



Micropex

Apex locator user manual











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# 1. Symbols

 <b>Warning</b>	If the instructions are not followed properly, operation may lead to hazards for the product or the user/patient.
 <b>NOTE</b>	Additional information, explanation of operation and performance.
	Do not dispose of with normal household waste.(WEEE)
	Serial number
	Catalogue number
	manufacture
	Date of manufacture
	Type B applied part
	Safety class II device
	Store in a dry place

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	<p>Can be autoclaved up to a maximum temperature of 135° Celsius</p>
	<p>Temperature limitation</p>
	<p>Relative humidity</p>
	<p>Transport and storage pressure conditions: 70 kPa - 106 kPa</p>

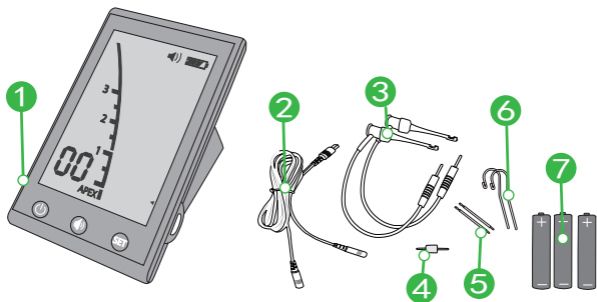
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## 2. Technical Data

Model	<b>Micropex</b>
Package Size	124mmx116mmx78mm
Package weight	Approx. 335g
Power supply	4.5V, 3 pcs of AAA batteries
Electrical safety class	Class II
Applied part	B
Operating conditions	Use: in enclosed spaces Ambient temperature: 5° C ~ 40 ° C Relative humidity: <80% Operating altitude < 2000m 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

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### 3. Parts Identification



#### Components and Accessories

1 Main unit	1 (pcs)	2 Measuring Wire	1 (pcs)
3 File clip	2 (pcs)	4 Tester	1 (pcs)
5 Probe	2 (pcs)	6 Lip Hook	2 (pcs)
7 AAA battery	3 (pcs)	User manual	1 (pcs)

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## 4. Intended use

This equipment applies to measurement of pulpits, pulp necrosis, periapical periodontitis and tooth length.

The device must be only used by or under instruction of qualified medical personnel. The personnel who use the device must be trained.

**FOR DENTAL USE ONLY !**

## 5. Contraindications

This equipment is contraindicated in cases where patient/user carry medical implants such as pace makers or cochlear implants etc.

Do not use the device for implants or other non-endodontic dental procedures.

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



### Warning

Read the following warnings before use:

The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.

Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.

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The device is intended for endodontic treatment and may only be used by trained and qualified professionals such as dentists in the hospital.

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.

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

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

Gloves and a rubber dam are compulsory during treatment.

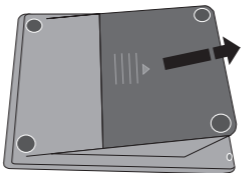
Do not charge this device.

## 6. Installation

### 6.1 Battery

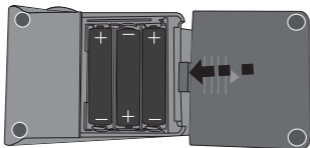
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1



Remove the battery cover on the device according to the picture above.

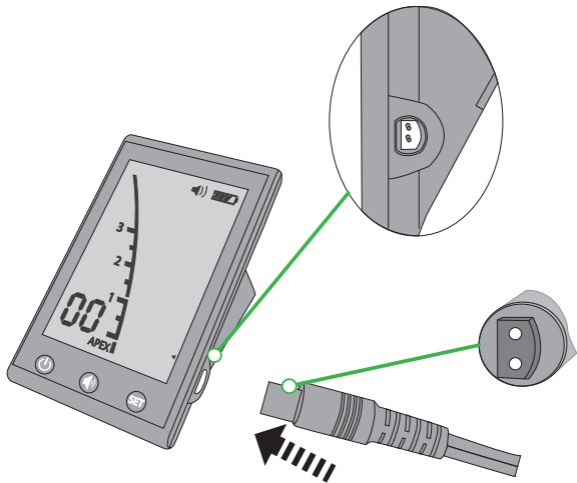
2



Install 3 pcs of AAA batteries into the device and then install the battery cover.

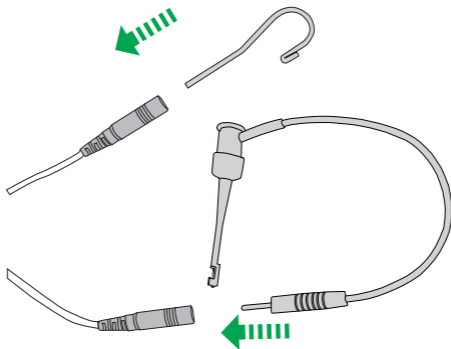
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## 6.2 Install accessories



Plug the measuring wire into the socket of the device.

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Insert the lip hook and file clip into the other end of the measuring wire.



#### NOTE

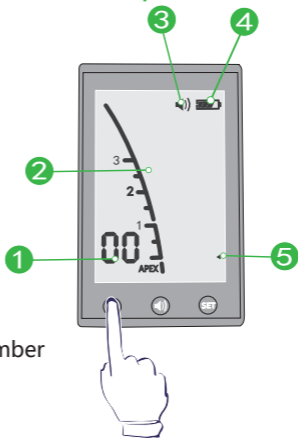
After the measuring wire is installed, gently pull the measuring wire, lip hook and file clip to ensure that they are firmly connected.

Only the original accessories can be used.

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## 7. Using

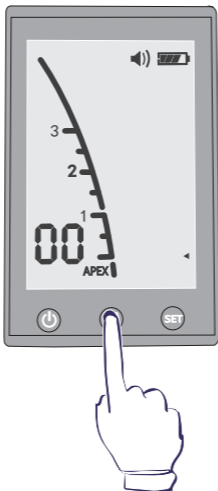
### 7.1 Power on and setup



- ① Measurement number
- ② Progress bar
- ③ Volume setting
- ④ Battery indicator
- ⑤ Reference point setting

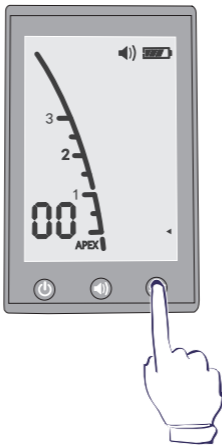
Short press the power button to turn device on.

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Pressing the volume button to set different volume settings.

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The reference point can be set between 0~1 mm, and the number "0.0" - "0.6" by pressing "SET" button .



## NOTE

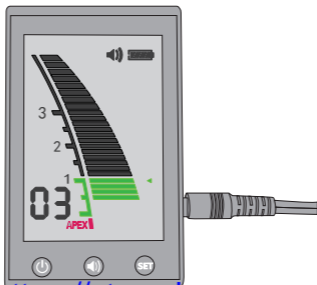
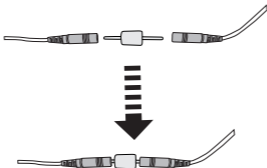
The device will automatically shut down after 8 minutes of inactivity

The reference point and the volume settings will be saved automatically when it changed.

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## 7.2 Testing the device

After installing the battery and the measuring wire, plug the tester into the two sockets of the measuring wire and observe the number displayed on the screen . If it is 02, 03 or 04.



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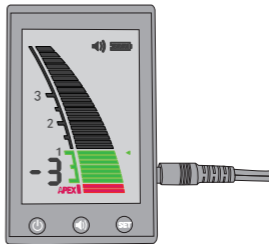
## NOTE

It is recommended to perform a test on the device every one or two weeks to ensure that the device is working well.

If the testing fails, stop using the device and contact your distributor.

## 7.3 Connectivity test

Check the measuring wire, file clip, lip hook and APEX LOCATOR are connecting properly. Make file clip hook with lip hook (short circuit).



Observing the device display, the "APEX" sign will flash, the number will display "-3", the root canal length strip will be all lighted, and a rapid bee sound will be generated at the same time. That means the device is working well.

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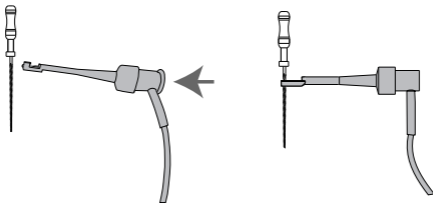
## NOTE

It is strongly recommended to test the device before use each time.

If the testing fails, stop using the device and contact your distributor.

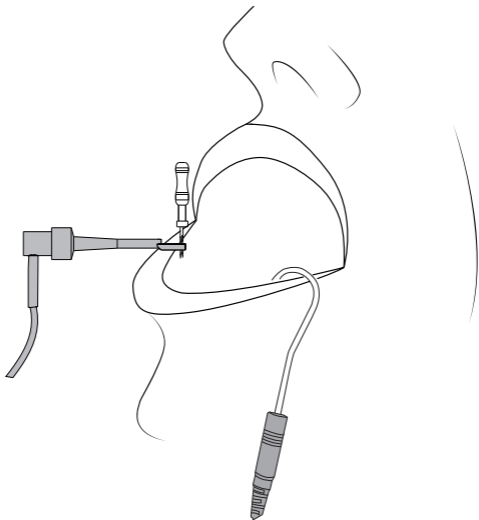
## 7.4 Making a measurement

Clip the file clip to the metal shaft the file. Press in direction of arrow and clip file, then release to finish installation



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Connect the lip hook to the patient' s lower lip and the file clip to the file that is inserted into the treated root canal. The progression of the file into the canal in reference to the apex will be indicated on the display.



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## Warning

Make sure that the connection between the root canal ,lip hook and the file clip is reliable, otherwise cannot make a measurement.

The following conditions are not suitable for root canal measurement:

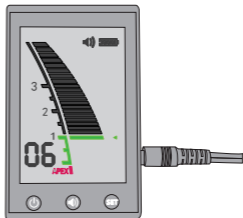
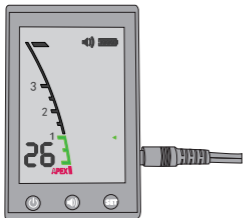
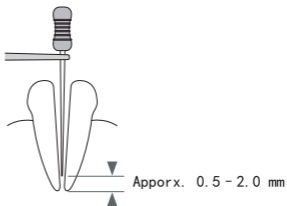
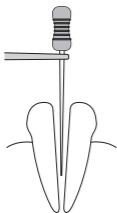
- (1) Apical foramen of the root canal has be expanded;
  - (2) The root canal which is bleeding or blood overflow apical foramen .
  - (3) The crown of the root canal is damage;
  - (4) The tooth root has cracks;
  - (5) The root canal filled with gutta-percha;
- Only the original accessories can be use.

Observing the strips and numbers indicated on the display while moving the file into the root canal slowly.

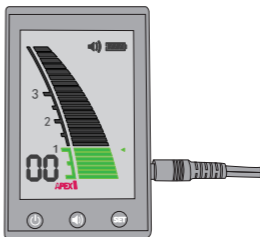
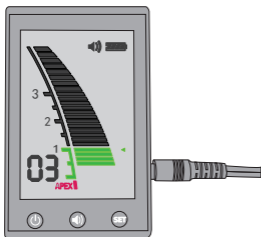
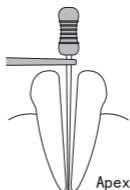
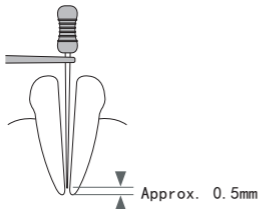
The numbers indicates the remaining number of strips before reaching the major apical foramen.

Strips become green into the apical zone. The minor and major apical foramens are separated by 7 strips form 0.0 to 0.6, "0.0" will display when the major apical foramen is reached and the beep will sound continuously.

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## Warning

The green part "00" display means major apical foramen (not the minor apical foramen), in clinic the measure length need minus 0.5 to 1mm as the root canal length.

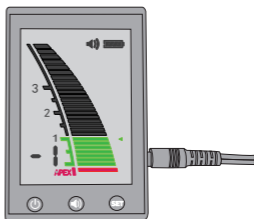
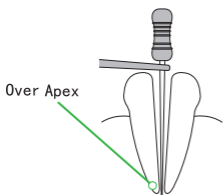
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The device's screen do not show the actual length of the root canal ,the number reducing only means a trend that file move to apical .

In order to prevent the liquid from contacting the gum or the adjacent root canal to interfere with each other and cause the measurement error, the mouth should be dry before measurement.

The accessories which contact with patient (file folder, lip hook) can be reused ,and should be sterilized by high temperature before every time use.

When the file tip over the apex, strips become red ,number becomes negative and the label "APEX" blinks with a rapid beep.



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## Warning

The measurement should be stopped and restarted when the file tip over the apex.

# 8. Maintenance and sterilization

## 8.1 Cleaning and disinfection

Step	Operation	Parts	Processing
1	cleaning	All	Remove debris under running water (except electronic parts), and then wipe off all components.
2	Disinfection	Main unit Measuring wire	Wipe the components with a piece of gauze impregnated with Ethanol (Ethanol 70 to 80% vol.). Make sure the components are dry before next step If use of washer-disinfectors, use only approved devices according to EN ISO15883 and refer to their manufacturer' s instructions for use.

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Step	Operation	Parts	Processing
3	Packing	Lip hook File clip Probe	Pack components in sterilization pouches Use pouches which resist to a temperature up to 141° C and comply with EN ISO 11607.
4	Sterilization	Lip hook File clip Probe	Steam sterilization at 135° C at least 4 minutes, or at 121° C at least 35 minutes. Minimum drying time after sterilization: 10 minutes
5	Storage	All	Keep the components in sterilization packaging in a dry and clean environment.



### Warning

Use only Ethanol for Disinfection (Ethanol 70 to 80% vol.)

Use only approved autoclave devices according to EN 13060 or EN 285. The sterilization procedure must comply with ISO17665. Waiting for cooling before touching.

Check the packaging before using it (packaging integrity, no humidity and validity period), otherwise sterilize again.

Disinfection before first use and after each use.

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## 8.2 Battery

Change the battery when the battery icon flashes on the display .

Please remove the battery from the device and store it separately if you do not use the device for a long time.

## 9. Troubleshooting

Problem	Cause	Solution	Ref. chap
Cannot turn the device on	The battery is too low	Change another one	5.1
	power button broken	contact your distributor	/
There is no sound	Volume is setting off	Change the setting	6.1
	PCBA broken	contact your distributor	/
No displays on the screen	PCBA broken	contact your distributor	/

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Problem	Cause	Solution	Ref. chap
Cannot make a measurement	Measuring wire damage	Change another one	/
	Unstable connection between the wire and the file clip or lip hook	Check the connection	/

## 10. EMC table

Guidance and manufacturer' s declaration – electromagnetic emissions		
The Apex loactor is intended for use in the electromagnetic environment specified below. The customer or the user of the Apex loactor should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Apex loactor 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.
	Class B	The Apex loactor is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.

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Harmonic emissions IEC61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

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

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrical fast transients/ bursts IEC 61000-4-4	±2kV 100kHz repetition frequency	N/A	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	N/A	Mains power quality should be that of a typical commercial or hospital environment.

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply lines 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	N/A	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 battery

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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			

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Guidance and manufacturer' s declaration – electromagnetic immunity

The Apex loactor is intended for use in the electromagnetic environment specified below.The customer or the user of the Apex loactor 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 %.

Conducted disturbances 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	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Apex loactor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended minimum separation distances See the RF wireless communication equipment table in "Recommended minimum separation distances"
Radiated RF EM fields IEC 61000-4-3	3 V/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz	3 V/m	
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 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 Apex loactor 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 Apex loactor 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

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

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 NOTE

1. Use of accessories and cable other than those specified or provided by the manufacturer of Apex locator could result in increased electromagnetic emissions or decreased electromagnetic immunity of Apex locator and result in improper operation.

Cable information			
Cable Name	Cable Length (m)	Shielded or not	Remark
measuring wire	1.5	No	/

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

## 11. Warranty

1. The main unit of Apex locator enjoys a 12-month warranty period, which starts on the day of delivery to the customer.
2. The host and other parts of the Apex locator are repaired by authorized repair service partners.
3. If it is proved that the damage is caused by improper daily maintenance by the user, it is not covered by the warranty.

## 12. Service life

The service life of the Apex locator series products is 3years.

## 13. Declaration

In the following cases, the manufacturer does not assume any responsibility:

1. Use Apex locator for purposes other than those specified in this manual.
2. The cleaning, disinfection or sterilization operation is not carried out according to the method stated in this manual.

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3. Use or maintenance by untrained personnel.
4. If you have any questions, please contact your local dealer.

## 14. Environmental protection

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.

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## 15. Warranty Card

Name of customer:	Tel:	Purchase date:
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Address detail:
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Product name:	Model:
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Serial number:
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Maintenance record	Date	Fault cause

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Thank you very much for using our products; This table is considered as the Protection to fix warranties, so please reserve them carefully, Lose don't repair

1. Calculated from the date of purchase, our company's product warranty period is 1\_year. During this any belongs to under normal usage circumstance cause because of the product. quality's problem of breakdown, our company will be responsible for giving free maintain.
2. In protect fix the period, if there is any breakdown, please return the faulty device and completed warranty card to our company for repair.
3. Those machines that has refitted or added other functions by yourself will not be accepted to repair.
4. Once the protect to fix card has been changed, the protection to fix immediately expired.

Free maintain won't be given under the following circumstance:

1. Without Protection to fix warranties.
2. Failure caused by improper installation, operation, and sterilization (don't comply with the user manual).
3. The breakdown caused by the dismantle movement of non-our-company authorized maintain.
4. The damage caused by customer inappropriate preservation, -maintain, breakdown, or the usage.
5. Easy damage pieces and present accessories are not concerned.
6. The breakdown and the damage caused by the force majeure.

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