ApexNRG•RiderS2™

Add-On Digital Apex Locator

OPERATING MANUAL

MEDICNRG
2.00
1.00
0.50
0.25
APEX
-0.00

36 Month Warranty!

MEDICNRG™
Precise Endo Technology

Optimizing Your Endo Performance

ApexNRG•Rider

The Digital Apex Locator is designed to meet international safety and performance standards. Personnel operating the instrument must have a thorough understanding of the proper operation of the instrument. These instructions have been prepared to aid medical and technical personnel to understand and operate the instrument. Do not operate the instrument before reading this manual and gaining a clear understanding of the operation of the instrument. If any part of this manual is not clear, please contact your representative for clarification.

The ApexNRG-Rider calculates the distance from the tip of your endodontic file to the Major Apical Foramen by using multi-frequency currents.

The ApexNRG-Rider measures the response of the root canal between two electrodes, depending on the frequency. The first electrode is the lip hook (3) (Pic.A). The second is the mini file holder (2) which makes contact with a file that has been inserted into the root canal.

The ApexNRG-Rider monitors the changes in the canal's response as the file probe approaches the apex.

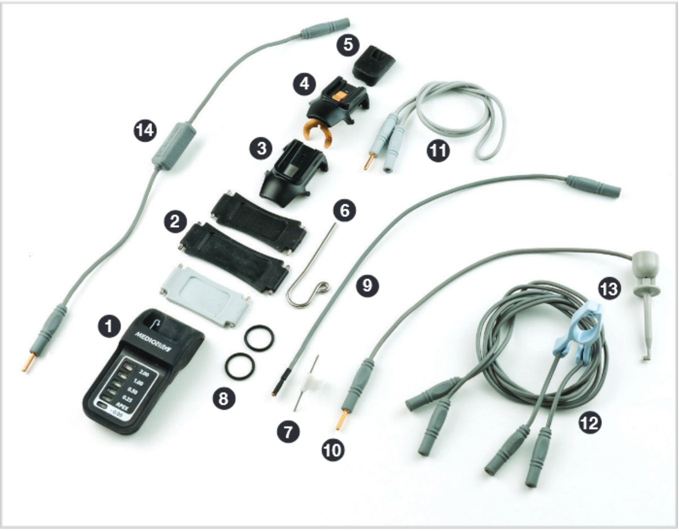
Technologically Advanced:

- There are 6 LEDs to mark the advancement of the file, for precise working length measurement.
- The use of DSP allows a much higher level of accuracy and control of the process with measurement results accurate to 0.1 mm in apical region and a display resolution of 0.25 mm in the critical measurement range.
- The ApexNRG-Rider provides precise measurements of the canal under all conditions, including wet, dry, and bleeding canals. You can immediately measure another canal, without any special preparation.
- Calibration is automatic. No manual calibration is required.

Contents

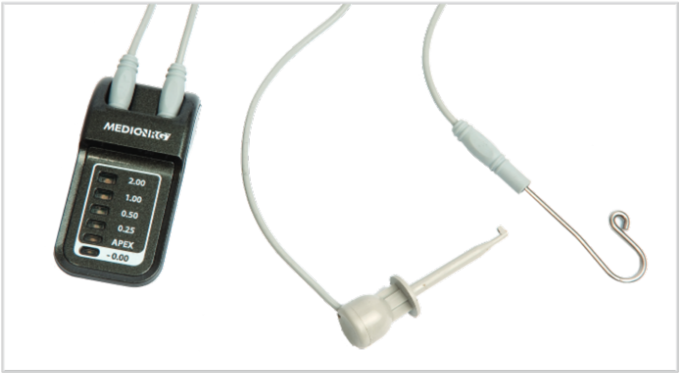
1. Initial Setup
1.1. Manual Mode
1.2. Assembling the Universal Connector
1.3. Using the Rider in "Riding Mode"
1.4. Using the Rider in "Satellite Mode"
1.5. Riding Mode for E-type Handpiece
1.6. Satellite Mode for E-type Handpiece
2. Directions For Use
3. Battery Power
4. Battery Replacement
5. Sterilization
6. Recommendations for a successful treatment
6.1. Recommendations for the measurement process
7. Troubleshooting
8. General information

1. Initial Setup



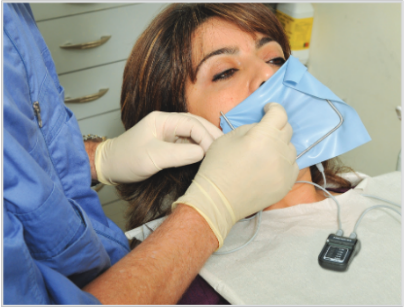
The ApexNRG Rider is a multi-purpose device used to measure the working length of the root canal. It can be used in three modes:
"**Manual**" as a stand alone apex locator.
"**Riding**" on a rotary handpiece.
"**Satellite**" connected but unattached to the handpiece.

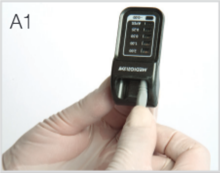
1.1 Manual Mode



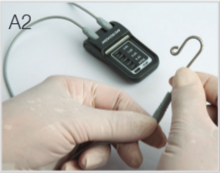
1. Insert the two main lead wires into the outlets at the top of the Digital Apex Locator. (Pic.A1)
2. Insert the lip hook ⑥ and the file clip cable ⑩ into the sockets located at the end of the lead wires (either left or right). (Pic.A2 + A3)
3. Attach the apron clasp ⑬ to the lead wires by inserting them into the two wire holders on the clasp handles (Pic.A4)
4. Insert the Digital Apex Locator into a disposable sleeve. (Pic.A5)
5. Place the Digital Apex Locator near the mouth of the patient, and attach the clasp to the apron.
6. Place the lip hook located at the end of the lead wire on the lower lip, preferably on the opposite side of the tooth being treated.
7. Place the file at the entrance to the canal and then connect it to the file clip cable.

The Digital Apex Locator is now ready for manual operation.



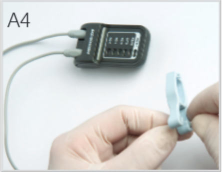


A1



A2

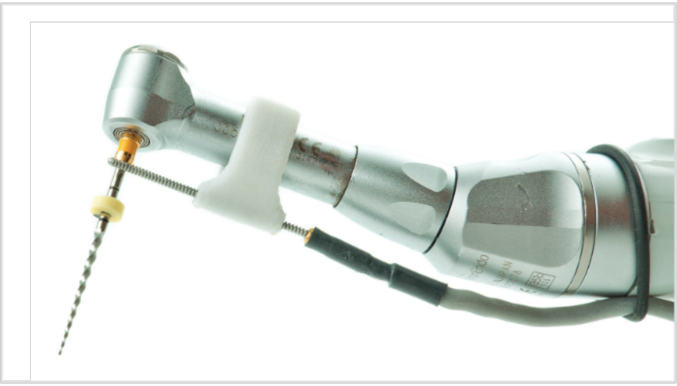
A3



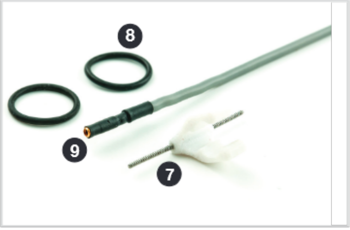
A4

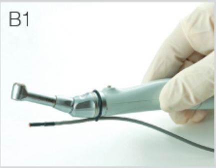
A5

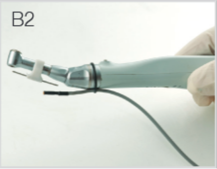
1.2 Assembling the Universal Connector

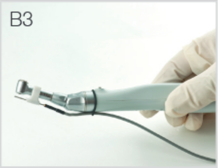


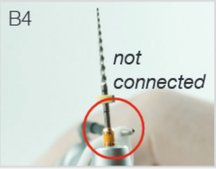
1. Attach the special adaptor cable ⑨ using an o-ring ⑧ to the handpiece. (Pic. B1)
2. Clip the universal connector ⑦ firmly to the handpiece and connect it to the cable. (Pic. B2, B3)
3. Ensure that the universal spring connector makes full contact with the file, in order to conduct the electric circuit from the file to the Rider. (Pic. B5)

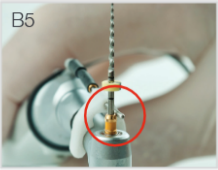



B1

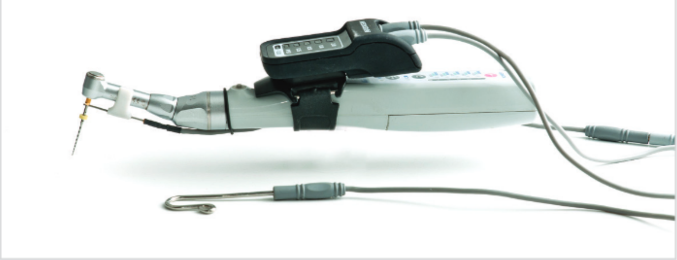

B2


B3


B4


B5

1.3 Using the Rider in "Riding Mode"



❶

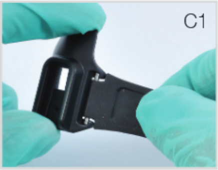
2.00
1.00
0.50
0.25
APEX

❷

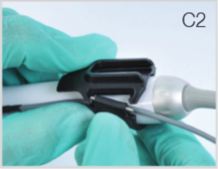
❸

1. Connect the “saddle” ❸ to the Handpiece by securing it with the strap ❷ that best fits the handpiece diameter. (Pic C1)
2. Secure the strap around the handle locking the two pins on both sides side of the strap into place. (Pic.C2)
3. Complete assembly by sliding the Rider ❶ into its track on the “saddle”. Pic.C 3, C4,
4. Connect the adaptor cable ❾ to the device using the extension cable ⓫ Pic. C5 Pic. C6
5. Attach the lip hook ❻ to the lead wire ⓭ Pic. C7
6. Connect the lead wire ⓭ to the socket on the right side of the device (the side with the LEDs and the printed lip hook symbol). (Pic. C8)
7. Insert a file into the handpiece and lock into place.
8. Place the lip hook located at the end of the lead wire on the lower lip, preferably on the opposite side of the tooth being treated.

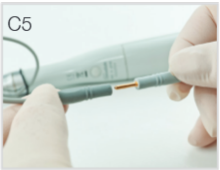
The Rider is now ready for operation.



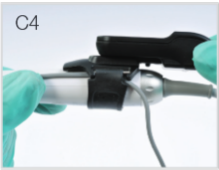
C1



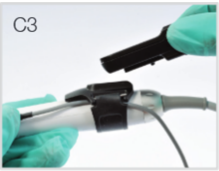
C2



C5



C4



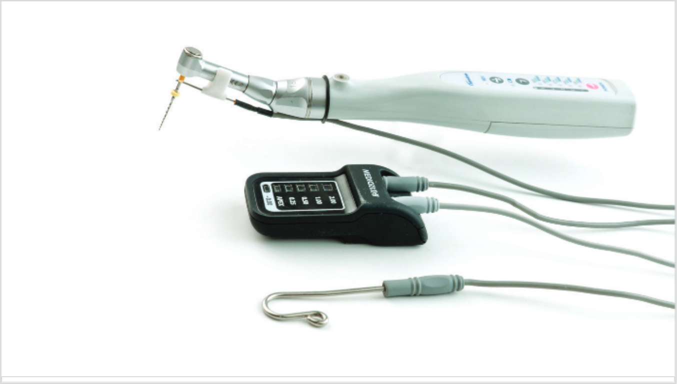
C3

C8

C7

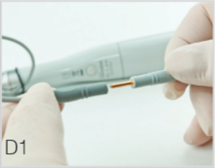
C6

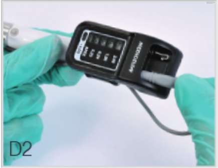
1.4 Using the Rider in "Satellite Mode"



1. Connect the adaptor cable ❾ to the device using the extension cable ⓫ (Pic. D1, Pic. D2)
2. Attach the lip hook ❻ to the lead wire ⓭ (Pic. D3)
3. Connect the lead wire ⓭ to the socket on the right side of the device (the side with the LEDs and the printed lip hook symbol). (Pic. D4)
4. Insert the Rider into a disposable sleeve. (Pic. D5)
5. Place the lip hook located at the end of the lead wire on the lower lip, preferably on the opposite side of the tooth being treated.
6. Insert a file into the handpiece and lock into place.

The Rider is now ready for operation.


D1

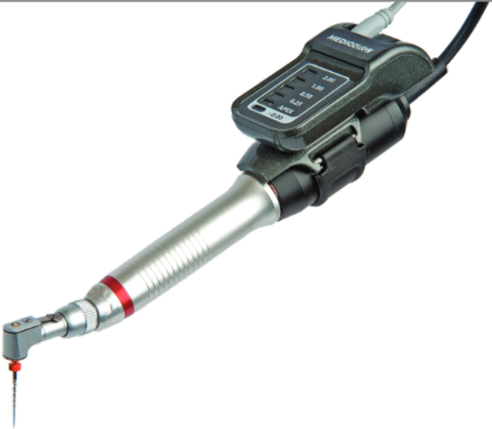

D2

D5

D4

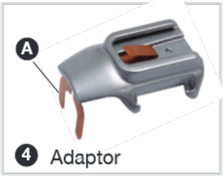
D3

1.5 Riding Mode for E-type Handpiece



❶

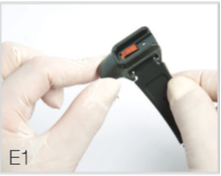
❷ Strap



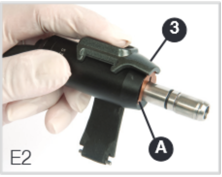
Riding Mode Installation for E-type

1. Connect the strap ❷ to the adaptor ❸. Use the strap size (22-25 or 24-27), best suited to the micro-motor diameter. (Pic.E1)
2. Place the adaptor ❹ on the micro-motor, positioning the metal tab 🅐 on the E-type connector (Pic.E2), while pushing the adaptor tab toward the micro-motor, ensuring a snug fit to the handle.
3. Secure the strap around the micro-motor by moving the two pins on both sides of the strap into place. (Pic.E3)
4. Complete assembly by sliding the Rider ❶ into its track on the adaptor. (Pic.E4)
5. Connect the handpiece to the micro-motor. (Pic.E5)
6. Connect the lead wire, to be used with the lip hook, to the pin on the **right** side of the device (the side with the LEDs and the printed lip hook symbol). (Pic E6)
7. Insert the lip hook into the socket located at the end of the lead wire. (Pic.E7)
8. Place the lip hook located at the end of the lead wire on the lower lip, preferably on the opposite side of the tooth being treated.
9. Insert a file into the handpiece and lock into place.

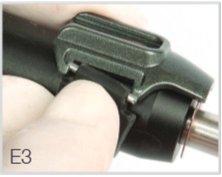
The Rider is now ready for operation.



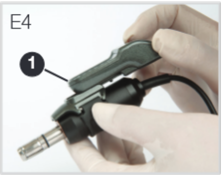
E1



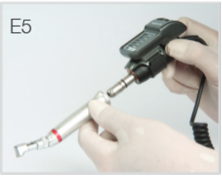
E2



E3



E4

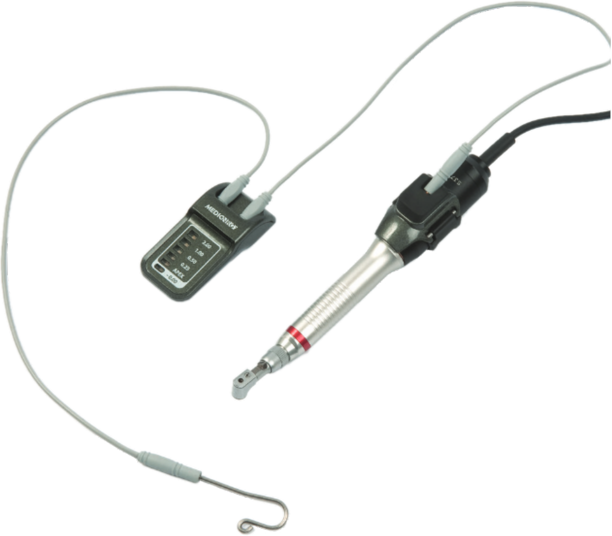


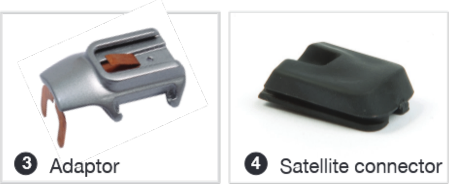
E5

E7

E6

1.6 Satellite Mode for E-type Handpiece





❸ Adaptor

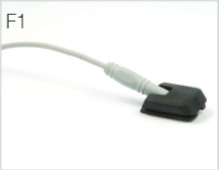
❹ Satellite connector

Satellite Mode Installation

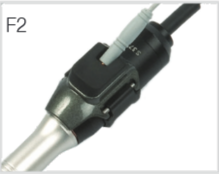
1. Follow steps steps 1-3 in section 1.5.
2. Insert the pin (plug) of the extension cable into the hole in the satellite connector. (Pic.F1)
3. Slide the satellite connector ❹ into place on the adaptor ❹ assembled on the Rider device.
4. Connect the cable's socket to either the right or left pin of the apex locator. (Pic.F3)
5. Insert the lip hook to the socket at the end of the lead wire and connect it to to the pin on the device (either left or right). (Pic.F4)
6. Insert the Rider into a disposable sleeve. (Pic.F5)
7. Place the lip hook located at the end of the lead wire on to the lower lip, preferably on the opposite side of the tooth being treated.
8. Insert a file into the handpiece and lock into place.

The Rider is now ready for operation.

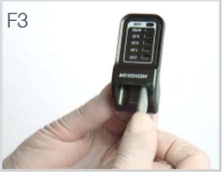
F1



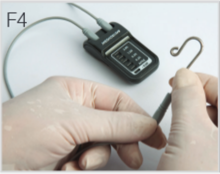
F2



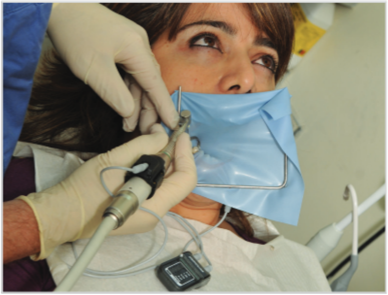
F3



F4



F5

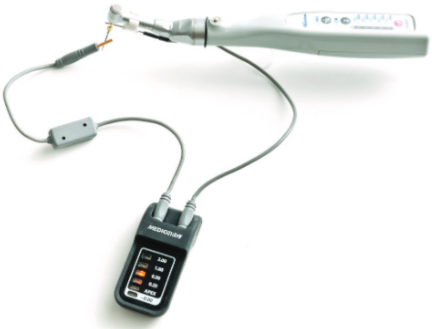


2. Directions For Use

NOTE: The Rider-Digital Apex Locator should be used only as an adjunct to normal endodontic procedures. While the unit can reduce the number of radiographs necessary, an initial radiograph must be taken to estimate working length. Clinical judgment, including knowledge of root canal anatomy, is paramount when interpreting results.

Note: The Rider's battery is assembled. Remove the protective plastic tab that insulates the battery from contact by pulling out firmly.

To verify conductivity between the handpiece and the Rider Digital Apex Locator, connect the 0.5 Validation Cable to the Rider Digital Apex Locator. Make contact between the endo file and the lip hook cable.
The 0.5 LED on the Rider Digital Apex Locator should light up, verifying the conduction of the electric current between the Rider Digital Apex Locator and the endo file, allowing accurate measurement of canal length.



1. Activate the Digital Apex Locator making contact between the lip hook and the file or the rubber dam clamp. Once activated, the LEDs will flash in sequence as a "self-check".
2. Following this check, the "2.00" green LED will blink, indicating the Digital Apex Locator is in stand by mode.
3. When the file reaches the "2.00" mm point, the green LED will stay lit and a very slow beep will sound.
4. Work the file towards the apex, passing LEDs "1.00" (green), "0.50" and "0.25" (orange).

2.00
1.00
0.50
0.25
APEX
-0.00

The frequency of the alarm increases as the file nears the apical constriction. This is a particularly sensitive area when working with a handpiece, and use of a file beyond this point requires great caution. To allow accurate measurement, continuous contact must be maintained between the file and the side of the canal. When the file reaches the apical constriction, the red “APEX” LED lights and the warning alarm reaches a higher frequency. If the file passes the apical constriction the warning alarm will reach the highest frequency and the “-0.00” (past apex) LED will flash. At this stage, gently pull file back out of the canal until the “APEX” red LED lights up and the alarm sound slows its frequency.

5. Mark the length of the canal with the rubber stopper. Measure the length of the file and prepare the rest of the files for the treatment according to this length.

NOTE: In order to fully prepare the canal using the handpiece and rotary files, keep the Rider Digital Apex Locator on and in measuring mode (connected), to ensure that the apex is not perforated. It is imperative to keep the irrigation solutions within the confines of the canals. The pulp chamber must be dry.

For more information, refer to our recommendations for a successful treatment (section 6) and our troubleshooting guide (section 7).

ATTENTION: The rubber dam is mandatory in endodontic procedures.
Using the rubber dam will avoid “false positive” readings that might occur when the handpiece makes contact with the soft tissues (lip, tongue, etc).
In the extreme cases, when using a rubber dam is not medically feasible, and the rubber sleeve is used, it is not a replacement for the rubber dam and may not, by any means, serve as an alternative for it. The rubber sleeve is a single use item and should be disposed after use to prevent cross infection. It cannot be sterilized.

3. Battery Power

When the battery is low the unit will turn off automatically.
Replace the battery immediately and proceed working.
The device can't be turned on when battery is low. While trying to activate the unit three intermittent LED lights will light simultaneously along with beeping Sound. Battery must be replaced.

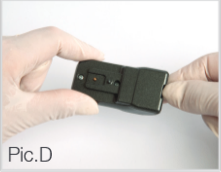
As an energy-conservation feature, the Digital Apex Locator will turn off after 2.5 Min. of inactivity.

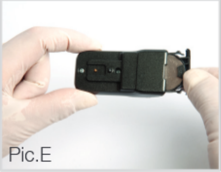
Note: When storing the Digital Apex Locator for an extended period of time without use, it is recommended to remove the battery from the device in order to lengthen the battery life. The battery may also leak after a long period of disuse, damaging the device and voiding the warranty.

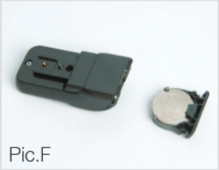
4. Battery Replacement

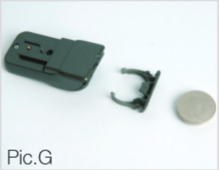
1. Locate the device with its back side facing upwards.
2. Using a fingernail, gently pull out the battery up drawer and remove the battery (pic.D, E, F).
3. Remove the battery from the drawer (Pic.G) and replace with a fresh battery (type CR2450).
4. Be sure to insert the battery with the + sign facing upwards, to the bottom of the device. (Pic.H)
5. Slide the drawer back into the battery housing, until it clicks. (Pic.I)

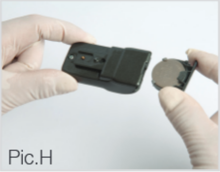
Dispose of depleted battery in accordance with local regulations.

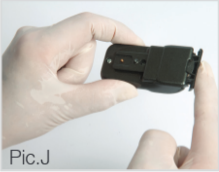

Pic.D


Pic.E


Pic.F


Pic.G


Pic.H


Pic.J

5. Sterilization

Warning! Do not place the Digital Apex Locator into the Autoclave!!
Do not submerge the device or allow liquid to enter the unit enclosure!

Attention! The Digital Apex Locator is not supplied in a sterile state. All surfaces of the device and its accessories should be disinfected when the unit is initially received and thereafter between procedures, to prevent cross-infection. Wipe the surface of the unit with a clean cloth moistened in 70% ethyl alcohol solution.

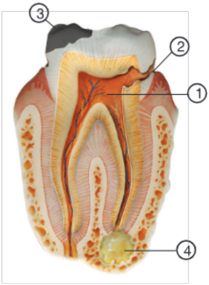
The main lead wires, mini file holder, lip hook traditional file clip, mini sensor probe and apron clasp can be sterilized in the autoclave at 121°C for 20 minutes or at 134°C for 5 minutes, or according to the manufacturer's instructions.

Only accessories specifically mentioned as autoclave safe may be sterilized in the autoclave.

NOTE: Standard, off the shelf, endo files may be used with the Rider apex locator, except for **anodize coated files**, which will interrupt the current between the canal and the apex locator.

6. Recommendations for a successful treatment

Prior to measuring root canal length with your Digital Apex Locator:



- Make sure that the pulp chamber ① is dry before inserting the measuring file. It is recommended to dry the pulp chamber with a cotton pellet or by a slight aspiration of the moisture with an aspiration syringe. Also ensure that all canals are isolated from each other. Excessive fluids in the pulp chamber or canals may form a conductive bridge between canals or with a metallic restoration or crown. Drying the canal with a paper point may help increase accuracy.

- When the walls of the pulp chamber are damaged ②, or there are damaged fillings ③, saliva leakage can occur from the oral cavity, which will prevent drying of the chamber. A moist chamber may cause the immediate formation of a closed electrical circuit, i.e., a short circuit. In this event, the apex locator will issue a warning (flashing red LED and audible alarm) as if it reached the apex (false positive reading). In such cases the missing chamber wall should be temporarily restored, but only with nonconductive materials such as Composite, IRM, GI (glass iononer), etc. After restoration, a dry chamber can be achieved and accurate measurement can be reached.

- Check that any damaged fillings ③ have been removed in order to prevent marginal leakage. Such leakage will result in a moist working area and may interfere with the Digital Apex Locator's reading. The red light will flash, indicating that it has identified the apex when in fact, the file is only at the canal entrance area.

- Continuous contact with metal or amalgam fillings will ground the device, so take special care to prevent contact between the file and any existing metal-based restoration of the tooth by amalgam filling or metal crown. In such instances, an adequate isolation of the file from the metallic environment can be achieved by fitting 2-3 rubber stoppers onto the part of the file that may contact the metal of the restoration.

- A preliminary extirpation is recommended before beginning measurement. Residual tissue may result in a premature and erroneous reading.
- When using a rubber dam, make sure that it is properly sealed around the insertion area. Any aperture between the rubber dam and tooth can be sealed with a temporary restoration. Leading endodontists recommend the use of rubber dams during every root canal treatment.
- Ensure the lip hook fully contacts the patient's moist mucosa. The lip hook should not make contact with any adjacent teeth, which may have metal fillings.
- Check all connections.
- While some of the accessories are autoclavable, if any accessory seems damaged after a number of autoclave cycles, please replace with a new part. Particularly check the lead wire cables. (see the section on "sterilization" for a full list of the autoclavable items).

6.1 Recommendations for the measurement process

Prepare a wide canal orificium and prepare the first 2/3 in a tapered way to prevent contact with premature constrictions in the canal.

- The file should be inserted into the canal in a filing motion (clockwise and counter-clockwise). Rotation of the file in one direction may cause the file to break inside the canal!
- Take care to ensure continuous contact between the file and the root canal wall. It is recommended to use the largest possible file that will reach the estimated working length. A loose file that does not make continuous contact with the canal wall will be unable to perform accurate measurements.
- Ensure continuous and strong contact between the file and its holder (this may be problematic with the thinner files 6, 8, 10 mm).
- In excessively desiccated canals, moistening is recommended to improve conductivity. This can be performed by slight irrigation and/or by slight lubrication of the file.
- If the canal is too dry, introduce NaOCl to the apical third of the canal.

Exceptions

- In a very wide canal, the Digital Apex Locator may be able to read the measurement only at the tip where the canal constricts toward the apical foramen. In such cases only a depth of 0.5 mm and apical foramen will be identified. Reading may be improved by using a larger file and making definite contact with the canal wall.

- The apex locator reading may be unstable in the following tooth pathology situations: decay (caries in the pulp chamber), strong bleeding in the canal, metallic restoration, periapical lesion, open apex ④, excessively wide canal.

- Bone or periodontal ligament loss (indicated by a radiolucency on the film) can cause inaccurate readings.

- A worn out battery will reduce the accuracy of the reading. The battery should be replaced as soon as the instrument's warning signal appears, as detailed in the user manual. Take care to follow the instructions for connecting the cables to the instrument as specified in the user manual.

- The Digital Apex Locator is a digital electronic device and as such requires a minimum residual battery voltage to drive the circuitry. It therefore requires replacement when this point has been reached even though there may be sufficient power left for the LEDs to turn on.

- In all instances of erroneous readings as described above only a premature reading situation is possible, due to ostensible recognition of the apex. However, the Digital Apex Locator will not show a delayed reading that may endanger the periapical tissues.

7. Troubleshooting

Question	**Solution** **(see user manual for fuller explanations)**
In rider mode: The “Rider” is connected and powered-on, but no reading is being given.	Make sure the following are correctly assembled: **1. For universal connector:** A. Ensure that the universal spring connector makes full contact with the file, in order to conduct the electric circuit from the file to the rider. B. Ensure that all of the wires are connected properly. **2. For E-type connector:** A. Ensure the adaptor’s **metal tab** is touching the micro-motor’s E-type connection. B. The Rider is assembled all the way to the end of the adaptor’s track. C. The endo file is firmly locked into place in the handpiece.

	D. The lead wire is connected to the pin on the **right** side of the device (the side with the LEDs). See pic. B6 E. The endo file may be anodize coated, isolating the current. Replace by a different type of file, and re-try. 3. If you wish to make a measurement using the satellite connector, make sure the following are correctly assembled: A. The satellite connector is assembled all the way to the end of the adaptor's track. B. The extension cable's pin is firmly inserted into the satellite connector's hole. See pic. C2. C. The endo file may be anodize coated, isolating the current.
Unit shows a display of LEDs when the file has only just been introduced to the canal.	The device has recognized the entrance to the canal and is searching for the exact location. The device will stabilize within a few seconds and you may begin measuring the canal.
Unit shows that the file is at the apex when instrument has only just been introduced to the canal ("false positive").	The correct reading should be applied starting from the apical part of the tooth only. Handpiece (in riding or satellite mode) is touching soft tissue. Ensure use of a rubber dam to avoid this contact. Either pulp chamber floor is not completely dry or the file has contacted a metallic restoration. In either case, the inaccurate readings are due to shorting the circuit. Dry the pulp chamber if it is wet.
Reading on unit is not steady.	File is in intermittent contact with the canal walls. Either place a curve at the tip of the file or try a larger size file so the tip touches the wall near the apex. The nature of the work with a handpiece dictates continual movement, so as not to overload stress on the file, reducing the danger of breakage. This continual movement is constantly read by the Rider, giving the impression that it is unstable. However, it is actually displaying actual file movements, on-line. For steadier readings of the working length measurement it is recommended to irrigate the canal, sequentially using sodium hypochlorite and EDTA (17%) solution and perform instrumentation with the canals filled with EDTA. Handpiece (in riding or satellite mode) is touching soft tissue. Ensure use of a rubber dam to avoid this contact.

The file is advancing in the canal and no reading is being given.	The device begins measuring 2 mm before the apical constriction. Check the following: A. The existence of an extremely long canal. B. The file is not making contact with the canal walls, a requirement for canal measurement. Change to a larger file. C. The canal may be extremely desiccated (dry) – introduce a lubricant into the canal.
No lights show.	Make sure you have closed the device's circuit by making contact with the two electrodes (lip hook and file). Battery is empty or has not been replaced correctly (see battery replacement instructions)
3 LEDs illuminate simultaneously.	Battery is empty.
Unit does not work when battery has been replaced.	Check each of the following items: A. The battery has been placed upside down. B. The battery was not fresh. Please ensure you are replacing with a new battery. C. Make sure you are using a CR2450 type battery.
The battery drawer will not slide back into place.	There is only one direction in which the drawer can be replaced. If it cannot be replaced, flip the drawer over and retry.
The adaptor strap will not close around the micro-motor /handpiece.	There are different sized straps – make sure you are using the correct size. Pull the strap tightly around the micro-motor handle and snap the pins in place on the adaptor.
Audible alarm does not sound.	Ensure the following: A. You have reached the 2.00 mm mark or lower in the canal (via LED display).

Compatible with the following handpieces:
Dentsply X-Smart, NSK EndoMate, SybronEndo EndoTouch, Brasseler USA EndoSequence II, SybronEndo TCM Endo III.)Using a Universial adaptor kit supplied.
Most standard E-type connections - sold separately.

Included in box

- Digital Apex Locator (1 unit)
- Universial Adaptor Kit for handpiece

- Saddle
- Extension cable (1 unit) - autoclave safe
- Micro-motor handle strap (3 units)
- Lead Wires (2 units) - autoclave safe
- Apron Clasp (1 units) - autoclave safe
- Lip Hook (1 units) - autoclave safe
- File Clip cable - autoclave safe
- Disposable Sleeves (20 units)
- Battery (type CR2450) (2 unit)
- 0.5 Validation Cable

Accessories (not included)

- E-type adaptor
- Long Sensor Probe - autoclave safe

Classification

- Type BF applied part.
- IEC 601-1 Compliant Medical Equipment
- Internally powered equipment
- Continuous operation
- Device is not supplied in a sterile state.
- Ordinary protection against ingress of water is required

Technical Specifications

- Power Supply: Single CR2450 battery
- Power input: 2.4 – 3.0 V
- Maximum current: 12mA
- Operating temperature: +10ºC - +40ºC
- Humidity: 10% - 90% without condensation.

Cautions and Warnings

DANGER: Not for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. Non-AP and non-APG equipment.

WARNING: The Apex Locator should NOT be used on a patient with a pacemaker.

WARNING: Do not plug any connectors or pins on the file clip or probes into any external power source, as it may cause a severe safety hazard to the patient.

WARNING: Only use the specified battery.

WARNING: Use of other accessories which are not authorized for use in connection with this device may cause malfunction and compromise patient safety.

CAUTION: This device has been investigated with regard to safety from electrical shock and fire hazard as well as electromagnetic compatibility (EMC). The device has not been investigated for other physiological effects.

CAUTION: For use by qualified and trained personnel only.

CAUTION: This device to be used in conjunction with other diagnostic procedures and not relied on exclusively.

CAUTION: Do not autoclave the unit.

CAUTION: This device has been tested and found to comply with EMC limits for the Medical Device Directive 93/42/EEC as last amended by 2007/47/EC
EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. The device generates radio frequency and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity.
If this device does cause harmful interference with other devices, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between devices
- Consult the manufacturer for help

CAUTION: To reduce the risk of electrical shock do not remove cover. Refer servicing to qualified service personnel.

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a healthcare professional.

CAUTION: contains parts and assemblies susceptible to damage by ElectroStatic Discharge (ESD).

Symbols

CE 0344	Corresponds to MDD 93/42/EEC as last amended by 2007/47/EC
⚠	Attention! Consult manual before use.
	Type BF Patient Applied Part
	Caution: contains parts and assemblies susceptible to damage by ElectroStatic Discharge (ESD)
	Consult Operator's Manual

Packaging / Handling Symbols

Fragile, handle with care

Temperature limits for storage and transportation

Keep dry

Disposal in municipal waste may be restricted by state or local ordinance. Dispose of in accordance with state and local regulations, or contact manufacturer for guidance.

Compliance with specification

Test	Standard	Class/Severity level	Test result
Emission			
Radiated emission Frequency range: 30-1000 MHz	clause 36.201.1 & CISPR 11	Group 1 Class B	Complies
Immunity			
Immunity from Electrostatic discharge (ESD)	clause 36.202.2 & IEC 61000-4-2	6 kV contact discharge 8kV air discharge	Complies
Immunity from radiated electromagnetic fields	clause 36.202.3 & IEC 61000-4-3	3.0 V/m, 80 MHz -2.5 GHz, 80% AM, 1 kHz	Complies
Immunity from power frequency magnetic field	clause 36.202.8 & IEC 61000-4-8	3 A /m @ 50Hz, 60Hz	Complies

MADE IN ISRAEL

Manufacturer
MedicNRG Ltd.
Kibbutz Afikim 15148 ISRAEL
Fax: +972-4-675-4278
Email: info@medicnrg.com
Web: www.medicnrg.com

Copyright © 2013 by MedicNRG Ltd. All rights reserved. No part of these instructions may be reproduced or copied in any form by any means – graphic, electronic or mechanical, including photocopying, typing or information retrieval systems – without written permission of MedicNRG Ltd.

EC REP

Obelis s.a.
Bd Général Wahis 53
1030 Brussels, Belgium
Tel: +(32) 2 732-59-54
Fax: +(32) 2 732-60-03
e-mail: mail@obelis.net

MedicNRG USA
Toll Free: 1-888-429-0240
Email: infoUSA@medicnrg.com
Web: www.medicnrg.com/usa

CE
0344

FDA 510(k) cleared

This device complies with the requirements of the MDD 93/42/EEC as last amended by 2007/47/EC

CE
0344

Caution: US Federal Law restricts the sale of medical devices to health care professionals.

MK-2URID05 (C)