

# NovApex

APEX LOCATOR

User Manual



## ***Table of Contents***

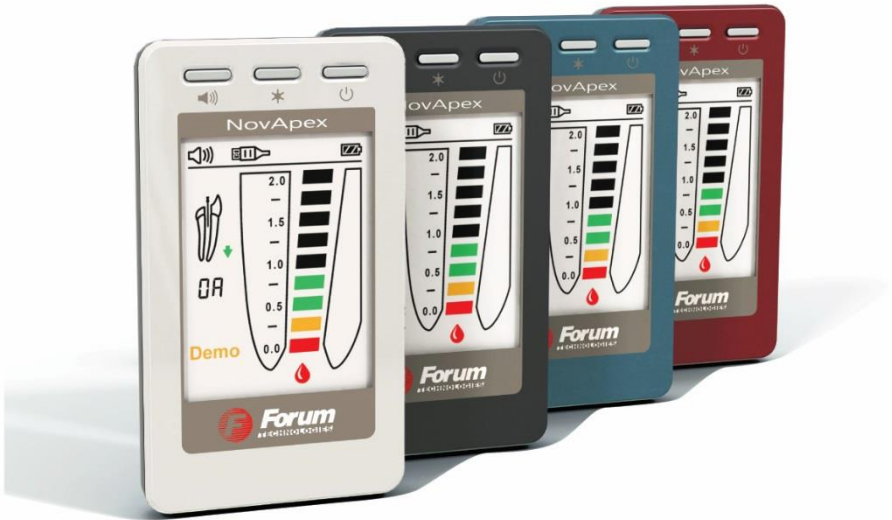
Introduction .....	2
1. Indications for use .....	3
2. Contraindications .....	3
3. Warnings .....	3
4. Precautions .....	3
5. Adverse Reactions .....	4
6. Step-by-Step Instructions .....	4
6.1. Packaging Box Content .....	4
6.2. Getting Started .....	4
6.3. Installing / Replacing the Batteries.....	5
6.4. Device operation .....	6
6.5. Cable connection test .....	6
6.6. Apex localization.....	7
6.7. Audio feedback .....	9
6.8. Demo Mode.....	9
6.9. Automatic Shutdown .....	9
7. Maintenance, cleaning and sterilization .....	9
8. Troubleshooting .....	11
9. Warranty .....	12
10. Disclaimer .....	13
11. Certification .....	13
12. European Authorized Representative .....	13
13. Technical Specifications .....	14
14. Standard symbols .....	14

**FOR DENTAL USE ONLY**

## **Introduction**

Congratulations, you have made a good choice with NovApex. Ergonomic user-friendly design of NovApex makes it a choice of preference in modern dental clinic.

Utilizing the advantages of well proven patented technology, NovApex is a precise, user-friendly, affordable apex locator suitable both for skilled endodontic experts and for general practitioners performing root canal treatments. Custom color graphic display of NovApex helps to achieve optimal performance during working length determination.



**NovApex Apex Locator**

## **1. *Indications for use***

NovApex is an electronic device used for apex localization and working length determination during root canal treatment. The device enables to obtain correct results in canals with various conditions – dry and wet.

## **2. *Contraindications***

The NovApex is not recommended for use in patients that have a pacemaker or other implanted electrical devices.

## **3. *Warnings***

This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

## **4. *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.
- During device operation protect NovApex from occasional spillage of liquids.
- Do not use NovApex in presence of flammable materials.
- NovApex should be used with the manufacturer's original accessories only.
- In order to prevent infectious agent transmission it is highly recommended to use a rubber dam system during the endodontic procedure.
- To ensure that short circuits do not impair the measurements, avoid any contact between metal crowns, bridges or amalgam fillings and the file or the lip clip.
- Make sure that the canal is wet enough to provide electrical conductivity.
- Ensure that the file does not touch other instruments.
- Avoid excessive liquids inside the tooth cavity to prevent overflow and incorrect measurements. Teeth with open apices may give imprecise results.
- Usage of NaOCl with concentrations higher than 5 % may result in reduced accuracy of the measurements.
- Apex locator may not be able to provide correct measurements in all conditions. In any case, it is recommended to take an X-Ray prior to device use and to compare the results obtained by both methods.
- For your own safety, please use personal protection gear (gloves, mask).
- NovApex should be stored at normal temperature (< 60°C) and humidity conditions.

## 5. **Adverse Reactions:**

None.

## 6. **Step-by-Step Instructions**

### 6.1. *Packaging Box Content*

Check the content of the packaging box before use:

- NovApex apex locator - 1 pc.
- Cradle - 1 pc.
- Lithium coin cell - 2 pc. battery CR2032
- Measuring cable - 1 pc.
- Lip clip - 2 pcs.
- File clip - 2 pcs.
- Touch probe - 1 pc.
- Screw driver - 1 pc.
- User Manual - 1 pc.

### 6.2 *Getting Started*

On the front panel 3 pushbuttons are located:



Sound



Mode



On/Off



Measuring cable receptacle is placed on the right side of the device. Battery compartment is located on the rear side of the device. The device can be used with or without cradle.




**Measuring cable receptacle**

## 6.3 Installing / Replacing the Batteries

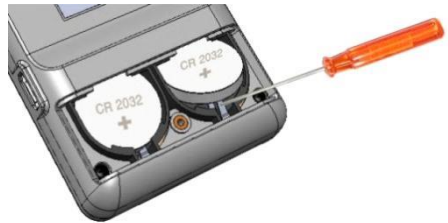
NovApex is powered by 2 standard Lithium coin cell batteries, type CR2032.

-  Prior to battery replacement the device must be turned off.
-  Before replacing the batteries measuring cable should be disconnected from the patient and removed from NovApex device.

- 6.3.1 To install / replace the batteries, release the screw and remove the battery compartment cover on the rear side of the device (Pic. 1a).
- Remove old batteries from battery holders using a small screwdriver as shown in Pic 1b.
  - Insert each of the new batteries into the battery holder, slide it forward and down until it is fully seated in the holder.
  - Close the battery compartment and secure the cover with the screw.
-  Take care for correct polarity ("+" must be on top of the battery).

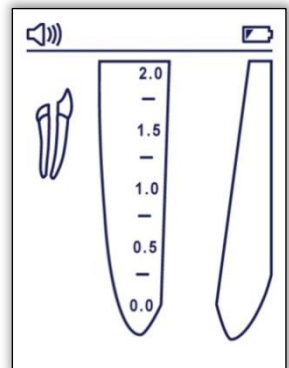


Pic. 1a



Pic. 1b


- 6.3.2 When the batteries are depleted, blinking Low Battery indicator will appear in the upper right corner of the screen (Pic.2). NovApex will continue normal operation even with low batteries, but the batteries should be replaced before it becomes flat.
- 6.3.3 If the batteries are flat, blinking Low Battery indicator will be accompanied by 3 beeps and the device turns off automatically.

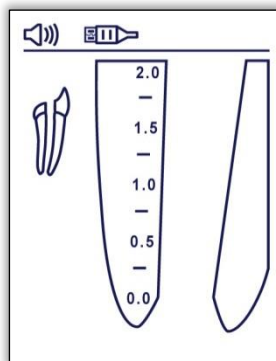


Pic. 2

## 6.4 Device operation

Prior the first use, it is recommended to sterilize the Lip Clip, the Touch Probe and the File Clip. Please refer to section 7 for further information regarding NovApex maintenance.

- 6.4.1. Turn the device on by pressing On/Off button . The main screen is displayed. Status bar with cable, battery and sound level indicators is located in the upper part of the display.
- 6.4.2. Insert the measuring cable into the device receptacle and make sure that the cable icon appears on the status bar (Pic. 3).
- 6.4.3. Connect the lip clip and the file clip/touch probe to the measuring cable.
- 6.4.4. Attach the lip clip to the patient.
- 6.4.5. Insert endodontic file into the canal and connect the file clip to the file (to ensure precise measurements the file size should be adjusted to the canal diameter). Alternatively, use the touch probe to provide electrical contact with the endodontic file.




Pic. 3

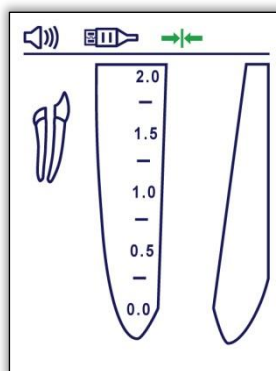
The file image inside the small tooth icon will appear accompanied by a double beep audio signal. The absence of file image and of audio feedback indicate a faulty connection. Check your connections, clean your file clip/touch probe contact, moisten the canal, if necessary, and start again.

No other adjustments are required before starting measurements.

## 6.5 Cable connection test

Connection test feature is included in NovApex in order to check the cables:

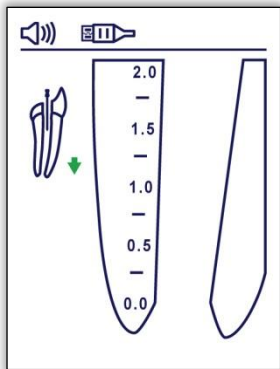
- Insert the measuring cable into the device receptacle and connect the file clip and the lip clip to the cable.
- Verify that the file clip contact and the lip clip are clean and make connection between them.
- **“Connection”** symbol  should appear on the status bar of the display, indicating proper connection (Pic. 4).
- If the symbol does not appear, the measuring cable or the file clip should be replaced.



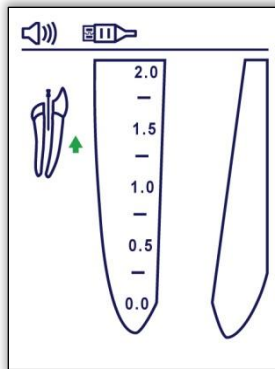
Pic. 4

## 6.6 Apex localization

Slowly introduce the file into the canal. Movement of the file inside the canal is reflected on the screen by green arrows Down and Up (Pics. 5 and 6).



Pic. 5

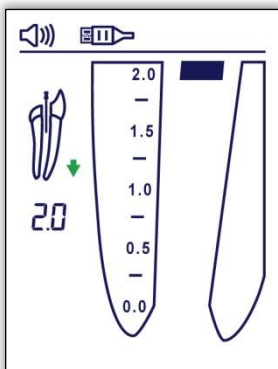


Pic. 6

Along the pre-apical zone a zoomed view of file progression in the canal is shown on the enlarged root image in the right side of the display, and numerical value appears on the left side of the display under the tooth image.

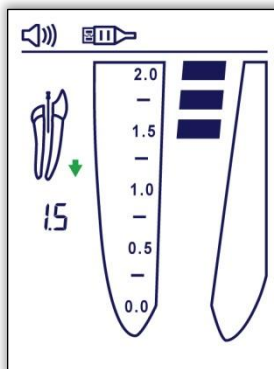
NovApex provides audio feedback of file progression as a series of beeps with variable rate.

Beginning of  
Pre-Apical Zone



Pic. 7

Pre-Apical Zone



Pic. 8

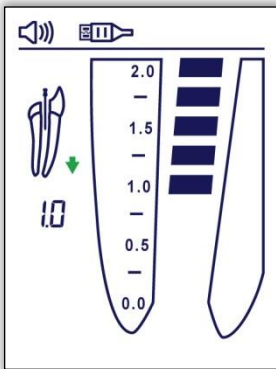


### 6.6.1 Apical Zone

File position in the Apical Zone is visually indicated by color segments inside the root canal image and numerical readings 1.0, 0.75, 0.5, 0.25 and 0.0 under the tooth image in the left part of the display.

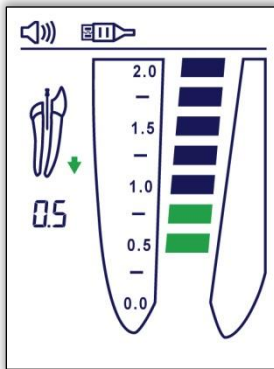
File progression in the apical zone is accompanied by a series of beeps with variable rate. When the apical position is reached (read bar at the mark 0.0), solid tone is emitted.

Beginning of the Apical Zone



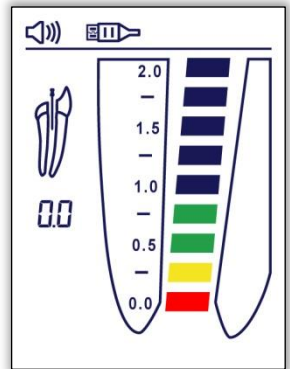
Pic. 9

Mid-Apical Zone



Pic. 10

Apical position



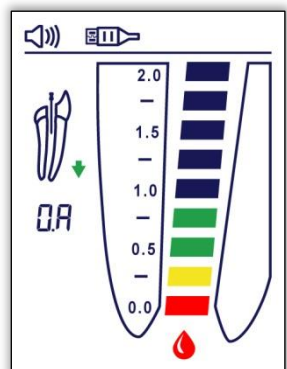
Pic. 11

The apical position indicated by NovApex (read bar at the mark 0.0) corresponds to file tip position at minor apical foramen.

Working length determination is a subject of dentist's professional judgment. In most cases subtraction of 0.5 mm from the apical length provides clinically acceptable working length. Nevertheless, in each case the dentist should define proper working length basing on his experience, apex locator readings, radiographs and other available data.

### 6.6.2 Over-instrumentation

A red "Blood drop" and warning sound indicate that the file has passed the apex. "O.A" reading appears in the left part of the screen under the tooth image (Pic. 12).



Pic. 12

## 6.7. Audio feedback

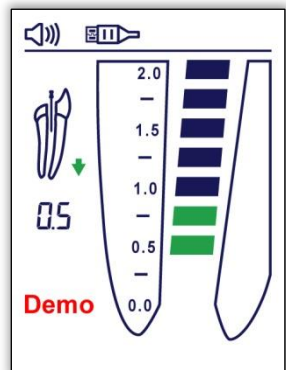
NovApex is equipped with an audio indicator which enables monitoring of the progression of the file within the canal in the pre-apical and apical zones.

The sound volume can be adjusted to one of four levels: mute, low, normal and high, by successively pressing the volume button (🔊).

## 6.8. Demo mode

The built-in Demo mode is available to demonstrate operation of the device and to improve the learning curve of the operator.

- 6.8.1 Disconnect the measuring cable from NovApex, if connected, and turn the device on.
- 6.8.2 To start Demo Mode, press and hold the Mode button ★ for about 1 sec. until the second beep sounds and “Demo” indication appears on the screen.
- 6.8.3 During Demo cycle the operating sequence of the device is shown on the screen. Press Mode button ★ to pause the simulation; press ★ button again to resume.
- 6.8.4 When Demo cycle is completed, it is repeated automatically until interrupted by the operator.
- 6.8.5 To exit Demo mode press and hold the Mode button ★ for about 1 sec. until a beep sounds.



Pic. 13

### **Note:**

If measuring cable is inserted into the device receptacle during Demo cycle, NovApex exits Demo mode and switches automatically to regular operation mode.

## 6.9. Automatic Shutdown

NovApex automatically shuts down after 2 minutes without use. In order to prolong the battery life, it is recommended to switch off the device after completing the measurements by pressing the On/Off button (🔌).

## 7. Maintenance, cleaning and sterilization

### 7.1. General

- The device does not contain user serviceable parts. The service and repair should be provided by factory trained service personnel only.
- All objects that were in contact with potentially infectious agents should be cleaned after each use:

**Lip Clip, File Clip** and **Touch Probe** should be disinfected and sterilized by autoclaving between treatments. Please follow “Disinfection and sterilization procedure” described in section 7.2.

**Measuring cable, the device and the cradle** should be cleaned using tissue or soft cloth impregnated with aldehyde free disinfecting and detergent solution (a bactericidal and fungicidal).



The measuring cable cannot be autoclaved.



Use of agents other than specified above may cause damage to the equipment and its accessories


## 7.2. Disinfection and sterilization procedure

#	Operation	Instructions	Details and Warnings
1	Preparation at the point of use prior to processing	No particular requirements.	
2	Preparation for decontamination/ preparation before cleaning	No particular requirements.	
3	Cleaning: Automated	The accessories are not intended for automated cleaning.	
4	Cleaning: Manual	Clean the accessories with an adequate brush or towel soaked in a disinfectant solution.	<ul style="list-style-type: none"> <li>- The file clip should be activated during cleaning process (pressed and released several times).</li> <li>- After cleaning no visible impurities should remain on the accessories.</li> </ul>
5	Disinfection	<ul style="list-style-type: none"> <li>- Soak the required accessories in a disinfectant solution combined with proteolytic enzyme if possible.</li> <li>- Rinse well the accessories in flowing water.</li> </ul>	<ul style="list-style-type: none"> <li>- Follow instructions given by the disinfectant manufacturer (concentration, immersion time, etc.).</li> <li>- Do not use disinfectant solution containing aldehyde, phenol or any products which may damage the items.</li> </ul>
6	Drying	No particular requirements.	
7	Maintenance, inspection and testing of the accessories	No particular requirements.	

#	Operation	Instructions	Details and Warnings
8	Packaging	Pack the devices in sterilization pouches.	<ul style="list-style-type: none"> <li>- Check the validity period of the pouch given by the manufacturer to determine the shelf life of the sterilized items.</li> <li>- Use packaging which is resistant up to a temperature of 141°C (286°F).</li> </ul>
9	Sterilization	<ul style="list-style-type: none"> <li>- Steam sterilization at 135°C (275°F) during 10 minutes in gravity type autoclave. (Table Top, N type)</li> <li>- Drying time after sterilization – 30 minutes.</li> </ul>	<ul style="list-style-type: none"> <li>- Follow maintenance and operation procedures of the autoclave provided by the manufacturer.</li> <li>-The only sterilization parameters to be used are those that have been validated and provided to the user in this User Manual.</li> </ul>
10	Storage	Keep devices in sterilization packaging in a dry and clean environment.	<ul style="list-style-type: none"> <li>- Sterility cannot be guaranteed if packaging is open or damaged (check the packaging before using the instruments).</li> </ul>

## 8. Troubleshooting

Please review the suggested solutions before calling customer service.

#	Problem	Possible Cause	Solution
1	The device does not turn on by pressing On/Off button.	<ol style="list-style-type: none"> <li>1. The button may be functioning incorrectly.</li> <li>2. The batteries may be empty.</li> <li>3. Electronic malfunction.</li> </ol>	<ol style="list-style-type: none"> <li>1. Press the On/OFF button several times.</li> <li>2. Replace the batteries.</li> <li>3. Contact your customer service.</li> </ol>
2	The device shuts off while measuring.	<ol style="list-style-type: none"> <li>1. The device was not used for more than 2 min.</li> <li>2. The batteries are flat.</li> </ol>	<ol style="list-style-type: none"> <li>1. Turn on the device.</li> <li>2. Replace the batteries.</li> </ol>
3	No sound while measuring.	“Sound control” set at “Mute” level.	Adjust the sound level by pressing the volume button  .
4	The device does not show file advance inside the canal	1. Bad electrical contact.	1. Clean contact surfaces of the file, the file clip and the lip clip and perform cable connection test as described in the § 6.5.

		2. Electronic malfunction.	2. Contact your customer service.
5	Incorrect measurements	<ol style="list-style-type: none"> <li>1. Dry/calcified canal.</li> <li>2. Restoration treatment - conductive pass is blocked.</li> <li>3. Blood or irrigation liquid overflow provides conductive path outside the canal.</li> <li>4. Deep caries provides conductive path outside the canal.</li> <li>5. Metal crown or metal filling provide conductive path outside the canal.</li> <li>6. Perforation.</li> </ol> <ol style="list-style-type: none"> <li>7. Large lateral canal.</li> </ol>	<ol style="list-style-type: none"> <li>1. Irrigate the canal.</li> <li>2. Remove old canal filling to open the path, irrigate the canal.</li> <li>3. Dry the excessive liquid.</li> </ol> <ol style="list-style-type: none"> <li>4. Block the external conductive path.</li> <li>5. Avoid contact between the file and metal crown/filling.</li> <li>6. Remove the file, close the perforation and repeat the measurements, carefully inserting the file into canal.</li> <li>7. Try to continue the measurements (gently advance the file towards apex until regular readings appear).</li> </ol>

## 9. **Warranty**

NovApex is warranted for 24 months from the date of purchase. The accessories (cables, batteries, etc.) are warranted for 6 months from the date of purchase.

The warranty is valid for normal usage conditions. Any damage caused by accident, abuse, misuse, or as a result of service or modification other than by a person authorized by the manufacturer will render the warranty void. The warranty is in lieu of any other warranty expressed or implied.

## **10. 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.

## **11. Certification**

NovApex complies with the following standards: IEC 60601-1 (Safety) and IEC 60601-1-2 (Electromagnetic compatibility), including conducted and radiated 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:



## **12. 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.**

**Tel. & Fax 33. 1.43.73.62.10**

**R.C.S. Paris B 397 769 480 (94B09899)**

**Email: [easydent@aol.com](mailto:easydent@aol.com)**

**President: Iris BAT-GENSTEIN**

### 13. **Technical Specifications**

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

- Internally powered equipment
- Type BF applied parts
- Not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide
- Continuous operation
- Ingress of liquids – not protected
- The device is intended for indoor use only
- 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.

#### Specifications:

Dimensions: 93 x 54 x 13 mm  
Weight: 60 gr.  
Type of screen: Custom Color Graphic LCD  
Screen dimensions: 51 x 38 mm  
Power source: 2 x CR2032 Lithium cell batteries

### 14. **Standard symbols**

On the device label appear standard symbols as follows:



Class II equipment



Type BF applied part



Direct current



Manufacturer



Consult instructions for use



Recycling : PLEASE DO NOT THROW AWAY! This product and all its components must be recycled through your supplier

**Forum Engineering Technologies (96) Ltd.  
1 Platin St., New Industrial Zone,  
Rishon Lezion 7565339, Israel  
Tel :972-3-9625517 Fax :972-3-9613355  
www.forumtec.net E-mail :info@forumtec.net**

