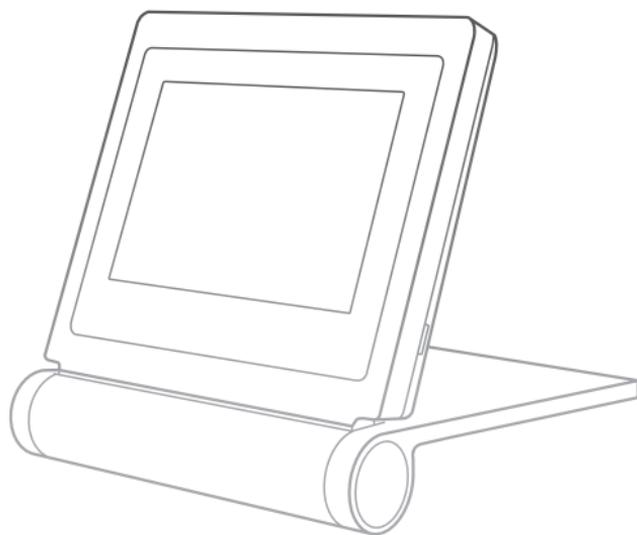


USER MANUAL



C-Root *i*
ROOT APEX LOCATOR

Congratulations on your purchase of the C-ROOT I root apex locator.

Please do not hesitate to contact 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 anytime and without prior notice.

The service life of this product is 10 years.

In the IEC 60601-1:2005+A1:2012 and IEC 60601-1-2:2014 standard tests, the C-ROOT I root apex locator can ensure the normal operation of the essential performance of the device. The display interface is normal, and the measurement accuracy is $\pm 0.5\text{mm}$.

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1.1 Symbols used in these User Manual

 WARNING	If the instructions are not being followed properly, operation may result in hazards for the product or the user/patient.	 NOTE	Additional information, explanation on operation and performance.
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1.2 Symbols used on Packaging, Device and Parts

 SN	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
	Direct current		Keep dry
	Fragile, handle with care		This way up
	Alternating current		Indoor use only

	Date of Manufacture	MD	Medical device
	Non-sterile		
Rx Only	Caution! Federal law restricts this device to sale by or on the order of a dentist, physician, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.		

2 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.

3 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 or perforated teeth, missing teeth and severe apical fracture.

4 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;
- Do not use a battery if it is leaking, deformed, discolored or if its label is peeled off. It might overheat;
- 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 manufacturer. If any fault occurs, contact your local supplier rather than have it repaired by an unauthorized person;
- Do not connect the device to or use it in combination with any other apparatus or system. Otherwise, the device will be damaged;
- 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 make sure that any possible electromagnetic interference does not pose any additional risk;
- In case of any doubt, contact your local supplier or the After Sales Service of manufacturer;
- Before each use, please use the tester to check the function of the device.

5 Step-by-Step Instructions

5.1 Overview



WARNING

- Do not install the device in damp places or in places where it will come into permanent contact with liquids of any kind;
- As shown is not the correct use of the instrument form.

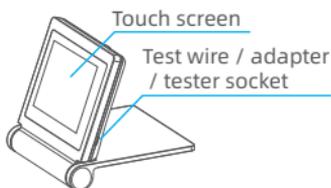


Incorrect placement of device

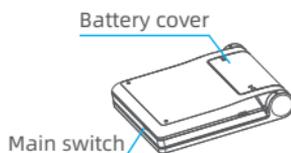


Correct placement of device

Front view



Rear view



5.2 Standard Components



Main Unit



File Clip



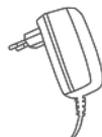
Test Wire



Lip Hook



Tester



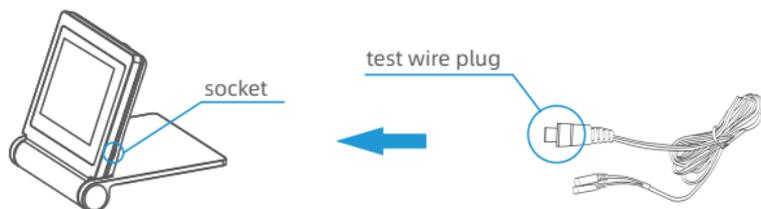
Adapter

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.
Tester	It is enables to test automatically the basic function of the device.
Adapter	Charging the main unit.

5.3 Installation

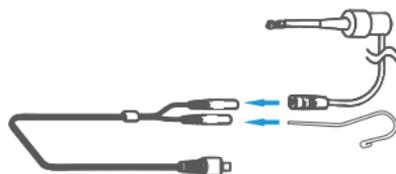
5.3.1 Connect Test Wire

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.



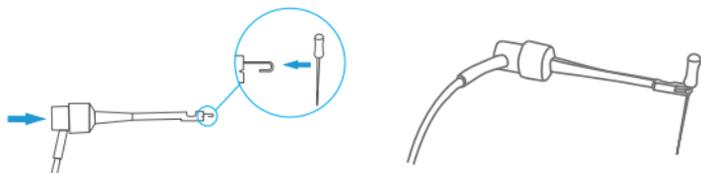
5.3.2 Connect File Clip and Lip Hook

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



5.3.3 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.



6

Operation

6.1 Battery Charging



WARNING

- Prior to first use, the battery must be charged for 5 hours!
- Use the original charger only.

To charge the battery, follow the next steps:

- Make sure that all the measurement cable is not connected to the patient;
- Remove the all the measurement cable from main unit;
- Connect the adapter to the device socket and plug it into the power outlet;
- If the battery is fully discharged, e.g. when it has not been used for a long period of time, it must be recharged for 5 hours;
- If the battery is low, 4 hours recharging is sufficient.



WARNING

For removing the adapter, follow the sequence below:

- Before removing the adapter from the power outlet, disconnect the adapter from the device;
- The device cannot be used while charging.

Battery status during the operation is shown on charging screen:

-  Indicates battery level is higher than 40%;
-  Indicates battery level is between 30% and 40%;
-  Indicates battery level is between 20% and 30%;
-  Indicates battery level is between 10% and 20%;
-  Indicates battery level is lower than 10%.



NOTE

- The device with  symbol is still functional and may be used for several treatments before the device shut down;
- The device with  symbol will flash and automatic shut down.

Battery status during charging is shown on charging screen:



6.2 Battery Replacement

The battery cover is located at the rear of device and is secured by screws.

- Release the screws and remove the battery cover;
- Remove the battery from battery compartment and disconnect the battery cable plug from the battery jack of device;
- Insert the cable plug of the new battery into the battery jack;
- Insert the battery into the battery compartment;
- Close the battery compartment and secure the cover with the screws.



WARNING

- Before replacing the battery, disconnect the charger from the device!
- The used battery must be disposed of in accordance with the local regulations.

6.3 Turn Power On/Off

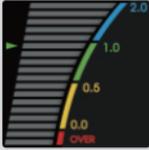
- Press the main switch to turn power on;
- The device automatically turns off after 5 minute when not in use.

6.4 Description of User Interface

The device has a tilt adjustable front panel with a large graphic TFT touch screen.

The main screen shows the following icons and symbols:



	Test wire Icon		Apical location arrow
	Volume icon		Brightness icon
	Up-down button of Apical location		Apical zoom image

6.5 Sound Level Selection

Click on the screen  to select volume; 4 gears volume from 0 to maximum.

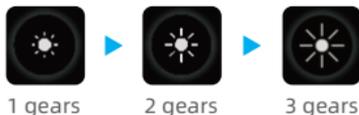


NOTE

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.

6.6 Brightness Level Selection

Click on the screen  to select brightness, 3 gears of brightness.



NOTE

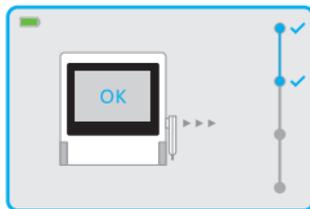
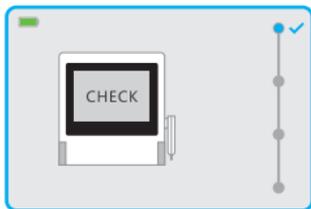
When device is turned off, the selected brightness level is stored in the device memory and is activated automatically when the device is switched on.

6.7 CHECK Mode

Measuring Function Check

Use the tester to check whether the measuring circuit of the device is normal. Follow the next steps:

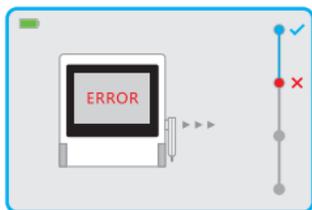
- Disconnect the test wire/adaptor from the device;
- Measuring Function Check will start automatically if the tester inserted in the Main Unit and the results will be shown on the screen;
- Either OK to indicate that the device fully operates or ERROR to indicate any malfunction.





WARNING

ERROR message indicates that the device is not functioning properly.



Please do not continue to use. For assistance call your local distributor or manufacturer directly.

Wire Function Check

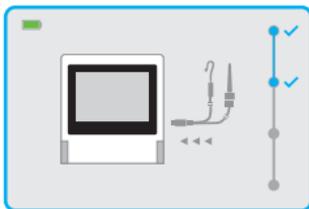


NOTE

If the device functional CHECK is OK, then you have to proceed to the cable functional CHECK.

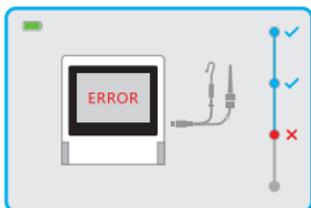
Use the tester to check whether the functions of the Test Wire and File Clip are normal. Follow the next steps:

- Connect the test wire to the device.



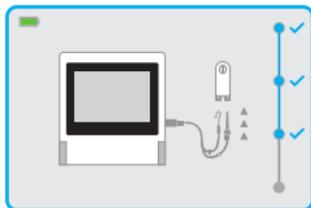
WARNING

ERROR message indicates that the test wire is not functioning properly or the contact area is dirty.

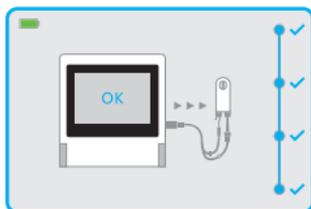


- Please do not continue to use. For assistance call your local distributor or manufacturer directly.
- CHECK Mode will exit after 3 seconds automatically.

- Connect the lip hook and file clip to the test wire;
- Connect the lip hook and file clip to the contact strips on the tester as shown on the screen.

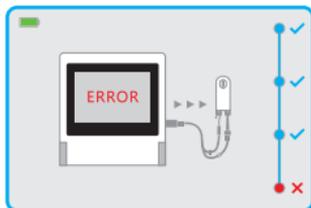


- Wire Function Check will start automatically and the results will be shown on the screen;
- Either OK to indicate that the test wire and file clip are normal or ERROR to indicate that the test wire or file clip has a malfunction.



WARNING

ERROR message indicates that the accessories are not functioning properly or the contact area is dirty.



- Please do not continue to use. For assistance call your local distributor or manufacturer directly.
- CHECK Mode will exit after 3 seconds automatically.

6.8 Measuring

6.8.1 Connection Status of Test Wire

-  (twinkle) Test wire is disconnect Insert the Test Wire into the socket on the right side of the instrument, the test wire flickers away, and the length can be measured, see chapter 6.8.3.

Wire connection test

From time to time it is recommended to check the cables.

- Connect the file clip contact to the lip clip.
-  (twinkle) The lip hook and file clip symbols is proper connected.



NOTE

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

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



WARNING

We do not recommend to continue the measurement if the faulty connection appears. Go to the CHECK Mode to check the performance of the device.

6.8.2 Set the Apex location position

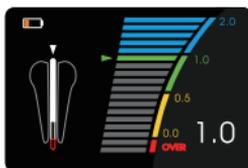
- 1) Press the  key on the home screen can preset position adjustment for apex positioning.



- 2) Can set the position of the apical positioning arrow between the first green dot and the last yellow dot; When adjusting, the apical positioning arrow and the number will jump with the adjustment.
(3 seconds after setting the apical positioning, the number will automatically disappear.)

6.8.3 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;
- Insert the file into the root canal and clamp the file clip to the file (Attach the file clip on the metal part - directly underneath the plastic handle);
- 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.



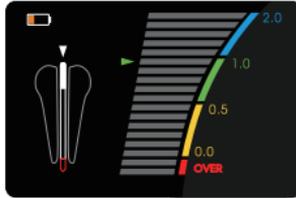
WARNING

We do not recommend to continue the measurement if the faulty connection appears. Go to the CHECK Mode to check the performance of the device.

6.8.4 Apex Location

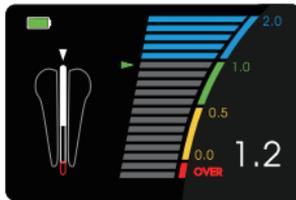
a. Coronal and Medial Section

- 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.

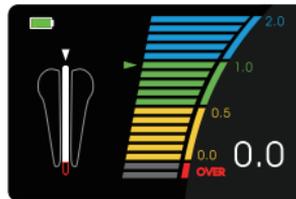
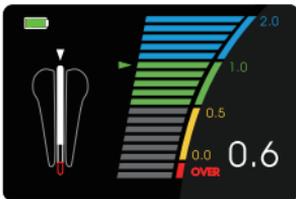


b. Apical Section

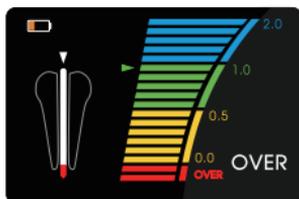
Zoomed view of the file progression is shown on the enlarged image of the apical part of the canal - the Apical Zoom.



In the apical section the indication arrow 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 indication arrow is marked red and a constant sound is emitted.

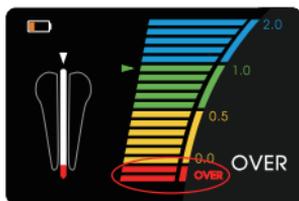


NOTE

The apical indication arrow show the file tip position inside the canal:

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

Once the file tip has passed the apical foramen, the warning red dot appears beneath the apical zoom image and warning beeps will sound.



WARNING

As with all electronic length determination devices, the bars shown in the apical zoom do not represent the distance in millimeters.

c. Interruption of measurement

During the length determination the file clip may be disconnected from the file and reconnected at any time (e.g. when the file is changed to a larger size or when the length of another canal should be determined). The device detects automatically that a new length determination cycle is initiated and indicates it with two short beeps.

6.8.5 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.

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.

Device:	<ul style="list-style-type: none"> • Main Unit, Adapter, File Clip, Lip Hook, Test Wire and Tester; • 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	<ol style="list-style-type: none"> a. The file clip and lip hook must be cleaned and sterilized prior to use and after each patient use. b. The main unit, adapter, test wire and tester must be decontaminated prior to use and after each patient use.
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 the reprocessing process; • Store the instruments in a humid surrounding.
Pretreatment of Main Unit, Test Wire, Tester 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.

<p>Preparation Decontamination:</p>	<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, Tester and Adapter; • The Main Unit, Test Wire, Tester and Adapter cannot be cleaned and disinfected in a washer/disinfector. For these parts, only a general wipe decontamination is possible!
<p>Decontamination of other parts than File Clip and Lip Hook:</p>	<ul style="list-style-type: none"> • After operation, take out the Main Unit, Test Wire, Tester 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 disinfects 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, Tester 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! • Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds; • Clean the surfaces with a soft bristle brush.

<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 Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.</p>
<p>Pre-cleaning preparation of File Clip and Lip Hook: (For US)</p>	<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.
<p>Cleaning of File Clip and Lip Hook: (For US)</p>	<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)	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.
Soaking of File Clip and Lip Hook: (For US)	Put the lip hook and file clip into the cleaning agent and soak them for 5 minutes to decompose the contaminants.
Flushing of File Clip and Lip Hook: (For US)	Flush the lip hook and file clip with running tap water (<40°C) for 2 minutes to remove the residue of cleaning agents.
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, Test Wire and Tester: (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.
Packaging of File Clip and Lip Hook:	<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 which are approved for its efficacy by FDA; • Recommended sterilization bag: SIGMA Sterilization Pouch and Roll. • 510(k) Number: K202462
Sterilization of File Clip and Lip Hook: (For EU)	<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 • Flash sterilization is not allowed on lumen instruments!
Sterilization of File Clip and Lip Hook: (For US)	<p>Gravity-Displacement Steam Sterilization Cycles Sterilization temperature: 135°C Holding time: 10 min (full cycle) Drying time: 30 min</p>
Storage:	<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>

8 Disposal of the device



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

9 Operation and Storage Environment

Operation Environment	
Temperature	5°C to 40°C
Humidity	20% to 80%RH
Atmospheric Pressure	86kPa to 106kPa
Storage Environment	
Temperature	-10°C to 55°C
Humidity	≤93%RH
Atmospheric Pressure	50kPa to 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.

Adapter	Input: AC 100-240 V, 50/60 Hz Output: DC 5V  1A
Li-ion Battery	DC 3.7V 1800mAh
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	Not suitable for use in proximity of inflammable anaesthetic mixtures containing air, oxygen or nitrogen oxide
Operating Mode	Non-continuous
Degree of Protection	IPX0
Measurement Accuracy	±0.5mm
Dimension	Folded: Width: 103 mm, Length: 110 mm, Thickness: 21.5 mm Open: Width: 103 mm, Length: 110 mm, Thickness: 100 mm
Weight	270g
Display Type	3.5" TFT colour display with touch panel
Display / Active Area	73.4mm x 48.9mm
<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. 	

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.

Guidance and Manufacture's Declaration - Electromagnetic Emission

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

Emission test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments directly connected to the public low-voltage power supply network with specific requirement.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacture's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device 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	±8 kV contact ±4 kV, ±8kV, ±15 kV air	±8 kV contact ±4 kV, ±8kV, ±15 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	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines ±1 kV for Input/output lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2kV common mode	±0.5 kV & ±1 kV differential mode ±0.5 kV, ±1 kV & ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100 %U _T (100% dip in U _T .) for 0.5 cycle 100 %U _T (100% dip in U _T .) for 1 cycle 30 %U _T (70% dip in U _T .) for 25/30 cycles 100 %U _T (100% dip in U _T .) for 250/300 cycle	100 %U _T (100% dip in U _T .) for 0.5 cycle 100 %U _T (100% dip in U _T .) for 1 cycle 30 %U _T (70% dip in U _T .) for 25/30 cycles 100 %U _T (100% dip in U _T .) for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from a unit eruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM Bands 3 V/m 80 MHz to 2.7 GHz</p>	<p>3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM Bands 3 V/m 80 MHz to 2.7 GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> <p>$d=1.2 \times P^{1/2}$ $d=1.2 \times P^{1/2}$ 80 MHz to 800 MHz $d=2.3 \times P^{1/2}$ 800 MHz to 2,5 GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601 -1-2:2014)</p>	<p>385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601 -1-2:2014)</p>	<p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:</p>



NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF 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		
	150 kHz to 80 MHz $d=1.2 \times P^{1/2}$	80 MHz to 800 MHz $d=1.2 \times P^{1/2}$	800 MHz to 2.5 GHz $d=2.3 \times P^{1/2}$
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) 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.

Revision Date: 2024-09-28 Ver 1.6
Software Version: Ver1.0