Datasheet

MAMMOMAT B.brilliant

Digital Mammography Platform for Screening and Diagnostics with 50° Wide-Angle Tomosynthesis and Biopsy and TiCEM option

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SIEMENS Healthineers

MAMMOMAT B.brilliant

Digital Mammography Platform for Screening and Diagnostics with 50° Wide-Angle Tomosynthesis and Biopsy and TiCEM option.

Women deserve fewer maybes.

MAMMOMAT B.brilliant is the first and only mammography system to feature PlatinumTomo, a completely new 3D mammography framework. It combines 50° Wide-Angle Tomosynthesis with unparalleled acquisition speed, excellent in-plane resolution and adaptable image impression. At the same time, MAMMOMAT B.brilliant is designed to make comfort a priority and provide more women access to care.

With MAMMOMAT B.brilliant, we are breaking new ground. It aims to offer uncompromised cancer detection for women who want straightforward answers. Experience high accuracy, easy workflows [1)], and efficient diagnostic processes – in a next-generation mammography system that was developed with women's wellbeing in mind.

MAMMOMAT B.brilliant is the first mammography device featuring PlatinumTomo combining 50° wide-angle tomosynthesis and impressive acquisition speed with excellent in-plane resolution and adaptable image impression. At the same time, MAMMOMAT B.brilliant is easy to work with – offering convenient decision processes for all mammography-based diagnostic applications. [1)]

[1)] *data on file*

Highlights

PlatinumTomo – New standard in image quality

MAMMOMAT B.brilliant delivers unprecedented image quality in both digital breast tomosynthesis and FFDM. Our new PlatinumTomo combines 50° Wide-Angle Tomosynthesis, next-level image reconstruction and the unique flying focal spot tube, which results in MAMMOMAT B.brilliant providing the highest in-depth resolution[1)] and excellent in-plane resolution – for precise characterization of lesions and microcalcifications.

With unprecedented 3D mammography brilliance, the MAMMOMAT B.brilliant offers a completely new way to acquire tomosynthesis with its PlatinumTomo technology. It integrates the benefits of 50° Wide-Angle Tomosynthesis in UltraHD and a completely new acquisition tube technology. The MAMMOMAT B.brilliant will set a new standard in mammography by offering you:

- Best in-depth resolution[1)] and excellent in-plane resolution for better visualization of lesions, and architectural distortions[2)] – thanks to PlatinumTomo.
- A comfortable transition from 2D and narrow angle systems – thanks to customizable image flavors
- Unprecedented quality of synthesized 2D images – thanks to new UltraHD PREMIA image reconstruction

ComfortPackage

For better technologist ergonomics and a positive patient experience, MAMMOMAT B.brilliant offers smart, fast, intuitive, and patient-centric workflows. Its state-of-the-art methods allow technologists to adapt their personal workflow and positioning preferences to individual patient conditions and exam situations.

By causing less physical strain and enabling users to completely focus on their patients, MAMMOMAT B. brilliant is easy and convenient to work with – and can help reduce anxiety during the examination.

- For the user:
  - Easier patient positioning for less physical strain, thanks to ComfortMove and an ergonomic system design
  - Continuous guidance and immediate feedback on current and next examination steps from the system for greater confidence, thanks to the ComfortGuide display
- For the patient:
  - More comfort thanks to the optimized face-shield and minimal compression time.

[1)] *Maldera A, De Marco P, Colombo PE, Orrigi D, Torresin A. Digital breast tomosynthesis: Dose and image quality assessment. Phys Med. 2017; 33: 56–67.*

[2)] *Hailing Huang, David Scaduto, Anastasia Plaunova, Kim Rinaldi, Paul R. Fisher, Wei Zhaoa: Comparison of lesion detection and conspicuity between narrow-angle and wide-angle digital breast tomosynthesis for dense and non-dense breasts Stony Brook Medicine, Department of Radiology, Stony Brook, NY, USA, 11794-8464*

Highlights

Breast Biopsy with InSpect [1)]

Utilize the same 50° Wide-Angle technology in biopsy, resulting in a target accuracy of ± 1 mm.

Reduce your biopsy workflow time thanks to easy one-click targeting and an integrated specimen scanner InSpect.

Get your specimen imaged within just 20 seconds right on the system without having to invest in another unit or leave your patient.

TiCEM (Titanium Contrast Enhanced Mammography) [1)]

TiCEM provides additional diagnostic information where a mammogram may be inconclusive. Easy image interpretion can help to detect or rule out lesions in difficult cases. It may be used as a cost-effective diagnostic alternative to MRI when MRI is not available or contraindicated.

Advantages of the unique Titanium filter:

- It reduces the X-ray tube load. [2)]
- It enables consecutive TiCEM exams without interruptions due to tube overheating.

MAMMOMAT B.brilliant brings together valuable features that increase accuracy and speed, including wide-angle tomosynthesis targeting, needle navigator, and convenient workflows.

Breast Density [1)]

Visual classification of breast density according to BI-RADS standards can be challenging.

Insight BD [3)] offers you an objective, volumetric-based classification correlating to ACR BI-RADS for instant risk stratification right at the acquisition workstation – for FFDM and tomosynthesis.

[1)] *Option*
[2)] *Compared to Copper-filtration*
[3)] *Data on file*

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System specifications

Basic unit

Digital mammography system for screening, diagnostic and biopsy procedures on standing, seated or recumbent patients

PRIME Technology, software-based anti-scatter solution for mammography

The system consists of a free-standing examination stand with integrated, microprocessor-controlled, high-frequency generator as well as an optional radiation shield with height-adjustable control desk in which the Acquisition Workstation (AWS) can be integrated

Swivel arm system consisting of X-ray tube unit with flying focal spot, compression device and object table with integrated detector

ComfortMove incl. positioning laser, provide the possibility to move tube-head out-of-the way for easier positioning in oblique projections

Motorized, isocentric rotation of the swivel arm with preset rotation angle (Ready Button), other angles preselectable

The motorized, height-adjustable object table can be adjusted from the examination stand as well as via the foot switch

Motorized and manual compression with preselectable compression force

Digital display of in eye-height indicating system status and next step guidance

Automatic collimation to the required radiation field size according to the compression plate selected

Integrated working/collimator light

OpComp – function for personalized compression supported with SoftSpeed

OpDose – five different exposure parameters for optimized patient dose

AEC (Automatic Exposure Control) – analyzes the entire breast surface on the detector, thereby providing an optimum dose

Fixed headrest with faceshield for all projection views

Automatic collision protection for higher security

Moodlighting integrated at the gantry. Different colors can be selected

Source-image distance	65 cm (25.6“), for high geometric resolution and optimum patient access during positioning
Compression	3 kg (6.5 lbs) to 20 kg (44 lbs), automatic (OpComp) and manual adjustment
Collimation	Automatic for all sizes
Grid	Reciprocating, grid ratio 5:1, 31 lines/cm
Magnification factors	1.5 / 1.8, geometric
Swivel range	+ 180° to – 180°, motorized, isocentric rotation with preselectable rotation angle
Height adjustment (motorized)	66 cm (26“) to 154.5 cm (60.8“) (object table)

System specifications

X-ray generator		
Microprocessor-controlled high-frequency generator		
Power output	5 kW (30 kV, 1 s, 60 s cycle time, acc. to IEC 60601-2-45)	
kV range	23 kV to 40 kV (adjustable in 1 kV increments) 45 kV to 49 kV (adjustable in 1 kV increments)	
mAs range (at 25 kV and maximum power)	W large focal spot 0.5 mAs to 630 mAs manual mode 0.5 mAs to 710 mAs in AEC mode	W small focal spot 0.5 mAs to 220 mAs manual mode 0.5 mAs to 239 mAs in AEC mode
Exposure times, automatic	30 ms to 4 s (large focus) 30 ms to 4.5 s (small focus)	

X-ray tube unit	
Mammography X-ray tube unit with double-focus rotating anode	
Focal spot nominal value	Tungsten focal spot: 0.15 / 0.3 (IEC 60336)
Anode-filter combinations	W / Al (1.0 mm) for 2D W / Ti (1.3 mm) for TiCEM W / Al (0.7 mm) for Tomo
Nominal voltage	49 kV
Heat storage capacity (tube unit)	1,310,000 HU; 970,000 J
Heat storage capacity (anode)	238,000 HU; 176,000 J
Optical anode angle	22° (relative to detector)
Inherent filtration	1 mm Be
Anode speed	≥ 7,800 rpm ≤ 9,000 rpm
Max. Power	5 kW (large focal spot) 1.3 kW (small focal spot)

System specifications

Flat detector

Solid-state detector of amorphous selenium (aSe)				
Detector size	24 cm x 30 cm (9.5" x 12")			
Material	Amorphous selenium (aSe)			
Conversion	direct-to-digital			
Pixel size	85 µm x 85 µm squared			
Image matrix	2816 x 3584 (24 cm x 30 cm / 9.5" x 12")			
Output Image Format	16 bit (for Processing)			
Analog to Digital conversion	16 bit depth			
Uncertainly index	$U \leq 1.5 \times 10^{-3}$			
Spatial frequency (MTF)	Spatial resolution power			
	(lp/mm)	Average	Horizontal	Vertical
	1/mm	0.93	0.95	0.91
	2/mm	0.85	0.89	0.81
	3/mm	0.75	0.79	0.81
	4/mm	0.65	0.69	0.60
	5/mm	0.55	0.60	0.50
	5.88/mm	0.45	0.50	0.40
DQE	at 1 lp/mm		> 65% at 150 µGy detector entrance air kerma	
DQE	at Nyquist frequency		> 25% at 60 µGy detector entrance air kerma	

Exposure formats

Exposure format according to used paddle size indicated by collimator light	
Survey exposure	24 cm x 30 cm (9.5" x 12") 18 cm x 24 cm (7" x 9.5")
Detail exposure	9 cm x 9 cm (3.5" x 3.5") 6 cm x 6 cm (2.4" x 2.4")
Axilla exposure	8 cm x 20 cm (3" x 8")

System specifications

PC hardware / software	
Workstation	Intel Core i3-10100E, 3.2 GHz, 32 GB RAM 4 TB hard disk with 3.5 TB data storage capacity for image data Data storage capacity sufficient for up to 175.000 images (20 MB per image) or ~ 2300 tomosynthesis scans (1.5 GB per scan for 50 mm breast thickness)
Operating system	Windows 10 operating system with *syngo*-based applications and proactive virus protection (whitelisting)

Displays	
1MP 19“ TFT color display	
Screen size	19“ (48 cm)
Image matrix	1280 x 1024
Maximum brightness, typical	350 cd/m^2
Horizontal/vertical viewing angle	178° / 178°
Contrast ratio, typical	2000 : 1
3MP 21“ TFT color display [1)]	
Screen size	21.3“ (54.1 cm)
Image matrix	1536 x 2048
Maximum brightness, typical	1100 cd/m^2
Horizontal/vertical viewing angle	178° / 178°
Contrast ratio, typical	1800 : 1

[1)] *Option*

Clinical workflow

Patient data administration	
Patient directory	Input of patient data (e.g. patient name, patient ID, date of birth), patient search Input via keyboard or directly via DICOM Modality Worklist[1)]

Image acquisition/display/processing	
Acquisition and preprocessing	Selection of pre-configured examination procedures or personalized configuration
Digital mammography	Digital technique with 2816 x 3584/16-bit matrix, digital filtration
Image processing – OpView	Pre-configured image flavors about following parameters: Contrast/brightness (Adjustable by customers) Edge enhancement Dynamic range control Noise reduction Detection of breast border Electronic shuttering
Text/graphic functions	Image orientation label Image annotation and comment Length and angle measurement Interactive zoom and pan Gray-scale inversion Split screen (2/4/16 on 1)
Integrated system operation	User programs with customized predefined parameter sets Preselection of patient orientation for automatic image orientation
Images lossless compression algorithm	JPEG Lossless Process 14 (selection value 1)
Automatic query of prior patient information	Automatic pre-fetching of prior images, studies and SR Reports of scheduled patients

[1)] Requires an information system that can provide a DICOM Modality Worklist

Clinical workflow

DICOM Images	
2D images	DICOM MG for processing and presentation
Tomo projection images	DICOM MG for processing and presentation
Tomo slices and Insight 3D	DICOM BTO
Insight 2D	DICOM MG for presentation
Biopsy Stereo Images	DICOM MG for processing and presentation
Biopsy Tomo Images	DICOM BTO
Biopsy InSpect	DICOM MG for processing and presentation
Combined Contrast Enhanced image Insight CEM	DICOM MG for presentation

Structure Reports	
Radiation Dose Report	DICOM X-Ray Dose SR
Insight BD Report	DICOM CAD SR

Clinical workflow

Data transfer and documentation	
DICOM network interfaces	
DICOM interface for image data communication based on the DICOM 3 standard	
DICOM Basic	DICOM Storage (Send/Receive) Sending and receiving of images DICOM Query/Retrieve Retrieval of studies from a digital archive, a workstation or other imaging systems DICOM Storage Commitment Archiving confirmation from the image archive
DICOM Basic Print	DICOM Print For connection to a DICOM-compatible camera or DICOM-compatible printer
DICOM HIS/RIS	DICOM Worklist Management For importing patient/examination data from an independent HIS/RIS system, including HIS/RIS queries via special search criteria MPPS (Modality Performed Procedure Step) For exporting examination data, including dose parameters, to an independent HIS/RIS system
DICOM Insight Breast Density Structured Report (InBD SR)	Information of the breast density calculation of the volumetric density assessment from digital x-ray images of the breast to aid healthcare professionals in the assessment of breast tissue composition The object is created during the end of examination. These objects can be automatically transferred for documentation or further evaluations to dose registries or archives
DICOM X-Ray Radiation Structured Report	Details of radiation exposure resulting from examinations is stored in DICOM X-Ray Radiation Structured Report (X-Ray Dose SR), which are created during end examination. These objects can be automatically transferred for documentation or further evaluations to dose registries or archives
Documentation	
DVD / CD burner	Writing of images in DICOM format to DVD/CD (multisession)
DICOM Basic Print	Follow DICOM 3 standard

Clinical workflow

IHE Integration Statement	
Mammography Image / Breast Tomosynthesis	The images contain all the relevant information for optimal display on workstations supporting this profile
Scheduled Workflow	Consistent data flow, from planning at the RIS through examination to storage in the PACS
Portable Data for Imaging	Reliable exchange of image data via external CD and DVD drive
Access to Radiology Information	Connection to the DICOM archive, typically used for fetching prior studies from the PACS
Consistent Presentation of Images	Print Composer is implemented
Mammography Acquisition Workflow	Handles mammography-specific exceptions like correction of view and laterality, and rejection of images

Smart Remote Service (SRS) [1) 2)]
Connect MAMMOMAT B.brilliant to the service experts in our Customer Care Center
Allows remote diagnosis of software and hardware
Allows remote system configuration, e.g. adding a DICOM node
Enables delivery of remote software updates
Remote Assist (based on TeamViewer) enables screen sharing between you and our application specialists for realtime support

[1)] Option
[2)] Special requisites are necessary at customer site (e.g. Smart Remote Service Connection)

Clinical workflow

Cyber Security	
Secure product lifecycle	Threat and Risk Analysis, Secure Architecture & Design, Secure Configuration and Hardening, Secure Coding & Testing with Vulnerability Scanning, Penetration Testing
Whitelisting	Malware protection based on Microsoft Device Guard
Hard disk encryption	Encryption of patient data on internal hard disk with Bitlocker (on customer request)
IPv6	It is possible to configure IP adresses in IPv4 or IPv6 format
High frequency hotfix delivery	Providing hotfixes for 3rd party components (e.g., Microsoft) every 90 days [2)]
Advanced security package [1)]	Advanced user management: Active directory integration Individual password management and user authorization
Audit trail management	Detailed tracking of user and system actions and centralized automated logging

[1)] *Option*
[2)] *Special requisites are necessary at customer site (e.g. Smart Remote Service Connection)*

Breast Tomosynthesis

50° PlatinumTomo

In a 2D mammogram, breast tissue can overlap, hiding or mimicking cancer. Tomosynthesis can help to overcome these challenges, by displaying breast tissue in layers through individual slices.

PlatinumTomo is the combination of 50° Wide-Angle tomosynthesis, a flying focal spot tube, a new detector, and a new image reconstruction pipeline (UltraHD PREMIA). PlatinumTomo delivers the highest depth resolution[1)] in tomosynthesis available in mammography and combines it with an impressive in-plane resolution and acquisition speed.

50° Platinum tomo incl. flying focal spot technology, enabling a tomo scan in less than 5 sec with brilliant image quality for uncompromised cancer detection [2)]

Each of the 25 projections acquired in tomosynthesis imaging use just a fraction of the dose that is used for single FFDM image acquisition

UltraHD PREMIA – A reconstruction algorithm calculates the individual slices from the projections for display on the AWS or reading workstation.

16 bit images in tomosynthesis unleash full detector potential and improved image processing

Optimized workflow through
– Reconstruction of tomo volume in the background: 10 4-views exams/hour [3)]
– Immediate quality control: the first pulse is used for the calculation of the AEC (Automatic Exposure Control) and instantly displayed as an image
– Automatic removal of the grid for tomosynthesis exposures

50° TomoFlow enables reconstruction of tomosynthesis volume in the background making it independent from image acquisition. Continue seamlessly to the next view without waiting for images to reconstruct.

Insight 2D & Insight 3D: Tomosynthesis slices visualized in a synthesized 2D or rotating 3D image.
Possibility to choose between different image flavors for seamless integration into your existing workflow.

Tube angulation	± 25°	
Scan time	< 5 seconds	for average breast size of 5 cm, 50/50% glandular/adipose tissue
	< 10 seconds	for high breast thickness and breast density
Number of projections	25	
Pixel size tomosynthesis	85 µm	
Distance between reconstructed slices	1 mm	
Reconstruction algorithms	Analytical or a unique combination of iterative and machine-learning algorithms for UltraHD PREMIA	
Data volume	20 MB per projection max. 20 MB per slice, depending on breast size	
Display on AWS	Projections; Reconstructed slices; Cine mode; Dose / projection; Dose / scan	

[1)] Maldera A, De Marco P, Colombo PE, Orrigi D, Torresin A. Digital breast tomosynthesis: Dose and image quality assessment. Phys Med. 2017; 33: 56–67.
[2)] For more details on the scan time, please see below.
[3)] Data on file

Breast Biopsy Option

Biopsy unit
The biopsy unit is used for automatic stereotactic and tomosynthesis-guided biopsy with MAMMOMAT B.brilliant
The biopsy unit includes a handbox for controlling the needle positioning device, a standard needle holder, a face shield to protect the patient from swivel arm movements, and calibration accessories
InSpect – Integrated functionality for specimen scanning directly on the system.
The biopsy unit is simply slid onto the object table
Full motorized movement of needle holder in X, Y and Z axis
The biopsy unit is automatically detected by MAMMOMAT B.brilliant and can immediately be used for biopsies from any projection (e.g. CC, MLO). Compatible with a wide range of different biopsy devices for core & vacuum biopsy and also needle guides for fine needles
The biopsy workflow is highly automated. The position of the tube for the stereo pair acquisition can be controlled at the AWS and thanks to one-click targeting the needle holder will automatically move in the position that it needs to be for a successful biopsy
Stereotactic and tomosynthesis-guided biopsy can be performed on seated and recumbent patients
OpView processing ensures the 2D image impression is identical for biopsy, screening, and diagnostic imaging.
UltraHD PREMIA image reconstruction ensures the tomosynthesis image impression is identical for biopsy, screening, and diagnostic imaging.
Spacer Plate[1)] is recommended to increase the distance of the breast from the detector for easier access with lateral approach, especially for smaller breasts (breast thickness < 30mm)
Worklight for better illumination during biopsy
Navigator display of needle orientation, safety distance, distance to paddle as guidance during targeting

Biopsy volume (vertical needle guidance)	50 mm x 40 mm x 100 mm (2" x 1.6" x 3.94") (w x d x h)
Biopsy volume (lateral needle guidance)	100 mm x 40 mm x 77 mm (3.94" x 1.6" x 3") (w x d x h) (with currently available needle holder)
Tube swivel range in stereo mode	– 15° and + 15°
Tube swivel range in tomosynthesis mode	– 25° till + 25° with 25 projections
Biopsy compression plate with window imaging area	96 mm x 100 mm (3.8" x 3.94") (window size 57 mm x 46 mm [2" x 1.8"], vertical needle guidance)
Biopsy compression plate without window imaging area	96 mm x 100 mm (3.8" x 3.94") (lateral needle guidance)
Weight of biopsy unit	< 5 kg
Biopsy unit measures	46 cm x 26 cm x 40 cm (18.1" x 10.2" x 15.7")

Options / Accessories

Insight Breast Density [1)]

Insight BD delivers automated breast density measurements at the point of examination

Titanium Contrast Enhanced Mammography (TiCEM)

Titanium Contrast Enhanced Mammography for functional breast imaging directly on the mammography system.

TiCEM can help to detect or rule out lesions in difficult cases and can be a cost-effective alternative to MRI as an supplementary examination. It can help to reduce scheduling conflicts on other modalities.

[1)] *Insight Breast Density is not an interpretive or diagnostic aid and should be used only as adjunctive information when the final assessment of breast density category is made visually by medical professionals*

Options / Accessories

Overview of options	
Compression plates	Compression plate with low edge, 18 cm x 24 cm (7" x 9.5") Compression plate with high edge, 18 cm x 24 cm (7" x 9.5") Compression plate with low edge, 24 cm x 30 cm (9.5" x 12") [1)] Compression plate with high edge, 24 cm x 30 cm (9.5" x 12") Flexible compression plate with high edge, 18 cm x 24 cm (7" x 9.5") Flexible compression plate with high edge, 24 cm x 30 cm (9.5" x 12") Shifting paddle with high edge, 18 cm x 24 cm (7" x 9.5") Shifting paddle with low edge, 18 cm x 24 cm (7" x 9.5") SoftComp compression plate with high edge, 12 cm x 24 cm (4.7" x 9.4") [1)] SoftComp compression plate with high edge, 18 cm x 24 cm (7" x 9.4") [1)] SoftComp compression plate with high edge, 20 cm x 26 cm (7.9" x 10.2") [1)] Spot Plus compression plate [1)] Spot Focus compression plate, 6 cm x 6 cm (2.4" x 2.4") Detail / spot compression plate, 9 cm x 9 cm (3.5" x 3.5") Axilla compression plate, 8 cm x 20 cm (3" x 8") 2D biopsy compression plate 2D biopsy attachement with crosshair assembly Compression plate 25 cm x 36 cm (10" x 14") Compression plate 24 cm x 30 cm (9.5" x 12")
Magnification attachment	Magnification table 1.5 / 1.8 Magnification compression plate, 16 cm x 20 cm (6.5" x 8") Mag Spot compression plate, 9 cm x 9 cm (3.5" x 3.5") Mag Focus compression plate, 6 cm x 6 cm (2.4" x 2.4")
Control desk	Operator console with radiation shield, 0.5 mm lead equivalent
Radiation release	Foot switch / Hand switch
Wall holder	Holder for 4 compression plates
Mobile installation	Mobile installation kit

[1)] *Usable for tomosynthesis*

Room planning

Operating data	
Power requirements	208 V, 220 V, 230 V, 240 V, ± 10 %, single-phase, 50/60 Hz ± 3 Hz; 208 V, 220 V, 230 V, 240 V, ± 10 %, two-phase, 50/60 Hz ± 3 Hz

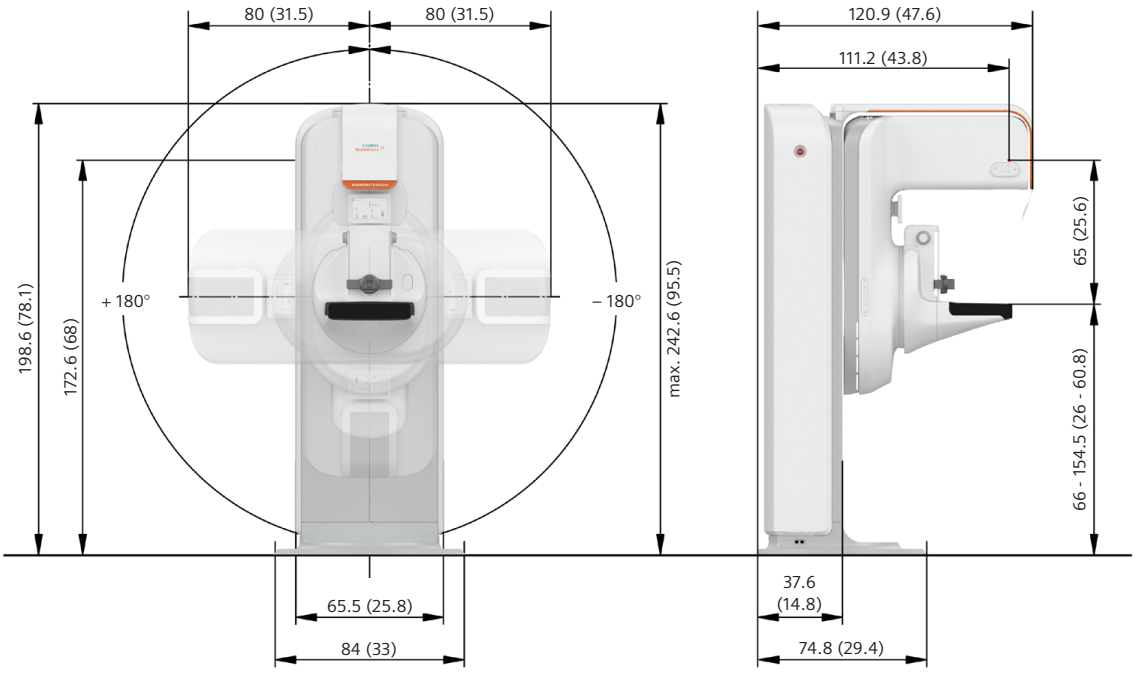
Power consumption	
Mains Power	7.5 kVA (short term) 0.5 kVA (continuous)

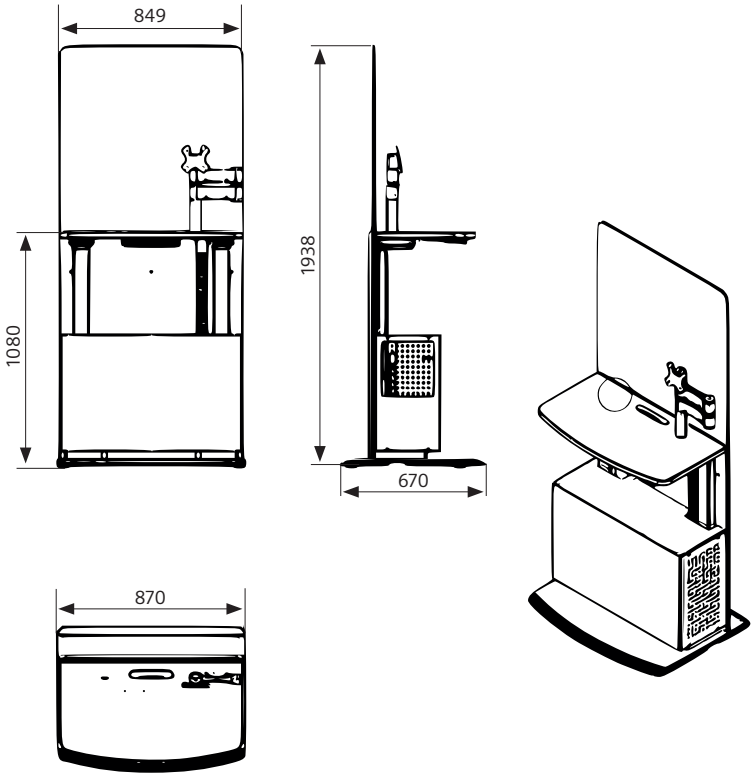
Weight	
Examination stand and generator	350 kg (770 lbs)
Control desk with radiation shield	124 kg (275 lbs)

Environmental conditions (operation)	
Temperature range	+ 12 °C to + 35 °C, maximum fluctuation of temperature < 10 °C / 60 min.
Relative humidity	30 % to 75 %, non-condensing
Atmospheric pressure	700 hPa to 1060 hPa

Room planning

Dimensions in cm (inches)





MAMMOMAT B.brilliant VA10 is not yet available in all countries. Due to regulatory reasons its future availability cannot be guaranteed. Please contact your local Siemens Healthineers organization for further details.

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For recycled components we use the same extensive quality assurance measures as for factory-new components.

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