User Manual

EN code 74 80 070

MAIN CONTENTS

User Manual

issued on 04/12/20

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Software Release: 2.5.x.x

ATTENTION:
Read all the enclosed documents before using the EM equipment.

This USER MANUAL is only considered complete when preceded by the document called the PREFACE.

Each part of this User Manual is preceded by a list of contents indicating the latest edition of each chapter.

This is a translation of the original Italian text, which prevails in case of doubt.

CONTENTS

1 INTRODUCTION

1.1 APPLICATIONS

Agility Plus is a mobile x-ray device used for radiological guidance and visualization during diagnostic, interventional and surgical procedures.
In particular, the device is to be applied during orthopaedic, neuro, abdominal, vascular, thoracic and cardiac procedures.

Agility Plus device can be used on all patients except pediatric patients within the limits of the device.

Note: *This EM equipment is not suitable for vascular diagnosis.*

The equipment comes in the following models:

	Name of Model	REF	CODE	Max X-ray generator power	Flat panel detector	Monitor Layout
1	**Agility Plus**	**Rk0521S**	**74 09 000-1**	5kW	aSi 21x21 cm²	Portrait 22"
2	**Agility Plus**	**Rk2021S**	**74 09 000-2**	20 kW	aSi 21x21 cm²	Portrait 22"
3	**Agility Plus**	**Rk0530S**	**74 10 000-1**	5kW	aSi 30x30 cm²	Portrait 22"
4	**Agility Plus**	**Rk2030S**	**74 10 000-2**	20kW	aSi 30x30 cm²	Portrait 22"

Table 1

Optional:

- DICOM functions,
- DSA functions.

It normally allows for imaging in the following modes:

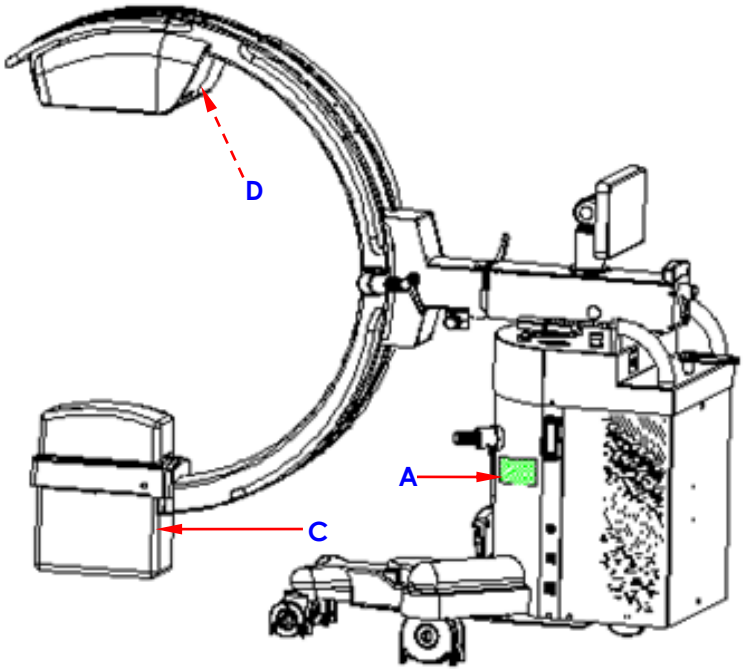
- **Low Dose** Fluoroscopy
- **High Quality** Fluoroscopy
- **Digital radiography (**Snapshot)
- Fluoroscopy in **Road Mapping** mode (optional)
- Fluoroscopy in **DSA** mode (optional)

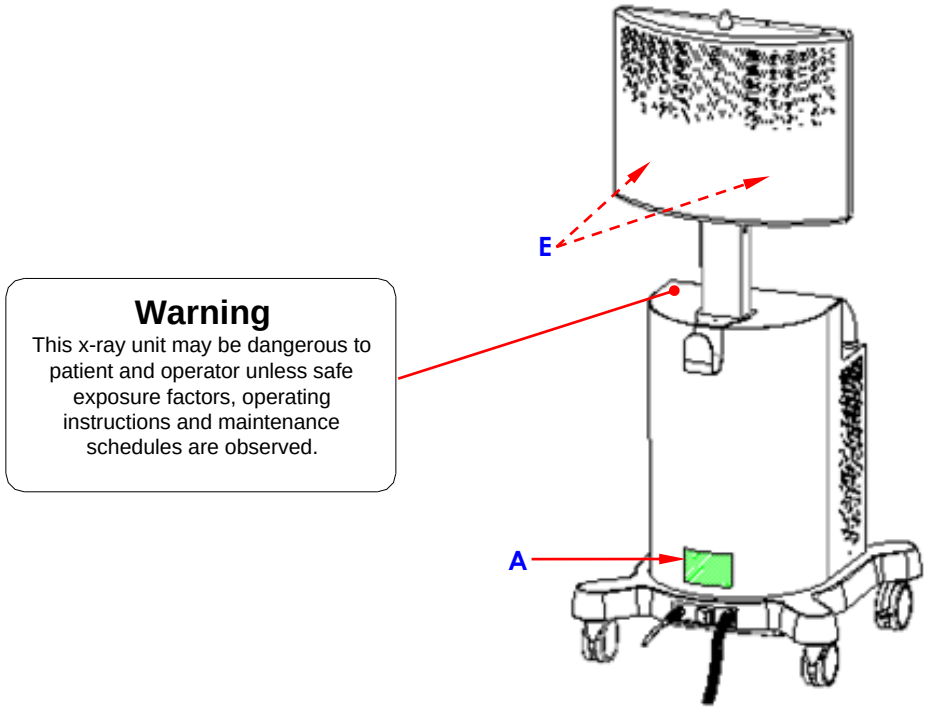
1.2 IDENTIFICATION / SERIAL NUMBERS

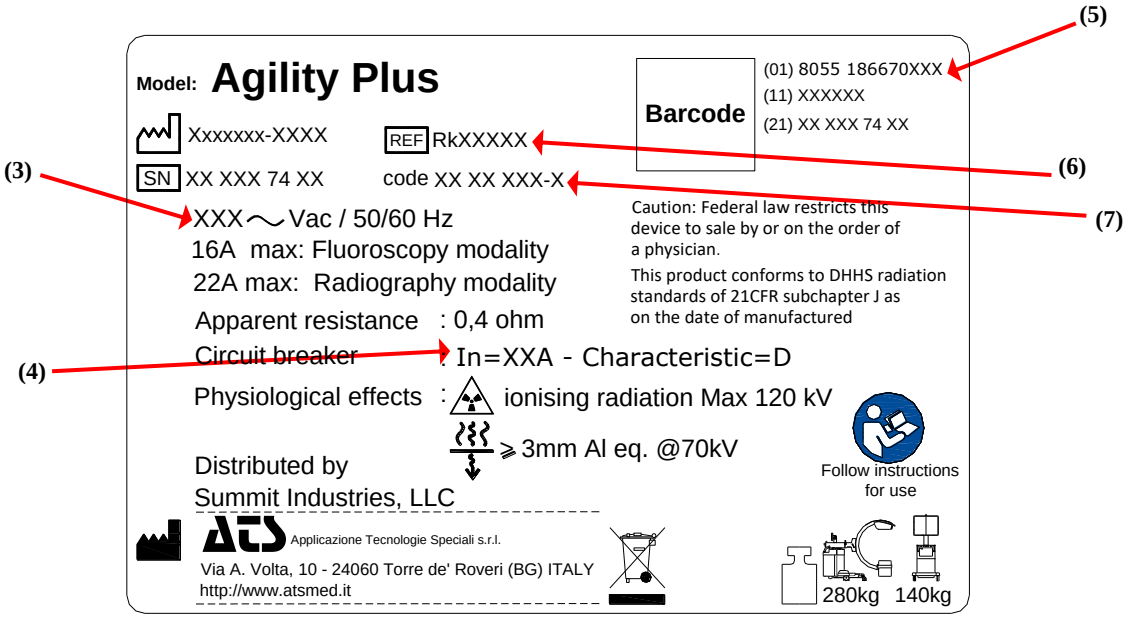
The equipment is identified by a label. The individual components are also labelled:
- C: X-ray monoblock
- D: Flat Panel Detector (1)
- E: Monitor (2)

Note (1): Label only accessible after removing the detector carter.
Note (2): Label only accessible after removing the monitor carter.

The positions of these labels are indicated in figures below:







Note (3) : ***100*** *Mains Power Supply 100V*
110 *Mains Power Supply 110V*
120 *Mains Power Supply 120V*
130 *Mains Power Supply 130V*
210 *Mains Power Supply 210V*
220 *Mains Power Supply 210V*
230 *Mains Power Supply 230V*
240 *Mains Power Supply 240V*

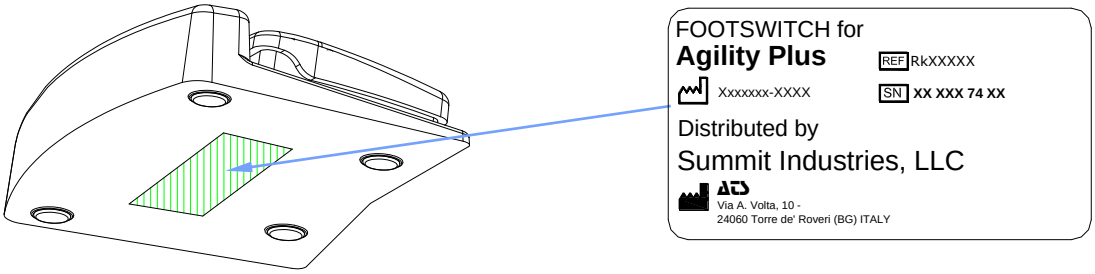
Note (4) : *With Mains Power Supply from 100 to 130 V,* ***16A*** *magnetothermal switch.*
With Mains Power Supply from 210 to 240 V, ***10A*** *magnetothermal switch.*

Note (5) : *UDI : 8055 186670****396*** *= model: Agility Plus-Rk****0521S***
*UDI : 8055 186670****402*** *= model: Agility Plus -Rk****2021S***
*UDI : 8055 186670****419*** *= model: Agility Plus -Rk****0530S***
*UDI : 8055 186670****426*** *= model: Agility Plus -Rk****2030S***

Note (6) : *REF :* ***0521S*** *= model: Agility Plus -Rk****0521S***
REF : ***2021S*** *= model: Agility Plus -Rk****2021S***
REF : ***0530S*** *= model: Agility Plus -Rk****0530S***
REF : ***2030S*** *= model: Agility Plus -Rk****2030S***

Note (7) : *code:* **74 09 000-1** *= model: Agility Plus -Rk****0521S***
code: **74 09 000-2** *= model: Agility Plus -Rk****2021S***
code: **74 10 000-1** *= model: Agility Plus -Rk****0530S***
code: **74 10 000-2** *= model: Agility Plus -Rk****2030S***

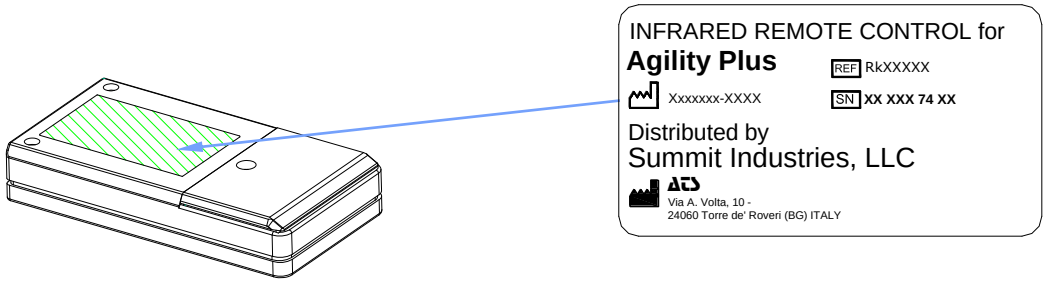
The following ID plates are also found on the components:



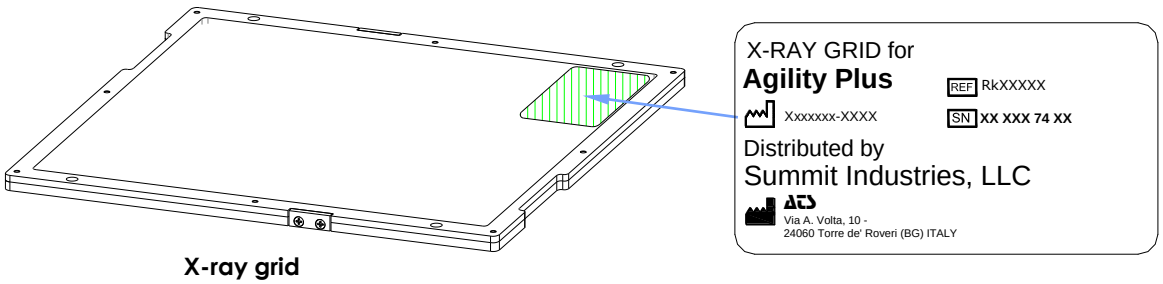
Footswitch

The **wired footswitch** has class **IP X7** protection:

- ("**X**"): no protection against the introduction of little-dimension solid foreign bodies.
- ("**7**"): protection against the infiltration of liquids during **temporary** immersion **(max 30 minutes)**.



Infrared remote control



X-ray grid

1.3 LIABILITY STATEMENT

The manufacturer can only be held liable for the safety of its products if serviced and repaired by the manufacturer or by suitably trained and qualified personnel. The manufacturer holds regular training courses for technicians, fitters and maintenance workers at its head offices for this purpose.

The manufacturer cannot be held liable for any malfunction, loss or danger arising from improper use of the EM equipment or from non-observance of the maintenance instructions.

The organisation responsible for the EM equipment is responsible for making sure that it is only and exclusively used by suitably trained and qualified operators.

Never attempt to modify the EM equipment without first obtaining written authorisation to do so from the manufacturer.

The manufacturer provides working diagrams and layout drawings, component lists and descriptions and calibration instructions to assist the technical personnel when repairing parts of the EM equipment.

1.4 CONFORMITY AND MANUFACTURER'S ADDRESS

This X-ray device is produced by:

Applicazione Tecnologie Speciali srl
Via A. Volta, 10
24060 Torre de' Roveri (BG) - Italy -
TEL. +39/035584311
FAX +39/035580220
e-mail: infoats@atsmed.it
http://www.atsmed.it/

The device complies with European Directive 93/42 EEC and subsequent amendments, 2007/47 EEC.
The following harmonised standards apply to the EM equipment:

EN 60601-1 :	2006 + A1 : 2013
EN 60601-1-2 :	2015 (4th edition)
EN 60601-1-3 :	2008 + A1 : 2013
EN 60601-1-6 :	2010 + A1 : 2013
IEC 60601-2-28 :	2017
EN 60601-2-54 :	2009 + A1 : 2015
EN 62304 :	2006 + A1 : 2015
EN 62366-1 :	2015
EN 62563-1 :	2010
EN ISO 14971:	2012
EN 60825-1:	2014
EN 60601-2-43:	2010 + A1 : 2017
EN ISO 15223-1:	2016
EN 1041:	2008
EN ISO 780:	2015

Note 1: *These standards are mentioned both in Technical and User manuals; please refer to this list if the edition of the standards is not specified.*
Note 2: *The system does not contain any patient applied parts.*

2 SAFETY

2.1 INTRODUCTION

The equipment must be used solely in accordance with the safety instructions contained in this manual and in accordance with local regulations. It must never be used for purposes other than those for which it is intended.

Attention:

The manufacturer can only be held liable for the safety of its products if serviced and repaired by the manufacturer or by suitably trained and qualified personnel. The manufacturer holds regular training courses for technicians, fitters and maintenance workers at its head offices for this purpose.

The manufacturer cannot be held liable for any malfunction, loss or danger arising from improper use of the EM equipment or from non-observance of the maintenance instructions.

The organisation responsible for the EM equipment is responsible for making sure that it is only and exclusively used by suitably trained and qualified operators.

The EM equipment must only be used by personnel with proper knowledge of ionising radiation protection and full training in the use of X-ray equipment.

The EM equipment must always be manned when switched on.

The equipment must not be used if there are any electrical, mechanical or radiological failures.
Likewise, it must not be used in the event of a faulty alarm or signal.

Prior authorisation must be obtained in writing from the manufacturer before making any modifications to this equipment or its safety system.

Never remove any parts or covers, as this could compromise the equipment's electromagnetic compatibility.

If you wish to use the equipment in combination with other devices, components or modules whose compatibility is not certain, you must make sure that there are no risks for patients or operators. Consult the manufacturer of the device in question or an expert.

As with any technical apparatus, the EM equipment must be used in a proper manner and receive regular checks and maintenance as specified in the "Maintenance" section of this manual.

The monoblock may reach a temperature close to 60 °C after prolonged use. Do not touch the monoblock or move it near the patient.
When not in use, remove the sterile covers to help the monoblock cool down.

The cover panels must be cleaned following the instructions described in *Chapter 7, Maintenance* of this manual.
Moreover, the device must be installed far enough from objects that could obstruct the air to come out.

Never use corrosive substances (such as sodium hypochlorite, commonly known as bleach) to clean and disinfect the EM equipment.

The quality of the equipment may deteriorate after 10 years of use.
You therefore need to check the mechanical integrity of the equipment, the electrical safety devices and the image quality at the same X-ray dose on a regular basis.

The user must comply to the device basic maintenance and updating recommendations described in this manual, keeping the device up to date.

2.2 SAFETY PROCEDURES

2.2.1 MECHANICAL SAFETY

Attention:

Always apply the parking brakes after positioning the EM equipment.

Only use the special handles to move the equipment.

Avoid knocks.

Never remove the guards unless for the maintenance operations expressly foreseen by and described in this manual.

2.2.2 ELECTRICAL SAFETY

Attention:

Never use the EM equipment in potentially explosive environments, for example in the presence of explosive gases or vapours (such as certain anaesthetic gases).

Never use the EM equipment in oxygen-rich environments.

Unplug the EM equipment from the mains before cleaning, disinfecting and sterilizing it.

Cleaning products and disinfectants, can form explosive gas mixtures. Therefore, only use products that comply with the relevant safety regulations.

Take care not to spill conducting liquids on the EM equipment as these could infiltrate and so damage the equipment making it unsafe to use.

Protection against electric shock is provided by an earth connection (**class I EM equipment**). Make sure that the electrical plant to which the EM equipment is connected is properly earthed in compliance with current laws and regulations.
Note: *the system does not contain any patient applied parts.*

Always switch the equipment off after use.
Switch the EM equipment off completely by following the monitor stand shut-down procedure; then turn the key switch OFF.

Only unplug at the mains after first switching the EM equipment off using the key switch on the monitor unit.
If the power cable becomes damaged, carefully remove it (holding it by the plug) and contact Technical Service for details on how to replace it.
Replace with a new cable obtained from the manufacturer of the EM equipment.

2.2.3 NETWORK SAFETY

The manufacturer provides the EM equipment free of malwares and viruses; this is assured by many precautions during the software installation on the unit. For example:

- the creation of a Master Disk with the latest software revision and operative system,
- the scanning of the Master Disk by an antivirus software (KASPERKY) that runs live from a PENDRIVE
- the software installation on the unit performed by cloning of Master Disk
- the continuous updating of the antivirus software that runs from the PENDRIVE

In case of obsolescence of the Operative System, the manufacturer will provide, on request of the hospital, a new software version, together with instructions for installing it.

The system is provided with the OS firewall enabled and configured according to the software functionalities needs.
In the equipment setup, the **Firewall Info** menu allows Advanced user to get notifications about Firewall status and possible alarms or warnings.

To ensure continuous safety and effectiveness of the device software during the life of the unit, it is recommended to:

- connect the access to network (DICOM) on a network that the Responsible Organization considers protected,
- avoid intentional access by malicious or not authorized persons,
- keep the operative system firewall updated (see next paragraph).

A stronger protection can be provided by ensuring that the system is connected to a local network that uses appropriate network security, such as firewalls and antivirus scanning at points of access.

Only a strong network security configuration can ensure that the system is protected against malicious network attacks and that patient data is protected against unauthorized access. It is recommended that the Responsible Organization uses an up-to-date, managed wireless infrastructure that is enterprise-grade and has strong security controls.

If required, it is possible to restore the video processor software using the backup pen drive provided with the equipment.

The system operates in **KIOSK mode**, with Windows Embedded. In this operative mode, it is not possible to start applications from USB pen drive. Furthermore, autorun of the USB pen drive has been disabled. The equipment is provided without antivirus software because its updates should lead to operative difficulties.

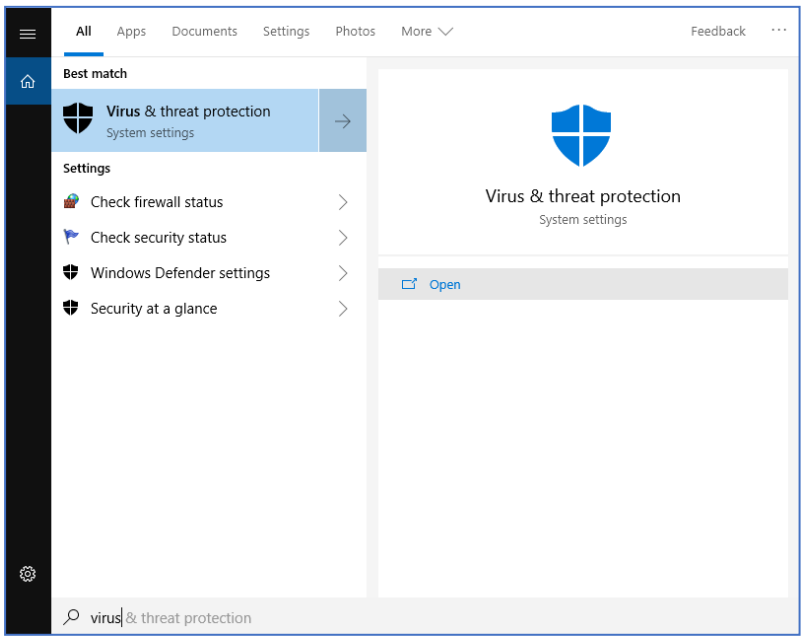
Anyway, if you notice strange system behaviour and/or performance occurring repeatedly, including after the system has been restarted, please call the Service.

2.2.3.1 UPDATE WINDOWS ANTIVIRUS

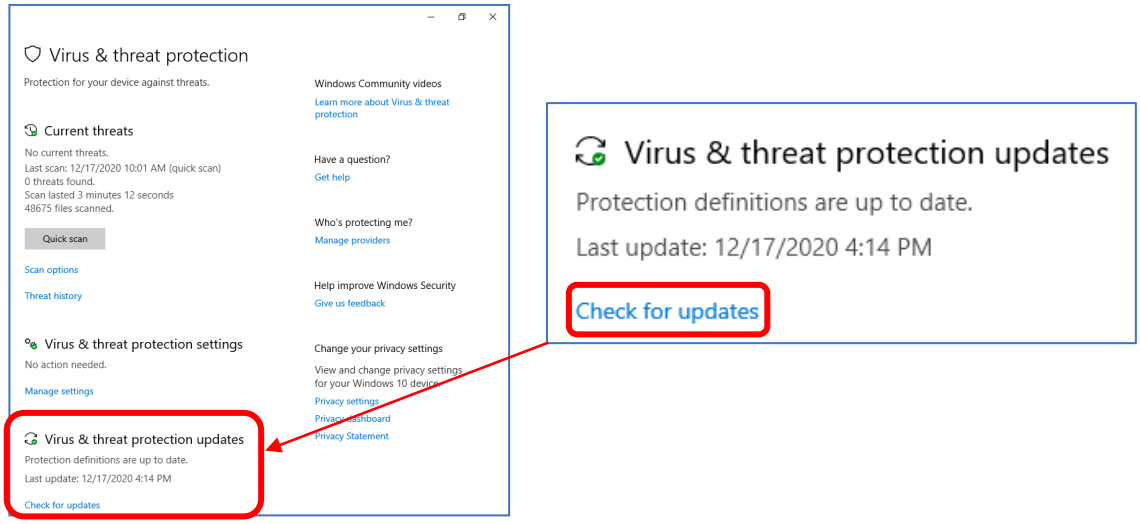
It is important to periodically update the system antivirus in order to grant a stronger protection.
The Manufacturer suggests to update it as a new upgrade is released.

First, you have to access as Windows Administrator (see *Paragraph 5.3* **Windows Administrator Login**, *in Part 2 of the Technical Manual*).

Now, open **Windows Start** menu and search **Virus and Threat Protection**:



- Open **Virus and Threat Protection** and click on **Check for Updates**.



- The system notices about possible updates to be installed.

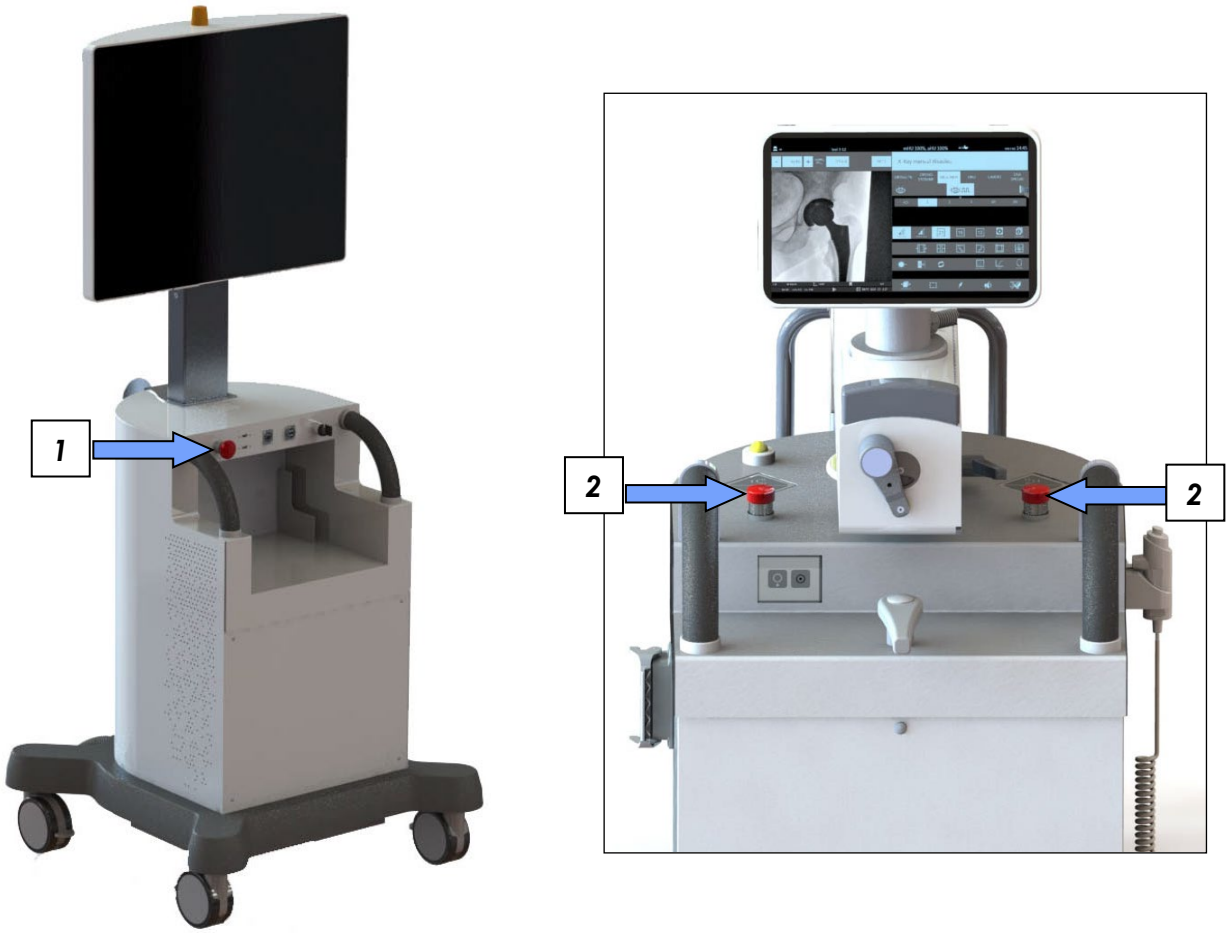
As the updating procedure has been successfully concluded, from **Windows Start** menu **Turn Off** or **Restart** the equipment.

2.2.4 EMERGENCY PROCEDURES

2.2.4.1 EMERGENCY BUTTONS

If the equipment suddenly malfunctions, use one of the emergency buttons on the monitor unit (1) or the stand (2), as shown by the arrows in the figure below:

- **The button on the monitor unit (1) switches the EM equipment off.**
- **The two emergency-stop buttons (2) on the stand ONLY stop the motorized movement of the column.**



Standard **EN 60601-2-43** requires that it be possible for the user to restore the system (even partial functioning) in the event of a software malfunction.

The procedure is described in detail in the **Emergency manual** provided with the system.

There are two basic scenarios:

1) **The application freezes** (hang up).
2) **The application closes** (crash), with a return to the Windows OS desktop.

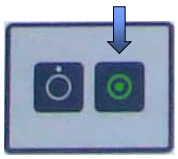
⇒ **In the first instance (hang up):**

Reboot the equipment.

- Switch the monitor unit off by turning the key to "OFF" (0).

- Wait about 10 seconds.
- Turn the equipment back on by turning the key on the monitor unit to "ON" (I).

- The stand will automatically turn ON.



⇒ **In the second instance (crash) the system automatically reboots the application and the LOGIN page appears after initialising.**

2.2.4.3 SYSTEM FAILURE

The equipment is a highly complex medical device that in very rare cases can fail, just like any other device, in spite of comprehensive tests and maintenance.

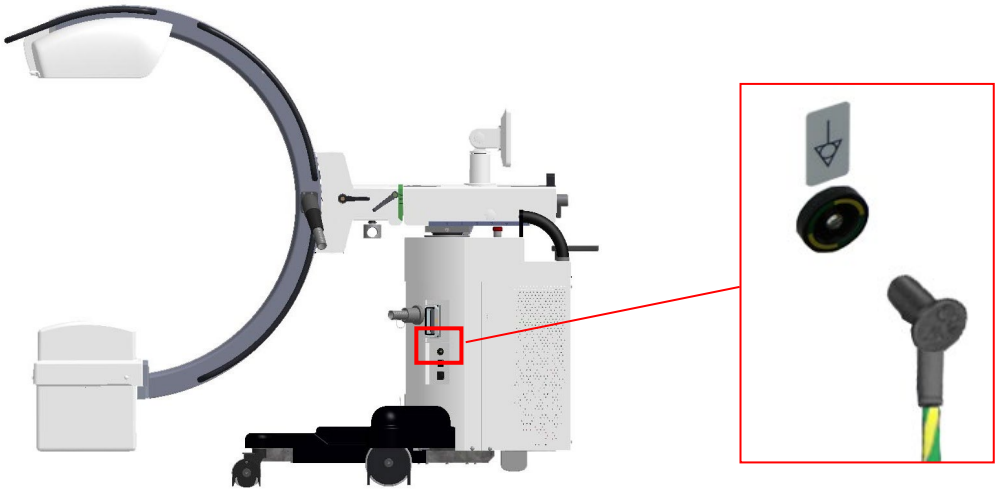
This may cause obstruction to the operational procedures.

Please, prepare an emergency plan and keep it ready for this case.

2.2.5 EQUIPOTENTIAL EARTH CONNECTOR

For maximum patient and medical staff safety, the patient bed must be earthed using the equipotential earth connector on the stand.

Use a cable with a Multi-Contact POAG-K4 or POAG-K6 connector to connect this (see detail in figure below).



The equipotential earth connector MUST NOT be used for connection to the EARTH (GND).

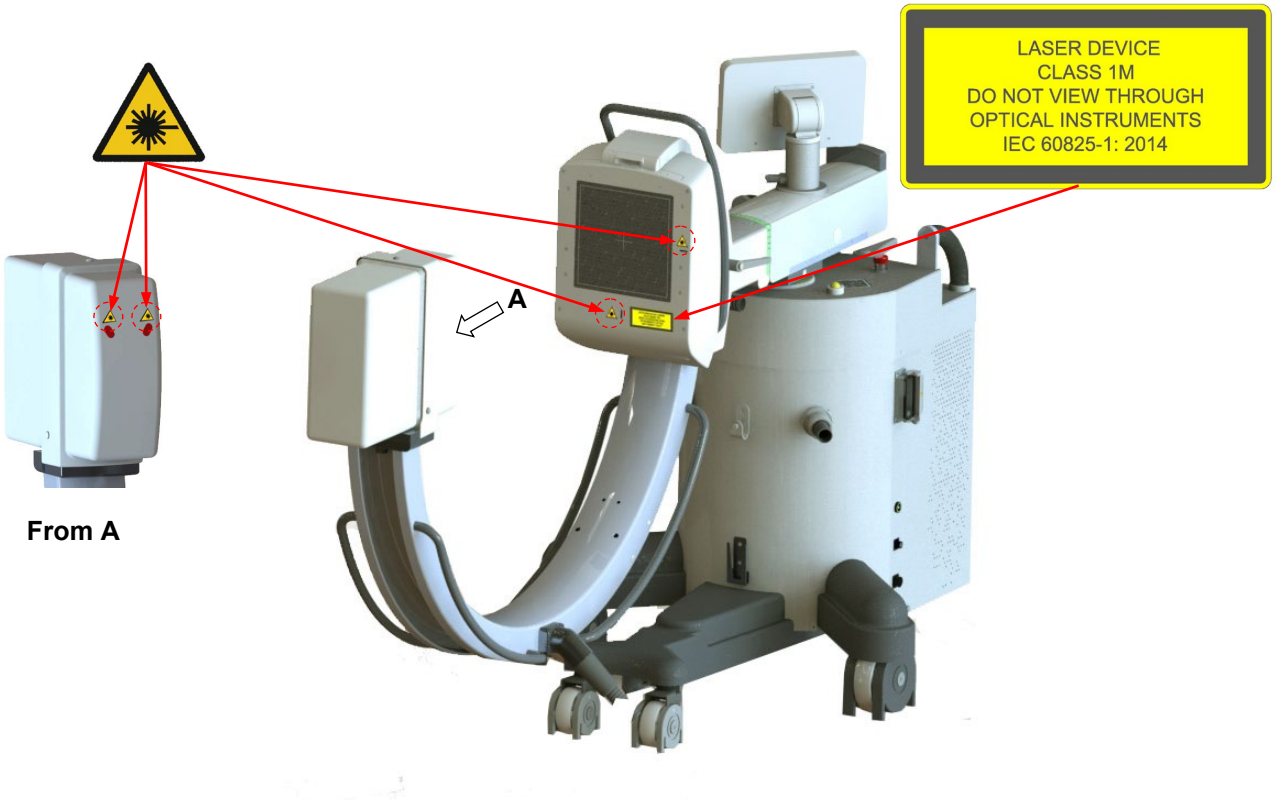
2.2.6 LASER IRRADIATION

In order to center the X-ray beam, the system uses laser light localisers (optional), class 1M, which are placed on the flat panel detector and on the X-ray monoblock.

LASER LOCALIZER *Consisting of 4 laser modules* **(Optional)**	
Class	1M
Laser diode power	< 5 mW
Optical output power	3.8 mW
Wavelength	635 nm
Laser light warning	

Never look directly at the laser beam through a lens.
Beware that the laser beam may be reflected by surgical instruments or other accessories used during an operation.

The warning sticker (see image below) is placed on the outside of the detector housing, right next to both lasers.



The laser diodes used are class 1M laser diodes (IEC standard 60825-1:2014).

2.2.7 PROTECTION AGAINST IONISING IRRADIATION

The EM equipment emits ionising irradiation for medical purposes.

X-ray equipment can be harmful if not used in a proper manner. **These instructions must therefore be read in full and fully understood** before the equipment can be used.

The use of this device involves two types of exposure to ionising irradiation:
- occupational, for operators;
- diagnostic, for patients being scanned.

Even though the EM equipment provides a high standard of protection against X-rays, no occupational measure can guarantee total protection. The operator must, therefore, take all the necessary safety precautions to avoid the risk of exposure, to himself and others, arising from incorrect or excessive exposure to irradiation (see **Paragraph 2.2.6.1** below for further information about contra-indications on using the EM equipment).

All operators must receive suitable training and adopt all necessary safety measures to avoid the risk of harm.

The equipment is sold on the following condition (clause in the sale contract):
THE MANUFACTURER, ITS AGENTS AND REPRESENTATIVES CANNOT BE HELD LIABLE FOR ANY LOSS OR INJURY THAT MAY BE CAUSED BY IMPROPER USE OF THIS EM EQUIPMENT.

Before carrying out any exposure, make sure that all the necessary irradiation protections have been activated.
During X-ray use, the personnel present in the X-ray room must observe the irradiation protection regulations in force.

Always provide patients with the necessary irradiation protection.

Use suitable personal radio-protective equipment. A radio-protective material equivalent to 0.35 mm of lead gives 99.95% protection against radiation of 50 kV and 94.5% protection against radiation of 100 kV.

Below are examples of such personal radio-protective equipment:

Protective aprons for operators

Protective aprons for patients

Head protection for operators

Thyroid protection for operators

Scrotum protection for male patients

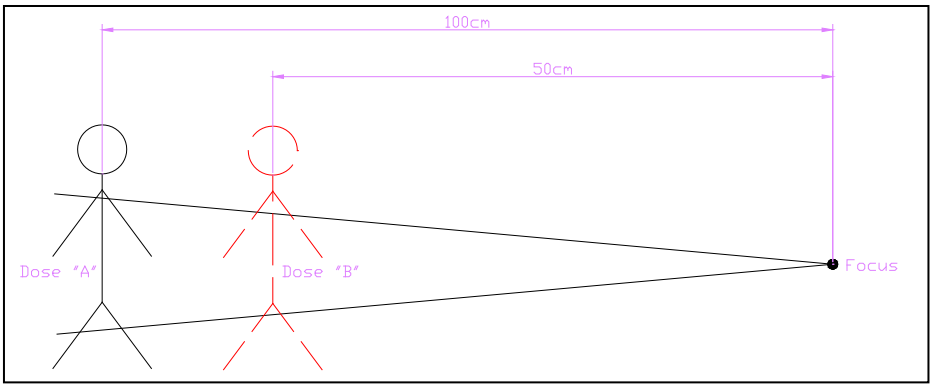
Ovary protection for female patients

Distance is the best protection against irradiation: always keep as far away from the source of the X-rays and from the patient.
Use the manual switch at least 2 m from the X-ray beam to protect yourself further from the risk of dispersed radiation.
Accordingly, the coiled cable of the manual switch is about 4 long when fully extended.

Always set the smallest exposure field possible by closing the collimator shutters/iris. In fact, dispersed irradiation depends to a large extent on the volume of the irradiated object.

Avoid moving or remaining within the X-ray trajectory.

Keep the patient as far away from the X-ray source as possible to minimise the absorbed dose.



The dose values for the patient shown above (distance from focus = 100 cm and 50 cm) are:

$$dose"A" = \left(\frac{50cm}{100cm}\right)^2 \times dose"B"$$

For example, if a patient at a distance of 50 cm from the focus receives a dose of 10uGy (dose "B"), when that distance becomes 100 cm the received dose is:

$$dose"A" = \left(\frac{50cm}{100cm}\right)^2 \times 10Gy = 2{,}5uGy$$

Twice the distance results in a four-fold reduction in the received dose.

During every exposure, always make sure that the edge of the iris collimator is visible on the image: if it is not possible to collimate this correctly, call the Technical Service as there is the risk that the collimator is not working and remains open at an excessive value.

Make sure that there are no materials within the X-ray beam that could diminish the intensity of the X-rays and so lead to sub-standard images. For example, the patient bed must conform with standard EN60601-2-54 table 203.104 (equivalent aluminium filtration less than 2.3mm).

Patient and operator radiation must be kept as low as reasonably possible without compromising the benefits of the radiological procedure. Where possible, use low dose settings and/or a low frame rate.

Deterministic effects can occur after prolonged exposure, when the X-ray dose received by a given organ or tissue exceeds a specific value (threshold dose).
The SKIN and the LENS are the tissues most affected during radio-diagnostics. The recommended threshold dose is **between 1Gy and 3Gy.**

2.2.7.1 CONTRA-INDICATIONS ON USING THE EM EQUIPMENT

The equipment should not be used if any of the following contra-indications exist (or are thought to exist):

- Acute skin burns, (patient).
- Acute hair loss, (patient).
- Chronic radiation injury (staff).

Note:

- *Special consideration must be given to the protection of the embryo or fetus during radiological examination or treatment of women known to be pregnant.*
- *Sensitive body organs (e.g., lens of eye, gonads) must be shielded whenever they are likely to be exposed to the working beam*

2.3 RESIDUAL RISKS

The EM equipment has been designed and built in full respect of the safety regulations.
Nevertheless, there are still some risks involved in the use of this equipment if it is used incorrectly or the prescribed safety measures are faulty.

With regard to risks due to improper use of the EM equipment, see the instructions and recommendations above.

Note also that:

- Patients or operators may be harmed by uncontrolled movement of the monitor unit or the stand due to excessively fast movement or steep surfaces.

- Never allow the monitor unit or the stand to pick up too much speed during movement.
- Never move the monitor unit or the stand on stairs or inclined surfaces with a gradient of more than 10°.
- When moving the stand, or monitor unit, avoid all obstacles on the ground (e.g. cables and steps).

- The stand has been tested for stability during movement on inclined surfaces (up to 10° and all other positions on slopes of up to 5°.

- Never use the stand on surfaces with an incline of more than 5° (or 10° during transit).
- Never try to move the stand when its parking brake is engaged.

- During transport, in case of uncontrolled movement of the C-arm, the mechanical structure may hit the patient or operators.

- Keep the movement of the C-arm under control at all times.

- The monoblock may overheat after continuous and prolonged use of the EM equipment.

- Never cover the surfaces of the monoblock with material that prevents heat dispersion (sterile sheets excepted).

- Inflammable gases may be ignited by electric arcs due to the operation of electrical components.

- Never use the equipment in the presence of anaesthetics or other inflammable products.
- Check that there is a fire extinguisher in the room where the EM equipment is to be used and that this is efficient.

With regard to residual risks due to faults in the prescribed safety measures, note that:

- Protection against electric shocks is provided by means of an efficient earth system for all metal parts covering the equipment.

- The full earth circuit (for both internal and external parts and the mains supply) should therefore be checked for efficiency on a regular basis (see the "Routine Maintenance" schedule described in the Technical Manual).

- If the LCD monitor screen is hit hard enough, it could break and scatter liquid crystal: this is toxic.

- Avoid hitting the monitor with any objects.

- The column that raises the monoblock C-arm is motorised.

- If the motor responsible for moving the column is accidentally powered up, the operator should immediately push one of the two emergency buttons on the stand or the emergency button on the monitor unit.

- If smoke is seen or unusual noises are heard:

- Switch the equipment off immediately and unplug at the mains.

- To control the residual risk of X-ray emission in the event of a system fault or incorrect adjustment, we recommend checking the dose level every day, immediately after switching the equipment on and before using it on patients (details of this test are given in *Chapter "Maintenance", Paragraph 7.4 of this Manual*).

Never remove any parts or covers, as this could compromise the electromagnetic compatibility of the system.

Portable and mobile radio communication devices may affect the efficiency of the device.

2.4 SCRAPPING THE EM EQUIPMENT

Once the EM equipment reaches the end of its useful life, dispose of all its components in accordance with the European Waste Electrical and Electronic Equipment Directive 2012/19/EC (WEEE).

Some parts of the EM equipment are built using hazardous materials, such as lead.

All flat batteries must be disposed of in accordance with European Directive 2006/66/EC and subsequent amendments (concerning batteries and accumulators and battery/accumulator waste).

See the Technical Manual *Chapter 4, Part 5* for full details.

2.5 WARNINGS

2.5.1 SYMBOLS USED

Symbols are used on the equipment and serial n° plate, as follows:

Caution: read the accompanying documents before use.
***Note**: This symbol, on the stand control panel, draws your attention to the absolute need to adhere to the instructions in this manual when using the equipment.*

Laser Localizer present

Live parts

Potentially harmful physiological effects

Risk of crushed hands

X-ray focal point

Date of manufacture

Serial number

Manufacturer

Equipment to be disposed of in accordance with European Directive 2012/19/EU requirements ("WEEE" - Handling of waste electrical and electronic equipment)

Weight in Kg

Equipotential pole

ON (full system)
OFF (full system)

ON (stand only)

OFF (stand only)

Movement prohibited (with C-arm raised)

Movement possible (transport position)

***Note:** The stand has been tested for stability during movement on inclined surfaces (up to 10° and all other positions on slopes of up to 5°.*
- Never use the stand on surfaces with an incline of more than 5° (or 10° during transit).
- Never try to move the stand when its parking brake is engaged.

Raise C-arm
Lower C-arm


Wheels in straight position


Wheels positioned for side-ways movement


Reference index (c-arm graded plaque)


Reference index


Brake ON


Brake OFF


X-ray emission indicator


Low Dose fluoroscopy


High Quality Fluoroscopy

X-ray emission command

Ethernet socket


USB socket


NFC Reader (optional)

Auxiliary video outputs: Live and Memory monitors

3 INSTALLATION

3.1 VIDEO PROCESSOR SETUP

3.1.1 INTRODUCTION

The **Advanced User** can configure the system to suit the specific installation needs.

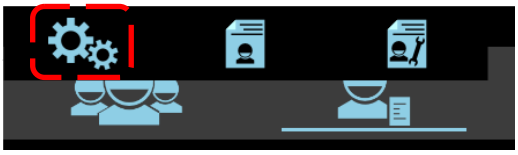
The configuration is performed on Memory Monitor (the touch screen monitor on the right) by specific setup pages, where only the required parameters are enabled.

The configuration procedure is described below, with details of the parameters that can be set.

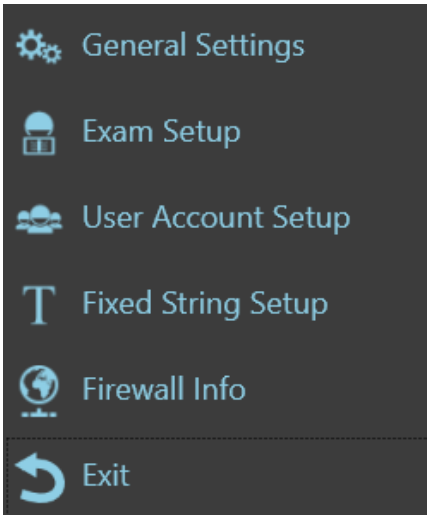
Setup	Settings	Ref. (paragraph)
General Settings	- Station Description - Technical Configuration - Image Option and Unit of Measure	**Installation: par. 3.1.2**
Unit Configuration	System date	**Installation: par. 3.1.3**
Exam Setup	Exam list organization	**Installation: par. 3.1.4/3.1.5**
Fixed String Setup	Composition and organisation of the fixed strings	**Installation: par. 3.1.6**
User Account Setup	Composition and organisation of Users	**Installation: par. 3.1.7**
Firewall Info	Info about firewall status and possible warnings or alarms.	**Installation: par. 3.1.8**

Use the USER icon in the top left-hand corner of the Memory Monitor to open the menu that lets you access the system SETUP to suit the User profile selected during LOG-IN.

Select the **Setup** option to access the SETUP menu:



List of SETUP menus:

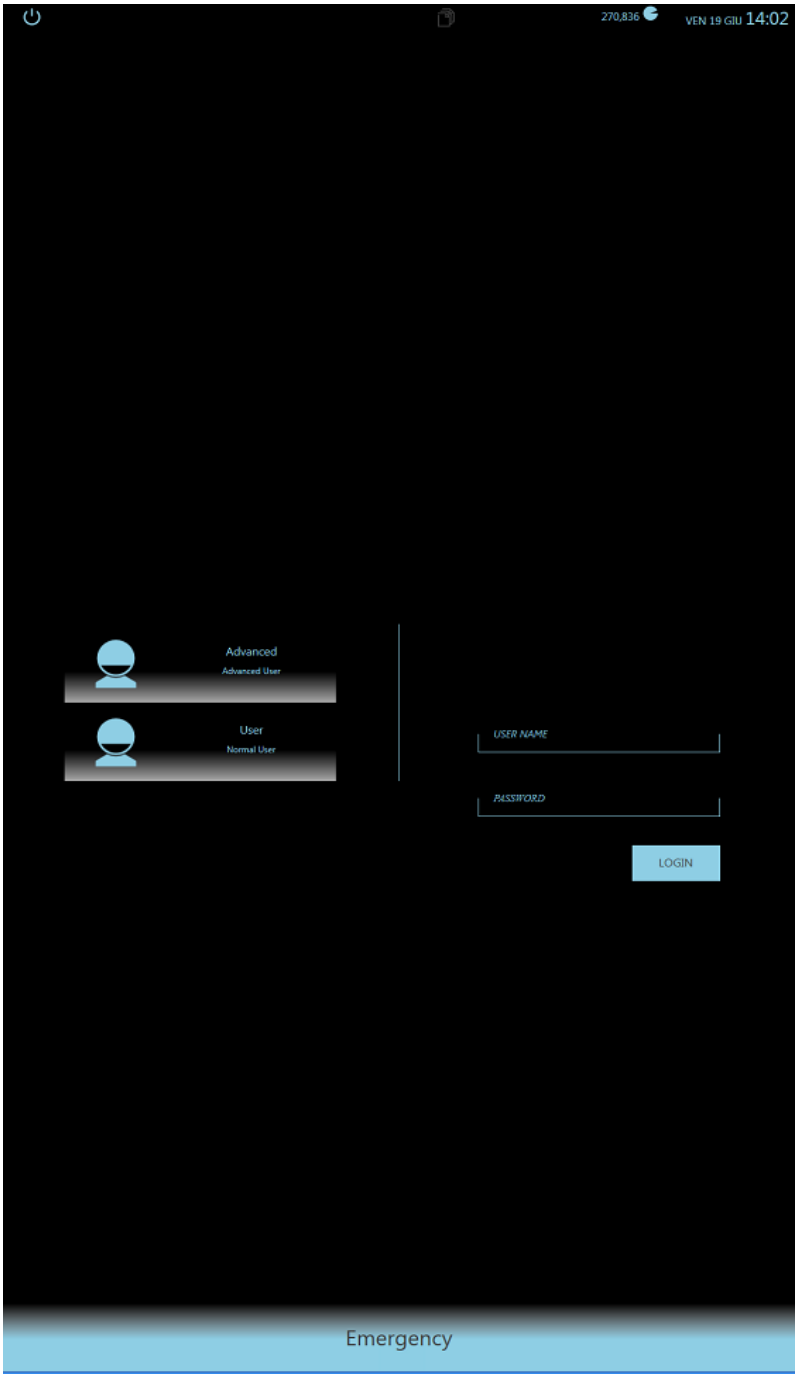


3.1.1.1 LOG-IN

- *When the LOG-IN page appears, log in as:*

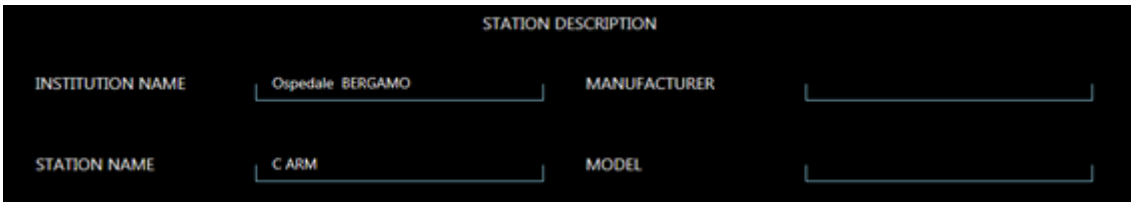
  ***Advanced**, by entering the default technical password: **12345678**.*

***Note:** it is recommended to personalize the Advanced default password at the installation.*



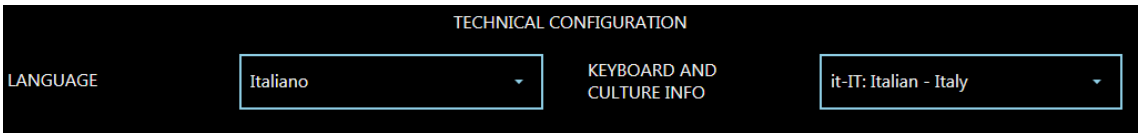
3.1.2 GENERAL SETTINGS

➢ **STATION DESCRIPTION:**



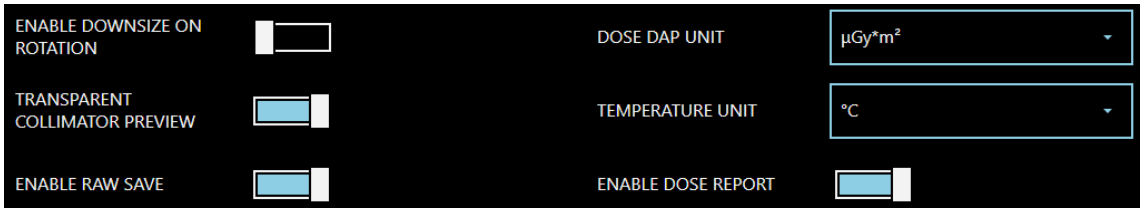
Option	Meaning / Settings	Notes
INSTITUTION NAME	Enter the name of the hospital/clinic where the EM equipment is installed.	This name does not appear on the screen but is needed for the DICOM services.
MANUFACTURER	The name of the manufacturer of the EM equipment.	This name does not appear on the screen but is needed for the DICOM services.
STATION NAME	Name given to the EM equipment.	This name does not appear on the screen but is needed for the DICOM services.
MODEL	EM equipment model.	This name does not appear on the screen but is needed for the DICOM services.

➢ **TECHNICAL CONFIGURATION:**



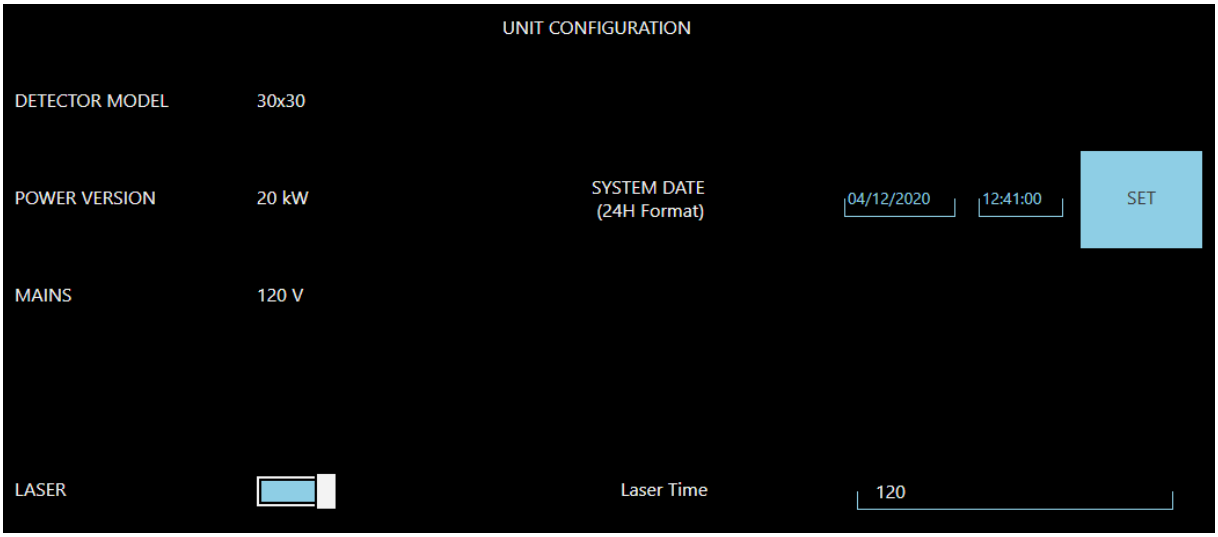
Option	Meaning	Settings	Notes
LANGUAGE	Used to select the user interface language.	Choose the preferred language. *For a full list of available languages, please contact the manufacturer.*	The technical installation and maintenance menus are only provided in Italian or English.
KEYBOARD AND CULTURE INFO	Used to select the geographical area where the EM equipment is installed.	Select one of the areas given.	This setting determines the date format, the decimals format and the virtual keyboard layout.

➢ IMAGE OPTION AND UNIT OF MEASURE:



Option	Meaning	Settings	Notes
ENABLE DOWNSIZE ON ROTATION	DISABLED: when rotated, the image dimensions are not changed. Depending on the angle of rotation, part of the corners of the image will be outside the screen (not displayed). ENABLED: when rotated, the image dimensions are reduced to allow you to see the full image.	Enable or disable this function to suit the required mode.	
TRASPARENT COLLIMATOR PREVIEW	DISABLED: When a virtual collimation is performed on the LIH, it is shown in black, getting dark the part of image that lies outside the collimation. ENABLED: When a virtual collimation is performed on the LIH, it is shown transparent, letting glimpse the part of image that lies outside the collimation.	Enable or disable this function to suit the required mode.	
DOSE DAP UNIT	Set dose unit of measure.	Choose **µGy*m²** or **mGy*cm².**	
TEMPERATURE UNIT	Set the unit of measure for the temperature of the x-ray monoblock.	Choose **°C** or **°F.**	
ENABLE RAW SAVE	When enabled, it allows to save images in **.raw** format on the hard disk.	Enable or disable this function to suit the required mode.	
ENABLE DOSE REPORT	When enabled, it allows to create the **Dose Report** image, containing data about study and the dose gave to the patient.	Enable or disable this function to suit the required mode.	*See Paragraph 5.3.7.2 of the User Manual.*

3.1.3 UNIT CONFIGURATION



➢ **UNIT CONFIGURATION**

Option	Meaning	Settings	Notes
DETECTOR MODEL	Indication of the FPD on the EM equipment.		
POWER VERSION	EM equipment max power indication: **5 kW** or **20 kW**		
MAINS	Indication of the mains power supply: **120 V** or **230 V.**		
SYSTEM DATE	The Advanced user has the possibility to restore date and time settings.	Set current date and time.	24 HOURS format
LASER	Laser modules to help centring patient during exams.	Enable / disable.	
LASER TIME	Set the default time after which laser automatically turns off.	Set the required time, in seconds.	

3.1.4 ANATOMICAL EXAM SETUP

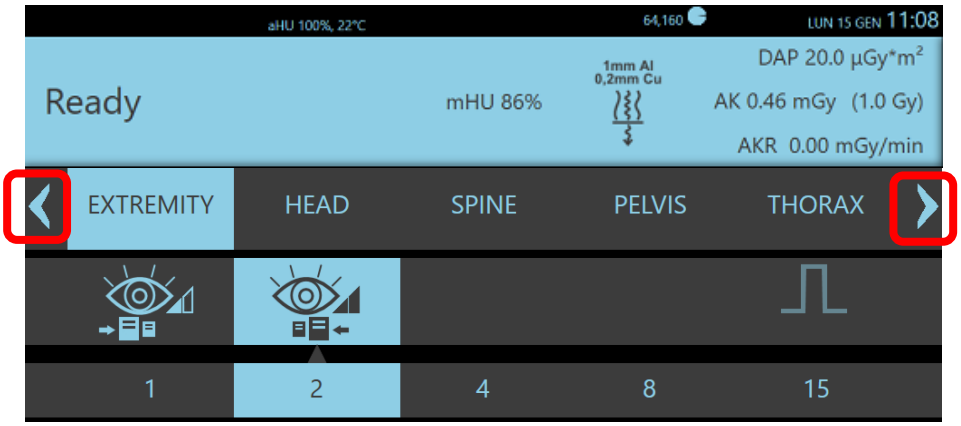
The EM equipment has exams already defined by the manufacturer, linked to the different device applications.

At the installation phase, the exam parameters can be modified by the **Advanced** user, according to the user requirements.
Like this, whenever the exam is selected, the related parameters will be automatically set.

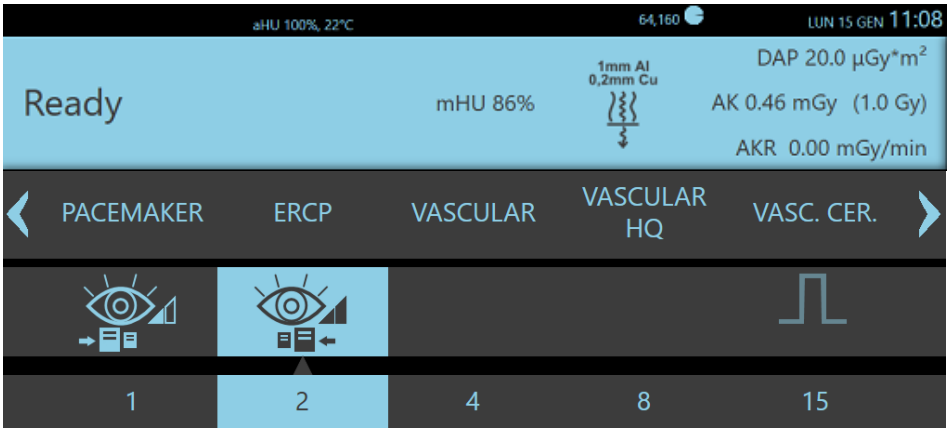
The exams are shown on the Control Panel in the order they have been set inside the Exam Setup.
The screen shows 5 exams at a time; use the respective arrows, circled in red in the image below, to browse through the exam list, scrolling thus to the next or previous 5 exams.

***Note**: If the operator needs to change some of the exam parameters, after the installation, it is required to login as **Advanced** user.*

The following images show an example of how an exam is set:



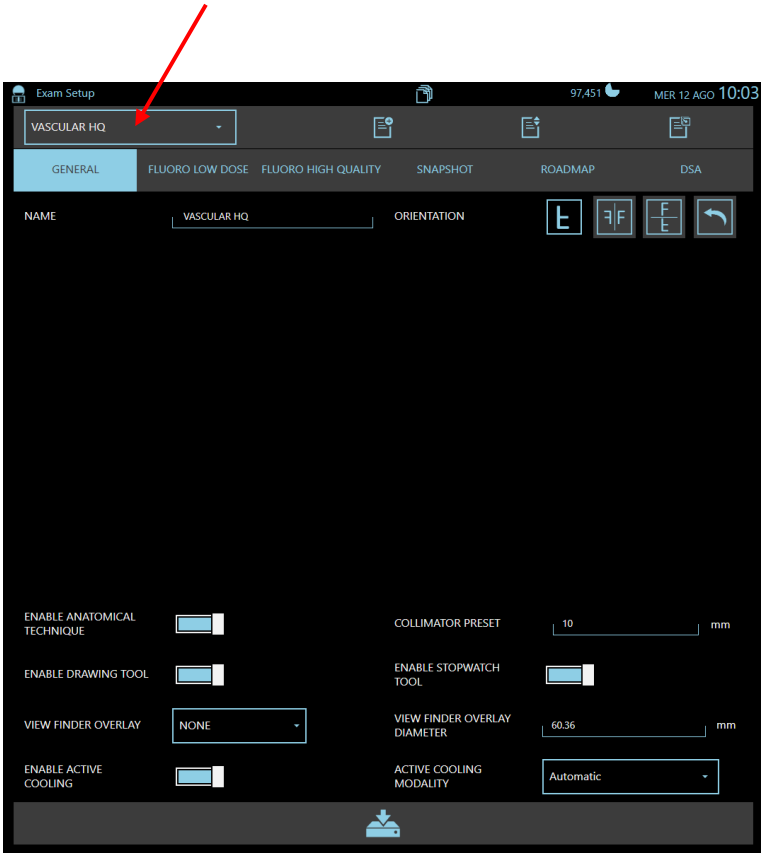
Use the indicated arrows to browse through the exam list, scrolling thus to the next or previous group.



3.1.4.1 PROGRAMMABLE PARAMETERS

Select the exam to set from the drop-down list. The following parameters can be set for each exam:

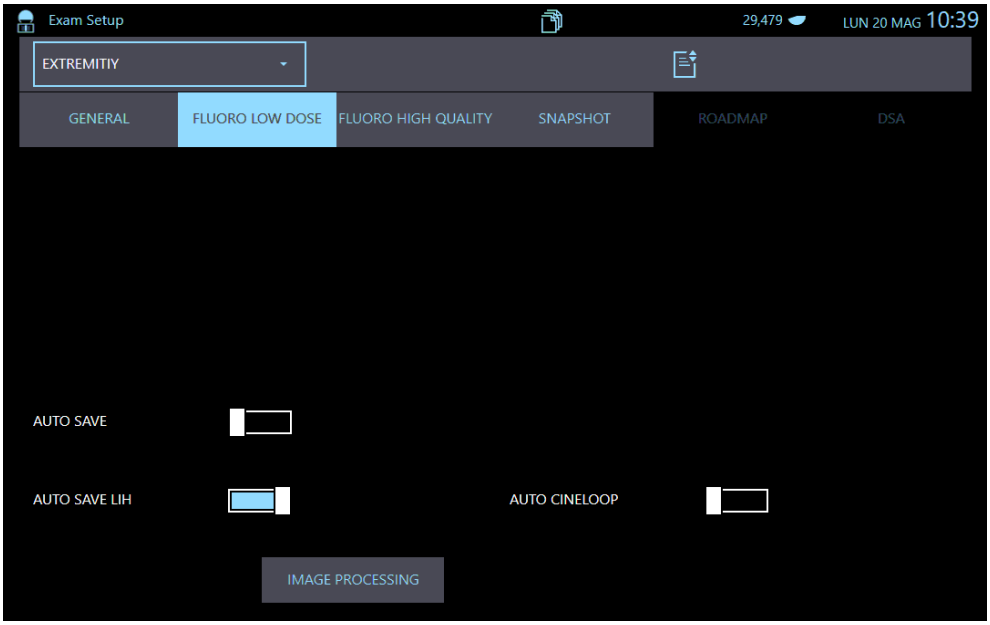
GENERAL:



Option	Meaning	Settings	Notes
NAME	Exam name	Max 30 characters	
ORIENTATION	Orientation of the image (inverted and/or rotated)	Horizontal flip Vertical flip Image rotation (±90°)	Orientation set when you open an exam.
ENABLE ANATOMICAL TECHNIQUE	This function allows to enable the exam, making it available from the Control Panel.	Yes / No	If the exam is not enabled, it will not be shown on the Control Panel.
COLLIMATOR PRESET	This function allows to set an opening default value for the collimator square iris. It will be possible to use this value, during an exam, by touching the relevant key on the Control Panel *(see Chapter "System Overview", Paragraph 4.2.1.1 of this Manual)*.	Enter the required value, range: **10** - **300 mm.** Entering **0,** the function is disabled and the relevant button will not be shown on the Control Panel.	The function involves **only** the collimator square iris.
ENABLE DRAWING TOOL	It enables or disables the **Live Drawing** function on Control Panel and Live Monitor. *(see Chapter "Operation", Paragraph 5.3.1.2 of this Manual)*.	Yes / No	If the function is disabled, the relevant button will not be shown on the Control Panel and Live Monitor.
ENABLE STOPWATCH TOOL	It enables or disables the **Stopwatch** function on Control Panel and Live Monitor. *See Chapter "Operation", Paragraph 5.2.7.12 of this Manual.*	Yes / No	If the function is disabled, the relevant button will not be shown on the Control Panel and Live Monitor.

VIEW FINDER OVERLAY	It is possible to activate a viewfinder (**Crosshairs** or **Circle** shaped) that will be shown on the image central part.	**None** or **Crosshairs** or **Circle.**	None: the function is disabled and the relevant button will not be shown on the Control Panel. *See Chapter "Operation", Paragraph 5.2.5.2 of this Manual.*
VIEW FINDER OVERLAY DIAMETER	Set overlay diameter (in mm).	**30 ÷ 80 mm**	
ENABLE ACTIVE COOLING	Enable to configure active cooling options.	**On / Off**	Activate only if the equipment is provided with a monoblock **I-40R 15 RF AC**
ACTIVE COOLING MODALITY	Set the operating mode to be applied when you are into the **Operative Framework.**	• **Off**: The active cooling system is not used. • **Soft**: when the temperature of the monoblock overcomes 35° C (95° F), the cooling fan operates at low speed. • **Auto**: when the temperature of the monoblock overcomes 35° C (95° F), the cooling fan operates at a speed directly proportional to the temperature detected inside the monoblock.	It is possible to set a different mode directly from the Control Panel (*see Paragraph 1.3.1.1, Part 1 of the User Manual)*.

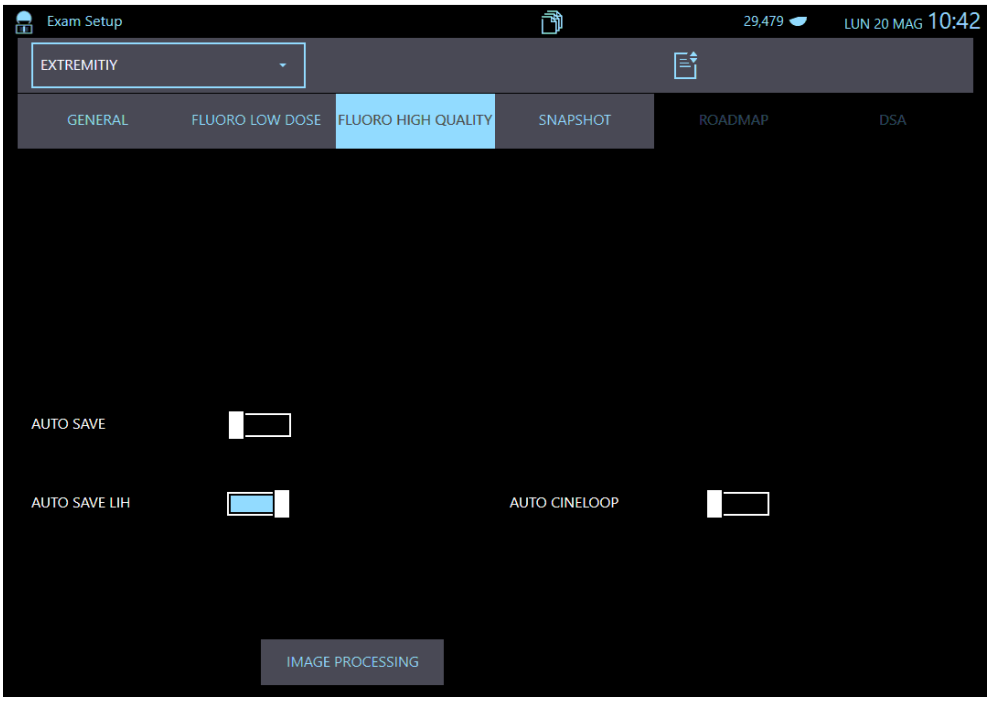
LOW DOSE FLUOROSCOPY:



LOW DOSE FLUOROSCOPY parameters

Option	Meaning	Settings	Notes
AUTO SAVE	Automatic saving to hard disk of all the image acquired.	Normally NOT enabled.	As an alternative to AUTO SAVE LIH
AUTO SAVE LIH	Automatic saving to hard disk of the last image hold (LIH).	Normally enabled.	As an alternative to AUTO SAVE
AUTO CINELOOP	Automatic activation of the cine loop after acquiring a run of images	Yes / No	This function is only active if a run has been saved.

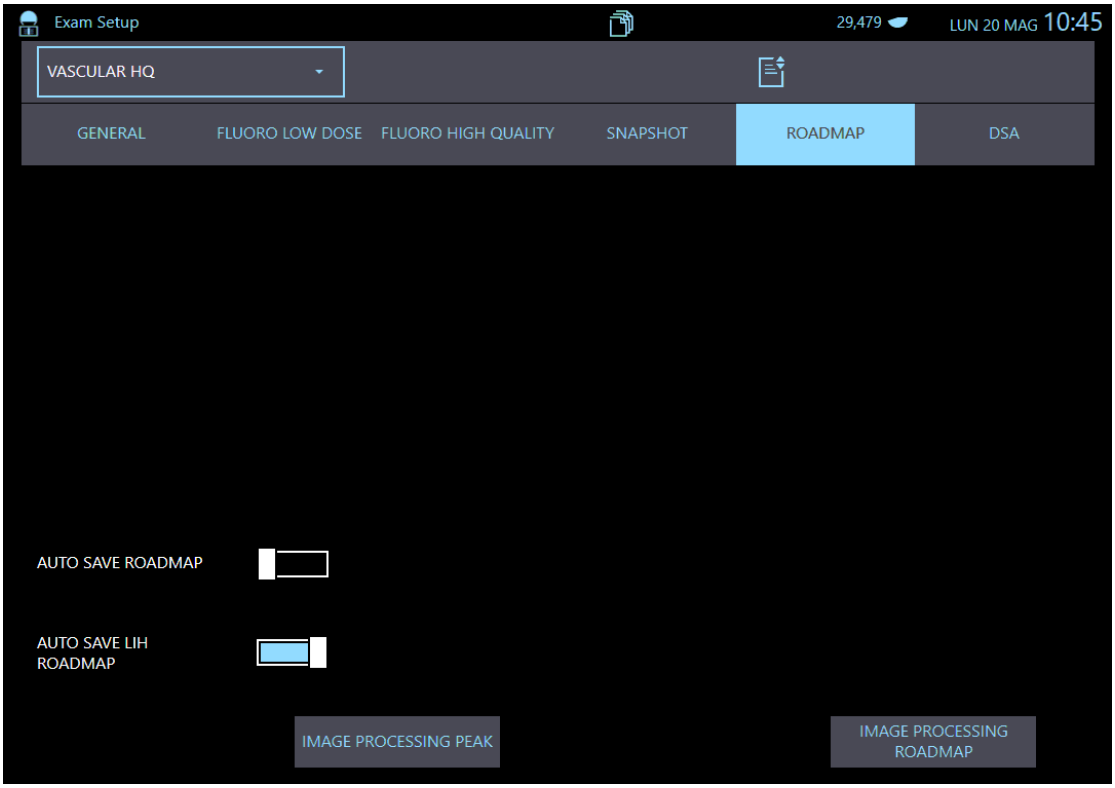
HIGH QUALITY FLUOROSCOPY:



HIGH QUALITY FLUOROSCOPY parameters:

Option	Meaning	Settings	Notes
AUTO SAVE LIH	Automatic saving to hard disk of the last image hold (LIH).	Normally NOT enabled.	As an alternative to AUTO SAVE
AUTO SAVE	Automatic saving to hard disk of all the image acquired.	Normally enabled.	As an alternative to AUTO SAVE LIH
AUTO CINELOOP	Automatic saving of the cine loop after acquiring a run of images	Yes / No	This function is only active if the images in the run have been saved to hard disk

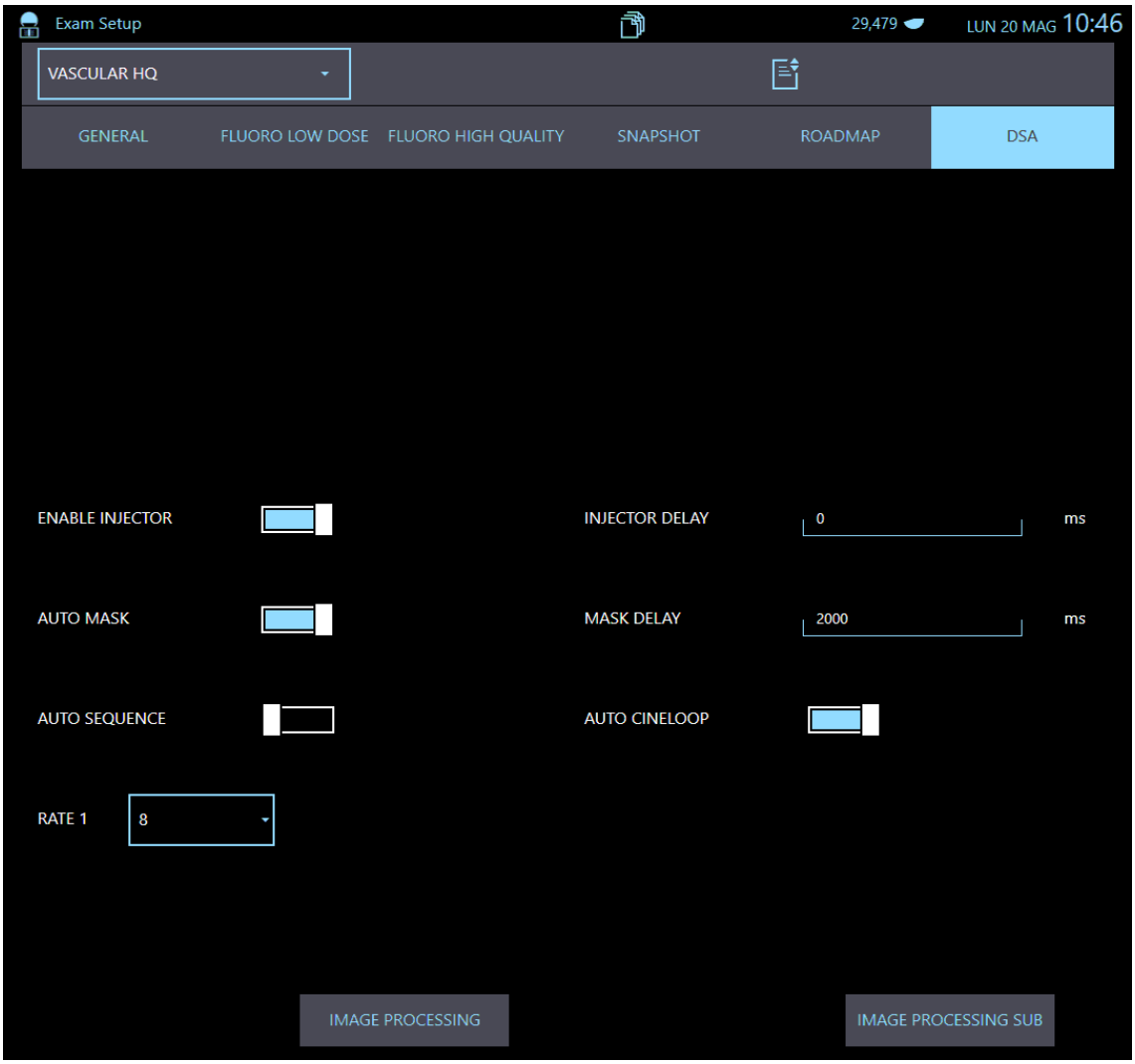
ROADMAP:



ROADMAP Parameters:

Option	Meaning	Settings	Notes
AUTO SAVE ROADMAP	If enabled, all the images in the run will be saved to hard disk.	Yes / No	As an alternative to AUTO SAVE LIH ROADMAP
AUTO SAVE LIH ROADMAP	If enabled, only the Last Image Hold (LIH) image is saved to hard disk.	Yes / No	As an alternative to AUTO SAVE ROADMAP

DSA Fluoroscopy:



You can program some specific parameters for a DSA exam during installation. These are automatically set once you open DSA acquisition mode:

- **Phase duration,** defined by duration and pulse rate; the exam can be set to have one or two acquisition phases, each one with its own acquisition rate. The exam ends 30 seconds after the x-ray emission started or when the x-ray command is released.
- **Number of acquisition phases**: the exam can be set to last max 40 seconds (up to 10 seconds of anticipation time for the injector, if needed, and up to 30 seconds of x-ray emission).
- **Automatic injector control:** to anticipate/delay the moment that the injector starts with respect to the start of X-ray emission.
- **Mask image uptake delay** from the start of X-ray exposure (0 – 25 seconds).

During the exam, the operator can adjust the default parameters directly from the Control Panel to suit actual needs.

DSA Fluoroscopy Parameters

Option	Meaning	Settings	Notes
ENABLE INJECTOR	When this function is enabled, the operator can use an injector controlled by the system.		If enabled, when the exam is opened, the injector icon will be shown.
INJECTOR DELAY	Delay (positive number) or anticipation (negative number), indicated in ms, for the start of the injector with respect to the start of X-ray exposure.	From **-10** to **+25** seconds.	Available if ENABLE INJECTOR option is enabled.
AUTO MASK	To enable the automatic mask uptake function, at the moment defined by **MASK DELAY** option.	Yes / No	
MASK DELAY	Delay, indicated in ms, between the X-ray exposure start and mask image uptake.		Once the mask image has been taken up, the system shows the image in subtraction mode.
AUTO SEQUENCE	This function divides the DSA exam into two phases: the operator can set the acquisition rate and duration of each phase.		
RATE 1 **RATE 2**	Acquisition rate of each phase.	Choose between shown values: **1 – 2 – 4 – 8 – 15** Or **1 – 3 – 6 – 12 – 25**	The operator can change the rate values on opening the exam. If high mA curve is set (curve 5, 100 mA), max acquisition rate value is automatically reduced by the system (from 15 fps to 8 fps, or from 25 fps to 12 fps) in order to not overcome Reference Air Kerma Limit, stated by **EN 60601-2-54** standard in 176 mGy per minute.
SPAN RATE 1	Phase 1 duration, in ms		
AUTO CINE LOOP	Automatic activation of the cine loop after acquisition of a run of images	Yes / No	This function is only active if the images in the run have been saved to hard disk

3.1.4.2 IMAGE PROCESSING

IMAGE PROCESSING parameters can be set for each exam in each acquisition mode.

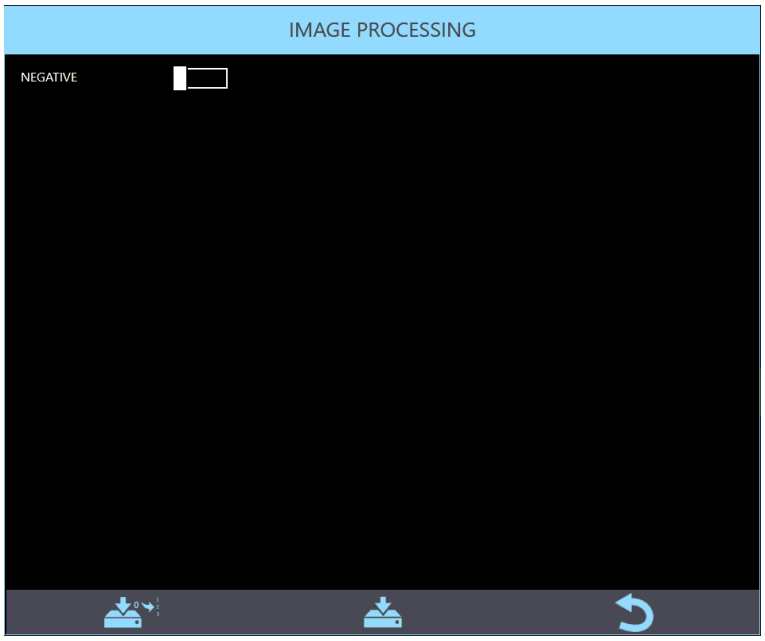


IMAGE PROCESSING parameters:

Option	Meaning	Settings	Notes
NEGATIVE	"Negative" display of the gray scale	Yes / No	Normally enabled for images acquired in digital radiography mode.

3.1.5 EXAMS MANAGEMENT

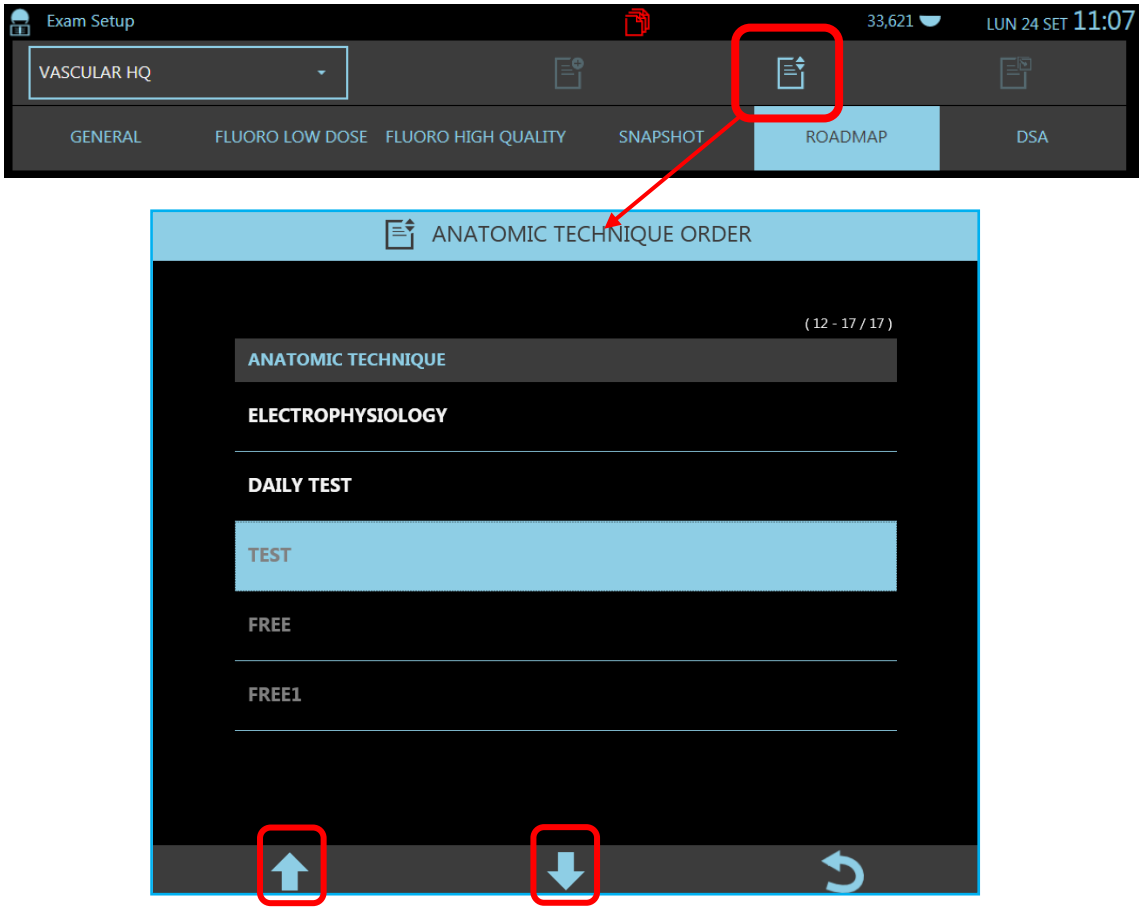
The EM equipment is provided with a set of already configured exams.

Advanced user could change the order of the exam in the relevant list (*see Paragraph 3.1.4.1 below*).

3.1.5.1 ORGANIZE THE EXAM LIST

The EM equipment stores all the exams created (enabled or not), in a same list. Only those enabled will be shown in the list of the **Control Panel**.

Exams order in the list is the same presented in the Control Panel.
Use the **ANATOMIC TECHNIQUE ORDER** (here below) to change an exam position: just select it and, using relevant tips, move it to the required position.



Note: *enabled exams are presented in white, while those not enabled in grey.*

3.1.6 FIXED STRING SETUP

You can program a series of texts ("fixed strings") to speed up the addition of frequently used words or short messages on the acquired image during post-processing.

To create and update this list of strings, use the **Fixed Strings Setup menu:**

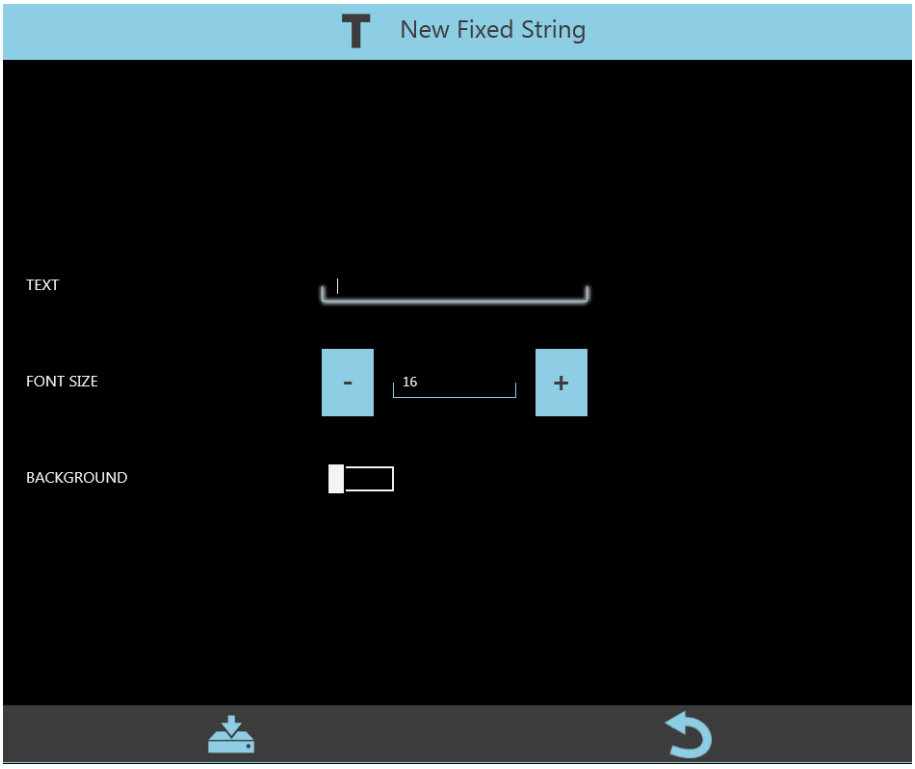
The commands are:

 *to add a new string,*

 *to delete the selected string from the list,*

 /  *to move the selected string up/down within the list.*

- Select the **New String** command  to open the user configuration page:



- Here you can set:

  - Text: contents of the string (max 20 characters);

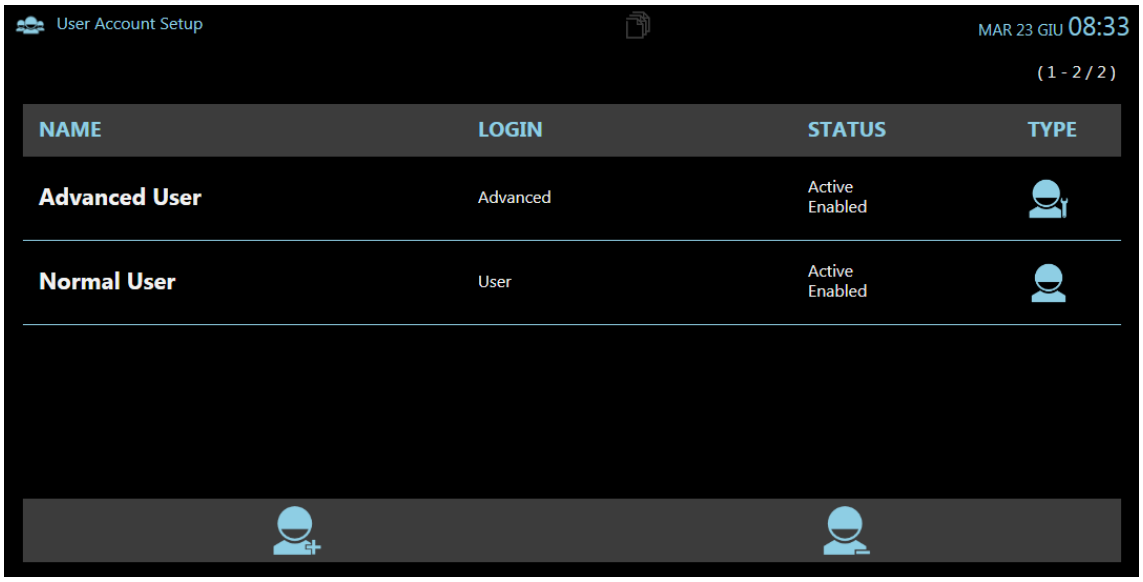
  - Font Size: size of the string;

  - Background: a black box is added as a background for the string.

- Use the  command to complete the creation of the new string and add it to the list of existing strings.

3.1.7 USER ACCOUNT SETUP

The **User Account Setup** menu (accessed by **Administrator** and **Advanced** users only) lets you manage the creation, enabling/disabling and deletion of system users.



There are three user levels:
- Administrator (user pre-set in factory)
- Advanced (set during installation)
- Operator

The privileges for each user type are:

- **Administrator:** full access to the EM equipment

- **Advanced:** routine operations and access to the following SETUP pages:

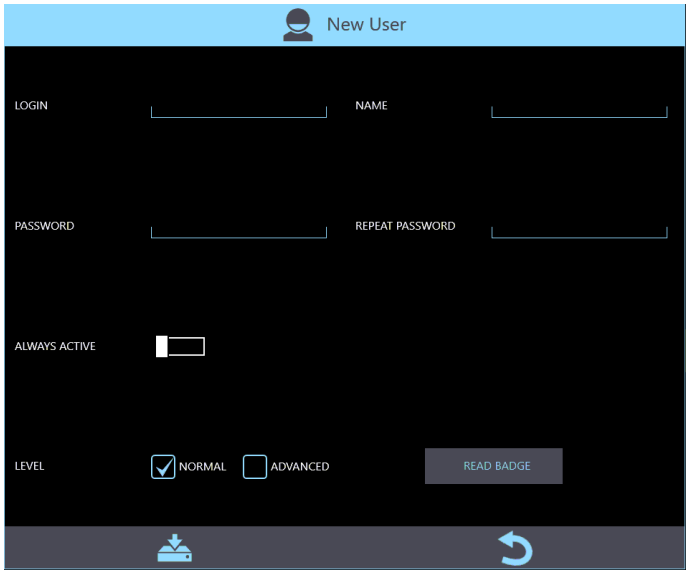
  - *General Settings* setup,
  - *Exam* setup,
  - *Fixed String* setup
  - *User Account* setup.

  Note: *some of the parameters should not be visible to* ***Advanced*** *user.*

- **Operator:** routine operations only.

Each user has a unique password.
The system is meant to have only one **Administrator** user, with a unique password (pre-set and that never expires).

- Select the  command to open the user configuration page:



- Here you can set:

  - **Login**: name used to identify the user accessing the equipment (user name);
  - **Name**: typically, the user's full first name and surname;
  - **Password** and **Repeat Password**: password to be entered in order to access the equipment (at least 8 characters);
  - **Always Active**: the created user will never be disabled;
  - **Level**: **Normal** / **Advanced** *(N.B.: a new Administrator cannot be created)*.
  - **Read Badge** function: This function allows to link a magnetic personal badge, to speed up the Login procedure. To enable this function, just place the badge near the reader and press the Read Badge key. A message appears to confirm the badge has been correctly linked to its user.

- Press the  command to complete the user entry and save the data.

Each password is valid for 90 days, after which time the user must enter a new one. 15 days before a password expires, a warning message appears whenever the user logs in, indicating that the password will expire shortly.

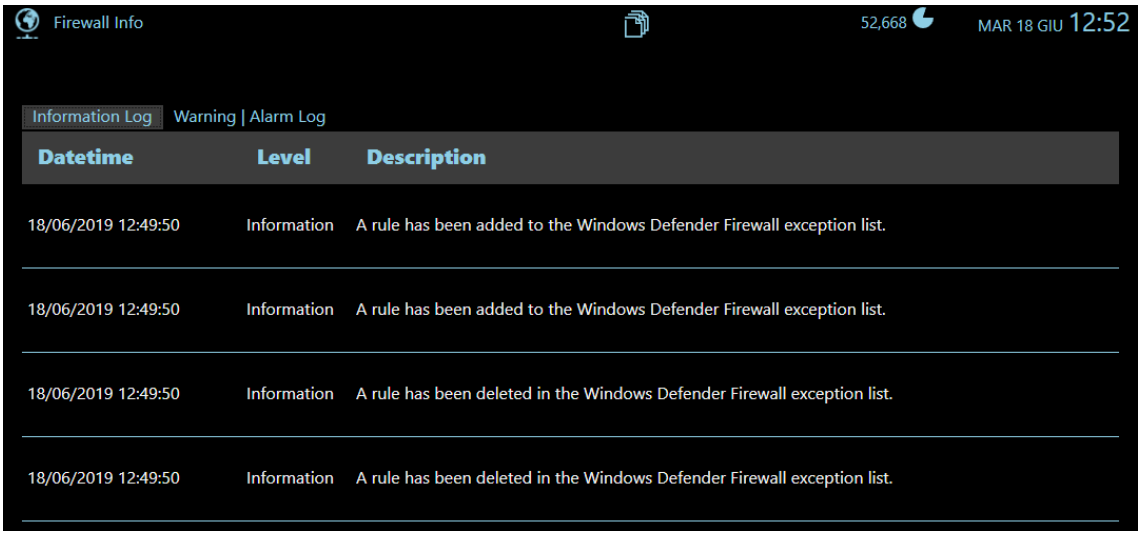
If a user does not use the equipment for 6 months, the corresponding user account is automatically disabled and will not be displayed in the LOGIN list.

3.1.8 FIREWALL INFO

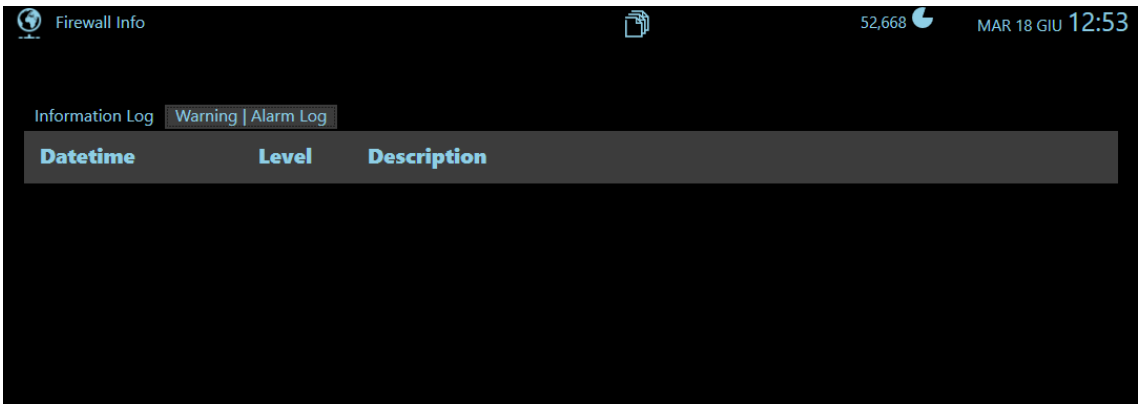
This menu is divided in two pages:

- **Information Log** page,
- **Warning /Alarm Log** page.

The first page provides information about **Windows Defender Firewall** status and possible updates. Logs are defined by Date and Time, Level and a brief Description.



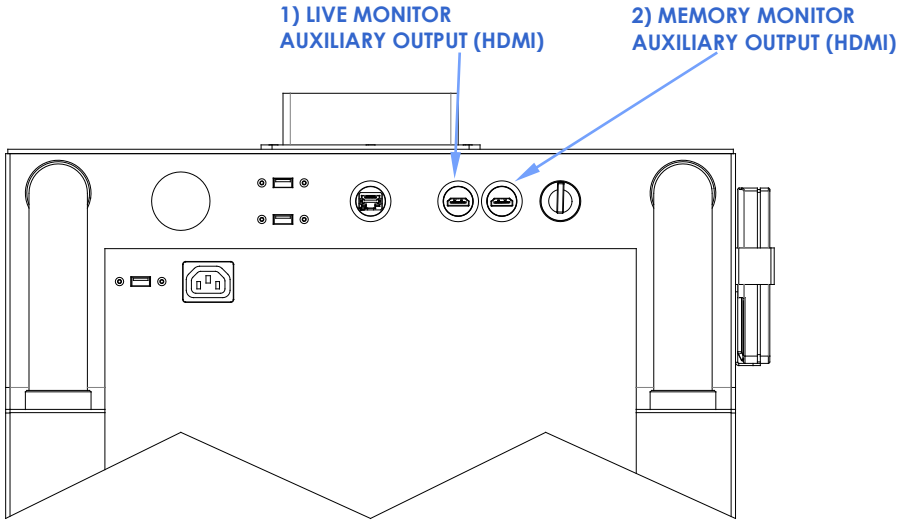
The second one provides information about possible external attacks to the system (security breach). Warnings or alarms are defined by Date and Time, Level and a brief Description.



3.2 CONNECTING EXTERNAL MONITOR

The equipment allows the connection to an external monitor (not provided with the equipment), through its **HDMI** socket.

Connection socket is placed on the monitor unit frontal part.



Note: *Before using an additionally connected monitor for diagnostic purposes, its performance must be validated for the intended use.*

It is preferable to use monitors of the same type as those that are used in the EM system.

If another type of monitor is used, make sure it is fully compatible with the EM equipment, it is **CE labelled** and in compliance to **IEC 60601-1** or **IEC 60950** (in this case it is mandatory to use a galvanic separation device, in compliance to **IEC 60601-1,** between monitor and its supply socket).

The two HDMI auxiliary outputs recreate respectively:

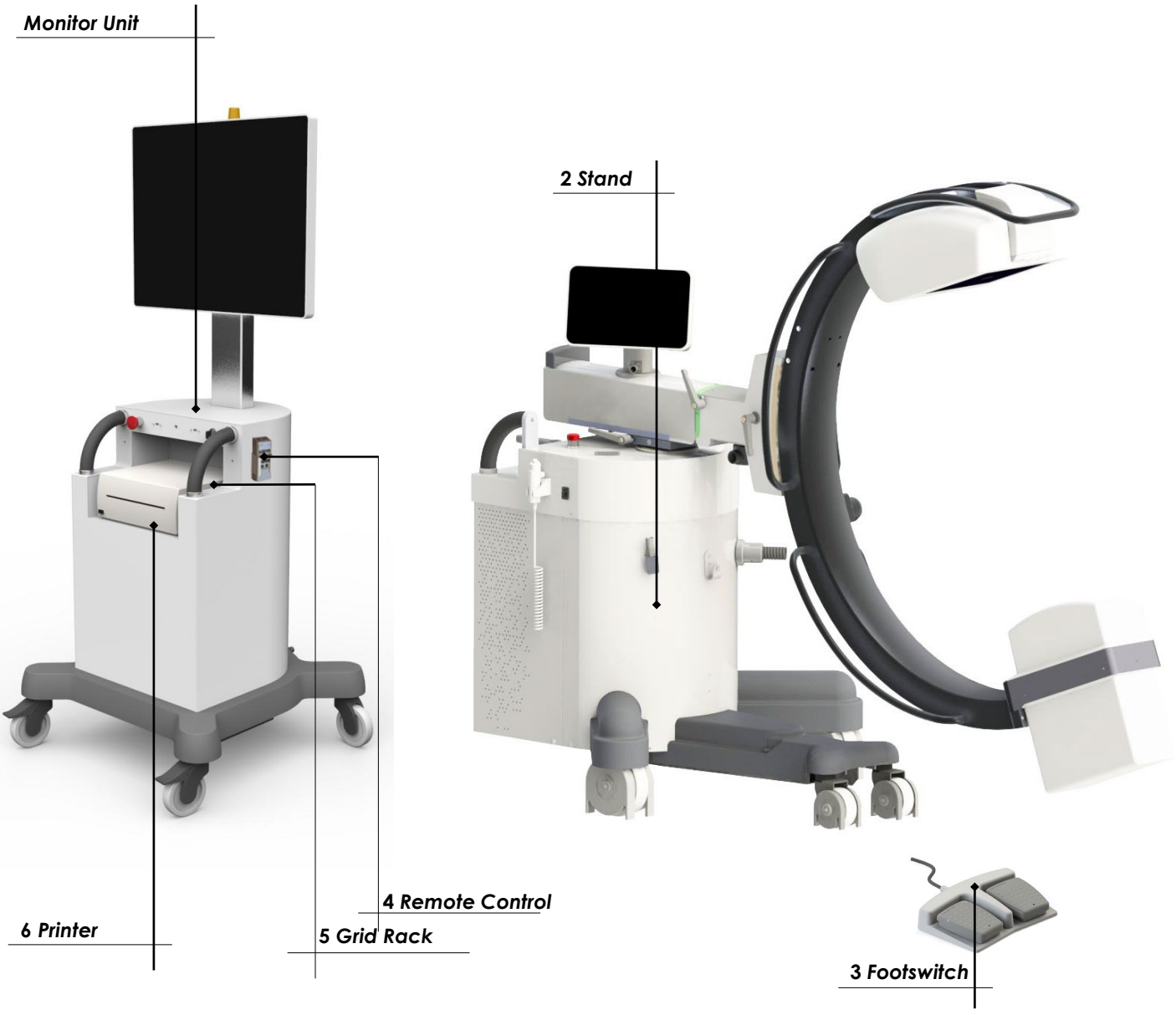
1 The image presented on the **Live** monitor,

2 The image presented on the **Memory** monitor.

4 SYSTEM OVERVIEW

4.1 COMPOSITION OF THE EM EQUIPMENT

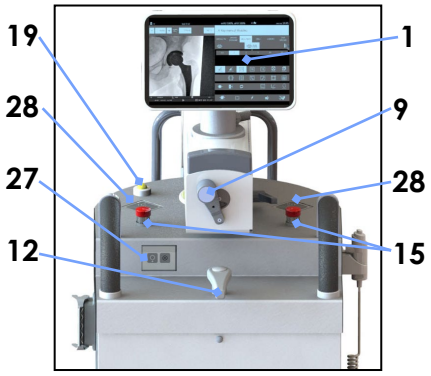
1 Monitor unit
2 Stand
3 X-ray footswitch
4 Remote control
5 Grid rack
6 Printer *(Optional)*



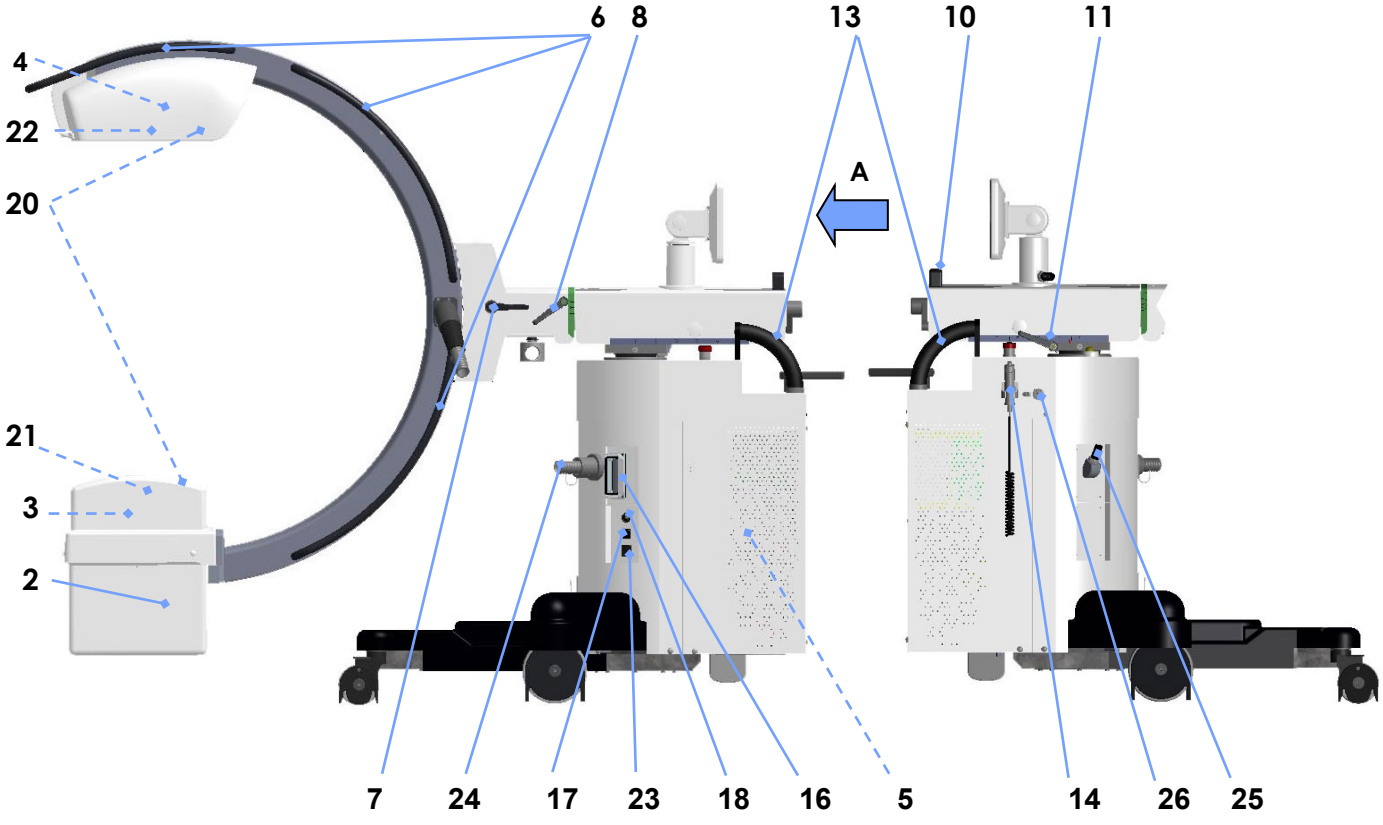
Attention: *While using the EM equipment,* ***DO NOT*** *touch the Control Panel and one of the screens on the Monitor Unit, contemporarily.*

4.2 STAND

1	Control panel	
2	X-ray monoblock	
3	X-ray collimator	
4	Flat Panel Detector	
5	Base, containing:	Control unit / X-ray power supply / X-ray power supply feeder / Column movement motor / Rear wheel rotation mechanism / Power transformer
6	C-arm orbiting grips	
7	C-arm orbiting brake	
8	C-arm rotation brake	
9	Horizontal C-arm positioning brake	
10	Horizontal C-arm movement grip	
11	"Wig-wag" angle brake	
12	Guide knob (±90°) for rear wheels and stand parking brake control	
13	Handles for moving the stand	
14	X-ray command button	
15	Emergency stop buttons (column motor)	
16	Stand / monitor unit connector	
17	Footswitch cable connector	
18	Equipotential earth connector	
19	X-ray emission warning light / Remote control receiver	
20	Laser light localisers *(optional)*	
21	DAP (optional)	
22	Anti-scatter grid	
23	Injector	
24	Stand cable/ C-arm	
25	Control panel cable	
26	Rx handswitch connector	
27	Stand On/Off button	
28	C-arm Up/Down button	



View from A



4.2.1 CONTROL PANEL

The control panel on the stand provides mainly all the functions needed for image acquisition.

These include:

- The live image or the last image acquired (LIH).
- Exam selection keys.
- Acquisition mode selection keys: Low Dose fluoroscopy, High Quality fluoroscopy, Digital Radiography, RoadMapping mode fluoroscopy and DSA mode fluoroscopy.
- X-ray generator setup keys for kV and mAs (only available on digital radiography).
- X-ray collimator control keys.
- Acquisition parameter setup keys (process algorithms, pulse rate, etc.).
- Image saving keys.
- Status and alarm information.

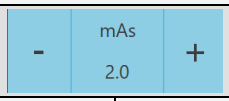
See below for a detailed description of the various controls and indications.

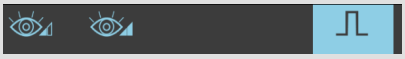
LOW DOSE FLUOROSCOPY:
For low dose X-ray exposures

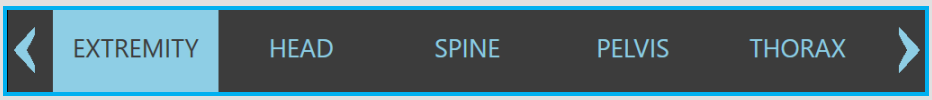
HIGH QUALITY FLUOROSCOPY:
For high quality X-ray exposures

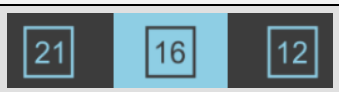
RAD:
For X-ray exposures in digital radiography mode

4.2.1.1 BUTTONS

TO ADJUST THE X-RAY PARAMETERS		Increase / decrease kV. This function is enabled in standby and during X-ray emission when you select the dose in manual fluoroscopy mode.
		Increase / decrease mAs. This function is enabled only in digital radiography mode.
		Fluoroscopy selection with automatic / manual dose control.

EXPOSURE MODES		Selection of Low Dose fluoroscopy and the acquisition rate.
		Selection of High Quality fluoroscopy and the acquisition rate.
		Selection of digital radiography.
		Selection of RoadMap mode and the acquisition rate.
		Selection of DSA mode and the acquisition rate.

ANATOMICAL EXAMS		Exam selection. The exams can be set in the relevant menu. The exam list can be scrolled further by pressing the lateral arrows.

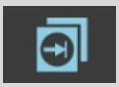
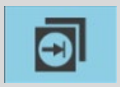
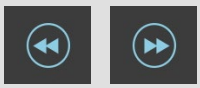
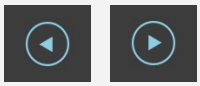
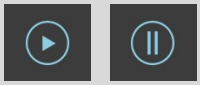
FLAT PANEL DETECTOR FIELD	**FPD 21 x 21**	
		Nominal Field (21 x21 cm^2)
		1st zoom (16 x 16 cm^2)
		2nd zoom (12 x 12 cm^2)

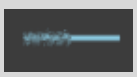
FLAT PANEL DETECTOR FIELD	FPD 30 x 30
	Nominal field (30 x30 cm2)
	1st zoom (21 x 21 cm2)
	2nd zoom (16 x 16 cm2)

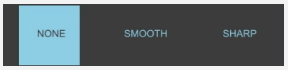
X-RAY COLLIMATOR AND LASER	OFF	ON
		 Laser localiser ON/OFF (the switch-on time can be set in Unit Configuration setup; *see Paragraph 4.3, Part 2 of the Technical Manual*).
		Activation/deactivation of the icons to adjust the opening of the collimator directly on the image (*See paragraph 2.3.10, Section 2 of this Manual*).
		 This key opens the collimator control menu (shutters and square field). The following commands are available:
		This key is meant to open the collimator square field to the default value that has been set in Exam Setup menu (*See Paragraph 4.4.1, Part 2 of the Technical Manual*).
		Activation / deactivation of the opening of the parallel shutters, independently of each other.
		This key completely opens the square field and the shutters.

IMAGE ORIENTATION		
		Use this button to open the image orientation menu with these functions:
		90° image rotation (anti-clockwise)
		Anti-clockwise image rotation (steps of 1°)
		Image rotation reset
		Clockwise image rotation (steps of 1°)
		90° image rotation (clockwise)
		This key gives the operator the possibility to freely rotate the image by dragging it with his finger.
	OFF 	ON  Horizontal image flip

	OFF	ON	
FULL SCREEN IMAGE			This key displays the image shown on the Control panel as a full screen image on Live Monitor (*see Chapter: "Operation", Paragraph 5.2.7.13 of this Manual*).

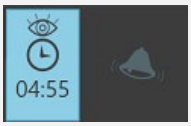
	OFF	ON	
IMAGE SAVING AND MANAGEMENT			Pressing this key, during fluoroscopy only, it saves and pins the current image.
			Save single live fluoroscopy image to hard disk (or LIH image)
			Save all subsequent fluoroscopy images in current study to hard disk.
			Use this button to open the menu that lets you manage saved images, shown on the memory monitor:
			Transfer image from Memory monitor to Live monitor.
			Find run of images within the study.
			Find images within a run.
			Start / Stop cine-loop of images in a run.
			The **Reference Image** key lets you keep the view of the selected reference image, it disables the search buttons for images and runs. Press the key again in order to leave the function (*see Chapter: "Operation", Paragraph 5.2.7.14 of this Manual*).
			**Pin image:** This key adds a marker to the image viewed.

POST-PROCESSING OF IMAGES		This key opens the **Live Drawing** function (*see Chapter: "Operation", Paragraph 5.3.1.2 of this Manual*).
		This key enables the stopwatch function. It is visible both on the Control Panel and on the Live Monitor. This function is useful whenever you need to measure the duration of specific procedures (*see Chapter: "Operation", Paragraph 5.2.7.12 of this Manual*).
		When enabled, this key allows to see on CP and LM, in the center of the image area, a viewfinder (two different shapes). It turns to be very useful in particular procedures (for further information, *see Chapter: "Operation", Paragraph 5.2.5.2 of this Manual*).
		This key opens the image processing menu for the selected image.
		This key lets you modify the value of the **Noise Reduction** factor which is applied to the image.
		This key allows to restore W and L image values, as they were at the acquisition.

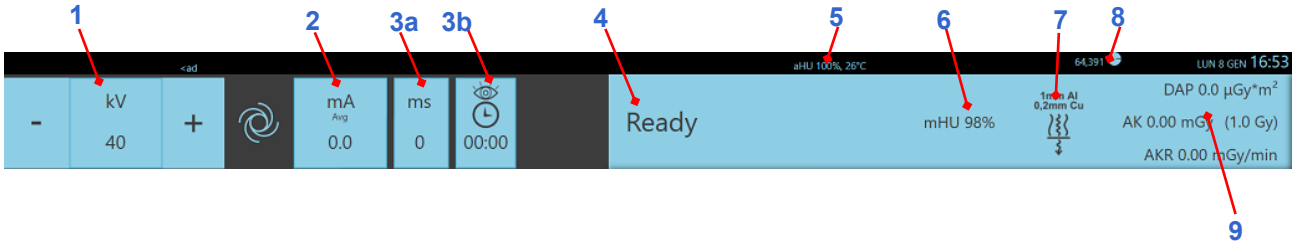
	OFF	ON	
			GREY SCALE inversion.
			Use these buttons to enable / disable the digital movement-sensitive recursive filter.
			Select the specific image dynamics control processes for the selected exam (DRC, dynamic range compression).
			Select the spatial digital filters (edge smoothing / sharpening).

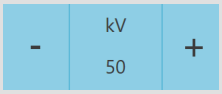
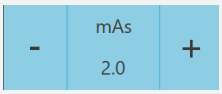
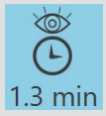
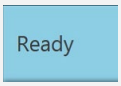
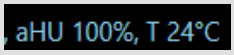
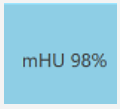
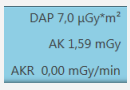
ACTIVE COOLING FUNCTION	 OFF	The active cooling system is switched off: the heat produced by the x-ray tube is dissipated passively.
	 SOFT	The active cooling system switches on when the temperature of the monoblock (see paragraph 1.3.1.2 below) overcomes 35° C (95° F): a warning message is shown on the Control Panel to advise the operator 10 seconds earlier. The cooling system operates at an automatically limited speed.
	 AUTO	The active cooling system switches on when the temperature of the monoblock (see paragraph 1.3.1.2 below) overcomes 35° C (95° F): a warning message is shown on the Control Panel to advise the operator 10 seconds earlier. The cooling system works at an automatically accelerated speed as the temperature of the monoblock increases.

	OFF	ON	
EXTRA FUNCTIONS			Enable / Disable acoustic X-ray emission signal in fluoroscopy.
			Enable / Disable X-ray commands.
			Start detector offset calibration (press for about three seconds).
			ROI manual selection for automatic KV/mA regulation, in fluoroscopy.

RESET INDICATIONS		Total fluoroscopy timer (minutes and seconds). Keep key pressed for at least 3 seconds to reset the timer.
		5 minutes' fluoroscopy alarm. Reset the alarm by touching the alarm icon.

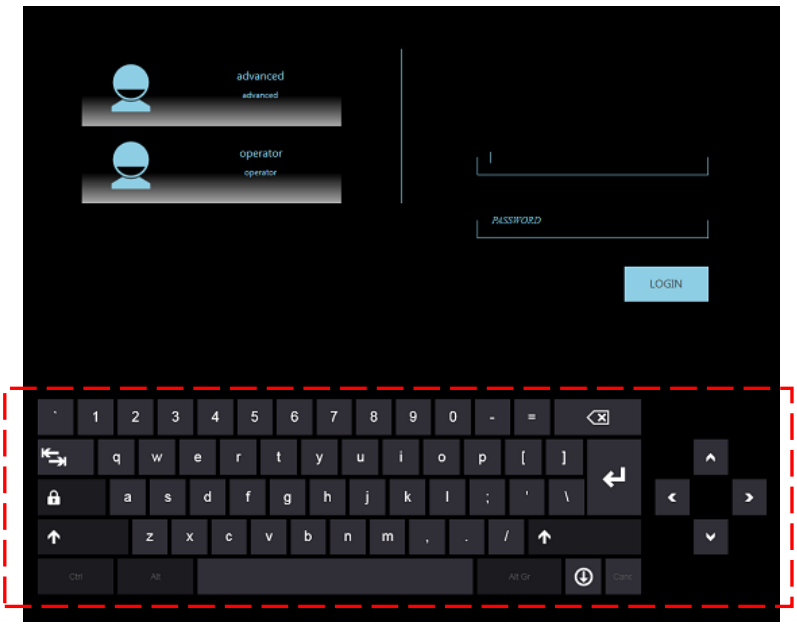
4.2.1.2 INDICATORS



1		Fluoroscopy / radiography kV
2	 	- radiography mAs - average mA per second in fluoroscopy
3a		X-ray pulse duration (in milliseconds)
3b		Accumulated fluoroscopy time reported in minutes and tenth of minutes (eg: 1.3 min is 1 minute and 18 seconds).
4		Mode / Status and alarm messages
5		% of heat units, available in anode (aHU). (100% = anode is cold) Monoblock temperature (in Celsius or Fahrenheit degrees: *see Paragraph 4.2 in Part 2 of the Technical Manual to set the required option*).
6		% of heat units, available in Monoblock (mHU). (100% = monoblock is cold)
7		It shows the X-ray beam filter set for the selected exam. It is possible to assign one of the available filters to each exam. *(see Paragraph 4.4, Part 2 of the Technical Manual)*.
8		Indication of number of images that could still be acquired. It is calculated on number of RAD images (those with the highest resolution).
9		DAP: Accumulated X-ray dose x area during study (Dose Area Product) AK: Air-Kerma accumulated during the study AKR: Air-Kerma Rate

4.3 USING THE KEYBOARD ON THE TOUCH SCREEN MONITOR

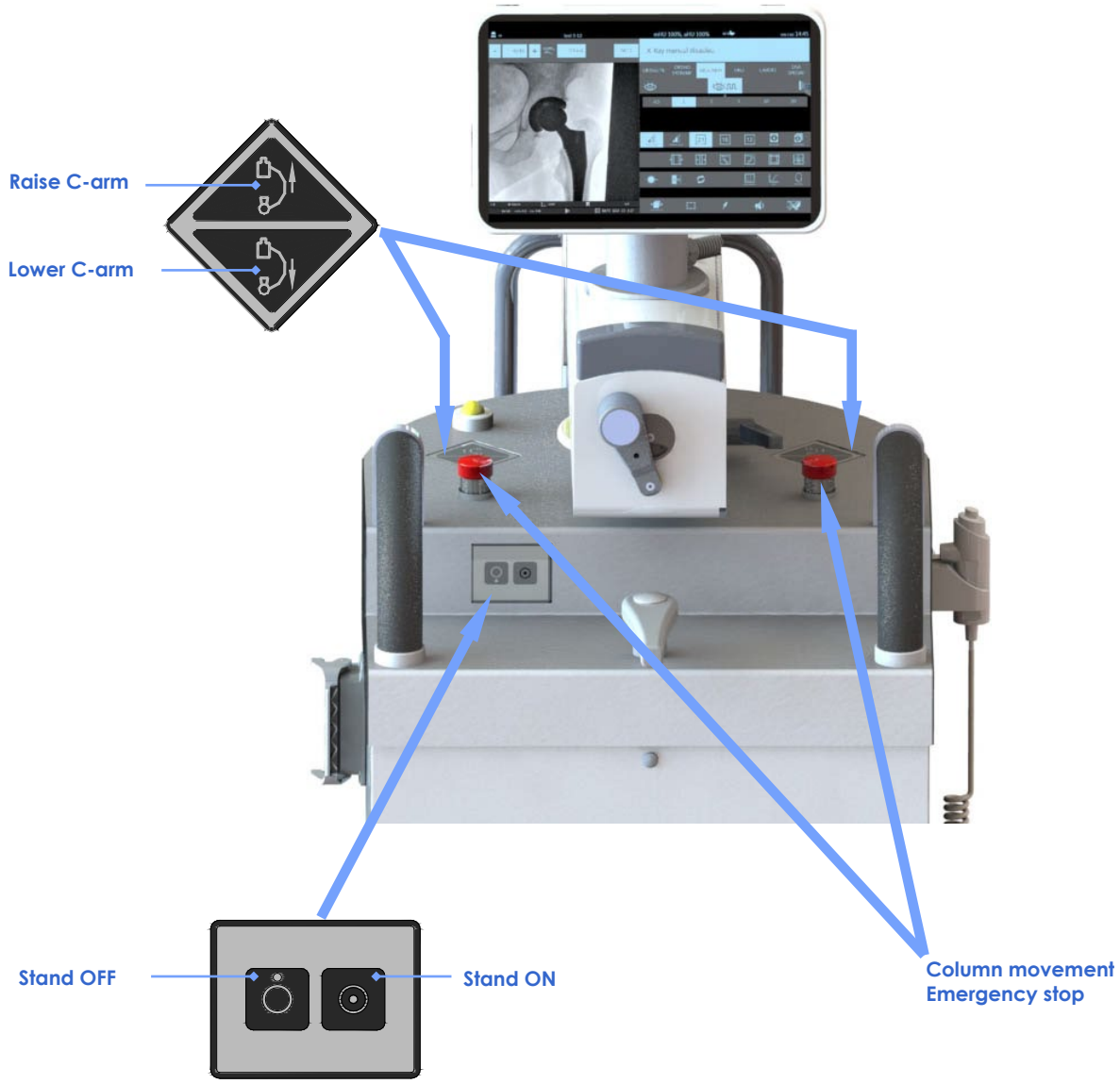
The touch screen monitor provides the only operator interface.
Whenever you are required to enter letters (like for example in the login screen, shown in the following image), an alphanumeric keypad will appear on the lower part of the monitor. This keypad can be moved to any point on the monitor by dragging it:



If you are asked to enter only numbers (e.g. when entering the weight of a new patient, as in the figure below), a number pad appears; again, you can move this to any point on the monitor.

4.3.1 STAND CONTROLS

The stand has its own ON/OFF commands, together with those for raising/lowering the C-arm, and emergency stop buttons for the up/down column movement:

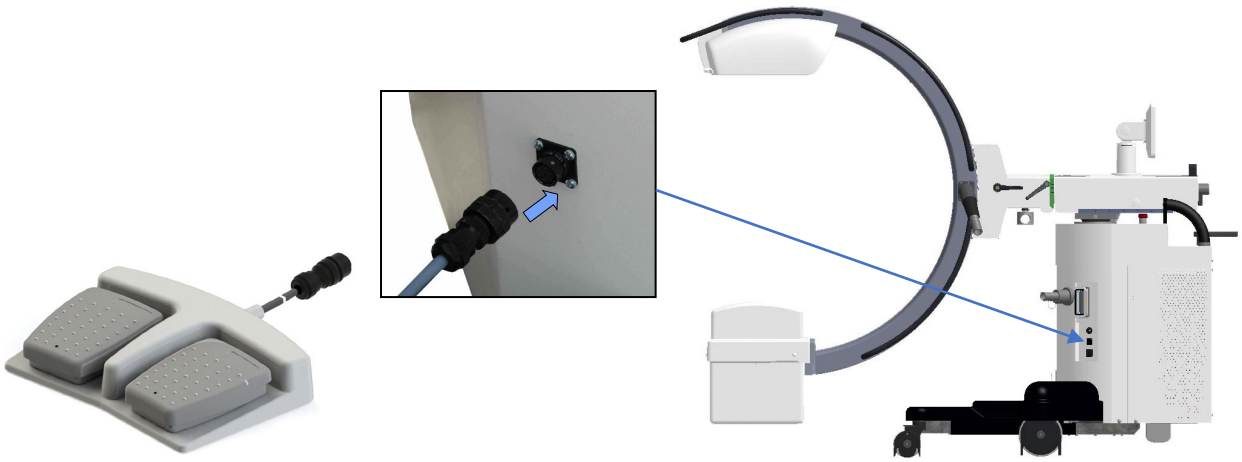


4.3.2 EXPOSURE COMMANDS

The system is equipped with a DOUBLE PEDAL FOOTSWITCH and a BI-FUNCTIONAL HANDSWITCH.

• DOUBLE PEDAL FOOTSWITCH

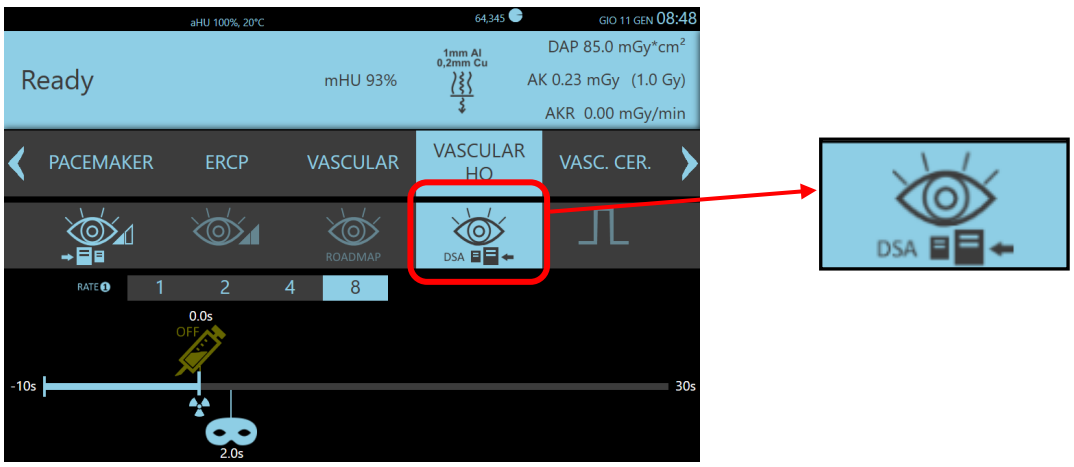
Connect the X-ray command footswitch to the stand as shown in the figure below.



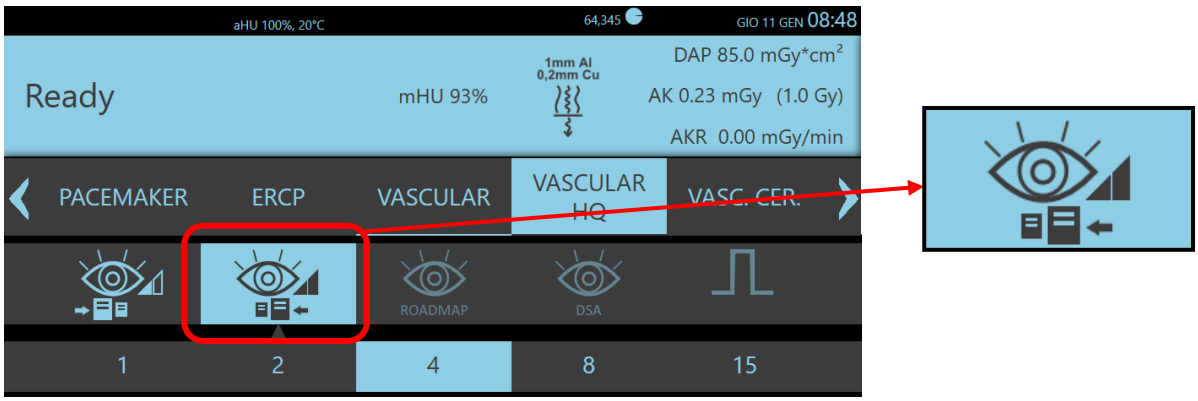
It is possible to assign different acquisition modes to the **two pedals** of the footswitch *(for configuration details, please refer to Paragraphs 4.3 and 4.4, Part 2 of the Technical Manual)*.

- As a default, the left pedal is configured to control the **Low Dose Fluoroscopy** mode.

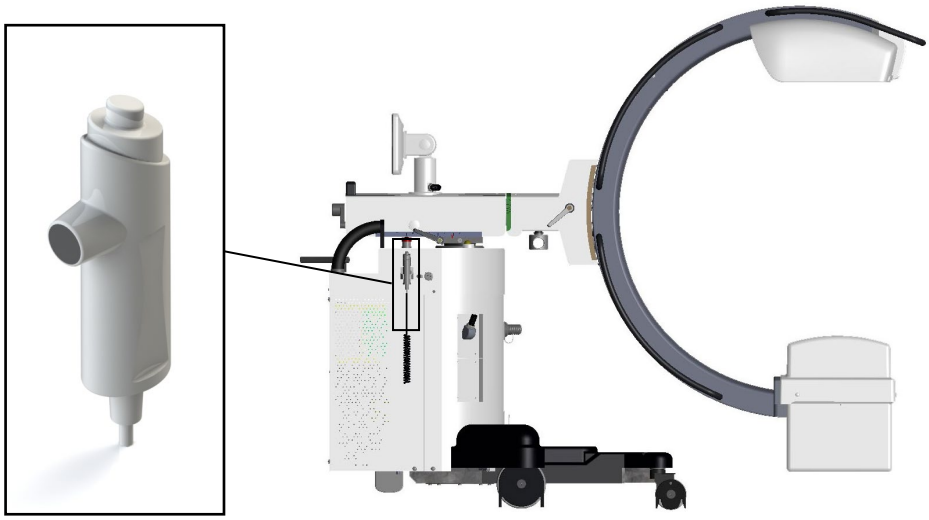
- The pedal on the right can be configured with another preset mode (**High Quality Fluoroscopy**, **Snapshot, RoadMap** or **DSA Fluoroscopy**), according to the specific needs.
  It is possible to decide, for each exam in the exam list, what kind of acquisition mode to associate to the right pedal.
  The preset mode will then be selected automatically when opening the exam.



However, it is possible to change these settings directly in the Control Panel but only for the exam currently carried out: simply press one of the other acquisition modes available for this type of exam, it will then become the temporary acquisition mode for the pedal on the right.



• BI-FUNCTIONAL HANDSWITCH



It is possible to assign different acquisition modes to each of the two function buttons of the **bi-functional handswitch**. Their setting is similar to the one of the two footswitch pedals: the **frontal function button** (black coloured) has the same setting as the left pedal and as a default is configured to control the **Low Dose Fluoroscopy** mode.

The **two-stage function button**, however, will follow the settings made for the pedal on the right. This means in detail, if the **High Quality Fluoroscopy** mode has been set:

- the first stage will give the X-ray emission command,
- the second stage will give the command to save the current image on hard disk (in case that automatic saving of the images is not already set).

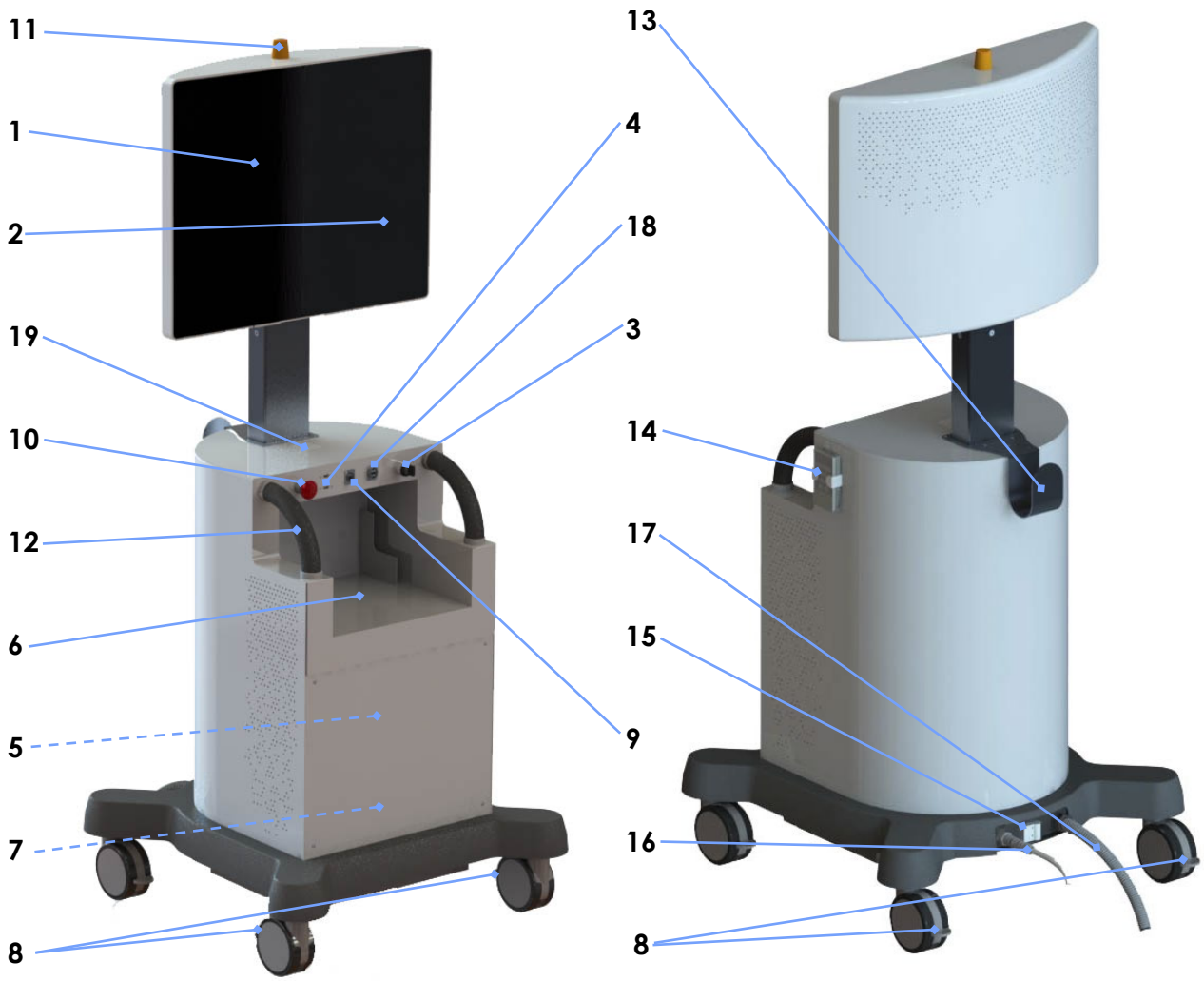
Note: *for the* ***RoadMap*** *and* ***DSA*** *functions, the runs are automatically saved.*

If the **Radiography** mode has been set:

- the first stage will give the digital radiography preparation command,
- the second stage will give the X-ray emission command.

4.4 MONITOR UNIT

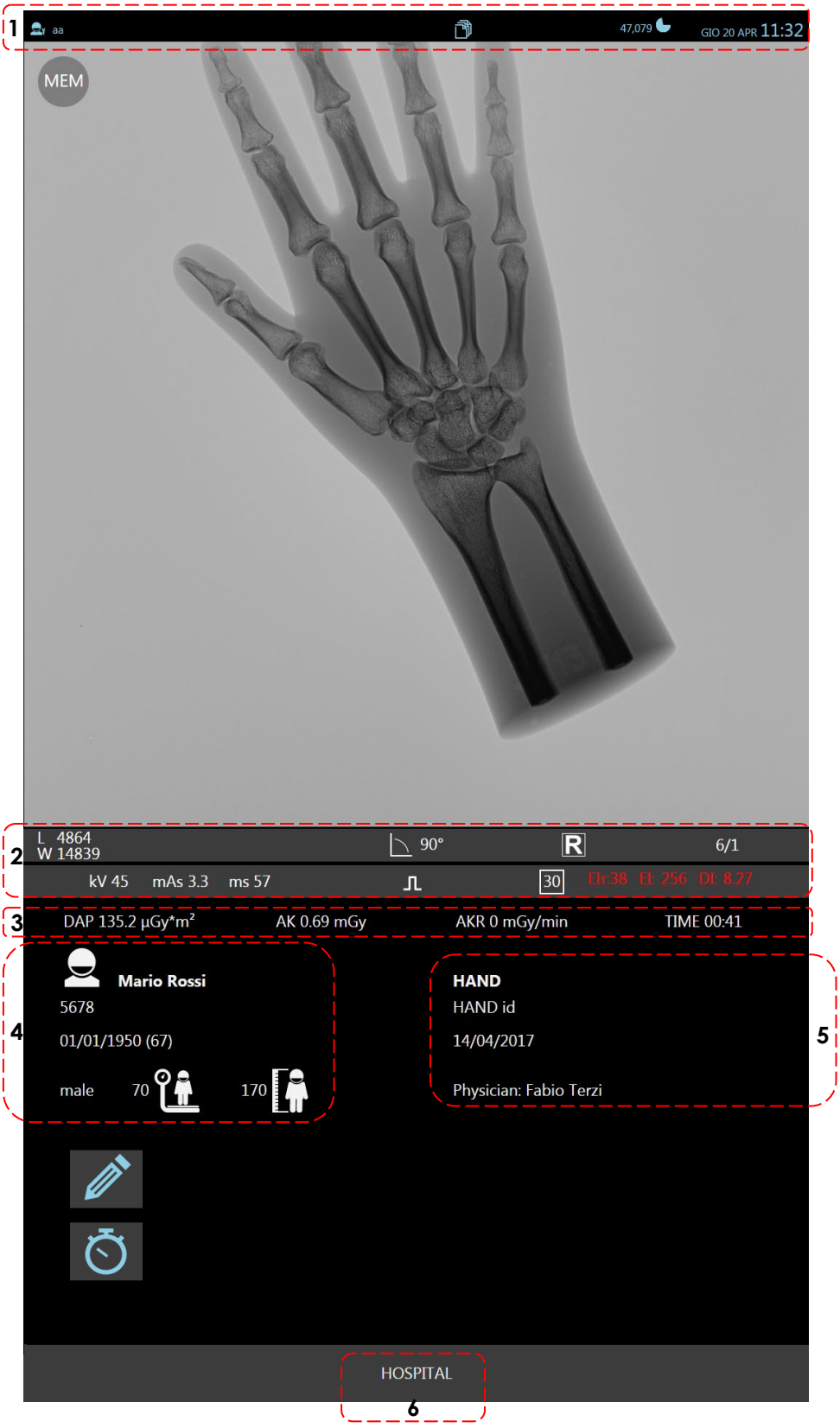
1 **LIVE** Monitor (L.M.): Touch screen monitor displays the images during X-ray emission and the last image hold (LIH).
2 **MEMORY** Monitor (M.M.): this touch screen monitor lets you enter the patient data, and then view and process the images saved to HD.
3 ON/OFF key
4 USB ports to export images
5 System process and management PC and image pre-processing PC
6 Printer compartment / grid rack
7 Power unit
8 Parking brakes
9 Ethernet cable connector (DICOM)
10 General EM equipment emergency stop button
11 X-ray warning light
12 Steering handles
13 Cable hook (when not in use)
14 Infrared remote control
15 General circuit breaker
16 EM equipment power cable
17 Stan connection cable
18 Video connector
19 NFC reader



4.4.1 LIVE MONITOR

During acquisition, the L.M. displays the **Working frame**.

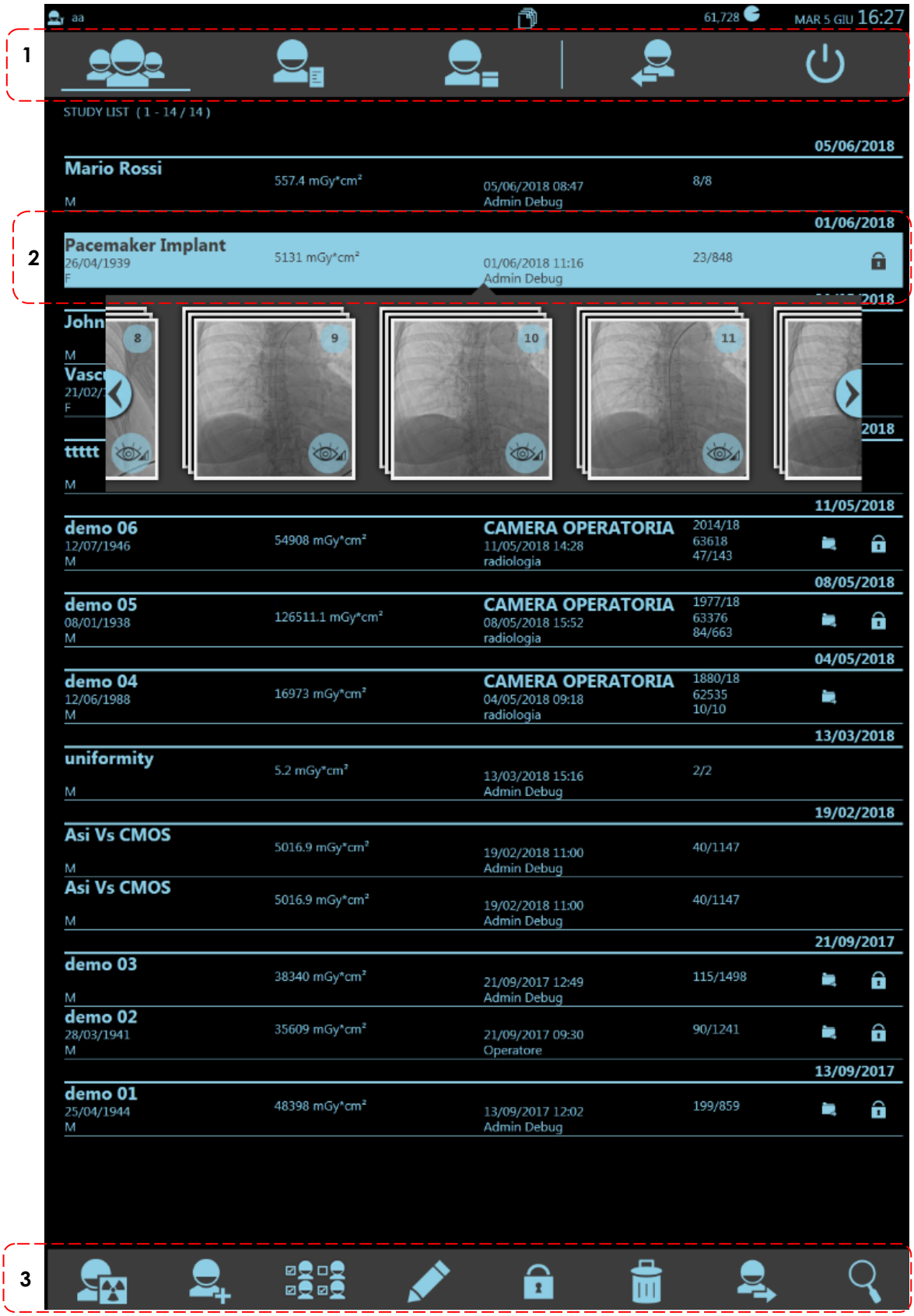
The images are accompanied by various data, split into 6 groups, as shown in the figure and table below:



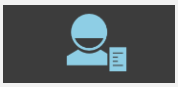
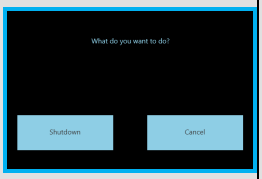
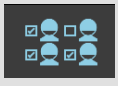
N°	Information	Example	Notes / Meaning
1	Authenticated operator	**User**	
	Free space on disk	**47079**	This is an estimate of the number of images that can still be saved, in terms of the largest image format (21x21 cm^2).
	Current date and time	**THU 20 APR 11:32**	
2 Image data	Image Level and Window	**L 4864 W 14839**	
	Image rotation angle	**90°**	
	Image orientation	**"R"**	
	Number of images in run	**6/1**	
	Exposure data	**kV 45 mAs 3.3 ms 57**	
	Exposure mode	**RAD**	
	Acquisition field	**30**	Detector field 30x30 cm^2
3 Dose	DAP	**135.2 µGy*m^2**	Accumulated X-ray dose x area during study measured by the DAP
	AK	**0.69 mGy**	Air-Kerma accumulated during the study
	AKR	**0.0mGy/min**	Air-Kerma rate in air during the X-ray emission
	TIME	**00:41**	Total fluoroscopy X-ray emission time
4 Patient data	Patient name	**MARIO ROSSI**	
	Accession Number	**5678**	
	Date of birth (age)	**01/01/1950 (67)**	
	Gender	**Male**	
	Weight	**70**	Patient's Weight
	Height	**170**	Patient's Height
5 Study data	Description of the study	**HAND**	
	Studio ID	**HAND id**	
	Operator	**Mario Rossi**	
	Exam start date	**14/04/2017**	
6	Hospital name	**HOSPITAL**	

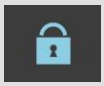
4.4.2 MEMORY MONITOR

4.4.2.1 STUDY LIST FRAME



This frame is split into 3 groups:

N°	Information	Icon / Example	Notes / Meaning
1	Study List		List of studies with at least once X-ray exposure. The blue line under the icon indicates the selected list.
	Study Worklist		List of studies still to be performed, either created manually or received from the DICOM WORKLIST.
	Study Query / Retrieve		List of studies received from the DICOM QUERY/ RETRIEVE utility *(optional)*.
	Shutdown	 	It is possible: - Turn off the system, - Cancel the shutdown selection.
	Log-out		Click this button to return to the log-in window.
2	Position of first and last study in current list and the total number of studies in the archive.	**STUDY LIST 1 – 10 / 10**	
	Date study created	**01/04/2015**	The studies are grouped by date of creation
	Patient first name and surname	**JOHN SMITH**	
	Date of birth	**25/11/1973**	
	Gender	**M**	
	Patient ID	**PATID123456**	
	Description of the study	**THORAX**	
	Date and time study created	**01/04/2015 13:28**	
	Name of operator responsible for study	**DR. GREEN**	
	Accession Number: unique patient access number	**ACCNUM789**	
	Number of runs / number of images in study	**11/193**	
3	Open working frame		
	Create new study		
	Select several studies		This lets you select and process more than one study at a time (e.g. for deletion)
	Edit study data		

	Lock a study		A locked study cannot be deleted
	Delete study		
	Send study to DICOM device		STORE, PRINT and USB
	Study List filter		This lets you search for stored studies by FIRST NAME or SURNAME

4.4.2.2 WORKING FRAME

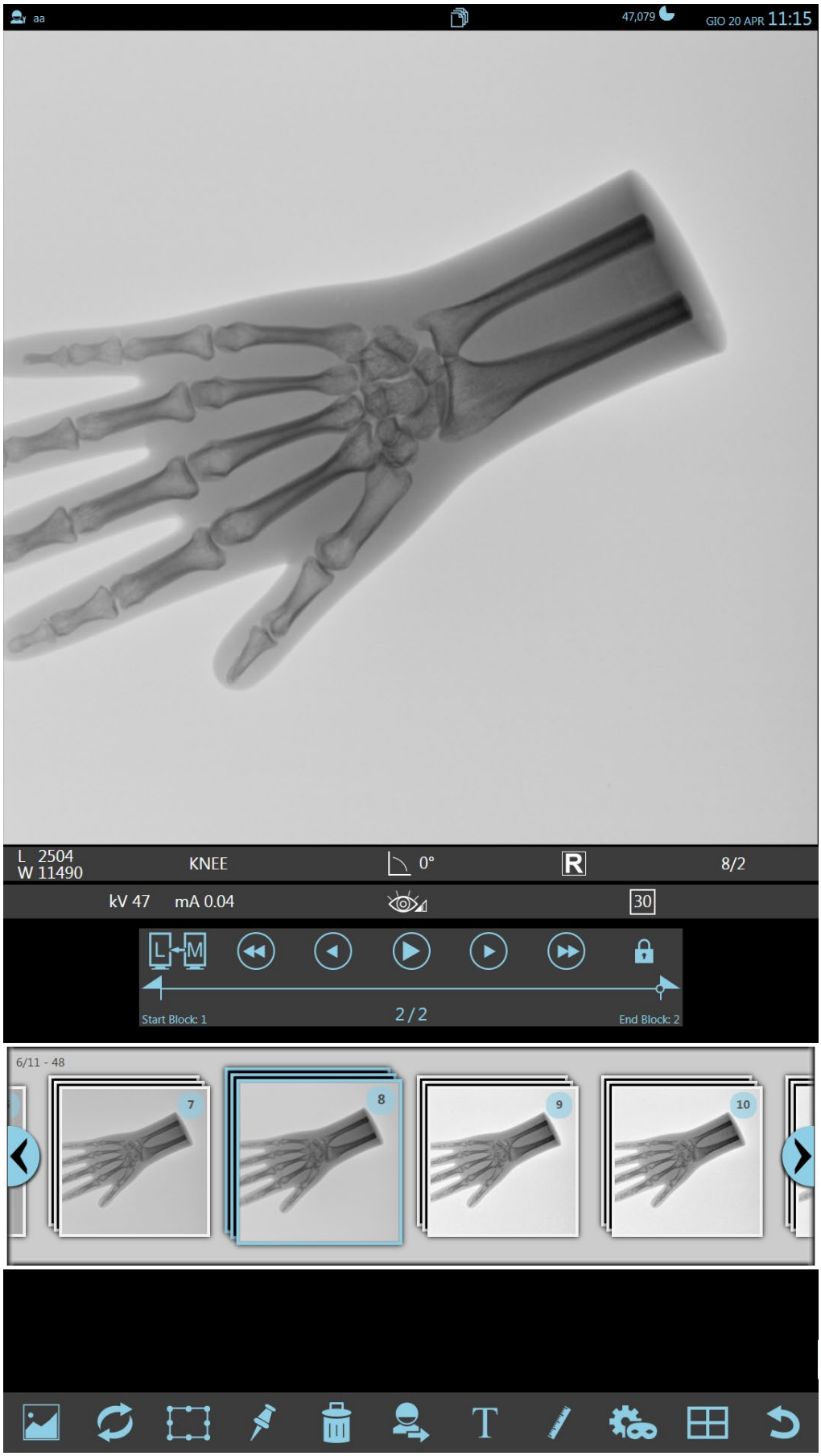


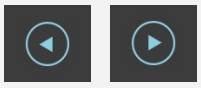
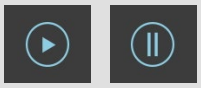
IMAGE MANAGEMENT		Transfer of saved image to Live Monitor
		Find run of images within the study
		Find images within a run. *(These keys do not appear unless a run is selected.)*
		Start / Stop cine-loop of images in a run. *(These keys do not appear unless a run is selected.)*
		The **Reference Image** key lets you keep the view of the selected reference image on the memory monitor. It disables the search buttons for images and runs. Press the key again in order to leave the function (see *Chapter: "Operation", Paragraph 5.2.7.14 of this Manual*).

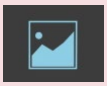
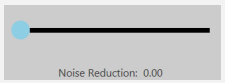
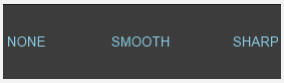
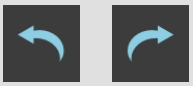
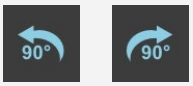
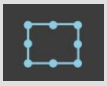
IMAGE PROCESSING		Use this key to open the **IMAGE PROCESSING** menu that lets you edit the selected image (see *Chapter: "Operation", Paragraph 5.3.2 of this Manual*). This menu contains the following functions:
		Automatic / manual WINDOW/LEVEL control
		By increasing this factor, it is possible to reduce possible noise on the image. The settings range from 0 (disabled) to 10.
	OFF ON 	GREY SCALE inversion
		Choice of spatial filters available for the exam: NONE (no filter), SMOOTH (softer edges), SHARP (sharper edges).
		Choice of DRC processes available for the exam

IMAGE ORIENTATION		Use this to open the **IMAGE ORIENTATION** menu for the selected image (see *Chapter: "Operation", Paragraph 5.3.3 of this Manual*). This menu contains the following functions:
		Clockwise / anti-clockwise 1° image rotation
		Clockwise / anti-clockwise 90° image rotation
		Image rotation reset (0°)
		This key gives the operator the possibility to freely rotate the image by dragging it with his finger.
	OFF ON 	Horizontal image flip

ELECTRONIC SHUTTERS		Use this button to apply the electronic shutters **(CROP)** (*see Chapter: "Operation", Paragraph 5.3.4 of this Manual*)

FLAG IMAGE		Use this to flag the selected image or run (*see Chapter: "Operation", Paragraph 5.3.5 of this Manual*)

DELETE IMAGE		Use this to delete the selected image or run (*see Chapter: "Operation", Paragraph 5.3.6 of this Manual*)

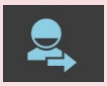
STUDY REPORTING		Use this to open the **STUDY REPORTING** menu that lets you send the study images to a DICOM device. This menu has the following options:
		STORE DICOM: send images in study to DICOM archive
		Send images in **DICOM** format to USB device
		PRINT DICOM: send images in study to DICOM printer
		PRINT: send the image on the monitor to the local printer
		Send RDSR file (detailing the irradiated dose given to the patient) to the storage device
		This displays the RDSR file detailing the irradiated dose given to the patient
		Send images in **DICOM for Processing format** to USB device (radiography images only).

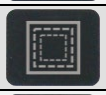
IMAGE OVERLAY		This lets you enable the TEXT function. (*see Chapter: "Operation", Paragraph 5.3.8 of this Manual*)
		This lets you enable the MEASUREMENT and GRAPHIC OBJECTS functions. (*see Chapter: "Operation", Paragraph 5.3.9 of this Manual*)

TOOLS		To activate the DSA functions. (*see Chapter: "Operation", Paragraph 5.4 of this Manual*)

IMAGE OVERVIEW		Use this to open the **IMAGE OVERVIEW** menu that lets you alter how the study images are viewed. This menu has the following options:
		Show single image
		Show multiple images

EXIT		Use this to quit the Study List

4.4.3 INFRARED REMOTE CONTROL

A	LED indicating that the infrared remote control is in use
	Image subtraction ON/OFF
	Mask pick-up
	Flag image
	Enable / Disable smart recursive filter (MOTION DETECTION)
	Select Flat Panel detector acquisition field
	Transfer saved image from M.M. to L.M.
	Save single live fluoroscopy image to hard disk
	Save all subsequent fluoroscopy images in current study to hard disk.
	Decrease / Increase fluoroscopy rate
	Find multiframe run of images within the study
	Find images within a run

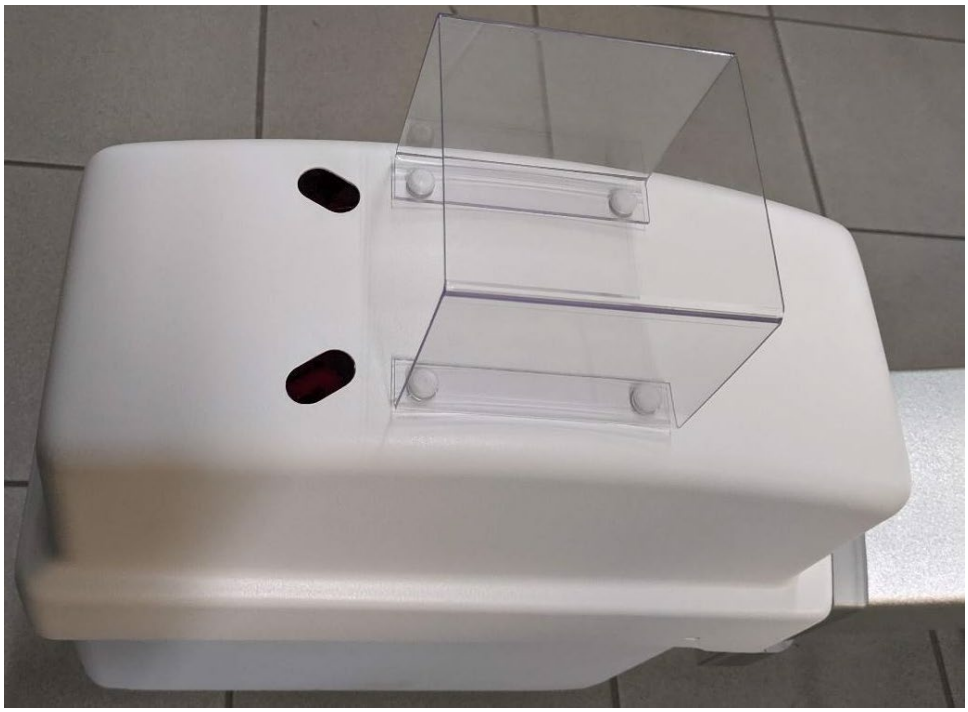
4.5 SPACER

The minimum source-skin distance is 22 cm.

In some countries, the minimum space required is 30 cm.

For those countries where it is applicable, the appropriate spacer is provided by the manufacturer with the system.

In figure below, the monoblock cover provided with the 8 cm spacer.



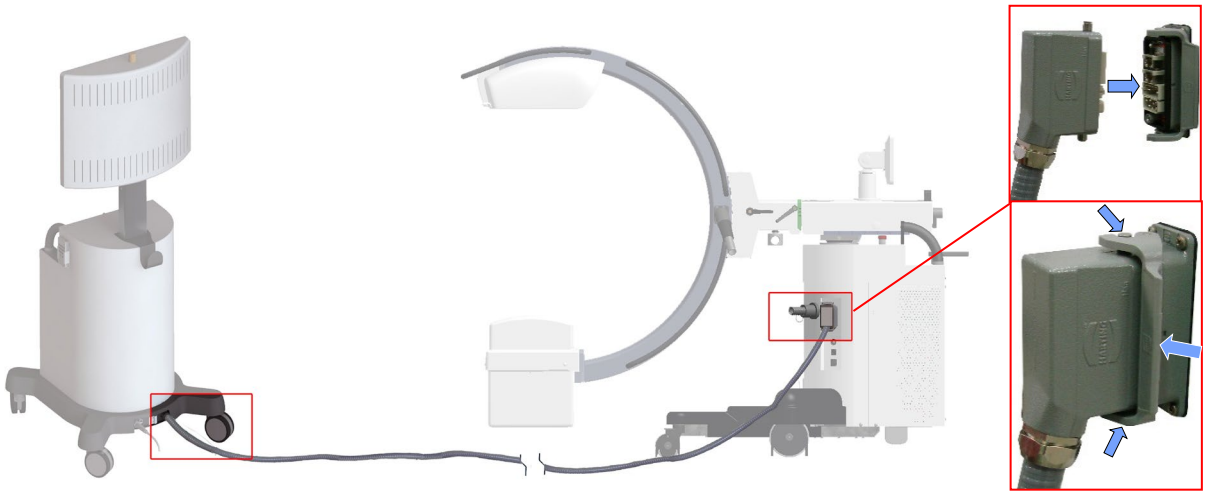
5 OPERATION

5.1 INSTRUCTIONS AT START AND END OF USE

5.1.1 SWITCHING-ON

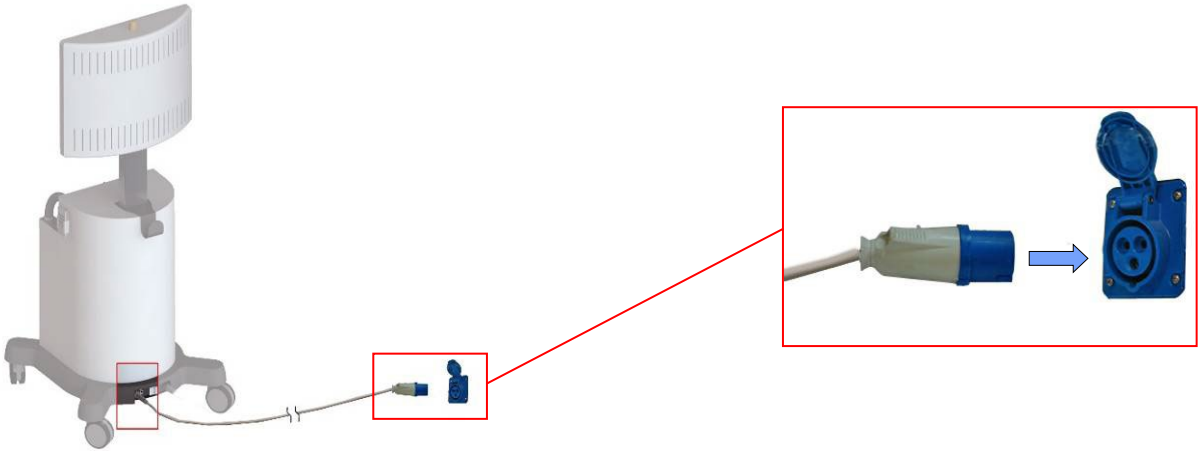
1. Connect the stand to the monitor unit:

- Insert the connector.
- Secure by turning the clip (make sure this is clipped in correctly way, as shown).

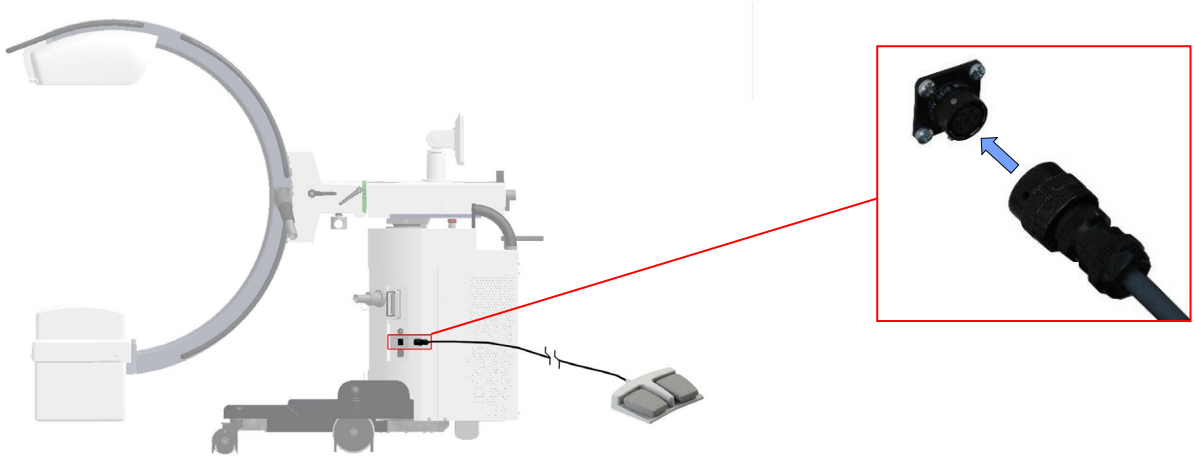


2. Connect the monitor unit to the mains.

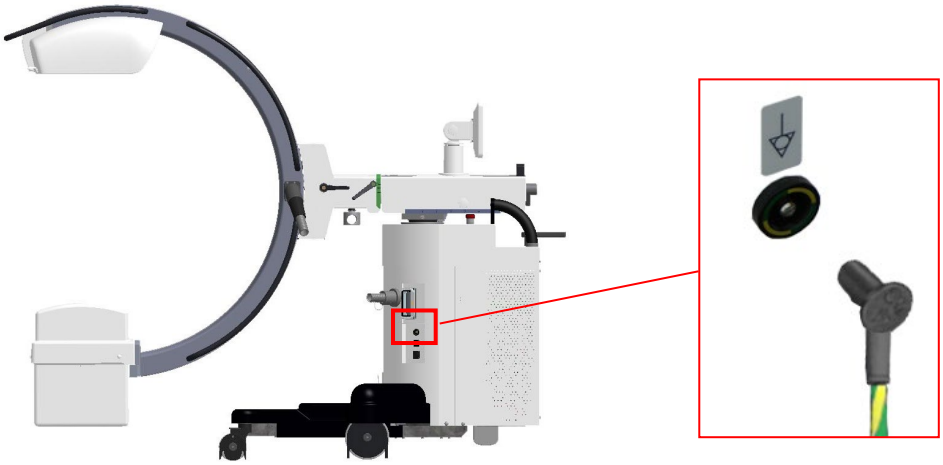
Attention: *Use only earthed-approved sockets, in compliance with EM equipement supply (120 VAC or 230 VAC). The resistance in the socket outlet must conform to supply specifications reported in Chapter: "Technical Data", Paragraph 9.2.1 of this Manual.*



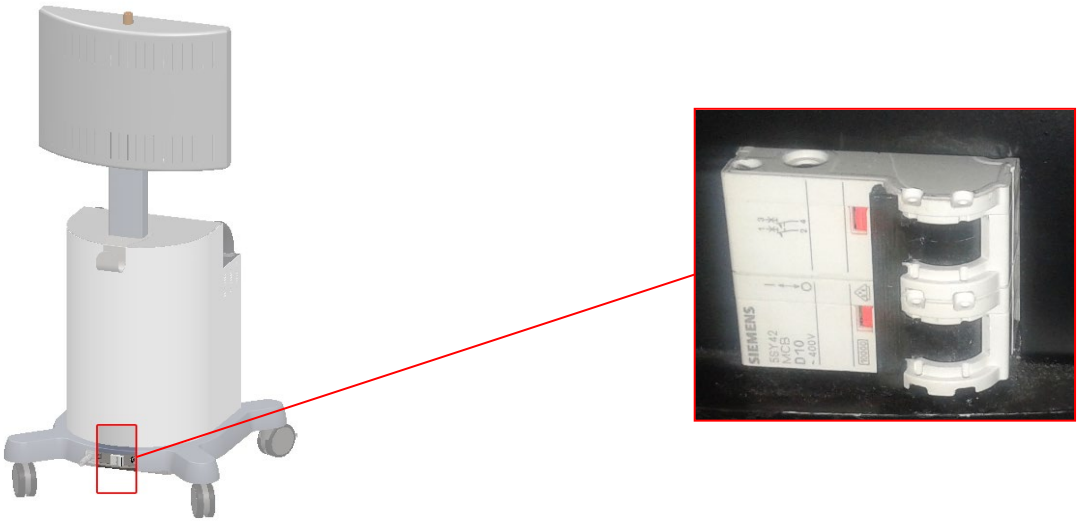
3. Connect the X-ray command footswitch:



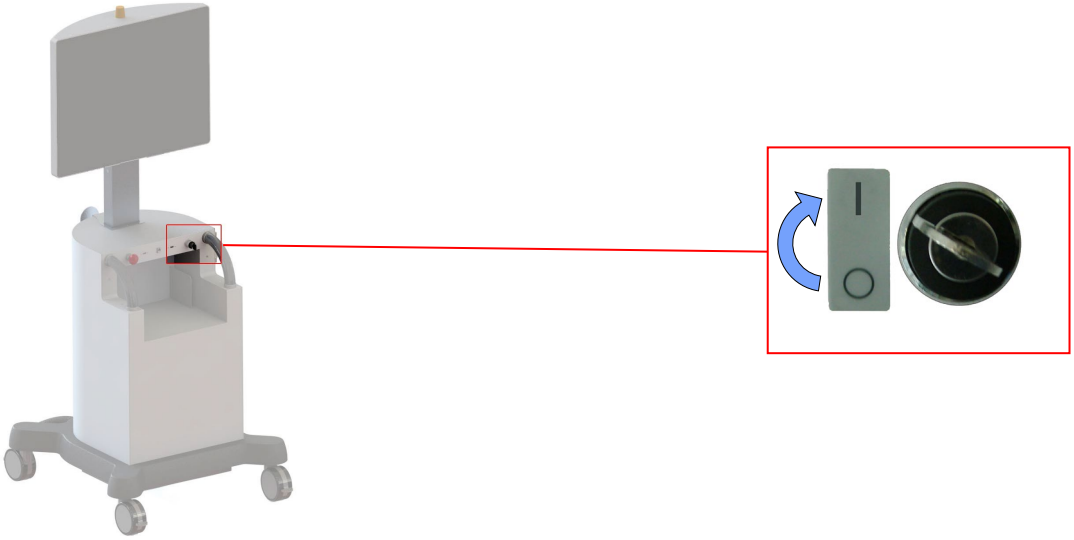
4. Connect the patient bed (not supplied with the EM equipment) to the equipotential earth connector on the stand:



5. Switch the magneto-thermal trip-switch found at the rear of the monitor unit **ON** (**I**).

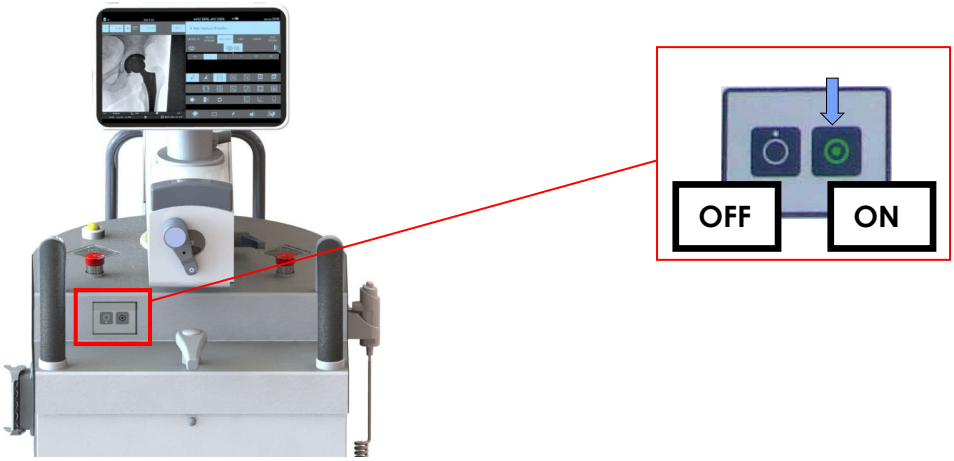


6. Switch the monitor unit key switch **ON** (**I**). The equipment turns on.



It activates the equipment initialitation phases, shown on Control Panel and on stand monitors.

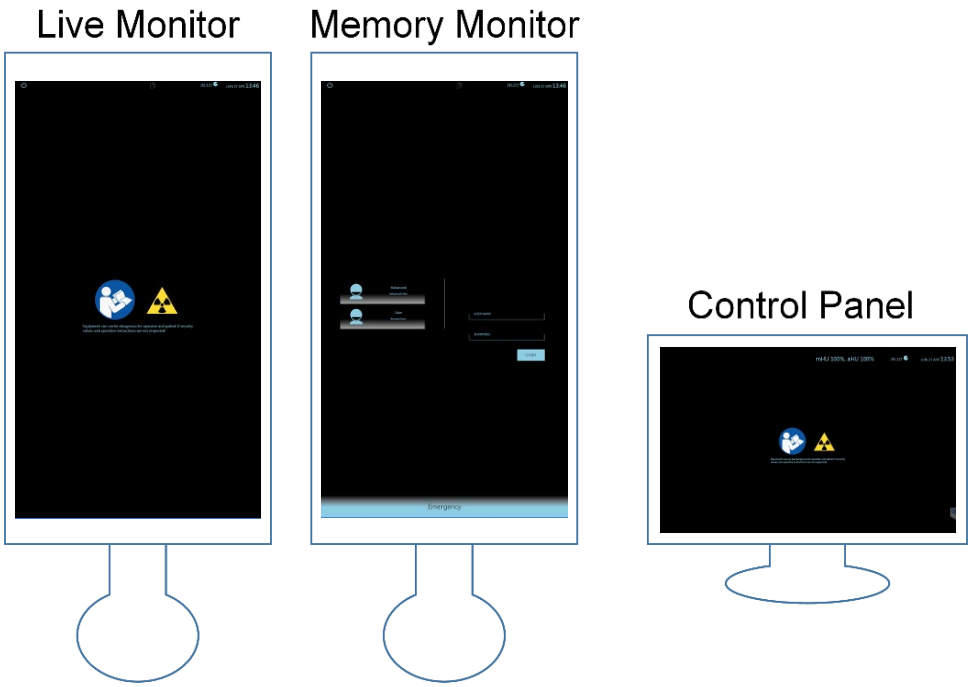
7. Switch the equipment on by pressing the ON button: the equipment is initialised, as shown on both the control panel and the monitors.



Note: *In case you are required to reboot the equipment, turn it off and wait at least 10 seconds before to switch it on again.*

5.1.1.1 LOGIN

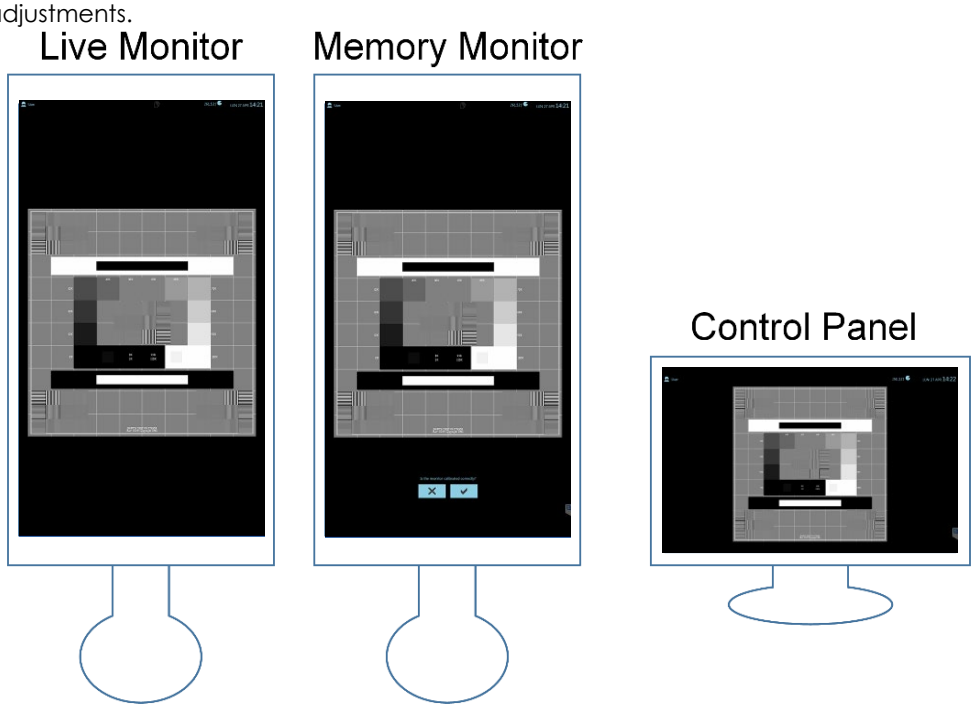
Once initialised, the EM equipment asks you to login (on the Memory Monitor).



Note: *a detailed login procedure description can be found in Chapter: "Operation", Paragraph 5.2.*

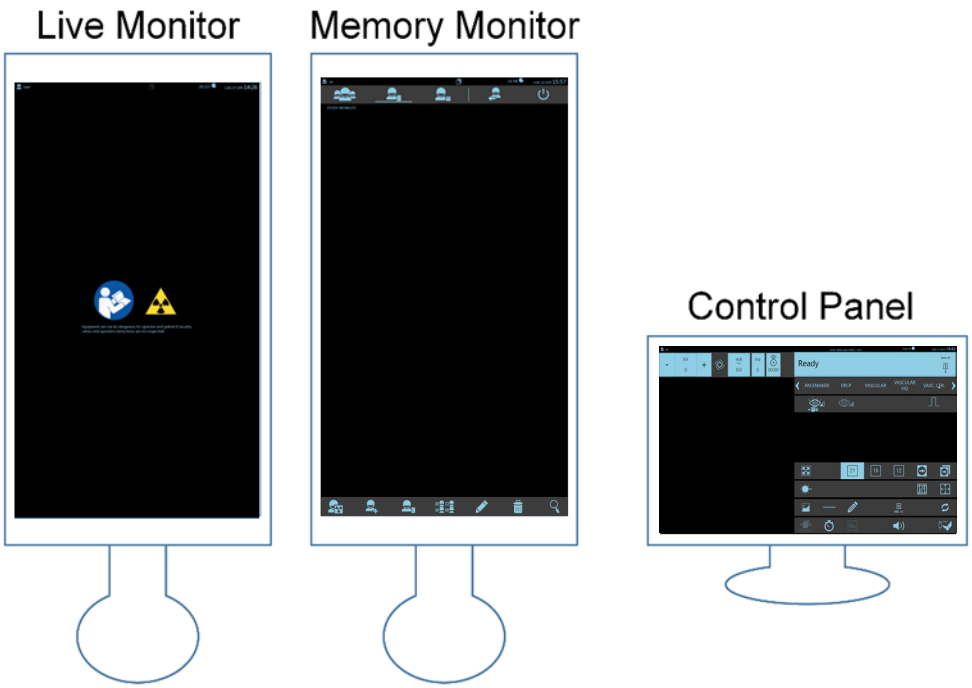
5.1.1.2 CHECKING THE MONITOR ADJUSTMENTS

After logging in as the operator (by entering the user name and password provided by the equipment manager), all the monitors display a test pattern that lets you check their correct brightness and contrast adjustments.



Note: *for detailed operation information, please refer to in Chapter: "Operation", Paragraph 5.2.*

After confirming the monitor settings, the Memory Monitor displays a list of all the studies stored in the archive:



5.1.1.3 MAINS FAILURE

The equipment automatically shuts down in the event of an interruption to its power supply (even if transitory).

When the power returns, the equipment will automatically turn on (if the key switch on the stand is still turned ON).

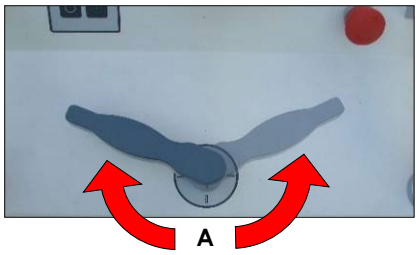
Note: *If this interruption happens during an acquisition, related images will not be shown within the study you were performing, but they have been saved on hard disk, anyway. To restore these images, it is required the Technical Service intervention. Dose data related to these images, instead, are not recoverable.*
If the interruption happens while sending images through DICOM network, when the equipment turns on, it will be possible to restart the procedure directly from the spooler.

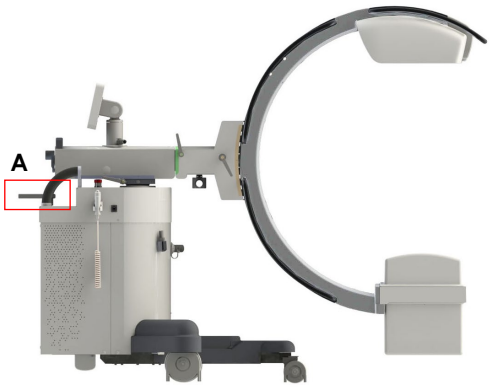
5.1.2 POSITIONING

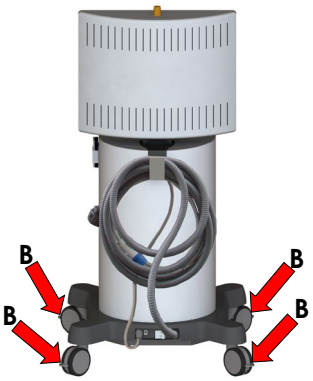
Never attempt to move the equipment when the brakes are on. Always use the handles provided to move the equipment.

After switching the EM equipment on and moving it to its final position:

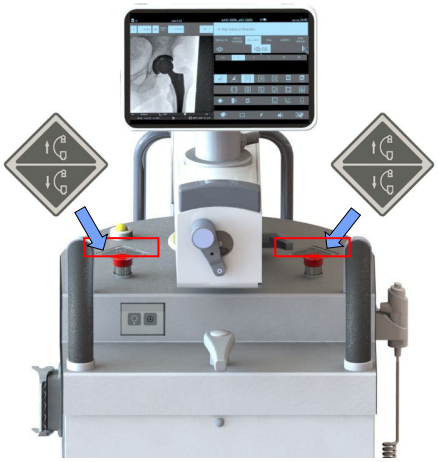
1. Engage the parking brakes on the stand (**A**) and on the monitor unit (**B**) (see figure).

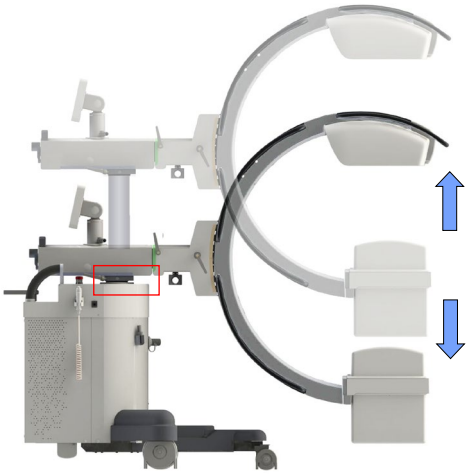






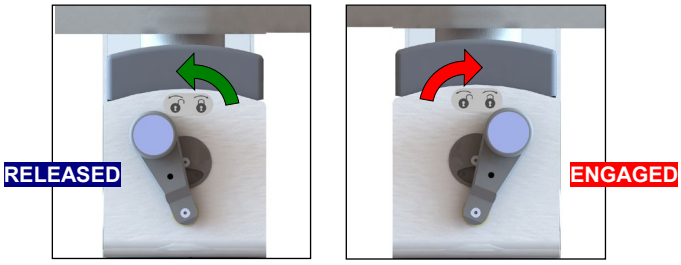
2. Adjust the **height** of the C-arm using the keys on the stand as shown in the figure below.
This operation is only possible when the equipment is switched on.

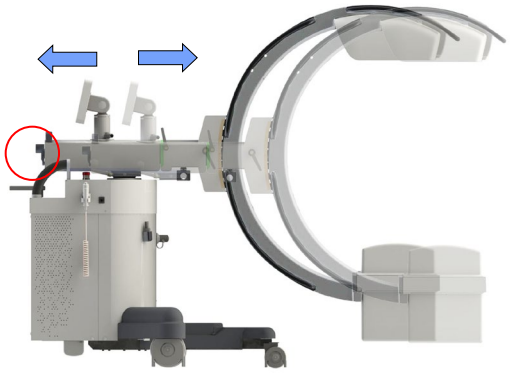




Warning: *Before using the C-arm up and down movement, be sure that it cannot collide with people or objects.*

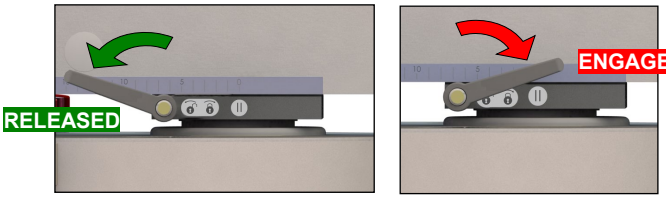
3. Adjust the **longitudinal** movement with the handle shown.
   Brake shown in purple.

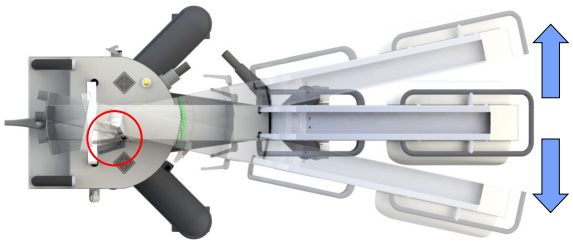




Warning: *Before moving the C-arm, be sure that it cannot collide with people or objects.*

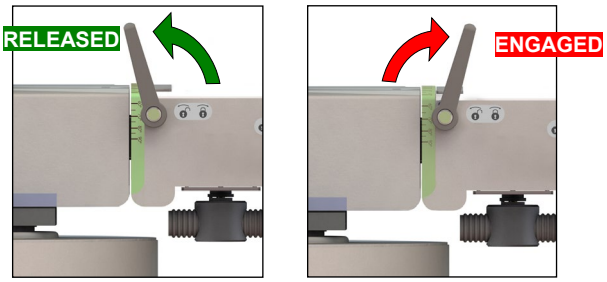
4. Adjust the **wig-wag** of the C-arm.
   Brake shown in yellow.

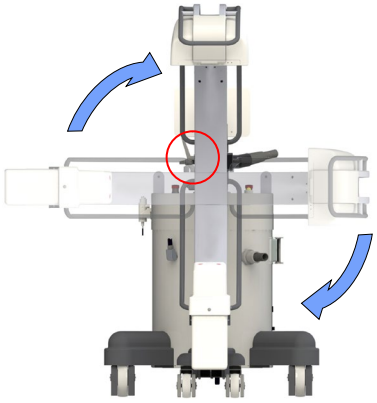




Warning: *Before swiveling the C-arm, be sure that it cannot collide with people or objects.*

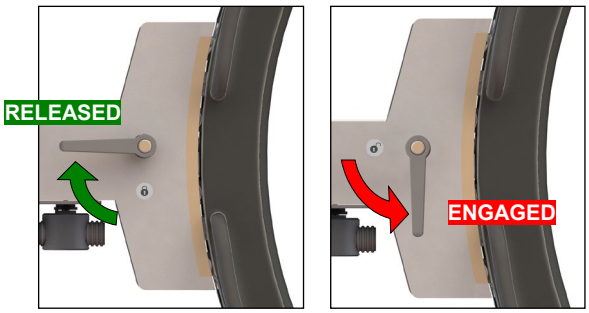
5. Adjust the **rotation** of the C-arm (the goniometer scale indicates the angle of rotation).
   Brake shown in green.

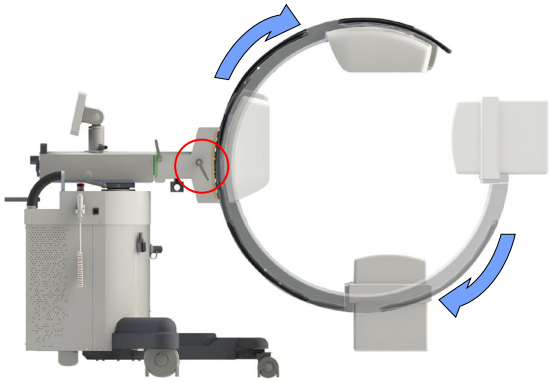




Warning: *Before rotating the C-arm, be sure that it cannot collide with people or objects.*

6. Adjust the **angle (orbiting)** of the C-arm.
   Brake shown in pink.

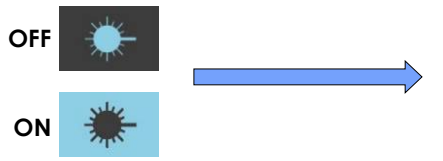




Warning: *Before sliding the C-arm, be sure that it cannot collide with people or objects.*

The scale on the inside of the C-arm indicates the angle of rotation with respect to the vertical position (0°).

7. You can now enable the laser localiser (*optional*) by pressing the corresponding key on the stand control panel (the laser beams will remain lit for one minute or until you press the key again).

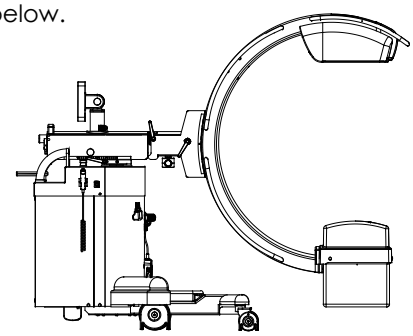


All brakes must be engaged after positioning.

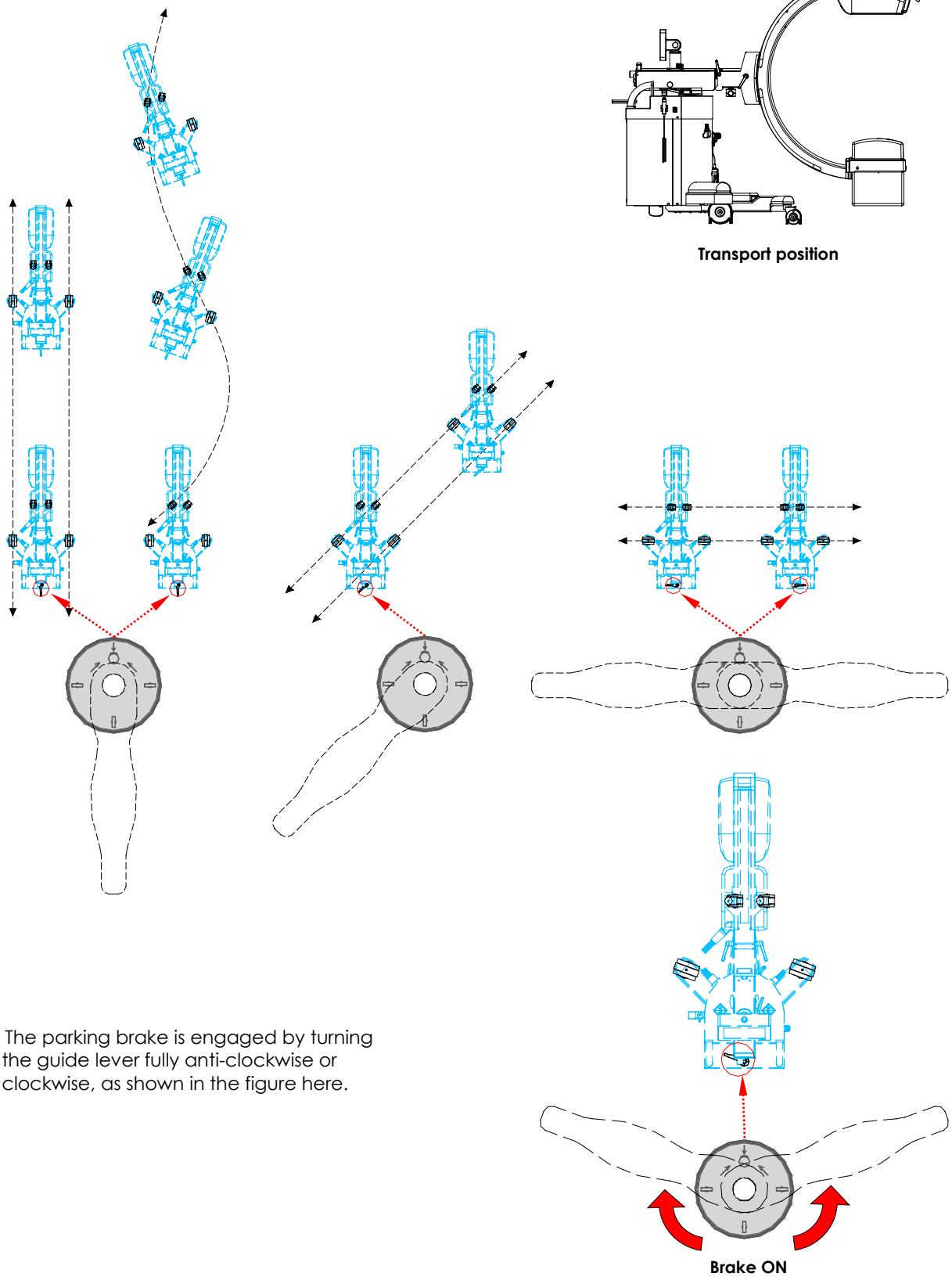
5.1.3 STEERING THE STAND

Warning: *Before moving the C-arm, be sure that it cannot collide with people or objects.*

The stand is fitted with guided rear wheels and free wheels at the front.
The rear wheels are steered by the guide lever shown in the figure below.



Transport position



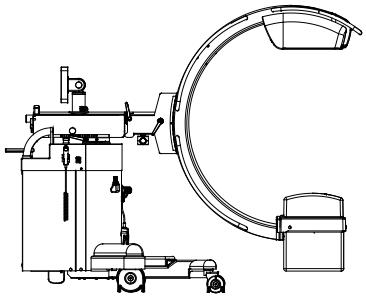
- The parking brake is engaged by turning the guide lever fully anti-clockwise or clockwise, as shown in the figure here.

Brake ON

5.1.4 INSERT/ REMOVE THE ANTI-SCATTERING GRID

Before inserting/extracting the anti-scattering grid into/from the dedicated drawer, you need to take the stand to its **transport position**, as indicated in Fig.1 *(see also paragraph 5.1.6.2 below)*.

Warning: Do not insert/extract the anti-scattering grid when the stand is in any position other than the transport position, as the grid could fall and be damaged.



Transport Position Fig.1

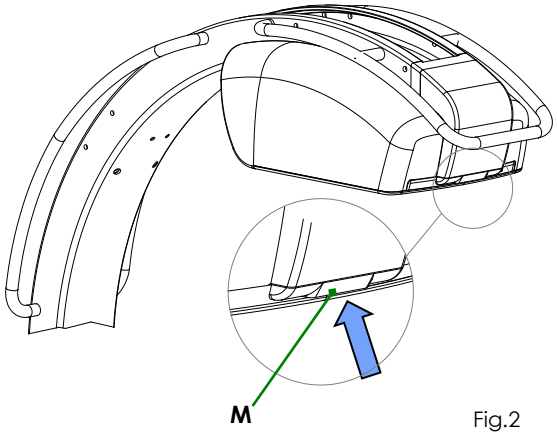


Fig.2

- Grab the handle (**M**) as indicated by the arrow in Fig.2

- Open the drawer containing the grid (**A**) as indicated in Fig. 3
- Unlock the grid, springing the clip (**B**) as shown in fig. 3

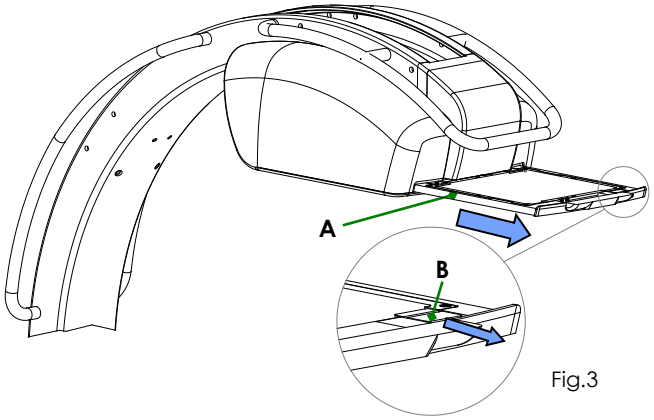


Fig.3

- **Extract the grid** (**G**): place the grid in its compartment on the monitor trolley.
- **Insert the grid** (**G**): there are some "*keys*" in the frame of the grid support and drawer that ensure the grid can only be inserted in the correct direction (see Fig. 4).
- Close the drawer (**A**).

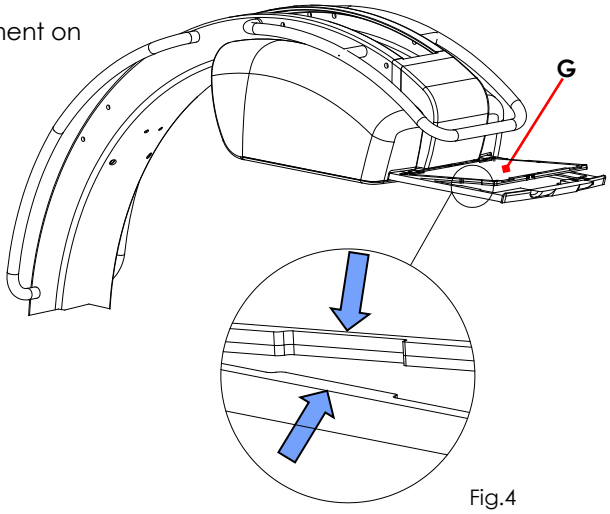


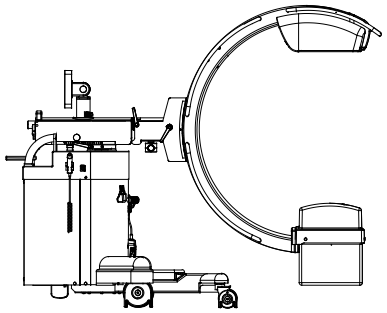
Fig.4

Note: *it is responsibility of the physician to decide if use or not the grid.*

5.1.5 END OF USE

Switch the equipment off at the end of a session as follows:

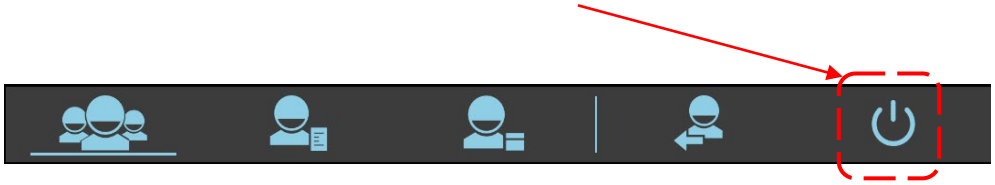
- Take the stand to its parking position *(see paragraph 5.1.6 below)*.



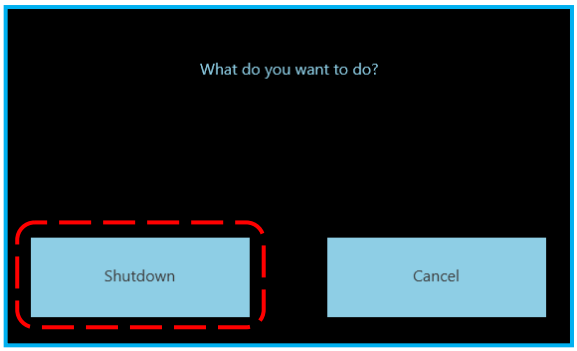
Transport position

- Close the current study and return to the Study List (on the Memory Monitor) by pressing this key:

- Press the **Shutdown** key in the Study List:



- Select the **Turn off** command:



- Wait for the monitor to turn itself off**: the screen should be black and the power LED, on the bottom, should turn from green to orange**.

Problems can arise in the PC operating system if you switch the monitor unit off before the Shutdown procedure has been completed.
It is therefore important that you follow the above procedure to switch the PC off.

- Then switch the system off by turning the key to "OFF" (0).

- Disconnect the cable between the stand and the monitor unit, and then wind it around its supports.

Never disconnect the stand/monitor unit cable before the stand has been switched off.

- Unplug the power cable and then wind it around its supports on the monitor unit.

Never unplug the cable before the monitor unit has been switched off.

- Park the monitor unit by engaging the brakes on the front and/or rear wheels *(see paragraph 5.1.6 below)*.

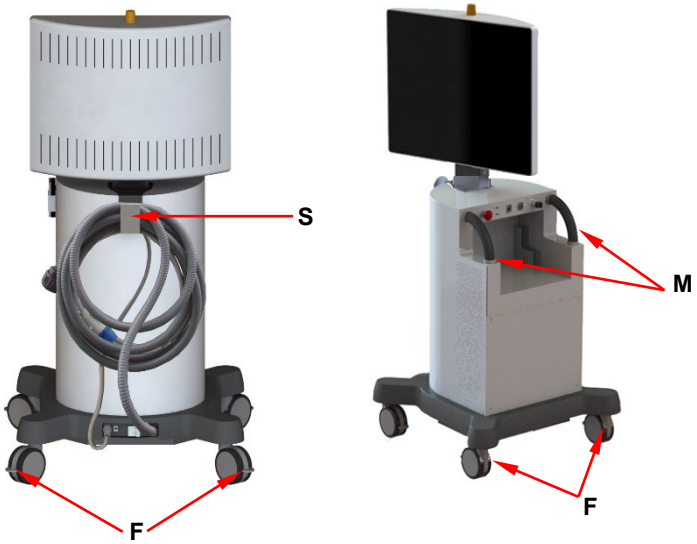
5.1.6 PARKING AND MOVING

To improve parking and moving safety, we recommend to read carefully *Chapter: "Safety", Paragraph 2.3 ("Residual Risks")*.

Warning: *Before moving the C-arm, be sure that it cannot collide with people or objects.*

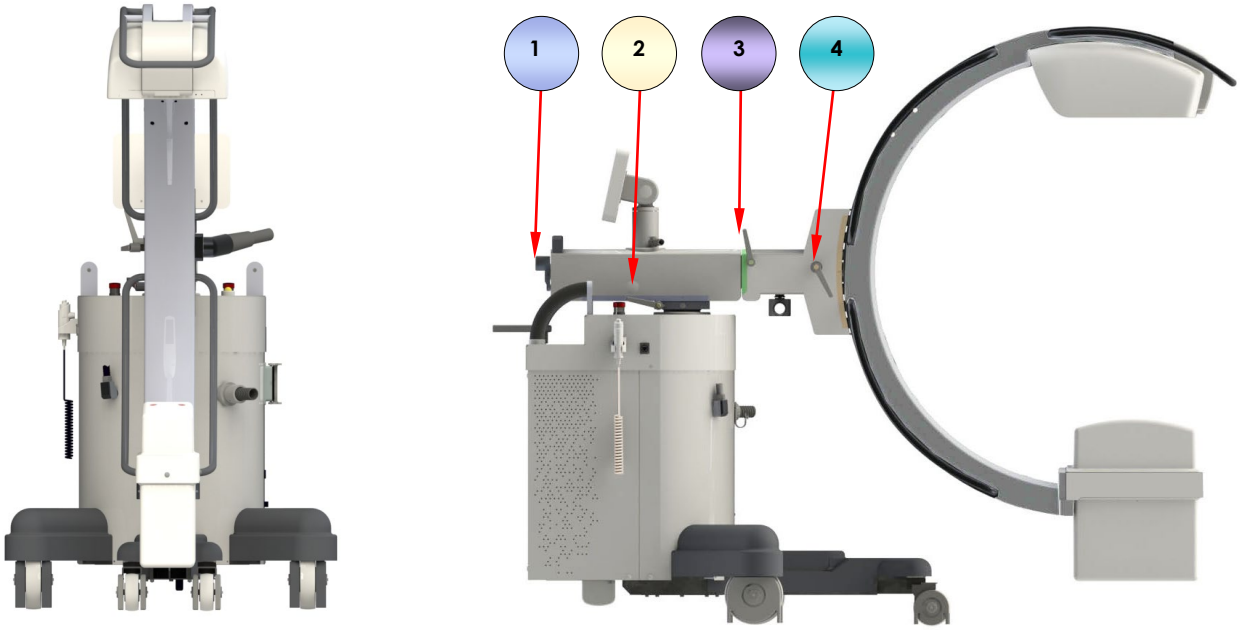
5.1.6.1 MONITOR UNIT

The **parking and moving positions** are shown in figures below: the power cable and the stand/monitor unit cable must be disconnected and wound around the cable supports at the back (**S**) and the monitors oriented in the same movement direction, in order to ease the view during carriage.



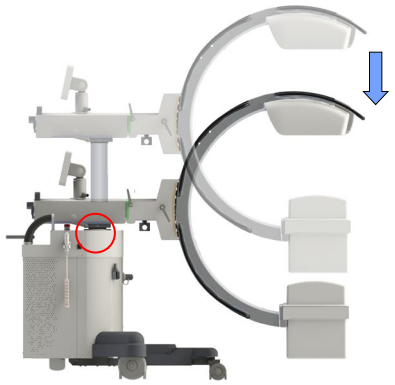
Only use the side handles (**M**) to **move** the equipment, after first releasing the parking brakes on the front and rear wheels (**F**).
Note*: We recommend lowering the monitors to make it easier to see where you are going.*

5.1.6.2 STAND

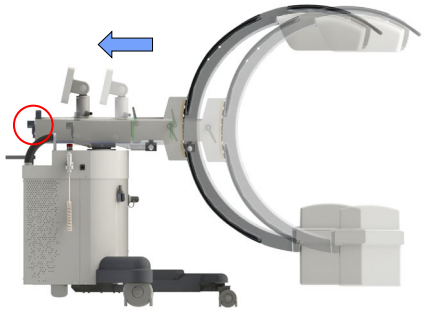


The **parking and transport positions** must be those shown in the figures on the next page.

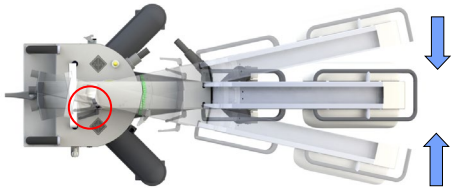
Note: *see paragraph 5.1.2 above on how to use the brakes.*



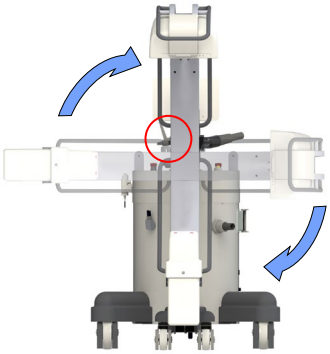
- C-arm fully lowered



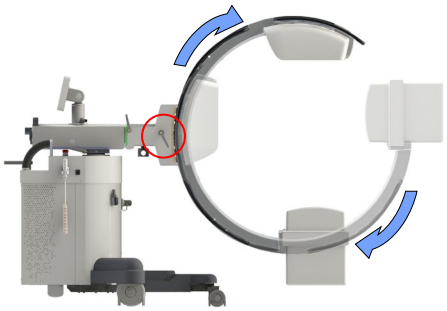
- Horizontal trolley fully retracted and locked in position by brake 1,



- Wig-wag at 0°, locked in position by brake 2,



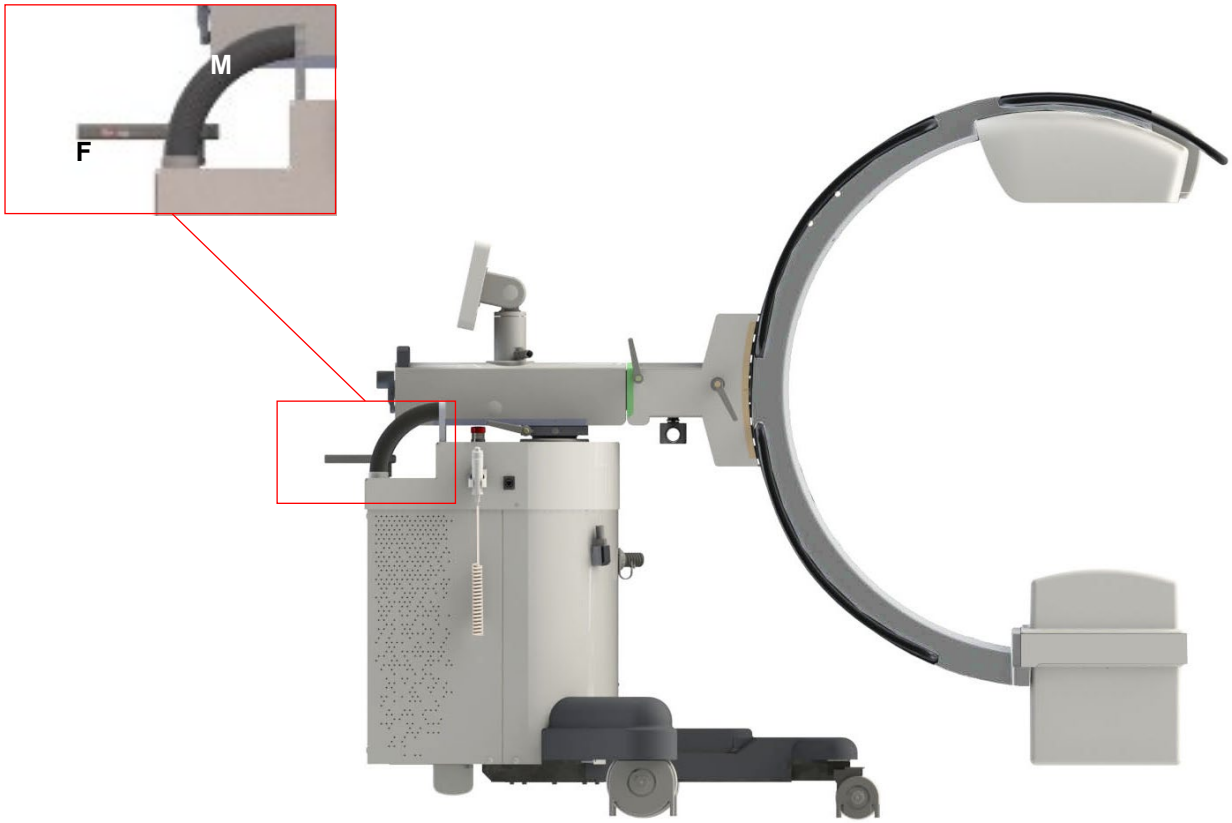
- C-arm rotated in the vertical position and locked in position by brake 3,



- Monoblock and detector sitting in a vertical position and locked by **brake 4**,

To **move**, release the parking brake (F) and use only the handles (M).
If necessary, turn the rear wheels using the steering lever (F).

Note: *See also paragraph. 5.1.3: "Steering the stand" above.*



5.2 INSTRUCTIONS FOR USE

5.2.1 OPERATOR AUTHENTICATION (LOGIN)

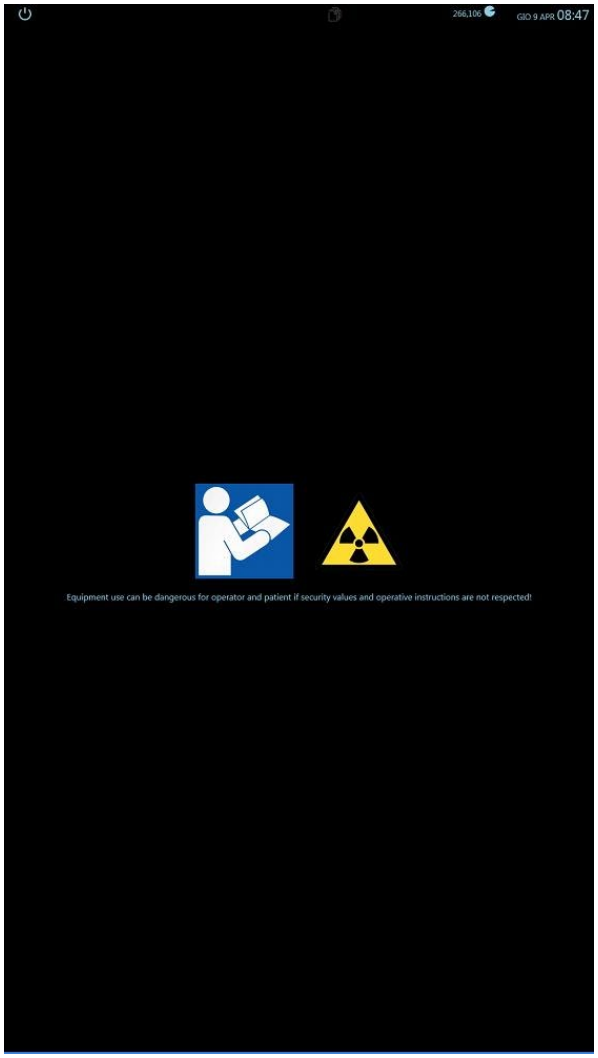
You need to log in by entering your username and password in order to start using the EM equipment.
There is no limit to the number of users who can register and log in.

There are three user levels, each being able to access different functions:

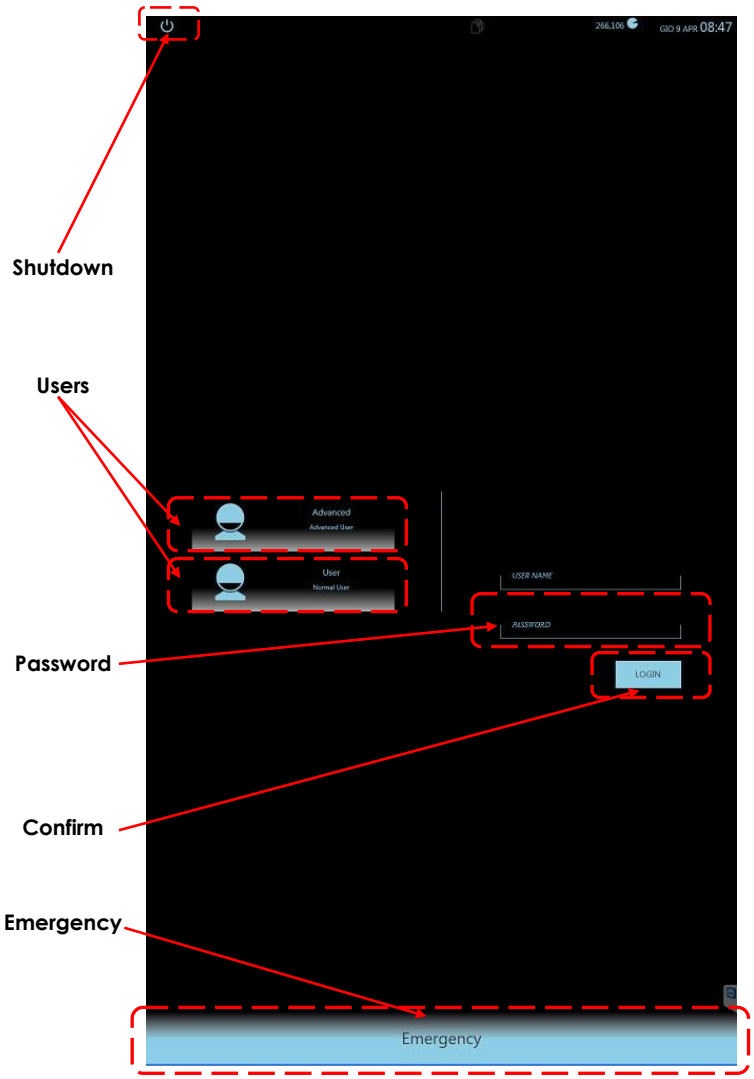
- *BASE* — *a normal user of the equipment,*
- *ADVANCED* — *the person responsible for the equipment,*
- *ADMINISTRATOR* — *the technician responsible for installing and servicing the equipment.*

The following windows appear after switching the EM equipment on:

LIVE IMAGE MONITOR (L.M.)



MEMORY MONITOR (M.M.)



Log In via the touch screen on the M.M. (the monitor on the right).
Select your username from those in the list and then enter the password in the box provided.
Confirm by pressing the LOGIN key.

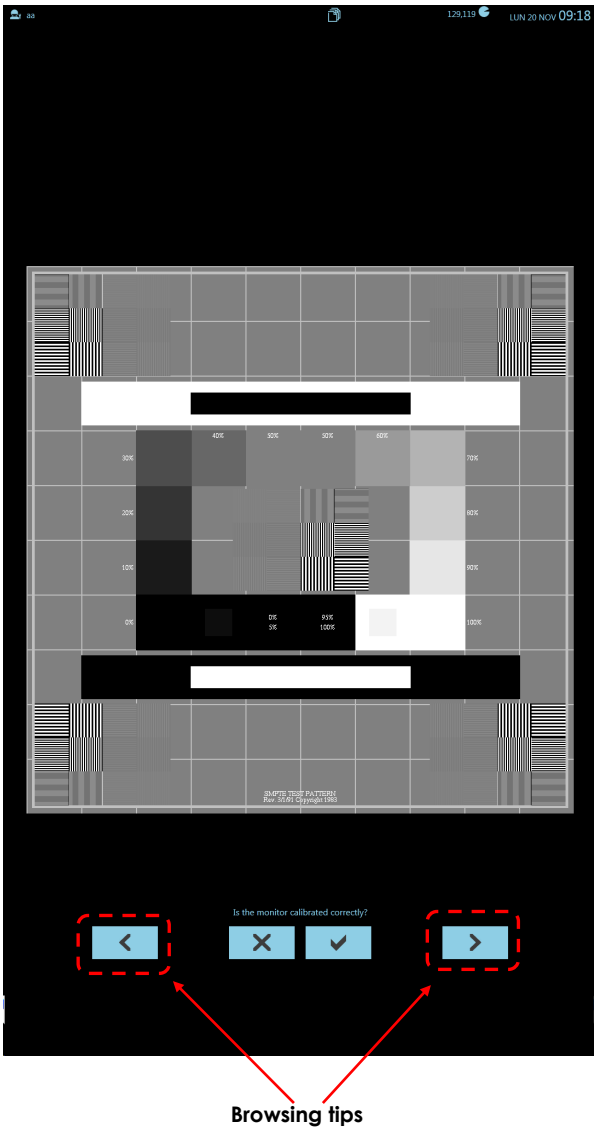
If a badge has been assigned to an user, he will be able to log in by simply approaching his badge to the reader (for setup of this function, *see paragraph 3.1.6* **User Account Setup** *of this Manual)*.

Note: *In an emergency, when you need to log in as quickly as possible, you can touch the EMERGENCY key to start using the equipment; there is no need to enter your username or password. On using the EMERGENCY option, you immediately access the working frame, without having to enter the patient data first. You can enter the relevant data at a later date, after logging in as normal.*

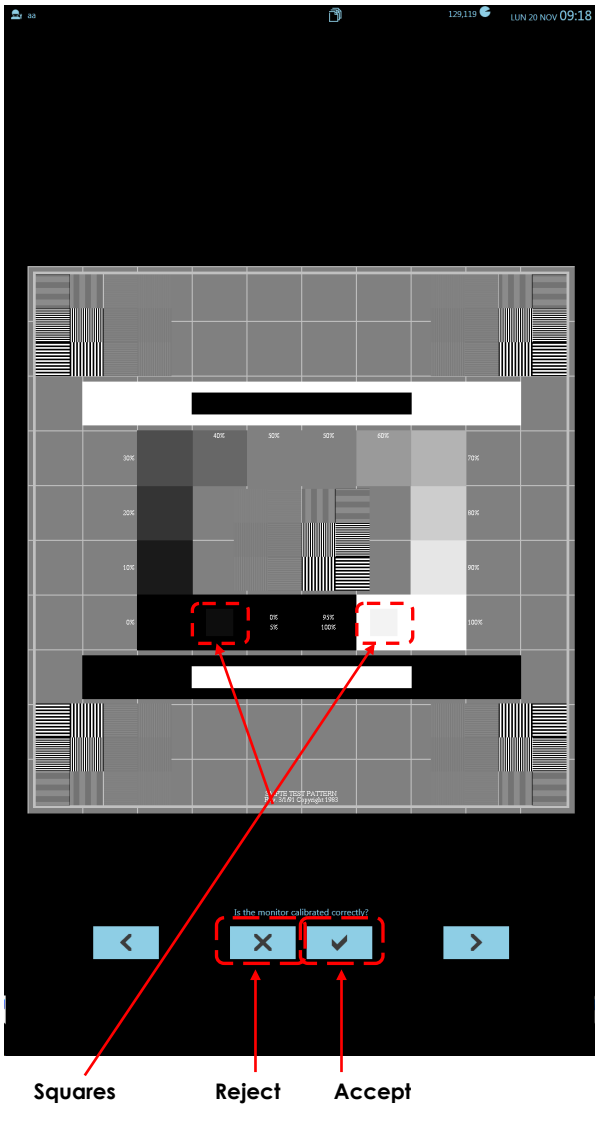
WARNING: *In EMERGENCY mode, the modality Digital Radiography is not available.*

After logging in, both the monitors display the Test Pattern so you can check the grey scale correct representation.

L.M.



M.M.



You need to check that the Test Pattern here is displayed correctly; if necessary, adjust the brightness of the monitors.More specifically, it must be possible to see:

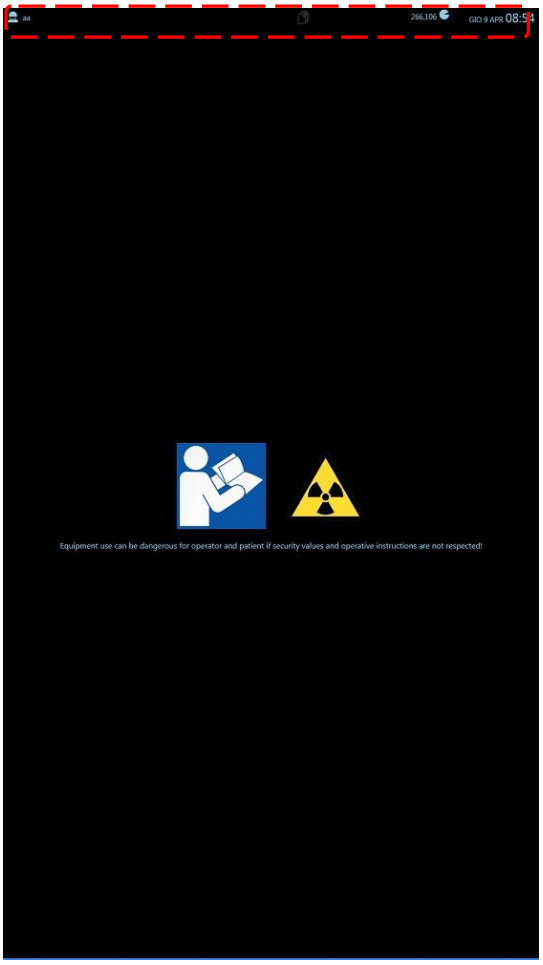
- the full grey scale (boxes from 0% to 100%),
- the grey square in the black box (0%),
- the grey square in the white box (100%).

It is possible to check the correctness of calibration on other images, too. Browse through the images with the relevant tips, checking the points above are satisfied. Press "Accept" if the Test Pattern is displayed correctly.

Note: *Monitors are provided correctly calibrated by the Manufacturer, already set with DICOM curve. In case the Test Pattern is not correctly visible, see Paragraph 2.5 in Part 4 of the Technical manual.*

The following screens now appear on the monitors:

L.M.



1. Status bar
2. Lists
3. Study List
4. Command icons

Attention: *While using the EM equipment,* ***DO NOT*** *touch two or more of the touch screen monitors* ***(LM, MM, CP)*** *contemporarily.*

Note: *as a security feature, it is possible to enable the automatic log-off after an inactivity period (to be set into* ***Security Setup****: see Paragraph 4.10, Part 2 of the Technical Manual).*

5.2.2 OPENING A STUDY

STUDY LIST FRAME

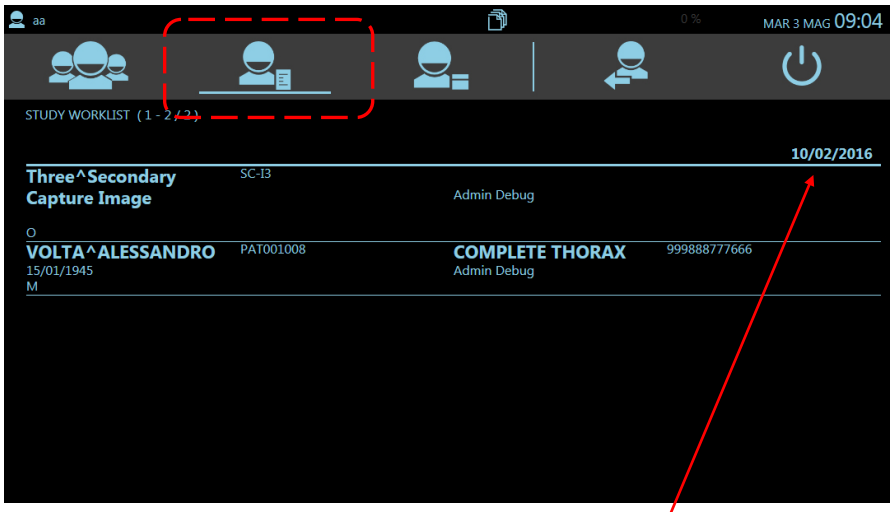
The Study List frame is split into 3 zones:

- List of studies to be performed (STUDY WORKLIST) – *see paragraph 5.2.2.1*
- List of studies already performed (STUDY LIST) – *see paragraph 5.2.2.2*
- List of query/retrieve studies (QUERY/RETRIEVE LIST) – *see paragraph 5.2.2.3*

5.2.2.1 STUDY WORKLIST (OPTIONAL)

Press the button indicated to open the Study Worklist:

M.M.



Each study can be identified using the following fields:

- Patient data: First name and Surname, Date of birth, Gender
- Patient ID
- Type of study required
- Name of operator responsible for study
- Accession Number

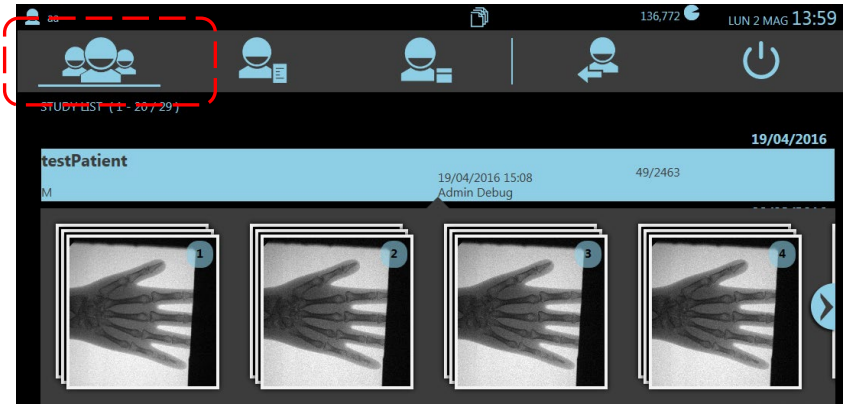
The studies are listed and grouped by their **creation date**. Groups are indicated by bold lines.

Touch the study you want to open twice in rapid succession ('tap').

5.2.2.2 STUDY LIST

Touch the indicated key in the working frame to access the Study List:

M.M.



Tap the study once to get a preview of the stored images.

Tap the study twice to open it and use the working frame commands.

5.2.2.3 QUERY/RETRIEVE LIST (OPTIONAL)

Select the pointed-out icon below to access the DICOM QUERY RETRIEVE function.

M.M.

For a description of the DICOM QUERY RETRIEVE function, see *the Paragraph 5.5.7 below*.

5.2.3 ONLINE MANUALS

You can recall the manuals for the equipment from the Study List frame (PDF format):

Touch **USER**, to open the **MENU** to:

M.M.

1 2 3

1) Access the setup menu (ADMINISTRATOR / ADVANCED users only)

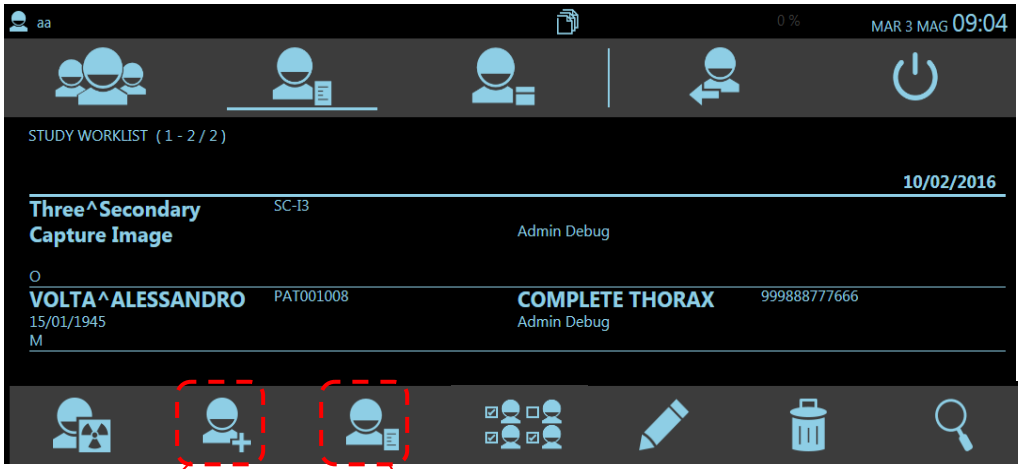
2) Open the **User Manual**

3) Open the **Technical Manual**

5.2.4 CREATING A NEW STUDY

There are two ways to open a new study from the **Study Worklist** frame:

M.M.



manually, by entering the data using the touch screen keyboard;

or **automatically**, using the data received from the **DICOM WORKLIST.**

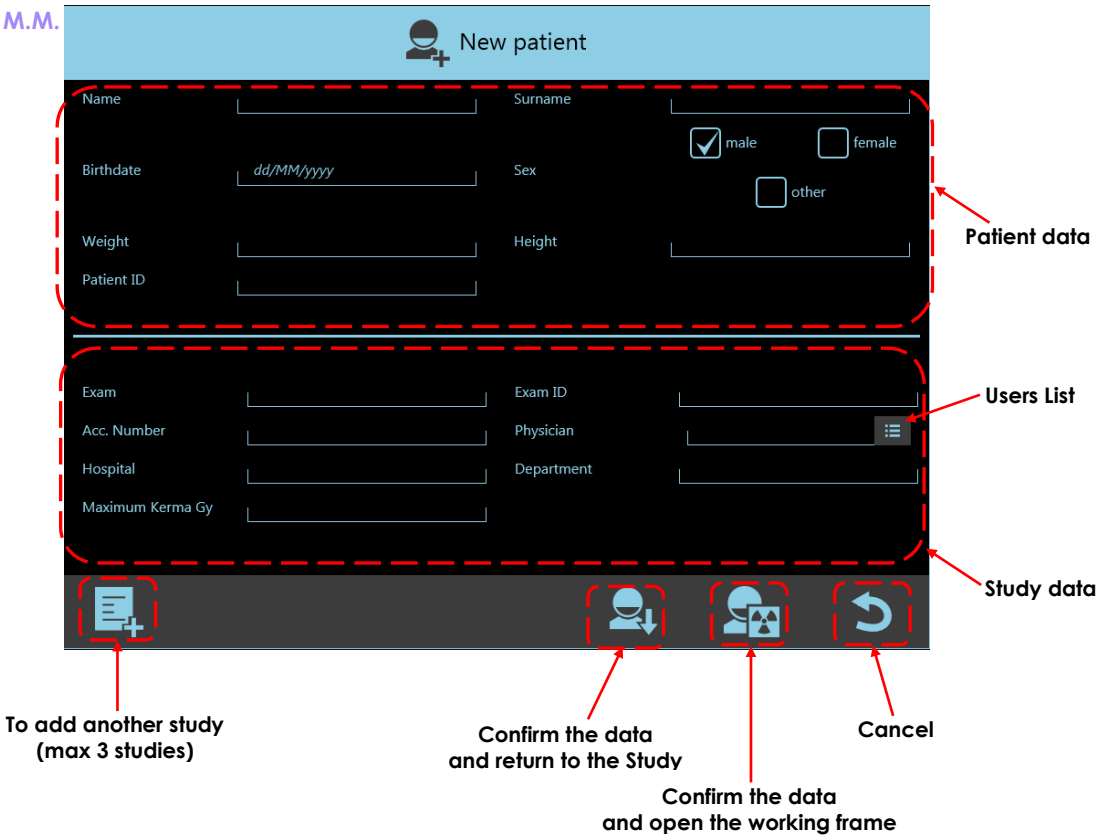
Touch key  to access the menu for manual entry of the study data and fill in the following fields:

Patient data:

- First name and Surname (mandatory)
- Unique ID code
- Date of birth
- Gender
- Weight
- Height

Exam data:

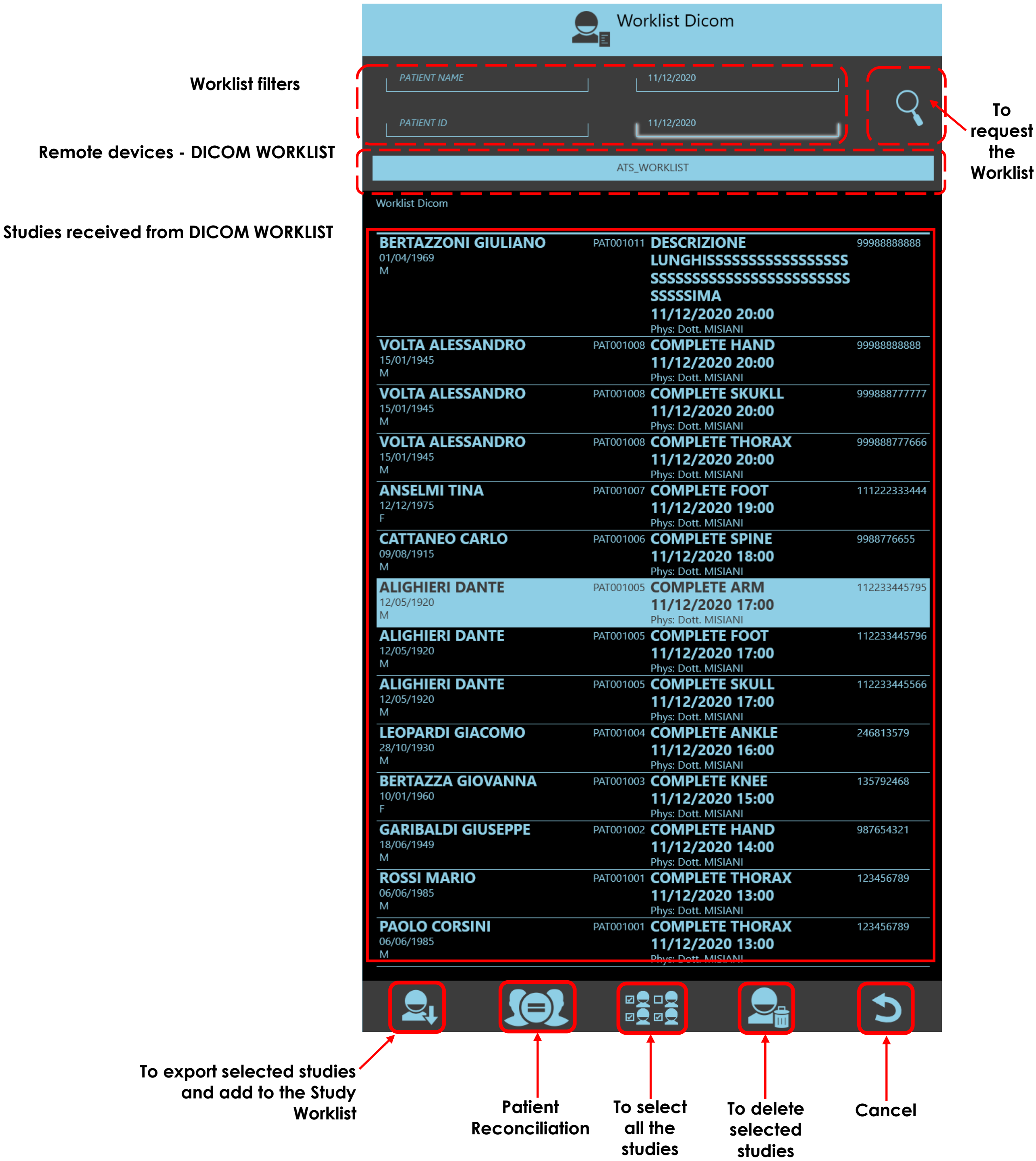
- Type of exam (mandatory field if you wish to create more than one study for the same patient)
- Exam ID code
- Accession Number
- Name of medical professional (it is possible to select within the user list, too)
- Name of hospital
- Name of department/ward
- Maximum Air Kerma (Gy): Set the maximum Air Kerma value (in Gy) for the study, beyond which the Control Panel will display the alarm message "POSSIBLE DETERMINISTIC EFFECTS".



You can enter up to 3 studies for the same patient. These will be treated as independent single studies. The first study is automatically opened when you access a patient directly from the working frame.

Attention: *before to save the just created study, the operator has to check the accuracy of the data entered and that the date the study is automatically saved with, it is today's date.*

Touch key  to import study data from DICOM WORKLIST.



- It is possible to import all the studies programmed for the C-arm, automatically (if the related option has been enabled in **Dicom setup**; *see Paragraph 4.5.2.3, Part 2 of the Technical Manual*).

Otherwise:

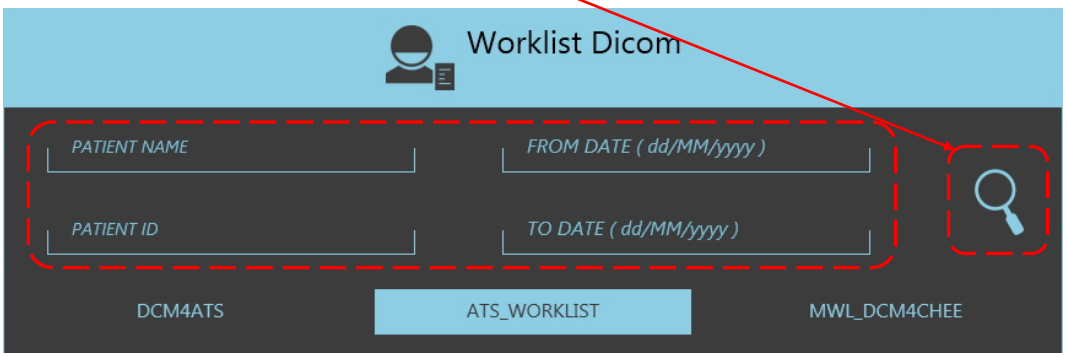
- Select the DICOM WORKLIST device from among those in the list in order to receive the studies;

- You may wish to use some search filters, such as:
  - the surname and/or name of your patient
  - patient ID code
  - accession number,
  - requested procedure ID code,
  - studies within a date interval

  If a PATIENT NAME search is unsuccessful, try again, this time adding an asterisk * before and after the search criteria (this inconvenience is due to the configuration of the WORKLIST server).

  Note: *it is possible to display the search fields* ***Accession Number*** *and* ***Requested Procedure ID*** *only if enabled during system configuration, in the* ***Dicom Setup*** *menu (see Paragraph 4.5.2.3, Section 2 of the Technical Manual).*

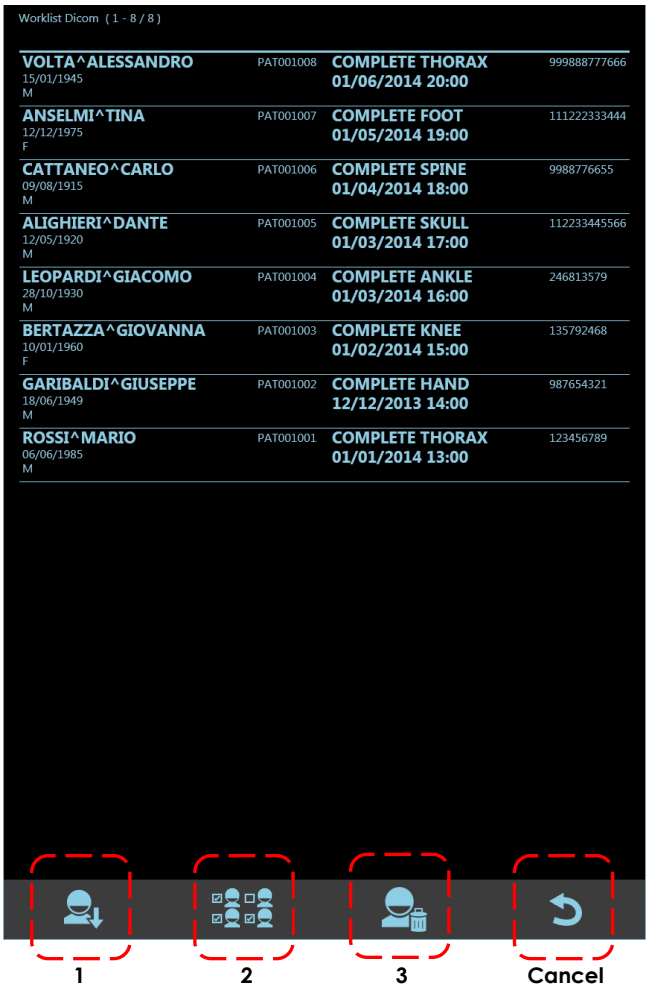
- Touch the **SEARCH** key to start searching.



- You can then **SELECT** single studies in the list by simply touching the patient name. You can also select all the studies by touching **KEY 2.**

- You can **EXPORT** one or more studies and add these to the Study Worklist by touching **KEY 1.**

- You can **DELETE** one or more selected studies by touching **KEY 3.**

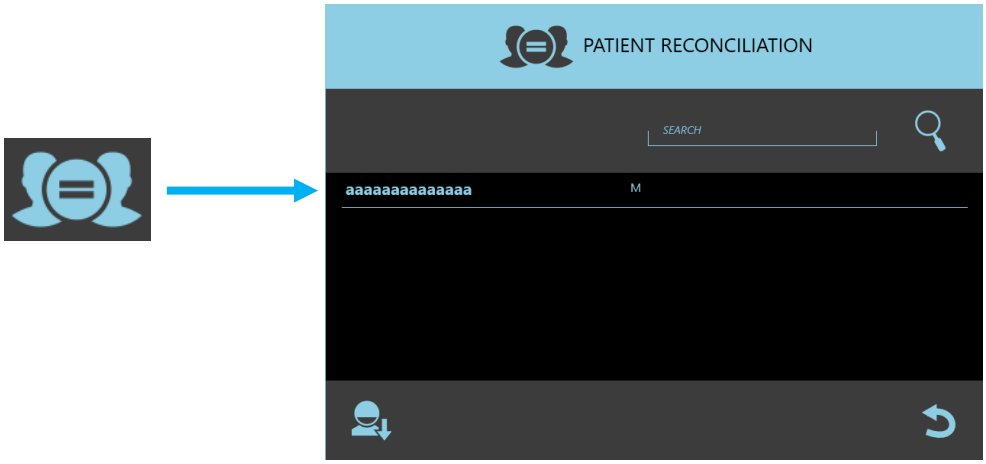


5.2.4.1 WORKLIST RECONCILIATION

The **Reconciliation** function allows to replace data of a study manually created, with data of a study selected from **Dicom Worklist**.

- First, the user selects a study from the Worklist (see previous Paragraph).

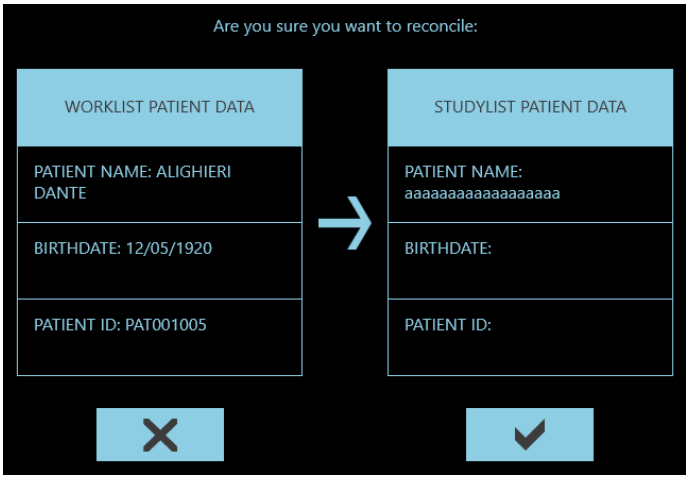
- Pressing the indicated key, a window containing the local Study List is shown. Studies previously imported from WorkList are **not** going to be shown.



- Select the needed study and **Confirm** with the indicated key.

Attention: make sure the correct studies have been selected. This operation is under the user responsibility, only.

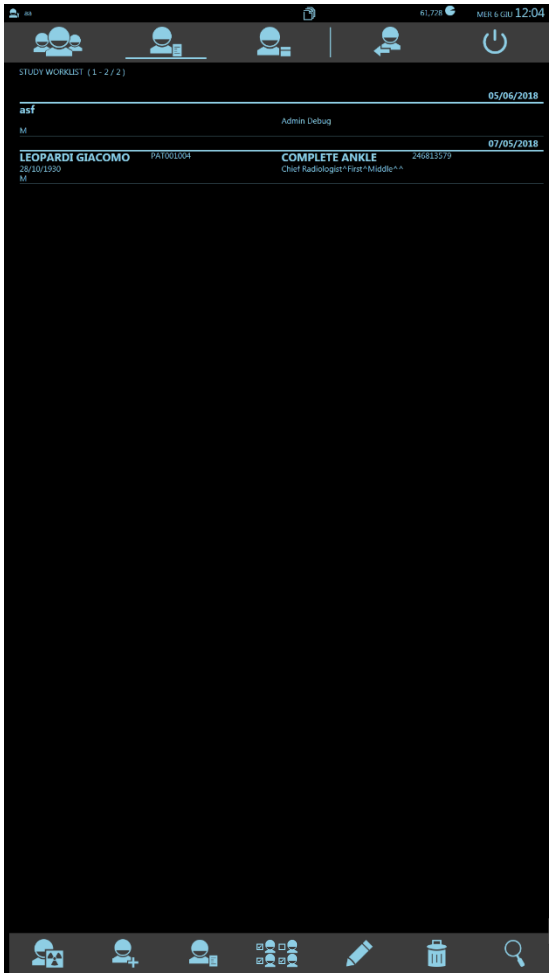
- A window appears to **Confirm** (or Cancel) the procedure of **Reconciliation**.



Check the correctness of the data to reconcile before to confirm.
All the related patient and study data will be overwritten with those of the study selected into Dicom Worklist.

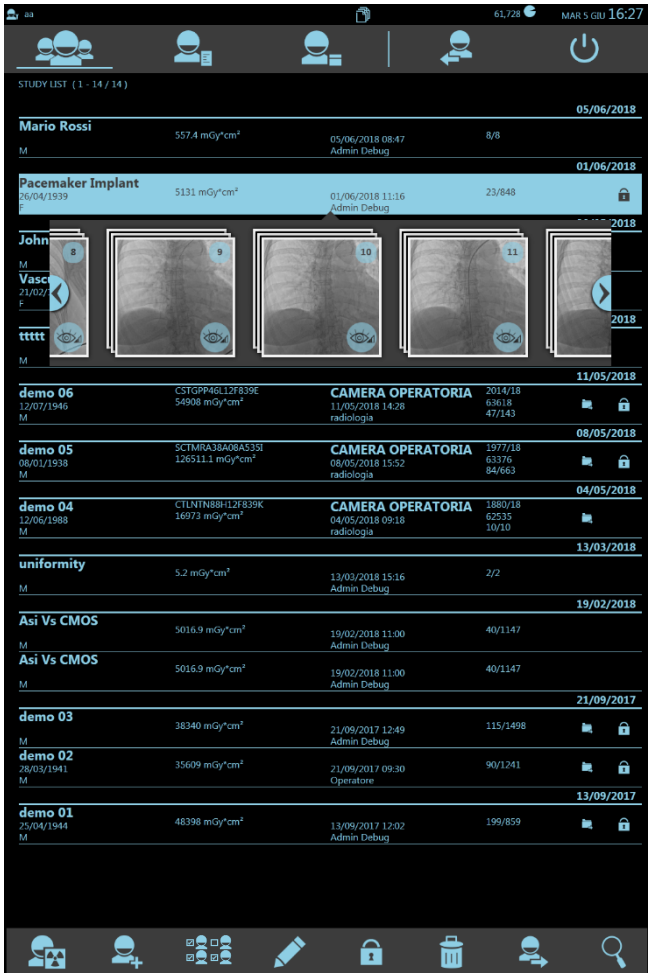
5.2.5 OPENING A STUDY

M.M.



STUDY WORKLIST

M.M.



STUDY LIST

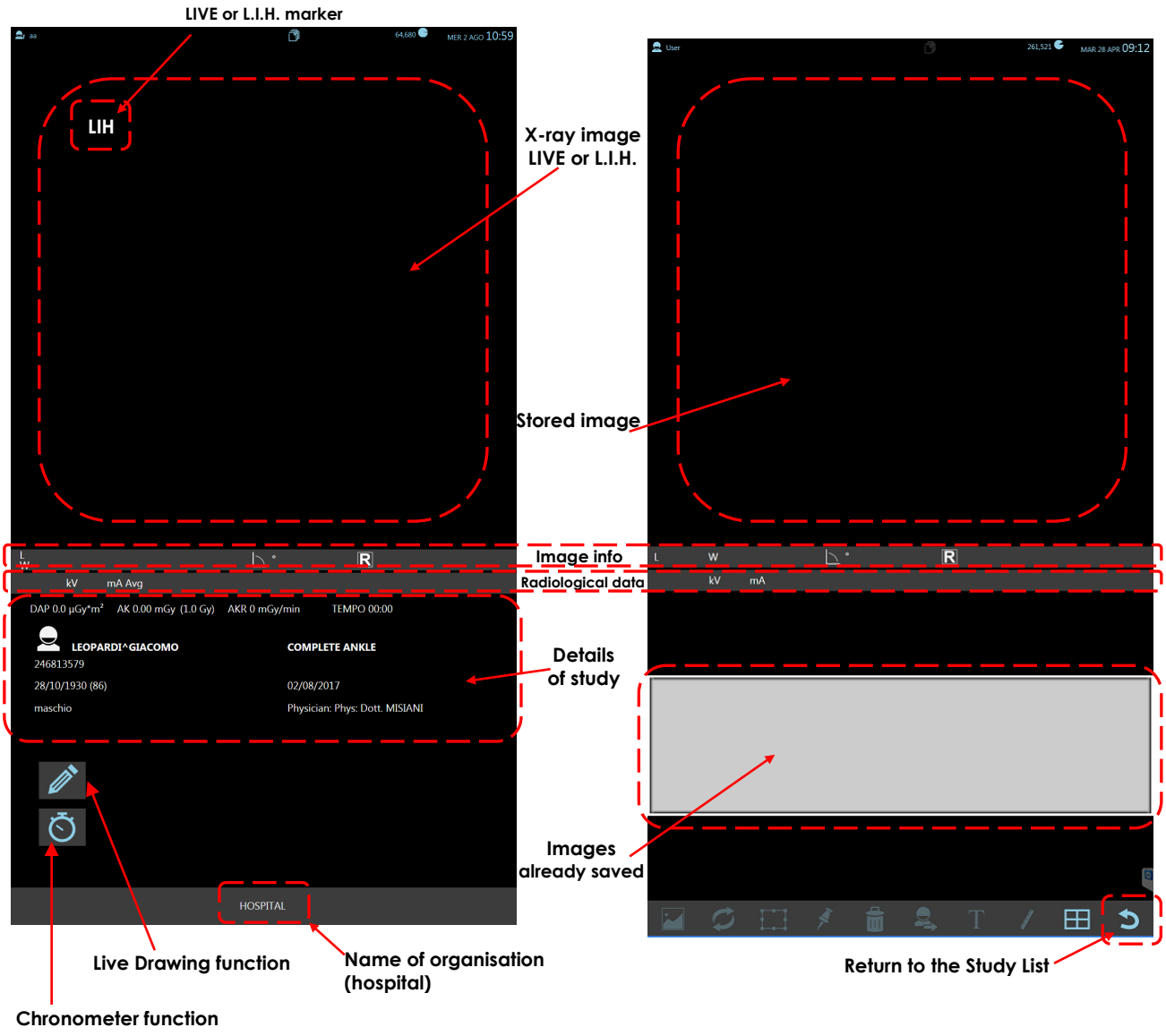
Tap the study you want to open from those listed in the STUDY WORKLIST (yet to be performed); the working frame opens, letting you acquire images:

You can also open a previous study to add some new images or process the existing images.
In this case, select the study from those in the STUDY LIST (previous studies) by tapping it.

The WORKING FRAME pages appear when you open a study:

The L.M. shows the images during X-ray emission (LIVE images), while the M.M. shows the images saved to Hard Disk.

L.M. **M.M.**

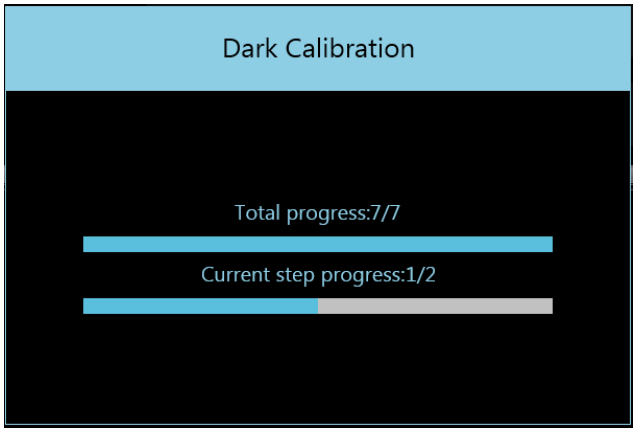


5.2.5.1 DETECTOR DARK CALIBRATION

Outside the WORKING FRAME, the system behaves in two different ways, according to what has been set in the **General Settings** menu (*See Paragraph 4.2, Part 2 of the Technical Manual*).

1. The system automatically calibrates the Offset of the detector (*Dark Calibration*) in background.

2. The system automatically calibrates the Offset of the detector (*Dark Calibration*) when a new study is created, too. During this procedure, the following window appears on the monitor and the control panel:



The complete calibration procedure takes about 25 seconds, at the end of which the detector will be ready for image acquisition.

When a study is open, the system **automatically** refreshes the **fluoroscopy offset** in background, during pauses between acquisitions; instead, **radiography offset** can only be refreshed **manually** (it differs between offset calibration for fluoroscopy images and radiography images).

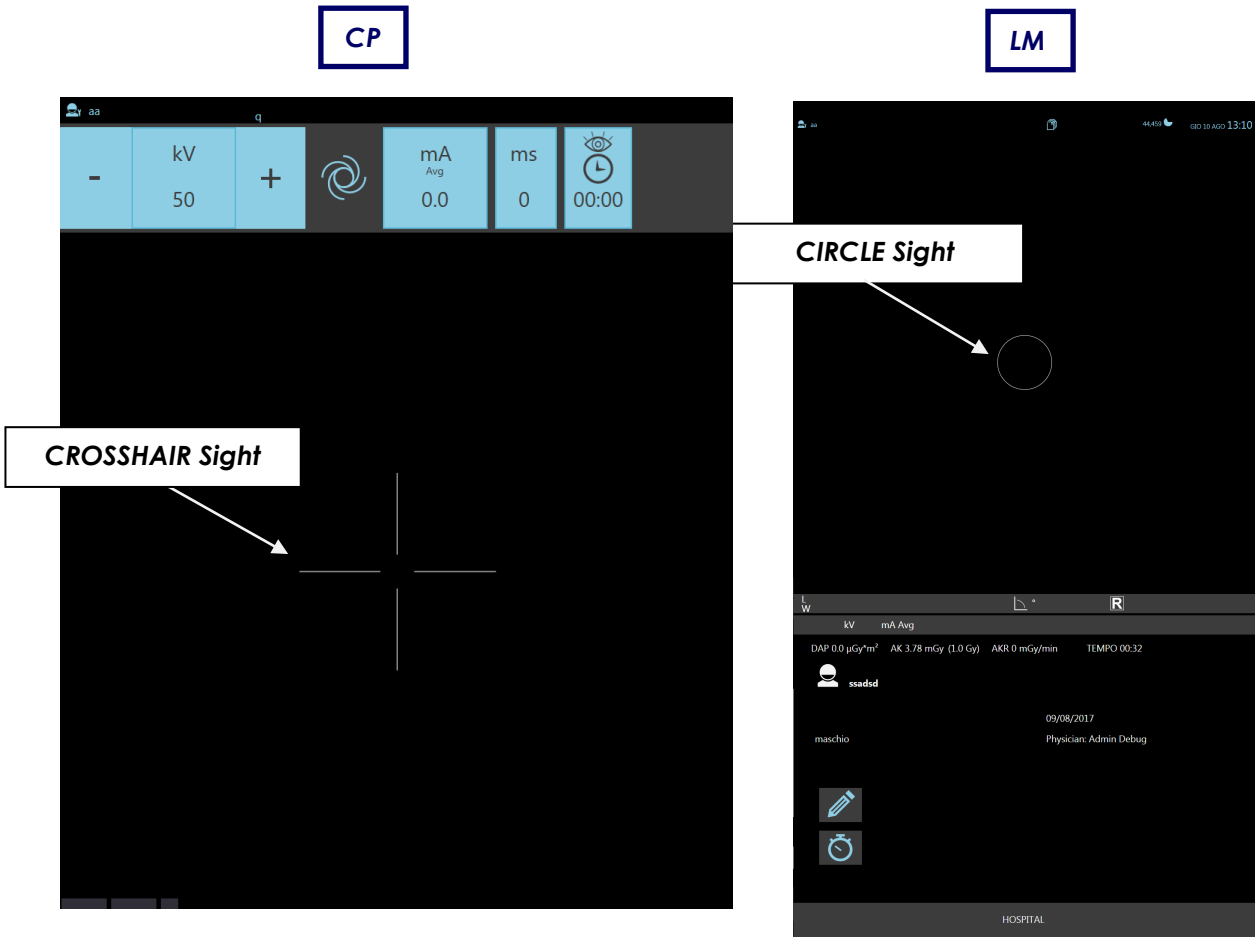
The operator is advised when the **radiography offset** is expired thanks to the dedicated key (in figure below), that starts blink once every 3 seconds.
It is always possible to acquire a radiography image, even if the offset is no longer valid. However, it is recommended to manually refresh the radiography offset as soon as possible, pressing the dedicated key, for at least 3 seconds: image acquisition is inhibited during the process.

5.2.5.2 SIGHT FUNCTION

The equipment lets you activate the display of a sight (crosshair or circular) on the center of the image, which will help you during the exam to execute peculiar centering of the anatomic region of interest.

When opening an exam and if enabled in the General Setup, the sight will be projected on the center of the image frame of the **Control Panel** and of the **Live Monitor**.

You can choose between two different sight formats: **Crosshair** or **Circle**.



To temporarily disable the function, press the relevant button on the **Control Panel**.

Note: *See Paragraph 4.4.1, Part 2 of the Technical Manual for the sight settings. If the value* ***None*** *is set, then no sight will be displayed.*

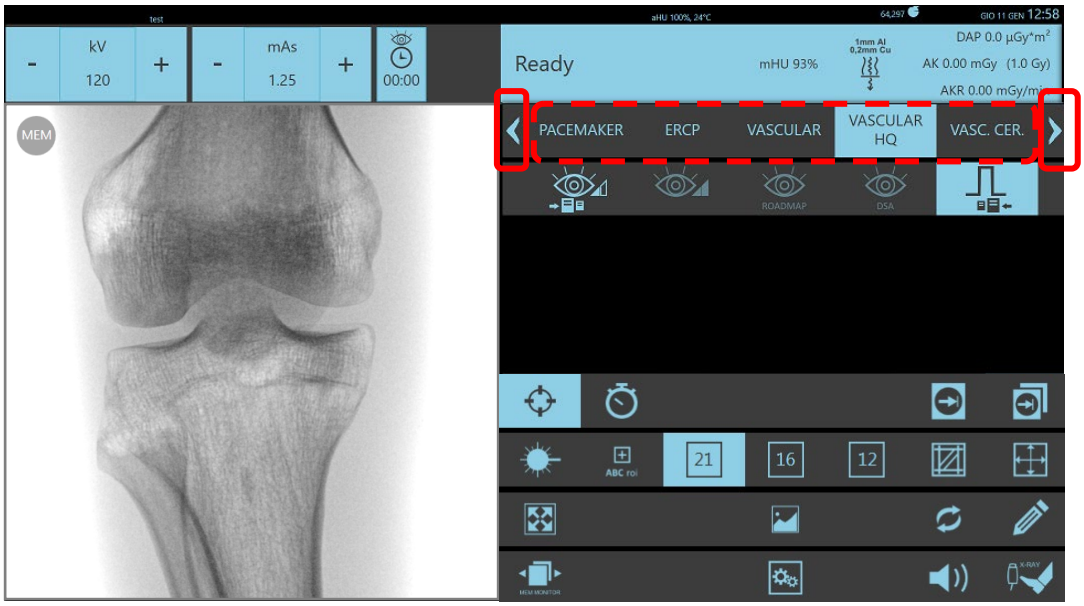
5.2.6 SELECTING AN EXAM TYPE

The equipment lets you choose among different exam types where certain parameters can be set to optimize the performance of the system when carrying out specific applications or to suit the user preferences.

The number of exams and the settings of the respective parameters are defined during the installation of the equipment in the **Exam Setup** menu *(see paragraph 4.4, Part 2 of the Technical Manual)* and after consultation with the user.

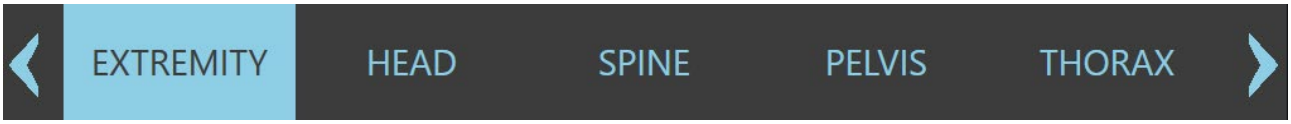
It is possible to browse through the exam lists on the Control Panel by using the respective arrows.

When selecting the exam, the main parameters of the function and of the acquisition mode will be assigned automatically and according to the values which have been preset to each pedal of the footswitch (or to the handswitch).



Note: *For a detailed description of the exam settings and the related parameters, in Chapter: "Installation", Paragraph 3.1.3.*

The example below shows the ribbon with the available exams. When pressing on one of them, the respective exam will be selected and the selected exam will be highlighted in blue:



Check that the automatically set parameters are those you require.
The default parameters must be checked and changed if necessary as required by the user.

5.2.6.1 DEFAULT EXAMS

The EM equipment comes with exams already defined by the manufacturer, linked to the different device applications.

EXAM	APPLICATION
EXTREMITY	Fracture repair for extremities and other bones.
HEAD	For Neuromodulation, Spine Fixation, Laser Nucleolysis and Pain management procedures.
SPINE	For Vertebral fracture repair, Pain management procedures and Scoliose-Lordose correction procedures.
PELVIS	To examine pelvis bone structures, especially in order to repair fracture.
THORAX	For inserting catheters in the thoracic region.
PACEMAKER	To implant Pacemaker or Resuscitation device.
ERCP	Endo Retrograde Cholangio-pancreatic procedure and for examination of abdominal organs, where a high contrast is required because of organs movement.
VASCULAR	Control of peripherical arterial bypasses (femoral, popliteal arteries etc.) and Endarterectomy procedures.
VASCULAR HQ	Abdominal Aortic Aneurysm procedures and other vascular procedures in abdomen.
VASCULAR CEREBRAL	Control of Intracranical aneurysms.
PAIN MANAGEMENT	For all bones structures; suitable to be used for Neuromodulation procedures, together with image subtraction technique, too.
UROLOGY	Urological and pelvic region intervention.
ELECTROPHYSIOLOGY	Electrophysiology procedures with great organ movement and very long procedures times.
DAILY TEST	Daily procedure, to be accomplished before using the device, in order to check that equipment works correctly.

5.2.6.2 IMAGE ACQUISITION

Before carrying out any exposure, make sure that all the necessary irradiation protections have been activated.

Before giving the X-ray command, also make sure that the patient bed has been earthed via the equipotential connector on the stand.

During X-ray emission, always make sure that the edge of the collimator can be seen on the image: if not, call the Technical Service as there is the risk that the collimator is not working and remains open at an excessive value.

If the COLLIMATOR FAULTY alarm is active, you can still continue fluoroscopy exposures in order to complete the procedure. Any such exposures should, however, be as brief as possible and only if absolutely necessary.
Contact Technical Service to restore the equipment to proper working order.

X-ray emission is indicated by the YELLOW lights on:
- the stand,
- the monitor unit, above the two monitors.

***Note:** it is suggested to **not** connect the EM equipment to Hospital Network if not required (e.g. during surgery).*

5.2.6.3 SELECTING THE ACQUISITION MODE

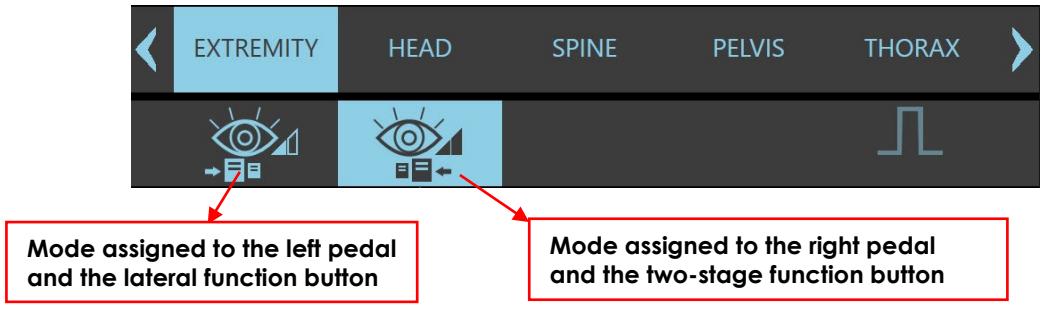
Possible acquisition modes:

- **Fluoroscopy:**
  - **Low Dose** Fluoroscopy
  - **High Quality** Fluoroscopy
  - Fluoroscopy in **Peak Opacification** + **Road Mapping** mode (optional)
  - Fluoroscopy in **DSA** mode (optional)

- **Digital radiography**

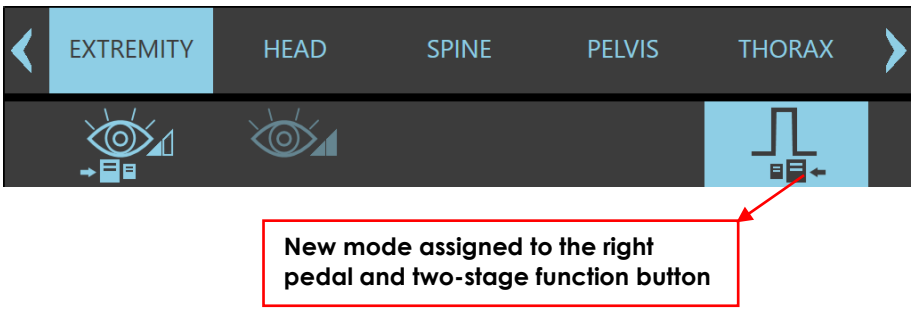
***Note:** the **Pixium 2121S** and **3030S** panels are indicated for use in generating real time fluoroscopic images in patients where medically indicated. They are also indicated for use in generating radiographic images of human anatomy.*

When opening the exam, the main acquisition mode is assigned automatically according to the values which have been preset to each pedal of the footswitch (or to each handswitch button).

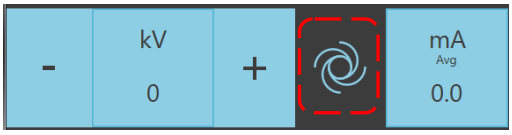


Modification of these settings is possible temporarily but will be limited to the current exam.

Once you select a new acquisition mode from those available for this exam, this new selection will determine the new mode assigned to the **right pedal** (or to the **two-stage function button**).

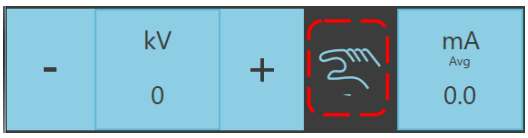


On startup and at the selection of a new exam, the device will be preset for automatic fluoroscopy dose control. The kV and mA values will be set automatically according to the examination subject.



This automatic regulation is generally calculated on a central Region Of Interest of the image (ROI).
ROI dimensions are set to be, in normal conditions, completely inside the anatomic section under exam.
If it is not possible to have the anatomic part in the center of the field, it is possible to manually move the ROI in the needed point.
When you press the "abc ROI" icon, a little green square appears in the centre of the image on the control panel screen. Simply touch the screen at the point where you want the ROI square to appear; the kV and mA values will be automatically recalculated.
Press the ROI icon again to return to the standard setting.
The function ends when you change detector field or exam.

You can always control the dose manually:
- select the **manual mode**,
- adjust the kV as required using keys to **decrease** (**-**) and **increase** (**+**).



5.2.6.4 5.2.7.2 ACQUISITION RATES

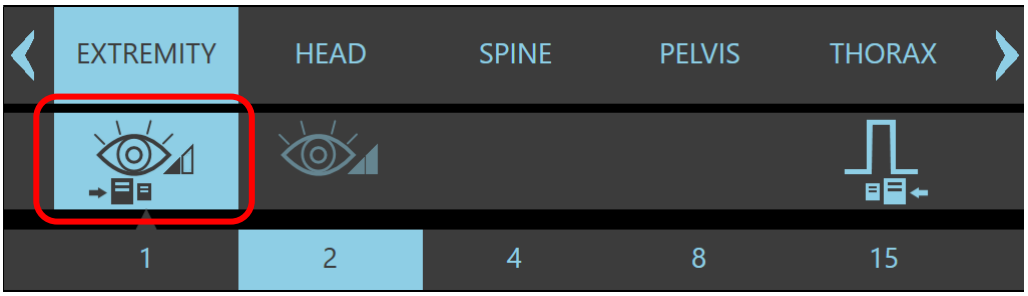
The fluoroscopy emissions can be carried out at different rates of X-ray pulses per second; the values presented on the Control Panel depend on the maximum admissible frame rate for this exam (*Set during installation. See Paragraph 4.4, Part 2 of the Technical Manual*).

Max admissible frame rate for the exam	Available rates
15 f/s	*1, 2, 4, 8, 15 f/s*
25 f/s	*1, 3, 6, 12, 25 f/s*

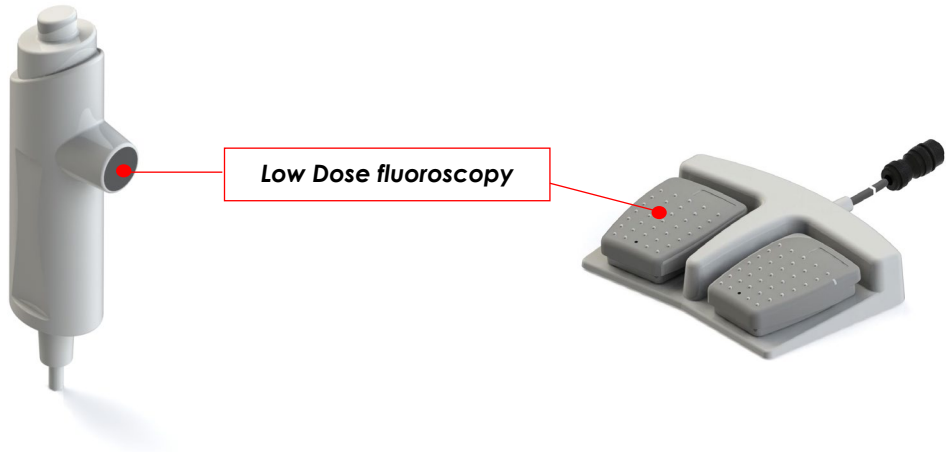
Note: *In case you intend to use mA peak values for a fluoroscopy acquisition (e.g. 100mA), the system will automatically adjust the maximum rate values (from 15f/s to 8f/s or from 25f/s to 12f/s) so that the maximum Air Kerma reference value of 176 mGy per minute, as stated in the standard* ***EN 60601-2-54****) is not exceeded.*

5.2.6.5 5.2.7.3 LOW DOSE FLUOROSCOPY

The **Low Dose** fluoroscopy is recommended for all centering and positioning operations during surgical and interventional procedures.



X-ray emission command is given with the left pedal or with the lateral switch of the bi-functional handswitch.

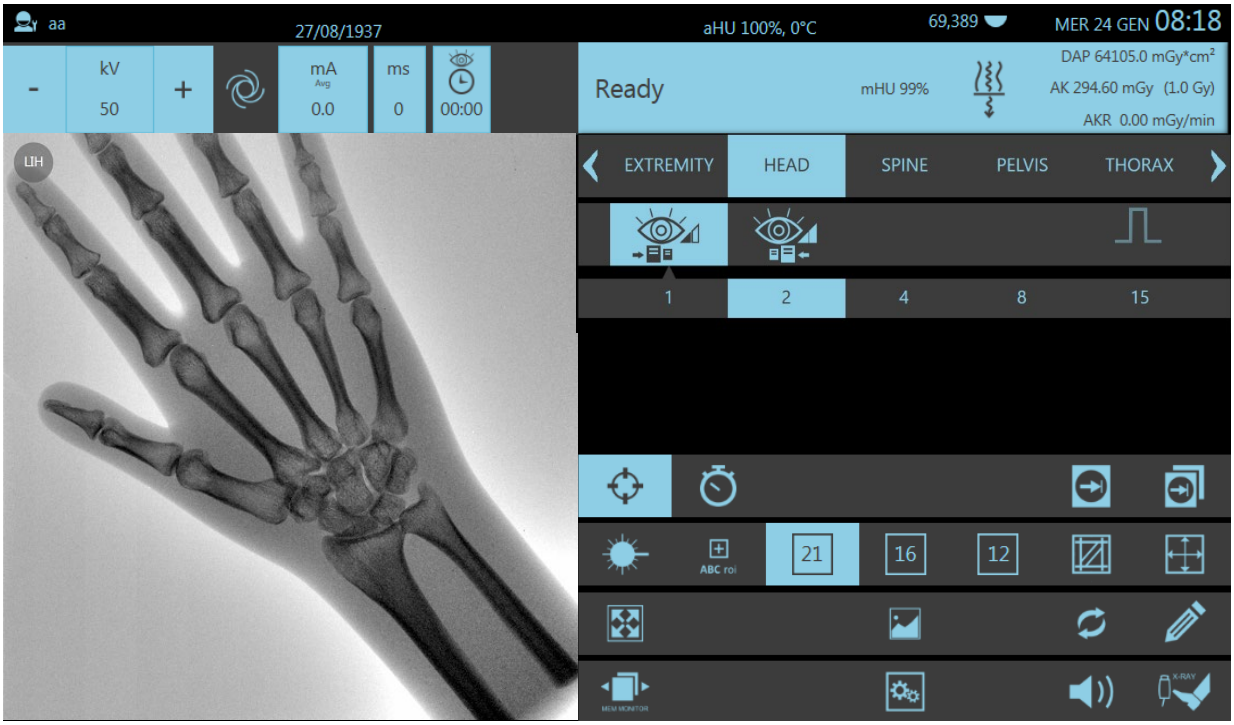


The number of X-ray pulses per second can be selected from the suggested rates. The available rates vary according to the max FPS set for that exam (*see Paragraph 4.4, Part 2 of the Technical Manual*).

The yellow warning lights on the stand and on the monitor unit will light up on X-ray emission. Furthermore, the equipment will emit an acoustic signal on each X-ray emission (if enabled).

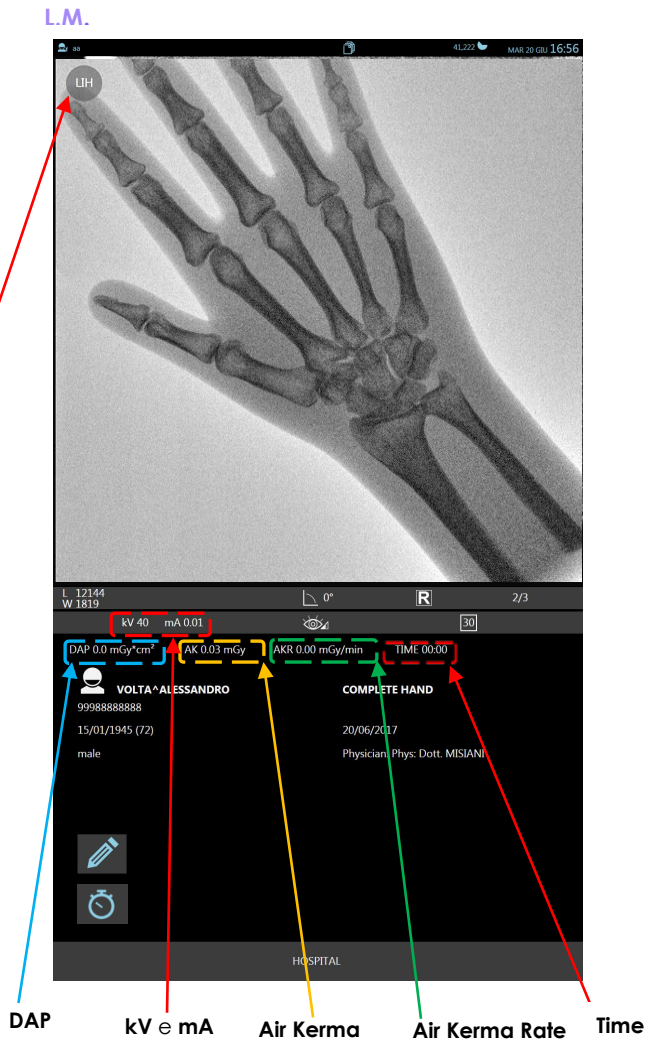
The **Control Panel** displays:

- The acquired image,
- The indication: **LOW DOSE FLUORO** (during x-ray emission)
- The value of the kV and average mA,
- The x-ray pulse duration (in ms),
- The fluoroscopy time (minutes and seconds),
- The available Heat Units (%) and the temperature of monoblock,
- The total dose * area during the study (**DAP**),
- The total Air-Kerma during the study (**Air-Kerma**),
- The Air-Kerma Rate.



The **L.M.** displays:
- The acquired image,
- The value of the **kV** and **mA**,
- The total dose x area value during the study (**DAP**),
- The total Air-Kerma during the study (**Air-Kerma**),
- The Air-Kerma Rate.
- The actual X-ray emission time

X-ray emission is cut when you release the command and the last image to be acquired is frozen on both the L.M. and the C.P.
This image is identified by the letters **LIH** (Last Image Hold).



During the installation phase of the equipment it is possible to determine whether all Low Dose Fluoroscopy images will automatically be saved to hard disk, or if it should only save the LIH (*Last Image Hold*), or no image at all.
Usually, the settings are made to save only the LIH.

In case the exam is not set to automatically save the images, it is nonetheless possible to save the required images during the exam using the manual commands.

- In order to **save the single image** currently acquired:
  - Press the **SAVE IMG** button on the control panel,
  - Or the corresponding key on the remote control,

You can also save the **LIH image** on the hard disk using the **SAVE IMG** button or the key on the remote control.

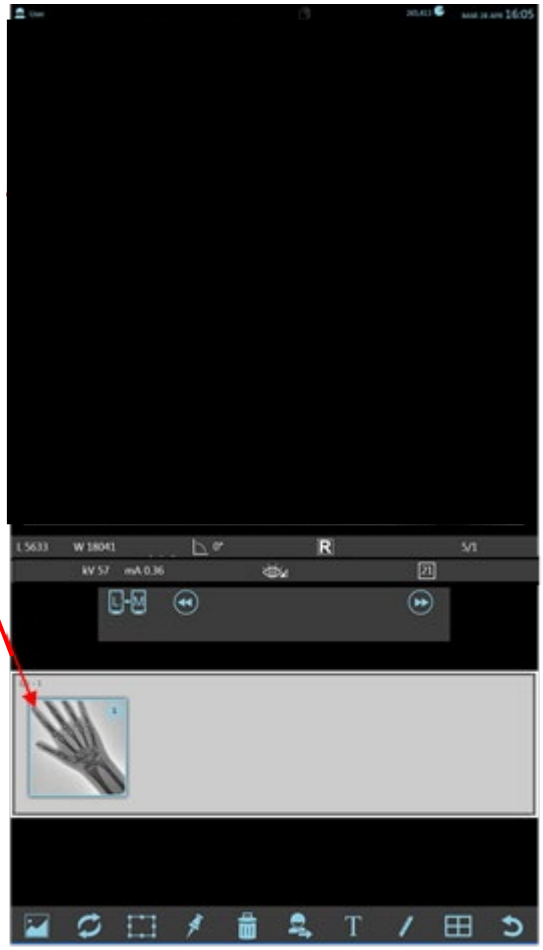
- To save **a whole run:**
  - touch **SAVE RUN** on the control panel,
  - or the corresponding key on the remote control.

All the images will be saved from the moment you use this key to the end of exposure.

This function remains valid only for the current X-ray emission. To save a run of images acquired with subsequent X-ray emissions, touch the **SAVE RUN** key again.
This function is disabled the next time you touch the SAVE RUN key again.

At the end of the emission, the Memory Monitor will display the small preview of the image saved to the hard disk.

M.M.

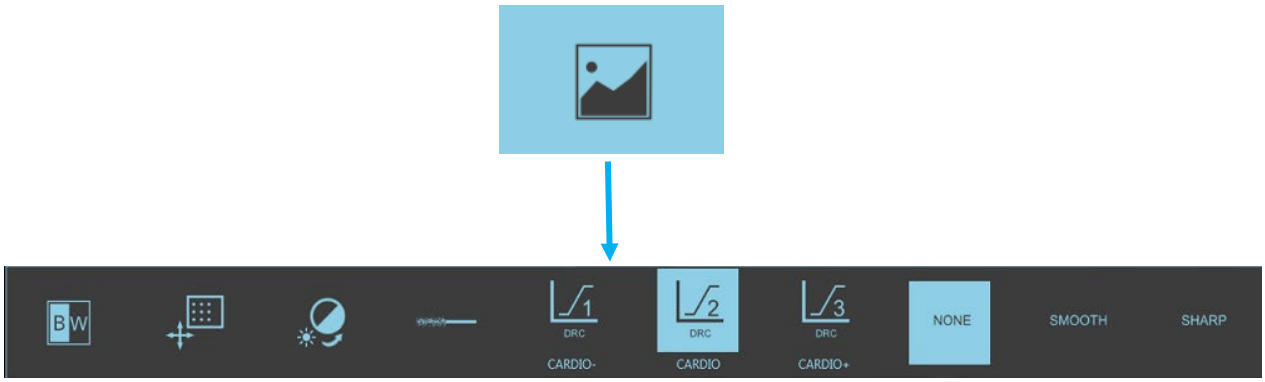


The images saved to hard disk can then be improved by using the post-processing function, printed and/or sent to a STORE DICOM server.

Note: *You can transfer as many images as you want during the study (the number is only limited by the storage capacity of the HD).*

- Your choice of exam also defines the type of possible image processing during acquisition:
  - Reduction of the noise via recursive filter,
  - Dynamic control of the image latitude and contrast (DRC),
  - Edge smoothing or sharpening.

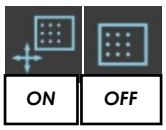
If necessary, you can change the programmed processing for the exam during the study. When pressing the indicated key, this will open the change menu:



Note: *Any such changes are only valid for the current exam. On changing the exam type or opening a new study, the default processing settings are restored, i.e. those set for the specific exam type.*

- **Grey scale inversion:** Invert the grey scales of the image by pressing the respective key.

- **Recursive filter:** you can add or remove the smart filter that detects movement and so make the filter more sensitive or less sensitive to any shifts in the patient or instruments (e.g. a catheter).
  This adaptive component (MOTION DETECTION) is very useful when using a 'heavy' recursive filter. It identifies any moving parts in the image (e.g. a catheter) and reduces the weight of the filter in that area, thus avoiding the 'dragging' effect.



- **Window and Level Reset:** This key allows to restore W and L image values, as they were at the acquisition.

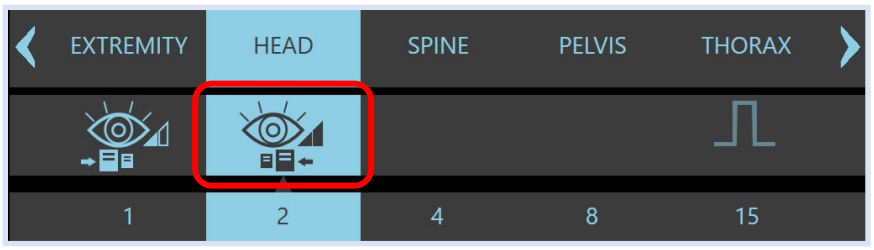
- **Noise Reduction:** the function allows to reduce possible noise present on the image by increasing this factor value. It goes from **0 to 10.**

- **Dynamic contrast control**: this lets you choose one of the values set for the specific exam type. The middle value is normally adopted when you select an exam type. The submenu lets you select less contrast (left-hand key) or more contrast (right-hand key).

- **Edge smoothing or sharpening**: you can decide to remove this filter or select either the SHARP filter or the SMOOTH filter as programmed for the specific exam type.
  The sub menu offers three choices.

5.2.6.6 5.2.7.4 HIGH QUALITY FLUOROSCOPY

The High Quality fluoroscopy is recommended whenever a higher image quality is required than the one obtained with the Low Dose fluoroscopy.



The number of X-ray pulses per second can be selected. The available rates vary according to the maximum rate settings for the specific exam (*see Paragraph 4.4, Part 2 of the Technical Manual*).

You can also change the emission rate using the remote control

- The X-ray emission can be started by pressing the footswitch or the handswitch command.

The yellow warning lights on the stand and on the monitor unit will light up on X-ray emission. Furthermore, the equipment will emit an acoustic signal on each X-ray emission (if enabled).

The **control panel** displays:

- The acquired image,
- The indication: **HIGH QUALITY FLUOROSCOPY** (during x-ray emission),
- The value of the kV and average mA,
- The x-ray pulse duration (in ms),
- The fluoroscopy time (minutes and seconds),

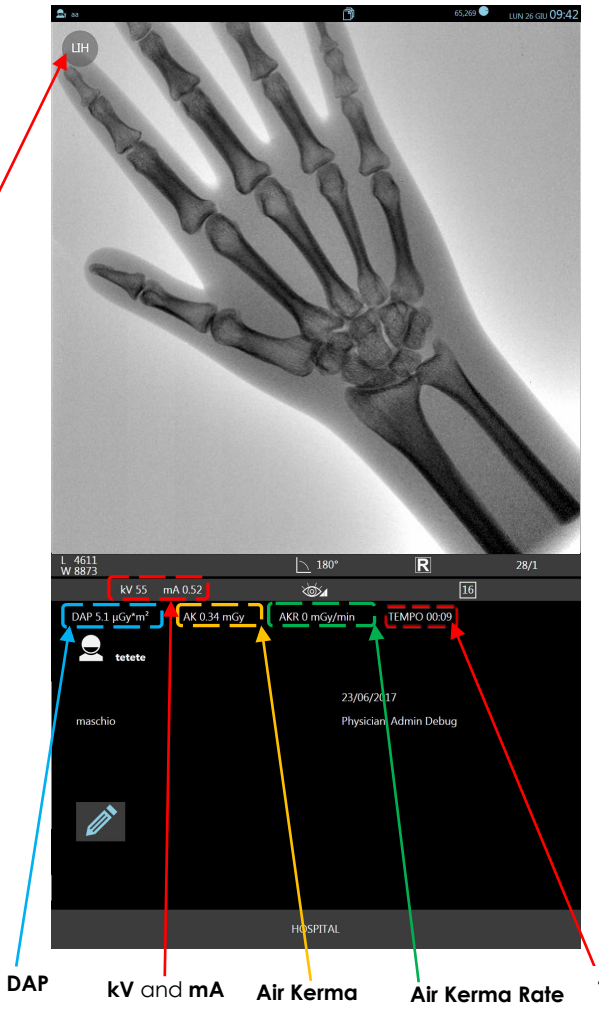
- The available Heat Units (%) and the temperature of monoblock,
- The total dose x area during the study (**DAP**),
- The total Air-Kerma during the study (**Air-Kerma**),
- The Air-Kerma Rate.

The **L.M.** on the monitor unit displays:

- The acquired image,
- The value of the **kV** and **mA**,
- The total dose x area during the study (**DAP**),
- The total Air-Kerma during the study (**Air-Kerma**),
- The Air-Kerma Rate
- The actual X-ray emission time.

X-ray emission is cut when you release the command and the last image to be acquired is frozen on both the L.M. and the control panel.
This image is identified by the letters **LIH** (Last Image Hold).

L.M.



Attention:
*In case an exam requires the use of elevated peak mA, the entrance Air Kerma for the patient **might exceed** the value of 88mGy/min (HIGH LEVEL COMMAND - HLC): Under these conditions, the equipment will emit a 500ms beeping sound every second.*
The use of this mode should be limited as far as possible in order to avoid an overexposure of the patient.

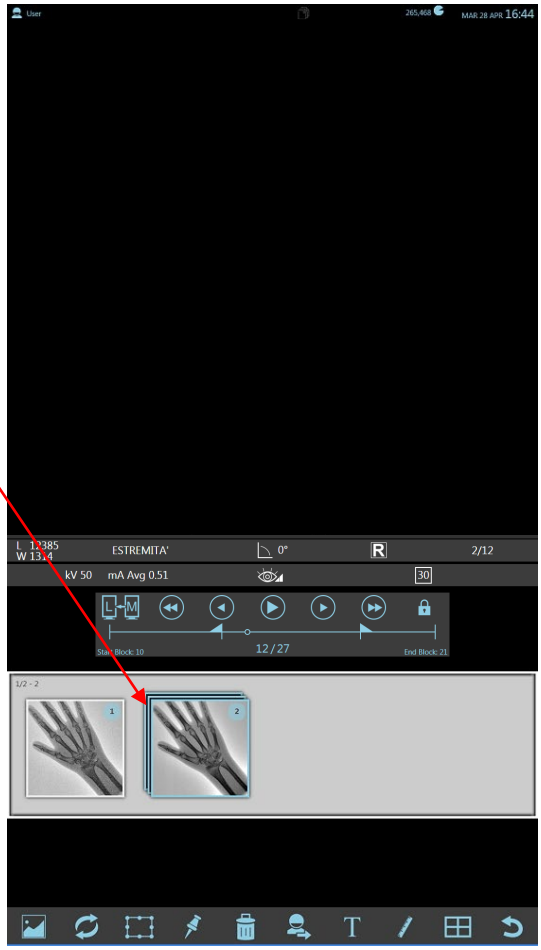
During the installation phase of the equipment it is possible to determine whether the High Quality Fluoroscopy images will automatically be saved to hard disk, or if it should only save the LIH or no image at all. The typical setting is to automatically save all the High Quality Fluoroscopy images to the hard disk.

In case the exam is not set to automatically save the images, it is nonetheless possible to save the required images during the exam using the manual commands (*see previous paragraph*)

At the end of the emission, the Memory Monitor will display the small preview of the images saved to the hard disk.

M.M.

Image saved to HD



The images saved to hard disk can then be improved by using the off-line processes, printed and/or sent to a STORE DICOM server.

Note: *You can transfer as many images as you want during the study (the number is only limited by the storage capacity of the HD).*

- Your choice of exam also defines the type of image processing possible during acquisition:
  - Recursive filter to reduce noise caused by movement,
  - Dynamic control of the image contrast (DRC),
  - Edge smoothing or sharpening.

If necessary, you can change the programmed processing for the exam during the study, as already described for Low Dose fluoroscopy in the previous *paragraph 5.2.6.6.*

Note: *Any such changes are only valid for the current exam. On changing the exam type or opening a new study, the default processing settings are restored, i.e. those set for the specific exam type.*

5.2.7.5 DIGITAL RADIOGRAPHY

This mode lets you acquire a single 'low noise' image in Radiography mode.

➢ ***All radiography images are automatically saved to hard disk.***

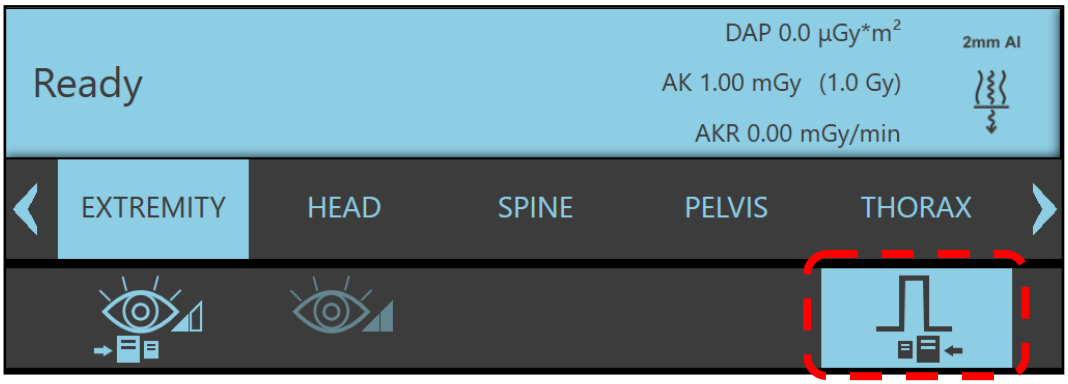
The exposure parameters are automatically set by the equipment:

- The kV value will be identical to the one of the preceding fluoroscopy,
- The mAs value will be automatically set by the equipment according to the exposure dose value preset for the exam. **If necessary, you still have the possibility to change the mAs values manually.**
- The X-ray collimator remains as open as it was during the preceding fluoroscopy.

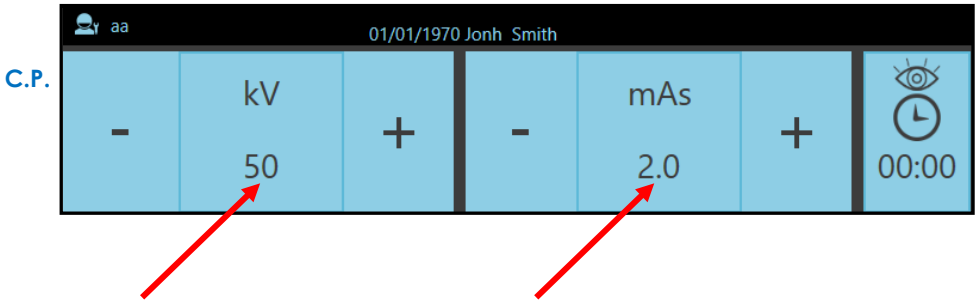
- The Digital Radiography mode is selected as follows:

- By pressing on the **One Shot** symbol displayed on the Control Panel,
- Or automatically, if it has been set for the selected exam, pressing the right pedal or the two-stage function button on the handswitch.

C.P.

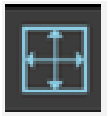


Change the exposure parameters as appropriate.

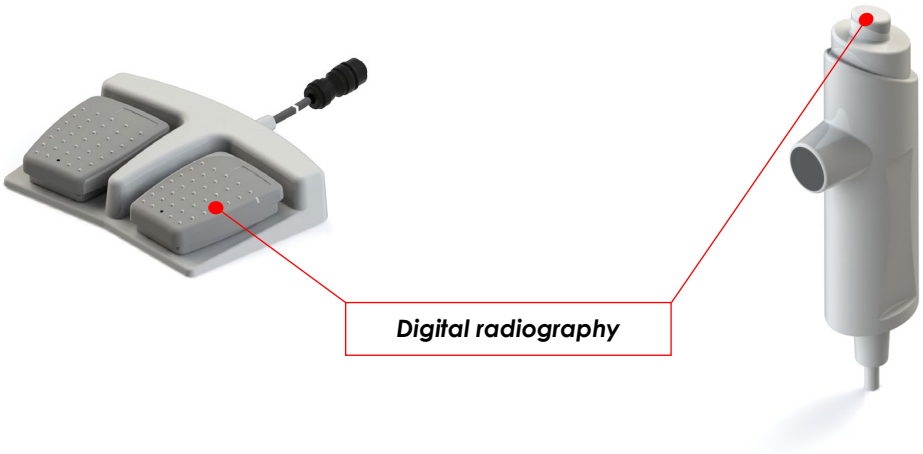


- The position of the collimator is the same as that used for fluoroscopy. This lets you expose only the anatomical part previously shown.

If necessary, you can open the shutters completely by touching this key on the control panel:



- X-ray emission starts when the button or the footswitch are pressed:



Always use the full length of the extensible handswitch cable (or footswitch cable) in order to stand as far away as possible from the irradiated zone.

- The first time you click on the button the equipment prepares for radiography. The following indications appear on the control panel: **RAD PREPARATION** and then, after preparation, **READY FOR RAD**.
- Click a second time for actual X-ray emission. The control panel now displays **RAD EXPOSURE.** Keep the button pressed down until the end of the exposure (3 beeps).
- When using the footswitch, however, the **RAD PREPARATION** and **RAD EXPOSURE** phases are carried out simultaneously with a single pressure on the right footswitch.

Keep button (or footswitch) pressed till the exposure is over; a sequence of three beeps advices the exposure ends.

The **control panel** displays:
- the acquired image,
- the available Heat Units (%).

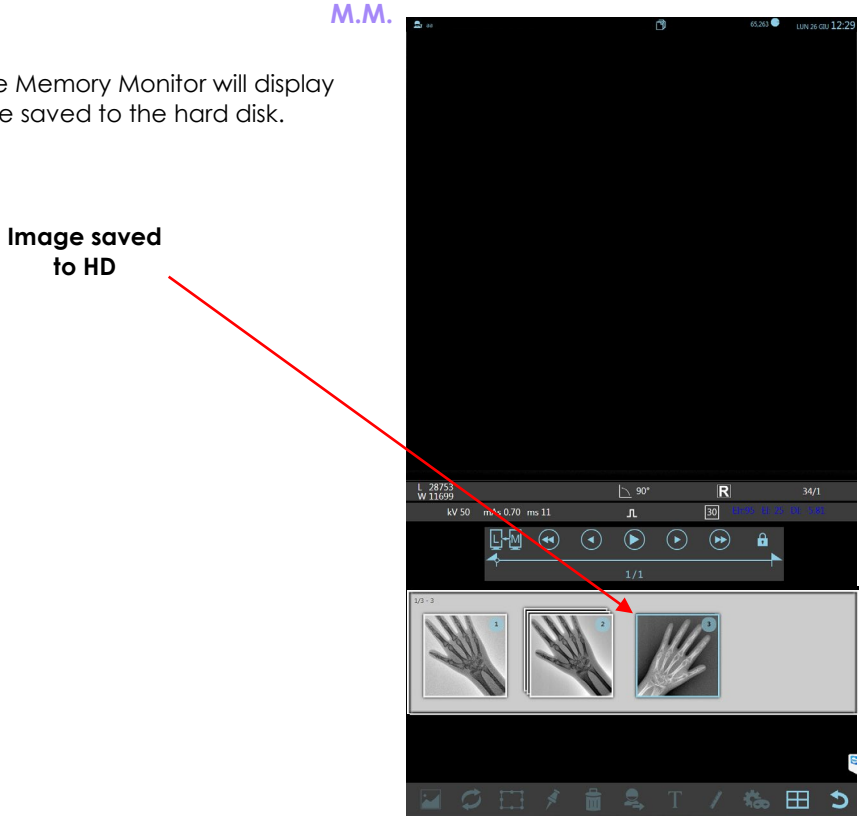
There is a constant acoustic alarm and corresponding alarm message if there is an alarm or you release the X-ray command button too early, thus interrupting exposure.

*Exposure is inhibited when the available heat units fall below the level required for the set exposure. The equipment warns you of this with the **X-RAY TUBE THERMAL SAFETY** alarm.*

- The image is automatically saved to hard disk and displayed on both the L.M. and the M.M. after X-ray emission.

M.M.

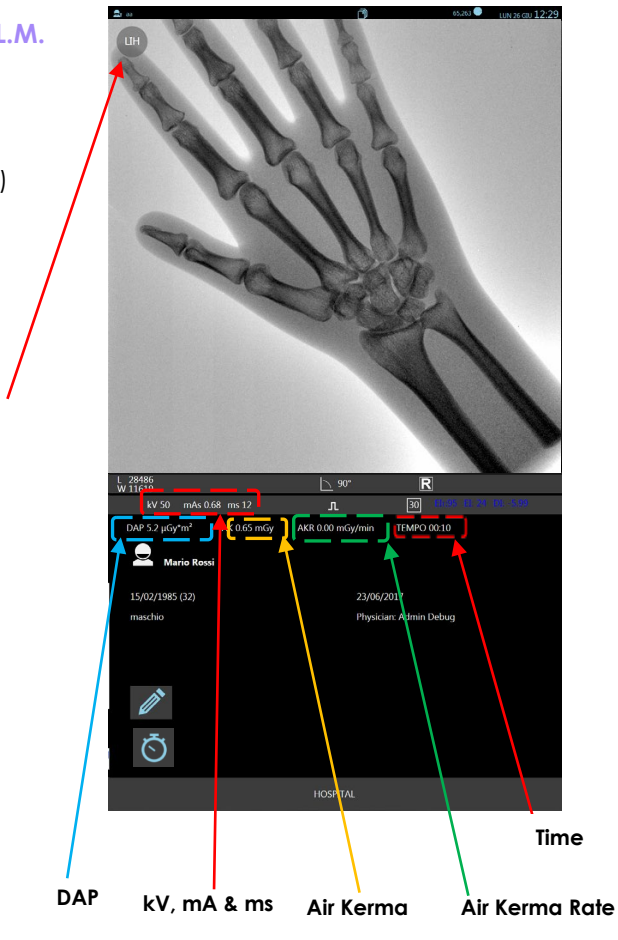
At the end of the emission, the Memory Monitor will display the small preview of the image saved to the hard disk.



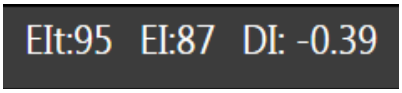
The **L.M.** on the monitor unit displays:

L.M.

- The acquired image,
- The value of the **kV**, **mAs** and length (time) of exposure in **ms**,
- The total dose x area during the study (**DAP**),
- The total Air-Kerma during the study (**Air-Kerma**)
- The Air-Kerma Rate
- The actual X-ray emission time.



In compliance with standard EN 62494-1:2008, the following values are also shown, providing evidence of the exposure dose at the relevant exam values:



- the **expected EXPOSURE INDEX** (**EIT**),
  indicating the expected dose (EI value) for the exam in question.
- the **detected EXPOSURE INDEX** (**EI**),
  measuring the response of the detector in the pertinent area of the image.
- the **DEVIATION INDEX** (**DI**),
  which quantifies the deviation of the EXPOSURE INDEX from the optimal value of the dose set for the exam in question.

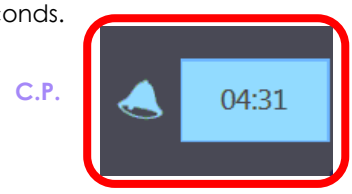
NOTE: *These indices are displayed in different colors, according to the exposure dose measured. If the image is overexposed, the indices will be displayed in red, while an underexposed image will be displayed with blue indices; the indices will be displayed in white if the image is correctly exposed.*

The table below provides an example of a difference in the EI and the DI after several exposures, with the dose set at 1 µGy:

set Dose Target (µGy)	EIt	Dose detected by detector (µGy)	EI	DI
1	100	2.6	260	4.0
1	100	2.0	200	3.0
1	100	1.6	160	2.0
1	100	1.25	125	1.0
1	100	1.00	100	0.0
1	100	0.8	80	-1.0
1	100	0.6	60	-2.0
1	100	0.5	50	-3.0
1	100	0.4	40	-4.0

5.2.7.6 X-RAY TIMER

- The control panel indicates the overall time you press the X-ray emission command (button or footswitch) in minutes and seconds.



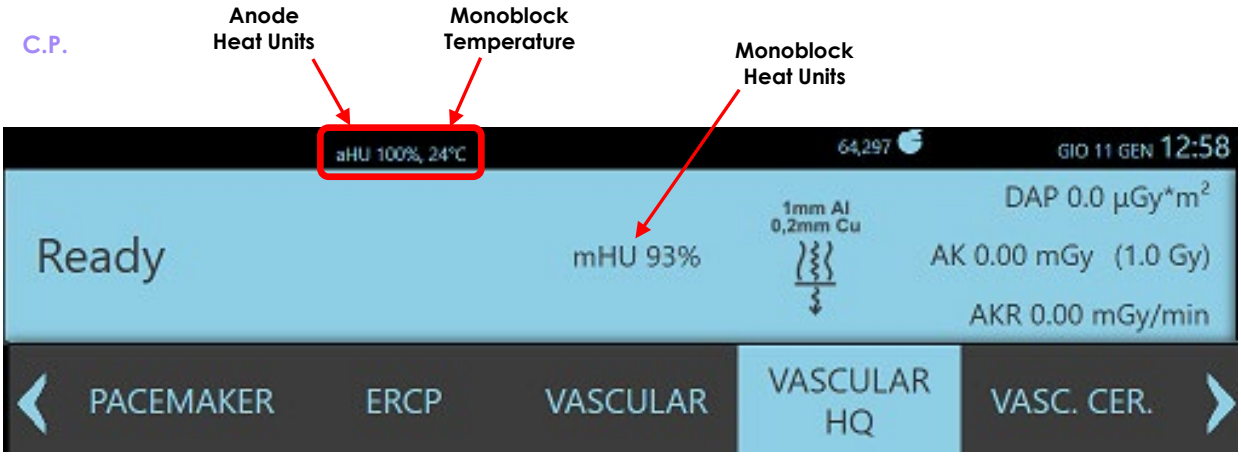
- There is an acoustic warning after every 5 minutes of X-ray emission (a continuous beep) and a bell warning appears on the screen.
- Reset the alarm by touching the alarm bell **icon**.
  This alarm starts 30 seconds before the 5 minutes are up. X-ray emission is stopped if you fail to reset the alarm within 30 seconds.
- You can reset the accumulated X-ray emission timer at any time by touching the **timer** (for at least 3 seconds).

X-ray emission is stopped *in any case whenever the X-ray command is constantly used for* ***10 minutes****. You can only continue after releasing the X-ray command.*
An acoustic warning sounds 30" before the 10 minutes are up, warning you that X-ray emission is about to be stopped.

5.2.7.7 HEAT UNIT INDICATION

The equipment counts the Heat Units:
- *in the anode (**aHU**)*
- *in the monoblock (**mHU**).*

The control panel displays both the anode and monoblock Heat Unit values (%):



An intermittent acoustic alarm sounds (double beep every 3 seconds) if the **anode or the monoblock Heat Units** fall below **10%** in fluoroscopy mode.

Exposure can continue, but the **mA value is automatically reduced** to prevent the X-ray monoblock from overheating.
The mA value returns to normal when the available Heat Units are again **more than 15% for the monoblock and more than 20% for the anode.**

Exposure is inhibited when the available heat units fall below the level required for the set exposure **in radiography mode**. The **X-RAY TUBE TOO HOT** alarm is generated if you use the X-ray command.

NOTE: *If the percentage of the remaining heat units is too low and if no further images have to be acquired, it is recommended to turn off the stand for a faster cooldown of the X-ray generator; **a stand which has been turned off needs approximately one and a half hours to change from mHU= 5% to mHU=55%.***
It is possible to leave the monitor station turned on. Like this, post-processing, storage and other operations can be carried out on the acquired images in the meantime.

5.2.7.7.1 MONOBLOCK WITH ACTIVE COOLING FUNCTION (OPTIONAL)

This function, available as an option, allows the x-ray monoblock to cool faster than passive cooling alone.

The cooling management system differs depending on whether you are within the operating panel (Patient study opened) or not (e.g. in the Study List).

When you are outside the operating panel, for example in the **Study List**, the cooling system is activated only if the temperature of the monoblock is higher than **35° C** (**95° F**): in this case, typically, the system will operate at maximum level (**Turbo** mode), so as to restore the available thermal units in the shortest possible time.
However, it is possible to configure a different management mode: for more information on the configuration and management of the cooling system, *see Paragraph 4.3, Section 2 of the Technical Manual.*

When in the operating panel, there are three different operating modes, depending on the temperature of the unit:

ACTIVE COOLING FUNCTION	 **OFF**	The active cooling system is switched off: the heat produced by the x-ray tube is dissipated passively.
	 **SOFT**	The active cooling system switches on when the temperature of the monoblock (*see paragraph 4.2.1.2, Section 1 of the User Manual*) overcomes 35° C (95° F): a warning message is shown on the Control Panel to advise the operator 10 seconds earlier. The cooling system operates at an automatically limited speed, activating the radiator fan, without generating noise.
	 **AUTO**	The active cooling system switches on when the temperature of the monoblock (*see paragraph 4.2.1.2, Section 1 of the User Manual*) overcomes 35° C (95° F): a warning message is shown on the Control Panel to advise the operator 10 seconds earlier. The cooling system works at a speed directly proportional to the temperature detected inside the monoblock: the higher the temperature grows, the higher the speed of the radiator fan rises (from a minimum of 2000 to a maximum of 4000 RPM).

5.2.7.8 FLAT PANEL DETECTOR ZOOM FIELDS

Depending on the FPD present on the unit, these are the available fields:

FPD 21 x 21
21 x 21 cm^2 , 16 x 16 cm^2 e 12 x 12cm^2

FPD 30 x 30
30 x 30 cm^2 , 21 x 21 cm^2 e 16 x 16cm^2

- In fluoroscopy, the working field can be selected among the 3 sizes displayed on the Control Panel.
- In digital radiography, however, the largest field is set and used automatically.

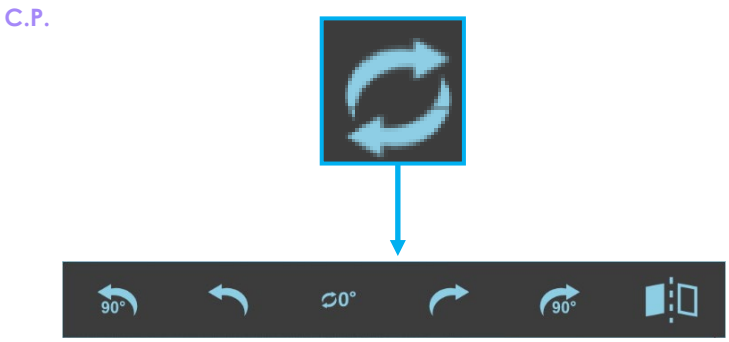
C.P.

nominal (30 cm) **zoom1** (21 cm) **zoom2** (16 cm)

nominal (21 cm) **zoom1** (16 cm) **zoom2** (12 cm)

5.2.7.9 IMAGE ROTATION / FLIP

During image acquisition, you can change the orientation of the image by using the rotation and horizontal flip commands. Access these commands by touching the key shown in the figure below, thus opening the relevant menu:



- **Rotation**:

	90° image rotation (anti-clockwise)
	Image rotation anti-clockwise (steps of 1°)
	Image rotation reset
	Image rotation anti-clockwise (steps of 1°)
	90° image rotation (clockwise)
	Free rotation of the image

You can also rotate the LIH image.
The orientation will be valid for the subsequent acquisition, meaning you can adjust the image orientation without X-ray emission.

- **Horizontal image flip**:

OFF	ON	
		Horizontal image flip

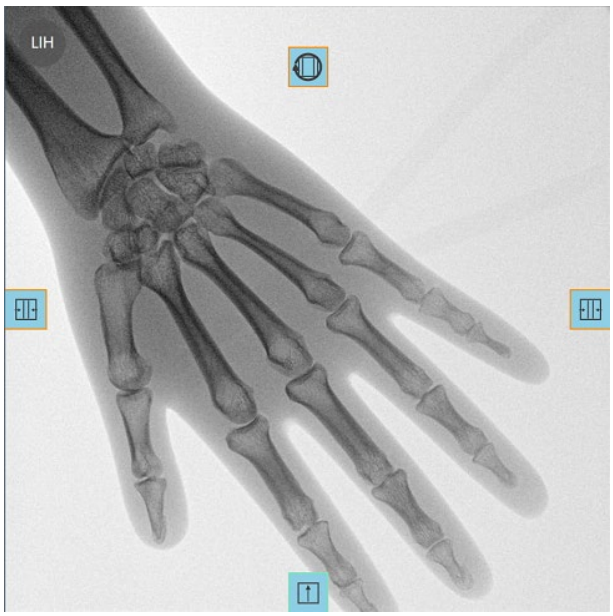
The horizontal flip can be used for both the LIVE image and the LIH image.

5.2.7.10 X-RAY COLLIMATOR

The X-ray collimator is equipped with a square field and an iris with adjustable parallel shutters: these can also be opened independently on each other (**asymmetrical collimation**).

The collimator opening is regulated from the Control Panel, pressing the dedicated button highlighted in blue:

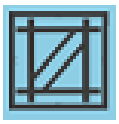
The adjustment buttons of the collimator are placed at the edges of the image area, as shown in the figure. The adjustment is obtained by moving the blue icon to the desired position.



	Square field opening/closing key.
	Shutters opening/closing key. When the **asymmetrical collimation** mode is active, each of the two commands only moves the corresponding shutter.
	Shutters rotation key.

To close the interface, press again the dedicated button.

The second button activates the additional functions of the collimator:



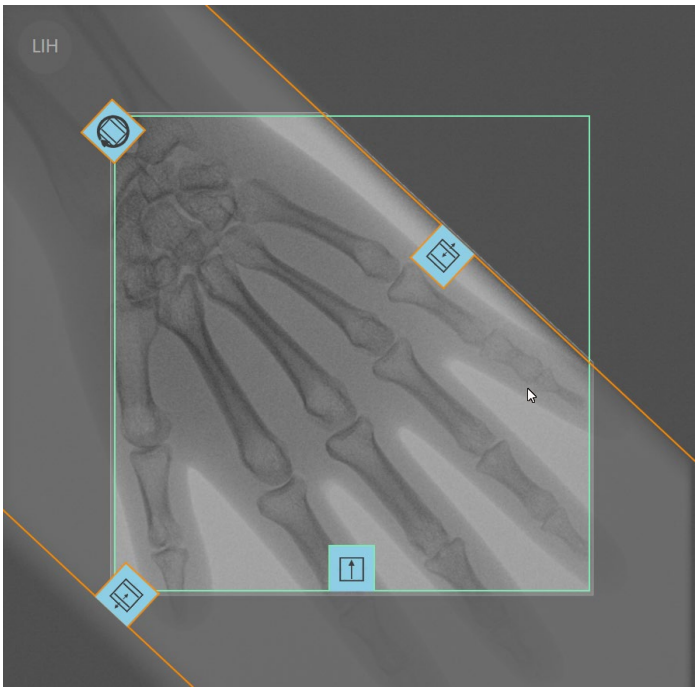
	This key is meant to open the collimator square field to the default value that has been set in Exam Setup menu (*See Paragraph 4.4.1, Part 2 of the Technical Manual*).
	Activation / deactivation of the opening of the parallel shutters, independently of each other.
	This key completely opens the square field and the shutters.

The max square field aperture is automatically decided, depending on the selected detector field.

5.2.6.7 5.2.7.11 VIRTUAL DISPLAY OF THE COLLIMATOR

The function allows the positioning of the collimator on the part of interest without X-ray emission, with evident dose reduction for the patient and for the operator. Then it shows the virtual opening superimposed on the last saved image.

To use the function, activate the control keys of the collimator by using the appropriate button on the Control Panel and adjust the position of the square field (indicated in green) and the parallel shutters (indicated in orange), as described above.

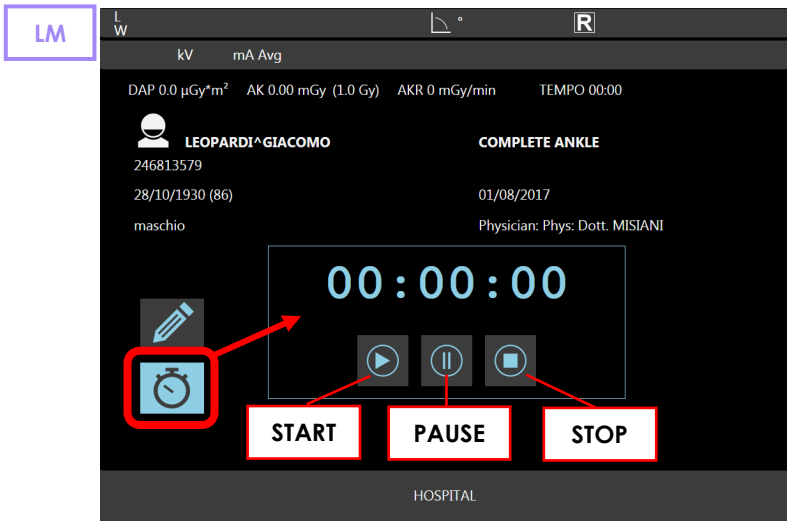


Note: *you can set the appearance of the virtual indication of the collimator position by choosing between two options:* ***transparent*** *or* ***black****. See Paragraph 4.2, Section 2 of the Technical Manual for more details.*

5.2.7.12 STOPWATCH FUNCTION

The EM device is equipped with a timing function which can be accessed either via the **Control Panel** or the **Live Monitor**. This function is useful whenever you need to measure the duration of specific procedures.

To activate the function, just press the corresponding key which can be found on the lower part of the Live Monitor**:**



This function can also be activated on the **Control Panel.**
The command keys are the same as those described for the Live Monitor.

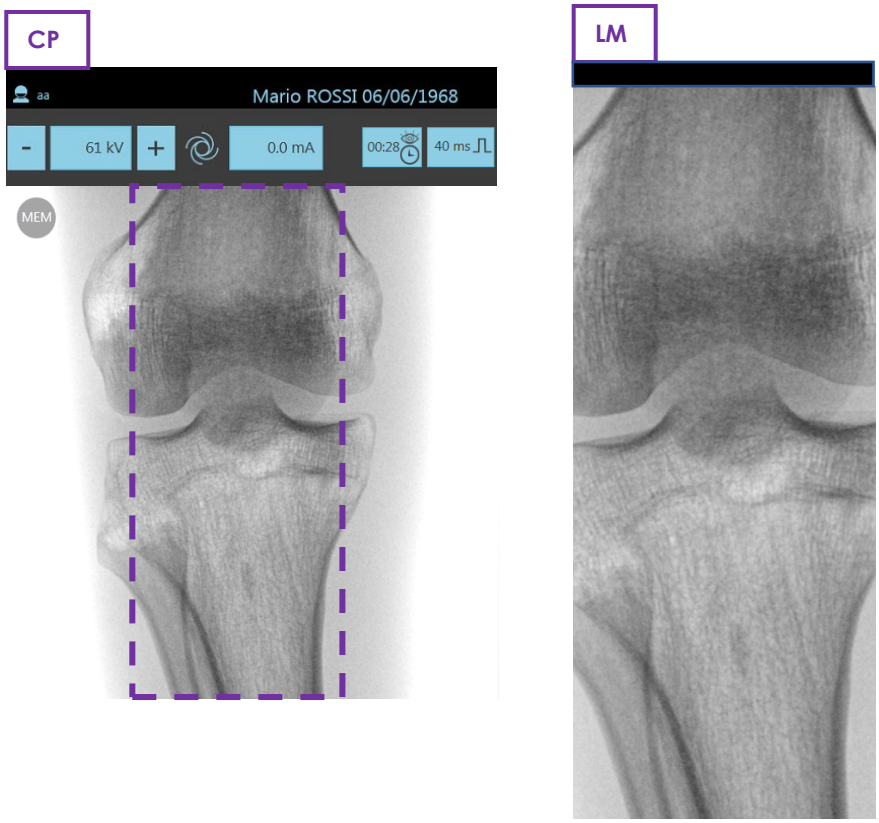
The function will be disabled by pressing once again the activation key or when the next X-ray command is given.

Note: *To enable the function see Paragraph 4.4.1, Section 2 of the Technical Manual.*

5.2.7.13 FULL SCREEN IMAGE

After an image has been acquired (whatever acquiring modality has been used), it is possible to view it in full screen mode, pressing the relevant key on Control Panel.

On the Control Panel, a part of the image is now framed by a purple rectangle: this part is shown on the Live Monitor in full screen mode.



The purple rectangle could be shifted left or right, therefore changing the part shown on the Live Monitor.

If required, it is possible to rotate or flip the image, using relevant keys on the Control Panel (see paragraph 5.2.7.9 above).
Note: *the image free rotation function is not usable when the full screen image function is activated.*

To quit the function, thus returning to normal image view, press again the relevant key.

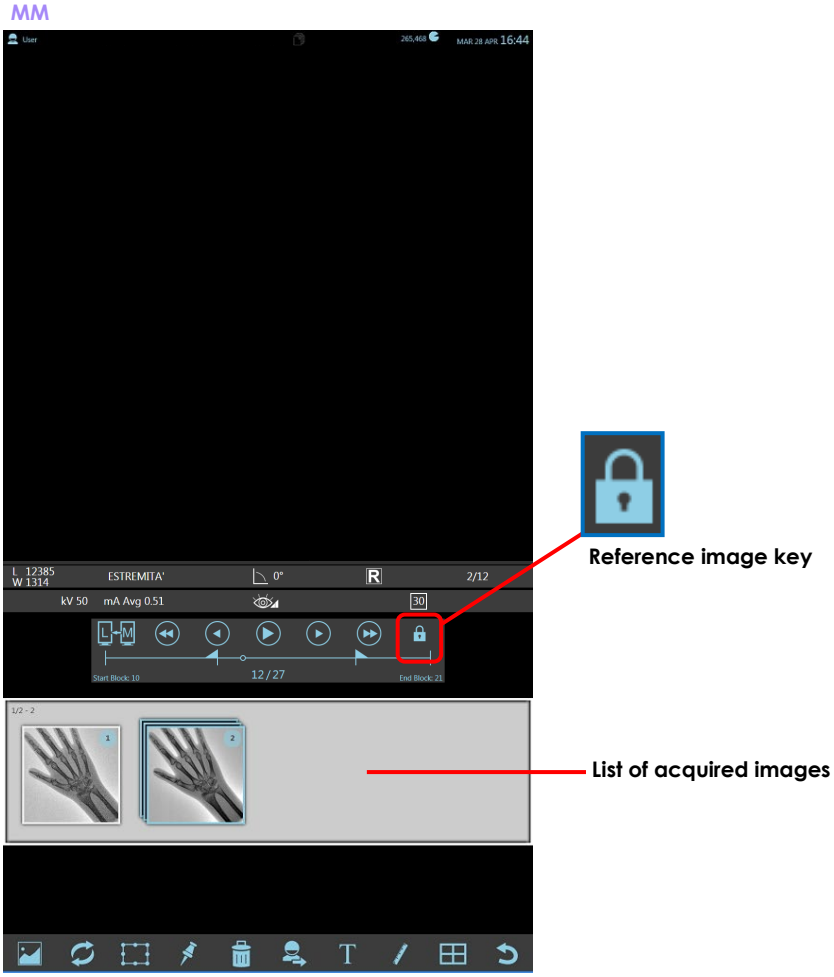
5.2.7.14 REFERENCE IMAGES

During the image acquisition, the Memory Monitor displays a previously saved image (**Reference Image**). Like this it can be compared to the last image acquired which is displayed on the Live Monitor.

There are two alternative operating modes:

a) At the beginning of each new acquisition, the Memory Monitor displays automatically the previously saved **LIH image**.

b) Alternatively, it is possible to choose a reference image from those acquired in the study by selecting it from the lower list and confirming this choice by pressing the **Reference Image** key.



This reference image remains fixed for every new acquisition until the choice is cancelled by pressing once again on the **Reference Image** key.

In that case, it will return automatically to the previous operating mode (**see item a)**).

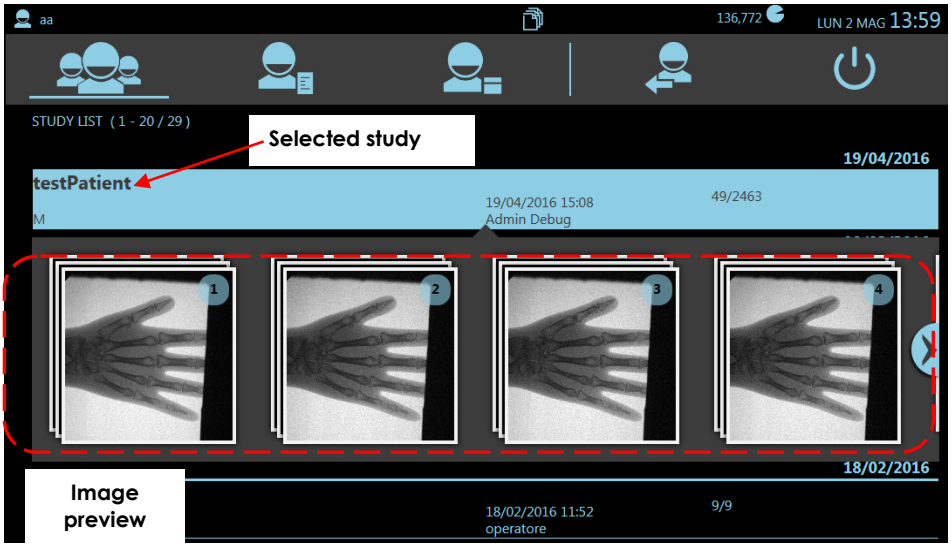
Note: *when the Reference Image function is enabled, the related image cannot be deleted.*

5.2.8 FINDING AND VIEWING IMAGES

5.2.8.1 FINDING IMAGES

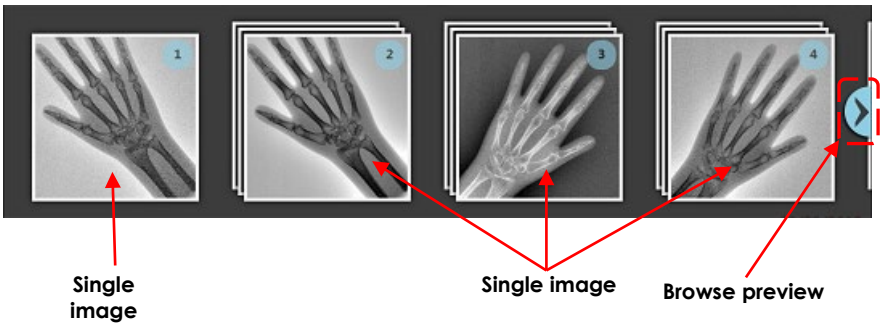
- You can use the preview function in the **Study List** frame to see the images in each run; this function makes it easier to select the studies you want.

M.M.



- The images are grouped in "runs", which correspond to each X-ray emission.

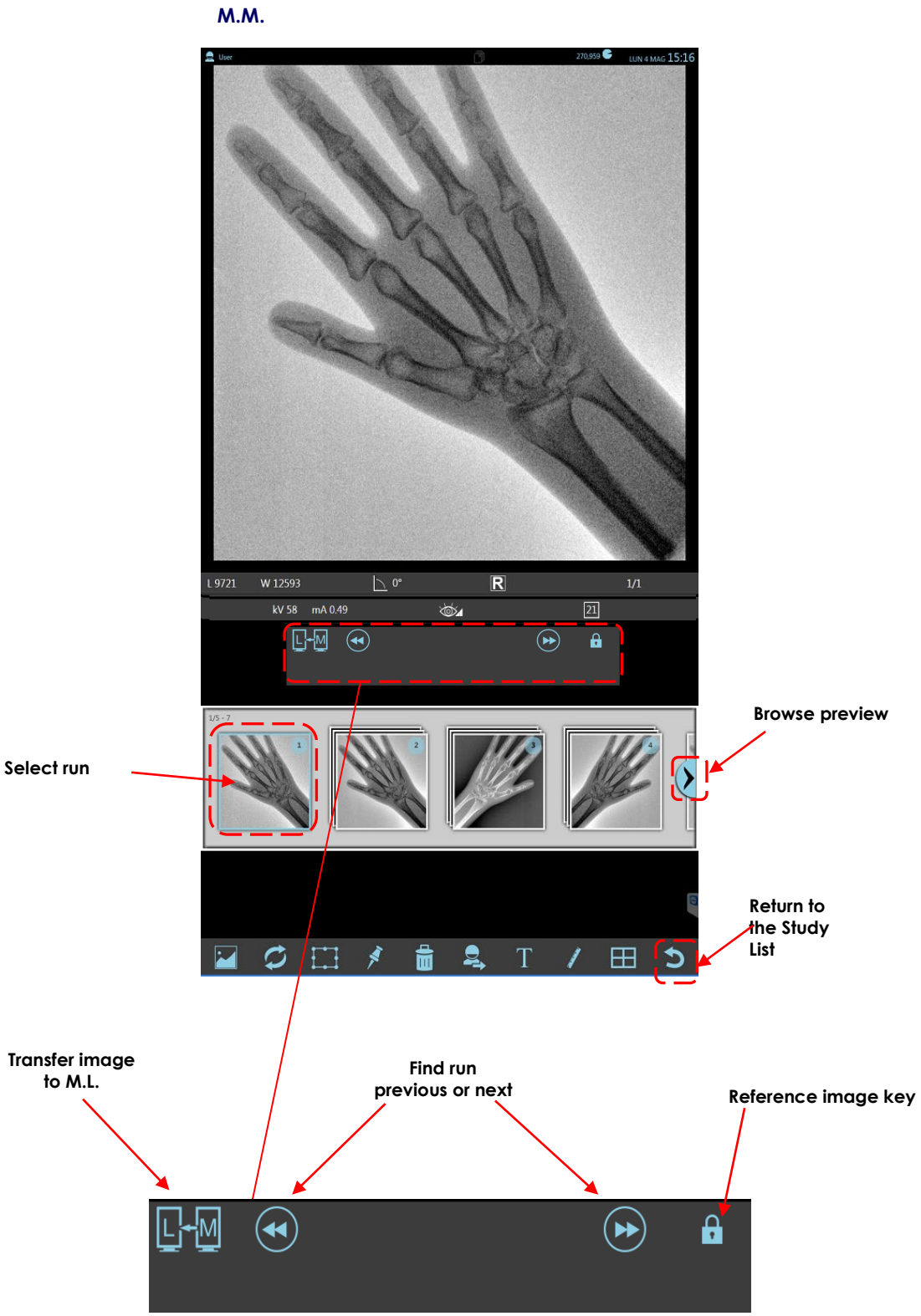
- A run can consist of a single image or a series of images (multiframe run):



- Browse the preview images to scroll all the runs in the study. When you 'tap' a preview image, the study opens and the first image in the run is displayed on the M.M.

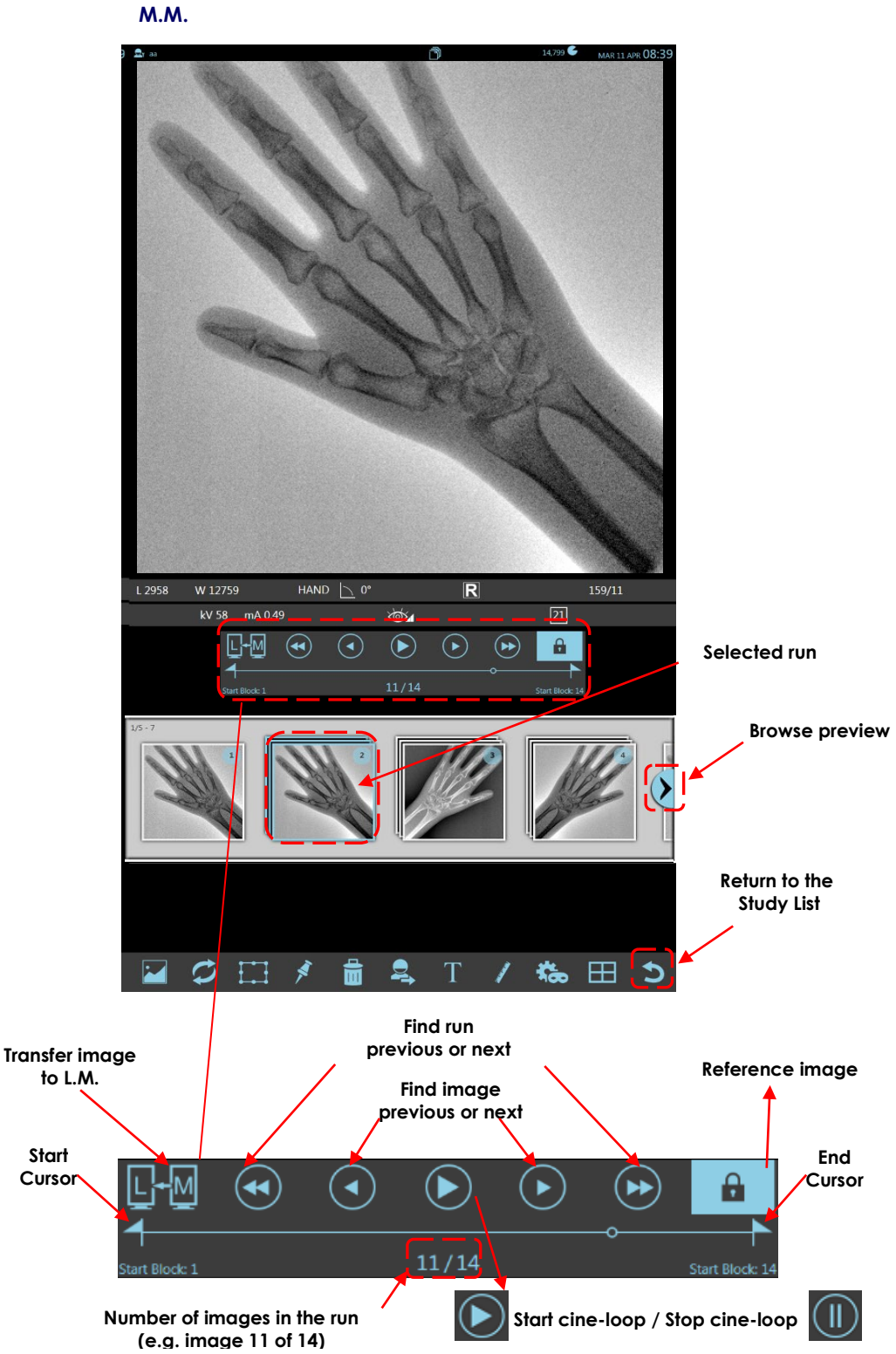
5.2.8.2 SINGLE IMAGE

If the preview image relates to a run containing just a **single image**, the screen will look like this:



5.2.8.3 MULTIFRAME RUN

If the preview image relates to a run containing a **series of images** (multiframe run), the screen will look like this:

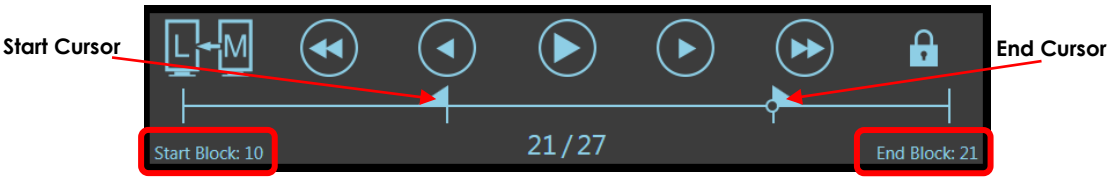


In addition to the keys letting you find the previous or next run and transfer this to the L.M., there are also:

- keys letting you find a single image in the run,

- the start/stop cine-loop key that lets you view all the images in the run in a dynamic loop (presentation mode).

- The **Cursors** are used to limit the scenes of images to be reproduced by the cine-loop. Move the **Start Cursor** in order to start the reproduction from an image other than the first one; move the **Stop Cursor** in order to end the reproduction at an image before the last acquired one. The image numbers of the first and last image of the scene are displayed under the start and the end of the progression bar.



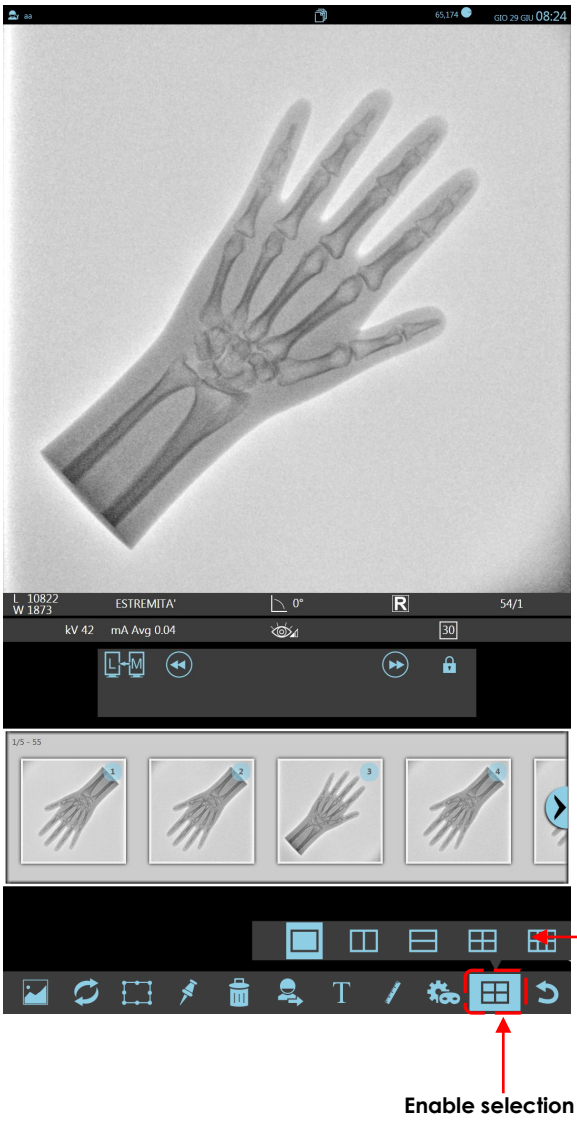
- The **Reference image** key stops the cine-loop at that image, thus disabling the other keys at the same time; press the key once again to end the function.

5.2.8.4 VIEWING MULTIPLE IMAGES

The Memory Monitor (M.M.) lets you view the images in OVERVIEW mode.

Touch the relevant key:

M.M.



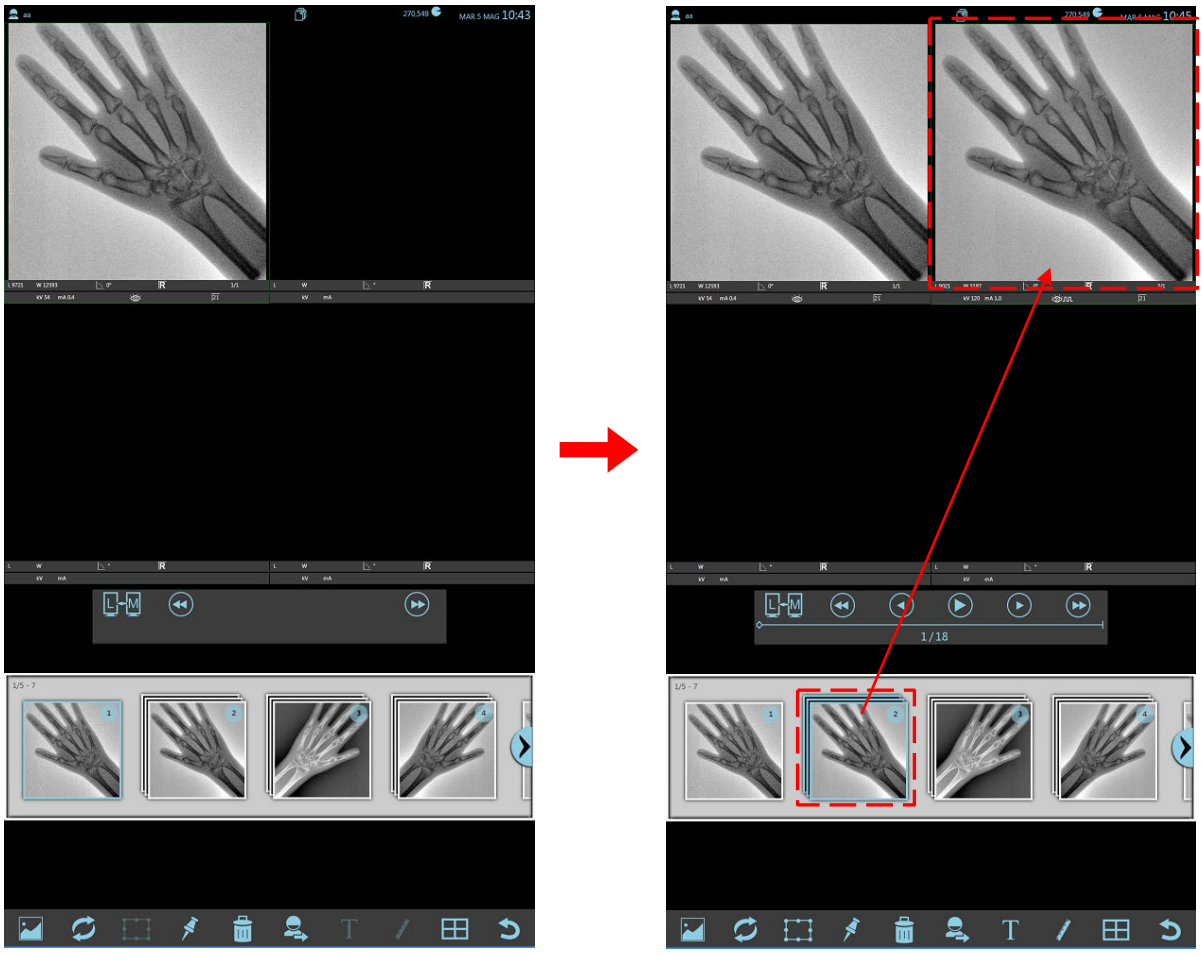
You can choose between 5 **different overview** formats:

Single 2 X 1 1 X 2 2 X 2 3 X 2

For example, if you select format 2x2, the screen will look like that below.

To load the runs into the overview boxes, first select the required box and then the run; once you choose the appropriate image, just drag it with your finger into the selected box.

M.M. **M.M**



The same interface as described above for a single image applies to each overview box; *see Paragraph 5.2.8.1 above for the functions available for each run.*

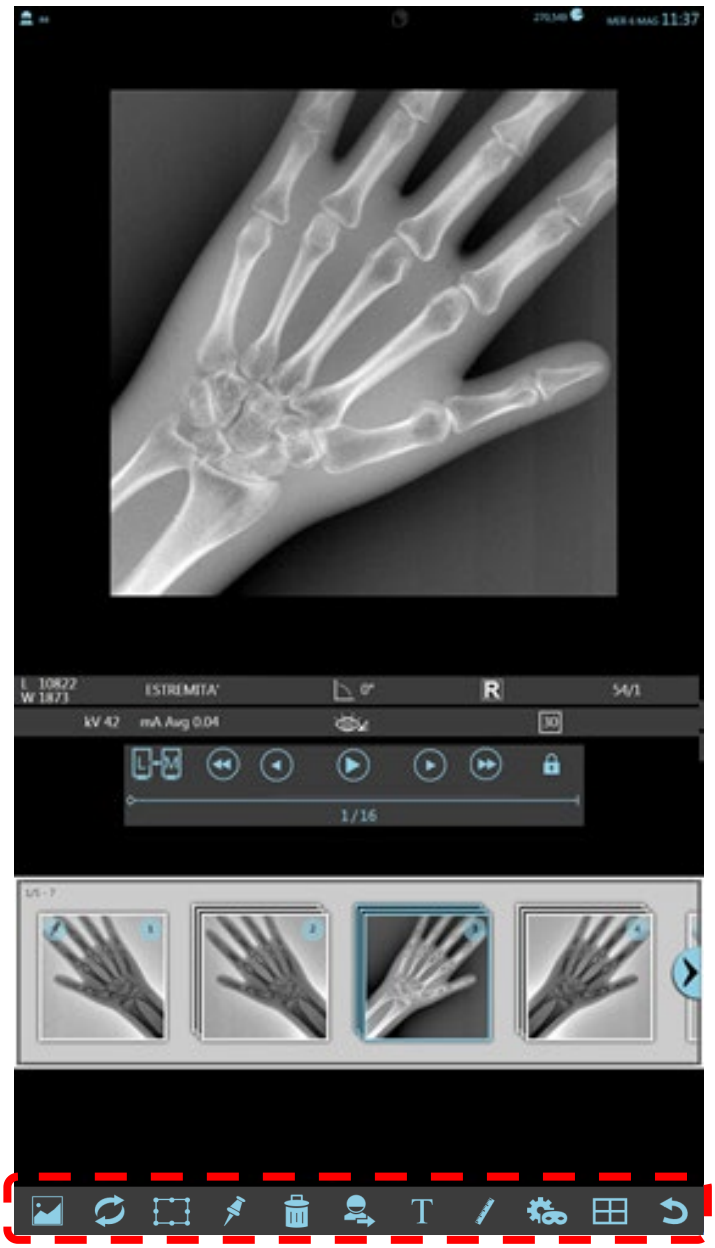
Note: *even in multi-image boxes, you can adjust the values of W and L using the dedicated gesture.*

5.3 POST-PROCESSING OF IMAGES

5.3.1 INTRODUCTION

Images saved to hard disk can be processed via the Memory Monitor (M.M.):

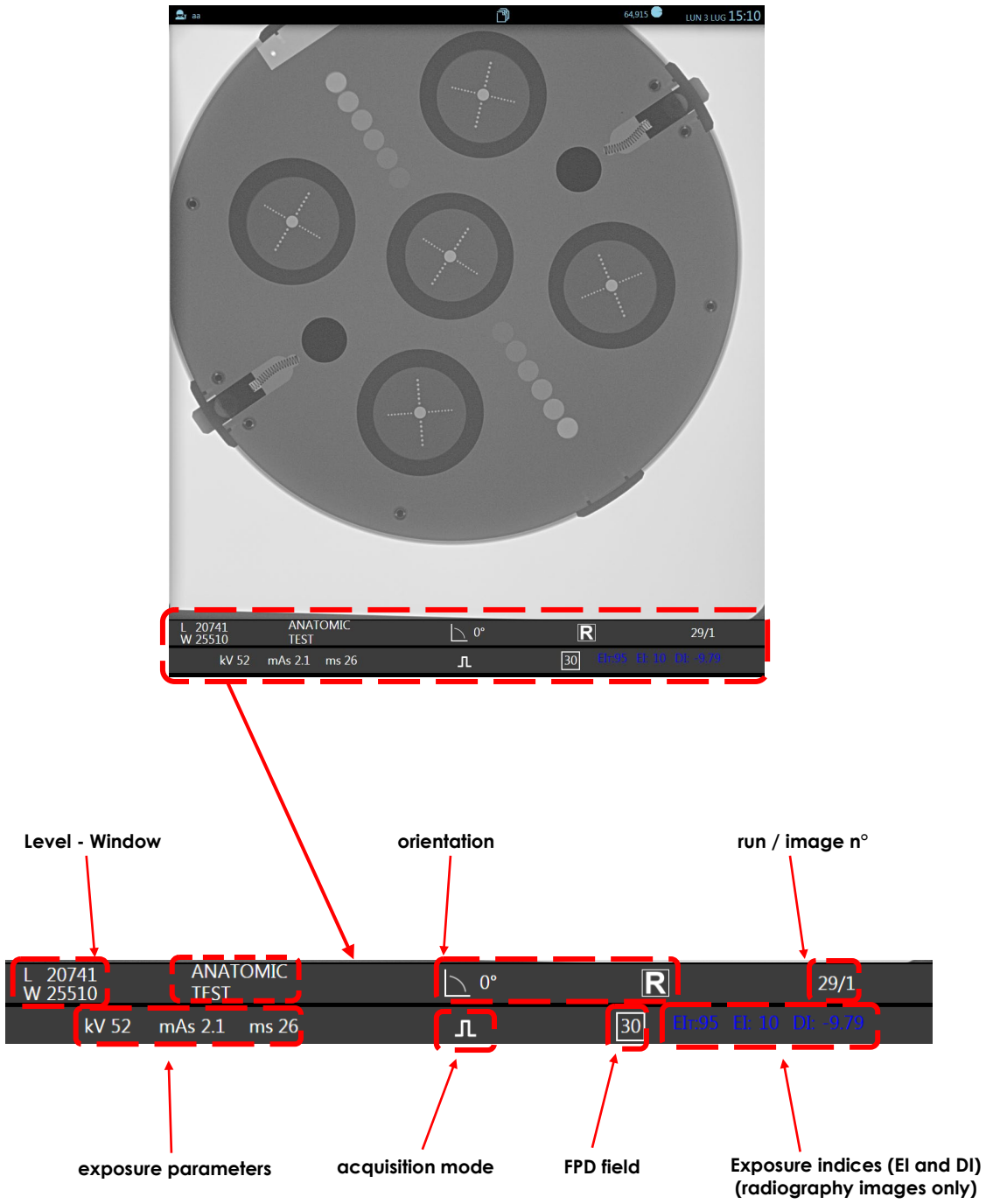
M.M.



Post-processing functions

Note: *The 'Find image', 'Overview' and 'Cine-loop' functions have already been described in Paragraph 5.2.8 above.*

5.3.1.1 ACQUIRED IMAGE DETAILS

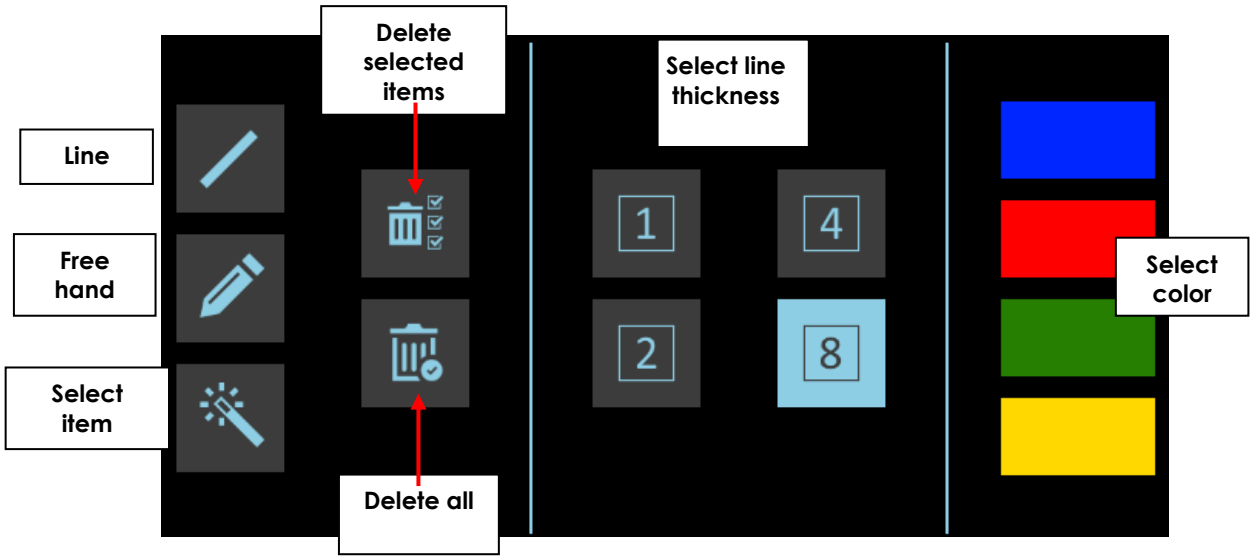


5.3.1.2 LIVE DRAWING FUNCTION

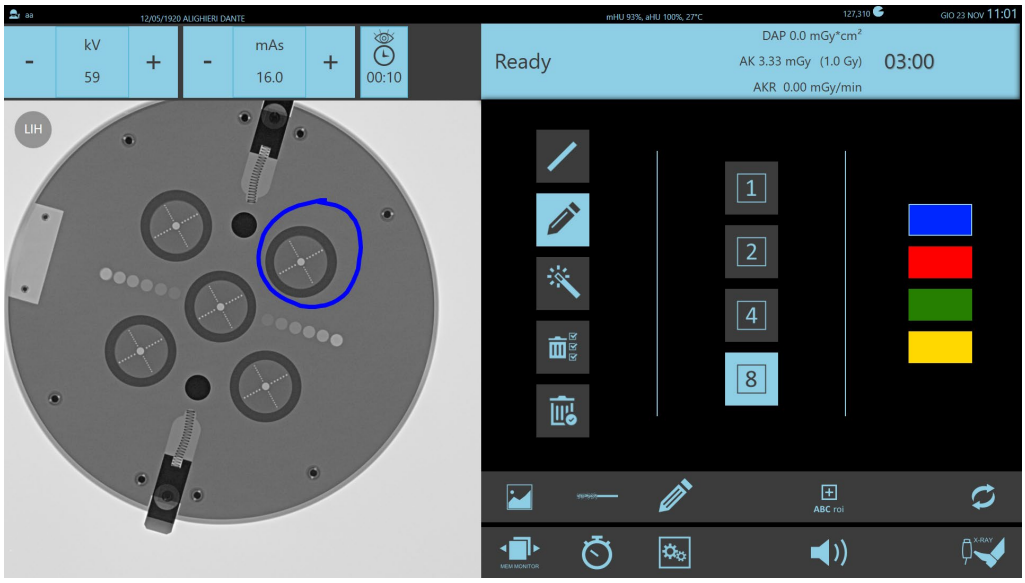
The **Live Drawing** function can be used on the **Live Monitor** and the **Control Panel**; this function allows you to make temporary drawings on the image by inserting straight lines or drawing in free hand mode. You can also select the thickness and the color of the line.

These lines will remain in the place they were drawn even for the following acquisitions. They can thus be used as points of reference during the intervention.

Press the corresponding key and the following menu will appear:



Once you have selected the line type, the thickness and the color, you can start drawing on the image.



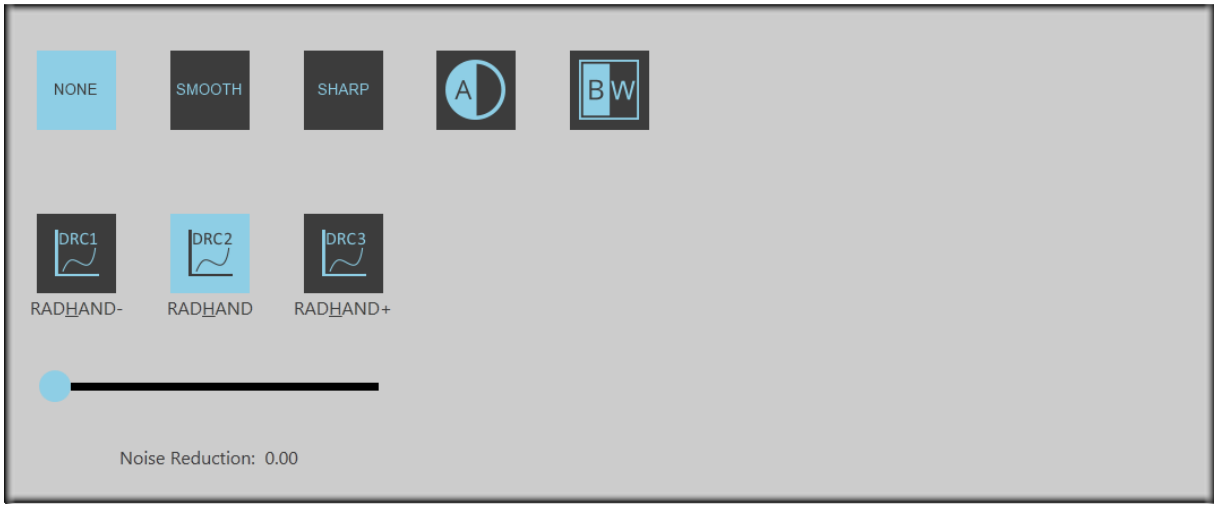
Use the corresponding key to delete the drawing (**Delete all**); in case there is more than one drawing, and if you do not wish to delete them all, you can press the key **Select item**, then select those you wish to delete (the selected image will appear in a dashed line) and use then the key **Delete selected items**.

When changing to another exam or when closing the study, the drawings will be deleted automatically (the drawings are not saved with the image).

Note: *to enable this function see Paragraph 4.4.1, Part 2 of the Technical Manual.*

5.3.2 IMAGE PROCESSING

Touch the key shown here to open the IMAGE PROCESSING menu:



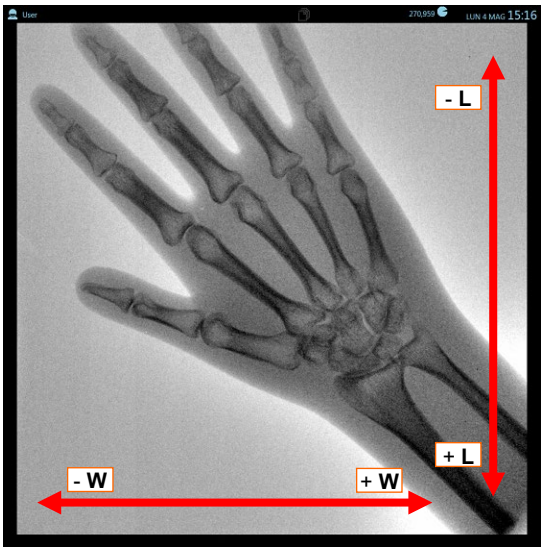
This menu offers these options:

- **Adjust the W and L**
  You can change the look of saved images by adjusting the contrast (Window - W) and brightness (Level - L) either automatically or manually:

In automatic mode, the EM equipment sets the W and L values to suit the contents of the image.

In manual mode, you can change the W and L values by swiping your finger across the image:

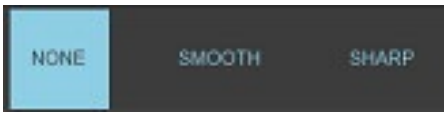
- swipe horizontally to change the W value.
- swipe vertically to change the L value.



- **Grey scale inversion**
  Select this key to invert the grey scale (negative or positive presentation):

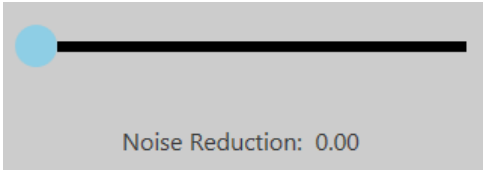
Positive	Negative
	

- **Select spatial filters**
  Each exam type can use one of two set spatial filters: SHARP (to enhance the edges) and SMOOTH (to soften the edges).
  Touch NONE for neither filter.



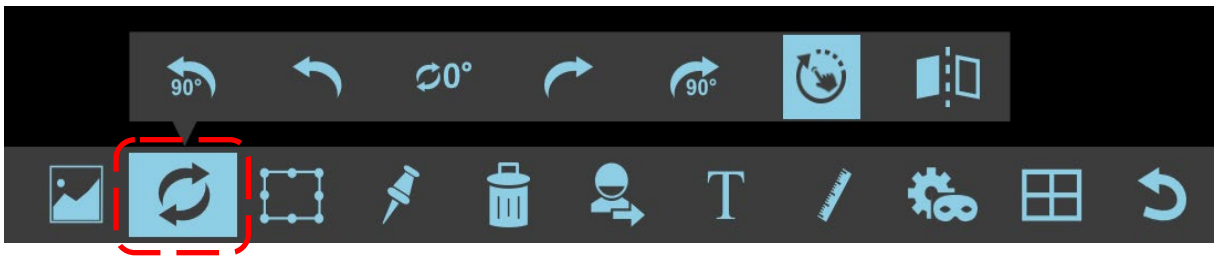
- **Select DRC**
  Each exam type can use one of three image dynamics and contrast control processes (**DRC**, **dynamic range compression**). These three processes are programmed during installation to suit the type of exam.

- **Noise Reduction factor**
  This function allows to reduce possible noise on the image by increasing the value of this factor; the **range** goes from **0** to **10**.



5.3.3 IMAGE ORIENTATION

Touch the key shown here to open the IMAGE ORIENTATION menu:

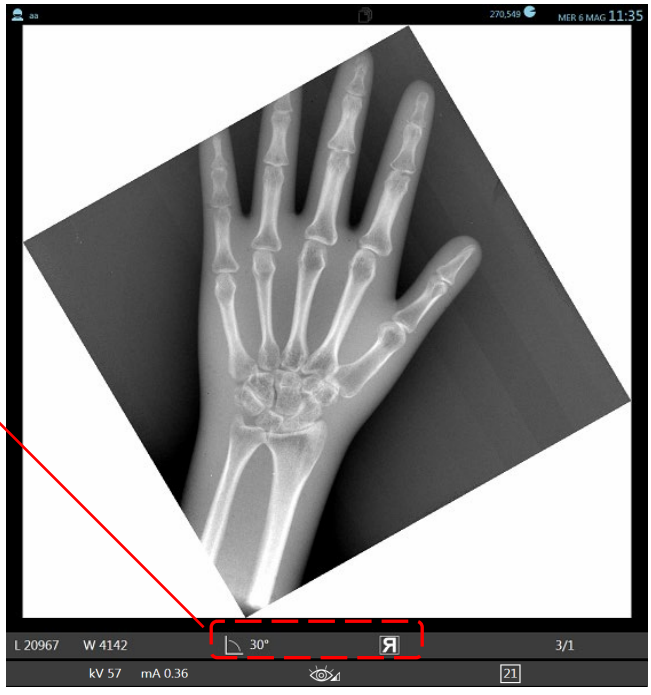


This menu offers these options:

	90° image rotation (anti-clockwise)
	Anti-clockwise image rotation (steps of 1°)
	Image rotation reset
	Clockwise image rotation (steps of 1°)
	90° image rotation (clockwise)
	Allows to freely rotate the image
OFF  **ON** 	Horizontal image flip

Example:

The image is rotated 30° clockwise and then flipped horizontally.



5.3.4 ELECTRONIC SHUTTERS

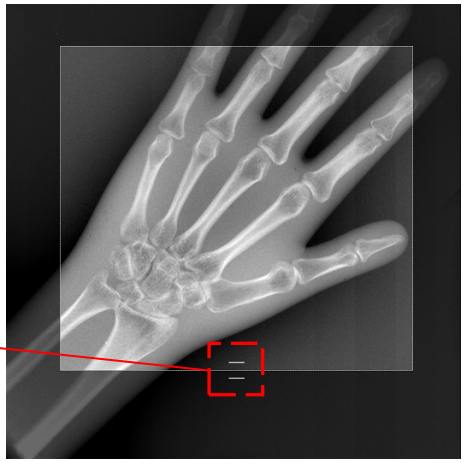
Electronic shutters let you cover unwanted parts of an image after acquisition.

To use this function, touch the key shown:

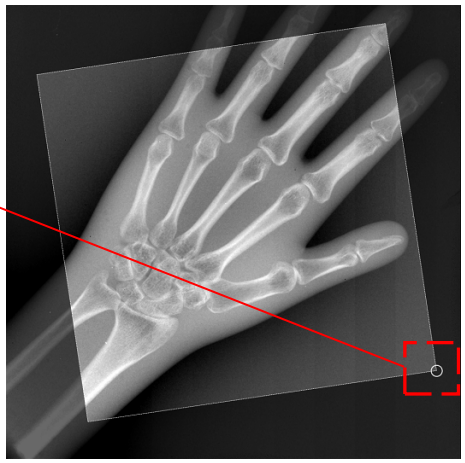
- Use your finger to draw a diagonal line across the rectangle you want to crop (all parts of the image outside this rectangle will be covered by a black background):

- After selecting the interested area, you can:

  - Change its size by touching one of its sides and then moving this as required.

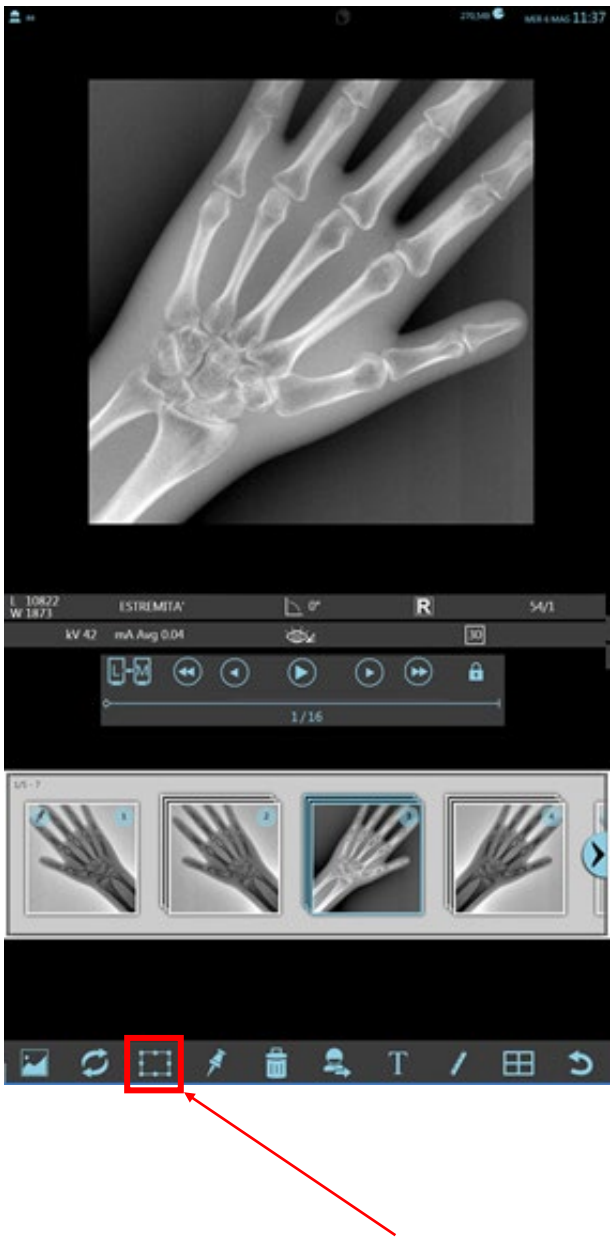


  - Rotate it, by holding one of the corners and dragging it to the required position



  - Shift it, by touching one point inside the collimated area and dragging it to the required position

- Quit this function, confirming the cropped image, by touching this command again: 



- You can then cancel the crop by touching this function again:

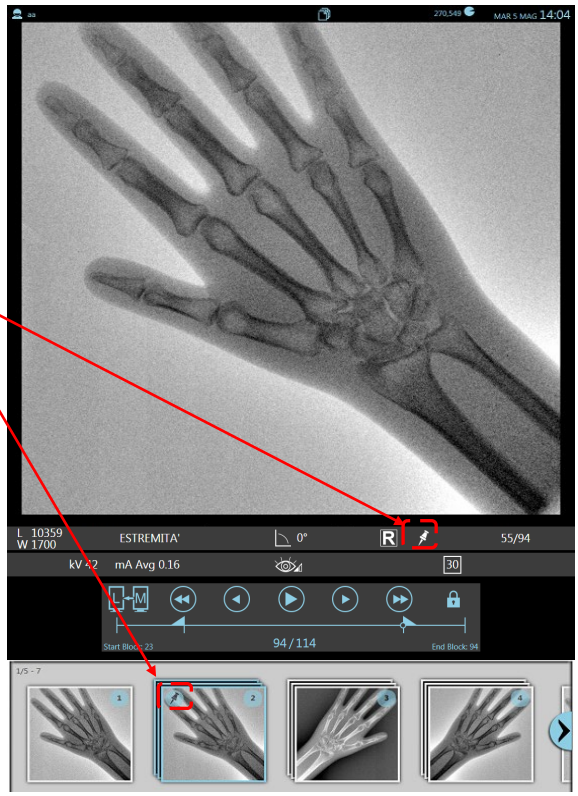
Note: *You can only crop an image if the portion of the image you want to retain is at least 2x2 cm.*

5.3.5 FLAGGING IMAGES

Saved images can be flagged (pinned) to facilitate the DICOM send operations (*see Paragraph 5.5 below*). In fact, the system checks whether there are any flagged images when you select these functions and displays them with a message so you can decide what to do.

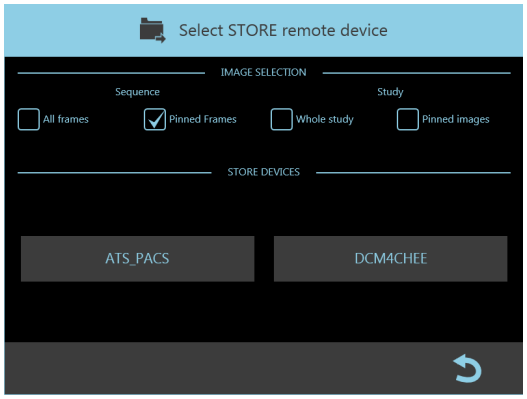
- Flag an image by touching this key:

The pin symbol appears next to flagged images:



- The following window appears when you send pinned images to a DICOM server. This lets you choose the server you want to send the images to. Furthermore, you can choose to send:

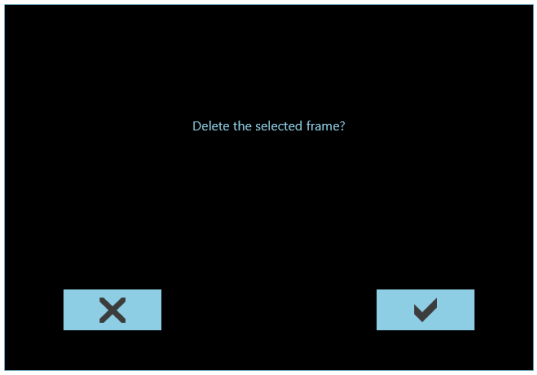
  - all the images in the selected run,
  - all the flagged frames in the selected run,
  - the whole study,
  - all the pinned images within the study.



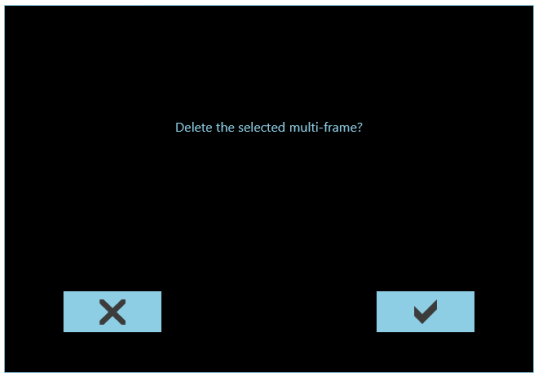
5.3.6 DELETING IMAGES

You can delete images on the screen by using this key:

You are asked to confirm deletion when you touch this key:



To cancel a single image

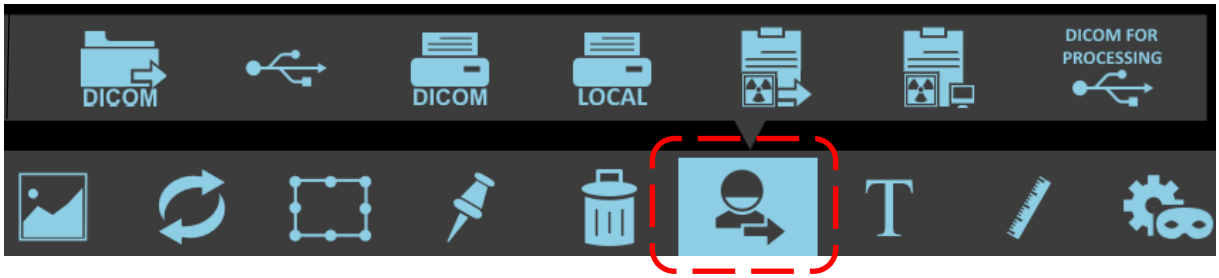


To cancel a multiframe run

You can also delete an entire **study** *(see paragraph 5.5.8.3 below)*.

5.3.7 IMAGE RECORDS

Touch the key shown here to open the IMAGE RECORDS menu:



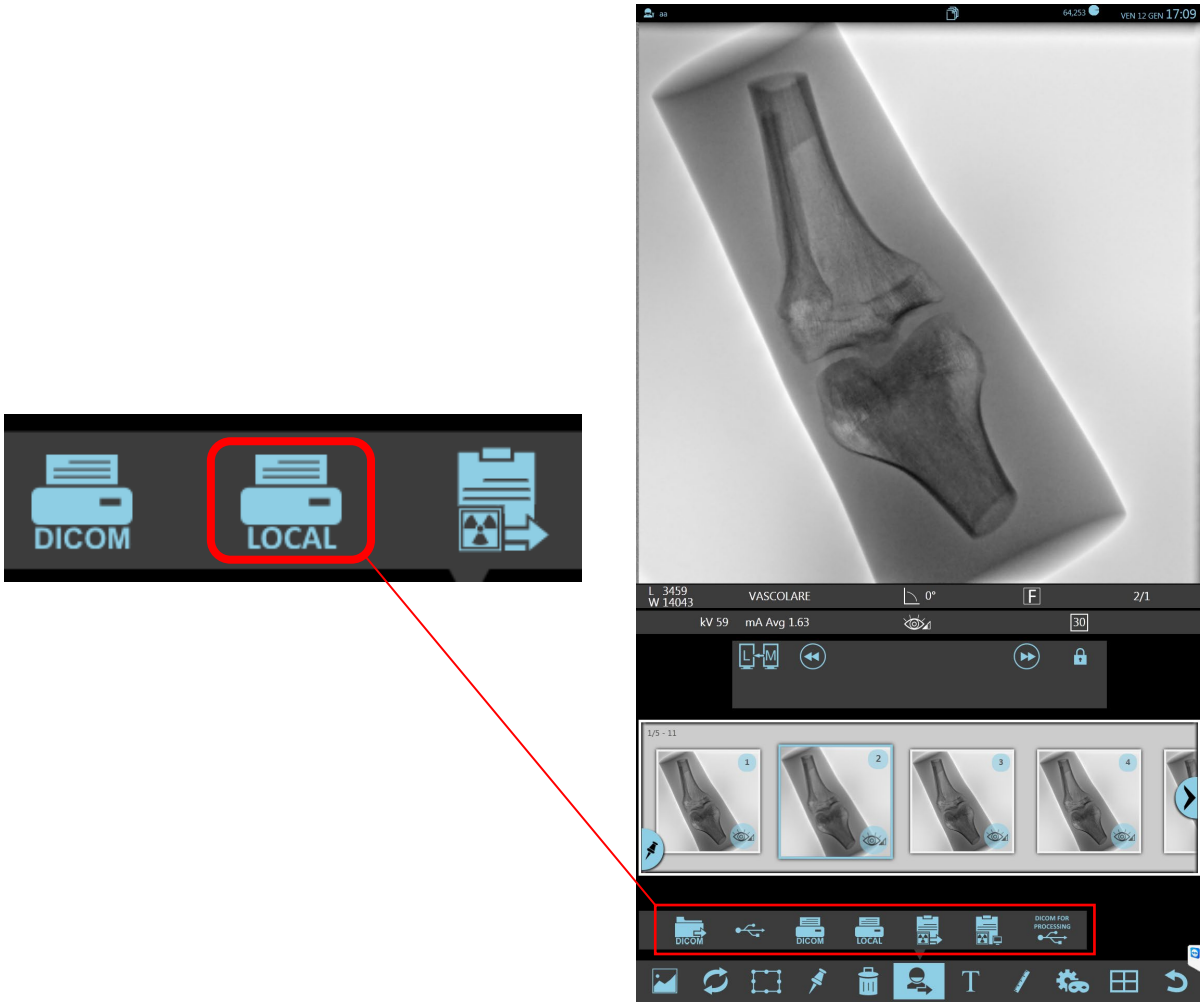
This menu offers these options:

DICOM	Send images to a DICOM node using the STORE DICOM function (*see paragraph 5.5.1 in this Chapter of the manual*).
	Save images in DICOM format to a USB device. (*see paragraph 5.5.4 in this Chapter of the manual*).
DICOM	Send images to a printer using the PRINT DICOM function (*see paragraph 5.5.2 in this Chaptert of the manual*).
LOCAL	Send images to a local Windows compatible printer *(see paragraph 5.3.7.1 below)*.
	Send RDSR file (information about irradiating dose given to the patient) to a default DICOM storage device used to record the X-ray dose given to the patient.
	To display the RDSR file on your monitor (irradiated dose given to the patient).
DICOM FOR PROCESSING	Send images to USB Driver in **DICOM for Processing** format. The function is available for *Advanced* and *Administrator* users, only.
	Creation of the **Dose Report Image** containing the study and dose data received by the patient during the exam (*see Paragraph 5.3.7.2 below*).

5.3.7.1 DIRECT PRINT-OUTS (OPTIONAL)

The single image shown on the memory monitor can be sent to the local printer.

Select the corresponding command in the IMAGE RECORDS menu:



Wait for the image to be printed: do not keep pressing the key (thereby sending new copies of the same image to the print queue).

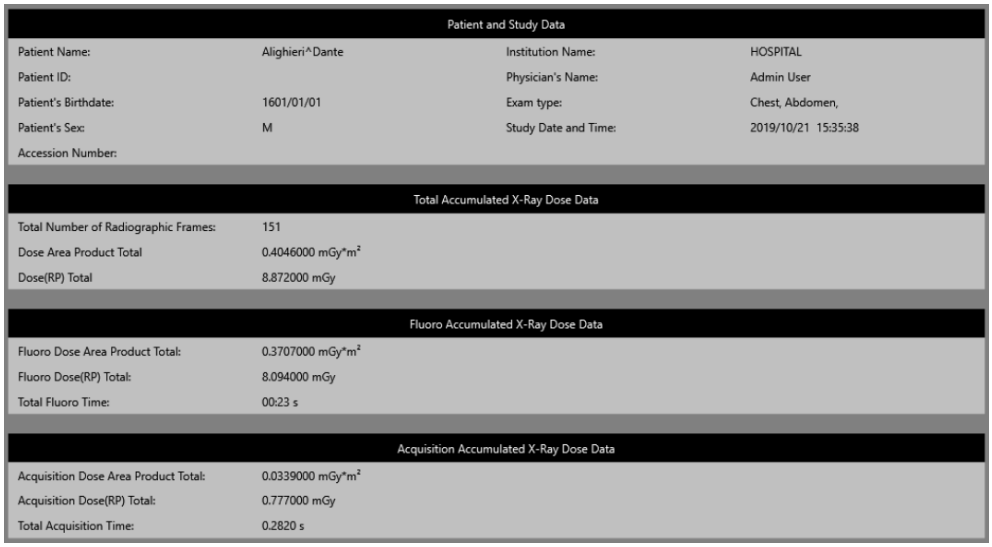
The EM equipment is provided with one of two possible printer models:

- **Sony Model UP-991AD,**
- **Sony Model UP D898MD.**

Note: *Printed images are* ***not*** *to be intended for clinical or diagnostic purposes.*

5.3.7.2 DOSE REPORT IMAGE

Pressing the dedicated button, the operator creates the **Dose Report Image** of the study. This will be displayed as the last image among the preview icons, numbered as a normal image of the study.



Patient and Study Data			
Patient Name:	Alighieri^Dante	Institution Name:	HOSPITAL
Patient ID:		Physician's Name:	Admin User
Patient's Birthdate:	1601/01/01	Exam type:	Chest, Abdomen,
Patient's Sex:	M	Study Date and Time:	2019/10/21 15:35:38
Accession Number:			

Total Accumulated X-Ray Dose Data	
Total Number of Radiographic Frames:	151
Dose Area Product Total	0.4046000 mGy*m²
Dose(RP) Total	8.872000 mGy

Fluoro Accumulated X-Ray Dose Data	
Fluoro Dose Area Product Total:	0.3707000 mGy*m²
Fluoro Dose(RP) Total:	8.094000 mGy
Total Fluoro Time:	00:23 s

Acquisition Accumulated X-Ray Dose Data	
Acquisition Dose Area Product Total:	0.0339000 mGy*m²
Acquisition Dose(RP) Total:	0.777000 mGy
Total Acquisition Time:	0.2820 s

The Dose Report image contains the study/patient data and dose parameters divided into four groups:

1 **Patient and Study data** that shows:
- Patient name,
- Patient ID,
- Patient's birthdate,
- Patient's sex,
- Institution name,
- Physician's name,
- Exam type,
- Study date and time,
- Accession number.

2 **Total Accumulated X-Ray dose data** that shows:
- Total number of radiographic frames,
- Total DAP dose,
- Total Air Kerma.

3 **Fluoro Accumulated X-Ray dose data** that shows:
- Total DAP dose in fluoroscopy mode,
- Total Air Kerma in fluoroscopy mode,
- Total acquisition time in fluoroscopy mode.

4 **Acquisition Accumulated X-Ray dose data** that shows:
- Total DAP dose in digital radiography,
- Total Air Kerma in digital radiography,
- Totale acquisition time in digital radiography.

Once the **Dose Report Image** has been created, the button is deactivated until a new acquisition is made. The image can be managed through the DICOM STORE, DICOM PRINT, LOCAL PRINT functions and can be saved on USB device.

Note: *to activate this function, see Paragraph 4.2, Section 2 of the Technical Manual.*

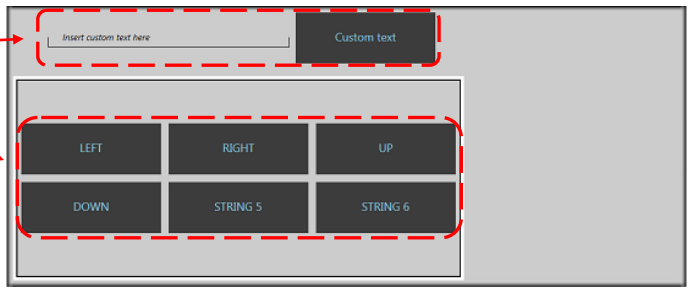
5.3.8 ENTERING TEXT

You can add a comment to the image (text) by using this key:

The following window appears, letting you:

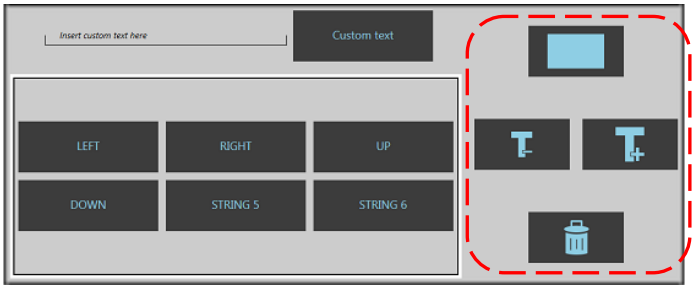
- Enter free text

- Enter set text programmed during installation (fixed strings)



- After selecting the type of text in this menu, touch the position on the image where you want to add the text; if necessary, drag the text with your finger to move it.

- If necessary, by touching the text you can also:



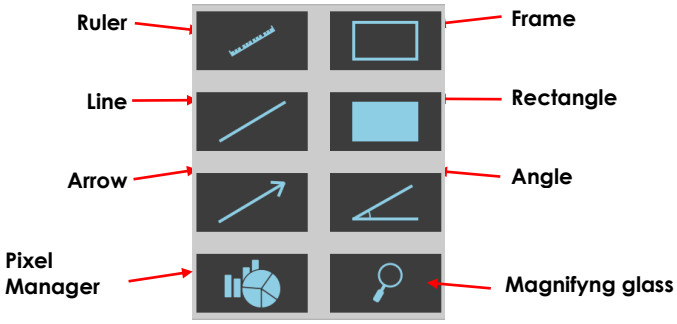
	change the background colour (clear or black)
	increase or decrease the size of the text
	delete the text

Note: *See the Technical Manual paragraph 4.8, Part 2 for instructions on how to create new "fixed strings".*

5.3.9 GRAPHIC FUNCTIONS

Touch the following key to activate the graphic functions:

The following window appears, with these symbols:



5.3.9.1 MEASUREMENTS - RULER

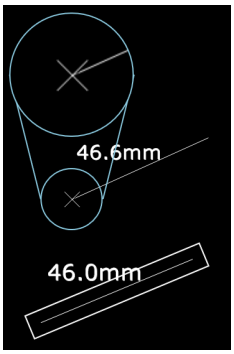
This function lets you measure linear segments in the image.

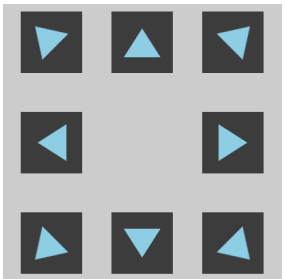
After selecting this function:

- Use your finger to draw a segment (ruler) between the two points you want to measure. A line automatically appears with the measurement in mm.

Note: *The measurement in mm refers to the surface of the FPD; if the anatomical part in question is not in contact with the FPD, you will need to calibrate the image as explained below.*

- You can also move the ruler to correct the position:
  - of the ends, by touching one of the ends and then moving it with your finger or the direction (arrow) keys.
  - the entire segment, by touching a central part of the line and then moving it with your finger or the direction (arrow) keys.





Note: *the direction keys move the object in steps of 1 pixel each time you touch these.*

In case that no calibration has been carried out on the image, the indicated measurement will be preceded by the **~** symbol (for instance: **~ 50.0 mm**).

The measurement is, however, shown without this symbol if the calibration has been carried out as described in the following chapter.

- You can also select the segment of an existing measurement and then:

  - decrease or increase the measurement font size using these commands:

  - delete the segment using this command:

Once you delete the segment, in order to make a new measurement it is required to press again the **Ruler** icon.

5.3.9.2 CALIBRATION

The calibration function lets you correct linear measurements by setting a known length (calibration detail) in the image.

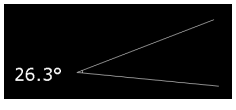
- Draw a segment over the calibration detail.
- Enter the known length of the calibration detail (in mm) in the relevant field and then touch the **Set** command: all the measurements on the image will be re-calculated on the basis of this new calibration.

Note: *The calibration applies to the whole run, provided that all the images were acquired using the same FPD zoom field.*
After the calibration procedure, the precision of the measurement is about ± 3%.

5.3.9.3 MEASUREMENTS – ANGLE

This function lets you measure angles in the image.
After selecting this function:

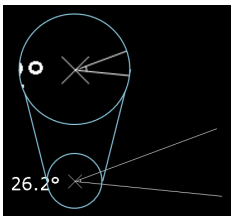
- Use your finger to select the 1st end, the vertex and then the 2nd end of the angle on the image.
  The angle is automatically drawn and its value shown.

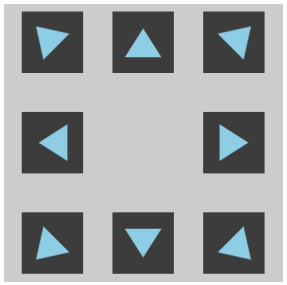


Note*: The angle measurement always refers to the smaller angle (less than 180°).*

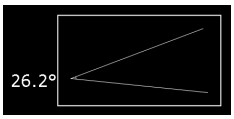
- You can also move the following to correct the position:

  - the ends or the vertex of the angle, by touching one of these and then moving it with your finger or the direction (arrow) keys.





  - the entire angle, by touching a central part of one of the two lines and then moving it with your finger or the direction (arrow) keys.



Note: *the direction keys move the object in steps of 1 pixel each time you touch these.*

- You can also select an existing angle and then:

  - decrease or increase the measurement font size using these commands:

  - delete the angle using this command:

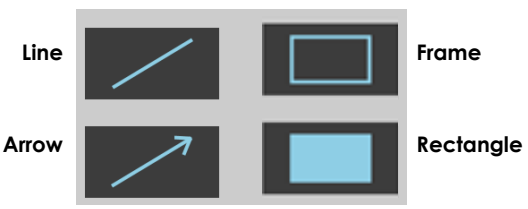
Once you delete the angle, you need to press the **Angle** icon again to make a new measurement.

5.3.9.4 GRAPHIC OBJECTS

You can also add graphic objects to the image.

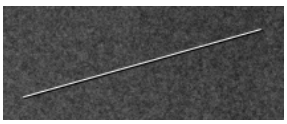
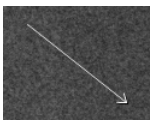
To highlight an area of interest in the image, use one of these objects:

- Line
- Arrow
- Frame



To cover a part of the image,
use the object:
- Rectangle

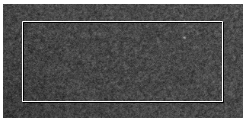
After selecting the relevant function:

- Use your finger to draw:
  - a line (for a Line or Arrow)

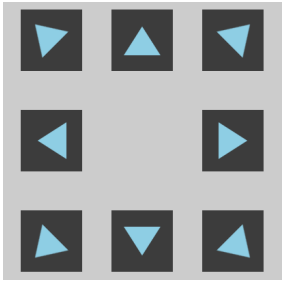
    or

  - the diagonal of the rectangle
    (for Frame or Rectangle)




The selected object is automatically drawn on the image.

- If necessary, by touching the object on the image you can also:
  - move it, by touching it and then moving it with your finger or the direction (arrow) keys.
  - change it, by touching a side or angle and then moving it with your finger or the direction (arrow) keys.



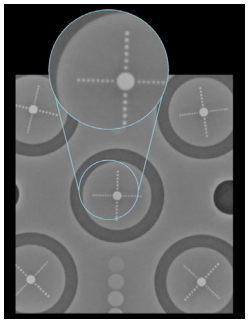
- delete the object using this command:

Once you delete an object, you need to press the relevant icon again to draw a new graphic object.

5.3.9.5 MAGNIFYING GLASS

Pressing the relevant key, this tool enlarges a particular point on the image.
It magnifies of two times (2x), a circular area of 150 pixels of diameter.

Touch the point of interest to see it enlarged, as shown in figure aside.
Until the function is enabled, whatever point is touched on the image, it will be shown enlarged.

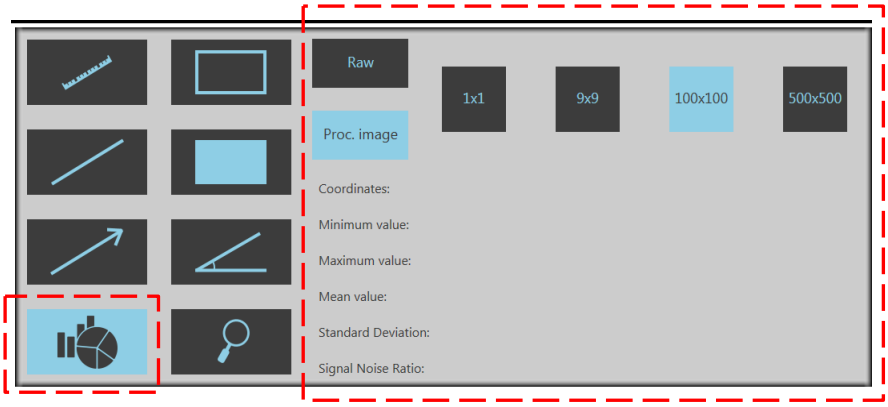


To disable the function, press again the relevant key.

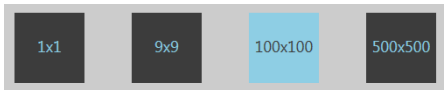
5.3.9.6 PIXEL MANAGER

The Pixel Manager function is used by the Technical Service when checking the system and can only be used by Administrator or Advanced user.
It lets you find the co-ordinates and the value of the pixels forming the image.

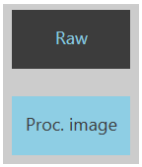
To use this function, touch the key shown:



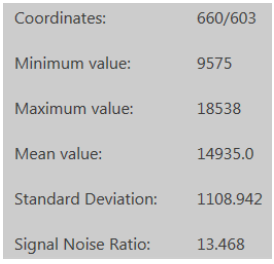
- You can select a portion of the image in which to read the pixel values:
  - 1x1 pixels
  - 9x9 pixels
  - 100x100 pixels
  - 500x500 pixels



Use the **Raw** setting to detect the unprocessed image levels at the time of acquisition by the FPD.
Alternatively, use the **Proc. image** setting to measure the levels after processing.



The following values are displayed:
- **Coordinates** : the X and Y coordinates of the pointer
- **Minimum value** (in LSB)
- **Maximum value** (in LSB)
- **Mean value** (in LSB)
- **Standard deviation**
- **Signal noise ratio**



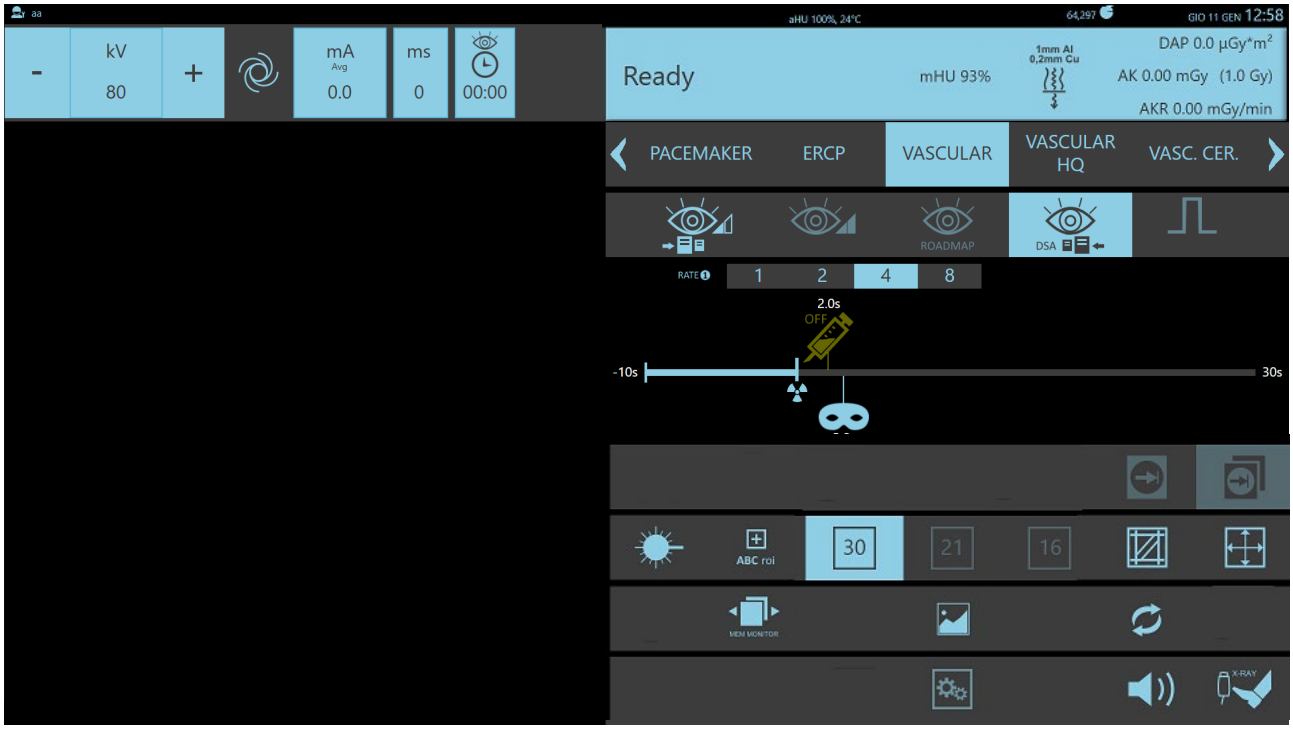
5.3.10 QUITTING THE STUDY

Touch the following key to close the current study and return to the Study List:

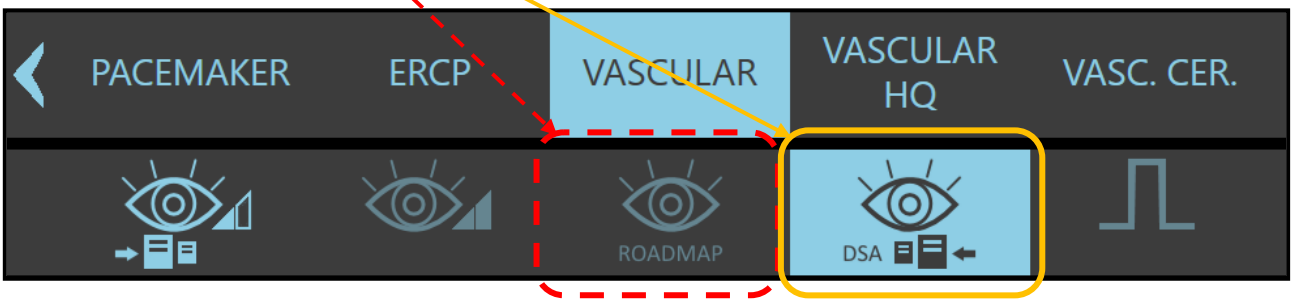
5.4 DIGITAL SUBTRACTION ANGIOGRAPHY (DSA)

The DSA function allows you to acquire images in subtraction mode.
This means that an image is subtracted from another, in order to see only the differences.

The DSA function can be used whenever you choose one of the DSA exams, preset during installation (to enable the DSA functions for a specific exam, see *Paragraph 4.4, Part 2 of the Technical Manual)*.



The various **DSA acquisition** modes possible for the chosen exam are shown together with the other preset techniques.



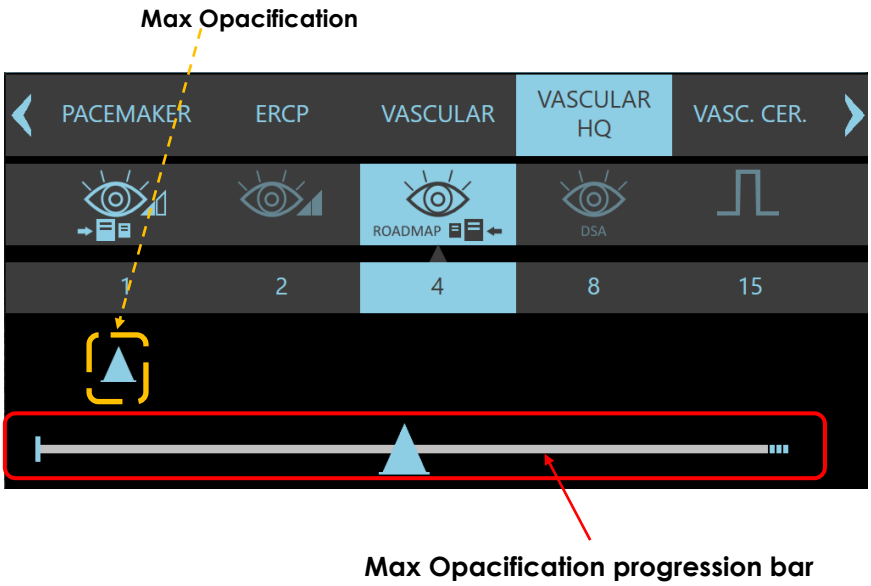
5.4.1 ROADMAP

ROADMAP mode consists of two phases:

- The first X-ray emission creates the **Max Opacification** image, fixing the opacity peak trace left by the contrast agent as this passes through the vessel.

- The following X-ray emissions produce images subtracted from the max opacification image that has been set as a mask. This function makes it easier for you to control the introduction of a catheter in the vessel (**Road Mapping**).

On selecting ROADMAP acquisition mode, icons appear for the two phases, together with the **Max Opacification** progression bar.



The triangle on the progression bar indicates when the function starts to 'fix' the path of the contrast agent. There is a 2-3 second delay between X-ray exposure and the start of the Max Opacification function (set during installation). This is needed to allow for automatic stabilization of the exposure parameters.

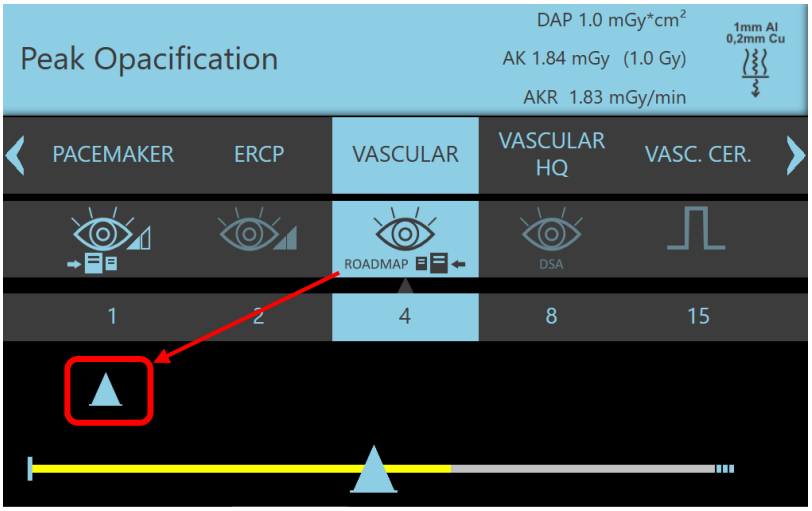
- When you press the X-Ray control (footswitch or button), X-Ray emission starts and the progression bar turns yellow.

  Max Opacification acquisition mode starts once the triangle is reached:

  - the **Injector** symbol to the **Max Opacification** triangle are added on the image in acquisition,

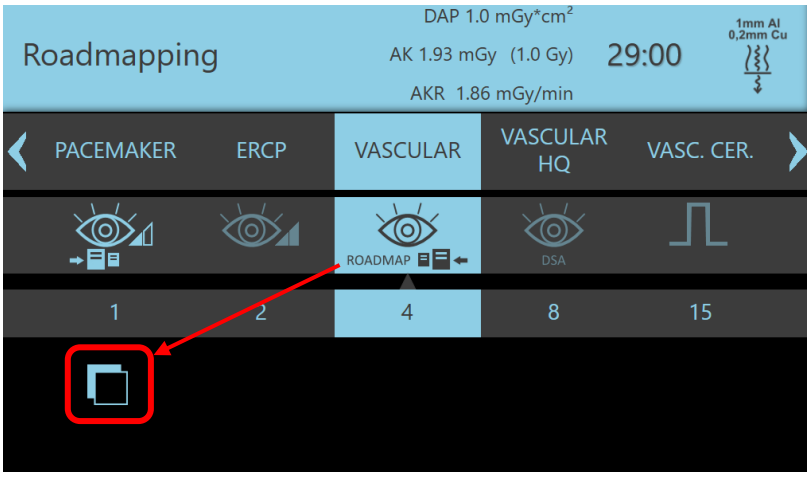
  - the operator can now start to inject the contrast agent,

  - the path of the contrast agent will be shown on the monitor and saved.



- When the injection is over, release the footswitch/handswitch x-ray command: on the monitor is displayed **Max Opacification** image.

- The **Road Mapping phase** starts with the next X-Ray emission**.** The subtraction between the live image and the Max Opacification image is now shown on the monitor: the vessel with the contrast agent appears "white", while the catheter shape will be "black".



- Any further X-ray emissions will still be in **Road Mapping** mode.

Press the ROADMAP button or another acquisition mode button to quit this function.

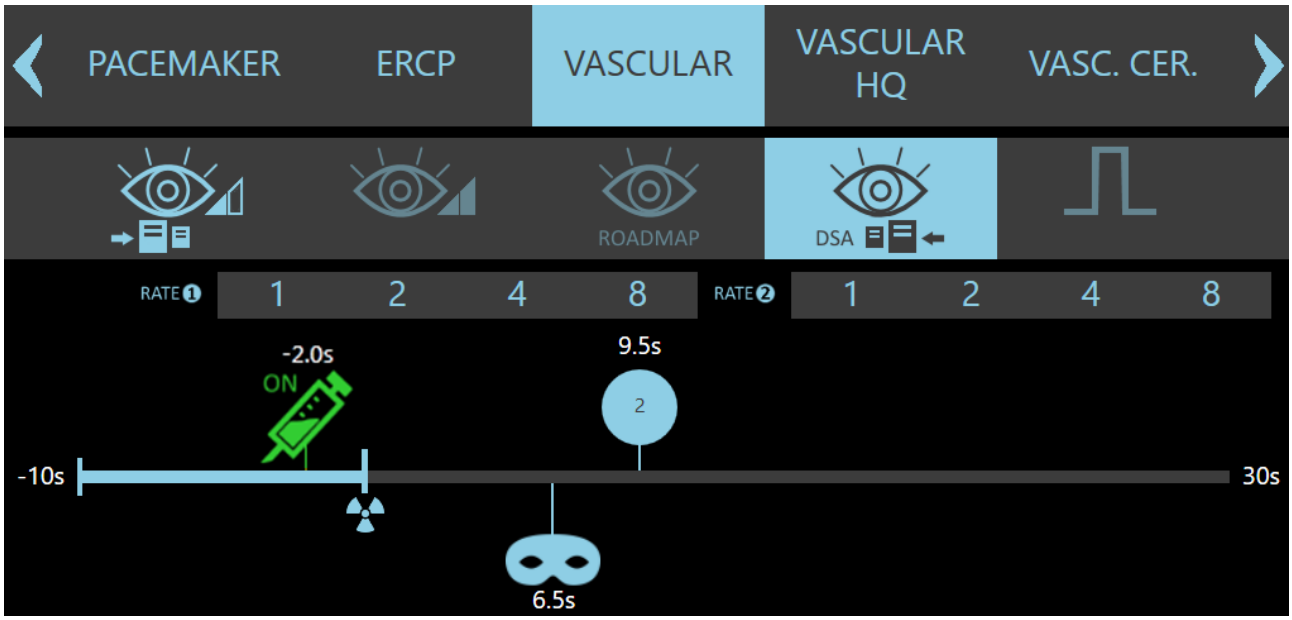
5.4.2 DSA FLUOROSCOPY MODE

The following parameters are automatically set when you choose a DSA exam in fluoroscopy mode, in addition to the normal parameters provided for non DSA exams. These DSA parameters can be programmed and set during installation:

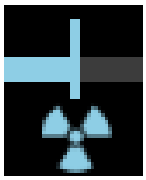
Parameter	Settings	Notes
Number of acquisition phases with defined duration and acquisition rate.	Two phases (**AutoSequence** ON) or a single phase (**AutoSequence** OFF).	The exam can have a maximum duration of 40 seconds (up to 10 seconds head start for the injector, if required, and up to 30 seconds X-ray emission).
Duration of the phases. With **AutoSequence** ON, the duration of the first phase can be set (the duration of the second is variable according to the operator's requirements).	With **AutoSequence** function enabled, you can set the duration of the first phase from 0 to 25 seconds. The second phase will end 30 seconds after the start of the X-ray emission or on releasing the exposure command.	Before carrying out the exam, the operator has the possibility to change the phase duration on the Control Panel.
Acquisition **Rate** for each phase.	It depends on **Max FPS** set in the **Exam Setup**. Usually, the acquisition rate of the subsequent phase is lower than the preceding one.	The operator has, however, the possibility to change the rate of the phase on the Control Panel. This is possible either before or during the exam.
Automatic injector command.	**Injector ON** or **OFF**.	If set to **Injector OFF**, the automatic injector command will be disabled. If set to **Injector ON** but the injector is not connected or not loaded, the automatic injector command will be disabled (yellow symbol, status OFF). If set to **Injector ON**, and if the injector is connected and loaded, the automatic command is enabled (green symbol, status ON): the injector start will be given according to the set advance or delay time (see following), which is indicated by the symbol on the sequence progression bar.
Advance or delay of the injector start with regard to the exposure start.	From **-10 seconds** (max. settable advance) to **+25 seconds** (max. settable delay).	This setting comes predefined with the exam, but the operator can still modify it on the Control Panel. Whenever the injector is programmed to work in advance, pressing the X-ray command will start the injector.
Delay for automatic mask pick-up with regard to start of the X-ray emission.	Ranging from no delay at all up to 25 seconds.	Before carrying out the exam, the operator has the possibility to change this parameter on the Control Panel.

Once you select DSA FLUORO, the window for setting the acquisition sequence will appear.

The following pictures show an example with 2 acquisition phases.



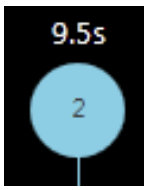
Sequence Progression bar



This icon represents the moment the X-ray exposure starts (zero point). This is the only icon you cannot move along the bar.
The section of the bar before this icon lets you set the anticipation between the injection and the start of X-ray exposure.

This symbol shows the injector status: if the injector is connected and loaded, the symbol will be green; otherwise it will be colored yellow and marked with the word OFF.
Moreover, the symbol shows the injector starting time (in seconds). It can be either negative, meaning an advance start or positive for a delayed start with regard to the start of the X-ray emission.
Before starting the acquisition, the time parameter can be changed by moving the injector symbol along the progression bar (it cannot be moved beyond the symbol for mask image pick-up).

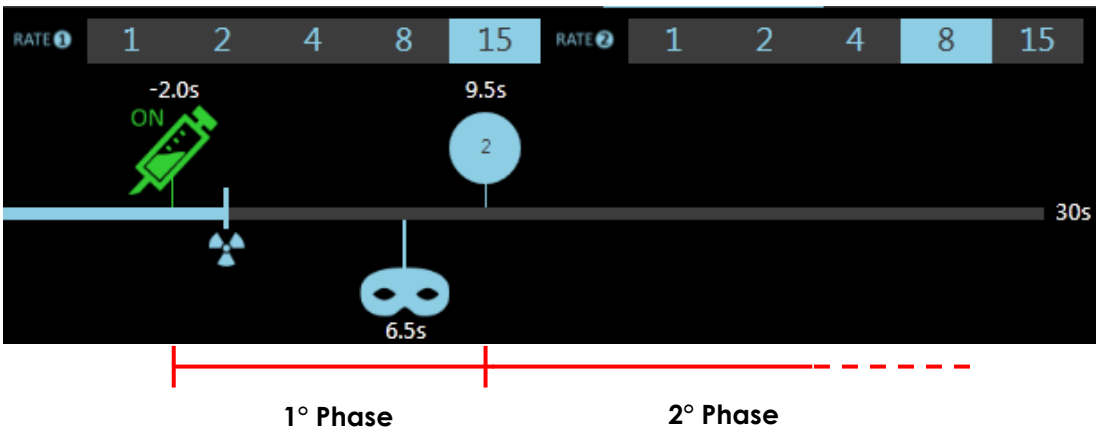
This symbol shows the delay (in seconds) with regard to the start of the X-ray emission for the mask image pick-up. Before starting the acquisition, the time parameter can be changed by moving the mask symbol along the progression bar.



The time in seconds indicated by this symbol corresponds to the starting time of the second phase with regard to the beginning of the X-ray emission, (it shows basically the duration of phase 1).
The time parameter can be changed by moving the symbol along the progression bar.

It is possible to change the rate of each phase by picking the required value from the selection list. The rates can even be changed during acquisition.

Note: *In case a **DSA** exam has been programmed with high mA (max 100 mA peak), the highest settable rate will be 8 fps (or 12 fps) instead of 15 (or 25 fps).*



● The sample picture above shows the following:

1) When pressing the X-ray command, this will trigger the injector start. After 2 seconds (advance time set for the injector start), the X-ray emission will begin at a rate of 15 fps.

2) After 6,5 seconds from the beginning of the X-ray emission, the mask pick-up command is given: from this moment on, the subsequent images will be shown in subtracted mode.

3) After 3 seconds (9,5 seconds from the beginning of the X-ray emission), the first phase comes to an end and the acquisition rate decreases to 8 fps (2nd phase).
The phase ends automatically once the time of 30 seconds from the beginning of the X-ray emission has been reached, or earlier if the X-ray command is released.
If the X-ray command is pressed once again, the same sequence will start over again.

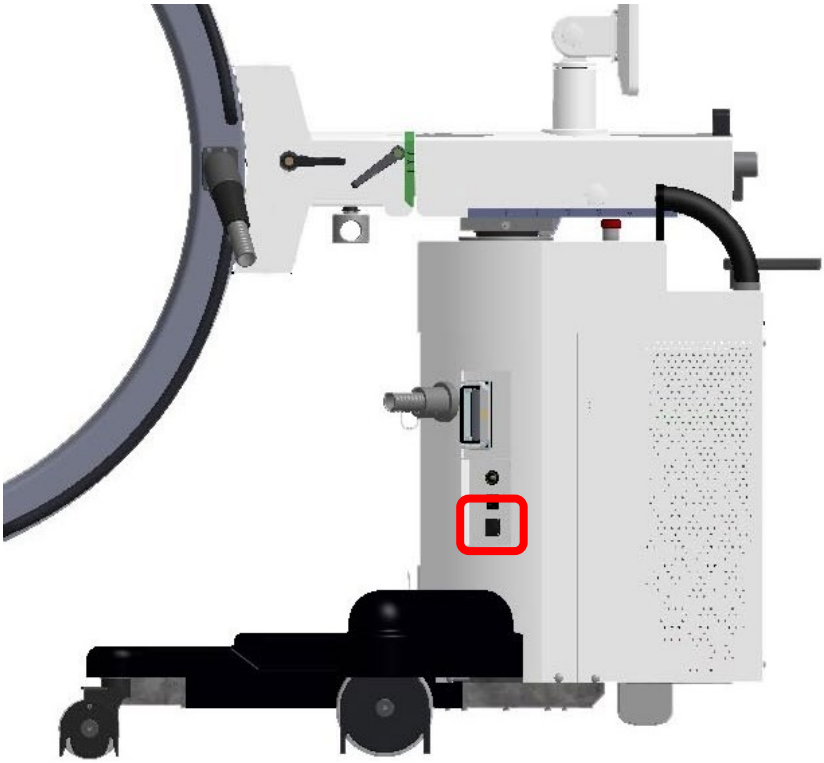
5.4.2.1 INJECTOR

The EM equipment is ready to command the start of a contrast media injector system. The function can be programmed within the DSA exams and allows a synchronized command of the device (either with a set advance or delay) with regard to the X-ray emission.
There is no preset injector: the connector shown below provides generic interface.
As a result, this function will only be available once the installer has completed the necessary electrical interface for a specific injector.

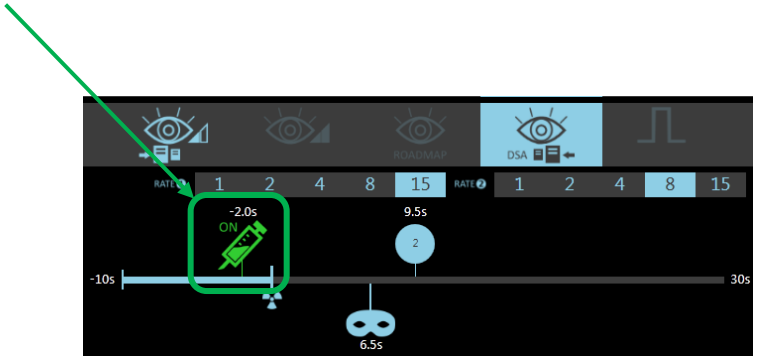
(*) Note: *See Paragraph 6.2, Part 5 of the Technical Manual for further details.*

With the equipment and all devices switched off, connect the injector interface cable to the connector shown in the figure below.

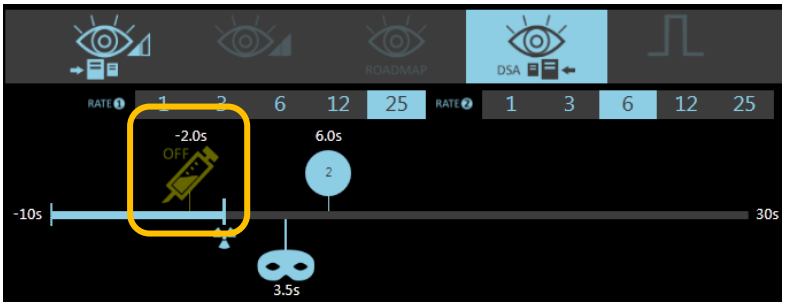
- Switch the equipment and devices on.
- Select an anatomical option compatible with the injector (**DSA exams only**).



If the injector is connected and loaded, the corresponding symbol will be green, meaning that the injector is ready for use during the exam.

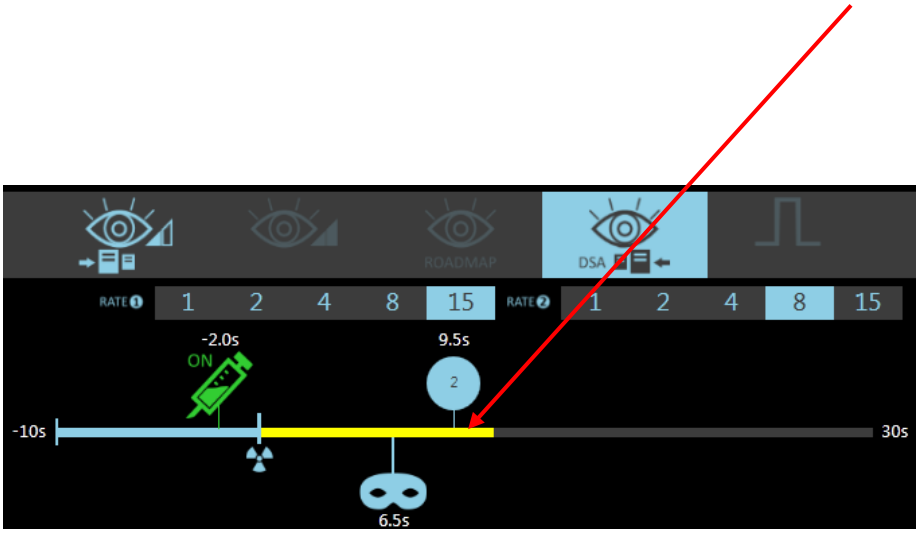


If, however, the injector is not connected nor loaded, the corresponding symbol will be yellow, meaning that the injector will **not** be activated by the EM equipment during the exam.



When pressing the X-ray command (foot- or handswitch), the DSA sequence will begin.
If the injector has been set to start in advance with regard to the X-ray emission, the DSA sequence will begin by starting the injector.

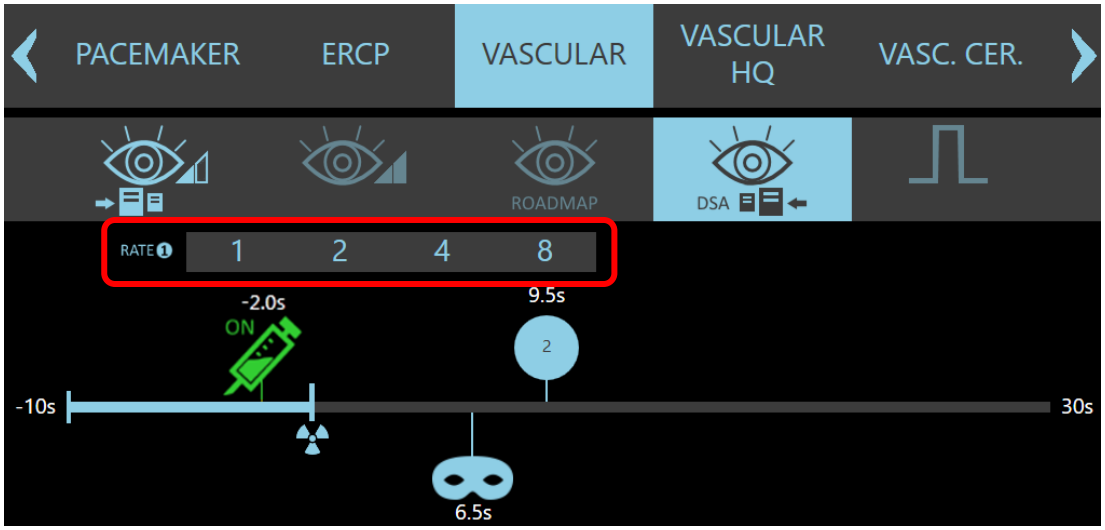
If, on the other hand, the injector has been set to start with a certain delay with regard to the X-ray emission, the EM equipment will start the injector once the sequence has reached the injector symbol; the progression of the sequence is shown by the corresponding bar which turns to yellow.



At the end of the acquisition, the injector returns disabled.

5.4.3 DSA ACQUISITION WITH FIXED PULSE RATE

In case the DSA sequence is programmed with a single acquisition phase (**Auto Sequence** function disabled, *see Paragraph 4.4.1, Part 2 of the Technical Manual*), the acquisition rate will be the same for the entire sequence.



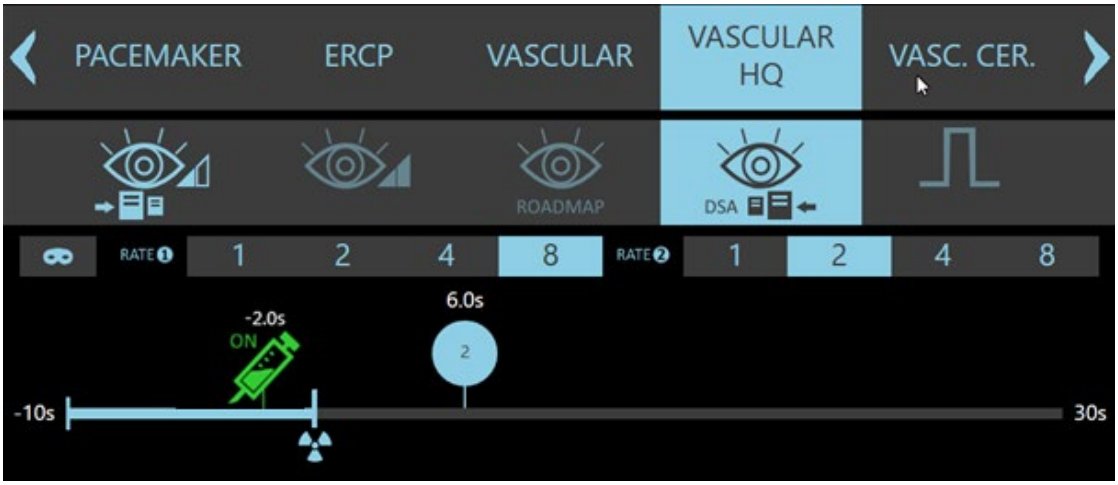
When selecting the DSA acquisition mode, the system automatically sets the rate predefined by the exam. The operator can, however, select a different value from those shown on the Control Panel either before or during the acquisition.

5.4.4 DSA ACQUISITION WITHOUT AUTOMATIC MASK PICK-UP

The sequence can be set without the automatic mask pick-up.

In this instance, the mask must be picked manually during acquisition using:

- the **mask icon** on the Control Panel,
- the **mask button** on the remote control.



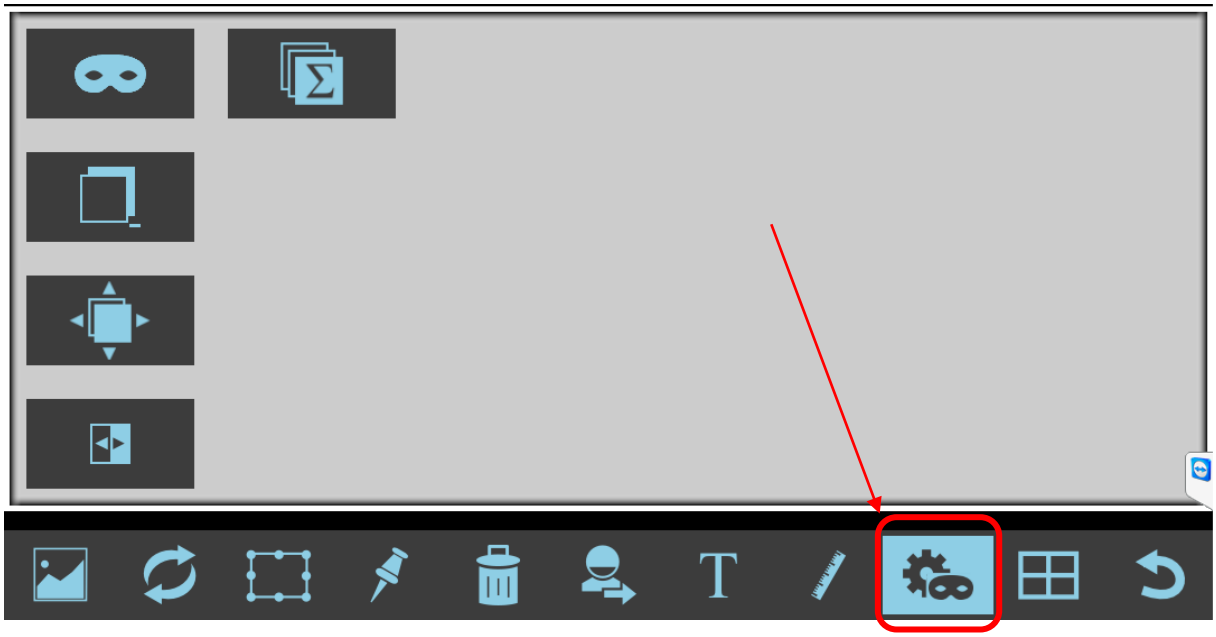
Note: *the mask can even be set after acquisition, during post-processing phase.*

5.4.5 DSA POST-PROCESSING

All the DSA sequences are saved to hard disk.

The images can thus be seen or processed on the MM using the post-processing functions. Certain post-processing functions are only available for DSA images.

Press the icon on the MM to access these functions:



1. **"Mask"** button 

2. **"Image Subtraction"** button. 

3. "**Shifting Pixels**" button. 

4. "**Land Marking**" button. 

5. "**Vascular Tracing**" button. 

5.4.5.1 DESCRIPTION OF ANGIOGRAPHIC FUNCTIONS

Once the DSA sequence of interest has been selected, it is possible to carry out the usual image viewing functions using the **Cine-loop** command (*see Paragraph 5.2.8.3, in this Chapter of the manual*) as well as the **Post Processing** commands (*see Paragraph 5.3, in this Chapter of the manual*) already described.
The **Cine-loop** starts with the image following the one picked as mask image.
Furthermore, the following functions are available:

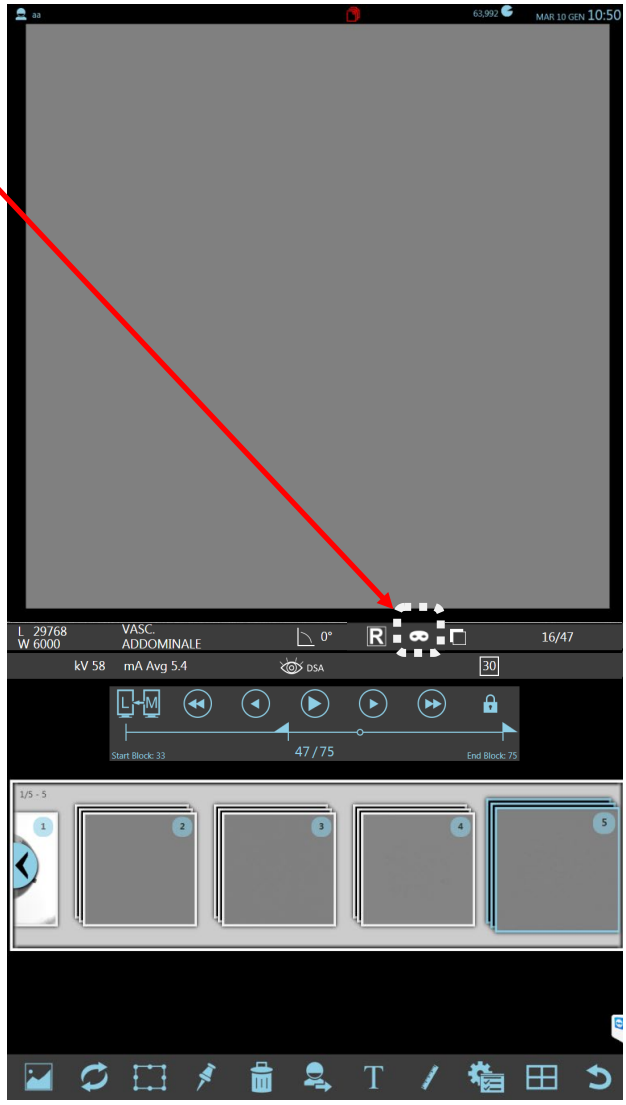
- **Mask**:

If you press this button, the viewed image will be set as the mask and this marker appears on the image.

This marker tags a mask image.

All the images in the sequence are now shown as subtracted images using this mask image.

You can repeat the procedure to choose a new **mask** image in the sequence (**Remasking**).



- **Image Subtraction**:

The images of the sequence can be displayed as normal or subtracted images.
Using the **Image subtraction** key, it is possible to switch the visualization mode of the images from subtracted to normal mode (and the other way round).

• **Pixel shift**:

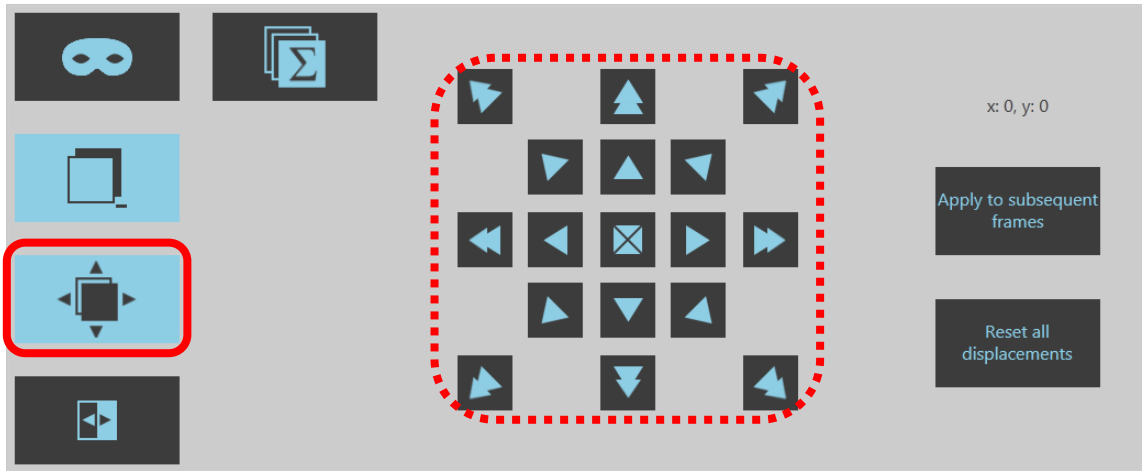
Movements made by the patient or positioning the C-arm during acquisition, can create artefacts on the subtracted image.
The **Pixel shift** function lets you move the image over the mask to realign them.

The menu shown below opens when you press this icon on a subtracted image.
Use the direction buttons to move the mask image to realign the edges.

You can move the image by:

- 0.25 pixel  or 1 pixel  steps.

- The central button restores the original image alignment. 



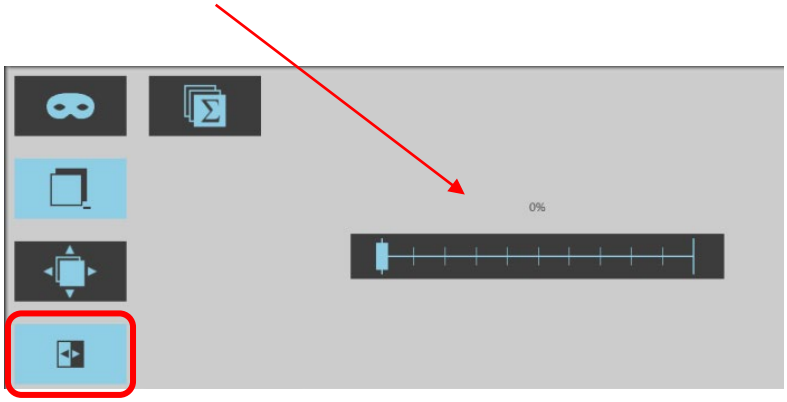
Once the necessary shift has been done, you can either apply it also to all subsequent frames or cancel all the movements carried out with one of the corresponding keys.

• **Land marking**:

The **Land mark function** lets you overlay a section of the mask image over the subtracted image in order to create an anatomical point of reference.

This function is only available for subtracted images.

The overlay percentage between the two images can be set using a dedicated slide bar:



- 0% Normal Subtraction

-100% Image not subtracted.

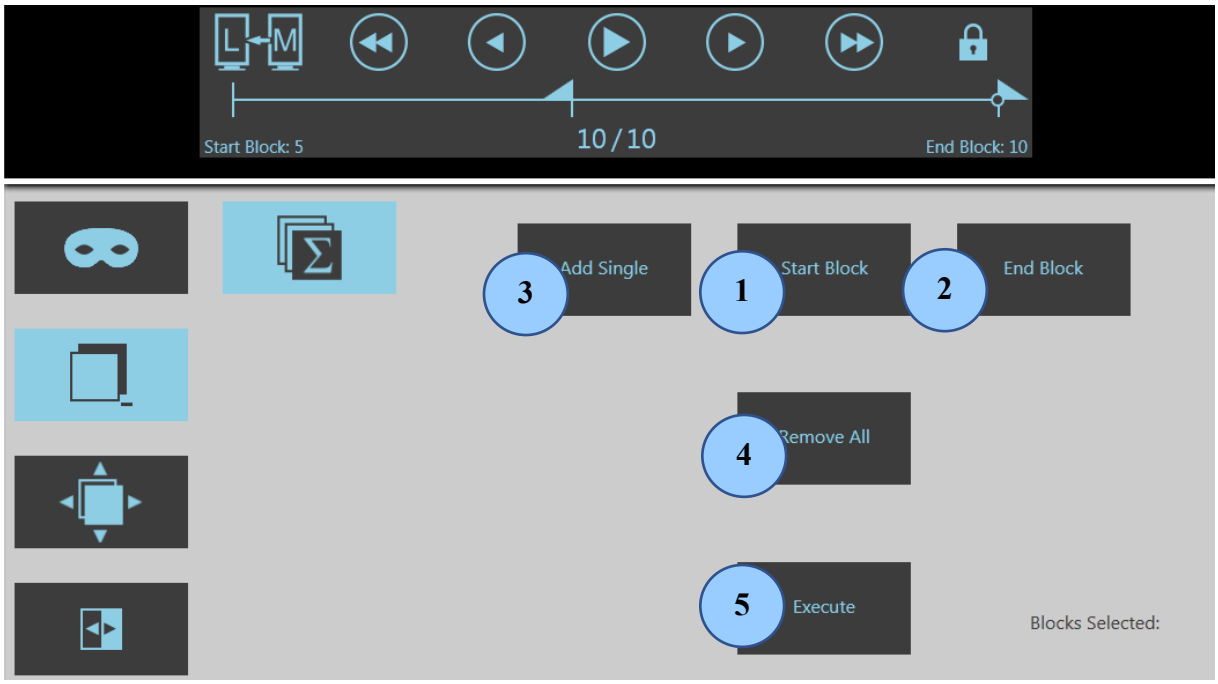
• **Vascular Tracing**:

This function lets you create a new image from the sum of any subtracted images selected within a run.

This function is only available for subtracted images. Press this button to open the following menu:

Image sum (vascular tracing):

This function is very useful and lets you reconstruct the entire course of the contrast media in the blood vessels. The following commands are available:



1) **Start block**: it defines the present image as the first image of the series that will be covered by the image sum function.

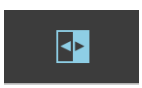
2) **End block**: it defines the present image as the last image of the series that will be covered by the image sum function.

3) **Add single:** it adds a single image to the sequence which will be covered by the image sum function (it will be sorted in the order of acquisition).

4) **Remove all**: it removes all images selected for the sum function.

5) **Execute**: it generates the image sum.

The image sum is stored and shown in the study previews.
If necessary, select the image and use the Land marking function (*see previous page*) to get a better visualization of anatomical landmarks.



5.5 TRANSFERRING IMAGES VIA DICOM

You can send images via the DICOM-3.0 protocol network:

- using the STORE DICOM function (see paragraph 5.5.1),
- using the PRINT DICOM function (see paragraph 5.5.2).

You can check whether transfer has been successful through the DICOM SPOOLER menu (see paragraph 5.5.3).

5.5.1 STORE DICOM

The EM equipment lets you transfer images to one or more STORE DICOM devices:

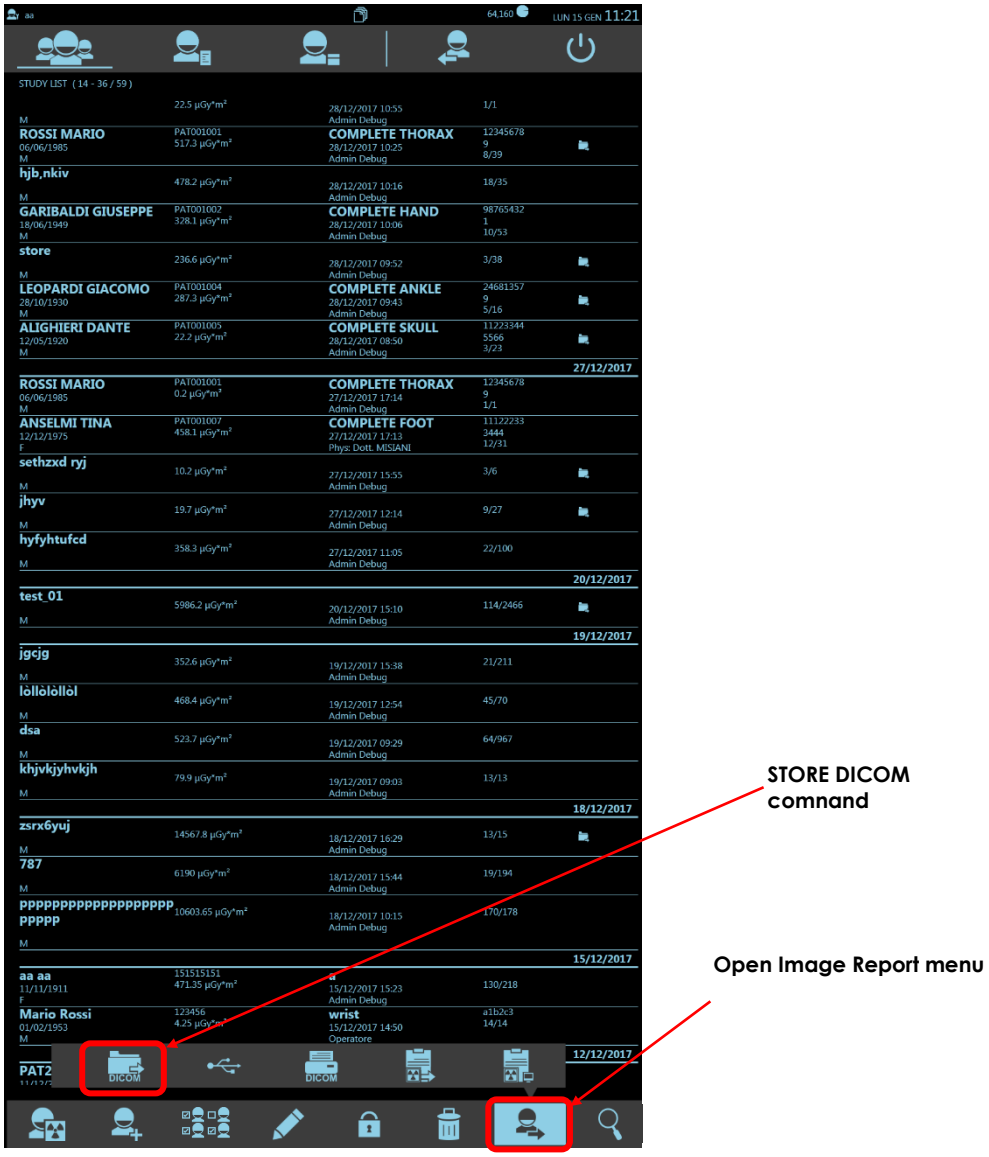
- from the Study List frame
- from the Image Processing frame

From the Study List frame you can send:

1) one or more selected studies:

- select the Store Dicom command in the Image Report menu:

M.M.

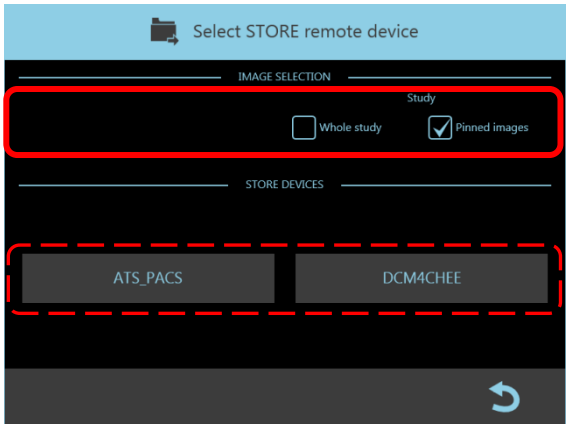


- The following selection window appears, letting you:

  - Select which images you want to send:
    Whole study

    Pinned images: only flagged images.

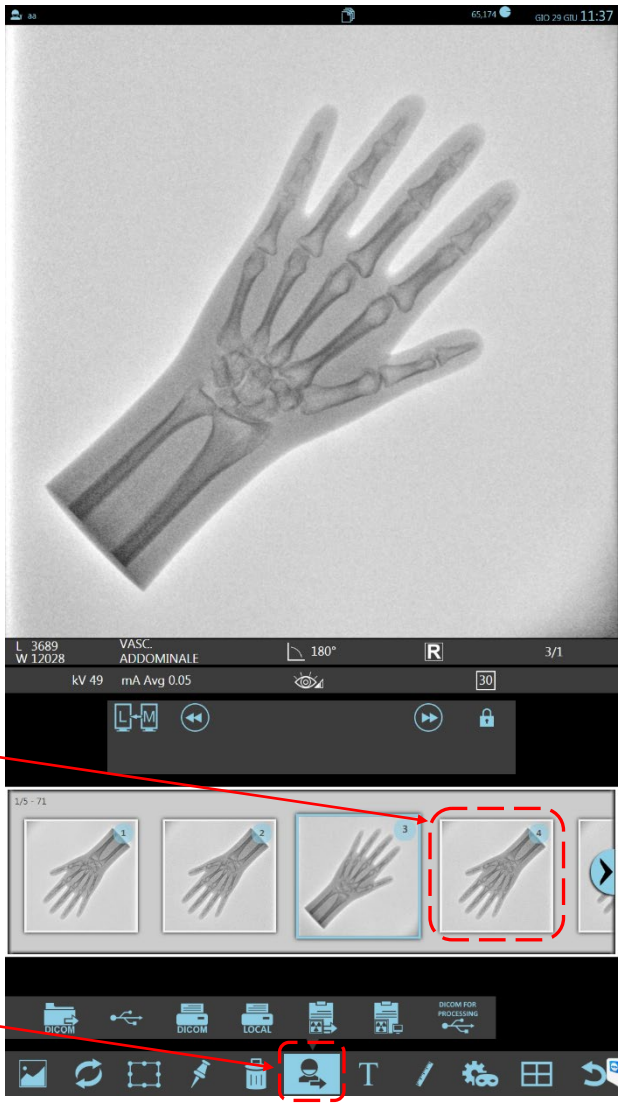
  - Select the store device you want to send the images to (if the system has more than one archive workstation).



The Image Processing frame offers a choice of export options to suit the type of image selected:

2) if you have selected a single image, touch the Store Dicom command in the Image Report menu:

M.M.



- The following selection window appears, letting you:

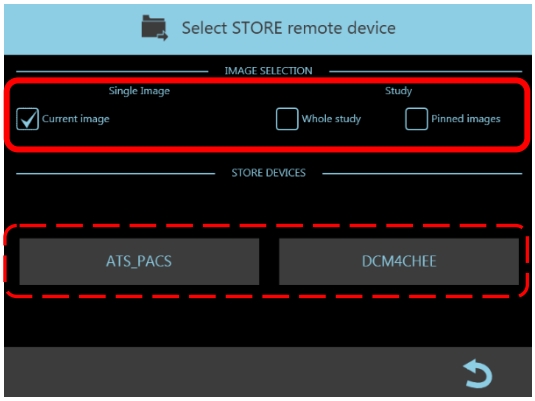
  - Select which images you want to send:

    Current image

    Whole study

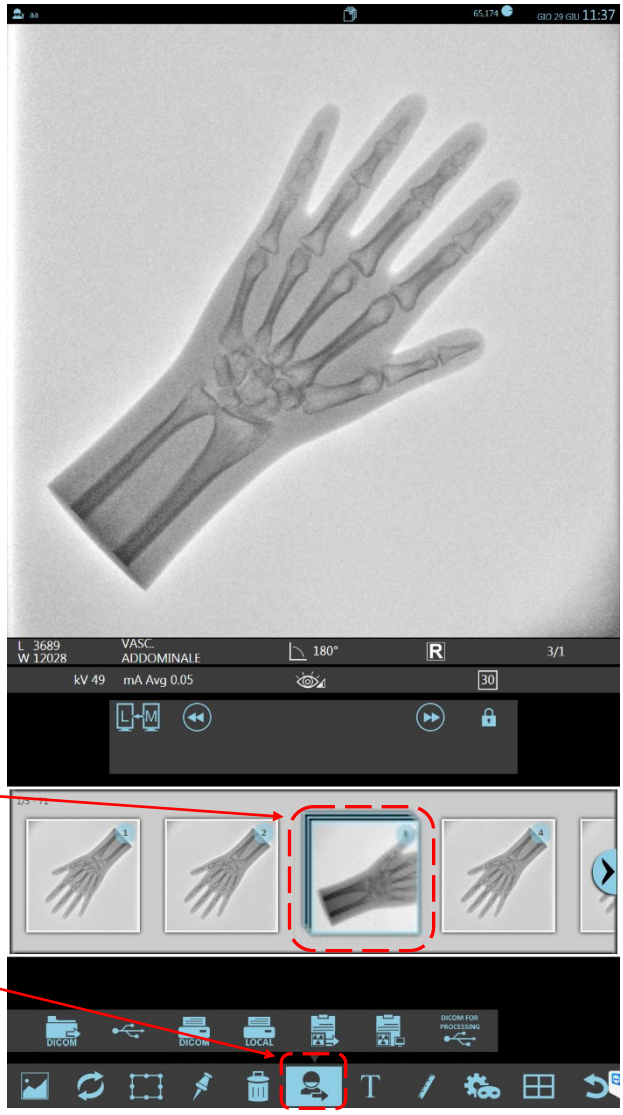
    Pinned images: only flagged images in study.

  - Select the store device you want to send the images to (if the system has more than one Store node).



3) if you have selected a multiframe run, touch the Store Dicom command in the Image Report menu:

M.M.



- The following selection window appears, letting you:

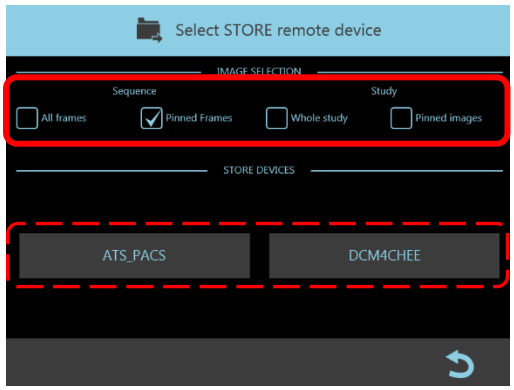
  - <u>Select which images you want to send</u>:

    All frames: all the images in the selected multiframe run.

    Pinned frames: all the flagged frames in the selected multiframe run.

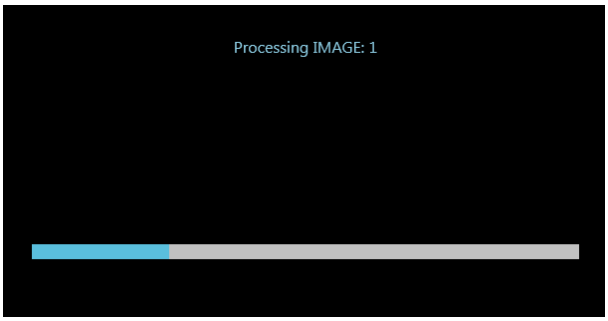
    Whole study

    Pinned images: all the flagged images in the study.



  - <u>Select the store device</u> you want to send the images to (if the system has more than one archive workstation).

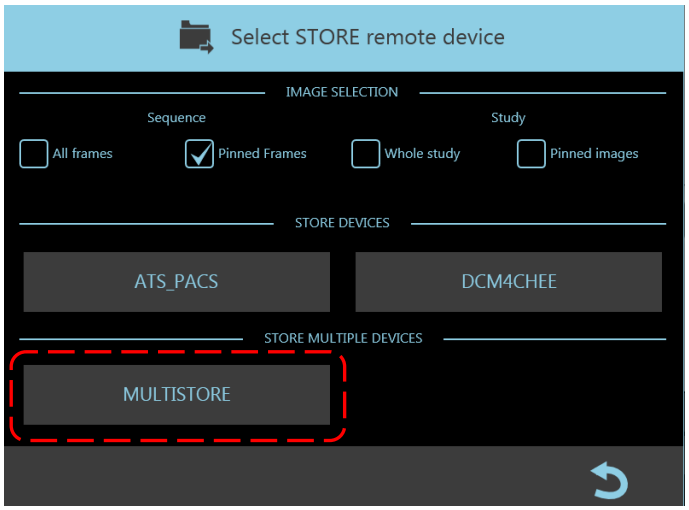
DICOM image creation and the following send spooler are notified by the message: **"Processing IMAGE: n"**.



<u>Attention:</u> During DICOM images creation, new images acquisition is inhibited. So, it is suggested to carry out sending to store operation once the exam has been finished.

Note 1: *If the images in the study are displayed in OVERVIEW mode, the procedure for sending these to the STORE DICOM device is the same as that indicated at points 2) and 3) above.*

Note 2: *If a MULTIPLE STORE DEVICE has been configured during installation (i.e. a device with several transmission nodes), you can select the node required as shown in the figure below:*



5.5.2 PRINT DICOM

The EM equipment lets you transfer images to a DICOM printer:

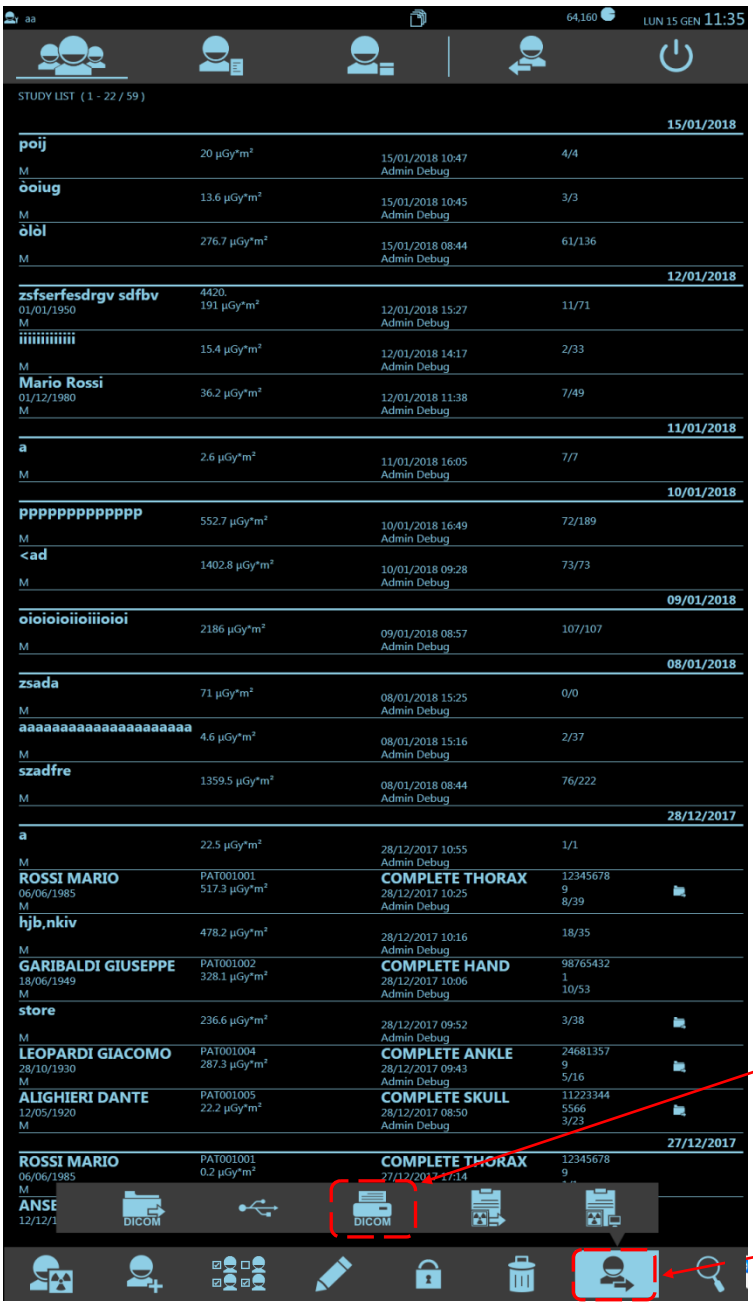
- from the Study List frame
- from the Image Processing frame

From the Study List frame, you can send:

1) one or more selected studies:

- select the Print Dicom command in the Image Report menu:

M.M.



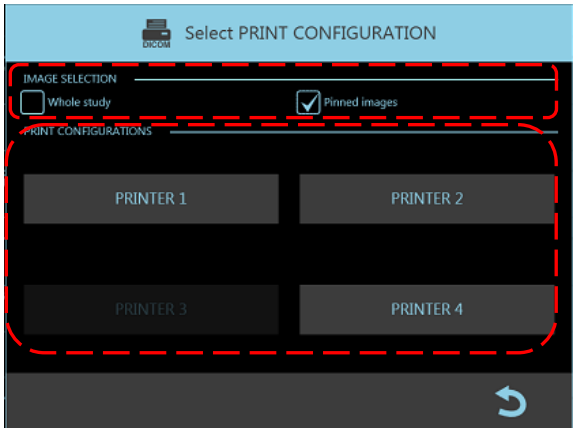
- The following selection window appears, letting you:

  - Select which images you want to send:

    Whole study

    Pinned images: only flagged images

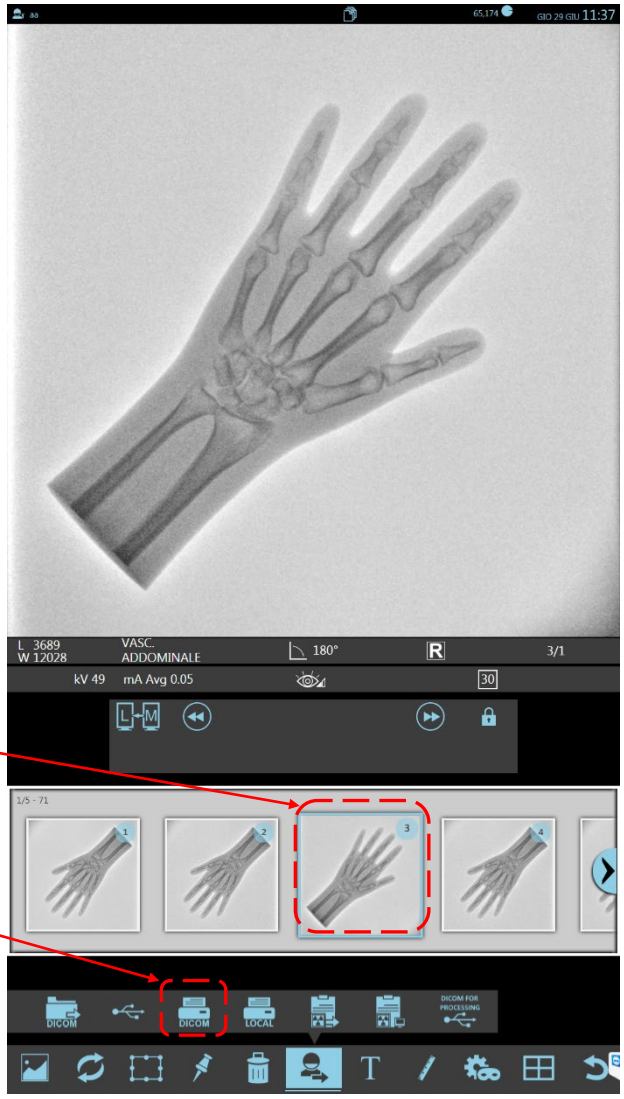
  - Select a print configuration from between those set during installation (max 4).



The Image Processing frame offers a choice of export options to suit the type of image selected:

2) if you have selected a single image, touch the Print Dicom command in the Image Report menu:

M.M.



- The following selection window appears, letting you:

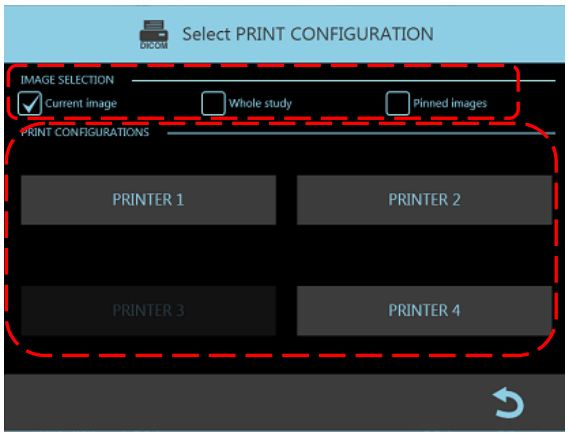
  - <u>Select which images you want to send</u>:

    Current image

    Whole study

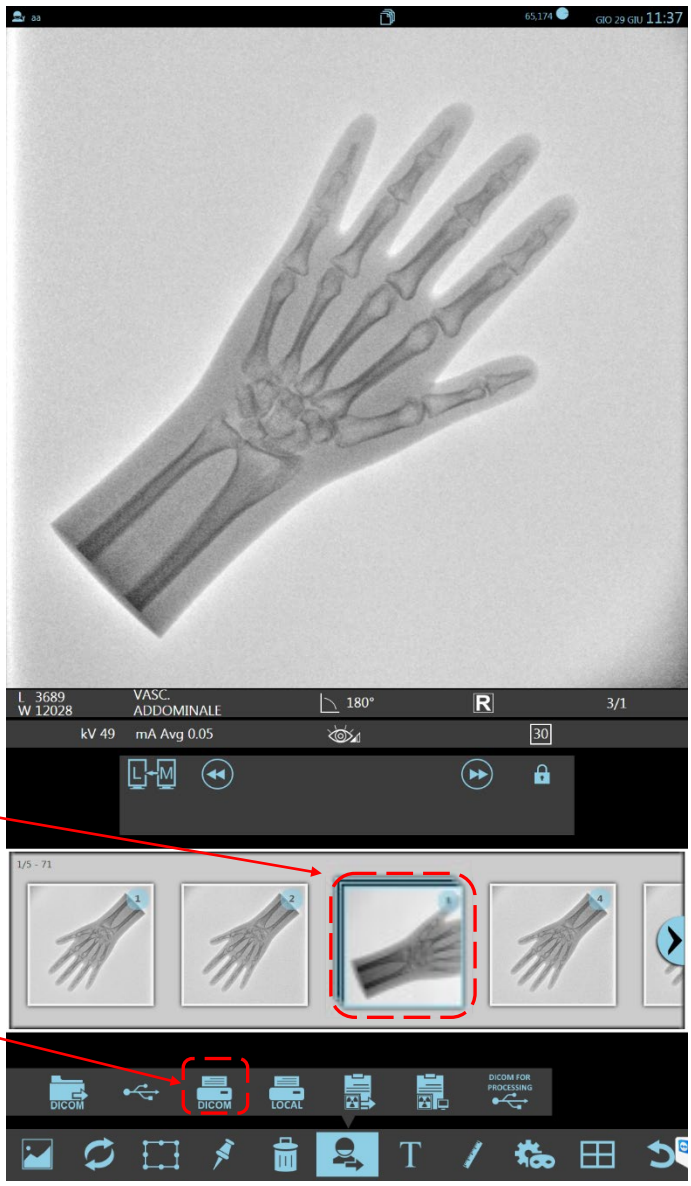
    Pinned images: only flagged images

  - <u>Select a print configuration</u> from between those set during installation (max 4).



3) if you have selected a multiframe run, touch the Print Dicom command in the Image Report menu:

M.M.



- The following selection window appears, letting you:

  - Select which images you want to send:

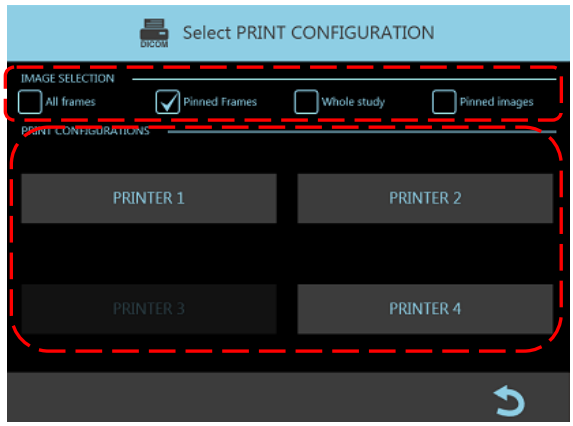
    All frames: all the images in the selected multiframe run.

    Pinned frames: all the flagged frames in the selected multiframe run.

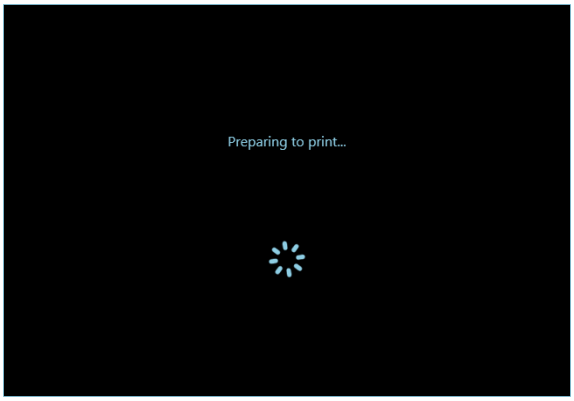
    Whole study

    Pinned images: all flagged images in study.

  - Select a print configuration from between those set during installation (max 4).



A message appears, telling you that the images are being sent to the transmission queue (Spooler): "Preparing to print...":



Note: *If the images in the study are displayed in OVERVIEW mode, the procedure for sending these to the STORE DICOM device is the same as that indicated at points 2) and 3) above.*

5.5.3 DICOM SPOOLER

The DICOM function explained earlier sends images to the DICOM SPOOLER module, responsible for managing the DICOM network and transmission.

As each image reaches the DICOM SPOOLER, it is added to the transmission queue and then sent to the relevant device as soon as possible; once printed, it is then deleted from the print queue.

You can access the DICOM SPOOLER menu from the Study List by touching this key:

The button above has the additional function of showing the spooler status. This can be:


Spooler: active


Spooler: not active


Spooler: error

The status of each image in the transmission queue is shown in the highlighted column in this figure:

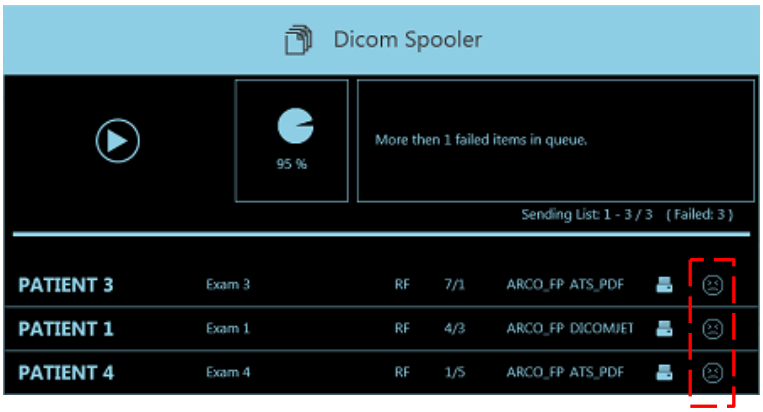
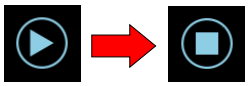
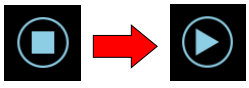


Image status	
	Being sent
	Queued, waiting to be sent
	Send error File creation error
	File deletion error after image has been sent

To manage any images remaining in the transmission queue, use this command: 

You can now:

- Select all the images in the queue with this command: 
- Make a new transmission request for the selected images using this command: 
- Delete the selected images using this command: 
- Return to the Study List using this command: 

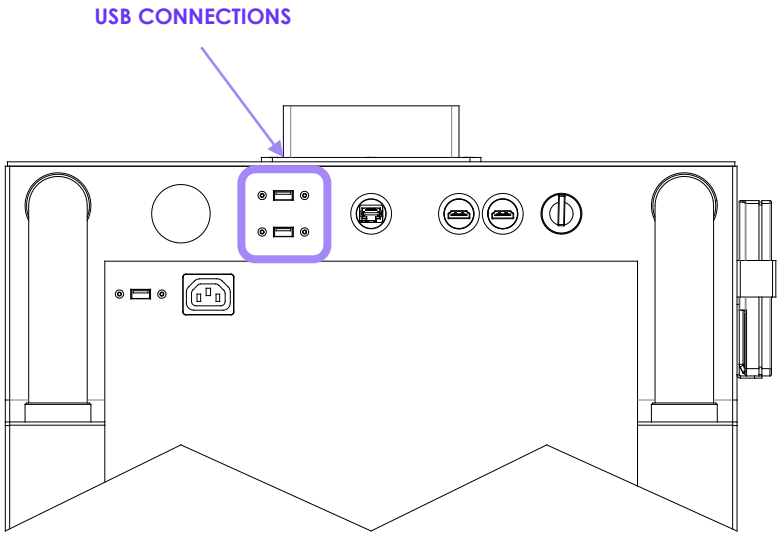
Use this command to restore the Spooler to normal operation: 

5.5.4 SAVING IMAGES TO USB DEVICE

The EM equipment lets you save images in DICOM format to a USB pen-drive:

- from the Study List frame
- from the Image Processing frame

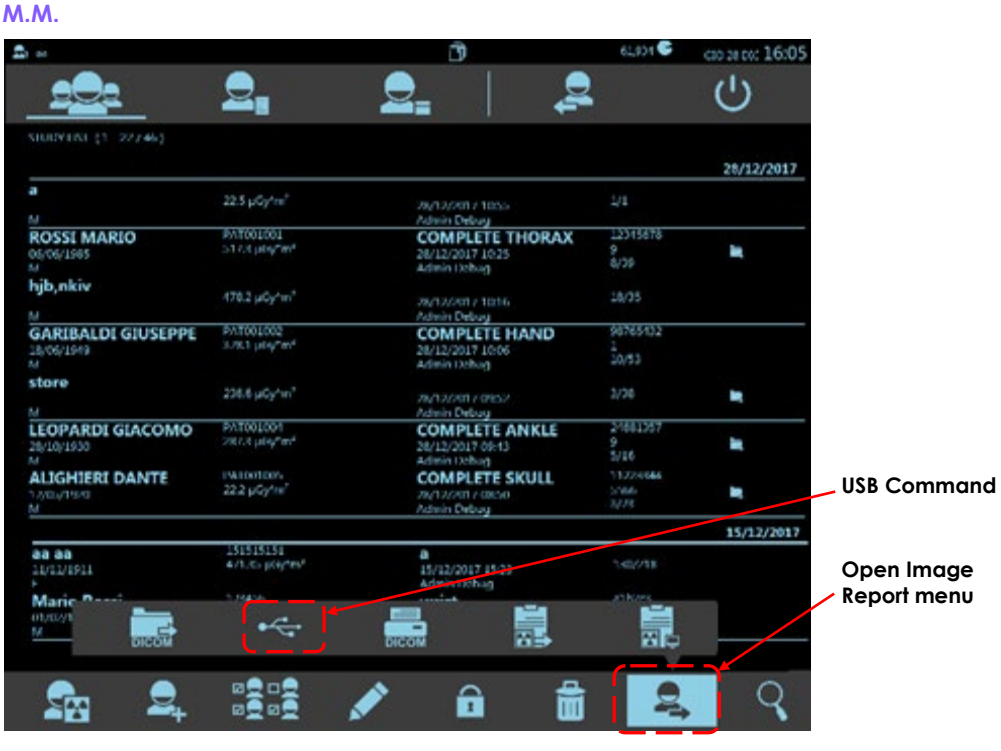
- Insert a pen-drive in one of the two USB connectors on the monitor unit:



From the Study List frame, you can save:

1) one or more selected studies:

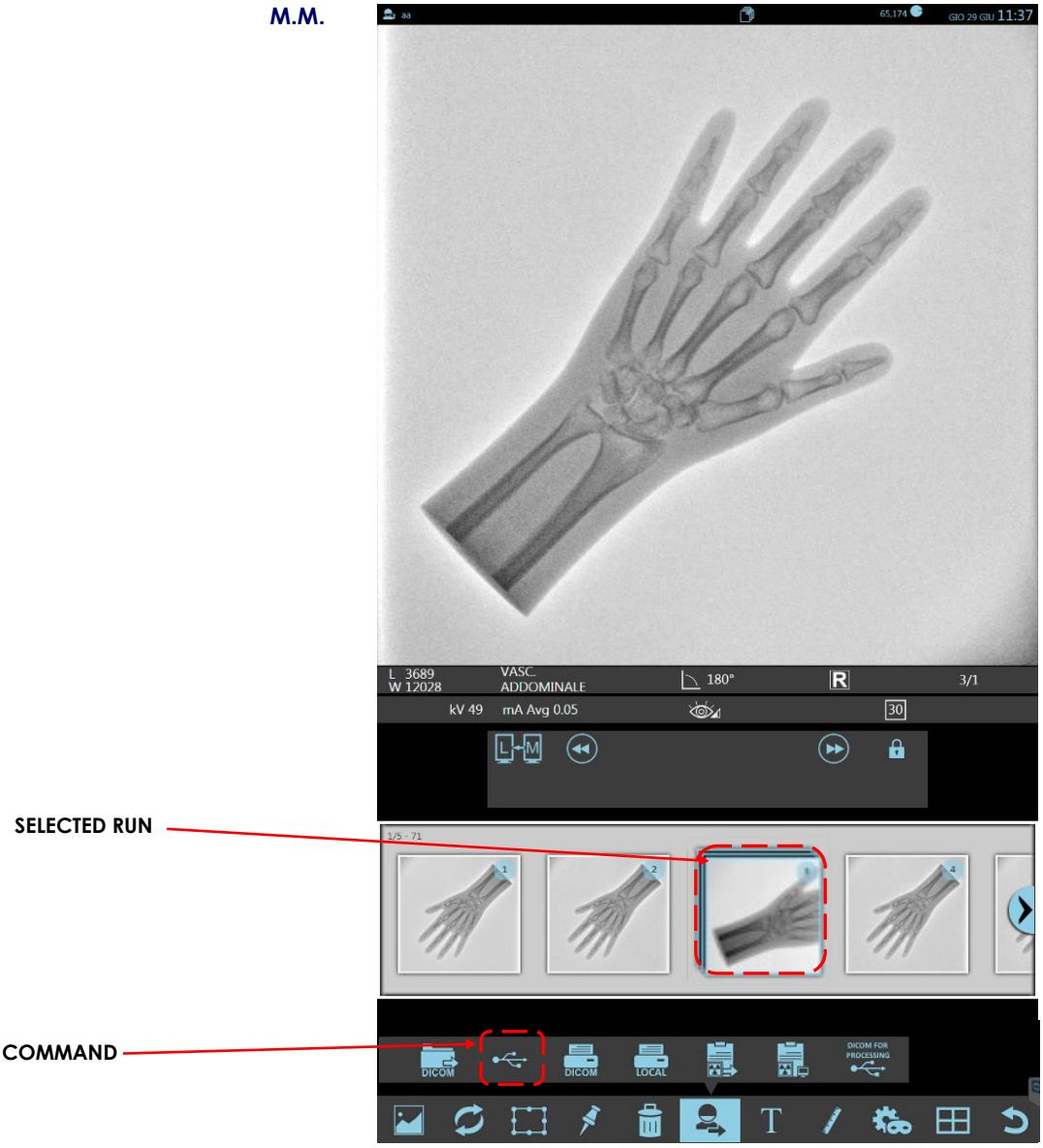
- select the USB command in the Image Report menu:



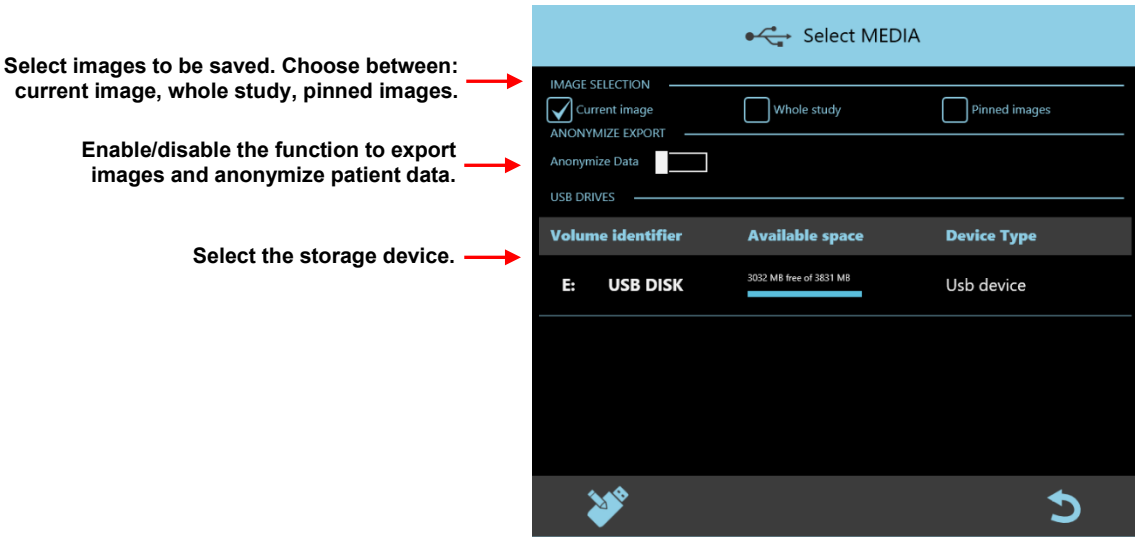
From the Image Processing frame, you can save:

2) the runs with selected images:

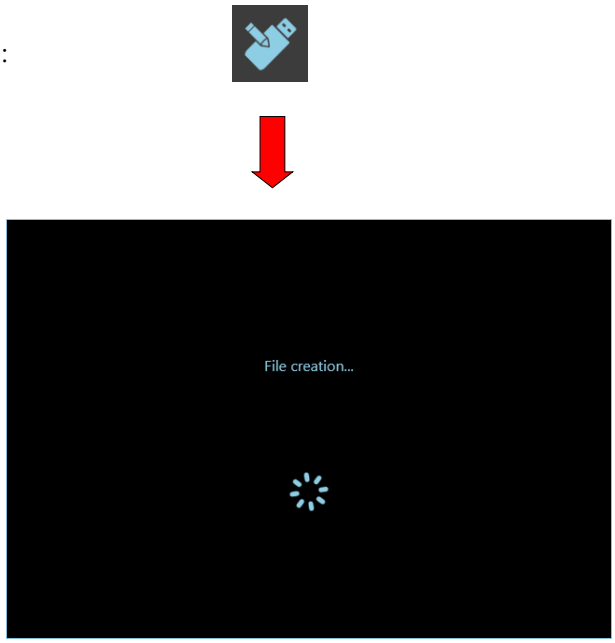
- select the USB command in the Image Report menu:



- In both cases the Export frame appears:



- You can now start copying the files by touching:



- Once the files have been copied, you can remove the pen-drive.

Note 1: *it is required an appropriate DICOM viewer software to consult these images.*

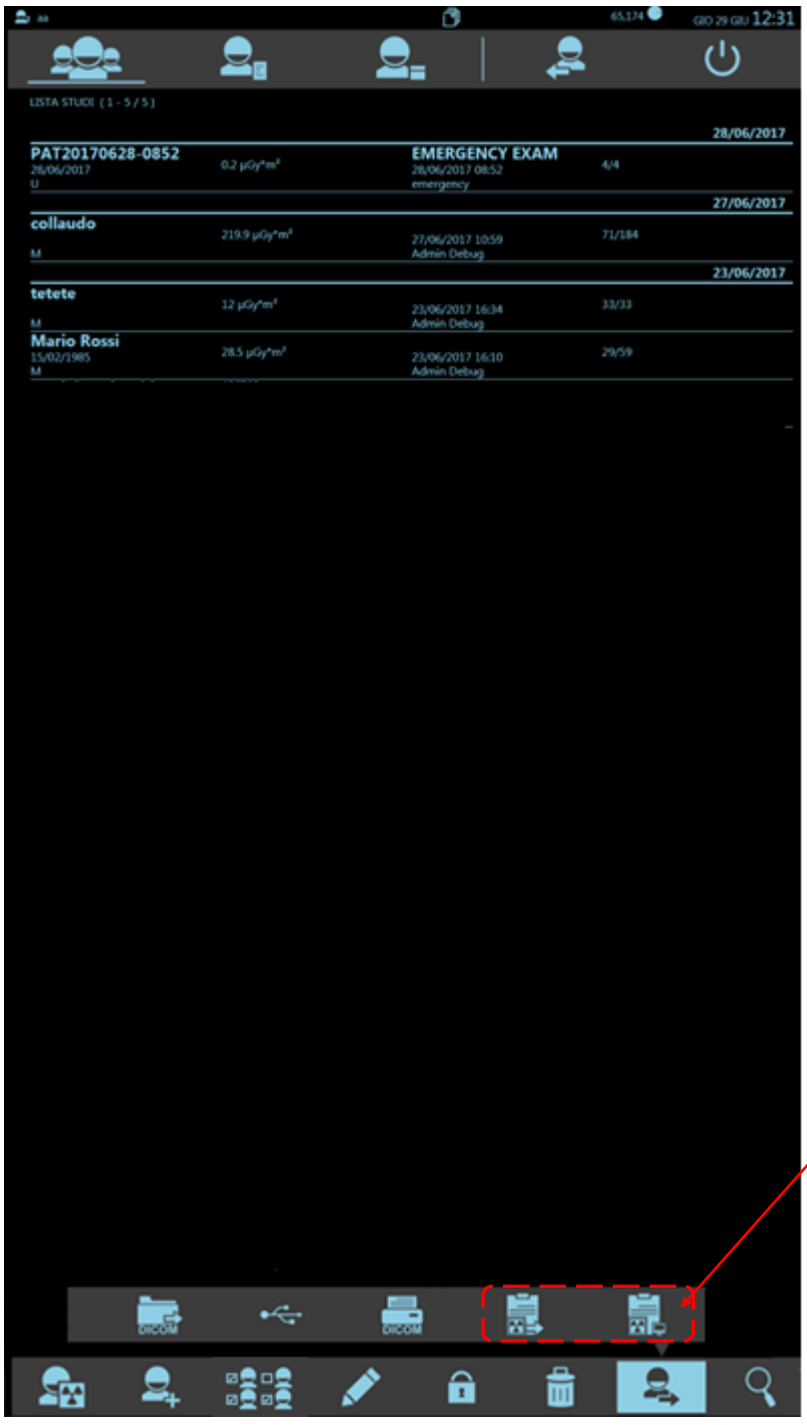
Note 2: *in DICOM Setup menu it is possible to enable the function to save several studies on the same device (see Paragraph 4.5.2.3, Section 2 of the Technical Manual). If necessary, the multiple saving option must then be confirmed by the operator before the transferring to a USB device.*

5.5.5 RADIATION DOSE STRUCTURED REPORT (R.D.S.R.) *(OPTIONAL)*

R.D.S.R. function lets you send information about the X-ray dose received by a patient during each study to a DICOM terminal.
The data can be sent automatically, manually or viewed on your monitor.

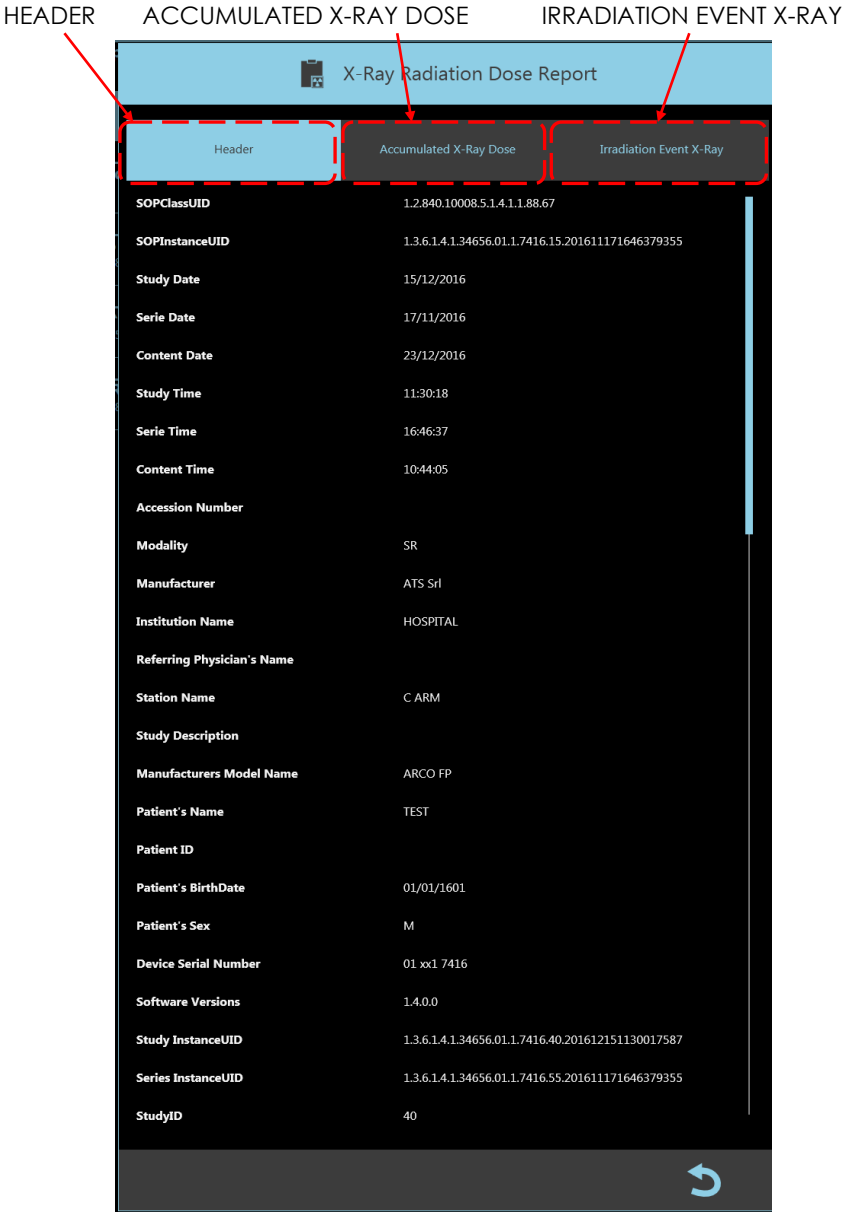
Automatic transmission of these data can be set up during installation. As a result, the dose report (R.D.S.R.) will be sent automatically as soon as the study is closed.

You can also press this button to send the dose information manually:



Press this button to view more details about the X-ray dose reports on the monitor:

The following page appears, with the following divisions:



These divisions show:

- HEADER — general details about the study
- ACCUMULATED X-RAY DOSE — the accumulated dose parameters during the study
- IRRADIATION EVENT X-RAY — X-ray exposure and dose parameters for each single X-ray emission

1. 5.5.6 QUERY / RETRIEVE (OPTIONAL)

The DICOM QUERY / RETRIEVE functions let you view digital images generated by other image diagnostics programs on the equipment (e.g. CT, MR, ECHO, etc.).
This is useful, for instance, when comparing acquired images with those in the hospital archive for the same patient.

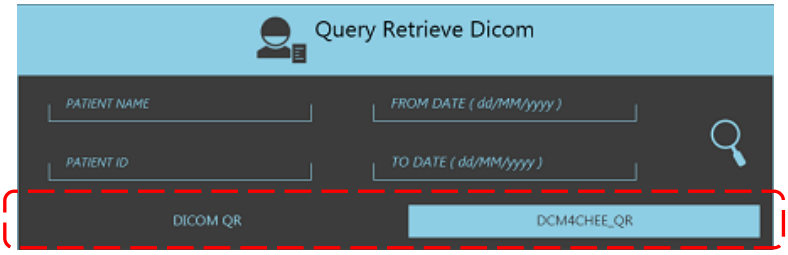
The QUERY function searches for all the studies concerning a given patient in the hospital archive.
This research may be done by using these parameters: PATIENT NAME and / or PATIENT ID and filtering by STUDY DATE, too.
All the results that satisfy the search conditions are then listed on the screen.

After selecting those of interest, use the RETRIEVE function to copy the selected study (or studies) on the local disk.

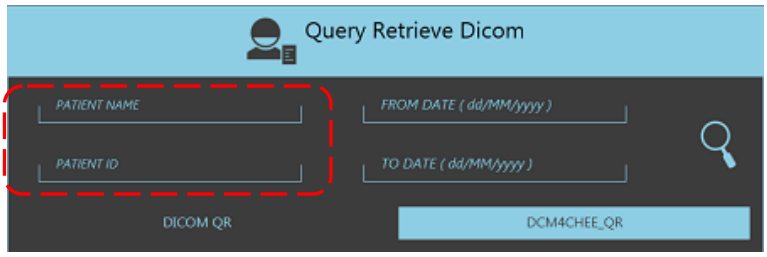
- The Query/Retrieve functions are found in the Study List, in the QUERY / RETRIEVE LIST frame, accessed with this command:

M.M.

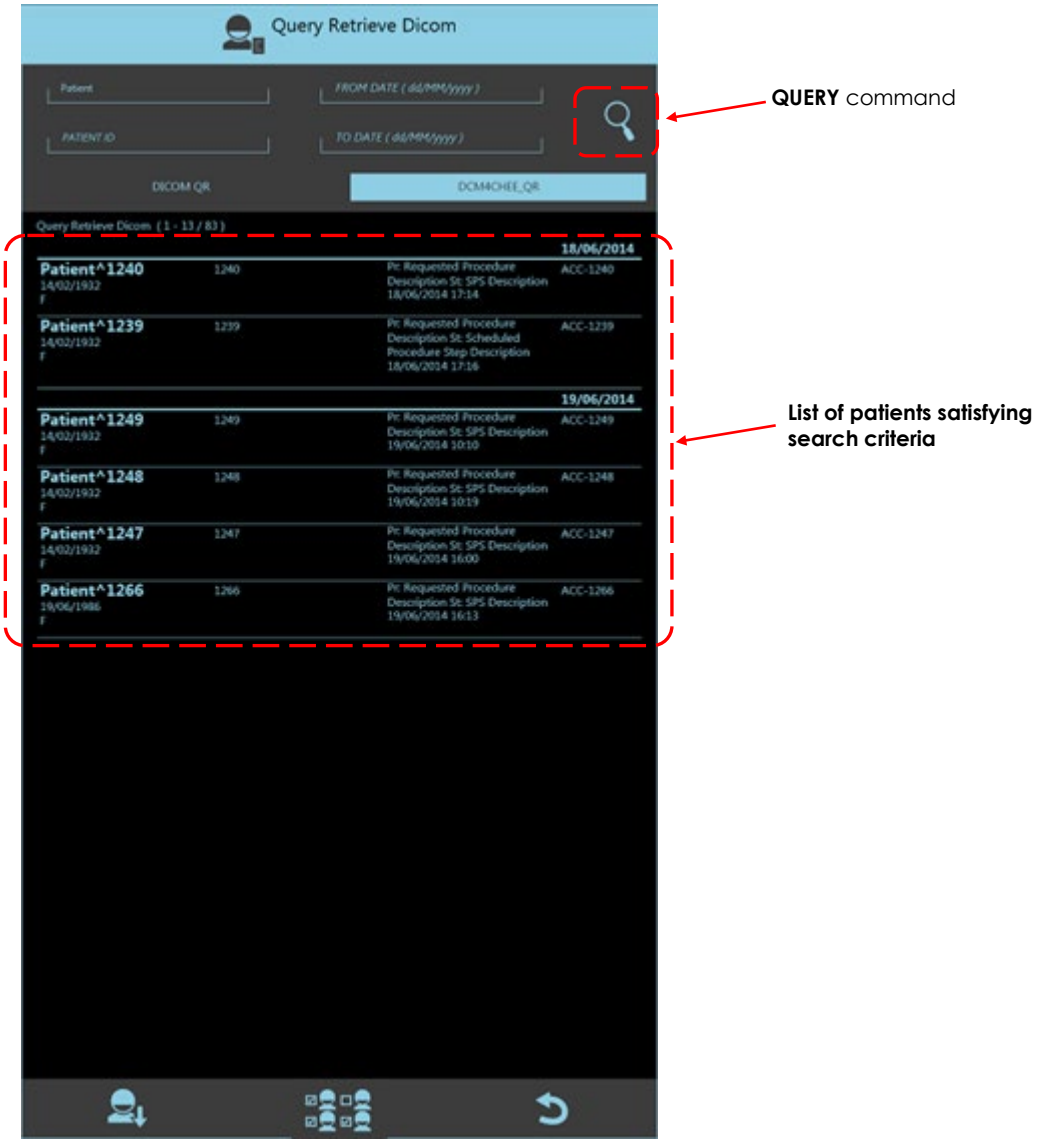
- Select the QR SERVER you want to use to find the studies (if more than one server is foreseen):



- Enter the key words to search for the study (or studies). These can be simply: the PATIENT NAME, the PATIENT ID or a combination of both.



- Now use the QUERY key to display a list of all corresponding studies.



QUERY command

List of patients satisfying search criteria

You can now:

- Manually select the studies of interest in the list using this command:

- Return to the Study List using this command:

- Use the Retrieve Study key to start transfer from the hospital archive (QR server) to the local disk on the EM equipment.
  The received study will appear in the QUERY / RETRIEVE LIST frame; doubleclick on it to consult its images.

The Query / Retrieve option includes a tested and validated program called **ETIAM Viewer**, that allows the visualization of images present in the imported studies. Its user manual (in English language, only) can be found together with all the other manuals on the CD supplied with the EM equipment.

***Note**: this option is only available at the sale moment. It cannot be installed in a second time.*

5.5.7 STUDY LIST MANAGER

Warning: *the study archive must not be considered as a permanent storage solution. Every day, before closing the application and switching off the system, it is good practice to transfer all images to an external, general archiving device via the DICOM network).*

The following functions help you use and manage the Study List:

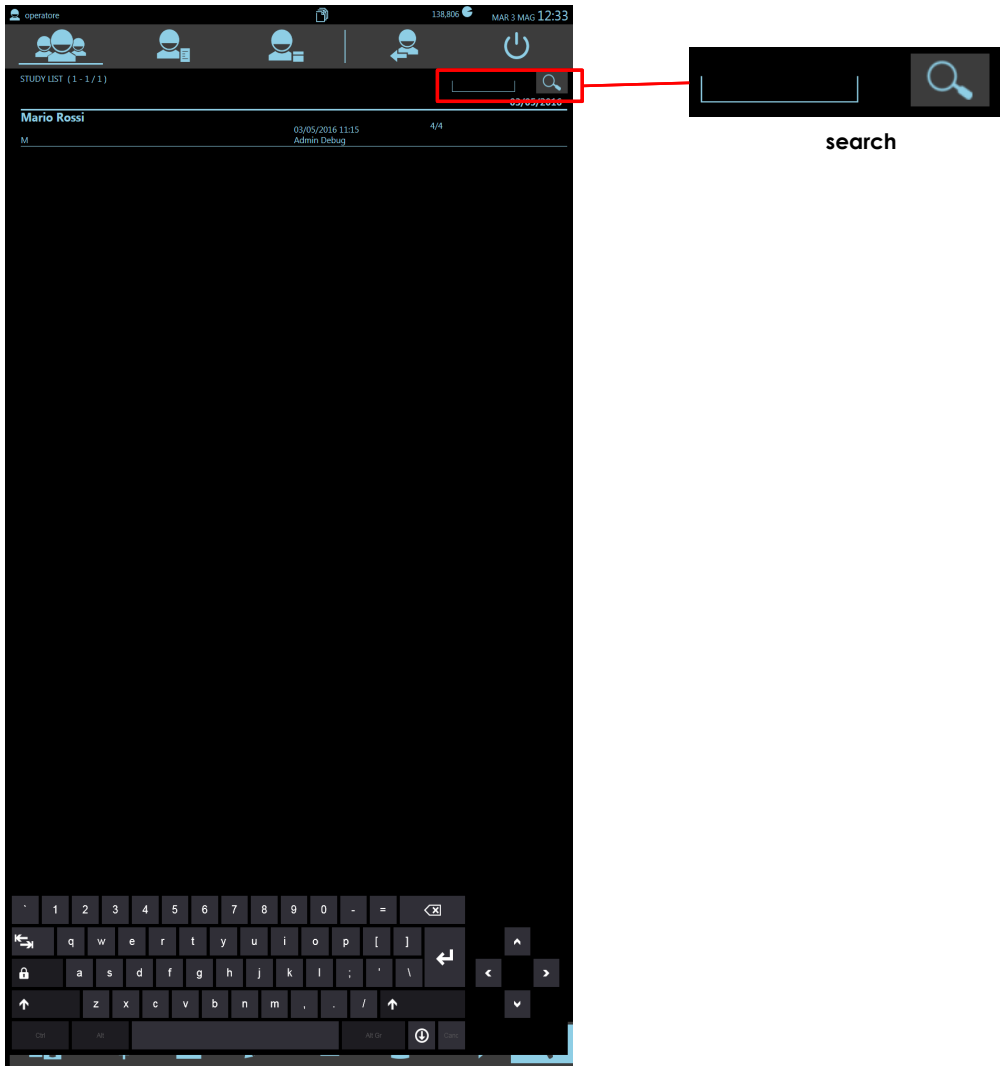
- Find study
- Select multiple studies
- Delete study

5.5.7.1 FINDING A STUDY

The usual way to find an existing study in the Study List is to use the patient name.

- To do this, touch Search: 
- Enter the full (or partial) name of the patient: only those studies containing these data will be displayed.
- Touch the Search command again to return to the full list with all the studies.

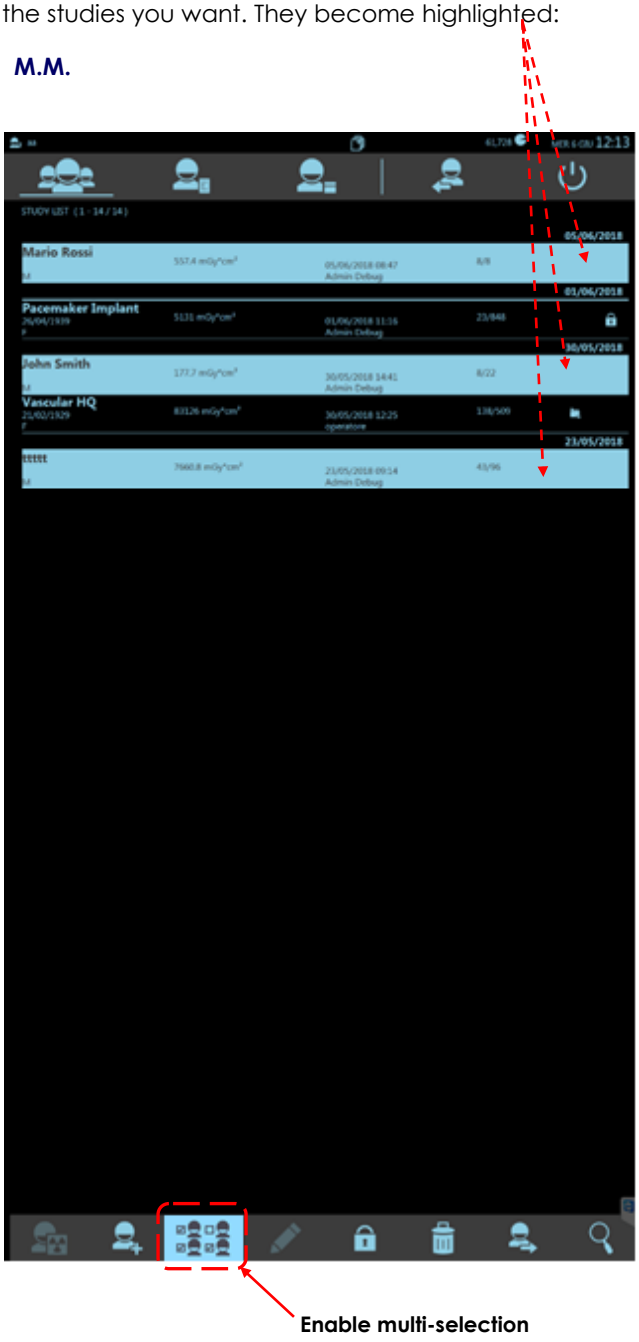
M.M.



5.5.7.2 SELECTING MULTIPLE STUDIES

Use the relevant command to select more than one study in the Study List (e.g. to send them to a DICOM device or to delete them):

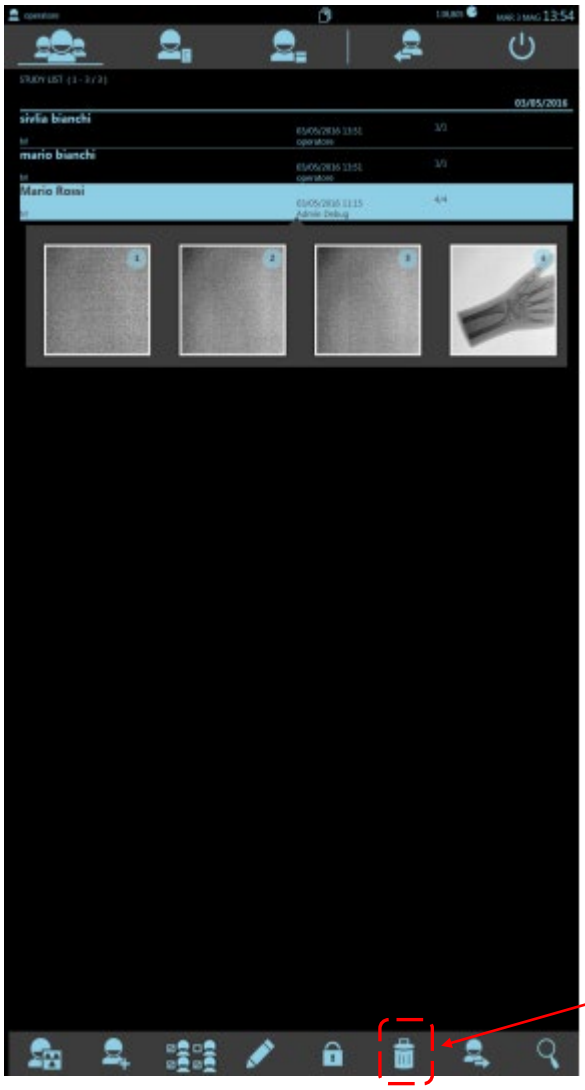
- You can now select the studies you want. They become highlighted:



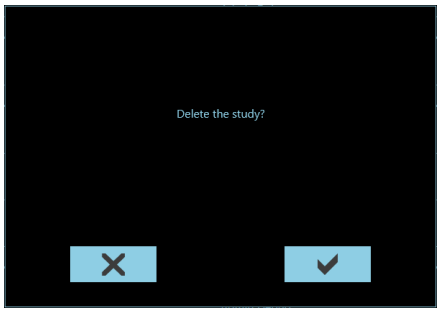
5.5.7.3 DELETING A STUDY

After selecting one or more studies in the Study List, use the relevant command to delete them:

M.M.



- Select the study you want to delete and then touch Delete.
- You are then asked for confirmation before these are actually deleted:



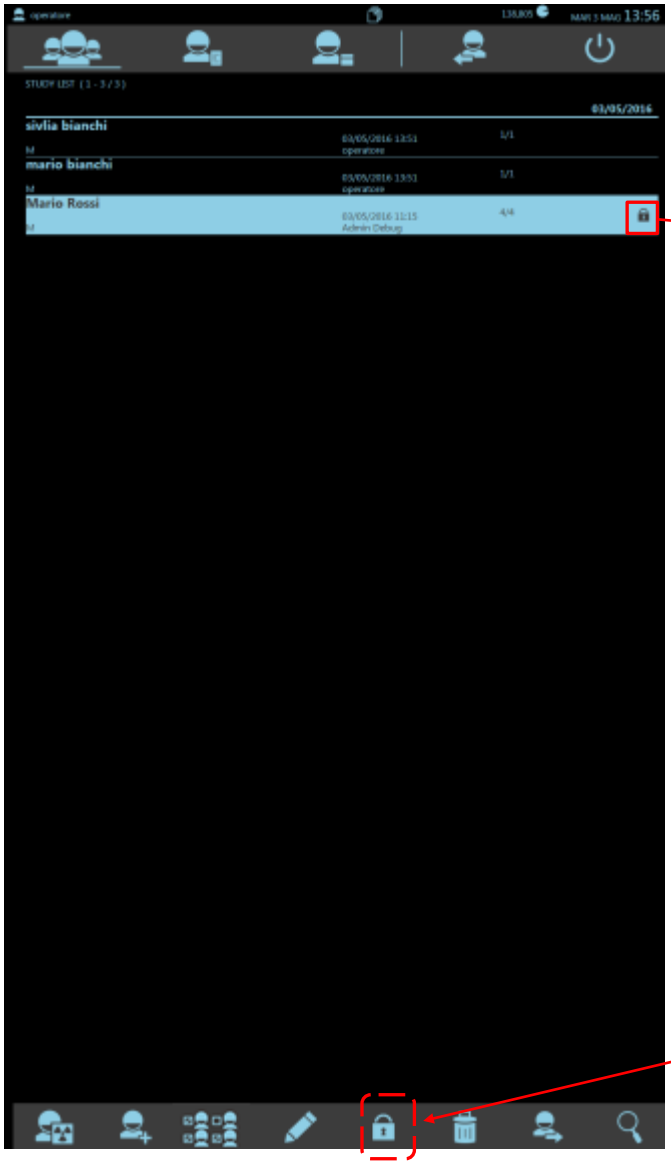
Note: *A study cannot be deleted if protected against deletion.*

See next paragraph.

5.5.7.4 PROTECTING A STUDY AGAINST DELETION

You can protect images in a study from accidental deletion.
After selecting the study, touch the protection command: Lock.

M.M.



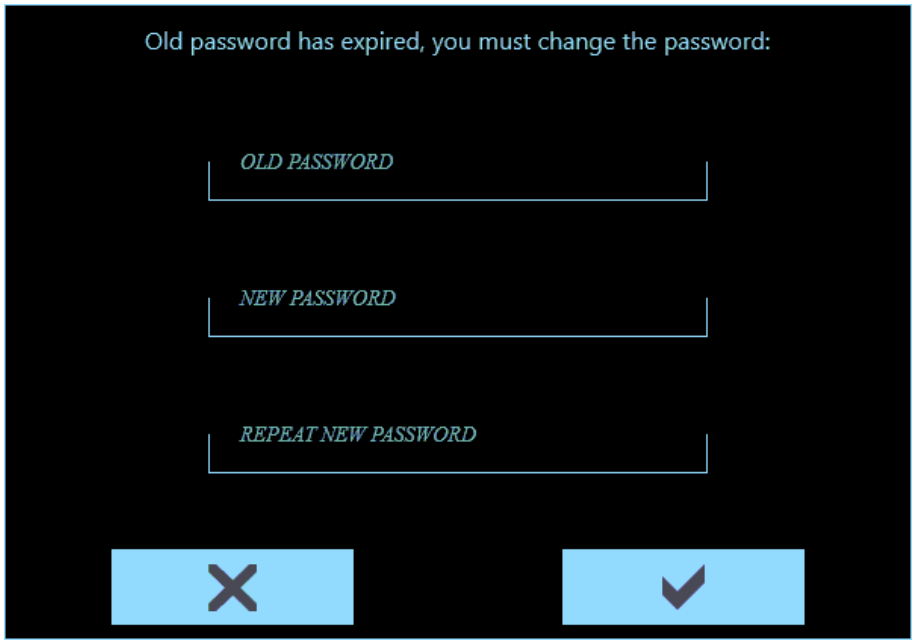
The locked study can be unlocked by simply touching the same key again: Lock.

Note: *Even single images in a protected study cannot be deleted.*

5.5.8 CHANGING THE USER PASSWORD

LOGIN passwords are only valid for 90 days. After this time, the system disables a user until the password is updated.

If a password is no longer valid, the following message appears during the Login process:

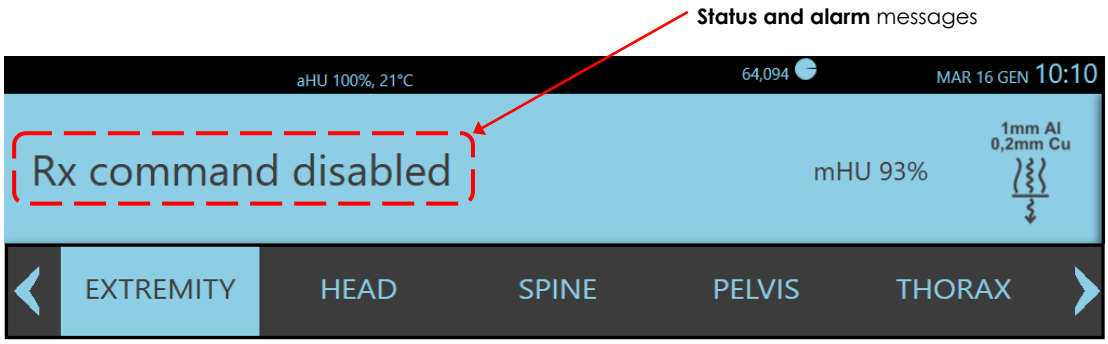


- To change the password, enter your old password and then a new one (twice); confirm with the accept command.

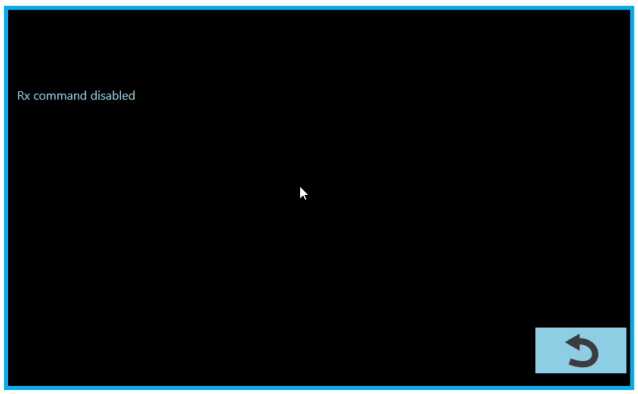
6 SYSTEM AND ERROR MESSAGES

6.1 STATUS AND ALARM MESSAGES ON THE CONTROL PANEL

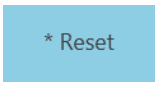
The status of the system and any active alarms are displayed on the control panel, in the relevant area, as shown in the figure below:



The most recent alarm generated by the system is displayed. Touch the alarm indication to open the frame with a list of all the possibly active alarms:



Note: *Alarms flagged with an asterisk (*) can be reset by the operator using the reset command, aside the exit key:*



The table below shows the list of messages foreseen by the equipment:

MESSAGE	MEANING	NOTES
READY	The equipment is ready to acquire images. You can now give the X-ray emission command.	
FLUOROSCOPY	X-ray emission in low dose fluoroscopy.	
HQ FLUOROSCOPY	X-ray emission in fluoroscopy mode for high quality images.	
FLUOROSCOPY DSA	X-ray emission in DSA fluoroscopy mode.	
RAD PREPARATION	Preparing for radiography.	
READY FOR RAD	RAD preparation completed.	
RAD	X-ray emission in radiography mode.	
PRE PEAK OPACIFICATION	The equipment is ready to run MAX OP function	
PEAK OPACIFICATION	MAX OP taking is running	

MESSAGE	MEANING	NOTES
ROADMAPPING	ROAD MAP taking is running	
STUDY NOT OPEN	The equipment cannot acquire images, as no study has been opened.	Open a study.
RX GRID STATUS INCONSISTENCY	A possible inconsistency between the Grid condition set in Exam Setup (YES or NO) and its current condition in the study, will be noticed to the operator with the relevant icon.	
RX SWITCH DISABLED	The X-ray emission commands (footswitch and button) are disabled.	Press the relevant button on the control panel to enable them.
MAX FLUOROSCOPY TIME, RELEASE COMMAND RX	Fluoroscopy exposure has been interrupted on reaching the max accumulated fluoroscopy time-out (10').	Release the X-ray command and reset the alarm.
5 MINUTES FLUORO	Fluoroscopy exposure has been interrupted on reaching the 5-minute fluoroscopy time-out without the warning being reset after 4 minutes and 30 seconds.	Release the X-ray command and reset the alarm.
MAX RADIOGRAPHY TIME	Radiography exposure has been interrupted on reaching the max admissible exposure time-out (970 milliseconds).	Check the quality of the image and repeat exposure if necessary.
MANUAL X-RAY STOP	The radiography command button has been released before exposure has ended.	Check the quality of the image and repeat exposure if necessary.
WAITING FOR FOCUS CHANGE	Wait for the equipment to change the focus.	
WAITING FOR CONNECTION	System fault.	Reboot the application. Call Technical Service if the alarm persists.
DETECTOR TEMPERATURE CLOSE TO MAX LIMIT	The temperature of the detector is close to its max limit.	Reduce the length of exposure as soon as possible to allow the detector to cool down.
DETECTOR TEMPERATURE TOO LOW	The temperature of the detector is below its minimum working limit.	Wait for the detector to warm up and reach its minimum working temperature.
DETECTOR TEMPERATURE TOO HIGH	The temperature of the detector has exceeded its max working limit.	Stop all exposures as soon as possible and wait for the detector to cool down.
NO X-RAY ENABLE FROM DETECTOR	Detector communication error.	Repeat exposure. Call Technical Service if the alarm persists.
ERROR SETTING X-RAY COLLIMATOR FILTERS	The X-ray collimator has been incorrectly set.	Select a different exam. If the problem persists, reboot the equipment. Call Technical Service if the alarm persists.
RX COLLIMATOR FAULT	The collimator fails to position itself correctly.	Check the position of the collimator. If the problem persists, reboot the equipment. Call Technical Service.
RX COLLIMATOR OFFLINE	The X-ray collimator is not connected or is faulty.	Call Technical Service.
CTBK OFFLINE	System fault.	Reboot the equipment. Call Technical Service if the alarm persists.
RECONNECTING CTBK...	The equipment modules are in the process of connecting.	Wait until completed.

MESSAGE	MEANING	NOTES
UNABLE TO INITIALIZE CTBK FW: VERIFY ALARM LIST ON CONTROL PANEL	System fault. Press the alarm message shown on the control panel: a window appears listing the current alarms. (***See page 2.11***)	Follow the procedure indicated in this table to resolve the problem shown in the current alarm list. Call Technical Service if the alarm persists.
CTBK INITIALIZATION FAILED	System fault. Impossible to initialize CTBK. Verify the alarm messages list shown on the control panel.	Check and follow the resolution procedure indicated in this table to resolve the problem shown in the current alarm list. Call Technical Service if the alarm persists.
CTBK HW FAULT	CTBK board fault.	Call Technical Service.
NEW EEPROM CTBK	A new EEPROM has been found by CTBK firmware.	Reboot the equipment. Call Technical Service if the alarm persists.
CTBK POWER SUPPLY +24V FAULT	Problem with the main controller power circuits in the equipment.	Reboot the equipment. Call Technical Service if the alarm persists.
COM-RX SIGNAL ACTIVE	The signal requesting COMMON acquisition (fluoroscopy and radiography) is already present on switching the equipment on.	Call Technical Service.
FLUOROSCOPY PEDAL LD CLOSED	Low Dose fluoroscopy pedal is already activated at the equipment starting.	Check whether the left pedal is pressed/blocked and release if necessary. If not, call Technical Service.
FLUOROSCOPY PEDAL HQ CLOSED	High Quality fluoroscopy pedal is already activated at the equipment starting.	Check whether the right pedal is pressed/blocked and release if necessary. If not, call Technical Service.
RAD PREP BUTTON CLOSED	Radiography preparation button is already activated at the equipment starting.	Check whether the X-ray button is pressed/blocked and release if necessary. If not, call Technical Service.
RAD BUTTON CLOSED	Radiography button is already activated at the equipment starting.	Check whether the X-ray button is pressed/blocked and release if required. If not, call Technical Service.
FLUOROSCOPY BUTTON CLOSED	Low Dose fluoroscopy button is already activated at the equipment starting.	Check whether the X-ray button is pressed/blocked and release if required. If not, call Technical Service.
BOOSTER FAULT	Problem in the feeder power circuits in the X-ray generator. Together with this alarm, the current booster capacitor voltage is shown.	Reboot the equipment. Call Technical Service if the alarm persists.
BOOSTER OVERVOLTAGE	Too much voltage from the feeder in the X-ray generator. Together with this alarm, the current booster capacitor voltage is shown.	Reboot the equipment. Call Technical Service if the alarm persists.
BOOSTER UNDERVOLTAGE	Too low voltage from the feeder in the X-ray generator. Together with this alarm, the current booster capacitor voltage is shown.	Reboot the equipment. Call Technical Service if the alarm persists.

MESSAGE	MEANING	NOTES
RX TUBE THERMAL SAFETY	The over-temperature thermal safety device in the X-ray monoblock has tripped. Exposure is inhibited when the available heat units fall below the level required for the set exposure.	Wait for the X-ray monoblock to cool down.
RX TUBE TOO HOT	Tube Heat Unit available are not enough to satisfy exposure parameters set.	Wait for the X-ray monoblock to cool down.
LOW POWER	Monoblock or Anode Heat Unit are lower than 10%. Fluoroscopy acquisition mode is still available but the equipment automatically decreases acquiring parameters in order to reduce monoblock heating.	If possible, wait for the X-ray monoblock to cool down.
ANODE STARTER FAULT	Problem in the rotating anode circuit.	Call Technical Service.
RX GENERATOR POWER SUPPLY FAULT	Problem in the X-ray power supply circuits.	Call Technical Service.
LOW DOSE AT MAX kV	Insufficient dose level detected at max kV setting.	Check that the collimator is not completely closed. Check that the actual kV level correctly matches the size of the patient being scanned. Change the exam type if necessary.
RX GENERATOR NOT CONNECTED	X-ray power supply communication error.	Reboot the equipment. Call Technical Service if the alarm persists.
FILAMENT FAULT	Problem with the circuit that switches on the X-ray tube filament.	Reset the alarm. Reboot the unit if the alarm persists. Call Technical Service if the alarm persists.
mA TOO LOW	The mA level is 1/3 lower than that foreseen.	Repeat exposure. Call Technical Service if the alarm persists.
mA TOO HIGH	The mA level is 1.5 higher than that foreseen.	Repeat exposure. Call Technical Service if the alarm persists.
kV UNBALANCED	The X-ray generator has detected incorrect voltage at the X-ray tube during exposure.	Reset the alarm. Check the connections between the CP1 connector of the S83 board mounted on the Monoblock and the CM2 connector of the S219 board of the inverter. Call Technical Service if this alarm persists at the next exposure.
MAX kV	The X-ray generator has detected too much voltage at the X-ray tube during exposure.	Reset the alarm. Check the connections between the CP1 connector of the S83 board mounted on the Monoblock and the CM2 connector of the S219 board of the inverter. Call Technical Service if this alarm persists at the next exposure.

MESSAGE	MEANING	NOTES
MIN kV	The X-ray generator has detected too little voltage at the X-ray tube during exposure.	Reset the alarm. Check the connections between the CP1 connector of the S83 board mounted on the Monoblock and the CM2 connector of the S219 board of the inverter. Call Technical Service if this alarm persists at the next exposure.
MAX mA	The X-ray power supply has detected too much current at the X-ray tube during exposure.	Reset the alarm. Call Technical Service if this alarm persists at the next exposure.
NO RX	The voltage at the X-ray tube fails to reach at least 75% the expected value during exposure.	Repeat exposure. Call Technical Service if the alarm persists.
DAP FAULT	Dose Area Product faulty.	Reboot the equipment to reset the alarm. Call Technical Service if the alarm persists.
POSSIBLE DETERMINISTIC EFFECTS	The Kerma value accumulated during the study has exceeded the threshold (possibly set by the user) beyond which DETERMINISTIC EFFECTS could be detected.	Take care when continuing the procedure.
NO X-RAY DOSE SIGNAL	The X-ray dose signal from the acquisition system has not been detected.	Repeat exposure. Call Technical Service if the alarm persists.
CAPACITOR CHARGING	The capacitor in the generator supply group is being charged.	Wait until fully charged.
X-RAY GENERATOR NOT CALIBRATED	X-ray generator not calibrated.	Call Technical Service to calibrate this.
MAX PREPARATION TIME	The radiography preparation command has been pressed for too long.	Release the RAD PREP command.
HARDWARE ERROR DETECTOR	Detector fault.	Call Technical Service.
INJECTOR FAULT	Injector cannot activate	Check that the injector is ready and connected to the stand.
X-RAY ACTIVATION NOT FOUND	Lack of synchronism with the detector during exposure. Rx activation button on the Control Panel is enabled.	Repeat exposure. Reboot the equipment if the alarm persists. Call Technical Service if the alarm persists.
FAULTY BEAM SIGNAL	The inverter signals x-rays presence even if they have not been commanded.	Call Technical Service.
X-RAY WATCHDOG ACTIVATED	X-ray command safety circuit has been activated: x-ray emission is inhibited.	Reboot the equipment. Call Technical Service if the alarm persists.
ACTIVE COOLING NOT AVAILABLE	Communication fault with the Active Cooling control board.	Reboot the equipment to reset the alarm. Call Technical Service if the alarm persists.
COOLING FAN IS ABOUT TO START	Message indicating the imminent activation of the cooling function (10 seconds before).	Wait for the function to be activated: the message is automatically removed.

MESSAGE	MEANING	NOTES
COOLING OIL PUMP FAULT (ON)	The pump motor current exceeds 100 mA, without the pump being switched on.	Reboot the equipment to reset the alarm. Call Technical Service if the alarm persists.
COOLING OIL PUMP FAULT (OFF)	The pump motor current is less than 100 mA even though it has been activated.	Reboot the equipment to reset the alarm. Call Technical Service if the alarm persists.
COOLING FAN FAULT (OFF)	The fan is stopped even though it has been activated.	Reboot the equipment to reset the alarm. Call Technical Service if the alarm persists.
COOLING OIL PUMP OVERCURRENT	The pump motor current exceeds 800 mA	Reboot the equipment to reset the alarm. Call Technical Service if the alarm persists.
X-RAY TUBE HEAD OUT OF RANGE	The temperature of the monoblock is outside the acceptable range between 10° C (50° F) and 65° C (149° F).	Wait for the temperature of the monoblock to return within the acceptable range. Call Technical Service if the alarm persists.

7 MAINTENANCE

See the Technical Manual for details of extraordinary maintenance, required in the event of a fault or the replacement of parts.
This manual only deals with routine maintenance operations.

7.1 ROUTINE MAINTENANCE

7.1.1 GENERAL RECOMMENDATIONS

The EM equipment requires regular checks and maintenance.
The following recommendations are aimed at avoiding malfunctions and maintaining proper safety conditions.
The equipment contains mechanical parts subject to wear and tear as a result of their use. After a prolonged period of use, it is possible that safety will be reduced due to wear and tear of the components.
Regular inspections and maintenance are also needed to protect patients and operators from injury arising from broken mechanical parts.
Correct adjustment of the electromechanical and electronic modules directly affects the efficiency of the equipment, image quality, electrical safety and the irradiation exposure level to which both hospital personnel and patients are subjected.
The maintenance schedule consists of checks and preventive measures. These are the responsibility of the owner and should only be carried out by expressly authorised personnel.

Always use original spare parts whenever parts that can affect machine safety need to be replaced.

7.1.2 USER CONTROLS AND INSPECTIONS

The user must ensure that his operators receive special training to carry out the daily and weekly checks detailed in the table below.
Any other checks should be carried out by authorised qualified Technical Service personnel.

Daily:	Check that the signals, displays, laser localizer and LEDs are working. Check that the warning and danger signs are not damaged. Check for unusual noises coming from the monoblock during X-ray emission. Check the X-Ray dose level (*see paragraph 7.4.1 below*). Check the efficiency of the DAP (*see paragraph 7.4.2 below*). Check the max aperture of the X-ray collimator (*see paragraph 7.4.3 below*). Check the safety of the motorised up/down C-arm movement (*see paragraph 7.4.4 below*). Check the adjustment of the two monitors (*see paragraph 7.4.5 below*).
Weekly:	Check for oil leaks coming from the monoblock. Check the state of the cable sheaths. Check the state of the connectors: the power supply, the X-ray command footswitch and the connections between the stand and the monitor unit.

Any other checks (described in the Technical Manual) should only be carried out by qualified and authorised Technical Service Personnel in line with local rules and requirements.

7.2 CLEANING AND DISINFECTING

Do not use cleaning products that have a high alcohol content to clean the surfaces of the equipment. Do not use corrosive detergents, abrasive products or solvents.

Only use disinfectants that fully comply with existing disinfecting and explosion prevention procedures and regulations.

Observe the following precautions when cleaning and disinfecting:

- Switch the equipment off and unplug at the mains.
- Make sure that no liquids infiltrate the equipment to prevent short circuits and corrosion of the electrical and electromechanical components.
- Clean the panels with a soft damp cloth and a little soapy water.
- Make sure the panels are completely dry before using the equipment again.
- When cleaning the monitor, always add the soapy water to the cloth first, before wiping the screen.
- **Before to clean the footswitch, unplug the connector from the stand, if present.** Footswitch must be cleaned regularly and thoroughly, using a soft fabric with a general-purpose detergent. Footswitch can be disinfected using isopropyl alcohol wipes (70%) or immersion in a disinfectant solution; finally rinse thoroughly under running water and dry carefully.

  ***Note: DO NOT** use **Chlorine** based disinfectants that may lead to deterioration of the device.*

  If using disinfectants that form explosive vapours/gaseous mixtures, make sure that these have had time to disperse before using the equipment again.

7.2.1 MICROBIC CONTAMINATION

To avoid problems with microbic contamination for patients and operators, *the user* must ensure that the equipment is protected using disposable sterile sheets, or sheets that can be sterilised.

***Note:** Sterile sheets are not provided from the EM equipment manufacturer. Always use sheets sterilised using methods that comply with current local sterilization standards.*

7.3 REPLACING BATTERIES

7.3.1 REPLACING THE REMOTE-CONTROL BATTERY

The infrared remote control is powered by a **9 V DC battery, model 6LR61.**

The battery is flat when LED (**L**) fails to light up when you press any of the keys (fig.1a).

If you need to replace a flat battery (**B**), undo the screw (**V**) to remove the cover (**C**) on the battery compartment (fig.1b).

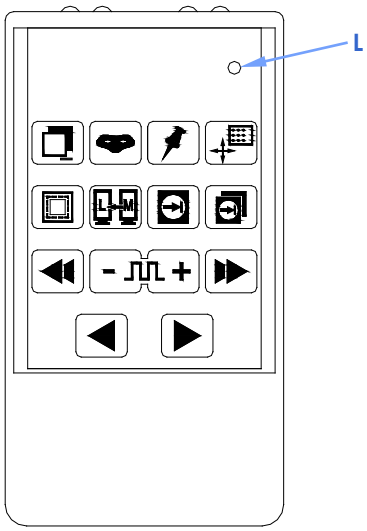


Fig.1a

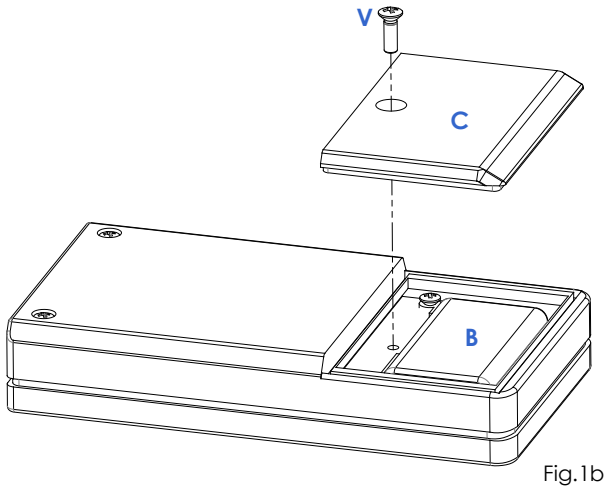


Fig.1b

Note: *The infrared remote-control receiver is integrated into the stand, behind the left handle.* (fig.2)

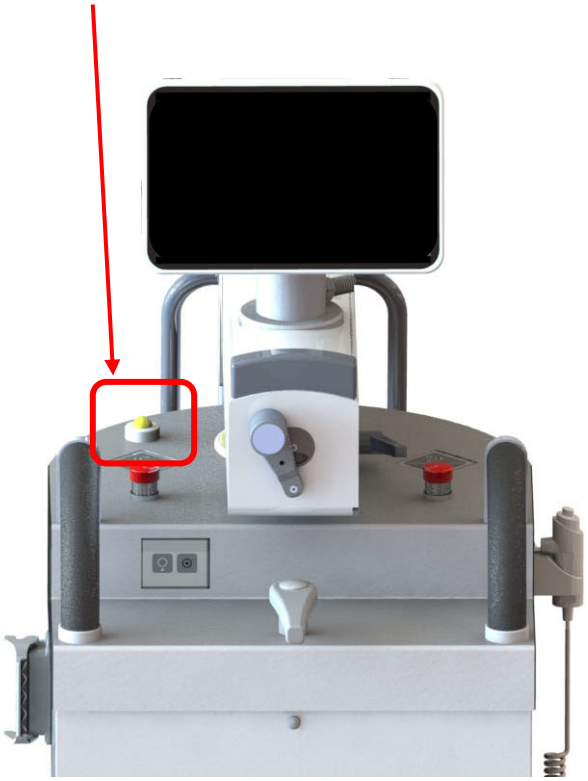
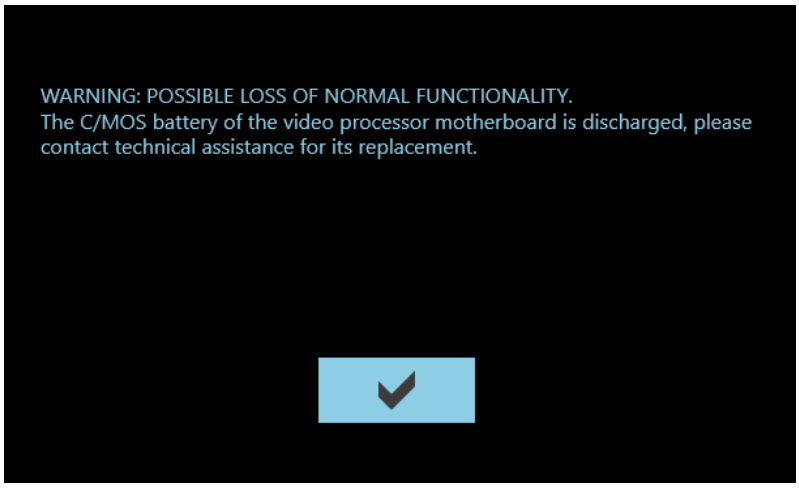


Fig.2

7.3.2 REPLACING THE BACKUP BATTERY ON THE MOTHER BOARD

The manufacturer recommends changing the buffer battery of the video processor every three years.

The user will be advised as this time is over, at the login.



See Paragraph 6.5, Part 5 of the Technical manual for the replacing procedure.

7.4 DAILY CHECKS

7.4.1 CHECKING THE DOSE LEVEL

To minimise the residual risk of X-ray emission at the wrong dose, it is required to perform the following test every day, immediately after switching the equipment on and before using it on patients (see details below).

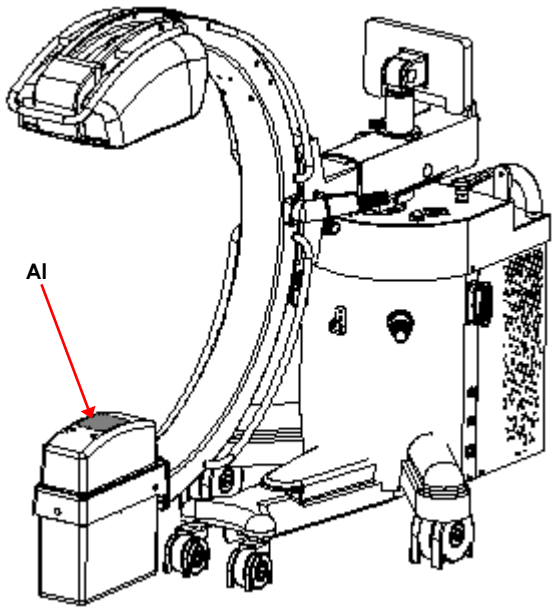
You need to compare the kV and mA values automatically set by the EM equipment for the envisaged working conditions with those detected under the same conditions during installation. These values are indicated in the Test Sheet filled in by the installer.
Regular checks that these values correspond will ensure the efficiency of the automatic dose control system.

a) Select the exam **DAILY TEST** (*). Check that the following configuration has been set:
   - Nominal detector field (21x21cm^2 or 30x30cm^2 depending on the detector model installed),
   - X-ray collimator completely opened.

b) Place both the **aluminium** plates (with **21 mm** and **10 mm** thickness) provided with the device, on the monoblock.

c) Give the **Low Dose fluoroscopy** command by pressing the X-ray pedal on the left:
   - Check that the kV and mA automatically set by the device are equal (or within the tolerances) to those indicated in the test sheet.

d) Then give the **High Quality fluoroscopy** command by pressing the X-ray pedal on the right:
   - Check that the kV and mA automatically set by the device are equal (or within the tolerances) to those indicated in the test sheet.



In case the kV and mA values collected should not be correct, analyse the error type. If there is a probability of a fault condition, stop using the device and request an intervention by the technical service.

The following table shows the typical kV and mA values which were collected in our factory with the aforementioned configuration settings:

	Version FPD 2121 (@4imm/s)		Version FPD 3030 (@4imm/s)			
	kV	**mA**	**kV**	**mA**	**Tolerance**	
Low Dose	60	0,45	60	0,45	±1kV	± 0,2mA
High Quality	60	0,90	60	0,90	±1kV	± 0,2mA

(*) The exam DAILY TEST is set in the factory with the following parameters:
- *Image dose low dose fluoroscopy = 12 nGy/i*
- *Image dose high quality fluoroscopy = 24 nGy/i*
- *With anti-scattering grid,*
- *Additional filter in the X-ray collimator: 1 mmAl and 0,2 mmCu.*

7.4.2 CHECKING THE DOSE AREA PRODUCT (DAP)

To minimise the residual risk of incorrect dose measurement, we recommend checking the dose level every day, immediately after switching the equipment on and before using it on patients (see details below).

a) Select the exam **DAILY TEST** (*). Check that the following configuration has been set:
   - Nominal detector field (21x21cm^2 or 30x30cm^2 depending on the detector model installed),
   - X-ray collimator completely opened.

b) Place both the **aluminium** plates (with **21 mm** and **10 mm** thickness) provided with the device, on the monoblock as specified in the previous paragraph.

c) Give the **Low Dose fluoroscopy** command in automatic mode and check that the DAP increase for an X-ray emission of 10 seconds is equal (or within the tolerances) to the value indicated in the test sheet.

The tables below show the typical DAP increase values which were collected in our factory with the aforementioned configuration settings:

Version FPD 2121 (@4imm/s)				
	kV / mA avg	**X-ray emission duration**	**Beam dimensions RX**	**DAP increase (uGy x m^2)**
Low Dose	80 / 1,5	10 seconds	21 x 21 cm^2	9,2 ± 50%

Version FPD 3030 (@4imm/s)				
	kV / mA avg	**X-ray emission duration**	**Beam dimensions RX**	**DAP increase (uGy x m^2)**
Low Dose	80 / 1,5	10 seconds	30 x 30 cm^2	18,8 ± 50%

Find out the reason for the error if the actual dose values do not fall within the tolerance limits. There is probably a fault somewhere, so do not use the equipment and call Technical Service.

(*) The exam DAILY TEST is set in the factory with the following parameters:
- *Image dose Low Dose fluoroscopy = 12 nGy/i*
- *Image dose High Quality fluoroscopy = 24 nGy/i*
- *With anti-scattering grid,*
- *Additional filter in the X-ray collimator being 1mmAl and 0,2mmCu.*

7.4.3 CHECKING THE MAX X-RAY COLLIMATOR APERTURE

With the collimator, fully open, check that this is still visible on each edge of the image: this ensures against the risk of excessive exposure resulting from either the incorrect calibration or the malfunctioning of the collimator.

If you cannot see the edge of the collimator when this is fully open, try closing this manually by using the relevant command on the control panel.
If not, call Technical Service and ask them to make the necessary adjustments.

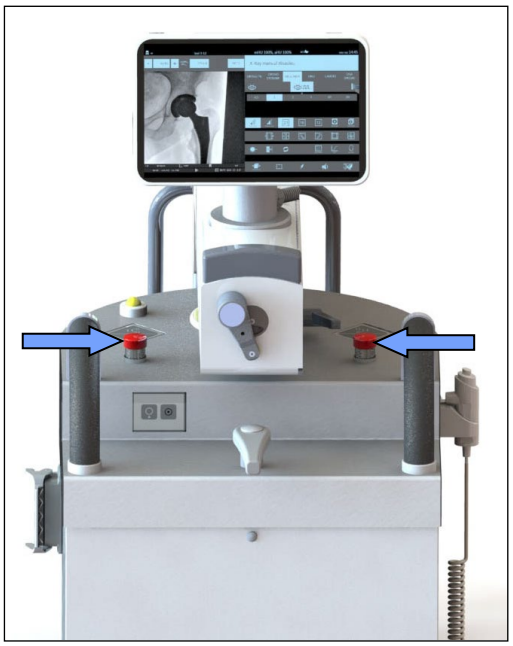
7.4.4 CHECKING THE SAFETY OF THE MOTORISED UP/DOWN C-ARM MOVEMENT

The safety circuit protecting against accidental movement of the C-arm column must be tested every day, **within 20 seconds from switching the equipment on.**

To do this:
- press both an UP and a DOWN key for a few seconds;
- on releasing these:
  - the column will not move if there is no problem;
  - the column will move by about 1 cm if there is a problem in the safety circuit, first up and then down.

If faulty, do not use the equipment and call Technical Service.

You also need to make sure that the 2 emergency stop buttons on the stand are working properly: press one of these and make sure the column cannot move.



7.4.5 CHECKING THE MONITOR ADJUSTMENTS

For details on how to check the monitor adjustments, please refer to *Chapter: "Operation", Paragraph 5.2.1 of this Manual.*

7.5 X-RAY TUBE SEASONING PROCEDURE

Typically, x-ray tube seasoning procedure is required:

- at the equipment installation,
- after a period of inactivity longer than 2 months,
- in case of an electrical discharge in the X-ray tube.

The procedure involves a series of exposures at increasing kV values in order to reduce possible residual gas in the X-ray tube, before to use it at full load.
Moreover, it minimizes the irregular distribution of the potential / electric field on the tube glass.

Carrying out the recommended training procedure will help to prolong the life of the X-ray tube and to prevent electrical discharges of the tube (perceived as a noise, like the sound of a strong slap) that can potentially cause irreversible damage to the X-ray tube.

Follow the steps below to perform the procedure:

- Select the EXTREMITY exam.
- Close the X-ray collimator completely.
- Execute the exposures following the parameters of the three phases below.

Attention: *before performing an X-ray exposure, control that all necessary radiation protections have been taken.*
During the emission of x-ray, the staff in the room must comply with the regulations regarding radiation protection.

Phase 1 X-ray emission in Digital radiography

ITEM	kV	mAs	Expositions number	Time between exposures (in seconds)
1	80	25	28	5
2	80	0,5	3	5
3	90	0,5	3	5
4	100	0,5	3	5
5	110	0,5	3	5
6	120	0,5	20	5

Phase 2 X-ray emission in Fluoroscopy Low Dose mode, at 4i/s

ITEM	kV	mA avg	Expositions time (in seconds)	Time between exposures (in seconds)
1	80	1,5	30	5
2	90	1,3	30	5
3	100	1,2	30	5
4	110	1,1	30	5
5	120	1,0	60	5

Phase 3 X-ray emission in Digital radiography

ITEM	kV	mAs	Expositions number	Time between exposures (in seconds)
1	80	8	5	5
2	90	8	5	5
3	100	8	5	5
4	110	8	5	5
5	115	8	10	5
6	120	8	20	5

8 PRODUCT DISPOSAL

8.1 PROCEDURES AND PRECAUTIONS

When scrapping the device, special care must be taken when handling the following components as these can be hazardous when scrapped:

- The flat panel detector contains **caesium iodide doped with thallium** and **lead** that must be considered toxic materials.

- The LCD monitor has a **screen** which, should it break, can send shards of glass flying and disperse substances that may be toxic.

- The monoblock contains a **vacuum tube** which, should it break, can send shards of glass flying; it also contains **lead** that must be considered a toxic material; it also contains exhaust **oil** which must be disposed of in accordance with the current local regulations.

- The X-ray collimator contains **lead**: this is a toxic material and must be treated as such.

- **Lead** counterweights to balance the C-arm.

- All flat **batteries** must be disposed of in accordance with European Directive 2006/66/EC and subsequent amendments (concerning batteries and accumulators and battery/accumulator waste).

Other parts of the equipment are made from:
- ferrous material (frames, etc.),
- plastic (covers and guards, etc.),
- wiring,
- optical materials.

These parts are not considered to be a potential source of hazards when scrapping the device.

All parts should be disposed of in accordance with the prevailing regulations in each country ***at the moment of scrapping***.

The symbol on the right appears on the equipment to remind you that the equipment meets European Environmental Directive 2012/19/EU (handling of Waste Electrical and Electronic Equipment - WEEE) *and so must be scrapped in accordance with the relevant laws for separated waste disposal.*

This equipment must not be disposed of as normal municipal solid waste: it must be taken to an expert waste disposal centre or returned to the dealer, should you wish to replace it with a new model.

9 TECHNICAL DATA

9.1 STANDARDS AND REGULATIONS

Never remove any parts or covers, as this could compromise the electromagnetic compatibility of the system.

Portable and mobile radio communication devices may affect the efficiency of the device.

9.1.1 ELECTROMAGNETIC EMISSIONS

Table 1

Manufacturer's guidelines and declaration - electromagnetic emissions		
In accordance with EN standard 60601-1-2 (4th edition), the system is intended for use in the electro-magnetic environment specified below. The client or user of the system must ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidelines**
RF emissions CISPR 11	Group **1**	The system uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class **A**	The system is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage mains supply for residential buildings. *Note:* *If the equipment is used in domestic environments (classified as CLASS B based on CISPR 11 standard), it should not provide an adequate protection against radiofrequency interferences.* *The user shall adopt countermeasures to reduce the effect, such as changing equipment placement or orientation.*
Harmonic emissions EN 61000-3-2	N.A.	
Voltage fluctuation / flicker emissions EN 61000-3-3	N.A.	

9.1.2 ELECTROMAGNETIC IMMUNITY

Table 2

Manufacturer's guidelines and declaration - electromagnetic emission			
In accordance with EN standard 60601-1-2:2007+ EC: 2010, the system is intended for use in the electro-magnetic environment specified below. The client or user of the system must ensure that it is used in such an environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment - guidelines**
Electro-static discharge (ESD) EN 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EN 61000-4-3	3 V/m 80 kHz - 2.7 GHz	3 V/m 80 kHz - 2.7 GHz	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the system, including cables.
Electrical fast transient / burst EN 61000-4-4	±2kV for power supply lines ±1kV for input/output lines >3 m	±2kV for power supply lines ±1kV for input/output lines >3 m	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF EN 61000-4-6	3 V 150 kHz to 80 MHz 6V ISM frequencies	3 V 150 kHz to 80 MHz 6V ISM frequencies	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the system, including cables.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	10 ms for 0% at 0°, 45°, 90°, 135°, 180°. 225°, 270°, 315° 20 ms for 0% at 0° 500 ms for 70% a 0° 5 s for 0%	10 ms for 0% at 0°, 45°, 90°, 135°, 180°. 225°, 270°, 315° 20 ms for 0% at 0° 500 ms for 70% at 0° 5 s for 0%	Mains supply quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during blackouts, it is recommended that the system be powered via a non-interruptible power supply.
Power frequency (50/60Hz) magnetic field EN 61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the monitor of the system further from source of power frequency magnetic field or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

9.1.3 RECOMMENDED SEPARATION DISTANCES BETWEEN SYSTEM AND PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT

The system is intended for use in an electromagnetic environment in which radiated RF interference is controlled.
The client or user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Tested frequency (MHz)	Band (MHz)	Service	Modulation	Max Power (W)	Distance (m)	Test immunity level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 480 FRS 460	FM ~ 5 KHz deviation 1 KHz sine	2	0.3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 – 900	GSM 800/900 TETRA 800 IDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700–1990	GSM 1800CDMA 1900 GSM 1900 DECT LET Band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LET Band 7.	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

9.2 DEVICE CLASS

Type of protection against electrical contacts:	Class **I**
Degree of protection against electrical contacts:	The system does not contain any patient applied parts
Degree of protection against water penetration:	**common** equipment.
Degree of safety in the presence of inflammable gases:	**not suitable** for use in the presence of inflammable gases
Operating mode:	**continuous**

9.3 TECHNICAL CHARACTERISTICS

9.3.1 MECHANICAL / ELECTRICAL DATA

C-ARM	**5 kW** Models	**20 kW** Models
MECHANICAL DATA		
Motorised vertical stroke	- stroke: 450 mm - speed: 1 cm/s	
Horizontal stroke	212 mm	
Wig-wag	± 12°	
Arc rotation around horizontal axis	± 275°	
C-arm sliding	160°	
Focal spot / flat panel detector distance (S.I.D.)	1066 mm *(on version with FPD 2121)* 1080 mm *(on version with FPD 3030)*	
Flat panel detector / X-ray monoblock distance	810 mm *(on version with FPD 2121)* 821 mm *(on version with FPD 3030)*	
Arc depth	707 mm	
Stand / monitor unit connection	6 m cable	
POWER SUPPLY		
Single-phase voltage	230 Vac ± 10%, 50Hz, 60 Hz	
	120 Vac ± 10%, 50Hz, 60 Hz	
Max consumption	- Fluoroscopy 16 A(1) - Radiography 22 A(2) (1) @ 120kV-8mA Average (2) @ 100kV-25mAs	- Fluoroscopy 16 A(3) - Radiography 22 A(4) (3) @ 120kV- 8mA Average (4) @ 100kV-25mAs
Line resistance	max 0.4 Ohms	
Connector	NEMA 5 - 20 A	
ENVIRONMENTAL CONDITIONS		
Storage	- Temperature: -10 to +55 °C - Relative humidity: 20 - 80 % (**not condensing**) - Pressure: 70 - 106 kPa	
Working	- Temperature 10 - 35 °C - Relative humidity: 20 - 70 % (**not condensing**)	

X-RAY POWER SUPPLY	**5 kW** version	**20 kW** version
Code	IRI.37.201.001	
Oscillation rate	40 kHz	
Max voltage	120 kVp	
§Max current in fluoroscopy mode	40 mA	100 mA
Max current in radiography mode	100 mA	200 mA
Max power for radiography	4 kW for exposures up to 1 kJ	20 kW for exposures up to 0.5 kJ

X-RAY MONOBLOCK	Passive Cooling	Active Cooling
Model	I-40R 15 RF	I-40R 15 RF AC
Max Power	20kW	
Heat Capacity	1020 kJ	
Continuous heat dissipation (in air)	130 W	250 W
Continuous heat dissipation (on c-arm)	150 W (12,5 KHU/min)	270 W (22,6 KHU/min)
Total filtering	3 mm Al_{eq} (@ 70 kV)	
Safety overload cut-out temperature	60°C ±5°C	
Max charging time for X-ray monoblock in fluoroscopy mode	53 min (Duty cycle: 60 sec. ON – 60 sec. OFF @ 15i/s, 75 kV – 6 mA_{avg})	87 min (Duty cycle: 60 sec. ON – 60 sec. OFF @ 15i/s, 75 kV – 6 mA_{avg})
Compliance	EN 60601-1 EN60601-2-28	
Leakage radiation	< 0,8mGy/h @ 120kV-4mA in Fluoroscopy mode or 120kV-14400mAs in Digital Radiography mode	

X-RAY TUBE	
Model	IAE RTM70H
Anode material	Rhenium/Tungsten/Molybdenum
Focus	- Small focus: 0.3 mm - Large focus: 0.6 mm
Anode angle	10°
Anode heat capacity	225 kJ
Max anode heat dissipation	750 W
Nominal anode power	- Small focus: 6 kW - Large focus: 25 kW
Anode rotation	3000 RPM

Multiple fields X-RAY COLLIMATOR with FPD 2121	
Model	R 650 QDASM /010D with secondary collimator RS 2248
Square field	- Continuously adjustable aperture - Automatic adjustment to suit detector field - Manual control
Shutters	- Continuously adjustable aperture - Clockwise/anti-clockwise rotation, continuously adjustable - Manual control - Shutters can be moved independently on each other
Max X-ray field	**21 x 21 cm²**
Additional X-ray beam filtering (4 possible conditions)	- No filter - 2mm Al - 1mm Al + 0.1mm Cu - 1mm Al + 0.2mm Cu

Multiple fields X-RAY COLLIMATOR with FPD 3030	
Model	R650 QDASM/010D
Square field	- Continuously adjustable aperture - Automatic adjustment to suit detector field - Manual control
Shutters	- Continuously adjustable aperture - Clockwise/anti-clockwise rotation, continuously adjustable - Manual control - Shutters can be moved independently on each other
Max X-ray field	**30 x30 cm²**
Additional X-ray beam filtering (4 possible conditions)	- No filter - 2mm Al - 1mm Al + 0.1mm Cu - 1mm Al + 0.2mm Cu

DOSE AREA PRODUCT (DAP) meter (Optional)	
Model	KermaX plus (mod. 120-123c)
Power supply	DC: 12 - 29V (max 50mA)
Useful Area Diameter	93 mm
Sensitivity	1mGy x cm²

LASER LOCALIZER *Consisting of 4 laser modules* (Optional)	
Model	ML635L - class 1M
Class	1M
Laser diode power	< 5 mW
Optical output power	3.8 mW
Wavelength	635 nm
Laser light warning	

9.3.2 IMAGING SYSTEM

FLAT PANEL DETECTOR			
Model		**Pixium 2121S**	
FPD Matrix		1344 x 1344 pixel	
Sensitive area		FLUOROSCOPY Nominal field= 207mm x 207mm (1344 x 1344 pixel) Zoom 1= 158mm x 158mm (1024 x 1024 pixel) Zoom 2= 119mm x 119mm (776 x 776 pixel) DIGITAL RADIOGRAPHY Nominal field= 207mm x 207mm (1344 x 1344 pixel)	
Thickness index		0.40	
Technology		amorphous silicon matrix	
Pixel size		154 µm x 154 µm	
Max frame rate		25 frames/s	
DQE @ 2 µ Gy, RQA5		0 lp/mm	77 %
		1 lp/mm	56 %
		2 lp/mm	46 %
		3,2 lp/mm	22 %
MTF	Horizontal	IEC 1 lp/mm	59 %
		IEC 2 lp/mm	29 %
		IEC 3 lp/mm	14 %
		IEC Nyquist	11 %
	Vertical	IEC 1 lp/mm	59 %
		IEC 2 lp/mm	29 %
		IEC 3 lp/mm	14 %
		IEC Nyquist	11 %
		- 0,5 lp/mm 80% - 1 lp/mm 59% - 2 lp/mm 29% - 3.25 lp/mm 11%	
A/D conversion		16 bits	
Power supply		24 VDC - 11W	
Max dimensions		283mm x 288mm x 78.5mm	
Weight		8.5 kg	
Cooling		Passive	
Room Temperature		- Working: 10° - 35° - Storage: -25° to +70°	
Filtering of detector protective element		0.4 mm Al $_{eq}$	
Offset		Automatic when a new study is created	

FLAT PANEL DETECTOR			
Model		**Pixium 3030S**	
FPD Matrix		1956 x 1956 pixel	
Sensitive area		FLUOROSCOPY Nominal filed=301mm x 301mm (1956 x 1956 pixel) Zoom 1=207mm x 207mm (1344 x 1344 pixel) Zoom 2= 158mm x 158mm (1024 x 1024 pixel) DIGITAL RADIOGRAPHY Nominal filed= 301mm x 301mm (1956x1956 pixel)	
Thickness index		0.52	
Technology		Amorphous Silicon matrix	
Pixel size		154 µm x 154 µm	
Max frame rate		25 frame/s	
DQE @ 2 µ Gy, RQA5		0 lp/mm	77 %
		1 lp/mm	57 %
		2 lp/mm	48 %
		3.2 lp/mm	22 %
MTF	Horizontal	IEC 1 lp/mm	59 %
		IEC 2 lp/mm	29 %
		IEC 3 lp/mm	14 %
		IEC Nyquist	11 %
	Vertical	IEC 1 lp/mm	59 %
		IEC 2 lp/mm	29 %
		IEC 3 lp/mm	14 %
		IEC Nyquist	11 %
		- 0,5 lp/mm 80% - 1 lp/mm 59% - 2 lp/mm 29% - 3.25 lp/mm 11%	
A/D conversion		16 bits	
Power supply		24 VDC - 14W	
Max dimensions		374mm x 374mm x 78.5mm	
Weight		12.7 kg	
Cooling		Passive	
Room temperature		- Working: 10° - 35° - Storage: -25° to +70°	
Filtering of detector protective element		0.4 mm Al $_{eq}$	
Offset		Automatic when a new studio is created	

Note: *the* ***Pixium 2121S*** *and* ***3030S*** *panels are intended for use in generating real time fluoroscopic images in patients where medically indicated. They are also intended for use in generating radiographic images of human anatomy.*

ANTI-SCATTER GRID	
Manufacturer	JPI
Model	ACS
Dimensions	215 mm x 215 mm (FPD 2121) 315 mm x 315 mm (FPD 3030)
Interspace	Aluminium
Ratio	8:1
Shutters	80 lines/cm
Focal distance	100 cm

TV MONITOR	
Model	TMM215W-V-TPU-H
Technology	21.5" colour LCD
Resolution	1920 x 1080 (full HD)
Contrast ratio	5000:1
Brightness	- 600 cd/m^2 (typical) - 1000 cd/m^2 (peak)
Viewing angle	Vertical and horizontal 178°
Power supply	110-230 VAC
Max consumption	45 w
Dimensions	531 x 339 x 70 mm
Weight	7.6 Kg

CONTROL PANEL	
Model	MUIP-2112
Technology	LCD 12,5 " colour, Touch screen
Effective display area	276,5 mm x 157,5 mm
Resolution	1920 x 1080 pixel
Contrast ratio	Max 1000:1
Brightness	400 cd/m^2 (typ)
Viewing angle	Vertical and horizontal: 80 °
Touch screen	P-Cap Multitouch, 10 touches (usable with surgical gloves)
Processor	CPU Intel Celeron N2930 (Quad core 1,83 Ghz, 2Mb cache)
SDRAM	4GB DDR3L 1333MHz RAM
Memory	32GB SATA onboard SSD
Ethernet	2 x Built-in Gigabit Ethernet LAN interfaces
USB	- 1 USB 2.0 port type A - 1 USB 2.0 port type A
Operating System	Microsoft: Windows 10 LTSB
Power supply	Range 12-24Vdc, nominal 19Vdc

MONITOR / CONTROL PANNEL SYNCRONIZATION FUNCTIONS
Image rotation and flip
Windows and Level adjustment
Noise Reduction Filter adjustment
Grey scale inversion
Recursive Filter activation/deactivation
Dynamic Range Compression Level selection
Space Filters activation/deactivation
Full Screen image activation/deactivation
Live Drawing function
Stopwatch activation/deactivation
Viewfinder activation/deactivation

<table>
<tr><th>VIDEO PROCESSOR</th><th colspan="2"></th></tr>
<tr><td>CPU</td><td colspan="2">Intel i7 - 11700 - 2,5GHz - Rocket Lake</td></tr>
<tr><td>Operating System</td><td colspan="2">WINDOWS 10 LTSC 2019 64bits</td></tr>
<tr><td>Video board</td><td colspan="2">GeForce RTX-3060 EAGLE OC 12G</td></tr>
<tr><td>Ethernet interface board</td><td colspan="2">2x: INTEL Server Adapter I210-T1</td></tr>
<tr><td>RAM</td><td colspan="2">16GByte DDR4</td></tr>
<tr><td>Hard Disk</td><td colspan="2">- HD 2,5" SATA3 500 Gbyte tecnologia SSD
- HD 2,5" SATA3 1 Tbyte tecnologia SSD</td></tr>
<tr><td>Number of images that can be saved in Fluoroscopy mode (1344 x 1344 pixels - 16bit)</td><td colspan="2">270.000</td></tr>
<tr><td>Number of images that can be saved in digital Radiography (1956 x 1956 pixels - 16bit)</td><td colspan="2">65.000</td></tr>
<tr><td>Interface</td><td colspan="2">- USB (for Windows compatible printer)

- USB (for saving images to USB memory stick)

- RJ45 (for DICOM 3 interface)</td></tr>
<tr><td>Acquisition</td><td colspan="2">- Max resolution matrix:
• 1344 x1344 pixels (FPD 2121)
• 1956x1956 pixels (FPD 3030)

- Image depth: 16 bits

- Speed: max 25 frames/second</td></tr>
<tr><td rowspan="2">Details of saved images on HD</td><td>Fluoroscopy</td><td>Digital Radiograpy</td></tr>
<tr><td>- field 30: 978 x 978 pixels
- field 21: 1344 x 1344 p.
- field 16: 1024 x 1024 p.
- field 12: 776 x 776 pixels</td><td>- 1344 x1344 pixels (FPD 2121)

- 1956x1956 pixels (FPD 3030)</td></tr>
<tr><td colspan="2">- Levels depth: 16 bits unsigned

- Little indian byte order</td></tr>
<tr><td>Image processing in real time</td><td colspan="2">- Reduction of quantum noise via recursive filter

- DRC (Dynamic Range Compression Dynamic) control of the image latitude and contrast

- Edge smoothing or sharpening, with specific kernel setting (from 3 x 3 to 9 x 9 pixels).

- Grey scale inversion (negative)

- Horizontal image flip.

- Digital image rotation (steps of 1°).

- Automatic Gain Control (AGC): automatic control of the images Window and Level

- L.I.H (Last Image Hold): the last acquired image is saved in RAM.

- DSA functions: *
- Images subtraction
- Max Opacification / Road Mapping</td></tr>
</table>

VIDEO PROCESSOR	
Post-processing functions	- Patient data entry - Cine-loop of acquired run - Image Magnification: up to **4X** (up to 2x with Pitch-to-Zoom + up to 2x with magnifying glass). - Contrast / Brightness control (W and L) - Edge enhancement/reduction (sharp/smooth), with specific kernel settings (from 3 x 3 to 9 x 9 pixels) - DRC (Dynamic Range Compression), digital process to optimise image and contrast latitude - Grey scale inversion (negative) - Multiframe display (max 6) - Electronic shutters - Virtual shutters - Angle/distance measurements - Text entry (free or fixed strings) -Printouts using Windows compatible printer - Saving of images to USB memory stick in DICOM format - DSA functions: * - Mask pick-up - Pixel Shift - Land marking
DICOM functions (*)	- Importing of studies to be performed from the "Worklist SCU" service - Sending of images via the "Store SCU" service - Sending of images to be printed via the "Print SCU" service - Management of studies via the "MPPS SCU" service - Confirmation of image storing via the "Storage Commitment SCU" service - Management of the patient dose via the "Dose Structured Report SCU" service - Request for images via the "Query / Retrieve SCU" service

(*) Optional

AUXILIARY CONNECTION OUTPUTS	
HUB USB	**3** (2 front USB connectors + 1 connector for System Printer, optional).
LAN ETHERNET	**1** (for connection to DICOM network, optional).
HDMI OUTPUT	**2** (*see Paragraph 3.2, Section Installation of the User Manual*).
PRINTER POWER SUPPLY	**1** (local printer power supply, optional)

9.3.3 EXPOSURE MODES

For a full description of the exposure modes:
- **Low Dose** fluoroscopy
- **High Quality** fluoroscopy
- **Radiography**
- mAs table
- kV/mA correlation
- Dose information

see Paragraph 9.9 below

For a full description of the exposure modes:
- Roadmap
- DSA Fluoroscopy

see Paragraphs 5.4.1 and 5.4.2 in Chapter: "Operation" of this Manual.

9.3.4 ACCURACY OF LOADING FACTORS

The accuracy of all loading factors is given in the following table.
Uncertainty values are compliant with standard **EN 60601-2-54 + A2: 2018.**

Accuracy of Radiological parameters	
Tube voltage deviation (kV) in Fluoroscopy modes and Digital Radiography	± 8%
Tube current deviation in Fluoroscopy modes (mA)	± 20%
Current time product in Digital Radiography (mAs)	± 10% + 0,2 mAs
Loading time	± 10% + 1 ms

9.4 FUSES

The power circuit of the EM equipment is protected by a magnetothermal trip-switch found on the monitor unit.
Simply reset the magnetothermal trip-switch if it trips.
If the magnetothermal trip-switch trips again immediately after resetting, the EM equipment is malfunctioning: call Technical Service.
The EM equipment is completely cut off from the mains supply when the magnetothermal trip-switch trips (both electrical poles are separated).

The EM equipment can work with mains power supply of 230 or 120 Vac. Both versions are provided with a specific magnetothermal trip-switch (it changes the tripping current). See table below for full details.

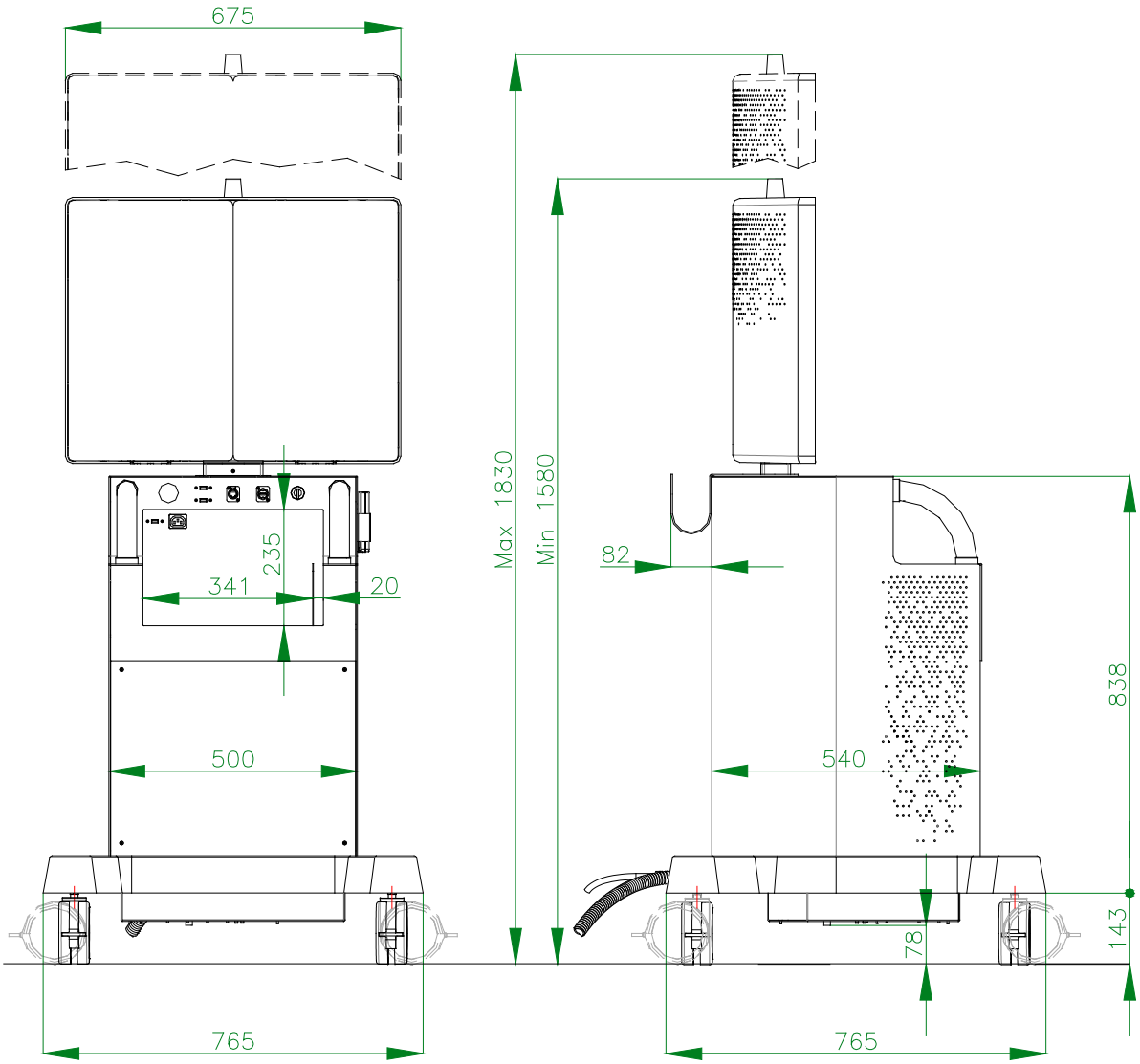
Characteristics of the magnetothermal trip-switch:

120 Vac Version	
Tripping type	**Type D**
Tripping current	**16A**
Number of poles	**2**
Tripping power	**10kA**
Nominal AC voltage	**400V**

230 Vac Version	
Tripping type	**Type D**
Tripping current	**10A**
Number of poles	**2**
Tripping power	**10kA**
Nominal AC voltage	**400V**

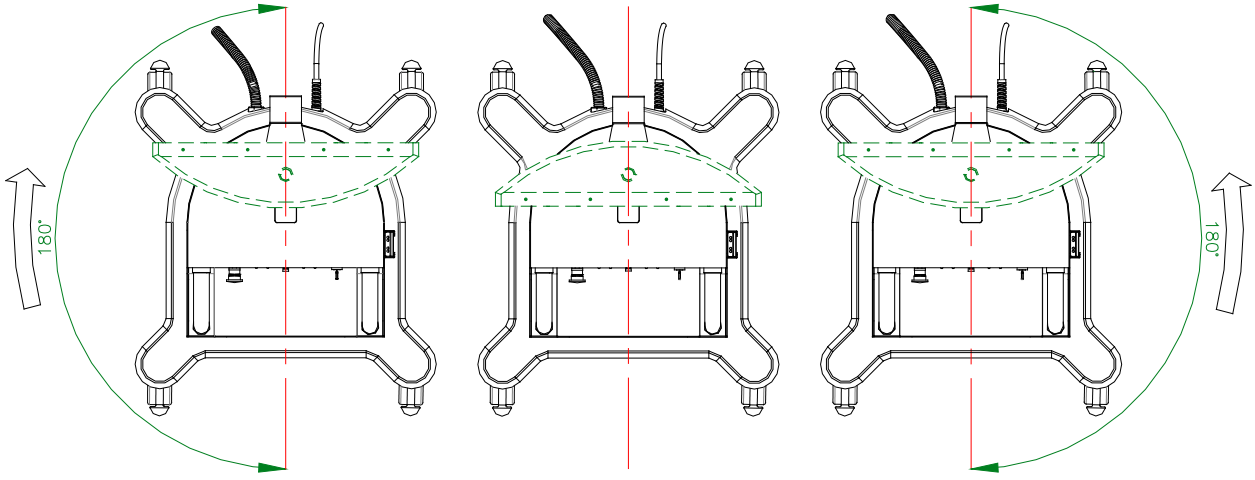
9.5 OVERALL DIMENSIONS AND WEIGHTS

9.5.1 OVERALL DIMENSIONS AND WEIGHT OF THE MONITOR UNIT



Note: *Dimensions shown in mm*

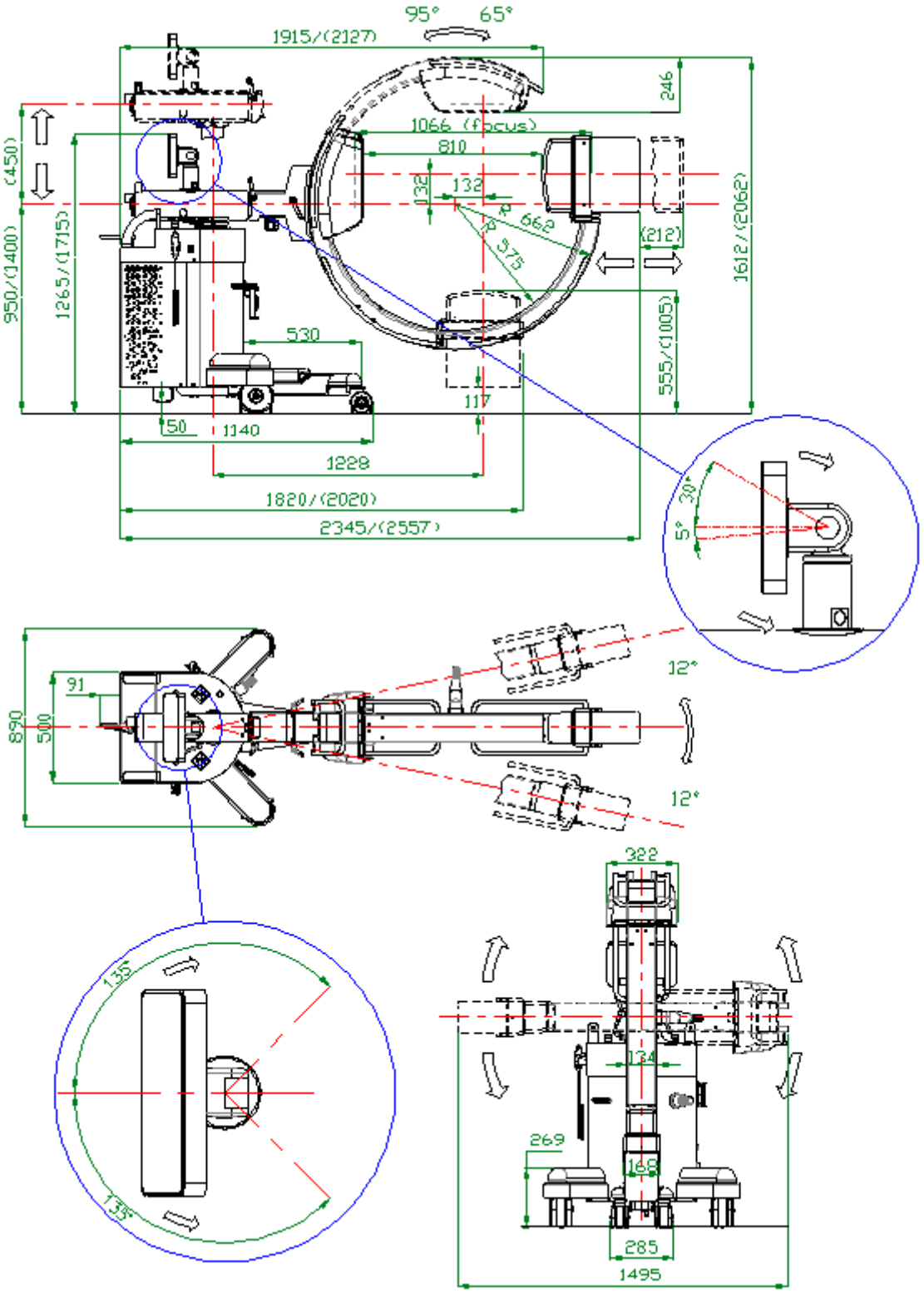
Weight: **140 kg**



Monitor Rotation

9.5.2 OVERALL DIMENSIONS AND WEIGHT OF THE STAND

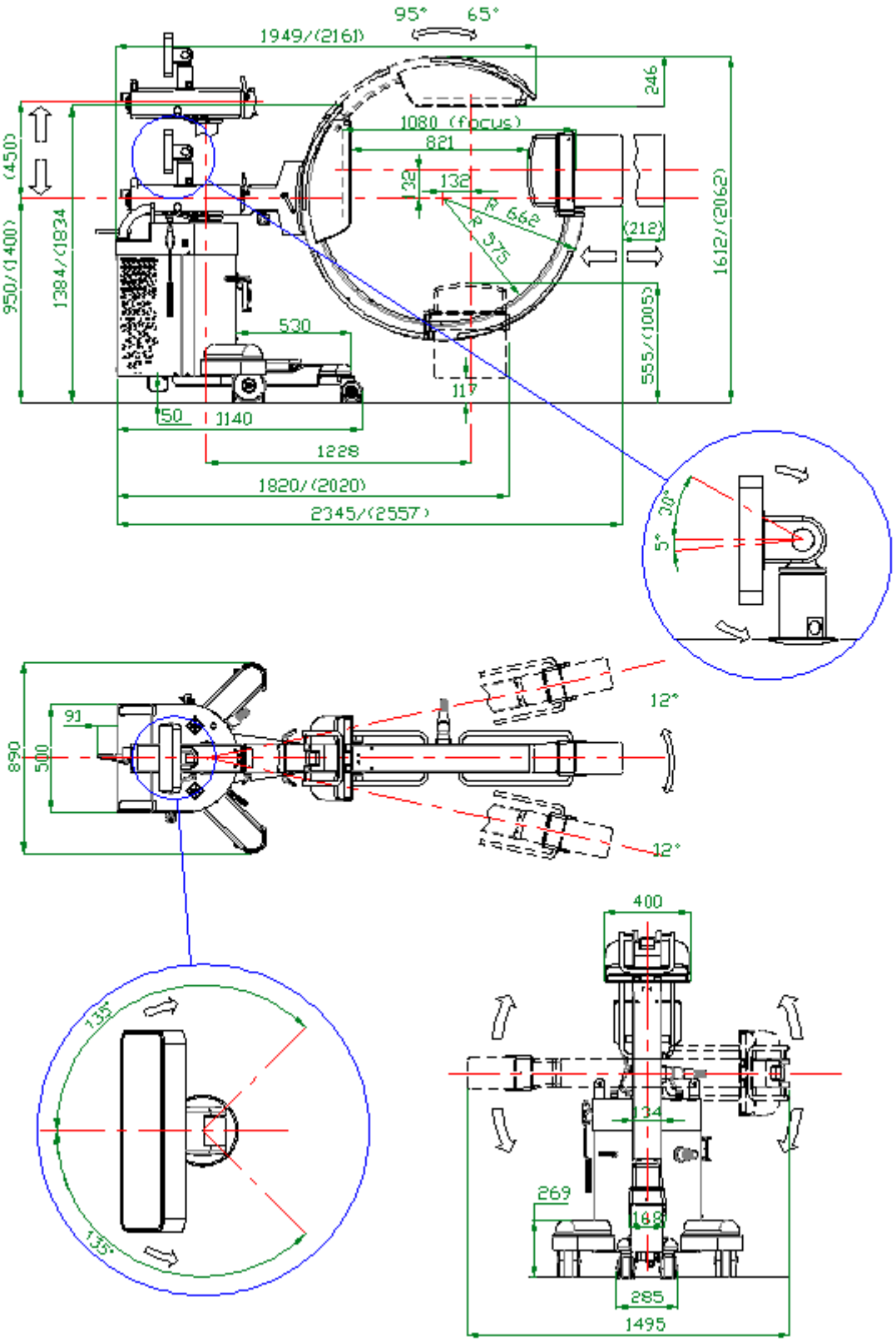
*Version with **FPD 2121***



Note: *Dimensions shown in mm*

Weight:

*Version with **FPD 3030***

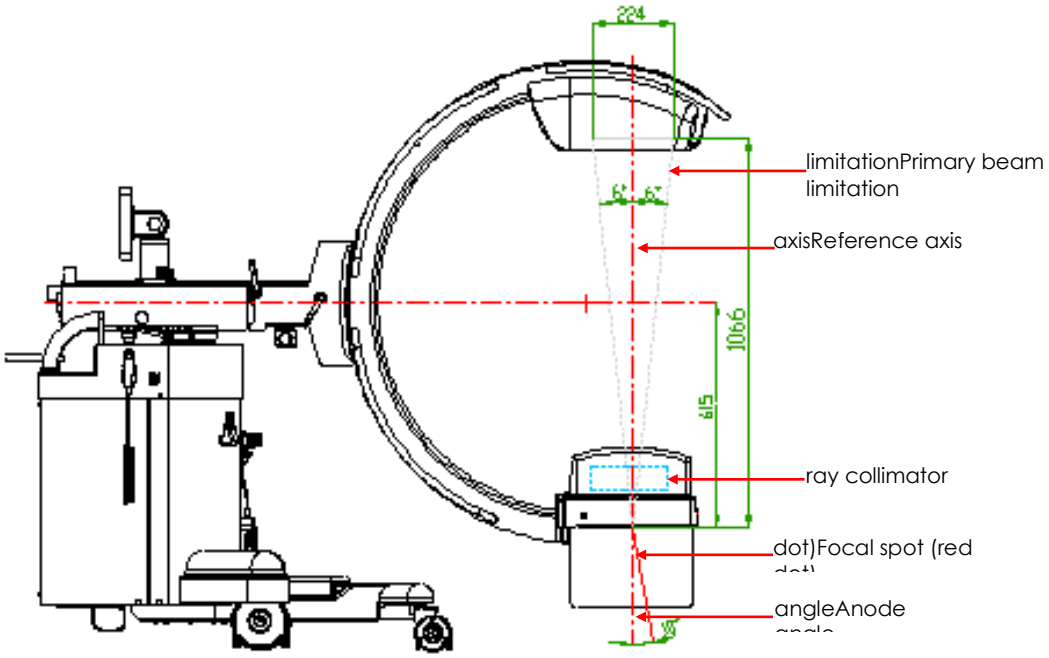


***Note:** Dimensions are shown in mm*

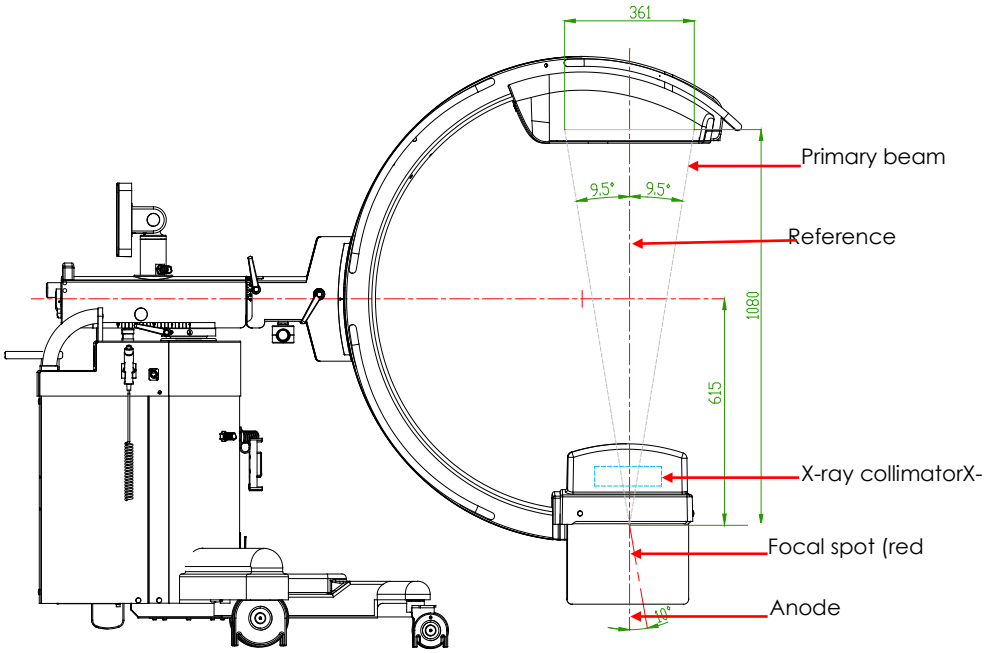
Weight: 280 kg

9.6 FOCAL SPOT POSITION

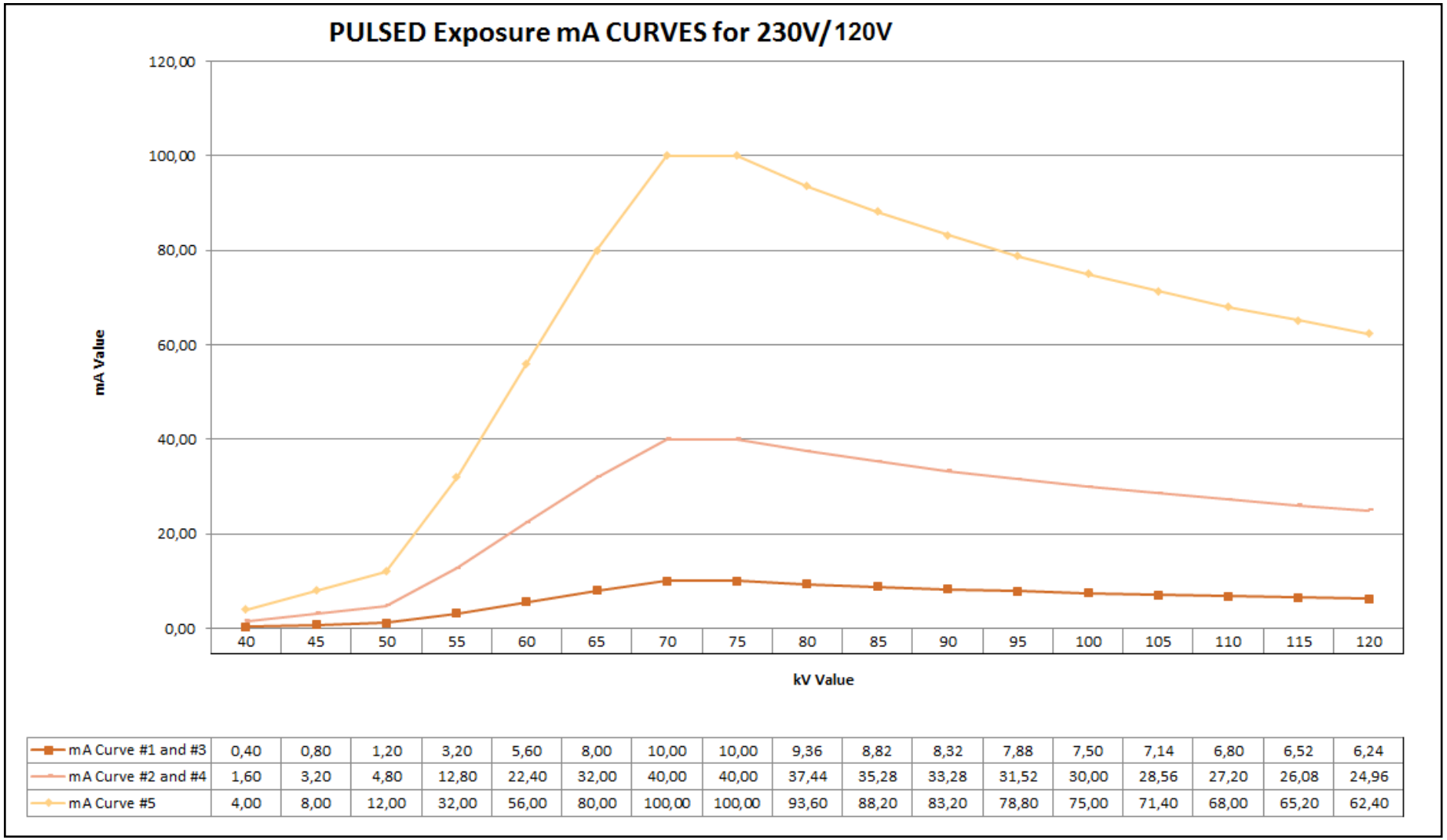
*Version with **FPD 2121***



*Version with **FPD 3030***



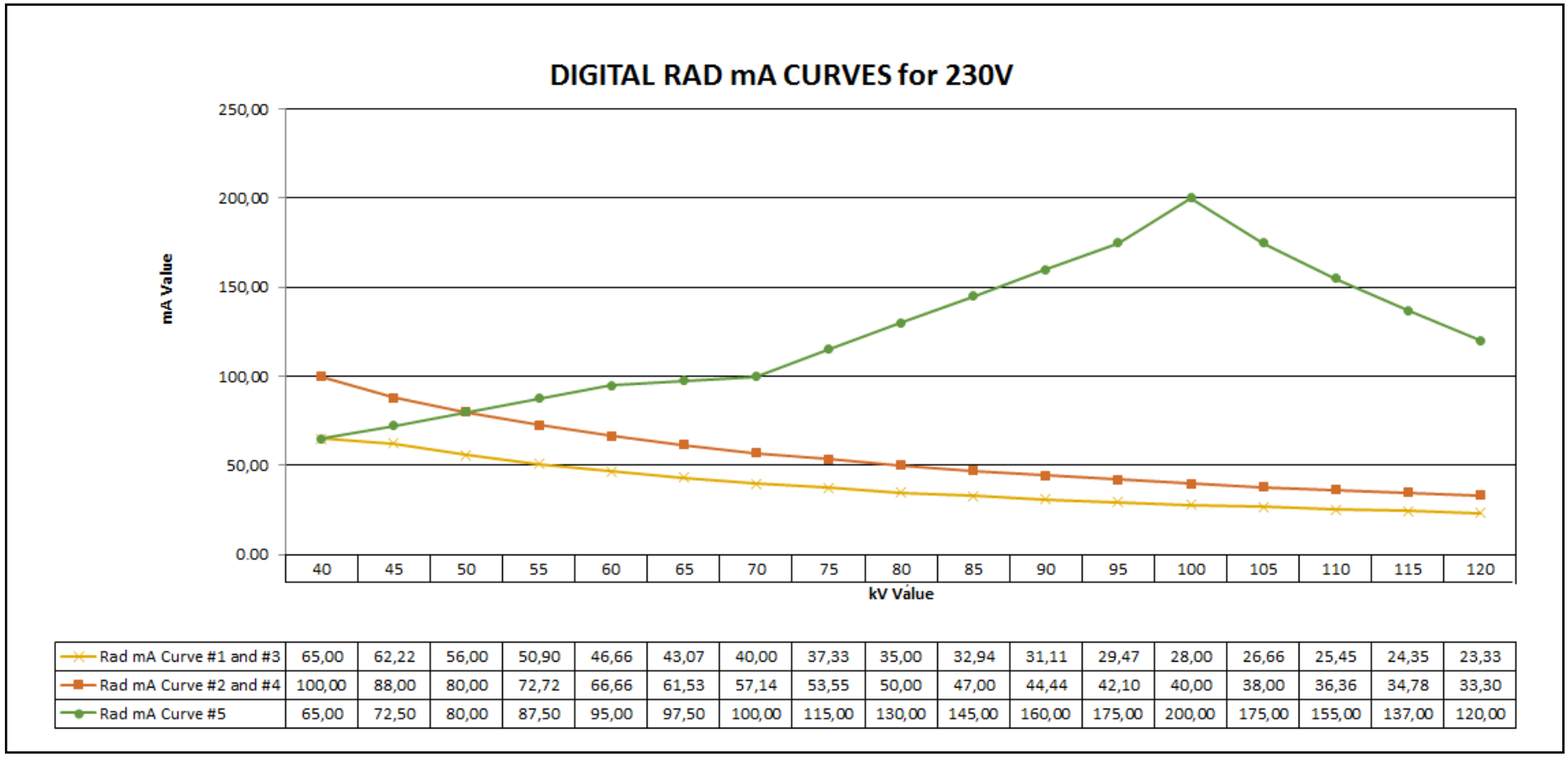
9.7 FLUOROSCOPY mA CURVES



mA Curve #1 and #3	0,40	0,80	1,20	3,20	5,60	8,00	10,00	10,00	9,36	8,82	8,32	7,88	7,50	7,14	6,80	6,52	6,24
mA Curve #2 and #4	1,60	3,20	4,80	12,80	22,40	32,00	40,00	40,00	37,44	35,28	33,28	31,52	30,00	28,56	27,20	26,08	24,96
mA Curve #5	4,00	8,00	12,00	32,00	56,00	80,00	100,00	100,00	93,60	88,20	83,20	78,80	75,00	71,40	68,00	65,20	62,40

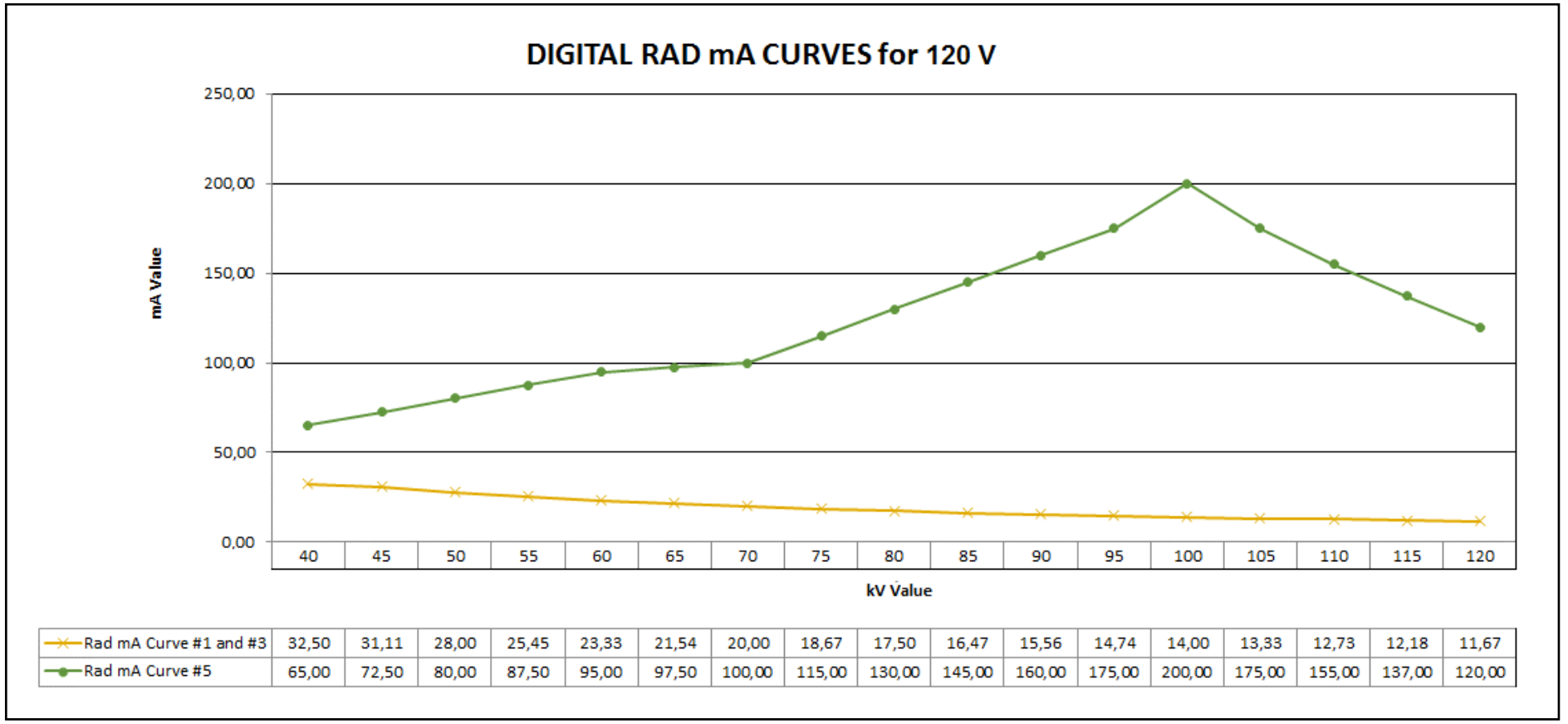
9.8 DIGITAL RADIOGRAPHY (SNAPSHOT) mA CURVES

9.8.1 RADIOGRAPHY CURVES WITH 230 V MAINS POWER SUPPLY



Rad mA Curve #1 and #3	65,00	62,22	56,00	50,90	46,66	43,07	40,00	37,33	35,00	32,94	31,11	29,47	28,00	26,66	25,45	24,35	23,33
Rad mA Curve #2 and #4	100,00	88,00	80,00	72,72	66,66	61,53	57,14	53,55	50,00	47,00	44,44	42,10	40,00	38,00	36,36	34,78	33,30
Rad mA Curve #5	65,00	72,50	80,00	87,50	95,00	97,50	100,00	115,00	130,00	145,00	160,00	175,00	200,00	175,00	155,00	137,00	120,00

9.8.2 RADIOGRAPHY CURVES WITH 120 V MAINS POWER SUPPLY



Rad mA Curve #1 and #3	32,50	31,11	28,00	25,45	23,33	21,54	20,00	18,67	17,50	16,47	15,56	14,74	14,00	13,33	12,73	12,18	11,67
Rad mA Curve #5	65,00	72,50	80,00	87,50	95,00	97,50	100,00	115,00	130,00	145,00	160,00	175,00	200,00	175,00	155,00	137,00	120,00

9.9 EXPOSURE MODES

9.9.1 LOW DOSE FLUOROSCOPY

	Rate max 15 fps	Rate max 25 fps
Automatic dose control	Yes	Yes
5'Timer alarm	Yes	Yes
10' Max. exposure duration safety	Yes	Yes
Range kV	40 ÷ 120 kV	40 ÷ 120 kV
Focus	0.6	0.6
X-ray pulse duration	7÷40ms	7÷13ms
Peak mA range	0,4 ÷ 10 mA (see § 9.9.5: FLUO curve 3)	0,4 ÷ 10 mA (see § 9.9.5: FLUO curve 3)
Dose value (typical)	12 nGy/frame	12 nGy/frame
kV/mA ratio	See par. 9.9.5	See par. 9.9.5
Frame/s	1 / 2 / 4 / 8 / 15	1 / 3 / 6 / 12 / 25

9.9.2 HIGH QUALITY FLUOROSCOPY

	Rate max 15 fps		Rate max 25 fps
		(*)	
Automatic dose control	Yes		Yes
5'Timer alarm	Yes		Yes
10' Max. exposure duration safety	Yes		Yes
Range kV	40 ÷ 120 kV		40 ÷ 120 kV
Focus	0.6		0.6
X-ray pulse duration	20ms	13ms	13ms
Peak mA range	1.6 ÷ 40 mA (see §9.9.5: FLUO curve 4)	4 ÷ 100mA (see §9.9.5 FLUO curve 5)	1.6 ÷ 40 mA (see § 9.9.5: FLUO curve 4)
Dose value (typical)	24 nGy/frame	48 nGy/frame	24 nGy/frame
kV/mA ratio	See par. 9.9.5		See par. 9.9.5
Frame/s	1 / 2 / 4 / 8 / 15		1 / 3 / 6 / 12 / 25

(*) For 20 kW version and DSA mode only.

9.9.3 DIGITAL RADIOGRAPHY

RADIOGRAPHY	Version 5kW	Version 20kW
Range kV	40 ÷ 120 kV	
Range mAs	0,5 ÷ 50 mAs	
Max X-ray emission time	970 ms	
Focus	0.6	0.6
Range mA	100 ÷ 40 mA (see § 9.9.5: RAD curve 4)	65 ÷ 200 mA (see §9.9.5: RAD curve 5)
kV/mA ratio	See par. 9.9.5	
Dose value	- With manual kV and mAs settings: depending on settings - With automatic settings: max 2.5 µGy/frame	
Maximum power	100kV x 40mA= 4kW	100kV x 200mA= 20kW

9.9.4 mAs TABLE

R' 10 mAs values		
	1.25	10.0
	1.60	12.5
	2.00	16.0
	2.50	20.0
	3.20	25.0
0.5	4.00	32.0
0.63	5.00	40.0
1.00	6.30	50.0
0.8	8.00	

9.9.5 kV/mA CORRELATION

For **5 kW** version:

kV	mA PULSED FLUOROSCOPY		mA RADIOGRAPHY	
	Low Dose fluoroscopy Large focus (FLUO curve 3)	High quality fluoroscopy Large focus (FLUO curve 4)	2,8kW Large focus (RAD curve 3)	4kW Large focus (RAD curve 4)
40	0,40	1,6	65,00	100,00
41	0,48	1,9	65,00	97,56
42	0,56	2,2	65,00	95,23
43	0,64	2,5	65,00	93,02
44	7,2	2,8	63,63	90,90
45	0,8	3,2	62,22	88,88
46	0,88	3,5	60,86	86,95
47	0,96	3,8	59,57	85,10
48	1,04	4,1	58,33	83,33
49	1,12	4,4	57,14	81,63
50	1,2	4,8	56,00	80,00
51	1,6	6,4	54,90	78,43
52	2,0	8,0	53,84	76,92
53	2,4	9,6	52,83	75,47
54	2,8	11,2	51,85	74,07
55	3,2	12,8	50,90	72,72
56	3,68	14,7	50,00	71,42
57	4,16	16,6	49,12	70,17
58	4,64	18,5	48,27	68,96
59	5,12	20,4	47,45	67,79
60	5,6	22,4	46,66	66,66
61	6,08	24,3	45,90	65,57
62	6,56	26,2	45,16	64,51
63	7,04	28,1	44,44	63,49
64	7,52	30,0	43,75	62,50
65	8,0	32,0	43,07	61,53
66	8,4	33,6	42,42	60,60
67	8,8	35,2	41,79	59,70
68	9,2	36,8	41,17	58,82
69	9,6	38,4	40,57	57,97
70	10	40,0	40,00	57,14
71	10	40,0	39,43	56,33
72	10	40,0	38,88	55,55
73	10	40,0	38,35	54,79
74	10	40,0	37,83	54,05
75	10	40,0	37,33	53,33
76	9,88	39,5	36,84	52,63
77	9,74	38,9	36,36	51,94
78	9,62	38,4	35,89	51,28
79	9,48	37,9	35,44	50,63
80	9,36	37,4	35,00	50,00
81	9,26	37,0	34,56	49,38
82	9,14	36,5	34,14	48,78
83	9,04	36,1	33,73	48,19
84	8,9	35,6	33,33	47,61
85	8,8	35,2	32,94	47,05
86	8,7	34,8	32,55	46,51
87	8,6	34,4	32,18	45,97
88	8,52	34,0	31,81	45,45
89	8,42	33,6	31,46	44,94
90	8,32	33,2	31,11	44,44
91	8,24	32,9	30,76	43,95
92	8,16	32,6	30,43	43,47
93	8,08	32,3	30,10	43,01
94	7,98	31,9	29,78	42,55
95	7,88	31,5	29,47	42,10
96	7,8	31,2	29,16	41,66
97	7,72	30,8	28,86	41,23
98	7,64	30,5	28,57	40,81
99	7,56	30,2	28,28	40,40
100	7,5	30,0	28,00	40,00
101	7,44	29,7	27,72	39,60
102	7,36	29,4	27,45	39,21
103	7,28	29,1	27,18	38,83
104	7,22	28,8	26,92	38,46
105	7,14	28,5	26,66	38,09
106	7,06	28,2	26,41	37,73
107	7,0	280	26,16	37,38
108	6,92	27,6	25,92	37,03
109	6,86	27,4	25,68	36,69
110	6,8	27,2	25,45	36,36
111	6,74	26,9	25,22	36,03
112	6,7	26,8	25,00	35,71
113	6,66	26,6	24,78	35,39
114	6,58	26,3	24,56	35,08
115	6,52	26,0	24,35	34,78
116	6,46	25,8	24,14	34,48
117	6,4	25,6	23,93	34,18
118	6,36	25,4	23,73	33,89
119	6,3	25,2	23,53	33,61
120	6,24	24,9	23,33	33,33

For **20 kW** version:

kV	mA PULSED FLUOROSCOPY			mA RADIOGRAPHY		
	Low Dose fluoro Large focus (FLUO curve 3)	High quality fluoro Large focus (FLUO curve 4)	High quality fluoro High mA Large focus (FLUO curve 5)	2,8kW Large focus (RAD curve 3)	4kW Large focus (RAD curve 4)	2,6÷20kW Large focus (RAD curve 5)
40	0,40	1,6	4,0	65,00	100,00	65,0
41	0,48	1,9	4,8	65,00	97,56	66,5
42	0,56	2,2	5,6	65,00	95,23	68,0
43	0,64	2,5	6,4	65,00	93,02	69,5
44	7,2	2,8	7,2	63,63	90,90	71,0
45	0,8	3,2	8,0	62,22	88,88	72,5
46	0,88	3,5	8,8	60,86	86,95	74,0
47	0,96	3,8	9,6	59,57	85,10	75,5
48	1,04	4,1	10,4	58,33	83,33	77,0
49	1,12	4,4	11,2	57,14	81,63	78,5
50	1,2	4,8	12,0	56,00	80,00	80,0
51	1,6	6,4	16,0	54,90	78,43	81,5
52	2,0	8,0	20,0	53,84	76,92	83,0
53	2,4	9,6	24,0	52,83	75,47	84,5
54	2,8	11,2	28,0	51,85	74,07	86,0
55	3,2	12,8	32,0	50,90	72,72	87,5
56	3,68	14,7	36,8	50,00	71,42	89,0
57	4,16	16,6	41,6	49,12	70,17	90,5
58	4,64	18,5	46,4	48,27	68,96	92,0
59	5,12	20,4	51,2	47,45	67,79	93,5
60	5,6	22,4	56,0	46,66	66,66	95,0
61	6,08	24,3	60,8	45,90	65,57	95,5
62	6,56	26,2	65,6	45,16	64,51	96,0
63	7,04	28,1	70,4	44,44	63,49	96,5
64	7,52	30,0	75,2	43,75	62,50	97,0
65	8,0	32,0	80,0	43,07	61,53	97,5
66	8,4	33,6	84,0	42,42	60,60	98,0
67	8,8	35,2	88,0	41,79	59,70	98,5
68	9,2	36,8	92,0	41,17	58,82	99,0
69	9,6	38,4	96,0	40,57	57,97	99,5
70	10	40,0	100,0	40,00	57,14	100,0
71	10	40,0	100,0	39,43	56,33	103,0
72	10	40,0	100,0	38,88	55,55	106,0
73	10	40,0	100,0	38,35	54,79	109,0
74	10	40,0	100,0	37,83	54,05	112,0
75	10	40,0	100,0	37,33	53,33	115,0
76	9,88	39,5	98,8	36,84	52,63	118,0
77	9,74	38,9	97,4	36,36	51,94	121,0
78	9,62	38,4	96,2	35,89	51,28	124,0
79	9,48	37,9	94,8	35,44	50,63	127,0
80	9,36	37,4	93,6	35,00	50,00	131,0
81	9,26	37,0	92,6	34,56	49,38	134,0
82	9,14	36,5	91,4	34,14	48,78	137,0
83	9,04	36,1	90,4	33,73	48,19	141,0
84	8,9	35,6	89,0	33,33	47,61	144,0
85	8,8	35,2	88,0	32,94	47,05	147,0
86	8,7	34,8	87,0	32,55	46,51	151,0
87	8,6	34,4	86,0	32,18	45,97	154,0
88	8,52	34,0	85,2	31,81	45,45	157,0
89	8,42	33,6	84,2	31,46	44,94	161,0
90	8,32	33,2	83,2	31,11	44,44	164,0
91	8,24	32,9	82,4	30,76	43,95	167,0
92	8,16	32,6	81,6	30,43	43,47	171,0
93	8,08	32,3	80,8	30,10	43,01	174,0
94	7,98	31,9	79,8	29,78	42,55	177,0
95	7,88	31,5	78,8	29,47	42,10	181,0
96	7,8	31,2	78,0	29,16	41,66	184,0
97	7,72	30,8	77,2	28,86	41,23	187,0
98	7,64	30,5	76,4	28,57	40,81	191,0
99	7,56	30,2	75,6	28,28	40,40	195,0
100	7,5	30,0	75,0	28,00	40,00	200,0
101	7,44	29,7	74,4	27,72	39,60	196,0
102	7,36	29,4	73,6	27,45	39,21	192,0
103	7,28	29,1	72,8	27,18	38,83	188,0
104	7,22	28,8	72,2	26,92	38,46	184,0
105	7,14	28,5	71,4	26,66	38,09	180,0
106	7,06	28,2	70,6	26,41	37,73	176,0
107	7,0	280	70,0	26,16	37,38	172,0
108	6,92	27,6	69,2	25,92	37,03	168,0
109	6,86	27,4	68,6	25,68	36,69	164,0
110	6,8	27,2	68,0	25,45	36,36	160,0
111	6,74	26,9	67,4	25,22	36,03	156,0
112	6,7	26,8	67,0	25,00	35,71	152,0
113	6,66	26,6	66,6	24,78	35,39	148,0
114	6,58	26,3	65,8	24,56	35,08	144,0
115	6,52	26,0	65,2	24,35	34,78	140,0
116	6,46	25,8	64,6	24,14	34,48	136,0
117	6,4	25,6	64,0	23,93	34,18	132,0
118	6,36	25,4	63,6	23,73	33,89	128,0
119	6,3	25,2	63,0	23,53	33,61	124,0
120	6,24	24,9	62,4	23,33	33,33	120,0

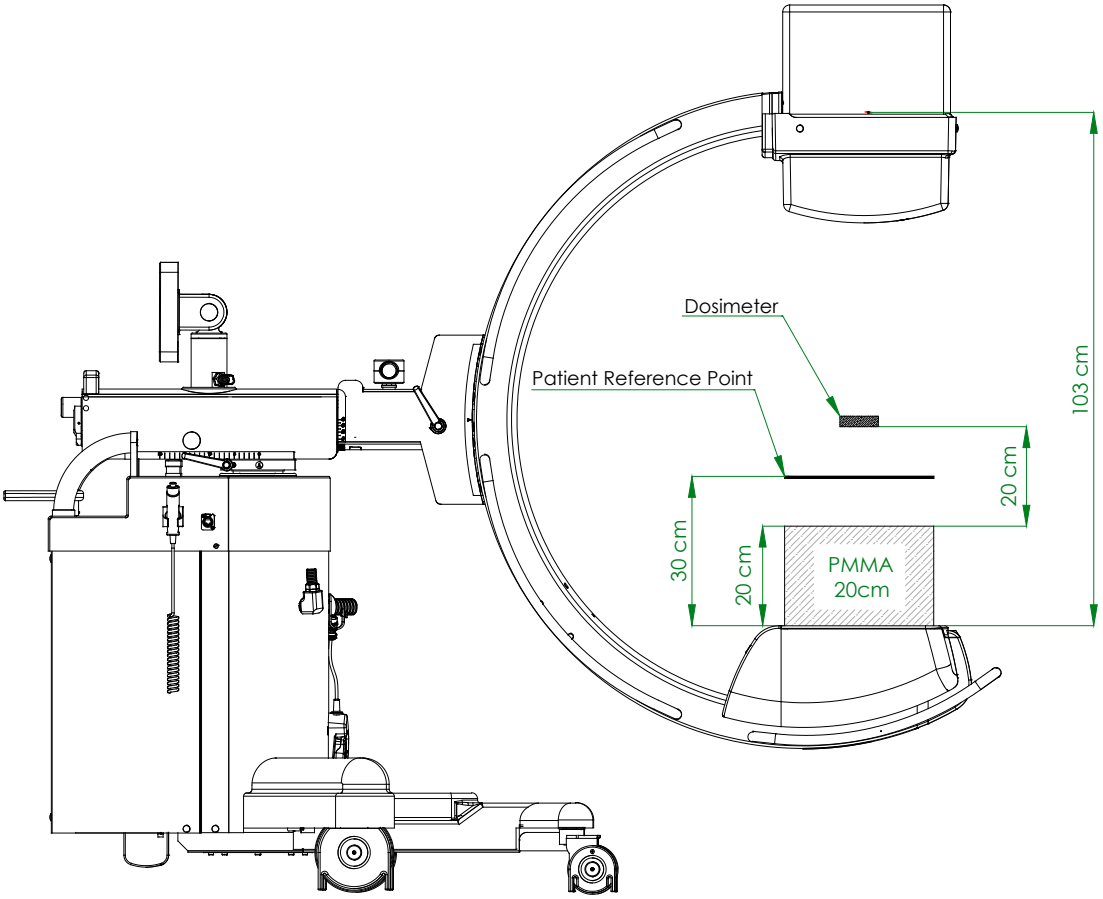
9.9.6 DOSE INFORMATION

9.9.6.1 INDICATIONS

	Unit of measurement	Instrument	Accuracy
DOSE - AREA PRODUCT	µGy x m²	Dose x Area Product (DAP)	± 25 %
REFERENCE AIR-KERMA	mGy	Calculated at the REFERENCE POINT OF ENTRY ON PATIENT, 30 cm from the Flat Panel detector.	± 35 %
REFERENCE AIR-KERMA RATE	mGy / min		

9.9.6.2 REFERENCE AIR-KERMA

The reference Air-Kerma has been measured and found to comply with standard EN 60601-2-54, paragraph 203.5.2.4.5.102, as shown in the figure below.



	Low Dose Fluoroscopy (Acquisition rate: 8 fps)			
	kV	mA Avg	Additional filter 1mm Al+ 0,1mm Cu Air-Kerma rate (µGy/frame)	Additional filter 1mm Al+ 0,2mm Cu Air-Kerma rate (µGy/frame)
Min Air-Kerma rate	40	0.13	0.6	0.03
	70	3.2	9.7	6.3
Max Air-Kerma rate	120	2.0	27.0	21.3

	High Quality Fluoroscopy (Acquisition rate: 8 fps)			
	kV	mA Avg	Additional filter 1mm Al+ 0,1mm Cu Air-Kerma rate (µGy/frame)	Additional filter 1mm Al+ 0,2mm Cu Air-Kerma rate (µGy/frame)
Min Air-Kerma rate	40	0.26	0.11	0.05
	70	6.4	19.4	12.5
Max Air-Kerma rate	120	4.0	54.0	42.7

	High Quality Fluoroscopy high mA (Acquisition rate: 8 fps)			
	kV	mA Avg	Additional filter 1mm Al+ 0,1mm Cu Air-Kerma rate (µGy/frame)	Additional filter 1mm Al+ 0,2mm Cu Air-Kerma rate (µGy/frame)
Min Air-Kerma rate	40	0.51	0.22	0.10
	70	13.0	39.4	25.4
Max Air-Kerma rate	120	8.0	108.0	85.4

	Digital Radiography			
	kV	mAs	Additional filter 1mm Al+ 0,1mm Cu Air-Kerma (mGy)	Additional filter 1mm Al+ 0,2mm Cu Air-Kerma (mGy)
Min Air-Kerma rate	40	1	0,003	0,001
	70	1	0,024	0,016
Max Air-Kerma rate	120	1	0,107	0,083

9.10 PATIENT DOSE INFORMATION

These are typical dose values (**Air-Kerma rate** or **Air-Kerma**) for the exams as they are set up by the manufacturer; dose values here reported are valid until the manufacturer's exams setup is not changed.

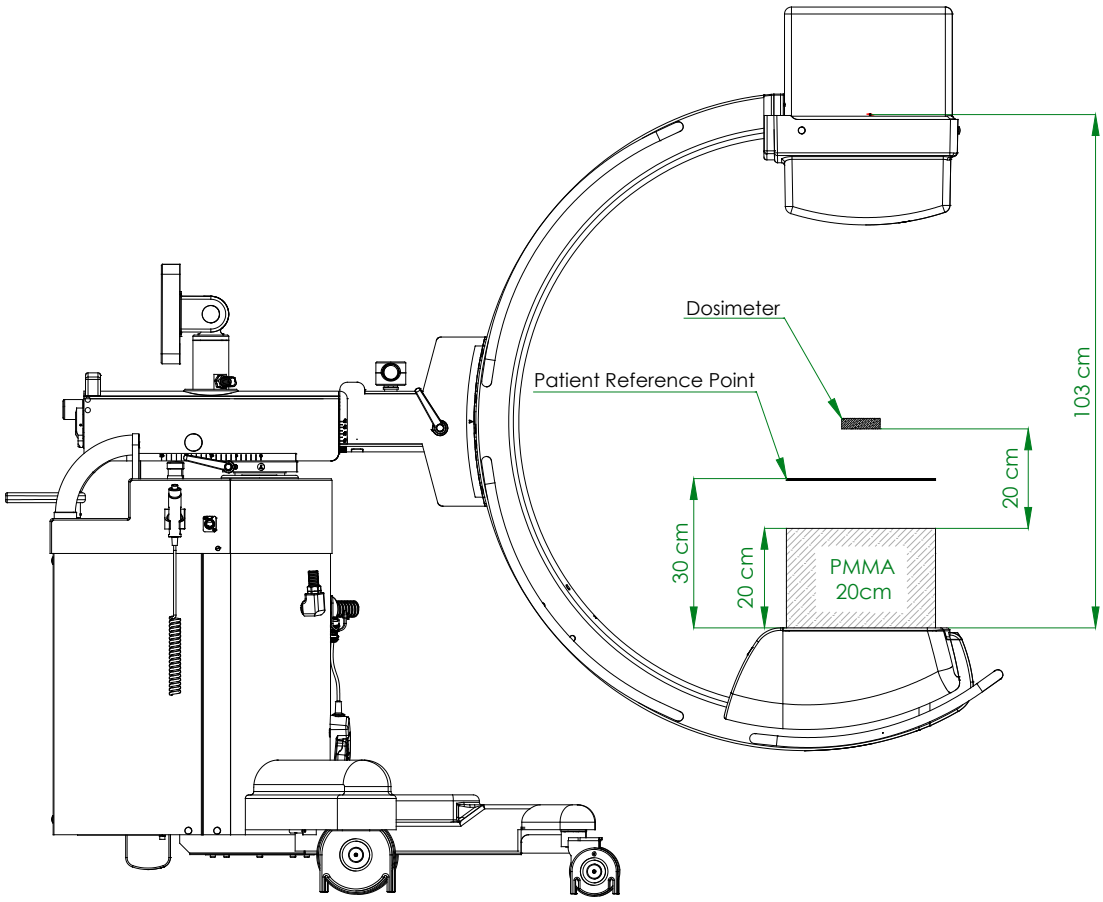
9.10.1 MEASURING THE DOSE

The **Surface dose entering the patient** (measured at 30 cm from the FPD) has been measured using the following method:

- Placing the 20cm PMMA phantom (simulating the patient) on the face of the FP detector.
- Positioning the dosimeter about 20 cm away from the phantom to prevent diffused irradiation from affecting the measurement.

The dosimeter reading has to be corrected, considering the distance of its sensor from the phantom:

Reading x (SID – 40)^2 / (SID - 30)^2



There are many factors that may cause variations in the dose entering the patient:

- The use of an anti-scatter grid (recommended when exposing large areas of the human body).
- High voltage at the X-ray tube (kV).
- The product of mA per exposure time (mAs) is directly proportional to the dose leaving the X-ray tube.
- The skin / focal spot distance.

EXTREMITY exam has been carried out using a **10 cm-thick PMMA phantom**.
This exam is performed **without Anti-scattering grid** and the deterministic effects threshold value is set at **1 Gy.**

For all the other exams, a **20 cm-thick PMMA phantom** has been used, in order to simulate an exam that involves an average patient.
In these exams the **Anti-scatter grid** is required and the deterministic effects threshold value is set at **2 Gy**.

Exposure parameters are determined from the **Automatic Dose Control** (ADC).
Using the same **20 cm-thick PMMA phantom,** it has been measured the dose value at **max kV value (120 kV)**, to simulate an exam that involves an overweight patient.

In the tables below, are reported:

- The collimator filter set for the exam.
- The acquisition rate used (*Note: the patient dose value is proportional to the acquisition rate)*.
- *For **Fluoroscopy** exposures:* the patient dose value, expressed in **mGy/min (Air-Kerma rate)** and the indication of the minutes of exposures required to reach the threshold for deterministic effects (**1** or **2Gy**).
- *For **Digital Radiography** exposures:* the patient dose value, expressed in **mGy/image (Air-Kerma)** and the indication of the numbers of exposures required to reach the threshold for deterministic effects (**1** or **2Gy**).

EXTREMITY Collimator filter: 1mm Al + 0.2 mm Cu, **NO GRID**							
@15imm/s	**10cm-PMMA PHANTOM**				**@ 120kV**		
	kV	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**
FLUORO LD	61	1.83	1.61	1242.24	1.86	13.67	146.31
FLUORO HQ	60	3.4	2.68	746.27	3.7	25.29	79.08
	kV	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**
SNAPSHOT	60	10	0.09	22222	2.0	0.17	11764

HEAD Collimator filter: 1mm Al + 0.1 mm Cu							
@15imm/s	**20cm-PMMA PHANTOM**				**@ 120kV**		
	kV	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**
FLUORO LD	62	4.0	4.17	479	3.7	24.09	83
FLUORO HQ	62	7.9	8.29	241	7.5	48.57	41
	kV	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**
SNAPSHOT	62	20	0.35	5714	10.0	1.07	1869

SPINE Collimator filter: 1mm Al + 0.1 mm Cu							
@15imm/s	**20cm-PMMA PHANTOM**				**@ 120kV**		
	kV	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**
FLUORO LD	62	4.0	4.17	479	3.7	24.09	83
FLUORO HQ	62	7.9	8.29	241	7.5	48.57	41
	kV	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**
SNAPSHOT	62	20	0.35	5714	10.0	1.07	1869

PELVIS Collimator filter: 1mm Al + 0.1 mm Cu							
@15imm/s	**20cm-PMMA PHANTOM**				**@ 120kV**		
	kV	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**
FLUORO LD	62	4.0	4.17	479	3.7	24.09	83
FLUORO HQ	62	7.9	8.29	241	7.5	48.57	41
	kV	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**
SNAPSHOT	62	20	0.35	5714	10.0	1.07	1869

THORAX Collimator filter: 1mm Al + 0.1 mm Cu							
@15imm/s	**20cm-PMMA PHANTOM**				**@ 120kV**		
	kV	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**
FLUORO LD	62	4.0	4.17	479	3.7	24.09	83
FLUORO HQ	62	7.9	8.29	241	7.5	48.57	41
	kV	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**
SNAPSHOT	62	20	0.35	5714	10.0	1.07	1869

PACEMAKER Collimator filter: 1mm Al + 0.1 mm Cu							
@15imm/s	**20cm-PMMA PHANTOM**				**@ 120kV**		
	kV	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**
FLUORO LD	67	11	13.74	145.56	7.5	48.57	41.18
FLUORO HQ	67	11	13.74	145.56	7.5	48.57	41.18
	kV	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**
SNAPSHOT	62	20	0.35	5714	10.0	1.07	1869

ERCP Collimator filter: 1mm Al + 0.1 mm Cu							
@15imm/s	**20cm-PMMA PHANTOM**				**@ 120kV**		
	kV	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**	**mA AVERAGE**	**Air-Kerma rate mGy/min**	**Minutes of exposure (2Gy) (1)**
FLUORO LD	62	4.0	4.17	479	3.7	24.09	83
FLUORO HQ	65	4.8	5.64	354	3.7	24.09	83
	kV	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**	**mAs**	**Air-Kerma mGy**	**Number of exposures (2Gy) (2)**
SNAPSHOT	62	20	0.35	5714	10.0	1.07	1869

UROLOGY

Collimator filter: 1mm Al + 0.1 mm Cu

@15imm/s	20cm-PMMA PHANTOM				@ 120kV		
	kV	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)
FLUORO LD	62	4.0	4.17	479	3.7	24.09	83
FLUORO HQ	62	7.9	8.29	241	7.5	48.57	41
	kV	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)
SNAPSHOT	62	20	0.35	5714	10	1.07	1869

PAIN MANAGEMENT

Collimator filter: 1mm Al + 0.1 mm Cu

@15imm/s	20cm-PMMA PHANTOM				@ 120kV		
	kV	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)
FLUORO LD	62	4.0	4.17	479	3.7	24.09	83
FLUORO HQ	62	7.9	8.29	241	7.5	48.57	41
	kV	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)
SNAPSHOT	62	20.0	0.35	5714	10.0	1.08	1869

VASCULAR

Collimator filter: 1mm Al + 0.1 mm Cu

@15imm/s	20cm-PMMA PHANTOM				@ 120kV		
	kV	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)
FLUORO LD	65	4.8	5.64	354	3.7	24.09	83
FLUORO HQ	65	4.8	5.64	354	3.7	24.09	83
ROADMAP	71	6.0	9.11	219	3.7	24.09	83
DSA @ 8 imm/s	63	9.0	9.29	215	8.0	48.5	41
	kV	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)
SNAPSHOT	63	10.0	0.18	11111	10.0	1.07	1869

VASCULAR HQ

Collimator filter: 1mm Al + 0.1 mm Cu

@15imm/s	20cm-PMMA PHANTOM				@ 120kV		
	kV	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)
FLUORO LD	72	6	13.19	151.63	3.7	24.09	83.02
FLUORO HQ	72	6	13.19	151.63	3.7	24.09	83.02
ROADMAP	71	6.0	9.11	219	3.7	24.09	83
DSA @ 8 imm/s	63	9.0	9.29	215	8.0	48.5	41
	kV	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)
SNAPSHOT	63	10.0	0.18	11111	10.0	1.07	1869

VASCULAR CEREBRAL

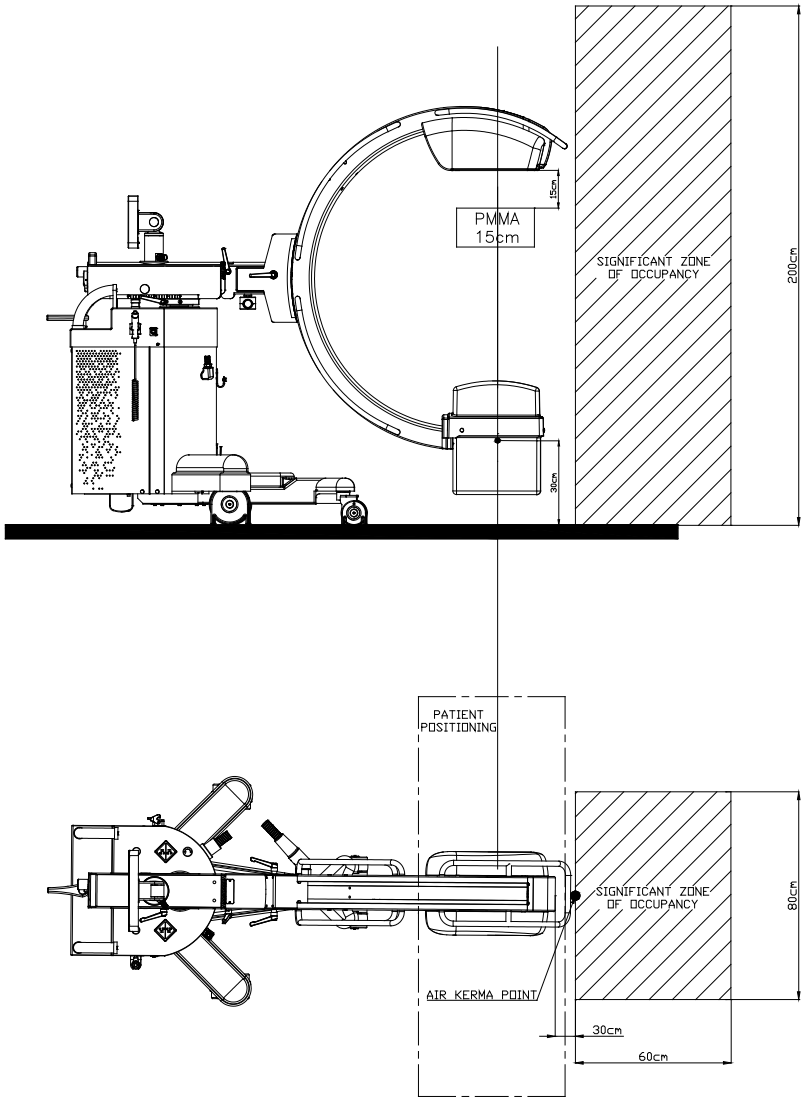
Collimator filter: 1mm Al + 0.1 mm Cu

@15imm/s	20cm-PMMA PHANTOM				@ 120kV		
	kV	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)
FLUORO LD	65	4.8	5.64	354	3.7	24.09	83
FLUORO HQ	65	4.8	5.64	354	3.7	24.09	83
ROADMAP	71	6.0	9.11	219	3.7	24.09	83
DSA @ 8 imm/s	63	9.0	9.29	215	8.0	48.5	41
	kV	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)
SNAPSHOT	63	10.0	0.18	11111	10.0	1.07	1869

ELECTROPHYSIOLOGY Collimator filter: 1mm Al + 0.1 mm Cu

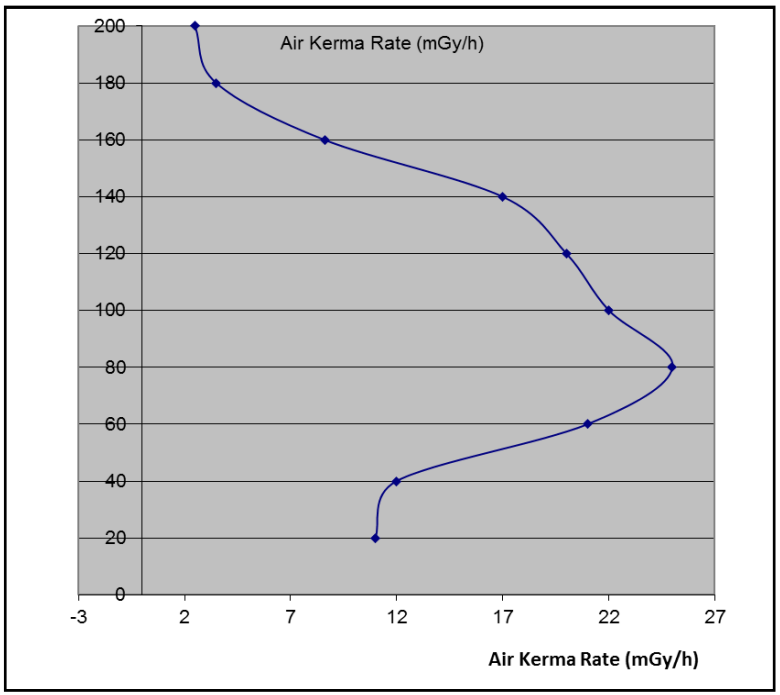
@15imm/s	20cm-PMMA PHANTOM				@ 120kV		
	kV	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)	mA AVERAGE	Air-Kerma rate mGy/min	Minutes of exposure (2Gy) (1)
FLUORO LD	67	11	13.74	145.56	7.5	48.57	41.18
FLUORO HQ	67	11	13.74	145.56	7.5	48.57	41.18
	kV	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)	mAs	Air-Kerma mGy	Number of exposures (2Gy) (2)
SNAPSHOT	63	10.0	0.18	11111	10.0	1.07	1869

9.11 DISPERSED RADIATION IN OCCUPIED AREAS

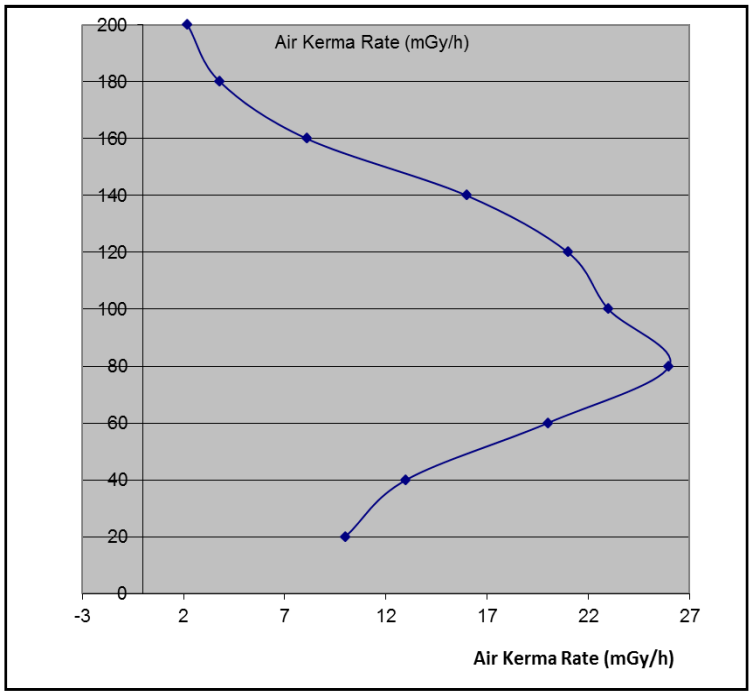


Measurement conditions (in compliance with EN60601-2-54 standard):

- Exposure: **DSA fluoroscopy - 120kV / 8mA$_{avg}$ / 8 fps**
- Additional beam filtration: **1 mmAl + 0.2 mmCu**
- Measuring instrument: **INOVISION 35050**



Dispersed radiation in occupied area, for version with **FPD 2121.**



Dispersed radiation in occupied area, for version with **FPD 3030.**

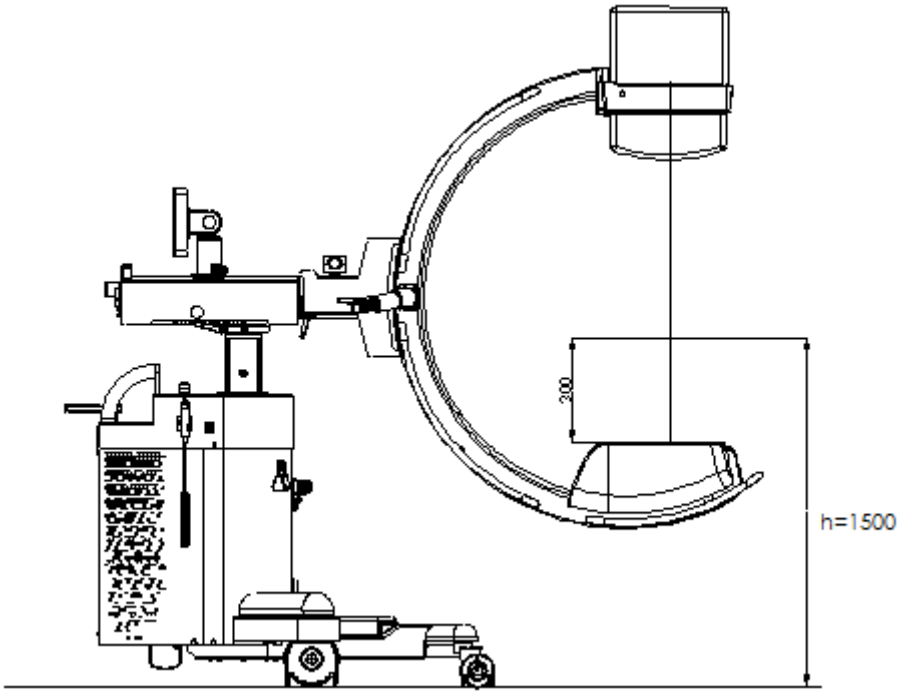
9.12 ISOKERMA MAPS (according to EN60 601-2-43)

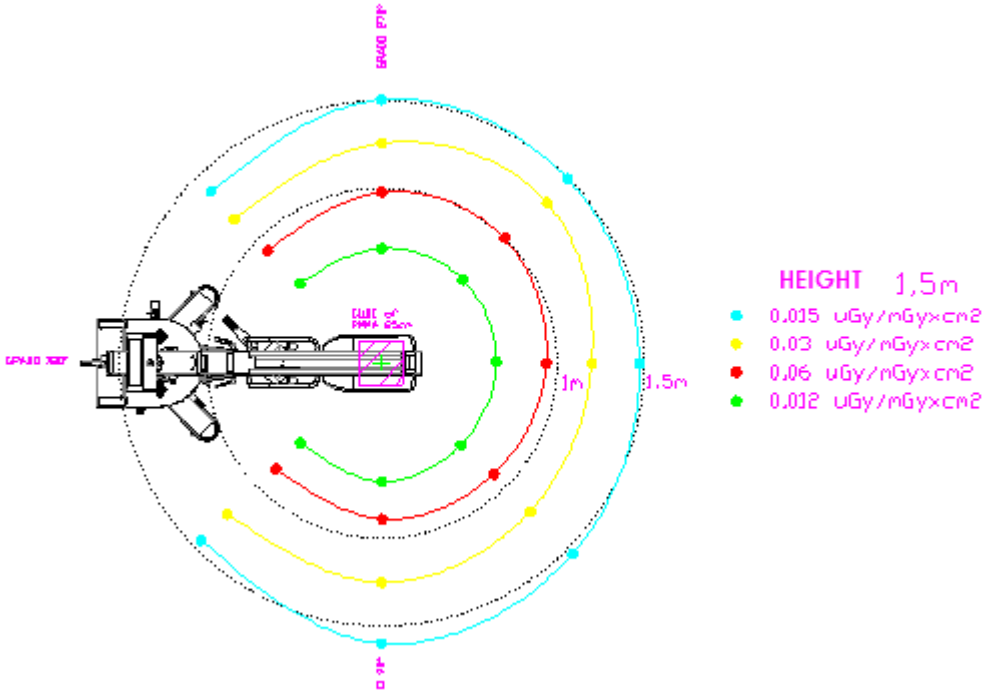
In accordance with Standard EN60601-2-43 (paragraph 203.13.4), below are details of the two most common isokerma map configurations.

9.12.1 VERTICAL PLACEMENT

Measurement conditions:

- **HQ** fluoroscopy, **Pulsed curve 4**, rate: **8 fps**.
- Detector **Nominal field.**

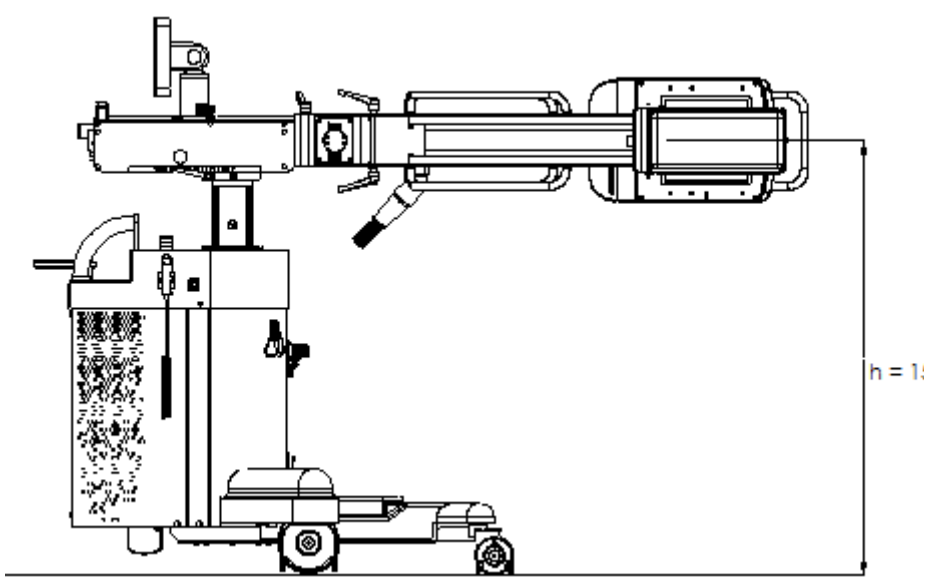


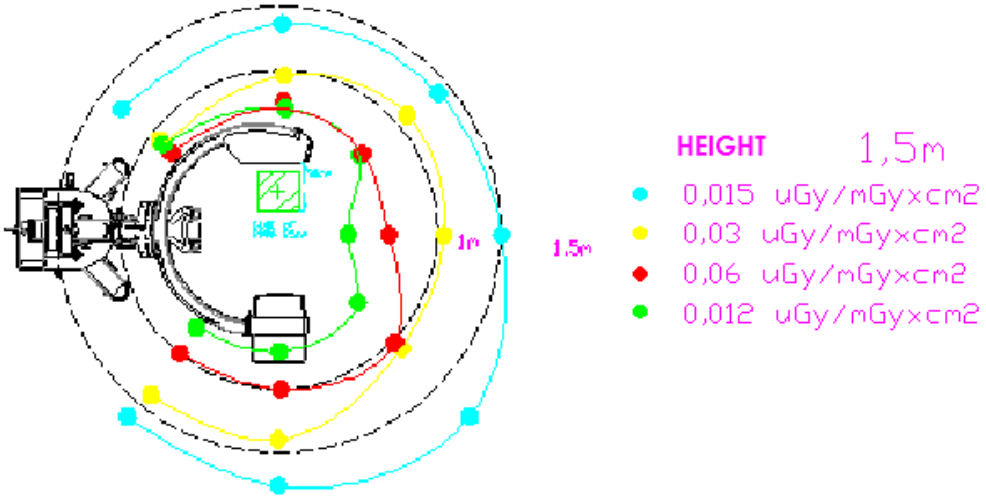


9.12.2 HORIZONTAL PLACEMENT

Measurement conditions:

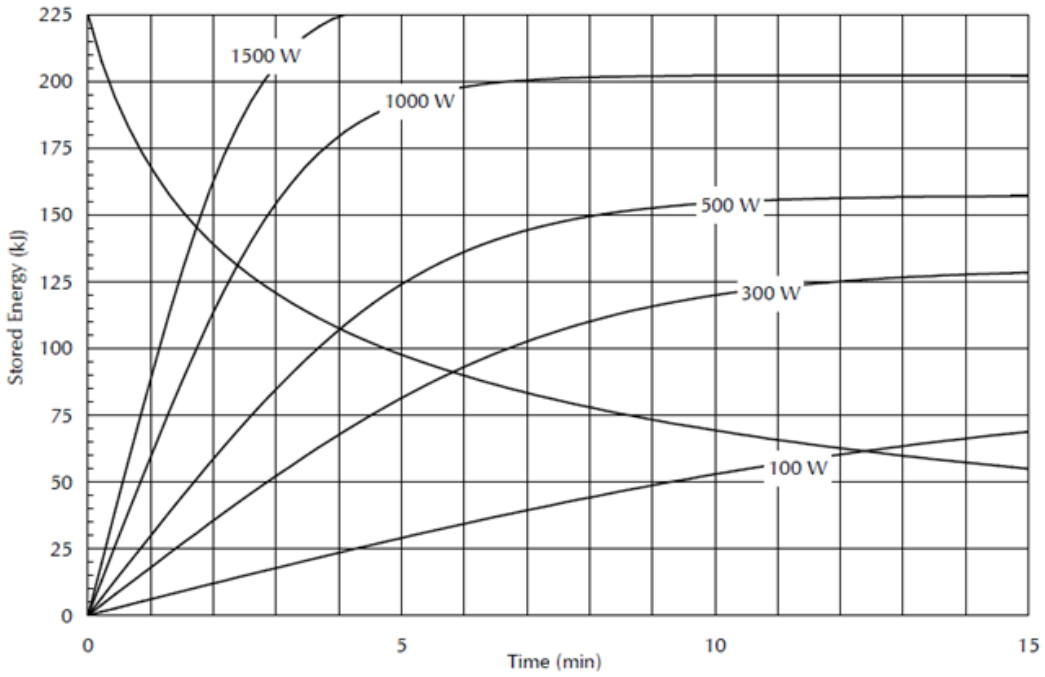
- **HQ** fluoroscopy, **Pulsed curve 4**, rate: **8 fps**.
- Detector **Nominal field.**



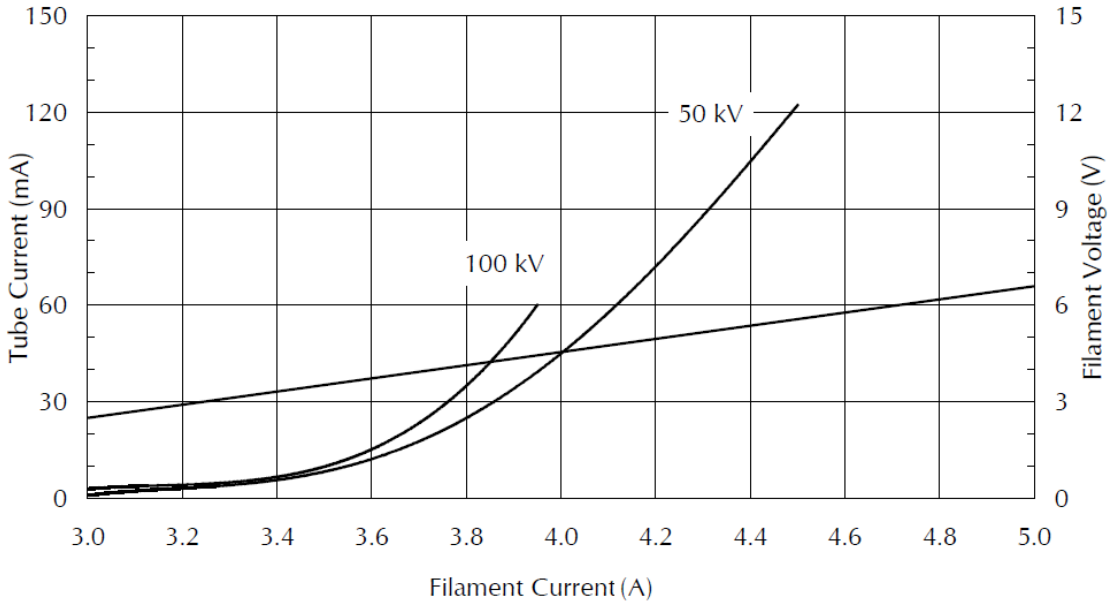


9.13 X-RAY TUBE IAE RTM70H CURVES

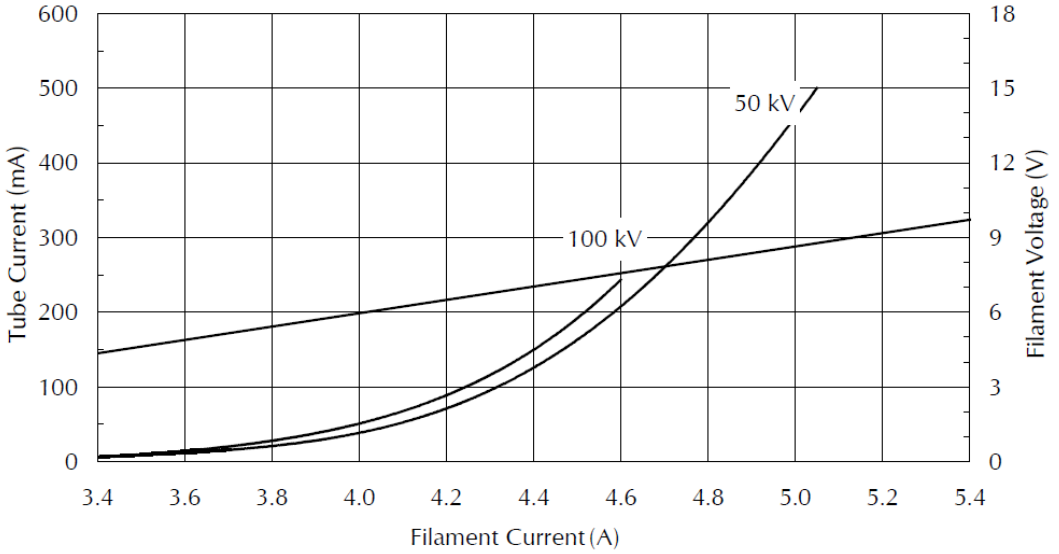
Anode heating and cooling curves



Cathode emission characteristic (small focus)



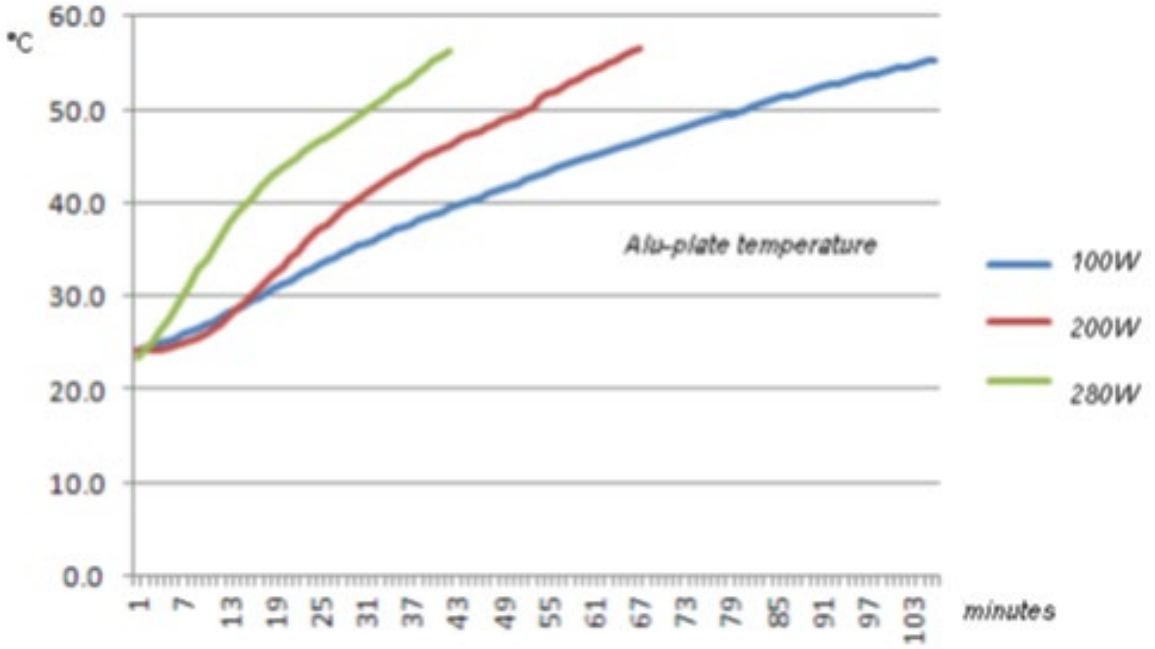
Cathode emission characteristic (large focus)



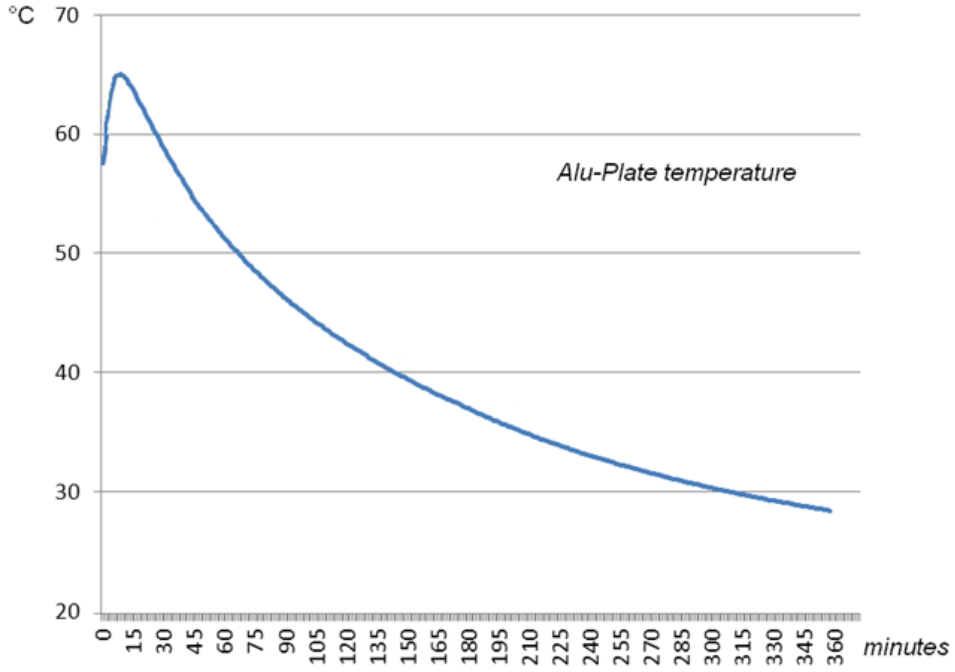
9.14 X-RAY MONOBLOCK HEATING AND COOLING CURVES

9.14.1 X-RAY MONOBLOCK I-40R 15 RF CURVES

Monoblock heating curves

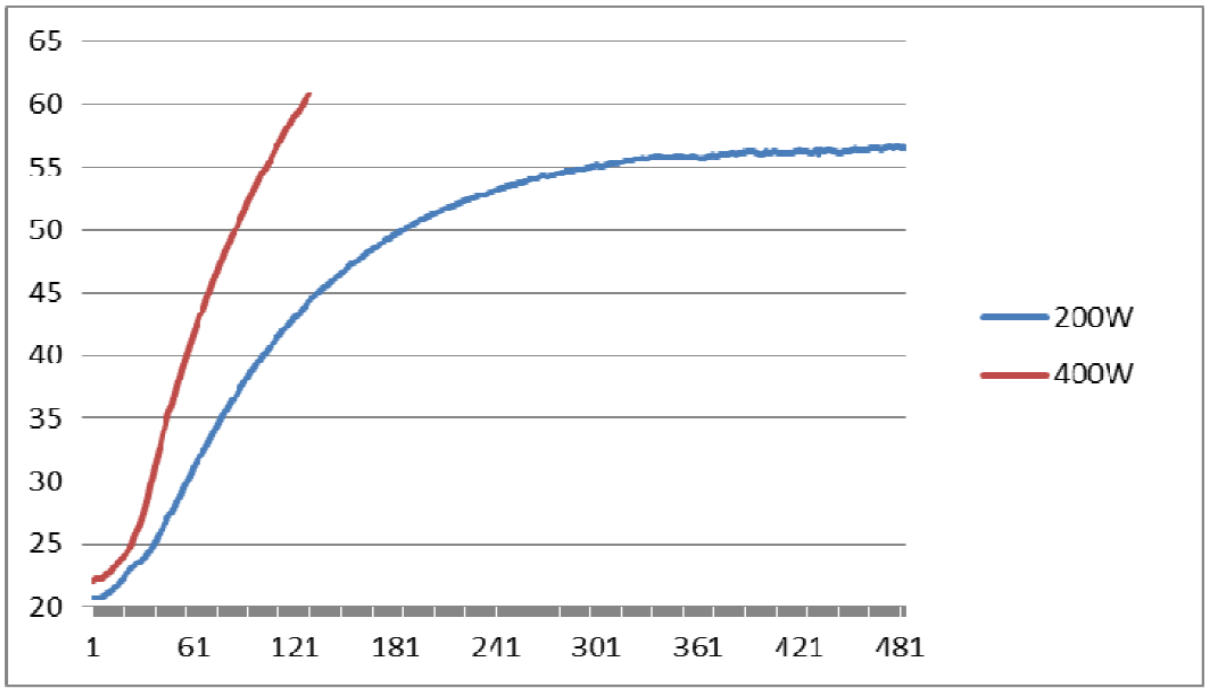


Monoblock cooling curves



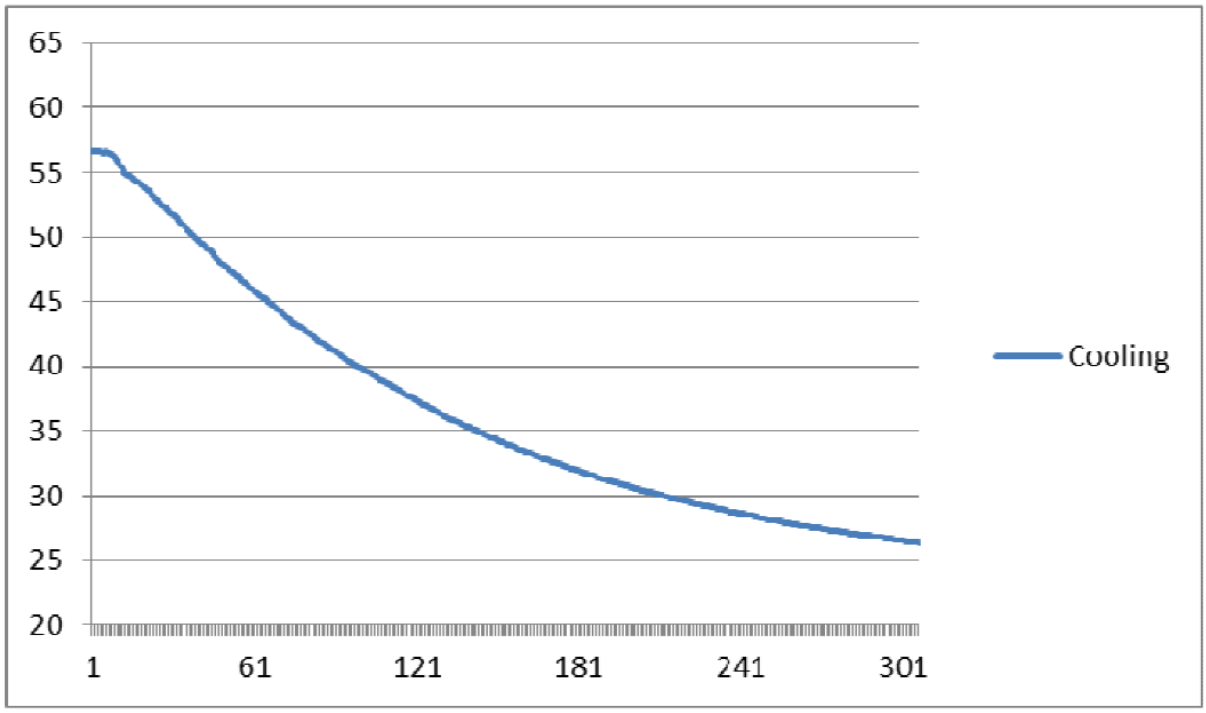
9.14.2 X-RAY MONOBLOCK I-40R 15 RF AC CURVES

Monoblock heating curves



Temperature C° - Exposure Time (Min.) - Exposure Power (W)

Monoblock cooling curves



Temperature C° - Cooling Time (Min.)

10 GLOSSARY

10.1 ABBREVIATIONS

Avg	average
CD	Compact Disc
CE	CE European Communities
DICOM	DICOM Digital Imaging and Communication in Medicine
EMC	EMC Electromagnetic Compatibility
ESD	ESD Electrostatic Discharge
HQF	HQF High-Quality Fluoroscopy
IEC	IEC International Electrotechnical Commission
IHE	IHE Integrating the Healthcare Enterprise
IP	IP address: Internet Protocol address
IR	IR Infrared
LCD	Liquid Crystal Display
LD	Low Dose Fluoroscopy
LED	Light Emitting Diode
LIH	Last Image Hold
Max	Maximum
MPPS	Modality Performed Procedure Step
OS	Operating System
PACS	Picture Archiving and Communications System
PC	Personal Computer
PMMA	Polymethyl-methacrylate
Rad	Radiography
RIS	Radiology Information System
SCU	Storage Class User
USB	Universal Serial Bus
VPN	Virtual Private Network
XA	X-ray Angiographic

10.2 DEFINITIONS AND TERMS

Acquisition patient
Current patient of which images are acquired.

Acquisition status
The status of the acquisition patient. As long as the patient has this status, images can be acquired. There is only one patient with this status.

Acquisition
All X-ray techniques that acquire images.

Anatomically Programmed Fluoroscopy (APF)
APF is a pre-programmed set of parameters such as storage speed and image processing. The APF sets are finding expression in the examination type. The parameters cannot be changed by the user. The Service Manual gives more information about setting the parameters.

Archiving
Copying the screen contents of the examination monitor to paper, transparency film, video, video DVD, USB memory device or exams/images to a DICOM PACS.

Automatic fluoroscopy
Fluoroscopy in which the kV and mA values are controlled automatically.

Cine Loop
Dynamic review of images within one run.

Current image
The current image displayed on the live monitor or the image highlighted by the square cursor in an overview display.

External video
Video from and external source can be replayed on the right monitor (reference monitor) by connecting a compatible playback device to the mobile view station and using the External video function. External video display is selected by pressing the External Video key [M11] on the mobile view station.

Fluoroscopy
Acquisition technique using continuous radiation to produce a live image on a monitor. The images can be simply viewed live and not stored, or they can be stored in a patient file for future reference.

High-Quality Fluoroscopy
Also called HQ. Used for a short period only, usually to obtain the best possible images.

Interventional reference point
The interventional reference point is intended to be representative of the point of intersection of the X-ray beam axis and the patient. The display of dose rate and cumulative dose is valid for this distance. The interventional reference point is 30 cm from the detector entrance surface. (Ref. IEC 60601-2-43.)

Isokerma
A contour line on a scattered radiation diagram showing the boundary where a certain radiation level is exceeded.

LIH
The image of the last X-ray is displayed on the examination monitor and is labeled with the LIH symbol in a corner of the image.

Live monitor
This is the left monitor for displaying live images and last image hold.

Low Dose Fluoroscopy
Also called LD. Used for C-arm (re)positioning and guiding purposes during catheterization procedures. The advantages over HQ Fluoroscopy are a reduced dose and no exposure time limitation.

Manual fluoroscopy
Fluoroscopy in which the kV and Ma values are set manually.

Measurement
Determination of the angle and (relative) size of an object visible in the image.

Overview
Display of a 4 x 4 images matrix on the examination monitor.

Patient study
A file where acquired images can be stored. Each stored image obtains an identification consisting of a run and image number. The maximum of image number depends on the memory extension size (2000, 10000, or 20000 images).

Phantom
An object used for calibration and verification purposes.

Post-processing
Performing activities to analyse images after acquisition.

Radiography
Acquisition technique using a single shot radiation at high dose to produce high quality image on a monitor. The image is automatically stored in the study file.

Memory monitor
This is the right monitor and the secondary display for images to use as a reference.

Review status
The moment the images of a patient are reviewed, it will get the 'review' status. The patient will keep this status until another patient is reviewed. There is only one patient with this status.

Reviewing
Looking at and post-processing images after an examination is terminated.

Roadmap
Display of fluoroscopy images on a vascular background.

Scheduled status
A patient has the 'scheduled' status prompt after input of the patient data. The patient will retain this status until acquisition is performed.

Static viewing
Viewing with the run cycle function deactivated.

Subtraction
Display of (live) mask-subtracted fluoroscopy images.

USB storage
The mobile view station provides connectors to attach USB memory devices, such as memory sticks. A screenshot of the image on the examination monitor can then be recorded and stored on the memory device.
The image is stored as a bitmap, a common graphics file format. This provides a fast and simple way to store images of interest. After connecting a USB memory device, press the USB key [M10] to store a screenshot of the examination monitor.

Vascular tracing
View trace uses acquired images to obtain a vascular-tree background during post-processing.

Viewing patient
Patient of which images are viewed or post-processed etc.

Viewing
Looking at images during and/or just after the acquisition run.

Zoom
An optional post-processing feature to enlarge a part of the current run.