24x30 cm format)
Image Matrix	2816x3584 (24x30 cm format)
Image Depth	16 bit
Fill factor	88 % geometric (for a-Se Detector) 80% geometric (for a-Si Detector)
MTF (Modulation Transfer Function)	**For a-Se Detector:** >90% @ 1 lp/mm >40% @ 5,8 lp/mm **For a-Se Detector v2:** >95% @ 1 lp/mm >50% @ 5,8 lp/mm **For a-Si Detector:** >75% @ 1 lp/mm (typical 85%) >10% @ 5 lp/mm for a-Si Detector (typical 20%) **For a-Si Detector v2:** >85% @ 1 lp/mm (Minimum>75%) >20% @ 5 lp/mm (Minimu>10%)
DQE (Detector Quantum Efficiency) (for exposure of 28kV)	**For a-Se Detector:** >50% @ 1 lp/mm >20% @ 5,8 lp/mm) **For a-Se Detector v2:** >70% @ 1 lp/mm >20% @ 5,8 lp/mm **For a-Si Detector:** >45% @ 1 lp/mm (typical 50%) >10% @ 5 lp/mm (typical 20%) **For a-Si Detector v2:** >50% @ 1 lp/mm (Minimum>45%) >20% @ 5 lp/mm (Minimu>10%)
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	EUREF 0,05

(Point n°2b.2.4.5 of "European Guidelines")	
Reconstruction time from last exposure (Model 020 BR3D CIRS phantom, 50 mm thick)	< 15 s (in 2D mode) **Tomosynthesis mode (all slices)**: 9 s (scan angle of 15°) 10 s (scan angle of 24°) 11 s (scan angle of 50°)
Time to display the image on the acquisition workstation from last exposure (Model 020 BR3D CIRS phantom, 50 mm thick)	< 15 s (in 2D mode) **Tomosynthesis mode (slab of 10 mm)**: 19 s (scan angle of 15°) 20 s (scan angle of 24°) 30 s (scan angle of 50°)
Tomosynthesis acquisition time	**Option a-Si Standard:** 5 s (with scan angles of 15°) 6 s (with scan angles of 24°) 11.5 s (with scan angles of 50°) **Option a-Se Standard:** 10 s (with scan angles of 15°) 12 s (with scan angles of 24°) 30 s (with scan angles of 50°) **Option a-Se Fast:** 2.5 s (with scan angles of 15°) 4 s (with scan angles of 24°) 7.7 s (with scan angles of 50°)

SOLO DM DETECTOR	
Detector Technology	Crystalline Silicon
Conversion Screen	CsI Direct Deposited on FOP / Hi-Res GadOx
Case dimensions	354 × 265.7 × 31.5 (mm)
Active area	228 x 291 (mm)
Top Cover /sensor protection material	Carbon Fiber (2.0 mm thick)
Chest wall distance	1,6mm
Housing material	Aluminum Alloy
Weight Limit (kg)	Applied to a single spot with diameter of 10 cm: 20 kg Distributed evenly over the detector area: 200 kg
Cooling Method	There are two cooling modes available: Active cooling (three stage, programmable) and Passive cooling (the fans are powered down). The cooling mode depends on the heat transfer conditions between the detector and environment and is determined by the user/integrator of the detector for the actual operating conditions of the detector. The evaluative criterion for increasing the fans power is temperature above 35 °C in the CMOS sensor area. This temperature can be checked using specific feature "TileTemperature".
Ingress protection	IP21
Pixel Size	49.5 × 49.5 μm

Pixel resolution limit (cyc/mm)	10.1
Usable Pixel Area (pixels)	4608 × 5888
Energy Range (kVp) Standard Option Rad-Hard Option	 20 – 40 20 – 160
Scan Method	Progressive, Rolling Shutter
A/D Conversion (bits) Standard Extended	Linear 14 16
Fill factor	79%
Dynamic Range (dB) Standard Extended	 72 82
Sensitivity (DN / µGy)	~105
MTF (Modulation ransferFunction)(%) 2 cyc/mm 4 cyc/mm 6 cyc/mm 8 cyc/mm	W/Rh Beam 70 43 25 15
DQE (Detector Quantum Efficiency) 1 cyc/mm 4 cyc/mm 6 cyc/mm 8 cyc/mm	W/Rh Beam 100 µGy 65 45 30 20
Resolution	5,9 lp/mm (Nyquist)
Signal to Noise Ratio (SNR) (with 45 mm PMMA Phantom)	10-14 (28,5 kV-10 mAs)
Ghost Image factor (Point n°2b.2.4.5 of "European Guidelines")	**<**0,2
Reconstruction time from last exposure	< 2 s (in 2D mode)
Time Between Two Consecutive Images Acquisition	< 5 s (in 2D mode)
Tomosynthesis acquisition time	**Option Standard:** 10 s (with scan angles of 15°) 12 s (with scan angles of 24°) 25 s (with scan angles of 50°) **Option Fast:** 5 s (with scan angles of 15°) 6 s (with scan angles of 24°) 12,5 s (with scan angles of 50°)

GRID	
Type	Linear, Vibrating
Interspace Material	Carbon Based Polymer (2D); Graphite (3D)
Ratio	6:1 (2D); 5:1 (3D)
Lines/cm	36(2D); 102 (3D)
Contrast factor	1,54 (2D); 1,30 (3D)

DEVICE FOR GEOMETRIC MAGNIFICATION (OPTIONAL)	
Type	Gridless, Interchangeable with Potter-Bucky
Magnification ratio	1,5X/1,8X/2X
Small focus selection	Automatic once fitted

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

"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 DICOM FOR PROCESSING (TOMO projection)

TOMOSYNTHESIS	
Number of X-Ray exposures (projections)	11 (with scan angle of 15°) 13 (with scan angle of 24°) 24 (with scan angle of 50°) Angular span remains constant during TOMO views
Reconstruction method	Back-projection technique (FBP) with incorporated iterative technique to improve image quality and remove artifacts
Distance between reconstructed slices	1 mm
Tomo acquisition control	Push-button with spiral cable Push-buttons on AWS (with AWS upgrade kit) Foot-control (optional)

RECONSTRUCTION SW OF SYNTHETIC VIEW FROM TOMO EXAM (OPTIONAL)	
Name	"M-VIEW/VI"

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*	1,4 mGy (a-Se detector) 1,5 mGy(a-Si detector)
AGD with a 4 cm PMMA phantom for TOMO (Measured 43 mm PMMA)	1,6 mGy (Narrow) 2,2 mGy (Intermediate) 2,3 mGy (Wide)
Dose limits	According to European Protocol for Dosimetry and EUREF protocol
*Only for 2D acquisition	

"SMART µPRESS" COMPRESSION SYSTEM	
Compression Paddle movement	Motor driven or manual with fine adjustment by double rotating controller
Standard compression Paddles	24x30 cm shifted for normal breasts 24x30 cm specific for TOMO breasts 18x24 cm with lateral shifting for small breasts
Compression Paddles	9x21 cm straight for magnification 18x24 cm with spot Φ7,5 cm for contact examination Φ7,5 cm spot for magnification examination 9x9 cm for magnification examination 18x24 cm with holes for bidimensional biopsy 10x24 cm for axillary examination 10x24 cm for prosthesis examination
Compression Paddle Holder	Fast mechanical unlock with rotating knob Right lock warning LED
Maximum free space available between Compression Paddle and top cover of Potter-Bucky/ top table of magnification device	182 mm with shifted Compression Paddles *In Magnification Mode* *(straight compression paddle)* 183 mm @ MAG. 1.5X 123 mm @ MAG. 1.8X 83 mm @ MAG. 2X
Compression Force (range)	Adjustable from 70 to 200 N
Minimum detectable value of compression force	30 N
Compression Force (visualization)	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 paddle release after exposure	Selectable from control panel
Compression paddle aluminum equivalence	< 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

TOUCH SCREEN COLOUR DISPLAYS (MAMMO TSD)	
Number and type	Two TFT LED backlight resistive touch screens on both sides of C-Arm
Screen Size (aspect ratio)	7" (4:3)
Display resolution	640x480
Informations	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 for motor driven compression unlock Two with two pedals and one push-button
Control Actions	Vertical movement of C-Arm Motor driven compression unlock

MULTIFUNCTIONS FOOT-CONTROLS	
Number and type	One or two with four pedals and one push-button for motor driven compression unlock
Control Actions	Vertical movement of C-Arm Vertical movement of compression Paddle Motor driven compression unlock

INTEGRATED ACQUISITION WORK STATION (AWS)

CALCULATOR (INTEGRATED IN MAMMO UNIT)	
Operating Systems	Windows 10 IoT Enterprise
CPU	Intel Core i5-6500 (Quad Core) 3.2 GHz
RAM	8 or 16 GB
HDD	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)
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 (diagonal)	24" (2MP), 21,3"(3MP), 21,3"(5MP)
Display Resolution (pixels)	1.920X1.200 (2MP), 2.048X1.536 (3MP), 2.800X2.100 (5MP)
Viewing Angle	178° horizontal and vertical
Response Time	7ms (2MP), 20ms (3MP), 12.5ms (5MP)
Brightness	600 cd/m² max-350 cd/m² DICOM calibrated (2MP) 900 cd/m² max-500 cd/m² DICOM calibrated (3MP) 1000 cd/m² max-500 cd/m² DICOM calibrated (5MP)
Contrast ratio	1000:1 typical (2MP), 1400:1 typical (3 and 5 MP)

ANTI-X PROTECTIVE BARRIER (OPTIONAL)	
Type	Half transparent screen (metallic lower part and transparent upper part)
Pb equivalence and thickness	> 0.34 mm @35 kV (IEC 60601-2-45) = 0.26 mm @49 kV (thickness 20 mm) >0.5mm up to 150kV (optional) (thickness 11mm)
Dimensions	773x2100x505 mm

SEPARATED ACQUISITION WORK STATION (AWS)

CALCULATOR (INTEGRATED IN MAMMO UNIT)	
Operating Systems	Windows 10 IoT Enterprise
CPU	Intel Core i5-6500 (Quad Core) 3.2 GHz
RAM	8 or 16 GB
HDD	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)
Power pack	250 W

CONSOLLE WITH TRANSPARENT ANTI-X PROTECTION BARRIER	
Pb equivalence	> 0.34 mm @35 kV (IEC 60601-2-45) = 0.26 mm @49 kV (thickness 20 mm) >0.5mm up to 150kV (optional) (thickness 11mm)
Pointing and selection device	Touchscreen on 15” or 17’’ color display
CD/DVD Recorder	24x
USB port	1 (3.1)
Dimensions	857x2003x640 mm
Weight	90 kg (0,34 mm Pb eq) 56 kg (0,50 mm Pb eq)

TOUCH SCREEN COLOUR DISPLAY (with optional AWS)	
Technology	Active matrix TFT LCD (resistive LCD screen for optional touch screen display)
Screen Size (aspect ratio)	15” or 17’’ (4:3)
Display Resolution (pixels)	1024x768
Viewing Angle	160° horizontal/150° vertical (160° horizontal/140° vertical for optional touch screen display)
Brightness	300 nits
Contrast ratio	800:1 (1000:1 for optional touch screen display)

2 MP (standard), 3 or 5 MP (optional) COLOR MONITOR	
Technology	TFT Color LCD
Screen Size (diagonal)	24’’ (2MP), 21,3’’(3MP), 21,3’’(5MP)
Display Resolution (pixels)	1.920X1.200 (2MP), 2.048X1.536 (3MP), 2.800X2.100 (5MP)
Viewing Angle	178° horizontal and vertical
Response Time	7ms (2MP), 20ms (3MP), 12.5ms (5MP)
Brightness	600 cd/m² max-350 cd/m² DICOM calibrated (2MP) 900 cd/m² max-500 cd/m² DICOM calibrated (3MP) 1000 cd/m² max-500 cd/m² DICOM calibrated (5MP)
Contrast ratio	1000:1 typical (2MP), 1400:1 typical (3 and 5 MP)

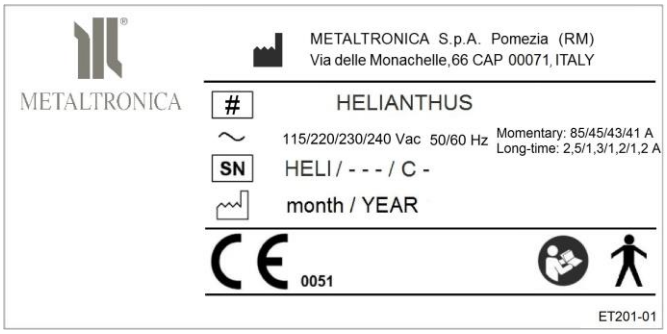
NOTE

ALL SPECIFICATIONS COULD BE SUBJECT TO CHANGE

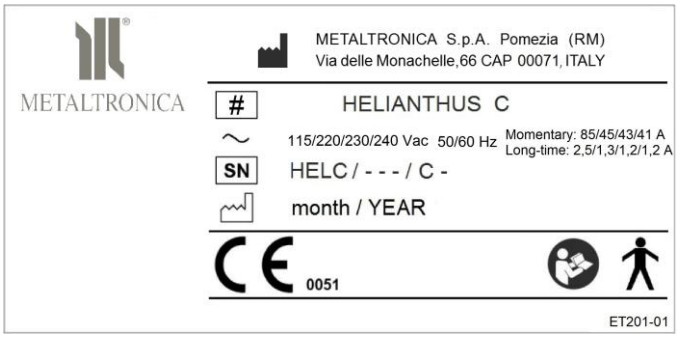
DEVICE CLASSIFICATION AND IDENTIFICATION LABEL

The identification label is placed on the back of the device and a true copy of it is also placed inside the gantry

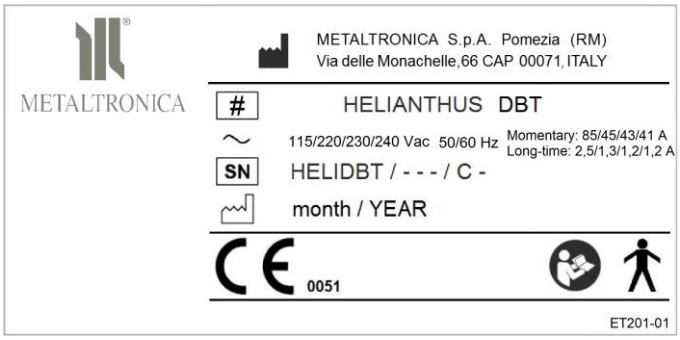
HELIANTHUS 115/220/230/240 Vac MAINS *(50/60 Hz)*



HELIANTHUS C 115/220/230/240 Vac MAINS *(50/60 Hz)*



HELIANTHUS DBT 115/220/230/240 Vac MAINS *(50/60 Hz)*

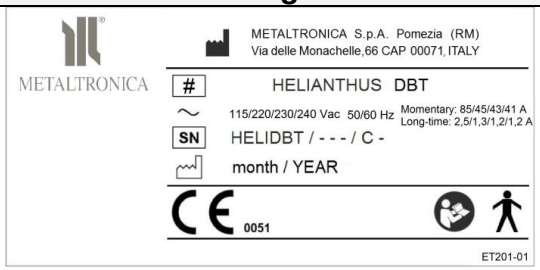
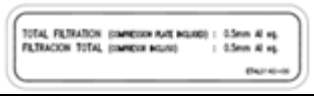
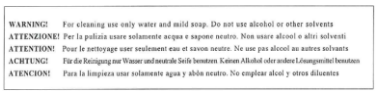


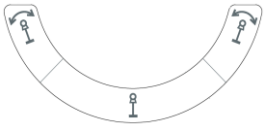
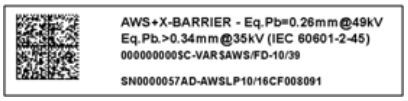
HELIANTHUS series belongs to Class I type B applied parts.

HELIANTHUS series belongs to Class IIb.

NOTE

The images depicting the mammographic unit or part of it are illustrative or schematic. The images where assembly instructions are given are faithful to the actual configuration of the mammography unit.

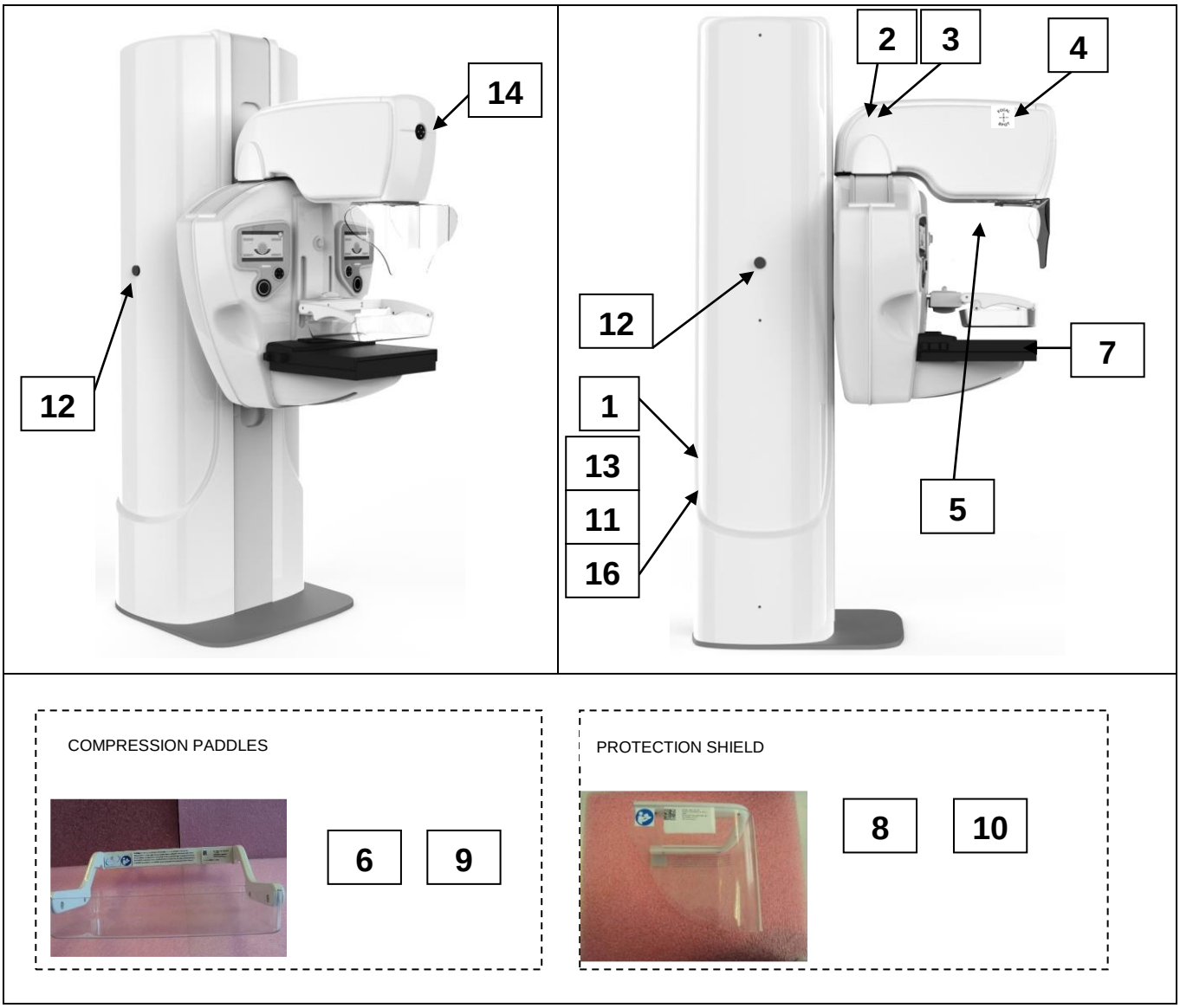
External Labels or symbols		Placement	Ref
Meaning	**Image**	**Description**	**#**
ID label		**Back panel of Mammo unit**	**1**
UDI label			
Medical Device label			
X-ray Tube identification	 **Optional tubes:** 	**Back Xray tube Cover on C-arm**	**2**
X-ray Tube Characteristics		**Back Xray tube Cover on C-arm**	**3**
X-ray Tube identification		On the Xray lateral cover of C-arm jn correspondence of real focal spot	4
Led indication		On the lower panel of C-arm near the collimation window	5
Component indications: • Refer to manuals • Applied Parts • Logo Brand • Part Number • SN Mammo Unit	   	On the Internal Metallic Frame of compression paddles	6
		On the Edge of Tables/Magn Device/Detector and on the lower panels	7
		On the Upper Part of protection screen	8
Cleaning Indications		On the Internal Metallic Frame of compression paddle	9
		On the Upper part of protection shield	10
Safety protection		On the Back Panel of Mammo Units and on the Cover near the opening screws	11
Emergency unlock		Below the Emergency controls (on lateral covers and remote AWS if available)	12

External Labels or symbols		Placement	Ref
Meaning	**Image**	**Description**	**#**
WEEE waste bin		On the back panel of Mammo Gantry	13
C-arm movements		On up/down rotation controller	14
X-ray Protection		On Metallic frame of AntiX Barrier or Back Panel of remote AWS if provided	15
eIFU		On the back panel of Mammo Gantry	16

NOTE

The X-ray tube labels shown in the figure above are representative. The data shown on them depend on the model installed on the mammography unit.

MAMMO UNIT IDENTIFICATION LABELS



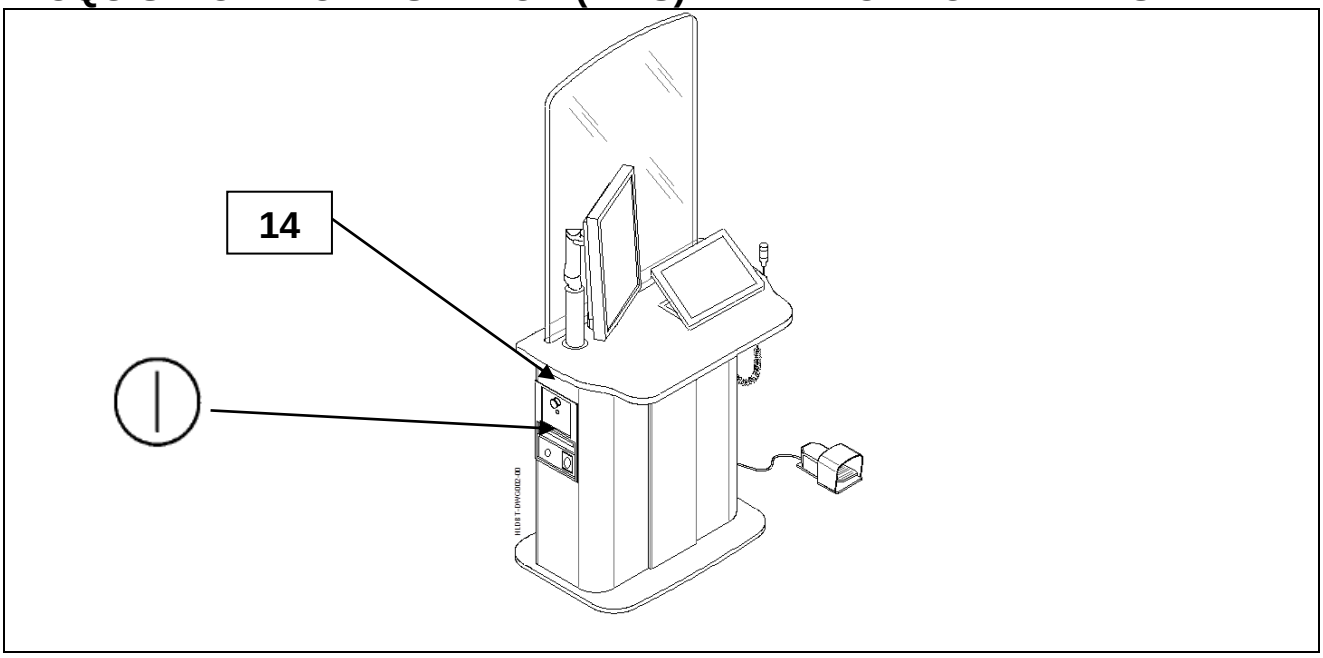
NOTE

This medical device is intended for professional use.
For this reason English easy to be understood by user is applied for some external labels.

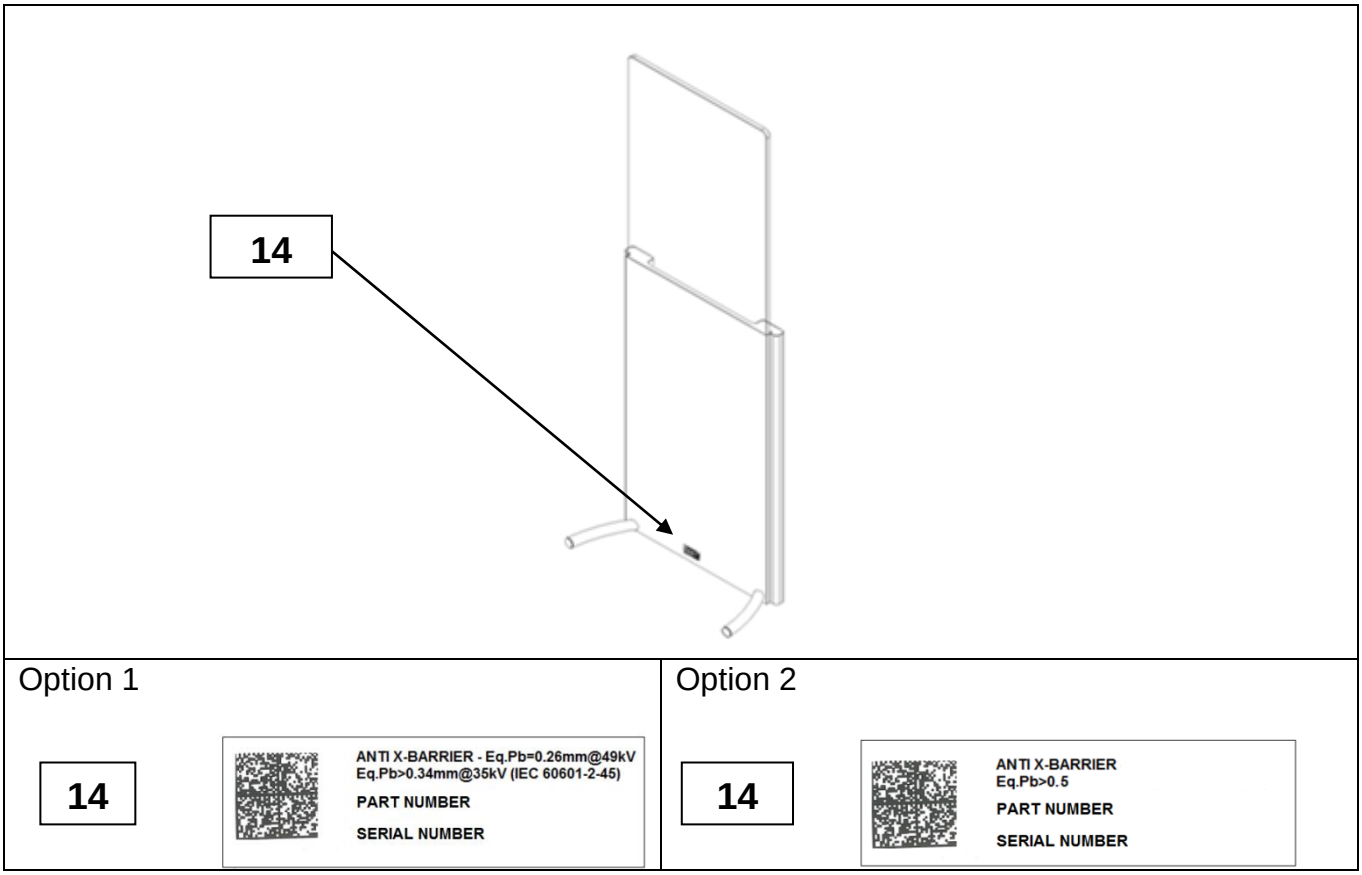
NOTE

Identification labels are important for a safe use of the equipment.

ACQUISITION WORK STATION (AWS) IDENTIFICATION LABELS



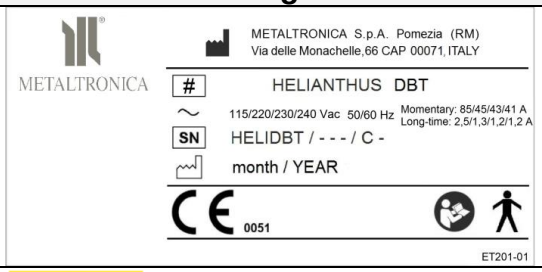
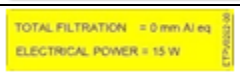
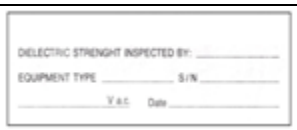
ANTI-X BARRIER IDENTIFICATION LABELS

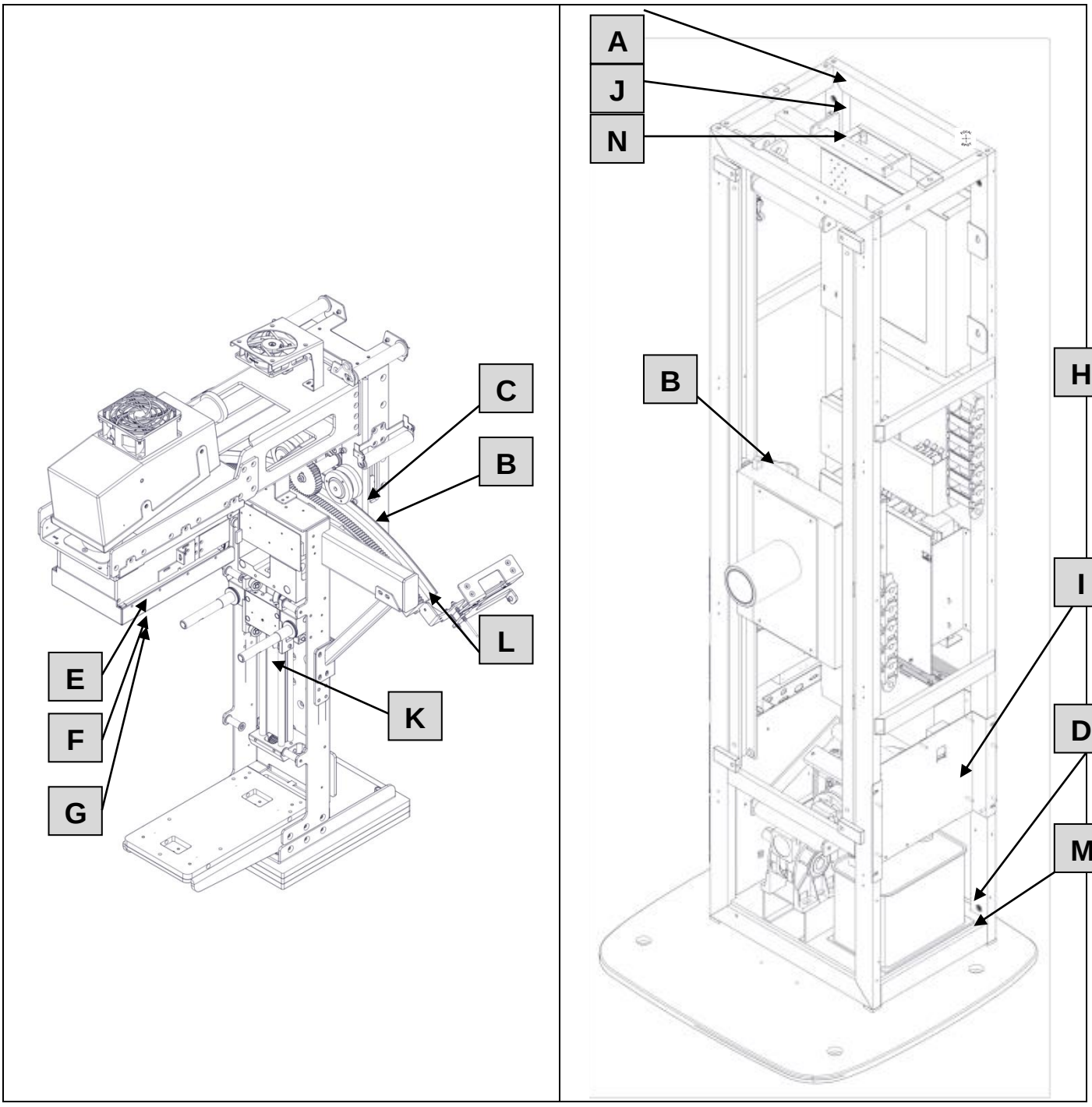


Option 1

Option 2

Anti-x barrier can be optionally provided with local AWS configuration.

Internal Labels		Placement	Ref
Meaning	**Image**	**Description**	**#**
ID label		**On the metallic frame of Mammo unit**	**A**
Mechanical Safety Labels		**On Tilting System** **On up/down trolley**	**B**
		**On Tilting System**	**C**
Electrical Safety Labels		On HV generator	**D**
Led indication		**On collimator Unit**	**E**
Total Filtration		**On collimator Unit**	**F**
Filtration		**On collimator Unit**	**G**
Part Number		**High Speed Starter**	**H**
		Inverter	**I**
		Metallic Frame/Gantry	**J**
		Compression system	**K**
		C-arm Rotation System	**L**
		HV Generator	**M**
Dielectric Strenght measurements		**On the metallic frame of Mammo unit**	**N**



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NOTE

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