BOMEDENT

Operation Manual for **iRoot apex**

Apex locator

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

Bondent

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Thank you very much for choosing iRoot 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.

Intended use:

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

CONTENTS

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

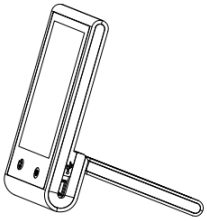
Model：iRoot apex

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

Wight：185g

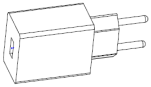
1.3 Components

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 C (optional)

Picture 2 (c)

Measuring cable A

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:

Components	Type	Number
Main unit	iRoot apex	1PC
Measuring cable A	BMMV2001	1PC
File clip	BMFC0001	3PCS
Lip hook	BMLH0001	3PCS
Power Adaptor	BMPA0001	1PC
USB cable	BMUC0001	1PC
Operation manual	\	1PC
Measuring cable C(optional)	BMMV3001	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

Patients fitted with pacemakers, artificial cochlea or other Implantable electronic device, and patients who are advised not to use the electric equipment (like electric shaver, electric blower), Do not recommend the use this product.

1.6 Main technical specifications

1.6.1 Battery：3.7V/950mAh

1.6.2 Adapter：~100–220V ± 10% , 50/60Hz

1.6.3 Consumption power：≤0.6W

1.6.4 Screen：3.5'' TFT Wide angle of view LCD

1.6.5 Sound alert：There will be sound alert when file tip is approaching the apex.

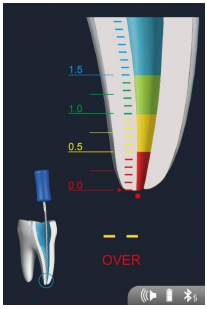
1.6.6 Operation condition：

a) Environment temperature：+10℃ ~ +40℃

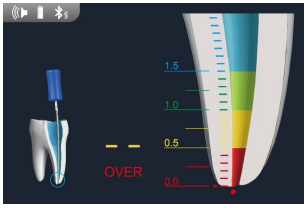
b) Relative humidity：10–70%

c) Atmosphere pressure：700hPa ~ 1060hPa

2. Function introduction



Picture 4（a）



Picture 4（b）

2.1 Interface display introduction

2.1.1 Icon introduction

Mute

Low volume

Middle Volume

High volume

Bluetooth normal open

Bluetooth has been built to connect

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


Battery charging status display


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

Appears when endo file reaches apical area

Appears when endo file go over apex point

Speed of the connecting device

Torque of the connecting device

The mode to turn on/off Bluetooth

The mode to adjust brightness of display

The mode to set reference point

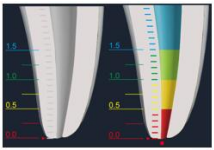
The mode to adjust sound volume

2.1.2 Testing interface introduction

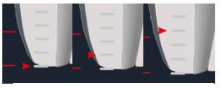
Picture 5(a)shows endo file in the dynamic operation of teeth in the solution. When not examined, no endo file; after detected data, the corresponding schematic diagram will display according to the different position in the file teeth; when tip of the file reached the apical area, the map will display with a blue circle represents the position of amplification.


Picture 5（a）

Picture 5 (b) is enlarged display area. When endo file has not reached the root canal area, the entire root apex area is gray. When file



Picture 5（b）



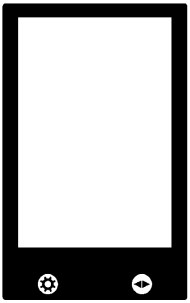
Picture 5（c）

get close to the apex slowly, the color scale will be gradually filled. The alarm sound will be more rapid (non-silence state); when the needle reached the reference point, the sound will ring urgently to remind that reaching of the apex. When file tip go over the apex, a red dot will show up below the area with a symbol of "OVER".

Picture 5 (c) is the position of reference apical point. The position of red arrows can be changed and presented (Factory default location of the red arrows is 03). When the reading reaches the red arrow position, it means the measurement results is just the reference position with display of "APEX" and alarm. If it goes over, it will display "--". In the menu of 

, the reference position can be adjusted from 0.0 - 0.9.

2.2 Key Function



Picture 6

2.2.1 Menu Key 

Press this key to launch the menu pages. Switch between each menu by continuous pressing.  —  —  — 

2.2.2 Select Key 

Press this key to adjust parameters under each menu.

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 iRoot apex 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.

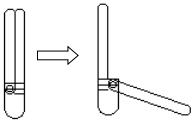
The USB micro interface is not only the measurement line interface is also charging line interface, taking into account the special nature and security of the product, can prevent the user to measure the root canal when charging. Please

contact the manufacturer to change the built–in battery.

2.6 Turn on / Turn off

Turn on: Open the supporter for no less than 60° , the device will be turned on.

Turn off: Automatically turned off with no operation after 3 mins.

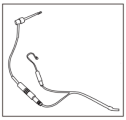


Picture 7

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.



Picture 8

【Notice】:

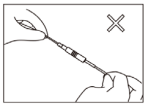
Please be careful to use the device, keep it stable avoid hit

Measurement can’t be proceeded without the complete Insertion of the plug.

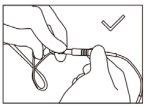
3.1.2 Insert the file clip and lip hook respectively into the two socket of the measuring wire（Pic8）.

【Notice】:

Be sure not to pull the wire when inserting or pulling out of the measuring wire and the file clip picture 9（a）,correct operation showed as picture 9（b）.

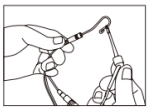


(a)



(b)

Picture 9



Picture 10

3.1.3 Test the wire connecting before use.

a) Turn on the unit, 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 10), 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 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.

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

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

3.2.3 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.

3.2.4 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 11)

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 12)

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 13)

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 14)

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

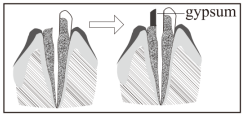
Clean the remaining material in the root canal and fill it with little normal saline before a measurement. (Pic 15)

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 16)

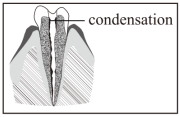
Picture 11

Picture 12

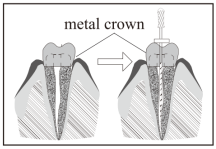


Picture 13

Picture 14

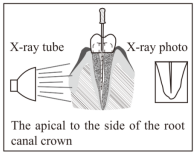


Picture 15



Picture 16

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. 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 17) 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.



Picture 17

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.

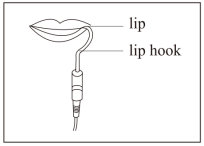
4.3.2 Connect the file clip and lip hook(Pic 10), this icon  appears on

the screen, means the connection is normal, the measurement can be start.

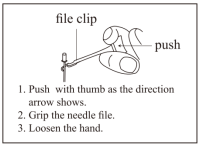
4.3.3 Please press the volume key to set the volume.

4.3.4 Hang the lip hook on the lip , make sure it contact the oral mucosa as a reference electrode（Pic 18）.

4.3.5 Clip the file with the file clip, approach to the apex, then there will be continuously alarm.（Pic 19）.



Picture 18



Picture 19

【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 partb(blade or moving part), it will wear the metal part of the file folder and the resin part.（Pic 20）

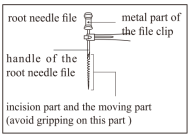
b）When measuring the length of the root canal, please don't use the metal needle file. If you operate the device without the dentistry glove, it will cause leakage and the result of the measurement will be inaccurate. Therefore, please use the resin needle file and remember don't touch the metal part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

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

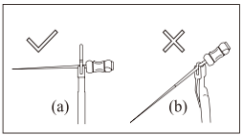
d) Please reference the picture 21 (a) to grip the needle file, if as picture 21 (b) it can’ t properly measure the length of the root canal due to the improper force, the front of the root canal pin is easy to wear.

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.



Picture 20



Picture 21

4.3.8 The device will automatically shut down after 3 minutes without operation.

4.3.9 Use with Dental endo motor of specified model

A、Connect the single line USB port connected with the Measuring cable C to the Dental endo motor(Model Marc Ⅲ);, the double line USB port to the root apex locator Model iRoot apex and hang the lip hook.

B、The rotation speed, torque and other parameters of the root canal preparation machine are displayed on the root apex locator screen.

C、The Dental endo motor connects the file into the root canal，at this time, the apex

locator will control the output speed and torque of the Dental endo motor according to the length of the file entering the root canal. The Dental endo motor automatically decelerates; when the file reaches or exceeds the preset apical point, the Dental endo motor automatically rotates in the reverse direction; as the file exits the root canal, the Dental endo motor resumes its initial operation.

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. 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 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.
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”.
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, Disinfection, Sterilization

CAUTION:

- No part of the device was sterilized before leaving the factory.

WARNNING:

- Do not immerse the central unit in the ultrasonic cleaner.
- Do not use liquid or spray cleaner directly, especially on the screen.
- Except the lip hook and file clamp, all other parts for the device can’t be sterilized by high temperature and pressure. See the following table for the cleaning methods of other parts
- Do not use any heat, radiation, formaldehyde, ethylene oxide or plasma for sterilization.

Advice:

- Reprocessing procedures have only limited implications to this dental instruments. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.
- In case of damage the device should be reprocessed before sending back to the manufacturer for repair.

Reprocessing Instructions

Step	Parameter
Preparation at the Point of Use:	Remove gross soiling of the instrument with cold water (<40℃) immediately after use. Don't use a fixating detergent or hot water (>40℃) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding, if required.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for Decontamination:	The devices must be reprocessed in a disassembled state, as far as possible. Only lip hook and file clamp can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the handpiece, power adapter, USB cord, measuring cable! The handpiece, power adapter, USB cord and measuring cabler cannot be cleaned and disinfected in a washer/disinfector! For these parts, only a general wipe decontamination is possible!
Decontamination of other parts than Lip hook and File clamp:	After operation, take the handpiece, power adapter, USB cord and measuring cable on the workbench. Soak a soft cloth completely with distilled water or deionized water, and wipe all the surfaces of these components, until the surface of the components is visually clean. For decontamination, soak a dry soft cloth with 75% alcohol or other disinfects which are approved for its efficacy by VAH/DGHM-listing, CE marking, FDA and Health Canada Approval. Wipe all surfaces of the handpiece, adapter and other components with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectants. Wipe the surface of the component with a dry soft lint-free cloth.
Following instructions are only relevant for lip hook and file clamp!	
Pre-Cleaning of Lip	Not use automated cleaning, disinfection and sterilization for other

hook and File clamp:	parts than lip hook and file clamp in this system! Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.
Cleaning:	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program: ● 4 min pre-washing with cold water (<40℃); ● emptying ● 5 min washing with a mild alkaline cleaner at 55℃ ● emptying ● 3 min neutralising with warm water (>40℃); ● emptying ● 5 min intermediate rinsing with warm water (>40℃) ● Emptying *The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).* Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.
Disinfection:	Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection at 90℃ has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93 ℃.
Drying:	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.

Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling, if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Before packaging and autoclaving, make sure that these devices have been maintained acc. to manufacturer's instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
Sterilization:	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134℃ (in EU: 5 min at 134℃) Maximum sterilization temperature: 137℃ Drying time: For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. After sterilization: a. Remove the product from the autoclave. b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged. Flash sterilization is not allowed on lumen instruments!
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

7. Storage, maintenance and transportation

7.1 Storage

7.1.1 The product should be handled with care, away from the source, and stored in a dry ventilated place.

7.1.2 Not mixed with toxic, corrosive, flammable and explosive materials.

7.1.3 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℃~ +50℃.

7.2 Maintenance

7.2.1 The product do not include accessories for repair usage, the repair should be carried out by authorized person or authorized after service center.

7.2.2 Keep the product in a dry storage condition.

7.2.3 Do not throw, beat or shock the product.

7.2.4 Do not smear the product with pigments.

7.3 Transportation

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

7.3.2 Don't put it together with dangerous goods during transportation.

7.3.3 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 of "Medical equipment directive 93/42/EEC".

Consult accompanying document (user manual)

Follow the waste of electric and electronic equipment (WEEE) Directive

Type B Particular protection against electric shock

Class II equipment Double insulated, fulfilling legal requirement of IEC-60601-1

Refer to the Operation Manual

Date of manufacture

Manufacturer

Direct current

Serial number

Authorized representative in the European Community

11. EMC Declaration

Ⅰ）Guidance and manufacturer’s declaration — Electromagnetic emissions

Guidance and manufacturer’s declaration — Electromagnetic emissions		
The iRoot apex is intended for use in the electromagnetic environment specified below. The customer or the user of the iRoot apex should assure that is used in such an environment.		
Emission test	**Conformity**	**Emission test Conformity Electromagnetic Environment - guidance**
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 iRoot apex 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

Guidance and manufacturer statement - Electromagnetic Immunity			
The iRoot apex is intended for use in the electromagnetic environment specified below. The customer or the user of the iRoot apex should assure that is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance Level**	**Electromagnetic environment - guide**
Electrostatic discharge(ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 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, IEC 61000-4-4	± 2 kV for power supply lines ± 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 61000-5	±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 IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) For 0.5 cycles 40% U_T (60 % dip in U_T) for 5 cycles < 5 % U_T 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) For 0.5 cycles 40% U_T (60 % dip in U_T) for 5 cycles < 5 % U_T 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 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 iRoot apex requires continued operation during power mains interruptions, it is recommended that the iRoot apex be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field 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 iRoot apex is intended for use in the electromagnetic environment specified below. The customer or the user of the iRoot apex should assure that is used in such an environment.			
Immunity test	**IEC60601 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. Recommended separation distance
Conducted RF GB/T17626.6	3V(Effective value) 150kHz~80MHz	3V(Effective value)	$d=1.2\sqrt{p}$
Radiated RF GB/T17626.3	3V/m 80MHz~2.5GHz	3V/m	$d=1.2\sqrt{p}$ 80MHz~800 MHz $d=2.3\sqrt{p}$ 800 MHz~2.5GHz
			P——Where P is the maxi mum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; d — — d is the recommended separation distance in meters (m) 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_T 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 at I 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 iRoot apex is used exceeds the applicable RF compliance level above, the iRoot apex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the iRoot apex.

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 $d=1.2\sqrt{p}$	80 MHz~800 MHz $d=1.2\sqrt{p}$	800 MHz~2.5 GHz $d=2.3\sqrt{p}$
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 at I 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：ARCM2009

Specification preparation date: 2021/08/30

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)

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

QUALIFIED

CERTIFICATE

INSPECTOR：_____

DATE：_____

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