



PRECISE APEX LOCATOR SMART PAL BLUETOOTH

UK patent No. GB 2431358

CE 2274



Operation and Maintenance Manual

PASSPORT

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1. GENERAL DATA

PRECISE APEX LOCATOR Smart PAL (Bluetooth)

INTRODUCTION

The Operation and Maintenance Manual describes the method to measure the working length of dental root canal and information for the cautions. The Operation and Maintenance Manual has been prepared for professional use in dental clinics.

The ***PRECISE APEX LOCATOR Smart PAL*** is the latest generation of apical constriction locators, representing an entirely new approach to endodontic measurements. The novelty of precise measurement method is protected by UK patent No.GB 2431358 which contains an automatic measuring error eliminating system. Bluetooth 4.0 communication between the unit and display makes an extraordinary convenience, visibility and ergonomic of operation.

Applying the newest computerized technology, the cross-sectional view of the root canal can be displayed in a clear visual format on smart phone/tablet/computer display. The working length can be measured with high accuracy, allowing for precise positioning of the endodontic file. The tool works equally well in wet or dry root canals and reveals any cracks or perforations in the dental root. The unit allows the apical constriction to be measured very precisely and quickly, without using radiography.

Innovation: To meet consumer needs and options the *universal* unit is designed for wireless Bluetooth 4.0 operation with:

1. Smart phones/tablets using Android OS version 4.3 and higher
2. iPhones/iPads using iOS version 8.0 and higher
3. PC computers or tablets using Windows OS with supplied Lumen APEX Treatment software of different levels

2. EXPLANATION OF SYMBOLS



This combination of symbol and keyword points to a situation of possible danger which may lead to serious injury or death unless avoided.



This combination of symbol and keyword points to a possibly dangerous situation which may lead to slight or minor injury unless avoided.



Do not dispose of this product as unsorted municipal waste.



Indicates the manufacturer, and date of manufacture



Observe the instructions for use!



Degree of protection BF



Certifies compliance with the Directive 93/42/EEC



DC current energy supply from battery

3. TECHNICAL DATA

The unit gives a display of three parameters on the screen: the distance from the tip of the file to the apical constriction during the approach, the apical constriction itself when **0,5** is shown and penetration beyond the apex when "APEX" is shown.

The unit contains a triple indication of apex location: view of the file position on display, digital read-out and audible signal.

Power supply with CR 2032 type battery	3V
Power consumption (W)	0,1
Weight (g)	26
Degree of Protection according to IEC 60529	IPX1
Dimensions (mm)	60×35×20
	CE 2274

The technical data of the unit complies with Council Directive 93/42/EEC of June 1993 of Medical Devices and standards EN60601-1, EN60601-2.

4. TRANSPORTATION AND STORAGE



Precise Apex Locator Smart PAL can be transported in the manufacturer's packing only.



Precise Apex Locator Smart PAL can be transported with all types of covered transport, when temperature of atmosphere is from -10°C up to $+60^{\circ}\text{C}$, relative air humidity till 80 %, atmospheric pressure up to 1,060 hPa.

5. SPECIFICATION AND OPERATION

5.1. Specification

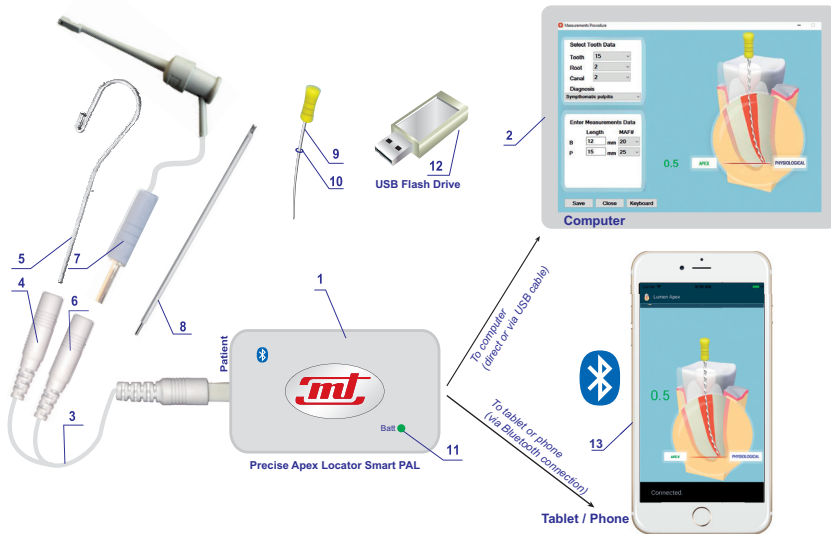






Fig. 1

1 – main unit, 2 – computer/tablet (not included), 3 – cable, 4 – socket for lip contact, 5 – lip contact, 6 – socket for endodontic clip probe, 7 – endodontic clip probe, 8 – extension probe, 9 – endodontic file (not included), 10 – rubber marker for determination of working length of root canal (not included), 11 – LED, 12 – USB Flash Drive (optional) or internet link download software (*Lumen APEX Treatment*), 13 – smart device

5.2. Directions for operation

MEASURING WORKING LENGTH OF DENTAL ROOT CANAL USING SMART IT (PHONE/TABLET)

INSTALLATION LUMEN APEX APP SOFTWARE

1. Download from  or from  *Lumen Apex App Bluetooth* and install in your smart device (phone/tablet). Smart device must have iOS 8.0 or higher version and OS Android 4.3 or higher version
 2. After the program *Lumen Apex* is installed the icon  *Lumen Apex* appears on the screen. Click on the icon and the crosssectional view of dental root canal model (white-black) appears on the screen (Fig. 2).
 3. Set the bluetooth mode of smart device in position **on**.
-  **Warning:** To prevent the interference of incoming phone calls during measuring procedure please set the smart phone into **DO NOT DISTURB** mode.
4. Plug the cable (3) into the unit socket labelled *Patient*. Insert the lip contact (5) into the socket (4) all the way to the end. Insert up to the end either the clip probe (7) or the extension probe (8) to the socket (6). Sockets (4) and (6) are identical for using both lip contact and clip probe. **To switch the unit on** connect the lip contact (5) with the metal end of the clip probe (7) or the extension probe (8) shortly and keep for a few seconds until the diode (11) once emits yellow light and starts flashing green every 4 seconds. In a short time the unit will communicate with the smart device via Bluetooth, and after connection the cross-sectional view of dental root canal model on display becomes colored (Fig. 3). The unit is ready to use.

Attach the lip contact (5) in order to maintain good contact with the oral mucosa (Fig. 4). The crown of the tooth **must be dry**. It is recommended that the canal should be wet for better contact.

5. Attach the endodontic clip probe (7) to the endodontic file (9) by pressing the spring next to the plastic head with your thumb (Fig. 4A). Move the rubber marker (10) down the file.

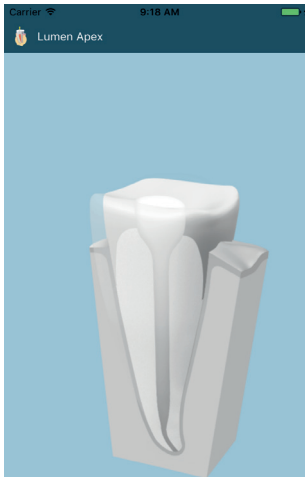


Fig. 2

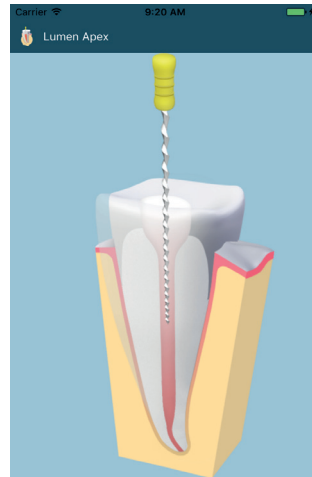


Fig. 3

6. The extension probe (8) may be used instead of the endodontic clip probe (7) when working with molars especially. Obtain the read-out showing the current position of the endodontic file in the canal by touching the “Y” end of the extension probe (8) to the endodontic file (9). This speeds up the treatment process by eliminating the need to keep the endodontic clip probe (7) in the mouth of the patient for the duration of the procedure (Fig. 4B).

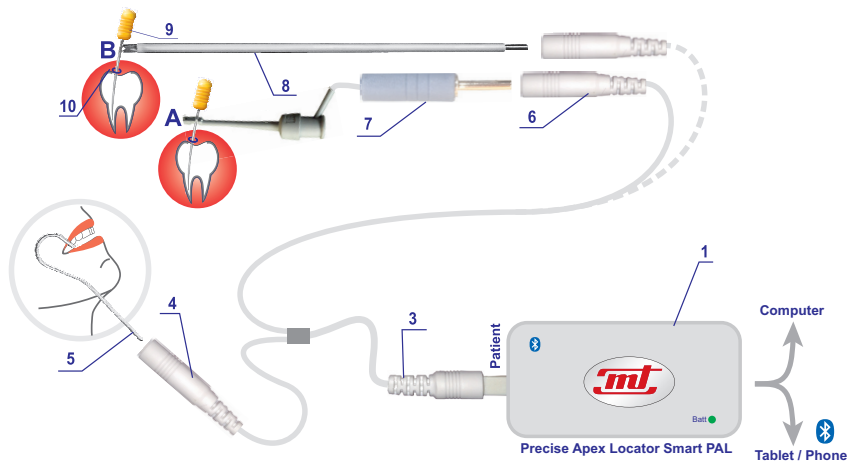



Fig. 4

7. Slowly insert the endodontic file (9) into the root canal. When the end of the file is approximately 2,0 mm or less from the apical constriction, you will see numbers appearing on the root canal model (Fig. 5). You will also hear a slow beeping signal.

Continue moving the endodontic file inwards and observe the distance on the display. The display will automatically switch to zoom mode as the distance decreases to the value 1,0 and the text APPROACH appears on display.

8. **When the endodontic file reaches the apical constriction (Fig. 6), the read-out on the display will read green colour number 0,5, you will hear a fast beeping sound and you will see the file tip touch the APEX PHYSIOLOGICAL line in the root canal model.**

 **Warning:** The read-out displays relative numbers, not the actual distance in millimeters.

To be sure dentist can take X-ray for comparison results.

If the unit is not operating it will automatically switch off after approx. 6 minutes. Upon exiting *Lumen Apex* program of the smart device the unit is simultaneously switched off.

The unit never switches off during measuring procedure.

9. After the apical constriction is determined (read-out 0,5), the length from the endodontic file tip to the rubber marker on the file will indicate the true measurement of the apical constriction (the working length). This distance should be measured in millimeters on the dentist's ruler and written in the patient's history. To get an accurate working length, the dentist should carefully choose the reference point on the tooth top which touches the rubber marker. If the endodontic file penetrates the apex (apex physiological) the notice "OVER" appears with indication of red numbers. If the endodontic file reaches apex anatomical a continuous sound is produced with a read-out 0.0 (Fig. 7). Lifting the file up one reaches the apical constriction again (Fig. 6) with a typical read-out 0,5 and interrupted sound.

10. **There is one very important extra feature.** If the unit senses a root crack or perforation when the dentist moves the endodontic file in the root canal, it will emit a long, continuous beep, the word “**OVER**” will appear, and the read-out will display **0.0** (similar to what is shown in Fig. 7). The crack or perforation may exist at any distance in the root canal and it must be carefully filled.

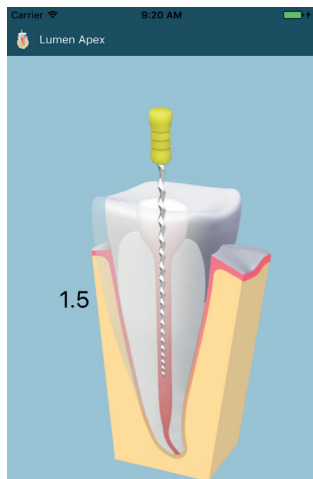


Fig. 5

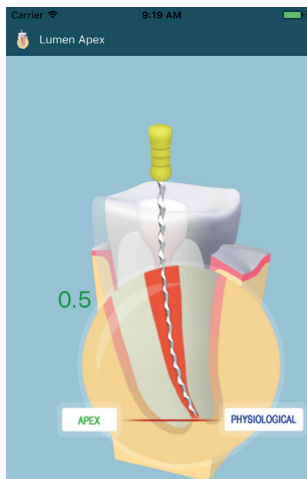


Fig. 6

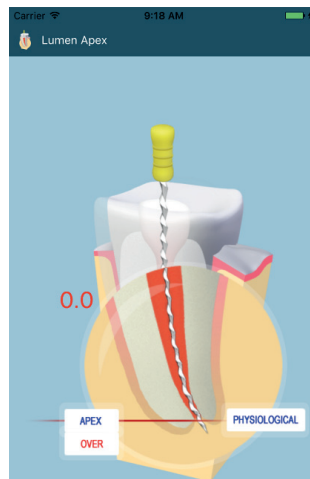


Fig. 7

6. UTILIZATION



After the lifecycle of components and units they must be disposed of in accordance with applicable regulations.

7. OPERATION SAFETY



CAUTION



WARNING

- **DO NOT USE THE UNIT IN CONJUNCTION ON PATIENTS HAVING THE PACEMAKERS**
- Do not use the unit with electric surgical operation instruments.
- The other devices or parts which have been not indicated by manufacturer should not be connected in conjunction of this unit.
- Please read the User's Manual before starting to operate.
- Keep away the unit from strong magnetic fields.
- Keep away the unit from water or high humidity, it is not water proof.
- Do not dismantle the unit. Warranty service shall not be applied in this case.
- Only authorized service can be used for the repair Precise Apex Locator Smart PAL.
- It is forbidden to make any modifications of the unit and its components.
- Clinic use only
- Use only the manufacturer's recommended accessories. Otherwise, the manufacturer is not responsible for the possible consequences.
- Use only CR 2032 type 3V battery.

8. MAINTENANCE AND REPAIR

CHECKING DEVICE IF TROUBLESHOOTING

The unit is automatic and does not require any adjustment or special maintenance. In case of no indication of the moving file on the display during work the dentist can check himself very easily the proper operation of unit and the integrity of the cable.

Place the lip contact (5) on the lip. While pressing the spring of clip probe (7) with the thumb, touch with the internal surface of the mouth or lip with its metal contact. The display should indicate “APEX” and the unit produces a continuous signal. This means that the **unit operates properly**, the cable (3) and clip probe (7) are good.

If there is no moving file on the display again, replace the endodontic file with another one of smaller diameter (number) that allows to reach apical constriction. If it does not help, replace the cable with a new one.

The unit will not indicate when the canal is plugged with pieces of dentin (take them out) or the apical constriction is calcified. To be sure take the X-ray picture.

If the unit indicates APEX permanently when the endodontic file is inserted in dental root canal and blood overflows the canal, clean and dry carefully the canal and try again to get exact readings of the working length of dental root canal.

The unit indicates APEX permanently when metal crown is on the tooth. The measurement is possible only if the endodontic file is isolated from metal crown.

Note. *The contact of clip probe (7) always must be clean and protected against oxidation.*

CLEANING AND STERILIZATION. The surface of main body of the unit should be cleaned with a cloth impregnated with soap and water. The surface of smart device display should be wiped with the soft cloth soaked with ethanol (80 vol %).

Cable cleaning instruction: Please wipe the cable with a soft cloth soaked with ethanol (80 vol %) and reuse it after it is completely dry. Do not autoclave the cable.

Instruction of autoclaving parts. Clip probe, lip contact and extension probe are recommended to be autoclaved at the temperature 135°C for more than 10 minutes when placed in a sterilization pouch. Front part of clip probe, lip contact and extension probe must be washed and cleaned before autoclaving. Autoclave sterilization is required after each patient.

BATTERY. Battery type CR 2032 is used. The unit uses innovative low energy BLE technology to assure very long lasting operation. When the red battery colour appears on smart device display the battery is to be replaced. Unscrew two screws on cover, gently remove electronic board and pressing the spring release the old battery. The new battery must be inserted with + symbol up side (Fig. 8).

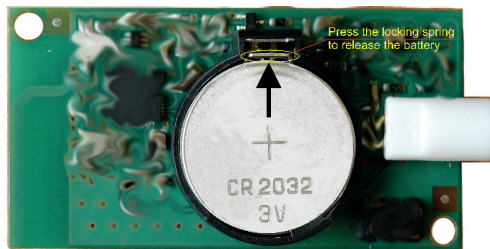


Fig. 8

Lifetime of Precise Apex Locator Smart PAL is 10 years.

9. COMPLETE AND SPARE PARTS

1. Precise Apex Locator Smart PAL (Main unit)		1 pcs.
2. Accessories		
• Cable	CA1	1 pcs.
• Clip Probe	CA2	1 pcs.
• Lip Contact	CA3	2 pcs.
• Extension Probe	CA4	1 pcs.
3. USB Flash Drive	CA5	1 pcs.
4. User Manual		1 pcs.
5. Packaging		1 pcs.



Cable CA1



Clip Probe CA2



Lip Contact CA3



Extension Probe CA4



USB Flash Drive CA5

10. PASSPORT

Manufacture's acceptance certificate

Precise Apex Locator Smart PAL is completed and licensed to use

S.N. _____

Precise Apex Locator Smart PAL fully complies with standards EN60601-1, EN60601-2 and directive 93/42/ECC requirements, tested and passed for use.

Manufacture's inspectors: _____

Manufacture's guarantee

The manufacturer guarantees compliance of technical characteristics of Precise Apex Locator Smart PAL, if the **User** observes the storage, transportation and operating conditions. The guaranteed service time of unit is 12 months from day of purchase and 6 months for accessories (cable and clip probe).

The manufacturer repairs and replaces damaged parts during all guarantee period on his own costs if guarantee service ticket with manufacturer and seller seals is provided.

Manufactured by:



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Date of selling

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Seller's signature: _____

11. TECHNICAL SERVICE NOTES

No.	Date	Actions	Responsible person's name and signature

00.2016.P1.SP.v10

User's manual