

PRECISE APEX LOCATOR COMPACT PAL

UK patent No. GB 2431358

CE 2274



Operation and Maintenance Manual

PASSPORT

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1. GENERAL DATA

The ***PRECISE APEX LOCATOR Compact PAL*** is the latest generation of apical constriction locators, representing a 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.

Applying the newest IT technology the working length of the root canal can be measured with high accuracy, presenting a visual positioning of the endodontic file in the cross-sectional view of the root canal which contains the marks for both *apex physiological* and *apex anatomical*. 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 quickly, without using radiography.

2. EXPLANATION OF SYMBOLS



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



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

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 consumption (DC) 2 × 1,5 V AA size batteries	3V
Power consumption (W)	0,1
Weight (g)	175
Degree of Protection according to IEC 60529	IPX1
Dimensions (mm):	120×68×28
	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 Compact PAL can be transported in the manufacturer's packing only.



Precise Apex Locator Compact 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

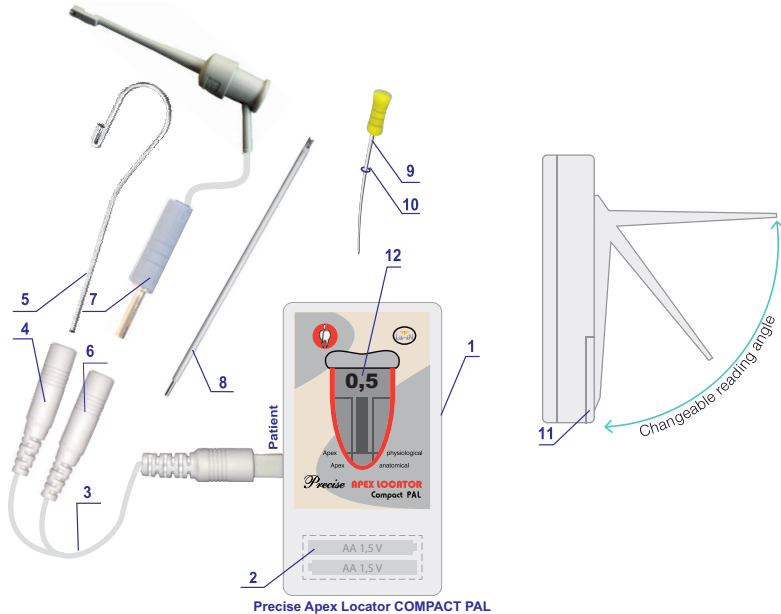


Figure 1

1 – main unit, 2 – batteries, 3 – cable, 4 – socket for Lip Contact, 5 – Lip Contact, 6 – socket for Clip Probe, 7 – Clip Probe, 8 – Extension Probe, 9 – endodontic file, 10 – rubber marker for determination of working length of root canal, 11 – battery cover, 12 – display.

5.2. Directions for operation

1. Remove cover *11* and place in the compartment 2 of the unit body 2 pcs. of 1,5V AA alkaline type batteries. Insert the cable 3 in the main unit body socket (Fig. 1).
2. Insert up to the end the Lip Contact 5 to the socket 4. 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. Pressing the spring with the thumb attach the Clip Probe 7 perpendicularly to the file 9 *close* to the plastic head. Move the rubber marker 10 down the file. The Extension Probe 8 can be used for convenience according to version B in Fig. 2.
3. To switch the unit on connect for few seconds shortly Lip Contact 5 with metal end of Clip Probe 7 (version A of Fig.2) or with Extension Probe 8 (version B of Fig. 2). The display 12 indicates the battery condition. If the notice “LOW BATTERY” is on the display replace the battery. After few seconds the root canal model will appear on the display 12. The unit is ready for the operation.
4. Attach the Lip Contact 5 in order to get good contact with the oral mucosa (Fig. 2). The crown of tooth **must be dry**. The canal should be naturally wet.
5. The anaesthetic should then be administered to the patient.
6. Slowly insert the endodontic file 9 into the canal. When the file approaches the distance 2,5–2,7 mm to the apical constriction, the display will show the moving file in the root canal model and relative digits. A slow beeping signal accompanies the read-out informing the approach to the apex (Fig. 3 A). Gently go on moving the file inwards and observing the distance on the display.

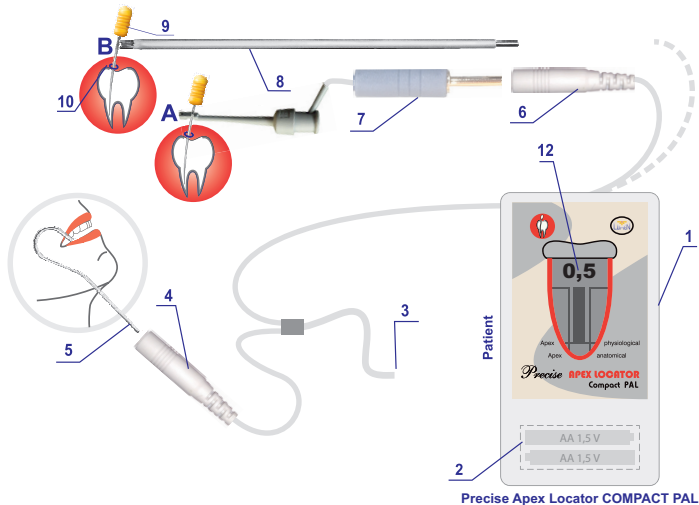


Figure 2

- When the file reaches the apical constriction (*apex physiological*) the read-out on the display is flashing 0,5, a fast beeping is produced and the file tip touches the flashing line in the root canal model (Fig. 3 B).

After the apical constriction is determined, the length of the endodontic file tip to the rubber marker on the file indicates the true distance of the apical constriction (working length).

NOTE. *Digits on the unit display do not mean millimeters. To be sure dentist can take X-ray for comparison results.*

8. If the instrument penetrates the apex (apex anatomical) a continuous sound is produced and the notice “APEX” appears (Fig. 3 C). Lifting the file up one reaches the apical constriction again (Fig. 3 B) with a typical read-out 0,5 and interrupted sound.
9. If the unit is not operating it will automatically switch off after 10 minutes. The unit never switches off during measuring procedure.

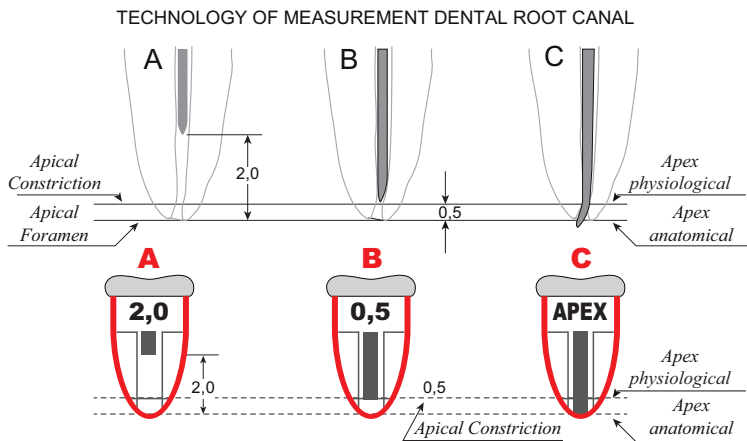


Figure 3

6. UTILIZATION



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

7. OPERATION SAFETY



- Only authorized service can be used for the repair Precise Apex Locator Compact PAL.
- It is forbidden to make any modifications of the unit and its components.
- Clinic use only
- Use only the manufacturer's recommended accessories and batteries. Otherwise, the manufacturer is not responsible for the possible consequences.



- **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.

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 calcificated. 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.*

The unit and accessories should be inspected in clinic minimum one time a year.

CLEANING AND STERILIZATION. The surface of main body of the unit should be cleaned with a cloth impregnated with soap and water.

Cable cleaning instruction: Please wipe the cable with the soft cloth stained 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 recommended to be autoclaved at the temperature 135°C more than 10 minutes 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.

9. COMPLETE AND SPARE PARTS

1. Precise Apex Locator Compact 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. User Manual		1 pcs.
4. Packaging		1 pcs.



Cable CA1



Clip Probe CA2



Lip Contact CA3



Extension Probe CA4

10. PASSPORT

Manufacture's acceptance certificate

Precise Apex Locator Compact PAL is completed and licensed to use

S.N. _____

Precise Apex Locator Compact 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 Compact 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

Seller's signature: _____

11. TECHNICAL SERVICE NOTES

No.	Date	Actions	Responsible person's name and signature

10.2016.P1.CP.v02