

CAUTION: Federal Law restricts this device to sale by or on the order of a licensed practitioner.

parkell inc.

INSTRUCTIONS FOR USE:

Digitest IITM

Pulp Vitality Tester
(Stock No. D640)

Device Description

The Digitest IITM Pulp Vitality Tester is a hand-held, battery-powered dental diagnostic device that identifies a living tooth nerve by stimulating it with a weak electric current. When the operator depresses the button, the strength of the electrical stimulus automatically increases at a rate preset by the operator. The unique waveform is designed to trigger a patient response in a vital nerve with a minimal amount of discomfort.

Intended use/indications

The Digitest II Pulp Vitality Tester is intended to be used as a diagnostic instrument to assist in the determination of the vitality of the dental pulp.

Contraindications

This device is contraindicated for use on a patient or by an operator wearing a cardiac pacemaker or any other intra-corporeal electronic device (internal defibrillator, insulin pump, etc.), or any personal electronic monitoring device.

Warning

- Do not modify this device. Modification may violate safety codes, endanger the patient and the operator, and void the warranty.
- This device should only be used by licensed dental professionals qualified in the use of the unit.
- Read and understand all instruction manuals before using the device.

Specifications

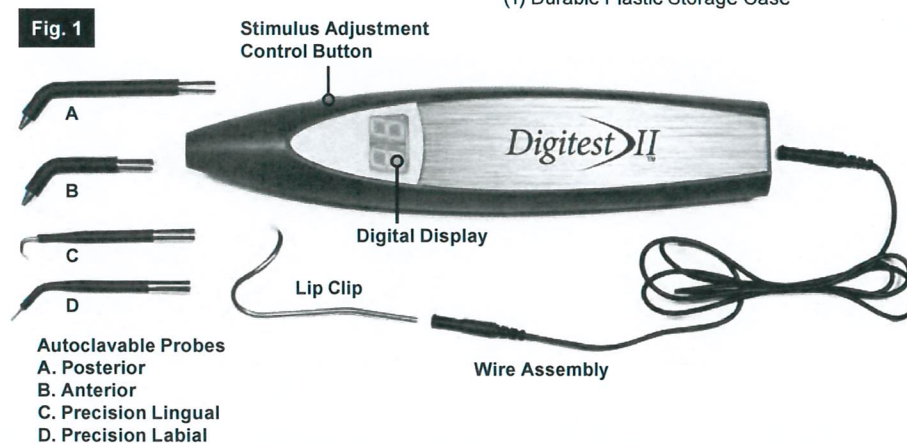
- Protection Against Electric Shock - Class 1, Type B applied part
- Equipment not suitable for use in the presence of flammable or explosive gases. Use of dental nitrous oxide/oxygen analgesia is acceptable.
- Protection Against Ingress of Liquids - Pulp Tester - IPX0 (Ordinary)
- Mode of Operation of Equipment - Continuous.
- Operating conditions: 15-40°C, 10-80% RH (non-condensing)
- Transport and Storage conditions: 10-40°C, 10-80% RH (non-condensing)

Conformance to Standards

Parkell's quality system is certified to ISO9001/ISO13485, and this device conforms with IEC 60601-1, UL 60601-1:2003, IEC 60601-1-2, CAN/CSA-C22.2 No. 60601-1-08 & Medical Device Directive 93/42/EEC.

The Digitest II kit includes (Figure 1)

- (1) Digitest II Pulp Vitality Tester
- (1) High-output alkaline battery (9-Volt) (already installed in the tester)
- (2) Autoclavable stainless steel standard size tooth probes (anterior and posterior)
- (2) Autoclavable stainless steel precision size tooth probes, for testing small or difficult-to-access labial or lingual surfaces or accessible crown margins.
- (1) Autoclavable Lip Clip with Wire Assembly
- (1) Instructions for Use / Warranty Registration Card
- (1) Durable Plastic Storage Case



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Cleaning and Infection Control of the Digitest II

- DO NOT AUTOCLAVE THE DIGITEST II POWER UNIT, AS THIS WILL CAUSE DAMAGE TO IT.
- Ideally, the Power Unit should be protected using appropriately-sized disposable plastic barrier sleeves. Since the Digitest II incorporates sophisticated electronic circuitry, it should not be directly sprayed with or soaked in disinfectant. The device may be disinfected by wiping it with a damp cloth or paper towel sprayed with an EPA-approved high-level surface disinfectant, and dried with a paper towel. Follow the surface disinfecting protocol specified by the disinfectant manufacturer.
- Autoclaving does not remove accumulated debris. Before autoclaving, scrub the autoclavable components with a brush, or clean in an ultrasonic cleaner, using warm, soapy water.
- The Tooth Probes, Lip Clip and Wire Assembly may be sterilized in any conventional steam autoclave (132-135C for 15 min for gravity displacement or 4 minutes for prevacuum cycle, or using the manufacturer's recommended procedure, if different). Minimum cool down interval is 15 min.

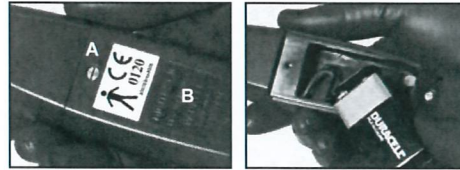
Service and Maintenance

- Do not open the Power Unit, except to change the battery. There are no user-serviceable parts inside. Internal repairs are to be made only by authorized Parkell personnel, by returning the unit to the service address at the end of these instructions.
- Avoid dropping the Power Unit or subjecting it to physical shock.
- Battery should be removed if unit is to be stored unused for more than 30 days.
- To prolong battery life, the device automatically turns off after 14 seconds of inactivity.
- When the battery capacity is low, the Left and Right digital display digits will flash alternatively while the unit is activated. Replace the battery as explained in the section "Changing the Battery".
- If a Tooth Probe becomes loose in the mount of the Power Unit, it may be tightened by carefully inserting a flat screwdriver blade into the split metal base of the probe and gently expanding the sides apart with a twist of the tool.
- Discard and replace any Tooth Probe if the metal or the insulation becomes damaged during use.

Changing the Battery (Figure 2)

- The Digitest II Pulp Vitality Tester comes with a high-output, 9 Volt alkaline battery factory installed.
- The replacement battery may be a Radio Shack 23-553, Duracell MN1604, Panasonic 6AM6 or equivalent. Although rechargeable 9 Volt batteries may be utilized, they will require more frequent changing and charging because of the considerable voltage required to perform the pulp testing procedure.
- To replace a weak battery, remove screw (A) and carefully lift off the plastic battery door (B) by gently pulling it away from the Power Unit. Withdraw the weak battery from the battery enclosure, and

Fig. 2

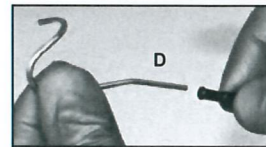
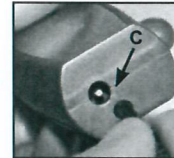


unsnap the wire battery connector. Discard battery in accordance with all applicable environmental laws.

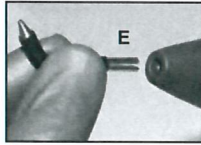
- The fresh battery should be snapped onto the connector and placed in the Power Unit so the top end attached to the connector is placed first into the opening. Slight pressure on the bottom of the battery will help it to slide home. Replace the plastic battery door (B) by engaging the tabs on the bottom first, and tighten the screw (A) gently.

Digitest II Setup, Prior to Performing Pulp Vitality Testing

- Standard infection control protocol should be followed during pulp testing, by wearing disposable rubber, vinyl or nitrile gloves. When wearing gloves, the circuit is completed by using the autoclavable Lip Clip and Wire Assembly. Plug one end of the wire assembly onto the bottom of the Power Unit (C), and insert the Lip Clip (D) into the other socket. Place a small amount of toothpaste on the lip to enhance electrical conductivity, and then place the Lip Clip over the patient's toothpaste-coated lip, making good contact with the mucosa.
- Although it is strongly recommended that gloves be worn when performing vitality testing to maintain accepted standards of infection control, if gloves are not being worn, the ground wire need not be used. The operator may complete the circuit by making contact with the metal plate of the unit and touching the patient's cheek or chin with the free hand.
- Remember that to accurately diagnose the condition of the tooth, pulp testing must be performed on a patient who has not been anesthetized or received gas analgesia. Make sure to use the Digitest II tester BEFORE you administer local anaesthesia or gas analgesia.
- The tooth to be tested and the adjacent teeth must be clean and dry. Interproximal embrasures should be made free of any impacted food debris, saliva, water or plaque by flossing or scaling with an instrument and air-drying before testing.
- It is often useful to electrically isolate the tooth being tested from neighboring teeth or metallic restorations by wrapping it with a clear mylar strip, such as those used in fabricating Class III composite restorations.

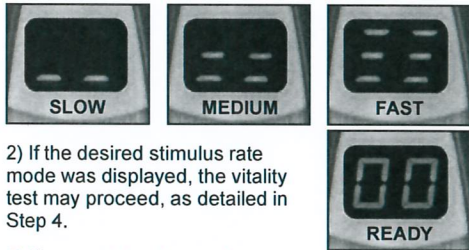
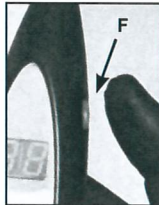


- A dry cotton roll should be placed in the buccal vestibule to isolate the tooth from the lip and cheek.
- A plastic mirror should be used to keep the tongue off of the tooth during testing.
- Insert Tooth Probe (E) into the open end of the Power Unit. To enhance electrical conductivity and contact between tooth and probe, apply a small amount of toothpaste to the metal tip.
- Metal or ceramic surfaces cannot be used as touch points for the Tooth Probes. Teeth selected for pulp testing must possess enough exposed enamel or dentin to allow the probe to make contact without touching the gingiva or a metal restoration. In certain cases, this may require the use of a Precision Probe (included).
- Fully instruct the patient as to what you will be doing, so they are not surprised during the test.
- Tell the patient that when the vitality test is underway, they should carefully raise their hand at the first sign of sensing the stimulus. This should avoid any patient discomfort.



Pulp Vitality Testing with the Digitest II Pulp Vitality Tester

- 1) To activate the unit, press and hold the start button (F) for a half second, and then release the button. When the button is depressed, the display will show one row of horizontal bars if the device is set for "SLOW", two rows for "MEDIUM", or three rows for "FAST". When the button is released, the display will read "00", indicating that it is ready to begin the vitality test. The display will shut off if the unit is not used within 14 seconds.



- 2) If the desired stimulus rate mode was displayed, the vitality test may proceed, as detailed in Step 4.
- 3) If you wish to change the stimulus rate mode, repeatedly press and release the button twice in quick succession. The display will cycle between the three stimulus rate modes. When the desired setting is displayed, press the button one more time to let the display return to "00", so the test may begin.

NOTE: The unit will remember the last stimulus rate mode setting, even if the device is powered down.

- 4) Place the toothpaste-covered tip of the Tooth Probe on the middle of the labial or lingual surface

of the tooth. Avoid soft tissue and restorations such as crowns, amalgams or composites.

- 5) Depress and hold the button, and the display number will rise, indicating that a gentle-pulse stimulus is being automatically applied to the tooth. When the patient indicates that they feel the stimulus, release the button. The stimulus will stop immediately. The display will freeze and hold the final reading for approximately 14 seconds, so it may be noted. The unit will then automatically turn itself off.
- 6) The maximum stimulus reading is 64. Even if there is no response at this level, there is still the possibility that the tooth is vital. No sensation at this number simply suggests that the tooth is non-responsive at the time of the test. However, since teeth have been known to recover from traumatic injury many days after presenting with a "non-vital" reading, follow up testing is almost always indicated after any initial readings. If this reading persists over several visits, it is reasonable to assume that the tooth is non-vital. However, this conclusion should always be confirmed by another accepted endodontic testing method.

- 7) To verify the reading, a corresponding control tooth in the same arch should be tested. Molars should be matched to molars, premolars to premolars, cuspids to cuspids, and incisors to incisors. If this is not possible because teeth are absent, endodontically treated, or have full coverage restorations, a similar tooth in the opposite arch should be used.

Clinical Observations

- It is not possible to prepare a "table of normal values" for pulp tester readings, because THERE IS NO "NORMAL" IN PULP TESTING. Rather, the clinician should perform sequential comparisons between the subject tooth and the control tooth at consecutive office visits, observing how the readings are changing as time progresses. By utilizing electric pulp testing, along with all available diagnostic information, it is often possible to predict where the tooth's vitality is heading. This allows the clinician to make informed decisions as to whether endodontic therapy is appropriate, and whether it is prudent to simply watch and wait.
- There are general anatomic trends in pulp vitality readings. Posterior teeth generally require greater stimulus than anteriors, probably because of the greater thickness of enamel and dentin in posterior teeth. Enamel requires a greater stimulus than dentin or cementum, because of the higher percentage of non-conductive mineral, and the lower percentage of water. Cross-arch teeth, or opposing teeth will have similar thresholds to stimulus.
- The stimulus threshold may also be affected by such factors as the age, gender and previous pain history of the patient, pulp chamber size, trauma, pathology and use of prescription and non-prescription medications, or illicit drug use.

Continued

Troubleshooting the Digitest Pulp Vitality Tester

- 1) Display does not light when button is depressed.
 - a) Battery weak or dead – Needs replacement.
 - b) Unit damaged – Needs service.
- 2) Tooth Probe loose or rotating in Power Unit.
 - a) Tooth Probe base too loose—Adjust base with screwdriver.
- 3) Vitality test showing no response at “64” reading, while control tooth is normal.
 - a) Tooth is actually non-vital.
 - b) Tooth Probe not adequately contacting tooth – Apply toothpaste to probe and reapply to tooth.
 - c) Lip Clip Wire Assembly not connected to Power Unit while wearing gloves – Connect Lip Clip and Wire Assembly as detailed above.
- 4) Vitality test showing immediate response at very low reading.
 - a) Tooth is hyperemic – recommend endodontic treatment.
 - b) If problem persists with all teeth tested, unit needs service.

Warranty

Parkell will repair or replace, at its option, a defective unit. This warranty does not cover repairs where the only fault found is a weak or dead battery. Always replace the battery with a fresh one before returning the unit for warranty service, to rule this out as the cause of the problem. **This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties, express or implied.** Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described. Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.



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