

DENT
GEO^{SOFT}

ESTÜS

USER'S MANUAL

ESTUS DENTAL COMPLEX:
APEXLOCATOR - CONTROL UNIT

ESTUS MULTI



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.

Tel.: +7(495)663-22-11 (extension 109),

E-mail: geosoftdent@geosoft.ru

JSC GEOSOFT DENT
(Russia)



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1. GENERAL INFORMATION

1.1. Intended use: Apexlocator - Control unit «Estus Multi» is main part of the dental complex "Estus", intended for carrying out procedures in the field of dentistry.

This device is designed for localization of the root canal apical constriction during the endodontic treatment.

Also «Estus Multi» is the link between all functional devices of the complex. When «Estus Multi» works together with devices of the Estus dental complex, «Estus Multi» it functions as a control unit.

1.2. Indication for use: Preparation of root canals during endodontic treatment.

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: «Estus Multi» is not recommended for use in patients who have a pacemaker.

1.6. Adverse reactions: Without finding.

1.7. Contact type with a patient: Short invasive contact through the oral cavity.

1.8. Operating principal: The device detects the apical constriction of the tooth root canal (apex) by measuring impedance between two

electrodes. The first electrode is a metal hook (lip clip), put on a patient lip. The second one is a file clip which is connected to the metal part of the endodontic instrument (file) inserted into the root canal of the examined tooth.

1.9. “ESTUS MULTI” functional abilities:

- Localization of the apical constriction of the root canal (apex) in the range of 3.0 - 0.0 units.
- Digital and graphic indication of the current file location in the canal on the device display.
- Audio indication in the measuring process and the volume adjustment function.
- Measuring correction function depending on the used irrigating solution - chlorhexidine, sodium hypochlorite or EDTA.
- “Making an apical stop point” function allowing to shift the localization point by a required distance from apex to:
 - avoid the canal processing deeper than the preset distance to apex;
 - make an apical stop point, preventing the outward of filling material beyond the apical constriction of the canal in the periodontal tissue.
- Marking function, allowing while measuring the working length to mark the canal curved areas for prognosing its filling more reliably.
- Indication of current charge level.
- Power saving function.

- | |
|--|
| <ul style="list-style-type: none">• The possibility of expanding “ESTUS MULTI” functionality at its using as a control unit for all devices of the “Estus”* dental complex in terms of settings and indications of their working parameters. |
|--|

** not included into the delivery set and should be purchased separately.*

1.10. Precautions and Warnings

! Use the product with the original “Geosoft Dent” accessories only (*see section 3*).

! Do not disassemble or modify the product. **Violation of the device integrity cancels the warranty.** Replacing the product’s power supply must be carried out only by authorized services.

! 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 between each patient use to avoid cross infection (*for more details see section 8*).

! When working in the patient's oral cavity, use a rubber dam.

! To avoid cable damage during its operation, always disconnect the cable from the apexlocator holding only the cable plug. Never disconnect apexlocator by holding the cable.

! In some situations apexlocator readings could be inaccurate and unreliable (*see section 6. “Basic rules of work with apexlocator”*). It is recommended to make an x-ray prior to using apexlocator and rely on the information got by both methods.

! This device requires special measures application for

electromagnetic capability (EMC) and should be installed and switched 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.

! The apexlocator dysfunction 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 different 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: *apexlocator cable of the maximal length 1,7 m; 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

Figure 1. Delivery set



- 1 - Apexlocator "ESTUS MULTI" - 1 pc
- 2 - Cable "Signal Line" (USB-B-plug) - 1 pc
- 3 - File clip "Probe Princh" - 1pc
- 4 - Lip clip "Oral Hook" - 1pc
- 5 - Apexlocator tester - 1 pc

- 6 - Charger cable USB - USB-B - 1 pc
- 7 - Power adapter (USB-socket) 2A - 1 pc
- User's manual - 1 pc
- Warranty Card - 1 pc

3. ACCESSORIES

File clip “Probe Princh” (3 pcs/ 1 pc)

GE99.047.000 / GE99.121.000

File clip is used as a clip of an active electrode (file) during the apex location procedure.



Lip clip “Oral Hook” (3 pcs/ 1 pc)

GE99.062.000 / GE99.123.000

Lip clip is used as a passive electrode during the apex location procedure. It is fixed on the patient's lip.



Cable “Signal Line” (USB-B-plug)

GE99.169.000

Connecting cable. USB-B-plug



Power adapter (USB-socket) 2A

Model: Robiton USB2100

Input voltage - (100-240) V, ~50/60Hz

Output voltage - 5 V; 2A.



! Accessories are delivered separately, additionally paid

4. “ESTUS MULTI” APPEARANCE

“ESTUS MULTI” appearance is on the figure 2, including:

Figure 2

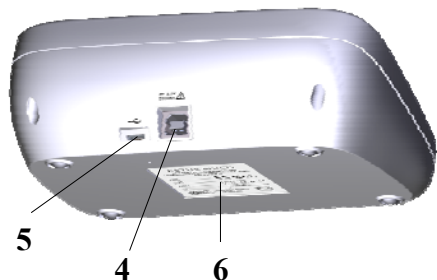


1. Touch-screen display.

2. Power supply button, one level up return in the program menu.

3. Power supply indicator (see table 1).

4. USB-B socket for connection the working cable “Single Line” or the charger cable.








5. Technological microUSB-socket for standard cable USB-microUSB* connection (for connecting to a computer in order to update the product software);

6. Information shield.

* not included into the delivery set, could be purchased separately, additionally paid.

Table 1. Power indicator meanings variants.

Power indicator color	Meaning
 WHITE	Power off
 ORANGE	Battery charging process
 GREEN	Battery is fully charged
 RED	Low charge level (<20%)
 RED blinking	Critical charge (<10%)

5. TECHNICAL SPECIFICATIONS

5.1. “ESTUS MULTI” device:

- Power supply - Li-Po battery (3,7 V; 4100 mAh)
- Electric shock protection - Product of class II. 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 3m in the direct vision.
- Touch-screen display - TFT-LCD (5”, resolution 800x480 px).
- Measurements range - from 3,0 to 0,0 units.
- Measurements accuracy in apical zone - $\pm 0,1$ units.
- Adjustment range of the apical stop point location - from 0,1 to 1,0 unit (step 0,1 unit.)

- Uninterrupted performance with the new fully charged battery without boost charge - not less than 13 hours.
- Standby working time until sleep mode activation - $10 \pm 0,5$ min.
- Stand-by operating time to automatic switch off - $30 \pm 0,5$ min.
- Battery resource - not less than 300 recharges.
- Audio indication parameters: audio frequency - from 1 to 6 kHz, volume level - not more than 70 dB.
- Dust and water protection rate - IP41.
- Dimensions - $(147*100*56) \pm 3$ mm;
- Weight - 235 ± 5 g;
- Service time of the device - 5 years.

5.2. Power adapter (USB-socket) 2A

- Input voltage - (100-240) V, $\sim 50/60$ Hz
- Output voltage - 5 V; 2A.

6. BASIC RULES OF WORK WITH APEXLOCATOR

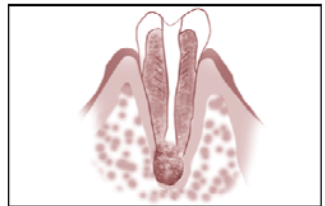
For more accurate apexlocator measurement results, please, follow these rules:

1. Carefully isolate the studied tooth and working file from saliva.
We recommend to use cofferdam, cotton swabs, saliva ejectors;
2. Work only in rubber gloves;
3. Use the file, corresponding to the root canal width in the apical area (usually ISO 10-20);
4. Do not use unclean or oxygenized files;
5. Use electroconductive gel for root canals (e.g. RC-Prep, Canal +) (*recommended*);
6. Prevent any contact of an instrument with metals in oral cavity (amalgam restorations, crowns, brackets etc.);
7. Do not touch the working file metallic parts and patient's mucosa with wet hands;
8. Provide wet contact of lip clip electrode with cavity.

Attention!!! *There is a possibility of measurements accuracy fall-off in the following cases:*

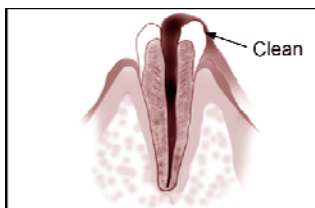
1. Root canal with large apical constriction

Root canal that has exceptionally large apical constriction due to a lesion or incomplete development cannot be accurately measured; the measurement results will be less than the actual length.



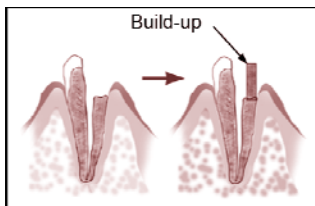
2. Root canal with blood, saliva or a chemical solution overflowing from the opening

If blood, saliva, or a chemical solution overflows from the opening of the root canal and contacts gums, this will result in electrical leakage and an accurate measurement can not be obtained. Wait for bleeding to stop completely. Clean the inside and opening of the canal thoroughly to get rid of all blood, saliva and chemical solutions and then make a measurement.



3. Broken crown

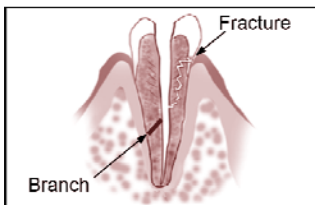
If the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, contact between the gingival tissue and the file will result in electrical leakage and an accurate measurement cannot be obtained. In this case, build up the tooth with a suitable material to insulate the gingival tissue.



4. Fractured tooth. Leakage through a branch canal

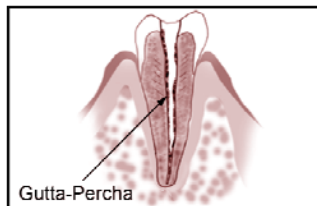
Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.

A branch canal will also cause electrical leakage.



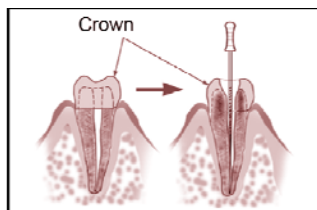
5. Retreatment of a root canal, filled with gutta-percha

The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, pass a small file all the way through apical constriction and then put a little saline in the canal, but do not let it overflow the canal opening.



6. Crown or metal prosthesis touching gingival tissue

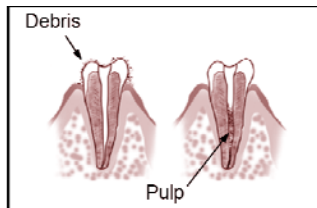
Accurate measurement cannot be obtained if the file touches a metal prosthesis that is touching gingival tissue. In this case, widen the opening at the top of the crown so that the file will not touch the metal prosthesis before taking a measurement.



7. Cutting debris on tooth. Pulp inside canal

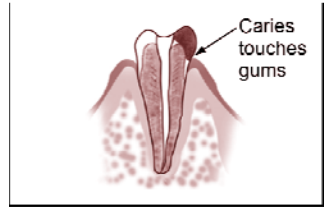
Thoroughly remove all cutting debris on the tooth. Thoroughly remove all the pulp inside the canal.

Otherwise an accurate measurement cannot be obtained.



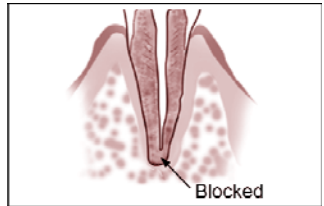
8. Caries contacts with gum

In this case, electrical leakage through the caries infected area to the gums will make it impossible to obtain an accurate measurement.



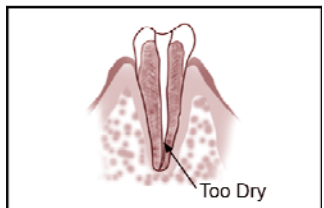
9. Blocked canal

The meter will not move if the canal is blocked. Open the canal all the way to the apical constriction to measure it.



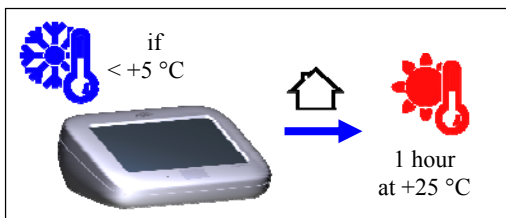
10. Extremely dry canal

If the canal is extremely dry, the meter will not move until it is quite close to the apex. In this case, try to moisten a canal with saline.



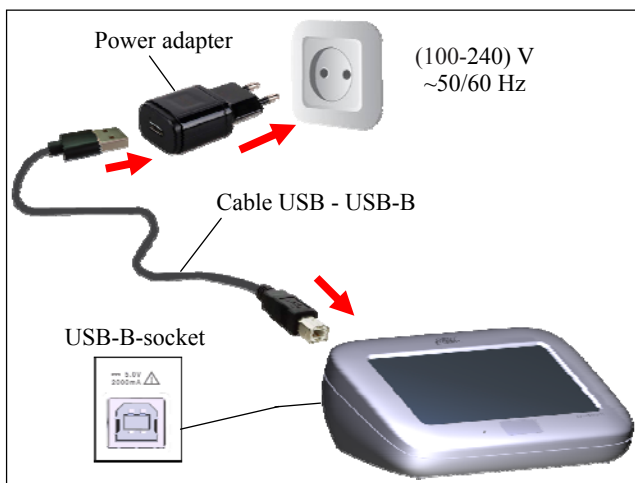
7. PREPARATORY STAGE AND WORKING PROCEDURE

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

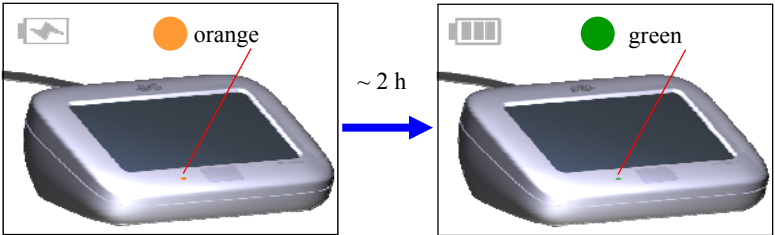


Step 1. Battery charging


A) Connect the cable USB - USB-B to the device and the power adapter, then put the power adapter into the mains socket.



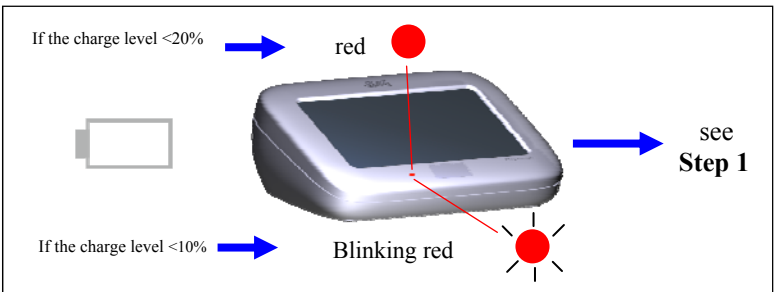
B) Wait till the battery is fully charged:



C) Disconnect the charger cable with power adapter first from the mains socket and then from the device.

 *Average charging time is about 2 hours, 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.*

Battery charge level indication:





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

Step 2. Power on and working mode choose

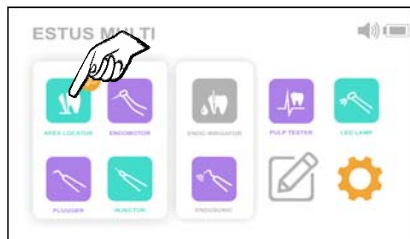
To switch power on press the power touch button.

The screen displays the manufacturer's logo and then - the main menu.






Prior to the device first use conduct its general setting (see Step 12)

For apexlocator mode press the icon APEXLOCATOR



The rest icons with modes are intended only for the joint work of "ESTUS MULTI" with the other devices of "Estus" dental complex. Detailed information is presented in the special user manual "Dental complex "Estus"".

The icons color in the menu depends on the connected device status:

Icon color	Is the pair between the Estus device and "ESTUS MULTI" created?	Is the device of Estus series active at the moment?
 lilac	Yes	Yes
 mint	Yes	No
 grey	No	No

Step 3. Apexlocator working ability check

Insert the apexlocator tester into the USB-B socket on the back side of the device.

The screen displays 0.5 (± 0.2), accompanied by the interrupted audio signal.

If the readings on the screen are out of the specified range, then the device is unserviceable.

To fix the failure, contact the service department.



Take out the tester from the apexlocator socket.

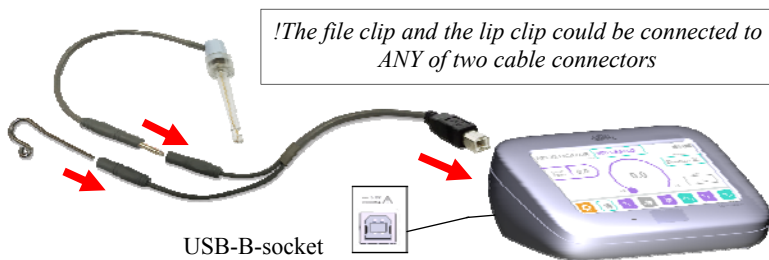


1. Check the apexlocator workability prior to the first usage, as well as at any moment if the readings seem inaccurate.

2. The apexlocator workability check should be conducted at the following switched off functions: apical stop point function and measurements correction function depending on the used irrigating solution (see Step 7,8).

Step 4. Connecting the cable, file clip and lip clip

Connect cable “Signal Line”, the file clip and the lip clip to the apexlocator:



Be sure to sterilize the file clip and the lip clip before use between each patient use (see section 8 “Sterilization and disinfection”).

Step 5. Apexlocator circuit continuity check



Apexlocator circuit continuity is the significant factor for the accurate and reliable localization of the canal apical constriction

Even the short-time electrical contact failure between any circuit elements could cause accuracy and/or stability measurements loss.

Apexlocator measuring circuit includes: apexlocator socket, cable “Signal Line”, file clip, lip clip, working file and the tooth.

Reasons of measurements circuit continuity failure:

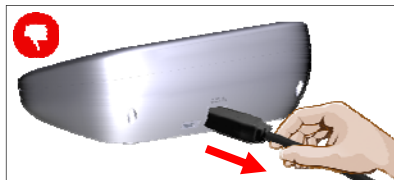
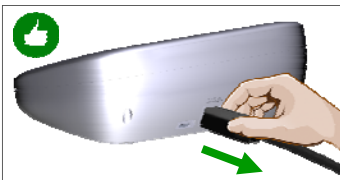
- wire break of the cable “Signal Line” or of the file clip;
- cable connectors damage (rarely, apexlocator socket damage) as a result of careless handling with the connectors while connecting/disconnecting the cable to/from the apexlocator, lip clip or the file clip;
- the use of contaminated or oxidized measuring files or file clips;
- using files not matching the width of the tooth canal.



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

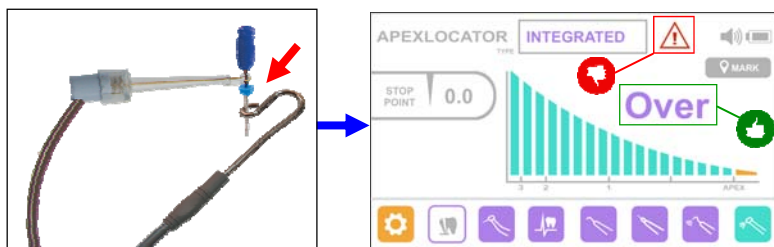
2. Do not use contaminated or oxidized files and file clips.

3. Check the apexlocator measuring circuit continuity every time before working and also if during the working process the readings are absent or unstable.




For checking the circuit continuity:

A) Switch on the power and close the lip clip and the working file to each other. The indication “Over” with a scale should appear on the display.

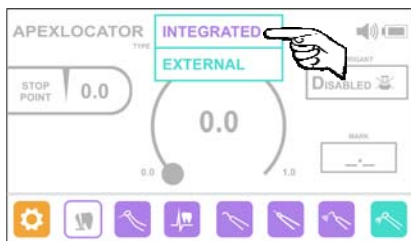


B) Gently tug the cable in all joints of the measuring circuit.


C) If the indication does not appear, the readings are not stable and/or the sign ⚠ lights up, it means the circuit continuity is failed and the apexlocator is inapplicable for further working.

 To find and remove the causes of failures, see section 10 “Troubleshooting” (table 4)

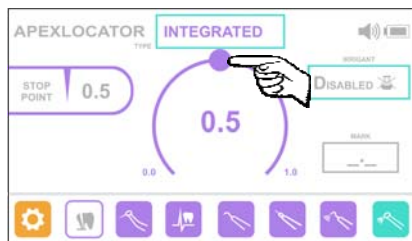
Step 6. Apexlocator type choosing



Press the box TYPE and in the drop-down list choose the apexlocator type INTEGRATED

 *EXTERNAL* type is used only at the joint work of “ESTUS MULTI” with the apexlocator “Estus Apex”.

Step 7. Setting an apical stop point- localization point displacing.



For setting the apical STOP POINT use the circular regulator.

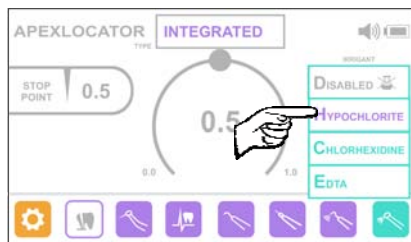
Set the required stop point value within 0,0 - 1,0 units, with the step 0,1 unit.

To switch off the function of an apical stop point set the regulator on the value 0.0 units (Apex)

Step 8. On/off the correction function; irrigating solution choosing

Activation of correction function allows to make measurements more accurate at applying sodium hypochlorite, EDTA or chlorhexidine as the irrigating solution.

To switch on the correction function press the box IRRIGANT and in the drop-down list choose the required irrigant: HYPOCHLORITE, CHLORHEXIDINE or EDTA



To switch the function off press the box DISABLED.

Step 9. Apexlocator operation - the measuring circuit closing

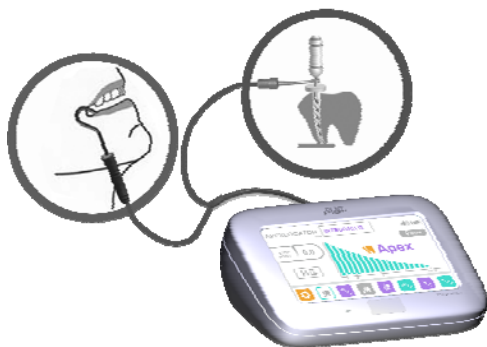


Prior to starting the measuring please read carefully the basic rules of the apexlocator operation, described in section 6 of this User's Manual

A) Insert the measuring file into the root canal of the examined tooth and place the electrodes in the patient's oral cavity in the following order :

- place the lip clip on the patient's lip;
- joint the file clip to the metal part of the file, inserted into the root canal of the examined tooth.

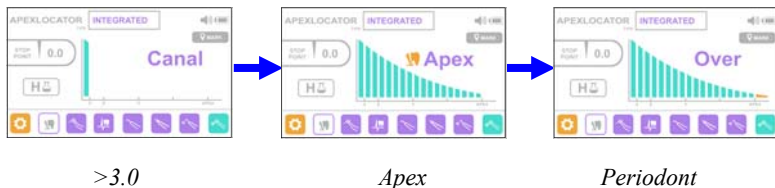
Apexlocator is activated automatically.



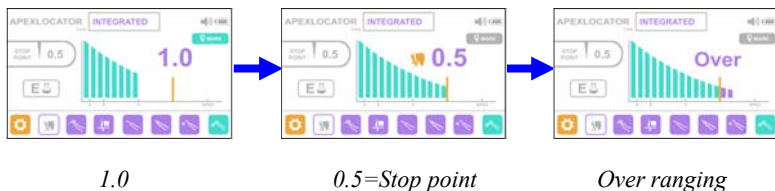
Depending on the distance between the top of the file and the localized point in the canal (apex or stop point), the corresponding graphic and digital information will appear on the display.

Examples of the apexlocator indication:

a) localizing point STOP POINT - 0.0 unit (apex)



b) point of localization STOP POINT - 0.5 unit



Additionally the measuring process is accompanied by the interrupted audio signal, which becomes more frequent as the file approaches to the localizing point.

When the tip of the file goes beyond the localizing point, the sound becomes *continuous*.

Step 10. The user's mark setting/delete

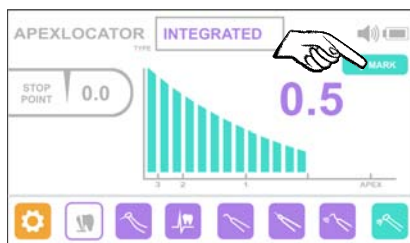
The mark setting allows to mark the canal curved zone, tactilely defined during the measuring process.

The user's mark could be set at any place in the measuring range above the localizing point.

The set mark helps the dentist and does not influence on the measuring results.

To set the mark start measuring, moving the file along the canal.

Press the button MARK in the place, defined as the canal curved zone.



On the display the current segment of the scale and the corresponding digital readings become orange, the mark is set.

After taking the file out of the canal the current mark value displays in the MARK box.



Closed circuit

Open circuit

To delete the mark close the apexlocator measuring circuit again and press the button RESET.



In addition the mark is deleted automatically when the power is off.

Step 11. Additional functions

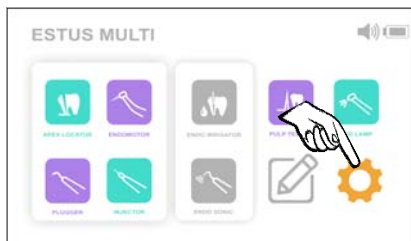
When "ESTUS MULTI" works together with devices of the Estus dental complex, such as "Estus Drive", "Estus Pack", "Estus Fill", "Estus Pulp", "Estus Light", "Estus Apex" and "Estus Sonic", "ESTUS MULTI", it functions as a control unit.

With the help of the ESTUS MULTI control unit, it becomes possible to expand the functionality of the listed products, simplify the process of setting them up and provide a more visual indication of their operating parameters. Data transmission and reception between ESTUS MULTI and other devices of the Estus dental complex is carried out via radio channel.



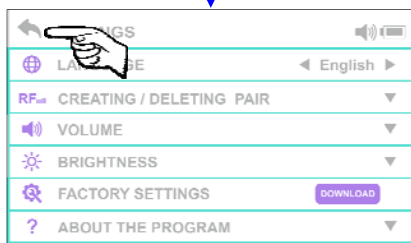
The detailed information of using “ESTUS MULTI” as a control unit for the “Estus” dental complex devices is presented in the User’s Manual «Dental complex “Estus”».

Step 12. General device settings



To start setting press the orange icon SET in the program main menu.

In the drop-down list box the whole list of the device settings is presented.



Choose the required setting from the settings list.

To return to the main menu press the Back arrow.

12.1. Language setting.

Device interface is presented in two languages: Russian and English. To choose language use Left-Right arrows.



12.2. Setting "Creating/Deleting pair" function

For “ESTUS MULTI” and other devices of the “Estus” dental complex joint work it is necessary to create pair with each of the devices on radio channel.

To create/ delete pair press the Down arrow.



12.2.1. Pair creating

A) Activate the creating pair mode on the pairing device as it specified in a device User's Manual (*see Step "Pair creating mode activation"*).

B) In the pop-up list box on the “ESTUS MULTI” display choose the required device name (for ex, «Estus Drive») with the corresponding serial number, specified on the device housing, and press the button Create:



C) Pair creation process starts. Successful completion of it results indication of the “ESTUS MULTI” display “Pairing complete”, and the paired device power supply should switch off (except for “Estus Apex”, on the display of which should also appear "Pairing complete").

PAIRING COMPLETE



Press the tick.

The pair is created.

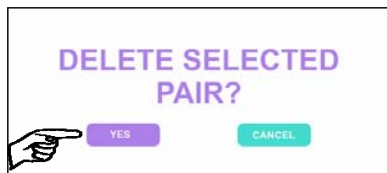
Then a device is able to work with the paired “ESTUS MULTI” control unit.

12.2.2. Pair deleting

A) To delete the pair, again choose the required device name (for ex, “Estus Drive”) with the corresponding serial number, specified on the device housing, and press the button Delete:

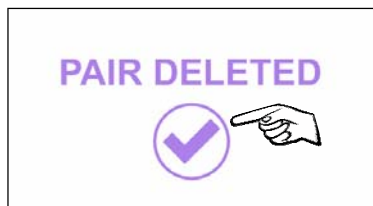


B) In the pop-up box confirm the pair delete by pressing Yes.



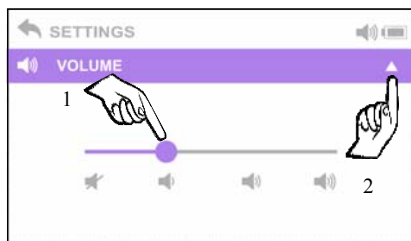
After this the “Pair deleted” would appear on the display.

Press the tick.



12.3. Volume setting

The device acoustic emitter has 4 volume levels: low, normal, high and off. To change volume level press the Down arrow .

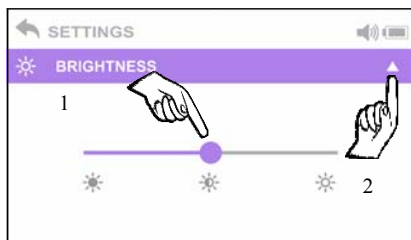


In the drop-down list box choose the required volume level with the line cursor.

To return to the Settings menu press the Up arrow .

12.4. Brightness setting

The device has 3 display brightness levels. To change brightness level press the Down arrow .

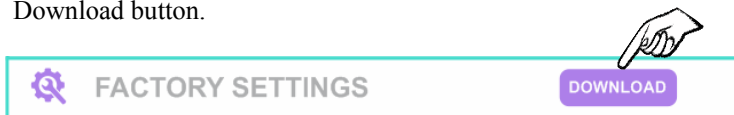


In the pop-up box choose the required brightness level with the line cursor.

To return to the Settings menu press the Up arrow .

12.5. Factory settings

To return to the device factory settings press the Download button.

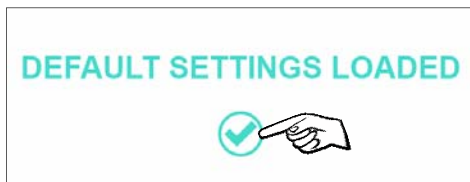


In the pop-up box confirm loading of the factory settings by pressing Yes button :



DEFAULT SETTINGS LOADED would appear on the display (the factory settings are loaded).

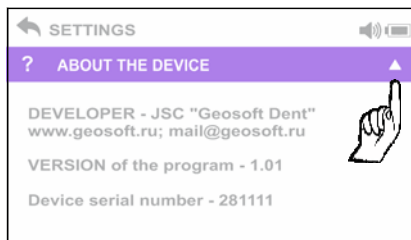
Press the tick.



! *Attention! At this setting activation ALL previous settings are canceled to the factory values, including a user settings in all working modes.*

12.6. About the device setting

To look through the information of a current program firmware version and the device serial number press the Down arrow.



To return to the Settings menu press the Up arrow .

12.7. Service information setting

! This information is only for the service specialists.



Step 13. Sleep mode

If the device is not used within 10 minutes, it switches over to sleep mode.

The device display goes out and power indicator lights WHITE.

To return the device from the sleep mode press the touch button on/off or the button on the display.



Step 14. Power off

Press the button 3 times to switch the power off or the device is switched off automatically in 30 minutes.



8. STERILIZATION AND DISINFECTION

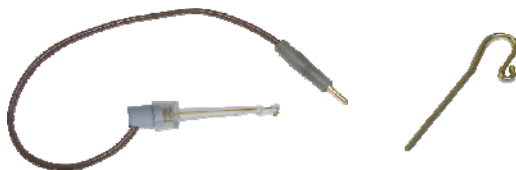
All the device's elements directly contacted with the patient's oral liquid, mucosa and tooth tissues must be preliminarily cleaned and terminally sterilized.

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:

- file clip «**Probe Princh**» and
- lip clip «**Oral Hook**»



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 2.



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 device not listed in this paragraph.

Instruction #1(on repeated sterilization and disinfection)Manufacturer: JSC Geosoft Dent (Russia)Product: **Lip clip «Oral Hook», File clip «Probe Princh»**

Table 2

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 –0,2MPa, Working temperature - 132±2 °C (270±3 °F). 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 apexlocator in any solution.

9. MAINTENANCE

- Charge the battery unit in a timely manner. *(see section 7, Step 1)*. Do not let the battery unit discharge completely.
- Replace the battery unit timely when it depletes its working resource.



Replacing the product's power source must be carried out only by authorized services. Do not disassemble the device for replacing the battery. It could be insecure. Opening the apexlocator housing by the user cancels the warranty.



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



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

- Check the apexlocator workability timely *(see section 7, Step 3)* if the readings seem inaccurate.
- Check the apexlocator measuring circuit continuity every time before working and also if during the working process the readings are absent or unstable *(see section 7, Step 5)*

10. TROUBLESHOOTING






Table 3. General problems and solutions

Problem	Possible cause	Solution
Apexlocator does not switch on.	<ul style="list-style-type: none"> • The battery is discharged. 	<ul style="list-style-type: none"> • Charge the battery (<i>see section 7, Step 1</i>).
Apexlocator switches off spontaneously.	<ul style="list-style-type: none"> • Energy saving function activates. • The battery is discharged. 	<ul style="list-style-type: none"> • <i>See Step 13,14</i> • Charge the battery .
The battery charges too fast and/or apexlocator working time till the next charging is drastically reduced.	<ul style="list-style-type: none"> • The battery resource is depleted. The battery is not suitable for use. 	<ul style="list-style-type: none"> • Apply to the maintenance service for replacing the battery.
The battery does not charge.	<ul style="list-style-type: none"> • Bad contact between the apexlocator, charger cable and the power adapter. • Charger cable is damaged. • Power adapter is defective. 	<ul style="list-style-type: none"> • Check connections. • Replace the charger cable. • Replace the power adapter
Problems with sound.	<ul style="list-style-type: none"> • Volume level is not set correctly. 	<ul style="list-style-type: none"> • Check settings (<i>see section 7, Step 12.4</i>)
Display brightness issues	<ul style="list-style-type: none"> • Display brightness level is not set correctly 	<ul style="list-style-type: none"> • Check settings (<i>see section 7, Step 12.5</i>)
In apexlocator mode readings on the display are absent or unstable, indicator lights up!	<ul style="list-style-type: none"> • The continuity of the apexlocator. measuring circuit is broken. • The canal is over-dry. 	<ul style="list-style-type: none"> • Check the circuit continuity (<i>see section 7 – Step 5</i>) and eliminate failure (<i>see table 4</i>) • Moist the canal.

Problem	Possible cause	Solution
Apexlocator works incorrectly (inaccurate measurements)	<ul style="list-style-type: none"> • The settings are incorrect. • The canal is over-dry 	<ul style="list-style-type: none"> • Check the apexlocator settings (<i>see section 7 – Step 7, 8</i>). • Moist the canal

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

Table 4. Troubleshooting if the continuity of the measuring circuit is broken

Po in ts	Action	“Over” indication with a scale appeared on the display	
		YES	NO
Switch on the apexlocator power (see section 7, Step 2)			
1	Check the correctness and reliability of the apexlocator and the working cable connection, the file clip and lip clip fixation (see section 7, Step 4) and fixation of the file in the file clip. Test the apexlocator circuit (see section 7, Step 5).	OK	See p. 2
2	Take the file out of the file clip and test the circuit, directly closing the lip clip to the file clip current-conducting part. 	The working file is contaminated or oxidized. Clean or replace the file. 	See p.3
3	Disconnect the file clip from the cable and test the apexlocator circuit, directly closing the lip clip to current-conducting part of the open cable socket. 	The file clip is oxidized or damaged. Replace the file clip. 	The cable is damaged. Replace the cable  In rare cases the socket on the apexlocator is damaged. Contact 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 MULTI belongs to the medical waste hazard category of class A (non-hazardous waste of medical institutions).

13. SYMBOL DESCRIPTIONS

Symbol	Description
	Warning: Address to supporting documentation
	Type of protection against electric-shock hazard. Device of the II class
	Protection level from electrical shock: Applied part BF type
	Do not throw away the device into system of daily rubbish
	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
	European authorized representative
	Mark of conformity to product quality and safety standards of the European Union (CE-mark)

APPENDIX

1. Electromagnetic Emissions and Immunity

Table 1

<p>The device «Estus Multi» 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.</p>		
Emission test	Conformity	Electromagnetic environment - guidance
RF Emissions CISPR11	Group 1	The device «Estus Multi» 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 Multi» 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

<p>The device «Estus Multi» 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.</p>			
Immunity test	Test level EN 60601-1-2	Compliance Level	Electromagnetic environment - guidance
<p>Electrostatic discharge (ESD) EN 61000-4-2</p>	<p>± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air</p>	<p>± 8 kV contact ± 2 kV air ± 4 kV air ± 8 kV air ± 15 kV air</p>	<p>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</p>
<p>Burst/Fast Transient EN 61000-4-4</p>	<p>±2 kV for power supply lines ±1 kV for input/output lines</p>	<p>±2 kV for power supply lines ±1 kV for input/output lines</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>
<p>Surge EN 61000-4-5</p>	<p>±0,5; ±1.0; ±2.0 kV for scheme «line-to-ground» ±0,5; ±1.0 kV for scheme «line-to-line»</p>	<p>±0,5; ±1.0; ±2.0 kV for scheme «line-to-ground» ±0,5; ±1.0 kV for scheme «line-to-line»</p>	<p>Mains power quality should be that of a typical commercial or hospital environment.</p>

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	<u>Voltage dips:</u> 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°) <u>Voltage interruptions:</u> 0% U _T for 250/300 cycle	<u>Voltage dips:</u> 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°) <u>Voltage interruptions:</u> 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 Multi» 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 Multi» 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.

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 Multi», 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)
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	$d = 1,2 \sqrt{P}$ (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)


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 Multi»			
The device «Estus Multi» 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

<i>Materials in the device</i>	<i>Description (if they are)</i>
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 01.02.23

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