Reference	Section – Paragraph	Actions	Date
MTHELIDMD-U04 chap1 TECHNICAL SPECIFICATIONS	X-RAY TUBE I.A.E. XM1016 T	Updated nominal values and tolerances of standard X-ray tube characteristics (green parts).	21-07-2023

~~OPTIONAL~~ X-RAY TUBE (STANDARD)	I.A.E. XM1016 T
Anode rotation speed	3000 rpm (optionally 10000 rpm)
Target material	Tungsten Focal track: RT (Tungsten+Rhenium) Bulk: TZM (Molibdenum+Titanium+Zirconium)
Anode Heat Storage Capacity	300 kHU (225 kJ)
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	500 kHU (375 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	108 HU/s (80 W)
Cooling method	Free air convection
Anode Disc Target Angle	10° (Small focus)/16° (Large focus)
Anode Disc Diameter	80 mm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	2400 W (Small)/9600 W (Large) (10000 rpm)
Nominal X-Ray Tube Voltage and Highest X-Ray Tube Current available at that voltage (IEC 60601-2-45: 201.7.9.2.1.a)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA **Tomosynthesis mode:** Large focus: 49kV; 140mA
Highest X-Ray Tube Current and Highest X-Ray Tube Voltage available at that current (IEC 60601-2-45: 201.7.9.2.1.b)	~~**2D mode:**~~ ~~Large Focus: 35kV; 135mA~~ ~~Small Focus: 35Kv;65mA~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 35kV; 200mA~~ **2D mode:** Large Focus: 32kV; 145mA Small Focus: 35Kv;65mA **Tomosynthesis mode:** Large Focus: 36kV; 190mA
Corresponding combination of X-Ray Tube Voltage and X-Ray Tube Current which results in Highest Electric Output Power (IEC 60601-2-45:201.7.9.2.1.c)	~~**2D mode:**~~ ~~Large Focus: 35kV*135mA= 4725W~~ ~~Small Focus: 42kV*55mA= 2310W~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 35kV*200mA= 7000W~~ **2D mode:** Large Focus: 32kV*145mA= 4640W

	Small Focus: 42kV*55mA= 2310W **Tomosynthesis mode:** Large Focus: 39kV*180mA= 7020W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	~~**2D mode:**~~ ~~Large Focus: 30kV*135mA= 4050W~~ ~~Small Focus: 30kV*50mA= 1500W~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 30kV*170mA=5100W~~ **2D mode:** Large Focus: 30kV*145mA= 4350W Small Focus: 30kV*50mA= 1500W **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	~~**2D mode:**~~ ~~Large Focus: 30kV*135mA= 4050W~~ ~~Loading time: 4.74"~~ ~~Small focus 30kV*50mA= 1500W~~ ~~Loading time: 4.40"~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 30kV*170mA=5100~~ **2D mode:** Large Focus: 30kV*145mA= 4350W Loading time: 4.74" Small focus 30kV*50mA= 1500W Loading time: 4.40" **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100 W
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode
For Mammographic X-Ray Equipment provided with automatic Exposure Control controlling Loading Time, shortest Loading Time and/or the lowest resulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8mAs (using 20mm PMMA phantom)
Range of X-Ray Tube Voltage when X-Ray Tube Voltage is controlled by AEC (IEC 60601-2-45: 201.7.9.2.1.i)	20-49 kV
X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>0.5 mm Al

Reference	Section – Paragraph	Actions	Date
MTHELIDMD-U04 chap1 TECHNICAL SPECIFICATIONS	X-RAY TUBE I.A.E. XK1016 T	Updated nominal values and tolerances of X-ray tube characteristics (green parts).	21-07-2023

~~STANDARD~~ X-RAY TUBE (OPTIONAL)	I.A.E. XK1016 T
Anode rotation speed	3000 rpm (optionally 10000 rpm)
Target material	Tungsten Focal track: RT (Tungsten+Rhenium) Bulk: TZM (Molibdenum+Titanium+Zirconium)
Anode Heat Storage Capacity	300 kHU (225 kJ)
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	500 kHU (375 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	108 HU/s (80 W)
Cooling method	FORCED air convection
Anode Disc Target Angle	10° (Small focus)/16° (Large focus)
Anode Disc Diameter	80 mm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	2400 W (Small)/9600 W (Large) (10000 rpm)
Nominal X-Ray Tube Voltage and Highest X-Ray Tube Current available at that voltage (IEC 60601-2-45: 201.7.9.2.1.a)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA **Tomosynthesis mode:** Large focus: 49kV; 140mA
Highest X-Ray Tube Current and Highest X-Ray Tube Voltage available at that current (IEC 60601-2-45: 201.7.9.2.1.b)	~~**2D mode:**~~ ~~Large Focus: 35kV; 135mA~~ ~~Small Focus: 35Kv;65mA~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 35kV; 200mA~~ **2D mode:** Large Focus: 32kV; 145mA Small Focus: 35Kv;65mA **Tomosynthesis mode:** Large Focus: 36kV; 190mA
Corresponding combination of X-Ray Tube Voltage and X-Ray Tube Current which results in Highest Electric Output Power (IEC 60601-2-45:201.7.9.2.1.c)	~~**2D mode:**~~ ~~Large Focus: 35kV*135mA= 4725W~~ ~~Small Focus: 42kV*55mA= 2310W~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 35kV*200mA= 7000W~~ **2D mode:** Large Focus: 32kV*145mA= 4640W Small Focus: 42kV*55mA= 2310W

	Tomosynthesis mode: Large Focus: 39kV*180mA= 7020W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	~~**2D mode:**~~ ~~Large Focus: 30kV*135mA= 4050W~~ ~~Small Focus: 30kV*50mA= 1500W~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 30kV*170mA=5100W~~ **2D mode:** Large Focus: 30kV*145mA= 4350W Small Focus: 30kV*50mA= 1500W **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100W
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	~~**2D mode:**~~ ~~Large Focus: 30kV*135mA= 4050W~~ ~~Loading time: 4.74"~~ ~~Small focus 30kV*50mA= 1500W~~ ~~Loading time: 4.40"~~ ~~**Tomosynthesis mode:**~~ ~~Large Focus: 30kV*170mA=5100~~ **2D mode:** Large Focus: 30kV*145mA= 4350W Loading time: 4.74" Small focus 30kV*50mA= 1500W Loading time: 4.40" **Tomosynthesis mode:** Large Focus: 30kV*170mA=5100 W
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode
For Mammographic X-Ray Equipment provided with automatic Exposure Control controlling Loading Time, shortest Loading Time and/or the lowest resulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8mAs (using 20mm PMMA phantom)
Range of X-Ray Tube Voltage when X-Ray Tube Voltage is controlled by AEC (IEC 60601-2-45: 201.7.9.2.1.i)	20-49 kV
X-Ray Window	0,5 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>0.5 mm Al

Reference	Section – Paragraph	Actions	Date
MTHELIDMD-U04 chap1 TECHNICAL SPECIFICATIONS	X-RAY TUBE VAREX M113T	Updated nominal values and tolerances of X-ray tube characteristics (green parts).	21-07-2023

~~OPTIONAL~~ X-RAY TUBE (OPTIONAL - ONLY FOR 2D models)	**VAREX M113T**
Anode rotation speed	3000 rpm 50 Hz
Target material	Tungsten Focal track: W-Re-Mo
Anode Heat Storage Capacity	300 kHU (225 kJ)
Maximum Anode Heat Dissipation Rate	60 kHU/min (750 W)
X-Ray Tube Assembly Heat Storage Capacity	500 kHU (376 kJ)
X-Ray Tube Assembly Heat Dissipation Rate	135 HU/s (100 W)
Cooling method	Free air convection
Anode Disc Target Angle	10° (Small focus)/16° (Large focus)
Anode Disc Diameter	77 mm
Focal spots	2
Focal spot size according to IEC 336, EN60336	0,1x0,1 mm (Small)/0,3x0,3 mm (Large)
Power (Nominal Anode Input Power)	1400 W (Small)/5900 W (Large) (3000 rpm)
Nominal X-Ray Tube Voltage and Highest X-Ray Tube Current available at that voltage (IEC 60601-2-45: 201.7.9.2.1.a)	**2D mode:** Large Focus: 49kV; 80mA Small Focus: 49kV; 42mA
Highest X-Ray Tube Current and Highest X-Ray Tube Voltage available at that current (IEC 60601-2-45: 201.7.9.2.1.b)	~~**2D mode:**~~ ~~Large Focus: 35kV; 135mA~~ ~~Small Focus: 35Kv;65mA~~ **2D mode:** Large Focus: 32kV; 145mA Small Focus: 35Kv;65mA
Corresponding combination of X-Ray Tube Voltage and X-Ray Tube Current which results in Highest Electric Output Power (IEC 60601-2-45:201.7.9.2.1.c)	~~**2D mode:**~~ ~~Large Focus: 35kV*135mA= 4725W~~ ~~Small Focus: 42kV*55mA= 2310W~~ **2D mode:** Large Focus: 32kV*145mA= 4640W Small Focus: 42kV*55mA= 2310W
Nominal electric power given as the highest constant electric output power in kilowatts which the X-Ray Generator can deliver at an X-Ray Tube Voltage of 30 kV, for a Loading Time of 1 s, a Cycle Time of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-Ray Tube Voltage nearest to 30 kV, for a Loading Time nearest to	~~**2D mode:**~~ ~~Large Focus: 30kV*135mA= 4050W~~ ~~Small Focus: 30kV*50mA= 1500W~~ **2D mode:** Large Focus: 30kV*145mA= 4350W Small Focus: 30kV*50mA= 1500W

but not less than 1 s and a Cycle Time of 1,0 minute and for an indefinite number of cycles (IEC 60601-2-45: 201.7.9.2.1.d)	
Nominal electric power shall be given together with the combination of X-Ray Tube Voltage and X-Ray Tube Current and Loading Time (IEC 60601-2-45: 201.7.9.2.1.e)	~~**2D mode:**~~ ~~Large Focus: 30kV*135mA= 4050W~~ ~~Loading time: 4.74”~~ ~~Small focus 30kV*50mA= 1500W~~ ~~Loading time: 4.40”~~ **2D mode:** Large Focus: 30kV*145mA= 4350W Loading time: 4.74” Small focus 30kV*50mA= 1500W Loading time: 4.40”
Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f)	1mAs for both operation mode
For Mammographic X-Ray Equipment provided with automatic Exposure Control controlling Loading Time, shortest Loading Time and/or the lowest resulting Current Time Product (IEC 60601-2-45: 201.7.9.2.1.h)	8mAs (using 20mm PMMA phantom)
Range of X-Ray Tube Voltage when X-Ray Tube Voltage is controlled by AEC (IEC 60601-2-45: 201.7.9.2.1.i)	20-49 kV
X-Ray Window	0,63 mm Beryllium
Housing X-Ray protection	>=0,5 mm Pb equivalent
Inherent filtration	0,0 mm Al IEC 522:1999-02
HVL measured at 28 kV	>0,5 mm Al equiv.
Total filtration	>0.5 mm Al

Reference	Section – Paragraph	Actions	Date
MTHELIDMD-U04 chap1 TECHNICAL SPECIFICATIONS	DIGITAL FLAT PANEL DETECTOR AXS2430, AXS2430V2, AXS2430FDI, AXS2430FDIV2 DETECTORS	Updated nominal values and tolerances of needed time to display images and perform new exposures (green parts).	21-07-2023

DIGITAL FLAT PANEL DETECTOR **AXS2430, AXS2430V2, AXS2430FDI, AXS2430FDIV2 DETECTORS**	
Detector Technology	(a-Si) TFT Array + Pin photodiode Amorphous Silicon Amorphous Selenium (a-Se)
Selenium thickness	200 μm
Case dimensions	35,9x34,6 cm (24x30 cm format)
Top Cover	Carbon fiber 0.1 mm Al equivalent
Chest Gap	3,9 mm
Cooling Method	Air + Fan (integrated) NOTE: The detector blowers will typically create a difference of around 4-5 degrees with respect to the ambient temperature.
Digitalization type	Logarithmic
Pixel dimension	85x85 μm
Pixel dimension in tomosynthesis reconstruced slices	85x85 μm (with any scan angle)
Pixel dimension in synthetic 2D images	85x85 μm
Active Area	23.9x30.5 cm (24x30 cm format)
Image Matrix	2816x3584 (24x30 cm format)
Image Depth	16 bit
Fill factor	88 % geometric (for a-Se Detector) 80% geometric (for a-Si Detector)
MTF (Modulation Transfer Function)	**For a-Se Detector:** >90% @ 1 lp/mm >40% @ 5,8 lp/mm **For a-Se Detector v2:** >95% @ 1 lp/mm >50% @ 5,8 lp/mm **For a-Si Detector:** >75% @ 1 lp/mm (typical 85%) >10% @ 5 lp/mm for a-Si Detector (typical 20%) **For a-Si Detector v2:** >85% @ 1 lp/mm (Minimum>75%) >20% @ 5 lp/mm (Minimu>10%)
DQE (Detector Quantum Efficiency) (for exposure of 28kV)	**For a-Se Detector:** >50% @ 1 lp/mm >20% @ 5,8 lp/mm) **For a-Se Detector v2:**

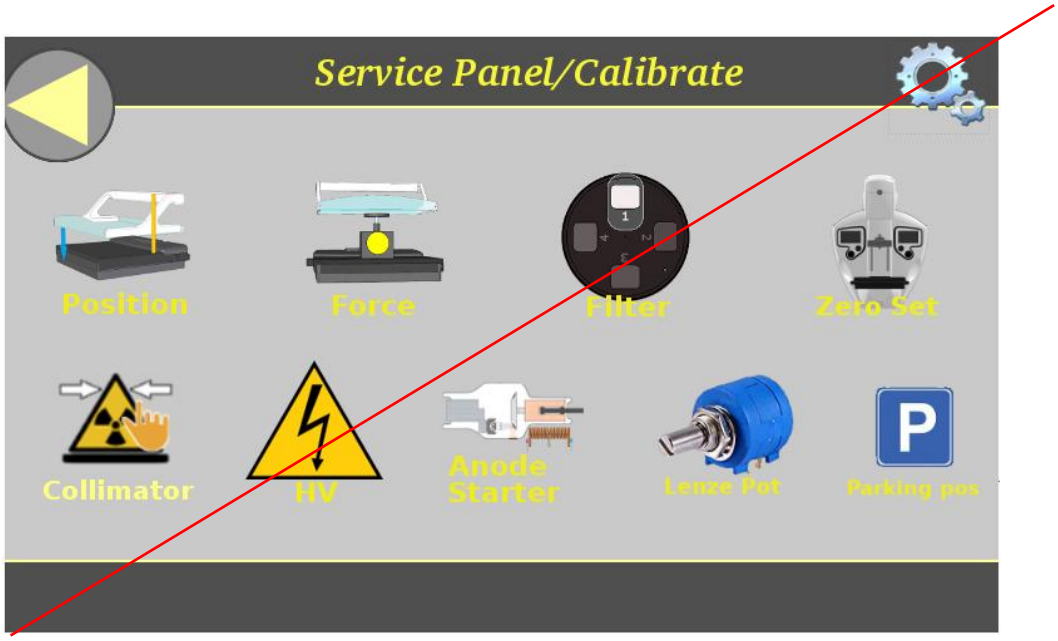
	>70% @ 1 lp/mm >20% @ 5,8 lp/mm **For a-Si Detector:** >45% @ 1 lp/mm (typical 50%) >10% @ 5 lp/mm (typical 20%) **For a-Si Detector v2:** >50% @ 1 lp/mm (Minimum>45%) >20% @ 5 lp/mm (Minimum>10%)
Resolution	5,9 lp/mm (Nyquist)
Signal to Noise Ratio (SNR) (with 45 mm PMMA Phantom)	15,19 (28,5 kV-10 mAs)
Ghost Image factor (Point n°2b.2.4.5 of "European Guidelines")	EUREF 0,05
Reconstruction time from last exposure (Model 020 BR3D CIRS phantom, 50 mm thick)	~~< 15 s (in 2D mode)~~ ~~**Tomosynthesis mode (all slices):**~~ ~~9 s (scan angle of 15°)~~ ~~10 s (scan angle of 24°)~~ ~~11 s (scan angle of 50°)~~ **FFDM mode** **All Detectors** 2 s ±20% **Tomosynthesis mode (all 1 mm slices)** **All Detectors** 9 s ± 20% (scan angle of 15°) 10 s ± 20% (scan angle of 24°) 11 s ± 20% (scan angle of 50°)
Time to display the image on the acquisition workstation from last exposure (Model 020 BR3D CIRS phantom, 50 mm thick)	~~< 15 s (in 2D mode)~~ ~~**Tomosynthesis mode (slab of 10 mm):**~~ ~~19 s (scan angle of 15°)~~ ~~20 s (scan angle of 24°)~~ ~~30 s (scan angle of 50°)~~ **FFDM mode** **a-Si (Standard)** 21 s ± 20% **a-Se Standard/Fast (Option)** 5.5 s ± 20% **Tomosynthesis mode (all 1mm slices)** **All Detectors** 19 s ± 20% (scan angle of 15°) 20 s ± 20% (scan angle of 24°) 30 s ± 20% (scan angle of 50°) **Tomosynthesis mode (default 10mm slab)** **All Detectors** 11 s ± 20% (scan angle of 15°)

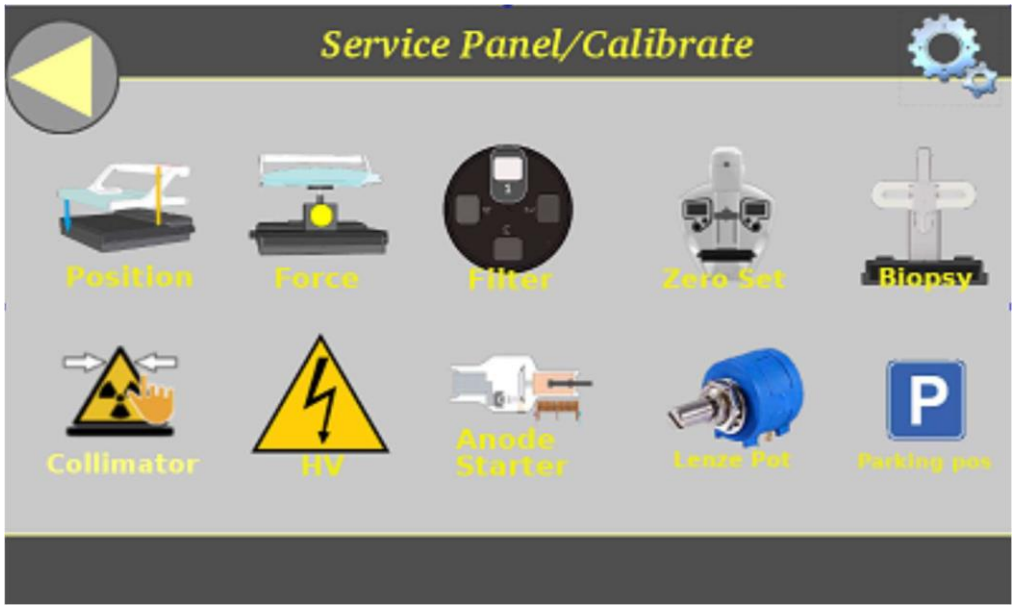
	12 s ± 20% (scan angle of 24°) 20 s ± 20% (scan angle of 50°)
Time to perform a new exposure from the end of the previous one (Model 020 BR3D CIRS phantom, 50 mm thick)	**FFDM mode** **a-Si (Standard)** 21 s ± 20% **a-Se Standard/Fast (Option)** 5.5 s ± 20% **Tomosynthesis mode (all 1mm slices)** **All Detectors** 19s ±20% (scan angle of 15°) 20s ±20% (scan angle of 24°) 30s ±20% (scan angle of 50°) **Tomosynthesis mode (default 10mm slab)** **a-Si (Standard)** 17 s ± 20% (scan angle of 15°) 17 s ± 20% (scan angle of 24°) 20 s ± 20% (scan angle of 50°) **a-Se Standard/Fast (Option)** 11 s ± 20% (scan angle of 15°) 12 s ± 20% (scan angle of 24°) 20 s ± 20% (scan angle of 50°)
Tomosynthesis acquisition time	**a-Si (Standard):** 5 s (with scan angles of 15°) 6 s (with scan angles of 24°) 11.5 s (with scan angles of 50°) **a-Se Standard (Option):** 10 s (with scan angles of 15°) 12 s (with scan angles of 24°) 30 s (with scan angles of 50°) **a-Se Fast (Option):** 2.5 s (with scan angles of 15°) 4 s (with scan angles of 24°) 7.7 s (with scan angles of 50°)

Reference	Section – Paragraph	Actions	Date
MTHELIDMD-U04 chap05 SETTING TO WORK AND DETECTOR CALIBRATION	1.4 CALIBRATION FUNCTIONS	Replace red text/image with green text/image	28-03-2023

1.4 CALIBRATION FUNCTIONS

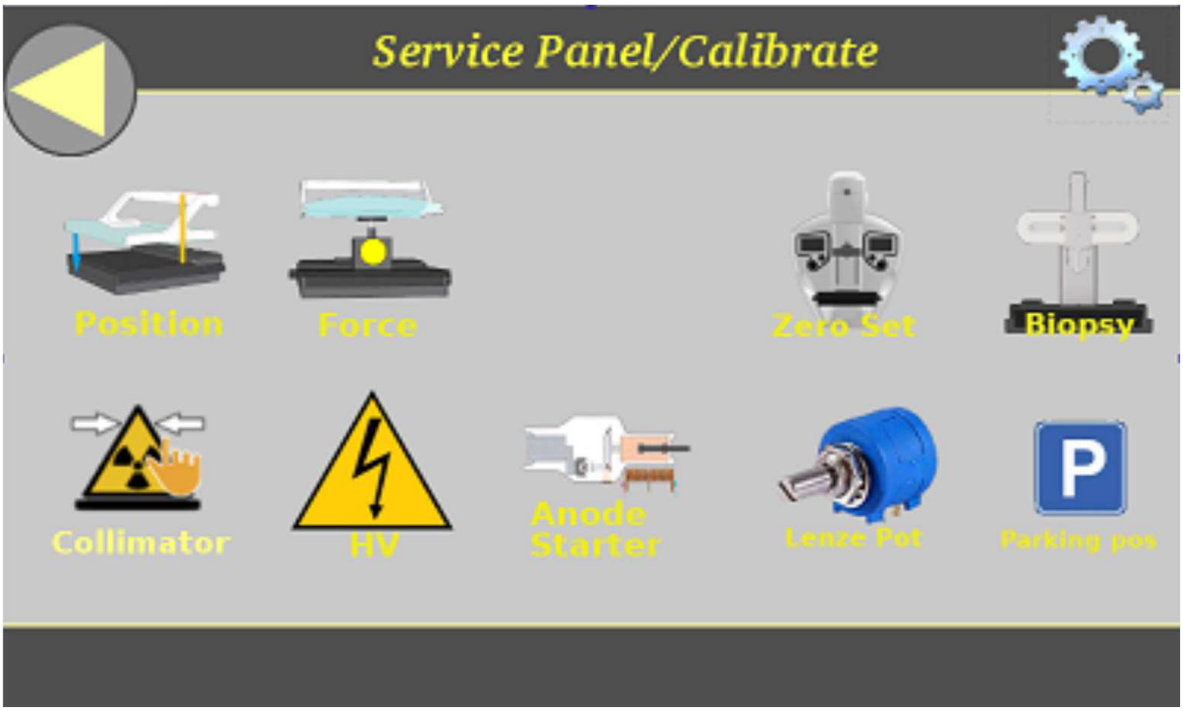
If the thickness value of compressed breast or force value are not correct, it is possible to calibrate their using a specific interface with service panel, directly accessible from MAMMO TSD. The service Panel shows a specific Menu to access to calibration functions.





- Position: position / thickness calibration;
- Force: calibration of the compression sensor;
- Filter: calibration of filter positions (if filter option is automatic);
- ZeroSet: on-board inclinometer calibration;
- Collimator: setting the Manual Collimation;
- HV: power supply reading calibration;
- Anode Starter: (low speed starter option only) launch current calibration. This icon is not shown if the machine is configured with the high speed IAE starter;
- Lenze Pot: potentiometer reading calibration for detecting the vertical position of arm
- Parking pos: parking position calibration

When the filter option is FIXED the following image will appear:



Reference	Section – Paragraph	Actions	Date
MTHELIDMD-U04 chap05 SETTING TO WORK AND DETECTOR CALIBRATION	2.3 ENHANCE tuning	Added green text/images	28-03-2023

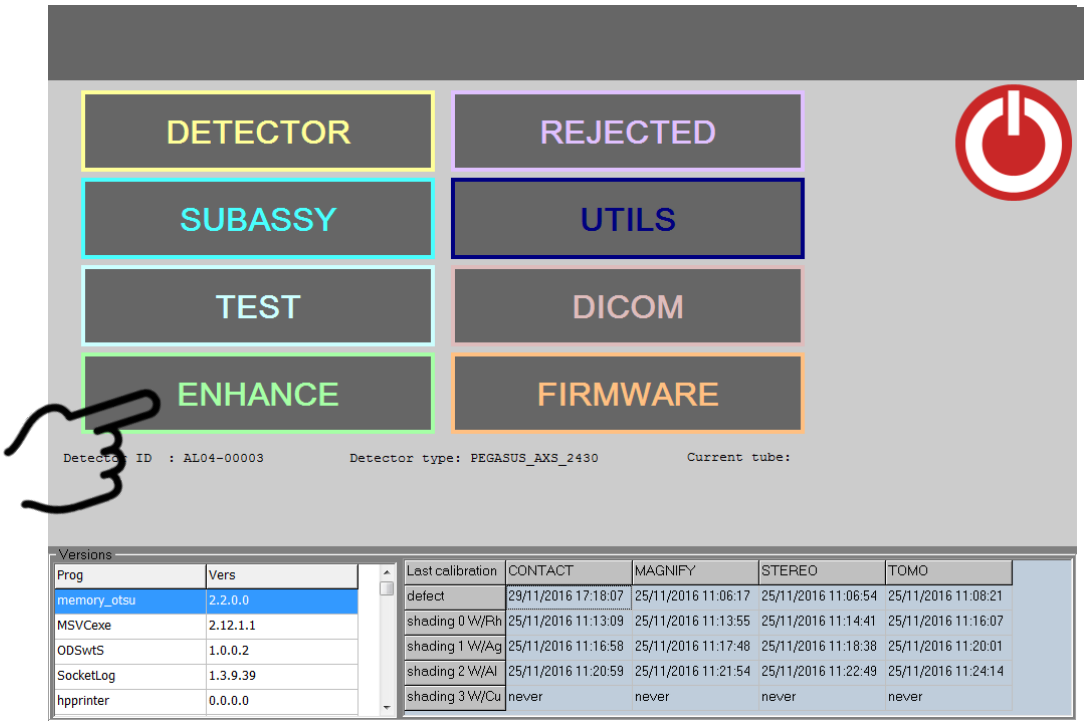
2.3 ENHANCE tuning

The default parameters of post-processing image algorithm are optimized following suggestions of many radiologists.

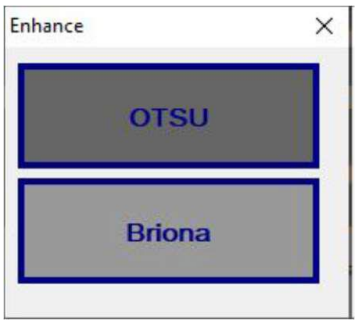
It is offered also the possibility of tuning these parameters according to specific requirements of the medical radiologist.

In DMDToolkit home page:

1. Select Enhance icon on the GUI of the AWS DSP



The following menu will appear.

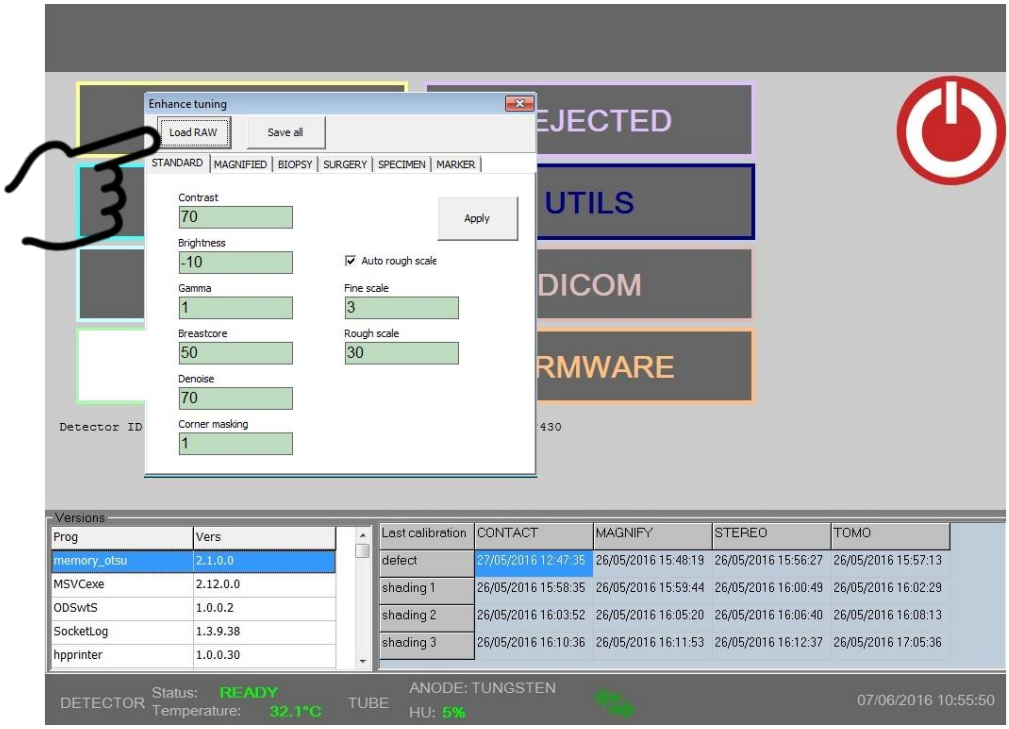


For 2D (OTSU) or 3D (Briona) images.

3D (image) is disabled by factory default.

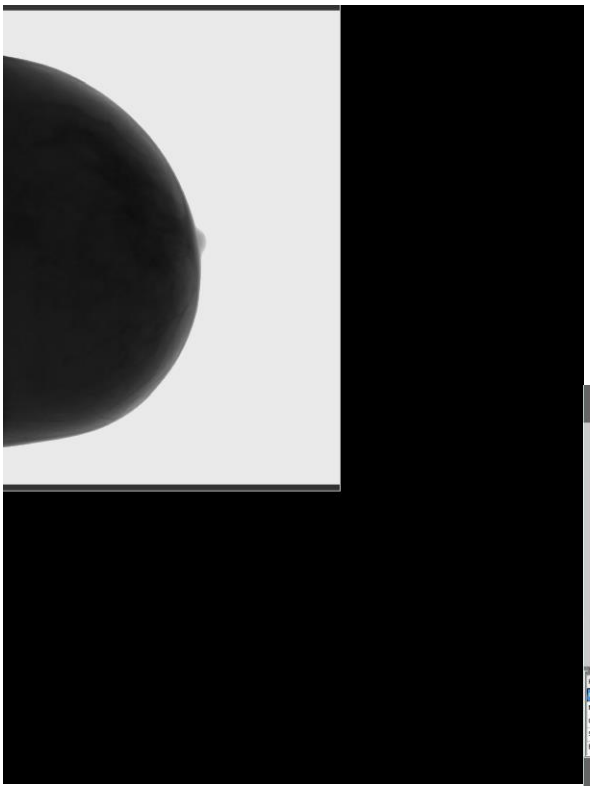
For 2D image Enhance:

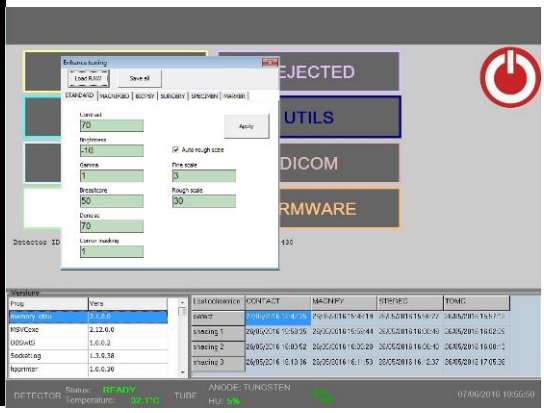
2. Click on “OTSU” icon
3. Select LOAD RAW, select a RAW image to load and then select OK



4. Select Load raw and select a RAW image to load and the select OK

5. The Raw images will be displayed on the AWS HRD whereas the Enhance tuning window for the parameters modification will be displayed on the AWS DSP as follow:





AWS HRD AWS DSP

6. Modify the parameters in the Enhance tuning window and then select Apply to apply the post processing algorithm.

7. If final image doesn't encounter the requirements requested from medical radiologist, the operator can change parameters according to the following note and, at the end, select apply again.

NOTE

- *SegmMode parameter is no more used. If modified, no effect is obtained.*
- *In case of further modification on post-processed image, after choosing the proper parameter set, the operator can lightly modify first Gamma parameter and then Brightness and Contrast parameters.*
- *Changing Gamma parameter by increasing or by decreasing 0.1 step and then, eventually, modifying also the second decimal place.*
- *Decreasing Gamma parameter compresses the black values and expands the white values. It emphasizes the black/white effect. Increasing*

Gamma parameter makes the image smooth. Acceptable value are: [0.5, 5.0]. Neutral value: 1. Typical value range: [0.6, 1.2].

- *Where necessary, changing Brightness parameter by increasing or by decreasing 10 and then changing units. Increasing Brightness parameter moves the image to the white, decreasing Brightness parameter moves the image to the black. *If white values are saturated, decreasing of Brightness parameter is strongly suggested*. Acceptable values: [-50, 50]. Neutral value: 0. Typical value range: [-20, 0].*