Product Data

Simply dr

X RAY SYSTEM

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ibis X RAY SYSTEMS

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

Simply *dr*
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:

IBIS S.r.l.

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 Simply range)

Simply is a mobile unit designed for radiological applications and diagnostic investigations in hospital environments (operating room, pediatrics, orthopedics, sports medicine) and emergency departments. Thanks to its light weight it is easily transportable inside the hospital unit between the various departments and directly in the hospitalization areas in cases where it is necessary to avoid the patient moving towards the imaging dept..
The combination of maneuverability and ease of use offers operators an intuitive product, with rapid activation.

Articulated arm allows you to move the monobloc vertically until you reach the correct position of exposure; the wide excursion ensures the possibility of use in various areas such as wheelchair patients, on stretcher, etc..

The possibility to freely rotate the Monobloc at an angle of 125 ° total (-20 ° / + 105 °) also allows the Simply unit to be used also with vertical stand bucky or in the case of particular positions. It is possible to orbit the monobloc by +/- 180 °, showing, through the built-in goniometer, the exact exposure angle.

The overall dimensions in transport conditions are very reduced, allowing easy maneuverability inside the departments and easy storage when not in use.

Rotation of the monobloc is facilitated by a comfortable grip; the unit is moved by a handle which also incorporates the brake.

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The brake is "dead man" type so, in the absence of pressure on the handle, the equipment activates the mechanical brakes preventing accidental movements of the unit.

The front twin wheels are designed to overcome small differences in level, such as entry into the elevator or low obstacles; in the case of higher obstacles, it is possible to tilt the unit through a light pressure of the foot on a bar placed under the unit.

A back pocket has been added to the Simply unit in order to be able to freely insert a panel detector or analog cassettes.

The unit is equipped with a double-snap button with spiral cable which allows the operator to perform the X-rays in complete safety at an adequate distance.

The units of the Simply series are available in the following versions:

Simply LP with 3,5 kW generator

Simply HP 6 with 6 kW generator

Simply HP 15 with 15 kW generator

Simply HP 32 with 32 kW generator

Simply *evo* with 32 kW generator and battery/plug powered

Simply *dr* with 32 kW generator

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Product Specification: Simply *dr*

Simply *dr* uses two types of radiological technique: two-point with choice of kV and mAs and three point with choice of kV, mA and mS. These values can be viewed on the large touch screen display.

The unit is equipped with an automatic shut-off system after 30 minutes of inactivity. This feature prevents the unit from being switched on by mistake for long periods, thus avoiding compromising the operation of the X-ray tube (focuses always on).

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.

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User interface and "touch screen" display includes virtual alphanumeric keyboard to type the types of exam to be memorized and the patient data to be printed when using a dosimetric system (DAP). The dose is displayed directly on the image (dap and printer are optional).

The unit is ready for the d.a.p. and for the potter bucky.

Manual radius button with double click and extensible cable

The pouch has been designed to accommodate a detector panel with a 35x43 format. The material is soft, shockproof and suitable for inserting the digital panel and has two pockets for housing two batteries.

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The relevant feature of Simply *dr* is the ability to immediately process images and offer them to the operator on the on-board HD screen. This operation is possible thanks to a PC inside the unit able to interface with most of the direct digital panels available on the market. The operation is facilitated by the touch screen panel on which you can view the software related to the panel in use; all exposure parameters can be freely entered through this 19 "high-definition panel. The image data is transferred from the panel to the computer via a wireless network generated directly by the unit through powerful antennas.

The computer is able to store the images acquired through an additional HD coupled to that used for the management of the operating system and software.

Simply dr can only be used with a power outlet inserted, however the computer is kept switched on via a UPS system inserted into the equipment; this allows the user to be able to move freely within the departments or between the various rooms without having to worry about switching off and restarting the operating system.

These features make Simply dr one of the most functional systems for acquiring the X-ray images on the market thanks to the manageability, the speed of acquisition of the exposures and the possibility of having an immediate result and being able to process it directly on the acquisition site.

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

Simply dr **Radiological and Electrical Characteristics of the Product**	
Generator	
Max Power	32 kW Large Focus – 11 kW Small Focus
Max Voltage of the Monobloc	125 kV
Max Current of the Monobloc (piloted)	25 – 400 mA
Work frequency	100 kHz
Ripple at Max Power	≤3%
Total Filtration	> 2,7 mm Al
Inverter Model	HF1 100/2
kV Variation	1 kV
Max mAs	220 mAs (28 Steps)
Step mAs	0,2 / 0,5 / 0,8 / 1 / 1,3 / 1,6 / 2 / 2,5 / 3,2 / 4 / 5 / 6,3 / 8 / 10 / 13 / 16 / 20 / 25 / 32 / 40 / 50 / 63 / 80 / 100 / 130 / 160 / 200 / 220
Exposure Time	0,001 – 5,0 s
Operating Modalities	2 or 3 points techniques
Anatomical Technique (APR)	Customizable
Monobloc*	
Monobloc Type	E 100R HF
Max Voltage of the Monobloc	125 kV
Max Current of the Monobloc	425 mA
Thermal Capacity of the Monobloc	900 kJ - 1200 kHU
Continuous Thermal Dissipation of the Monobloc	60 W
Available Thermal Capacity (X-Ray)	600 kJ – 800 kHU
Ripple Monobloc at Max Power	1%
standard model; available with different models. Please refer to technical manual.	

Tube*		
Insert Type	IAE X22C	Kailong KL65
Focuses Dimensions	0,6 – 1,3 mm	0,6 – 1,3 mm
Type of tube	Rotating Anode	Rotating Anode
Anode speed	3000 rpm	3000 rpm
Anodic Angle	15°	15°
Maximum Thermal Capacity of the Insert	80 kJ - 107 kHU	80 kJ - 107 kHU
Maximum Capacity Dissipation of the	300 W	300 W

standard models; available with different models. Please refer to technical manual.

Power features	
Main system power supply voltage	Single Phase, 230 Vac +/-10%
Frequency	50/60 Hz
Absorption connected to the network	0,5 A standby; 230 Vac - 12 A pulsed

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Simply dr	
Collimator characteristics	
Model *	RALCO R104 – Claymount Optica 10
Shutters	2 pairs of mobile leaded shutters + extra fixed focal length
Light	LED light high intensity 250 lux at 100 cm, with 30 sec ON / OFF timer (standard).
Dimensions	271x222x140 mm
Field covered	Square field with single plane, variable from 0x0 cm to 43x43 cm at 100 cm DFF
Angle of the light cone	24°
Minimal inherent filtration	Equivalent to 2 mm Al
Additional Filtration (Optional)	RO258 = Al + (0,1 mm Cu / 0,2 mm Cu / 2 mm Al) RO258/1 = Al + (0,1 mm Cu / 0,2 mm Cu / 0,3 mm Cu)

* Also available in R108 or R221 for Ralco and Optica 20 for Claymount. For further details refer to technical dept IBIS S.r.l.

Simply dr	
Operational Features	
User Interface	21.5 "touch FHD color monitor (also working with work gloves) for entering all parameters and for viewing images and any error messages or system anomalies. Optional 18.5 "medical grade HD touch FHD color monitor with Dicom color curves (also works with work gloves) for entering all parameters and for viewing images and any error messages or system anomalies .
DAP / Kerma Camera	Yes (optional)
Automatic Closedown	An automatic device automatically shuts down the system after 30 minutes of inactivity for tube prevention (based on the chosen management software).
X-Ray Button	Double click manual with extensible spiral cable
Safety devices	• Protection and automatic control of filament current • Protection against over current and over voltage • Overload protection of the x-ray tube • Indications of operational errors or malfunction
Net Interface	Wireless or ethernet LAN connections
Dose data transfer	DAP and KAP transfer on Dicom header

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Simply *dr*	
Operational Features	
Wireless command (optional)	Wireless command with operating frequency of 433,92 MHz for X-ray emission with indicative range of 10 meters* *the range depends on any obstacles present, walls, bulkheads, etc.
Uninterruptible Power Supply	Uninterruptible Power Supply system (UPS) to ensure the operation of the computer and display, even in a leak of power source. Additional protection for any current and voltage overloads. Command for switching off the on-board auxiliary system.
Storage capacity	Around 32.000 images in RAW format with 1TB disk and around 64.000 images in RAW format with 2TB disk.
Flat panel connection	WiFi or cable connection
Dicom features*	• Storage • Print • Worklist (worklist acquisition) • MPPS • PACS/RIS interfacing • Stitching
Print features	Local or net printers, with or without Dicom protocol language

**features are referred to VxVue software. Specs may vary with different softwares.*

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Mechanical characteristics

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Mechanical characteristics	
Monobloc inclination (rotation on Y axis)	-20° / +105°
Monobloc rotation (rotation on X axis)	+/- 180°
Collimator rotation	+/- 90°
Width	632 mm
Length (at maximum arm extension)	1890 mm
Length (in transport configuration)	1170 mm
Height (in transport configuration)	1466 mm
Maximum focus height	1959 mm
Maximum DFF at floor level	1959 mm
Minimum DFF to the floor	547 mm
Maximum front reach (from the column)	1071 mm
Stop system	"Dead man" braking system on the handlebar
Weight	~ 200 kg *(without optional)*
Rear wheels diameter	200 mm
Front wheels diameter	100 mm
Maximum obstacle height that can be overcome	110 mm

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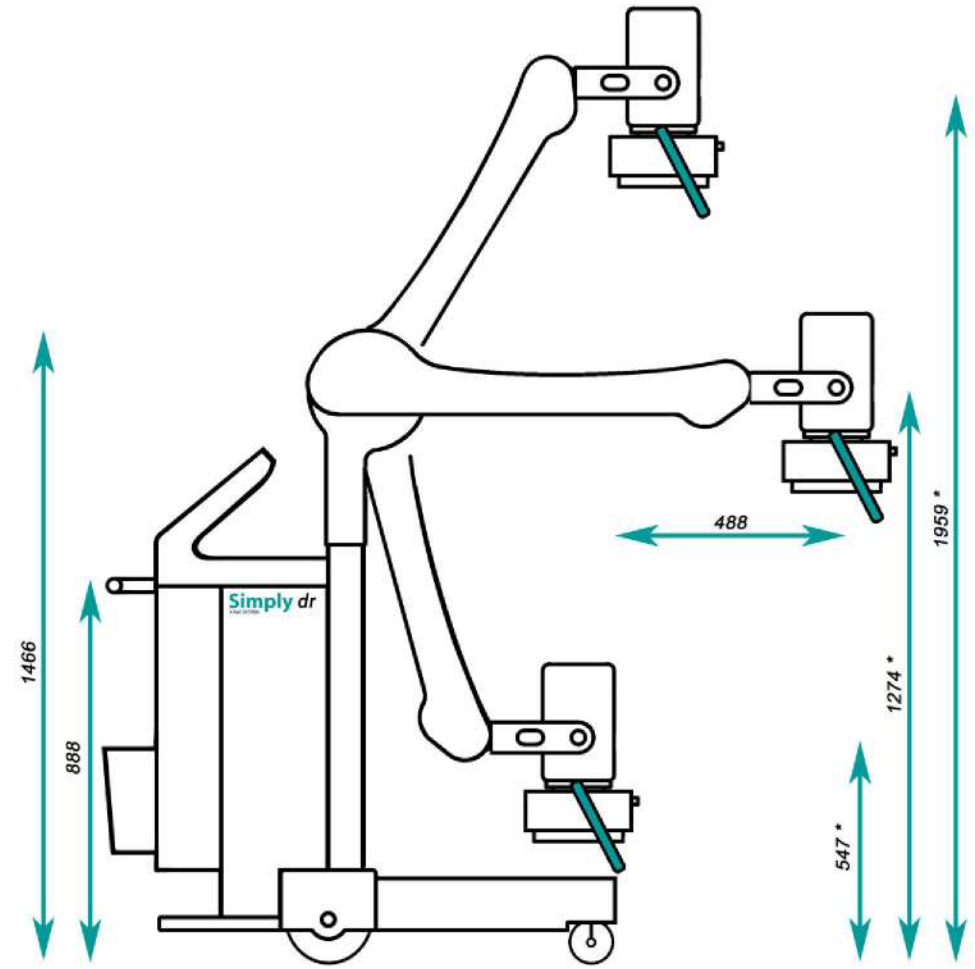
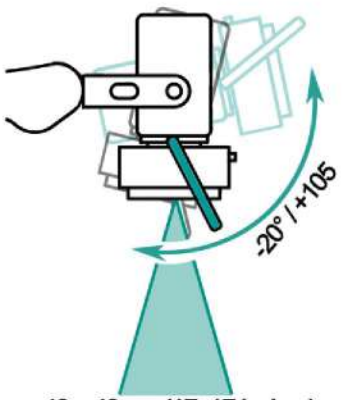
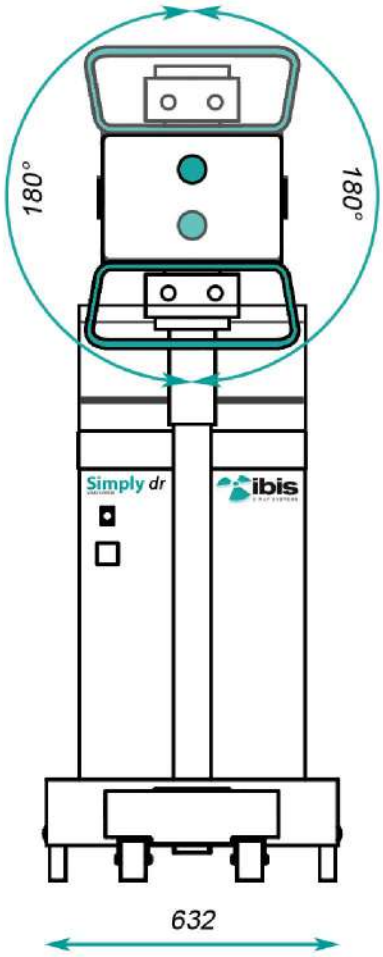
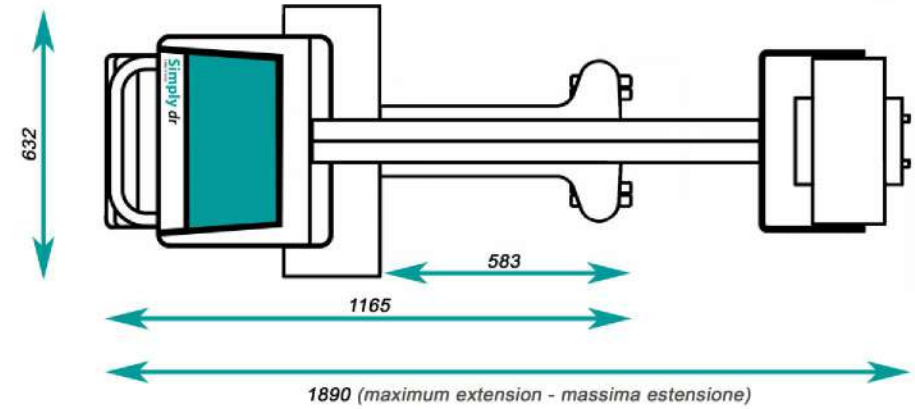
Dimensions





43 x 43 cm (17x17 inches)
Collimator light - Luce collimatore
24 ° Light Cone - Cono di Luce
(Values calculated at 1.000 mm from focus -
Valori calcolati a 1.000 mm dal fuoco)





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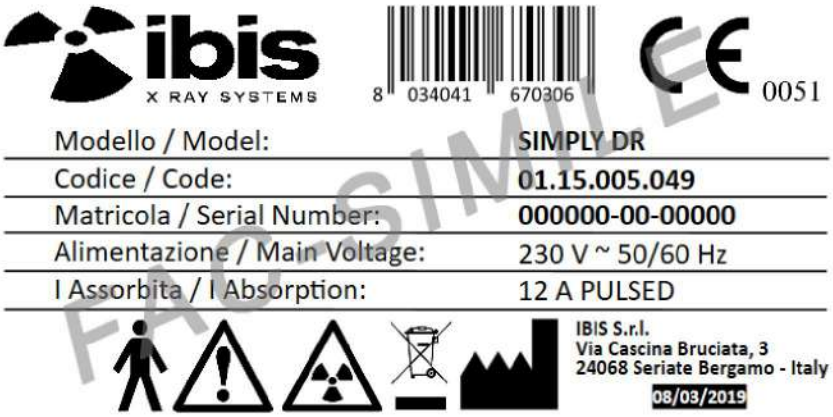
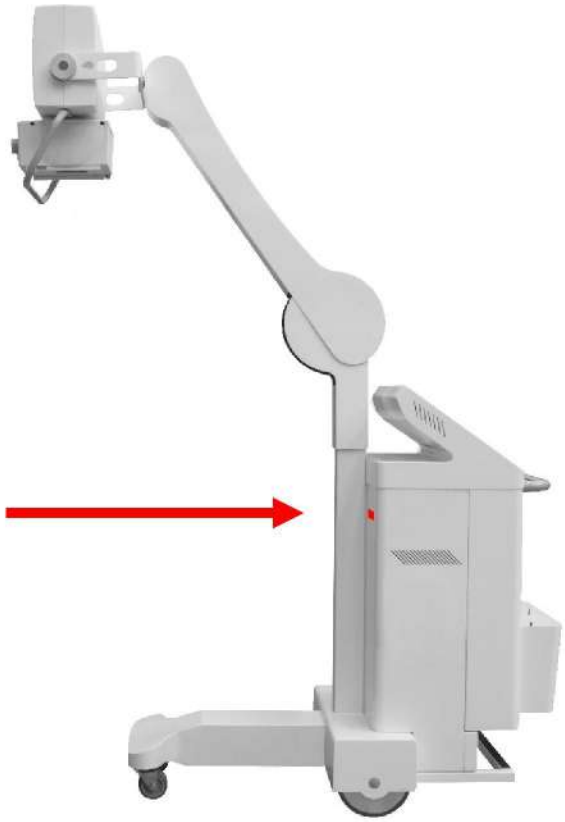
Labelling

Fac- Simile of the label used for the Simply *dr* 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 (EN60601-1)
	ATTENTION
	SYMBOL OF DANGER: IONIZING RADIATIONS - PHYSIOLOGICAL EFFECTS
	DEVICE THAT REQUIRES A CORRECT DISPOSAL (2012/19 / EC)
	MANUFACTURER
	CE MARKING PURSUANT TO DIRECTIVE 93/42 / EEC AND SUBSEQUENT AMENDMENTS AND INTEGRATIONS

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Product Certifications

The Simply dr mobile unit 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

Simply dr 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***
Commercial and model name:	***SIMPLY DR***
Registration ID:	***BD/RDM 1947610***
CND code:	***Z11039016***
GMDN code:	***37647***
Product code:	***01.15.005.049***
GS1 code:	***8034041670306***
Date of first publication:	***27th April 2020***

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Installation and Warranty

Simply *dr* 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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IBIS has no obligation to communicate any changes to this document.

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Document revisions

Revision Number	Date	Modifications
Rev.00	10-01-2019	N/A
Rev.01	18-04-2020	First product image Product Specification: Simply *dr* Radiological and Electrical Characteristics of the Product Mechanical Characteristics Registration to the Ministry of Health Conclusive notes

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