

Apex ID™

Instructions For Use



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Figure 1.1



Figure 1.2



Figure 1.3



Figure 1.4



Figure 1.5



Figure 1.6

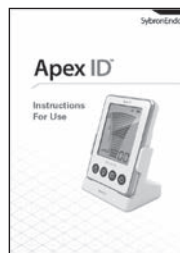


Figure 1.7



Figure 1.8



Figure 1.9

FIGURES



Figure 2.1

Figure 2.2

Figure 2.3



Figure 2.6

Figure 2.7

Figure 2.8

Figure 2.9



Figure 3.3



Figure 2.4



Figure 2.5

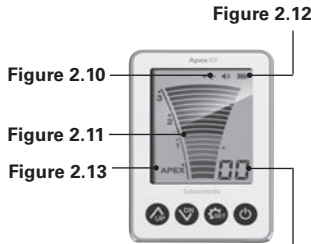


Figure 2.12

Figure 2.10

Figure 2.11

Figure 2.13

Figure 2.14



Figure 3.1



Figure 3.2



Figure 3.5



Figure 3.6



Figure 4.1

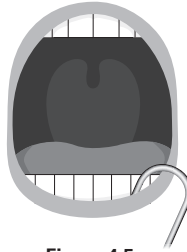


Figure 4.5



Figure 4.8

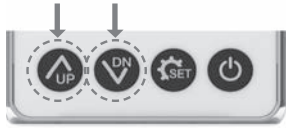


Figure 4.2

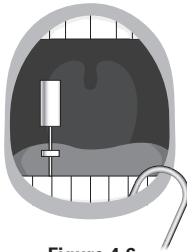


Figure 4.6



Figure 4.9



Figure 4.3

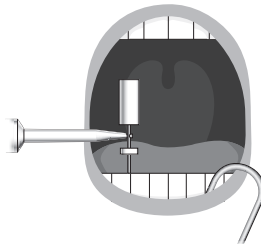


Figure 4.7



Figure 4.10



Figure 4.4

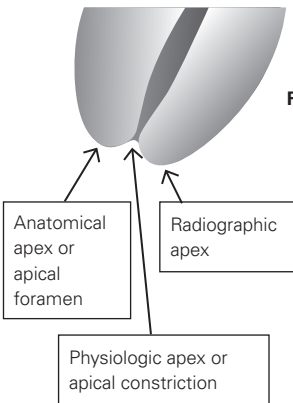
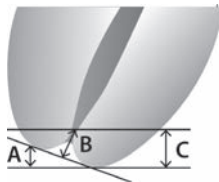


Figure 5.2



- A) Distance between radiographic apex and anatomical apex
- B) Distance between physiological apex and anatomical apex
- C) Distance between radiographic apex and physiological apex

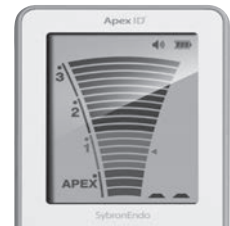


Figure 5.1

This manual provides instruction on how to measure the working length of root canals using the Apex ID Electronic Apex Locator.

- This instruction manual has been prepared for use by dental professionals.
- This manual and the product may be subject to change without notice if required.
- The product has been tested for electromagnetic application test compliance with EN60601-1-2 and is designed to protect against harmful interference when installed and operated according to instructions. This product could produce, use, and discharge wireless wavelength energy; and it may cause harmful interference with other equipment nearby. In this event, the user should resolve the interference using one or more of the recommendations described below:
 - o Increase the distance between the Apex ID and the device which is experiencing interference.
 - o Reinstall and restart the Apex ID again.
 - o Contact your distributor or SybronEndo.

SAFETY PRECAUTIONS

Please read this manual carefully. The purpose of this instruction manual is to provide effective & safe operation of the Apex ID for users and patients.

SAFE OPERATION

Symbols: This instruction manual contains various symbols to assist the operator in correct and safe operation of the device and to protect against injury, damage or loss of property. The symbols and meanings are as follows:



DANGER

Could result in injury or death.



CAUTION

Could result in injury or death.



NOTICE

May result in injury or death.

May result in incorrect data.



DANGER

- Do not use on patients with pacemakers.
- Do not use with electrosurgery devices.
- Products or parts which have not been approved by SybronEndo shall not be connected or attached to this product. Use of un-approved products or parts may result in malfunction of the device and injury to the patient.
- Do not use this device in the presence of oxygen-oxidized substances, nitrogen-oxidized substances or combustible anesthetic mixtures.



CAUTION

“Caution: Federal law restricts this device to sale by or on the order of a dentist.”

- This device is not waterproof. Exposure to moisture could result in electric shock or damage to the device.
- Do not disassemble the device. Disassembly and touching the inside of the device could result in electric shock or burn. (If you disassemble the product intentionally, warranty shall not be honored irrespective of guarantee period.)
- Disassembly or repair should only be done by those authorized by SybronEndo.
- This product is for dental operative use only.
- Confirm the device is operating normally prior to use.
- When the volume of battery is low, discontinue use and replace the batteries.
- Do not try to use in high humidity conditions.
- Protect the device from the effects of atmospheric pressure, wind, sun and salt.
- Do not use where explosive products or gases are stored.
- Stop using if not operating correctly.
- Not indicated for any use except for measuring the working length of root canals.



NOTICE

- This product is for use by dental professionals only.
- To avoid electrical shock or explosion, keep the device away from high temperature or high humidity. Keep the metal parts of this product away from conductors. Fire, electric shock, or damage may result.
- Do not put heavy items on the device. Fire or electric shock may result.
- Confirm all measurements of canal length with radiographs.
- Blocked root canals cannot be measured correctly.
- When you give this device to others, include the Instructions For Use.
- Remove the batteries if the Apex ID device is not likely to be used for sometime.

Label maintenance and repair:

- The label for notice or caution shall be maintained soundly with regular inspection.
- Replace: If the label for notice or caution has been lost or damaged, please contact SybronEndo for replacement.

1 – INDICATIONS FOR USE AND PRINCIPLE OF OPERATION

1.1 – Indications for use

Apex ID is an Electronic Apex Locator designed for use in measuring the working length of root canals.



NOTICE Use the device to measure the working length of root canals only.

1.2 – Principle of operation

Micro signals consisting of dual frequencies sent from

the unit return to the unit after travelling along the electric circuit that is composed of: unit - probe cord – file holder - file - patient - lip holder - probe cord. The impedance of the electric circuit may be changed depending on the distance between the end of a file and the apex of the root canal, which results in a change in the micro signals that are input back into the unit. The micro process of the unit calculates the change in micro signals to convert the difference into a distance value, which will be displayed on the Apex ID LCD display.

2 – DEVICE CONTENTS AND FUNCTIONS

2.1 – Device contents and functions

Contents of product:

Apex ID Unit (1) – Fig 1.1 AAA Alkaline Batteries (3) – Fig 1.2 Stand (1) – Fig 1.3 Lip Hooks (5) – Fig. 1.4 File Holder A (1) – Fig 1.5	File Holder B (2) – Fig 1.6 Instructions For Use (1) – Fig 1.7 Probe Cord (1) – Fig 1.8 Checker (1) – Fig 1.9
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2.2 – Accessories and their functions

Name	Functions
Probe cord – Fig 1.8	Connects between the Apex ID & file holder & Lip Hook
Lip Hook – Fig 1.4	For contact to patient's lip
File holder A – Fig 1.5	Touch to file (designed for molar teeth)
File holder B – Fig 1.6	Holds File
Checker – Fig 1.9	Confirms that the Apex ID is functioning correctly

2.3 – The features of the Apex ID and their functions

Feature	Functions
LCD Screen – Fig 2.1	Shows the status of settings and indicates the distance between the end of file inserted in root canal & root apex
Control panel – Fig 2.2	Select power ON/OFF & control functions
Stand – Fig 2.3	Placing the Apex ID on a counter
Battery compartment – Fig 2.4	Contains batteries 1.5V x 3 (DC 4.5V).
Probe cord jack – Fig 2.5	Connect to probe cord for measuring working length of root canal
Up button (▲) – Fig 2.6	Push the button to increase the root apex standard value by 0.1 and the volume of buzzer is increased 1 step up
Down button (▼) – Fig 2.7	Push the button to decrease the root apex standard value by 0.1 and the volume of buzzer is decreased 1 step down
Setting button (⚙️) – Fig 2.8	Push the button to fix the setting mode
Power button (⏻) – Fig 2.9	Push the button to turn the unit ON/OFF
Buzzer volume signal – Fig 2.10	Indicates the volume of the Buzzer
Graph signal – Fig 2.11	Graph shows the distance between the end of file and root apex
Battery signal – Fig 2.12	Indicates remaining battery life
Root apex signal – Fig 2.13	Indicates when file has reached the apical foramen, or the “0” point set by the operator
Numeric signal – Fig 2.14	Indicates the distance between the end of file & root apex

3 – PRODUCT SYMBOLS

 Serial number	 Authorized Representative in the European Community
 Part number	 Refer to instruction manual
 Manufacturing date	 CSA marking
 CE marking of conformity Meets CE marking requirements	 Do not dispose this product into the ordinary municipal waste or garbage system
 Type B applied part	 Manufacturer
 Caution	Rx ONLY Caution: U.S. federal law restricts this device to sale by or on the order of a dentist.
 Temperature limitation	 Keep dry
 Atmospheric pressure limitation	 Humidity limitation
 Stack 12 maximum	 Fragile, handle with care
 This way up	 GOST conformity marking

4 – BEFORE USE

4.1 – Check contents

- Confirm that all the components listed in the Contents are in the box before using the device for the first time. (Please refer to Kit Contents in section 2)
- Please check the exterior of the device for damage.



NOTICE SybronEndo shall not be responsible for any damage caused by misuse of the product.

4.2 – Check connection between probe cord and file holder

Insert lip hook and file holder B into probe cord [Fig 3-1]. Insert probe cord into probe cord jack of the main unit. [Fig 3-2]

After turning on the power, make sure the numeric indications are displayed on the screen when you contact file holder B and lip holder.

Note: If the power button (⏻) doesn't work, make sure that the insulation plastic is completely removed from the battery cover in the back of the product. Remove the insulation plastic piece before use. [Fig 3-4]

4.3 – Performance inspection with checker

Power on by pushing power button (⏻). [Fig 3-5]

Plug in Checker (to the probe cord jack) provided in the original packaging and see if the value on the LCD screen is '0.5'. [Fig 3-6]

If '0.5' is displayed on the LCD screen, the unit is ready for clinical usage.

5 – SET UP AND USE

5.1 – Probe cord connection

Connect the file holder and lip hook to the probe cord. [Fig 3-1] The probe cord should be connected to the probe cord jack of the main unit. [Fig 3-2]

5.2 – Setting the standard value for root apex

Turn on the product by pushing the power button (⏻). [Fig 4-1] The position of the file tip is shown by the canal length indicator bar on the display. Working Length: The 0.5 reading indicates that the tip of the file is at or very near the apical construction (physiological foramen). [Fig 5.2]

Push the up button (⬆) and down button (⬇) simultaneously for about 3 seconds. [Fig 4-2]

Set at '0.0' at this point by pushing the up button (⬆) or down button (⬇). [Fig 4-2] Change back by following the same process.

Push the setting button (⚙) then the desired value of the root apex shall be fixed. [Fig 4-3]



NOTICE The standard value for the apex of Apex ID is set as 0.0 at the factory. This value means that the file has reached the anatomical foramen. [Fig 5.2]

Continue inserting the file to -0.1 (if the standard value of the root apex is set at 0.0) then move the file back until 0.0 is displayed on the screen. This helps to confirm the location of the apex. [Fig 4-8~Fig 4-10]

After positioning the rubber stop of file on the tooth at the reference point the file should be removed from the canal. Measure the working length from the tip of the file to the rubber stop with a ruler. After positioning the rubber stop on the file to a reference point, the file should be removed from the tooth.

5.3 – Setting of the buzzer volume

Turn on the Apex ID by pushing the power button (⏻). [Fig 4-1]

Push the up button (⬆) and down button (⬇), simultaneously for about 3 seconds, and push setting button (⚙) once. [Fig 4-4]

Adjust the volume of the buzzer by pressing the up button (⬆) or the down button (⬇). [Fig 4-2]

Push the setting button (⚙) to keep the set volume. [Fig 4-3]

5.4 – Measuring the working length of the root canal

Turn on the Apex ID by pushing the power button (⏻). [Fig 4-1]



NOTICE The measurement result shown by the Apex ID and the length of file may vary depending on the operator's angle of view.



The insertion angle of the file after enlarging the canal may vary from the original working length measurement angle.



Re-confirm the working length after enlarging the canal.



NOTICE Before use, sterilize the lip hook using a steam sterilizer at 121°C for 30 minutes.

Place the lip hook on the patient's lip. [Fig 4-5]

Turn off the Apex ID by pushing the power button (⏻). The power will automatically shut off after 5 minutes of non-use. The working length should be confirmed by radiograph.



NOTICE Place the lip hook on the opposite side of the mouth from the tooth being measured. Use with Stainless Steel hand file.

Insert the file into the canal. [Fig 4-6]

Attach the file holder B to the file (If using holder A, touch the file below the handle with the file holder). [Fig 4-7]



NOTICE A radiograph may show a different measurement result than the Apex ID. This is not an indication of malfunction by the unit or the x-ray. Often the apical foramen is located coronal to the radiographic apex. [Fig 5.2] Another possibility is the angle of the x-ray beam and film may be off angle to the perpendicular.

Insert the file slowly into the root canal while checking the graph and the number value on the screen. Stop insertion when the distance between the file and root apex reaches the standard value of the root apex (pre-set factory setting at 0.0mm or your chosen value). As the file nears the apical constriction, the unit will beep more rapidly. When the apex is reached the file is touching the periodontal membrane and a red bar will appear at the "Apex" on the screen. As it goes past the apical constriction, the frequency of beeps increases until the screen reads "-0.5." Then the sound will remain steady and the entire screen will flash.

6 – GUIDE FOR ACCURATE MEASUREMENT

Turn on the Apex ID prior to use.

Plug the Checker [Fig 1-9] (provided in the original packaging) into the probe cord jack [Fig 2-5] and confirm the value on the LCD screen is 0.5.

It is recommended to insert the file into the canal first and then connect the file to the file holder.

If the signals do not change as the file approaches the APEX, it is possible the root canal is too dry; therefore it should be filled with saline.

Necrotic tissue or other matter in the root canal may affect accuracy. It is advisable to take several measurements during enlargement of the canal.

Start with a larger file at first. If the APEX indication (graph and numeric signal on the screen) does not reach the APEX, gradually try a smaller file to measure the working length of the root canal.

To minimize error, it is recommended the working length be measured more than twice.

If root canals within a tooth are connected, as in the case of multiple root canals with anastomoses or cracks, mis-measurement is possible. It is recommended to verify the tooth's anatomy radiographically.

Contact with metal restorations by the file during measurements may result in errors.

Remove blood or exudate from the canal before measurement.

In cases where the foramen is not completely formed or the foramen has been overly expanded, the measurement value of the working length may be shorter than the actual measurement value.

7 – MAINTENANCE AND STORAGE

7.1 – Sterilization

The 'Lip Hook' and 'File holder A' should be sterilized at 121°C for 30 minutes with high-pressure steam.

The 'File holder B' should be sterilized at a temperature of 121°C for 30 minutes with high-pressure steam in a sterilization pouch, then dried at least 10 minutes after sterilization.



CAUTION Parts used in direct intraoral contact are to be steam sterilized.



NOTICE It is highly recommended to place File holder B in a sterilization pouch for autoclaving.

- The metal of the File holder B may be corroded when it is in direct contact with steam.
- Temperature should not exceed 135°C during sterilization as the product may be damaged.

7.2 – Recommended sterilizer type

- Sterilizer: Vacuum type (B)
- Sterilization temperature: 121°C,
- Sterilization time: 30min

7.3 – Method used to validate recommended sterilization method:

Sterility Assurance Level (SAL): 10⁻⁶

- 1) Sterilization validation samples are wrapped with BIs.
- 2) 3 times of sterilization cycles as a half cycle are carried out at 121°C for 15 minutes.
- 3) 1 time of sterilization cycle as a full cycle is carried out at 121°C for 30 minutes.
- 4) Incubate BIs at 55~60°C for 7days.

7.4 – Sterilizer used for validation

- Manufacturer: DAIHAN LABTECH CO., LTD
- Model name: LAC-5105SP
- Serial No. : 20101202138
- Control No. : TE-10-23
- Valuable room: 100 liter
- Power supply: AC 220V, 50/60Hz
- Pressure: 2.6kgf/cm²
- Range of sterilization temperature: 105°C~135°C

7.5 – Cleaning

Clean the Apex ID or probe cord with dry gauze and a small amount of ethanol. Any ethanol left on the product after cleaning should be completely wiped off with a dry cloth.



CAUTION Use protective sleeves on the cords and Apex ID during operation, followed by removal of the sleeve and wiping with alcohol after operation.



CAUTION Do not use the Apex ID when wet with ethanol. There is a possibility of electric shock or product damage.

-20~50°C, atmospheric pressure 70~106 kPa and relative humidity 5~90%.

7.7 – Disposal

Dispose of the product in accordance with your local waste disposal regulations and/or laws

7.6 – Operating, Storage, Transport

The Apex ID should be operated in temperatures ranging from 10~40°C, atmospheric pressure 70~106 kPa and relative humidity 30~75%. The Apex ID should be stored and transported in temperatures ranging from

8 – TROUBLE SHOOTING

If any problems occur, refer to the table below. If there are any further problems or issues please contact your distributor or SybronEndo.

Problem	Possible Causes	Solutions
No power	Low Battery / No Battery	Replace the batteries
No power	Battery replacement does not solve the problem	Check the connection to the batteries
No buzzer sound	No sound setting	Adjust the buzzer volume
Power ON, but no measurements show	Probe cord disconnected from the main unit	Check the connection of Probe cord and the main unit
Power ON, but not measured	File holder disconnected from Probe cord	Check the connection of file holder and Probe cord

9 – PRODUCT SPECIFICATIONS

- Rated voltage: DC4.5V (1.5V Alkaline Battery AAA x 3EA)
- Input current: less than DC 60mA
- Power consumption: less than 0.27VA
- Patient auxiliary current: less than AC 10µA
- Oscillation frequency: 500Hz ±0.2Hz, 5kHz ±0.002kHz
- Size: W70mm ±1mm x D25mm ±1mm x H100mm ±1mm
- Weight: 205g ±15g (including stand, except battery)
- Protection type and level against electric shock: Type B applied part
- Internally powered equipment, Ordinary equipment (IPX0)
- Continuous operation time: 62 hours (at 1250mAh Battery x 3EA)

10 – GUIDANCE AND MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions

The Apex ID is intended for use in the electromagnetic environment specified below. The customer or the user of the Apex ID should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Apex ID uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Apex ID is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity

The Apex ID is intended for use in the electromagnetic environment specified below. The customer or the user of the Apex ID should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruption, and voltage variations on power supply input lines IEC 60601-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) < 5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) < 5% UT (>95% dip in UT) for 5s	Main power quality should be that of a typical commercial or hospital environment. If the user of the Apex ID requires continued operation during power main interruptions, it is recommended that the model Apex ID be powered from an uninterruptible power supply or battery.
Power frequency(50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC61000-4-6	3 V/m 150 kHz to 80MHz	3 V/ms 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Apex ID, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5GHz	3V/m 80 MHz to 2.5GHz	

Note: UT is the A.C. mains voltage prior to application of the test level.

Note: At 80MHz and 800MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Apex ID is used exceeds the applicable RF compliance level above, the Apex ID should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Apex ID.

^b Over the frequency range 150kHz to 80MHz, field strengths should be less than [V1] V/m.

Recommended separation distance
 $d = [3.5/V1] \sqrt{P}$

$d = [3.5/E1] \sqrt{P}$ 80MHz to 800MHz

$d = [7/E1] \sqrt{P}$ 800MHz to 2.5GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.^b

Interference may occur in the vicinity of equipment marked with the following symbol:





WARRANTY AND EXCLUSIONS

Warranty

SybronEndo warrants the non-consumable components of Apex ID electronic apex locator to be free from defects in materials and workmanship for a period of one (1) year from the original date of purchase, in accordance with SybronEndo's warranty regulations. If the Apex ID shows any defect within the specified warranty period that are not excluded from this warranty, SybronEndo shall, at its discretion, either replace or repair Apex ID using suitable new or reconditioned parts. In the case other parts are used which constitute an improvement, SybronEndo may, at its discretion, charge the customer for the additional cost of these parts. If the warranty claim provides to be justified, the product will be returned to the user freight prepaid.

Warranty claims other than those indicated herein, are expressly excluded.

Exclusions

Damages and defects caused by the following conditions are not covered by the warranty:

- Improper handling/disassembly/modifying, neglect or failure to operate the unit in compliance with the instructions given in the Instruction for Use/User Manual.
- Force majeure or any other condition that is beyond the control of SybronEndo.
- This device is manufactured for the uses specified in this Instruction for Use. SybronEndo shall not be responsible for any damages caused by customer misuse or uses other than those specified.

Responsibility

SybronEndo shall not be responsible for damages or injuries caused by any of the following:

- Use by unauthorized personnel.
- Changes to or modifications of the device.
- Use of other manufacturer's devices or parts with the Apex ID.
- Use of unapproved parts or repair of the device by unauthorized parties.
- Disregard of the care or cautions listed in the instruction manual.
- Use of the device for any applications not included in the instruction manual.
- Use of a power supply other than that specified in the instruction manual.
- Fire, flood, lightning or from natural disasters.
- Customer carelessness or intentional misuse.