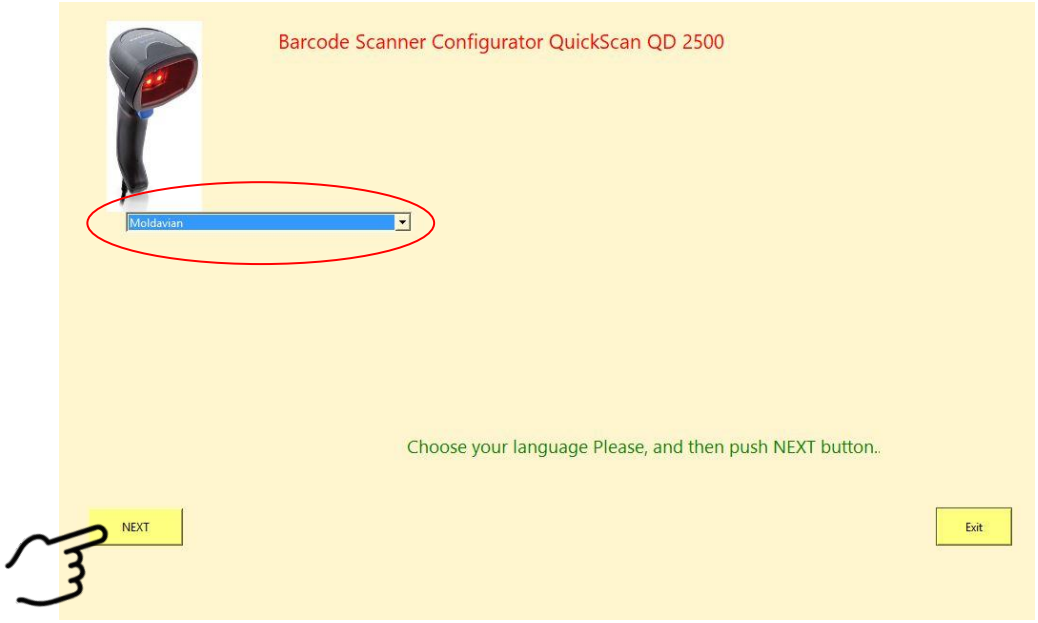
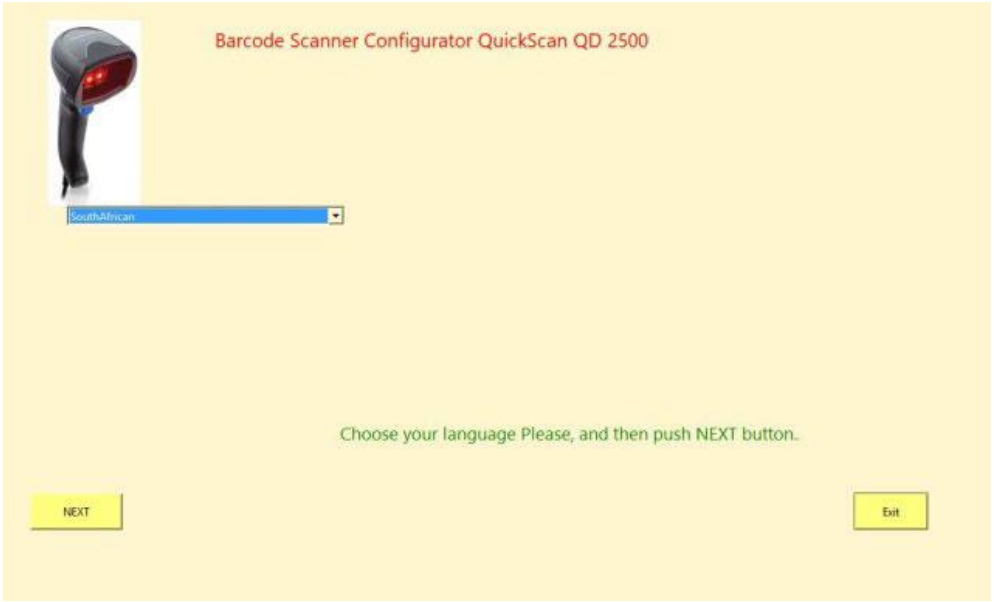
Reference	Section – Paragraph	Actions	Date
MOHELIDMD-U04	**6.3.3 QR Reader procedure Subpar. 5**	New context “South Africa” added in QRscanner application (green parts)	28-03-2023

5 In the next screen, the operator will have the possibility with a drop-down menu to select the language of the country from which to take the identity documents and can continue by selecting NEXT;



Moldavian context



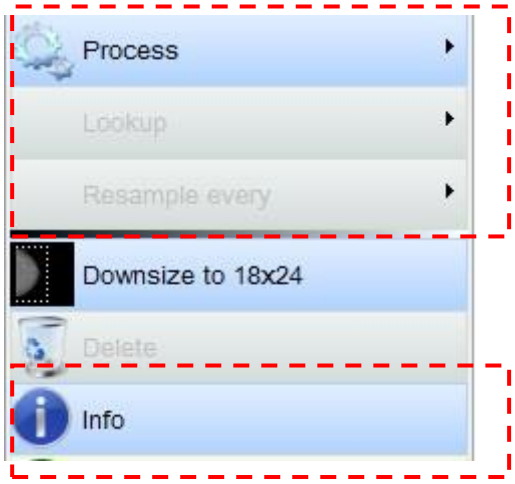
South Africa context

The value can be used in both UNSCHEDULED and RIS windows.

Reference	Section – Paragraph	Actions	Date
MOHELIDMD-U04	**6.9.3 Process, Lookup, Resample every and Info**	Added dedicated reconstruction parameters for DBT images with implants in green	28-03-2023

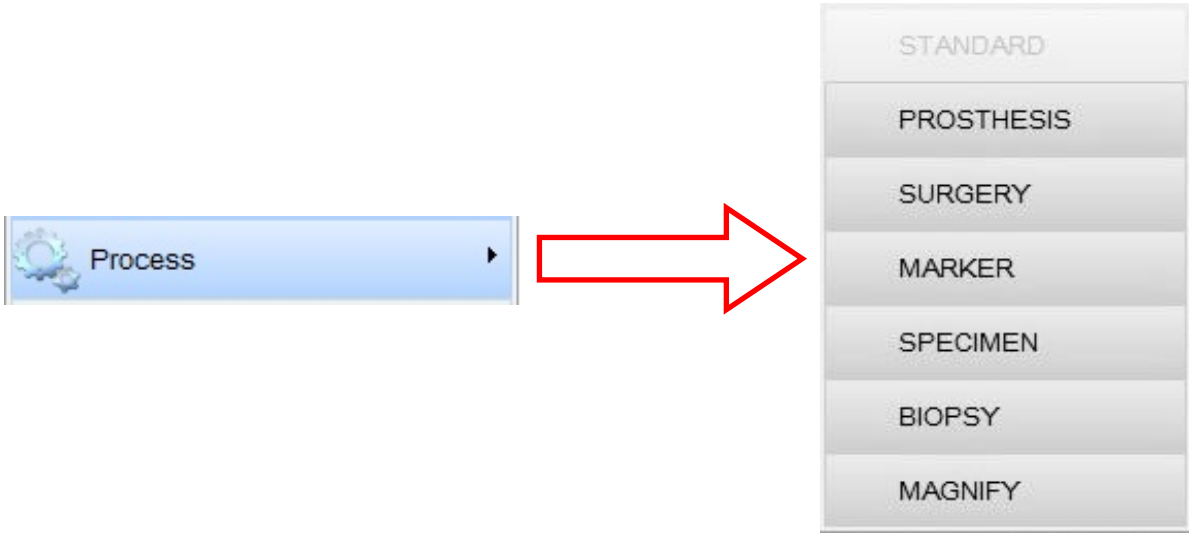
6.9.3 Process, Lookup, Resample every and Info

To access these functions right click with the mouse on the desired image.



The “Process” function allows to modify some parameters of reconstruction algorithm in order to enhance all structures and reducing noise to show the images on display of Acquisition Work Station with a reading better quality.

Clicking on “Process” button, a submenu appears.



The operator can choose between several optimized algorithms. I.e, for magnification, biopsy, examination of surgical anatomical parts, examination of specimen and in case of metallic clips, surgical makers or numerous clusters of micro calcifications. In case of

acquisition in magnification mode with spot compression paddle, it is recommended to select a "STANDARD" option.

When the PROSTHESIS protocol is selected, the subsequent DBT image (simple DBT, VI or COMBO) is processed using dedicated parameters for implants. By selecting the STANDARD protocol instead, the standard parameters will be used.

The parameters dedicated to DBT reconstructions with implants are the same for all scan angles. While the STANDARD protocol uses different parameters according to the chosen scan angle.

CAUTION

For specific request of the reporting physician, at the end of the X-ray exposure and with the image acquired, only the previous button “Process” has to be used to modify the main post processing filter selection. Instead, if you want modify the selection “HARD”, “MEDIUM” or “SOFT”, this option has to be selected using the corresponding push button on the AWS DSP.

The “Lookup” function allows to modify the image contrast.

Clicking on “Lookup” button, a submenu appears showing all the available options (“Low Noise”, “High contrast”).

CAUTION

The selected option from this menu, will remain saved and it will be automatically applied also on ALL images acquired by the Mammo Unit.

The “Resample Every” function allows to navigate through Slices within a custom step different to the default one (default value is set to 10 mm). The function is enabled only for TOMO exams.

The "Resample Every" function will use always the last used lookup.

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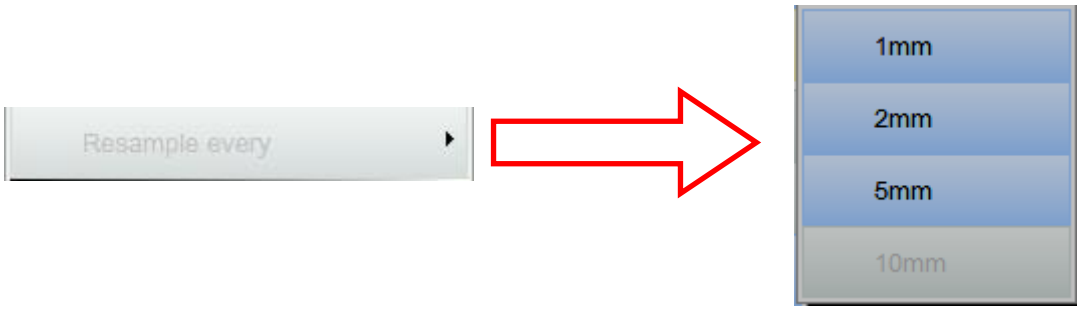
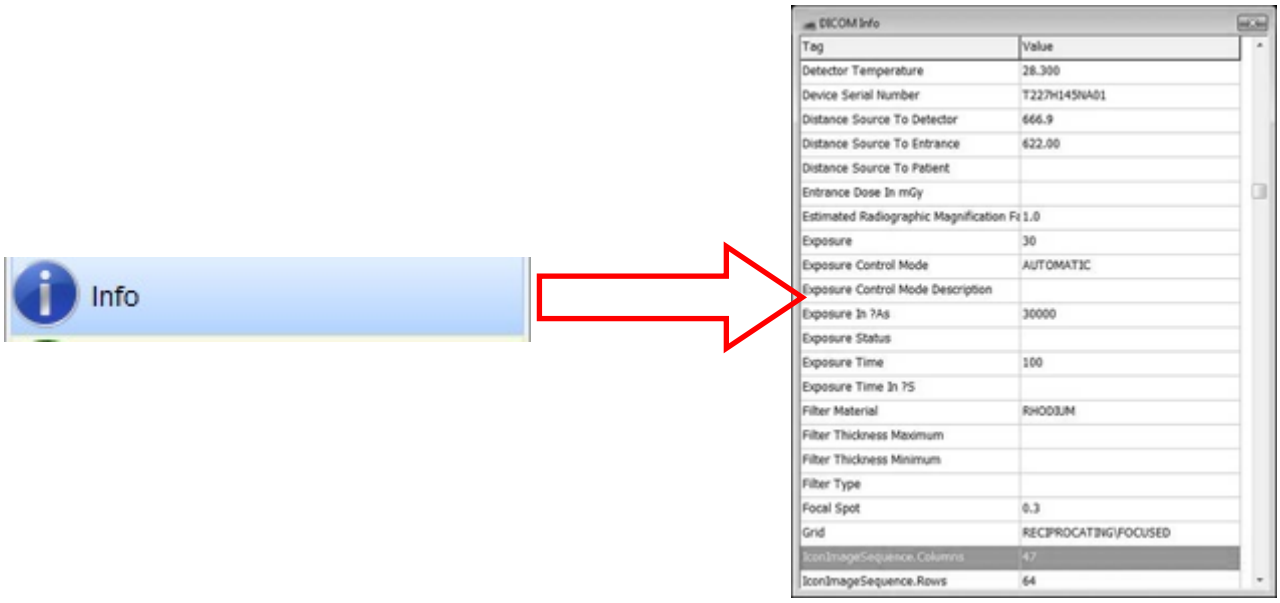
The available values for step are 1 mm, 2 mm, 5 mm, 10 mm. The function is disable for 2D images.



Clicking on “Info” button, a window appears showing all DICOM data and parameters regarding the selected image.



Reference	Section – Paragraph	Actions	Date
MOHELIDMD-U04	**11 – X-RAY TUBE I.A.E. XM1016 T**	Updated nominal values and tolerances of standard X-ray tube characteristics (green parts).	21-07-2023

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
MOHELIDMD-U04	**11 – 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

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	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=5100W
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
MOHELIDMD-U04	**11 – 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
MOHELIDMD-U04	**11 – 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°)