parkell D655 Digitest 3 Pulp Vitality Tester Instruction Manual

D655 Digitest 3 Pulp Vitality Tester
Instruction Manual

Contents [hide

DEVICE DESCRIPTION

The Digitest® 3 Pulp Vitality Tester is a handheld, battery-powered dental diagnostic device that identifies es 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 one of three preset rates. The unique waveform is designed to trigger a patient response in a vital nerve with a minimal amount of discomfort.

INTENDED USE/INDICATIONS

The Digest 3 Pulp Vitality Tester is intended to be used as a diagnostic instrument to assist in the determination of the vitality of the dental pulp. It is indicated for use on vital and non-vital adult human teeth.

CONTRAINDICATIONS

This Digitest 3 Pulp Vitality Tester 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Digest 3 unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may result.
- Use of this equipment adjacent to, or stacked with other equipment, should be avoided because it may result in improper operation.
- This device is to be operated with Parkell accessories only. Use of accessories other than those specified, or provided by Parkell Inc., may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment or improper operation.

SPECIFICATIONS

- **Protection Against Electric Shock:** Type BF applied part.
- Equipment not suitable for use in the presence of l flammable or explosive gases. The 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).
- **Stimulator Output:** The voltage output at the electrode can be characterized as discretely pulsed voltage packets that gradually increase in amplitude as the display count is incremented.
  The output voltage is purely AC and contains no
  DC component. For further electrical specific cations, see below.

ELECTRICAL SPECIFICATIONS

- **Maximum DC Component Amplitude:** None
- **Maximum AC Component Amplitude:** 500 V peak to peak
- **Peak Output Current Maximum:** 250uA
- **Pulse Durations (Packet Width):** High (3 bars): 60.5ms Medium (2 bars): 100ms Low (1 bar): 124ms
- **Pulse Repetition Period: High (3 bars):** 140ms Medium (2 bars): 228ms Low (1 bar): 284ms

- **Average Voltage Increment:** 7 V
- The tooth enamel of a patient is simulated using a 2 Megaohm resistive load. Using this load as a reference, the absolute maximum voltage that can appear at the electrode is 500V at a maximum output current of 250uA.

CONFORMANCE TO STANDARDS

- Parkell's quality system is certified to ISO 13485, and this device conforms with IEC 60601-1, IEC 60601-1-2, CAN/CSA-C22.2 No. 60601-1, and IEC 60601-2-40.

Fig. 1

A. Stimulus Adjustment / Control Button	E. Posterior Autoclavable Probe
B. Digital Display	F. Anterior Autoclavable Probe
C. Ground Clip	G. Precision Labial Autoclavable Probe
D. Lead Wire	H. Precision Lingual Autoclavable Probe

KIT INCLUDES (FIG. 1):

- (1) Digitest 3 Pulp Vitality Tester
- (4) Autoclavable Stainless Steel Tooth Probes
- (1) Lead Wire
- (1) Ground Clip
- (1) High-Output Alkaline 9-Volt Battery

CLEANING AND INFECTION CONTROL OF THE DIGITEST 3

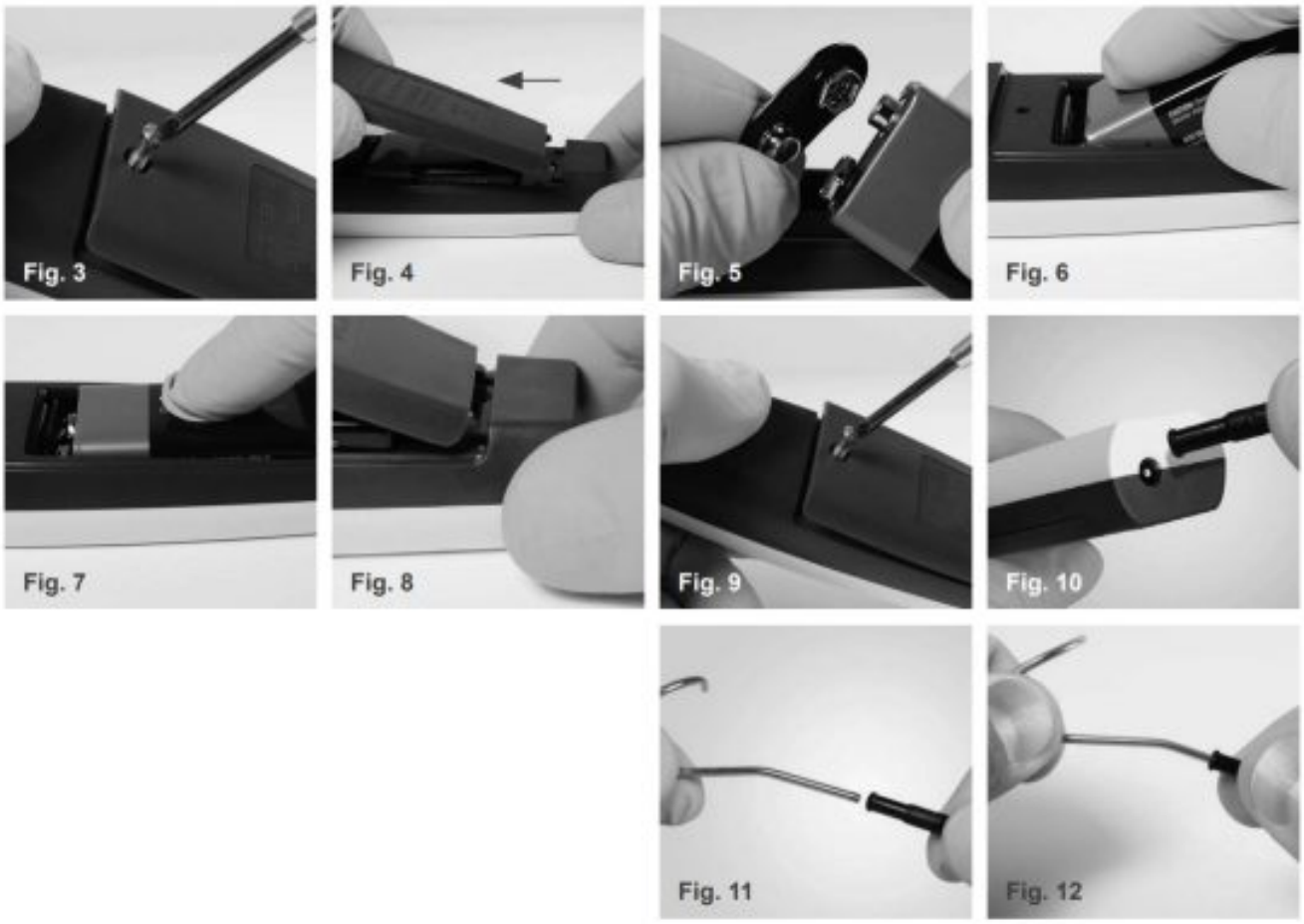
- Autoclaving and disinfecting do not remove accumulated debris. Before autoclaving or disinfecting accessories: Rinse the accessories under warm running water for 30 seconds to remove any external or internal soil or debris. Using a soft soapy cleaning brush to assist in the cleaning, if neces-sary. Use non-ammoniated detergent or dish-washing soap. Do not use ammoniated cleansers or disinfectants. Rinse the item again under warm running water for 30 seconds to remove any resid-ual soap and blot dry with a dry lint-free towel.
- DO NOT AUTOCLAVE THE DIGITEST 3 POWER UNIT, AS THIS WILL CAUSE DAMAGE TO IT.

- The Power Unit should be protected using proper-ly-sized disposable plastic barrier sleeves
- Since the Digitest 3 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 lint-free towel moistened with an EPA-approved disinfectant containing not more than 30% alcohol, alcohol-free surface disinfectant wipes, or disinfecting wipes containing 3-5% Hydrogen Peroxide. Any disinfectant used on the lens and the housing should eventually be wiped off as per the instructions given on disinfectant labeling to remove chemical residue. If the lens becomes hazy or scratched, NOVUS No. 2- Fine Scratch Remover can be used to remove the damage as per the manufacturer's instructions.
- Follow the surface disinfecting protocol specified by the disinfectant manufacturer.
- For further information, consult the Centers for Disease Control website at CDC.gov, referencing the most recent version of the *Guidelines for Infection Control in Dental Health-Care Settings".
- The Tooth Probes, Ground Clip, and Lead Wire may be sterilized in any conventional steam auto-clave (130°-134°C for 15 min for Gravity Displacement units, or 4 minutes for Pre-vacuum Cycle units, followed by a 15-minute minimum cooldown interval). Comply with the autoclave manufacturer's recommended procedure, if different. These items can be autoclaved for 250 cycles before requiring replacement.

SERVICE AND MAINTENANCE

- Do not open the Digitest 3 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 the 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 is low, the letters "LO" will blink on the screen when the device is initially turned on. If the battery is low, replace it as explained in the section "Installing/Replacing the Battery".
- If a Tooth Probe becomes loose in the mount of the Power Unit, it may be tightened by carefully inserting an l at screwdriver blade into the split metal base of the probe and gently expanding the sides apart with a twist of the tool (Figure 2).

Fig. 2



- Discard and replace any Tooth Probe if the metal or the insulation becomes damaged during use.

INSTALLING / REPLACING THE BATTERY

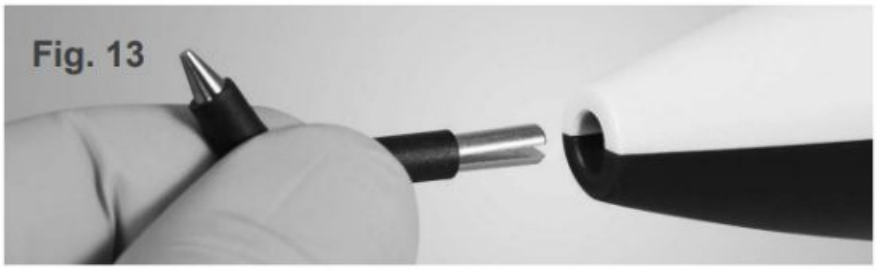
- The Digitest 3 Pulp Vitality Tester comes with a high-output, 9-Volt alkaline battery.
- To install the battery, remove the screw (Figure 3) and carefully lift off the plastic battery door by gently pulling it away from the Power Unit (Figure 4). Withdraw the old battery from the battery enclosure, and unsnap it from the wire battery connector (Figure 5). Discard in accordance with applicable 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 into the opening first (Figure 6). Slight pressure on the bottom of the battery will help it to slide home (Figure 7). Replace the plastic battery door by engaging the tabs on the bottom first (Figure 8), and tighten the screw gently (Figure 9).
- The replacement battery may be a Duracell® MN1604, Panasonic® 6AM6, or equivalent. Although rechargeable 9-Volt batteries may be utilized, they will require more frequent charging because of the considerable voltage required to perform the pulp testing procedure.

DIGITEST 3 SETUP PRIOR TO PERFORMING PULP VITALITY TESTING

- To accurately diagnose the condition of the tooth, pulp testing must be performed on a patient who has not received local anesthesia or gas analgesia.
  Make sure to use the Digitest 3 BEFORE you perform these procedures.
- Fully explain to the patient what you will be doing prior to the pulp test, so they are not surprised during the test. Using the words “ feeling” or “discomfort ” is always preferable to the word “pain”.
- Standard infection control protocol must be followed by the operator during pulp testing, by wearing disposable

rubber, vinyl, or nitrile gloves.

- 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, scaling with an instrument, and air-drying before testing.
- Electrically isolate the tooth being tested from neighboring teeth or metallic restorations by wrap-ping it with a clear mylar strip, such as those used in fabricating Class 3 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 the tooth during testing.
- The circuit is completed by using the autoclavable Ground Clip and Lead Wire. Plug one end of the Lead Wire into the socket on the bottom of the Power Unit (Figure 10), and insert the Ground Clip into the other socket (Figure 11).
- Place a small amount of toothpaste on the Ground Clip and ask the patient to hold the metal of the clip between their right thumb and forefinger. Then ask them to hold the black plastic wire socket between their left thumb and forefinger (Figure 12).
- Explain to the patient that the test should not hurt, but that they are in control, and that they can stop it at any time. Tell them that when they first feel a change in the tooth being tested, such as puls-ing, buzzing, tingling, or slight discomfort, all they need to do is let go of the metal Ground Clip and the test will be over.
- Insert Tooth Probe into the open end of the Power Unit (Figure 13). To enhance electrical conductivity and contact between the tooth and the probe, apply a small amount of toothpaste to the metal tip.



- Metal or ceramic surfaces cannot be used as touchpoints 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).

VITALITY TESTING WITH THE DIGITEST 3 PULP TESTER

1. To activate the unit, press and hold the start button (Figure 14) 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 stimulus rate is set for ‘SLOW, two rows for “MEDIUM”, or three rows for ‘FAST’ (Figure 15).

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, simply press the button and the mode will change after the button is released.

NOTE: The unit will remember the last stim-ulus 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 stimulus is being automatically applied to the tooth. When the patient indicates that they feel the stimulus, they should let go of the metal Ground Clip, which will stop the test immediately. The display will freeze and hold the final reading for approxi-mately 14 seconds, so it may be written down. 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 may simply indicate that the tooth is non-responsive at the time of the test, possibly from trauma. However, since teeth have been known to recover from a 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 confirm the diagnosis, 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 read-ings 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, or 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 interiors, 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 minerals, and the lower percentage of water. Similar cross-arch teeth will have similar thresholds to stimulus.
- The stimulus threshold may also be affected by such factors as age, gender, previous pain history of the patient, pulp chamber size, trauma, pathology and use of prescription and non-prescription medications, or illicit drug use.
- The Parkell Digitest 3 is to be used in conjunction with other diagnostic tests such as x-rays, temperature tests, percussion, etc. in order to confirm tooth pulp vitality.

TROUBLESHOOTING THE DIGITEST 3 PULP TESTER

Display does not light when the button is depressed.

- Battery is weak or dead – needs replacement.
- Unit damaged – needs service.
- Ground wire not in use.

Tooth Probe lose or rotate in Power Unit.

- Tooth Probe base too loose—adjust base with a screwdriver (See Figure 2).

Vitality test showing no response at “64” reading, while control tooth is normal.

The tooth is non-vital.

- Tooth Probe not adequately contacting tooth – apply toothpaste to probe and reapply to the tooth.
- Ground Clip Lead Wire not connected to Power Unit.
- Patient not holding “Ground Clip” tightly, or without toothpaste on it.

Vitality test showing immediate response at very low reading.

- Tooth is hyperemic – recommend endodontic treatment.
- If the problem persists with all teeth tested, the unit needs service.

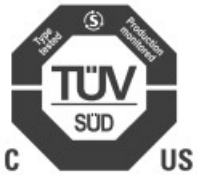
WARRANTY AND TERMS OF USE

For full Warranty and Terms of Use information, please see **www.parkell.com**. Parkell’s Quality System is certified to ISO 13485.
If you have any questions, please email our Technical Support Service at: **techsupport@parkell.com**

EXPLANATION OF SYMBOLS USED

	Professional use only
	Serial number
	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Non-sterile
	Temperature limit

	Do not use it if the package is damaged. This symbol is on the packaging.
	Follow instructions for use
	Keep dry
	Do not dispose of this product into the ordinary municipal waste or garbage system
	Package contents
	Catalogue / stock number
	Manufacturer
	Pulp Tester
	Autoclavable Probe(s)
	Lead Wire
	Ground Clip
	9V Battery
	Unique Device Identifier
	Medical Device
	Importer
	Translation



Type “BF”
Applied Part

CE
1639

Certified to MDD
93/42/EEC

This precision dental device was designed, manufactured, and is serviced in the United States of America by:

Parkell, Inc.,
300 Executive Dr., Edgewood, NY 11717 USA
(800) 243-7446 • www.parkell.com

UKRP: Topdental (Products) Ltd,
12 Ryeield Way, Silsden, West Yorkshire BD20, 0EF England UK

mt-g medical translation GmbH & Co KG
Stuttgarter Straße 155 • D-89075 Ulm

MADE IN USA

Documents / Resources

	parkell D655 Digitest 3 Pulp Vitality Tester [pdf] Instruction Manual D655, D655E, D833T, Digitest 3 Pulp Vitality Tester

References

- Dental Tools, Devices and Materials
- Centers for Disease Control and Prevention
- Dental Tools, Devices and Materials