Chapter VI:
PERIODICAL MAINTENANCE AND REPLACEMENT

1 – PERIODICAL INSPECTIONS

SUGGESTED EVERY 6 MONTHS, RECOMMENDED EVERY YEAR

Fill this form and send it back to to validate warranty.

HELIANTHUS series Model_____S/n_____

INSTALLATION PLACE _____

INSTALLATION DATE _____

INSTALLATOR SIGNATURE _____

RESPONSIBLE PERSON _____

1.1	External damages to shield or unit	[ ]
1.2	H.T. tank oil leakage, X-Ray tube oil leakage	[ ]
1.3	Correct insertion of boards connectors	[ ]
1.4	Available mains and configuration of the voltage selector	[ ]
1.5	Check of mains and earth connections, cables and corrugated tube	[ ]
1.6	Operation of emergency buttons	[ ]
1.7	Operational Check of all buttons	[ ]
1.8	Operational Check of AWS DSP	[ ]
1.9	Operational Check of MAMMO TSD	[ ]
1.10	C-Arm UP/DOWN movement to end of travel	[ ]
1.11	C-Arm rotation: movement to end of travel	[ ]
1.12	C-Arm tilting movement	[ ]
1.13	Chain-Reducer-Gears-C-Arm mechanical system	[ ]
1.14	General check of the mechanical status of the C-Arm assembly	[ ]
1.15	Mechanical Safety Device integrity and functionality test	[ ]
1.16	Compression movement, power and calibration	[ ]
1.17	Mirror check	[ ]
1.18	X-ray Beam Centering	[ ]
1.19	kV Calibration	[ ]
1.20	Anodic Current Calibration	[ ]
1.21	Automatic Rh/Ag/Al Filter Functionality	[ ]
1.22	Detector Calibration	[ ]
1.23	Batteries Status	[ ]
1.24	C-arm Anti-collision System	[ ]

DATE_____SIGNATURE_____

1.1 - EXTERNAL DAMAGES TO SHIELD OR UNIT

Check external damages to shield or unit. All the labels must be legible (See Chap. 1, paragraph “Device classification”). The lead equivalent thickness value must be legible on the shield.

1.2 - H.T TANK OIL LEAKAGE, X-RAY TUBE OIL LEAKAGE

Open the lateral cover of the unit and verify any oil leakage of the generator. Open lateral tube cover and verify for oil leakage (if Oil tube is provided).

1.3 - CORRECT INSERTION OF BOARDS CONNECTORS

Visual Check that all the connections between one board and other are correctly inserted and fixed.

1.4 - AVAILABLE MAINS AND CONFIGURATION OF THE VOLTAGE SELECTOR

Check the mains voltage. Verify that the mammography unit is installed according to the mains voltage configuration (refer to Chapter 3).

Line resistance (refer to Chapter 3) has to be 0.5 Ω as maximum (see electrician certificate). If it is more than 0.50 Ω at 230 V, refer to qualified electrician to improve line characteristics.

1.5 - CHECK OF MAINS AND EARTH CONNECTIONS, CABLES AND CORRUGATED TUBE

Check the condition of the power cable and its connections, earth cable and its connections, and the corrugated tube.

For damage of power cable contact Manufacturer for spare parts and for dedicated technical note to replace it.

Check the condition of foot pedal switches cables, the functionality of the door contact, if present, and of the external signal lamp, if present. Check the condition of AWS-MAMMO connection.

1.6 - OPERATION OF EMERGENCY BUTTONS

Push one emergency pushbutton when the unit is on, and verify that the unit switches off immediately (it stops movements, etc) and the button remains locked.

Calculator, detector and logic controls remain switched on by means of UPS powering.

Unlock the button and repeat the same procedure with the other emergency buttons.

1.7 - OPERATIONAL CHECK OF ALL BUTTONS

Verify that all the buttons (Manual Rotation Controller and C-arm Movement) work properly.

1.8 - OPERATIONAL CHECK OF AWS DSP

Press Touch screen. If a mouse click comes out moving on touch screen it means that it works properly. AWS LCD: Turn on the LCD, check that the monitor are working.

1.9 - OPERATIONAL CHECK OF MAMMO TSD

Select ACR menu on MAMMO TSD and check correct functioning of touch screen panel. Check if movements are smooth and clear, if not a calibrations will be necessary. Call technical service.

1.10- C-ARM UP/DOWN MOVEMENT TO END OF TRAVEL

The moving system of the arm is controlled by two normal travel end contacts (hardware), MW1 and MW2, which directly act on the motor supply, locking it.

Over-travel contacts check is carried out by manually actuating them when the arm is moving.

WARNING

Please, pay attention to your hands during C-arm movement.

1.11 C-ARM ROTATION: MOVEMENT TO END OF TRAVEL

Verify that the rotation is smooth and noiseless through the entire range.

Verify that in sliding case (collision, manual push, etc.) the device is auto-restoring and does not synchronization.

Verify correct functioning of C-arm rotation:

1. *Move the C-arm in “CC” position*
2. *turn CC and CCW the C-arm.*
3. *Move the C-arm in “Park” position*
4. *Move the compression trolley downside by checking the movement block when micro-switch is crossed*

Verify that the C-Arm rotation is disabled without tables (Potter-Bucky, magnification device or stereotactic biopsy device).

1.12 - C-ARM TILTING MOVEMENT

Verify integrity of mechanical parts, fixation screws, ring gear, worm screw, belt and eventually adjust worm gear clearance.

Verify the correct tilting angle of X-ray tube as follow:

1. *Tilt X-ray tube to different angles (see operator's manual for manual tilting commands)*
2. *Check if X-ray tube angle is correct and matches with set tilt position.*

1.13 - CHAIN-REDUCER-GEARS-C-ARM MECHANICAL SYSTEM

Verify that the wheels do not show any damage or sign of wear.

Verify that the rails do not show any damage or sign of wear or loosened fixation.

Verify that the chain, chain fixation and gear box do not show any damage or sign of wear or loosened fixation.

Verify that the vertical travel is smooth and noiseless.

1.14 - GENERAL CHECK OF THE MECHANICAL STATUS OF THE C-ARM ASSEMBLY

Rotate the arm to all positions verifying that there are no clear symptoms of rigidity loosening of the assembled mechanical parts.

1.15 – MECHANICAL SAFETY DEVICE INTEGRITY AND FUNCTIONALITY TEST

Refer to the same procedure described in the chapter 4.

1.16 - COMPRESSION MOVEMENT, POWER and CALIBRATION

Visual Check of integrity of compression holder, its connection to Mammo unit (double shafts) and the holder identification connector.

Check correct functioning of compression paddle locking.

To check **compression force**:

1. Put the C-Arm in vertical position (CC),
2. rise the shifted compression paddle
3. place on Potter-Bucky a force balance and an appropriately sized object.
4. Check shown value is correct

For the test refer to IEC 601-2-45 (203.8.5.4.102.5 point) Standard:

The following test equipment is required:

- *Appropriately sized objects, one for each X-RAY IMAGE RECEPTOR format, leading to sufficiently realistic force distributions when under compression. E.g., the objects can be sand-filled bags or soft rubber blocks. Their thickness shall be in the range from 20 mm to 50 mm. the objects shall be 100 mm to 120 mm long and wide for the smallest X-RAY IMAGE RECEPTOR format and 120 mm to 150 mm long and wide for larger formats.*

To check decompression force:

1. move compression paddle at about middle run

2. Move up compression paddle by means footswitch control, keeping manually the compression paddle itself
3. Verify the possibility to avoid rising of compression paddle even if motor is moving. After about 4 seconds, motor will be automatically disabled.

To verify compression thickness:

1. Insert 2D/3D Potter
2. Verify that Mammo Unit correctly identify the Potter type
3. Check the compression thickness shown on MAMMO and AWS DSP
4. insert a shifted compression paddle; compress phantom blocks
5. verify that the thickness of the compressed breast shown on the display is correct.

If provided, repeat with magnification Device and its compression paddle

1.17 – MIRROR CHECK

1. Switch ON the unit.
2. See the mirror of collimation device under the X-ray Tube. Its position depends by last operating conditions.

If mirror is out of the field check:

- Correct Movement of Mirror. An audible sound comes out (similar to printer carriage)

If mirror is in the field:

- Open a study
- Select exposure parameters
- Make an exposure
- Check Movement of Mirror. It will be positioned out of the field and an audible sound (similar to printer carriage) comes out.

1.18 - X-RAYS BEAM CENTERING

This procedure is described in Quality Manual

1. Place a lead sheet, a 10 mm PMMA, an image of X-ray field and two spacers with 60 mm high and X-ray ruler
2. Open a local study then insert a random access number
3. Select Rh filter, set Manual Mode, 35 kV and 100 mAs as exposure parameters
4. Select RCC projection
5. Push X-ray button and check the ruler, each point highlighted over the line, towards the outside of patient support, is referred to a 2.5 mm X-ray beam excess

1.19 - kV CALIBRATION

A) CALIBRATION BY SOFTWARE

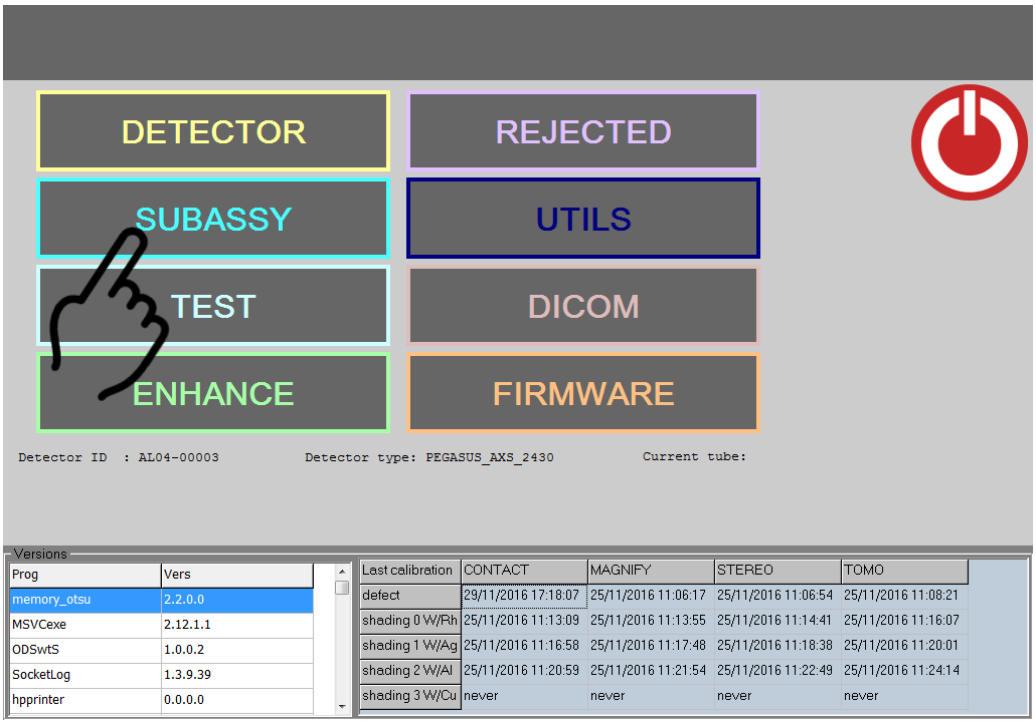
By means of a software procedure installed on the Acquisition Work Station, it is possible to correct the kV values.

NOTE

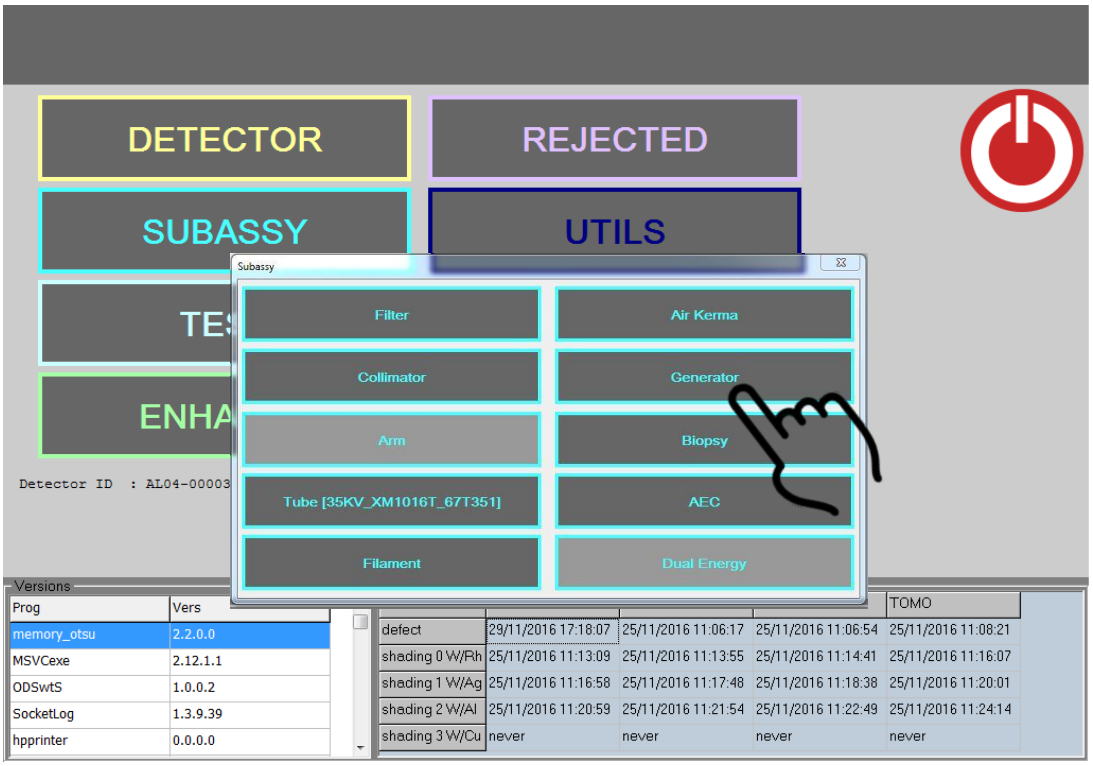
The procedure here below described has to be followed on the field only to fine adjust the kV values which were just been previously calibrated in factory.

To enter the calibration procedure:

1. Run “DMDToolkit” (following the procedure of Section 4., 1.5 “Start Application Software”;
2. Place, if available, a protective shield on the Potter Bucky and place on it a not invasive kV value measuring instrument
3. Select SUBASSY menu from the AWS DSP:

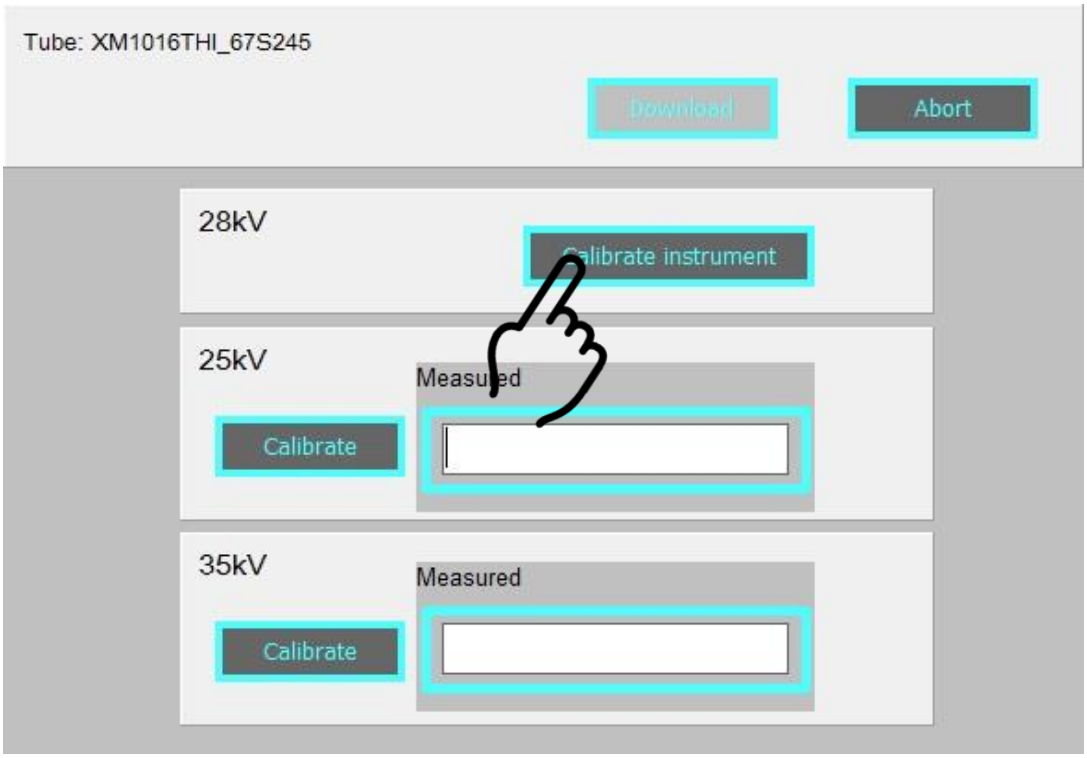


4. Click on “GENERATOR”:

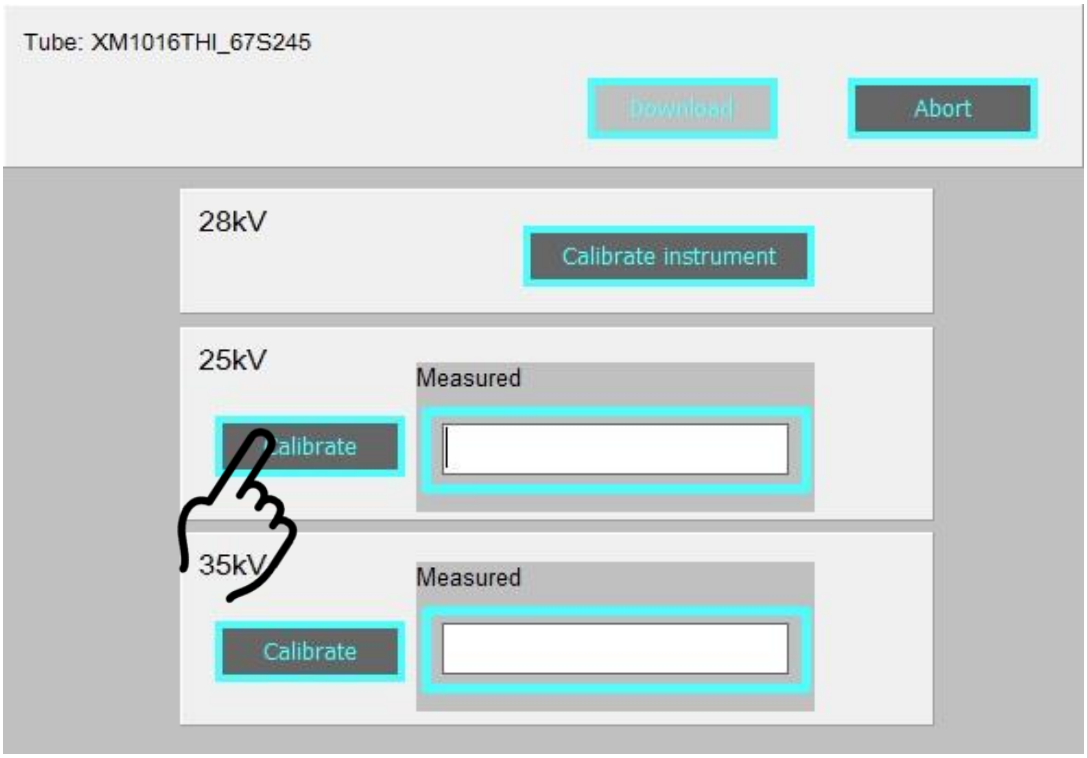


5. The following window will appear:

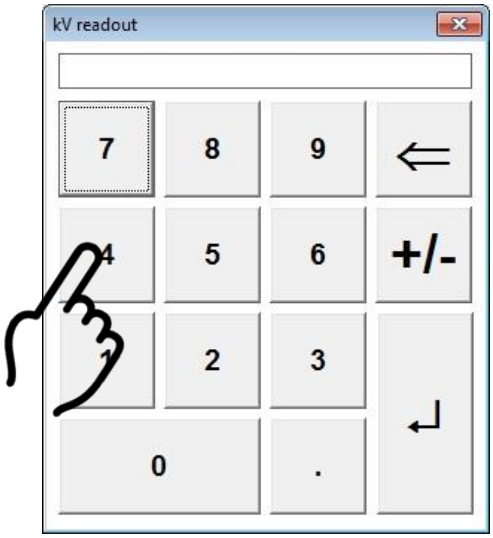
6. Check the correct position of the measuring instrument clicking on “Calibrate instrument”



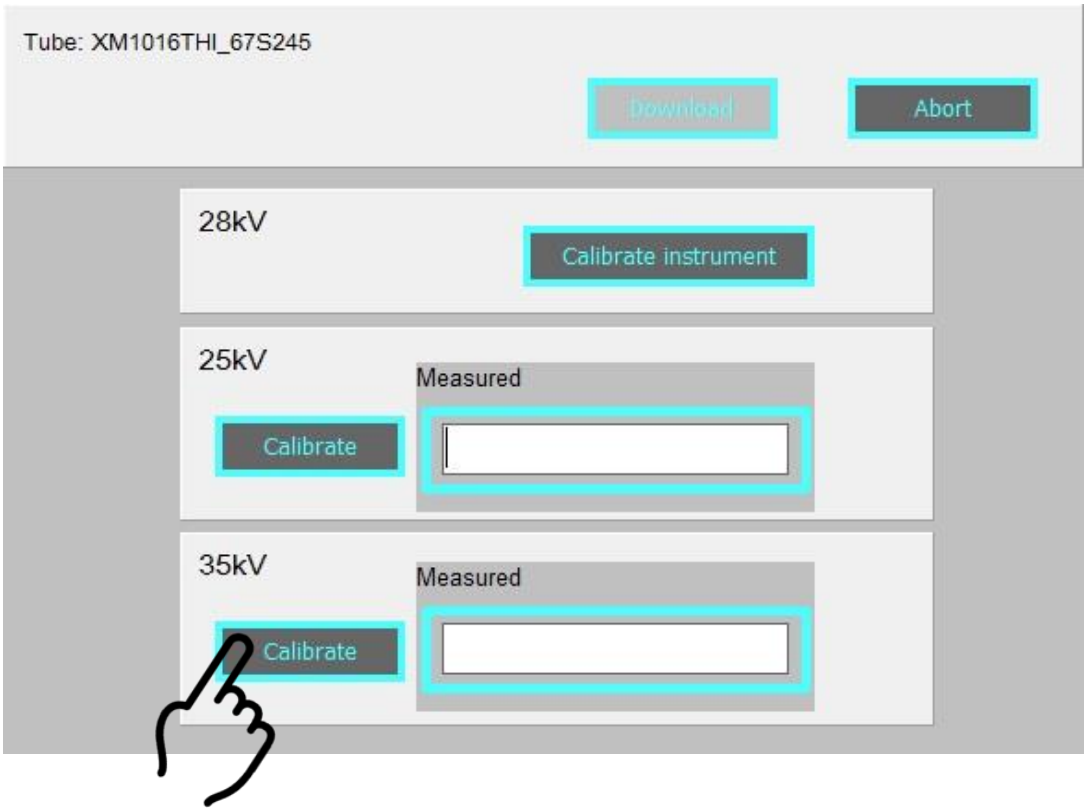
7. When the indication of “Calibration instrument” changes in “Shot”, press the exposure push buttons to start the X-Ray emission
8. If the measuring instrument is properly placed on the Potter Bucky, it will be possible go ahead with the following procedure otherwise it will be necessary adjust the instrument position and repeat the previous steps 6. and 7.until it will be ok.
9. Click on the push button “Calibrate” in the window corrisponding to the value of 25 kV



10. When the indication of “Calibrate” changes in “Shot”, press the exposure push buttons to start the X-Ray emission.
11. Insert manually in the field “Measured” the value return from the measurement instrument:

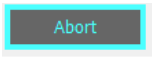


12. Repeat point 9 -> 11 also for the voltage value of 35 kV:



13. At the end, to finalize the procedure, click on “DOWNLOAD” push button in the upper part of the window; in this way, the calibration data will be acquired and saved.

NOTE

In every moment it is possible to exit from the procedure without save it clicking on “ABORT” push button 

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1.20- ANODIC CURRENT CALIBRATION

B) GENERAL INFORMATION

Tube anode current I_a is calibrated, for every value of kV and every focal spot, by means of Filament current I_f.

Increasing filament current, anodic current increases too.

Because of the space charge, to obtain the same value of anodic current, when kV increases filament current must decrease and viceversa.

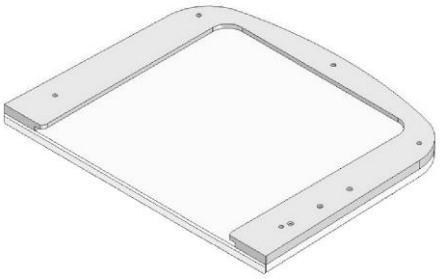
C) CALIBRATION BY SOFTWARE

By means of a software procedure installed on the Acquisition Work Station, it is possible to calibrate the filaments current of all the available tube.

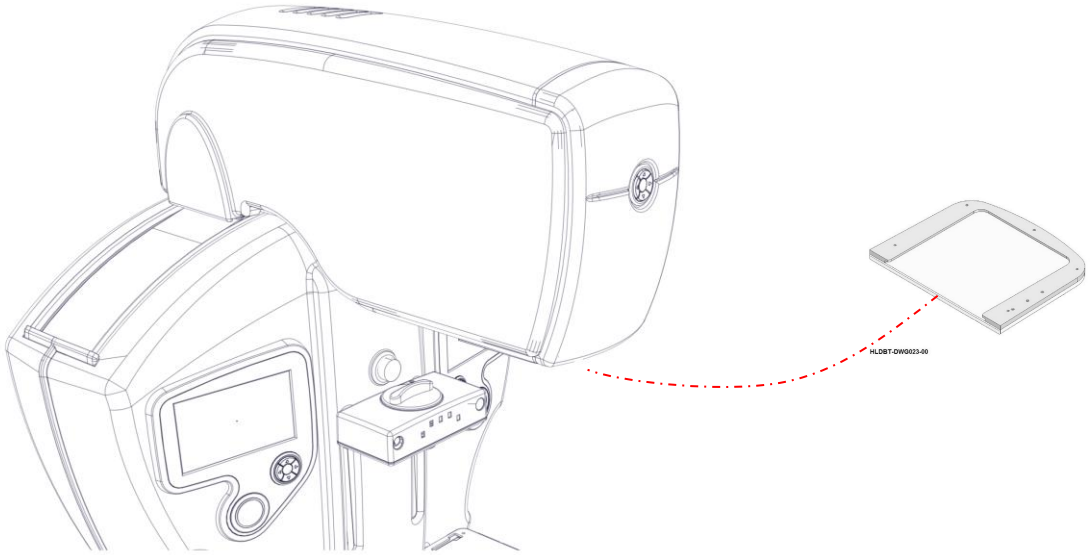
The calibration must be performed for all the available kV as they appears in the specific Target page W.

To enter the calibration procedure:

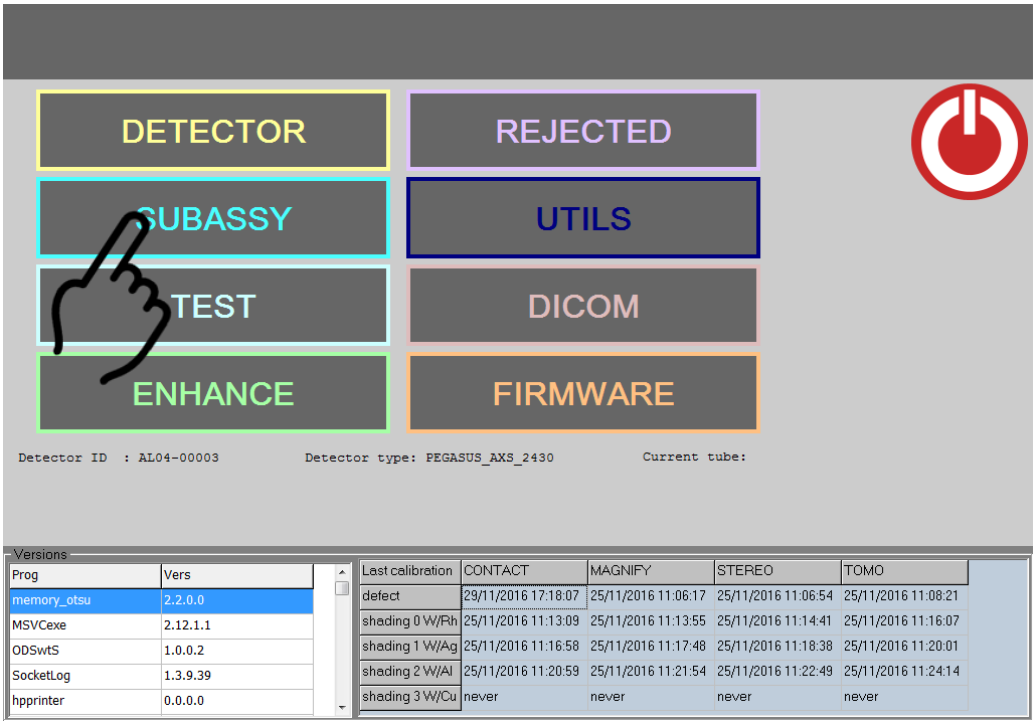
1. Run “DMDToolkit” (following the procedure of Chap. 4.par 1.5 “Start Application Software”);
2. Plug the calibration shield in:



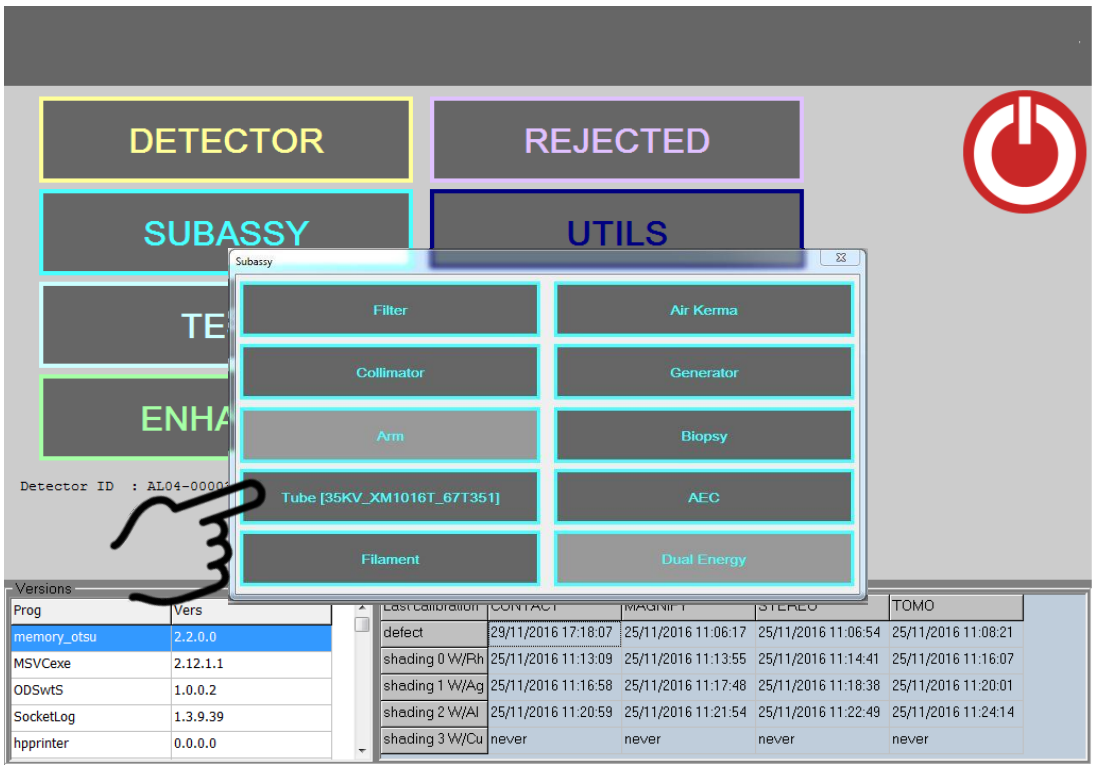
3. Place it as shown in the following picture:



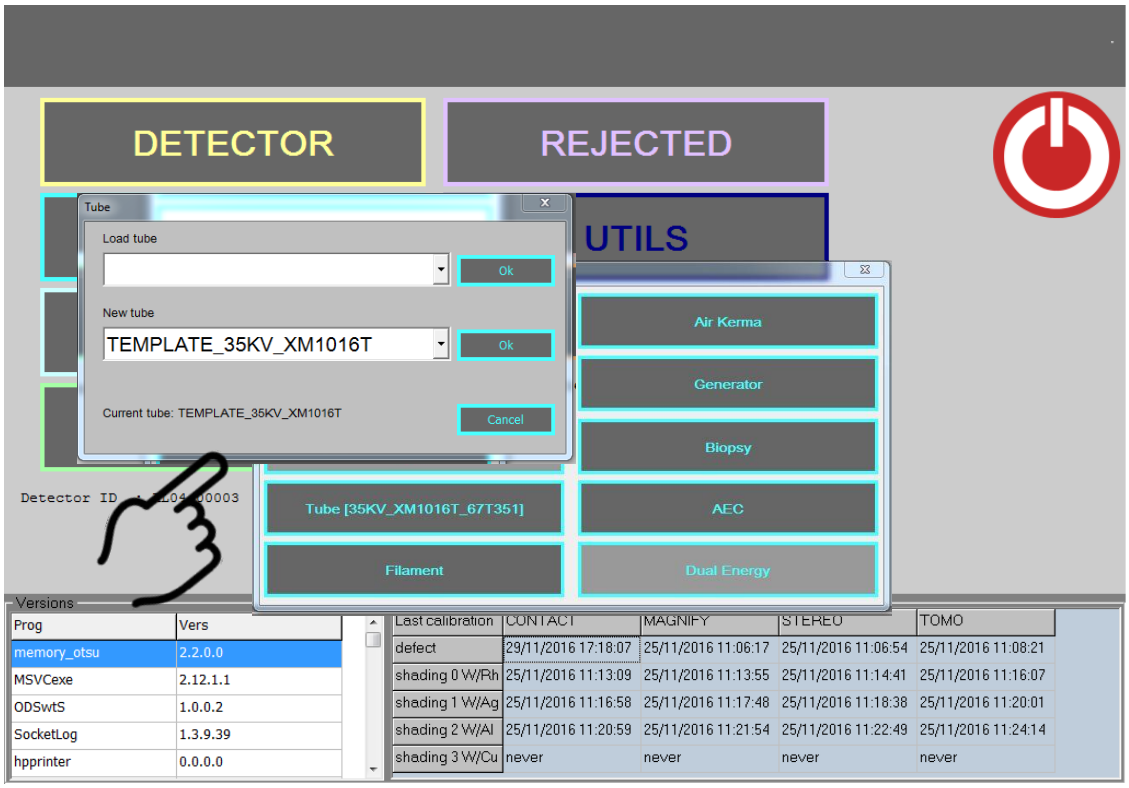
4. Select SUBASSY menu from the AWS DSP:



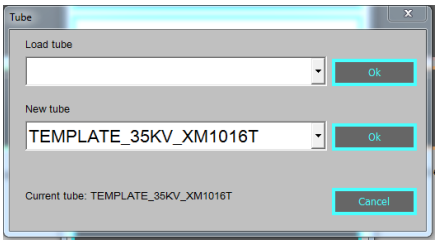
5. Click on “TUBE” or on “FILAMENT” (see from step 7):



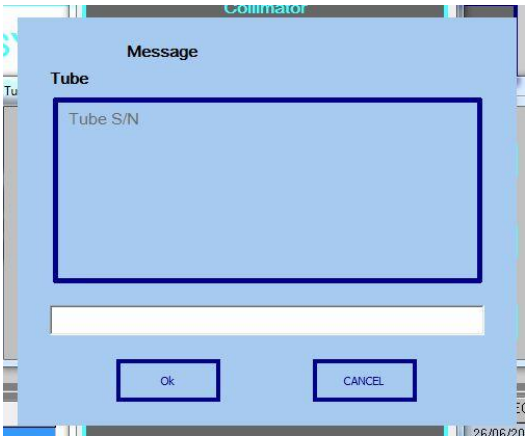
6. The following drop-down menu appears and shows all the calibration data available for the specific unit under examination:



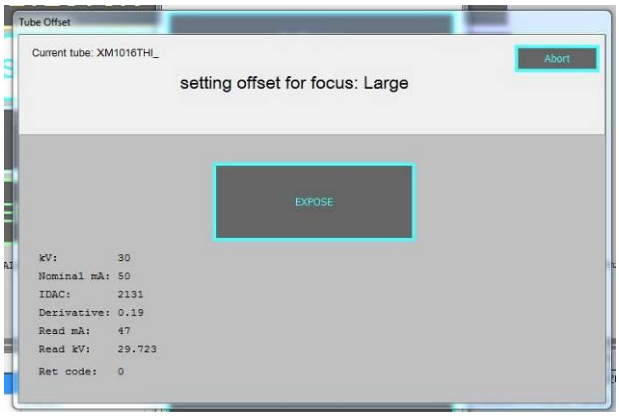
Using the GUI shown below, it is possible loading an existing tube using “LoadTube” or create a new one using “New tube”. As example is reported a TEMPLATE_35KV_XM1016T tube.



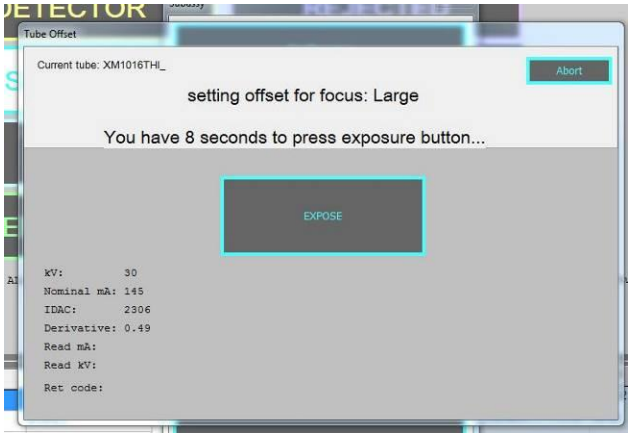
a. Choosing “New Tube” template and clicking “Ok” the following window appears: it permits to insert the S/N of the tube.



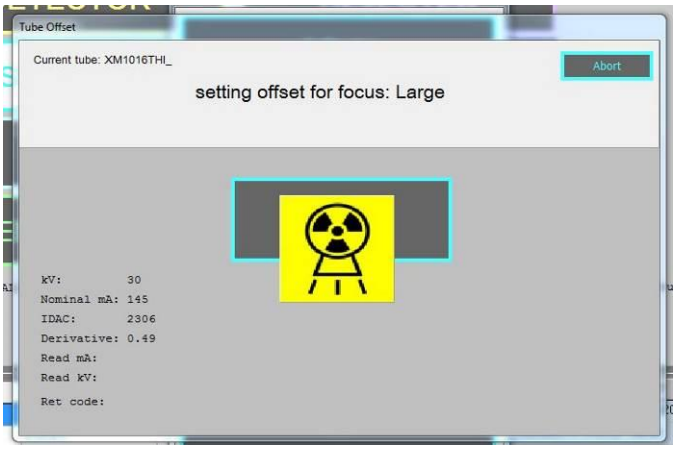
b. Clicking “OK”, the Offset calibration window appears, as shown in the following figure:



c. Press “Expose” in order to start Large focus (LF) offset calibration or “Abort” to end the procedure:

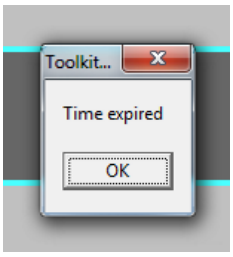


d. Push the X-Ray button for 10 seconds:



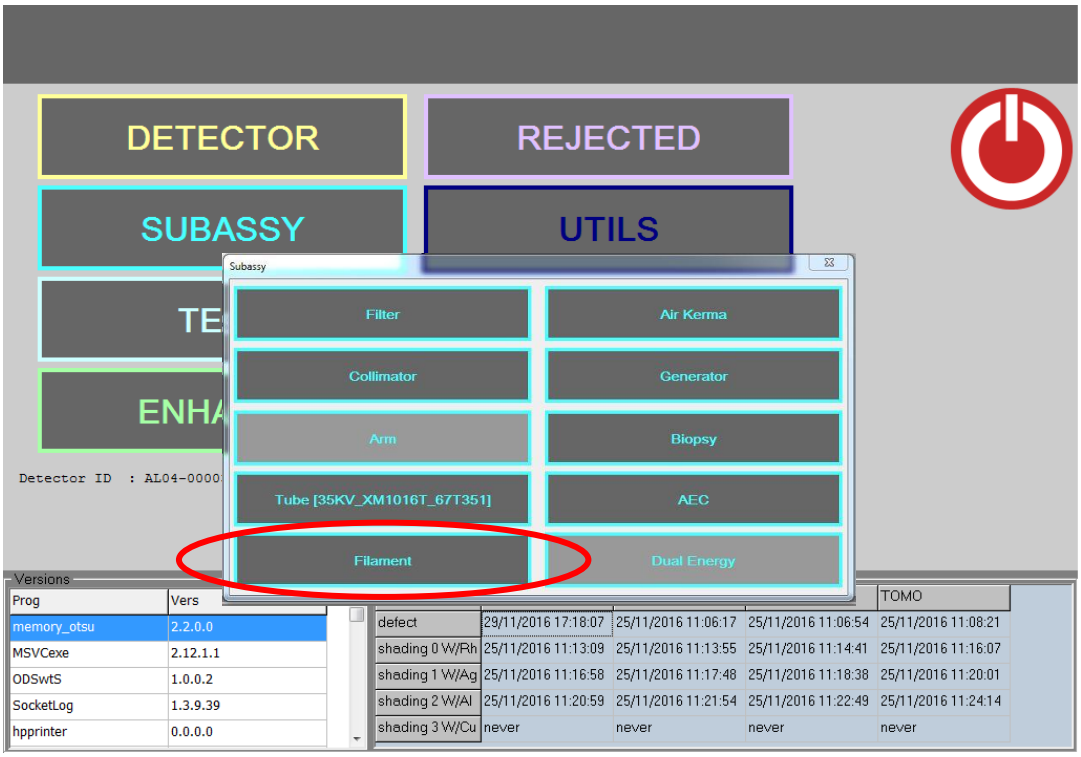
e. Repeat steps from a to d in order to calibrate the Offset for Small focus (SF);

In case of timeout, the following message appears:



NOTE

7. If the procedure is successfully accomplished, the Tube offset window will closed automatically and will open the Filament window as shown in the following figure:



8. Once choose the calibration data file, on the AWS DSP appears the following :

In the upper section it is possible select:

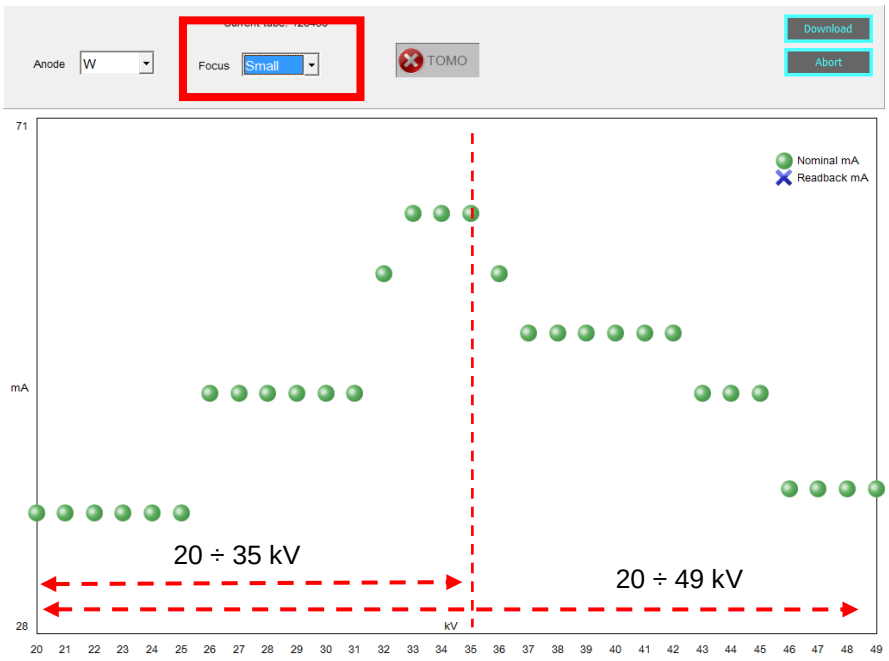
- Anode material (usually only Tungsten);
- Focus (Large or Small);
- Calibration data specific for TOMO exam to modify.

Select anode material (W) and focus (Large).

The reference curve shown in form of nominal mA on kV (up to 49 kV), will be automatically modified by the SW on the base of the selection of the previous values according to H.V. generator embedded.

For example, for a LARGE Focus selected:

For a Small Focus selected:



NOTE

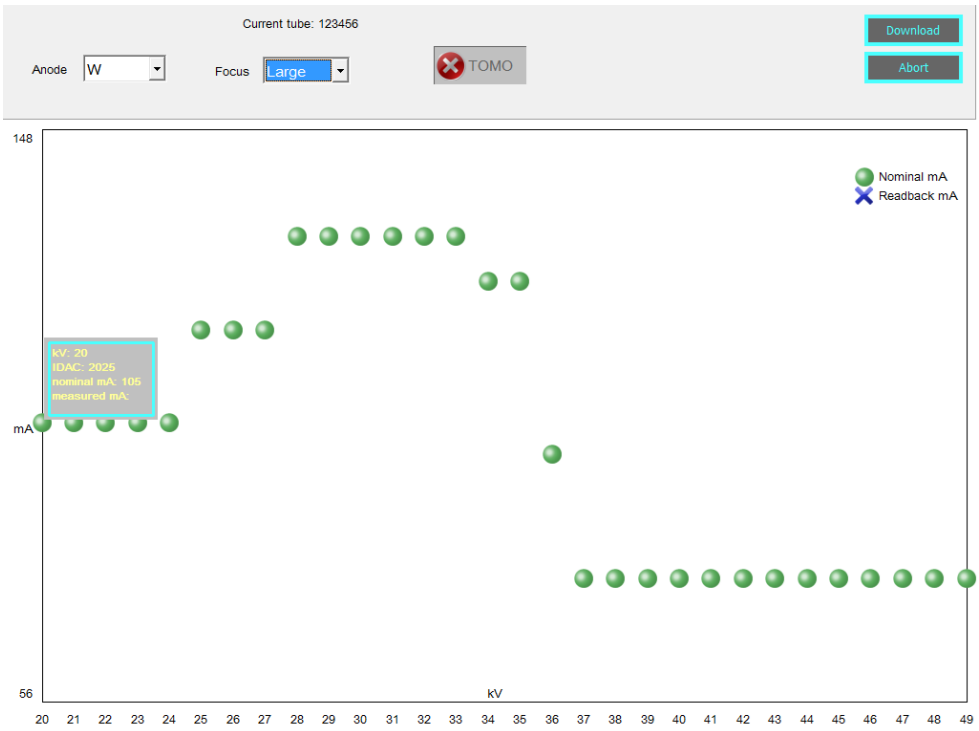
In calibration windows above different anodic default curves are reported according to different generator kV range allowed.

or, finally, for a TOMO calibration enabled (only for TOMO option):

NOTE

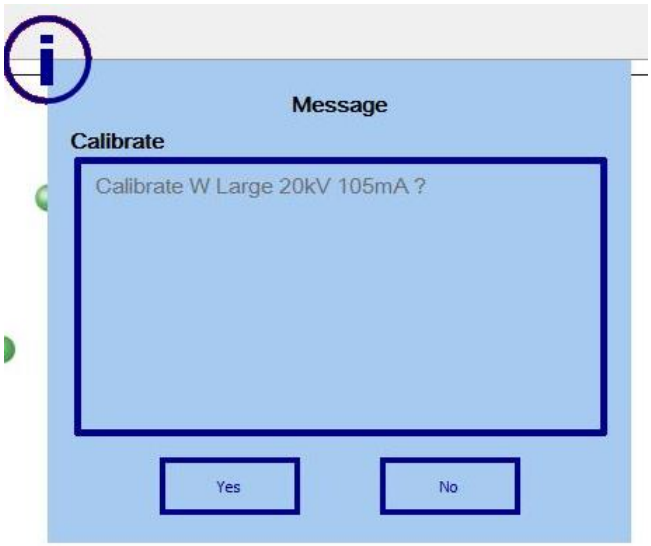
TOMO button for anodic current calibration is disabled for 2D option (20 ÷ 35 kV)

Using the trackball and positioning the cursor in correspondence of nominal mA (the green points on the graph), all the data available for that point will be shown:

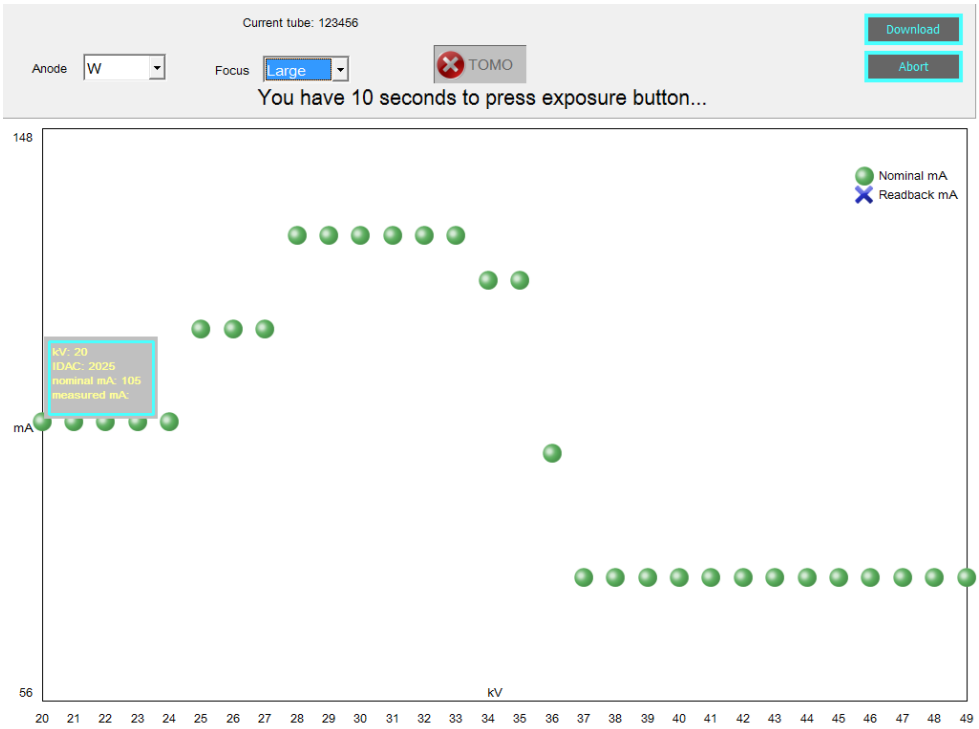


9. Choose one of them to start the calibration (e.g. 20 kV):

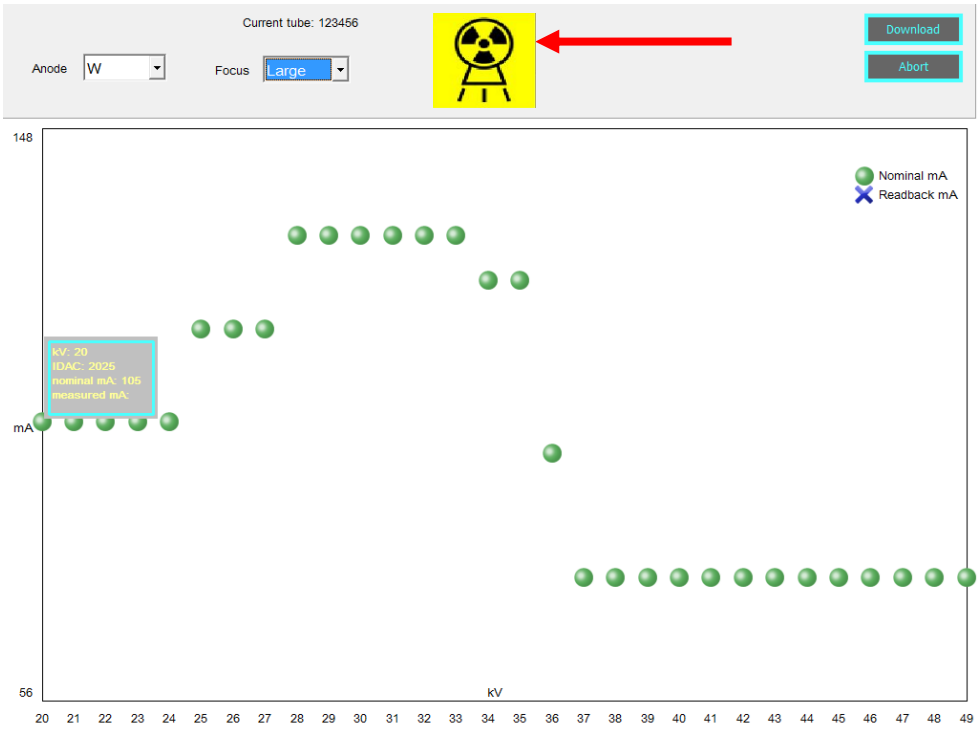
10. Before starting the procedure, the SW automatically asks to confirm the point to calibrate:



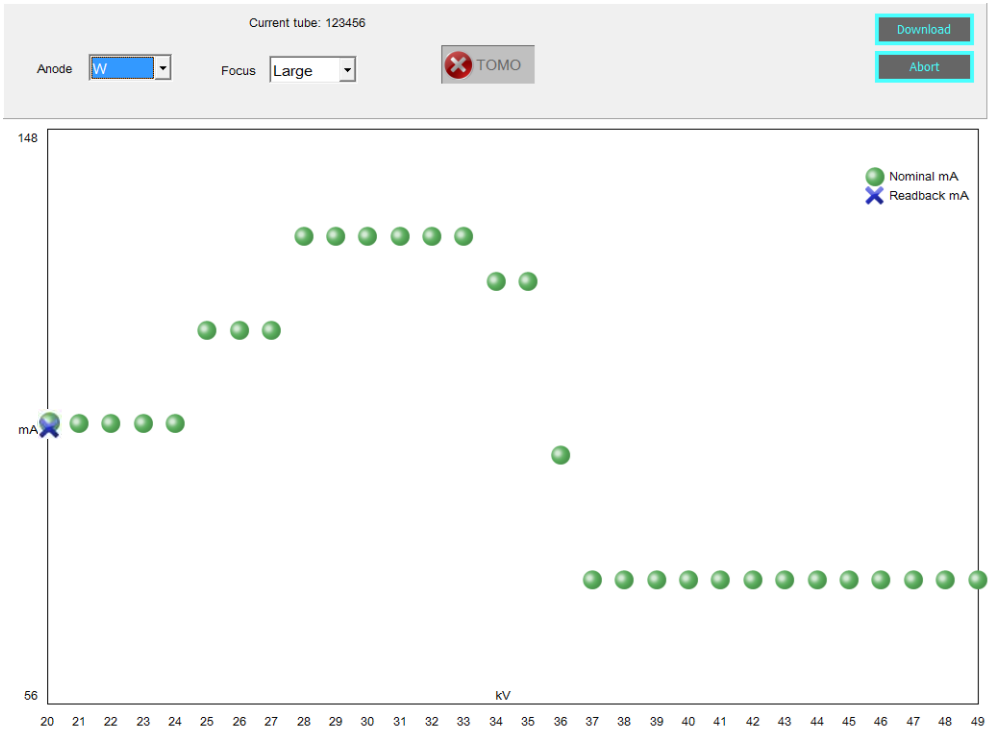
11. Once defined the starting point, press the X-ray push button when indicated in the upper window:



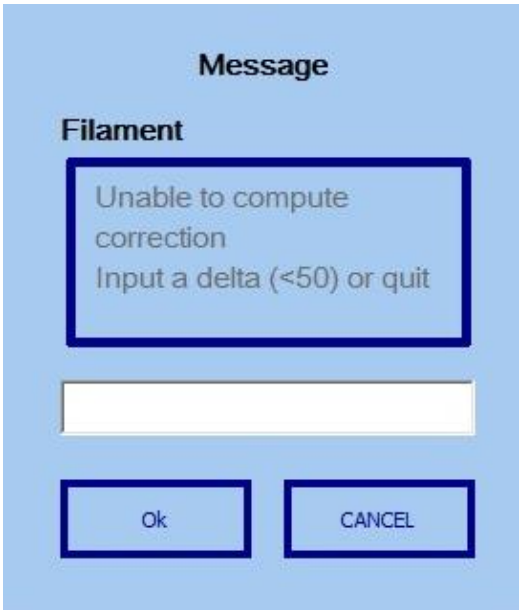
With the push button pressed, the following icon appears on the AWS DSP to indicate the X-Ray emission in progress:



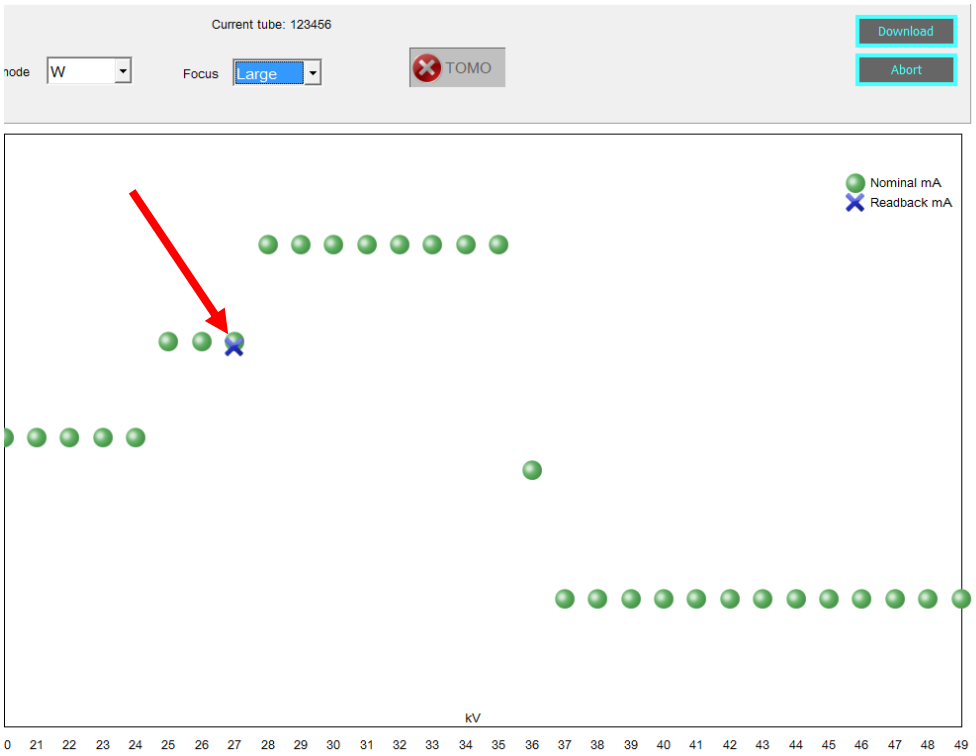
Press the X-ray push button until the green circle appears marked with the symbol “X”: it indicates that anodic current has been calibrated



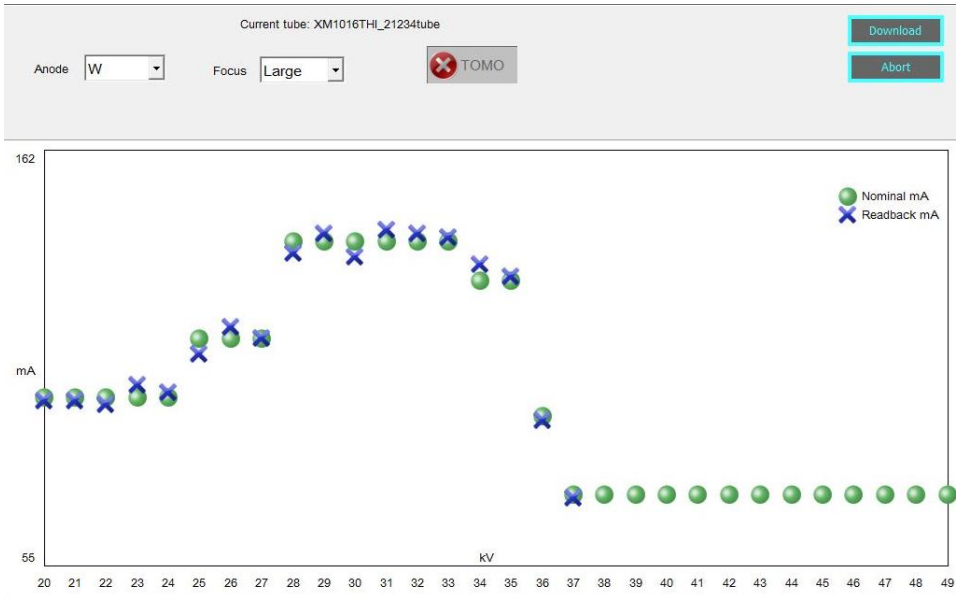
- If, after several times, the automatic correction procedure fails, the following message will be displayed allowing to input a delta value:



12. When the procedure returns an acceptable value, the point measured and accepted will be signed as “Readback mA” and marked with the symbol “X”.



13. Repeat all steps in order to evaluate the kV spectrum of interest

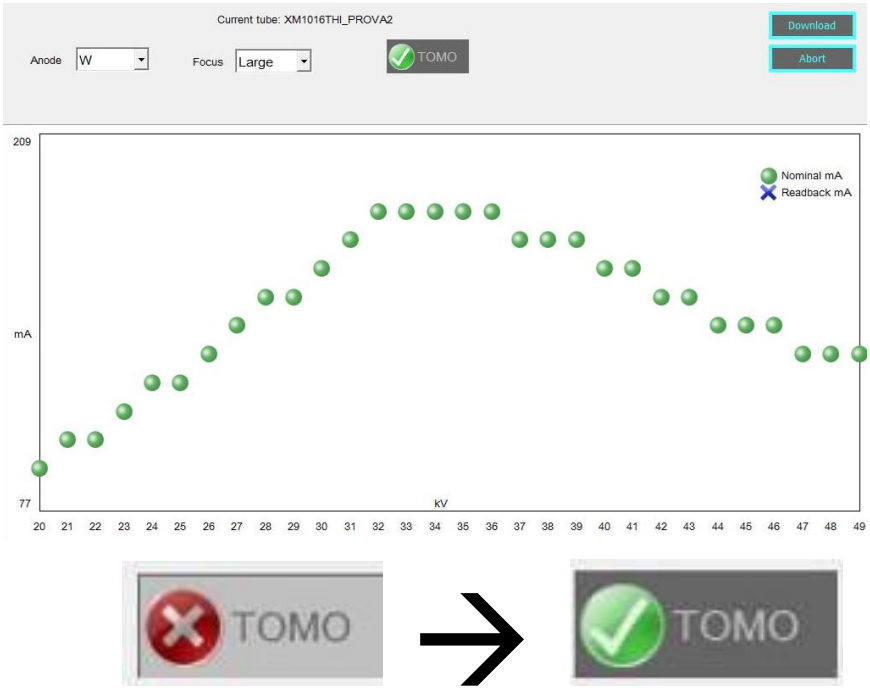


14. To finalize the procedure, click on “DOWNLOAD” push button in the upper part of the window; in this way, the calibration will be acquired and saved for that specific tube selected:

NOTE

In every moment it is possible to exit from the procedure without save it clicking on “ABORT” push button Abort.

15. Repeat the procedure described above for Small Focus (SF) and for Tomo



1.21 - AUTOMATIC Rh/Ag/Al FILTER FUNCTIONALITY

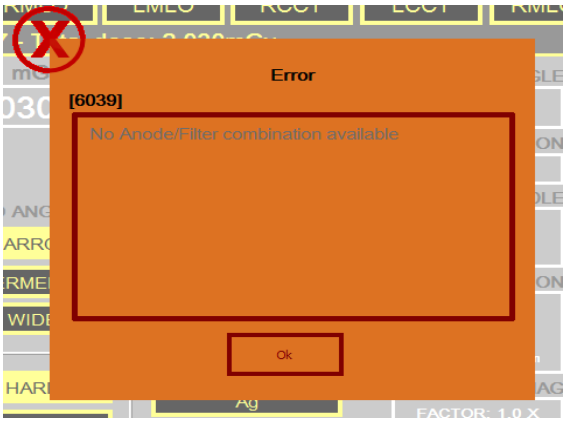
To verify Filter functionality:

1. Open a study
2. In manual mode select Rh or Ag or Al filter from the AWS DSP,
3. Check that you can hear an audible sound when the filter moves.

If you have doubts on filter functionality, you can try to observe if the filter moves looking through the C-Arm X-ray window.

The anode/filter automatic management is set within AEC mode and Auto filter.

If no configuration available can be found automatically, the following error will be shown after pressing X-ray pushbutton. (See chapter 9: Fault finding and Troubleshooting)



1.22 – DETECTOR CALIBRATION

Refer to Chapter 5, Detector calibration

NOTE

At the end of inspection, clean the unit using the materials recommended in the Operator's Manual and repair any damaged paint.

1.23 BATTERIES STATUS

Battery provided with Mammo unit have a defined life.

- UPS Battery /

Disconnect Mammo unit from mains and check mammo status from light inside the TSD cover. UPS battery works also as backup battery for compression release.

Please perform the following check:

1. Open a study;
2. Apply compression using a phantom;
3. Switch OFF the unit;
4. Check for correct maintaining of compression.

NOTE

A minimum amount of loss in compression force is normal.

5. Push the n°2 pushbutton of the rotating controller for fine manual compression: the compression paddle must move-up and release the compression.

If step 4 - 5 fails, UPS battery must be replaced.

Ask to Service for a Spare parts and follow instructions sent with the item.

CODE	DESCRIPTION
PB12V-7Ah	Lead battery VRLA 12V /7 Ah

NOTE

It is recommended to check the battery status and replace it if necessary (see Chap. 9)

CAUTION

This check is suggested every 6 months and recommended every year but it is highly suggested to replace battery every year even if test is OK because of risk of failure related to lead technology.

1.24 C-ARM ANTI-COLLISION SYSTEM

To verify this functionality move C-arm with relative command by TSD.

1. Set a defined rotation angle and click on relative icon;
2. During C-arm movement, touch lateral x-ray tube cover;
3. C-arm immediately stops its travel;
4. Check if a visible warning message is provided on TSD and on AWS (if provided);
5. Repeat steps above testing C-arm movement in opposite direction;

If system does not stop C-arm movement immediately, there is a system failure.

1) In case of one sensor only should show this problem (the other sensors stop the ARM), then the single sensor is damaged, or the cable of that sensor is damaged.

2) In case all the sensors shouldn't work properly, then check the cable connecting the PCB273 board to the sensors, or the cable connecting the PCB273 board to Tilting motor or, in the case of no tilting option, check the connection from the sensors to the Rotation motor IO connector.

2 – PERIODICAL REPLACEMENT

RECOMMENDED EVERY 2 MONTHS

WARNING

Considering the cleaning environmental condition in which the Mammo Unit is placed, the frequency of filter replacement may be increased.

Fill this form and send it back to to validate warranty.

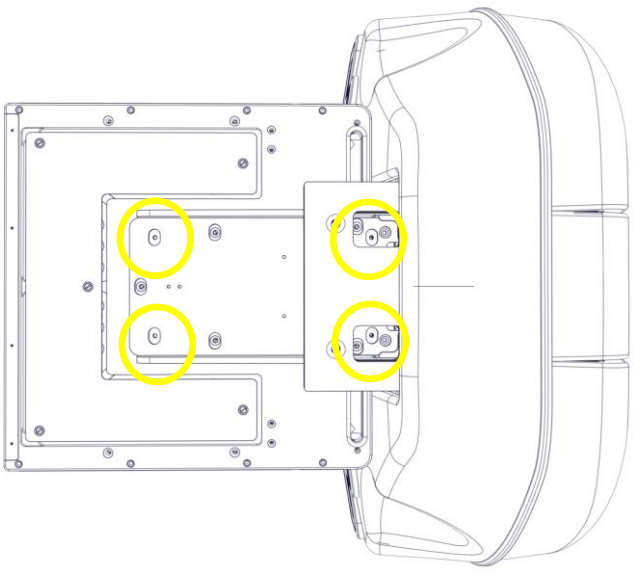
HELIANTHUS Series Model_____S/n_____
INSTALLATION PLACE _____
INSTALLATION DATE _____
INSTALLATOR SIGNATURE _____
RESPONSIBLE PERSON _____

2.1 Detector filter Check [ ]

2.1 – FILTER REPLACEMENT

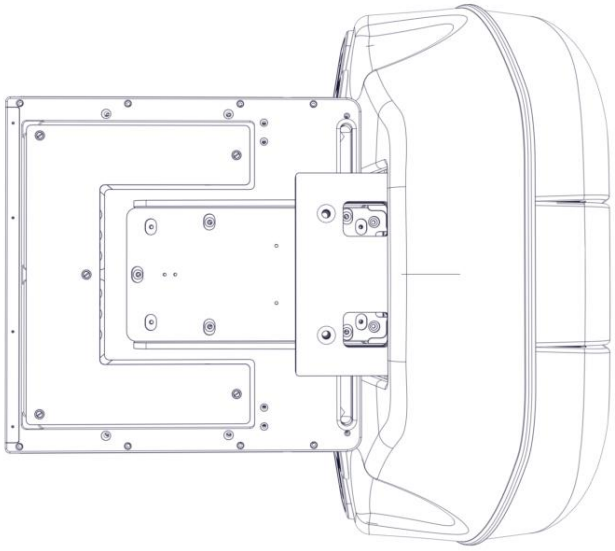
WARNING

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

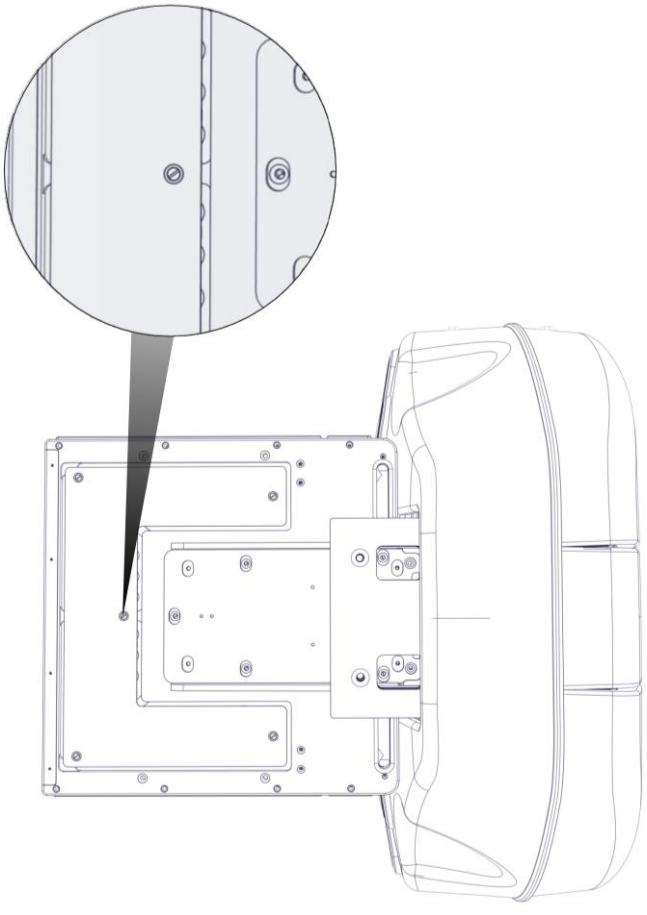


CAUTION Before to proceed with filter substitutions, switch off mammogragh!

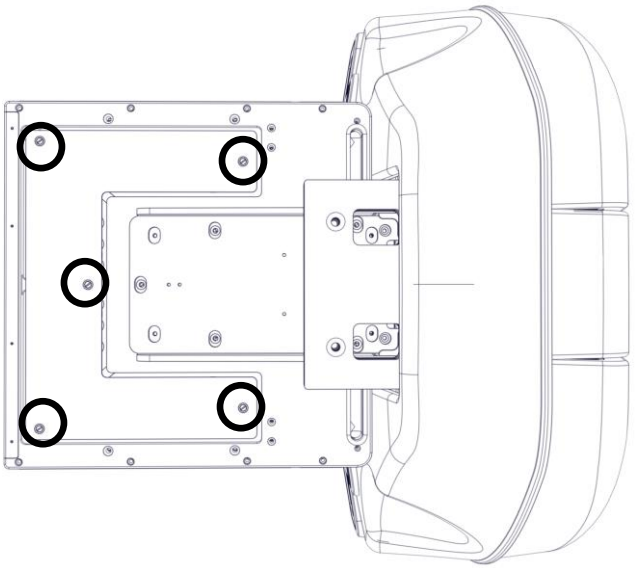
1) **<u>Turn C-arm in Caudo Cranial position and switch off the unit</u>**



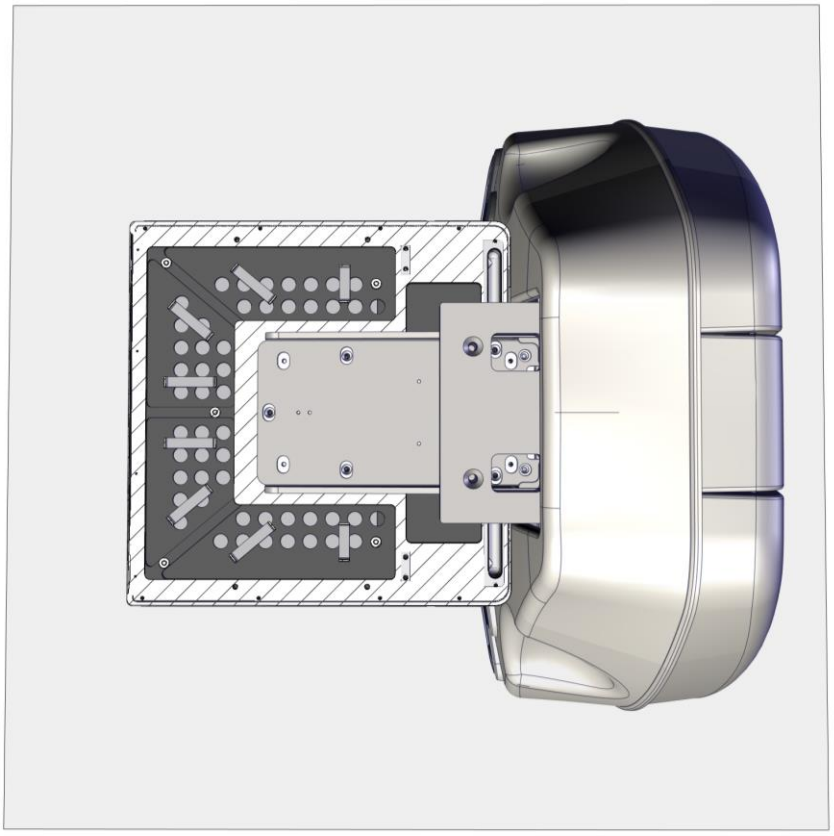
2) **Remove n°5 screws**



3) Remove screws



4) Check filter status, remove and clean filter (If necessary, replace with news one).



3 – AIR KERMA CALIBRATION

SUGGESTED EVERY 12 MONTHS

HELIANTHUS Series Model_____S/N_____
INSTALLATION PLACE _____
INSTALLATION DATE _____
INSTALLATOR SIGNATURE _____
RESPONSIBLE PERSON _____
Measuring device Type _____ S /N _____ Date __ /__/____

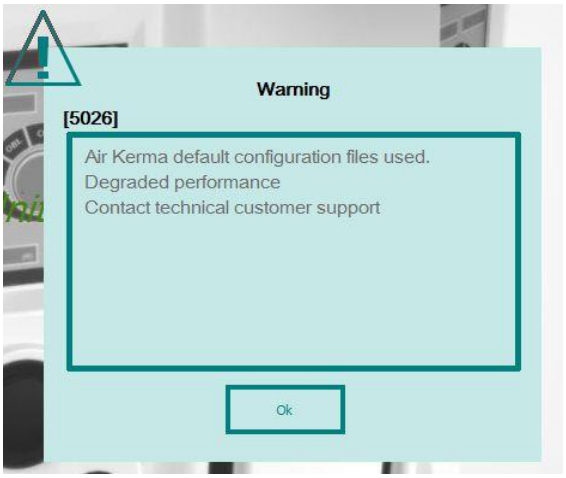
3 AIR KERMA CALIBRATION [ ]
- X-ray tube replacement [ ]
- X-ray tube ageing / unit check [ ]

Air Kerma calibration consists on a specific procedure recommended for:

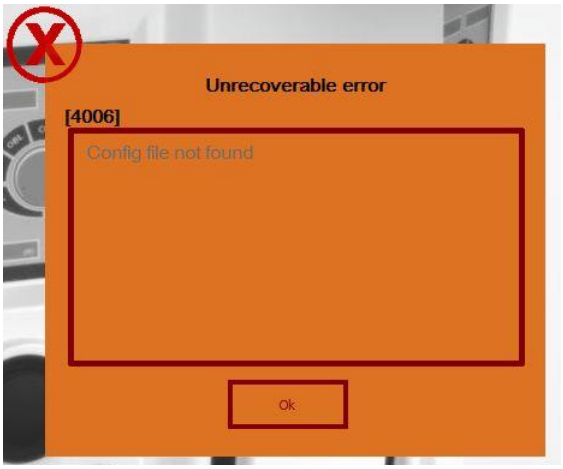
1. X-ray Tube replacement,
2. X-ray Tube ageing,

Periodical check is suggested every years of standard use.
Please contact Customer technical service to perform the Air Kerma calibration. Refer to the detailed technical note (TN-084) for check and calibration procedures.

The mammographic unit has Air Kerma default files and configuration files already stored for each Anode/filter combination. If one of configuration file are missing device will use default files for AGD evaluation forward a specific warning message:



If one of these default files is missing the mammo unit will signaling a defined error:



If the unit shows the error [4006] or warning [5026] in operative, the maintenance is requested.

4 - *LIST OF TRANSFORMERS*

TRANSFORMERS PROTECTION ACCORDING TO STANDARD CEI 62-5 IEC60601-1

WARNING modifying fuse type and/or value may create risks of fire!

MAMMO UNIT

TF 155
TF 165

Protected by thermo-switch that acts on mains breaker turning off the device and avoiding self power-on at the thermo-switch restoration.

5 - *LIST OF FUSES*

In case of necessity of fuse replacement, refer to the following list:

FUSES AND FUSE HOLDERS

	Technical Data	Note	Fuse Holders
F1	gG 20 A,10 x 38	In case of power input: 230 V a.c.	10x38
	gG 40 A, 14 x 51	In case of power input: 115 V a.c.	14x51
F2	gG 20 A, 10 x 38	In case of power input: 230 V a.c.	10x38
	gG 40 A, 14 x 51	In case of power input: 115 V a.c.	14x51
F3	T 3.15 A, 6,3 x 32	In case of power input: 230 V a.c.	6x32
	T 6. 3 A, 6,3 x 32	In case of power input: 115 V a.c.	6x32
F4	T 3.15 A, 6,3 x 32	--	6x32
F5	T 500 mA, 6,3 x 32	--	6x32
F6	gG 10 A, 10 x 38	--	10x38
F9	gG 10 A, 10 x 38	--	10x38
F10	T 10 A, 6,3 x 32	--	6x32
F11	T 4 A, 6 x 32	--	6x32
F13	gG 10 A, 10,3 x 38	--	10x38
F14	T10 A	--	6x32
F15	T10 A	--	6x32
F16	T10 A	--	6x32
F17	T 5 A	--	6x32
F18	T 5 A	--	6x32
FB3 (F19)	T 10 A	--	6X32
F20	T 0.2 A, 6 x 30	--	6x32
FB1 (F21)	T 25 A	--	6x32
FB2 (F21)	T 25 A	--	6x32

PCB/14-240-x

	Technical Data	Note
F1	T1 A	LITTLEFUSE P/N 0154001.DRT

PCB/05-190-x

	Technical Data	Note
F1	T5 A	LITTLEFUSE P/N 0154005.DRT
F2	T5 A	LITTLEFUSE P/N 0154005.DRT
F3	T1 A	LITTLEFUSE P/N 0154001.DRT
F4	T1 A	LITTLEFUSE P/N 0154001.DRT

INVERTER MODULE

	Technical Data	Note
FUSE	BUSSMANN, BS 88 ET, ET040, 40 A 690 V	Pz 1

ACQUISITION WORK STATION

	Technical Data	Note	Fuse Holders
F1	T 10 A	For AWS 24 Vdc	6x32

CAUTION

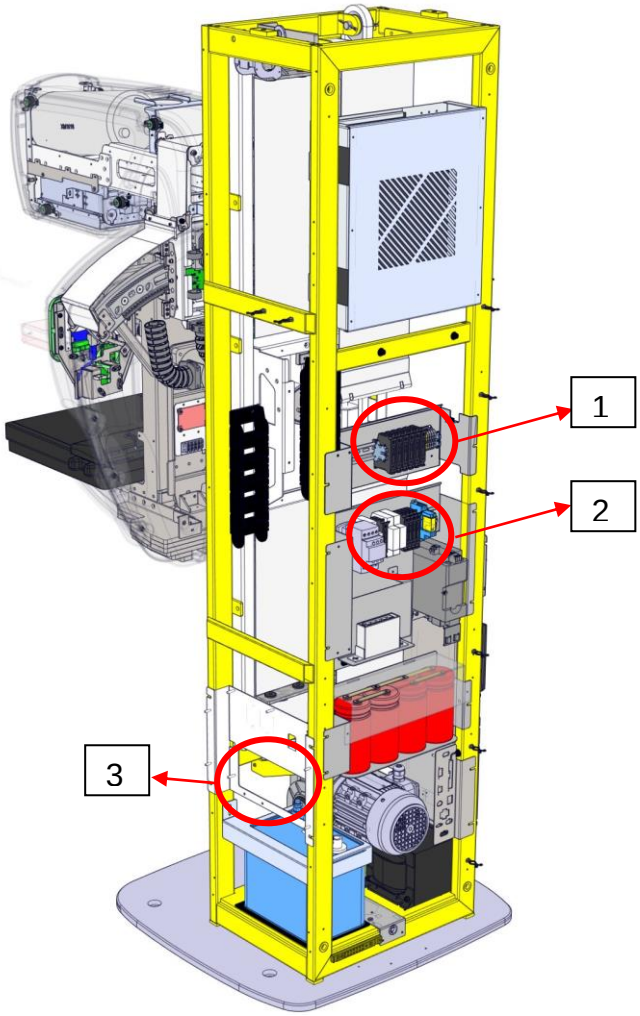
Most of the fuses in this list belongs to “list of critical safety components”. Please, in case of replacement of fuses, contact Metaltronica S.p.A and refer to the spare part list for the correct models.

NOTE

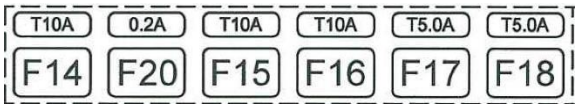
In case of replacement of Acquisition Work Station fuses, refer to the previous paragraph “Acquisition Work Station parts replacement” in order to open the back side cover and access to the components.

FUSES POSITION

Mammo unit rear view

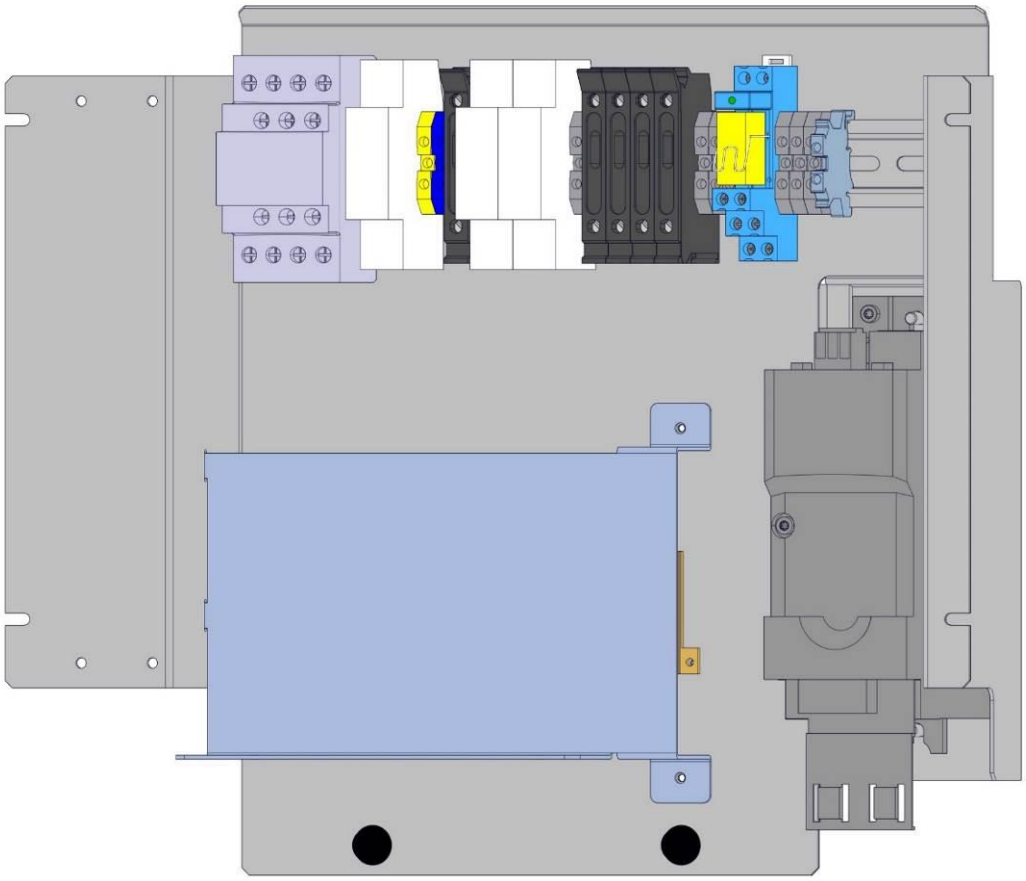


1. Fuses are the black elements in the figure below (the table indicates the identification number of each fuse):



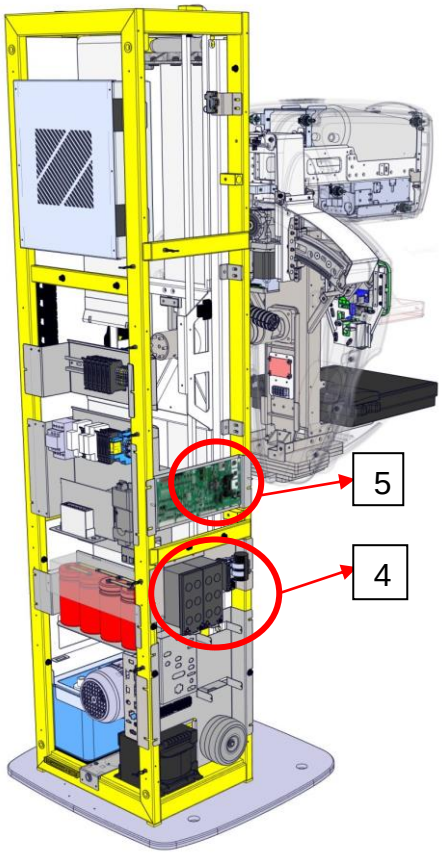
2. Fuses are the white and the black elements in the figure below (the table indicates the identification number of each fuse):

20A	T3.15A	10A	10A	T4.0A	T10A	T500mA	T3.15A
F1	F3	F6	F9	F11	F10	F5	F4

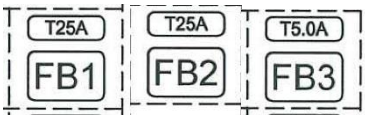


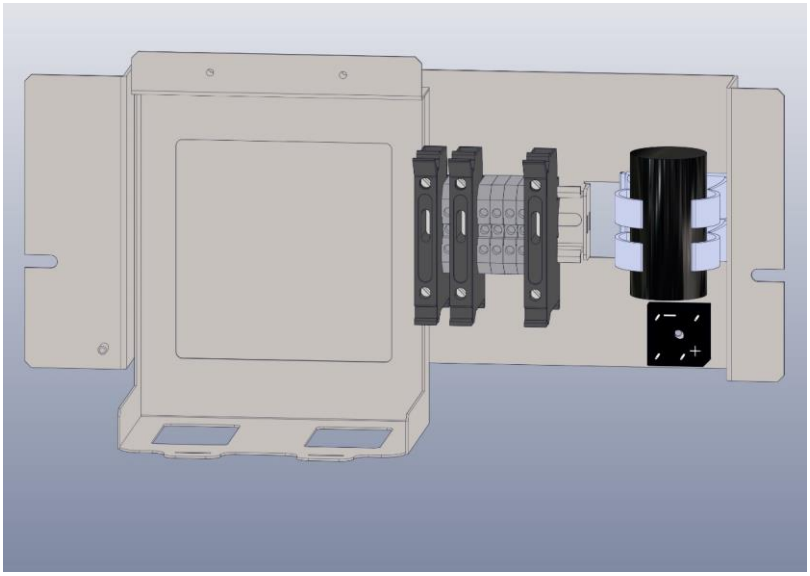
3. In this position there are Inverter Module fuse and PCB/05-190 fuses

Mammo unit rear view



4. Fuses are the three rectangular black elements in the figure below (the table indicates the identification number of each fuse):





5. F1 of PCB/14-240

AWS internal view

6. Fuse is the black element in the figure below (the table indicates the identification number of the fuse)