

CLINODIGIT OMEGA SYSTEM

Multifunctional DR+DRF system with
Dynamic Flat Panel Detector

Product Data



One system
All examinations
No compromises

REV. 9 (May 2017)

CLINODIGIT OMEGA SYSTEM

CLINODIGIT OMEGA is a revolutionary system that allows to perform ALL TYPES of DIGITAL RADIOGRAPHY and DIGITAL RADIO-FLUOROSCOPY EXAMS with one single compact unit.

CLINODIGIT OMEGA is equipped with a latest-generation 43cm x 43cm (17" x 17") DYNAMIC FLAT PANEL DETECTOR, thus ensuring exceptional image quality, unsurpassed productivity, and minimal patient dose.

CLINODIGIT OMEGA, thanks to its innovations, dramatically enhances departmental productivity and efficiency, while providing maximum comfort and safety for both patients and operators.

CLINODIGIT OMEGA is a



DIGITAL RADIOGRAPHY SYSTEM



DIGITAL FLUOROSCOPY SYSTEM



DIGITAL CHEST IMAGING SYSTEM



DIGITAL EMERGENCY ROOM SYSTEM

CLINODIGIT OMEGA:

- ✓ guarantees superb image quality and minimal dose thanks to the extremely high sensitivity, resolution, and contrast of its dynamic flat panel detector
- ✓ enables department productivity enhancement since all examinations can be performed on one single unit thus perfectly adapting to varying morning/afternoon exam type mixes, with maximum return on investment and system utilization
- ✓ delivers an overall costs reduction thanks to its minimized space requirements and reduced training, personnel, and service costs for only one system
- ✓ provides unsurpassed patient comfort with its extremely low tabletop height and the capability of head-to-toe scanning, on both tabletop or external mobile table, with no patient movement
- ✓ is characterized by intuitive ease of use with its innovative touch-screen operator console with exam specific predefined working positions and system settings
- ✓ ensures total connectivity with external RIS/PACS systems via its proven and versatile DICOM 3.0 layer.

CLINODIGIT OMEGA SYSTEM

TYPICAL EXAMINATIONS FULLFILLED WITH CLINODIGIT OMEGA SYSTEM



AP thorax exam with 200 cm SID



Full-spine on a supine patient



Weight bearing lateral projection for lower limbs



Merchant projection



Tomography and movements for Tomosynthesis reconstruction



Lateral projection on a stretcher



Exam with contrast medium



Trendelenburg

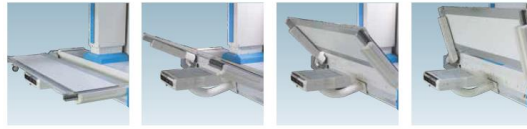


Fluoroscopy with compression procedure

MAIN CARACTERISTICS

TTT (Tilting-Table-Top) MOVEMENT

Tabletop motorized movement that removes patient table from detector active area, ALL RADIOGRAPHY EXAMS are now possible with no limitation due to the tabletop presence (exams on a stretcher, exam in contact with detector ...).



Furthermore, this movement reduces patient-detector distance and permits patient positioning with no impediments for perfect projections.

BEST-IN-CLASS 200 CM FOCAL DISTANCE

All distortions are eliminated for chest imaging, improving outstanding image quality. This represents an important feature also for full-spine imaging for stitching procedure.

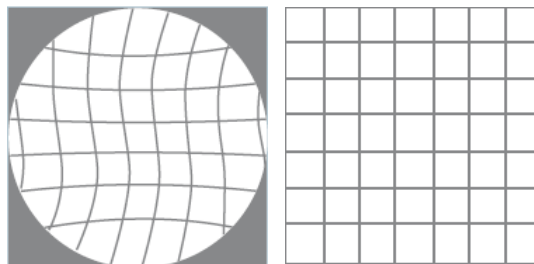


DYNAMIC FLAT PANEL DETECTOR

CLINODIGIT OMEGA is based on a dynamic flat panel detector featuring amorphous Silicon (a-Si) technology and a Caesium Iodide (CsI) scintillator. With this 43cm x 43cm detector, every anatomical districts can be imaged.



Comparison with a 16" II.



The Flat Panel Detector removes the distortion problem typical of systems with Image Intensifier.

Its 16-bit acquisition depth guarantees for an incredible greyscale dynamic range where most subtle details and the most diverse structures can be easily identified without further image retakes.

MAIN CHARACTERISTICS

ALL-IN-ONE TOUCH SCREEN CONSOLE AND PREDEFINED WORKING POSITIONS

All motorized movements (tabletop, column, x-ray tube and detector), are strongly controlled by the "All-In-One" touch screen console positioned in the control room



Predefined system working positions guarantees an unmatched ease of use. Operators can perform the entire examination from the control room hence eliminating any risk of X-ray exposure.

TOTAL PATIENT ACCESSIBILITY

For the minimum height of patient table, access to examination is granted also to disabled patient, which can be positioned on tabletop without any risk of further traumas.



With patient tabletop at minimum height, CLINODIGIT OMEGA SYSTEM is operative for all examinations, without having to be repositioned to centre of the system, since any further movement can be traumatizing for already injured patients.

90/90 FULLY SIMMETRIC

Footrest can indifferently be positioned both on the right and on the left side.



AUTOMATIC STITCHING^(*)

The Stitching function involves the automatic acquisition and re-composition of a set of radiography images. Each time a different section of the patient is irradiated until a complete large format image is obtained. This function is fully automatic and typically used for exams concerning the full-spine or full-leg imaging.



Graphic functions ^(*) available for Stitching exams:

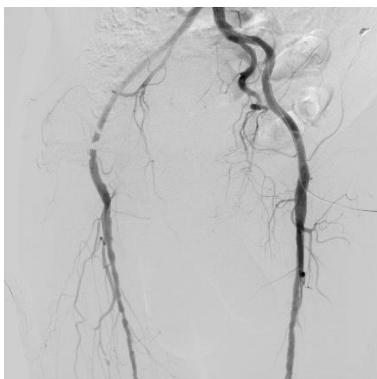
- Level difference;
- Cobb angle;
- Double Cobb angle;
- Right-angle lines;
- Leg measurements;
- Manual Stitching

^(*) Optional

MAIN CHARACTERISTICS

ANGIOGRAPHY – DSA – ROADMAPPING^(*)

Acquisition of radiography images in DSA mode, with variable acquisition rate during exam procedure and automatic start of injector with acquisition (x-ray emission).



- Functions available with DSA ^(*):
- Stenosis measure
 - QA Software: to study vessels and stenosis in angio images. The QA function identifies automatically the outline of a section of a vessel and measure its stenosis:
 - reference diameter;
 - min diameter within section;
 - mean diameter of stenosis;
 - mean percentage of stenosis.

This function is selected on angio exams to monitor the passage of the contrast medium in consecutive vessels.



- Angio functions:
- Mask pickup;
 - Shifting mask;
 - Image subtraction;
 - Pixel shift;
 - Vascular tracing
 - Land marking

3D VOLUMETRIC ACQUISITION (TOMOSYNTHESIS)^(*)

Tomosynthesis is a limited-angle 3D-technique that allows reconstruction of three-dimensional planes basing on the information contained in the images acquired during a tomographic acquisition. Tomosynthesis eliminates overlapping structures, increases the separation of adjacent tissues, and provides in-depth information about the structures of interest.



^(*) Optional

CONTROL AND SAFETY

COLLISION PREVENTION

All automatic movements are software controlled, in order to avoid collision with surrounding environment (floor, ceiling, walls). The geometric limits of the room within moving the system without collisions are set via software.

Optical sensors around the tube avoid collisions during SID variation, just stopping the column once an obstacle is detected.



In addition to keep everything under control, each movement is only of intentional type (deadman).

TECHNICAL SPECIFICATIONS

MOVEMENTS

Tilting	±90° (footrest can indifferently be positioned both on the right 90° and on the left side). Motorized.
Tilting speed	Max. 6°/s
Table top longitudinal travel	Complete patient coverage is guaranteed by the long travel of column/detector assembly
Table top transversal travel	30 cm [-15; +15] cm. Motorized
Tabletop transversal speed	Max. 5 cm/s
Table top vertical travel	Motorized. 51 cm (from 49 cm to 100 cm). 91 cm (from 49 cm to 140 cm) ^(*)
Tabletop vertical speed	6 cm/s
Table top tilting (TTT Movement)	90°. Motorized
Column longitudinal travel	145 cm. Motorized
Column longitudinal speed	12 cm/s
SID	From 115 cm to 200 cm (with programmed stops: 150 cm and 180 cm). Motorized
SID travel speed	6 cm/s
Tube rotation	±45°. Motorized
Tube rotation speed	10°/s
Detector longitudinal travel	145 cm. Motorized
Detector longitudinal speed	12 cm/s
Patient exploration	188 cm just with the movement of tube and detector, with no patient repositioning

TECHNICAL SPECIFICATIONS

PATIENT TABLE

Length	229,4 cm
Width	74 cm
Composition	- Polycarbonate. - Carbon fibre ^(*)
Filtration for standard table top	< 0,5 mm Al eq @ 70 kVp
Table top – Detector distance	7,5 cm
Detector surface – Image receptor distance	2,8 cm
Max. patient weight (full operation)	205 kg
Max. patient weight (limited movements)	230 kg

GRID

Grid Control	Yes. Automatic
Grid extraction	Yes
Grid type	Stationary
Standard grid	SID: 140 cm - Ratio: 12 - 80 lp/cm
Additional grids	Yes ^(*) . SID: 160 cm - Ratio 12 - 80 lp/cm

COMPRESSOR ^(*)

Compression force (kg)	Set by 3 buttons of programmable values. Halfway steps are 5 kg, 10 kg, and 15 kg
Minimum distance compressor cone/tabletop	10 cm

TOMOGRAPHY ^(*)

Angles	10°, 20° and 40°
Speeds	FAST mode: 280 mm/s SLOW mode: 187 mm/s
Tomography exposure times	FAST mode: 2 s (layer height=300 mm, angle=40°) SLOW mode: 3 s (layer height=300 mm, angle=40°)
Tabletop height	From 49 to 86 cm
Layer height	From 0 to 300 mm

TOMOSYNTHESIS ^(*)

Angle	40°
Acquired images	60
Acquisition rate	8 img/s
Exposure duration	From 4,3 to 10 s
Scan duration	From 6 to 12 s

^(*) Optional

CLINODIGIT OMEGA SYSTEM

TECHNICAL SPECIFICATIONS

H. V. GENERATOR	Pixel DRF 65 kW	Pixel DRF 80 kW ^(*)	Pixel DRF 100 kW ^(*)
Switching frequency	Up to 400 kHz		
Output power	65 kW	80 kW	100 kW
Low ripple	< 1%		
Dual Speed Starter	Yes		
Radiography kV range	40 - 150 kV		
Fluoroscopy kV range	40 – 125 kV		
Radiography mA range	10 - 800 mA	10 - 1000 mA	10 - 1000 mA
Continuous Fluoroscopy mA range	0,5 – 20 mA		
Pulsed Fluoroscopy mA range	5 - 99 mA		
mAs	0,1 – 1000 mAs		
Exposure time	1 - 6300 ms		
Anatomical programs	Yes. Unlimited and managed by acquisition workstation		
Independent Operation	Yes. X-ray Generator can also work independently with other imaging supports i.e. film and/or CR		
Dose Area Product (DAP)	Yes ^(*) , With dose information stored in image DICOM header		

TECHNICAL SPECIFICATIONS

X-RAY TUBE

Type	Rotating anode		
Anode speed	3000 and 10.000 routes/min		
Tube construction	RT-TZM-C		
Tube voltage	Up to 150 kV		
Anode Storage Capacity	1120 kHU		
Maximum heat dissipation rate	160.000 HU/min		
Maximum tube assembly heat content	1700 kHU		
Target angle	13°		
Focal spot number	2		
Focal spot size	Standard: 0,6 x 0,6 mm (s. f.) 1,2 x 1,2 mm (l. f.)	Option 1 ^(*) : 0,6 x 0,6 mm (s. f.) 1,0 x 1,0 mm (l. f.)	Option 2 ^(*) : 0,4 x 0,4 mm (s. f.) 1,0 x 1,0 mm (l. f.)
Focal spot power	P _{max} =37 kW (s. f.) P _{max} =100 kW (l. f.)	P _{max} =40 kW (s. f.) P _{max} =80 kW (l. f.)	P _{max} =18 kW (s. f.) P _{max} =80 kW (l. f.)
Inherent filtration	0,7 mm Al		

COLLIMATOR

Collimation	Automatic, square field (48 x 48 cm @ 90 cm), remote-controlled
Display	Yes. LCD and touch screen.
Al eq contribution to total filtering	Min 1,2 mm Al
Additional filtration	Automatic, based on selected exam: <ul style="list-style-type: none"> • 0 mm Al • 1 mm Al + 0,1 mm Cu • 1 mm Al + 0,2 mm Cu • 2 mm Al + 0,3 mm Cu

^(*) Optional

TECHNICAL SPECIFICATIONS

DIGITAL IMAGING SYSTEM

FLAT PANEL DETECTOR	Pixium 4343 FL
Detector type	Dynamic
Technology	Amorphous silicon
Scintillator	Cesium Iodide (CsI)
Format (ISO 4090)	43 x 43 cm
Effective Pixel matrix	2880 x 2880 pixels
Image depth	16 bit
Pixel pitch	148 µm
Image transfer time	1 s (no preview)
Typical DQE (@ 0 lp/mm RQA5)	65%
Modulation Transfer Function (MTF)	@ 1 lp/mm: 55% @ Nyquist: 7%
Spatial resolution	3,4 lp/mm

ACQUISITION AND POST-PROCESSING WORKSTATION: X-FRAME DRF@

HARDWARE

HDD	System hard disk: 250 GB Hard disk for image archive: SATA2 250 GB (320 GB / 500 GB / 1TB available on request)
CPU	Intel® Core™ i7
RAM	8 GB
CD/DVD recorder	Yes ^(*) . External via USB 2.0 port
Operating system	Windows 7 (64bit)
UPS	Yes ^(*) . Emergency power unit system for safe and controlled switch off preventing any data loss or damage
N° storable images	> 16.000 img high resolution for standard HDD

STANDARD MONITOR

Type	Medical Grade LED Color Display, 1,3 MP
Size	19"
Recommended resolution	1280 x 1024
Contrast	2000:1
Brightness	300 cd/m ²

ACQUISITION MODALITY

Continuous fluoroscopy	16 fps (Active area: 43x43 cm) 12 fps (Active area: 30x30 cm) 20 fps (Active area: 20x20 cm) 6 fps (Active area: 15x15 cm)
Pulsed fluoroscopy	1 ... 12 fps (Active area: 43x43 cm / 30x30 cm / 20x20 cm) 1 ... 6 fps (Active area: 15x15 cm)
Radiography	0,5 ... 6 fps (Active area: 43x43 cm)

^(*) Optional

TECHNICAL SPECIFICATIONS

ACQUISITION AND POST-PROCESSING WORKSTATION: X-FRAME DRF@

SOFTWARE

Image acquisition time	For diagnostic image: 1 s
Image size	15,6 MB (high resolution radiography) 2 MB (pulsed fluoro)
Image enhancement	everest-X
Real time processing	<ul style="list-style-type: none"> ▪ Pulsed fluoroscopy/ continuous fluoroscopy ▪ Harmonization ▪ Auto ROI ▪ DSA ^(*): <ul style="list-style-type: none"> - Peak opacification - Road mapping - Digital Subtraction - Auto Masking
Display functions	<ul style="list-style-type: none"> ▪ Oriented Exam LUT ▪ Spatial filters ▪ Harmonisation ▪ H&V image reverse ▪ 90° image rotation ▪ Electronic shutters (square and circular) ▪ Reverse image polarity ▪ Multi-image display ▪ Scaled image, variable (from 1.0 to 2.9) ▪ Zoom, variable (from 1.0 to 3.0) ▪ Brightness and contrast control ▪ Reference images ▪ DSA ^(*): <ul style="list-style-type: none"> - Remasking - Land Marking - Pixel shift - Vascular tracing - QA Analisis
Graphics (overlay)	<ul style="list-style-type: none"> ▪ Grid ▪ Distances ▪ Angles ▪ Text and marker overlay ▪ Virtual collimator ▪ COBB angle and orthopaedic measurement
APR	YES, preconfigured and editable
Exposure Index	YES
Deviation Index	YES
Multi-language	English, Italian, Spanish, French, ...
STITCHING ^(*)	
Image Paste	Automatic (manual stitching also available)
Max. n° of images	3
Max. length	120 cm
Time for acquisition and reconstruction	From 15 s to 45 s (it depends on the number of images requested to inspect the complete anatomic area)

^(*) Optional

TECHNICAL SPECIFICATIONS

NETWORKING

DICOM functions

DICOM Storage (SCU)	Yes. Send Image to PACS
DICOM Modality Worklist (SCU)	Yes. Interface with HIS / RIS with auto refresh option
DICOM Print management Class	Yes. Covers the general cases of printing medical images in standardized layouts.
DICOM Media exchange (DICOM DIR)	Yes ^(*) . Patient images export to DVD/CD
DICOM MPPS (SCU)	Yes ^(*) . Send the status of exams to HIS / RIS
DICOM Storage commitment (SCU)	Yes ^(*) . Send commitment status
DICOM Query / Retrieve (SCU)	Yes ^(*) . Query and retrieve images from PACS

IHE Integration Profile

Scheduled Workflow	Acquisition Modality : Patient Based Worklist Query / Assisted Acquisition protocol Setting / PPS Exception Management
Patient Information Reconciliation	Acquisition Modality
Consistent Presentation of Image	Acquisition Modality
Radiation Exp. Monitoring	Acquisition Modality
Network	Ethernet TCP/IP

REMOTE ASSISTANCE

Remote access	CLINODIGIT OMEGA SYSTEM is equipped with a remote service system that allows ITALRAY service engineers to have access the system via remote network for servicing and upgrading purposes. The remote servicing system availability is subordinate upon the technical/policy characteristics of the local Hospital network
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^(*) Optional

CLINODIGIT OMEGA SYSTEM

TECHNICAL SPECIFICATIONS

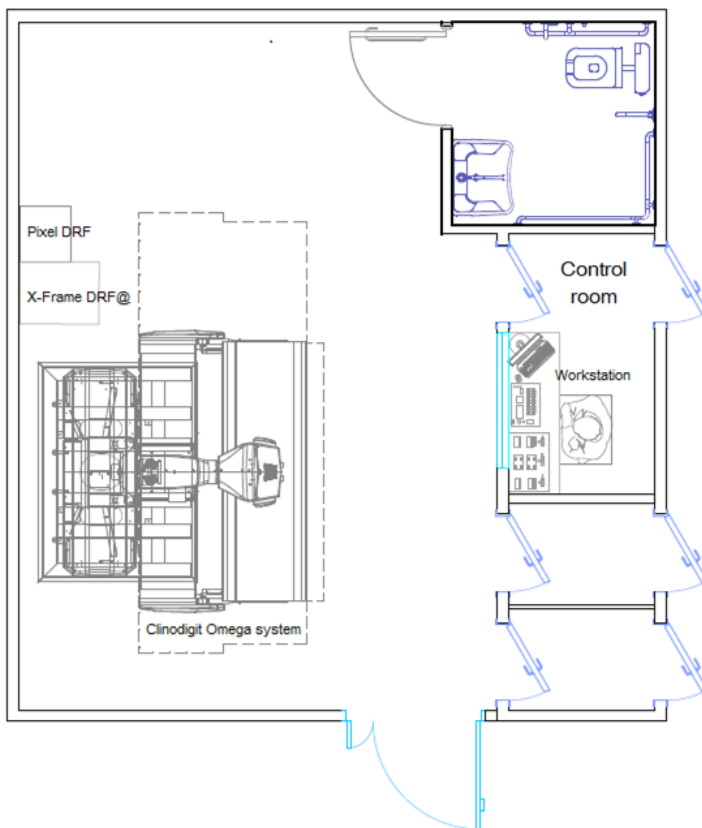
INSTALLATION DATA

Power supply	380 Vac +/- 10%, 50/60 Hz (Optional 220 Vac)
System (CLINODIGIT OMEGA)	DIMENSIONS: 249 x 238 x 183 cm WEIGHT: 1690 kg (with accessories)
Generator cabinet (PIXEL DRF)	DIMENSIONS: 50 x 41 x 105 cm WEIGHT: 91 kg
System cabinet (X-FRAME DRF@)	DIMENSIONS: 65 x 52 x 88 cm WEIGHT: 120 kg

ENVIRONMENTAL CONDITIONS

OPERATING	
Temperature	15°C ÷ +35°C
Humidity	30% ÷ 75%
Atmospheric Pressure	700 mbar ÷ 1060 mbar
TRANSPORT AND STORAGE	
Temperature	10°C ÷ +55°C
Humidity	20% ÷ 80%
Atmospheric Pressure	500 mbar ÷ 1060 mbar

ROOM CONSIDERATION (TYPICAL LAYOUTS)

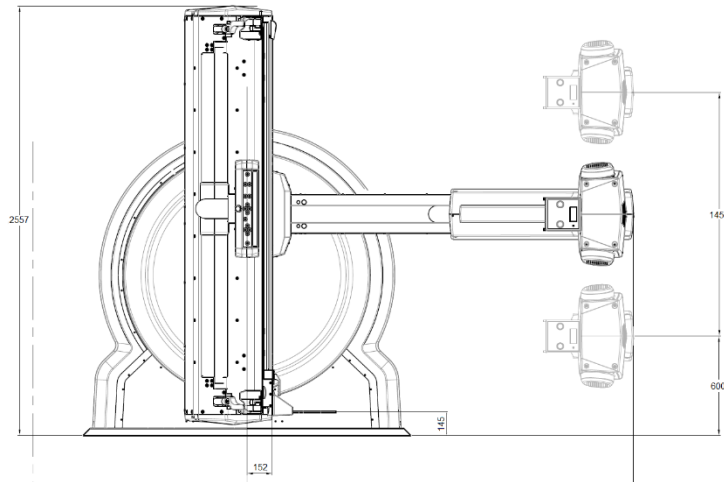


CLINODIGIT OMEGA SYSTEM

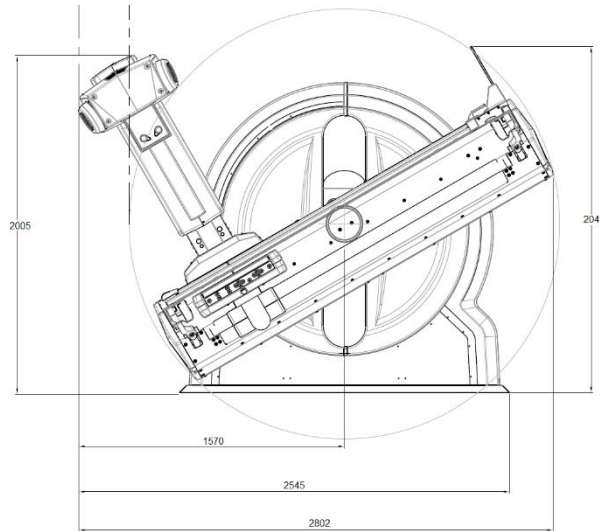
SIZE AND DIMENSIONS

CLINODIGIT OMEGA SYSTEM

FRONT VIEW

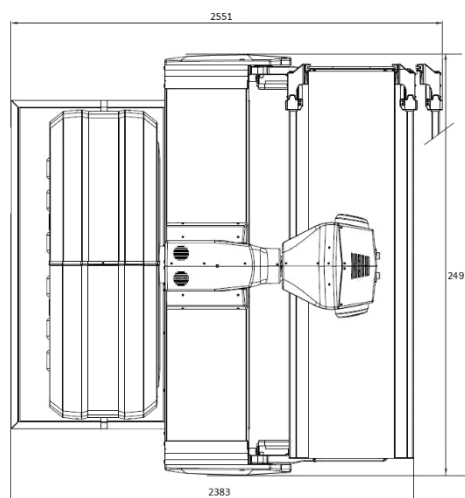


FRONT VIEW



SID: 120 cm – Tilting: 30°

TOP VIEW

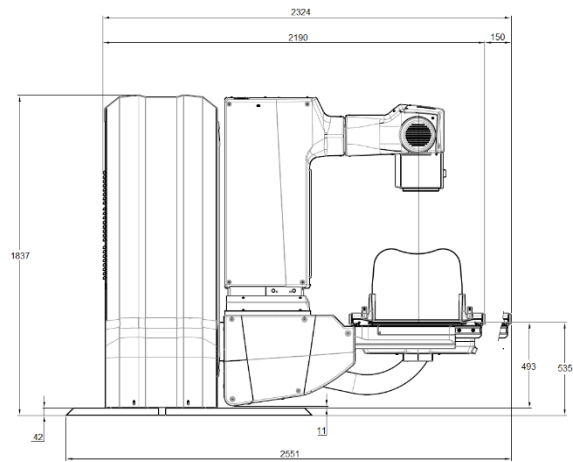


CLINODIGIT OMEGA SYSTEM

SIZE AND DIMENSIONS

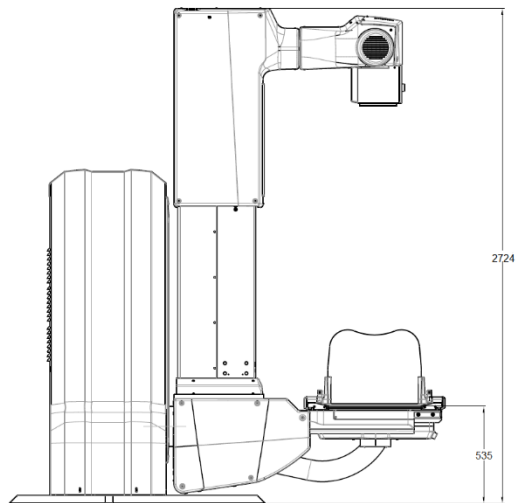
CLINODIGIT OMEGA SYSTEM

LATERAL VIEW



Min. SID – Min. tabletop height

LATERAL VIEW



Max. SID – Min. tabletop height

ACCESSORIES

REMOVABLE PATIENT FOOTREST



PATIENT HANDGRIPS



SHOULDER SUPPORT (*)



COMPRESSION BAND (*)



REMOTE CONTROLLED CONIC COMPRESSOR (*)



(*) Optional

ACCESSORIES

ARMPIT SUPPORT (*)



ACCESSORY FOR FULL-LEG/FULL-SPINE EXAMS (*)



RADIOTRANSSPARENT STRETCHER (*)



MOBILE TROLLEY FOR 1 OR 2 ADDITIONAL MONITORS IN EXAM ROOM (*)



(*) Optional

CERTIFICATION, INSTALLATION AND WARRANTY

CERTIFICATION

According to European Directive 93/42 CEE CLINODIGIT OMEGA SYSTEM is a class II b device. CLINODIGIT OMEGA SYSTEM has been developed in compliance with the UNI EN ISO 9001:2008 and UNI EN ISO 13485:2012. Moreover, CLINODIGIT OMEGA SYSTEM complies with the following Technical Norms:

- EN 60601-1:2006 Medical electrical equipment– Part 1: General requirement for safety.
- EN 60601-1-2:2007/AC:2010 Medical electrical equipment– Part 1: General requirement for safety. 2- Collateral standard: Electromagnetic compatibility – Requirements and tests.
- EN 60601-1-3:2008 Medical electrical equipment– Part 1: General requirement for safety. Collateral standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
- EN 60601-1-6:2007 Medical electrical equipment. - Part 1: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 62304:2006 Medical Device Software - Software life-cycle processes
- EN 60601-2-28:1993 Electrical Equipment Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis
- IEC 62366:2007 Medical devices - Application of usability engineering to medical devices
- EN ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN ISO 14971 Medical devices - Application of risk management to medical devices

INSTALLATION

Only authorized technical personnel that has been appropriately trained by ITALRAY can install CLINODIGIT OMEGA SYSTEM. Upon request, ITALRAY Installation Office can prepare system installation layouts (including eventual construction/electrical)

WARRANTY

ITALRAY guarantees its products for one year from the delivery date. ITALRAY can offer to its customers a wide range of service plans that will perfectly fit all needs and preferences

ITALRAY reserves the right to make modifications without any prior notice.



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