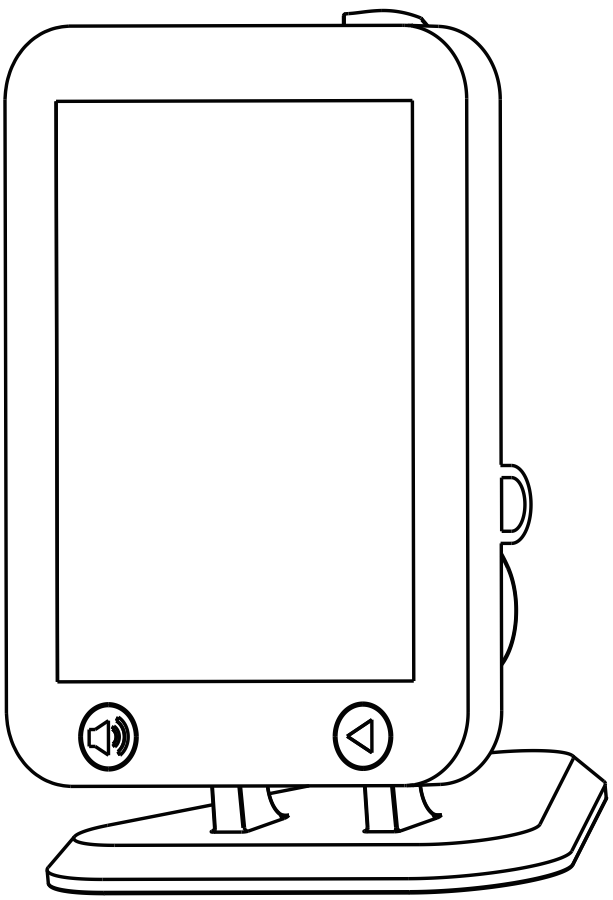
DentalDeal



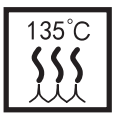
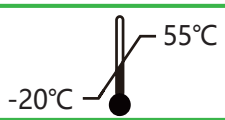
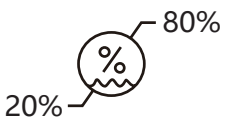
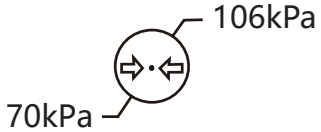
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DentalDeal

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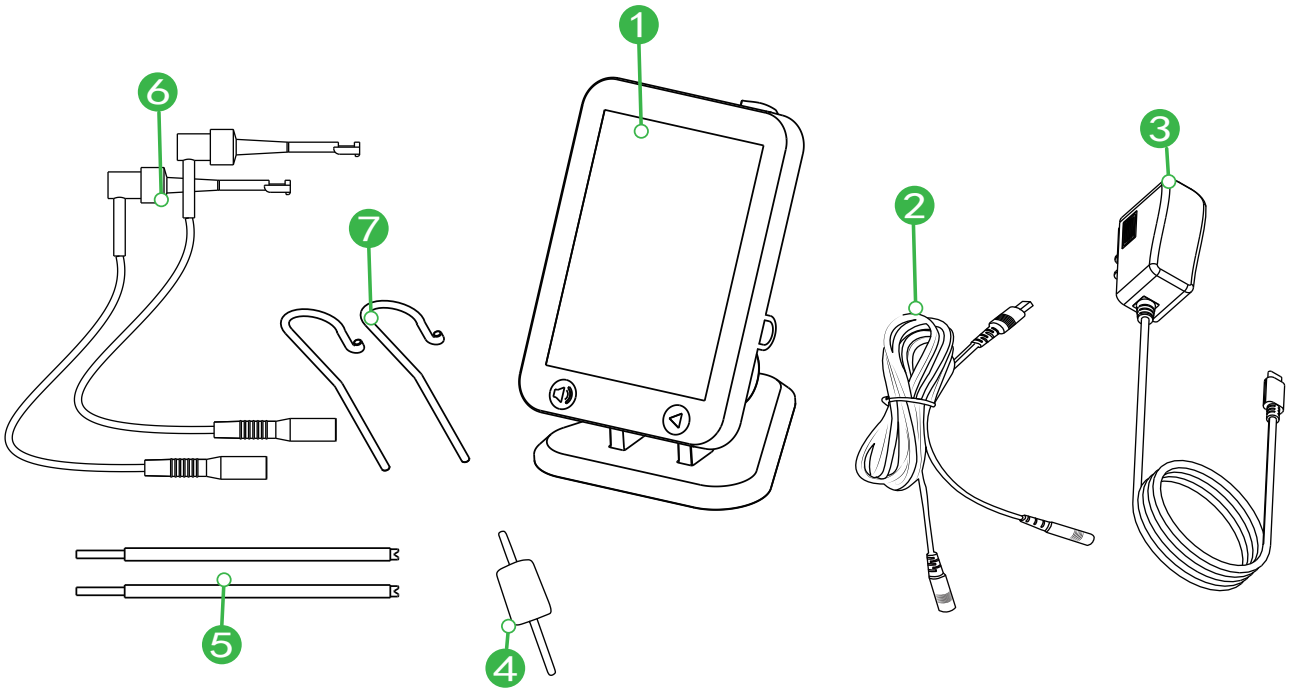
1. Symbols

Warring	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.
	Do not dispose of with normal household waste. (WEEE)
SN	Serial number
REF	Catalogue number
	manufacture
	Date of manufacture
	Direct current
	Type BF applied part
	Safety class II device
	Store in a dry place
	Can be autoclaved up to a maximum temperature of 135° Celsius
	Temperature limitation
	Relative humidity
	Transport and storage pressure conditions: 70 kPa - 106 kPa

2. Technical Data

Model	**ProPex**
Package Size	205 mm x 185 mm x 50mm
Package weight	Approx. 550g, ±10%
Power supply	ICR14500, 3.7V 800mAh ±10%
Charger power supply	AC100-240V，50/60Hz
Charger nominal power input	5VA
Degree of Protection	IPX 0
Electrical safety class	Class II
Applied part	BF
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

3. Parts Identification



Components and Accessories

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

4. Intended use

ProPex is an electronic apparatus for determining the apex location during an endodontic treatment.

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.

Warring

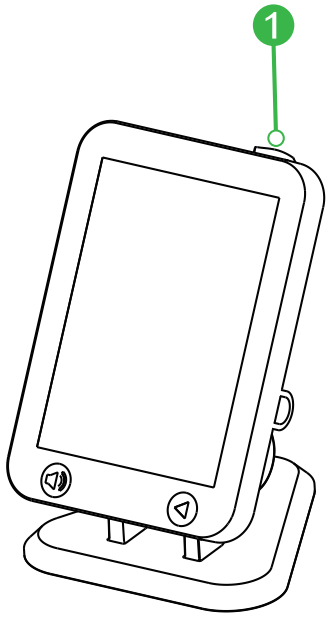
Read the following warnings before use:

1. The device must not be placed in humid surroundings or anywhere where it can come into contact with any type of liquids.
2. The device is intended for endodontic treatment and may only be used by trained and qualified professionals such as dentists in the hospital.
3. Do not expose the device to direct or indirect heat sources. The device must be operated and stored in a safe environment.
4. 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.
5. Gloves and a rubber dam are compulsory during treatment.
6. If irregularities should occur in the device during treatment, switch it off. Contact the agency.
7. Do not open or repair the device by yourself, otherwise, void the warranty.

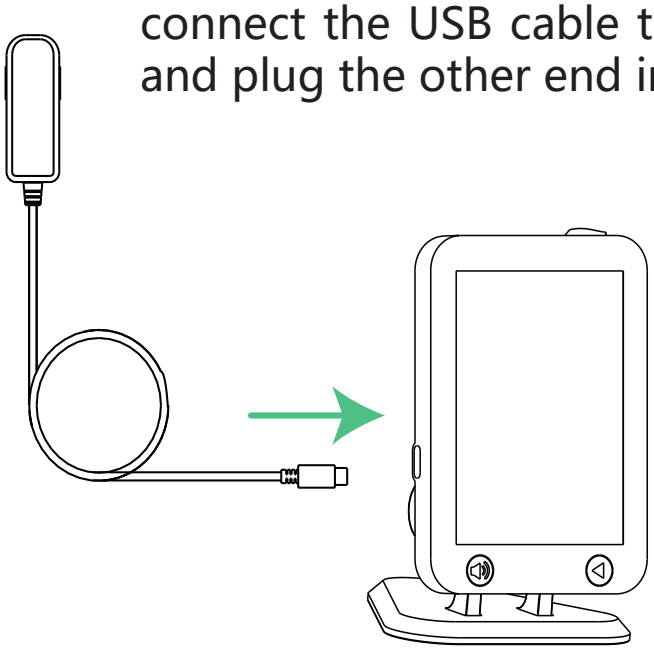
6. Installation

6.1 Charging

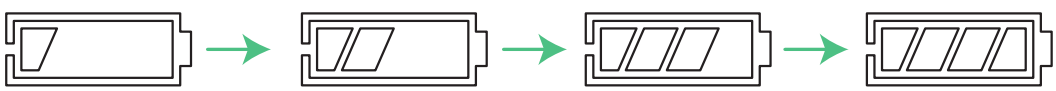
Turn the device on by pressing the 1 button.



connect the USB cable to the unit power connector, and plug the other end into a power outlet.

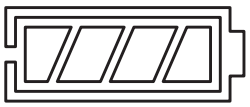


While charging, the battery symbols on the screen is displayed in sequence as bellow:



Fully charged will take about 4 hours, depending on residual battery power and battery state.

When the charging is completed, the battery symbols displays as :



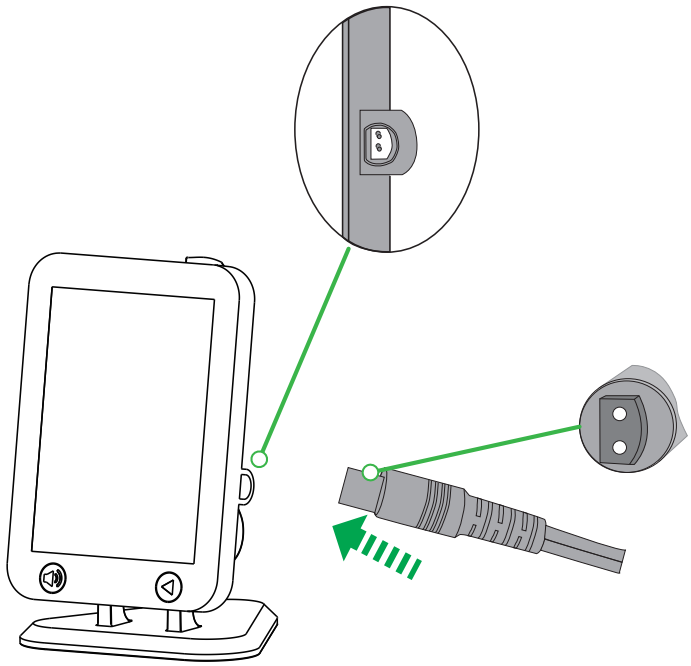
IF the power is too low, the battery indicator will flash in:



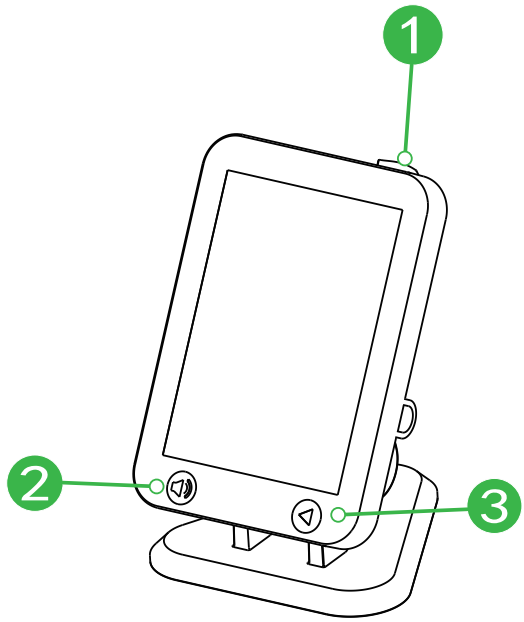
Warring

1. Charge the device for more than 4 hours before using the product for the first time.
2. Only the original adapter and battery can be used.
3. Disposal of waste batteries in accordance with local regulations.
4. Do not use the device while charging.
5. 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. Need to charge immediately, if the battery is low.

6.2 Install accessories and power on-off



Plug the measuring wire into the socket of the device .make sure connect properly.



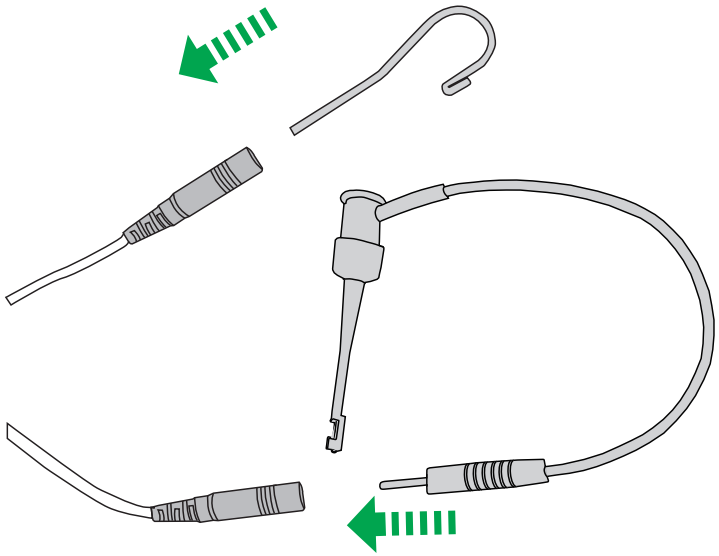
1 Power button
2 Volume key
3 Reference key

Turn power on:

Short press the power button 1 on the top of the machine, the machine will boot and enter the standby interface.

Turn power off:

Short press the power button 1 .



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

NOTE

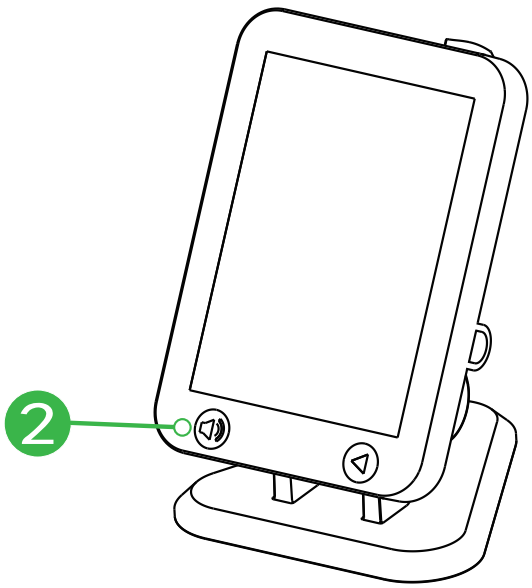
After the measuring wire is installed, gently pull the measuring wire, lip hook and file clip to ensure that they are firmly connected.

Only the original accessories can be used.

7. Using

7.1 Volume setting

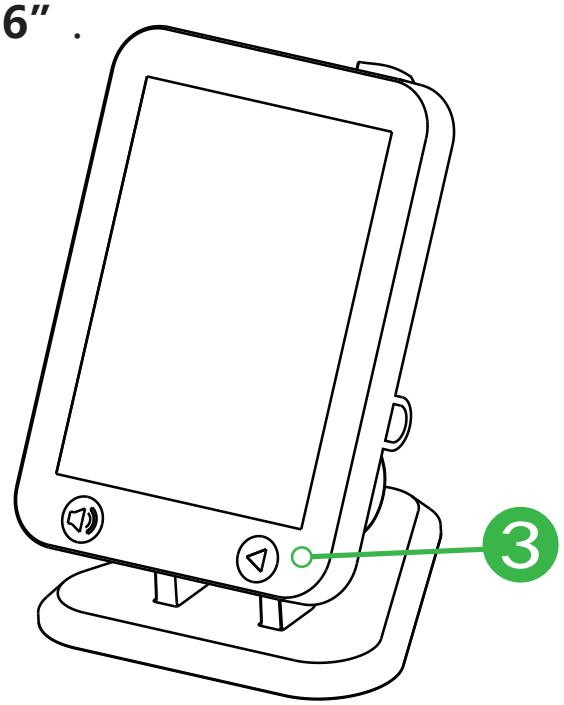
Touch the volume button(❷)in the panel to select different volume settings, and the modified volume settings will be saved automatically.



Volume indicator			
	beeper off		Medium volume
	Low volume		High volume

7.2 Setting the reference point

Touch (❸) on the device, can set the reference point, between 0~1 mm, and the number **“00” - “06”** .



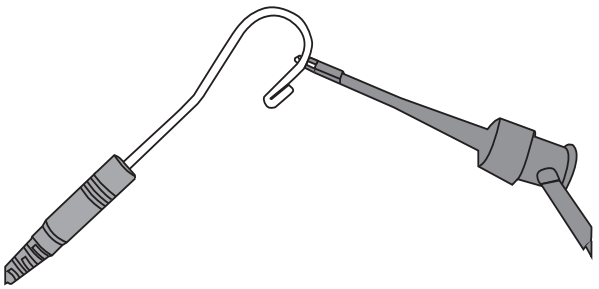
The reference point will be saved automatically.

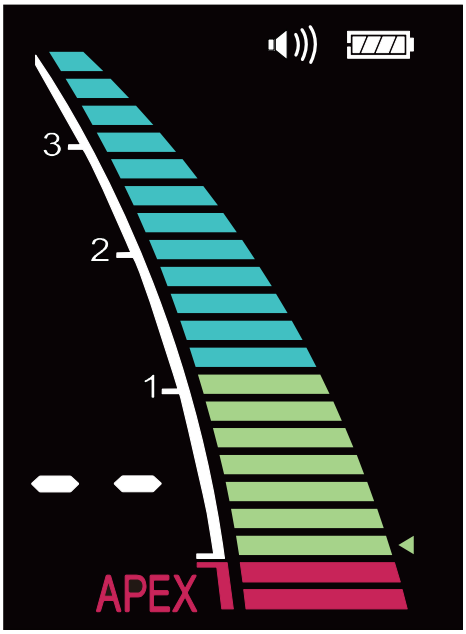
7.3 Connection test

Check the measuring wire, file clip, lip hook and the **APEX LOCATOR** are connecting properly.

Make file clip hook with lip hook (short circuit).

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Observing the device display, the **"APEX"** sign will flash, the number will display **"--"** ,the root canal length strip will be all lighted,and a rapid bee sound will be generated at the same time,

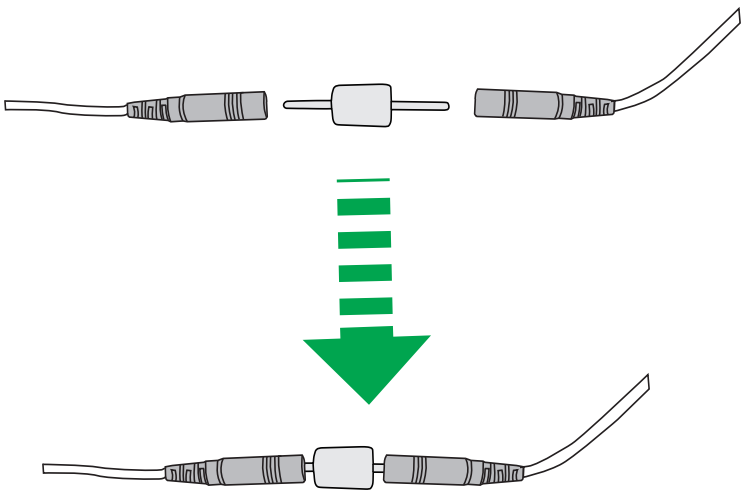
That means the device is working well.

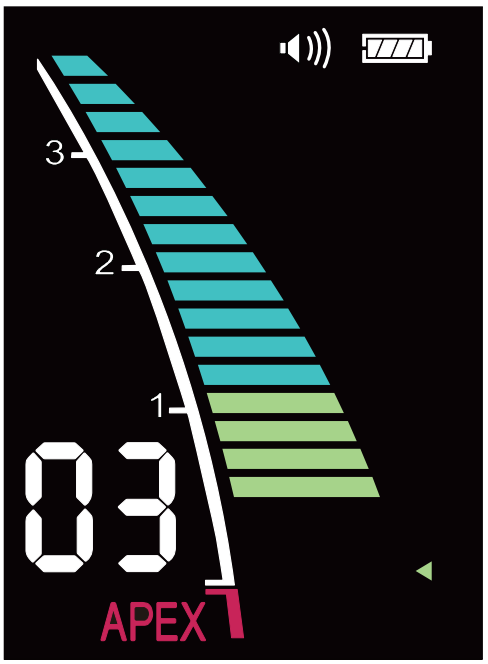
Warring

1. Testing the device before using every time.
2. If the testing fails, stop using the device and contact your distributor.

7.4 Accuracy the device

After installing 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.



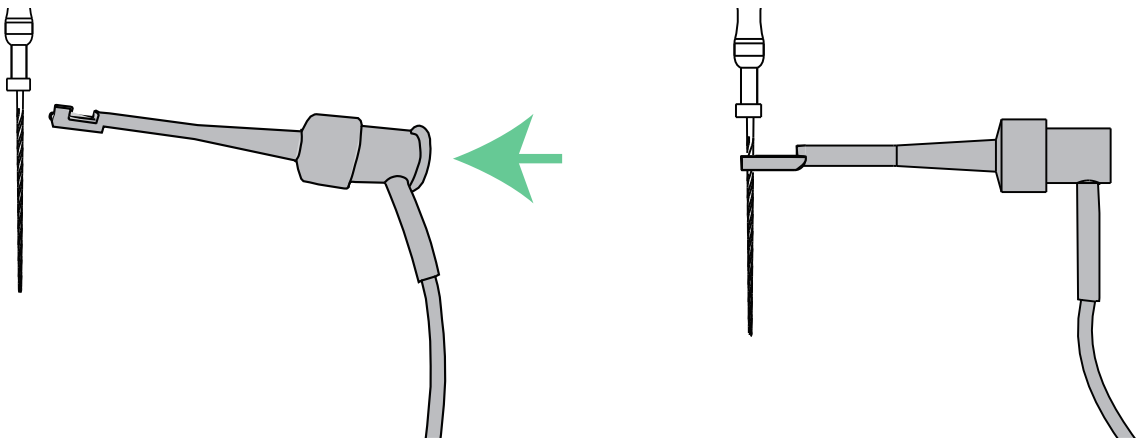


Warring

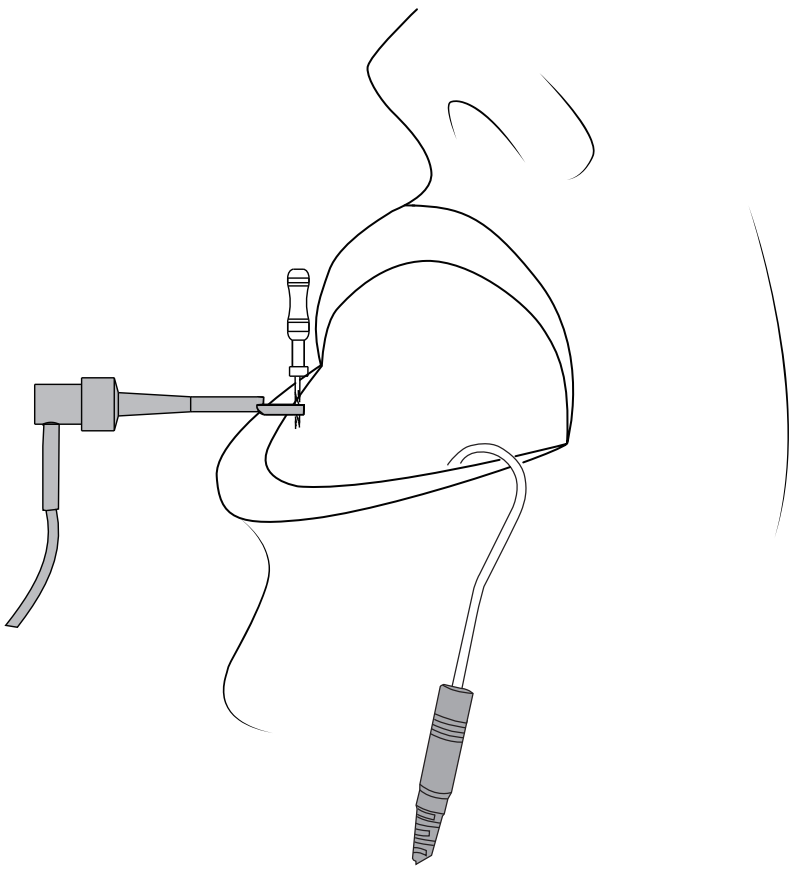
1. It is recommended to perform a test on the device every one or two weeks to ensure that the device is working well.
2. If the testing fails, stop using the device and contact your distributor.

7.5 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



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.



Warring

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:

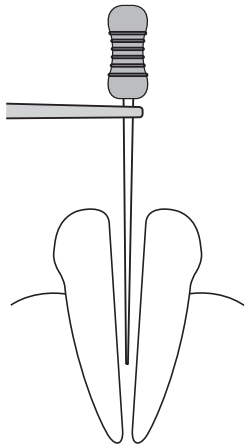
(1) Apical foramen of the root canal has be expanded;
(2) The root canal which is bleeding or blood overflow apical foramen .
(3) The crown of the root canal is damage;
(4) The tooth root has cracks;
(5) The root canal filled with gutta-percha;

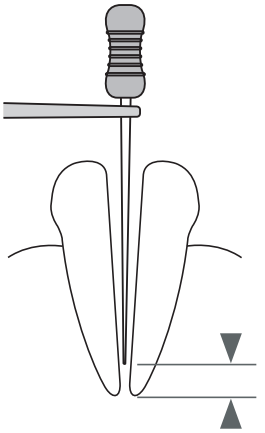
Only the original accessories can be use.

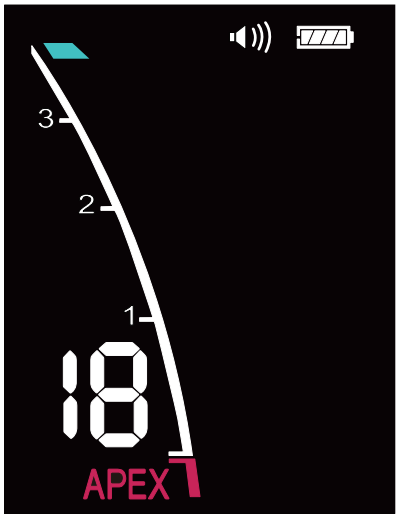
Observing the strips and numbers indicated on the display while moving the file into the root canal slowly.

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

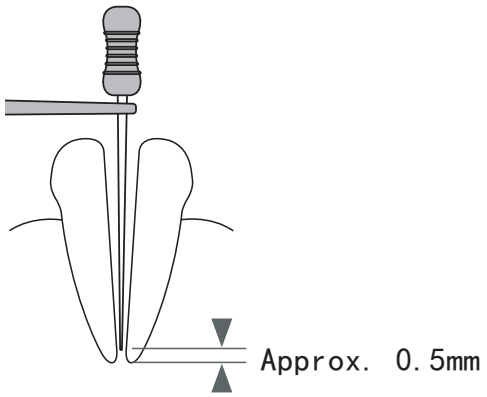
Strips become yellow into the apical zone. The minor and major apical foramens are separated by 7 strips form 00 to 06, **“00” will display when the major apical foramen is reached and the beep will sound continuously.**

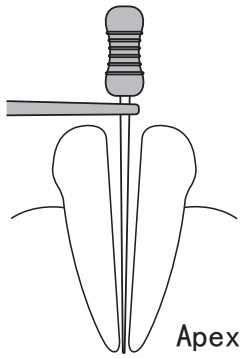



Apporx. 0.5－2.0 mm

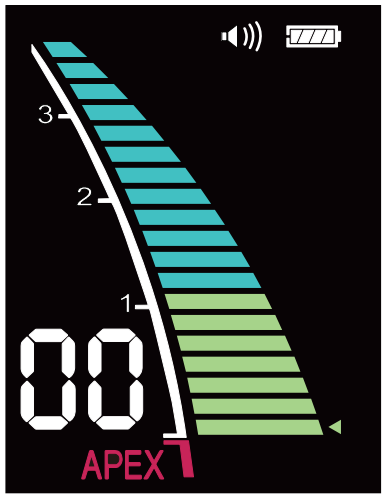

3
2
1
18
APEX


3
2
1
06
APEX









Warring

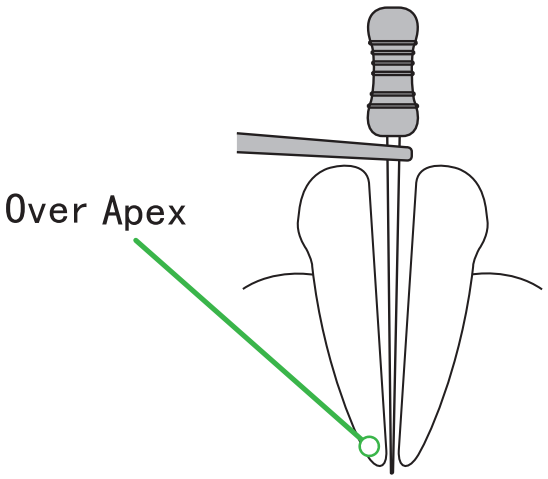
The “00” display means major apical foramen (not the minor apical foramen), in clinic the measure length need minus 0.5 to 1mm as the root canal length.

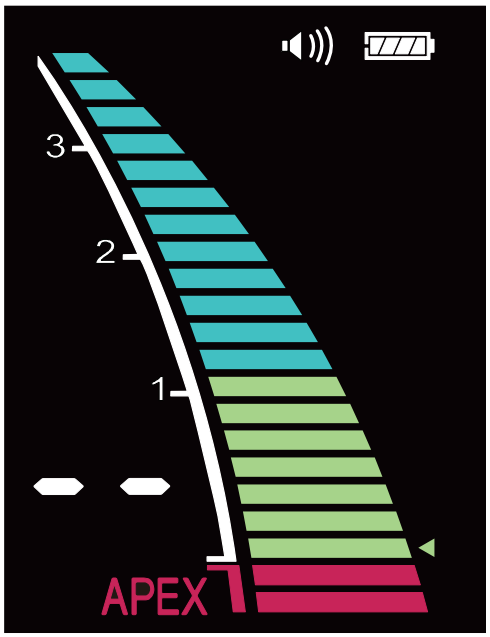
The device's screen do not show the actual length of the root canal ,the number reducing only means a trend that file move to apical .

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 using every time.

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





Warring

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

7.6 Connect with the Endo Smart II endomotor

The **ProPex** can be used with our company's endomotor **Endo Smart II**. After the connection, it can activate more functions of the endomotor. For details, refer to the instruction manual of the **Endo Smart II.**

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, Adapter	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.
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 ISO11607.

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Step	Operation	Parts	Processing
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.

Warring

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.

8.2 Battery Maintenance

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

If you do not use the device for a long time, you need to keep the device fully charged at least once a month to ensure that the battery is not too low.

9. Troubleshooting

If trouble occurs during the use of the product, please check the following points before contacting your distributor.

Problem	Cause	Solution	Ref. chap
Cannot turn the device on	The battery is too low	Please charge	6.1
	Press the main switch button too short time	Press the button more than 0.8 seconds	/
There is no sound	Volume is setting off	Change the setting	7.1
	PCBA broken	contact your distributor	/
No displays on the screen	PCBA broken	contact your distributor	/
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	/
Cannot charge	Wrong adapter used	Use original adapter only	6.1

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

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° , 134° ,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° , 134° ,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 continue operation during power mains interruptions, it is recommended that devices be powered form an uninterruptible power supply or a battery
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 ProPex is intended for use in the electromagnetic environment specified below. The customer or the user of the ProPex should assure that itis 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 Radiated RF EM fields IEC 61000-4-3 Proximity fields from RF wireless communication equipment IEC 61000-4-3	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/m, 80 MHz – 2,7 GHz, 80 % AM at 1 kHz See the RF wireless communication equipment table in "Recommended minimum separation distances"	3 V 3V/m Complies	Portable and mobile RF communications equipment should be used no closer to any part of the ProPex, 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".

Recommended minimum separation distances
Nowadays, many RF wireless equipment 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 ProPex has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the ProPex as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

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	/
Adapter Cable	1.5	No	/

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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 **ProPex** main unit 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.
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.

15. Right

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 the manufacturer. The industrial design, inner structure, etc, have claimed for several patents by the manufacturer, any copy or fake product must take legal responsibilities.

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16. Warranty Card

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

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.