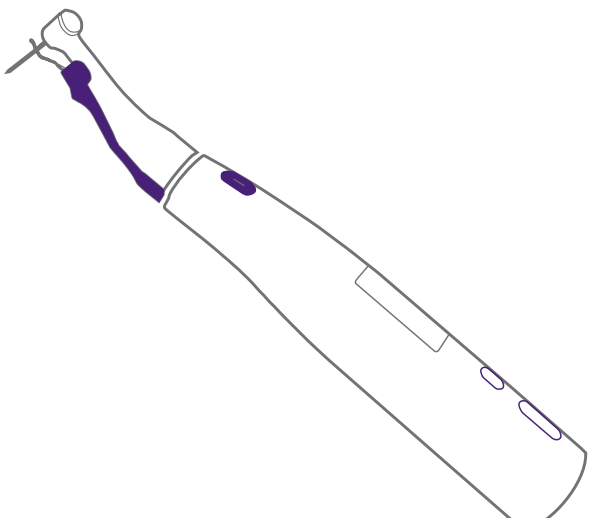
FKG
swiss endo



EN

Rooter® Universal

User Manual

CE 0197

Introduction

Thank you for purchasing the device.
For optimum safety and performance, read this manual thoroughly before using the device and pay close attention to warnings and notes.
Keep this manual in a handy place for quick and easy reference.

Notice

Fig. A Components and Accessories

Motor Handpiece
(08.970.00.001.FK)

Battery Charger
(08.970.00.002.FK)

Tester
(08.970.00.004.FK)

AC Adapter
(08.970.00.003.FK type C)
(08.970.00.014.FK type I)
(08.970.00.015.FK typeG)

Test Wire A
(08.970.00.005.FK)

Test Wire B
(08.970.00.006.FK)

Wrench
(08.970.00.012.FK)

File Clip
(08.970.00.007.FK)

Dust Cap
(08.970.00.016.FK)

Silicone Plug
(08.970.00.017.FK)

Spray Nozzle
(08.970.00.013.FK)

Lip Hook
(08.970.00.008.FK)

Geared Angle Handpiece
(08.970.00.011.FK)

Lightning Device
(08.970.00.009.FK)

Lithium-ion battery
(08.970.00.019.FK)

Protective Sleeve
(08.970.00.010.FK)

Fig. B Handpiece and Switch

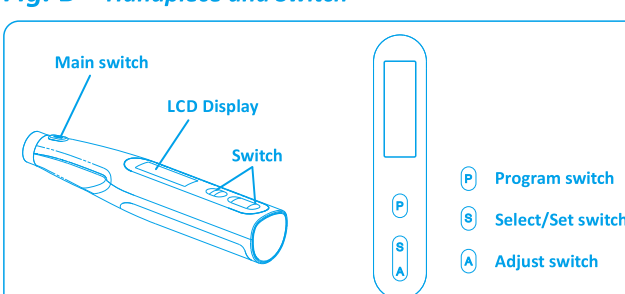


Fig. C Geared Angle Handpiece & File connection

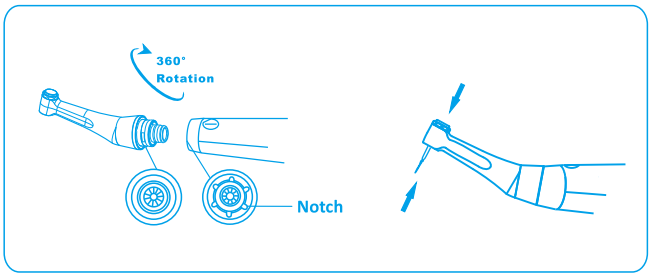


Fig. D Accessory Connection

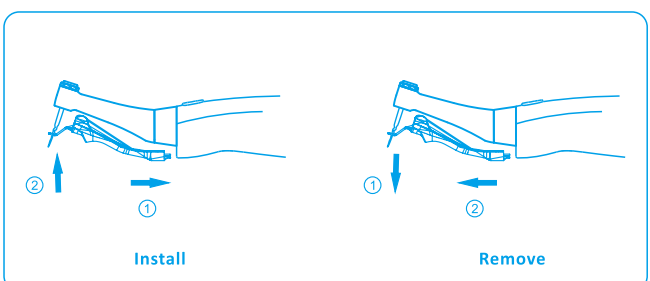


Fig. E *Apex Locator Mode*

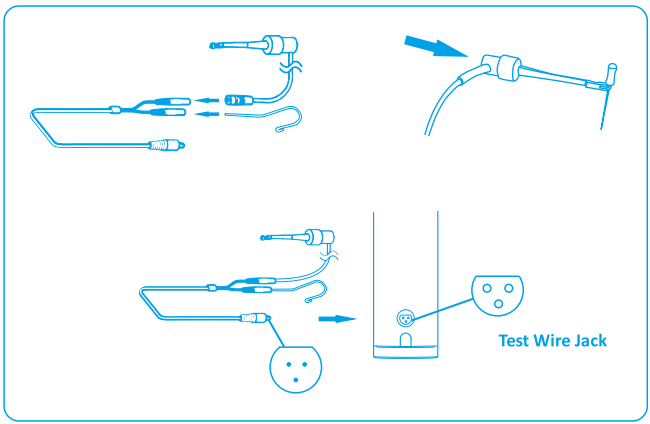


Fig. F *Multi-function Mode*

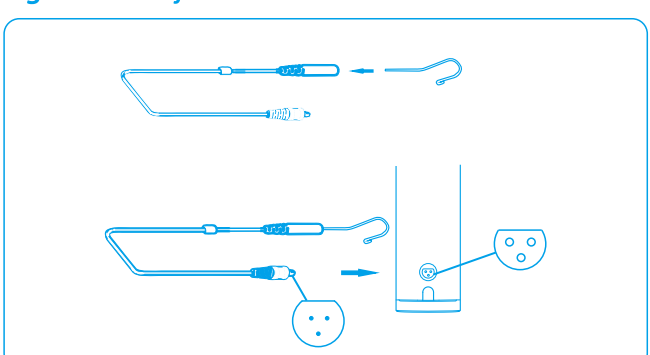


Fig. G Charging

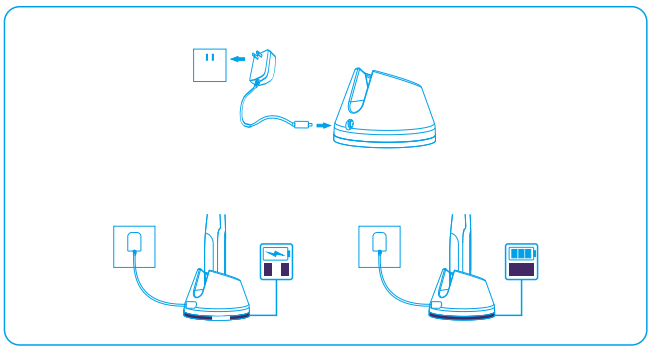


Fig. H Replace the battery

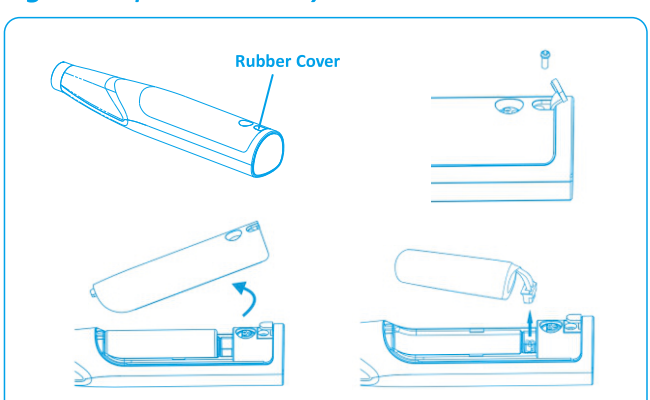


Table of Contents

1. Attention

1.1 Attention Customers

Do not fail to receive clear instructions concerning the various ways to use this device as described in this accompanying Operation Instructions.

1.2 Prevent Accidents

Most operation and maintenance problems result from insufficient attention being paid to basic safety precautions and not being able to foresee the possibilities of accidents.

Problems and accidents are best avoided by foreseeing the possibility of danger and operating the device in accordance with the manufacturer's recommendations.

First, thoroughly read all precautions and device pertaining to safety and accident prevention; then, operate the device with the utmost caution to prevent either damaging the device itself or causing bodily injury.

WARNING:

This alerts the user of possibility of extremely serious injury or complete destruction of the device as well as other property damage including the possibility of fire.

CAUTION:

This alerts the user of possibility of minor or moderate injury or damage to the device.

NOTE:

Informs the user of important points concerning operation or the risk of device damage.

Do not use this device for anything other than its specified dental treatment purpose.

WARNING

No modification of this device allowed.

PROHIBITION

Do not use this device on patients who have implanted pacemakers or defibrillators.

IMPORTANT PRECAUTIONS

These caution remarks are especially critical for safe operation and use.

Do not use the wireless transmission devices listed below in the examination area:

a) Cell phone terminals.

b) Wireless transmitting devices such as ham radios, walkie-talkies, and transceivers.

c) Personal Handy-phone System.

d) Routers for intra-building paging systems, wireless LAN, cordless analogue telephones, and other electric wireless devices.

- This device might be adversely affected by the electromagnetic radiation produced by electrical scalpels, illumination devices etc. that are being used nearby.
- Do not perform maintenance while using the device for treatment.

1.3 Disclaimer

Manufacturer will not be responsible for accidents, device damage, or bodily injury resulting from:

a) Repairs made by personnel not authorized by manufacturer.
b) Any changes, modifications, or alterations of the device.
c) Maintenance or repairs using parts or components other than those specified by manufacturer and other than in their original condition.
d) Operating the device in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being observed.
e) Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
f) Fires, earthquakes, floods, lightning, natural disasters, or acts of God.

1.4 In Case of Accident

If an accident occurs, the device must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.

1.5 User Qualifications

Intended Operator Profile

a) Qualification: Legally qualified person such as dentists for endodontic device operation (it may differs among countries).
b) Education and Knowledge: It is assumed the user is thoroughly familiar with root canal measuring and treatment including the prevention of cross contamination.

c) Language Understanding: English (Intended for professional use as described above)

d) Experience: Experienced person with operating endodontic instrument.

1.6 Intended Use

The Rooter® Universal is an electro-medical device intended to drive mechanical instruments intended for dental root canal treatment (files). In addition, it is intended to help to determine the working length (apex locator functionality).

2. Usage

CAUTION:

- Do not expose the device to direct sunlight for an extended period of time.
- If the device has not been used for some time, make sure it works properly before using it again.
- Refer to the geared angle handpiece operation manual for all operations regarding the geared angle handpiece

2.1 Operation and Storage Environments

Operating Temperature: +5°C to +40 °C

Humidity: 20% to 80% (without condensation)

Atmospheric Pressure: 86 kPa to 106 kPa

Transport and Storage Temperature: -10 °C to +55 °C

Humidity: ⩽ 93% (without condensation)

Atmospheric pressure: 50 kPa to 106 kPa

2.2 Operation Modes

The device has 3 modes:

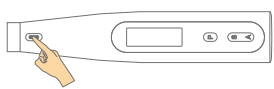
Endo motor: *Prepare the root canal, without apex locator function.*

Apex Locator: *Measure the length of the root canal, without motor function.*

Multi-function: *Measuring the length while root canal preparation.*

2.3 Power On/Off

Hold down ⊖ to turn power on/off.



⚠ **CAUTION:**

- Have components been sterilized? (**Refer to chapter 7**)
- Is the battery sufficiently charged? (**Refer to chapter 5.1**)

2.4 Endo Motor Mode

If not any test wire connected to the device, it's in Endo Motor Mode.

Please refer to Fig. C, D

2.4.1 Connect the Components

a) Connect geared angle handpiece

Line up the projection inside the geared angle handpiece with the notch inside the motor and slide it in until it clicks securely into place.

b) Connect file

Hold down the push button on the geared angle handpiece and insert the file. Turn the file back and force until it is lined up with interior latch groove and slips into place. Release the button to lock the file into the geared angle handpiece

c) Connect lighting device

Insert the lighting device into the motor handpiece and clip the electrode on the file.

WARNING:

- Make sure the connection ends of the motor handpiece and th geared angle handpiece is not damaged. If these are damaged, the load on the geared angle handpiece could cause the motor to reverse rotation, and this might result in an injury to the oral cavity.
- Files are expendable, and they eventually wear out. Replace them before they break.
- Never use stretched, deformed or damaged files.
- Make sure the file is all the way in. Give the file a light tug to confirm it is securely held in place. If the file is not securely placed, it could come out and injure the patient.

CAUTION:

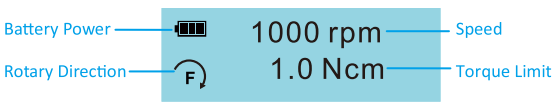
- Be careful when inserting and removing files to avoid injury to fingers.
- Inserting and removing files without holding the push button may damage the chuck.
- When installing/removing the lighting device, do not shake them at will to avoid damaging the plug.
- Take care not to touch  when installing or removing the file. This will cause the file to rotate.

NOTE:

Hold down the push button on the contra angle and pull the file straight out.

2.4.2 LCD Display

Standby 1

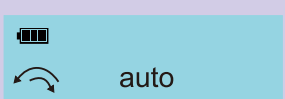


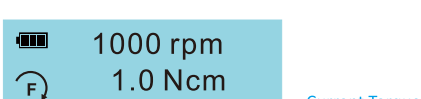
Standby 2

NOTE:

Some preset files have automatic parameters.

If such a file has been selected, the speed and torque value will display "auto".





Working

2.4.3 File systems libraries

The device contains libraries of file systems with preset parameters.

a) Hold down (P) to enter selection interface and press (P) again to select the file systems library

NOTE:

The change will be saved automatically. Press (S) or (A) to exit the selection interface.

b) Press (P) to choose the file system.

c) Press (S) to choose the file.

WARNING:

- Follow the file manufacturer's instructions for use of endodontic files. Do not use files designed for reciprocating motion in Continuous Rotary File Mode.
- The file system shown on the display must always match the file in use.

2.4.4 Start Working

a) Start Motor

Press ⊖ to start the motor handpiece and press again to stop it.

The lighting device will continue to illuminate while the motor handpiece is running.

WARNING:

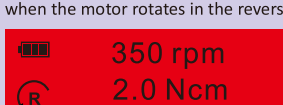
If the geared angle handpiece 's file release button is pressed against the teeth opposite the one being treated, the file could come out and injure the patient. Before use, run the device outside the oral cavity to make sure it is operating normally.

b) Change Motor direction of rotation

Only in User file systems, press (A) to change the motor direction of rotation.

NOTE:

The screen is red when the motor rotates in the reverse direction.

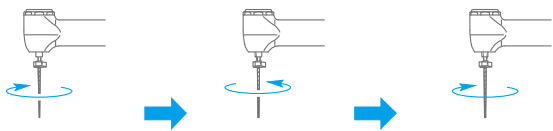


F Means forward rotation

R Means reverse rotation

2.4.5 Auto Reverse

If, during operation the load reaches the preset torque limit value, the motor handpiece will automatically rotate in the reverse direction. When the load is reduced, the motor handpiece returns to normal forward rotation automatically.



Load within the torque limit value

Load beyond the torque limit value

When the load is reduced, the motor is automatically restored

CAUTION:

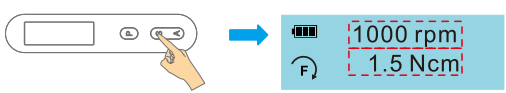
- Do not apply excessive force. Even when using the torque reverse function, files may break depending on the torque setting.
- The Auto Reverse function is not available when the motor rotates in the reverse direction.

2.4.6 Change Speed and Torque

CAUTION:

- While the motor handpiece is in motion, speed and torque cannot be changed;
- In User Recipro File system, speed and torque cannot be changed.
- In all FKG file systems, rotation direction, speed, torque and rotation angle cannot be changed. (fixed settings)
- In User Rotary File reverse direction, the torque limit is not activated.

a) Hold down (S) until the Speed flash and press (S) again to select speed or torque to adjust.

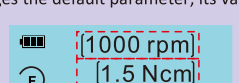


b) Press (A) to adjust desired value.

c) The change will be saved automatically. Press (P) to exit the setting, or exit the setting automatically after a few seconds.

NOTE:

When the user changes the default parameter, its value will prompt [ ].



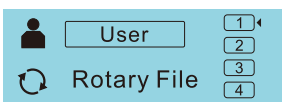
2.4.7 User library file systems

The device contains two user-created file systems: **Rotary File** and **Recipro File**. Users can set parameters by themselves.

a) Rotary File

(4 memories preset at original default settings: 1000rpm FW 1.5Ncm)

To change speed and torque refer to 2.4.6



b) Recipro File

(1 memory preset at original default settings: +30°/-150° 150rpm)

speed and rotation angle.

To change rotation angle, follow the next step:

a) Hold down (S) until the Rotation angle flash.

b) Press (A) to adjust desired value.

2.5 Apex Locator Mode

While the test wire A is connected to the motor handpiece, the device enters the Apex Locator Mode automatically. Please refer to Fig. E

2.5.1 Connect the Components

a) Connect lip hook and file clip

b) Connect file

c) Connect test wire A

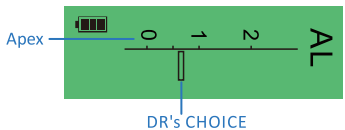
CAUTION:

- When clipping the file clip onto the metal part of a file or reamer, clip the file clip onto the metal shaft near the handle. Do not clip it onto the cutting part or transition part of the file or reamer. This will cause the file clip to wear out very quickly.
- Do not bang or bump the plugs when they are inserted.
- Make sure the plug is all the way in. Otherwise canal measurements cannot be made.
- Do not wind the probe cord around the device.

NOTE:

To measure a root canal, use a file or reamer with a plastic handle. If you do not wear gloves, do not use a file with a metal handle. Current leakage from a metal handle to your fingers will prevent an accurate measurement. Do not use damaged or worn file clip, otherwise accurate measurements cannot be made.

2.5.2 LCD Display



2.5.3 Measurement

a) Hook the lip hook in the corner of the patient's mouth.

WARNING:

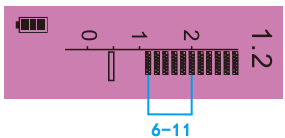
- Never use an electric scalpel when the lip hook is hooked in the patient's mouth. These devices emit electrical noise that could interfere with accurate measurement or cause the device to malfunction.
- Make sure that the lip hook, file clip and their connectors do not come into contact with an electric power source such as a power outlet. This will result in an electric shock.
- If connections are not securely plugged in the device may not make an accurate measurement. If the meter does not change as the file goes down the canal, stop using the device immediately and make sure all the connectors are securely inserted.

CAUTION:

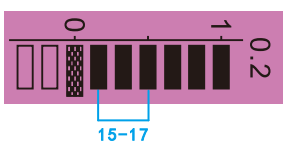
- The lip hook could cause an adverse reaction if the patient has an allergy to metals. Ask the patient about this before using the lip hook.
- Take care that medicinal solutions such as formalin cresol or sodium hypochlorite do not get on the lip hook or the file clip. These could cause an adverse reaction such as inflammation.

b) Slowly insert the measuring file into the canal.

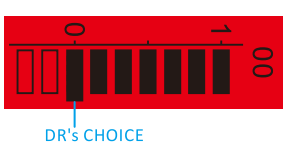
Bar in meter show the location of the file tip. The color of the display:



There is slow beeping sound between bars 6-11.



There is fast beeping sound between bars 15-17.



A sustained beep sounds when the file tip reaches or exceeds the DR's CHOICE.

WARNING:

- In some cases such as a blocked root canal, a measurement cannot be made. **(Refer to chapter 3)**
- Accurate measurement is not always possible, especially in cases of abnormal or unusual root canal morphology. Make sure to take an X-ray to check the results.
- Stop using the device immediately if it does not seem to be working properly.
- If the canal length indicator bar does not appear even when the file is inserted, the device may be malfunctioning and must not be used.

CAUTION :

- If the canal is too dry, the meter may not move until the file is near the apex. If the meter does not move, stop the measurement. Moisten the canal with oxydol (hydrogen peroxide) or saline, and then try measuring again.
- Occasionally the meter will make a sudden and large movement as soon as the file is inserted into the root canal, but it will return to normal as the file is advanced down towards the apex.
- After measuring the root canal, make sure to take an X-ray to check the measurement results.
- The numerals 1, 2, and 3 do not represent length in millimeters from the apical. These numbers are used to estimate the canal's working length.

2.5.4 Set the DR's CHOICE

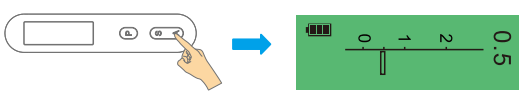
This feature enables to mark an individual predetermined reference position at the required distance from the apex.

When DR's CHOICE apical arrow is set, clear visual and audio indication is given that the file has reached this pre-selected position.

To set the DR's CHOICE, follow the next step:

Hold down (S) until the apex setting icon flash.

Press (A) to adjust the apex position.



NOTE:

- The apex position set by the user will be saved automatically. Exit the setting automatically after a few second.
- The DR's CHOICE is preset at 0.5 by default.

2.6 Multi-function Mode

While the test wire B is connected to the motor handpiece, the device enters the Multi-function Mode automatically. Please refer to Fig. C, D, F

2.6.1 Connect the Components

a) Connect lip hook

b) Connect test wire B

c) Connect geared angle handpiece and file.

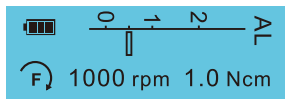
d) Connect lighting device

CAUTION:

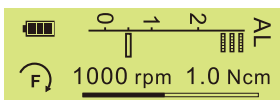
- Do not bang or bump the plugs when they are inserted.
- Make sure the plug is all the way in. Otherwise canal measurements cannot be made.
- Do not wind the probe cord around the device.
- Always clip the electrode on the file when using it. Otherwise, measurements may not be accurate or rotation may not be properly controlled. (It may not be possible to measure a canal if blood or some other liquid overflows the canal or if the canal is completely blocked.)

2.6.2 LCD Display

Standby 1



Standby 2



Working

2.6.3 File systems library **(Refer to chapter 2.4.3)**

2.6.4 Start Working **(Refer to chapter 2.4.4)**

2.6.5 Auto Reverse and Apical functions

NOTE:

Auto Reverse function (Refer to Chapter 2.4.5)

Apex Rev function and Apex Slow function (Refer to Chapters 6.6 and 6.7)

2.6.6 Set the DR's CHOICE and Change Speed and Torque

Hold down (S) can change the DR's CHOICE, Speed and Torque.

Press (S) again to choose the DR's CHOICE, Speed or Torque to change.

a) Set the DR's CHOICE

Press (A) to adjust the apex position.

b) Change Speed and Torque **(Refer to chapter 2.4.6)**

3. EMR (Electric Measurement of Root canal length)

Accurate measurement cannot be obtained with the root canal conditions shown below.

Root canal with a large apical foramen

Root canal that has an exceptionally large apical foramen due to a lesion or incomplete development cannot be accurately measured. The results may show shorter measurement than the actual length.

Root canal with blood overflowing from the opening

If blood overflows from the opening of the root canal and contacts the gums, this will result in electrical leakage and an accurate measurement cannot be obtained. Wait for bleeding to stop completely. Clean the inside and opening of the canal thoroughly to get rid of all blood, and then make a measurement.

Root canal with a chemical solution overflowing from the opening

An accurate measurement cannot be obtained if some chemical solution is overflowing from the canal opening. In this case, clean the canal and its opening. It is important to get rid of any solution overflowing the opening.

Broken crown

If the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, contact between the gingival tissue and the file will result in electrical leakage and an accurate measurement cannot be obtained. In this case, build up the tooth with a suitable material to insulate the gingival tissue.

Fractured tooth

Leakage through a branch canal

Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.

A branch canal will also cause electrical leakage.

Re-treatment of a root filled with gutta-percha

The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, pass a small file all the way through the apical foramen and then put a little saline in the canal, but do not let it overflow the canal opening.

Crown or metal prosthesis touching gingival tissue

Accurate measurement cannot be obtained if the file touches a metal prosthesis that is touching gingival tissue. In this case, widen the opening at the top of the crown so that the file will not touch the metal prosthesis before taking a measurement.

Cutting debris on tooth

Pulp inside canal

Thoroughly remove all cutting debris on the tooth.

Thoroughly remove all the pulp inside the canal. Otherwise an accurate measurement cannot be obtained.

Caries touching the gums

In this case, electrical leakage through the caries infected area to the gums will make it impossible to obtain an accurate measurement.

Blocked canal

The meter will not move if the canal is blocked.

Open the canal all the way to the apical constriction to measure it.

Extremely dry canal

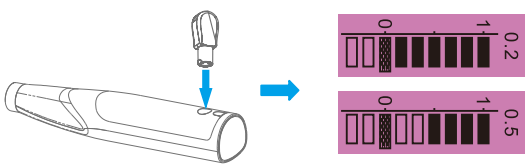
If the canal is extremely dry, the meter may not move until it is quite close to the apex. In this case, try moistening the canal with oxydol or saline.

4. Operation Check

4.1 Check with Tester

a) Connect the tester to the test wire jack on the back of the motor handpiece.

b) Check that the canal length indicator bars light up between number 0.2 and number 0.5.



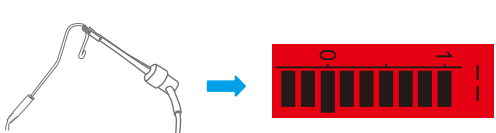
WARNING:

If the canal length indicator bars does not light up between number 0.2 and number 0.5, an accurate measurement cannot be made. In this case, stop using the device immediately and have it repaired.

4.2 Check Canal Measurement Function

a) Check Test Wire A

Touch the lip hook with the clip on the end of the file clip and check that all the flash bars on the meter in the LCD display light up.



b) Check Test Wire B

Touch the lip hook with the file in the geared angle handpiece and check that all the bars on the meter in the display light up.

WARNING:

Check the device's function before use with each patient. If all the indicator bars do not light up, an accurate measurement cannot be made. In this case, stop using the device immediately and have it repaired.

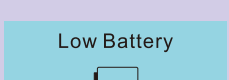
5. Battery and Charging

5.1 Battery Power

The number of bars shows how much power is left.

NOTE:

The display of low voltage:



Charge the battery as soon as the indicator gets down to only one bar.

5.2 Battery Charging

Please refer to Fig. G

a) Plug the DC end of the adapter cable all the way into the charger, and plug the other end into a power outlet.

NOTE:

The battery is inside the motor handpiece.

WARNING:

- Always use the adapter that comes with the device. Using another adapter can result in electric shocks, malfunctions, fires, etc.
- The charger and its adapter must be located at least 2 meters away from the patient.
- Do not use the battery charger for any other device than the motor handpiece.

b) Put the handpiece all the way into the battery charger. The Ready LED (steady still purple) will go out and the Charge LED (purple) will flash and start charging.

c) When the battery is fully charged, the Charge LED (pulsating purple) goes out and the Ready LED (steady still purple) will light up.

WARNING:

- Do not touch the AC adapter if there is lightening while the battery is being charged. This will result in an electric shock.
- Do not use the battery charger in a place where it might get wet.

CAUTION:

Do not charge the handpiece with the probe cord connected or wrapped around the handpiece. This could break a wire inside the cord or damage the jack.

NOTE:

- If the Charge LED (purple) goes off immediately or doesn't light up when the handpiece is put into the charger, the battery is already fully charged. To make sure, take the handpiece out and put it back in again.
- Do not leave the battery charger where it will be exposed to direct sunlight.
- Unplug the battery charger when it is not being used.

5.3 Replacement Battery

Please refer to Fig. H

Replace the battery if it seems to be running out of power sooner than it should.

a) Turn the power off

b) Use tweezers to open the rubber cover and then remove the screw.

c) Remove the battery cover as shown in the illustration.

d) Remove the old battery and disconnect the connector.

e) Connect the new battery and put it in the motor handpiece.

f) Install the cover and its screw.

CAUTION:

- Use only battery designed for the motor handpiece. Other batteries could cause overheating.
- Do not use a battery if it is leaking, deformed, discolored or if its label is peeled off. It might overheat.

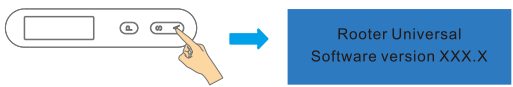
NOTE:

- Do not leave the power on when disconnecting the battery.
- Open the rubber cover carefully. Don't pull too hard. It might come off the motor handpiece.
- Do not remove the battery cover if the handpiece is wet.
- Do not tighten the cover screw too much. This could strip the threads.
- Dispose of old batteries in an environmentally safe way and in strict according to local regulations.

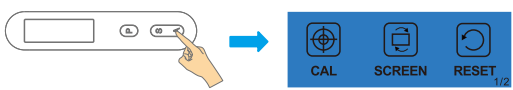
6. Calibration and Settings

6.1 Enter Setting Mode

a) Hold down (A) to enter setting mode



b) Press (A) again to enter setting interface.



c) Press (A) again to choose the function you need to set.

6.2 Calibration

a) Press (A) to choose the calibration function.

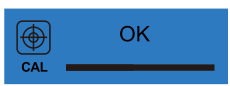
b) Press (S) to start the calibration process.

NOTE:

Press (S) again to continue or press any other key to exit.

c) During the calibration process, the motor handpiece begins to rotate.

d) When the calibration process is completed, the rotation stops.



Display shows OK, indicates that the device function is normal.

Display shows NG, indicates that there is a fault.

CAUTION:

- NG message indicate that the device is not operating properly. Please contact your local dealer or contact the factory directly for assistance.
- Do not touch the file or apply pressure to the motor handpiece, otherwise the calibration will fail.

6.3 Set Dominant Hand

This will rotate the display direction 180°.

Set this for right or left depending on the user's dominant hand.

a) Press (A) to choose the screen function.

b) Press (S) to start the process.

NOTE:

Press (S) again to continue or press any other key to exit.

c) This will rotate the display direction 180° when (S) has been pressed.

6.4 Reset Memories to Original Default Settings

NOTE:

All memories and handpiece settings will revert to their original default settings.

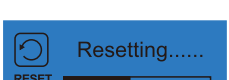
a) Press (A) to choose the reset function.

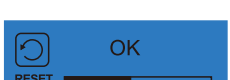
b) Press (S) to start the reset process.

NOTE:

Press (S) again to continue or press any other key to exit.

c) The reset process is completed.

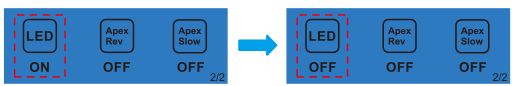




6.5 LED function (for endo motor and multi-function modes)

By default, the lighting device automatically lights up when the motor starts running.

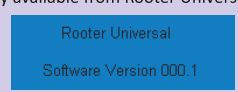
a)Press (A) to choose LED function and then press (S) to turn it ON/OFF;



b)Press (P) to exit and then press ( ) on motor handpiece to start working.

NOTE:

- The setting will be automatically saved.
- This function is only available from Rooter Universal software version 000.1.



6.6 Apex Rev function (for multi-function mode)

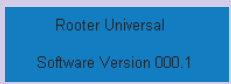
The Apex Rev function applies when the file reaches the user-defined apex position (DR's CHOICE).
The motor automatically reverses the rotation direction when the file reaches the DR's CHOICE. The motor goes back automatically to initial rotation direction when the file is pulled away from the DR's CHOICE.

a)Press (A) to choose Apex Rev function and then press (S) to turn it ON/OFF;

b)Press (P) to exit and then press ( ) on motor handpiece to start working.

NOTE:

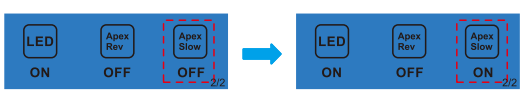
- When motor reverses, screen turns red and alert by sound.
- The Apex Rev function is available for CW (clockwise) continuous rotation mode only.
- The setting will be automatically saved.
- This function is only available from Rooter Universal software version 000.1.



6.7 Apex Slow function (for multi-function mode)

When the Apex Slow function is activated, if the file reaches apex position "1", the motor speed will automatically slow down.

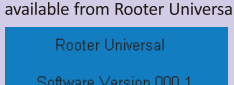
a)Press (A) to choose Apex Slow function and then press (S) to turn it ON/OFF;



b)Press (P) to exit and then press ( ) on motor handpiece to start working.

NOTE:

- When file reaches "1", screen turns purple, when it exceeds "0", it will turns red.
- This function is not available with R-Motion and Recipro File programs.
- The setting will be automatically saved.
- This function is only available from Rooter Universal software version 000.1.



7. Cleaning, Disinfection and Sterilization

NOTE:

Cleaning, disinfection, and sterilization have limited impact on the reusable part of the motor handpiece. Therefore, the number of times the procedure is repeated is determined by the degree of wear of the part. If visual inspection reveals damaged parts, stop using them and purchase new parts from the manufacturer or dealer.

CAUTION:

- Refer to the geared angle handpiece operation manual for all operations regarding the geared angle handpiece.

7.1 Preparation after Using

Immediately after use, the reusable parts should be immersed in tap water <40 ° C (The quality of drinking water, the 'water' mentioned in this chapter, is required to meet this standard.) to remove dirt. Do not use a fixed detergent or warm water (>40 °C), as this will cause the residue to be fixed and affect the post-treatment effect.

Transportation: Transport to the post-processing area for safe storage to avoid any damage and environmental pollution.

7.2 Preparation before Cleaning

a)Disassemble the Lip Hook, File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece and place them in a stainless steel box.

b)Decontamination preparation(pre-cleaning) flush the Lip Hook, File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece with running tap water <40°C until all visible residue is removed.

7.3 Manual Cleaning

a) Rinsing the Lip Hook, File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece in flowing tap water (<40°C)

b) After cleaning, wipe off remaining liquid with a lint-free cotton cloth, and then dry with compressed air (1-2 Bar).

WARNING:

Do not put the Lip Hook, File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece into the disinfectant container to soak. Because the remaining liquid may corrode internal parts.

7.4 Manual Disinfection

Place the lint-free cotton cloth in a container filled with LIRCON® medical device cleaning solution (metal type), wring it out and wipe the Test Wire, Lip Hoop, File Clip, Protective Sleeve, Lighting device and Geared Angle Handpiece at least 3 times.

It is recommended to use the medical device cleaning solution (metal type) of LIRCON®, which with an effective chlorine content of 1.0%-1.2% (W/V).

WARNING:

Do not put the Lip Hook, File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece into the disinfectant container to soak. Because the remaining liquid may corrode internal parts.

CAUTION:

If you want to use other disinfectant, use a disinfectant that complies with local national regulations (such as CE certification, FDA certification), and follow the instructions provided by the disinfectant manufacturer.

7.5 Automatic Cleaning and Disinfection

It is recommended to use a washer-disinfector to clean and disinfect Lip Hook, File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece.

Put Lip Hook, File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece on the tray of the washer-disinfector, select the “surgical instrument”, and start the automatic cleaning.

Cleaning and disinfection procedure:

a) Pre-cleaning: Pre-clean with tap water less than 40 ° C for 4 minutes

b) Cleaning: Immerse and wash with a multi-enzyme cleaner for 6 minutes at 55 °C

c) Rinse stage I: Flush with tap water less than 40 ° C for 1 minute

d) Rinse stage II: Flush with tap water less than 40 ° C for 1 minute

e) Disinfection: The temperature is 80 °C and the action time is 10 min

f) Drying: The temperature is 100 °C and the action time is 15 min

CAUTION:

- The user must follow the special instructions of the manufacturer of the fully automatic washing machine. In order to ensure the cleaning and disinfection effect, the cleaning and disinfection time should not be less than the time recommended by the manufacturer.
- We recommend the use of proven LIRCON® multi-enzyme cleaning solution or multi-enzyme cleaning solution that complies with local regulations (e.g. CE, FDA approval).
- Please use a washer-disinfector that meets the requirements of ISO 15883.
- Considering that some countries have different requirements for A0 values, please refer to ISO 15883 for temperature and time of disinfection.

7.6 Drying

Manual drying: Removing any liquid residue with a lint-free cotton cloth, and then blow dry with compressed air (1-2 Bar).

Automatic drying: Refer to chapter 7.5 f)

7.7 Inspection and Maintenance

After cleaning and disinfection, visually inspect the File Clip, Protective Sleeve, Lighting Device and Geared Angle Handpiece have been cleaned. If damage is found by visual inspection, stop using it and purchase damaged parts from the manufacturer or dealer.

7.8 Package

Immediately after drying, put the Lip Hook, File Clip, Protective Sleeve, Lighting device and Geared Angle Handpiece into the steam sterilization bag for sealed packaging.

CAUTION:

Steam sterilization bag should comply with ISO 11607-1 and must be sealed with a sealing machine.

7.9 Sterilization

Use a high pressure steam sterilizer in accordance with ISO 17665-1 for sterilization.

a) Sterilization parts: The Lip Hook, File Clip,Protective Sleeve, geared angle handpiece and Lighting device.

b) Sterilization method: Autoclave

c) Sterilization conditions: 134 °C for not less than 5 minutes

CAUTION:

Keep the accessories in a dry, dust-free environment after sterilization.

7.10 Storage

Store the sterilizing equipment in a dry, clean and dust-free environment at a suitable temperature of 5 ° C to 40 ° C.

8. Troubleshooting

Problem	Cause	Solution
Cannot turn on the power	The battery is low	Please charge in time
	Battery failure	Replace the battery
Cannot charge the battery	The adapter is not reliably connected	Check that the adapter connection is reliable
	Battery failure	Replacement battery
The battery is running out quickly	The charging time for the battery is too short	Charging time for more than 5 hours
	Battery aging	Replacement battery
Apex locator imprecise/ not sensitive	Test wire connection unreliable	Reconnect the test wire or you can contact the file clip to lip hook directly to check the connection status
	The test wire has an open circuit or a short circuit	Replace test wire
	The root canal is in poor condition	**Refer to chapter 3**
Cannot start the motor/ motor does not work	Low voltage protection	Please charge in time
	Geared angle handpiece stuck	Clean or replace the geared angle handpiece
When the motor is running, the torque value is high	Geared angle handpiece wear,resistance becomes larger	Enter the setup mode and run the calibration procedure. If the calibration fails, replace the geared angle handpiece

9. Technical Specifications

Classification	Safety according to IEC 60601-1, IEC 60601-1-2 European Directive 93/42/EEC IIa
Degree of Protection (IEC 60529)	IPX0

Motor Handpiece	
Free running speed	150 to 1000rpm
Rated Torque	min.0.6 Ncm, max.3.5 Ncm
Degree of Protection against Electric Shock	Type B applied part
Battery	Lithium ion battery (DC 3.7V)

Battery Charger	
Rated Input Voltage	DC 10V
Rated Input Current	1.5 A

AC Adapter	
Rated Input Voltage	AC 100 - 240 V
Rated Input Frequency	50-60 Hz
Classification of Protection against Electric Shock	Class II

10. Symbols

	Warning		Note
	Caution	LOT	Lot number
	Manufacturer	SN	Serial number
	Temperature limit		Avoid the sun
	Type B applied part		Keep dry
CE	CE marked product		Atmospheric pressure limit
	Humidity limit		Fragile
	Vertical up		Class II product
	DC current (continuous current)	EC REP	Authorized representative in the European community
	Thermo-Disinfector		Autoclave
	Special disposal of waste electrical and electronic equipment (Directive2002/96/EEC)		Refer to the operation manual

11. Guarantee

Product and technical services are in charge of our company, the technical department will provide technical support for you when there are technical problems.

The motor handpiece (geared angle handpiece and battery are not included) and battery charger are guaranteed for 24 months from the date of purchase.

The geared angle handpiece is guaranteed for 12 months from the date of purchase.

The accessories are guaranteed for 6 months from the date of purchase.

The guarantee is valid for normal usage conditions. Any modification or accidental damage will render the guarantee void.

12. Disposal of Medical Devices

In accordance with the principles, standards and requirement of the country(region) in which you are located, dispose of the old electrical equipment. Ensure that pollution are not produced in the process of waste disposal.

13. Guidance and manufacturer's declaration--EMC:

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this instrument can be affected by portable and mobile RF communications equipment.

Caution:

Do not use a mobile phone or other devices that emit electromagnetic fields, near the instrument. This may result in incorrect operation of the instrument.

This instrument has been thoroughly tested and inspected to assure proper performance and operation!

This instrument should not be used adjacent to or stacked with other instrument and that if adjacent or stacked use is necessary, this instrument should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission		
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the instrument should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The instrument use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The instrument is suitable for use in all establishments, including domestic establishments directly connected to the public low-voltage power supply network with specific requirement.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of instrument 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	±8 kV contact ±4 kV, ±8kV,±15 kV air	±8 kV contact ±4 kV, ±8kV,±15 kV air	Floors should be wood, concrete or ceramic tile. If floor 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 ±1 kV for input/ output lines	±2kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2 kV common mode	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2 kV common mode	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	100 % U_T (100% dip in U_T.) for 0.5 cycle 100 % U_T (100% dip in U_T.) for 1 cycle 30 % U_T (70% dip in U_T.) for 25/30 cycles 100 % U_T (100% dip in U_T.) for 250/300 cycle	100 % U_T (100% dip in U_T.) for 0.5 cycle 100 % U_T (100% dip in U_T.) for 1 cycle 30 % U_T (70% dip in U_T.) for 25/30 cycles 100 %U_T (100% dip in U_T.) for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model instrument requires continued operation during power mains interruptions, it is recommended that the instrument be powered from a unit eruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The instrument is intended for use in the electromagnetic environment specified below. The customer or the user of instrument should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM ban 3 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM ban 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2xP^{1/2}$ $d=1.2xP^{1/2}$ 80 MHz to 800 MHz $d=1.2xP^{1/2}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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:
Radiated RF IEC 61000-4-3	385MHz- 5785MHz Test specifications for ENCLOSUREPORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz- 5785MHz Test specifications for ENCLOSUREPORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	

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 instrument is used exceeds the applicable RF compliance level above, the instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the instrument.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the instrument.

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d=1.2xP^{1/2}$	80 Mhz to 800 MHZ $d=1.2xP^{1/2}$	80 MHz to 800 Mhz $d=2.3xP^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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) according 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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