

APEX LOCATOR NovApex

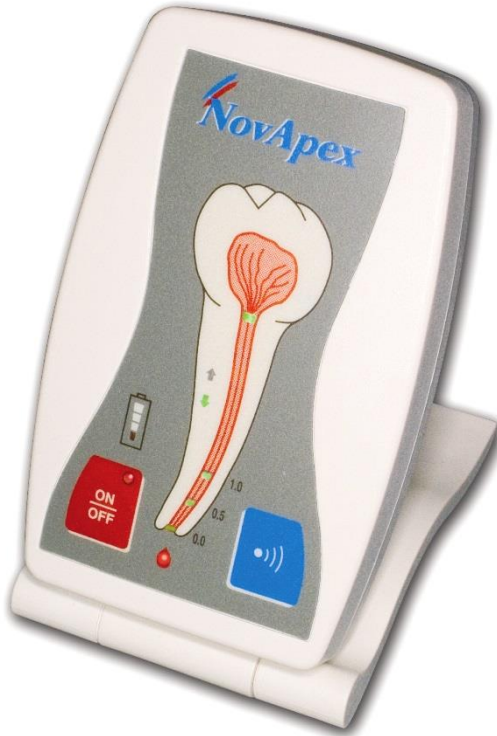
USER MANUAL



FOR DENTAL USE ONLY



Introduction

Thank you for purchasing our apex locator NovApex - the device based on innovative technologies, USA patent No. 6,425,875. NovApex combines compact ergonomic design, user friendly approach, high precision of measurements within any canal conditions: wet, dry, blood, saline, hypochlorite and other canal contents.



External view of NovApex apex locator

1. Short description.

- 1.1. Portable microcomputer controlled apex locator NovApex is a modern device for precise apex localization during root canal treatment.
- 1.2. On the front panel of NovApex appears image of tooth and root canal, indicators of file position and two buttons: **On-Off**, and . **On-Off** button is used for turning the device on and off,  button is used for sound level selection.

- 1.3. On the left side of the device measurement cable receptacle is placed.
- 1.4. On the rear part of the device enclosure battery compartment and holding clip are placed. NovApex is supplied with additional stand.

2. Battery replacement.

NovApex is powered by two standard AA size batteries 1.5V. To ensure longer battery life time use alkaline batteries.

- 2.1. In the left part of the front panel **BAT LOW** indicator is placed. If the batteries are low, **BAT LOW** indicator is turned on. NovApex is designed to operate normally even with low batteries, but the batteries should be replaced before they become flat.

If the batteries are flat, **BAT LOW** indicator is turned on, three audio beeps appear and the device is turned off automatically. If the batteries are completely flat, the device doesn't turn on at all.

- 2.2. To replace the batteries, open the battery compartment on the rear side of the device, remove the old batteries using built-in puller, replace the batteries and close battery compartment.

WARNING! Before replacing the batteries disconnect measuring cable from the patient and remove the cable from the device.

3. Device operation.

- 3.1. Insert measurement cable plug into the receptacle on the left side of the device, connect the lip clip and the file clip to the cable.
- 3.2. Press **On-Off** button. **On-Off** led is turned on.
- 3.3. Put the lip clip on the patient's lip, insert the endodontic file into the root canal and connect the file clip to the endodontic file. To ensure precise measurements the file size should be compatible to the width of the canal. NovApex detects automatically beginning of measurements and checks the quality of the electrical contact and the conductivity of the root canal. **If the contact is good, an audio signal (two consequent beeps) indicates beginning of normal measurement cycle.** The green LED in the beginning of root canal is turned on. If there are no beeps, clean the file clip and the file, fill the canal with hypochlorite or sodium chloride solution, if required, and continue the measurements. **It is not recommended to continue measurements if there still are no beeps.**
- 3.4. NovApex operates completely automatically. No manual adjustments are required. The microcomputer analyzes parameters and the status of the canal and provides automatic adjustment to ensure optimal performance. NovApex enables precise apex localization independently of root canal status (dry, wet, with blood, etc.). In the case of very dry canal or during restoration you may use hypochlorite or sodium chloride solution to provide conductive path during measurements.

- 3.5. Forward or reverse movement of the file inside the canal is reflected on the left side of the tooth image by green arrows “↓” and “↑” providing visual feedback.
- 3.6. When the file is approaching the apex, the green LED 1.0 is turned on. Advance of the file in the apex zone is accompanied by audio signals. Duration of audio beeps is increased in accordance with the advance enabling precise localization of file tip in the apex area.
- 3.7. When the file tip is in the middle point between apical constriction and the apex, green LED 0.5 is turned on. When the file tip reaches the apex, red LED 0.0 is turned on and constant tone appears instead of the beeps.
- 3.8. If the file tip has passed the apex, the blood drop is illuminated accompanied by frequent short beeps.
- 3.9. The file clip may be disconnected from the file and connected back during measurement cycle without affecting normal device operation (for instance, when the file is changed to a larger number during root canal treatment or when another canal should be measured). In such cases the device detects automatically that the new measurement is initiated, the electrical contact and conductivity of the root canal are checked once more and two beeps appear as described in p. 3.3 above.
- 3.10. To prolong the lifetime of the battery it is recommended to turn the device off between measurements. After completing the measurement press **On-Off** button. If NovApex wasn't turned off manually, automatic shut-down is activated after 5 min. of idle state.
- 3.11. When NovApex is turned on, previously selected sound level is set automatically. Press **•)))** button in order to change sound volume or to turn the sound off.

4. Limited Warranty.

The manufacturer warrants this product against defects in materials and workmanship for a period of 24 months from the date of purchase, but not more than 30 months from the date of manufacture (not including cables and batteries). The warranty period for cables and batteries is 6 months. During the warranty period a product determined by the manufacturer to be defective will be repaired or, at our option, will be replaced at no charge. The warranty does not apply if the product has been damaged by accident, abuse, misuse, or as a result of service or modification other than by person authorized by the manufacturer. The warranty is in lieu of any other warranty expressed or implied.

5. Disclaimer.

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

The manufacturer reserves the right to implement changes and modifications of the product at any time, to revise this publication and to make changes in the contents hereof without obligation to notify any person of such changes, modifications or revisions.

6. Precautions.

Do not use NovApex near devices emitting electromagnetic noise such as fluorescent lamps, film viewers, ultrasonic devices, etc. Cellular phones, remote controls or other devices generating electromagnetic waves may cause abnormal operation of NovApex. Such devices should be turned off.

NovApex was not tested on patients with implanted electro-medical devices (pacemakers, etc.). Use of NovApex on patients or by personnel with such devices should be avoided.

7. Maintenance, cleaning and sterilization.

NovApex is maintenance free and doesn't require any routine maintenance. The device doesn't contain user serviceable parts. The service and repair should be provided by trained service personnel only.

The device may be cleaned from dust using slightly wet cloth or tissue.

The accessories that are inserted into the patient's mouth during device operation (Lip Clip and File Clip) should be sterilized between the patients to avoid disease transfer from patient to patient. These items are designed to withstand multiple standard wet sterilization in autoclave at 134 °C.

8. Certification.

NovApex complies with the following standards: IEC 60601-1 (Safety) and IEC 60601-1-2 (Electromagnetic compatibility), including immunity tests as specified for equipment of Group 1 Class B.

NovApex is covered by the “CE Marking of Conformity” certificate. The device bears the following CE identification mark:



9. European Authorized Representative.

European Authorized Representative who has been empowered to enter into commitments in our behalf:

EASYDENT
13 Place de la Nation 75011 Paris, France.
Tél. & Fax 33. 1.43.73.62.10
R.C.S. Paris B 397 769 480 (94B09899)
Email: easydent@aol.com
President: Iris BAT-GENSTEIN

10. Technical description.

NovApex electronic apex locator belongs to following category of medical devices:

- Internally powered equipment (2 AA type 1.5V batteries)
- Type BF 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

NovApex is intended for use in electromagnetic environment specified for equipment of Group 1 Class B.

Technical specifications

Dimensions: 114 x 74 x 22 mm (4.5" x 3" x 0.85")
Weight: 130 gr. (4.5 oz.)
Power source: 2x AA 1.5V batteries

11. Standard symbols.

On the device label appear standard symbols as follows:



Class II equipment



Type BF applied part



Consult instructions
for use



Direct current



Disposal of device in
accordance with European
requirements



Manufacturer

BOX CONTENT

No	Description	Code	Qty
1	Apex locator NovApex	Y-N21-001	1 pc.
2	AA 1.5V Batteries	Y-EP9-651	2 pc.
3	Measuring cable	Y-EP8-530	1 pc.
4	File clip	Y-EP8-522	2 pcs.
5	Lip clip	Y-MC1-501	2 pcs.
6	User manual	Y-AN2-212	1 pc.



Do not connect or plug any other accessories except the items specified above.

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