

PRODUCT DATA

Full Field Digital Mammography system for Breast Tomosynthesis



Milady TS is a complete mammography solution optimized for digital imaging in 2D screening, 3D tomosynthesis and stereotactic biopsy.

It is composed of:

- Mammography Unit with 24x30 cm format Direct Conversion Amorphous Selenium detector with Isocentric C-Arm;
- Integrated X-Ray control and image acquisition console;

MILADY TS

CLASSIFICATION (IEC 60601-1)

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|--|---|
| Protection against electric shock | Class I, with type B applied parts |
| Protection degree according to IEC 529 | IPX0 (mammography system) IPX1 (multifunctions foot-controls) |
| Degree of safety in the presence of flammable anesthetics mixture with. air or with oxygen or with nitrous oxide | Not suitable for use in the presence of Flammable Anesthetics Mixture with air or with oxygen or with nitrous oxide |
| Mode of operation | Continuous operation with intermittent loading |

POWER SUPPLY

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|------------------|--|
| Line voltage | 220/230/240 Vac +/-10% 50/60 Hz 115 Vac +/-10% 50/60 Hz (optional) |
| Power | 220/230/240 Vac: 1,3 A (45 A max per 5 s) 115 Vac: 2,5 A (85 A max per 5 s) |
| Number of phases | 1 or 2 configurable |
| Connection | Permanently installed (IEC 601-1) |
| Wall connection | 20 A fuse or Thermal-magnetic circuit breaker (40 A fuse or Thermal-magnetic circuit breaker in 115 Vac option) |
| Mains resistance | <0.50 Ω |

ENVIRONMENTAL CONDITIONS

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|--|---|
| Operating conditions (24 h) | Temperature + 20° C / + 25° C Relative humidity 30%/75% Barometric pressure 700 hPa/1060 hPa (24 h) |
| Heat dissipated in max load condition of 35 kV 500 mAs (1 shot every 5 minutes) | 316 kCal/h |

EMERGENCY STOPS

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|-----------------|---|
| Function | To switch totally off the Mammography System except detector |
| Number and Type | Two red push-buttons on both sides of mammography unit One red push-button on Acquisition Station |

MILADY TS

X-RAY HIGH-VOLTAGE GENERATOR

| | |
|--|--|
| Line voltage compensation | AUTOMATIC H.V. generator with kV closed loop and line Feed forward compensation |
| Inverter Technology | Current fed, Mosfet bridge with output current limit capability and short circuit protection |
| Inverter Frequency | 50 kHz |
| Ripple Frequency/Amplitude | 100 kHz < 2% |
| Generator output power | 7,4 kW (@ 37 kV) |
| kV range | 20 / 49 kV |
| kV resolution (all modalities) | 0,5 kV |
| kV precision | +/- 1% |
| kV repeatability | +/- 0,1% |
| kV risetime | <= 1.5 ms from 0 to 100% |
| kV display | XX,X kV (3 digits) |
| Lowest Current Time Product (IEC 60601-2-45: 201.7.9.2.1.f) | 1 mAs |
| mAs maximum value | 640 mAs |
| mAs resolution (Automatic) | 0,1 mAs |
| mAs values | in accordance with R'20 series (Note: values rounded down on the base of standards tolerance and series limited to 640 mAs) |
| mAs display | XXX,X mAs (4 digits) |
| Exposure Time range | 0.02 / 4.7 s (640 mAs @135 mA) (Automatically selected in function of selected mAs) |
| Safety timer | 10 s |

MILADY TS

STANDARD X-RAY TUBE (IAE XM1016 T)

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|--|---|
| Anode rotation speed | 10000 rpm |
| Target material | Tungsten Focal track: RT (W+Re)/Bulk: TZM (Mo+Ti+Zr) |
| 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 | 425 kHU (320 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 | 0,1x0,1 mm (Small Focus) 0,3x0,3 mm (Large Focus) |
| Power (Nominal Anode Input Power) | 2400 W (Small) - 9600 W (Large) |
| Nominal X-Ray Tube Voltage | 49 kV |
| 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 MODALITY: 135 mA (@ 35 kV) (Large Focus) 65 mA (@ 35 kV) (Small Focus) TOMO MODALITY: 200 mA (@ 35 kV) (Large Focus) |
| Combination of X-Ray Tube Voltage and X-Ray Tube Current which results in the highest electric output power (IEC 60601-2-45:201.7.9.2.1.c) | 2D MODALITY: 35 kVx135 mA=4725 W TOMO MODALITY: 35 kVx200 mA=7000 W |
| X-Ray Window | 0,5 mm Beryllium |
| Housing X-Ray protection | >=0,5 mm Pb equivalent |
| Inherent filtration | 0,0 mm Al IEC 522/1976 |
| HVL measured at 28 kV | >0,3 mm Al equivalent |
| Total filtration at 28 kV | >0,5 mm Al |

TUBE ASSEMBLY THERMAL OVERLOAD PROTECTION

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| With active temperature sensor under main CPU control | Upper limit temperature 65° outside tube assembly. HU and °C display available in technical menu. |
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FILTER

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| Filter materials | 50 µm Rhodium (Rh) - 0,55 mm Al eq. a 28 kV 50 µm Silver (Ag) - 0,51 mm Al eq. a 28 kV 500 µm Aluminium (Al) - 0,51 mm Al eq. a 28 kV |
| Method of filter selection | Manual or Automatic |

MILADY TS

ISOCENTRIC C-ARM

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|---|---|
| F.D.D. (Focus Detector Distance)/S.I.D. | 66 cm |
| Motorized Movements | Vertical and rotation +/- 15° Rotation (only with Bym 3D DBT) |
| Tomosynthesis scan angles | +/- 7,5° (15°) +/- 12° (24°) +/- 18° (36°) |
| Range of Vertical Movement (from Floor) | From 75 to 160 cm (travel of 85 cm) |
| Speed of Vertical Movement | 5 cm/s |
| Range of Rotation | +/-180° (+/-135° with C-Arm in the lowest position) (CW, CCW continuous to any position) |
| Projection Preset positions | N° 5 Programmable projections (LAT, OBL, CC, OBL, LAT) |
| Speed of Rotation | 11°/s with acceleration and deceleration ramp for smooth operation |

COLLIMATION DEVICE

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|---------------------------------|--|
| Type | Automatic recognition of format and position of compression paddle |
| Light source | LED (Class 1 Device-320 µW power) |
| Light beam | Switch ON by push-button or automatic when operating compression (selectable by service) Electronic timer |
| Light intensity | >= 150 lux |
| Light beam collimation accuracy | according to IEC 60601-2-45: 203.8.5.4 |
| Mirror | With automatic out of field function |
| Formats | 24x30 cm for normal breast 18x24 cm for small breast 10x14 cm for magnification Trapezoidal dynamic for tomosynthesis |
| Protection of examination field | 2D patient's face protection polycarbonate screen 3D wide patient's face protection polycarbonate screen |

CONTROL SWITCHES

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|-----------------|---|
| Number and Type | Four multiswitches (five push-buttons) on both sides of C-Arm and X-Ray tube |
| Control Actions | Vertical movement of C-Arm Continous rotation of C-Arm Switch-on of collimation light |

MILADY TS

DIGITAL FLAT PANEL DETECTOR

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|--|---|
| Detector Technology | 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) |
| Pixel Dimension | 85x85 µm |
| Pixel Dimension in Tomosynthesis | 85x85 µm (full resolution) |
| Pixel Dimension in reconstructed slices | 85x85 µm |
| Active Area | 23,9x30,5 cm (24x30 cm format) |
| Image Matrix | 2816x3584=10092544 (formato 24x30 cm) |
| Image Depth | 16 bit |
| Fill Factor | 88 % geometric |
| MTF (Modulation Transfer Function) | >90% @ 1 lp/mm - >40% @ 5,8 lp/mm |
| DQE (Detector Quantum Efficiency) | >50% @ 1 lp/mm - >20% @ 5,8 lp/mm |
| Maximum Spatial Resolution | 7 lp/mm |
| Nyquist Frequency | 5,88 lp/mm |
| 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") | 0,02 |
| Image Display Time on Acquisition Station | <15 s (2D) <25 s (TOMO - thickness of 50 mm) |
| Time Between Two Images Acquisition | <15 s (2D) <25 s (TOMO - thickness of 50 mm) |
| Tomosynthesis acquisition time | 10 s (with a scan angle of 15°) 12 s (with a scan angle of 24°) 18 s (with a scan angle of 36°) |

GRID

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|---------------------|-------------------|
| Type | Linear, vibrating |
| Interspace Material | Graphite |
| Ratio | 5:1 |
| Lines/cm | 102 |
| Contrast factor | 1,30 |

OPTIONAL DEVICE FOR GEOMETRIC MAGNIFICATION

| | |
|--------------------------------|---|
| Type | Gridless, interchangeable with Potter-Bucky |
| Magnification Ratio (variable) | x1,5/x1,8/x2 |
| Small Focus Selection | Automatic once fitted |

MILADY TS

“SensROI” AUTOMATIC EXPOSURE CONTROL

| | |
|------------------------------------|--|
| Controlled parameters | Auto kV / Auto mAs (Zero Point Mode) Manual kV / Auto mAs (One Point Mode) |
| Auto parameters selection criteria | Dual mode: PRE and FAST PRE: tissue composition based (parameters evaluated by short X-Ray exposure) FAST: compressed breast thickness based |
| Sensitive area (only for PRE mode) | Mosaic of 96 areas (ROI) of detector automatically selected in function of breast size and projection |

“POEt” POST-PROCESSING ALGORITHM

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|-----------------------------|--|
| Type | Specific for mammography to optimize the quality of acquired images |
| Description | Processing of acquired RAW images and display in “For Presentation” format to enhance breast tissue structures and reduce the noise |
| Dedicated Filters | For geometric magnification and in case of prosthesis, metallic clips, surgical markers, clusters of microcalcifications, breast specimens and surgical anatomical parts |
| Format of image compression | JPEG LOSSLESS (JL) JPEG 2000 LOSSLESS (J2L) |
| Format of image save/export | DICOM FOR PROCESSING FFDM DICOM FOR PROCESSING (TOMO projections) |

TOMOSYNTHESIS

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|---|--|
| Number of X-Ray exposures (projections) | 11 (15°) 13 (24°) 19 (36°) |
| Reconstruction method | Back-projection technique with incorporated iterative technique to improve image quality |
| Distance between reconstructed slices | 1 mm |

DOSE CALCULATOR

| | |
|------------------------------|---|
| Method of Calculation | Average Glandular Dose (AGD) according to: “D.R. Dance et al.” |
| Data visualization (mGy) | On Acquisition Station |
| Method of recording | Image Header (DICOM) |
| AGD with a 4 cm PMMA phantom | 1,216 mGy (2D acquisition) |
| Dose limits | According to European Protocol for Dosimetry and EUREF protocol |

MILADY TS

“Smart μ Press” COMPRESSION SYSTEM

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|--|--|
| Compression Paddle Movement | Motor driven or manual with fine adjustment by double rotating controller |
| Standard Compression Paddles | 24x30 cm shifted specific for TOMO exams 24x30 cm shifted for 2D exams (normal breasts) 18x24 cm with lateral shifting for 2D exams (small breasts) |
| Optional Compression Paddles | 9x21 cm for magnification Φ 7,5 cm spot for magnification Φ 7,5 cm shifted spot for contact examination 10x24 cm for axillary examination 18x24 cm shifted for 2D biopsy |
| Compression Paddle Holder | Fast mechanical unlock by rotating knob Right lock warning LED |
| Maximum free space available between Compression Plate and top cover of Potter-Bucky | 325 mm with with shifted Compression Paddles <i>In Magnification Mode (straight compression paddle)</i> 231 mm (1,5x) - 191 mm (1,8x) - 131 mm (2x) |
| Compression Force | Adjustable from 70 to 200 N |
| Compression Force Display | Effective applied force with 1 N resolution |
| Compression Paddle Descent Speed | 4 cm/s at the start Proportionally decreasing compressing the breast |
| Maximum Compression Force Safety Device | Triple: electronic, electro-mechanical, mechanical |
| Soft Compression release after exposure | Selectable from control panel |
| Compression paddle aluminium equivalence | < 0.2 mm Al (0.135 mm Al \approx 30 kV) |

CONTROLLERS FOR MANUAL COMPRESSION WITH FINE ADJUSTMENT

| | |
|-----------------|---|
| Number and Type | Two rotating wheels with central push-button on both sides of C-Arm |
|-----------------|---|

TOUCHSCREEN COLOUR DISPLAYS

| | |
|-------------------------------------|---|
| Number and Type | Two TFT LED backlight resistive touchscreens on both sides of C-Arm |
| Screen Size (format) and resolution | 5,7" (4:3) - 640x480 |
| Informations | Compression force, compressed breast thickness, patient name, projection angle, breast laterality, ACR code, collimation format, magnification factor |

MULTIFUNCTION FOOT-CONTROLS

| | |
|-----------------|--|
| Number and Type | Two with four pedals and one push-button |
| Control Actions | Vertical movement of C-Arm Vertical movement of Compression Paddle Motor driven compression unlock |

MILADY TS

ANTI-X PROTECTION BARRIER

| | |
|-----------------|---|
| Type | Integrated |
| Pb equivalence | > 0,34 mm (@ 35 kV) - IEC 60601-2-45 Standard |
| Dimensions | 857x2003x640 mm |
| Glass thickness | 20 mm |

PERSONAL COMPUTER

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|------------------------------------|--|
| Operating System | Windows Embedded Standard 7 |
| CPU | Intel Core i7 2600 3,4 GHz |
| RAM | 16 GB DDR3-1333 |
| HDD | 128 GB SSD for Operating System, Acquisition Software and Toolkit Software 1 TB SATA for images storage (~ 25.000 images) |
| DVD Recorder | 48x SATA DVD +/-RW DL |
| UPS (Uninterruptible Power Supply) | 650 VA |

TOUCHSCREEN COLOUR DISPLAY

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|-----------------------------|-------------------------------|
| Technology | Active matrix TFT LCD |
| Screen Size (aspect ratio) | 15" (4:3) |
| Display Resolution (pixels) | 1024x768 |
| Colours | 16,2 million with dithering |
| Viewing Angle | 140° horizontal/115° vertical |
| Response Time | 14,5 ms |
| Brightness | 250 nits |
| Contrast Ratio | 500:1 max |

POINTING AND SELECTION DEVICE

| | |
|------------|---|
| Type | Trackball with scroll ring Four customizable buttons |
| Technology | Optical tracking |

2 MP COLOR MONITOR

| | |
|-----------------------------|--|
| Technology | TFT LCD IPS |
| Screen Size (diagonal) | 21,3" (541 mm) |
| Display Resolution (pixels) | 1600 x 1200 |
| Viewing Angle | 178° horizontal and vertical |
| Response Time | 20 ms |
| Brightness | 440 cd/m ² max (250 cd/m ² DICOM calibrated) |
| Contrast Ratio | 1500:1 typical |

Subject to change without notice



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