



Technical Manual

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Technical Manual

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ATTENTION:

Read all the enclosed documents before using the EM equipment.



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

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

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

Part 1: GENERAL DESCRIPTION

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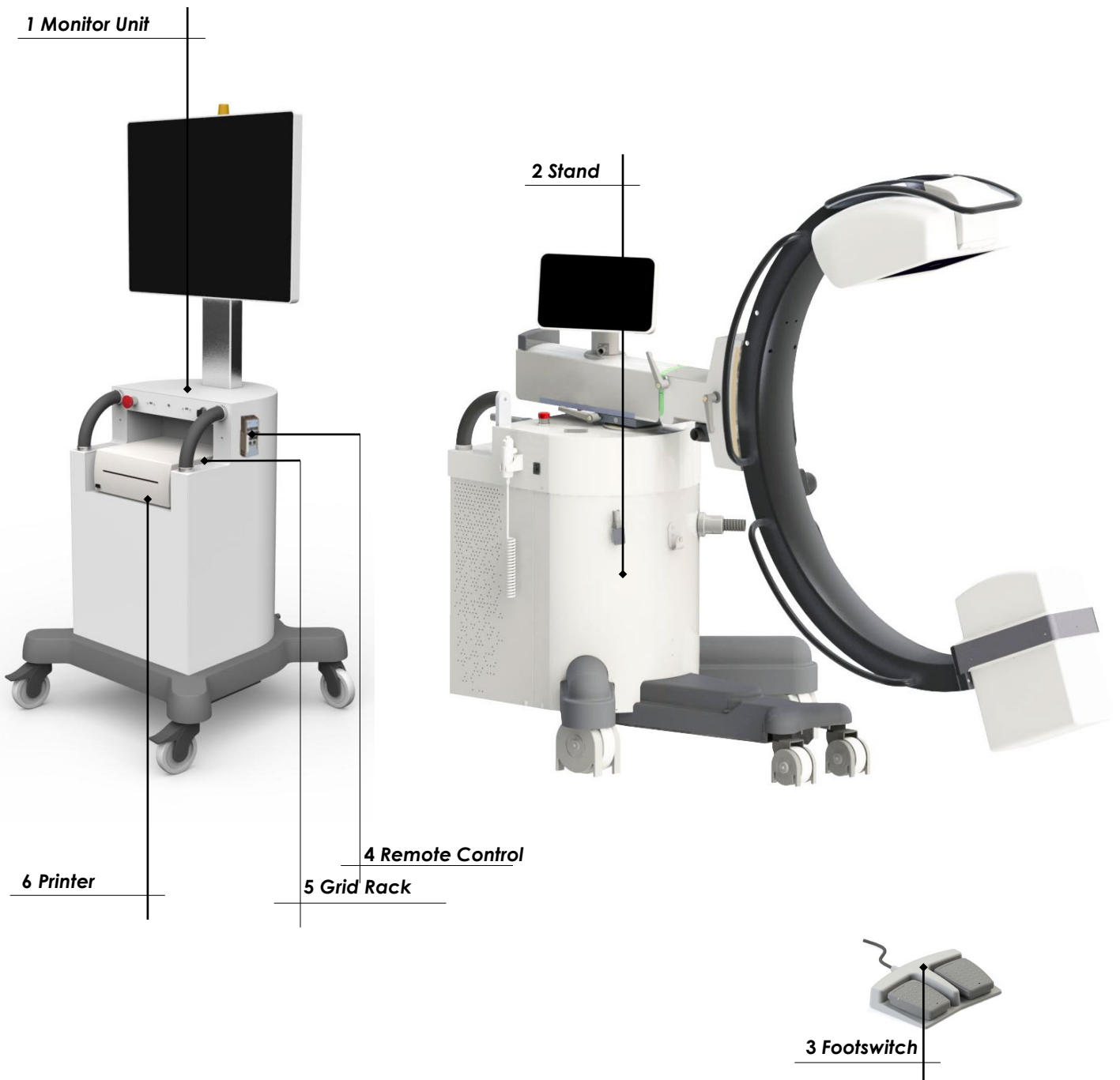
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1 DESCRIPTION OF THE ELECTRICAL MEDICAL (EM) EQUIPMENT

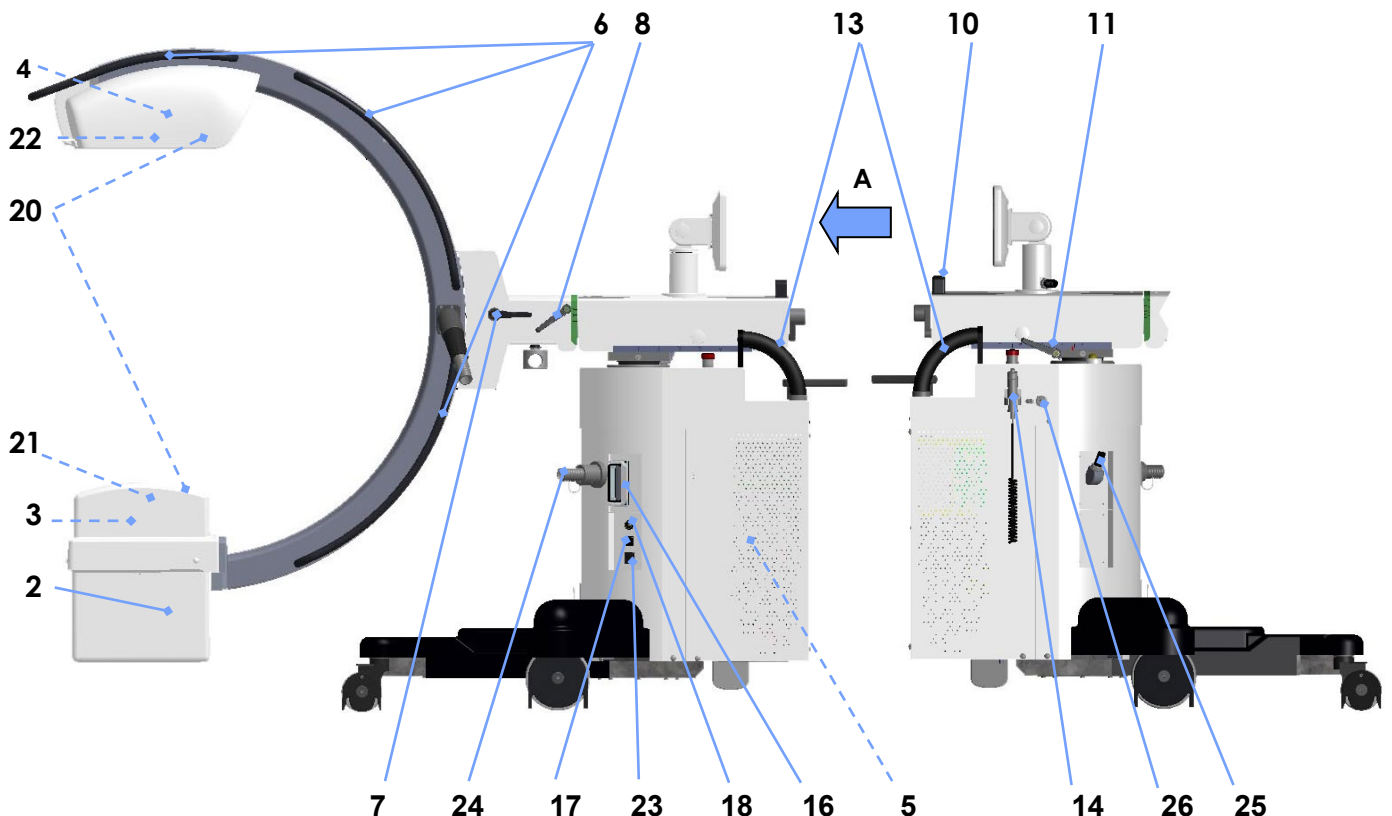
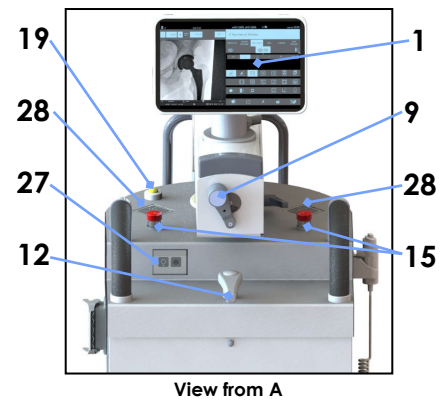
1.1 COMPOSITION OF THE EM EQUIPMENT

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



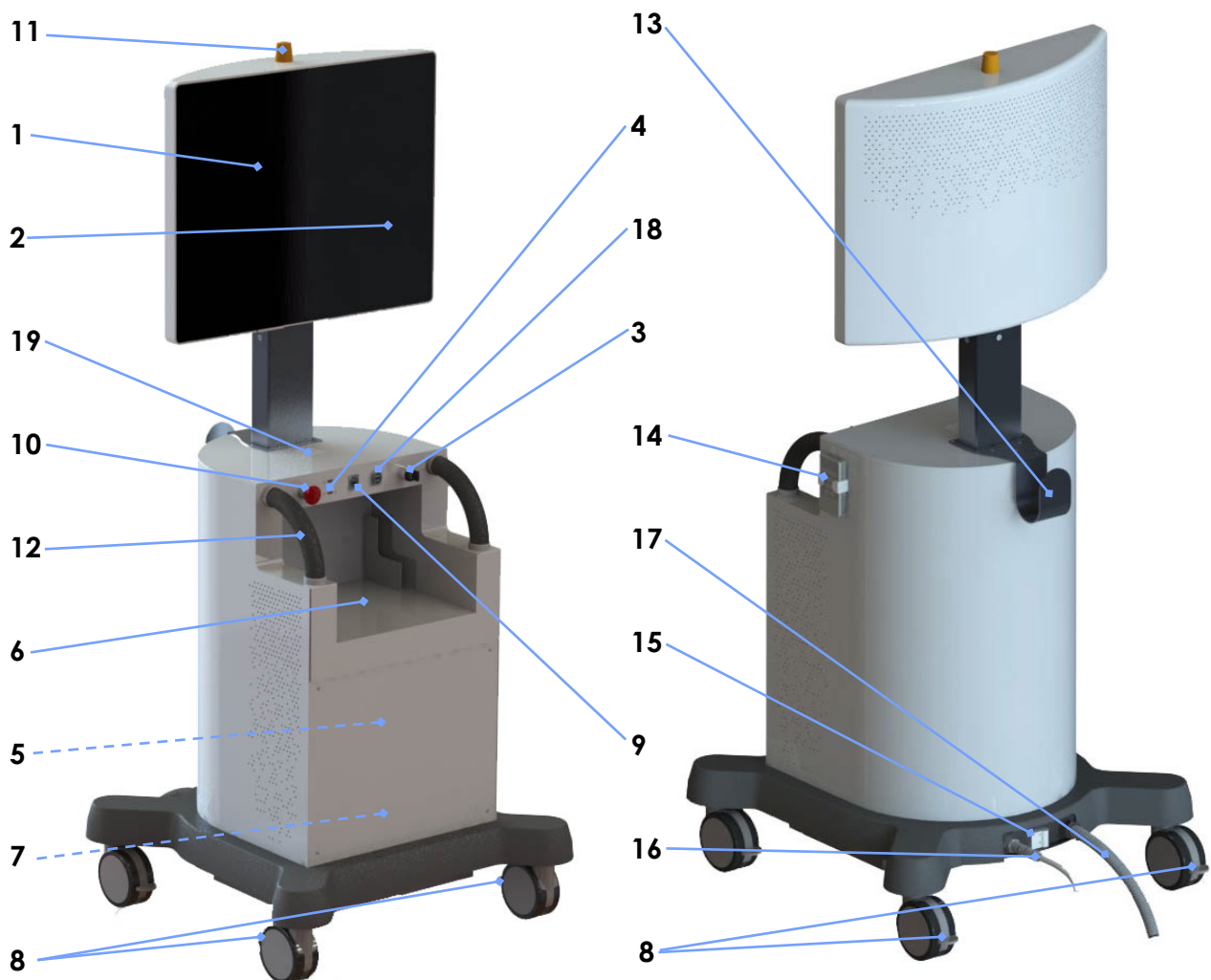
1.1.1 STAND

- 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 ($\pm 90^\circ$) 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



1.1.2 MONITOR UNIT

- 1 **LIVE** Monitor (L.M.): this touch screen monitor displays the images during X-ray emission and the last image (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 for exporting images
- 5 PC for processing and managing the equipment
- 6 USB 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 emission warning light
- 12 Steering handles
- 13 Cable hook (when not in use)
- 14 Infrared remote control
- 15 General magnetothermal switch
- 16 EM equipment power cable
- 17 Monitor / Stand connection cable
- 18 Video connector
- 19 NFC reader



1.2 APPLICATIONS AND MODES

The EM equipment lets you acquire images in the following modes:

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

See the User Manual for a description of each function.

See the "Technical Data" chapter below for full details of the technical data and characteristics.

1.3 SAFETY

1.3.1 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 protection against ionising radiation and full training in the use of X-ray equipment.



The EM equipment must always be manned when switched on.



The EM 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 EM 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.



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 must 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.

1.3.2 SAFETY PROCEDURES

1.3.2.1 MECHANICAL SAFETY

Attention:



Always apply the parking brakes after positioning the EM equipment.



Only use the special steering handles to move the EM equipment.



Avoid knocks.



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

1.3.2.2 ELECTRICAL SAFETY

Attention:



Never use the EM equipment in potentially explosive environments, e.g. in the presence of explosive gas or vapor (such as some anesthetics).



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, including those used for patients, 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 and render it unsafe to use.



Protection against electric shock is provided by an earth connection (**EM equipment, class I**).

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 EM equipment off properly after use:

- start the monitor unit shut-down procedure,
- then use the key switch, once this procedure has been completed.



Unplug at the mains only after first switching the EM equipment off using the key switch on the monitor unit.

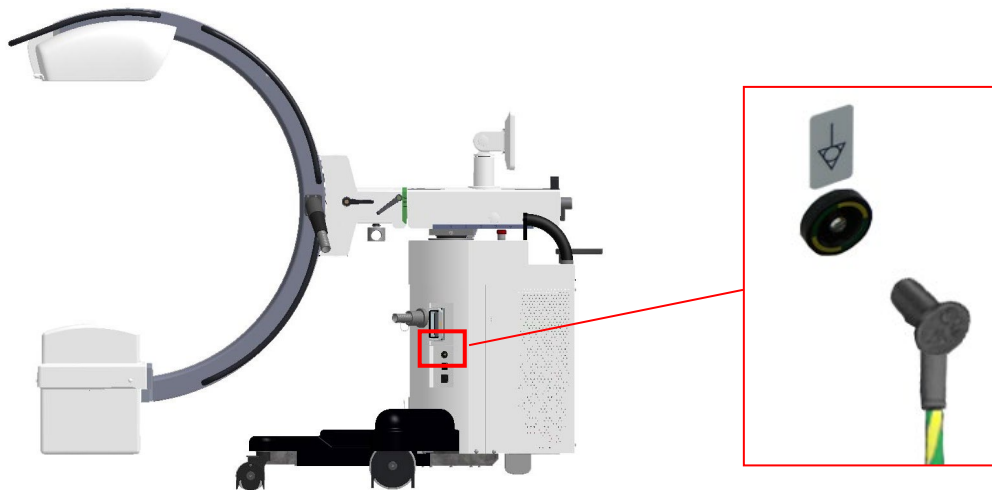
If the power cable becomes damaged, carefully remove it (holding it by the plug) and contact Technical Service for details on how to replace it.

Replace with a new cable obtained from the manufacturer of the EM equipment.

1.3.2.3 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 provide the **EARTH PROTECTION** for the EM equipment.

1.3.2.4 LASER RADIATION

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.

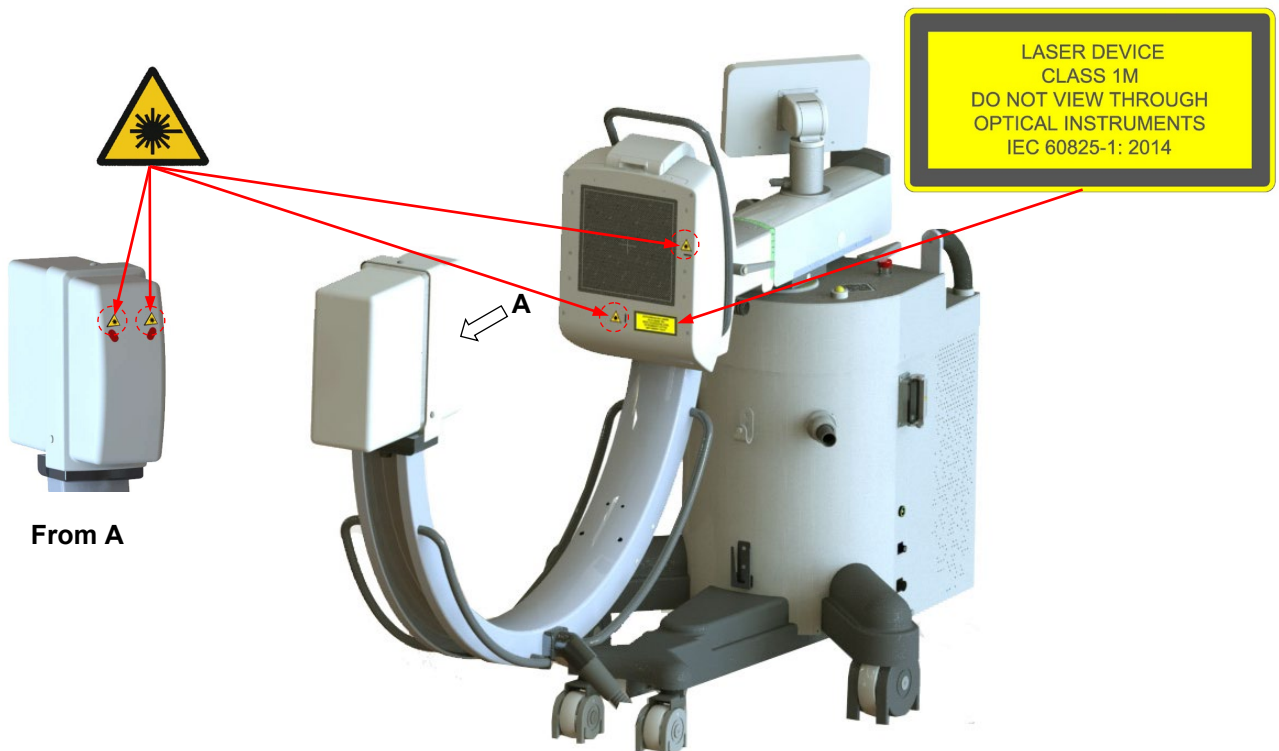
LASER LOCALIZER <i>Consisting of 4 laser modules (Optional)</i>	
Class	1M
Laser diode power	< 5 mW
Optical output power	3.8 mW
Wavelength	635 nm
Laser light warning	



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).

1.3.2.5 PROTECTION AGAINST IONISING RADIATION

The EM equipment emits ionising radiation 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 EM equipment can be used.**

The use of this device involves two types of exposure to ionising radiation:

- ❖ 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 1.3.2.6** 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 with the following clause:

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 precautions against unnecessary irradiation have been taken. During X-ray use, the personnel present in the X-ray room must observe all the radiation 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 irradiation of 50 kV and 94.5% protection against irradiation 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 the exposure objective as possible.

Use the manual switch at least 2 m from the X-ray beam to protect yourself further from the risk of dispersed irradiation.

Accordingly, the coiled cable of the manual switch is about 4 m long when fully extended.



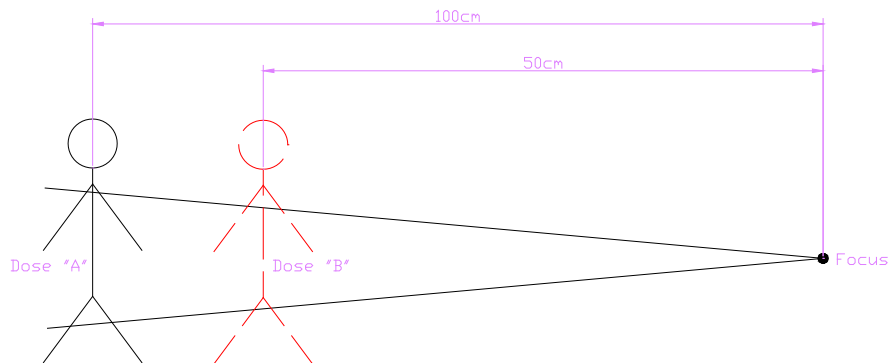
Always set the smallest exposure field possible by closing the collimator shutters/iris. In fact, dispersed irradiation depends to a large extent on the volume of the irradiated object.



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:

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

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:

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

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 irradiation must be kept as low as reasonably possible without compromising the benefits of the radiological procedure. If possible, always use the lowest dose and/or low rate pulsed fluoroscopy.



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.**

1.3.2.6 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*

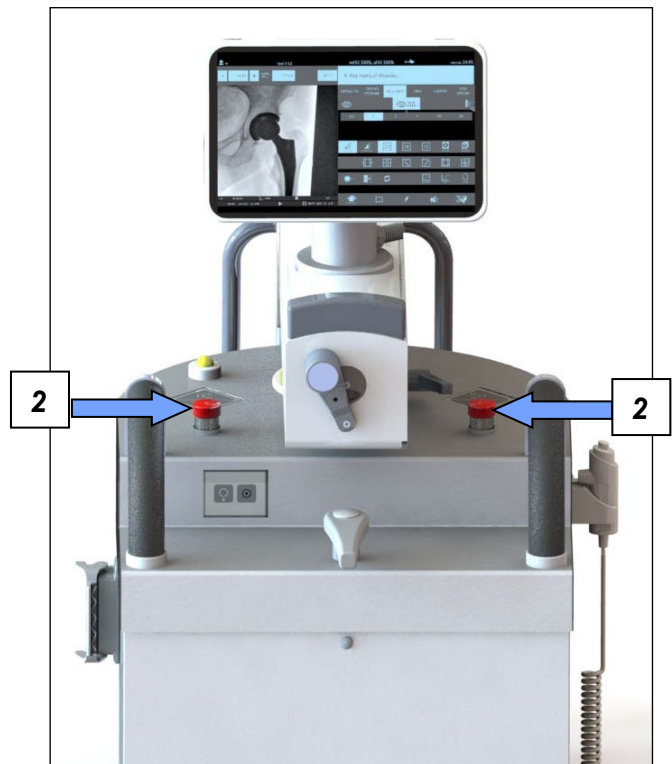
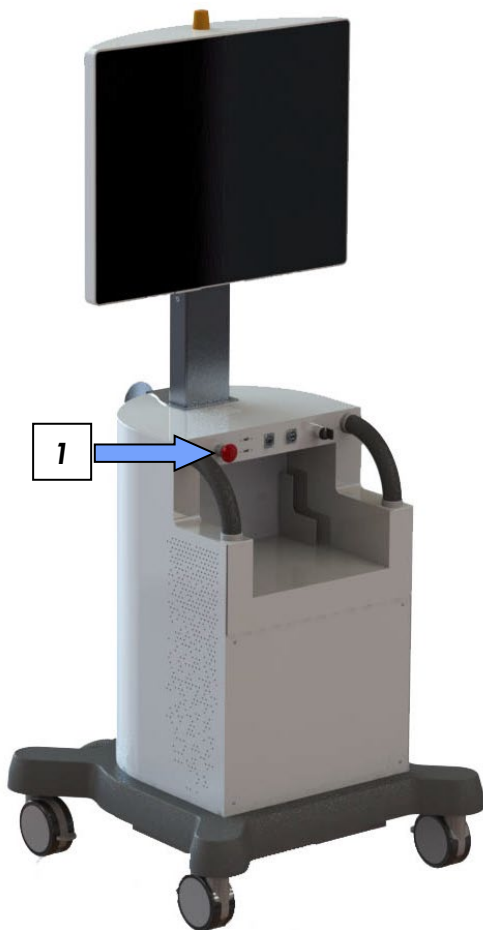
1.3.3 EMERGENCY PROCEDURES

1.3.3.1 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.



1.3.3.2 SOFTWARE GLITCHES

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.

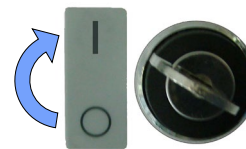
⇒ **In the first instance (hang up):**

Reboot the equipment.

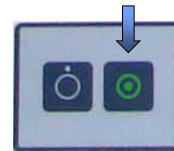
- Switch the monitor unit off by turning the key to "OFF" (0).



- 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 application automatically reboots and the LOGIN page appears after initializing phase.**

1.3.3.3 SYSTEM FAILURE



The equipment is a highly complex medical device that in very rare cases can fail, just like any other electrical 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.

1.3.4 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.



- Avoid hitting the monitor with any objects.
- The LCD screen is protected by a layer of plastic material that prevents the projection of shards of glass and the escape of the gel should the screen be hit.
NEVER TOUCH THE SCREEN WITH YOUR BARE HANDS if the screen is severely damaged (shattered); in the event of accidental contact with the gel, DO NOT TOUCH YOUR EYES OR MOUTH and wash any exposed skin immediately and thoroughly.
See a doctor if there is a reaction, pointing out that the substance involved is liquid crystal gel from the LCD panel.

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



- If the motor 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 EM equipment on and before using it on patients (details of this test are provided in *Paragraph 1.6, Part 2 of the User Manual*).



1.3.5 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/EU (WEEE).

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

All old batteries must be disposed of in accordance with European Directive 2006/66/EC and subsequent amendments.





See Chapter 4 in Part 5 of this manual for more information.


1.3.6 WARNINGS


1.3.6.1 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 (the value is the weight of the part the plate is located on: stand or monitor unit).
- 


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

1.3.6.2 STATUS AND ALARM MESSAGES ON THE CONTROL PANEL

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	
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.

MESSAGE	MEANING	NOTES
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.
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.

MESSAGE	MEANING	NOTES
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.
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.

MESSAGE	MEANING	NOTES
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.
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.

MESSAGE	MEANING	NOTES
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.
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.

1.3.7 MANUFACTURER'S GUIDELINES AND DECLARATION



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.

1.3.7.1 ELECTROMAGNETIC EMISSIONS

Table 1

Manufacturer's guidelines and declaration - electromagnetic emissions		
In accordance with EN standard 60601-1-2 (4 th edition), the system is intended for use in the electro-magnetic environment specified below. <u>The client or user of the system must ensure that it is used in such an environment.</u>		
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.
Harmonic emissions EN 61000-3-2	N.A.	Note: <i>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.</i>
Voltage fluctuation / flicker emissions EN 61000-3-3	N.A.	

1.3.7.2 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% at 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.

1.3.7.3 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	704 – 787	LTE Band 13, 17	Pulse modulation	0.2	0.3	9
745			217 Hz			
780						
810	800 – 900	GSM 800/900 TETRA 800 IDEN 820 CDMA 850 LTE Band 5	Pulse modulation	2	0.3	28
870			18 Hz			
930						
1720	1700–1990	GSM 1800CDMA 1900 GSM 1900 DECT LET Band 1, 3, 4, 25 UMTS	Pulse modulation	2	0.3	28
1845			217 Hz			
1970						
2450	2400-2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LET Band 7.	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation	0.2	0.3	9
5500			217 Hz			
5785						

2 TECHNICAL DATA

2.1 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

2.2 TECHNICAL CHARACTERISTICS

2.2.1 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 orbiting	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⁾	- Fluoroscopy 16 A ⁽³⁾ - Radiography 22 A ⁽⁴⁾
	⁽¹⁾ @ 120kV-8mA Average ⁽²⁾ @ 100kV-25mAs	⁽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	<ul style="list-style-type: none"> - Continuously adjustable aperture - Automatic adjustment to suit detector field - Manual control
Shutters	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Continuously adjustable aperture - Automatic adjustment to suit detector field - Manual control
Shutters	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - 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 cm ²

LASER LOCALIZER <i>Consisting of 4 laser modules (Optional)</i>	
Model	ML635L - class 1M
Class	1M
Laser diode power	< 5 mW
Optical output power	3.8 mW
Wavelength	635 nm
Laser light warning	

2.2.2 IMAGING SYSTEM

FLAT PANEL DETECTOR			
Model	Pixium 2121S		
FPD Matrix	1344 x 1344 pixel		
Sensitive area	<p>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)</p> <p>DIGITAL RADIOGRAPHY Nominal field= 207mm x 207mm (1344 x 1344 pixel)</p>		
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)		
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

VIDEO PROCESSOR		
CPU	Intel core i7-8700 – 3,2GHz (8°gen.) LGA 1151	
Operating System	WINDOWS 10 LTSC 2019 64bits	
Video board	GeForce RTX-3060 EAGLE OC 12G	
Ethernet interface board	2x: INTEL Server Adapter I210-T1	
RAM	16GByte DDR4	
Hard Disk	- HD 2,5" SATA3 500 Gbyte tecnologia SSD - HD 2,5" SATA3 1 Tbyte tecnologia SSD	
Number of images that can be saved in Fluoroscopy mode (1344 x 1344 pixels - 16bit)	270.000	
Number of images that can be saved in digital Radiography (1956 x 1956 pixels - 16bit)	65.000	
Interface	- USB (for Windows compatible printer) - USB (for saving images to USB memory stick) - RJ45 (for DICOM 3 interface)	
Acquisition	- Max resolution matrix: • 1344 x1344 pixels (FPD 2121) • 1956x1956 pixels (FPD 3030) - Image depth: 16 bits - Speed: max 25 frames/second	
Details of saved images on HD	Fluoroscopy	Digital Radiography
	- field 30: 978 x 978 pixels - field 21: 1344 x 1344 p. - field 16: 1024 x 1024 p. - field 12: 776 x 776 pixels	- 1344 x1344 pixels (FPD 2121) - 1956x1956 pixels (FPD 3030)
	- Levels depth: 16 bits unsigned - Little indian byte order	
Image processing in real time	<ul style="list-style-type: none"> - 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: * <ul style="list-style-type: none"> - Images subtraction - Max Opacification / Road Mapping 	

VIDEO PROCESSOR	
<p>Post-processing functions</p>	<ul style="list-style-type: none"> - 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: * <ul style="list-style-type: none"> - Mask pick-up - Pixel Shift - Land marking
<p>DICOM functions (*)</p>	<ul style="list-style-type: none"> - 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)

2.2.3 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 1.5 in Part 1 of the User Manual.

For a full description of the exposure modes:

- Roadmap
- DSA Fluoroscopy

see Paragraphs 5.4.1 and 5.4.2 in Part 5 of the User Manual.

2.2.4 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**.

Radiological parameters accuracy	
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

2.3 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:

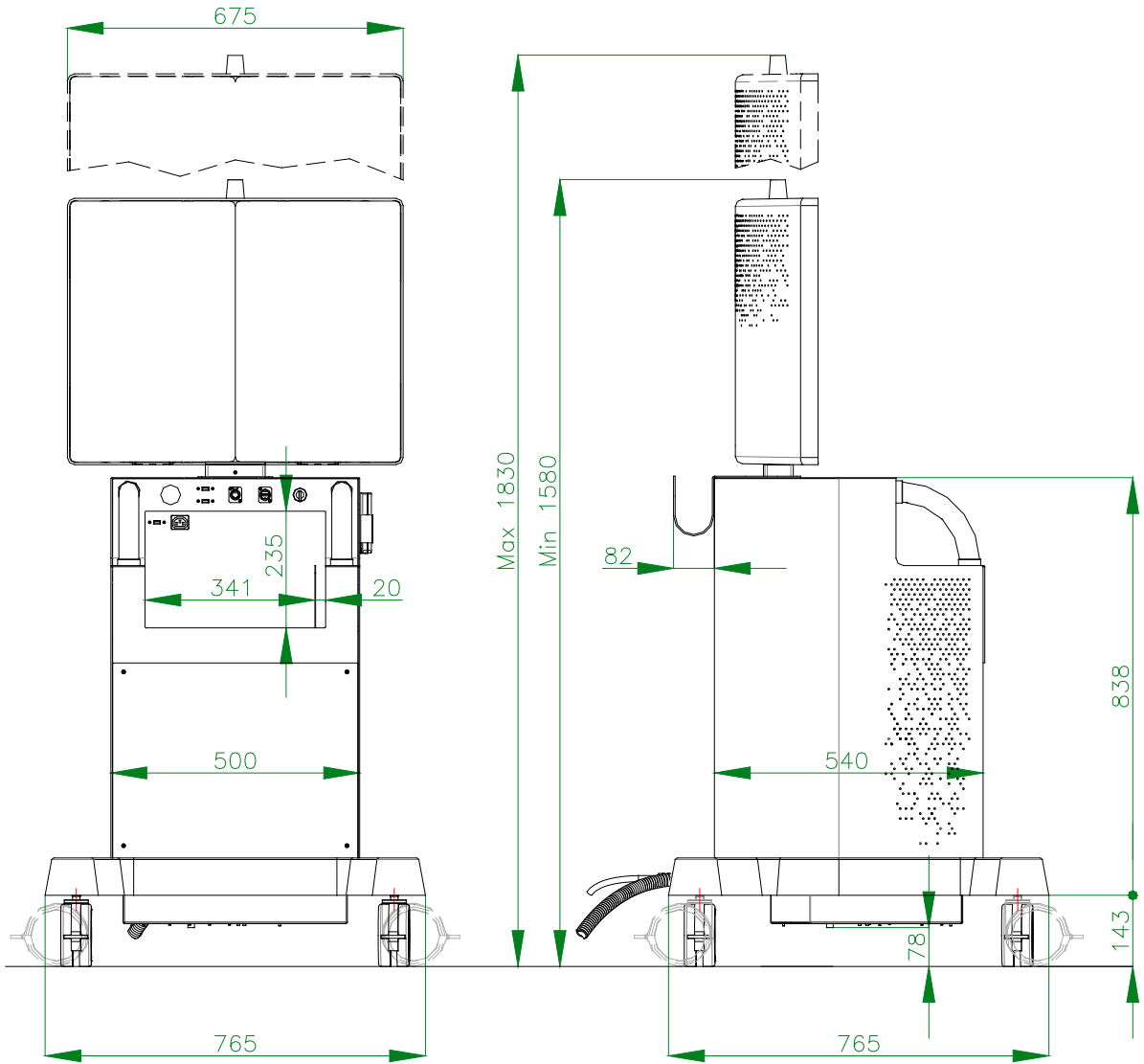
120 Vac Version	
Tripping type	Type D
Tripping current	16A
Number of poles	2
Tripping power	10kA
Nominal AC voltage	400V

230 Vac Version	
Tripping type	Type D
Tripping current	10A
Number of poles	2
Tripping power	10kA
Nominal AC voltage	400V



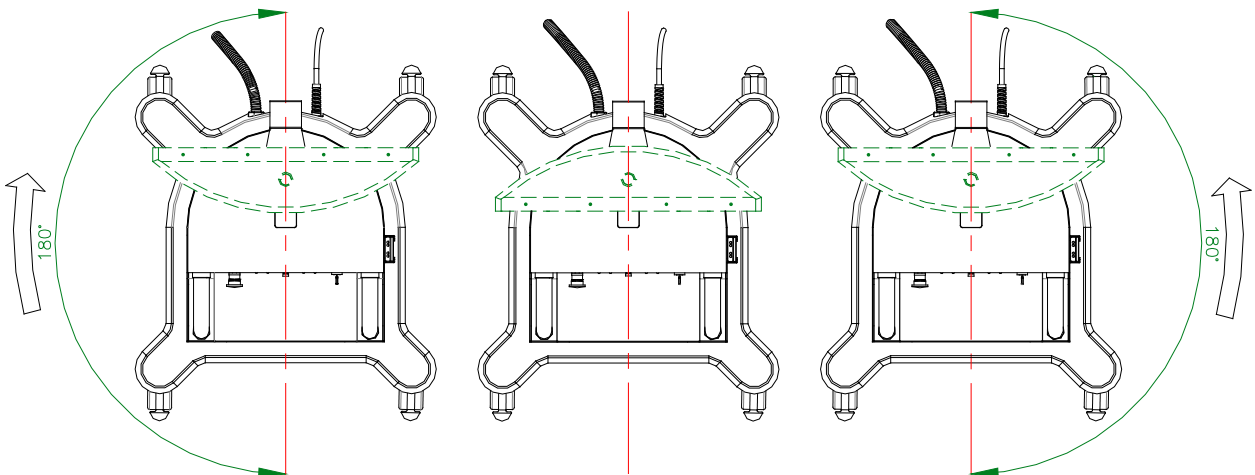
2.4 OVERALL DIMENSIONS AND WEIGHTS

2.4.1 OVERALL DIMENSIONS AND WEIGHT OF THE MONITOR UNIT



Note: Dimensions shown in mm

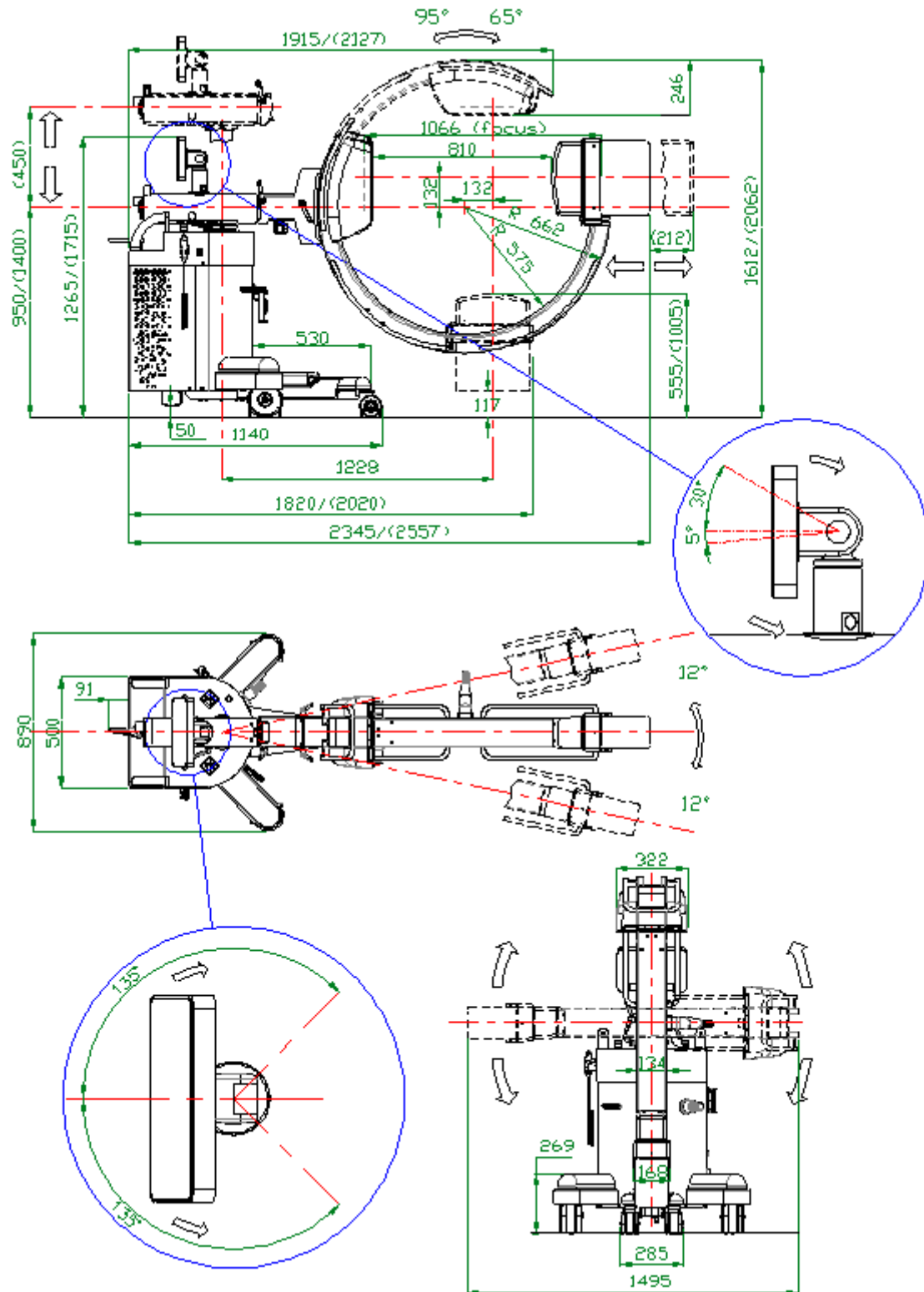
Weight: 140 kg



Monitor Rotation

2.4.2 OVERALL DIMENSIONS AND WEIGHT OF THE STAND

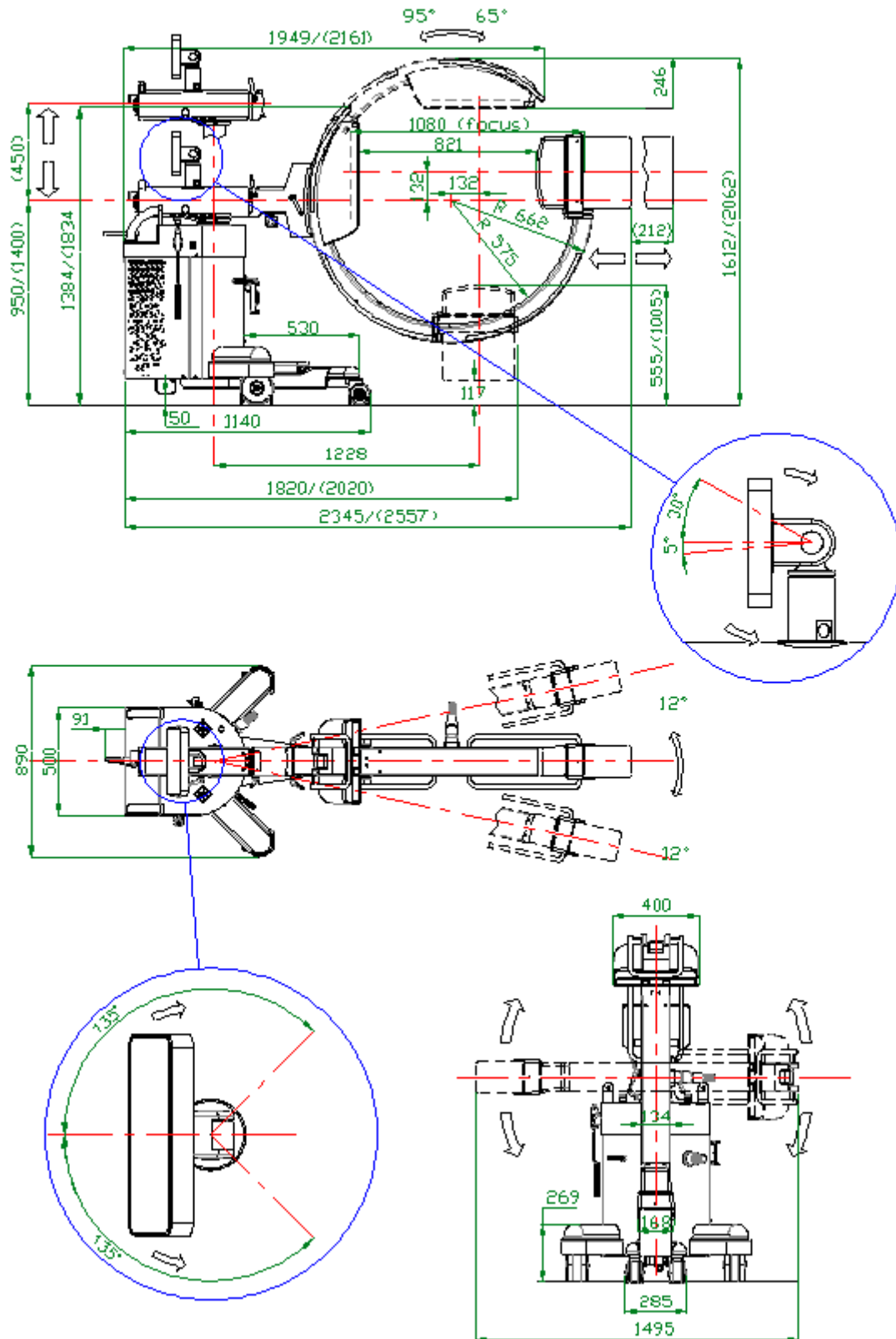
Version with **FPD 2121**



Note: Dimensions shown in mm

Weight:

Version with **FPD 3030**

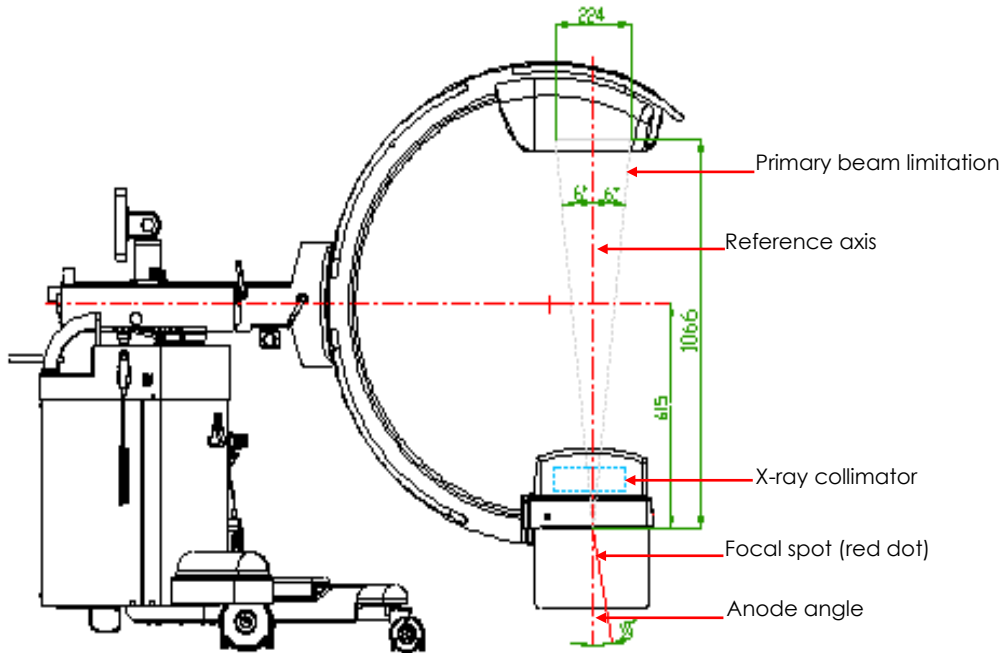


Note: Dimensions are shown in mm

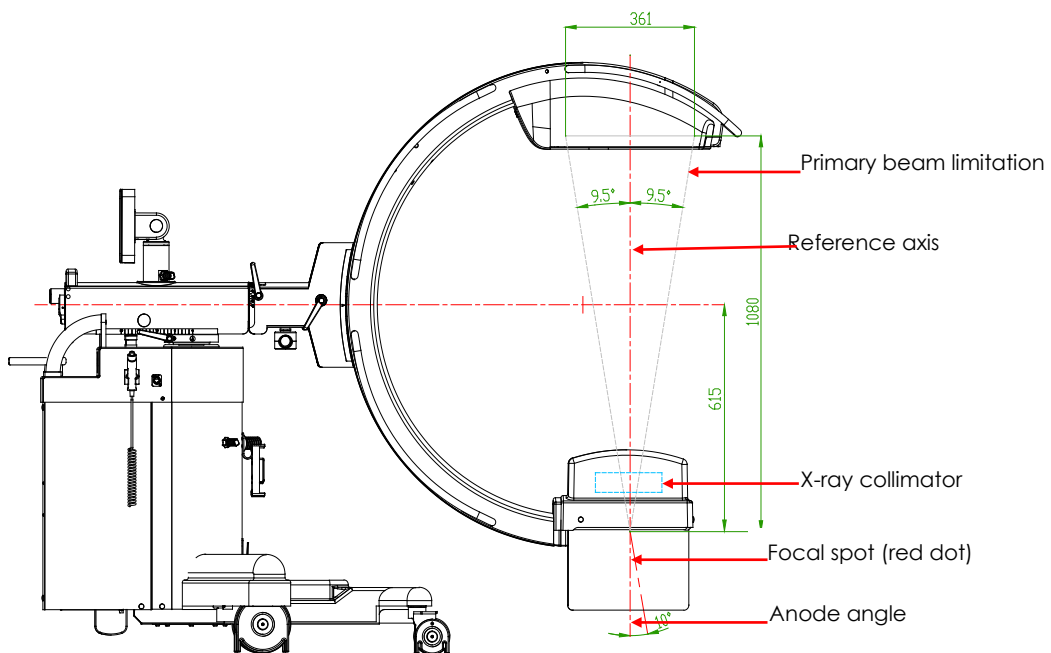
Weight: 280 kg

2.5 FOCAL SPOT POSITION

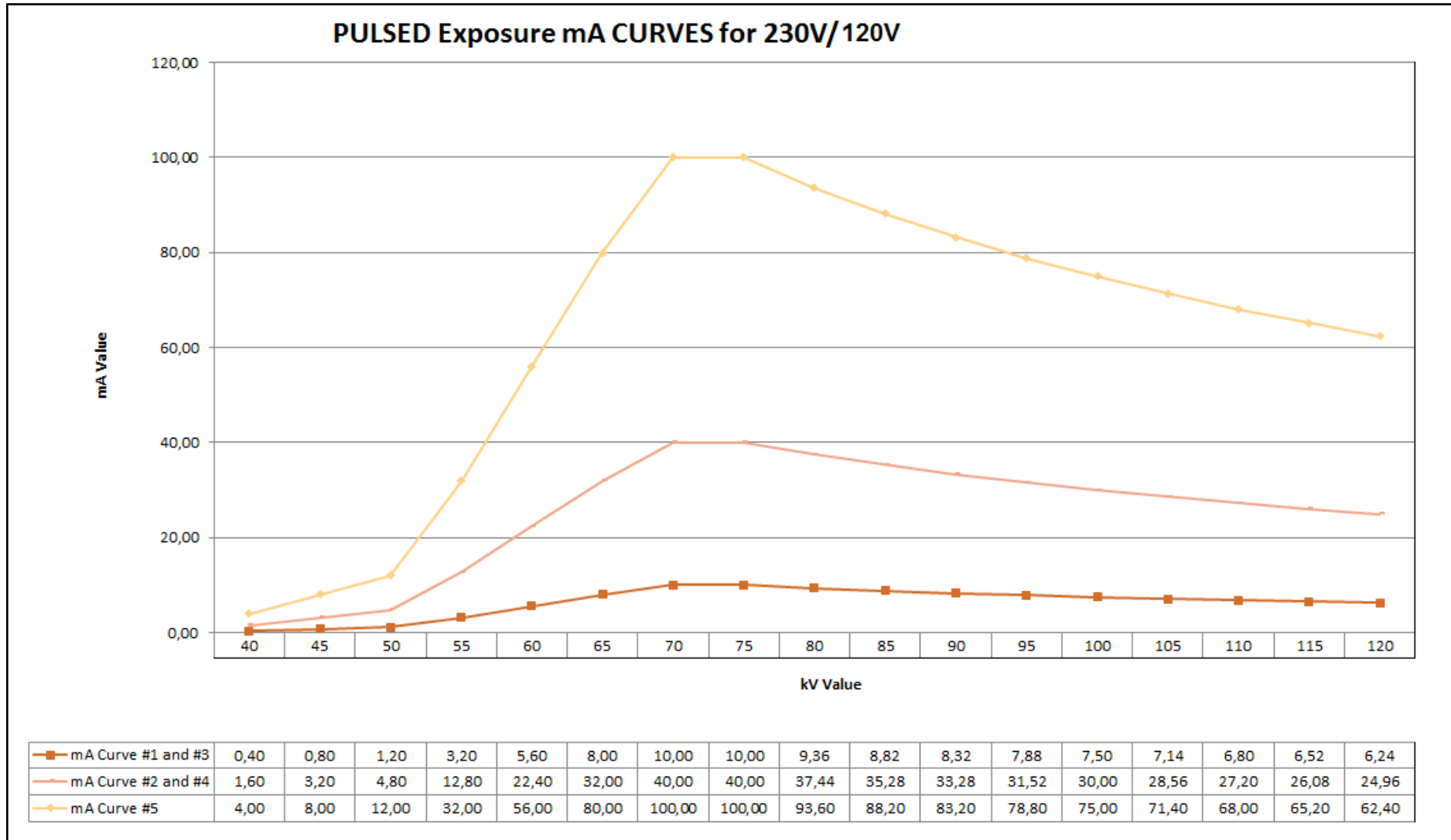
Version with **FPD 2121**



Version with **FPD 3030**



2.6 FLUOROSCOPY mA CURVES

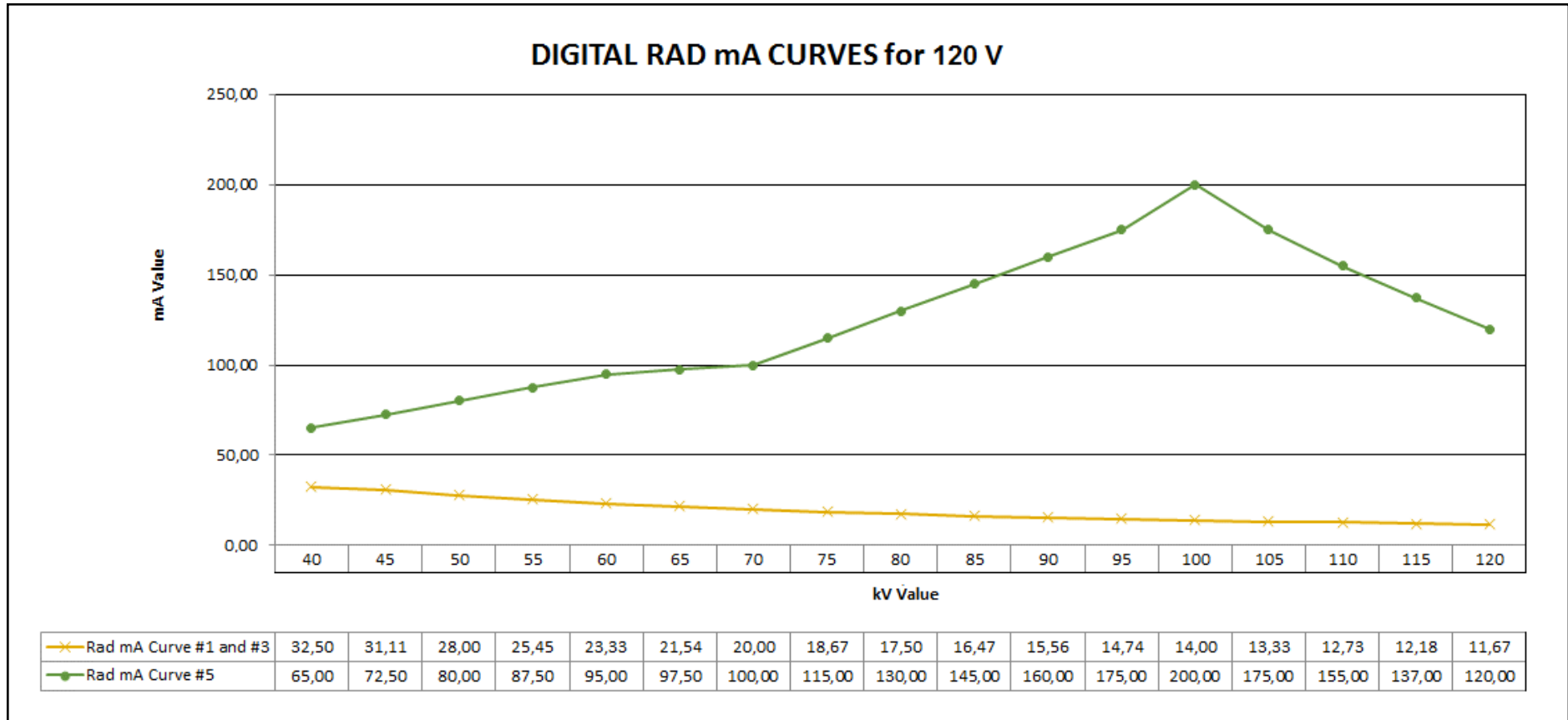


2.7 DIGITAL RADIOGRAPHY (SNAPSHOT) mA CURVES

2.7.1 RADIOGRAPHY CURVES WITH 230 V MAINS POWER SUPPLY



2.7.2 RADIOGRAPHY CURVES WITH 120 VAC MAINS POWER SUPPLY



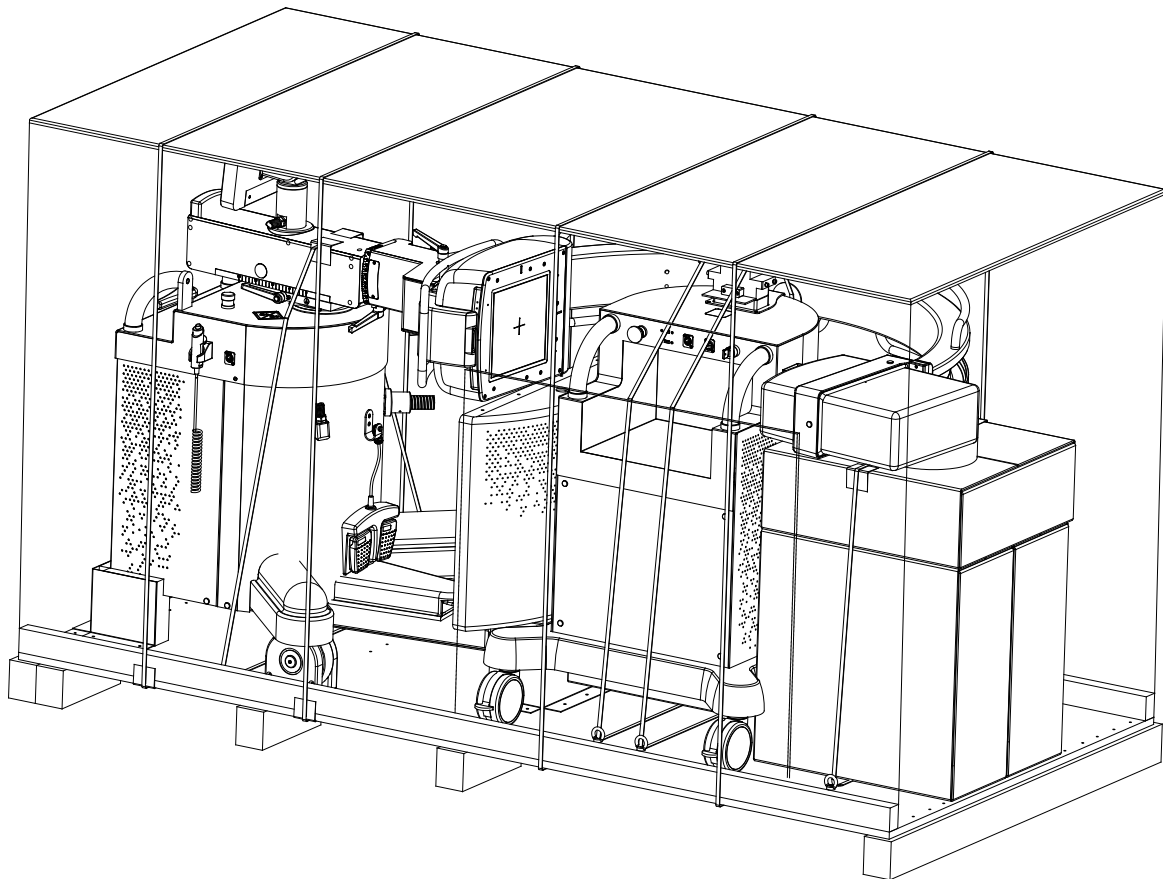
3 STORAGE AND HANDLING

3.1 PACKAGING

The EM equipment sits on a pallet and is then covered with cardboard, anchored to the pallet by straps and screws.

A ramp, needed to remove the stand and the monitor unit from the pallet, is also enclosed.

Follow the unpacking instructions in reverse order should the system need to be repacked in the future (see paragraph 1.2 in Part 2 of this manual).



3.2 STORAGE

The environmental conditions indicated in the table below should be guaranteed for both storage and transportation:

	Max values	Recommended value
Temperature	from -10 °C to +55 °C	from +10 °C to +35 °C
Relative humidity	from 20 % to 80 % (not condensing)	from 20 % to 70 % (not condensing)
Pressure	from 70 kPa to 106 kPa	from 70 kPa to 106 kPa

Part 2: INSTALLATION

CONTENTS

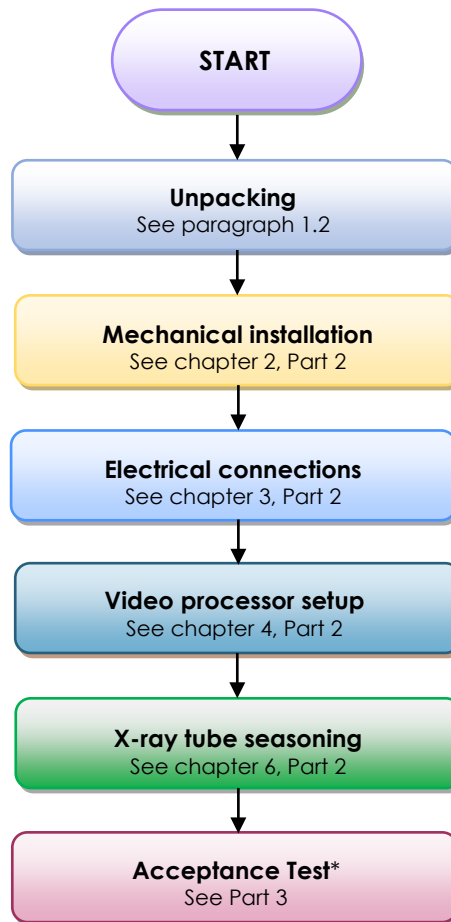
	page	rev.	date
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1.1 Installation procedure			
1.2 Unpacking			
1.2.1 Unpacking: cardboard packaging			
1.2.1 Unpacking: wooden packaging			
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2.2 Installing the monitors and covers			
2.3 Installing the printer (<i>optional</i>)			
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3.2 Connections			
3.2.1 Connecting the monitor unit			
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3.2.3 Peripheral/optional connections			
3.2.4 Main power supply			
4 <u>VIDEO PROCESSOR SETUP</u>	4.1 - 4.57	A	18/07/22
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4.2 General Settings			
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4.4.1.1 DSA Programmable parameters			
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4.5.2.7 Radiation Dose Structured Report			

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	4.5.4 Spooler			
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	4.6 DRC Group setup			
	4.7 DRC name setup			
	4.8 User Account Setup			
	4.9 Fixed String Setup			
	4.10 Firewall Info			
	4.11 Security setup			
5	<u>ANNEXES A</u>	5.1 – 5.12	0	04/12/20
	5.1 Connecting the printer (<i>optional</i>)			
	5.1.1 Power supply and usb connections			
	5.2 Monitor configuration			
	5.2.1 Resetting the monitors			
	5.2.2 Touch screen calibration			
	5.3 Windows administrator log-in			
	5.4 Ethernet setup			
	5.4.1 Physical characteristics of the network connections			
	5.4.2 Windows settings			
	5.4.3 Network connections test			
	5.5 Online manuals			
	5.5.1 How to consult the manuals			
	5.6 Software version			
	5.7 Video processor back-up			
	5.8 Customize the opening screen logo			
6	<u>ANNEXES B</u>	6.1 – 6.2	0	04/12/20
	6.1 X-ray tube seasoning procedure			

1 INTRODUCTION

1.1 INSTALLATION PROCEDURE

The flow chart below shows the various steps in the installation procedure:



* Installation ends with an **Acceptance Test** (also valid for extraordinary maintenance) and the filling-in of the relevant "Test Sheet".
The Acceptance Test is described in Part 3 of this manual.

Each step in the installation process is described in detail in the following chapters.

Note: *The EM equipment is fully adjusted in the factory to suit the user's specific requirements. Adjustments may only become necessary when components are replaced (see Part 4 of this manual).*



Only qualified and suitably trained personnel should be allowed to install the EM equipment.



The EM equipment mains power supply must be consistent with that reported on its serial number plate (see Paragraph 3.2.4, Part 2 of this Manual).

*The electrical circuit to which the EM equipment is to be connected must conform to IEC standard 60364:2005 section 710 (Electrical plant in medical environments) and **be properly earthed.***

1.2 UNPACKING



Only suitably trained personnel should be allowed to unpack the EM equipment.

The following paragraphs report the unpacking procedure for cardboard packaging and for wooden packaging, respectively.

1.2.1 UNPACKING: CARDBOARD PACKAGING

To unpack the equipment:

- Cut the 4 straps around the cardboard cover.

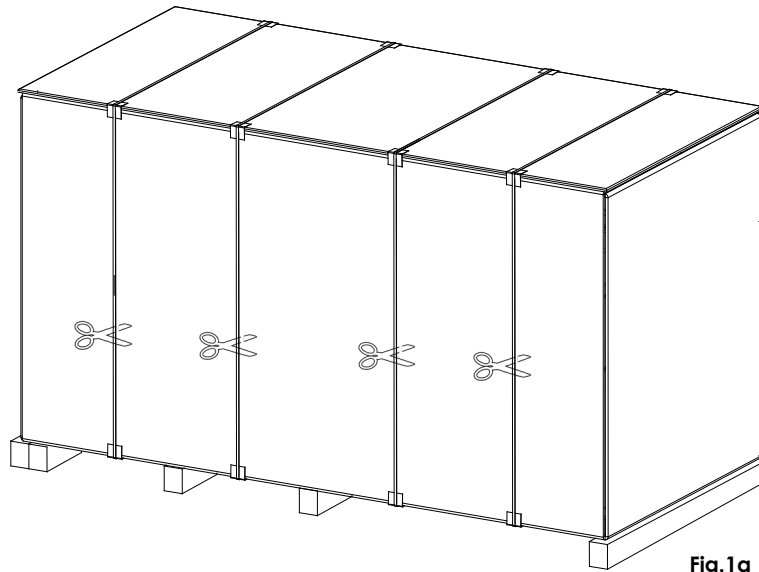


Fig.1a

- Remove the lid (A) and the screws fixing the cardboard cover (B) to the pallet (C) and then remove the cardboard by lifting this upwards.

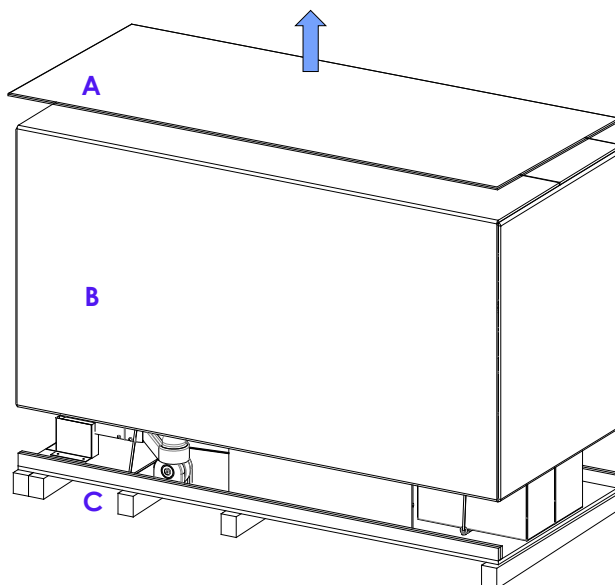


Fig.1b

- Remove the cling-film covering the material inside.
- Extract the wooden ramp (S) and place as shown in figure 1d.
- Remove the monitor/monitor cover supports (D). These need to be returned later (see paragraph 2.1 below).
- Cut the straps securing the stand, the monitor unit and the monitor/accessories packing boxes.



Caution: the monitor support will rise freely when you cut the straps securing the monitor unit.

- Remove the boxes holding the monitors (B1 and B2) and the accessories (B3).
- Remove the anchor supports (E1 and E2) securing the stand. To do this, undo the screws fixing them to the base of the pallet (C).

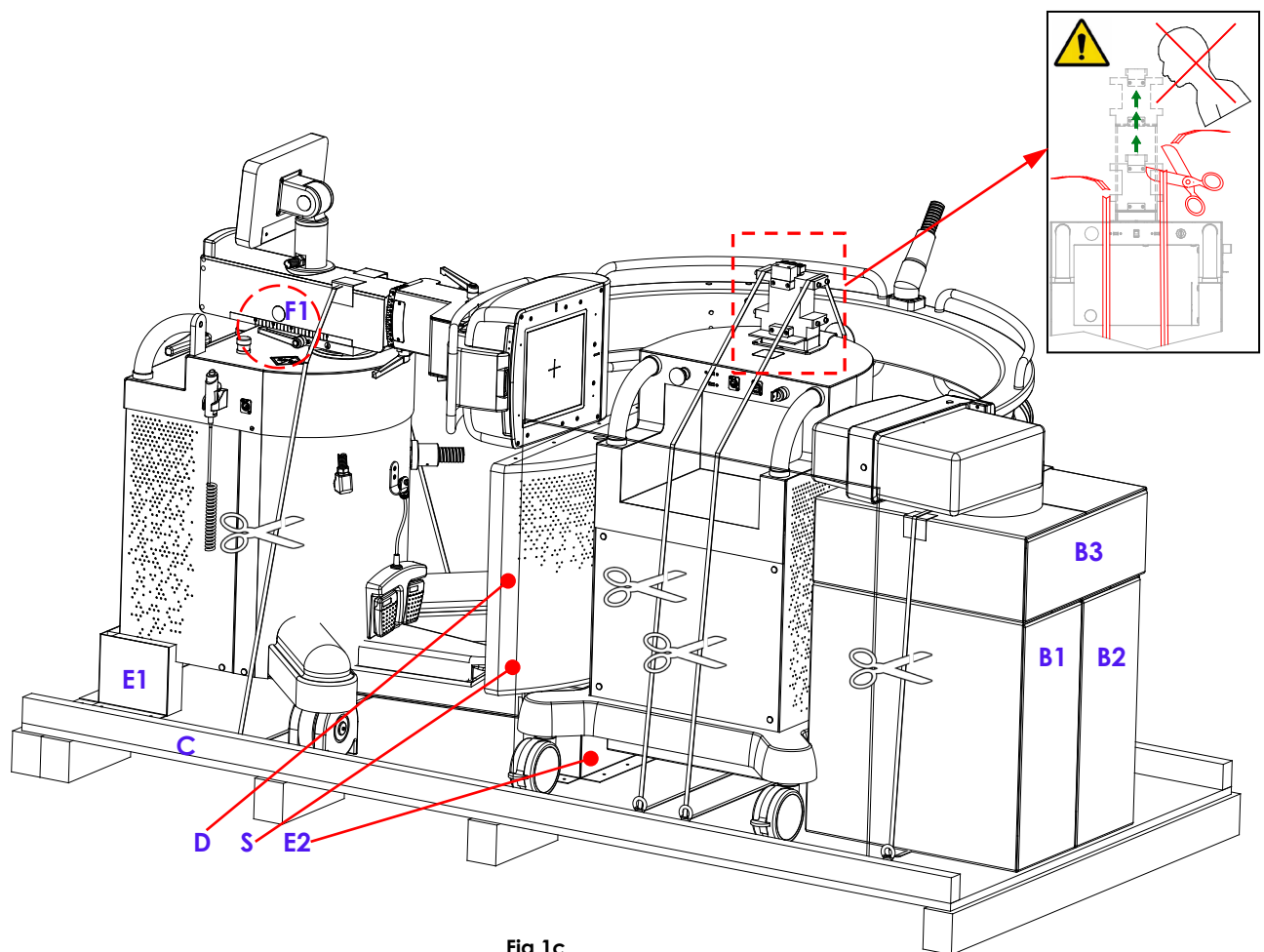


Fig.1c

- Turn the C-arm as shown in figure 1d by releasing the wig-wag brake (F1 in fig.1c) and the C-arm rotation brake (F2 in fig.1d), then slide the station down the ramp (S).

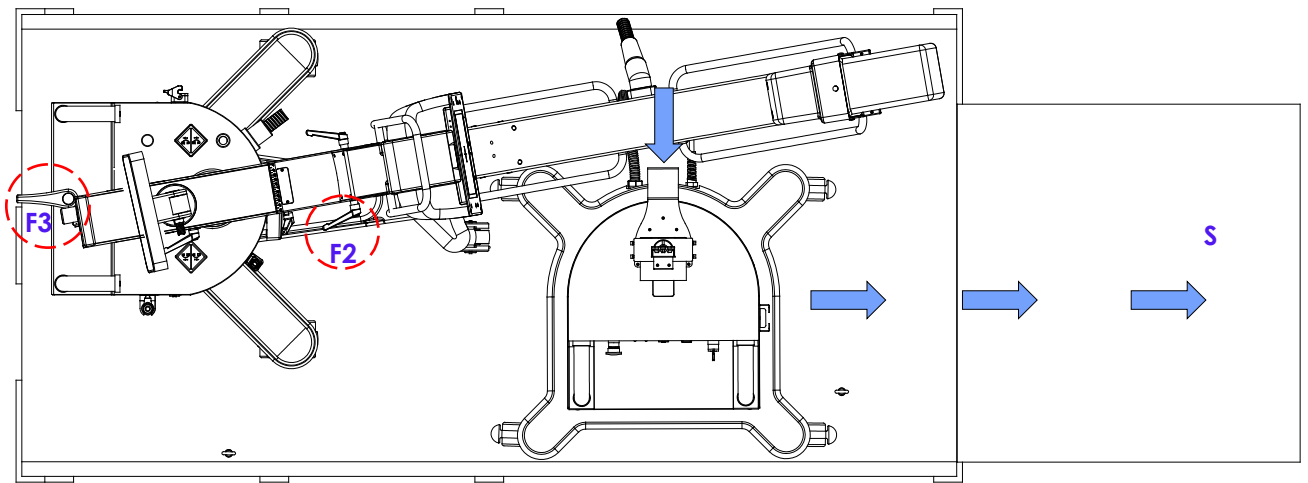


Fig.1d

- Move the ramp (S) in front of the stand (figure 1e) and then slide the stand down the ramp after turning the handle (F3) to release the stand brake, as shown in fig. 1d.

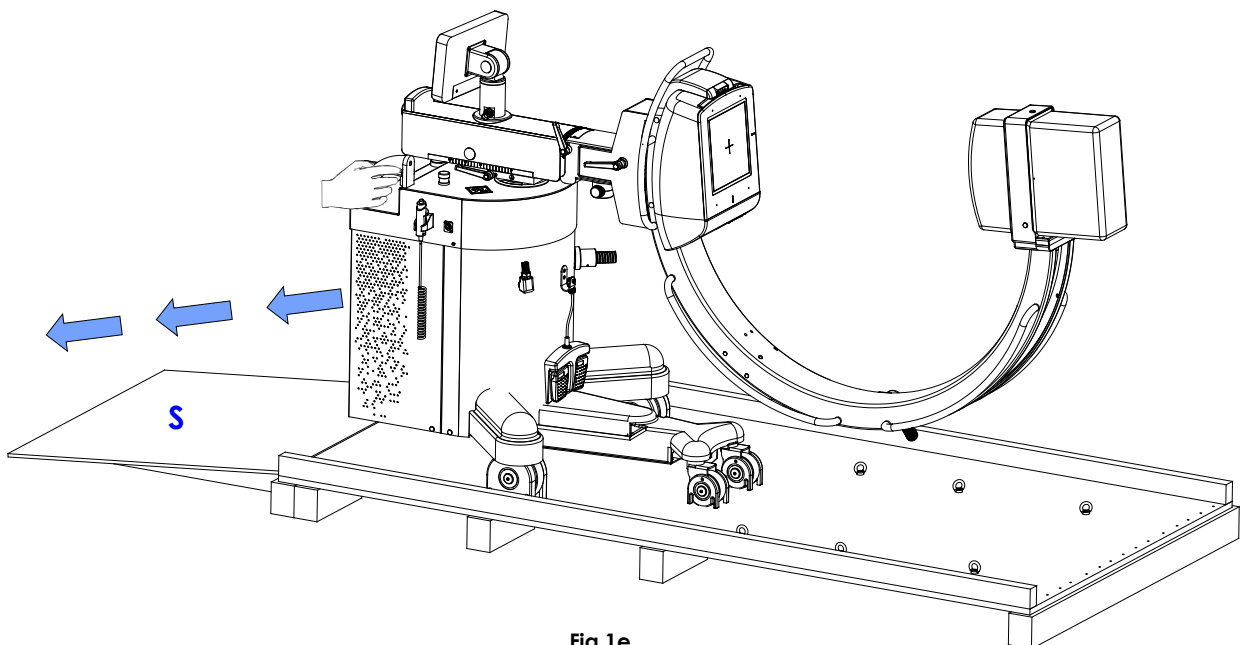


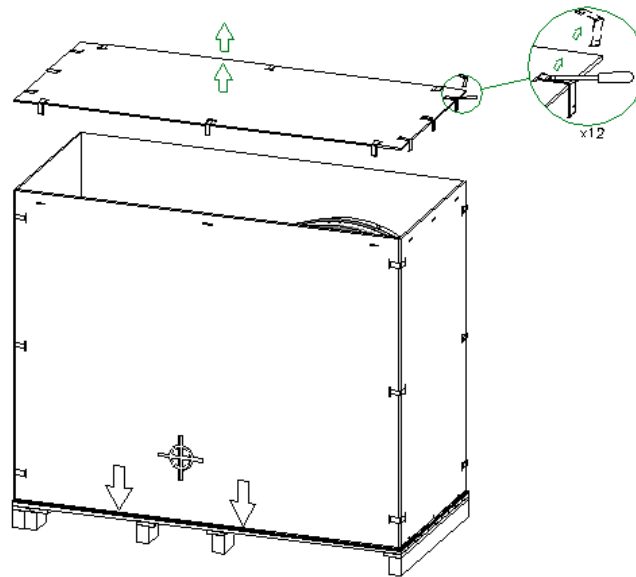
Fig.1e

1.2.2 UNPACKING: WOODEN PACKAGING

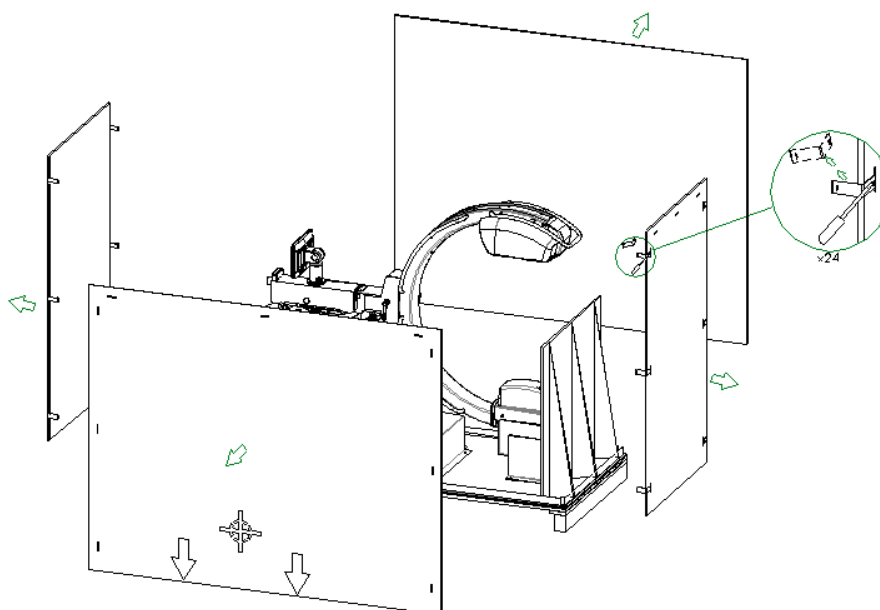
The equipment is shipped in two separate cases, the first containing the stand and the second containing the viewing station.

To unpack the crate containing the stand, proceed as follows:

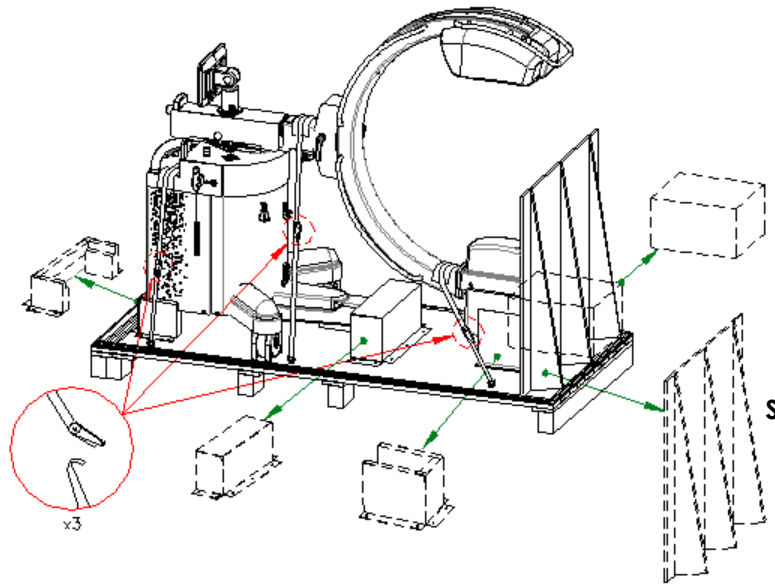
- Using a flat-blade screwdriver or similar tool, remove the outer catches from the top cover of the crate and then remove it.



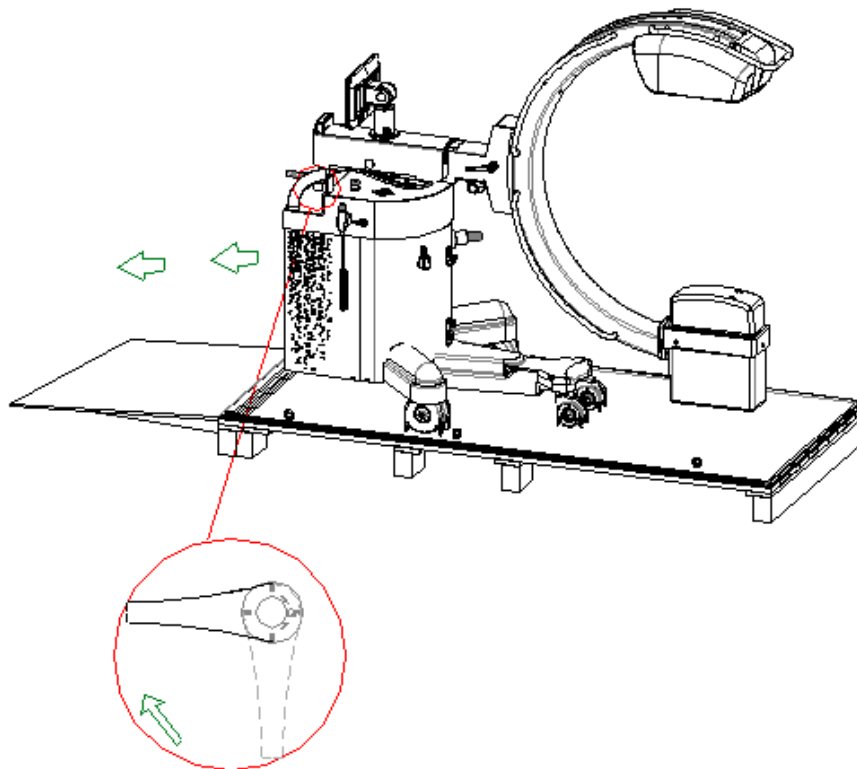
- Proceed by removing the remaining retainers so you can remove the case walls.



- Unlock the retaining straps and remove the protective shims, as shown.



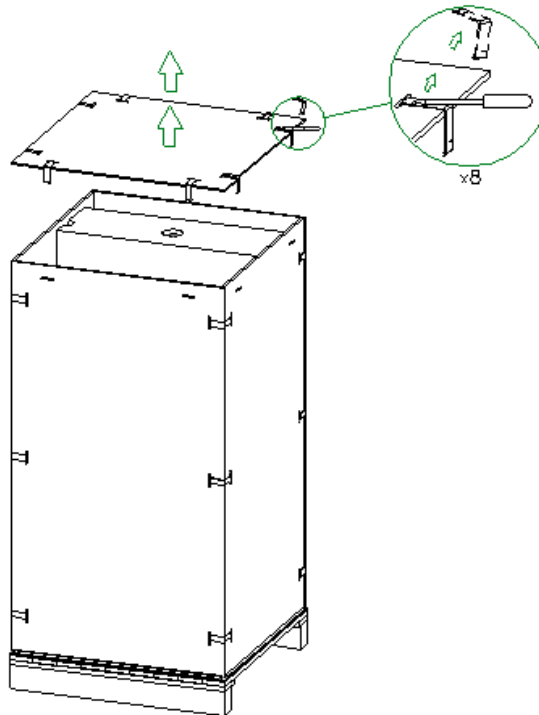
- Remove the wooden slide (S) and position it as in the figure. Release the brake lever and lower the stand.



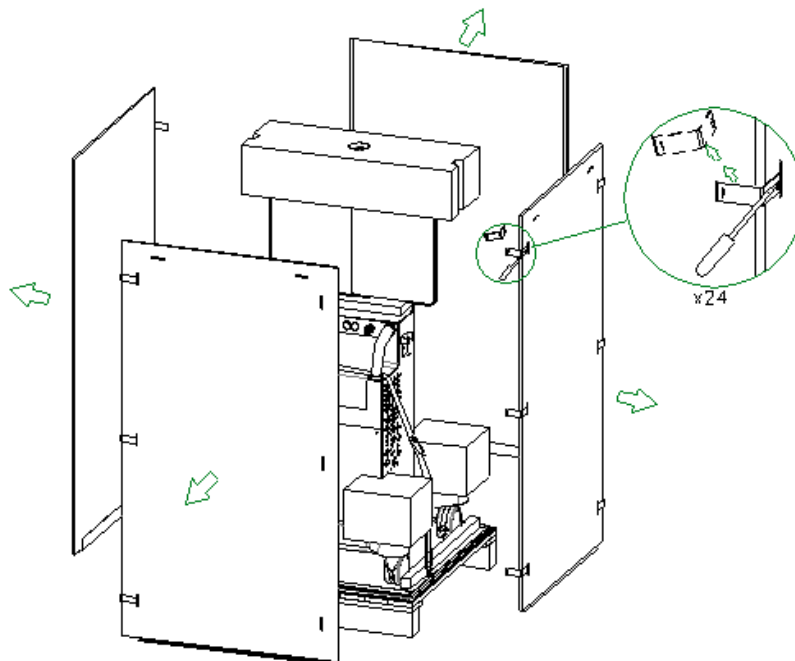
Attention: the slide (S) is to be used for the visual station, too.

To unpack the crate containing the visual station, proceed as follows:

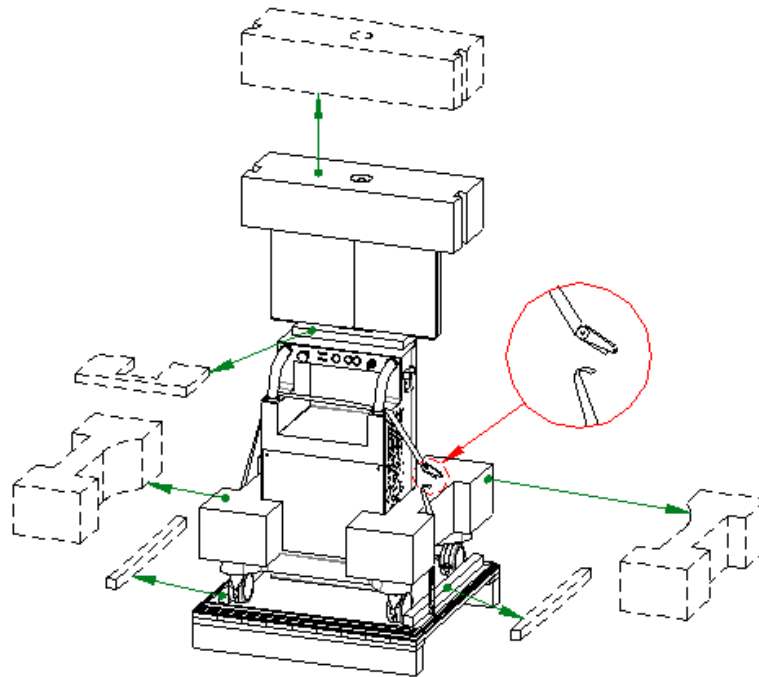
- Using a flat-blade screwdriver or similar tool, remove the outer catches from the top cover of the case and then remove it.



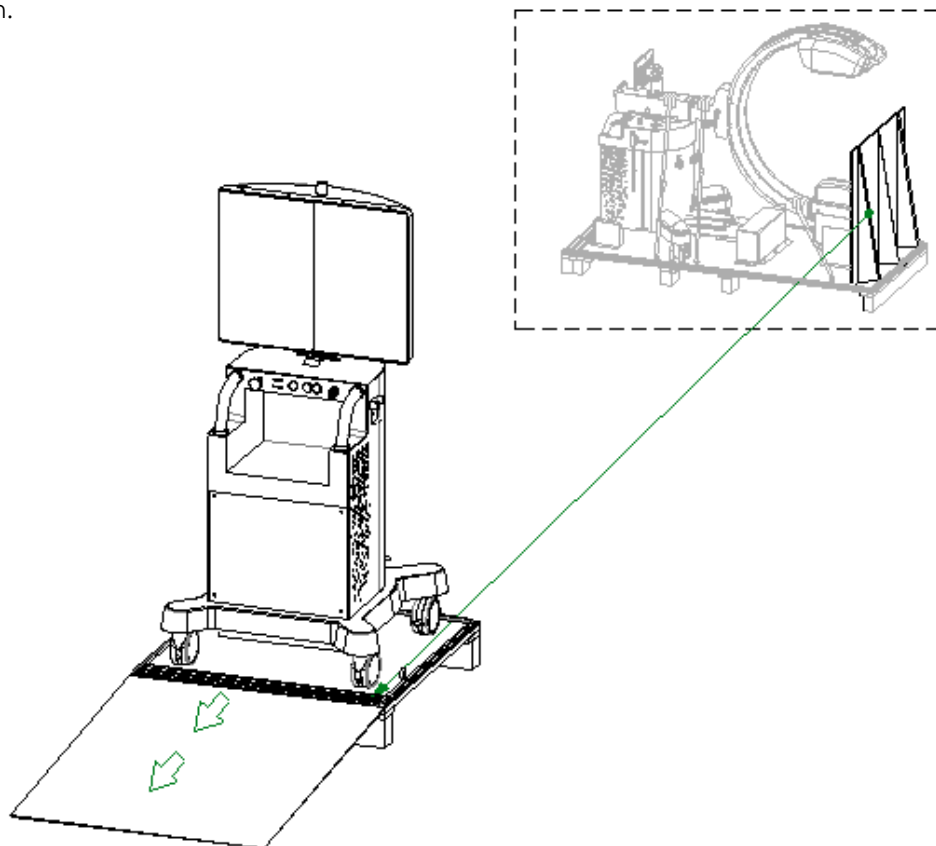
- Proceed by removing the remaining retainers so you can remove the case walls.



- Unlock the retaining straps and remove the protective shims, as shown.



- Use the wooden slide (S), previously used for the stand, and position it as in the figure. Release the wheel brakes (if necessary, see Section 1.9.1, Section 2 of the User's Manual) and lower the visual station.



Note: If you need to repack the equipment, follow the instructions above in reverse order, first for the viewing station and then for the stand. Use the original protective material, clips, and straps.

2 MECHANICAL INSTALLATION

Mechanical installation involves:

- 1) Installing the monitor supports on the monitor unit.
- 2) Installing the monitors and covers.
- 3) Mounting stand/C-arm cable
- 4) Installing the printer (optional) on the monitor unit.

2.1 ASSEMBLING THE MONITOR UNIT

The monitor unit is supplied with the monitor supports (A) and (B) in a separate pack.

To assemble these:

- Fit the monitor support (S) on support (A), as shown in figure 1.
- Secure by tightening the 8 M5x10 screws (V) provided, after inserting washers.

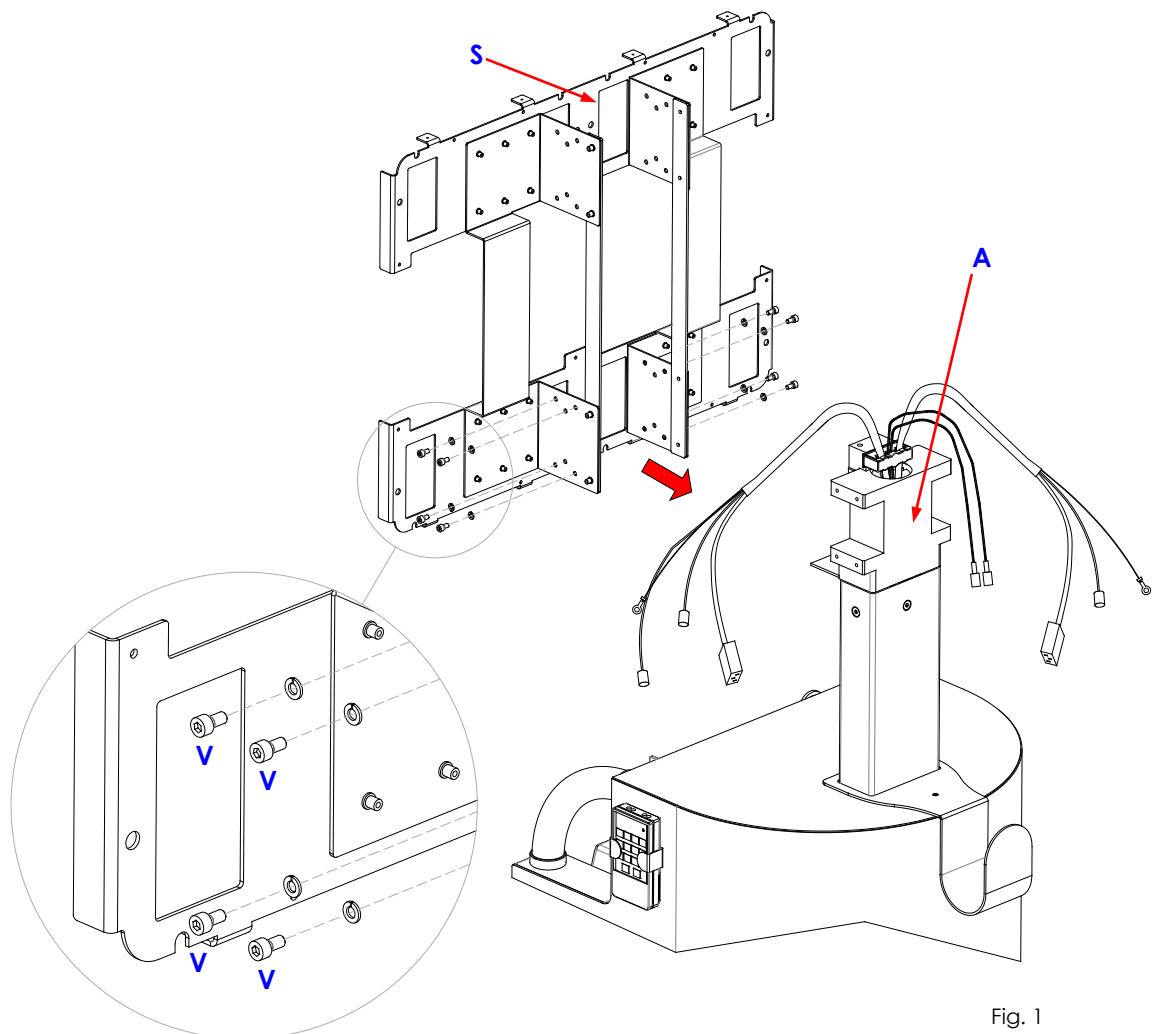


Fig. 1

2.2 INSTALLING THE MONITORS AND COVERS

The monitors are installed vertically (portrait orientation), with the cable sockets on the right of the monitor (as seen from behind) (fig. 2a).

- Secure the monitors to support (**S**) using the screws (**V**) provided, as shown in fig. 2a.
- Connect the cables to the monitors, see *Paragraph 3.2.1, Part 2 of this Manual*.

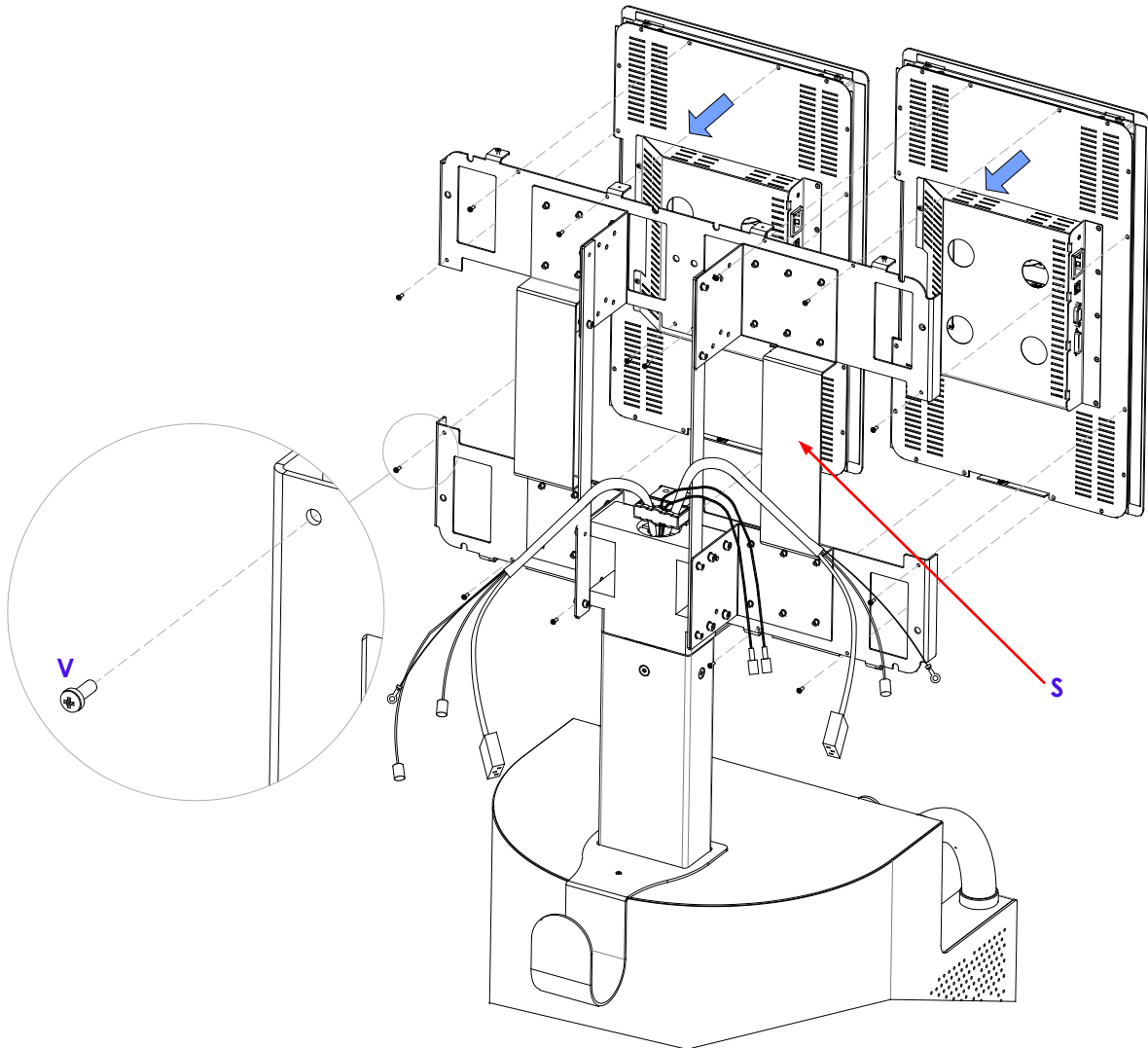


Fig. 2a

- Place cover (C) near to the monitors.
- Connect cables (A) to boards (S) and cables (B) to lamp (L).
- Fit the monitor cover (C) using the 8 screws (V) provided (fig. 2b).

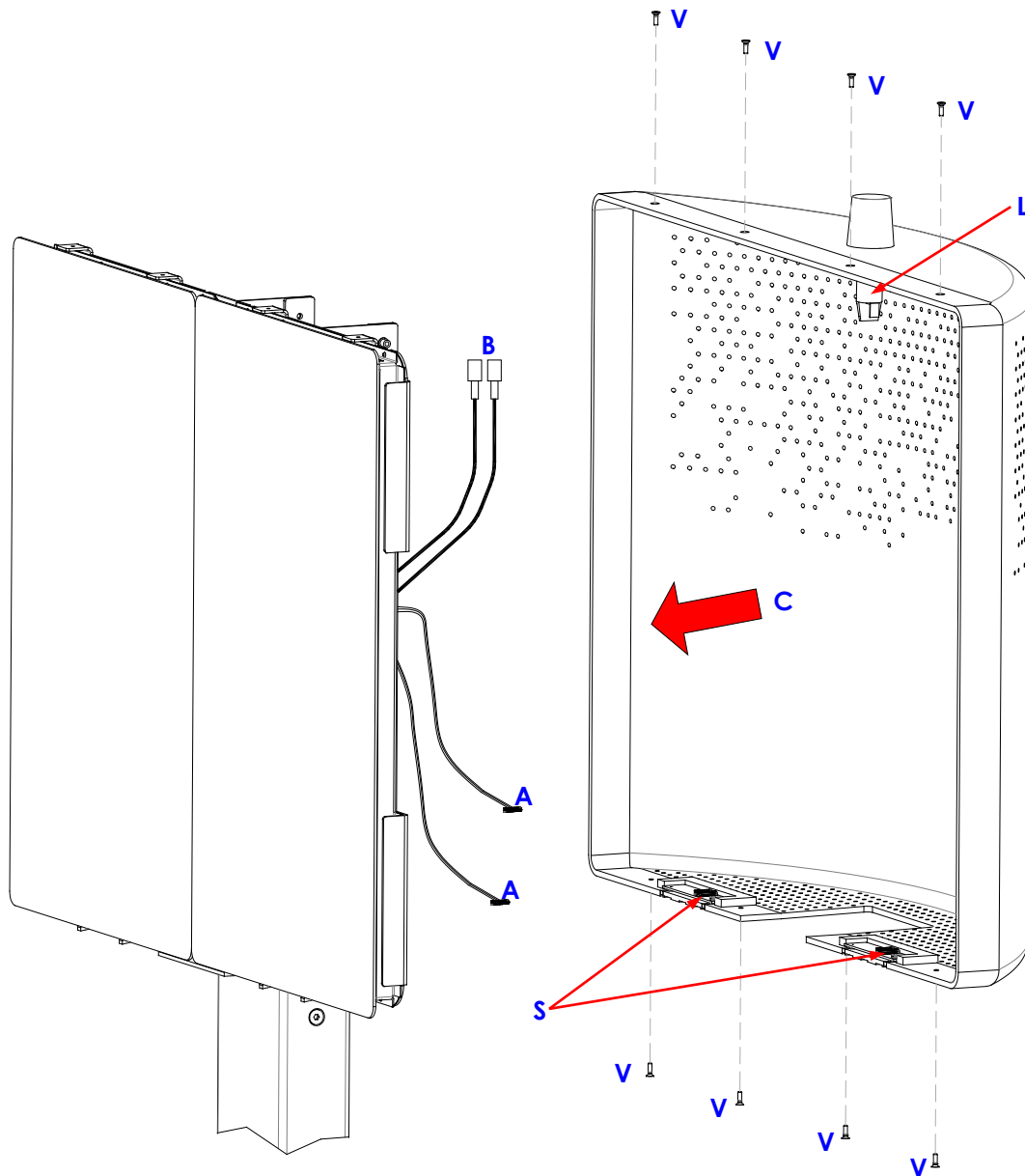
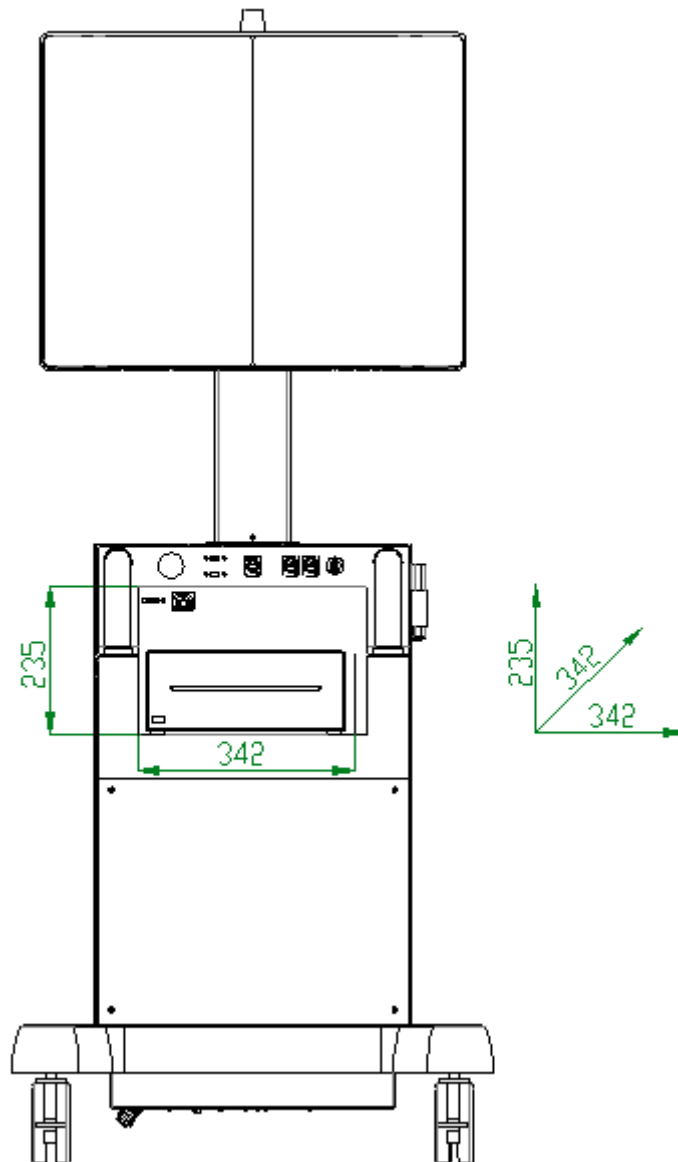


Fig. 2b

2.3 INSTALLING THE PRINTER (OPTIONAL)

A printer (S) can be fitted, by placing it in the printer compartment on the monitor unit (max dimensions: 342 x 342 x 235 mm).

See chapter 5 (Annexes) in this part of the manual for details of the electrical connections and printer setup.



3 **ELECTRICAL CONNECTIONS**

3.1 **CONNECTORS**

Module / Figure	Connector	Connected to:
Stand (Fig. 9)	CB1	Footswitch
	CB2	Monitor unit
	CB3	Equipotential earth connector (X-ray theatre)
	CB4	Injector
Monitor unit (Fig. 10/Fig. 15)	MAINS	Monitor (230VAC power supply)
	EARTH	Monitor (earth connection)
	DVI	Monitor (video connection)
	CB7	Ethernet (DICOM)
	ASPS 00 – CP6	X-ray emission warning light
Monitor (Fig.11)	DVI	DVI video cable
	MAINS	Mains supply (230VAC)
	EARTH	Fuses
	USB T.S.	USB cable (touch screen)
	OSD	Monitor control board
Video processor ARCO FP-VP/3 (Fig. 12)	POWER SUPPLY MAINS	Mains supply (230VAC)
	USB port	Touch screen L.M.
	USB port	Touch screen M.M.
	USB port	HUB USB: 2 USB front connectors + System printer (optional) + NFC Reader (optional)
	LAN 1	Monitor unit: CM1 (DICOM Network)
	LAN 2	Board CTBK-HW
	LAN 3	Flat Panel Detector
	HDMI out	Live Monitor / Memory Monitor
	DVI out	Auxiliary Live Monitor
DP out	Auxiliary Memory Monitor	

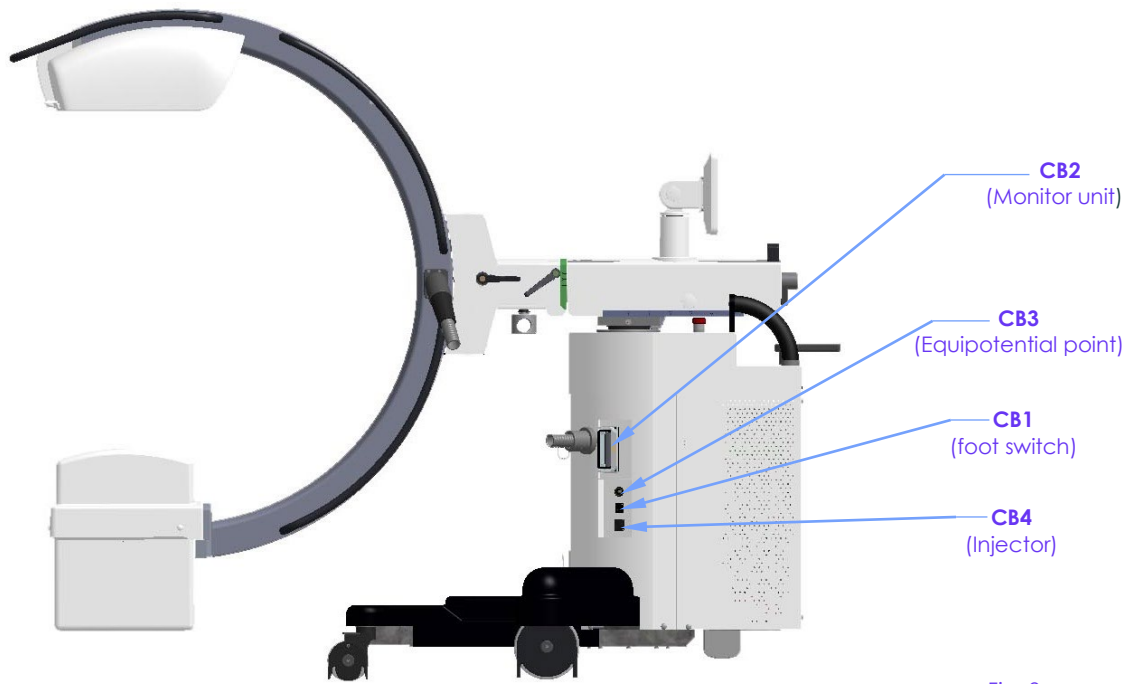


Fig. 9
(Stand)

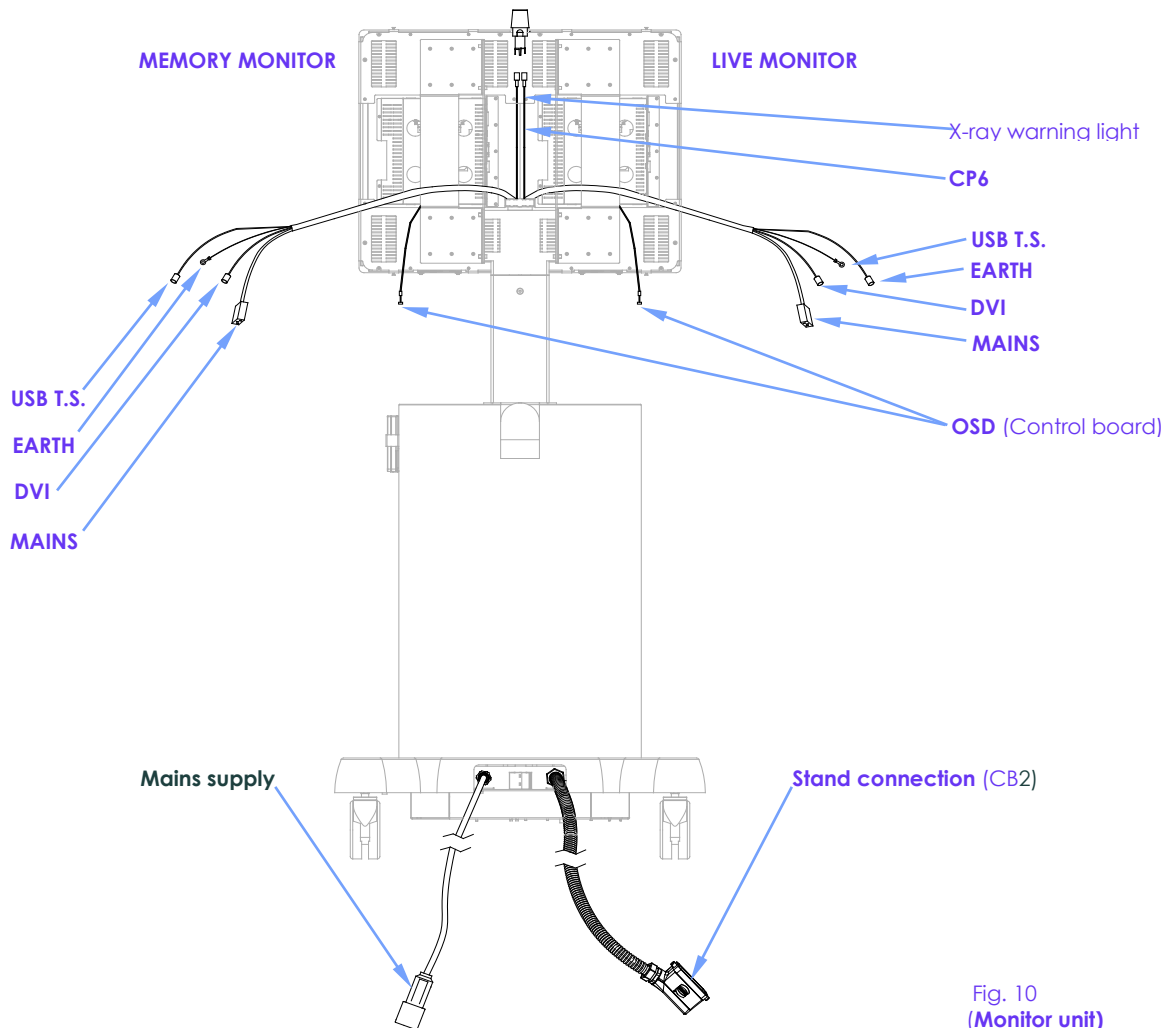


Fig. 10
(Monitor unit)

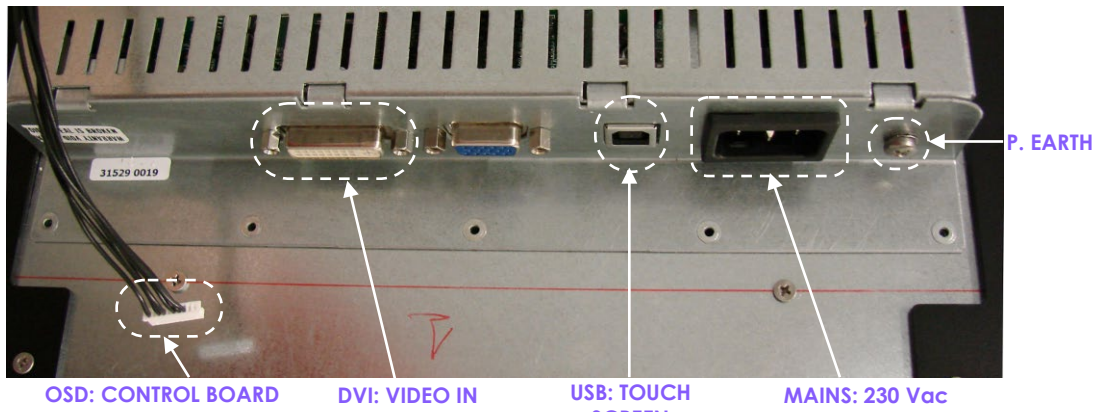


Fig. 11
21.5" colour monitor

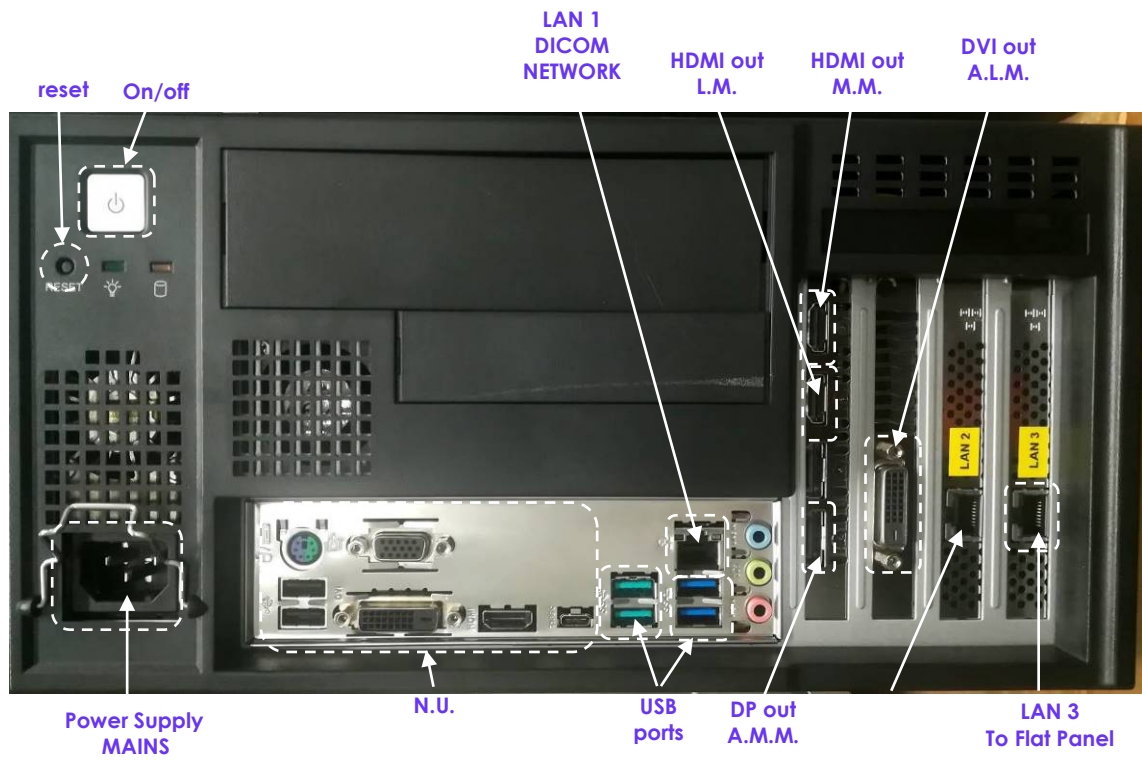


Fig. 12
Video Processor
ARCO FP-VP/3

3.2 CONNECTIONS

The connections required during installation are described in the paragraphs below.

Note 1: See the block diagram in Figure 17 below for the default connections.

Note 2: See Annex 5.1 at the end of this part of the manual for details of the printer connections (optional).

3.2.1 CONNECTING THE MONITOR UNIT

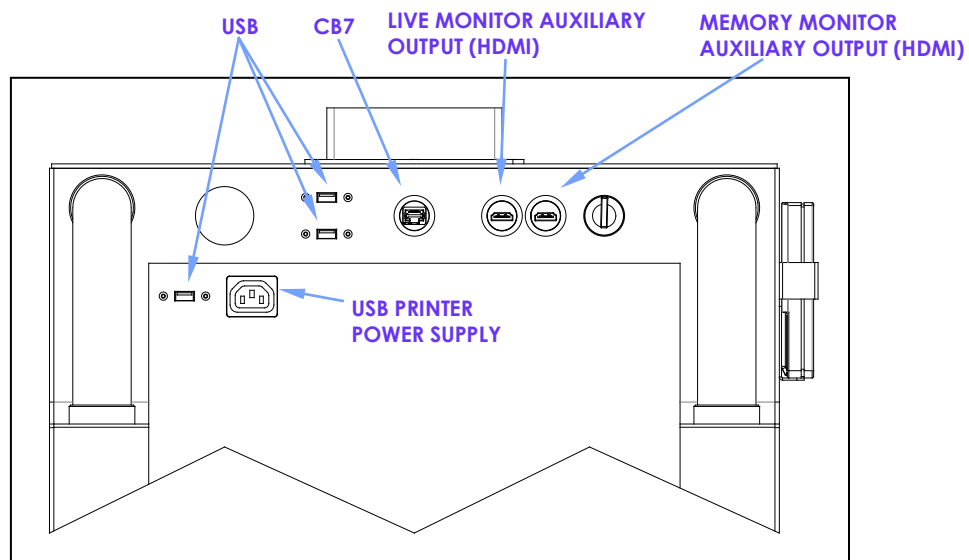
- Connect the following components to each monitor (see Fig.10 and 11):
 - The earth cable to the EARTH terminal,
 - The power cable to the MAINS terminal,
 - The DVI video cable,
 - The USB T.S. cable,
 - The OSD cable to the OSD control board (fixed on the monitor cover).
- Connect cable **CP6** to the X-ray emission warning light (see Fig.10 above).
- Connect the monitor unit to connector **CB2** on the stand (see Fig.9 above).

3.2.2 CONNECTING THE FOOTSWITCH

- Connect the footswitch cable to connector **CB1** on the stand (see Fig.9 above).

3.2.3 PERIPHERAL/OPTIONAL CONNECTIONS

- Connect the Ethernet cable for the DICOM network to connector **CB7** on the monitor unit (fig.15).
- Insert a pen-drive in one of the two **USB** connectors on the monitor unit (Fig.15).



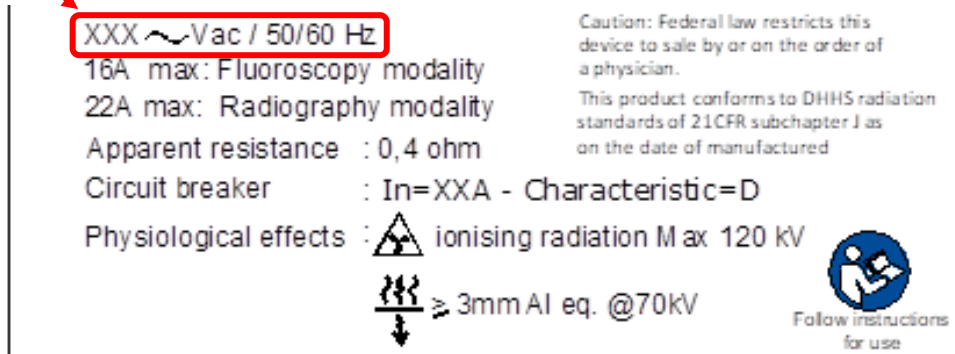
- Connect the injector cable to connector **CB4** on the stand (see Fig. 9 above).

Note: See paragraph 6.2 in the Annex to Part 5 of this manual for details of the injector cable.

3.2.4 MAINS POWER SUPPLY

The EM equipment is provided already prepared to work with **230 V AC** or **120 V AC** properly earthed mains, depending on customer needs.

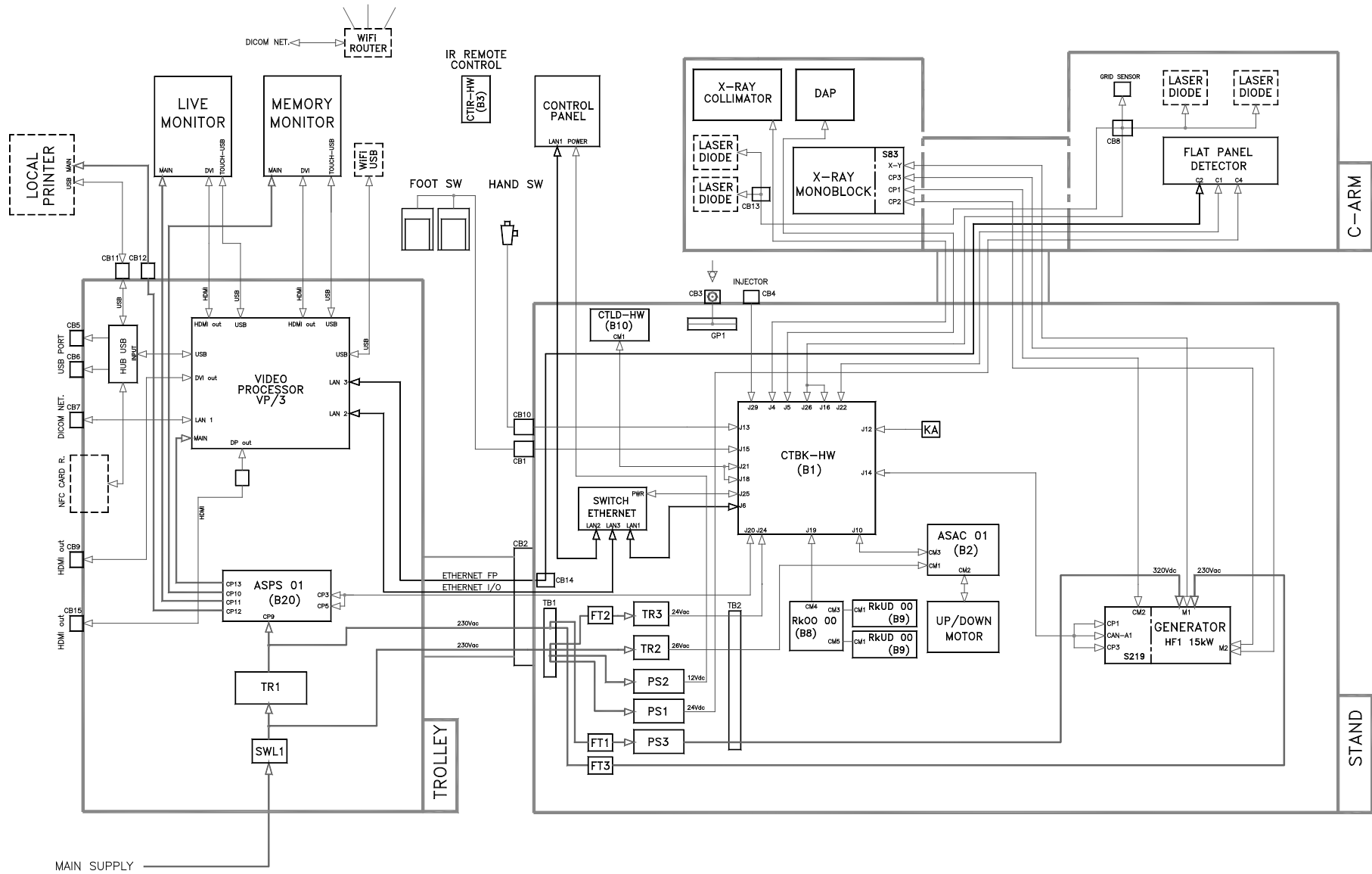
Mains power supply is reported on the serial number plate, on the monitor unit.



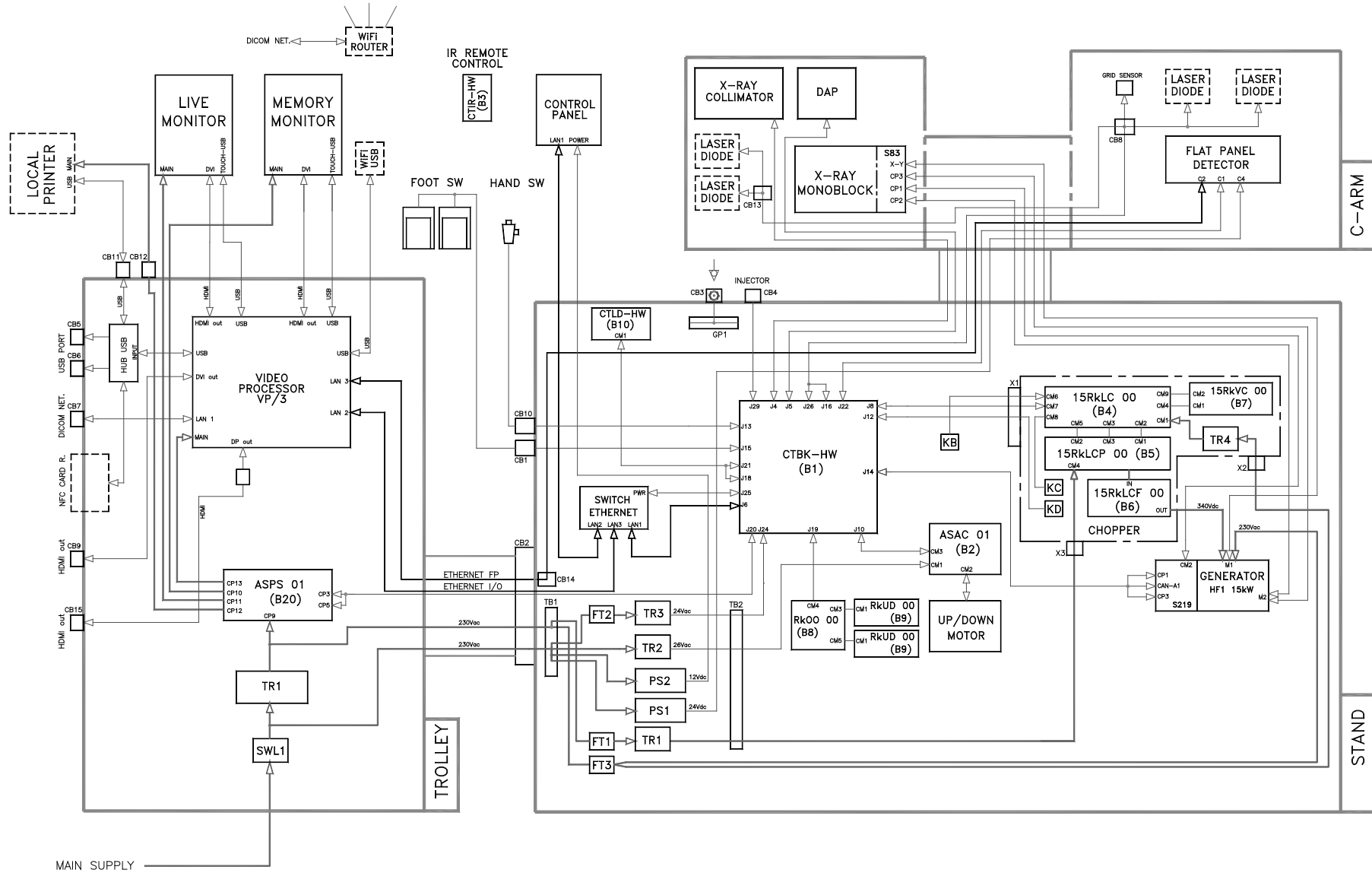
The EM equipment must be connected to a properly-earthed mains, with a correct supply tension.

Maximum absorbed current is approximately 16 A in fluoroscopy mode and 26 A in radiography mode.

• Power Version : 5 kW



• Power Version : 20 kW



4 VIDEO PROCESSOR SETUP

4.1 INTRODUCTION

The Memory Monitor (the touch screen monitor on the right) is used for the general setup of the EM equipment (using the specific setup pages).

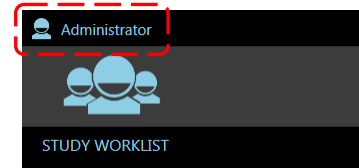
The setup procedure is described below, with details of the parameters that can be adjusted to suit the specific installation needs.

Setup	Settings	User	Ref. (paragraph)
General Settings	- Station Description - Technical Configuration - Autosshutter Configuration - Snapshot specific configuration - Detector Sensitivity - Image Option and Unit of measure	Administrator Advanced	Para. 4.2
Unit configuration	- CTBK connection parameters - CI connection parameters - Unit Configuration - Rx sound control	Administrator Advanced	Para. 4.3
Exam Setup	- Exam acquisition parameters and image processing	Administrator Advanced	Para. 4.4
Dicom Setup	- Dicom Setting - Dicom Services (Store, Worklist, Media, Storage commitment, MPPS, Dose SR, Query / Retrieve) - Dicom Devices - Spooler - Print Config	Administrator Advanced	Para. 4.5
DRC Group Setup	Composition and organisation of the DRC Group	Administrator Advanced	Para. 4.6
DRC Name Setup	Change the process names to make them clearer for the operator.	Administrator Advanced	Para. 4.7
User Account Setup	Composition and organisation of Users	Administrator Advanced	Para. 4.8
Fixed String Setup	Composition and organisation of the fixed strings	Administrator Advanced	Para. 4.9
Security setup	Security features	Administrator	Para. 4.11
Detector Calibration	Calibration of the detector.	Administrator Advanced	Part 4 Chapter 3
Collimator Calibration	Calibration of the X-ray collimator.	Administrator	Part 4 Para. 2.2
Generator Calibration	Calibration of the X-ray generator.	Administrator	Part 4 Para. 2.1
Software Version	List of the software versions used.	Administrator Advanced	Para. 5.6

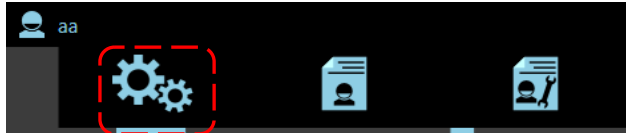
Note:

- The setup menu highlighted in blue are available for the Advanced user, too (some of the parameters should not be available for this user). In order to grant the full access to Video Processor setup functions, it is required to enter as ADMINISTRATOR in the Login frame of the **Systema DRF** application.
- See paragraph 4.1.1. below for details on the Log-in procedure.

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.

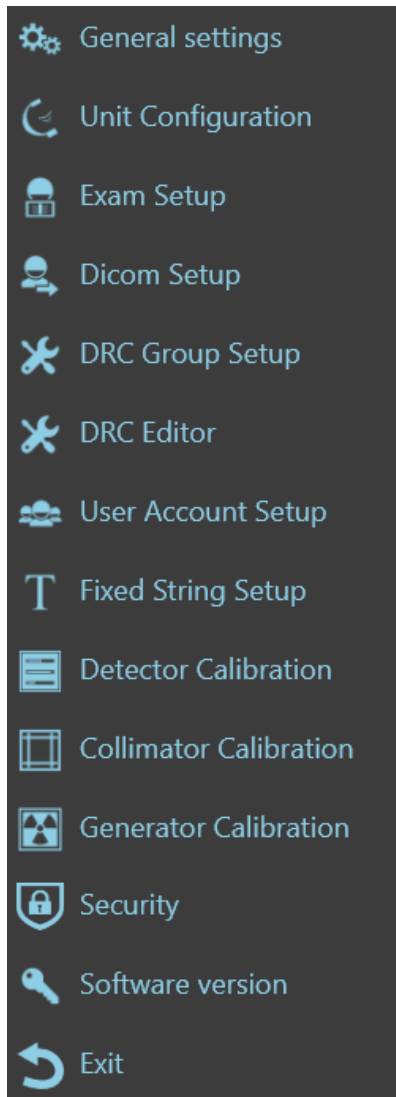


Select the **Setup** option to access the SETUP menu:

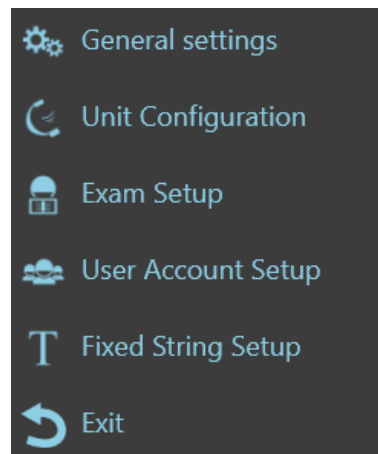


List of SETUP menus:

- accessed after logging in as ADMINISTRATOR:



- accessed after logging in as ADVANCED:



4.1.1 LOG-IN

- When the LOG-IN page appears, log in as:
 - **Administrator**, by entering the technical password: *********.
(**this password could be provided by the manufacturer, upon request**).
 - **Advanced**, by entering the default technical password: **12345678**.

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



4.2 GENERAL SETTINGS

General settings:

General settings
137,162
MAR 22 OTT 11:28

STATION DESCRIPTION

INSTITUTION NAME	HOSPITAL	MANUFACTURER	ATS Srl
STATION NAME	C ARM FP	MODEL	ARCO FP

TECHNICAL CONFIGURATION

LANGUAGE	English	KEYBOARD AND CULTURE INFO	it-IT: Italian - Italy
DEMO MODE	<input type="checkbox"/>	DEBUG MODE	<input checked="" type="checkbox"/>

SNAPSHOT SPECIFIC CONFIGURATION

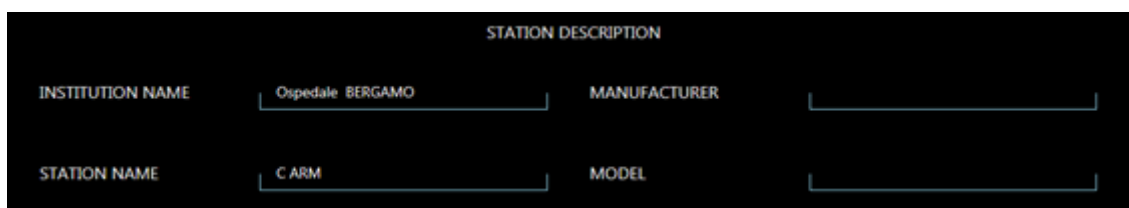
MIN DOSE ACCEPTANCE	50	%	MAX DOSE ACCEPTANCE	200	%
DOSE ROI REDUCTION FACTOR	25	%			

DETECTOR SENSITIVITY

FLURO DETECTOR SENSITIVITY lsb/nGy	10.00	SNAPSHOT DETECTOR SENSITIVITY lsb/nGy	1.05
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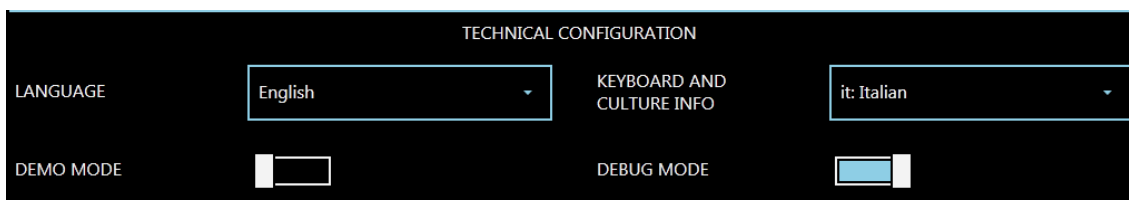
ENABLE DOWNSIZE ON ROTATION	<input type="checkbox"/>	DOSE DAP UNIT	μGy·m ²
TRANSPARENT COLLIMATOR PREVIEW	<input checked="" type="checkbox"/>	TEMPERATURE UNIT	°C
ENABLE RAW SAVE	<input checked="" type="checkbox"/>	ENABLE DOSE REPORT	<input checked="" type="checkbox"/>

➤ **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	Enter 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. <i>For a full list of available languages, please contact the manufacturer.</i>	The technical installation and maintenance menus are only provided in 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.
DEMO MODE	Used to enable the DEMO mode.	Do not select.	This option is only used for demonstrations of the EM equipment during conferences.
DEBUG MODE	Used to create LOG and DUMP folders.	Do not select.	Only used by the Technical Service.

➤ **SNAPSHOT SPECIFIC CONFIGURATION:**

SNAPSHOT SPECIFIC CONFIGURATION

MIN DOSE ACCEPTANCE	50	%	MAX DOSE ACCEPTANCE	200	%
DOSE ROI REDUCTION FACTOR	25	%			

This lets you set the parameters for the X-ray dose exposure index in radiology mode (EXPOSURE INDEX).

The X-ray dose depends on the image levels and the sensitivity of the detector.

Option	Meaning	Settings	Notes
MIN DOSE ACCEPTANCE %	X-ray dose percentage compared to the value expected for the exam. The image will be "under-exposed" if the actual value is below this.	Typical value 25%	The EI and DI values are shown in blue on the monitor if the detected X-ray dose is below the value set here.
MAX DOSE ACCEPTANCE %	X-ray dose percentage compared to the value expected for the exam. The image will be "over-exposed" if the actual value is above this.	Typical value 300%	The EI and DI values are shown in red on the monitor if the detected X-ray dose is above the value set here.
DOSE ROI REDUCTION FACTOR %	This setting determines the size of the X-ray dose reading area, starting from the image processing ROI.	Typical value 30%	The image levels are read within the image processing ROI. If, for example, you set this at 30%, the calculation will be based on an area 30% smaller than the processing ROI.

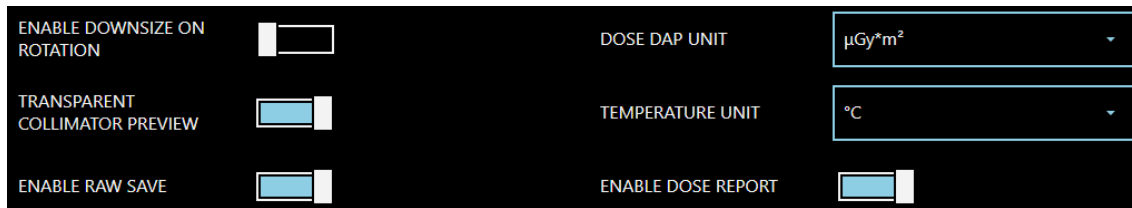
➤ **DETECTOR SENSITIVITY:**

DETECTOR SENSITIVITY

FLUORO DETECTOR SENSITIVITY lsb/nGy	10.00	SNAPSHOT DETECTOR SENSITIVITY lsb/nGy	1.00
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Option	Meaning	Settings	Notes
FLUORO	Sensitivity of the detector in fluoroscopy acquisition modes.	10 lsb/nGy (typical)	These values are set in the factory during the calibration of the EM equipment.
SNAPSHOT	Sensitivity of the detector in digital radiography mode.	1 lsb/nGy (typical)	

➤ **IMAGE OPTION AND UNIT OF MEASURE:**



Option	Meaning	Settings	Notes
ENABLE DOWNSIZE ON ROTATION	<p>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).</p> <p>ENABLED: when rotated, the image dimensions are reduced to allow you to see the full image.</p>	Enable or disable this function to suit the required mode.	
TRANSPARENT COLLIMATOR PREVIEW	<p>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.</p> <p>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.</p>	Enable or disable this function to suit the required mode.	
DOSE DAP UNIT	Set dose unit.	Choose $\mu\text{Gy}\cdot\text{m}^2$ or $\text{mGy}\cdot\text{cm}^2$.	
TEMPERATURE UNIT	Set the unit of measure for the temperature of the x-ray monoblock.	Choose $^{\circ}\text{C}$ or $^{\circ}\text{F}$.	
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 given to the patient.	Enable or disable this function to suit the required mode.	See Section 5.3.7.2 of the User Manual.

4.3 UNIT CONFIGURATION

Unit Configuration is composed by the following tabs:

- Unit Configuration (see Paragraph 4.3.1),
- Sound Control (see Paragraph 4.3.2).

The screenshot displays the 'UNIT CONFIGURATION' interface, which is divided into three main sections:

- CTBK CONNECTION PARAMETERS:** Includes 'CTBK IP ADDRESS' (192.168.3.2) and 'CTBK IP PORT' (35000).
- CI CONNECTION PARAMETERS:** Includes 'DETECTOR IP ADDRESS' (192.168.0.2), 'DETECTOR IP PORT COMMUNICATION' (30000), and 'DETECTOR IP PORT IMAGING' (50000).
- UNIT CONFIGURATION:** Includes 'DETECTOR MODEL' (21x21), 'POWER VERSION' (20 kW), 'SYSTEM DATE (24H Format)' (11/12/2020 09:25:27), 'MAINS' (120 V), 'MONITOR CORRECTION FACTOR' (20), 'INJECTOR' (slider), 'LASER' (slider), 'Laser Time (s)' (60), 'ENABLE ACTIVE COOLING' (checkbox), and 'ACTIVE COOLING MODALITY (ON EXAM CLOSED)' (Turbo).

4.3.1 UNIT CONFIGURATION

➤ CTBK CONNECTION PARAMETERS

This close-up shows the 'CTBK CONNECTION PARAMETERS' section with the following values:

- CTBK IP ADDRESS: 192.168.3.2
- CTBK IP PORT: 35000

Option	Meaning	Settings	Notes
CTBK IP ADDRESS	IP Address for board CTBK.	Set: 192.168.3.2	
CTBK IP PORT	IP Port used for communication with board CTBK.	Set: 35000	

➤ **CI CONNECTION PARAMETERS**

CI CONNECTION PARAMETERS

DETECTOR IP ADDRESS DETECTOR IP PORT COMMUNICATION

DETECTOR IP PORT IMAGING

Option	Meaning	Settings	Notes
DETECTOR IP ADDRESS	IP Address for the flat panel detector.	Set: 192.168.2.2	
DETECTOR IP PORT COMMUNICATION	IP Port used for communication with the flat panel detector.	Set: 30000	
DETECTOR IP PORT IMAGING	IP Port used to receive images from the flat panel detector.	Set: 50000	

➤ **EQUIPMENT CONFIGURATION PARAMETERS**

UNIT CONFIGURATION

DETECTOR MODEL

POWER VERSION SYSTEM DATE (24H Format)

MAINS

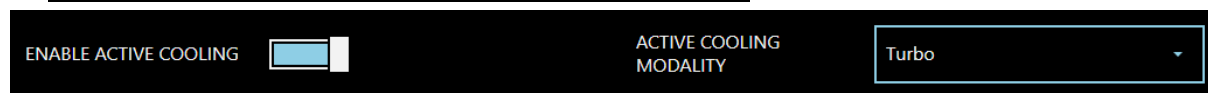
MONITOR CORRECTION FACTOR INJECTOR

LASER Laser Time (s)

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 <i>Advanced</i> and <i>Administrator</i> users have the possibility to restore date and time settings.	Set current date and time.	24 HOURS format
MONITOR CORRECTION FACTOR	The grey levels visible on the monitors range from 0 to 255 (8 bits). This function lets you set the minimum grey value you can see on the monitors.	Range value: 0 - 50 (typ. 10)	
INJECTOR	Contrast agent injector	Enable if an external injector will be plugged to the EM equipment	

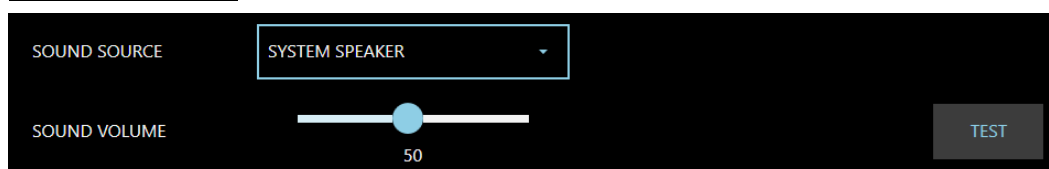
LASER	Laser modules to help centring patient during exams.	Enable / disable.	
LASER TIME	Set the default time after which laser modules automatically turn off.	Set the required time, in seconds.	

➤ **ACTIVE COOLING CONFIGURATION PARAMETERS (OPTIONAL)**



Option	Meaning	Settings	Notes
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 (ON EXAM CLOSED)	Select the operating mode when you are outside the Operative Framework , for example in the Study List .	<ul style="list-style-type: none"> • 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. • Turbo: When the temperature of the monoblock overcomes 35° C (95° F), the cooling fan operates at its maximum speed. 	It is possible to set a different mode for each of the anatomical techniques, when you are inside the Operating Framework : see <i>Paragraph 4.4.1 below</i> .

4.3.2 SOUND CONTROL



Option	Meaning	Settings	Notes
SOUND SOURCE	Source of the sound that warns that the X-ray emission is in progress.	Select between: - CTBK - SYSTEM SPEAKER	
SOUND VOLUME	Option active only if SYSTEM SPEAKER is selected as the sound source. Allows the sound volume to be adjusted.	0 ÷ 100	Press the TEST button to check the set volume.

4.4 EXAM SETUP

The EM equipment can be configured with as many exam types as requested by the user.

Once the operator selects an exam, the parameters set for that type of exam are automatically loaded.

The exams are pre-set in the factory to provide a typical equipment configuration.

When installing the equipment in a hospital, the installer and the user must check these settings and, if necessary, adjust them to suit the specific applications foreseen.

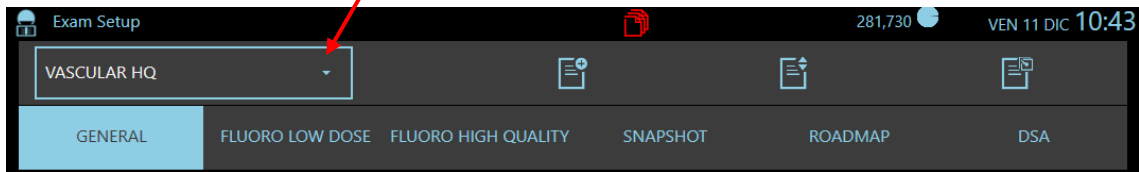
The following page appears when you open the EXAM SETUP menu:



4.4.1 PROGRAMMABLE PARAMETERS

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

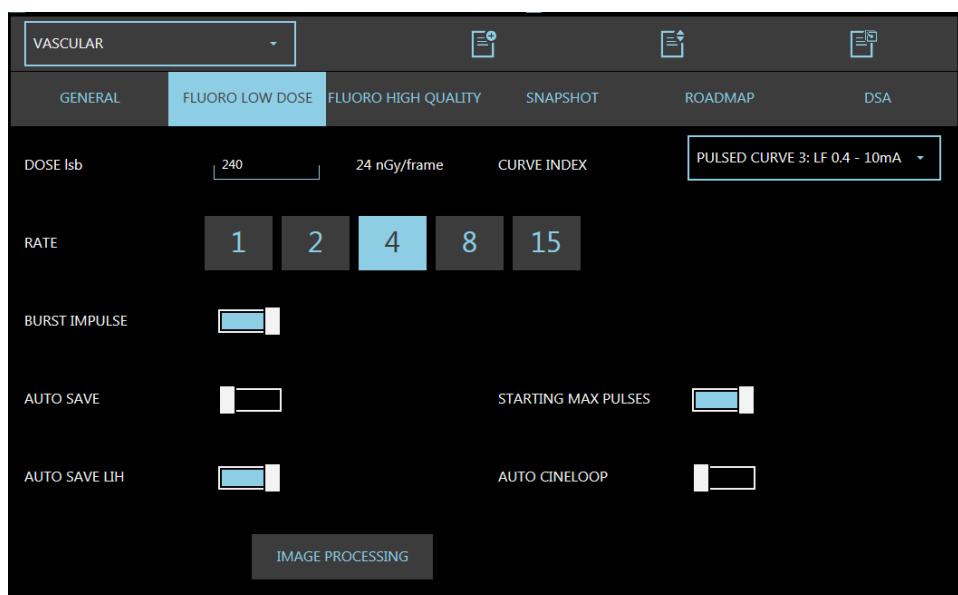
GENERAL:



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	Orientation set when you open an exam.
ZOOM	FPD Pixium3030Asi Detector acquisition field	30cm x 30cm 21cm x 21cm 16cm x 16cm	Field set when you open an exam.
ZOOM	FPD Pixium2121Asi Detector acquisition field	21cm x 21cm 16cm x 16cm 12cm x 12cm	Field set when you open an exam.
GRID	Anti-scatter grid	Yes / No	The grid must be manually inserted/removed. A possible inconsistency between the Grid condition set in Exam Setup (YES or NO) and its current condition in the examination, will be noticed to the operator with the relevant icon.
RX FILTER	Additional X-ray beam filter. Useful if you need to reduce the dose given to the patient.	Filter: 1mm Al + 0.1mm Cu Filter: 1mm Al + 0.2mm Cu	The filter is inserted automatically by the equipment. It cannot be changed during a study.
kV INITIAL	kV value automatically set on opening the exam	40 - 120kV	The kV value during an exam is adjusted automatically (or manually by the operator) to suit the anatomic region.
kV MAX	Max permissible kV value that can be set (automatically or manually) during the exam	60 - 120kV	
ANATOMIC REGION	Region of the body being scanned	Select any of those in the list that appears.	This setting is used by the DICOM STORE and DICOM RDSR services.
MAX FPS	Select the Max Frame Per Second number required for the exam you are setting.	15 or 25. If Max FPS=15 , the acquisition rate available are 1, 2, 4, 8, 15. If Max FPS=25 , the acquisition rate available are 1, 3, 6, 12, 25.	In DSA Fluoroscopy, when the high mA curve (curve 5) is associated to an exam, the highest frame rate available will be 8 (if Max FPS=15) or 12 (if Max FPS=25).
MULTI IMAGES	Definition of the DICOM image type used for runs	RF or XA	These parameters define the type of DICOM image that will be used by default, unless specified for each single study.
SINGLE IMAGE	Definition of the DICOM image type used for a single image	CR or DX	
ENABLE DSA OPTIONS	To enable DSA functions.	Yes / No	
LEFT PEDAL	Low Dose fluoroscopy mode is associated to left pedal as a default.		The same acquisition modality is associated to handswitch side button.

DEFAULT RIGHT PEDAL	It allows to associate one of the other acquisition modalities to right pedal.	HQ Fluoroscopy or RAD . If enabled, it is possible to associate even Roadmap or DSA Fluoroscopy modes.	The same acquisition modality is associated to handswitch double-click button. Modification of this setting is possible temporarily but will be limited to the current exam, directly on the Control Panel (see Paragraph 2.3.1, Part 2 of User Manual).
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 Paragraph 1.3.1.1, Part 1 of the User 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 Paragraph 3.1.2, Part 2 of the User 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 Paragraph 2.3.11, Part 2 of the User 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 Paragraph 2.2.4.2, Part 2 of the User 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 .	<ul style="list-style-type: none"> • 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 4.2.1.1 of the User Manual).

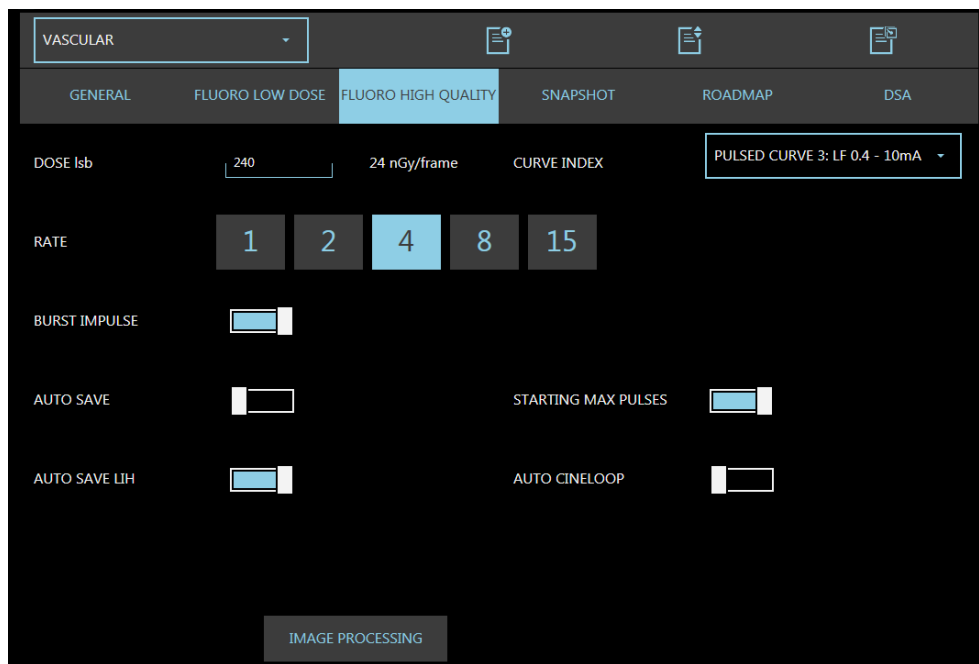
LOW DOSE FLUOROSCOPY:



LOW DOSE FLUOROSCOPY parameters

Option	Meaning	Settings	Notes
DOSE lsb	Reference dose value expressed as image levels (lsb)	50 - 1000 (typ. 120)	
CURVE INDEX	Select mA curve for this acquisition mode.	Pulsed curve 1: SF 0.4 - 10 mA Pulsed curve 2: SF 1.6 - 40 mA Pulsed curve 3: LF 0.4 - 10 mA Pulsed curve 4: LF 1.6 - 40 mA	
RATE	Acquisition rate set when the exam is opened. Rate values available depend on MAX FPS value set in GENERAL .	Select between: 1 - 2 - 4 - 8 - 15 or 1 - 3 - 6 - 12 - 25	The operator can change the acquisition rate during the exam.
BURST IMPULSE	The function will increase the acquisition rate to Max FPS during the Automatic Dose Control regulation, in order to make the correction faster. When the optimal dose value is reached, the rate will decrease to the set value.	Yes / No	
STARTING MAX PULSES	The equipment starts every acquisition at the to Max FPS set for this exam (15 or 25 fps), for 0.6 seconds, regardless of the set rate.	Yes / No	This is a useful function if you have set both a high recursive filter value (i.e.: k = 6-12) and a low acquisition rate, as it lets you obtain immediately an image without noise.
AUTO SAVE	Automatic saving to hard disk of all the image acquired.	Normally enabled.	As an alternative to AUTO SAVE LIH
AUTO SAVE LIH	Automatic saving to hard disk of the last image hold (LIH).	Normally NOT 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 the images in the run have been saved to hard disk
IMAGE PROCESSING	Opening of the image processing parameters setup menu - continuous fluoroscopy	See paragraph 4.4.2	

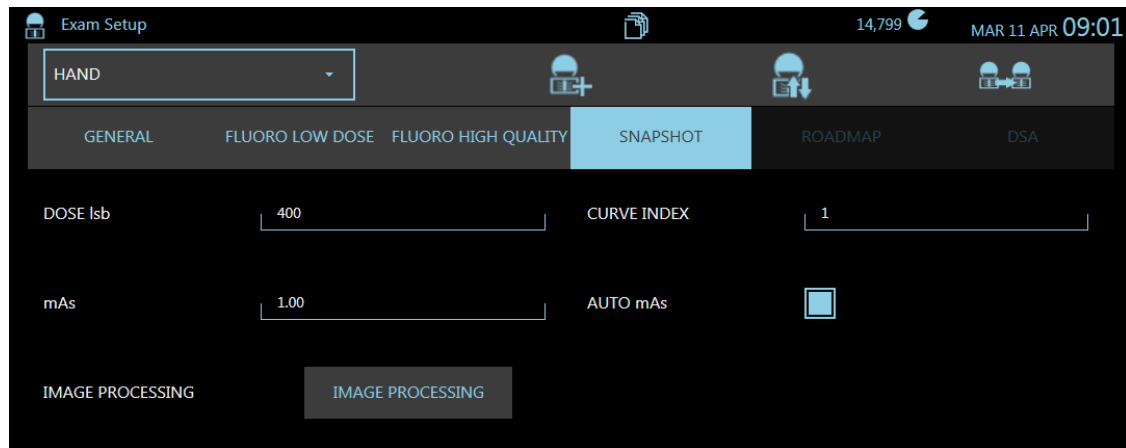
HIGH QUALITY FLUOROSCOPY:



HIGH QUALITY FLUOROSCOPY parameters:

Option	Meaning	Settings	Notes
DOSE lsb	Reference dose value for high quality fluoroscopy, expressed as image levels (lsb)	50 ÷ 2000 (typ. 240)	
CURVE INDEX	Select mA curve for low dose fluoroscopy acquisition mode.	Pulsed curve 1: SF 0.4 - 10 mA Pulsed curve 2: SF 1.6 - 40 mA Pulsed curve 3: LF 0.4 - 10 mA Pulsed curve 4: LF 1.6 - 40 mA	In Fluoroscopy, when the curve 5 is associated to an exam, the highest frame rate available will be the second to last.
RATE	Acquisition rate set when the exam is opened. Rate values available depend on MAX FPS value set in GENERAL .	Select between: 1 - 2 - 4 - 8 - 15 or 1 - 3 - 6 - 12 - 25	The operator can change the acquisition rate during the exam.
BURST IMPULSE	The function will increase the acquisition rate to Max FPS during the Automatic Dose Control regulation, in order to make the correction faster. When the optimal dose value is reached, the rate will decrease to the set value.	Yes / No	
STARTING MAX PULSES	The equipment starts every acquisition at the to Max FPS set for this exam (15 or 25 fps), for 0.6 seconds, regardless of the set rate.	Yes / No	This is a useful function if you have set both a high recursive filter value (i.e.: k = 6-12) and a low acquisition rate, as it lets you obtain immediately an image without noise.
AUTO SAVE	Automatic saving to hard disk of all the image acquired.	Normally enabled.	As an alternative to AUTO SAVE LIH
AUTO SAVE LIH	Automatic saving to hard disk of the last image hold (LIH).	Normally NOT enabled.	As an alternative to AUTO SAVE
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
IMAGE PROCESSING	Opening of the image processing parameters setup menu – continuous fluoroscopy	See paragraph 4.4.2	

SNAPSHOT (DIGITAL RADIOGRAPHY):



DIGITAL RADIOGRAPHY parameters:

Option	Meaning	Settings	Notes
DOSE lsb	Reference dose value expressed as image levels (lsb)	100 - 2500 (typically 1000)	
CURVE INDEX	Select mA curve to use in radiography mode.	Mains power supply 230 VAC: Rad Curve 1: SF 100 kV – 28 mA Rad Curve 2: SF 100 kV – 40 mA Rad Curve 3: LF 100 kV – 28 mA Rad Curve 4: LF 100 kV – 40 mA Rad Curve 5: LF 100 kV – 200 mA Mains power supply 120 VAC: Rad Curve 1: SF 100 kV – 14 mA Rad Curve 3: LF 100 kV – 14 mA Rad Curve 5: LF 100 kV – 200 mA	Rad Curve 5 is only available on 20 kW version.
mAs	Establishes the default mAs value when the Auto mAs function is not selected	0,5 ÷ 50 (with mains power supply 230 VAC) 0,5 ÷ 25 (with mains power supply 120 VAC)	You can alter the value during an exam.
AUTO mAs	If enabled, the mAs are automatically set to suit the set working dose	Yes / No	You can alter the value during an exam.
IMAGE PROCESSING	Opening of the image processing parameters setup menu – radiology	See paragraph 4.4.2	

4.4.1.1 DSA PROGRAMMABLE PARAMETERS

The DSA function offers two possible image acquisition modes:

- RoadMapping
- DSA fluoroscopy.

RoadMapping mode produces subtracted images that let you observe and adjust the position of a catheter in the blood vessel during a fluoroscopic exam.

DSA fluoroscopy is a technique that lets you see a blood vessel distinctly within bone structures and soft tissues. Once the contrast agent has been injected, the images will be shown subtracted from a **mask image** (acquired before injecting the contrast agent).

These functions can be enabled for each of the six exam types that can be set in Exam Setup; check the relevant option in the **GENERAL** window to enable DSA functions (see the beginning of paragraph 4.4.1 in this chapter).

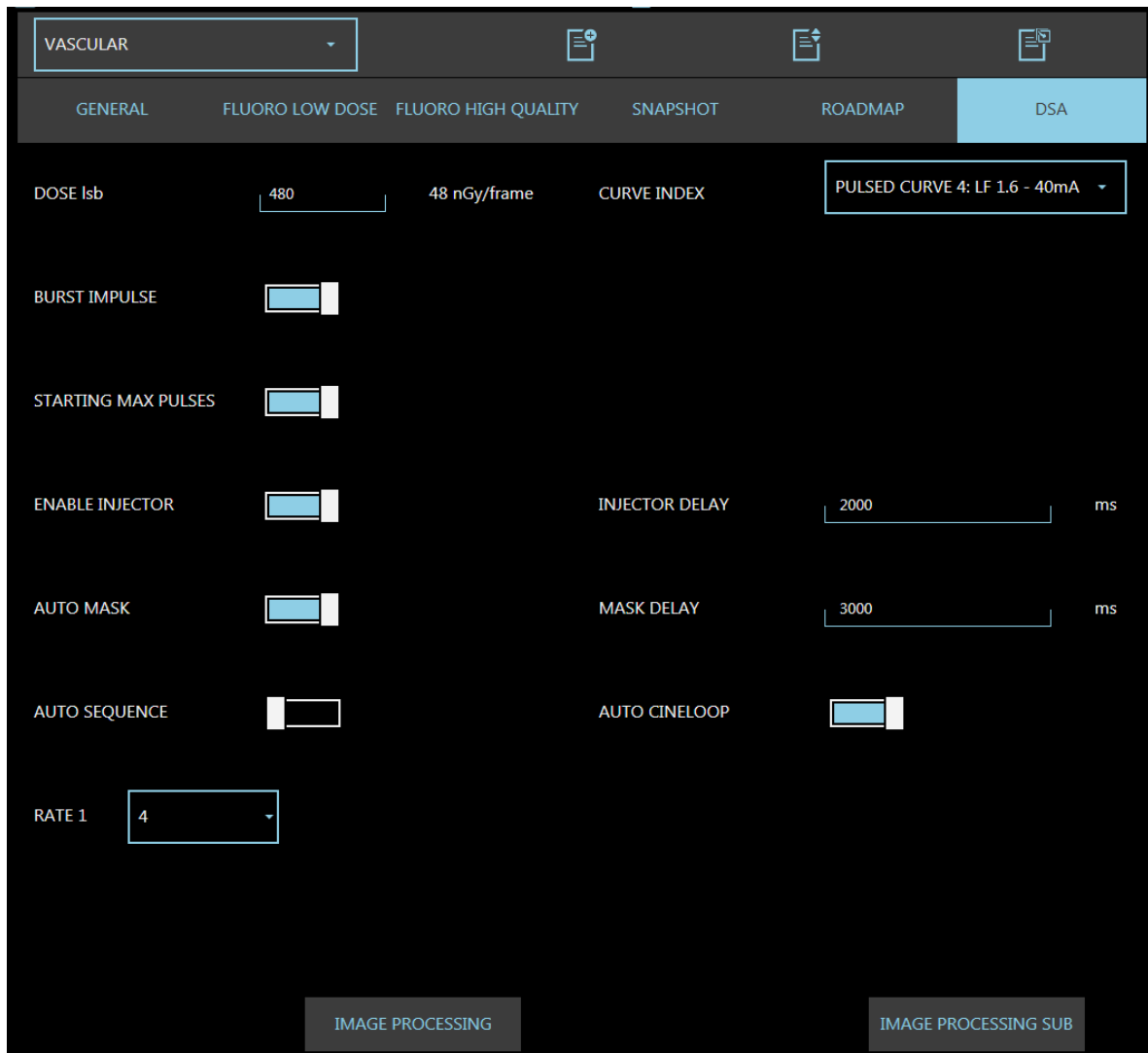
To set the parameters for each function:

ROADMAP:

The screenshot displays the 'ROADMAP' configuration window. At the top, a dropdown menu is set to 'VASCULAR'. Below it, a series of tabs includes 'GENERAL', 'FLUORO LOW DOSE', 'FLUORO HIGH QUALITY', 'SNAPSHOT', 'ROADMAP' (which is highlighted), and 'DSA'. The main area contains several controls: 'DOSE Isb' is set to 480, with a unit of 48 nGy/frame; 'CURVE INDEX' is set to 'PULSED CURVE 3: LF 0.4 - 10mA'; 'RATE HCF' has buttons for 1, 2, 4, 8, and 15, with 4 selected; 'BURST IMPULSE' is a slider; 'MAX OPACIFICATION DELAY' is set to 2000 ms; 'STARTING MAX PULSES' is another slider; 'AUTO SAVE ROADMAP' and 'AUTO SAVE LIH ROADMAP' are sliders. At the bottom, there are two buttons: 'IMAGE PROCESSING PEAK' and 'IMAGE PROCESSING ROADMAP'.

ROADMAP Parameters

Option	Meaning	Settings	Notes
DOSE lsb	Reference dose value expressed as image levels (lsb)	50 - 1000 (typ.480)	
CURVE INDEX	Select kV-mA correlation curve to use with this acquisition mode.	Pulsed curve 1: SF 0.4 - 10 mA Pulsed curve 2: SF 1.6 - 40 mA Pulsed curve 3: LF 0.4 - 10 mA Pulsed curve 4: LF 1.6 - 40 mA	When the curve 5 is associated to an exam, the highest frame rate available will be the second to last.
RATE	Acquisition rate set when the exam is opened. Rate values available depend on MAX FPS value set in GENERAL .	Select between: 1 - 2 - 4 - 8 - 15 or 1 - 3 - 6 - 12 - 25	The operator can change the acquisition rate during the exam.
BURST IMPULSE	Not available in RoadMap mode	Keep DISABLED.	
STARTING MAX PULSES	The equipment starts every acquisition at the to Max FPS set for this exam (15 or 25 fps), for 0.6 seconds, regardless of the set rate.	Typically enabled.	
MAX OPACIFICATION DELAY	Delay time between x-ray exposure start and Max Opacification image acquisition (stated in msec).	Typ: 2000	Time the system requires to automatically adjust the kVs value.
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
IMAGE PROCESSING PEAK	To open the post processing parameters setting menu for Max Opacification images.	See para. 4.4.2	
IMAGE PROCESSING ROADMAP	To open the post processing parameters setting menu for ROADMAP images.	See para. 4.4.2	

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
DOSE Isb	Reference dose value for DSA fluoroscopy, expressed as image levels (Isb)	50 - 4000 (typ. 480)	
CURVE INDEX	Select mA curve to use with this acquisition mode.	Pulsed curve 1: SF 0.4 - 10 mA Pulsed curve 2: SF 1.6 - 40 mA Pulsed curve 3: LF 0.4 - 10 mA Pulsed curve 4: LF 1.6 - 40 mA Pulsed curve 5: LF 4 - 100 mA	In DSA Fluoroscopy, when the high mA curve (curve 5) is associated to an exam, the highest frame rate available will be: 8 (if Max FPS=15) or 12 (if Max FPS=25).
BURST IMPULSE	The function will increase the acquisition rate to Max FPS during the Automatic Dose Control regulation, in order to make the correction faster. When the optimal dose value is reached, the rate will decrease to the set value.	Yes / No	
STARTING MAX PULSES	The equipment starts every acquisition at the to Max FPS set for this exam (15 or 25 fps), for 0.6 seconds, regardless of the set rate.	Yes / No	This is a useful function if you have set both a high recursive filter value (i.e.: k = 6-12) and a low acquisition rate, as it lets you obtain immediately an image without noise.
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	RATE 1 phase 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
IMAGE PROCESSING	Opening of the DSA image processing parameters setup menu (not for subtracted images).	See paragraph 4.4.2	
IMAGE PROCESSING SUB	Opening of the DSA image processing parameters setup menu.	See paragraph 4.4.2	

4.4.2 IMAGE PROCESSING

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

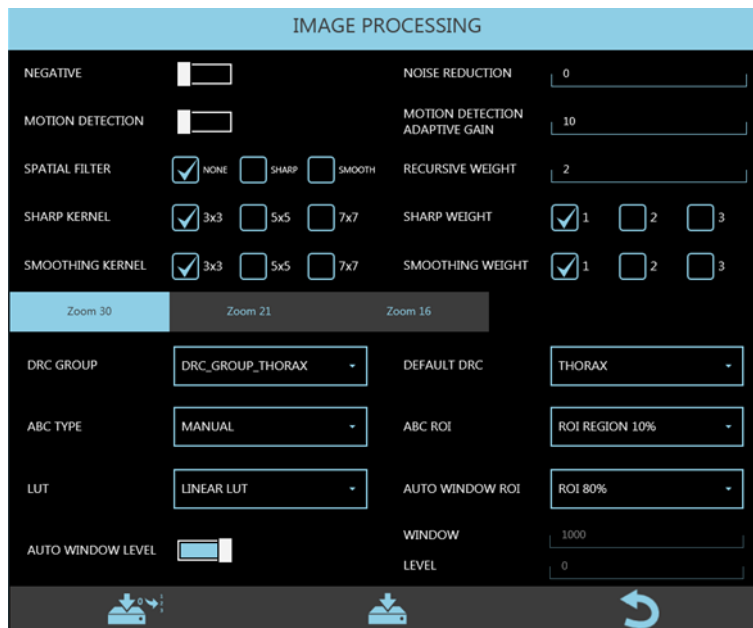


IMAGE PROCESSING parameters:

Option	Meaning	Settings	Notes
NEGATIVE	“Negative” display of the gray scale	Yes / No	Normally enabled for images acquired in digital radiography mode.
NOISE REDUCTION	Set the weight of the Noise Reduction spatial filter.	(0 ÷ 10) 0 = function disabled, 10 = max noise reduction.	
MOTION DETECTION	Component of the noise reduction algorithm for fluoroscopy images. This reduces the time component of the recursive filter (<i>recursive filter weight</i>) in proportion to the movement detected in the image. <u>This parameter is not available for SNAP SHOT IMAGE PROCESSING.</u>	Yes / No	Used to establish whether the “MOTION DETECTION” function is active or not on opening an exam. You can alter the setting during an exam.
MOTION DETECTION ADAPTIVE GAIN	Parameter used to set how sensitive the MOTION DETECTION function should be. <u>This parameter is not available for SNAP SHOT IMAGE PROCESSING.</u>	0 ÷ 1000 (typically, 10)	The higher the value of this parameter, the greater the sensitivity to movement.
SPATIAL FILTER	Type of default spatial filter applied on opening an exam. - Sharp for enhanced edges, - Smooth for softer edges.	You can choose between: - No filter - Sharp filter - Smooth filter (typically, No filter)	You can alter this default setting during an exam. Choose between: -no filter, or -sharp/smooth filter, as set in the next parameters
RECURSIVE WEIGHT	Weight of the noise reduction recursive filter used for fluoroscopy images. <u>This parameter is not available for SNAP SHOT IMAGE PROCESSING.</u>	1 – 16 (typically, 4)	

SHARP KERNEL	Kernel of the Edge Sharpening filter	You can choose between: 3 x 3 5 x 5 7 x 7	
SHARP WEIGHT	Weight of the Edge Sharpening filter	You can choose between: 1, 2, 3, 4, 5	
SMOOTHING KERNEL	Kernel of the Edge Smoothing filter	You can choose between: 3 x 3 5 x 5 7 x 7	
SMOOTHING WEIGHT	Weight of the Edge Smoothing filter	You can choose between: 1, 2, 3, 4, 5	

The following parameters are foreseen **for each detector field** (in each acquisition mode used for each exam):

Option	Meaning	Settings	Notes
DRC GROUP	The DRC GROUP containing the 3 DRC processes possible for each exam (Dynamic Range Compensation). See Paragraph 4.6 for information on choosing the groups.	Select the default DRC GROUP from among those shown.	You can alter this default setting during an exam by selecting any of the other DRC processes shown here.
DEFAULT DRC	DRC process in the selected group automatically set on opening an exam.	Select one of the 3 processes in the DRC GROUP shown.	
ABC Type	Select the preferred set for x-ray dose calculation .	Manual or Auto	AUTO: the system automatically adjusts the portion of image used to calculate, depending on the image in acquisition. MANUAL: the system uses the dimension of the ROI entered in ABC ROI field.
ABC ROI	Size of the side of the Region of Interest (ROI) used by the equipment to control the X-ray dose. The ROI is a square, centred on the image.	Select one of the options shown.	The size of the side of the ROI is expressed as a % of the size of the image on the monitor.
LUT	LUT used to display the image on the monitor	Select one of the LUT settings shown (typically, LINEAR)	
AUTO WINDOW ROI	To set the parameters for the Auto window function (this automatically calculates the W and L used to display the image on to suit the image histogram).	Select one of the settings shown.	ROI = Region of Interest, used for automatic calculation of the W and L. B and W = parameters used to calculate the W and L depending on the histogram.
AUTO WINDOW LEVEL	To enable the Auto window function. If not selected, the W and L will be fixed at the values set in the following parameters.	YES / NO (typically, YES)	
WINDOW	Setting for the W value when the Auto window is not active		
LEVEL	Setting of the L value when the Auto window is not active		

Note: the button aside allows to apply the parameters set to all detector zoom fields. This function is available only if detector nominal field is selected.



4.4.3 EXAMS MANAGEMENT

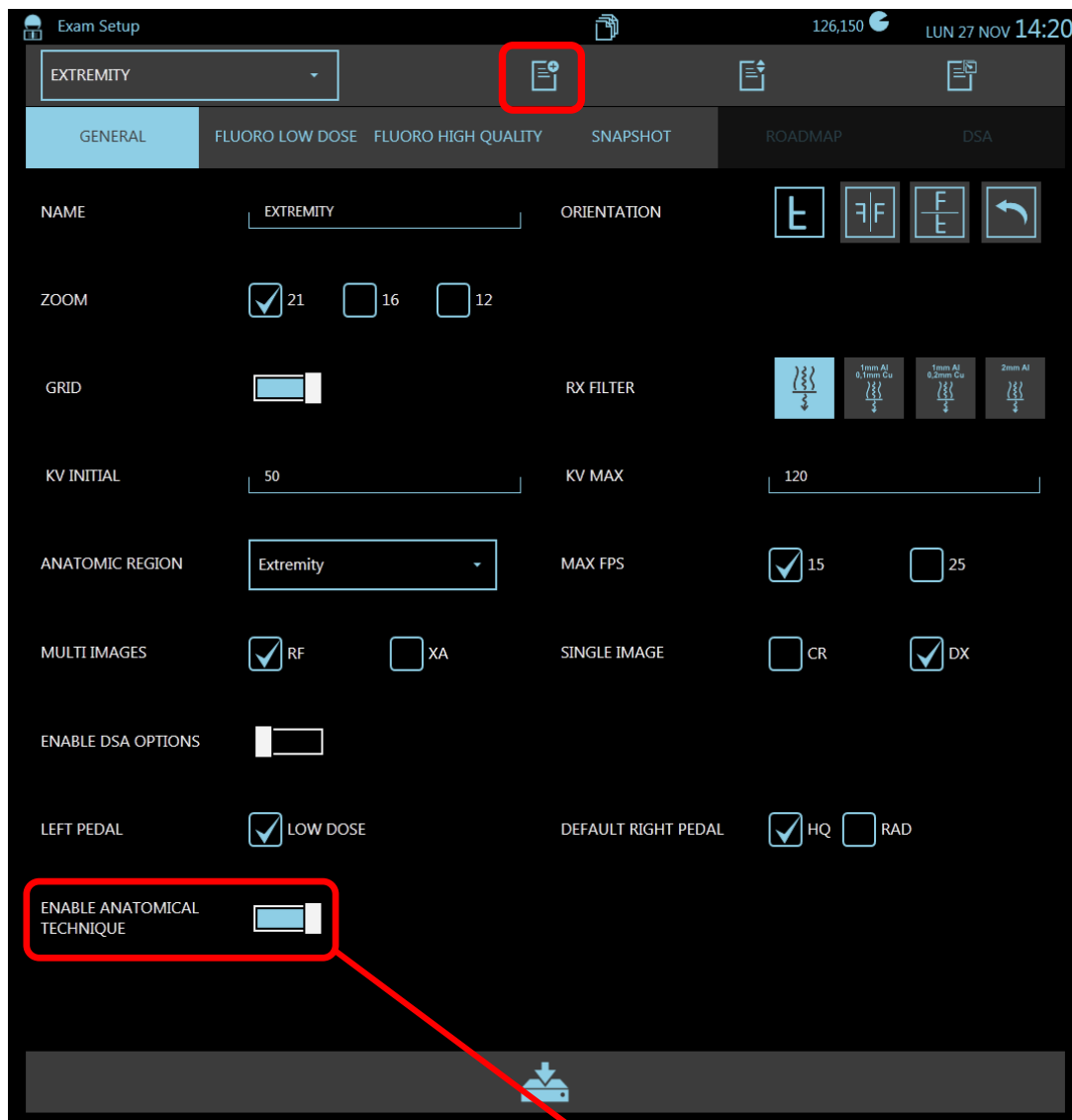
The EM equipment is provided with a set of already configured exams.

The Administrator could add new exams and modify or disable those configured by the manufacturer. While the Advanced user could change the order of the exam in the relevant list (see Paragraph 4.4.3.2 below).

4.4.3.1 CREATING A NEW EXAM

Pressing the relevant key, the new exam creation page is opened. You can set:

- An exam name,
- Exam parameters as explained in previous paragraphs 4.4.1 and 4.4.2.



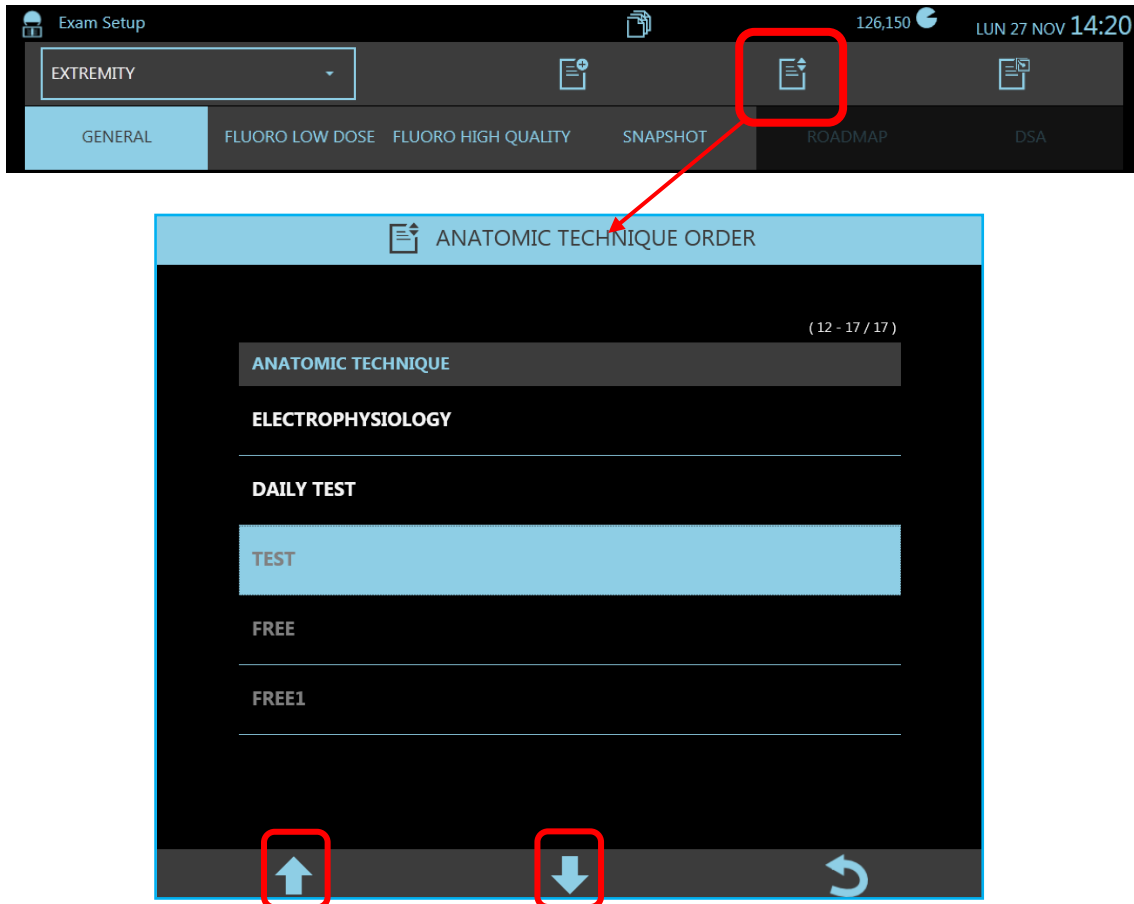
Once the exam has successfully been created, use the relevant key to enable and make it available on the Control Panel.

4.4.3.2 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.

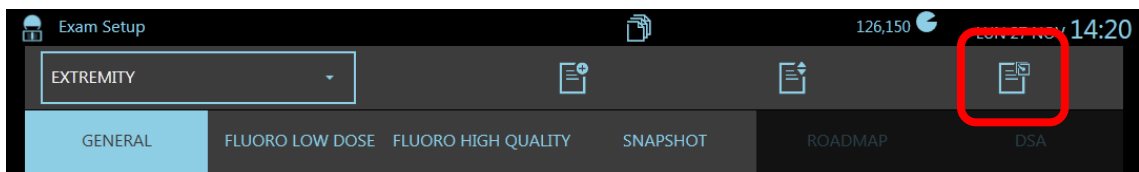
Use the **ANATOMIC TECHNIQUE ORDER** (here below) to change an exam position: just select it and, using relevant tips, move it to the required position.



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

4.4.3.3 DUPLICATE AN EXAM

This is a very useful function to create a new exam quite similar to another one already present in the list.



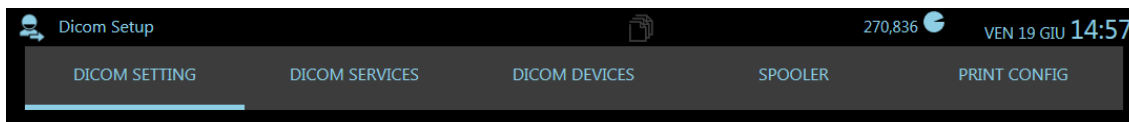
Create a new exam and press the relevant key: select from the drop-down list the exam required; this will automatically be copied. Change parameters, if needed, and save to add the exam to your list.

4.5 DICOM SETUP

Note: After connecting the EM equipment to the mains supply (see paragraph 3.2.3 above), configuration of the DICOM functions involves the following steps:

- setting of the network parameters (see Annex 5.4)
- definition of the remote DICOM devices and configuration of the various working modes (DICOM SETUP menu).

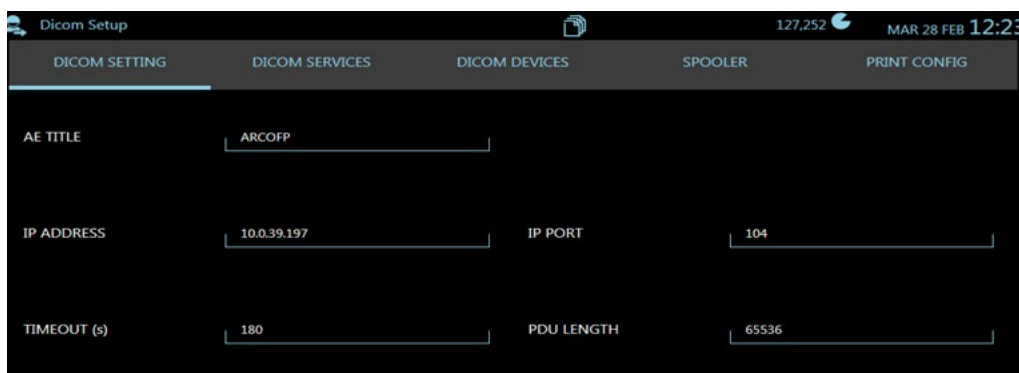
The DICOM setup menu has 5 sub-menus:



- **DICOM SETTING:** used for the general DICOM configuration of the system;
- **DICOM SERVICES:** used to set the individual services available in the system;
- **DICOM DEVICES:** used to manage the list of remote DICOM devices available;
- **SPOOLER:** used to manage the transmission of images over the network;
- **PRINT CONFIG:** used for the 4 DICOM print configurations.

4.5.1 DICOM SETTINGS

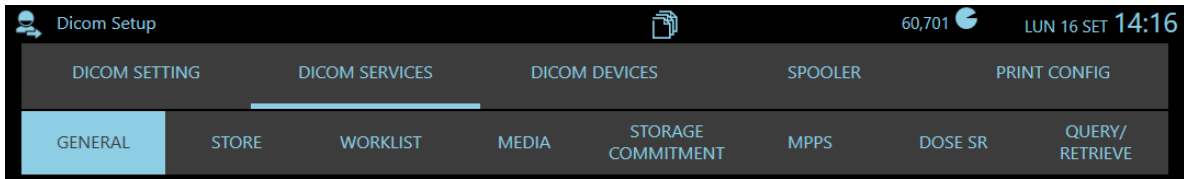
The **DICOM SETTING** menu is used to determine the equipment addressing. The hospital network administrator should be consulted when setting these parameters.



Option	Meaning	Settings	Notes
AE Title	Conventional name of device in the hospital's DICOM network.	Typically: C-ARM	
IP Address	TCP network address to be used for the DICOM services.	Defined by the network administrator. It must be equal to the network address used for the Windows operating system.	If a fixed address has not been set, the device automatically creates an address compatible with the network (based on IP address and Net Mask).
IP Port	TCP port number to be used for the DICOM services.	Typically: 104	
Timeout (s)	Time, in seconds, before the system states that transmission has failed (no answer from the DICOM server).		
PDU length		Typically: 65536	

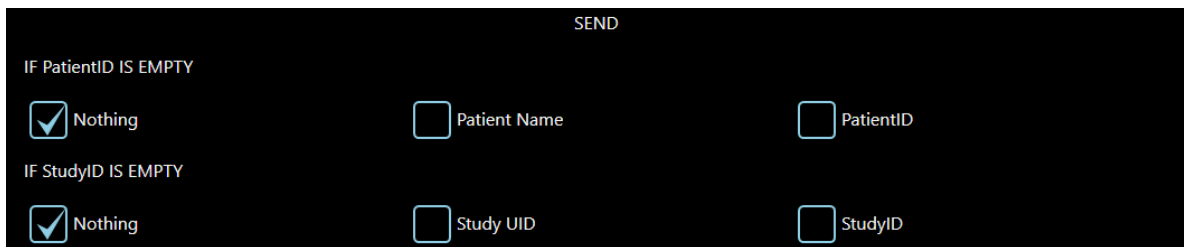
4.5.2 DICOM SERVICES

This menu lets you configure the various DICOM services in the system.



4.5.2.1 GENERAL

In the General page, you can set your preferred operating options if the PATIENT ID and STUDY ID fields are empty.



Send Options		Note
If Patient ID is empty	If the "Patient ID" is not available, the DICOM field can be filled according to one of these choices: - Nothing: The "Patient ID" field remains empty. - Patient name: the patient's name is entered. - Patient ID: the words "Patient ID" is entered.	Attention: this option is applied to all Dicom services except the Media service (see Paragraph 4.5.2.4 below).
If Study ID is empty	If the "Study ID" parameter is not available, the DICOM field can be filled according to one of these choices: - Nothing: The "Study ID" field remains empty. - Study UID: the parameter Study UID is inserted. - Study ID: the words "STUDY ID" is entered.	Attention: this option is applied to all Dicom services except the Media service (see Paragraph 4.5.2.4 below).

4.5.2.2 STORE

The **Store** tab lets you set the function options (these depend on the behaviour of the specific receiving device).



Image Options		Notes
Writings on Image	Image transferred together with its text (patient name, image n°, etc.) as shown on the monitor.	If not enabled, the image is sent without any writings. These will, in any case, be sent via the relevant DICOM fields.
Graphics on Image	Transfer of the image with overlay (text or measurements) added by the operator.	If not enabled, the image is sent without any graphic overlay.

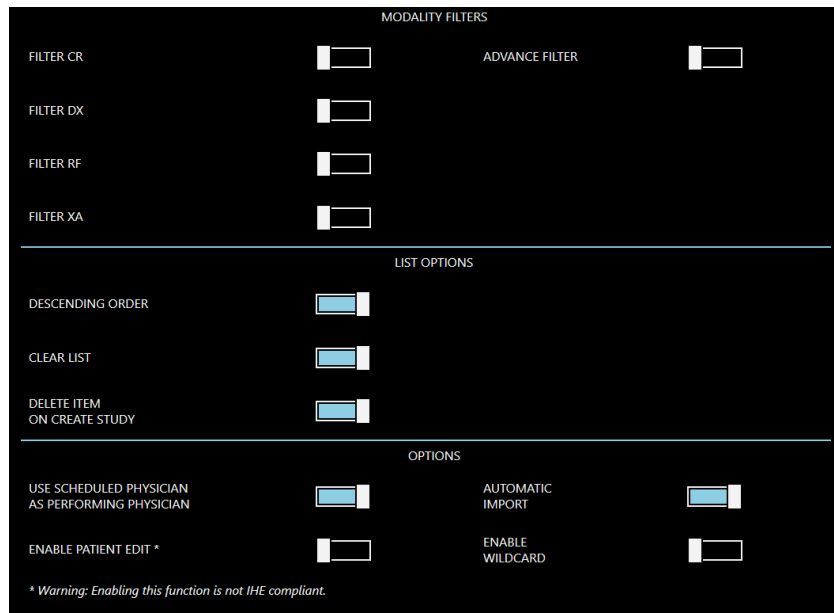
Modality Options		Notes
Presentation LUT	Enables the "complete" transfer of the image, followed by the presentation LUT parameters.	Only suitable for DX images.
W/L LUT expansion	Option only active when the Presentation LUT option is disabled. This lets you determine the level of the LUT expansion for the image sent to the server compared to that used for its presentation on the monitor. Possible values: 0 - 30% , towards both black (B) and white (W).	This function lets you include in the image parts of the histogram outside the image actually shown on the monitor.
Bits per pixel for CR/DX	The number of bits/pixel for the image being sent (CR/DX modes). Possible values: 8 - 12 - 16 bits/pixel.	The actual setting will depend on the characteristics of the server.
Bits per pixel for RF/XA	The number of bits/pixel for the image being sent (RF/XA modes). Possible values: 8 - 12 - 16 bits/pixel.	The actual setting will depend on the characteristics of the server.

Auto Store Options		Notes
Image Selection	Options: <ul style="list-style-type: none"> - All Images: to send all the images in the study - All not Stored: to send all the images not already sent to the server - All Pinned: to send only the images selected by the operator using the PIN function 	
Autostore on Close	Enables the auto store function when the study is closed (default server).	

4.5.2.3 WORKLIST

The DICOM Worklist function is used to request a list of the studies to be performed (and the relevant procedures) from the server.

The following parameters are used to set the Worklist request.



Modality Filters		Notes
Filter CR	Enables the filter for studies in CR mode.	Only exams in CR mode are requested.
Filter DX	Enables the filter for studies in DX mode.	Only exams in DX mode are requested.
Filter XA	Enables the filter for studies in XA mode.	Only exams in XA mode are requested.
Filter RF	Enables the filter for studies in RF mode.	Only exams in RF mode are requested.
More than one filter can be enabled at the same time. If no filter has been selected, the Worklist will be requested without any mode restrictions.		

List Options		Notes
Descending Order	The received studies are shown in chronological order, as per the Date-Time field (most recent first).	If not selected, the studies will appear in their order of reception.
Clear list	Used to delete the current Worklist before requesting a new one (Get List).	If not selected, the new studies will be added to those already in the Worklist.
Clear item on create study	Used to delete the study from the Worklist once it has been created.	If not selected, the study will continue to appear in the Worklist, but marked with a check sign.

List Options		Notes
Use scheduled physician as performing physician	The name of the operator received from the Worklist (Scheduled Physician) is entered in the field indicating the operator responsible for the study (Performing Physician).	
Enable patient edit	Enable the possibility to change patient's data in a study received through Worklist.	Attention: IHE standards do not provide for the possibility to edit patient data received through Dicom Worklist. Enabling this option, patient data management does not comply to these standards.
Automatic Import	When the option is enabled, today's Worklist is automatically imported.	It is suggested to enable the option.
Enable Wildcard	This option makes easier the search by Patient's name , allowing to enter even a partial text.	For example, entering "John", all patient containing "John" will be recalled and shown in the list.

4.5.2.4 MEDIA

The DICOM Media function lets you transfer the studies to USB Pen Drive (memory stick).

This function has the following options:

Image Options		Notes
Writings on Image	Image transferred together with its text (patient name, image n°, etc.) as shown on the monitor.	If not enabled, the image is sent without any writings. These will, in any case, be sent via the relevant DICOM fields.
Graphics on Image	Transfer of the image with overlay (text or measurements) added by the operator.	If not enabled, the image is sent without any graphic overlay.

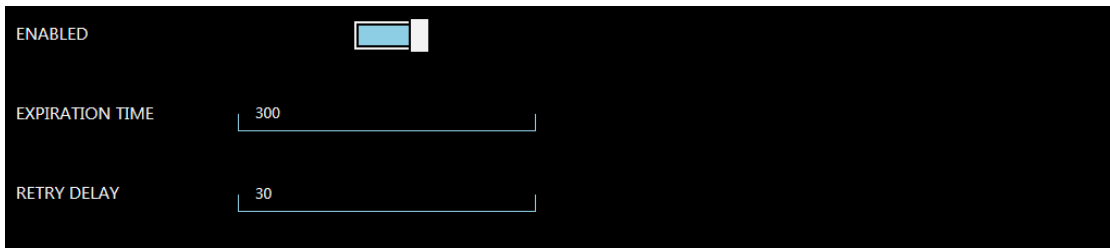
Modality Options		Notes
Presentation LUT	Enables the "complete" transfer of the image, followed by the presentation LUT parameters.	Only suitable for DX images.
W/L LUT expansion	Option only active when the Presentation LUT option is disabled. This lets you determine the level of the LUT expansion for the image sent to the server compared to that used for its presentation on the monitor. Possible values: 0 - 30% , towards both black (B) and white (W).	This function lets you include in the image parts of the histogram outside the image actually shown on the monitor.
Bits per pixel for CR/DX	The number of bits/pixel for the image being sent (CR/DX modes). Possible values: 8 - 12 - 16 bits/pixel.	
Bits per pixel for RF/XA	The number of bits/pixel for the image being sent (RF/XA modes). Possible values: 8 - 12 - 16 bits/pixel.	

If PatientID IS EMPTY	If the "Patient ID" is not available, the DICOM field can be filled according to one of these choices: - Patient name: the patient's name is entered. - Patient ID: the words "Patient ID" is entered.	
If StudyID IS EMPTY	If the "Study ID" parameter is not available, the DICOM field can be filled according to one of these choices: - Study UID: the parameter Study UID is inserted. - Study ID: the words "STUDY ID" is entered.	

Other options		Notes
Charset	Character Set used for DICOM transfer.	Select one of the available options.
Image Dir	Name of the temporary directory used to save the data during the creation of the DICOM files you want to transfer.	Fix setting D:\Media_tmp
Viewer Dir	Directory where the DICOM viewer is saved; this will be loaded on the memory device together with the images.	Fix setting D:\cd_utility
Enable the store of multiple studies	It enables the possibility to save multiple studies on the same device. Warning: <i>this operation is not compliant with DICOM standard.</i>	To activate this function, it is necessary to tick the corresponding box during saving procedure.
Anonymized Export	If enabled, it allows to export images in the study by anonymizing patient data.	If not selected, you can still enable the function during the Export phase (see Paragraph 6.6, Section 2 of the User Manual).
Export Type	Image export type. Choose between: - DICOM = in DICOM format - WEB VIEW = in WEB view format - DICOM AND WEB VIEW = both formats	
Single Image Export Format	Format of the single images to be exported. Choose between: - BMP - JPEG	
Sequence Image Export Format	Format of the sequences of images to be exported. Choose between: - AVI - MP4 - BMP - JPEG	

4.5.2.5 STORAGE COMMITMENT

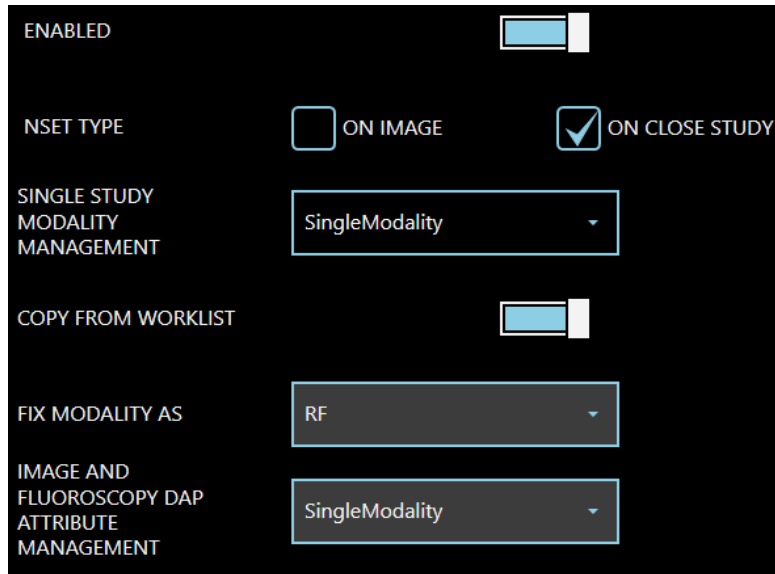
The DICOM Storage Commitment function lets you receive confirmation that the images sent to the Storage server have been archived successfully.



Storage Commitment Settings		Notes
Enabled	Enabling of the Storage Commitment service.	
Expiration Time	Used to set the pause (in seconds) for receipt of confirmation from the Storage Commitment server.	If no confirmation is received within this period, the STORAGE COMMITMENT function has failed.
Retry Delay	Used to set the delay (in seconds) before a new STORAGE COMMITMENT request following a failed attempt.	5 - 300 s (Default 5s)

4.5.2.6 MPPS

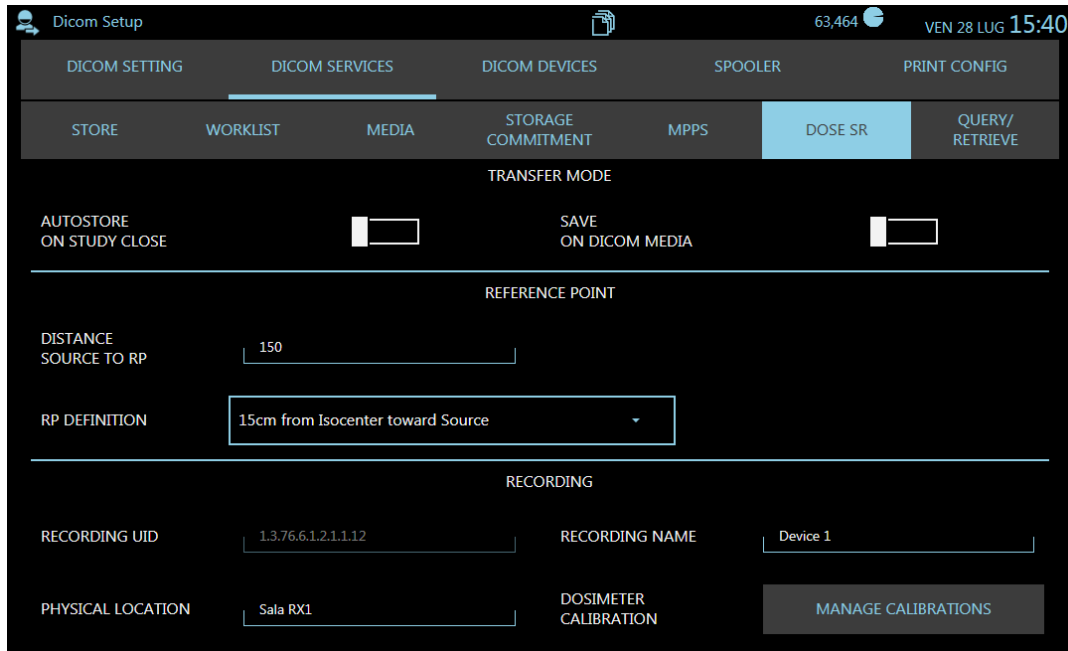
The DICOM MPPS server is used by the equipment to communicate progress in the performance of a study (study in progress, study completed, study archived).



MPPS Settings		Notes
Enabled		Enabling of the MPPS service.
N-SET TYPE	ON IMAGE	Orders the creation of the MPPS message sent to the server after the first acquisition. This is then updated after each acquisition. As soon as the study is closed, the MPPS message is then flagged as "completed".
	ON CLOSE STUDY	Orders the creation of the MPPS message sent to the server after the first acquisition. As soon as the study is closed, the MPPS message is updated with all the acquisitions and flagged as "completed".
SINGLE STUDY MODALITY MANAGEMENT	Single modality	The MPPS message is sent as a single "pack" containing all the images information together (even if acquired with different modality).
	Multiple modality	A new MPPS message is sent every time the acquisition modality is changed.
COPY FROM WORKLIST		The acquisition modality attribute (CR, DX, RF, XA) is compiled with the corresponding attribute present into the Worklist. The option can be enabled only if the "Single modality" option is selected.
FIX MODALITY AS		Select a default acquisition modality attribute (CR, DX, RF, XA). The option can be enabled only if the "Copy from Worklist" function is disabled.
IMAGE AND FLUOROSCOPY DAP ATTRIBUTE MANAGEMENT	Single modality	The MPPS complete message contains only the DAP dose of the images grouped into that sequence. The function can be enabled only if the "Multiple modality" option is selected.
	Whole Study	Last MPPS complete message contains the total DAP dose reached so far. Please, refer to MPPS SCP provider on how to configure this value. A wrong configuration could lead to collect wrong accumulated dose data.

4.5.2.7 RADIATION DOSE STRUCTURE REPORT (RDSR)

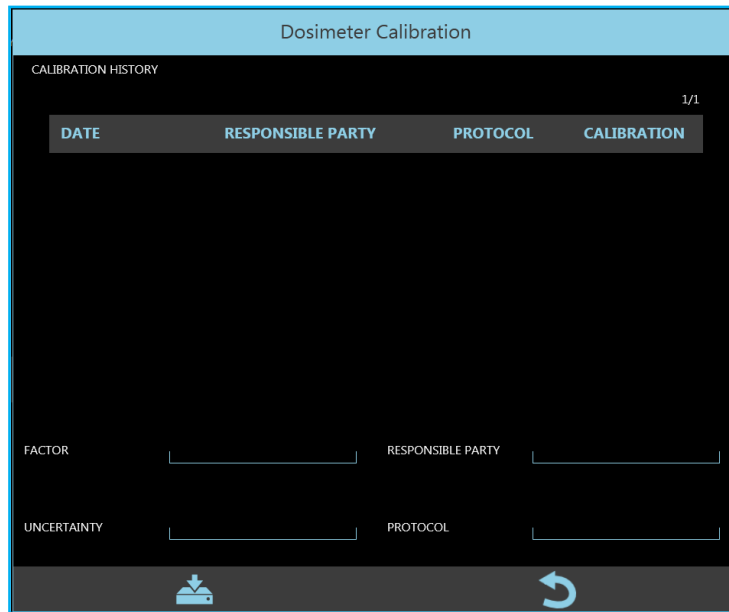
The DICOM Radiation Dose Structure Report (RDSR) is used to transmit the exposure parameters and the X-ray doses for each image in a study, together with the X-ray doses for all exposures during a study. The **Dose SR** sub-menu in the **DICOM Setup** menu lets you set the following parameters:



Transfer Mode		Notes
AUTOSTORE ON STUDY CLOSE	Enables the automatic transmission of the DOSE REPORT when the study is closed.	
SAVE ON DICOM MEDIA	Enables the transfer of the DOSE REPORT to USB pen drives.	

Reference Point		Notes
DISTANCE SOURCE TO RP	Distance of the reference point used to calculate the X-ray dose and the X-ray source.	Set: 766mm
RP DEFINITION	Distance of the reference point used to calculate the X-ray dose and the FPD surface. - 15cm from Isocenter toward Source - 30cm in Front of Image Input Surface - 1cm above Tabletop - 30cm above Tabletop - 15cm from Table Centerline - Entrance exposure to a 4.2cm breast thickness - In Detector Plane	Select: 30cm in Front of Image Input Surface

Recording		Notes
RECORDING UID	Identification of the recording device.	Fixed setting
RECORDING NAME	Name of the recording device.	Set by the user.
PHYS. LOCATION	Physical position of the recording device.	Set by the user.
DOSIMETER CALIBRATION	Calibration of the recording device.	See image and table below.



Dosimeter Calibration		Notes
FACTOR	Calibration factor used for the device.	Multiplication factor to correct the value measured by DAP in order to get the right value. Set 1 if the value provided does not require any correction.
RESPONSIBLE PARTY	Body responsible for dosimeter calibration.	
UNCERTAINTY	Inaccuracy of the device.	± 0=100%
PROTOCOL	Description of the calibration protocol.	

4.5.2.8 QUERY / RETRIEVE

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.).

OPTIONS	
SERVICE AE TITLE	AET_QR
SERVICE IP PORT	105
SEARCH FROM PATIENT ROOT	<input checked="" type="checkbox"/>
ENABLE WILDCARD	<input type="checkbox"/>
CONFIGURATION	
RETRIEVE DIR	D:\dicom_retrieve_data
VIEWER PATH	C:\Program Files (x86)\ETIAM\Open LiteBox\DcmLtBox.exe

Options		Notes
Service AE title	AE Title of the remote device providing the Query / Retrieve service.	
Service IP Port	TCP Port used by the remote device providing the Query / Retrieve service.	
Search from Patient Root	If a problem with the recovery of the images occurs during installation, it may be due to a PACS setting. The activation of this option increases the compatibility and allows to solve the problem.	
Enable Wildcard	This option makes easier the search by Patient's name, allowing to enter even a partial text.	For example, entering "John", all patients containing "John" will be recalled and shown in the list.




Configuration		Notes
Retrieve Dir	Position on the HD of the directory that will hold the exams received from the remote Query / Retrieve device.	
Viewer Path	Position on the HD of the DICOM Viewer that lets you view the exams received from the remote Query / Retrieve device.	

4.5.3 DICOM DEVICES

The **DICOM Devices** setup menu lets you manage the settings of all the remote DICOM devices.

NAME	IP ADDRESS	AETITLE	TYPE
DICOM QR	10.0.39.39:12	dCIOM	QUERY_RETRIEVE
DCM4CHEE	10.0.39.186:11112	DCM4CHEE	STORE
DCMPRINT	10.0.39.79:10006	PRINTSCP	PRINTER
DCM4ATS	10.0.39.195:11112	DCM4ATS	WORKLIST
ATS_PRINTER	10.0.39.195:4007	ATS_PRINTER	PRINTER
JDICOM	127.0.0.1:7104	JDICOM	PRINTER
ATS_WORKLIST	10.0.39.195:4005	ATS_WORKLIST	WORKLIST
DVTK_MW_SCP	10.0.39.87:107	DVTK_MW_SCP	WORKLIST
DVTK_MPPS_SCP	10.0.39.87:108	DVTK_MPPS_SCP	MPPS
MPPS_DCM4CHEE	10.0.39.186:11112	DCM4CHEE	MPPS

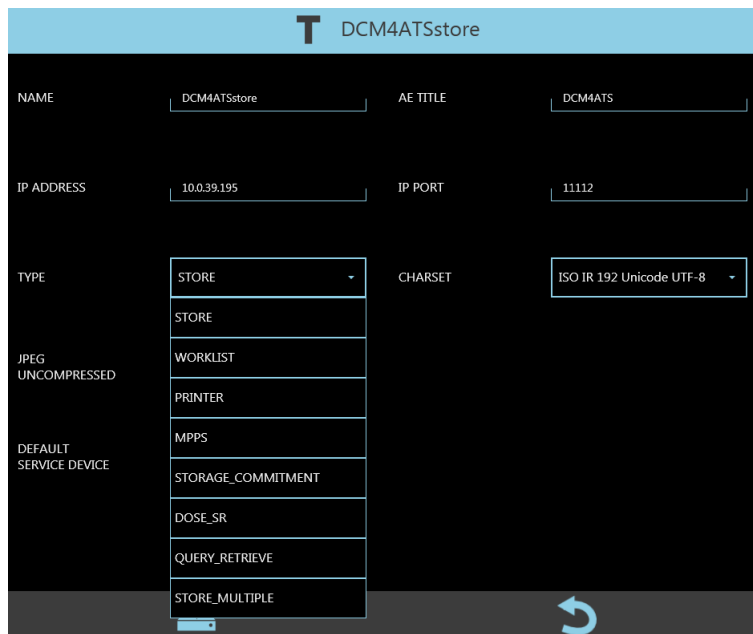
You can:

- **Add** new devices, using the  command;
- **Delete** devices, using the  command;
- **Set the options** for each device (see list below);
- **Check** the connection with the selected remote device (Verify), using the  command.

Note: In DICOM devices list, all the devices set as default are marked with a star.



The following parameters can be set for all the remote devices:



Device configuration.		Notes
Name	Conventional name of the remote DICOM device within the hospital network.	Decided by the network administrator.
AE Title	AE Title of the remote DICOM device.	Decided by the network administrator.
IP Address	IP address of the remote DICOM device within the hospital network.	Decided by the network administrator.
IP Port	TCP port of the remote DICOM device.	Decided by the network administrator.
Type	Type of DICOM service provided by the remote DICOM device.	Select one of the options.
Charset	Character set used to send DICOM files.	This parameter must match that set in Windows and the keyboard properties.

Depending on the service being provided, the remote device may be enabled for one of these functions:

- **Store:** image archiving service.
- **Worklist:** service that gathers the studies to be performed (WORKLIST SCP).
- **Printer:** image printing service (PRINTER SCP).
- **MPPS:** study status data and updating service (study in progress, study completed, study archived, etc.).
- **Storage Commitment:** service that confirms (via the PACS) that the received images have been archived successfully.
- **Dose SR:** service that gathers information on the X-ray dose.
- **Query/Retrieve:** service that requests archived studies from other imaging systems (Q/R SCP).
- **Store Multiple:** service that lets you archive studies on several devices.

➤ **STORE DEVICES**

In addition to the general parameters, the following parameters also must be set for STORE devices:

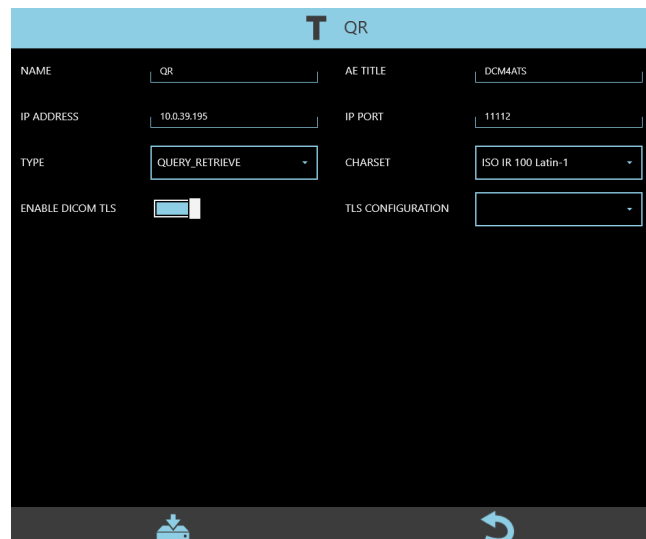
Device configuration.		Notes
Enable DICOM TLS	Option to be selected if you want to use a cryptographic protocol.	
TLS Configuration	Drop-down menu for selecting the folder that contains the details of the encryption system (DICOM TLS) to be combined with the Store device.	See Paragraph 4.5.3.1 below for more details.
JPEG uncompressed	Select this option if the receiving server cannot handle compressed JPEG images (XA and RF modes).	
Default Service device	Used to select the device to be used as the default unit for the Store service.	The selected device will automatically receive the images as soon as the study is closed (Auto Store function).

➤ **WORKLIST DEVICES**

In addition to the general parameters, the following parameters also have to be set for WORKLIST devices:

Device configuration		Notes
Enable DICOM TLS	Option to be selected if you want to use a cryptographic protocol.	
TLS Configuration	Drop-down menu for selecting the folder that contains the details of the encryption system (DICOM TLS) to be combined with the Worklist device.	See Paragraph 4.5.3.1 below for more details.
Request AET	If enabled, the AE Title (AET) of the equipment is added to the Worklist request sent to the remote device.	Selection is recommended.
Filter AET	If enabled, the AET of the equipment is used as a filter for the Worklist received from the remote device.	Selection is recommended. Only those studies containing the AET set are displayed. (See Paragraph 4.5.1: Dicom Settings)
Default Service device	Current device can be used as the default Worklist device.	Used if there are more than one remote Worklist devices.

➤ **QUERY/RETRIEVE DEVICES**



In addition to the general parameters, the following parameters also must be set for QUERY/RETRIEVE devices:

Device configuration		Notes
Enable DICOM TLS	Option to be selected if you want to use a cryptographic protocol.	
TLS Configuration	Drop-down menu for selecting the folder that contains the details of the encryption system (DICOM TLS) to be combined with the Query/Retrieve device.	See Paragraph 4.5.3.1 below for more details.

➤ **MPPS DEVICES**

In addition to the general parameters, the following parameters also must be set for MPPS devices:

Device configuration		Notes
Enable DICOM TLS	Option to be selected if you want to use a cryptographic protocol.	
TLS Configuration	Drop-down menu for selecting the folder that contains the details of the encryption system (DICOM TLS) to be combined with the MPPS device.	See Paragraph 4.5.3.1 below for more details.
Associated device	Worklist server to be used for the MPPS service.	The list contains all the set Worklist servers previously set.

➤ **STORAGE COMMITMENT DEVICES**

In addition to the general parameters, the following parameters also must be set for STORAGE COMMITMENT devices:

Device configuration		Notes
Enable DICOM TLS	Option to be selected if you want to use a cryptographic protocol.	
TLS Configuration	Drop-down menu for selecting the folder that contains the details of the encryption system (DICOM TLS) to be combined with the Storage Commitment device.	See Paragraph 4.5.3.1 below for more details.
Associated device	Store server to be used for the Storage Commitment service.	The list contains all the set Store servers.

➤ **RDSR DEVICES**

In addition to the general parameters, the following parameters also must be set for RDSR devices:

Device configuration.		Notes
Default Service device	Used to select the device to be used as the default unit for the RDSR service.	if selected, it will automatically receive the RDSR reports about a study.

➤ **MULTIPLE STORE DEVICES**

The remote MULTIPLE STORE device is a virtual device that manages the transfer of images to be archived to several Store servers at the same time. Up to 3 Store servers can be selected to create this virtual device.

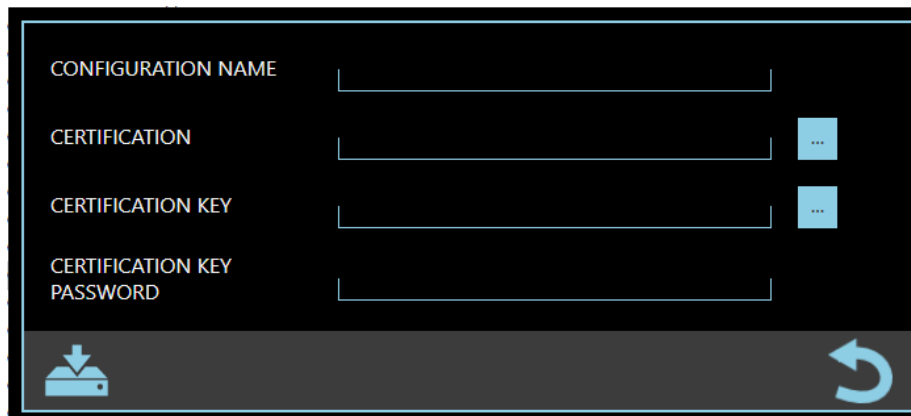
Configuration		Notes
Associated Store device	Store servers to be used for the Multiple Store service.	The list contains all the set Store servers.

4.5.3.1 DICOM TLS

The DICOM TLS cryptographic protocol provides a secure communication between client and server. To create a DICOM TLS to be coupled with a DICOM device, the **ISIX Dicom TL Configuration Manager** application must be used.

Note: to run the application it is necessary to log in as Windows Administrator (see Paragraph 5.2, Part 2).

- Run the application and enter the access password: **breatheme**
- The following window opens:



- **Configuration Name:** enter the name of the folder to be associated with the DICOM device (see paragraph 4.5.3 above)
- **Certification*:** select the file containing the certificate
- **Certification key*:** select the file containing the certification key
- **Certification key Password*:** enter the password to be linked with the certification key

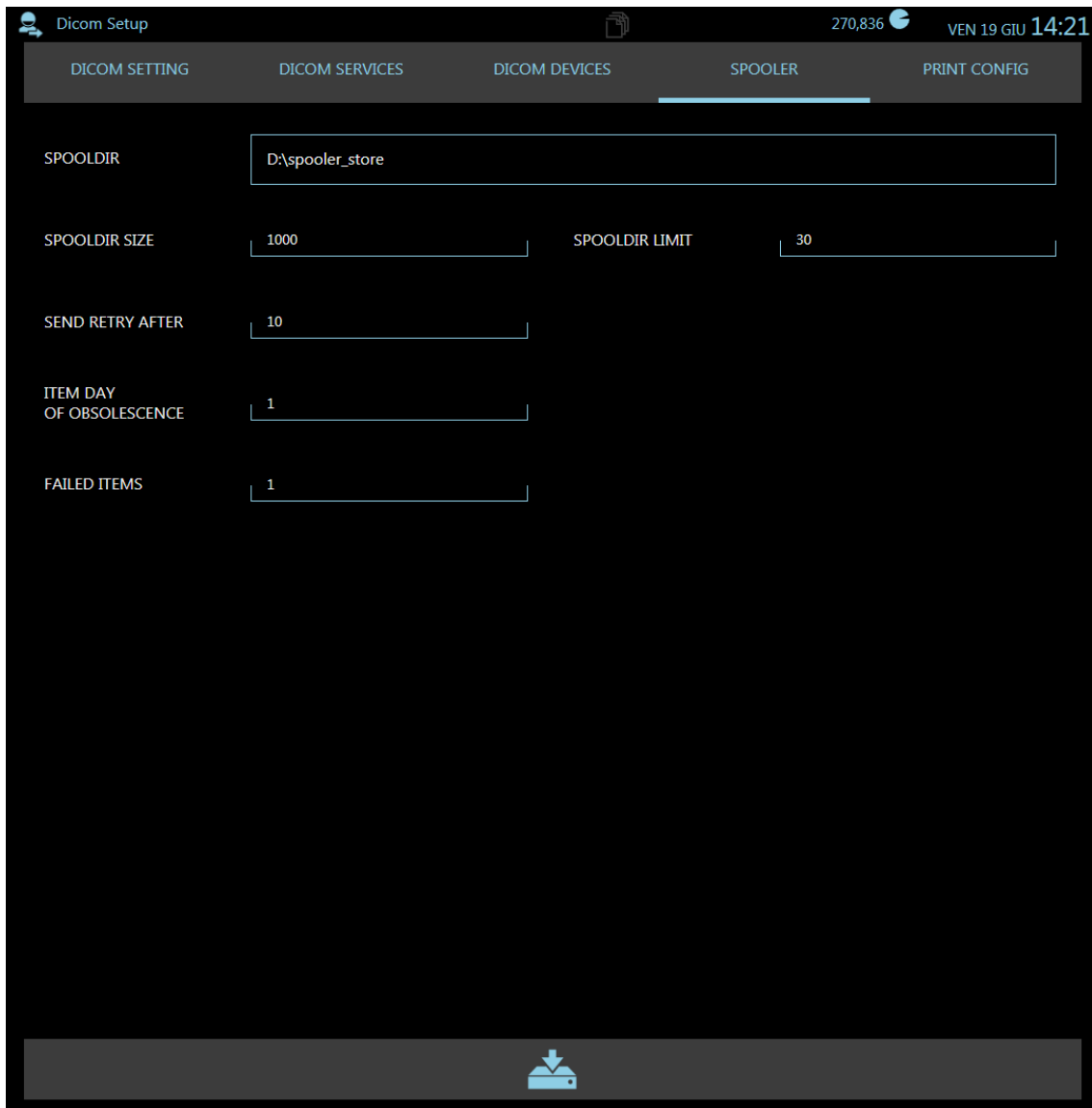
***Note:** the files and password must be provided by the person in charge of the structure in which the equipment is installed.

- Save the set parameters by pressing the button:



4.5.4 SPOOLER

This menu contains the DICOM Spooler settings.



Spooler Settings		Notes
Spooldir	Name of the directory where the DICOM files to be sent are initially saved.	
Spooldir size	Size of the Spooldir directory (MByte).	
Spooldir limit %	Filling limit of Spooldir directory (in percentage); once reached, a warning is generated indicating that the directory is full.	
Send retry after	Pause (in seconds) before the next attempt at transmission.	The DICOM file is flagged as "failed" after 3 unsuccessful attempts.
Item day of obsolescence	Number of days that a DICOM item remains in the Spooldir .	An alarm is generated when this limit is reached.
Failed Items	Max number of DICOM files flagged as "failed" in the Spooldir .	An alarm is generated when this limit is reached.

4.5.5 PRINT CONFIGURATION

The selected images in the study (selected using the "PINNING" function) are automatically sent to the chosen DICOM printer (see procedure below).
Up to 4 print configurations are possible. These will be listed as options for the operator.

Configuration includes:

- Choice of printer
- General printing settings
- Post-processing of images
- Film size
- Film orientation (portrait / landscape)
- Print format (lines and columns)

The PRINT CONFIG menu lets you set these 4 print configurations:

General configuration		Notes
Name	Name given to the configuration	This name will be used by the equipment to identify the specific print configuration.
Printers	List of DICOM printers from which to choose one to configure.	The list contains all the set Print servers.

The printing parameters are:

Options		Possible values provides by standard DICOM*								
Priority	Print priority for the printer.	HIGH MED (default) LOW								
Copies	Number of copies to be printed.	1 (default)								
Medium Type	Type of print medium.	PAPER CLEAR FILM BLUE FILM UNDEFINED								
Film Destination	Film destination.	MAGAZINE PROCESSOR BIN_1 BIN_2 BIN_10 UNDEFINED								
Magnification Type	Type of interpolation used by the printer to adapt the image to the envisaged size of the film.	REPLICATE BILINEAR CUBIC NONE								
Smoothing type	Type of interpolation only valid for the CUBIC Magnification Type .	These values must suit the Conformance Statement accompanying the printer.								
Border Density	Density of the area around and between the images.	BLACK WHITE								
		Number that specifies the required density in 100ths of OD (150 corresponds to 1.5 OD).								
Empty Image Density	Density of the frame on the film in the absence of an image.	BLACK WHITE								
		Number that specifies the required density in 100ths of OD (150 corresponds to 1.5 OD).								
Orientation	Film orientation	PORTRAIT = film arranged vertically LANDSCAPE = film arranged horizontally								
Film Size	Size of the film.	8INX10IN 8_5INX11IN 10INX12IN 10INX14IN 11INX14IN 11INX17IN 14INX14IN 14INX17IN 24CMX24CM 24CMX30CM A4 A3 Note: 10INX14IN = 25.7CMX36.4CM A4 = 210x297 mm. A3 = 297x420 mm.								
Bits per Pixel	Bits per Pixel	8, 12,16								
Annotation	Annotations on the image.	ON = annotations enabled. OFF = annotations disabled.								
Format	Type of image format STANDARD	The film contains rectangles, all of the same size, with R rows and C columns. Set the required values as follows: <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td>Field1</td> <td>Field2</td> <td>Field3</td> <td>Field4</td> </tr> <tr> <td>C</td> <td>R</td> <td></td> <td></td> </tr> </table>	Field1	Field2	Field3	Field4	C	R		
Field1	Field2	Field3	Field4							
C	R									

Options		Possible values provides by standard DICOM*								
	ROW	<p>The film contains rows with equal rectangles and with R1 images in the first row, R2 images in the second and R3 in the third, etc.</p> <p>If used, set the required values as follows:</p> <table border="1"> <tr> <td>Field1</td> <td>Field2</td> <td>Field3</td> <td>Field4</td> </tr> <tr> <td>R1</td> <td>R2</td> <td>R3</td> <td>R4</td> </tr> </table>	Field1	Field2	Field3	Field4	R1	R2	R3	R4
Field1	Field2	Field3	Field4							
R1	R2	R3	R4							
	COL	<p>The film contains columns with equal rectangles and with C1 images in the first row, C2 images in the second and C3 in the third, etc.</p> <p>If used, set the required values as follows:</p> <table border="1"> <tr> <td>Field1</td> <td>Field2</td> <td>Field3</td> <td>Field4</td> </tr> <tr> <td>C1</td> <td>C2</td> <td>C3</td> <td>C4</td> </tr> </table>	Field1	Field2	Field3	Field4	C1	C2	C3	C4
Field1	Field2	Field3	Field4							
C1	C2	C3	C4							

***Note:** Values depend on the the printer model used. Therefore, refer to printer Conformance Statement during setup procedure.

4.5.5.1 PRINT ANNOTATION SETUP

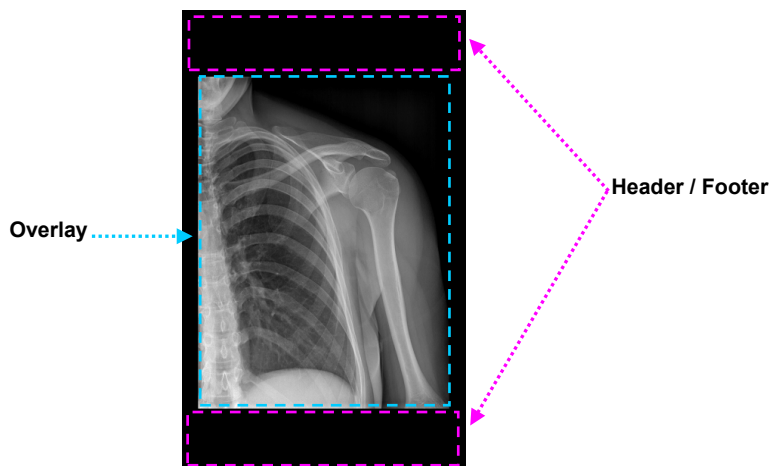
You can set the layout of the writings to be added to the print film.

This is done using the **PRINT ANNOTATION** menu, which lets you establish the text to be added, its position and size.

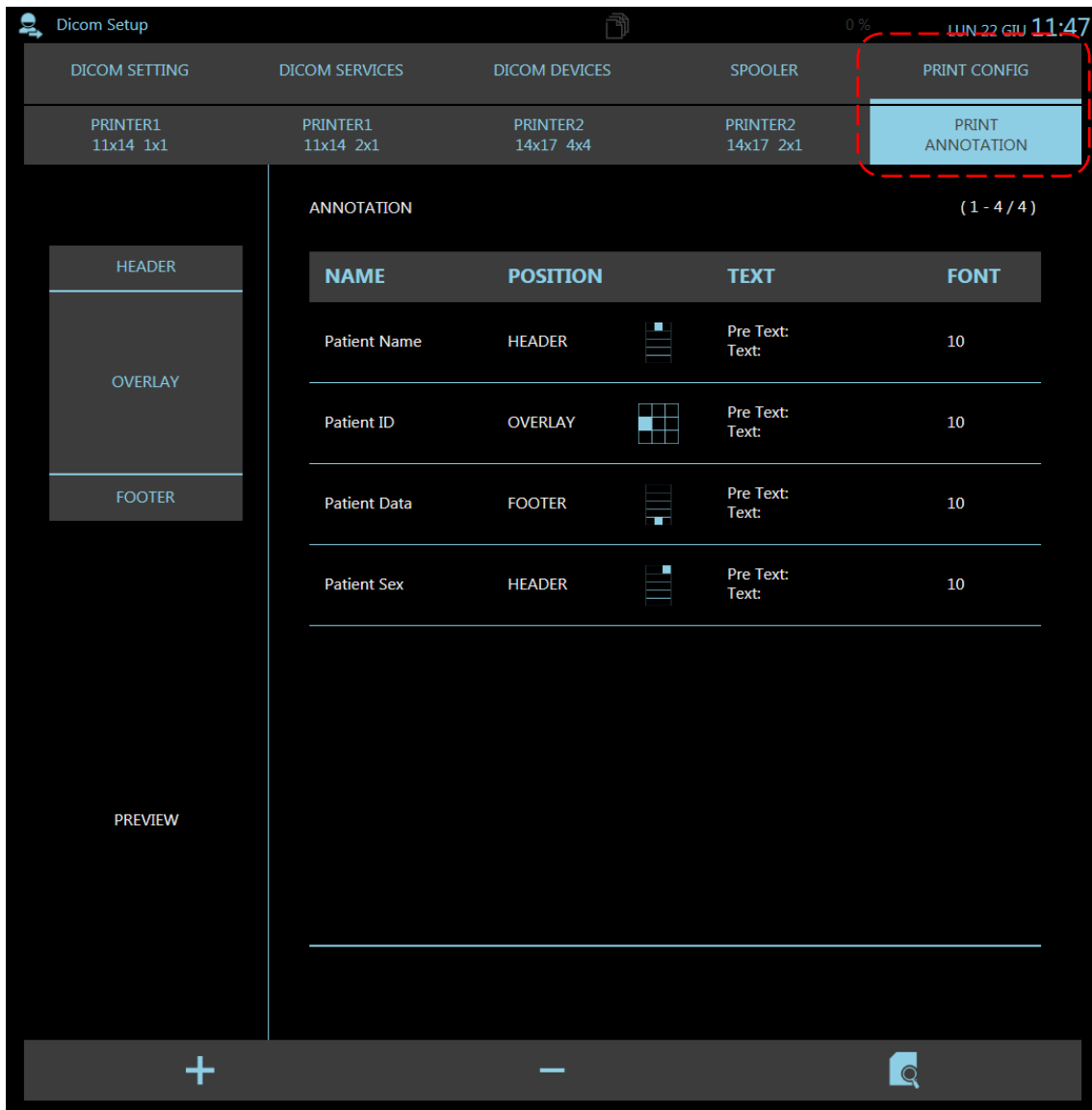
This text box is added to each image, regardless of the layout and printer selected.

The text is normally split into the following components:




- **Header/ footer:** typically, with the common study data (hospital name, patient name, etc.).
- **Image overlay:** typically, with the image data (image n°, date/time acquired, etc.).



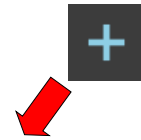
Access the **Print annotation** sub-menu from the PRINT CONFIG menu:



You can:

- Add a new annotation, using the  command;
- Delete an annotation in the list, using the  command;
- View an annotation in the list, using the  command (having first selected it and then enlarged its preview);

- Use the **Add annotation** command to add a new box:



🖨️ New Print Annotation

POSITION	<input type="text" value="HEADER"/>	ELEMENT	<input type="text" value="Free text"/>
PRE TEXT	<input type="text"/>	TEXT	<input type="text"/>
FONT SIZE	<input type="button" value="+"/> <input type="text" value="10"/> <input type="button" value="-"/>		
Position inside HEADER			
	LEFT	CENTER	RIGHT
ROW 1	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 2	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 3	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 4	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 5	<input type="text"/>	<input type="text"/>	<input type="text"/>

📄
↻

- Use the POSITION field to select the position of the new annotation. Options:
 - HEADER
 - OVERLAY
 - FOOTER

POSITION

The position grids for the HEADER and FOOTER fields have:

- 5 rows (**Row 1, 2, 3, 4, 5**)
- 3 columns (**Left, Center, Right**)

Position inside HEADER

	LEFT	CENTER	RIGHT
ROW 1	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 2	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 3	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 4	<input type="text"/>	<input type="text"/>	<input type="text"/>
ROW 5	<input type="text"/>	<input type="text"/>	<input type="text"/>

While the position grid for the OVERLAY field has:

- 3 rows (**Top, Middle, Bottom**)
- 3 columns (**Left, Center, Right**)

Position inside OVERLAY

	LEFT	CENTER	RIGHT
TOP	<input type="text"/>	<input type="text"/>	<input type="text"/>
MIDDLE	<input type="text"/>	<input type="text"/>	<input type="text"/>
BOTTOM	<input type="text"/>	<input type="text"/>	<input type="text"/>

- Select the box in the grid where you want to add the new annotation.
- Select one of the field options for the ELEMENT field:
 - Free text
 - Patient Name
 - Patient ID
 - Patient Birthday
 - Patient Sex
 - Accession Number
 - Study Date
 - Physician
 - Study Description
 - Hospital Info
 - Print Date
 - Image data time
 - Serie / Image Number

- Add extra text in the PRE-TEXT / TEXT fields.

PRE TEXT TEXT


- Set the size of the **Font** (text size, in mm), using the + and - commands.

FONT SIZE

- In the case of OVERLAY, you can also set the position of the annotation within the grid by using the 2 offset values:

X OFFSET Y OFFSET



- Once you have set the new annotation, save it using the  command. The new annotation is now added to the list of saved annotations.
- Repeat this procedure for each new annotation.

- After selecting an annotation in the list, you can get a preview in the space shown:

NAME	POSITION	TEXT	FONT
Patient Name	HEADER	Pre Text: Text:	10
Patient ID	OVERLAY	Pre Text: Text:	10
Patient Data	FOOTER	Pre Text: Text:	10
Patient Sex	HEADER	Pre Text: Text:	10

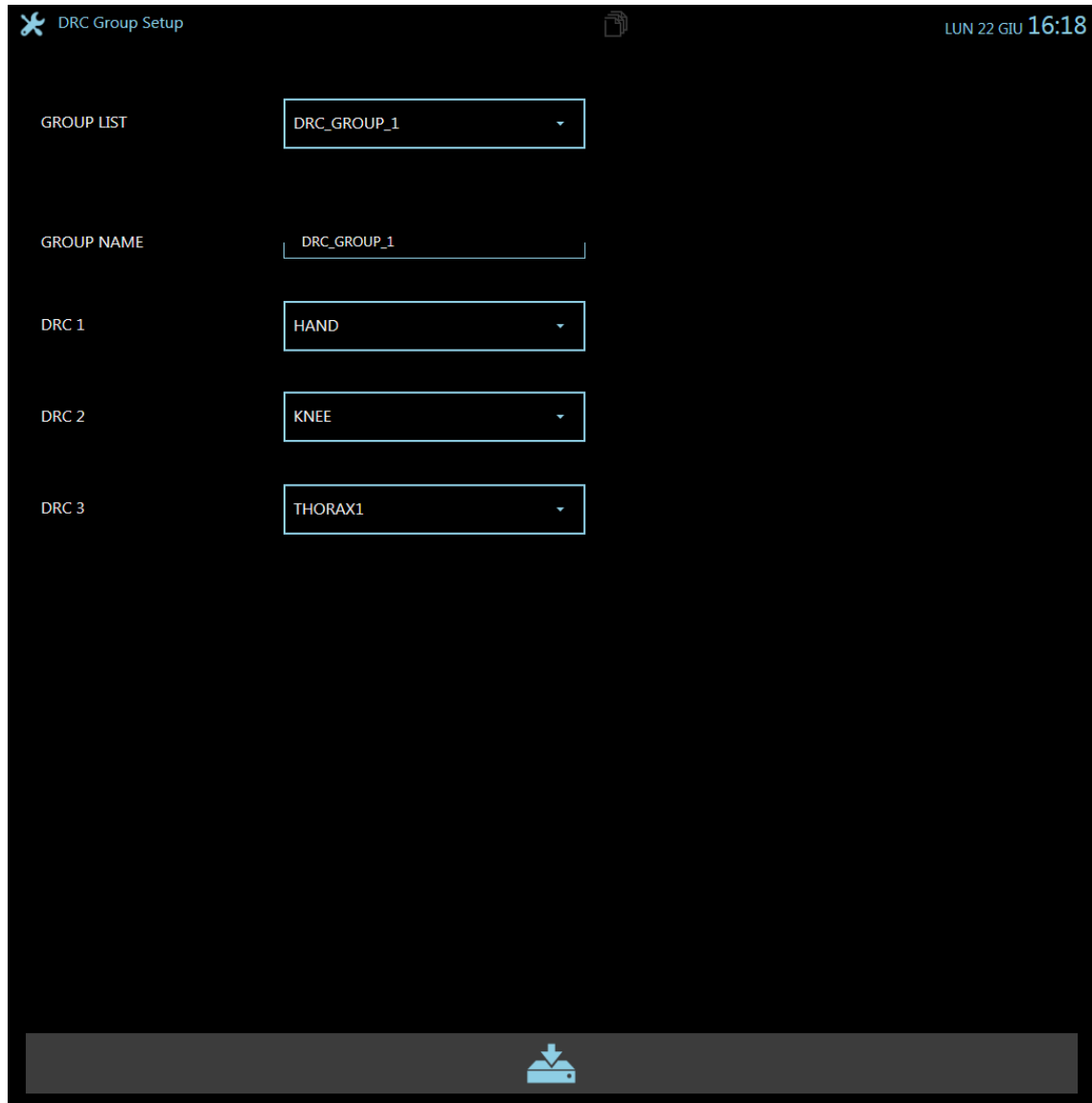
4.6 DRC GROUP SETUP

The EM equipment can be programmed for up to 6 exam types. Once the operator selects an exam, the parameters set for that type of exam are automatically loaded.

Each exam can use one of three **DRC processes (dynamic range compression)** from within a single **DRC GROUP**.

These three processes are set during installation to suit the type of exam.

You can use the **DRC GROUP SETUP** menu to set "n" groups of 3 processes from among those that appear in a pre-set list.



- Select one of the groups in the GROUP LIST box.
- You can change its name in the GROUP NAME box.
- Select the 3 processes to be associated with the selected group (DRC1, DRC2 and DRC3).

- Save them using the  command.


4.7 DRC NAME SETUP

This menu allows to customize the name of the available **DRC processes**, in order to help the operator during the execution of the exam.

DEFAULT NAME	NAME
	NO DRC
	LOG
	HAND-
	HAND
	HAND+
	KNEE-
	KNEE
	KNEE+
	HEAD-
	HEAD
	HEAD+
	URO-
	URO
	URO+
	THORAX-

DEFAULT NAME _____

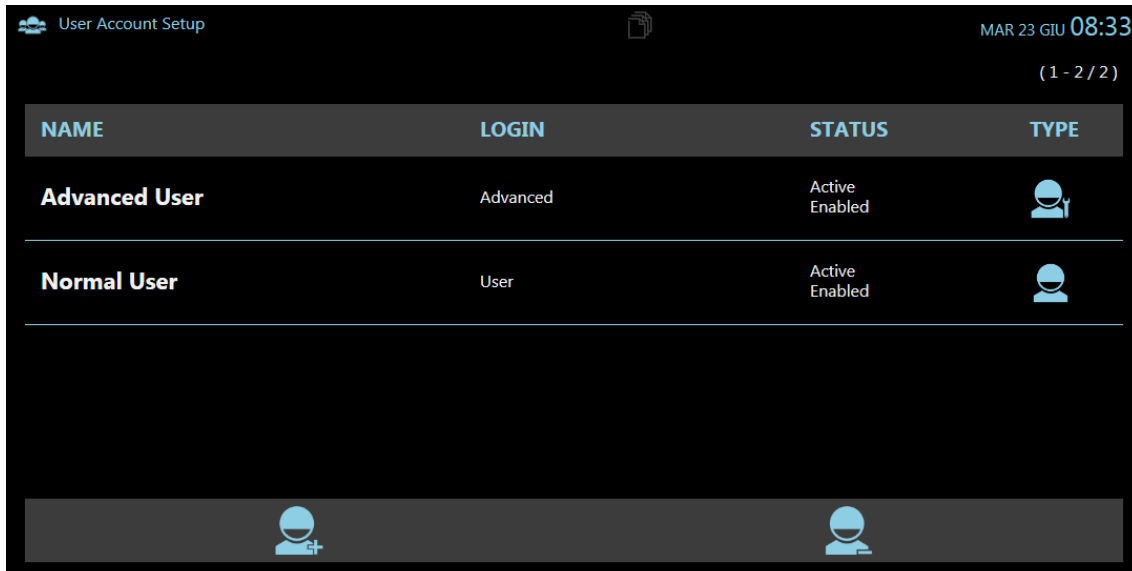
NAME





- Select the name of the process to be edited.
- Enter the required name and save. In the list, the selected name is updated.

4.8 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.



The screenshot shows the 'User Account Setup' screen. At the top, it displays 'User Account Setup' on the left, a date and time 'MAR 23 GIU 08:33' on the right, and a page indicator '(1 - 2 / 2)'. Below this is a table with four columns: NAME, LOGIN, STATUS, and TYPE. The table contains two rows: 'Advanced User' with login 'Advanced' and status 'Active Enabled', and 'Normal User' with login 'User' and status 'Active Enabled'. At the bottom of the screen, there are two user icons with plus signs, indicating options to add or manage users.

NAME	LOGIN	STATUS	TYPE
Advanced User	Advanced	Active Enabled	
Normal User	User	Active Enabled	

There are three user levels:

- Administrator (user pre-set in the factory)
- Advanced (set during installation)
- User

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,
 - *User Account* setup,
 - *Fixed String* setup.

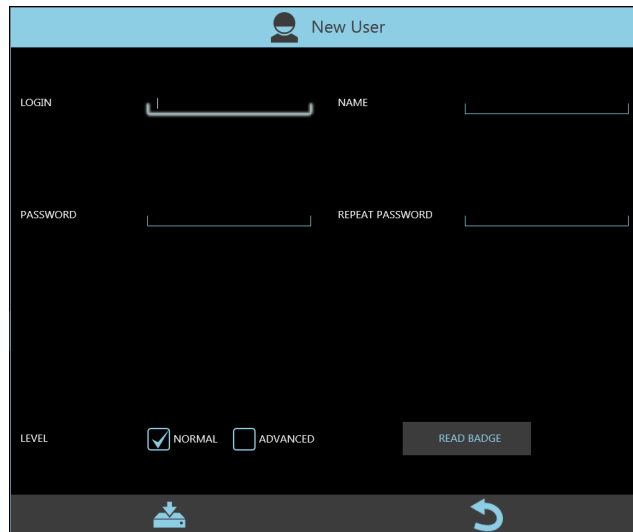
Note: some of the parameters should not be available to the **Advanced** user.

- **User:** routine operations only.

Each user has a unique password.

The system is meant to have only one **Administrator**, 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);
 - **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.

4.9 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**:



Any number of strings can be added (max length 20 characters).
The commands are:



to add a new string (after all the existing ones),

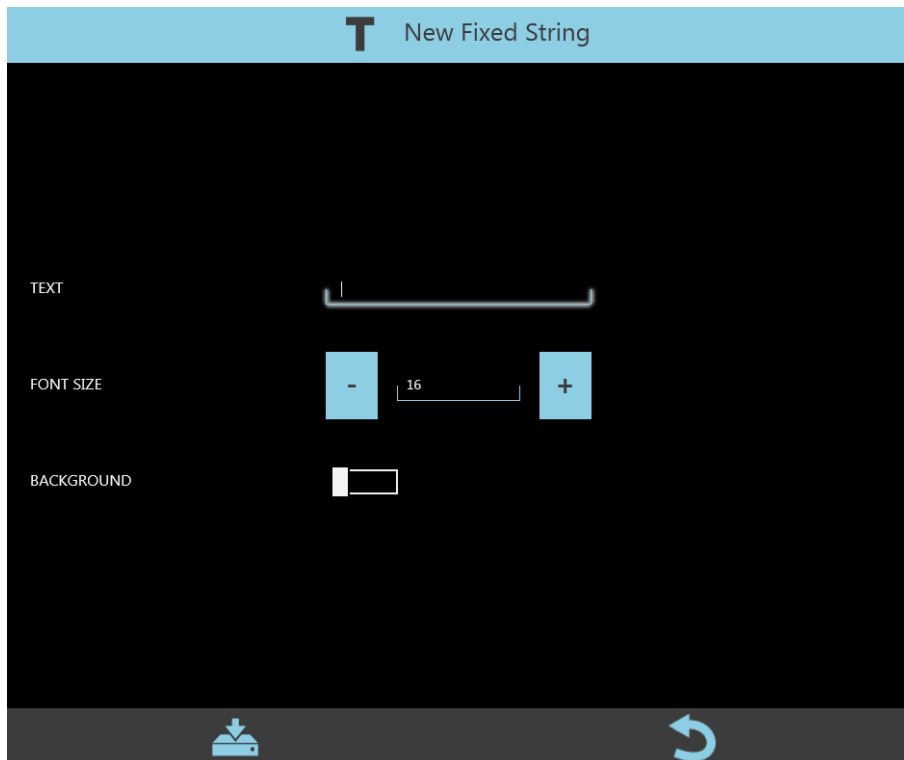


to delete the selected string from the list,




to shift 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.

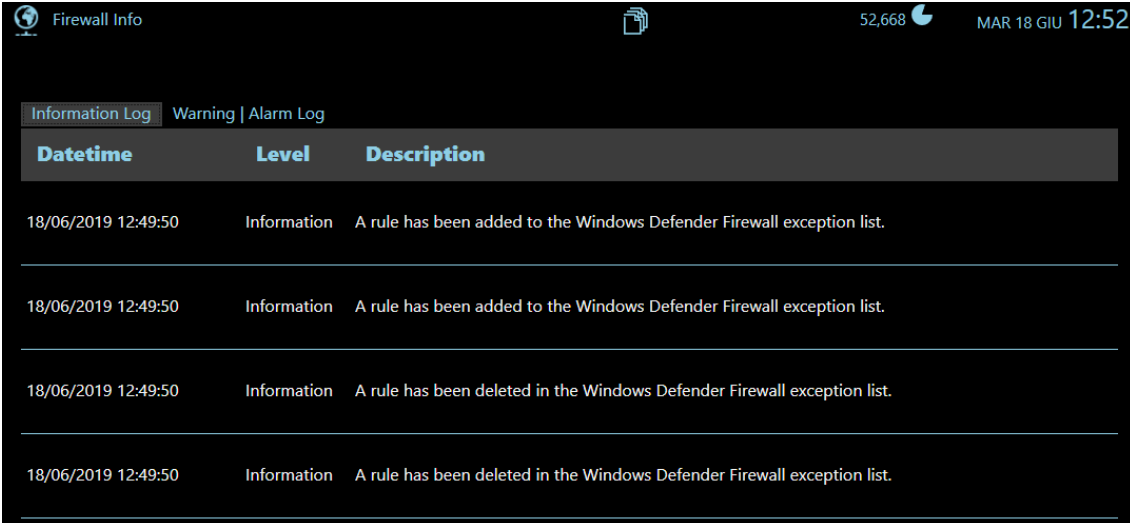
- Use the  command to complete the creation of the new string and add it to the list of existing strings.

4.10 FIREWALL INFO

This menu is divided in two pages:

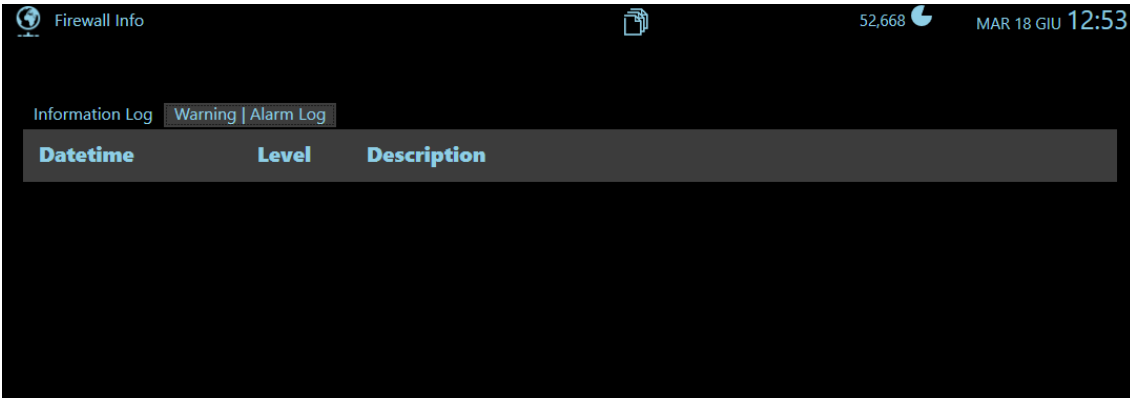
- **Information Log** page,
- **Warning /Alarm Log** page.

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.



Datetime	Level	Description
18/06/2019 12:49:50	Information	A rule has been added to the Windows Defender Firewall exception list.
18/06/2019 12:49:50	Information	A rule has been added to the Windows Defender Firewall exception list.
18/06/2019 12:49:50	Information	A rule has been deleted in the Windows Defender Firewall exception list.
18/06/2019 12:49:50	Information	A rule has been deleted in the Windows Defender Firewall exception list.

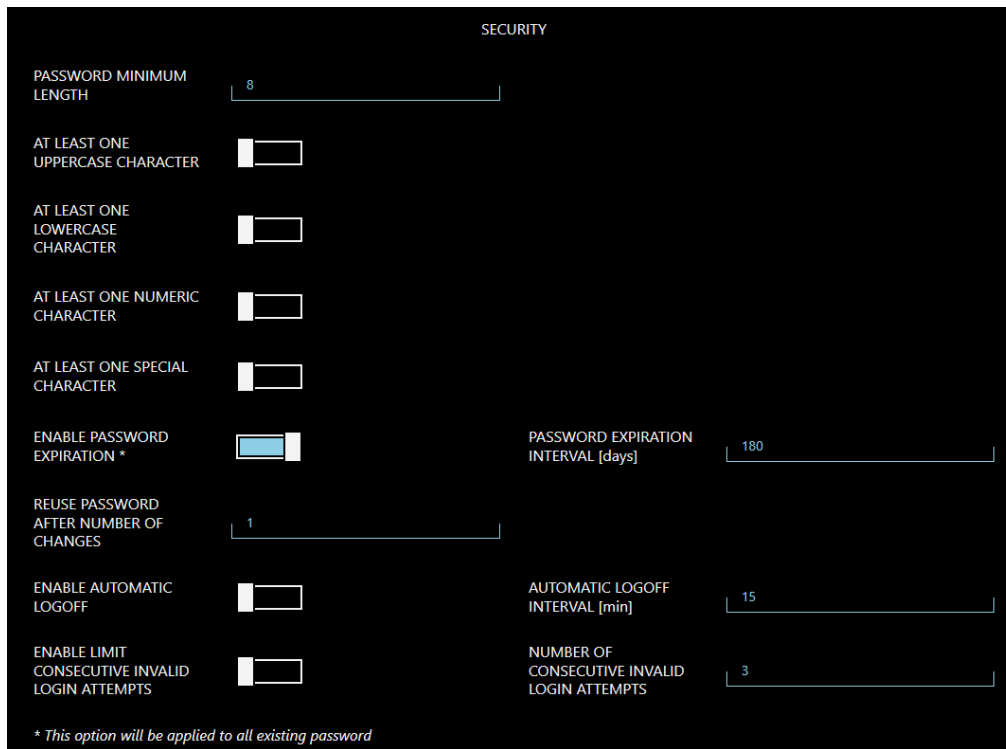
The second one provides information about possible external attacks to the system (security breach). Warnings or alarms are defined by Date and Time, Level and a brief Description.



Datetime	Level	Description
----------	-------	-------------

4.11 SECURITY SETUP

The **Security Setup** menu (accessed by **Administrator**, only) lets you manage some additional security features about automatic logoff and password effectiveness.



Option	Meaning	Settings	Notes
PASSWORD MINIMUM LENGTH	Minimum number of characters of the password.	4-30 characters	
AT LEAST ONE UPPERCASE CHARACTER	Passwords must contain at least one uppercase character.		
AT LEAST ONE LOWERCASE CHARACTER	Passwords must contain at least one lowercase character.		
AT LEAST ONE NUMERIC CHARACTER	Passwords must contain at least one numeric character.		
AT LEAST ONE SPECIAL CHARACTER	Passwords must contain at least one special character.		
ENABLE PASSWORD EXPIRATION	The password does not have an expiration date.		
PASSWORD EXPIRATION INTERVAL (days)	The password expires after the number of days set.	1-3650 days	
REUSE PASSWORD AFTER NUMBER OF CHANGES	An old password can be reused after the number of changes set.	1-10 times	
ENABLE AUTOMATIC LOG OFF	The system automatically returns to the login page after an inactivity interval.		
AUTOMATIC LOG OFF INTERVAL [min]	The system automatically logs off the user after the interval set.	1-60 min	
ENABLE LIMIT CONSECUTIVE INVALID LOGIN ATTEMPTS	The system blocks the possibility to log in after the number of wrong attempts set.		After 5 minutes, it will be possible to try to log in again.
NUMBER OF CONSECUTIVE INVALID LOGIN ATTEMPTS	Number of wrong attempts after which the system temporarily blocks the access.	3-15 times	

5 ANNEXES A

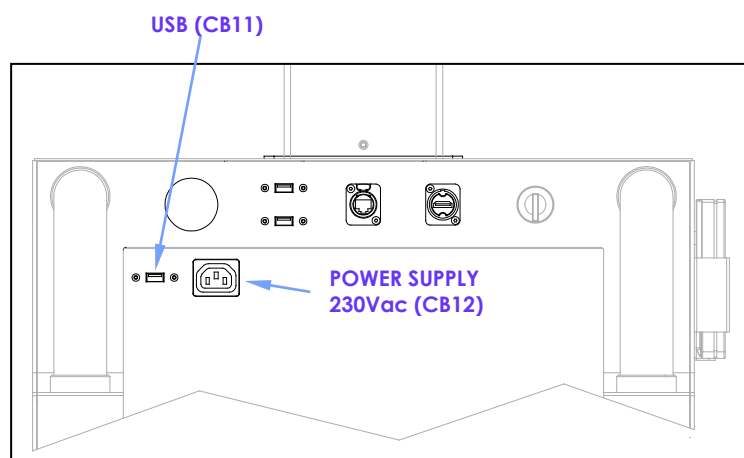
5.1 CONNECTING THE PRINTER (optional)

It is possible to connect the EM equipment to a Windows compatible printer. It allows to print single images in **BMP** format.

It is necessary to make sure that the corresponding driver files have been installed before connecting the printer.

5.1.1 POWER SUPPLY AND USB CONNECTIONS

The 230V AC power supply for the printer comes from connector CB12 on the monitor unit. Use CB11 connector as the USB connection (see figure below):



Note: Do not use a printer requiring more than 200V AC. 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).

5.2 MONITOR CONFIGURATION

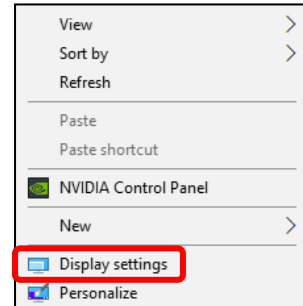
5.2.1 RESETTING THE MONITORS CONFIGURATION

The PC has the following standard monitor configuration:

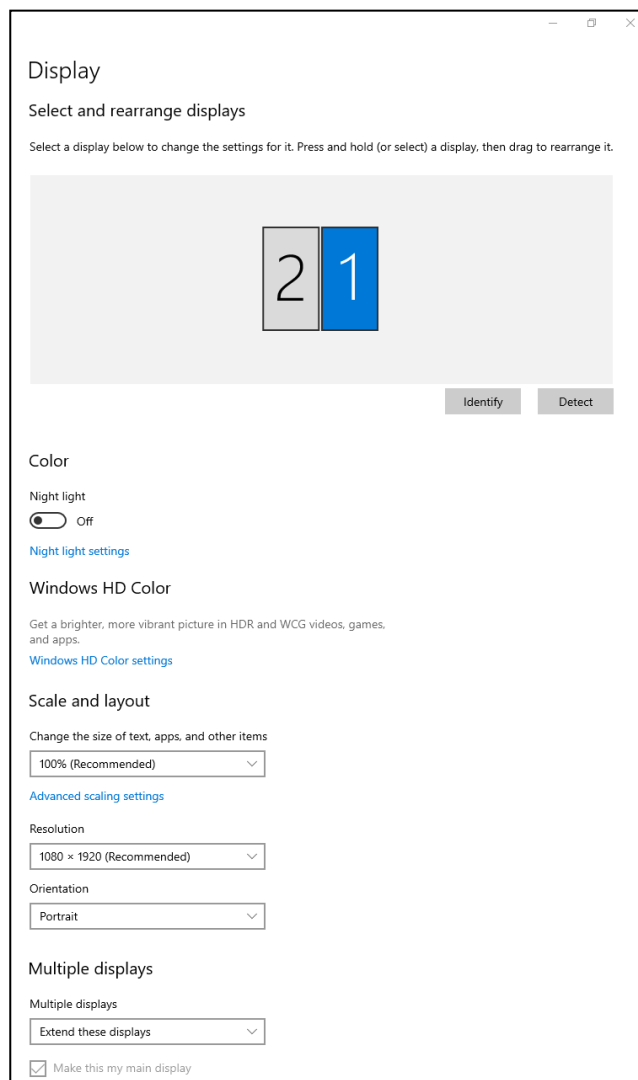
- **Multiple Displays: Extended Desktop**
- **Orientation: Portrait**
- **Resolution: 1080 x 1920 pixels (FULL-HD)**

If the PC loses its configuration, you can reset it as follows:

- Access the video processor operative system with **Administrator** privileges (see Paragraph 5.3 below).
- Click on the screen with the right-click of the mouse and select **Display Settings**.



- Selecting one of the 2 monitors in the window opened, the corresponding video settings are displayed. For both monitors, check that the settings are as follow:
 - ✓ The **memory monitor MM** (right monitor) is identified with the number **1**. For Windows operating system it is the main monitor (MAIN DISPLAY).
 - ✓ The **live monitor ML** (left monitor) is identified with the number **2**. For Windows operating system it is the secondary monitor.
 - ✓ Night light: **OFF**
 - ✓ Scale and Layout: **100%**
 - ✓ Resolution: **1080 x 1920**
 - ✓ Orientation: **Portrait**
 - ✓ Multiple displays: **Extend these displays**

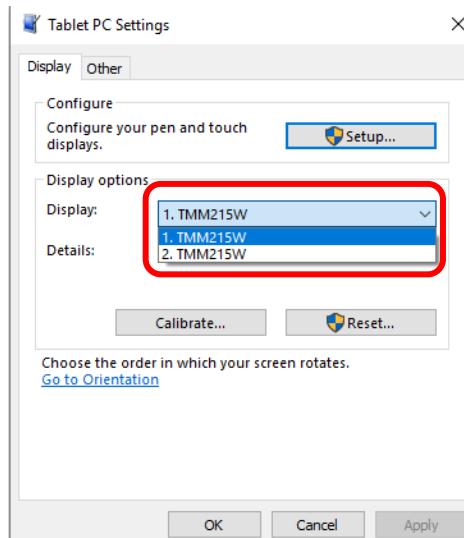


5.2.2 TOUCH SCREEN CALIBRATION

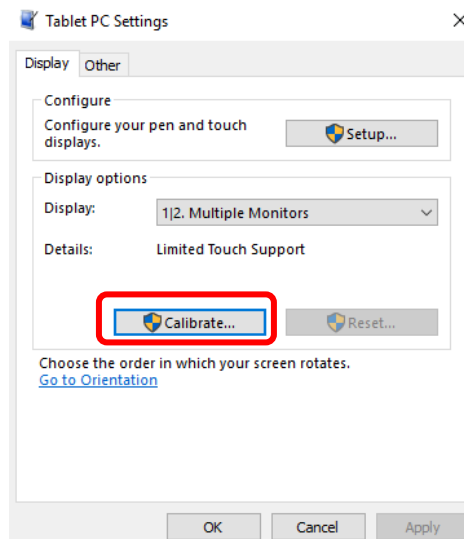
The equipment is supplied with the monitors already configured and calibrated.

If you need to recalibrate the touch screen monitor, follow these instructions:

- Access the system as **Windows Administrator** (see the next Paragraph 5.3).
- Touch START on the Windows tool bar and then select: **Control Panel > Tablet PC Settings**.
- In the window that opens select the monitor that must be calibrated; the **memory monitor MM** (right monitor) is identified with the number **1**, while the **live monitor ML** (left monitor) is identified with the number **2**.



- Press the **Calibrate** key:



- Press with your finger on the **viewfinder** that appears in a corner of the monitor; repeat for the other corners.
- Select the **Yes** command to confirm and complete the calibration procedure.

Note: the same procedure can be used to calibrate the touch screen of the **Control Panel**.

5.3 WINDOWS ADMINISTRATOR LOG-IN

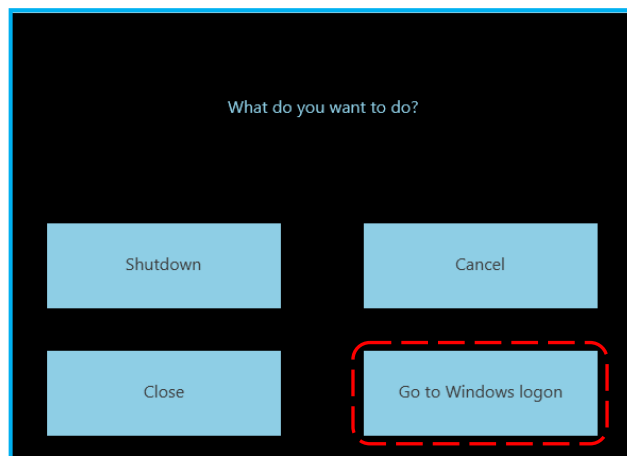
To set up the Windows operating system (or other applications on the PC) you need to log onto the PC as "Administrator".

To log in as **Windows ADMINISTRATOR**:

- Switch on the equipment and log in as administrator.
- From the Study list, select the Shutdown icon:

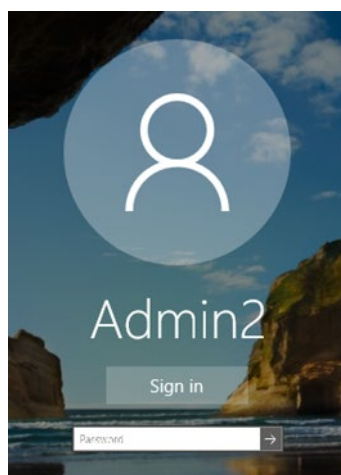


- Select the **Go to Windows Logon** command:



- The **SystemA DRF** application is now closed and Windows authentication screen is opened:

In the selection box select the user: **Admin2**, enter the corresponding password (**24060**) and confirm.



Note: Repeat the user selection procedure to return to the normal Operator mode, this time selecting:

- user: **operator**
- password: **operator**

5.4 ETHERNET SETUP

This procedure is only needed when the equipment is supplied with DICOM functions (optional). The video processor PC is supplied with the ETHERNET settings used in the factory.

The Responsible Organization is accountable for changing these to suit the network to which the EM equipment is connected.

Connecting the equipment to the IT-network, the Responsible Organization should also consider that:

- connection of the equipment to an IT-NETWORK that includes other equipment could result in previously unidentified risks to **patients, operators** or **third parties**;
- Subsequent changes to the IT-network could introduce new risks and require additional analysis; changes to the IT-network include:
 - changes in the IT-network configuration,
 - connection of additional items to the IT-network,
 - disconnecting items from the IT-network,
 - update of equipment connected to the IT-network,
 - upgrade of equipment connected to the IT-network.

Warning: The Responsible Organization should identify, analyze, evaluate and control these risks in compliance with **IEC 80001-1:2010** standard.

5.4.1 PHYSICAL CHARACTERISTICS OF THE NETWORK CONNECTIONS

Type of network connection:

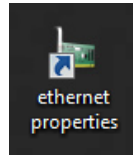
- Type: Ethernet 10/100/1000 Mbits - connector RJ45.
- Rate: Autosensing 10/100/1000 Mbits.

Note: The network cabling is that shown here:

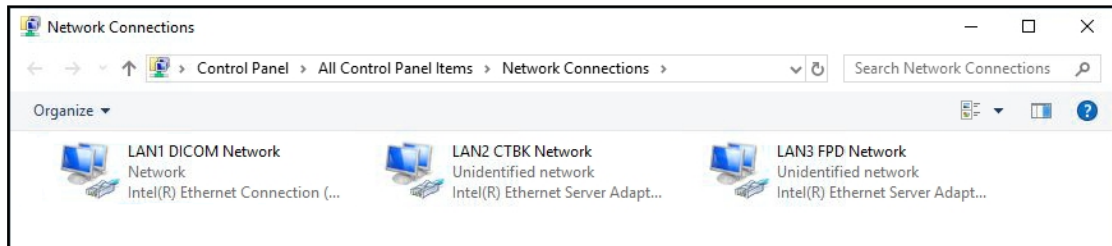
Connection between two points via RJ45 crossed cable.					HUB connection via RJ45 parallel cable.				
Name	NIC1		NIC2	Name	Name	Pin	Cable Colour	Pin	Name
TX+	1	---	3	RX+	TX+	1	White/Orange	1	TX+
TX-	2	---	6	RX-	TX-	2	Orange	2	TX-
RX+	3	---	1	TX+	RX+	3	White/Green	3	RX+
RX-	6	---	2	TX-		4	Green	4	
						5	White/Blue	5	
					RX-	6	Blue	6	RX-
						7	White/Brown	7	
						8	Brown	8	

5.4.2 WINDOWS SETTINGS

- Log in as **admin2** and then 'double click' on the desktop icon **Ethernet Properties:**



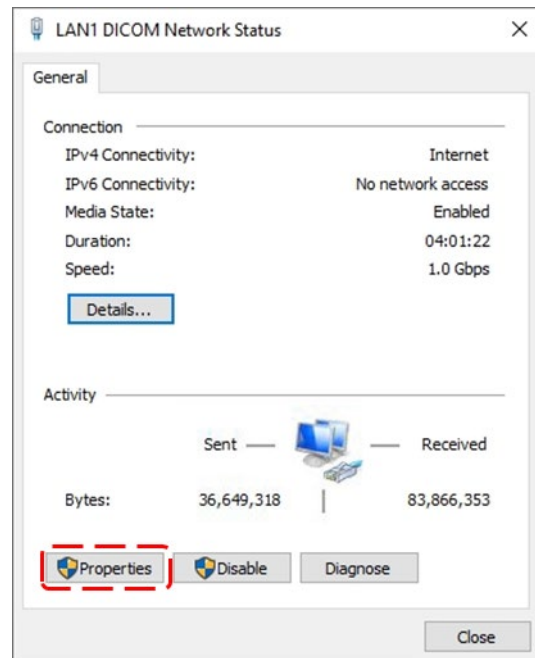
- The following frame appears:



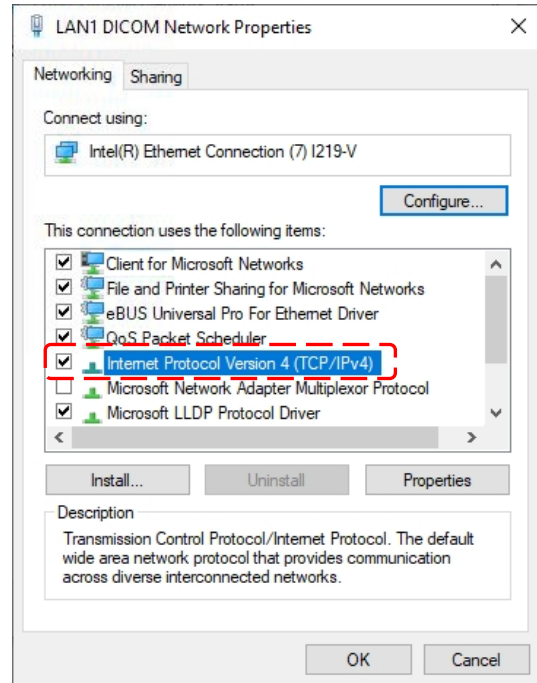
There are 3 network connections:

- **LAN1 DICOM Network** connecting the video processor with the Hospital local network
- **LAN2 CTBK Network** connecting the video processor to Main Controller board
- **LAN3 FPD Network** connecting the video processor to the detector

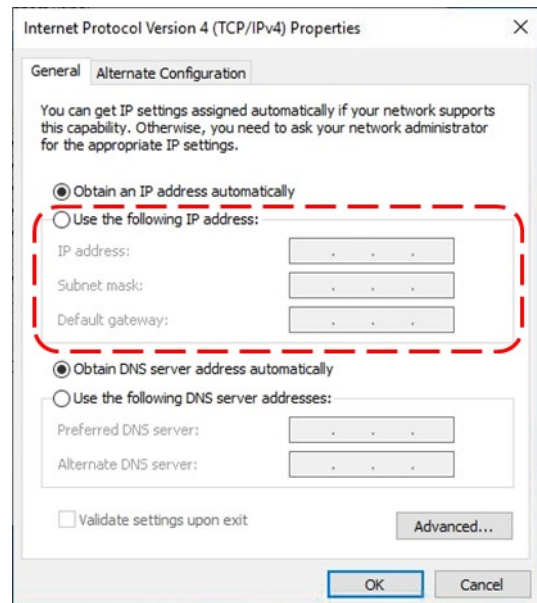
- The following frame appears when you select the **LAN1 DICOM Network:**



- The following frame appears when you select the **Properties** command:



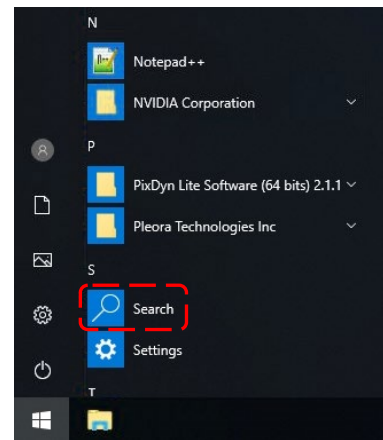
- The following frame appears when you select **Internet Protocol Version 4 (TCP/IPv4)**:
- Enter the **IP Address** and the **Subnet Mask** for the workstation in question, as agreed with the hospital network administrator.



5.4.3 NETWORK CONNECTIONS TEST

After entering and confirming the network settings, you must test the connections.

- To activate the DOS prompt:
 - select **Start > Search** in the applications bar.
 - enter "**cmd**" in the search box and then press **Enter**.



- At the DOS prompt, enter the **PING** command followed by the **IP Address** (provided by the network administrator) of another network device connected to the equipment. Then press **Enter**.
- If the screen that now appears shows **Reply** values of **<1ms**, the network settings are correct.

```
Command Prompt
Microsoft Windows XP [Version 5.1.2600]
(C) Copyright 1985-2001 Microsoft Corp.

C:\Documents and Settings\Administrator>ping 10.0.39.195

Pinging 10.0.39.195 with 32 bytes of data:

Reply from 10.0.39.195: bytes=32 time<1ms TTL=128
Reply from 10.0.39.195: bytes=32 time<1ms TTL=128
Reply from 10.0.39.195: bytes=32 time<1ms TTL=128
Reply from 10.0.39.195: bytes=32 time<1ms TTL=128

Ping statistics for 10.0.39.195:
    Packets: Sent = 4, Received = 4, Lost = 0 (0% loss),
    Approximate round trip times in milli-seconds:
        Minimum = 0ms, Maximum = 0ms, Average = 0ms

C:\Documents and Settings\Administrator>
```

- We recommend repeating the PING command for the other devices in the network.
- If, however, the error page below appears, there is a connection failure and so you need to check both the cable and the network settings.

```
Command Prompt
Microsoft Windows XP [Version 5.1.2600]
(C) Copyright 1985-2001 Microsoft Corp.

C:\Documents and Settings\Administrator>ping 10.0.39.182

Pinging 10.0.39.182 with 32 bytes of data:

Request timed out.
Request timed out.
Request timed out.
Request timed out.

Ping statistics for 10.0.39.182:
    Packets: Sent = 4, Received = 0, Lost = 4 (100% loss),

C:\Documents and Settings\Administrator>
```

- Close the DOS window after completing the test (exit).

5.5 ONLINE MANUALS

The User and Technical Manual for the EM equipment are provided on the monitor in **PDF** format:

- See paragraph 5.5.1 below for details on how to consult these.

5.5.1 HOW TO CONSULT THE MANUALS

- To consult the manuals, select the **user** icon from the Study List frame and then the relevant **manual** icon:

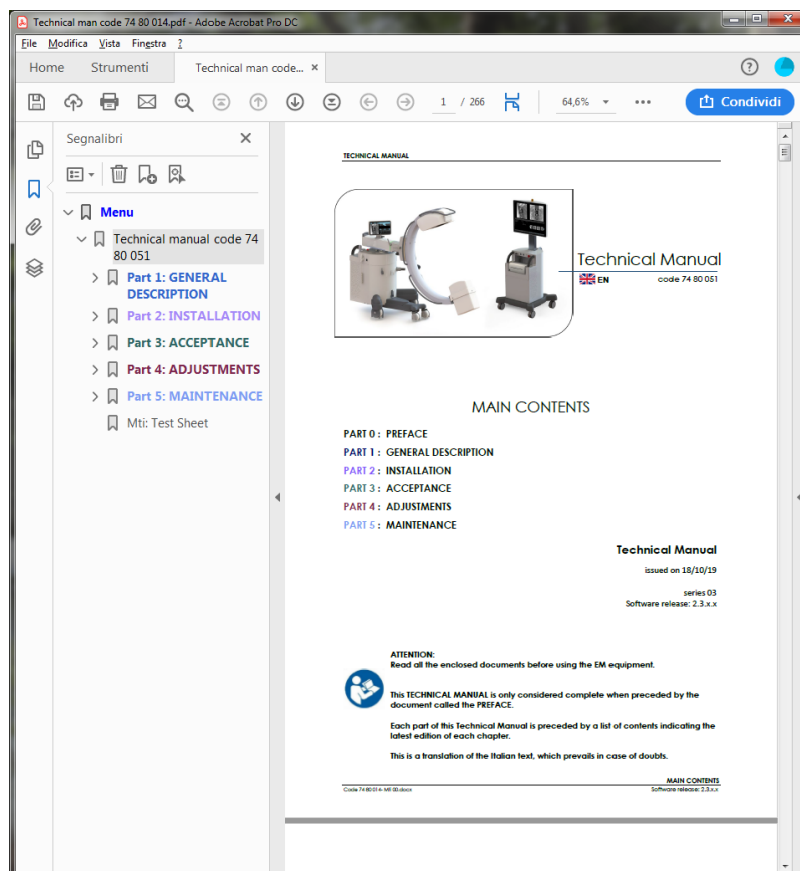


to consult the User Manual.



to consult the Technical Manual.

Both these commands cause the **Acrobat Reader** application to open and display the manual together with its list of contents (Bookmarks):



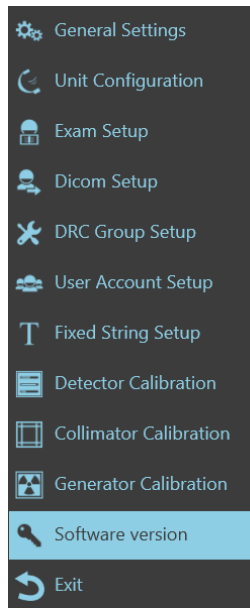
Note: For faster consultation, the list of contents has hyperlinks to each paragraph.

5.6 SOFTWARE VERSION

- To consult the list of SW versions (Administrator user only), select the **user** icon from the Study List frame and then the **setup** icon:



- Select **Software version** in the list of setups:



- The page showing the current SW release for the EM equipment appears:

The image shows a screenshot of the 'Software version' page. At the top, it says 'Software version' and 'VEN 20 SET 17:06'. Below is a table with two columns: 'Description' and 'Version'.

Description	Version
SYSTEMA DRF	2.2.0.19261
ControlPanel	2.2.0.19261
CTBK Protocol Version	1.0
CTBK Hardware Version	2.0
CTBK-FW Version	5.30
CTBK Hardware SN	CTBK-HW - 20kW - RTM70 - 230V
Inverter Version	2.3
Collimator Version	Fw 10.2
API OsVersion	Windows 10 Enterprise LTSC 2019, Version : 6.3 build 17763
API SwVersion	2.1.1
Detector DateCode	DC1707
Detector PartNumber	PN63116075A
Detector SerialNumber	17021G
Detector SwVersion	SW63118065A
PU BiosVersion	Not available
PU DateCode	Not available
PU GhostVersion	Not available
PU HwVersion	Not available
PU SerialNumber	Not available
PU SwVersion	Not available
Devert Connector Version	8.6.729.0
Leadtools Version	17.0.4.0
IPP Version	7.1.1 (r37466)
Cuda Runtime Version	9.0

5.7 VIDEO PROCESSOR BACK-UP

After installing the equipment, we recommend creating a back-up of the EM equipment setup and calibration data by saving a copy of the system hard disk:

- to a “back-up” USB PEN-DRIVE, to be kept by the technical service department.

A back-up guarantees fast recovery of the EM equipment functions and settings in the event of a hardware problem with the hard disk or corruption of the data held on the HD.

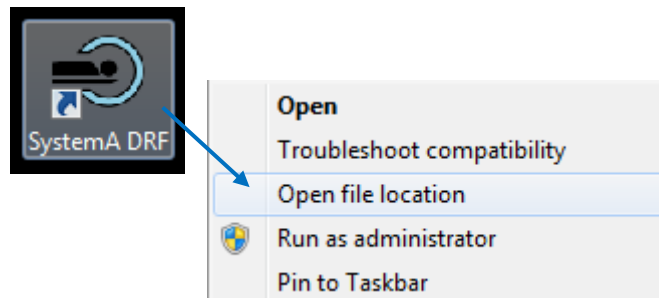
See Paragraph 6.1 in Part 5 of this manual for details of the back-up procedure.

5.8 CUSTOMIZE THE OPENING SCREEN LOGO

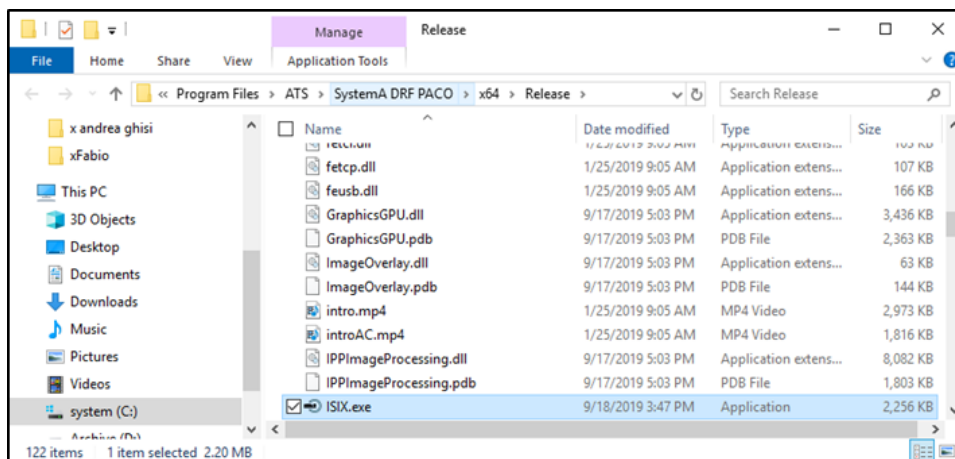
The equipment lets you customize the logo that will be shown once the program booted up, in the **Login** frame.

To change the logo, just follow the procedure below:

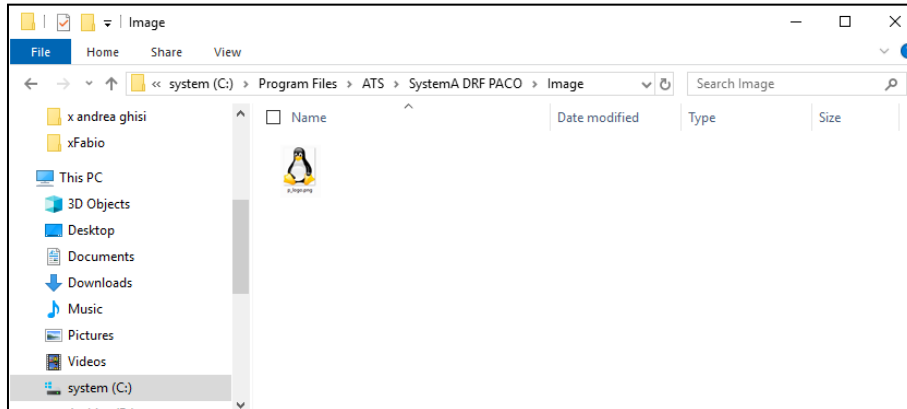
- Access the video processor operative system with **Administrator** privileges (see Paragraph 5.3 below).
- Choose an image and save it (**.png** format).
- From your desktop, using the right button of your mouse, click on **Systema DRF** icon and select **Open file location**.



- Go back to the **Systema DRF PACO** folder.



- Open the **Image** folder and import here the image previously saved. Rename your image: **p_logo**.



- Now, close the folder and restart the **Systema DRF** program. In the **login** screen, it is shown the new logo.

6 **ANNEXES B**

6.1 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 Rx, 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

Fase 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

Fase 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

Part 3: ACCEPTANCE

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1.2 Mechanical checks			
1.3 Electrical and efficiency checks			
1.4 Image quality check			
1.5 Test sheet			
2 <u>ANNEX: X-RAY DOSE AND IMAGE QUALITY CHECKS</u>	2.1 - 2.6	0	04/12/20
2.1 X-ray dose intensity in fluoroscopy mode			
2.2 Automatic dose control function			
2.3 Image quality			
2.3.1 Grey scale			
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2.3.3 Noise level			
2.3.4 Low contrast resolution			
2.4 Dose Area Product meter (DAP)			
2.5 Air Kerma and Air Kerma Rate indications			

1 ACCEPTANCE TEST

The acceptance test covers all the checks and tests listed in the TEST SHEET.

The various checks and tests described below are split into the following groups:

- Cable and connector checks.
- Mechanical checks.
- Electrical and functional checks.
- Image quality check.

Each operation is identified by a code, used in the TEST SHEET.

1.1 CABLE AND CONNECTOR CHECKS

Visually check each cable and connector for signs of damage or crushing:

CHECKS	CODE
Equipment power cable and connector.	A.1
Monitor unit/stand connection cable.	A.2
Stand cable sheath (C-arm connection).	A.3
X-ray footswitch cable and connector.	A.4
X-ray button cable.	A.5
Control panel connection cable sheath.	A.6

1.2 MECHANICAL CHECKS

Check:

- **Movement:** all movements must be smooth and easy.
- **Brakes:** brakes must be efficient and easy to engage/release.
- **Component fixing:** check for play, indicating loose screws (panels, monitors, X-ray warning light).
- **Safety devices:** check for breakage or dents that may affect the efficiency and/or safety of the equipment.

The various checks and tests are listed below:

CHECKS	CODE
C-arm orbiting.	B.1
C-arm orbiting brake.	B.2
C-arm rotation.	B.3
C-arm rotation brake.	B.4
Horizontal C-arm movement.	B.5
Horizontal C-arm movement brake.	B.6
C-arm angling (wig-wag).	B.7
C-arm angling brake.	B.8
Motorised up/down column movement.	B.9
Smooth movement of stand wheels on floors.	B.10
Parking brakes on stand wheels.	B.11
±90° rotation of rear stand wheels.	B.12
Smooth movement of monitor unit wheels on floors.	B.13
Parking brakes on monitor unit wheels.	B.14
Fixing of the monitors on the monitor unit.	B.15
Fixing of the covers on the monitor unit.	B.16
Fixing of the covers on the stand.	B.17
State of the monoblock.	B.18
State of the top cover on the monoblock.	B.19
State of the control panel.	B.20
State of the ON/OFF commands on the stand.	B.21
State of the Up/Down controls on the column.	B.22
State of the emergency switches on the stand and on the monitor unit.	B.23
State and efficiency of the general ON/OFF key switch on the monitor unit.	B.24
Vertical movement of the monitors.	B.25
Orientation of the monitors.	B.26
Smooth movement of the anti-scatter grid carriage.	B.27
State of the anti-scatter grid.	B.28

1.3 ELECTRICAL AND EFFICIENCY CHECKS

Check:

- **Safety devices**
- **Warnings**
- **Exposure functions**
- **Compliance with radiological parameters.**

The table below sets out the full procedure, with the individual checks that appear in the **Test Sheet**.

Operations	Code
- WITH THE EM EQUIPMENT SWITCHED OFF:	
Remove the cover on the stand and the front cover on the monitor unit.	
Check the general state of the monitor unit power unit components (dirt and corrosion).	C.1
Check the general state of the stand power unit components (dirt and corrosion).	C.2
- Return the covers. Connect the stand to the monitor unit, connect the Rx command footswitch and then connect the monitor unit to the electricity mains.	
- SWITCH THE MONITOR UNIT ON using the key switch.	
Check that the LED for the ON button on the stand lights up.	C.3
Check that the LOGIN page appears correctly on the Memory Monitor.	C.4
Log in and adjust the monitors as required.	C.5
- SWITCH THE STAND ON by touching the ON key.	
Check that the stand powers up correctly (indicated by a sequence of 4 beeps). The word READY should appear on the CONTROL PANEL, indicating that the equipment is ready to start acquiring images.	C.6
Use the PC Shutdown command on the Memory Monitor. Then use the emergency stop button on the monitor unit. Check that all equipment components switch off.	C.7
Reset the emergency button and then switch both the monitor unit and the stand on again.	
Check the smoothness of the up/down movement of the motorised column. Use all 4 stand column control keys to do this (on the right and the left).	C.8
Use the emergency stop buttons on the stand (on both the right and left) and check that all up/down movement of the motorised column actually stops.	C.9
Check the safety of the up/down movement of the motorised column (see paragraph 1.5.4 in Part 2 of the User Manual).	C.10
Select the DAILY TEST EXAM indicated in the TEST REPORT accompanying the equipment	
- Select Low Dose fluoroscopy with: collimator fully open, FPD max field (30x30 or 21x21) and automatic kV search. Place both the aluminium filters (21 mm and 10 mm thickness) provided with the EM equipment, in the path of the X-ray beam (resting on the X-ray monoblock). Give the X-ray emission command (using the footswitch and/or the button) and then check that:	
Both the X-ray warning light (on the monitor unit) and the LED (on the stand) light up.	C.11
The image appears on the Live Monitor together with the FLUOROSCOPY icon and that the correct exposure status and acquisition status are displayed.	C.12
The image appears on the Control Panel together with the word FLUOROSCOPY and the radiological parameters.	C.13
The kV on the display are the same (or within tolerance) as those indicated on the Test Report supplied with the equipment.	C.14
Correct positioning of the X-ray collimator on all FPD fields.	C.15
Check the DAP value displayed on the Live Monitor (see paragraph 1.5.2 in Part 2 of the User Manual).	C.16
<u>In standby</u> (using the collimator commands), check the virtual collimators (electronic shutters) are displayed correctly on the Control Panel and the Live Monitor.	C.17
Display on the Memory Monitor of an image saved to hard disk.	C.18

Operations	Code
- Select High Quality fluoroscopy with: collimator fully open, FPD max field (30x30 or 21x21) and automatic kV search. Place both the aluminium filters (21 mm and 10 mm thickness) provided with the EM equipment, in the path of the X-ray beam (resting on the X-ray monoblock). Give the X-ray emission command (using the footswitch and/or the button) and then check that:	
Both the X-ray warning light (on the monitor unit) and the LED (on the stand) light up.	C.19
The image appears on the Live Monitor together with the HQ FLUOROSCOPY icon and that the correct exposure status and acquisition status are displayed.	C.20
The image appears on the Control Panel together with the word HQ FLUOROSCOPY and the radiological parameters.	C.21
The kV on the display are the same (or within tolerance) as those indicated on the Test Report supplied with the equipment.	C.22
Check the DAP value displayed on the Live Monitor (see paragraph 1.5.2 in Part 2 of the User Manual).	C.23
- Select radiography mode:	
For version with 230 V AC power supply: Set 40 kV and 50 mAs .	
For version with 120 V AC power supply: Set 40 kV and 25 mAs .	
Give the X-ray emission command (with the X-ray button held down until end of exposure) and check that:	
Both the X-ray warning light (on the monitor unit) and the LED (on the stand) light up.	C.24
Indication of the radiography phases on the Control Panel: RAD PREPARATION, READY FOR RAD, RAD	C.25
The image appears on the Live Monitor together with the RADIOGRAPHY icon and that the correct exposure status and acquisition status are displayed.	C.26
For version with 230 V AC power supply: Verify the exposure time reported on the Control Panel: 770ms ($\pm 15\%$).	C.27
For version with 230 V AC power supply: Verify the exposure time reported on the Control Panel: 765ms ($\pm 15\%$).	
For version with 230 V AC power supply: Set 80 kV and 20 mAs .	
For version with 120 V AC power supply: Set 80 kV and 12.5 mAs .	
Give the X-ray emission command (with the X-ray button held down until end of exposure) and check that:	
For version with 230 V AC power supply: Verify the exposure time reported on the Control Panel: 570ms ($\pm 15\%$).	C.28
For version with 120 V AC power supply: Verify the exposure time reported on the Control Panel: 715ms ($\pm 15\%$).	
Check the DAP value displayed on the Live Monitor (see paragraph 1.5.2 in Part 2 of the User Manual).	C.29
<i>If the EM equipment uses the Laser Localizer (optional):</i>	
- Switch it on and check that:	
- the laser beam is centred on the monoblock cover.	C.30
<i>If the EM equipment uses the system printer (optional):</i>	
- Use the print command to get a printout of an image and check:	
- The quality of the printed image.	C.31

1.4 IMAGE QUALITY CHECK

The checks listed below let you assess the quality of the image in fluoroscopy mode. See the Annexes to this part of the manual for details on how to solve any problems.

Operations	Code
<p>X-ray dose intensity</p> <p>Reference value: The reference value for the X-ray dose in HQ fluoroscopy mode is 24 nGy at a frame rate of 15 fps (360 nGy/s);</p> <p>These values are measured on the surface of the FPD under these conditions:</p> <ul style="list-style-type: none"> - No anti-scatter grid - 21mm Al X-ray beam filter on the monoblock. <p>Procedure: See Annex 2.1 in this part of the manual.</p>	D.1
<p>Automatic X-ray dose control</p> <p>Reference value: Adjustment of the radiological parameters (kV and/or mA) must be fast, progressive and repeatable.</p> <p>Procedure: See Annex 2.2 in this part of the manual.</p>	D.2
<p>Grey scale.</p> <p>Reference value: The manufacturer uses a "LEEDS Test GS 2" phantom to assess this parameter. All grey levels must be legible on the monitor.</p> <p>Procedure: See Annex 2.3 in this part of the manual.</p>	D.3
<p>Spatial resolution.</p> <p>Reference value: The manufacturer uses an "18-inch FUNK Resolution Test" phantom to assess this parameter. Check that the values obtained during the test are close to those indicated in the Test Report accompanying to the equipment.</p> <p>Procedure: See Annex 2.4 in this part of the manual.</p>	D.4
<p>Noise level</p> <p>Reference value: The manufacturer uses a "LEEDS Test N3" phantom to assess this parameter. The manufacturer accepts noise levels that allow for "reading" of targets with a minimum contrast percentage of no more than 2%.</p> <p>Procedure: See Annex 2.7 in this part of the manual.</p>	D.5
<p>Min contrast.</p> <p>Reference value: The manufacturer uses a "Nuclear Associates model 07-645" phantom to assess this parameter. The manufacturer accepts a minimum contrast percentage of no more than 3.5%.</p> <p>Procedure: See Annex 2.8 in this part of the manual.</p>	D.6

1.5 TEST SHEET

In addition to during acceptance, the Test Sheet should be filled in by the person responsible for the equipment:

- during routine maintenance,
- after all extraordinary maintenance.

A "blank" copy of the acceptance test is attached to this manual as one of the "loose pages".

The various controls and checks are identified by an alphanumerical code, which refers to the paragraphs above, listing the operations with a brief description.

Code	Operation	Notes	Results
A.1	Mains power cable and connector.		
A.2	Monitor unit / stand cable and connector.		
A.3	Stand cable sheath.		
A.4	Footswitch cable and connector.		
A.5	X-ray emission command button cable.		
A.6	PC connection sheath.		
B.1	C-arm orbiting.		
B.2	C-arm orbiting brake.		
B.3	C-arm rotation.		
B.4	C-arm rotation brake.		
B.5	Horizontal C-arm movement.		
B.6	Horizontal C-arm movement brake.		
B.7	C-arm angling ("wig-wag").		
B.8	C-arm angling brake.		
B.9	Up/down column movement.		
B.10	Smooth movement of stand wheels.		
B.11	Stand parking brake.		
B.12	±90° rotation of stand wheels.		
B.13	Smooth movement of monitor unit wheels.		
B.14	Monitor unit wheel brakes.		
B.15	Fixing of the monitors.		
B.16	Fixing of the cover on the monitor unit.		
B.17	Fixing of the covers on the stand.		
B.18	State of the monoblock.		
B.19	State of the monoblock cover.		
B.20	State of the control panel on the stand.		
B.21	State of the ON/OFF controls on the stand.		
B.22	State of the up/down column commands.		
B.23	State of the emergency stop buttons.		
B.24	General ON/OFF key switch.		
B.25	Vertical movement of the 2 monitors on the monitor unit.		
B.26	Orientation of the monitors on the monitor unit.		
B.27	Smooth movement of the anti-scatter grid carriage.		
B.28	State of the anti-scatter grid.		
C.1	Monitor unit power supply unit.		
C.2	Stand boards.		
C.3	Stand ON		

Code	Operation	Notes	Results
C.4	LOGIN page.		
C.5	Log-in and monitor adjustments.		
C.6	Automatic stand initialising test.		
C.7	Emergency stop button on the monitor unit.		
C.8	Stand column movement.		
C.9	Emergency stop buttons on the stand.		
C.10	Stand column movement safety.		
C.11	X-ray warning light and LEDs – Low Dose fluoroscopy.		
C.12	Image + indicators on monitors – Low Dose fluoroscopy.		
C.13	Image + indicators on stand – Low Dose fluoroscopy.		
C.14	Correct automatic kV search.		
C.15	Collimator iris and shutters.		
C.16	DAP value.		
C.17	Indication of virtual collimators on the monitors.		
C.18	Saving of images to HD and transfer to Memory Monitor.		
C.19	X-ray warning light and LEDs – High Quality fluoroscopy.		
C.20	Image + indicators on monitors – High Quality fluoroscopy		
C.21	Image + indicators on stand – High Quality fluoroscopy.		
C.22	Correct automatic kV search.		
C.23	DAP value.		
C.24	X-ray warning light and LEDs – radiography.		
C.25	Image + indicators on monitors – radiography.		
C.26	Image + indicators on stand – radiography.		
C.27	230 V AC power supply: Radiography time for 40 kV, 50 mAs	Limits: 654 ÷ 885 ms	
	120 V AC power supply: Radiography time for 40 kV, 25 mAs	Limits: 650 ÷ 880 ms	
C.28	230 V AC power supply: Radiography time for 80 kV, 20 mAs	Limits: 485 ÷ 655 ms	
	120 V AC power supply: Radiography time for 80 kV, 12.5 mAs	Limits: 608 ÷ 822 ms	
C.29	DAP value.		
C.30	Centring of Laser Localizer (<i>optional</i>)		
C.31	Video printer (<i>optional</i>)		
D.1	X-ray dose intensity.		
D.2	Automatic X-ray dose control.		
D.3	Grey scale.		
D.4	Spatial resolution.		
D.5	Noise level.		
D.6	Min contrast.		

2 ANNEX: X-RAY DOSE AND IMAGE QUALITY CHECKS

2.1 X-RAY DOSE INTENSITY IN FLUOROSCOPY MODE

During installation, the EM equipment can be configured to work with different X-ray doses to suit specific exam types.

Below are details of the measuring conditions and the typical dose rates used in the factory to assess the quality of the images.

Low Dose fluoroscopy: 12nGy/i

High Quality fluoroscopy: 24nGy/i

Measuring conditions:

- X-ray beam filtering with a **2mm copper filter** on the X-ray monoblock.
- X-ray dose measured on the front surface of the FPD (**no grid**).
- Select exam **DAILY TEST**.



Procedure:

- Set **Low Dose** or **High-Quality** fluoroscopy with automatic dose control,
- Give the X-ray emission command and wait for the control to stabilize kV and mA values.
- Make sure the measured dose is $\pm 20\%$ the expected value.

LOW DOSE FLUOROSCOPY, FIELD 21 x 21cm² or 30 x 30cm²

CONDITIONS	DETECTED DOSE	kV / mA _{avg} (@ 15 fps)
Additional filter on X-ray collimator: 1mm Al + 0.2mmCu	12 nGy/i	62 / 4.0

HIGH QUALITY FLUOROSCOPY, FIELD 21 x 21cm² or 30 x 30cm²

CONDITIONS	DETECTED DOSE	kV / mA _{avg} (@ 15 fps)
Additional filter on X-ray collimator: 1mm Al + 0.2mmCu	24 nGy/i	63 / 8.5

2.2 AUTOMATIC X-RAY DOSE CONTROL FUNCTION

After checking the dose used as described in the previous paragraph, you need to make sure that the automatic adjustment of the radiological parameters (kV and mA) is quick and repeatable.

Conditions:

- Fluoroscopy with automatic X-ray dose control,
- Flat Panel Detector nominal field (30x30 or 21x21 cm),
- X-ray beam filtered using a 2mm copper filter on the X-ray monoblock.

Procedure:

- Manually set 90 kV and give the X-ray command at **4 fps**.
Check that the equipment automatically adjusts the kV to the value shown in the previous paragraph (tolerance: ± 1 kV) within 1 second and without oscillation.
- Set 40kV and give the X-ray command at **4 fps**.
Check that the equipment automatically adjusts the kV to the value shown in the previous paragraph (tolerance: ± 1 kV) within 1 second and without oscillation.

2.3 IMAGE QUALITY

Below are the tests and conditions used to check the image quality.
The results for each EM equipment are provided in the corresponding **Test Report** (attached).

2.3.1 GREY SCALE

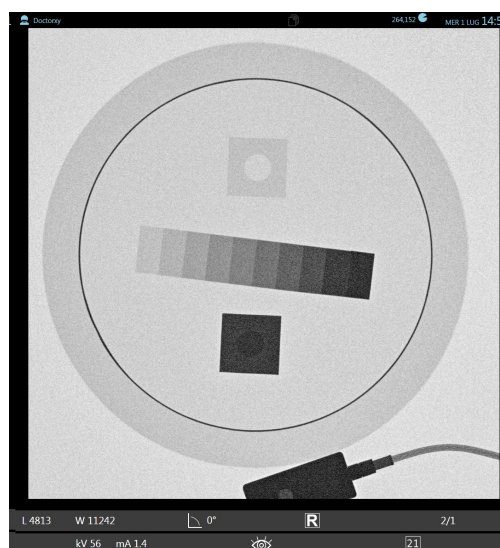
The grey scale is checked using a UNIVERSITY OF LEEDS Test GS2 phantom:

Measuring conditions:

- DAILY TEST indicated in the Test Report supplied with the equipment.
- 1 mm copper filter on the X-ray monoblock.
- LEEDS Test GS2 phantom on the face of the FPD.
- Flat Panel Detector nominal field (30x30 or 21x21).
- Frame Rate: 4 fps
- Automatic X-ray dose control.

Procedure:

Acquire images in **Low Dose** or **High-Quality** fluoroscopy and check that all grey levels of the phantom are visible on the monitor.



GS2
test object

2.3.2 SPATIAL RESOLUTION

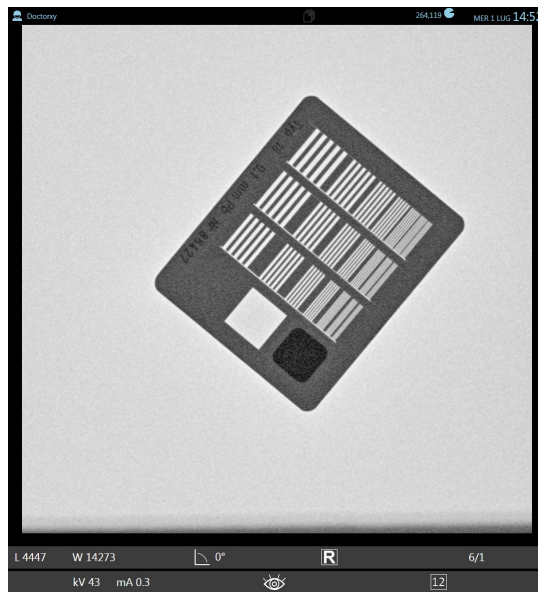
Spatial resolution is measured with:

- **FUNK type 18** resolution test, (or equivalent) at 45° on the FPD (as shown in the figure below).

Measuring conditions:

- DAILY TEST indicated in the Test Report supplied with the equipment.
- No X-ray beam filtering (use only the collimator filter already set for the exam).
- Frame Rate: **4 fps**.
- Automatic X-ray dose control.

Acquire images in Fluoroscopy (LD and HQ) and Radiography modes and read the number of pair of lines on the monitor.



Resolution Type 18
test object

The table below shows the **typical values**, for **Low Dose** fluoroscopy, **High Quality** fluoroscopy and **Radiography**.

Field size	Low Dose (lp/mm)	High Quality (lp/mm)	Grafia (lp/mm)
30x30	1,8	1,8	2,0
21x21	2,24	2,5	
16x16	2,5	3,15	/
12x12			/

Note: Check that the values are close to those indicated in the Test Report attached to the equipment.

2.3.3 NOISE LEVEL

The noise level is checked using the LEEDS Test N3 phantom.

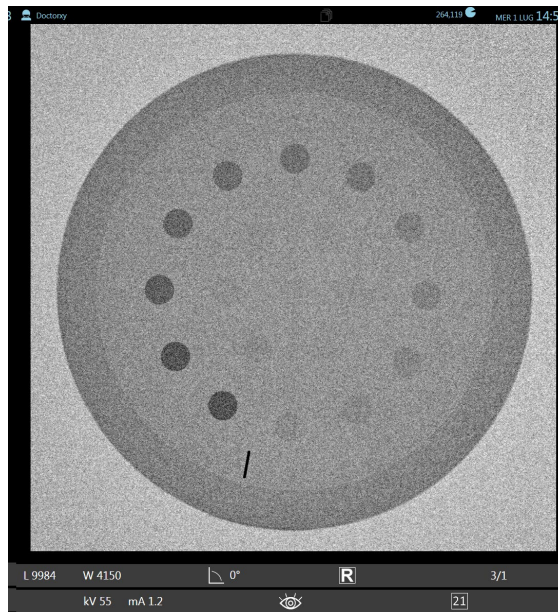
[This test is based on the use of a phantom with 19 circular targets having the same diameter, but different contrast: the lowest contrast target visible indicates the actual noise level.]

Measuring conditions:

- DAILY TEST indicated in the Test Report supplied with the equipment.
- 1 mm copper filter on the X-ray monoblock.
- LEEDS Test N3 phantom on the face of the FPD.
- Detector field: **21x21**
- Frame rate: **4 fps.**
- Automatic X-ray dose control.

Procedure:

- Acquire images in **Low Dose** and **High-Quality** fluoroscopy.
- Count how many targets are clearly visible on the monitor.



N3
test object

The table below shows the typical values for the two acquisition modes.

Mode	N° targets
LD fluoroscopy	12
HQ fluoroscopy	13

Note: Check that the values are close to those indicated in the Test Report attached to the equipment.

2.3.4 LOW CONTRAST RESOLUTION

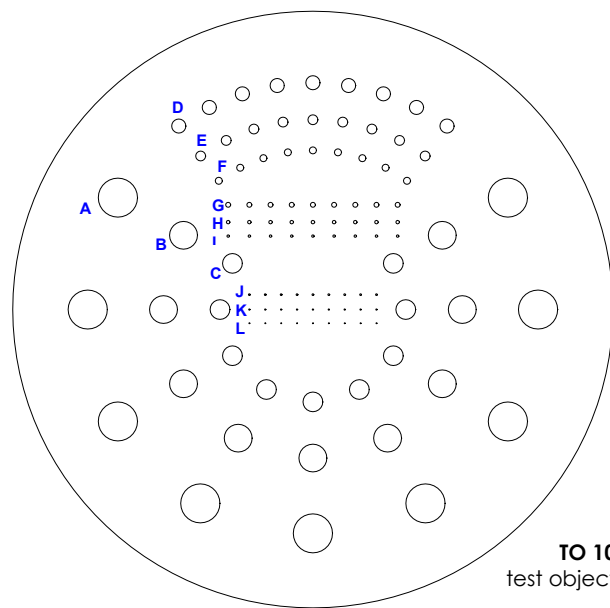
The low contrast resolution is checked using the LEEDS Test TO10 phantom.

Measuring conditions:

- DAILY TEST indicated in the Test Report supplied with the equipment.
- 1 mm copper filter on the X-ray monoblock.
- LEEDS Test TO10 phantom on the face of the FPD.
- Detector field: **21x21**
- Frame rate: **4 fps.**
- Automatic X-ray dose control.

Procedure:

- Acquire images in **Low Dose** and **High-Quality** fluoroscopy and establish how many details are clearly visible (each series, indicated by a letter, has 9 details).



Series	Visible details (typical values)	
	LD fluoroscopy	HQ fluoroscopy
A	8	8
B	7	8
C	6	7
D	8	8
E	7	8
F	6	7
G	7	8
H	6	7
I	6	7
J	6	6
K	4	5
L	3	3

2.4 DOSE AREA PRODUCT METER (DAP)

See paragraph 2.1.4.1 in Part 4 of this Manual.

2.5 AIR KERMA AND AIR KERMA RATE INDICATIONS

See paragraph 2.1.4.2 in Part 4 of this Manual.

Part 4: ADJUSTMENTS

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1 GENERAL INFORMATION

1.1 INTRODUCTION



The EM equipment is fully adjusted in the factory.

During its installation, the equipment simply needs to be setup, as described in Chapter 4 in Part 2 above.

The information given in this section of the manual is needed to adjust/calibrate the equipment during routine maintenance or after replacing components.

The following abbreviations will be used, where possible, in this manual for the electronic boards:

Stand boards:	CTBK-HW 00 board	=	B1
	ASAC 01 board	=	B2
X-ray generator board:	S219	=	S219
Monitor unit board:	ASPS 01 board	=	B20
Infrared remote control board:	CTIR-HW 00 board	=	B22

There are basically six areas of adjustment/calibration:

- Adjusting the X-ray generator (see *Paragraph 2.1*).
- Adjusting the X-ray collimator (see *Paragraph 2.2*).
- Adjusting the laser beam centring devices (see *Paragraph 2.3*).
- Adjusting the up/down column movement (see *Paragraph 2.4*).
- Adjusting the monitors (see *Paragraph 2.5*).
- Calibration of the Flat Panel Detector (see *chapter 3*).

2 ADJUSTMENTS

2.1 ADJUSTING THE X-RAY GENERATOR

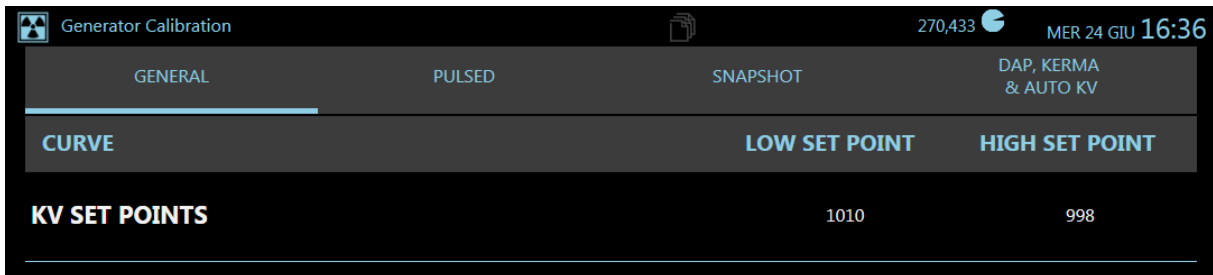
The procedure for adjusting the X-RAY GENERATOR is split into the following menus:



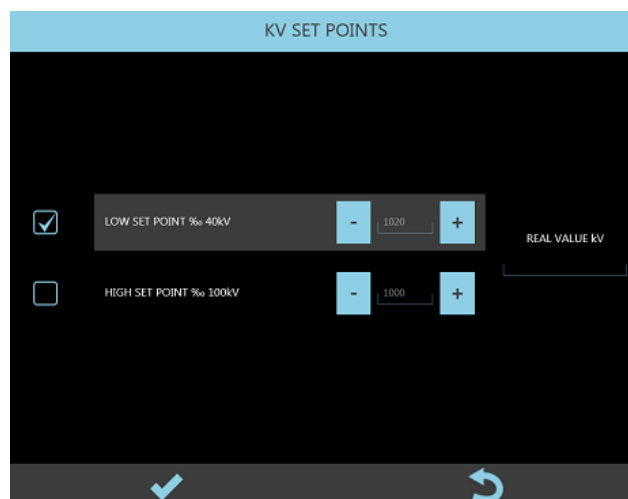
- **General:** calibration of the **set kV** parameter,
- **Pulsed:** calibration of the **filament current** in Fluoroscopy mode,
- **Snapshot:** calibration of the **filament current** in Digital Radiography mode,
- **DAP, Kerma & Auto kV:** calibration of the **DAP** and the **Air-Kerma** values and setting of the **automatic kV adjustment** parameters.

2.1.1 GENERAL

This menu lets you set the percentage of correction for the **set kV** value sent to the X-RAY GENERATOR, so that the actual kV value matches the set value.



To calibrate the **Set kV**, 'double touch' the **kV SET POINTS** field. The following panel opens:



Calibration of the **Set kV** involves setting two kV values:

- LOW SET POINT: 40kV
- HIGH SET POINT: 100kV

You can change the SET POINTS within the range 80‰ (800%) and 120‰(1200‰).
1000 ‰ = no correction; in this case, the nominal value of the **Set kV** is sent 'as is' to the X-ray generator.

To calibrate:

- 1) Select **LOW SET POINT ‰ 40 kV**:
the equipment automatically sets **HQ Fluoroscopy, 40 kV** and **15 FPS**.
- 2) Give the X-ray command and read the value shown in the **Real Value kV** field, on the right.
- 3) If this reading is other than the set value ± 1 kV, you need to correct the **LOW SET POINT ‰ 40 kV** parameter proportionally.

For example:

- Read kV = 42 kV
- Current LOW SET POINT ‰ 40 kV = 1000
- Lower the LOW SET POINT ‰ to $(40/42) * 1000 = 952$

- 4) Select **HIGH SET POINT ‰ 100 kV**:
the equipment automatically sets **HQ Fluoroscopy, 100 kV** and **15 FPS**.
- 5) Give the X-ray command and read the value shown in the **Real Value kV** field, on the right.
- 6) If this reading is other than the set value ± 1 kV, you need to correct the **HIGH SET POINT ‰ 100 kV** parameter proportionally.

For example:

- kV reading = 95 kV.
- Actual HIGH SET POINT ‰ = 1000
- Increase HIGH SET POINT ‰ to $(100/95) * 1000 = 1052$

2.1.2 PULSED

The EM equipment uses the following mA curves in FLUOROSCOPY modes (see table below).

5 kW version

mA curve	FOCUS	mA RANGE / SET POINT	NOTES
PULSED CURVE 1: SF 0.4 – 10mA	Small	40kV - 0.4mA / low set point	
		70kV - 10mA /high set point	
PULSED CURVE 2: SF 1.6 – 40mA	Small	40kV - 1.6mA / low set point	
		70kV - 40mA /high set point	
PULSED CURVE 3: LF 0.4 – 10mA	Large	40kV - 0.4mA / low set point	
		70kV - 10mA /high set point	
PULSED CURVE 4: LF 1.6 – 40mA	Large	40kV - 1.6mA / low set point	
		70kV - 40mA /high set point	

20 kW version only.

mA curve	FOCUS	mA RANGE / SET POINT	NOTES
PULSED CURVE 5: LF 4 – 100mA	Large	40kV - 4mA / low set point	
		70kV - 100mA /high set point	

The PULSED menu lets you calibrate each mA curve.

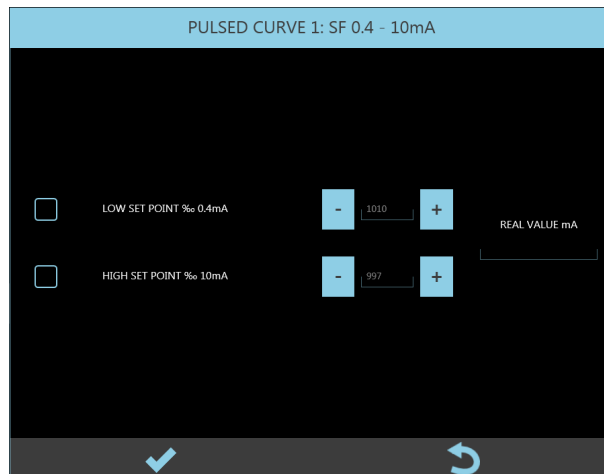
CURVE	LOW SET POINT	HIGH SET POINT
PULSED CURVE 1: SF 0.4 - 10mA	995	977
PULSED CURVE 2: SF 1.6 - 40mA	1028	992
PULSED CURVE 3: LF 0.4 - 10mA	995	998
PULSED CURVE 4: LF 1.6 - 40mA	995	976
PULSED CURVE 5: LF 4 - 100mA	1000	994

Calibration of a mA curve involves adjusting the filament current at 2 points in the curve (LOW SETPOINT and HIGH SETPOINT) to get the required mA value.

For example, the values of the 2 setpoints in the case of **PULSED CURVE 1** are:

- 40 kV – 0.4 mA,
- 70 kV – 10 mA.

Select the curve you want to calibrate by 'double touching' (tapping) the relevant field (e.g. **PULSED CURVE 1: ...**). The following menu opens:



Adjust the setpoints, from 80% (800‰) to 120% (1200‰) of the nominal value, to correct the filament current in order to get the mA value envisaged for the setpoint.

1000‰ means no correction.

For example, in the case of **PULSED CURVE 1**:

- 1) Select **"LOW SET POINT % 0.4mA"**:
The equipment automatically sets **HQ Fluoroscopy, 40 kV** and **15 FPS**.
- 2) Command x-ray emission and read the value shown in the **Real Value mA** field, on the right.
- 3) No calibration is required if this value matches the expected value: **0.4 mA (± 5%)**.

Otherwise:

- If the REAL VALUE mA is lower than expected: increase the LOW SET POINT % 0.4 mA,
- If the REAL VALUE mA is higher than expected: reduce the LOW SET POINT % 0.4 mA.

- 4) Select **HIGH SET POINT % 10 mA**:
The equipment automatically sets **HQ Fluoroscopy, 70 kV** and **15 FPS**.
- 5) Command x-ray emission and read the value shown in the **Real Value mA** field, on the right.
- 6) No calibration is required if this value matches the expected value: **10 mA (± 5%)**.

Otherwise:

- If the REAL VALUE mA is lower than expected: increase the HIGH SET POINT % 10mA,
- If the REAL VALUE mA is higher than expected: reduce the HIGH SET POINT % 10mA.

Repeat this procedure for each mA curve foreseen by the equipment (see table above).

2.1.3 DIGITAL RADIOGRAPHY (SNAPSHOT)

The equipment uses the mA curves shown in the table below for X-ray emissions in RADIOGRAPHY mode.

5 kW version

mA curve	FOCUS	mA RANGE / SET POINT	NOTES
RAD CURVE 1: SF 100kV – 28mA	Small	40kV - 65mA / low set point	Isowatt power = 2.8 kW
		100kV - 28mA /high set point	
RAD CURVE 2: SF 100kV – 40mA	Small	40kV - 100mA / low set point	For exposure times with Joule < 1000 Isowatt power = 4kW (with Joule > 1000 RAD CURVE 1 is automatically selected)
		100kV - 40mA /high set point	
RAD CURVE 3: LF 100kV – 28mA	Large	40kV - 65mA / low set point	Isowatt power = 2.8 kW
		100kV - 28mA /high set point	
RAD CURVE 4: LF 100kV – 40mA	Large	40kV - 100mA / low set point	For exposure times with Joule < 1000 Isowatt power = 4kW (with Joule > 1000 RAD CURVE 3 is automatically selected)
		100kV - 40mA /high set point	

Furthermore, for 20 kW version only.

mA curve	FOCUS	mA RANGE / SET POINT	NOTES
RAD CURVE 5: LF 100kV – 200mA	Large	40kV - 65mA / low set point	For exposure times with Joule < 500 Power = 2,6kW ÷ 20kW (with Joule > 1000 RAD CURVE 4 is automatically selected)
		100kV - 200mA /high set point	

The SNAPSHOT menu lets you calibrate each mA curve.

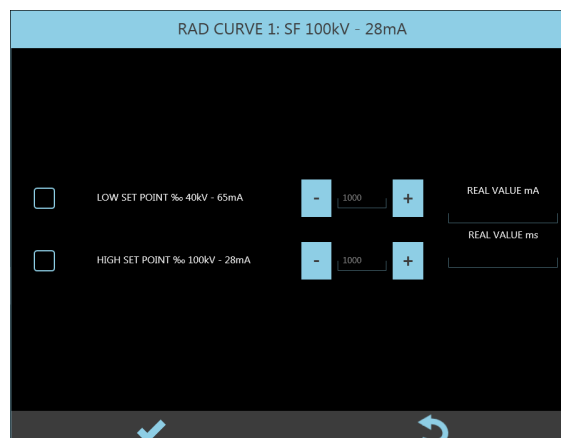
CURVE	LOW SET POINT	HIGH SET POINT
RAD CURVE 1: SF 100kV - 28mA	999	988
RAD CURVE 2: SF 100kV - 40mA	998	979
RAD CURVE 3: LF 100kV - 28mA	1005	1003
RAD CURVE 4: LF 100kV - 40mA	965	970
RAD CURVE 5: LF 100kV - 200mA	1004	1020

As for X-ray emissions in fluoroscopy modes, calibration of a mA curve involves adjusting the filament current at 2 points in the curve (LOW SETPOINT and HIGH SETPOINT) to get the required mA value.

For example, the values of the 2 setpoints in the case of **RAD CURVE 1** are:

- 40 kV – 65 mA,
- 100 kV – 28 mA.

Select the curve you want to calibrate by 'double touching' (tapping) the relevant field (e.g. **RAD CURVE 1: ...**). The following menu opens:



Adjust the setpoints, from 80% (800‰) to 120% (1200‰) of the nominal value, to correct the filament current and so get the mA envisaged for the setpoint.

1000‰ means no correction.

For example, in the case of **RAD CURVE 1**:

- 1) Select **LOW SET POINT ‰ 40 kV – 65 mA**.
The equipment automatically sets an exposure at **40 kV** and **5 mAs**.
- 2) Give the RAD exposure command and read the value shown in the **Real Value mA** field, on the right.
- 3) No calibration is required if the Real Value mA matches the expected value: **65 mA (± 5%)**.

Otherwise:

- If the REAL VALUE mA is lower than expected: increase the LOW SET POINT parameter.
- If the REAL VALUE mA is higher than expected: reduce the LOW SET POINT parameter.

- 4) Select **HIGH SET POINT ‰ 100 kV – 28 mA**.
The equipment automatically sets an exposure at **100 kV** and **5 mAs**.
- 5) Give the RAD exposure command and read the value shown in the **Real Value mA** field, on the right.
- 6) No calibration is required if the REAL VALUE mA matches the expected value: **28 mA (± 5%)**.

Otherwise:

- If the REAL VALUE mA is lower than expected: increase the HIGH SET POINT parameter,
- If the REAL VALUE mA is higher than expected: reduce the HIGH SET POINT parameter.

➤ **Note:** After exposure, check that:

$$\mathbf{REAL\ VALUE\ mA * REAL\ VALUE\ ms = 5mAs (\pm 5\%).}$$

Repeat this procedure for each mA curve foreseen by the equipment (see table below).

2.1.4 DAP, AIR-KERMA & AUTO kV

This menu lets you:

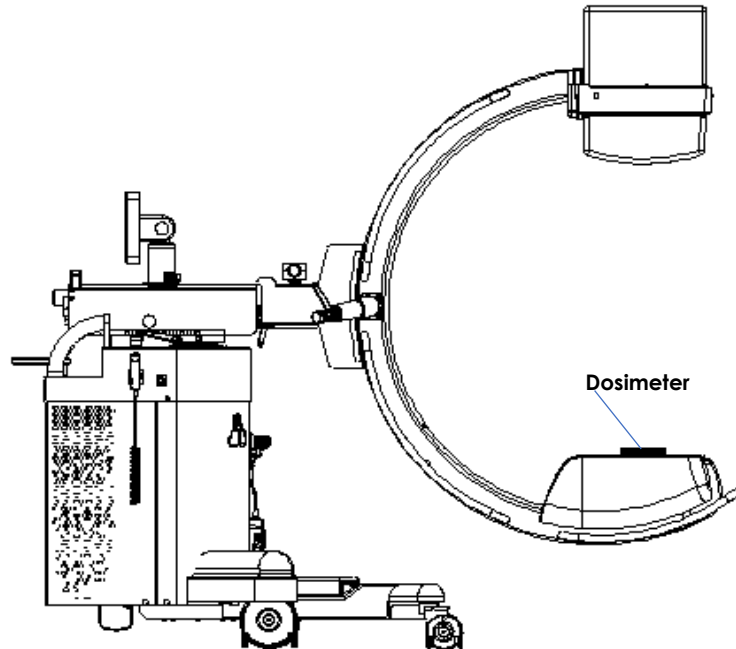
- Calibrate the value of the DOSE AREA PRODUCT received from the DAP meter.
- Calibrate the value of the AIR-KERMA calculated by the system.
- Calibrate the automatic kV control.

The screenshot shows a mobile application interface for 'Generator Calibration'. At the top, there are four tabs: 'GENERAL', 'PULSED', 'SNAPSHOT', and 'DAP, KERMA & AUTO kV'. The 'DAP, KERMA & AUTO kV' tab is selected. Below the tabs is a table with two columns: 'CALIBRATION ITEM' and 'CURRENT VALUE'. The table lists several calibration items with their corresponding values.

CALIBRATION ITEM	CURRENT VALUE
DAP CALIBRATION FACTOR ‰	1000
KERMA CALIBRATION FACTOR ‰	1000
DOSE % FOR kV +++	20
DOSE % FOR kV ++	30
DOSE % FOR kV +	50
DOSE % FOR kV -	200
DOSE % FOR kV --	500
DOSE % FOR kV ---	1000
% HISTERESYS	19

2.1.4.1 DAP CALIBRATION FACTOR

The **Dose Area Product** meter (**DAP**) is checked by comparing the indication on the Live Monitor against that calculated using an external reference dosimeter.



To do this:

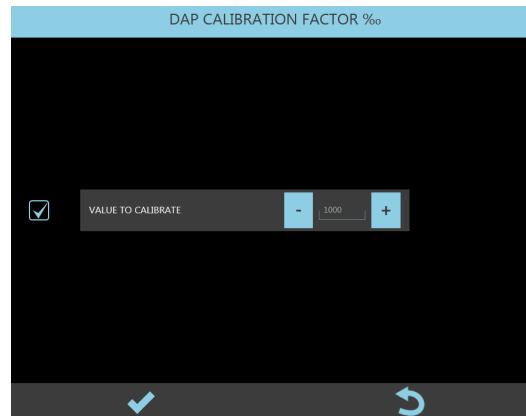
- 1) In General Setup menu, set **mGy*cm²** as the dose unit of measurement (see Paragraph 4.2, Part 2 of this Manual).
- 2) Place an external dosimeter on the **detector**, and then set it for readings in **mGy**.
- 3) Open a new study, select **HQ Fluoroscopy**, **acquisition rate: 8 fps**, **detector field zoom: 16**.
- 4) Set **60 kV** and **Manual dose control**.
- 5) Give the fluoroscopy command for about 10-15 seconds and make a note of the reading on the dosimeter.
- 6) Multiply the dosimeter reading (**mGy**) by the value of the sensitive area: since it has been set FPD field: 16, the area is 16cm * 16cm = **256cm²**.
- 7) Calculate the ratio **R** between the value of the read "**dose x area**" and that shown on the Live Monitor.

Example:

- dosimeter sensitive area:	256 cm ²
- dosimeter reading:	0.253 mGy
- calculated dose*area:	0.253 mGy x 256 cm ² = 64.8 mGy x cm²
- Live Monitor reading:	61 mGy x cm²

- ratio between the 2 values: **R = calculated value / monitor value = 1.06**

- 8) Open Setup and select **Generator Calibration** menu; open **Dap, Kerma and Auto kV** sub-menu and select **DAP CALIBRATION FACTOR** (tap on this option). The following panel appears:



- 9) Calculate:

- New DAP CALIBRATION FACTOR = actual CALIBRATION FACTOR * **R**.

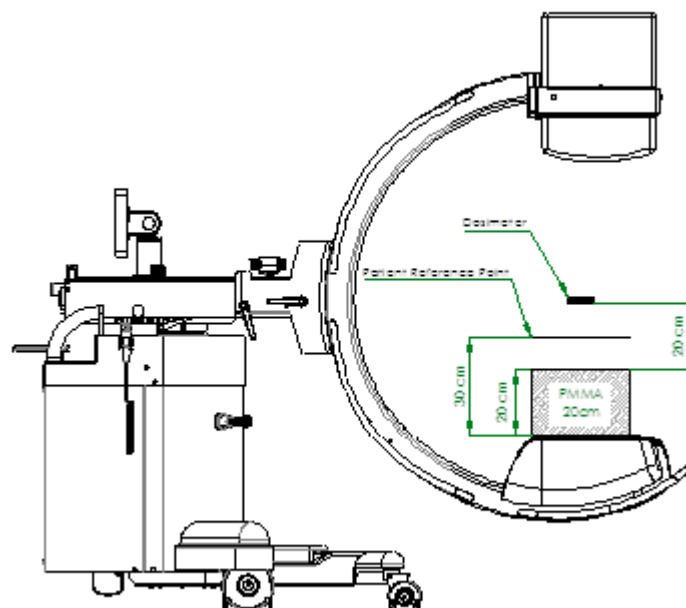
Note: The DAP CALIBRATION FACTOR settings range is 500 - 1500‰.

2.1.4.2 AIR-KERMA RATE CALIBRATION FACTOR

The AIR-KERMA RATE is checked by comparing the AIR-KERMA RATE shown on the Live Monitor against that read by a reference dosimeter placed at the PATIENT ENTRY REFERENCE POINT.

The PATIENT ENTRY REFERENCE POINT is on the X-ray axis, 30 cm from the detector, using the measuring conditions specified by standard EN 60601-2-54 (paragraph 203.6.3.102), as shown in the figure below.

Standard EN 60601-2-54 (203.5.2.4.5.101) foresees a display tolerance of 50%.



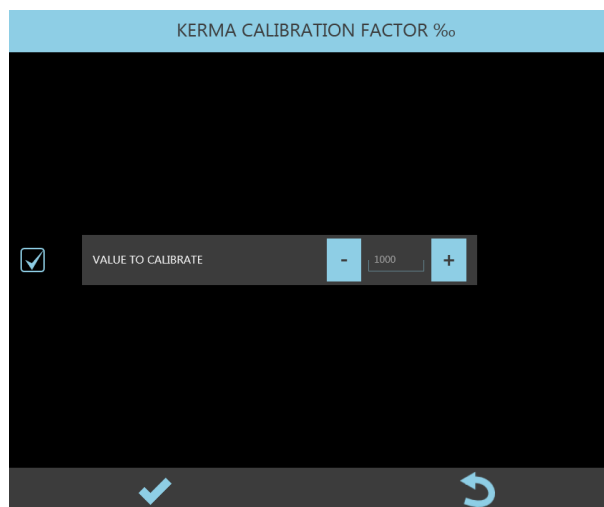
To do this:

- 1) Place the reference dosimeter at the REFERENCE POINT OF ENTRY ON PATIENT and set this for readings in mGy/min.
- 2) Open a new study.
- 3) Set: **HQ** Fluoroscopy, **70 kV**, acquisition rate **8 fps**, detector field: **16**.
- 4) Give the X-ray emission command and make a note of the reading on the dosimeter.
- 5) Calculate the ratio **R** between the measured AIR-KERMA RATE and that shown on the monitor.

Example:

- AIR-KERMA RATE read by the dosimeter: 2.8 $\mu\text{Gy}/\text{min}$
- AIR-KERMA RATE shown on the monitor: 3.3 $\mu\text{Gy}/\text{min}$
- ratio between the 2 indications: $R = 2.8 / 3.3 = 0.84$.
- error between the 2 indications in %: $(3.3 - 2.8) / 2.8 * 100 = 17.8\%$.

- 6) Select **KERMA CALIBRATION FACTOR**, with double tap. The following panel appears:



- 7) Calculate:
 - new KERMA CALIBRATION FACTOR = actual CALIBRATION FACTOR * **R**.

Example:

- actual KERMA CALIBRATION FACTOR = 1020 (102%),
- $R = 0.84$ (as in the previous example),
- corrected KERMA CALIBRATION FACTOR = $1020 * 0.84 = 856$.

The KERMA CALIBRATION FACTOR settings range is 500 - 1500‰.

2.1.4.3 AUTO kV CALIBRATION

The working X-ray dose is set, for each acquisition mode, in the EXAM SETUP menu.

The automatic dose control function (ADC) can be enabled for FLUOROSCOPY. This function automatically sets the required value of the kV and correlated mA so that the actual value of the dose is always the same as that set in the exam card (Target Dose).

The equipment calculates the X-ray dose in terms of image levels from the detector.

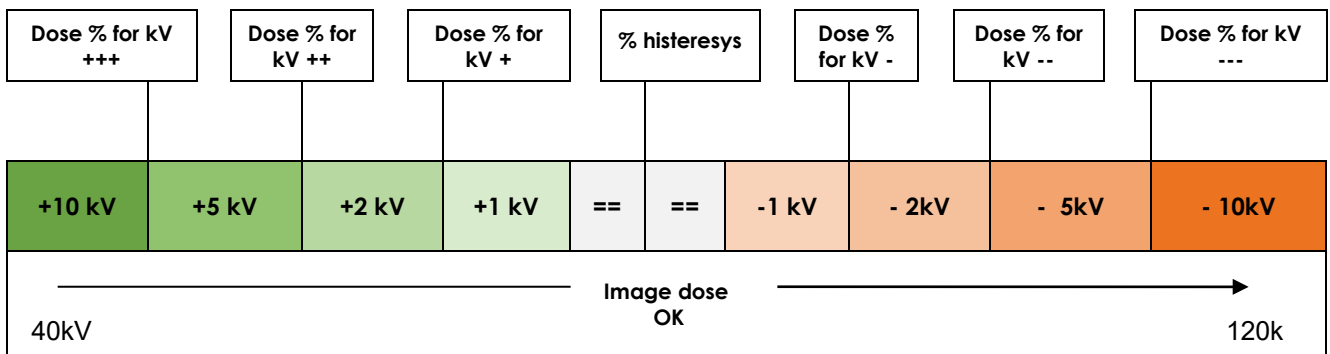
Note: The dose in nGy is obtained by dividing the image levels by the sensitivity of the detector (lsb/nGy). The table below provides an example.

Image levels	Nominal detector sensitivity (Typ.)	X-ray dose
200	10 lsb/nGy	20 nGy/i

The ADC function constantly checks the difference between the TARGET DOSE and the ACTUAL DOSE and adjusts the kV of a set value, depending on this difference: the variation in the kV will be small if the actual dose is close to the target dose; on the other hand, the variation in the kV will be greater if this difference is substantial.

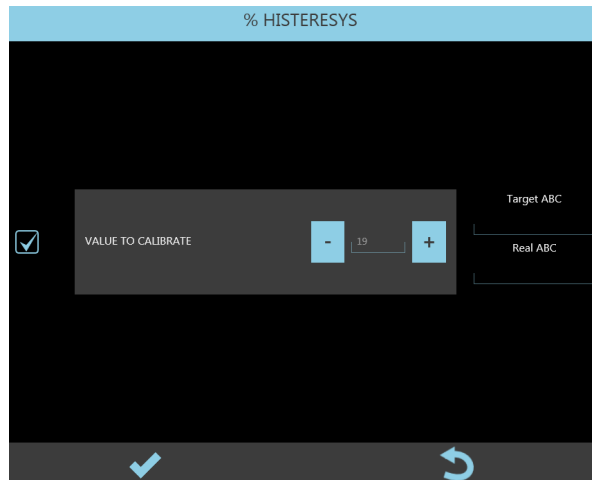
To calibrate this function, you need to set:

- 6 adjustment thresholds (% of the TARGET DOSE level): 3 to increase the kV and 3 to reduce it,
- a hysteresis threshold (% of the TARGET DOSE level): the ADC function stops adjusting the kV if the deviation (%) of the ACTUAL DOSE from the TARGET DOSE is below this hysteresis threshold.

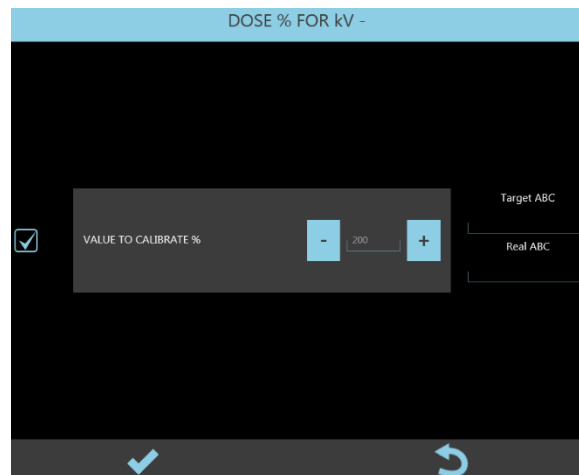


To calibrate the ADC function parameters:

- 1) Place a 2mm copper filter on the monoblock cover.
- 2) Select **% HYSTERESIS**:

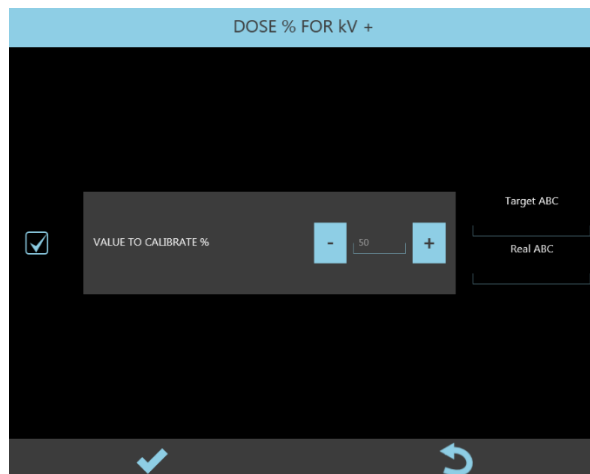


- 3) The equipment automatically sets **HQ Fluoroscopy** with **Automatic Dose Control**. Then set **40 kV**.
- 4) Give the X-ray emission command and check the system reaches the correct dose.
- 5) Release the X-ray command and make a note of the kV reached.
- 6) Now set the kV previously noted (+1kV and – 1kV). Give the X-ray command and check that the kV always reach the noted value.
- 7) If this value is still +/- 1 kV, lower the **% HYSTERESIS** and repeat the process.
- 8) Select **DOSE % FOR kV–** :



- 9) Set the noted kV value +2 kV and -2 kV and then give the X-ray emission command.
- 10) Adjust the **DOSE % FOR kV–** parameter if the required kV value is reached slowly or fluctuates:
 - Increase the value if the kV value is adjusted slowly,
 - Reduce the value if the kV value fluctuates.

11) Select **DOSE % FOR kV+**:

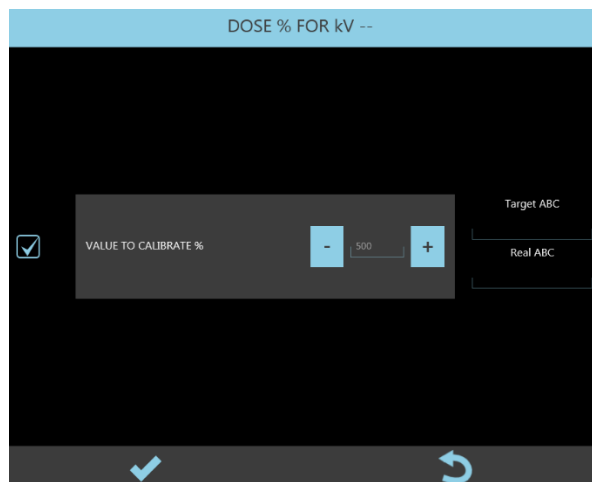


12) Set the noted kV value -2 kV and then give the X-ray emission command.

13) Adjust the **DOSE % FOR kV+** parameter if the required kV value is reached slowly or fluctuates:

- Increase the value if the kV value is adjusted slowly,
- Reduce the value if the kV value fluctuates.

14) Select **DOSE % FOR kV--**:

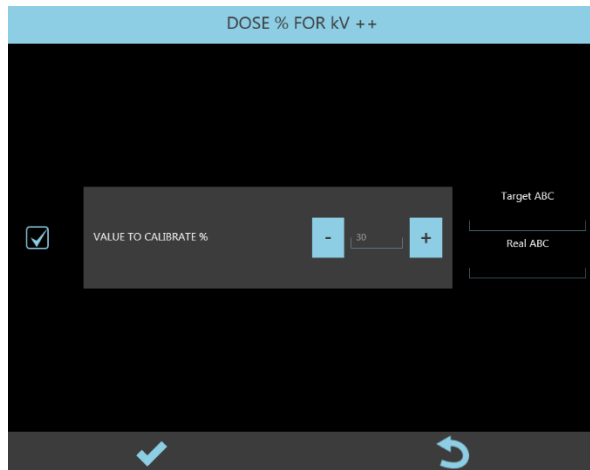


15) Set the noted kV value +5 kV and then give the X-ray emission command.

16) Adjust the **DOSE % FOR kV--** parameter if the required kV value is reached slowly or fluctuates:

- Increase the value if the kV value is adjusted slowly,
- Reduce the value if the kV value fluctuates.

17) Select **DOSE % FOR kV++**:

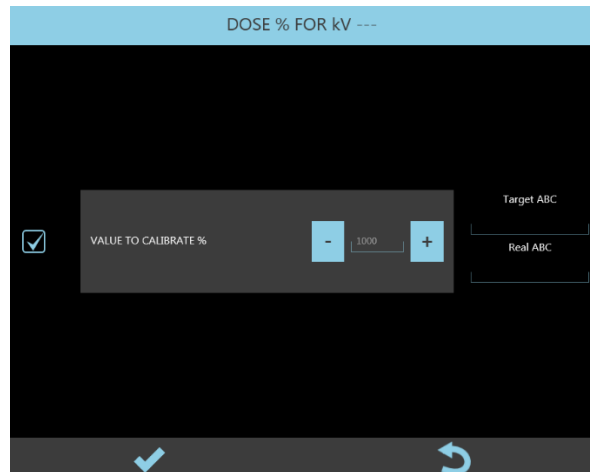


18) Set the noted kV value -5 kV and then give the X-ray emission command.

19) Adjust the **DOSE % FOR kV++** parameter if the required kV value is reached slowly or fluctuates:

- Increase the value if the kV value is adjusted slowly,
- Reduce the value if the kV value fluctuates.

20) Select **DOSE % FOR kV---**:

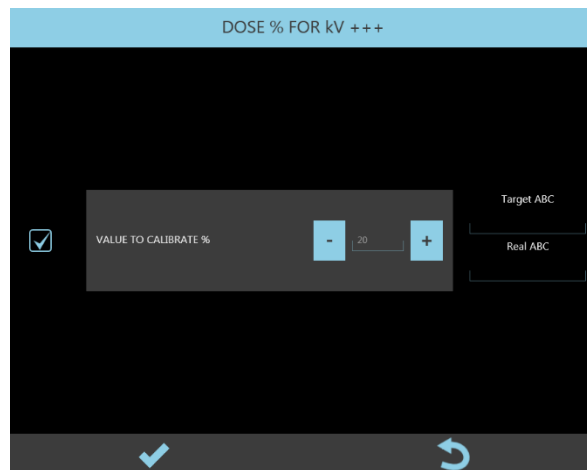


21) Set the noted kV value +10 kV and then give the X-ray emission command.

22) Adjust the **DOSE % FOR kV---** parameter if the required kV value is reached slowly or fluctuates:

- Increase the value if the kV value is adjusted slowly,
- Reduce the value if the kV value fluctuates.

23) Select **DOSE % FOR kV+++**. The following panel opens:



24) Set the noted kV value -10 kV and then give the X-ray emission command.

25) Adjust the **DOSE % FOR kV+++** parameter if the required kV value is reached slowly or fluctuates:

- Increase the value if the kV value is adjusted slowly,
- Reduce the value if the kV value fluctuates.

2.1.5 CHECKING THE kV and mA

After adjusting the mA, you need to check the **kV** value and the **mA** directly on the X-ray generator inverter.

The kV uncertainty value foreseen by **standard EN 60601-2-54** is **± 8%**.

If the kV value is not correct, check your earlier adjustments.

- Connect an oscilloscope to board S219 on the inverter:
 - channel 1: between Tp5 (+) and Tp2 (GND), to read the **kV** (REAL KV signal),
 - channel 2: between Tp8 (+) and Tp2 (GND), to read the **mA** (REAL mA signal),

The REAL KV signal at TP5 is negative (format: 1 V = -30 kV)

The format for the REAL mA signal at TP8 is:

- 1 V = 10 mA, if the mA set by the kV/mA curve are ≤ 10 mA, led DL23 OFF
- 1 V = 100 mA, if the mA set by the kV/mA curve are > 10 mA, led DL23 ON.

1) Checking the kV and mA in **Low Dose FLUOROSCOPY** (CURVE 3)

- Select the exam **DAILY TEST**
- Select **Low Dose** fluoroscopy with Manual dose control.
- Set **60 kV** and acquisition rate: **15 fps**.
- Give the X-ray emission command and then read the kV and mA values on the oscilloscope.
- Repeat, this time setting **100 kV**.
- Check that the resulting values are correct respect values in the table below and then check the wave-length by comparing it to the typical wave-lengths shown in figures 4a (60 kV) and 4b (100 kV) below.

kV		mA		Pulse duration (in ms)	Wavelengths
Set	Accepted range	Set	Accepted range		
	In S219 (Tp5) [1V = -30kV]		In S219 (Tp8) [1V = 10mA]		
60	57 ÷ 63	5.6 mA	0,504 ÷ 0,616 V	20	Fig. 4a
100	95 ÷ 105	7.5 mA	0,675 ÷ 0,825 V	20	Fig. 4b

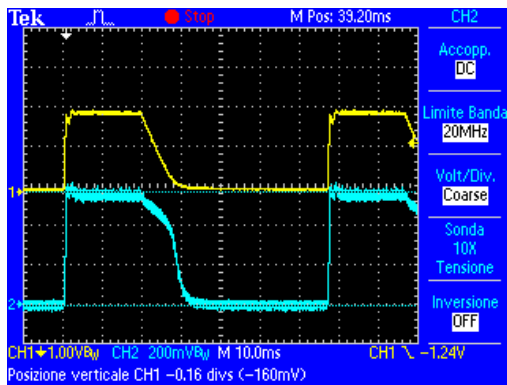


Fig. 4a

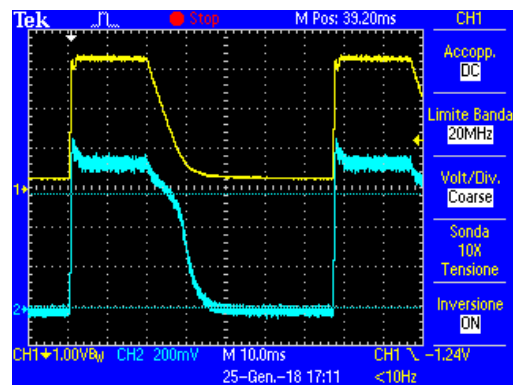


Fig. 4b

The mA value shown by the Control Panel for LD FLUOROSCOPY is the average mA value in a second of exposure.

2) Checking the kV and mA in **High Quality FLUOROSCOPY (CURVE 3)**

- Select the exam **DAILY TEST**.
- Select **High Quality** fluoroscopy with Manual dose control.
- Set **60 kV** and acquisition rate: **15 fps**.
- Give the X-ray emission command and then read the kV and mA values on the oscilloscope.
- Repeat, this time setting **100 kV**.
- Check that the resulting values are correct respect values in the table below and then check the wave-length by comparing it to the typical wave-lengths shown in figures 5a (60 kV) and 5b (100 kV) below.

kV		mA		Pulse duration (in ms)	Wavelengths
Set	Accepted range	Set	Accepted range		
	In S219 (Tp5) [1V = -30kV]		In S219 (Tp8) [1V = 10mA]		
60	57 ÷ 63	5.6 mA	0,504 ÷ 0,616 V	40	Fig. 5a
100	95 ÷ 105	7.5 mA	0,675 ÷ 0,825 V	40	Fig. 5b

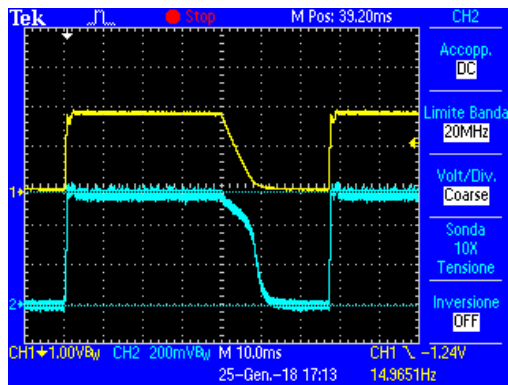


Fig. 5a

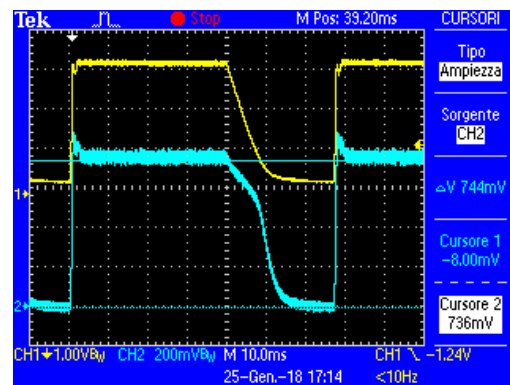


Fig. 5b

The mA value shown by the Control Panel for HQ FLUOROSCOPY is the average mA value in a second of exposure.

3) Checking the kV and mA in **RADIOGRAPHY** (CURVE 3)

- Select the exam **DAILY TEST**.
- Select Radiography mode.
- Set **60 kV - 8 mAs**.
- Give the X-ray emission command and then read the kV and mA values on the oscilloscope.
- Repeat, this time setting **100 kV - 8 mAs**.
- Check that the resulting values are correct respect values in the table below and then check the wave-length by comparing it to the typical wave-lengths shown in figures 6a (60 kV) and 6b (100 kV) below.

kV		mA		Pulse duration (in ms)	Wavelengths
Set	Accepted range In S219 (Tp5) [1V = -30kV]	Set	Accepted range In S219 (Tp8) [1V = 10mA]		
60	57 ÷ 63	47 mA	0,423 ÷ 0,517 V	170	Fig. 6a
100	95 ÷ 105	28 mA	0,252 ÷ 0,308 V	275	Fig. 6b

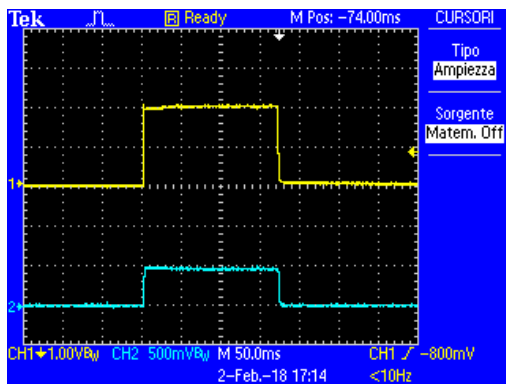


Fig. 6a

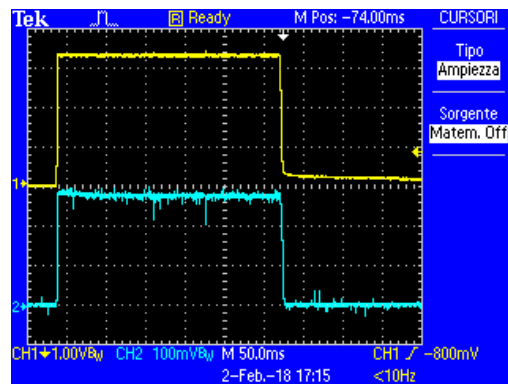


Fig. 6b

You also need to check that the set mAs value matches the product of the mA * Pulse duration for both kV values.

In this example:

- at 60kV: 47 mA * 0.170 s = 7.99 mAs
- at 100kV: 28 mA * 0.275 s = 7.7 mAs.

2.2 ADJUSTING THE X-RAY COLLIMATOR

The calibration procedure of the x-ray collimator remains the same both with **FPD 2121 aSi** version and **FPD 3030 aSi** version.

This procedure lets you set the following parameters:

- the correspondence between the actual aperture of the collimator and its "virtual" display on the LIH image,
- the max aperture (in mm) of the collimator squared iris for each detector field,
- the angle of correction between the actual and virtual positions on the monitor of the parallel shutters.

The calibration can be checked directly using the image of the collimators on the monitor, and so requires X-ray emission.

During calibration, the equipment automatically sets:

- the right detector field for the current calibration,
- **Low Dose** fluoroscopy, Acquisition rate: **4 fps**.
- **40 kV**.

Live Monitor (L.M.)

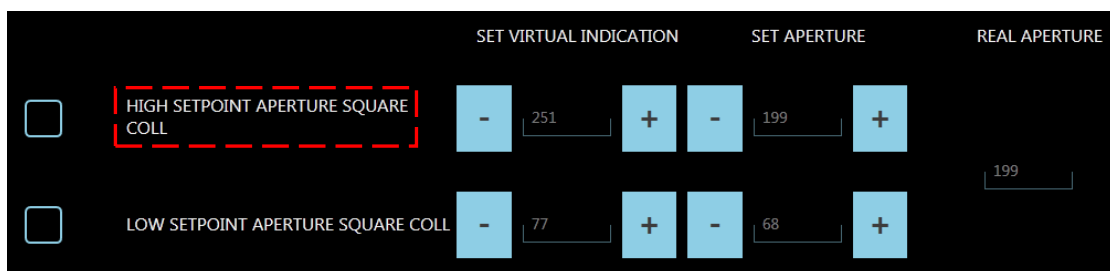


Memory Monitor (M.M.)



• Adjusting the correspondence between the actual aperture and that shown on the monitor of the Square Field (Square Coll).

- 1) Select the **High SetPoint Aperture Square Coll** parameter (the collimator positions itself to produce the size specified in the SET APERTURE field).

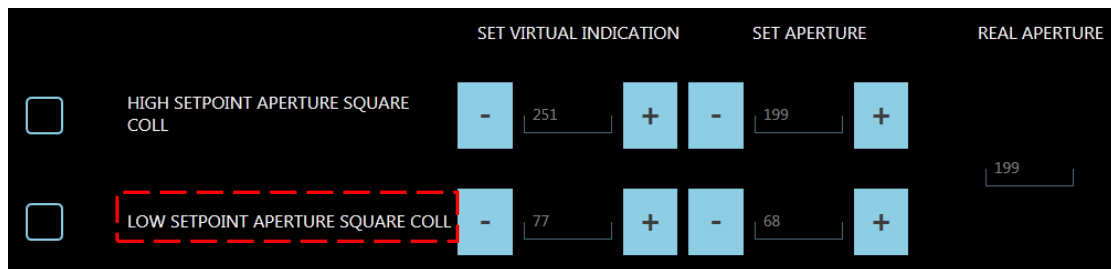


- 2) Give the X-ray emission command and adjust the **SET APERTURE** parameter so that the edges of the real collimator covers about 1 cm of the image.

- In stand-by, adjust the **SET VIRTUAL INDICATION** parameter (120 ÷ 210) so that the opening of the virtual collimators coincides with that of the actual collimators (see figure below).



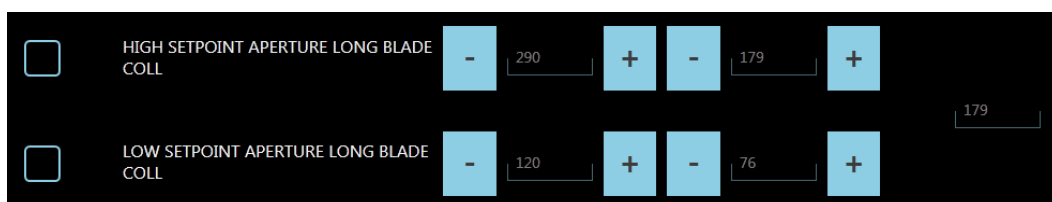
- Select the **Low SetPoint Aperture** parameter (the collimator positions itself to produce the size specified in the SET APERTURE field).



- Give the X-ray emission command and adjust the SET APERTURE parameter so that the size of the actual collimator is about 1/4 that of the image (about 5 cm for FPD 2121 aSi, about 7,5cm for FPD 3030 aSi)
- In stand-by, adjust the **SET VIRTUAL INDICATION** parameter (0 ÷ 100) so that the opening of the virtual collimators coincides with that of the actual collimators.




- Adjusting the correspondence between the actual aperture and that shown on the monitor of the Shutters (Long Blade Coll).**




Carry the regulation out following the steps shown above for the Square Field.



• **Setting the max aperture of the collimator for each detector field**

Adjust the max aperture of the collimator (square iris) for each flat panel detector field.

Pixium aSi 3030	Field Size	Min (in mm)	Max (in mm)
	300 x300 mm ²	270	350
	210 x210 mm ²	180	230
	160 x160 mm ²	130	180

Pixium aSi 2121	Field Size	Min (in mm)	Max (in mm)
	210 x210 mm ²	180	230
	160 x160 mm ²	130	180
	120 x120 mm ²	90	140

- 1) Select the field you want to calibrate.
- 2) Give the X-ray emission command and adjust the corresponding aperture parameter so that the edges of the collimator are "slightly" visible inside the image.



Important: The adjustment of the max aperture for each detector zoom factor must be adjusted so that the edge of the collimator is still visible. This guarantees correct collimation of the X-ray beam.

• **Correcting the angle of rotation of the shutters**

You may need to correct misalignment between the angle of the shutters and their virtual display. To do this:

- 1) Select the parameter:



The square iris opens fully, whereas the shutters open by just 5 cm.

- 2) Give the X-ray emission command.
- 3) In standby, make sure that the angle of the virtual shutters matches that of the actual shutters; if necessary, adjust the parameter in question (-90 ... + 90).

- On completion of the calibration procedure, save the parameters by touching this button:



2.2.1 CENTRING THE X-RAY COLLIMATOR

The collimator consists of two distinct elements:

- collimator shutters,
- square iris collimator.

To centre the collimator, you need to adjust the position of each element.

We recommend adjusting the position of the shutters first and only then that of the square iris.



X-ray emission is required in order to check the correct adjustment.
Protect yourself and move to a safe distance during this check.

2.2.1.1 CENTRING THE SHUTTERS

Centring involves checking the image of the shutters on the monitor.

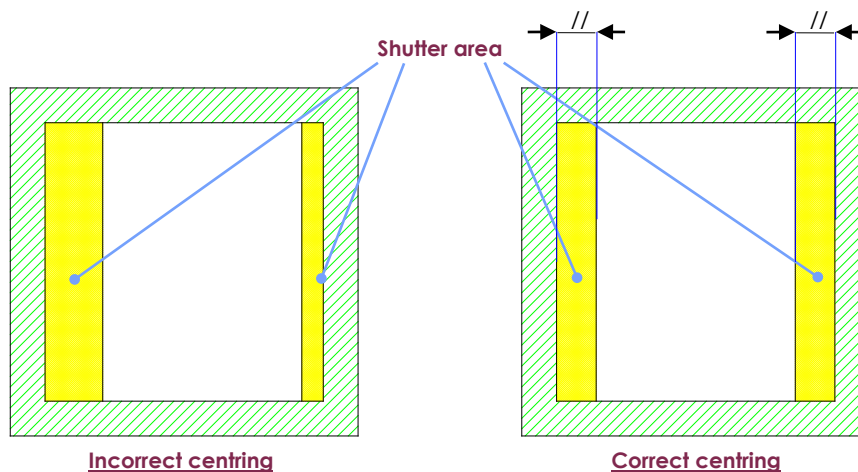
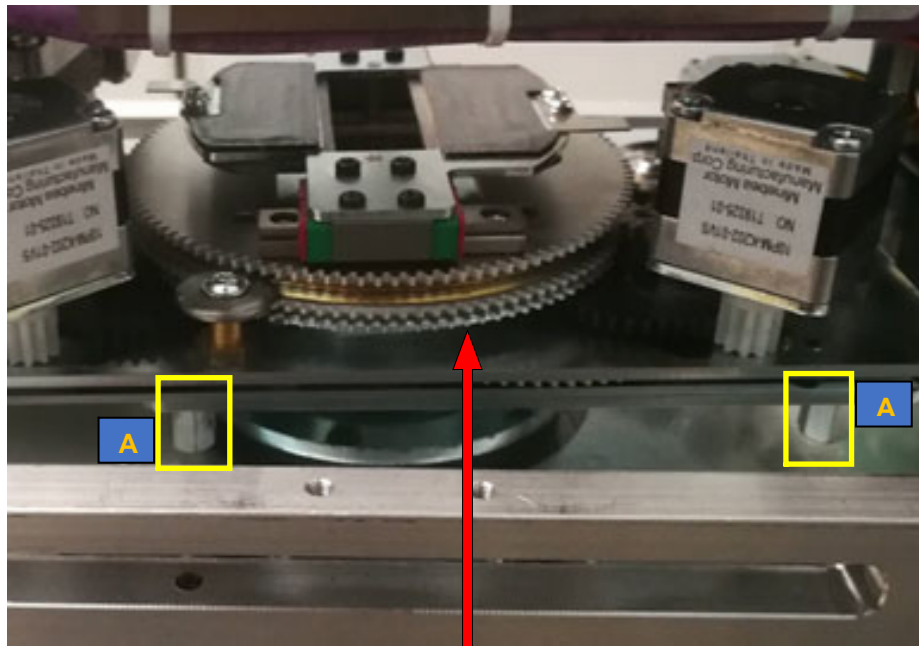


Fig.1

- Move the C-arm with the X-ray axis perfectly vertical and the monoblock lowered.
- Remove the top cover from the monoblock (see Paragraph 5.1.1 in Part 5 of this Manual).
- If present, remove dosimeter support, unscrewing its fixing screws near the collimator cover.
- Remove the cover from the collimator (see Paragraph 5.2.2.1 in Part 5 of this Manual).
- Select fluoroscopy with manual dose control and set 40 kV.
- Select Flat Panel detector nominal field and open the squared iris fully.
- With X-ray emission, rotate the shutters until you can see them in vertical position on the screen and then adjust their aperture so that they appear about 2 cm from the edges of the image.
- If not properly centred, loosen the 3 rods "A" (Fig. 2a and 2b), shifting this unit as required.
- Once centred vertically, rotate the shutters until they are horizontal and then give the X-ray emission command. Check their position on the image. If needed, move the shutter unit as required to get the best compromise between the vertical and the horizontal position.

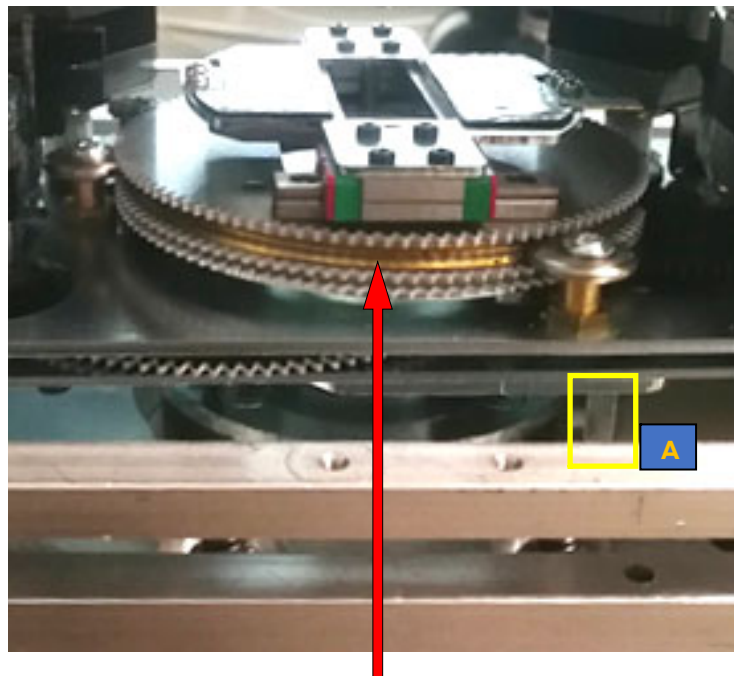
- Then fix the shutter unit in position by tightening the 3 rods "A".



Shutters Unit

Fig.2a

Note: The specific split makes the centring procedure easier



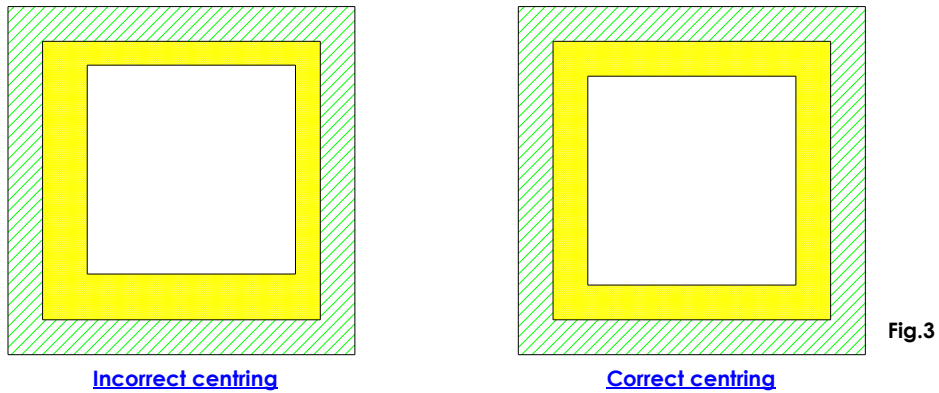
Shutters Unit

Fig.2b

Note: The figure shows the collimator without its cover and without the DAP supports.

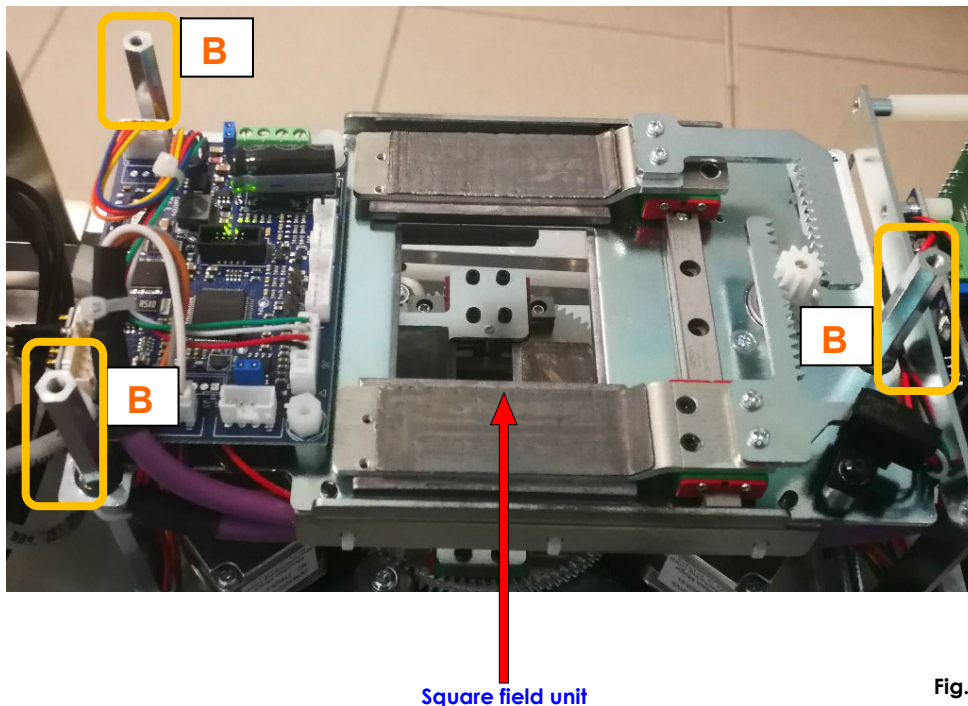
2.2.1.2 CENTRING THE SQUARE FIELD

The square iris should only be centred after centring the shutters. Centring involves checking the image on the monitor.



With the same working conditions used to centre the shutters:

- Open the square iris fully,
- With X-ray emission, set an aperture in the square field so that the square iris is visible within the image (both horizontally and vertically).
- If not properly centred, loosen the 3 rods "B" (Fig. 4) used to secure the unit in position and then shift this as required.
- Check the centring for all the detector fields.
- Once properly centred, fix the position of the iris unit by tightening the 3 rods "B".



Note: The figure shows the collimator without its cover and without the DAP supports.

2.3 ADJUSTING THE LASER BEAM CENTRING DEVICES

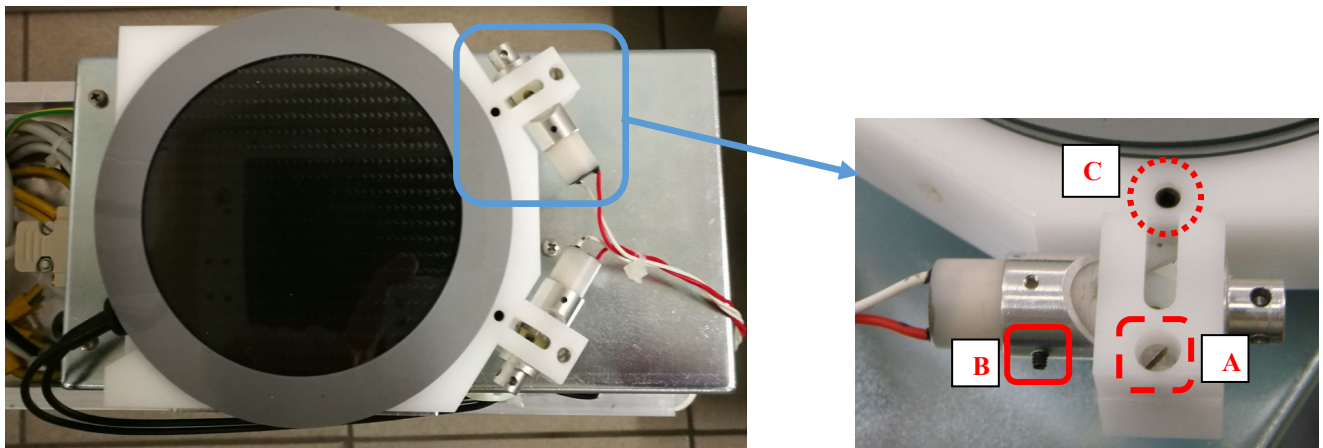
In order to centre the X-ray beam, the equipment uses 2 x class 1M laser beam centring devices (optional) placed on the X-ray monoblock and 2 x class 1M laser beam centring devices (optional) placed on the Flat Panel detector.

The two laser modules placed on the monoblock have the same position both on the FPD 2121 Asi version, and on the FPD 3030 Asi one; the laser modules placed on the flat panel have different positions, instead.

The resulting differences during a regulation procedure are explained in paragraph 2.3.2 below ("Adjusting the laser centring devices on the FPD").

2.3.1 ADJUSTING THE LASER CENTRING DEVICES ON THE MONOBLOCK

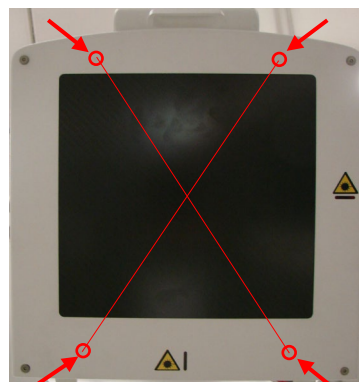
The two laser modules are housed in a dedicated support; to adjust their centring, it is required to remove the upper monoblock cover. (See Sec. 5, paragraph 5.1.1). In order to check the centring, switch on the laser beams using the relevant key on the control panel.



Note: the equipment shown in figure is provided with a DAP device (optional).

The laser projection now appears on the FPD cover, where you can find four landmarks to easier accomplish the procedure (see the figure below).

Place your C-arm vertically, with the monoblock downward.



Operate on the laser module clamping points to carry out the centring procedure:

- loosening the **screw A**, you can move the metallic support, centring the laser beam with the relevant exit of its plastic support,
- loosening the **grub screw B**, you can adjust the laser beam grade, rotating only the laser module in its metallic support,
- loosening the **grub screw C**, you can tilt the whole plastic support, to shift the laser beam on the right or on the left.

If required, repeat the same procedure with the second device.

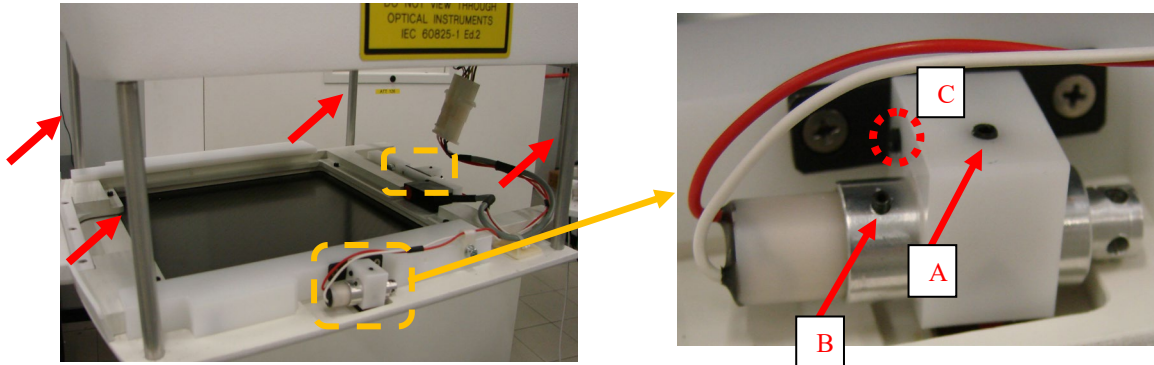
2.3.2 ADJUSTING THE LASER CENTRING DEVICES ON THE FPD

The laser modules position, on the FPD, is different depending on the detector versions (**FPD 2121Asi / FPD 3030Asi**).

On the FPD cover, the points where the laser modules lay, are marked with this symbol:



This is the centring procedure to follow for the **FPD 2121 Asi** version.



To reach the laser modules, it is required to remove the FPD cover (see Paragraph 5.3.2, Part 5 of this Manual). Laser devices are fixed rear the panel.

To make the calibration procedure more comfortable, the equipment is provided with four cylinder-shaped poles (pointed at in figure with a red arrow), that work as spacers between the cover panel and the FPD group.

Insert the poles between the panel and the FPD, as shown in figure.

In order to check the laser beam centring, turn on the laser beams using the relevant key on the control panel; a cross projection now appears on the monoblock (shown in the figure below).



To adjust the laser devices centring, follow the same procedure as in the previous paragraph (operating on the clamping points **A, B, and C**).



With **FPD 3030 Asi** version, follow the same procedure described above; the only difference is that the modules make a X-shaped projection with a grade of 30° between the beams, as shown in the figure aside.



2.4 ADJUSTING THE UP/DOWN COLUMN MOVEMENT

The motorized movement of the stand column lets you adjust the up/down speed of the column and limit the maximum motor current.

There are 3 potentiometers on board B2 (ASAC) used for these adjustments (see Fig.5). You need to check these adjustments should this board be replaced.

Potentiometer	Name	Function
P1	UP SPEED	Adjustment of the speed of the upwards movement.
P3	DOWN SPEED	Adjustment of the speed of the downwards movement.
P2	CURRENT LIMITATION	Adjustment of the max motor current

- First adjust:
 - potentiometer **P2** (CURRENT LIMITATION), by turning this as far clockwise as it can go to disable all current limitation,
 - potentiometers **P1** (UP SPEED) and **P3** (DOWN SPEED), by turning these as far clockwise as they can go (min speed).
- Adjust potentiometer **P1** so that the UP speed of the column is roughly 1 cm/s (the column takes at least 45 seconds to reach to its max height).
- Adjust potentiometer **P3** so that the DOWN speed of the column is roughly 1 cm/s (the column takes at least 45 seconds to reach to its min height).

You need to adjust the max motor current (and thus the max motor force) at its minimum setting to ensure upwards movement to guarantee safe movement in the event of the column unit accidentally hitting any external elements.

- With the longitudinal trolley of the C-arm (200 mm) fully forwards, adjust potentiometer **P2** to get the min current value that still ensures smooth upwards movement.

Note: The motor absorbs more current as it reaches its upper limit switch.
Typical motor current values:

- UP: 5 A max
- DOWN: 1 A max

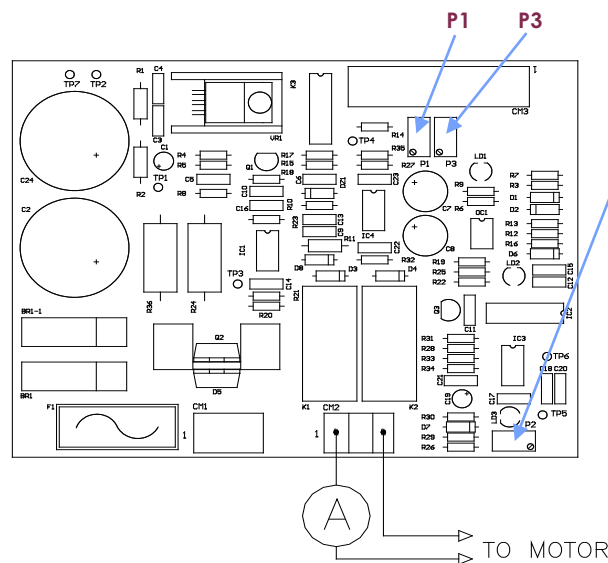


Fig.5
B2 board

2.5 ADJUSTING THE MONITORS

Monitors are provided already set to be **compliant with DICOM standards**.

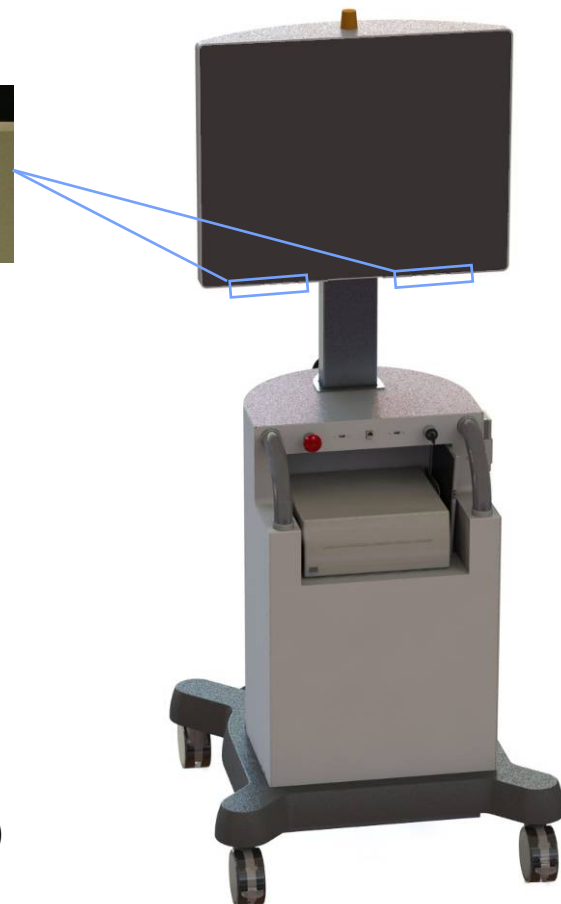
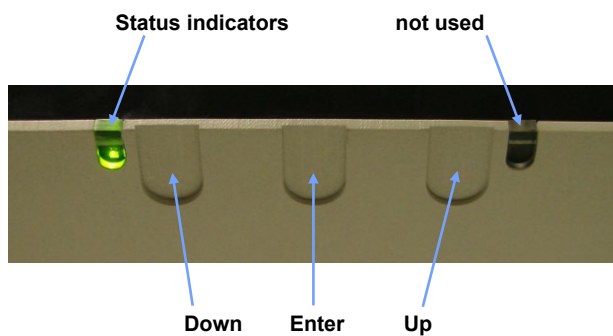
➤ **Attention: Never** change this parameter.

In case that monitors loose this setting, it is required to enter the setup menu (menu OSD).

On the lower side, you can find the accessing commands:

Status Indicator Leds:

Off	= OFF
Orange	= Standby
Green	= ON

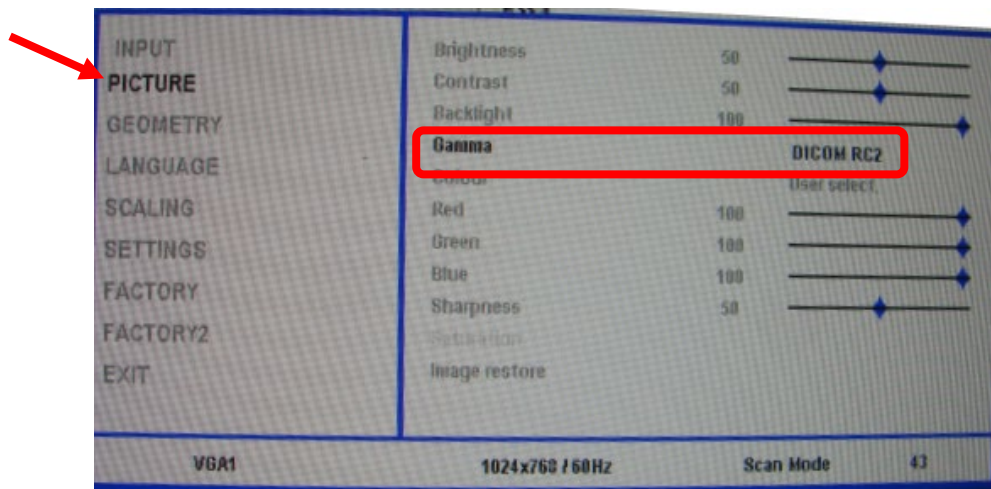


Commands

- **Up:** Browse through setup menu
Go to next parameter
Increase value of selected parameter
- **Down:** Browse through setup menu
Go back to previous parameter
Decrease value of selected parameter
- **Enter:** Open setup menu
Confirm selected parameter
Return to main OSD setup menu
(hold for 3 seconds)
Lock/Unlock OSD setup (hold for 5 seconds)

Note: *These three commands are normally inhibited to avoid accidental access to the setup menu. You must touch the **Enter** key for at least 15 seconds to enable them. After making the required adjustments, disable them by pressing the **Enter** key for a further 5 seconds.*

- Enable the setup by touching the **Enter** key for at least 15 seconds.
- Using **Up** and **Down** commands, enter the **Picture** menu and then select **Gamma**. Set **DICOM RC2** option.



Note: At the end of this procedure lock again the menu commands by pressing the **Enter** key for at least 5 seconds.

3 DETECTOR CALIBRATION

3.1 INTRODUCTION

The detector is calibrated in the factory.

Every 6 months the detector needs to be re-calibrated.

Calibration lets you update the **Gain** and **Defect Map** parameters, associated to each detector pixel, and find any defective (bad) pixels.

There is a separate calibration procedure for each **acquisition configuration**.

During the calibration procedures, the system uses the configurations indicated in the tables below:

FPD Pixium 3030 ASi					
Fluoroscopy					
Configuration	FIELD	Detector mode	i/s	X-ray window (ms)	Nominal Sensitivity (lsb/nGy)
1	30x30	m2g0	15	22	12.6
2	21x21	m1g0	15	14	12.6
3	16x16	m1g0	15	20	12.6
Digital radiography (SNAPSHOT)					
Configuration	FIELD	Detector mode	i/s	X-ray window (ms)	Nominal Sensitivity (lsb/nGy)
4	30x30	m1g3	1	970	1.3

FPD Pixium 2121 ASi					
Fluoroscopy					
Configuration	FIELD	Detector mode	i/s	X-ray window (ms)	Nominal Sensitivity (lsb/nGy)
1	21x21	m1g0	15	20	12.6
2	16x16	m1g0	15	20	12.6
3	12x12	m1g0	15	24	12.6
Digital radiography (SNAPSHOT)					
Configuration	FIELD	Detector mode	i/s	X-ray window (ms)	Nominal Sensitivity (lsb/nGy)
4	21x21	m1g3	1	970	1.3

Calibration involves, for each configuration, the acquisition of 13 images at 4 different X-ray dose levels:

- 13 images at Dose 1
- 13 images at Dose 2
- 13 images at Dose 3
- 13 images at Dose 4

The detector software uses these images to create the **Gain** map and the **Defect Map** needed to generate correct images (clean images).

Exposures must be performed:

- with the same X-ray beam filtering conditions,
- with the anti-scatter grid,
- with the collimator fully open in order to irradiate all areas of the detector,
- after the equipment has been switched on for at least 1 hour.

These conditions are absolutely necessary in order to ensure the calibration procedure is performed correctly.

The exposure dose must be that indicated here in order to generate image levels of the detector within the set range.

If not, the calibration might not be reliable.

For this reason, the dose must be determined before starting the calibration procedure, by measuring the dose level (see paragraph 3.2 below).

The X-ray doses used for calibration are:

FPD Pixium 3030 ASi				
Modality	Fluoroscopy			Digital radiography (SNAPSHOT)
Field	30	21	16	30
Dose 1	1.25 µGy / i	1.0 µGy / i	1.0 µGy / i	14.5 µGy / i
Dose 2	0.125 µGy / i	0.1 µGy / i	0.1 µGy / i	1.45 µGy / i
Dose 3	0.25 µGy / i	0.2 µGy / i	0.2 µGy / i	2.9 µGy / i
Dose 4	2.5 µGy / i	2.0 µGy / i	2.0 µGy / i	29 µGy / i

FPD Pixium 2121 ASi				
Modality	Fluoroscopy			Digital radiography (SNAPSHOT)
Field	21	16	12	21
Dose 1	1.0 µGy / i	1.0 µGy / i	1.0 µGy / i	14.5 µGy / i
Dose 2	0.1 µGy / i	0.1 µGy / i	0.1 µGy / i	1.45 µGy / i
Dose 3	0.2 µGy / i	0.2 µGy / i	0.2 µGy / i	2.9 µGy / i
Dose 4	2.0 µGy / i	2.0 µGy / i	2.0 µGy / i	29 µGy / i

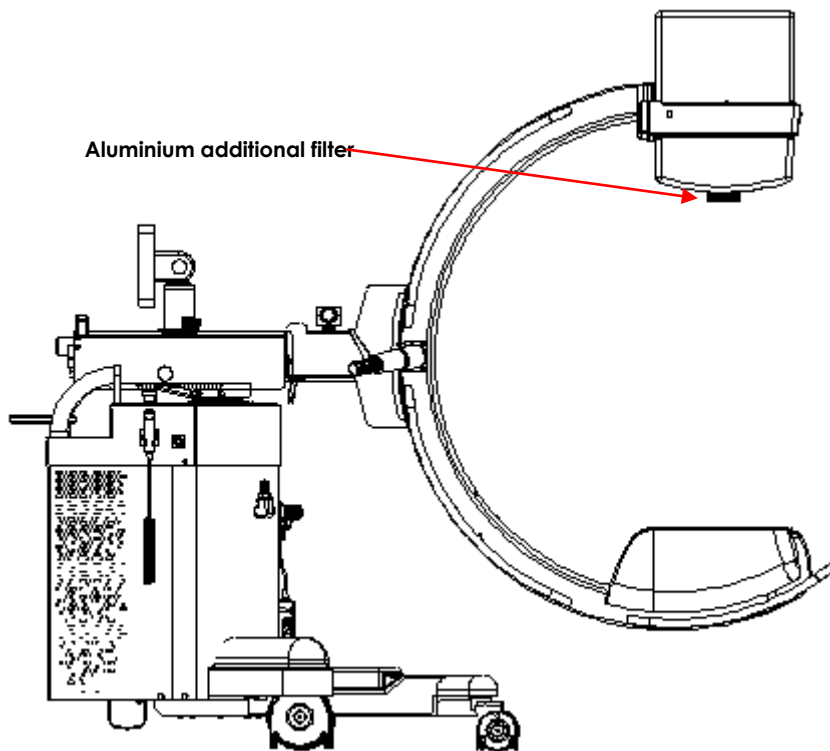
3.2 FINDING THE EXPOSURE VALUES FOR CALIBRATION

You need to know the radiological parameters needed to expose the detector correctly at the required doses before starting the calibration procedure. These parameters must be set during the calibration procedure.

Below are the factory X-ray emission conditions needed to get the required values.

FPD Pixium 3030 ASi								
Fluoroscopy								
Field	Dose (µGy/i)	kV	Filament Curve	Peak mA	Collimator filter	Grid	Additional filter	LSB level
30	1.25	67	Pulsed Curve 3: LF 0.4-10 mA	8.7	No	Present	10 mm Al	11800 ÷ 19600
	0.125	54		2.7				1180 ÷ 1960
	0.25	58		4.9				2360 ÷ 3930
	2.5	78		9.4				23600 ÷ 39300
21, 16	1.0	66	Pulsed Curve 3: LF 0.4-10 mA	8.7	No	Present	10 mm Al	9450 ÷ 15750
	0.1	54		2.6				945 ÷ 1575
	0.2	57		4.1				1890 ÷ 3150
	2.0	75		9.3				18900 ÷ 31500
Digital radiography (230 VAC)								
Field	Dose (µGy / i)	kV	Filament Curve	mAs	Collimator filter	Grid	Additional filter	LSB level
30	14.5	70	Rad Curve 3: LF 100kV– 28mA	10	No	Present	21 mm Al	13700÷22800
	1.45	70		1.0				1370÷2280
	2.9	70		2.0				2740÷4560
	29	70		20				27400÷45600
Digital radiography (120 VAC)								
Field	Dose (µGy / i)	kV	Filament Curve	mAs	Collimator filter	Grid	Additional filter	LSB level
30	14.5	75	Rad Curve 3: LF 100kV– 14mA	10	No	Present	21 mm Al	13700÷22800
	1.45	75		1.0				1370÷2280
	2.9	75		2.0				2740÷4560
	29	75		16				27400÷45600

FPD Pixium 2121 ASi								
Fluoroscopy								
Field	Dose (µGy / i)	kV	Filament Curve	Peak mA	Collimator filter	Grid	Additional filter	LSB level
21,16,12	1.0	66	Pulsed Curve 3: LF 0.4-10 mA	8.7	No	Present	10mm Al	7500÷12500
	0.1	54		2.6				750÷1250
	0.2	57		4.1				1500÷2500
	2.0	75		9.3				15000÷25000
Digital radiography (230 V)								
Field	Dose (µGy / i)	kV	Filament Curve	mAs	Collimator filter	Grid	Additional filter	LSB level
21	14.5	70	Rad Curve 3: LF 100kV-28mA	10	No	Present	21 mm Al	13700÷22800
	1.45	70		1.0				1370÷2280
	2.9	70		2.0				2740÷4560
	29	70		20				27400÷45600
Digital radiography (120 V)								
Field	Dose (µGy / i)	kV	Filament Curve	mAs	Collimator filter	Grid	Additional filter	LSB level
21	14.5	75	Rad Curve 3: LF 100kV-14mA	10	No	Present	21 mm Al	13700÷22800
	1.45	75		1.0				1370÷2280
	2.9	75		2.0				2740÷4560
	29	75		16				27400÷45600



3.3 CALIBRATION PROCEDURE

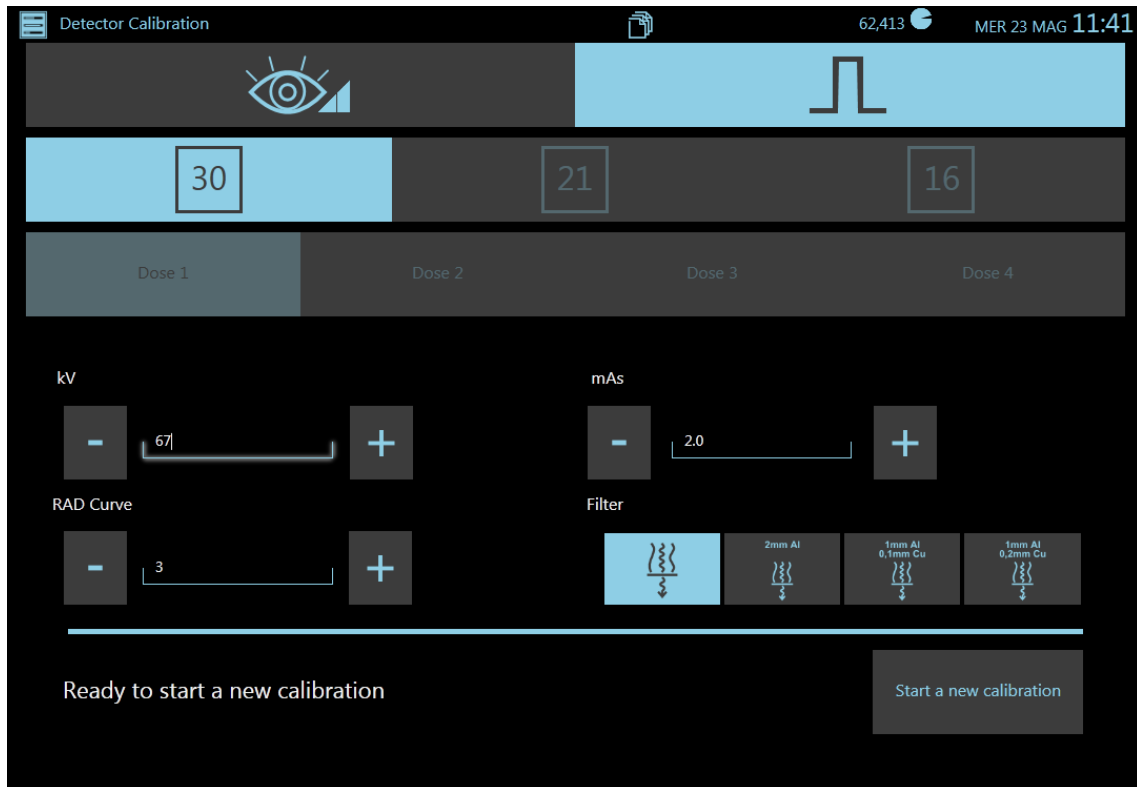
Log in as **Administrator** to access the calibration menu.
You can calibrate just one configuration at a time or all 4 configurations in a single cycle.

FLUOROSCOPY:



Below are full details on how to calibrate the 21x21 fluoroscopy configuration (the same procedure applies to all other Fluoro configurations, and with 30x30 FPD, too).

- 1) When the calibration menu is opened, the system automatically calibrates the offset (**Dark Calibration**) for all configurations, if necessary.
- 2) Select Fluoroscopy and field 21x21.
- 3) Touch the **Start a new calibration** key.
- 4) The procedure indicates condition **Dose 1** and asks you to "**Set dose to: 1.0 μ Gy**".
- 5) Set the kV value required for the exposure dose required.
- 6) Touch "**Continue**" (bottom button).
- 7) The procedure now asks you to "**Start X-Ray**".
- 8) Press the X-ray emission command button within 15 seconds and keep it pressed until you are asked to "**Stop X-ray**".
- 9) Touch "**Continue**" (bottom button).
- 10) Repeat the procedure from point 4 onwards for the other 3 dose levels:
0.1 μ Gy/i - 0.2 μ Gy/i - 2.0 μ Gy/i.
- 11) Repeat the procedure from point 2 onwards for the other two fields: 16 and 12.

DIGITAL RADIOGRAPHY:

Below are full details on how to calibrate the 21x21 radiography configuration (the same procedure applies to 30x30 FPD, too).

- 1) When the calibration menu is opened, the system automatically calibrates the offset (**Dark Calibration**) for all configurations, if necessary.
- 2) Select **Radiography** mode (with this acquisition mode, only FPD nominal field is available).
- 3) Touch the **Start a new calibration** key.
- 4) The procedure indicates condition **Dose 1** and asks you to "**Set dose to: 14,5 µGy**".
- 5) Set the kV value required for the exposure dose requested.
- 6) Touch "**Continue**" (bottom button).
- 7) The procedure now asks you to "**Start X-Ray**".
- 8) Press the X-ray emission command button within 15 seconds and keep it pressed until you are asked to "**Stop X-ray**".
- 9) Touch "**Continue**" (bottom button).
- 10) Repeat the procedure from point 4 onwards for the other 3 dose levels:
1.45 uGy/i - 2.9 uGy/i - 29 uGy/i.

4 ANNEXES

4.1 POTENTIOMETER LIST

POSITION	NAME	VALUE	DESCRIPTION	NOTES
B4 (BOARD ASAC 01)	P1	10K	UP SPEED	
	P2	2K	CURRENT LIMITATION	
	P3	10K	DOWN SPEED	
B10 (BOARD 15RkLC 00) (Rk20-xxS version only)	P1	2K	SET V.	Fixed: <u>do not touch</u>
	P2	2K	SET I.	
BOARD S83 (X-Ray tube)	P1	20K		Fixed: <u>do not touch</u>
	P2	20K		
	P3	20K		
	P4	20K		
Relay (Rk20-xxS version only)	KA KA ¹	80.01.0.240.0000	Timed relay switch	Set at 4s

4.2 LED LIST

POSITION	NAME	VALUE	DESCRIPTION	NOTES
B1 (BOARD CTBK-HW 00)	LD1	Orange	N.U.	
	LD2	Green	Power ON for DOOR security check circuit	
	LD3	Blue	RS-232 activity (CTBK RS232 transmit)	
	LD4	Blue	RS-232 activity (CTBK RS232 receive)	
	LD5	Blue	N.U.	
	LD6	Blue	N.U.	
	LD7	Blue	DAP readout	
	LD8	Blue	N.U.	
	LD9	Blue	N.U.	
	LD10	Green	+5V for Analog out circuit	
	LD11	Green	+12V for Analog out circuit	
	LD12	Orange	Injector running	
	LD13	Orange	Booster OK	
	LD14	Orange	Injector is available and ready	
	LD15	Yellow	Enable Booster capacitor charge output	
	LD16	Yellow	Injector start relay	
	LD17	Yellow	Injector start output	
	LD18	Yellow	Injector enable start output	
	LD19	Yellow	Injector inhibit relay	
	LD20	Orange	Motor UP command input	
	LD21	Yellow	Injector inhibit output	
	LD22	Orange	Motor DOWN command input	
	LD23	Yellow	Motor UP output	
	LD24	Yellow	Motor DOWN output	
	LD25	Yellow	Injector stop relay	
	LD26	Yellow	Injector stop output	
	LD27	Yellow	Security motor UP/DOWN command (from uP)	
	LD28	Yellow	Pre X-Ray output	
	LD29	Yellow	Inverter Supply output	
	LD30	Orange	Rad preparation input	
	LD31	Orange	Rad command input	
	LD32	Orange	Enable Hand switch input	
	LD33	Orange	Footswitch LEFT input	

POSITION	NAME	VALUE	DESCRIPTION	NOTES
	LD34	Yellow	Enable X-Ray generator output	
	LD35	Yellow	X-Ray generator RX command	
	LD36	Yellow	Spare	
	LD37	Yellow	Spare	
	LD38	Orange	Footswitch RIGHT input	
	LD39	Orange	Footswitch One shot input	
	LD40	Orange	X-Ray generator Exposure ok input	
	LD41	Orange	Enable X-Ray command switch(J27)	
	LD42	Orange	Spare	
	LD43	Orange	X-Ray command switches COMMON REQUEST	
	LD44	Orange	Spare	
	LD45	Orange	Grid present input	
	LD46	Green	Power ON (C-Arm)	
	LD47	Yellow	X-Ray lamp 1 (trolley lamp) output	
	LD48	Yellow	X-Ray lamp 2 (C-Arm lamp) output	
	LD49	Green	Power ON (trolley)	
	LD50	Orange	InfraRed data input	
	LD51	Yellow	Detector FREQ signal output	
	LD52	Yellow	Detector Valid X-Ray signal output	
	LD53	Yellow	Spare	
	LD54	Yellow	Spare	
	LD55	Orange	Detector X-Ray Enable input	
	LD56	Orange	Spare	
	LD57	Orange	Spare	
	LD58	Green	Power ON for logic circuit	
	LD59	Green	Power ON for microprocessor circuit	
	LD60	Green	Power ON for RS-232, Detector interface and IR communication circuit	
	LD61	Green	Power ON 24V main supply	
	LD62	Green	Power ON for Can-Bus communication circuit	
	LD63	Green	Watch Dog is ON	
	LD64	Red	Watch Dog fault	
	LD65	Green	Laser Supply ON	
	LD66	Yellow	Enable Laser ON output	
	LD67	Yellow	Laser ON output	
	LD68	Orange	DAP pulses input	
	LD69	Orange	Door closed input	
	LD70	Yellow	Light room output	
B4 (BOARD ASAC 01)	LD1	Green	MOTOR COMMAND	
	LD2	Green	MOTOR RUNNING	
	LD3	Red	OVER CURRENT LIMITATION	
B10 (BOARD 15RkLC 00) (Rk20-xxS version only)	LD1	Green	Power ON	
	LD2	Green	Power ON	
	LD3	Green	Power ON	
	LD4	Yellow	Enable charge capacitor	
	LD5	Red	Fault	
	LD6	Green	Boosted OK	
B11 (BOARD 15RkLCP 00) (Rk20-xxS version only)	LD1	Green	Power ON	
B12 (BOARD 15RkLCF 00) (Rk20-xxS version only)	LD1	Green	Power ON	
B14 (BOARD 15RkVC 00) (Rk20-xxS version only)	LD1	Green	V Power OK	

POSITION	NAME	VALUE	DESCRIPTION	NOTES
B20 (BOARD ASPS 00)	LD1 LD2 LD3	Green Yellow Yellow	Power ON C-ARM: CONNECTED C-ARM: ON	
B22 (BOARD IRT 00)	LD1	Green	InfraRed ON	
BOARD S219	DL1 DL 2 DL 3 DL 4 DL 5 DL 6 DL 7 DL 8 DL 9 DL 10 DL 11 DL 12 DL 13 DL 14 DL 15 DL 16 DL 17 DL 18 DL 19 DL 20 DL 21 DL 22 DL 23		Power on 24V COM FAULT COM OK Δ kV MAX kV>110% kV min mA Rx max COM RX HW kV>85% COM Rx ON Inverter PWM COM "B" PWM COM "A" Pre Rx N.U. Starter ok Starter Rad Starter Fluoro N.U. Filament Fault Filament Ok Small Filament Indication of the kV/mA signal format on test point TP8. (1V=10mA led OFF 1V=100mA led ON)	

4.3 FUSE LIST

POSITION	NAME	VALUE	DESCRIPTION	NOTES
TB1 (Stand)	F1 F2	20 AT 20 AT	GENERATOR SUPPLY GENERATOR SUPPLY	
TR1 (Stand/Chopper)	F1	10 AT	MAIN SUPPLY 380 Vac	
B1 (BOARD CTBK-HW)	F1	2,5AT	GENERAL SUPPLY	
B4 (BOARD ASAC 01)	F1	10 AT	+26V AC	
B10 (BOARD 15RkLC 00)	F1	800 mAT	MAIN SUPPLY	
B12 (BOARD 15RkLCF 00)	F1	80 AF	+350V DC	
B20 (BOARD ASPS 00)	F1 F2	315 mAT 1 AT	MAIN SUPPLY 21V AC	

Part 5: MAINTENANCE

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6 ANNEXES

6.1 - 6.22

B 18/07/22

- 6.1 Creating a back-up disk for the video processor
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1 ROUTINE MAINTENANCE

1.1 GENERAL RECOMMENDATIONS

See the instructions in the User Manual (see Paragraph 5.1.1 in Part 2).

1.2 DAILY/WEEKLY CHECKS AND INSPECTIONS

See the instructions in the User Manual (see Paragraph 5.1.2 in Part 2).

1.3 CLEANING AND DISINFECTING

See the instructions in the User Manual (see Paragraph 5.2 in Part 2).

1.4 SIX-MONTHLY CHECKS AND INSPECTIONS

Carry out the complete Acceptance Test procedure once every 6 months or, in any case, in line with current safety regulations.

Make a note of the results on the TEST SHEET (see Paragraph 1.5 in Part 3 of this Manual), together with details of any action taken.

2 EXTRAORDINARY MAINTENANCE

2.1 TROUBLESHOOTING

The troubleshooting tables below give indications of the most common malfunctions plus their most probable causes.

N°	PROBLEM	PROBABLE CAUSE	RECOMMENDED ACTION
1	No stand commands work.	No power supply at stand input.	Check to see if the magnetothermal switch has tripped: reset if necessary. Check to see if the emergency buttons on the monitor unit and stand have been used: reset if necessary. Check for voltage at connector TB1-3.5 (stand). Check for voltage on the secondary of transformer TR1 on board B1 (stand).
2	Stand comes on, but the control panel is 'dead'.	Control panel power unit faulty.	Check fuses F1 and F2 on terminal board TB1.
3	Equipment works, but no X-rays. No alarm on the stand control panel.	X-ray emission footswitch / button faulty.	Check the footswitch cable and connector. Check the X-ray emission button cable.
4	Monitor blank.	- Monitor faulty. - Incorrect brightness and contrast adjustment. - Video processor faulty.	Check position of the ON/OFF switch. Adjust settings. Check monitor fully / Replace.
		Video cable faulty.	Check / replace.
5	The control panel reads: CTBK +24V SUPPLY FAULT	Problem with power circuits on boards or fuses have blown: VR3 power circuit faulty.	Replace board.
6	The control panel reads: FILAMENT FAULTY	X-ray generator filament board faulty.	Replace the X-Ray generator.
		X-ray tube filament broken.	Replace the monoblock.
		X-ray generator power circuits faulty.	Check fuses TB1- F6 and F7.
7	The control panel reads: X-RAY GENERATOR FAULT	Check alarm LED on X-ray generator board S219.	Call Technical Service.
8	The stand reads: MAX kV	The X-ray generator has detected too much voltage at the X-ray tube during exposure.	Check the mains voltage feeding the X-ray generator. Check whether the problem also occurs at low kV.
9	The control panel reads: MAX FLUOROSCOPY TIME, RELEASE X-RAY COMMAND	Fluoroscopy has exceeded 5'.	Reset time with reset key on stand control panel.
10	The stand reads: X-RAY TUBE THERMAL SAFETY	Monoblock overheated.	Do not command X-rays (unless absolutely necessary) and wait for the monoblock to cool down.
11	The control panel reads: X-RAY TUBE TOO HOT	Monoblock too hot for exposure in radiography mode using the current parameters.	Do not command X-rays (unless absolutely necessary) and wait for the monoblock to cool down.
12	The control panel reads: NO X-RAYS	Fuses TB1- F1, F2, F6 and F7 blown (X-ray generator).	Replace fuses TB1- F1, F2, F6 and F7.
		X-ray generator faulty.	Replace the X-Ray generator.
		Reduce mains voltage.	Check the mains voltage. Check the apparent resistance of the mains circuit.
13	The control panel reads: MANUAL X-RAY STOP	The X-ray emission command button has been released too early during a radiography exposure.	Repeat radiography.
14	The control panel reads: MAX RADIOGRAPHY TIME	Radiography exposure has exceeded the limit of 1 s.	Check mA. Check mA reading on the LIVE monitor.

N°	PROBLEM	PROBABLE CAUSE	RECOMMENDED ACTION
15	The control panel reads: ANODE STARTER FAULTY	During preparation for radiography, the anode fails to start turning.	Check X-ray generator/monoblock connections. X-ray generator faulty.
16	The control panel reads: mA TOO LOW	mA value has dropped below 10 mA during radiography.	Check the mains voltage. Check the filament SET values in the Set-Up menu.
		mA value too low in fluoroscopy (1/3 the set value).	Check the mains voltage. Check the filament SET values in the Set-Up menu.
17	The control panel reads: mA TOO HIGH	mA value too high in fluoroscopy (1.5 times the set value).	Check the mains voltage. Check the filament SET values in the Set-Up menu.
18	The control panel reads: NO XRAY ENABLE FROM DETECTOR	The video processor is not ready to acquire images or the detector fails to provide the XRAY ENABLE signal (XREN).	Check that the working frame opens on the Live Monitor.
19	The control panel reads: X-RAY COLLIMATOR FAULT	X-ray collimator fails to reach the correct position or does not communicate with board CTBK (CAN messages).	Check collimator power supply and CAN connections with board B1 (CTBK).
20	The control panel reads: DAP FAULT	The DAP meter fails to send the correct number of calibration pulses immediately after being switched on.	Check the DAP output signal (pulses).
21	The control panel reads: FLUOROSCOPY PEDAL LD CLOSED	Low Dose Fluoroscopy footswitch found to be closed when equipment switched on.	Check efficiency of fluoroscopy footswitch and its connections.
22	The control panel reads: FLUOROSCOPY PEDAL HQ CLOSED	High Quality Fluoroscopy footswitch found to be closed when equipment switched on.	Check efficiency of fluoroscopy footswitch and its connections.
23	The control panel reads: RAD PREP BUTTON CLOSED	Radiography preparation button found to be closed when equipment switched on.	Check efficiency of the button and its connections.
24	The control panel reads: RAD BUTTON CLOSED	Radiography button found to be closed when equipment switched on.	Check efficiency of the button and its connections.
25	The control panel reads: LOW DOSE AT MAX kV	Insufficient dose level detected at max kV (120) (Vabc signal from detector).	
26	The control panel reads: CHOPPER FAULT (20 kW version only)	Problem in the feeder power circuits in the Xray generator.	The CHOPPER unit is faulty: call Technical Service.
27	The control panel reads: CHOPPER OVERVOLTAGE (20 kW version only)	The CHOPPER output voltage has exceeded the alarm threshold (355V).	Call Technical Service.
28	The control panel reads: CHOPPER UNDERVOLTAGE (20 kW version only)	The CHOPPER output voltage has dropped below the alarm threshold (260V).	Call Technical Service.
29	The control panel reads: NO X-RAY DOSE SIGNAL	Fault in the dose reading circuit: the DOSE CONTROL messages are not received from the VIDEO PROCESSOR.	Check the video processor SW LOG.
30	The control panel reads: POSSIBLE DETERMINISTIC EFFECTS	<u>Attention:</u> The accumulated Kerma Rate has exceeded the threshold during the study and so there is a risk of DETERMINISTIC EFFECTS.	

Note: The manufacturer undertakes to supply, upon request, full information (wiring diagrams, component lists, calibration instructions, etc.) to assist qualified technical personnel in repairing any equipment components that the manufacturer feels can be repaired.

2.2 REPLACING COMPONENTS

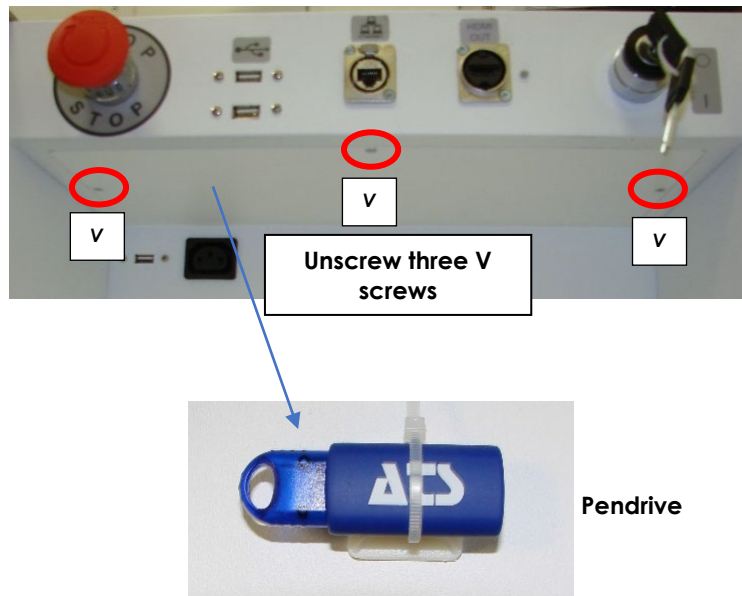
Every time a component is replaced, a series of checks and adjustments need to be performed. Consult the table below which covers the most common situations.

N°	COMPONENT REPLACED	ADJUSTMENTS AND CHECKS REQUIRED	REFERENCE
MONITOR UNIT			
1	B20 (ASPS 01)	Check correct power up of stand, monitor unit and video processor	No adjustments required
2	Video processor ARCO FP-VP 3	Check and configure	Part 2, chapter 4
3	Monitor	Check monitor adjustments	Part 4, para. 2.4
STAND			
1	Flat panel detector	Calibrate detector	Part 4, chapter 3
2	Monoblock / X-ray generator	Adjust X-ray generator	Part 4, para. 2.1
3	X-ray collimator	Adjust X-ray collimator	Part 4, para. 2.2
4	B2 (ASAC 01)	Check column up/down movement adjustments	Part 4, para. 2.3
5	B1 (CTBK-HW)	Check and configure	Part 5, para. 2.4.1
8	Replacement power unit (Chopper)		Part 5, para. 5.4.4
9	DAP	Check and configure	Part 4, para. 2.1.4

2.3 RESTORING THE VIDEO PROCESSOR SYSTEM HARD DISK

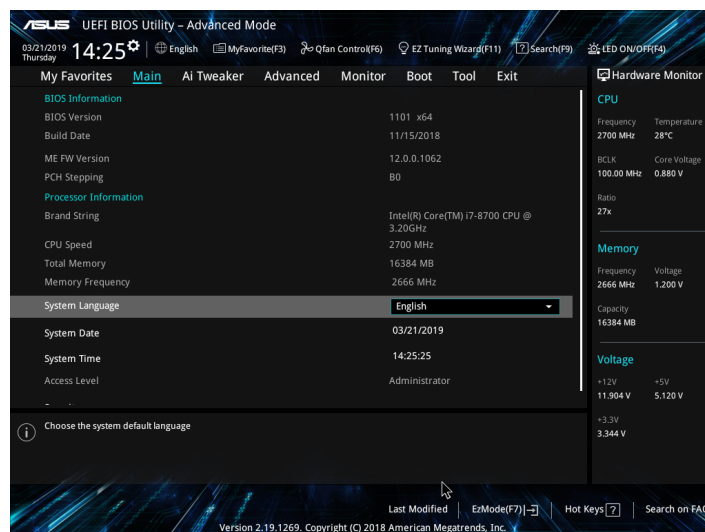
If necessary, you can restore the video processor software using the backup USB PEN DRIVE (the "snapshot file") provided with the equipment.
The manufacturer made this backup on completion of factory testing.

The USB drive is located inside the upper housing in the printer compartment of the visual station (see photo below).

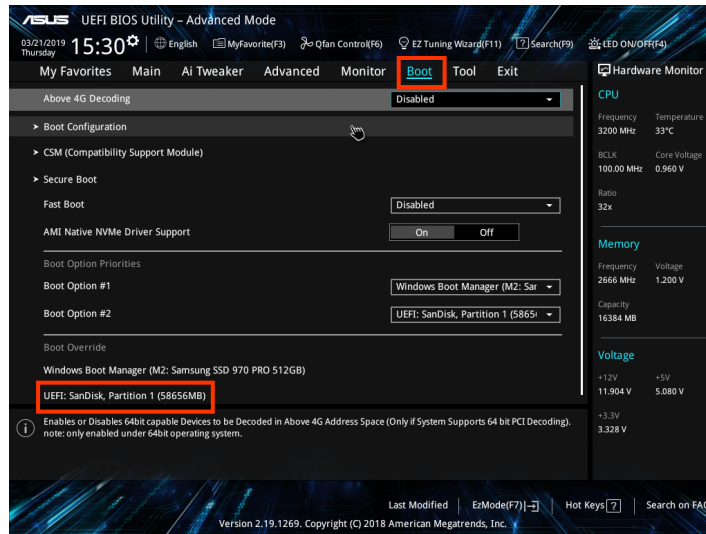


To restore the processor:

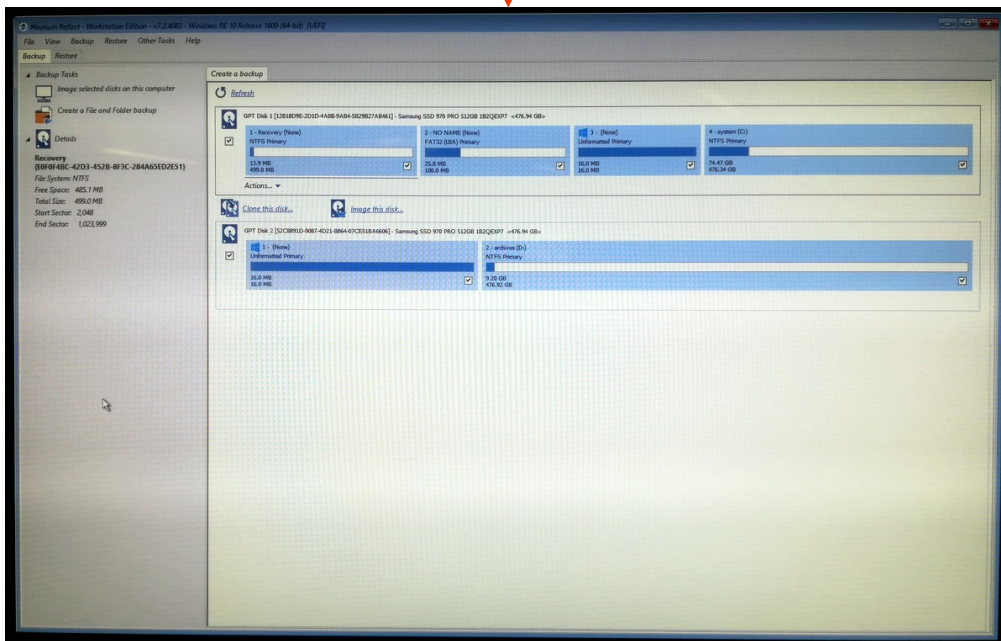
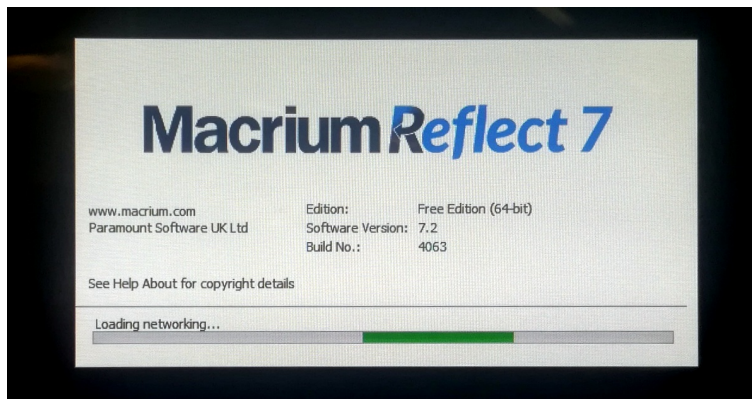
- 1) Insert the USB pen drive in one of the two ports on the front of the monitor unit.
- 2) Connect a USB keyboard and USB mouse at the front of the monitor unit.
- 3) Switch the equipment ON and then press the "DEL" key on the keyboard to enter the UEFI BIOS Utility:



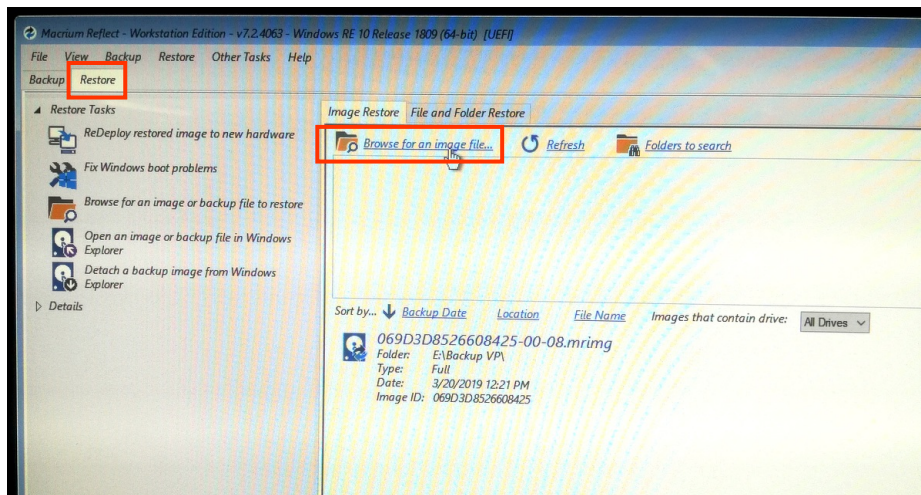
4) Enter the **Boot** menu and select the USB drive (**UEFI: SanDisk**) as the Boot device:



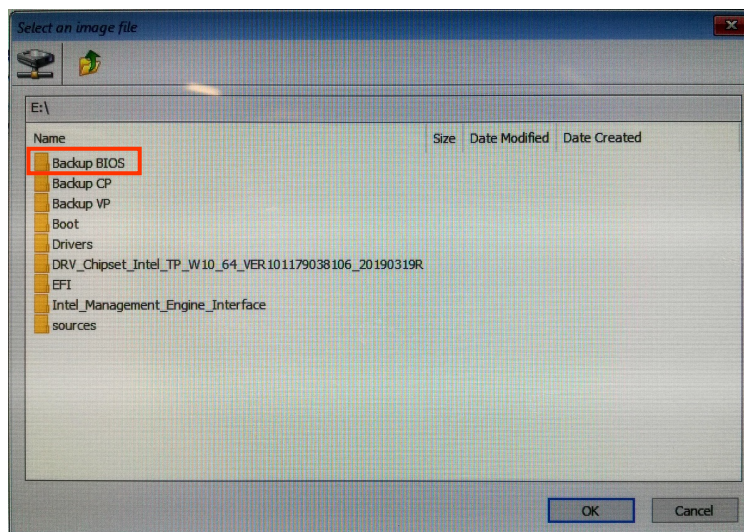
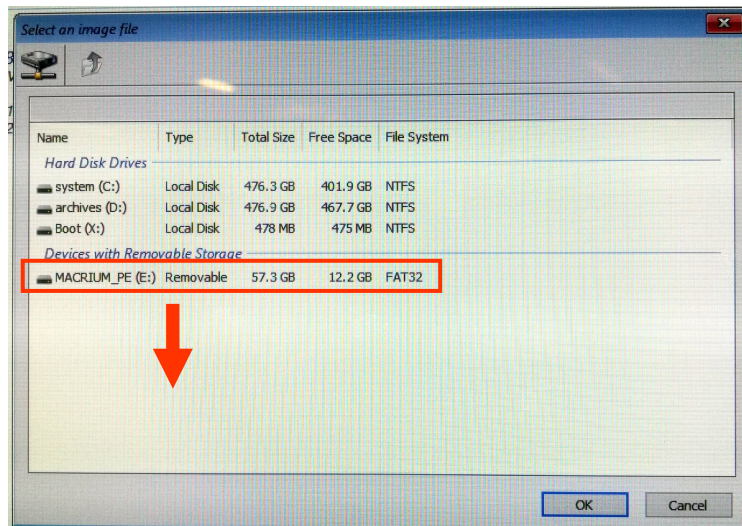
5) The processor restarts automatically and the startup screen of the **Macrium Reflect** recovery application is presented:



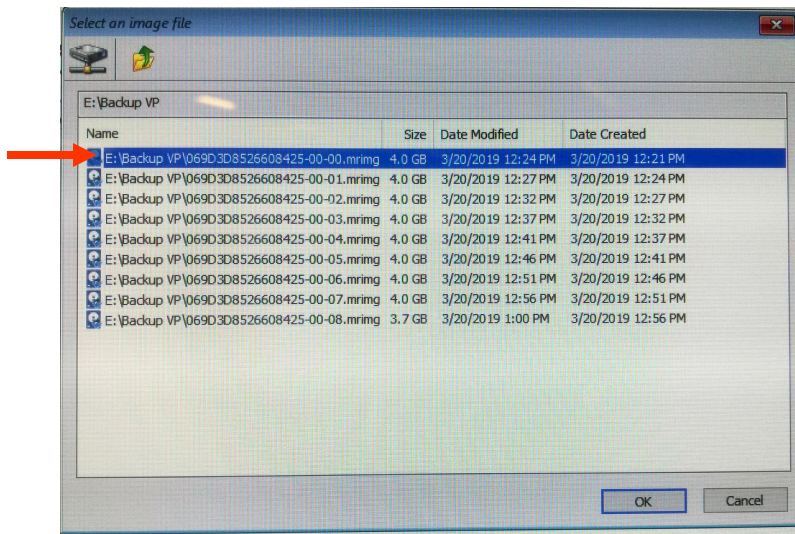
6) On the main screen, click on the **"Restore"** TAB and then on **"Browse for an image file..."**



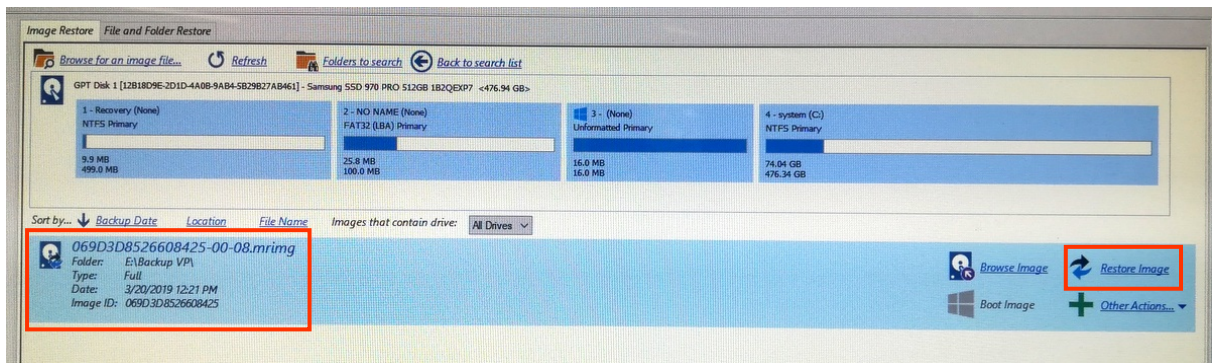
7) Select the USB drive (**Removable Storage**) and then the folder **"Backup VP"**:



8) Then select the first file in the list of the backup and press "OK":



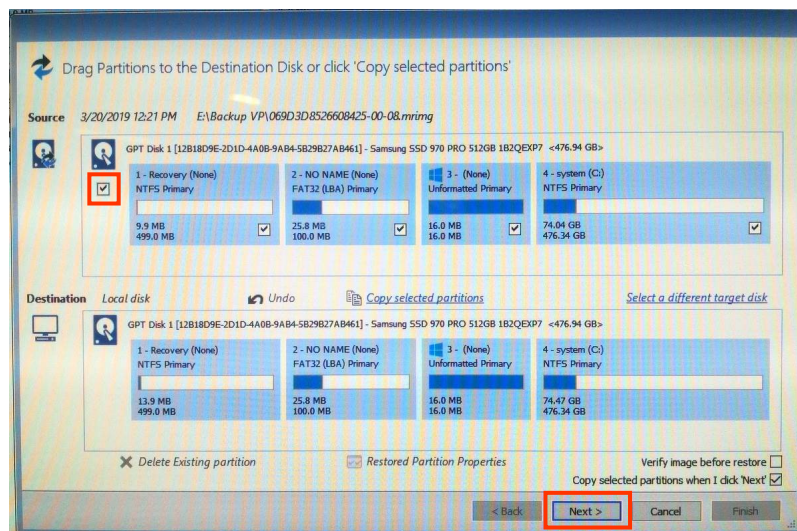
9) The selected backup will be displayed on the main screen; then select the "Restore Image" command.



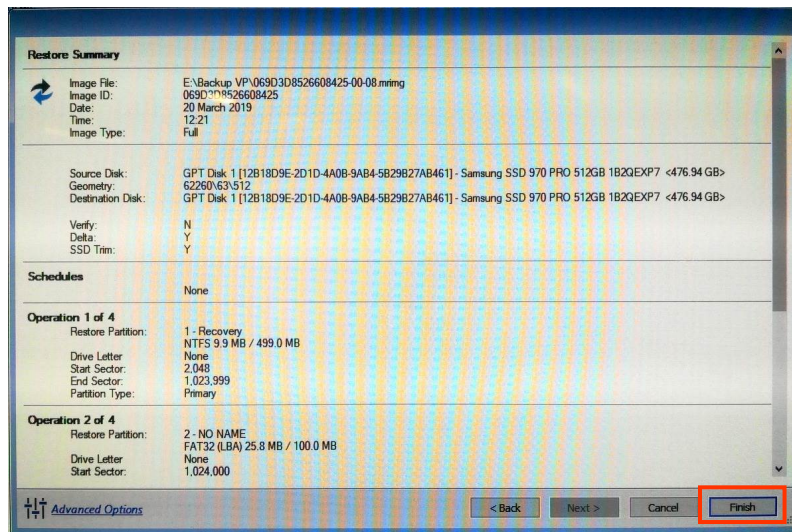
10) Check that:

- in the "Source" box the 4 partitions that make up the system disk are selected
- in the "Destination" box the same 4 partitions are present

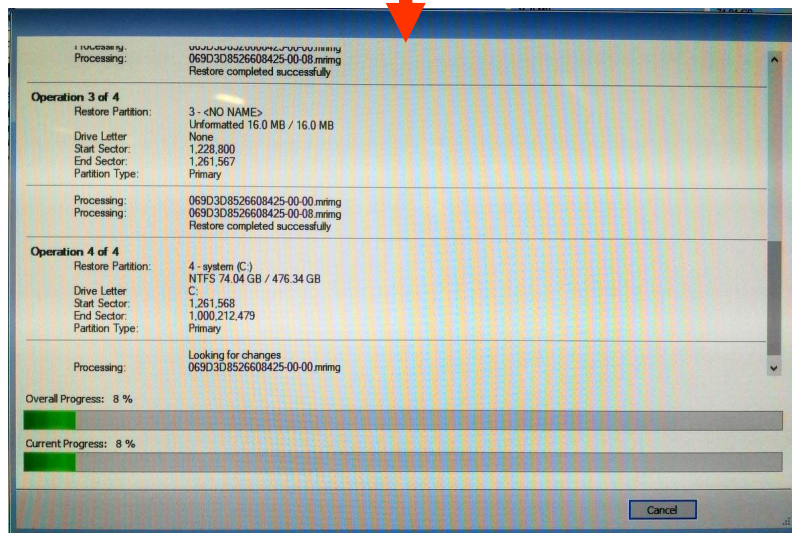
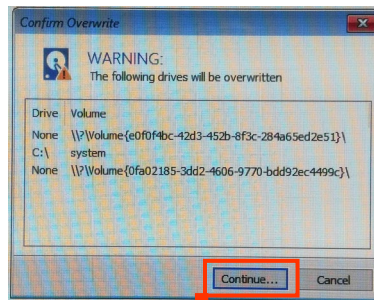
Then select the "Next" command.



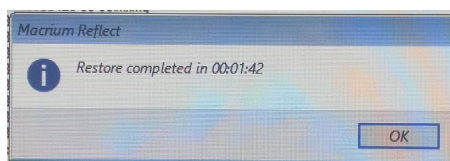
11) In the summary screen, select the "Finish" command:



12) Confirm with the command "Continue..." to start data recovery on the system disk



13) When the reset is complete, press "OK" and close the application.



The video processor restarts automatically; remove pendrive, keyboard and mouse.

2.4 SOFTWARE UPGRADES

This chapter describes the update procedure for the:

- board CTBK-HW software
- VIDEO PROCESSOR software

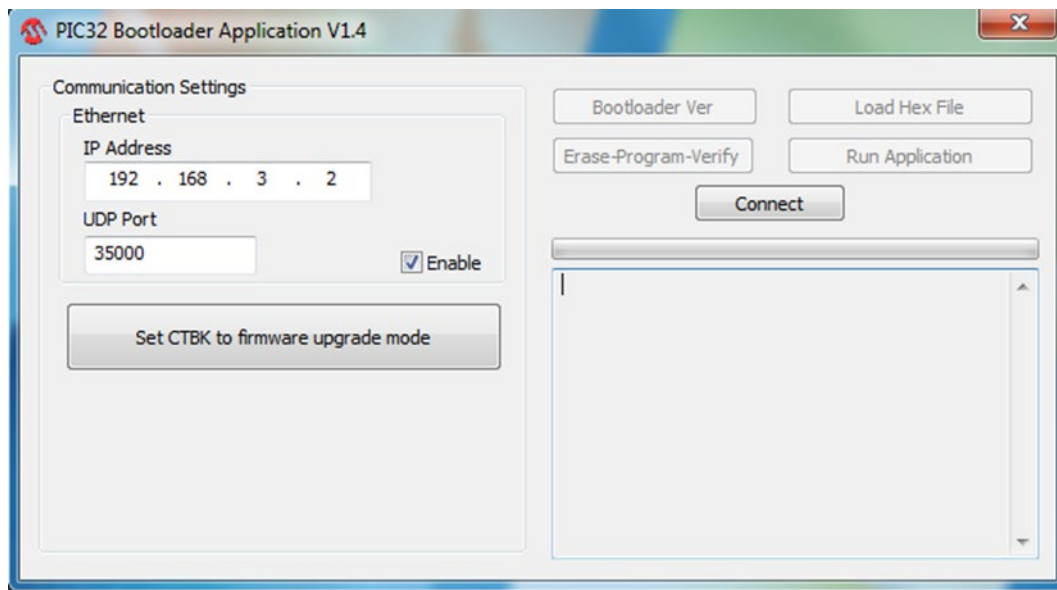
2.4.1 UPGRADING THE MAIN CONTROLLER SOFTWARE (CTBK-HW)

The Main Controller software is found on board B1 – CTBK-HW (stand).

Upgrade procedure:

Components needed:

- **PIC32 Bootloader Application V1.4** (installed on the monitor unit PC).
 - **CTBK.X.production.hex** binary file containing the new firmware.
- Connect a USB keyboard and USB mouse at the front of the monitor unit.
 - Switch the equipment on.
 - Exit the SystemA DRF application and then access the video processor as “Administrator” (see paragraph 5.3 in Part 2 of this manual).
 - Run the **PIC32 Bootloader Application** by using the icon on the desktop:

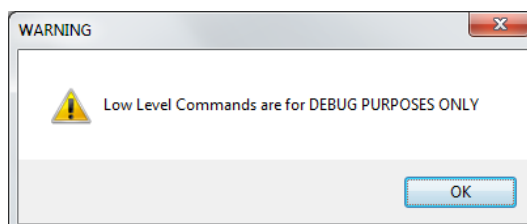


- Set the board CTBK connection as shown in the figure:

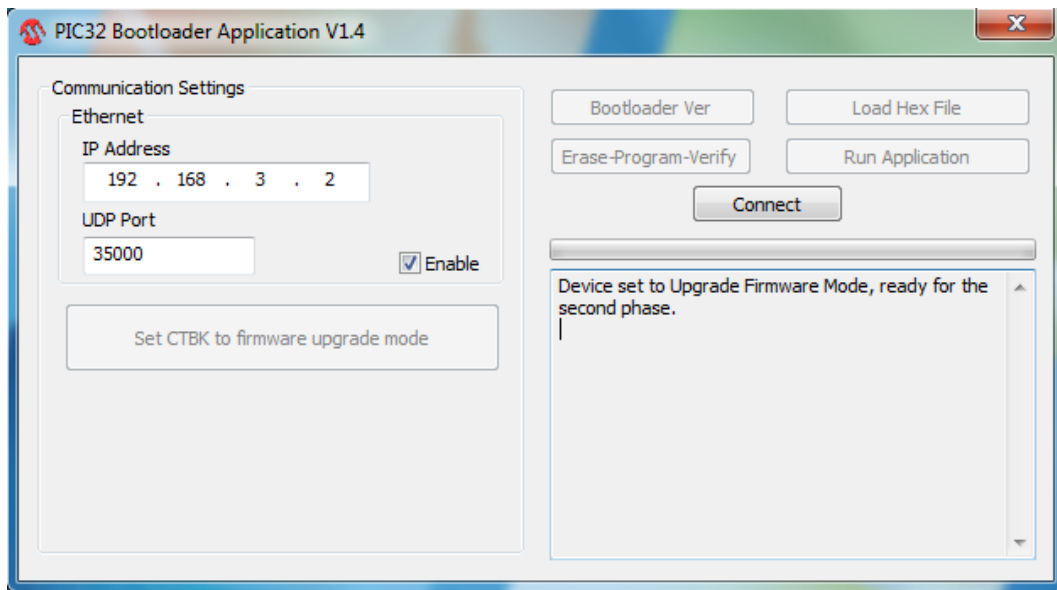
- o IP Address: **192.168.3.2**
- o UDP Port **35000**

- Make sure that **Enable** is checked.

- Put board CTBK-HW in FIRMWARE UPGRADE mode by selecting the **Set CTBK to firmware upgrade mode** button.
- The following page opens:

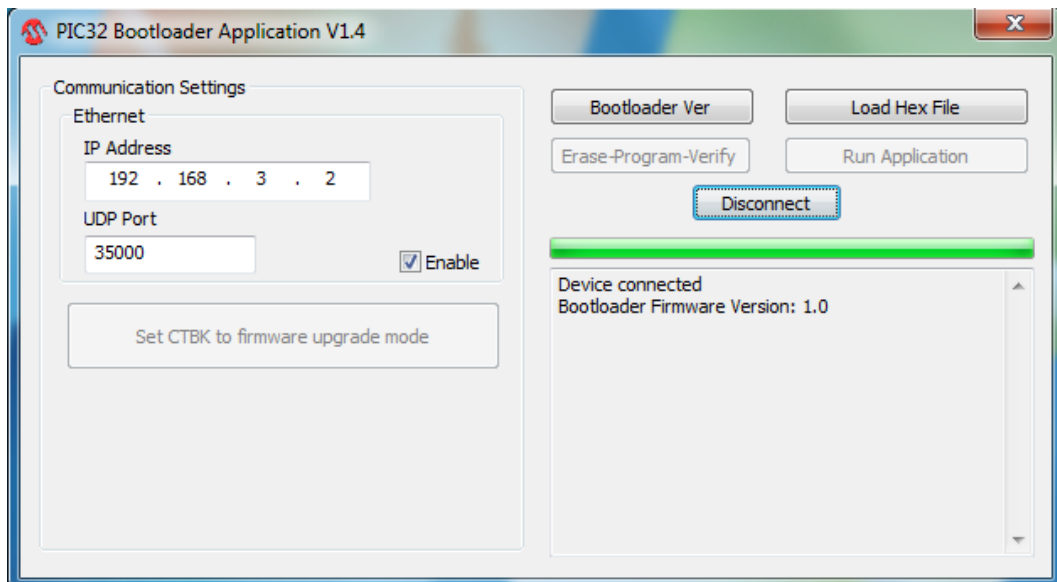


- Confirm with OK.
- If the equipment successfully enters the firmware upgrade mode, the following message appears: **“Device set to Upgrade Firmware Mode, ready for the second phase”**



- Wait about 20 seconds to allow the Bootloader to run and for propagation of the IP ADDRESS for board CTBK-HW.
- Connect by selecting **Connect**.
- Connection with board CTBK-HW has been successful if "Bootloader Firmware Version 1.0" appears in the window below.

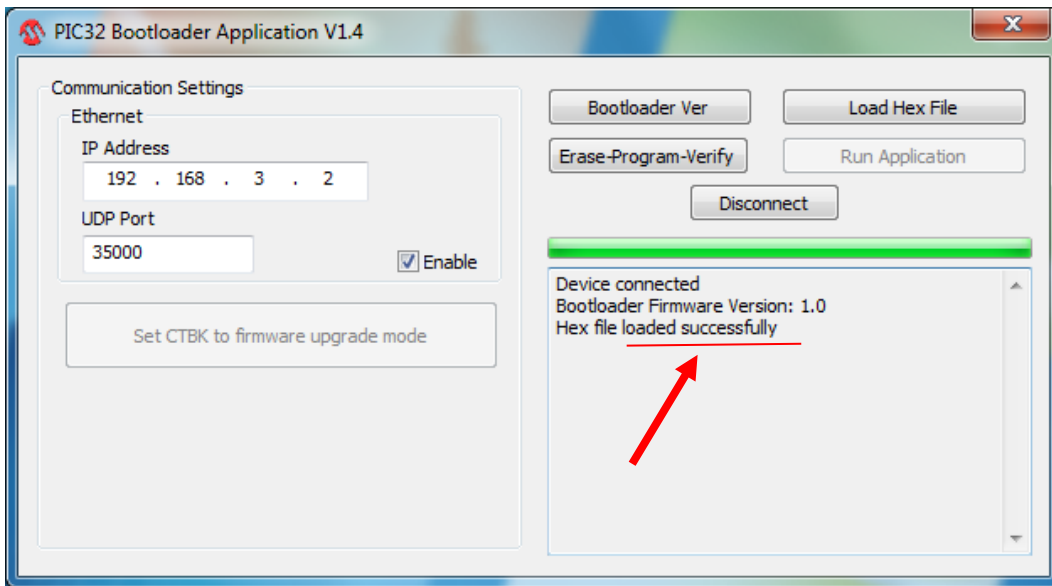
If connection is not established, try again to press **Connect** key after 30 seconds.



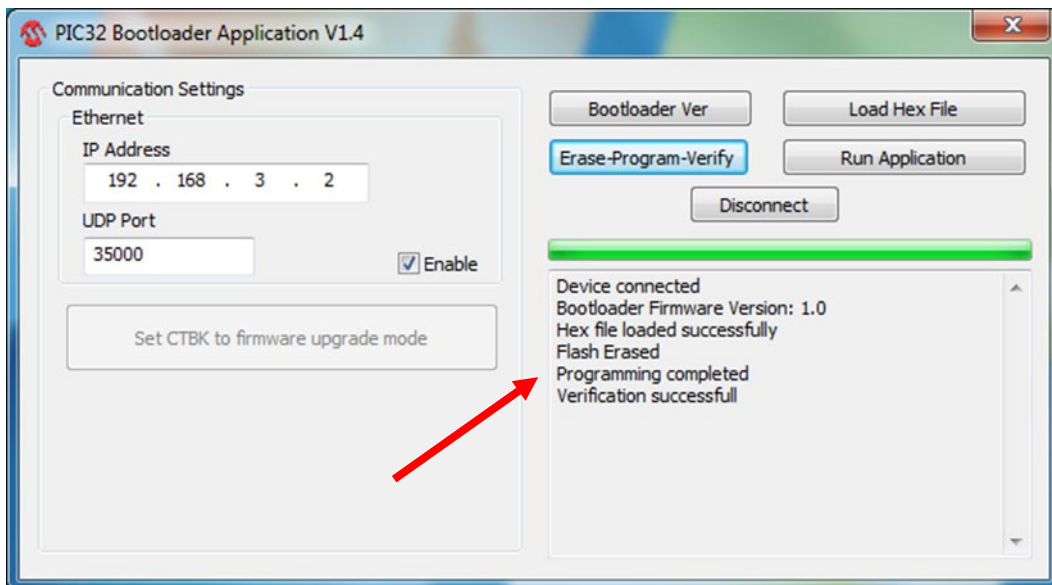
- Touch the Load Hex File button and select the file containing the new firmware. This is normally called:

CTBK.X.production.hex

- The line “Hex file loaded successfully” should now appear.



- Select **Erase-Program-Verify** button
- The following lines will appear in this order:
 - **Flash Erased**
 - **Programming completed**
 - **Verification successful**



- Select **Run Application**; you will hear a beep indicating that the new firmware is running.
- Close the **PIC32 Bootloader Application** by selecting **Disconnect** and then the close window command “X”.

2.4.2 UPGRADING THE SYSTEMA DRF SOFTWARE

The **SYSTEMA DRF** application is an all-in-one software package, to be installed on the monitor unit computer and on the Control Panel computer.

The same version must be used on both devices, of course.

This means that whenever a software upgrade is needed, you must update the software on both computers.

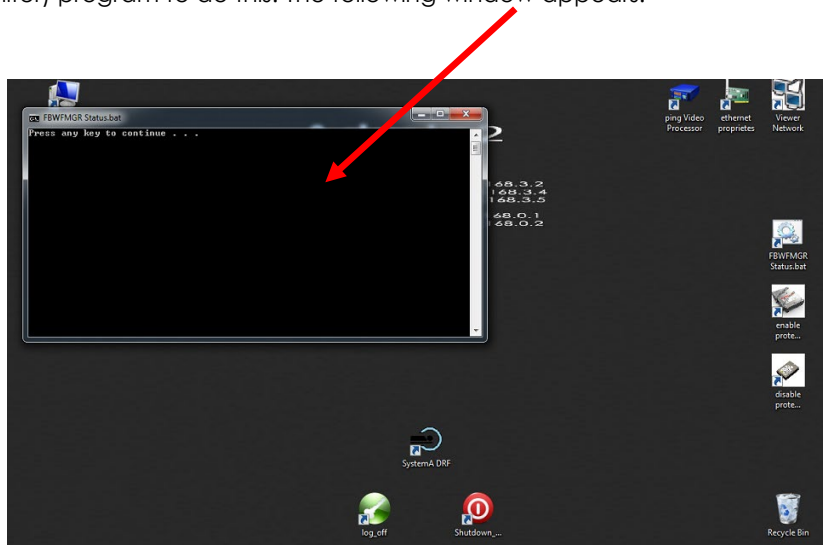
Upgrade procedure:

a) VIDEO PROCESSOR

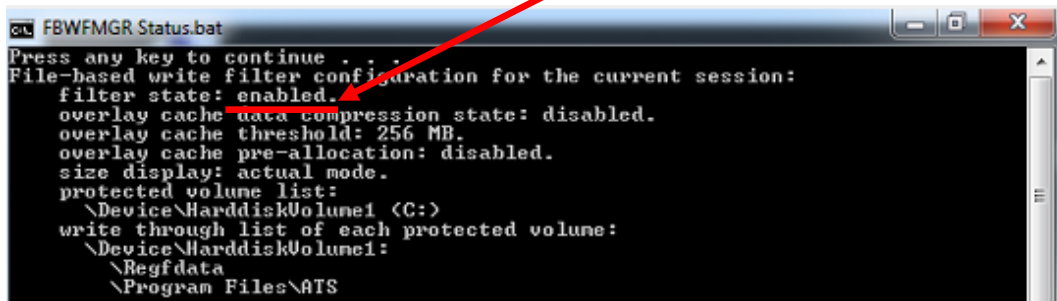
- 1) The software must be saved on an USB drive:
 - **Setup_systema_drf ver x.x**
- 2) Insert the USB drive in one of the two ports on the front of the monitor unit.
- 3) Connect a USB keyboard and USB mouse and then log onto the operating system as user Admin 2 (Password: 24060); the following page appears:



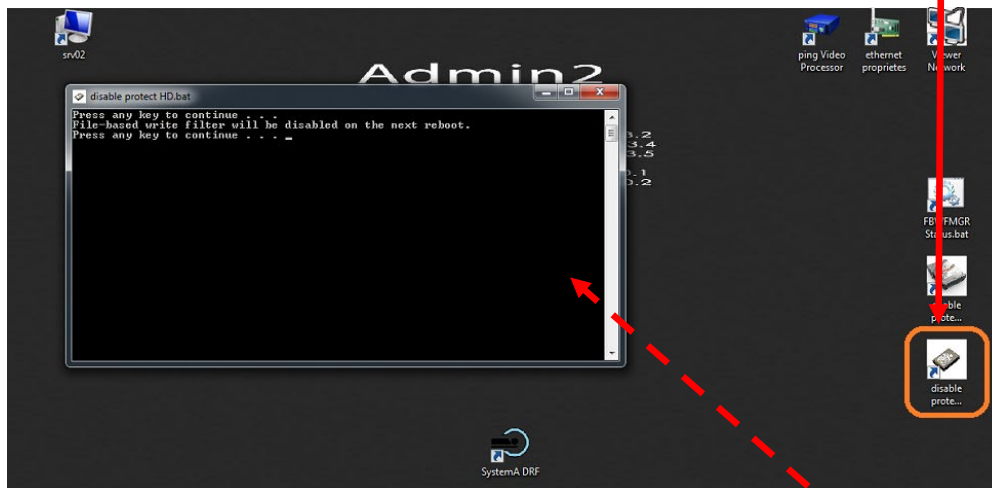
- 4) Check whether "**PROTECT HD**" is enabled. You need to open the "**FBWFMGR STATUS**" (File-Based Write Filter) program to do this. The following window appears:



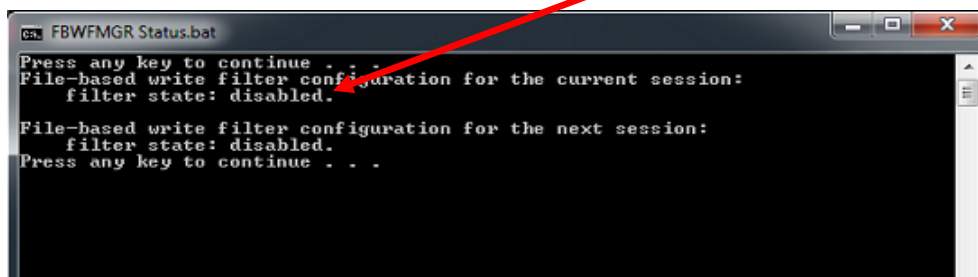
Press any key and the program will now run and produce a report on its current configuration. If the software is operating, "filter state: enabled" will appear on the third line; if turned off, "filter state: disabled" will appear. Close the window with the "X" key.



- 5) If the program is disabled, skip to point 8). If the program is active, open the "**DISABLE PROTECT HD**" software.

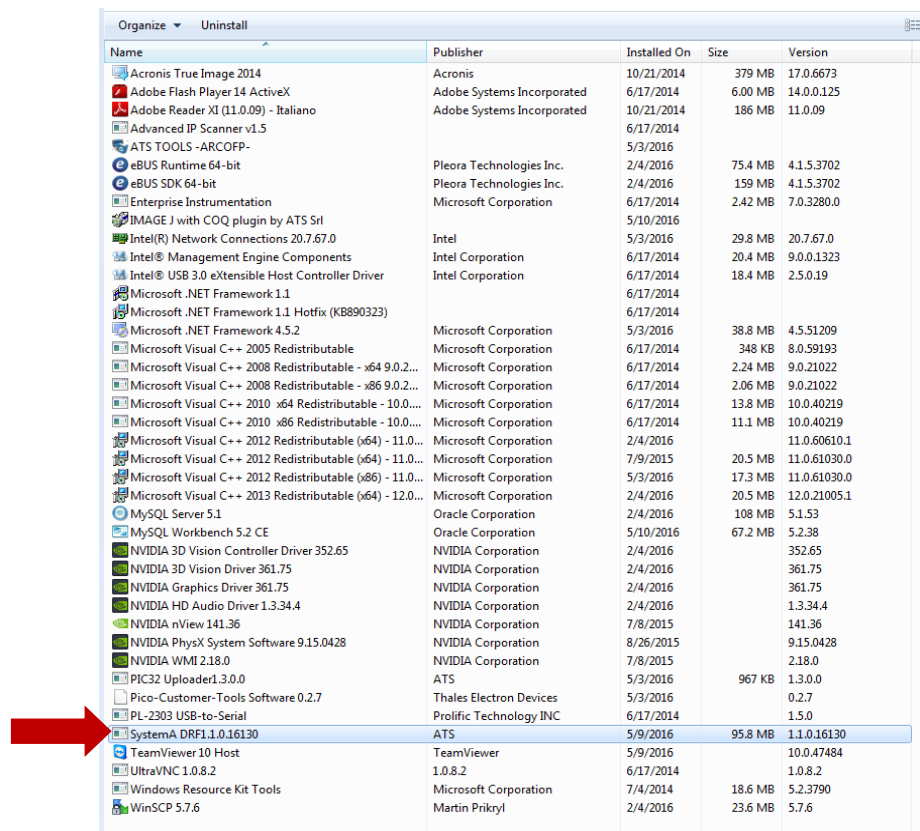


- 6) This window opens. Press any key to run the program. The message "**PROTECT HD** will be disabled on the next reboot" appears.
- 7) Now close the window using the "X" key and reboot the computer.
- 8) Open the "**FBWF MGR STATUS**" program again to check that the deactivation procedure successfully accomplished. Press any key and the line "filter state: disabled" should now appear.

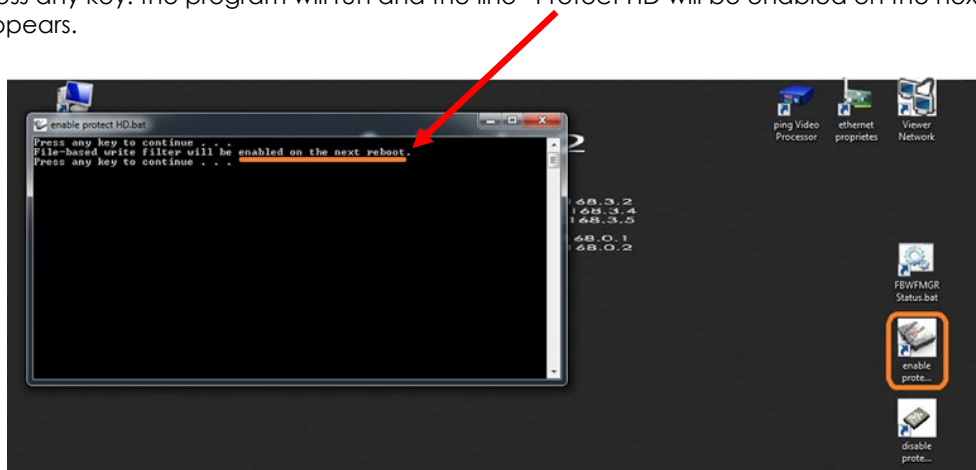


Close the window using the "X" key

- 9) Open the Windows Control Panel and then open the “**Program and Features**” folder. The window shown below now opens.
- 10) Uninstall the **SystemA DRF** program, as shown in the figure below.



- 11) Open “**Explore resources**” and run the **Setup_systema_drf** program on the USB pen drive. Select the option to install on video processor and complete the procedure.
- 12) Enable “**PROTECT HD**” software by double-clicking on the icon indicated by the orange square in the figure below. A new window appears. Press any key: the program will run and the line “Protect HD will be enabled on the next reboot” appears.



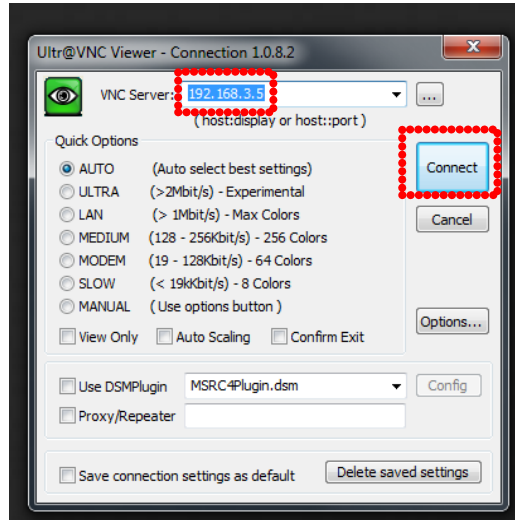
- 13) Finally, reboot the equipment to enable both the new Video Processor program manager (**SYSTEMA DRF**) and **PROTECT HD software**.

Now upgrade the software of the CONTROL PANEL (see point b, below).

b) CONTROL PANEL (PC panel)

Use the computer on the monitor unit to access the Control Panel (you cannot connect a keyboard or mouse directly to the Control Panel). To use this, open the “Ultra VNC viewer” remote access application.

- 1) Open the “Ultra VNC viewer” application and enter the **IP Address: 192.168.3.5**, as shown in the figure below, then click on “**Connect**”.

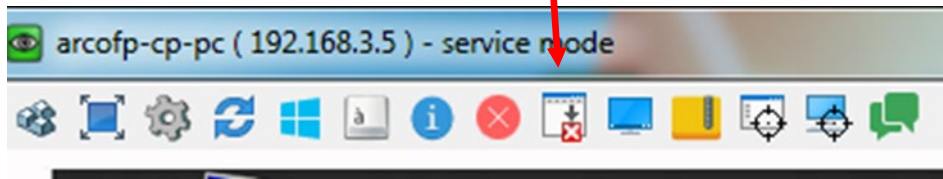


- 2) Log onto the operating system as user **Admin2** and follow points from **3)** to **8)** of the previous paragraph A.
- 3) Close the window using the “X” key and go to the Windows Control Panel. Open the “**Program and Features**” folder. The window shown below now opens.

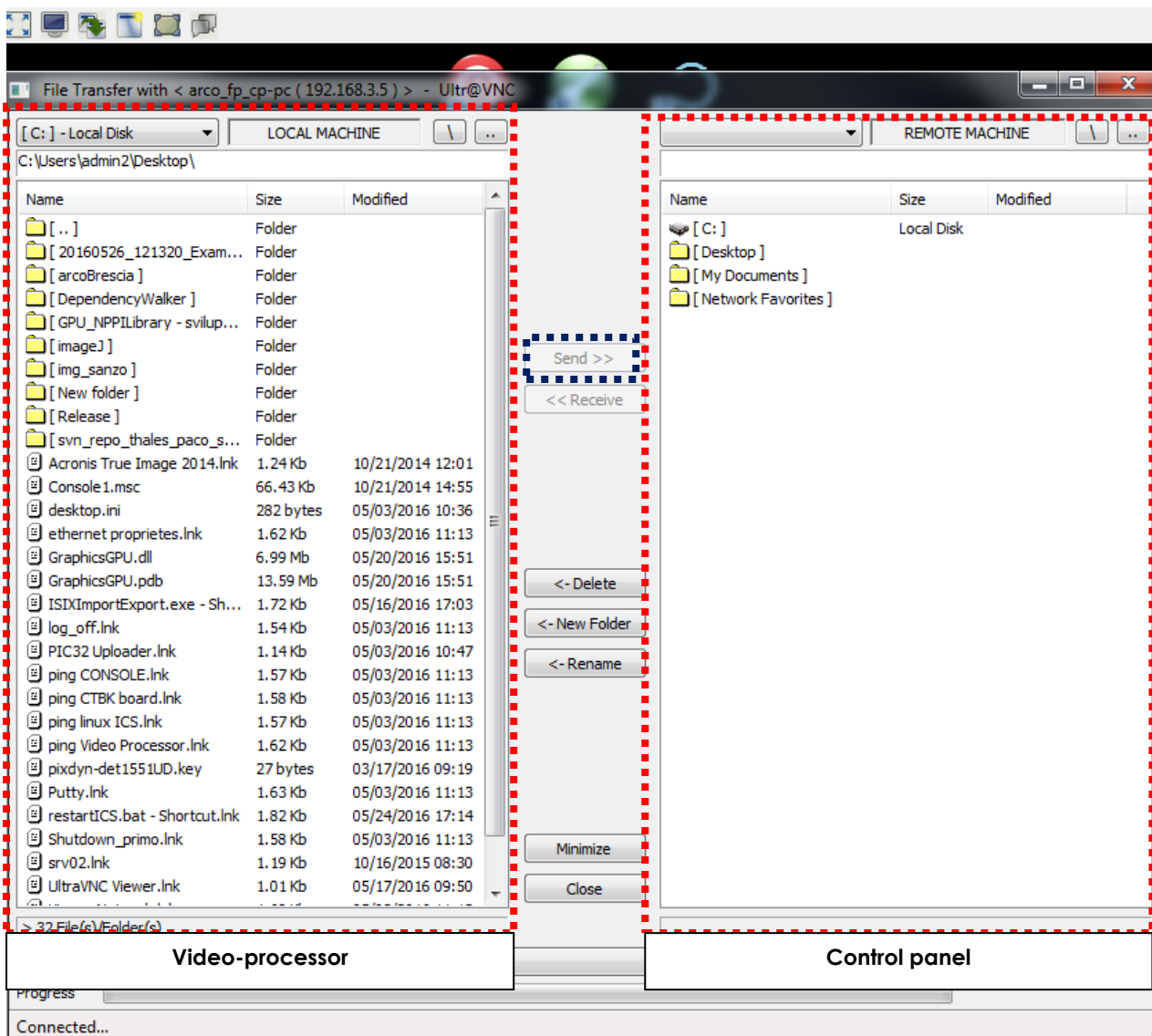
Name	Publisher	Installed On	Size	Version
ATS TOOLS -ARCOFF-		2/10/2016		
COMODO Time Machine	COMODO	5/11/2016	49.1 MB	2.8.155286.178
eGalaxTouch	eGalaxTouch	2/9/2016		5.12.0.10517
Intel(R) Manageability Engine Firmware Recovery Ag...	Intel Corporation	2/9/2016	54.8 MB	1.0.0.35132
Intel(R) Network Connections 20.4.207.0	Intel	2/9/2016	30.4 MB	20.4.207.0
Intel® Control Center	Intel Corporation	2/9/2016	1.46 MB	1.2.1.1007
Intel® Graphics Driver	Intel Corporation	2/11/2016	74.2 MB	10.18.10.4276
Intel® Management Engine Components	Intel Corporation	2/9/2016	20.4 MB	8.0.0.1351
Intel® Trusted Connect Service Client	Intel Corporation	2/9/2016	10.6 MB	1.23.216.0
Intel® USB 3.0 eXtensible Host Controller Driver	Intel Corporation	2/9/2016	18.4 MB	1.0.3.214
Microsoft .NET Framework 4.5.2	Microsoft Corporation	2/11/2016	38.8 MB	4.5.51209
Microsoft Visual C++ 2008 Redistributable - x64 9.0.3...	Microsoft Corporation	2/9/2016	792 KB	9.0.30729
Microsoft Visual C++ 2008 Redistributable - x64 9.0.3...	Microsoft Corporation	2/10/2016	778 KB	9.0.30729
Microsoft Visual C++ 2010 x64 Redistributable - 10.0...	Microsoft Corporation	2/9/2016	13.6 MB	10.0.30319
Microsoft Visual C++ 2010 x86 Redistributable - 10.0...	Microsoft Corporation	2/9/2016	11.0 MB	10.0.30319
Microsoft Visual C++ 2012 Redistributable (x64) - 11.0...	Microsoft Corporation	5/10/2016	20.5 MB	11.0.61030.0
SystemA DRF1.1.0.16130	ATS	5/10/2016	57.4 MB	1.1.0.16130

- 4) Uninstall the **SystemA DRF** program shown in the figure below.

- Transfer the **Setup_systema_drf_x.x** installation file on the USB pen drive to the Control Panel computer using UltraVNC by clicking the key shown in the figure below.

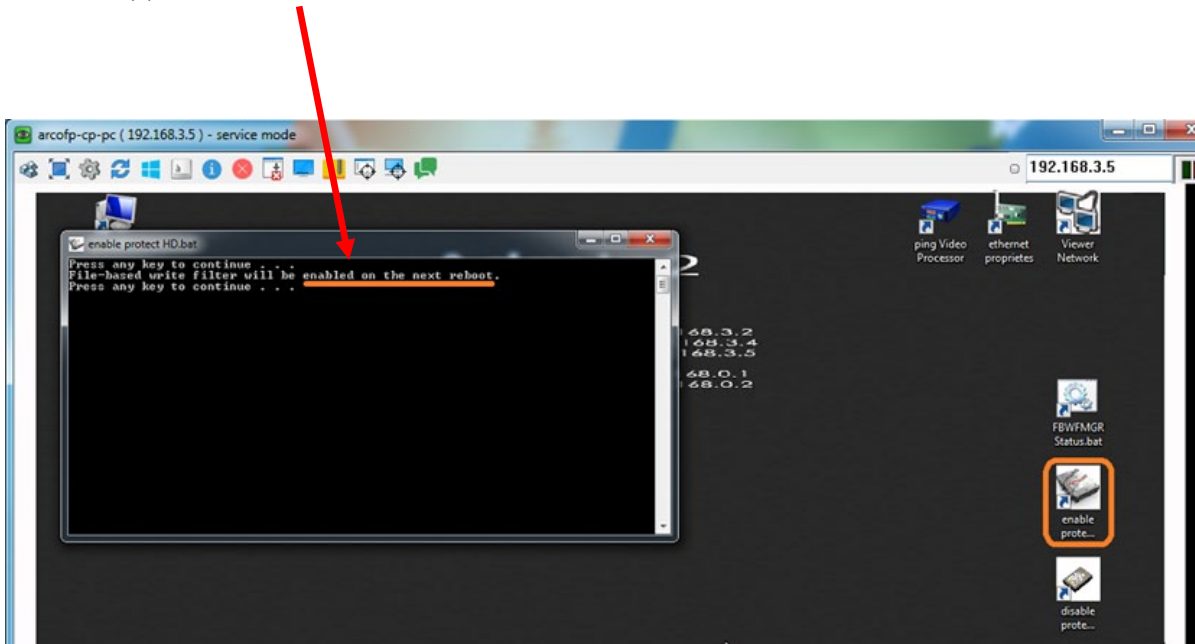


- The following page now appears. Select the file in the left-hand window that you want to send to the Control Panel. Click on SEND to send this to the Control Panel.



- Now run the installation file, select the option to install on Control Panel and complete the procedure.

- 8) Enable "**PROTECT HD**" software by double-clicking on the icon indicated by the orange square in the figure below. A new window appears. Press any key; the program will run and the line "Protect HD will be enabled on the next reboot" appears.



- 9) Finally, reboot the Control Panel computer to enable both the new Control Panel program manager (**SYSTEMA DRF**) and **PROTECT HD software**.

3 SPARE-PARTS

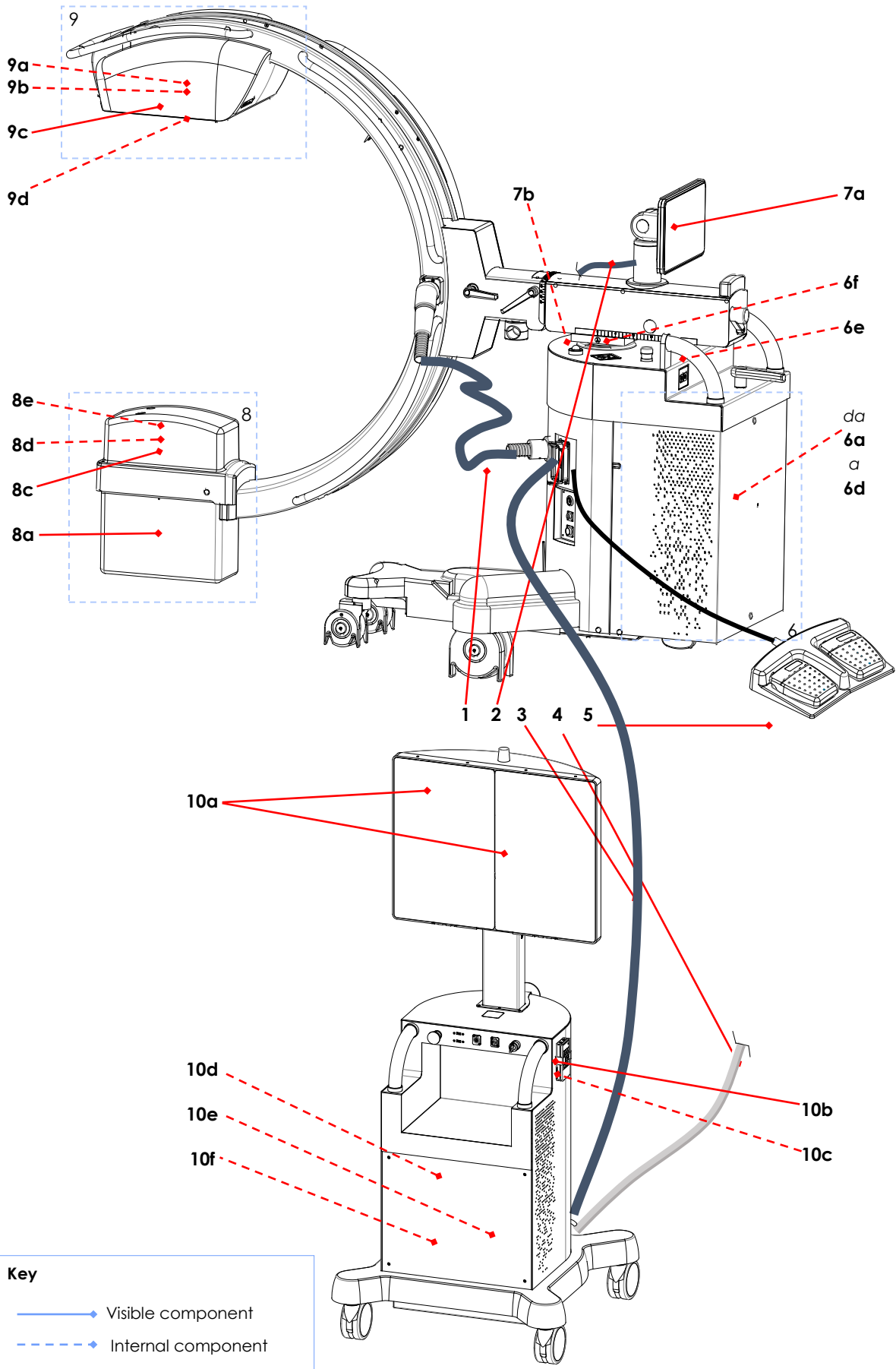
3.1 LIST OF SPARE-PARTS

Note: - When ordering spare parts, please quote the item code.

- The numbering system used in the list refers to the figures below.

- Please contact the authorised dealer for parts that are not included in the list below, or that are not numbered in the figures.

N°	Description	Code	Note / Model
1	Stand/C-arm cable	550 74 019	
2	Control Panel cable	550 74 015	
3	Stand / monitor unit connection cable	550 74 017	
4	Monitor unit power cable	550 74 011A	
5	2-command footswitch	74 07 400	
6 Stand rack unit			
6a	X-ray generator	IN 74 001	IMD model HF1 15kW
6b	5kW stand power unit	74 05 720	5 kW model only
	- 132VA actuator transformer (TR3)	19 02 110A	
	- Board B1 (CTBK-HW)	74 01 100A	
	- Board B2 (ASAC 01)	19 10 010A	
	- 12V TDK-Lambda feeder HWS100a 12 ME	HW 74 001	
	- 24V TDK-Lambda feeder HWS150 24 ME	HW 86 401	
	- CTBK-HW Board transformer	TSFRKD100	
6c	20 kW stand power unit	74 15 720	20 kW model only
	- 230V/380V-2kVA auto-transformer (TR2)	44 01 810	20 kW model only
6d	20 kW stabilizer unit	74 15 730	20 kW model only
	- Board B4 (15RkLC 00)	44 01 100A	20 kW model only
	- Board B5 (15RkLCP 00)	44 01 400A	20 kW model only
	- Board B6 (15RkLCF 00)	44 01 500A	20 kW model only
	- Board B7 (15RkVC 00)	44 01 700	20 kW model only
6e	Board B8 (RkOO 00) ON/OFF unit	59 01 500	
6f	Board B9 (RkUD 00) UP/DOWN unit	59 01 400	
7 Control panel unit			
7a	Control Panel Mod.Muij-2112.	MO 12 002	
7b	Board B10 (CTLD-HW)	74 01 300	
8 Monoblock unit			
8a	Monoblock with rotating anode (Passive Cooling)	MR 66 001	IMD mod. I-40R 15RF
	Monoblock with rotating anode (Active Cooling)	MR 74 001	IMD mod. I-40R 15RF AC
8b	Collimator protection cover	74 05 904A	
8c	Collimator	CO 95 001	Mod. R 650 QDASM / 010D
	Secondary collimator	CO 74 101	Cod. RS 2248 (only with FPD 2121Asi)
8d	Dose Area Product meter	DS 74 001	
9 Detector unit			
9a	aSi 30x30 cm ² flat panel detector	DT 74 002	
9b	aSi 21x21 cm ² flat panel detector	DT 74 001	
9c	Detector aSi 21x21 cover	74 05 824A	
	Detector aSi 30x30 cover	74 05 834A	
9d	Anti-scatter grid ACS AL 215x215mm	GRDF215X21580CM	
	Anti-scatter grid ACS AL 315x315mm	GRDF315X31580CM	
9e	Single laser diode	44 10 012A	
10 Monitor unit			
10a	21.5" LCD colour monitor	MO 22 003	model TMM215W-V-TPU
10b	Remote control receiver	74 05 910	
10c	Board B3 (CTIR-HW)	74 01 200	
10d	Board B20 (ASPS 01)	66 10 110	
10e	3KVA insulating transformer (TR1)	TRASFP2	
10f	Video processor FP-VP3A	74 20 325	



4 SCRAPPING

4.1 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.

5 FITTING/REMOVING COMPONENTS



Before attempting to fit or remove any components, you must switch the EM equipment off and unplug it from the mains power supply.

Respect all the safety procedures reported in Paragraphs and Sub-Paragraphs 1.3.1, 1.3.2, 1.3.3, in Part 1 of this Manual.

5.1 FITTING / REMOVING THE COVERS

5.1.1 X-RAY MONOBLOCK COVER

To remove the X-ray monoblock cover:

- Undo the 3 screws (V) and remove the plastic washer (R).
(Attention: you can access a screw only after you remove its protective cap(T)).
- Extract the cover (C).

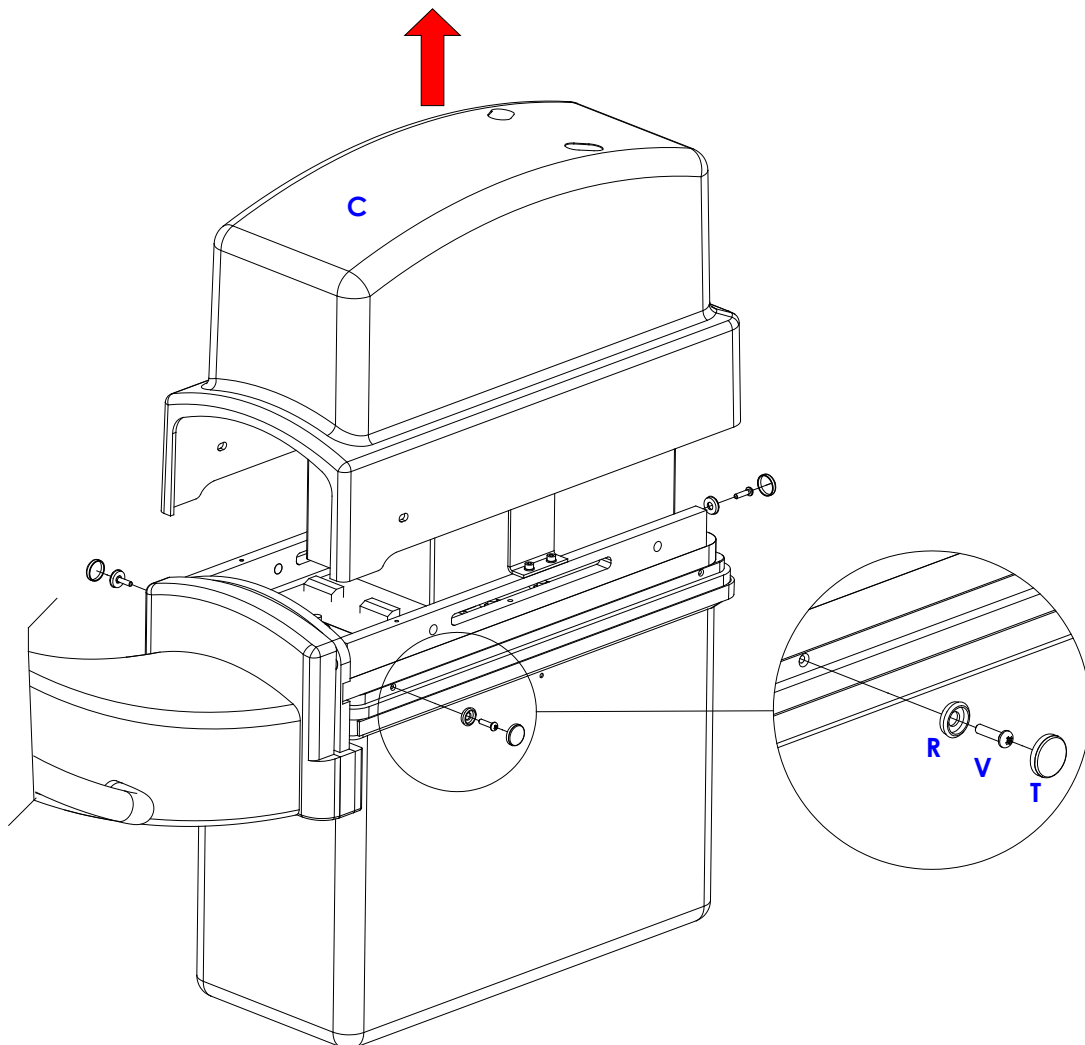


Fig. 1



Repeat the above steps in reverse order to remount the cover.

5.1.2 FLAT PANEL DETECTOR (FPD) COVER

To remove the FPD cover (C):

- Undo the 4 screws (Va). (In Fig.2a is shown the 21x21 FPD version).
- Remove the handle (M).
- Remove the laser unit (see paragraph 5.3.2).
- Remove the FPD (see paragraph 5.3.1).
- Undo the 6 screws (V). (In Fig.2b is shown the 21x21 FPD version).
- Extract the cover (C).

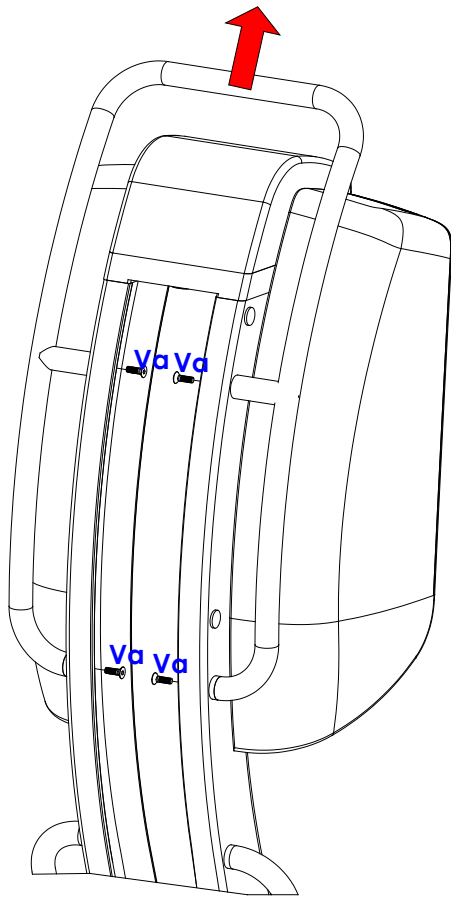


Fig. 2a

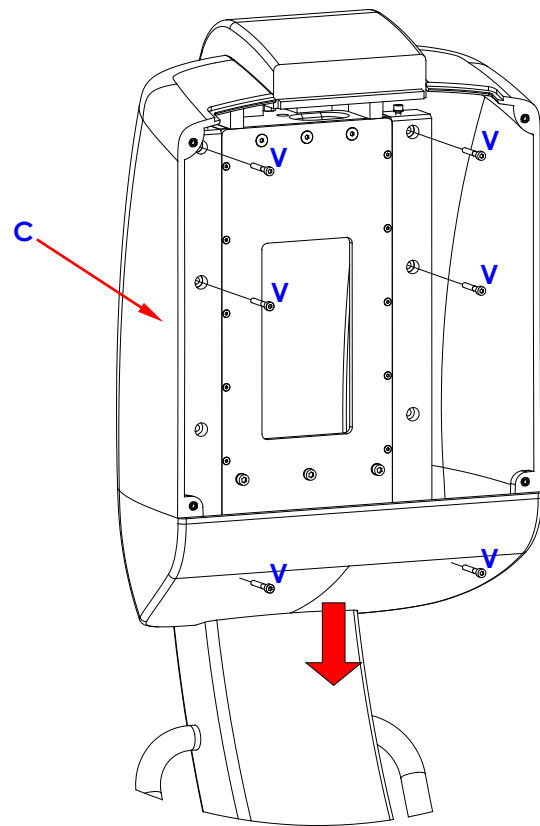


Fig. 2b



Repeat the above steps in reverse order to remount the cover.

5.1.3 STAND COVER

To remove the stand cover:

- Undo the 4 screws (V) and remove the plastic washers (R).
Attention: these screws can only be accessed after removing their safety plugs (T).
- Extract the cover (C)

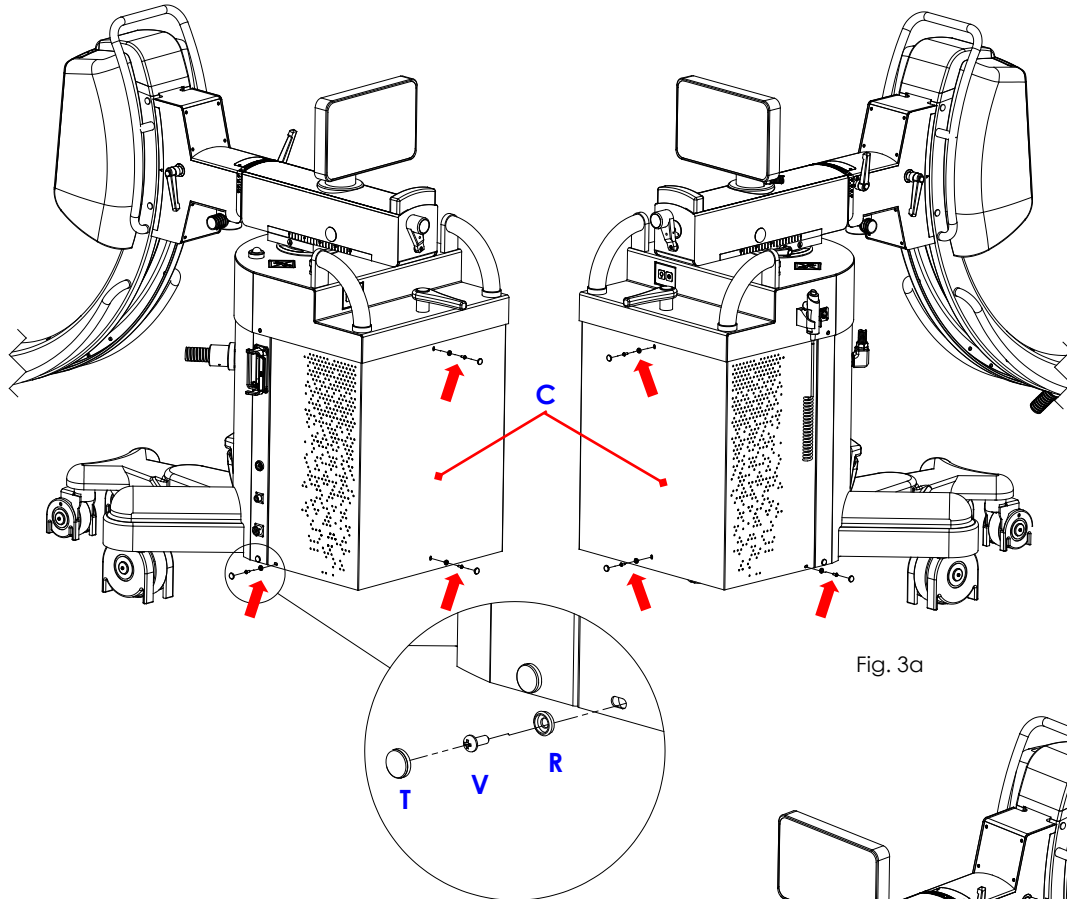


Fig. 3a

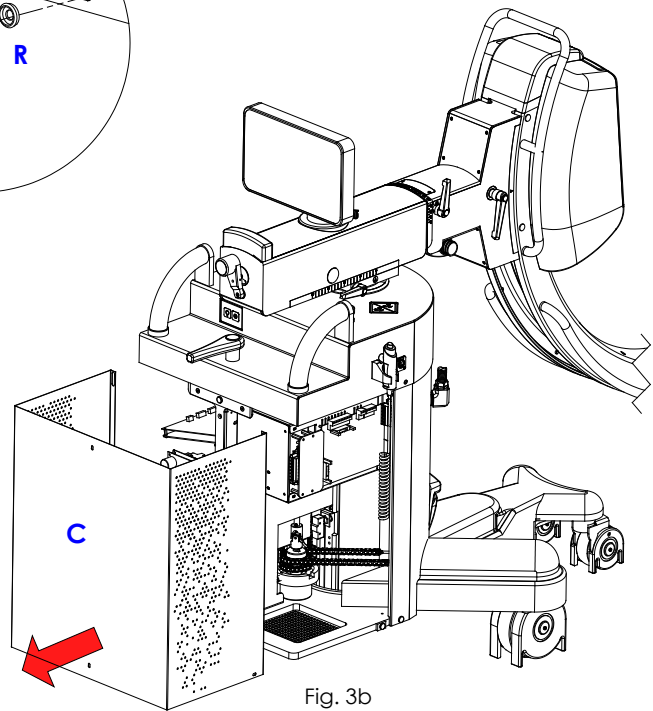



Fig. 3b

 Repeat the steps above in reverse order to remount the cover.

5.2 FITTING / REMOVING THE X-RAY MONOBLOCK UNIT COMPONENTS

5.2.1 X-RAY MONOBLOCK



Attention: Before dismantling the X-ray monoblock, you must rotate the C-arm as shown in Fig.4a (with the FPD fully extended) and engage the brake (F) on the C-arm support, making sure that this stops the C-arm correctly. You also need to place a wooden block under the stand (see Fig.4a) to prevent the equipment from toppling over when the X-ray monoblock is removed.

To remove the X-ray monoblock:

- Remove the X-ray monoblock cover (see paragraph 5.1.1 above).
- Disconnect the X-ray collimator connector.
- Remove the X-ray collimator (see paragraph 5.2.2 below).
- Remove the plate holding the collimator cone (see paragraph 5.2.2.1 - Fig.5b below).
- Unscrew the 2 screws (V) and remove the plate (P).
- Disconnect the X-ray monoblock connectors.
- Remove the 7 nuts (D) and their spring washers (R) (see Fig.4b).
- Remove the X-ray monoblock.

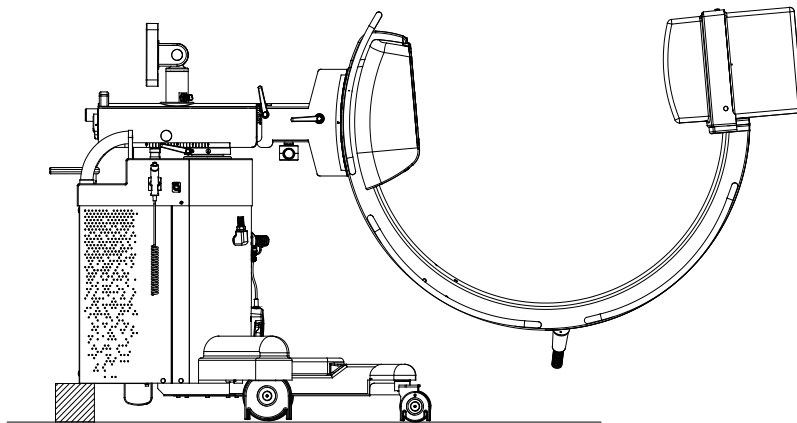


Fig. 4a

Wooden block

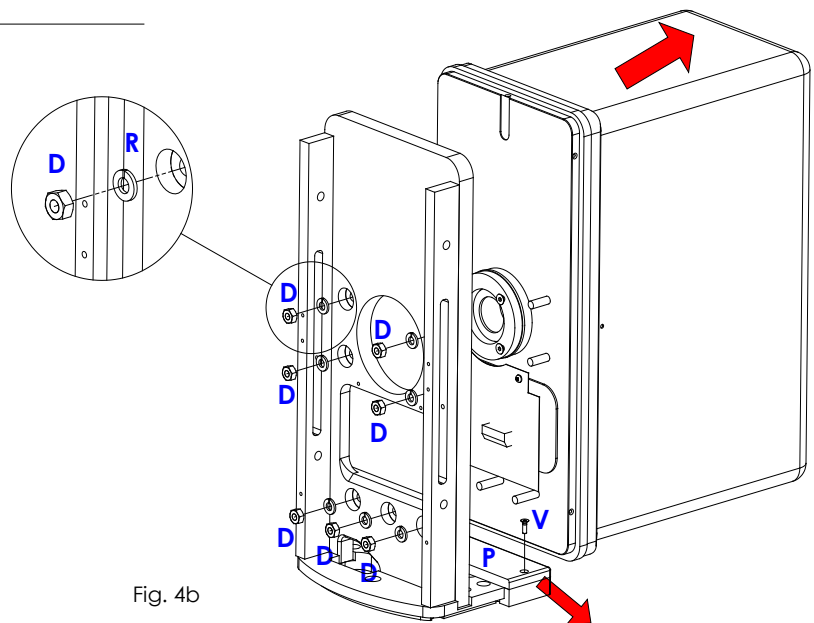


Fig. 4b



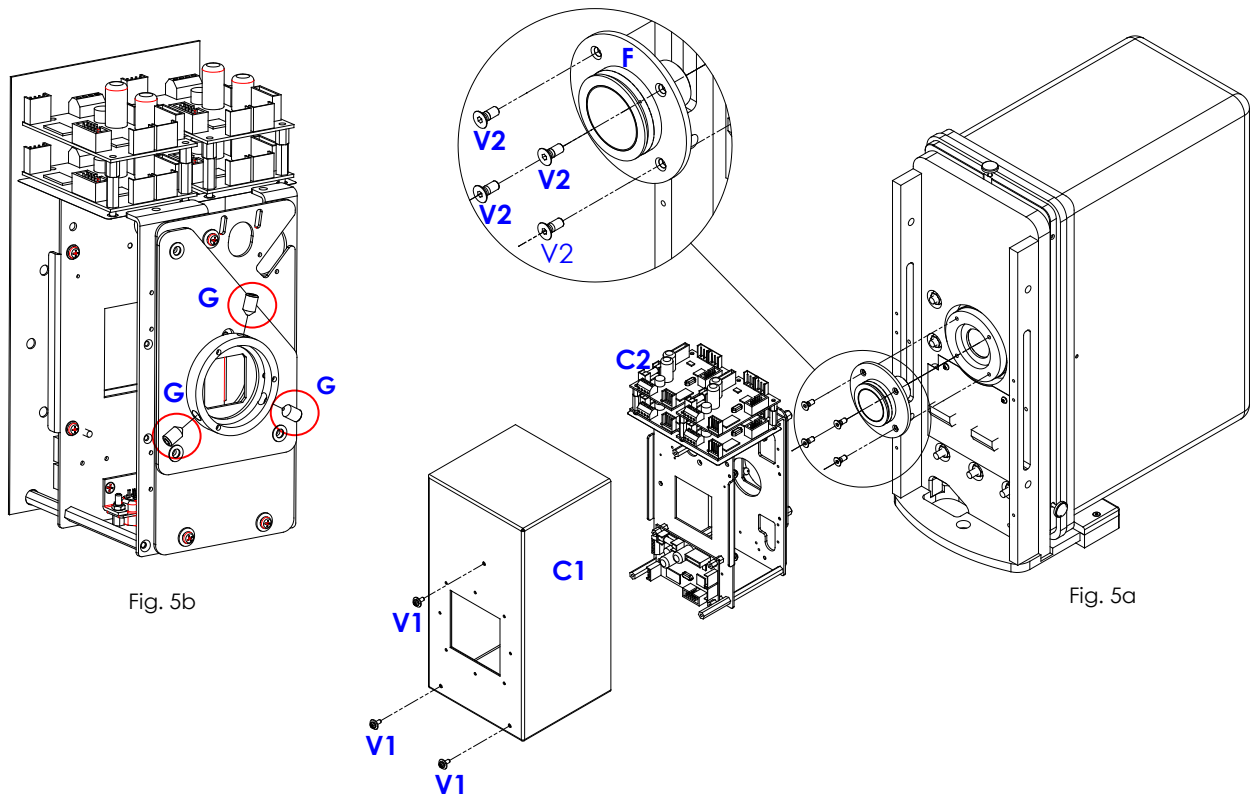
Repeat the above steps in reverse order to remount the X-ray monoblock. After replacing the monoblock, you must re-calibrate the X-ray generator (see Chapter 2.1 in Part 4).

5.2.2 X-RAY COLLIMATOR UNIT

5.2.2.1 X-RAY COLLIMATOR

To remove the X-ray collimator:

- Remove the X-ray monoblock cover (see paragraph 5.1.1 above).
- Remove the Dose Area Product meter if present (optional) (see paragraph 5.2.2.2 below).
- Disconnect the X-ray collimator cable.
- Undo the 3 screws (V1) and then remove the cover (C1) on the X-ray collimator (see Fig.5a).
- Loosen the 3 grub screws (G) (see Fig.5b) and extract the X-ray collimator (C2).



To remove the X-ray collimator cone (see Fig.5a):

- Undo the 4 screws (V2).
- Remove the flange (F) holding the cone.
- Extract the cone from the flange.



Repeat the above steps in reverse order to remount the X-ray collimator.

Note: Check the centring of the X-ray collimator after re-mounting it (see Paragraph 3.3 in Part 4). You also need to check its calibration (see Chapter 2.2 in Part 4).

5.2.2.2 DOSE AREA PRODUCT METER (DAP)

To remove the DAP meter (optional):

- Remove the front cover on the X-ray monoblock (see paragraph 5.1.1 above).
- Disconnect the cable.
- Undo the 4 screws (V).
- Remove the support (S).
- Loosen the two grub screws (G).
- Extract the DAP meter (D).

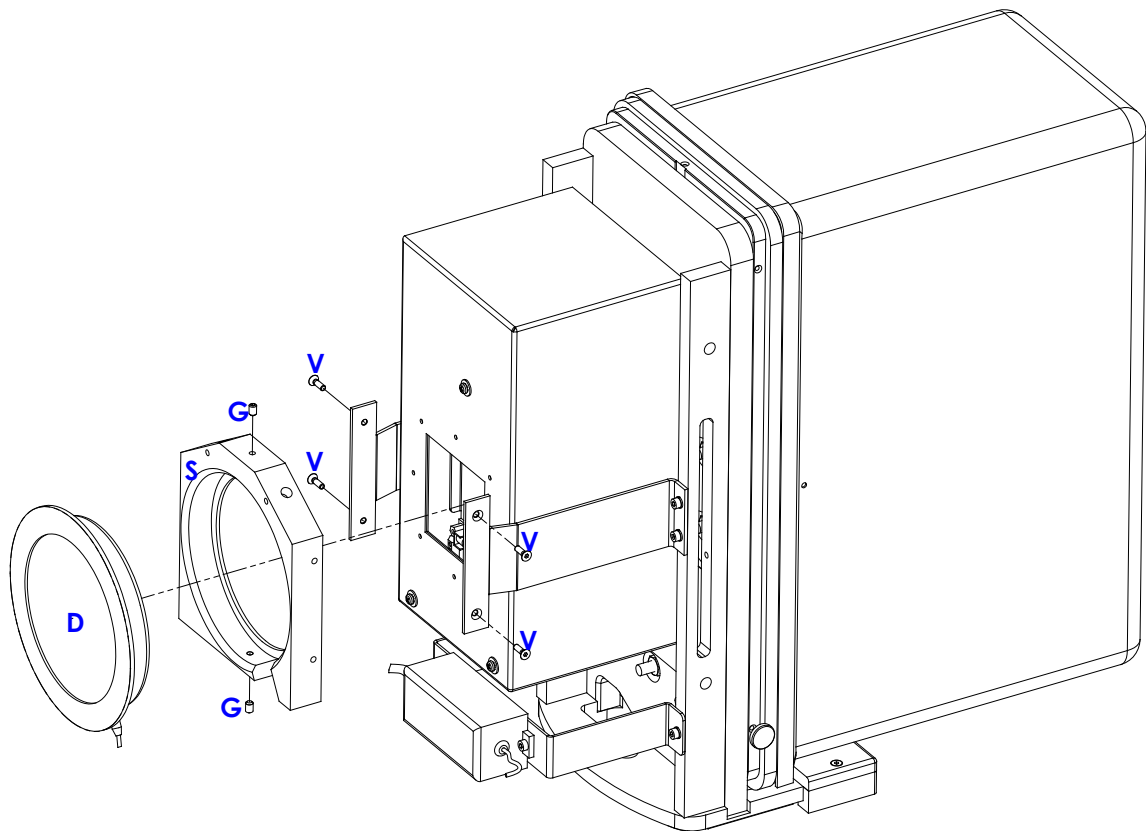


Fig. 6



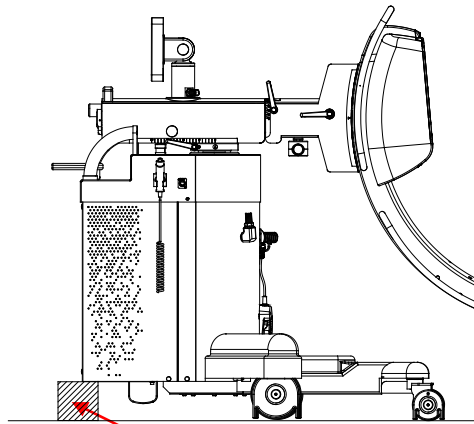
Repeat the above steps in reverse order to remount the DAP meter.
After replacing the DAP meter, you need to check the DAP reading (see paragraph 2.1.4.1 in Part 4).

5.3 FITTING / REMOVING THE FLAT PANEL DETECTOR (FPD) COMPONENTS

5.3.1 FPD



Attention: Before removing the FPD, you **must** rest the rear section of the stand on a suitable wooden block (Fig. 7a). You **must** also rotate the C-arm so that the **X-ray monoblock rests** on a suitably strong support (Fig.7b).



Wooden block Fig. 7a

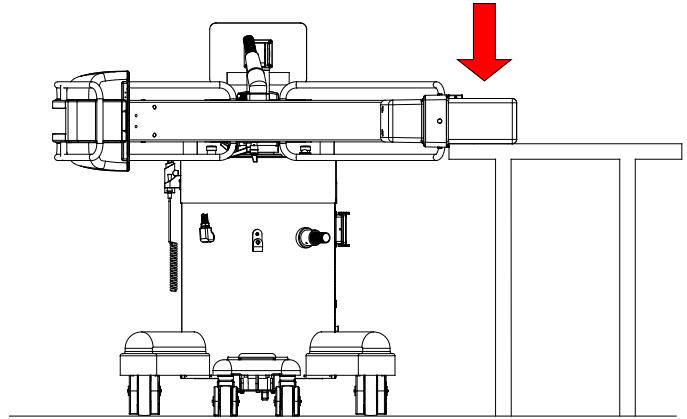


Fig. 7b

To remove the FPD (follow the same steps in reverse order to remount it, taking care not to damage any wiring):

- Remove the laser unit (see paragraph 5.3.2 below).
- Undo the 4 screws (V1) (Fig.7c) and then remove the counterweight (C) (Fig.7d).
- Disconnect all the cables.
- For 21x21 FPD version: undo the 3 screws (V2) (Fig.7e) and the 2 screws (V3) (one on either side), together with their washers.
For 30x30 FPD version: undo the 5 screws (V4) (Fig.7f) and the 2 screws (V5) (one on either side), together with their washers.
- Remove the FPD and its plate of support as shown in Fig.7e/ Fig.7f. During this procedure, maintain the FPD in order to prevent accidental fallings.
- Taking care not to damage any cables, undo the 6 screws (V6) and remove the FPD by its plate of support (P) (Fig.7h).

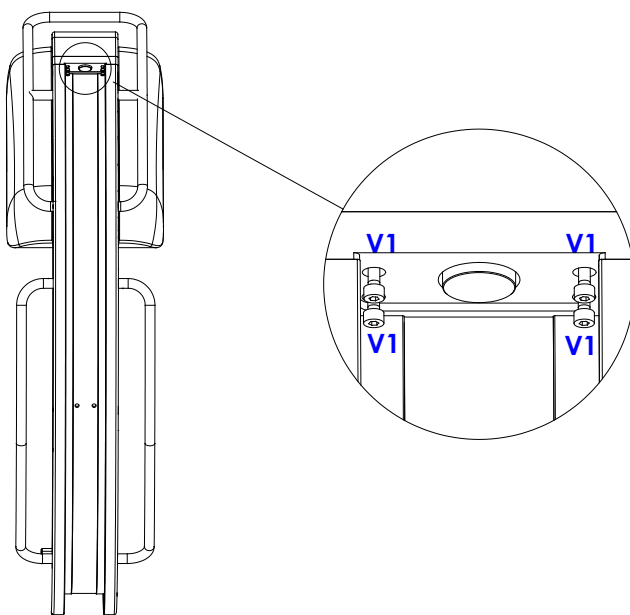


Fig. 7c

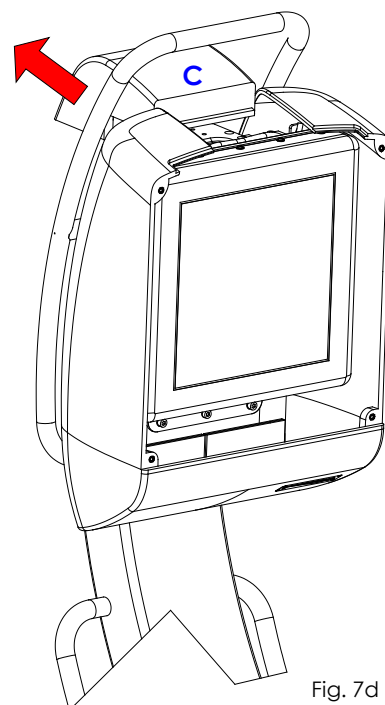


Fig. 7d

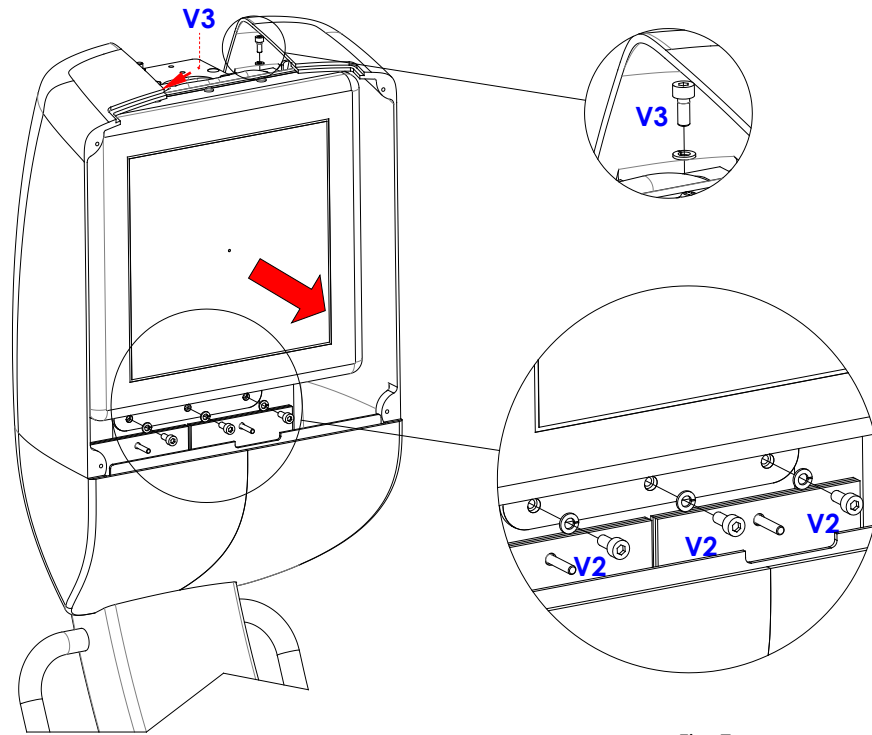


Fig. 7e

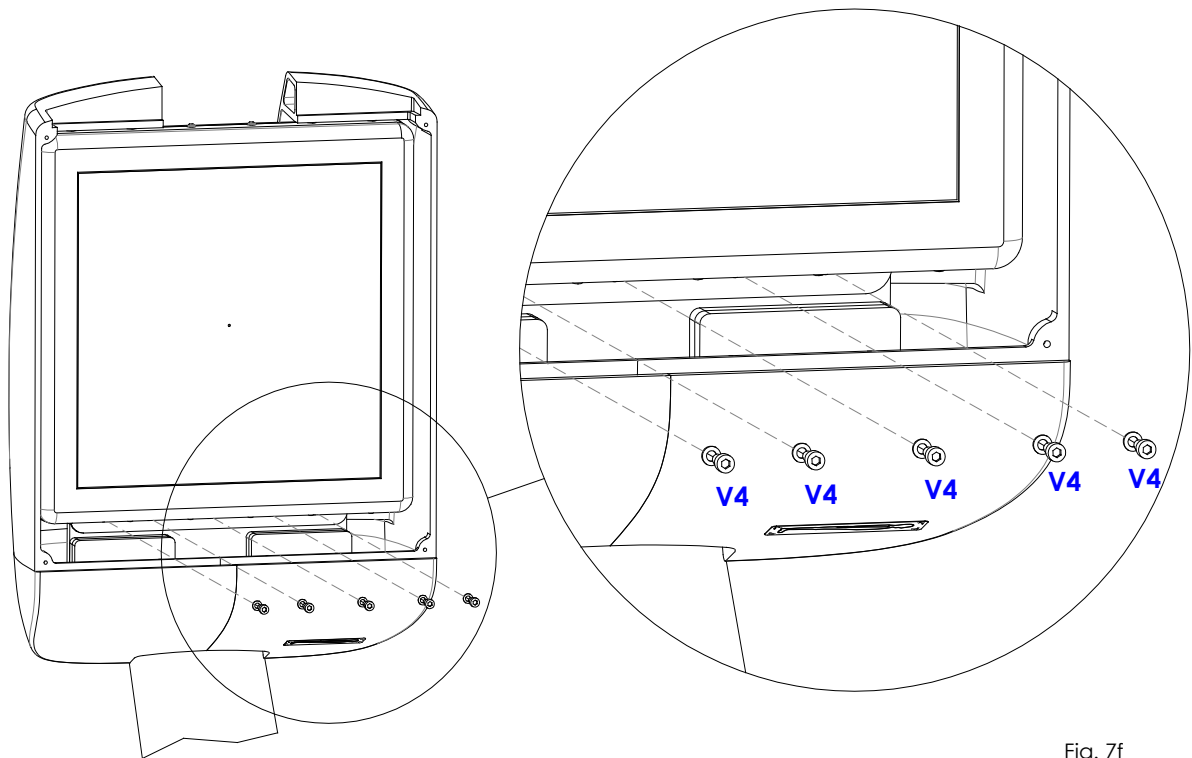


Fig. 7f

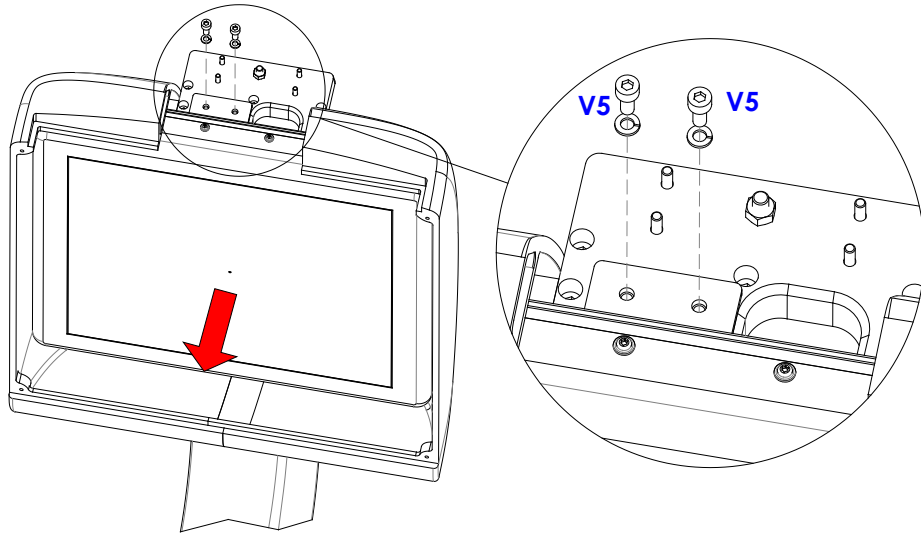


Fig. 7g

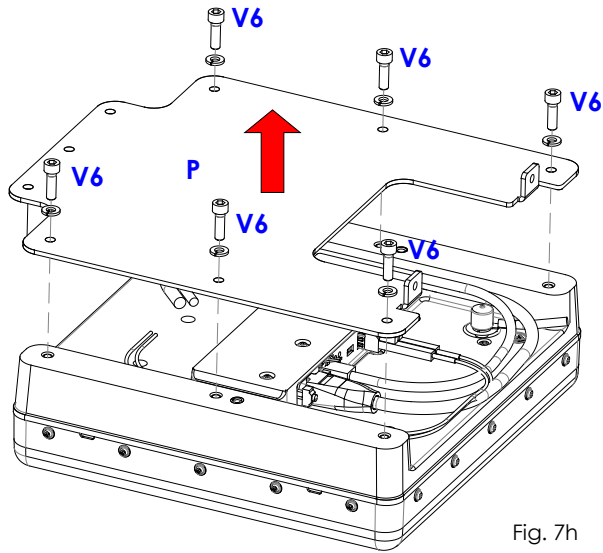


Fig. 7h

After replacing the FPD, you need to perform the following operations.

- 1) Connect a USB keyboard and USB mouse to the front of the monitor unit.
- 2) Switch the equipment on and then log onto the operating system as user Admin2 (see paragraph 5.3 in Part 2).
- 3) On your desktop, open the **Isix Internal Setup** application.



- 4) The following window will be displayed. In the **Detector** field, enter the Detector **Serial Number** (found in the attached documentation or on the serial number plate of the detector).
Now select the correct model: **Thales 30x30** or **Thales 21x21**.
Press **Set**, close the program and restart the equipment.

The screenshot shows the following configuration options in the Isix Internal Setup application:

- Serial Number:** Input field containing "01 001 74 15" with a "Set" button to its right.
- Detector:** A dropdown menu currently showing "THALES 30x30" with a "Set" button to its right.
- Clear DSA parameter:** A "Clear" button.
- Clear RDSR parameter:** A "Clear" button.
- Update PU License:** An "Upload Licence" button.
- Update Detector IP:** Input field containing "192.168.0.2" with an "Update Detector IP" button below it.
- Collimator Type:** A dropdown menu currently showing "Symmetrical" with a "Set" button to its right.

A close button (a blue square with a white 'X') is located in the bottom right corner of the window.

5.3.2 LASER / ANTI SCATTERED GRID UNIT

To remove the laser / grid unit:

- Undo the 4 screws (V).
- Remove the panel (P) in the direction shown by the arrow in Fig.8.
- Disconnect the laser cables and the anti-scattered grid cables so that you can detach the panel (P).

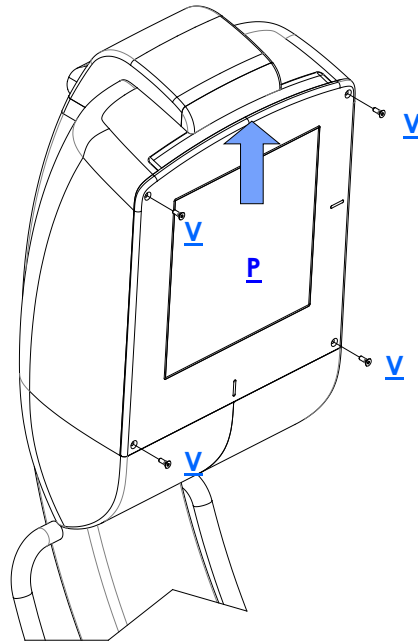


Fig. 8a



Repeat the above steps in reverse order to remount the unit.

5.4 FITTING / REMOVING THE STAND COMPONENTS

5.4.1 PARKING BRAKES

If the braking system should fail, check the state of the brake pads "P" on the 2 side wheels. If necessary, follow the steps below to replace the pads:

- Remove the cover on the leg of the stand (see paragraph 5.4.2 below).
- Raise the leg slightly so you can place a block of wood under this, lifting the wheel from the ground (at least 2 men should be used to do this).
- Remove the 2 screws (V) and their washers (R) fixing the hub caps (C); then remove the covers.
- Remove the nut (D) and extract the pin (P) from the wheel.
- Extract the wheel (A).
- Extract the pin (S) fixing the pad (B) and then remove the pad itself.
- Insert a new pad and then repeat the above steps in reverse order.

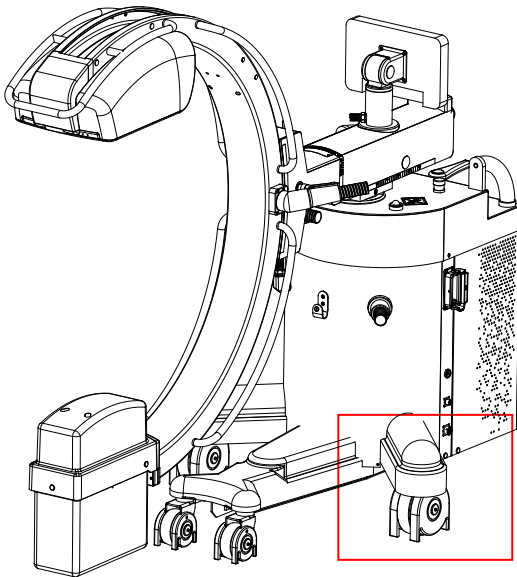


Fig. 9a

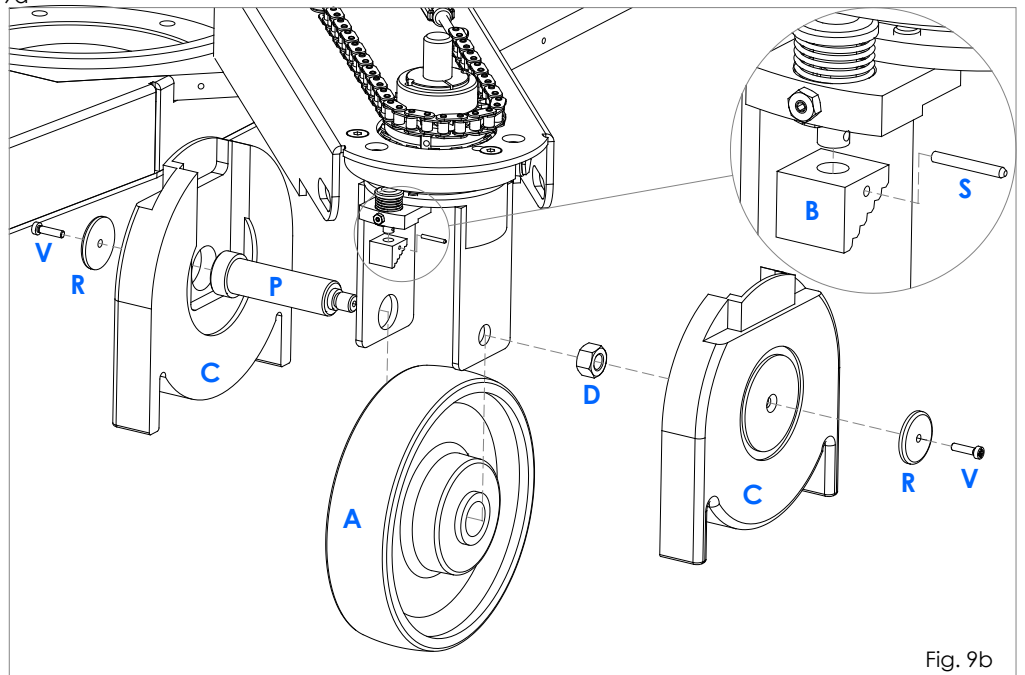


Fig. 9b

5.4.2 STAND WHEEL ROTATION CHAINS

a) **To restore the correct tension of the lower chains** responsible for rotating the rear wheels:

- Remove the cover on the leg (C2) by undoing the 2 screws (V) and their washers (under the leg).



For better access to tie-rods (T), you can also remove the rear stand cover (C1) (see paragraph 5.1.3 above).

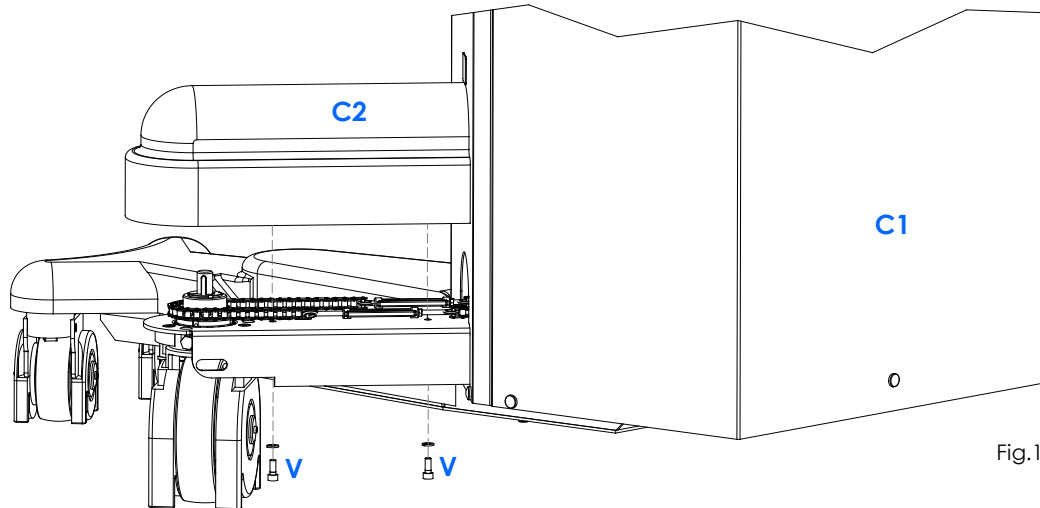


Fig.10

- Loosen the counter-nut (D) and tension the chain using tie-rod (T).



Attention: To avoid altering the direction of the wheels, you should repeat this operation symmetrically on both tie-rods.

- Tighten the counter-nut (D).
- Check the movement of the chain by using the steering handle on the console.
- Finally, return the stand cover and leg covers.

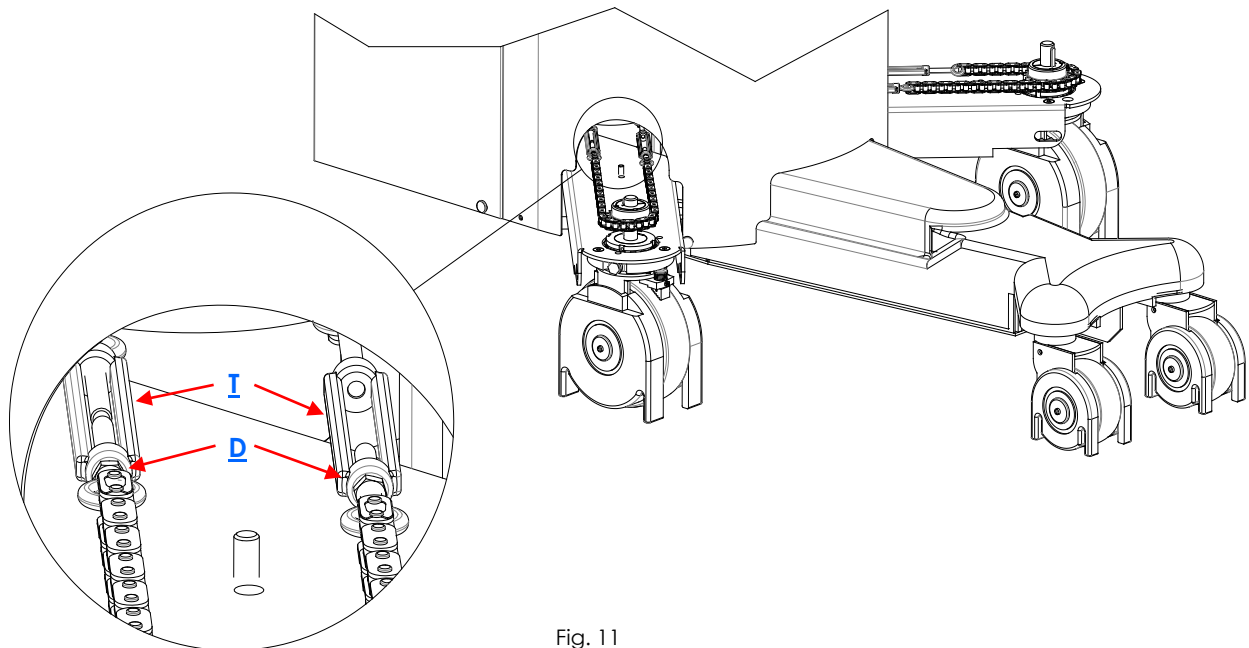


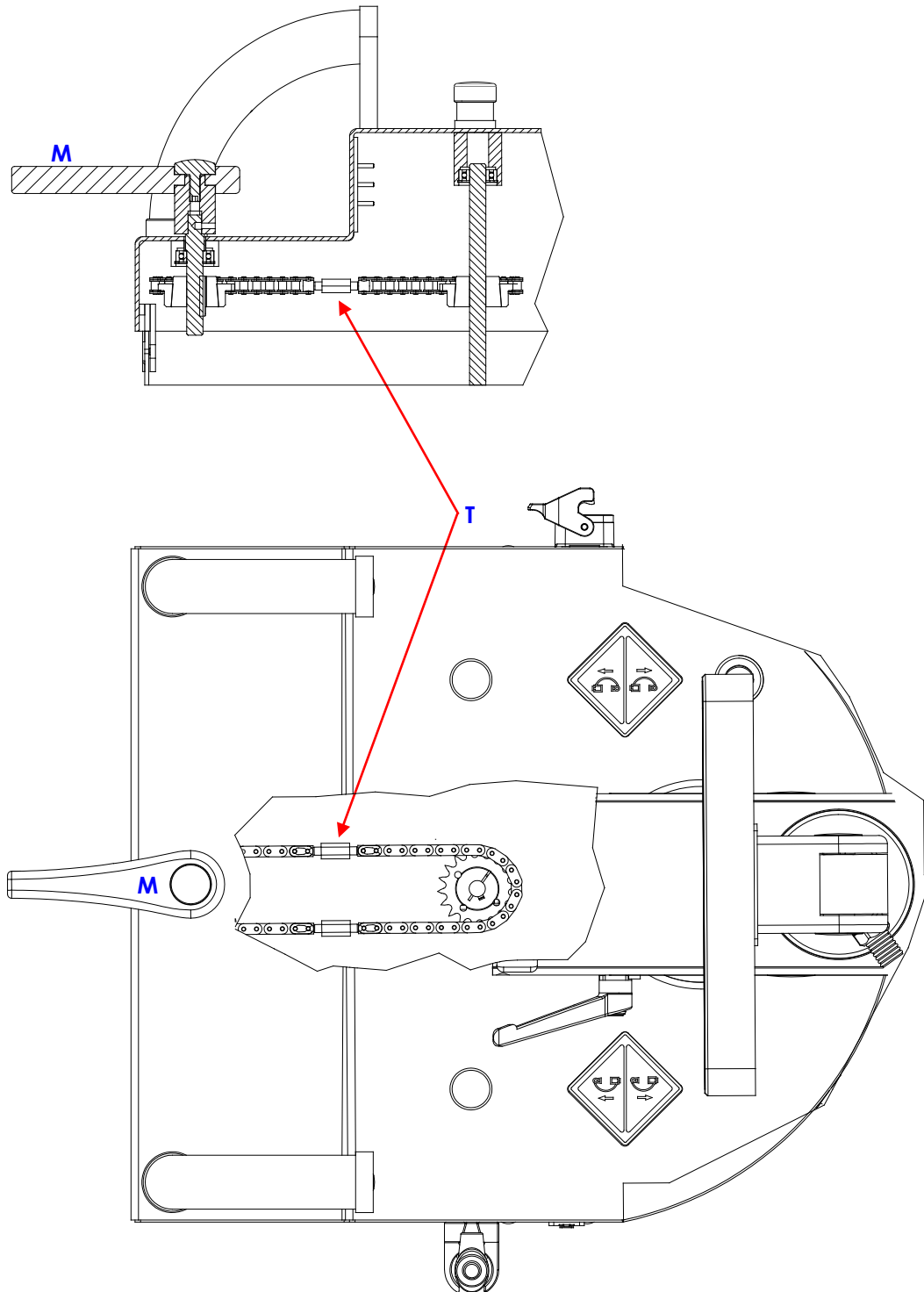
Fig. 11



Instructions valid for both chains.

b) To remove and replace **the upper chain** responsible for rotating the wheels:

- Remove the rear cover on the stand (see paragraph 5.1.3 above).
- Unscrew the tie-rod (T) and extract the chain to be replaced.
- Insert the new chain, connect it to the tie-rod and tighten to get the right tension.
- Check the system works correctly using steering knob (M).
- Return the cover.



5.4.3 ADJUSTING THE C-ARM BEARINGS

- If the C-arm does not move smoothly, you need to adjust the trolley bearings:
Remove the 8 plugs (T), using a small flat screw-driver in order to access the lateral and front bearings through the holes (F1), (F2), (F3) and (F4).

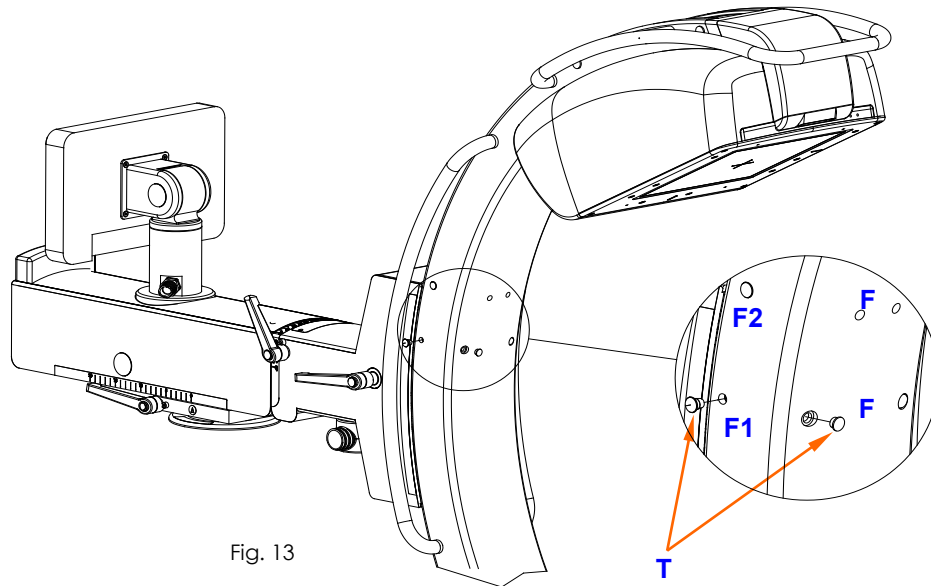


Fig. 13

a) *Adjusting the front bearings "C1":*

- Take the C-arm to the position shown in Fig.14 in order to align one of the holes (F4) with the eccentric pin on one of the bearings (C1), while the holes (F1) are lined up with the grub screws locking the pins.
- Using a 2.5 mm Allen wrench in the hole (F1), loosen the grub screw (G1) on the eccentric pin (P1). Adjust the play of the bearing by using a 5 mm Allen wrench in the hole (F4).
- Fix the position of the bearing by tightening the grub screw (G1).

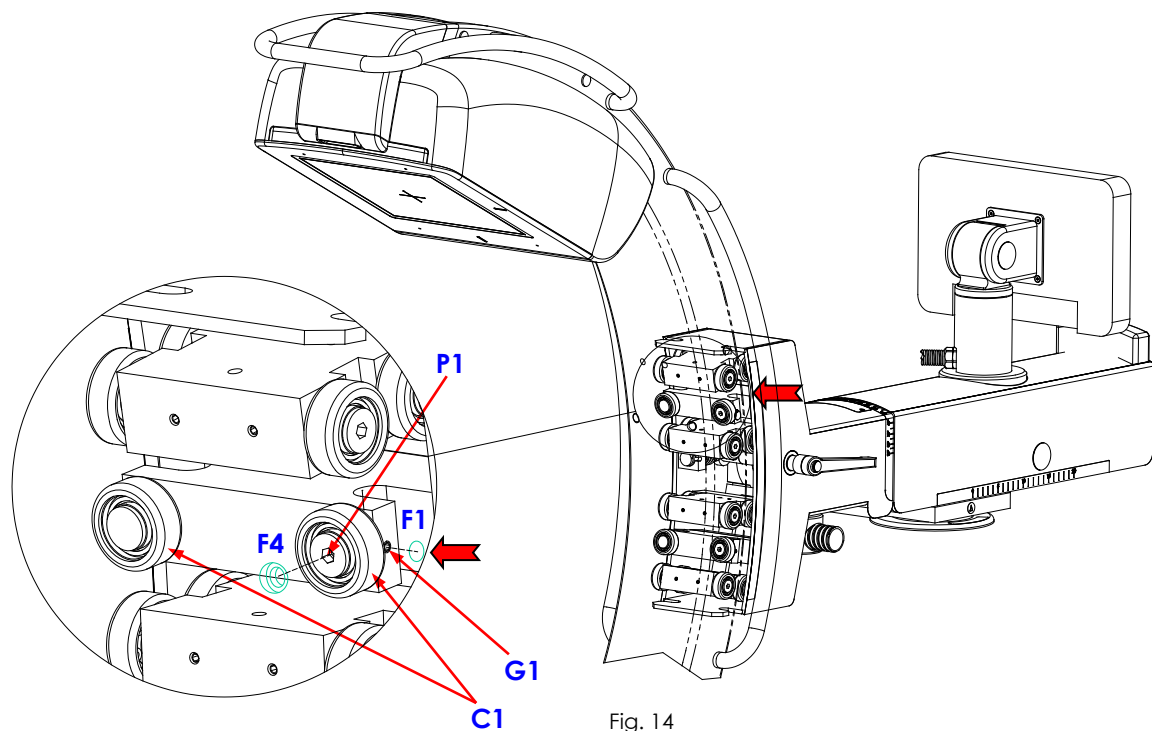


Fig. 14

b) Adjusting the front bearings "C2":

- Take the C-arm to the position shown in Fig.15 in order to align one of the holes (F4) with the eccentric pin on one of the bearings (C2).
- Adjust the play as explained above for bearings (C1).

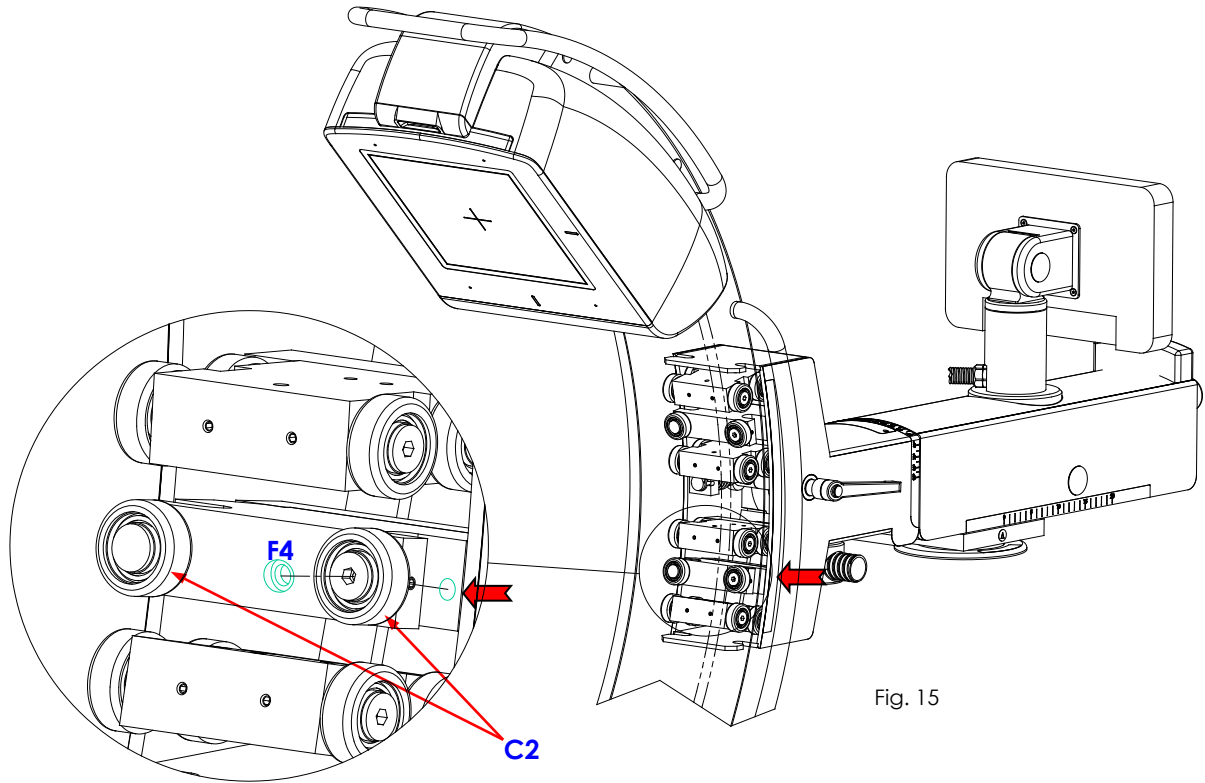


Fig. 15

c) Adjusting the lateral bearings "C3":

- Take the C-arm to the position shown in Fig.16a in order to align the hole (F2) with the eccentric pin on the bearing (C3), while the holes (F3) are lined up with the grub screws (G3) locking the pins.
- Using a 2.5 mm Allen wrench in the hole (F3), loosen the grub screw (G3) on the eccentric pin (P3). Adjust the play of the bearing by using a 5 mm Allen wrench in the hole (F2).
- Fix the position of the bearing by tightening the grub screw (G3).

Note: Repeat for both the bearings (C3)

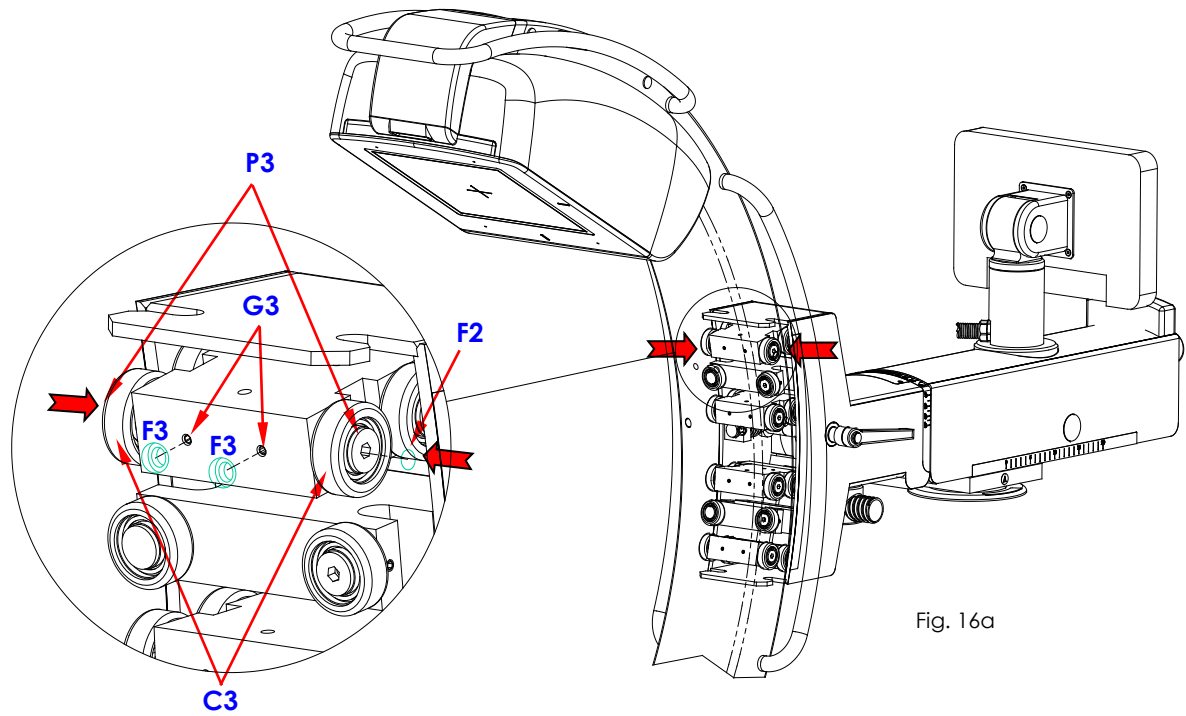


Fig. 16a

d) Repeat the steps in part c) above for all the other pairs of bearings (C4), (C5) and (C6) (see Fig.16b).

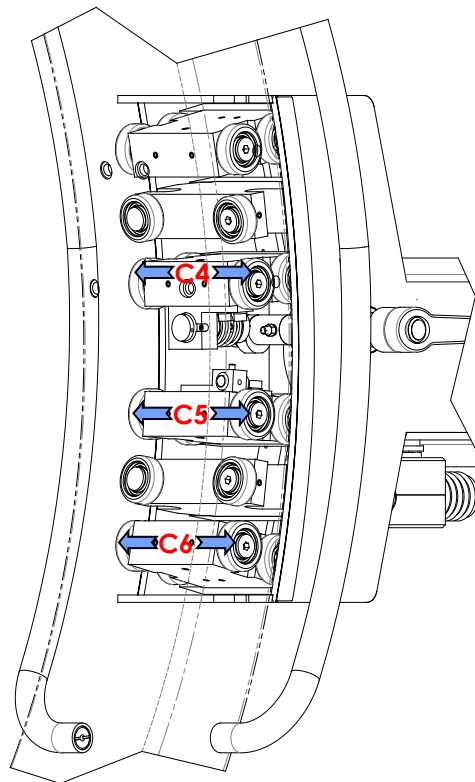


Fig. 16b

5.4.4 REPLACING THE X-RAY GENERATOR POWER UNIT (CHOPPER)

To replace the chopper:



WARNING: Make sure of the equipment has been turned off and unplugged from the mains for at least five minutes, before to manage these operations.

- Remove the cover on the stand (see paragraph 5.1.3 above).
- Remove the cover (A) on the chopper by undoing the 5 screws (V1) shown in Fig.17.

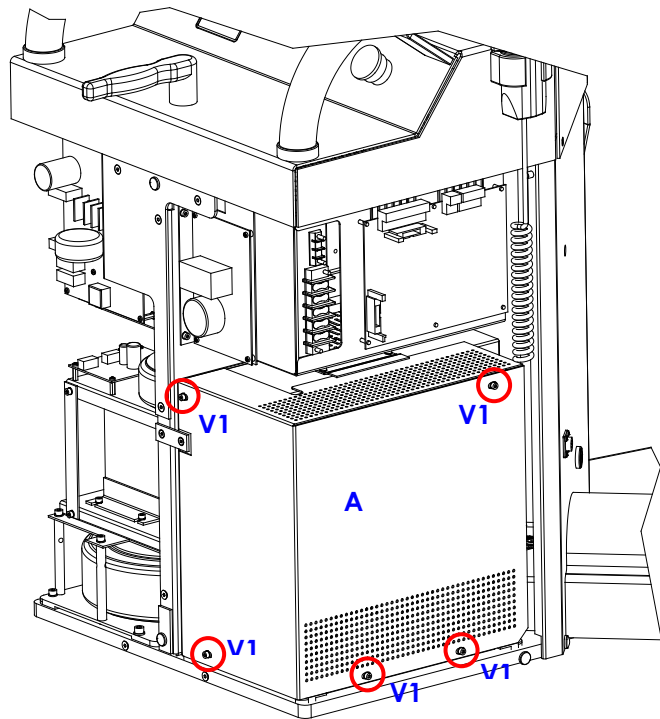


Fig.17

- Remove the chopper by undoing the 2 screws (V2) and the single screw (V3) in Fig.18a and the single screw (V4) in Fig.18b.

Fig.18a

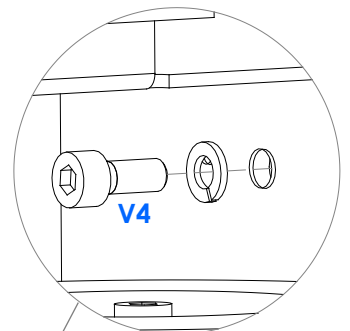
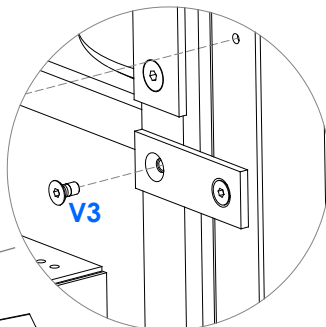
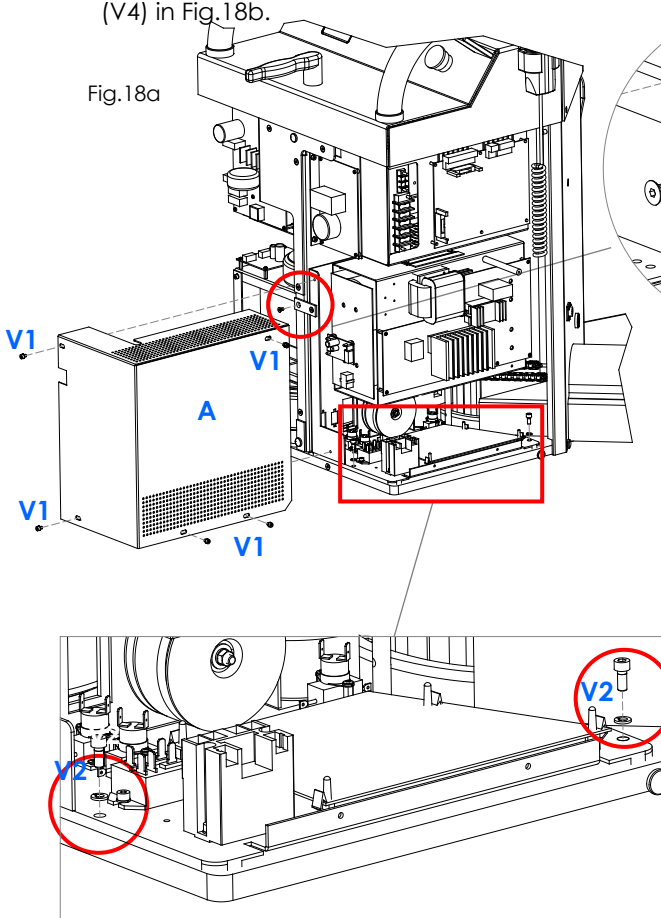
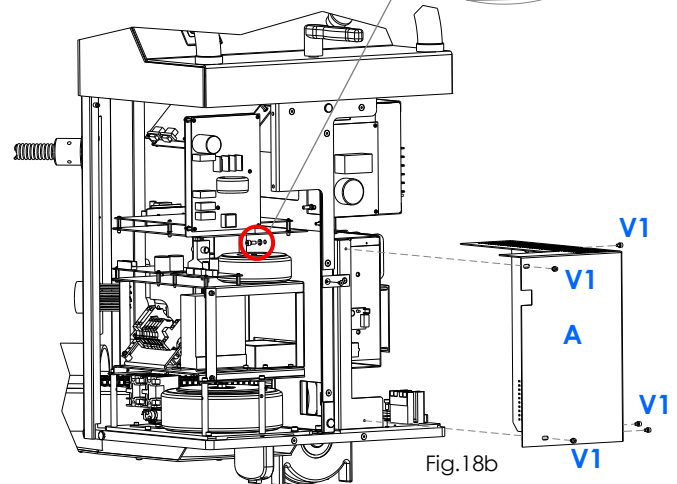


Fig.18b



5.4.5 REPLACING BOARDS CTBK-HW AND ASAC 01

- Remove the cover on the stand (see paragraph 5.1.3 above, in this chapter)

To replace board CTBK-HW (A):

- Disconnect the cables connected to the board.
- Undo the 7 screws (V1).

To replace board ASAC 01 (B): (see Note below)

- Disconnect the cables connected to the board.
- Undo the 4 screws (V2).

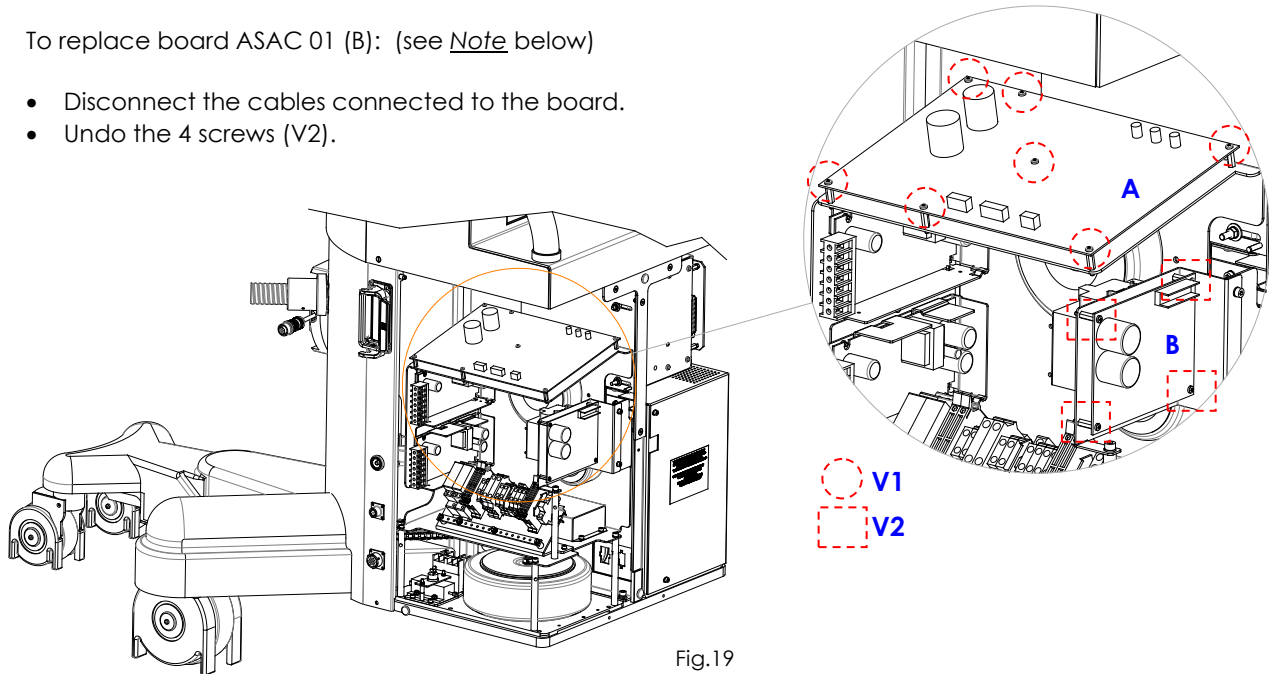


Fig.19



Follow the above steps in reverse order to remount the boards.



Note: After replacing board ASAC 01, check the up/down speed of column and the max limits.

5.4.6 REPLACING THE CONTROL PANEL (PC panel)

To remove the control panel:

- Undo the 2 screws (V1) and remove the rear cover (A).
- Disconnect all the cables.
- Undo the 4 screws (V2) and extract the control panel (B).

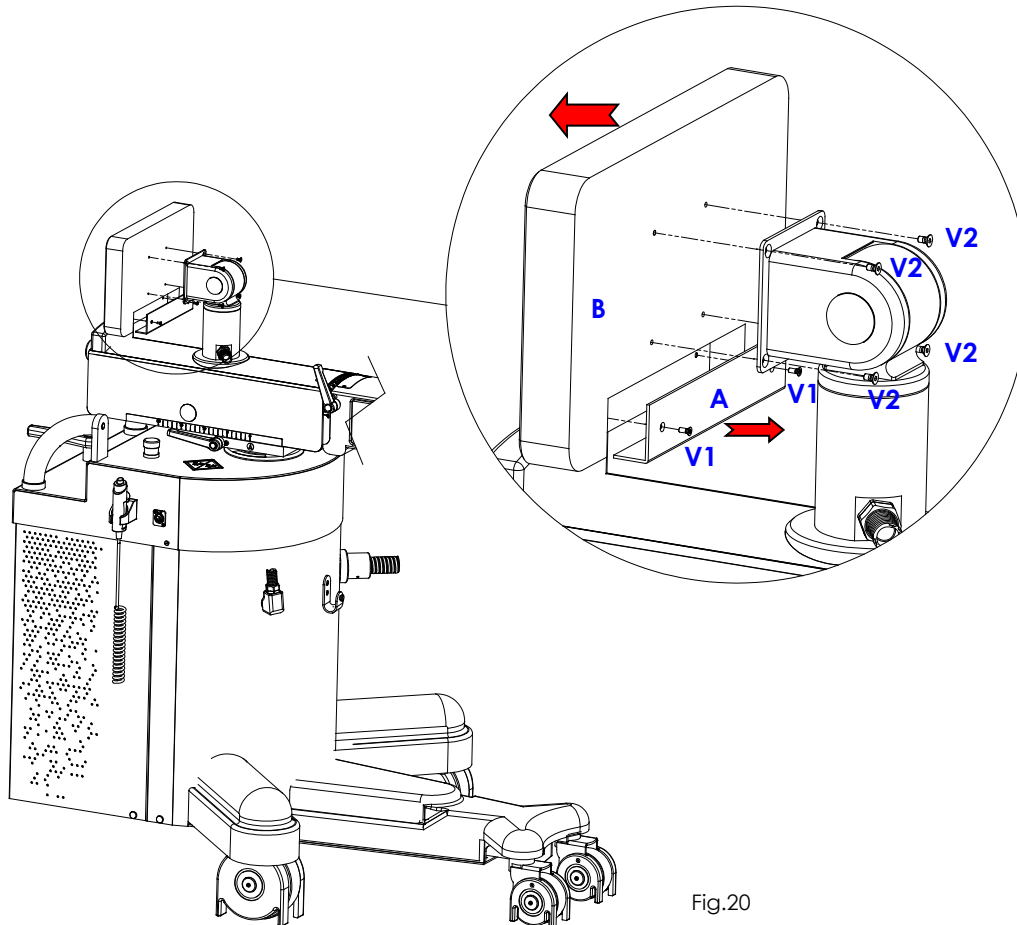



Fig.20

 Follow the above steps in reverse order to remount the control panel.

 Make sure that the software release (SystemA DRF) installed on the new control panel is the same as that used on the video processor. If not, you will need to upgrade the software, as described in paragraph 2.4.2 in Part 5 of this manual.

5.5 FITTING / REMOVING THE MONITOR UNIT COMPONENTS

5.5.1 MONITOR COVER

To remove the monitor cover:

- Follow the procedure described in chapter 2.2 in Part 2 of this manual, but in reverse order (Fig.2b).

5.5.2 BASE COVER

To remove the base cover:

- Block all the trolley wheels with their brakes.
- Undo the 8 screws (V) under the trolley and then remove the corresponding washers (R).
- Extract the cover (C).

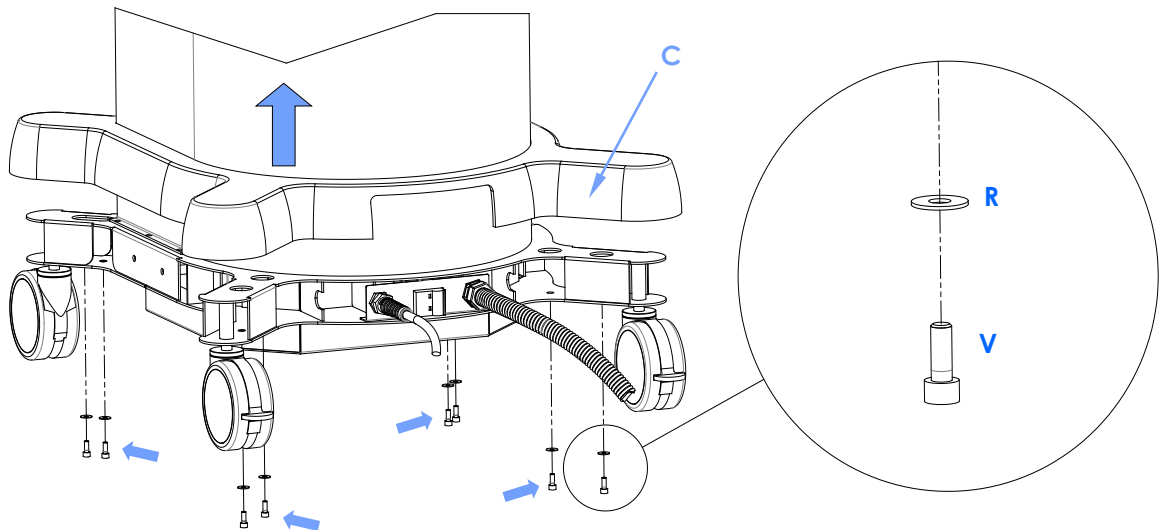


Fig. 21

5.5.3 FRONT COVER

To remove the front cover:

- Undo the 4 screws (V) and remove their plastic washers (R).
Attention: you can access a screw only after you remove its protective cap (T).
- Partially extract the front cover (C).
- Disconnect the ground wire cable.
- Remove the cover (C).

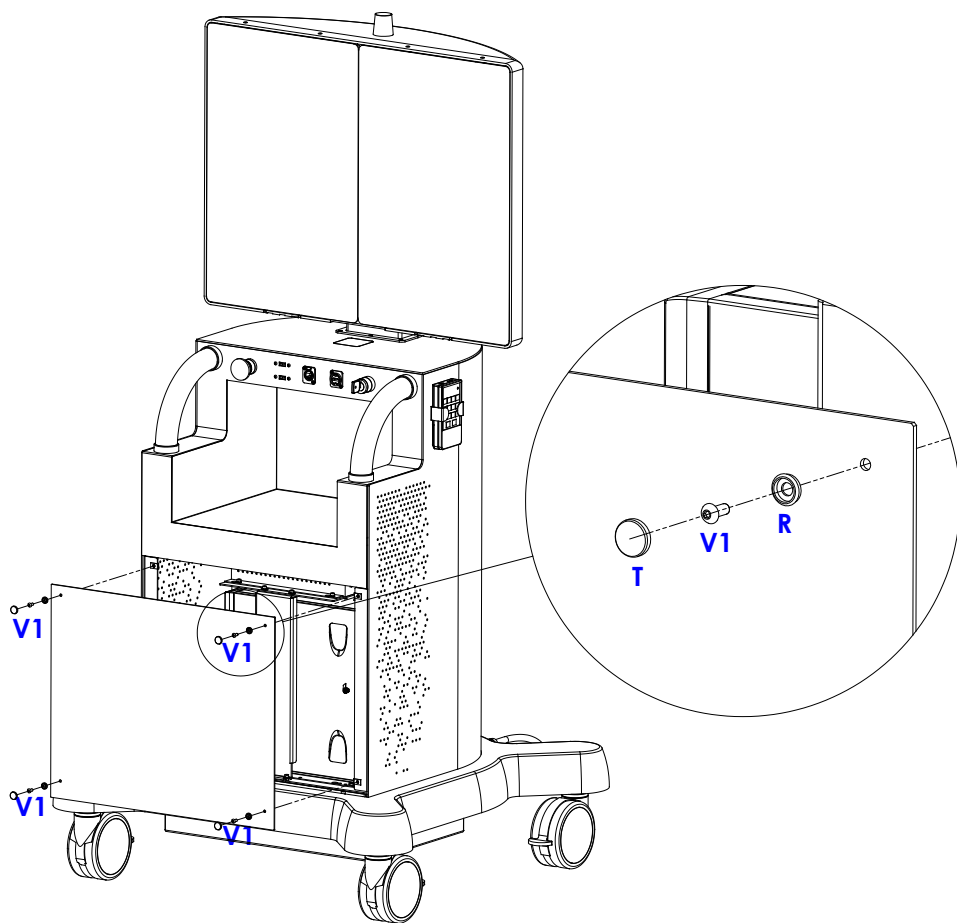
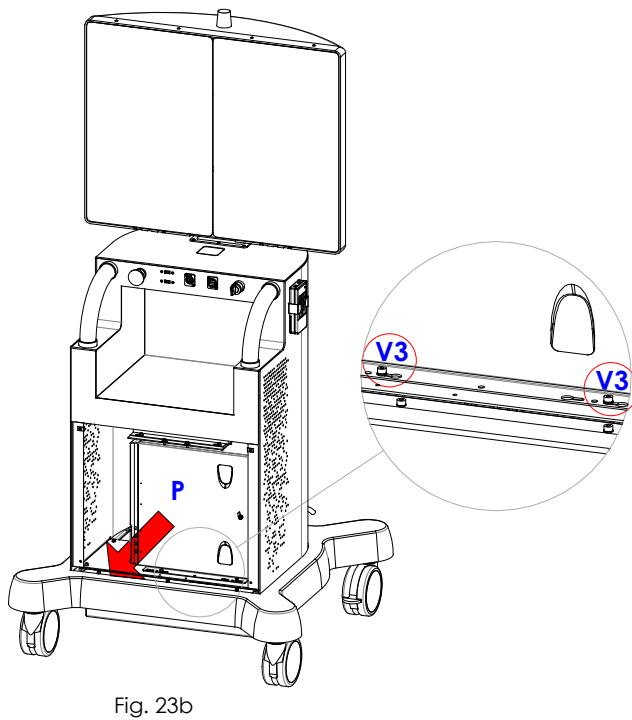
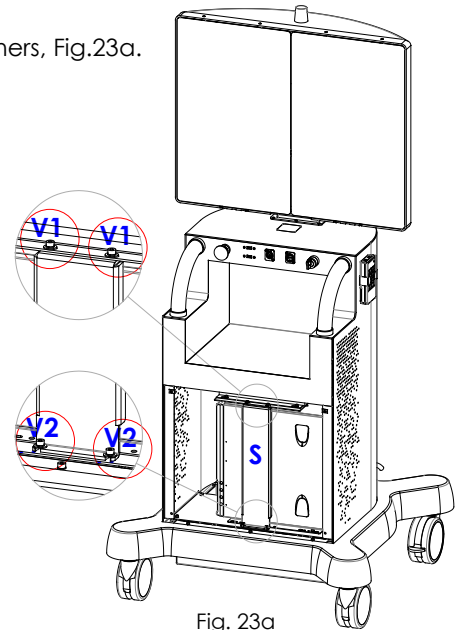


Fig. 22

5.5.4 VIDEO PROCESSOR

To remove the video processor:

- Remove the cover on the base (see paragraph 5.5.2 above).
- Remove the front cover (see paragraph 5.5.3 above).
- Undo the 2 screws (V1) and the 2 screws (V2) and remove their washers, Fig.23a.
- Remove the support (S), Fig.23a.



- Disconnect the video processor cables.
- Undo the 2 screws (V3) and remove their washers, Fig. 23b.
- Remove the video processor (P).



Follow the above steps in reverse order to remount the video processor.



ATTENTION:

When You replace the video processor, you need to check the software releases (SystemA DRF) installed on the video processor and the control panel. These should both have the same software release and be compatible with the firmware installed on board CTBK-HW.

5.5.5 ACCESSING THE POWER UNIT

To access the power unit:

- Remove the cover on the base (see paragraph 5.5.2 above).
- Remove the front cover (see paragraph 5.5.3 above).
- Remove the video processor (see paragraph 5.5.4 above).
- Undo the 4 screws (V1) and remove the plate (P), Fig. 25.

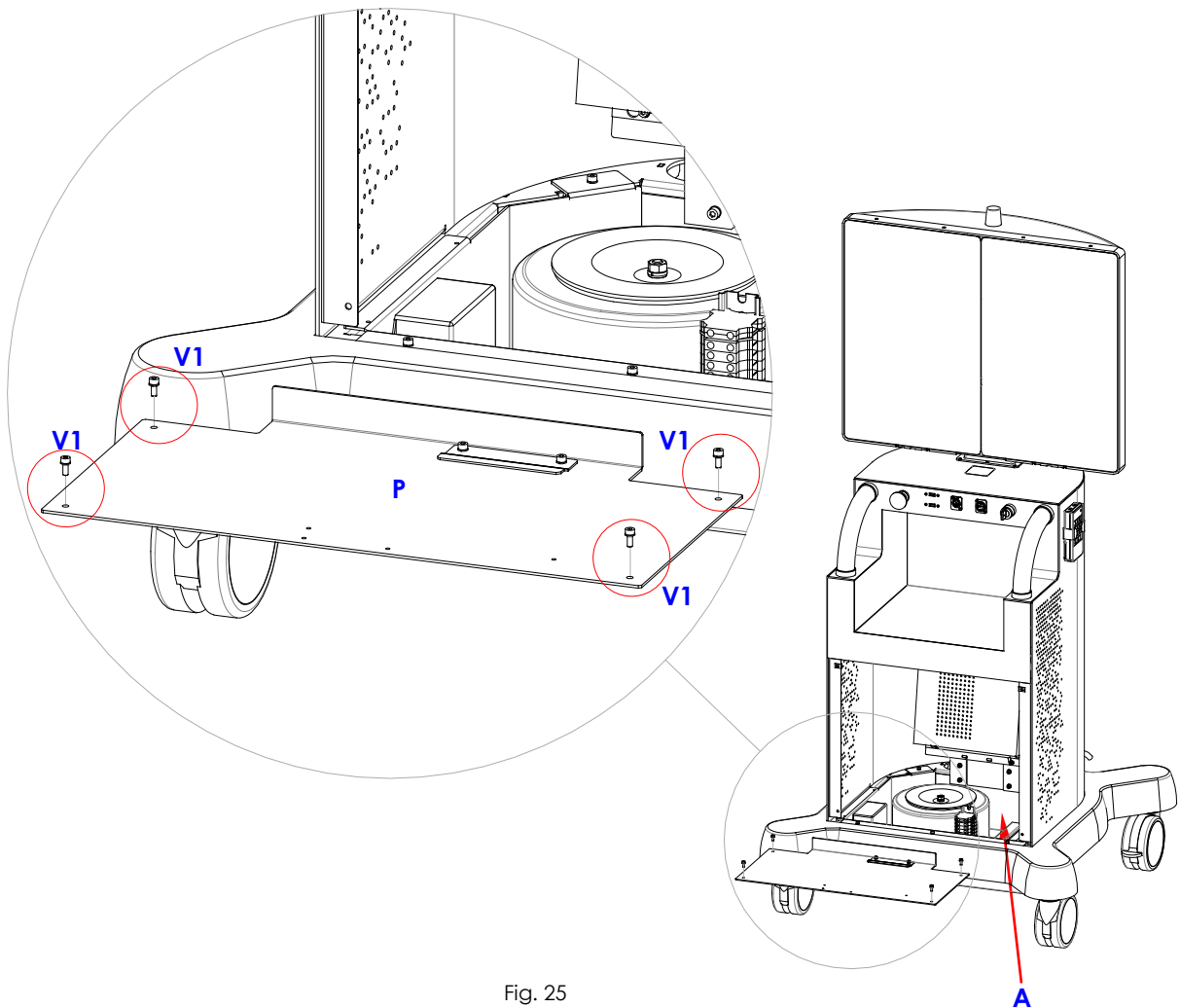


Fig. 25

5.5.6 REPLACING THE MAIN POWER CABLE

The power cable for the monitor unit may become worn or damaged with use, with evident signs of cuts or scratches.

Only authorised technical service personnel are permitted to replace this should the need arise.

Cable characteristics:

- Length 6m
- Form 2 conductors (blue or brown) + earth (yellow/green)
cross-section 3 x 4mm²
- Sheath colour Grey
- Outside diameter 13mm
- Mix PVC

The new cable must be requested directly from the manufacturer, indicating code **550 74 011**.

Follow these steps to ensure that the new cable is correctly connected and fixed:



Switch the EM equipment off and unplug at the mains.

- Access the power unit as described in paragraph 5.5.6.
- Remove the screw (**V1**) fixing the yellow eyelet terminal used for the earth wire (yellow/green wire), Fig.26

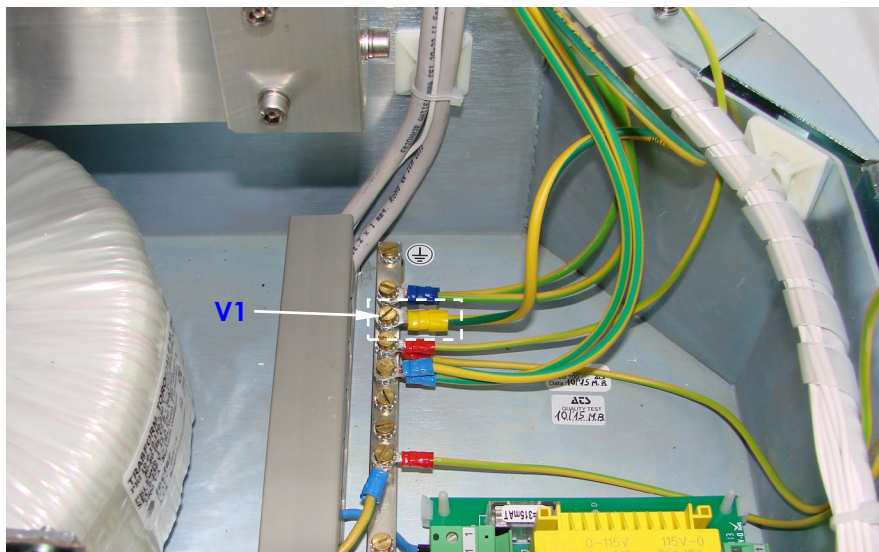


Fig.26

- Undo the 2 screws (**V2**) and then remove the cable holder (**S**), Fig.27.

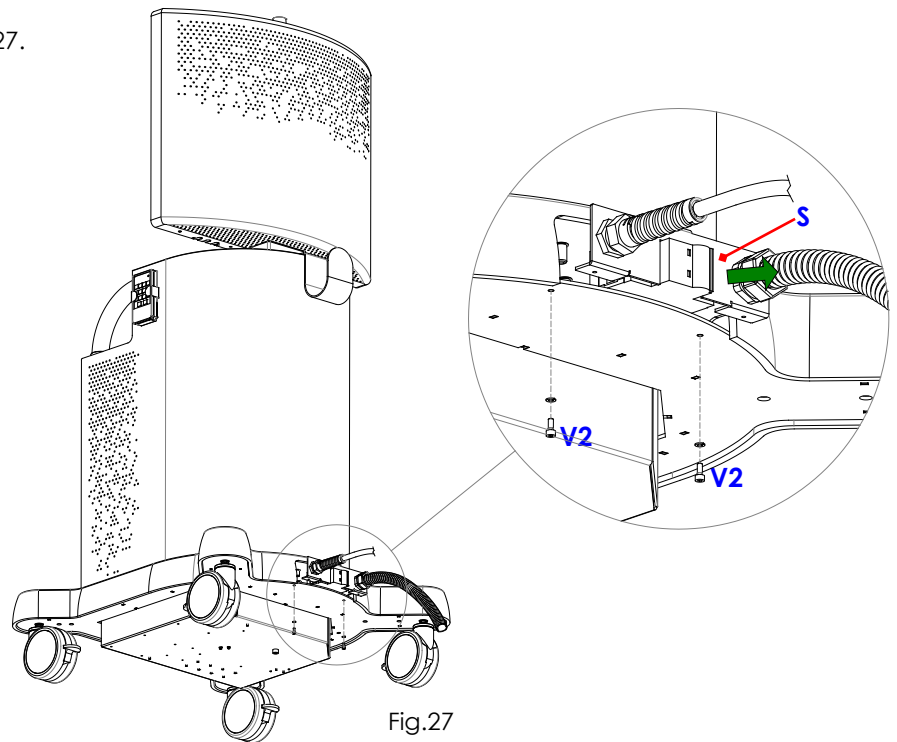


Fig.27

- Remove the remote switch (**T**) by pushing this downwards (Fig.28) in order to access screws (**V3**), Fig.29.
- Loosen the 2 screws (**V3**) and remove the 2 yellow terminals (**P**) for the 2 power wires (blue and brown wires), Fig.29.
- Undo the cable ring nut (**G**) and extract the cable you want to replace from the cable hole, Fig.28.
- Repeat the above steps in the reverse order to fit and secure the new original cable code **550 74 011** supplied by the manufacturer.

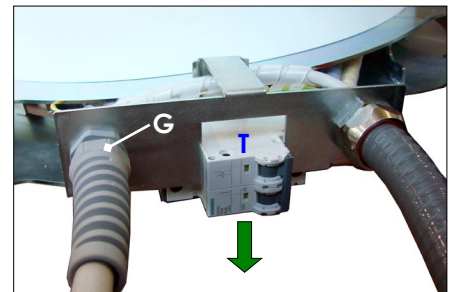


Fig.28

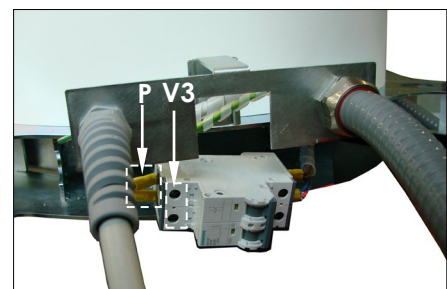


Fig.29

6 ANNEXES

6.1 CREATING A BACK-UP DISK FOR THE VIDEO PROCESSOR

We recommend creating a ghost image disk after any significant software upgrades or changes to the system settings (e.g. DICOM settings, network settings).

The computer has a single Hard Disk split into two partitions, "C" and "D".

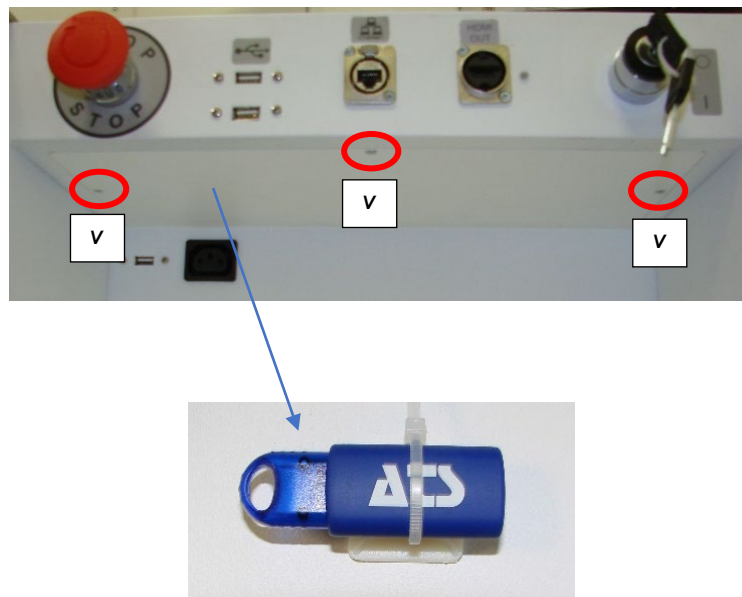
Partition "C" contains the files for the operating system and installed applications. It also contains the calibration data for the:

- X-ray generator
- X-ray collimator

Partition "D" contains the database, which holds:

- Patient data
- DICOM settings
- Exam settings
- Acquired images

The USB pen drive, on which the backup is made, is located inside the upper casing in the printer compartment of the visual station (see photo below).

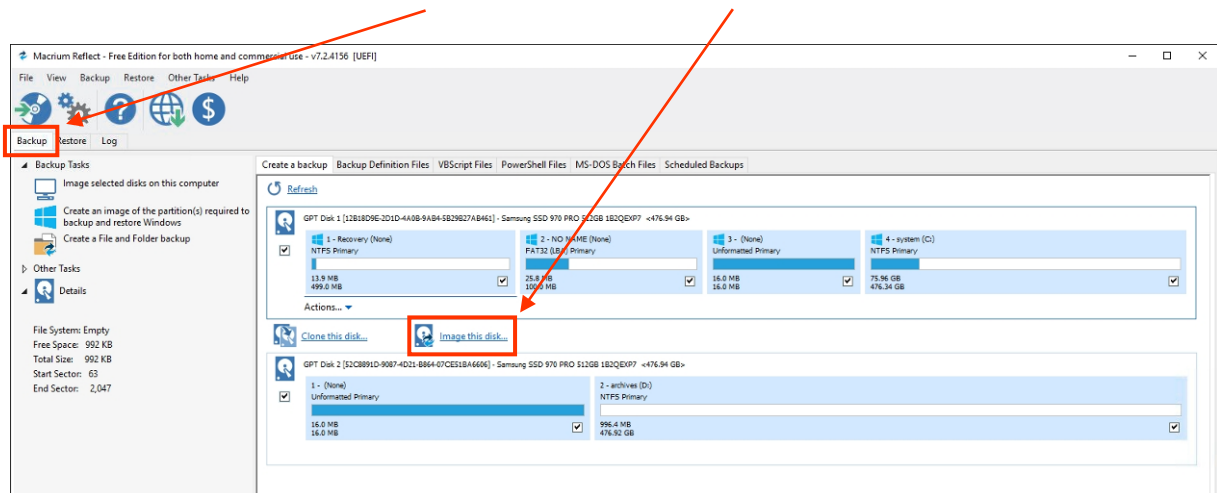


To make a backup of the processor:

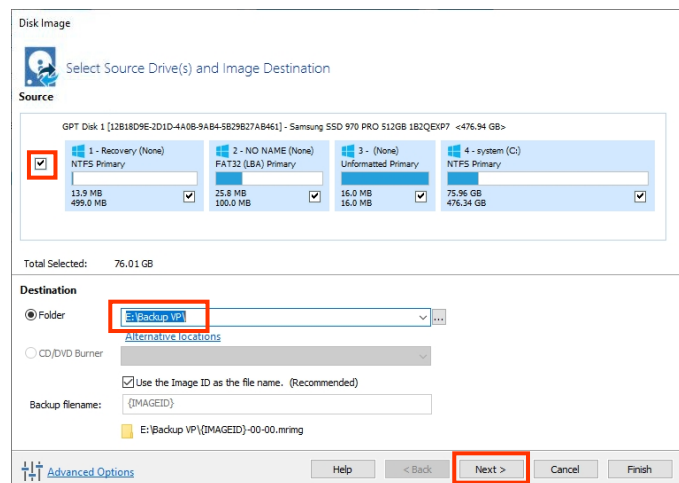
- 1) Insert the USB pen drive in one of the two ports on the front of the monitor unit.
- 2) Connect a USB keyboard and USB mouse at the front of the monitor unit.
- 3) Switch the equipment on and then open the BIOS, setting the USB pen drive as the start device.
- 4) From the desktop open the application **Macrium Reflect**



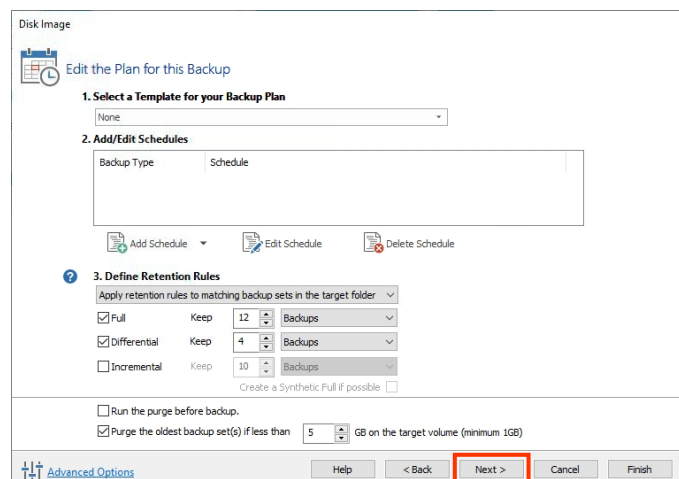
5) In the main screen (TAB **"Backup"**) click on **"Image this disk..."**



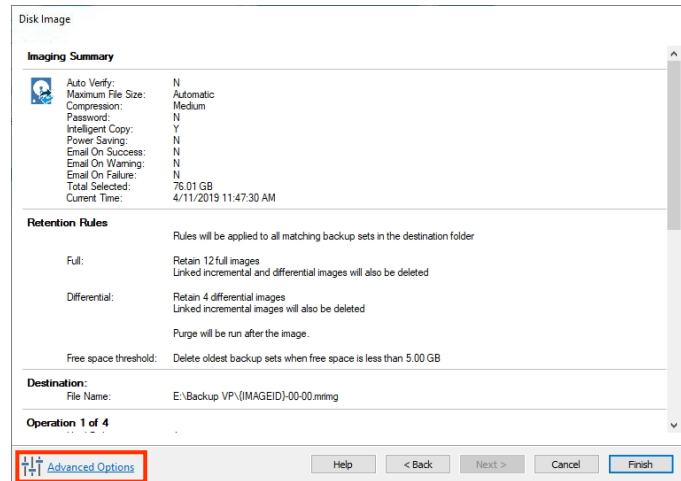
6) The **Disk Image** screen is presented. Verify that:
 - in the **"Source"** box, all 4 partitions that make up the system disk are selected
 - in the **"Destination"** box, the path of the USB drive is indicated: **"E:\Backup VP\"**
 Then select the **"Next"** command:



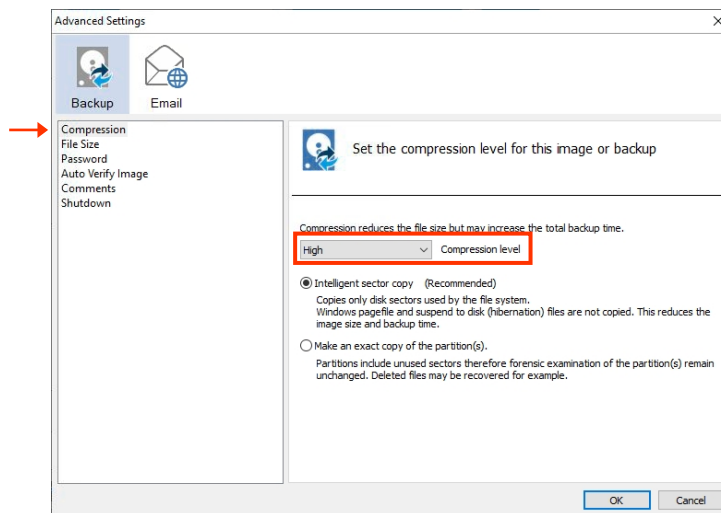
7) On the next screen, check that the settings are configured as in the next image and then select the **"Next"** command:



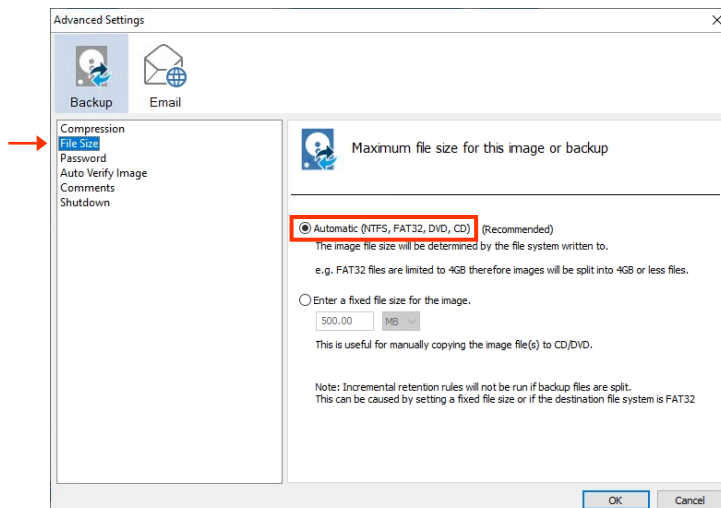
8) In the summary screen, select the "**Advanced Options**" command:



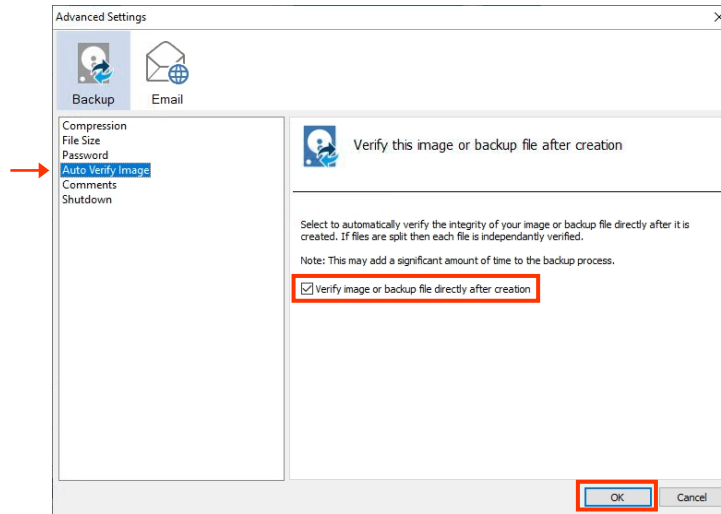
9) On the **Advanced Settings** screen, check that:
 - In the "**Compression**" TAB, the Compression Level field is set to **High**:



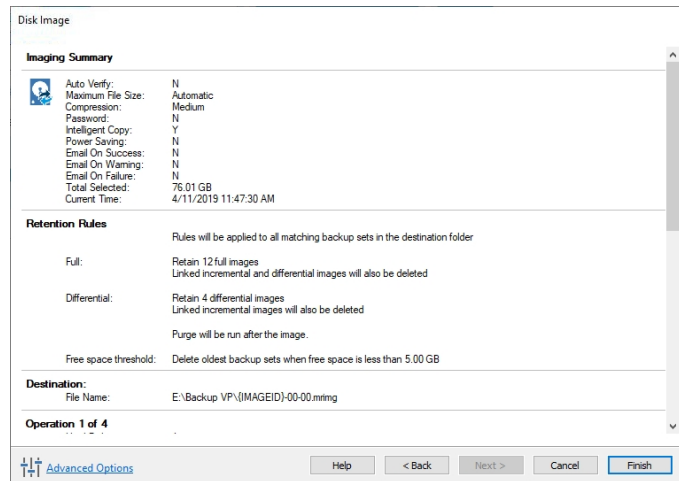
- the **Automatic** option is set in the **File Size** TAB:



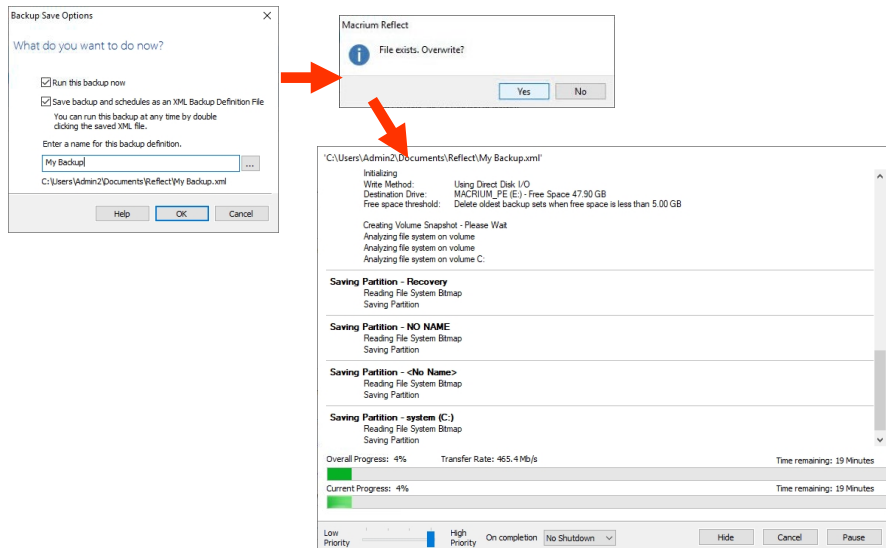
- the option **Verify image or backup file directly after creation** is enabled in the **Auto Verify Image** TAB. Then select the "OK" command:



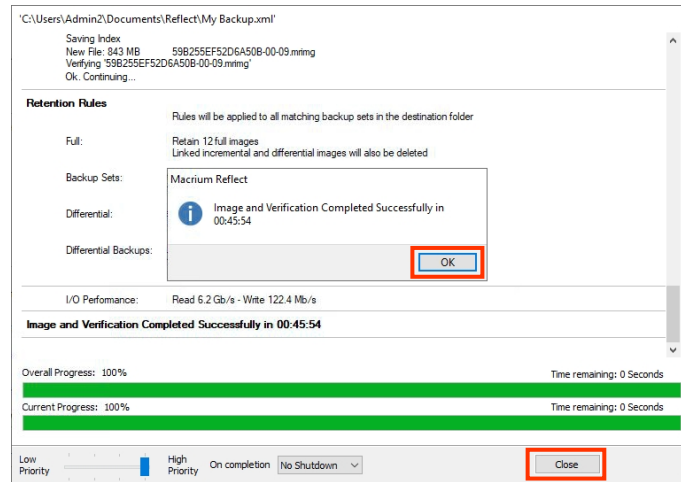
10) In the summary screen, select the "Finish" command:



11) In the **Backup Save Options** screen select the "OK" command. Then, with the "Yes" command, confirm the request of the system to overwrite the XML file to start the data backup:



12) At the end of the backup, select the command "OK" and then close the application with the command "Close":



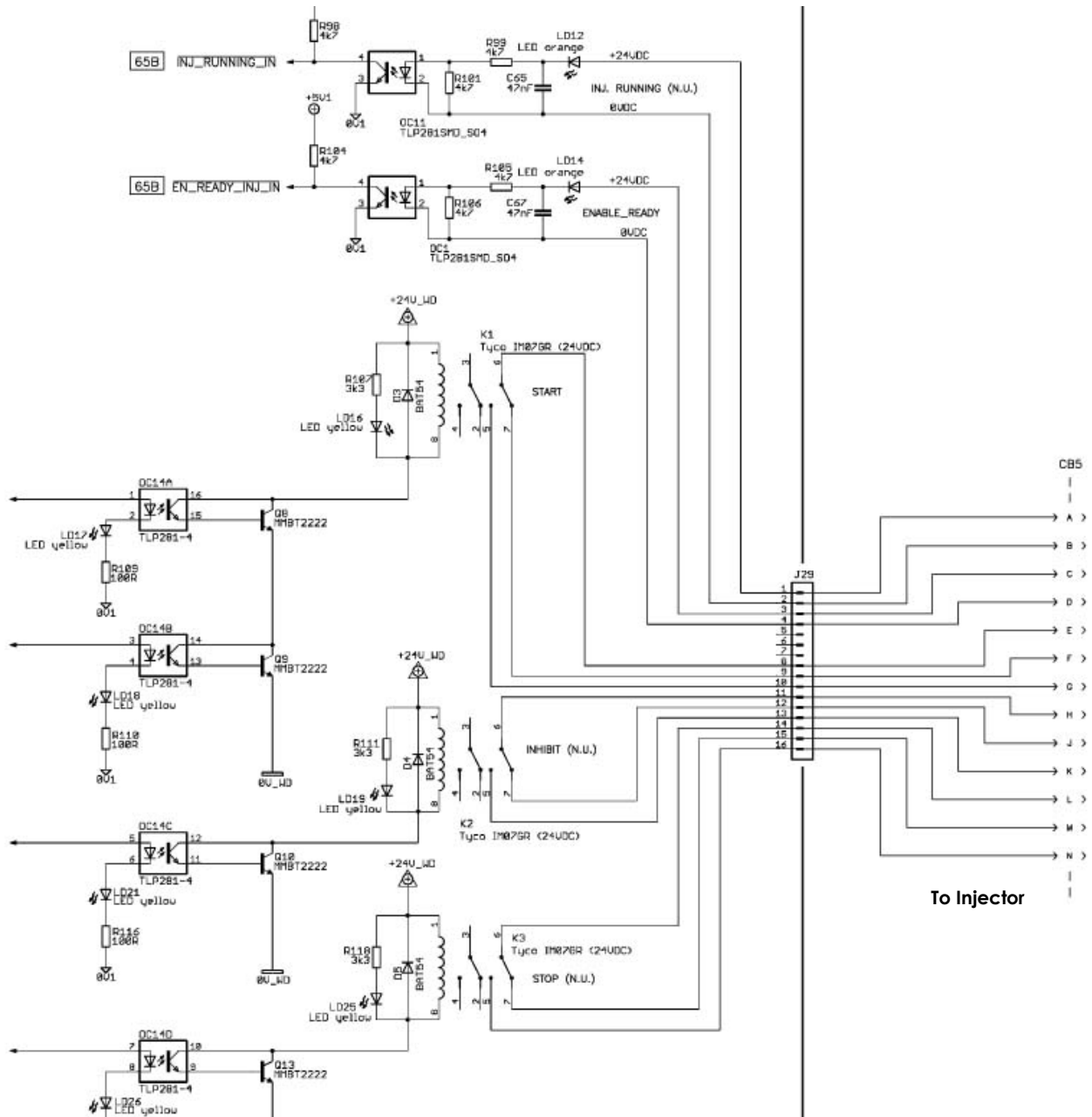
13) Remove the USB pen drive, keyboard and mouse.

6.2 CONTRAST MEDIUM INJECTOR INTERFACE

The EM equipment, provided without an injector, can be connected to a generic injector.

Preset interface signals allow for automatic synchronization between the start of the injector and the start of X-ray emission.

To connect these signals, you need to fit an adaptive cable between the connector on the EM equipment and that on the injector.

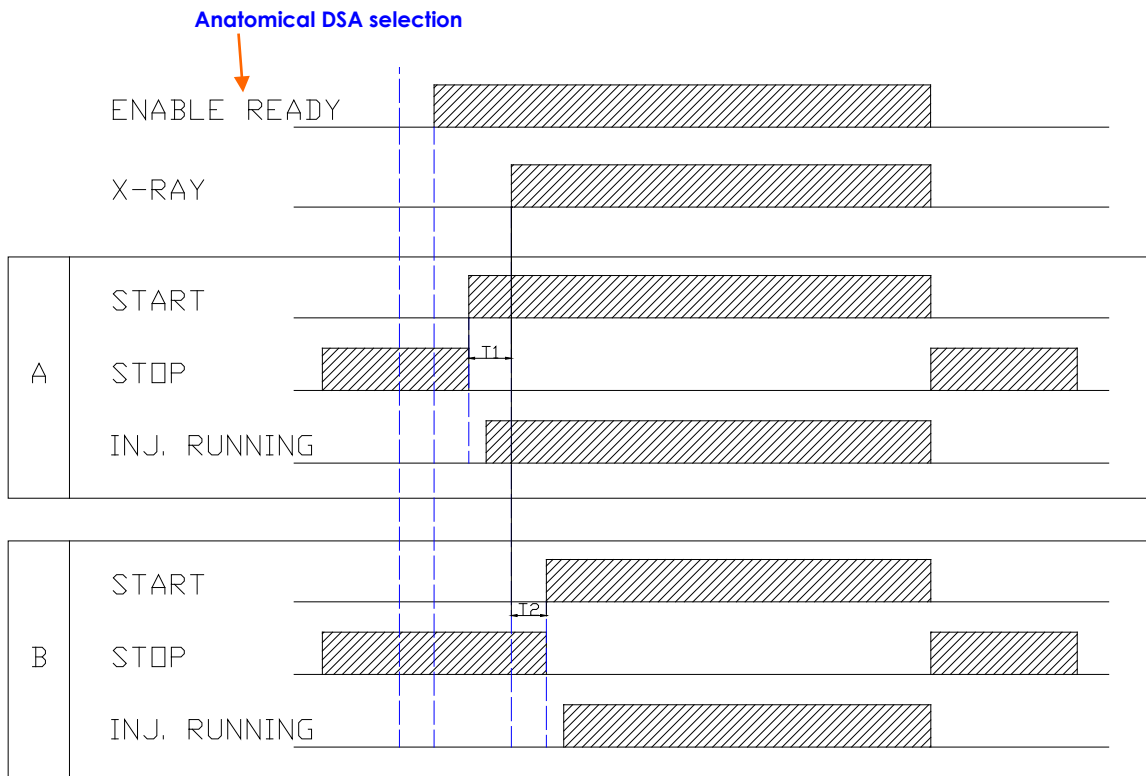


SIGNAL	DESCRIPTION	CONNECTOR
ENABLE READY	Ready signal (active high +24V DC) coming from the injector.	CB5/J29 Pins C, D
START	Command used to start the injector. Depending on the timing programmed for the DSA + injector exam, this signal is activated when you request X-ray emission.	CB5/J29 Pins E, F, G
STOP	Signal normally active: injector cannot start. This signal is deactivated (to allow the injector to start) by the START signal, to which it is linked.	CB5/J29 Pins L, M, N

The interface signal timings for x-ray emission are as follows:

In "A", the injector starts before X-ray emission (T1=anticipated).

In "B", the injector starts after X-ray emission (T2=delayed).

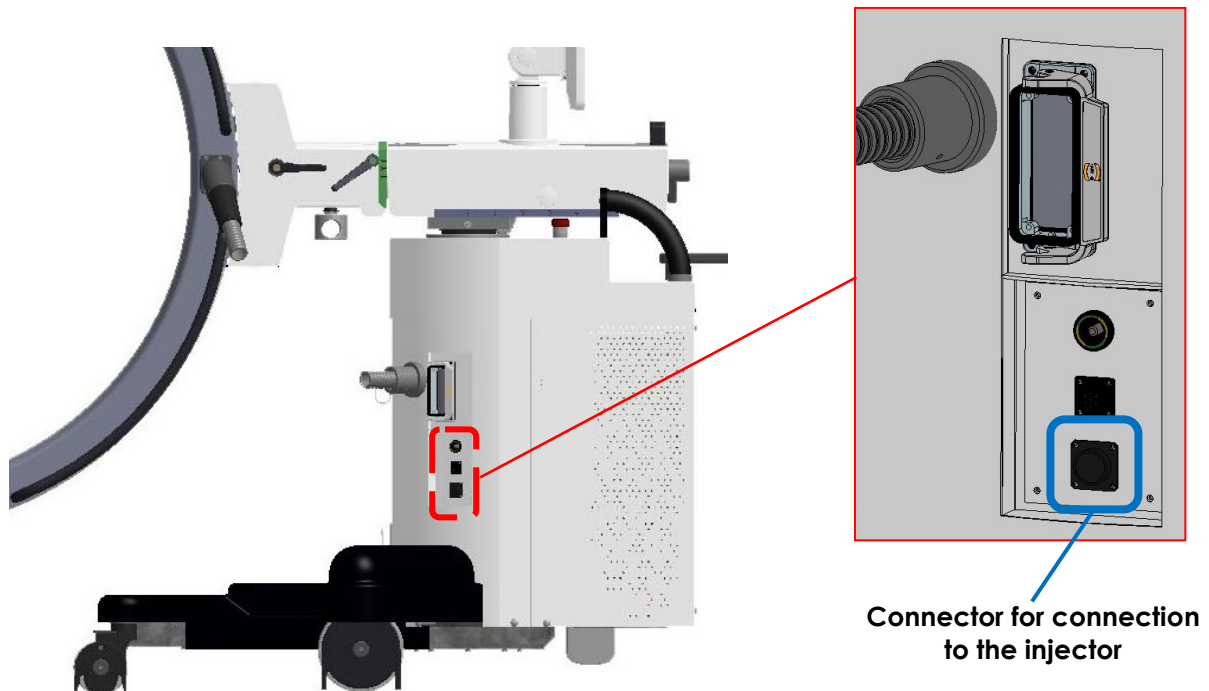


6.2.1 CREATING THE INJECTOR INTERFACE

There is a circular 19-pin female connector at the front of the stand to be used for physical connection to the injector (CM107).

The equipment can also be supplied with a corresponding male connector.

The installer needs to prepare an adaptor cable for the injector, using all the foreseen interface signals: full use of the signals is required to ensure safe interface.



6.2.2 INJECTOR SETUP

There are two settings needed to configure the equipment for an injector:

A. *Presence of an injector:*

- **Enable the option "INJECTOR" in the "UNIT CONFIGURATION" SETUP**, as described in *Paragraph 4.3, Part 2 of this Manual*.

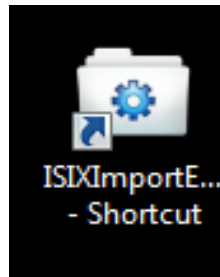
B. *Use of an injector for an individual DSA exam.*

- **Enable the option "ENABLE INJECTOR" in "DSA Parameters" SETUP**, regarding the anatomical DSA exam required, as described in *Paragraph 4.4.1.1, Part 2 of this Manual*.
- **Set the anticipation/delay of the injector start regard to X-ray emission, in "INJECTOR DELAY" parameter.**
When a positive time is set, the injector starts after X-ray emission beginning; set a negative value if you want the injector to start before X-ray emission beginning.

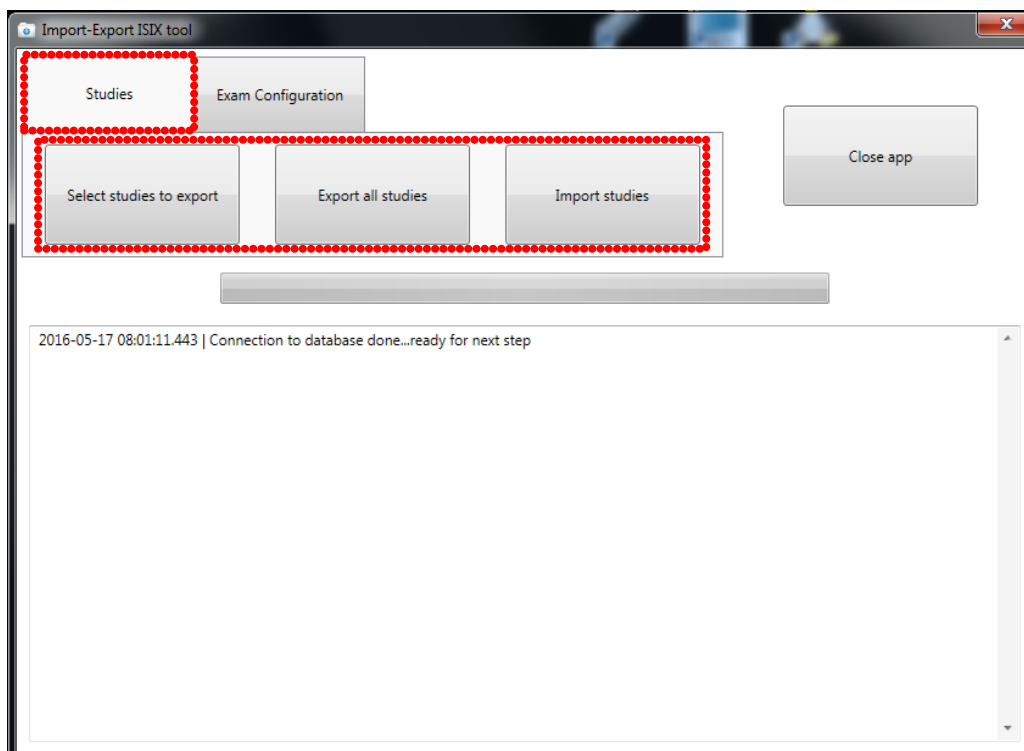
6.3 EXPORTING/IMPORTING IMAGES

Images are stored in the "RAW" format on the hard disk of the video processor. To export these, you need to use a special tool, as explained below:

- 1) Connect a USB keyboard and USB mouse to the monitor unit.
- 2) Switch on the equipment and log onto the equipment as user Admin2 (see Paragraph 5.3, Part 2 of this Manual).
- 3) Use the icon on the desktop shown below to open the tool:



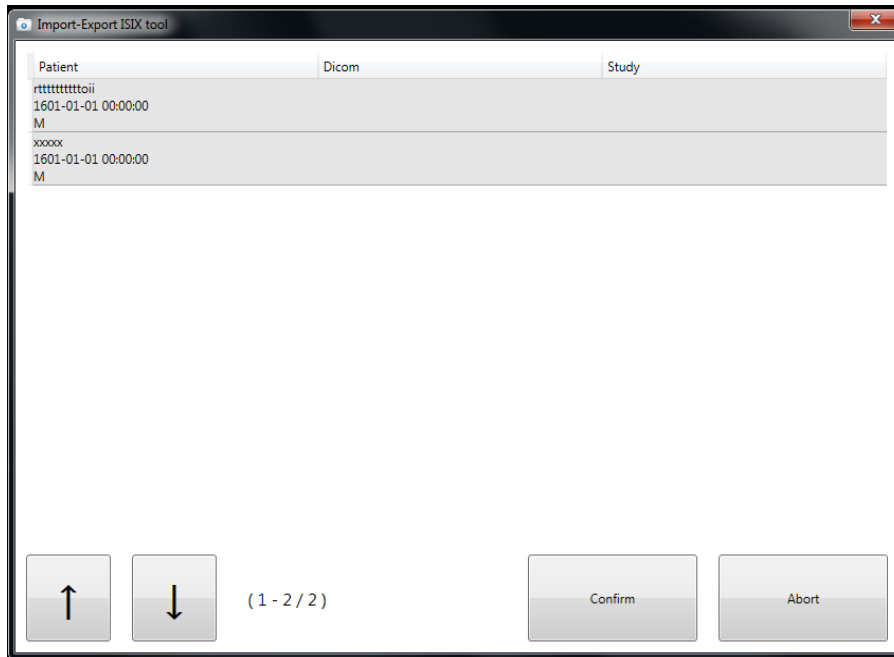
- 4) The following page appears, letting you **export/import studies** and **export/import exam configurations**.



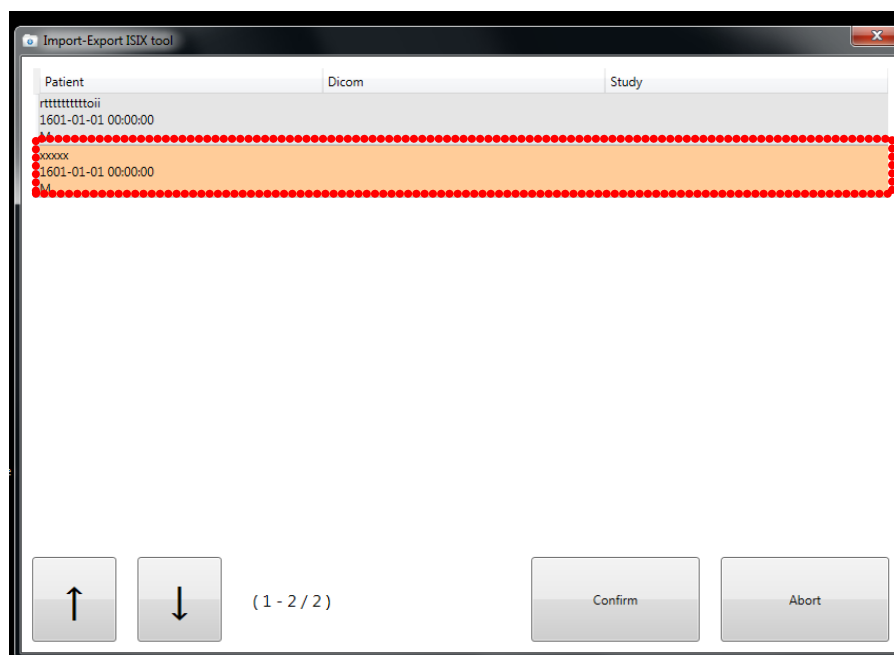
5) Select the “**STUDIES**” tab. This has three options:

- “**Select studies to export**”;
- “**Export all studies**”;
- “**Import studies**”.

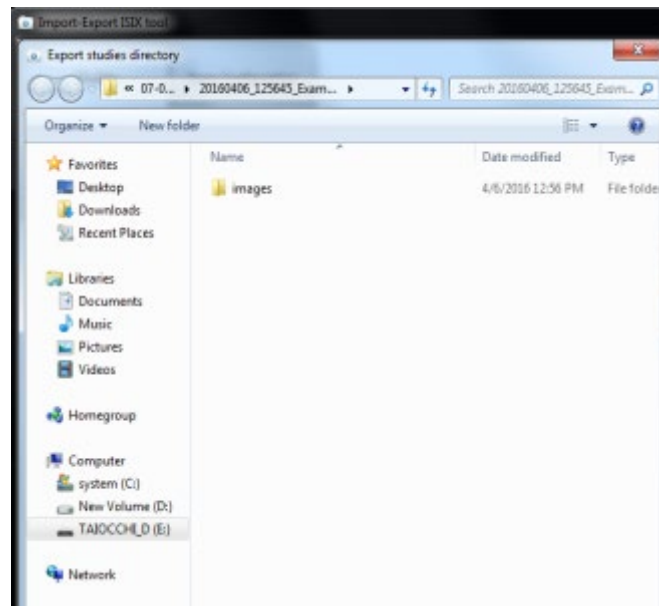
6) To export a study/studies, select “**Select studies to export**” or “**Export all studies**”



7) After selecting “**Select studies to export**”, you need to select the studies you want to export (a single study has been selected in the example below). Then click on “**Confirm**”.



- 8) A window now opens letting you select the destination directory for the exported study/studies.



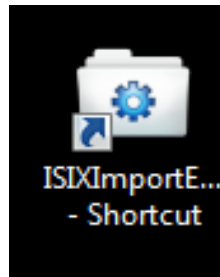
- 9) If, on the other hand, you want to import a study/studies, select "**Import studies**". Like earlier, a window opens letting you select the directory containing the study/studies you want to import.

Note: to protect patient's privacy, studies are exported with an alphanumeric ID instead of patient's data.

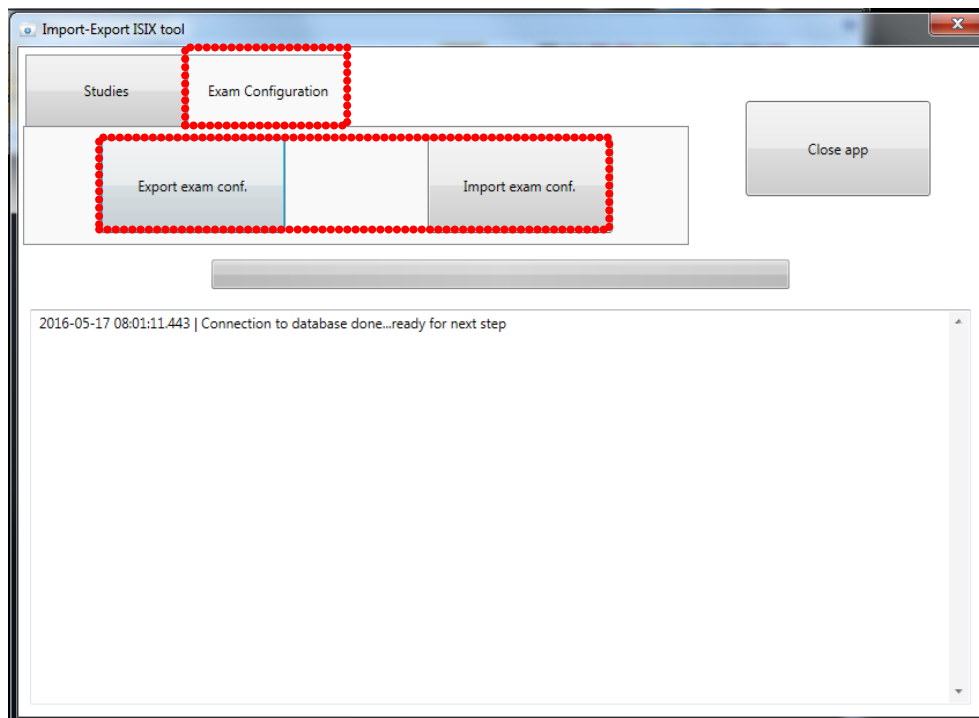
6.4 EXPORTING/IMPORTING EXAMS

Exam settings are stored on the Hard Disk of the video processor computer (partition "D"). To export these, you need to use a special tool, as explained below:

- 1) Connect a USB keyboard and USB mouse to the front of the monitor unit.
- 2) Switch the equipment on and then log onto the equipment as user Admin2 (see *Paragraph 5.3, Part 2 of this Manual*).
- 3) Use the icon on the desktop shown below to open the tool:



- 4) Select "**Exam Configuration**".



- 5) Select "**Export exam conf.**" to export the settings.
- 6) Select "**Import exam conf.**" to import the settings.
- 7) In both cases, a window now opens letting you select the directory you want to export the settings to (the destination directory) or the directory containing the settings to be imported (the original directory).

6.5 REPLACEMENT OF THE MOTHERBOARD BACKUP BATTERY

The manufacturer recommends changing the buffer battery of the video processor every 3 years. When this time has elapsed, the operator will be notified at the login, through this message:

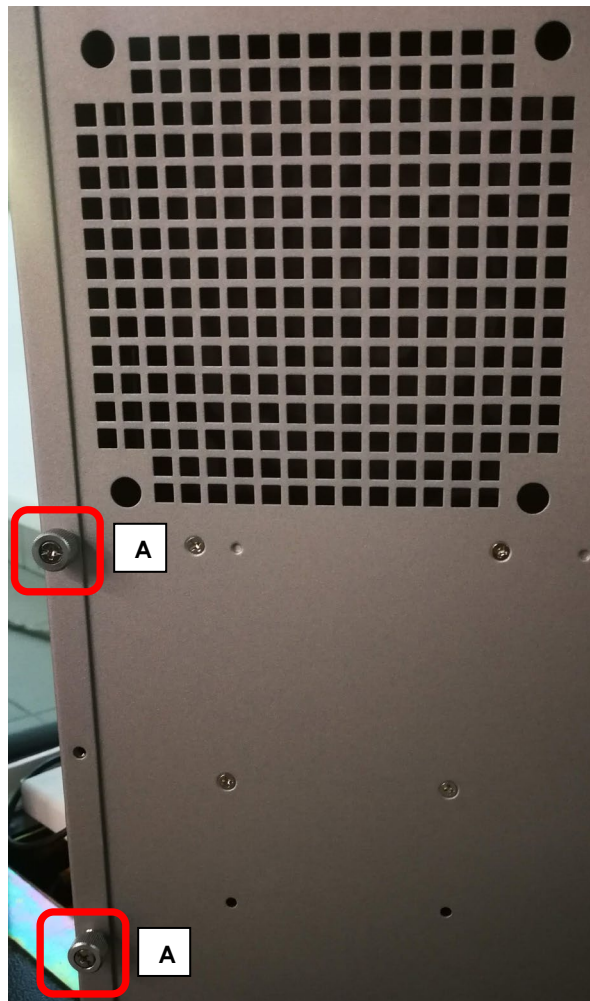
WARNING: POSSIBLE LOSS OF NORMAL FUNCTIONALITY.
The C/MOS battery of the video processor motherboard is discharged, please contact technical assistance for its replacement.

To replace the battery, follow the instructions below.



Turn off the equipment and make sure that the power cable is not connected to the socket.

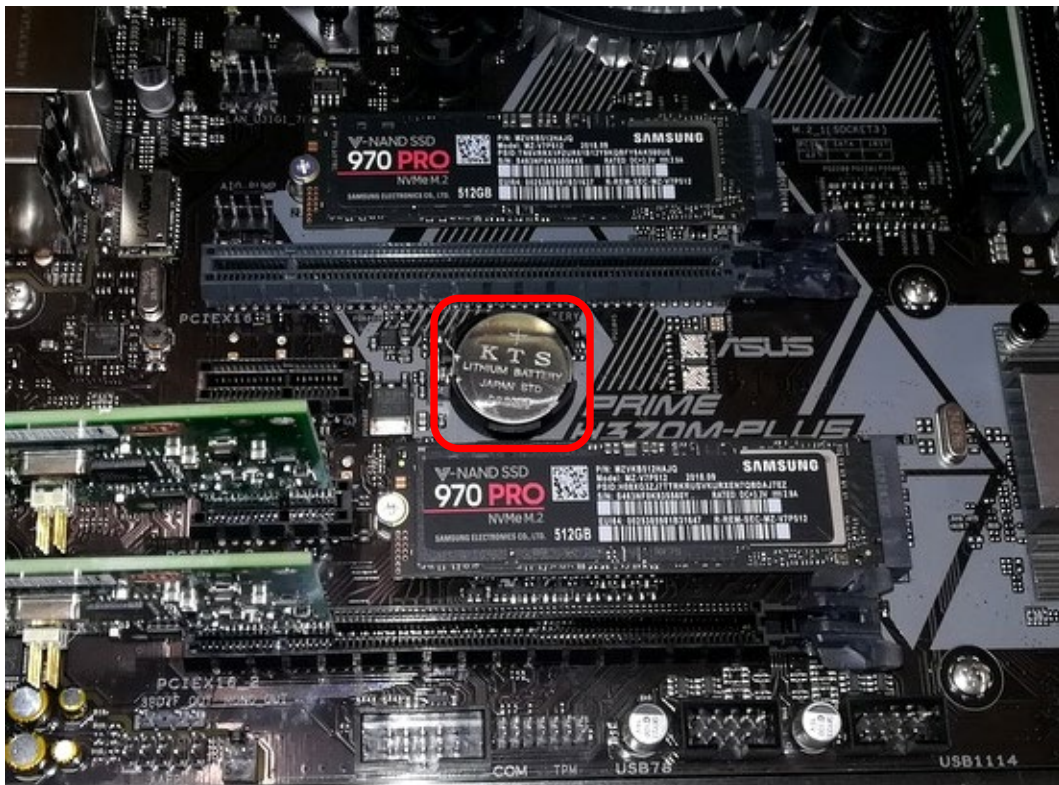
- Remove the front cover of the visual station (see Paragraphs 5.5.2 and 5.5.3, Section 5 of the Technical Manual).
- Remove the video processor holder and then extract it (see Paragraphs 5.5.4, Section 5 of the Technical Manual).
- Remove the side cover of the video processor by unscrewing the screws shown in figure (A).



- Unscrew the indicated screws (B) to remove the SSD holder.



- The motherboard is now visible and accessible.
- Remove the backup battery shown in the following picture using a suitable tool:



Now install the new battery: ONLY USE LITHIUM BATTERIES, 3V, TYPE CR2032.



Follow the above instructions in reverse order to reassemble the graphics card and the video processor in the stand.

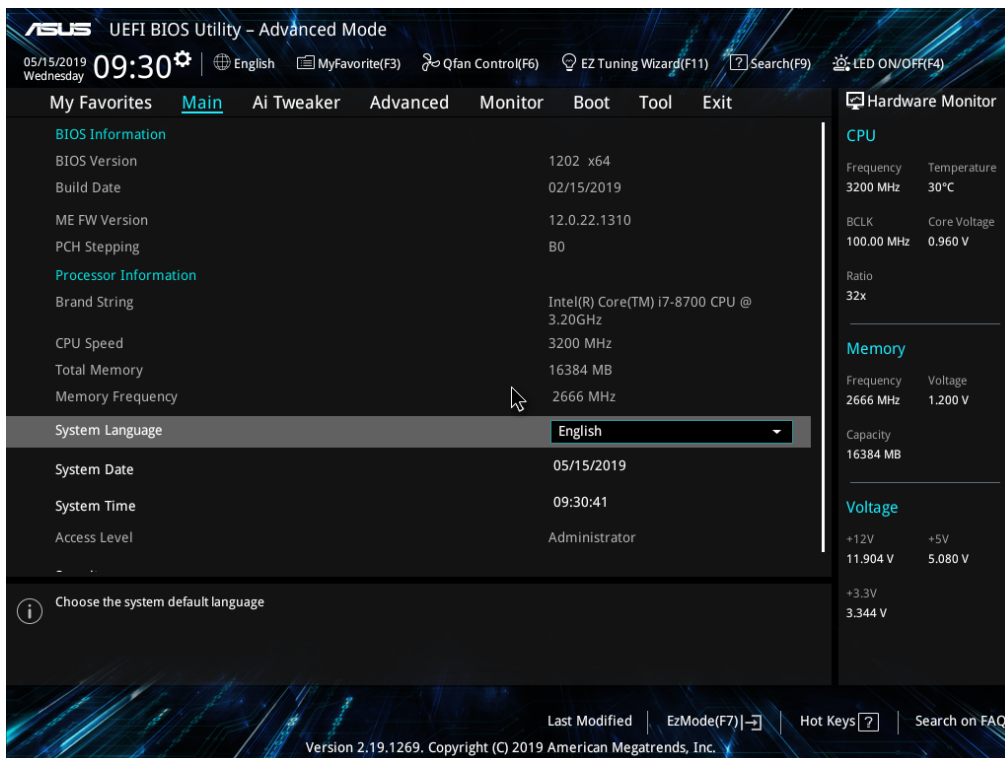
- Connect a keyboard to the USB port of the visual station.
- Connect the backup USB drive supplied with the EM equipment (see Paragraph 2.3, Section 5 of the Technical Manual).

- Connect the power cord of the EM equipment to the power outlet and turn on the video processor, using the PC power button shown in the figure below.

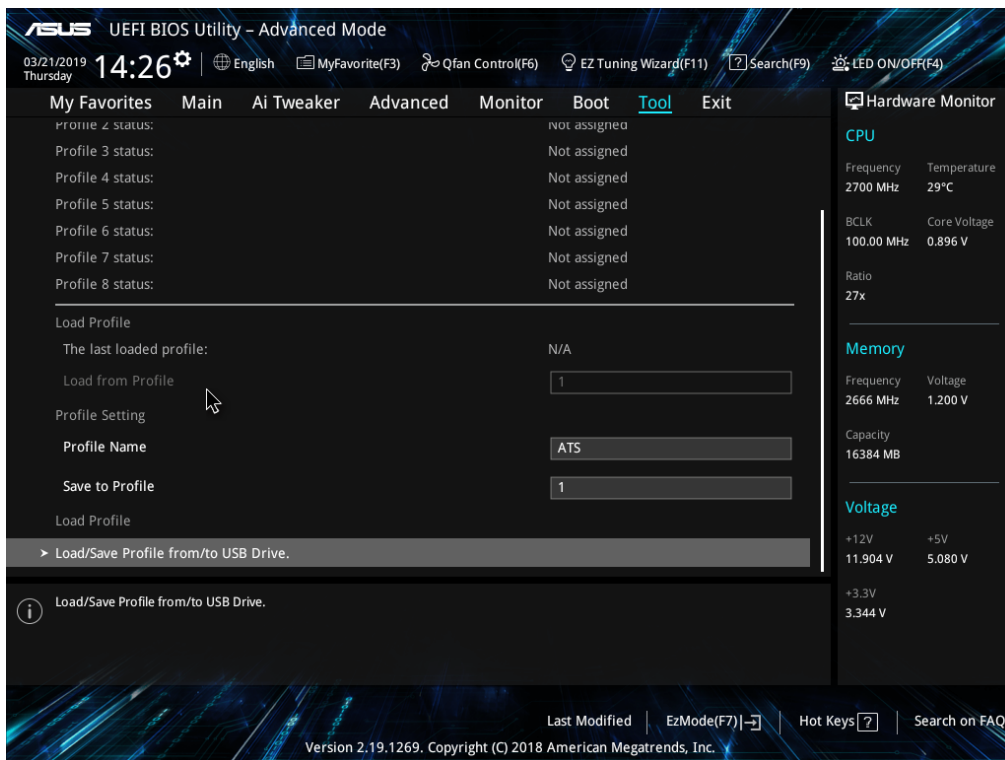


As soon as the device is switched on, press the "DEL" key on the keyboard to enter the UEFI BIOS Utility menu. Follow the recovery procedure below to restore the BIOS configuration.

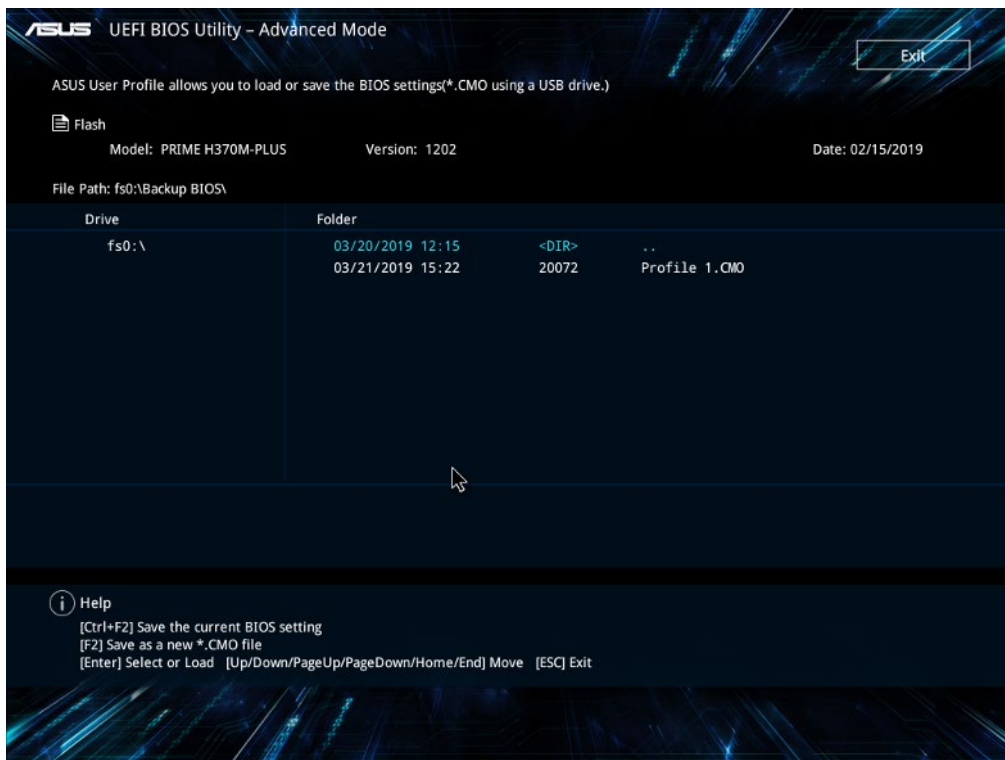
- The main page of the UEFI BIOS Utility menu is opened (Advanced Mode):



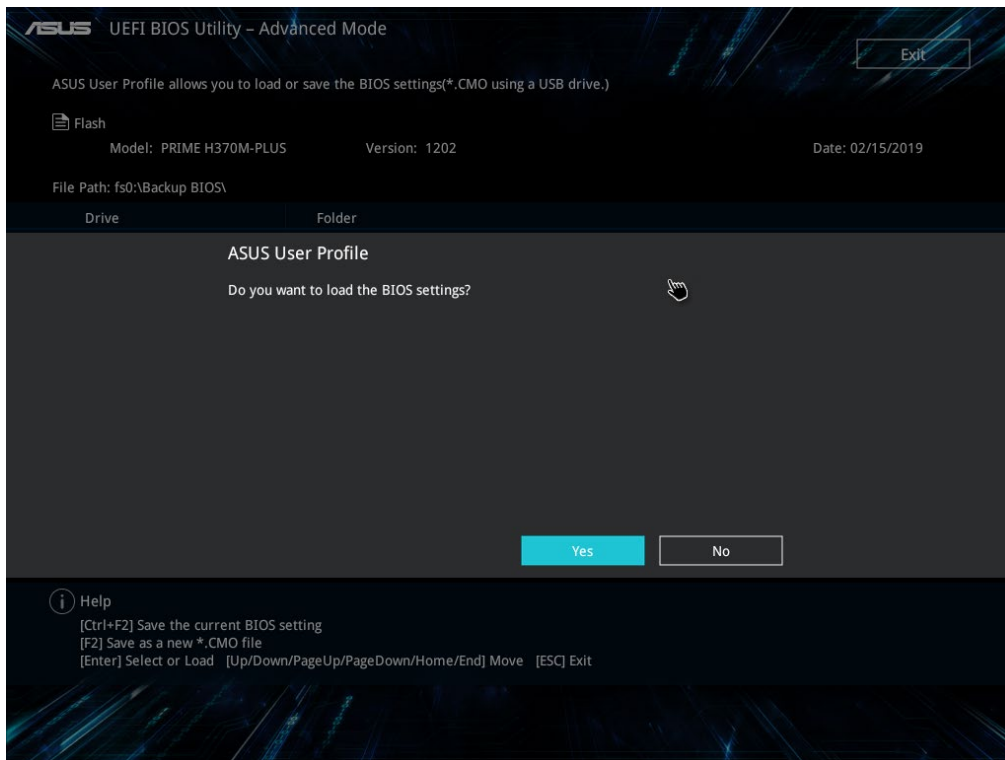
- Enter the **Tool** menu and select **Load/Save Profile from/to USB Drive**:



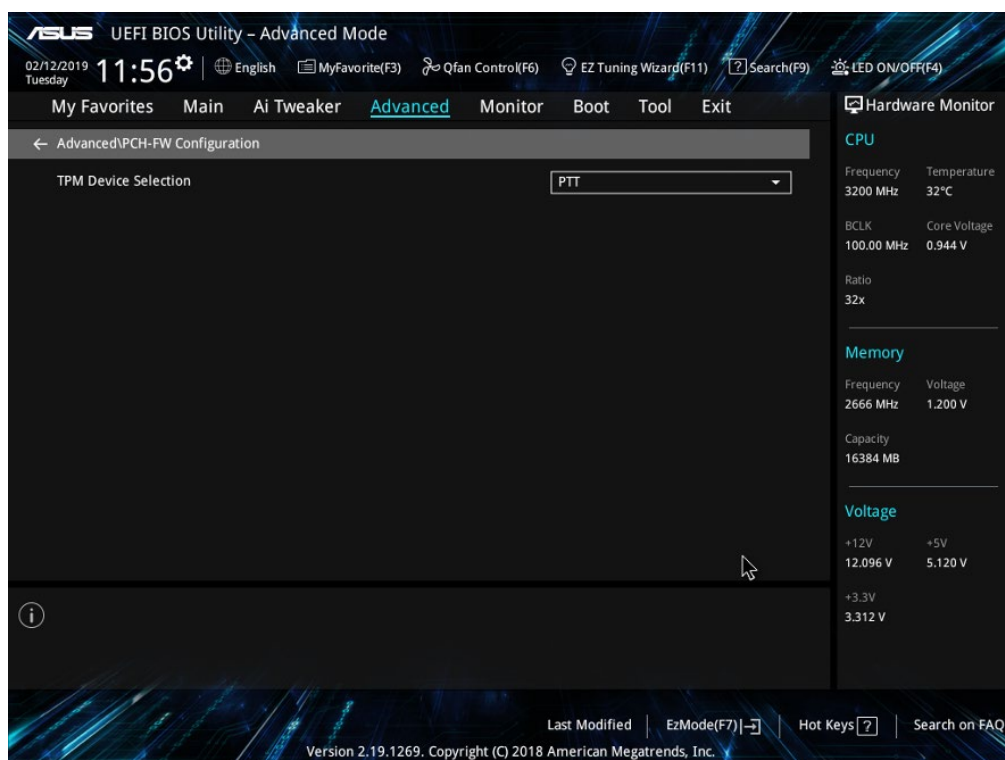
- Load the BIOS configuration file saved on the backup USB drive, supplied with the device, into the **BACKUP BIOS** folder:



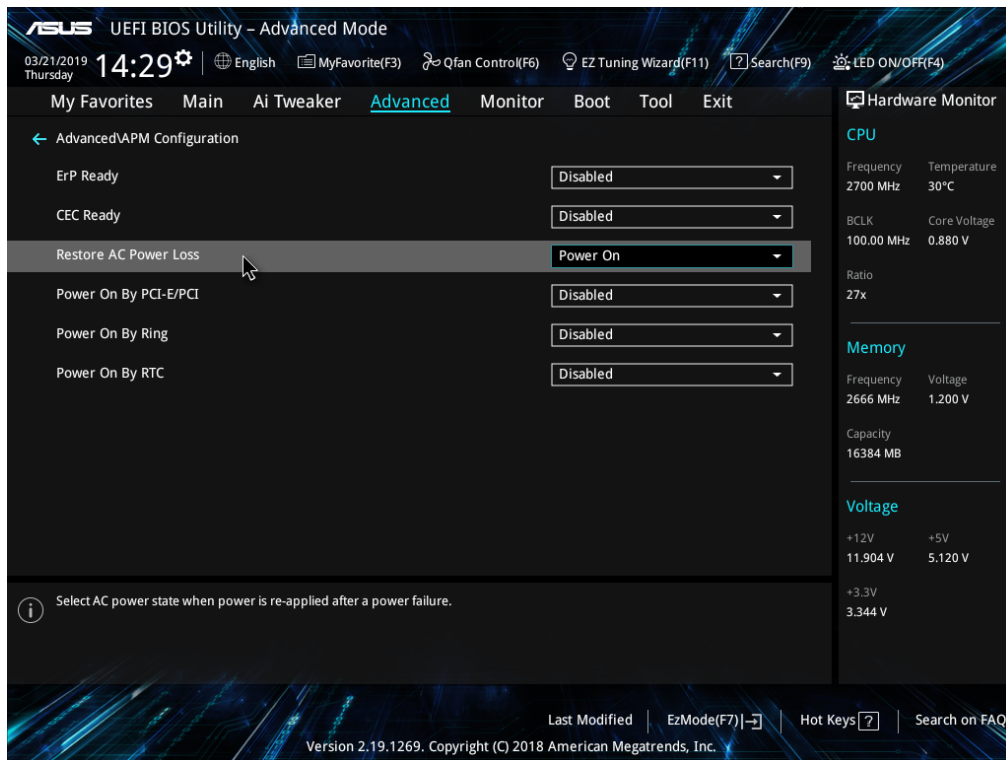
- Confirm the loading of the BIOS settings with the **Yes** command:



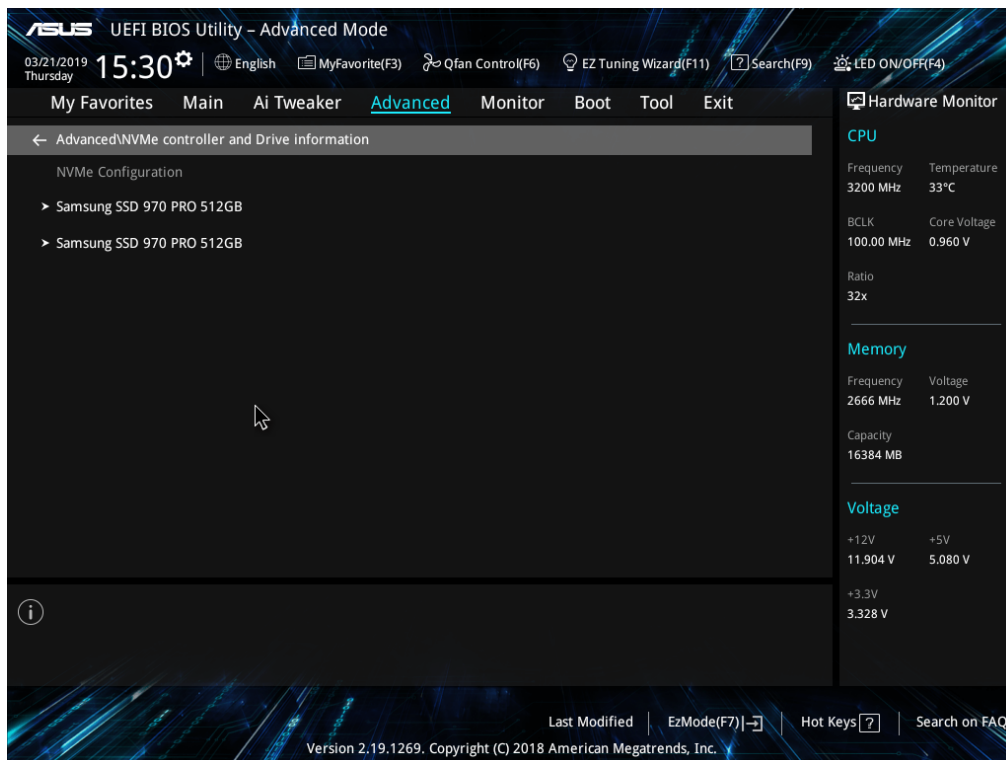
- Now, check that the following menus are set correctly.
- Enter the **Advanced** menu, select **PCH-FW Configuration** and verify that the **PTT** option is set in the **TPM Device Selection** field.



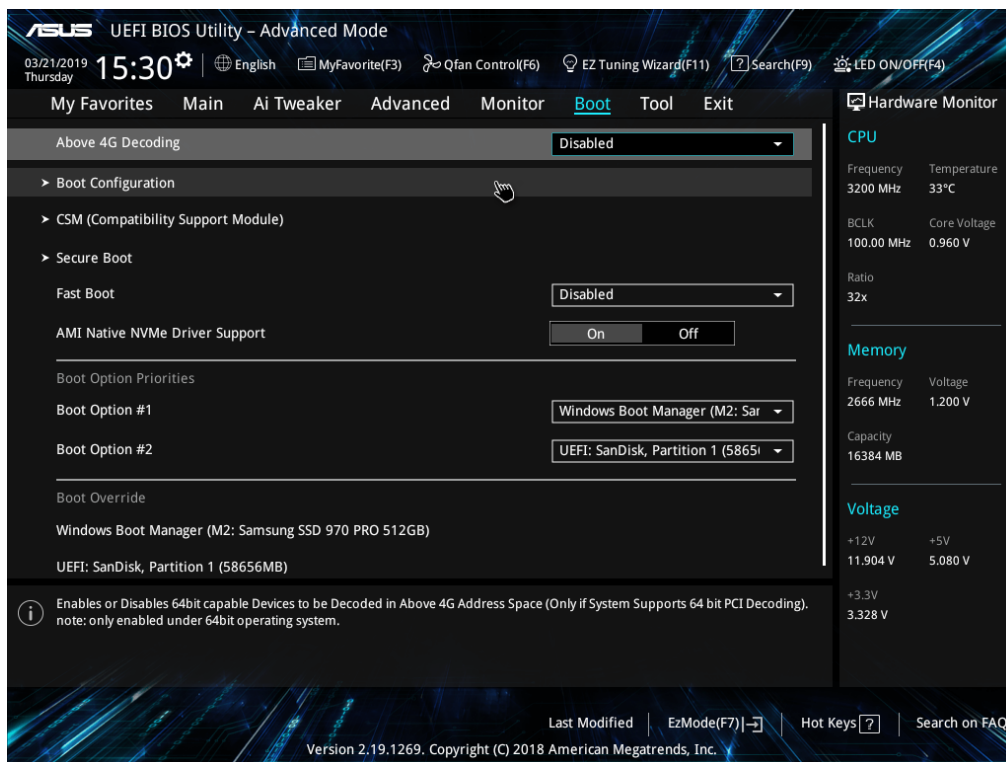
- Enter the **Advanced** menu, select **APM Configuration** and verify that the **Power On** option is set in the **Restore AC Power Loss** field.



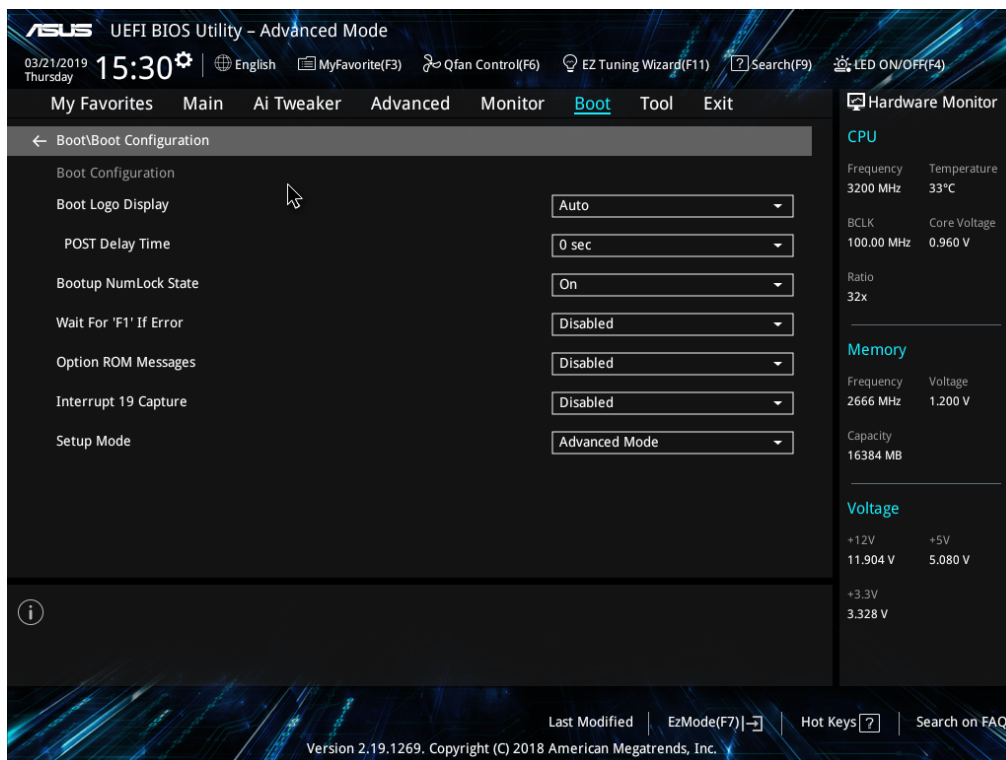
- Return to the **Advanced** menu, select **NVMe Configuration** and check that the two **Samsung SSD 970 PRO 512GB** Hard Disk are present.



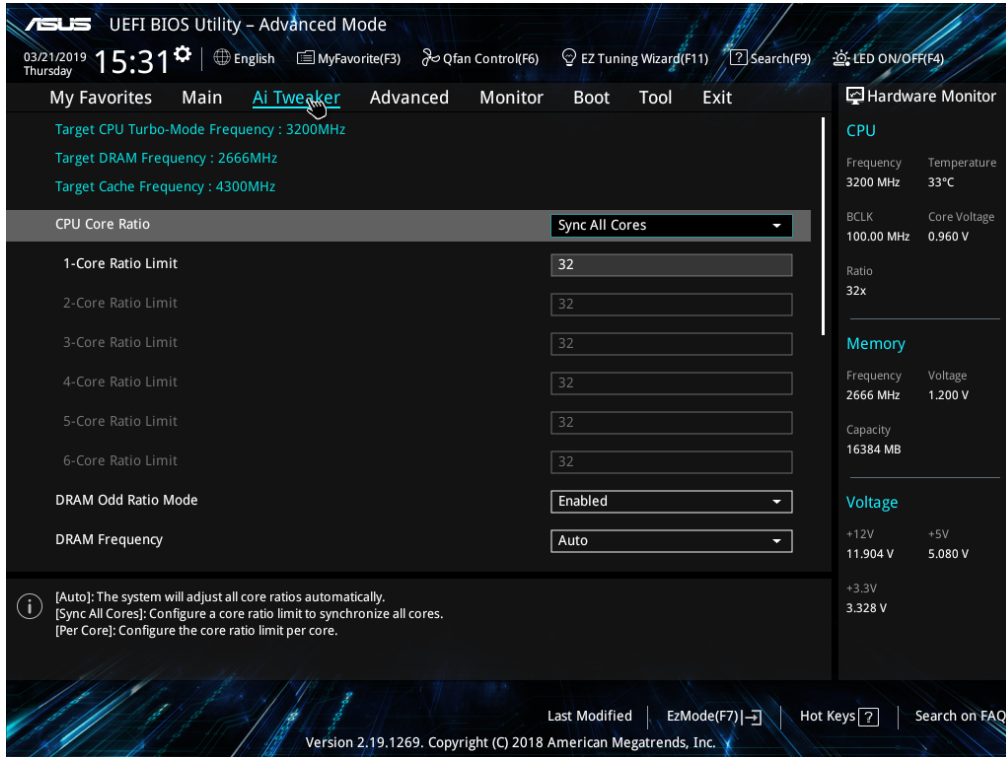
- Enter the **Boot** menu and verify that the **Disabled** option is set in the **Fast Boot** field.



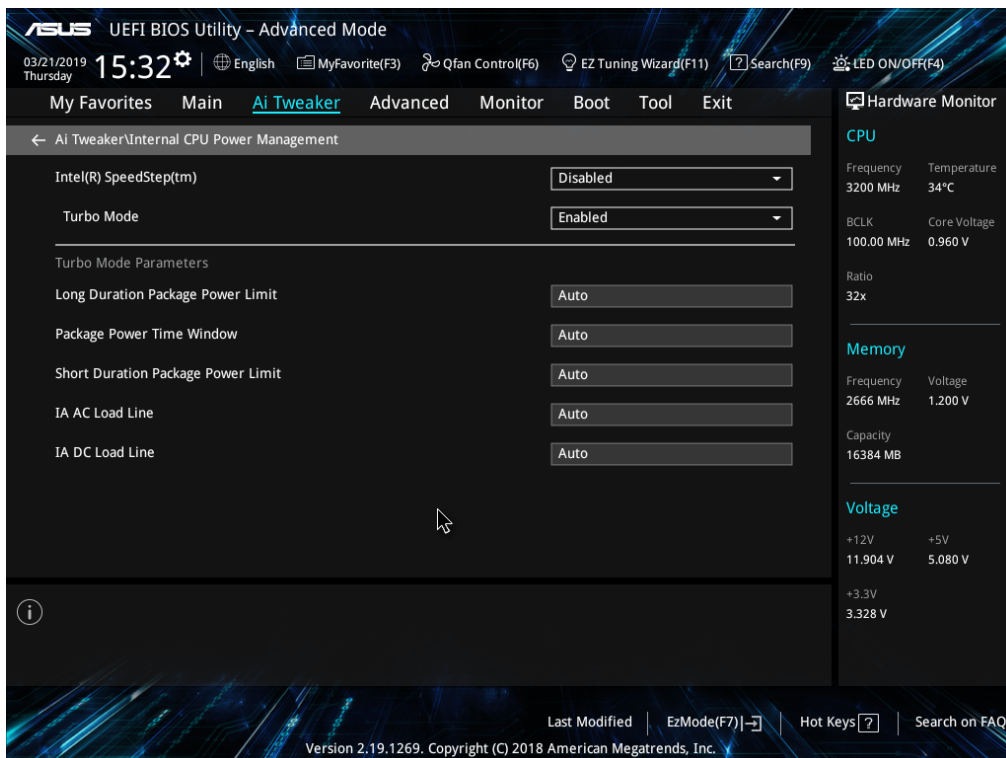
- Also in the **Boot** menu select **Boot Configuration** and check that the settings correspond to those shown in the following image:



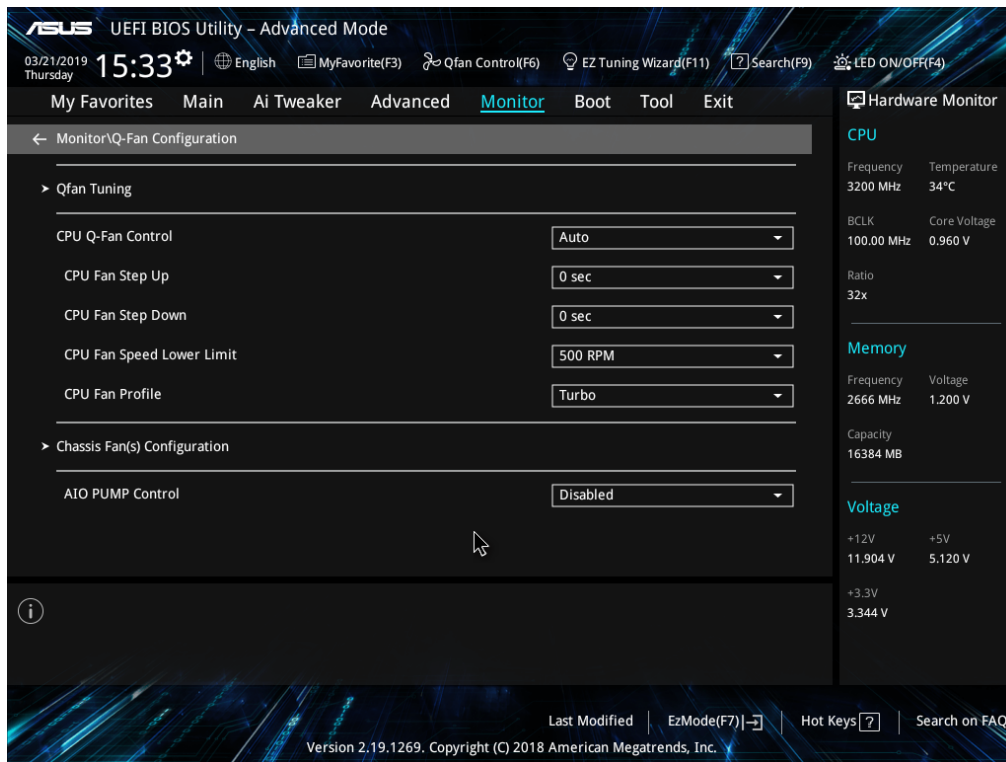
- Enter the **Ai Tweaker** menu and check that the settings correspond to those shown in the following image:



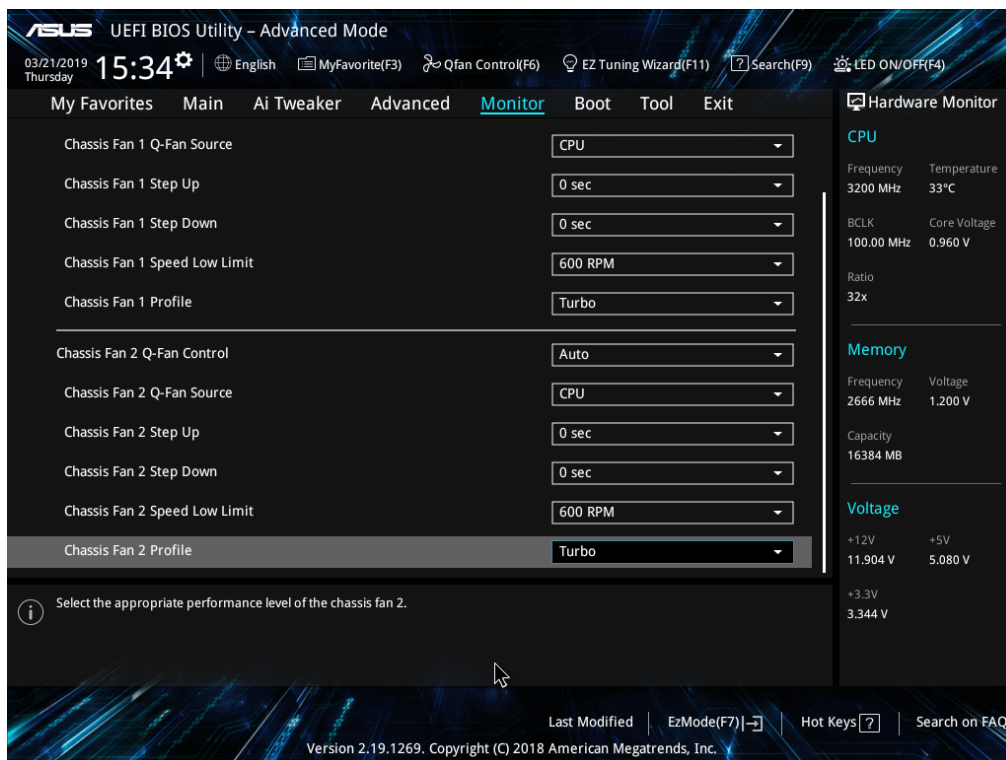
- Also in the **Ai Tweaker** menu, select **Internal CPU Power Management** and check that the settings correspond to those shown in the following image:



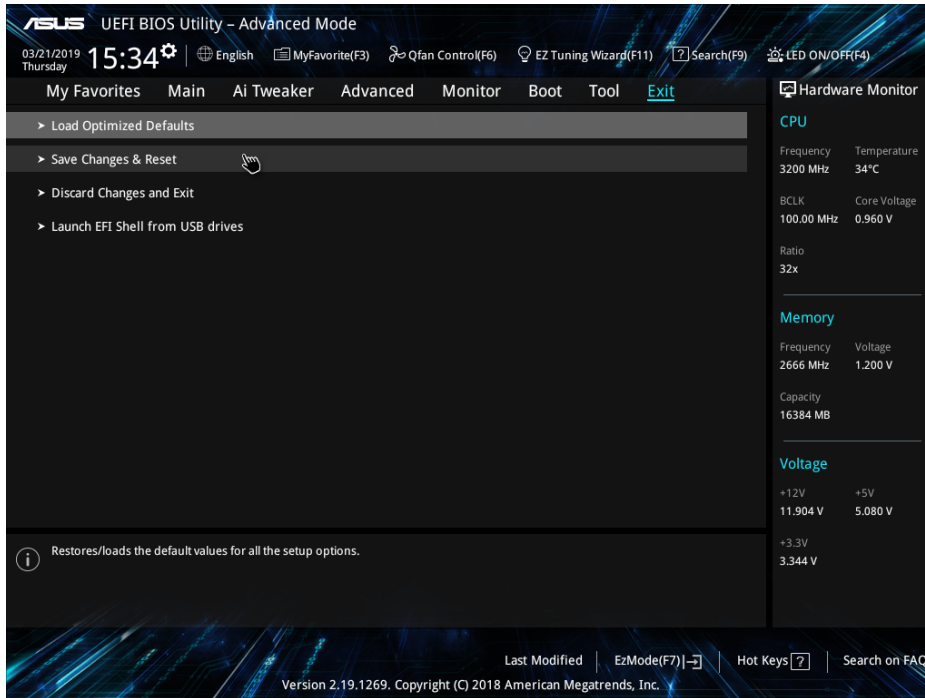
- Enter the **Monitor** menu, select **Q-Fan Configuration** and verify that the settings correspond to those shown in the following image:



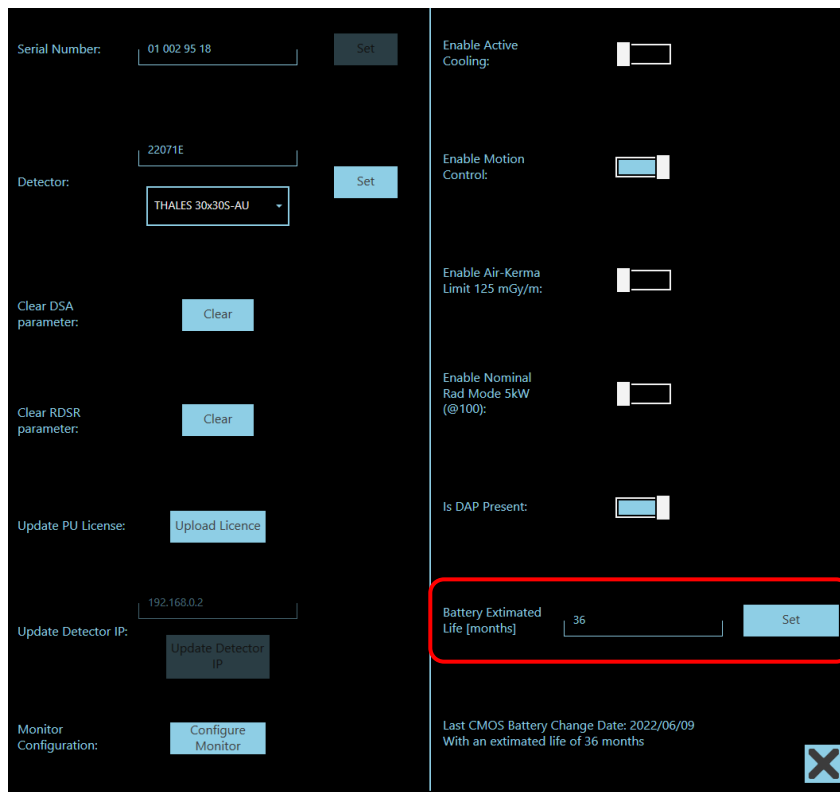
- Also in the **Monitor** menu, select **Chassis Fan(s) Configuration** and verify that the settings correspond to those shown in the following image:



- Enter the **Exit** menu and select **Save Changes & Reset**.



- The video processor restarts automatically. Disconnect the keyboard and reassemble the stand crankcase.
- Login as **Windows Administrator** (see Paragraph 5.2, part 2) and run the **ISIX Internal Setup** application.
- Enter the login password: **breatheme** and in the field **Battery Estimated Life [months]** enter the battery life (recommended setting = **36**). Then press **Set**.



- The **Last CMOS Battery Change Date** will be updated automatically.

TEST SHEET:

The Acceptance Test covers all the checks and tests listed in the Test Sheet below.

The Test Sheet should be filled in by the user:

- immediately after installing the equipment,
- during routine maintenance,
- after all extraordinary maintenance.

Code	Operation	Notes	Results
A.1	Mains power cable and connector.		
A.2	Monitor unit / stand cable and connector.		
A.3	Stand cable sheath.		
A.4	Footswitch cable and connector.		
A.5	X-ray emission command button cable.		
A.6	PC connection sheath.		
B.1	C-arm orbiting.		
B.2	C-arm orbiting brake.		
B.3	C-arm rotation.		
B.4	C-arm rotation brake.		
B.5	Horizontal C-arm movement.		
B.6	Horizontal C-arm movement brake.		
B.7	C-arm angling ("wig-wag").		
B.8	C-arm angling brake.		
B.9	Up/down column movement.		
B.10	Smooth movement of stand wheels.		
B.11	Stand parking brake.		
B.12	±90° rotation of stand wheels.		
B.13	Smooth movement of monitor unit wheels.		
B.14	Monitor unit wheel brakes.		
B.15	Fixing of the monitors.		
B.16	Fixing of the cover on the monitor unit.		
B.17	Fixing of the covers on the stand.		
B.18	State of the monoblock.		
B.19	State of the monoblock cover.		
B.20	State of the control panel on the stand.		
B.21	State of the ON/OFF controls on the stand.		
B.22	State of the up/down column commands.		
B.23	State of the emergency stop buttons.		
B.24	General ON/OFF key switch.		
B.25	Vertical movement of the 2 monitors on the monitor unit.		
B.26	Orientation of the monitors on the monitor unit.		
B.27	Smooth movement of the anti-scatter grid carriage.		
B.28	State of the anti-scatter grid.		
C.1	Monitor unit power supply unit.		
C.2	Stand boards.		
C.3	Stand ON		
C.4	LOGIN page.		
C.5	Log-in and monitor adjustments.		
C.6	Automatic stand initialising test.		
C.7	Emergency stop button on the monitor unit.		
C.8	Stand column movement.		
C.9	Emergency stop buttons on the stand.		
C.10	Stand column movement safety.		
C.11	X-ray warning light and LEDs – Low Dose fluoroscopy.		
C.12	Image + indicators on monitors – Low Dose fluoroscopy.		
C.13	Image + indicators on stand – Low Dose fluoroscopy.		
C.14	Correct automatic kV search.		
C.15	Collimator iris and shutters.		

Code	Operation	Notes	Results
C.16	DAP value.		
C.17	Indication of virtual collimators on the monitors.		
C.18	Saving of images to HD and transfer to Memory Monitor.		
C.19	X-ray warning light and LEDs – High Quality fluoroscopy.		
C.20	Image + indicators on monitors – High Quality fluoroscopy		
C.21	Image + indicators on stand – High Quality fluoroscopy.		
C.22	Correct automatic kV search.		
C.23	DAP value.		
C.24	X-ray warning light and LEDs – radiography.		
C.25	Image + indicators on monitors – radiography.		
C.26	Image + indicators on stand – radiography.		
C.27	230 V AC power supply: Radiography time for 40 kV, 50 mAs	Limits: 654 ÷ 885 ms	
	120 V AC power supply: Radiography time for 40 kV, 25 mAs	Limits: 650 ÷ 880 ms	
C.28	230 V AC power supply: Radiography time for 80 kV, 20 mAs	Limits: 485 ÷ 655 ms	
	120 V AC power supply: Radiography time for 80 kV, 12.5 mAs	Limits: 608 ÷ 822 ms	
C.29	DAP value.		
C.30	Centring of Laser Localizer (<i>optional</i>)		
C.31	Video printer (<i>optional</i>)		
D.1	X-ray dose intensity.		
D.2	Automatic X-ray dose control.		
D.3	Grey scale.		
D.4	Spatial resolution.		
D.5	Noise level.		
D.6	Min contrast.		

Date:

Operator's signature: