Pac-Dent
Passion for Excellence

Read this manual carefully before operating.
Keep it in a safe place for further consultation.

USER AND OPERATING MANUAL

PACENDO™

iRoot Pro *Plus*™

Cordless Endo Handpiece with Apex Locator

REF RPCL02

#06IFURPCL02 Rev.032221

Pac-Dent, Inc.
670 Endeavor Circle, Brea, CA 92821
info@pac-dent.com 909.839.0888
www.pac-dent.com

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IEC 60601-1 EN ISO 13485	This equipment has been designed and developed in compliance with Electric Safety standard IEC 60601-1 in force. It was designed and manufactured in accordance with an EN ISO 13485-certify quality assurance system.

1. Introduction

Thanks for purchasing the iRoot Pro Plus. The **iRoot Pro Plus** medical device that you are about to install and use in your practice is a medical device designed for professional use. It comprises the chosen tool with which you will provide treatment within the context of your work.

To ensure optimum safety for yourself and your patients, comfort in your daily practice and to benefit fully from the technology of your medical device, please read the documentation provided carefully.

If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected.

The **iRoot Pro Plus** is mainly used in endodontic treatment to perform mechanical instrumentation with engine-driven latch files and electronic working length determination with the built-in foramen locator. It is a battery-operated portable cordless endodontic motor electronically connected with the base unit which is compatible with the most know rotary and reciprocation endodontic file systems. It can be used as an endodontic motor alone, as an apex locator to determine electronically the foramen position, and as an apex locator together with the endodontic motor. **iRoot Pro Plus** is a medical device that provides highly precise controlled movements, with apex locator embedded, which gives the advantage of accurate file position readings alone or during the instrumentation procedure.

WARNING

a. Read all instructions before operating this unit. The manufacturer accepts no liability for any damage resulting from improper use of this unit and/or for any purpose other than those covered by these instructions.

b. Use only for the intended use. Failure to comply with the operating instructions may result in serious injury to the patient or operator. Before operating this device, verify that you have read and

understood the operating instructions.

c. U.S. Federal law restricts this unit to sale by or on the order of a dentist.

d. As per Endodontic Standards of Care, **always use a rubber dam when performing endodontic treatment**.

e. Do not insert any object into the base or handpiece.

f. Do not install near an explosive risk. Systems are not designed to operate in the presence of anesthetic gases or any other flammable gas.

g. Connect the power cord to an appropriate outlet. Use only the supplied power adapter.

h. Do not use dry heat sterilization on any of the device's components.

i. Do not perform repairs or make changes to the device without prior consent from Pac-Dent, Inc.

j. In the event of an abnormality, contact Pac-Dent, Inc. Do not call any other repair service, which may cause your device to be dangerous to you and your patients.

1.1 Operator population: Operation of this medical device is limited only to certified, capable, and qualified dental professionals in their regular place of business. The operator must master and comply with the rules of dental practice in accordance with science and principles of medical hygiene, such as the cleaning, disinfection, and sterilization of medical devices.

This medical device may be used regardless of the characteristics of the (adult) operator, such as weight, age, height, sex, and nationality. The operator should wear gloves. The operator must not be the patient.

Operators should not have:

- Vision problems, unless wearing a form of vision correction.
- A disability of the upper limbs (gripping a rotary tool).
- Hearing problems (use of audible indicators, depending on the device).

• Memory or concentration problems (settings, sequences, or care protocols, etc.).

Special operator training:

• No special training other than basic professional training is required to operate this medical device.

1.2 Patient population: this medical device is intended for use with the following patient population: children, teenagers, adults, and senior citizens.

a. This medical device may be used regardless of the characteristics of the patient, such as weight (except for children), age, height, sex, and nationality. Operation of this medical device is **prohibited** in the following patient population: implanted heart pacemaker patient (or other electrical equipment), patients who had been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.) infants, pregnant or lactating women, patients with medical complications, allergic patients, patients with a clinical site not suited for the treatment. The patient should be calm, relaxed, immobile, and ideally lying down in a dental chair.

1.3 Body parts or tissue types treated: treatment should be limited only to the patient's buccal cavity.

1.4 Principal of operation of the medical device: an electric signal issued by the medical device is supplied to the micro-motor. The micro-motor is electronically connected to the medical device by means of an electronic signal. The micro-motor is equipped with a rotary instrument holder, on which an endodontic file is attached. The rotation of the micro-motor activates the endodontic file.

1.5 Interactions

a. The device conforms to applicable electromagnetic compatibility standards. Operators must ensure that no electromagnetic interference causes an increased risk (presence of radiofrequency emissions, electronic devices, etc.).

b. Interference may occur when used on patients wearing a pacemaker. This system emits electromagnetic fields, which present potential risks. Implantable devices, such as pacemakers and ICDs (implantable cardioverter defibrillators), may malfunction.

c. Before using this product, ask patients and operators whether they are wearing an implanted device. Explain the reason for your question.

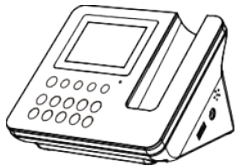
d. Determine the risk/benefit ratio and contact your patient's cardiologist or applicable specialist before carrying out the treatment.

e. Keep this product away from implanted devices.

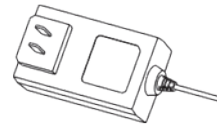
f. Take necessary emergency measures and immediate action if the patient becomes ill.

1.6 Product configuration

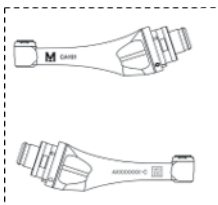
Parts

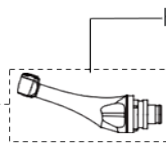


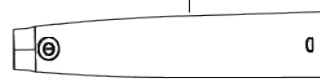
Base without cordless handpiece



Power adapter







Handpiece

Contra-angle head

Motor

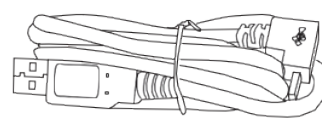
Measuring wire

File clip
(apex locator)

Lip hook
(apex locator)

Touch probe
(apex locator)

Tester
(apex locator)



USB measuring cable
(apex locator)

Protective silicone cover

Lubrication nozzle

1.8 Indications for use

iRoot Pro Plus is a cordless endodontic motor with root canal measurement capability. It can be used as an endodontic motor for preparation and enlargement of root canals, or device for measuring canal length. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

1.9 Contraindications

In cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers, etc.) it is recommended not to use this device.

1.10 Device safety classification

a. Type of operation mode: Continuous operating device.

b. Type of protection against electric shock: Class II.

c. Base and motor handpiece: internally powered device.

d. Degree of protection against electric shock: B type applied part.

e. Degree of protection against harmful ingress of water: Ordinary equipment (IPX0).

f. Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment **cannot be used** in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

g. Applied part: contra-angle, lip hook, file clip, touch probe.

h. The contact duration of applied part: 1 to 10 minutes.

i. The temperature of the surface of applied part may reach 46.6℃.

1.11 Primary technical specifications

a. Battery:

- Base: built in a 11.1V/2600mAh Li-ion battery pack, and charge voltage is 15Vd.c.,1.6A.
- Motor handpiece: built in a 3.7V/2000mAh Li-ion battery pack.

b. Power adapter:

- Input: ~100V-240V 50/60Hz 800mA.

- Output: DC15V/1.6A.

c. Torque range: 0.4-5.0Ncm(4-50mNm).

d. Speed range: 100-1200rpm.

e. Contra-angle head gear ratio is 6:1 (Model: CA161).

f. Wireless charging:

- Frequency range: 112-205KHz.
- Maximum RF output power of the product: 9.46dBuA/m@3m.

1.12 Working environment

- Environment temperature: +5-+40℃.
- Relative humidity: 30-75%.
- Atmosphere pressure: 70-106kPa.

a. Use the specified battery for this device. Never use any other batteries.

b. Do not expose the device to direct or indirect sources of heat. Operate and store the device in a safe environment.

c. The device requires special precautions as regards electromagnet compatibility (EMC) and must be installed and commissioned in strict conformity with the EMC information provided in this user operation manual. Specifically, do not use the device close to **fluorescent lamps, radio transmitters and remote controls**.

d. The USB port of the base must only be connected to USB port of the handpiece through the USB cable wire. Do not use it for other purposes.

e. Over-heat scorching: handpiece **cannot be used for 10 minutes continuously**.

f. If the handpiece works for 10 minutes continuously, the temperature of the surface of the handpiece and contra-angle may reach 56℃.

g. Only use the original contra-angle head (CA161 model). **Do not**

use any other contra-angle or other reduction rate other than original one.

h. Never press the contra-angle push button when the motor handpiece is running or if it is coming to a stop. This will lead to detachment of the endodontic file or cause the push button to overheat.

i. Never remove the contra-angle from the motor handpiece during operation.

j. Only use new endodontic files. Refer to the information provided by the manufacturer regarding speed, torque and other precautions.

IMPORTANT:

- **iRoot Pro Plus** motor has features like torque-controlled auto-reverse, auto stop, apex locator controlled apical stop, auto start and apical reverse, that may help the operator in regards to endodontic file separation prevention. The aforementioned features **will not** fully halt endodontic file separation due to the nature of the endodontic instruments, and instrumentation itself. Factors like canal morphology, obstructions, calcifications, patient and tooth age, presence of foreign materials, retreatment, instrument type and number of uses, among others, are key aspects that determine the risk of endodontic file separation during instrumentation and may not be surpassed by the motor file separation prevention features.

a. Only insert the endodontic file when the motor is OFF.

b. Only use engine-driven latch files. Do not use or try to adapt other endodontic files.

c. Never place your fingers on the moving parts of the endodontic file or motor while it is running or coming to stop.

d. Before treatment, check the contra-angle for any damage or loose parts.

e. Before use, make sure the endodontic file is securely locked in

place.

f. Never use rotary instruments in left cutting reciprocating (counterclockwise angle greater than the clockwise angle) mode.

g. **Never** use left cutting reciprocating endodontic files (i.e., Wave One, Wave One Gold, M-One, M-One Gold, EdgeOne Fire, Rex and ESR) in forward **rotary** mode.

h. Use the torque, speed and angles settings recommended by the endodontic file manufacturer.

i. The pre-setting files on the **iRoot Pro Plus** program are exclusively offered and controlled by Pac-Dent, Inc. Any modifications on the pre-set values can result in endodontic file damage.

j. Wireless charging will generate heat, and the surface temperature of the tail of motor handpiece will rise. Pay attention to the effect of temperature rise on users when using motor handpiece.

- The device must only be used in suitable locations and only by specialized physicians licensed to practice dentistry.
- Overuse of the device will lead to motor overheating. Pausing the use will let the motor cool down. If the overheating persists, contact Pac-Dent, Inc.

2. Installation

- Have all of the connections between your device and the power grid made by a certified dental installation technician. The power grid to which the iRoot Pro Plus connects must comply with the US applicable standards.

2.1 Unpacking and installation

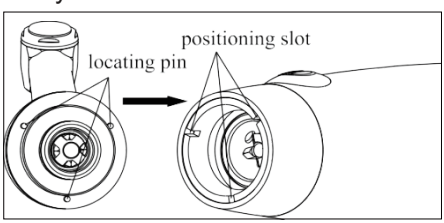
- Remove the box and its accessories from their original packaging and place them on a flat surface. Do not install near direct or indirect sources of heat.

- Verify the contents of the box, referring to Section 1.6 “Parts”.
- Do not bend the power cord, which may cause damage.
- All supplied accessories have not been sterilized.
- Place the base on a stable, horizontal surface with a slope no greater than 5°.

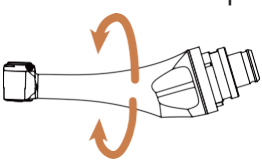
2.2 Installing and removing the contra-angle (CA 161)

2.2.1 Installing

- Align any locating pin of the contra-angle with the positioning slot on the motor and push the contra-angle horizontally. The three locating pins on the contra-angle are inserted into those three positioning holes on the motor handpiece. A “click” sound indicates that the installation is in place. The contra-angle can be rotated 360° freely.

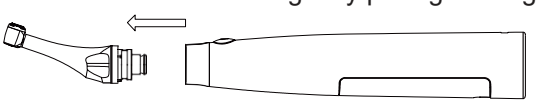


- The contra-angle is free to rotate, adapting to the operator needs in different positions.



2.2.2 Removing

- Remove the contra-angle by pulling it straight out.

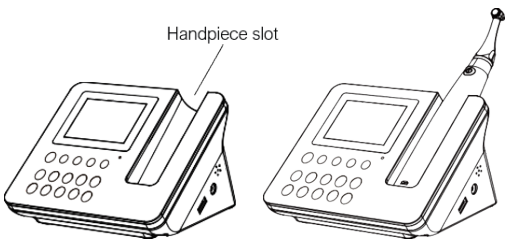


CAUTION

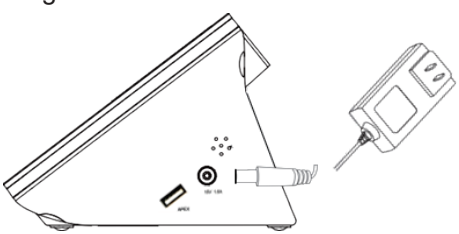
- Turn the motor off when inserting and removing the contra-angle.
- Charge the unit immediately upon purchase, after each use and every 30 days.

2.3 First battery charge (for more information see Section 3, 3.8)

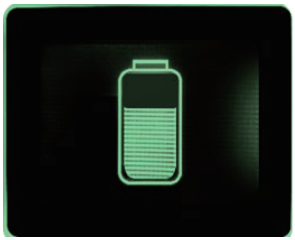
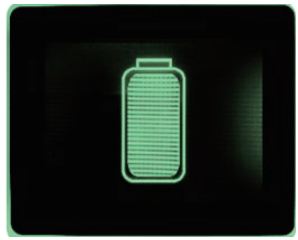
- Place the handpiece at the base handpiece slot.
- The base has a built-in energy storage lithium battery.



- Insert the AC power adapter cable on the AC power socket at the right lateral side of the base.



- Once the AC power cable is connected to the base, a battery icon will show up at the display showing the status of the base lithium battery.

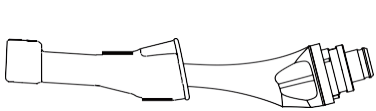
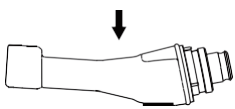
- After charging, pull out the power adapter.
- Once the AC power cable is connected to the base, the battery icon at the upper right side of the base panel will blink in blue indicating that the handpiece lithium battery is being charged.

a. Leave the base with the handpiece resting in position connected to the power adapter charging when the **iRoot Pro Plus** is not in use.
b. Do not open the device, or attempt to change the battery. That may cause circuitry damage.
c. If the battery leaks, please stop using immediately. Return to Pac-Dent, Inc. for repairing.
d. Do not use any other power adapter or USB charging adapters. **Only use the original power adapter charger**.
e. Have all of the connections between your device and the power grid made by a certified dental installation technician.
f. The power grid to which the device connects must comply with the applicable standards in your country.

2.4 Installing and removing the protective silicone cover

2.4.1 Installing

- Put the protective silicone cover onto the contra-angle.

2.4.2 Removing

- Pull the protective silicone cover straight out slowly.

2.5 Inserting and removing the endodontic file

2.5.1 Inserting

- Insert the endodontic file into the chuck until it stops.

2.5.2 Removing

- Press the push-button and pull out the endodontic file.

- Turn the motor OFF when inserting and removing the endodontic file.

3. Settings: Motor only mode

iRoot Pro Plus has basically three different operation modes. Depending on operator's preferences, **iRoot Pro Plus** can be used as **motor only** (or motor alone), **apex locator only** (for electronically foramen position determination), and **motor combined with apex locator** (the motor will work simultaneously with the apex locator, giving readings as an apex locator and during the translation of the endodontic file inside the canal).

IMPORTANT:

- The motor modes and settings will be defined by the operator. Prior training in typodont models, or extracted teeth, should be done to be familiarize with the equipment and its features.
- If the operator is not trained in the use of the motor concurrently with the apex locator (**motor and apex locator combined** mode), it is recommended to use the **motor only** mode. Operators always can use the **apex locator only** mode to determine the working length, and then use the motor only mode for instrumentation.

3.1 Settings: **motor only**

3.1.1 Base on and off.

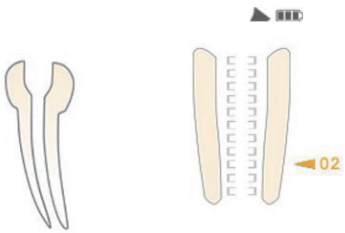
3.1.1.1 **Turn the base on.** Touch and hold the POWER button for 3 seconds. A double beep will sound.

IMPORTANT:

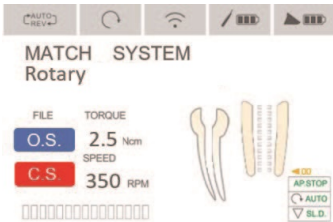
- If you have the power cord inserted, the screen will show the base battery status. Touch and hold the POWER button for 3 seconds. A double beep will sound. The display will show Pac-Dent, Inc. welcome screen.
- After the welcome screen, the display will show the last mode chosen display (one of the three) as follows:

Motor only mode display

Apex locator only mode display



Motor and apex locator combined mode display



IMPORTANT:

- Display figures above may vary based on the chosen sub-settings of each mode.
- Display will match with the last mode (and sub-settings) used on the previous use.
- The **base** will enter battery saving (sleep) mode after 10 minutes if it is not used. A beep will sound.
- The handpiece will enter battery saving (sleep) mode after 5 minutes if it is not used. A beep will sound.
- The SET button will remain blue **during the battery saving (sleep) mode**.
- There are two ways of return from battery saving (sleep) mode to ready-on mode:
  - Press the handpiece ON/OFF button once. An ascending three-tone beep will sound). The ON/OFF button will turn blue and the handpiece is ready-ON. To start the motor, press again the ON/OFF button. The button will start to blink blue while the motor is ON.
  - Touch and hold the POWER button for two seconds (a fast-double beep will sound). Device will shut down. Touch and hold the power button again for two seconds. After the welcome screen, the last used display will appear.

• The device will **shut down** automatically after 30 minutes if it is not used. A double beep will sound. The SET button blue light will be off.

3.1.1.2 **Turn the base off**. Touch and hold POWER button for 2 seconds. A fast-double beep will sound. The screen slowly gets dark, and the device will shut down.

IMPORTANT:

• The handpiece can be used with the base on battery saving (sleep) mode. In this case, the handpiece performance (working mode and sub-settings) will be under the last specs chosen.

Choose operation mode.

3.1.1.3 With the base ON, touch En-Ap button to navigate between the three displays modes, motor only, apex locator only and motor and apex locator combined.

3.1.1.4 Choose motor only display.

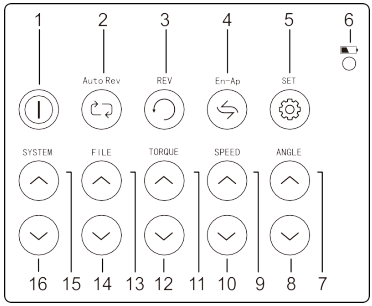
Motor only display

WARNING

a. The touch screen buttons light up in blue depending on the operation mode chosen. Only the light up buttons will be used on the different modes to adjust parameters.

b. Changing operation mode or operation parameters is allowed only when the handpiece is **ready-ON or OFF**.

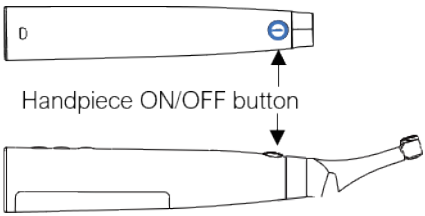
Base touch screen buttons.



1	Power		Base power on/off
2	Auto Rev	Auto Rev	Automatic reverse modes
3	Rev	REV	Forward or reverse endodontic file direction during rotation
4	En-Ap	En-Ap	Mode selection (motor only, apex locator only, motor and apex locator combined)
5	Set	SET	• Set forward (clockwise) and reverse (counterclockwise) angles in reciprocation mode • Contra-angle calibration
6	Batt		Blue LED flashes when the handpiece is on the base and it is being charged. Stay on when battery is full.
7	Angle		In reciprocating mode, increase the angle
8	Angle		In reciprocating mode, decrease the angle
9	Speed		Increase rotation speed (rpm)
10	Speed		Decrease rotation speed (rpm)
11	Torque		Increase torque
12	Torque		Decrease torque
13	File		Select previous file
14	File		Select next file
15	System		Select previous file's system
16	System		Select next file's system

3.1.2 Handpiece (ON and OFF)

3.1.2.1 With the base ON (see 3.1.1.1), press the handpiece ON/OFF button. The power icon will turn blue indicating that the handpiece is ready to be used (ready on mode). Press the button again to start the motor. The button will blink in a blue color while motor is working. Press again to stop the motor.



IMPORTANT:

- The handpiece will go to battery saving (sleep) mode after 5 minutes if it is not used.
- Press the handpiece ON/OFF button to exit battery saving mode.

3.1.2.2 With the base ON and handpiece ready-ON, a wireless communication connection icon will appear showing that the handpiece had established wireless communication with the base. If the base is ON but the handpiece is OFF, the icon changes to . When the handpiece ON/OFF button is pressed, the handpiece will start based on the set mode (**motor only** or **motor and apex locator combined** modes only).

3.1.2.3 Press again the handpiece ON/OFF button to stop.

3.1.2.4 Long press the handpiece ON/OFF button, and the handpiece will turn off (descending three-tone beep will sound).

3.2 AUTO REVERSE, AUTO STOP, and AUTO REVERSE OFF

IMPORTANT:

- All settings and sub-settings should be done for motor performance under motor only and motor and apex locator combined modes.
- Once the operator chooses and sets the following settings and sub-settings, the motor will respond to the chosen options until the operator sets new parameters.
- If the base and handpiece are turned OFF and ON again, the set parameters will be the same.
- Once the operator sets the parameters, no further action is needed unless the operator decides to change any of the parameters.

iRoot Pro Plus motor offers three settings for the automatic reverse options.

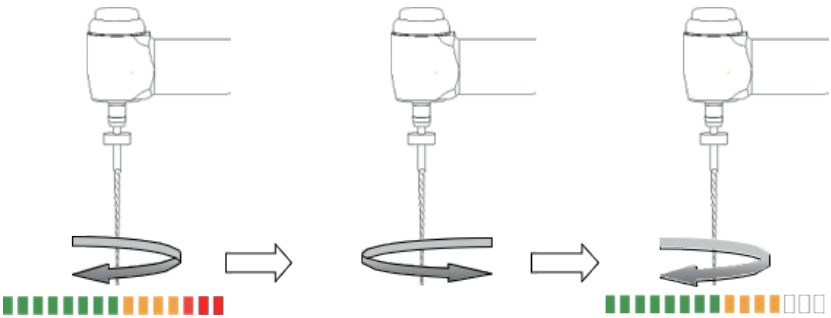
WARNING

a. The AUTO REVERSE sub-setting is an important feature to avoid endodontic file torsional and cyclic fatigue stresses, and subsequently file separation. Although it is an important resource, other preventive measures must be taken during the course of all instrumentation. This feature alone **may not be sufficient to prevent file separation** in all cases.

b. AUTO REVERSE is available both in rotary and reciprocating movement.

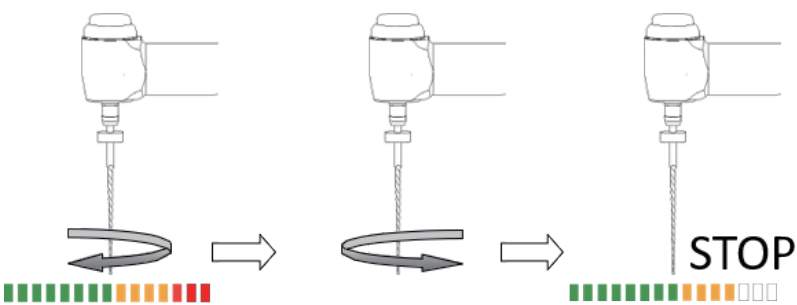
3.2.1 AUTO REVERSE ON

When the file reaches the defined torque value, the motor switches to reverse rotation until the file has been released. The motor then returns to forward rotation.



3.2.2 AUTO STOP

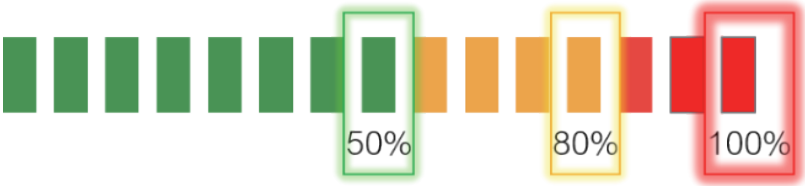
When the file reaches the defined torque value, the motor switches to reverse rotation until the operator stops the motor. The next time it is started, it uses forward rotation.



3.2.3 AUTO REVERSE OFF

When the file reaches the defined torque value, the motor stops without switching to reverse rotation. Push the handpiece button twice to restart the handpiece.

3.3 TORQUE bar



- Last green square: torque load is 50% of the preset load.
- Last yellow square: torque load is 80% of the preset load.
- Last red square: torque load is 100% of the preset load.

3.4 FILE SYSTEM and FILES

Touch SYSTEM buttons up or down to select the different pre-set file's system. Touch the FILE buttons up and down to select the different type of file from the system chosen.

IMPORTANT:

• There are innumerous different files' systems available in the global endodontic market. All them with different specs of speed, torque, angles in reciprocation, among others. Pac-Dent's files systems are preset and saved on the **iRoot Pro Plus** motor database. The pre-set values of torque, speed and reciprocation angles were fully developed and tested by Pac-Dent, Inc.

Pac-Dent's endodontic files systems (pre-set list)

System Name	File	RPM	Torque	Movement	Angles
One File G					
One File G	All	400		Reciprocation	FWD 30°/REV 150°
Pac-Taper					
Pac-Taper & Pac-Taper Conform	CX-C1	300	1.5	Rotary 360° Forward	
	C2-A1	300	2.0	Rotary 360° Forward	
	A2-A5	300	2.5	Rotary 360° Forward	
Pac-File					
Pac-File & Pac-File Conform (.04 and .06)	15-20	300	1.5	Rotary 360° Forward	
	25-35	300	2.0	Rotary 360° Forward	

IMPORTANT:

• The pre-set specs are saved on the system. The operator can occasionally change pre-set parameters before starting the instrumentation. For safety reasons, changes in parameters of the pre-set files' systems list will **NOT** be automatically saved, returning to the manufacturer's originals specs after turning off and on.

WARNING

a. The pre-set list of files with parameters is an important feature to avoid the wrong use of the specific endodontic file and subsequently file separation. Although it is an important resource, other preventive measures must be taken during the course of all instrumentation. This feature **may not be sufficient to prevent file separation**.

b. Although **iRoot Pro Plus** motor program allows user to interact and change the parameters of the files, it is highly recommended that the operator follows the pre-set list saved specs since they were fully tested previously.

3.5 SPEED and TORQUE

• Select the desired speed by touching SPEED up and down buttons (speed range: 100-1200 rpm).

• Select the desired torque by touching TORQUE up and down buttons (torque range: 0.4-5.0 Ncm).

IMPORTANT:

• Torque values define the trigger point of AUTO REVERSE and AUTO STOP modes. Low torque values are safer but can influence the efficacy of the file. Follow the files' instructions for the right torque

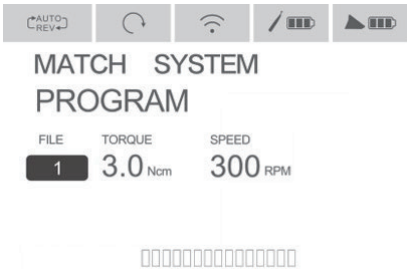
values to be used for each file. Pac-Dent's files' torque and speed are pre-set on the SYSTEM list.

3.6 User-defined system

iRoot Pro Plus motor allows the operator to save **8 different sets of continuous rotation** parameters, and list them from number 1 to 8. Likewise, the operator can set 3 different sets of reciprocation parameters (including angles forward and reverse), and list them from number 1 to 3. Furthermore, operator can choose AutoSense mode with different levels of sensibility.

3.6.1 To set the PROGRAM mode parameters in rotation:

• Touch SYSTEM buttons up and down until find PROGRAM.



• Touch FILE buttons up or down until find number 1.

• Set up the speed, torque and auto-reverse mode using the equivalent SPEED, TORQUE, and Auto Rev buttons. The range of speed in rotation is from 100 to 1200 rpm. Torque will range from 0.4 to 5.0 Ncm.

• Proceed with the same steps changing the file group numbers by touching FILE buttons (1-8).

IMPORTANT:

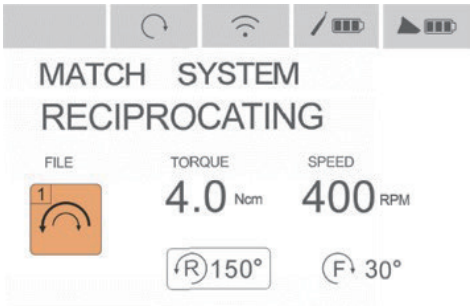
•Once the operator changes the values of the different parameters on the user-defined programs it will be saved. There is no extra

action to be done.

• The operator can go back to PROGRAM any time to change parameters. Once changed, they will be saved.

3.6.2 To set the PROGRAM mode parameters in reciprocation:

• Touch SYSTEM buttons up or down until find RECIPROCATING.



• Touch FILE buttons up or down until find number 1.

• Set up the speed and torque using the equivalent buttons.

• The adjusting range of speed in reciprocation is 100 to 500 rpm. Range of torque is 2.0 to 5.0 Ncm.

• Touch SET button to switch between the forward (F) and reverse (R) angles.

• Touch ANGLE up or down buttons to increase/decrease the angle of reciprocation. The adjusting range of angles is 20° to 400°, with 10° interval for each adjustment.

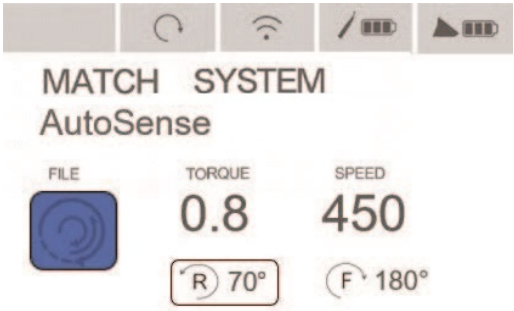
• Proceed with the same steps changing the file group numbers by touching FILE buttons (1-3).

WARNING

a. Before using the set-up feature of reciprocation angles, consult the files' instruction of use to determine if the reciprocation **cutting** angle is clockwise (forward) or counterclockwise (reverse).

3.6.3 To set the PROGRAM mode in **AutoSense**:

This unique feature allows the operator to work automatically with the two movements (rotary and reciprocation). With light apical pressure on the file, movement changes from rotary for reciprocating. The sensitivity may be altered by changing torque values.



• Touch SYSTEM buttons up or down until AutoSense.

To **change parameters:**

•Set up the speed, torque (sensitivity), and angles using the equivalent buttons.

3.7 Calibration (contra-angle and motor handpiece)

This function is to decrease fluctuation in the rotation speed of the motor and the difference in torque by the contra-angle.

Calibration is recommended when using a new contra-angle or after an extended period of operation (more than 30 days), as the running properties can change with usage, cleaning and sterilization.

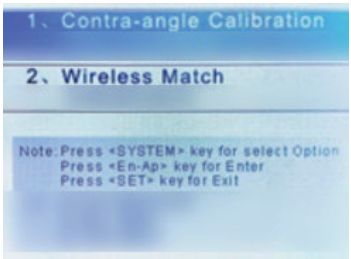
3.7.1 Turn base ON (see 3.1.1.1) and the handpiece ready-on (see 3.1.2.1). Install the contra-angle to the motor (see 2.2.1).

3.7.2 Leave the handpiece resting on the handpiece slot at the base.

3.7.3 Touch En-Ap button and select **motor alone** mode (see 3.1.1.3).

3.7.4 Long touch SET button to enter setting interface.

Setting interface



3.7.5 Touch SYSTEM button to select “1. Contra-angle Calibration” option.

3.7.6 Touch En-Ap button to enter “1. Contra-angle Calibration”.

3.7.7 Press ON-OFF button at the handpiece to start calibration.

3.7.8 The motor will start changing speeds for about 20 seconds. The screen will display “Calibration Succeed” . The display automatically returns to **motor only** mode display.

3.8 Battery charging

3.8.1 The base has a built-in energy storage lithium battery.

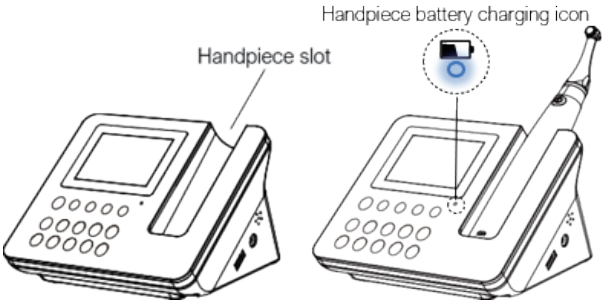
When the battery power sign is shown on the screen, immediately stop using the motor, and connect the AC power adapter cable plug to the power socket of the base. When charging, the screen panel power icon will scroll display. Battery is fully charged when the battery power sign no longer scroll display

After charged, remove the AC power adapter cable.

3.8.2 Motor handpiece charging

The motor handpiece has a built-in energy storage lithium battery and is equipped with **wireless inductive charging**. With the base on, rest the handpiece properly in the handpiece base slot. The wireless charging indicator on the base starts to flash . After the handpiece is fully charged, the wireless charging indicator would

be on. At the screen the icons (handpiece battery low), and (handpiece battery full) will show the handpiece battery status.



a. Do not open the device, or attempt to change the battery. That may cause circuitry damage.
b. If the battery leaks, please stop using immediately. Return the device to Pac-Dent, Inc. for repairing.
c. Do not use other power adapter or USB charging adapters.

3.8.3 **Motor only** mode**. Advanced clinical sequence sequence (in rotary and reciprocation modes):**

IMPORTANT:

- Electronic working length determination (apex locator) steps will be shown ahead in Section 4.
- The settings to be used in this example are:
  FILE: to be determined during operation.

AUTO REVERSE:

3.8.3.1 Place rubber dam isolation prior to beginning endodontic treatment.

3.8.3.2 Obtain an initial radiograph and measure the distance between a reference point (i.e. incisal edge, peak of the cusp, etc.) to the image of the anatomical apex for the canal you will be working on. Subtract 3-5mm to establish TEMPORARY working length.

3.8.3.3 Select the file system to be used by touching the up or down SYSTEM buttons.

IMPORTANT:

- The pre-set files are shown in crescent order of use on the FILE option. This detail indicates the suggested sequence of use of files instrumentation protocol.

3.8.3.4 Select the auto reverse option by touching the AUTO REVERSE button. Select AUTO REVERSE on

3.8.3.6 Fill the canal with irrigant solution and/or endodontic lubricant.

3.8.3.7 Scout the canal with a K-File #10 or 15. Establish patency to TEMPORARY working length.

3.8.3.8 Insert the **first** file to the contra-angle. Ensure the canal is filled with irrigant solution and/or endodontic lubricant.

3.8.3.9 Start the motor by pressing the ON/OFF button at the handpiece. Gently insert the file towards the canal entrance.

3.8.3.10 Preflare the canal. Use copious irrigation to partially remove canal contents. Preferably use ultrasonic activation with constant flow irrigation.

- To ensure proper performance, verify that the canal is not completely dry or calcified.

3.8.3.11 Working length determination sequence with built in apex locator (see Sector 4 for sequence details).

3.8.3.12 After determining the working length, touch SYSTEM button down to select the next file.

3.8.3.13 Remove the file and place the next file in sequence.

3.8.3.14 Turn on the motor and insert the file inside the canal.

3.8.3.15. After proper enlargement, remove the file. Turn the motor off.

3.8.3.16 Use copious irrigation. Use preferably ultrasonic activation with constant flow irrigation. Always keep the canal filled with irrigant solution.

3.8.3.17 Select the next file in sequence by touching the FILE bottom down.

3.8.3.18 Place the file.

3.8.3.19 Insert the file partially inside the canal. Turn on the motor.

3.8.3.20 If the apical pressure applied to the file exceeds the torque limit, auto reverse function will be initiated. Withdraw the file to return to the forward continuous rotation.

3.8.3.21 After proper enlargement, remove the file from the canal. Turn the motor off.

3.8.3.22 Use copious irrigation. Use preferably ultrasonic activation with constant flow irrigation.

3.8.3.23 Repeat steps 3.8.3.17 to 3.8.3.22 with the desired final enlargement file.

IMPORTANT:

- The handpiece will enter battery saving (sleep) mode after 5 minutes without use. The base will enter battery saving (sleep) mode after 10 minutes without use. To return (handpiece and base)

to ready-ON mode just press the ON/OFF button once.

4. Settings: apex locator only

iRoot Pro Plus motor has basically three different operation modes. Depending on operator's preferences, iRoot Pro Plus can be used as motor only (or motor alone), **apex locator only** (for electronically foramen position determination), and motor combined with apex locator mode (the motor will work simultaneously with the apex locator, giving readings during the translation of the endodontic file inside the canal).

IMPORTANT:

- The motor modes and settings will be defined by the operator. Prior training in typodont models, or extracted teeth, should be done to familiarize with the equipment and its features.
- If the operator is not trained in the use of the motor concurrently with the apex locator (motor and apex locator combined mode), it is recommended to use the motor only mode. Operators always can use the apex locator only mode first to determine the working length, and then use the engine only mode for instrumentation.
- Basic training and knowledge about the operating principles of the electronic working length determination (apex locator) are necessary to operate the **apex locator only** mode.

WARNING

a. As per Endodontic Standards of Care, **always use rubber dam isolation when performing endodontic treatment**.

4.1 Apex locator only

- Do not use this unit with patients who have a pacemaker, as its effect has not been evaluated.

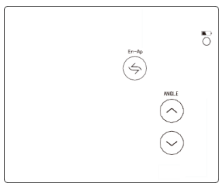
4.1.1 Turn base ON (see 3.1.1.1).

4.1.2 Touch En-Ap button to navigate between the three display modes: motor only, apex locator only and motor combined with apex locator. Choose apex locator only display.

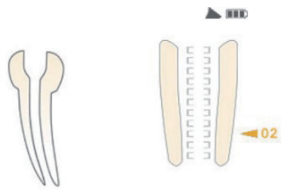
IMPORTANT:

- The handpiece will be disabled (off) in this mode.

Base touch screen buttons (apex locator only mode)



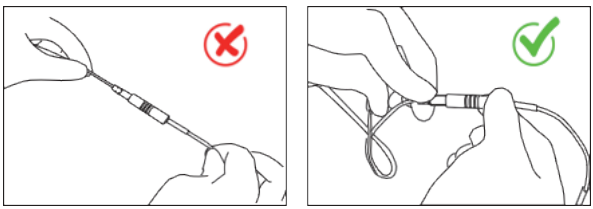
Apex locator only mode display



4.1.3 Connect the measuring wire. Insert the plug of the measuring wire (A) into the socket (B) on the left side of the base.

4.1.4 Connect the terminals. Insert the file clip into the gray female socket and the lip hook to the white socket at the other end of the measuring wire.

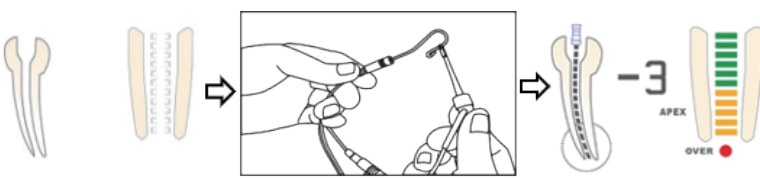
CAUTION



4.1.5 Turn the base ON. Touch the En-Ap button choosing **apex locator only** mode display (see 3.1.1.1).

4.1.6 **Wire connection test**.

Prior to each use, the measuring wire and connectors should be checked for functionality. Grab the lip hook with the bent wire of the file clip. All instruction bars will be displayed alongside '-3' and a repeated beep sound alarm. Proceed with the electronic working length determination.



WARNING

a. Apex locators' measurement wire is a delicate part of the device. Even though it is flexible, do not bend or angle it. Store the wire stretched out. Due to the polymer protection, it is difficult to see if any damage is present caused by improper handling of the wire.

b. The connectors of the wire are also sensitive. Due to the use of a

very weak electronic signal during the electronic measurement, any interruption will cause malfunction and misreading. Make sure that the connections between the measurement wire and the base, and measurement wire and the two terminals – lip hook and file clip – are tightly connected.

c. Always carefully dry the terminals after cleaning. Do not leave humidity on the connectors. All connections need to be clean, without debris, corrosion, patina, or oxidation.

d. If the wire connection test fails, contact Pac-Dent, Inc. to replace the measurement cable/connectors.

4.1.7 **Apex locator test**.

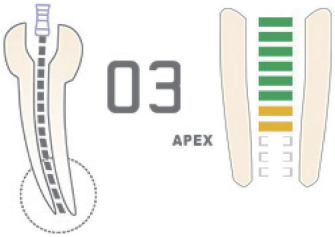
iRoot Pro Plus has the apex locator built-in, allowing the operation of electronic working length determination. The device has an accurate and reliable hardware and firmware that allows an accurate determination of the foramen position. **No calibration is needed.** An “apex locator tester” is provided to test if the device is working properly.

4.1.7.1 Pull out the measure wire and turn OFF the device.

4.1.7.2 Insert the tester on the same slot of the measurement wire (see 4.1.3).

Tester
(apex locator)

4.1.6. Turn the base on. Display will show 01, or 02, or 03, or 04. A repeated beep will sound. All the aforementioned results show that the apex locator is working properly.



4.1.7 Turn the base off. Remove the apex locator tester.

4.1.8 Turn the base on to continue.

4.2 Apex locator only. **Clinical operation sequence**.

WARNING

a. As per Endodontic Standards of Care, **always use rubber dam isolation when performing endodontic treatment.**

b. Do not use this unit with patients who have a pacemaker, as its effect has not been evaluated.

c. Verify the electronic measurements with an endodontic file and radiograph, as abnormal canal anatomy or unusual canal morphology may cause inaccurate measurements (i.e. blocked canals, immature teeth).

d. Do not use damaged file clips or any accessory because it could result in an inaccurate measurement.

e. Do not use dry heat sterilization on the measurement wire, file clips, and touch probes.

f. The LCD screen readings 10, 9, 8, 7, 6, 7, 6, 5, 4, 3, 2, and 1 **do not** correspond to any actual distance in millimeters. They serve as a convenient reference to estimate the file tip position in relation to the apical foramen.

g. Sometimes the electronic reading and the x-ray image will not correspond. This can be due to the actual location of the apical foramen and inaccuracies of the x-ray angulation made before and during endodontic treatment.

- Verify that the tooth has been properly isolated and that there are no metallic restorations present which can make contact with the file.
- Ordinarily **iRoot Pro Plus** motor built-in apex locator provides accurate measurements during foramen location in dry and wet canals, and in presence of various electrolytic solutions (Sodium Hypochlorite, EDTA, saline, etc.).
- An endodontic K-file #15 is the minimum recommended file size for apical foramen localization. However, smaller or larger files may be used when anatomically necessary.
- For convenience of use, it is recommended for the selected file to be about 5mm longer than the radiographic working length.
- Before measuring, check the accessories and verify good connectivity. Proceed the wire connection test and the apex locator test periodically.
- When disconnecting the lip hook, file clip or measuring wire, always grip the connectors. Do not pull directly on the wires to disconnect.
- Ensure the measuring wire is installed with correct connection.
- The items which may come into contact with the patient during intended use of the device (lip hook, file clip and touch probe) must be cleaned and sterilized before the first use and between patients to avoid the risk of cross-contamination.
- Care should be exercised when the **iRoot Pro Plus** motor is used around devices emitting electromagnetic noise such as fluorescent lamps, film viewers, ultrasonic devices, radio frequency transmitters, cell phones, remote controls, or devices that radiate electromagnetic (EM) fields, areas where there are strong magnetic fields, or conditions where there is high static electricity (ESD). While the **iRoot Pro Plus** motor has been built to withstand these conditions, EM and ESD fields may interfere with the device's proper operation (specially with the apex locator function). If the **iRoot Pro Plus** motor must be used under these conditions, ensure that the device is operating normally.

4.2.1 **Place rubber dam isolation prior to beginning endodontic treatment**.

4.2.2 Obtain an initial radiograph and measure the distance between a reference point (i.e. incisal edge, peak of the cusp, etc.) to the image of the anatomical apex for the canal you will be working on. Subtract 3-5mm to establish TEMPORARY working length.

4.2.3 Preflare the canal to partially remove canal contents and establish patency to TEMPORARY working length.

4.2.4 To ensure proper measurements, verify that the canal is not completely dry or calcified. If needed, fill the canal with an electrolytic solution (i.e. Sodium Hypochlorite, Saline, etc.).

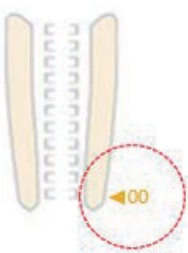
4.2.5 Depending on the size of the canal, insert a hand K-File #15 or another appropriate file into the canal up to TEMPORARY working length.

4.2.6 Connect the measuring wire. Insert the plug of the measuring wire into the socket on left side of the base (see 4.1.3).

4.2.7 Connect the terminals. Insert the **file clip to the gray** female socket and the **lip hook to the white** socket at the other end of the measuring wire.

4.2.8 Touch En-Ap button to navigate between the three display modes: motor only, apex locator only and motor combined with apex locator. Choose **apex locator only** display (see 4.1.2).

4.2.9 Touch ANGLE buttons up or down to determine the continuous alarm position on the color instruction bar grid. Suggestion is 00.



IMPORTANT

- Some apex locators from other brands used to define this feature as “calibration”, a false impression that this is a true hardware/ software calibration procedure. This feature is **only** to offer a different **continuous alarm position** related to the proximity of the foramen. If the operator chooses the 00 position, the continuous alarm will sound at the foramen position. Positions from 10 to 1 will only warn the operator that the tip of the file is getting closer to the foramen position.

a. Once the apical position alarm is chosen, other sub-settings will be affected by the apical position setup. Chose 00 for the foramen exit position.

4.2.10 Put the lip hook onto patient’s lip.

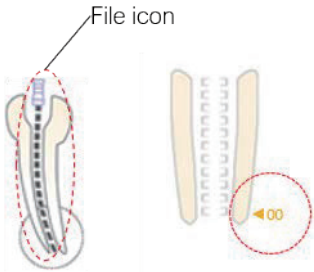
4.2.11 Place the file inside the canal up to TEMPORARY working length.

IMPORTANT:

- It is critical that the tip of the endodontic file touches the majority of the internal dentin walls (last millimeters). The electronic signal is weak and needs continuity between the tip end of the file and dentin to be able to pass through and return to be measured.
- If you feel that the endodontic hand file is free and loose, change to a bigger diameter (20, 25, etc.) until it fits better.
- Always preflare the cervical and medium thirds of the canal before choosing the right endodontic hand file to perform the electronic reading.

4.2.12 With the file in position (TEMPORARY working length) inside the canal, connect the file clip to the endodontic hand file. **iRoot Pro Plus** motor built-in apex locator will

automatically detect that root canal measurement has started. If the electrical contact is good and the conductivity of the root canal is sufficient, the file icon inside the tooth canal image will appear.



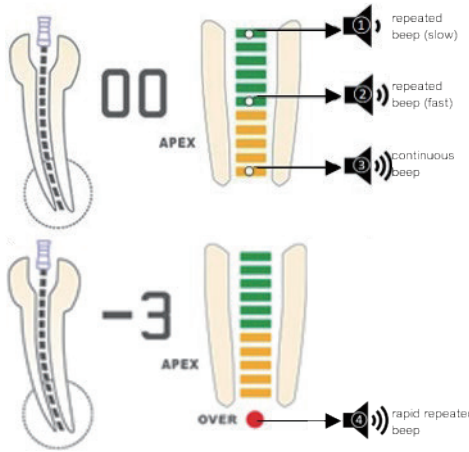
WARNING

a. If the file icon inside the tooth canal image does not appear, stop measurement, clean the file clip and the file, irrigate the canal if required, and resume measurements.

b. Ensure that irrigation solutions, blood, or saliva don't fill the access cavity. Dry the pulp chamber cavity if required before performing measurements.

4.2.13 Continue to advance the file by moving it smoothly in a watch-winding motion. As the instrument progresses toward the foramen, color instruction bars inside the zoomed root canal image (right side of the display) accompanied by repeated beep tones with varied frequencies will indicate the file's progress. Numerical readings from 10 to 01 (repeated beeps), and 00 (foramen exit position, continuous beep) will appear in the left side of the root canal zoomed image. If the file progresses beyond the foramen exit to the apical PDL, negative numbers (-1, -2 or -3) and OVER will appear (under the root canal image with a rapid repeated beeps sound alarm).

4.2.14 Interfaces displayed: screen displays the approach of the file to the apical foramen by color instruction bars and alarms.



❶Approximately 2.0mm off the apical foramen (slow repeated beeps).

❷Approximately 0.5mm off the apical foramen (fast repeated beeps).

❸Apical foramen position (continuous beep).

❹Beyond the foramen (rapid repeated beeps)

IMPORTANT:

• Due to different nomenclatures for the terminology apex being used by different authors, the term foramen is adopted as the main exit of the root canal, or canal terminus. This point **is not** C.D.C., or apical constriction (minor foramen). To determine the working length, the operator needs to decide how far from the foramen the mechanical instrumentation will end. This is a personal preference decision and needs to be calculated by using the position determined by the electronic reading subtracted by a value in millimeters (0.5 to 1.0 mm). Furthermore, some authors/techniques suggest the 00 point (foramen exit) as the final extension of mechanical instrumentation, coincidently with the electronic reading 00.

a. The red **OVER** indication accompanied by rapid repeated beeps indicates that the file tip has progressed beyond the foramen into the periapical P.D.L. region. Foramen over-instrumentation.

b. Erratic movement of the file may cause unstable readings.

4.2.15 Reaching the apical foramen (00) is indicated by the last orange color segment at the instruction bar inside the root canal image, and constant beep tone.

4.2.16 Adjust the rubber stop, unplug the file clip and gently withdraw the file.

4.2.17 Determine the working length by using the electronically obtained length and an endodontic ruler. To establish the working length, subtract 0.5 - 1.0mm from the electronic length.

IMPORTANT:

- Some authors/techniques advocate the foramen position as the final landmark for mechanical instrumentation.
- The file clip may be disconnected from the file and connected back during measurement without affecting normal device operation (for instance, when the file is changed to a larger number during root canal treatment or when another canal should be measured). In such cases the device detects automatically that the new measurement is initiated.
- The components that touch the body must be autoclaved under high temperature and high pressure. The base and measuring wire should be cleaned by 75-80% ethanol (alcohol). See Section 10.

5. Settings: Motor and apex locator combined mode

iRoot Pro Plus has essentially three different operation modes. Motor only (or motor alone), and apex locator

only (for electronically foramen position determination) were discussed previously in this operating manual. The **motor and apex locator combined** is an option in which the motor will work simultaneously with the apex locator, giving readings during the translation of the endodontic file inside the canal. Moreover, this mode has sub-settings that allow the motor to work under the apex locator readings, i.e., starting automatically when the file is inserted, and/or decrease the speed when the endodontic file gets closer to the foramen.

IMPORTANT:

- The motor modes and settings will be defined by the operator's preferences. Prior training in typodont models, or extracted teeth, should be considered to be familiarize with the equipment and its features.
- If the operator is not trained in the use of the motor concurrently with the apex locator (**motor and apex locator combined** mode), it is highly recommended to use the motor only, and apex locator only modes. Operators without experience are encouraged to use the apex locator only mode first to determine the working length, and then use the motor only mode for instrumentation.
- Basic training and information about the operating principles of the electronic working length determination are necessary to operate the **motor and apex locator combined** mode.

WARNING

a. As per Endodontic Standards of Care, **always use rubber dam isolation when performing endodontic treatment**.

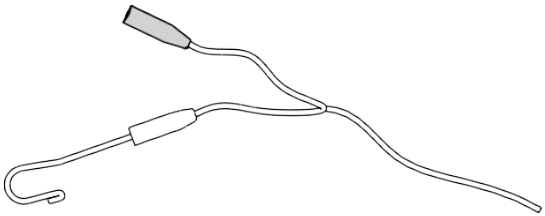
b. **Motor combined with apex locator** mode has sub-settings that allow the built-in apex locator to control endodontic file start/stop, and endodontic file directions (clockwise and counterclockwise) close to the foramen. If the operator has technical difficulties during the electronic length determination prior to the use of the **motor and apex locator combined** mode, it is recommended that the operator use the **motor only** mode.

5.1 Motor and apex locator combined. **Operation**.

Installing the measuring wire to the base.

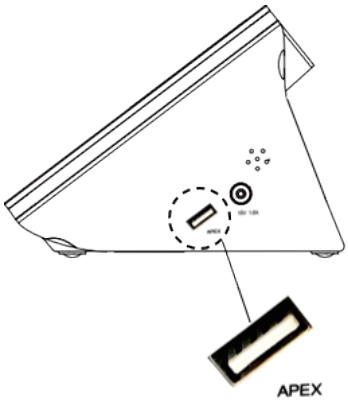
5.1.1 Connect the measuring wire. Insert the plug of the measuring wire into the socket on left side of the base (see 4.1.3).

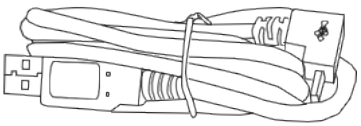
5.1.2 Insert the lip hook into the female white socket at the other end of the measuring wire. Leave the gray socket empty (for now).



Installing the USB measuring cable to the handpiece

5.1.3 Insert the USB measuring cable's male large plug into USB's female socket located at the right side of the base.



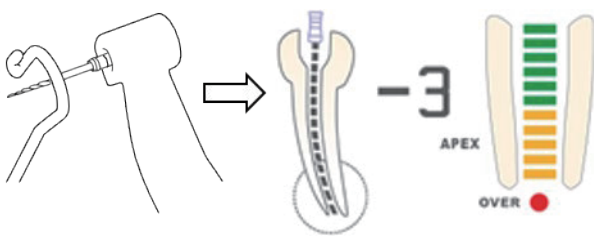


5.1.4 Insert the USB measuring cable's male small plug into the female socket of the motor handpiece.

Base setting and connection test.

5.1.5 Turn the device ON. Touch the En-Ap button choosing **motor and apex locator combined** mode display (see 3.1.1.1).

5.1.6 Prior to each use, the measuring wire, USB measuring cable and connectors should be checked for functionality. Insert an endodontic engine-driven file in the contra-angle. Touch the file with the lip hook. Touch the lip hook to the file. All instruction bars will be displayed alongside '-3' and a repeated beep sound.



WARNING

a. As per Endodontic Standards of Care, **always use rubber dam isolation when performing endodontic treatment.**

b. Do not use this unit with patients who have a pacemaker, as its

effect has not been evaluated.

c. Verify the electronic measurements with an endodontic file and radiograph as abnormal canal anatomy or unusual canal morphology may cause inaccurate measurements (i.e. blocked canals, immature teeth).

d. Do not use damaged file clips or any accessory because an inaccurate measurement could result.

e. The LCD screen readings 10, 9, 8, 7, 6, 7, 6, 5, 4, 3, 2, and 1 **do not** correspond to any actual distance in mm. They serve as a convenient reference to estimate the file tip position in relation to the apical foramen.

f. Sometimes the electronic reading and the x-ray image will not correspond. This can be due to the actual location of the apical foramen and inaccuracies of the x-ray angulation made before and during endodontic treatment.

g. Ensure that the engine driven endodontic file that you chose allows the passage of the electronic signal.

CAUTION

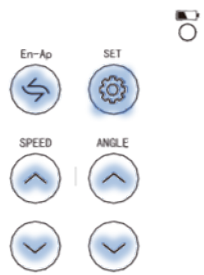
- Verify that the tooth has been properly isolated and that there are no metallic restorations present which may contact the file.
- Ordinarily, **iRoot Pro Plus** built-in apex locator provides accurate measurements during foramen location in dry and wet canals, in presence of various electrolytic solutions (Sodium Hypochlorite, EDTA, saline, etc.).
- Before starting, check the accessories and verify good connectivity.
- Ensure the measuring and USB wires are installed with correct connections.
- The items which may come into contact with the patient during intended use of the device (lip hook) must be cleaned and sterilized before the first use and between patients to avoid the risk of cross-contamination (See Section 10).

DANGER

a. Care should be exercised when the **iRoot Pro Plus** motor is used around devices emitting electromagnetic noise such as fluorescent lamps, film viewers, ultrasonic devices, radio frequency transmitters, cell phones, remote controls, or devices that radiate electromagnetic (EM) fields, areas where there are strong magnetic fields, or conditions where there is high static electricity (ESD). While the **iRoot Pro Plus** motor has been built to withstand these conditions, EM and ESD fields may interfere with the device's proper operation. If the **iRoot Pro Plus** motor must be used under these conditions, take care to see that the device is operating normally.

Motor and apex locator combined mode <u>sub-settings</u>

5.1.7 With the base and handpiece ON, touch and hold the SET button. The bellow buttons will be highlighted in blue.



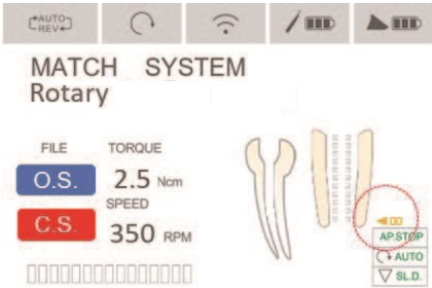
IMPORTANT:

- **iRoot Pro Plus** motor enter saving battery (sleep) mode after 5 minutes of not use. Touch any button on the touch screen display (except power) to exit saving battery (sleep) mode.

5.1.8 To navigate the sub-settings touch **SPEED** up or down buttons.

5.1.9 To select the sub-setting mode desired touch **En-Ap** button.

5.1.10 Touch **ANGLE** buttons up or down to determine the continuous alarm apical position on the color instruction bar grid. Suggestion is 00.



IMPORTANT:

- This feature offers a different continuous alarm position related to the proximity of the foramen. If the operator chooses the 00 position, the continuous alarm will sound at the foramen position. Positions up to 01 will only warn the operator that the tip of the file is closer to the foramen position.
- Adverse conditions to the use of an apex locator indicate that the operator should use **motor only** mode instead of **motor and apex locator combined** mode. The **motor and apex locator combined** mode is not recommended if erratic readings appear during the previous working length determination.

5.1.11 Sub-settings. Functionality.

WARNING

- The follow sub-settings are designed to be an extra-precaution to instrumentation errors. The features related **do not** guarantee that over-instrumentation will not happen as other factors related to this endodontic procedure can affect the operator's performance.
- Previously to instrumentation itself the operator should determine the working length. **iRoot Pro Plus** cordless endodontic motor in

motor and apex locator combined mode can be used as an apex locator, with the same sequence of events described previously in **Section 4**.

Sub-settings on motor and apex locator combined mode		
	Select the apical position by touching ANGLE up or down buttons.	The 00 position relates to the apical foramen exit. See 4.2.9
	The motor will stop when the file tip reaches the pre-selected apical position.	This function will be controlled by the built-in apex locator based on the pre-selected apical position.
	The motor will reverse when the file tip reaches the pre-selected apical position.	This function will be controlled by the built-in apex locator based on the pre-selected apical position.
	The motor will not be affected by reaching the pre-selected apical point.	
	The motor will start automatically when the endodontic file is inserted inside the canal.	This function will be controlled by the built-in apex locator.
	The motor will start only by the operator.	
	The motor slows down the rotation as it approaches the selected apical position.	This function will be controlled by the built-in apex locator. This function is not available in reciprocation.
	The motor continues to selected rotation mode.	

5.1.12 After selecting the desired sub-settings, touch SET button to return to **motor and apex locator combined** mode display.

5.1.13 The **motor and apex locator combined** mode have the same options of motor only mode. Options such as files' system, different settings for files inside each system, torque, speed and auto reverse settings are available. See Section 3, 3.4 to 3.6.

Motor and apex locator combined mode**. Advanced clinical sequence**

IMPORTANT:

• The motor and apex locator combined mode has different sub-settings. The basic sequence described is based on the following sub-settings:

- SYSTEM: Preferred
- FILE: to be determined during operation
- AUTO REVERSE

- Sub-settings:

(reverse when the file is at the foramen),

(auto start and auto stop),

(slow the rotation speed close to the foramen). See Section 5, 5.1.11 to 5.1.12 for more details. Apical position alarm set to 00 (see 5.1.7 to 5.1.10).

5.1.14 **Place rubber dam isolation prior to beginning endodontic treatment.**

5.1.15 Obtain an initial radiograph and measure the distance between a reference point (i.e. incisal edge, peak of the cusp, etc.) to the image of the anatomical apex for the canal you will be working on. Subtract 3-5mm to establish TEMPORARY working length.

5.1.16 Place the lip hook onto the patient's lip.

5.1. 17 Select the file system to be used by touching the up or down SYSTEM buttons.

5.1.18 Select the file to be used first.

5.1.19 Select the auto reverse option by touching the AUTO REVERSE button. Select AUTO REVERSE o n

.

5.1.20 Touch and hold the SET button to access sub-settings. Select the desired sub-settings. Navigate between the sub-settings options by touching SPEED up or down buttons. Select the desired sub-setting touching En-Ap button. Select AP.REV , AUTO , and SL.D. . Select the apical position alarm point by touching the ANGLE buttons up or down. Select 00. Return to the **motor and apex locator combined** mode display by touching SET button once.

5.1.21 Fill the canal with irrigant solution and/or endodontic lubricant.

5.1.22 Scout the canal with a K-File #10 or 15. Establish patency to TEMPORARY working length .

5.1.23 Insert the file. Ensure canal is filled with irrigant solution. Gently insert the file towards the canal entrance. The motor will automatically start in rotation forward (clockwise) direction.

5.1.24 Preflare the canal. Use copious irrigation to partially remove canal contents. Use preferably ultrasonic activation with constant flow irrigation. The motor will stop automatically when the file is outside the canal.

- To ensure proper performance, verify that the canal is not completely dry or calcified.

Working length determination (see 5.1.25 to 5.1.33)

- It is highly recommended to determine the working length

previously of the instrumentation continuation. In this way the operator will have double proof of the working length by using the hand file and during instrumentation. An x-ray of the file in position is also recommended.

5.1.25 Ensure the measuring wire (see 4.1.3) is connected and the lip hook in position.

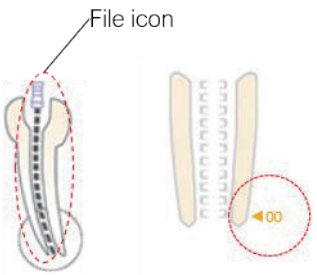
5.1.26 Connect the file clip to the gray female socket.

5.1.27 Place a hand K-file of proper diameter inside the canal up to TEMPORARY working length.

IMPORTANT:

- It is critical that the tip of the hand endodontic file touches the majority of the internal dentin walls (last millimeters). The electronic signal is weak and needs continuity between the tip end of the file and dentin to be able to pass through and return to be measured.
- If the endodontic hand file is free and loose, change to a bigger diameter (20, 25, etc.).

5.1.28 Connect the file clip to the endodontic hand file that is positioned at TEMPORARY working length.. Root canal electronic measurement will automatically start. If the electrical contact is good and the conductivity of the root canal is sufficient, the file icon inside the tooth canal image will appear.



WARNING

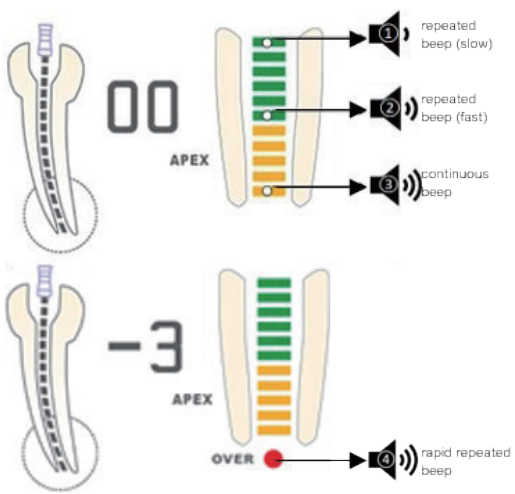
a. If the file icon inside the tooth canal image does not appear, stop measurement, clean the file clip and the file, irrigate the canal, if required, and resume measurements.

b. Make sure that irrigation solutions, blood, or saliva don't fill the access cavity.

c. Place the file clip with the file already inside the canal, positioned at the TEMPORARY working length.

5.1.29 Continue to advance the file by moving it smoothly in a watch-winding motion. As the instrument progresses toward the foramen, color instruction bars inside the zoomed root canal image accompanied by audio signals with varied frequency will indicate the file's progress. Numerical readings from 10 to 01, and 00 (Foramen), negative numbers (-1 to -3), and OVER (beyond the foramen position) will appear.

5.1.30 Stop the file apical movement when the instructions bars reach 00 (continuous beep).



5.1.31 After determining the foramen position, adjust the rubber stop, unplug the file clip and gently withdraw the file. Calculate the working length by using the electronically obtained length and an endodontic ruler. To establish the working length, subtract 0.5-1.0mm from the electronic length.

5.1.32 Disconnect the file clip. **Leave the lip hook in position placed on patient's lip.**

5.1.33 Remove the file and place the next file in sequence**.**

5.1.34 Insert file inside the canal. The motor will start automatically.

5.1.35 As the file approaches the working length, the display will show the progress of the file with the apex locator details. If the file tip incidentally reaches the foramen position, the motor will turn to **rotation reverse** until the file is withdrawn (AP. REV sub-setting). By the time that the file is not at the foramen, the motor automatically goes back to reciprocation.

5.1.36 After the proper enlargement, remove the file. The motor will stop automatically.

5.1.37 Use copious irrigation. Use preferably ultrasonic activation with constant flow irrigation.

5.1.38 Select the next file in sequence by touching the FILE bottom down.

5.1.39 Remove the file and place the next in sequence.

5.1.40 Insert file inside the canal. The motor will start automatically.

5.1.41 As the file approaches the working length, the display will show the progress of the file with the apex locator details. If the file tip incidentally reaches the working length, the motor will turn to rotation reverse until the file is withdrawn (AP. REV sub-setting). By the time that the file is not at the foramen, the motor automatically goes back to forward rotation.

5.1.42 After the proper enlargement, remove the file. The motor will stop automatically.

5.1.43 Use copious irrigation. Use preferably ultrasonic activation with constant flow irrigation.

5.1.44 Repeat steps 5.1.38 to 5.1.43 with the desired final enlargement file.

IMPORTANT:

- The handpiece will enter battery saving (sleep) mode after 3 minutes without use. The base will enter battery saving (sleep) mode after 5 minutes without use. To return (handpiece and base) to ready-on mode just press the ON/OFF button on the handpiece.

5.2 Reverse rotation

Although not common, **reverse (counterclockwise) rotation** can be set. Touch the Rev button

to reverse the rotation. Not applied to reciprocation motion. At the top display area, the rotation direction icon will change .

The three icons on directions are:

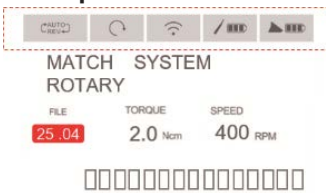
	Rotation in clockwise direction
	Rotation in counterclockwise direction
	Reciprocation

DANGER

a. Only use the **reverse direction** option when it is indicated. Normally, endodontic file cutting direction is clockwise.

b. The REVERSE direction rotation can cause endodontic file separation.

6. Auto reverse, rotation direction, battery charging and motor-handpiece connection icons



AUTO REV	Auto-reverse on (see 3.2.1).
AUTO REV	Auto-stop on (see 3.2.2).
	Auto-reverse off (see 3.2.3).
	Rotation in clockwise direction.
	Rotation in counterclockwise direction.
	Reciprocation.
	Handpiece (motor) and base connected (both base and handpiece need to be ON).
	Base is ON and handpiece is OFF, or handpiece (motor) and base are not connected (both base and handpiece need to be ON).
	Handpiece battery is full.
	Handpiece battery is 70% charged.
	Handpiece battery is 30% charged.
	Handpiece battery is low. Recharge it.
	Base battery is full.
	Base battery is 70% charged.
	Base battery is 30% charged.
	Base battery is low. Recharge it.

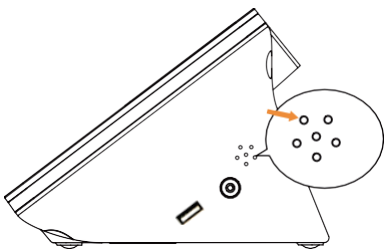
7. Battery saving (sleep) mode

If the handpiece is not used for around 5 minutes, it will enter the battery saving (sleep) mode (descending beep sound). Press the handpiece ON/OFF button to return to ready ON mode (ascending beep sound).

If the base is not used for around 10 minutes, it will enter the battery saving (sleep) mode (single beep). Touch any bottom (except power) to return to ON (single beep). After around 30 minutes without use the device shuts down automatically.

8. Reset function (in case of accidental base crash or touch button display failure).

Use a needle to push the internal button for more than 3 seconds to complete reset. Use the reset hole indicated by the orange arrow below.



9 Troubleshooting

Installation		
Problem	Cause	Solution
With the base and handpiece ON, the wireless communication connection status indication is . Wireless connection between the handpiece and the base fails.	1. The wireless connection has failed; 2. Handpiece is too far from the base.	1. Press the handpiece ON/ OFF button more than 5 seconds to power off. Press again to power on. 2. Place the handpiece near the base. Press the handpiece ON/ OFF button more than 5 seconds to power off. Press again to power on.
Blank display screen after use.	Battery saving (sleep) mode	1. The base automatically shuts down after 5 minutes without use - touch any screen button to turn the device on. 2. Battery is completely dead. Recharge it. 3. Device has malfunctioned – contact Pac-Dent, Inc.
Touch screen buttons are not responding.		Use the reset function (Section 8).

Contra- angle cannot be calibrated.	The calibration procedure may have been interrupted by increased resistance in the contra-angle.	1. If calibration has been interrupted, calibrate the motor handpiece again to rule out the possibility of a motor fault. 2. Clean and lubricate the contra-angle. 3. Start the calibration procedure again.
Motor handpiece is hot.	Run time is too long, especially in reciprocating mode.	Allow the device to cool down and start again the handpiece.
Apex locator only mode		
Display doesn't show any progress of the file.		Perform the apex locator test. Section 4, 4.1.7.
Display showing no or partial progression of the file towards the apical area/ foramen.	Various adverse procedure situations.	1. Poor connection. Check all connections and ensure lip hook is contacting the oral mucosa and file clip is clean and free of debris. Perform the wire connection test. Section 4, 4.1.6. 2. Fill the canal with an electrolytic solution, if required (i.e. Sodium Hypochlorite, Saline, etc.). 3. The endodontic file is not touching the internal canal walls. Replace the file using a larger diameter file. 4. If the behavior persists, the measuring wire or file clip may need to be replaced and/or the device should be sent in for service – contact Pac-Dent, Inc.
Failure on the wire connection test.	Poor connection or measuring wire damaged.	1. Make sure the measuring wire is properly connected. 2. If the behavior persists, the measuring wire may need to be

		replaced and/or the device should be sent in for service. Contact Pac-Dent, Inc.
No progression on the display indicators even when the file is moving towards the apical area.		1. Replace the endodontic hand file to a bigger diameter file. Ensure that the tip of the file is touching 2/3 of dentin walls. Place the file to TEMPORARY working length first and, with the file inside the canal in place, connect the file clip. 2. Ensure the canal is filled with irrigant. 3. The file clip is not properly connected with the endodontic file. 4. Check all connections and ensure lip hook is contacting the oral mucosa and file clip is clean and free of debris. 5. Perform the wire connection test. If the behavior persists, the measuring cable may need to be replaced and/or the device should be sent in for service. Contact Pac-Dent, Inc.
The OVER indication appears accompanied by repeated beeps.		1. The file tip has progressed beyond the apical foramen - move the file back until the OVER indication disappears.
The file position indicators are unstable with erratic performance. The OVER indication flashes even in the cervical third of the canal.	1. Is second electrode (lip hook) making good contact with mucosa? 2. Dirty (oxidation present) file clip. 3. Blood or other fluids over flowing the	1. Make sure the lip clip makes good contact with the oral mucosa. 2. Clean the file clip with Ethanol 70-80% vol. If the oxidation persists, replace the file clip. 3. If blood or other fluids are overflowing the access cavity, they may create a conductive path outside the canal and cause incorrect measurements (“OVER” indication, unstable readings, etc.). Check the rubber dam isolation,

	access cavity.	use caulking or flowable composite to repair rubber dam leaks. You may use tissue control substances to control gingival tissue bleeding. Clean and dry the pulp chamber and tooth crown thoroughly. 4. Large volume of vital inflamed pulp can cause a short circuit, giving an erratic “OVER” position. Remove 2/3 of the canal content (preflaring) and restart the reading.
Measurements results are too short or too long. Apparently poor accuracy.	1. Is the canal filled with blood, or chemical solutions? 2. Is the tooth surface covered with tooth debris, smear layer or chemical solutions? 3. Is the file touching the gingival tissue? 4. Vital inflamed pulp tissue present in large volume inside the canal. 5. Is the file touching metal prosthesis or filling? 6. Are proximal surfaces presenting caries lesions? 7. Are there external resorption or is	1. The canal length indicator may suddenly swing when it breaks the surface of fluids inside the canal, but it will return to normal as the file is advanced toward the apical third. 2. Clean the entire tooth surface. 3. File touching gingiva invagination to the access cavity might lead to incorrect readings or cause the canal length indicator suddenly to jump all the way to the “OVER” position. 3. If a large amount of vital inflamed pulp tissue is left inside the canal, particularly in wide canals such as upper incisors and canines, it may cause incorrect measurements. Preflare the canal. Proceed copious irrigation. Try again with a larger diameter file. 4. Touching a metal prosthesis of filling with the file may create a conductive path outside the canal and cause incorrect measurements (“OVER” indication, unstable readings, etc.). 6. Deep caries may create a conductive path outside the canal and cause incorrect measurements (“OVER” indication, unstable

	the tooth fractured? 8. Is there a lesion at the apex?	readings, etc.). 7. The canal length indicators may jump to “OVER” position when it reaches a resorption area or a fractured root tooth. 8. A chronic lesion can destroy the apical foramen through resorption and cause incorrect measurements.
Unstable electronic reading.	File diameter	Use a larger diameter file. Ensure that the final portion of the file (tip) is touching at least two thirds of dentin walls. Preflare the canal with larger files at the cervical and medium thirds before choose the suitable file for the electronic reading. Do not use thin files in large canals.
Motor only. Motor and apex locator combined.		
Different noise during rotation or reciprocation	Lubrication	Proceed with contra-angle lubrication
File stops during the instrumentation.	Speed and torque settings	Each file system has specific specs for speed and torque. Consult the files’ instructions to properly set up the speed and torque values.
File is reversing or stopping during instrumentation.	Torque settings. Apical pressure.	Ensure that the torque value for each file is correct. Low torque values will influence on the file’s performance. Be gentle during the instrumentation. If the file doesn’t progress apically, retrieve the file. Preflare. Use smaller diameters files for glidepath. Use hand files of little diameter to open space for the engine-driven files. Use an endodontic lubricant and ensure that the canal is filled with irrigant during instrumentation.

The handpiece doesn't start automatically. The handpiece doesn't slow the rotation, stop or reverse rotation direction near the foramen.	Built-in apex locator is not performing the electronic reading.	1. Poor connection (measuring wire, USB measuring cable or connectors). Check all connections and ensure **lip hook is contacting the oral mucosa**. 2. Ensure that the endodontic file is designed to be used concomitantly with electronic signal passage. 3. Fill the canal with an electrolytic solution, if required (i.e. Sodium Hypochlorite, Saline, etc.). 4. The endodontic file is not touching the internal canal walls. Replace the file using a larger diameter file. 5. If the behavior persists, measuring wire, or USB measuring cable may need to be replaced and/or the device should be sent in for service – contact Pac-Dent, Inc.
Erratic measurement. The motor is slowing down, stopping or reversing during the instrumentation.	Built-in apex locator is not performing the electronic reading correctly.	Review all troubleshooting regarding apex locator only mode. In some cases, the **motor and apex locator** mode will not perform a stable instrumentation due to adverse conditions of the case. Perform the electronic reading with the **apex locator only** mode, and use motor **only** mode.
Motor is not working	Motor doesn't turn on but the ON/OFF button is blue.	Ensure that the display is not in **apex locator only** mode. The motor will be disabled in this mode.

If the problem persists, contact Pac-Dent, Inc.

10 Cleaning, Disinfection and Sterilization

• For hygiene and sanitary safety purposes, the contra-angle, lip hook, file clip, protective silicone cover and touch probe must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use, as well as all subsequent uses.

10.1 General recommendations

a. Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, CDC, FDA and Health Canada approval) and in accordance with the IFU of the disinfecting solution manufacturer.

b. Do not place or immerse the contra-angle in a disinfectant solution or in an ultrasonic bath.

c. Do not use **bleach or chloride disinfectant** materials.

d. For your own safety, please wear personal protective equipment (gloves, glasses, mask).

e. The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterility.

f. The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.

g. To sterilize the endodontic files, refer to the manufacturer's instructions for use.

h. The contra-angle needs to be lubricated after cleaning and disinfection, **but before sterilization**.

10.2 Cleaning and disinfection steps for the motor handpiece, the AC adapter and the base

Before and after each use, all the objects that were in contact with infectious agents should be cleaned using tissue or soft cloth

impregnated with a disinfecting and detergent solution (bactericidal, fungicidal and aldehyde free solution) approved by VAH/DGHM-listing, CE marking, CDC, FDA and Health Canada.

• Do not sterilize the motor handpiece, the AC adapter and the base.

• Use of agents other than specified above may cause damage to the equipment and its accessories.

10.2.1 Pre-operation processing

Before each use, the handpiece, charger, and base must be cleaned and disinfected. The specific steps are as follows:

• The handpiece, charger, and base cannot be cleaned and disinfected with automatic equipment. Manual cleaning and disinfection are required.

Manual cleaning steps:

a. Take out the handpiece, charger, and base on the workbench.

b. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece, charger, base, etc. until the surface of the component is not stained.

c. Wipe the surface of the component with a dry soft nap-free cloth.

d. Repeat the above steps at least 3 times.

IMPORTANT:

• Use distilled water or deionized water for cleaning at room temperature.

Manual disinfection steps:

a. Soak the dry soft cloth with 75-80% alcohol.

b. Wipe all surfaces of headpiece, charger, base and other components with a wet soft cloth for at least 3 minutes.

c. Wipe the surface of the component with a dry soft nap-free cloth.

IMPORTANT:

- The cleaning and disinfection must be performed within 10min before use.
- The disinfectant used must be used immediately, no foaming is allowed.
- In addition to 75-80% alcohol, you can use non-residue disinfectants such as Oxytech (Germany), but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.
- After cleaning and disinfecting the handpiece, you must install a disposable barrier sleeve before use and repeat steps 1, 2 and 3 to clean the disposable barrier sleeve.
- Same to the base. Install a barrier film (4” per 6”) before use.

10.2.2 Post-operation processing

After each use, clean and disinfect handpiece, charger, and base within 30 minutes. The specific steps are as follows:

Tools: Nap-free soft cloth, tray

a. Remove the contra-angle from the handpiece, place it in a clean tray, and then remove the disposable isolation sleeve from the handpiece.

b. Soak the nap-free soft cloth with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece, charger, base, etc. until the surface of the component is not stained.

c. Wet the dry soft cloth with 75-80% alcohol, and then wipe all surfaces of the handpiece, charger, base and other components for 3 minutes.

d. Put the handpiece, charger, base, and other components back into the clean storage area.

IMPORTANT:

• The cleaning and disinfection must be performed within 10min before use.

• The disinfectant used must be used immediately, no foaming is allowed.

• In addition to 75-80% alcohol, you can use non-residue disinfectants such as Oxytech (Germany), but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

10.2.3 The cleaning, disinfection and sterilization of contra-angle, lip hook, file clip, protective silicone cover, and touch probe is as follows. Unless otherwise stated, they will be hereinafter referred to as “products”.

WARNING

• The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

• The products may not be exposed to temperature above 138℃.

10.2.3.1 Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However, with every renewed preparation for use, thermal and chemical stresses will result in aging of the products. The maximum number of sterilizations for products is 250 times.

a. Processing principles. It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

b. Also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

10.2.3.2 Post-operation treatment

The post-operation treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

a. Remove the products from the base, and rinse away the dirt on the surface of handpiece with pure water (or distilled water/deionized water).

b. Dry the products with a clean, soft cloth and place it in a clean tray.

IMPORTANT:

• The water used here must be pure water, distilled water or deionized water.

Preparation before cleaning:

Tools: tray, soft brush, clean and dry soft cloth.

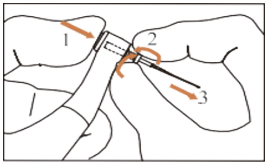
a. Remove the shanks/files.

b. Remove the file clip, isolation sleeve,contra-angle and connecting wire from the handpiece in sequence, and then put them into a clean tray.

c. Use a clean soft brush to carefully brush lip hook, file clip,

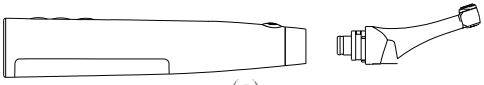
protective silicone cover, touch probe, head and back cover of the contra-angle until the dirt on surface is not visible. Then use a soft cloth to dry the products and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

Disassembling steps



(a)

(b)



(c)

a) Remove the file. Press the push-button (1), and pull out the shank/file (2, 3).

b) When removing the protective silicone cover, pull it straight out slowly.

c) Remove the contra-angle pulling it out on the same direction of the motor.

10.3 Cleaning

Cleaning should be performed no later than 24 hours after the operation. Cleaning can be divided into **automated cleaning** and **manual cleaning.** Automated cleaning is preferred if conditions permit.

Automated cleaning

a. The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

b. There should be a flushing connector connected to the inner cavity of the product.

c. The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

d. It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section (10.4) Disinfection.

IMPORTANT:

• The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. Ensure that the selected cleaning agent is compatible with the product.

• In washing stage, the water temperature should not exceed 45°C, otherwise the protein will solidify and it would be difficult to remove.

• After cleaning, the chemical residue should be less than 10mg / L.

10.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

Automated disinfection-Washer-disinfector

a. The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

b. Use high temperature disinfection function. The temperature does

not exceed 134°C, and the disinfection under the temperature cannot exceed 20 minutes.

c. The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

10.4.1 Cleaning and disinfecting steps by using Washer-disinfection

a. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to make contact with each other.

b. Use a suitable rinsing adapter, and connect the internal water lines to the rinsing connection of the washer-disinfector.

c. Start the program.

d. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

IMPORTANT:

• Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

• With this equipment, cleaning, disinfection and drying will be carried out together.

• Cleaning: (c1) the cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45°C, otherwise the **protein will solidify and it is difficult to remove.** (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is Neodisher MediZym (Dr. Weigert).

• Disinfection: (d1) direct use after disinfection: temperature ≥ 90°C,

time ≥ 5 min or A0 ≥ 3000;

• Sterilize it after disinfection and use: temperature ≥ 90°C, time ≥ 1 min or A0 ≥ 600.

• (d2) for the disinfection, temperature is 93°C, time is 2.5 min, and A0>3000.

• Only distilled or deionized water with a small number of microorganisms (<10 cfu/ml) can be used for all rinsing steps. For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia.

• After cleaning, the chemical residue should be less than 10mg / L.

• The air used for drying must be filtered by HEPA.

• Regularly repair and inspect the disinfector.

10.4.2 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

a. Spread a clean white paper (or white cloth) on the flat table, point the product against the white paper (or white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bars). At the time that no liquid is sprayed onto the white paper (or white cloth), the product drying is completed.

b. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80°C-120°C and the time should be 15-40 minutes.

IMPORTANT:

• Drying of product must be performed in a clean place.

• Drying temperature should not exceed 138°C.

• The equipment used should be inspected and maintained regularly.

10.1 Inspection

In this segment, we only check the appearance of the product.

a. Check the product. If there is still a visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

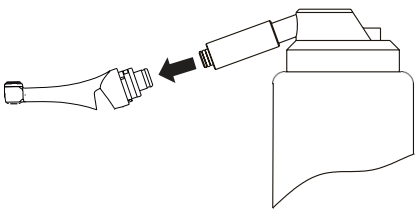
b. Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

c. Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

d. If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

10.2 Maintenance

Oil lubrication of sterilized and dried products. The nozzle of cleaning lubricant is aligned with the air intake hole at the end of the contra-angle to inject oil for 1-2 seconds.



10.3 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

WARNING

a. The package used conforms to ISO 11607.

b. It can withstand high temperature of 138°C and has sufficient steam permeability.

c. The packaging environment and related tools must be cleaned

regularly to ensure cleanliness and prevent the introduction of contaminants.

d. Avoid contact with parts of different metals when packaging.

10.4 Sterilization

• Use **only the following steam sterilization procedures** (fractional pre- vacuum procedure*) for sterilization.

a. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665.

b. The highest sterilization temperature is 138°C.

c. The sterilization time is at least 4 minutes at a temperature of 132° C / 134°C and a pressure of 2.0 - 2.3 bars.

d. Allow a maximum sterilization time of 20 minutes at 134°C.

e. Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

a. Only products that have been effectively cleaned and disinfected are allowed to be sterilized.

b. Before using the sterilizer for sterilization, read the instruction user manual provided by the equipment manufacturer and follow the instructions.

c. Do not use hot air sterilization and radiation sterilization as this may result in damage to the product.

d. Use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended.

If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

* *Fractional pre-vacuum procedure*. Steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

10.5 Storage

a. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10-93%, an atmospheric pressure of 70-106KPa, and a temperature of -20°C to +55°C.

b. After sterilization, the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

IMPORTANT:

- The storage environment should be clean and must be disinfected regularly.
- Product storage must be batched and marked and recorded.

10.6 Transportation

a. Prevent excessive shock and vibration during transportation, and handle with care.

b. It should not be mixed with dangerous goods during transportation.

c. Avoid exposure to sun or rain or snow during transportation.

11 Storage, transport and maintenance

11.1 Storage

a. This equipment should be stored in a room where the relative humidity is 10-93%, atmospheric pressure is 70-106kPa,

and the temperature is -20°C to +55°C.

b. Avoid storing in a too hot condition. High temperature will shorten the life of electronic components, damage battery, reshape or melt some plastic.

c. Avoid storing in a too cold condition. Otherwise, when the temperature of the equipment increases to a normal level, there will be dew that will possibly damage the PCB board.

11.2 Transport

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

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

c. Avoid solarization and getting it wet in rain and snow during transportation.

11.3 Maintenance

a. This device does not include accessories for repair usage. Repair should be carried out by an authorized person or authorized after service center.

b. Keep the equipment in a dry storage condition.

c. Do not throw, beat or shock the equipment.

d. Do not smear the equipment with pigments.

e. In order to ensure the normal operation of the equipment, it is recommended to maintain it once every month, including checking whether the equipment starts up and charging the battery. Calibration is recommended when using a new/other contra-angle or after an extended period of operation (at least once a month), as the running properties can change with usage, cleaning and sterilization.

f. Before and after each use, it is imperative to disinfect your device using products recommended by the manufacturer.

g. Before servicing, it is imperative to use accessories that have been cleaned and disinfected.

11.3 Battery replacement

a. When the battery of the base or motor handpiece cannot be charged (or the base or the motor handpiece cannot be switched on) and the battery needs to be replaced, it must be sent back to Pac-Dent, Inc.

12 Environmental protection

Dispose according to the local laws.

13 After service

From the date this equipment has been sold, based on the warranty card, Pac-Dent, Inc. will repair this equipment free of charge if there are quality problems. Please refer to the warranty card for the warranty period.

14 Symbol instruction

ACE	Trademark		Do not use near patients with pacemaker
	Date of manufacture	CE 0197	CE market product
	Type B applied part		Use indoor only
	Manufacturer for	134℃	Sterilizable up to the temperature
	Class II equipment		Keep dry
	Special disposal of waste electrical and electronic equipment		Follow instructions for use
WARNING	Warning and precautions	106kPa 70kPa	Atmospheric pressure for storage
	Important information or explanations intended for users. Notes	+55℃ -20℃	Humidity limitation for storage
DANGER	Maximum level of danger	CAUTION	A hazardous situation that can cause material damage
FDA	Food and Drug Administration (US) marked product		

15 Statement

15.1 The manufacturer, its representatives and its dealers shall have no liability or responsibility to customers or any other person or entity with respect to any liability, loss or damage caused or alleged to be caused directly or indirectly by equipment sold or furnished by us, including, but not limited to, any interruption of service, loss of business or anticipatory profits, or consequential damages resulting from the use or operation of the equipment.

15.2 The manufacturer reserves the right to implement changes and modifications of the product at any time, to revise this publication and to make changes in the contents hereof without obligation to notify any person of such changes, modifications or revisions. All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The industrial design, inner structure, etc., have claimed for several patents.

16 EMC-Declaration of conformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The model iRoot Pro Plus, is intended for use in the electromagnetic environment specified below. The customer or the user of the model iRoot Pro Plus should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The iRoot Pro Plus uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model iRoot Pro Plus is suitable for used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Technical Description Concerning Electromagnetic Immunity
Table 2: Guidance & Declaration- electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The model iRoot Pro Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the model iRoot Pro Plus should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV 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	±2kV for power supply lines ±1kV for Input/ output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	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 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model iRoot Pro Plus requires continued operation during power mains interruptions, it is recommended that the model iRoot Pro Plus be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/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.			

Table 3; Guidance & Declaration – electromagnetic immunity concerning Conducted RF & Radiated RF			
Guidance & Declaration - Electromagnetic immunity			
The model iRoot Pro Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the models iRoot Pro Plus should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models iRoot Pro Plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d=1.2×P1/2 d=2×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.7 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 I At 80 MHz end 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 model iRoot Pro Plus is used exceeds the applicable RF compliance level above, the model iRoot Pro Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model iRoot Pro Plus.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the model iRoot Pro Plus

Recommended separation distances between portable and mobile RF communications equipment and the model iRoot Pro Plus

The model iRoot Pro Plus is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model iRoot Pro Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model iRoot Pro Plus as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,7GHz d=2.3×P1/2
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) accordable to the transmitter manufacturer.

NOTE I 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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www.pac-dent.com

Pac-Dent
Passion for Excellence

Manufactured for:

Pac-Dent, Inc.

670 Endeavor Circle, Brea, CA 92821
909.839.0888
info@pac-dent.com
www.pac-dent.com

casr