Chapter IV:
SETTING TO WORK: MECHANICAL AND ELECTRICAL SETTING

1. MECHANICAL AND ELECTRICAL SETTING CHECK LIST

HELIANTHUS series Model_____S/n_____

INSTALLATION PLACE _____

INSTALLATION DATE _____

INSTALLATOR SIGNATURE _____

RESPONSIBLE PERSON _____

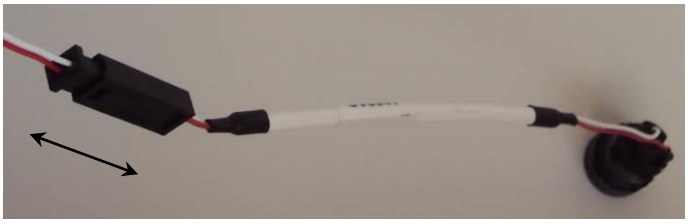
1.1	Electrical connection of lateral cover			[ ]
1.2	C-Arm cover identification			[ ]
1.3	System and detector assembly			[ ]
1.4	Acquisition Work Station assembly			[ ]
	1.4.1 top mounting			[ ]
	1.4.2 ANTI-X PROTECTIVE SCREEN			[ ]
	1.4.3 Monitor assembly			[ ]
1.5	Monitor and Keyboard assembly			[ ]
1.6	Emergency cut off			[ ]
1.7	Switch on unit			[ ]
1.8	Start Application Software			[ ]
1.9	Mechanical Safety Device integrity and functionality check			[ ]
1.10	C-ARM vertical movement	UP [ ]	DOWN	[ ]
1.11	C-ARM rotation movement			[ ]
1.12	C-ARM stereo rotation ±15° with Biopsy Device			[ ]
1.13	Compression movement	UP [ ]	DOWN	[ ]
1.14	Breast thickness check			[ ]
1.15	Compression force check			[ ]
1.16	C-arm movement with compression			[ ]
1.17	X-ray beam collimation check			[ ]
1.18	Light beam collimation check			[ ]
1.19	Column covers assembling			[ ]
1.20	Unit cleaning			[ ]

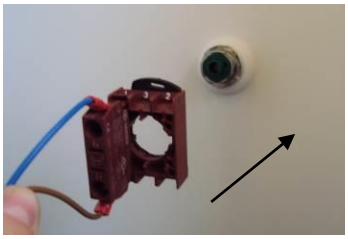
DATE_____SIGNATURE_____

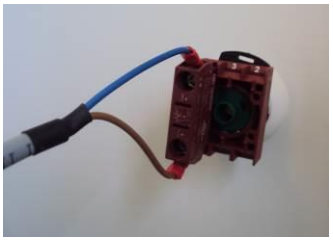
1.1 ELECTRICAL CONNECTION OF LATERAL COVER

Mammo unit is packed with C-arm lateral Covers disassembled.

- Move lateral cover besides Mammo Unit gantry and connect standby lamp cable (CV0641) and emergency pushbutton for each cover, as shown in the following pictures:

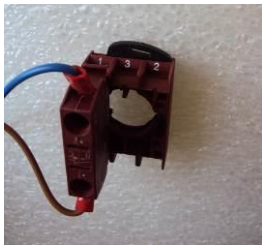






CAUTION

Before connection check emergency push buttons is connected on “1” (or “2”). No other connections are possible.

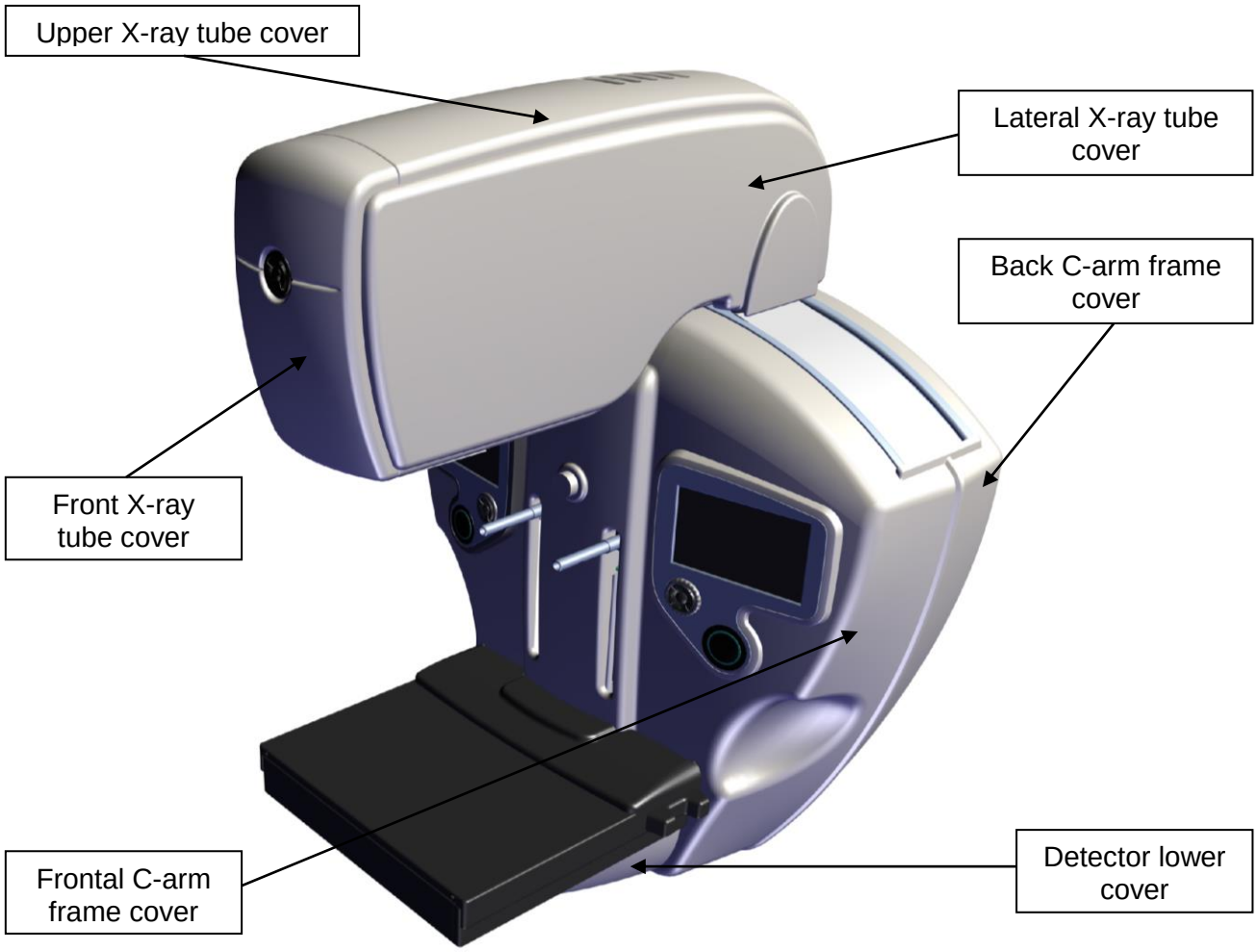


NOTE

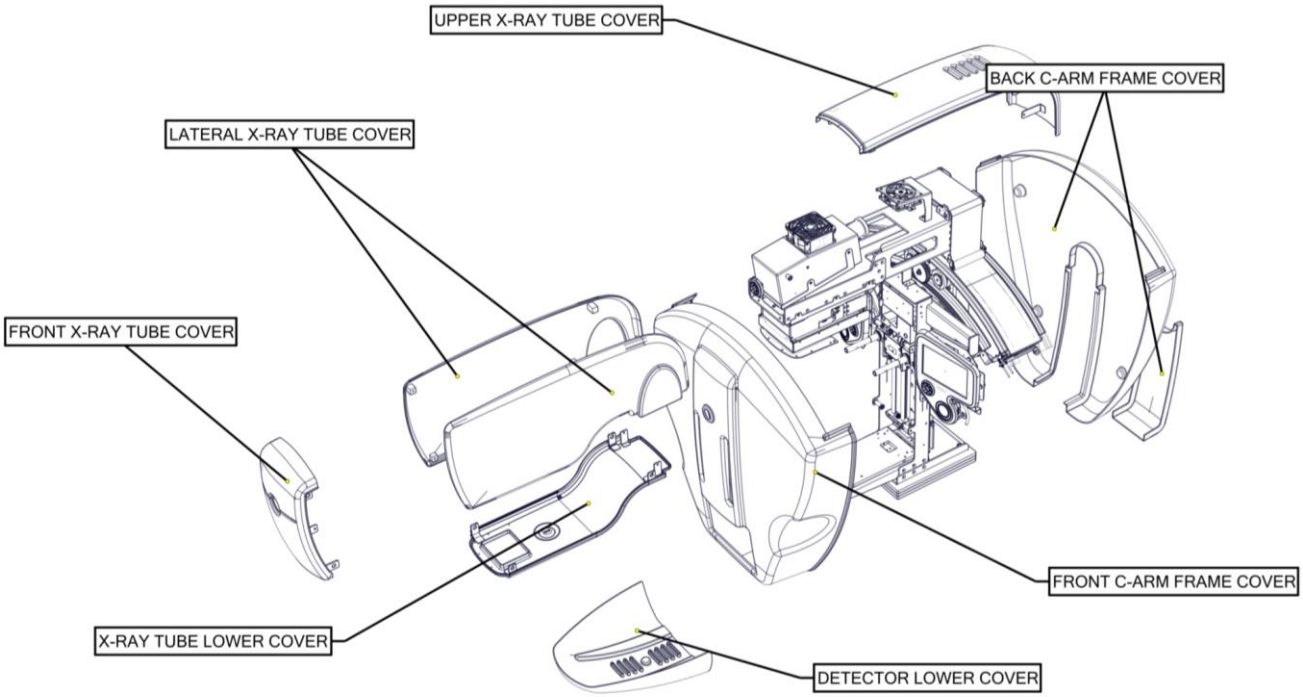
Do not assemble all covers on gantry because you need to inspect components inside during mechanical and electrical setting.
Cable are along enough to allow service inspection without assembling.

- After connection verify functionality of both emergency push buttons and lamps

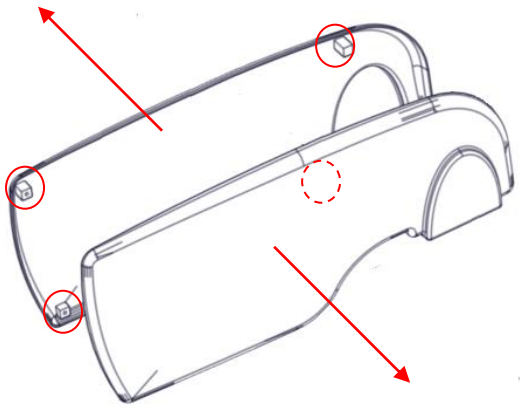
1.2 C-ARM COVER IDENTIFICATION



Mammo Unit is packed with all C-arm cover assembled.
To remove them in case of detector assembling or for any internal replacement, please refer to the following exploded view drawing in order to identify each cover.



Lateral X-ray tube covers can be removed easily unlocking lateral fasteners. Remove lateral protection pulling each one; no tools required.



Removing lateral covers it is possible to access to main parts of C-arm such as X-ray tube, collimation device, HV cables, cooling FAN and other point

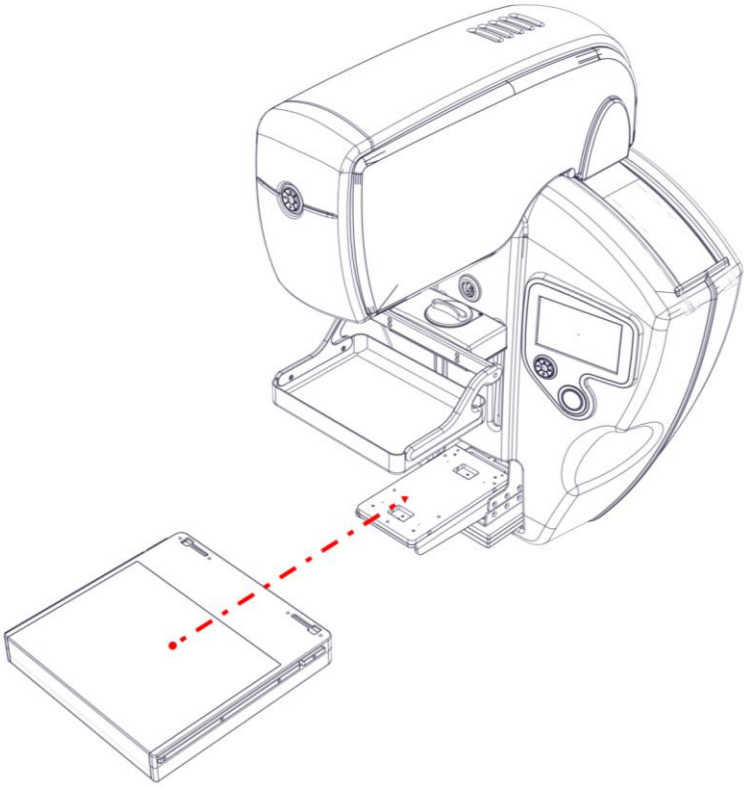
1.3 SYSTEM AND DETECTOR ASSEMBLY

DETECTOR

1) Unpack the DETECTOR from antistatic bag (for unpacking package see chap.2 of Technical manual).

2) Place the DETECTOR on a flat and clean surface covered with soft material (eg. Bubblewrap); put the antistatic bag back into the box.

3) Remove the cover under the DETECTOR support and place the same on it. Centre it and slide it slowly in order to insert the male rear connectors into female connectors of C-Arm.

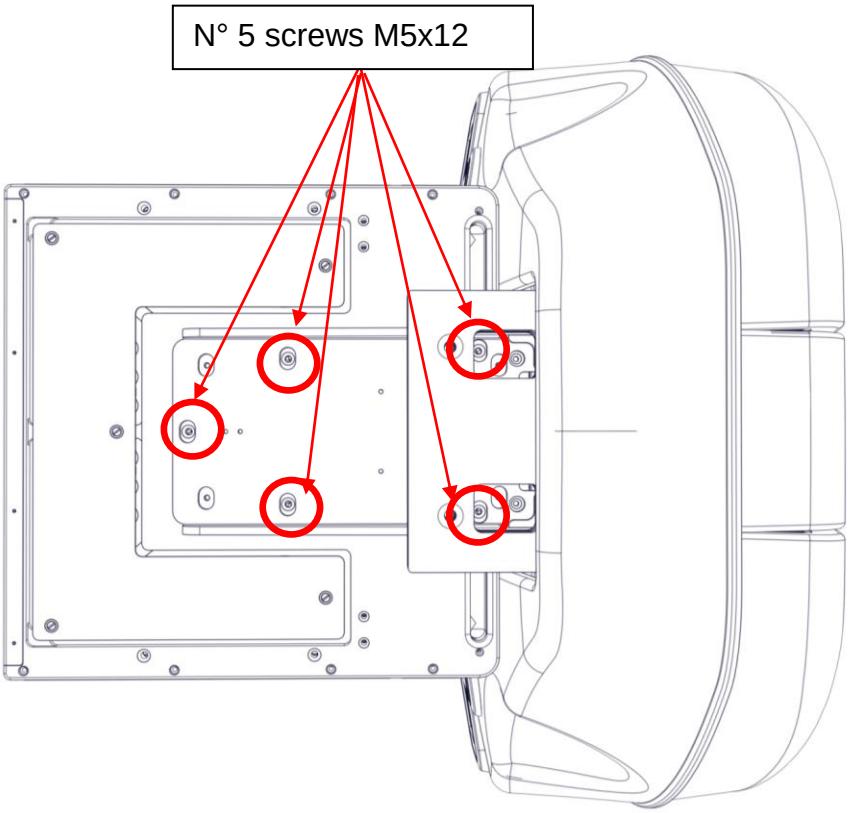


Now the DETECTOR is electrically connected to mammography unit.

NOTE

Pay attention during connector cabling. A wrong insertion may compromise pin connector functions and may generate errors (See chap. 9 “Fault finding - Troubleshooting”)

4) Fix the DETECTOR to the support with n°5 screws M5X12

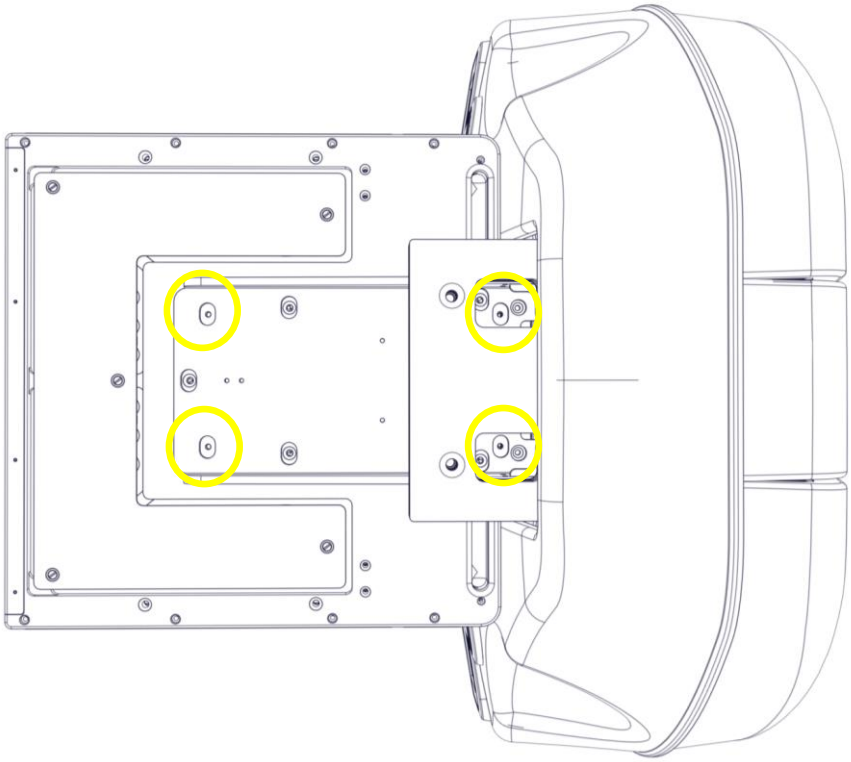


NOTE

In case of Detector Replacement, the operator has to follow detailed procedure provided by Metaltronica S.p.A.

WARNING

Pay attention to not move the fixing screws (screws encircled in yellow) of the detector support in order to avoid the X-ray beam misalignment.

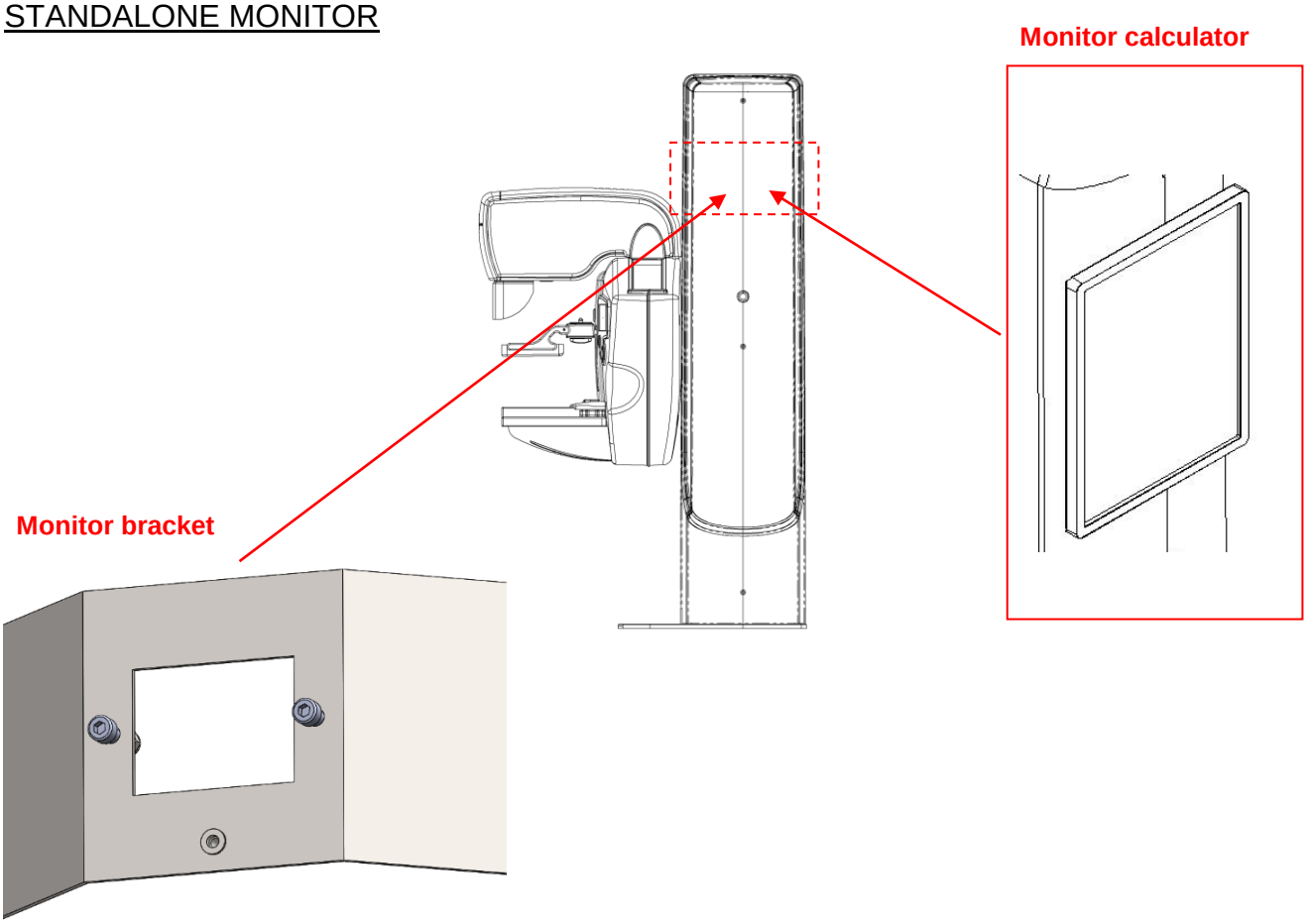


1.4 ACQUISITION WORK STATION ASSEMBLY

See Chapter 02 - Section “AWS Unpacking”.

1.5 MONITOR AND KEYBOARD ASSEMBLING

STANDALONE MONITOR



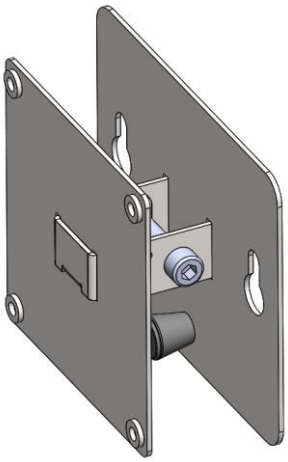
Calculator control monitor is fixed to the mammographic unit stand with a specific bracket.

Connect the video and power cable to the monitor side.

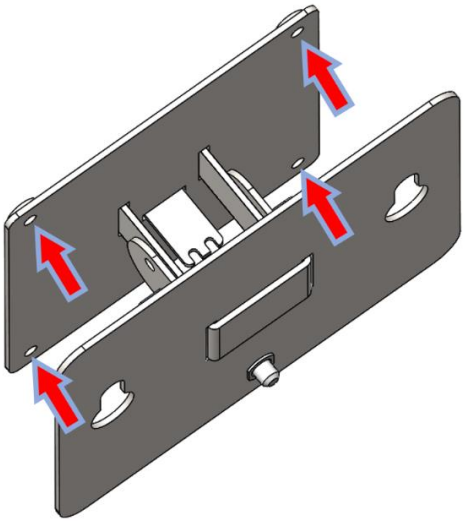
CAUTION Before fix the monitor on the stand, place the lateral cover.

In order to fix PC control monitor follows steps below:

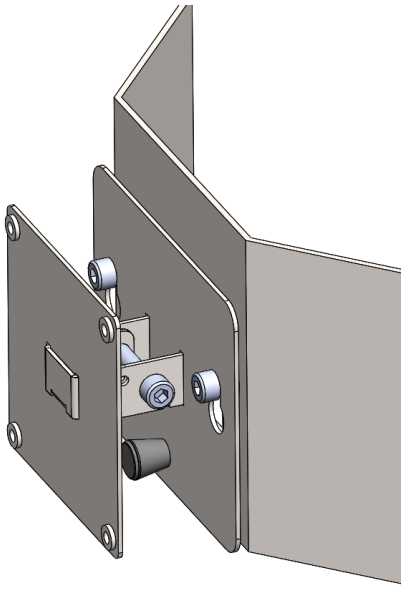
Monitor support



Follow the two following steps:

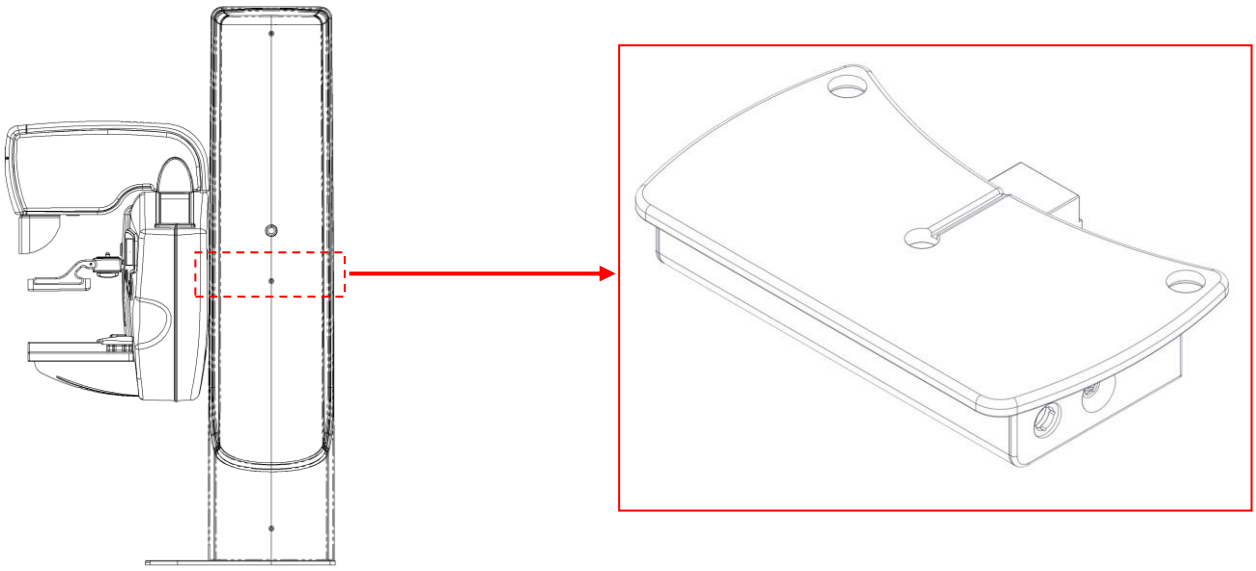


1. Tighten 4 screws to the rear of monitor for monitor support

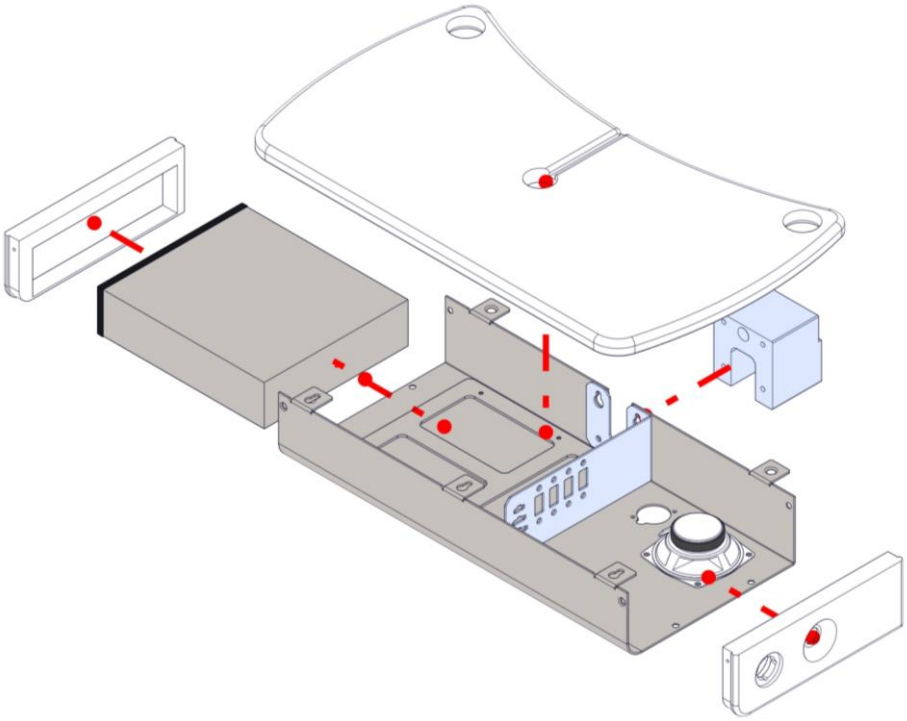


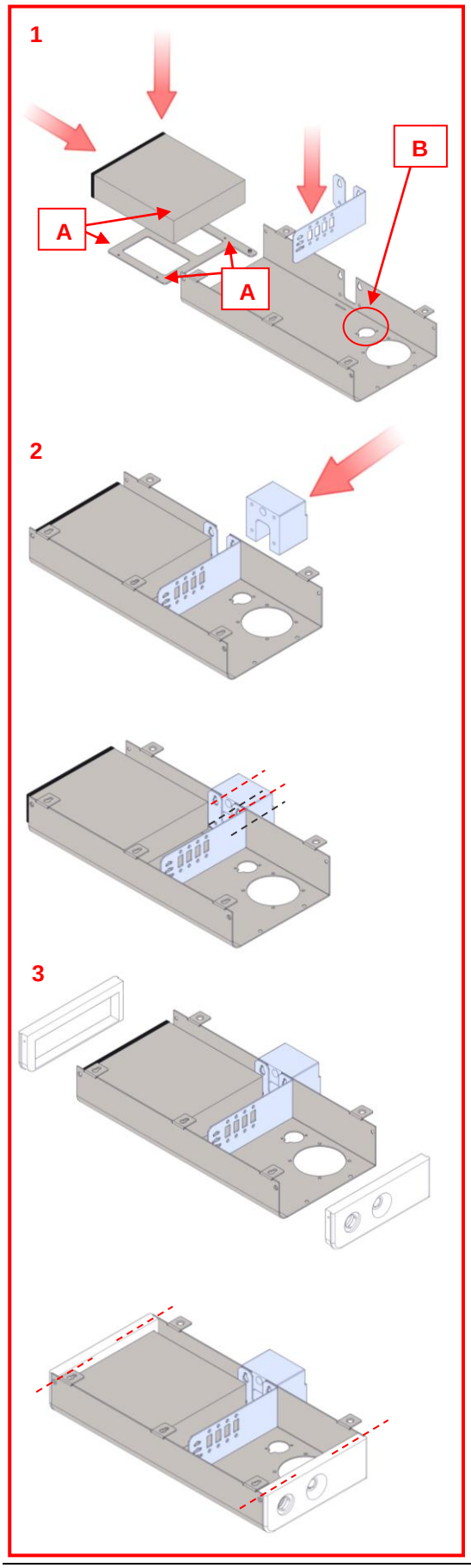
2. Fix the support to the bracket with two M8 screws using a ratchet wrench

LATERAL KEYBOARD SUPPORT



MECHANICAL FRAME “exploded view”

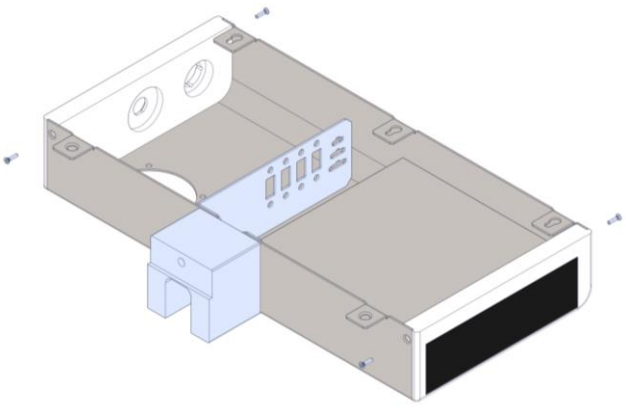


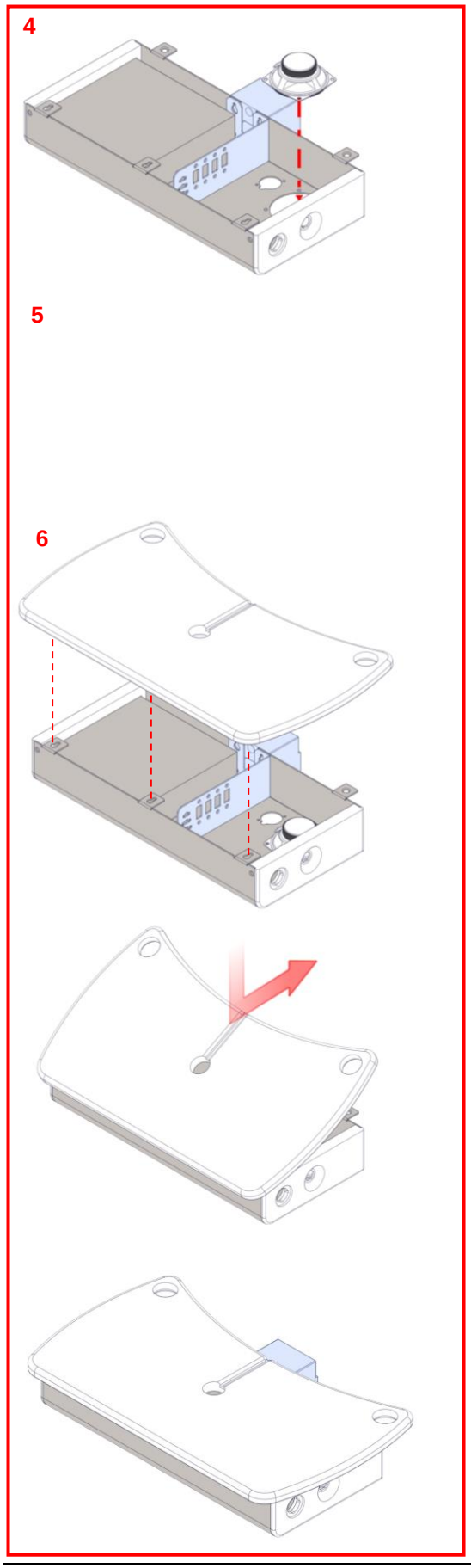


1. Fix DVD maker to mechanical slide using 4 screws provided with DVD reader (A), plug the amp-modu/F connector to the amp-modu/M for X-ray pushbutton connection and FIX the connector to the hole provided (B);
   Fix mechanical slide with DVD marker to bracket with screw and regulate it to the minimum.
   Insert the baffle into the bracket as show in the figure. Connect DVD marker with cable provided (CV0818-X)

2. Place rear support for bracket stand connection fixing it with screws provided with kit (M5x15), as shown in figure 2.

3. Place laterals to the bracket and connect as follow:
   Fix laterals with 4 screws provided (M3x8) as shown in figure 3;

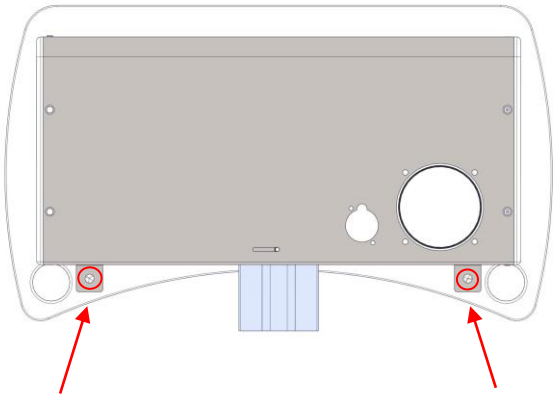




4. Insert speaker into the frame and connect it (CV0826-X)

5. Insert and connect On/Off push button, USB port (CV0835-X)

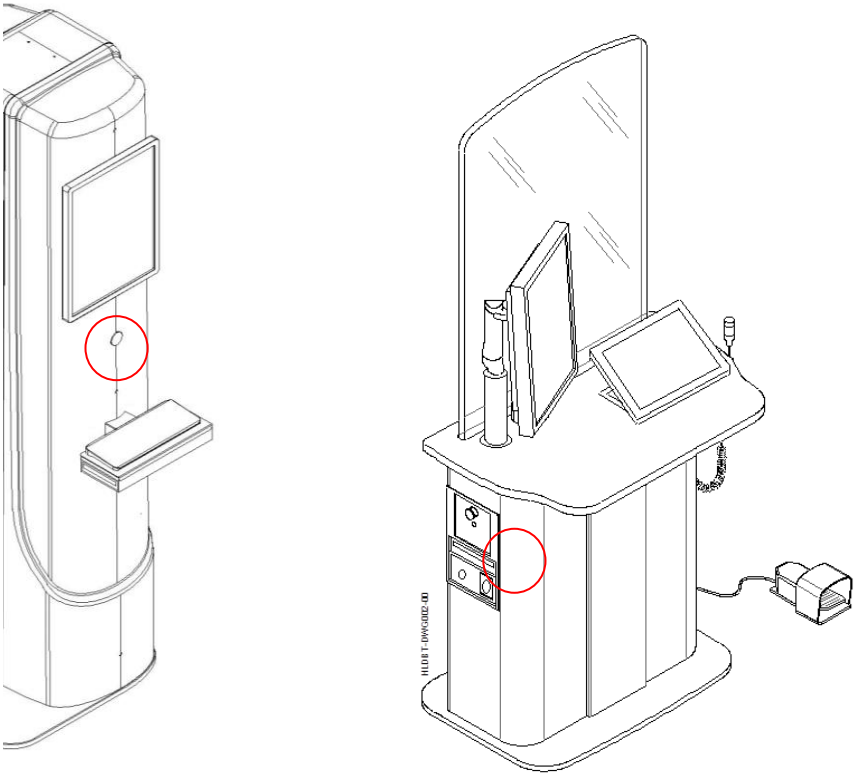
6. Close the bracket mounting top and fixing it with screw provided into the kit (M4x8).



1.6 EMERGENCY CUT OFF

On both sides of the Mammography Unit there are two Emergency Pushbuttons. They will switch OFF immediately main supply and the unit is switched OFF (only calculator, Detector and parts described in Chap.03, par. “PROTECTIVE MEASURES” remain powered).

Another Emergency stop is provided on Acquisition WorkStation (if provided).



In case of emergency, to immediately remove power supply and turn the system completely OFF, push any of the pushbuttons.

The Emergency Pushbuttons are only intended for operator's use in a condition of real or presumed danger. Only calculator and detector remain switched ON (logic power-on).

In such a circumstance, the unit is disconnected from the mains, X-ray emission is blocked, and every motorized movement is blocked.

In this state the operator may get the patient free by pushing the n°2 PushButton of the rotating controller for fine manual compression.

In case of Emergency stop activation, to continue operation is necessary to unlock the Emergency pushbutton and restart again.

The Emergency Pushbuttons cannot be used for normal switch off of the unit.

These Pushbuttons are provided of self-lock function to prevent any self-release. To unlock, turn them clockwise.

If you cannot switch on the unit, please inspect all emergency pushbuttons.

Before switching ON the unit, check that Emergency PushButtons are unlocked and Blue Lamp inside the touch screen cover is bright; if not, check main switch on the wall.

1.7 SWITCH ON UNIT

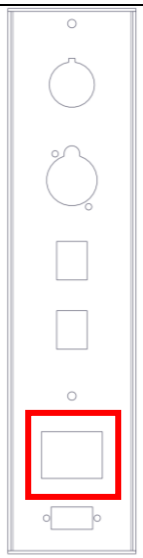
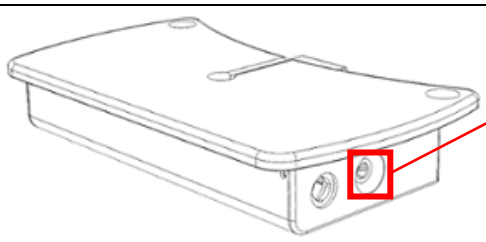
At this point in the HELIANTHUS series Installation procedures:

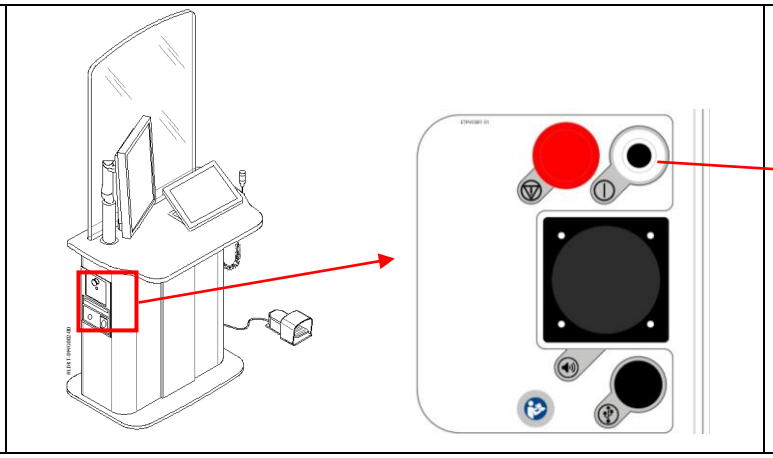
1. Both the mammo unit and Acquisition Work Station (if provided) are permanently mounted in position
2. All supply connections are complete;
3. Detector is installed;
4. All emergency push buttons are reset (2 on Unit, one on AWS, If provided)

Before switching ON the unit, check that Emergency Push Buttons are unlocked and Blue led inside the TSD monitors (see “MAIN PARTS”) is bright; if not, check main switch on the wall.

1. Switch ON UPS pushbutton on the backside panel (see Chapter 3). It is usually switched on during normal use of device.

2. Push the ON/OFF button (See “Main Parts” paragraphs)

PHASE	PROCEDURE	
1		
2*		

2**		

**represents the power-ON/emergency push buttons label provided on the acquisition workstation. The unit can be switch-on directly from Acquisition workstation (if provided).

Automatically system will switch ON Mammo unit, detector and run DMDAcquisition. Wait about 5 minutes for ready status (visible on AWS DSP). Refer to Operator's Manual for detailed procedure and specific cases.

1.8 START APPLICATION SOFTWARE

The software runs automatically. During initialization, the Acquisition Work Station switch ON detector and mammography unit.

NOTE

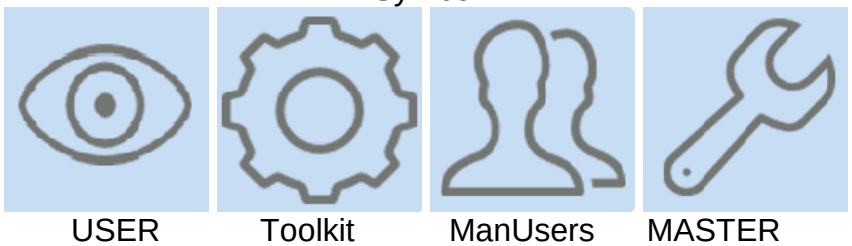
During the start-up phase, it is possible to check on the progress of the system boot by means of the indications visualized on the MAMMO TSD.

The following accounts are pre-installed in the System:

1. “DMDAcquisition”: this is the account for the clinical practice. It allows the access to all the main functions of images acquisition and visualization;
2. “DMDToolkit”: this is the account for Service activities; it allows the access to all the main functions of calibrations and controls in order to guarantee the correct functioning of the Mammograph.
   Its use is reserved only to the authorized Technical Assistance personnel;
3. “ManageUsers”: this is the account for management, creation and configuration of the user’s list authorized to access to the DMDAcquisition SW.
   For more information about the use of this Account, contact Metaltronica S.p.A;
4. “Master”: this is an account reserved to Metaltronica S.p.A.

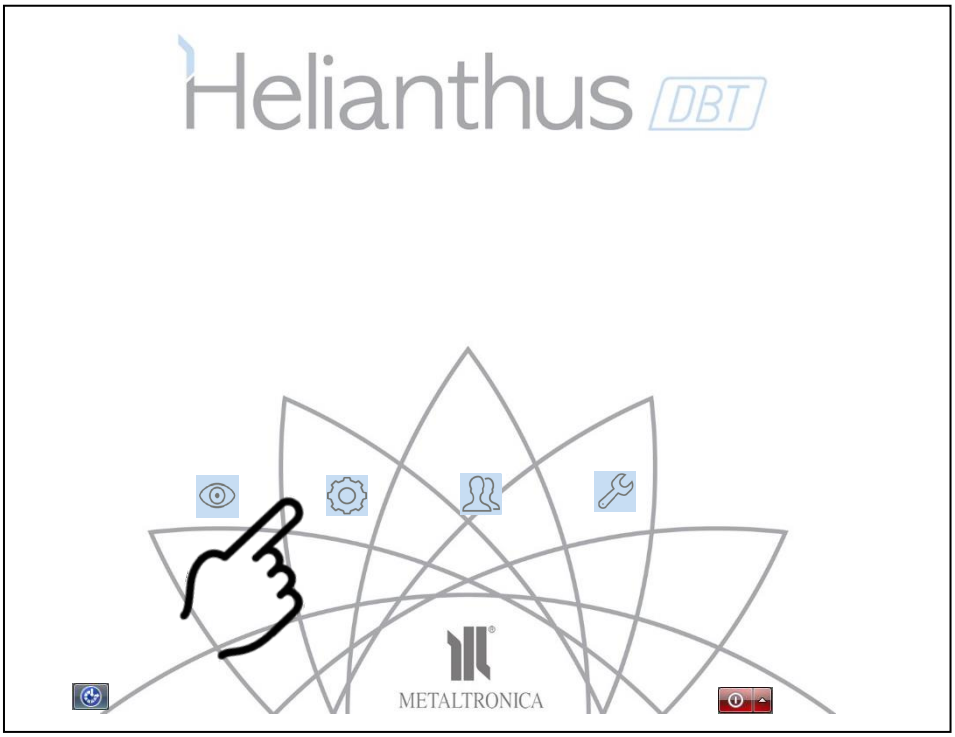
At the end of the initialization, a GUI with the four buttons appears, as indicated below:

Symbol

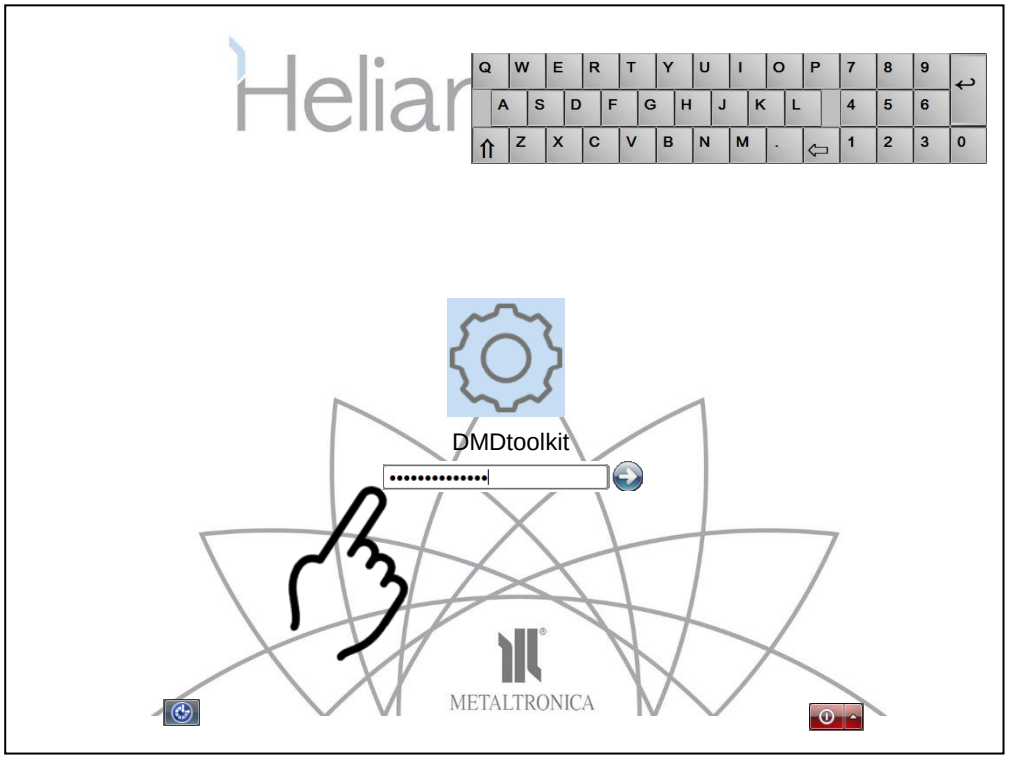


USER Toolkit ManUsers MASTER

In order to access to DMDToolkit SW, it is necessary to click on the correspondence icon which appears on the AWS DSP:



and key the password using the virtual keyboard at the top-right of the screen:

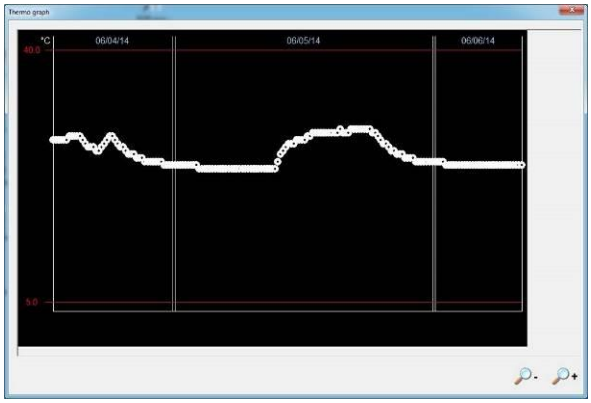


NOTE

In case of virtual keyboard not active, it can be refreshed clicking on the icon  located at the bottom left on the AWS DSP.

The password corresponds to the detector PANEL ID. This code is reachable in the detector accompanying documents (test report and CD-ROM) which are shipped with the Mammo Unit and which should be opportunely stored.

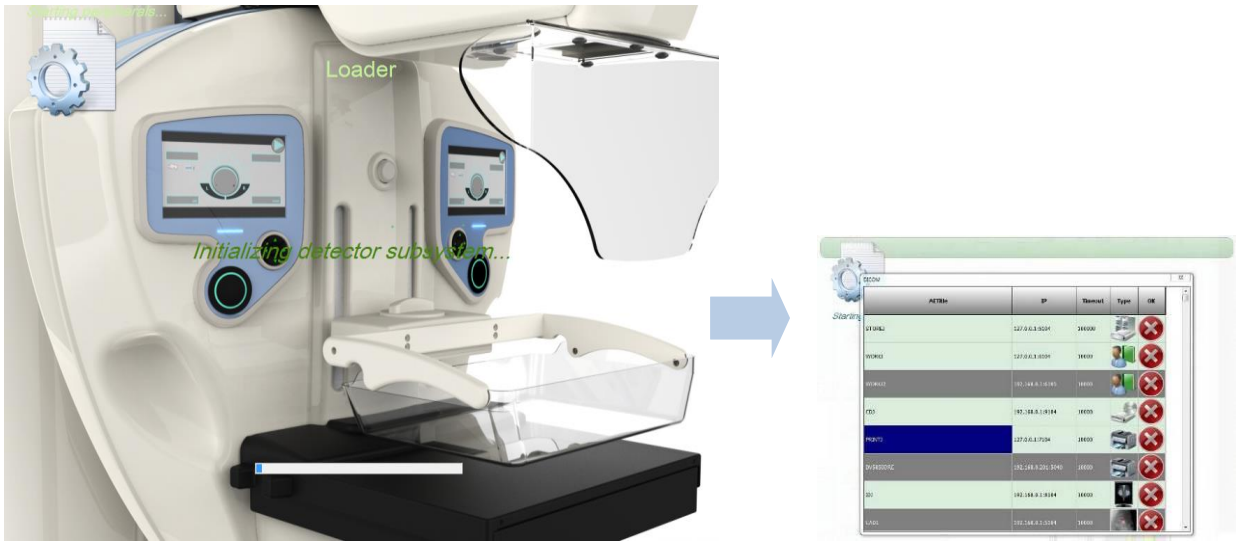
At the beginning, a window shows a thermo graph with temperature room trend in the time.
If room temperature exceeded upper or lower limits an error message appears (refer to Error codes section contained in this manual).



NOTE

Lens buttons let to the user to zoom in or zoom out the thermo graph. The two red lines in the thermo graph window indicate the operative range of working of FFDM unit

The thermo graph window disappears in few second.
After the selection of the SW DMDToolkit profile and the password insertion, the initialization of whole system will start. During this phase, the unit checks the presence and the functionality of all devices and components to which is connected.



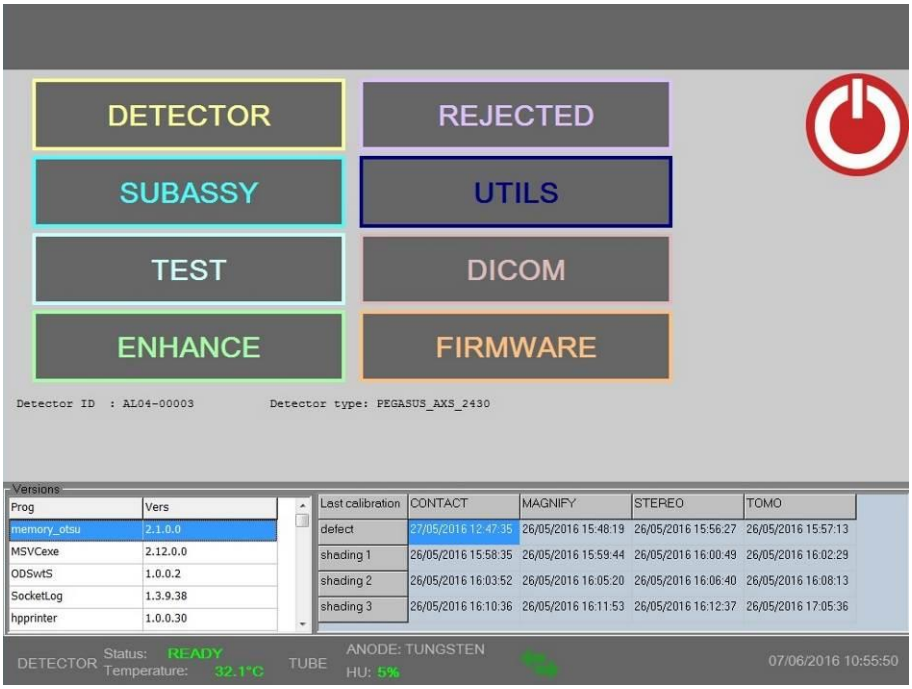
At the end of this verification and only after having press the pushbutton placed on the rear of the Mammo Unit and marked with the label “MAMMO SUPPLY ON-OFF”, the operator can click on “Yes” button to continue the tuning phase.

If it is the first start-up of DMDtoolkit (No A/F contexts has been assigned, see procedure in section 5, par. 1.5), it is necessary to assign the A/F contexts:

NOTE

If one A/F has been already assigned, filter menu does not appear. A/F menu is always available on “Subassy” section as reported in chap. 5

At the end of tuning phase, after about 5 minutes, the following User Interface is shown on the AWS DSP.



It is divided in several areas:

- **<u>UPPER SECTION</u>** shows the SERVICE functions (“DETECTOR”, “REJECTED”, “UTILS”, “ENHANCE”, “SUBASSY”, “TEST”, “DICOM” and “FIRMWARE”);

  For a detailed descriptions of those functions, refer to their dedicated sections of this manual.

  In particular for:

  - “DETECTOR”;
  - “REJECTED”;
  - “UTILS”;
  - “ENHANCE”

  see the related paragraphs in chapter 5.

  Whereas for:

  - “SUBASSY” (filament and generator)

  see the related paragraph in chapter 4.

  For more informations about the functions and advanced procedure of:

  - “TEST”;
  - “FIRMWARE”

  contact Metaltronica S.p.A.

- **MIDDLE SECTION** shows SW VERSION and CALIBRATION data. In particular, it provides indications about:
    - FIRMWARE and SOFTWARE versions installed;
    - last calibrations performed;

- **LOWER SECTION** shows the STATUS BAR. In particular, it provides indications about:
    - Detector status (i.e, “READY” or “NOT READY”);
    - Tube status (i.e, anode material and HU%);
    - Connection status between Acquisition Work Station and Mammo Unit.

  In this phase, a green message on this bar reveals the Mammo Unit and the Acquisition Work Station correctly communicate and the mammography system is now “ready” to use.

1.9 MECHANICAL SAFETY DEVICE INTEGRITY AND FUNCTIONALITY CHECK

The safety belt is composed of the following parts:

- an upper retractor provided of a protective cover and fixed on the Mammo Unit unified frame (see the paragraph "*Inside view main internal components location*" of chapter 3);
- a lower retractor provided of a pillar roller and fixed on the trolley of the Mammo Unit (see the paragraph "*Inside view main internal components location*" of chapter 3);
- a tape of transmission between the two retractors (see the paragraph "*Inside view main internal components location*" of chapter 3);
- a control microswitch of which the variation of position (and closed in normal condition) allows the CPU to generate a not restorable error message of "**DROP C-ARM SIGNAL DETECTED!"**

On this safety belt it is necessary during the mechanical setting to work phase and the in phase of periodical maintenance, to proceed with the following integrity and functionality tests.

INTEGRITY TEST

1. With the C-Arm in caudo-cranial position and in correspondence of its lower end travel, switch off the Mammo Unit and:

   - in correspondence of the upper retractor, stretching the tape of transmission until its allowed end, verify that its movement results flowing;

   - in correspondence of the lower retractor, moving the pillar roller to the top, verify the opening of the control microswitch (normally closed).

FUNCTIONALITY TEST

2. With the C-Arm in caudo-cranial position and in correspondence of its lower end travel, switch on the Mammo Unit and:

   - in correspondence of the lower retractor, moving the pillar roller to the top, verify the opening of the control microswitch (normally closed) and the presence of the error message "**DROP C-ARM SIGNAL DETECTED! "** on MAMMO TSD and AWS DSP.

1.10 C-ARM VERTICAL MOVEMENT

By means of the pushbuttons placed on Control Panel and the keyboards placed on both sides of C-Arm verify the vertical movement of C-Arm up to end of travel.

CAUTION

For this test compression trolley must be in the middle of its run and no compression force must be applicable because any vertical movement is disabled if any force is applied

1.11 C-ARM ROTATION MOVEMENT

By means of the pushbuttons placed on Control Panel and the keyboards placed on both sides of C-Arm. Verify the continuous rotation of C-arm to any position over ±180° and pre-selectable views (Pre-selectable C-arm angles as shown by TSD interface):

- CC
- LAT cw
- LAT ccw
- OBL cw
- OBL ccw

Rotation is disable if unit is switched OFF or if the compression force is applied.

NOTE

Please pay attention because compression force is applied even if compression trolley has reached the lower end of travel without any compressor paddle mounted (e.g. this one may be a test condition). Also In this case, the force sensor is active and any rotation of the C-Arm is disabled. If you need check C-arm rotation in this case, please lift up the compression trolley to enable rotation.

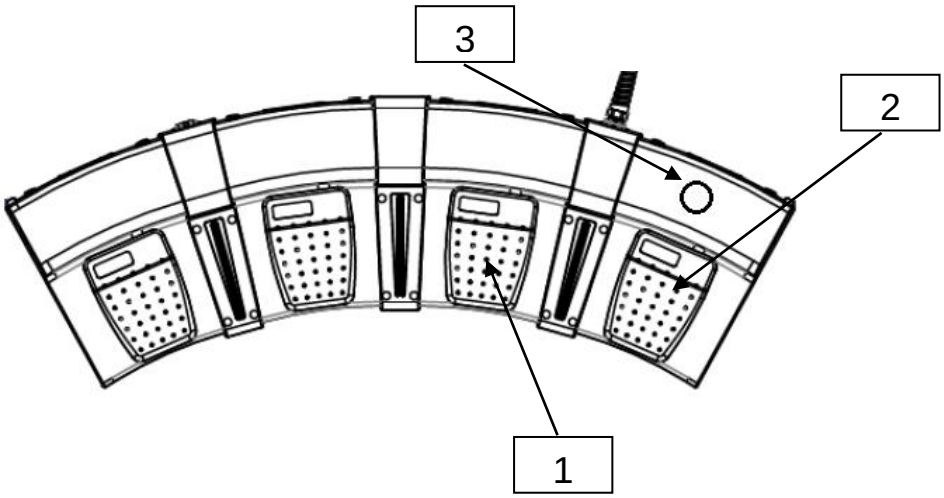
1.12 C-ARM STEREO ROTATION ±15° with stereotactic Biopsy device

Verify +/-15° rotation of C-Arm respect to Stereotactic Biopsy Device axis by means of Acquisition software projections in “Stereo” study mode.

With Stereotactic Biopsy Device inserted, C-Arm vertical and rotation movements are disabled. Only pushing and keeping pressed a safety interlock placed on *SBD DMD* is possible adjust C-Arm positioning it at the most appropriate inclination and height (see dedicated manuals).

1.13 COMPRESSION MOVEMENT

The breast compression is motor driven with fine adjustment. Verify the functionality of foot-control for motorized compression.



Push the pedal n°1, the compression paddle moves downward;

Push the pedal n°2, the compression paddle moves upward;

Push the button n°3, breast is released.

The compression movements can be verified with fine adjustment

The continuous rotation of encoder clockwise allows the compression paddle to move downward; the encoder's counterclockwise rotation guarantees upward movement. The force exerted on the breast at the end of compression is shown on mammo touchscreens.

1.14 BREAST THICKNESS CHECK

To verify the value of breast thickness, compress a phantom with a fixed and well known thickness (metacrilate phantom or PMMA), and verify that value shown corresponds with effective measure. Equipment to perform measure:

- Ruler
- Metacrilate phantom (PMMA)

Refer to chap. 5 - par. 1.4.1 "Breast thickness calibration" for calibration procedure.

1.15 COMPRESSION FORCE CHECK

The compression device consists on a motor driven trolley coupled with a torque limiter and load cell to measure compression force.

Maximum compression force is limited to 200 N and depends on max selected force selected on control panel depending on applied force measured by load cell.

Overload protection is assured by torque limiter and a redundant optical safety system inside the load sensor.

Equipment:

- Force balance
- Phantom (120x120x50mm)

It's possible to verify that the value shown on mammo touchscreens corresponds to the force really exerted on the breast at the end of compression with the following test:
Put the C-Arm in vertical position (CC), rise the compression paddle and place on Detector a force balance and an appropriately sized object. For the test refer to IEC 60601-2-45 (203.8.5.4.102.5 point) Standard.

Refer to chap. 5 - par. 1.4.2 "Compression force calibration" for calibration procedure.

1.16 C-ARM MOVEMENT WITH COMPRESSION

Any movement is not possible if compression is applied. UP/DOWN movements are not compatible with compression of breast.
To verify this safety measure compress breast's phantom and verify if it is not possible to move C-arm during compression.

NOTE

Compression force is applied even if you reach lower end of travel even if the compressor is not mounted because the force sensor is active.
In this circumstance, every movements (rotation or up/down movement) is disabled.

1.17 X-RAY BEAM COLLIMATION CHECK

In order to verify X-ray collimation check, perform "Daily check" whose procedure is described on operator's manual.

1.18 LIGHT BEAM COLLIMATION CHECK

Check the correct light beam switch. When breast compression is activate, the light beam must switch on for about 20s.

CAUTION Don not watch directly the collimation lamp

1.19 COLUMN COVERS ASSEMBLING

To assemble the mammography unit insert the covers appropriately. The n°3 holes in the cover must correspond to related holes in the metal chassis.

There are three fixing holes for each side of the HELIANTHUS series

After assembling verify again the correct functionality of the emergency pushbuttons and stand by lamp.

1.20 UNIT CLEANING

MAMMOGRAPHY UNIT

Regular cleaning of the compression paddle, Potter, magnification device and detector is necessary prior to proceed with examination.

Use only a soft cloth and distilled water to avoid damage polycarbonate plate of compression paddle getting it hard with risks of cracks. For other surfaces use cleaning agents that do not damage plastics, aluminum and carbon fiber.

CAUTION

Do not use abrasive detergents or harsh cleaners.
Do not use excess of liquid and be careful washing liquid does not drip inside mammography unit, particularly inside detector.
Do not use steam or high temperature liquid.
Do not use cleaning sprays directly to avoid to damage electronic components.

Wipe any parts that contact the patient using a clean lint-free or pad.

WARNING

To cleaning and disinfecting parts that has come in contact with blood fluids or other potentially infectious materials follows a protocol assigned by your Infection Control representative.
Using a germicide follow manufacturer's instructions ad all precautions to ensure effective and safe use of the product.

To avoid electrostatic dust collection over plastic covers, use anti-static dashboard wet-wipes.

WARNING

To clean the carbon fiber cover of the DETECTOR, use only a soft cloth lightly dampened with a neutral detergent.
Never use wet clothes that can provoke the infiltration of liquids in the DETECTOR.

ANTI-X TRANSPARENT PROTECTIVE BARRIER

To clean the transparent anti-X barrier on Acquisition Work Station use any specific glass cleaner and a clean soft, lint-free cloth. Then wipe carefully the surface with another dry cloth.

CAUTION

Never spray any cleaning solutions directly onto the anti-X protective barrier, spray it into the cleaning cloth.
Be careful detergent liquid does not drip on desk.