



Operation Manual for **iRoot apex**

Apex locator



Read this Operation carefully before use. Keep this Operation Manual for future reference.



Thank you very much for choosing the apex locator

In order to give full play to the function of the equipment, correct operation, and safe maintenance, please read this manual carefully before operating, keep this manual for reference at any time.

### **Application:**

This product is apex locator used for the measurement of the length of apical teeth.

### **User:**

Only qualified personal is allowed to use this unit only in dentistry.

### **Classification of Device:**

- Classification by type of protection against electric shock: Class II devices
- Classification by degree of protection against electric shock: Applied part type B
- Degree of protection against ingress of water: IPX0
- Sterilization or disinfection method: refer to Sterilization part in the manual
- Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen of nitrous oxide: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
- Classification by mode of operation: Continuously operating device

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# 1. Product Introduction

## 1.1 Product introduction

Apex locator is equipment used for measuring the length of apical teeth, helping dentists to finish the endodontic treatment.

Feature of device:

- a) High resolution, wide angle of view LCD, the root canal changes can be clearly observed from different angles;
- b) Based on multiple frequency network impedance measurement technology , automatic calibrating ensures the measurements are accurate;
- c) Equipped with high precision gyroscope, switch the display mode according the state of display;
- d) Bluetooth wireless transmission, get rid of the long line;
- e) File clip and lip hook can be autoclaved under high temperature and high pressure. Avoiding cross infection effectively;
- f) Built in non-removable battery;
- g) Angle adjustable, easy to adjust the angle of view.

## 1.2 Model and dimensions

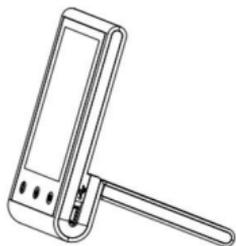
Model: iRoot apex

Dimensions: 110mm ( length ) × 65mm ( width ) × 20mm ( height )

Wight: 185g

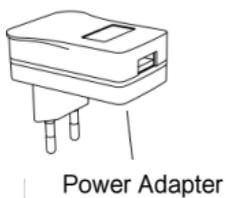
## 1.3 Components

### 1.3.1 Picture of main unit



Picture 1

### 1.3.2 Main accessories



Power Adapter

Picture 2 ( a )

USB cable



Picture 2 ( b )



Measuring cable

Picture 3 ( a )



File clip

Picture 3 ( b )



Lip hook

Picture 3 ( c )

The **iRoot apex** system is made up of the components listed below:

| <b>Components</b> | <b>Type</b> | <b>Number</b> |
|-------------------|-------------|---------------|
| Main unit         | iRoot apex  | 1PC           |
| Measuring cable   | BMMV2001    | 1PC           |
| File clip         | BMFC0001    | 3PCS          |
| Lip hook          | BMLH0001    | 3PCS          |
| Power Adaptor     | BMPA0001    | 1PC           |
| USB cable         | BMUC0001    | 1PC           |
| Operation manual  | \           | 1PC           |

If the user wants to purchase an additional attachment, he or she needs to contact the local designated dealer or manufacturer, and can't change the attachment at will, otherwise the risk is not acceptable.

#### 1.4 Application scope

The product is used for the measurement of root canal length.

#### 1.5 Contraindication

1.5.1 The product cannot be used for treatment other than implantation or other root canal therapy;

1.5.2 Hemophilia patients, patients with pacemakers and doctors are prohibited;

1.5.3 Patients with heart disease, pregnant women and young children are cautious.

#### 1.6 Main technical specifications

1.6.1 Battery: 3.7V/1000mAh

1.6.2 Adapter: ~100-220V, 50/60Hz

1.6.3 Consumption power:  $\leq 0.6W$

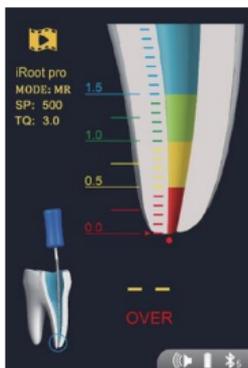
1.6.4 Screen: 3.5" TFT Wide angle of view LCD

1.6.5 Buzzer alert: The buzzer will alert when the endo file is less than 2.2 mm to the apex.

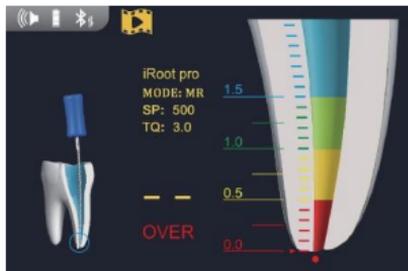
1.6.6 Operation condition:

- a) Environment temperature: +5°C ~ +40°C
- b) Relative humidity: ≤80%
- c) Atmosphere pressure: 70kPa ~ 106kPa

## 2. Function introduction



Picture 4 ( a )



Picture 4 ( b )

### 2.1 Interface display introduction

#### 2.1.1 Icon introduction



Mute



Woof



Mediant



Alt



Bluetooth is starting or is being initialized



Bluetooth normal open



Bluetooth open when charging



Bluetooth has been built to connect



Battery power status indicator: 0%, 25%, 50%, 75%, 100%



Battery charging status display



Demo mode, this icon will appear when the device is in demo mode



Connection test, when the measurement line short circuit will appear this icon

**APEX**

This icon will appear when the measurement results are in pre-setting the root tip

**OVER**

This icon will appear when the measurement result is beyond the root tip

**iRoot pro**

Display the type of connected device when the Bluetooth is on

**MODE: MR**

Display the working mode of connected device when the Bluetooth is on

**SP: 500**

Display the rotation speed(r/min) of connected device when the Bluetooth is on

**TQ: 3.0**

Display the torque(N.cm) of connected device when the Bluetooth is on

### 2.1.2 Testing interface introduction

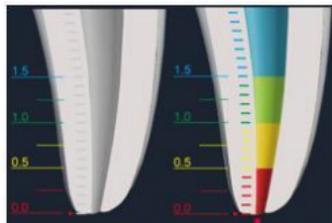
Picture 5 ( a ) shows root canal file in the dynamic operation of teeth in the solution. When not examined, no root canal file; after detected data, the corresponding schematic diagram will display according to the different position in the file teeth; when the tip of the root canal file arrived near the root of tooth, tooth solution of plane map will display the blue circle represents the position of amplification.



Picture 5 ( a )

Picture 5 ( b ) is enlarged display area. When the root canal file did not reach near the root tip, the entire root apex area is gray. When the needle slowly close

to the root tip, color scale will gradually fill, the alarm sound will be more rapid (non-silence state); when the needle reached the preset of the root file, the alarm will ring often to remind that has reached the apex; when file tip needle penetration, red dot prompt is displayed below the enlarged area with accompanying alarm.



Picture 5 ( b )

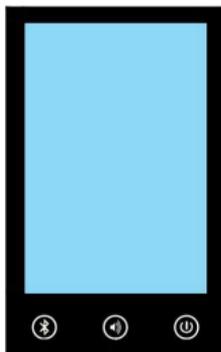
Picture 5 ( c ) is the position of the apical region of the root. The position of red arrows point is preset root tip, when the red arrow is located at a scale (the red arrows are located in the 0 scale for product factory), the measurement



Picture 5 ( c )

results to or beyond this scale, will display “APEX” with alarm. The method for adjusting the position of the red arrow is long press the volume key for 1 seconds, and the moving range is 0 ~ 0.4.

## 2.2 Key Function



Picture 6

### 2.2.1 Bluetooth

- a ) Click: on/off Bluetooth ( normal )
- b ) Press more than 2 seconds: Bluetooth Initialization ( first use or unable to establish connection )
- c ) This key does not work in the demo mode

### 2.2.2 Volume key

- a ) Click: switch the volume size
- b ) Press more than 1 seconds: switch apex alarm location, check picture 5
- ( c )

### 2.2.3 Power Key

- a ) Click when it' s off: Power on
- b ) Click when it' s on: Adjust screen brightness
- c ) Press more than 1 seconds when it' s on: Power off
- d ) Press more than 2 seconds when it' s off: Enter demo mode
- e ) Click or press in demo mode: Exit demo mode

## 2.3 Bluetooth Function

Bluetooth of this product can establish a wireless signal transmission with our endo motor. In the connection state, the endo motor can send the measured data by the Bluetooth signal to the apex locator to display.

### 2.3.1 Bluetooth link for the first time

- a) Device: 1 pc apex locator ( iRoot apex ), 1 pc endo motor ( iRoot pro )
- b) Environment: make sure no other Bluetooth signal interference within 5 meters, (please turn off the phone Bluetooth)
- c) Turn on the Bluetooth of endo motor, placed in the apex locator within 5 meters.
- d) Turn on the Bluetooth of apex locator and Initialization, after the Bluetooth

normal work, it will automatically search near Bluetooth of endo motor and connect.

After connecting the screen will display a Bluetooth signal transmission icon.

Display

the working mode, rotation speed and torque of the iRoot pro.

f) After the Bluetooth connection is established, the device will automatically switch to mute mode to prevent sound overlap with the iRoot pro, which can be opened manually if there is a special need.

### 2.3.2 Connect again

After the apex locator or the Bluetooth is turned off, if you need to connect the Bluetooth of same device, turn on the Bluetooth. No need to initialize the Bluetooth again. There's no relationship with the turn on sequence.

For the device has been connected, turn on Bluetooth again and will only be able to connect to the last connected Bluetooth slave device; please take 2.3.1 for reference to connect a new Bluetooth.

The effective signal transmission distance is 5 meters.

## 2.4 Gyroscope

With high precision gyroscope chip inside, the screen orientation can be constantly monitored, automatically switch the screen orientation when the screen is tilted direction.

## 2.5 Charging and USB introduction

Using professional lithium battery charging management chip, charging current can be up to 600mA. There is a slight fever during charging, which is normal. Please use the original charger to charge the battery, we will not assume any responsibility for the damage caused by using other chargers.

The USB micro interface is not only the measurement line interface is also

charging line interface, taking into account the special nature and security of the product, can prevent the user to measure the root canal when charging, the user can still use the Bluetooth mode when charging.

### 3. Installation

#### 3.1 Connect the measurement line

3.1.1 Insert the plug of the measuring wire into the right side USB socket of the unit.

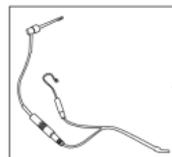
**[ Notice ]:**

- I) Please be careful to use the device, keep it stable avoid hit.
- II) Measurement can't be proceeded without the complete Insertion of the plug.

3.1.2 Insert the file clip and lip hook respectively into the two socket of the measuring wire ( Pic 7 ) .

**[ Notice ]:**

Be sure not to pull the wire when inserting or pulling out of the measuring wire and the file clip picture 8 ( a ) , correct operation showed as picture 8 ( b ) .

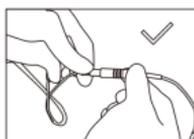


Picture 7

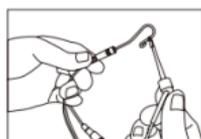


(a)

Picture 8



(b)



Picture 9

3.1.3 Test the wire connecting before use.

a )Turn on the unit( not demo mode ) , confirm that Bluetooth connection is not established.

b ) Make sure the measuring line inserting into the USB interface and well

connected with the file clip and lip hook.

c ) make the lip hook touch the file clip ( Pic 9 ) , when this  signal appears on the screen and stable, the connection is normal, Or else that file clip or measuring line is damaged, must be replaced.

## 3.2 Demo function

The demo function is used to demonstrate the movement of the root canal needle during the real measurement, specific operation is as follows :

When the device is off, press the power key for more than 2 seconds,  icon will appear on the upper left corner of the screen.

After entering the demo interface, Bluetooth key will not work, you can adjust the sound size by the volume key.

Press the power key again to exit the demo mode.

## 3.3 Battery charging

When the battery becomes red on the screen, it indicates that the battery is not enough, and it needs to be charged in time.

3.3.1 The charging line and test line share a USB interface.

3.3.2 Connect the charger and charging line, plug into the USB interface for charging.

3.3.3 If in Bluetooth mode or demo mode when charging, the display icon of the battery power will become green with charging animation effect, if the battery is full, the power icon will keep full green.

3.3.4 When charging in normal detection mode, battery charging status display will appear in full screen, when the battery is full, it will be in a state of full grid and no changing.

3.3.5 Expected full charging time is about 120 minutes, can guarantee the device running about 5 hours with maximum power consumption.

## **4. Product operation**

### **4.1 Operation Notice**

4.1.1 Please read this manual before operation.

4.1.2 The digital indication on the screen does not represent the length or distance determined by a millimeter or other linear unit, digital reduced only shows the needle moving toward the apical.

4.1.3 When just put in the file into the root canal, the number showed on the screen may appear larger or direct show "OVER" , continue pushing toward the file slowly, display return to normal.

4.1.4 To prevent the measurement error caused by the contact of the liquid, the gums and adjacent root canal. Please use a cotton ball dry pulp bottom before test.

4.1.5 Please choose the file matched with the diameter of the root canal, if use a small file in a big root canal, the digital on the screen will be instability.

4.1.6 Line link test must be performed before operation every time ( please check 3.1.3 ) , make sure the contact of file clip and measuring line is good.

4.1.7 Accessories contact with patient ( file clip and lip hook ) can be used repeatedly, but should be sterilized by high temperature and high pressure before use.

4.1.8 Do not disassemble the product without permission. Once demolition there will no warranty.

### **4.2 Usage requirement**

4.2.1 To measure according to the specific description in the manual.

4.2.2 The dentists should have the knowledge of teeth position and average length and the skill to operate the device.

4.2.3 An fully exposed access cavity to show the pulpal cabin.

4.2.4 A X-Ray photo to show the whole length and the root canal of the teeth.

4.2.5 The endo file should not be too big nor too small to avoid cutting through the apical foramen.

4.2.6 Mark an anatomized symbol on the diseased tooth and memorize it on the case history. This symbol should be marked on the health bridge or on the tooth filed integrated. The position of the mark should be on the incisal edge of the anterior tooth or on the spire of the molars. For those bridge that' s broken obviously. This symbol should be on the tooth surface supported by the dentin instead of on the suspended enamel.

4.2.7 The acute inflammation surrounding the apex has been gone and the infected material has been cleaned. It is also necessary to get rid of the pulp and necrosis tissue.

4.2.8 The following cases are not suited for a normal measurement :

a) The size of the root similar to the size of apical foramen

In this case, the measurement result of the length of the root canal will be shorter ( than its real because of the hypoplasia of the root. ( Pic 10 )

b ) Bleeding or the blood overflow from the apical foramen

In this case, the blood will overflow from the root canal and reaches gingival that the blood and the gingival will be on a conducting state which will cause an inaccurate result while measuring. The measurement can be continued when the bleeding is stopped. ( Pic 11 )

c ) The tooth crown is broken

The tissue of the gingival may reach the cavity of the endo hole at the broken point which will cause inaccuracy because of the electronic conduction. The measurement can be continued when the crown is fixed by gypsum or other insulators. ( Pic 12 )

d ) There' s a crack on the tooth root

In this case, the crack may cause the electric leakage which will affect the accuracy of the measurement. ( Pic 13 )

e ) A retreatment to an endo which was filled with gutta-percha

Clean the remaining material in the root canal and fill it with little normal saline before a measurement. ( Pic 14 )

f ) There is a metal crown which has connected to the gingival

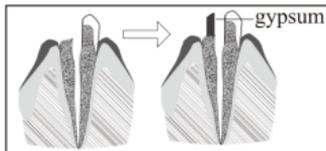
It will cause an inaccuracy when the endo file touches metal crown. ( Pic 15 )



Picture 10



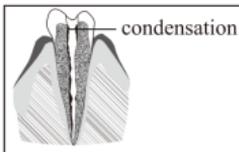
Picture 11



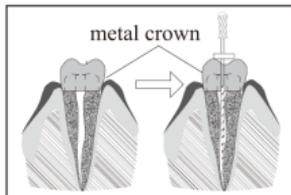
Picture 12



Picture 13

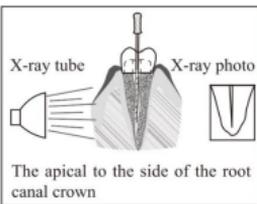


Picture 14



Picture 15

Sometimes, the results of the Apex Locator and X-Rays do not meet each other, which is neither because the machine is not normal, nor the photo is incorrect taken. The actual position of the apical foramen is different from the anatomical one it is very common that the apical slightly to the side of the root canal crowns.



Picture 16

In this case, according to the shooting angle as the bellowing picture show, it will cause illusion that the front tip of the root canal haven' t reached the canal tip.

( picture 16 ) Because of the angle of X-Rays, sometimes it can't take photo of the apical foramen properly, so it can't show the accurate position of the apical foramen.

### 4.3 Instruction

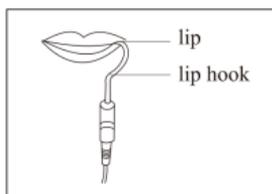
4.3.1 Please insert the plug into the socket on the right side of the main unit, turn on the device, the instrument is normally on and without warning, which indicates that the instrument is normal. Please refer to the troubleshooting section when there is a warning.

4.3.2 Connect the file clip and lip hook ( Pic 9 ) , this  icon appears on the screen, means the connection is normal, the measurement can be start.

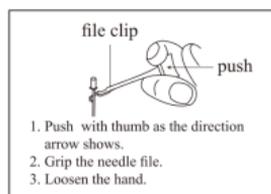
4.3.3 Please press the volume key to set the volume.

4.3.4 Hang the lip hook on the lip , make sure it contact the oral mucosa as a reference electrode ( Pic 17 ) .

4.3.5 Clip the file with the file clip, approach to the apex, then there will be continuously alarm when the distance is less than 2.2mm ( Pic 18 ) .



Picture 17



Picture 18

#### 【 Notice 】

a ) When grip the root canal with a needle file, please grip the upper of the metal part(near the root canal at the needle handle). If you grip the lower part (blade or moving part), it will wear the metal part of the file folder and the resin part. ( Pic 19 )

b ) When measuring the length of the root canal, please don't use the metal needle file. If you operate the device without the dentistry glove, it will cause leakage and the result of the measurement will be inaccurate. Therefore, please use the resin needle file and remember don't touch the metal part with finger.

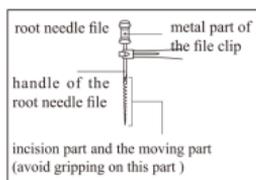
c ) Please don't use the worn file clip, it will make the result of the measurement inaccurate.

d ) Please reference the picture 20 ( a ) to grip the needle file, if as picture 20 ( b ) it can't properly measure the length of the root canal due to the improper force, the front of the root canal pin is easy to wear.

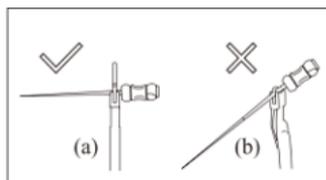
4.3.6 When the file reaches the apex, adjust the rubber piece set on the endo file to the reference point (incisal edge or fossa edge), then pull out the endo file, measure the length between the top of the file and the rubber piece, and this is the working length of the tooth.

4.3.7 The components that touch body must be autoclaved under high temperature and high pressure. The shell and measuring line should be cleaned by 75% alcohol.

4.3.8 Press the Power key more than 1 second to turn off the device, the device will automatics shutdown after 10 minutes without operation.



Picture 19



Picture 20

## 5. Trouble shooting

| Problem                                 | Check points  | Responses   |
|---|---|---|
| No Power                                | Check if the appearance is damaged?   | If ok: connect the charging wire to check if it's power on, if not in 2 seconds, please remove the charging line immediately.<br>If no: don't do this.  |
| Cannot make a Measurement               | Check if the Bluetooth is connected   | If Bluetooth is connected, the screen will display the data received from Bluetooth, and cannot display the measurement data. Turn off the Bluetooth, measurement will return to normal   |
|   | Check cord connections<br>Check probe cord for broken wire?   | Check that all connections are properly secured. Touch the contrary electrode to the file holder to check probe cord conductivity.  |
| Display" Calibration failure"           | If turn on unit normally and display " Calibration failure" , please press power to exit, , if not, the device can be used normally | Please note, if in this situation, there must be something wrong with the circuit inside, the measurement will be not accurate, please contact with your dealer to solve this problem   |
| Bluetooth is on, but can't be connected | Check if the Bluetooth display is normally, and not connected yet   | For the first use, Bluetooth needs to be initialized, press the Bluetooth for more than 3 seconds, Bluetooth will be a short period of initialization, if Bluetooth always be in an initial state, there must be something wrong with the Bluetooth |
|   | If the Bluetooth of device need to be connect turned on   | If not for the first connect, turn on the Bluetooth of two device, the signal will connect automatically, or please take 2.3.1 for reference  |

|  |   |  |
|--|---|--|
| No sound   | Check if sound is turned off?   | Turn on the sound.   |
| Problem  | Check points  | Responses  |
| Display not steady while measuring; the measurement result is rather long or shorter; numerical display irregular. | Is the lip hook making good contact with oral mucosa?                   | Make sure the lip hook making good contact with oral mucosa.   |
|  | Is blood or saliva overflowing from the opening of the crown?           | Blood, saliva or chemical solutions that overflow and leak onto the crown or neck can cause an electrical shortage. Clean away all overflowing fluids.                                 |
|  | Is the root canal filled with blood, saliva or chemical solutions?      | The canal length indicator bar may suddenly jump to "OVER" when it breaks the surface of fluids inside the root canal but it will return to normal as it approaches the apex.          |
|  | Is the tooth surface covered with cutting debris or chemical solutions? | Clean entire tooth surface.  |
|  | Is the file touching the gingival tissue?                               | This will cause the canal length indicator bar to suddenly jump all the way to the "OVER" .  |
|  | Is there pulp tissue left inside the root canal?                        | An accurate measurement cannot be obtained if a large amount of pulp tissue is left inside the root canal.   |
|  | Are proximal surfaces infected with caries?                             | Caries on proximal surfaces can allow the current to flow to the gingival tissue and make it possible to measure the length of a root canal.   |
|  | Are there lateral canals or is the tooth fractured?                     | The canal length indicator bar may be opening of a lateral root canal or the opening of a fractured tooth which allows the current to flow to the gingival tissue. This will cause the |

|  |   | canal length indicator bar to suddenly jump all the way to the “OVER” .   |
|--|---|---|
| Problem  | Check points                              | Responses   |
| Display not steady while measuring; the measurement result is rather long or shorter; numerical display irregular. | Is there a lesion at the apex?            | Foramen through absorption and an accurate measurement cannot be obtained.  |
|  | Is the file holder broken or dirty?       | Replace or clean the file holder.   |
|  | Measuring line is damaged or bad contact? | Connect the two ends of measuring line the screen shows a short connection, and the link of the measuring line is not abnormal. |
| Canal length Indicator bar does not move only when very near the apical foramen                                    | Is root canal blocked?                    | Canal length indicator will return to normal when the file reaches apical constriction.   |
|  | Is root canal extremely dry?              | Moisten the root canal with hydrogen peroxide or a saline solution.   |
|  | A small file in a large root canal.       | Choose right size of the file.  |

## 6. Cleaning and disinfection

6.1 The main unit and measuring cable can only be cleaned with cotton cloth dipped in alcohol.

6.2 Cleaning with chemical solution may cause damage to the main unit and measuring cable.

6.3 The lip hook and file clamp have biocompatibility (in line with EN ISO 10993-1). Before using to every patient, these parts must be disinfected. It is suggested that the method of high temperature and high pressure steam disinfection be adopted. The parameters of high temperature and high pressure steam disinfection are recommended as follows:

a) Steam sterilization at 121° C (250° F) for 20 minutes (placed in a sterilization bag), high temperature sterilization should not exceed 135° C (275° F). Steam sterilizer should follow standard EN 13060.

b) The lip hook and file clamp can be repeatedly disinfected.

6.4 Except the lip hook and file clamp mentioned above, all other parts for the device can't be sterilized by high temperature and pressure.

**[ CAUTION ]**

No part of the device was disinfected before leaving the factory.

## **7. Storage, maintenance and transportation**

### 7.1 Storage:

- a. The product should be handled with care, away from the source, and stored in a dry ventilated place.
- b. Not mixed with toxic, corrosive, flammable and explosive materials.
- c. The product should be stored in a space where the relative humidity is not exceed 80%, atmospheric pressure is 70kPa, and the temperature is -10°C~ +50°C.

### 7.2 Maintenance

- a. The product do not include accessories for repair usage, the repair should be carried out by authorized person or authorized after service center.
- b. Keep the product in a dry storage condition.
- c. Do not throw, beat or shock the product.
- d. Do not smear the product with pigments.

### 7.3 Transportation:

- a. Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly, don't invert it.

- b. Don't put it together with dangerous goods during transportation.
- c. Avoid solarization and getting wet in rain and snow during transportation.

## 8. Environment protection

There's no harmful factor in this product. You can deal with it based on the local law.

## 9. After service

From the date this equipment has been sold out, based on the warranty card we will repair this equipment free of charge if there's quality problem. Please refer to the warranty card.

## 10. Symbol instruction

 This conforms to CE European Directive

 Follow the waste of electric and electronic equipment (WEEE) Directive to dispose of the product and accessories.

 Class II equipment

 Type B applied part

 Refer to the instruction Manual

 Consult accompanying documents (user manual)

 Manufacturer  Serial number

 Date of manufacture  Direct current

 Authorized representative in the European Community

## 11. EMC Declaration

### 1) Guidance and manufacturer's declaration — Electromagnetic emissions

| <b>Guidance and manufacturer's declaration — Electromagnetic emissions</b>   |                   |  |
|--|-------------------|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in such an environment. |                   |  |
| <b>Emission test</b>   | <b>Conformity</b> | <b>Emission test Conformity Electromagnetic Environment – guidance</b>   |
| RF Emissions CISPR 1   | Group 1           | The appliance use 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 1   | Class B           | The device is suitable for use in at I 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  | Conforms          |  |

## 2 ) Guidance and manufacturer statement – Electromagnetic Immunity

| <b>Guidance and manufacturer statement – Electromagnetic Immunity</b>  |  |  |  |
|--|--|--|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in such an environment. |  |  |  |
| <b>Immunity test</b>   | <b>IEC60601 test level</b>   | <b>Compliance Level</b>  | <b>Electromagnetic environment – guide</b>   |
| Electrostatic discharge(ESD)<br>EN 61000–4–2   | ± 6kV contact<br>± 8kV air   | ± 6kV contact<br>± 8kV 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 transient/burst,<br>IEC 61000–4–4  | ± 2 kV for power supply lines<br>± 1 kV for input/ Output lines  | ± 2 kV for power supply lines  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge IEC<br>61000–4–5   | ± 1 kV differential mode   | ± 1 kV differential mode   | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000–4–11   | < 5 % $U_T$<br>( > 95 % dip in $U_T$ )<br>For 0.5 cycles<br>40% $U_T$<br>( 60 % dip in $U_T$ ) for 5 cycles<br>< 5 % $U_T$ 70 % $U_T$<br>( 30 % dip in $U_T$ ) for 25 cycles<br>< 5 % $U_T$<br>( > 95 % dip in $U_T$ ) for 5 s | < 5 % $U_T$<br>( > 95 % dip in $U_T$ )<br>For 0.5 cycles<br>40% $U_T$<br>( 60 % dip in $U_T$ ) for 5 cycles<br>< 5 % $U_T$ 70 % $U_T$<br>( 30 % dip in $U_T$ ) for 25 cycles<br>< 5 % $U_T$<br>( > 95 % dip in $U_T$ ) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000–4–8   | 3 A/m  | 3 A/m  | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |

### Guidance and manufacturer statement – Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in such an environment.

| Immunity test               | IEC 60601 test level                | Compliance Level    | Electromagnetic environment – guide  |
|-----------------------------|-------------------------------------|---------------------|--|
|                             |                                     |                     | Portable and mobile RF communications equipment should be used no closer to any part of apex locator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance   |
| Conducted RF<br>GB/T17626.6 | 3V(Effective value)<br>150kHz-80MHz | 3V(Effective value) | $d=1.2\sqrt{P}$  |
| Radiated RF<br>GB/T17626.3  | 3V/m<br>80MHz-2.5GHz                | 3V/m                | $d=1.2\sqrt{P}$ 80MHz-800 MHz<br>$d=2.3\sqrt{P}$ 800 MHz-2.5GHz  |
|                             |                                     |                     | P—Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer;<br>d—d is the recommended separation distance in meters (m)<br>Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. |



NOTE:  $U_r$  is the ac. mains voltage prior to application of the test level.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cord less) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

3 ) Determine the function of the basic performance

This product is used for the measurement of the length of apical teeth.

4 )The equipment is not provided for use only in the shielding place, for the non life support equipment

**Recommended separation distance between Portable and mobile RF communications equipment and apex locator**

The apex locator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the apex locator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF according to the maximum output power of the communications equipment

| Rated maximum output power of transmitter Watts [W] | Separation distance according to frequency of transmitter (in meters) Meters [m] |                                   |                                    |
|---|--|-----------------------------------|------------------------------------|
|   | 150 KHz ~80 MHz<br>$d=1.2\sqrt{P}$   | 80 MHz~800 MHz<br>$d=1.2\sqrt{P}$ | 800 MHz~2.5 GHz<br>$d=2.3\sqrt{P}$ |
| 0.01  | 0.12   | 0.12                              | 0.23                               |
| 0.1   | 0.38   | 0.38                              | 0.73                               |
| 1   | 1.2  | 1.2                               | 2.3                                |
| 10  | 3.8  | 3.8                               | 7.3                                |
| 100   | 12   | 12                                | 23                                 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

### **Warning note**

The apex locator has special tips in EMC, must be installed and used in accordance with the electromagnetic compatibility specification.

Portable and mobile RF communications equipment may affect the use of apex locator.

Make sure to use the cable produced or designed by manufacturer and installed in accordance with Chinese installation procedures for the cable connection.

Apex locator should not be used stacked or close to other equipment, if adjacent or stacked use is necessary, you should observe and verify it works normally.

Using the specified peripherals. Avoid to use not specified equipment, otherwise it may cause the lower performance of EMC.

Check the function of the corresponding sections of vital signs range this product can be detected. If the device is operating at less than the stated minimum value, the device may result in inaccurate results.

## **12. Statement**

The pictures are only for reference, the industrial design have claimed for patent, any copy must undertake legal responsibilities.

Production date and time limit please check product label.

Batch number of printing: ARCM2001  
Specification preparation date: 2019/05/24



## Warranty Card

**Dear user:**

**For the warranty:**

1. We offer 1 year warranty for the product iRoot apex(excluding the accessories).
2. The following circumstance does not belong to the scope of free warranty:
  - a) Using the product did not follow the matters needing attentions in user`s manual;
  - b) Disassembling the product by yourself;
  - c) Altering the invoice or without the invoice.
3. Fill up the following information, then send it back to us with our products.

User` s Name: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
Trouble Description:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(The information such as: When, Where and How it happened. How many times)

ChangZhou BoMedent Medical Technology Co.,Ltd.  
NO.9 Changyang road, West Taihu Science & Technology Industrial Park,  
Changzhou City,Jiangsu,China.  
Website:www.bomedent.com  
Tel: 86 0519-88991980





**QUALIFIED CERTIFICATE**

INSPECTOR: \_\_\_\_\_

DATE: \_\_\_\_\_







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Park, Changzhou City, Jiangsu, China.

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