MEDICAL TECHNOLOGIES
- An American-Lithuanian Joint Venture Company

PRECISE APEX LOCATOR SMART PAL

UK patent No. GB 2431358

CE 2274

Operation and Maintenance Manual

PASSPORT

CONTENT

1. GENERAL DATA

PRECISE APEX LOCATOR Smart PAL
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.

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 quickly, without using radiography.

> *Innovation*: **To meet consumer needs and options the *universal* unit is designed for operation with:**
> 1. **Smart phones/tablets using Android OS**
> 2. **PC computers or tablets using Windows OS**

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 from phone/computer

Double insulation (class II equipment)

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 via USB OTG cable	**5V**
Power consumption (W)	**0,1**
Weight (g)	**35**
Degree of Protection according to IEC 60529	**IPX1**
Dimensions (mm):	**80×40×20**
	$C\epsilon$ 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

WARNING

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

WARNING

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°C, relative air humidity till 80 %, atmospheric pressure up to 1,060 hPa.

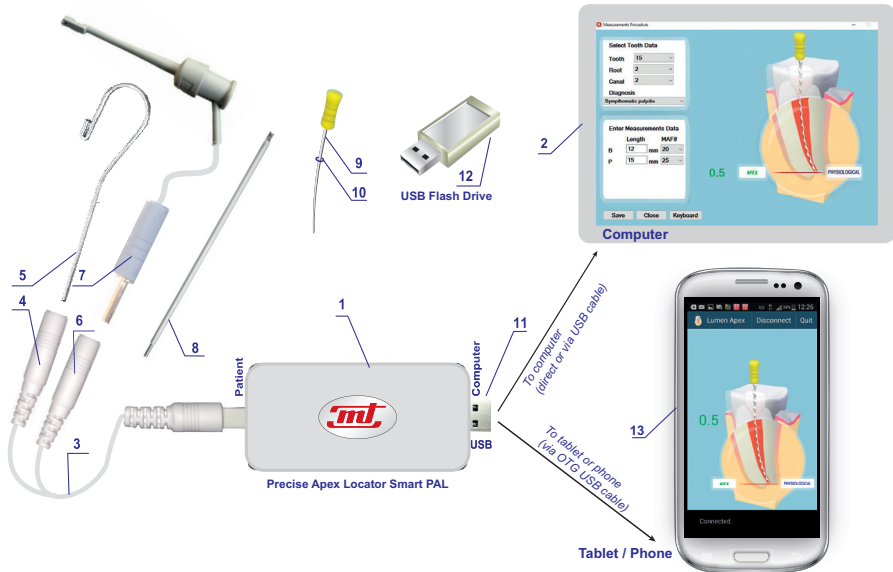## 5.1. Specification

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* – USB connection, *12* – USB Flash Drive with software (*Lumen APEX Treatment*)**,** 13-smart phone/tablet (not included)

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 app *Lumen Apex* and install in your smart device (phone/tablet). Device must have OS Android 4.0 or higher version and USB – OTG cable support.

2. After the program *Lumen Apex* is installed the icon Lumen Apex appears on the screen. Click on the icon and the crossectional view of dental root canal model (white-black) appears on the screen (Fig. 2).

3. Connect the unit to the phone/tablet using a standard USB-OTG cable (Fig. 1). Press button **Connect** (Fig. 3). The crossectional view of dental root canal model changes into colorful picture. This means that the unit is energized and ready to use (Fig. 4).

⚠ **Warning:** To prevent the interference of incoming phone calls during measuring procedure please set the smart phone into **Blocking calls,** e.g. **Airplane** 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. Attach the lip contact (*5*) in order to maintain good contact with the oral mucosa (Fig. 5). 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. 5A). Move the rubber marker (*10*) down the file.
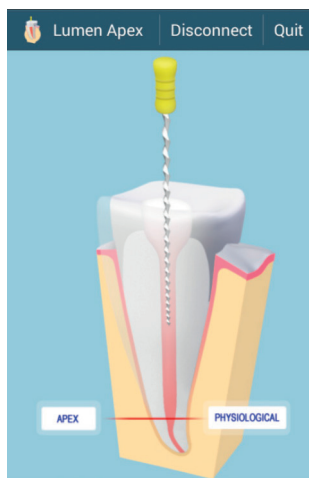
| Fig. 2 | Fig. 3 | Fig. 4 |

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. 5B).

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. 6). 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.
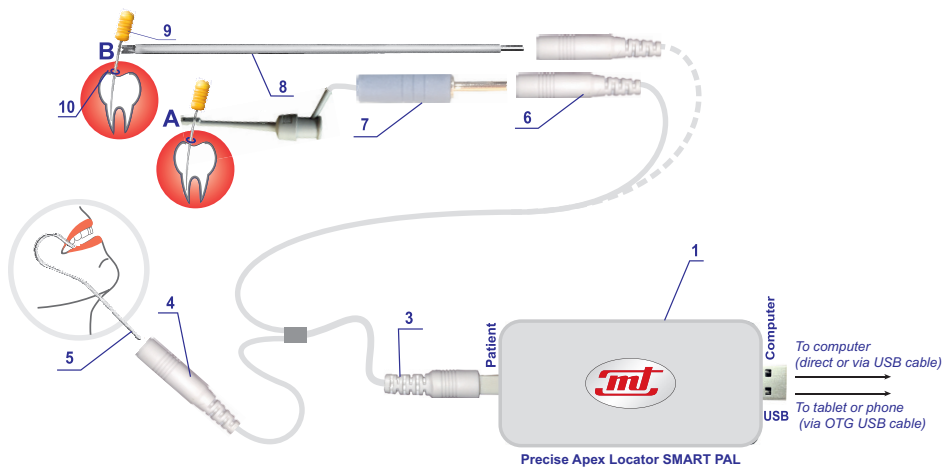

Fig. 5

8. **When the endodontic file reaches the apical constriction (Fig. 7), 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. 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.

⚠️ **Warning:** If the endodontic file penetrates the apex (apex physiological) the notice "**OVER**" appears. If the endodontic file reaches apex anatomical a continuous sound is produced with a read-out 0.0 (Fig. 8). Lifting the file up one reaches the apical constriction again (Fig.7) with a typical read-out 0,5 and interrupted sound.

⚠️ **Warning:** 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. 8). The crack or perforation may exist at any distance in the root canal and it must be carefully filled.
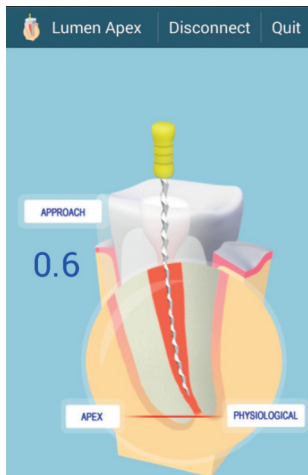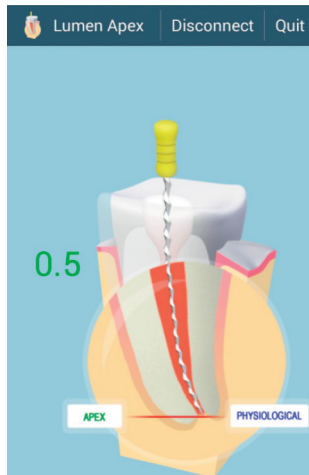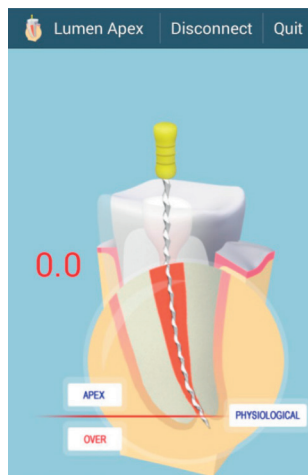
| Fig. 6 | Fig. 7 | Fig. 8 |

**MEASURING WORKING LENGTH OF DENTAL ROOT CANAL
USING COMPUTER (WINDOWS 7 OR HIGHER OS)**

INSTALLATION OF THE LUMEN APEX TREATMENT PROGRAM SOFTWARE

1. Insert the ***Lumen APEX Treatment*** software USB Flash Drive into the USB port of the computer. Launch Lumen Apex Treatment install wizzard ⚡ ApexInstallWizard.exe file from USB Flash Drive.

2. Click the ***Lumen APEX Treatment*** button on the installation wizard menu (Fig. 9). This will run the ApexSetup.exe file and start the installation process (Fig. 10). Approximately 100 MB free space of hard disk is required. Windows 7 or higher OS version is applicable.
3. The next screen allows you to identify the location on the computer's hard drive where the program will be installed. The default option is *program files*. If you would like to modify this, click the ***Change...*** button and select the directory where you would like the program to be installed (Fig. 11).
4. If you would like to change some of the selections that you have made on the installation screens, pressing the ***Back*** button will return you to the previous screen (Fig.12).
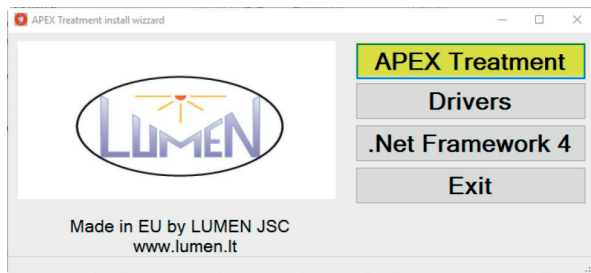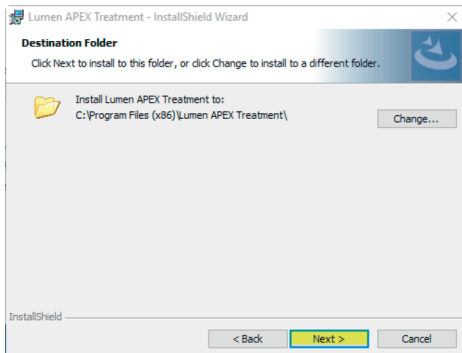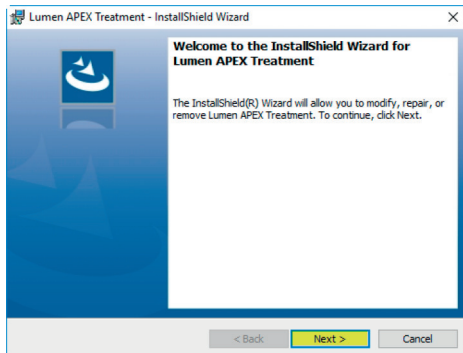

Fig. 9

Fig. 10

Fig. 11
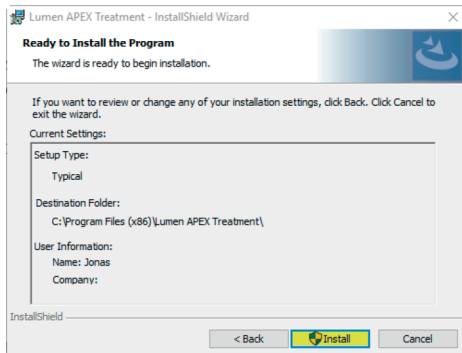
Fig. 12

5. Pressing the ***Install*** button on the last screen will start the installation process (Fig.12).
6. The installation process takes a few minutes only. When it has been completed, press the ***Finish*** button to exit the installation screen. Installation wizard creates shortcut icon that will be placed on your computer's desktop:

Lumen APEX Treatment

⚠️ **Warning:** During the software installation process the drivers and the .Net Framework will be installed automatically. In case of the software installation process without internet access drivers and .Net Framework must be installed manually. In that case press buttons ***Drivers, .Net Framework 4*** on the installation wizard menu and install manually (Fig.13).
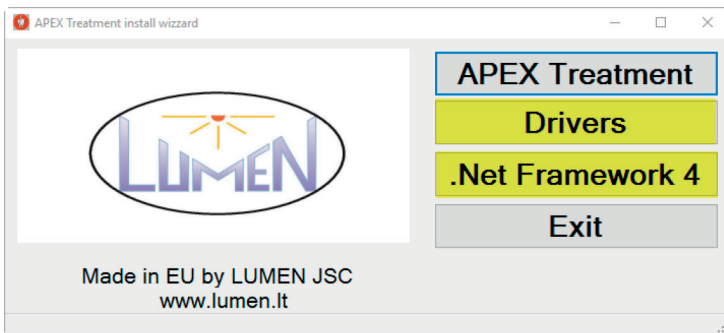
Fig. 13

Use of Software LumenAPEX Treatment

1. Connect the unit to the computer directly or via extension USB cable (Fig. 1). You will hear a beep when the unit is properly connected. This should be done every time before starting the software program.
2. To start the program, double click on the ⬤ *Lumen APEX Treatment* icon on the computer desktop.
3. The window *Measurements Procedure* will pop up.
4. Press button *Settings* to setup software for first time using. (Fig. 14)
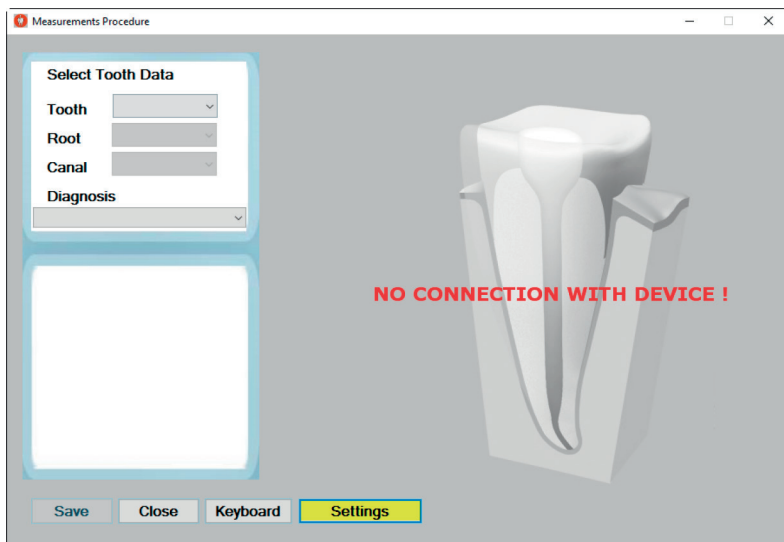
Fig. 14

5. Setup settings (Fig. 15):
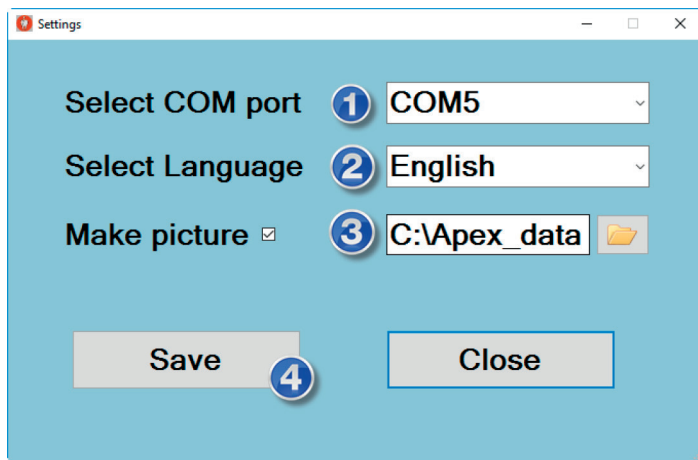
Fig. 15

① *Select COM port* – open lookup form and select COM port ID;

② *Select Language* - open lookup form and select language;

③ *Make picture -* select check box if you would like to save picture file with measurement data.

The default directory to save file is *C:\Apex_data\Apex_Pic*. If you would like to modify this, click the 📁 button and select the directory where you would like the save picture file with measurement data.

④ Press *Save* button to save setup settings**.**

Blue color background of the window *Measurements Procedure* *indicates that the* unit *is now ready for use.* (Fig. 16)
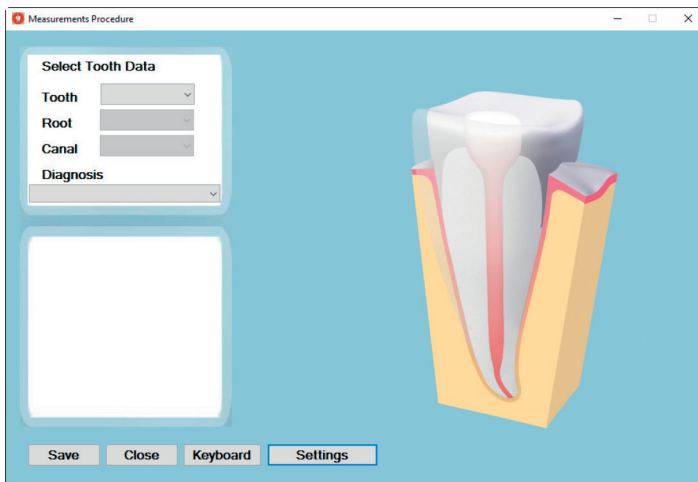
Fig. 16

6. Plug the cable (*3*) into the socket labelled *Patient*. Insert the lip contact (*5)* into the socket (*4)* all the way to the end. Attach the lip contact (*5)* in order to maintain good contact with the oral mucosa (Fig.17). The crown of the tooth **must be dry.** It is recommended that the canal should be wet for better contact.

7. Attach the endodontic clip probe (*7*) to the endodontic file (*9*) by pressing the spring next to the plastic head with your thumb (Fig. 17, **A** version). Move the rubber marker (*10*) down the file.
8. 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. 17, **B** version).
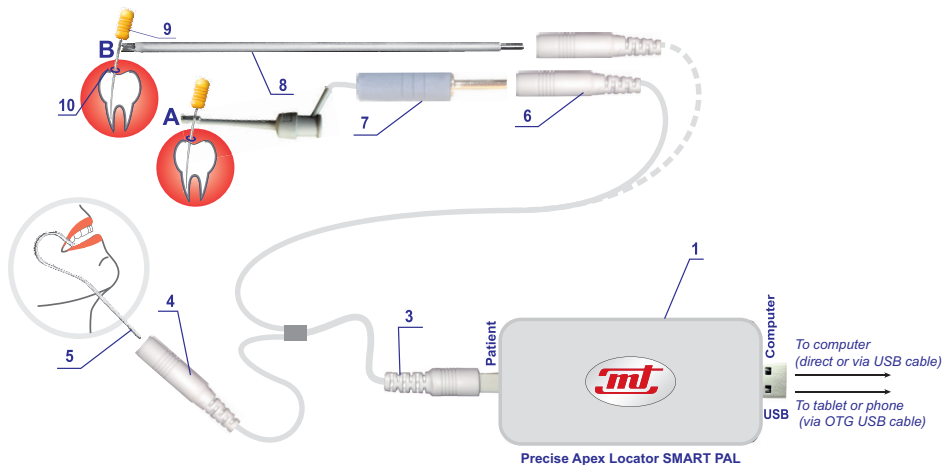
Fig. 17

💡 There are two options how you can use ***Lumen APEX Treatment*** software:

- Visualization of measuring data on PC computer display without any measuring data entry and saving (Fig. 18).
- Visualization of measuring data can be saved as measurement jpg format file data picture (Fig. 23).
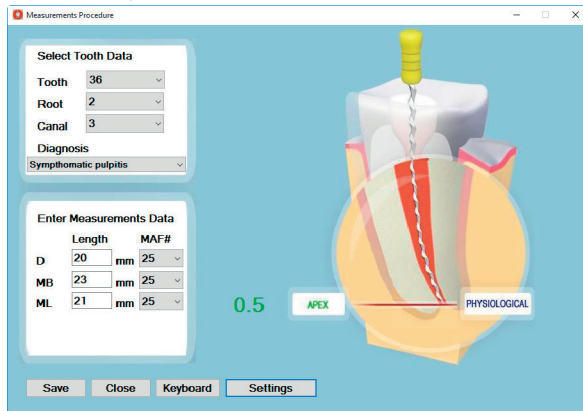
Fig. 18

9. In the ***Select Tooth Data*** window identify the Tooth, Root, & Canal numbers, select the type of diagnosis. After this step is done the corresponding windows will appear in the ***Enter Measurements Data*** window below. (Fig. 19)

10. Slowly insert the endodontic file (*9*) into the root canal. When the end of the file is approximately 2,9 mm or less from the apical constriction, you will see it appearing on the root canal model (Fig. 20). 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.

11. When the endodontic file reaches the apical constriction (Fig. 21), the read-out on the display will read 0,5, you will hear a fast beeping sound and you will see the file tip touching the APEX PHYSIOLOGICAL line in the root canal model.

⚠ **Warning:** The read-out displays relative numbers, not the actual distance in millimeters.
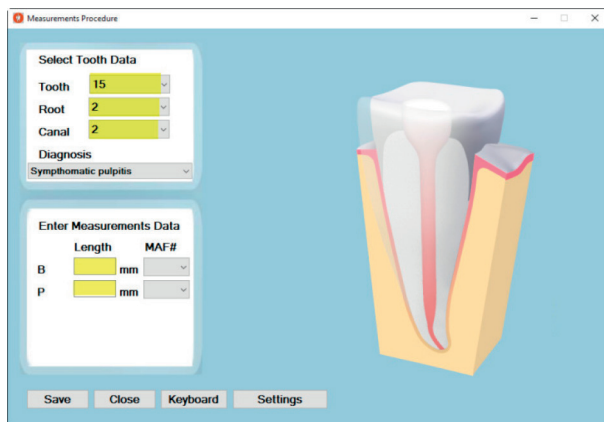
Fig. 19
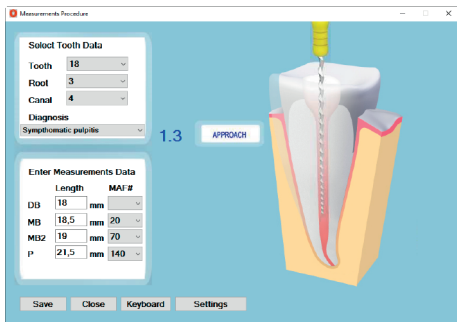
Fig. 20
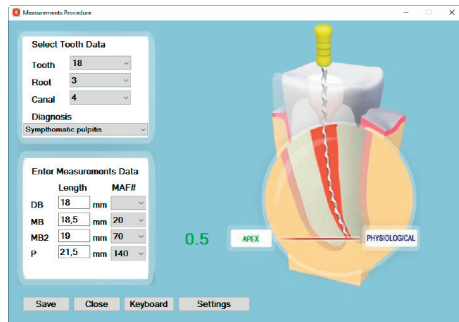
Fig. 21

12. After the apical constriction is determined, 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 recorded on the dentist's ruler and written in the corresponding window of the dental root canal (Fig. 22). To get an accurate working length, the dentist should carefully choose the reference point on the tooth top which touches the rubber marker. Enter measured working length data in the table and numbers of used Master Apical File (MAF) numbers in the right column. Press the *Save* button to save picture file with measurement data (Fig. 23)**.**
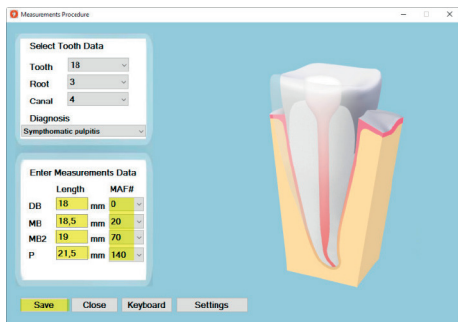
Fig. 22
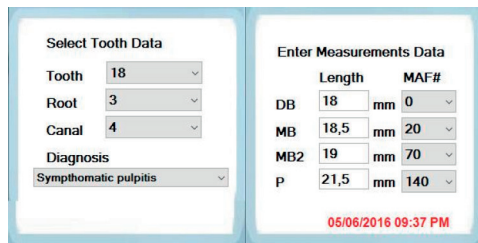
Fig. 23

By default settings current apex working length data (jpg format) file (Fig. 23) will be saved in the *C:\Apex_data\Apex_Pic* directory.

⚠️ **Warning:** Saving a new apex working length data entry (Fig. 22) the previous apex working length data (jpg format) file (Fig. 23) will be deleted from *C:\Apex_data\ Apex_Pic* folder.

💡 **Essential advantage** is to import apex working length data (jpg format) file into X-ray software to obtain unified data of two measurement methods: 1. X-ray picture, 2. Apex working length picture, 3. Intraoral view picture (Fig. 24).
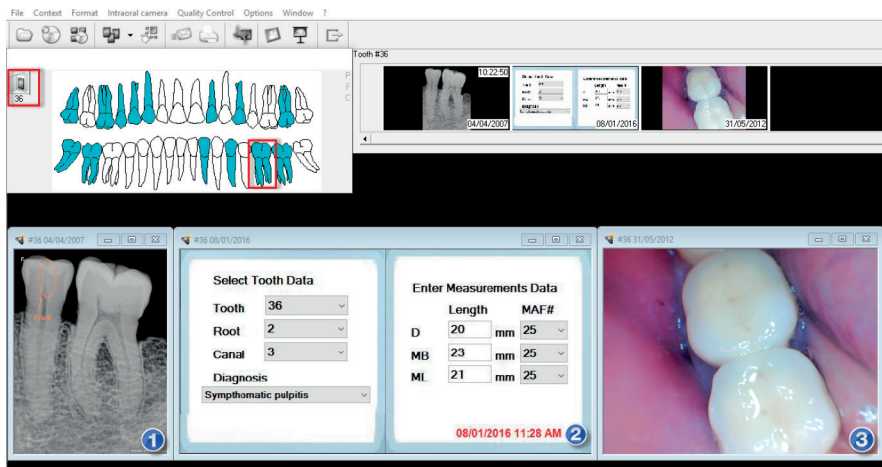
Fig. 24

⚠️ **Warning:** If the endodontic file penetrates the apex (apex physiological) the notice "**OVER**" appears. If the endodontic file reaches apex anatomical a continuous sound is produced with a read-out 0.0 (Fig. 25). Lifting the file up one reaches the apical constriction again (Fig.21) with a typical read-out 0,5 and interrupted sound.

⚠️ **Warning:** 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** (Fig. 25). The crack or perforation may exist at any distance in the root canal and it must be carefully filled.
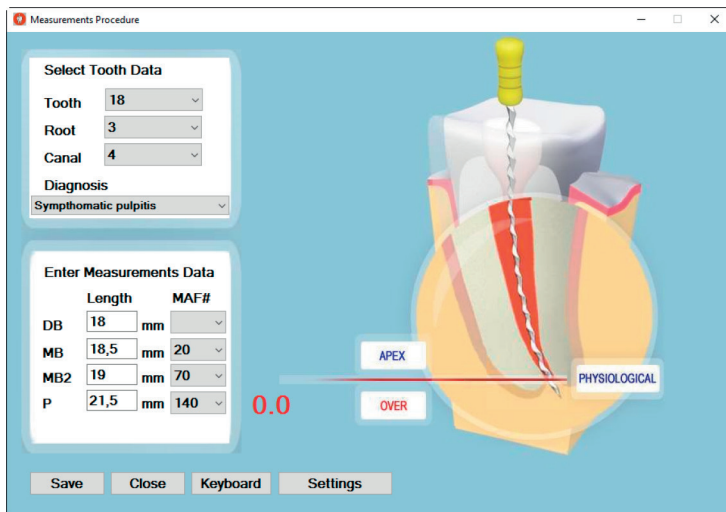
Fig. 25

6. UTILIZATION

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

7. OPERATION SAFETY

WARNING

- **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.**

CAUTION

- **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.*

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 phone/tablet 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.

<u>**Lifetime of Precise Apex Locator Smart PAL is 10 years.**</u>

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 OTG cable   **CA5 (optional)**   **1 pcs.**

4. USB Flash Drive **CA6**   **1 pcs.**

5. User Manual   **1 pcs.**

6. Packaging   **1 pcs.**

Cable CA1   Clip Probe CA2   Lip Contact CA3

Extension Probe CA4   USB OTG cable CA5   USB Flash Drive CA6

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:

md *MEDICAL TECHNOLOGIES*
- An American-Lithuanian Joint Venture Company

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Date of selling

Seller's signature: _____

11. TECHNICAL SERVICE NOTES

No.	Date	Actions	Responsible person's name and signature