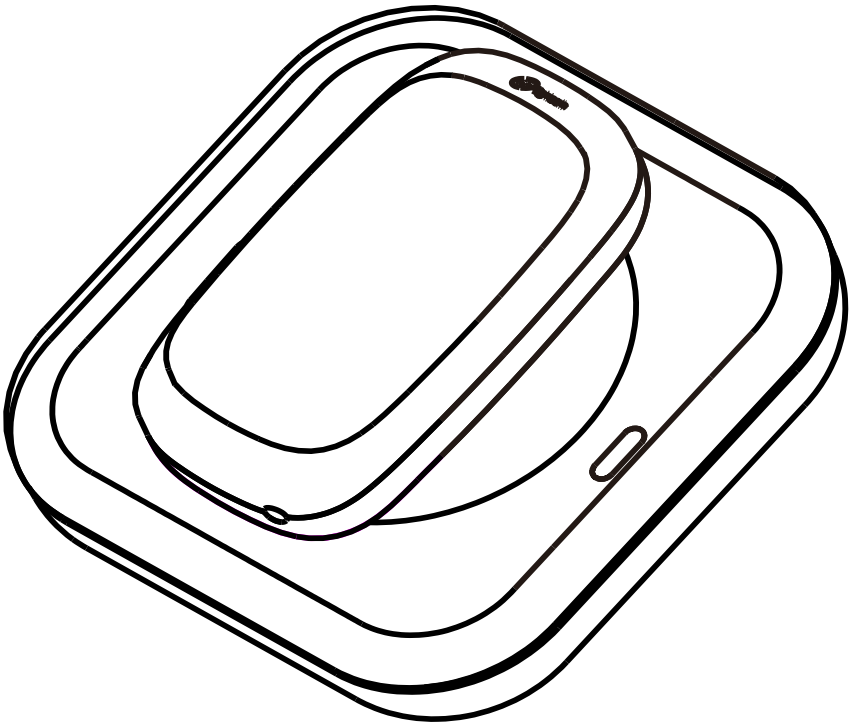
Eighteeth



AirPex

Apex locator USER MANUAL

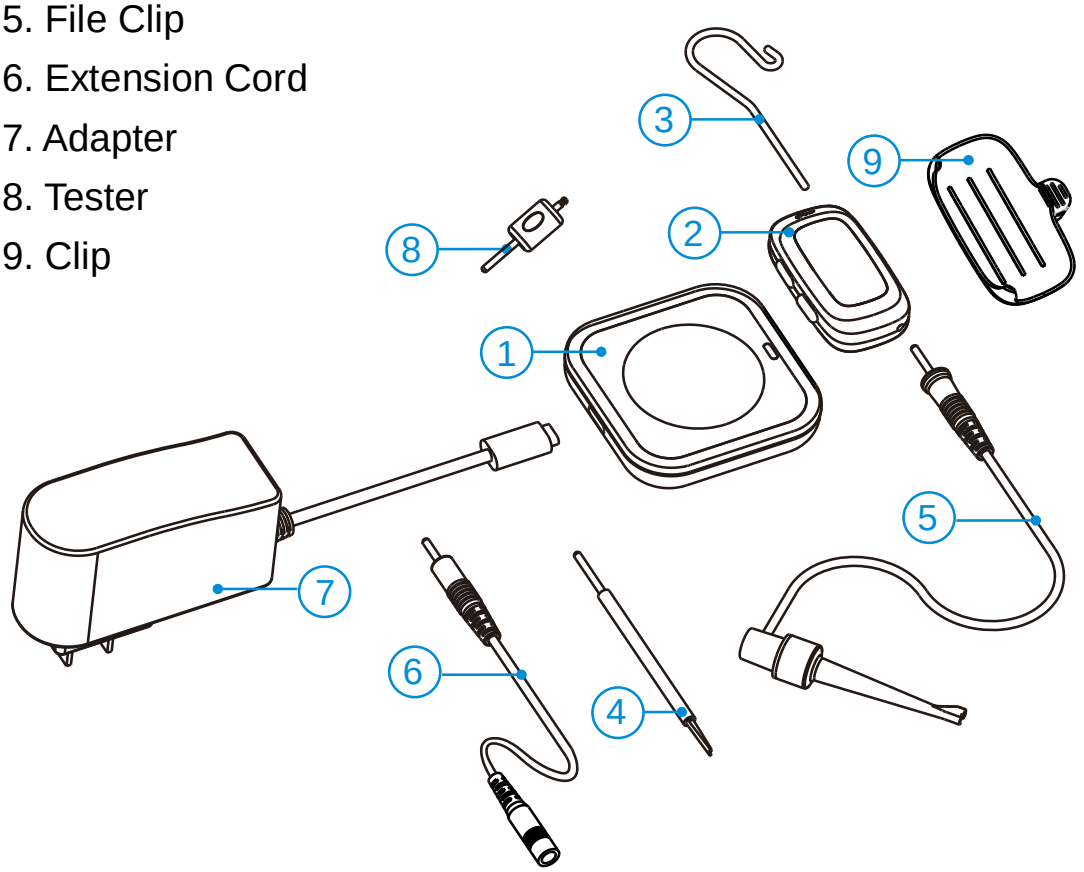
Changzhou Sifary Medical Technology Co.,Ltd.

Content

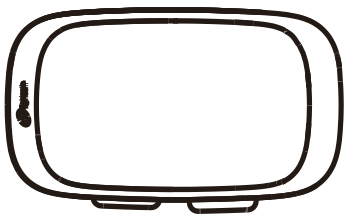
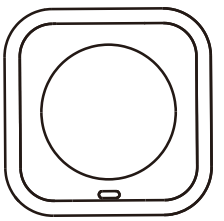
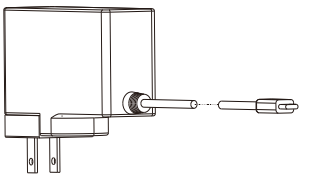
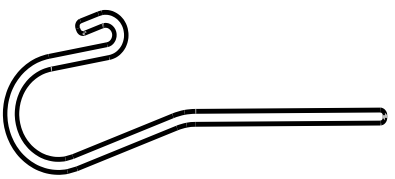
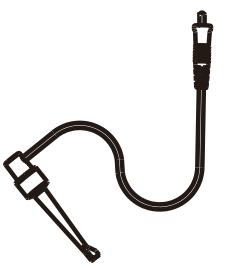
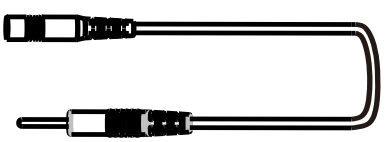
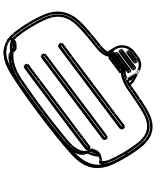
1. Scope of AirPex

1.1 Parts Identification

1. Charge Base
2. APEX Locator
3. Lip Hook
4. Touch Probe
5. File Clip
6. Extension Cord
7. Adapter
8. Tester
9. Clip

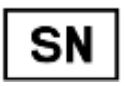
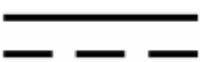


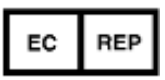
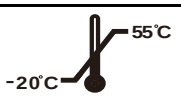
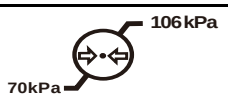
1.2 Components and Accessories

APEX Locator(1pcs) Part No. 6151002 	Charge Base (1pcs) Part No. 6151001 	Adapter (1pcs) Part No.6516001 
Lip Hook (2pcs) Part No. 6072002 	Touch Probe (1pcs) Part No. 6101001 	File Clip (2pcs) Part No. 6151003 
Extension Cord (2pcs) Part No.6151004 	Tester (1pcs) Part No.6151005 	Clip(1pcs) Part No.6151008 

1.3 Options (sold separately)

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
	Lot of manufacture
	Safety class II device
	Type B applied part
	CE marking
	Direct current
	Do not dispose of with normal household waste

	Store in a dry place
	Can be autoclaved up to a maximum temperature of 134° Celsius
	Authorized Representative in the European Community
	Temperature limitation
	Relative humidity
	Atmospheric pressure
	Manufacturer’s LOGO
	Refer to instruction manual/booklet

3. Before Use

3.1 Intended Use

AirPex is intended for measuring canal length.

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

This device must not be used in cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.)

Safety and effectiveness have not been established in pregnant women and children.

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 and do not use this system near the active HF Surgical Equipment in the hospital. 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 AirPex, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Do not charge, operate or store at high temperatures. Comply with the specified operating and storage conditions.

4. Gloves and a rubber dam are compulsory during treatment.

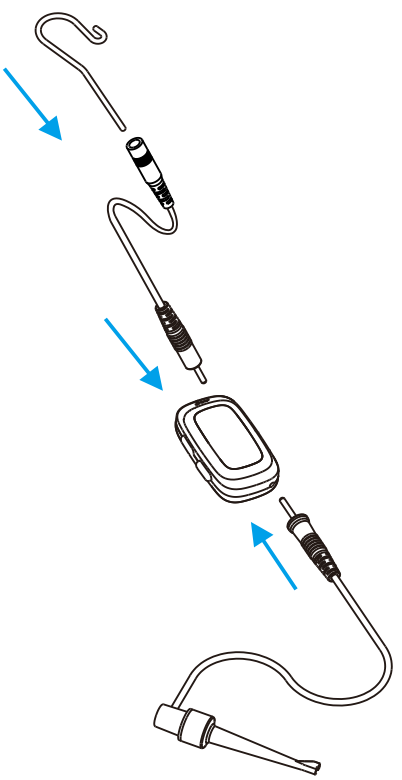
5. If irregularities occur in the device during treatment, switch it off. Contact the agency.

6. Never open or repair the device yourself, otherwise, void the warranty.

4.Installing the AirPex

4.1 Connecting file clip, lip hook and extension cord

Connect file clip, extension cord and lip hook to APEX locator as shown in the picture. Also, use both extension cords according to actual situation.

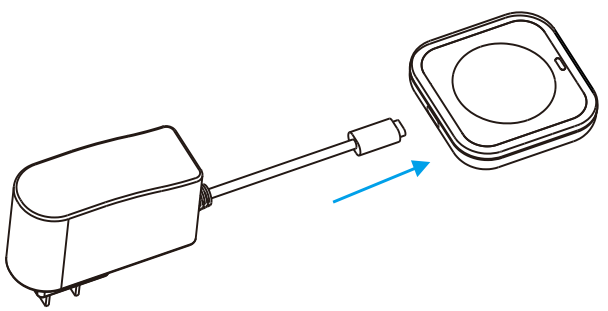


NOTE

Please use the original file clip and lip hook that manufactured by Sifary. Because the size of the unoriginal file clip and lip hook are different, it may damage the APEX locator or cause deviation of measurement accuracy.

4.2 Connecting charge base

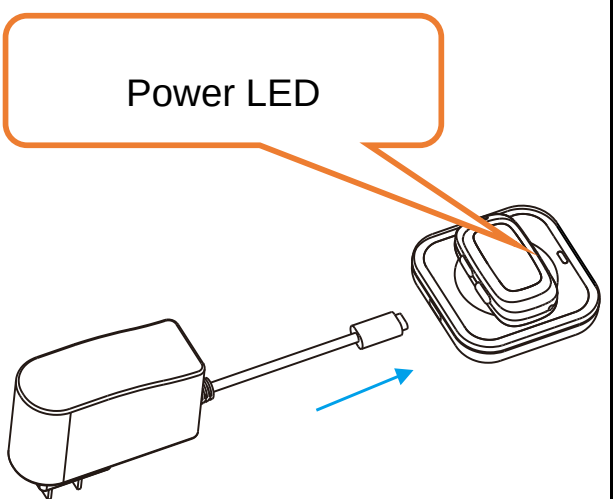
Plug the USB of adapter into the charge base, and plug the other end into a power outlet.



NOTE

Only the original adapter could be used.

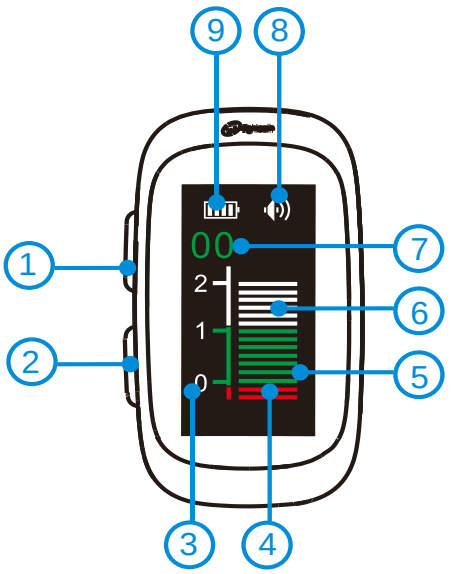
Put the APEX locator in the groove in the middle of the charge base. The power LED on charge base will light up. And the interface of APEX locator will light up to show that is charging.



NOTE

Put the APEX locator on the charge base in the right direction, otherwise the APEX locator will not be charged.

5.Use Interface



① Set key Ⓢ
② Power key
③ Reference range
④ Apical area display
⑤ Reference point
⑥ Measuring bar
⑦ Measured value
⑧ Volume display
⑨ Power display

Turn Power On/Off

Press to turn on. Long press more than 2 seconds, or no operation for 3 minutes to turn off.

Volume control

During standby state, shot press to cycle the volume through the minor to the maximum.

Setting the reference point

During standby state, press Ⓢ to set the reference point between 0~1. Seven points can be selected circularly. The cursor flashing position indicates the selected reference point.

Power display

Display the remaining power through the number of grid.

Reference range

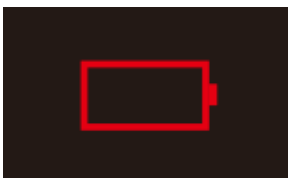
The flash of the measuring bar is the current measured vale, represents the estimated distance from the apical foramen in millimeters.

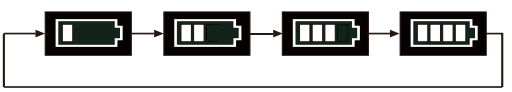
Display reversing

During standby state, press and Ⓢ together to reverse the display.

6.Operation

6.1 Charge

<table>
<tr>
<td> 
 
</td>
<td>Display the present remaining amount of the battery.
Less than 15% remains, please charge.</td>
</tr>
<tr>
<td></td>
<td>NOTE
If the power if less than 15%, the device must be recharged within 30 days, otherwise the battery will be damaged.</td>
</tr>
</table>



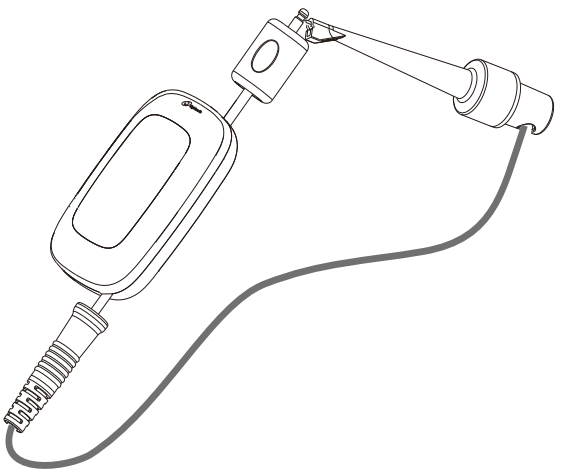
Charging indication appears on the screen, and flashes slowly, when battery is fully charged or in a state near full charge, the flash will stop. Fully charged will take about 4-5 hours, depending on residual battery power and battery state.

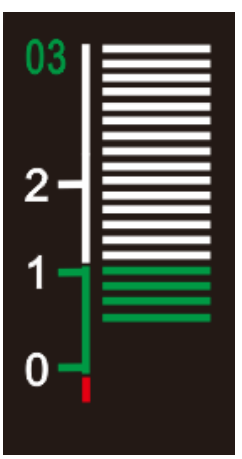
It can be recharged 300-500 times, depending on the operating conditions of the device.

WARNING

Do not change the battery, only trained technician or distributor can change the battery, the electronic parts will be damaged if use a wrong battery or install with a wrong way.

6.2 Function checking of APEX locator

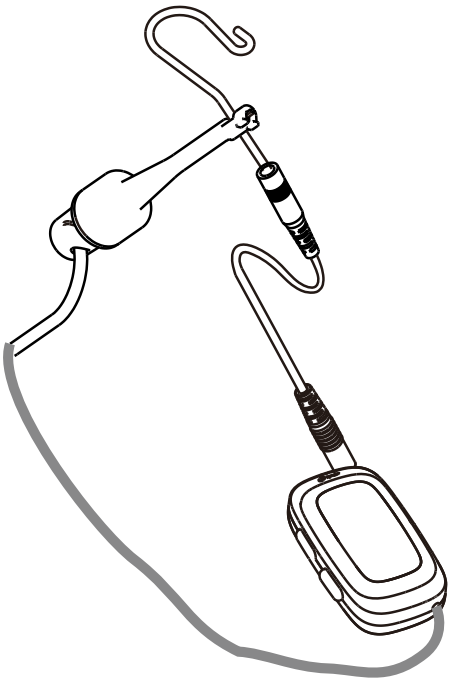


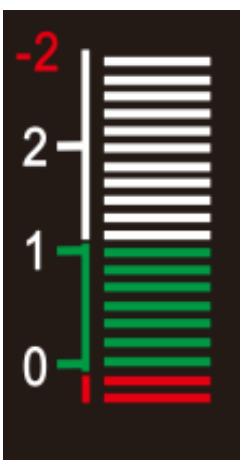


- After turning on, insert the tester into the APEX locator.
- Clamp the groove of tester with file clip.
- The measuring bar on the screen flashes at point 02, 03 or 04.
- Recommend to test the APEX locator with tester once a week.

NOTE

If the measurements are not expected, check that the tester is connected properly. If the normal connection still does not show the expected value, please stop using the device and contact the local dealer for processing.



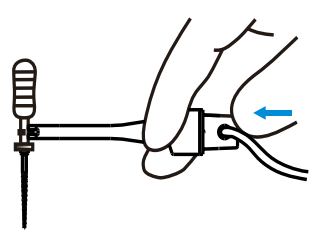


- Confirm the device with short touch file clip and lip hook before.
- Confirm that the tester is not installed on the APEX locator. Then connect the file clip, lip hook and extension cord according to chapter 5.1. Finally, touch the lip hook with exposed metal position on file clip, the measurement on the screen should be shown as -2.

NOTE

If the measurement shown is not -2, check that the connection is normal. If the normal connection still does not show the expected value, please stop using the device and contact the local dealer for processing.

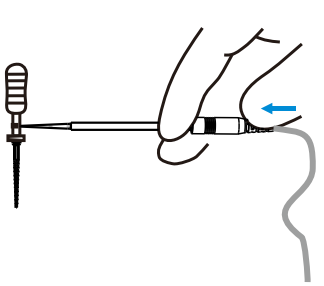
6.3 Operation and not suitable condition



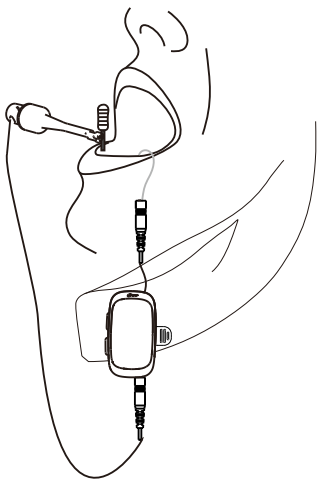
- Press the back cover of the file clip to make the hook of the file clip stick out. And hook the metal handle of the root canal file. Release the pressure and use the elasticity of the file clip to complete the connection between the file clip and the root canal file.

NOTE

- When connecting the root canal file, make sure that the file clip and the root canal file handle are basically perpendicular, otherwise the chuck of the file clip will be easily damaged.
- This equipment does not include the root canal file. We need to buy another suitable model according to the clinical needs. The metal part of the root canal file should be well conductive.



- When the file clip can't enter the patient's mouth, the file clip can be replaced by the extension cord with the touch probe. Press the touch probe on the metal handle of the root canal file to complete the connection between the touch probe and the root canal file.



- Hook the lips to the patient's lips. Ensure contact with the lips fully. Then the root canal file is slowly inserted into the unblocked root canal.
- If the patient is fitted with a metal crown or other conductive devices, the root canal file clip and the metal part of the file clip should not be in contact with it, so as to avoid causing wrong measurement results.
- APEX locator should be fixed in patient's collar with the clip.

NOTE

- To prevent measurement errors caused by conduction between the gums or adjacent root canals, dry the pulp chamber floor with cotton balls or other means before testing.
- Using the correct number and taper of the canal file, make it fully contact with the canal wall, is conducive to accurate measurement.

- As the root canal file is inserted, the measurement bar on the screen lights up from top to bottom.
- When displayed as shown in figure 1, the

Fig.1

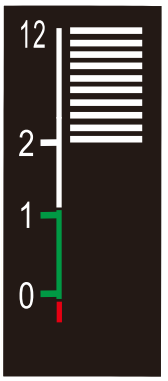
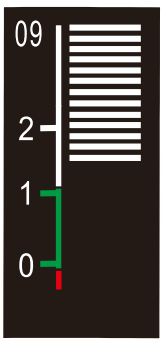


Fig.2



value of the reference range is 2, indicating that the distance from the tip of the tooth root is about 2mm at this time. At the same time, the APEX locator emits a "di" alarm sound at a long interval.

- When displayed as shown in figure 2, it means that the distance from the tip of the tooth root is close, about 1.5 mm, and the time interval of "di~di~" alarm sound emitted by the APEX locator becomes shorter.
- When displayed as shown in figure 3, it means that it reaches the tip of the tooth root. The measured value is 00, which is the actual length of the root canal to be measured.
- When displayed as shown in figure 4, it means that the root canal file has gone beyond the tip of the tooth, and the main body emits a very urgent "di~~" alarm sound.

NOTE

- The tip of the tooth root position (measured value: 00) measured by this device is the Major/Anatomic apical foramen. In clinical practice, in order to prevent surgical failure caused by piercing the root apical orifice, 0.5-

Fig.3

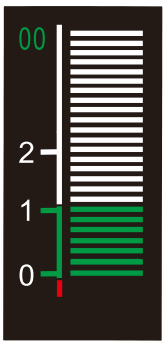
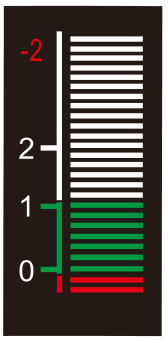


Fig.4



1.0 mm is usually taken from the measured value, which is the Minor/Physiological apical foramen prepared for root canal.

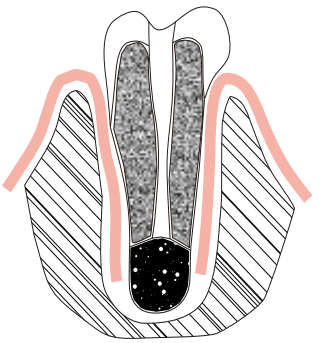
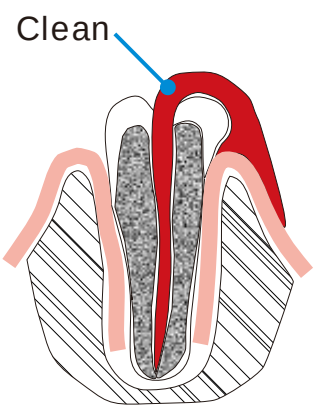
- The value of the reference distance is only an estimated value, not a clinical basis.
- The measured value does not represent the distance, only the trend of gradual entry.

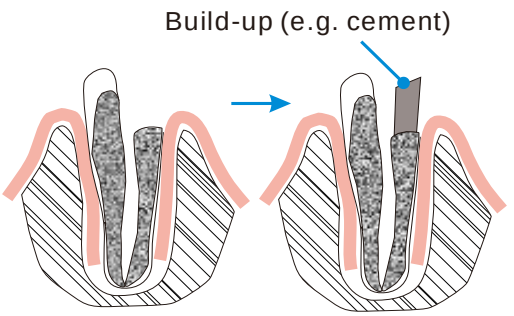
WARNING

- During measuring, enter slowly to prevent piercing the tip of the root.
- The APEX locator is used to determine the working length of the root canal. In clinical use, it must be combined with X-ray and other means to determine the working length of the root canal.
- The device should be used by dentists with knowledge of dental root canal length and skill in operation.

Unsuitable situation of root canals for Electric Measurement

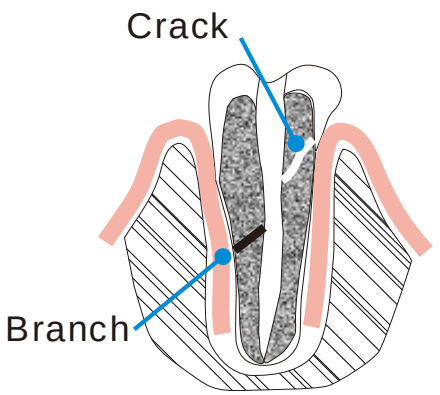
Cannot obtain precise measurements if the root canal conditions as below

	**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

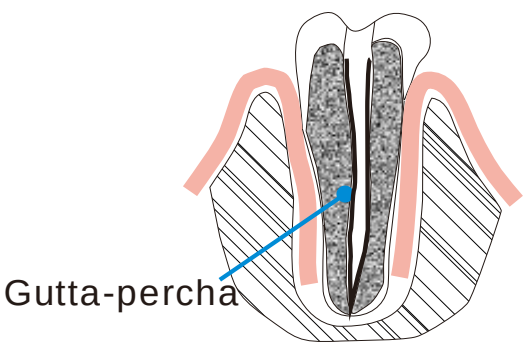
If the crown is broken, a segment of the gingival tissue enters the lumen, and the contact between the gingival tissue and the root file causes electrical leakage, which cannot be accurately measured. In this case, the appropriate material should be used to isolate the gingival tissue.



The crack tooth Leakage through branch of the root canal

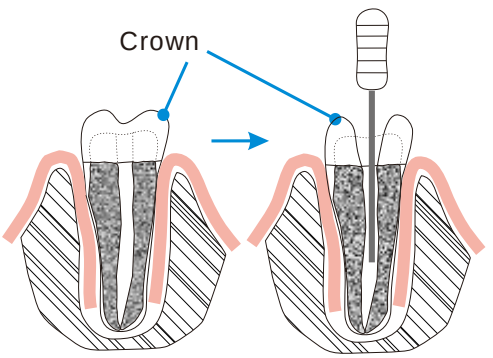
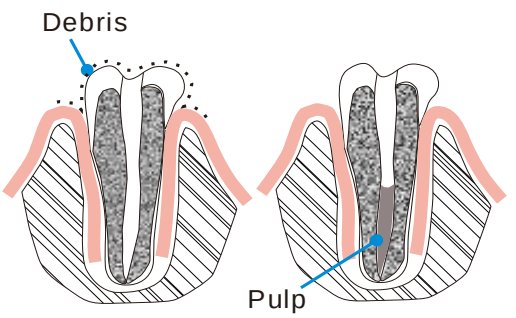
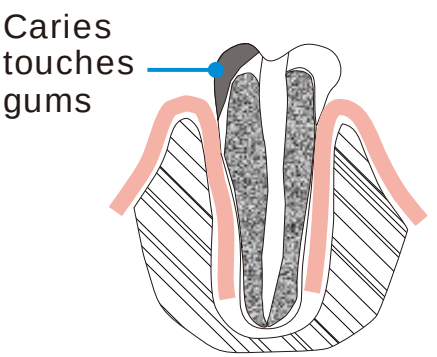
Broken teeth can cause electrical leakage and cannot be accurately measured.

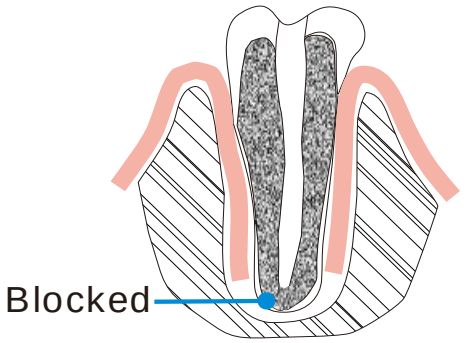
Branch tubes can also cause leakage.



Retreatment canal which was filled with gutta-percha

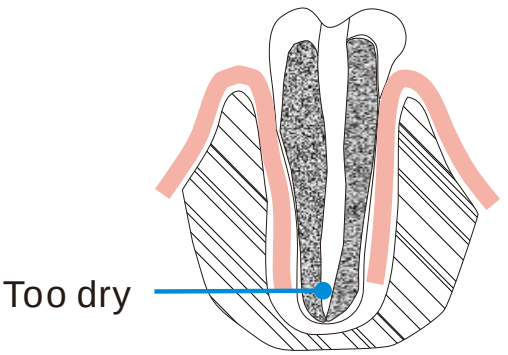
The gutta-percha must be completely removed to eliminate its insulation, then pass a small file all the way through the apical foramen and then put a little saline in the canal, but do not let it overflow the canal opening.

	**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.



Blocked canal

The meter will not run if the canal is blocked. Opening the canal all the way to the apical construction to measure it.

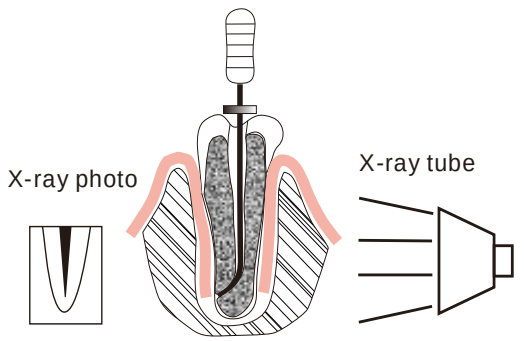


Extremely dry canal

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

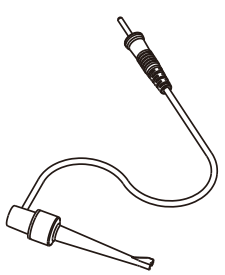
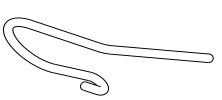
Difference measuring result between Apex locator reading and Radiography

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.Maintenance

<table>
<tr><th colspan="4">Autoclavable Components</th></tr>
<tr><td>File clip
  </td><td>Lip hook
  </td><td>Touch probe
  </td><td>Extension cord
  </td></tr>
<tr><td colspan="4">NOTE
File clip and lip hook must be pre-cleaned and sterilized before every use.</td></tr>
<tr><td colspan="4">Pre-cleaning: Use a soft brush or moist cloth to remove visible contaminations, then wipe all the surfaces with a cloth lightly moistened with Ethanol for disinfection (Ethanol 70 to 80vol%) at least 1 min, repeat for 5 times.</td></tr>
<tr><td colspan="4">Packing: Pack each component in a separate steam-sterilization pouch.</td></tr>
</table>

Sterilization: Steam sterilization at 134°C at least 6 minutes .

Minimum drying time after sterilization: 10 minutes.

Storage: Keep the components in sterilization packaging in a dry and clean environment.

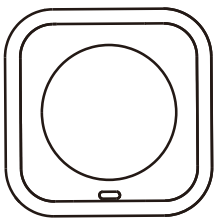
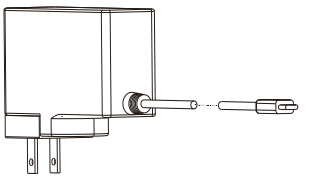
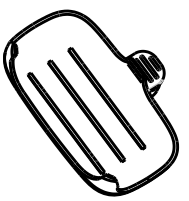
WARNING

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

Be careful to avoid cross contamination when performing maintenance.

Must be autoclaved after use for each.

Disinfection components

APEX locator 	Charge Base 	Adapter 
Tester 	Clip 	

Wipe all the surfaces with a cloth lightly moistened with Ethanol for Disinfection (Ethanol 70 to 80 vol%) at least 2min, 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.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	AirPex
Dimensions	13cm x 11cm x 8cm±1cm (Outer box)
Weight	0.35kg±10%
Power supply	Lithium ion battery: 3.7V, 120mAh, ±10%
Charger power supply	AC 100-240 V, ±10%
Charger power output	5V ⎓ 1A
Frequency	50/60Hz, ±10%
Power rating	＜1W
Degree of protection	IPX 0
Electrical safety class	Class II

Applied part	B
Operation mode	Continuous operation
Operating conditions	Use: in enclosed spaces Ambient temperature: 5°C ~ 40 °C Relative humidity: <80% Operating altitude < 3000m above sea level Atmospheric pressure: 70kPa-106kPa
Transport and storage conditions	Ambient temperature: -20 °C ~ +55 °C Relative humidity: 20% ~ 80 % Atmospheric pressure: 70kPa~106kPa

10.EMC Tables

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The AirPex is intended for use in the electromagnetic environment specified below. The customer or the user of the AirPex should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The AirPex 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The AirPex 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.</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>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The **AirPex** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AirPex** 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 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.

Voltage dips IEC 61000-4-11 Voltage interruptions 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 form an uninterruptible power supply or a battery
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 **AirPex** is intended for use in the electromagnetic environment specified below. The customer or the user of the **AirPex** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted disturbances 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	Portable and mobile RF communications equipment should be usedno closer to any part of the **AirPex**, 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

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

Recommended minimum separation distances

Nowadays, many RF wireless equipments 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 **AirPex** 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 equipments and the **AirPex** as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max power (W)	Distance (m)	Immunity test level (V/m)
385	380-	TETRA	Pulse	1.8	0.3	27

	390	400	modulation 18Hz			
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/90, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-	Bluetooth	Pulse	2	0.3	28

	2570	**WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7**	**modulation 217Hz**			
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 **AirPex** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **AirPex** and result in improper operation.

   Cable information:

Cable Name	Cable Length (m)	Shielded or not	Remark
Adapter Cable	1.2	No	/
Measuring Cable	0.8	No	/

2. Use of **AirPex** adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, **AirPex** and the other equipment should be observed to verify that they are operating normally.

11.Statement

Service Life

The service life of AirPex series products is 3 years.

Maintenance

MANUFACTURE 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

Changzhou Sifary Medcial Technology Co., Ltd

Add: NO.99, Qingyang Road, Xuejia County, Xinbei District, Changzhou City, 213000 Jiangsu, China

Tel: +86-0519-85962691

Fax: +86-0519-85962691

Email: ivy@sifary.com

Web: www.eighteeth.com

EC REP

Llins Service & Consulting GmbH

Tel: +49 175 4870819

Add: Obere Seegasse 34/2, 69124, Heidelberg, Germany

Email：Llins.Service@gmail.com

Version: S01

IFU-6335101

Issued: 2019.12.02