DENTALAIRE DC

User Manual

EN

FOR VETERINARY USE ONLY

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DENTALAIRE DC
User Manual
Edition ENGLISH

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Summary

1. INTRODUCTION 5

2. GENERAL INFORMATION 6
2.1 Intended use 6
2.2 Support documentation 6
2.3 User profile 6
2.4 User obligations 6
2.5 Contraindications 7
2.6 Useful life 7
2.7 Essential performance 7
2.8 Symbology 8

3. WARNINGS 9

4. TECHNICAL DESCRIPTION 12
4.1 Models and main components 12
4.2 Accessories 13
4.3 Technical specifications 13
4.4 Principle of operation 15

5. TYPES OF INSTALLATION 16
5.1 WM model installation 16
5.2 Control panel placement 16

6. COMMANDS AND FUNCTIONS 18
6.1 Control panel structure 18
6.1.1 Anatomical regions 19

6.1.2 Patient body size 19
6.1.3 Exposure parameters 20
6.1.4 Kind of receptor 20
6.1.5 Kind of BLD 21
6.1.6 Device status 21
6.1.7 DAP Information 22
6.1.8 X-ray emission button 22
6.1.9 Settings menu 23

7. PREPARATION OF THE EXPOSURE 33
7.1 Preparation of the exposure 33
7.1.1 Moving of the mobile unit 33
7.1.2 Turning ON the unit 33
7.1.3 THA positioning 33
7.1.4 Receptor placement 34
7.2 Starting exposure 34
7.3 Turning OFF the unit 37

8. EXPOSURE TIMES AND INDICES 38
8.1 Range of exposure times 38
8.2 Image receptor exposure index 39
8.2.1 Exposure values in s 40
8.2.2 Exposure values in mAs 41

9. CARE AND MAINTENANCE 42
9.1 Cleaning 42
9.2 Disinfecting 42
9.3 Inspection and Maintenance 42
9.4 Disposal of obsolete equipment 43

10. ELECTROMAGNETIC COMPATIBILITY 44
10.1 Electromagnetic emissions 44
10.2 Electromagnetic immunity 44
10.3 Frequencies table of portable RF equipment 45

11. ERROR MESSAGES 47

12. MARKING LABELS 49

1. INTRODUCTION

Dear customer,

Thank you for choosing DENTALAIRE DC!

Before using the device and exposing your patients to x-rays, we invite you to read the instructions and the radiation protection standards in force.

2. GENERAL INFORMATION

2.1 Intended use

DENTALAIRE DC is an intraoral dental radiographic equipment to be used together with a special receptor (films, phosphor plates, or digital sensors). The device must only be used for veterinary purposes in clinics or veterinary centers by experienced and qualified personnel who have received appropriate training.

Such a device is designed to be used for veterinary purposes.

Any other use than that provided for in the user manual is to be considered improper.

2.2 Support documentation

The instructions for use supplied with the device are an integral part of the product. The original language of the user manual is Italian. We invite you to carefully read these instructions before installation, to allow proper, safe, and effective operation and familiarize yourself with the equipment. The device must be used in accordance with the procedures set out in this manual, the manufacturer cannot be held responsible if the device is not properly used and maintained.
An installation and maintenance manual is provided together with the equipment to support the technician in performing proper installation and maintenance. Inspection and service are not part of the equipment warranty.

The information contained in the manuals may be subject to change without notice, justification, or notification to the data subjects. Manuals may not reflect product changes, but may not affect operating methods and safety of use. The manufacturer is not liable for direct, indirect, or accidental damage arising from or relating to the supply or use of this information. This document cannot be reproduced, adapted, or translated, in whole or in part, without the manufacturer's prior written authorization.

2.3 User profile

Radiologist, veterinarian, or qualified and trained personnel, possessing the following skills:

- x-ray equipment and radiation protection,
- risk / benefit ratio associated with image radiology techniques,
- use of ionizing radiation emissions,
- dental radiology technique,
- risks of biological damage due to the excessive use of ionizing radiation,
- methods to reduce the risk of excessive radiation to the patient,
- patient management,
- English language at the elementary level.

2.4 User obligations

It is the responsibility of the user to:

- follow the instructions, recommendations and pay attention to the warnings contained in this manual,
- keep the device in perfect working condition following the manufacturer's recommended maintenance schedule, failure to maintain relieves the manufacturer and its agent of responsibility for any damage, injury, or non-compliance that may result,
- verify compliance with the local regulations in force and/or ask a Qualified Expert,
- to ensure that the legislative obligations regarding the protection of workers, patients, and the population from radiation are met,
- promptly report to the competent Health Authority and to the manufacturer, or to his agent, the occurrence of an accident involving this medical device or the alteration of

characteristics and/or performances that could cause death, injury, or endanger the health of the patient and/or operator. The important information to include in the report to the manufacturer is the type and serial number of the items involved, which are reported on the technical labels.

FONA S.r.l. disclaims all responsibility for:

- use of the device other than that described in this manual,
- damage to the device, operator, or patient caused by both installation and maintenance other than the procedures indicated in the documentation provided with the device,
- installations / repairs carried out by unauthorized persons.

2.5 Contraindications

There are no contraindications to the use of the equipment within the intended use other than those related to exposure of the patient to ionizing radiation which must be limited to the maximum.

2.6 Useful life

The expected life is beyond 10 years of normal use, and, in this regard, a prospectus is provided to keep preventive maintenance under control for up to 20 years.

2.7 Essential performance

The essential performance of the device, necessary to reach the intended use, are:

- accuracy of loading factors,
- reproducibility of the radiation output.

The essential performance is guaranteed by the manufacturer through specific tests carried out during the production phase and through the firmware of the device, which allows the loading factors to always be within the established ranges.
Essential performance can be assessed through:

- absence of noise, artifacts, or distortion in an image,
- absence of errors in the visualized numeric values, which cannot be attributed to physiological effects and that can alter the diagnosis,
- absence of alarms,
- proper operation of the device.

The basic safety of the device has been tested according to the requirements of the following regulations:

- IEC 60601-1,
- IEC 60601-1-3,
- IEC 60601-2-65,
- IEC 60601-1-2.

2.8 Symbology

List of symbols used in this manual and device labels:

CE	Low voltage directive compliance mark.
	Attention, possible dangerous situation can harm the patient or operator.
	Prescription, potentially harmful situation that could harm the product. Also used for other important information.
	Avoid cutter.
	Instruction for use.
SN	Serial number.
	Separate collection, not disperse into the environment. Dispose of the product in accordance with the regulations in force.
	Warning electrical shock.
	Do not step onto the base plate or legs.
	Switch OFF.
	Switch ON.
	Small focal spot.
L	Mains phase 1 live.
N*	Mains phase 2.
	Non-ionizing electromagnetic radiation.
	Irradiation light on control panel.
	Earth.

	Manufacturer.
	Manufacturer date.
	The symbol is located on the device label and indicates to follow the instructions for use.
	Device weight.
	Use, transport and storage temperature limits.
REF	Reference number.
	Use, transport and storage humidity limits.
	Warning x-rays.
	Carry the mobile unit by the appropriate handle.
	Use, transport and storage pressure limits.
	Type B applied part.
	Inherent filtration.
N	Mains neutral.
	Protective earth (PE).
	Irradiation light on remote switch.
	Irradiation command on remote switch.

3. WARNINGS

SCOPE	RECOMMENDATAONS AND WARNINGS
GENERAL INFORMATION 	For the correct use of the device refer to the user manual. 
	Use the equipment only if no malfunctions are found during use or put it out of service and call the authorized technician for repair.
	This device is intended exclusively for use by properly trained personnel to avoid the risk of misuse.
	No modification of this medical device is allowed. For safety reasons, this device should only be used with the original accessories, the user is responsible for any damage caused by unapproved accessories. In particular, the use of cables with RJ11 connectors, instead of the supplied cables with RJ45 connectors, causes failures to the connector itself, resulting in equipment malfunction.
	The equipment must not be left unattended.
INSTALLATION 	The device requires to be assembled and installed as indicated in the installation and maintenance manual provided and only by authorized personnel. Risk of malfunction due to incorrect installation.
	The electromedical device requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and put into service in accordance with the EMC information provided.
USE, CARE AND MAINTENANCE 	In order to avoid the risk of infection, take appropriate measures to avoid cross-contamination between patients.
	Risk of cross-contamination. Follow a protocol that covers all phases, from preparation to exposure and processing, in order to maintain the entire aseptic process. Always protect the edge of the spacer / BLD (applied part) with adequate hygienic barrier.
	For preventive maintenance operations, follow the manufacturer's instructions. Risk of malfunction due to incorrect maintenance.
	If it is necessary to replace the power cord or carry out other preventive or corrective maintenance activities, it is necessary to contact only qualified and authorized technical personnel.
	Only qualified and trained service personnel are allowed to remove the covers and access the electrical circuits. Risk of electric shock.
	The cables of the power supply system must comply with the laws in force and must be equipped with terminals for ground protection.
	Check regularly, as required by the recommended maintenance plan, the status of the supports and arms of the suspension system, causing a service technician to intervene for any maintenance. Risk of breakage or blockage of movements.
	Perform the cleaning and disinfection operations detailed in §9.
	Turn OFF the equipment, disconnect it from the mains (with the general switch) and always wait at least 30 seconds before cleaning and disinfection.
	Comply with local laws when using and disposing of the product. 

SCOPE	RECOMMENDATAONS AND WARNINGS
RADIATION 	Risk of exposure to ionizing radiation. Before exposing the patient to the x-rays, move to a minimum distance of 2 m (78 $^{47}/_{64}$ in) from the focal spot indicated on the THA, moving away from the trajectory of the x-ray beam.
	X-ray equipment produces ionizing radiation that can be harmful if not properly controlled. The equipment must only be used by qualified and trained personnel, in accordance with the existing radiation protection laws.
	In the case of intensive use of the equipment by a single operator, exceeding an average of 100 exposures per day, the operator is recommended to take radiation protection measures, such as wearing an equivalent 0.25 mm (0 $^{1}/_{64}$ in) Pb shielding gown, or to protect himself behind an adequate barrier. This is in order not to exceed an additional radiation dose of 1 mSv per year, on an absorbed dose of natural radiation of about 3 mSv per year. For the calculation of the amount of diffuse and dispersed radiation absorbed by the operator at 2 m (78 $^{47}/_{64}$ in) from the patient, outside the primary radiation beam, consider that they are equal to about 1/40000 of the direct radiation at 20 cm (7 $^{7}/_{8}$ in).
	The radiation protection equipment required by law must be used for the patient and the operator, and the operator must ensure the patient's safety during use.
ENVIRONMENT 	As a result of extreme temperature fluctuations, condensation may occur; therefore, do not turn on the device until normal room temperature has been reached. Risk of malfunction.
	The covers are in class IP00 and do not protect against dust and liquids. Corrosion risk.
	The equipment must not be used in the presence of flammable gases or vapours. Risk of explosion.
ELECTRICAL SAFETY 	To avoid the risk of electric shock, this equipment must only be connected to a grounded mains power source, using the plug only for the mobile version.
ELECTROMAGNETIC COMPATIBILITY 	Risk of electromagnetic interference.
	Use the equipment only after proper assembly and installation according to the manufacturer's instructions. X-ray equipment produces ionizing radiation that can be harmful if not properly controlled. The equipment must only be used by qualified and trained personnel in accordance with the laws in force.
	The use of the device in an adjacent or stacked position compared to other equipment is to be avoided as it may cause incorrect operation. If such use is necessary, it is necessary to verify the normal operation of DENTALAIRE DC and the other equipment. The presence of electromagnetic disturbances could degrade the diagnostic performance of the equipment (e.g. interruption of examination, presence of artifacts, etc.). The need to repeat an X-ray examination must be justified for each patient in order to demonstrate that the benefits outweigh the risks.

<table>
<tr><th>SCOPE</th><th>RECOMMENDATAONS AND WARNINGS</th></tr>
<tr><td></td><td>The use of accessories, transducers, and cables other than those specified or provided by FONA may cause higher electromagnetic emissions or less electromagnetic immunity of DENTALAIRE DC, thus causing incorrect operation.
The following table presents a list of equipment interface cables:
<table>
<tr><th>INTERFACE CABLES</th></tr>
<tr><td>Universal connection spiral cable HMICPU-PWD-REMOTE BUTTON 8AWG26</td></tr>
<tr><td>HV cable (4 wires: 3 HV signals + EARTH GROUND) 4AWG16</td></tr>
<tr><td>FIL cable (3 wires: FIL+, FIL-, EARTH GROUND) 3AWG16</td></tr>
<tr><td>50 cm (19 $^{11}/_{16}$ in) ethernet cable for HMICPU-PWD connection 26AWGX4P</td></tr>
<tr><td>1000 cm (393 $^{45}/_{64}$ in) ethernet cable for HMICPU-PWD-REMOTE BUTTON universal connection 26AWGX4P</td></tr>
<tr><td>Main input power cable 3AWG16</td></tr>
<tr><td>Power cables from main switch to driver 1AWG16</td></tr>
</table></td></tr>
<tr><td></td><td>Although in accordance with the requirements of the electromagnetic compatibility standard, it is recommended not to use the device in the presence of strong external electromagnetic fields and electrostatic emission sources such as those generated by mobile phones, as interference may occur.</td></tr>
<tr><td></td><td>The functionality of implanted systems such as heart stimulators or cochlear implants can be altered by electromagnetic fields. Ensure that the patient does not bring such implants and do not use radiological equipment unless immunity to electromagnetic fields is ensured.</td></tr>
<tr><td></td><td>Portable or mobile radio frequency communication equipment can affect electromedical equipment such as DENTALAIRE DC. Portable radio frequency communication equipment (including peripherals such as antenna cables and external antennas) must not be used at a distance of less than 30 cm (11 $^{13}/_{16}$ in) from any part of the device, including cables specified by the manufacturer. Otherwise, the performance of the equipment may alter.</td></tr>
<tr><td></td><td>For more details related to electromagnetic compatibility refer to §10.</td></tr>
<tr><td>DISPLAY
  </td><td>The device is equipped with touch-sensitive control technology. The display must not be operated with sharp objects, which could damage or scratch the surface, always operate the display by gently pressing it with the fingertips.</td></tr>
</table>

Further information and warnings can be found in the manual.

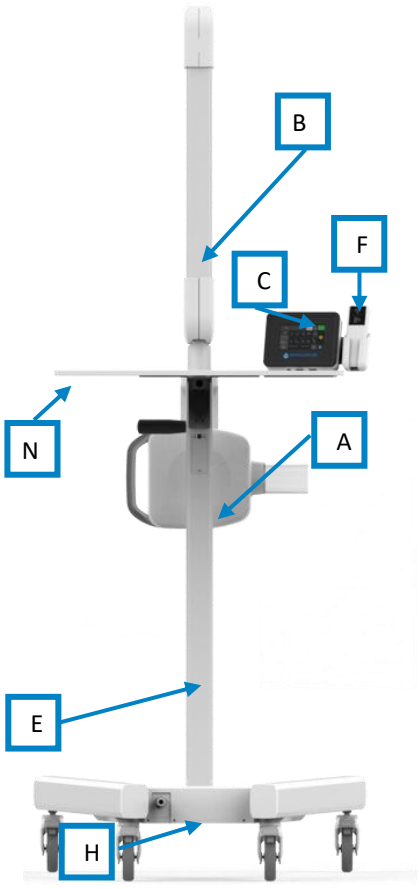
4. TECHNICAL DESCRIPTION

4.1 Models and main components

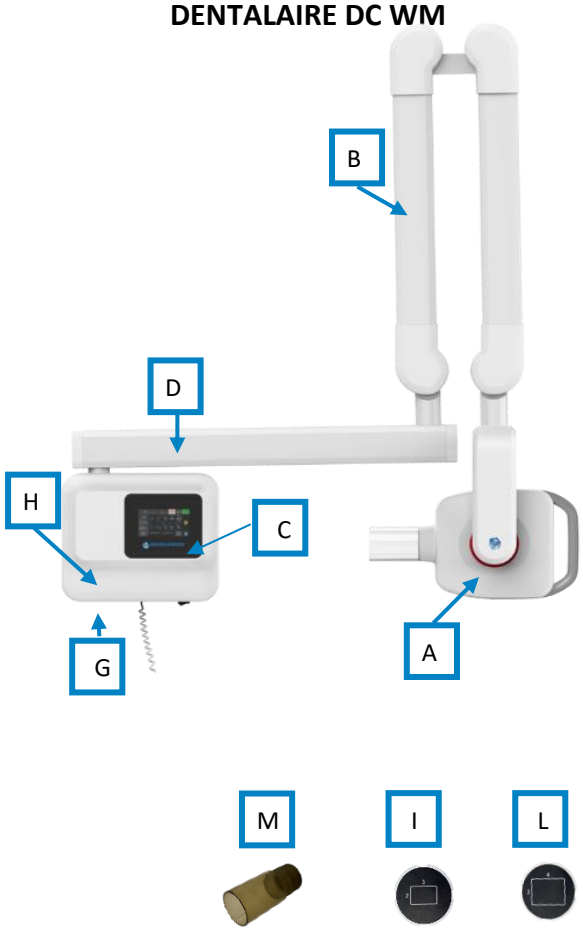
DENTALAIRE DC devices are available for wall mounting or on mobile stand base:

MODEL	CODE	NOTE
DENTALAIRE DC FM	971200100	Intraoral generator with mobile stand base
DENTALAIRE DC WM	971000100	Intraoral generator wall mounted with support arm (D) 30 cm (11 13/16 in)
	971000200	Intraoral generator wall mounted with support arm (D) 60 cm (23 5/8 in)
	971000300	Intraoral generator wall mounted with support arm (D) 80 cm (31 1/2 in)
	971000400	Intraoral generator wall mounted with support arm (D) 100 cm (39 3/8 in)

DENTALAIRE DC FM



DENTALAIRE DC WM



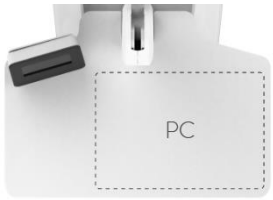
ID	DESCRIPTION	CODE
A	THA	931000100
B	Scissor arm	931000200
C	Control panel (HMICPU)	931000300
D	Support arm 30 cm (11 13/16 in) S	931000400
	Support arm 60 cm (23 5/8 in) M	931000500
	Support arm 80 cm (31 1/2 in) L	931000600
	Support arm 100 cm (39 3/8 in) XL	931000700
E	Mobile stand base	931200100

ID	DESCRIPTION	CODE
F	Remote switch	931000800
G	Wall support	931000900
H	Power driver (PWD)	931001000
ACCESSORIES		
I	BLD 2x3	911000100
L	BLD 3x4	911000200
M	Cone extension	911000300
N	PC support tray	911200100

4.2 Accessories

The basic x-ray device allows the operations at a source-skin distance of 20 cm (7 $^{7}/_{8}$ in) with a circular radiation beam.

On request, the following accessories are available:

ACCESSORIES		DESCRIPTION
Cone extension		10 cm (3 $^{15}/_{16}$ in) cone extension for operation at the souce-skin distance (SSD) of 30 cm (11 $^{13}/_{16}$ in).
BLD 2x3		2 x 3 cm (0 $^{25}/_{32}$ x 1 $^{3}/_{16}$ in) rectangular radiation beam limiter diaphragm.
BLD 3x4		3 x 4 cm (1 $^{3}/_{16}$ x 1 $^{37}/_{64}$ in) rectangular radiation beam limiter diaphragm.
PC support tray		PC support. It is possible to fix the control panel on both the right and left side using the additional bracket supplied with the purchase of the tray.

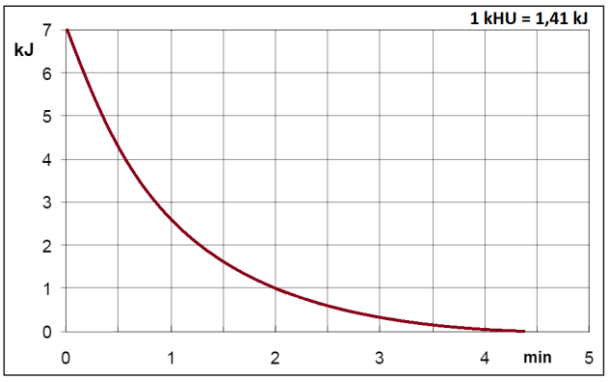
4.3 Technical specifications

POWER SUPPLY	
Nominal Line Voltage	120 - 230 V ± 10%
Line Frequency	50 - 60 Hz
Rated current	7 A at 120 V, 3.5 A at 230 V
Permissible apparent impedance of supply mains	< 1.0 Ohm
Maximum rated power	840 W at maximum loading factors 70 kV - 7 mA
Line fuses	T6.3 AL 250 V
Additional high breaking capacity fuses for FM model	T6.3 AH 250 V with an interrupting rating of 1500 A at 250 Vac

PERFORMANCE	
Mode of operation	Continuous (long time operation)
Nominal Duty Cycle	1:20
Irradiation time	0.01–3.2 s ± 5% + 1 ms, R20 scale
Tube Voltage	60, 65 or 70 kV ± 5% selectable
High-voltage waveform	High Frequency DC, residual ripple ≤ 4 kV
Tube Current	7 mA ± 10%
Frequency HV generator	70 kHz
Source Skin Distance (SSD)	20 cm (7 $^{7}/_{8}$ in), optional 30 cm (11 $^{13}/_{16}$ in)
Radiation output field	Section < 6.0 cm (2 $^{23}/_{64}$ in)
Circular BLD	Circular field: diameter 5.8 cm (9 $^{9}/_{32}$in), 26 cm^2 (4.03 in^2) area at 20 cm (7 $^{7}/_{8}$ in) SSD, eccentricity < 10%
BLD 3x4	Field 2.2 x 3.2 cm (0 $^{55}/_{64}$ x 1 $^{17}/_{64}$ in), 7 cm^2 (1.09 in^2) area at 20 cm (7 $^{7}/_{8}$ in) SSD
BLD 2x3	Field 3.2 x 4.4 cm (1 $^{17}/_{64}$ x 1 $^{47}/_{64}$ in), 14 cm^2 (2.17 in^2) area at 20 cm (7 $^{7}/_{8}$ in) SSD

CONTROL PANEL	
Exposure factor	Set in s [0.01-3.2] or mAs [0.071-22.4]
Precision	± 0.02 s or 5% (whichever is greater) with power supply at the mains nominal value
Exposure factor settings	Automatic with a selection of tooth type and patient size or manual selection, for use with film, phosphor plate, or digital sensor
X-ray indication	Yellow light on the remote switch, illustration on the control panel display and buzzer
X-ray ON	• Remote switch with cable extendable to 3 m (118 $^{7}/_{64}$ in) • Button on the control panel display

RADIATION QUALITY	
First half value layer HVL	≥ 2 mm (0 $^{5}/_{64}$ in) Al at 70 kV
Total filtration	2 mm (0 $^{5}/_{64}$ in)
Dose yield at 60 kV	6.5 mGy/s ±20% at 20 cm (7 $^{7}/_{8}$ in) from the source
Dose yield at 65 kV	7.8 mGy/s ±20% at 20 cm (7 $^{7}/_{8}$ in) from the source
Dose yield at 70 kV	9.2 mGy/s ±20% at 20 cm (7 $^{7}/_{8}$ in) from the source
Radiation leakage	< 0.25 mGy/h (< 28.75 mR/h) at 1 m (39 $^{3}/_{8}$ in)
Focal spot mark	Dot embossed on plastic covers of the THA

X-RAY TUBE	
Anode material	Tungsten
Anode angle	16°
Focal Spot	0.4 (IEC 60336:2006)
Nominal continuous power	110 W
X-ray tube cooling curve	

DIMENSIONS and WEIGHTS WM model		
Suport arm length	S	30 cm (11 $^{13}/_{16}$ in)
	M	60 cm (23 $^{5}/_{8}$ in)
	L	80 cm (31 $^{1}/_{2}$ in)
	XL	100 cm (39 $^{3}/_{8}$ in)
Useful Reach SSD 20 cm (7 $^{7}/_{8}$ in)	143 cm (56 $^{3}/_{8}$ in) with support arm S	
	173 cm (68 $^{3}/_{16}$ in) with support arm M	
	193 cm (76 $^{1}/_{16}$ in) with support arm L	
	213 cm (83 $^{15}/_{16}$ in) with support arm XL	
Weights	Wall support	3.5 kg

DIMENSIONS and WEIGHTS WM model			
	Support arm	S	3.0 kg
		M	4.3 kg
		L	5.1 kg
		XL	6 kg
	Scissor arm	12 kg	
	THA	6.5 kg	

DIMENSIONS and WEIGHTS FM model		
Mobile stand base width	71 cm (27 $^{27}/_{32}$ in)	
Mobile stand base length	92.5 cm (36 $^{27}/_{64}$ in)	
Overall height	193 cm (75 $^{23}/_{32}$ in)	
Weights	Mobile stand base	31 kg
	Scissor arm	12 kg
	THA	6.5 kg

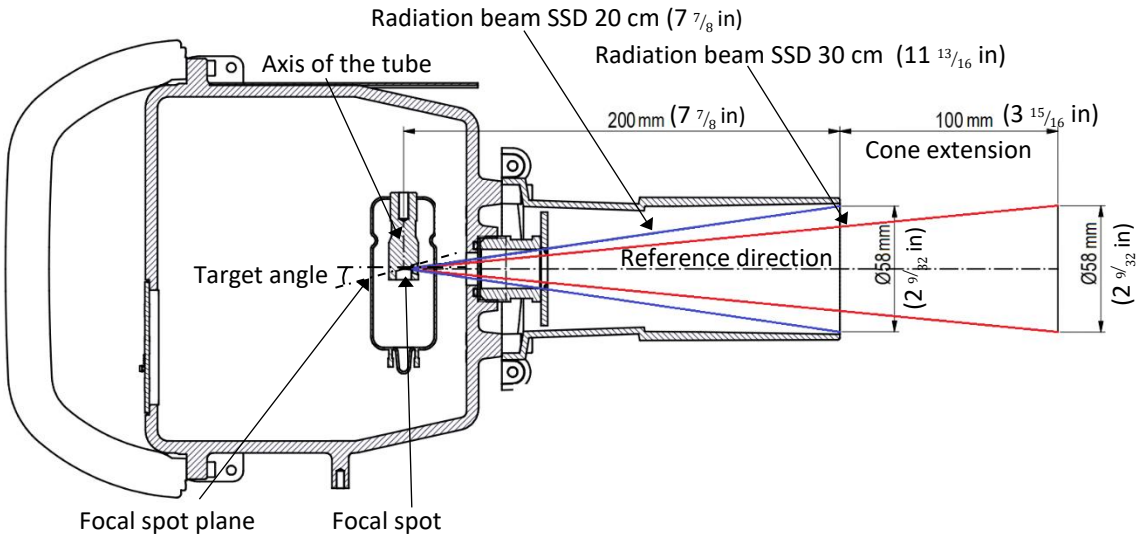
ENVIRONMENTAL CONDITIONS		
Transport and storage	Temperature	From -20 to +50°C
	Relative humidity	From 10 to 90%
	Pressure	From 500 to 1060 hPa
Operation	Temperature	From 15 to 40 °C
	Relative humidity	From 30 to 75%
	Pressure	From 700 to 1060 hPa

4.4 Principle of operation

From a functional point of view, the device consists of a radiogenic generator, which voltage values can be set to 60, 65 or 70 kV, while the anodic current value of the tube is fixed at 7 mA.

The control panel then allows the user to control irradiation from a minimum of 0.01 s to a maximum of 3.2 s.

THA section seen from the opposite side with respect to the joint for the attachment of the scissor arm (lung side).



The focal spot is indicated by a raised point on the plastic cover of the THA.

5. TYPES OF INSTALLATION

5.1 WM model installation

TYPOLOGY	DESCRIPTION	ILLUSTRATION
I1	Control panel and remote switch inside the room.	
I2	Control panel inside the room and remote switch outside the room.	
I3	Control panel outside the room (with optional remote switch connection).	

5.2 Control panel placement

With the WM model it is possible to position the control panel both inside and outside the wall support.

CONTROL PANEL INSIDE THE WALL SUPPORT	CONTROL PANEL OUTSIDE THE WALL SUPPORT
	

In the case of FM model, the control panel is mounted directly on the pole of the mobile stand base. It is possible to position the remote switch both on the right and left side of the control panel.

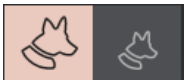
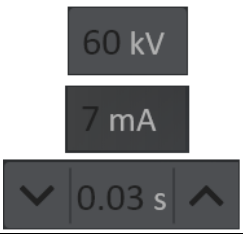
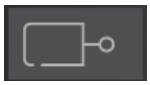
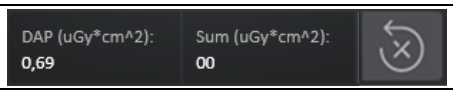
In case of request of the PC support tray, an additional bracket will be provided that allows the positioning of the control panel both on the right and left side of the tray itself.

WITHOUT PC SUPPORT TRAY	WITH PC SUPPORT TRAY
	

6. COMMANDS AND FUNCTIONS

6.1 Control panel structure

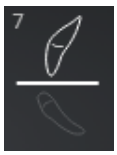
Below the control panel home page:

ICON	DESCRIPTION	PARAGRAPH
	Selectable anatomical regions	§6.1.1
	Patient body size	§6.1.2
	Exposure parameters	§6.1.3
	Kind of receptor	§6.1.4
	Kind of BLD	§6.1.5
	Device status	§6.1.6
	DAP Information	§6.1.7
	X-ray emission button	§6.1.8
	Settings menu	§6.1.9

The pink color indicates the selected icon.

6.1.1 Anatomical regions

10 anatomical regions are selectable:

ANATOMICAL REGION	ICON
Maxillary incisors	
Maxillary canines / premolars	
Maxillary molars	
Maxillary occlusal	
Bitewing	

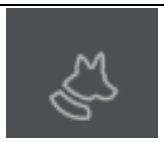
ANATOMICAL REGION	ICON
Mandibular incisors	
Mandibular canines / premolars	
Mandibular molars	
Mandibular occlusal	
Endodontic	

Press the button corresponding to the anatomical region of interest to automatically set the exposure value, in relation to the kind of image receptor, kV value, patient body size and source-skin distance.

6.1.2 Patient body size

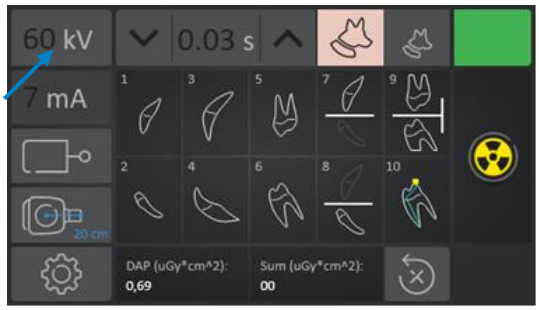
2 patient body sizes are selectable:

PATIENT BODY SIZE	ICON
Large size	

PATIENT BODY SIZE	ICON
Small size	

6.1.3 Exposure parameters

Exposure voltage selection

STEP	DESCRIPTION	ILLUSTRATION
A	• Press the icon that indicates the voltage that is currently selected.	
B	• Choose the desired voltage between 60, 65 and 70 kV. Radiographs with higher contrast are obtained at 60 kV than at 70 kV. At 70 kV there is a more penetrating X-ray beam than at 60 kV. • Press the voltage icon again to confirm the choice.	

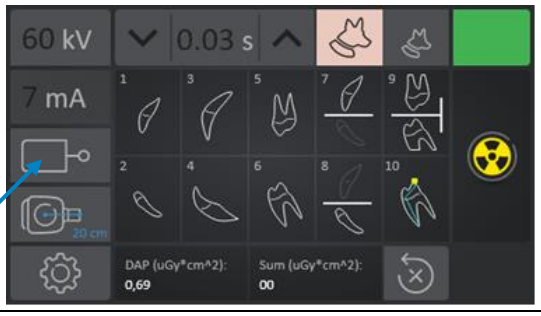
Exposure current selection

The exposure current is a fixed parameter set to 7 mA, so it is not editable.

Exposure time selection

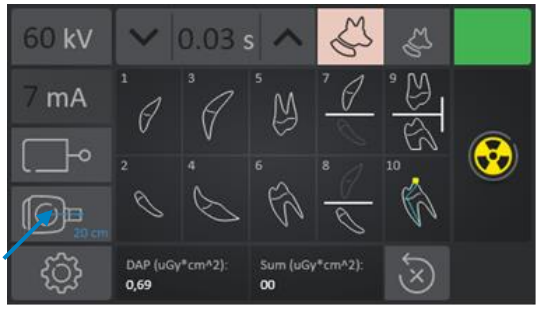
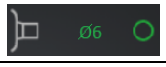
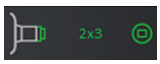
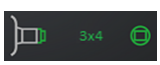
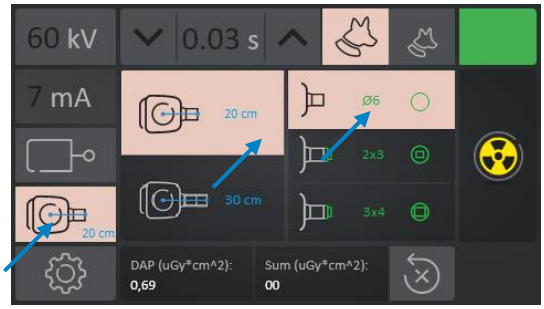
STEP	DESCRIPTION	ILLUSTRATION
A	The arrows allow the manually set of the exposure time. It is possible to increase (^) or decrease (v) the exposure time shown on the control panel display. This switch to manual setting. In the settings, it is possible to choose whether to display the value in s or mAs (refer to §6.1.9).	

6.1.4 Kind of receptor

STEP	DESCRIPTION	ILLUSTRATION
A	• Press the icon that indicates the kind of receptor currently selected.	

<table>
<tr><th>STEP</th><th>DESCRIPTION</th><th>ILLUSTRATION</th></tr>
<tr><td>B</td><td>
• Choose the kind of receptor between:
<table>
<tr><td>  </td><td>Film</td></tr>
<tr><td>  </td><td>Phosphor plate</td></tr>
<tr><td>  </td><td>Digital sensor</td></tr>
</table>
Below each image is shown the value of the exposure index. Refer to §6.1.9 to change this parameter.
• Press the receptor kind icon again to confirm the choice.
</td><td> 
</td></tr>
<tr><td>C</td><td colspan="2">Nominal characteristics of image receptors:
• Films of class D, E, or F.
• Phosphor plate composed of BaSrFBr:Eu with typical luminescence of ~ 400 nm (1.57x10^{-5} in).
• Intraoral digital sensors with CsI or GOS scintillator, pixel size 20 x 20 µm (7.87x10^{-4} x 7.87x10^{-4} in), pixel pitch 20 µm (7.87x10^{-4} in), USB connection to PC.</td></tr>
</table>

6.1.5 Kind of BLD

<table>
<tr><th>STEP</th><th>DESCRIPTION</th><th>ILLUSTRATION</th></tr>
<tr><td>A</td><td>
• Press the icon that indicates the kind of BLD currently selected.
</td><td> 
</td></tr>
<tr><td>B</td><td>
• Choose the source-skin distance between:
<table>
<tr><td>  </td><td>SSD 20 cm (7 $^{7}/_{8}$ in)</td></tr>
<tr><td>  </td><td>SSD 30 cm (11 $^{13}/_{16}$ in), cone extension added</td></tr>
</table>
• Choose the BLD between:
<table>
<tr><td> 
</td><td>Circular BLD Ø 6 cm (2 $^{23}/_{64}$ in)</td></tr>
<tr><td> 
</td><td>BLD 2x3 cm (0 $^{25}/_{32}$ x 1 $^{3}/_{16}$ in)</td></tr>
<tr><td> 
</td><td>BLD 3x4 cm (1 $^{3}/_{16}$ x 1 $^{37}/_{64}$ in)</td></tr>
</table>
• Press the receptor kind icon again to confirm the choice.
</td><td> 
</td></tr>
</table>

6.1.6 Device status

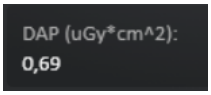
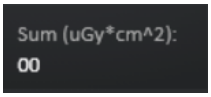
<table>
<tr><th>DEVICE STATUS</th><th colspan="2">ICON</th></tr>
<tr><td>The device is ready for radiation</td><td></td><td>GREEN</td></tr>
</table>

DEVICE STATUS	ICON	
Error / Alarm		RED
Radiation in progress		YELLOW
Cooling of the device (not ready for radiation)		BLUE
Trial mode > 90%		ORANGE

6.1.7 DAP Information

DAP values (dose area product) are obtained by multiplying the dose of radiation in microGy produced at the indicated kV level and delivered at the indicated distance, multiplied by the area in square meters of the actual output window, whether circular or rectangular. For the values shown, a tolerance of 20% should be considered to compensate for measurement errors and changes in the device and instruments.

DAP values can also be viewed on the display:

ICON	DESCRIPTION
	DAP value (µGy*cm^2) corresponding to the selected technical factors (kV, mA, s or mAs) and configured parameters (source-skin distance, image receptor exposure index). It is necessary to enable the DAP function, refer to §6.1.9.
	The sum of the DAP values. This command allows to view the total dose emitted in multiple exposures.
	Button for resetting the sum of the DAP values.

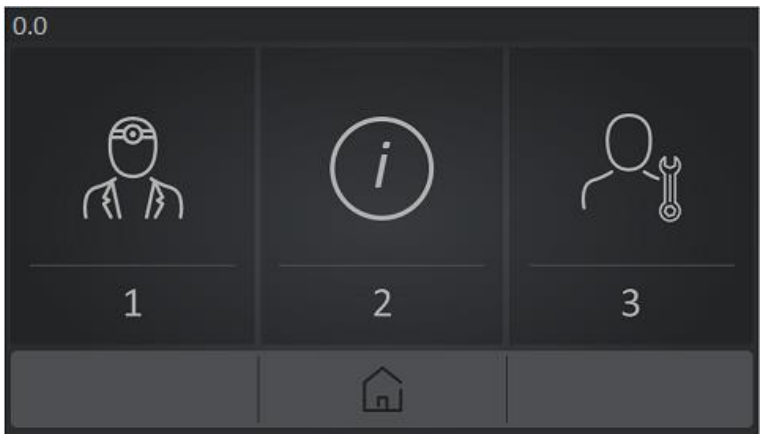
On request, are available the DAP tables containing the values at source-skin distance of 20 cm (7 $^{7}/_{8}$ in) or 30 cm (11 $^{13}/_{16}$ in) in each of the exposure conditions at 60, 65 or 70 kV. It is possible to measure the doses using an appropriate instrument (DIGITAL SOLIDOSE DOSIMETER), subjected to adequate maintenance and calibration.

6.1.8 X-ray emission button

ICON	DESCRIPTION
	The command allows the activation of the x-ray emission. This button can be used as an alternative to the remote switch to perform the exam. Enabling this command is performed by the installer. If the device is installed inside the room, it is possible to set an arming time, to allow the operator to move away before the x-ray emission takes place, refer to §6.1.9.

6.1.9 Settings menu

Pressing the settings button  shows the following screen:



The menu is divided into 3 sections:

1. user menu,
2. diagnostic and usage information,
3. service menu.

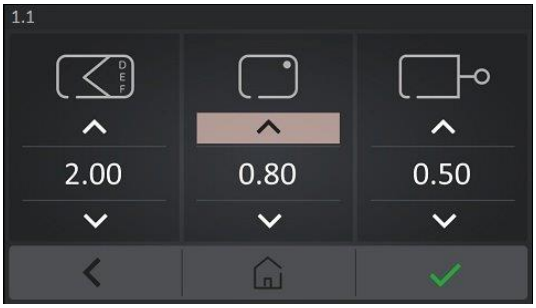
This manual depth describes the functions present in the first 2 sections (user menu and device information). For more details on the service menu, refer to the installation and maintenance manual (code: 691000220).

User menu:

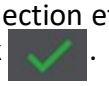
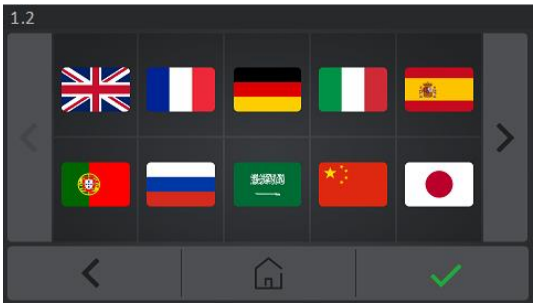
The following paragraphs show the various settings that are present once entered the user menu.

ID 1.1 - Setting of exposure indices

STEP	DESCRIPTION	ILLUSTRATION
A	• The icon indicated allows the modification of the exposure indices.	

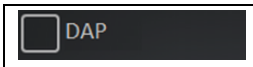
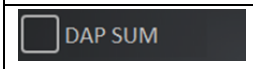
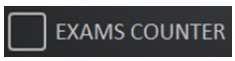
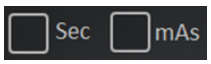
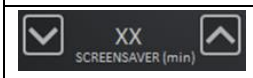
<table>
<tr><th>STEP</th><th>DESCRIPTION</th><th>ILLUSTRATION</th></tr>
<tr><td>B</td><td>
• For each kind of receptor, set the desired exposure index, through the arrows.
<table>
<tr><td>Film</td><td>Typical values:
- 0.8 class F,
- 1.0 class E,
- 2.0 class D.</td></tr>
<tr><td>Phosphor plate</td><td>Typical values 0.5-2.</td></tr>
<tr><td>Digital sensor</td><td>Typical values 0.25-1.</td></tr>
</table>
• To make the selection effective, press the green check  .
• The button  allows the return to the previous screen (ID 1-1).
• The button  allows the return to the home page.
</td><td> 
</td></tr>
</table>

ID 1.2 - Setting of the language

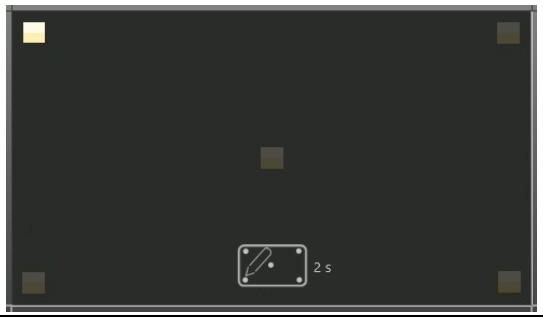
<table>
<tr><th>STEP</th><th>DESCRIPTION</th><th>ILLUSTRATION</th></tr>
<tr><td>A</td><td>• The icon indicated allows the modification of the language set in the control panel.</td><td> 
</td></tr>
<tr><td>B</td><td>
• Select the desired language.
• To make the selection effective, press the green check  .
• The button  allows the return to the previous screen (ID 1-1).
• The button  allows the return to the home page.
</td><td> 
</td></tr>
</table>

ID 1.3 - Other user settings

<table>
<tr><th>STEP</th><th>DESCRIPTION</th><th>ILLUSTRATION</th></tr>
<tr><td>A</td><td>
• The icon indicated allows the opening of the screen that enables the modification of the following parameters:
- DAP view,
- DAP sum view,
- exam counter view,
- selection of display time view in s or mAs,
- setting of an arming time,
</td><td> 
</td></tr>
</table>

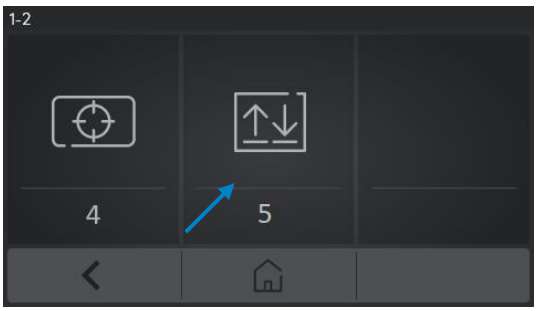
<table>
<tr><th>STEP</th><th>DESCRIPTION</th><th>ILLUSTRATION</th></tr>
<tr><td></td><td>- screensaver setting.</td><td></td></tr>
<tr><td>B</td><td>
• Set the desired parameters.
<table>
<tr><td> 
</td><td>Allows the visualization of the DAP value on the home page.</td></tr>
<tr><td> 
</td><td>Allows the visualization of the sum of the DAP values on the home page.</td></tr>
<tr><td> 
</td><td>Enable the exam counter. To view this counter, refer to point 2.2 of §6.1.9.</td></tr>
<tr><td> 
</td><td>Allows to choose whether to view the technical factor in s or in mAs on the home page.</td></tr>
<tr><td> 
</td><td>It is possible to increase ( ) or decrease ( ) the exam arming time.</td></tr>
<tr><td> 
</td><td>It is possible to increase ( ) or decrease ( ) the inactivity time in addition to which the screensaver images are visualized.</td></tr>
</table>
• To make the selection effective, press the green check .
• The button allows the return to the previous screen (ID 1-1).
• The button allows the return to the home page.
</td><td> 
</td></tr>
</table>

ID 1.4 - Display calibration

STEP	DESCRIPTION	ILLUSTRATION
A	• The icon indicated allows the re-calibration of the display of the control panel.	
B	• 5 display calibration buttons will appear on the screen one at a time. • Press and hold each display calibration button for at least 2 seconds. • If the procedure is completed correctly at display appear the button " OK", press it to return to the previous screen (ID 1-2).	

Display calibration may be automatically called up when the device is turned ON if the device itself does not detect calibration offsets. If the problem persists, contact technical support.

ID 1.5 - Data upload / download

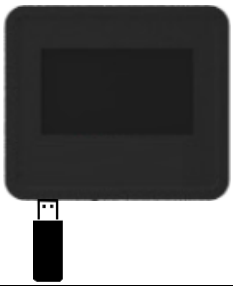
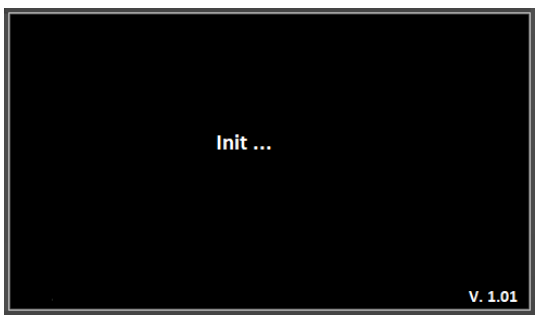
STEP	DESCRIPTION	ILLUSTRATION
A	• The icon indicated allows the data upload and download using a USB key.	
B	 Download data from USB key to device.  Upload data from device to USB key. • On this screen it is possible to see the STATUS of data transmission: - USB E01: error configuration file not found, - USB E02: error configuration file size out of limits (> 6 kb), - USB E03: error configuration file unreadable, - USB E04: error configuration file cannot be opened,	

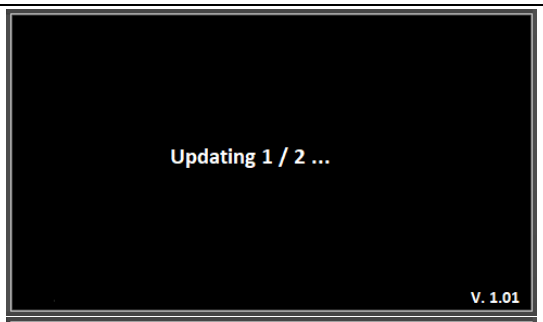
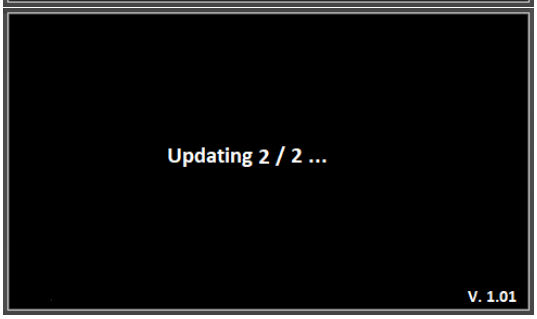
STEP	DESCRIPTION	ILLUSTRATION
	- USB E05: error configuration file not accessible, - USB E06: error incorrect cfg trial mode, - USB E07: error cfg file not compliant, - OK: done. • The button allows the return to the previous screen (ID 1-2). • The button allows the return to the home page.	

If technical assistance is required, a file can be generated containing the state of the art of the device parameters.

After inserting the USB key into the appropriate USB HOST under the display, use the data upload function ( ) on the ID 1.5 screen, a confxxxx file will be automatically loaded on the USB key (where xxxx are the last 4 digits of the serial number of the HMICPU).

Through this function it is possible to update the firmware of the device.

STEP	DESCRIPTION	ILLUSTRATION
A	• Insert a USB key (2.0 at least) in the PC USB port and copy in the USB key the following files supplied by FONA: - hmi_0102.bin - img_0101.bin - upgrade.ini	
	Copy in the USB key DIRECTLY the files, and not a folder.	
B	• When the device is turned OFF, insert the USB key with the appropriate firmware version in the appropriate or USB HOST under the display.	
C	• Turn ON the device and wait for the firmware update home page visualization (auto-detect).	
D	• Wait for messages: - "Init…", - "Updating 1/2…" (FW update), - "Updating 2/2…" (images update). Wait for the update procedure to complete and the application to start to make sure that the firmware download process has completed successfully.	

STEP	DESCRIPTION	ILLUSTRATION
		 

Status / error messages are displayed in the centre of the screen:

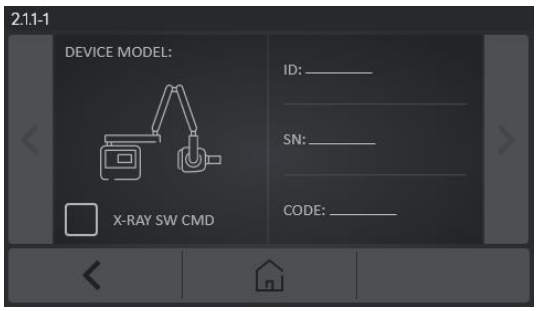
- Init: initialization,
- Updating 1/2: FW update in progress,
- Updating 2/2: QSPI update in progress,
- FW E01: error no valid FW detected,
- FW E02: error incorrect FW dimensions,
- FW E03: error FW downgrade not allowed,
- FW E04: error incorrect QSPI size,
- FW E05: error QSPI downgrade not allowed.

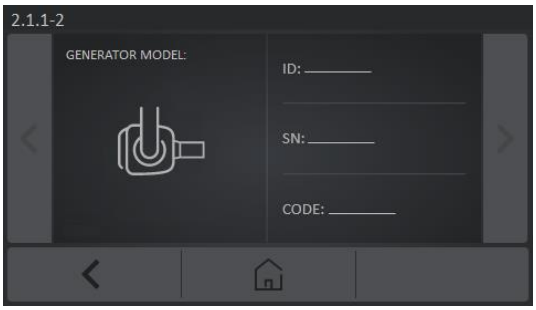
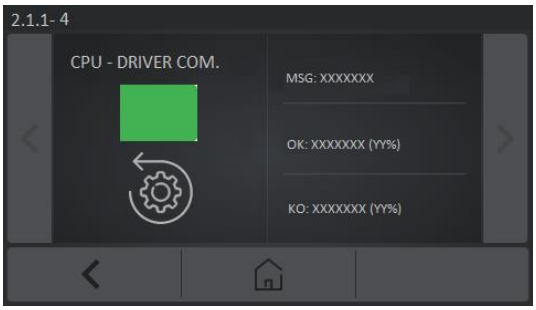
During the FW update, it is possible to see the bootloader version at the bottom right.

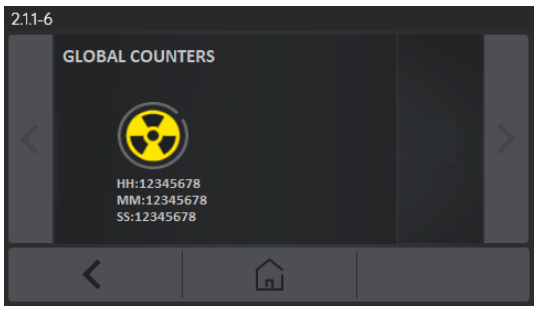
Diagnostic and usage information:

The following paragraphs show the various settings present once entered the diagnostic and use information menu.

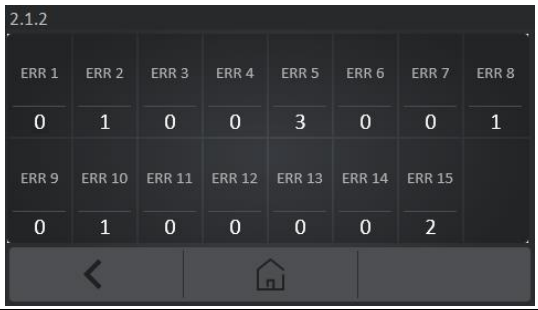
ID 2.1.1 - Device information

STEP	DESCRIPTION	ILLUSTRATION
A	• The icon indicated allows the access to the device information.	
B	• The icon indicated allows the access to the device diagnostic.	
With side icons  and  it is possible to navigate between the following screens:		
B-1	• On screen ID 2.1.1-1 it is possible to see: - "ID": device model (XVI-150 WM or XVI-150 FM), - "SN": device serial number, - "CODE": device code (§4). • "X-RAY SW CMD": selected if the x-ray emission button on the control panel display was activated during installation.	

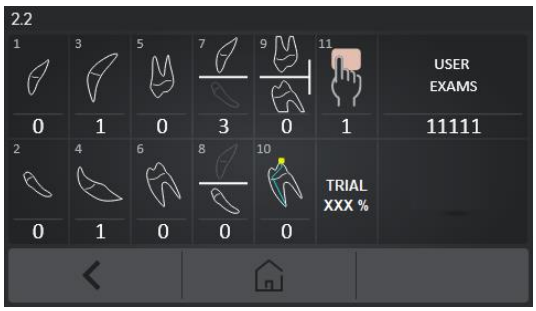
STEP	DESCRIPTION	ILLUSTRATION
B-2	• On screen ID 2.1.1-2 it is possible to see: - "ID": THA model, - "SN": THA serial number, - "CODE": THA code.	
B-3	• On screen ID 2.1.1-3 it is possible to see: - "CPU SN": CPU board serial number, - "FW CPU": CPU firmware version, - "PWD SN": PWD board serial number, - "FW PWD": PWD firmware version, - "MSG": message table version.	
B-4	• On screen ID 2.1.1-4 it is possible to see: - "CPU-DRIVER COM.": - Green: CPU-PWD stable communication, - Red: CPU-PWD instable communication. - "MSG": number of total messages exchanged between CPU and DRIVER, - "OK": number of "MSG" exchanged correctly, - "KO": number of "MSG" exchanged incorrectly. • The command  allows the reset of the counters.	
B-5	• On screen ID 2.1.1-5 it is possible to see:  - The status of optional security contacts:  - Green: security contacts 1 and 2 ON, - Red: security contacts 1 or 2 OFF.  - The status of the buzzer ON/OF. To run a functional test press  .  - The status of the remote switch PRESSED / RELEASED.	

STEP	DESCRIPTION	ILLUSTRATION
B-6	• On screen ID 2.1.1-6 it is possible to see the total working time of the device.	
• The button allows the return to the previous screen (ID 2.1). • The button allows the return to the home page.		

ID 2.1.2 - Alarms counter

STEP	DESCRIPTION	ILLUSTRATION
A	• The icon indicated allows the access to the device information.	
B	• The icon indicated allows the access to the alarm counter.	
C	• On this screen it is possible to see the repeatability of errors (refer to §11 to know the errors). • The button allows the return to the previous screen (ID 2.1). • The button allows the return to the home page.	

ID 2.2 - Exposure counter

STEP	DESCRIPTION	ILLUSTRATION
A	• The icon indicated allows the access to the exposure counter (the icon is visible only if the "EXAMS COUNTER" option has been enabled on screen ID 1.3-1).	
B	• On this screen it is possible to see the number of exams performed. • The icon  represents the number of manual exams. • If the device is used in trial mode, the percentage of exams performed is visualized. When "TRIAL xxx %" is > 90%, the status of the device visualized on the home page turns orange for 10 seconds following an examination to report the situation. Contact technical support. • The button  allows the return to the previous screen (ID 2.0). • The button  allows the return to the home page.	

7. PREPARATION OF THE EXPOSURE

7.1 Preparation of the exposure

7.1.1 Moving of the mobile unit

- Use the handles to position the unit and lock it permanently by lowering the brake levers of the wheels. The scissor arm must remain closed in the resting position when the unit is moved.

Risk of overturning.

Do not step onto the base plate or legs.

Carry the mobile unit by the appropriate handle.

7.1.2 Turning ON the unit

- Turn ON the device with the switch.

Do not press the remote switch button when turning ON the device.

- At the end of switching on, the home page will appear on the display. The green icon at the top indicates that the unit is ready for irradiation.
  The last used exposure parameters are proposed.

7.1.3 THA positioning

- Place the patient.
- Place the image receptor in the anatomical area of interest and orient the THA accordingly.

Place the THA by using the appropriate handle.
Avoid touching the patient during the placement of the THA.

7.1.4 Receptor placement

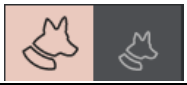
Parallel technique

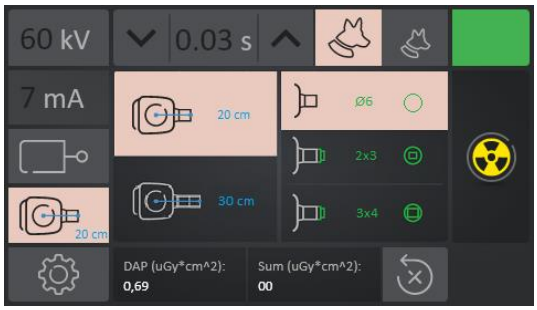
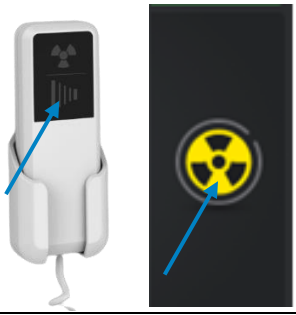
IMMAGE	DESCRIPTION
	Receptor positioned parallel to the object to be radiographed and the x-rays are directed perpendicular to both the receptor and the tooth / root.

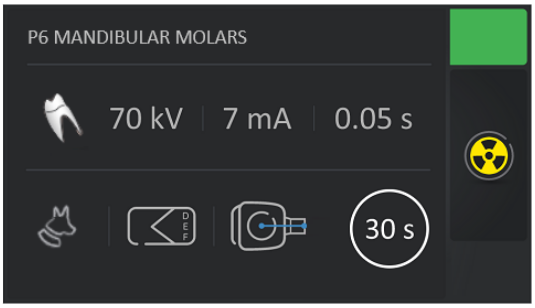
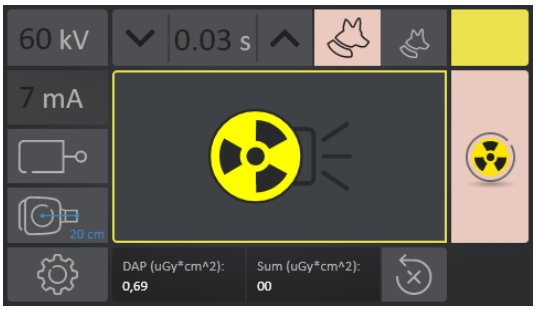
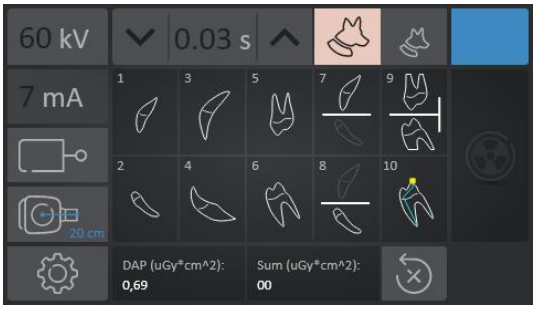
Bisector technique

IMMAGE	DESCRIPTION
	Receptor positioned parallel to the tooth, the x-rays are directed perpendicular to an imaginary line that divides in two the angle between the sensor plane and the long axis of the tooth.

7.2 Starting exposure

STEP	DESCRIPTION	ILLUSTRATION
A	• Selection of the anatomical region of interest (refer to §6.1.1).	
B	• Selection of the patient body size (refer to §6.1.2).	
C	• Selection of the exposure parameters (refer to §6.1.3).	

STEP	DESCRIPTION	ILLUSTRATION
D	• Selection of the kind of receptor (refer to §6.1.4).	
E	• Selection of the kind of BLD (refer to §6.1.5).	
F-1	• If the device is installed as indicated in points **I2** or **I3** of §5.1: - get out of the room.	
F-2	• If the device is installed as indicated in point **I1** of §5.1 or if it is mobile: - hold the command and take at least 2 m (78 $^{47}/_{64}$ in) from the patient, out of the trajectory of the x-ray beam, to protect against diffuse and dispersed radiation.	
G	• Press the remote switch or the x-ray emission icon on the control panel display (if enabled), hold it until the yellow light and buzzer turn OFF to indicate the end of the irradiation.	
⚠	Release the button earlier than expected only in case of need: the radiation emission is interrupted immediately, and the related alarm is generated. If the interruption of exposure occurs during the heating of the filament there has been no irradiation and the image receptor has not been exposed.	

STEP	DESCRIPTION	ILLUSTRATION
H	• If the arming function is enabled, a summary screen will be visualized with the data entered and the waiting time before the x-ray emission. • Follow the instructions at point **G** to start the exposure.	
I	• The device status icon becomes yellow and the x-rays icon is visualized.	
J	• When exposure is finished, an animation indicates to release the x-rays button.	
K	• Once irradiation is complete, hang up the remote switch and remove the exposed image receptor.	
L	• After each exposure, the device manages the cooling according to the established working cycle (1:20). During the cooling period the device is inhibited, the device status icon is blue, and a new exposure cannot be performed. At the end of the cooling time the icon goes green again and the device is ready for a new exposure.	
M	• If the DAP presentation is selected, the DAP value corresponding to the exposure parameters and those of the declared device (source-skin distance and BLD shape) is shown at the bottom of the display.	

7.3 Turning OFF the unit

If the device is no longer to be used, it must be turned off.

FM MODEL RESTING POSITION	WM MODEL RESTING POSITION
	

8. EXPOSURE TIMES AND INDICES

8.1 Range of exposure times

The exposure table in s and mAs (current product on time) at 7 mA includes 51 steps from 0.01 to 3.2 s (i.e. from 0.07 to 22.40 mAs) according to the R20 scale (20 steps per decade, doubling the value every 6 steps forward, halving it every 6 steps backward).

mAs R'20	EXP TIME [s]
0.071	0.010
0.080	0.011
0.090	0.013
0.100	0.014
0.110	0.016
0.125	0.018
0.140	0.020
0.160	0.023
0.180	0.026
0.200	0.029
0.220	0.031
0.250	0.036
0.280	0.040
0.320	0.046
0.360	0.051
0.400	0.057
0.450	0.064
0.500	0.071
0.560	0.080
0.630	0.090
0.710	0.101
0.800	0.114
0.900	0.129
1.000	0.143
1.100	0.157
1.250	0.179

mAs R'20	EXP TIME [s]
2.200	0.314
1.400	0.200
1.600	0.229
1.800	0.257
2.000	0.286
2.500	0.357
2.800	0.400
3.200	0.457
3.600	0.514
4.000	0.571
4.500	0.643
5.000	0.714
5.600	0.800
6.300	0.900
7.100	1.014
8.000	1.143
9.000	1.286
10.000	1.429
11.200	1.600
12.500	1.786
14.000	2.000
16.000	2.286
17.500	2.500
20.000	2.857
22.400	3.200

8.2 Image receptor exposure index

Before using the unit, load the exposure indices of the available image receptors, if different from the factory-set values (refer to §6.1.9).

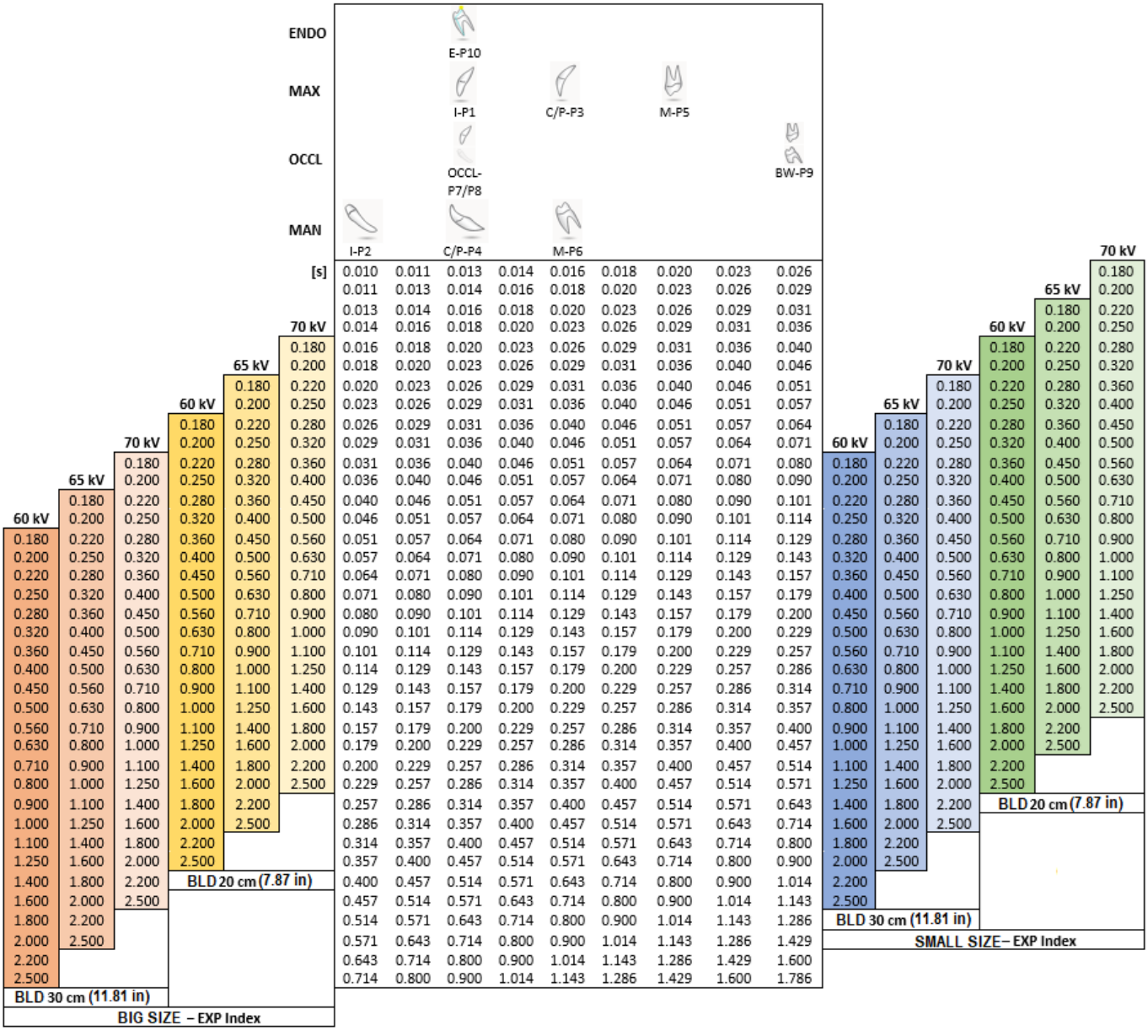
EXP INDEX	CLASS	RECEPTOR
0.180		
0.200		
0.220		
0.250		
0.280		
0.320		
0.360		
0.400		
0.450		
0.500	1/2 E	Digital sensor
0.560		
0.630		
0.710		
0.800	F	
0.900		
1.000	E	Phosphor plate
1.100		
1.250		
1.400		
1.600		
1.800		
2.000	D	Film
2.200		
2.500		

- The exposure index 1 corresponds to class E receptors which are taken as a dose reference for exposure.
- In the case of type D image receptors that require twice the dose as type E receptors, increase the exposure index value by 6 steps, which doubles the exposure index to 2.
- Type F film requiring less dose than type E should be used with exposure index 0.8.
- Digital sensors requiring half a dose compared to type E should be used with exposure index 0.5 (E/2).

8.2.1 Exposure values in s

Pre-programmed exposure values expressed in s (time) recommended for the use of different classes of receptor sensitivity, at a source-skin distance of 20 cm (7 $^{7}/_{8}$ in) or 30 cm (11 $^{13}/_{16}$ in).

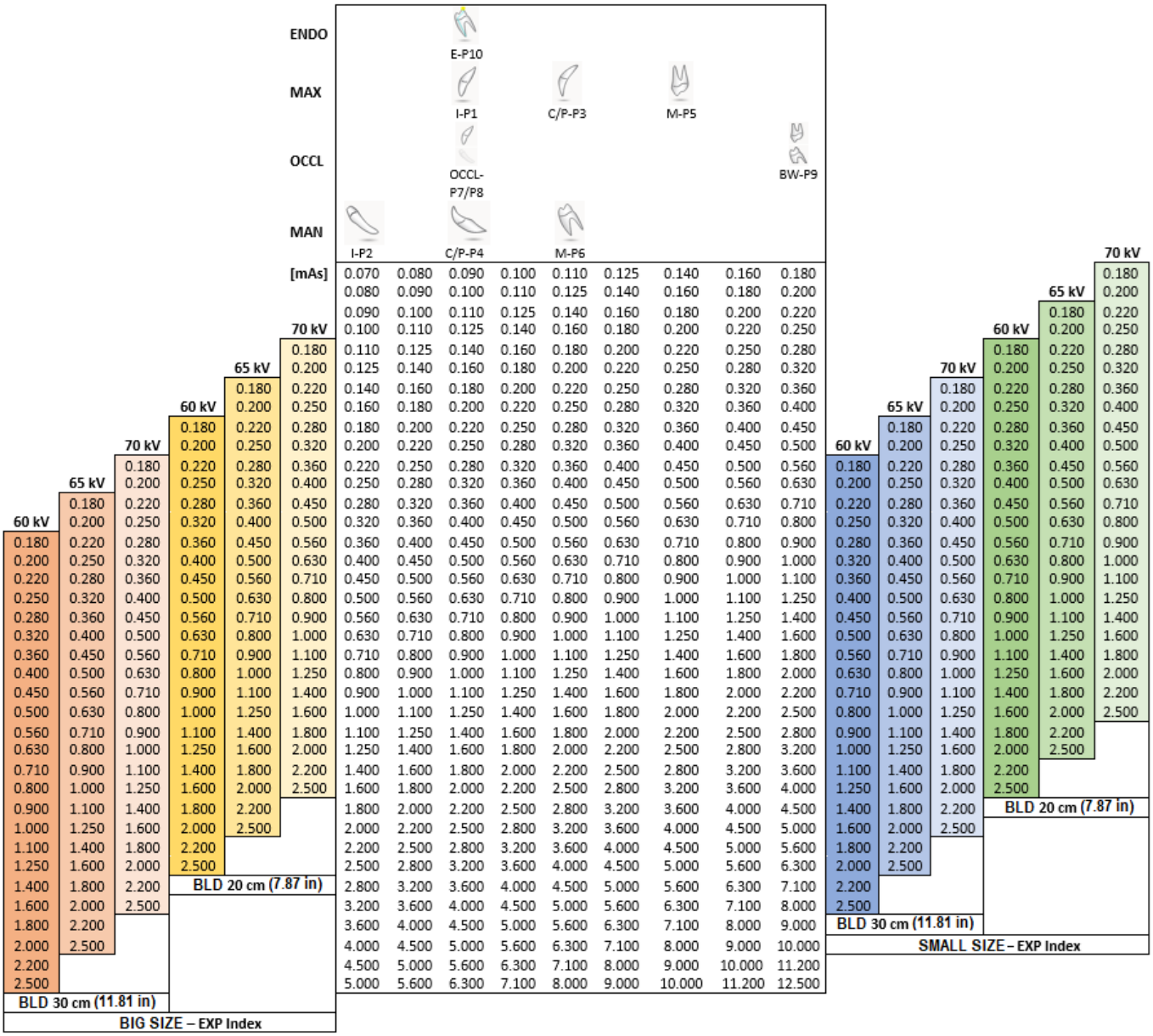
The exposure indices of the different classes of receptor sensitivity are given at §8.2.



8.2.2 Exposure values in mAs

Pre-programmed exposure values expressed in mAs (time and current product) recommended for the use of different classes of receptor sensitivity, at a source-skin distance of 20 cm (7 $^{7}/_{8}$ in) or 30 cm (11 $^{13}/_{16}$ in).

The exposure indices of the different classes of receptor sensitivity are given at §8.2.



9. CARE AND MAINTENANCE

Risk of electric shock.
All the cleaning, disinfection, inspection, and maintenance operations described must be carried out with the device disconnected from the network, turning OFF the general switch.

9.1 Cleaning

- Use a mild soap to remove fingerprints or other traces of dirt, taking care that liquid substances do not enter the equipment as they may damage electronic components.

Risk of corrosion.

- Clean the plastic covers with a soft cloth and a mild detergent or cloth soaked in 70% isopropyl alcohol. It is recommended to use only certified disinfectants. Do not expose the product to non-specific liquids, do not use solvents or corrosive substances.
- The display can be cleaned with a microfiber cloth (possibly slightly damp).

9.2 Disinfecting

- Parts that can come into contact with the patient after each use must be cleaned with a detergent (e.g. 2% ammonia solution) and then disinfected. Do not expose the product to non-specific liquids, do not use solvents or corrosive substances.

Risk of corrosion.

9.3 Inspection and Maintenance

Preventive inspection and maintenance operations must be carried out regularly to preserve the safety and health of patients, operators, and third parties.

Preventive and corrective maintenance must be carried out regularly by qualified, trained, and authorized personnel after 4, 7, and 10 years from the date of installation and then every two years to cover the following aspects:

- movements of mechanical parts,
- locking of the yellow-green conductors at the PE points of grounding protection,
- accuracy of anodic voltage,
- accuracy of anodic current,
- accuracy of exposure time,
- adequacy of irradiation level.

To perform preventive or corrective inspection and maintenance, follow the instructions in the installation and service manual. When carrying out maintenance work on the unit, it is recommended that the technician in charge draw up a report with the details of the intervention performed, the list of any parts replaced, the changes made to the system parameter settings, if applicable, in addition to the name and address of the customer and the technical assistance company involved, completing with date and signature. When components fail with possible safety effects, they must be replaced with original spare parts.

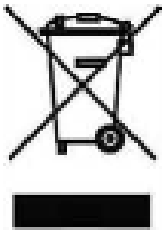
Also recommended that the user inspect the device each year to verify the following aspects:

- availability of manuals,
- absence of mechanical damage,
- presence and readability of labels,
- proper operation of the display,

- proper operation of light and buzzer at irradiation,
- proper functioning of voluntary interruption of irradiation (dead man function).

9.4 Disposal of obsolete equipment

The device is composed of different materials: including different types of metal, plastics, electronic components, and dielectric oil in the THA.



The symbol of the "crossed-out bin" on the product indicates that: when the product has reached the end of its useful life, it should not be disposed of as urban waste but must be subject to separate collection and transfer to specialized operators for recycling waste disposal of electrical and electronic appliances (WEEE), in compliance with the laws in force. This avoids possible negative effects on human health and the environment, and also promotes the recycling of the materials of which the product is composed. The law provides for sanctions in the case of illegal disposal.

FONA and its local resellers take on the commitments associated with the management of WEEE of a professional nature, according to European Directives 2002/96/EC and 2003/108/EC.

Contact the dealer if final disposal of the product is necessary.

10. ELECTROMAGNETIC COMPATIBILITY

Risk of electromagnetic interference.

10.1 Electromagnetic emissions

DENTALAIRE DC is suitable for use in the specified electromagnetic environment. The customer or user must ensure that it is used in that environment.

EMISSIONS TEST	LEVEL OF COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
RF emissions CISPR 11	Group 1	DENTALAIRE DC uses radio frequency energy only for its own internal function. Therefore, the radio frequency emission is extremely low and should not cause interference to nearby electronic equipment.
	Class B	DENTALAIRE DC is suitable for use in household complexes and complexes directly connected to the low voltage power supply network that powers buildings used for domestic applications.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 11	Group 1	

10.2 Electromagnetic immunity

DENTALAIRE DC is suitable for use in the specified electromagnetic environment. The customer or user must ensure that it is used in that environment.

IMMUNITY TEST	TEST LEVEL 60601-1-2	LEVEL OF COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
Electrostatic discharges (ESD) IEC 61000-4-2	8 kV contact 2/4/8/15 kV air	Test level IEC 60601-1-2	The floor must be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Radiated electromagnetic field IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz	Test level IEC 60601-1-2	Portable or mobile radio frequency communications equipment should not be used in close proximity to any component of the device, including cables. Minimum distance of 30 cm (11 $^{13}/_{16}$ in).
Electrical fast transient /burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input / output lines > 3 m (118 $^{7}/_{64}$ in)	Test level IEC 60601-1-2	The quality of network power should be that for standard commercial or hospital environments.
Surge IEC 61000-4-5	0.5/1 kV differential mode 0.5/1/2 kV common mode	Test level IEC 60601-1-2	The quality of network power should be that for standard commercial or hospital environments.

IMMUNITY TEST	TEST LEVEL 60601-1-2	LEVEL OF COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V from 150 kHz to 80 MHz	Test level IEC 60601-1-2	Portable or mobile radio frequency communications equipment should not be used in close proximity to any component of the device, including cables. Minimum distance of 30 cm (11 $^{13}/_{16}$ in).
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	10 ms – 0% at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°. 20 ms – 0% at 0°. 500 ms – 70% at 0°. 5 s – 0%.	Test level IEC 60601-1-2	The quality of network power should be that for standard commercial or hospital environments. If the user of DENTALAIRE DC requires continuous operation even in the event of a power failure. It is recommended to power the device from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Test level IEC 60601-1-2	Magnetic fields at feeding frequency should have the characteristic levels of a standard commercial or hospital environments.

10.3 Frequencies table of portable RF equipment

The device must remain at least at a minimum distance of 30 cm (11 $^{13}/_{16}$ in) from other portable equipment which may generate frequencies such as those shown in the table:

TEST FREQUENCY (MHz)	BAND [a]	SERVICE [a]	MODULATION [b]	MAXIMUM POWER (W)	DISTANCE (m)	IMMUNITY TEST LEVEL
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3 (11 $^{13}/_{16}$ in)	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3 (11 $^{13}/_{16}$ in)	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3 (11 $^{13}/_{16}$ in)	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3 (11 $^{13}/_{16}$ in)	28
870						
930						
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT,	Pulse modulation [b] 217 Hz	2	0.3 (11 $^{13}/_{16}$ in)	28
1845						
1970						

TEST FREQUENCY (MHz)	BAND [a]	SERVICE [a]	MODULATION [b]	MAXIMUM POWER (W)	DISTANCE (m)	IMMUNITY TEST LEVEL
		LTE Band 1, 3, 4, 25; UMTS				
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3 (11 13/16 in)	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	2	0.3 (11 13/16 in)	9
5500						
5785						
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m (39 3/8 in). The 1 m (39 3/8 in) test distance is permitted by IEC 61000-4-3.						
[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using a 50% duty cycle square wave signal. [c] As an alternative to FM modulation, pulse modulation of 50% can be used with a frequency of 18 Hz, as it does not represent effective modulation, but the worst condition.						

11. ERROR MESSAGES

In case of error or alarm condition the icon indicating the device status turns red and the error message is shown on the device display in the form of an error code. The device is in a safe state and does not allow exposures to be carried out until the alarm is resolved.

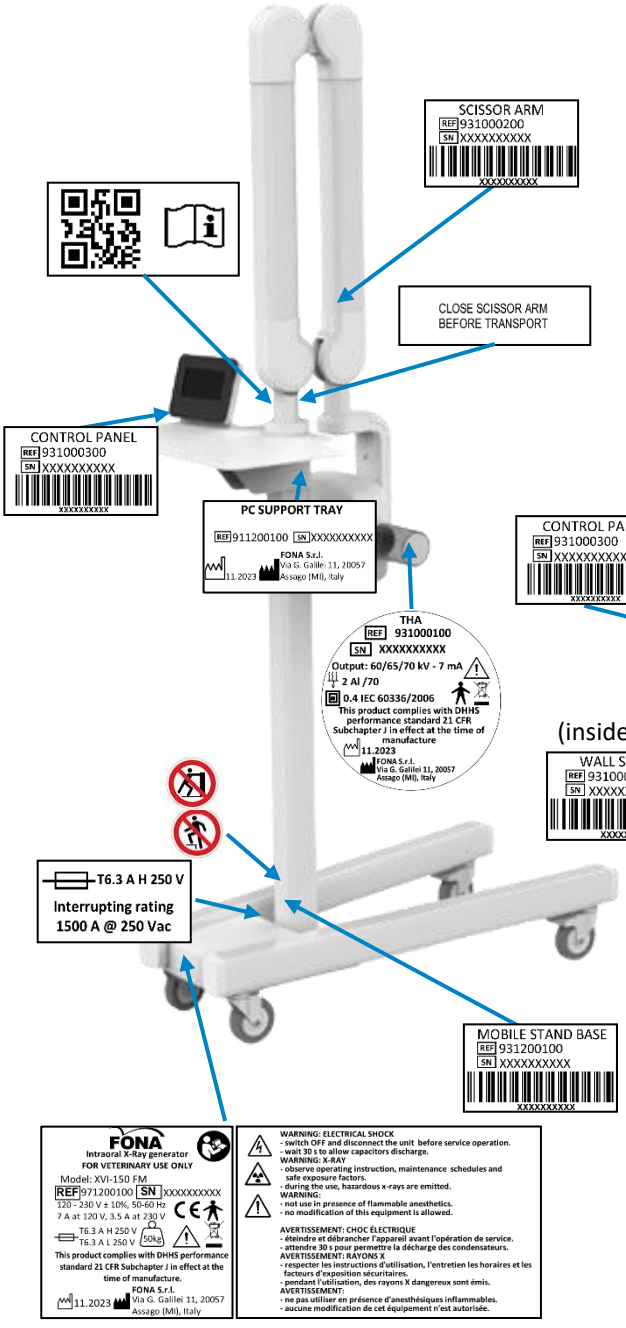
Error codes are structured according to the following table:

CODE	DESCRIPTION	ACTION REQUIRED
E01	Error safety contacts open	Check that the safety contacts are in the closed position. Try again and call technical assistance if it persists.
E02	Error software (data error)	Turn OFF the device and call technical assistance.
E04	Error filament supply	Turn OFF the device and call technical assistance.
E08	Exposure interrupted by back-up timer exhaustion	Turn OFF the device and call technical assistance.
E16	Error High Voltage regulation	Turn OFF the device and call technical assistance.
E32	Error HMICPU – PWD communication	Turn OFF the device and call technical assistance.
E33	Error HMICPU – PWD parameters	Turn OFF the device and call technical assistance.
E34	Exposure interrupted by operator	Make sure that the remote switch has been keep pressed down throughout the exam period. Try again and call technical assistance if it persists.
E35	Error EEprom	Turn OFF the device and call technical assistance.
E36	Error software (Checksum)	Turn OFF the device and call technical assistance.
E37	Error parameter out of range	The parameter just entered is outside the allowed limits. Check the entered value again. Try again and call technical assistance if it persists.

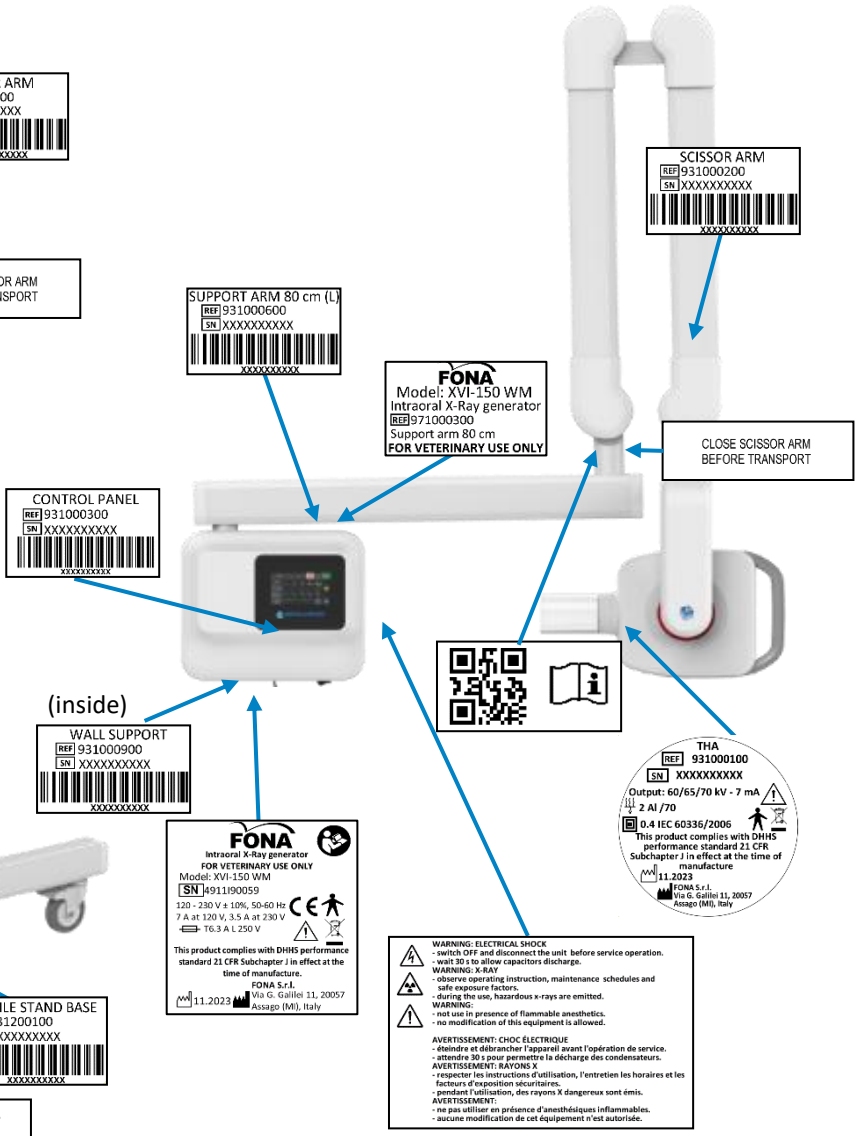
CODE	DESCRIPTION	ACTION REQUIRED
E38	Error wrong password	The password just entered is incorrect. Check the entered password again. Try again and call technical assistance if it persists.
E39	Error remote switch pressure	The remote switch is detected ON: • when the device is turned ON, • after the device has cooled down. Try again and call technical assistance if it persists.
E40	Error device configuration	Turn OFF the device and call technical assistance.
E41	Error Trial Mode Expired (***)	Turn OFF the device and call technical assistance.
E42	Error Trial Mode configuration	Incorrect Trial settings (service). Turn OFF the device and call technical assistance.
E43	Error wrong SN	The SN just entered is incorrect. Check the entered SN again. Try again and call technical assistance if it persists.

12. MARKING LABELS

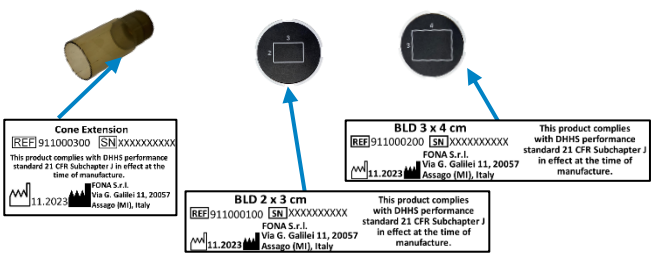
DENTALAIRE DC FM



DENTALAIRE DC WM



ACCESSORIES



PACKAGING

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User Manual

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FONA S.r.l.
Via Galileo Galilei 11,
20057 Assago (MI), Italy

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