Operation Manual for **iRoot pro**

Endo motor for root canal preparation
with integrated apex locator.

Read this Operation carefully before use.

Keep this Operation 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:

	Refer to instruction manual/ booklet		Caution：In case of application as a safety sign.
	Type B APPLIED PART		Class II equipment
	The product complies with the directive on WEEE. This device must be disposed of as municipal solid waste when abandoned	SN	Serial number
	Manufacturer		Date of manufacture
	For indoor use		Upward
	Keep dry		Fragile, handle with care
EC REP	Authorized representative in the European Community/ European Union	MD	Medical device
CE 0197	CE Marking		Direct current

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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.

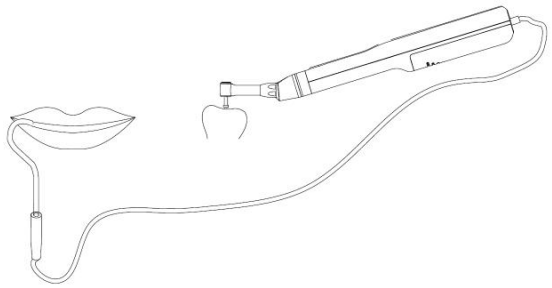
Conditions for Operation

- This equipment is for indoor use only.
- Environment temperature: 10−40℃.
- Relative humidity: 10−70%.
- 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

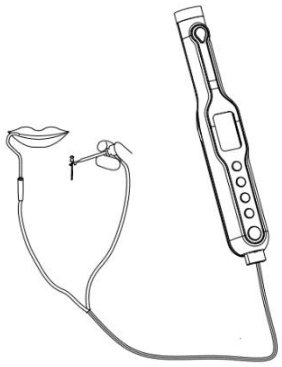
2.1 Functions description and installation

- 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.

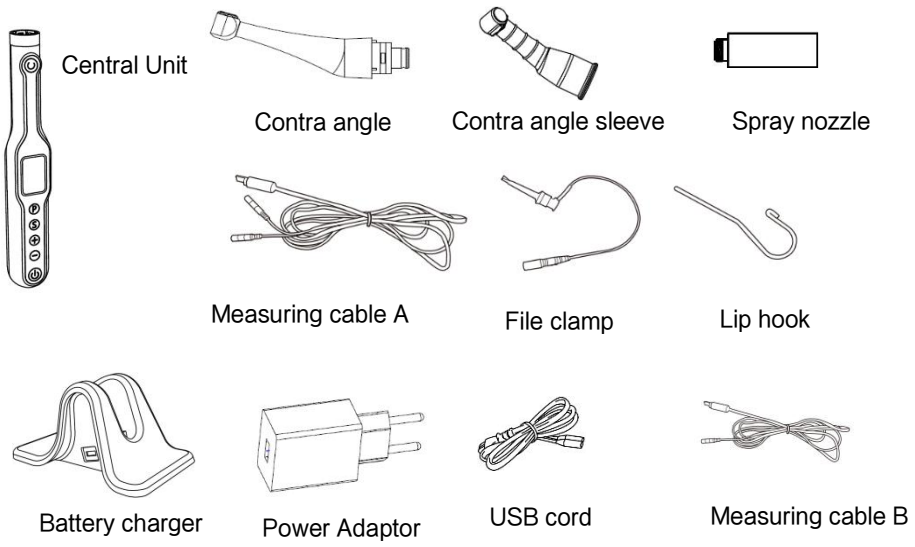
- Apex locator function



  - When start only apex locator mode, the user can insert the measuring cable to start root canal measurement.

- Endo motor function
  - User program
  - Forward (Auto reverse)
  - Reverse
  - Optimum Torque Reverse (Reciprocating)

2.2 Discription of each part and its accessories



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

Components	Type	Number
Central Unit	iRoot pro	1PC
Contra angle	BMCA0004	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

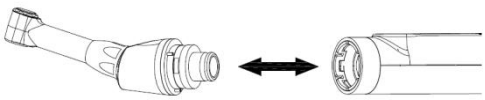
Remarks:

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

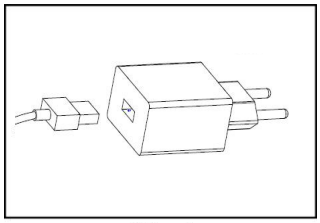
2.5 Charging

a) Insert the power cord jack into the inlet at the back of the battery charger. (Fig. a)

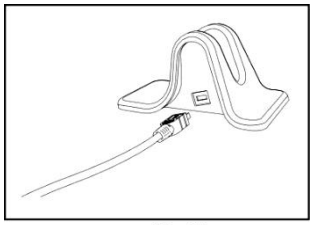
b) Insert the power cord and plug in. Make sure you have the correct model.(Fig. b)

c) Turn on the power switch. At this time, check that the power lamp lights up.

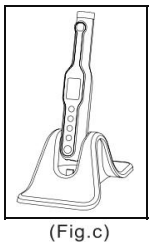
d) Insert the central unit into the battery charge. Charging starts with the charge mark flashing on oled screen. (Fig. c) When the buzzer sounds and is played on the oled screen, charging is completed.



(Fig.a)



(Fig.b)



(Fig.c)

- 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. 180 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.

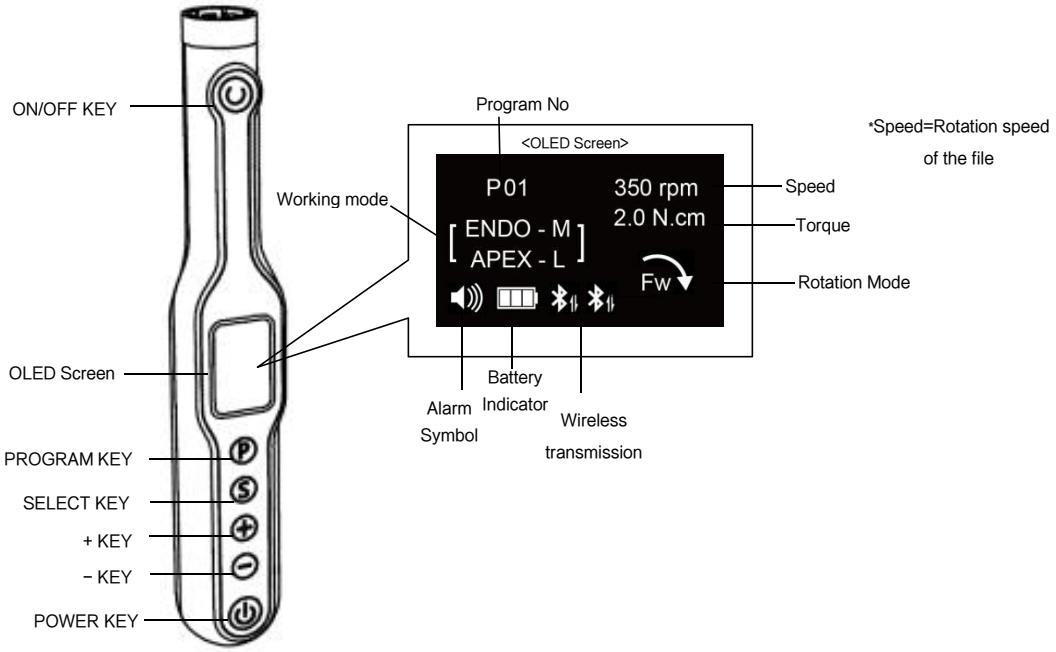
- The completely discharged will cause the damage of the battery. The user should charge the battery completely once a month if the central unit will not be used for long term.
- Pull out the central unit from the charger base up straightly after the battery fully charged.

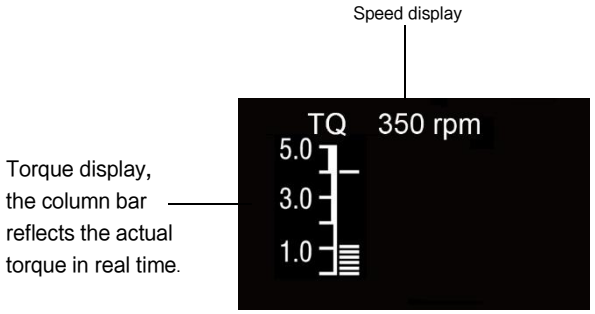
⚠Warning:

- 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 to find out the problem.

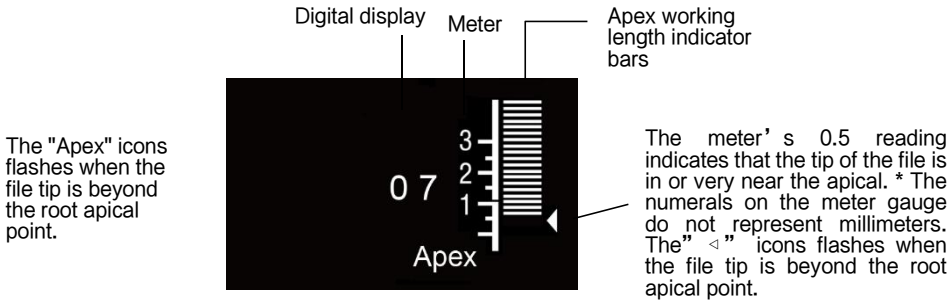
3. Description of user-interface

3.1 Keypad and Display

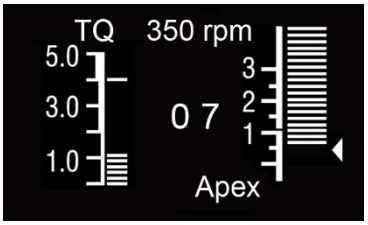




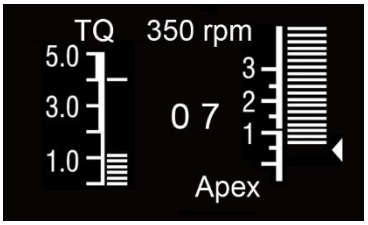
Independent endo motor



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.

SELECT Key ( )

- 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—Auto Start & Stop" by "+/−" key, the settings will be saved automatically, and press "P" to exit.

PROGRAM Key ( )

- A program can be selected

+/− Key (/)

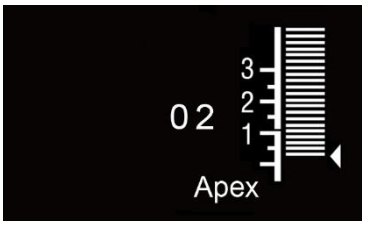
- Use these keys to increase or reduce the speed of the motor.
- As other function to adjust the value.

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
  — Fw : 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.
  — Rv : Reverse, Rotation is in anti−clockwise motion.
  — OTR : 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

: About 60−100 % remains.
: About 30−80 % remains.
: About 10−40 % remains.

: About 0−10 % remains. Batteries are drained or in a remarkably low voltage. Charge the batteries.

: The symbol flashing with alarm. Please turn off the motor, and charge the batteries 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 "4.4.2 Alarm Sound Setting")

: Max alarm

: Medium alarm

: Lower alarm

: OFF

4. Operations

4.1 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.

4.1.1 Four working mode

- There are four types of working mode related to Endo motor an Apex Locator.
  - [ENDO - M / APEX - L] Mode, Apex locator control motor how to rotate.
  - ONLY APEX - L Mode, Apex locator is working independently, and endo motor is invalid.
  - ONLY ENDO - M Mode, Independent Endo motor, Apex locator is invalid.

- ■ ENDO - M APEX - L 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 ENDO - M 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 [ENDO - M APEX - L] working mode, motor and apex locator will work at same time, apex locator will control the preparation of motor. Endo motor will auto start, auto reverse out according to the root canal measurement of the apex locator.

4.1.2 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.

4.1.3 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.

4.1.4 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.

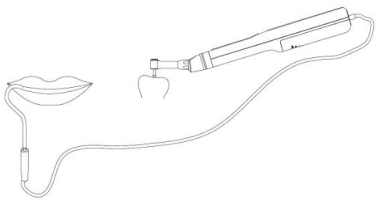
4.1.4.1 Connecting

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

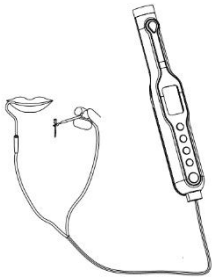
- Connect the lip clip cable to the Micro USB port at bottom of the central unit. Insert the lip clip into the connector at the end of the cable. Ensure the connection is solid.
- Put the pip clip in the patient’s mouth (we recommend positioning it on the opposite side of the tooth undergoing therapy).

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



Independent apex locator measurement

4.1.4.2 Measuring loop detection

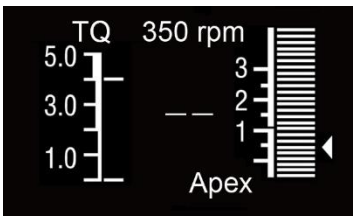
A. For combined apical length measurement（Insert a Measuring cable B, contact with the lip clip and file, select the Apex locator control motor rotation mode）

Combined apical length measurement

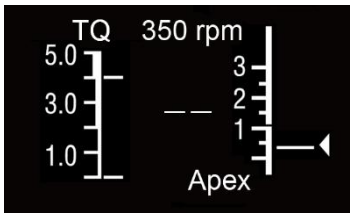
Contact the file installed on the Contra angle with the lip hook will cause the following conditions：

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



Circuit detection normal display interface



Abnormal operation interface of loop detection

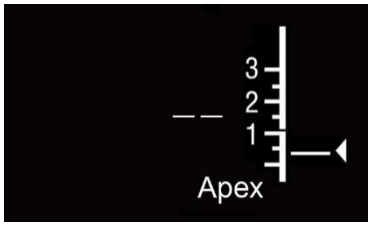
B. For Independent apex locator(insert a Measuring cable A and select the Independent endo motor mode) Contact with the lip clip and file clamp will cause the following conditions：

1) The warning will sound rapidly

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

Independent apex locator measurement

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

4.1.4.3 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：

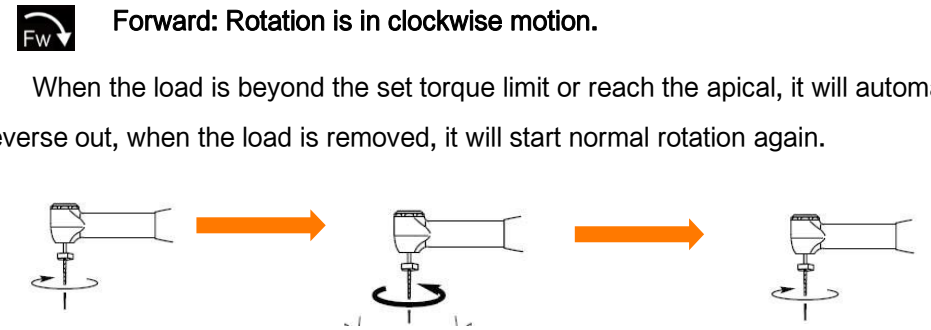
With the file depth, alarm sound from slow to fast, to APEX, the alarm sound becomes constant, over APEX the alarm sound rapidly changes

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 "- -" .

4.2 Rotation and settings in different modes

4.2.1 Rotation in different modes



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.

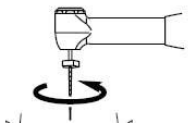
Load lower than the set torque limit value

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.

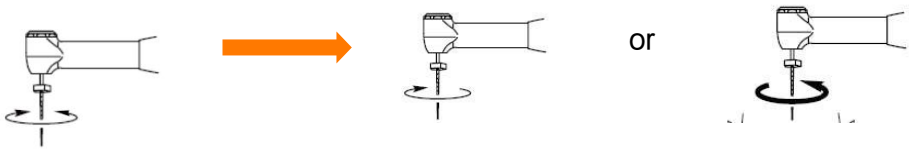
Reverse: Rotation is in Anti-clockwise Motion.

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)

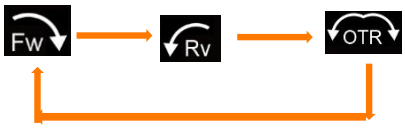
Load higher than the set torque limit value，motor will exit the root canal automatically, The exiting direction is opposite to the direction of reciprocating cutting.

NOTICE:

- To set the reciprocating of rotation direction see 4.4.3 OTR Settings

4.2.2 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.



4.3 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.

4.4 Convenient function

4.4.1 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.

4.4.2 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.

4.4.3 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.

4.4.4 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:

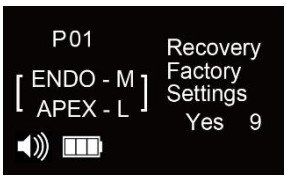
Bluetooth off Bluetooth on Bluetooth connected

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.

4.4.5 Factory Default Parameters

- 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”, automatically shut down and complete the Factory settings.
- If the value "0" has not been reached, press the "P" key to exit the setting and give up restoring to the factory settings.



⚠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.

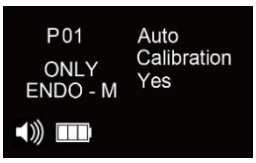
4.4.6 Left-hander & Right-hander setting

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

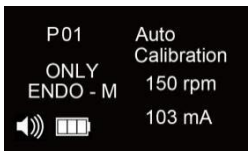
- Long press “S” key to enter into background, short press “S” key until in to Left-hander & Right-hander option, adjust by “+/-” key for left and right hand use.
- To press “P” key to quit the setting; and the settings will be saved automatically.

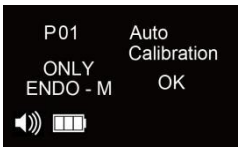
4.4.7 Auto Calibration setting

- 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.
- As shown in the figure below, when "yes" is displayed (if the battery is insufficient, it will display “NO VOLT Low”, it should be fully charged until it displays “yes”), press “+” to enter the automatic calibration mode;



- During the calibration process, the root canal preparation machine rotates with the decelerating machine, please do not touch it, and wait for the automatic operation to complete;
- After the calibration is completed, it will display "OK" as shown in the figure below, and it will automatically shut down and complete the automatic calibration;





- To press “P” key to quit the setting; and the settings will be saved automatically.

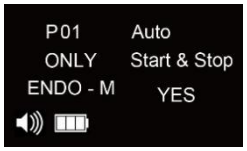
⚠ CAUTION:

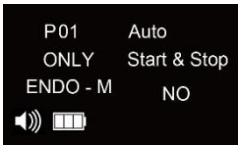
- Before calibrating, you need to display "yes", that is, the battery must have sufficient power. It is recommended to calibrate after fully charged;
- Before calibration, be sure to clean the contra angle first, because if there are residual impurities in the process of use into the contra angle, the 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.

4.4.8 Setting of Auto Start/Stop function

In the mode of Apex locator control motor, the rotation will auto start when file tip enters root canal (and auto stop when taken out from root canal). User can turn on/off the function according to the need by following steps.

- When the device is on, long press “S” to enter background settings. Short press “S” and switch to “Auto Start & Stop” as shown below.
- Press “+” to switch between YES and NO to turn ON and turn OFF the function
- Press “P” to save and quit.





5. Cleaning, Disinfection, Sterilization

⚠CAUTION:

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

⚠ Warning:

- 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, contra angle sleeve, contra angle 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, contra angle sleeve, contra angle and file clamp can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the Central Unit, Measuring cable, Power

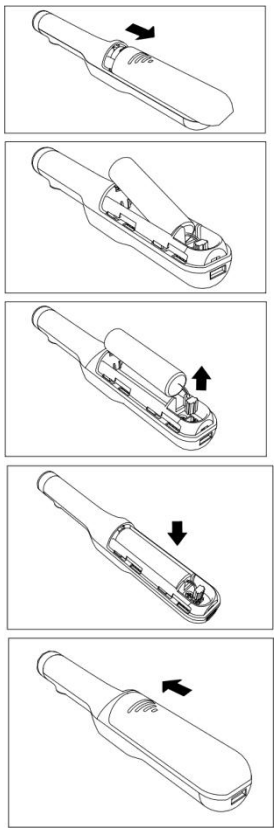
	Adaptor, USB cord, Battery charger and Wireless pedal! The Central Unit, Measuring cable, Power Adaptor, USB cord, Battery charger and Wireless pedal cannot be cleaned and disinfected in a washer/disinfector! For these parts, only a general wipe decontamination is possible!
Decontamination of other parts than lip hook, contra angle sleeve, contra angle and file clamp:	After operation, take the Central Unit, Measuring cable, Power Adaptor, USB cord, Battery charger and Wireless pedal 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 Central Unit, Measuring cable, Power Adaptor, USB cord, Battery charger 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, contra angle sleeve, contra angle and file clamp!	
Pre-Cleaning of lip hook, contra angle sleeve, contra angle and file clamp:	Not use automated cleaning, disinfection and sterilization for other parts than lip hook, contra angle sleeve, contra angle 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.	

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

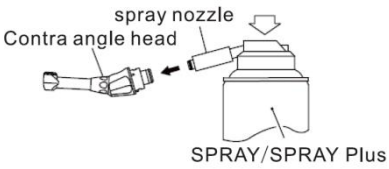
Put in the new battery.

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 2−3 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:	208x 25 x 26mm(central unit include contra angle) 123 x 61 x81mm (battery charger)
WEIGHT:	780g
POWER TYPE:	Battery powered, 750mAh/3.7VDC
BATTERY CHARGER VOLTAGE SUPPLY:	100-240VAC
VOLTAGE FLUCTUATIONS:	Max. ± 10%
FREQUENCY:	50-60 Hz(± 10%)
BATTERY CHARGER POWER RATING:	1A
ELECTRIC SAFETY:	CLASS Ⅱ
APPLIED COMPONENT TYPE:	TYPE B
LEVEL OF SAFETY IN PRESENCE OF INFLAMMABLE ANAESTHETIC MIXTURE OR OXYGEN:	NOT SUITABLE FOR USE IN PRESENCE OF INFLAMMABLE ANAESTHETIC MIXTURES OR OXYGEN
OPERATING MODE:	CONTINUOUS
ENVIRONMENT CONDITIONS FOR USE:	+10-+40ºC, RH: 10-70% (Non condensing),700-1060h Pa
PROTECTION AGAINST LIQUID PENETRATION:	IPX0
TRANSPORT AND STORING CONDITIONS	-10—+50ºC, RH: 10-80% (Non condensing), 500-1060h Pa
USEFUL LIFE	FOUR YEARS

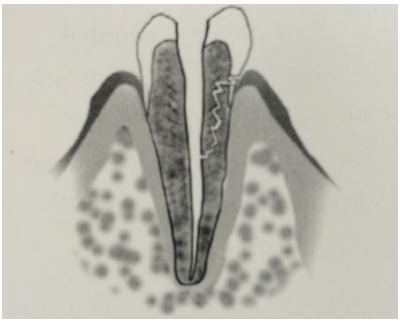
8. Troubleshooting

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.

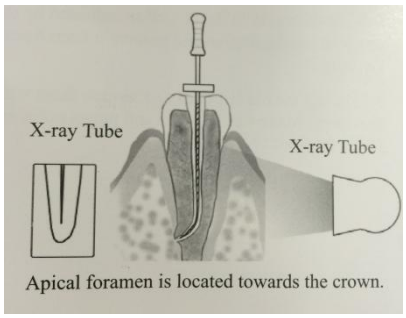
If the problem persists please contact either your local dealer or manufacturer.

Problem	Cause	Solution
The power is unable to turn on.	Battery has fully discharged.	Recharge the battery.
	No battery inserted.	Insert battery.
	The internal fuse has burnt.	Contact your dealer.
Charge failure	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
	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
	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 working.	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
	There is some residual contamination on the rotating shaft of the contra angle	Clean the contra angle head
Apex locator no response	Measuring line, lip clip, file clamp loose contact.	Reconnect
	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	Read instruction manual carefully,

	correctly	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



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.

9. 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.

10. 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.

11. 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.

<table>
<tr><td colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td>Emission test</td><td>Conformity</td><td>Emission test Conformity Electromagnetic Environment – guidance</td></tr>
<tr><td>RF Emissions CISPR11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF Emissions CISPR11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Conforms</td></tr>
</table>

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.			
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	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 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	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.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

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.			
Immunity test	level EN 60601-1-2	Compliance Level	Electromagnetic environment - guide
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:
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 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.			

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 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 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)

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