Product Data

Neeo C arm R9

X RAY SYSTEM

ibis
X RAY SYSTEMS

CSQ 9120.IBI1 · IQNet IT-30485 · CSQ MED 9124.IBI2 · CE 0051

Neeo C+ arm R9

X RAY SYSTEM

INDEX

IBIS S.r.l.
Headquarters: Via Cascina Bruciata, 3 I 24068 Seriate - Bergamo – Italy
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Premise

This document was created by IBIS in order to provide its customers and / or potential new customers with all the necessary information on the products; the purpose of this document is to group all the technical specifications of each device created by IBIS.

However, it is necessary to take into account that, according to the model chosen, it is possible to use different electrical, mechanical or radiological components which can be listed in the product technical dossier.
In the case of special requests, therefore, we invite you to contact our technical service that will send you all the details and technical specifications related to the configuration you have chosen.
The specifications indicated in this document refer to standard configurations.

IBIS designs and manufactures medical x-ray equipment for both the human and veterinary sectors. The human range includes Mobile Units, complete Radiology rooms, "C" arms for fluoroscopy examinations, Image Intensifiers and portable generators; for the veterinary sector we produce the CDR vet tables used both in multifunctional clinics and in veterinary clinics, "C" arms for clinics and portable units useful for in-field diagnostics or for radiological examinations on large animals.

The company operates worldwide through distributors that provide the end customer with direct technical support; all internal and external technicians are properly trained to solve any hardware and software problems.
The strong points of IBIS are the continuous commitment to develop new products, the relationship with the customer, the great reliability of the products and the technical assistance.

IBIS, as a manufacturer of imaging equipment, is constantly improving its products; we therefore invite you to download the most up-to-date revision concerning the product of your interest from the website www.ibisray.it.

If you need further technical details you can contact our technical department by contacting us by phone or by sending an e-mail to technical@ibisray.it; one of our technicians will answer you and give you all the required details.

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Company data and contacts

Below are the references to contact our staff:

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Headquarters: Via Cascina Bruciata, 3 – Seriate Bergamo – ITALY

Phone: 0039 035 4236343

Sales Department :	sales@ibisray.it
Technical Department :	technical@ibisray.it
Technical Assistance :	service@ibisray.it
Quality Department :	quality@ibisray.it
Administration :	administration@ibisray.it
General Information:	info@ibisray.it

General description

(Valid for the whole Neeo range)

Neeo "C" Arm is easy to move, position and use and is expressly designed for use in surgery, orthopedics, traumatology, abdominal surgery, urology. The radiological techniques available in the most complete version are:

Continuous fluoroscopy
Pulsed fluoroscopy
One Shot Fluoroscopy
Continuous, pulsed and one shot low dose fluoroscopy
Radiography with cassette.

The unit consists of a monitor trolley and a base with a "C" arm supporting the monobloc and the image intensifier.
The unit is supplied with a 40 kHz RX generator with 120 kV rotating anode tube (Neeo R9 / Neeo R12) or with a fixed 110kV anode (Neeo S9 / Neeo S12). Image intensifier 9 "and 12" with 3 fields zoom.

The maneuverability of the Neeo unit is facilitated by twin wheels and a steering system integrated into the main chassis. The brakes guarantee the stability of the equipment and prevent accidental movements during use or parking.
Every movement, from the revolution to the orbital rotation, can be locked by clamping levers.

The vertical movement is ensured by a powerful linear motor, which allows an excursion up to 450 mm, which can be controlled via the on-board control panel.

The Neeo unit is equipped with a separate monitor trolley that can be positioned at will to guarantee the operator an optimal view of the exam he is performing.

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The trolley carries 2 19 "high resolution monitors able to move freely; the possible excursions of the monitor also depend on the type of monitor but in general, for all the available versions, it is possible to tilt up and down, rotate sideways up to +/- 90 °, raise and lower.

On the monitor holder trolley there is a comfortable keyboard and a mouse to use the functions offered by the RTP system (optional). On the cart you can find also, depending on the version and options chosen, a DVD slot and a thermal printer available in both A4 and A6 format.

The monitor trolley can be easily positioned thanks to four wheels, 2 of which with brake.

The Neeo system integrates a high contrast touch screen system (can also be used with work gloves) that allows immediate viewing of all exposure data. Thanks to the ease of use of the integrated digital system, the user can quickly modify the exam data and see the variations related to the exposure on the monitors. On the touch screen display is also possible see messages of any abnormal conditions (microprocessor management).

The Neeo series maintains the use of Image Intensifiers that have, for many years, guaranteed a soft image with very high details.

The wide range of combinations makes the Neeo system fully customizable according to the needs of the individual customer, clinic or hospital.

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Among the various available options you can find:

- 625 lines CCD camera
- 1K x 1K high definition Camera
- SBFM board - 110 volatile images
- SBFM board 330 or 2700 with non-volatile images with digital rotation, 100 Hz video out and keyboard
- RTP Real Time Processing NW
- Dosimetric system
- Stainless steel cassette holder
- Cross laser locator
- Sony Thermal printer A4 format
- Sony Thermal printer A6 format
- Sterile drapes

The monitors that can be used vary depending on the memory board chosen: for the SBFM boards must be used a medical grade monitor B/W or Color with BNC input.

With the RTP it is possible to use the high definition monitors with DVI or VGA input among those proposed on the price list. The choice is entrusted to the customer according to the needs.

Dicom features: **D**igital **I**maging and **CO**mmunications in **M**edicine (available only with RTP):

- DSA *(Digital Subtraction Angiography)*
- QA *(Quantitative Analysis)*
- HCF (High Contrast Fluoroscopy)
- Dicom BASE Verify and Storage
- Dicom PRINT Print on a DICOM Printer *
- Dicom WORKLIST *
- Dicom MPPS *(Modality Performed Procedure Step)*
- Dicom STCOMMIT *(Storage Commitment)*

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- Dicom QUERY/RETRIEVE
- Dicom CD/DVD *

** Dicom Print, Worklist and CD/DVD must be used along Dicom BASE*

Functional details of the RTP software

DSA Digital Subtraction Angiography

DSA is a fluoroscopy technique used in interventional radiology to clearly visualize blood vessels in a bony or dense soft tissue environment. Images are produced using contrast medium by subtracting a "pre-contrast image" or *mask* from subsequent images, once the contrast medium has been introduced into a structure.

The "subtraction" of the acquired pre-contrast image is performed autonomously by the RTP system software.

QA Quantitative Angiography

Angiographic measurement is used in cardiac imaging, for example for the measurement of coronary stenosis, or for measurements of blood vessels or for atherectomy operations for the disruption of the coronary arteries.

HCF High Contrast Fluoroscopy

This function greatly increases the contrast of the image and consequently the improvement of the image.

Dicom BASE

The service is used to send images or structured reports, etc. to a PACS or workstation.

Dicom PRINT

The DICOM Print service is used to send images to a printer with DICOM protocol.

Dicom WORKLIST

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Allows one of the Dicom modes to obtain patient details and the exams worklist, avoiding having to manually type this information and obviating any typing errors.

Dicom MPPS

Modality Performed Procedure Step, more commonly known as MPPS, supplies a mechanism to pass information about images which are transferred to the Server. An MPPS object contains all of the data concerning the study, the procedures carried out and the series/images created during the execution of a procedure. MPPS management can be activated or deactivated for every study. Activation depends on the configuration of the machine (see MPPS Setup restricted to the installing technician) and on the presence of the software option in the key.

Dicom STCOMMIT

The Dicom service of Storage Commitment allows a Dicom device that has transferred images to another device (normally a workstation or an archive), to make the second device responsible for the storage of the images. Once the notification of acceptance has been received, the first device is free to do as it wishes with the images, including delete them.

Dicom QUERY/RETRIEVE

QR allows the RTP module to find lists of images or other objects and then retrieve them from a PACS.

Dicom CD/DVD

Dicom CD/DVD allows to store images and related diagnostic information on removable media including information contained in Meta files.

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Neeo Series Versions

The Neeo range includes the following versions:

Neeo R9

9 inches Image Intensifier with three fields

3,5 kW Power Generator - Rotating Anode

Neeo R9

9 inches Image Intensifier with three fields

5 kW Power Generator - Rotating Anode

Neeo S9

9 inches Image Intensifier with three fields

3,5 kW Power Generator - Fixed Anode

Neeo R12

12 inches Image Intensifier with three fields

5 kW Power Generator - Rotating Anode

Neeo R12

12 inches Image Intensifier with three fields

3,5 kW Power Generator - Rotating Anode

Neeo S12

12 inches Image Intensifier with three fields

3,5 kW Power Generator - Fixed Anode

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Product Specification: Neeo R9

Neeo R9 mount a monoblock with rotating anode and use the 2 points technique (kV-mAs) in radiology mode and the automatic technique (or 0 points) to control kV and mA on fluoroscopy mode. The values can be viewed on the large touch screen display.

Through the acquisition system with SBFM image processor or RTP system it is possible to use one of the following working modes: continuous fluoroscopy, pulsed fluoroscopy and one shot fluoroscopy.

The unit allows the selection of the electronic zoom according to the number of fields of the I.I. In this case the iris collimator automatically limits the RX field according to the field I.I. selected.

As per regulations, all the radiological units of IBIS can be equipped with a dosimetric system. Patient data can be entered via the virtual keyboard and then printed, with the related dose values acquired, for appropriate archiving.

If RTP is used, patient data can be entered via the keyboard and then printed or sent to the PACS with the related dosimetric data.

ATTENTION: for the correct use of the equipment refer to the user manual of the product.

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Radiological and Electrical Characteristics of the Product

Neeo R9

Radiological and Electrical Characteristics of the Product

Generator		
Radiological Features		
Generator Power	3,5 kW	5 kW
kV Range	40-120 kV	
Max mA on one-shot fluoroscopy	12 mA	
mAs Range	1-250 mAs	
Max Monobloc Current (piloted)	65 mA Radiography– 12 mA Boosted	
Total Filtration	>2,7 mm Al	
Additional Filtration	Not removable – 1mm Al	

Monobloc	
Monobloc Type	E 40R HF
Ripple Monobloc at Max Power	1%
Max Current of the Monobloc (fluoroscopy)	5 mA - 10 mA (in pulsata) – 12 mA One Shot
Max Current of the Monobloc (radiography)	100 mA
Focuses dimension	Small Focus 0,3x0,3 mm Large Focus 0,6x0,6 mm
Thermal Capacity of the Monobloc	900 kJ - 1200 kHU
Continuous Thermal Dissipation of the Monobloc	60 W
Available Thermal Capacity (X-Ray)	300 kJ
Additional Filtration	Not removable – 1mm Al

Tube	
Insert Type	**IAE X20 P**
Focuses dimension	0,3 – 0,6 mm
Type of tube	Rotating Anode
Anode speed	3000 rpm
Anodic Angle	10°
Maximum Thermal Capacity of the Insert	150 kJ - 200 kHU
Maximum Capacity Dissipation of the Insert	300 W

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Power features		
Main system power supply voltage		Single Phase, 230 Vac +/-10%
Frequency		50/60 Hz
Maximum Current Absorbed	In fluoroscopy	6 A – 230 Vac Fluoro Pulsed
	In Radiography	22 A – 230 Vac Radio Pulsed
Line compensation		Automatic
Line resistance		0,4 ohm

Neeo R9	
Collimator characteristics	
Model	RALCO R605 DASM
Shutters	2 pairs of mobile leaded shutters with variable opening and rotation
Dimensions	210 x 98 x 94 mm
Iris	Control from console, with adjustable opening to the maximum allowed depending on the Image Intensifier fields.

Neeo R9		
Image Intensifer characteristics		
Model	TOSHIBA E5764D P4A	THALES TH 9428 HP2
Useful Entrance Field Size	215 mm / 160 mm / 120 mm	215 mm / 160 mm / 120 mm
Output Image Diameter	20 mm ± 0,5 mm	20 mm
Central Resolution	48 lp/cm, 56 lp/cm, 66 lp/cm	48 lp/cm, 56 lp/cm, 64 lp/cm
Contrast Ratio on large area	25:1	23:1, 25:1, 30:1
DQE Detective Quantum Efficiency	65% (IEC Standard)	65% (IEC Standard)
Conversion Factor (Gx)	240 Cd/m²/mR/s	240 Cd/m²/mR/s

Neeo R9	
Grid characteristics	
Grid Ratio	8:1
Grid shutters	40 L/cm (103 L/inch)
Focusing of the Grid	90 cm

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Neeo R9	
Cameras characteristics	

Camera CCD 625 lines	
Sensor Type	CCD, High Resolution 1/2" Low Lag
Video Standard	CCIR: 625 lines interlaced, 50 Hz EIA: 525 lines interlaced, 60 Hz
Pixels	752(H) x 582(V), 50 Hz 768(H) x 494(V), 60 Hz
Band width	14 MHz
Scan Ratio	4:3
Signal / Noise Ratio	40 dB at 0.12 lux
Video Signal Amplitude	1 Vpp Max

CCD Camera Thales 1024 x 1024	
XRII Output Diameter	25,2 mm
Image resolution	1000 x 1000 Pixels
Digital Video Output	12 bits
Maximum frame speed	30 fps
Minimum exposure time	33 ms @ 1000x1000
Sensitivity	Motorized Lens >64 LSB/Cd/m² Manual lens >18 LSB/Cd/m²
MTF	Motorized Lens ≥ 50% Manual Lens ≥ 40%
Iris Aperture Range	Motorized Lens: from F/1.5 to F/11 Manual Lens: from F/2.8 to F/11

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Neeo R9

SBFM Single Board Characteristics

Model	SBFM 76/110/DS	SBFM-78 330/DS/KEY/50Hz	SBFM-78 2700/DS/KEY/50Hz
Memory Type	Volatile	Permanent	Permanent
Images on primary Display		1	
Images on secondary Display	110 Volatile	330	2700
A/D Converter	8 bit	10 bit	10 bit
D/A Converter		8 bit	
Sampling Rate		15 MHz	
Video Input	Standard CCIR 1 Vpp Composite Video Signal 75 Ohm termination		
Video Output	Standard CCIR 1 Vpp Composite Video Signal 75 Ohm termination	Standard CCIR 1 Vpp Composite Video Signal 75 Ohm termination 2 out 625 line 100Hz 1 Vpp 2 out 625 line 100Hz 1 Vpp	
Processing	Recursive Filter OFF/2/4/8/16 frame integration Real Time Digital Rotation Left-Right Inversion Edge Enhancement	Recursive Filter OFF/2/4/8/16 frame integration Real Time Digital Rotation Left-Right Inversion Edge Enhancement Gray Scale Inversion	
Functionality	N/A	Editing Data Patient Automatic data/time registration	

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Neeo R9	
RTP NW Characteristics	
Model	**RTP-NW**
Hardware Type	**PC Case**
Acquisition	- Fluoroscopy 25 images per second 1024x 1024 x 12 bit - Recursive filter and movement detection - Pulsed Fluoroscopy - Acquisition rate 1,3,6,12, 25 image/sec - Electronic rotation with 1° step - Horizontal and vertical inversion - Brightness and contrast - Grey scale inversion - Maximum opacity fluoroscopy acquisition - Real time subtraction with auto/manual mask - Storage on disk up to 25 images per second - Virtual collimators
Post Processing	- Electronic rotation with 1° step - Horizontal and vertical inversion - Grey scale inversion - Spatial filters (edge enhancement) - Cineloop - Electronic collimators - Shifting pixels - Electronic Zoom - Image subtraction - Landmarking - Overview 4-9-16 images - Print on Windows USB2 printers - Storage examination on removable drive (USB2 Pen drive) in BMP
Measures	- Distance Calculator - Angles - Stenosis - Overwrite text

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Neeo R9	
Operational Features	
User Interface	Display touch screen (also working with work gloves) backlit and high contrast for the insertion of all parameters and for the display of any error messages or system issues.
Radiography	2 Points technique (kV – mAs)
Fluoroscopy	• *"Automatic"* Technique (0 Points) with automatic control on kV and mA • *"Manual"* Technique (1 Point) with manual control on kV and mA
Radiography Command	Double click manual with extensible spiral cable
Fluoroscopy Command	Pedal footswitch
I.I. Field Selection	Electronic zoom selection according to the number of fields of the Image Intensifer
Safety	- Filament current - mA min and mA max - Max Exposure Time - Max Temperature of the monobloc - Counting monoblock thermal units - Timer with RX stop every 5 minutes (up to 99 minutes) - max kV, min kV, max kV, max I - Anode Rotation - Microprocessor auto test

Neeo R9		
Accessories		
Thermal Printer	Sony A6 UP898HD	Sony A4 UP991 AD
Dosimeter	Kermax 120-122	
Laser Localizer	Diode Laser Class II 630-680 mm <1mW Cross Sign	
Sterile Draps	Drap for Arm, Image Intensifer, Monobloc, Sled	

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Neeo R9

Optimal Operating Conditions

Transport and Storage Conditions

Max Temperature	-10°C ÷ +55° C
Recommended Temperature	0°C ÷ +40° C
Relative humidity	20% ÷ 90%
Atmospheric pressure	500 hPa ÷ 1060 hPa

Operating conditions

Max Temperature	+10°C ÷ +40° C
Relative humidity	30% ÷ 70%
Atmospheric pressure	700 hPa ÷ 1060 hPa

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Mechanical characteristics

Neeo R9 Mechanical characteristics	
Vertical Movement (Motorized)	450 mm
Horizontal Movement	210 mm
Wig – Wag	± 12°
Lateral Rotation	± 270°
Orbital movement	130° (90°+ 40°)
S.I.D.	1010 mm
Depth	659 mm
Free Space	740 mm
Movement	Manual with steering rear wheels and parking position. Rotating front wheel.
Lenght Min/Max	2018 ÷ 2463 mm
Max Width	830 mm
Height Min/Max	1827 ÷ 2277 mm
Weight *	275 Kg

** Weight referred to Neeo R9 with RTP, Monitor Tecnint, I.I. Toshiba; excluded any other accessories.*

For further details refer to the drawings below.

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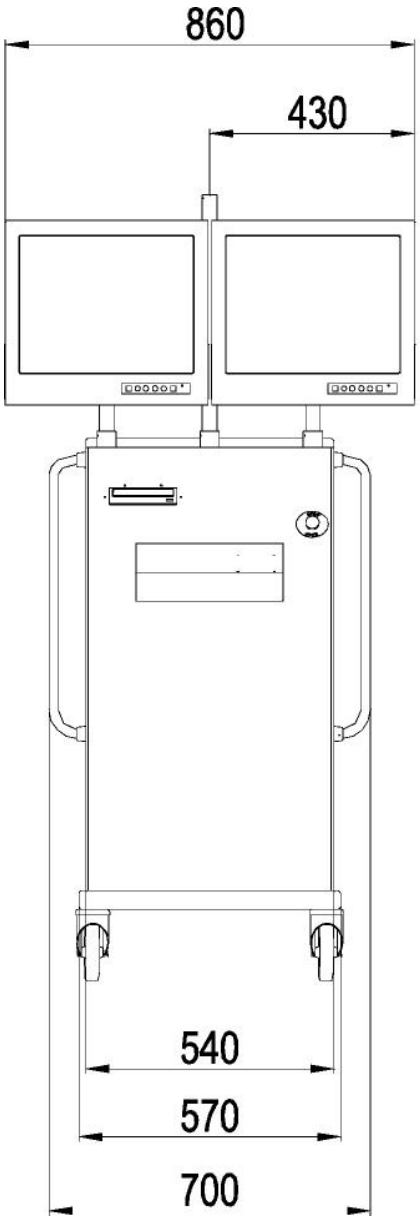
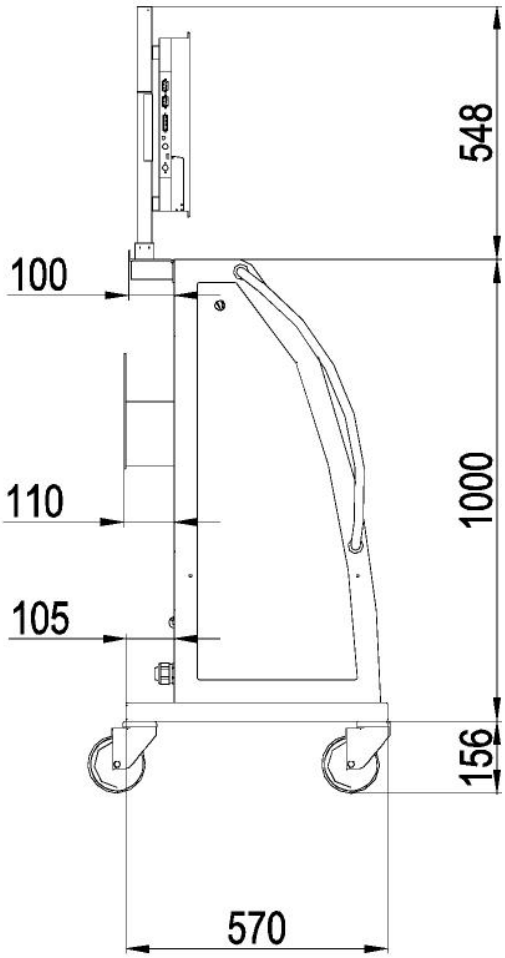
Dimensions of Monitor Stand





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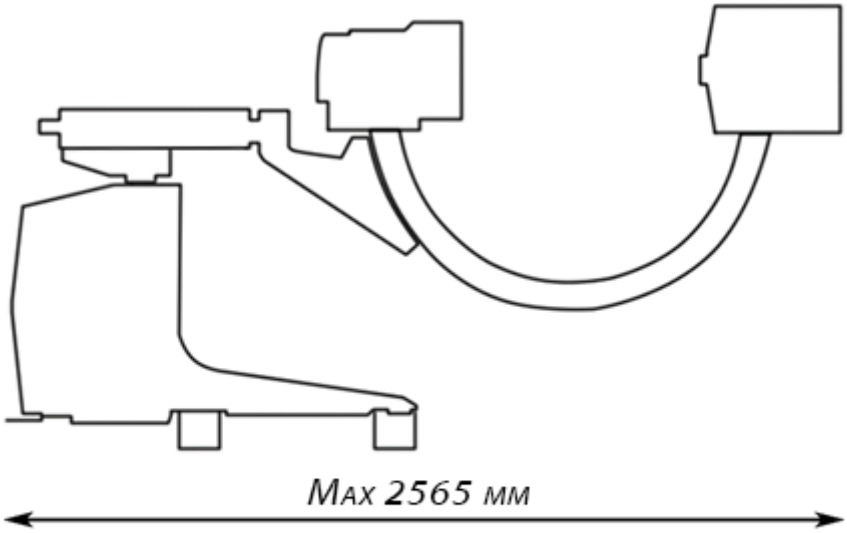
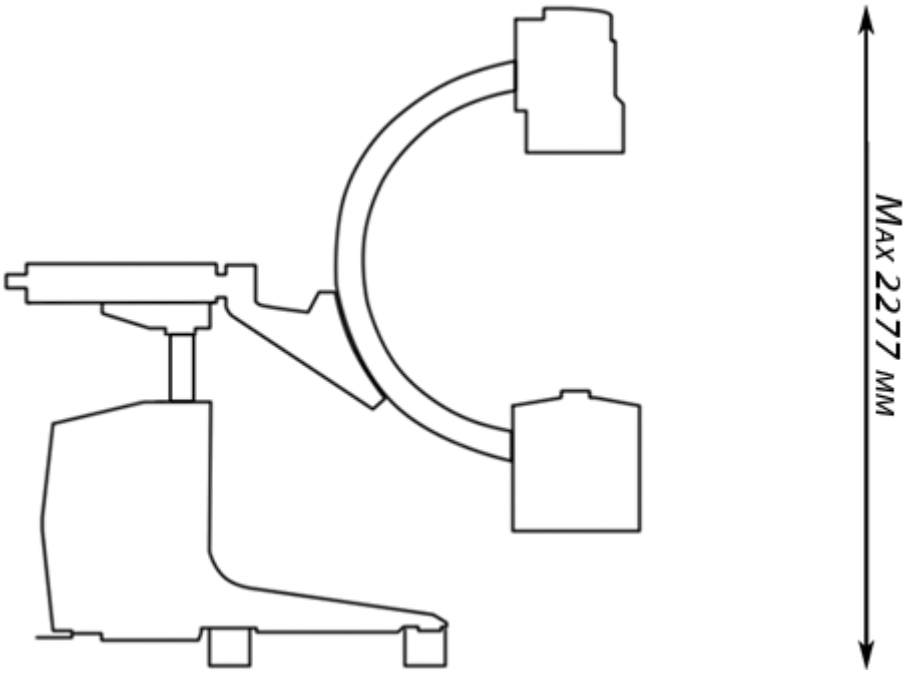
Dimensions of the C-Arm structure





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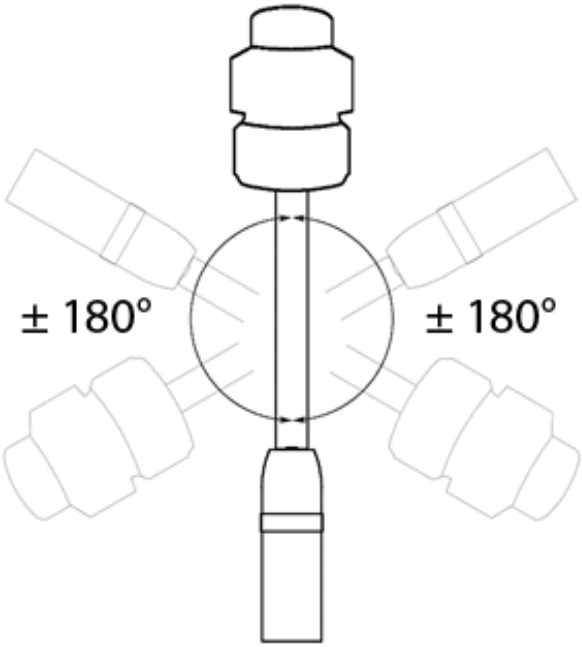
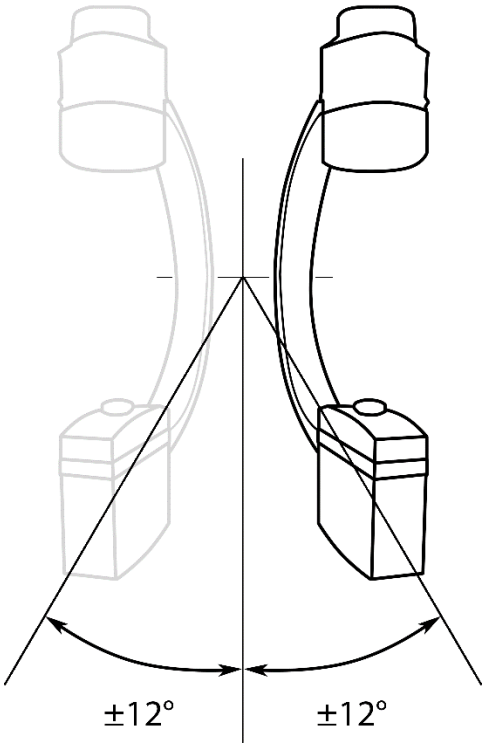
Arm Movements





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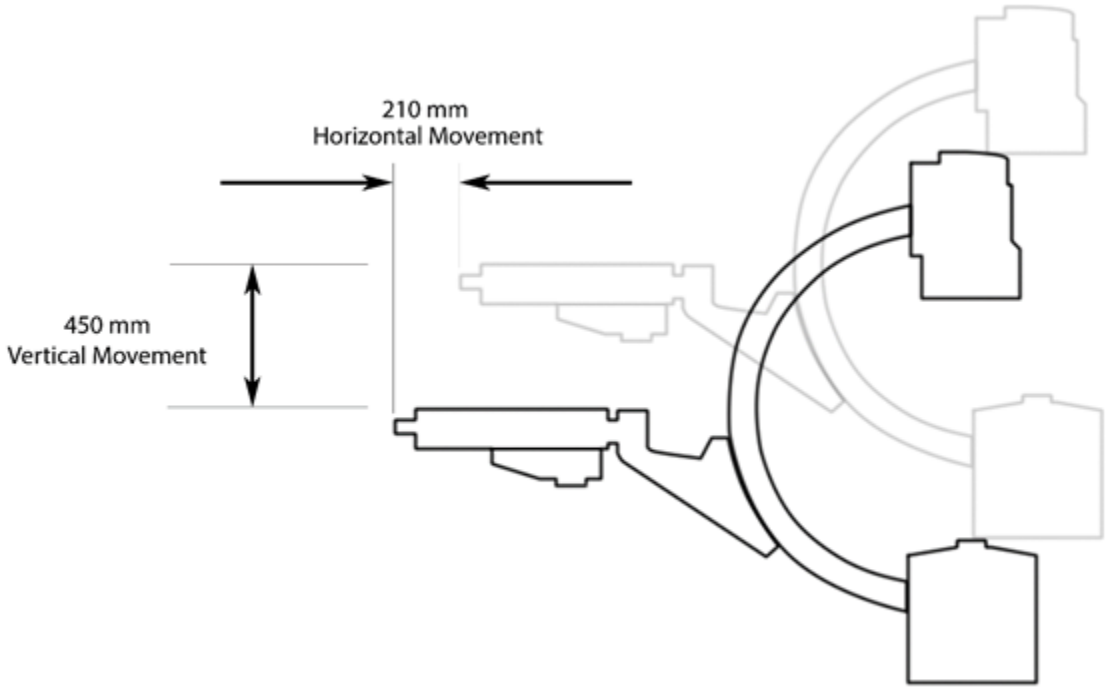
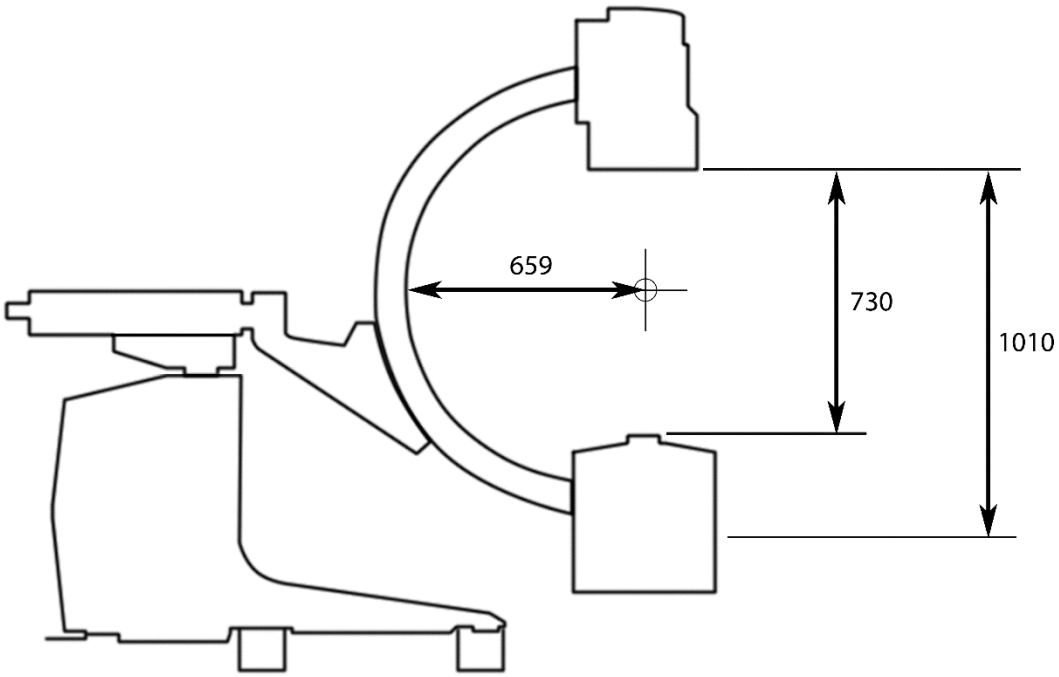
Vertical and horizontal excursions



SID, Free Space and depth



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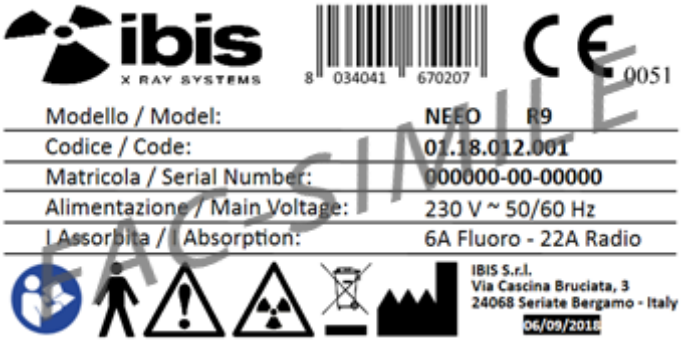
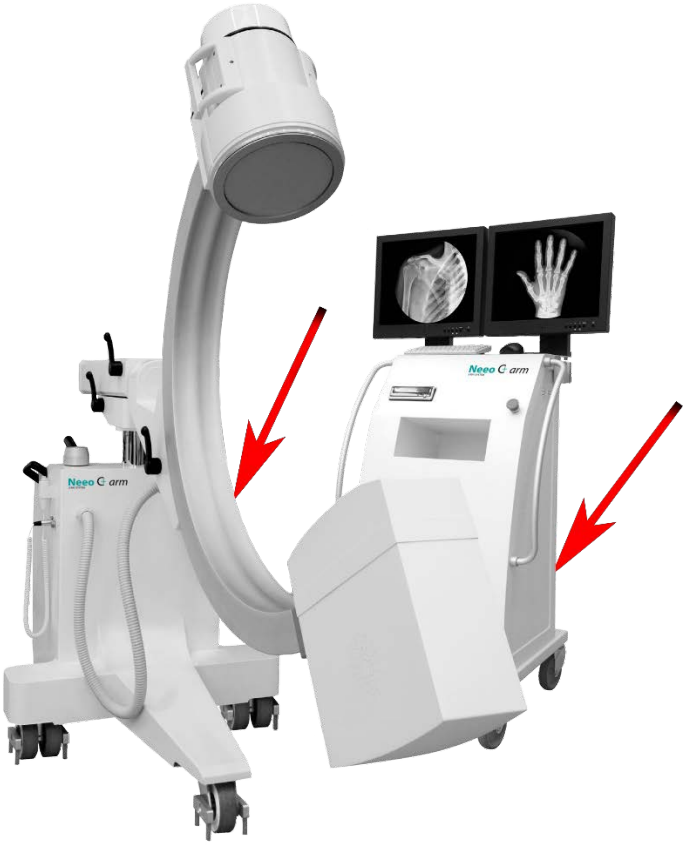
Labelling

Fac- Simile of the label used for the Neeo R9 and its usual positioning.



The positioning of the label is shown below. Further identification label is applied inside the equipment next to the inverter label.



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Reference Symbols

	CONSULT THE ANNEXED DOCUMENTATION
	CLASS B EQUIPMENT (NORM EN60601-1)
	ATTENTION
	SYMBOL OF DANGER IONIZING RADIATIONS - PHYSIOLOGICAL EFFECTS
	DEVICE THAT REQUIRES A CORRECT DISPOSAL (2012/19 / EC)
	MANUFACTURER
	CE MARKING COMPLYING TO DIRECTIVE 93/42 / EEC AND SUBSEQUENT AMENDMENTS AND INTEGRATIONS

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Product Certifications

The Neeo R9 is classified in class II b (annex IX 93/42 / CE) and complies with the requirements of the European directive 93/42 EEC and subsequent amendments (07/47 / EEC).

The product has been developed according to UNI EN ISO 9001: 2008 and UNI EN ISO 13485: 2012.

It complies with the following standards:

CEI EN 60601-1
CEI EN 60601-1-2
CEI EN 60601-1-6

9120.IBI1 IT-30485 9124.IBI2 CE 0051

Registration to the Ministry of Health

Neeo R9 is a Class IIb medical device regularly registered at the Italian Ministry of Health.

The product identification code is as follows:

Medical Device Class:	***IIB - Class IIb***
Trade name and model:	***NEEO R9***
Registration ID:	***BD/RDM 1497893***
Date first publication:	***26/11/2016***

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Installation and Warranty

Neeo R9 must only be installed by properly trained IBIS authorized personnel.

Each device produced or sold by IBIS has one year warranty from the date of shipment unless otherwise agreement between IBIS and the Customer.

The contractual guarantee can be extended to the necessary terms.

The warranty conditions are detailed in the General Conditions of Sale in force on the date of purchase of the product.

Conclusive Notes

All information contained in this document is confidential and its disclosure, even partial, is forbidden without due notice and authorization by IBIS S.r.l ..

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