USER’S GUIDE

DEVICE FOR ELECTRIC DENTAL PULP TESTING

«PULPEST»

PulpEst
Congratulations!

! On buying the device, be sure to check the delivery set, presence and correctness of the Quality Warranty Card filling, the acceptance certificate and product selling marks.

! Please, thoroughly read the user’s guide before using the device. Keep the User’s guide for future use.

! Please, address to the manufacturer if you have some questions when using the device.
Hotline: +7(495)663-22-11 (extension 170),
E-mail: hotline @ geosoft.ru
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1. GENERAL INFORMATION

1.1. The device brief summary:

«PulpEst» - is a compact device, designed to determine the clinical condition of dental pulp - electro odonto diagnosis (EOD).

The device is manufactured in two modifications according to table 1.

Table 1.

<table>
<thead>
<tr>
<th>Modifications</th>
<th>Operating area</th>
<th>LED illumination</th>
</tr>
</thead>
<tbody>
<tr>
<td>PulpEst</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>PulpEst (L)</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

The operational principle of the device is the estimation of the patient threshold to irritation by an electric current.

Under pathological processes in tooth and periodontal tissues the excitability of pulp nervous receptors is reduced, and, as the consequent, the sensitivity of the patient to value of an irritant electric current changes.

1.2. Field of application:

The device is designed for use in dentistry (endodontics) and can be used only in hospitals by medical specialists licensed to practice dentistry. The manufacturer is not responsible for the device misuse.

1.3. Contraindications

Do not use the device on patients with pacemakers.
1.4. Safety measures and warnings

! Use the device only with the “Geosoft Dent” authentic accessories (see part 3. “Accessories”).

! Do not dismount and do not change the device construction anyhow. **In the case of the device integrity damage warranty is considered to be invalid.** The device power source should be changed by authorized service departments only.

! Avoid any liquid ingress into the device case.

! Do not use the device close to inflammables. The device is not operational in the presence of inflammable anesthetic mixtures with air, oxygen or nitrogen oxides.

! Use only sterile and disinfected device components. The device should be sterilized and disinfected directly before the first device use and also after each patient in order to avoid cross infection (for more details see part 7 “The device sterilization and disinfection”).

! The device requires special safety precautions with regard to electromagnetic compatibility (EMC), and the EMC information contained in this manual must be strictly adhered to during installation and operation. It is especially important not to use the device near fluorescent lamps, radio transmitters or remote controls, portable or mobile radio frequency communications equipment.

! Do not use this device in conjunction with other equipment, or as part of other equipment.

! Do not use the accessories, transducers and cables other than those listed below. This may result in increased emissions or decreased immunity performance of the device. The manufacturer guarantees the electromagnetic compatibility of the following elements: **Cable with maximum length 105 cm; Mains charger (model DN500) with a maximum cable length 1.8m**

! The device normally operates at temperatures 10-35°C, relative air humidity not more than 80%, atmosphere pressure (101±3) kPa. Any
violation of the pointed restrictions may lead to the device failure.

1.5. Side effects: Not found out.

2. DELIVERY SET

- Control unit. ................................................................. 1 pc
- Probe “EOD” standard (Ø 1,2 mm). ................................. 1 pc
- Lip clip «Oral Hook». ..................................................... 1 pc
- Cable ................................................................. 1 pc
- Charger stand............................................................. 1 pc
- Mains charger............................................................ 1 pc
- User’s guide.............................................................. 1 pc
- Package.................................................................. 1 pc

3. ACCESSORIES

1. Probe «EOD» standard (Ø 1,2 mm)
GE99.147.000
Is used as the active electrode for electric pulp testing.

2. Probe «EOD» sharp (Ø 0,3 mm)
GE99.148.000
Is used as the active electrode for electric pulp testing. Is used for front teeth groups.
3. **Probe «EOD» blunt (Ø 2,5 mm)**
   GE99.149.000
   Is used as the active electrode for electric pulp testing. Applied to the chewing teeth groups.

4. **Set of probes «EOD»**
   GE99.150.000
   The set contains:
   - Probe “EOD” standard (Ø 1,2 mm) -1
   - Probe “EOD” sharp (Ø 0,3 mm) -1
   - Probe “EOD” blunt (Ø 2,5 mm) - 1

5. **Cable «Signal Line» (single)**
   GE99.162.000
   Cable for electric pulp testing.
   Length - 100± 3 cm
   Plug - micro pin (2 mm)

6. **Lip clip «Oral Hook” (3pcs/1 pc)**
   GE99.062.000 / GE99.123.000
   Is used as passive electrode.
   Should be fixed on patient’s lip.

7. **Mains charger**
   GE99.049.000
   Input voltage: (220±10%) V~50/60Hz.
   Output voltage: 4,5V; 500 mA.
   Plug - 3,5 mm

! Accessories are shipped apart at extra cost
4. THE DEVICE OUTWARD APPEARANCE

Outward appearance of the «PulpEst” is represented in the figure 1.

Fig.1. PulpEst

**B. Charger stand:**

**C. Probe «EOD»** - active electrode

**D. Lip clip** - passive electrode

**E. Cable** to connect the lip clip

**F. Mains charger**

* only for modification «PulpEst (L)»

Fig. 2. The display symbols description

1 - a value of "diagnostic" current (0 to 80 mcA);
2 - given rate of increase "diagnostic" current (9 levels and Auto ("A"));
3 - indicator of sound signal switch on “Sound”.
4 - «LB» battery discharge indicator.
5. SPECIFICATIONS

Electrical and maintenance device specifications answer the requirements of:

5.1. Control unit
- Power source - Li-Po battery (3,7V; 700 mAh);
- Electrical safety - type BF;
- Monochrome LCD display - 16*32 mm;
- Range of "diagnostic" current - from 0 to 80mcA (step 1 mcA);
- Min. current rate rise (level 1) - 1,0 ± 0,2 mcA / sec;
- Max. current rate rise (level 9) - 3,8 ± 0,2 mcA / sec;
- Max. the voltage at the working part - 160V ± 10% (at short-time pulse);
- Effective max. voltage at the working part - 6.5V ± 10%;
- Time of the device operation in the “sleep” mode until the device automatic power switch off – 30±0,5 min;
- The device operation time with a new fully charged battery without recharging – not less 20h;
- The device battery full charge period – 1,5±0,5 h;
- The battery life cycle - not less 300 recharge cycles;
- Overall dimensions - (165*32*23) ±3 mm /Weight - 68±5 g.

5.2. Charger stand
- Electrical safety - class II, type B;
- Overall dimensions - (98*98*60) ±3 mm; Weight -175±5 g;

5.3. Mains charger
- Input voltage- (220±10%)V, ~50/60Hz;
- Output voltage- 4,5 V; 500 mA.

The device life time - 5 years.
6. MAKE READY AND USING

After the device transportation at temperature below +5 °C, you should let it warm up for an hour at room temperature before switching it on.

6.1. Battery charging

Chargeable lithium-polimeric (Li-Po) battery is the “PulpEst” source power. Before the first device use it is necessary to fully charge the battery.

The battery should be charged in the following way:

- Connect the mains charger (F) to the stand (B), insert the charger cable into the socket (14-fig.1) on the stand case;
- Connect the mains charger to the mains supply socket 220 V;

**Attention!** Do not use mains chargers of other types. Use only the charger in the device set of delivery.

- Insert the device control unit (A) into the charger socket (12-fig.1) on the charger stand (B).
Red light (13-fig.1) indicates that battery is being charged. When the battery is fully charged, indicator changes color to yellow-green.

**Note:** Standard time for the battery charging is about 1,5 hours, however, it depends on the battery current charge, level of its wear, temperature. Operation and charge time of the old battery is shorter than of a new one. In the case of meaningful reduction of the device operation duration you should address to the service department to replace the old battery for a new one.

hotline @ geosoft.ru
6.2 Indication of the battery discharge

When the battery charge is lower than minimally allowable level (<20%), warning “LB” indicator (4-fig.2) appears on the device display.

Having seen such an indicator, charge the battery according to the p.6.1.

Otherwise, when the battery charge falls to the critic level (<10%), the device switches off automatically. You will see “LB” indicator displaying when you try to switch the device on again.

*Attention!* When discharged, charge the device power supply in time. Exclude the battery full discharge.

6.3. Power saving function

To increase time between the battery charging and to extend the device life time, the device has power saving function - automatic switch off in 30 minutes after the last device operating controls activation.

6.4. The active electrode connecting/disconnecting

The active electrode connecting (fig.3):

- Select the probe “EOD” (C) fixing angle (one of the 6 fixed positions) comfortable for work and insert the probe into the corresponding socket (1-fig.1) on the device control unit (A) until bumping, having fixed the hexagon edges on the probe fixing cap and on the control unit.
The active electrode disconnecting:

- To disconnect the probe “EOD” from the control unit pull it with a little effort, holding the probe cap.

**Attention!** Be sure to sterilize the probe “EOD” before using it after each patient. (see part 7 “The device sterilization and disinfection”).

6.5. The cable and passive electrode connecting/disconnecting (fig.4)

- Connect the cable (E) plug to its counterpart on the device control unit end view (to the socket 11-fig.1)
- Insert the lip clip (D) into the cable socket until bumping.

**Attention!** Be sure to sterilize the lip clip before its use after every patient (see part 7 “The device sterilization and disinfection”).

**Note:** To disconnect the working cable from the control unit, take the isolating part of the cable plug and pull it with small effort.

**Attention!** Do not disconnect the cable, holding its wire to avoid cable breakdown. Avoid wire twisting.
6.6. The device switching on (fig.5)

Press the button «POWER/SET” to switch on the device.

6.7. Adjusting the rate of "diagnostic" current rise (fig. 6)

This device has nine levels of slew rate of "diagnostic" current and one automatic control duty ("A"), in which the rate of current rise is automatically increased from the third to the ninth level as its value increasing.

In order to reduce the time of diagnosis and to obtain the most reliable results, set the rate of current rise in the display, focusing on the data presented in Table 2

Table 2

<table>
<thead>
<tr>
<th>A presumptive diagnosis</th>
<th>Recommended level of &quot;diagnostic&quot; current rise rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact tooth or caries</td>
<td>1-3 or A</td>
</tr>
<tr>
<td>Pulpitis</td>
<td>4-6 or A</td>
</tr>
<tr>
<td>Necrosis of the pulp, or Periodontitis</td>
<td>7-9 or A</td>
</tr>
</tbody>
</table>

- To increase / decrease the rate of current rise, use the "+" or "-" buttons respectively.

Briefly press one of these buttons to move to the next / previous level of speed or hold down the button to quickly find the desired value on the display (display «RATE»).
6.8. Adjusting the volume of sound signals

This device has 4 sound settings: loud, medium, quiet signals and sound off. On default the device factory settings have "medium" level of sound volume.

To change the current setting:

- Turn off the device power, then press and hold the «POWER / SET» button (Figure 5) until you hear the right beep. Changing sound indication will occur in a cyclic circuit.

After the sound signal switching off, indicator should go down and flash when activating again.

Settings saving:
All the user preferences save automatically after the device switching off.

6.9. Led illumination switching on/off (fig. 7,8) (only for modification «PulpEst (L)»)

- LED illumination on/off is accomplished by twice pushing on the touch button ««».

The LED on the control unit should come on or off respectively.
6.10. Diagnostic procedure (fig. 9)

- Place the passive electrode - a Lip-clip (D) on the lip of the patient, and the tip of the active electrode - probe "EOD" (C) touch the sensitive point of the test tooth.

After the electrodes are placed, start diagnostics, be sure to warn patients that at the first reaction on pain he must send a signal.

- Short press (or press and hold) «START / STOP» button. The device starts to increase the voltage gradually and indicates on the display the current value of "diagnostic" current passing through the tooth (display «LEVEL»). Measurements will be accompanied by an intermittent beep.

- When you reach the pain response in the patient (as soon as the patient will signal), remove the active electrode from the tested tooth and re-press (or release) «START / STOP» button.

In this case, the device display will record measured value of "diagnostic" current. Interpretation of the results of the measurements is presented in Table 3.
Table 3.

<table>
<thead>
<tr>
<th>Diagnostic current value, mcA</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-8</td>
<td>Intact tooth</td>
</tr>
<tr>
<td>9-14</td>
<td>Caries</td>
</tr>
<tr>
<td>15-24</td>
<td>Deep caries</td>
</tr>
<tr>
<td>25-44</td>
<td>Pulpitis</td>
</tr>
<tr>
<td>45-80 / no reaction</td>
<td>Periodontitis</td>
</tr>
</tbody>
</table>

Attention! The diagnosis, shown in Table 3, is based on average data and can only serve as a guide for the dentist. To install a definitive diagnosis using EOD results together with the data history, examination of the patient with additional diagnostic methods.

Resetting the measurement result occurs automatically after about 6-7 seconds.

- To force the reset of measurement results, briefly press the «POWER / SET» button (fig. 5).

6.11. The device switching off

The device switches off automatically (see p. 6.3 “Power saving function”)
- Press and hold down the button “POWER/SET” (fig.5) for about 1 seconds for the device forced switching off.
7. THE DEVICE STERILIZATION AND DISINFECTOIN

7.1. Pre-sterilization cleaning and sterilization

All the device components, having direct contact with patient’s mucosa (the probe “EOD” (C) and the lip clip (D)), are subject to pre-sterilization cleaning and sterilization.

According to the regulatory documents, the pre-sterilization cleaning should be carried out by hand or mechanically, using ultrasound in special wash liquids. The method of mechanical cleaning must correspond to the user’s guide, attached to the ultrasound equipment. It is recommended to use ultrasound baths “UltraEst”, “UltraEst-FSM” or “UltraEst-M” manufactured by the “Geosoft Dent”.

The belongings sterilization should be carried out directly before the first device use and after every patient to avoid cross infection.

All the belongings pointed should have autoclave sterilization. The vapor pressure in the sterilization chamber is 0,2 MPa at the temperature equal to 132±2°C during 20-22 minutes (or pressure - 0,21MPa, temperature - 134±1°C during 5-6 min).

Attention! Taking into account the conditions above, the sterilizable components can stand not more than 250 sterilizing cycles.

Other sterilization methods in the regulatory documents are allowed to use.

Attention! It is expressly prohibited to carry out any thermal treatment (in autoclave, dry-air sterilizer, glass-perlen sterilizers etc.) of any other device components not indicated in this point.
7.2. Disinfection

All the device components are to be disinfected.

The device disinfection should be carried out before the first use and after every patient to avoid cross infection.

Disinfection must be carried out by chemical method of the device surface wiping with a napkin wetted in the ethanol and wrung according to the corresponding regulatory documents.

Attention!
1. To avoid the disinfectant ingress into the device case it’s expressly prohibited to disinfect the control unit case (A) and/or the device stand (B) by dipping it into any solutions.
2. Prevent any disinfectant ingress into the metal sockets.

8. MAINTENANCE

- When discharged, charge the battery in due time (see p. 6.1 and 6.2). Exclude the battery full discharge.

- Replace the battery in due time in the case of durability yield.

Note: Replace the battery once in two years period for its optimal operation.

Attention! It’s only specialists of authorized service departments who should replace the battery. Do not open the device to replace the battery yourself. It may be unsafe. Besides, in the case of device opening by user, warranty is considered to be invalid.
# 9. TROUBLESHOOTING

Table 4

<table>
<thead>
<tr>
<th>Malfunction</th>
<th>Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The device doesn’t switch on. “LB” displays</td>
<td>• The battery is discharged</td>
<td>• Charge the battery <em>(see p.6.1)</em></td>
</tr>
<tr>
<td>The device switches off automatically</td>
<td>• Power saving function activates</td>
<td>• <em>See p.6.3</em></td>
</tr>
<tr>
<td></td>
<td>• The battery is discharged</td>
<td>• Charge the battery <em>(see p.6.1)</em></td>
</tr>
<tr>
<td></td>
<td>• The program hung. The WDT timer (“watch dog timer”) activated</td>
<td>• Switch on the device <em>(see p.6.6)</em> and continue working.</td>
</tr>
<tr>
<td>The battery gets charged very quickly but the device using time until the</td>
<td>• The battery resources are exhausted. The battery is out of use.</td>
<td>• Address the department service to replace the battery</td>
</tr>
<tr>
<td>moment of battery recharging dropped off.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The battery does not charge</td>
<td>• There is a bad contact between the control unit and stand and/or</td>
<td>• Check the connections</td>
</tr>
<tr>
<td></td>
<td>• Absence of voltage in the net</td>
<td>• Check if there is voltage in power line</td>
</tr>
<tr>
<td></td>
<td>• The mains charger is broken</td>
<td>• Replace the mains charger or address to the service department</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Malfunction</th>
<th>Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is no increase of &quot;diagnostic&quot; current</td>
<td>• &quot;Diagnostic&quot; circuit &quot;tooth-probe-control unit-cable- hook-lip&quot; is open.</td>
<td>• Check the integrity of the &quot;diagnostic&quot; circuit and eliminate the gap. If necessary, replace the cable</td>
</tr>
<tr>
<td>Sound problems</td>
<td>• Sound signal volume level doesn’t set correctly</td>
<td>• Check the device settings <em>(see p.6.8)</em></td>
</tr>
</tbody>
</table>
| The device does not react at the control unit buttons pressing | The program is hung. The WDT timer was not activated              | • Restart the program:  
  - Press “Reset”*(9-fig.1)* button using any thin subject (e.g. a needle). Herewith the device power switches off automatically.  
  - Switch on the device power *(see p.6.6)* |

If you have not found the necessary information, You may consult the manufacturer on the hotline phone: +7(495)663-22-11 (extension 170), E-mail: hotline @ geosoft.ru or address to the service department
10. STORAGE CONDITIONS, TRANSPORTATION AND USE

- The device should be stored in heated and ventilated locations at temperature from +5°C to +40 °C with relative air humidity of 80% (at +25°C) in the authentic package of the manufacturer.
- The device should be transported by any kinds of covered means of transport at temperature from -50 °C to +50°C with relative air humidity not more than 100% (+25°C) in the authentic package of the manufacturer.
- The device should be used only in heated and ventilated locations at temperature from +10°C to +35 °C with the relative air humidity not more than 80% at atmosphere pressure of (101± 3) kPa.

11. INFORMATION ON UTILIZATION

! Do not throw the device into the system of household rubbish. Utilize the device according to the utilization regulations of the country where it is used.

12. INFORMATION ON CERTIFICATION

EC Quality Assurance System Certificate: Reg № MED 26039 of 27.03.2017 ("CERMET" (Italy))
Certificato CE del Sistema di Garanzia della Qualità/EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell’Organizzazione/We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:

GEOSOFT DENT Jsc

Sede Operativa / Operational Headquarter:
Build. 14 Ap. 16, 3-ya Mytishichinskaya ul.
129628 Moscow - Russia

Sede legale / Registered headquarter
Build. 5, 2-nd Troitsky per., 6A
Moscow - Russia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato Il escluso il punto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:

Dispositivi elettrodiagnostici per test elettrici della polpa dentale / Devices for electric dental pulp testing
Dispositivo per otturazione canali radicolari con gutta-percha riscaldata ed endoattivazione / Device for root canals obturation with heated gutta-percha and endoactivation
Locatori d’apice / Apex locators
Motori endodontici / Endodontics motor

Rif. analisi documentazione tecnica/Ref. technical documentation analysis: 17/02/2017

Chief Operating Officer
Gianpietro Belcredi
13. WARRANTY

1. The manufacturer guarantees the device successful operation according to the technical specification requirements, technical conditions 94542-003-56755207-2013 when the user follows all the regulations, service and storage conditions.

2. Warranty period of the device use is 2 years since the day of sale, but not more than 2,5 years since the day of manufacturing (except p.3).

3. The battery warranty period in the device delivery set is 6 months since the sale date. The cable using warranty period includes 1 month since the sale date.

4. Devices, having mechanical defects or used improperly according to the user’s guide, invalidate the guarantee of repair.

5. The manufacturer or other authorized service department repair the device. The device delivery to service department for warranty or extended services is done at the expense of the device owner. **Before addressing to the service department connect to the manufacturer consultant on the hotline: Phone: +7(495) 663-22-11 (extension 170), E-mail: hotline @ geosoft.ru**

6. The device is accepted for warranty repair only IN COMPLETE package, involving the user’s guide with the stamp of the manufacturer and with the product selling mark. If the user’s guide is filled improperly, it can be a reason for warranty repair rejection.

7. The manufacturer reserves the right to make changes and supplements to the device construction not worsening its basic technical specification.
## 14. SYMBOL DESCRIPTIONS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Warning: Address to supporting documentation</td>
</tr>
<tr>
<td></td>
<td>Type of protection against electric-shock hazard. Device of the II class</td>
</tr>
<tr>
<td></td>
<td>Protection level from electrical shock: Applied part BF type</td>
</tr>
<tr>
<td></td>
<td>Continuous current</td>
</tr>
<tr>
<td><img src="image1" alt="Image" /></td>
<td>Only use the device with the mains charger provided</td>
</tr>
<tr>
<td><img src="image2" alt="Image" /></td>
<td>Do not throw away the device into system of daily rubbish</td>
</tr>
<tr>
<td><img src="image3" alt="Image" /></td>
<td>The device serial number</td>
</tr>
<tr>
<td><img src="image4" alt="Image" /></td>
<td>Date of the device manufacturing</td>
</tr>
<tr>
<td><img src="image5" alt="Image" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td>REV.</td>
<td>The device revision version</td>
</tr>
<tr>
<td><img src="image6" alt="Image" /></td>
<td>Ingress Protection Rating dust and moisture</td>
</tr>
<tr>
<td><img src="image7" alt="Image" /></td>
<td>European authorized representative</td>
</tr>
<tr>
<td><img src="image8" alt="Image" /></td>
<td>Conformity mark of the device to Russian GOST</td>
</tr>
<tr>
<td><img src="image9" alt="Image" /></td>
<td>Mark of conformity to product quality and safety standards of the European Union (CE-mark)</td>
</tr>
</tbody>
</table>
APPENDIX

Electromagnetic Emissions and Immunity

Table 1

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Conformity</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR11</td>
<td>Group 1</td>
<td>The device “PulpEst” uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF Emissions CISPR11</td>
<td>Class B</td>
<td>It is possible to use the device “PulpEst” in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic emissions EN 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flier emissions EN 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>
Table 2

The device “PulpEst” is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level EN 60601-1-2</th>
<th>Compliance Level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 2 kV contact</td>
<td>± 2 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td>
</tr>
<tr>
<td>EN 61000-4-2</td>
<td>± 4 kV contact</td>
<td>± 4 kV contact</td>
<td></td>
</tr>
<tr>
<td></td>
<td>± 5 kV contact</td>
<td>± 5 kV contact</td>
<td></td>
</tr>
<tr>
<td></td>
<td>± 2 kV air</td>
<td>± 2 kV air</td>
<td></td>
</tr>
<tr>
<td></td>
<td>± 4 kV air</td>
<td>± 4 kV air</td>
<td></td>
</tr>
<tr>
<td></td>
<td>± 5 kV air</td>
<td>± 5 kV air</td>
<td></td>
</tr>
<tr>
<td>Burst/Fast Transient</td>
<td>±2 kV for power supply lines</td>
<td>±2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>EN 61000-4-4</td>
<td>±1 kV for input/output lines</td>
<td>±1 kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±0,5; ±1,0; ±2,0 kV for scheme “wire-to-ground”</td>
<td>±0,5; ±1,0; ±2,0 kV for scheme “wire-to-ground”</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>EN 61000-4-5</td>
<td>±0,5; ±1,0 kV for scheme “wire-to-wire”</td>
<td>±0,5; ±1,0 kV for scheme “wire-to-wire”</td>
<td></td>
</tr>
</tbody>
</table>
Continuation of Table 2

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>Test level EN 60601-1-2</th>
<th>Compliance Level</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11</td>
<td>&lt;5% Un (&gt;95 % voltage dip in Un) for 0.5 period</td>
<td>&lt;5% Un (&gt;95 % voltage dip in Un) for 0.5 period</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the device “PulpEst” requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td></td>
<td>40% Un (60 % voltage dip in Un) for 5 periods</td>
<td>40% Un (60 % voltage dip in Un) for 5 periods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>70% Un (30 % voltage dip in Un) for 25 periods</td>
<td>70% Un (30 % voltage dip in Un) for 25 periods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5 % Un (&gt;95 % voltage interrupt in Un) for 1 period</td>
<td>&lt;5 % Un (&gt;95 % voltage interrupt in Un) for 1 period</td>
<td></td>
</tr>
<tr>
<td></td>
<td>120% of Un (20 % voltage emission in Un) for 25 periods</td>
<td>120% of Un (20 % voltage emission in Un) for 25 periods</td>
<td></td>
</tr>
<tr>
<td>Magnetic field of power frequency (50/60Hz) EN 1000-4-8</td>
<td>3 A/m</td>
<td>3 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

Note: Un- level mains voltage prior to filing of the test exposure
The device “PulpEst” is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th><strong>Immunity test</strong></th>
<th><strong>Test level EN 60601-1-2</strong></th>
<th><strong>Compliance Level</strong></th>
<th><strong>Electromagnetic environment - guidance</strong></th>
</tr>
</thead>
</table>
| RF conducted EN 61000-4-6 | 3 V from 150 kHz to 80 MHz | 3 V from 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the device “PulpEst”, including cables, than the recommended separation distance calculated from that equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$ (from 150 kHz to 80 MHz) 
$\quad d = 1.2 \sqrt{P}$ (from 80 MHz to 800 MHz) 
$\quad d = 2.3 \sqrt{P}$ (from 800 MHz to 2.5 GHz) 
where: $P$ - the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ - the recommended separation distance in meters (m) |
| RF radiated EN 61000-4-3 | 3 V/m from 80 MHz to 2.5 GHz | 3 V/m from 80 MHz to 2.5 GHz | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: |

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Table 4

Recommended working clearances between portable and mobile RF communication devices and the device “PulpEst”

The device “PulpEst” is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of the transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>from 150 kHz to 80 MHz d = 1,2 √P</td>
</tr>
<tr>
<td>0,01</td>
<td>0,12</td>
</tr>
<tr>
<td>0,1</td>
<td>0,38</td>
</tr>
<tr>
<td>1</td>
<td>1,2</td>
</tr>
<tr>
<td>10</td>
<td>3,8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes: (1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Certificate of acceptance

<table>
<thead>
<tr>
<th>Modification</th>
<th>PulpEst</th>
</tr>
</thead>
<tbody>
<tr>
<td>(mark the appropriate)</td>
<td>PulpEst (L)</td>
</tr>
<tr>
<td><strong>Serial number</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Date of manufacture</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Version</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Controller</strong></td>
<td></td>
</tr>
</tbody>
</table>

The stamp of the manufacturer

Sales mark

| **Date of sale** |         |
| **Seller** |         |

Stamp of trading organization

Sales mark is obligatory! The warranty is invalid without sales mark.
DECLARATION OF CONFORMITY

93/42/EEC, 2007/47/EC

JSC “Geosoft-Dent”
5-6а, 2nd Troitsky per., Moscow 129090 Russia

Authorized Representative in European Union
DENTAL WORLD S.R.L.
Via Antichi Pastifici, 15-70056 Molfetta (BA). Italy

Declares that the products listed below comply with the requirements of Medical Device Directive Communities 93/42/EEC on medical equipment (taking into account the Directive amendments 2007/47/EC of the European Parliament) transposed in Italy by Dlgs. n. 46 of 24/2/1997 and by Dlgs. n. 37 of 25/1/2010, Annex II excluded point 3.4

Equipment: Device for electric dental pulp testing
Model names: PulpEst
Quality System: ISO 13485/2003
Classification: Class IIa
GMDN code: 13187

The compliance with the 93/42/EEC and 2007/47/EC Directive is under the monitoring of the Notified Body: Kiwa Cermet Italia S.p.A.
Via Cadriano, 23 – 40057 Cadriano di Granarolo Emilia (BO) – Italy

Signature: __________________                    Data _________________
Name: Gofshteyn Vladimir A
Position: General Director

2017
Manufactured by

CJSC GEOSOFT DENT

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