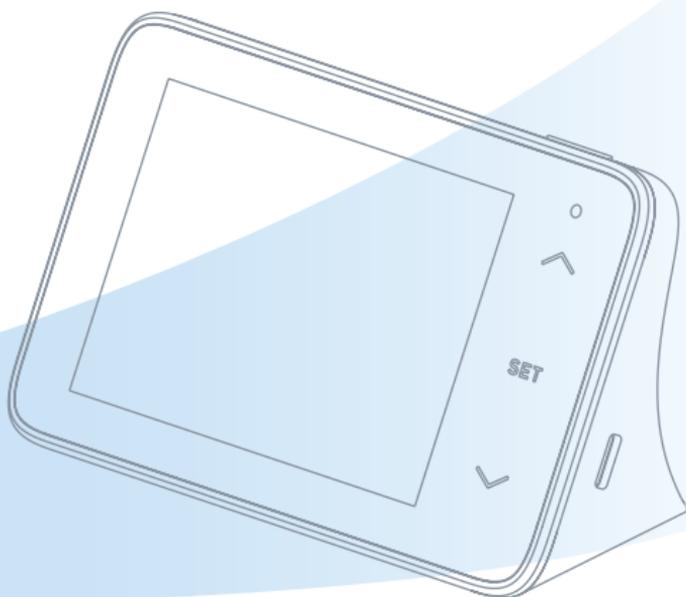


COXO[®]

Root Apex Locators

User Manual

C-Root I(V)



CE 0197

Congratulations on your purchase of the C-Root I(V) Root Apex Locators.

Please do not hesitate to contact the manufacturer for help with any doubt or problem related to this manual. Kindly keep this manual for further reference.

Manufacturer reserves the right to change the information and data contained in these user manuals at any time and without prior notice. The service life of this product is 15 years.

The C-Root I(V) Root Apex Locators has been tested according to the IEC 60601-1:2005+A1:2012+A2:2020 and IEC 60601-1-2:2014+A1:2020 standards and ensures the normal operation of its essential performance. The display interface is normal, and the measurement accuracy is $\pm 0.5\text{mm}$.

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01 Symbols

	General warning		Note
	Serial number		Refer to instruction manual/booklet
	Manufacturer		Class II equipment
	Do not dispose of the product into the ordinary municipal waste or garbage system		Type B applied part
	Caution		Catalogue number
	CE Marking		Keep dry
	Fragile, handle with care		This way up
	Authorized representative in the European Community/European Union		Indoor use only
	Direct current		Alternating current
	Date of Manufacture		Medical device

02 Indications for Use

The Root Apex Locator is used to detect the apex of root canal. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

03 Contraindications

- Use of the device is contraindicated on patients or by operators having implanted electronic devices such as pacemaker, etc;
- It is forbidden to use this device for patients with broken, missing, or perforated teeth and severe apical fracture.

04 Warnings

In this chapter a description of serious adverse reactions and potential safety hazards for the product or the user/patient is included. Please read the following warnings before use.



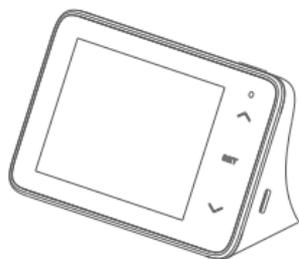
WARNINGS

- The device may be used only by qualified dentists acting in accordance with the national regulations
- The device may be used only in suitable locations and not outdoor; Make sure that the cords do not hinder the free passage of people.
- Before use, please check whether the cable of the device (including test wire, file clip and adapter cable) is damaged. If damaged, please stop using it immediately, otherwise electric shock may be caused;
- Do not expose the device to direct or indirect sources of heat. Store and use the device in a safe environment.

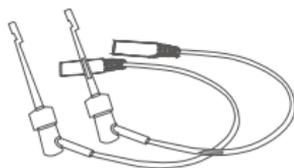
- Do not use the device in the presence of inflammable anaesthetic mixtures.
- Do not expose the device to water, otherwise it may cause damage to electrical parts and affect the normal use of the device.
- Use only original accessories.
- The external charger to which the device is connected should comply with standards in force.
- Do not use the device if it appears to be damaged or defective.
- Do not carry out repairs or modifications to the device without prior authorization by the manufacturer. If any fault occurs, contact your local supplier rather than have it repaired by an unauthorized person.
- Do not connect or use the device with any other apparatus or system not approved by the manufacturer, as this may cause damage to the device.
- Do not use the device as an integral component of any other apparatus or system. The manufacturer will not be responsible for accidents, equipment damage, bodily injury or any other trouble which results from ignoring this prohibition.
- Please ensure that any potential electromagnetic interference does not compromise the safety or functionality of the device.
- In case of any doubt, contact your local supplier or the After Sales Service of manufacturer.
- Main unit and adapter shall not be serviced or maintenance during normal treatment.
- Not to position the device to make it difficult to operate the disconnection device.

05 Step-by-Step Instructions

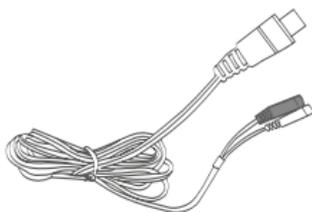
5.1 Standard components



Main Unit



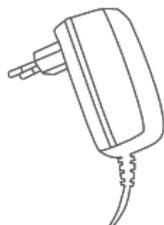
File clip



Test Wire



Lip Hook



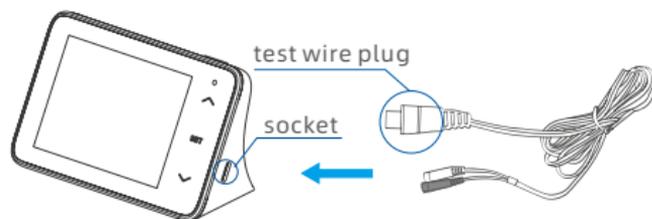
Adapter

Components	Function
Main Unit	Display of information (such as the position of root file from the root tip, battery power, etc.), setting of parameters (such as sound volume, brightness level, reference position of root tip, etc.)
File Clip	It is used to clamp root canal file for root canal measurement.
Test Wire	Connect the lip hook and file clip.
Lip Hook	As a measuring electrode, it is hung at the mouth corner of the patient to form a measuring circuit.
Adapter	Charging the main unit.

5.2 Installation

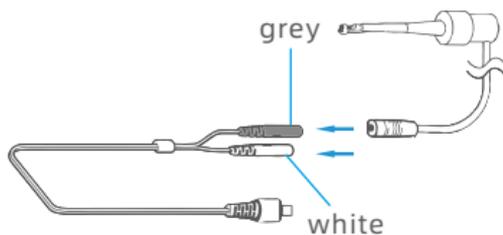
5.2.1 Connect Test Wire

Connect the test wire to the main unit. Line up the test wire plug with the socket on the side of the main unit and push it all the way in.



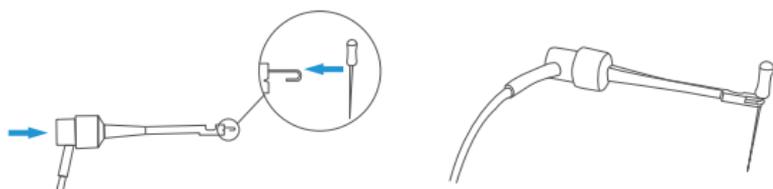
5.2.2 Connect File Clip and Lip Hook

Connect the file clip and lip hook to the test wire.



5.2.3 Install File

Hold down the push button on the file clip and insert the file. Release the button to lock the file into the file clip.



06 Operation

6.1 Battery Charging



WARNING

- Prior to first use, the battery must be charged for 5 hours!
- Use the original charger only.
- If not used for a long period of time, it is recommended that it be charged at least once a month.
- The device cannot be used while charging.
- Charging in a humid environment is strictly prohibited.
- For removing the adapter, follow the sequence below:
before removing the adapter from the power outlet,
disconnect the adapter from the device.

To charge the battery, follow the next steps:

- Remove the test wire from main unit;
- Connect the adapter to the device socket and plug it into the power outlet;

This device is powered by a rechargeable lithium-ion battery. Battery status during the operation is shown on screen:



NOTE

- The bars represent the remaining battery capacity.
- When only one bar remains, recharge the battery promptly.

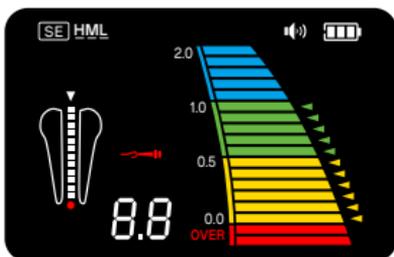
While charging, the battery indicator light flashes orange. When fully charged, the light remains solid green.

6.2 Turn Power On/Off

- Long press the main unit to turn on/off;
- The device automatically turns off after 3 minutes when not in use.

6.3 Description of User Interface

The main screen shows the following icons and symbols:



	File clip and lip hook connect icon		Sensitivity icon
	Volume icon		Full canal image
	Apical zoom image		Number of Apical distance
	Apical location arrow		



NOTE

- Like all Root Apex Locators, the number shown in the apical zoom image does not indicate the true length.
- The length measured on the apical foramen subtract 0.5-1.0mm to get the working length. Due to the different shapes of teeth and root canals, clinical judgment should be applied.

6.4 Use

6.4.1 Sound Level Selection

Press the   key in standby to select the volume.



off



1 gear



2 gears



3 gears

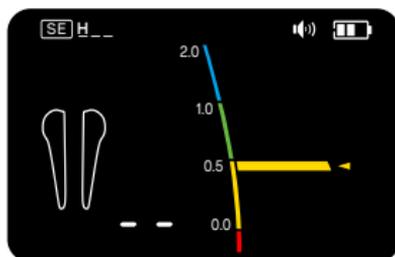


NOTE

When device is turned off, the selected sound volume is stored in the device memory and is activated automatically when the device is switched on.

6.4.2 Set the Apex location position

- Press the **SET** key in standby, the apical location line and apical location arrow flash on the screen.
- Press the **▲** **▼** key to preset position adjustment for apex positioning.
- Apical location position can be set between the first green bar and the last yellow bar.



NOTE

When device is turned off, the selected apex location position is stored in the device memory and is activated automatically when the device is switched on.

6.4.3 Sensitivity Level Selection

- Press the **SET** key twice consecutively in standby, the **H__** flash on the screen.

- Press the   key to select root measurement sensitivity.



High



Medium



Low



NOTE

When device is turned off, the selected sensitivity level is stored in the device memory and is activated automatically when the device is switched on.



NOTE

After Press the  key, the device will automatically return to standby mode if there is no operation within 3.5 seconds.

6.5 Measuring

6.5.1 Connection status of Test Wire

Insert the test wire into the socket on the right side of the device to start measuring the length of the root canal of the tooth.

Wire connection test

- Connect the file clip contact to the lip hook.
-  (twinkle) indicates the lip hook and file clip is properly connected.



NOTE

In connection test status, if the connectors symbol does not twinkle, it indicates faulty connection:

- Check proper connection of the cables.
- Clean the file clip contact.

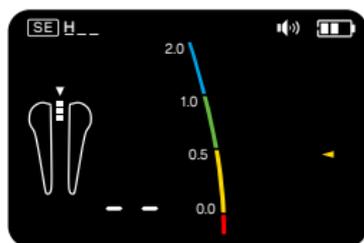
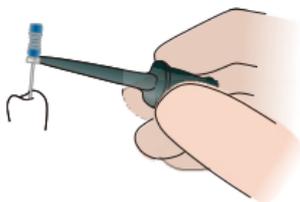


WARNING

We do not recommend continuing the measurement if the faulty connection appears.

6.5.2 Starting Length Determination

- Connect the file clip and the lip hook to the test wire;
- Place the lip hook on the patient's lip on the opposite side of the tooth to be treated;
- Clamp the file to the file clip (Attach the file on the metal part - directly underneath the plastic handle), insert the file into the root canal;
- The file movement in the canal is shown on the full canal image.





NOTE

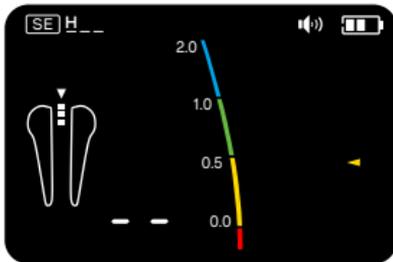
In no progress of the file indicate faulty connection:

- Check proper connection of the cables;
- Clean the file clip contact;
- Irrigate the canal if necessary, and start again.

6.5.3 Apex Location

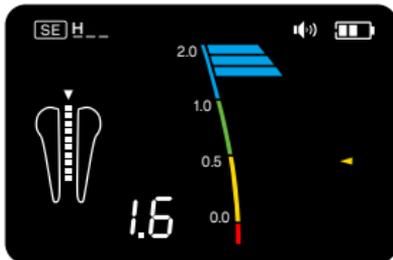
a. Coronal and Medial Section

- Slowly insert the measuring file into the canal;
- File movement along the coronal and medial section towards the apical region is represented on the full canal image by the white block continuously moving down.



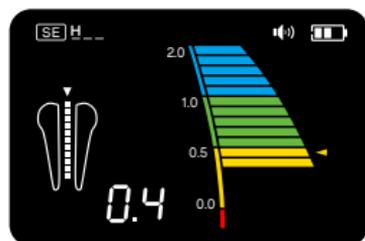
b. Warning Zone

- Zoomed view of the file progression is shown on the enlarged image of the apical part of the canal.

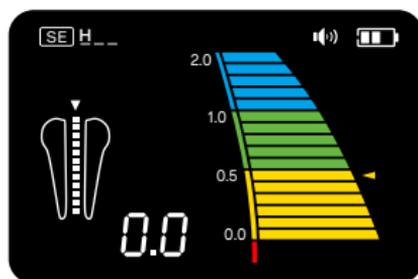


c. Apical Section

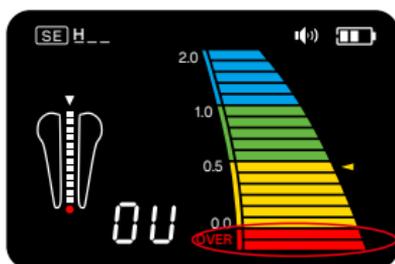
- In the apical section the apical location line indicates the exact position and changes accordingly from blue to green and then to yellow.



- File movement in the apical zoom is accompanied by audio signals, which serve as additional indication of the file tip position. The interval between the beeps becomes shorter the more the file approaches the apex;
- When the file tip reaches the apical foramen, the apical location line is marked the 0.0 position and a constant sound is emitted.



- Once the file tip has passed the apical foramen, the apical location line turns red and a constant sound is emitted.



NOTE



The apical location line show the file tip position inside the canal:

- Blue section: warning zone very close to the pical region;
- Green to yellow section: apical section;
- Red section: apical foramen is passed.

6.5.4 Tips for Successful Length Determination

Please review the below checklist to better understand any implausible measuring results and to take appropriate actions:

Too fast movement or even jumping to the apex is indicated for the following reasons:

Symptom	Solution
Excess liquid in the pulp chamber or root canal (rinsing solution, blood or saliva), creating wrong conductive path and incorrect measurements.	Dry the access cavity with a cotton pellet/ air-blower. Wait until excess bleeding can be stopped.
Gingival proliferation can lead to direct contact with the measuring file causing a short circuit and incorrect measurements.	Isolate the access cavity by: <ul style="list-style-type: none">• adequate preparation filling;• placing a rubber dam;• electrocauterizing.
The measuring file contacting metallic restorations(crown, parapulpal post, amalgam filling) may cause a short circuit and incorrect measurements.	Carefully enlarge the access cavity and isolate with flow composite. Widen carefully the opening at the top of the crown.

Too lazy or extremely delayed movement is indicated for the following reasons:

Symptom	Solution
Obliterated root canal impeding the conductive path and preventing normal device functioning.	<ul style="list-style-type: none"> • Check the comparative x-ray for hints; • Catheterize with ISO 06/ 08 file till the working length.
Retreatment: Blockage by old canal filling material residue, impeding the conductive path and preventing normal device functioning.	Take an x-ray to re-check and try to completely remove the old canal filling material prior to measuring.
Blockage by remnants of a medicated substance (e.g. calcium hydroxide) impeding the conductive path and preventing normal device functioning.	Completely remove the remnants prior to measuring.
Extremely dry root canal impeding the conductive path and preventing normal device functioning.	Rinse root canal with irrigating solution such as NaCl or NaOCl and dry the access cavity with a cotton pellet/air-blower.



WARNING

In some cases precise determination of file position cannot be obtained.

Symptom	Solution
Special condition symptom: Exceptionally large apical foramen due to lesion or incomplete formation.	May lead to shorter measurement than the actual length.
Root fracture or perforation.	May lead to incorrect measurements.

07 Cleaning, Disinfection and Sterilization

Device:	<ul style="list-style-type: none"> • Main Unit, Adapter, File Clip, Lip Hook and Test wire; • The procedure for cleaning, disinfection and sterilization applies only to the accessories File Clip and Lip Hook.
Advice:	<ul style="list-style-type: none"> • Reprocessing procedures have only limited implications to this dental instrument. The limitation numbers of reprocessing procedures are 250 times. The device should no longer be reused in case of signs of material degradation; • In case of damage the device should be reprocessed before sending back to the manufacturer for repair.
Warning	<p>a. The file clip and lip hook must be cleaned and sterilized prior to use and after each patient use.</p> <p>b. The main unit, adapter and test wire must be decontaminated prior to use and after each patient use.</p>
Reprocessing Instructions	
Preparation at the Point of Use: (For EU)	<ul style="list-style-type: none"> • Disconnect the Test Wire from the Main Unit, the File Clip and Lip Hook from the Test Wire. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of there processing process; • Store the instruments in a humid surrounding.
Pretreatment of Main Unit, Test Wire and Adapter: (For US)	Soak the aseptic soft cloth in purified water and wipe the main unit and test wire thoroughly for 10 times.

Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation Decontamination:	<ul style="list-style-type: none"> • The devices must be reprocessed in a disassembled state; • Only File Clip and Lip Hook can be cleaned and disinfected with automated methods and sterilized with steam sterilization process; • Do not sterilize the Main Unit, Test Wire, and Adapter; • The Main Unit, Test Wire and Adapter can not be cleaned and disinfected in a washer/disinfector. For these parts, only a general wipe decontamination is possible!
Decontamination of other parts than File Clip and Lip Hook:	<ul style="list-style-type: none"> • After operation, take out the Main Unit, Test wire and Adapter on the workbench; • Soak a soft cloth completely with distilled water or deionized water, and wipe all the surfaces of these components, until the surface of the components is visually clean; • For decontamination, soak a dry soft cloth with 75% alcohol or other disinfectants which are approved for its efficacy by VAH/ DGHM-listing, CE marking, FDA and Health Canada Approval; • Wipe all surfaces of Main Unit, Test wire and Adapter and other components with the wet soft cloth for about 3 minutes; • Please follow the instructions of manufacturer of disinfectants. Wipe the surface of the component with a dry soft lint-free cloth.

<p>Pre-Cleaning of File clip and Lip hook: (For EU)</p>	<ul style="list-style-type: none"> • Following instructions are only relevant for File clip and Lip hook! • Not use automated cleaning, disinfection and sterilisation for other parts than File clip and Lip hook in this system! <p>Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds;</p> <ul style="list-style-type: none"> • Clean the surfaces with a soft bristle brush.
<p>Automated Cleaning: (For EU)</p>	<p>Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.</p> <p>Automated Cleaning:</p> <p>Use a washer-disinfector meeting the requirements of the ISO 15883 series.</p> <p>Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program;</p> <ul style="list-style-type: none"> • 4 min pre-washing with cold water (<40°C); • Emptying • 5 min washing with a mild alkaline cleaner at 55°C • Emptying • 3 min neutralising with warm water (>40°C); • Emptying • 5 min intermediate rinsing with warm water (>40°C); • Emptying

	<p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).</p> <p>Note: according to EN ISO 17664, no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.</p>
Pre-cleaning preparation of File Clip and Lip Hook: (For US)	<ul style="list-style-type: none"> • Flush the lip hook and file clip with running tap water (<40°C) for 2 minutes until all visible residue is removed; • NOTE: In order to better clean the inside of the file clip, press the file clip continuously for at least 5 times during the cleaning process.
Cleaning of File Clip and Lip Hook: (For US)	<p>Immerse a soft cloth in the cleaning reagent and thoroughly wipe the surface of lip hook and file clip for 5 times. After each wipe, replace with a clean soft cloth. If there are still visible contaminants, wipe repeatedly until there are no visible contaminants.</p>
Brushing of File Clip and Lip Hook: (For US)	<p>Under running tap water (< 40°C), use a soft brush with multiple enzyme cleaning agents to wash the lip hook and file clip for 3 minutes.</p>
Soaking of File Clip and Lip Hook: (For US)	<p>Put the lip hook and file clip into the cleaning agent and soak them for 5 minutes to decompose the contaminants.</p>
Flushing of File Clip and Lip Hook: (For US)	<p>Flush the lip hook and file clip with running tap water (<40°C) for 2 minutes to remove the residue of cleaning agents.</p>

Automated Disinfection: (For EU)	<ul style="list-style-type: none"> Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883); A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.
Disinfection of Main Unit and Test Wire: (For US)	Thoroughly soak the aseptic soft cloth in 75% ethyl alcohol, clean the main unit and test wire for 10 times, and replace the aseptic cloth after each clean.
Disinfection of File Clip and Lip Hook: (For US)	Soak the File Clip and Lip Hook in 75% medical alcohol for not less than 10min.
Automated Drying: (For EU)	<p>Automated Drying:</p> <p>Drying of outside of instrument through drying cycle of washer/ disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.</p>
Manual Drying: (For US)	Use a dry, absorbent cloth to wipe away any traces of water that remain on the surface of the lip hook and file clip.
Functional Testing, Maintenance:	<ul style="list-style-type: none"> Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean; Defective accessories should be immediately discarded. The defects include: plastic deformation and corrosion; Maintenance is not required. Instruments oil must not be used.

<p>Packaging of File Clip and Lip Hook:</p>	<ul style="list-style-type: none"> • Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to ISO 11607; • (For US) Please the sterilization bags which are approved for its efficacy by FDA; • Recommended sterilization bag: SIGMA Sterilization Pouch and Roll. • 510(k) Number: K202462
<p>Sterilization of File Clip and Lip Hook: (For EU)</p>	<ul style="list-style-type: none"> • Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements; • Minimum requirements: 3 min at 134°C (in EU: 5 min at 134°C) • Maximum sterilization temperature: 137°C
<p>Sterilization of File Clip and Lip Hook: (For US)</p>	<p>Gravity-Displacement steam Sterilization Cycles Sterilization temperature: 135°C Holding time: 10 min (full cycle) Drying time: 30 min</p>
<p>Storage:</p>	<p>Pack the instruments in an appropriate packaging material after sterilization. The packaging material and system refer to ISO 11607. Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures refer to label and instructions for use.</p>
<p>Reprocessing validation study information</p>	<p>The above-mentioned reprocessing process (cleaning, disinfection sterilization) has been successfully validated.</p>
<p>Additional Instructions: None</p>	
<p>It is the duty of the user to ensure that the reprocessing processes including resources materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.</p>	

08 Disposal of the device



In accordance with the principles, standards and requirement of the country (region) in which you are located, dispose of the old electrical equipment. Ensure that pollution is not produced in the process of waste disposal.

09 Operating, Transport and Storage Environment

Operation Environment	
Temperature	+5°C - 40°C
Humidity	20% - 80%
Atmospheric Pressure	80kPa - 106kPa
ALT	≤ 2000m
Transport and Storage Environment	
Temperature	-10°C - +55°C
Humidity	≤ 93%
Atmospheric Pressure	50kPa - 106kPa

10 Warranty

- The main unit is guaranteed for 24 months from the date of purchase. The accessories are guaranteed for 6 months from the date of purchase;
- The guarantee is valid for normal usage conditions. Any modification or accidental damage will render the guarantee void;
- Contact the manufacturer for technical instructions, product and component repairs.



NOTE

The instrument requires no routine maintenance, users are not permitted to perform repairs. It can only be serviced and repaired by factory-trained service personnel.

11 Technical Data

Adapter	Input: AC 100-240V ~ 50/60 Hz Output: DC 5V  1.5A
Input Power	20VA
Li-ion Battery	DC 3.7V 1200mAh
Protection Against Electric Shock	Type B
Classification of Protection against Shock	Class II (adapter)
Level of safety in Presence of Inflammable Anaesthetic Mixtures or oxygen	Non-AP / APG type
Operating Mode	Continuous
Degree of Protection	IPX0
Measurement Accuracy	±0.5mm
Dimension	Length: 114mm, Width: 57mm, Height: 62 mm
Weight	136 g
Display Type	LCD colour display
Display / Active Area	74 mm x 51mm
Applied part	Lip hook: plastic PI with stainless steel File clip: stainless steel
Overvoltage category	Class II
Pollution degree	Degree 2
<p>This product is suitable for the following standard files:</p> <ul style="list-style-type: none"> • File of Root Apex Locators: ISO 3630-1 Type 1 Nominal size: 20~140; • Material of the file: Nickel titanium (NiTi); • Note: This product does not provide files. 	

12 EMC

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this device can be affected by portable and mobile RF communications equipment.



WARNING

- Do not use a mobile phone or other unit that emit electromagnetic fields near this device. This may result in incorrect operation of the device;
- This device has been thoroughly tested and inspected to assure proper performance and operation!
- This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- This equipment is not use with hf surgical equipment.

Serial number	Name	Cable length (m)	Shielded wire	Remarks
1	Adapter cable	1.5	No	/
2	Test wire	1.4	Yes	/



Caution

According to the FDA Guidance Electromagnetic Compatibility (EMC) of Medical Devices, the risks associated with exposure to specific common EM emitters such as radio frequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), wireless power transfer (WPT), Cellular 5G, and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment, that are not adequately addressed by IEC 60601-1-2.

Therefore, please stay away from the equipment listed above during the use of our products.

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Root Apex Locators use RF energy only for its internal function. Therefore, its RF emissions is very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Root Apex Locators is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration - electromagnetic immunity

The Root Apex Locators is intended for use in the electromagnetic environment specified below. The customer or the user of the Root Apex Locators 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	$\pm 8\text{kV}$ contact $\pm 2\text{kV}$, $\pm 4\text{kV}$, $\pm 8\text{kV}$, $\pm 15\text{kV}$ air	$\pm 8\text{kV}$ contact $\pm 2\text{kV}$, $\pm 4\text{kV}$, $\pm 8\text{kV}$, $\pm 15\text{kV}$ air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	$\pm 2\text{kV}$ for power supply lines	$\pm 2\text{kV}$ for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ line-to-line	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ line-to-line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($> 95\%$ dip in U_T .) for 0.5 cycle $< 5\% U_T$ ($> 95\%$ dip in U_T .) for 1 cycle $70\% U_T$ (30% dip in U_T .) for 25/30 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T .) for 5/6 sec	$< 5\% U_T$ ($> 95\%$ dip in U_T .) for 0.5 cycle $< 5\% U_T$ ($> 95\%$ dip in U_T .) for 1 cycle $70\% U_T$ (30% dip in U_T .) for 25/30 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T .) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Root Apex Locators require continued operation during power mains interruptions, it is recommended that the Root Apex Locators 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: U_T is the a.c. mains voltage prior to application of the test level.

Guidance & Declaration - Electromagnetic immunity

The Root Apex Locators is intended for use in the electromagnetic environment specified below. The customer or the user of the Root Apex Locators should assure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz 6Vrms in ISM bands and amateur radio bands	3Vrms 150kHz to 80MHz 6Vrms in ISM bands and amateur radio bands	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Root Apex Locators, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2: 2014+A1: 2020)	10V/m 80MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2: 2014+A1: 2020)	

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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		
	150kHz to 80MHz $d=1.2 \times \sqrt{P}$	80 MHz to 800MHz $d=1.2 \times \sqrt{P}$	800 MHz to 2,5GHz $d=2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: 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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EU REP

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