



E-PEX

USER MANUAL

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1. Scope of E-PEX

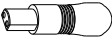
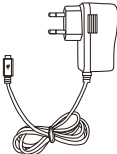
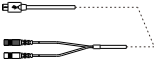
1.1 Parts Identification



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

1. Scope of E-PEX

1.2 Components and Accessories

Apex Locator (1pcs)  A handheld electronic device with a large screen and buttons. The screen displays 'E-PEX' and 'α'. Below the screen are buttons labeled 'U', 'α', and 'SET'.	File clip (2pcs)  A thin metal wire with a small clip at one end and a rounded tip at the other.	Tester(1pcs)  A cylindrical metal component with a threaded section in the middle.
Adaptee (1pcs)  A power adapter with a three-pronged plug and a coiled cable ending in a USB connector.	Measuring Wire (1pcs)  A thin metal wire with a clip at one end and a rounded tip at the other. A dashed line indicates the wire is bent into a U-shape.	Lip Hook (2pcs)  A thin metal wire bent into a hook shape.

2.Symbols used in the User Manual

 WARNING	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
 NOTE	Additional information, explanation of operation and performance.
	Serial number
	Catalogue number
	Manufacturer
	Date of manufacture
	Class II equipment
	Type B applied part
	CE marking
	Direct current

2. Symbols used in the User Manual

	Dispose of in accordance with the WEEE directive
	Keep dry
	Consult instructions for use
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Authorized Representative in the European Community
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Manufacturer's LOGO

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 Contraindications

Do not use this unit in conjunction with an electric scalpel or on patients who have a pacemaker.

Blocked canals cannot be accurately measured.



WARNING

Read the following warnings before use:

- 1、 The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
- 2、 Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
- 3、 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.

3. Before Use

- 4、Gloves and a rubber dam are compulsory during treatment.
- 5、If irregularities occur in the device during treatment, switch it off. Contact the agency.
- 6、Never open or repair the device yourself, otherwise, void the warranty.

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.



NOTE

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

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.

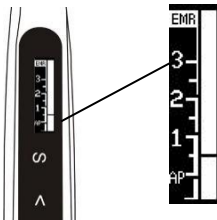
CONNECTED !

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



4. Installing the E-PEXg

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. Installing the E-PEXg

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.



WARNING

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.

5.Functions Setting

5.1 Function Checking

1. Press the Power switch to turn the device on. The display will show measuring interface.
(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.



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).



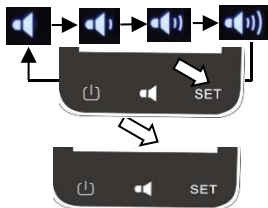
3. Observe the E-PEX display. All the meter indicator bars on the display will light up, and a rapid beep sound will be generated at the same time. The "APEX" sign will be flashed, which means that the E-PEX is working normally.



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



WARNING

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

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



NOTE

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).



WARNING

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

Do not hit device and splash liquids.



NOTE

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.

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.
- Do not use bleach or chloride disinfectant materials.

Autoclavable Components	
	
File clip	Lip hook

7. Cleaning, Disinfection and Sterilization



WARNING

- 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 code 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.  WARNING 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.  WARNING ● Do not fail to take out the file before cleaning the file clip. ● Observe suitable personal protective measures.

7. Cleaning, Disinfection and Sterilization

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 <i>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).</i>

7. Cleaning, Disinfection and Sterilization

	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.  WARNING ● 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

7. Cleaning, Disinfection and Sterilization

	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.  WARNING ● 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°C 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!  WARNING ● 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.

7. Cleaning, Disinfection and Sterilization

	● 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.  WARNING 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: - Changzhou Sifary _Cleaning Disinfection Validation Report - Changzhou Sifary _Sterilization Validation Report_File clip
 WARNING 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	

7. Cleaning, Disinfection and Sterilization

consequences.

7.3 Disinfection

Wipe with Ethanol for Disinfection
Ethanol 70 to 80 vol%



Charger



Measuring wire

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.



NOTE

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. Technical Data

Manufacturer	Changzhou Sifary medical technology Co., Ltd
Model	E-PEX
Dimensions	13cm x 11cm x11cm±1cm (package)
Weight	560±10%
Display	3.5' color LCD
Power supply	Lithium ion battery: 3.7V, 1500mAh
Charger power supply	AC100-240V
Frequency	50/60Hz
Charger nominal power input	5.5VA
Power Rating	0.3 W
Degree of Protection	IPX 0
Electrical safety class	Class II
Applied part	BF
Ambient conditions	Use: in enclosed spaces Ambient temperature: 10°C ~ 40 °C Relative humidity: <80%; non-condensing at 0° Operating altitude: < 3000 m above sea level
Transport and storage conditions	Ambient temperature: -20°C ~ +55°C Relative humidity: 20% ~ 80%, non-condensing at > 40 °C Atmospheric pressure: 50 kPa ~106 kPa

9. EMC Tables

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The E-PEX uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The E-PEX is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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

9. EMC Tables

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 earth: ±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV	Mains power quality should be that of a typical commercial or hospital environment.

9. EMC Tables

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; 250/300 cycle	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; 250/300 cycle	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 from an uninterruptible power supply or a battery
Voltage interruptions IEC 61000-4-11			
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			

9. 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
Conducted dis-turbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz, 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM at 1 kHz	3 V	Portable and mobile RF communications equipment should be used no 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"

9. EMC Tables

Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"	Complies	
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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 60601-1-2:2014. 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 $\pm$ 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						

9. EMC Tables

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						

**WARNING**

1. 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	/

2. 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.

10.Statement

Service Life

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

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.



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