DENT GEOSOFT

ESTüS

USER'S MANUAL

ESTUS DENTAL COMPLEX:
DEVICE FOR ELECTRIC DENTAL PULP TESTING

ESTUS PULP

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, read the user's manual carefully before the operation. Keep the User's manual for future use.

! Please, address to the manufacturer if you have some questions when using the device.
Tel.: +7(495)663-22-11 (extension 109),
E-mail: geosoftdent@geosoft.ru

JSC GEOSOFT DENT
(Russia)

CONTENT

1. GENERAL INFORMATION

1.1. Intended use: Device for electric dental pulp testing «Estus Pulp» is part of the dental complex "Estus", intended for carrying out procedures in the field of dentistry.
This device is designed for assess pulp status - electro-odonto-diagnostics (EOD).

1.2. Indication for use:

- diagnosis of the depth of carious lesion;
- diagnosis of pulpitis; - diagnosis of periodontitis;
- detection of cysts on the roots of the tooth;
- traumatic damage to the jaws and teeth;
- inflammation of the maxillary sinus;
- osteomyelitis;
- actinomycosis;
- tumors of the jaws of various etiologies;
- neuritis and neuralgia;
- radiation damage;
- treatment with orthodontic devices.

The manufacturer is not responsible for any dangerous situation while using the device for purposes other than that intended.

1.3. Application field: The device is for use ONLY in medical facilities.

1.4. Potential users: ONLY the licensed dentists (qualified specialist in the field of endodontics).

1.5. Contraindications: - the patient has a pacemaker;
- there are mental disorders;
- it is impossible to effectively dry the surface under study;

- intolerance to electric current;
- the patient is less than 5 years old.

1.6. Adverse reactions: Without finding.
1.7. Contact type with a patient: Short invasive contact through the oral cavity.

1.8. Operating principal: Assessment of the threshold of patient sensitivity to electric stimulation. With pathological processes in the teeth and peridental tissues, the irritability of pulp nerve receptors is reduced, and, as a result, the patient's sensitivity to the magnitude of the irritating diagnostic electric current changes.
Depending on the magnitude of the diagnostic current, which leads to the patient's sensitivity to electrical effects, the state of the tested pulp is diagnosed, which allows to determine the affected tooth, make a preliminary diagnosis and plan the treatment.

1.9. Functional abilities:

- The mode of automatic change in the rise rate of the diagnostic current over the entire range of values.
- The diagnostic result displaying on the LED scale on the handpiece.
- Audio indication during operation and function of the audio signal volume adjustment.
- Indication of the power supply discharge.
- Power saving function
- Possibility of expanding the device functionality in terms of settings and displaying the values of its working parameters when the device is operating as a part of the “Estus” dental complex together with the “Estus Multi”* main control unit.

** not included into the delivery set and should be purchased separately, additionally paid*

1.10. Precautions and Warnings

! Use the product with the original "Geosoft Dent" accessories only.
! Do not disassemble or modify the product. **Violation of the device integrity cancels the warranty**.
! Avoid letting any liquid inside the product's housing.
! Do not use the device close to flammable agents. The device is not suitable for use in presence of flammable anesthetic agents with air, oxygen or nitric oxide.
! Use sterile and disinfected parts and accessories of the device only. Sterilization and disinfection must be conducted directly before the initial use and also between each patient use to avoid cross infection.
! When working in the patient's oral cavity, use a rubber dam.
! This device requires special measures application for electromagnetic capability (EMC) and should be installed and put into operation accordingly with the information in the Appendix of the User's Manual. It includes the requirement not to use the device close to daylight lamps, radio transmitting equipment and remote controls.
! Dysfunction of the device operation is possible if used in electromagnetic interference (EMI) area. Do not use the device close to the electromagnetic equipment. This equipment is usually marked by the sign
! Do not use the device jointly with the other equipment or as a part of the equipment, not included into the manufacturer's product list.
! Do not use the accessories, adapters and cables, different from the listed below. It can direct to the emission interference increase or reduce interference immunity of the device. The Manufacturer guarantees electromagnetic compatibility of the following accessories: *working cable of the maximal length 105 cm*; *the charger cable of the maximal length 1.8 m.*
! The device operates normally at a temperature of 10-35°C, relative humidity of air not more than 80%, atmospheric pressure (101±3) kPa. Any violation of these restrictions may cause the device error.

2. DELIVERY SET

Delivery set variants are in the table 1

Table 1

The device element	Quantity in delivery set variants, pcs		
	GE33-PP	GE33-P0	GE33-P4
Control unit “Estus Pulp”	1	1	1
Battery unit (8V)	1	1	0
Battery unit (4V / Type-C)	0	0	1
Probe EOD standard (Ø 1,2 mm)	1	1	1
Cable *(micro pin 2 mm, single)*	1	1	1
Lip clip “Oral Hook”	1	1	1
Stand “Estus One-B”	1	0	0
Charging stand “Estus Energy-S”	1	0	0
Charger cable USB - USBB	1	0	0
Charger cable USB-Type-C	0	0	1
Power adapter (USB-socket) 1A	1	0	1
User’s manual “Estus Pulp”	1	1	1
Warranty Card “Estus Pulp”	1	1	1
Warranty Card “Estus Energy-S/D”	1	0	0

3. ACCESSORIES

Probe EOD standard (Ø 1,2 mm)
GE99.147.000
Used as an active electrode in the EOD procedure.

Probe EOD sharp (Ø 0,3 mm)
GE99.148.000
Used as an active electrode in the EOD procedure.

Probe EOD blunt (Ø 2,5 mm)
GE99.149.000
Used as an active electrode in the EOD procedure.

EOD probes set
GE99.150.000
Set includes:
Probe EOD standard (Ø 1,2 mm) - 1 pc
Prode EOD sharp (Ø 0,3 mm) - 1 pc
Probe EOD blunt (Ø 2,5 mm) - 1 pc

Cable Signal Line (single)
GE99.162.000
Cable for EOD procedure
length - 100± 3 cm
plug – micro pin (2 mm)

Lip clip "Oral Hook" (3pcs/1 pc)
GE99.062.000 / GE99.123.000
Used as a passive electrode in the EOD procedure.

Battery unit (8V) GE99.205.000
Additional battery unit (8V) with charging from the Estus Energy-S / Estus Energy-D charging stand for the "Estus Pulp" handpiece (2x3.7V, 800mAh).

Stand "Estus One-B" GE99.208.000
Single-stand for the "Estus Pulp" handpiece.

Stand "Estus Two-B" GE99.209.000
Double stand for all handpieces from "Estus" series

Charging stand "Estus Energy-S"
GE42.000.000
One-port charging stand for the battery unit (8V) of the "Estus Pulp" handpiece.

Charging stand "Estus Energy-D"
GE39.000.000
Two-ports charging stand for two battery units (8V) of the "Estus Pulp" handpiece.

Charger cable USB-USBB
GE99.001.00P
Cable for charging stand "Estus Energy-S" / "Estus Energy-D". Length 1.8 m

Battery unit (4V / Type-C)
GE99.250.000
Additional battery unit (4V) with mains charging via Type-C connector for the "Estus Pulp" handpiece (3.7V, 800mAh)

Charger cable USB - Type-C
GE99.004.00P
Cable for charging the battery unit GE99.250.000

Power adapter (USB-socket) 1A. GE99.005.00P
Model: Robiton USB1000/White
Input voltage - (100-240) V, ~50/60 Hz
Output voltage - 5 V; 1A.

Power adapter (USB-socket) 2A. GE99.006.00P
Model: Robiton USB2100
Input voltage - (100-240) V, ~50/60 Hz
Output voltage - 5 V; 2A.

Control unit "Estus Multi"
GE28.000.000
External apexlocator and control unit for extended setting and indication of the working parameters of the "Estus Pulp" handpiece.

! *Accessories are delivered separately, additionally paid*

4. “ESTUS PULP” APPEARANCE

“Estus Pulp” appearance is on the figure 1, including:

A. **Handpiece “Estus Pulp”:**
1. Control unit.
2. Probe EOD.
3. Removable battery unit 8V.
3’ Removable battery unit 4V/Type-C:
   3’a - Battery charge indicator;
   3'b - Socket Type-C for the charger cable;
4. Control ring switch *(see table 3)*.
5. STATUS indicator *(see table 2)*.
6. LED scale of the 5 indicators to display the testing results.
7. Discharge indicator of the removable battery unit.
8. Socket for the working cable connection.

B. Stand “Estus One-B” for the handpiece

C. Charging stand “Estus Energy-S”:
9. Charging socket.
10. Charge indicator.
11. Socket USBB for the charger cable;

D. Charger cable USB- USBB

E. Power adapter (USB-socket)

F. Working cable

G. Lip clip

Figure 1. "Estus Pulp"

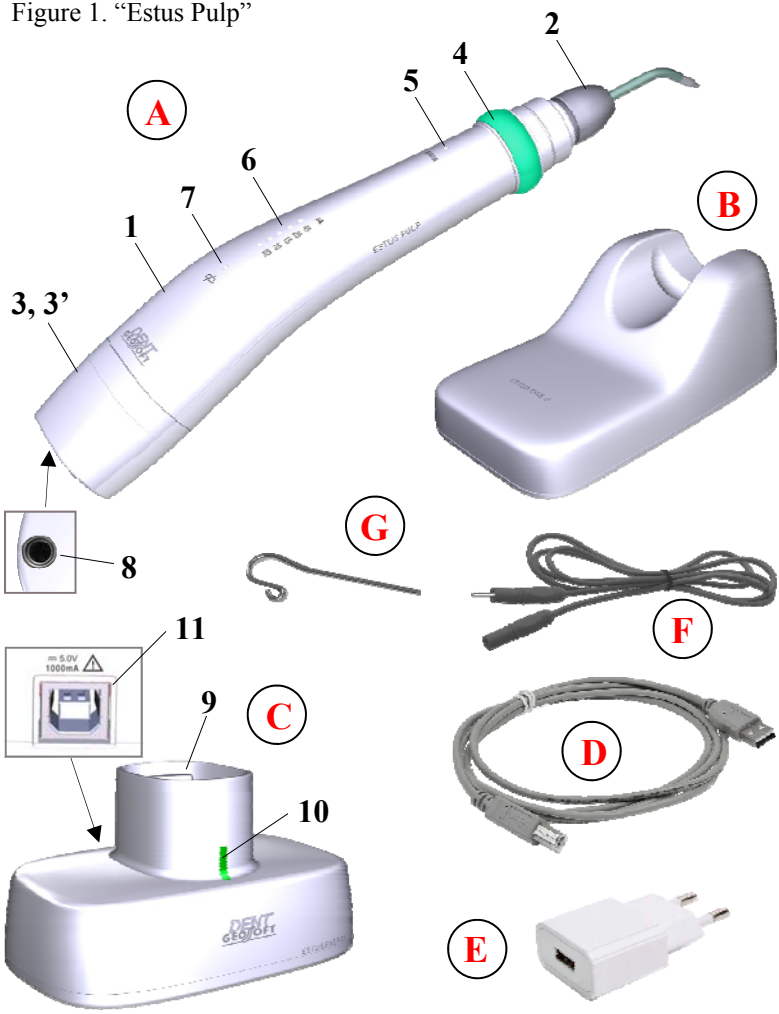


Table 2. STATUS indicator variants

STATUS indication color		Meaning
STATUS	WHITE	Power on
STATUS	WHITE blinking	Activation of the pair creation mode or a warning that the current settings are different from the factory settings (changed by the user).
STATUS	MINT	Testing result 2 –9 µA
STATUS	LALAC	Testing result 10 –24 µA
STATUS	ORANGE	Testing result 25 –44 µA
STATUS	RED	Testing result 45 –80 µA
STATUS	RED blinking	Warning about a break in the diagnostic circuit (see section 10)

Table 3. Variants of using the ring switch

	Power	Press ring switch	Result
	**OFF**	1 time	Power on
		Holding up to 10 sec.	Volume adjustment
		Holding > 20 sec.	Pair creating mode activation
	ON	1 time	Start/Stop current rise or reset
		1 time with holding till off	
		3 times	Power off
		3 times with holding	Return to the factory settings

5. TECHNICAL SPECIFICATIONS

5.1. "Estus Pulp" handpiece:

- Power supply - Li-Po battery unit (2x3,7 V; 800 mAh) or Li-Po battery unit (3,7 V; 800 mAh)
- Electric shock protection - Device with the built-in power supply. Working part is of the BF type.
- The built-in radio module NF-03: frequency range - 2,4-2,525GHz, max output capacity - 7 dBm (0,00501W), cover range -up to 3 m in the direct vision.
- Diagnostic current range – from 0 to 80μA (step 1 μA)
- Maximal voltage on the working part - 160V ± 10% (in a short-time pulse)

- Effective voltage on the working part - 6,5V ± 10%.
- Performance duration with the new fully charged battery unit (8V) without boost charge - not less than 20 h.
- Stand-by operating time to automatic switch off - 10 ±0,5 min.
- Battery unit charging time - no more than 3 hours
- Battery resource - not less than 300 recharges.
- The working area of the ring switch on the front side of the handpiece - 180°
- The operating force of the ring switch - not more than 1N
- Audio indication parameters: audio frequency - from 1 to 6 kHz, volume level - not more than 70 dB.
- Dust and water protection rate - IP41.
- Dimensions - (202*33*43) ±3 mm
- Weight - 85 ±10 g
- Service time of the device - 5 years.

5.2. Charging stand "Estus Energy-S":

- Power - 5V, 1A.
- Electric shock protection - the product is of the class II.
- Dust and water protection rate - IP41.
- Dimensions - (87*56*49) ±3 mm
- Weight - 130±10 g
- Service time of the device - 5 years.

5.3. Power adapter (USB-socket) 1A

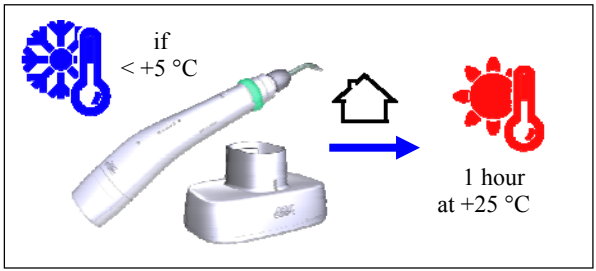
- Input voltage - (100-240) V, ~50/60 Hz .
- Output voltage - 5 V; 1A.

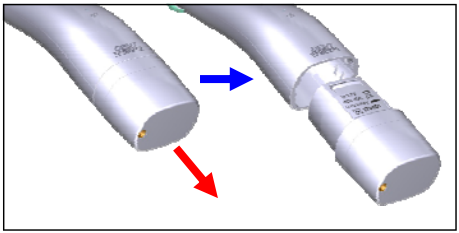
5.4. Stand "Estus One-B":

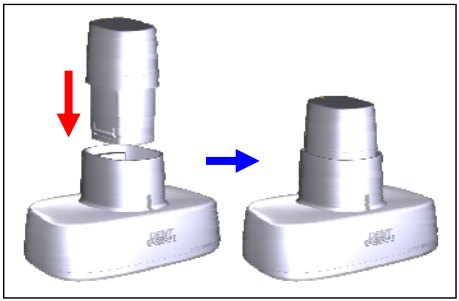
- Dimensions- (100*60*40) ±3 mm
- Weight - 132 ±10 g

6. PREPARATORY STAGE AND WORKING PROCEDURE

After transporting the device at the temperature less than + 5°C, before use, keep it at the indoor temperature for 1 hour







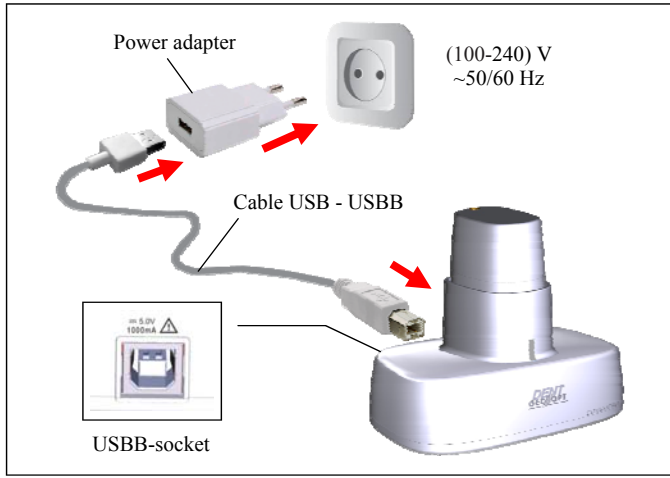
Step 1. Battery unit charging

Disconnect the battery unit from the handpiece *(in package the battery unit is packed separately from the handpiece)*

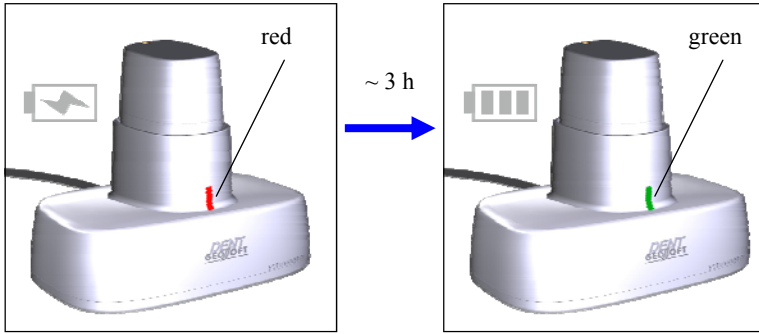
1.1. Battery unit 8V charging

A) Put the battery unit into the charging socket of the charging stand "Estus Energy-S"

B) Connect the cable USB- USBB to the charging stand and the power adapter, then put the power adapter into the mains socket.



C) Wait till the battery is fully charged.



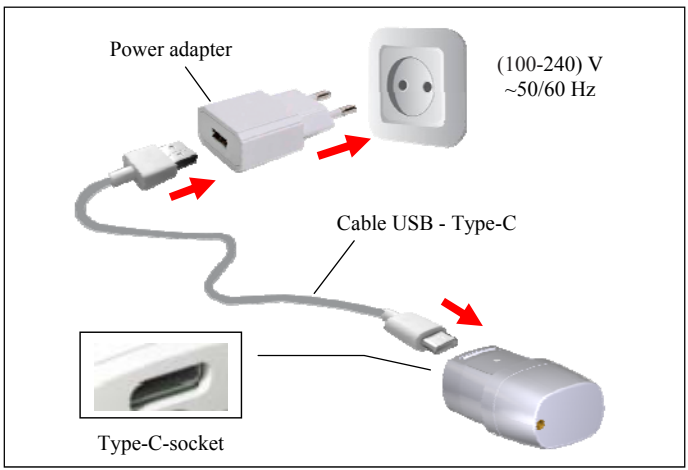
D) Take the charged battery unit out of the **c**harging stand and connect

the battery unit into the handpiece.

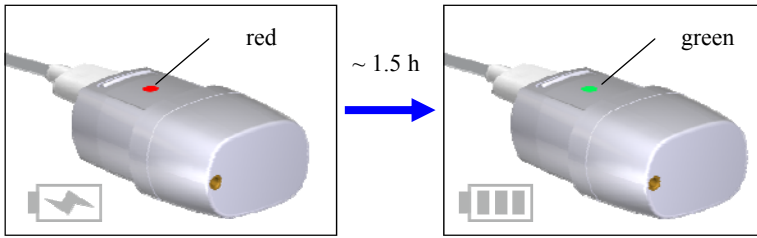
In the absence of the battery unit in the socket of the charging stand, the voltage is automatically disconnected from the terminals of the charging stand, ensuring complete electrical safety of the product. In spite of it, do not allow any liquids to get into the socket of the charging stand. In a case of liquid getting to avoid the terminals corrosion, carefully wipe the charging cavity of the charging stand with a napkin, after disconnecting the charge cable from the mains socket.

1.2. Battery unit 4V /Type-C charging

A) Connect the cable USB– Type-C to the battery unit and the power adapter, then put the power adapter into the mains socket.



B) Wait till the battery is fully charged.



C) Disconnect the charging cable from the battery unit and connect the battery unit into the handpiece.

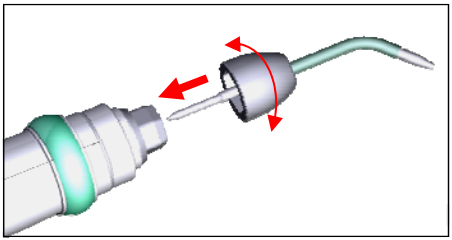
The standard charging time for an 8V/4V battery unit is approximately 3/1.5 hours respectively, but it depends on the current charge level, the battery wear rate and outer temperature. The used battery performance and the charging process is shorter than the new ones. At the significant reduction of the battery performance time and/or charging time you should apply to the maintenance service for replacing the battery unit (see section 3).

The battery discharge indication:

Charge the handpiece battery unit in a timely manner. Do not let the battery unit discharge completely.

Step 2. EOD probe installation

Be sure to sterilize the EOD probe before first use and between each patient use (see section 8 «Sterilization and disinfection»)

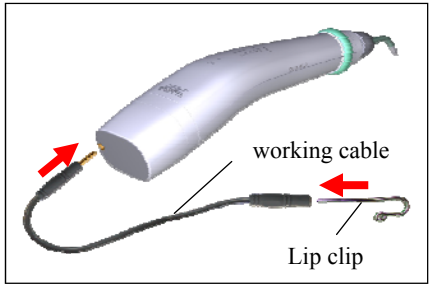


Choose the convenient for work the EOD probe's fixing angle (one of the six fixed positions) and install the probe in the handpiece socket.

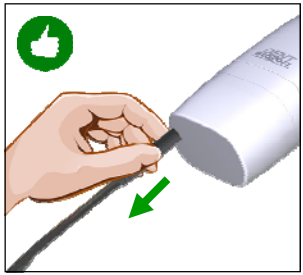
Step 3. Connection of the working cable with the lip clip

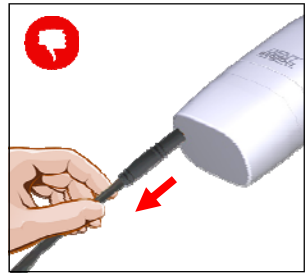
Connect the working cable and the lip clip to the handpiece.

Be sure to sterilize the lip clip before the first use and between each patient use (see section 8 «Sterilization and disinfection").



To avoid the circuit failure be sure not to disconnect the working cable, holding the wire. Take the isolated part of the plug and with minor effort pull the plug.

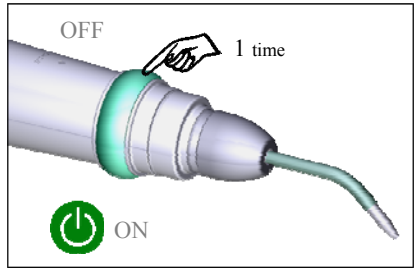




Step 4. Power on

To switch the power on press the ring switch.

STATUS indicator would light up **WHITE**.



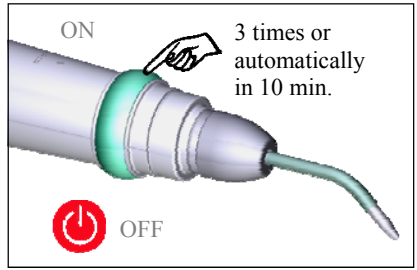
If the STATUS indicator flashes white three times when the device is powered on, it means that the settings are different from the factory settings (that is, they were changed by the user using " Estus Multi").

To return to the factory settings, see Step 8

Step 5. Power off

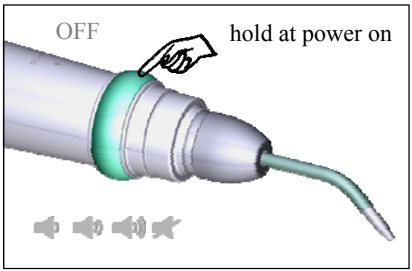
Press the ring switch 3 times to turn the power off or the device is switched off automatically in 10 minutes.

All the indicators on the handpiece go out.



Step 6. Audio volume adjustment

"Estus Pulp" acoustic emitter has 4 volume levels: low, normal, high and off.



To select the required volume level hold the ring switch when switching the power on.

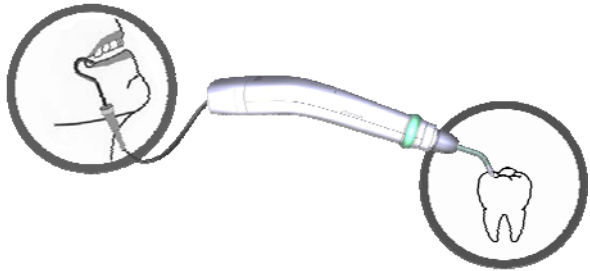
Within ~10 sec. volume levels change one another cyclically.

To choose the required volume level stop pressing the ring switch.

Step 7. Testing procedure

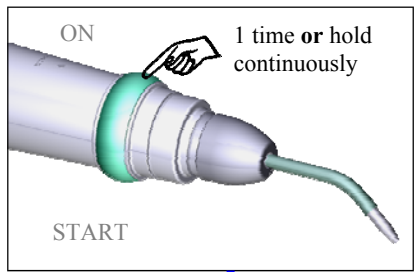
Prior to starting testing, please read the basic rules of the electro-odonto-diagnosis conducting carefully in section 7 of this User's Manual.

A) Place the lip clip on the patient's lip and with the EOD probe tip touch the sensitive point of the tested tooth.

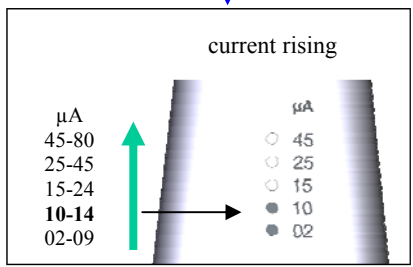


B) Starting the diagnostics, be sure to warn the patient that at the first pain reaction he should give a sign.

Press the ring switch briefly
OR
Press and hold the ring switch to start the procedure



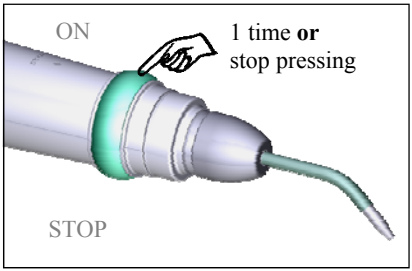
The device starts rising diagnostic current magnitude and displaying it on the handpiece LED scale.



The measurements are accompanied by the pulsed audio signal.

*If the STATUS indicator flashes **RED** during the diagnostic process, then the diagnostic circuit is broken and measurements cannot be taken. To find and remove the causes of violations of the measuring circuit continuity, see section 10 "Troubleshooting" .*

C) At the pain reaction achieving (as soon as a patient gives a sign),



press the ring switch briefly

OR stop pressing at its holding.

Then take the EOD probe off the tested tooth.

At taking the probe off the diagnostics results are fixed on the handpiece LED scale. Diagnosis is made relying on the results.

Table 4 - Measurement results indication

STATUS indicator color	Diagnostics current	Possible diagnosis
STATUS MINT	2 –9 μA	Intact tooth
STATUS LILAC	10 –24 μA	Plain pulpitis
STATUS ORANGE	25 –44 μA	Irreversible pulpitis
STATUS RED	45 –80 μA	Possible pulp necrosis

The diagnosis presented in table 4 is based on average statistics and can only serve as a guide for the dentist. To make the final diagnosis, use the results of EOD in conjunction with the anamnesis, inspection and examination of the patient with the additional diagnostic methods.

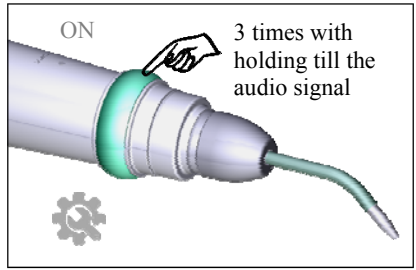
The measurement result is reset automatically after ~ 10 sec.

To re-diagnose, without waiting for the result to be reset, press the button again.

Step 8. Return to the factory settings

The handpiece settings could be changed at its joint work with the "ESTUS MULTI" control unit. To return to the factory settings :

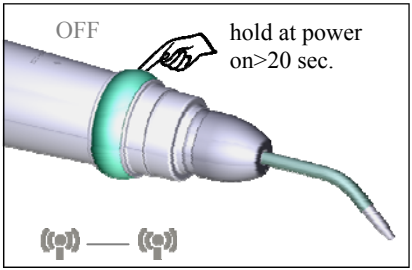
When the device is powered on, press the ring switch 3 times and hold it about 5 seconds after the device power is turned off. Release the button when the audio signal has sounded.



In this case, all settings will return to the factory values.

Step 9. Pair creating mode activation

For the joint work of the handpiece and the "Estus Multi" control unit by radio channel it is necessary to create a pair.



To activate pair creating mode on the handpiece:

Press and hold the ring switch at switching the power on.

After 3 cycles of the audio signals with different intensity and 1 single audio signal (wait for 20 sec.) STATUS indicator would constantly blink **WHITE**

The pair creation further procedure of the handpiece with "Estus Multi" is described in the *User's Manual "Estus Multi"* ***(p. 12.2. Setting "Creating/Deleting pair" function)***

7. BASIC RULES OF ELECTRO-ODONTIC-DIAGNOSIS PROCEDURE

1. Preliminary preparation of the examined tooth:

- To obtain more accurate diagnosis, before starting measurements, the examined teeth should be cleaned of dental tartar and plaque (at least in the areas to be examined). In this case, intensive actions that can cause a decreased irritability of tooth pulp receptors (ultrasound, aqua-, pneumo-, kinetic processing, etc.) should not be used.
Therefore, it is considered advisable to conduct EOD on the next visit after a full professional brushing, if the clinical situation allows it.
In this case, before measurements it is enough to clean the surface of the tooth crown from soft plaque with cotton swabs soaked in antiseptic solutions, for example, 3% hydrogen peroxide solution, and then dry.

- To prevent leakage of electric current through the saliva along the tooth surface into the gum, the examined teeth should first be dried and isolated from the saliva with cotton rolls. The tooth surface is dried with cotton balls in the direction from the cutting edge to the neck of the tooth (but not vice versa). It should be remembered that at breathing, the teeth are quickly moistened (especially molars), therefore, after examination of one or two points, other parts of the tooth to be examined must be re-dried.

- To obtain accurate and reliable results the EOD procedure should be performed before applying local anesthesia or drug analgesia.

To dry the tooth, do not use chemicals (spirit, ether), as well as a stream of air, because this can cause additional irritation of the tooth pulp and lead to a change in the threshold of excitability.

2. Sensitive point choosing

During EOD procedure the active electrode (EOD probe) should be located on the most sensitive point of the examined tooth, where a patient reaction appears at the minimal current value.

Such sensitive point could be in the following zones:

- the middle of the incisal edge of incisors;
- tops of a dental cusp of the fangs;
- tops of a buccal cusp of premolars;
- tops of the mesiobuccal cusp of molars

In carious teeth, along with the usual sensitive points (if they are), the electroexcitability can be checked by touching the bottom of the carious cavity after removing the softened dentin and drying the cavity. Examining should be conducted in 3-5 points. An orienting point of excitability is the minimum current value obtained at any point.

It is unacceptable to choose a point on the surface of the filling as a sensitive point, regardless of whether it is made of cement, plastic, epoxy resin or amalgam. In these cases, it is impossible to achieve high diagnostics accuracy, because cement, plastic, epoxy resin do not conduct electric current, and in the case of amalgam - due to the significant current leakage. Thus it is necessary to remove the filling and conduct a diagnostics, touching the bottom of the carious cavity.

3. Additional rules:

- The patient must be warned not to wait until the expressed pain

appears! At the first discomfort sense in a tooth - slight pricking or burning, weak push or a light electric shock - patient must let the dentist know of it.

- For the EOD procedure the patient is placed in a dental chair in a sitting or lying position. The patient's head should rest on the head support. During the procedure, the dentist's office should not have intense irritants scattering attention: loud music, the sound of working dental equipment (turbine handpieces, ultrasonic scaler, dental aspirator - vacuum cleaner), extraneous conversations, etc.
- To prevent current leakage, the doctor should work in rubber, latex or nitrile gloves.
- Instead of a mirror, when manipulating in the oral cavity, the dentist should use a plastic spatula, plastic retractors or hold the patient's lip with the fingers (in gloves).
- Each time before starting the examining, it is necessary to lubricate the tip of the active electrode (probe) with an electrically conductive gel (for example, toothpaste or ROCS Medical Minerals).
- During the diagnostics conducting, it is necessary to carefully ensure that the active electrode does not slip from the sensitive point of the tooth.
- Avoid contact of the active electrode to the mucosa of the lips, cheeks, gums;
- Do not examine more than 3-4 teeth in a row.

8. STERILIZATION AND DISINFECTION

All the device's elements directly contacted with the patient's oral liquid, mucosa and tissues must be preliminarily cleaned and terminally sterilized. All the rest elements and surfaces of the device must be disinfected for further using without sterilization.

1. Preliminary cleaning and terminal sterilization

Sterilizable elements: **EOD probe and lip clip**

The specified elements must be sterilized directly before the initial use of the device and between each patient use to avoid cross infection. Instruction on repeated sterilization and disinfection of the specified elements is in the table 5.

It is strictly forbidden to carry out any heat treatment (in an autoclave, dry heat cabinets, glass bead sterilizers, etc.) of any other components of the product not listed in this paragraph.

Instruction #1
Manufacturer: JSC Geosoft Dent (Russia)
Product: Lip clip "Oral Hook", Probe EOD

Table 5

ATTENTION	
Restrictions at repeated processing	The minimal guaranteed number of processing cycles is 150. In practice, the number of processing cycles is significantly higher, but depends on the regularity and quality of processing by the clinic personnel.
INSTRUCTIONS	
Place of use	Dental office and sterilization room.
Protection and transportation	No special requirements.
Decontamination preparation	No special requirements
Automatic cleaning/ disinfection	Not applied in this case
Hand cleaning/ disinfection	Clean the product surface. Rinse with distilled water and dry with a clean napkin.
Inspection, maintenance and testing	Not applied in this case
Packing	Recommended to pack the product in the craft package for sterilization.
Sterilization	Steam sterilizer (autoclave). Pressure – 0,2 MPa, Working temperature - 132±2 ºC (270±3 ºF). Sterilization time-20±2 min.
Drying	Not required
Keeping	To keep in a sealed craft package not longer than it is specified by the craft package manufacturer (from 21 to 60 days)

Instruction # 1 was validated by the Manufacturer of the medical product as suitable for repeated using. The company, conducting the processing, is responsible for repeated processing and for using the equipment, materials and the recruitment of the personnel providing the required result. The process must be validated and checked. Any procedure departures, declared in the instruction, must be estimated from the point of effectiveness and probability of possible adverse effects.

2. Disinfection.

The device elements, not contacted directly with the patient oral liquid, tooth tissues and mucosa during the treatment, must be disinfected for further using without sterilization.
Prior to disinfection of the used product, preliminary clean the contaminated surface .
Disinfection should be conducted chemically by wiping the product surface with thoroughly wrung napkin, soaked in 70% ethyl spirit solution.

To avoid entering the disinfectant into the product housing, it is strictly forbidden to carry out disinfection by immersing the handpiece or the battery unit in any solutions.

9. MAINTENANCE

- Charge the battery unit in a timely manner. *(see section 6, Step 1)* Do not let the battery unit discharge completely.
- Replace the battery unit timely when it depletes its working resource.

Do not dispose of the used battery unit in the household waste system. Dispose of the battery unit in accordance with the disposal regulations of the country in which this product is used.

-For optimal battery unit performance, replace it about once every 2 years.

- It is not recommended to purchase an additional battery unit in advance, as during its long-term storage, the technical characteristics of the batteries deteriorate.

- An additional battery unit is not included into the delivery set and is purchased separately additionally paid (see section 3 "Accessories").

10.TROUBLESHOOTING

Trouble 6.

Problem	Possible cause	Solution
Handpiece does not switch on.	• The battery unit is discharged.	• Charge the battery unit *(see section 6, Step 1).*
The handpiece switches off spontaneously.	• Energy saving function activates. • The battery unit is discharged.	• *See section 6, Step 5* • Charge the battery unit.
The battery unit charges too fast and/or the handpiece working time till the next charging is drastically reduced.	• The battery unit resource is depleted. The battery unit is not suitable for use.	• Replace the battery unit.

Table 6 continued

Problem	Possible cause	Solution
The battery unit does not charge	• Bad contact between the battery unit, charging stand, cable, power adapter	• Check connections
	• Charging stand is failed	• Replace the charging stand or apply to the maintenance service
	• Charger cable is damaged.	• Replace the charger cable.
	• Power adapter is defective.	• Replace the power adapter
	• Type-C socket on 4V battery unit is defective	• Replace the battery unit
Sound problems	• Audio volume settings are incorrect	• Check the settings *(see section 6, Step 6)*
Diagnostic current does not rise - STATUS indicator flashes red 	• Diagnostic circuit tooth -probe-control unit-cable-lip clip-lip is opened	• Check the diagnostic circuit continuity and fix the break.
	• The working cable is failed.	• Replace the working cable.
	• The cable socket on the handpiece battery unit is failed.	• Replace the battery unit.

If you have not found the necessary information, You may consult the manufacturer on the phone: +7(495)663-22-11 (extension 109), E-mail: geosoftdent@geosoft.ru or address to the service department

11. STORAGE, TRANSPORTATION AND USE

• The product should be stored in heated and ventilated place at temperatures from + 5°C to + 40°C, with a relative humidity of 80% (at + 25°C), in the original packaging of the manufacturer.

• The product should be transported by any type of covered vehicles at temperatures from -50°C to + 50°C with a relative humidity of not more than 100% (+25°C) in the original packaging of the manufacturer.

• The product should be used in heated and ventilated place at temperatures from + 10°C to + 35°C, with a relative humidity of not more than 80%, at atmospheric pressure (101 ± 3) kPa

12. INFORMATION ON UTILIZATION

! It is strictly forbidden to dispose of the used product in the household waste system. Dispose of the product in accordance with the disposal regulations of the country in which this product is used.

The device “ESTUS PULP” belongs to the medical waste hazard category of class A (non-hazardous waste of medical institutions).

13. SYMBOLS DESCRIPTION

Symbol	Description
	Warning: Address to supporting documentation
	Type of protection against electric-shock hazard. Device of the II class
	Direct current
	Protection level from electrical shock: Applied part BF type
	Do not throw away the device into system of daily rubbish
SN	The device serial number
	Date of the device manufacturing
	Manufacturer
	Non-ionizing radiation sign - the product contains a radio frequency transmitter
REV.	The device revision version
IP41	Ingress Protection Rating dust and moisture
	Consult the USER'S MANUAL
EC REP	European authorized representative
CE	Mark of conformity to product quality and safety standards of the European Union (CE-mark)

APPENDIX

1. Electromagnetic Emissions and Immunity

Table 1

The device “Estus Pulp” is intended for use in the electromagnetic environment specified below. The customer ore the user of the device should assure that it is used in such an environment.		
Emission test	**Conformity**	**Electromagnetic environment - guidance**
RF Emissions CISPR11	Group 1	The device “Estus Pulp” 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.
RF Emissions CISPR11	Class B	It is possible to use the device “Estus Pulp” 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.
Harmonic emissions EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Not applicable	

Table 2

The device "Estus Pulp" is intended for use in the electromagnetic environment specified below. The customer ore the user of the device should assure that it is used in such an environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air	± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Burst/Fast Transient EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±0,5; ±1.0; ±2.0 kV for scheme "line-to-ground » ±0,5; ±1.0 kV for scheme "line-to-line»	±0,5; ±1.0; ±2.0 kV for scheme "line-to-ground » ±0,5; ±1.0 kV for scheme "line-to-line»	Mains power quality should be that of a typical commercial or hospital environment.

Continuation of Table 2

Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	Voltage dips: 0% U_T for 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 70% U_T for 25/30 cycles (at 0°) Voltage interruptions: 0% U_T for 250/300 cycle	Voltage dips: 0% U_T for 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T for 1 cycle 70% U_T for 25/30 cycles (at 0°) Voltage interruptions: 0% U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device “Estus Pulp” requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Magnetic field of power frequency (50Hz) EN 1000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T- level mains voltage prior to filing of the test exposure			

Table 3

The device "Estus Pulp" is intended for use in the electromagnetic environment specified below. The customer ore the user of the device should assure that it is used in such an environment.

Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guidance**
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 "Estus Pulp" , 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) $d = 1,2 \sqrt{P}$ (from 80 MHz to 800 MHz) $d = 2,3 \sqrt{P}$ (from 800 MHz to 2.7 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 2.7 GHz	3 V/m from 80 MHz to 2.7 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: 

Table 4

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

The device “Estus Pulp” 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.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of the transmitter (m)**		
	from 150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	**from 80 MHz to 800 MHz** $d = 1,2 \sqrt{P}$	**from 800 MHz to 2,7 GHz** $d = 2,3 \sqrt{P}$
0,01	0,12	0,12	0.23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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.

2. Information on the availability in the medical device of a pharmaceutical product for medical use, materials of animal and (or) human origin

Materials in the device	*Description (if they are)*
Pharmaceutical product for medical use	absent
Materials of animal and (or) human origin	absent

3. The list of european standards used by the manufacturer of the medical device

EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 61000-4-2:2009, EN 61000-4-3:2020, EN 61000-4-4:2012, EN 61000-4-5:2014, EN 61000-4-6:2014, EN 1000-4-8:2010, EN 61000-4-11:2020, CISPR 11(2019), EN 80601-2-60:2015, EN ISO 14971:2019/A11:2021, EN 62304:2006/A1:2015, EN ISO 10993-1:2020, EN ISO 10993-2:2006, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-9:2021, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-18:2020, MEDDEV. 2.7.1 Rev.4, MEDDEV 2.12-1 rev.8, MEDDEV 2.12/2 rev.2, EN ISO 15223-1:2021, EN ISO 17664:2004, EN ISO 17665-1:2006, RoHS 2011/65/EU, EN 62353:2014, RED 2014/53/EU

Manufactured by

JSC GEOSOFT DENT

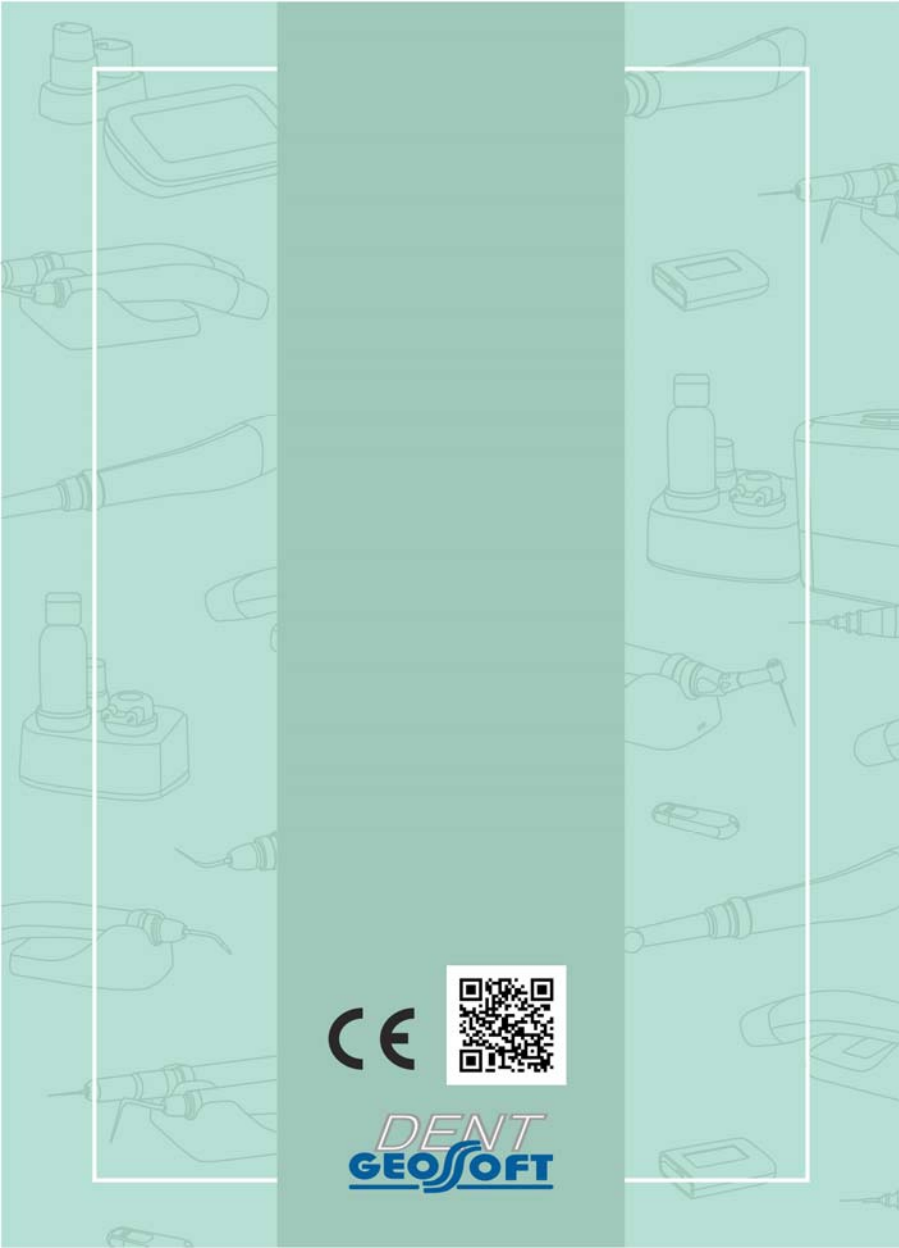
129090, Russia, Moscow, Vasnetsov pereulok, 7
TEL./ FAX: +7(495) 663-22-11 (ext.109),
E-mail: geosoftdent@geosoft.ru
Web: www.geosoft-dent.ru/en

Representative in Europe:

DENTAL WORLD SRL

Via Antichi Pastifici,
15-70056 Molfetta (BA). Italy
Tel +39 080 3381004; Fax+39 080 3386617

Version 13.03.23


CE
DENT
GEOSOFT