

NovApex

APEX LOCATOR

User Manual



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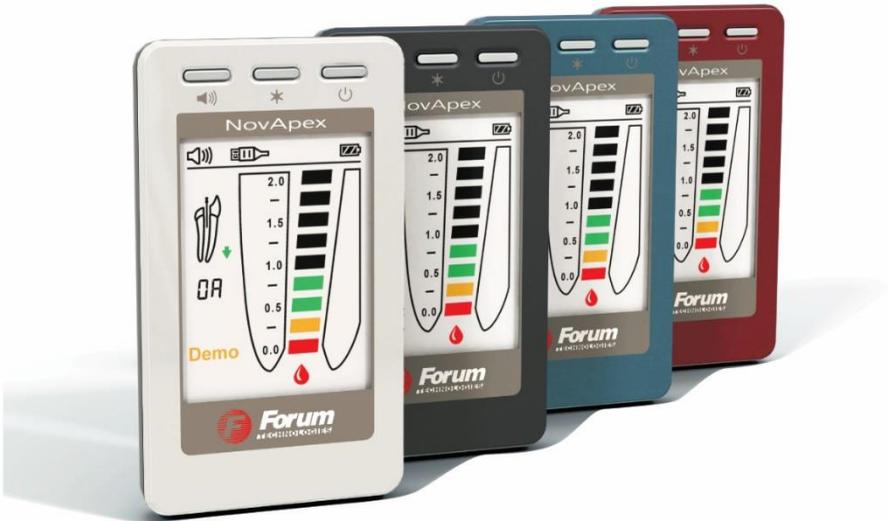
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DIRECTIONS FOR USE

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, be particularly careful with patients fitted with metal crowns or bridges (avoid any metallic contact with the file or the Lip Clip).
- High concentrations of sodium hypochlorite may result in a lower accuracy of the measurements. For working length determination, we recommend to use sodium hypochlorite solution at maximum 3% concentration.
- Make sure that the canal is wet enough to ensure reliability of the measurement.
- 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.
- 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).

5. *Adverse Reactions:*

None.

6. Step-by-Step Instructions

6.1 Installing the Batteries

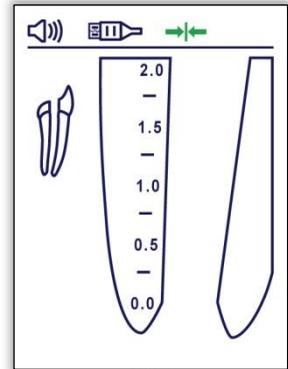
Before the first use of **NovApex** install the batteries as explained in section 7.

6.2 Cable connection test

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

- Insert the Measurement cable with attached Lip Clip and File Clip into the device receptacle.
- 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. 1).
- If the symbol  does not appear, the Measurement cable or the File Clip should be replaced.

Note: Measurement cable with attached Lip Clip and File Clip constitute Applied Parts of the device.

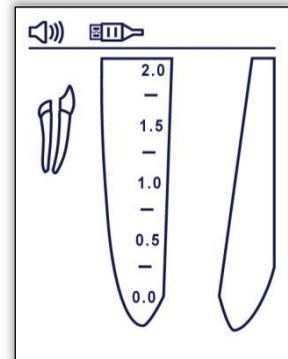


Pic. 1

6.3 Getting Started

Prior the first use, it is recommended to sterilize the Lip Clip, the File Clip and the Touch Probe. Please refer to section 8 for further information regarding **NovApex** maintenance.

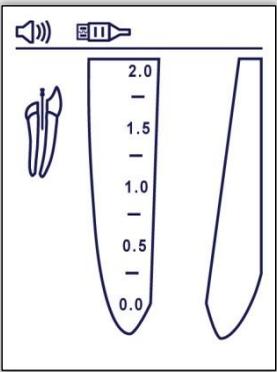
- 6.3.1. Turn the device on by pressing  (On/Off) button. The main screen is displayed. Status bar with battery and sound level indicators is located in the upper part of the display.
- 6.3.2. Before connecting the Measurement cable with attached Lip Clip and File Clip to the patient, plug the Measurement cable into the device receptacle and make sure that the cable icon appears on the status bar (Pic. 2).
- 6.3.3. Attach the Lip Clip to the patient.
- 6.3.4. Gently insert endodontic file into the root canal and connect the File Clip to the file (to ensure precise measurements the file size should be adjusted to the canal diameter).



Pic. 2

Alternatively, use the Touch Probe to provide electrical contact with the endodontic file.

6.3.5 The file image inside the small tooth icon will appear accompanied by a double beep signal (Pic. 3). Absence of file image and of audio signal indicates a faulty connection. In such case disconnect the Measurement cable from the patient, check cable connections, clean File Clip/Touch Probe contact, moisten the canal, if necessary, and start again.
No other adjustments are necessary before starting measurements.

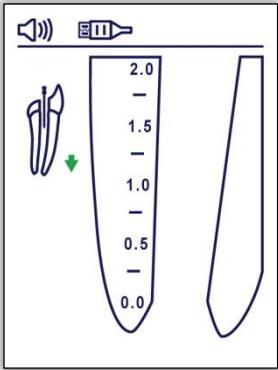


Pic. 3

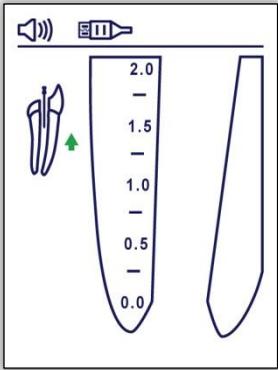
6.4 Apex localization

6.4.1 Coronal and Medial Zone

Slowly move the file forward inside the root canal. The progression of the file inside the canal is reflected on the screen by green arrows Down and Up (Pic. 4 and Pic. 5).



Pic. 4

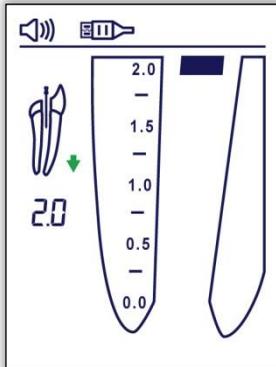


Pic. 5

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 values from 2.0 to 1.25 appear on the left side of the display under the tooth image (Pic. 6 and Pic. 7).

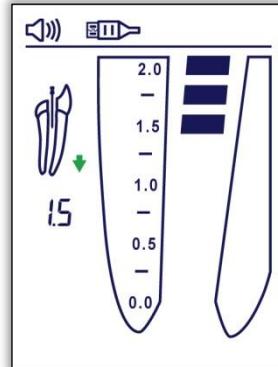
NovApex provides audio feedback of file progression as a series of progressive rate beeps.

Beginning of Pre-Apical Zone



Pic. 6

Pre-Apical Zone



Pic. 7

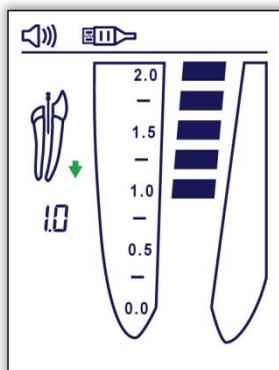
6.4.2 Apical Zone

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 appearing under the tooth image in the left part of the display (Pic. 8 and Pic. 9).

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 (Pic. 10).

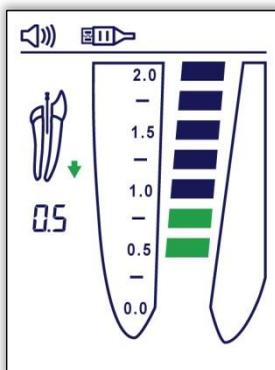
The apical position indicated by **NovApex** corresponds to file tip position at minor apical foramen.

Beginning of the Apical Zone



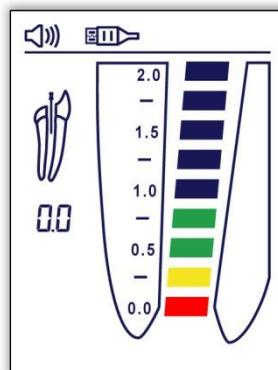
Pic. 8

Mid-Apical Zone



Pic. 9

Apical position



Pic. 10

6.4.3 Over-instrumentation

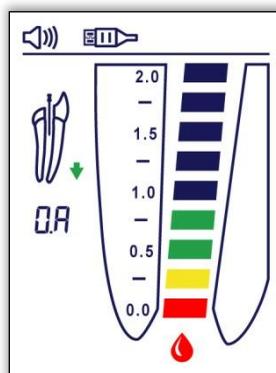
A red "Blood drop" icon and warning sound indicate that the file has passed the apex. "O.A" reading appears in the left part of the screen under the tooth image (Pic. 11).

To return to the apical position, gently retreat the file until the "Blood drop" disappears and "0.0" indication returns.

Note: Numerical values shown in the pre-apical and apical zones serve as a convenient reference to judge the file tip position in relation to the apex, but they do not represent the actual distance from the apex in mm.

6.4.4 Completion of the measurements

- Before unplugging the Measurement cable from the device receptacle, disconnect the Lip Clip and the File Clip from the patient.
- Move the file stopper to the selected reference point on the tooth.



Pic. 11

- Gently remove the file from the canal and measure the apical length between the stopper and the file tip.
- Determination of working length for canal shaping is a subject of dentist's professional judgment. In most cases subtraction of 0.5 mm from the measured 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.

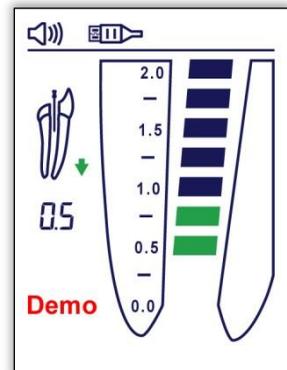
6.5 Audio feedback

NovApex is equipped with an audio indicator which accompanies file progression within the canal in the pre-apical and apical zones. This function, is activated in parallel with Apical Zoom display and enables monitoring of file advance in the apical zone, even without seeing the display. Successively pressing the volume key  you may adjust the sound volume to one of four levels: Mute, Low, Normal and High.

6.6 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 Measurement cable from the device, 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 (Pic. 12).
- 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. 12

Note: If Measurement cable is plugged into the device receptacle during Demo cycle, **NovApex** exits Demo mode and switches automatically to regular operation mode.

6.7 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  button.

7. **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 Measurement cable should be disconnected from the patient and removed from the device.

7.1 To install / replace the batteries, release the screw and remove the battery compartment cover on the rear side of the device (Pic. 13a).

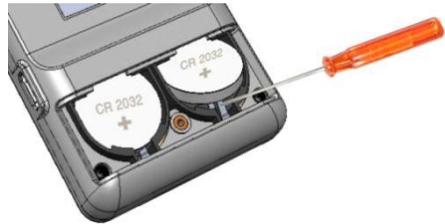
- Remove old batteries from battery holders using a small screwdriver as shown in Pic 13b.
- Insert each of the new batteries into the battery holder, slide it forward and down until it is fully seated in the holder.
- Close the battery compartment and secure the cover with the screw.



Take care for correct polarity ("+" must be on top of the battery).



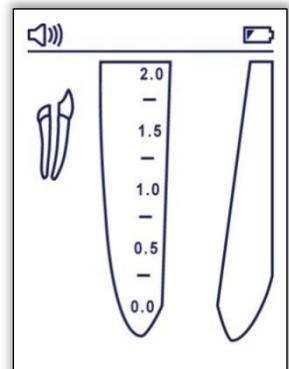
Pic. 13a



Pic. 13b

7.2 When the batteries are depleted, blinking Low Battery indicator will appear in the upper right corner of the screen (Pic.14). **NovApex** will continue normal operation even with low batteries, but the batteries should be replaced before it becomes flat.

7.3 If the batteries are flat, blinking Low Battery indicator will be accompanied by 3 beeps and the device turns off automatically.



Pic. 14

8. Maintenance, cleaning and sterilization

8.1 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 8.2.

Measurement 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 Measurement cable cannot be autoclaved.



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

8.2 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	- The File Clip should be activated during cleaning process (pressed and released several times) - After cleaning no visible impurities should remain on the accessories
5	Disinfection	- Soak the required accessories in a disinfectant solution combined with proteolytic enzyme if possible. - Rinse well the accessories in flowing water	- Follow instructions given by the disinfectant manufacturer (concentration, immersion time, etc.) - Do not use disinfectant solution containing aldehyde, phenol or any products which may damage the items

6	Drying	No particular requirements.	
7	Maintenance, inspection and testing of the accessories	No particular requirements	
8	Packaging	Pack the devices in sterilization pouches	<ul style="list-style-type: none"> - Check the validity period of the pouch given by the manufacturer to determine the shelf life of the sterilized items - Use packaging which is resistant up to a temperature of 141°C (286°F)
9	Sterilization	<ul style="list-style-type: none"> - Steam sterilization at 135°C (275°F) during 10 minutes in gravity type autoclave. (Table Top, N type) - Drying time after sterilization – 30 minutes 	<ul style="list-style-type: none"> - Follow maintenance and operation procedures of the autoclave provided by the manufacturer - The only sterilization parameters to be used are those that have been validated and provided to the user in this User Manual
10	Storage	Keep devices in sterilization packaging in a dry and clean environment	Sterility cannot be guaranteed if packaging is open or damaged (check the packaging before using the instruments)

9. *Troubleshooting*

Please review the suggested solutions before calling customer service.

#	<i>Problem</i>	<i>Possible Cause</i>	<i>Solution</i>
1	The device does not turn on by pressing  button	<ol style="list-style-type: none"> 1. Malfunction of the button 2. The batteries are flat 3. Electronic malfunction 	<ol style="list-style-type: none"> 1. Press  button several times 2. Replace the batteries 3. Contact your customer service
2	The device shuts off while measuring	The batteries are flat	Replace the batteries
3	No sound while measuring	“Sound control” set at “Mute” level	Adjust the sound level by pressing  button
4	The device does not show file advance inside the canal	<ol style="list-style-type: none"> 1. Bad electrical contact 2. Electronic malfunction 	<ol style="list-style-type: none"> 1. Perform cable connection test as described in section 6.25 2. Contact your customer service

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

10. 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. Within the warranty period the manufacturer undertakes, at its sole discretion, to repair or replace the faulty item without charge.

This product has been developed specifically for use in dentistry and is intended to be operated only by qualified dental professionals in accordance with the instructions contained in this manual. However, notwithstanding anything contained herein, the user shall at all times be solely responsible for determining the suitability of the product for the intended purpose and the method of its use. Any guidance on technology application offered by or on behalf of the manufacturer, whether written, verbal or by demonstration, shall not relieve the dental professional from his/her obligation to control the product and to make all professional judgments regarding its use.

Except for the warranties specifically set forth in this manual, the manufacturer provides no warranties or guarantees of any kind covering the product, expressed or implied, including, without limitation, any warranties as to merchantability or fitness for a particular purpose. Any claim for damage or breakage to the product in transit should be made to the carrier promptly upon discovery.

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.

11. 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.

12. 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:



13. European Authorized Representative

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

CEpartner4U B.V.
ESDOORNLAAN 13, 3951 DB MAARN, THE NETHERLANDS.
Contact Person: Mr. Ton Pennings
Tel. +31 343 442 524, Fax +31 343 442 162
Email: office@cepartner4u.com

14. Technical Specifications

NovApex electronic apex locator is a programmable electrical medical device

- 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 storage/transportation:
 - Temperature: -20 °C to +60 °C (0 °F to 140 °F)
 - Relative humidity: 10% to 90%, non-condensing
 - Atmospheric pressure: 106 kPa to 19 kPa
- Environmental conditions during device usage:
 - Temperature: +10 °C to +40 °C (50 °F to 104 °F)
 - Relative humidity: 10% to 90%, non-condensing
 - Atmospheric pressure: 106 kPa to 70 kPa

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 (6V)

15. 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

16. 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
- Measurement cable - 1 pc.
- Lip clip - 2 pcs.
- File clip - 2 pcs.
- Touch probe - 1 pc.
- Screw driver - 1 pc.
- User Manual - 1 pc.

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