

RomipeX™ D-30 Apex Locator – User Manual

We congratulate you for making the right choice of preferring our new and advanced Apex-Locator **RomipeX™ D-30** over other good quality and known apex locators available on the market.

Utilizing the advantages of its innovative, patent protected technology, the **RomipeX™ D-30** apex locator offers the highly skilled endodontist as well as the general practitioner performing root canal treatments a precise user-friendly easy to use apex locator equipped with unique large graphic display and digital readouts for getting the optimal endodontic performance required during your root canal treatments.



RomipeX™ D-30 apex locator

1. Package Contents

- 1 RomipeX™ apex locator
- 1 Charger
- 1 Measurement cable
- 2 Lip clips
- 2 File clips
- 1 Touch Fork
- 1 User manual

2. Short description

Design of RomiiAPEX™ is based on innovative technology (USA patent No. 6,425,875). Advanced microcomputer based electronics combined with proprietary software algorithm results in precise, easy-to-use apex locator. Large graphic display with additional digital readout enables visual feedback during entire root canal measurements as well as precise determination of file position in the apical region.

Graphic display includes:

1. Canal region (Round target shape).
2. Apical region with digital readout (Circle inside the target shape).
3. File status indicator (root shape with file icon)
4. Battery indicator.
5. Cable indicator.
6. Sound volume indicator.

On the front panel two pushbuttons are placed:



Battery charging LED is placed in the bottom of the panel and it turns on during battery charging.

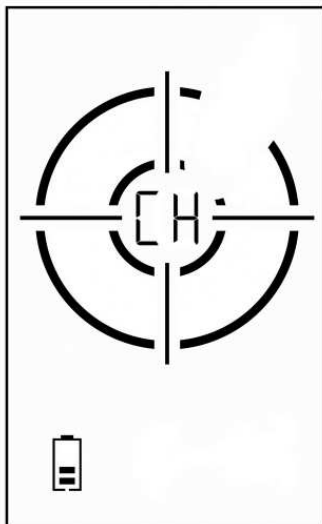
On the left side of the device 2 receptacles are placed: the upper one - communication port and the lower one for measuring cable and charger connection. Rear support may be unfolded during operation and folded for transportation.

3. Battery charging

RomiiAPEX™ is powered by a NiMH rechargeable battery. The battery status is shown in the bottom left part of the display during operation and while recharging.

If the battery is fully discharged (the device doesn't turn on) or is flat (the last segment on the battery status blinks) the battery should be recharged.

- Remove the measurement cable from the patient and disconnect it from the device.
- Connect the charger to the device and then to the power line outlet. The device turns on, charge screen appears and red battery charging indicator is lit.



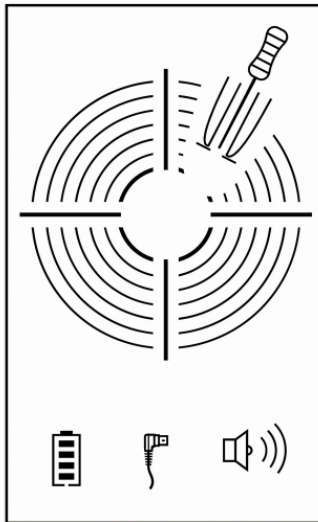
Battery status during charging is shown on battery indicator in the lower left part of the display.

To ensure maximum performance of the battery, fully discharged battery must be charged for 24 hours. When the battery is low, it must be charged overnight.

- Rechargeable battery is not intended to be replaced by the operator, but by the service personnel, if required.

4. Device operation

- Insert measurement cable into the lower receptacle on the left side of the device, connect lip clip and the file clip to the cable.
- Press **On-Off** button. The initial image appears on the display.



If cable icon is blinking, check proper cable connection. Blinking file icon indicated that the measuring circle is not closed.

- Using  pushbutton select required volume level. Selected volume level is stored in the memory and remains unchanged when **RomiAPEX™** is turned off and on again. Volume indicator is placed in the bottom part of the display.

Sequence of volume level control



- Place lip clip on patient's lip, insert endodontic file into the root canal and connect file clip to the file. To ensure precise measurements the file size should be compatible to the width of the canal. Beginning of measurements is detected automatically and two beeps appear indicating that electrical contact and conductivity of the root canal are normal. If there are no beeps, clean the hook and the file, add hypochlorite or sodium chloride solution, if required, and continue the measurements. **It is not recommended to continue measurements if there still are no beeps.**
- **RomiAPEX™** operates completely automatically without need for manual adjustments or calibrations enabling precise localization of the apex independently of root canal content (dry, wet, blood, pus, pulp, gangrene, etc.). For very dry canals use hypochlorite or sodium chloride solution to provide conductive path during measurements.

- Position of the file inside root canal is indicated by wide ring segments inside the target shape.



- When the file reaches the apical region, digital readings from 2.0 to 0.0 appear, indicating relative distance from the apex.



Advance of the file in the apical region is accompanied by audio signals. Duration of audio beeps is increased in accordance with file position. Solid tone indicates apical position of the file (0.0).

- Special visual and audio warning is provided in the case the file has passed the apical foramen: root shape with file icon is blinking, the letters "Fo" (Foramen) appear inside the circle accompanied by audio alarm signal.



- During the measurements the file clip may be disconnected from the file and connected back without affecting normal device operation (for example, when the file is changed to a larger number during root canal treatment). The device detects automatically that new measurement is initiated, the electrical contact and conductivity of the root canal are checked, and two beeps appear.
- After completing the measurements, turn **RomiAPEX™** off to prolong lifetime of the battery. The device is turned off automatically after 5 min. of idle state.

5. Precautions.

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

6. Maintenance, cleaning and sterilization.

RomiAPEX™ 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, File Clip and Touch Fork) 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.

7. Certification.

RomiAPEX™ complies with IEC60601-1 safety standard and the requirements of "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices. The device meets the provisions of the EC-Directive which apply to Class IIa, category. Manufacturer's Quality System approved for production and final inspection of the device is in accordance with Annex V of the EC-Directive.

The device bears following CE identification mark:



8. European Authorized Representative.

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

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Email: dental@romidan.com

Website: www.romidan.com

Company Number: 4768293

Contact Person: Mr. Eitan Margalit, General Manager

9. Limited Warranty.

The manufacturer warrants this product against defects in materials and workmanship for a period of 24 months from the date of purchase. During the warranty period a product determined by us 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 us. 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. Technical description.

RomiiAPEX™ belongs to following category of medical devices:

- Internally powered equipment (2.4 V NiMH rechargeable battery)
- Type BF applied parts
 - Not suitable for use in the presence of flammable anesthetic 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

Dimensions: 150 x 85 x 35 mm
Weight: 200 gr.
Power source: Rechargeable NiMH battery 2.4 v
External charger: AC input 230v, 50 Hz / 115v, 60 Hz, DC output: 7.5v

Warning: The charger should comply with the requirements of IEC 60950 standard.

12. Standard symbols.

On the device label appear standard symbols as follows:

