

INSTRUCTIONS FOR USE

Parkell Product Information:

DEVICE DESCRIPTION: A battery-powered, dental electronic device used to determine the working length of a tooth's root canal(s) during endodontic treatment. The Foramatron establishes a safe, low current, electrical circuit through a tooth using an endodontic file or reamer, which is monitored to calculate when the instrument's tip reaches the apical foramen. The Foramatron uses LED lights and sound to indicate when the apex is reached.

INDICATIONS / INTENDED USE: The Foramatron is indicated for use as an aid in establishing the working length of a root canal in a tooth that requires endodontic treatment.

CONTRAINDICATIONS: To function properly, this device requires that the tooth have an intact periodontal ligament. Erroneous readings may be obtained if:

- 1) the periodontal ligament has been seriously damaged or destroyed by periapical disease,
- 2) the tooth is ankylosed to the bone,
- 3) the apex is excessively open (as may be the case in primary teeth or incomplete secondary teeth),
- 4) pre-operative radiographs indicate the presence of a well-defined, long-standing, periapical radiolucency, a crack in the tooth, internal or external resorption or excessively deep root caries, or
- 5) a metal restoration cannot be bypassed and is interfering with the apex locator's electronic signal.

WARNINGS: Because of the potential for electromagnetic interference, this device should not be used on patients with cardiac pacemakers, internal defibrillators, intracorporeal fluid pumps or any other implantable electronic devices. Avoid use in the vicinity of electrical surgery equipment, which may interfere with readings.

Full EMC related information Emission/ immunity tables will be available upon request.

Except for the battery compartment, do not open the case. There are no user-serviceable parts inside. Opening the case will void all warranties. Do not modify this device in any way. Modification could violate safety codes and endanger patient and/or operator, and will void all warranties.

This device is designed to be powered by a 9-volt alkaline battery only. To reduce battery drain, if accidentally left on, the Foramatron "goes to sleep" after approximately 20 minutes of non-use. To "wake up" the device once it has "gone to sleep", turn it OFF

The Foramatron® Endodontic Apex Locator — Stock No. D645

and then ON again. Even in "sleep mode", the unit drains a small amount of current from the battery, so always turn off the unit at the end of the procedure.

CONFORMANCE TO STANDARDS: The Parkell Foramatron is TUV listed and conforms to IEC 60601-1, 60601-1-2 and CAN/CSA C22.2 No. 60601-1-08. Parkell's quality system is certified to ISO 9001/ISO13485. The device is CE marked—certified to European Medical Device Directive (93/42/EEC).

HOW SUPPLIED:

- Digital Foramatron Endodontic Apex Locator (with 9-volt battery installed)
- Accessory Bag (Stock No. D611) containing:
 - 1 - Instrument Cable (autoclavable)
 - 1 - Red Instrument Clip (autoclavable) (Stock No. D619RH)
 - 2 - Lip Contacts (autoclavable) (Stock No. D619GC)
 - 1 - Green Self-Test/Calibration Plug
 - 1 - Quick-Probe (autoclavable) (Stock No. D613)
 - 1 - Plastic Insulation Sheath
- Operator's Manual/Instructions for Use

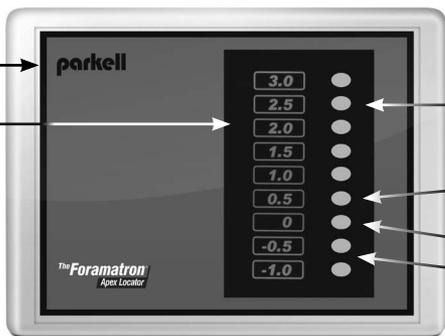
Replacement parts are available from Parkell Customer Service at 800-243-7446, or at www.parkell.com

DIRECTIONS FOR USE: The following suggested clinical technique may be modified by experienced clinicians as needed.

- 1) Before each use, inspect the cables to be sure they are not frayed, bent or that the insulation is not damaged.
- 2) Administer local anesthesia. Inadequate anesthesia may result in patient discomfort.
- 3) Isolate the operative field with a rubber dam. Ensure that clamp does not touch the Lip Contact (#13).
- 4) Remove all carious or undermined tooth tissue and obtain appropriate access opening into the pulp chamber.
- 5) Extirpate the coronal pulp tissue completely from the pulp chamber. Flush the chamber with an irrigant solution such as water, hydrogen peroxide, sodium hypochlorite, EDTA, anaesthetic solution or saline. For consistent, accurate readings, the pulp chamber should be dried with a cotton pledget, while the root canals should be left slightly moist with irrigant. Make sure to control any pulpal bleeding which may refill the pulp chamber. Dry the outer tooth surfaces with the air syringe.

Front view:

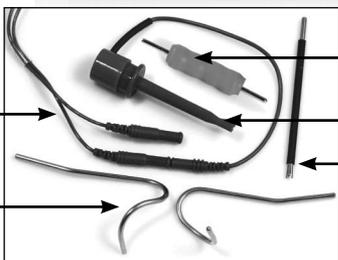
- #1 Illuminated Parkell logo
- #2 Illuminated Display Scale



- #3 Green Tracking Lights (indicates passage down root canal)
- #4 Yellow Tracking Lights (indicates "approaching" apex)
- #5 Red "APEX" Light (indicates "at" apex)
- #6 Orange "OVER" Lights (indicates "past" apex)

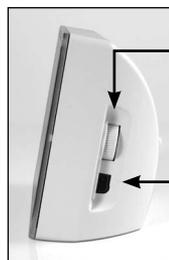
Accessories:

- #9 Instrument Cable
- #13 Lip Contact



- #11 Self-Test/Calibration Plug
- #12 Red Instrument Clip
- #10 Quick-Probe

Side view:



- #7 On/Off Volume Control
- #8 Instrument Cable Socket

- 6) Plug the Instrument Cable (#9) into the Foramatron via the Instrument Cable Socket (#8) on the side of the unit. The Instrument Cable plug is directional, so be sure that the round side of the plug corresponds to the round side of the Socket.
- 7) Connect a Lip Contact (#13) to one of the open sockets at the end of the Instrument Cable (#9). Drape the Lip Contact over the lower lip, using a small amount of toothpaste on the Contact to enhance conductivity. The metal Lip Contact may be bent if desired.
- 8) Connect either 1) the Red Instrument Clip (#12) or 2) the Quick-Probe (#10) to the other open socket at the end of the Instrument Cable (see photo). The Clip is designed to be attached to the corrosion-free metal neck of an endodontic instrument using the spring mechanism, or the Quick-Probe can be periodically touched to the file to get a reading. If necessary, remove any file-neck corrosion with a sharp hand instrument. Attach a rubber stopper to the metal neck of the instrument for measurement.
- 9) Turn the device on via the On/Off/Volume Control (#7). A self-test will occur where the Parkell logo (#1) will blink for a few seconds and the display scale (#2) will light up and then fade. If the Parkell logo fails to illuminate or starts to blink after the self-test, replace the battery. If the problem persists, contact Parkell for assistance.
- 10) To avoid traumatizing the periapical tissues (which may cause bleeding and post-operative pain), initially instrument with a file or reamer that has an apical diameter that is larger than that of the root apex, as estimated by visualizing the pre-operative radiograph. Slowly work your way down through progressively smaller file sizes until the apical foramen is reached, without passing the apex and entering into the periapical tissues.
- 11) As the tip of the instrument approaches the apex, a fast audio "chirping" will be heard and four Green Tracking Lights (#3) and the Display Scale (#2) will light in sequence. When the tip of the instrument gets very close to the apex, two Yellow Tracking Lights (#4) will light in sequence and the audio "chirping" will slow. These warn the clinician to proceed with caution, as the apex is quite near. When the instrument tip arrives at the apical foramen (with an intact periodontal ligament), the Red "APEX" Light (#5) will illuminate and the audio will change to an extremely slow beeping.
- 12) When the apex is reached, STOP INSTRUMENTING! To confirm, pull the instrument back slightly until the Red "APEX" Light turns off. Then re-advance the instrument slowly until the light just re-illuminates. The file is now positioned at the correct working length. Move the rubber stopper to contact an appropriate external tooth landmark (e.g. a cusp tip or marginal ridge). Remove the instrument from the canal and measure the file length from the tip to the rubber stopper. Record the working length and tooth landmark in the patient's record and proceed to the next canal.
- 13) If Orange "OVER" Lights (#6) illuminate, and a continuous audio tone is heard, the device is warning you that the file is past the apex. In some clinical situations (such as considerable periapical pathology), the Orange "OVER" Lights may not illuminate when the apex is passed. It is recommended that instrumentation stop as soon as the Red "APEX" Light illuminates. Good clinical judgment should always be exercised.

14) When working through a metal restoration, use a plastic sheath (enclosed) to isolate the metal file and avoid contact between the file and the metal restoration. Make sure the Red Instrument Clip grips some exposed metal of the file to ensure good electrical conductivity.

15) The most accurate readings will be found when the apex locator is used at the beginning of the procedure. As the canal or the apex is widened via instrumentation, the periapical/periodontal tissues may be slightly traumatized by the cutting action of the sharp file or reamer. As the insertion point of these fibers appears to “migrate” apically, the root canal may seem to be “getting longer”, although this is not actually the case. For best results, you should trust your initial readings and fill to the initial working length, as determined by your Foramatron. Using this method, your final outcome should be consistently accurate.

CLEANING AND INFECTION CONTROL:

- **DO NOT AUTOCLAVE THE FORAMATRON ITSELF, AS AUTOCLAVE HEAT WILL DESTROY THE UNIT.** It should be cleaned with a damp cloth, wiped with ethyl alcohol and dried immediately.
- To assure adequate sterilization of accessories, wash them in warm, soapy water before bagging them for processing in the steam autoclave. Make sure to gently clean the inner surface of the instrument clip that grasps endodontic instruments, being careful not to scrape off the gold plating.
- The Lip Contact, Red Instrument Clip, Instrument Cable and Quick-Probe may be bagged and sterilized in a steam autoclave as per the autoclave manufacturer’s instructions, or at 121°C @ 15psi for 20+ minutes. Do not attempt sterilization using dry heat.

USER MAINTENANCE AND AUTHORIZED SERVICE:



Bottom view of battery compartment



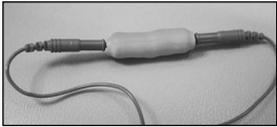
Rear view/ open battery compartment

- Replace the 9V battery if the blue Parkell logo (#1) fails to illuminate or blinks during use. Because the load on a battery increases during its use, the device may not blink to indicate a weak battery until the file is in the root canal.
- To replace the battery, remove the battery compartment door on the rear of unit by pressing the Battery Door Latch (#14) on the underside. Note the position of the Positive (+) Terminal (#15). Replace the battery, being careful to install it with the

positive terminal towards the top of the unit. Push the bottom of the battery firmly into place in the battery holder until it snaps.

- Remove the battery from the Foramatron if the device won't be used for a prolonged period.
- Used batteries must be discarded according to local environmental regulations.
- Call Parkell at 1-800-243-7446 for factory service.
- If you purchased this product directly from Parkell, your unit is automatically registered. Your invoice is your “Warranty Registration” receipt. If you purchased this product from a domestic or overseas dealer, please register your product via the Internet at www.parkell.com. From the Home screen, “Page Down” to the bottom of the screen and click on the “Product Registration” button found under “Manage Your Account”. Fill out the online form, print a copy for your records, and click the “Submit” button. Store the printout in a safe place.

TESTING THE CALIBRATION OF YOUR FORAMATRON:

- 1) Unplug the Lip Contact (#13) and the Red Instrument Clip (#12) from the Instrument Cable (#9). In their place, insert the two ends of the green, dual-ended Self-Testing Plug (#11) into each of the open sockets of the Instrument Cable.
 
- 2) Turn the Foramatron on and wait a few seconds.
- 3) A properly operating device will illuminate the Red “APEX” Light (#5) and sound a very slow beeping tone. If this is not the case, the battery should be replaced with a fresh one. If the problem persists, call Parkell at 1-800-243-7446 for further instructions about factory service.

RESOLVING COMMON CLINICAL PROBLEMS:

- 1) The instant the file enters the root canal, the Red APEX Light or the Orange OVER Lights are illuminated.
 - a) **Cause:** Excess fluid in the canal is overflowing into the chamber. **Solution:** Remove excess fluid from chamber with a pledget or paper point, while keeping the canal moist.
 - b) **Cause:** Instrument is touching a metallic restoration or rubber dam clamp. **Solution:** Insulate top of instrument with plastic sheath(s) provided.
 - c) **Cause:** Pulp chamber and/or outer tooth surfaces are wet. **Solution:** Be sure that they are dry before using the device.
 - d) **Cause:** The pulp chamber has been perforated. **Solution:** Inspect meticulously for signs of perforation, caries or resorption. If present, an alternate method of apex location may be indicated.
 - e) **Cause:** A wet glove is touching the file causing a short circuit. **Solution:** Change to a dry glove.

- 2) The lights blink on and off irregularly as you are working, giving erratic readings:
- a) **Cause:** Canal is too dry. **Solution:** Lubricate or irrigate to restore conductivity.
 - b) **Cause:** Instrument is touching a metallic restoration or RD clamp. **Solution:** Insulate top of instrument with plastic sheath(s) provided.
 - c) **Cause:** Broken wire in the cable assembly. **Solution:** Replace with new cables about every 2-3 years.
 - d) **Cause:** Dead or dying battery. **Solution:** Replace with new battery.
 - e) **Cause:** Debris on the inner surface of the instrument clip causing intermittent contact.
Solution: Wipe the instrument clip with alcohol-soaked gauze pad until clean.
 - f) **Cause:** Undersized file or reamer is significantly smaller at the tip than the diameter of the apical foramen.
Solution: Always use file/reamer of appropriate diameter to ensure that there is good electrical contact with apical tissues.
- 3) Red "APEX" light does not illuminate until the instrument passes the foramen, at which time Orange "OVER" Lights illuminate.
- a) **Cause:** The canal is too dry. **Solution:** Moisten the root canal with irrigant solution.
- 4) Readout remains unchanged even though the instrument is descending into the canal. Then the LEDs begin to light before you reach the apex:
- a) **Cause:** An ancillary or lateral canal is present. **Solution:** When the instrument passes a short lateral canal, the device reads its length and continues to do so until the distance to the apex is shorter than to the ancillary canal. Irrigation with sodium hypochlorite followed by water will remove the organic tissue from the lateral canal and allow the apex to properly register the length.

WARNING: No modification of the equipment is allowed.

In the event that The Foramatron needs to be disposed, the disposal of waste electrical and electronic equipment as unsorted municipal waste is prohibited and requires that it be recycled or disposed of separately. Hazardous substances are present in electrical and electronic equipment and present potential risks to human health and the environment if disposed of in municipal landfills which are not designed to prevent migration of substances into the soil and groundwater. Follow all local governmental requirements for proper disposal.

GLOSSARY OF SYMBOLS



Attention, consult accompanying documents



Type BF Equipment



European Authorized Representative (Not a dealer/distributor):

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