



Rooter[®] X3000 User Manual



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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 noozle	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
12	Lithium-ion battery	08.971.00.013.FK
13	Measuring Wire - USB - C	08.971.00.014.FK
-	User manual	-
-	Package content list	-







1.Motor handpiece

4.Spray noozle

6.File clip

9.Protective silicon cover



2.Motor handpiece

11







3.Contra-angle

0

5.Measuring wire

7.Lip hook

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 400mA
 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



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).
- 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).
- 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.

- 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.
- 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^{*} 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.





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.
- 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





4. Device operating instructions

4.1 Setting interface and button description



4.2 Power ON and power OFF the device

 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:



 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.

 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 10 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

- a) Make sure the Operation Mode is adequate before to start the motor.
- b) All the parameters must be set according to the file manufacturer recommendations.
- c) Make sure all the parameters are verified before to start the motor handpiece.
- d) M0-M9 User Programs parameters modified by the user are memorized.
- e) 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:

- 1. To select the desired parameter, press the Setting button "P".
- 2. To modify the parameter setting, press the Adjusting button "+"/"-".
- 3. Press the Main button or wait 5 seconds to confirm.
- 4.4.3 User Program parameters list

Operation Mode	Operation modes list: CW, CCW, REC, ATR, EAL
CW	(refer to Chapter 3 for modes description)

	Set Working Speed
	In continuous rotation modes (CW and CCW), the working speed can be adjusted from 100rpm to 3'300rpm (50rpm increments).
Speed	In REC mode, the working speed can be adjusted for 100rpm to 500rpm (50rpm increments).
250rpm	In ATR mode, the working speed can be adjusted for 100rpm to 500rpm (50rpm increments).
	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).
	Set Torque Limit
	In CW continuous rotation mode, the torque limit can be adjusted from 0.4Ncm to 4.0Ncm depending on the set speed:
	100-200rpm Max torque limit : 4.0Ncm
	250-400rpm Max torque limit : 3.5Ncm
	 700-950rpm Max torque limit : 2.5Ncm
Torque Limit	1'000-1'450rpm Max torque limit : 2.0Ncm
1 0Ncm	 1'500-1'950rpm Max torque limit : 1.5Ncm 2'000-2'200rpm Max torque limit : 1.0Ncm
1.0110111	• 2 000-5 Soorphi Max torque innit . 1.0kcm
	In REC mode, the torque limit can be adjusted from 2.0Ncm to 4.0Ncm depending on the set speed:
	100-250rpm Max torque limit : 4.0Ncm
	 300-400rpm Max torque limit : 3.5Ncm 450-500rpm Max torque limit : 3.0Ncm
	In ATP mode the Trigger Torque can be adjusted from 0.4Ncm to 3.0Ncm
	In COW continuous rotation mode, the torque limit cannot be set
	The Apical action applies when the file reaches the set apical reference point (refer to Flash Bar Position)
Apical Action	OFF: Disable Apical Action
OFF	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.
	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.
	Set Auto Start
Auto Start	OFF: Disable Auto Start (the Main button is needed to start the motor handpiece).
OFF	ON: The motor starts automatically when the file is inserted into the canal (from when the file progression indicator shows 2 bars).
	Set Auto Stop
Auto Stop	OFF: Disable Auto Stop (the Main button is needed to stop the motor handpiece).
OFF	ON: The motor stops automatically when the file is taken out the canal.

	Set Flash Bar Position (Apical reference point)
Flash Bar Position	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)
AF I 2 3	Apical Action and Apical Slow Down are triggered by the apical reference point.
	Set Apical Slow Down
Apical Slow Down	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 .
	OFF: Disable Apical Slow Down
Apical Slow Down	In CW continuous rotation mode, the final speed can be adjusted from 100rpm to the current set speed (50rpm increments).
200rpm	The Apical Slow Down function is available for CW & CCW continuous rotation mode only.
	The final speed must be lower than the nominal speed.
	Forward Angle
Forward Angle	In REC mode, the Forward Angle can be adjusted from 20° to 400° (10° increments)
30°	In ATR mode, the Forward Angle can be adjusted from 60° to 400° (10° increments).
	Reverse Angle
Reverse Angle	In REC mode, the Reverse Angle can be adjusted from 20° to 400° (10° increments)
150°	In ATR mode, the Reverse Angle can be adjusted from 20° to the Forward Angle (10 $^\circ$ increments).

4.4.4 User Programs parameters availability table

Parameter User Program Operation Mode	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
CW	YES	YES	YES	YES	YES	YES	YES	n/a	n/a
ссw	YES	NO	NO	NO	NO	YES	YES	n/a	n/a
REC	YES	YES	YES	YES	YES	YES	NO	YES	YES
ATR	YES	YES	YES	YES	YES	YES	NO	YES	YES
EAL	n/a	n/a	n/a	n/a	n/a	YES	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".
- 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
RACE EVO XP-endo Treatment XP-endo Retreatment R-Motion	RACE EVO All files	All files 1000rpm	1000rpm 5- 3- 2- Ncm

XP-endo[®] Treatment

File systems selection	File selection	Stand-by interface	Operation interface
	XP-endo Treatment Glider Shaper Finisher	XP-endo T. Glider 1000rpm	1000rpm 5- 3- 2- Ncm
RACE EVO XP-endo Treatment XP-endo Retreatment R-Motion	XP-endo Treatment Glider Shaper Finisher	XP-endo T. Shaper 1000rpm	1000rpm 5- 3- 2- Ncm
	XP-endo Treatment Glider Shaper Finisher	XP-endo T. Finisher 1000rpm	1000rpm 5- 3- 2- Ncm

XP-endo[®] Retreatment

File systems selection	File selection	Stand-by interface	Operation interface
	XP-endo Retreatment DR1 Shaper(for GP removal) Shaper(for shaping)	^{XP-endo R.} 1000rpm DR1 CW 1.5Ncm	1000rpm 5- 3- 2- Ncm
RACE EVO XP-endo Treatment	XP-endo Retreatment DR1 Shaper(for GP removal) Shaper(for shaping)	XP-endo R. Shaper (for GP removal) 2500rpm CW 1.0Ncm	2500rpm 5- 4- 3- 2- Ncm
XP-endo Retreatment R-Motion	XP-endo Retreatment DR1 Shaper(for GP removal) Shaper(for shaping)	XP-endo R. Shaper (for shaping) 1000rpm CW 1.0Ncm	1000rpm 5- 3- 2- Ncm
	XP-endo Retreatment Finisher R	XP-endo R. Finisher R 1000rpm	1000rpm 5- 3- 2- Ncm

R-Motion[®]

File systems selection	File selection	Stand-by interface	Operation interface
RACE EVO XP-endo Treatment XP-endo Retreatment R-Motion	R-Motion All files	R-Motion All files F: auto	rpm 4- 3- 2-

Finisher

File systems selection	File selection	Stand-by interface	Operation interface
Finisher	Finisher All files	Finisher All files 1000rpm	1000rpm ⁵ ⁴ ³ ² ² Ncm

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 All Files	\boxtimes	imes	YES	YES	YES	YES	YES	n/a	n/a
XP-endo Treatment Glider	\boxtimes	imes	YES	YES	YES	YES	YES	n/a	n/a
XP-endo Treatment Shaper	\boxtimes	\succ	YES	YES	YES	YES	YES	n/a	n/a
XP-endo Treatment Finisher	\bowtie	\succ	YES	YES	YES	YES	YES	n/a	n/a
XP-endo Retreatment DR1	\bowtie	\succ	YES	YES	YES	YES	YES	n/a	n/a
XP-endo Retreatment Shaper (for GP removal)	\bowtie	imes	YES	YES	YES	YES	YES	n/a	n/a
XP-endo Retreatment Shaper (for shaping)	\bowtie	\succ	YES	YES	YES	YES	YES	n/a	n/a
XP-endo Retreatment Finisher R	\bowtie	\succ	YES	YES	YES	YES	YES	n/a	n/a
R-Motion All files	\bowtie	\boxtimes	YES	YES	YES	YES	NO	\bowtie	\boxtimes
Finisher All files	\bowtie	\boxtimes	YES	YES	YES	YES	YES	n/a	n/a

4.5.2 FKG File Systems parameters availability table

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

	Calibration		
Collibration	Make sure the original contra-angle is installed before to launch the motor calibration.		
OFF	OFF: No action.		
	ON: Start motor calibration		
	The motor must be calibrated before the first use and after lubrification.		
	Beeper volume		
Beeper Volume	The device sound volume can be adjusted from Vol. 0 to Vol. 4.		
Vol.3	Vol.0: Mute.		
	Restore Defaults		
Restore Defaults	OFF: No action.		
OFF	ON: Device parameters returns to original setting.		

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.



Load value is higher than

preset torque value

Load value is lower than preset torque value



Warnings

- a) In reciprocation motion mode (REC), when the load value is higher than the torque limit:
 - if the Forward angle is greater than the Reverse angle, the motor automatically switches to counterclockwise rotation (reverse direction).

Load value is lower than

preset torque value again

- 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.

	Root canal with a large apical foramen
	Root canal with exceptionally large apical foramen due to a lesion or incomplete development might disturb the electrical signal.
	Root canal with liquid overflowing from the opening Root canal with blood or any other liquid overflowing from the opening and in contact with the gingival tissue might disturb the electrical signal.
	Broken crown
gypsum	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.
	Fractured tooth
	Fractured tooth might disturb the electrical signal.
	Re-treated root canal filled with gutta-percha
gutta-percha	Debris of gutta-percha might disturb the electrical signal.
	Crown or metal prosthesis touching gingival tissue
metal crown	The contact between the prosthesis and the file might disturb the electrical signal.



5. Troubleshooting

Failure	Possible cause	Solutions
The motor handpiece does not rotate.	Device in EAL mode 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. Vol.0: Mute.	Set Beeper Volume to 1,2,3,4.
The continuously rotating file is stuck at the root canal.	Incorrect specification setting. 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 immerge 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-	
		probe protective silicon cover)	
		from handniece and base	
2	Automated Cleaning	Put the accessories (contra- angle, lip hook, file clip, touch	- Avoid any contact between the contra-angle and any instruments, kits, supports or container.
	with washer-	probe, protective silicon cover)	- Follow instructions and observe
	disinfector	into the washer disinfector (Ao	concentrations given by the manufacturer (see
		value >3000 or, at least 5 min at	also general recommendations).
		90°C/194°F)	- Use only approved washer-disinfector
			according to EN ISO 15883, maintain and
			calibrate it regularly.
			 Make sure accessories (contra-angle, lip hook,
			file clip and touch probe, protective silicon
			cover) are dry before moving to the next step.
3	Inspection	Inspect the accessories (contra-	- Dirty accessories (contra-angle, lip hook, file
		angle, lip hook, file clip, touch	clip, touch probe, protective silicon cover) must
		probe, protective silicon cover)	be cleaned and disinfected again.
		and sort out those with defects.	- Lubricate the contra-angle with an adequate
4	Packaging	Back the accessories (contra-	- Check the validity period of the pouch given by
-	Tackaging	angle lin book file clin touch	the manufacturer to determine the shelf life
		probe, protective silicon cover)	- Use packaging which is resistant to a
		in "Sterilization pouches".	temperature up to 141°C (286°F) and in
		•	accordance with EN ISO 11607.
5	Sterilization	Steam sterilization at 134°C,	- Use only autoclaves that are matching the
		2.0bar- 2.3bar(0.20Mpa-	requirements of EN 13060, EN 285.
		0.23MPa), for 4 minutes.	 Use a validated sterilization procedure
			according to ISO 17665.
			- Respect the maintenance procedure of the
			autoclave device given by the manufacturer.
			- Use only this recommended sterilization
			- Control the officiency (nackaging integrity, no
			- control the enciency (packaging integrity, no
			indicators physico-chemical integrators digital
			records of cycles parameters).
			- Control the absence of corrosion on the
			contra-angle
			- Maintain traceability of procedure records.

6	Storage	Keep the accessories (contra-	- Sterility cannot be guaranteed if packaging is
		angle, lip hook, file clip, touch	open, damaged, or wet.
		probe, protective silicon cover)	 Check the packaging and the contra-angle
		in sterilization packaging in a	before use (packaging integrity, no humidity and
		dry and clean environment.	validity period).

7. Maintenance

7.1 Calibration

Perform calibration after replacement or lubrification 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.



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% \sim 93%, atmospheric pressure is 70kPa \sim 106kPa, and the temperature is -20°C \sim +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





CHREP Authorised Representative in CH

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	Group 1	The model Rooter [®] X3000 uses RF energy only for its internal
CISPR 11		function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class B	The model Rooter [®] X3000 is suitable for used in all
CISPR11		establishments, including domestic establishments and those directly connected to the public low-voltage power supply
Harmonic emissions	Class A	network that supplies buildings used for domestic purposes.
IEC 61000-3-2		
Voltage fluctuations	Complies	
IEC 61000-3-3		

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) IEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±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 IEC 61000-4-4	±2kVfor powersupply lines±1kVfor output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 , ± 1 kV line to line ± 0.5 , ± 1 , ± 2 kV line to earth	± 0.5 , ± 1 kV line to line ± 0.5 , ± 1 , ± 2 kV 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 (>95% dip in UT.) for 0.5 cycle	<5 % UT (>95% dip in UT.) 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 (>95% dip in UT.)	<5 % UT (>95% dip in UT.)	interruptions, it is recommended that the models Rooter [®] X3000 be powered from an uninterruptible power supply or a battery.	
	70% UT	70% UT		
	(30% dip in UT)	(30% dip in UT)		
	for 25 cycles	for 25 cycles		
	<5% UT	<5% UT		
	(>95 % dip in UT)	(>95 % dip in UT)		
	for 250 cycles	for 250 cycles		
Power frequency (50/60 Hz) magnetic field 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 \mbox{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 Compliance Electromagnetic environment - guidance level level 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. Recommended separation distance 3 Vrms d=1.2×P1/2 150 kHz to 80 Conducted RE IEC MHz d=2×P1/2 61000-4-6 3V 6 Vrms d=1.2×P1/2 80 MHz to 800 MHz Conducted RF IEC 6V d=2.3×P1/2 800 MHz to 2.7 GHz 61000-4-6 ISM frequency band 3V/m where P is the maximum output power rating of the Radiated RF IEC transmitter in watts (W) according to the transmitter 3 V/m 61000-4-3 manufacturer and d Is the recommended separation 80 MHz to 2.7 distance in meters (m). GHz 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.) 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 Rooter^{*} X3000 is used exceeds the applicable RF compliance level above, the model Rooter^{*} 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 Rooter^{*} 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 Rooter[®] X3000

The model Rooter^{*} X3000 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Rooter^{*} X3000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Rooter^{*} X3000 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter [m]				
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2,7GHz		
[vv]	d=1.2×P1/2	d=1.2×P1/2	d=2.3×P1/2		
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		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.



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ZMN-SM-027

Version 1.6 / 03.01.2024