Eighteeth

CE
0197

E-PEX

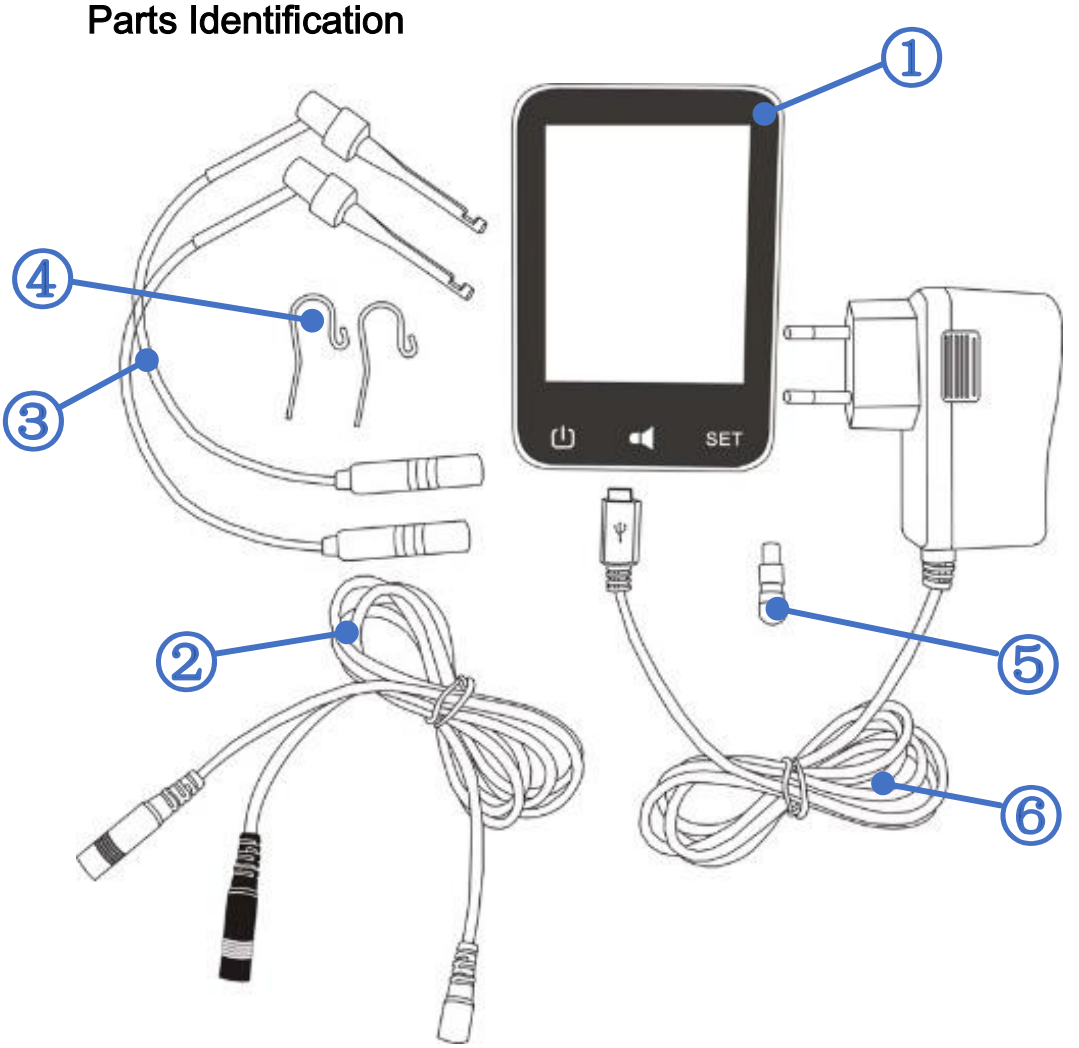
USER MANUAL

P/N: IFU- 6135003
Version: 09
Issued: 2025.04.18
Size: 96mm×119mm

Content

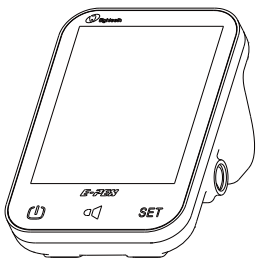
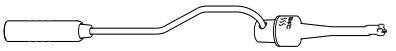
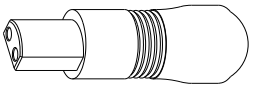
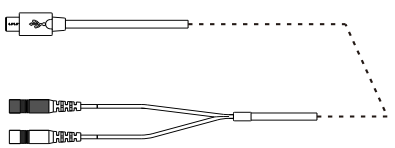
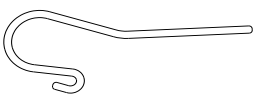
1. Scope of E-PEX

1.1 Parts Identification

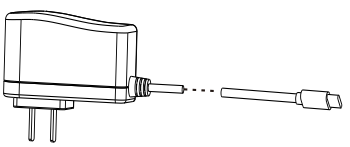


① Apex Locator(main unit)
② Measuring Wire
③ File Clip
④ Lip Hook
⑤ Tester
⑥ Adapter

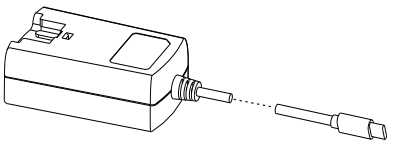
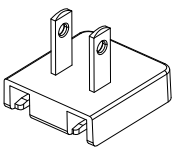
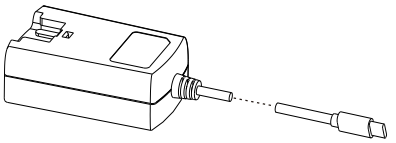
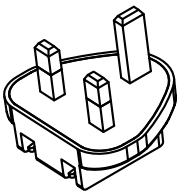
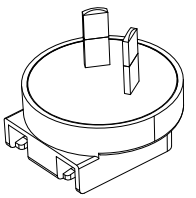
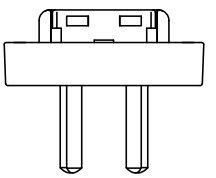
1.2 Components

Apex Locator (1pcs) Part No: 6051004 	File clip (2pcs) Part No: 6151012 	Tester(1pcs) Part No: 6015007 
Measuring Wire (1pcs) Part No: 6015002 	Lip Hook (2pcs) Part No: 6072002 	

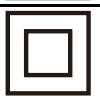
For different regions, there are several different adapter options to be selected as follows.

Standard	Adapter	Power plug
European standard	Adapter (1pcs) Part No: 6016020 	/

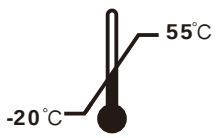
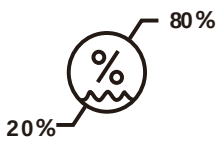
1. Scope of E-PEX

<table>
<tr><td>American standard</td><td>Adapter (1pcs)
Part No: 6016007
  </td><td>American standard power plug (1pcs)
Part No: 6016011
  </td></tr>
<tr><td rowspan="3">Multi-standard</td><td rowspan="3">Adapter (1pcs)
Part No: 6016007
  </td><td>British standard power plug (1pcs)
Part No: 6016009
  </td></tr>
<tr><td>Australian standard power plug (1pcs)
Part No: 6016010
  </td></tr>
<tr><td>Argentina standard power plug (1pcs)
Part No:6016014
  </td></tr>
</table>

2.Symbols used

	General warning sign
	Caution
SN	Serial number
REF	Catalogue number
MD	Medical device
EU REP	Authorized representative in the European Community
	Manufacturer
	Country of manufacture + Date of manufacture
	Class II equipment
	Type BF applied part
	Keep dry
CE 0197	CE marking
	Dispose of in accordance with the WEEE directive
	Direct current

2. Symbols used in the User Manual

	Consult instructions for use
	Manufacturer‘s Logo
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation

3. Before Use

3.1 Intended Use

This apex locator is used to detect the apex of root canal.
This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel and not used in the oxygen-rich environment.

3.2 Contra-indications

Do not use this unit in conjunction with an electric scalpel or on patients who have a pacemaker.
Blocked canals cannot be accurately measured.

Read the following warnings before use:

- The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- The device requires special precautions with regard to electromagnetic compatibility (EMC) and must be installed and operated in strict compliance with the EMC information. In particular, do not use the device in the vicinity of fluorescent lamps, radio transmitters, remote controls, portable or mobile RF communication devices and do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

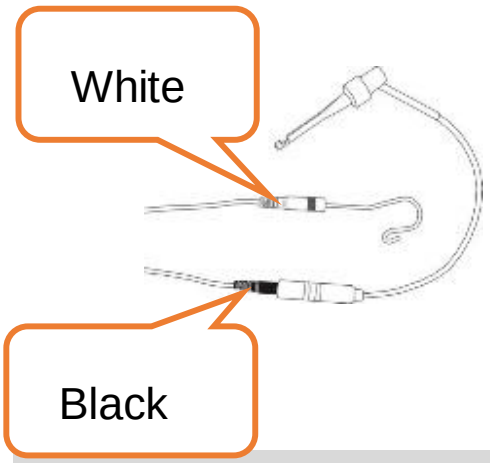
- Gloves and a rubber dam are compulsory during treatment.
- If irregularities occur in the device during treatment, switch it off. Contact the agency.
- Never open or repair the device yourself, otherwise, void the warranty.
- If there is any liquid leaked, it indicates that the battery is leaked. Remove all of the leaked liquid and contact the local agency.
- When used in ESD environment, the display or charging process of the d evice may be affected. Restart the device to revcover. If it still cannot wo rk normally, contact the local agency.
- To restore power supply after power failure occurs during charging, it is necessary to confirm whether the device is charging normally. If it cannot be charged, it can be restored by plugging the adapter again.
- 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 **E-PEX**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- It is forbidden to use non-original parts for the equipment.
- Only trained technician or distributor can change the battery, the electronic parts will be damaged if use a wrong battery or install it in a wrong way.

4.Installing the E-PEX

4.1 Install the E-PEX

Insert the measuring wire into the socket as shown in left picture, make sure connect properly.

Connect the file clip, measuring wire and lip hook as shown in the picture.

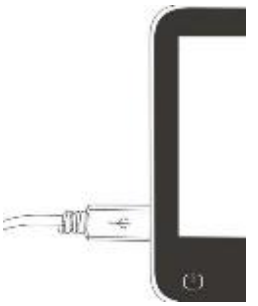


- When installing the measuring wire, please pay attention to the orientation of the slots in the attachment part and do not apply too much force while

4.2 Connection Operation

Make sure E-CONNECT in standby. Open rubber cover, plug data transfer cable into E-CONNECT.

Turn on the E-PEX, and insert the other end of data transfer cable into E-PEX.



After connect the cable, the screen of the E-CONNECT will display “CONNECTED !” indicating that the connection is properly.

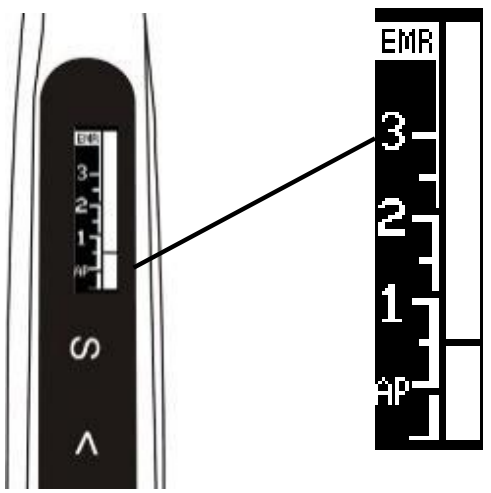
E-PEX can only connect to E-CONNECT manufactured by Sifary. After connecting E-CONNECT and E-PEX, do the below steps to make sure the device is working normally.

adapting it.

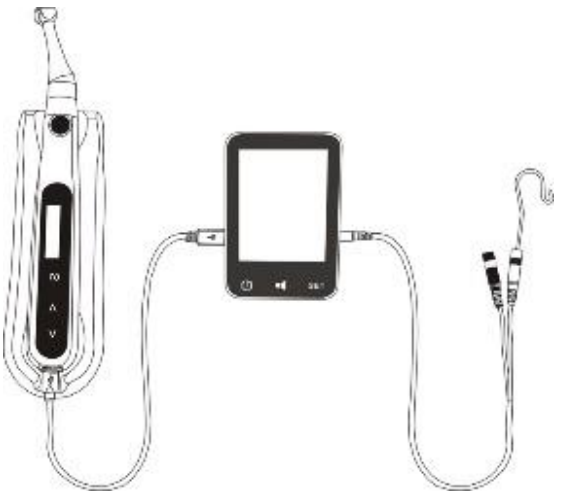
- Incorrect connection will result in inaccurate measurement, even the device cannot be used.

If connect lip hook with black slot , the funtion of apex detection ca nnot be realized.

1. Insert the file into the contra angle.
2. Make the file touch the lip hook (short circuit).
3. Press the main switch of E-CONNECT. All the indicator bars in the screen will light up. That means the system is working normally.



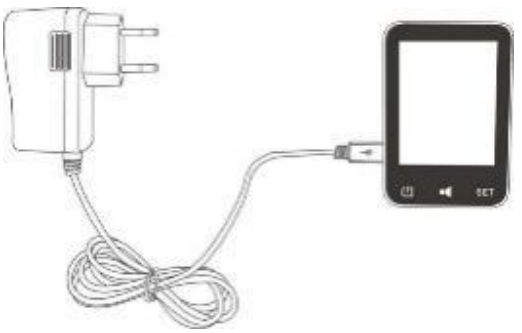
After confirming the system can working normally, user can hang the lip hook into the patient's mouth, and start the treatment.



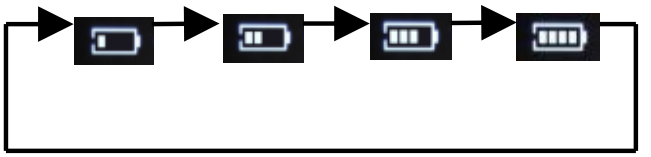
4.3 E-PEX Charging

When the power indicator flashes, please stop using the device and charge it immediately. We suggest the user to charge the device when there is only one bar left.

Connect the Apex Locator main unit with the power adapter.



When the power indicator is as shown below, it indicates that the device is in charging.



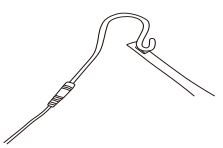
- Keep the device away from the heat source and make sure that there is no combustible surrounding.
- When battery is low charge the device fully. Charging frequently in low power state for short time will reduce the battery life.
- Do not use other power adapter to charge the device, otherwise it will damage the device.
- Do not charge the device while using it.
- Do not use other battery for the device，otherwise it will damage the device.
- Don't position the device where it is difficult to operate the disconnection device.

5.Functions Setting

5.1 Function Checking

1. Press the Power switch to turn the device on. The display will show measuring interface. Then press the Power switch again to turn the device off.
(The device will automatically shut down if it is not used for 10 minutes.)

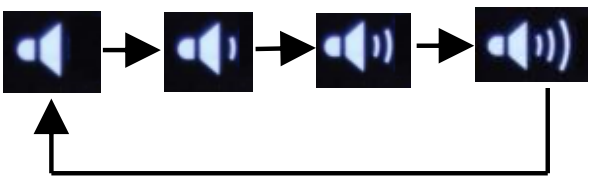
2. Check that the measuring wire, file clip, lip hook and APEX LOCATOR main unit are properly connected. Touch the metal part of the file clip with the lip hook (short circuit).

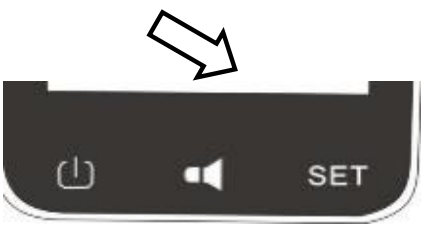


3. Observe the E-PEX display. All the meter indicator bars on the display will light up, and a rapid beep sound will be generated at the same time. The “APEX” sign will be flashed, which means that the E-PEX is working normally.

5.2 Volume control

The E-PEX’s volume of the key and alarm sounds can be adjusted. Press the volume keys to cycle the volume through the minor to the maximum.





5.3 Setting the Reference point

Press SET switch to set the reference point (between 0~1).

Press SET to adjust reference point ◀

The point will be automatically saved.

6.Display

6.1 Instruction

1. When the file reaches the front region of the apical foramen, the screen displays the white indicator bars (As shown in picture 1).

Pic. 1

2. When the file reaches the position near by the apical foramen, the screen displays the green indicator bars (As shown in picture 2).

Pic. 2

3. When the red indicator bars light up, it means that the file has exceeded the apical foramen. A rapid beep sound will be generated at the same time (As shown in picture 3).

Pic.3

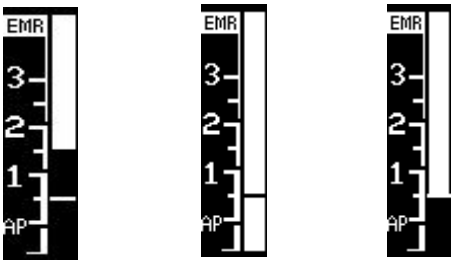
Avoid using apex locator for working length determination in the following conditions:

- Open apex cases.
- Draining canals.
- Poor isolation from oral environment (avoid seepage of oral fluids into access cavity).
- Root fractures / perforation.
- Gutta percha filled canals；
- Please use the original accessories, otherwise the device may measure inaccurately or not even function.

- The green part “00” display means major apical foramen (not the minor apical foramen). Hence it is recommended to reduce the working length by 0.5-1 mm.
- The device's screen does not show the actual length of the root canal, the number reducing only means a trend that file is progressing apically.
- The gingival crevicular fluid / saliva / gingival polyp will interfere with device functioning. Hence it is recommended to isolate the tooth.
- The accessories which contact with patient (file clip and lip hook) can be reused and should be sterilized by high temperature before first use and after each use.

6.2 Display the root canal on E-CONNECT

1. The white band on handpiece screen displays the progression of the file into the root canals.
2. The closer the file tip reaches the apical foramen, the more rapid the beep sound makes.
3. After connection, it will activate the advanced setting in chapter 9.5.



1 2 3

6.3 Combination Function

Set “ON” to choose the combination function.

The position of the reference point is automatically set with the E-PEX, and the cursor is displayed on the E-CONNECT screen.
When the file reaches the reference point, E-CONNECT will start Apical Reverse, Apical Slow Down and Apical Torque Reduction function (If the function is activated).

- Do not use a non - specified data transfer cable, otherwise it will damage the device.
- Do not hit device and splash liquids.

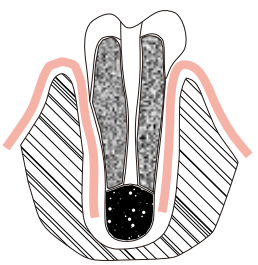
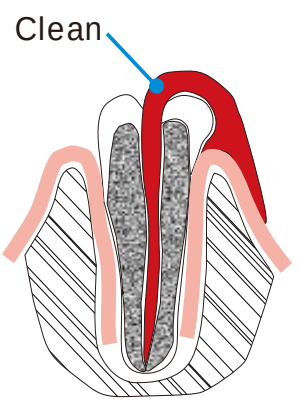
- Make sure to connect the two devices with right position.
- After connecting the two devices with the cable, gently push and pull the interface to ensure that the connection is stable, otherwise the data transmission may not be accurate.
- In certain cases, for example when the canal is blocked, the measurement may be unable.
- The device will not be able to perform a precise measurement for every time, especially in cases of abnormal or unusual morphology of the root canal. The user needs to coordinate with x-ray to check the results of the measurement.
- If the meter does not move when you insert the file, it is possible that the device is not working normally, therefore, stop using.
- Make sure to take an X-ray to

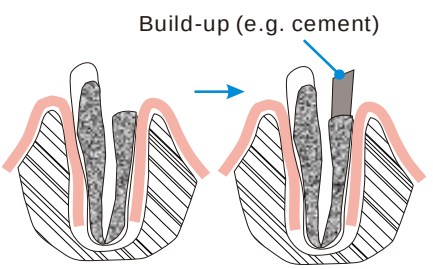
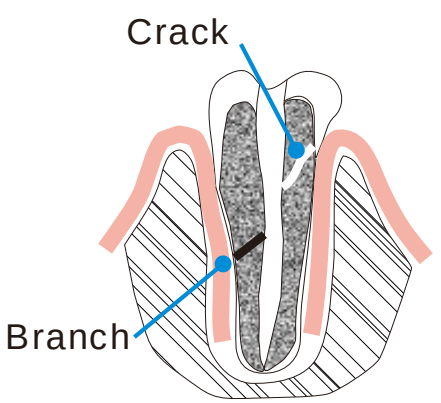
	check the results. Accurate apex location may not always possible. It depends on tooth condition, case complexity, as well as degradation of the device.

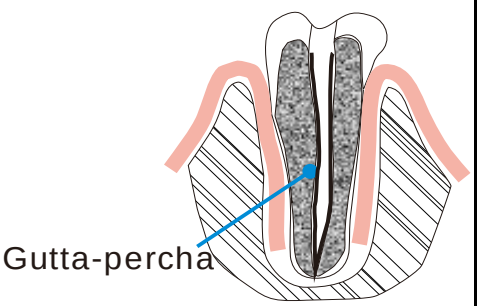
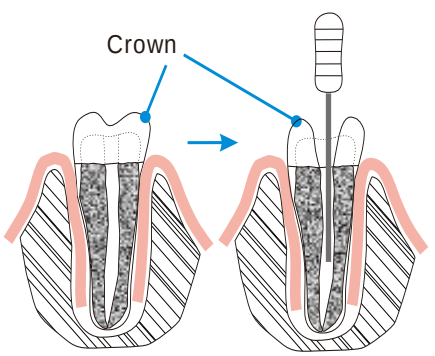
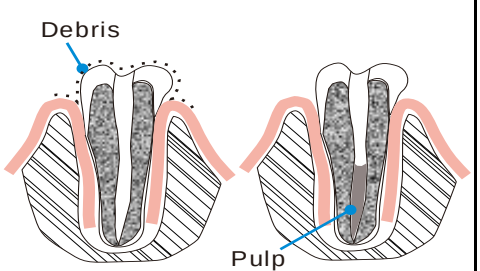
6.4 Not suitable condition

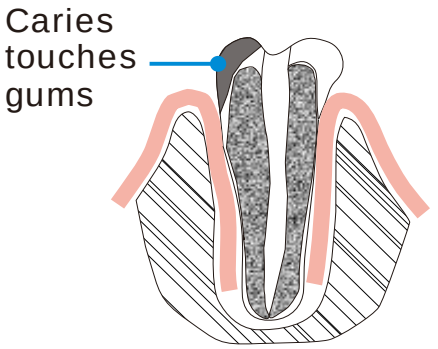
Unsuitable situation of root canals for Electric Measurement

Cannot obtain precise measurements if the root canal conditions as below

	**Root canal with a large apical foramen** The root canal cannot be accurately measured because of the lesion or incomplete development of the apical foramen. The results may show that the length measured is shorter than the actual one.
	**Root canal blood overflow from the opening** If blood spills from the root opening and contacts the gums, it will cause leakage of electricity, which cannot be accurately measured. Wait for the bleeding to stop completely. Clean the root canal and the opening, completely empty the root canal

	blood, and then measure it. **The root canal uses a chemical solution to flow out from the opening** If a chemical solution flows out of the root canal, it is impossible to get an accurate measurement. It is important to remove the overflow from the opening.
	**Broken crown** If the crown is broken, a segment of the gingival tissue enters the lumen, and the contact between the gingival tissue and the root file causes electrical leakage, which cannot be accurately measured. In this case, the appropriate material should be used to isolate the gingival tissue.
	**The crack tooth Leakage through branch of the root canal** Broken teeth can cause electrical leakage and cannot be accurately measured. Branch tubes can also cause leakage.

	**Retreatment canal which was filled with gutta-percha** The gutta-percha must be completely removed to eliminate its insulation, then 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 that touches gingival tissue** Accurate measurement cannot be obtained if the file touches a mental 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 mental prosthesis before taking a measurement.
	**Cutting debris on tooth Pulp inside canal** Remove all cutting debris on the tooth. Remove all the pulp inside the canal. Otherwise an accurate measurement cannot be obtained.

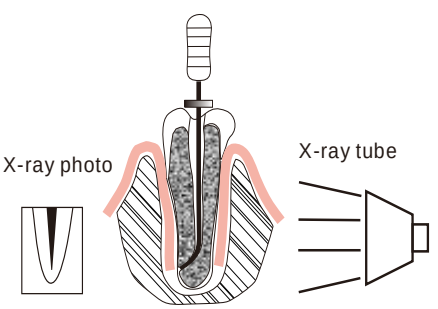


Caries touching the gums

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

Difference measuring result between Apex locator reading and Radiography

Sometimes the reading of the apex locator reading does not correspond to the X-ray image. This does not mean inaccurate of apex locator or X-ray, depending on the angle of the X-ray beam, the root tip may not be displayed correctly. The position of the root tip seems to differ from its true position.



The X-ray photo shows that the actual apex of the root canal is not the same as the anatomic end. In fact, the apical foramen is located at the coronal end. In this case, X-ray may indicate that the file needle has not reached the apical foramen, even if it has actually reached the apical foramen.

7.Cleaning, Disinfection and Sterilization

7.1 Foreword

For hygiene and sanitary safety purpose, the components (file clip, lip hook) must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use as well use the subsequent uses.

Comply with your national guidelines, standards and requirements for cleaning, disinfection and sterilization.

Reprocessing procedures have only limited implications to this dental instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation. In case of damage, the device should be reprocessed before sending back to the manufacturer for repair.

7.2 General recommendations

- The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments, where applicable after sterility.
- For your own safety, please wear personal protective equipment (gloves, safety glasses, etc.).
- Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, and FDA approval) and in accordance with the DFU of the disinfecting solution manufacturer.
- The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
- Thoroughly clean and wash the components before autoclaving.

Autoclavable Components	
	
File clip	Lip hook

- Do not use bleach or chloride disinfectant materials.

- Only the components above can be autoclaved.
- Before first use and after each use, sterilize the above components heat sources.

Autoclave Procedure:

Reprocessing Instructions	
Preparation at the Point of Use:	Disconnect the components (Lip hook and file clip) from the main unit. Remove gross contaminations from the components with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding.  ● Do not submerge the components or wipe them with any of the following functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agents to the components.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state.  ● Do not fail to take out the file before cleaning the file clip.

	● Observe suitable personal protective measures.
Pre-Cleaning:	Do a manual pre-cleaning, until the components are visually clean. Submerge the components in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristol brush.
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. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Carefully put the instrument into the washer-disinfector on a tray and set the parameters as follows and start the program: • 4 min pre-washing with cold water (<40°C) • emptying • 5 min washing with a mild alkaline cleaner at 55°C • emptying • 3 min neutralising with warm water (>40°C) • emptying • 5 min intermediate rinsing with warm water (>40°C) • emptying *The automated cleaning processes have been*

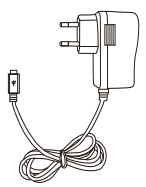
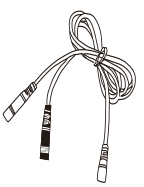
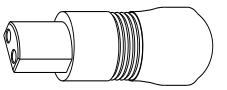
	validated by using 0.5% neodisher MediClean forte (Dr. Weigert). Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.  ● Use only approved washer-disinfectors according to EN ISO 15883, maintain and calibrate it regularly. ● Follow instructions and observe concentrations given by the manufacturer (see general recommendations).
Disinfection:	Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN ISO 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000. After manual cleaning, the instrument should be automated disinfected or sterilized immediately. A manual disinfection is not recommended.
Drying:	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

Functional Testing, Maintenance:	Visual inspection for cleanliness of the components and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until the component is visibly clean. Before packaging and autoclaving, make sure that the device has been maintained acc. to the manufacturer's instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization.  ● Check the validity period of pouch given by the manufacturer to determine the shelf life. ● Use pouches which resist to a temperature up to 141℃ and in accordance with EN ISO 11607.
Sterilization	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134 °C (in EU: 5 min at 134 °C) Maximum sterilization temperature: 137°C Flash sterilization is not allowed on lumen instruments!  ● Use only approved autoclave devices according to EN 13060 or EN 285. ● Use a validated sterilization procedure according to EN ISO 17665.

	● Respect the maintenance procedure of the autoclave device given by the manufacturer. ● Use only this recommended sterilization procedure. ● Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physicochemical integrators, digital records of cycles parameters). ● The sterilization procedure must comply with EN ISO 17665. ● Wait for cooling before touching.
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.  ● Sterility cannot be guaranteed if packaging is open, damaged or wet. ● Check the packaging before using (packaging integrity, no humidity and validity period).
Reprocessing validation study information:	The above-mentioned reprocessing process (cleaning, disinfection, sterilization) has been successfully validated. Refer to test reports: - Cleaning Disinfection Validation Report No. RDS2020D0063 001 - Sterilization Validation Report No. RDS2020S0067 001 and RDS2020S0066 001
	

- The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

7.3 Disinfection

			
Adapter	Measuring wire	Apex locator	Tester

Wipe all the surfaces with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 to 80vol%) at least 2 min, repeat for 5 times.

- Do not use anything except Ethanol for Disinfection (Ethanol 70 to 80 vol%).
- Do not use too much ethanol as it’s going into machine and damage the components inside.

8.Troubleshooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

Problem	Cause	Solution
The power is not turned on.	The battery is flat.	Charge the battery.
	Press the power switch too short time.	Long press the power switch.
No charge indicator flash on handpiece screen.	Put the APEX locator on the charge base in the wrong location.	Check the location.
	Charging is completed.	Checking the instructions of the battery.
	The charge base is broken.	Contact your distributor.
No sound.	Beep volume is set to 0.	Set beep volume to 1, 2 or 3.

9.Technical Data

Manufacturer	Changzhou Sifary Medical Technology Co., Ltd
Model	E-PEX
Dimensions	13cm x 11cm x11cm±1cm (package)
Gross weight	0.56Kg±10%
Display	3.5’ color LCD
Power supply	Lithium ion battery: 3.7V, 1500mAh
European standard Adapter	Model No: UE05LV2-050100SPA Input: AC 100-240 V,50/60Hz,0.2A Output: DC 5V/1A, 5W
Multi-standard adapter	Model No: UES06WOCP-050100SPA Input: AC 100-240 V，50/60Hz，0.2A Output: DC 5V/1A
Degree of protection	IPX 0
Electrical safety class	Class II
Applied part	BF
Operation conditions	Use: in enclosed spaces Ambient temperature: 10°C ~ 40 °C Relative humidity: 30% ~ 75% Atmospheric pressure: 70kPa~106kPa
Transport and storage conditions	Ambient temperature: -20°C ~ +55°C Relative humidity: 20% ~ 80% Atmospheric pressure: 70 kPa ~106 kPa

10.EMC Tables

This product has no essential performance.

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">The E-PEX is intended for use in the electromagnetic environment specified below. The customer or the user of the E-PEX should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Professional healthcare facility environment and Home healthcare environment</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">Professional healthcare facility environment</td></tr>
<tr><td>Harmonic emissions
IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3"> 
The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.</td></tr>
</table>

10. EMC Tables

Guidance and manufacturer's declaration – electromagnetic immunity			
The **E-PEX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **E-PEX** 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 +/- 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 transients/bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line to line: ±0.5kV, ±1kV	Line to line: ±0.5kV, ±1kV	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	0% UT; 0.5 cycle at 0°, 45°,90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles sine phase at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of devices require continued operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
Rated Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	30 A/m 50Hz or 60Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz			

Guidance and manufacturer's declaration – electromagnetic immunity			
The **E-PEX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **E-PEX** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted dis-turbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands be-tween 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be usedno closer to any part of the E-PEX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF EM fields IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz	3V/m	**Recommended minimum separation distances** See the RF wireless communication equipment table in "Recommended minimum separation distances"

Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	

Recommended minimum separation distances

Nowadays, many RF wireless equipment's have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The **E-PEX** has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the **E-PEX** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						

810	800-960	GSM 800/900, TETRA 800, iDEN 820,CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n,RFID 2450，LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Guidance and manufacturer’s declaration – electromagnetic immunity			
The **E-PEX** is intended for use in the electromagnetic environment specified below. The customer or the user of the **E-PEX** should assure that it is used in such an environment.			
Proximity magnetic fields	IEC 61000-4-39 test level	Compliance level	Electromagnetic environment – guidance
Proximity magnetic fields	134.2kHz Pulse modulation 2.1 kHz	65A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields	13.56MHz Pulse modulation 50 kHz	7.5A/m	

- Use of accessories and cables other than those specified or provided by the manufacturer of **E-PEX** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **E-PEX** and result in improper operation.

Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter Cable	1.2	No	/

- Use of **E-PEX** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **E-PEX** and the other equipment should be observed to verify that they are operating normally.
- If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

11.Statement

Service Life

The service life of E-PEX series products is 3 years.

It is recommended that the equipment be checked and repaired at the dealer once a year.

Maintenance

MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Disposal

The package should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. The lithium batteries are disposed as special refuse. Please deal with them according to the local environmental protection laws and regulation.

Rights

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to Changzhou Sifary Medical Technology Co., Ltd. The industrial design, inner structure, etc, have claimed for several patents by SIFARY, any copy or fake product must take legal responsibilities.

Changzhou Sifary Medical Technology Co., Ltd.

Add: No. 26 Yandanghe Road, Xinbei District, 213000 Changzhou, Jiangsu, China
Tel: +86-0519-85962691
Fax: +86-0519-85962691
Email: info@sifary.com
Web: www.sifary.com

EU REP

Caretechion GmbH
Tel: +49 211 2398 900
Add: Niederrheinstr. 71, 40474 Düsseldorf, Germany
Email: info@caretechion.de