Multilingual
Instruction for use
ROOTER® X4000

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Endo Motor and Apex Locator Unit
Instruction For Use

Please read this IFU carefully before using the device for the first time

Rooter® X4000

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1 Introduction

The Rooter® X4000 endodontic motor is mainly used in endodontic treatment to perform mechanical instrumentation with engine-driven latch files and electronic working length determination with the built-in foramen locator. It is a battery-operated portable endodontic motor electronically connected with the base unit, which is compatible with the most well-known rotary and reciprocating endodontic file systems. It can be used as an endodontic motor alone, as an apex locator to determine electronically the foramen position, and as an apex locator together with the endodontic motor. The Rooter® X4000 endodontic motor is a medical device that provides precise, controlled movements, with an apex locator embedded, which offers the advantage of accurate file position readings both alone and during the instrumentation procedure.

WARNINGS:

a. Before operating this unit, please read all the instructions thoroughly. The manufacturer is not liable for any damage resulting from improper use of this unit or for any purposes not covered by these instructions.

b. Use only for the intended use. Failure to comply with the operating instructions may result in serious injury to the patient or operator. Before operating this device, verify that you have read and understood the operating instructions.

c. As per Endodontic Standards of Care, always use a rubber dam when performing endodontic treatment.

d. Do not insert any object into the base or handpiece.

e. Do not install near an explosive risk. Systems are not designed to operate in the presence of anesthetic gases or any other flammable gas.

f. Connect the power cord to an appropriate outlet. Use only the supplied power adapter.

g. Do not use dry heat sterilization on any of the device's components.

h. Do not make repairs or alterations to the device without prior consent from the manufacturer or distributor.

It is not recommended to wipe the surfaces of the machine housing with "quaternary ammonium salt" disinfectants.

1.1 Product overview

The Rooter X4000 is primarily designed for endodontic treatment.

Rooter X4000 come with a built-in apex locator. These devices can operate in three modes: motor only, apex locator only, or a combination of both. This versatility allows for the preparation and enlargement of root canals with real-time displays of apex locator readings.

The main unit (base) of Rooter X4000 also supports apex locator alone functionality.

1.1.1 Intended use

The Endo Motor and Apex Locator Unit is a cordless endo motor with root canal measurement capability. It can be used as an endodontic motor for the preparation and enlargement of root canals or as a device for helping to measure canal length. The device enables canal enlargement while monitoring the position of the file tip inside the canal.

1.1.2 Intended users

Professional dentists. Operation of this medical device is limited only to certified, capable, and qualified dental professionals in their regular place of business. The operator must master and comply with the rules of dental practice, adhering to the principles of medical hygiene and the science behind the cleaning, disinfection, and sterilization of medical devices.

This medical device may be used regardless of the characteristics of the (adult) operator, such as weight, age, height, sex, and nationality. The operator should wear gloves.

Operators should not have:

- Vision problems, unless wearing a form of vision correction.
- A disability of the upper limbs (gripping a rotary tool).
- Hearing problems (use of audible indicators, depending on the device).
- Memory or concentration problems (settings, sequences, or care protocols, etc.).

Special operator training:

No special training other than basic professional training is required to operate this medical device.

WARNINGS:

a. This medical device may be used regardless of the characteristics of the patient, such as weight (except for children), age, height, sex, and nationality. Operation of this medical device (Rooter X4000) is not recomended in the following patient population:

- Implanted heart pacemaker patients (or those with other electrical equipment)
- Patients advised to avoid small electrical appliances (e.g., electric shavers, hair dryers, etc.)
- Infants
- Patients with medical complications
- Allergic patients
- Patients with a clinical site unsuitable for treatment

b. Treatment should be limited to the patient's buccal cavity only.

WARNINGS:

a. The device conforms to applicable electromagnetic compatibility standards. Operators must ensure that no electromagnetic interference causes an increased risk (the presence of radiofrequency emissions, electronic devices, etc.).

b. Interference may occur when used on patients wearing a pacemaker. This system emits electromagnetic fields, which present potential risks. Implantable devices, such as pacemakers and ICDs (implantable cardioverter defibrillators), may malfunction.

c. Before using this product, ask patients and operators whether they are wearing an implanted device. Explain the reason for your question.

d. Determine the risk/benefit ratio and contact your patient's cardiologist or applicable specialist before carrying out the treatment.

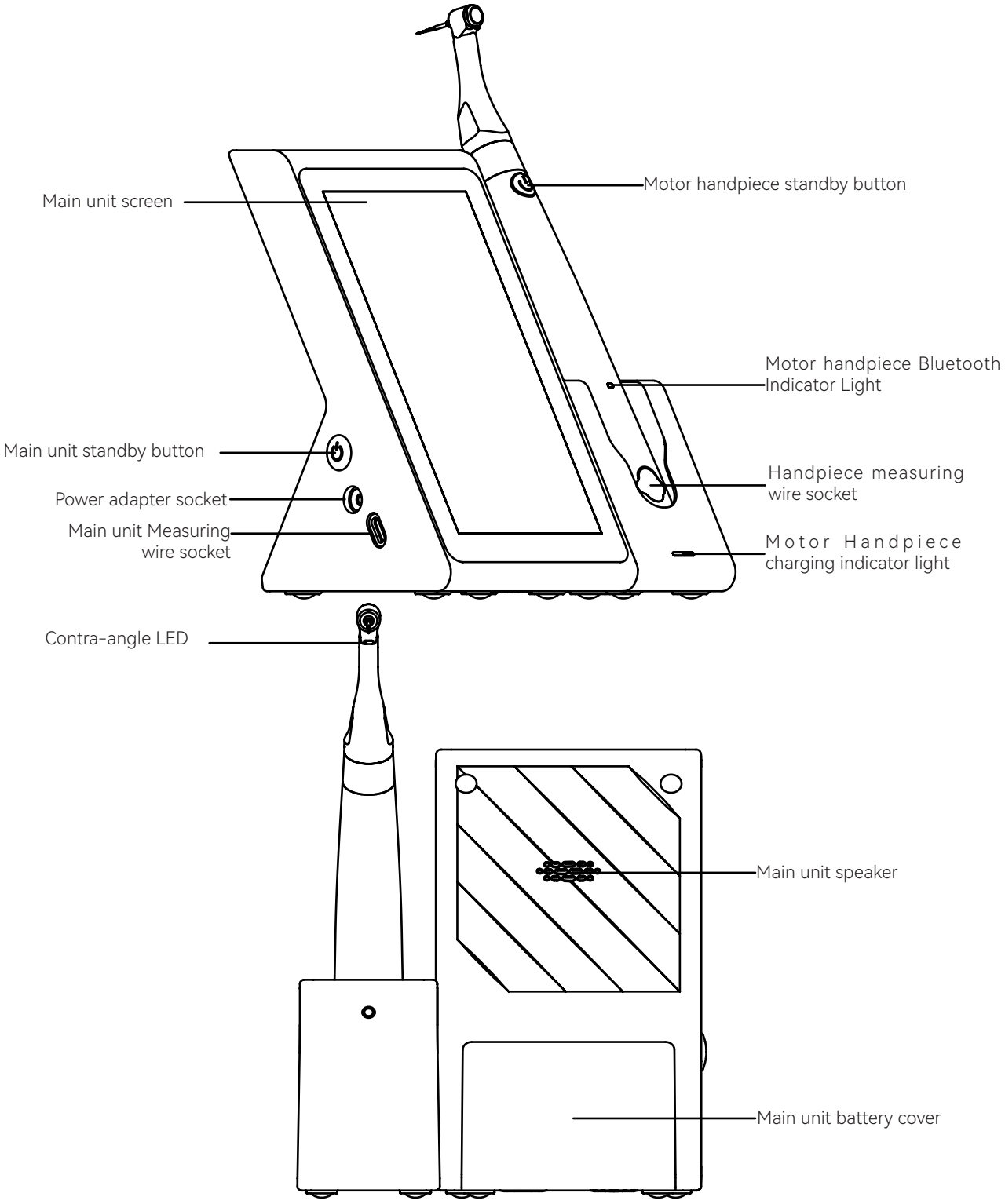
e. Keep this product away from implanted devices.

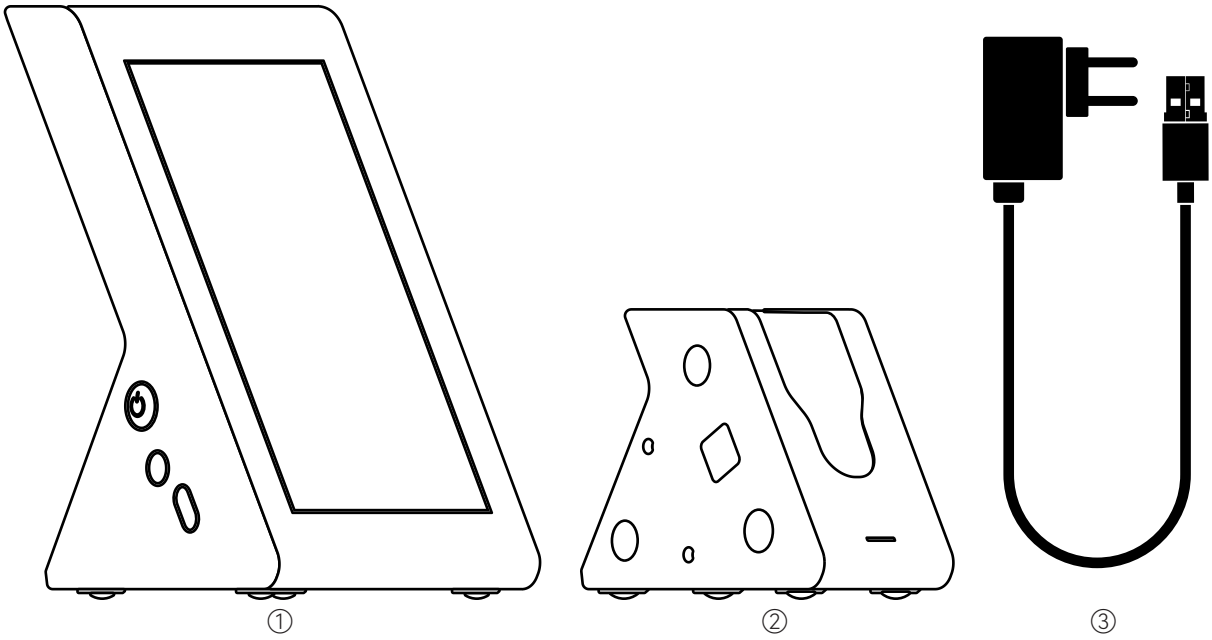
1.2 Product configuration

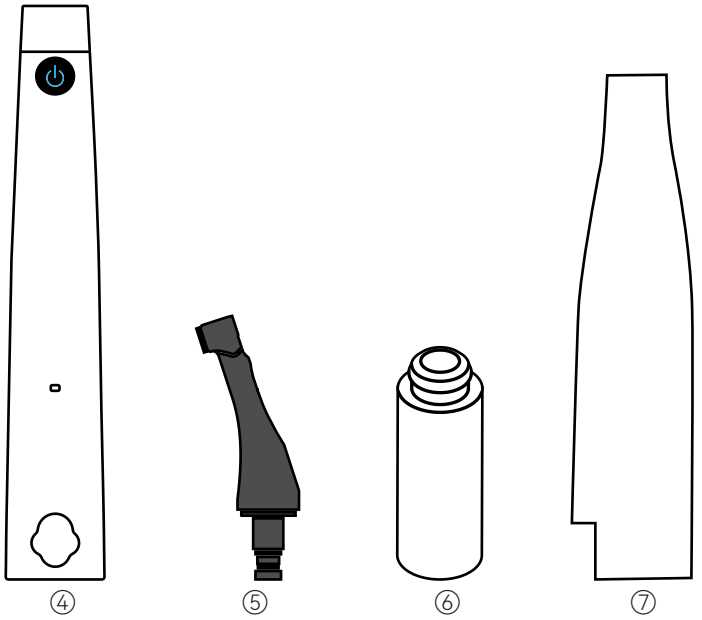
The product includes the following components:

FKG REF	Designation
08.972.00.010.FK	Main unit
08.972.00.001.FK	Motor handpiece
08.972.00.002.FK	Charging base
08.972.00.003.FK	Contra-angle
08.972.00.004.FK	Spray Nozzle
08.972.00.005.FK	Measuring wire
08.972.00.006.FK	File clip

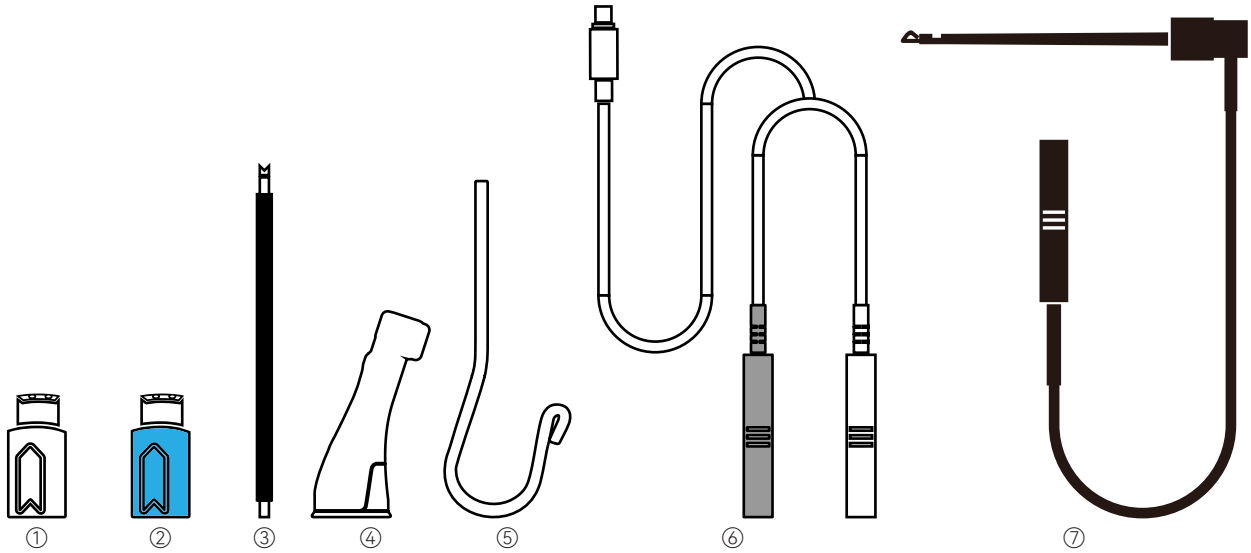
08.972.00.007.FK	Lip hook
08.972.00.008.FK	Touch probe
08.972.00.009.FK	Protective silicone cover
08.972.00.011.FK	Disposable isolation sleeve
08.972.00.013.FK	Lithium Battery main unit
08.972.00.014.FK	Tester
08.972.00.015.FK	Power adapter
08.972.00.016.FK	Handpiece OTA Upgrade Adapter







① Main unit
② Charging base
③ Power adapter
④ Motor handpiece
⑤ Contra-angle
⑥ Spray Nozzle
⑦ Disposable isolation sleeve



① Tester
② Handpiece OTA Upgrade Adapter
③ Touch probe
④ Protective silicone cover
⑤ Lip hook
⑥ Measuring wire
⑦ File clip

1.3 Contraindications

a. Dentists with cardiac pacemakers are prohibited from using this device.
b. Patients with cardiac pacemakers (or other implanted electronic devices) are prohibited from using this device. Caution is advised for such patients when operating small appliances (e.g., electric razors, hair dryers).
c. Hemophilia patients are prohibited from using this device.
d. Use with caution in patients with heart disease, pregnant women, and young children.

1.4 Device safety classification

1.4.1 Type of operation mode: Intermittent operation

a. When the speed is ≤ 1500 r/min, work for 10 minutes and stop for 5 minutes;
b. When the speed is > 1500 r/min, work for 6 minutes and stop for 20 minutes.

1.4.2 Type of protection against electric shock: Class II equipment with internal power supply

1.4.3 Degree of protection against electric shock: The contra-angle, file clip, touch probe, and lip hook are B type applied parts.

1.4.4 Ingress protection (IP) rating:

Ordinary equipment: IPX0 (No water protection)

1.4.5 Safety in flammable atmospheres: Not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen, or nitrous oxide.

1.4.6 Applied parts: Contra-angle, lip hook, file clip, touch probe, protective silicone cover.

1.4.7 List of detachable parts: Lip hook, file clip, touch probe, contra-angle, battery.

1.5 Primary technical specifications

1.5.1 Battery:
- Main unit lithium battery: 11.1 V / 2600 mAh
- Motor handpiece lithium battery: 3.7 V / 1200 mAh

1.5.2 Power adapter
- Power adapter for main unit (UES24LCP-150160SPA):
- Input: 100V-240V ~ 50Hz/60Hz, 800mA
- Output: 15V ⎓ 1.6A

1.5.3 Main unit input power: 100V-240V ~ 50Hz/60Hz, 0.8A—0.3A
1.5.4 Torque range: 0.4 N·cm ~ 4.0 N·cm (4 mN·m ~ 40 mN·m)
1.5.5 Speed range: 50 r/min ~ 4000 r/min
1.5.6 The contra-angle uses precision gear transmission inside, and the gear ratio is
4.7: 1 (Model: CA1471L).
1.5.7 Software release version: V1
1.5.8 Wireless charging:
- Frequency range: 110-205 kHz
- Maximum RF output power: 25.27dBuA/m @3m

1.5.9 Bluetooth and WiFi frequency ranges:
- Motor handpiece Bluetooth frequency range: 2402-2480 MHz, Maximum RF output power: -6.41 dBm
- Main unit Bluetooth frequency range: 2402-2480 MHz, Maximum RF output power: 4.12 dBm
- Main unit WiFi frequency range: 2412-2472 MHz, Maximum RF output power: 14.93 dBm
- Wireless foot switch Bluetooth frequency range: 2402-2480 MHz, Maximum RF output power: 0.26 dBm

1.6 Working environment

1.6.1 Environment temperature: +5℃ ~ +35℃
1.6.2 Relative humidity: 30% ~ 75%

1.6.3 Atmosphere pressure: 70 kPa ~ 106 kPa

WARNINGS:

• Read this instruction manual thoroughly before operating for the first time.

• This device shall be operated exclusively by professionally qualified dentists within qualified dental clinics or dental hospital settings.

• Do not directly or indirectly place this device near heat sources. Operate and store this device in a reliable environment.

• This device requires special precautions regarding electromagnetic compatibility (EMC) and must be installed and used in strict accordance with the EMC information provided (see Chapter 14). Avoid operating this device near fluorescent lamps, radio transmitters, remote control systems, or handheld and mobile high-frequency communication equipment.

• Prolonged use of the reciprocating motion mode may cause the motor handpiece to overheat. Allow it to cool down before reusing. If overheating occurs frequently, please contact your local distributor.

• Use only the original contra-angle. Use of unauthorized accessories may result in malfunction or potential harm.

• Do not modify the device. Unauthorized alterations may compromise safety standards and put patients at risk. The manufacturer assumes no liability for any modifications made to devices.

• Use only the original power adapter. Third-party adapters may damage the lithium battery and control circuitry.

• The motor handpiece cannot be autoclaved. Use a neutral pH disinfectant or ethyl alcohol to clean its surface.

• Do not press the contra-angle's push button until it stops rotating. Pressing it prematurely may cause damage to the contra-angle.

• Do not remove the contra-angle until the motor handpiece stops rotating; otherwise, the contra-angle and the gear inside the motor handpiece may be damaged.

• Confirm whether the file is well installed and locked before starting the motor handpiece.

• Adjust the torque and speed settings to match the specifications provided by the manufacturer.

• Incorrect replacement of lithium batteries may pose significant risks. Always use the original battery and follow the replacement steps provided in the instructions (see Chapter 6.3).

• Do not place the device in areas where it is difficult to disconnect the power supply.

• Remove the battery if the main unit will not be used for a long time.

• Before using the instrument, ensure that it is securely locked in place.

• Do not use continuous rotary instruments in left-cutting reciprocating mode if the forward angles are larger than the reverse angles.

• Never use left-cutting reciprocating endodontic files (i.e., R-motion) in forward rotary mode.

• Do not use left-cutting reciprocating endodontic files (i.e., R-motion) in CW/CCW/ATR mode.

• Always use the torque and speed settings recommended by the instrument manufacturer.

• Wireless charging generates heat, which may increase the surface temperature at the tail of the motor handpiece. Monitor temperature changes to avoid user discomfort.

• When using an adapter, ensure it is placed where it can be quickly and safely disconnected from the mains

supply.

IMPORTANT:

Rooter X4000 motors feature torque-controlled auto-reverse, auto-stop, apex locator-controlled apical stop, auto-start, and apical reverse, which may help prevent endodontic file separation for the operator. The aforementioned features will not entirely halt endodontic file separation due to the nature of the endodontic instruments and instrumentation itself. Factors like canal morphology, obstructions, calcifications, patient and tooth age, presence of foreign materials, retreatment, instrument type, and number of uses, among others, are key aspects that determine the risk of endodontic file separation during instrumentation and cannot be surpassed by the motor file separation prevention features.

2 Installation and Settings

CAUTION:

• Have all the connections between your device and the power grid made by a certified dental installation technician. The power grid to which the motor is connected must comply with the applicable international standards.

Unpacking and installation

• Rooter® X4000 parts undergo thorough checks before shipment. Conduct an inspection promptly after delivery.

• Remove the box and its accessories from their original packaging and place them on a flat surface. Do not install direct or indirect sources of heat.

• Verify the contents of the box, referring to Section 1.2 “Product Configuration”.

• Do not bend the power cord, which may cause damage.

• All supplied accessories have not been sterilized.

• Place the base on a stable, horizontal surface with a slope no greater than 5°.

2.1 Contra-angle

IMPORTANT:

a. This is the only contra-angle that is suitable with the Rooter® X4000. The contra-angle uses an internal gear transmission system with a gear ratio of 4.7:1 (Model: CA1471L).

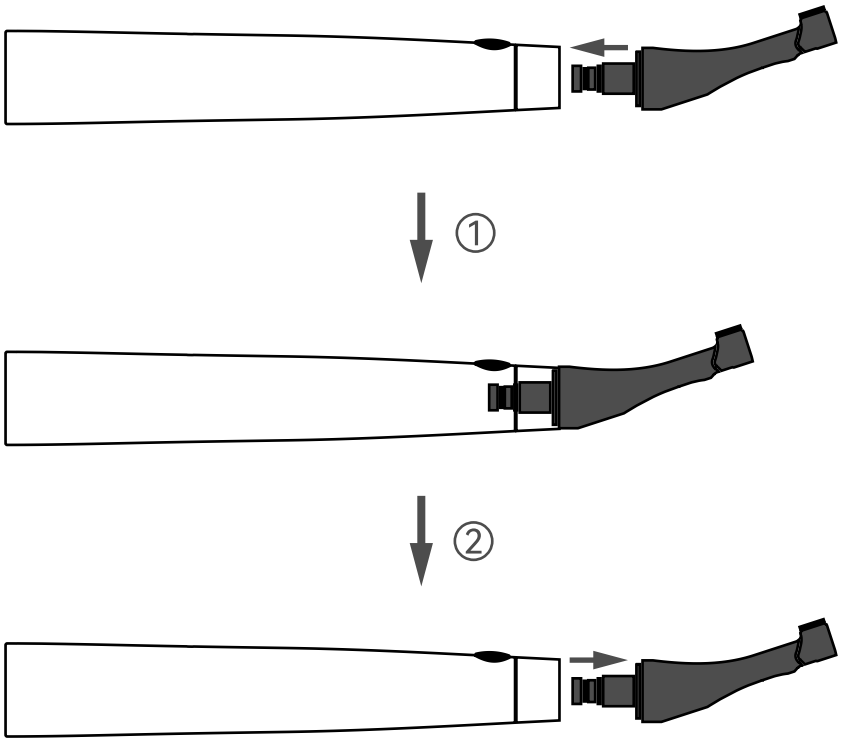
b. Before first use and after each subsequent use, please clean and sterilize the contra-angle according to Section 8.

c. The contra-angle (c) must only be used with its original endo motor. Do not modify or use this contra-angle with incompatible motors, as this may result in damage to the device or compromised performance.

d. The service life of the contra-angle is 10 years, but it may vary depending on the frequency and duration of clinical use, as well as the difficulty of the root canals being treated.

① Installation

Insert the contra-angle horizontally into the motor handpiece. Once you feel slight resistance and hear a “click” sound, the Contra-angle is firmly secured.



② Removal

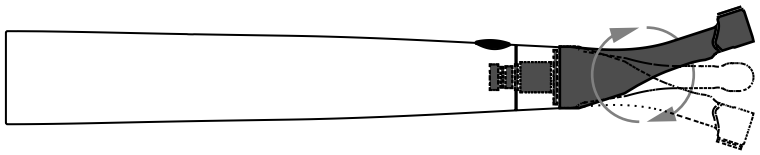
When the motor handpiece is turned off, simply pull the contra-angle out horizontally.

Warnings

- Stop the motor handpiece before inserting or removing the contra-angle.
- After installing the contra-angle, make sure it is securely locked in place.

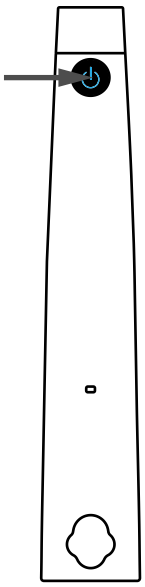
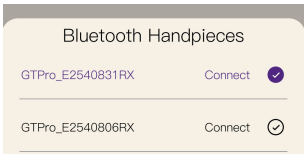
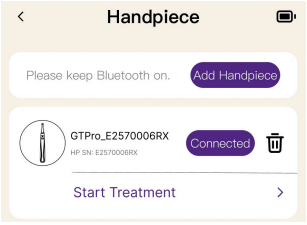
IMPORTANT:

The contra-angle can freely rotate to adapt to root canals in various positions.



2.2 Motor handpiece connection to the main unit (base)

① Connection

	1. Turn on the motor handpiece.
	2. Turn on the main unit (see Section 3.1 for startup instructions). 3. Select “Settings” on the main interface. 4. In the System Settings interface, tap on “Motor Handpiece.” 5. In the Motor Handpiece interface, tap “Add Device” at the top (As shown in the figure).
	6. In the pop-up list of Bluetooth devices, choose the serial number of the motor handpiece you want to connect, then tap “Start Connection.” Once the connection is successful, the corresponding serial number will display “Connected” (as shown in the figure on the right). 7. For the connected handpiece, tapping “Start Treatment” will take you directly to the working mode interface.

② Disconnection

On the main unit handpiece device interface, tap the to open the pop-up window.

Warnings

The operation steps described need to be performed only once. Each time the motor is turned on subsequently, the parameter will be saved, and the connection will be established automatically.

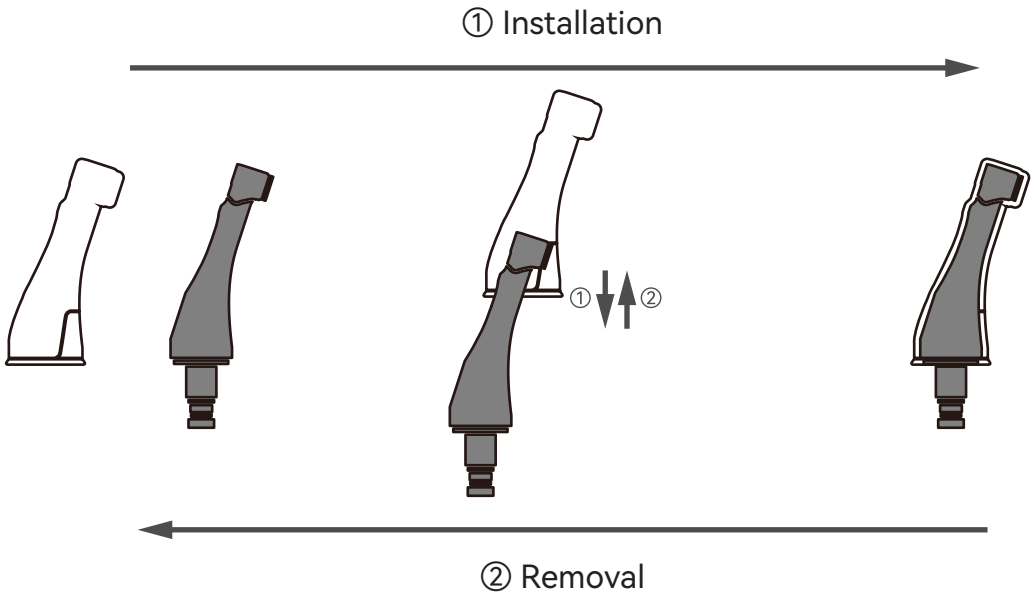
2.3 Protective silicone cover

① Installation

Put the protective silicone cover onto the contra-angle.

Warnings

The silicone cover must completely encase the contra-angle handpiece.



② Removal

When removing the protective silicone cover, pull it straight out slowly.

Warnings

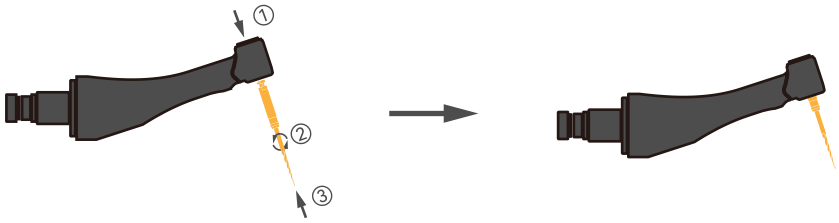
The silicone protective cover must be cleaned, disinfected, and sterilized according to Section 8 after each use.

2.4 Engine-driven file

① Installation

1. With the device turned off, insert the file into the chuck of the contra-angle head.

2. While gently rotating the file with one hand to find the insertion point, press the push button on the contra-angle with the other hand and carefully push the file in.

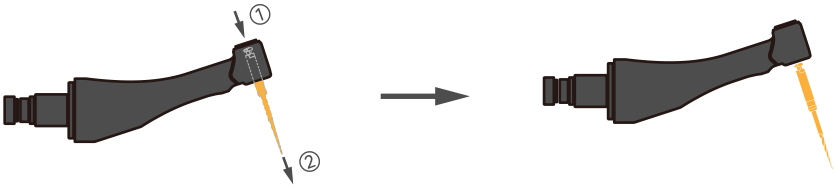


Warnings

- Once the file is inserted into the handpiece, release the push button, and the file should not come out.
- Be careful when inserting the file to avoid finger injuries.

② Removal

After the motor handpiece has stopped rotating, press the push button on the contra-angle head to remove the file.



Warnings

• Be sure to stop the motor handpiece before inserting or removing the file.

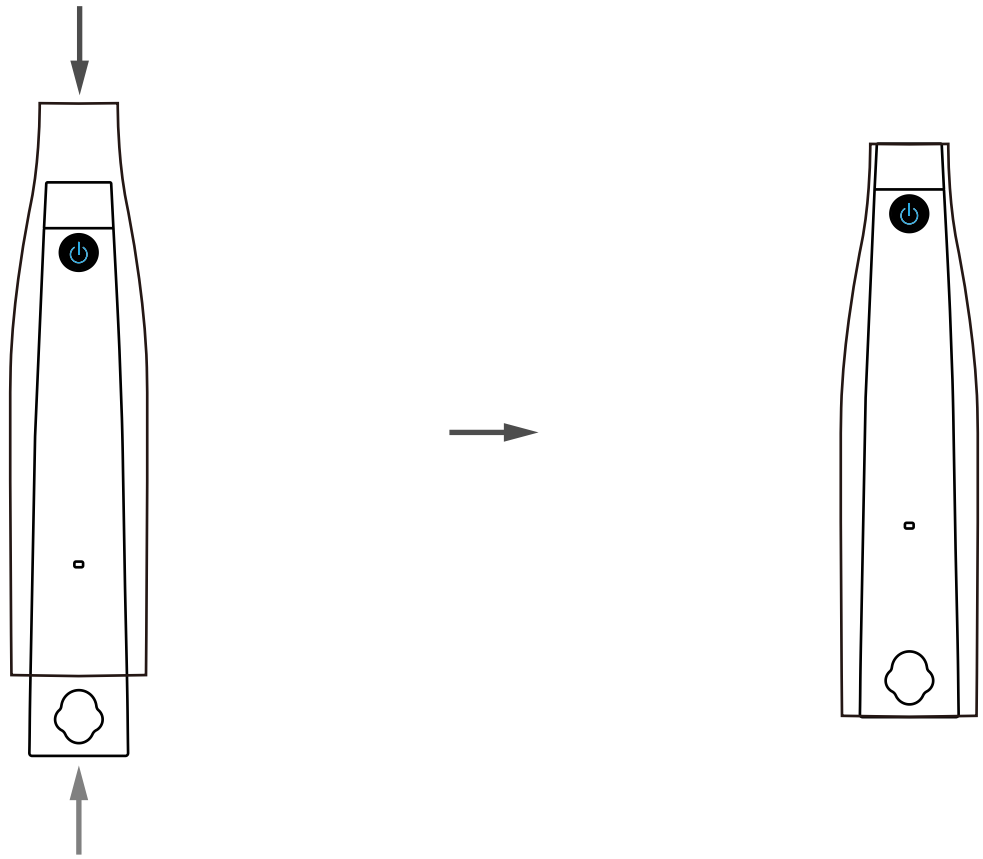
• When the file is installed, if you do not press the push button and try to gently pull out the file, it will remain locked.

• Do not touch the rotating file to avoid injury.

• After completing root canal preparation, carefully remove the device from the patient's mouth to avoid injuring the patient.

• Inserting the file without pressing the contra-angle push button may damage the chuck.

2.5 Disposable isolation sleeves



① Installation

1. Before each use of the handpiece, and after it has been cleaned and disinfected, put on a disposable isolation sleeve. Remove the isolation sleeve from the box and insert it into the motor handpiece from the narrow end. Make sure the sleeve fits smoothly without any visible wrinkles.

2. Once the disposable isolation sleeve is installed, wrap barrier film around the surface of the handpiece. After that, clean and disinfect the surface according to the procedures outlined in Section 8.3.

② Removal

After each use, carefully remove the barrier film and gently pull the isolation sleeve from the narrow end of the handpiece.

Warnings

Isolation sleeves are not reusable.

2.6 Measuring wire, lip hook, touch probe, and file clip

Applicable for the apex locator alone and the motor and apex locator combined modes

The Rooter X4000 endodontic motors feature three distinct operation modes. Depending on the operator's preferences, it can be used as motor only (or motor alone), apex locator only (to help determine electronically the position of the apical constriction), and motor combined with apex locator or combined mode (the motor will work simultaneously with the apex locator, giving readings during the translation of the endodontic file inside the canal).

IMPORTANT:

a. Prior training in typodont models or extracted teeth is recommended to familiarize oneself with the equipment and its features.

b. If the operator is not trained in the use of the motor concurrently with the apex locator (motor and apex locator combined mode or combined mode), it is recommended to use the motor-only mode. Operators can always use the apex locator only mode first to help determine the working length, and then use the motor only mode for instrumentation.

c. Basic training and knowledge about the operating principles of the electronic working length determination (apex locator) are necessary to operate the apex locator only mode.

WARNING:

WARNING

According to the Endodontic Standards of Care, always use rubber dam isolation when performing endodontic treatment.

CAUTION:

- Do not use this unit with patients who have a pacemaker, as its effect has not been evaluated.

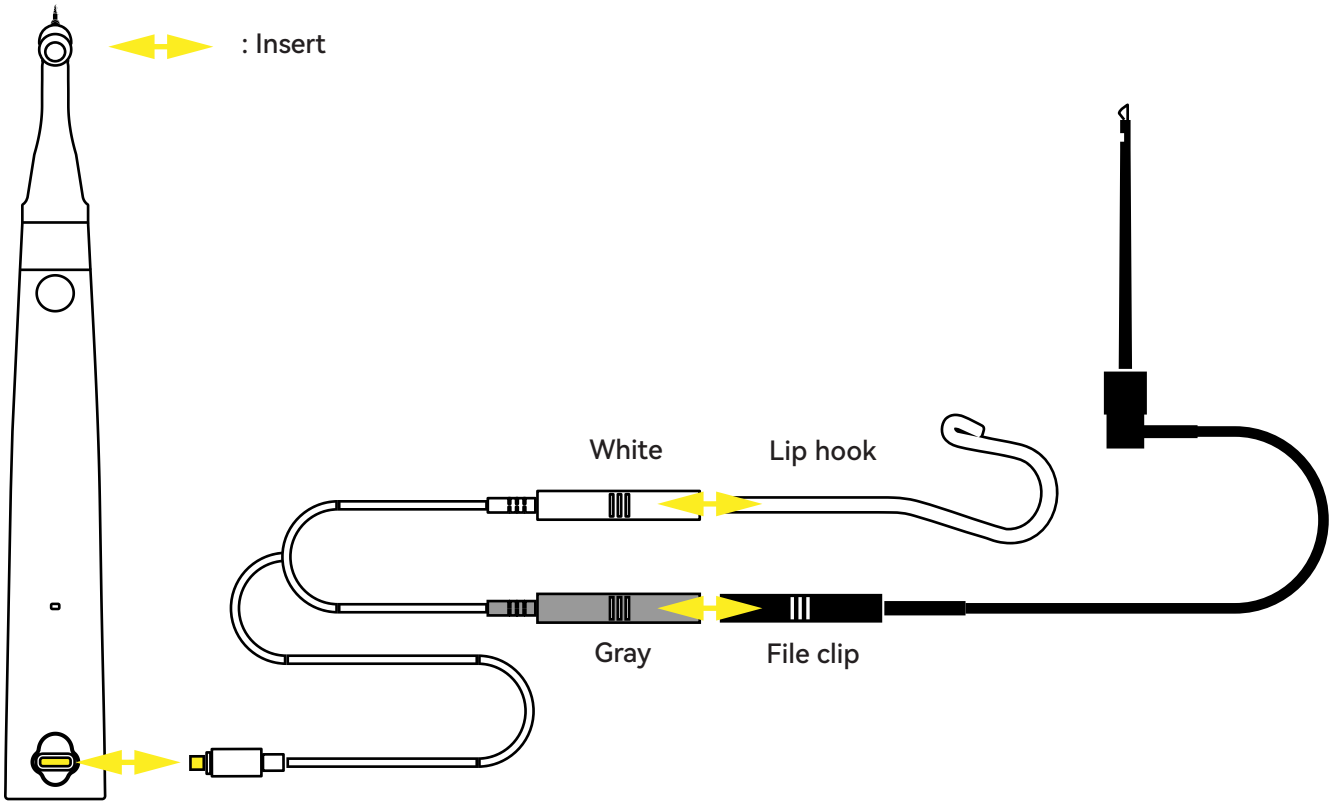
Perform the apex locator alone function using the apex locator built into the motor handpiece

1. Insert the Type-C connector of the measurement wire into the root canal measurement port (APEX) located at the lower end of the motor handpiece.

2. Plug the lip hook into the white socket of the measurement wire and connect the file clip to the gray socket.

3. Power on the device according to the instructions provided to initiate the electronic working length determination. The display of the main unit will indicate the file's position in relation to the foramen's position (0.0).

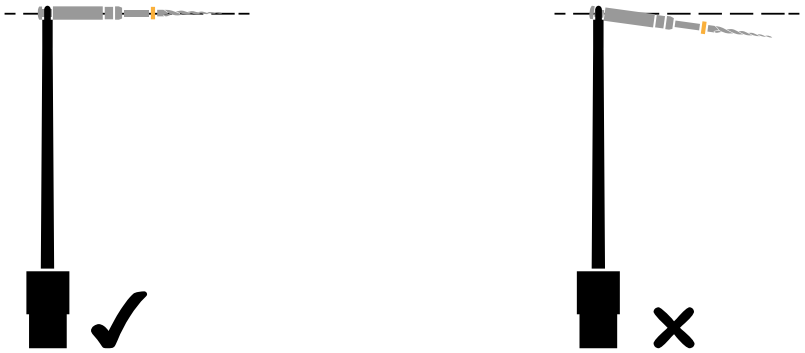
4. Insert a hand file with the appropriate diameter and adjust it to the temporary working length, which should be approximately 4-5 mm shorter than the length indicated by the radiographic image of the canal. Once the file is appropriately positioned, secure it in the file clip.



Warnings

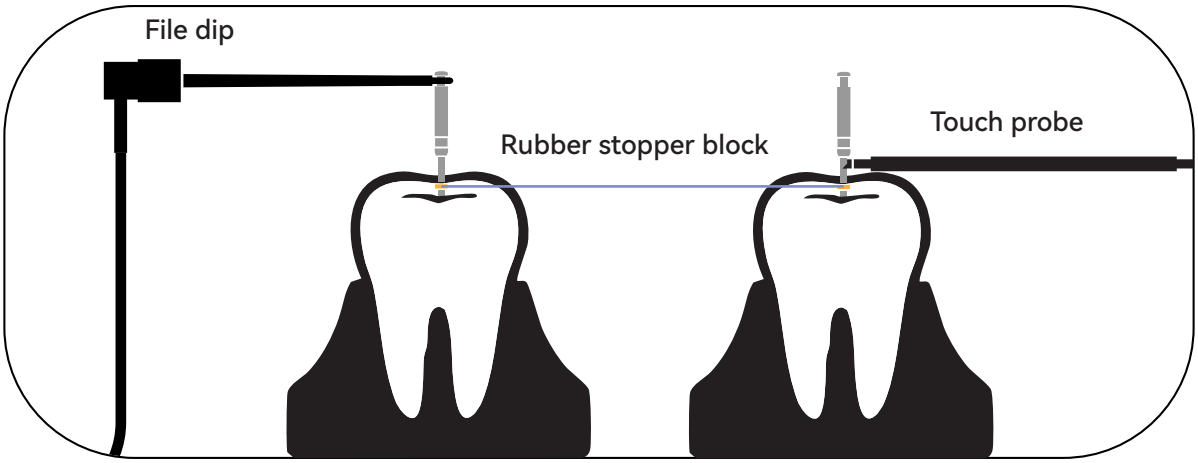
• In this mode, the motor handpiece is powered but not in use. Do not pull the wire by hand when inserting or removing the measuring wire and file clip.

• Do not use a worn file clip, as this may lead to inaccurate measurements. Always grip the file as shown in (a) and avoid the incorrect grip demonstrated in (b).



• When the file reaches the apical constriction (0.0), adjust the rubber stopper to align with the reference point, such as the incisal edge or the tip of the cuspid. Remove the file and measure the distance between the stopper and the file tip using an endo ruler; this distance indicates how far the apical constriction is. Determine the working length according to your preferred technique.

• If access is limited, such as in posterior teeth, use the touch probe instead of the file clip.



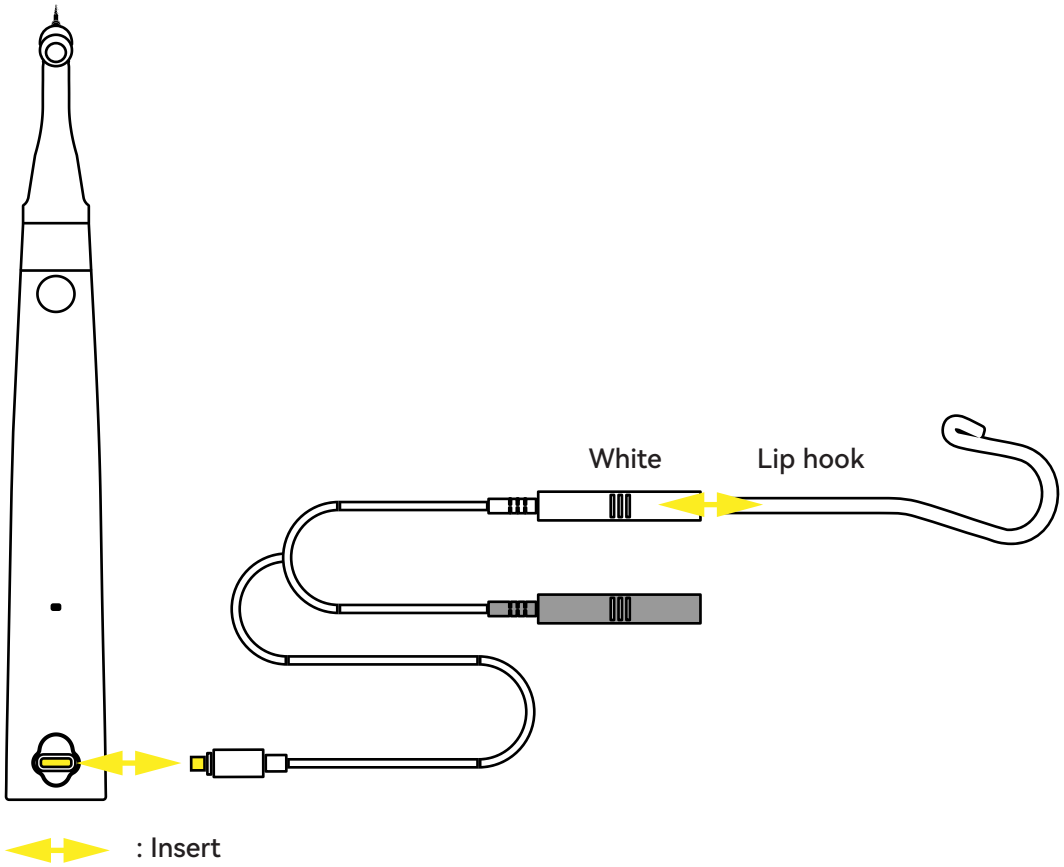
Perform the instrumentation with the apex locator's concomitant electronic measurement using the apex locator built into the motor handpiece.

1. Connect the contra-angle to the motor handpiece and then attach a suitable rotary file to the contra-angle.

2. Insert the Type-C connector of the measuring wire into the root canal measurement port (APEX) located at the lower end of the motor handpiece.

3. Plug the lip hook into the white socket of the measuring wire, leaving the gray socket unused.

4. Power on the handpiece. Once the file starts to operate inside the canal, the main display will then show the electronic measurements and the position of the file tip relative to the apical constriction.



Warnings

Choose 00 for the apical constriction position.

Use the main unit to perform the apex locator function only.

1. Insert the Type-C connector of the measurement wire into the root canal measurement port (labeled APEX)

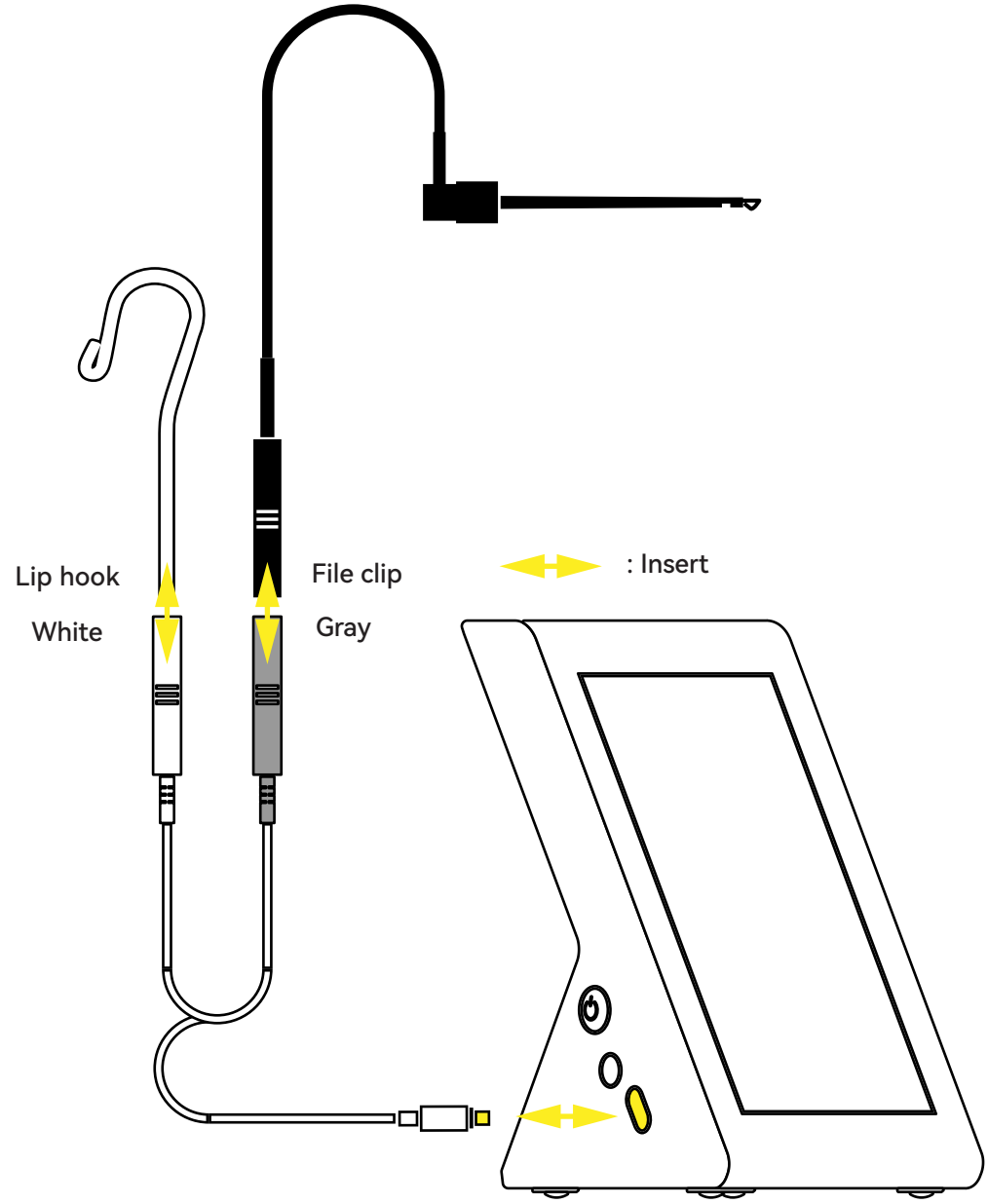
located on the lower left side of the main unit.

2. Plug the lip hook into the white socket of the measurement wire and connect the file clip to the gray socket.

3. Power on the device provided to initiate the electronic working length determination. The display of the main unit will indicate the file's position in relation to the apical constriction's position (0.0).

4. Insert a hand file with the appropriate diameter and adjust it to the temporary working length, which should be approximately 4–5 mm shorter than the length indicated by the radiographic image of the canal. Once the file is properly positioned, secure it in the file clip.

5. When the file starts to move toward the apical constriction, the main display will show the electronic measurements and the position of the file tip relative to the apical constriction.



Warnings

The motor handpiece is not required in this mode.

2.6.1 Connection test (test before each use)

Check the electronic connection under the apex locator in the alone mode

Use the file clip to clamp the hook. If all the indicator bars on the screen are fully lit and "-1" is displayed while

the short circuit icon remains active, this indicates that the connection is strong. If this is not the case, it suggests that either the measurement wire or the file clip is poorly connected or damaged and needs to be replaced.

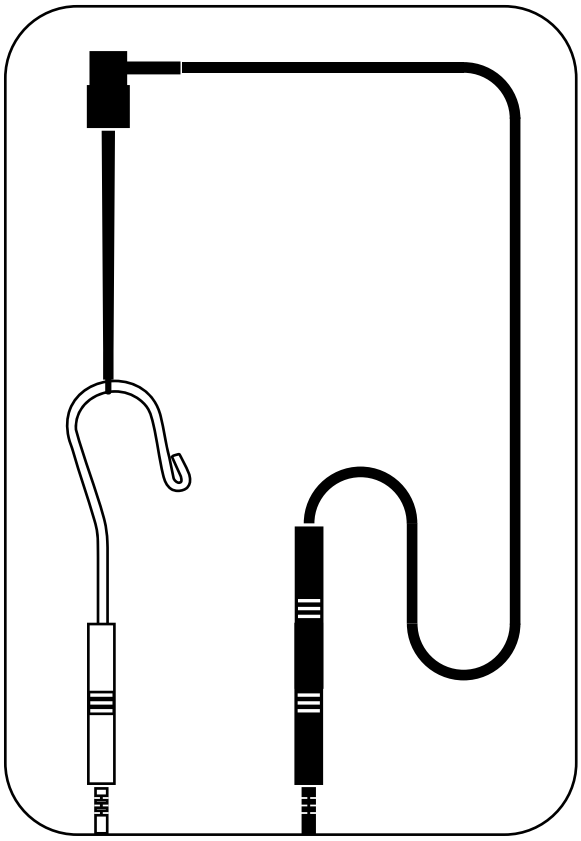
Check the electronic connection under the apex locator in the motor combined with apex locator mode

1. Connect the contra-angle, motor handpiece, measurement wire, and lip hook according to the preparation with the apex locating function.

2. Insert the file.

3. Apply moderate pressure with the lip hook to ensure contact with the file.

4. The LCD should display all measurement bars, “-1”, and a stable short circuit icon. If this is not the case, it suggests that either the measurement wire or file clip is poorly connected or damaged and needs to be replaced.



Warnings

1. Conduct a connection test before using the apex locator in apex locator only mode each time.

2. Conduct a connection test before using the apex locator in motor with apex locator or combined mode mode each time.

2.6.2 Testing the device by the tester

The tester can be used to check if the device is functioning correctly.

a. Remove the measuring wire from the device.
b. Insert the tester into the measuring wire port of the device.
c. Ensure the charging base is connected to the motor handpiece, then turn on the device. The main unit of the Rooter X4000 can also be tested separately.
d. If the screen displays a reading within ±1 bar of the 0.0 scale, the device is functioning normally.

WARNING: WARNING:

a. Apex locators’ measurement wire is a delicate part of the device. Even though it is flexible, do not bend or

angle it. Store the wire stretched out. It is impossible to perceive if any damage is present caused by improper handling of the wire due to the polymer protection.

b. The connectors of the wire are also sensitive. Due to the use of a very weak electronic signal during the electronic measurement, any interruption will cause malfunction and misreading. Make sure that the connections between the measurement wire and the base, and the measurement wire and the two terminals – the lip hook and the file clip – are tightly connected.

c. Always carefully dry the terminals after cleaning. Do not leave humidity on the connectors. All connections must be clean, free from debris, corrosion, patina, and oxidation.

d. If the wire connection test fails, contact the distributor to replace the measurement cable/connectors.

3 Functions and Operations

3.1 Switching on/off the main unit (base)

The arrow in Figure 3.1-1 indicates the standby button on the main unit.

a. Power on: Press the standby button briefly to power on the unit. The screen will display the product model and then switch to the last-used mode, indicating a successful startup.
b. Power off: Long press the button, the screen will pop up to indicate whether to shut down, select “YES” to shut down immediately, and “NO” not to turn off

IMPORTANT:

- The default auto-off time is 60 minutes. It can be adjusted to 30, 60, or 90 minutes as needed.

c. Safe shutdown: After completing the procedure, make sure to turn off the motor handpiece and ensure that the file has stopped rotating. Unplug the power adapter to disconnect it from the power supply. You can then remove the file, contra-angle, and any accessories for cleaning, disinfection, and sterilization, as outlined in Section 8.

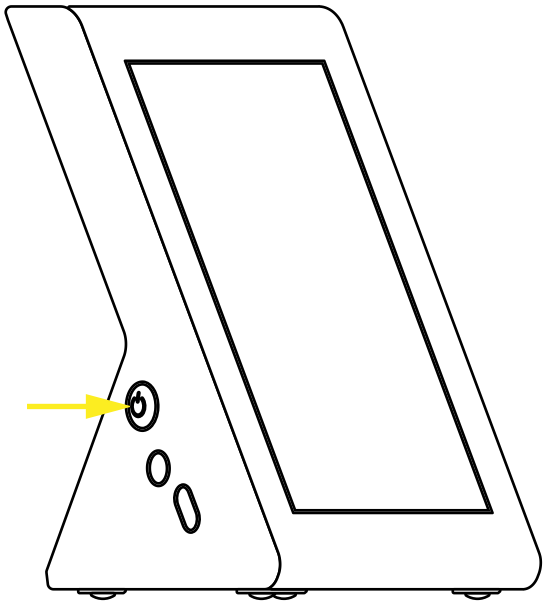


Figure 3.1-1

Figure 3.1-2

3.2 Starting and stopping the motor handpiece

a. Start: To activate the motor in standby mode, short-press the standby button. The indicator light on the stand-by button will begin to flash.

b. Standby: To enter standby mode from the off or running state, short-press the standby button. In standby mode, the indicator light on the standby button will remain on continuously.

c. Stop: To turn off the motor handpiece in either standby or running mode, long-press the standby button. The indicator light on the standby button will turn off.

IMPORTANT:

• If the motor handpiece is started independently while the main unit is powered off, it will operate using the last saved settings.

• Once the motor handpiece is successfully connected to the main unit, it will automatically reconnect in future uses.

• The motor handpiece cannot be started while charging or in apex locator mode.

3.3 Software update for main unit

There are two methods to update system programs:

Update via USB:

a. Contact the supplier or distributor to obtain the installation package. Transfer the upgrade package to a USB flash drive.

b. With the main unit powered off.

c. Open the battery cover and insert the USB flash drive into the USB port located beneath the battery compartment.

d. Plug in the power adapter.

e. The screen will display the system upgrade progress. Once the upgrade is complete, unplug the power adapter, remove the USB flash drive, and power on the main unit.

f. The system will now be successfully upgraded.

Update with Wi-Fi:

Before updating, make sure the power adapter is connected

a. Enter the design interface, select “General Settings”, slide down to select “About”, select “Update via WiFi”, turn on WIFI, select wireless network, and enter the password.

b. After successfully connecting, select “Update System”, select the corresponding software update package, select “Download”, update the package, and wait for the download to complete.

c. Wait for “Updating” to complete, select “Confirm”, and the machine will automatically restart to complete the update.

3.4 Firmware update fo motor handpiece

Handpiece Upgrade:

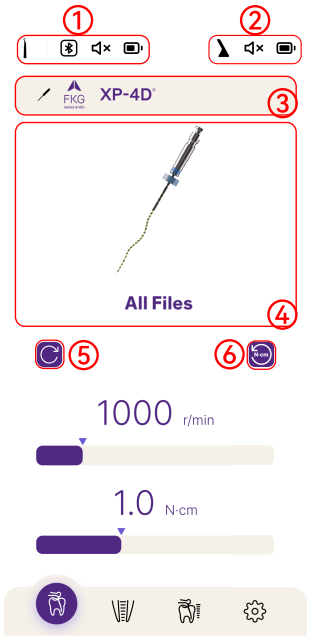
Handpiece Firmware Upgrade

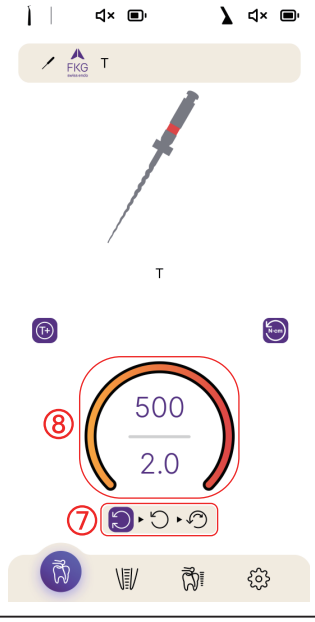
1. Connect the handpiece to the OTA upgrade adapter.
2. When the handpiece’s button light and Bluetooth indicator start flashing, it enters upgrade mode.

3. On the screen, tap the option to upgrade the handpiece via Bluetooth.
4. A progress bar will appear, indicating the update status.
5. Once the progress bar is complete, the firmware upgrade is successful.
6. Disconnect the adapter, then long press the power button to shut down and restart the handpiece. The upgrade process is now complete.

4 Operation interface description

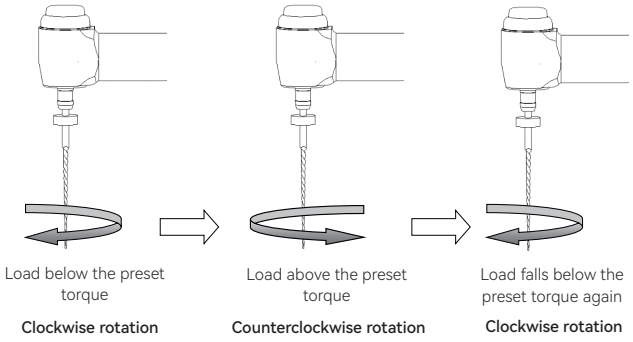
4.1 Motor only mode (treatment without electronic measurements)

Interface	NO.	Icons meaning and usage
Motor handpiece status: Not started 	①	: Bluetooth connection between motor handpiece and main unit
		: Motor handpiece volume
		: Motor handpiece battery level
	②	Volume and battery level of the main unit.
	③	Current file system name
	④	Swipe left or right to switch between files in the same system, Or click on the file name to preview all files in the current file system.
	⑤	File mode display icons, such as CW, CCW, SGP, ATR. When displayed as a CW icon, touch can temporarily switch to CCW mode, and touch again to switch back to CW mode.
	⑥	Auto reverse function status. Purple indicates it is enabled, while gray indicates that the function is off.

Interface	NO.	Icons meaning and usage
Motor handpiece status: Started 	⑦	The T-mode running status. Purple indicates the current mode is active.
	⑧	Real-time torque status display. Gradient from yellow to orange. Orange is orange when the torque reaches 100% of the set value, and 0% of the torque reaches the set value is yellow.

4.2 Automatic reverse protection function

If the load exceeds the preset torque value during operation, the file will automatically switch to reverse rotation mode. Once the load falls below the preset value, the file will revert to forward rotation.



IMPORTANT:

a. The automatic reverse protection function is applicable only in forward rotation mode and reciprocating mode.

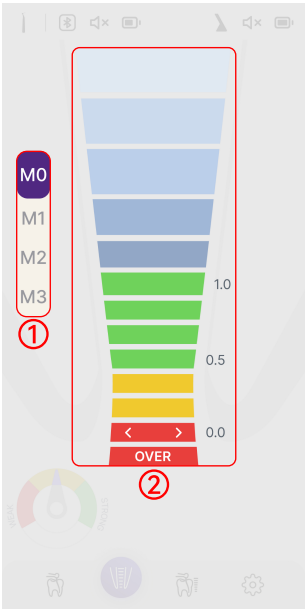
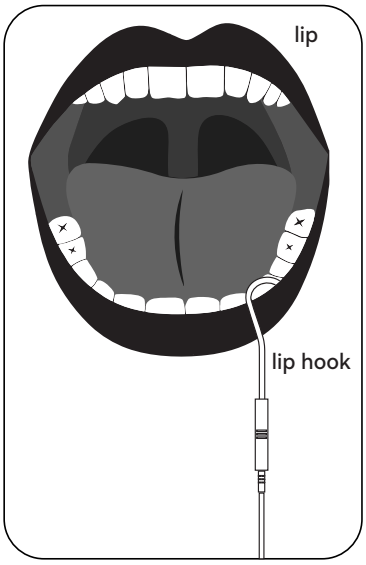
b. In reciprocating mode enable automatic reverse protection function, if the load exceeds the preset torque value and the forward angle is greater than the reverse angle, the rotation will automatically switch to reverse. Conversely, if the forward angle is less than the reverse angle, the rotation will switch back to forward.

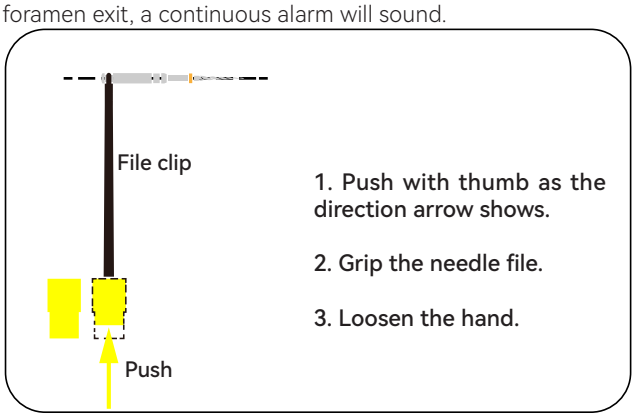
c. This function is disabled in reverse and ATR modes.

d. If the battery icon on the base screen indicates low battery and there is insufficient remaining power to allow the motor handpiece to reach the maximum torque value, the automatic reverse function may not operate correctly. Please charge the battery of motor handpiece promptly.

e. If the motor handpiece remains under load for an extended period, it may automatically stop due to overheating protection. In such cases, turn off the motor handpiece and allow it to cool down before resuming use.

4.3 Apex locator mode

<table>
<tr><th>Interface</th><th>NO.</th><th>Icons meaning and usage</th></tr>
<tr><td rowspan="2"> 
</td><td>①</td><td>Four memory apical stops.
Adjustment: Long-press the 0.0–1.0 scale area on the screen to display the up/down arrows and adjust the saved apical stop settings.</td></tr>
<tr><td>②</td><td>a) Connect accessories and perform a connection test according to Section 2.5.
b) Place the lip hook securely on the patient's labial commissure, ensuring good contact with the oral mucosa to serve as a reference electrode.
 

c) Clamp the file with the file clip. When the file is approximately less than 2 mm from the foramen exit, a continuous alarm will sound.
 

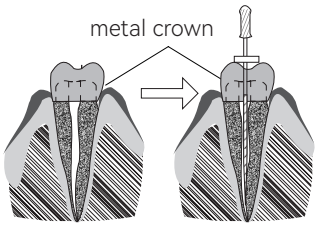
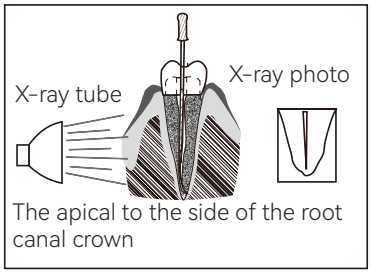
d) When the indicating bar reaches the 0.0 position on the scale, the file has arrived at the foramen exit, also known as the foramen equator. Depending on the technique chosen, maintain or subtract 0.5–1.0 mm to determine the working length.
When the indicating bar reaches the red area marked "OVER," it indicates that the file has exceeded the apical foramen.</td></tr>
</table>

4.3.1 Clinical conditions unsuitable for accurate measurement

WARNING:

Accurate measurements are challenging to obtain if the root canal conditions are shown as below:

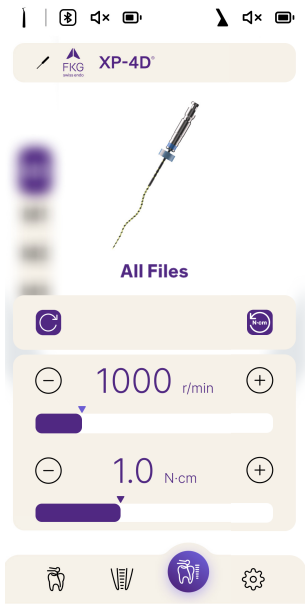
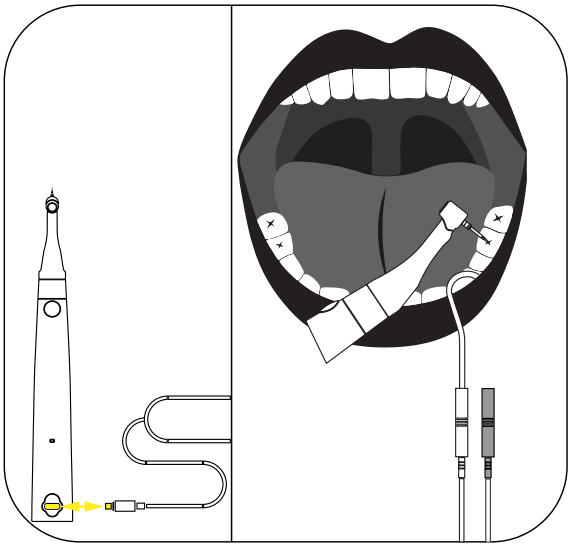
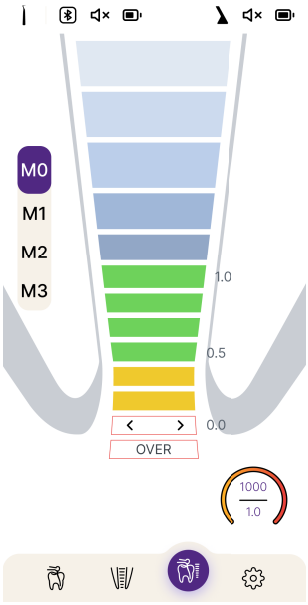
	Large apical foramen Root canals with an excessively large apical foramen due to apical resorption from clastic inflammatory cell reactions or incomplete development (open apex) cannot be accurately measured. The measurement result may be shorter than the actual foramen position.

<table>
<tr><td>  </td><td>Bleeding or irrigant overflow
An accurate measurement cannot be obtained if blood or chemical solutions overflow from the canal opening and touch metallic restorations. In such cases, dry the pulp chamber and ensure that no liquid is in contact with metallic restorations.</td></tr>
<tr><td> 
</td><td>Crown or metal restorations
Accurate measurements cannot be obtained if the file comes into contact with a metallic restoration that is touching the gingival tissue. To prevent this, widen the opening at the top of the crown so that the file does not touch the metal before taking a measurement.</td></tr>
<tr><td> 
Too dry</td><td>Extremely dry canal
If the canal is very dry, the signal transmission through dentin may be affected. Irrigate properly.</td></tr>
<tr><td colspan="2">Discrepancy between the apex locator electronic reading and the radiographic images
The electronic reading might not perfectly match the radiographic image measurement with the traditional Ingle technique. This discrepancy does not necessarily indicate a malfunction of the apex locator or an error with the X-ray itself. The X-ray image may not accurately reveal the position of the foramen exit due to the angle of the X-ray beam and the nature of a two-dimensional image. As a result, the foramen exit may appear to be in a different location than its actual anatomical position.
 

The apical to the side of the root canal crown</td></tr>
</table>

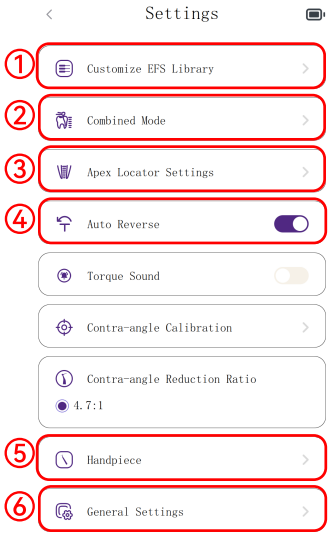
4.4 Combined mode.

Motor combined with the apex locator electronic measurements mode

Interface	Icons meaning and usage
Motor handpiece status: Not started 	The meaning of each icon corresponds to those in two other modes. 1. When using Motor combined with apex locating mode, the measuring wire must be connected with the motor handpiece. 2. The white socket is connected to the patient's labial commissure via the lip hook, while the gray socket remains unused.  3. Set parameters of automatic functions as needed, such as Apical Action, Auto Start, etc. (See Section 4.5)
Motor handpiece status: Started 	

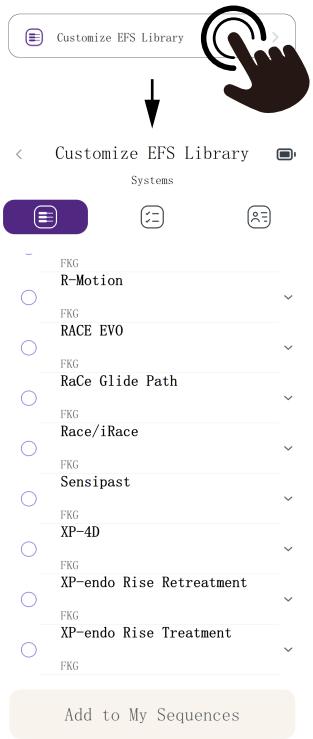
4.5 User settings interface

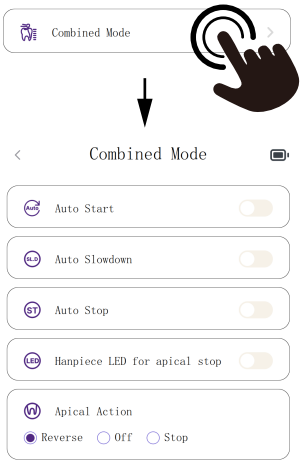
Icon Meaning

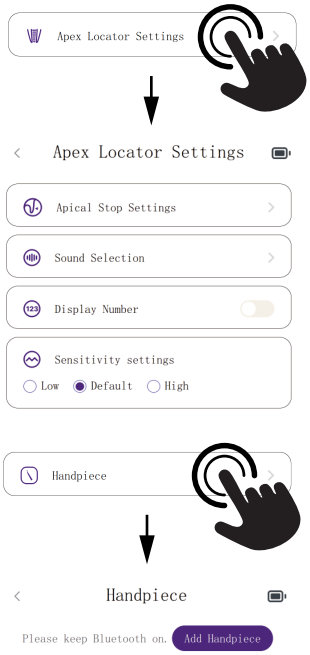


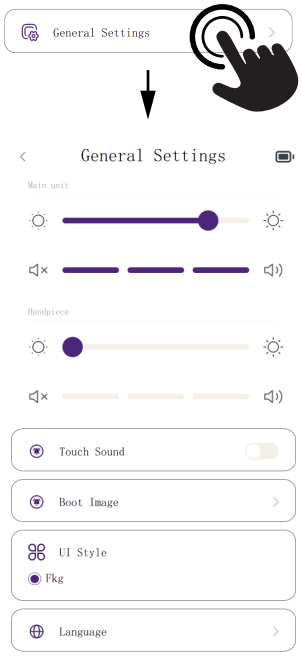
①: File system: See Section 4.5 for details.
②: Combined Mode
③: Apex locator settings
④: Auto-reverse setting
⑤: Motor handpiece management
⑥: General Settings

Secondary Interface

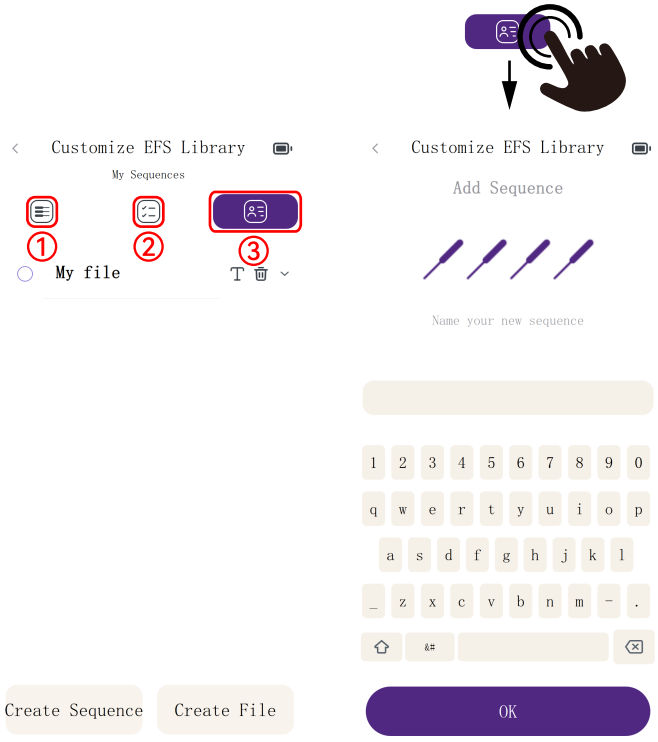








4.6 File systems



①: File Systems: the default library includes FKG files with their recommended settings. You can select them and add them to My Sequences.
②: File Sequences: The default library includes FKG files with their recommended settings. You can select entire sequences and add them to My Sequences.
③: My Sequences: Create a named file sequence and add existing or create files.

WARNING

The preset specifications are saved in the system. Before starting the instrumentation, the operator has the option to modify these preset parameters. However, for safety reasons, any changes made to the parameters in the pre-set files will not be automatically saved. Instead, they will revert to the manufacturer's original specifications upon restarting the system.

5 Calibration

5.1 Torque calibration

This function reduces torque fluctuations caused by replacing or high-temperature sterilizing the contra-angle, ensuring greater torque accuracy.

WARNING:

It is recommended to calibrate the torque on the contra-angle when replacing it or after every 1-2 months of use.

5.2 Calibration procedure

a. Properly connect the contra-angle to the motor handpiece (do not install the file).
b. In the “Settings” interface, tap on “Calibration” to enter the calibration menu.
c. Follow the on-screen instructions to start the motor handpiece and initiate the calibration process. The main unit will display [Calibrating]. Avoid performing any other operations during this time.
d. The motor handpiece will gradually accelerate from the lowest to the highest speed to automatically measure the inertia and no-load resistance of the contra-angle.
e. Once calibration is complete, the charging base screen will display [calibration successful]. Tap “Confirm” to return to the settings menu.

IMPORTANT:

If the charging base screen displays “Contra-angle calibration failed” after calibration, please cease using the current contra-angle and replace it with a new one.

6 Battery Charging

Battery Icon	Icon Meaning
	Full battery
	2 bars of battery
	1 bar of battery
	Low battery. Please charge immediately.
	Battery critically low! The device will shut down soon.
	Charging
	Charging complete

6.1 Main unit charging

a. Before first use, connect the power adapter to the main unit for charging.
b. When the main unit indicates a low battery, stop using it and charge immediately to avoid treatment delays.
c. After charging is complete, unplug the power adapter.

6.2 Motor handpiece charging

a. The motor handpiece has a built-in rechargeable lithium battery and supports wireless induction charging.
b. Handpiece wireless charging:

- Ensure the charging base is magnetically connected to the main unit.
- Place the handpiece onto the charging base. The purple charging indicator light on the base will flash, indi-

cating that charging is in progress. When the light remains steadily on, the handpiece is fully charged.

IMPORTANT:

It is recommended to fully charge the handpiece before its first use.

- When the motor handpiece battery icon on the main unit indicates a low battery, stop using the handpiece and charge it to avoid delaying treatment.
- The motor handpiece cannot be started while charging.

6.3 Battery replacement

If the battery continues to drain rapidly after charging, it may need to be replaced.

Battery replacement steps for the main unit:

a. Use a Phillips screwdriver to remove the screws on the battery cover of the base and open the cover.
b. Remove the lithium battery and replace it with a new one of the same specification.
c. Close the battery cover and tighten the screws.

IMPORTANT:

For motor handpiece battery replacement, contact your local distributor for assistance.

7 Troubleshooting

If a malfunction occurs, refer to the checklist below before contacting your distributor. If the issue remains unresolved after following the suggested actions, the product may be faulty. Inform your distributor.

Issues	Possible Causes	Solutions
Installation		
After the motor handpiece is activated and the Bluetooth status shows "", it indicates a failed connection between the handpiece and the main unit.	1. Bluetooth pairing failed 2. The handpiece is too far from the base	1. Reconnect the motor handpiece to the main unit via Bluetooth. 2. Place the handpiece closer to the main unit and restart both.
The contra-angle cannot be calibrated.	The calibration procedure may have been interrupted by increased resistance in the contra-angle.	1. If calibration has been interrupted, calibrate the motor handpiece again to rule out the possibility of a motor fault. 2. Clean and lubricate the contra-angle. 3. Start the calibration procedure again.
The motor handpiece cannot be charged	Poor contact between the charging base and the main uint	Clean the charging contacts with a soft cloth dipped in medical alcohol. Reconnect the charging base to the main unit magnetically, and place the motor handpiece on the base.
Automatic reversal of the file when unloaded.	The contra-angle may contain debris	1. Clean and lubricate the contra-angle. 2. Start the calibration procedure again.
Apex Locator		
Unstable electronic reading.	File diameter is too thin	Use a larger diameter file. Ensure that the tip of the file is in contact with at least two-thirds of the dentin walls. Pre-flare the canal with larger files in the cervical and middle thirds before selecting the appropriate file for electronic measurement. Avoid using thin files in large canals.
The display doesn't show any progress of the file.		Perform the apex locator test. Section 2, 2.6.1

Display showing no or partial progression of the file towards the apical area/foramen.		1. Poor connection. Check all connections and ensure lip hook is contacting the oral mucosa and file clip is clean and free of debris. Perform the wire connection test. Section 2.6.1. 2. Fill the canal with an electrolytic solution, if required (i.e. Sodium Hypochlorite, Saline, etc.). 3. The endodontic file tip is not touching the internal canal walls. Replace the file with a larger diameter file. 4. If the behavior persists, the measuring wire or file clip may need to be replaced and/or the device should be sent in for service – contact distributor.
Failure on the wire connection test.	Poor connection or damaged measuring wire.	1. Make sure the measuring wire is connected correctly. 2. If the behavior persists, the measuring wire may need to be replaced and/or the device should be sent in for service.
No progression on the display indicators even when the file is moving towards the apical area.		1. Replace the endodontic hand file to a bigger diameter file. Ensure that the tip of the file is touching 2/3 of the dentin walls. Place the file in the TEMPORARY working length first and, with the file inside the canal in place, connect the file clip. 2. Ensure the canal is filled with irrigant. 3. The file clip is not connected correctly to the endodontic file. 4. Check all connections and ensure the lip hook is contacting the oral mucosa and the file clip is clean and free of debris. 5. Perform the wire connection test. If the behavior persists, the measuring cable may need to be replaced and/or the device should be sent in for service.
The OVER indication appears accompanied by repeated beeps.		The file tip has progressed beyond the apical foramen – move the file back until the 'OVER' indication disappears.
The file position indicators exhibit unstable performance with erratic behavior. The OVER indication flashes even in the cervical third of the canal.	1. Is the lip hook making good contact with mucosa? 2. Dirty (oxidation present) file clip. 3. Blood or other fluids overflowing the access cavity.	1. Make sure the lip clip makes good contact with the oral mucosa. 2. Clean the file clip with 70-80% ethanol. If oxidation persists, replace the file clip. 3. If blood or other fluids are overflowing the access cavity, they may create a conductive path outside the canal and cause incorrect measurements ("OVER" indication, unstable readings, etc.). Check the rubber dam isolation, use caulking or flowable composite to repair rubber dam leaks. You may use tissue control substances to control gingival tissue bleeding. Clean and dry the pulp chamber and tooth crown thoroughly. 4. Large volume of vital inflamed pulp can cause a short circuit, giving an erratic "OVER" position. Remove 2/3 of the canal content (preflaring) and restart the reading.
Measurement results are too short or too long. Apparently, poor accuracy.	1. Is the canal filled with blood or chemical solutions? 2. Is the tooth surface covered with tooth debris, smear layer, or chemical solutions? 3. Is the file touching the gingival tissue? 4. Vital, inflamed pulp tissue is present in large volume inside the canal. 5. Is the file touching the metal restorations? 6. Are proximal surfaces presenting caries lesions? 7. Is there external resorption, or is the tooth fractured? 8. Is there a lesion at the apex?	1. The canal length indicator may suddenly swing when it breaks the surface of fluids inside the canal, but it will return to normal as the file is advanced toward the apical third. 2. Clean the entire tooth surface. 3. File touching gingiva invagination to the access cavity might lead to incorrect readings or cause the canal length indicator suddenly to jump all the way to the "OVER" position. 4. If a large amount of vital, inflamed pulp tissue is left inside the canal, particularly in wide canals such as upper incisors and canines, it may cause incorrect measurements. Preflare the canal. Proceed with copious irrigation. Try again with a larger diameter file. 5. Touching metal restorations with the file may create a conductive path outside the canal and cause incorrect measurements ("OVER" indication, unstable readings, etc.). 6. Deep caries may create a conductive path outside the canal and cause incorrect measurements ("OVER" indication, unstable readings, etc.). 7. The canal length indicators may jump to "OVER" position when it reaches a resorption area or a fractured root tooth. 8. A chronic lesion can destroy the apical foramen through resorption and cause incorrect measurements.
Motor only. Motor and apex locator combined (Guided Instrumentation)		
Different noise during rotation or reciprocation	Lubrication	Proceed with contra-angle lubrication

Motor handpiece overheating	Prolonged use in reciprocating mode or at high speed	Allow the device to cool down and restart the motor handpiece.
Continuous rotary file blocks in the root canal	Incorrect file settings or excessive pressure on the file	Change the rotational direction by tapping the "↻" button to turn it into "↺". Start the handpiece, reverse the file rotation, and gently withdraw the file.
The file stops during the instrumentation.	Speed and torque settings	Each file system has specific specs for speed and torque. Consult the files' instructions to properly set up the speed and torque values.
The file is reversing or stopping during instrumentation.	Torque settings. Apical pressure.	Ensure that the torque value for each file is correct. Low torque values will influence the file's performance. Be gentle during the instrumentation. If the file doesn't progress apically, retrieve the file. Preflaring. Use smaller diameter files for the glide path. Use hand files of a small diameter to open space for the engine-driven files. Use an endodontic lubricant and ensure that the canal is filled with irrigant during instrumentation.
The handpiece doesn't start automatically. The handpiece doesn't slow the rotation, stop or reverse rotation direction near the foramen.	Built-in apex locator is not performing the electronic reading.	1. Poor connection (measuring wire or connectors). Check all connections and ensure the lip hook is contacting the oral mucosa. 2. Ensure that the endodontic file is designed to be used concomitantly with electronic signal passage. 3. Fill the canal with an electrolytic solution, if required (i.e., Sodium Hypochlorite, Saline, etc.). 4. The endodontic file is not touching the internal canal walls. Replace the file using a larger diameter file. 5. If the behavior persists, the measuring wire may need to be replaced, and/or the device should be sent in for service – contact the distributor.
Erratic measurement. The motor is slowing down, stopping, or reversing during the instrumentation.	The built-in apex locator is not performing the electronic reading correctly.	Review all troubleshooting related to the Apex Locator only mode. In some cases, the motor and apex locator mode will not perform stable instrumentation due to adverse conditions of the case. Perform the electronic reading with the apex locator only mode, and use the motor only mode.

8 Cleaning, Disinfection, and Sterilization

8.1 Foreword

For hygiene and safety purposes, the main unit, motor handpiece, AC adapter, charging base, measurement wire, and tester must be cleaned and disinfected.

The contra-angle, lip hook, file clip, protective silicone cover, and touch probe must be cleaned, disinfected, and sterilized before each use to prevent contamination.

This applies to the first use as well as all subsequent uses.

8.2 General recommendations

8.2.1 Use only a disinfecting solution which is approved for its efficacy (VAH/ DGHM-listing, CE marking, FDA and Health Canada approval) and in accordance with the DFU of the disinfecting solution manufacturer.

8.2.2 Do not place the contra-angle in a disinfectant solution or in an ultrasonic bath.

8.2.3 Do not use chloride detergent materials.

8.2.4 Do not use bleach or chloride disinfectant materials.

8.2.5 For your own safety, please wear personal protective equipment (gloves, glasses, mask).

8.2.6 The user is responsible for maintaining product sterility during the first use and all subsequent procedures. Additionally, the user is responsible for identifying and avoiding the use of damaged or contaminated instruments, even after sterilization, where applicable.

8.2.7 The water quality must comply with local regulations, especially for the final rinsing step or when using a washer-disinfector.

8.2.8 To sterilize the endodontic files, refer to the manufacturer's instructions for use.

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

8.3 Cleaning and disinfection steps for the main unit, motor handpiece, AC adapter, charging base, measurement wire, and tester

Before and after each use, all components that have come into contact with potentially infectious materials should be cleaned using towels soaked in a disinfectant and detergent solution (a bactericidal, fungicidal, and aldehyde-free solution) approved by VAH/DGHM listing, CE marking, FDA, or Health Canada.

Warning:

Cleaning and Disinfection Instructions:

- Do not sterilize the main unit, motor handpiece, AC adapter, charging base, measurement wire, or tester using steam sterilization.
- It is not recommended to wipe the surfaces of the housing with "quaternary ammonium salt" disinfectants.

9.3.1 Pre-use processing

Before each use, the handpiece, charger, and base must be cleaned and disinfected. The specific steps are as follows:

Warning:

The main unit, motor handpiece, AC adapter, charging base, and measurement wire cannot be cleaned or disinfected using automatic equipment. Manual cleaning and disinfection are required.

8.3.1.1 Manual cleaning steps:

1. Place the handpiece, charger, and base on a clean workbench.
2. Soak a soft cloth completely with distilled or deionized water, and wipe all surfaces of the components (handpiece, charger, base, etc.) until they are visibly clean and free of stains or debris.
3. Wipe the surfaces with a dry, soft and lint-free cloth.
4. Repeat the above steps at least 3 times.

Note:

a) Use distilled or deionized water at room temperature for cleaning.

8.3.1.2 Manual disinfection steps:

1. Soak a clean, soft cloth with 75% alcohol.
2. Wipe all surfaces of the handpiece, charger, base, and other components with the soaked cloth for at least 3 minutes.
3. Dry the components with a soft, lint-free cloth.

Notes:

a) The cleaning and disinfection must be performed within 10min before use.
b) Disinfectants must be applied immediately after preparation and should not produce foam.
c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.
d) After cleaning and disinfecting the handpiece, you must install a disposable isolation sleeve before use and repeat steps 1, 2 and 3 to clean the disposable isolation sleeve (For detailed installation steps, see section 2.5).

8.3.2 Post-op processing

After each use, clean and disinfect the handpiece, charger, and base within 30 minutes. The specific steps are as follows:

Tools: Nap-free soft cloth, tray

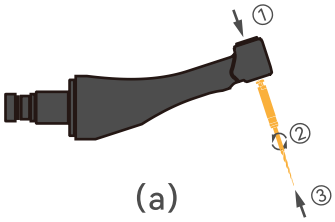
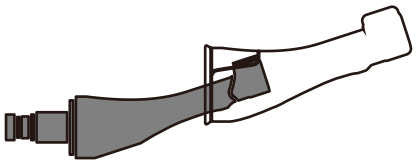
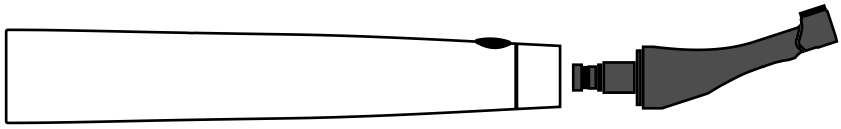
1. Remove the contra-angle from the handpiece, place it in a clean tray, and then remove the disposable isolation sleeve from the handpiece.
2. Soak the nap-free soft cloth with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece,
charger, base, etc. until the surface of the component is not stained.
3. Wet the dry soft cloth with 75% alcohol, and then wipe all surfaces of the handpiece, charger, base and other components for 3 minutes.
4. Put the handpiece, charger, base and other components back into the clean storage area.

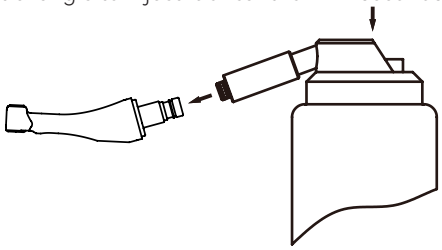
Note:

a) The cleaning and disinfection must be performed within 10min before use.
b) The disinfectant used must be used immediately, no foaming is allowed.
c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

8.4 The cleaning, disinfection, and sterilization of the contra-angle, lip hook, file clip, protective silicone cover, and touch probe are described in this section. Unless otherwise stated, they will hereinafter be referred to as “products”.

Warnings	The use of strong detergents and disinfectants (alkaline pH > 9 or acidic pH < 5) will shorten the product lifespan. In such cases, the manufacturer assumes no responsibility.
Resistance to sterilization procedures	These products have been designed to withstand a high number of sterilization cycles. The materials used in their manufacture were selected accordingly. However, with each repeated preparation, thermal and chemical stress may cause product aging. The maximum number of sterilization cycles is 900.
Preparation at the point of use	The post-operative process must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows: Remove the shanks/files and disconnect the contra-angle from the motor handpiece. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don’t use hot water (>40°C), as this can cause the fixation of residues which may affect reprocessing outcomes.
Transportation	The products should be safely stored and transported to the point of reprocessing to avoid any damage and environmental pollution.

Preparation for reprocessing	The products must be reprocessed in a disassembled state. a) Press the push button and pull out the shank/file. b) When removing the protective silicone cover, pull it straight out slowly. c) When inserting and removing the contra-angle, ensure the handpiece is powered off beforehand. Disassembling steps  (a)  (b)  (c)
Pre-cleaning	Tools: tray, soft brush, clean and dry soft cloth Perform manual pre-cleaning until the handpiece is visibly clean. Rinse the bur chuck under running water for at least 10 seconds. Clean the surface with a soft-bristle brush. Note: The water temperature should not exceed 40℃ during washing; otherwise, proteins may coagulate and become difficult to remove.
Cleaning	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automatic cleaning The washer-disinfector should meet the requirements of the ISO 15883. Place the products in the washer-disinfector carefully. Ensure that products cannot move freely in the washer-disinfector. Contra-angles must not come into contact with one another. Start the program: • 4min pre-washing with cold water (<40℃); • Emptying • 5min washing with a mild alkaline cleaner at 55℃; • Emptying • 3min neutralizing with warm water (>40℃); • Emptying • 5min intermediate rinsing with warm water (>40℃); • Emptying • Drying the device at 80℃ for 15min The automated cleaning processes have been validated using 0.5% neodisher MediClean forte (Dr. Weigert)
Disinfection	Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see Disinfection EN 15883). A 5-minute disinfection cycle at 93℃ has been validated for this device to achieve an A_0 value of 3000.

Drying	Drying of outside of instrument through drying cycle of washer disinfector. If necessary, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air. If your washer-disinfector does not have an automatic drying function, please dry the device after cleaning and disinfection. The drying method is as follows: 1) Spread a clean white sheet of paper (or white cloth) on the flat table. Place the products on it, and then dry the contra-angle with filtered, dry compressed air (maximum pressure: 3 bar). When no liquid is sprayed on the white paper (or white cloth), it indicates that the products are completely dry. 2) The products can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80 ℃ and the time should be 15minutes. Notes: 1) Dry the products repeatedly if necessary (refer to section “Drying”). 2) The air used for drying must be filtered by HEPA. 3) The products should be dried in a clean area.
Maintenance	1. Functional test and visual inspection Visually inspect the cleanliness of the handpiece. Perform functional test according to instructions for use. If there are still visible stains on the device after cleaning, the entire cleaning process must be repeated. Before packaging and sterilization, make sure that the contra-angle has been maintained according to manufacturer’s instructions. If the device is obviously damaged, smashed, detached, corroded or bent, it must be discarded and must not be used again. If any accessory is found to be damaged, please replace it before use. The new accessories for replacement must be cleaned, disinfected and dried. 2. Use lubricant to lubricate the handpiece and dry it prior to sterilization. Aim the nozzle of lubricant bottle to the air hole at the end of the contra-angle to inject lubricant for 1-2 seconds. 
Packaging	The products should be promptly packaged in a medical sterilization pouch (or a dedicated sterile holder or box). Precautions 1) Use only legally marketed or FDA-cleared sterilization pouches; 2) The packaging environment and related tools must be regularly cleaned to ensure cleanliness and prevent the introduction of contaminants; 3) Avoid direct contact between different metals during packaging.
Sterilization	Sterilize instruments using a fractionated pre-vacuum steam sterilization process (in accordance with EN 285, EN 13060, or EN ISO 17665), while complying with the regulations of the respective country. Minimum requirements: at least 4 min at 132℃/134 ℃ (in EU: 5 min at 134 ℃, in US: 4 min at 132 ℃) Flash sterilization is not allowed on lumen instruments!
Storage	Sterilized products should be stored in a dry, clean and dust-free environment. Refer to the product label and instructions for use for specific storage guidelines.

9 Storage, Maintenance and Transportation

9.1 Storage

9.1.1 The device should be stored in an environment with a relative humidity of 10% ~ 93%, atmospheric pressure of 70 ~ 106 kPa, and a temperature range of −20℃ ~ +55℃.

9.1.2 Avoid storing the device in excessively hot conditions. High temperatures may shorten the lifespan of electronic components, damage the battery, or deform/melt plastic parts.

9.1.3 Avoid storing the device in excessively cold conditions. Otherwise, condensation may form as the device warms to room temperature, potentially damaging the PCB.

9.2 Maintenance

9.2.1 This device does not include user-serviceable parts. Repairs must be performed by authorized personnel or an authorized service center.

9.2.2 Store the device in a dry environment.

9.2.3 Do not drop, hit, or shake the device.
9.2.4 Do not apply pigments, paint, or other substances to the device.

9.3 Transportation

9.3.1 Avoid excessive impact and vibration during transportation. Handle with care and do not place the device upside down.
9.3.2 Do not transport the device together with hazardous materials.
9.3.3 Avoid direct sunlight, rain, or snow exposure during transportation.

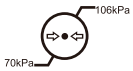
10 Environmental protection

Please dispose of the device under local regulations and environmental laws.

11 After-sales Service

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

12 Symbol Instruction

	A possibly dangerous situation that could result in serious bodily injury		Application instructions and other important information.
	Follow the instructions for use		Indoor use only
	Stand-by		Manufacturer
	Class II equipment		Date of manufacture
	Serial number		Type B applied part
	Do not dispose of the product into the ordinary municipal waste or garbage system		Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Keep dry		Fragile, handle with care
	Recyclable packaging materials		Humidity limitation
	Temperature limitation		Atmospheric pressure for storage
IPX0	Ordinary equipment		CE marked product
	eIFU		Authorised Representative in the EUROPEAN COMMUNITY

13 Statement

All rights to modify the product are reserved by the manufacturer without prior notice. Product images are for reference only. GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. reserves the right of final interpretation. The industrial design, internal structure, and other aspects are protected by patents owned by WOODPECKER. Any unauthorized copying or counterfeiting will be subject to legal liability.

14 Electromagnetic Compatibility

⚠ Warning:
Without the explicit consent of Woodpecker, unauthorized changes or modifications to the device may cause electromagnetic compatibility issues affecting this or other nearby devices.

Special precautions regarding electromagnetic compatibility (EMC) must be observed for this device. Installation and use should follow the EMC information provided in this manual. Portable and mobile radio frequency communication equipment may affect this device. The following cables must be used to meet electromagnetic emission and anti-interference requirements:

Name	Cable length	Shielded?	Remark
Power adapter connecting cable	1.8m	NO	/
Measuring wire	1.6m	NO	/
File clip	0.2m	NO	/

Except for cables (transducers) sold as spare parts of internal components, the use of accessories and cables (transducers) other than those specified may result in increased emission or reduced immunity of the device or system.

The device or system should not be used in close proximity to or stacked with other devices. If such usage is necessary, it must be confirmed that the device operates normally under this configuration.

14.1 Guidance and manufacturer's declaration-electromagnetic emission

Guidance and manufacturer's declaration - electromagnetic emissions		
The Endo Motor and Apex Locator Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Endo Motor and Apex Locator Unit should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment -guidance
RF emissions CISPR 11	Group 1	The Endo Motor and Apex Locator Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR11	Group B	The Endo Motor and Apex Locator Unit is suitable for use 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 IEC 61000-3-2	Group A	
Voltage fluctuation/ flicker emission IEC 61000-3-2	Complies	

14.2 Guidance & declaration - electromagnetic immunity

Guidance & declaration — electromagnetic immunity			
The Endo Motor and Apex Locator Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Endo Motor and Apex Locator Unit should ensure 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV 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	±2kV for power supply 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 kV, ±1 kV line to line	±0.5 kV, ±1 kV line to line	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 IEC 61000-4-11.	0 % U_T, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T, 1 cycle and 70% U_T, 25/30 cycles at 0° 0% U_T, 250/300 cycle	0 % U_T, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T, 1 cycle and 70% U_T, 25/30 cycles at 0° 0% U_T, 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Endo Motor and Apex Locator Unit requires continued operation during power mains interruptions, it is recommended that the Endo Motor and Apex Locator Unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields and proximity magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	CW 8A/m for 30kHz Pluse modulation 2.1kHz, 65A/m for 134.2kHz Pluse modulation 50kHz, 7.5A/m for 13.56MHz.	CW 8A/m for 30kHz Pluse modulation 2.1kHz, 65A/m for 134.2kHz Pluse modulation 50kHz, 7.5A/m for 13.56MHz.	
NOTE U_T is the a.c. mains voltage prior to the application of the test level.			

14.3 Guidance & declaration – electromagnetic immunity concerning conducted RF & radiated RF

Guidance & Declaration – Electromagnetic immunity			
The Endo Motor and Apex Locator Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Endo Motor and Apex Locator Unit should ensure 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	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio bands	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands & amateur radio bands	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Endo Motor and Apex Locator Unit, including cables specified by the manufacturer. Otherwise, performance degradation of this device may occur.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014 + A1:2020)	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014 + A1:2020)	

14.4 Declaration – RF parameter of Bluetooth and Wi-Fi

Declaration – RF parameter of Bluetooth and Wi-Fi				
Types	Frequency band of transmission	Type of Modulation	Frequency characteristics	Effective radiated power
Bluetooth	2402 ~ 2480 MHz	GFSK	2.4G wireless technology	4.87 dBm
Wi-Fi	2412 ~ 2472 MHz	DSSS/ CCK/ BPSK/ QPSK/ 16QAM/ 64QAM	2.4G wireless technology	21.16 dBm

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