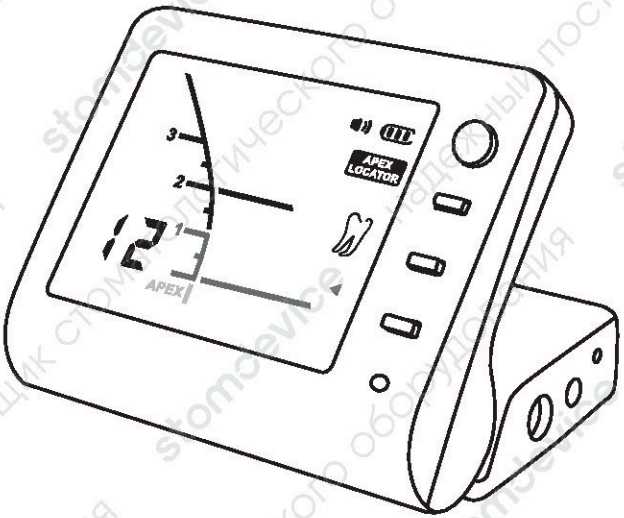
stomdevice

APEX LOCATOR & PULP TESTER

C-ROOT I (VI)

INSTRUCTIONS



CE 0482

*Thanks for applying the apex locator & pulp tester instrument. For the sake of safety and efficient use of the product, please read this manual carefully.

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CONTENT

Introduction	1
Intended use/indications	1
Contraindications	2
Warnings	2
Precautions	2
Adverse Reactions	2
Contents	3
LCD Screen	4
Recharging the Battery	5
Sound Adjustment	5
How to use your apex locator	6
How to use your pulp tester	14
Automatic Shutdown	17
Troubleshooting	18
Service and Maintenance	20
Guarantee	20
Technical Specifications	21
Standard symbols	21

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Introduction

Congratulations on the purchase of C-Root I (VI), as an apex locator which is precise, ergonomic, and able to determine the exact working length in seconds, as a pulp tester which is a wise assistant to judge the pulp vitality.(Fig.1)

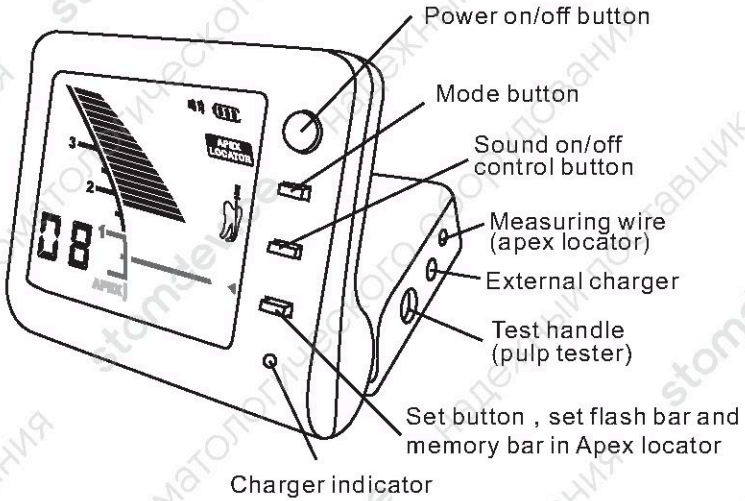


Fig.1

Intended use/indications

C-Root I (VI) is an electronic device used for apex location determination and as an aid in establishing pulp vitality.

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Contraindications

In case where a patient has been fitted with an implanted heart pacemaker (or other electrical instrument) and has been cautioned against the use of small electrical appliances (such as electric shavers, hair dryers etc.) it is recommended that the C-Root I (VI) not be used.

Warnings

Do not modify this instrument. Modification may violate safety codes and endanger patient and operator. Any modification will void the warranty.

Precautions

Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection with such use.

- *C-Root I (VI) is only used by a properly licensed practitioner.*
- *We do not advise the use of C-Root I (VI) on patients fitted with pacemakers (or other electrical instrument) for safety reasons.*
- *Do not expose C-Root I (VI) to any liquid.*
- *C-Root I (VI) must be stored in normal temperature (< 70 C) and humidity conditions.*
- *Do not use in the presence of inflammable products.*

Adverse Reactions

None known.

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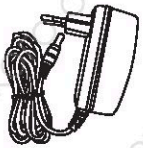
Contents

Before use, please check the exact contents of the new instrument:

- 1 C-Root I (VI) main unit
- 1 charger
- 1 Li-ion battery (Already installed in instrument)
- 1 Measuring wire (apex locator)
- 2 file holders (apex locator)
- 4 lip clips
- 2 tooth probes (pulp tester)
- 1 test handle (pulp tester)
- 1 Handle base
- Instructions



C-Root I (VI) main unit



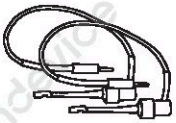
charger



Li-ion battery



Measuring wire



file holders



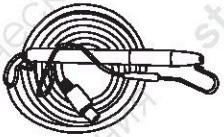
lip clips



tooth probes



Handle base



test handle



Instructions

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LCD Screen

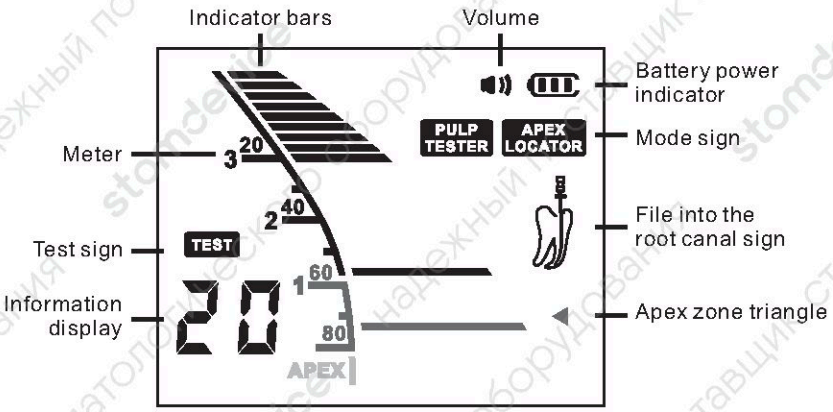


Fig.2

Recharging the Battery

The C-Root I (VI) is delivered with a rechargeable battery.
The C-Root I (VI) screen has an indicator showing the level of charge of the battery. When it's empty, the battery requires recharging.

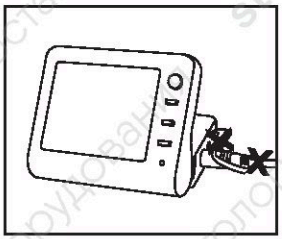


Fig.3

Procedure for recharging the battery:

1) Disconnect the Measuring wire or test handle.(Fig.3)

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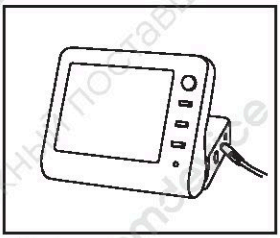


Fig.4

2) Connect the charger cable to the instrument. (Fig.4)

3) Connect the charger to the mains.

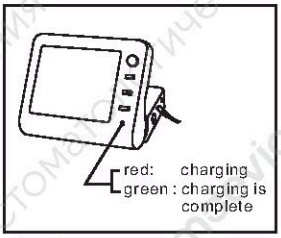


Fig.5

When the instrument is connected to the charger, it will power off automatically, and the charger indicator turns on. Indicator is red during charging procedures and turns green when charging is complete.(Fig.5)

Duration of charging: about 4 hours (8 hours after long periods without use).

Note:

C-Root I (VI) cannot be used while charging.

Used batteries must be disposed of in accordance with any applicable legislation.

Sound Adjustment

C-Root I (VI) is equipped with a sonic indicator which enables monitoring of the progression of the file within the canal or the stimulus on the probe.

On/off the sound by press the Sound on/off control button.

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How to use your apex locator

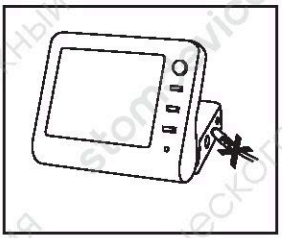


Fig.6

Getting Started:

1) Disconnect the charger from the instrument if connected.(Fig.6)

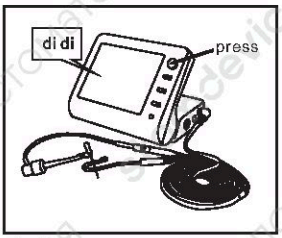


Fig.7

2) Connect the measurement wire and switch on the instrument, two tones audio signal are emitted when the unit is turned on.(Fig.7)

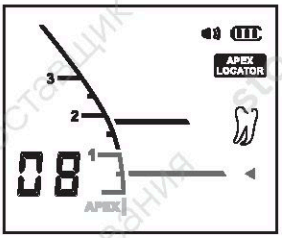


Fig.8

3) Switch to apex locator mode by successive presses on the MODE SWITCH button, visual information appears APEX LOCATOR appear indicates that the apex locator is ready for use. (Fig.8)

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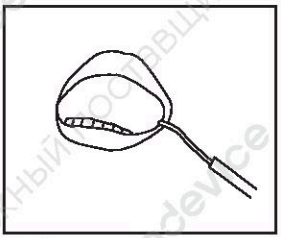


Fig.9

4) Link the lip clip to the patient.(Fig.9)

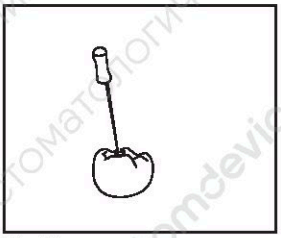


Fig.10

5) Insert the file into the canal.(Fig.10)

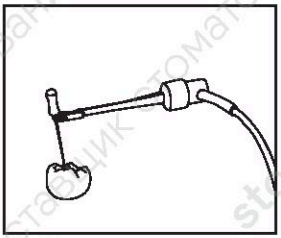


Fig.11

6) Connect the file holder to the file. (Fig.11)

Note: no other specific adjustment is necessary before commencing measurement.

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Set flash bar

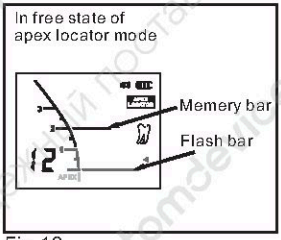


Fig.12

The position of the flash bar can be set as guide for canal measurement and enlargement.(Fig.12)

The reference point for measurement of enlargement can be set anywhere between 2 and APEX.(Fig.13)

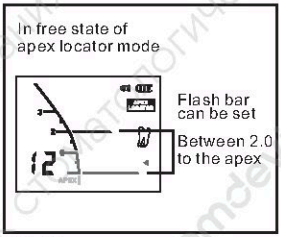


Fig.13

When the file reaches the position 2.0mm away from the apex of the root-canal, there will be continuous alarm. (Fig.14)

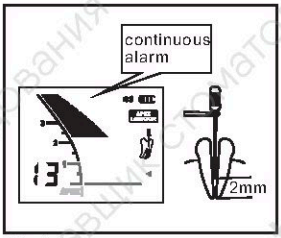


Fig.14

During measurement, information display number of bars left before flash bar is reached.

Set method:
flash bar can be set in free state of apex locator mode, press set button and the reference position will change and memorized automatically. (Fig.15)

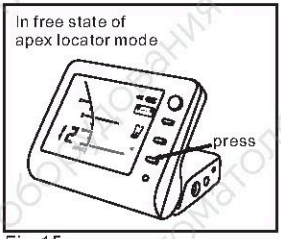


Fig.15

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Memory bar

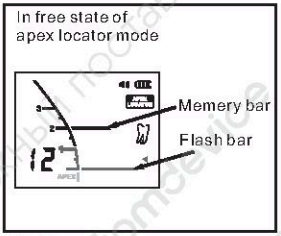


Fig.16

During operation , dentist can memory the current position of the file tip. It can be used to mark the beginning of a sharp curve or some certain distance from the apex. It can also be used as a guide when the file size is changed for canal enlargement.(Fig.16)

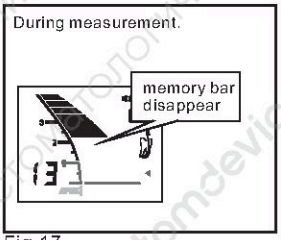


Fig.17

Memory bar can't be shown on screen during measurement. In free state , memory bar will appear and the information display the bars number from the memory bar to the flash bar.(Fig.17)

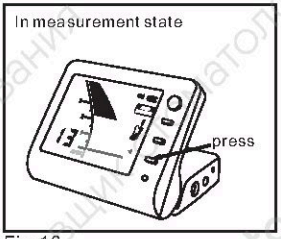


Fig.18

Set method:
the memory bar can be set by press the set button in measurement state. (Fig.18)

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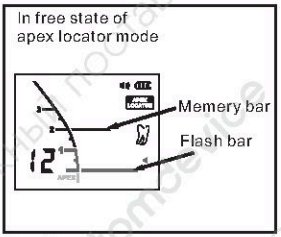


Fig.19

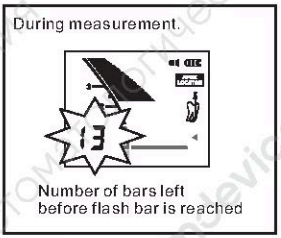


Fig.20

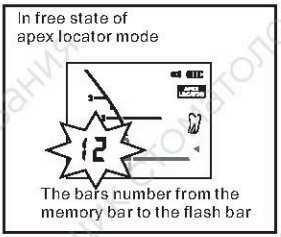


Fig.21

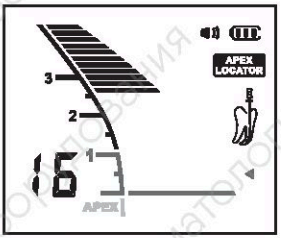


Fig.22

Operation method :

1) Free state (without measurement)

In apex locator mode, if the file isn't inserted into root canal, the screen displays the memory bar and the flash bar, the information display the bars number from the memory bar to the flash bar. (Fig.19)

Meter of 1,2,3 show that the distance from the apex is not in mm as a unit, but it mean that file tip is near the apex hole.

Information display : Number of bars left before flash bar is reached (during measurement). (Fig.20) The bars number from the memory bar to the flash bar (in free state). (Fig.21)

The information shows not the root canal length, but the number of bars.

2) Pre-apical zone (2 - 3mm away from the apex of root-canal)

The meter is activated when the file is inserted into a root canal. The number of bars remaining before the file reaches the flash bar is shown by the information display. (Fig.22)

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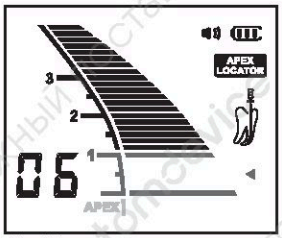


Fig.23

3) Narrow zone (0.5 - 1 mm away from the apex of root-canal)

When the file tip reaches a position near the apex, on the screen, the bar color changes to green to indicate you have reached narrow zone. The number of bars remaining before the file reaches the flash bar is shown by the information display. (Fig.23)

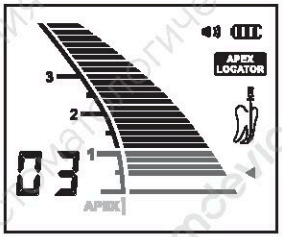


Fig.24

4) Apical zone (0.5-0mm away from the apex of root-canal)

When the file tip approaches the apical zone, the green triangle is flashing indicates the point set for reference. At this point, please fasten the file with the rubber vernier caliper on the reference point of the tooth crest rather than keep up probing into the root-canal. (Fig.24)

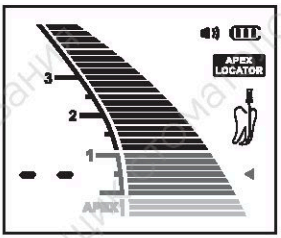


Fig.25

5) Beyond the apex

The position of the apex is represented by the word “APEX” and information display“--”.The meter bars in this area are pink, indicates that you have passed the Apex (Fig.25)

Deciding the working length of root canal

Measure the distance from the bottom of rubber vernier caliper to the tip of the file. Note down this distance. So subtract 0.5-1.0mm from the above data is the working length of root-canal.

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REMARKS: The working length of root-canal varies from each other for the reason of different shapes of teeth and root-canal.

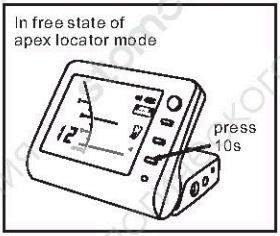


Fig.26

Check the instrument

Dentist should check the instrument at least once a week to make sure it is working properly.

- In free state of apex locator mode, press the set button about 10s, LCD display in Fig.26, means the instrument entered the test state.

Please confirm the bar is at which up and down the green triangle within 3 steps, otherwise it can not test correctly. (Fig.27)

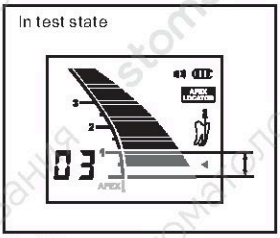


Fig.27

In test state, measurement is not available.

- Power off the instrument, connect the test wire to the main unit.(Fig.28)

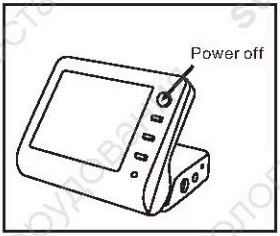


Fig.28

Connect the file holder, stainless clip to the test wire.

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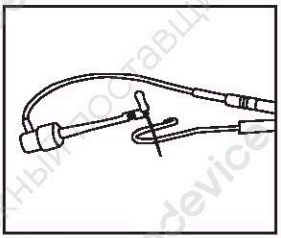


Fig.29

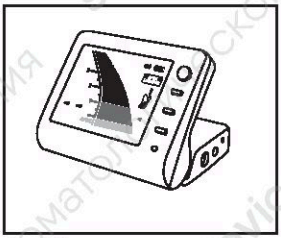


Fig.30

Contact with the file holder and stainless clip, (Fig. 29)Confirm all the bars displayed on screen and the green triangle is flashing. (Fig. 30).

Precautions for Apex Locator Use

. To ensure that short circuits do not impair the measurements, be particularly careful with patients fitted with metal crowns or bridges.
. Avoid excessive liquids inside the tooth cavity to prevent overflow and incorrect measurements.
. Make sure that the canal is wet enough to ensure reliability of the measurement.
. Ensure that the file does not touch another instrument.
. Measurements in canals with open apex may provide results with reduced precision.
.The result of measurement is for reference only, dentist should check by X-ray film.
.Sometimes, bars will unusually shake in the moment of the file inserted into the root canal, and when the file tip moved in the direction of apex, the result will get right.

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How to use your pulp tester

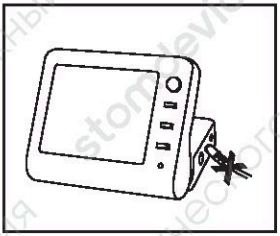


Fig.31

Preparation

1) Disconnect the charger from the instrument if connected.(Fig.31)

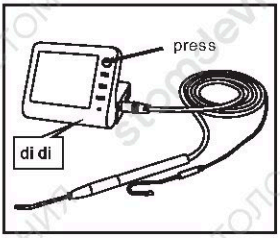


Fig.32

2) Connect the test handle and switch on the instrument, two tones audio signal are emitted when the unit is turned on.(Fig.32)

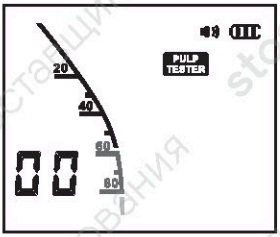


Fig.33

3) Switch to pulp tester mode by successive presses on the MODE SWITCH button, visual information appears, PULP TESTER appear indicates that the pulp tester is ready for use (Fig.33).

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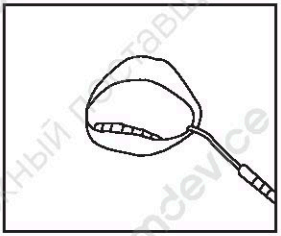


Fig.34

4) Link the lip clip to the patient's lip; instead the patient may hold the lip clip firmly in the hand.(Fig.34)

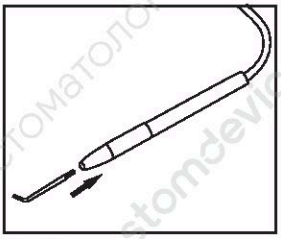


Fig.35

5) Insert the tooth probe into the handle. (Fig.35)

Note: no other specific adjustment is necessary before commencing test.

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Getting Started

1) Clean and dry the tooth to be tested.

2) To improve contact between tooth and probe, apply a little prophy paste or toothpaste to the metal tip.

3) Place the probe on the middle of the labial or lingual surface of the tooth. Avoid soft tissue and restorations such as crowns, amalgams or composites.

4) When the probe contact tooth unquestionable, the unit activated automatically. The number will indicate that an increasing Gentle-Pulse stimulus is being applied to the tooth.

5) When the patient feels the stimulus, leave the probe from the tooth. The stimulus will stop immediately. The display will flash and hold the final reading for approximately 5 seconds, so it can be noted, at this time contact tooth again, the unit will apply stimulus continuative. After 5 seconds the unit will automatically turn to ready status.

6) During 20-50, beeper emits tone slowly. During 50-80, emits tone faster. After 80,emits a fastest tone.

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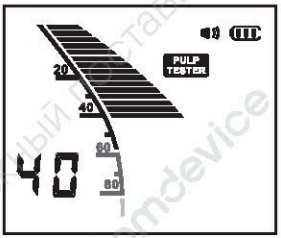


Fig.36

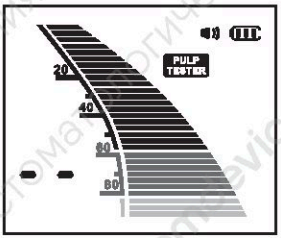


Fig.37

Clinical Observations:

1) The reading corresponding to the n–ormal stimulus is 1-99, is estimated that the tooth is vital (Fig.36).

2) No sensation at the maximum stimulus (--) suggests that the tooth is non -vital, This conclusion should be confirmed by thermal testing.(Fig.37)

3) Generally, incisors have similar thresholds about 10 – 30, premolars about 25 – 45, molars about 35 – 70.

4) Molars generally require greater stimulus than premolars, but the threshold may also be affected by such factors as the age of the patient, trauma and pathology.

Automatic Shutdown

C-Root I (VI) automatically shuts down after 3 minutes without use. It is advisable, however, to manually switch off instrument after working by simply press the POWER button.

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Troubleshooting

If the equipment is not normal work, before call our after-sales center, please check the table below

Phenomenon	Reason analyses	Problem shooting
Can't power on	Is battery installed properly ?	Check the battery
	Low battery?	Charge the battery
	Is the charger is connected to main unit?	Remove the charger plug from main unit
Can't measurement the length of canal	Is all the connection reliable?	Check the connection
	Is test wire in good state?	Check the test wire
No alarm	Is volume in mute condition?	Turn on the sound
Can't set memory bar	Is instrument in free state?	The memory bar can be set only by measurement state.
Can't set flash bar	Instrument is in measurement state?	The flash bar can be set only by free state.
Inaccurate apex value	The unit is in unstable condition	Check the unit and compare with X-ray film.
	Bad condition in root canal	Clean the liquid and remnant
	Electromagnetic interference	Don't use other electronic equipment
Canal Length Indicator overreacts or is too sensitive. (Measurements are too short. Poor accuracy. Erratic results.)	Is blood or saliva overflowing from the opening of the crown?	If blood or other fluids overflow the canal, the current will leak to the gums and the meter will jump to Apex. Clean the canal, canal opening and tooth crown thoroughly.
	Is the root canal filled with blood, saliva or chemical solutions?	The canal length indicator bar may suddenly swing when it breaks the surface of fluids inside the root canal, but it will return to normal as it approaches the apex

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Canal Length Indicator overreacts or is too sensitive. (Measurements are too short. Poor accuracy. Erratic results.)	Is the tooth surface covered with cutting debris or chemical solutions?	Clean entire tooth surface.
	Is the file touching the gingival tissue?	This will cause the canal length indicator bar to suddenly jump all the way to the “APEX”
	Is there pulp tissue left inside the root canal?	An accurate measurement cannot be obtained if a large amount of pulp tissue is left inside the root canal.
	Is the file touching a metal prosthesis	Touching a metal prosthesis with the file allows a flow of current to the gingival tissue or periodontal pocket and will cause the meter to jump to the “APEX”.
	Are proximal surfaces infected with caries?	Current can flow through the caries infected area to the gums and prevent an accurate measurement from being made.
	Does a broken crown allow leakage of electric current?	Build up an insulating barrier to stop the leakage.
	Is there a lesion at the apex?	A lesion can destroy the apical foramen through absorption and an accurate measurement cannot be obtained.
	Is the file holder broken or dirty?	Replace or clean the file holder.
Can't test the tooth vital	Is stainless clip making good contact with oral mucosa?	Make sure the stainless clip make good contact with oral mucosa
	Is probe making good contact with tooth surface?	Make sure the probe make good contact with tooth surface
Inaccurate pulp test value	Is tooth surface clean and dry?	Make sure the tooth surface is clean and dry

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Service and Maintenance

- The instrument doesn't contain user serviceable parts. The service and repair should be provided by trained service personnel only.
- The instrument may be cleaned with a damp cloth and wiped with a cold sterilant. Use of chemical agents may cause damage to the instrument.
- The measuring wire and test handle can't be autoclaved.
- The accessories (lip clip, file holder, tooth probe) can be sterilized between treatments (by autoclave at 134 C).

Note: autoclaving does not remove debris that may have accumulated. To assure adequate sterilization, wash the autoclavable components in warm, soapy water (before autoclaving).

Guarantee

C-Root I (VI) main unit is guaranteed for 24 months from the date of purchase. The accessories (wire, battery etc.) are guaranteed for 6 months.

The guarantee is valid for normal usage conditions. Any modification or accidental damage will render the guarantee void.

We will repair or replace, at its option, a defective unit. This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties express or implied. We do not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described.

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Technical Specifications

C-Root I (VI) belongs to following category of medical devices:
-Internally powered equipment (7.4 V Li-ion rechargeable battery)
-Type LF (Low Frequency) applied parts
-Not suitable for use in the presence of flammable anaesthetic mixtures with air or with oxygen or nitrous oxide
-Continuous operation
-Ingress of liquids - not protected
-Environmental conditions during transportation:
temperature: -20 C to +60 C (0 to 140 F)
relative humidity: 10% to 90%, non-condensing

Technical specifications

Type of screen:	liquid crystal
Supply:	Li-ion 7.4 V battery
External charger:	Input : AC100-240V 50/60 Hz or 220V /50 Hz
	Output: DC 10V 1.5A

Standard symbols

On the instrument or external charger label appear standard symbols as follows:


Class II equipment


Type B applied part


Attention, consult accompanying documents


Direct current


Certified to MDD93/42/EEC


WEEE

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stomdevice



Foshan COXO Medical Instrument Co., Ltd
Address: 21 Wufeng Si Road, Foshan, Guangdong, China

EC REP

Wellkang Ltd.
Address: Suite B, 29 Harley Street, London W1G 9QR, United Kingdom

Ver1.0

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