

OPERATION and MAINTENANCE INSTRUCTION MANUAL

AEU-40 Endopex V *Vector Based Root Apex Locator*



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To prevent injury to people and damage to property, please heed relevant warnings and remarks. They are marked as follows:

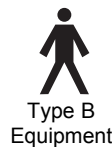
- WARNING:** Serious injury or death may result if ignored.
- CAUTION:** Damage to property or the environment may result if ignored.
- NOTE:** Important additional information and hints.

SPECIFICATIONS:

Model:	AEU-40
Power Source:	One 9-Volt DC Battery
Power Consumption:	.8 Watts Maximum
Measurement Voltage:	150mVp-p = 53mVrms Maximum
Display:	Active Illumination, Light Emitting Diodes
Audio:	Piezoelectric Transducer
Outer Dimensions:	W90 x D32 x H145 mm
Weight	Approx 275g
Operating Temperature range:	0 degrees C to 45 degrees C
Storage Temperature range:	-10 degrees C to 65 degrees C
Relative Humidity	20 to 85% RH

CLASSIFICATIONS:

- Internally Powered Equipment
- Type B Equipment
- Ordinary Equipment - degree of protection against ingress of water
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.



MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE & MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601.1 AND CAN/CSA C22.2 NO. 601.1 41EJ



SYMBOL DEFINITIONS:



Type B Equipment



Dangerous Voltage



Attention - Consult Accompanying Documents

The UL 2601 Standard Duty Cycle for Intermittent Use is 1 min. on / 5 min. off.

You've purchased the very latest in Apical Foramen Location technology. Aseptico has developed a new technology called "Impedance Vector Mapping". This approach uses a single pure tone signal to precisely identify the electrical characteristics of the endodontic file's present position. These characteristics are used to develop an index to an internally stored collection of clinical experience regarding the electrical characteristics of the Apical Foramen. This collection of clinical experience is called a "Personality Mapping" for the device.

The Endopex V is microprocessor controlled and may be operated in dry and moist tooth canals.

Congratulations!

The accuracy and efficacy of the Endopex V has been developed and affirmed via studies at a major American dental school and in the hands of professional endodontists.

Watch for new Aseptico products that contain Impedance Vector Personality Maps to assist in more unusual, difficult, or special cases.

Rubber dam should be used in all endodontic cases. We recommend the use of HandiDam™ - Aseptico's premium pre-framed rubber dam, available online at www.aseptico.com or contact a sales representative at 1-800-426-5913.

PACKAGE CONTENTS:

- | | |
|------------------------------------------------|------------|
| • AEU-40 Endopex V Apical Foramen Locator Unit | P/N 120285 |
| • Stainless steel lip electrodes (5) | P/N 461112 |
| • Autoclavable E-ZHook™ file clip assembly (5) | P/N 73050 |
| • Cable Assembly | P/N 875032 |
| • 9-Volt Battery | P/N 820008 |
| • Trim Adjust Tool | P/N 490069 |
| • Manual | P/N 420355 |

OPERATION FUNCTIONS:

1. **Power Switch** – Controls power On/Off to the unit. When turned on, self-test will initiate and should illuminate a green power LED within a few seconds to indicate a properly functioning unit.
 - a. A flashing yellow LED indicates a low battery requiring replacement.
 - b. The unit will automatically turn off if it fails the battery of power on tests. Low batteries will cause self test failures.
 - c. If a subsequent attempt to power on succeeds, the unit will function properly, but should still be returned for service if it continues to automatically turn off during self test with fresh batteries. Low batteries will cause self test failures.
2. **Display Switch** – Allows the selection of one of three display modes. The following modes are indicated by the illumination of a corresponding LED color below the Display Switch;
 - a. Single Bar March (Green) – One bar is illuminated to indicate proximity to the apical foramen. This mode is most conservative of battery life.
 - b. Logarithmic March (Yellow) – Further away from the apical foramen, 3 bars will light, mid range proximities will produce 2 illuminated bars, near proximities will illuminate only one bar or light. This mode is also conservative of battery life.
 - c. Persistent On March (Red) – Each illuminated bar remains on during progression toward the apical foramen. This mode is least conservative of battery life, but certainly gives the most visible indications.
3. **Sound Switch** – Controls sound indication On/Off. The state of the sound indication is indication by the On/Off illumination of an LED beneath the Sound Switch. When active the following audio indications will be provided;
 - a. Distant proximity – silence.
 - b. Near proximity – 1/24th pulse chirp.
 - c. Impending proximity (one light bar preceding the Apex indicating 0.5mm) – 1/3rd pulse beep.
 - d. Apex – 1/2 pulse beep.
 - e. Perforation – solid tone alarm.

Illustration 1 - Endopex control panel

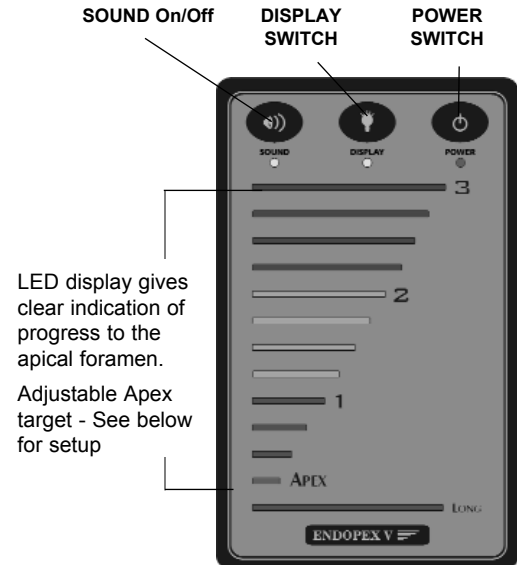


Illustration 2 - Lip electrode and EZ Hook™ electrode



Illustration 3 - Endopex Set Up



SETTING UP THE UNIT:

1. Unpack the unit and verify it carries the proper certification markings.
2. Open the battery door on the back of the unit using a

Phillips head screwdriver. Install the enclosed 9V battery (for approx. 5 hours of use). The unit will accept three 9V batteries, resulting in battery life of approximately 15 continuous operating hours. Close the battery door and secure with screw.

NOTE: The blinking “target indication is set to the “APEX” indication at the factory. This setting can be changed upward by adjustment through the set access opening in the back of the unit. This does not change the performance of the unit as programmed based on collected clinical data. It does provide a means to accommodate a preference for a different “target” indication from the canal.

Illustration 4 - EZ Hook connect to file



3. Connect the Cable Assembly to the connector jack on the side of the unit.
4. Connect one lip probe to the gray receptacle jack on the cable assembly.
5. Connect one Autoclavable E-ZHook™ file clip assembly to the white receptacle jack on the cable assembly.

OPERATION:

After the unit has been set up and you have made yourself familiar with the operation functions, you are ready for operation as follows:

1. Press the power switch in the upper right hand corner of the unit. The power indicator will turn red and yellow during self-test. Successful completion of self-test is signified with a quick sequence of light illumination on the front panel and an audible indication if sound is turned on. The power indicator will turn green indicating the unit is ready for normal operation. The self-test sequence should take only a few seconds to complete.
2. Attach the stainless steel lip probe securely to the patient's lip at the corner of the mouth. Secure contact to the patient's oral mucosa is crucial for an accurate measurement reading.
3. Attach the file clip assembly to a file or reamer. Attach the file clip to the upper part of the file near the handle. The cutting part of a file can damage the file clip.
4. Verify all cable assembly connections are secure to the lip clip, file clip and the unit. A poor connection can prevent accurate measurement. Do not pull on the cords of the cable assembly when attaching or removing the clips or when disconnecting the cable assembly from the unit. This could compromise the electrical connection integrity inside the cable assembly.
5. Insert the file (usually size 10) into the root canal until the unit indicates one bar above apex target. Advance the file with slow clockwise turns until Apex is indicated.
6. Illuminating the red LED bar at the bottom of the indicator column with a solid audio tone if sound is activated, indicates perforation.
7. Turn the file with slow counterclockwise turns until the unit indicates one bar above apex target again. This procedure will provide assurance that the apical constriction has been identified and the indication is not due to a non-apical constriction inside the canal.
8. Position the file marker on the surface of the tooth as a reference to determine the canal's working length.
9. Press the power switch again to turn the unit off. The unit will automatically turn off after 20 minutes of no display activity.
10. Always take an x-ray to check the results.
11. **DETECTING POST PERFORATION:** Connect the file clip to a large file and make contact with the post. In the case of post perforation, the Endopex V will indicate a perforation illuminating the red LED at the bottom of the indication column accompanied by a solid audio tone if sound is active.

DISINFECTION AND MAINTENANCE:

1. Main Unit

Wash display and outside of the enclosure with a soft cloth using a mild detergent. Rinse off the unit by wiping with a damp cloth. Never submerge unit or saturate with any disinfectant fluids.

2. Electrodes

The electrodes must be sterilized between each patient use. Sterilize the file clip and lip clips at 132° C (270° F) for 5 minutes. Do not autoclave any other part.

3. Cable Assembly

The Cable Assembly may be wiped or dipped in a disinfectant solution. Do not soak the Cable Assembly.

3. Batteries

Replace batteries with fresh cells when unit indicates low battery when power light is yellow and blinking. From one to three 9V batteries may be used together, for an estimated 15 hrs of battery life.

CAUTIONS:

1. Do not use this unit in conjunction with an electric scalpel or on patients with pacemakers.
2. Replace the battery when the power light starts blinking yellow. Accurate readings cannot be assured with batteries that are low on power.
3. Always remove the batteries for shipping or long-term storage.
4. Use files and reamers with a plastic (resin) handles.
5. Numbers indicating distances are for reference only. The dentist's judgment must be used to interpret indication results. Clinical experience, including knowledge of root anatomy, is crucial when interpreting indication results.
6. Always verify good connection of the lip clip to the patient's oral mucosa and all connections to the cable assembly including the connection to the unit. A poor connection can prevent accurate measurements.
7. Always take an x-ray to confirm the results.
8. Do not clean the main unit with Gluteraldehyde, Ethanol, or similar chemicals to avoid discoloration and surface corrosion of the unit. If the unit contacts any of these chemicals, wipe off immediately with a damp cloth.
9. Indications vary slightly depending on individual tooth characteristics and canal shape; the dentist should apply clinical judgment on each case.

TROUBLESHOOTING:

1. Nothing happens on the display after the main switch is pressed.

- a. The button should be held down firmly for two seconds to turn the unit on.
- b. Verify the battery is properly installed.
- c. Verify the battery is fresh.

2. The power indicator turns red and the unit turns off after a couple of minutes.

- a. Verify the battery is fresh.
- b. The first battery of self-tests has failed, wait 5 seconds, turn the unit back on. If this does not solve the problem, contact your local dealer or our office listed on page 8 of this manual.

3. The power indicator turns yellow and the unit turns off after a couple of minutes.

- a. The second battery of self-tests has failed, wait 5 seconds, turn the unit back on. If this does not solve the problem, contact your local dealer or our office listed on page 8 of this manual.

4. The power indicator is yellow and blinking.

- a. Replace the battery.

5. The display gives unstable indications.

- a. The file may be following the canal at a sharp angle. When this happens, the display sometimes "jumps" to a perforation indication. If this seems the case, retract the file just enough so the perforation indication stops.
- b. Verify that the lip clip has a good connection to the patient's oral mucosa.
- c. Verify the file clip metal is clean, free of debris and corrosion, clean if not.
- d. Verify the pulp chamber is clean and dry.

6. The display indicates only when the file is very near the apex.

- a. The canal may be obstructed by dentin debris or shavings. The unit will only indicate correctly when the file passes through the apical constriction.
- b. The canal may be extremely dry, moisten the canal with water or sodium hypochlorite.
- c. If the apical foramen is too large or incompletely formed, the indication may suddenly jump as the file tip approaches the foramen.

7. There are no audio indications.

- a. Verify audio indication has been turned on.

8. The display gives no indications or gives incorrect indications.

- a. Verify that the lip clip has a good connection to the patient's oral mucosa.
- b. Make sure all connections to the cable assembly are secure. Specifically check the cable assembly jack is properly inserted in the unit, the lip clip is well seated in its receiving connector, and the file clip assembly is well seated in its receiving connector.
- c. Verify the file clip metal is clean, free of debris and corrosion, clean if not.
- d. Verify the pulp chamber is clean and dry.
- e. The file clip plastic or metal may be damaged, replace it if so.
- f. Verify the file clip is securely attached to the file and the file is inserted in the canal.
- g. Verify the canal has not been retreated with silver points.
- h. Verify the apex is complete.

- i. The canal may be calcified.
- j. The canal may be obstructed by dentin debris or shavings. The unit will only indicate correctly when the file passes through the apical constriction.
- k. The canal may be extremely dry, moisten the canal with water or sodium hypochlorite.
- l. The canal may be exiting at a sharp angle. Sometimes the file is not able to follow a sharp bend and the file cannot be inserted any further.

9. The display indicates perforation right away or provides imprecise, erratic or short indications.

- a. Verify the pulp chamber is clean and dry.
- b. The canal maybe filled with blood or electrolytic fluids. In this case, the meter sometimes jumps when the file tip breaks the surface of the fluid. The display will return to normal as the file approaches the apex.
- c. The tooth maybe covered with cutting debris or chemicals. Clean off the surface of the tooth if so.
- d. The file may be making contact with the gums or other soft tissue in the mouth. This will cause inaccurate readings.
- e. Too much pulp may be left in the canal. Sometimes a large amount of pulp in the canal can interfere with accurate readings.
- f. Amalgam restorations or crowns may cause the unit to overreact if the restoration is in contact with the file probe. If this is the case, move the file out of contact with the metal restoration.
- g. Caries on proximal surfaces can cause inaccurate readings.
- h. If a lateral canal is present, the unit may indicate apex at the branch canal.
- i. If the crown has been lowered by removal of the occlusal surface, the possibility of electrical contact with the gums is increased. Wash the canal with sodium hypochlorite in this case.
- j. Verify the file clip metal is clean, free of debris and corrosion, clean if not.
- k. The unit often overreacts if the canal has an exceptionally large foramen and is filled with an electrolytic solution. The unit should return to normal display as the file advances toward the apex.
- l. If the unit still overreacts near the apex, dry some of the electrolytic solution and use a larger file closer to the size of the apex.

- If these responses do not solve the problem, check the unit operation by touching the file clip to the lip clip. A consistent "LONG" display indication shows the unit is operating properly.
- If the unit is not operating properly, turn the unit off, wait 5 seconds, then turn it back on to reset. Verify the unit passes the self-test, and repeat the above operation check.
- If the problem is still not solved, contact your local dealer or our office listed on page 8 of this manual.

WARRANTY:

Aseptico warrants this product against defects in material or workmanship for a period of one year, from date of original invoice. Handpieces are warranted for 90 days under the same conditions. Expendable components such as light bulbs, are covered by shorter warranty periods, or have no warranty. Aseptico's sole obligation under product warranty is (at its sole option and discretion) to repair or replace any defective component or product in part or whole. Aseptico shall be the sole arbiter of such action.

In the event of alleged defect under warranty, the purchaser is to notify Aseptico's Customer Service Department promptly. Customer Service will provide instructions, usually directing that the product be returned for service. Shipment to Aseptico and the cost thereof is always the responsibility of the purchaser.

Accidental misuse, inappropriate installation, or failure to perform directed maintenance voids the warranty.

Aseptico does not assume, under this warranty, any risks or liabilities arising from the clinical use of its products, whether or not such use involves coincidental utilization of products manufactured by others.



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