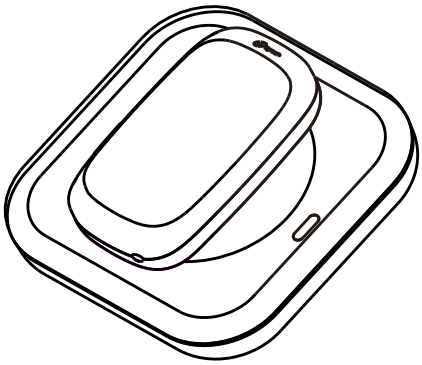
Eighteeth

CE 0197



AirPex

Apex locator USER MANUAL

Changzhou Sifary Medical Technology Co.,Ltd.

Version: 02
IFU-6135002/02
Issued: 2020.11.30
Size: 96mmx119mm

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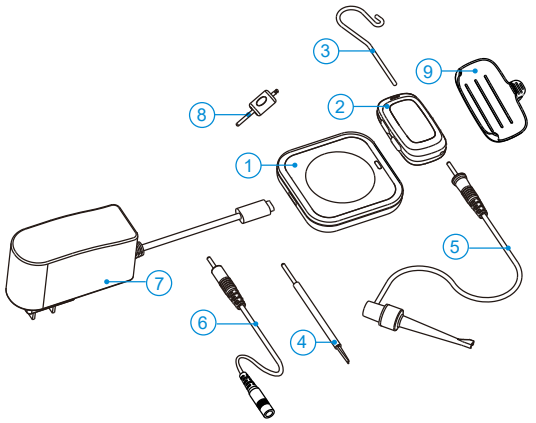
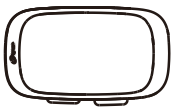
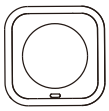
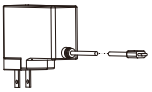
3. Lip Hook
4. Touch Probe
5. File Clip
6. Extension Cord
7. Adapter
8. Tester
9. Clip



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. 6151011 	File Clip (2pcs) Part No. 6151003 
Extension Cord (2pcs) Part No.6151004 	Tester (1pcs) Part No.6151005 	Clip(1pcs) Part No.6151008 

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.
SN	Serial number
REF	Catalogue number
	Manufacturer
	Date of manufacture
LOT	Lot of manufacture
	Class II equipment
	Type B applied part
CE 0197	CE marking
	Direct current
	Dispose of in accordance with the WEEE directive

	Keep dry
134℃	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
EC REP	Authorized Representative in the European Community
-20℃ 55℃	Temperature limitation
20% 80%	Humidity limitation
70kPa 106kPa	Atmospheric pressure limitation
Eighteeth	Manufacturer's LOGO
	Follow instructions for use
	Washer-disinfector for thermal disinfection

3. Before Use

3.1 Intended Use

AirPex 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

AirPex is not recommended for use in patients who have a pacemaker or other implanted electrical devices, or have been cautioned by their physicians against the use of small electric appliances such as shavers, hair dryers, etc., and in patients allergic to metal.

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 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. No modification of this device is allowed. Never open or repair the device yourself, otherwise, void the warranty.

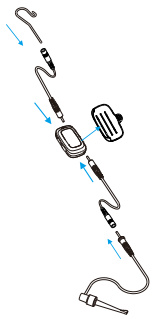
7. The device must be used with the manufacturer's original accessories only.

8. If there is any liquid leaked, it indicates that the battery is leaked. Remove all of the leaked liquid and contact the local agency.

4.Installing the AirPex

4.1 Connecting file clip, lip hook, extension cord and clip

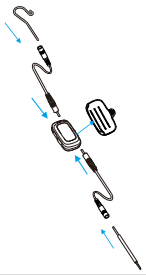
Connect file clip, extension cord and lip hook to APEX locator as shown in the picture. Also, use both extension cords according to actual situation. Then place APEX locator in clip for better fixation.



4.2 Use of touch probe

The equipped touch probe can replace the use of file clip.

When using the touch probe, connect the lip hook, touch probe, extension cord to APEX Locator as shown in below picture.

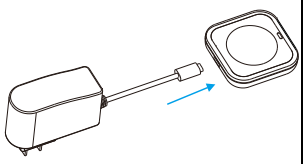


NOTE

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.
Please check the connection of the device before use to make sure the device functions well.

4.3 Connecting charge base

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



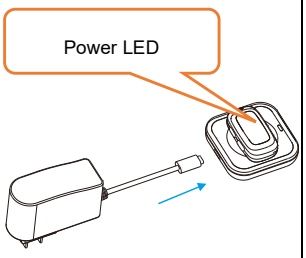
NOTE

Only the original adapter can be used.

Do not use the device while charging.

APEX Locator power connector can only be used to connect the original adapter cord for charging purpose.

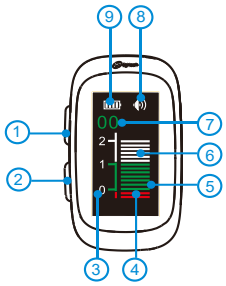
Put the APEX locator in the groove in the middle of the charge base. The power LED on charge base will light up. And the interface of APEX locator will light up to show that is charging.



NOTE

Put the APEX locator on the charge base in the right place, 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

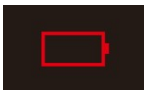
The flash of the measuring bar is the current measured value, represents the estimated distance from the apical foramen in millimeters.

Display reversing

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

6.Operation

6.1 Charge

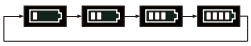


Display the present remaining amount of the battery.

Less than 15% remains, please charge.

NOTE

If the power is less than 15%, the device must be recharged within 30 days, otherwise the battery will be damaged.



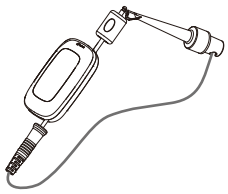
Charging indication appears on the screen, and flashes slowly, when battery is fully charged or in a state near full charge, the flash will stop. It takes about 4-5 hours for full charge, depending on residual battery power and battery state.

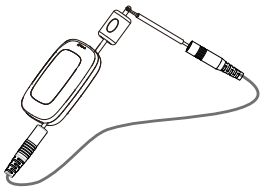
It can be recharged 300-500 times, depending on the operating conditions of the device.

WARNING

Do not change the battery. Only trained technicians or distributors can change the battery. The electronic parts will be damaged if use a wrong battery or installed with a wrong way.

6.2 Function checking of APEX locator

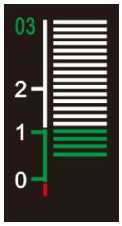




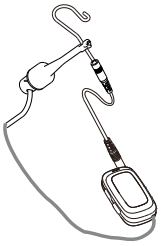
- After turning on, insert the tester into the APEX locator.
- Clamp the groove of tester with file clip or touch the groove of tester with touch probe.
- The measuring bar flashes at the point when the displayed measured value is 02, 03 or 04
- Recommend to test the APEX locator with tester once a week.

NOTE

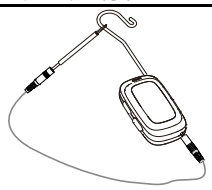
If the measurements are not expected, check whether the tester is connected properly. If the connection is normal but the screen still does not show the expected value, please stop using

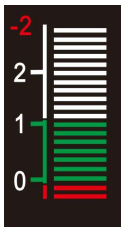


the device and contact the local dealer for processing.



- Before each use, make the file clip touch the lip hook, or use the touch probe to touch the lip hook to confirm the device condition (short circuit).
- Make sure that the tester is not installed on the APEX locator. Then connect the file clip, lip hook and extension cord according to chapter 4.1. Finally, make the lip hook



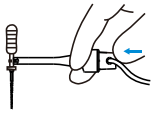


touch the metal part of file clip. The measured value on the screen should be shown as -2.

NOTE

If the measurement shown is not -2, check if the connection is normal. If the connection is normal but the screen still does not show the expected value, please stop using the device and contact your local dealer.

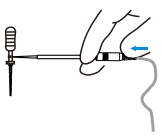
6.3 Operation and not suitable condition



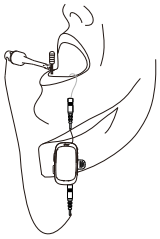
- Press the back cover of the file clip to make the hook of the file clip stick out. And hook the metal handle of the root canal file. Release the pressure and use the elasticity of the file clip to complete the connection between the file clip and the dental file.

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 files. Please select suitable root canal files 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 lip hook to the patient's lip. Make sure that the lip hook contacts with the lip fully. Then slowly insert the root canal file into the prepared root canal.
- If the patient is fitted with a metal crown or other conductive device, the root canal file and the metal part of file clip should not be in contact with it, to avoid causing wrong measurement results.
- APEX locator should be fixed in patient's collar with the clip.

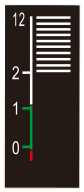
NOTE

- To prevent measurement errors caused by conduction between the gums or adjacent root canals, dry the pulp chamber floor with a cotton pellet or other means before testing.
- Use the root canal file with correct number and taper. Make the file fully contact with the canal wall, which facilitates accurate measurements.

- As the file progresses in the root canal, subsequent measuring bar lights up gradually.
- When displayed as shown in figure 1, it

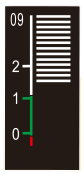
indicates that the distance from the apical foramen is about 2mm at this time. Meanwhile, the APEX locator makes a "didi" alarm sound at a long interval.

Fig.1



- When displayed as shown in figure 2, it means that the distance from the apical foramen is close, about 1.5 mm, and the time interval of "di~di~" alarm sound made by the APEX locator becomes shorter.
- When displayed as shown in figure 3, it means that it reaches the apical foramen. The measured value is 00. Meanwhile, the Apex Locator emits a long beep sound with no internal.

Fig.2



- When displayed as shown in figure 4, it means that the root canal file has penetrated the apical foramen, and the main unit makes a very urgent "di~~" alarm sound.

NOTE

- The position of apical foramen (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, 0.5-1.0 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. It simply indicates the file progression towards the apex.

Fig.3

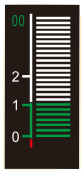
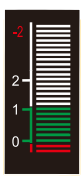


Fig.4

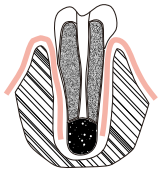


WARNING

- During measuring, insert the file slowly to prevent penetrating the apical foramen.
- The APEX locator is used to detect the apex of 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.

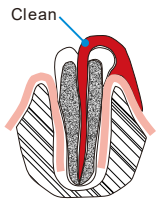
Unsuitable situation of root canals for Electric Measurement

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.

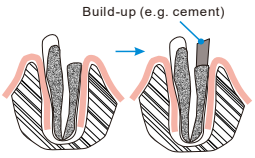
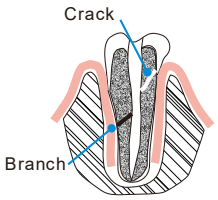


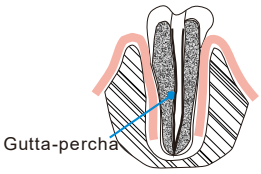
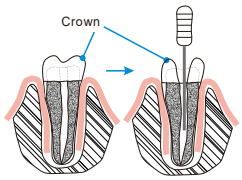
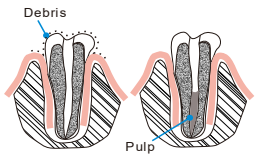
Root canal blood overflow from the opening

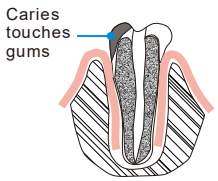
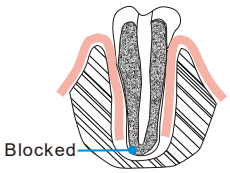
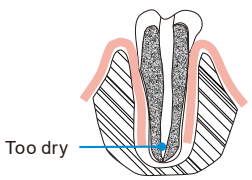
If blood spills from the root opening and contacts the gums, it will cause leakage of electricity, which cannot be accurately measured. Wait for the bleeding to stop completely. Clean the root canal and the opening, completely empty the root canal blood, and then measure it.

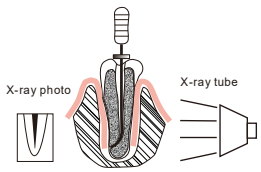
The root canal uses a chemical solution to flow out from the opening

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.Cleaning, Disinfection and Sterilization

7.1 Foreword

For hygiene and sanitary safety purpose, the file clip, lip hook, touch probe and extension cord 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	Touch probe	Extension cord
			

WARNING

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

Preparation at the Point of Use: Disconnect the components (Lip hook, file clip, touch probe and extension cord) 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.

Pre-Cleaning: Do a manual pre-cleaning, until the components are visually clean. Submerge the components in a cleaning solution. 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.

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 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℃ 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: 5 min at 134 °C
Maximum sterilization temperature: 137°C
Drying time: 8 min
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.
- 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.

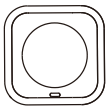
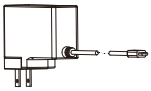
Check the packaging before using (packaging integrity, no humidity and validity period).

Reprocessing validation study information: The above-mentioned reprocessing process (cleaning, disinfection, sterilization) has been successfully validated. Refer to test reports:
Cleaning Disinfection Validation Report No. RDS2020D0063 001
Sterilization Validation Report No. RDS2020S0067 001 and RDS2020S0066 001

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 consequences.

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	Li-Polymer Battery: 3.7V, 110mAh, ±10%
Charger power supply	AC 100-240 V, ±10%
Charger power output	5V ⎓ 1A
Frequency	50/60Hz, ±10%
Power rating	＜2W
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

Guidance and manufacturer's declaration – electromagnetic emissions		
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.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	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.
RF emissions CISPR 11	Class B	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.
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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

	±0.5kV, ±1kV, ±2kV	±1kV, ±2kV	
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 **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 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	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**

Proximity fields from RF wireless communication equipment IEC 61000-4-3	See the RF wireless communicati on equipment table in "Recommen ded minimum separation distances"	Complies	See the RF wireless communication equipment table in "Recommended 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	**380-390**	**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 800/90, 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;**	**Pulse modulation 217Hz**	**2**	**0.3**	**28**
1845						
1970						

		DECT; LTE Band 1,3,4, 25; UMTS				
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 **AirPex** could result in increased electromagnetic emissions or decreased electromagnetic immunity of **AirPex** and result in improper operation.

Cable information:

Cable	Max. cable length shielded/unshielded	Number	Cable classification

Adapter cable	1.2m	Unshielded	1 set	AC Power
Measuring cable	0.8m	Unshielded	2 set	

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

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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