




< RX DC X-RAY UNIT>

Table of contents:

1.	LIST OF MODIFICATIONS	2
2.	USE	2
3.	PRODUCT CLASSIFICATION	2
4.	FORESEEN VARIANTS	3
5.	GENERAL PRODUCT DESCRIPTION	3
6.	TECHNICAL PERFORMANCE.....	5
7.	FUNCTIONS OF WIRELESS HANDHELD CONTROL DEVICE	6
8.	TECHNICAL SPECIFICATIONS	8
9.	APPLICABLE INSTRUMENTS	8
10.	APPLICABLE ACCESSORIES.....	8

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CONTROLLO DOCUMENTO							
Documento	UT DP044			Descrizione Prodotto Radiografico RX DC			
Revisione	Indice	0	del	05/06/07	Controllo pagine		1 di 8
Posizione documento		C:\Documents and Settings\TESTAMAR\Desktop\FCC\F DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					
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	CEFLA DENTALE ENGINEERING DEPARTMENT			PAGE
	Product Description	CODE DP069	REVISION 0	No. 2 DI 8
	< MYRAY RX DC X-RAY UNIT >			

1. LIST OF MODIFICATIONS

First issue

2. USE

The "RX DC" intra-oral x-ray unit is a medical device designed to examine the oral cavity at constant potential in the field of dentistry.

The device may be installed only by highly skilled authorized technicians in compliance with current standards.

The equipment must be installed in class A doctor offices in compliance with standard CEI 64-4 in Italy and IEC 364 in Europe.

There must not be any risks of explosions and the office must not be pressurized.

The operating temperature should range from +10°C to +40°C.

The storage temperature should range from -15°C and +50°C.


Relative humidity should fall within 25% and 75%.

3. PRODUCT CLASSIFICATION

In accordance with the classification terms stated in addendum IX of EEC Directive 93/42 for medical devices the x-ray unit is classified as: **Class IIb**.

In accordance with the classification terms given in paragraph §5 of standard EEC EN 60 601-1/1998 Medical electrical equipment, general requirements for safety the x-ray unit is classified as: **Class I – Type B**.

Codice documento	DP0069	Indice revisione	0	del	05/06/07	Pag. 2 di 8
Posizione documento	C:\Documents and Settings\TESTAMAR\Desktop\FCC\F) DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					

	CEFLA DENTALE ENGINEERING DEPARTMENT			PAGE
	Product Description	CODE DP069	REVISION 0	No. 3
	< MYRAY RX DC X-RAY UNIT >			DI 8

4. FORESEEN VARIANTS

The MYRAY "RX DC" x-ray unit comes in just one model.

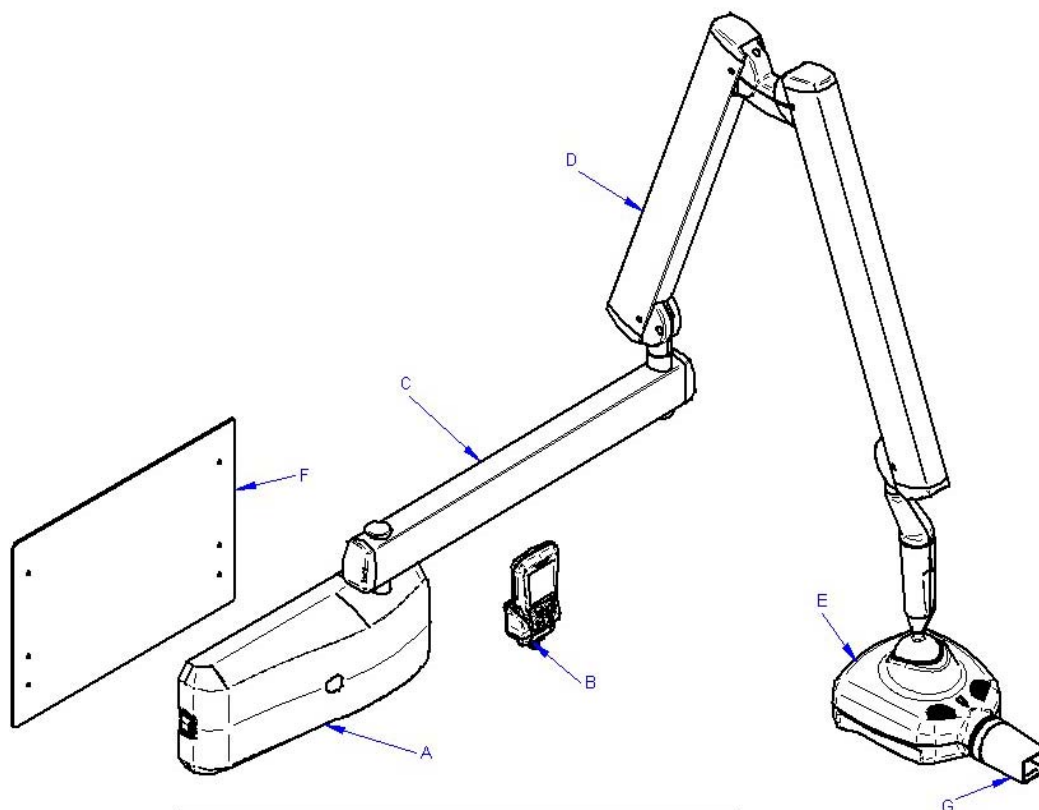
The standard composition includes a wall-mounting plate complete with digital control panel, a wireless handheld control device with shoot button that allows the exposure times to be set, a 90 cm extension arm, an arm with two joints, an x-ray generator and a removable SSD 30 35x45 cm 12" rectangular cone.

Compared to this composition the variants may be:

- 40 cm extension arm;
- 60 cm extension arm;
- Counter-plate for walls that are not strong enough;

NOTE – The variants may be performed only by authorized technicians.

5. GENERAL PRODUCT DESCRIPTION



a) Control panel/ wall-mounting plate.


The control panel / wall-mounting plate consists of an extruded aluminium plate needed for wall mounting and an extruded aluminium arm support. The latter can be secured to the wall-mounting plate in three different positions to set the wall-mounting plate in the way most suitable for the installation compartment. The entire unit is covered with a plastic cover that has three openings for the arms to come out in the various positions.

The main switch and basic control panel card are housed inside it.

The aluminium plate is designed to support the extension arm and articulated arms with the x-ray head.

The control panel card housed inside governs the power supply to the equipment.

Codice documento	DP0069	Indice revisione	0	del	05/06/07	Pag. 3 di 8
Posizione documento	C:\Documents and Settings\TESTAMAR\Desktop\FCC\F\ DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					

	CEFLA DENTALE ENGINEERING DEPARTMENT			PAGE
	Product Description	CODE DP069	REVISION 0	No. 4
	< MYRAY RX DC X-RAY UNIT>			DI 8

b) X-ray handheld control device.

The handheld control device consists of a plastic structure with the controls for emitting the x-rays and controlling the shooting parameters on the front panel.

The handheld is wireless. The exposure times are set from the control panel and are shown on the 116 segment display.

The handheld runs on alkaline batteries that are not rechargeable.

c) Extension arm.

The extension arm supports the articulated arm and allows the x-ray head to work in an enlarged area.

It is available in 3 lengths depending on the size of the office and the dentist's requirements:

L = 90 cm;

L = 60 cm;

L = 40 cm.

d) Pantograph arm

This unit includes two pantograph arms that allow the generator to be elongated and travel vertically while keeping it perfectly balanced at all times.

It is kept balanced thanks to compression of a spring that provides the thrust needed for balancing when the arm is changed.

Each individual arm moves 90° and comes with mechanical end-stops. This feature permits extensive vertical travel, allowing the patient's oral cavity to be conveniently reached regardless of the position of the dental chair.

It is constructed in painted extruded aluminium with shiny white ABS outer coverings.

The power cord for connection to the x-ray head runs inside it.

e) X-ray head.

The head consists of a plastic structure that contains the x-ray unit and a number of electronic cards.

The single-piece x-ray generator contains, immersed in highly dielectric insulating oil, the high voltage transformer, x-ray tube and expansion unit.

The expansion unit is provided to adequately compensate for oil dilatation during operation.

The control electronics and full-swivel ball joint for head movement are found inside the head.

The single-piece unit is secured to the device that moves the head which, along with acting as a support, it allows it to swivel around the ball. The unit is joined to the front of the arms through a screw connection that attaches the ball to the arms.

The head swivels around the ball by touching the keys found on the top of the head in the area near the collimator cone.

f) Wall counter-plate.

The wall plate is a device that needs to be used when the unit is installed on walls that are not very strong (drilled bricks or similar).

In this case, the plate has to be walled in the wall or on the side of the wall opposite the one the unit is installed on.

g) Collimator cone.


The collimator is the part that permits the correct focal point-skin distance, X-ray beam dimension, direction and centering to be obtained.

In addition, it permits different x-ray techniques to be used (bisecting technique and parallel technique).

One collimator is completely built into the structure of the equipment therefore it cannot be removed under any circumstances. Its features are:

- 8" SSD 20cm <Ø60mm; this condition is reached by taking out the rectangular collimator cone.

Codice documento	DP0069	Indice revisione	0	del	05/06/07	Pag. 4 di 8
Posizione documento	C:\Documents and Settings\TESTAMAR\Desktop\FCC\F) DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					

	CEFLA DENTALE ENGINEERING DEPARTMENT			PAGE
	Product Description	CODE DP069	REVISION 0	No. 5 DI 8
	< MYRAY RX DC X-RAY UNIT>			

The removable collimator is constructed in plastic to determine the distance and has a forged lead diaphragm to establish the beam dimensions. It comes with a quick-connect coupler and automatic switch:

- 12" SSD 30 cm rectangular 35 x 45 mm.

6. TECHNICAL PERFORMANCE


A four-digit display mainly shows the exposure times set in seconds and other parameters under particular conditions or with menus.

The control panel and electronics on the head perform all the functions to control and govern the x-ray unit.

The task is performed by four microcontrollers, which supported by specific software, carry out the following functions:

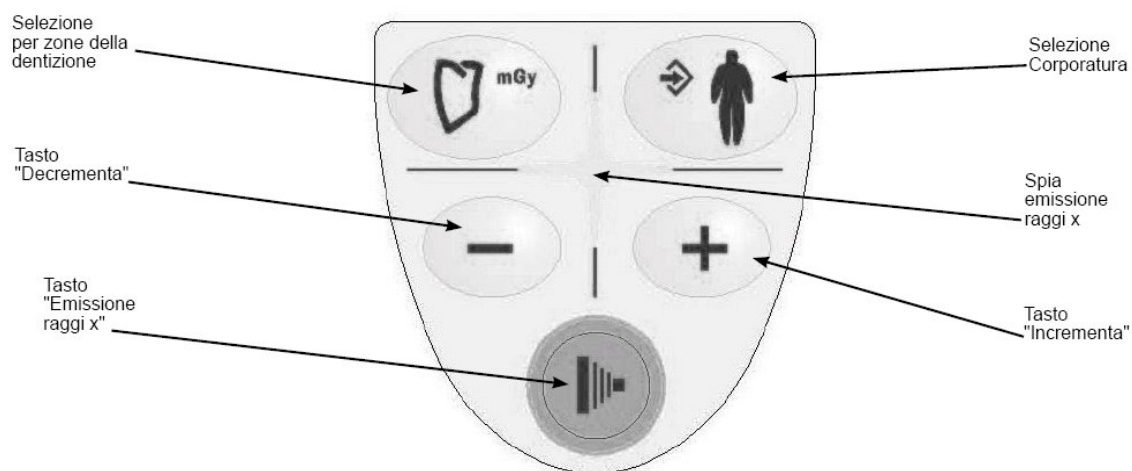
- Control wireless dialog between the handheld control device and x-ray head
- Self-diagnostics when turned on
- Run time self-diagnostics.
- Automatic setting and digital display of the exposure times based on the stored tables
- Automatic stabilization of the load parameters (KVp, mA) when the mains voltage varies $\pm 15\%$.
- Safety feature that prevents the generator from overheating. After each exposure, the control system checks the generator's heat load and, if necessary enters pause mode thereby preventing a new exposure. The system is able to limit the duty cycle to maximum 1/60.
- Management of a certain number of malfunctions stopping x-ray emission and displaying an E on the screen followed by a code depending on the type of error present.
- Management of the ready indicator light.

Codice documento	DP0069	Indice revisione	0	del	05/06/07	Pag. 5 di 8
Posizione documento	C:\Documents and Settings\TESTAMAR\Desktop\FCC\F\ DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					

	CEFLA DENTALE ENGINEERING DEPARTMENT			PAGE
	Product Description	CODE DP069	REVISION 0	No. 6 DI 8
	< MYRAY RX DC X-RAY UNIT >			

7. Functions of wireless handheld control device

RX DC handheld control device



Selection of area of tooth

Patient's build selection

"Decrease" key


X-ray emission light

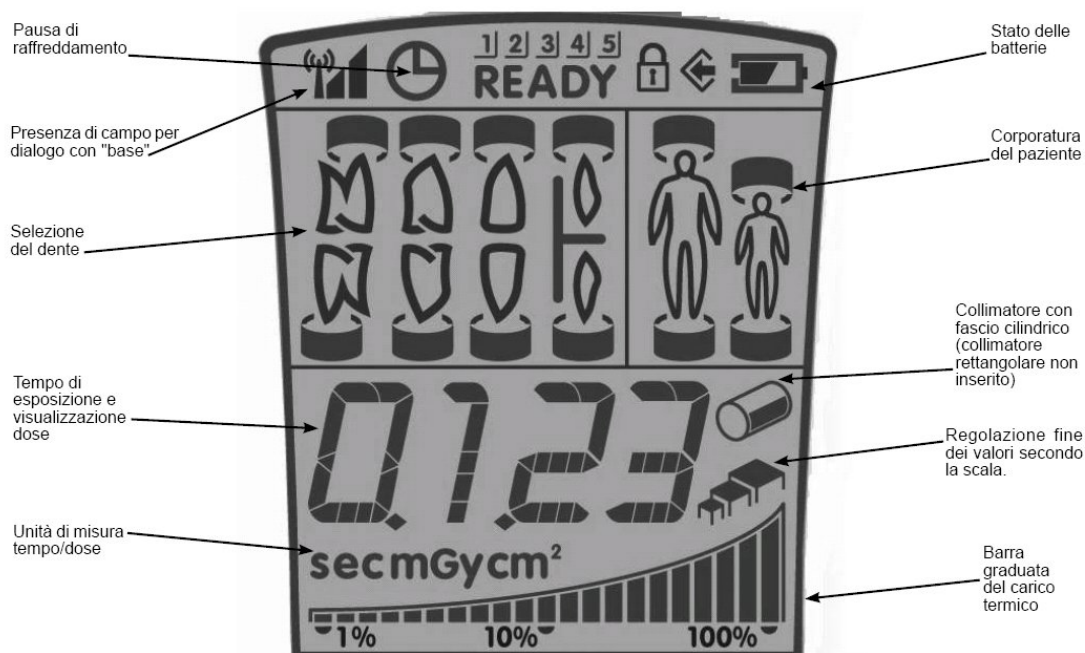
"X-ray emission" key

"Increase" key

Display and description of icons

Codice documento	DP0069	Indice revisione	0	del	05/06/07	Pag. 6 di 8
Posizione documento	C:\Documents and Settings\TESTAMAR\Desktop\FCC\F) DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					

	CEFLA DENTALE ENGINEERING DEPARTMENT			PAGE
	Product Description	CODE DP069	REVISION 0	No. 7 DI 8
	< MYRAY RX DC X-RAY UNIT >			



Cool down pause

Signal presence for dialog with "base"

Tooth selection

Exposure time and dose indication

Time/dose unit of measure

Battery charge level


Patient's build

Collimator with round beam (rectangular collimator not inserted)

Fine adjustment of values according to the scale

Heat load graduated bar

Codice documento	DP0069	Indice revisione	0	del	05/06/07	Pag. 7 di 8
Posizione documento	C:\Documents and Settings\TESTAMAR\Desktop\FCC\F DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					

	CEFLA DENTALE ENGINEERING DEPARTMENT			PAGE
	Product Description	CODE DP069	REVISION 0	No. 8
	< MYRAY RX DC X-RAY UNIT >			DI 8

8. TECHNICAL SPECIFICATIONS

Installation plan	See IN044 – u.r.* par.
Supply voltage	230 Vac \pm 15% Or 115Vac \pm 15% depending on model
Type of power supply	50-60 Hz
Rated current	6A (230 Vac) 10A (115Vac)
Power absorption	1.4 kVA
High voltage	60 kVp
Current to tube	7mA in “norm” mode 3.5mA in “sens” mode
Focal spot	0.4mm (IEC 336)
Total filtration	Equivalent to 2.5mm Al at 70 kVp
Focal point-skin	Minimum 200mm
Tube type	Toshiba D-041
Apparent line resistance	0.5 Ω
Exposure time	0.01sec. – 1sec. (in R20 steps)
Exposure interval	Limited to 1/60 average
X-ray beam diameter to skin	\leq 60mm – without removable rectangular collimator 45x35mm – with removable rectangular collimator
X-ray head weight	5.6 Kg.
Total weight	20 Kg.

9. APPLICABLE INSTRUMENTS

N.A.

10. APPLICABLE ACCESSORIES

N.A.

* u.r. = last revision

Codice documento	DP0069	Indice revisione	0	del	05/06/07	Pag. 8 di 8
Posizione documento	C:\Documents and Settings\TESTAMAR\Desktop\FCC\F DESCRIZIONE PRODOTTO\DP069-0 descrizionepr_GB.doc					