



EN

# Rooter® X3000

## User Manual



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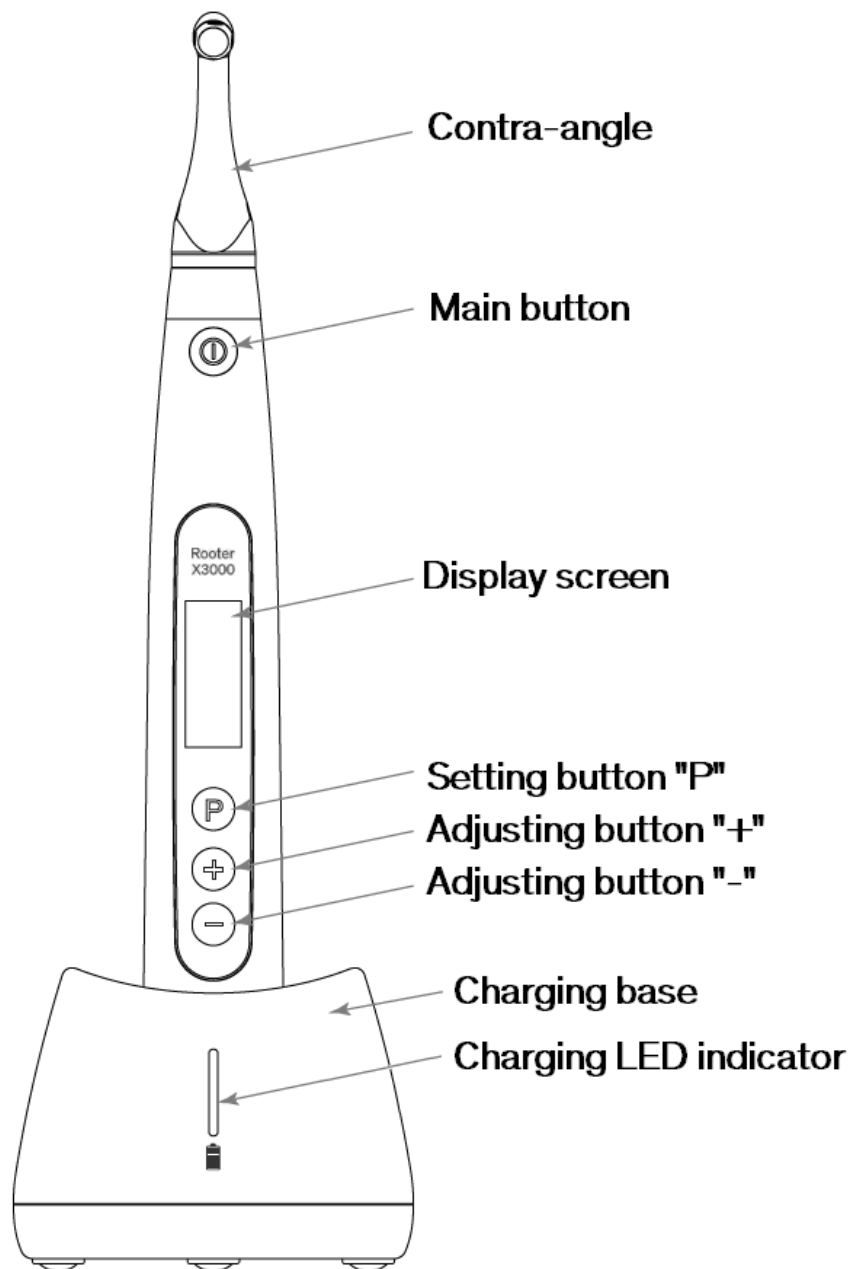
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# 1. Product introduction

## 1.1 Description of the device

The Rooter® X3000 device is a cordless endo motor with an integrated root canal apex locator. It can be used as an endo motor for preparation of tooth root canals, or as an apex locator device to help to determine the root canal working length. It can also be used to prepare the canals while monitoring the relative position of the endodontic instrument tip inside the canal (combined Motor and Apex locator mode).



## 1.2 Components and accessories

| #  | Designation                       | Reference FKG    |
|----|-----------------------------------|------------------|
| 1  | Motor handpiece                   | 08.971.00.001.FK |
| 2  | Charging base                     | 08.971.00.002.FK |
| 3  | Contra-angle [4.7/1]              | 08.971.00.003.FK |
| 4  | Spray nozzle                      | 08.971.00.004.FK |
| 5  | Measuring wire                    | 08.971.00.005.FK |
| 6  | File clip                         | 08.971.00.006.FK |
| 7  | Lip hook                          | 08.971.00.007.FK |
| 8  | Touch probe                       | 08.971.00.008.FK |
| 9  | Protective silicone cover         | 08.971.00.009.FK |
| 10 | "O"-ring                          | 08.971.00.010.FK |
| 11 | Universal AC-Adapter              | 08.971.00.011.FK |
| -  | User manual                       | -                |
| -  | Apex locator troubleshooting card | -                |
| -  | Package content list              | -                |



1. Motor handpiece



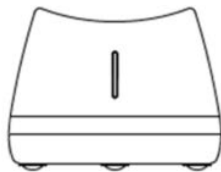
4. Spray nozzle



6. File clip



9. Protective silicone cover



2. Charging base



5. Measuring wire



7. Lip hook



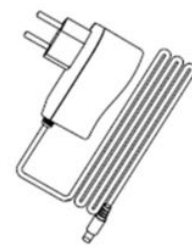
10. O-ring



3. Contra-angle



8. Touch probe



11. AC-Adapter

### 1.3 Technical specifications

- a) Motor handpiece lithium battery specification  
3.7V / 2000mAh
- b) Power adapter specification  
Input: ~100V-240V 50Hz/60Hz 0.5-0.2A  
Output: DC5V/1A
- c) Motor handpiece mechanical specification  
Torque range: 0.4Ncm-4.0Ncm  
Speed range: 100rpm-3'300rpm
- d) Wireless charging specification  
Frequency range: 112-205KHz  
Maximum RF output power of the product: 9.46dBuA/m@3m



### 1.4 Warnings

Please carefully read this Instruction Manual before first operation.

- a) Do not use this device for anything else than its intended use (refer to Chapter 1.9).
- a) Use original components and accessories only.
- b) Always set torque and speed following the recommendations of the file manufacturer.
- c) Make sure the contra-angle is well connected before to start the motor handpiece (refer to Chapter 2.1).
- d) Make sure the instrument is well connected and locked before to start the motor handpiece (refer to Chapter 2.2).
- e) Do not connect or disconnect the contra-angle while the motor is running.
- f) Do not disconnect the instrument while the motor is running.
- g) Be sure to be able to power OFF the device at any time.
- h) Operate and store the device in reliable environment (refer to Chapter 1.7 and Chapter 8).
- i) Do not use the device in the vicinity of fluorescent lamps, radio transmitting devices, remote control devices, handheld, and mobile high-frequency communication devices.
- j) The motor handpiece, power adapter and charging base are not autoclavable (refer to Chapter 6).
- k) Replace the lithium battery according to the instructions (refer to Chapter 7.4).
- l) Do not make any changes or modifications to the device. Any change, modification or any other alteration of the device may violate safety regulations, causing harm to the patient.
- m) In case of motor handpiece frequent overheat, contact a local distributor.
- n) Do not directly or indirectly place the device near heat sources.
- o) Do not cover the device.
- p) Remove the battery of the device in case of long period storage.

## 1.5 Important precautions

These precautions are critical to insure safe operation and use.

- a) Do not use this device on patients who have implanted pacemakers, defibrillators, or any other implantable devices.
- b) Do not use this device on patients suffering from Hemophilia.
- c) Use with caution on patients with heart disease, pregnant women, and young children.

## 1.6 Device safety classification

- a) Type of Operation mode: Continuous operating electromedical device
- b) Type of protection against electric shock: Class II equipment with internal power supply
- c) Degree of protection against electric shock: B type applied part
- d) Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)
- e) Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- f) Applied part: contra-angle , lip hook, file clip, touch probe.  
The contact duration of applied part: 1 to 10 minutes.  
Maximum temperature of applied part: 46.6°C.

## 1.7 Environmental parameters

- a) Operating ambient temperature: +5°C ~ +40°C
- b) Operating relative humidity: 30% ~ 75%
- c) Operating atmospheric pressure: 70kPa ~ 106kPa

## 1.8 User qualification

- a) The device must be operated in hospital or clinic by legally qualified dentists.
- b) It is assumed that the operator is familiar with root canal apex locator.

## 1.9 Intended use

- a) The Rooter<sup>®</sup> X3000 is an endo motor, an electro-medical device intended to drive mechanical instruments intended for dental root canal treatment (endodontic files).
- b) In addition, it is intended to help to determine the working length (apex locator functionality).

# 2. Device setup instructions

## 2.1 Contra-angle setup

### 2.1.1 Before the first use and after each treatment

- a) Clean and disinfect the contra-angle (refer to Chapter 6).
- b) Lubricate the contra-angle (refer to Chapter 7.2).
- c) Sterilize the contra-angle (refer to Chapter 6).



### 2.1.2 Warnings

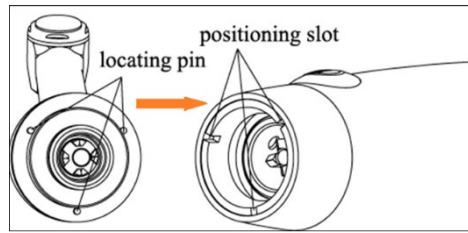
- a) Use original contra-angle only.
- b) Make sure the contra-angle is well connected before to start the motor handpiece.
- c) Do not connect or disconnect the contra-angle while the motor is running.

### 2.1.3 Connecting the contra-angle

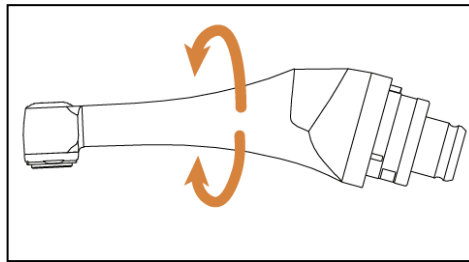
1. Align the three pins of the contra-angle with the positioning slots of the motor handpiece.



2. Push the contra-angle horizontally. A “click” sound indicates that the installation is in place.

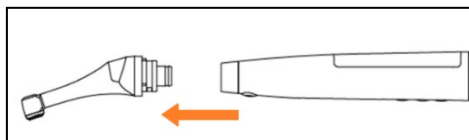


3. The contra-angle must rotate 360° freely.



#### 2.1.4 Disconnecting the contra-angle

Pull out the contra-angle horizontally.



## 2.2 File setup



### 2.2.1 Warnings

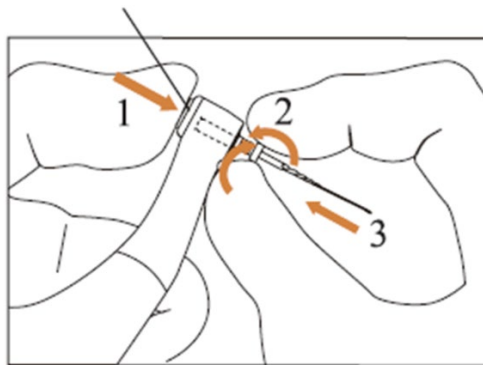
- a) Make sure the instruments are compliant to ISO1797 standard (Shanks for rotary and oscillating instruments).
- b) Connecting and disconnecting files without holding down the Push button may damage the chuck of the contra-angle.
- c) Be careful when manipulating files to avoid injury to fingers.
- d) Make sure the file is well connected and locked before to start the motor handpiece.
- e) Do not disconnect the file while the motor is running.

### 2.2.2 Connecting a file

Plug the file into the hole of contra-angle head.

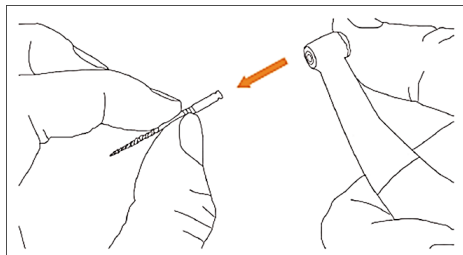
1. Hold down the Push button on the contra-angle and push the file.
2. While pushing, rotate the file clockwise and counterclockwise until its shank is aligned with the contra-angle latch groove.
3. When the shank is aligned and slips into place, release the Push button to lock the file into the contra-angle.

### Push Button



### 2.2.3 Disconnecting a file

Hold down the Push button and pull out the file.

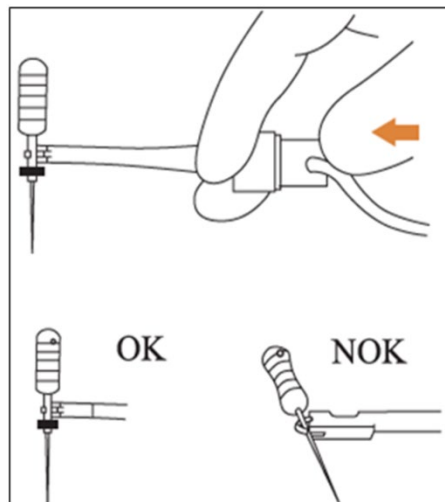


## 2.3 Apex locator setup



### 2.3.1 Warnings

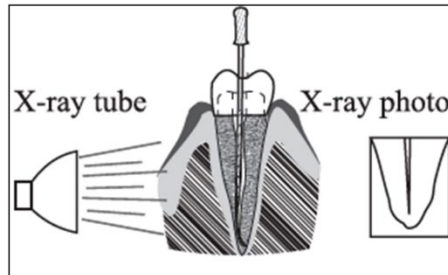
- a) In Apex locator mode, the file clip must properly hold the file.



- b) In case of bad or wrong connection signal, replace the measuring wire.  
c) In apex locator mode it is suggested to install the motor handpiece in the charging base to get better visual angle.



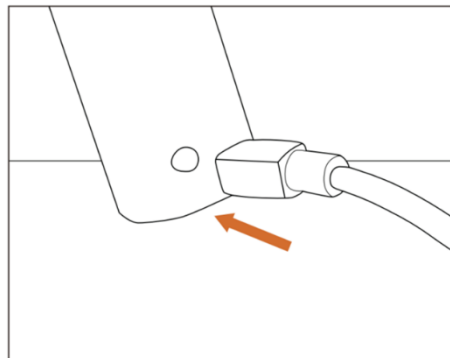
- d) The Apex locator detects the canal apical foramen, not the tooth anatomical apex. This could explain some differences between the apex locator signal and an X-ray image.



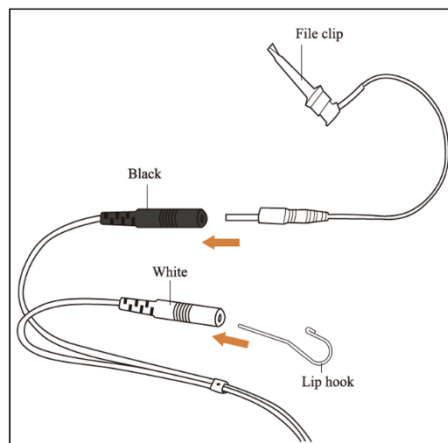
- e) Not all conditions are ideal for working length determination. To be informed about the Apex locator limitations, refer to Chapter 4.8.

### 2.3.2 Connecting apex locator wires

1. Connect the measuring wire to the motor handpiece (USB socket at the back).



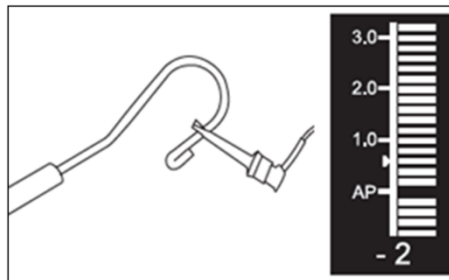
2. Connect the lip hook to the white socket of the measuring wire.
3. Connect the file clip plug to the black socket of the measuring wire (this is not required in combined Motor and Apex locator mode).



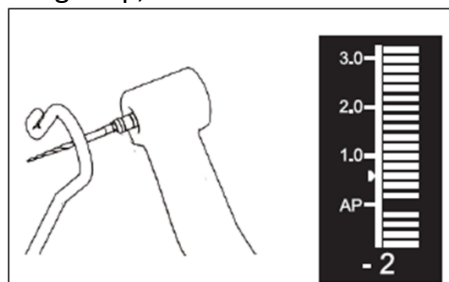
### 2.3.3 Connection testing

It is strongly recommended to check the connection quality before every use.

1. In Apex locator mode, clip the holder on lip hook and check that all the indicator bars light up, as shown below:



2. In combined Motor and Apex locator mode, touch the lip hook with the file and check that all the indicator bars light up, as shown below:

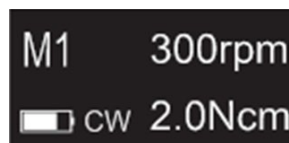


## 3. Device Operation modes and display interface

### 3.1 Motor modes

#### 3.1.1 CW Operation Mode (Clockwise continuous rotation mode)

In this mode, the motor handpiece rotates in clockwise direction only (forward direction).



#### 3.1.2 CCW Operation Mode (Counterclockwise continuous rotation mode)

In this mode, the motor handpiece rotates in counterclockwise direction only (reverse direction).

In this mode, a double beep sounds continuously.



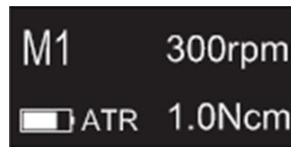
#### 3.1.3 REC Operation Mode (Reciprocating motion mode)

In this mode, the motor handpiece generates reciprocating motion only (F: Forward angle, R: Reverse angle).



### 3.1.4 ATR Operation Mode (Adaptive Torque Reverse mode)

In this mode, the motor handpiece rotates in clockwise direction and generates reciprocating motion when the torque load on the file is higher than the set torque limit.



## 3.2 Apex locator Operation mode

### 3.2.1 EAL Operation Mode (Electronic Apex Locator)

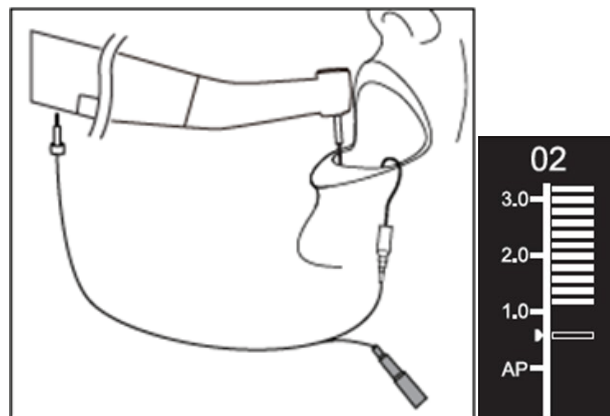
This mode is intended for working length determination only.

In this mode, the motor handpiece does not run.



## 3.3 Combined Motor and Apex locator Operation mode

When a file is inside the canal and the lip hook is in contact with patient's lip, the device enters automatically in the combined Motor and Apex locator mode.

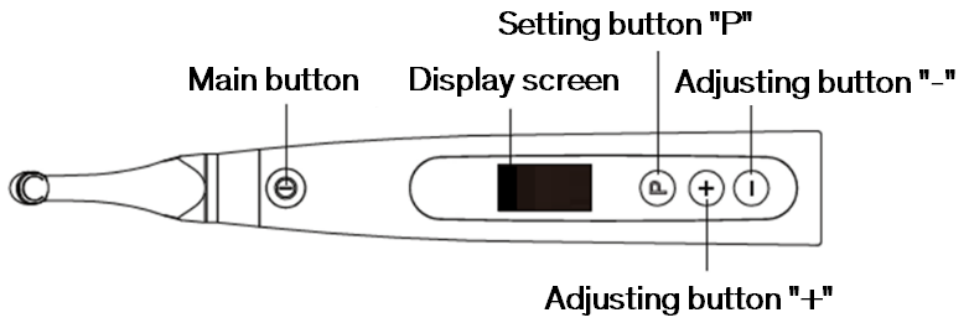


### 3.4 Display interface

|  |   |
|--|---|
|  | <p>Stand-by interfaces</p> <p>While the motor is not running, the display shows the actual settings of the motor.</p> <ol style="list-style-type: none"> <li>User Program (M0-M9)<br/>or<br/>Manufacturer preset program (refer to Chapter 4.5)</li> <li>Battery level</li> <li>Set speed (rpm)</li> <li>Set torque limit (Ncm)</li> <li>Motor Operation mode</li> <li>Set forward angle (°deg)</li> <li>Set reverse angle (°deg)</li> </ol>  |
|  | <p>Motor Operation interface</p> <p>While the motor is running, the display shows the torque load on the file.</p> <ol style="list-style-type: none"> <li>Set speed (rpm)</li> <li>Set torque limit (Ncm)</li> <li>Real time torque (Ncm)</li> <li>Torque display scale (Ncm)</li> </ol>  |
|  | <p>Combined Motor and Apex locator Operation interface</p> <ol style="list-style-type: none"> <li>File progression indication bar</li> <li>File progression indication number</li> </ol> <p>The numbers 1.0, 2.0, 3.0 (a) and numbers “00”-“16” (b) do not represent an absolute length. It simply indicates the relative file position towards the apical foramen. These numbers are used to help the determination of the working length.</p> <ol style="list-style-type: none"> <li>Apical foramen (AP)</li> </ol> <p>The digital number “00” (b) indicate that the file has reached the apical foramen. The digital numbers “-1” and “-2” (b) indicate that the file has passed the apical foramen.</p> |
|  | <p>Apex locator Operation interface (EAL mode)</p> <ol style="list-style-type: none"> <li>User Program (M0-M9)</li> <li>Battery level</li> <li>File position indication bar</li> <li>Apical reference point</li> <li>Motor Operation mode</li> </ol>  |

## 4. Device operating instructions

### 4.1 Setting interface and button description



### 4.2 Power ON and power OFF the device

1. To power ON the device, press the Main button. The device enters in stand-by state. The display shows the stand-by interface of the last program used. For example:



2. To start the motor from the stand-by state, press the Main button. The display shows the working interface according to the program used. For example:

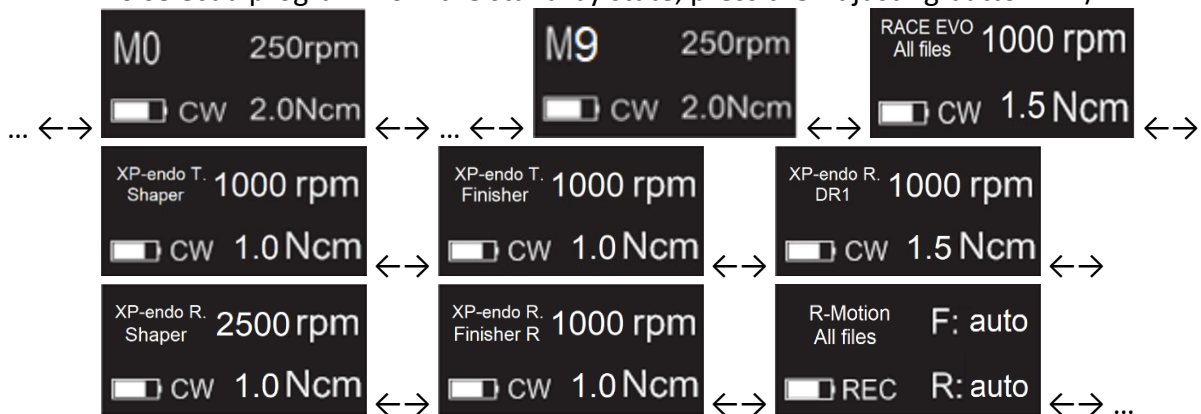


3. To stop the motor, press the Main button again. The device goes back in stand-by state.
4. To power OFF the device, hold down the Setting button "P", and press the Main button. In stand-by state, the device will automatically shut down after 5 minutes.

### 4.3 Select User Programs

The device contains 10 memorized User Programs (M0-M9) and 7 preset FKG File Systems available directly from the stand-by state.

1. To select a program from the stand-by state, press the Adjusting button "+" / "-".



2. To select a specific FKG File System, refer to Chapter 4.5.

## 4.4 Set User Program parameters



### 4.4.1 Warnings

- Make sure the Operation Mode is adequate before to start the motor.
- All the parameters must be set according to the file manufacturer recommendations.
- Make sure all the parameters are verified before to start the motor handpiece.
- M0-M9 User Programs parameters modified by the user are memorized.
- FKG File Systems parameters cannot be modified by the user (refer to Chapter 4.5).

### 4.4.2 Parameter setting

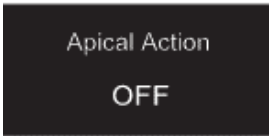
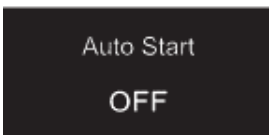
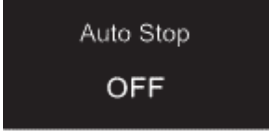
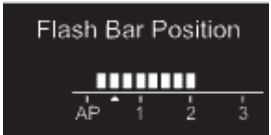
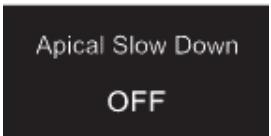
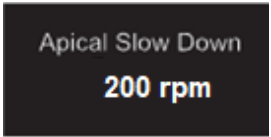
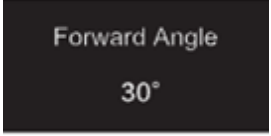
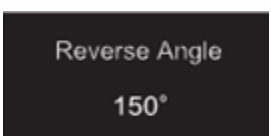
To modify User Program parameters from the stand-by state:

- To select the desired parameter, press the Setting button “P”.
- To modify the parameter setting, press the Adjusting button “+”/“-”.
- Press the Main button or wait 5 seconds to confirm.

### 4.4.3 User Program parameters list

|   |  |
|---|--|
| <p>Operation Mode</p> <p><b>CW</b></p>    | <p>Set Operation Mode</p> <p>Operation modes list: CW, CCW, REC, ATR, EAL</p> <p>(refer to Chapter 3 for modes description)</p>  |
| <p>Speed</p> <p><b>250 rpm</b></p>        | <p>Set Working Speed</p> <p>In continuous rotation modes (CW and CCW), the working speed can be adjusted from 100rpm to 3'300rpm (50rpm increments).</p> <p>In REC mode, the working speed can be adjusted for 100rpm to 500rpm (50rpm increments).</p> <p>In ATR mode, the working speed can be adjusted for 100rpm to 500rpm (50rpm increments).</p> <p>In REC and ATR modes, the working speed represents the mean speed of one single angle movement (speed set for both Forward and Reverse angles).</p>  |
| <p>Torque Limit</p> <p><b>1.0 Ncm</b></p> | <p>Set Torque Limit</p> <p>In CW continuous rotation mode, the torque limit can be adjusted from 0.4Ncm to 4.0Ncm depending on the set speed:</p> <ul style="list-style-type: none"> <li>100-200rpm Max torque limit : 4.0Ncm</li> <li>250-400rpm Max torque limit : 3.5Ncm</li> <li>450-650rpm Max torque limit : 3.0Ncm</li> <li>700-950rpm Max torque limit : 2.5Ncm</li> <li>1'000-1'450rpm Max torque limit : 2.0Ncm</li> <li>1'500-1'950rpm Max torque limit : 1.5Ncm</li> <li>2'000-3'300rpm Max torque limit : 1.0Ncm</li> </ul> <p>In REC mode, the torque limit can be adjusted from 2.0Ncm to 4.0Ncm depending on the set speed:</p> <ul style="list-style-type: none"> <li>100-250rpm Max torque limit : 4.0Ncm</li> <li>300-400rpm Max torque limit : 3.5Ncm</li> <li>450-500rpm Max torque limit : 3.0Ncm</li> </ul> <p>In ATR mode, the Trigger Torque can be adjusted from 0.4Ncm to 3.0Ncm.</p> <p>In CCW continuous rotation mode, the torque limit cannot be set.</p> |



|   |  |
|---|--|
|  <p>Apical Action<br/>OFF</p>  | <p>Set Apical Action</p> <p>The Apical action applies when the file reaches the set apical reference point (refer to <b>Flash Bar Position</b>)</p> <p>OFF: Disable Apical Action</p> <p>STOP: The motor stops automatically when the file reaches the reference point. The motor restarts automatically when the file is pulled away from the reference point.</p> <p>REVERSE: The motor automatically reverses the rotation direction when the file reaches the reference point. The motor goes back automatically to initial rotation direction when the file is pulled away from the reference point.</p>        |
|  <p>Auto Start<br/>OFF</p>   | <p>Set Auto Start</p> <p>OFF: Disable Auto Start (the Main button is needed to start the motor handpiece).</p> <p>ON: The motor starts automatically when the file is inserted into the canal (from when the file progression indicator shows 2 bars).</p>   |
|  <p>Auto Stop<br/>OFF</p>  | <p>Set Auto Stop</p> <p>OFF: Disable Auto Stop (the Main button is needed to stop the motor handpiece).</p> <p>ON: The motor stops automatically when the file is taken out the canal.</p>   |
|  <p>Flash Bar Position</p>  | <p>Set Flash Bar Position (Apical reference point)</p> <p>The apical reference point (flash bar) can be set from 2 to AP (Apical foramen). (0.5 indicates that the file tip is located very near the physiological apical foramen)</p> <p><b>Apical Action</b> and <b>Apical Slow Down</b> are triggered by the apical reference point.</p>  |
|  <p>Apical Slow Down<br/>OFF</p>  <p>Apical Slow Down<br/>200 rpm</p> | <p>Set Apical Slow Down</p> <p>When the Apical Slow Down is activated, the motor slows down to a set final speed as the file tips approaches the apical reference point. The motor speed decreases starting from the position “3.0” of the file progression indication bar .</p> <p>OFF: Disable Apical Slow Down</p> <p>In CW continuous rotation mode, the final speed can be adjusted from 100rpm to the current set speed (50rpm increments).</p> <p>The Apical Slow Down function is available for CW &amp; CCW continuous rotation mode only.</p> <p>The final speed must be lower than the nominal speed.</p> |
|  <p>Forward Angle<br/>30°</p>  | <p>Forward Angle</p> <p>In REC mode, the Forward Angle can be adjusted from 20° to 400° (10° increments)</p> <p>In ATR mode, the Forward Angle can be adjusted from 60° to 400° (10° increments).</p>  |
|  <p>Reverse Angle<br/>150°</p>   | <p>Reverse Angle</p> <p>In REC mode, the Reverse Angle can be adjusted from 20° to 400° (10° increments)</p> <p>In ATR mode, the Reverse Angle can be adjusted from 20° to the Forward Angle (10° increments).</p>   |

#### 4.4.4 User Programs parameters availability table

| Parameter<br>User Program<br>Operation Mode | Set<br>Working<br>Speed | Set<br>Torque<br>Limit | Set<br>Apical<br>Action | Set Auto<br>Start | Set Auto<br>Stop | Set Flash<br>Bar<br>Position | Set<br>Apical<br>Slow<br>Down | Set<br>Forward<br>Angle | Set<br>Reverse<br>Angle |
|---|-------------------------|------------------------|-------------------------|-------------------|------------------|------------------------------|-------------------------------|-------------------------|-------------------------|
| <b>CW</b>                                   | <b>YES</b>              | <b>YES</b>             | <b>YES</b>              | <b>YES</b>        | <b>YES</b>       | <b>YES</b>                   | <b>YES</b>                    | n/a                     | n/a                     |
| <b>CCW</b>                                  | <b>YES</b>              | <b>NO</b>              | <b>NO</b>               | <b>NO</b>         | <b>NO</b>        | <b>YES</b>                   | <b>YES</b>                    | n/a                     | n/a                     |
| <b>REC</b>                                  | <b>YES</b>              | <b>YES</b>             | <b>YES</b>              | <b>YES</b>        | <b>YES</b>       | <b>YES</b>                   | <b>NO</b>                     | <b>YES</b>              | <b>YES</b>              |
| <b>ATR</b>                                  | <b>YES</b>              | <b>YES</b>             | <b>YES</b>              | <b>YES</b>        | <b>YES</b>       | <b>YES</b>                   | <b>NO</b>                     | <b>YES</b>              | <b>YES</b>              |
| <b>EAL</b>                                  | n/a                     | n/a                    | n/a                     | n/a               | n/a              | <b>YES</b>                   | n/a                           | n/a                     | n/a                     |

### 4.5 Select FKG File Systems

To help the user set the file parameters according to FKG recommendation, the most popular FKG File Systems are already preset in the device.

1. To select a preset FKG File System from the stand-by state, long press the Setting button “P”.
2. To select the desired FKG File System, press the Adjusting button “+”/“-” and press the Setting button “P” to confirm.
3. To select a file, press the Adjusting button “+”/“-” and press the Main button to confirm.

#### 4.5.1 FKG File Systems list

##### RACE® EVO

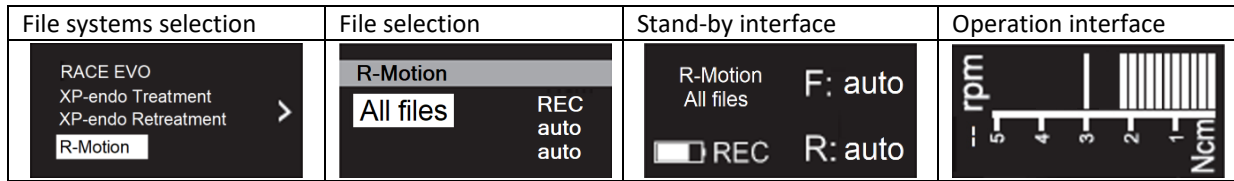
| File systems selection | File selection | Stand-by interface | Operation interface |
|------------------------|----------------|--------------------|---------------------|
|                        |                |                    |                     |

##### XP-endo® Treatment

| File systems selection | File selection | Stand-by interface | Operation interface |
|------------------------|----------------|--------------------|---------------------|
|                        |                |                    |                     |
|                        |                |                    |                     |

##### XP-endo® Retreatment

| File systems selection | File selection | Stand-by interface | Operation interface |
|------------------------|----------------|--------------------|---------------------|
|                        |                |                    |                     |
|                        |                |                    |                     |
|                        |                |                    |                     |



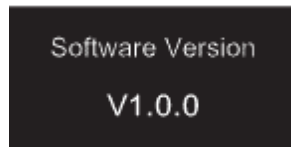
4.5.2 FKG File Systems parameters availability table

| Parameter \ FKG File System    | Set Working Speed | Set Torque Limit | Set Apical Action | Set Auto Start | Set Auto Stop | Set Flash Bar Position | Set Apical Slow Down | Set Forward Angle | Set Reverse Angle |
|--------------------------------|-------------------|------------------|-------------------|----------------|---------------|------------------------|----------------------|-------------------|-------------------|
| RACE EVO                       | X                 | X                | YES               | YES            | YES           | YES                    | YES                  | n/a               | n/a               |
| All Files                      | X                 | X                | YES               | YES            | YES           | YES                    | YES                  | n/a               | n/a               |
| XP-endo Treatment Shaper       | X                 | X                | YES               | YES            | YES           | YES                    | YES                  | n/a               | n/a               |
| XP-endo Treatment Finisher     | X                 | X                | YES               | YES            | YES           | YES                    | YES                  | n/a               | n/a               |
| XP-endo Retreatment DR1        | X                 | X                | YES               | YES            | YES           | YES                    | YES                  | n/a               | n/a               |
| XP-endo Retreatment Shaper     | X                 | X                | YES               | YES            | YES           | YES                    | YES                  | n/a               | n/a               |
| XP-endo Retreatment Finisher R | X                 | X                | YES               | YES            | YES           | YES                    | YES                  | n/a               | n/a               |
| R-Motion All Files             | X                 | X                | YES               | YES            | YES           | YES                    | NO                   | X                 | X                 |

4.6 Set device parameters

To set the device parameters:

1. To access the device parameters from the power OFF state, hold down the Setting button “P” and press Main button.



2. To select the desired parameter, press Setting button “P”
3. To set the parameter, press the Adjusting button “+”/“-” and the Main button to confirm.

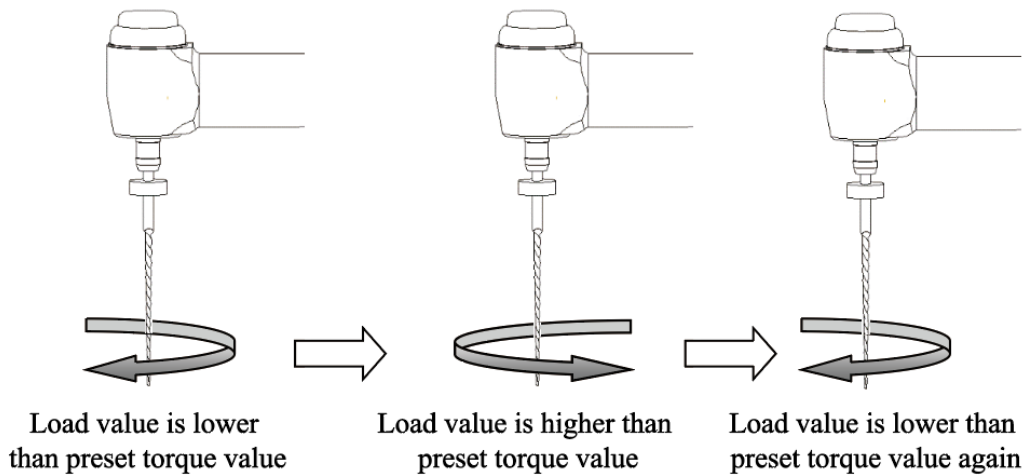
4.6.1 Device parameters list

|                            |  |
|----------------------------|--|
| Auto Power OFF<br>5 min    | Auto Power OFF<br>In stand-by state, the device automatically turns OFF after the set timer.<br>The timer can be adjusted from 3 minutes to 30 minutes (1 minute increments)               |
| Auto Standby Scr<br>30 sec | Auto Standby Scr<br>The display switches automatically back to the stand-by interface after the set timer.<br>The timer can be adjusted from 3 seconds to 30 seconds (1 second increments) |
| Dominant Hand<br>Right     | Dominant Hand<br>The device can be adjusted for left-handed or right-handed user (180° rotation of the display).   |

|   |  |
|---|--|
| <div style="background-color: black; color: white; padding: 10px; text-align: center;"> <p>Calibration</p> <p>OFF</p> </div>      | <p>Calibration</p> <p>Make sure the original contra-angle is installed before to launch the motor calibration.</p> <p>OFF: No action.</p> <p>ON: Start motor calibration</p> <p>The motor must be calibrated before the first use and after lubrication.</p> |
| <div style="background-color: black; color: white; padding: 10px; text-align: center;"> <p>Beeper Volume</p> <p>Vol.3</p> </div>  | <p>Beeper volume</p> <p>The device sound volume can be adjusted from Vol. 0 to Vol. 4.</p> <p>Vol.0: Mute.</p>   |
| <div style="background-color: black; color: white; padding: 10px; text-align: center;"> <p>Restore Defaults</p> <p>OFF</p> </div> | <p>Restore Defaults</p> <p>OFF: No action.</p> <p>ON: Device parameters returns to original setting.</p>   |

## 4.7 Torque overload protection

During operation, if the measured torque load exceeds the torque limit, the motor will automatically reverse the direction of rotation. The motor returns to initial Operation mode (CW) when the torque load goes back below the torque limit.



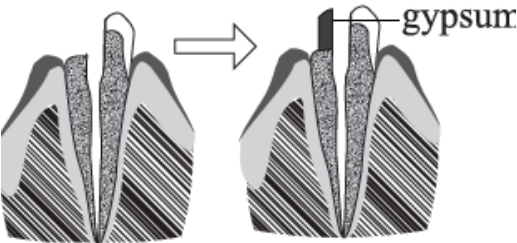

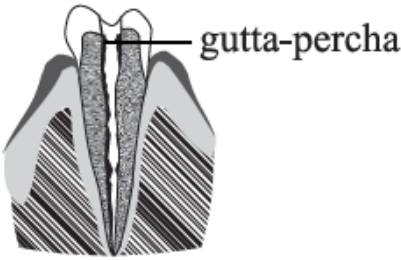
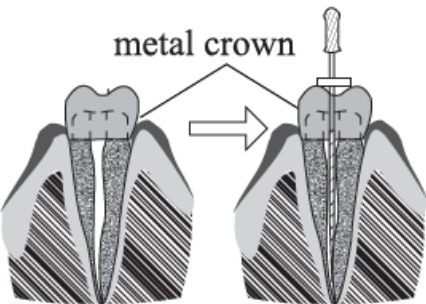



### 4.7.1 Warnings

- a) In reciprocation motion mode (REC), when the load value is higher than the torque limit:
  - i. if the Forward angle is greater than the Reverse angle, the motor automatically switches to counterclockwise rotation (reverse direction).
  - ii. if the Reverse angle is greater than the Forward angle, the motor automatically switches to clockwise rotation (forward direction).
- b) The auto-reverse protection is not available for CCW and ATR modes.
- c) The auto-reverse protection might not work properly in case of low battery level.
- d) Under continuous load, the motor may stop automatically due to overheat. In that case, the device must be powered OFF enough time to naturally cool down.

## 4.8 Apex locator limitations

Not all conditions are ideal for root canal length evaluation. Accurate signal cannot be obtained if the root canal shows the conditions listed below.

|   |  |
|---|--|
|    | <p>Root canal with a large apical foramen</p> <p>Root canal with exceptionally large apical foramen due to a lesion or incomplete development might disturb the electrical signal.</p>   |
|    | <p>Root canal with liquid overflowing from the opening</p> <p>Root canal with blood or any other liquid overflowing from the opening and in contact with the gingival tissue might disturb the electrical signal.</p>                    |
|   | <p>Broken crown</p> <p>If the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, the contact between the gingival tissue and the file might disturb the electrical signal.</p> |
|  | <p>Fractured tooth</p> <p>Fractured tooth might disturb the electrical signal.</p>   |
|  | <p>Re-treated root canal filled with gutta-percha</p> <p>Debris of gutta-percha might disturb the electrical signal.</p>   |
|  | <p>Crown or metal prosthesis touching gingival tissue</p> <p>The contact between the prosthesis and the file might disturb the electrical signal.</p>  |

|  |   |
|--|---|
|  <p>Too dry</p> | <p>Extremely dry root canal</p> <p>A dry canal might disturb the electrical signal.</p> |
|--|---|

## 5. Troubleshooting

| Failure   | Possible cause  | Solutions  |
|---|---|--|
| The motor handpiece does not rotate.                                  | Device in EAL mode<br>EAL mode is only for canal measurement.                       | Changing to CW, CCW, REC or ATR mode.                              |
| There is a continuous beep sounds after starting the motor handpiece. | The continuous beep sound is indicating that the motor handpiece is under CCW mode. | Stop the motor handpiece and change the operating mode to CW Mode. |
| Contra-angle calibration failure                                      | Calibration failure caused by strong resistance of contra-angle                     | Clean the contra-angle and recalibrate after oil injection.        |
| Motor handpiece heating   | Under Reciprocating Motion Mode, the using time is too long.                        | Stop use. Use after the temperature of motor handpiece drops.      |
| The time of endurance becomes shorter after charging.                 | Battery capacity becomes smaller.   | Contact local distributor.   |
| No sound  | Beeper Volume set to 0.<br>Vol.0: Mute.   | Set Beeper Volume to 1,2,3,4.                                      |
| The continuously rotating file is stuck at the root canal.            | Incorrect specification setting.<br>Too high load torque of file.                   | Choose CCW Mode, start the motor handpiece, and take the file out. |

## 6. Cleaning, Disinfection and Sterilization

### 6.1 Foreword

For hygiene and sanitary safety purposes, the contra-angle (including the O-ring), the lip hook, the file clip, the protective silicon cover, and the touch probe must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use, as well as all subsequent uses.

### 6.2 General recommendations

- a) After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfection agent.
- b) Use OXYTECH® disinfecting solution or any other disinfection agent compliant with local national regulations (such as VAH/DGHM-listing, CE marking, FDA, and Health Canada approval) and in accordance with the IFU of the disinfecting solution manufacturer.

- c) Do not immerse the contra-angle in a disinfectant solution or in an ultrasonic bath.
- d) Do not use chloride detergent materials.
- e) Do not use bleach or chloride disinfectant materials.
- f) For your own safety, please wear personal protective equipment (gloves, glasses, mask).
- g) The user is responsible for the sterility of the product and of the instruments.
- h) The water quality must be compliant to the local regulations especially for the last rinsing step or with a washer-disinfector.
- i) Do not sterilize the motor handpiece, the AC-Adapter, or the charging base.
- j) The contra-angle needs to be lubricated after cleaning and disinfection, but before sterilization (refer to Chapter 7.2).
- k) To sterilize the endodontic files, refer to the manufacturer's instructions for use.

### 6.3 Step-by-Step Procedure

| # | Operation                                  | Operating Mode   | Warning   |
|---|--|--|---|
| 1 | Preparation                                | Remove accessories (contra-angle, lip hook, file clip, touch probe, protective silicon cover) from handpiece and base.   |   |
| 2 | Automated Cleaning with washer-disinfector | Put the accessories (contra-angle, lip hook, file clip, touch probe, protective silicon cover) into the washer disinfector (Ao value >3000 or, at least 5 min at 90°C/194°F) | <ul style="list-style-type: none"> <li>- Avoid any contact between the contra-angle and any instruments, kits, supports or container.</li> <li>- Follow instructions and observe concentrations given by the manufacturer (see also general recommendations).</li> <li>- Use only approved washer-disinfector according to EN ISO 15883, maintain and calibrate it regularly.</li> <li>- Make sure accessories (contra-angle, lip hook, file clip and touch probe, protective silicon cover) are dry before moving to the next step.</li> </ul>   |
| 3 | Inspection                                 | Inspect the accessories (contra-angle, lip hook, file clip, touch probe, protective silicon cover) and sort out those with defects.  | <ul style="list-style-type: none"> <li>- Dirty accessories (contra-angle, lip hook, file clip, touch probe, protective silicon cover) must be cleaned and disinfected again.</li> <li>- Lubricate the contra-angle with an adequate spray before packaging.</li> </ul>  |
| 4 | Packaging                                  | Pack the accessories (contra-angle, lip hook, file clip, touch probe, protective silicon cover) in "Sterilization pouches".  | <ul style="list-style-type: none"> <li>- Check the validity period of the pouch given by the manufacturer to determine the shelf life.</li> <li>- Use packaging which is resistant to a temperature up to 141°C (286°F) and in accordance with EN ISO 11607.</li> </ul>   |
| 5 | Sterilization                              | Steam sterilization at 134°C, 2.0bar- 2.3bar(0.20Mpa- 0.23MPa), for 4 minutes.   | <ul style="list-style-type: none"> <li>- Use only autoclaves that are matching the requirements of EN 13060, EN 285.</li> <li>- Use a validated sterilization procedure according to ISO 17665.</li> <li>- Respect the maintenance procedure of the autoclave device given by the manufacturer.</li> <li>- Use only this recommended sterilization procedure.</li> <li>- Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physico-chemical integrators, digital records of cycles parameters).</li> <li>- Control the absence of corrosion on the contra-angle</li> <li>- Maintain traceability of procedure records.</li> </ul> |

|   |         |  |  |
|---|---------|--|--|
| 6 | Storage | Keep the accessories (contra-angle, lip hook, file clip, touch probe, protective silicon cover) in sterilization packaging in a dry and clean environment. | <ul style="list-style-type: none"> <li>- Sterility cannot be guaranteed if packaging is open, damaged, or wet.</li> <li>- Check the packaging and the contra-angle before use (packaging integrity, no humidity and validity period).</li> </ul> |
|---|---------|--|--|

## 7. Maintenance

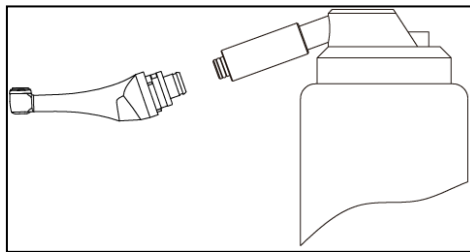
### 7.1 Calibration

Perform calibration after replacement or lubrication of the contra-angle (refer to Chapter 4.6).

### 7.2 Lubrification of the contra-angle

The contra-angle needs to be lubricated after cleaning and disinfection, but before sterilization.

1. Screw the oil injection nozzle to the oil bottle (around 1 to 3 turns).
2. Plug the nozzle into the end part of contra-angle



3. Fill the contra-angle with oil until the oil flows out of contra-angle head part.
4. Position contra-angle vertically for at least 30 minutes to let go the redundant oil under gravity via the end part.



#### 7.2.1 Warnings

- a) Use original oil injection nozzle only.
- b) Motor handpiece shall not be filled with oil.

### 7.3 Charging of the battery

1. Insert the power adapter plug into the charging base power socket and make sure they are correctly connected.
2. Leave approximately 10cm around the charging base for easy access to inlet and the power cord.
3. Insert the motor handpiece into the charging base (the motor handpiece must be correctly aligned with the charging base).
  - i. While the motor handpiece is charging the LED indicator on the charging base flashes.
  - ii. When the motor handpiece is fully charged, the LED indicator on the charging base is always on.
4. After charging, unplug the power adapter.

### 7.4 Replacement of the battery

1. Power off the device.
2. Use a tweezer or a screwdriver to open the rubber cover and then remove the screw.
3. Remove the battery cover.
4. Remove the old battery and disconnect the connector.
5. Connect the new original battery and put it in the motor handpiece.
6. Replace the cover and the screw.





### 7.4.1 Warnings

- a) Use original battery only.
- b) It is recommended to contact local distributors to replace the battery.

## 8. Storage

- a) The device and accessories should be stored in a room where the relative humidity is 10% ~ 93%, atmospheric pressure is 70kPa ~ 106kPa, and the temperature is -20°C ~ +55°C.
- b) Remove the battery of the device in case of long period storage.

## 9. Transportation

- a) Avoid excessive shocks during transportation.
- b) Don't store together with dangerous goods during transportation.
- c) Avoid sun, rain and snow exposure during transportation.

















## 10. Environmental protection

Please dispose the product according to the local laws.

## 11. After sales service

- a) This package does not include spare parts or accessories for repair servicing.
- b) The after sales service should be carried out by admitted personnel only.

## 12. Symbol instruction

|   |                                  |   |                                     |
|---|----------------------------------|---|-------------------------------------|
|  | Follow Instructions for Use      |  | Serial number                       |
|  | Date of manufacture              |  | Manufacturer                        |
|  | Type B applied part              |  | Class II equipment                  |
| IPX0  | Ordinary equipment               |  | Recovery                            |
|  | Used indoor only                 |  | Keep dry                            |
|  | Handle with care                 |  | Appliance compliance WEEE directive |
|  | Humidity limitation              |  | Temperature limitation              |
|  | Atmospheric pressure for storage |  | CE marked product                   |
|  | Warning                          |   |                                     |

 Authorised Representative in the EUROPEAN COMMUNITY

### **13. Statement**

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc. have claimed for several patents by WOODPECKER, any copy or fake product must undertake legal responsibilities.

## 14. EMC-Declaration of conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

### 14.1 Technical Description Concerning Electromagnetic Emission

Table 1: Guidance & declaration - electromagnetic emissions

| The model Rooter® X3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the model Rooter® X3000 should assure that it is used in such an environment. |            |   |
|---|------------|---|
| Emissions test  | Compliance | Electromagnetic environment - guidance  |
| RF emissions<br>CISPR 11  | Group 1    | The model Rooter® X3000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.  |
| RF emissions<br>CISPR11   | Class B    | The model Rooter® X3000 is suitable for used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2   | Class A    |   |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3   | Complies   |   |

### 14.2 Technical Description Concerning Electromagnetic Immunity

Table 2: Guidance & Declaration - electromagnetic immunity

| The model Rooter® X3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the model Rooter® X3000 should assure that It is used in such an environment. |  |   |   |
|---|--|---|---|
| Immunity test   | IEC 60601 test level                                       | Compliance level  | Electromagnetic environment - guidance  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | ±8kV contact<br>±2, ±4, ±8, ±15kV air                      | ±8kV contact<br>±2, ±4, ±8, ±15kV air                   | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.                              |
| Electrical fast transient/burst<br>IEC 61000-4-4  | ±2kV for power supply lines<br>±1kV for Input/output lines | ±2kV for power supply lines                             | Mains power quality should be that of a typical commercial or hospital environment.   |
| Surge<br>IEC 61000-4-5  | ±0.5, ±1kV line to line<br>±0.5, ±1, ±2kV line to earth    | ±0.5, ±1kV line to line<br>±0.5, ±1, ±2kV line to earth | Mains power quality should be that of a typical commercial or hospital environment.   |
| Voltage dips, short interruptions and voltage variations on power supply input lines  | <5 % UT<br>(>95% dip in UT.)<br>for 0.5 cycle              | <5 % UT<br>(>95% dip in UT.)<br>for 0.5 cycle           | Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Rooter® X3000 requires continued operation during power mains |

|  |  |  |   |
|--|--|--|---|
| IEC 61000-4-11   | <5 % UT<br>(>95% dip in UT.)<br>for 1 cycle<br>70% UT<br>(30% dip in UT)<br>for 25 cycles<br><5% UT<br>(>95 % dip in UT)<br>for 250 cycles | <5 % UT<br>(>95% dip in UT.)<br>for 1 cycle<br>70% UT<br>(30% dip in UT)<br>for 25 cycles<br><5% UT<br>(>95 % dip in UT)<br>for 250 cycles | interruptions, it is recommended that the models Rooter® X3000 be powered from an uninterruptible power supply or a battery.              |
| Power frequency (50/60 Hz)<br>magnetic field<br>IEC 61000-4-8              | 30A/m  | 30A/m  | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: UT is the a.c. mains voltage prior to application of the test level. |  |  |   |

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

| The model Rooter® X3000 is intended for use in the electromagnetic environment specified below. The customer or the user of the models Rooter® X3000 should assure that it is used in such an environment. |   |                  |  |
|--|---|------------------|--|
| Immunity test  | IEC 60601 test level  | Compliance level | Electromagnetic environment - guidance   |
| Conducted RF IEC 61000-4-6<br>Conducted RF IEC 61000-4-6<br>Radiated RF IEC 61000-4-3  | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms<br>ISM frequency band<br>3 V/m<br>80 MHz to 2.7 GHz | 3V<br>6V<br>3V/m | Portable and mobile RF communications equipment should be used no closer to any part of the models Rooter® X3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d=1.2 \times P^{1/2}$<br>$d=2 \times P^{1/2}$<br>$d=1.2 \times P^{1/2}$ 80 MHz to 800 MHz<br>$d=2.3 \times P^{1/2}$ 800 MHz to 2.7 GHz<br><br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a.) should be less than the compliance level in each frequency range (b.)<br><br>Interference may occur in the vicinity of equipment marked with the following symbol: |
| NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.   |   |                  |  |

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model Router® X3000 is used exceeds the applicable RF compliance level above, the model Router® X3000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Router® X3000.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the model Router® X3000

| <p>The model Router® X3000 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Router® X3000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Router® X3000 as recommended below, according to the maximum output power of the communications equipment.</p>   |   |   |  |
|--|---|---|--|
| Rated maximum output power of transmitter [W]  | Separation distance according to frequency of transmitter [m] |   |  |
|  | 150kHz to 80MHz<br>$d=1.2 \times P^{1/2}$                     | 80MHz to 800MHz<br>$d=1.2 \times P^{1/2}$ | 800MHz to 2,7GHz<br>$d=2.3 \times P^{1/2}$ |
| 0,01   | 0.12  | 0.12                                      | 0.23                                       |
| 0,1  | 0.38  | 0.38                                      | 0.73                                       |
| 1  | 1.2   | 1.2                                       | 2.3  |
| 10   | 3.8   | 3.8                                       | 7.3  |
| 100  | 12  | 12  | 23   |
| <p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.</p> <p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> |   |   |  |





**Guilin Woodpecker Medical Instrument Co., Ltd.**

Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi,  
541004 P. R. China

Sales Dept.: +86-773-5873196

[Http://www.glwoodpecker.com](http://www.glwoodpecker.com)

E-mail: [woodpecker@glwoodpecker.com](mailto:woodpecker@glwoodpecker.com)



**MedNet EC-Rep GmbH**

Borkstrasse 10 – 48163 Muenster - Germany

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