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1. GENERAL WARNINGS

1.1 Foreword

The device described in this manual is manufactured by CEFLA s.c. - via Selice Prov.le 23/A - 40026 Imola (BO) Italy, a manufacturer complying with the European Directive on medical devices 93/42/EC (Class 2, B).

These instructions are intended for all the personnel who service and/or repair the Cefla s.c. equipments. All the specific information required is provided.

IMPORTANT READ CAREFULLY BEFORE USE
KEEP FOR FUTURE REFERENCE

1.2 Safety instructions

All the safety instructions that help prevent any hazardous situations and operate the equipment in a trouble-free manner are given in the user’s manual as explained below:

⚠️ WARNING: This alert symbol indicates that the users and/or the patients run high risks and can be seriously injured if the equipment or certain devices are used incorrectly or improperly, or the recommended safety precautions are not taken to avoid hazardous situations.

⚠️ CAUTION: Indicates that the operator is to take all the required precautions in order for all devices and/or equipment to be used safely and efficiently.

When the equipment is received, check the packing container for any damage suffered. If evident damage is found, immediately call the shipping agents and file a claim for damage. Carefully inspect the equipment for any missing or damaged parts. For any complaints, immediately contact Cefla s.c.. Cefla s.c. shall be responsible for the reliability and efficiency of the equipment as well as the safety of the operating personnel provided that:

• the installation, modifications, settings or repairs are made by authorised persons using Cefla s.c. original spare parts;
• the electrical wiring in the surgery complies with IEC 60364-7-710:2002 engineering regulations (Standards regarding electrical systems in a medical environment) or equivalent standards currently in force in the country where the equipment is installed);
• the equipment is used as outlined in User’s Manual.
• the place where the x-ray unit is installed must comply with official directives regulating radiation in the country where the equipment is used.
2. PACKAGING

2.1 Dimensions and contents

WALL MOUNTED VERSION

- 1 PACKAGE Dimensions: 103x53x36 cm
- Weight: 38 kg
- Contents:
  - Documentation and guarantee
  - Disposable jig for installation
  - Kit
  - Wall back-plate (if requested)
  - Wall-mounted plate
  - Generator
  - Tube
  - Extension
  - Collimator:
    » Round collimator if eXTend version
    » Round + rectangular collimator if HyperSphere version
  - Double pantograph arm

MOBILE STAND INSTALLATION

- N° 2 PACKAGES Dimensions: 103x53x36 cm
- 1ST PACKAGE Weight: 38 kg
- Contents 1ST PACKAGE:
  - Documentation and guarantee
  - Disposable jig for installation
  - Kit
  - Wall back-plate (if requested)
  - Wall-mounted plate
  - Generator
  - Tube
  - Extension
  - Collimator
  - Double pantograph arm

- 2ND PACKAGE WEIGHT: 30KG
- CONTENTS 2ND PACKAGE:
  - Trolley mechanical parts
  - general kit bag

2.2 Handling and storage

Indications regarding storage, handling and unpacking are given on the outside of the cardboard packaging.

These indications must be strictly observed.

1) The package must be kept upright in the direction indicated by the arrows at all times during handling and storage.
2) Avoid banging the package.
3) Keep the package free from damp.
4) Do not use hooks to handle the package.
5) A nameplate indicates the required ambient conditions for storage.
   a) temperature from -15° to 50° C.
   b) relative humidity from 10 to 90%
   c) atmospheric pressure from 500 to 1060 hPa.
3. BEFORE INSTALLATION

3.1 Environmental conditions

The equipment is to be installed in rooms that satisfy the following requirements:
- Temperature from +10 to +40° C.
- Relative humidity from 25 to 75% without condensate.
- Atmospheric pressure from 700 to 1060 hPa.
- The electrical wiring in the room in which the equipment is installed must conform to I.E.C. 60364-7-710;V2 specification (i.e. the regulations concerning the electrical wiring to be used in surgeries) or equivalent standards in force in the country where the equipment is installed.

3.2 Mechanical specifications required

The wall-mount plate that supports the x-ray unit shall be securely fixed to the wall.
If the wall is thin (hollow bricks or similar), use the backplate (part no. 9660048) to be mounted on the wall or placed on the side of the wall opposite the wall where the unit is to be installed.
Decide on a suitable system for fixing the plate according to the characteristics of the wall and its ability to resist a pull force of 220 Kg applied at each anchorage point.
If the wall is made of cement or solid bricks, use the wall plugs supplied.
Alternatively we recommend using the “FISHER” chemical wall plugs which include:
- Braid type injection insert (item FIP 16X85).
- Threaded bar with bar and washer (item FIP 16M, 8X110).
- Chemical fixer (item FIP C 150).

**NOTE:** Connection for remote handheld unit (For RXDC******C* models only)
If the 5m coiled cable of the handheld unit is not sufficient to exit the room, it is necessary to provide a buried wiring by preparing 3 0.5/1 sq.mm wires with independent and separated canalisation (L<10m).

3.3 Central control unit power supply

- **POWER SUPPLY:**

<table>
<thead>
<tr>
<th>Voltage</th>
<th>Frequency</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>230-240Vac</td>
<td>50-60Hz</td>
<td></td>
</tr>
<tr>
<td>115-120Vac</td>
<td>50-60Hz</td>
<td></td>
</tr>
</tbody>
</table>

**ATTENTION:** RESPECT THE CORRECT CONNECTION POLARITY.

**NOTE (1):** verify that the voltage indicated on the name plate is suitable before attempting the connection.
**NOTE (2):** check that the fuse fitted to protect the unit is correct for the power supply voltage, see installation manual.

- **MINIMUM REQUIREMENT:**

Power cord 3x2,5mm - The power cord must run at least 1 meter out of point (K).
The electrical wiring must be effectively grounded in compliance with I.E.C. - us national electrical code - and C.E.I standards (or in any case all current local standards).
In Italy the electrical wiring must be done in compliance with electrical code C.E.I. 64-8 sez.710, that require a differential switch with the following specifications is installed before the system:

<table>
<thead>
<tr>
<th>WITH POWER SUPPLY 230-240Vac, 50-60Hz</th>
<th>WITH POWER SUPPLY 115-120Vac, 50-60Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOMINAL CURRENT: 10A (BEND D)</td>
<td>NOMINAL CURRENT: 16A (BEND D)</td>
</tr>
<tr>
<td>DIFFERENTIAL SENSITIVITY: 0.03A</td>
<td>DIFFERENTIAL SENSITIVITY: 0.03A</td>
</tr>
<tr>
<td>A CLEARANCE OF AT LEAST 3mm</td>
<td>A CLEARANCE OF AT LEAST 3mm</td>
</tr>
</tbody>
</table>

The color of the 3 wires must be as set forth by the standards. If the differential switch is found in a hard-to-reach area, install another switch in a place that the operator can easily access.

- **SIGNAL LAMP CONNECTION:** Provide an independent power supply with 2 1.5mm wires. Use 2 0.5/1mm wires for lamp control.
3.4 Wiring connection between central control unit and generator light

This connection enables the generator ready located outside the surgery to be turned on. To connect the LP generator light (e) to the central control unit (c), use 2 conductors having a cross-section of 0.5 mm (see section "Wall-mounted plate wiring connections"). LP light supply: 230V - 3x2.5 mm line.

**Legenda:**
- a) SUPPLY LINE
- b) CIRCUIT BREAKER 10 A
- c) CENTRAL CONTROL UNIT
- d) INTERLOCK
- e) SIGNALLING LAMP
4. INSTALLATION

The x-ray unit must be installed by a qualified technician in compliance with the installation instructions given below as regards both the mechanical and electrical parts.

⚠️ WARNING!
Always check that the voltage indicated on the generator’s nameplate corresponds to that for the electrical system.

4.1 Positioning the x-ray unit’s structure

Figure POSITIONING
- Block the middle clamp in the opening provided (d) according to which of the three positions available the structure needs to be placed in:
  1) PRESET CONFIGURATION WITH WALL-MOUNTED STRUCTURE SET HORIZONTALLY TO THE RIGHT.
  2) WALL-MOUNTED STRUCTURE SET VERTICALLY DOWNWARD.
  3) WALL-MOUNTED STRUCTURE SET HORIZONTALLY TO THE LEFT.
- Secure the pin to the plate using the screws (f) and washers (e) provided.

For detailed instructions on all installation configurations watch the video on: extranetmedical.cefla.it

4.2 Wall-mounted plate for supporting the x-ray unit

Figure A
- Determine the position of the x-ray unit by using the INSTALLATION JIG.(accompanying documentation).
- First check that the plate is at the correct height and perfectly horizontal and then mark out the four points where it is to be fixed on the wall. Drill the holes and install the most suitable type of fastening system according to the characteristics of the wall (see section "Mechanical specifications required").
- Pass the supply cable through one of the holes in the wall-mount plate and fix this to the wall by partially tightening the top and bottom screws.

For detailed instructions on all installation configurations watch the video on: extranetmedical.cefla.it
4.2.1 Vertical SINGLE STUD installation with wooden post

- Insert the 4 TPSEI M8x35 screws with heads that allow them to be driven with a screw driver provided in the interface plate
- Run the power cord through one of the holes in the interface plate
- Attach the interface plate to the wooden post with no. 3 dia. 3/8" x L 3" wood screws (not supplied)
- Attach the x-ray unit’s wall-mounting plate to the interface plate by tightening the washers and nuts provided on the TPSEI M8x35 screws with heads that allow them to be driven with a screw driver

4.2.2 Horizontal SINGLE STUD installation with wooden post

The interface plate is not needed for 1.5" wooden posts with 16" spacing. Simply attach the RX-DC plate with no. 4 dia. 3/8" x L 3" wood screws (not supplied)

4.2.3 Vertical SINGLE STUD installation with iron post

- Attach the wall-mount counter-plate to the iron posts (not completely seen) with the threaded bars and screws provided
- Attach the interface plate to the counter-plate. Secure the x-ray unit’s wall-mounting plate to the latter
4.3 Extension arm

⚠️ WARNING! Do not lubricate the pin of the extension arm: the wall-mounted plate is provided with self-lubricating bushings.

**Figure B**
- Insert the pin (b) of the extension arm (c) in the hole provided in the wall-mounted plate.
- Take the clutch (a) from the kit, install it on the plate using the corresponding screws and adjust the arm (c) as required.

**Figure C**
- Use a spirit level to check that the arm (c) is slightly tilted upwards (approx. 1°). If necessary add a shim to the plate near the bottom wall plugs (d).
- Fully secure the plate.

**Figure D**
- If the x-ray unit is installed in one of the corners of the dental surgery, make sure the extension arm cannot rotate too far (90°) by installing the two end-stop pins (included in the kit) on the x-ray unit itself.
- Find the right position for installing the pair of pins (a, b) and insert them in the holes provided using a hammer.
4.3.1 PASS THROUGH installation extension arm

Install inside cabinet model PXTG92 42.5” x 49”

Check the direction of the pin support: it should be set as shown in figure (A) for this type of installation.

Insert the extension arm pin in the hole in the wall-mounting plate from below. Place the washer supplied on top of the pin and forcefully tighten the ring nut with the pin spanner provided, as shown in the figure (B).

⚠️ WARNING!
After installation of the PASS THROUGH arm, ensure that there is no clearance and that horizontal arm has no end float.

Install the clutch (a) as directed in section "Extension arm" figure (B).
4.4 Installing the trolley

- **M10x45 TPSEI N°2 PZ**
- **M10x45 TPSEI N°6 PZ**
- **M6x16 EI T/BOMB INOX N°2 PZ**
- **M4x8 EI T/BOMB**

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**GB**

**INSTALLATION**
ETICHETTE / LABELS / ÉTIQUETTES / ETIKETTEN / ETIQUETAS

TRADE MARK LABEL

GB
INSTALLATION
4.5 Installing the double pantograph arm

⚠️ WARNING!
The arms are supplied secured together by a belt.

This belt **should not be removed** until the two free ends of the arms have been connected to their corresponding attachments: the extension arm (already secured to the wall) and X-ray head. If the belt is loosened before fixing the arms in place, releasing them abruptly could damage them and the operator risks being injured.

**Figure E**
- Take the washer (f) from the kit and position it at point (i) corresponding to the extension arm (c).
- Pass the cable (m) of the pantograph arm (e) through the extension arm (c) so that it comes out of the hole below.
- Install the pantograph arm (e) on the extension arm (c)
  - **NOTE:** The extension arm's bushing is self-lubricating.
  - Do not lubricate the pin of the double-pantograph arm.
- Pass the cable (m) through the inside of the extension arm (c) so that it comes out of the wall-mounted plate.
- Install the plugs (g) in the corresponding holes in the extension arm (c).
Figure F
• Take the grubscrew used to stop rotation (o) from the x-ray unit kit and tighten it at point H (tighten it fully and then loosen by ½ turn).

NOTE: Turn the pantograph arm to check that the adjustment has been made properly.

Take the clutch assembly (friction element, screw and 4 curved washers) from the x-ray unit kit and install it at point L.

NOTE: Insert the curved washers (j) and the friction element (k) as indicated in figure F.

NOTE: The friction element (k) can be placed in the correct position (vertical cut) by inserting a screwdriver in the hole provided for the screw (n).

Figure G
• Adjust the clutch which has just been installed.

NOTE: Turn the pantograph arm during the adjustment to check that the clutch is providing the correct amount of friction.

• Install the plugs (p) on the extension arm (c).
• Attach the adhesive bumper (q) (supplied in the kit) in the centre of the plug at the point indicated in the diagram.
Figure H

- There are 2 end-stop screws in the wall-mounted plate to which Loctite has been applied to provide friction. These have been adjusted according to the length of the extension arm supplied.

NOTE: Work on the screw itself (a) in order to make the extension arm stop before or after.

4.6 Installing the RX DC with "ball end socket joint" generator

Figure I

- Take the generator out of the packaging.
- Insert the pin (a) in the sleeve making sure the respective openings match and secure with the screws (b) provided.
- Insert the power cable in the generator’s pin and run it out of the opening (c) provided.
- Lastly, put on the two side covers montare (d).

4.7 Installing the RX DC with standard joint generator

- Take the generator out of its packaging.
- Lubricate the bush of the pantograph arm and the generator pivot point with grease designed for bearings. (FIAT MR3).
• Take the washer (a) from the kit supplied and fit it in the pin (b) with the protruding tooth (c) pointed towards the right-hand head. (see fig.K)

Position the protruding tooth (c) of the washer (a) in zone 1 of the pin (b). (see figure L)

⚠️ WARNING! DO NOT position the protruding tooth (c) of the washer (a) in zone 2 of the pin (b).
• Insert the power supply cable of the pantograph arm in the generator pin until it comes out of the hole below (see point C – figure M).
• Raise the cover (a).
• Insert the pin in the sleeve so that it corresponds to the openings provided and then Fit the mounting yoke (d) supplied.
• Lower the cover (a) so that the hole (f) in the cover (a) is aligned with the hole in the internal washer (e).
• Fit the M4x6 self-locking grub screw (g) into the hole (f) and tighten it to 1 mm below the outer surface of the cover (a).

![Figure M](image1.png)

• Fit the connector of the pantograph arm cable to that of the generator cable.
• Place them inside the hole provided (c).
• Fit the plug (e) supplied into the hole then tighten the screw that is already in place. (see figure N)

![Figure N](image2.png)
4.8 Installing the collimator

- Take the collimator out of the packaging:

- round in case of RX DC with standard joint

- round or rectangular in the case of RX DC with "ball end socket joint"

- Insert it in the generator and block it in place by the bayonet attachment system.
4.9 Balancing the double pantograph arm

Figure Q
If the double pantograph arm does not stay in a stable position, adjust the spring tension by using an 8mm Allen wrench about 20cm long, provided with the device.
• To adjust the arm (a) connected to the extension: position it as shown in the figure and place the wrench at point A.

**NOTE:**
TIGHTEN (clockwise) if the arm tends to move down.
LOOSEN (anti-clockwise) if the arm tends to move up.
• To adjust the arm (b) connected to the generator: put the 2 covers (c) and (d) on the front pivot point, move the arm (b) into a horizontal position and insert the key in point B.

**NOTE:**
TIGHTEN (clockwise) if the arm tends to move down.
LOOSEN (anti-clockwise) if the arm tends to move up.

4.10 Adjusting the double pantograph arm end-stops

Figure R
If the end-stops of the double pantograph arm need to be adjusted, work on the screws (i - l - m - n) shown in the diagram.

**NOTE:**
To adjust the screw (n) on the articulated joint of the extension side place the relevant arm (a) in a horizontal position.
4.11 Wall-mounted plate wiring connections

- Connect the power cable (LINE) to terminal K2, observing the following positions:
  - L - SUPPLY (BROWN WIRE)
  - - GROUND (YELLOW/GREEN wire)
  - N - NEUTRAL (BLUE wire)

- Connect the generator’s power cable to the respective connectors, observing the following positions:
  - K6 - brown wire and blue wire.
  - Eyelet connectors - Both found near the card (see figure S).

**NOTE:** Place the excess cable under the card.

- If an external "ready" indicator light is installed, connect the 2 light control (LP) wires (0.5 mm cross-section) to connector K3;
- If INTERLOCK is installed, connect the 2 wires (0.5 mm cross-section) to connector K18, otherwise short-circuit it;
- In case of handheld unit with wire, connect it to K15.

<table>
<thead>
<tr>
<th>K15</th>
<th>PIN 1</th>
<th>PIN 2</th>
<th>PIN 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Red</td>
<td>White / Brown</td>
<td>Blue</td>
</tr>
</tbody>
</table>

4.12 Completion of wall-mounting plate and holder for handheld.
Figure T and Figure U

- Pick up the cover (a) and place it over the wall-mounting plate fully tightening the grub screws (b) provided and pre-screwed on the plate.
- Place the cover (c) in the area shown in the figure. The door (d) will automatically close when the controller is closed.
- Put the controller label in the required area (e) on the cover directed according to the position in which the wall-mounting plate is installed.
- To install the handheld’s mount (f), refer to the INSTALLATION TEMPLATES.

NOTE: In case of wired handheld unit, let the coiled cable come out of the groove located close to the ON/OFF button.
5. FACTORY SETTINGS

The x-ray unit is supplied with the following factory settings:

• Operative mode: AUTO.
• Sensitivity: level 19.
• Handheld stand by: 5 minutes
• Patient’s built: adult (ADULT symbol selected).
• Collimator presence signaled on the display (collimator symbol off if the collimator is turned on in the head).
• Exposure times according to standard R20: 0.020-0.022-0.025-0.028-0.032-0.036-0.040-0.045-0.050-0.056-0.063-
  0.071-0.080-0.090-0.100-0.110-0.125-0.140-0.160-0.180-0.200-0.220-0.250-0.280-0.320-0.360-0.400-0.500-0.560-
  0.630-0.710-0.800-0.900-1.000.

**NOTE:** These times comply with current standards I.E.C. 60601-1-3:2008 and the ISO 497 series R20 recommendations and CANNOT BE MODIFIED.

6. TURNING ON AND FUNCTIONING OF THE DEVICE

6.1 Turning on the basic X-ray unit

The control unit is turned on and off with the main switch (A), as illustrated in the figure below. The switch lights up when the control unit is energized.

**NOTE:** Whenever turned on, the equipment performs an operational test that takes a few seconds. Once the test has been completed, a buzzer rings and the indicator light (B) on the X-ray generator lights up at the same time.

**NOTE:** The exposure time and the parameters displayed when the unit is turned on are the last ones set before the central control unit was turned off. If the central control unit is left untouched for a few minutes it will go into stand-by mode. Simply press any key on the control panel to reactivate it.
6.2 Handheld Functions

WIRELESS HANDHELD

NOTE: This section applies only to models RX DC REF: MRPU***W*, MRXU***W*
(Character * can be any alphanumeric value)

The handheld is turned on by pressing any key, except for the one for x-ray emission. A buzzer rings to confirm that the unit has been turned on. The unit will be in the standard configuration and it will start searching for the base it works with. If the base is off, the handheld will not indicate the field or the status “ready”. If the base is later turned on, the handheld will detect it within thirty seconds or by pressing any function key on the push-button panel.

NOTE: To optimise the range of the handheld while it is being used, keep it away from walls and metal instruments and, above all, do not cover its built-in antenna on top of the screen. In addition, performance may be reduced if the handheld is moved too quickly while x-rays are being taken. Error E302 / E303 may be displayed if out of range problems occur.

AUTOMATIC HANDHELD SHUT OFF:
Once the control unit has been turned off, the handheld automatically shuts off after approximately one minute. The handheld also automatically shuts off when it is at a further distance from the maximum range of the control until.

HANDHELD TIMED STAND-BY:
The entire x-ray unit will switch over to stand-by (even if the base is on) and the handheld will automatically shut off after approximately five minutes of non-use to save battery power.

BATTERIES AND CHARGE LEVEL INDICATION:
The handheld runs on two standard AA alkaline batteries to assure sufficient stand-alone operation. The charge level of the batteries is shown on the screen as follows:

Battery fully charged (no symbol appears in the area that shows the battery charge level).
Battery half-charged.
Battery charge level low or almost dead (causing the handheld to automatically shut off).

NOTE: The batteries should be removed from the handheld if it is not going to be used for an extended period.

WIRED HANDHELD

NOTE: This section applies only to models RX DC REF: MRPU***C*, MRXU***C*
(Character * can be any alphanumeric value)

AUTOMATIC HANDHELD SHUT OFF:
The handheld will automatically turn off after switching off the control unit.
6.3 Handheld display functions

1. Field present for dialoguing with “base”
2. Pause for cooling
3. Handheld identification number
4. Memorising
5. Battery status
6. Patient size selection
7. 8” round collimator on (12” rectangular collimator not attached)
8. Interlock active
9. Graduated bar for thermal load
10. Time/dose unit of measure
11. Exposure time and dose display
12. Tooth selection
6.4 Use of handheld

As illustrated in the figure below, the handheld has four function keys and a single x-ray emission key.

![Diagram of handheld keys]

1. “Dentition area selection” key
2. “Body size selection” key
3. X-ray emission light
4. “Increase” key
5. “Decrease” key
6. “X-ray emission” key

The main functions of the keys on the handheld, depending on how they are pressed, are:

<table>
<thead>
<tr>
<th>KEY</th>
<th>BRIEFLY PRESSED (less than 3 sec.)</th>
<th>PRESSED LONGER (more than 3 sec.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>💼</td>
<td>Changes over from ADULT to CHILD and vice versa (takes place when key is released).</td>
<td>Saves the selected setting (exposure time, sensitivity, etc…). The memo icon (📝) lights up when the data item can be saved.</td>
</tr>
<tr>
<td>👤</td>
<td>Selects the various types of teeth to choose the area to be examined.</td>
<td>Displays the values corresponding to the tooth exposure times in mGy and in mGy*cm² if pressed again.</td>
</tr>
<tr>
<td>📈</td>
<td>Increases the exposure times in steps according to the set scale.</td>
<td>Increases the scroll speed of the values in increasing order.</td>
</tr>
<tr>
<td>📉</td>
<td>Decreases the exposure times in steps according to the set scale.</td>
<td>Increases the scroll speed of the values in decreasing order.</td>
</tr>
<tr>
<td>🎤</td>
<td>NO EFFECTS ARE OBTAINED IF THE KEY IS PRESSED FOR LESS THAN A SECOND.</td>
<td>Starts x-ray exposure (the key has to be held down throughout the x-rays emission, “dead man” function).</td>
</tr>
</tbody>
</table>

**NOTE:** “Dead man” function: the system that starts x-ray exposure with the dedicated key on the wireless handheld allows x-rays to be emitted only when the user presses and holds down the exposure key. X-ray emission will stop if the key is released ahead of time.

**NOTE:** The function related to pressing the key briefly is performed by pressing the key which will
activate the function assigned to it. On the other hand, to perform the function carried out when the key is held down longer, press the key until the relative function is started. The buzzer will beep shortly to signal that the function has been activated.

**NOTE:** Warm-up: When the equipment has not been used for a prolonged period (more than 3 months) or when turned on for the first time, it is advisable to perform a series of emissions with short times (0.01-0.02 sec.) and then, progressively, some pictures with 0.1 sec. intervals to better stabilise the operation of the x-ray tube before using it.

### 6.5 X-RAY unit stand-by time

The entire x-ray unit will switch over to stand-by (even if the base is on) and the handheld will automatically shut off after several minutes of non-use. Press any key, except for the “exposure” key, to turn the handheld back on showing the last selection made by the user. To change the stand by time, refer to chapter 7 regarding the handheld’s “Technician and user setup menu”.

### 6.6 Checking the parameters

Before actually taking an exposure, make sure the exposure parameters for the examination in progress are correctly set:

- Controlling the type of collimator selected.
  Make sure the cone icon shown on the handheld matches the desired cone:
  ICON **ON:** indicates that the x-ray unit is using the built in round cone (diameter 60mm, focal spot-skin distance 20cm).
  ICON **OFF:** indicates that the external removable rectangular or round cone is attached to the x-ray device (source-skin distance 30cm).

**NOTE:** After the rectangular collimator (12”) has been attached or detached, the icon and set exposure times will automatically be modified within a few seconds.

- Checking the selected body build.
  - “Child” selected: indicates the x-ray unit is set for patients with small builds.
  - “Adult” selected: indicates the x-ray unit is set for patients with average-large builds.

<table>
<thead>
<tr>
<th>Average/large build (ADULT) selected</th>
<th>Small build (child) selected</th>
</tr>
</thead>
</table>

**NOTE:** After the change has been made, the preset exposure times will automatically be modified.
• Checking the selected type of intraoral exam.

<table>
<thead>
<tr>
<th>Upper molars</th>
<th>Lower incisors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper canines/bicuspid or rear &quot;bite-wing&quot;</td>
<td>Lower canines/bicuspid</td>
</tr>
<tr>
<td>Upper incisors or front &quot;bitewing&quot;</td>
<td>Lower molars</td>
</tr>
</tbody>
</table>

6.7 Factory settings

RX DC x-ray unit is supplied with the following factory settings:

• Operative mode: AUTO.
• Sensitivity: level 19.
• Handheld stand-by: 1 minute
• Exposure times as per standard R20: 0.020 - 0.022 - 0.025 - 0.028 - 0.032 - 0.036 - 0.040 - 0.045 - 0.050 - 0.056 - 0.063 - 0.071 - 0.080 - 0.090 - 0.100 - 0.110 - 0.125 - 0.140 - 0.160 - 0.180 - 0.200 - 0.220 - 0.250 - 0.280 - 0.320 - 0.360 - 0.400 - 0.500 - 0.560 - 0.630 - 0.710 - 0.800 - 0.900 - 1.000

**NOTE:** These times comply with current standards I.E.C. 60601-1-3:2008 and the ISO 497 series R20 recommendations and CANNOT BE MODIFIED.

6.8 Positioning the X-ray head

Position the X-ray head so that the cone is aligned with the image receiver.

BALL JOINT TECHNOLOGY

**NOTE:** This section applies only to models RX DC REF: MRPU*****

(Character * can be any alphanumeric value)

In the versions equipped with ball joint, the X-ray head can freely rotate on both its horizontal and vertical axis.

An electromechanical brake initially locks the X-ray head. To release the head and let it rotate on the positioning ball, work on the touch sensitive unlocking areas located on it (see points A in the figure on the side).

Touching the unlocking areas allows positioning the X-ray head at the desired angle to perform the exposure. To lock it again, simply release the unlocking areas.

**NOTE:** Firmly hold the X-ray head with both hands when putting it in place.

It is possible to set a safety unlocking mode that allows the head to be turned only by pressing both unlocking keys. This prevents the head from unlocking unexpectedly after one of the two unlocking keys has been accidentally pressed. To activate this mode, see section “Setting the safety unlock mode”.
ARCH TECHNOLOGY

NOTE: This section applies only to models RX DC REF: MRXU****
(Character * can be any alphanumeric value)

In the versions equipped with arch technology, the X-ray head can freely rotate on both its horizontal and vertical axis. Simply moving the X-ray head allows positioning it at the desired angle to perform the exposure.

6.9 Position of the x-ray plate or sensor

The parallel technique, where applicable, provides more accurate images in terms of size compared to the bisecting technique. A rectangular collimator, with 30 cm (12"), focus-skin distance, is always preferable to obtain better quality pictures. To avoid exposing the image receiver only partly (whether it is a sensor or photostimulable phosphorus plate system) an alignment device that gives rectangular collimators guidelines should be used. These lines are usually given on the alignment ring.

- Parallel technique.

1 Incisors
2 Canines
3 Premolars
4 Molars
5 Upper arch
6 Lower arch

The x ray emission axis is perpendicular to the image receiver (for example a sensor or photostimulated phosphor plate) which in turn is parallel with the tooth's long axis.

- As a result, the picture of the tooth will only be deformed by the divergence of the x rays in relation to the focus spot.
• Radiographic enlargement may reach up to 15%.
• For some “special” pictures, for example occluded ones, it may be necessary to remove the rectangular collimator and use the round one if a positioner is not present.

6.10 Procedure to be followed when taking the x-ray

• Pick up the handheld and move to a safe distance (at least 2 meters) maintaining visual contact with the patient and x-ray unit during the exposure. Make sure “ready” is indicated.
• Tell the patient to stay still.
• Press and hold down the “Exposure” key on the handheld until the audible warning sound (beep) stops and the yellow light goes out.

NOTE: If the “EMIT X-RAY” key is released at any time, exposure will be interrupted and error code E01 will appear on the display.

• Once exposure has been completed, it is possible to proceed with the next exposure unless the x-ray unit has reached the maximum allowable temperature. The percentage the cone exceeds the maximum allowable temperature is always shown on the screen (see icon below).

• Once the temperature has been reached, wait the pause time for cooling signaled by symbol .
• At this point the exposure function will be disabled until the screen shows “ready” again
• As soon as “READY” appears on the handheld, another exposure can be taken.

7. TECHNICIAN AND USER SETUP MENU

The handheld allows a number of work parameters to be viewed and edited by simply pressing a combination of keys present on the control panel.

Key serves to confirm/save the function, key is used to undo/quit the menu while keys and edit the values of the selected parameters on all the setup menus.

Proceed as directed below to access the menus:
### Combination of keys

<table>
<thead>
<tr>
<th>Combination of keys</th>
<th>Description</th>
</tr>
</thead>
</table>
| ![key combination](image) | **Sensitivity levels**  
Press these two keys to adjust the sensitivity levels (determined based on the table given in the user manual). Set the current sensitivity level to a value within the allowable range (on a scale from 13 to 26), with keys + and : to confirm the desired level and go back to the main screen press key ⊗. |
| ![key combination](image) | Hold down these two keys to go to the set up menu (from P01 to P08).  
Press key ⊗ to make the selection. Once within the individual configurations, they can be scrolled with keys + and − and selected by pressing key ⊗ again. Key ⊗ quits set up without saving the setting.  
The configurations are given in detail below:  
P 01: Sets hand held unit stand by time (from a minimum of 0 to a maximum of 240 minutes).  
P 02: Assigns an identification tag to the x-ray unit’s base (from 1 to 5 or none).  
P 03: Shows the list of software versions. (handeld, X-ray head, basis)  
P 04: Sets X-ray head stand by time  
P 05: Activates/deactivates the safety unlock mode (see section "Setting the safety unlock mode") - only RX DC with "ball end socket joint"  
P 06: Selects the operating mode (Fixed 70,65,60 KV or AUTO) - (see section "Setting the operating mode")  
P 07: Sets the type of removable cone used - (see section "Setting the type of movable collimator")  
P 08: Selects anode current (H = 8mA, L = 4mA) |
| ![key combination](image) | **Technician setup menu**  
Hold these two keys depressed, within user menu in position P08, to access an advanced technical setup menu (T01 to T07).  
Like in the previous menu, select by pressing the ⊗ key.  
Once you are inside the single settings, you can scroll them using + and − keys and select them by pressing again the ⊗ key. In detail, these settings include:  
T01: HANDHELD UNIT POWER VOLTAGE  
T02: HANDHELD UNIT-X-RAY HEAD MATCHING PROCEDURE  
Press ⊗ key to start the procedure. If successful, handheld unit will reboot and search for the SSID of the matched machine. If handheld unit displays EE, the procedure was not successfully completed (see section "Handheld unit-X-ray head association").  
T03: HANDHELD UNIT DEMO SELECTION.  
Save this mode by pressing the ⊗ key.  
T04: X-RAY HEAD DEMO SELECTION.  
Save this mode by pressing the ⊗ key.  
T05: X-RAY HEAD CALIBRATION (Enter the menu by pressing the ⊗ key.)  
Hold depressed the ⊗ key to start the calibration procedure. This procedure provides a certain number of shots depending on the selected work mode. Perform all emissions.  
Pressing + and ⊗ keys at the same time will reset calibration values.  
T06: SELECT WIRELESS CHANNEL  
Press the keys + and ⊗ at the same time to activate the wireless channel automatic selection function (when active, icon is displayed). In this condition, should the manually selected channel be busy, the X-ray device will automatically select the first free channel available in order to minimise any interference with the handheld device. If the function deactivates (icon not shown), the channel is always the one displayed.  
T07: SELECT TYPE OF BATTERIES IN USE  
Choose between rechargeable and alkaline. This selection will change battery icon voltage thresholds.  
T08: UPDATE OF X-RAY DEVICE FIRMWARE (see section "Firmware update procedure"). |
7.1 Setting the safety unlock mode

The RX DC x-ray unit has a safety unlock for the ball joint. The default setting allows the ball joint to be disengaged by simply touching one of the keys present on the front of the head. To prevent accidental contact with the keys from unexpectedly disengaging the ball joint (and therefore causing undesired movement of the head), the safety unlock mode can be activated. In this mode, the ball joint is disengaged only if both keys are activated at the same time.

To set the safety unlock mode, press keys \( \text{[ ]} \) and \( \text{[ ]} \) to go to the set up menu. Scroll the parameters up to parameter P05 and press key \( \text{[ ]} \). Scroll the options to select “ON” and press key \( \text{[ ]} \). Press key \( \text{[ ]} \) to quit the set up menu.

7.2 Setting the operating mode

X-ray unit features the following operating modes:

- **AUTO**: the system automatically selects the best setting available for each tooth-patient size combination
- **USER**: the system automatically proposes the optimum exposure time according to the selected tooth and patient size - En65: all exposures are performed at 65KV and 6mA.

For both operating modes, the exposure time is in the range 0.02s - 1s. The permitted anode voltage and current combinations are shown in the following table:

NOTE: This section applies only to models RX DC REF: **PU*6***, **XU*6***

(Character * can be any alphanumeric value)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>60-7</td>
<td>60 kV</td>
<td>7 mA</td>
</tr>
<tr>
<td>63-6</td>
<td>63 kV</td>
<td>6 mA</td>
</tr>
<tr>
<td>65-6</td>
<td>65 kV</td>
<td>6 mA</td>
</tr>
</tbody>
</table>

NOTE: This section applies only to models RX DC REF: **PU*7***, **XU*7***

(Character * can be any alphanumeric value)

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>60-8</td>
<td>60 kV</td>
<td>8 mA</td>
</tr>
<tr>
<td>65-8</td>
<td>65 kV</td>
<td>8 mA</td>
</tr>
<tr>
<td>70-8</td>
<td>70 kV</td>
<td>8 mA</td>
</tr>
<tr>
<td>60-4</td>
<td>60 kV</td>
<td>4 mA</td>
</tr>
<tr>
<td>65-4</td>
<td>65 kV</td>
<td>4 mA</td>
</tr>
<tr>
<td>70-4</td>
<td>70 kV</td>
<td>4 mA</td>
</tr>
</tbody>
</table>

To set the operative mode, press keys \( \text{[ ]} \) and \( \text{[ ]} \) to go to the setup menu. Scroll the parameters up to parameter P06 and press key \( \text{[ ]} \). Scroll the options to find the desired operating mode and then press key \( \text{[ ]} \). Press key \( \text{[ ]} \) to quit the setup menu.

NOTE: the current setting is displayed on the handheld for approximately 1 second for each tooth-patient size selected before the relative exposure time is shown.
7.3 Setting the type of movable collimator

The RX DC x-ray unit has the following removable cones:

• Rectangular 35x45 mm (only RX DC with “ball end socket joint”)
• Round Ø55 mm
• Rectangular 31x41 mm (to be attached to the Ø55 mm round cone)
• Rectangular 22x35 mm (to be attached to the Ø55 mm round cone)

It is possible to select the collimator through the P07 menu.

*NOTE: in order to obtain top performance of the x-ray unit, set the cone according to the type used.*

7.4 Calibrating the X-ray head

This operation requires the execution of a certain number of shots, at a pre-set time, during which X-ray emission occurs. It is therefore necessary to pay close attention.

Switch on the handheld unit and go to menu T05. To access this menu press \( + \) keys, scroll the menu using the key \( \downarrow \) until P08 is displayed, press \( \downarrow \) \( + \) \( \downarrow \) to access the technical menu and press the \( + \) key several times until T05 is displayed, to enter the menu and press again and hold the key to activate the calibration. press the key \( \uparrow \) to enter the menu and press again and hold the \( \uparrow \) key to activate the calibration. Perform the shots until the counter reaches 0. Press the \( \downarrow \) key to quit the menu. Be careful never to release the shot key in advance as, in case of error, it could be necessary to repeat the operation. Press simultaneously \( + \) keys from T05 to set the use of the default calibration values. Press simultaneously \( \downarrow \) \( + \) \( \uparrow \) keys from T05 to set the use of the default calibration values.
8. ADJUSTING THE ACTUATOR UNIT (ONLY RX DC WITH "BALL END SOCKET JOINT")

ACCOMPANYING DEVICE
FOR ADJUSTING THE ACTUATOR UNIT

A. Loosen the grub screw shown in figure 3 to release the brake.

B. Position the device for adjusting the actuator unit in the gap shown in picture 4 to verify that the gap is 2.7mm

C. Position the device for adjusting the actuator unit as shown in picture 5 and verify that the grub screw is flush with the surface of the template.
If the conditions above are not true, adjust the plastic ring and grub screw as shown here below:

Verify if the brake mechanism operates normally after having performed the adjustment.

If the head is not steady in all angles, proceed with further adjustment as shown below.

**NOTE:** don't change the position of the grub screw that was set in phase 3-4-5

Draw a reference mark on the two plastic rings and rotate clockwise by 180°.
Verify if the brake mechanism operates normally after having performed the adjustment.

If the head is not steady yet, tighten the plastic ring further for another 90°.
## 9. ELECTRONIC BOARDS

### 9.1 Power Board (Code 97661585)

#### Diagnostic Led indicators

<table>
<thead>
<tr>
<th>LED</th>
<th>Colour</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DL1</td>
<td>Vac</td>
<td>Green</td>
<td>On, It indicates mains power on</td>
</tr>
<tr>
<td>DL2</td>
<td>Vdc</td>
<td>Yellow</td>
<td>On, H jumper BUS voltage enabled</td>
</tr>
<tr>
<td>DL3</td>
<td>PC</td>
<td>Yellow</td>
<td>On, It indicates bypassed pre-charge resistors</td>
</tr>
<tr>
<td>DL4</td>
<td>15V</td>
<td>Green</td>
<td>On, It indicates 15V power supply on</td>
</tr>
<tr>
<td>DL5</td>
<td>3.3V</td>
<td>Green</td>
<td>On, It indicates 3.3V power supply on</td>
</tr>
<tr>
<td>DL6</td>
<td>12V</td>
<td>Green</td>
<td>On, It indicates 12V driver power supply on</td>
</tr>
<tr>
<td>DL7</td>
<td>ISO</td>
<td>Green</td>
<td>On, It indicates insulated power supply presence (handheld unit, interlock and trigger)</td>
</tr>
<tr>
<td>DL9</td>
<td>CPU</td>
<td>Yellow</td>
<td>Flashing, It indicates proper operation of the CPU</td>
</tr>
<tr>
<td>DL10</td>
<td>ERR</td>
<td>Red</td>
<td>Off, If on, it indicates basic error condition</td>
</tr>
<tr>
<td>DL11</td>
<td>LIN</td>
<td>Green</td>
<td>Flashing, It flashes for every LIN transmission towards the head (Communication OK)</td>
</tr>
<tr>
<td>DL12</td>
<td>COMM</td>
<td>Green</td>
<td>Flashing, It flashes for every LIN transmission towards the handheld unit (Communication OK)</td>
</tr>
<tr>
<td>DL15</td>
<td>RDYL</td>
<td>Green</td>
<td>On, When ready relay is activated (contact closed)</td>
</tr>
<tr>
<td>DL17</td>
<td>TRIG</td>
<td>On</td>
<td>It indicates external emission key activated</td>
</tr>
<tr>
<td>DL19</td>
<td>ILK</td>
<td>Yellow</td>
<td>Off, If on, it indicates external Interlock switch open</td>
</tr>
<tr>
<td>DL20</td>
<td>5V</td>
<td>Green</td>
<td>On, It indicates 5V driver power on</td>
</tr>
<tr>
<td>DL21</td>
<td>PWM</td>
<td>Yellow</td>
<td>On, It indicates PWM command from head (in ready and in x-ray on)</td>
</tr>
<tr>
<td>LED</td>
<td>Colour</td>
<td>Status</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>--------</td>
<td>-------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>DL22</td>
<td>ENB</td>
<td>Green</td>
<td>On when H jumper enabled</td>
</tr>
<tr>
<td>DL23</td>
<td>RUN</td>
<td>Green</td>
<td>On with H jumper in switching mode</td>
</tr>
</tbody>
</table>

### Fuses

<table>
<thead>
<tr>
<th>F2 - Main fuse</th>
<th>Voltage</th>
<th>Amperage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>230-240 Vac</td>
<td>-&gt; 8 A</td>
<td></td>
<td>General Fuse; if broken all leds are off</td>
</tr>
<tr>
<td>115-120 Vac</td>
<td>-&gt; 12 A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Connector list

<table>
<thead>
<tr>
<th>Connector</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K1</td>
<td>Ignition switch connection</td>
</tr>
<tr>
<td>K2</td>
<td>Mains power supply</td>
</tr>
<tr>
<td>K3</td>
<td>Contact for external lamp (max 2A - clean contact)</td>
</tr>
<tr>
<td>K4</td>
<td>External emission key</td>
</tr>
<tr>
<td>K5</td>
<td>Arm cable (head)</td>
</tr>
<tr>
<td>K6</td>
<td>Arm cable (power)</td>
</tr>
<tr>
<td>K15</td>
<td>Handheld unit connection</td>
</tr>
<tr>
<td>K18</td>
<td>Interlock contact</td>
</tr>
</tbody>
</table>

In case of board replacement check on P03 that the firmware versions of the handheld unit, X-ray head and basic board are aligned and correspond to those of the selected update package.

In case of misalignment, carry out the firmware update procedure described in this manual.
9.2 Basic X-ray head control card (Code 97661586)

<table>
<thead>
<tr>
<th>LED</th>
<th>Colour</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DL1</td>
<td>Green</td>
<td>On</td>
<td>It indicates presence of external power supply (from base)</td>
</tr>
<tr>
<td>DL2</td>
<td>Green</td>
<td>On</td>
<td>It indicates 5V power supply on</td>
</tr>
<tr>
<td>DL3</td>
<td>Green</td>
<td>On</td>
<td>It indicates 3.3V power supply on</td>
</tr>
<tr>
<td>DL4</td>
<td>Green</td>
<td>On</td>
<td>It flashes for every LIN transmission (communication OK)</td>
</tr>
<tr>
<td>DL5</td>
<td>Green</td>
<td>Off</td>
<td>On with no external collimator</td>
</tr>
<tr>
<td>DL6</td>
<td>Green</td>
<td>On</td>
<td>On when the RH touch screen is active</td>
</tr>
<tr>
<td>DL7</td>
<td>Green</td>
<td>On</td>
<td>On when the LH touch screen is active</td>
</tr>
<tr>
<td>DL8</td>
<td>Green</td>
<td>Off</td>
<td>On when network is created</td>
</tr>
<tr>
<td>DL9</td>
<td>Yellow</td>
<td>Flashing</td>
<td>It indicates proper operation of the CPU</td>
</tr>
<tr>
<td>DL10</td>
<td>Red</td>
<td>Off</td>
<td>On with X-ray head error condition</td>
</tr>
<tr>
<td>DL11</td>
<td>Yellow</td>
<td>On</td>
<td>On when actuator is powered</td>
</tr>
<tr>
<td>DL12</td>
<td>Yellow</td>
<td>Off</td>
<td>When on, it indicates 46V voltage present on capacitor bench</td>
</tr>
<tr>
<td>DL15</td>
<td>Yellow</td>
<td>On</td>
<td>It indicates PWM control from the head (in ready o in X-Ray ON)</td>
</tr>
<tr>
<td>DL16</td>
<td>Green</td>
<td>On</td>
<td>It indicates PWM control from the head (in ready o in X-Ray ON)</td>
</tr>
</tbody>
</table>
Connector list

<table>
<thead>
<tr>
<th>CONNECTOR</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>K1</td>
<td>Monobloc feedback connection</td>
</tr>
<tr>
<td>K2</td>
<td>Base connection</td>
</tr>
<tr>
<td>K3</td>
<td>Connection of actuator + thermal sensor</td>
</tr>
<tr>
<td>K4</td>
<td>Cone/sensor board connection</td>
</tr>
<tr>
<td>K5</td>
<td>External collimator switch connection</td>
</tr>
<tr>
<td>K10</td>
<td>Capacitor bench connection</td>
</tr>
</tbody>
</table>

DIP switches

<table>
<thead>
<tr>
<th>DIP SWITCH NUM.</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>SW1</td>
<td>ON: WIRED</td>
</tr>
<tr>
<td></td>
<td>OFF: WIRELESS</td>
</tr>
<tr>
<td>SW2</td>
<td>ON: 60-63-65 kV</td>
</tr>
<tr>
<td></td>
<td>OFF: 60-65-70 kV</td>
</tr>
<tr>
<td>SW3</td>
<td>ON: 60 kV only</td>
</tr>
<tr>
<td>SW4-5-8</td>
<td>NOT used - all OFF</td>
</tr>
<tr>
<td>SW6-7</td>
<td>WiFi channel manual selection (see section &quot;Forcing the Wi-Fi channel through DIP switches&quot;)</td>
</tr>
</tbody>
</table>

BOARD RESET

Press and hold the yellow key. The reset of calibration and of X-ray head-handheld unit association is carried out.
9.2.1 Replacing the basic X-ray head control card

Pull out the collimator and panel stop ring. Remove the generator bottom cover.

RX DC Extend:

RX DC Hypersphere:
Detach all the connectors and work on the two support pins to pull out the card. Put the new card back in the correct position, being careful to run the cables behind the card support pins as shown in the figure. Make sure they do not pass in front of the x-ray collimator. Before closing the cover, turn on the x-ray unit and make sure the diagnostic led indicator is as shown in the table. When the X-ray head’s basic control card is replaced, in presence of wireless handheld, the handheld has to be associated to the head by following the instructions given in section "Handheld unit-X-ray head association".

**DIP switches**

Make a note of the positions of the DIP switches of the pcb being replaced.

![Image of DIP switches](image1)

**NOTE**: The X-ray head has to be calibrated with function T05 on the technical menu when this card is replaced (see section "Calibrating the X-ray head"). Check on P03 that the firmware versions of the handheld unit, head and basic board are aligned and correspond to those of the selected update package. In case of misalignment, carry out the firmware update procedure described in this manual.
10. X-RAY HEAD

Replacement

Follow the instructions given above to remove the basic X-ray head control card. Detach all the cables connected to the head that may get in the way. Loosen the screw "A" that secures the head, move it to the rear and lift it as shown in the figure.

⚠️ WARNING! After replacing the x-ray tube it is mandatory to replace the sticker with the tube serial number as well. The serial number sticker is provided together with the spare part (x-ray tube).

NOTE: The X-ray head has to be calibrated with function T05 on the technical menu when replaced (see Par."User and technician configuration menu").

To reinstall the X-ray head, perform the procedure in reverse order, being careful to lay the cables properly.

10.1 Handheld unit-X-ray head association

In case of handheld replacement or in case of X-ray head control board replacement it is only necessary to associate the handheld with the X-ray head. To do this, you first need to set the head in combination mode, then send a recognition signal from the head's remote control.

After a 30" time of inactivity, the handheld unit turns off if it is not in "ready" mode.
10.2 Setting the X-ray head in combination mode

This procedure can only be activated within THREE MINUTES of the radiographic unit being turned on.

Remove the collimator from the X-ray head, turn on the radiographic unit then turn the collimator microswitch on and off at least 6 consecutive times. The head will emit a beep that confirms it has switched to combination mode.

If the procedure is unsuccessful, turn off the X-ray head, wait a few seconds and start again.

10.3 Send the recognition signal from the handheld unit to the X-ray head

Turn on the handheld and go to menu T02. This menu is accessed by pressing keys + . Scroll the menu with key until P08 appears. Press + to access the technical menu and press key + until T02 is displayed. Press key + to open the menu and confirm association.

If association has been successfully completed the radio field icon should appear on the control handheld with the word READY. If this is not the case (Error “EE”), repeat the operation.

At the end of the matching procedure check on P03 that the firmware versions of the handheld unit, X-ray head and basic board are aligned and correspond to those of the selected update package.

10.4 Inspections and modifications of Wi-Fi parameters on RX unit

If the device loses too easily the wireless signal, it may be that the fault is not the settings but, rather, there are other wireless networks present that unfortunately cause interference problems.

If you use a Windows operating system, to find the channels used by other wireless networks, just download a simple free program called Acrylic WiFi.


After installing this program, click on the voice called “AP channels in 2.4GHz”, to see which channels are used by the different wireless networks.

You can easily understand which channels are less used by looking at the number that identifies each wireless channel; in the same way the overlapping of the most saturated wireless channel can be checked (if you cannot see the AP channels in 2.4GHz you will have to press on the menu in the upper right, represented with three horizontal lines, and activate the Advanced Mode function).

How to find the best Wi-Fi channel?

To solve connection problems you have to find a better Wi-Fi channel.

The modem router, in fact, to properly communicate with several devices present, must necessarily use one of the 13 channels belonging to the 2.4 GHz band.

The channels belonging to the 2.4 GHz band are not all spaced from each other, as you can see from the following image, and consequently, very often, they overlap each other causing interferences.

The signal of each channel overlaps with the 4 on the right and with the 4 on the left. Set on the device a specific channel (i.e.:1, 6, 11 or 2, 7, 12 or 3, 8, 13).
The network RXDC_XXXXXXXXXXXXXXXXXXXXXXX (created based on the MAC address of the paired handheld device) is the Wi-Fi generated by the radiographic. Even DECT systems, microwave ovens, wireless speakers, wireless cameras, baby-monitors use the frequency of 2.4 Ghz.

To have a more powerful system capable of detecting the interferences of the other devices, it is necessary to use this tool: https://www.metageek.com/products/ and the version to be purchased is Chanalyzer Essential.

10.4.1 Change Wi-Fi settings

Make sure the handheld is in READY mode. The handheld allows a number of work parameters to be viewed and edited by simply pressing a combination of keys present on the control panel.

Key serves to confirm/save the function, key is used to undo/quit the menu while keys and edit the values of the selected parameters on all the setup menus.

Proceed as directed below to access the menus: + : Hold down these two keys to go to the set up menu (from P01 to P08).
Select P08 with key and press + to see the Technical Menu.
Select T06 with key and press .

T06: SELECT WIRELESS CHANNEL

Press the keys and at the same time to activate the wireless channel automatic selection function (when active, icon is displayed). In this condition, should the manually selected channel be busy, the X-ray device will automatically select the first free channel available in order to minimise any interference with the handheld device. If the function deactivates (icon not shown), the channel is always the one displayed.

Re-perform the devices matching procedure T02:

T02: HANDHELD UNIT-X-RAY HEAD MATCHING PROCEDURE

Press key to start the procedure. If successful, handheld unit will reboot and search for the SSID of the matched machine and the icon will appear steady at the top left side. If handheld unit displays EE, the procedure was not successfully completed.
10.4.2 Forcing the Wi-Fi channel through DIP switches

Should the wireless channel currently selected on the X-ray device be disturbed, it may be difficult to connect handheld device and head, therefore it will be impossible to set a free channel. It is possible to force a Wi-Fi channel by setting the DIP switches [see section "Basic X-ray head control card (Code 97661586)" - DIP switches] as follows (the X-ray device must be off):

| 6 OFF 7 OFF | no change to the settings |
| 6 ON 7 OFF | channel 2 selection and automatic scanning deactivated |
| 6 OFF 7 ON | channel 5 selection and automatic scanning deactivated |
| 6 ON 7 ON | channel 10 selection and automatic scanning deactivated |

Upon turning on the device, check that the correct channel is created and perform the handheld device pairing procedure (see section "Handheld unit-X-ray head association")

Then, reset both DIP switches to OFF to allow a further change of the channel through the handheld device.

10.5 Replacing the SLIP RING assembly (only RX DC with "ball end socket joint")

1. Pull off the collimator and ring that secures the panels, remove the caps that protect the screws and loosen the screws that secure the bottom cover.
2. Disconnect all the connectors and work on the two pins to remove card 97661586.
3. Detach all the cables connected to the X-ray head that may get in the way. Loosen screw A that secures the X-ray head, push it back towards the rear and pull it up.
4. Remove the SLIP RING cable loosening the 3 Allen screws that secure it and put away the silicone ring.
5. Get the new SLIP RING and two clamps: attach one to the end of the clear sheath and the other 10.5 cm away, as shown in the figure:

6. Insert the SLIP RING in the ball and secure with 3 hexagonal screws and respective washers:
7. Insert the silicone ring shown in the figure:

8. Secure the cable:
   a) under the metal plate, being careful to keep the clamps to the left of the plate.
   b) with a clamp in the hole provided. Be careful not to tighten the clamp: there should be a few millimeters between the silicone ring and inside wall. It is also advisable to verify the clamp is not crushed between the monoblock and lever when the monoblock is installed on top of the levers:

9. Secure the cables to the actuator unit with another clamp, as illustrated in the figure:

10. Connect the wires in the nine-pole connector provided, observing the colors as shown in the figure:

<table>
<thead>
<tr>
<th>Wire Color</th>
<th>Side View</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purple</td>
<td>Grey</td>
</tr>
<tr>
<td>Red</td>
<td>Orange</td>
</tr>
<tr>
<td>Black</td>
<td>Brown</td>
</tr>
</tbody>
</table>
11. Perform the steps in reverse order to reinstall the X-ray head. Be careful to run the cables behind the card mounting pins, as shown in the figure, so that they are not crushed or pass in front of the x-ray collimator.

12. Close the cover, tightening the four fixing screws and put the caps back on the screws.

11. ERROR CODES GIVEN ON THE HANDHELD

When an error appears on the handheld screen it can be reset by pressing keys [ ] or [ ] to set the x-ray unit back to READY. If the error is still displayed even after pressing the two keys mentioned above, refer to the error code and solution given in the table below.

<table>
<thead>
<tr>
<th>ERROR NUMBER</th>
<th>ERROR TYPE</th>
<th>DESCRIPTION</th>
<th>TROUBLESHOOTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>W002</td>
<td>GENERAL WARNING</td>
<td>External shot key pressed upon start-up</td>
<td>Check that the external shot key is not stuck (remove the K4 connector from the basic board and restart the device).</td>
</tr>
<tr>
<td>W005</td>
<td>GENERAL WARNING</td>
<td>Configuration data reading error</td>
<td>Configuration data not present inside X-ray head. Perform the handheld unit matching procedure. If warning is still present upon device restart, contact the Technical Service</td>
</tr>
<tr>
<td>W006</td>
<td>GENERAL WARNING</td>
<td>Missing or wrong tube calibration</td>
<td>This warning may happen after a X-ray head board replacement or after a complete reset. The warning means that X-ray head board does not contain a proper configuration for tubehead. Perform tube calibration (see section &quot;Calibrating the X-ray head&quot;).</td>
</tr>
<tr>
<td>W007</td>
<td>GENERAL WARNING</td>
<td>Calibration data reading error</td>
<td>Tube calibration data not present inside X-ray head. Perform the calibration procedure (see section &quot;Calibrating the X-ray head&quot;). If warning is still present upon device restart, contact Technical Service.</td>
</tr>
<tr>
<td>E102</td>
<td>X-RAY HEAD ERROR</td>
<td>Wrong technical parameters. No X-Ray exposure.</td>
<td>Wrong technical parameters. Power cycle the machine and if the problem persists, please contact Technical Service.</td>
</tr>
<tr>
<td>E104</td>
<td>X-RAY HEAD ERROR</td>
<td>Line voltage below 200Vac.</td>
<td>Check mains value. Unless voltage line is within accepted range is not possible to take a shoot.</td>
</tr>
<tr>
<td>ERROR NUMBER</td>
<td>ERROR TYPE</td>
<td>DESCRIPTION</td>
<td>TROUBLESHOOTING</td>
</tr>
<tr>
<td>--------------</td>
<td>-----------------</td>
<td>---------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>E105</td>
<td>X-RAY HEAD ERROR</td>
<td>SW fault</td>
<td>Try to repeat exposure. If the problem persists, replace the X-RAY HEAD control board.</td>
</tr>
<tr>
<td>E107</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E108</td>
<td>COMMUNICATION ERROR</td>
<td>No communication between head board and base board</td>
<td>Check the continuity of the arm cable.</td>
</tr>
<tr>
<td>E130</td>
<td>X-RAY HEAD ERROR</td>
<td>Overvoltage fault</td>
<td>Detected too high anodic voltage. Check X-ray head board to tubehead cable. Tubehead fault.</td>
</tr>
<tr>
<td>E131</td>
<td>X-RAY HEAD ERROR</td>
<td>Overcurrent fault</td>
<td>Detected too high anodic current. Check X-ray head board to tubehead cable. Tubehead fault.</td>
</tr>
<tr>
<td>E132</td>
<td>X-RAY HEAD ERROR</td>
<td>Loss of anode voltage regulation</td>
<td>Detected too low anodic voltage. Check X-ray head board to tubehead cable. X-ray head board fault.</td>
</tr>
<tr>
<td>E133</td>
<td>X-RAY HEAD ERROR</td>
<td>Loss of anode current regulation</td>
<td>Detected too low anodic current. Check X-ray head board to tubehead cable and pantograph arm cable. X-ray head board fault.</td>
</tr>
<tr>
<td>E134</td>
<td>X-RAY HEAD ERROR</td>
<td>Anode voltage not zero</td>
<td>Detected non zero anodic voltage during standby. Check X-ray head board to tubehead cable. X-ray head board fault.</td>
</tr>
<tr>
<td>E135</td>
<td>X-RAY HEAD ERROR</td>
<td>Anode current not zero</td>
<td>Detected non zero filament current during standby. Check X-ray head board to tubehead cable. X-ray head board fault.</td>
</tr>
<tr>
<td>E136</td>
<td>X-RAY HEAD ERROR</td>
<td>Excessive regulation on filament</td>
<td>Detected too high filament current. Check X-ray head board to tubehead cable. Tubehead fault.</td>
</tr>
<tr>
<td>E137</td>
<td>X-RAY HEAD ERROR</td>
<td>Feedback not connected (or filament broken)</td>
<td>Detected too low filament current. Check X-ray head board to tubehead cable. Filament fault.</td>
</tr>
<tr>
<td>E138</td>
<td>X-RAY HEAD ERROR</td>
<td>Offset error during init</td>
<td>Detected wrong offset on analog inputs. Check X-ray head board to tubehead cable. X-ray head board fault.</td>
</tr>
<tr>
<td>E139</td>
<td>POWER SECTION ERROR</td>
<td>Signal and/or power wires of the arm cable interrupted</td>
<td>Check the continuity of the arm cable. If other errors appear after resetting the error, check in sequence: base board, monobloc and head board.</td>
</tr>
<tr>
<td>E150</td>
<td>BRAKE ERROR</td>
<td>Overvoltage fault</td>
<td>Detected capacitor too high voltage. X-ray head board fault.</td>
</tr>
<tr>
<td>E151</td>
<td>BRAKE ERROR</td>
<td>Undervoltage fault</td>
<td>Detected brake too low voltage. X-ray head board fault or brake shortcircuit fault.</td>
</tr>
<tr>
<td>ERROR NUMBER</td>
<td>ERROR TYPE</td>
<td>DESCRIPTION</td>
<td>TROUBLESHOOTING</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>-------------</td>
<td>----------------</td>
</tr>
<tr>
<td>E153</td>
<td>BRAKE ERROR</td>
<td>Actuator not connected or thermal open</td>
<td>Detected brake too low current. Check capacitors board cable and brake cable. Brake fault or brake unplugged.</td>
</tr>
<tr>
<td>E154</td>
<td>BRAKE ERROR</td>
<td>Brake fault</td>
<td>Detected non zero current during stand-by. Check capacitors board cable and brake cable. X-ray head board fault or brake fault.</td>
</tr>
<tr>
<td>E155</td>
<td>BRAKE ERROR</td>
<td>Brake fault</td>
<td>Detected non zero voltage during stand-by. Check capacitors board cable. X-ray head board fault.</td>
</tr>
<tr>
<td>E200 E201</td>
<td>POWER BOARD ERROR</td>
<td>Overcurrent fault</td>
<td>Shortcircuit detected. Check the cable inside the pantograph arm. Tubehead or power board fault.</td>
</tr>
<tr>
<td>E202</td>
<td>POWER BOARD ERROR</td>
<td>Driver disabled while running</td>
<td>Detected unexpected disable during exposure. Check interlock.</td>
</tr>
<tr>
<td>E203 E204</td>
<td>POWER BOARD ERROR</td>
<td>Backup timer overflow</td>
<td>Detected wrong exposure time. Software or hardware error in power or head board.</td>
</tr>
<tr>
<td>E206 E211</td>
<td>EXTERNAL X-RAY KEY ERROR</td>
<td>External X-ray key released too early</td>
<td>Hold down the key until the image has been captured. If the problem persists, replace the X-Ray key.</td>
</tr>
<tr>
<td>E212</td>
<td>POWER BOARD ERROR</td>
<td>FW update error</td>
<td>Check the pantograph arm cable. Restart the device.</td>
</tr>
<tr>
<td>E300</td>
<td>HANDHELD ERROR</td>
<td>Unexpected pressure of the shot key</td>
<td>The shot key of the wired or wireless handheld unit was active during device turning on or it was still pressed during the 4 seconds after emission.</td>
</tr>
<tr>
<td>E301</td>
<td>HANDHELD ERROR</td>
<td>X-Ray key released during shoot</td>
<td>Hold X-Ray key pressed until exposure end.</td>
</tr>
<tr>
<td>E302 E303</td>
<td>HANDHELD ERROR</td>
<td>Handheld communication error</td>
<td>In case of wireless handheld device, the error may be caused by communication interferences. In this case perform the selection procedure of the free channel. In case of wired handheld device check the cable.</td>
</tr>
<tr>
<td>E304 E306</td>
<td>HANDHELD ERROR</td>
<td>Handheld error</td>
<td>Internal handheld error. If the error persists replace the handheld device.</td>
</tr>
<tr>
<td>E307</td>
<td>COMMUNICATION ERROR</td>
<td>No communication between wired handheld and base board</td>
<td>Check the continuity of the handheld device cable.</td>
</tr>
</tbody>
</table>
12. FIRMWARE UPDATE PROCEDURE

Check on the Extranet the presence of a more updated Firmware version compared to the one of the X-ray device (it can be displayed in the P03 menu of the handheld device). See “Firmware” section, download the .zip file.

Download also the RXDC Updater software.

The update procedure consists of the two following steps:

1. **Firmware transfer towards the X-ray device.**
   Use a PC connected to the device via a WiFi network.
   This step can require from 2’ to 4’ to be completed, depending on WiFi signal quality.

2. **Update of X-ray device firmware.**
   The firmwares of all the boards of the device are updated.
   This step can require from 5’ (with wireless handheld unit) to 15’ (with wired handheld unit) to be completed.

To start the update procedure:

1. Select technical menu T08 of the handheld unit and press “SIZE” to confirm. The display shows “UPD”.

2. Hold key “SIZE” pressed on the handheld unit to activate the update procedure (a confirmation beep sound will be emitted). The device activates an ad hoc WiFi network called “RXDC_UPLOAD”.

3. Connect the PC to the “RXDC_UPLOAD” WI-FI network, and enter password “1234567890”.

4. Launch the “RXDC Updater” application.
5. Use the key highlighted in the picture to connect to the X-ray unit.

As a consequence, the “DUT connected” message will be displayed at the bottom right, and the current FW versions of the three boards, sorted by code, will appear.

6. Press the key highlighted in the figure and select the .zip file (not uncompressed) containing the previously downloaded update.
7. The new firmware version will be displayed next to the current one.

8. Tick the box “Update” for all the three boards.

9. Press the key highlighted in the figure to start the FW update procedure.

10. Wait for the update process to be completed. In case of procedure positive outcome, the message “Update OK” will be displayed. In case of errors, turn off and on again the device and repeat the procedure.
During the update the error code E108 will appear on the handheld device. At the end, simply press one key on the handheld device to eliminate the error.

11. The device will then automatically start the firmware update procedure. Turn the handheld unit on: the display shows the progress status (see figure) and the machine emits a beep sound every 2s.

![](image)

12. Once the procedure is completed, the device will be automatically restarted (approximately 6 minutes are required in wireless mode and 16 minutes in wired mode).

13. Check on P03 that the firmware versions of the handheld unit, X-ray head and basic board are aligned and correspond to those of the selected update package.
13. ELECTRIC WIRING DIAGRAMS

13.1 REF. **P*****S
RX DC X-RAY UNIT

13.3 REF. **P*****I
14. PERIODICAL MAINTENANCE

These instructions describe the maintenance procedures for the x-ray unit. These instructions apply to all versions of said equipment.

In order to ensure the operational safety and functional reliability, at least once a year an authorised service technician must perform a full inspection of the device.

When taking measurements that require a multimeter, always use a calibrated digital multimeter.

All the following tests must be carried out:

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Reference in Manual</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Check that all labels located: - on the wall-mounted cover - on the x-ray tube - inside the collimator/s are intact, correctly applied and readable.</td>
<td>User Manual, Section &quot;Identification nameplates&quot;</td>
</tr>
<tr>
<td>2</td>
<td>Check there are no external damages to the equipment, which may reduce protection against radiation.</td>
<td>User Manual, Section &quot;Description of the x-ray unit&quot;</td>
</tr>
<tr>
<td>3</td>
<td>Pull out the collimator and panel stop ring, take off the screw cover caps and loosen the screws that secure the lower cover. Check there is no oil leakage on the tube-head.</td>
<td>Technical Manual, Section &quot;Replacing the basic head control card&quot;</td>
</tr>
<tr>
<td>4</td>
<td>Check the electromechanical brake that locks/unlocks the movement of the generator and adjust it if necessary – ball joint model units only</td>
<td>Technical Manual, Section &quot;Adjusting the actuator unit&quot;</td>
</tr>
<tr>
<td>5</td>
<td>Power off the unit and remove the wall mounting cover. Disconnect the unit from the main power supply and check the condition of the main power supply cable. Replace it in case of damage. Connect it back making sure the safety ground is securely connected. Install the wall-mounted cover back again.</td>
<td>Technical Manual, Section &quot;Wall-mounted plate wiring connections&quot;</td>
</tr>
<tr>
<td>6</td>
<td>Check the battery level of the wireless remote control.</td>
<td>User Manual, Section &quot;Handheld functions&quot;</td>
</tr>
<tr>
<td>7</td>
<td>Check the remote control functionality: keys must respond to interaction</td>
<td>User Manual, Section &quot;Use of Handheld&quot;</td>
</tr>
<tr>
<td>8</td>
<td>Check the power switch verifying that the switch is working properly and the main switch green light switches on when the switch is in the ON position.</td>
<td>User Manual, Section &quot;Turning the x-ray unit on and off&quot;</td>
</tr>
<tr>
<td>9</td>
<td>Check proper functioning of x-ray generator indicator light – ball joint model units only</td>
<td>User Manual, Section &quot;Type of x-ray head&quot;</td>
</tr>
<tr>
<td>10</td>
<td>Check the exposure buzzer during a trial x-rays emission</td>
<td>User Manual, Section &quot;Performing the exposure&quot;</td>
</tr>
<tr>
<td>11</td>
<td>Verify that exposure is immediately interrupted when x-ray key is released</td>
<td>User Manual, Section &quot;Performing the exposure&quot;</td>
</tr>
<tr>
<td>12</td>
<td>Check the scissors arm balance and adjust it if necessary</td>
<td>Technical Manual, Section &quot;Installing the double pantograph arm&quot;</td>
</tr>
<tr>
<td>13</td>
<td>Calibrate the X-ray head</td>
<td>Technical Manual, Section &quot;Technician and user setup menu&quot;</td>
</tr>
</tbody>
</table>

All inspection and maintenance work performed by the system owner and/or service engineer must be recorded in the Operator's Manual and kept near the unit. (see User Manual - Section 16.2 TECHNICAL MAINTENANCE)
RX DC X-RAY UNIT

15. RX DC WITH "BALL END SOCKET JOINT" / WITH STANDARD JOINT - INSTALLATION CHECK LIST (FOR USA ONLY)

It is the responsibility of the Assemblers or Installers to report the installation to the manufacturer within 15 days of the date of installation.

Upon completion of an installation, please fill out and review the manufacturer’s INSTALLATION CHECKLIST (document number 97050989, supplied with the device or available on "extranetmedical.cefla.it") in its entirety. Return a copy, along with the original manufacturer’s INSTALLATION AND TEST REPORT (document number 97011067) to CEFLA North America, Inc. 6125 Harris Technology Blvd. Charlotte, NC 28269 USA.

It is the responsibility of the Assemblers (defined as “any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem”) to fill out and distribute the “Report of assembly”, using the Form FDA 2579, upon completion of an installation and within 15 days of the date of installation. For more guidance, please refer to FDA document number 1751 “Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment”.

Please send a photocopy of the Form FDA 2579 to the manufacturer along with the INSTALLATION CHECKLIST and the INSTALLATION AND TEST REPORT: fax 704-631-4608 or e-mail: service@cefladental.com. Please also keep a copy for yourself.

In the event of a technical maintenance, if components bearing a serial number are replaced, an authorized technician must:

- repeat all the steps prescribed by the installation checklist,
- fill out a new installation report bearing the new serial number of the replaced component,
- send the new installation report and installation checklist to the manufacturer,
- fill out and distribute the Report of Assembly, using the Form FDA 2579 - for a list of exceptions to reporting requirements, please refer to 21CFR 1020.30(d)(2).