

# Operation Manual for iRoot pro

Endo motor for root canal preparation with integrated apex locator.



Manual for future reference.

Thanks you for purchase of the Endo Motor with integrated apex locator.

Read this Operation Manual carefully before use for operation instructions and care and maintenance guidelines. Keep this Operation Manual for future reference.

Please do not hesitate to contact manufacturer for help with any doubt or problem that may arise during consultation of this manual.

# Consult accompanying documents (user manual)

This symbol, found on the labels of the unit and accessories, reminds the user to consult this User Manual.

## Intended use

 This device is a cordless micro-motor used primarily for mechanical root canal preparation with integrated apex locator for endodontic treatment. While root canal preparation is made, the root canal measurement can be simultaneously carried out. Alternatively, the Independent apex locator measurement is possible, using the separate file clamp for measuring file.

### User

 This device is only allowed to be used in hospital environments, clinics or dental offices by qualified dentists and other legally licensed professionals. Do not use this device for anything other than its specified dental purpose.

# Prohibition

- The product cannot be used to expand the grossly twisted root canal;
- The product cannot be used for treatment other than implantation or other root canal therapy;
- · Hemophilia patients, patients with pacemakers and doctors are prohibited;
- Patients with heart disease, pregnant women and young children are cautious.

## **Classification of Devices**

Classification by type of protection against electric shock

- Class II devices

Classification by degree of protection against electric shock

Applied part type B

Classification by sterilization or disinfection method allowed by the manufacturer

Refer to Sterilization

Classification by mode of operation

- Continuously operating device

# Symbols:



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# 1. General Precautions

Most operation and maintenance problems result from insufficient attention being paid to basic safety precautions and not being able to foresee the possibilities of accidents.

Problems and accidents are best avoided by foreseeing the possibility of danger and operating the unit in accordance with the manufacturer's recommendations.

# Warning:

If the instructions are not being followed properly, operation may result in hazards for the product or the user/patient.

# Note:

Additional information, explanation on operation and performance.

# 1.1 General Warnings and Conditions for Operation

# Warning: CONTRAINDICATION

• Use of the device is contraindicated in patients and in users with pacemaker!

# General Warnings

- Use the specified battery for this product. Never use any other battery than manufacturer specifies
- · High pressure from the outside will cause a liquid leakage or explosion
- Keeping the central unit away from water, high-temperature and chemical solution which may
  cause short circuit, fire, and other dangerous environment.
- · Sterilizing the motor by heat or steam may cause a liquid leakage or explosion.
- Do not disassemble the central unit.
- The product is used for dental treatment only by qualified personnel.

#### **Conditions for Operation**

- This equipment is for indoor use only.
- Environment temperature: 10-40°C.
- Relative humidity: 10-70% (Non condensing).
- The accuracy of the torque, rotation speed and apical position is guaranteed only when the
  original contra angle is used which is supplied by manufacturer.
- Do not sterilize the central unit, nor place it into autoclave or ultrasonic tank.
- Do not use the system in the presence of free oxygen or flammable gas mixtures.
- Portable and mobile RF communications equipment can affect Medical Electrical equipment. Do not use RF equipment outskirts for the product.
- Follow the instruction of file manufacture to set the rotation and speed of the motor.
- If the Central unit has not been used for long time, check it before use
- There is electric circuit which control the torque (TORQUE LIMITER Function) to prevent files from breaking; however, files may still break due to metal fatigue if the torque is conditioned to be higher. Please check the working instruction of file before use.
- The battery charger must be supplied at a voltage in the range: 100V-240V (+/-10%), 50-60Hz (+/-10%). Use only original parts.
- Should any anomalies arise during operation, suspend work and contact your technical service center.

# 2. Getting Started

#### 2.1 Functions description and installation

- Apex locator and Endo motor collaborative working function
  - Automatically rotate when entering the root canal
  - Automatically slow down when approaching to the apical
  - · Automatically reverse when reaching the apical
  - Automatically stop when exiting the root canal



- The device automatically identifies whether the lip hook cable is inserted
- Inserting the lip hook cable means that the user needs to start the root canal measurement and root canal preparation at the same time.
- Apex locator function



- When start only apex locator mode, the user can insert the measuring cable to start root canal measurement.
- Endo motor function
  - Quick start
  - User program
  - Forward (Auto reverse)
  - Reverse
  - Optimum Torque Reverse (Reciprocating)

# Smarter Mode



change the reciprocating speed and direction.

- The default setting in the quick start mode is: Machine standby in Reciprocating mode I—Rotation in Reciprocating mode I—Standby in Reciprocating mode II —Rotation in reciprocating mode II, in sequence.
- Machine standby in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode I—Rotation in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode I, standby in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode II, Rotation in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode II, in sequence.
- Operation setting details, please refer to 4.1.2.

## 2.2 Discription of each part and its accessories



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

Components	Туре	Number
Central Unit	iRoot pro	1PC
Contra angle	BMCA0001	1PC
Contra angle sleeve	BMCA1001	3PCS
Spray nozzle	BMSN0001	1PC
Measuring cable A	BMMV2001	1PC
Measuring cable B	BMMV1001	1PC
Lip hook	BMLH0001	3PCS
File clamp	BMFC0001	1PC
Power Adaptor	BMPA0001	1PC
USB cord	BMUC0001	1PC
Battery charger	BMBC0001	1PC
Operation manual	\	1PC
Wireless Pedal (optional)	BMWP0001	1PC

## **Remarks:**

Measuring cable A to connect lip hook and file clamp (for only apex locator mode)

Measuring cable B to connect lip hook (Apex locator control motor mode, or separately working together)

## 2.3 Installation contra angle

The contra angle can be connected with the central unit at 6 adjustable head positions. Align the positioning pins of the contra angle with the positioning slots of the central unit and insert the head until they click. When removing the contra angle head, pull it out axially.





#### Warning:

- Turn off the power to remove or attach the contra angle
- Do not use the contra angle other than manufacturer specifies
- · Check that the contra angle is securely connected to the central unit

## 2.4 Mounting and Removing File

Mounting: Insert file to contra angle, lightly turn the file until it engages with the latch mechanism.

Removing: Press the push-key and pull out the file



#### 2.5 Charging

- a) Insert the power cord jack into the inlet at the back of the battery charger. (Fig. a)
- b) Insert the power cord and plug in. Make sure you have the correct model.(Fig. b)
- c) Turn on the power switch. At this time, check that the power lamp lights up.
- d) Insert the central unit into the battery charge. Charging starts with the charge mark flashing on oled screen. (Fig. c) When the buzzer sounds and is played on the oled screen, charging is completed.



- The central unit can be charged directly by USB cable.
- Please ensure the central unit and the battery charger is placed in dry and clean condition.
- Never use the battery charger for anything other than the device of this product by manufacturer.
- The charging normally takes approx. 90 minutes, but it depends on battery use conditions, battery freshness, ambient temperature, etc.
- Under the charging condition, the central unit was not allowed to rotate.
- The completely discharged will cause the damage of the battery. The user should charge the battery completely once a month if the central unit will not be used for long term.
- Pull out the central unit from the charger base up straightly after the battery fully charged.

#### Warning:

 When the central unit is charging, but the buzzer does not sound and the charging animation is not displayed, please take the central unit out from the battery charger, check the "ERROR CODE" to find out the problem.

# 3. Description of user-interface

## 3.1 Keypad and Display



Independent apex locator



Apex locator control motor rotation



Apex locator and endo motor working separately with no control

# POWER Key (

• The POWER key: long press power key to turn on or turn off the motor.

# ON/OFF ( ())

- Normal rotation operation: when the power is on
- Pressing this key to start the motor and pressing this key again to stop the motor.
- QS (Quick Start Key): when the power is off, press this key to enter in the quick start mode.

# SELECT Key ( (S))

- Torque, Rotation, Working mode setting and other operation setting.
- 1) Short press this key to set torque, rotation and working mode, when the machine is on.
- To adjust the settings in the select box by "+/-" key, the sequence are as follows "Torque—Rotation—Working mode", the setting will be saved automatically, to press "P" to exit.
- 2) Long press this key to start other operation setting, when the machine is on.
- To adjust the icon of "Volume—Reciprocating—Apex—Bluetooth—Factory Default—Left-Hander & Right-Hander—Auto Calibration" by "+/-"key, the settings will be saved automatically, and press "P" to exit.

# PROGRAM Key ( (P))

- A program can be selected
- QS( Quick Start Key) setting(The details to see "4.1.2 The QS quick start key setting" )

# +/- Key ( 🕂 / 😑

- Use these keys to increase or reduce the speed of the motor.
- As other function to adjust the value.

## **OLED** Screen

 Working mode option display: When the machine is on, press "S" key ,and to select the working mode (Apex locator control endo motor—Apex locator only—Endo motor only—Independent Endo motor and Independent apex locator) by "+/-"key as follows: (The details to see " 4.2.1 Four working mode" )



- Motor working for the root canal preparation and apex locator working for the measurement
  of the apical length at the same time, apex locator will control the rotation of motor.
- Apex locator only, motor will not work
- Motor only, apex locator will not work
- Motor and apex locator will work at same time, but apex locator will not control motor rotation

## Apical length display

 The position of the file tip is shown by the canal length indicator bar on the display. The Flash bar flashes ON and OFF once file is inserted into root canal.



— APEX 00 displays reaching the apical, "--" and flashing means beyond the apical. The meter's 0.5 reading indicates that the tip of the file is in or very near the apical.

(The numerals on the meter gauge do not represent millimeters.)

 If the file tip reaches the apical foramen, a single, sustained beep will sound, and the word "APEX" and the little triangle next to the Flash Bar will start to flash ON and OFF.

## Rotation mode

 Forward, Rotation is in clockwise motion. When the load is beyond the set torque limit or reach the apical, it will automatically reverse out, when the load is removed, it will start normal rotation again.

- Ry : Reverse, Rotation is in anti-clockwise motion.

- Optimum Torque Reverse, Rotation is in reciprocating mode.

## Battery Symbol

The symbol is indicating the capacity of battery. The symbol will be animated when the battery is being charged

- The battery is full power or nearly full power
- : About 30-80 % remains
- : Less than about 30% remains
- : Battery are drained or the symbol flashing with alarm. Please charge the battery at once.

# Notice:

The symbol indicating the remaining capacity of the battery. When load is applied to the file, the symbol indicating the remaining capacity of the battery appears to become lower. • Alarm Symbol ( The details to see "4.5.2 Alarm Sound Setting" )

🜒 : Max alarm

- Image: Medium alarm
- E Lower alarm

◀× : OFF

# 4. Operations

# 4.1 QS (Quick Start ON/OFF KEY function)

## 4.1.1 QS quick start key using

In order to make maximum imitation of dentists' operation habits, we develop this Quick start function.

The doctor can set the most commonly used parameters to this function. Such as speed, rotation mode.

# When the machine is off, press "<sup>(()</sup>" key to enter in quick start function:

- 1. Standby in reciprocating mode I
- 2. Rotation in reciprocating mode I
- 3. Standby in reciprocating mode II
- 4. Rotation in reciprocating mode II



mode II, in sequence.

#### Further options for quick start mode:

Machine standby in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode I—Rotation in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode I, —standby in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode II, —Rotation in in (Reciprocating/Clockwise Rotation/Anti-Clockwise Rotation) mode II, in sequence.

#### Enter the setting:

When the motor is in quick start mode, long press "P" to enter in Quick Start mode setting, to select OTR (reciprocating) —Forward (Clockwise Rotation)—Reverse, adjust by "+/-"key



## Adjustable Parameters:

- Speed can adjust by "+/-"key
- > Torque are adjustable in Forward / Reverse mode
- The Reciprocating direction and angle are adjustable in OTR mode (Note: Details please refer to Guide for Quick start function.)

#### Exit setting:

Long press "P" key or short press on/off key to exit the setting.

## 4.2 Integrated Apex Locator

iRoot pro is equipped with an integrated apex locator.

# WARNING:

- Combined apical length measurement by using the contra angle and lip clip give only accurate results when using the original contra angle by manufacturer supplied.
- Use only endodontic NiTi files with a metal handle for this type of root canal measurement.
- In some clinical cases accurate root canal measurement is impossible! ( for details see chapter 9 "Troubleshooting")
- Electric root canal measurement uses minimal auxiliary current. The values used in the device are far below the values required in IEC 60601-1. Nevertheless, in rare cases electrical sensation during the apical length measurement can occur. In this case, do not continue the treatment with this patient.

#### 4.2.1 Four working mode

- There are four types of working mode related to Endo motor an Apex Locator.
  - [ENDO M] Mode, Apex locator control motor how to rotate.

Mode, Apex locator is working independently, and endo motor is invalid.



Mode, Independent Endo motor, Apex locator is invalid.

- ADEX 1 Mode, Apex locator and motor work separately.
- To short press "S" key to enter the working mode option, to select working mode in the select box by "+/-"key, when the machine is on.



# NOTICE:

- In APEX-L working mode, motor and apex locator will work at same time, but both work independently without control to each other. When reach apical, the apex locator only indicate the apical length, will not control motor to switch to anti-clockwise rotation and reverse out.
- In working mode, motor and apex locator will work at same time, apex locator will control

   **[ENDO-K]** the preparation of motor. Endo motor will auto start, auto reverse out
   according to the root canal measurement of the apex locator.

4.2.2 Useful tips for accurate length determination

- Gloves and rubber dam are recommended in order to isolate the tooth.
- Dry the access cavity with the suction pump or a cotton-pellet.
- Avoid any direct contact between the contra angle file and mucosa. Use the silicone sleeve for the contra angle.

## 4.2.3 Optional Apical Line

- This feature is convenient for users to make marks of the relative distance from apical point;
- The range of markers is from 15 to 27;
- According to user labeled apical scale, when reaching marker position, better visual and sound cues.





Set the apical line from 15 to 27

#### Complete following steps to change the marks of apical point

 Long press "S" to enter other operation mode, keep short press "S" until it indicates apex locator working length bar, to adjust by "+/-" key.

# **NOTICE:**

- Settings will be saved automatically
- This mark for the apical is available in all working mode including QS mode and apex locator control motor working mode once set.

## 4.2.4 Operation of Apex Locator

We are committed to producing safe and reliable medical equipment to let doctors handier to use, so we recommend doctors to use the apex locator control motor mode.

#### 4.2.4.1 Connecting

For combined apical length measurement use the contra angle, covered by the silicone sleeve.

- Connect the lip clip cable to the Micro USB port at bottom of the central unit. Insert the lip clip
  into the connector at the end of the cable. Ensure the connection is solid.
- Put the pip clip in the patient's mouth (we recommend positioning it on the opposite side of the tooth undergoing therapy).

For **independent apex locator measurement** use the separate file clamp with a manual measuring file instead of the contra angle.

- Connect the Measuring cable for apex locator to the Micro USB port at bottom of the central unit. Insert the lip clip into one of the connectors, insert the file clamp into another connector. And ensure both the connection is solid.
- Put the lip clip in the patient's mouth ( on the opposite side of the tooth undergoing therapy)





Combined apical length measurement

# 4.2.4.2 Measuring loop detection

 A. For combined apical length measurement (Insert a Measuring cable B, Contact with the lip clip and file, select the Apex locator control motor rotation mode.)

Contact the file installed on the Contra angle with the lip hook will cause the following conditions:

- 1) File will anti-clockwise rotate
- 2) The warning will sound rapidly

3) Display on the screen: Root canal indicator scale full grid, the root canal indicator data: "--", APEX non-stop flashing

At this time, it is proved that the measuring circuit is normal, and the next operation can be carried out



Combined apical length measurement





Circuit detection normal display interface

Abnormal operation interface of loop detection

Independent apex locator

measurement



B. For Independent apex locator(insert a

Measuring cable A and select the Independent endo motor mode)

Contact with the lip clip and file clamp will cause the following conditions:

The warning will sound rapidly 1)

Display on the screen: Root canal indicator scale full grid, the root canal 2) indicator data: "- -", APEX non-stop flashing



Circuit detection normal display interface



Abnormal operation interface of loop detection

If the above-mentioned problems are not present, the reason for abnormal loop may be as follows:

- One cable may be broken or in bad contact
- The connecting of the cable is not good
- The contact between lip hook and file climp or the lip hook and file is too short
- The file is in poor conductivity

#### 4.2.4.3 Application steps

Operation: After setting above parameters, connecting measuring cable, detecting measurement

loop, hand the lip hook on the patient's lip, the treatment can be started

The response of motor:

1 ) Putting the file into the root canal, the file will self-acting rotate as setting speed, torque. Or press ON/OFF to drive the file to rotate

2) When the file approaching the apical foramen, the motor will automatically slow down, when reaching the apical foramen, the motor will auto reverse.

#### Response of alarm:

With the file depth, alarm sound from slow to fast, to APEX, the alarm sound becomes constant, over APEX the alarm sound rapidly changes

### Screen display:

With the file depth, the root canal relative value will change to the apical/APEX appears, Root canal scale is full, the root canal relative value is "00"; over apical, APEX flashing, Root canal scale is full, the root canal relative value is "- -".

## 4.3 Rotation and settings in different modes

# 4.3.1 Rotation in different modes



# orward: Rotation is in clockwise motion.

When the load is beyond the set torque limit or reach the apical, it will automatically reverse out, when the load is removed, it will start normal rotation again.



Load lower than the set torque limit value

Load higher than the set torque limit value, anti-clockwise

Reverse rotation when load continues or reach the apical, stop and return to clockwise rotation when load is removed.



# Reverse: Rotation is in Anti-clockwise Motion.

In the general condition, when the Endo Motor Rotate in counter- clockwise motion will be claim as reverse motion. The traditional rotary files are drawing from the canal by reverse motion. Therefore, beep sound will occur when using this function.



Anti-Clockwise Rotation

OTR Optimum Torque Reverse: Rotation is in Reciprocating motion.







Load lower than the set torque limit value, clockwise and anticlockwise in turns (reciprocating)

Load higher than the set torque limit value, motor will exit the root canal automatically. The exiting direction is opposite to the direction of reciprocating cutting.



# NOTICE:

To set the reciprocating of rotation direction see 4.5.3 OTR Settings

## 4.3.2 Rotation Mode setting

- Pressing this SELECT Key to adjust rotation mode in the select box, when the machine is on.
- Enter the Rotation Mode selection: To adjust the rotation mode of Forward (AUTO REVERSE)—REVERSE—Optimum Torque Rotation (RECEPROCATING), in sequence by "+/\_" key.
- To press "P" key to exit, and all the settings will be saved automatically.



## 4.4 Speed, Torque Settings

- Start setting: When the machine is on.
  - ◆ Speed: To Press "+/-"key to adjust the speed;
  - ◆ Torque: To press "S" then to adjust the current torque in the select box by "+/-"key;
- To press "P" key to exit, and all the settings will be saved automatically.



### 4.5 Convenient function

## 4.5.1 Program

- The device offers 10 memory programs, press "P" key to select different program from P01-P10 in sequence.
- User can set the speed, torque, rotate direction, working mode according to personal habits or the order of file.
- All the parameters will be saved automatically.

#### 4.5.2 Alarm Sound Setting

- Long press "S" key, when the machine is on, the screen will display the volume icon as in the following pictures.
- To adjust the volume by "+/-"key.
- Long press "S" key or short press "P" key to exit the setting, and all the settings will be saved automatically.



## 4.5.3 OTR Settings (Normal reciprocating mode)

- Long press "S" key to enter the other operation mode, when the machine is on; then keep short
  press until OTR icon shows on the screen display as in the pictures., short press "S" key to shift
  the direction of OTR, adjust the angle data by "+/-"key. The angle difference is no less than 80
  degree.
- Long press "S" key or short press "P" key to exit the setting, all data will be automatically saved.



#### 4.5.4 Wireless Transmission (Optional)

We designed the product from the point of view of the doctor's use to make the operation easier. The device is a safe, accurate, compact and convenient product, but cannot meet some users who like big screen. In order to meet the needs of users, we provide an optional wireless solution. At the same time, when doctors treat the molar, they need to go deep into the mouth, switch the parameter mode manually and press the button on the machine inconveniently. In order to provide more convenient operation for doctors, we also provide an optional wireless control solution.

The device has two wireless transmission modules built in. Users can choose one or two wireless transmission modules according to their needs to connect with the corresponding products.

The device plus's built-in wireless transmission module connection mode: one mode is that an apex locator with the same type of wireless transmission module can be wirelessly connected with the device, and the information of the device's work can be reflected on its large screen (the wireless transmission module of the device o and the apex locator need to be opened simultaneously); the other one mode is that a wireless pedal control device with the same type of wireless transmission module can be wirelessly connected with the device. The device can be operated, stopped, turned forward and reversed by the device. (See the pedal instructions for the operation of connecting with the wireless pedal control device.) Two wireless transmission modules, users can choose one or two products to connect with it freely.

- The device wireless transmission uses Bluetooth transmission technology to meet the requirements of various radiation indicators.
- Transmission distance is not more than 5 meters.
- Display information is transmitted in milliseconds to avoid the delay problem.

#### The device wireless transmission connection settings:

- Wireless transmission display features on and off. Long press "S" key to enter into other operation mode, short press "S" until the Bluetooth icon shows, press"+/-" to select "Bluetooth turn on" or "Bluetooth turn off".
- When Bluetooth turn on, the Bluetooth icon shows, when connected, the display as follows:



CAUTION:

- This wireless transmission module is one-to-one connection and does not support one-to-many
  connection, that is, one module can only connect with one product.
- When multiple devices automatically connected at the same time, there may be a connection error. Please connect one by one as required
- Wireless transmission function automatically save once start, factory setting this function is off.

#### 4.5.5 Factory Default Parameters

The program can be restored to factory default settings, if setup is in confusion.

 Long press "S" to enter other operation mode, short press "S" key until it turns into "Recovery Factory Settings". Then select yes by pressing"+/-", counting from"9" to "0", turn off and RESTART the device to complete the Factory settings.  Long press "S" key or short press "P" key to exit the setting, and all the settings will be saved automatically.



# CAUTION:

If this function is used, all programs will disappear and return to the originally set values. Record the present program details if required before you carry out this operation.

### 4.5.6 Left-hander & Right-hander setting

The program is applicable to Left-hander & Right-hander user.

- Long press "S" key to enter into background, short press "S" key until in to Left-hander & Right-hander option, adjust by "+/-" key for left and right hand use.
- Long press "S" key or short press "P" key to exit the setting, and all the settings will be saved automatically.



### 4.5.7 Auto Calibration setting

- Install the fully lubricated contra angle on the central unit and place it on a flat platform.
- When the device is on, Long press "S" key to enter into other operation settings, short
  press "S" key until in to Auto Calibration. Press "+/-" key to choose "yes" and enter in
  Auto Calibration Mode. The motor starts running from the lowest to the highest speed for
  automatic calibration.
- During the calibration, the motor rotates with the contra angle. Please don't touch it and wait for the automatic operation to be completed.
- When the calibration is finished, the motor stops rotating and shuts down automatically after 30 seconds.
- If you want to stop this operation, press the "S" key for a long time or press the "P" key for a short time to exit the setting.



# CAUTION:

Before the calibration operation, the battery should have sufficient power. It is recommended
that the motor be calibrated after full charge.

- Before calibration, be sure to clean the contra angle first, because if there are residual impurities in the process of use into the contra angle, the calibration will cause deviation.
- When calibrating, please don't bring file or any load on the contra angle.
- Do not shake the motor during calibration.
- Do not do this operation during charging.



### 5. Cleaning, Disinfection



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

# WARNNING

- Do not immerse the central unit in the ultrasonic cleaner.
- The central unit can only be cleaned with cotton cloth dipped in alcohol.
- The metal holder can only be cleaned with cotton cloth dipped in alcohol.
- The device disinfectable parts: lip hook, contra angle sleeve, contra angle and file clamp.



The lip hook, contra angle sleeve, contra angle 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, contra angle sleeve, contra angle and file clamp can be repeatedly disinfected.

# WARNING:

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

# 6. Maintenance

## 6.1 Change battery

1 Remove the battery cover

Remove the battery cover by sliding it toward the charging terminal.

2 Remove the old battery

Pull out the battery a little part, and then pull out the battery plug from central unit by hand carefully.

- 3 Replace with new battery Put in the new battery.
- 4 Close the battery cover

Slide the cover from the button to the top with a little force by the finger.



#### 6.2 Lubricating contra angle

- Insert the spray nozzle into the contra angle head (insert to the part connect to the central unit).
- Insert the lubricants spray nozzle to the provided spray nozzle loop, inject the lubricants for 1-2 seconds till the outlet liquid from the head of the contra angle clean.



# WARNING:

- Do not lubricate the micromotor in the central unit for any reason, because lubricant contamination of the micromotor can have a strong negative effect on its safe operation.
- When lubricating the contra angle, check that no lubricant penetrates the micromotor.
- Never introduce any foreign objects into the micromotor.
- Do not disassemble or alter the central unit.

# 7. Technical Specification

MANUFACTURER:	Changzhou Bomedent medical technology CO.,LTD
MODEL:	iRoot pro
METERIAL	208 x 25 x 26mm(central unit include contra angle)
METERIAL.	123 x 61 x81mm (battery charger)
WEIGHT:	780g
POWER TYPE:	Battery powered, 750mAh/3.7VDC
BATTERY CHARGER VOLTAGE	100 240844
SUPPLY:	100-240VAC
VOLTAGE FLUCTUATIONS:	Max.±10%
FREQUENCY:	50-60 Hz(±10%)
BATTERY CHARGER POWER RATING:	2A
ELECTRIC SAFETY:	CLASS II
APPLIED COMPONENT TYPE:	ТҮРЕ В
LEVEL OF SAFETY IN PRESENCE OF	NOT SUITARI E EOD USE IN DRESENCE OF INFLAMMARI E
INFLAMMABLE ANAESTHETIC	ANA ESTIMATIC MINTURES OF OVACEN
MIXTURE OR OXYGEN:	ANAESTHETIC MIXTURES OR OXIGEN
OPERATING MODE:	CONTINUOUS
ENVIRONMENT CONDITIONS FOR USE:	+10-+40°C, RH: 10-70% ( Non condensing ),700-1060h Pa
PROTECTION AGAINST LIQUID	IDVO
PENETRATION:	IPAU
TRANSPORT AND STORING	10 1509C BH 10 809/ (New see descine ) 500 10/0h Br
CONDITIONS	-10-100°C, KH: 10-80% ( Ixon condensing ), 500-1060n Pa
USEFUL LIFE	FOUR YEARS

# 8. Error code

	Error code	Error	Cause	Check Remedy
	E-0	Self-Check error	Malfunction of circuit	Contact your dealer
When	E-1	Overcurrent	The motor handpiece is locked. (auto reverse	Remove payload
working	E-2	Overvoltage	Malfunction of circuit	Contact your dealer
	E-3	Charger failure	Malfunction of circuit	Contact your dealer
	E-4	Low voltage of battery	Battery out of service	Chang Battery
When	E-5	High voltage of battery	Battery out of service	Chang Battery
Charging	E-8	Low voltage of adaptor	Adaptor out of service	Change adaptor
	E-9	High voltage of adaptor	Adaptor out of service	Change adaptor
When	F-7	Calibration failure	Motor damaged or	Replace the motor
calibration	2-7		handpiece blocked	handpiece or motor

# 9. Troubleshooting

If your device does not seem to work properly, it does not necessarily mean that the central unit does not work correctly. Please first review the below checklist in order to exclude any user error or anatomic/other peculiarities before contacting your dealer.

If the problem persists please contact either your local dealer or manufacturer.

D 11	â	8 I S
Problem	Cause	Solution
	Battery has fully discharged.	Recharge the battery.
I ne power is unable to turn	No battery inserted.	Insert battery.
011.	The internal fuse has burnt.	Contact your dealer.
	Battery has been completely discharged.	Replace with new battery.
	The power cord plug is not inserted into the outlet	Plug the power cord or adaptor properly
Charge failure	The motor handpiece is not correctly set to the charger	Insert the power cord plug into the outlet.
	There is some residual contamination on the charger base	Remove the residual contamination
	An error code is displayed.	Refer to No. 8Error Code.
	Nothing is displayed on the panel of the handpiece even when it is set to the charger	Contact your dealer.
	The charger out of service	Charge the motor by cable, then contact your dealer
The motor handpiece does not rotate.	The contra angle has been blocked	Clean or reset the contra angle
The alarm sounds when the motor is working	The contra angle head has jammed up.	Clean the contra angle head

The alarm sounds when the motor is	Set to Auto Reverse mode, take off contra angle, there is NO click sound when working	Contact your dealer.
	set to Auto Reverse mode, take off contra angle, there is click sound	Clean the contra angle head
working.	There is some residual contamination on the rotating shaftof the contra angle	Clean the contra angle head
A	Measuring line, lip clip, file clamp loose contact.	Reconnect
Apex locator no response	Measuring line, file clamp is aging	Changes measuring, file clamp
Apex locator cannot control the motor working	Check if control working mode setting is correct	Read instruction manual carefully, set the main unit in apex locator control motor working mode
	If the measuring line and lip clip connect correctly	Read instruction manual carefully, make sure the installation and connection is correct
	If the contra angle directly contacts with the human body	Read instruction manual carefully, put sleeve or rubber dam on the contra angle
	If contra angle is installed in place.	Read instruction manual carefully, make sure the installation and connection is correct
No warning sound	Check if the sound is on	Turn on the sound



X-ray Tube X-ray Tube Apical foramen is located towards the crown.

In case of root fracture or perforation, it is impossible to take a precise length determination as the electric current leaks along the fracture gap. The X-ray image of the canal curvature may show a shorter working length than with the device, When the bending direction of the root canal is in line with the direction of irradiation.

## Electric Length Determination and X-Ray Technique

As radiographs only reproduce in a two-dimensional way a three-dimensional root canal system, there are a few cases in which the X-ray image and the result obtained with electric length determination do not match. This does not mean that your device is not working properly or that the X-ray image is inaccurate.

These discrepancies indetermination occur due to anatomical variation. The actual apical foramen may not be located at the radiographic apex.

# **10. Disposing Product**

- Please consult with the dealer from whom you purchased regarding waste disposal.
- The used Li-ion batteries are recyclable, but their disposal may sometimes not be permitted by the respective country. Return them to your dealer.

## 11. Warranty

- Manufacturer warrants its products to the original purchaser against defects in material and workmanship under normal practices of installation, use and servicing. Battery etc., are disposable components, and are not covered by this warranty.
- Manufacture's information can be found in warranty card.

#### 12. Electromagnetic emissions and immunity

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

Guidance and manufacturer's declaration - electromagnetic emissions			
The device is intended for use in the	he electromagnetic en	vironment specified below. The customer or the user of the	
device should assure that is used in	n such an environmen	t.	
Emission test	<b>a a b</b>	Emission test Conformity Electromagnetic Environment -	
Emission test	Conformity	guidance	
RF Emissions CISPR11		The appliance use RF energy only for its internal function.	
	Group 1	Therefore, its RF emissions are very low and are not likely to	
		cause any interference in nearby electronic equipment.	
PE Emissions CISPP11	Class B		
	Chaos D		
Harmonic emissions		The device is suitable for use in all establishments, including	
IEC61000-3-2	Class A	domestic establishments and those directly connected to the	
Voltage fluctuations/		public low-voltage power supply network that supplies	
flicker emissions	Conforms	buildings used for domestic purposes.	
IEC 61000-3-3			

Guidance and manufacturer's declaration - electromagnetic emissions

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.

	r		
Immunity test	IEC 60601 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 61000-4-5	$\pm 1 \text{ kV}$ differential mode $\pm 2 \text{ kV}$ common mode	$\pm 1 \text{ kV}$ differential mode $\pm 2 \text{ kV}$ common 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% UT (>95% dip in UT For 0.5 cycles 40% UT (60% dip in UT) for 5 cycles <5% UT 70% UT (30% dip in UT) for 25 cycles <5% UT <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT For 0.5 cycles 40% UT (60% dip in UT) for 5 cycles <5% UT 70% UT (30% dip in UT) for 25 cycles <5% UT <5% UT (>95% dip in UT) 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 IEC 61000-4-8 NOTE: UT is the a.c.	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.

The device is intended for use in the electromagnetic environment.Immunity testlevel EN 60601-1-2Compliance LevelElectromagnetic environment - guideImmunity testlevel EN 60601-1-2Compliance LevelElectromagnetic environment - guideConducted RF EEC3 VrmsPortable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance61000-4-63 Vrms3 Vrms150 kHz to 80 MHz3 Vrms3 V/m3 Vrms80 MHz to 2.5 GHz3 V/m80 MHz to 2.5 GHz3 V/mNOTE 1:At 80 MHz, the higher frequency range applies.NOTE 1:At 80 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 RF transmitters, such as base stations for radio (cellular/cordless) 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 field strengths in which the device is used exceeds the applicable RF compliance level albox, the device how the divice should be used the over in the vicinity of equipment marked with the following symbol: accuracy. To assess the electromagnetic environment due to fixed RF framitiers, an electromagnetic stressary should be considered. If the measured field strength in the location in which the device is used execeds the applicable RF c	Guidance and manufacturer's declaration - electromagnetic emissions			
should assure that is used in such an environment.Electromagnetic environment - guideImmunity testlevel EN 606011-1-2Compliance LevelElectromagnetic environment - guideImmunity testlevel EN 606011-1-2Compliance LevelElectromagnetic environment - guideImmunity testlevel EN 606011-1-2Compliance LevelElectromagnetic environment - guideImmunity testlevel EN 606011-1-2Compliance LevelPortable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance61000-4-6150 kHz to 80 MHz3 Vrms $d = 1.2\sqrt{P}$ 80 MHz to 2.5 GHz3 V/m $d = 2.3\sqrt{P}$ 80 MHz - 800 MHz61000-4-380 MHz to 2.5 GHz3 V/mField strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: (())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/cordless) 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 sits survey should be considere	The device is int	ended for use in the ele	ctromagnetic environme	nt specified below. The customer or the user of the device
Immunity testlevel EN 60601-1-2Compliance LevelElectromagnetic environment - guideImmunity testlevel EN 60601-1-2Compliance LevelPortable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distanceConducted RF IEC3 Vrms3 Vrms $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ $80$ MHz - 800 MHzRadiated RF 61000-4-33 V/m3 Vrms $d = 2.3\sqrt{P}$ $80$ MHz to 2.5 GHz61000-4-380 MHz to 2.5 GHz3 V/mWhere P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 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. Interference may occur in the vicinity of equipment marked with the following symbol: (())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/cordless) 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	should assure that is used in such an environment.			
Conducted RF IEC3 VmsPortable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ $80 \text{ MHz} - 800 \text{ MHz}$ 61000-4-6150 kHz to 80 MHz a Vms3 Vms $d = 2.3\sqrt{P}$ $800 \text{ MHz} - 2.5 \text{ GHz}$ 61000-4-33 V/m3 V/mWhere P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).61000-4-350 MHz to 2.5 GHz3 V/mField strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: Less than the collowing symbol: Less than the collowing symbol: arked with the following symbol: araked with the followi	Immunity test	level EN 60601-1-2	Compliance Level	Electromagnetic environment - guide
<ul> <li>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.</li> <li>a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) 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.</li> <li>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</li> </ul>	Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ~ 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 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. Interference may occur in the vicinity of equipment marked with the following symbol: $((\mathbf{v}))$
reflection from structures objects and people. a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) 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.	NOTE 2: These	e guidelines may not ap	ply in all situations. Elec	ctromagnetic propagation is affected by absorption and
<ul> <li>a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) 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.</li> <li>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</li> </ul>	reflection from s	structures objects and po	eople.	
<ul> <li>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.</li> <li>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</li> </ul>	a) Field stren	gths from fixed transmi	tters, such as base station	ns for radio (cellular/cordless) telephones and land mobile
accuracy. 10 assess the electromagnetic environment due to Tixed KF 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.	radios, am	ateur radio, AM and FN	1 radio broadcast and T	/ broadcast cannot be predicted theoretically with
<ul> <li>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.</li> <li>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</li> </ul>	should be	10 assess the electroma	gneuc environment due	to fixed KF transmitters, an electromagnetic site survey
<ul> <li>observed, additional measures may be necessary, such as re-orienting or relocating the device.</li> <li>over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</li> </ul>	should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RE compliance level above, the device should be observed to verify normal operation. If abnormal performance is			
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.	observed, additional measures may be necessary, such as re-orienting or relocating the device.			

Recommended separation distances between portable and mobile RF communications equipment and the device The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device 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	Separation distance according to frequency of transmitter (in meters) Meters [m]			
power of transmitter	150 kHz ~ 80 MHz	80 MHz ~ 800 MHz	800 MHz ~ 2.5 GHz	
Watts [W]	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	
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.

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# Warranty Card

#### Dear user:

# For the warranty:

- 1. We offer 1 year warranty for the product iRoot pro (excluding the battery and 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	
INSPECTOR:	>
DATE:	

ChangZhou BoMedent Medical Technology Co.,Ltd.



NO.9 Changyang road, West Taihu Science & Technology Industrial Park, Changzhou City, jiangsu, China. Tel: 0519-88991980 Landlink GmbH.

EC REP

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