ToDent RomiApex™ A-15

APEX LOCATOR

User Manual

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Introduction

We congratulate you for making the right choice of preferring our new and advanced Apex Locator **ToDent RomiApex™ A-15** over other good quality and known devices available on the market.

Utilizing the advantages of its well proven patented technology, **ToDent RomiApex™ A-15** offers both the highly skilled endodontic and the general practitioner performing root canal treatments a precise, user-friendly, easy to use apex locator. Custom color graphic display of **ToDent RomiApex™ A-15** helps to achieve optimal endodontic performance required during your root canal treatments.

ToDent RomiApex™ A-15 apex locator

1.   Indications for use

- **ToDent RomiApex™ A-15** is an electronic device used for apex localization and working length determination during root canal treatment.
- ToDent RomiApex™ A-15 is indicated for patients who need to undergo root canal treatment, which requires precise determination of position of the dental file in the canal relatively to the root apex
- This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

2.   Precautions

ToDent RomiApex™ A-15 was not tested on patients with implanted electro-medical devices (pacemakers, etc.). Use of **ToDent RomiApex™ A-15** on patients or by personnel with such devices should be avoided.

Do not use **ToDent RomiApex™ A-15** 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 **ToDent RomiApex™ A-15**. Such devices should be turned off.

- ToDent RomiApex™ A-15 should not be used in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- ToDent RomiApex™ A-15 must be stored in a dry place at temperatures between +10°C and 50°C (50⁰F and 104⁰F).
- Caution: Federal law restricts this device to sale by or on the order of a physician or licensed dental practitioner.

3.   Adverse Reactions:

None.

4.   Package Contents

Check the contents of the package before use:

- 1 **ToDent RomiApex™ A-15** apex locator
- 1 Cradle
- 1 AAA 1.5V alkaline battery
- 1 Measurement cable
- 2 File clips
- 5 Lip clips
- 1 Touch Probe
- 1 Screwdriver (for battery compartment)
- 1 User Manual

5.   Getting Started

5.1   General

On the front panel two pushbuttons are placed:

⏻   On/Off

◀)   Sound adjustment

Measuring cable receptacle is placed on the left side of the device.

Battery compartment is located on the rear side of the device.

The device can be used with or without its cradle.

Prior the first use, it is recommended to sterilize the Lip Clip, the Touch Probe and the File Clip. Please refer to section 6 for further information regarding maintenance of **ToDent RomiApex™ A-15**.

5.2   Installing / Replacing the Battery

ToDent RomiApex™ A-15 is powered by standard AAA size 1.5V alkaline battery.

5.2.1   To install / replace the battery, release the screw and remove the battery compartment cover on the rear side of the device (Pic. 1a).
Remove the old battery (if was installed) using the built-in strip; insert the new battery (correct battery polarity ⊕ is marked inside the battery compartment, Pic. 1b), close the battery compartment cover and secure it with its screw.
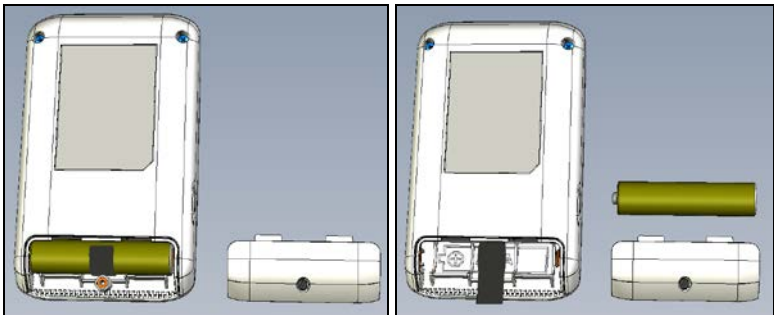

Pic. 1a   Pic. 1b

- 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 the ToDent RomiApex™ A-15 device.

5.2.2 When the battery is depleted, blinking Low Battery indicator will appear on the screen (Pic.2). **ToDent RomiApex™ A-15** will continue normal operation even with low battery, but the battery should be replaced before it becomes flat, as described in section 5.2.1 above.
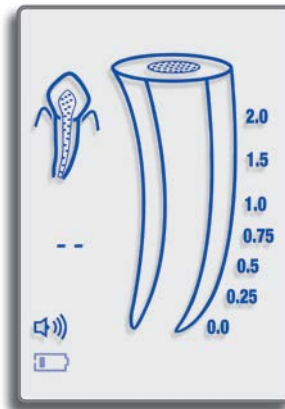
Pic. 2

5.3 Device operation

5.3.1 Plug-in the measurement cable into the device, and connect the lip clip and the file clip to the cable.

5.3.2 Press the On-Off ⏻ button to turn the device on. The initial image appears on the display (Pic. 3). The small tooth image will blink indicating no measurement signal.
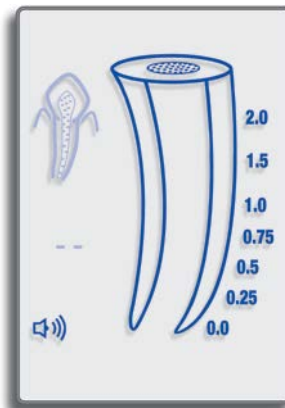
Pic. 3

5.3.3 Put the lip clip on the patient's lip.

5.3.4 Insert the endodontic file into the root canal and connect the file clip to the endodontic file.

⚠️ **Make sure that irrigation solution, blood or saliva are not overflowing from the tooth cavity, dry the cavity before performing measurements.**

5.3.5 **ToDent RomiApex™ A-15** detects automatically beginning of measurements, checks the quality of the electrical contact and the conductivity of the root canal.

5.3.6 When the electrical contact is good, an audio signal of two beeps indicates beginning of normal measurement cycle. Tooth image will stop blinking.

⚠️ If there are no beeps, clean the file clip and the file, irrigate the canal, if required, and continue the measurements. **It is not recommended to continue measurements if the tooth image blinks.**

5.3.7 Movement of the file inside the canal is reflected by the **DOWN** (Pic. 4) and **UP** (Pic. 5) arrows on the screen.
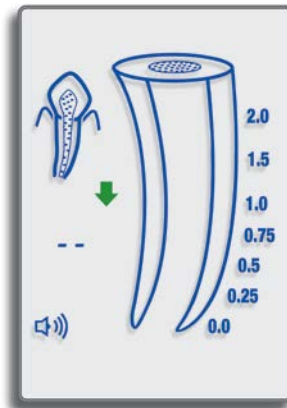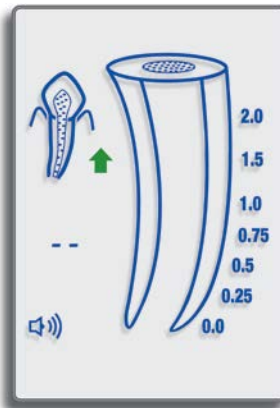
Pic. 4   Pic. 5

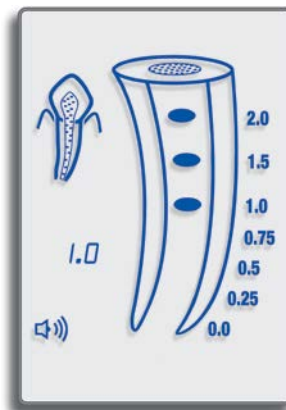5.3.8 File position in the median and the apical zones is visually indicated by color segments inside the root canal image and numerical readings 2.0, 1.5, 1.0, 0.75, 0.5, 0.25, 0.0 (Apex/Foramen) accompanied by audio signals with varied frequency (Pic. 6-9).
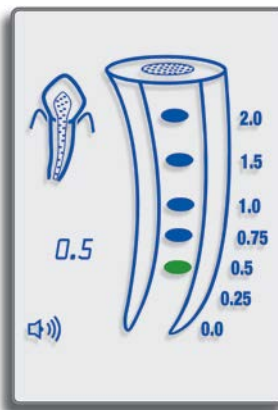
Median Zone (Blue)
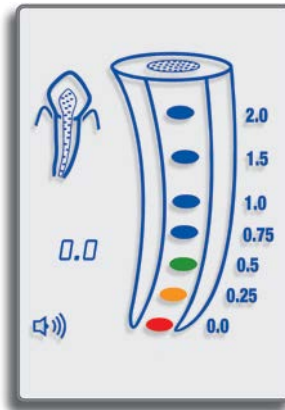

Pic. 6

Beginning of the Apical Zone (Blue)   Mid Apical Zone (Green)

Pic. 7   Pic. 8

5.3.9 At the apical file position (0.0) solid audio tone is emitted (Pic. 9).

Apex (Red)

Pic. 9

5.3.10 In the case of over-instrumentation, the red **OVER** indicator is turned on, accompanied by alarm beeps. "**Fo**" reading - indicates 'Foramen over-instrumentation'-, appears in the numerical field (Pic. 10).

OVER (Red)
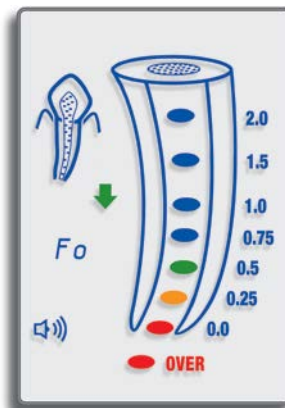
Pic. 10

5.3.11 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 again and two beeps are sounded.

5.3.12 **ToDent RomiApex™ A-15** 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. **ToDent RomiApex™ A-15** enables precise apex localization independently of root canal conditions (dry, wet, with blood, pulp, gangrene, etc.). In case of very dry canal or during restoration you may use irrigation solution as hypochlorite or sodium chloride etc. to provide conductive path during measurements.

5.4   Audio feedback

ToDent RomiApex™ A-15 is equipped with an audio indicator which enables monitoring of the progression of the file within the canal in the apical zone.
This function is activated in parallel with progression of the file. It enables monitoring of file advance in the apical zone even without seeing the display.

The volume can be adjusted to one of the four levels: mute, low, normal and high. The adjustment is performed by successive pressings of the volume key 🔊.

5.5   Automatic Shutdown

ToDent RomiApex™ A-15 automatically shuts down after 5 minutes without use. In order to prolong the battery life, after completing the measurements it is recommended to switch the device off by pressing the On/Off key ⏻.

6.   Maintenance, cleaning and sterilization

6.1 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 6.2.

  Measurement cable, **the device and its 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.**

6.2 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.	- Check the validity period of the pouch given by the manufacturer to determine the shelf life. - Use packaging which is resistant up to a temperature of 141°C (286°F).
9	Sterilization	- Steam sterilization at 135°C (275°F) during 10 minutes in gravity fed type autoclave. (Table Top, N type) - Drying time after sterilization – 30 minutes.	- 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).

7.   Certification

ToDent RomiApex™ A-15   is tested for compliance with IEC 60601-1:1988 safety standard, and IEC 60601-1-2:2007 (Electromagnetic compatibility), including conducted and radiated immunity tests as specified for equipment of Group 1 Class B.

ToDent RomiApex™ A-15   is covered by the "CE Marking of Conformity Certificate", reference number: 5017.04.01/0 issued on 09.06.2006 and delivered by MDC Medical Device Certification GmbH, Notified Body Identification number 0483. The device bears following CE identification mark:

CE
0483

8.   European Authorized Representative

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

Romidan (UK) LTD.
122-126 Tooly Street, London Bridge
London SE1 2TU,
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Fax:	+44 (0) 207-403-1026 / 1028
Email:	export@romidan.com
Website:	www.romidan-dental.com
Contact Person:	Mr. Eitan Margalit, General Manager

9.   Limited Warranty

ToDent RomiApex™ A-15 is warranted for 24 months from the date of purchase. The accessories (cables, battery 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.

Any modifications made to the equipment without explicit approval from Tandartsen Onderling voids warranty obligations and poses a potential safety threat to both operator and patient.

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.   Technical Specifications

ToDent RomiApex™ A-15 electronic apex locator belongs to the following category of medical devices:

- Internally powered equipment (AAA 1.5V alkaline battery)
- Type BF applied parts
- Not suitable for use in 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: –20ºC to +60ºC
 (0 to 140ºF); relative humidity: 10% to 90%, non-condensing

ToDent RomiApex™ A-15 is intended for use in electromagnetic environment specified for equipment of Group 1 Class B.

Specifications:
Dimensions: W55 x H92 x T16 mm
Weight: 100 gr.
Type of screen: Custom Color Graphic LCD
Screen dimensions: 51 x 38 mm
Supply: AAA 1.5V alkaline battery

12.   Standard symbols

On the device label appear standard symbols as follows:

1.5V	Direct current		Type BF applied part
	Consult instructions for use		Manufacturer
	Recycling : PLEASE DO NOT THROW AWAY! This product and all its components must be recycled through your supplier		
Rx	Caution: Federal law restricts this device to sale by or on the order of a physician or licensed dental practitioner.		

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BUNNIK, The Netherlands

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55022 Kiryat Ono, Israel