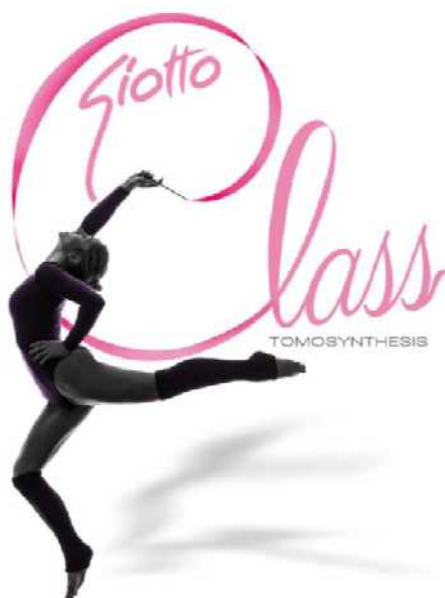


SERVICE AND INSTALLATION MANUAL





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This manual is considered an integral part of the equipment. It must be immediately replaced with another copy if any part of it is ruined or illegible.

Before performing any type of operation on the equipment, **IMS S.r.l.** requires that anyone of any title involved in using the equipment carefully read the entire contents of this manual, paying special attention to the important warnings.

IMS S.r.l. may not be held responsible for the improper use of the equipment, and for damages caused by unreasonable operations.

The equipment must only be used to meet the needs for which it was expressly designed. Any other improper use is considered dangerous.

IMS S.r.l. is considered responsible for the equipment only if it is in its original configuration determined in the design phase. Any modifications to the structure and the equipment's operating cycle must be expressly authorized by the **IMS S.r.l.** Technical Department.

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IMS S.r.l. is considered responsible for the descriptions written in Italian. The translations cannot be fully verified, therefore if the buyer finds a discrepancy in the text, this person should refer to the Italian version and possibly contact our Technical Documentation Office, which will make any necessary changes.

IMS S.r.l. would like to thank you for choosing one of our machines and we are sure that it will fully satisfy your needs for a long period of time.

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Internazionale Medico Scientifica
Via Sagittario 5 - 40037 Pontecchio Marconi - Bologna - Italy
Tel ++39 051 846851 - Fax ++39 051 846856
e-mail: Export Dept.: imscomm@imsitaly.com
Technical Dept.: imstech@imsitaly.com
<http://www.imsitaly.com>



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Intended use

The **Giotto Class** and its accessories are designed and built mammography examination for the screening in modality of Full-Field Digital mammography (FFDM) and for diagnosis in modality of Digital-Breast Tomosynthesis (DBT) for breast cancer detection and cannot be used for other examinations or for purposes other than those specified by the Manufacturer. Its practical use is therefore exclusively limited to personnel with medical training.

Using the accessory devices Smart Finder and Flexi table the system is able to perform stereotactic biopsy examination with the optional possibility to perform the examination with patient in prone position.

CE: 1936

CLASSIFICATION AND COMPLIANCE

IEC 60601-1	Class	I
	Type	B
Medical Device Directive 93/42/CE	Class	II B

DOCUMENT N°:	M189_EN
REVISION:	0.1
DATA:	01/07/15

REVISIONS OF THE MANUAL

N° REV.	DATE	Purpose of the revisions	Modified PAGES	Modified SECTION
01	01/07/15	Initial release		

Please comply with that reported in Section 1 - "Safety".

Carefully read Section 1 - "Safety" before operating the equipment.

MANUFACTURER'S WARNINGS

This product has the CE marking in conformance with the provisions outlined in Annex II of 93/42/EEC of 14 June 1993 concerning medical devices.

The CE marking is only valid for technical medical products/medical devices put on the market during the validity of the EC directive indicated above.

If modifications are made to the product without our authorization, the declaration will no longer be valid.

The original version of this manual was drafted in Italian.



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DO YOU HAVE ANYTHING TO REPORT WITH REGARD TO THIS MANUAL?

Your opinion means a great deal to us!

We strive to constantly improve the documentation of our equipment. To help do this, we give you the opportunity to directly inform us of any need, suggestion or comment relating to this instruction manual.

Use the following number to send notices via FAX:

• **+39 051 846851.**

If you prefer to communicate via e-mail, please use this address:

• imstech@imsitaly.com

In this case, please indicate **the complete print reference code reported on the third page.**
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1. Safety

1.1. Conventions

In order for the manual to be read quickly and rationally, symbols have been employed for highlighting practical advice, simple information or situations in which great care must be taken. Said symbols can be found alongside a section of text (and therefore refer only to that text), alongside a figure (and refer to the subject illustrated in the figure and to the relative text) or at the top of the page (in which case they refer to all the subjects treated on that page).

Pay maximum attention to the meaning of the symbols: their aim is not to have to repeat technical concepts or safety warnings and therefore should be considered as proper “reminders”.

Thus, refer to the list of symbols whenever doubts arise as to their meaning. The symbols shown in the following pages are not found on the device or its accessory parts; they are only present in this manual. The series of the manuals supplied with the device usually contains some documents not made up by **I.M.S. S.r.l.**, which could use edition symbols that are graphically different from the ones shown in this publication. Therefore, it is advisable to consult all the documents supplied in order to “store” all the subjects for which the symbols themselves have been used.

It is **important** not to confuse the edition symbols on the device with the “safety” plates, which are applied in predetermined points on the device, auxiliary units, etc...

1.1.1. Structure of the manual

Sections	This manual is made up of various sections, the titles of which are reported in the heading.
Paragraphs	Every section can have one or more paragraphs, the title of which is reported in the text below the heading.
Page numbers	The page footer shows the progressive page numbers.



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1.1.2. Text formatting

This manual contains certain text formats that are helpful in understanding the function of the text more quickly.

The following characters were used:

Instruction	◆	Fornisce istruzioni sul corretto utilizzo dell'apparecchiatura. Questo testo è preceduto da un rombo.
LIST OF EXPLANATORY TEXT	• —	This text is preceded by a dot. Divides an instruction or a list into various sub-parts. This text is preceded by a dash.
REFERENCE	→	Refers to more detailed instructions reported in another page of the manual or another document. This text is marked by an arrow.
NOTE		This is used in two ways: <ul style="list-style-type: none">➤ highlights important safety information, without which there is an immediate risk➤ contains a summary of the main information regarding a subject matter This text is highlighted inside a grey box.
Menu		The names of the menus are in bold type.

1.1.3. Warning, cautions and information

- The icons in a box give information .
- The symbols in a triangle are DANGER/WARNING symbols.
- The symbols in a circle represent an OBLIGATION/PROHIBITION..



1.1.3.1. Warning

Warnings indicate the possible presence of risks for the health and safety of patients, operators and third parties.

	WARNING Firstly, the source of the danger is indicated. The possible consequences are then reported. Finally, you are informed on how to avoid the danger.
	LIFT ONLY FROM THE TOP Operations that require the use of qualified personnel and specific equipment, and the respect of the conditions stated by the Manufacturer and current regulations.



1.1.1.1. Caution

This indication reports that an incorrect command could cause minor injuries or damage to the equipment.






	CAUTION Firstly, the source of the danger is indicated. The possible consequences are then reported. Finally, you are informed on how to eliminate the danger.
	NO! Operations to be absolutely avoided.

1.1.1.1. Information

This indication provides further explanations about an issue.

	INFORMATION Il relativo testo è scritto in corsivo dentro il box grigio
	EQUIPMENT TURNED OFF With electrical power supplies isolated

1.1.1.1. Safety symbols

OBLIGATION symbols	
	Use PROTECTIVE GLOVES This symbol indicates that the maintenance engineer must wear protection gloves to avoid injuries.
	Use PROTECTIVE GLASSES This symbol indicates that the maintenance engineer must wear protective glasses to avoid injuries
PROHIBITION symbols	
	No MAINTENANCE/REPAIRS ON MOVING MEMBERS It is forbidden to repair, adjust, clean or lubricate moving members of the machine
HAZARD/CAUTION symbols	
	CAUTION: ELECTRIC SHOCK HAZARD It indicates the presence of electric devices and powered components and warns the operator against electric shock hazards. The electric maintenance engineer is the only operator that is qualified to carry out adjustments or maintenance of the electric cabinets and junction boxes
	CAUTION! It indicates the presence of ionizing radiation.





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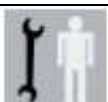


1.1.1.1. Manuals symbols

SYMBOLS FOR THE MANUALS	
	THIS OPERATOR MANUAL Descriptions inherent to this manual.
	SUBCONTRACTING MANUALS Consult the attached documents relating to subcontracting.

1.1.1.1. Qualification of the personnel in charge with operation of the equipment

The operators that have access to the equipment must be specifically qualified, trained and responsible for the tasks they are in charge with.

A description of the professional qualifications of the operators and maintenance personnel is given below. Each profile is graphically described by an icon.

OPERATORS	
	Radiological technician: the person in charge of preparing the equipment, positioning the patient and performing the mammography examination, according to the indications given by the doctor.
	Doctor: the person who visits the patient in advance in order to decide the examination method. This person observes the plates taken by the radiological technician. He/she carries out the invasive operations (biopsy) on the patient.
	Mechanical maintenance personnel: qualified technician able to intervene on the mechanical parts of the equipment to perform any necessary maintenance interventions and repairs. This person is not qualified to work on live-electrical circuits.
	Electrician: qualified technician able to carry out any necessary interventions of an electrical or electronic nature. This person is qualified to work on live-electrical circuits.
	Manufacturer's technician: qualified personnel provided by the Manufacturer to perform complex operations under particular situations or when agreed upon with the Buyer



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The names and data of all the patients and devices used in this manual as examples are fictitious. Any similarity or correspondence to the actual names of people or institutions are purely coincidental.

All the parameters and images reported in this manual are examples. The parameters seen in your system are determining factors.



INFORMATION

In some figures the equipment may be highly equipped or outfitted with optional accessories.

1.1.1. Regulations and laws

If there are regulations with legal implications for the installation and/or use of the device, the installer and user must respect them. The national standards must be respected in every country. With the exception of that given in this manual, the values can be set based on the national standards.

This product has the CE marking in conformance with the provisions contained in directive 93/42/EEC of 14 June 1993 concerning medical devices,

Personal data are protected.

Please respect the regulations pertaining to this matter. During the manufacturing phase, the equipment is checked according to applicable product standards.



INFORMATION

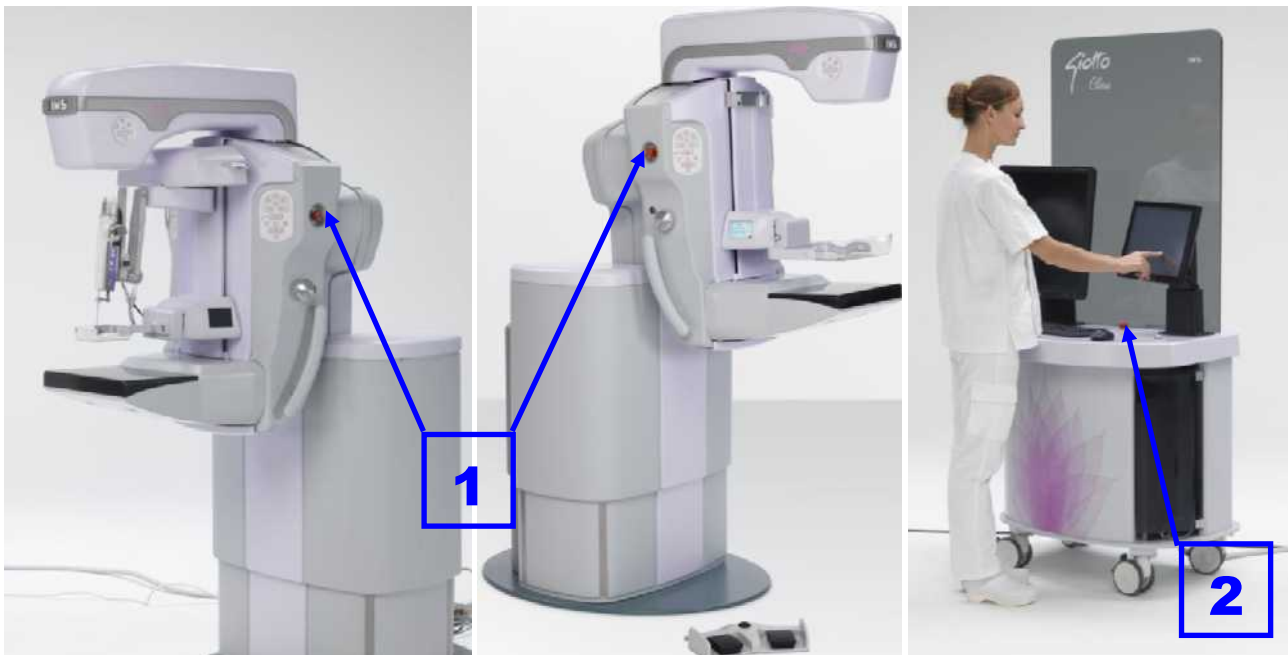
A test report shall be filed in **I.M.S. S.r.l.** archive.

The tests to be performed at the equipment installation site are the responsibility of the customer.

1.2. Safety systems

1.2.1. Emergency stop buttons



Three emergency stop buttons are installed on the equipment described in this manual. If pressed, they immediately stop all equipment functions.



- 1) EMERGENCY STOP button located on both sides of the vertical X-ray unit (GANTRY) near two columns push-button panels.
- 2) EMERGENCY STOP button located on control table of the acquisition workstation (AWS).

Never use the emergency stop button as a **normal stop** device to immediately stop all functions of the equipment, but only in cases of an **actual emergency** and if malfunctions occur.

After the EMERGENCY STOP button has been activated, keep in mind the following:

	<p>INFORMATION</p> <p>After pressing one of these three emergency stop buttons, the following message appears on the touchscreen panel</p> <div data-bbox="619 1832 1104 1915" data-label="Image">  </div> <p>and an acoustic signal is simultaneously emitted.</p>
---	--



INFORMATION

The emergency stop button does not cut power to the workstation **1**. The workstation is also protected by an uninterruptible power supply UPS **2**. The UPS takes power from the equipment's circuit; thus turning on "0" position the main switch, the UPS switches to the batteries and the operator is informed of this operation by an acoustic signal.

In the case of a power interruption, only the AWS acquisition workstation is powered by the UPS for a few minutes (depending on the state of the battery). When the battery of the uninterruptible power supply reaches 20%, the workstation automatically turns off, following the operating system's safety sequence.



1.3. Resuming operation after an emergency stop



INFORMATION

After pressing one of these three emergency stop buttons, the following message appears on the touchscreen panel

ALARM 134: EMERGENCY ON

and an acoustic signal is simultaneously emitted.

- Release the pressed emergency stop button by turning it (slightly). The acoustic signal will be silenced and the alarm message on the touch screen panel will disappear (· see [Section 12 - "Breakdowns and diagnosis"](#)).
- **To resume operations**, press the engage circuits push-button **1** sited on the acquisition workstation control table switching it to the **"OFF"** position (LED off). What a few seconds and then press the engage circuits pushbutton **1** again, switching it to the **"ON"** position (LED on).
- If the cause of the stop has been eliminated, the device will then be operational again.



1.3.1. Control and signals

The acquisition workstation has a main switch **1**, an engage circuits push button **2** and a touch screen panel **3** that is used to control and monitor the appliance. The touch screen panel displays set parameters and alarm messages.





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1.4. General Safety precautions

- The device may be dangerous to the patient and operator if the X-ray exposure values and operating instructions are not respected. Observe all operating and safety instructions before performing an X-ray exam.
- **Check the following before installation:** observance of minimal safety regulations, location and operating efficiency of the equipment, measuring ambient conditions (temperature, humidity and lighting) and checking the suitability of the work space.
- **Always work** with suitable clothing and the required personal protective equipment.
- **While X-rays are being emitted**, the operator must remain shielded behind the X-ray lead glass panel supplied with the vertical X-ray unit (GANTRY).

1.5. Protection and safety regulation

- The person who is about to activate the radiological device must check that nobody else is in the room, that the doors are closed and that all those present are protected by walls or by shielded doors.
- During X-ray emissions, always stay behind the X-ray lead glass panel.
- Whenever necessary, always wear the personal dose-meter.
- Reduce the size of the beam and the value of the radiological parameters to a minimum (voltage, current and radiography time) in so far as they are compatible with the diagnostic needs.

1.6. Warnings and precautions

- The following is **strictly forbidden**: tampering with the equipment, controls and safety devices.
- **Any modifications** or tampering, however slight. The use of non-original spare parts, or spare parts that are not compatible with the quality standards and electro-mechanical characteristics specified by the Manufacturer, shall relieve the Manufacturer of all liability and shall void the warranty rights.
- **It is strictly forbidden** to place and/or leave objects or anything else not foreseen by the Manufacturer on the equipment that is potentially harmful to the safety of persons or the integrity of the equipment.
- **Carefully read** the steps in this manual that are marked: "INFORMATION" and "CAUTION".
- If you have any requests, always indicate the model and serial number of the equipment.
- **Access** to the workstation is password protected.
- It is **forbidden** to modify the configuration of the workstation.



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- **It is forbidden** to install software different from the original software that was installed by **I.M.S. S.r.l.** service personnel.
- **The workstation** can be connected to a LAN/WAN network, but the user is responsible for protecting against viruses, intrusions or data leaks.
- **The AWS acquisition workstation TFT monitor** can only be used for QA before diagnosis. No clinical evaluation is allowed.
- **Diagnosis** can be done both through analysis of laser printed images and the images on the workstation of reporting workstation (RWS) (optional). The monitor type and performance must comply with the **I.M.S. S.r.l.** specifications.
- **The “DICOM CD” function** of the “Raffaello” application software is not built for the permanent filing of data.

This function is only used for data transfer.

- **The “Raffaello” application software** installed on the AWS acquisition workstation is able to store a certain number of examinations (the number depends on the capacity of the hard disks). This archive is not a legal archive, so any lost data is not the responsibility of **I.M.S. S.r.l.**



CAUTION!

It is strictly forbidden to operate the equipment if it is not permanently fixed to the floor. Refer to the relative Section.

1.6.1. Mechanical safety

The assembly procedure of some part of the device can be critical for the functionality of the device itself and to assure the safety performance of fine movement.

Following the list of screws and bolt must be used for each critical mechanical group.

Mechanical group	List of screws	Reference draw



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1.7. General safety warning

The device was designed and built in compliance with the most severe safety Regulations and left our production plant in perfect working order. In order to ensure that these conditions are maintained and that the device is used correctly, the technician must follow the instructions contained in this manual.



CAUTION!

X-ray machines can be extremely dangerous to the patient and the operator if the specified protective measures are not scrupulously observed

RESIDUAL RISKS

- Although the equipment described in this manual was built in full compliance with the most severe safety Regulations, the emission of X-rays is a potential hazard and the equipment therefore cannot be used or handled by unappointed, unqualified, or unauthorized personnel.
- **Over-exposure** to X-rays can cause serious damage to the human body.
- Although X-ray radiation is in itself dangerous, the GIOTTO TOMO equipment does not cause any dangerous conditions if used correctly.
- It is therefore essential that all technical and healthcare personnel be suitably informed and instructed with regard to the hazards of X-ray exposure.

1.8. Radiation protection warnings

- **Exposure to X-rays is a health hazard**, and therefore great care should be taken in using adequate means of protection. Radiation can accumulate over time and its effects can be manifested after many years.
- **Primary radiation is the most dangerous kind**, therefore, avoid exposure; any object struck by primary radiation produces secondary radiation, which is also highly dangerous.
- The unit is equipped with an protective X-ray temperate glass screen coupled to the console, which protects people against diffused radiation.

1.9. Electrical safety device

- The device must have an electrical supply line equipped with an earth circuit complying to current Standards.
For any type of simple maintenance, such as cleaning the equipment, always disconnect it from the mains to avoid damage to persons and/or the electrical - electronic part of the mammography equipment.
- To ensure the isolation integrity for the system, use only **I.M.S. S.r.l.** approved accessories on the equipment. Any changes to the interconnections must be performed by **I.M.S. S.r.l.** authorized personnel.
- **To ensure proper isolation maintain a 1.5 meter distance between the patient and any devices not approved for use in the Patient Area.** Devices not approved for use in the patient area (such as the data management computer, the medical recording workstation, laser printers) must not be installed in this area (see IEC 60601-1-1).



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CAUTION!

In accordance with EN 60601-1, the unit must be permanently connected to the electrical mains.
(The protective earth conductor must be connected directly to the protective earth terminal of the electrical panel).

1.10. Explosion hazard

- Gas or flammable vapors cannot be used with this equipment.
- Some types of disinfectants could vaporize, thus forming an explosive mixture. If used, they must be allowed to disperse before powering up the equipment.

1.11. Risk associated with cleaning the device

- Gas or flammable vapors cannot be used with this equipment.
- Some types of disinfectants could vaporize, thus forming an explosive mixture. If used, they must be allowed to disperse before powering up the equipment.

1.12. X-ray emission safety

The device uses two separate methods to assure that the generator doesn't exceed the maximum exposure limit.

- a) A software counter that includes the anode current over time and stops the exposure when the maximum time has been reached; the counter is protected by a watch dog circuit.
- b) A hardware counter that cuts off the electrical power supply to the generator if the maximum allowed exposure time is exceeded.

1.13. Regulations, laws and normative reference

If there are regulations with legal implications for the installation and/or use of the device, the installer and user must respect them. The national standards must be respected in every country. With the exception of that given in this manual, the values can be set based on the national standards.

This product has the CE marking in conformance with the provisions contained in directive 93/42/EEC of 14 June 1993 concerning medical devices,
Personal data are protected.

Please respect the regulations pertaining to this matter. During the manufacturing phase, the equipment is checked according to applicable product standards.



INFORMATION

A test report shall be filed in **I.M.S. S.r.l.** archive.

The tests to be performed at the equipment installation site are the responsibility of the customer.







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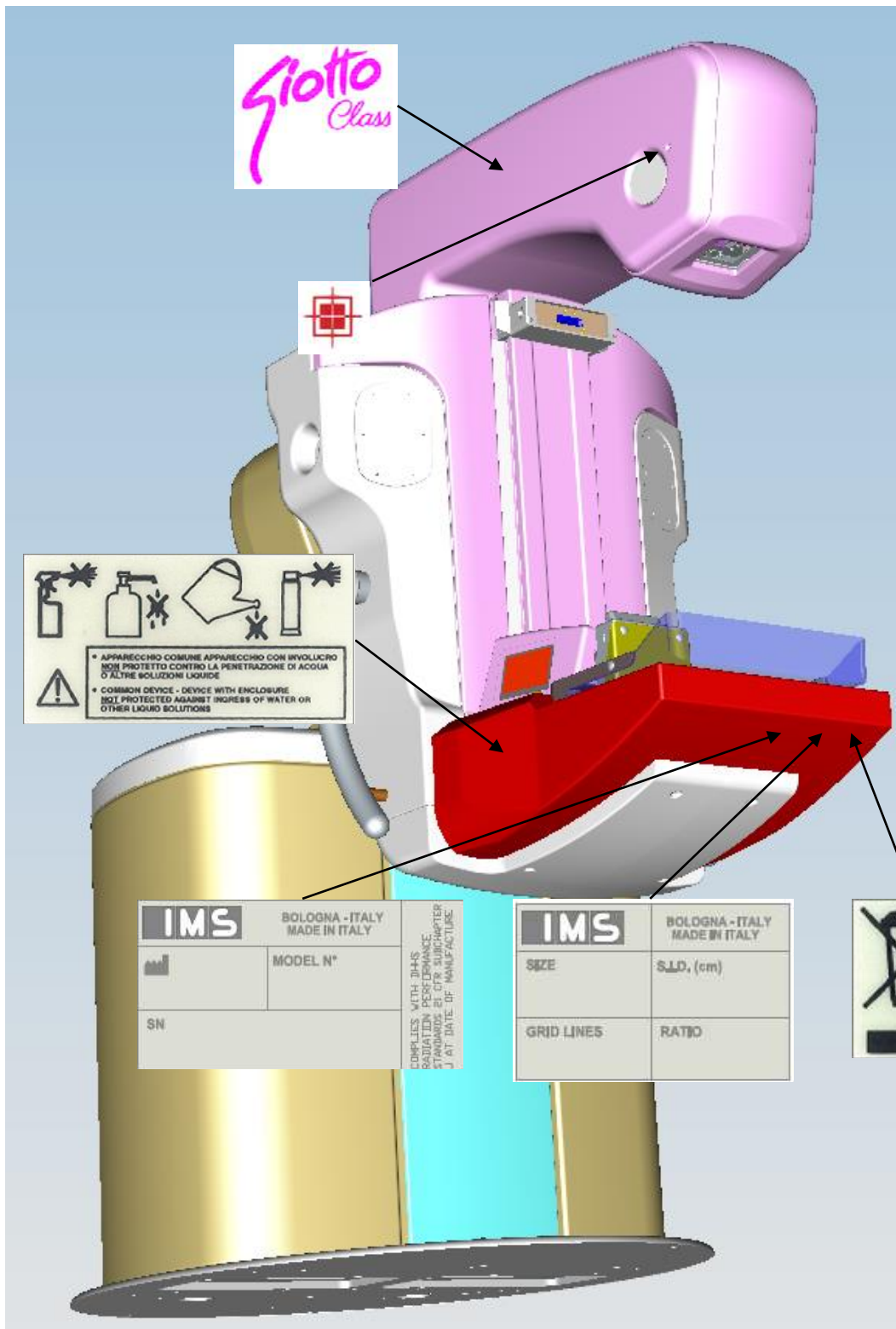


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2. General Information

2.1. Labels

	<p>Keep the hands away</p>
	<div>   </div>
	<p>Radiation High Tension</p>
<p>Main Identification label</p>	
<p>Moving part</p>	<p>IPX0 Protection class label</p>
<div>   </div>	
<p>Earth point Focal Spot</p>	<p>Electrostatic discharge</p>
<p>WEEE Label</p>	<p>Component Identification</p>



2.1.3. Labels on the internal component

Label ID	Label	Component	Description
1		IMS accessory	Identification data
2		High-Voltage Generator	Identification data
3		X-ray tube:	Identification data
4			Focal spot position

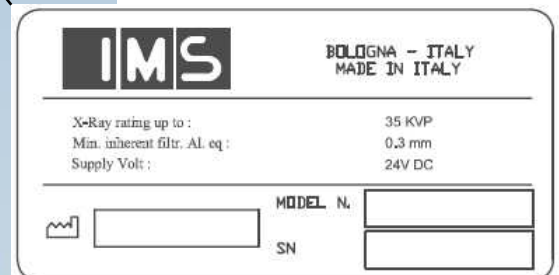
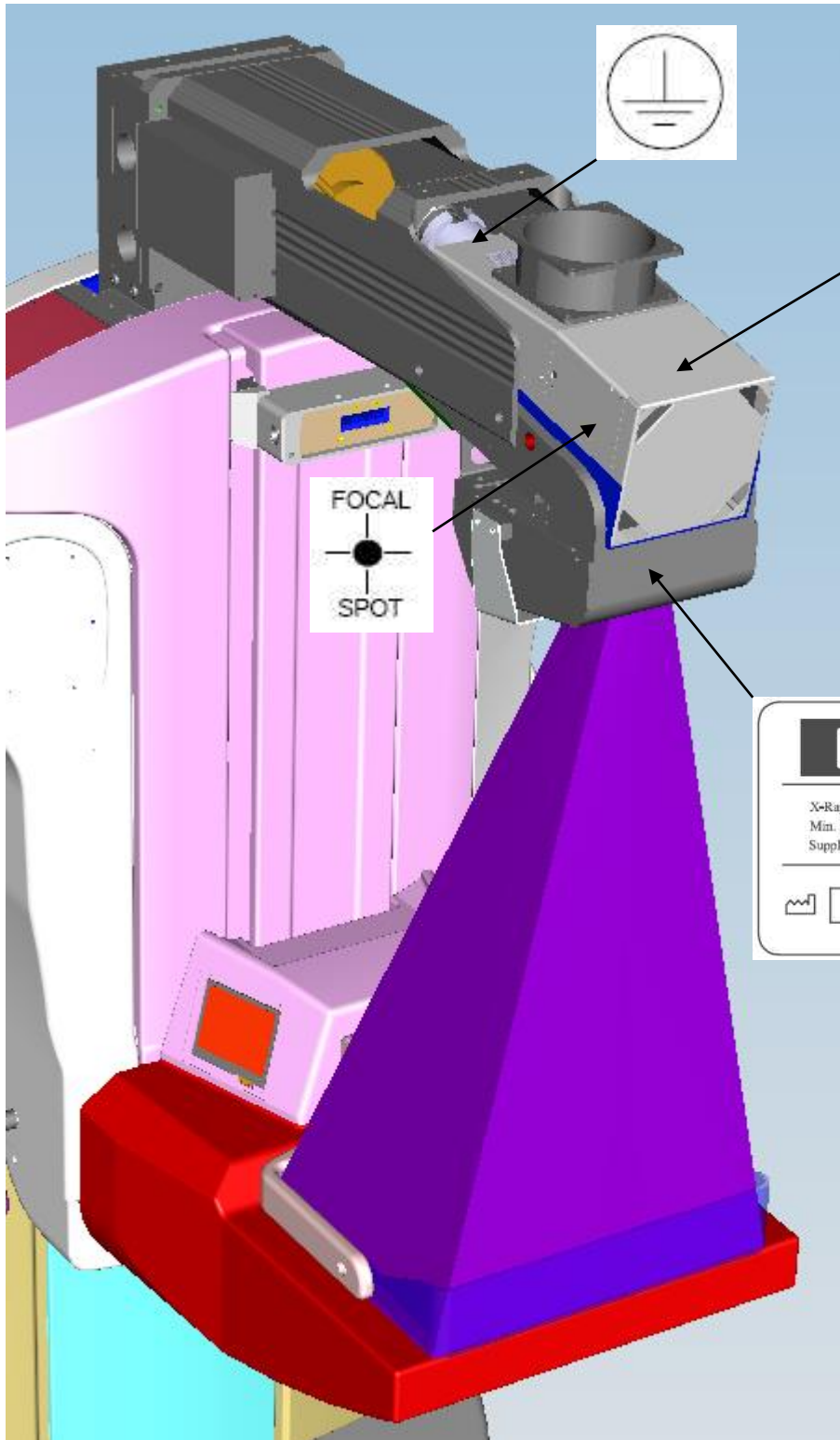


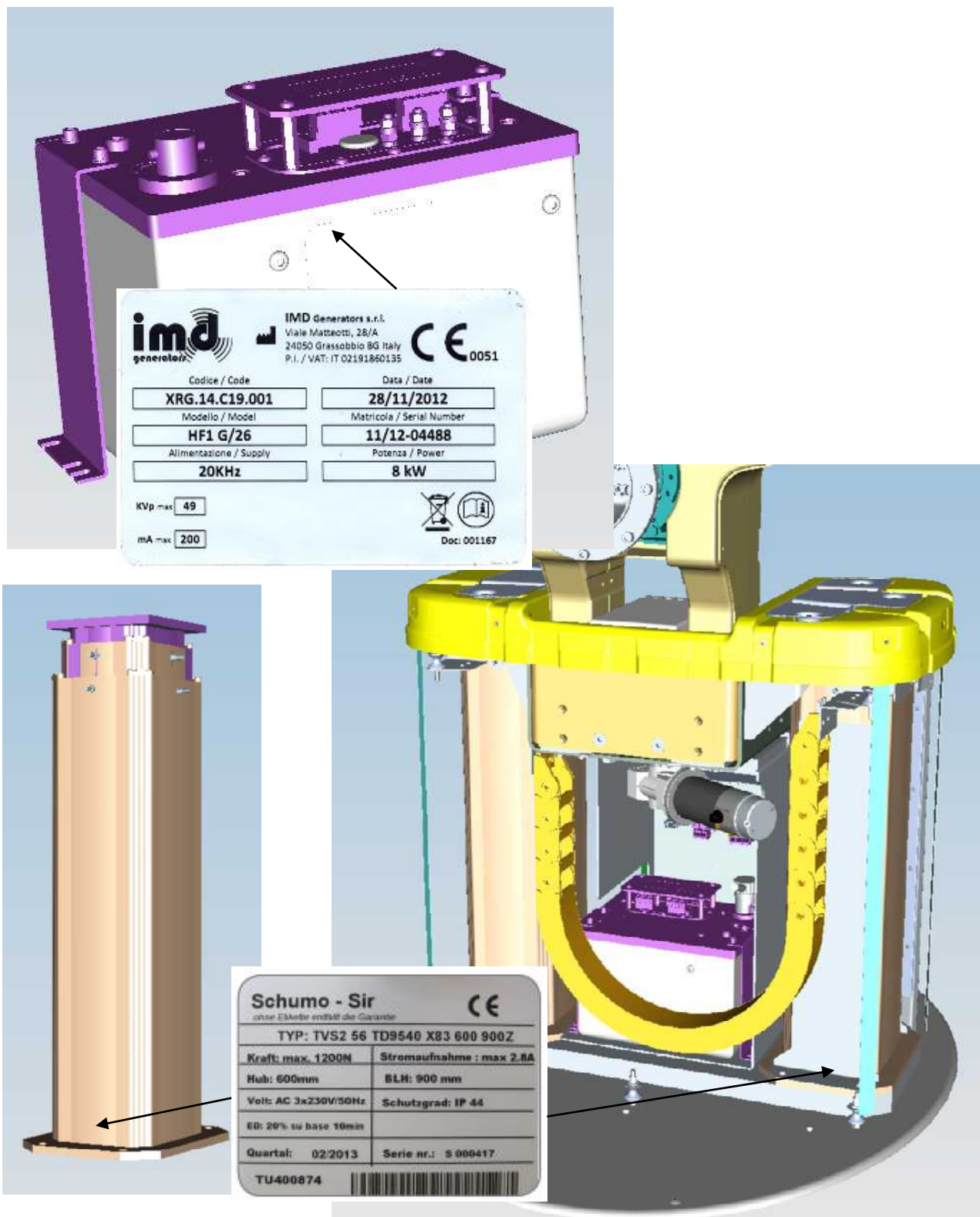
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Label ID	Label	Component	Description
4			Earth point
5		Vertical movement motor	Identification data
6		Anti-scatter grid	Identification and specifications data
7	INSERIRE IMMAGINE CON IDENTIFICAZIONE E HVL	Collimator	Identification and specifications data
8		Monitor	Identification data





2.2. Technical data

The equipment can only be used in rooms designed for medical use.

The current national standards apply. In order to ensure the safety of users, patients and third parties, it is recommended that you fully comply with the standards mentioned in this document (unless they are inconsistent with the national standards).

THIS IS A DRAFT VERSION; ALL THE DATA WITH THE * MARK ARE UNDER REVISION.

2.2.1.1. X-ray unit and operator console storage conditions

	Min	Max
Humidity	10%	80%
Temperature	-10 °C = 14 °F	80 °C = 176 °F
Atmospheric pressure	700 hPa	1060 hPa



WARNING

If the equipment is stored while packed, do not stack the packing crates on top of one another.

2.2.1.1. Digital image receptor storage conditions

	Min	Max
Humidity	10%	95%
Temperature	5 °C = 41 °F	45 °C = 113 °F
Atmospheric pressure	700 hPa	1060 hPa



WARNING

If the equipment is stored while packed, do not stack the packing crates on top of one another.



CAUTION

Do not stack other crates on top of the digital detector crate!!!



CAUTION

If the temperature is below 5 °C or is over 45 °C, there is a risk of permanent damage to the digital detector.



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2.2.1.2. Operating conditions

Temperature range	From +12 °C to +27 °C. If the detector internal temperature drops below 5 °C or exceeds 45 °C, there is a risk that the detector may be permanently damaged.
Maximum ratio	0 °C in 20 minutes
Relative humidity range	Up to 95% non condensing
Maximum warm-up time for operation	10 minutes

2.2.1.3. Enclosures protection class

The Giotto Class is a IPXO protection class device. Device is not sealed, not suitable for use in the presence of flammable anesthetic mixture from the air, oxygen, or nitrogen oxides.

2.2.1.4. Electrical power supply

Tension	230 VAC \pm 10%, 50/60 Hz \pm 5%, single phase, permanent connection
Maximum Power	25 A – 230 VAC duty cycle 3s ON 60s OFF*
Fuses	40 A*
Permanent connection with protective conductor	Required network filter with minimum attenuation of 10 dB*



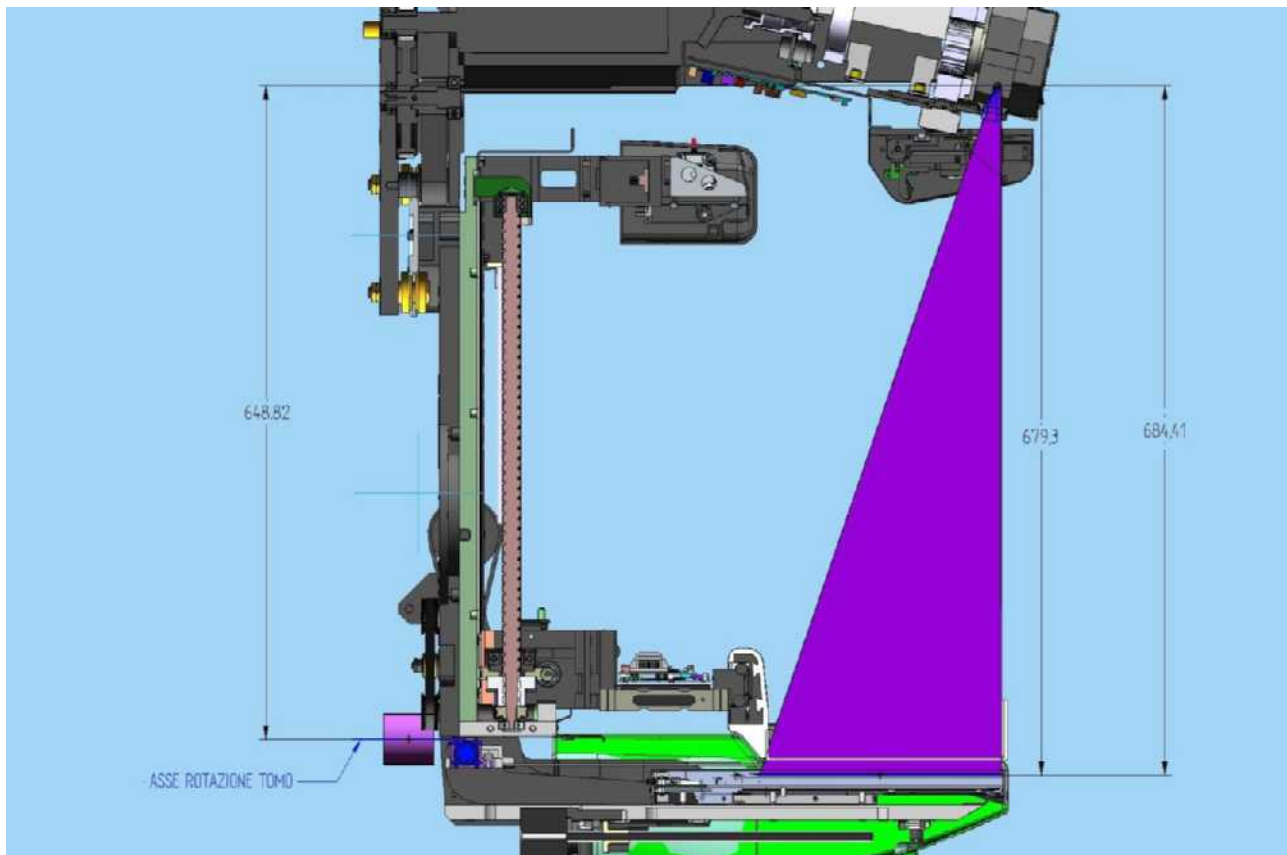
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2.2.1.5. X-ray unit specifications

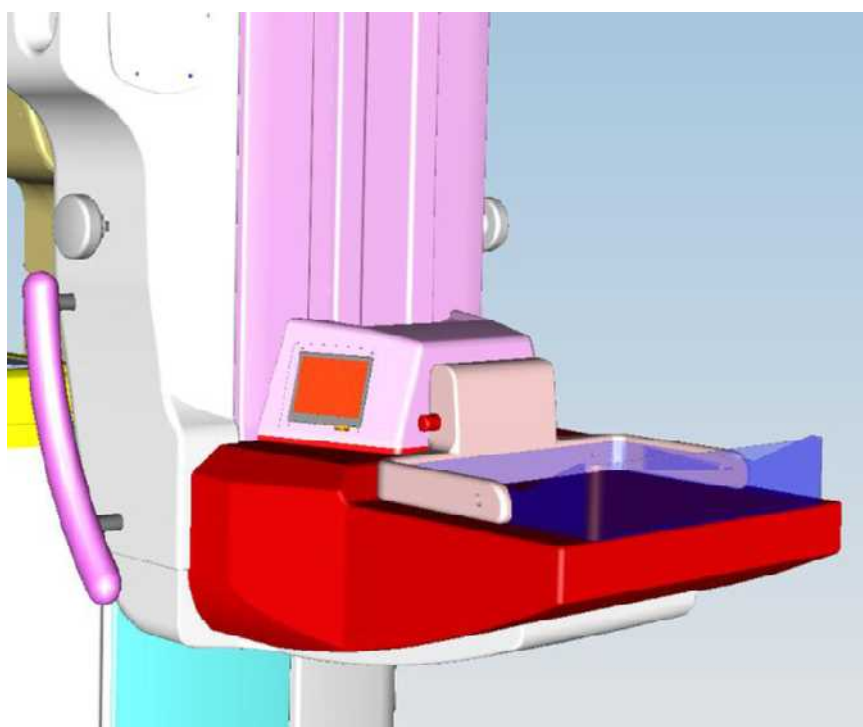
Vertical movement	Total 630 mm (850 mm with consequence of inclination movement)
Potter/Bucky - Floor: (unit in vertical position)	Min: 630 mm Max: 1260 mm
Potter/Bucky - Floor: (unit in horizontal position)	Min: 1360 mm Max: 1990 mm
Gantry rotation range	- 177.0° / + 177.0° (Motorized)
Gantry inclination range	- 15.0° / + 90.0 ° (Motorized)
Angular range of emission	- 14.5° / + 14.5 ° (Motorized)
Source-to-Image Distance (SID)	685 mm
Source-to-Breast Support Distance	668 mm
Magnification factor	1.8 X (optional)
Dimension of x-ray unit (H x W x D)	147.6 x 80.0 x 149.8 cm (in vertical position)
Dimension of operator console unit (H x W x D)	195.0 x 88.6 x 66.0 cm *
Weight of x-ray unit	270 kg
Weight of operator console unit	120 kg
Weight of Flexi Table	250 kg



*SOURCE-to-IMAGE DISTANCE (SID), DIRECT FOCAL DISTANCE, and SOURCE-to AXIS
ROTATION DISTANCE (SAD)*

2.2.1.6. Breast compression system

Actuator type	Stepper Motor - Pedal or Manually with control knob
Maximum compressor force	200 N (motorized) 300 N (manual)
Minimum Force for AEC activation	5 N
Compression Force accuracy	± 1 kg
Compression Thickness	± 2 mm
Release after exposure	Automatic or manually in case of inhibition by operator
Compression velocity	2 mm/s during approaching 1 mm/s during compression *
Compressor plates material	PET-G
Compressor plate maximum flexion	< 5 mm for asymmetric compression
Compressor plate absorption	16.5% \div 0.003 mm Al for 28 kV W/Ag





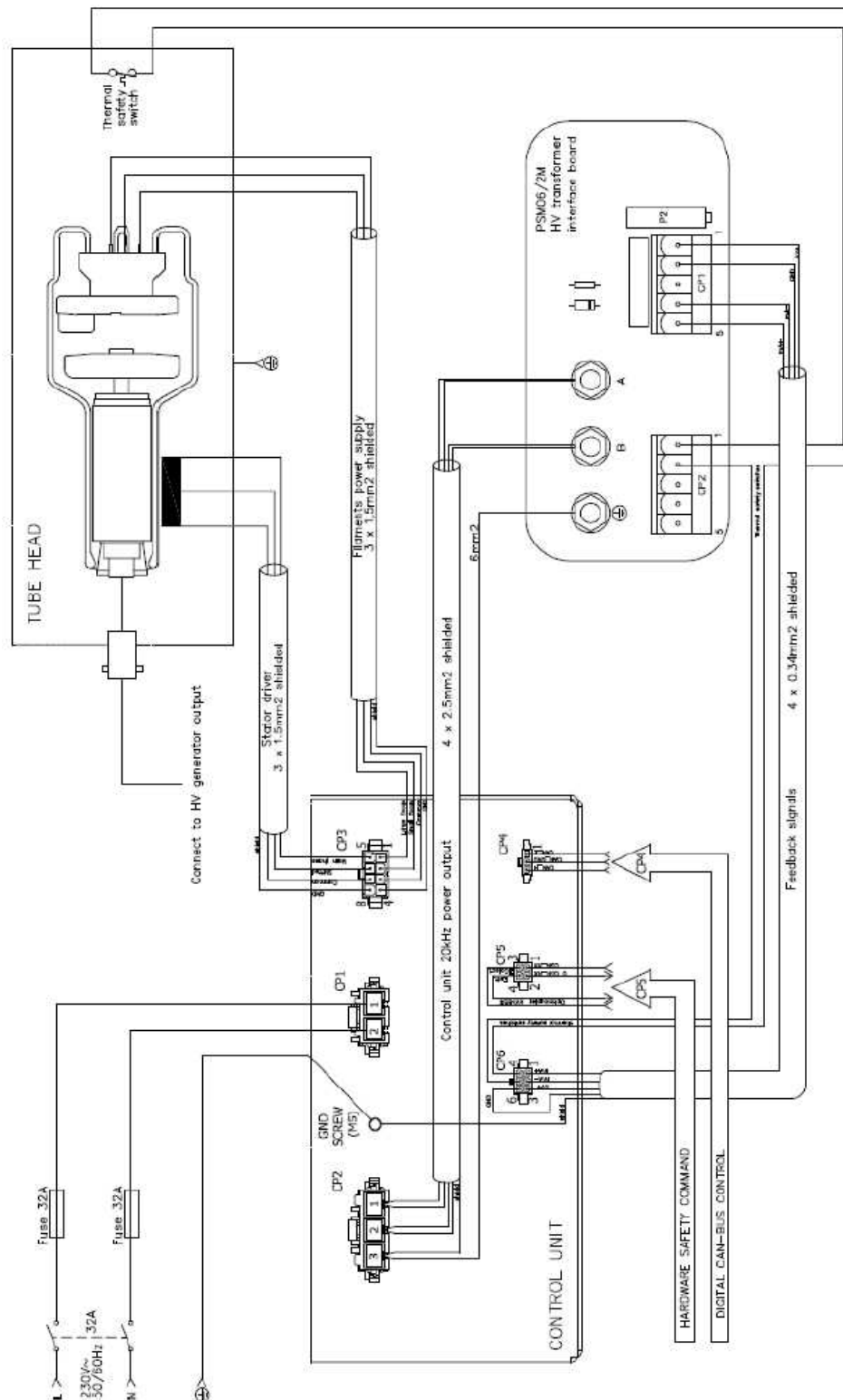
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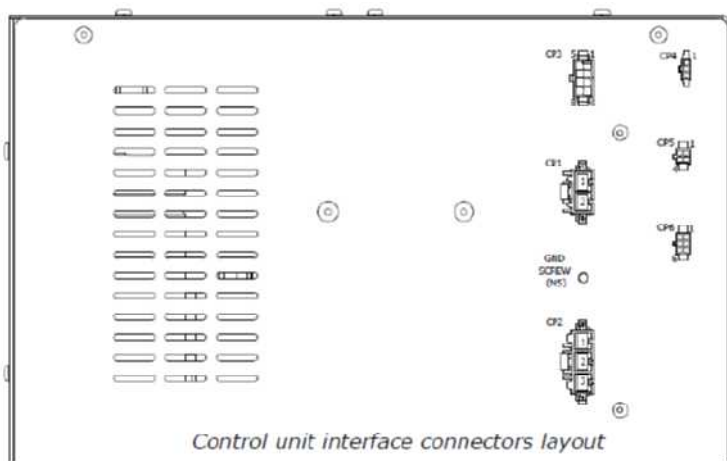
2.2.1.7. High Voltage Generator specifications

Manufacturer	IMD Generators
Model	HF1 Mammo 8kW
Input power supply (Inverter + Filament + Stator power supply)	Single phase 230VAC 50/60Hz
Rated input max power	11 kVApk (max 32Apk) Depending on the exposure parameters
Max input current protection breakers	32A 400 Vac aM 20 kA
Recommended thermo- magnetic circuit breaker	Un = 230 Vac 50/60 Hz
	In = 32 A;
	Number of poles = 2
Protection class	C as per IEC-EN 60898
Power output	Single phase 20 kHz (Max 210 VAC _{rms})
Filament power board output:	Single phase 16 kHz (Max 5.5 A _{rms})
Stator driver power board output:	Single phase + shifted phase 150 Hz (Max 230 VAC _{rms} / 7Apk)
Inverter	
Pulsed load output power	8 kW (200mA @ 40 kV 0,1 sec)
kV Range	22 - 49 kV _{DC}
Max Ripple	< 1%
Max RAD mode load output	200 mA @ 40 kV (0,1 sec)
Max frame per second rate	30 fps
Filament	
Max load output power	65VA (5A @ 13V)
Stator driver	
Steady state nominal power	280 VA
Maximum surge power (launch max 1msec)	1600 VA



High Voltage Generator Electrical connections

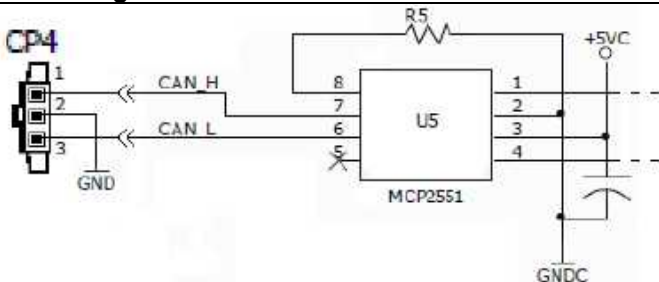
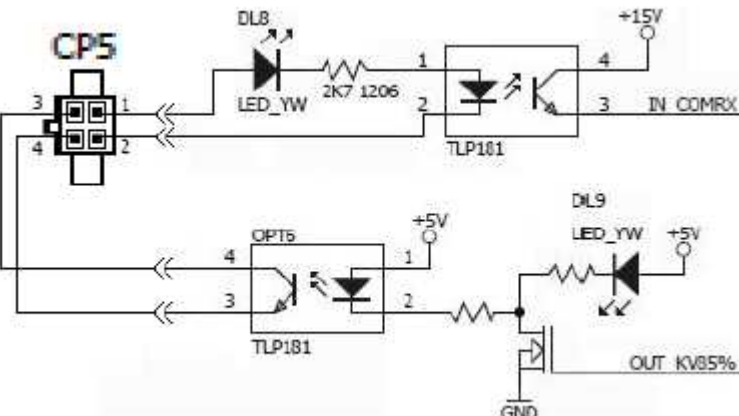
2.2.1.8. High Voltage Generator Electric characteristics and I/O (power and signals)



All the control unit interface connectors are from Molex (except power GND).
In order to connect the unit, following headers are needed:

CP1 = 2ways Minifit SR 42816 series connector
CP2 = 3ways Minifit SR 42816 series connector
CP3 = 8ways (4x2) Minifit Jr 5557 series connector
CP4 = 3ways Microfit 43645 series connector
CP5 = 4ways (2x2) Microfit 43645 series connector
CP6 = 6ways (3x2) Microfit 43020 series connector
GND = M5 brass nut

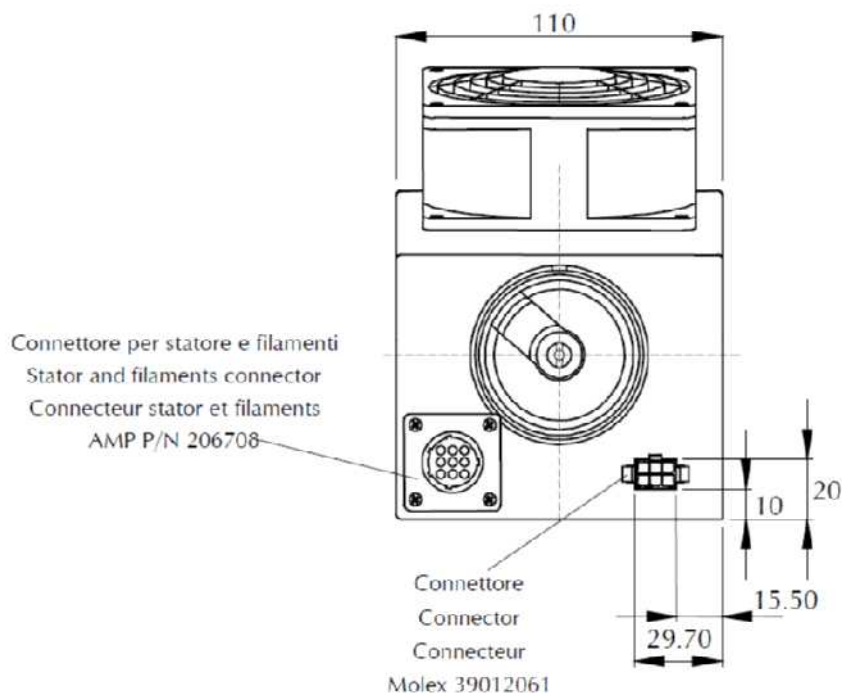
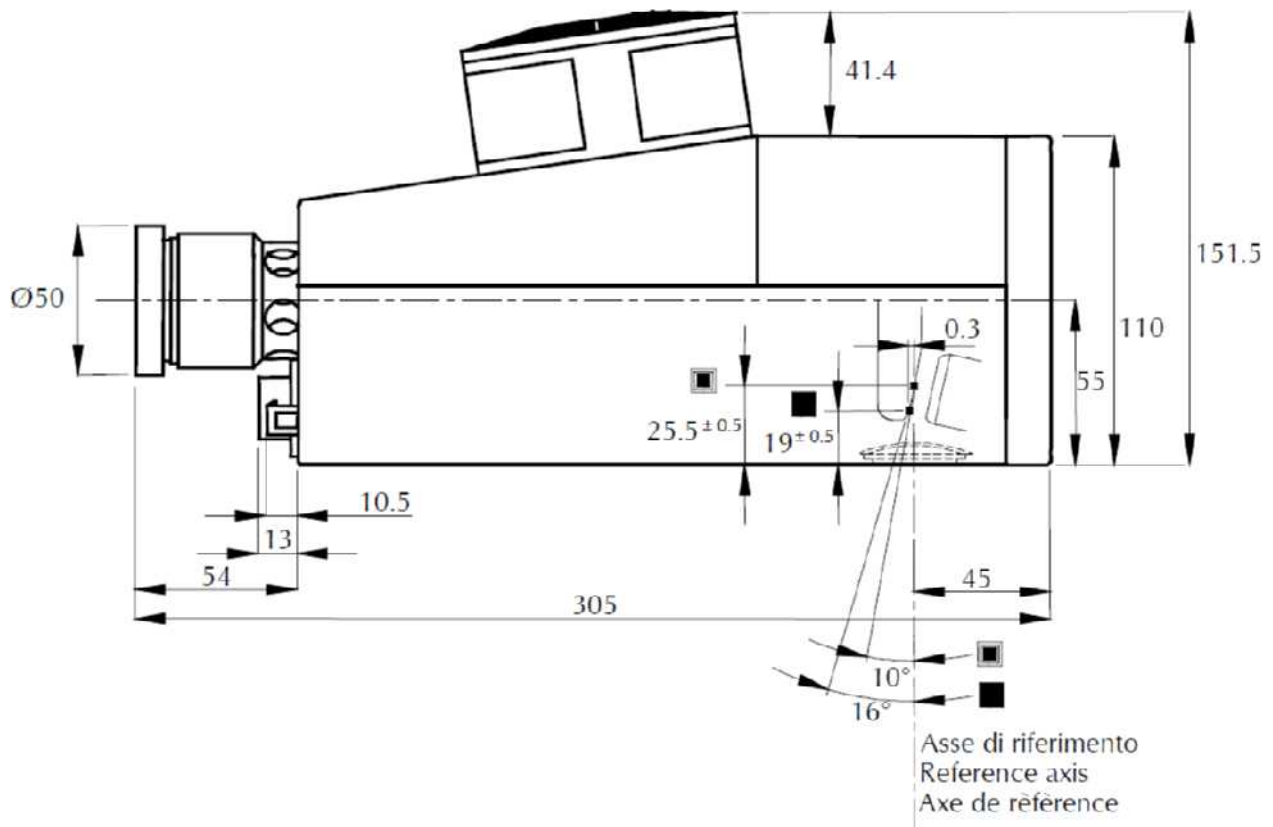
Terminals	Input / Output characteristic	
CP1-1,2	Input power supply (Inverter + Filament + Stator power supply)	Single phase 230Vac 50/60Hz
	Rated input max power	11kVApk (max 32Apk) Depending on the exposure parameters
	Max input current protection breakers	32A 400Vac aM 20kA
	Recommended thermo-magnetic circuit breaker	Un = 230Vac 50/60Hz In = 32A Number of poles = 2 Protection class = C as per IEC-EN 60898
GND Screw	GND	Connected to the Control unit chassis
CP2-1,2	Power output	Single phase 20kHz (Max 210Vacrms)
CP3,1: (LF) CP3,2: (SF) CP3,3: (CM) CP3,4: GND	Filament power board output: (LF) = Large Focus (SF) = Small focus (CM) = Common	Single phase 16kHz (Max 5.5Arms)
CP3,5: (P) CP3,6: (S) CP3,7: (C) CP3,8: GND	Stator driver power board output: (P) = Main phase (S) = Shifted (C) = Common	Single phase + shifted phase 150Hz (Max 230Vacrms / 7Apk)

Terminals	Signal	Block diagram
1,3 (CP4-2: GND)	INPUT CAN BUS	
CP5-1,2	INPUT Digital* Command X-Ray	
CP5-3,4	OUTPUT Digital* HV > 85%	
CP6-4,5	INPUT Digital Thermal safety switch	<i>This input manages the normally closed contact which comes from the safety switch in the HV transformer.</i>
CP6-1 mA+ CP6-2 mA-	INPUT Analog Feedback Anodic mA	<i>These inputs have to be connected to the load as indicated in the chapter 8.3</i>

2.2.1.9. High Voltage Generator: conditions of storage and usage

Transport and storage conditions	
Range of temperature	0° – 50° C
Relative humidity (non condensing)	20 – 90 %
Atmospheric pressure	700 – 1060 hPa
Working conditions	
Range of temperature	10° – 40° C
Relative humidity (non condensing)	30 – 75 %
Atmospheric pressure	700 – 1060 hPa

2.2.1.10. X-ray tube assembly





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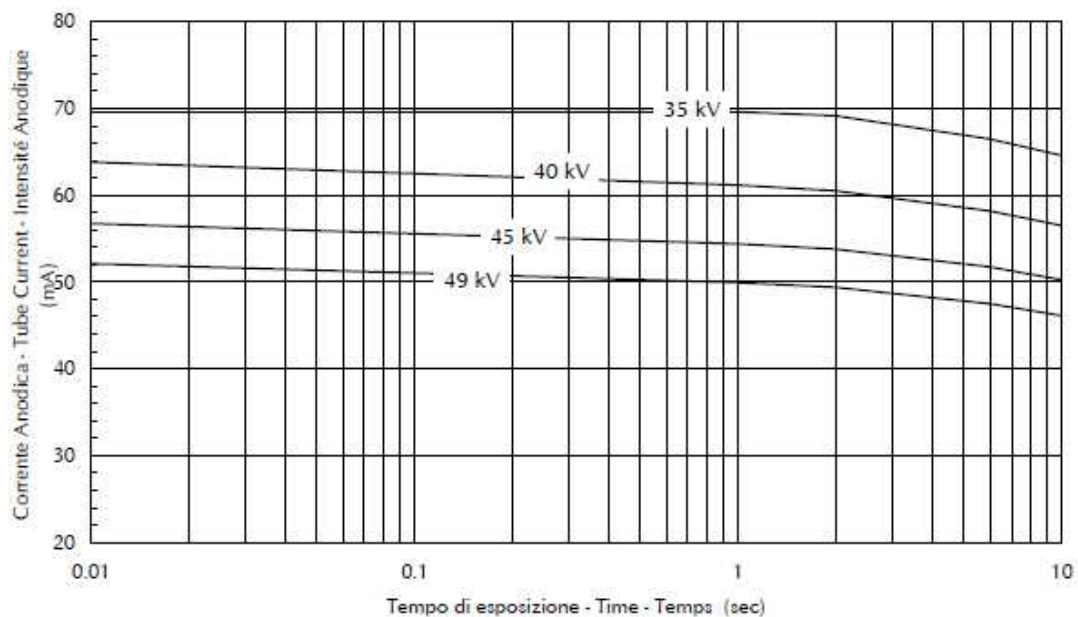


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Manufacturer	I.A.E.
Model	XK116T
Focal Spot dimension	0.1-0.3 mm
Anode Angles	10°-16°
Anode rotation speed	3000-10000 rpm
Anodic Material	RT-TZM
Inherent Filtration	0.5 mm Be
Thermal Anodic capacity	225 kJ - 300 kWh
Continuous anode heat dissipation	715 W
Maximum anode heat dissipation	750 W
Equivalent anode input power	100 W - 38% of max
Dimensions	110 x 155 x 305 mm
Weight	5.5 kg
Temperature condition for transportation and storage	-10 / + 80 °C
Humidity condition for transportation and storage	max 80 %
Maximum High Tension	49 kV
Maximum heat dissipation with fan	300 W
Maximum leakage radiation at 1 m from focal spots	63 µGy/h - 7 mR/h
93/42/CEE Classification	IIb
IEC 60601-1 equipment class	I
IEC 60601-1 equipment type	B

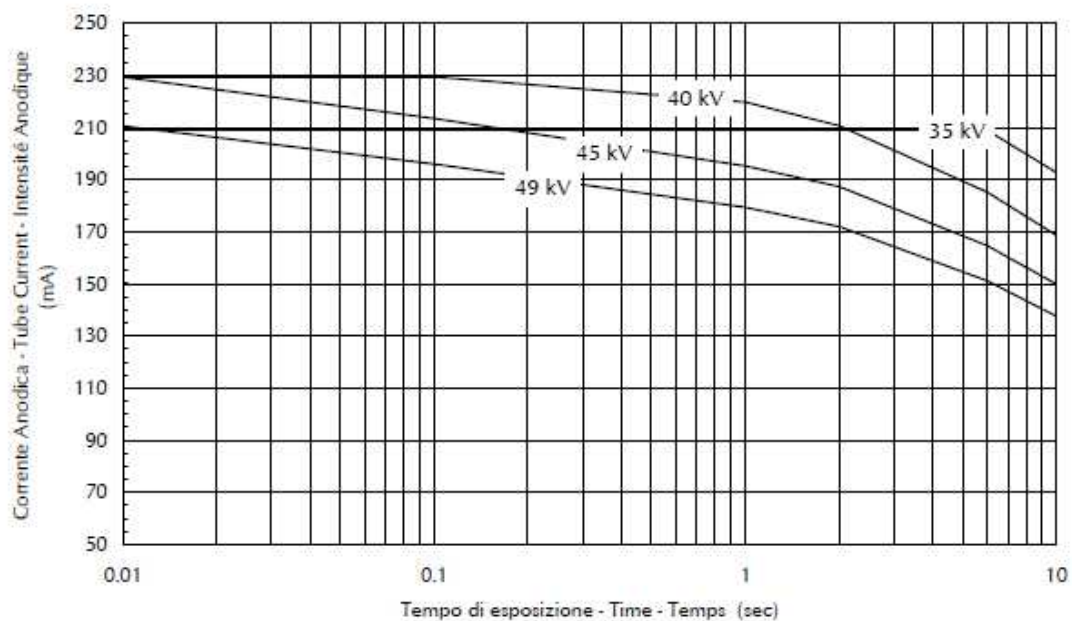
CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

■ 0.1 - 3 ~ - 10000 min⁻¹

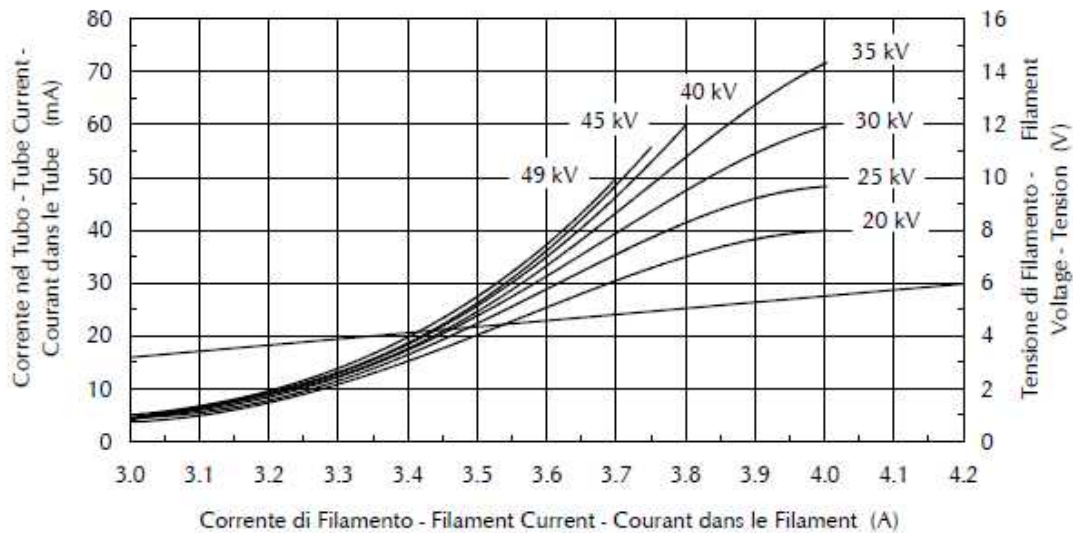


CURVE DI CARICO SINGOLO - SINGLE LOAD RATING - ABAQUE DE CHARGE UNIQUE

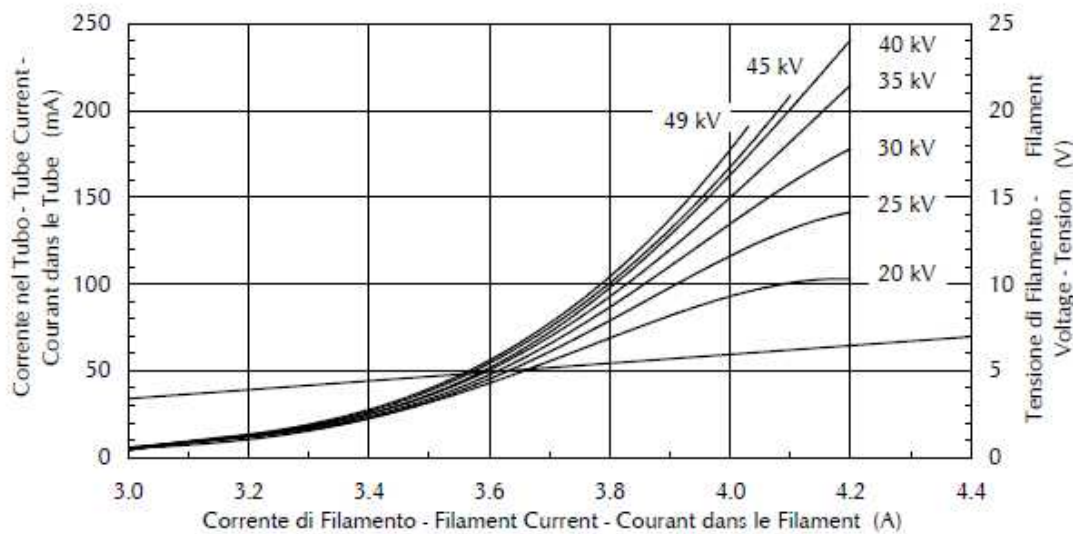
■ 0.3 - 3 ~ - 10000 min⁻¹



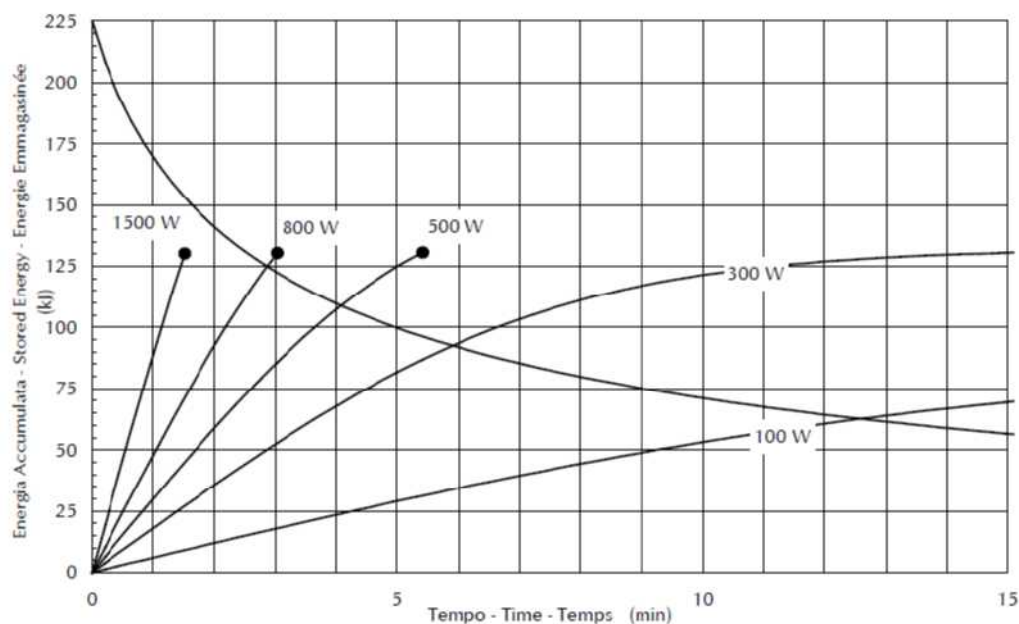
Caratteristica di emissione del catodo
Cathode emission characteristic
Caractéristique d'émission de la cathode
▣ 0.1 - 3 ~ - (± 0.2 A)



Caratteristica di emissione del catodo
Cathode emission characteristic
Caractéristique d'émission de la cathode
■ 0.3 - 3 ~ - (± 0.2 A)



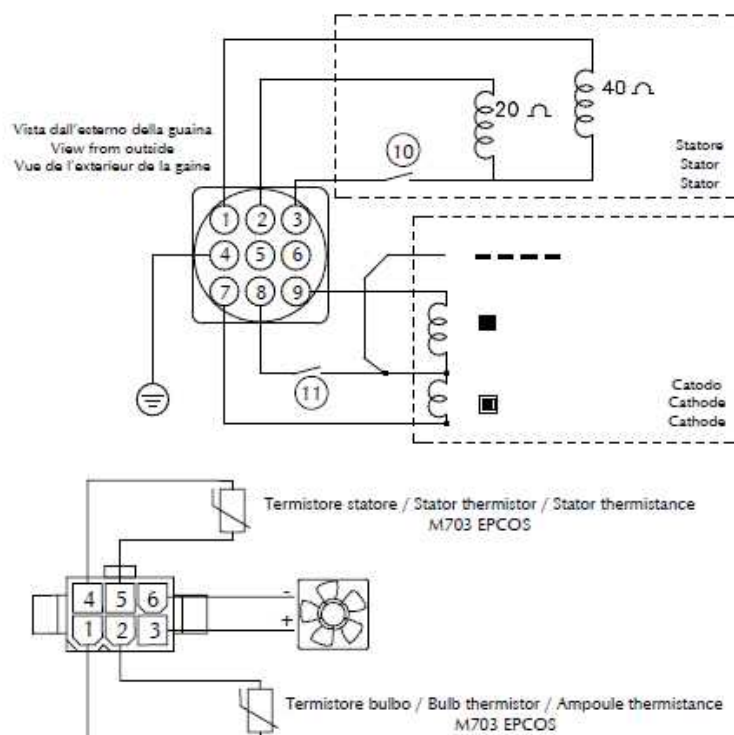
Curve di riscaldamento e raffreddamento dell'anodo
Anode heating and cooling curves
Courbes d'échauffement et de refroidissement de l'anode



Simbologia - Symbols - Symboles

	Tubo a raggi X	X-ray tube	Tube radiogène
	Guaina a raggi X	X-ray source assembly	Gaine à rayonnement X
	Filtrazione	Filtration	Filtration
	Fuoco piccolo	Small focal spot	Petit foyer
	Fuoco grande	Large focal spot	Grand foyer
	Apparecchio di Tipo B	Type B equipment	Appareil de type B
	Posizione fuoco	Focal spot position	Position des foyers
	Terra di protezione	Protective earth (ground)	Terre de protection
	Tensione pericolosa	Dangerous voltage	Tension dangereuse

Collegamenti connettore - Connector connections - Connexions du connecteur



Statore - Stator - Stator

Principale	Line	Principal	2
Comune	Common	Commun	3
Ausiliario	Phase shift	Auxiliaire	1
Termostato interno normalmente chiuso apre a: 105° C ± 4° C	Internal thermal switch, normally closed opens at: 105° C ± 4° C	Sécurité thermique interne, contact fermé au repos ouvre à: 105° C ± 4° C	10

Catodo - Cathode - Cathode

Fuoco piccolo	Small focal spot	Petit foyer	7
Fuoco grande	Large focal spot	Grand foyer	9
Comune <i>Il cavo del comune di filamento deve essere collegato a terra o direttamente oppure attraverso il circuito di misura mA</i>	Common <i>Common filament conductor must be connected to ground either directly or through mA measurement circuit</i>	Commun <i>Le câble commun du filament doit être raccorder à la terre ou directement travers le circuit de mesure mA</i>	8
Termostato interno normalmente chiuso apre a: 105° C ± 4° C	Internal thermal switch, normally closed opens at: 105° C ± 4° C	Sécurité thermique interne, contact fermé au repos ouvre à: 105° C ± 4° C	11

Ventilatore - Fan - Ventilateur

Ventilatore DC 24V - 12.2 W	Fan DC 24V - 12.2 W	Ventilateur DC 24V - 12.2 W	3 - 6
Termistore statore *	Stator thermistor *	Stator thermistance *	4 - 5
Termistore bulbo *	Bulb thermistor *	Ampoule thermistance *	1 - 2
* $R_T = R_N \exp B(1/T - 1/T_N)$ $T_N=25^\circ\text{C}$; $R_N=10k\Omega$; $B=3998$			



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Range kV/mA

kV	Large Focus (0.3mm ²) - mA	Small Focus (0.1mm ²) - mA
22	110	41
23	115	42
24	120	43
25	125	44
26	130	45
27	135	46
28	140	47
29	145	46
30	150	45
31	155	44
32	150	43
33	145	42
34	140	41
35	135	40

* Data under revision

Range current-time product (mAs):

- LARGE FUOCUS (0.3 mm²) 2-600 mAs with steps of 1 mAs
- SMALL FOCUS (0.1 mm²) 2-185 mAs with steps of 1 mAs

The Giotto Class unit does not apply the loading factors from TABLES R10 – R20.



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2.2.1.11. X-ray beam filtration

Material	Silver (Ag)
Thickness	0.0050 ± 5 mm
Purity	≥ 99.9 %
Half-Value Layer (HVL)	W/Ag (50 µm) 25 kV = 0.48 ± 0.02 mm Al * 28 kV = 0.53 ± 0.02 mm Al * 31 kV = 0.57 ± 0.02 mm Al *

2.2.1.12. Radiation Output

Reproducibility	< 5%
Linearity	R ² > 0.999
kV accuracy	± 1 kV of nominal value
mAs accuracy	± 5% o ± 1mAs of nominal value
Dose output	~ 1 mGy for 26 kV W/Ag 20 mAs at SID distance (~ 7.0 mGy/s at 685 mm from source); *

2.2.1.13. Beam Limiting device

Automatic collimation depending on the compressor format and angle of emission.
The image dimension is depending on the collimation format (collimation diaphragm never visible)

Light field source	LED + mylar mirror
Light field intensity	> 160 lux
Light field activation	Single pressure of keyboard button or when compressor is moving with pedal
Light field duration	20 s
X-ray field / Light field misalignment	< 2 % of SID according to IEC 60601-2-45



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2.2.1.14. Radiation Protection

Operator protection	➤ Anti-X ray Protective barrier
Anti-X ray protective barrier material and dimension	Temperate glass 760 x 1960 x 5 mm
Equivalent filtration	The protective barrier installed on the control cabinet guarantees an equivalent absorption of 0.1 mm Pb as required by IEC 60601-1-3 and IEC 60601-2-45 standards.
Patient protection	<ul style="list-style-type: none"> ➤ Patient face protection ➤ Automatic collimator ➤ AEC system

2.2.1.15. Acquisition Work Station (AWS)

Operating system	WINDOWS 7 Embedded SP1
Processor	INTEL DUAL- CPU
Memory RAM	24 GB
Capacity hard drive	1TB or superior, DVD READER/BURNER
Graphic board	Integrated display port
LCD Display	1600x1200 – 20" da 180 cd/m ² Optional Diagnostic 3 MP
Network interface	3GB Ethernet
Remote diagnostic	Internet
G.U.I.	<ul style="list-style-type: none"> ➤ Machine state ➤ Work-list modality ➤ Patient data management ➤ Brightness and contrast control ➤ Magnification Lens ➤ Tomosynthesis scroll tools with kinetic modality ➤ Q.A. test tools ➤ Biopsy examination modalities
Digital Images Formats	DICOM 3.0 – See Informance Statement
DICOM Functions	Verification SCU/SCP Store SCU/SCP Query /retrieve SCU Print SCU WORKLIST CU STORAGE COMMITMENT SCU MPPS SCU *
Image processing and reconstructions	RAFFAELLO software



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2.2.1.16. Digital image receptor

Manufacturer	Analogic
Model	AXS-2430
Sensor Physical Dimensions	239.36 x 304.64 mm
Active Area	2816 x 3584 pixels
Image matrix	2812 x 3580 pixels
<i>N.B. The first two lines and columns at the edge of the active area are declared dead</i>	
Pixel size	0.085 x 0.085 mm
Geometric Fill Factor	88%
Detection Method	Direct Conversion (DR) using Amorphous Selenium (a-Se)
Read out technology	TFT array
Saturation Dose	~ 3.0 mGy (mammographic context) ~ 0.7 mGy (tomosynthesis context)
Response	Linear ($R^2 > 0.99$)
DQE @ 1lp/mm	> 50 %
DQE @ 5.8 lp/mm	> 20 %
MTF @ 1lp/mm	> 90 %
MTF @ 5.8 lp/mm	> 40 %
Lag	< 0.005 after 30 s
Ghost	0.05 (Euref Method)
ACR Mammography Accreditation Phantom	≥ 4 Masses ≥ 3 Fibres ≥ 3 Speck groups For every modality of acquisition (MAMMO, TOMO, COMBO) using the AEC system
ADC Bit depth	16 bits min
Image bit depth	13 Bit for mammographic and projections images
	14 Bit for reconstruction
Image dimension	19 MB for mammographic and projections images
	Depending on the volumetric reconstruction dimension
Maximum defective pixels	< 5000
Maximum correctable defective lines/columns	< 10
Maximum correctable defective cluster	150 cluster (max 8 pixel)



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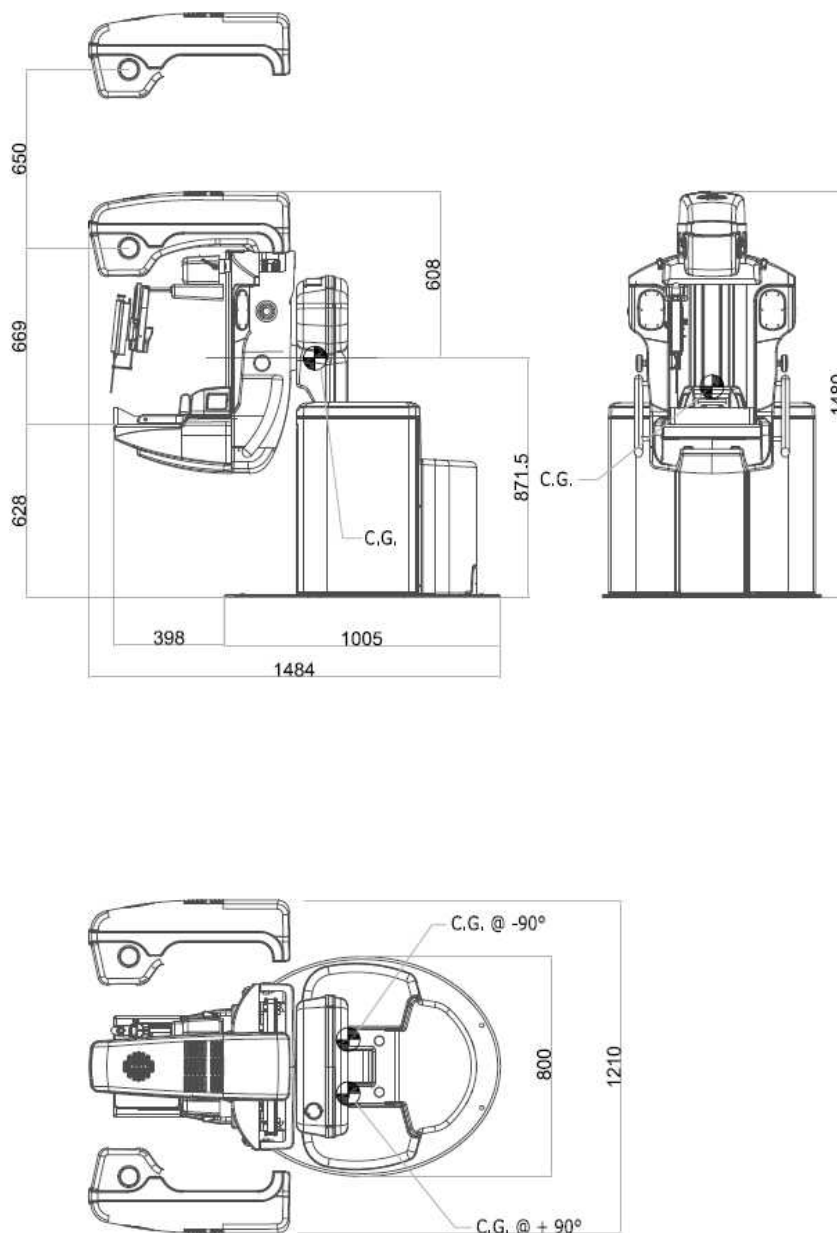
2.2.1.17. Automatic Exposure Ccontrol (AEC) system

Principle of function	The compressed breast thickness determinate the optimum values of the kV and mAs for the pre-exposure (for tomosynthesis scan the first exposure id used as pre-exposure) Analyzing the image received the AWS determinates the maximum density inside the breast and select the mAs needed.
Sensible areas	The analysis area is rectangular, aligned with chest wall and laterally centered. 1. 2D Mammo : 15 cm x 19 cm 2. 3D Tomo : 10 cm x 19 cm 3. Biopsy : 4 cm x 1 cm
Techniques	- Manual: manual selection of kV, filter, mAs - Automatic: automatic selection of Focus type, kV, filter, mAs
Short term reproducibility	< $\pm 5\%$
Long term reproducibility	< $\pm 10\%$

2.2.1.18. Anti-scatter grid

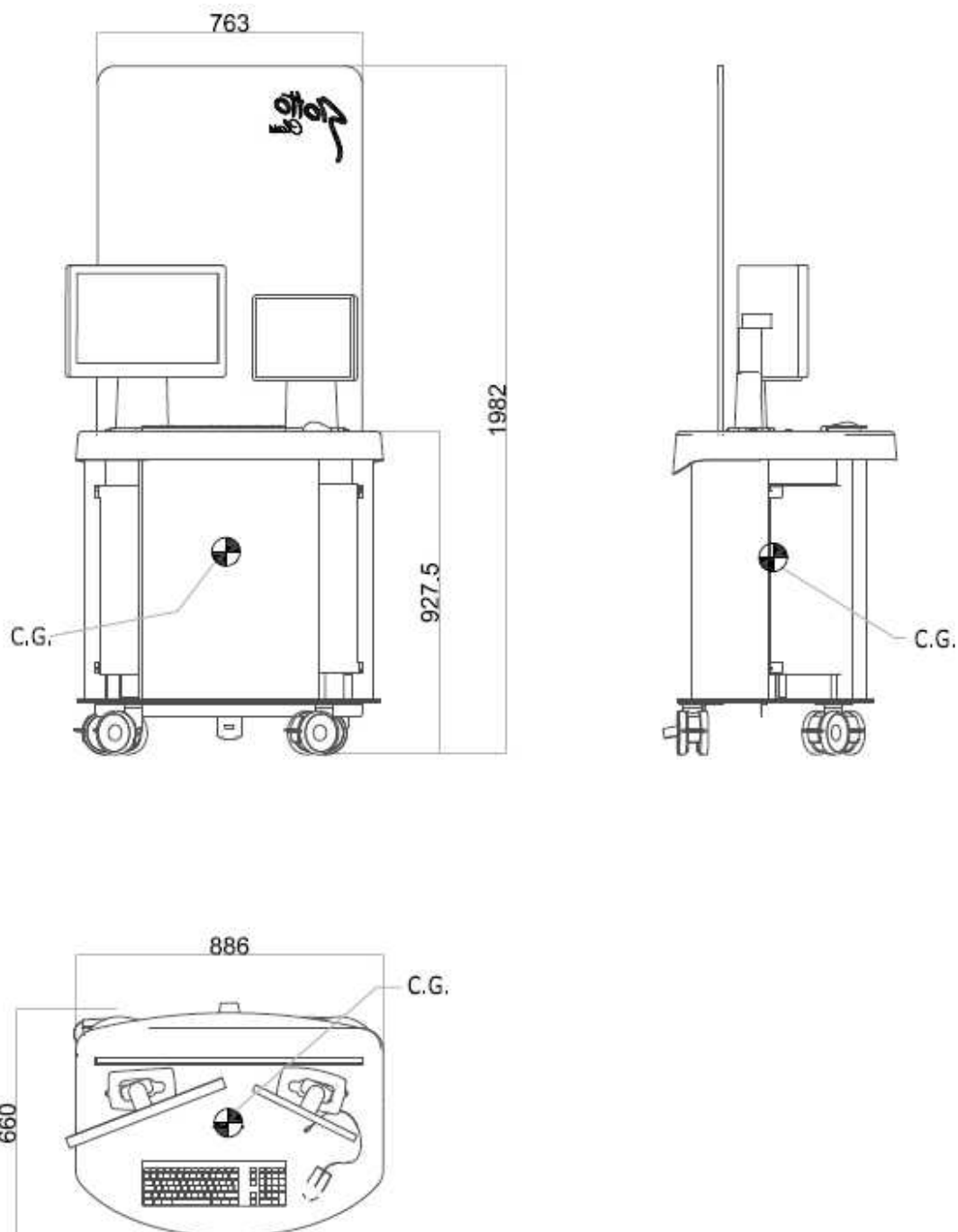
Manufacturer	JPI Healthcare solution
Model	2100
Type	linear focused grid
Ratio	4 : 1
Line density	31 lp / cm
Focal Distance	65 cm
Interspace material	Pure carbon (C)
Absorbed material	Lead alloy (Pb)
Cover material	CFRP
Application limit (f1 ~ f2)	43 ~ 180 cm
Transmission of primary radiation (Tp)	73%
Transmission of scatter radiation (Ts)	26%
Transmission of total radiation (Tt)	58%
Grid selectivity (Σ)	$2.81 \pm 5\%$
Contrast improvement fator (K)	$1.26 \pm 5\%$
Grid exposure factor (B):	$1.72 \pm 10\%$

2.2.1.19. Dimension of the X-ray unit



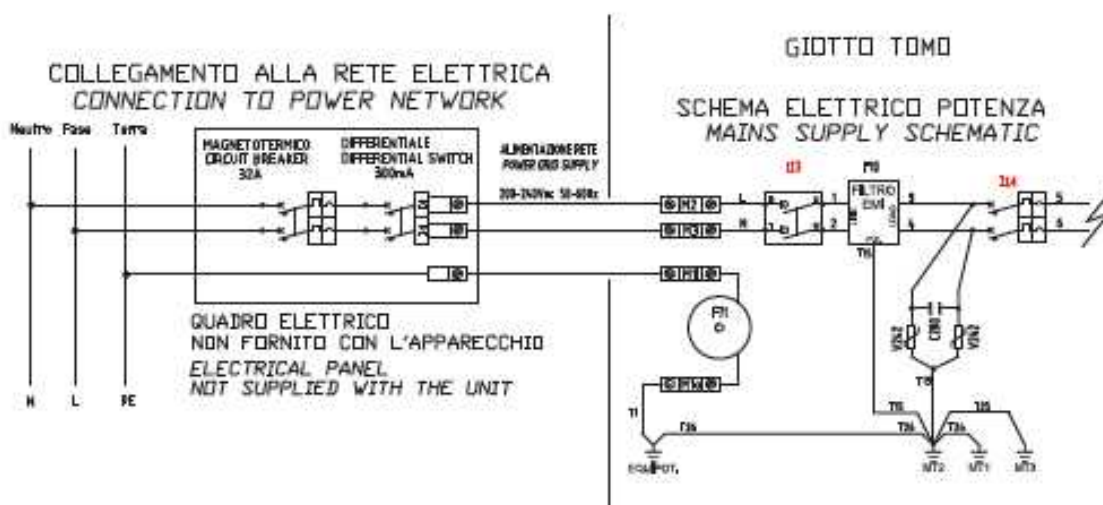
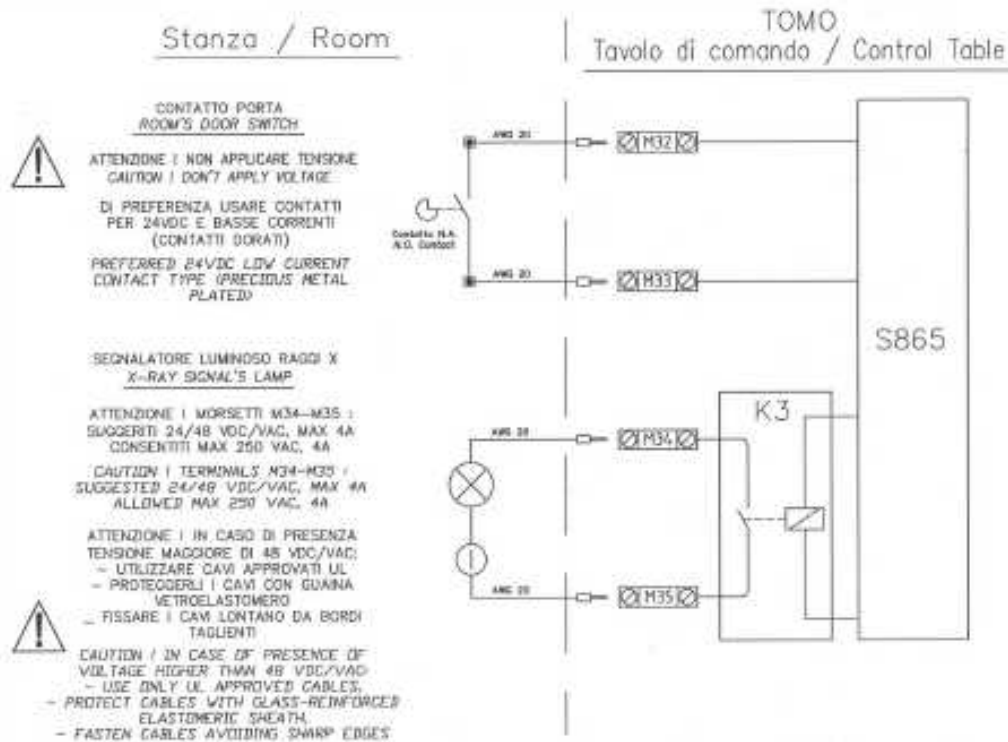
Max Height	2320 mm
Isocentric height	30 mm over the detector support
Breast support height	70 - 145 (± 2) cm
Source-to-image distance (SID)	690 mm
Gantry rotation range	+180° (in anticlockwise) -120° (in clockwise)
Weight	450 kg

2.2.1.20. Dimension of the operator console unit



Dimension (H x W x D)	1982 x 886 x 660 mm
Weight	180 kg

2.2.2. Electrical connections



Temporary images (is not the final version)



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2.2.3. Warning on electromagnetic compatibility (EMC)

The unit is certified as a fixed installation electro medical device and was built in conformity with the applicable provisions of directive 93/42/EEC concerning medical devices modified by directive 2007/47/EC.

The unit is built in compliance with the IEC 60601-1-2 standard.

	CAUTION In accordance with EN 60601-1, the unit must be permanently connected to the electrical mains. (The protective earth conductor must be connected directly to the protective earth terminal of the electrical panel).
	CAUTION THE UNIT AND IT'S ACCESSORIES MUST ONLY BE INSTALLED AND USED IN SHIELDED ROOMS (MINIMUM SHIELDING RATIO 20 dB).
	INFORMATION The fixed cables for systems and devices that cannot be disconnected by the user are not listed. These cables are part of the system and were always taken into consideration when measuring the EMC. The device or system would not function without these cables.
	CAUTION Use of accessories, transformers or cables different than those indicated. Possible increase in the emissions or reduction in the resistance to disturbances for the device or system! Use only transformers and cables sold by the manufacturer of the device or system as replacement parts for the internal components.



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2.2.4. Manufacturer's declaration and guidelines - Electromagnetic emissions

The system is intended for operation in an electromagnetic environment indicated below. The customer or user of the system must ensure that it is used within this environment.

Measurement of the emission disturbances	Compliance	Guidelines - Electromagnetic Environment
Conducted RF Radiated RF CISPR 11	Group 1	The system uses HF energy only for its internal functioning. Therefore its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The unit/system is suitable for use in all environments other than domestic and those directly connected to the public low voltage power supply network that supply buildings used for domestic purposes. The system has a nominal input current greater than 16 A per phase.
Conducted RF Radiated RF CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker IEC 61000-3-3	Not applicable	



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2.2.5. Manufacturer's declaration and guidelines - Immunity to electromagnetic interferences

The system is intended for operation in an electromagnetic environment indicated below. The customer or user of the system must ensure that it is used within this environment.

Electromagnetic interference tests	Test level - IEC 60601	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact discharge ±8 kV Air discharge	±6 kV Contact discharge ±8 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply cables ±1 kV for input and output cables	±2 kV for power supply cables ±1 kV for input and output cables	The mains power quality must be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV Common mode	±1 kV differential mode ±2 kV Common mode	The mains power quality must be that of a typical commercial or hospital environment.
Voltage drops, short term interruptions and fluctuations in the supply voltage IEC 61000-4-11	<5% UT (> 95% drop in UT) for 0.5 cycle 40% UT (> 60% drop in UT) for 5 cycles 70% UT (> 30% drop in UT) for 25 cycles <5% UT (> 95% drop in UT) for 5 s	Not applicable <5 % UT (>95 % dip in UT) for half cycle 40 % UT (>60 % dip in UT) for 5 cycles 70 % UT (>30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	The mains power quality must be that of a typical commercial or hospital environment. If the user of the system requires continuous operation during power outages, it is recommended that it be powered with an uninterruptible power supply. The system has a nominal input current greater than 16A per phase.
Magnetic field at the supply frequency (50-60 Hz) IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields at mains frequency should correspond to the typical values seen in a typical business or hospital environment.

Note: UT is the alternative current voltage before the application of the test level.



CAUTION

Use of the device or system immediately next to other devices or stacked on top of other appliances.

Proper operation cannot be guaranteed!

◆ If the device or system must operate alongside other appliances or be stacked on top of them, it should be execute a functional test to check that it functions properly in this layout.

Portable and mobile HF communication devices should be used no closer to any part of the equipment, including cables, than the recommended separation distance. The separation distance is calculated based on the applicable transmission frequency equation.

P is the maximum nominal power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

The field strength from the stationary RF transmitter, as determined by a local electromagnetic site survey a should be less than the compliance level b at each frequency range. Interference may



occur near equipment marked with the following symbol

Electromagnetic interference tests	Test level - IEC 60601	Compliance level	Recommended separation distance:
Conducted HF interference IEC 61000-4-6	3 V _{rms} from 150 kHz to 80 MHz	3 V _{rms}	$d = 1, 2\sqrt{P}$
Radiated HF interference IEC 61000-3-2	3 V/m from 80 MHz to 2,5 GHz	3 V/m	$d = 1, 2\sqrt{P}$ per 80 MHz - 800 MHz $d = 2, 3\sqrt{P}$ per 800 MHz - 2,5 GHz

Note 1: The higher frequency range applies at 80 MHz and 800 MHz.

Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic emissions is affected by the absorption and reflection by buildings, objects and people.

A) The field strengths of stationary transmitters, e.g. base stations for radio telephones (mobile/cordless) and mobile radio equipment, amateur radio stations, AM and FM radio and television transmitters cannot be predicted theoretically with accuracy. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of the location should be carried out. If the field strengths measured at the location where the system will be used exceed the compliance level given above, the system should be monitored to see that it operates properly. If unwanted performance characteristics are observed, additional measures may be necessary, such as reorienting or repositioning the system.

B) At the frequency range from 150 kHz to 80 MHz, the field strengths should be lower than 3 V/m.



CAUTION

PORTABLE AND MOBILE RADIO COMMUNICATION DEVICES CAN INFLUENCE THE OPERATION OF THE UNIT AND ITS ACCESSORIES.



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2.2.6. Recommended separation distances between the system and portable and mobile HF communication devices

The system is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference.

This can be achieved by maintaining a minimum distance between portable and mobile HF communication devices (transmitters) and the system, based on the rated maximum output power of the communication devices.

Maximum rated output power of transmitter (W)	Separation distance according to frequency of the transmitter [m]		
	da 150 kHz a 80 MHz $d = 1, 2\sqrt{P}$	da 80 MHz a 800 MHz $d = 1, 2\sqrt{P}$	da 800 MHz a 2,5 GHz $d = 2, 3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation from the applicable column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: The higher frequency range applies at 80 MHz and 800 MHz.

Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic emissions is affected by the absorption and reflection by buildings, objects and people.



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2.2.7. List of compatible components

The person who connects additional devices to the medical product is considered to be the system configure and therefore must guarantee under his/her own responsibility that the configuration of the current versions conform to the main standards (system standard IEC 60601-1-2 and/or other applicable standards). Please contact the local reference person if further clarifications are required.

2.2.7.1. Standard accessories

Description	Product Code
Compressor Paddle 24x30 cm for Tomosynthesis scan	XXXXXX
Face protection for mammo	XXXXXX
Face protection for tomo	XXXXXX
Foot switches for vertical movement	XXXXXX
Foot switches for compressor	XXXXXX
Visualization Monitor	XXXXXX
Touch-Screen monitor	XXXXXX
2MP Monitor	XXXXXX
3MP Monitor	XXXXXX
Operator Protection (Glass barrier)	XXXXXX

2.2.7.2. Optional accessories

Description	Product Code
Biopsy unit: Smart Finder	28000-00
Patient support: Flexi Table	29000-00
Review Work Station (RWS) with two 5 MPixel monitors	31010-00
Review Work Station (RWS) with two 5 MPixel monitors + 1 additional LCD 21.3" 2 MPixel monitor	31020-00
Review Work Station (RWS) with one 10 MPixel monitor	31040-00
Review Work Station (RWS) with one 10 MPixel monitor + 1 additional LCD 21.3" 2 MPixel monitor	31060-00
Mammographic Compressor Paddle 24x30 cm	25100-00
Compressor Paddle 15x30 cm	25200-00
Compressor Paddle 05x05 cm	25980-00
Compressor Paddle 10x10 cm	25900-00
Magnification Platform with Compressor Paddle 24 x 30 cm	26100-00
Software Raffaello Viewer	31003-00
Software CAD Galileo	31070-00
Software G-View (synthetic 2D image from 3D reconstruction)	31002-00
Supplement foot pedal	25030-00
Wireless foot pedal for vertical movement	25010-10
Wireless foot pedal for compressor movement	25020-00



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3. Panoramic view of the system

3.1. Description of the system

3.1.1. Introduction

1.1.1.1 Field of application

This device is a Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT) system with an integrated digital image receptor based on amorphous selenium (a-Se) material and TFT readout method.

Using the accessory device Smart Finder the device is able to perform biopsy examination in stereotactic or tomosynthesis modalities.

Using the accessory device Flexi Table the Giotto Class permits to perform the biopsy examination also with patient in prone position.

The equipment is used under the guidance of qualified medical personnel to perform digital mammograms, that is to say for diagnostic imaging using the contact technique.

1.1.1.2 Targeted mammographic view using the magnification device (optional)

The targeted mammographic view is used to better represent a particular area of the breast. The result is a better view of a small portion of the breast.

1.1.1.3 Automatic mode for X-ray optimization

The equipment has special automatic functions to optimize the X-ray parameters and therefore obtain the best possible image quality with the lowest dose level possible.

The Automatic Exposure Control (AEC) system is integrated in the digital image receptor and is available for all the modalities of acquisition present: Contact mammography, Geometrical Magnification, Targeted mammographic views, Tomosynthesis scan, Combined modality and biopsy.

1.1.1.4 Automatic Exposure control (AEC) system for 2D images

Principle of operation: using a short pre-exposure, based on the compressed breast thickness read by the compression system, an initial image is taken and analyzed for the evaluation of the densest area inside the breast, for the optimization of the final dose level for the best compromise between the image quality obtained and the dose absorbed by the patient.

1.1.1.1 Automatic Exposure control (AEC) system for 3D images

Principle of operation: the first projection is based on the compressed breast thickness read by the compression system, and the first image is taken and analyzed for the evaluation of the densest area inside the breast for the optimization of the final dose level for the best compromise between the image quality obtained and the dose absorbed by the patient. To maintain the symmetry of the acquisition the final projection is made with the same dose level of the first one.

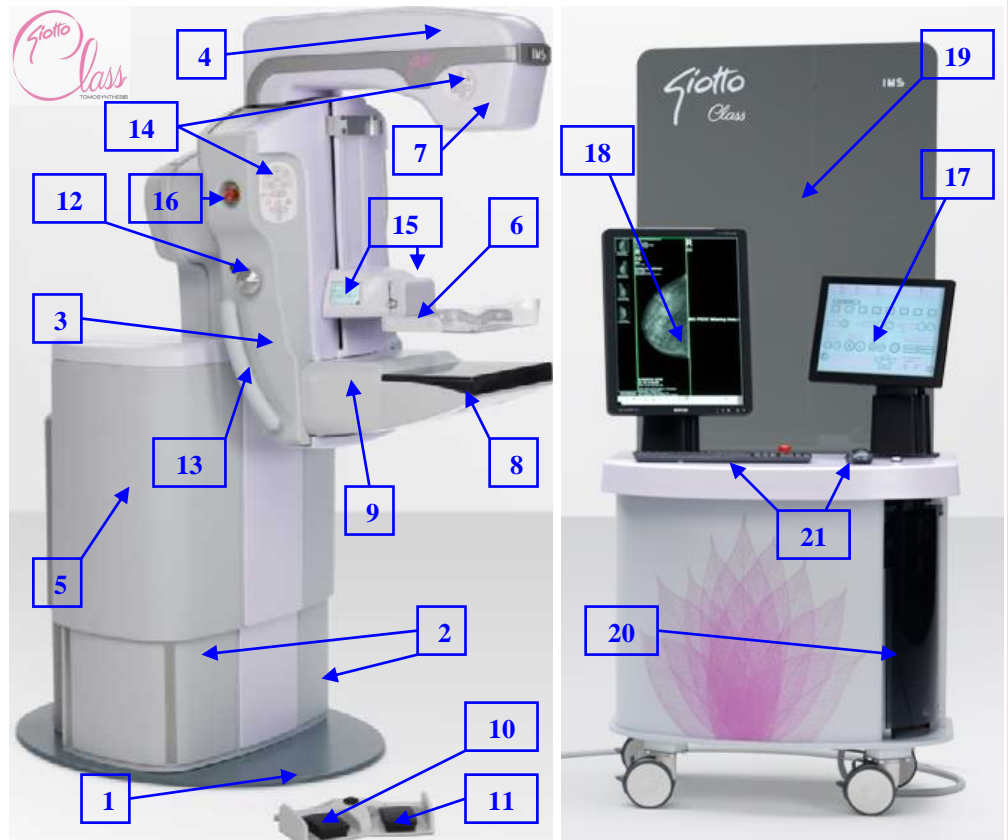
1.1.1.2 Manual mode

If you cannot or do not want to use the automatic exposure control functions, the equipment's exposure parameters can also be adjusted manually.

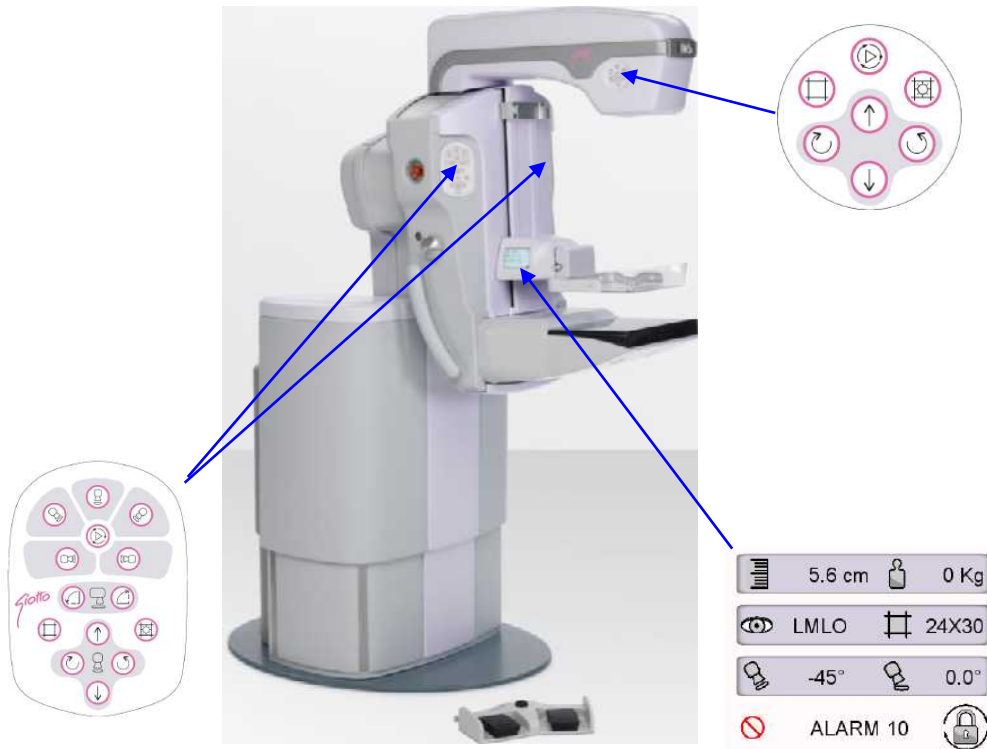
3.1.2. Over all view of the system

The equipment includes the following components:

1. Floor mount base
2. Columns for vertical movement
3. Gantry
4. X-ray tube housing
5. High voltage generator
6. Compressor unit
7. Collimator system
8. Digital detector
9. Retractable potter-bucky system
10. Foot pedal control for compressor
11. Foot pedal control for columns
12. Compressor knob
13. Grab bars
14. Gantry movements keyboards
15. LCD display
16. Emergency push buttons
17. Touch screen monitor
18. 5Mpixel Monitor
19. Anti X-ray barrier
20. PC (AWS) with integrated CD reader/writer
21. Keyboard and mouse
22. UPS
23. Patient support
Flexi Table
24. Biopsy device
Smart Finder



3.1.3. Mammographic X-ray unit



3.1.3.1. Keyboards

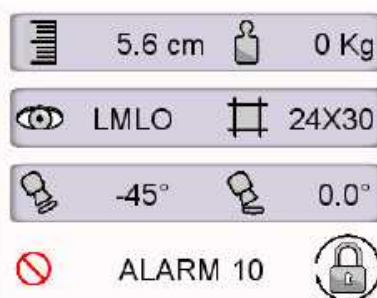


1. Sequences of isocentric positioning
2. Manual selection of collimator format
3. Light indicator (automatic switch-off)
4. Gantry vertical movement to the top
5. Gantry vertical movement to the bottom
6. Rotation gantry clockwise
7. Rotation gantry anticlockwise
8. Preset isocentric position
9. Automatic gantry inclination to horizontal position
10. Automatic gantry inclination to vertical position



1. Sequences of isocentric positioning
2. Manual selection of collimator format
3. Light indicator (automatic switch-off)
4. Gantry vertical movement to the top
5. Gantry vertical movement to the bottom
6. Rotation gantry clockwise
7. Rotation gantry anticlockwise

3.1.3.2. Display



Horizontal view (for tilt angle < 70°) Vertical view (for tilt angle > 70°)

1. Height of compressor paddle (in cm)
2. Compression force (in Kg)
3. Selected projection (laterality and point of view)
4. Collimation format selected
5. Gantry angle
6. Tube angle
7. Status
8. Alarms
9. Movement inhibition

3.1.4. Operator control console



3.1.4.1. Protective barrier

The protective wall prevents the operator performing the exam from being exposed to X-rays.

3.1.4.2. Touch screen panel

→ see the documentation supplied with the touch screen panel.

3.1.4.3. Visualization Monitor TFT

→ see the Documentation supplied with the monitor.

3.1.4.4. Workstation con unità CD-R/DVD-R

→ see Documentation supplied with the workstation.

3.1.4.5. Control table

The following devices are found on the control table:

- X-ray emission button
- Emergency stop button
- Keyboard
- Mouse

3.1.4.1. X-ray emission button

Pressed by the operator to begin the exposure to X-rays.

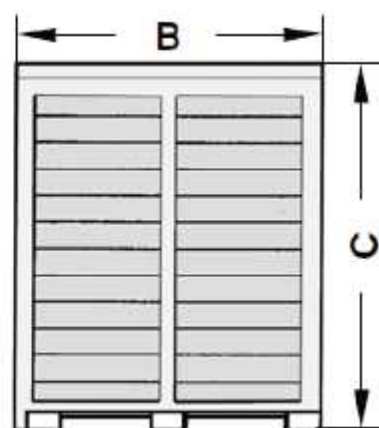
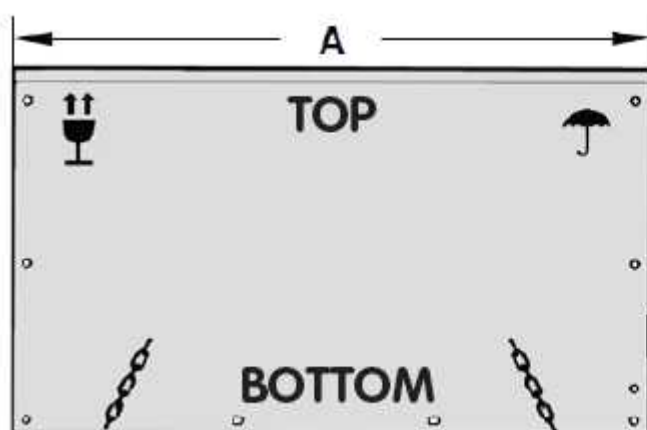
3.1.4.2. Emergency stop button

→ see the "Emergency stop button" paragraph in Section 1 - "Safety".

4. Transport and moving

4.1. Contents of the delivery

4.2. Packing characteristic



	kg	A	B	C
GANTRY	550	2070	870	1960
AWS	185	930	580	1270
DIGITAL DETECTOR	70	113	107	85
RWS (optional)	120	120	70	100

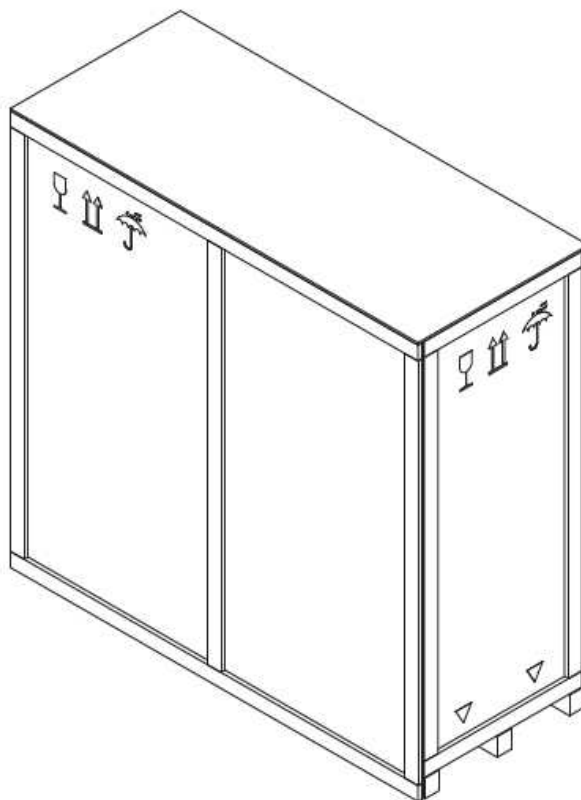
4.3. Components inside the gantry packing



INFORMATION

Irrespective of the type of protective packing used for the GANTRY, the packing case for individual parts or accessories contains the following components:

- **Equipment** secured to a wooden pallet, properly oriented on supporting brackets dedicated.
- **X-ray emission tube**, packed separately in a dedicated box.
- **Accessories supplied with equipment** (face protector), packed in cardboard box.
- **Touchscreen panel and TFT monitor**, protected by plastic material.
- **Pedal controls** protected by plastic material.
- **Keyboard and mouse**, protected by plastic material.



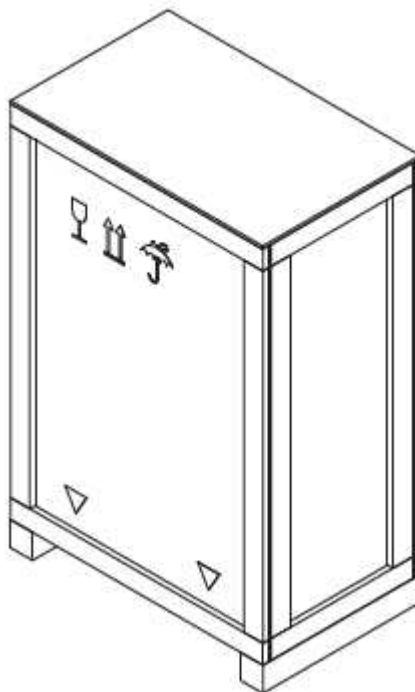
4.4. Components inside the AWS packing



INFORMATION

Irrespective of the type of protective packing used for the AWS, the packing case for individual parts or accessories contains the following components:

- **Acquisition workstation**, protected by plastic material.
- **X-ray protective wall**, properly protected by plastic material.





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4.5. Lifting and moving of packing



- Fully consider the packing characteristics (dimensions and weight).
- All the information below concerning lifting and handling of the packing, should be considered as a guide;

these operations must be strictly entrusted to qualified operators who, according to the characteristics of the

load, lifting equipment, means of transport, and available space, must organize all the operator



INFORMATION

The GANTRY or AWS packing crate can be lifted from above by a crane, hoist, bridge crane, etc., or from below by a fork lift truck; in both cases, take great care (since the contents are “delicate”) and avoid sudden manoeuvres, jerks, impacts, etc...



CAUTION

The Manufacturer declines all liability for damage of any kind caused by incorrect lifting or handling.

4.5.1. Forbidden lifting system



- The lifting systems having the characteristics indicated below, cannot be used:
- Lifting capacity less than three times the equipment's weight.
- Inadequate mechanical characteristics (e.g. forks too short).
- Load-bearing structures, lifting ropes, cables and belts that are either worn or not up to standard.



CAUTION

Keep the pack in a vertical position. If the pack is inclined or resting on one of its sides, this could seriously compromise the condition of the equipment.

4.6. Storage of packed equipment

The GANTRY or • AWS crates (with the exception of the DIGITAL DETECTOR) can be stored for no more than 15 weeks, at the following environmental conditions:

- The digital detector crate can be warehoused or transported for no more than 2 weeks after the thermos bottles are correctly preconditioned. A label on the Digital Detector crate reports the expiry date.

4.6.1. Gantry and AWS storage conditions

- The table below gives the conditions that must be met during storage of the GANTRY and the AWS.

	MIN	MAX
Humidity	10%	80%
Temperature	10°C = 14°F	- 80°C = 176°F
Atmospheric pressure	700hPa	1060hPa



WARNING

If the equipment is stored while packed, do not stack the packing crates on top of one another



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4.6.2. Digital image receptor storage conditions

- The table below gives the conditions that must be met during storage of the DIGITAL DETECTOR.

	MIN	MAX
Humidity	10%	95%
Temperature	5 °C = 41°F	45°C = 113°F
Atmospheric pressure	700hPa	1060hPa



WARNING

If the equipment is stored while packed, do not stack the packing crates on top of one another.



CAUTION

Do not stack other crates on top of the digital detector crate!!!

4.7. Removing the gantry from the pack

- Be careful of any nails, especially on the top of the pack.
- Remove protective plastic and check that the contents correspond to the attached packing list; promptly notify **I.M.S.** of any missing items or damage to the equipment.
- Remove the bags containing the dehumidifying salts and store them in a dry place.

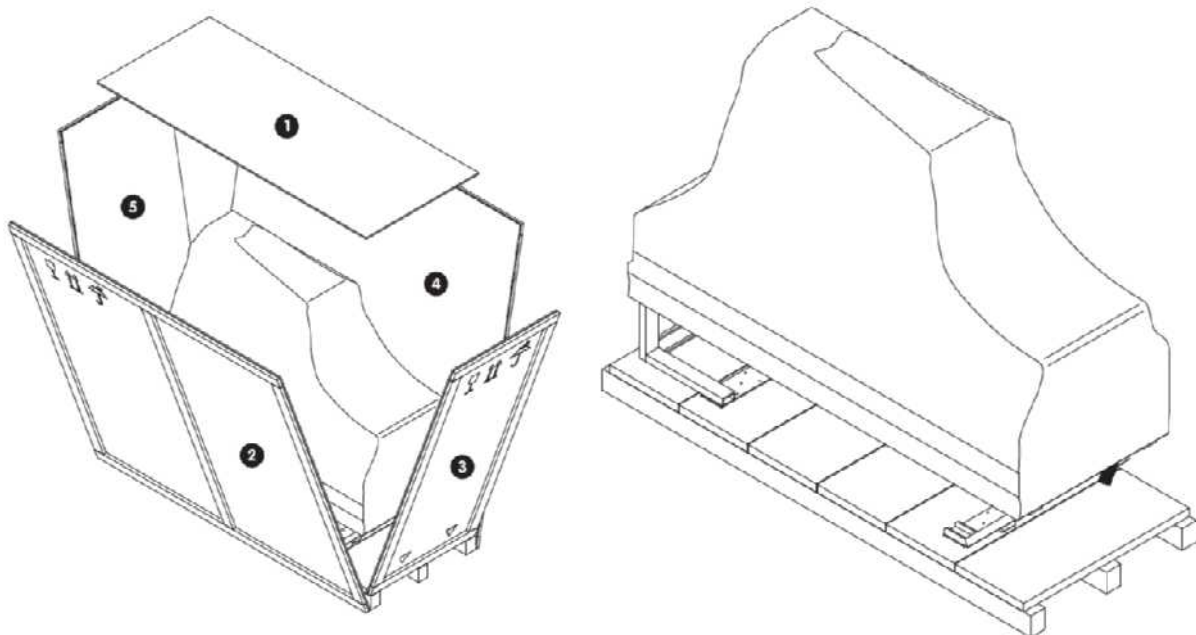


Image under revision



WARNING

The equipment should be unpacked according the order shown in the figure. Make sure not to bang any parts of the equipment as it may cause damage.

- Remove the other packs from the wooden pallet and open them with caution.
- Remove the packing material from the equipment.

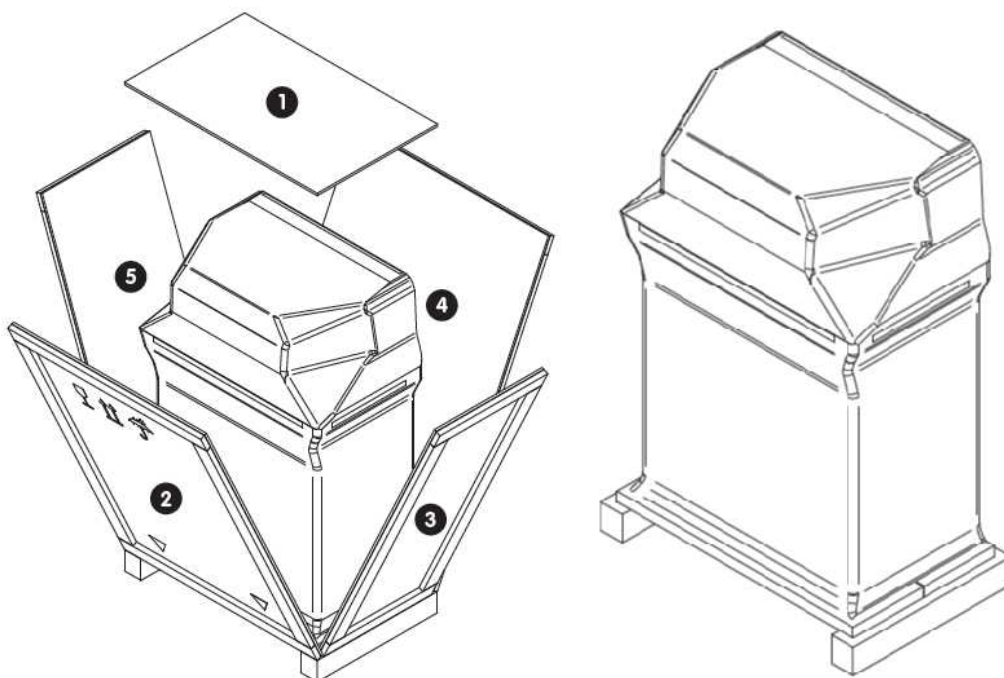


INFORMATION



We recommend that at least **two people** be used to remove the GANTRY from the wooden pallet.

4.8. Removing the AWS from the pack

- Be careful of any nails, especially on the top of the pack.
- Remove protective plastic and check that the contents correspond to the attached packing list; promptly notify **I.M.S.** of any missing items or damage to the equipment.
- Remove the bags containing the dehumidifying salts and store them in a dry place.



- Remove the other packs from the wooden pallet and open them with caution.
- Remove the packing material from the equipment.

	<p>WARNING</p> <p>The equipment should be unpacked according the order shown in the figure. Make sure not to bang any parts of the equipment as it may cause damage.</p>
	<p>INFORMATION</p> <p>We recommend that at least two people be used to remove the GANTRY from the wooden pallet.</p>

4.9. Disposal of the packing

- Separate the packing materials and dispose of them in compliance with current regulations on the disposal of solid waste.
- The packing materials (wood, cardboard and pluribool) are 100% recyclable.





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4.10. Instructions for the handling, storing and packing of digital detector

	<p>CAUTION</p> <ul style="list-style-type: none">• If the temperature of the detector drops below 10°C, it may be irreparably damaged (the nature of the damage is equal to about 80% of the total cost of the detector).• It has been statistically calculated that this pack has a duration of about 15 days.• Once the detector has been received from I.M.S. S.r.l., it must be stored in a room with a temperature between 5°C and 45°C.• If the detector must be shipped by air or by truck in temperature conditions that are outside the limits, only the original pack can be used and it must be prepared as described below.• The warranty will be void if there has been tampering with the anti-intrusion labels.• The warranty will be void if the temperature sensor shows that the limits have been exceeded.
	<p>INFORMATION</p> <p>If the detector is not returned in its original packaging, immediately take a picture of the packaging and the detector and report this to the UT for verifications of the case</p>

4.10.1. Instruction for packing the digital detector before shipment

1. Insert the mammography Detector inside a transparent "ESD" plastic bag.



2. Hermetically seal the bag and wrap it with adhesive packing tape.
3. Open the box and insert insulating material.
4. Place the prepared Detector inside the cardboard box, with the carbon fiber side facing upwards.



5. Close the cardboard box and seal the flaps with adhesive packing tape.
6. Prepare the "EXOGENS" containers by heating them until the material contained in the bottles become completely liquid (the oven thermostat must be positioned at the temperature reported on the oven, or rather max. 45°C) for about 8-10 hours.



CAUTION

Put the containers in the oven at about 17:30 and leave the oven on overnight. Once the EXOGENS containers are completely heated, remove them from the oven and let then "rest" for about 15-20 minutes. After this period, check the temperature of each container using the **I.M.S. S.r.l.** 118 infra-red thermometer; their temperature must be approximately 35°C (not higher than 37°C).

7. The containers can now be placed in their casings. Once the EXOGENS containers are inserted, make sure that the temperature inside the pack does not exceed 45°C.



8. Insert the box containing the Detector, inside the cardboard packing box.
9. Install the insulation foreseen for the EXOGELS containers, inside the pack. See recommendations in part 7.




10. Insert a copy of these instructions (in English) in the pack along with a photograph of the bottom part of the detector showing the status of the thermometers and the detector serial number. Put the pack's cover on. Apply a label containing all the identification data of its content on the outside of the packing.





11. Apply the label below (in A4 format) to all sides of the pack (besides the bottom).
12. Write the pack preparation date and the initials of the operator; indicate the expiry date of the thermal package (15 days from preparation date).




	<p align="center">ATTENZIONE / CAUTION!</p> <p align="center">Imballo termico / Thermic package</p> <p align="center">Preparato il / Prepared on _____ da / by _____</p> <p align="center">Scade il / Expires on _____</p> <p align="center">Oltre la data di scadenza immagazzinare tra 5°C e 45°C After the expiring date store in a temperature within 5°C and 45°C</p>
---	---

13. The duration of this thermal package depends on the external temperature. After several shipments between Italy and Canada performed during the winter, we have determined that the package lasts about 15 days. Therefore, the shipment must be organized in such a way that the time between its departure from I.M.S. S.r.l. and its receipt by the end customer does not exceed 15 days.

5. Installation

5.1. Ambient requirements conditions

→ see the [“Technical Data” paragraph in Section 2 - “General Information”](#).

	<p>CAUTION!</p> <p>If the temperature drops below the temperature value indicated in the table, the detector is at risk of being permanently damaged. In this case the warranty will no longer be valid.</p>
	<p>CAUTION!</p> <p>The equipment must be installed in environmental conditions that respect the conditions given in the table. It must not be installed in places where appliances that alter these environmental characteristics are present.</p> <p>The operating temperature must be maintained within the range of +12°C to +27°C. If the detector temperature drops below +5°C or exceeds +45°C, there is a risk that the detector may be permanently damaged.</p>
	<p>CAUTION!</p> <p>The detector needs a special pack for transportation. This pack ensures a suitable temperature for a certain period of time. This time depends on the transport conditions (cannot be more than two weeks). Consult the I.M.S. S.r.l. Technical Service Dept. for more information about transportation and storage conditions. If the detector temperature drops below +5°C or exceeds +45°C, there is a risk that the detector may be permanently damaged.</p> <p>The detector must be transported under controlled temperature conditions.</p> <p>Using the pack provided by I.M.S. S.r.l., the internal temperature is guaranteed to remain above +10°C with an outside temperature of -40°C for 48 hours (if the pack was correctly prepared). See I.M.S. S.r.l. packing instructions.</p>



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5.2. Preliminary radiology room inspection

Before beginning installation, inspect the X-ray room to ensure that it complies with the following specifications:

- Door minimum width: 75 cm
- Electric line with distribution box (→ see the [“Environmental requirements conditions”](#) paragraph at this Section).
- Floor plan with the layout of the equipment.
- ETHERNET data network.
- X-ray protection devices.

5.3. Preliminary mechanical clamping inspection

Check the integrity of the mechanical clamping after transport, in the following critical mechanical group before to proceed with the installation.



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5.4. Installation procedure

5.4.1. Necessary tools

- HAMMER DRILL
- CONCRETE BITS Ø 10 - Ø 18
- VARIOUS WRENCHES (socket and Allen wrenches)
- STANDARD AND PHILIPS HEAD SCREWDRIVERS (in different sizes)
- HAMMER
- PINCERS (in different sizes)
- LEVEL



WARNING

The selecting of the position to install the equipment must not depend only on the it's actual dimensions, but one should also make sure that there is sufficient perimeter space to ensure that all preparation, inspection, routine and non-routine maintenance operations can be carried out in a highly rational manner, and that the work area is ergonomic.

5.4.2. Positioning and fixing of the gantry

- Move all the equipment into the room and position them as close to their final locations as possible. Leave working area around each equipment until final assembly is complete.
- Before beginning the final positioning, check that the floor of the room is able to withstand the declared weight (with the safety margins specified by the current regulations) and that the surface is as uniform as possible.
- When you have determined the final position where the equipment will be permanently installed (fixed), position the base of the equipment and drill the holes **1** in the floor for anchoring the base-plate.



CAUTION!

The supplied anchoring kit must be used to fasten the equipment to the floor.

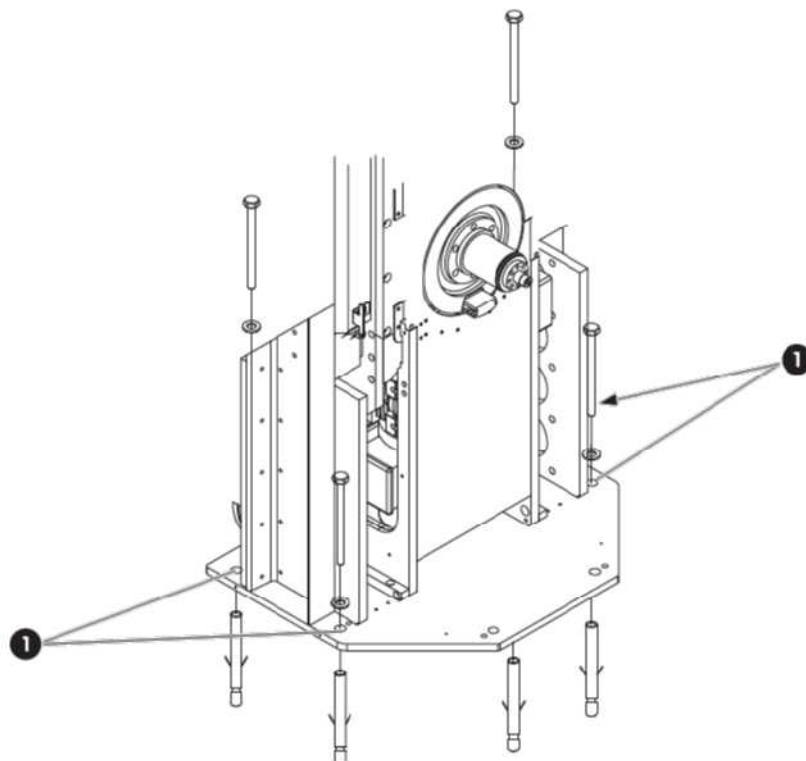


Image under revision



CAUTION!

The levelling screws can protrude about 1 cm, insert a spacer if this is not sufficient.





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- Floor loading: 1000 kg/m² (200 lb/ft²)
- Tension load 4KN
- Anchor point shear load 3KN

	<p>INFORMATION</p> <p>Bolt hole locations are approximate, and represent the recommended locations for equipment placement.</p> <p>It is the responsibility of the customer, or their agents to verify that the floor is capable of supporting the equipment floor loading, and anchorage requirements.</p>
---	--

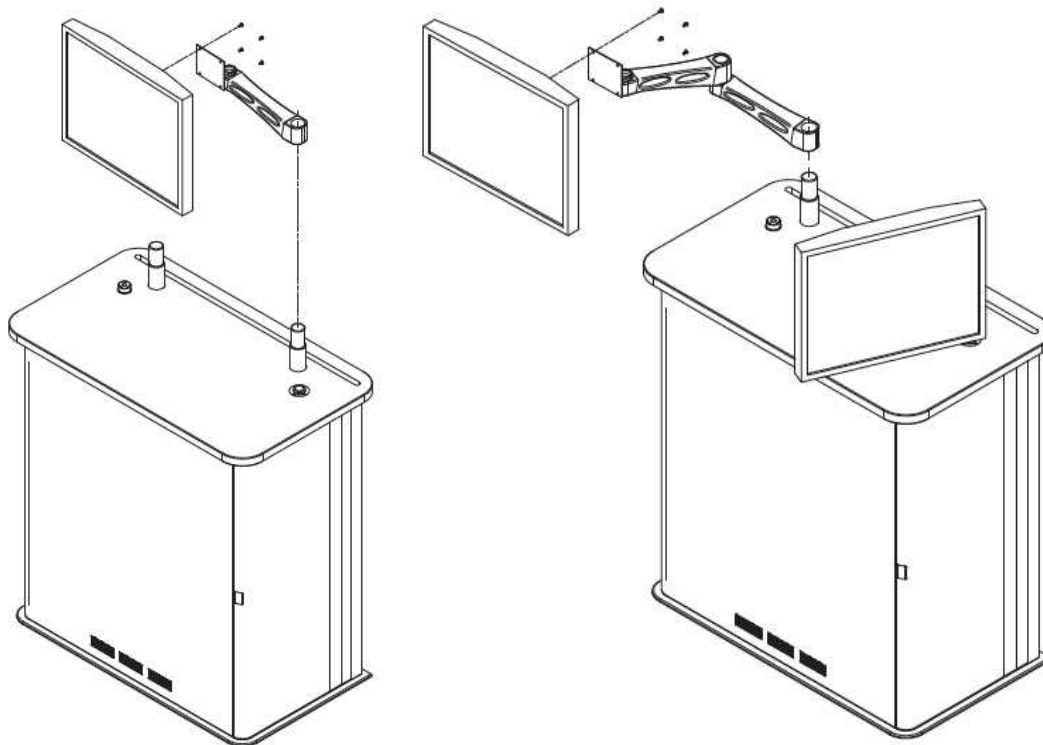
	<p>CAUTION!</p> <p>Before starting, it is recommended that at least two people carry out the listed operations.</p>
---	--

- Position the unit near the foreseen installation area.
- Remove the two lateral guards **3** and **4**.

5.4.3. Installation of base cover



5.4.4. Touch Screen Panel and TFT Monitor Installation

Refer to the monitor replacement procedure.



Images under revision

5.4.5. Installation of the operator protective barrier

	<p>CAUTION!</p> <p>The screen protecting the radiology technician during the mammography examination must be handled very carefully.</p>
	<p>INFORMATION</p> <p>The protective screen conforms to the following standards: EN 60601-2-45 / EN 60601-1-3 and is equivalent to 0.1 mm Pb</p>

Proceed as follows to install it:

- Remove the front panel **1** from the electric cabinet.
- Fit (with extreme care) the X-ray lead glass panel **2** inside the special housing **3** on the control table **4**.
- “Accompany” the glass panel with both hands until it reaches the end of the housing.



INFORMATION

Install the X-ray lead glass panel, with the word “Giotto” at the top and legible from the side opposite the operator.

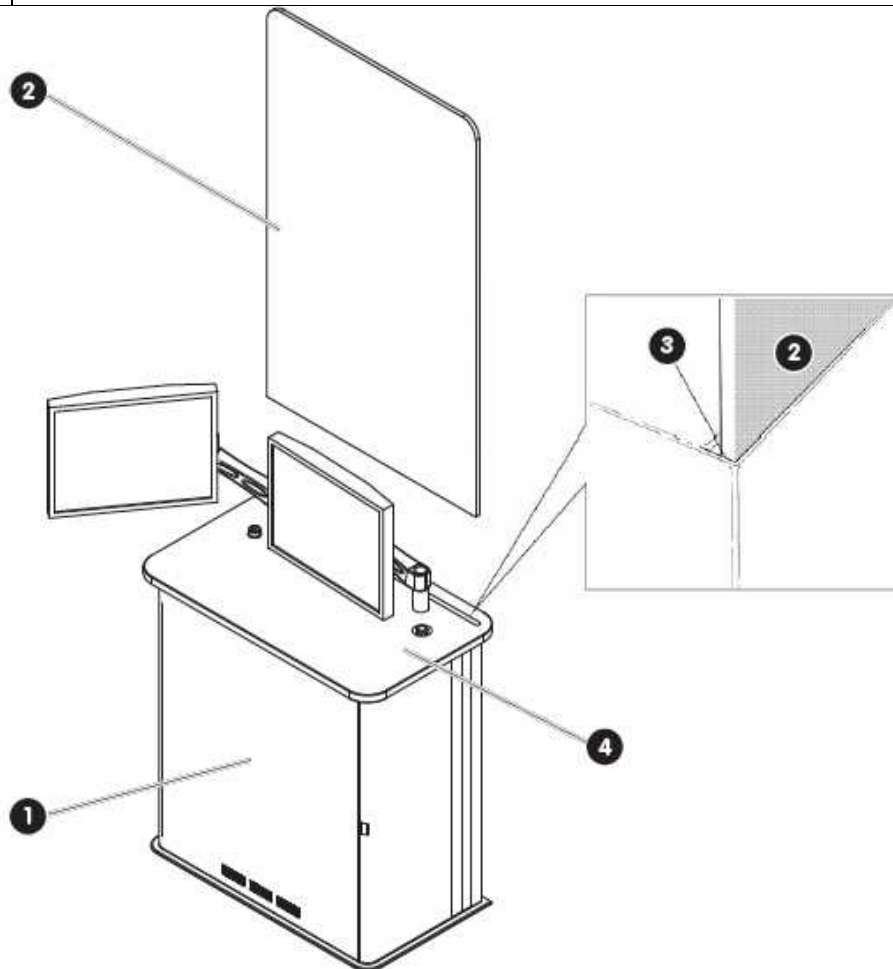


Image under revision



INFORMATION

The weight of the glass and the “mandatory” housing should be sufficient to ensure the stability of the glass. However, the glass panel must be anchored to the structure of the electric cabinet by four nylon screws.

After installing the panel, reposition and secure the electric cabinet panel.

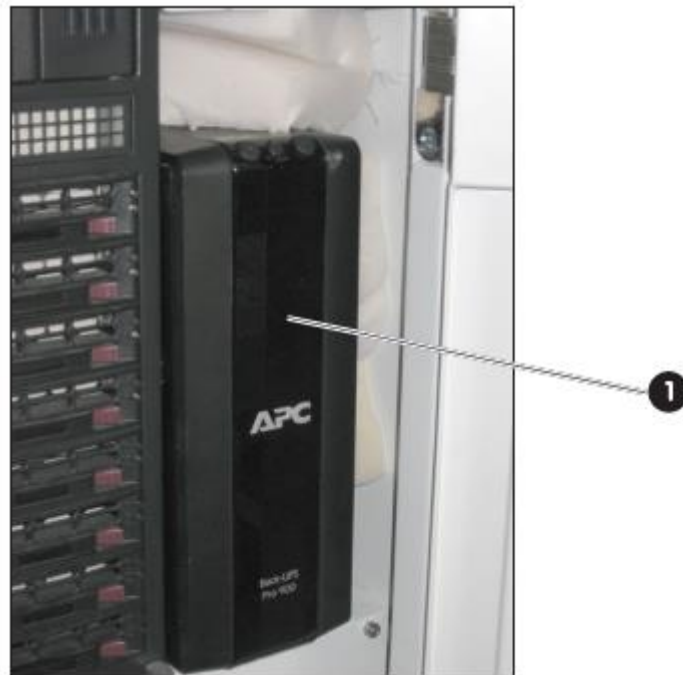


CAUTION!

It is strictly forbidden to use the vertical X-ray unit (GANTRY) without the electric cabinet panel.

5.4.6. Removing the U.P.S. locking material

The upper and side part of the U.P.S. 1 may be locked (depending on the type of packaging) with a plastic shim (or other material). This shim must be removed and stored for future moving of the unit.



5.4.7. Connections between X-ray unit (Gantry) and Acquisition Work Station (AWS)

The various cables coming from the vertical X-ray unit (GANTRY) enter through the lower part of the acquisition workstation (AWS) and are connected as shown in the figure.



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5.4.8. Connection of High-Voltage cable

5.4.9. Installation and connection of the X-ray tube

5.4.10. Digital detector installation

5.4.11. Connection of the equipment to the power supply line

5.4.12. Electrical safety checks

5.4.13. Auxiliary signaling and safety connections

5.4.13.1. Connection of door contact and the warning lights



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6. Preliminary operating check

6.1. Checks before using the unit

Each equipment is tested at the factory before shipment. List of the tests performed:

- Mechanical alignment of moving parts.
- Mechanical calibration of transducers (potentiometers, encoder pressure sensors).
- Calibration of mechanical actuators software through PARAM TOMO software.
- X-ray tube software calibration.
- Calibrate touch screen software.
- Calibrate acquisition geometry.
- High voltage check with voltage divider and oscilloscope.
- Check of the anode current with oscilloscope.
- Check of the mAs with mAs meter.
- High voltage check with non-invasive instrument.
- (HVL) filtration check.
- Check of dose and dose rate.
- Check of X-ray field and light field collimation.
- Check of the electrical interface with digital detector.
- Check of the digital detector's electrical noise level.
- Digital detector high voltage and lamp voltage check.
- Digital detector calibration check.
- Check of defective pixels and image artefacts.
- Check of the Potter-Bucky diaphragm and grid erasing.
- Check of the automatic exposure meter.
- Check of digital image acquisitions with "Raffaello" application software.
- Check image quality.
- Check of DVD mastering function.
- Network connection check (service and image transfer).
- Check of USB interface.
- Check that all the accessories are included in the shipment.
- Check electrical safety.



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6.2. Initial start-up

The following must be checked the first time the system is started up:

- Emergency stop buttons.
- Surface of the compressors.
- Head rest surface.
- All parts in contact with patients.
- Breast support table.
- LCD display in the base of the equipment.
- Visual check of external parts to the equipment.
- Cable ducts.
- Mounting of the covers.
- Stability of the equipment.
- Tightness of fastening screws.
- Correct collimation of the X-ray field.
- Since the equipment was completely tested before shipment, the operations to be performed are limited and the risk of damaging the equipment is very low.
- The connection cables between the control console and the stand are all different from one another in order to avoid connection errors. All the boards have circuit breakers if the polarity of the power supply is inverted.

Therefore, after the power supply check, the equipment can be switched ON.

Instruments: digital multimeter.

- With all cables connected and the equipment connected to the mains network and to the data network:
- Main switch in OFF position. Apply power through the external electrical panel and check that the voltage on the input terminals of the main switch is correct. Also check the protective earth connection.
- Turn the main switch to the ON position. Verify that all the boards are powered, that LEDs are illuminated and fans are working, the message OFF STATE must appear after approximately 30 sec.
- Turn on the UPS switch. Wait a few seconds and verify that the UPS switches from battery to mains power. (The UPS always uses the battery when turned ON and after a few seconds, if the mains power is present, it switches to mains power. When operating on the battery, an intermittent




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buzzer sounds; the switch to the mains network is recognized by the sound of a relay and by the fact that the buzzer no longer sounds.

- Check of digital image acquisitions with “Raffaello” application software.
- Check of DVD mastering function.
- Network connection check (service and image transfer).
- Check of USB interface.
- Turn ON the workstation using the start button.
- Wait for the operating system to start then enter the password (Username: **administrator**).

	INFORMATION For security reasons, the password occasionally changes. (Consult the I.M.S. S.r.l. website http://www.imsitaly.com).
---	--

- Turn ON the power circuits, green button located under the main switch. The main contactor of the power circuitry must close and the equipment must perform the following self-diagnostic operations within a few seconds:
 - Test collimator, change filter and lamp.
 - Filter wheel and lamp test.
 - Test the anti-scatter grid and potter movement.
 - Test movement of the X-ray tube.
 - Test the compressor.
- If all the tests are successful, the message AUTO will appear on the touch screen display and the machine will be ready for use.
- Manually check the up/down movement of the column, the rotation both manual and programmed and the tomo movement by performing the relative test (Consult the PARAM TOMO programme guide for further details).
- If present, check the operation of the MAMMOBED and BIOPSY.
- Checking the correct collimation of the X-ray field. (• see the “Collimator “ paragraph in Section 13 -“Interventions on the unit”).



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6.3. Troubleshooting before initial start-up

- After turning the main switch ON, the message “OFF STATE” does not appear on the control console:
- Based on the type of alarm message, consult the alarm message section for further information.

The typical problems are:

No communication between the boards:

Check that the cables for the Ethernet network and for the equipment are inserted correctly.

No power to the electronic boards:

Check that all the boards have +24V logic, check the fuses, power packs and connection cables.

Emergency chain open:

Check the emergency stop buttons and verify the connections of the equipment's real time bus cables. The control console S856 board has two red LEDs that must be ON (one is for the emergency stop button and one for the equipment's fault chain).

If there is no power to the 24V logic, check the fuses in the control console and in the boards, check the insulation tester, etc.

Data network connection error:

If the hospital data network is connected to the SERVICE port (connector JC56) instead of the external port (connector JC26), communication between the electronic boards may not be activated and the unit does not start. The error could also have consequences on the hospital data network. Check the connections in the AWS workstation.

The UPS does not turn on:

The UPS battery must be recharged at least every 3 months if inactive. If the battery is completely dead the UPS may not start correctly.

Check that the power switch on the front of the UPS is in the ON position.

The workstation doesn't turn on:

Check for the presence of electrical power.

Verify that the power switch on the workstation is in the ON position.

Check that the control connector from the workstation to the control console keyboard is correctly connected.



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The LCD monitor doesn't turn on:

Check the power supply voltage.

Check that the DVI cable is connected to the workstation.

WINDOWS doesn't start:

Check that the mouse and keyboard are connected.

Use the USB pen drive attached to the equipment. Put it in the USB port located on the metal frame of the control console and start the workstation; if Windows starts normally, this means that the hard disk is corrupt.

The motors do not move:

Verify the compression force reading if the display on the base shows a compression force > 3 kg, all the movements are inhibited and the compressor is free (without compression active). The compression force reading mechanism needs to be checked (without compression force it must always be 0 kg).

Verify the presence of the supply voltages: +24V power and 30V motors.

Vertical motor doesn't move:

Verify that the 320V voltage is present in **board S865**, this voltage comes from the high voltage inverter and there is a delay circuit to activate this voltage. This is due to the charging time of the filter capacitors inside the inverter.

Errors with X-ray sequence in "M2" service mode:

Check the connection cables between the X-ray tube and the S866 board. All the X-ray functions are managed by this board.

In normal operating mode with "Raffaello" application software the system is not ready for X-ray emission (red or orange):

Wait at least 5 minutes.

Check the communication with the detector using the GMD SERVICE program.

Check with the ParamTomo program, under the menu **Diagnostic->Detector->Digital IOs**, that the PLATE_

SYNC signal pulses correctly 2.8 sec. (MAMMO) / 1 sec. (TOMO). For versions of the "Raffaello" application prior to 2.2.x.x. check that the PLATE_SYNC signal is pulsing correctly 3.5 sec. (MAMMO) / 1 sec. (TOMO).



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Verify the power supply voltage for the detector, board S801.
Check the status LEDs on board S878.

6.4. Quality checks before clinical application

After checking that all the equipment's functions are ON and operational, the radiological parameters, image quality and compression values, collimation, etc. must be checked using suitable instruments that are calibrated and in good working order before the clinical examination can be performed on the patient.



CAUTION!

To perform mammograms on patients the quality checks must be carried out by qualified personnel and must be within the acceptance limits. **I.M.S. S.r.l.** cannot guarantee the clinical result if all these checks are not performed.

These are standard quality checks for mammography equipment. Refer to the "Quality assessment of the Flat-Field image" Section in this manual for a brief guide or refer to the digital mammography quality protocols (vary from country to country).

These checks must be done in accordance with local laws.

To evaluate Flat-Field images, or for problems relating to the correct operation of the X-ray tube or the digital detector, refer to the specific chapter.

6.5. Connection to the DICOM network

The equipment can be connected to the DICOM network through the "Raffaello" application software in order to exchange images and clinical data.

Refer to the DICOM CONFORMANCE STATEMENT for more information on the available functions.

To configure the equipment for a DICOM connection, some parameters in "Raffaello" application software and the equipment's AWS acquisition workstation normally need to be set.

Read the of "Raffaello" application software guide for further details.



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6.6. Operator instructions

To complete the commissioning of the equipment the operators, radiologists and technicians need to be trained on its use.

For this, the following must be done:

- Explain the operator's manual.
- Power ON and power OFF procedure.
- Procedure to identify an alarm on the equipment and how to resolve it.
- Both manual and automatic movements for the equipment.
- Installation of accessories and use.
- Use of the "Raffaello" application software.
- Daily quality checks.
- Breast phantom and mammography simulation and technical explanations of radiographic work techniques.
- Use of the BIOPSY.
- Use of the MAMMOBED.
- Transmission of the images to PACS and RWS.
- How to manipulate images for diagnostic use.
- Printing of images and image transfer to CD DICOM.

7. Method of use

7.1. Equipment

7.1.1. Preliminary operations before switching on

7.1.1.1. Cleaning

→ see Section 1 - "Safety".

7.1.2. Switching on/Operating

The X-ray unit, the operator control console and the UPS are switched on separately by means of their own switches.

The monitors can be switched off separately or using the main switch.

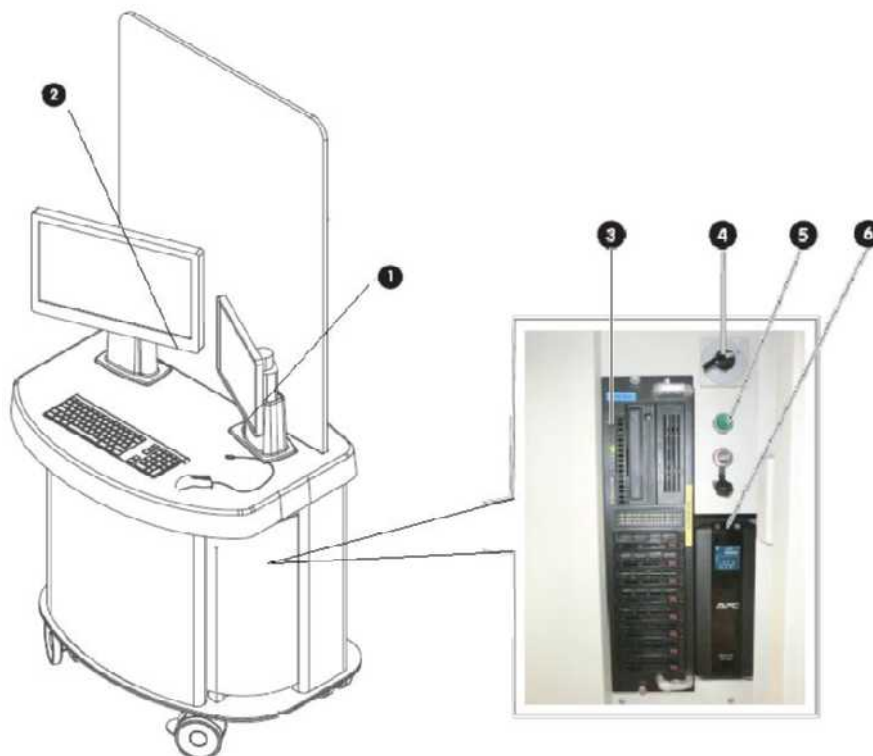


Image under revision

- 1) On/Off switch for the touchscreen panel
- 2) On/Off switch for the TFT monitor
- 3) On/Off switch for the workstation
- 4) Main On/Off switch
- 5) On/Off switch On/Off switch for insertion circuits
- 6) On/Off switch for the UPS



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Starting the system when off

If the equipment was switched off using the master switch, the entire system needs to be restarted.



CAUTION

Limited image quality caused by incorrect use.

The equipment's detector needs to warm up for about 15 minutes before images can be generated.

- ◆ Switch on the master switch located in the room.
- ◆ Press the On switch on the control unit to start the equipment.
 - The internal control system automatically performs a functional check of the equipment.
- ◆ Switch on the UPS.
- ◆ Switch on the workstation, the touchscreen panel and the monitor of the acquisition workstation.
 - The workstation switches on.
- ◆ Log into the workstation.
- ◆ Let the equipment warm up for about 30 minutes before performing an optimal image quality test or a calibration.
- ◆ Login with a username and password is required if access protection was set in the user management section.

For further information refer to Section 9 - "User management and access protection" of the GIOTTO CLASS Operator Manual.

7.1.1. Calibration

The detector settings may be modified by outside factors (for example: changes in temperature, humidity and vibrations). This is why the detector must be regularly calibration.

The calibration procedures must be performed by **IMS S.r.l.** technical personnel at the frequency indicated by the "Raffaello" application software".



CAUTION

Limited image quality caused by incorrect use.

If the software indicates that a calibration has gone beyond its foreseen interval, optimal image quality cannot be guaranteed.

Contact the Support Service as soon as possible.

7.1.1.1. Daily check

Prima di iniziare la sessione di esami è richiesta una verifica della qualità di immagine mediante una procedura automatizzata.

→ see Section 7.11 - "Quality Control Procedures".



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7.1.2. Method for basic use

7.1.2.1. Safety during the examination



WARNING

Risk of injury due to moving parts on the equipment.

The equipment's motorized movements can crush or trap parts of the body.

- ◆ Make sure that the patient is positioned correctly. Be aware of possible spots on the equipment that can cause injuries or crushing.
→ see Section 1 - "Safety".
- ◆ In case of emergency, immediately press one of the red emergency stop buttons located on the vertical X-ray unit and on the acquisition unit
→ see Section 1 - "Safety".
- ◆ Before activating the isocentric functions, make sure that the patient, staff and third parties are not exposed to risks during the movement of the mobile arm.



WARNING

Incorrectly recorded patient data can lead to incorrect results.

Incorrect diagnosis or unnecessary exposure to radiation if the X-ray needs to be repeated!

- ◆ Before every exam, check that the patient corresponds to the data and to the procedure loaded into the system.



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7.1.2.2. Performing the examination

How to perform the exam:

On the acquisition workstation

- 1) Open a new study using the appropriate procedure.
→ see in the present section at the paragraph "[Patient Registration](#)".
- 2) Select the exposure mode (Auto/Man) and, if necessary, manually set the exposure parameters.
esposizione
→ see in the present section at the paragraph "[Exposure data setting](#)".
- 3) Select the side of the first projection (if an exam protocol has been configured, the first projection will be automatically proposed).
→ see in the present section at the paragraph "[Manual setting the projections](#)".

On the x-ray unit

- 4) Mount a suitable compression paddle for the exam.
→ see in the present section at the paragraph "[Compressor Paddle](#)".
- 5) Eventually apply the face protector.
→ see in the present section at the paragraph "[Face protection](#)".
- 6) Set the gantry to the desired projection angle.
→ see in the present section at the paragraph "[Gantry position setting](#)".
- 7) Set the gantry to the appropriate height and tilt angle.
→ see in the present section at the paragraphs "[Gantry height adjustment](#)" and "[Gantry tilt angle adjustment](#)".
- 8) Place the breast to be examined on the breast support surface based on the view selected from the acquisition workstation.
- 9) Lower the compression paddle using the foot switch or the handle.
→ see in the present section at the paragraph "[Compression using the foot-switch](#)".
- 10) Make sure that the breast is correctly compressed. Use the lighting to ensure that the compression does not cause folds in the skin. If possible, the profile of the nipple should be visible.
- 11) Make sure that only the breast to be examined is in the irradiation field.



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On the acquisition workstation

12) Check the exposure parameters.

13) Wait for the X-ray button to light (green) before beginning the X-ray.

14) Press and hold the X-ray button on the control unit for the entire time you hear the acoustic signal.

- During the X-ray, the radiation symbol will appear on all the displays (black clover with yellow background).

- The irradiation begins and the first exam image is created.

15) The irradiation indicator must remain on only when the start X-ray button is pressed. Comply with the measures regarding radiation protection.

16) After the image has been created, it will be displayed in the appropriate area.

17) Make sure that the breast is automatically or manually decompressed after the X-ray.

18) Check the image's quality.

If necessary, cancel the image and repeat the operations from 10 to 20.

→ refer to the "[Delete images](#)" paragraph of this section.

19) Repeat the operations from 2 to 18 until all the projections have been performed.

20) Finish the exam.

→ refer to the "Concluding the exam" paragraph of this section.



CAUTION

Unnecessary exposure to radiation if the X-ray needs to be repeated.

If the button is released before the acoustic signal finishes, the exposure will be interrupted and the image will be underexposed.

The digital X-ray is automatically displayed on the TFT monitor about 3 - 5 s after the end of the entire acquisition. The AWS P.C. needs this time to acquire the image, apply the standard corrections and to adapt the image to the mammography standard. During this stage, the image is adapted to improve the aspects when viewed by the technician for the first time. In the case of tomosynthesis or combo acquisition, the reconstructed volumetric image will instead be available about 1-2 minutes later depending on the volume dimension.

7.1.3. Compressor Paddle

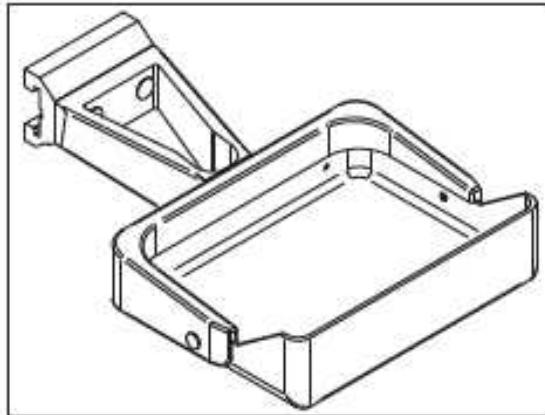
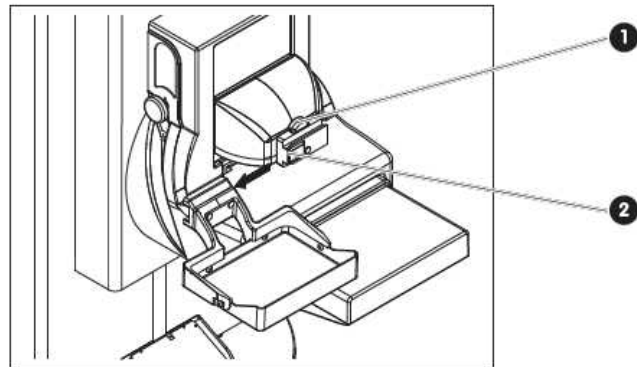
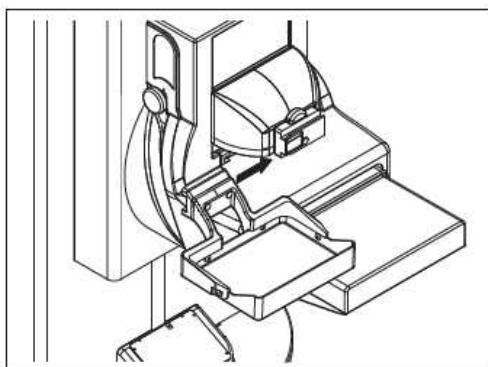


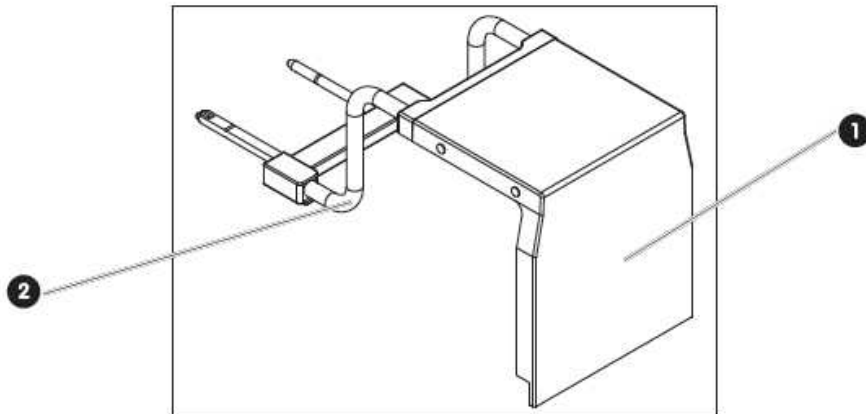
Image under review

- ◆ Insert the compression paddle with the guide into the compression housing unit by making a left to right movement.
- The compression paddle automatically locks.
- ◆ Keep lever **1** pressed.
- ◆ Slide the compression paddle out laterally by removing it from the housing guide **2**.



Images under review

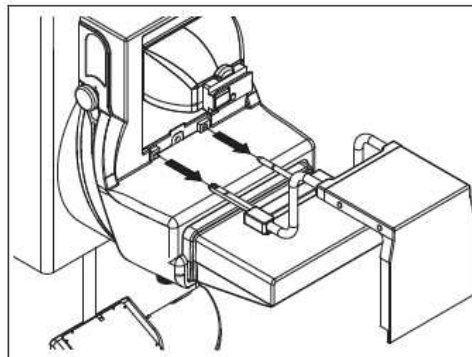
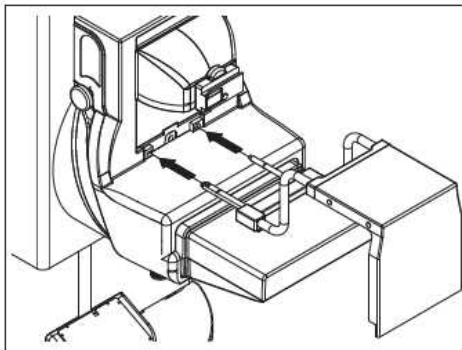
7.1.4. Geometrical Magnification device



Images under review

The magnification device provides a 1.8 magnification factor.

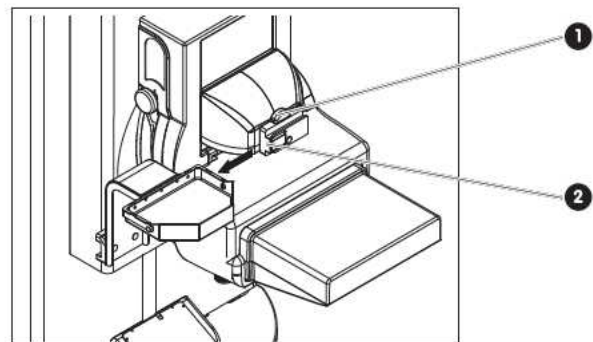
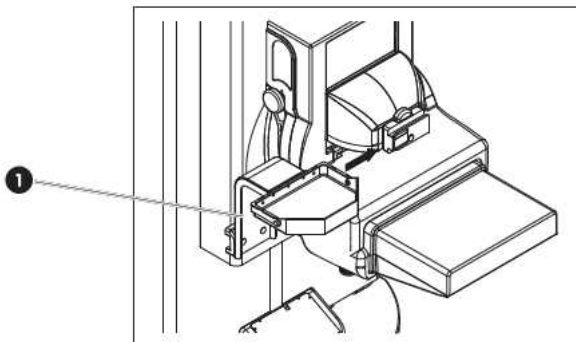
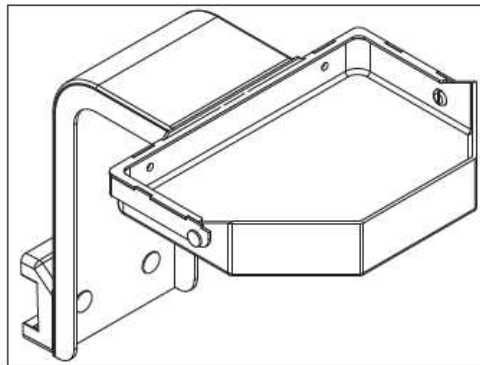
- ◆ Using the side handles, insert the magnification device into the support.
- ◆ Grasp the handles on the side of the magnification device and pull towards yourself to remove it from the support.



Images under review

For selective spot projection, use a compression paddle for zooming or for spot projections and zooming.

7.1.1. Compressor Paddle for Magnification device



Images under review

Insert the magnification device compression paddle with the guide in the compression housing unit by making a left to right movement.

– The compression paddle automatically locks.

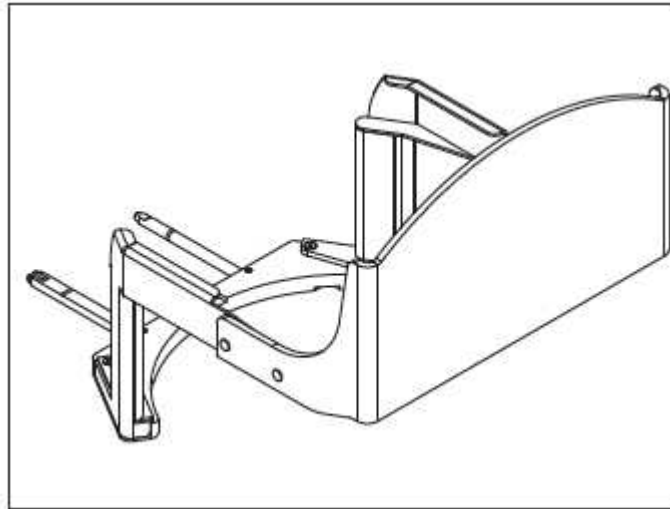
1) Area for grasping the magnification device compressor when mounting and dismounting.

◆ Keep lever **1** pressed.

◆ Slide the magnification device compression paddle out laterally by removing it from the housing guide **2**.

7.1.1. Face protection

The face protector prevents the patient's head from being in the trajectory of the X-rays.



Images under review

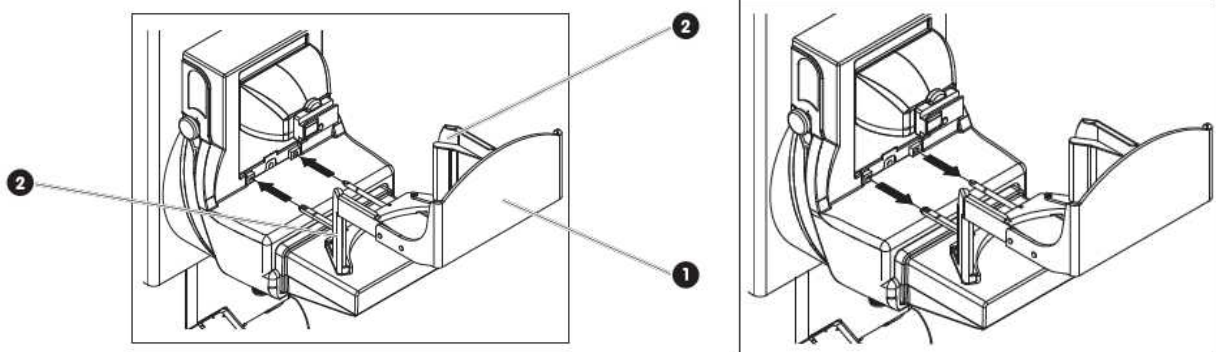
◆ Using the handles, insert the face protector in the support.

1) Face protector

2) Area for grasping the face protector when mounting and dismounting.

The face protector must be removed when using the magnification device.

◆ Grasp the handles on the side of the face protector and pull towards yourself to remove it from the support.



Images under review

7.1.2. Gantry position setting


The setting of the projection angle and the gantry height is motor assisted.

The special keys on both sides of the mobile arm and the compression unit are used to control the movements (→ see Section 3 - “Panoramic view of the system”).

The height can also be adjusted using the foot switch (→ see Section 3 - “Panoramic view of the system”).



7.1.2.1. Gantry movements warnings

	<p>WARNING Risk caused by the motorized movements of the equipment. Injuries caused by collision or entrapment of the patient.</p> <ul style="list-style-type: none"> ◆ When adjusting the gantry height, make sure that no parts of the patient's body are in the risk zone (→ see Section 1 - “Safety”). ◆ When the gantry is rotating, make sure that the patient is at a safe distance from the vertical X-ray unit. Be especially careful with patients in wheelchairs. ◆ When the gantry is tilting in horizontal position, make sure that the patient is at a safe distance from the vertical X-ray unit. Be especially careful with patients in wheelchairs.
---	--

The rotation and height adjustment are always blocked when there is a compression force of 30 N (3 kg) or higher.

7.1.2.2. Gantry rotation angle adjustment

The gantry can isocentrically rotate between $+180^\circ$ (in a counter-clockwise direction) and -120° (in a clockwise direction).



Positioning on the pre-set projection angle

The angle for every projection is predefined in the configuration of the workstation.

→ see Section 10 - "Configuration".

- ◆ Briefly press the Store isocentric position button.
- The gantry automatically moves to the predefined angular position for the next projection.

– The angular position appears on the vertical X-ray unit's display.

- ◆ Press any key to stop the movement before it is done.

– The rotation movement stops in its current angular position.

- ◆ Press the Store isocentric position button again to restart the movement.

For safety purposes, the rotational movement will automatically stop if there is the risk of collision with the floor.

In alternative to the protocol, 5 preset isocentric positions can be individually selected.

Fine adjustment of the projection angle

If necessary, the rotation angle can be adjusted in a more precise manner by pressing the rotation movement set keys.

- ◆ Press and hold the gantry rotation key and turn it in the counter-clockwise or clockwise direction.
- ◆ Release it when the desired angular position is reached.
- The rotation movement stops in its current angular position.
- The angular position appears on the vertical X-ray unit's display.

For safety purposes, the rotational movement will automatically stop if there is the risk of collision with the floor. To continue the movement, move the equipment upwards and then continue the rotation.

7.1.2.3. Gantry height adjustment

With reference to the 0° angular position, the gantry can be moved to a height between 70 cm and 145 cm above the ground.

Adjusting the height with the keys

- ◆ Press and hold the gantry movement key up or down.
- ◆ Release it when the desired height is reached.
- The gantry stops at the height reached at the moment it is released.

Adjusting the height with the foot switch

The height adjustment foot switch is marked with the words “UP” and “DOWN”.

- ◆ Press and hold the foot switch up or down.
- ◆ Release the foot switch when the desired height is reached.

The gantry stops at the height reached at the moment it is released.

7.1.2.1. Gantry tilt angle adjustment

With reference to the 0° angular position, the gantry can be tilted between -15° (with respect to the patient direction) and +90° to permit use of patient support device *Flexi Table* for the biopsy exam with patient in prone position.

Adjusting the tilt angle with the keys

- ◆ Press and hold the gantry movement key in direction of the patient side or in the opposite direction.
- ◆ Release it when the desired height is reached.
- The gantry stops at the angle reached at the moment it is released.





7.1.1. Compression/Decompression


Compression and decompression are motorised and are done using either the foot switch or the handles located on the compression unit. The compression speed automatically decreases when the compression paddle touches the breast and the compression force exceeds 10 N (1 kg).

The compression force and the compressed thickness are always shown on the display of the X-ray unit and on the touchscreen panel.


7.1.1.1. Warnings regarding compression/decompression

	<p>WARNING Risk caused by the involuntary activation of the compression foot switch. Possible crushing injury to the patient. ◆ As soon as the patient's breast is compressed, move the foot switch out of range of the patient and personnel.</p>
	<p>CAUTION An inappropriate compression setting can cause poor image quality. Incorrect diagnosis or unnecessary exposure to radiation if the X-ray needs to be repeated. ◆ Make sure that the breast remains compressed during the entire X-ray.</p>

In the case of an electrical black-out, the motorized decompression cannot be performed. In this situation, manually raise the compression paddle using the handles, → see "Compression/decompression adjustment handle" paragraph in Section 3 - "Panoramic view of the system").

	<p>INFORMATION The maximum compression force that can be applied by the motor is 200 N (20 kg). A force of 300 N (30 kg) can only be reached using the handles.</p>
---	--

7.1.1.2. Compression using the foot-switch

The compression/decompression foot switches are marked with the compression/decompression symbol ().

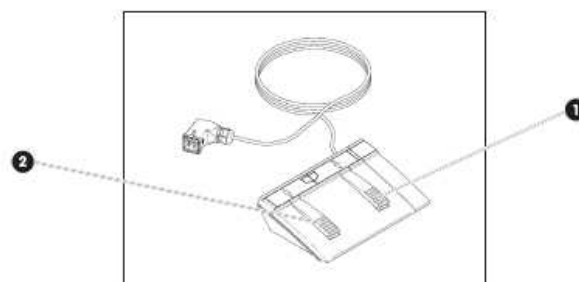


Image under revision

- 1) Compression paddle downwards (compression)
- 2) Compression paddle upwards (decompression)



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- ◆ To move it, press and hold the foot switch up (compression) or down (decompression).
 - When performing compression, the light will automatically switch on.
- ◆ Release the foot switch when the desired compression force is reached.
 - The compression paddle stops at the height reached at that moment.

7.1.1.1. Compression using the manual knobs

The compression/decompression handles are located on both sides of the compression unit.

- ◆ Rotate the handle downwards (compression) or upwards (decompression).
- ◆ Release the handle when the desired compression force is reached.
 - The compression paddle stops at the height reached at that moment.

7.1.1.2. Automatic decompression

When automatic decompression is active, the compression paddle lifts approximately 8 cm after every X-ray.

The use of automatic decompression is preset when the exam procedure is selected on the workstation. If necessary, it can be manually activated or deactivated, → see the “Decompression in case of electrical black-out” paragraph in this section.

The automatic decompression is also active when an X-ray is interrupted before it is completed.

7.1.1.3. Decompression in case of black-out

If motorized decompression cannot be performed, you must activate the emergency release located on top of the compression unit.

- ◆ Firmly press the compression emergency release.
 - The compression is mechanically released.
- ◆ Manually raise the compression paddle.




INFORMATION

After the emergency release has been activated, an automatic system reset is performed. Confirm the error message.

7.1.2. Lighting

The lighting functions as an X-ray indicator for the correct positioning of the breast and normally switches on automatically when the compression foot switch is pressed.

	<p>WARNING If the breast is positioned incorrectly, other parts of the body may enter into the radiation field Possible unnecessary radiation exposure to the patient!</p> <ul style="list-style-type: none"> ◆ Using the lighting, position the patient so that only the breast to be examined is in the radiation field. ◆ Make sure that no part of the breast is in the shaded area.
---	--

The lighting can be manually switched on at any time using the control keys located on the sides of the vertical X-ray unit.


- ◆ Press the lighting key.

The lighting will automatically switch off after a certain amount of time (defined during installation of the equipment, normally 20 seconds).

The lighting also switches off as soon as an X-ray is started (if the X-ray is performed before the predefined time has expired)..

7.1.3. Shut down

Shut down the system at the end of every work day. To avoid any data loss, finish the exam and correctly shut down the workstation before switching the equipment off.

	<p>WARNING Interrupted exam. Unnecessary exposure to radiation if the X-ray needs to be repeated!</p> <ul style="list-style-type: none"> ◆ Make sure that the Off key on the control unit is not pressed during the exam.
---	--

7.1.3.1. Shutting down the workstation

- ◆ Shut down the system using the standard Windows procedure: **Start > Close Session > Shut down the system.**
- The workstation switches off.

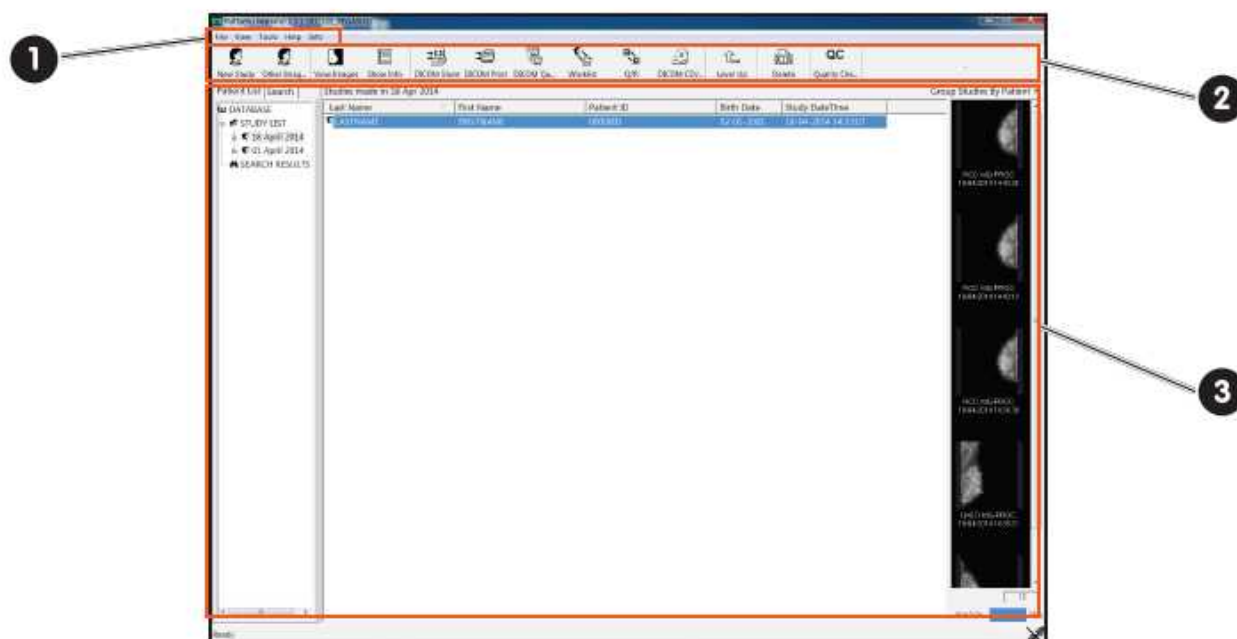
7.1.3.2. Shutting down the system

- ◆ Press the Off switch on the control unit to shut down the equipment.
- ◆ Shut down the workstation.
- ◆ Switch off the UPS.
- ◆ Turn off the master switch.

7.2. Acquisizione Work Station

7.2.1. Software Raffaello

After login, the interface of the “Raffaello” software will appear on the touchscreen panel, which is divided into the following areas:



- 1) Menu bar
- 2) Functions bar
- 3) Study List (search option)


The workstation is only to be used for performing the X-rays and is not intended to function as a report station or long term archive.

7.2.2. Monitor

In its standard configuration, the TFT monitor is a 2 MP colour monitor.

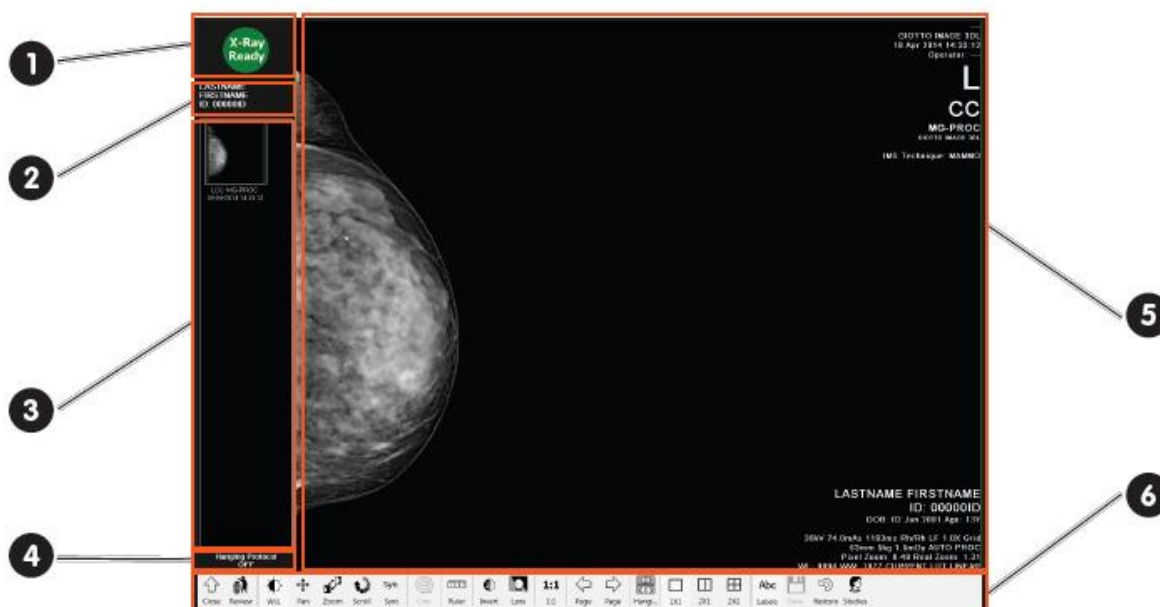
The X-rays are viewed on this second monitor.

Alternatively, a 3 MP TFT monitor can be installed on the workstation, which allows you to view the X-rays images in high resolution with diagnostic capability.

	INFORMATION Even with the high resolution monitor, the workstation is only to be used for performing X-rays and is not intended to function as a report station or long term archive.
---	---

After login, there are no active screens on the TFT monitor.

During the acquisition phase, the TFT monitor shows a screen that is divided into six functional zones:



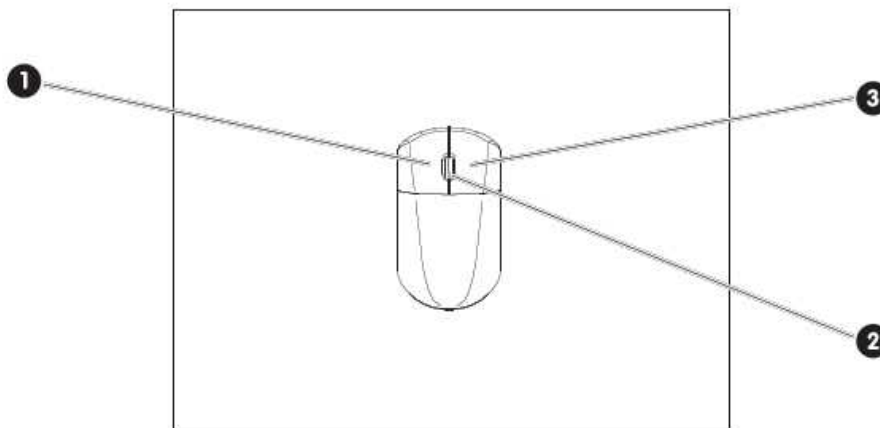
- 1) Acquisition status
 - 2) Patient and acquisition data
 - 3) Preview of the acquired images
 - 4) Hanging protocol information
 - 5) Image display area
 - 6) Task bar
- see Section 6 - "Operator Interface".

7.2.3. Mouse and keyboard

Use the mouse and/or keyboard to give commands or enter data into the computer.

7.2.3.1. Mouse

The mouse is equipped with three keys.

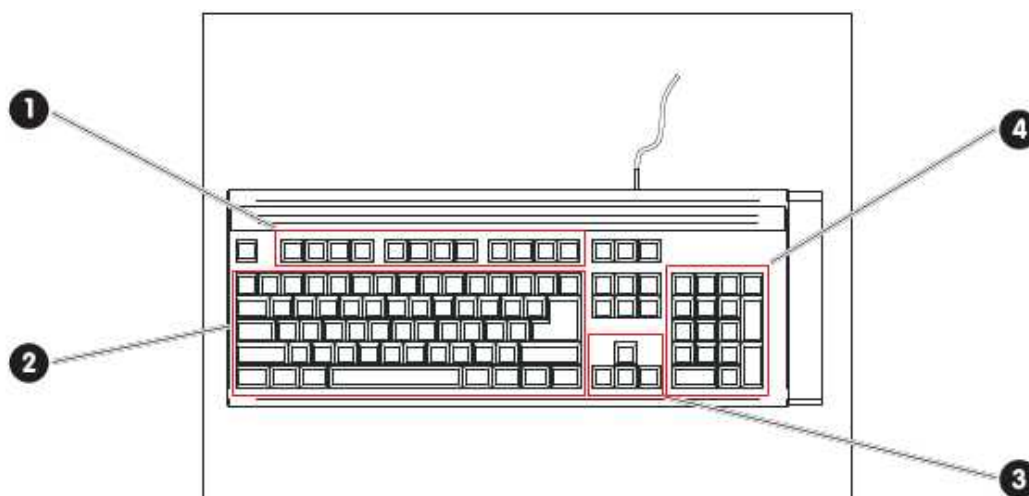


- 1) Use the left mouse key to select objects or launch commands and applications.
- 2) Use the central key to modify the contrast and brightness of images ("window/level").
- 3) Use the right mouse key to open the context menus.

7.2.3.2. Keyboard

The keyboard is used to enter text and numbers. It is also used to access certain functions and to launch programs using key combination and the symbols keypad.

A virtual keyboard can also be activated from the touchscreen panel.



- 1) Functions keys
- 2) Alphanumeric keyboard
- 3) Cursor movements button
- 4) Symbol keypad



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Typing text and numbers

The keys on the alphanumeric keyboard are used to enter text and numbers or commands.

Deleting characters

The **Backspace** key is used to cancel the character preceding the cursor and the **Canc** key is used to cancel the character that follows it. When a text is highlighted, either of these two keys can be used to delete it.

Moving the cursor

The arrow keys are used to move the cursor within an input field. The **Pos 1** and **Fine** keys are used to move the cursor to the beginning or end of an input field.

Function keys

→ see Section 6 - "Operator Interface".

F1 Preset 1

F2 Preset 2

F3 Preset 3

F4 Preset 4

7.2.3.1. Using the keyboard

Almost all the commands can be given either with the mouse, the keyboard, or the touchscreen panel.

Using combinations of keys

The combination of the **Ctrl** or **Alt** keys and another key let you quickly give certain commands to the computer.



INFORMATION

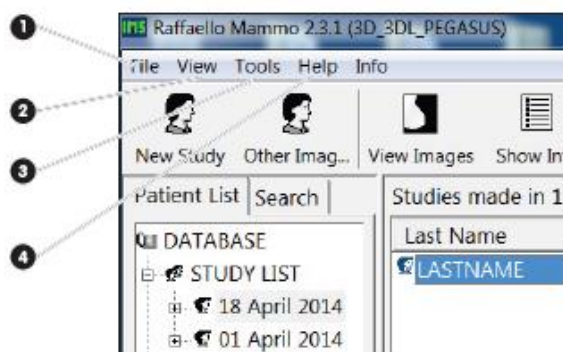
All functions can be performed by simultaneously pressing the Alt key and the underlined letter for the key or in the menu item. This allows you to use the program without the mouse.

The table below shows the main key combinations:

Alt + F4	Closes the selected window
Ctrl + C	Copy (only text)
Ctrl + X	Cut (only text)
Ctrl + V	Paste (only text)
Ctrl + I	Shows information about the selected element
Ctrl + P	DICOM printing of the selected element
Ctrl + Alt + W	Allows the window/level to be manually configured

7.2.4. Menu

The menu bar occupies the upper part of the screen and consists of a series of keys (icons) that open menus in separate windows.



1 File

With this button you can import or export a DICOM file or close the program.

2 View

With this button you can choose whether the toolbar and the status bar are displayed or hidden.

3 Tools

With this key you can choose to configure or modify the default configuration data for the “Raffaello” software.

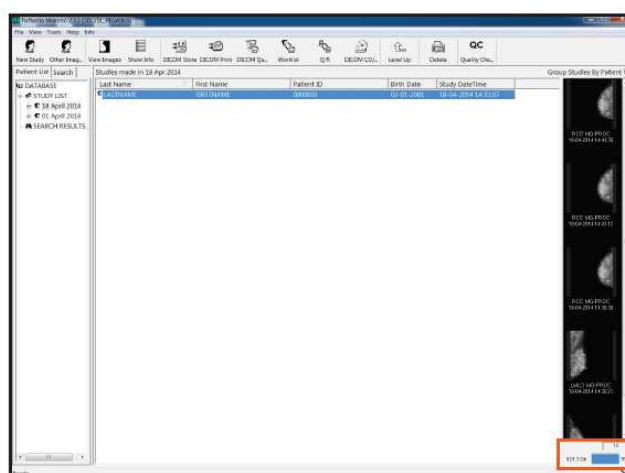
4 Help

This indicates the version of the “Raffaello” software installed and gives access to the in-line Help.

7.2.4.1. Reusource control

The system keeps track of the occupied memory space, the capacity of the main database, the daily calendar and the virtual memory.

Main database



INFORMATION

The disk space is insufficient when the “Raffaello” software reports “Free Space < 20%”.

- ◆ To have a sufficient amount of free memory space, promptly file the patient and exam data and cancel them from the patient list.



CAUTION

An insufficient working memory or space on the hard disk can cause system instability or blocking.

Risk of data loss.

- ◆ Pay attention to the warning symbols relating to memory space and make sure that the available free space is sufficient.

7.2.5. Exit the program

Before shutting down the workstation or the equipment, you must exit the “Raffaello” software using the **Exit** key. In this manner, all the programs being used are closed correctly. The Windows 7 interface will appear when finished.



CAUTION

When exiting the program, unsaved data may be lost.

Possibility of data loss!

- ◆ Save the data before exiting the program.



CAUTION

Danger if you switch off the computer from stand-by mode or before the system has fully shut down.

Possibility of data errors, data losses, system blockage and system damage!

- ◆ Shut down the system before switching the computer off.

7.3. System Messages

7.3.1. Messages Classification

Various types of system messages can appear on the touchscreen panel.

ALARMS	Error messages report an irregular situation.
WARNINGS	Informational messages help the user perform the exam or search in the database. The questions ask the user to confirm an operation started by the system or the user before continuing with the procedure.



INFORMATION

Confirm the error message.

Reset the displayed error messages using the appropriate key.

The concerned components are automatically reset and the exam can continue.

→ see Section 11 - “Breakdowns and diagnosis”, for more information on system messages.



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7.4. Patient Registration



WARNING

The system time is used for the internal identification of patient data such as exams, series and images. If the system time is reset, two identification codes may be created or the data may be assigned to the wrong patient.

Risk of interchanging patient data and errors in assigning the data!

◆ Do not register patients, perform exams or process the images if the system time is set to a value different from the original value.

A patient must be registered before undergoing an exam.

All the patient related information that are required during the exam are communicated to the system during the patient registration.

The operator can select from the various registration procedures depending on how the exams are performed in the hospital and the available time for the registration.



CAUTION

If the patient and exam data are only saved locally, it will no longer be available after cancellation.

Risk of data loss!

◆ Save the data in an external archive, for example in a HIS/RIS system or on CD-ROM. The data can be transferred back to the local database at any time.

7.4.1. Open a new study

A new study can be opened in three different ways.

If it is decided that a patient will be the next to be visited during normal activities, then firstly enter the patient's data (New Study) or recall it from the database and then perform the exam (Other Images).

New Study

This key, located on the task bar, is used to acquire images for a new patient. By pressing the New Study key, the "Patient Info" dialog window appears. You must complete the fields, select the exam mode and start the acquisition.

Other Images

This key allows other images of a patient already present in the database to be acquired.

Worklist

If there is a worklist system that assigns all the patients foreseen for that day to every equipment, as soon as the individual exams start this data just needs to be recalled and possibly completed. This saves time during the actual exams.

Since the equipment can interface with the worklist system, this requirement needs to be communicated during the installation phase.

When the Worklist function key is pressed the dialog box will appear.

- Select the day or days to search for the scheduled exams.
- Select the exam mode to be searched.
- Select the workstations on which to perform the search.



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- Press the Search Worklist key.
- Position the mouse over the patient data and left click to select it.
- Press New Study if you would like to open a study for this patient.
- The Patient Info Dialog box will open. Fill in the necessary information to open the new study.

Once the “Patient Info” dialog box opens, the necessary fields need to be set.

7.4.2. Patient Info Dialog

Patient data

The patient's folder appears in the upper part of the control area and includes the patient's recorded data.

Select the acquisition protocol

If more than one acquisition protocol is configured, you must select the one to be used for the exam. If only one protocol is configured, this will be automatically proposed by the interface. If no protocol is configured or selected, the image acquisition sequence must be autonomously chosen.

“Quality Control” key

To acquire and process phantom images for quality control checks, mark the study as “Quality Control”. This will disable the automatic image processing and the sending of the images to the PACS and the medical recording workstation.



CAUTION

If the nature of the acquisition is not correctly indicated, the image will not be appropriate for the quantitative analysis of the concerned physical sizes.

Breast implants

For the correct acquisition and processing of images, indicate the presence of any breast implants when opening the study.

Even if automatic mode is selected, the AEC is not used and a preset exposure table is instead used that is based on the thickness.



WARNING

If the implants are not taken into account, there can be treatment errors and incorrect contrast settings during the exam.

Risk of injury during the compression. Unnecessary exposure to radiation if the X-ray needs to be repeated!

- ◆ Before performing the exam, ask the patient if she has breast implants. Inform the patient of the risks of false indications.
- ◆ Consequently, adjust the preparation and exam for the patient (i.e. compression, system parameter settings).

Once the “Patient Info” dialog has been completed and the acquisition modality (Mammo/Tomo/Combo) selected, press the “Start Acquisition” key to open the acquisition interface.



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7.5. Exposure data setting

The acquisition can be performed in automatic or manual mode.

7.5.1. Automatic exposure mode

The equipment has special automatic functions to optimize the X-ray parameters and therefore obtain the best possible image quality.

If the compression force is greater than 50 N (5 kg), the exposure mode is enabled by means of the AEC (Automatic Exposure Control).

→ see the “Automatic modes for X-ray optimization” paragraph in Section 3 - “Panoramic view of the system”.

If the presence of an implant is detected in the breast, the automatic mode will be enabled but the preset system parameters will be used.



WARNING

An inappropriate compression setting can cause poor image quality.

Diagnosis error or unnecessary exposure to radiation if the X-ray needs to be repeated!



◆ If possible, use a compression greater than 10 kg (100 N).

7.5.2. Manual exposure mode

The individual exposure parameters (kV, mAs and target/filter combination) can be adjusted in manual mode using the special keys on the acquisition interface.

Table of manual exposures (glandularity 50/50)

Compressed Breast Thickness (mm)	Filter	kV	MAMMO (mAs)	TOMO (mAs)	COMBO (mAs)
10-20	Rh	23	40-45	60-70	80-90
20-30	Rh	24	50-60	75-90	100-120
30-40	Ag	25	60-70	90-100	120-140
40-50	Ag	26	80-90	110-130	160-180
50-60	Ag	28	90-100	130-150	180-200
60-70	Ag	30	100-110	150-170	200-220
70-80	Ag	31	110-120	170-190	220-240
80-90	Ag	33	120-140	190-210	240-280
>90	Ag	35	140-160	210-240	280-320

	<p>INFORMATION</p> <p>The parameters for the last exposure are displayed in the exposure data box. In manual exposure mode, these will also be used for the next exposure, unless changes are made before the emission of the X-rays.</p>
	<p>WARNING</p> <p>Changing the exposure parameters can cause inadequate anode/filter, mAs and kV combinations.</p> <p>Diagnosis error or unnecessary exposure to radiation if the X-ray needs to be repeated!</p> <ul style="list-style-type: none"> ◆ When changing the settings manually, follow the recommended exposure parameters (→ see table on the next page). ◆ If possible, use the automatic AEC mode to optimize the exposure parameters.


The maximum mAs value that can be set depends on the set kV value.

kV	23	24	25	26	27	28	29	30	31	32	33	34	35
mAs max.	560	560	500	500	500	500	450	450	400	400	400	400	360

7.6. Performing the exposure


7.6.1. Safety during the irradiation

- ◆ Follow the manufacturer's instructions for use and the safety warnings.
- see Section 1 - "Safety" and Section 7 - "Method of use".

	<p>WARNING</p> <p>Incorrectly recorded patient data can lead to incorrect results.</p> <p>Diagnosis error or unnecessary exposure to radiation if the X-ray needs to be repeated!</p> <ul style="list-style-type: none"> ◆ Before every exam, check that the patient corresponds to the data and to the procedure loaded into the system.
---	--

7.6.2. Manual setting the projections

- ◆ Set the equipment's mobile arm based on the first desired projection.
- ◆ Select the lateral projection on the touchscreen panel and check that the expected projection appears.
- ◆ Place the breast to be examined on the Potter/Bucky surface based on the projection selected from the acquisition workstation.

	<p>WARNING</p> <p>If the projection is set manually without the use of a protocol, only the projections permitted at that position of the gantry will be selectable.</p> <ul style="list-style-type: none"> ◆ Before selecting the laterality, move the gantry to the desired position.
---	---



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7.6.3. Using the pre-set protocols for the sequence

7.6.3.1. Selezione del protocollo di acquisizione

Selecting the acquisition protocol

The acquisition protocol can be selected from the “Patient Info Dialog” page.

If only one protocol is configured, this will be always proposed for the acquisition.

If more than one protocol is configured, the first on the list that respects the operator filters, study description and presence of implants will be automatically proposed. In any case, the selection can be manually changed using the drop down menu.

Using the acquisition protocol

- ◆ Press the **isocentric position sequence** key.
- ◆ Adjust the column height (only for the first projection).
- ◆ Place the breast to be examined on the Potter/Bucky surface based on the projection indicated on the acquisition workstation.

When the acquisition session begins, the Giotto TOMO will automatically set the lateral projection, the position for the projection and the projection modifier according to the first point in the sequence for the protocol.

These indications and the progressive projection number in the sequence are also reported in the upper left of both monitors (→ see Section 6 - “Operator Interface”).



INFORMATION

If the gantry position is not compatible with the selected view, the following warning message will appear: “206: INCORRECT ISOCENTRIC POS”.



INFORMATION

If the operator manually modifies the lateral projection or position, the acquisition protocol will be disabled. By returning to the programmed data for that projection, the protocol will be re-enabled.



INFORMATION

If the exposure for the previous projection is done again, the protocol will be re-enabled after the acquisition. If a different projection is acquired, the operator must then proceed to the acquisition of the other images by manually setting the lateral projection and the view position and manually move the gantry into the correct position (the **Isocentric position sequence** key can no longer be used).



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7.6.4. Acquisition procedure

- ◆ Wait until the status indicator on the TFT monitor indicates that the system is ready for the next acquisition.
- ◆ Compress the breast and return to the acquisition workstation.
- ◆ Place the breast to be examined on the Potter/Bucky surface based on the projection indicated on the acquisition workstation.
- ◆ Wait for the X-ray button to light (green) before beginning the X-ray.
- ◆ Press and hold the X-ray button on the control unit for the entire time the acoustic signal is heard.
 - During the X-ray, the radiation symbol will appear on all the displays (black clover with yellow background).
 - The irradiation begins and the first exam image is created.
- ◆ After the image has been created, it will be displayed in the appropriate area.



WARNING

During the Combo examination a second type of acoustic signal indicates the movement of the X-ray tube between the end of the tomo portion and the start of the mammography.

- ◆ Keep the button pressed until the entire examination is completed.

7.6.5. Correcting the projection

The exposures displayed in the image area must correspond to the expected projections. If there are differences, a successive correction needs to be performed.



WARNING

If the exposure was done on the wrong side or if an incorrect exposure was performed, the image will be saved with the wrong projection.

Possibility of diagnosis or treatment error!

- ◆ Check that the correct projection is associated with the image and correct it if it's wrong.

Correction

- ◆ Using the right mouse key click on the concerned image.
 - A context menu will open.
- ◆ Select the menu entry **Other Toolbar Functions > Show Image Info.**
 - The dialog box showing the image information will open.
- ◆ Using the drop down menu modify the incorrect data and press **Close.**
 - A confirmation window will open.
- ◆ Press **Yes** to make the change.
 - Enter the password (if requested).

7.6.6. Repeat the image processing

If the quality of an image is unsatisfactory, it can be reprocessed by modifying the parameters and without repeating the X-ray.

→ see Section 8 - "Image transfer and presentation" for more information.



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7.6.7. Discard images

If you were not able to sufficiently improve the quality of the image through reprocessing, it should be discarded (i.e. if there are artefacts or noise) before closing the study.

- ◆ Select the concerned image with the mouse.
- ◆ Select the Review key and indicate the reason for refusal.

The selected image will not be sent to the archiving and recording workstations.

The discarded images will not be deleted and can be viewed together with the others in the acquisition workstation.

Restore a discarded image:

- ◆ Select the Review key and re-accept the image.

7.6.1. Delete images

Delete images using the Delete key.



CAUTION

Possible data loss.

Deleted images cannot be restored.

- ◆ Check that the image that you really want to delete has been selected before continuing with the operation.

7.6.2. Request image exposure data

The projection and the exposure parameters used are saved along with the image in the form of attributes. This data can be viewed individually for all images.

- ◆ Using the right mouse key click on the desired image.
 - A context menu will open.
- ◆ Select the menu entry **Other Toolbar Functions > Show Image Info.**
 - The “Image Info” dialog box will open.
 - The dialog box is composed of three tabs with the attributes about the image, the series and the study to which the image belongs.
- ◆ Select the image page and view the interested data.
- ◆ Press **Close.**
 - The dialog box will close.
 - see “Show Info” paragraph in Section 6 - “Operator Interface”.



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7.7. Printing the exam images

→ see Section 8 - “Image transfer and presentation”.

7.8. Concluding the exam

After the exposures, the last image created appears on the monitor. At this point the exam on the current patient can be concluded. If necessary, the relative documentation can be drawn up later.

◆ Select **Close** on the TFT monitor's task bar or press **Close** key on the touchscreen panel.

– The exam on the current patient is finished.

– If the system is configured for automatic forwarding to other DICOM archiving/reporting or printing workstations the images marked QA will be sent when the study is closed.
The next patient can now be registered.

7.9. Manually sending images to other DICOM workstation

If you want to send part or all of the exam to DICOM workstation not configured for automatic sending upon closing of the study, this can be done manually.

→ see Section 8 - “Image transfer and presentation”..



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8. Image quality assessment



INFORMATION

For further details on the checks described in this Section or the quality controls recommended for the equipment, consult manuals M176 and M172 "Quality Control Procedures for Medical Physicists".

Image quality can be assessed visually or numerically through different tests.

This section reports three tests that cover both approaches, which are:

- Automatic Exposure Control (AEC) Test
- Dose Calibration Test
- Artefacts evaluation



CAUTION

When any quality control test is performed on the image, **only the raw images are visually and numerically analysed**, since the processing is optimized for the clinical application and artefacts can be created when applied to phantom images.

It is also recommended that the flat-field images be analysed that are obtained with PMMA blocks certified for homogeneity, material purity and thickness precision, or that are supplied directly by **I.M.S. S.r.l.**

The general acceptance criteria for the visual analysis of the Flat-Field images are the following:

There must be no:

- Areas of clear inhomogeneity → wrong Flat-Field correction, visible MCMs;
- White or black bands in the peripheral zones → incorrect collimation;
- Clear horizontal structures → grid visibility or noise;
- Clear vertical structures → visible MCMs or noise;
- Artefacts in terms of:
 - rows/columns or clusters of uncorrectable defective pixels;
 - central line;
 - objects or dirt of any kind;
 - shadows from previously radiographed objects (latent or ghost images).

8.1. AEC Test for Installation

This test is performed during installation by the service technician to perform a self-diagnosis of the system to check that the equipment's performance (in terms of image quality) is sufficient to carry out clinical exams. The test includes the following checks:

- Communication of the detector with the AWS acquisition workstation;
- Correct collimation of the X-ray field;
- Flat Field correction;
- Homogeneity of the signal and uniformity of the SNR parameter;
- Presence of uncorrectable defects from the detector;
- Presence of any artefacts;
- Visibility of the anti-scatter grid;
- Efficiency of the digital detector;
- Clear and structured noise;

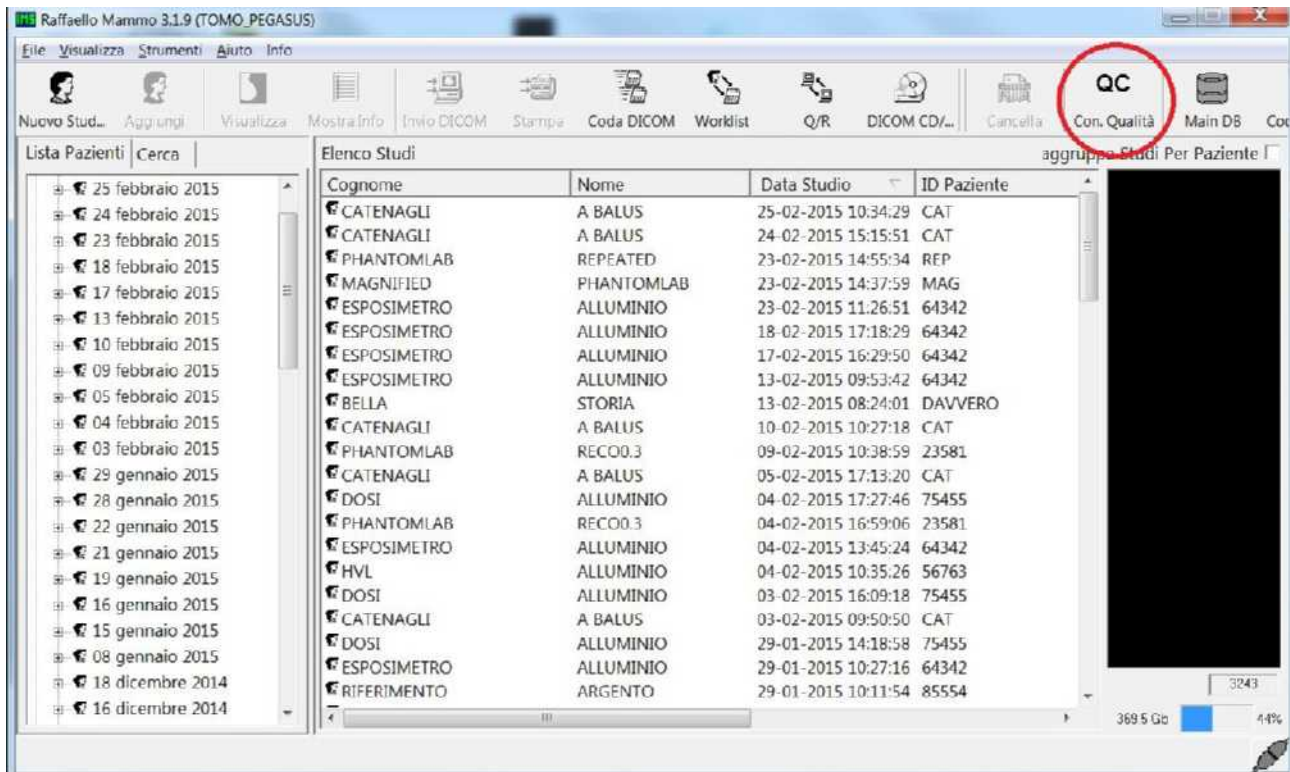
The results are automatically assessed by the software, which decides the outcome of the test through testing parameters. It is however recommended that the image be visually evaluated in terms of homogeneity, visible noise, visibility of the anti-scatter grid, the presence of uncorrectable defects by the detector and the possible artefacts that cannot be detected through the numeric analysis relative to this test (→ see the [“Assessment of artefacts and image homogeneity” paragraph](#) at this Section).

Required instrumentation:

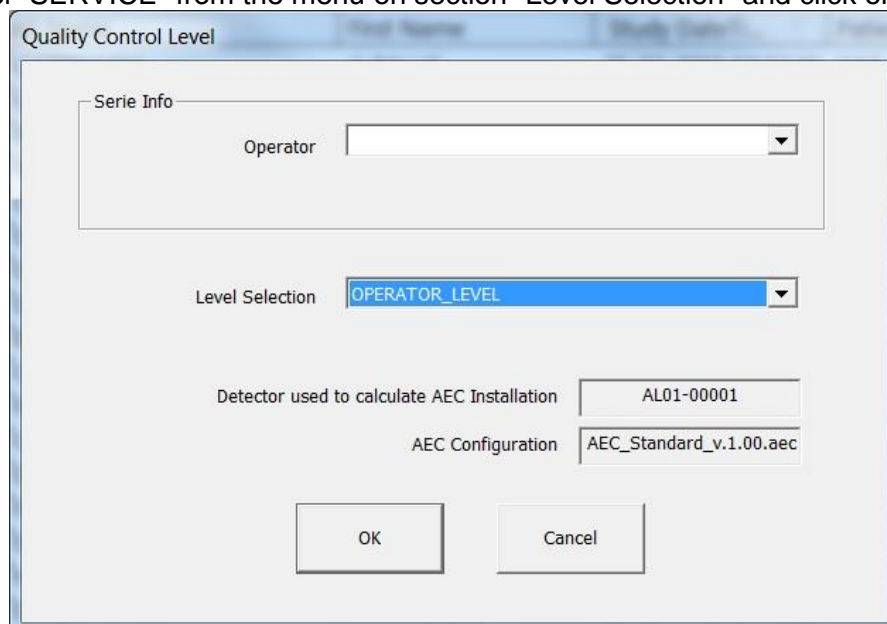
- 2 PMMA blocks, thickness 20 mm each covering the entire detection area (supplied with the equipment).




Click on QC key



Select the level "SERVICE" from the menu on section "Level Selection" and click on "OK"



Enter the password “master” and click on “OK”



Insert Password

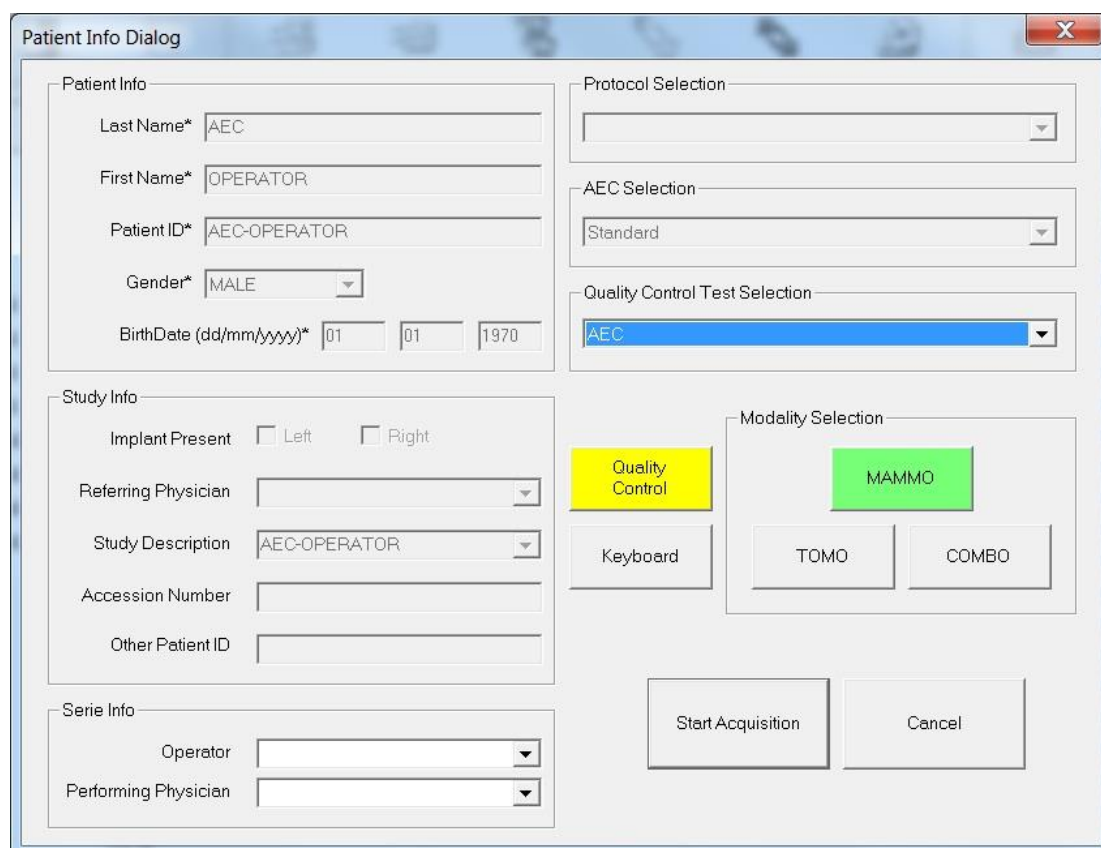
Required User level: User / Admin

Please insert the password to enable the Quality Control Mode

☐ Don't ask again for this session

OK Cancel

Select from menu of the section “Quality Control Test Selection” the test AEC and click on “Start Acquisition”.



Patient Info Dialog

Patient Info

Last Name* AEC

First Name* OPERATOR

Patient ID* AEC-OPERATOR

Gender* MALE

BirthDate (dd/mm/yyyy)* 01 01 1970

Protocol Selection

AEC Selection

Standard

Quality Control Test Selection

AEC

Study Info

Implant Present ☐ Left ☐ Right

Referring Physician

Study Description AEC-OPERATOR

Accession Number

Other Patient ID

Modality Selection

Quality Control

MAMMO

Keyboard

TOMO

COMBO

Start Acquisition

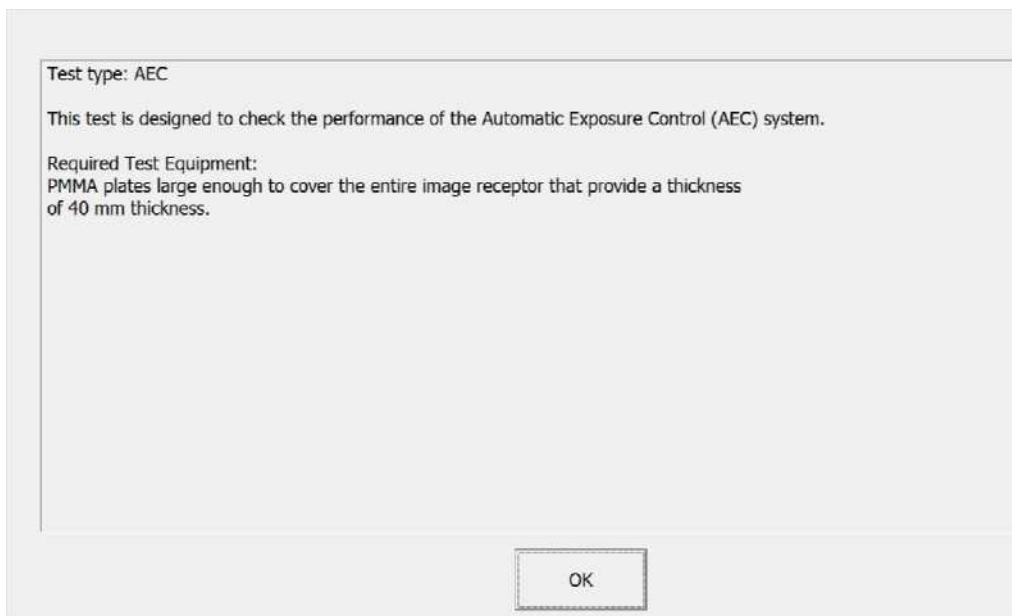
Cancel

Series Info

Operator

Performing Physician

Follow the instruction shown in the monitor and click on “OK”



Put 40 mm di PMMA (supplied with the Giotto Class) in the breast support surface and apply a compression force of at least 5 kg (max suggested compression force 10 kg) , as shown in picture



Image under review



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Wait the ready state and select the view R-CC



AEC - AEC-OPERATOR

Scheduled Images:
DISABLED

Acquired Images:

AEC OPERATOR
01-01-1970
AEC-OPERATOR

R L
R CC

ISOCENTRIC POSITION

Tomo Angle: 0° Rotation: 0° Thickness: 3.9cm Compression: 20kg

READY

MAMMO AUTO

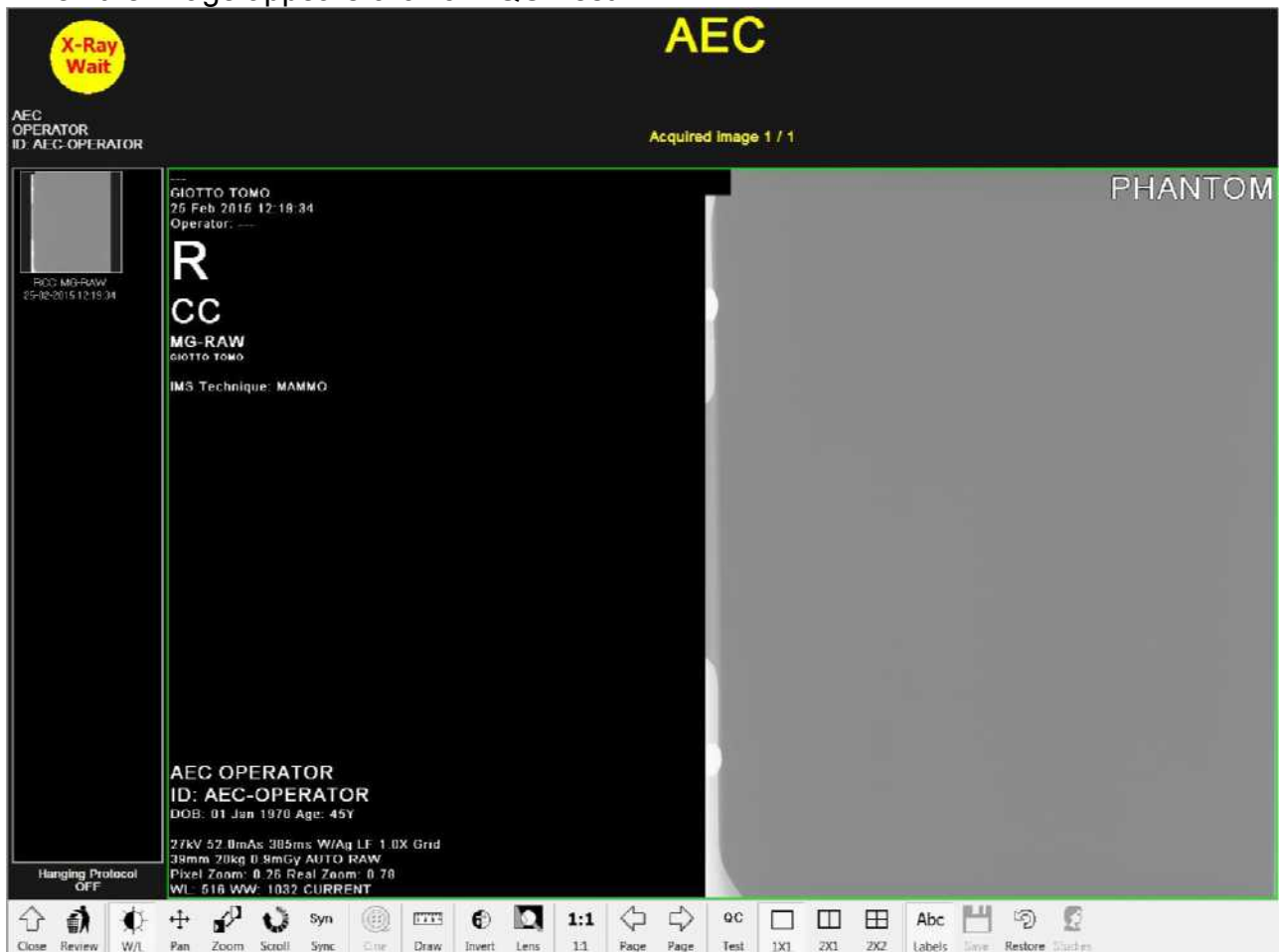
LAST EXPOSURE DATA
Technique: AUTO
mAs: 52 Filter: Ag
kV: 27.0 kg: 20
mGy: 0.9 cm: 3.9

CURRENT STATUS
Filter: Ag
Paddle: 24x30TH
Collimator: 24x30
Tube Heat: 1%
Magnific.: 1.0

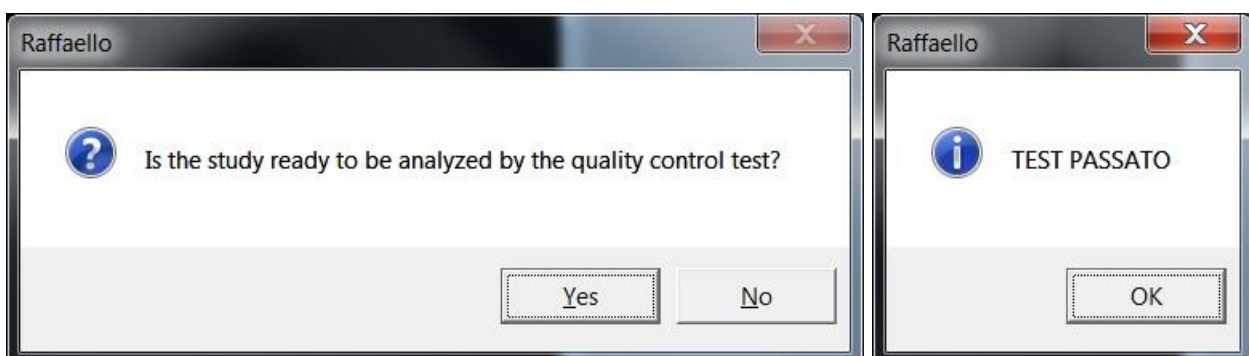
CLOSE

Advanced

Make an exposure to acquire an image.
When the image appears click on “QC Test”.



Confirm the analysis of the image.



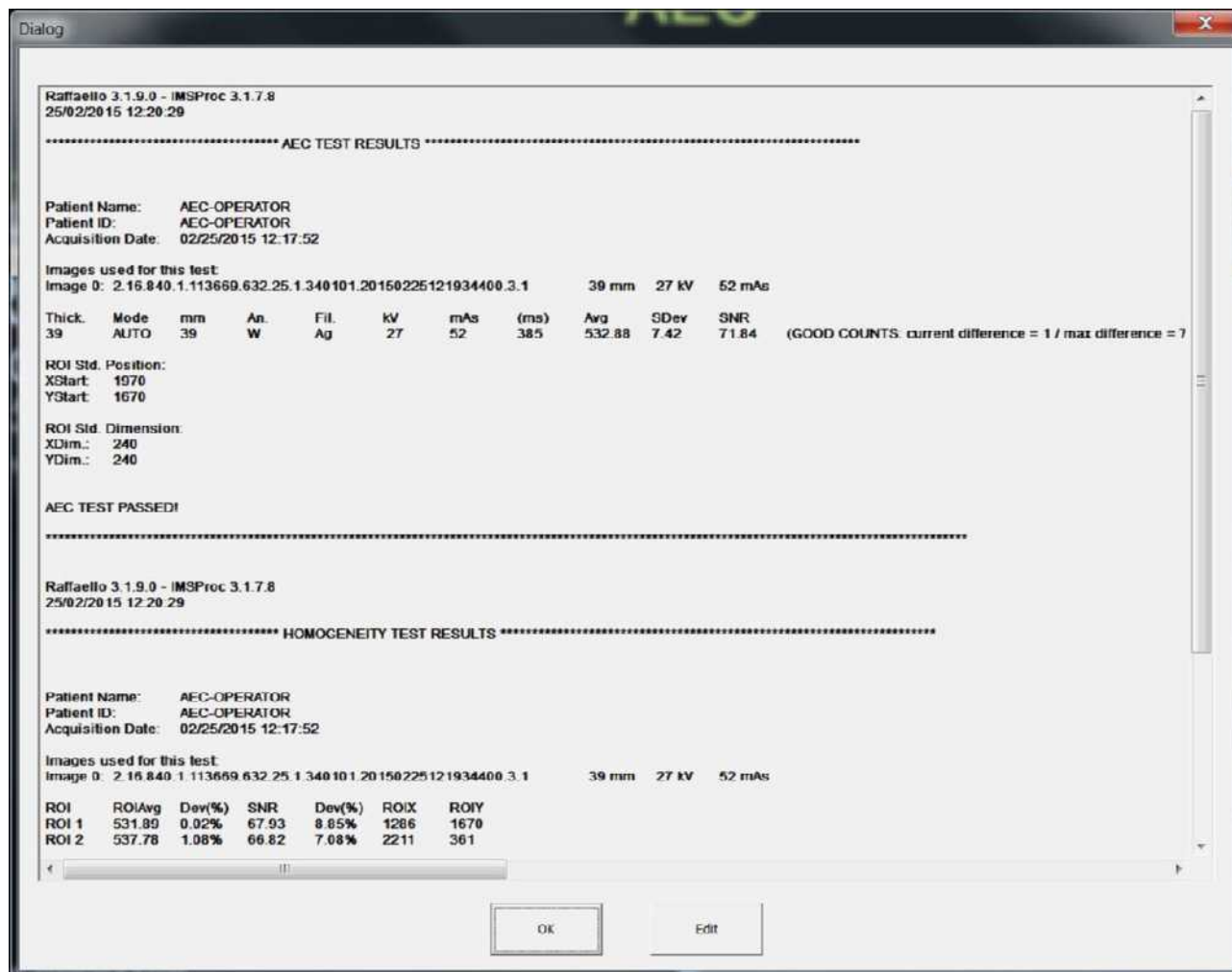
Click on “OK” to visualize the details of the calculation performed.



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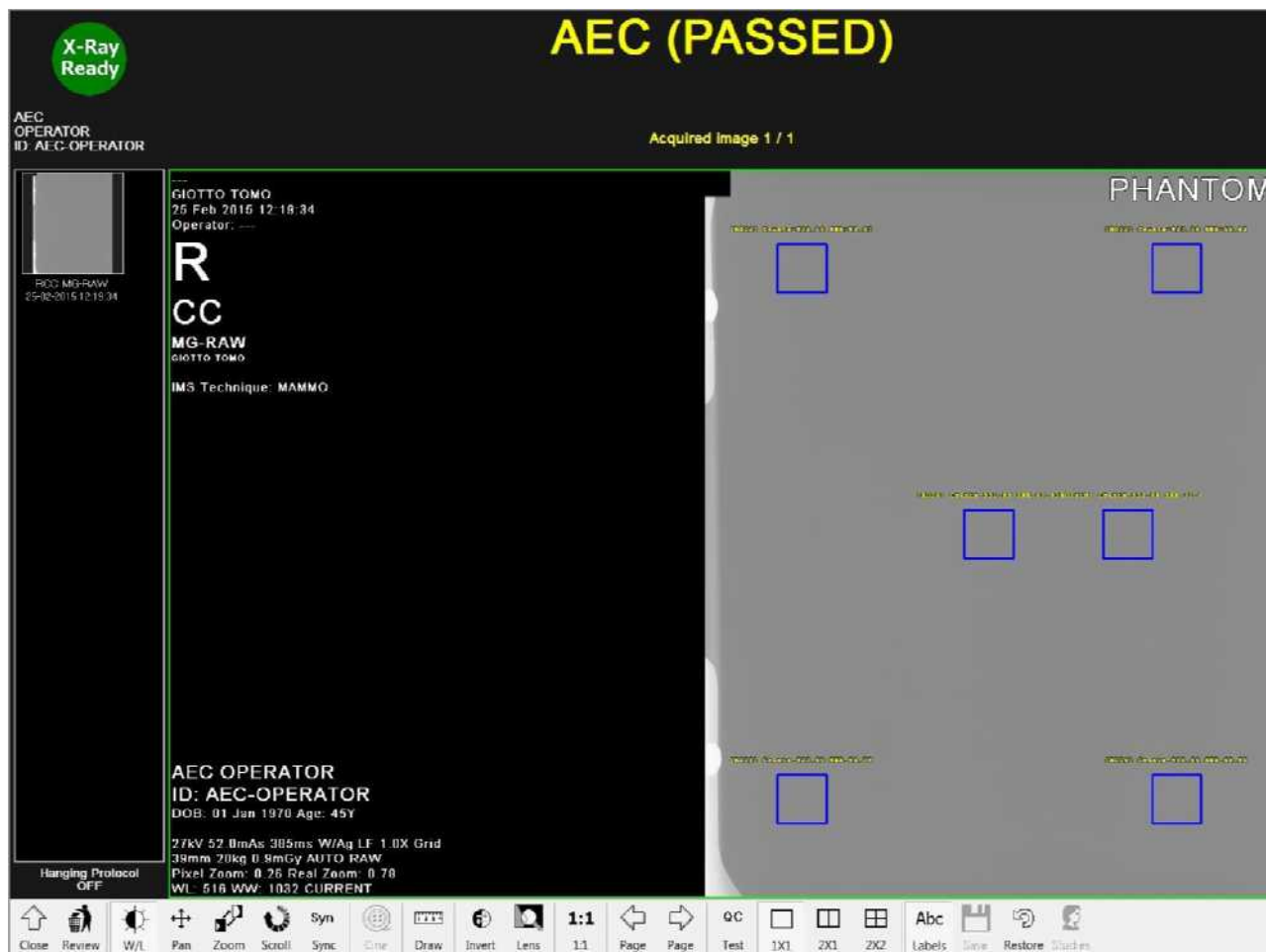
Click on "OK" to visualize the Region Of Interest (ROI) used for the average pixel value levels and for the signal-to-noise ratio (SNR) calculations.



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Acceptance criteria:

The test is passed if:

1. The compressed thickness read is ± 3 mm with respect to the nominal value;
2. The maximum percentage deviation between the average pixel value of the single ROI with respect to the total average value of the 5 ROIs used is minor than 5%;
3. The maximum percentage deviation between the SNR of the single ROI with respect to the SNR average value of the 5 ROIs used is minor than 5%;



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8.2. Dose Calibration check

8.3. Image Homogeneity and defective element evaluation

The purpose of this test is to check that the final image obtained is void of large artefacts caused by the presence of dust or small objects on the surface of the detector or in the anti-scatter grid. This test will also assess significant inhomogeneity caused by sensitivity differences in certain parts of the detector or by an incorrect calculation of the detector's gain map during the flat-field correction, obtained with the long calibration.

Required instrumentation:

- 2 PMMA blocks, thickness 20 mm each covering the entire detection area (supplied with the equipment).

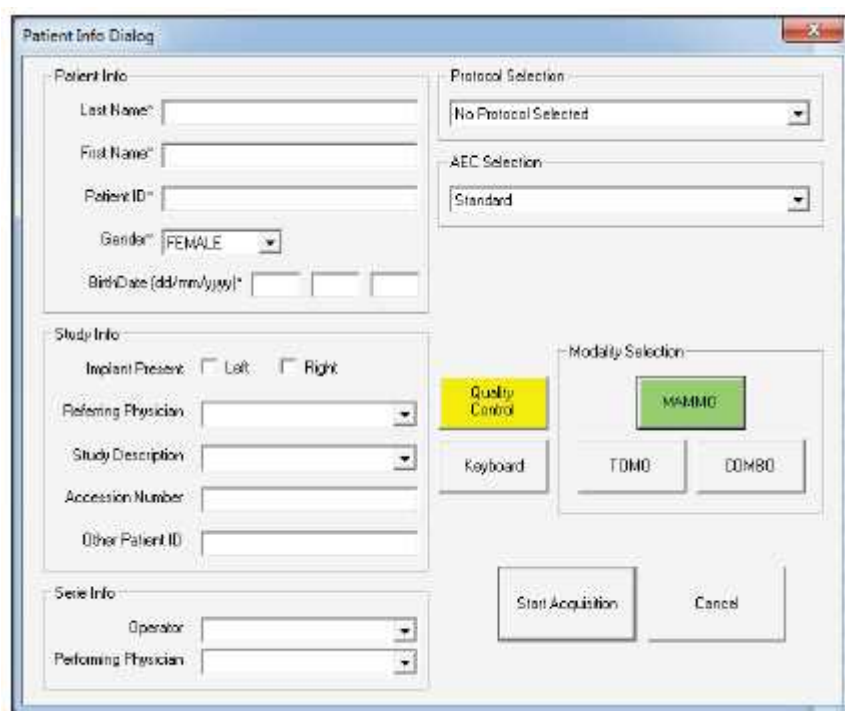


Frequency:

Weekly, after replacement of the X-ray tube or the detector and after performing calibrations.

Procedure:

1. Open "Raffaello" application software (the image acquisition software) and open a new study called "Artefact Assessment", assign a patient ID number, enter a date of birth, click on Quality Control button, select the MAMMO mode and then click on Start Acquisition;



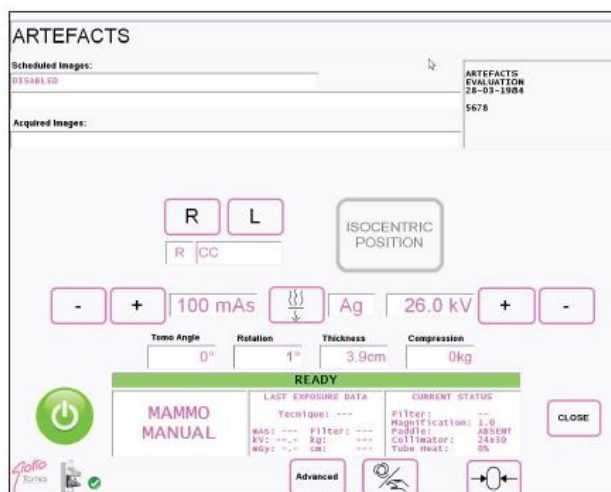
The 'Patient Info Dialog' box contains the following sections:

- Patient Info:**
 - Last Name*
 - First Name*
 - Patient ID*
 - Gender* (FEMALE)
 - Birth Date (dd/mm/yyyy)*
- Protocol Selection:**
 - No Protocol Selected
- AEC Selection:**
 - Standard
- Study Info:**
 - Implant Present: ☐ Left ☐ Right
 - Referring Physician
 - Study Description
 - Accession Number
 - Other Patient ID
- Modality Selection:**
 - Quality Control (highlighted in yellow)
 - MAMMO (highlighted in green)
 - TOMO
 - COMBO
- Buttons:**
 - Keyboard
 - Start Acquisition
 - Cancel
- Series Info:**
 - Operator
 - Performing Physician

- Position the two 20 mm thick PMMA plates (**total 40 mm PMMA**) supplied with the equipment on the resting surface for the breast (on the anti-scatter grid) so that the entire active detection area is covered, as shown in the figure;



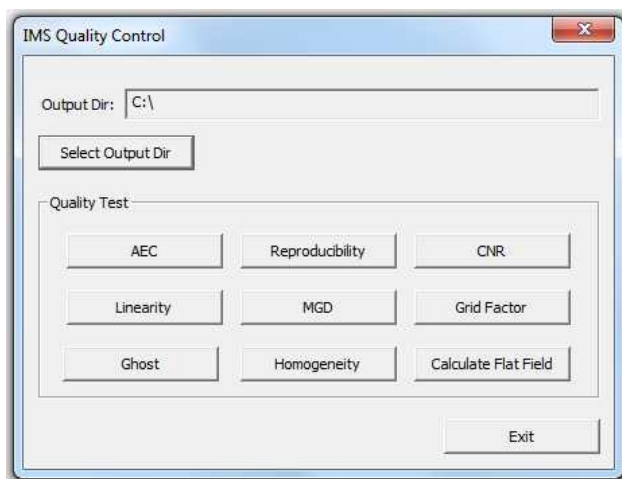
- Remove the compressor;
- Select the automatic exposure mode, select R-CC view (Right Cranio-Caudal) and perform an exposure with the following parameters Filter Ag, 26kV, 100mAs, acquiring the image;



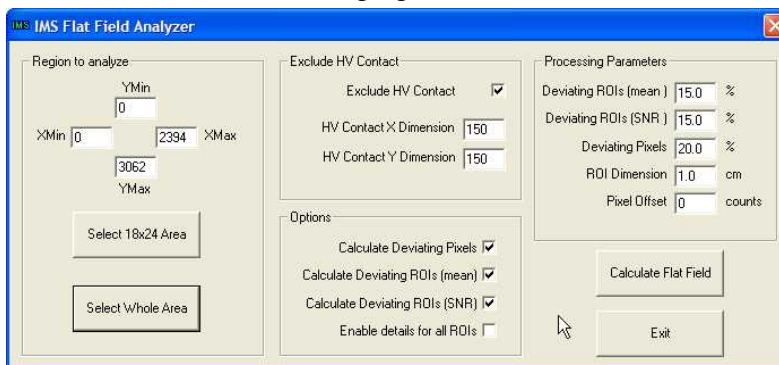
5. Repeat this procedure **6 times**, **changing the position of the PMMA plates** (rotate or slide slightly, always keeping the detector completely covered) for every image acquired.

ANALYSIS OF THE DATA AND INTERPRETATION OF THE RESULTS

1. Open the study just performed in “Raffaello” application software and select the raw images that were just acquired;
2. **Right click** and the series of interest and select “Export DICOM file” and export the raw images into a reference folder;
3. Open the “IMS Quality Control” program.
4. Click on the “**Select Output Dir**” button and select a folder to where the files containing the test results are to be saved;
5. Click on the “**Calculate Flat Field**” button and select the exported images through the dialog box;



6. Select the parameters shown in the following figure;



7. If the analysis is successful, the “Processing Successful” message should appear in the dialog box;

8. A “Flat-Field.txt” file must have been created in the test results folder.

9. Open the file created and read the last line in the file, where the test results of all six images are reported.

ACCEPTANCE CRITERIA

No pixel can be above the selected threshold for the result of the merging of the 6 images.

If there are pixels that are above the set threshold for the merging of the 6 acquired images, identify the pixels from the coordinates reported on the Flat-Field.txt report and search for the cause of this deviation through a visual analysis of the images. If these pixels are all in peripheral areas, the collimation of the X-ray beam may be incorrect. If they are all on the same row or column, there may be an uncorrectable row or column.

No ROI can deviate beyond the set threshold based on the mean count.

If the maximum percent deviation of the mean from the merging of the 6 images is not within the threshold limit, the system fails the Artefact Assessment test.

After visual analysis of the raw images, the following must not be present at any of the thicknesses:

- Areas of clear inhomogeneity (wrong Flat-Field correction);
- White peripheral bands (incorrect collimation);
- Clear horizontal structures (grid visibility or noise) or vertical structures (visible MCMs or noise);
- Artefacts (uncorrectable defective rows or columns, objects of any kind).



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If this test fails, the source of the problem must be identified and corrective action must be made by a specialized technician. When the problem is resolved, the test must be performed again and it must be successful before proceeding with clinical exams.

TROUBLESHOOTING

If the system fails this test, check these options for a possible cause:

- Clean the surface of the detector.



IMPORTANT WARNING

The use of liquids of any kind is strictly forbidden.

- Presence of an object (dirt or dust) on the filter used: large, square blurred object that is not present if an image is acquired with another filter (if available).
- Presence of an object (dirt or dust) on the mirror: large, square very blurred object, present on images obtained with both filters.
- Presence of an object (dirt or dust) on the anti-scatter grid: small, focused object.
- Presence of an object (dirt or dust) on the surface of the detector: small, focused object.
- Presence of an object (dirt or dust) during the calibration without grid: black object that is always present.



IMPORTANT WARNING

If the problem turns out to be an object (dirt or dust) on a filter, clean the filter **very delicately** using a clean, non abrasive cloth and avoid damaging it. In this case, the fast calibration relating to the dirty filter must be repeated and you must check that the resulting image is good. If the fast calibration is not enough to give an image that can meet the acceptance criteria, **all** the calibrations must be repeated! If the problem turns out to be an object (dirt or dust) that was present during the long calibration, **all** the calibrations must be repeated! If the problem turns out to be an object (dirt or dust) on a filter, clean the filter **very delicately** using a clean, non abrasive cloth and avoid damaging it. In this case, the fast calibration relating to the dirty filter must be repeated and you must check that the resulting image is good. If the fast calibration is not enough to give an image that can meet the acceptance criteria, **all** the calibrations must be repeated! If the problem turns out to be an object (dirt or dust) that was present during the long calibration, **all** the calibrations must be repeated!



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9. Components diagnosis

9.1. Geometry of acquisition setting



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9.2. Detector

To perform a complete diagnosis of the digital detector, a set of images must be acquired that is composed of:

- CgrabbDiff.dat
- Dark Farne.dat
- Dark Sub.dat
- Flat-Field image with the anti-scatter grid
- Flat-Field image without the anti-scatter grid

Through a visual and numeric analysis, this set of images can be used to check for the presence of structural artefacts from the detector, such as the presence of groups of defective lines or columns, or the presence of structural noise, which degrade the quality of the clinical image.

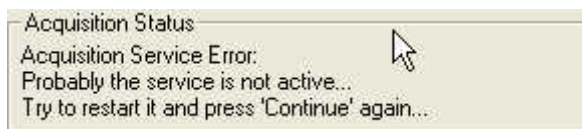
The acquisition conditions are specified in the following section.

9.2.1. Dark Frame and Dark Sub analysis

DARK FRAME

Follow the procedure below to acquire a **Dark Frame** image:

1. Open the GMDService program (if closed) in the Mammo mode by following the path:
Start/Program/ Raffaello/GMDService;
2. Make sure that the **Image Acquisition Services** are **ON**; perform the following procedure to check whether the services have started correctly:
 - a. Click on Test Acquisition and look at the dialog box. If the message "Acquisition Service Error: The service is probably not active" appears, proceed as follows:



- b. Click on **Actions/Open Control Dialog**;
- c. Click on the **Stop** button in the Acquisition Services section;

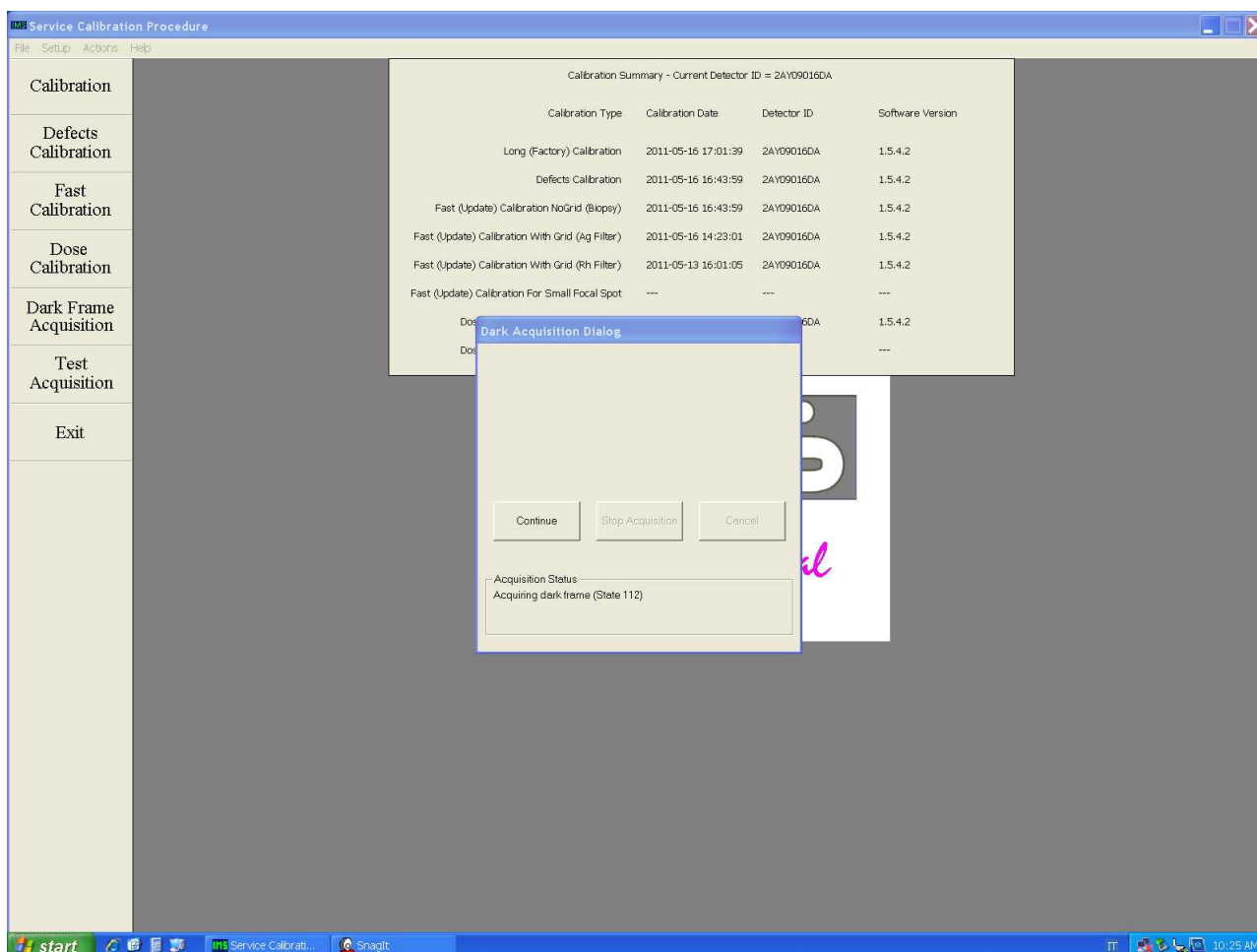


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- d. A message confirming that the acquisition services have been disabled should appear in the dialog box;
 - e. Click on the **Start Console** button in the Acquisition Services section;
 - f. Observe the sequence of events until (after about one minute) the detector status changes to 12 = IDLEMode.
3. Click on **Test Acquisition** and send high voltage to the detector by clicking on **Start Acquisition**.
 4. Observe the detector status from the control console (if activated in the special window). The high voltage is active when the detector's status is "ready".
 5. When the detector has high voltage, click on Dark Frame and wait a few seconds.





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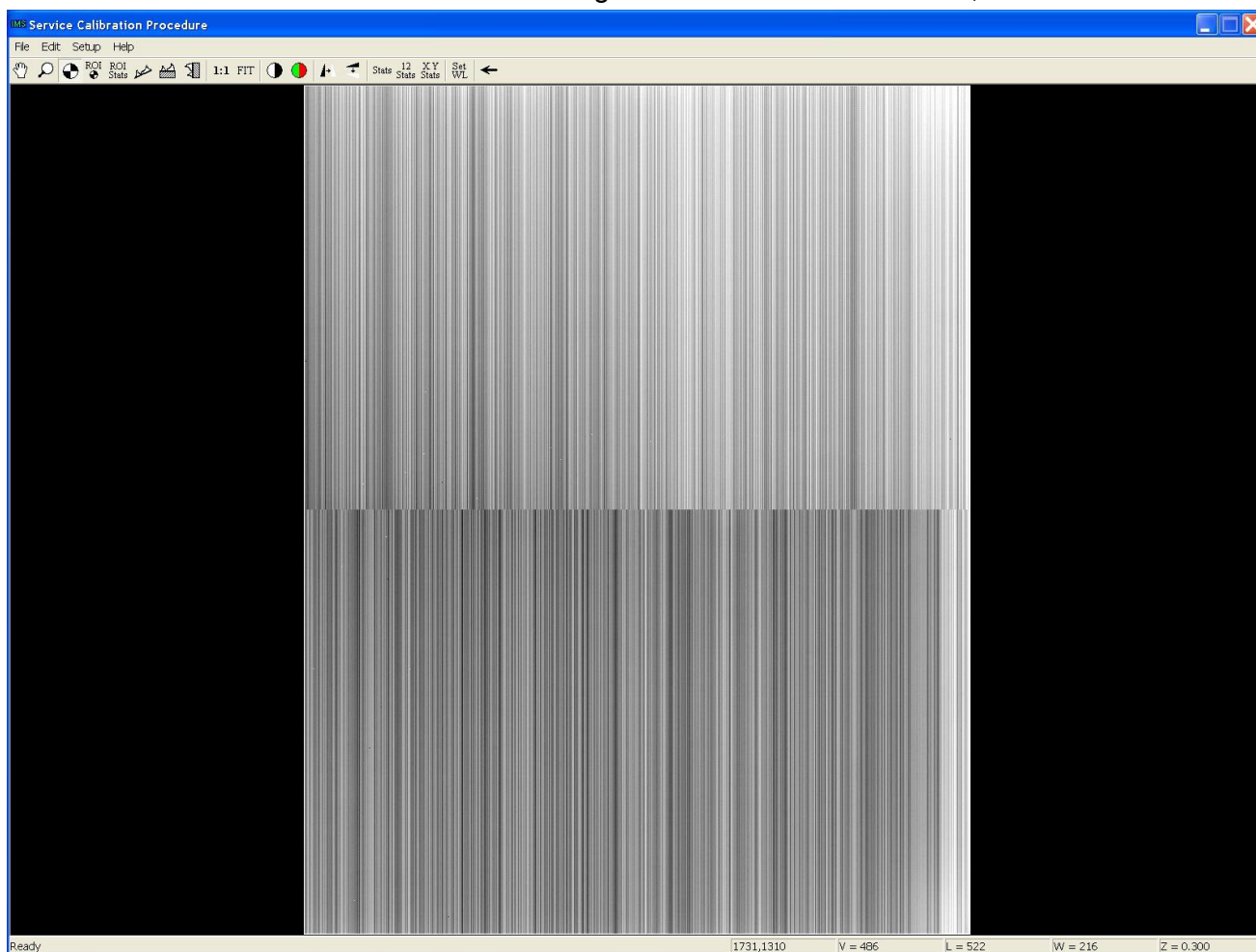


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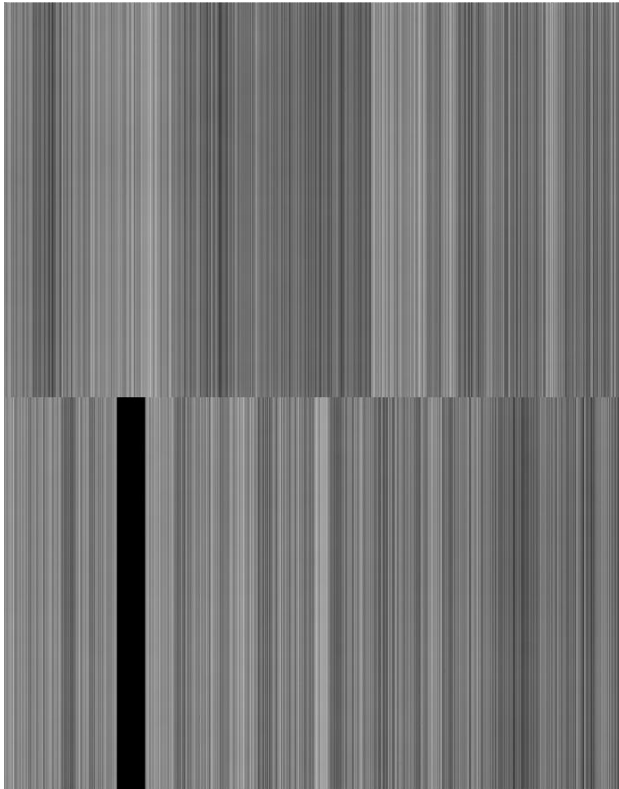
Acceptance Criteria

When the Dark Frame image is generated, visually analyse it using the following acceptance criteria:

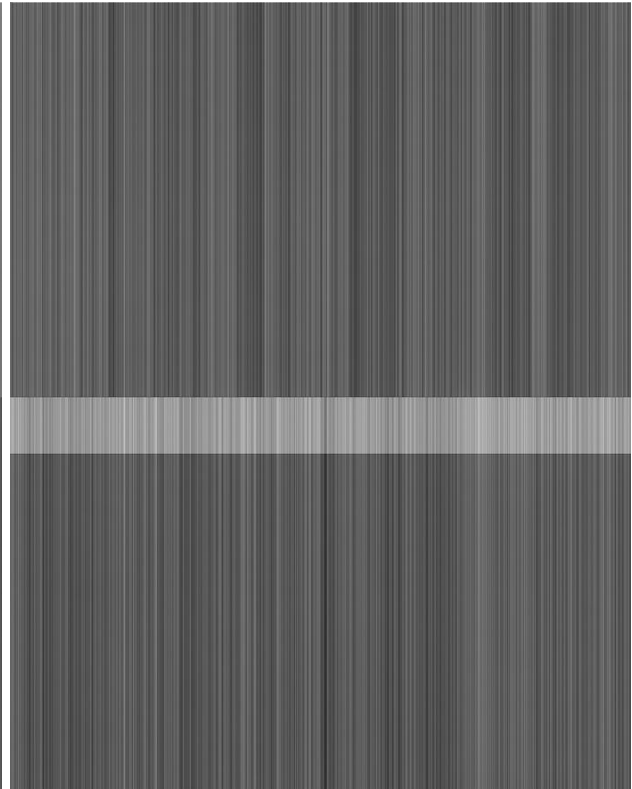
- There must be no clear defects in terms of large vertical or horizontal bands;



Correct Dark Frame image



Example of Faulty MCM

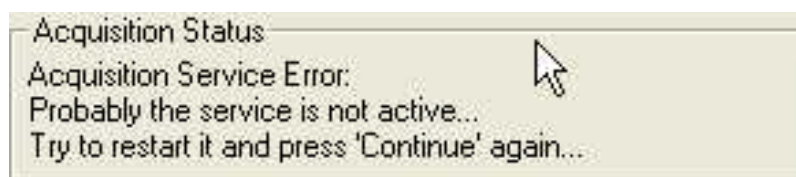


Example of Faulty gate drive

DARK SUB

Follow the procedure below to acquire a **Dark sub** image:

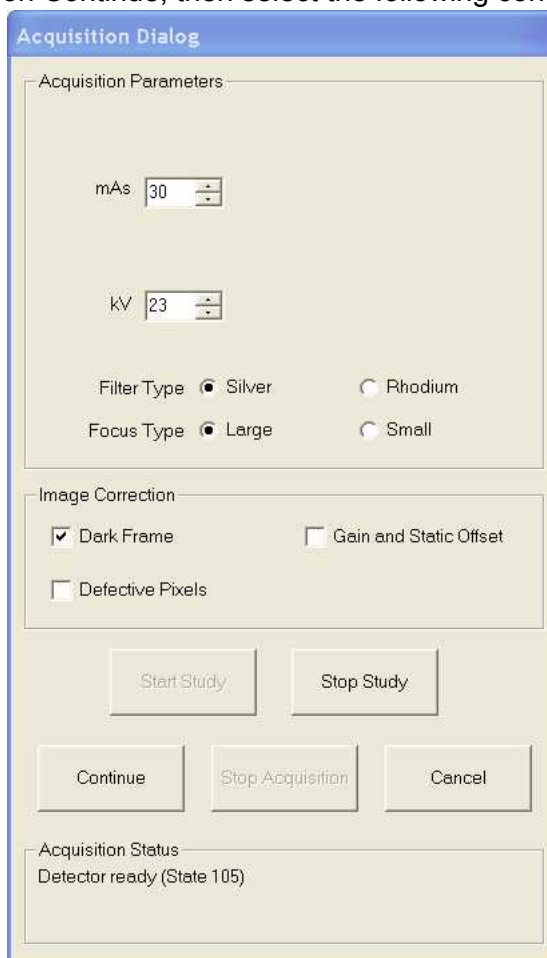
1. Open the GMDService program (if closed) in the Mammo mode by following the path:
Start/Program/ Raffaello/GMDService;
2. Make sure that the **Image Acquisition Services** are **ON**; perform the following procedure to check whether the services have started correctly:
 - a. Click on Test Acquisition and look at the dialog box. If the message "Acquisition Service Error: The service is probably not active" appears, proceed as follows:



- b. Click on **Actions/Open Control Dialog**;

- c. Click on the **Stop** button in the Acquisition Services section;
 - d. A message confirming that the acquisition services have been disabled should appear in the dialog box;
 - e. Click on the **Start Console** button in the Acquisition Services section;
 - f. Observe the sequence of events until (after about one minute) the detector status changes to 12 = IDLEMode.
3. Click on **Test Acquisition** and send high voltage to the detector by clicking on **Start Acquisition**.
 4. Observe the detector status from the control console (if activated in the special window). The high voltage is active when the detector's status is "ready".
 5. When the detector has high voltage, click on Continue, then select the following conditions.

- W/Ag
- Large Focus
- 23kV
- 30mAs
- No Gain and Offset correction
- No defect correction
- Only Dark Frame correction
- No anti-scatter grid
- No Compressor
- No PMMA plates



Acquisition Dialog

Acquisition Parameters

mAs 30

kV 23

Filter Type ☒ Silver ☐ Rhodium

Focus Type ☒ Large ☐ Small

Image Correction

☒ Dark Frame ☐ Gain and Static Offset

☐ Defective Pixels

Start Study Stop Study

Continue Stop Acquisition Cancel

Acquisition Status

Detector ready (State 105)

IMAGE UNDER REVISION

Acceptance Criteria

When the Dark Sub image is generated, visually analyze it using the following acceptance criteria:

- There must be no completely black or white MCMs (large vertical bands formed by 128 channels).
- None of the edges of the image must be cut off → incorrect collimation.
- There must be no artefacts of any kind (→ see the [“Assessment of artefacts and image homogeneity”](#) paragraph in Section 8 - “Quality assessment of the flat-field image”).



Artefacts created by the presence of object on filter, mylar mirror or Be window.



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9.2.2. Communication with ASW troubles

The first check on the correct communication between the AWS acquisition workstation and the digital detector, can be done simply by opening the “Raffaello” application software and observing the last icon in the bottom right of the applications bar.

If the icon is crossed out, this means that the detector is not communicating correctly with the AWS.

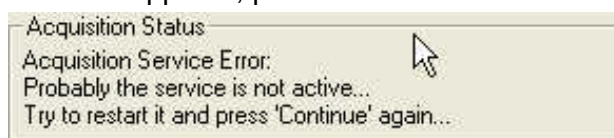


	INFORMATION After the equipment is switched on, you must wait about one minute before the detector begins to send data packets to the AWS. This time is needed before you can proceed with other communication checking actions.
---	--

Follow the procedure below if the communication is not correct.

1. Make sure that the **Image Acquisition Services** are **ON**; perform the following procedure to check whether the services have started correctly:

a. Click on Test Acquisition and look at the dialog box. If the message “Acquisition Service Error: The service is probably not active” appears, proceed as follows:



b. Click on **Actions/Open Control Dialog**;

c. Click on the **Stop** button in the Acquisition Services section;

d. A message confirming that the acquisition services have been disabled should appear in the dialog box.

e. Click on the **Start Console** button in the Acquisition Services section;

f. Observe the sequence of events until (after about one minute) the detector status changes to 12 = IDLEMode.

g. If the services are active, but the communication is still not correct, stop the services by closing the console and click on Actions/Open Control Dialog; then click on the **Check** button in the Detector section.

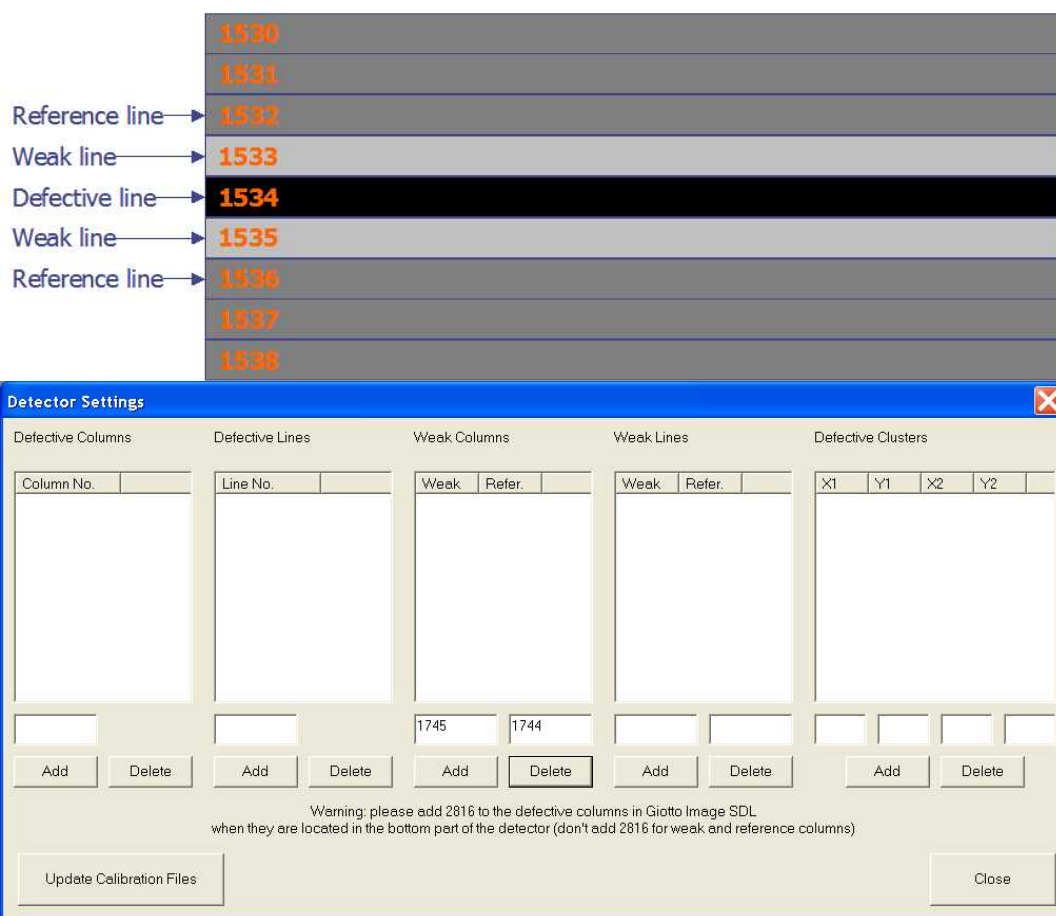
h. If communication is correct, the temperature value read by the detector should appear. If communication

is not correct, an error message will appear relating to the failed attempt to open the corresponding COM port.

9.2.3. Weak lines or columns

It's possible that the lines or columns near defective lines/columns are affected by a different offset than the others. To correct this visual effect as a greyscale value different from the background for the lines and columns adjacent to the defective lines/columns, you need to identify these lines or columns in the appropriate section of GMDService and also identify their references in order to make the correction.

The image below shows an example of two weak lines and the relative references to enter into the GMDService section.





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9.2.4. Acquisition and analysis of defects map

Follow the procedure below to obtain the defect map after the defect calibration:

1. Open the “Raffaello” application software.
2. Open a new study by entering a patient name, surname, ID and date of birth;
3. When the detector’s status is “ready” (green light in upper left) click on the following combination of buttons: **Ctrl+Alt+D**.
4. The image of the defect map from the detector obtained after the defect calibration will appear after a few seconds. This image can be exported by Raffa “Raffaello” application software ello either in DICOM format or in .dat binary format.



INFORMATION

The defect map does **not** include any weak lines/columns that were added by the user.

Acceptance Criteria

For analysis of the defect map, the following acceptance criteria must be taking into consideration:

Single correctable pixel	< 2500 pixels (3D); < 5000 pixels (3DL)
Correctable dead lines and columns (at least 3 good lines/columns in between)	No more than a total of 10 lines and columns (2 half-columns make 1 column).
Correctable dead lines and columns	Adjoining dead columns/lines are not accepted (there must be at least 3 good lines/columns in between). No more than a total of 10 lines and columns (2 half-columns make 1 column) The score excludes all the pixels from the 2 lines around the panel and the extreme corner of the high voltage contact (150 x 150 pixels) from the chest wall.
Correctable pixel groups (clusters)	< 100 clusters (3D); <150 clusters (3DL) (max. 8 pixels) The score excludes all the pixels from the 2 lines around the panel and the extreme corner of the high voltage contact (150 x 150 pixels) from the chest wall.



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9.1. X-ray tube

The X-ray tube is an instrument whose performance slowly decays over time. The emission efficiency (intended as the emitted dose for the selected mAs) decays rapidly for approximately the first 100 exposures, and then decays very slowly over time.

The X-ray tube can be operational until the tungsten filament, which emits electrons for thermoionic emission, becomes so thin (due to the sublimation of the metals at high temperature) that it breaks and creates electrostatic discharges. The formation of small craters at the anode (generated by the constant impact of the electrons) also modifies the spectral quality; in particular, the half value layer (HVL) parameter, or rather the thickness of aluminium needed to reduce the emitted dose by half, which indicates its penetrating ability, or the energy carried by the photons, tends to increase over time.

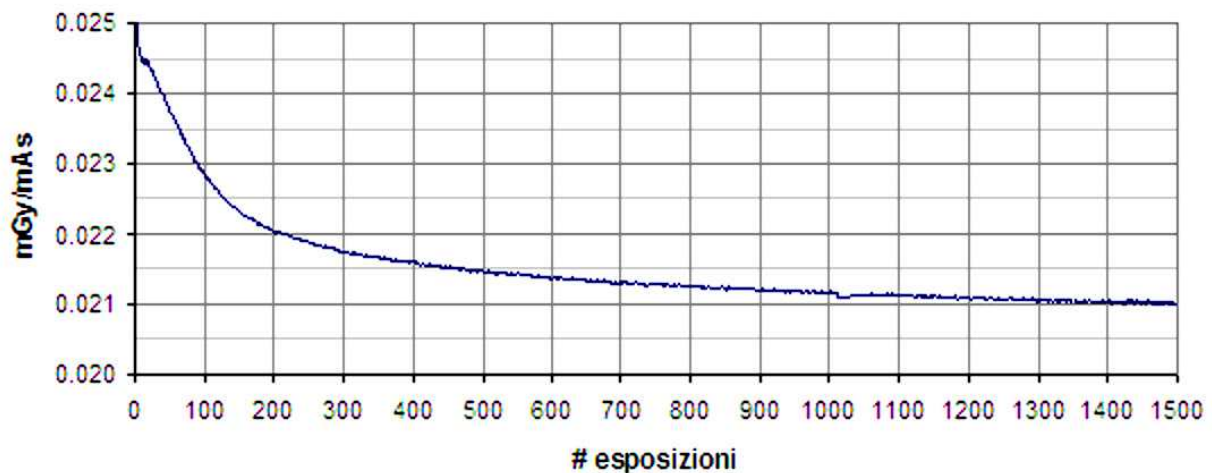
For mammograms, there is a serious operating limit in the need to have reduced exposure times (or high output rates or rather, dose emitted per unit of time) in order to reduce the patient pain as much as possible and to prevent organ movement, which reduce the quality of the diagnostic image.

There are three tests for the diagnosis of the operating status of the X-ray tube:

1. Measurement of **kV accuracy and reproducibility**;
2. Measurement of the **X-ray tube emission values** - measurement of **Efficiency**;
3. Measurement of the **exposure time** at clinical conditions.

The operating status of the tube can be assessed through these simple tests and whether it needs to be replaced.

Decadimento tipico del rendimento di un tubo radiogeno



INFORMATION

The curve of the graph was obtained using the following **fixed exposure meter parameters: 30kV 100mAs** and is reported for **1 m focal distance**.

At normal clinical use, the decay curve cannot be used as a preview curve because the operating conditions are not comparable.

Before making efficiency measurements, check the number of exposures by the tube through the appropriate section in the Param Class program.



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9.1.1. Tube Tension, accuracy and reproducibility

This test is designed to check that the kV supplied by the X-ray system are accurate and reproducible. This test and its relative tolerance limits make reference to the Fourth Edition of the European protocol on Quality Control "European protocol for the quality control of the physical and technical aspects of mammography screening 4th edition (2b.2.1.3.3 and 2b.2.1.3.4)".

Required instrumentation:

- Digital multimeter calibrated for measuring kV in the mammographic range (~20-40 kV) with accuracy of ± 1 kV and precision not less than 0.5 kV;



IMPORTANT WARNING

- The system uses different Anode/Filter combinations. Before making the measurement, make sure that the multimeter can correctly read the kV for the required spectrum (W/Rh (50um) Paddle or No Paddle).

- Plate of steel or lead large enough to cover the entire detector area, able to completely shield it from the X-ray field.

Frequency:

Every six months and when there are inconsistencies between the displayed mean glandular dose and that measured through the special test.

Procedure:

1. Turn off the generator;
2. Perform the M2 service sequence in order to use the system without acquiring images;



IMPORTANT WARNING

In this mode, the X-ray tube can emit radiation without waiting the time needed for image creation. It is however recommended that **no more than one emission be performed per minute** in order to avoid damaging the anode of the X-ray tube.

In this manner the detector does not send signals to the AWS acquisition



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workstation, thus preventing the generation of latent or “ghost” images. It is therefore **absolution necessary that all the detection surfaces of the detector be covered with a shielding material** suitable for the energy range used in mammography (2 mm of steel, iron or lead) that can absorb 99% of the incident radiation.

Do not use this mode if a shield of this type is not available, but instead use the **GMDService/Test Acquisition** program.

If a solid state multimeter is used, be careful not to irradiate the dosimeter sensor numerous times, placed in the same position in order to avoid creating latent or ghost images.

3. Turn on the generator;
4. **Cover all the detection surfaces of the detector with a plate of X-ray shielding material;**
5. Position the multimeter sensor in the standard dosimetric measuring position (**6 cm from the chest wall side and laterally centred**, as shown in the figure below); set it for the correct measuring of the configuration W/Rh 50 μ m with or without the compressor, depending on the selected measuring conditions.
6. Select the manual exposure mode, or use the GMDService program and perform an exposure for every possible kV value (from 22 to 35 kV) using W/Rh and 20 mAs.
7. After performing this series of measurements, make 10 repeated exposures, using W/Rh 28kV 20mAs.

ANALYSIS OF THE DATA AND INTERPRETATION OF THE RESULTS

1. Compare the set nominal kV values with the measured values.
2. To determine the repeatability of the measurement, calculate the mean and the standard deviation.

Calculate the percent variation as a ratio between the standard deviation and the mean, and check that every value measured is within $\pm 5\%$.

ACCEPTANCE CRITERIA

The tolerance limit for the accuracy test is ± 1 kV and the reproducibility of the measurement must be within ± 0.5 kV of the mean value.

If the nominal kV value differs by more than 1 kV from the value measured with the multimeter, the system fails the test.



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If the variation of the mean value is $> \pm 0.5$ kV, the system fails the reproducibility test.

If this test fails, the source of the problem must be identified and corrective action must be made by a specialized technician. When the problem is resolved, the test must be performed again and it must be successful before proceeding with clinical exams.

TROUBLESHOOTING

If the system fails this test, check these options for a possible cause:

- Check that the measurement configuration used and the digital multimeter setting correspond exactly.
- Check the position the digital multimeter sensor: standard dosimetric measuring position (6 cm from the chest wall side and laterally centred).
- Check the X-ray emission graphs and the nominal emission values read by the system in the appropriate section of the Param Class.

9.1.2. Radiation output: X-ray tube emission efficiency

The purpose of this test is to assess the correct emission of the X-ray tube in terms of efficiency (uGy/mAs), output rate, exposure time, and quality of the X-ray beam (half value layer - HVL).

Required instrumentation:

- Solid state digital dosimeter (or digital multimeter) or ionization chamber calibrated for dose measurements in the energy range, and for the spectra used, in mammography applications (~20-40 keV);
- Plate of steel or lead large enough to cover the entire detector area, able to completely shield it from the X-ray field.



IMPORTANT WARNING

The system uses different Anode/Filter combinations. Before making the measurement, make sure that the multimeter is able to correctly measure the dose for the required spectrum (W/Ag (50um) Paddle or No Paddle).

Frequency:

Upon acceptance, every six months, and when problems occur relating to the mean glandular dose and exposure time.

Procedure:

1. Turn off the generator;
2. Perform the M2 service sequence in order to use the system without acquiring images;



IMPORTANT WARNING

In this mode, the X-ray tube can emit radiation without waiting the time needed for image creation. It is however recommended that **no more than one emission be performed per minute** in order to avoid damaging the anode of the X-ray tube.

In this manner the detector does not send signals to the AWS acquisition workstation, thus preventing the generation of latent or "ghost" images. It is therefore **absolutely necessary that all the detection surfaces of the detector be covered with a shielding material** suitable for the energy range used in mammography (2 mm of steel, iron or lead) that can absorb 99% of



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the incident radiation.

Do not use this mode if a shield of this type is not available, but instead use the GMDService program-Test Acquisition button.

If a solid state multimeter is used, be careful not to irradiate the dosimeter sensor numerous times, placed in the same position in order to avoid creating latent or ghost images.

3. Turn on the generator;
4. Cover all the detection surfaces of the detector with a plate of X-ray shielding material;
5. Position the multimeter sensor in the standard position (**6 cm from the chest wall side and laterally centred**, as shown in the figure below); set it for the correct measuring of the configuration W/Rh 50 μ m with or without the compressor, depending on the selected measuring conditions.
6. Select manual exposure mode and perform an exposure using W/Rh 28kV LF 20 mAs.

ACCEPTANCE CRITERIA

Reference values for installation:

Reference values for the periodic check:

If this test fails, perform the test below (exposure time at clinical conditions) and the source of the problem must be identified and corrective action must be made by a specialized technician. When the problem is resolved, the test must be performed again and it must be successful before proceeding with clinical exams.



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9.3.2 POSSIBLE SOLUTIONS

If the system fails this test, check these options for a possible cause:

- Check that the measurement configuration used and the digital multimeter setting correspond exactly.
- Check the position the digital multimeter sensor: standard dosimetric measuring position (6 cm from the chest wall side and laterally centred).
- Perform the test below (Exposure time at clinical conditions) or the exposure test in automatic mode.



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9.1.3. Exposure time

The purpose of this test is to evaluate the exposure time at clinical conditions.

Required instrumentation:

- Dedicated instrument or solid state digital multimeter for measuring exposure time
- PMMA plates with a total thickness of 45 mm

Frequency:

Annually or when incorrect exposure problems occur

Procedure:

1. Position 45 mm of PMMA on the surface of the anti-scatter grid;
2. Open "Raffaello" application software and open a new study called "EXPOSURE TIME TEST", assign a patient ID number and enter a date of birth;
3. Select the automatic exposure mode and perform an exposure;
4. Put the sensor of the digital multimeter or the dedicated instrument in the standard dosimetric measuring position (6 cm from the chest wall side and laterally centred);
5. Perform an exposure using the same parameters obtained with the automatic exposure;
6. Record the exposure time obtained and compare it with that shown on the monitor.

ACCEPTANCE CRITERIA

The exposure time must be within the limits reported in the reference table below.

Acceptable: < 1.5 s **Optimal:** < 1.0 s

If this test fails, the source of the problem must be identified and corrective action must be made by a specialized technician (**X-ray tube must be replaced**). When the problem is resolved, the test must be performed again and it must be successful before proceeding with clinical exams.

TROUBLESHOOTING

If the system fails this test, check these options for a possible cause before asking for the X-ray tube to be replaced:

- Check that the measurement configuration used and the digital multimeter setting correspond exactly.



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- Check the position the digital multimeter sensor: standard dosimetric measuring position (6 cm from the chest wall side and laterally centred).

Perform the previous test again (X-ray tube emission values - Efficiency) or the exposure test in automatic mode.



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10. Electronic boards

10.1. Electronic boards topographic diagram

INSERIRE IMMAGINE POSIZIONE SCHEDE

Electronic boards present on the equipment are the following:

Code	Description
I008	Collimator
I009	Compressor
I009 PB	Compressor Piggy Back
I009 RF	RFID board
I010	Detector
I011	Biopsy
I012	Gantry
I013	Actuation of SELEMA
I014	Gantry keyboard
I015	Tube keyboard
I017	Wireless footpedal power
I020	Powers switching
I021	Operator control table commands
I022	Cabling switching of operator control table
Master Can Open IXXAT	Central managment



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10.2. I008 – Collimator board

Connettore	Funzione
X400	Connessione di terra piste di shield segnali
X401	Alimentazioni In
X402	Connettore motore paletta 1
X403	Connettore motore paletta 2
X404	Connettore motore paletta 3
X405	Connettore motore paletta 4
X406	Connettore motore carrello/ruota filtri
X407	Connettore sensori fine corsa palette 1
X408	Connettore sensori fine corsa palette 2
X409	Connettore sensori fine corsa palette 3
X410	Connettore sensori fine corsa palette 4
X411	Connettore sensori posizione CW-CX-CCW filtro
X412	Connettore lampada
X413	Sensori termici e pilotaggio ventola tubo
X414	Connessione tastiere tubo
X415	Ingresso segnale sensore raggi
X416	Alimentazioni Out
X417	CAN bus in-out
X950	Connettore ICSP PIC



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10.3. I009 Compressor board

Connettore	Funzione
JC76	
JC77	
X491	Cella di carico 1 misurazione forza di compressione
X492	Cella di carico 2 misurazione forza di compressione
X493	Antenna RFID
X950	Connettore ICSP PIC



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10.4. I009PB Compressor Piggy Back board

Connettore	Funzione
X484	Alimentazioni Out modulo display 1
X485	Seriale RS232 modulo display 1
X486	Alimentazioni Out modulo display 2
X487	Seriale RS232 modulo display 2
X488	Interfacciamento transceiver CAN a periferica FlexCAN Modulo Display 1
X489	Interfacciamento transceiver CAN a periferica FlexCAN Modulo Display 2
JC75LT	Segnali interconnessione I021-I009PB via flat lato sinistra paziente
JC75RT	Segnali interconnessione I021-I009PB via flat lato destra paziente
JC76	Connessione piggyback alla I009
JC77	Connessione piggyback alla I009
JC81	CAN bus via cavo singolo



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10.5. I010 Detector

JC72	Segnali interconnessione I012-I010
JC75	Segnali interconnessione I010-I021
JC78	Segnali interconnessione I010-I021
JC79	Bus Segnali Real Time
JC80	Segnali abilitazione movimenti supporto paziente
X440	Connessione di terra piste di shield segnali
X441	Alimentazioni In-Out
X442	Uscita alimentazioni azionamento Compressore
X443	Segnali verso azionamento compressore
X444	Segnali verso azionamento asse Z biopsia
X445	Iniezione tensione in circuiti Fault/Emergenza
X446RT	Segnali fungo emergenza destra
X446LT	Segnali fungo emergenza sinistra
X447	Segnali seriale terminale biopsia
X448LT	Alimentazioni e segnali terminale biopsia, attacco di sinistra
X448RT	Alimentazioni e segnali terminale biopsia, attacco di destra
X449	Segnali verso azionamento carrello Potter
X450	Ingresso sensore ingrandimento x1.5
X451	Ingresso sensore ingrandimento x1.8
X452	Segnali interfacciamento Detector LMAM II
X453	Sensore fine corsa 1 asse Z Biopsia
X454	Sensore fine corsa 2 asse Z Biopsia
X455	Segnali Encoder braccio Tomo, segnale pilotaggio Relè statico freno braccio Tomo
X456	Segnali verso azionamento braccio Tomo
X457	Segnali azionamento griglia anti-diffusione
X458	Sensore fine corsa carrello Potter IN (griglia anti-diffusione in campo raggi)
X459	Sensore fine corsa carrello Potter OUT (griglia anti-diffusione fuori campo raggi)



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10.6. I011 Biopsy board

Connettore	Funzione
X530	Connessione di terra piste di shield segnali
JC82	Alimentazioni, segnali, CAN azionamenti
X532	Segnali verso azionamento asse X biopsia
X533	Segnali verso azionamento asse Y biopsia
X534	Segnali CAN
X535	Pulsante enable movement
X536	Sensore fine corsa asse X Biopsia
X537	Sensore fine corsa asse Y Biopsia
X538	alimentazioni e segnali encoder angolo biopsia
X539	alimentazioni e segnali encoder carrello pistola



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10.7. I011AC Biopsy cabling switching

Connettore	Funzione
X530	Connessione di terra piste di shield segnali
JC78RT	Connessione segnali biopsia/accessori tramite cavo flat lato dx paziente
JC78MD	Connessione segnali biopsia/accessori tramite cavo flat lato TBD paziente
JC78LT	Connessione segnali biopsia/accessori tramite cavo flat lato sx paziente
JC82	Alimentazioni, segnali, CAN degli azionamenti Assi X-Y biopsia

10.8. I012 Gantry boards

Connettore	Funzione
JC70	Segnali fungo emergenza tastierino operatore AWS
JC71	Segnali tastierino operatore AWS
JC72	Segnali da/verso scheda I010
X460	Connessione di terra piste di shield segnali
X461	Alimentazioni In
X462	CAN bus in-out
X463	Segnali controllo e monitoraggio globale alimentatore XP XM10
X464	Segnali controllo e monitoraggio moduli alimentatore XP XM10
X465	Segnali controllo e monitoraggio modulo spare alimentatore XP XM10
X466	Connessione tastiere stativo
X467	Ingresso sensore 1 antichiacciamento
X468	Ingresso sensore 2 antichiacciamento
X469A	Pedaliere movimento verticale Gantry e Compressore
X469B	Pedaliere movimento verticale Gantry e Compressore (clone di X469A)
X469C	Pedaliere movimento verticale Gantry e Compressore (clone di X469A)
X470	Segnali inverter alta tensione raggi-X
X471	Uscita Comando raggi automatici
X472	Ingresso comando ausiliario raggi automatici
X473	Contatto porta stanza raggi e segnalazione apparecchio attivo
X474	Comando segnalazione luce esposizione in corso, per stanza raggi
X475	Comando Teleruttore Potenza Inverter
X950	Connettore ICSP PIC
X951	Segnali JTAG CPLD



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10.9. I013 SELEMA actuation

Connettore	Funzione
X500	Connessioni CAN/RS422 di servizio
X501	Alimentazioni In-Out
X502	I/O Digitali
X503	I/O Digitali APPS
X504	Segnali Encoder
X505	Motore e freno
X506	I/O TEN
X507	Sicurezza termica
X508	Segnali fasatura motore brushless
X509	CAN bus In-Out
X510	Indirizzo cablato nodo CAN
X511	Ingresso potenziometro o sensore analogico
X512	Connessione SPI tra azionamento Master e Slave in modalità accoppiata. Master e Slave in modalità accoppiata.

10.10. I014 Gantry keyboard

Connettore	Funzione
X466RT	Connessione tastiera di destra paziente
X466LT	Connessione tastiera di sinistra paziente

10.11. I015 Tube keyboard

Connettore	Funzione
X414RT	Connessione tastiera di destra paziente
X414LT	Connessione tastiera di sinistra paziente



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10.12. I017 Wireless foot pedals power board

Connettore	Funzione
X380	Ingresso alimentazione 18-36Vdc
X381	Uscita alimentazione +12Vdc 500mA

10.13. I020 Power switching board

Connettore	Funzione
PL1_OUT	Uscita alimentazione +24V logica
PL1_IN	Ingresso alimentazione +24V logica
PL1_THRU1	Presa intermedia distribuzione alimentazione +24V logica
PL1_THRU2	Presa intermedia distribuzione alimentazione +24V logica
PL1_THRU3	Presa intermedia distribuzione alimentazione +24V logica
PL1_THRU4	Presa intermedia distribuzione alimentazione +24V logica
PL2_OUT	Uscita alimentazione +24V potenza
PL2_IN	Ingresso alimentazione +24V potenza
PL2_THRU1	Presa intermedia distribuzione alimentazione +24V potenza
PL2_THRU2	Presa intermedia distribuzione alimentazione +24V potenza
PL2_THRU3	Presa intermedia distribuzione alimentazione +24V potenza
PL2_THRU4	Presa intermedia distribuzione alimentazione +24V potenza
PL3_OUT	Uscita alimentazione +36V potenza interrompibile
PL3_IN	Ingresso alimentazione +36V potenza interrompibile
PL3_THRU1	Presa intermedia distribuzione alimentazione +36V potenza interrompibile
PL3_THRU2	Presa intermedia distribuzione alimentazione +36V potenza interrompibile
PL3_THRU3	Presa intermedia distribuzione alimentazione +36V potenza interrompibile
PL4_OUT	Uscita alimentazione +48V potenza non interrotta
PL4_IN	Ingresso alimentazione +48V potenza non interrotta
PL4_THRU1	Presa intermedia distribuzione alimentazione +48V potenza non interrotta
PL4_THRU2	Presa intermedia distribuzione alimentazione +48V potenza non interrotta
PL4_THRU3	Presa intermedia distribuzione alimentazione +48V potenza non interrotta, con diodo antirimonto



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10.14. I021 Operator control table command board

Connettore	Funzione
X490	Connessione di terra piste di shield segnali
X481	Alimentazioni In
X482RT	CAN bus in
X482LT	CAN bus out
X483	Iniezione tensione in circuiti Fault/Emergenza
X495	Alimentazioni Out per azionamento asse Z biopsia
X496	Sensore di collisione carrello Compressore contro carrello asse Z Biopsia
X497	Biopsy CAN and signals to Z axis
X444A	Intercettazione segnali I010 verso azionamento asse Z biopsia
JC75	Segnali interconnessione I010-compressore
JC75LT	Segnali interconnessione compressore via flat lato sinistra paziente
JC75RT	Segnali interconnessione compressore via flat lato destra paziente
JC78	Segnali interconnessione I010-biopsia/accessori
JC78RT	Connessione segnali biopsia/accessori tramite cavo flat lato dx paziente
JC78MD	Connessione segnali biopsia/accessori tramite cavo flat lato TBD paziente
JC78LT	Connessione segnali biopsia/accessori tramite cavo flat lato sx paziente
JC81RT	CAN bus via cavo singolo (alternativo CAN andata)
JC81LT	CAN bus via cavo singolo (alternativo CAN ritorno)
X950	Connettore ICSP PIC

10.15. I022 Operator control table Cabling switching board

Connettore	Funzione
JC71	Segnali tastierino operatore AWS
JC71LO	Diramazione segnali 1-12 connettore JC71
JC71HI	Diramazione segnali 13-26 connettore JC71
X521	Connessione pulsante ON/OFF e Buzzer esterno
X522A	Connessione pulsante XRAY
X522B	Connessione pulsante XRAY ausiliario
X522C	Connessione pedaliera XRAY ausiliaria



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11. Maintenance

11.1. Warnings on routine maintenance



INFORMATION

The equipment requires only minimum maintenance. The normal precautions in using the equipment will ensure optimal, continuous and reliable operation. Nevertheless, we advise you to run periodic checks and controls on the operation of the equipment and its parts, in order to ensure that its performance and reliability are maintained.



WARNING

Whenever the equipment is started, make sure that the safety devices are functioning correctly.



CAUTION

If you note any faults or malfunctions, stop using the equipment immediately and contact the Authorized Technical Service.



CAUTION

For any type of preventive maintenance, always disconnect the equipment from the mains to avoid damage to persons and/or the electrical - electronic parts of the mammography equipment.

Maintenance jobs must only be carried out by authorized personnel.






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11.2. Cleaning

	CAUTION When cleaning, take care not to allow solvents to penetrate inside the equipment, as this could cause serious damage to the various parts.
	INFORMATION For the normal cleaning of the various guards, do not use solvents, thinners or products that contain "aggressive" substances towards paint and plastic. Use exclusively neutral liquid soap and a soft sponge.
	Do not use chemical products, thinners or solvents to clean the equipment. All parts of the equipment in contact with the patient must be disinfected with specific products like, for example, CHLORHEXIDINE .

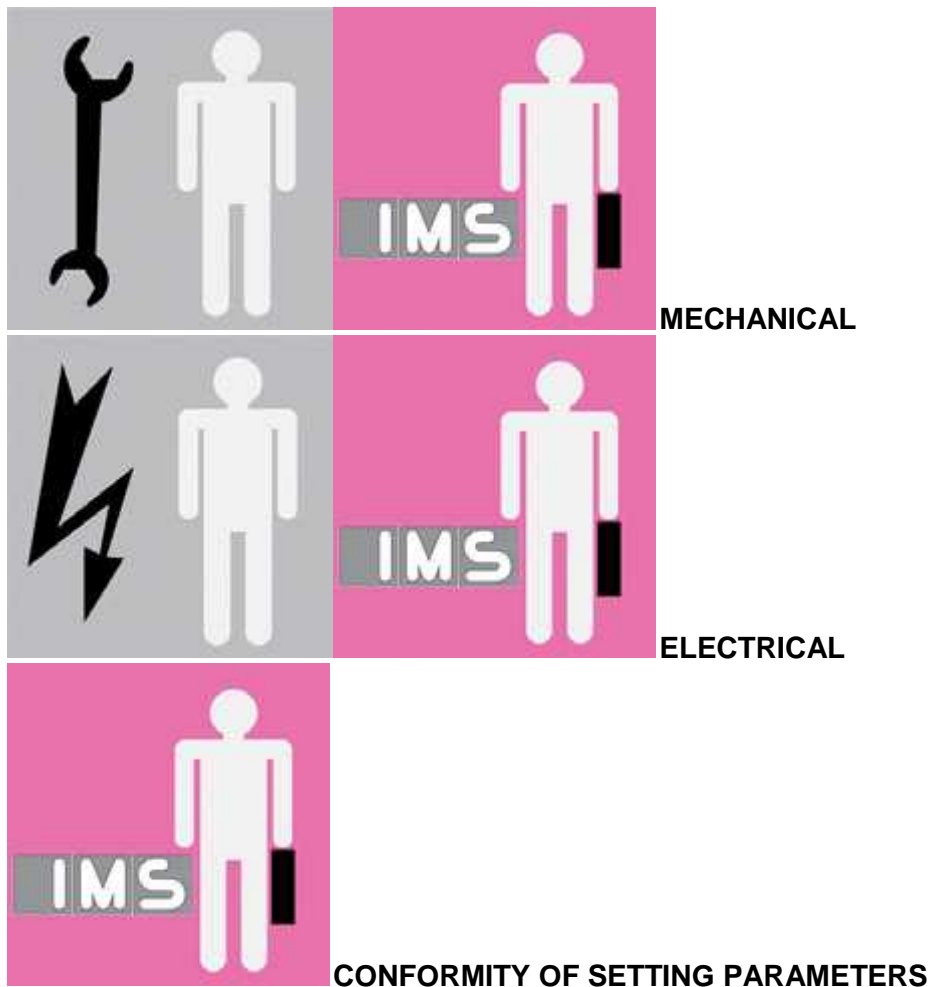
Do this before every radiological examination.

Never use alcohol to clean the acrylic components (compressor, surface for magnification technique, headrest).

The anti-Xray lead glass panel should be cleaned with a glass cleaning product, or denatured alcohol. Use specific products for cleaning the monitor (water based and neutral soap).

	CAUTION The incorrect use of products can cause damage to the monitor.
	WARNING To keep the equipment in perfect working order and to avoid malfunctions and/or faults, organize systematic, rational cleaning of the various parts of the equipment and of the room where it is installed. When cleaning, take care not to allow solvents to penetrate inside the equipment, as they could cause serious damage to the parts.
	CAUTION The scrapping of waste materials and parts of the equipment, including the batteries of the UPS, must only be done by SERVICE PERSONNEL.

11.3. Preventive maintenance program





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DESCRIPTION	FEQUENCY	PROCEDURE
Vertical movement	12 months	Check the safety bolt; Clean and lubricate the columns; Check elevator movement speed; Check the cables positions inside the chain;
Compression system	12 months	Check compression force setting; Check maximum compression force (30 kg); Check programmed compression force limit (20 kg); Check thickness value during compression; Check the cables positions inside the chain;
Tube Arm	12 months	Check integrity of the brake system Check the integrity of the belt; Lubricate the guide;
Gantry rotation	2 years	Check the integrity of the moto-redactor
Gantry inclination	2 years	Check the integrity of the moto-redactor
Collimator	12 months	Check the x-ray field collimation; Check and lubricate the four screws of the motors;
Digital Detector	12 months	Defect calibration
	12 months	Fast calibration
	12 months	Check the efficiency of the detector fans
	12-24 months	Long Calibration
Potter/Bucky system	12 months	Lubricate the rail; Check the anti-scatter grid motor; Check the cables positions inside the chain;
Biopsy Z axis	12 months	Lubricate the screw; Check the cables positions inside the chain;
Enclosure	2 years	Check the integrity of the enclosures;
AWS Workstation	12 months	Check the integrity of the breaking system of the control table; Check the proper functionality of the UPS system;
Image quality	12 months	See dedicated chapter
X-ray protection	Refer to local laws	



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11.4. Disposal and scrapping of the obsolete equipment

According to **Directive 2012/19/UE**, on **Waste Electrical and Electronic Equipment (WEEE)**, and in reference to Italian Legislative Decree no. 151 of 25/07/05, we inform users of this device of the following aspects:

- 1) When the equipment is decommissioned, it must not be disposed of as unsorted municipal waste and must be collected and disposed of separately;
- 2) WEEE must be delivered to appropriate collection facilities, or returned to the distributor if a new equipment is purchased;
- 3) If disposed of improperly, WEEE may have negative effects on human health and on the environment;
- 4) Every WEEE has the symbol reported below, indicating that the equipment must not be disposed of as unsorted municipal waste;
- 5) In case of unlawful disposal of WEEE, the penalties indicated in art. 16 of Italian Legislative Decree no. 151 of 25/07/05 will be applied.

COMPOSITION

The Giotto Class medical device and its components have been built according to **Directive 2011/65/UE**, on **Restriction of Hazardous Substances (RoHS)**.

- Steel: 50%
- Aluminum: 10%
- Plastic: 10%
- Copper/Brass/Bronze: 27%
- Glass: 2%
- Oil: 1%

There are no radioactive materials present in the equipment.



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12. Breakdowns and diagnosis

12.1. Introduction

During operation the equipment's touchscreen panel shows a series of messages indicating the status and any emergency situations.

This section gives a list of the signals and, for each one, a brief explanation of the possible causes and the operations to be performed to restore the equipment to normal working order. These explanations are only valid for the cases in which the problem may be easily and safely resolved.



ATTENTION

All operations must be performed by specialized personnel.



INFORMATION

If the problem may not be resolved by means of the instructions given in this section, the Manufacturer's Technical Support Service should be immediately contacted.

The progressive number in front of the message is also the message ID number and appears on the panel during signalling.

The numbering of the messages in the following list might not be consecutive since the equipment in question may not have certain optional parts.

All interventions to resolve the problems must be done respecting the same prevention and safety standards that are valid for any other type of intervention on the equipment.

I.M.S. S.r.l. declines all liability for damage of any kind caused by insufficient maintenance, and the use of unoriginal spare parts or spare parts that are incompatible with the quality standard and electro-mechanical characteristics of the equipment.

12.2. Alarms management

Giotto Class signals the presence of an alarm acoustically by means of three repeated sounds and visually by showing the alarm code and an error message on the touchscreen. The presence of an alarm inhibits exposure to X/rays. There are 2 types of alarm: those that can be reset by pressing a button and those requiring the machine to be switched off and on again.

Some alarms can derive from different events. A good way of understanding what problem generates an alarm is the Param Class “Error Log”. The Error Log is a register of alarms, errors and other significant events taking place while Giotto Class is operating

12.2.1. Opening and consulting the Error Log

1. Execute the “Param Class” application. Once the software is running open the “File” menu and select “Connection”.

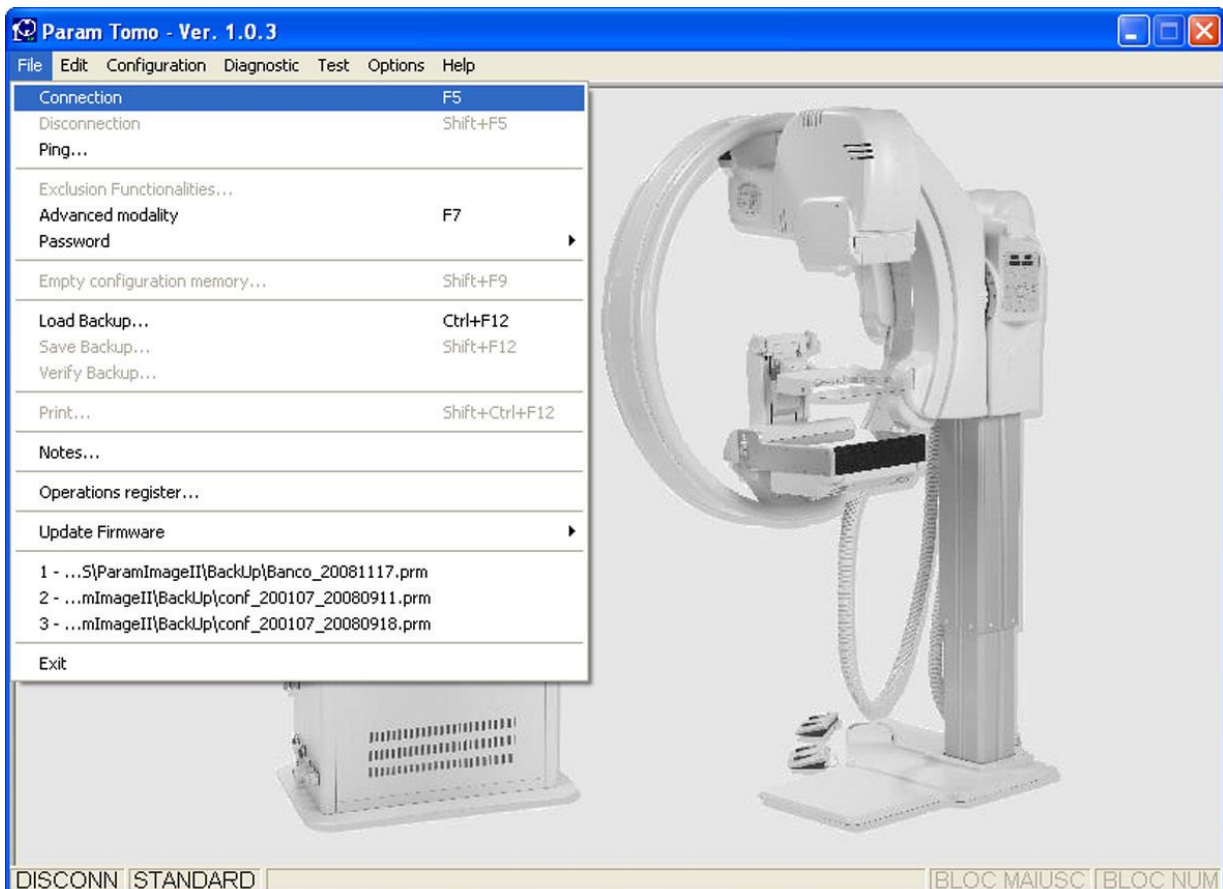
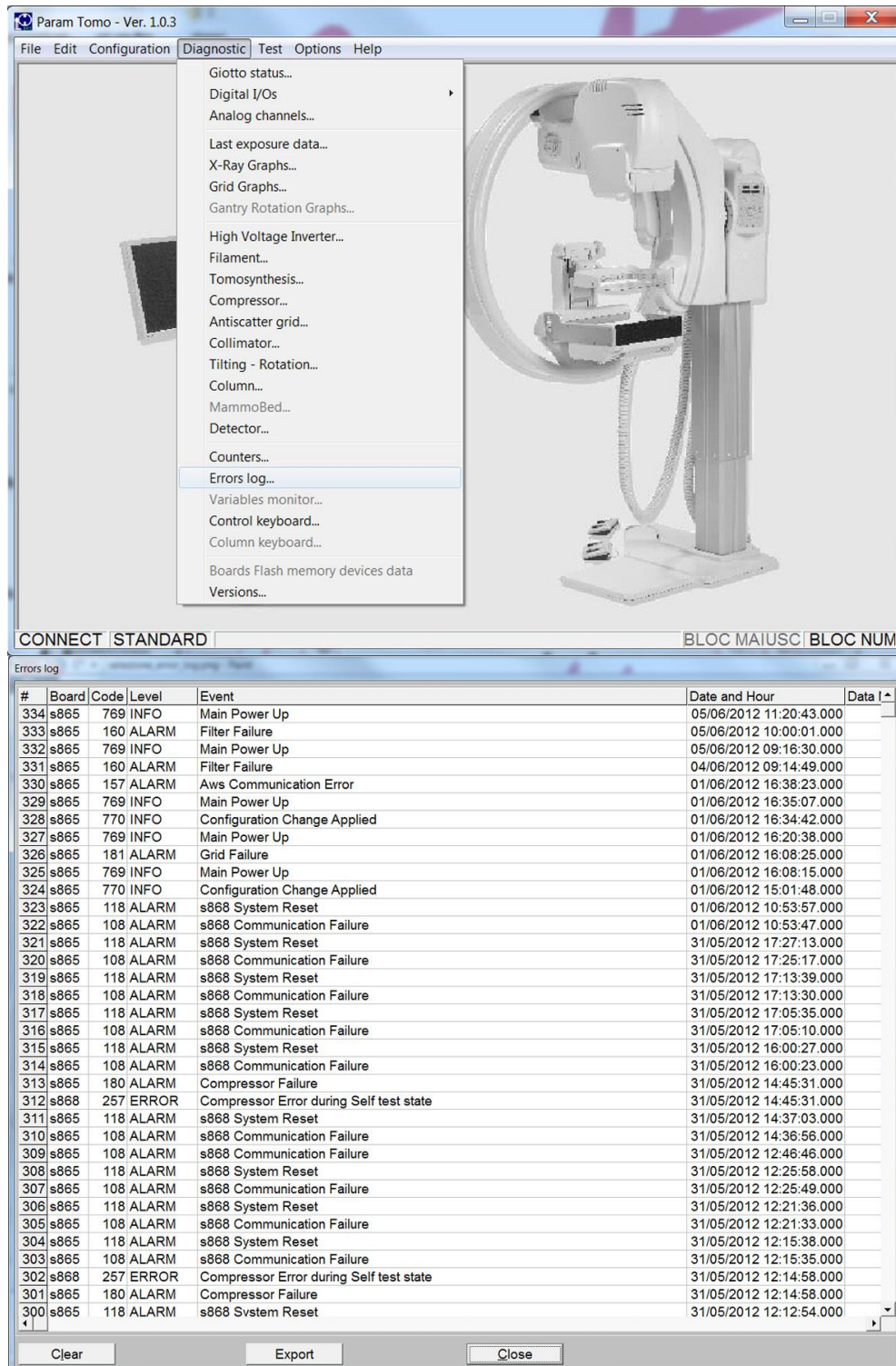


IMAGE UNDER REVISION

3. Open the “Diagnostic” menu and select “Error Log”



IMAGES UNDER REVISION



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Each row corresponds to an event. The following information is available for each event:

- Electronic board that recorded the event.
- Event code: the codes are univocal for the alarms. The other event types are identified by their board-code combination.
- Event level: this can be of 4 types:
 - o ALARM: alarm thrown by GiottoTomo. Inhibits exposure to X-rays (e.g.: Compressor fault alarm).
 - o ERROR : operating error. This can generate an alarm. It refers to a fault that must be analysed in order to understand what action to take on the machine. (e.g.: Error in rotation movement potentiometer)
 - o WARNING: Reporting of situations that are on the verge of an error, but that do not compromise correct machine operation. (e.g.: Signalling elevated temperature in the vertical movement motor)
 - o INFO: Information about significant events that do not generate operating problems. (e.g.: Information concerning switching on the machine).
- Description of event.
- Date and time the event was recorded.
- Number of pieces of information associated with the event. An event can have one or more associated data, such as potentiometer values, current values, machine status, and so on.
- Code of the first piece of associated information. Double click on the event row to turn the codes into descriptive text.
- Value of the first piece of associated information.
- ...
- ...
- Code of the last piece of associated information.
- Value of the last piece of associated information.

To understand what generated an alarm, check if an associated error is present in the adjacent rows. If the date and time of an error coincide with that of an alarm, it was probably that error which triggered the alarm.



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Errors log

#	Board	Code	Level	Event	Date and Hour	Data
035	s868	259	ERROR	Motor Driver serial communication error	24/05/2012 14:52:44.000	
034	s865	180	ALARM	Compressor Failure	24/05/2012 14:52:44.000	
033	s868	257	ERROR	Compressor Error during Self test state	24/05/2012 14:52:44.000	
032	s868	263	ERROR	Motor driver responses on serial bus have some data corrupted	24/05/2012 14:52:12.000	
031	s868	259	ERROR	Motor Driver serial communication error	24/05/2012 14:45:20.000	
030	s865	180	ALARM	Compressor Failure	24/05/2012 14:45:01.000	
029	s868	257	ERROR	Compressor Error during Self test state	24/05/2012 14:45:01.000	
028	s868	257	ERROR	Compressor Error during Self test state	24/05/2012 14:44:00.000	
027	s865	180	ALARM	Compressor Failure	24/05/2012 14:44:00.000	
026	s868	259	ERROR	Motor Driver serial communication error	24/05/2012 14:44:00.000	
025	s868	263	ERROR	Motor driver responses on serial bus have some data corrupted	24/05/2012 14:43:59.000	
024	s868	257	ERROR	Compressor Error during Self test state	24/05/2012 14:29:08.000	
023	s868	259	ERROR	Motor Driver serial communication error	24/05/2012 14:29:08.000	
022	s865	180	ALARM	Compressor Failure	24/05/2012 14:29:08.000	
021	s868	263	ERROR	Motor driver responses on serial bus have some data corrupted	24/05/2012 14:29:08.000	
020	s865	769	INFO	Main Power Up	24/05/2012 14:28:53.000	
019	s865	118	ALARM	s868 System Reset	24/05/2012 14:09:52.000	
018	s865	108	ALARM	s868 Communication Failure	24/05/2012 14:09:02.000	
017	s868	263	ERROR	Motor driver responses on serial bus have some data corrupted	24/05/2012 14:07:55.000	
016	s865	118	ALARM	s868 System Reset	24/05/2012 14:07:35.000	
015	s865	108	ALARM	s868 Communication Failure	24/05/2012 14:07:29.000	
014	s865	118	ALARM	s868 System Reset	24/05/2012 14:06:15.000	
013	s865	108	ALARM	s868 Communication Failure	24/05/2012 14:05:57.000	
012	s868	257	ERROR	Compressor Error during Self test state	24/05/2012 10:41:47.000	
011	s865	180	ALARM	Compressor Failure	24/05/2012 10:41:47.000	
010	s868	259	ERROR	Motor Driver serial communication error	24/05/2012 10:41:47.000	
009	s868	257	ERROR	Compressor Error during Self test state	24/05/2012 10:40:42.000	
008	s865	180	ALARM	Compressor Failure	24/05/2012 10:40:42.000	
007	s868	259	ERROR	Motor Driver serial communication error	24/05/2012 10:40:42.000	
006	s865	118	ALARM	s868 System Reset	24/05/2012 10:40:10.000	
005	s866	772	INFO	Anodic Current too High	24/05/2012 10:40:10.000	
004	s866	771	INFO	Filament Current too High	24/05/2012 10:40:10.000	
003	s866	770	INFO	Filament Current too Low	24/05/2012 10:40:10.000	
002	s865	108	ALARM	s868 Communication Failure	24/05/2012 10:39:41.000	
001	s868	259	ERROR	Motor Driver serial communication error	24/05/2012 10:38:19.000	

Clear Export Close

12.3. List of alarms

List of machine status messages and instructions to restore operation:

INSERT THE LIST OF THE ALARMS UPDATED



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13. Interventions on the equipment

13.1. Introduction

This chapter covers all operations to repair or replace groups or components that are worn, defective or damaged.

	WARNING After every intervention, check that the equipment's various cable harnesses are like they were originally.
	CAUTION Only specialized personnel can perform these interventions.
	INFORMATION I.M.S. is not responsible for damage of any kind due to improper maintenance, the using of non original replacement parts, or that do not meet the equipment's quality standards and electromechanical characteristics.

13.2. X-RAY TUBE

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - X-ray tube thermal safety switch:
 - Rotating anode jammed:
 - Reduction in X-ray tube efficiency:
 - Filament fault:

13.3. COLLIMATOR

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - Collimator filters change disk:
 - Collimator size change:



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- Centring led lamp:

13.4. FILTER WHEEL

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - Faulty coupling between motor and disc. Excessive noise. Disc blocked.
 - Faulty motor
 - Faulty position sensors
 - Damaged filters

13.5. COMPRESSOR MOTOR

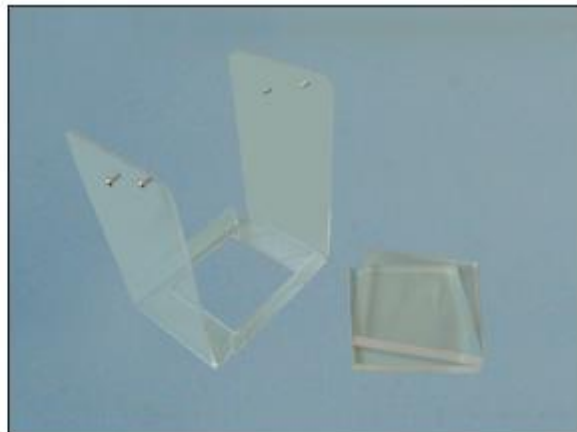
- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - The compressor does not move.
 - Compression impossible.
 - The compressor is not automatically released.

13.6. LOAD CELL

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - The grid does not move.
 - The grid doesn't move correctly, increase in the noise in the acquired images.

13.7. DETECTOR

- Replacement:
- Calibration and auxiliary operations:
 - Necessary tools



- Supporto dedicato;
- 2 blocchi di PMMA dello spessore di 20 mm ciascuno e di dimensioni di 150x145 mm;
- 2 blocchi di PMMA dello spessore di 20 mm ciascuno coprenti l'intera area di rivelazione (in dotazione con l'apparecchiatura);
- Dosimetro (opzionale) oppure Multimetro digitale (consigliato UNFORS Xi).



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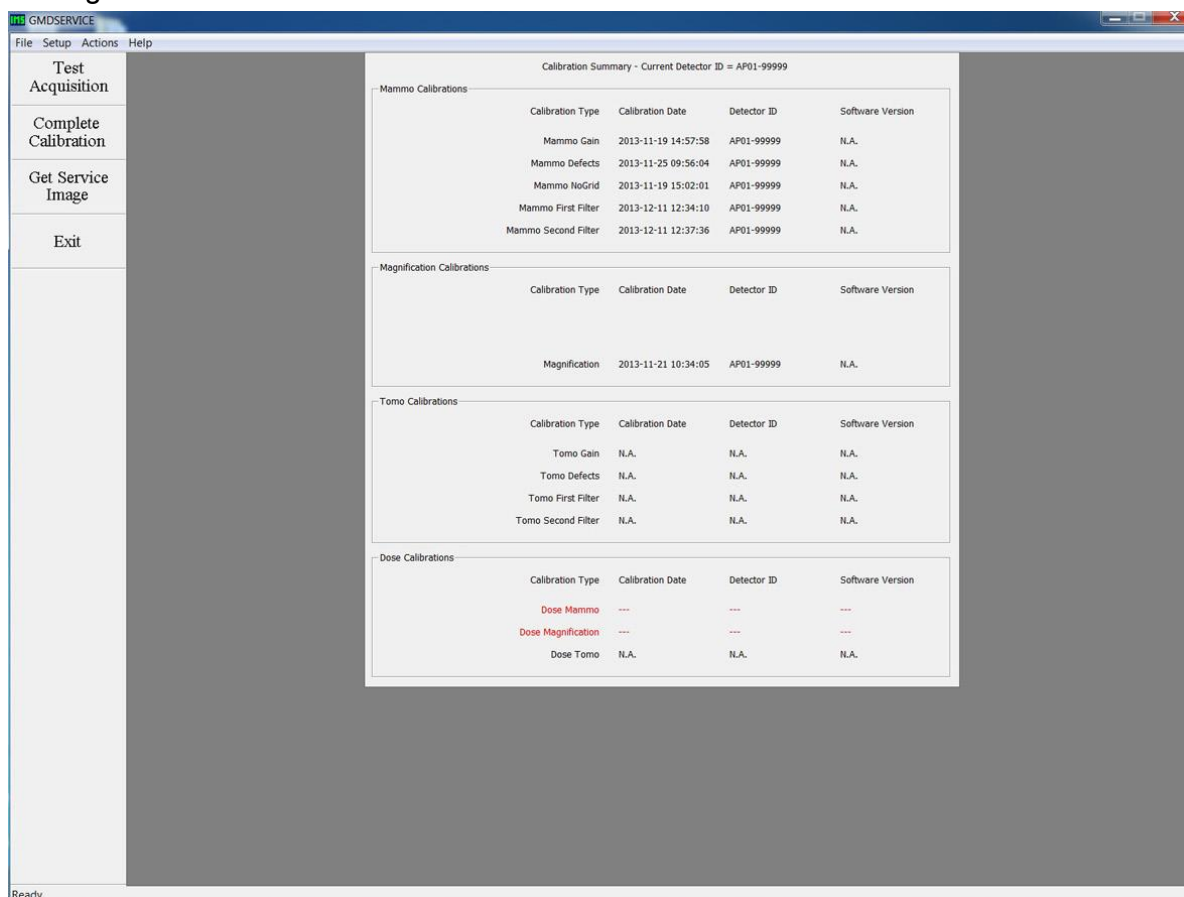


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In questa sezione sono descritte le procedure complete per la calibratura del detector che comprendono la **calibrazione del guadagno** (che dura all'incirca 5 minuti) che ha lo scopo di correggere l'immagine acquisita per la sottrazione del the dark frame, del guadagno degli amplificatori di segnale e dell'offset;

la procedura per la **calibrazione dei difetti** che ha lo scopo di correggere l'immagine acquisita per la presenza di pixel/righe/colonne difettose (che dura all'incirca 2 minuti); e le **calibrazioni disuniformità filtri** che comprendono la correzione delle disomogeneità dei filtri e della griglia anti-scatter, della piattaforma d'ingrandimento e della biopsia (che durano all'incirca 3 minuti ciascuna); infine vi è descritta la procedura per effettuare la **calibrazione della dose** emessa dal tubo radiogeno, che ha lo scopo di compensare la visualizzazione della dose ghiandola media, per il decadimento naturale dell'efficienza dello stesso.

Le calibrazioni vanno eseguite per l'installazione dell'apparecchiatura e vanno ripetute periodicamente, o quando insorgono problemi relativi ad artefatti o relativi alla qualità dell'immagine.



Prima di effettuare una qualsiasi calibrazione del detector, e nel caso in cui una di queste non dovesse avviarsi correttamente, seguire attentamente le seguenti avvertenze:

IMPORTANT WARNING

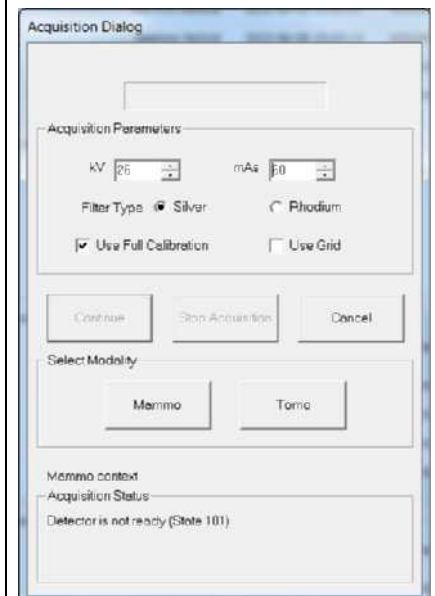
- Assicurarsi di avere eseguito il Login come Amministratore.
- Assicurarsi che l'apparecchiatura **non sia in modalità M2**;
- Assicurarsi che il **cavo Raggi Automatici** (connettore X34) sia connesso;
- Chiudere l'applicativo "Raffaello";
- Assicurarsi che i **Servizi di Acquisizione** siano **attivi**; Per controllare che i servizi siano partiti correttamente seguire la seguente procedura:

- 1) Aprire il programma GMDService da Start->Programs->Raffaello->GMD Service;
- 2) Premere "Service Procedure", e inserire la password di servizio: **"giottomdsrv"**.



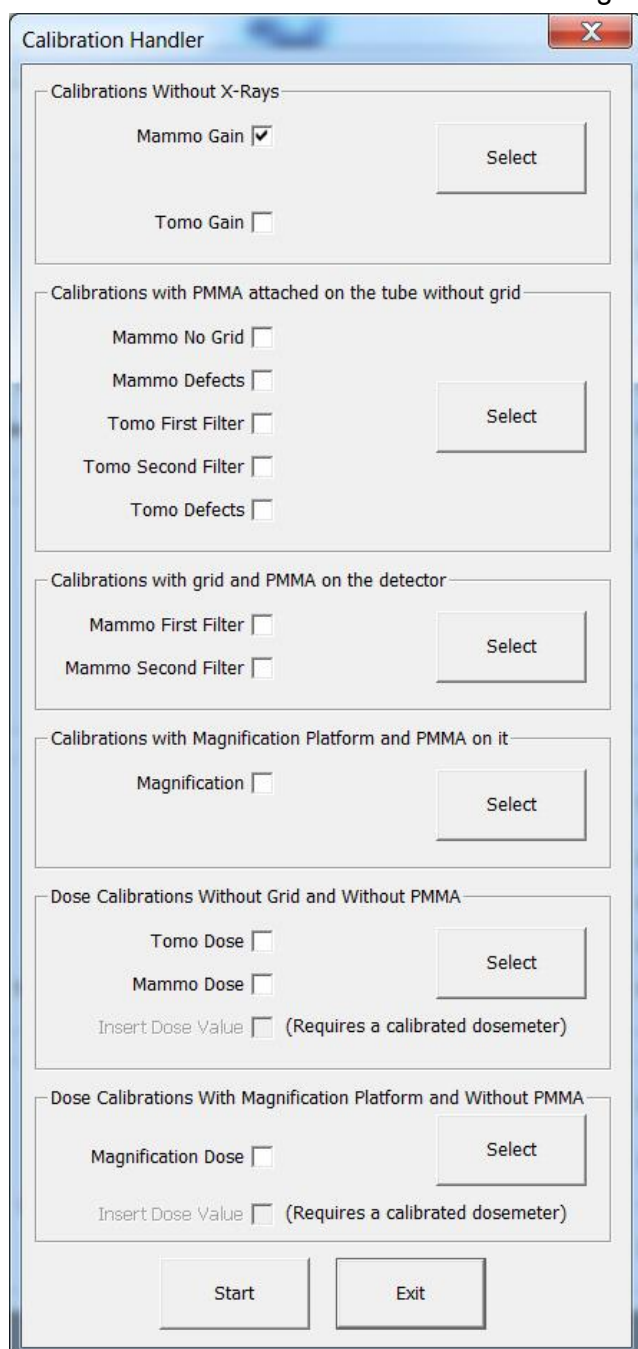
- 3) Premere "Test Acquisition" e osservare la finestra di dialogo. Entro un minuto deve apparire il messaggio "Detector ready". Se è presente il messaggio "Acquisition Service Error: Probably the service is not active" seguire la procedura:

- a. Premere "Actions/Open Control Dialog";
 - b. Nella sezione "Servizi di Acquisizione" premere il tasto "Stop";
 - c. Nella finestra di Dialogo deve apparire un messaggio di conferma dello stato disattivo dei servizi di acquisizione;
 - d. Nella sezione "Servizi di Acquisizione" premere il tasto "Start Console";
 - e. Osservare la sequenza di eventi sulla console.
- Assicurarsi che la **collimazione** del campo raggi sia **corretta**.



CALIBRAZIONE DEL GUADAGNO

La calibrazione del guadagno dura circa 5 minuti per essere completata ed è composta dall'acquisizione di diversi dark frame, per il calcolo della mappa di guadagno del detector, al fine di ottenere la correzione di flat-field sull'immagine finale.



Calibration Handler

Calibrations Without X-Rays

Mammo Gain ☒ Select

Tomo Gain ☐

Calibrations with PMMA attached on the tube without grid

Mammo No Grid ☐

Mammo Defects ☐

Tomo First Filter ☐ Select

Tomo Second Filter ☐

Tomo Defects ☐

Calibrations with grid and PMMA on the detector

Mammo First Filter ☐ Select

Mammo Second Filter ☐

Calibrations with Magnification Platform and PMMA on it

Magnification ☐ Select

Dose Calibrations Without Grid and Without PMMA

Tomo Dose ☐ Select

Mammo Dose ☐

Insert Dose Value ☐ (Requires a calibrated dosimeter)

Dose Calibrations With Magnification Platform and Without PMMA

Magnification Dose ☐ Select

Insert Dose Value ☐ (Requires a calibrated dosimeter)

Start Exit

Strumentazione richiesta:



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- Nessuno

Frequenza:

All'accettazione e ogni anno.

Questa calibrazione è da ripetersi nel caso in cui appaiano sull'immagine finale delle **evidenti** disomogeneità.



AVVERTENZE SPECIFICHE PER LA CALIBRAZIONE DEL GUADAGNO IN MODALITÀ MAMMOGRAFICA

Se dal momento in cui viene effettuata la calibrazione del guadagno, al momento in cui si acquisisce l'immagine finale, vi è una variazione di temperatura superiore a 10°C, è possibile che nell'immagine finale siano presenti evidenti **disomogeneità**, con la possibilità di vedere la struttura di amplificazione (MCM) del detector.

Se si dovesse verificare questa condizione, **occorre necessariamente ripetere l'intera procedura di calibrazione.**



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CALIBRAZIONE DEI DIFETTI

La calibrazione dei difetti dura 2 minuti per essere completata ed è composta dall'acquisizione di 2 immagini (una al minuto), per il calcolo della mappa dei pixel, righe o colonne difettose, al fine di ottenere la correzione dei difetti sull'immagine finale. Terminata la calibrazione dei difetti viene generato un file di testo con il report dei risultati ottenuti, e un'immagine (file dati .dat) caricabile attraverso Raffaello (vedi apposita sezione), per la visualizzazione della mappa dei difetti.

Strumentazione richiesta:

- Supporto dedicato;
- 2 blocchi di PMMA dello spessore di 20 mm ciascuno e di dimensioni di 150x145 mm.

Frequenza:

All'accettazione e ogni anno.

Questa calibrazione è da ripetersi anche nel caso in cui qualche nuovo pixel difettoso viene scoperto nel detector, o sia presente su uno dei filtri (o sullo specchio) un qualche oggetto che altera l'immagine creando un artefatto visibile. Va inoltre eseguita nuovamente nel caso in cui si sostituisca il detector.

Procedura:

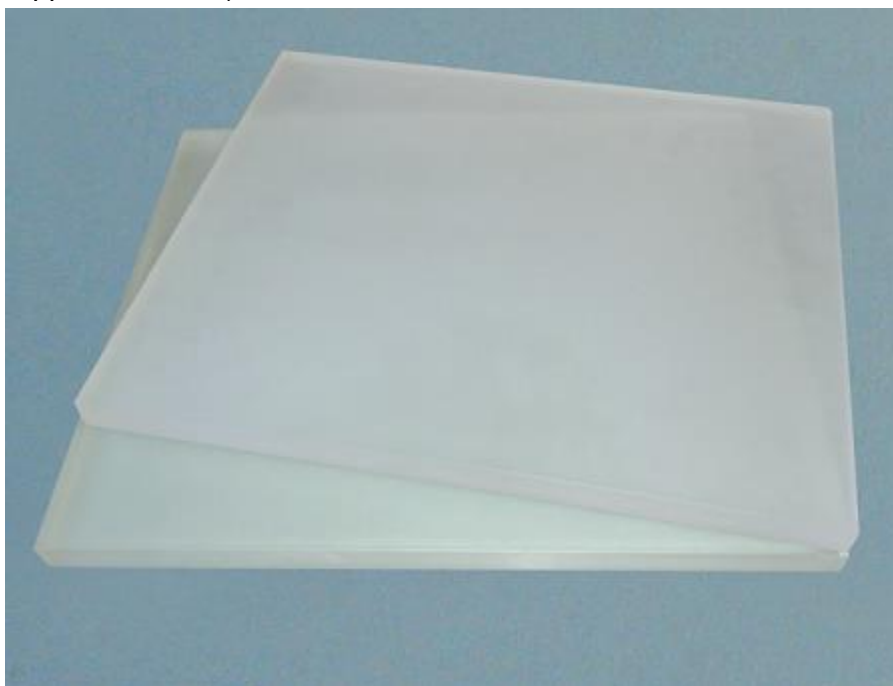
1. Accendere il generatore;
2. Assicurarsi che l'apparecchiatura **non sia** in modalità M2;
3. Assicurarsi che il cavo Raggi Automatici (connettore X34) sia connesso;
4. Chiudere l'applicativo "Raffaello";
5. Aprire il programma GMDService da Start->Programs->Raffaello->GMD Service;
6. Premere "Service Procedure", e inserire la password di servizio: "**giottomdsrv**";
7. Assicurarsi che i "Servizi di Acquisizione" siano attivi;
8. Premere il tasto "**Complete Calibration**";
9. Selezionare "Mammo Gain" e premere il tasto "Start";
10. Assicurarsi che la procedura sia partita correttamente. Se la calibrazione non parte correttamente ricontrollare le avvertenze riportate a inizio Sezione!

CALIBRAZIONI DISUNIFORMITÀ FILTRI IN MODALITÀ MAMMOGRAFICA

Le calibrazioni disuniformità filtri durano 5 minuti ciascuna e sono composte dall'acquisizione di 5 immagini (una ogni minuto), per la correzione sull'immagine finale delle disomogeneità dei filtri, della griglia anti-scatter, della piattaforma d'ingrandimento e per la correzione delle immagini di Biopsia.

Strumentazione richiesta:

- 2 blocchi di PMMA dello spessore di 20 mm ciascuno coprenti l'intera area di rivelazione (in dotazione con l'apparecchiatura).



Frequenza:

All'accettazione e ogni anno.

Questa calibrazione è da ripetersi anche nel caso in cui venga sostituita la griglia anti-scatter, o la piattaforma d'ingrandimento e nel caso in cui vengano ripetute la calibrazione del guadagno o dei difetti.

Calibration Handler

Calibrations Without X-Rays

Mammo Gain ☐ Select

Tomo Gain ☐

Calibrations with PMMA attached on the tube without grid

Mammo No Grid ☐

Mammo Defects ☐

Tomo First Filter ☐

Tomo Second Filter ☐

Tomo Defects ☐ Select

Calibrations with grid and PMMA on the detector

Mammo First Filter ☒

Mammo Second Filter ☒ Select

Calibrations with Magnification Platform and PMMA on it

Magnification ☐ Select

Dose Calibrations Without Grid and Without PMMA

Tomo Dose ☐

Mammo Dose ☐ Select

Insert Dose Value ☐ (Requires a calibrated dosimeter)

Dose Calibrations With Magnification Platform and Without PMMA

Magnification Dose ☐ Select

Insert Dose Value ☐ (Requires a calibrated dosimeter)

Start Exit



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Calibration Handler

Calibrations Without X-Rays

Mammo Gain ☐ Select

Tomo Gain ☐

Calibrations with PMMA attached on the tube without grid

Mammo No Grid ☐

Mammo Defects ☐

Tomo First Filter ☐ Select

Tomo Second Filter ☐

Tomo Defects ☐

Calibrations with grid and PMMA on the detector

Mammo First Filter ☐ Select

Mammo Second Filter ☐

Calibrations with Magnification Platform and PMMA on it

Magnification ☒ Select

Dose Calibrations Without Grid and Without PMMA

Tomo Dose ☐ Select

Mammo Dose ☐

Insert Dose Value ☐ (Requires a calibrated dosimeter)

Dose Calibrations With Magnification Platform and Without PMMA

Magnification Dose ☐ Select

Insert Dose Value ☐ (Requires a calibrated dosimeter)

Start Exit

Procedura:

1. Se le calibrazioni disuniformità filtri sono state appena effettuate, saltare i seguenti punti e proseguire direttamente dal punto 9;
2. Accendere il generatore;
3. Assicurarci che l'apparecchiatura **non sia** in modalità M2;
4. Assicurarci che il cavo Raggi Automatici (connettore X34) sia connesso;
5. Chiudere l'applicativo Raffaello;
6. Aprire il programma GMDService da Start->Programs->Raffaello->GMD Service;
7. Premere "Service Procedure", e inserire la password di servizio: **"giottomdsrv"**;
8. Assicurarci che i "Servizi di Acquisizione" siano attivi;
9. Rimuovere il compressore, se presente;
10. Premere il tasto **"Complete Calibration"** e assicurarsi della corretta configurazione seguendo le avvertenze;



11. Selezionare "Mammo Dose";
12. Assicurarci che la procedura sia partita correttamente;
13. Dopo queste 3 immagini il programma chiede di acquisire la quarta immagine con la misura della dose emessa tramite dosimetro tarato per spettro W/Rh. Se si è in possesso del dosimetro, leggere attentamente nella finestra di dialogo il messaggio per settare correttamente il dosimetro e poi premere "yes", oppure selezionare "no"; Se si sceglie l'opzione "no", il programma chiede se si vuole cancellare il precedente valore di riferimento.

Dose Calibration [X]

Please insert the uGy read from the dosimeter

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OK Cancel

CalibrationProcedure [X]

? Value at 10/Dec/2009 12:28:55 is 0.050800
Do you want to save it?

OK Cancel

CalibrationProcedure [X]

i Dosimeter value saved

OK

CalibrationProcedure [X]

Dose Calibration correctly finished:
Calibration data saved

OK



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Fax. ++39 051 846856
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Calibration Handler

Calibrations Without X-Rays

Mammo Gain ☐ Select

Tomo Gain ☐

Calibrations with PMMA attached on the tube without grid

Mammo No Grid ☐

Mammo Defects ☐

Tomo First Filter ☐ Select

Tomo Second Filter ☐

Tomo Defects ☐

Calibrations with grid and PMMA on the detector

Mammo First Filter ☐ Select

Mammo Second Filter ☐

Calibrations with Magnification Platform and PMMA on it

Magnification ☐ Select

Dose Calibrations Without Grid and Without PMMA

Tomo Dose ☐ Select

Mammo Dose ☐

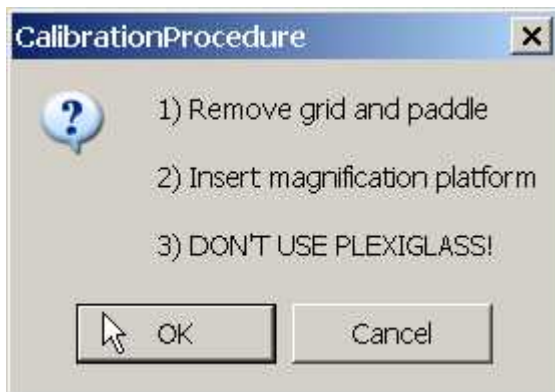
Insert Dose Value ☐ (Requires a calibrated dosimeter)

Dose Calibrations With Magnification Platform and Without PMMA

Magnification Dose ☒ Select

Insert Dose Value ☒ (Requires a calibrated dosimeter)

Start Exit



• **Possible Faults:**

- The detector does not acquire images.
- Communication error between the AWS and the detector.

13.8. DIGITAL DISPLAYS FOR THE VERTICAL X-RAY UNIT

• **Replacement:**

• **Calibration and auxiliary operations:**

• **Possible Faults:**

- Display not switched on
- Display switches off unexpectedly
- Displayed information not updated
- Unintelligible data displayed

13.9. HIGH VOLTAGE CABLE

• **Replacement:**

• **Calibration and auxiliary operations:**

• **Possible Faults:**

- Cable discharge:

In this case, there is an anode power spike that is intercepted by both the high voltage inverter and the filament control circuit, which causes the immediate interruption of the exposure. If the inverter alarm is tripped, one of the following LEDs will light on the inverter board: LD8 KV>110%, LD9 KV min, LD7 mA max; the power must be cut to reset the alarm.



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Fax. ++39 051 846856
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CAUTION

When a cable discharges H.V. it can't be detected by a normal ohm meter because the testing voltage is too low.

- Interrupted cable:

This type of fault cannot be safely detected with a normal ohm meter because the testing voltage is too low. The cable may be good with the ohm meter but applying H.V. it may be open.



CAUTION

Don't bend or twist the H.V. cable, as it could become damaged.

When locking the connectors together, be careful not to break the plastic body.

13.10. UNINTERRUPTABLE POWER SUPPLY (UPS)

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - The UPS does not turn on.
 - The UPS does not keep the system running during a power failure.

13.11. FILAMENT DC-DC CONVERTER

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - oo Communication error of auxiliary processor on S866
 - oo Filament current error
 - oo Anodic current error
 - oo Filament power supply voltage error

13.12. AWS WORKSTATION

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**



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Fax. ++39 051 846856
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- oo The workstation does not turn on.
- oo There are problems in the workstation's internal boards.

13.13. DVD – CD BURNER

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - oo The DVD – CD burner does not turn on.
 - oo The DVD – CD burner does not write data.
 - oo The data recorded on the disc are illegible.

13.14. MONITOR

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**
 - oo The monitor doesn't turn on.
 - oo There are parts of the monitor that do not work.

13.15. IXXAT

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**

13.16. Board I008: Collimator

- **Replacement:**
- **Calibration and auxiliary operations:**
- **Possible Faults:**

13.17. Board I009: Compressor

- **Replacement:**



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- Calibration and auxiliary operations:
- Possible Faults:

13.18. Board I010: Detector group

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.19. Board I011: Biopsy

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.20. Board I012: Gantry

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.21. Board I013: Actuator

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.22. Board I014: Gantry keyboards

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.23. Board I015: Tube keyboards

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:



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13.24. Board I017: Wireless pedals control power supply

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.25. Board I020: Power supply switching

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.26. Board I021: Operator commands

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults:

13.27. Board I022: Operator console connections

- Replacement:
- Calibration and auxiliary operations:
- Possible Faults: