



USER'S MANUAL

ESTUS DENTAL COMPLEX: ENDODONTIC ULTRASONIC SCALER

ESTUS SONIC

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)



CONTENTS

1. General information	4
2. Delivery set	7
3. Accessories	9
4. Technical specifications	13
5. "Estus Sonic" appearance	15
6. Preparatory stage and working procedure	18
7. Sterilization and disinfection	29
8. Maintenance	31
9. Troubleshooting	32
10. Storage, transportation and use	35
11. Information on utilization	35
12. Symbol descriptions	36
Appendix	37

1. GENERAL INFORMATION

1.1. Intended use: Endodontic ultrasonic scaler «Estus Sonic» is part of the dental complex "Estus", intended for carrying out procedures in the field of dentistry.

This device is designed for ultrasonic treatment of the tooth root canals.

1.2. Indication for use:

- finding and breaking into hidden canals and access enhancement;
- removing of the calcific dental deposit and ledges;
- root canals unsealing (removing gutta-percha);
- extraction of endodontic instruments fragments;
- removing of the post constructions;
- condensing of gutta-percha;
- passive ultrasonic irrigation and activation;
- root end surgical preparation

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 Sonic» 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: Creation of mechanical longitudinal vibrations of ultrasonic frequency at the end of the endodontic tip due to piezoelectric conversion of electrical energy into sound energy.

1.9. Functional abilities:

- Four working modes with the different vibration amplitude (power) («High-SCAN», «High», «Middle», «Low»);
- The additional function of the modulation (scanning) of the resonance frequency for the connected tip in «High-SCAN» mode, allowing to improve mixing the irrigating solution in a canal significantly, which in turn raises the effectiveness of the treatment;
- Automatic adjustment of the resonance frequency of the tip during operation;
- The working mode indication on the handpiece LED scale;
- Audible indication during work and audible signal volume level control;
- Battery discharge indication;
- 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 in the delivery set and purchased separately for an additional fee.

1.10. **A** Precautions and Warnings

! Use the device with the original "Geosoft Dent" accessories only *(see section 3).*

! Do not disassemble or modify the device. Disassembly of the device, violation of the device integrity cancels the warranty.

! Avoid letting any liquid inside the device'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 time of use to avoid cross infection. *(for more details see section 7).*

! To avoid thermal burns do not touch the ultrasonic tip in the handpiece working mode. Avoid contact the tip with the patient's lips and oral mucosa. Change the tip only after switch the handpiece power off.

! 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 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 device 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 ((a)).

! 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: *the charger cable of the maximal length 1,8 m*

! The device operates normally at a temperature of $10-35^{\circ}$ 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		tity in ery set its, pcs
		35-SP	35-S0
1	Control unit «Estus Sonic»	1	1
2	Battery unit	1	1
3	Tip "E4ES" 22 mm	1	1
4	Tip-endochuck "E1/07ES"	1	1

Table 1 continued

	The device element	Quantity i delivery so variants, p	
		35-SP	35-80
5	File for tip-endochuck "E1/07ES" (21 mm)	1	1
6	Tip "E5DES" 16mm with diamond-coated	1	1
7	Hygienic case	1	1
8	Wrench for tips	1	1
9	Stand «Estus One-B»	1	0
10	Charging stand «Estus Energy-S»	1	0
11	Charger cable USB - USBB	1	0
12	Power adapter (USB-socket) 1A	1	0
13	User's Manual «Estus Sonic»	1	1
14	Warranty Card «Estus Sonic»	1	1
15	Warranty Card «Estus Energy-S/D»	1	0
16	Package	1	1

3. ACCESSORIES

Battery unit GE99.205.000 Additional battery unit for the «Estus Sonic» tip (2x3.7 V,800mA/h)

Stand «Estus One-B» GE99.208.000 Single-stand for the «Estus Sonic» tip

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

Charging stand "Estus Energy-S" GE42.000.000

One-port charging stand for the battery unit of the «Estus Sonic» handpiece.

Charging stand "Estus Energy-D" GE39.000.000

Two-ports charging stand for two battery units of the «Estus Sonic» handpiece.











USER'S MANUAL



Charger cable USB-USBB GE99.001.00P Cable for charging stand "Estus Energy

Cable for charging stand "Estus Energy-S" / "Estus Energy-D". Length 1.8 m



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 Sonic" handpiece.



Tip-endochuck «E1/08ES». GE99.228.000 Tip-endochuck for fitting endo files 120° for front teeth and premolars treatment. File clamping hole diameter 0.8 mm.



Tip-endochuck «E1/07ES». GE99.247.000 Tip-endochuck for fitting endo files 120° for front teeth and premolars treatment. File clamping hole diameter 0.7 mm.

Tip «E3ES». GE99.230.000

The tip for a lateral gutta-percha condensation in a canal.

Tip **«E3DES».** GE99.232.000

The diamond coated tip for unsealing a canal and for a calcificate removing.

Tip «E4ES». GE99.233.000

The tip for the ledges removal during a root canal filling at its repeated processing. The working part length is 22 mm.

Tip «E4DES». GE99.235.000

The diamond coated tip for the removal of the calcified fragments and the filling material residue in a tooth canal at its repeated processing. The working part length is 22 mm.

Tip «E5ES». GE99.236.000

The tip for the ledges removal during a root canal filling at its repeated processing. The working part length is 16 mm.

Tip «E5DES». GE99.237.000

The diamond coated tip for the ledges removal during a root canal filling at its repeated processing. The working part length is 16 mm.















Tip «E10ES». GE99.241.000

The tip for the retrograde preparation of the tooth canals. Small diameter length is 4,5 mm.



Tip «E10DES». GE99.242.000

The diamond coated tip for the retrograde preparation of the tooth canals. The diamond coating length is 3,3 mm.



Tip «E11ES». GE99.243.000

The tip for the retrograde preparation of the tooth canals. Small diameter length is 3,5 mm.



Tip «E11DES». GE99.244.000

The diamond coated tip for the retrograde preparation of the tooth canals. The diamond coating length is 2,2 mm.

Files for the «E1/08ES» tip-endochuck.

GE99.246.000 Machine U-drillburs for the canals processing with ultrasound. They are used with GE99.228.000 endochuck. Sizes: #20, #25, #30, #35 (6 pcs. in a pack)



Files for the «E1/07ES-21» tip-endochuck. (1 pc./3 pcs.). GE99.252.000/ GE99.268.000 Ni-Ti files for canal treatment with ultrasound. Used with GE99.247.000 tip-endochuck. Working part length 21 mm

13

Files for the «E1/07ES-25» tip-endochuck. (1 pc./3 pcs.). GE99.269.000/ GE99.270.000 Ni-Ti files for canal treatment with ultrasound. Used with GE99.247.000 tip-endochuck. Working part length 25 mm

Hygienic case. GE99.248.000

Reusable, sterilizable silicone hygiene case for the «Estus Sonic» handpiece.

The «Sonic-KeyES» wrench for the tips. GE99.238.000

The wrench for fixation of the working tips of the «Estus Sonic» handpiece. Autoclavable.

! Accessories are delivered separately for an additional fee

4. TECHNICAL SPECIFICATIONS

4.1. «Estus Sonic» handpiece:

- Power supply Li-Po battery unit (2x3,7 V; 800 mAh)
- Electric shock protection Device with the built-in power supply. Applied 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.
- Maximum power 6 W;







- Resonance frequency- 34 45 kHz;
- Uninterrupted performance with the new fully charged battery is not less than 100 working cycles.
- Stand-by operating time to automatic switch off is 10 ± 0.5 minutes
- Battery unit charging time no more than 3 hours
- Battery resource is not less than 300 recharges
- The working area of the ring switch on the front side of the handpiece 180°
- The operation force of the ring switch not more than 1N
- Audible indication parameters: audio frequency from 1 to 6 kHz, volume level not more than 70 dB;
- Dust and moisture protection rate IP41;
- Dimensions (181*33*43) ±3 mm
- Weight 110 ±5 g
- Service time of the device 5 years.

4.2. Charging stand «Estus Energy-S»:

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

4.3. Power adapter (USB-socket) 1A

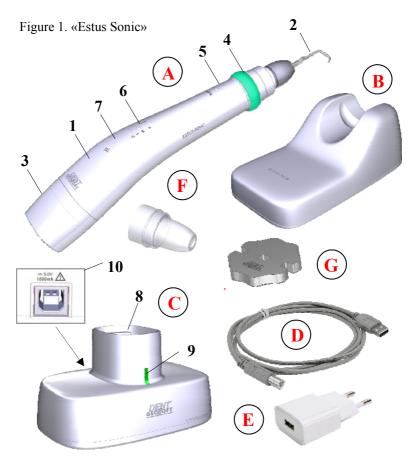
- Input voltage (100-240) V, ~50/60 Hz
- Output voltage 5 V; 1A

4.4. «Estus One-B» stand:

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

5. "ESTUS SONIC" APPEARANCE

Appearance of the «Estus Sonic» is on the figure1



A. «Estus Sonic» handpiece:

- 1. Control unit;
- 2. Working tip;
- 3. Removable battery unit;
- 4. Ring switch (see table 2);
- 5. «STATUS» indicator (see table 3);

6. LED scale includes 5 indicators to display the chosen working mode;

- 7. Discharge indicator of the removable battery unit;
- B. Stand «Estus One-B» for the handpiece;

C. Charging stand «Estus Energy-S» :

- 8. Charging socket;
- 9. Charge indicator;
- 10. Socket USBB for the charger cable;
- D. Charger cable USB- USBB;
- E. Power adapter (USB-socket);
- F. Hygienic case; G. Wrench for a tip

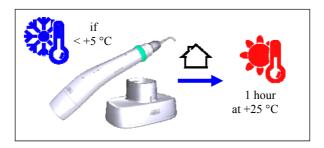
Table 2.	Variants	of using	the	ring	switch
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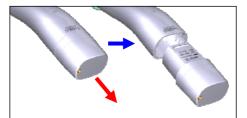
	Power supply	Press ring switch	Result
	OFF	1 time	Power on
6		Holding up to 10 sec.	Volume adjustment
		Holding > 20 sec.	Pair creating mode activation
		1 time	Scaler Start/ Stop
	ON	2 times	
		2 times with holding	The working mode selection
		3 times	Power off
		3 times with holding	Return to the factory settings

STATUS	indication color	Meaning
STATUS	WHITE	Power on. The tip is not identified
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	The tip is identified
STATUS	MINT blinking	The process of identifying the tip
STATUS	ORANGE	Scaler working mode activation
STATUS	ORANGE blinking	Search for resonance in the scaler working mode
STATUS	RED blinking	Malfunction (see section 9)

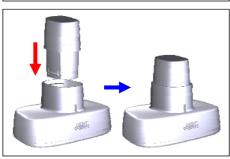
6. PREPARATORY STAGE AND

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





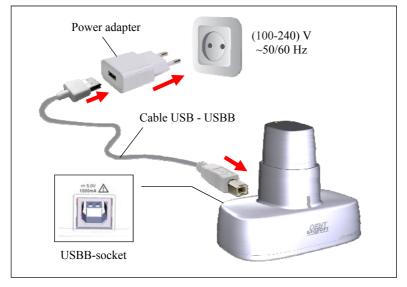
A) Disconnect the battery unit from the handpiece (*in package the battery unit is packed separately from the handpiece*)



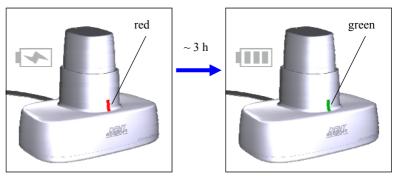
B) Insert the battery unit into the charging socket of the charging stand "Estus Energy-S"

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



D) Wait till the battery is fully charged.

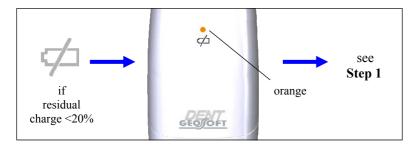


E) Take the charged battery unit out of the charging stand and connect it to the handpiece.

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.

Average charging time is about 3 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 unit. (see section 3).

The battery discharge indication:



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

Step 2. Working tip installation

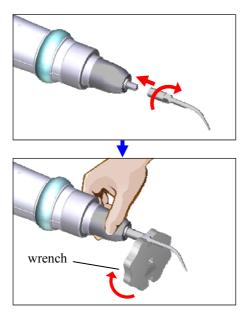


- Use the tips and files, recommended by the manufacturer (see section 3).

- Be sure to sterilize the tips and files, if specified by the manufacturer, before using them after each patient (see section 7).

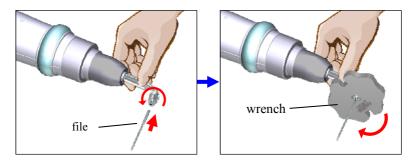


Replace a tip and file ONLY when the handpiece power is off.



A) Screw the working tip on the handpiece thread connection, rotating the tip clockwise.

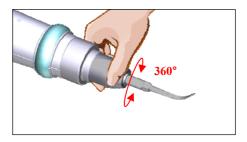
B) Carefully tighten the tip with the special wrench from the delivery set, while holding the tip by the dark gray holder



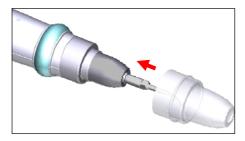
C) In case of using an tip-endochuck, loosen the fixing nut on the endochuck, insert the working file into the endochuck and carefully tighten the nut by turning the wrench clockwise.

Be sure to use the wrench to secure the attachment tip and/or file. Insufficient fixation of these components can lead to malfunctions of the scaler.

D) To change the angle of rotation of the tip, rotate the gray holder in the desired direction within a range of 360 degrees.



Step 3. Hygienic case application



Put the hygienic case on the handpiece from the side of the working tip.

To avoid cross infections at the contact of the handpiece with oral mucosa use the hygienic case from the delivery set. Be sure to sterilize the hygiene case before use after each patient (see section 7)

Step 4. Power on



To switch the power on press the ring switch. At the same time, the STATUS indicator will blink several times and light up in MINT color,

STATUS

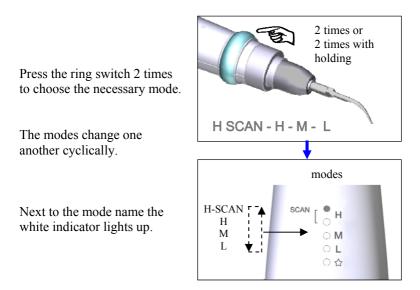
confirming that the connected tip is detected correctly.

f the tip is missing or connected incorrectly (for example, when the tip is not screwed on properly), the STATUS indicator will turn WHITE color. In this case, turn off the power to the handpiece, install the tip and/or re-tighten the tip using the special wrench (see Step 2) and turn on the power to the handpiece again.

If the STATUS indicator blinks white three times when the device is turned on, it means that the settings have been changed by the user with the "Estus Multi" device. For default factory setting return see Step 10.

Step 5. Working mode choosing

The handpiece has 4 working modes with the different vibration amplitude (power) («High-SCAN», «High», «Middle», «Low»).



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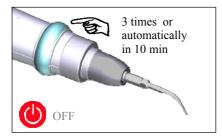
Working mode	Ultrasound power, % from max value	Cycle time of work, sec	Availability of scanning function in SCAN frequency
«H-SCAN»	100	2.0	yes
«H» High	100	30	no
«M» Middle	70	30	no
«L» Low	50	30	no

Table 4: Parameters factory settings:

The working parameters changing in modes «H-SCAN», «H», «M», «L» is IMPOSSIBLE, but using the "Estus Multi"* control unit the additional working mode is activated « Δ » (Favorite), allowing to change the scaler working parameters in a large range of values.

* not included in the delivery set and purchased separately for an additional fee.

Step 6. Power off



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

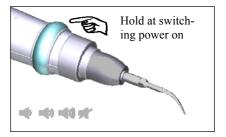
All the indicators on the handpiece go out.

Step 7. Volume adjustment

The device 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.



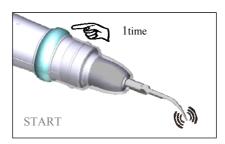
To choose the required volume level stop pressing the ring switch.

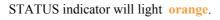
Step 8. Scaler starting

During work with tip-endochuck, You must activate the device only directly in the root canal of the tooth. During work with all other tips, on the contrary, you must activate the operation of the tip in air and only then place the tip into the tooth cavity.

Press the ring switch to start the scaler.

Scaler operating is accompanied with the intermittent beep.





STATUS

If, when the scaler is activated, the "STATUS" indicator does not light up, but BLINKING orange, accompanied by a specific "error" sound, then the resonant frequency of the tip could not be determined. This can happen in two reasons: 1. if the tip was connected while the handpiece was powered on, and 2. if too much force is applied to the end of the tip.

In the first case, you should immediately stop the scaler (Step 9), turn off the handpiece power (Step 6), turn on the power again (Step 4), make sure that the tip is detected correctly, if it necessary, eliminate the problem (Step 2) and only then reactivate device to working scaler mode.

In the second case, it is enough to simply loosen the force on the tip, for example, by pulling it out from the tooth cavity for 2-3 seconds into the air, then put the tip back into the tooth and make sure that the "STATUS" indicator stops blinking and the device starts working in normal mode.

To avoid thermal burns do not touch the tip during the handpiece operation. Avoid contact the tip with the patient's lips and oral mucosa.

Itime

Step 9. Scaler stop

The scaler stops automatically in a preset in a program time period (*default after 30 seconds*).

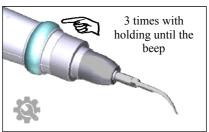
For the forced stop of the scaler press the ring switch again.

Step 10. Return to the factory settings

The handpiece settings can be changed at its joint operation with the «Estus Multi» control unit.

To return to the stand 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.



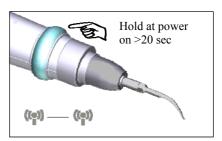
When the power is on again, all the handpiece settings will be returned to their initial values.

Step 11. Pair creating mode activation

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

To activate pair creating mode on the handpiece:

Press and hold the ring switch at turning the power on. After 3 cycles of the beeps with different intensity and 1 beep (wait for 20 sec.), "STATUS" indicator will constantly blink



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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. 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 sterilize. All the rest elements and surfaces of the device must be disinfected for further using without sterilization.

1. Preliminary cleaning and sterilization

<u>Sterilizable elements:</u> working tips, files, wrench for tips and hygienic case



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 ovens, glass bead sterilizers, etc.) of any other components of the product not listed in this paragraph.

Instruction № 1

Manufacturer: JSC Geosoft Dent (Russia) Product: Working tips, Hygienic case, Wrench for tips, Files for tipendochuck

Table 5

ATTENTION	
Restrictions at repeated processing	The minimal guaranteed number of processing cycles is: - 250 - for working tips, hygienic case, wrench for tips; - 10 - for tip-endochuck files
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 °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 the used product disinfection conduct the cleaning of the contaminated surfaces.

Disinfection should be conducted chemically by <u>wiping the product</u> <u>surface</u> with thoroughly wrung napkin, soaked in 70% ethyl alcohol solution.

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

8. 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 timely when it depletes its working resource.

It is forbidden to 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 its long-term storage impairs its technical characteristics. - An additional battery unit is not included into the delivery set and should be purchased separately for an additional fee. (see section 3 "Accessories").

9.TROUBLESHOOTING

Table 6.

Problem	Possible cause	Solution
TT 1 1		• Charge the battery unit (see p. 6– Step 1)
spontaneously.	activates.	<i>See. p.6 - Step 6</i>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 for a new one
The battery unit does not charge	 Bad contact between the battery unit, charging stand, cable, power adapter Charging stand is failed 	

Problem	Possible cause	Solution
The battery unit does not charge	damaged.	Replace the charger cable
	 Power adapter is defective. 	• Replace the power adapter
Problems with sound.	• Volume level is not set correctly.	• Check the settings <i>(see section 6 – Step 7)</i>
Tip installed but not detected (STATUS light is WHITE instead of MINT)	• The tip is set during handpiece power switched on	• Switch the handpiece power off, then switch it on again and check the tip defining correctness
	• The tip is not connected correctly - not screwed on properly	• Switch the handpiece power off, tighten the tip with a wrench (see p. 6 - Step 2), then switch it on again and check the tip defining correctness
	• The using tip is not recommended by the manufacturer	• Use the tip, recommended by the manufacturer (see section 3)
	-	 Replace tip with a new one Calibrate the handpiece by disconnecting the working tip, press the ring button 5 times and wait for the device to turn off
• Uncharacteristic sharp sound (rattle) during scaler operation	• The file in the tip- endochuck is not fixed properly	• Turn off the power of the device, tighten the file fixing nut in the endochuck with a wrench, turn on the power again and activate the scaler

Problem	Possible cause	Solution
During scaler work the STATUS LED blinked ORANGE	thomas up	• See Step 8
STATUS indicator blinking ORANGE in STANDBY mode	• During the last cycle of the scale, the resonant frequency of tip was not found	• Turn the scaler on and off in air by pressing the ring button once. If after that the indicator does not change color to MINT -turn off the device power and check the correct installation of the tip
Indicator STATUS blinking RED	The resonator is broken	Contact service

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

10. STORAGE, TRANSPORTATION AND USE

• The product should be stored in heated and ventilated place at temperatures from $+5^{\circ}$ C to $+40^{\circ}$ C, with a relative humidity of 80% (at $+25^{\circ}$ 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

11. 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 SONIC" belongs to the medical waste hazard category of class A (non-hazardous waste of medical institutions).

12. SYMBOLS DESCRIPTION

Symbol	Description		
\triangle	Warning: Address to supporting documentation		
	Type of protection against electric-shock hazard. Device of the II class		
	Direct current		
Ϋ́	Protection level from electrical shock: Applied part BF type		
)X	Do not throw away the device into system of daily rubbish		
SN	The device serial number		
~~~	Date of the device manufacturing		
	Manufacturer		
(( <u></u> ))	Non-ionizing radiation sign - the product contains a radio frequency transmitter		
REV.	The device revision version		
IP41	IP41 Ingress Protection Rating dust and moisture		
63	Consult the USER'S MANUAL		
EC REP	<b>REP</b> 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 Sonic" 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 Sonic" 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 Sonic" in all establishments, including domesti
Harmonic emissions EN 61000-3-2	Not applicable	establishments and those directly connected to the public low-voltage power supply network that supplies
Voltage fluctuations/ flicker emissions EN 61000-3-3	Not applicable	buildings used for domestic purposes.

# Table 2

The device "Estus Sonic" 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	$\pm 0.5$ ; $\pm 1.0$ ; $\pm 2.0$ kV for scheme "line-to-ground » $\pm 0.5$ ; $\pm 1.0$ kV for scheme "line-to-line»	$\pm 0.5$ ; $\pm 1.0$ ; $\pm 2.0$ kV for scheme "line-to-ground » $\pm 0.5$ ; $\pm 1.0$ 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% UT for 0.5           cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°)           0% UT for 1 cycle           70% UT for 25/30           cycles (at 0°)           Voltage           interruptions:           0% UT 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 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 Sonic" 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 Sonic" 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	Complianc e 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 Sonic", 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 Sonic"

The device "Estus Sonic" 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	Separation distance according to frequency of the transmitter (m)		
output power of transmitter (W)	from 150 kHz to 80 MHz d = 1,2 √P	from 80 MHz to 800 MHz d = 1,2 √P	from 800 MHz to 2,7 GHz d = 2,3 √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

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