

### **USER'S MANUAL**

DENTAL LIGHT CURING DEVICE

### **ESTUS LIGHT**



### 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.

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### ESTUS LIGHT

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#### 1. GENERAL INFORMATION

**1.1. Intended use:** Dental light curing device «Estus Light» is part of the dental complex "Estus", intended for carrying out procedures in the field of dentistry.

This device is designed for photopolymerization of composite lightcured filling materials containing:

- -the traditional photoinitiator camphorquinone, polymerizing in the blue light spectrum in the range of 440-475 nm, and
- next-generation photoinitiators polymerizing additionally in the ultraviolet light spectrum in the range 400-420 nm (for example, "IVOCERIN" by "Ivoclar Vivadent") during restoration work in the patient's oral cavity the <u>main purpose of the product.</u>

The function is implemented using the polymerizing tips specified in the table below:

№	Tip name	Emission spectrum, nm	Photoinitiator
1	ESTUS LED - BLUE (2500 / 1500)	440-475	camphorquinone
2	ESTUS - BLUE POINT	440-475	camphorquinone
3	ESTUS - FULL BLUE	400-420, 440-475	Ivocerin, camphorquinone

The "ESTUS-BLUE POINT" tip allows to conduct the point polymerization of photosensitive materials, for example, when installing veneers. Also the tip is used for adhesive polymerization inside the root canal at the stage of fixing fiberglass pins and for fixing all-ceramic orthopedic structures, which allows to release paroxysmal and cervical areas from the fixing material.

### Additional "Estus Light" options when using special tips:

- 1. Transillumination diagnostics of initial carious changes, hidden carious cavities or defects, enamel cracks, quality control of restoration and adaptation of composite materials to hard tooth tissues using a light source emitting in the spectrum of orange light in the range 585-595 nm. The function is implemented with the diagnostic tip ESTUS LED ORANGE.
- 2. Photodynamic therapy (PDT) diagnosing the development of malignant tumors in the early stages, conducting cancer cell therapy, treating discoloritis when changing color of the elements of the dentition, performing antibacterial and antifungal treatment of the patient's oral cavity using special photosensitive substances (photosensitizers), activated by the source light emitting in the deep red light spectrum in the range 650-670 nm (peak 660 nm) (for example "Photoditazine"). The function is implemented with the therapeutic tip "ESTUS LED RED 660".
- 3. Luminescent diagnostics diagnosing of some diseases of the oral mucosa and tongue, contrasting of the old filling material, as well as detection of bacterial deposits on the surface of the teeth using a light source emitting in the ultraviolet spectrum in the range of 400-420 nm (peak 405 nm). The function is implemented with the diagnostic tip "ESTUS LED LUMI".

#### 1.2. Indication for use:

- restoration of the tooth crown
- diagnosis of caries
- diagnosis of tooth enamel quality
- diagnosis of the quality of tooth restoration

- diagnosing the development of malignant tumors in the early stages, conducting cancer cell therapy,
- treating discoloritis when changing color of the elements of the dentition,
- performing antibacterial and antifungal treatment of the patient's oral cavity
- diagnosing of diseases of the oral mucosa and tongue,
- contrasting of the old filling material,
- detection of bacterial deposits on the surface of the teeth

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 and adverse reactions:** Without finding.
- **1.6. Contact type with a patient:** Short invasive contact through the oral cavity.

### 1.7. Operating principal:

- <u>1. Polymerization:</u> The photoactivator of the polymerization process is a powerful light source acting on the initiator of the polymerization process as part of a composite material. The polymerization process (curing) of the filling material occurs by local exposure with the emitter.
- 2. Photodynamic therapy (PDT): The photosensitizer is input into the oral cavity by the most suitable way, where it selectively accumulates in pathogenic cells without affecting healthy tissue. The affected

tissue is then irradiated with a certain wavelength emitter. As a result of the photochemical reaction, atomic oxygen is released that destroys pathologically changed cells and inflammatory microflora.

- 3. Transillumination: The effect of transillumination is based on differences in the ability to absorb light from different tissues and materials. It is carried out with passing rays of light, by translucence of the tooth crown from the palatine or lingual surface. The method is based on the assessment of shadow formations that appear when a cold light stream of orange color passes through a tooth and is harmless to the body.
- <u>4. Luminescent diagnostics</u> is based on the ability of tissues and their cellular elements to change their natural color under the influence of ultraviolet rays.

#### 1.8. Functional abilities:

- Operation with 7 tips:
  - 4 tips of the BLUE ("ESTUS LED BLUE 2500", "ESTUS LED BLUE 1500", "ESTUS BLUE POINT" , «ESTUS FULL BLUE") type;
  - 1 tip of the RED ("ESTUS LED RED 660") type;
  - 1 tip of the ORANGE ("ESTUS LED ORANGE") type and
  - 1 tip of the LUMI ("ESTUS LED LUMI") type.

Automatic recognition of the connected tip type with the following activation of the corresponding working program.

- 3 modes (High, Middle, Low) for every of 7 tips with fixed values of all working parameters:
- emitter light intensity and exposure time for the tips of BLUE and RED type and
- emittance brightness level for tips of ORANGE and LUMI type
- The chosen working mode indication on the handpiece LED scale;

- Gradual light intensity increase (Soft function) when working in polymerization mode with the tips of BLUE type.
- 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

### 1.9. 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.
- ! 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 cleaned and disinfected parts of the device only. Cleaning and disinfection must be conducted directly before the initial use and also between each patient use to avoid cross infection (see section 7).

- ! In order to avoid thermal injury to the patient when working with high-power polymerization tips "ESTUS LED BLUE 2500" and "ESTUS FULL BLUE", after a cycle of 4 consecutive activations of the emitter in any operating mode, it is not recommended to use the photoactivator for at least 45 seconds.
- ! In order to avoid overheating and failure of working tips of the "BLUE" type, after continuous use of the emitter for  $\sim 1$  minute in polymerization modes, it is necessary to allow the product to cool for at least 2 2.5 minutes.
- ! The light emission generated by the photoactivator when working with tips such as BLUE and RED is dangerous for your vision. In order to avoid direct and reflected emission from the light source entering the eyes of the dentist, patient, and auxiliary personnel during operation, the following should be done:
- to use special protective glasses with orange lenses for working with the tips of BLUE type or the sunglasses for working with tips of RED type.
- to switch on the photoactivator only in the patient oral cavity.
- ! If it is impossible to exclude the effect of reflected blue light on the patient's soft tissues, do not use the photoactivator with high-power polymerization tips, as such exposure may damage the soft tissues.
- ! The light emission generated by the photoactivator when working with the tip of LUMI type is completely non-hazardous for your vision at brief influence. Nevertheless, the following safety measures should be adhered during operation:
- do not direct the light into the eyes of the dentist or patient,
- turn on the photoactivator only in the patient's oral cavity.

- ! 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 Manual. It includes the requirement not to use the device close to daylight lamps, radio transmitting equipment and remote controls.
- ! The device operates normally at a temperature of  $10-35^{\circ}$ C, relative humidity of air not more than 80%, atmospheric pressure ( $101\pm3$ ) kPa. Any violation of these restrictions may cause the device error.
- ! 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 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 ( $101\pm3$ ) kPa. Any violation of these restrictions may cause the device error.

#### 2. DELIVERY SET

Delivery set variants are in the tables 1,2.

Table 1. Delivery sets with an 8V battery unit with charging from a charging stand "Estus Energy-S".

The device element	Quantity, pcs in the delivery set variant						
	BL	FB	BP	OR	RED 660	LU	FB/BP/OR/ RED660/LU
Control unit "Estus Light"	1	1	1	1	1	1	1
Battery unit (8V)	1	1	1	1	1	1	1
Tip "ESTUS LED-BLUE 2500"	1	0	0	0	0	0	0
Tip "ESTUS - FULL BLUE"	0	1	0	0	0	0	1
Tip "ESTUS-BLUE POINT"	0	0	1	0	0	0	1
Tip "ESTUS LED-ORANGE"	0	0	0	1	0	0	1
Tip "ESTUS LED-RED 660"	0	0	0	0	1	0	1
Tip "ESTUS LED-LUMI"	0	0	0	0	0	1	1
Stand "Estus One-B"	1*	1*	1*	1*	1*	1*	1
Charging stand "Estus Energy-S"	1*	1*	1*	1*	1*	1*	1
Charger cable USB - USBB	1*	1*	1*	1*	1*	1*	1
Power adapter (USB-socket) 1A	1*	1*	1*	1*	1*	1*	1
User's manual «Estus Light»	1	1	1	1	1	1	1
Warranty Card «Estus Light»	1	1	1	1	1	1	1
Warranty Card «Estus Energy-S/D»	1*	1*	1*	1*	1*	1*	1

<sup>\*</sup> These components are supplied in the "Plus" package only.

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Table 2. Delivery sets with 4V / Type-C battery unit with mains charging

The device element	Quantity, pcs in the delivery set variant			ınt	
	BL	BP	OR	RED 660	LU
Control unit "Estus Light"	1	1	1	1	1
Battery unit (4B / Type-C)	1	1	1	1	1
Tip "ESTUS LED-BLUE 1500"	1	0	0	0	0
Tip "ESTUS-BLUE POINT"	0	1	0	0	0
Tip "ESTUS LED-ORANGE"	0	0	1	0	0
Tip "ESTUS LED-RED 660"	0	0	0	1	0
Tip "ESTUS LED-LUMI"	0	0	0	0	1
Charger cable USB-Type-C	1	1	1	1	1
Power adapter (USB-socket) 1A	1	1	1	1	1
User's manual «Estus Light»	1	1	1	1	1
Warranty Card «Estus Light»	1	1	1	1	1

### 3. ACCESSORIES

### Tip "ESTUS- FULL BLUE"\* GE99.221.000

Polymerizing tip. UV light (400-420 нм) +Blue light (440-475nm) Lens diameter - 9,5 mm



### Tip "ESTUS LED-BLUE 2500"\* GE99.223.000

Polymerizing tip.
Max. light intensity 2500 mW/cm<sup>2</sup>.
Blue light (440-475 nm).
Lens diameter - 9,5 mm



### Tip "ESTUS LED-BLUE 1500" GE99.249.000

Polymerizing tip. Max. light intensity 1500 mW/cm<sup>2</sup>. Blue light (440-475 nm). Lens diameter - 9,5 mm



### Tip "ESTUS-BLUE POINT" GE99.220.000

Polymerizing "point" tip. Blue light (440-475 nm).



<sup>\*</sup> These tips are work when used with an 8V battery unit only.



Tip "ESTUS LED-RED 660" GE99.196.000

Therapeutic tip.

Dark-red light (peak 660 nm).

Lens diameter - 9.5 mm



### Tip "ESTUS LED-ORANGE" GE99.152.000

Diagnostic tip.

Orange light (585-595 nm).

Lens diameter - 9,5 mm



### Tip "ESTUS LED-LUMI" GE99.219.000

Diagnostic tip.

UV emission (peak 405 nm).

Lens diameter - 9,5 mm



### Seal ring for the handpiece (3 pcs) GE99.183.000

Additional silicon sealing ring for all types of the tips.



#### 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 Light" handpiece (2x3.7V, 800mAh).



### Stand "Estus One-B" GE99.208.000

Single-stand for the "Estus Light" handpiece.

### 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 (8V) of the "Estus Light" handpiece.



### Charging stand "Estus Energy-D" GE39.000.000

Two-ports charging stand for two battery units (8V) of the "Estus Light" 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 Light" 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 Light" handpiece.



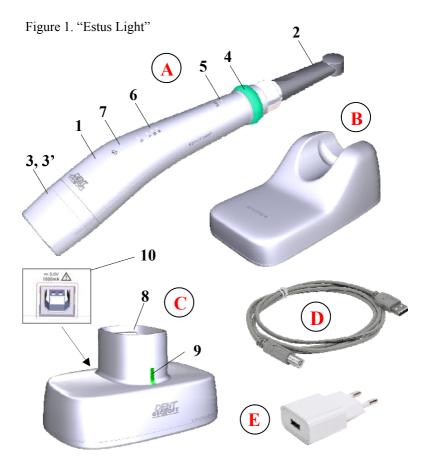
## Gel-penetrator of light radiation "Photoditazin®" GE99.002.00P

(sterile disposable syringe) 0.5%, Volume - 1.0 ml for photodynamic therapy

! Accessories are delivered separately, additionally paid

### 4. "ESTUS LIGHT" APPEARANCE

"Estus Light" appearance is on the figure 1





### A. Handpiece "Estus Light":

- 1. Control unit.
- 2. Tip (of BLUE, RED, ORANGE or LUMI type).
- 3. Removable battery unit 8V.
- 3' Removable battery unit 4B/Type-C:
  - 3'a Battery charge indicator;
  - 3'b Socket Type-C for the charger cable;
- 4. Control ring switch (see table 4).
- 5. STATUS indicator (see table 3).
- 6. LED scale of the 4 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)

Table 3. STATUS indicator variants

STATUS	indication color	Meaning
STATUS	WHITE	No tip connection
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	BLUE	Tip of the BLUE type is connected.
STATUS	RED	«ESTUS LED - RED660» tip is connected.
STATUS	ORANGE	"ESTUS LED - ORANGE" tip is connected
STATUS	LILAC	"ESTUS LED - LUMI" tip is connected
STATUS	ORANGE blinking	Warning that the lens of the tips "ESTUS LED - BLUE 2500" or "ESTUS - FULL BLUE" is overheated (see more page 34)
STATUS	RED blinking	Warning about the tip overheating protection - blocking the operation of the emitter (see more page 34)

Table 4. Variants of using the ring switch

	Power	Press ring switch	Result
	OFF.	1 time	Power on
	Holding up to		Volume adjustment
a a		Holding > 20 sec.	Pair creating mode activation
-(1	1 time		Emitter On / Off
	ON	2 times	Working mode choosing
		2 times with holding	
	3 times		Power off
		3 times with holding	Return to the factory settings

### 5. TECHNICAL SPECIFICATIONS

### 5.1. "Estus Light" 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 B 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.
- Performance duration with the new fully charged battery unit (8V) without boost charge is not less than 250 emitting cycles in «H» mode

- Stand-by operating time to automatic switch off is  $10 \pm 0.5$  min.
- Max. full charge time of a new 8V/4V battery unit 3/1.5 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 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  $(215*33*43) \pm 3 \text{ mm}$
- Tip (lens) working diameter 9,5 mm
- Weight  $95 \pm 10 \text{ g}$
- Service time of the device 5 years.

#### Table 5

Parameters	Parameters factory settings	Values when Estus-Multi* using
with the tip of BLUE type:		
Light source: - ESTUS - FULL BLUE - ESTUS LED - BLUE 2500 - ESTUS LED - BLUE 1500 - ESTUS - BLUE POINT	LED UV + 2 I 3 LED BLUE 2 LED BLUE LED BLUE	LED BLUE
Emission spectrum, nm - ESTUS - FULL BLUE - ESTUS LED - BLUE 2500 - ESTUS LED - BLUE 1500 - ESTUS - BLUE POINT	400-420, 440- 440-475 440-475 440-475	475

Table 5 continued

Parameters	Parameters factory settings	Values when Estus-Multi* using			
Light intensity in modes with accuracy ±20%, mW/cm <sup>2</sup> - ESTUS - FULL BLUE - ESTUS LED - BLUE 2500 - ESTUS - BLUE POINT	H=2500, M=1500, L=1000	H=2500, M=1500, L=1000, ★ = from 500 to 2500, step 500			
Exposure time in modes, ±1 sec ESTUS - FULL BLUE - ESTUS LED - BLUE 2500 - ESTUS - BLUE POINT	H=5, M=10, L=20	H=5, M=10, L=20, ★= from 5 to 20, step 5			
Light intensity in modes with accuracy ±20%, mW/cm <sup>2</sup> - ESTUS LED - BLUE 1500	H=1500, M=1000, L=500	H=1500, M=1000, L=500, ☆ = from 300 to 1500, step 100			
Exposure time in modes, ±1 sec ESTUS LED - BLUE 1500	H=10, M=20, L=30	H=10, M=20, L=30, <b>☆</b> = from 5 to 45, step 5			
Norm, Soft, Pulse functions in modes.	H/M/L= only Soft	H/M/L= only Soft  ★= Norm, Soft, Pulse			
with "ESTUS LED- RED660" tip:					
Light source	2 LED DEEP RED				
Emission spectrum, nm	650-670 (peak 660)				

### Table 5 continued

Parameters	Parameters factory settings	Values when Estus-Multi* using	
Light intensity in modes with accuracy ±20%, mW/cm <sup>2</sup>	H=1000, M=800, L=600	H=1000, M=800, L=600, ♣ = from 300 to 1500, step 100	
Exposure time in modes, ±1 sec.	H=30, M=60, L=90	H=30, M=60, L=90, ♠= from 30 to 90, step 10	
with "ESTUS LED- ORANGE" tip:			
Light source	LED AMBER		
Emission spectrum, nm	585-595		
Light brightness in modes, # of level	H=9, M=5, L=1	H=9, M=5, L=1, <b>☆</b> = from 1 to 9, step 1	
with "ESTUS LED-LUMI'	' tip:		
Light source:	LED UV		
Emission spectrum, nm	400-420 (peak 405)		
Light brightness in modes, # of level	H=9, M=5, L=1	H=9, M=5, L=1 <b>☆</b> = from 1 to 9, step 1	

<sup>\*</sup> not included into the delivery set, could be purchased separately, additionally paid.

### 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  $(87*56*49) \pm 3 \text{ mm}$
- Weight 130±10 g
- Service time of the device 5 years.

### 5.3. Power adapter (USB-socket) 1A

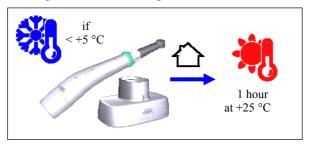
- Input voltage (100-240) V, ~50/60 Hz.
- Output voltage 5 V; 1A.

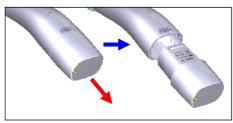
#### 5.4. Stand "Estus One-B":

- Dimensions-  $(100*60*40) \pm 3 \text{ mm}$
- Weight  $132 \pm 10 \text{ g}$

# 6. PREPARATORY STAGE AND WORKING PROCEDURE

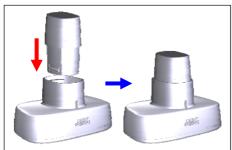
After transporting the device at the temperature less than + 5°C, before use, keep it at the indoor temperature for 1 hour





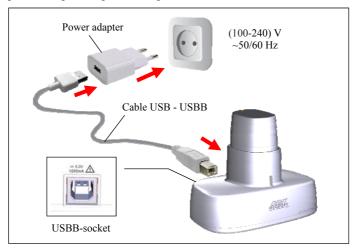
Step 1. Battery unit charging

Disconnect the battery unit from the handpiece

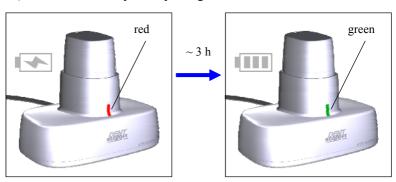


# 1.1. Battery unit 8V charging

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.



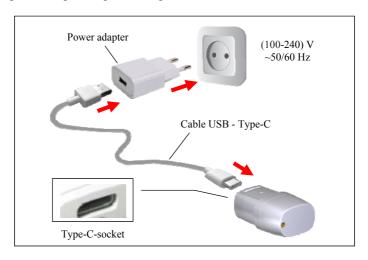
D) Take the charged battery unit out of the charging stand and connect

the battery unit into the handpiece.

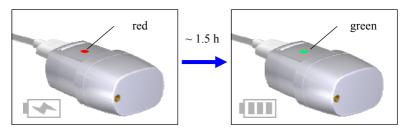
In the absence of the battery unit in the socket of the charging stand, the voltage is automatically disconnected from the terminals of the charging stand, ensuring complete electrical safety of the product. In spite of it, do not allow any liquids to get into the socket of the charging stand. In a case 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:



A

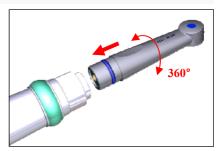
Charge the handpiece battery unit in a timely manner. Do not let the battery unit discharge completely.

### Step 2. Working tip installation



Be sure to clean and disinfect the working tip before first use and between each patient use (see section 7). Use disposable sterile protective covers to avoid cross infection.

With a slight pressure and rotation, insert the working tip into the control unit <u>until</u> it stops. If you need to change the angle of rotation of the tip, turn it in the desired direction.

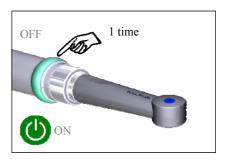


If considerable efforts are required to install the tip in the control unit, then the seal ring on the tip lost its elasticity. In this case, replace the seal ring (see section 8-1)

#### Step 3. Power on

To switch the power on press the ring switch. The tip type is defined automatically.

Depending on the tip type the STATUS indicator lights up with the according color

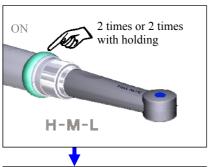


Activation of the according program confirms the defined tip.

No tip	BLUE	RED	ORANGE	LUMI
STATUS	STATUS	STATUS	STATUS	STATUS
white	blue	red	orange	lilac

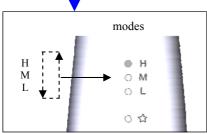
If the STATUS indicator flashes white three times when the device is powered on, it means that the settings are different from the factory settings (that is, they were changed by the user using "Estus Multi"). To return to the factory settings, see Step 9

Step 4. Operating mode choosing



The device has 3 operating modes H, M, L for each of the seven tips.

Press the ring switch 2 times to choose the required mode.



The modes change one another cyclically.

Next to the chosen mode the white indicator lights up.

Table 6. Factory settings

Operat-	Working tip type				
ing mode	BLUE (except 1500)	BLUE 1500	RED	ORANGE, LUMI	
H	2500 mW/cm <sup>2</sup>	1500 mW/cm <sup>2</sup>	1000 mW/cm <sup>2</sup>	9 level (max)	
High	5 sec	10 sec	30 sec	3 minutes	
M	1500 mW/cm <sup>2</sup>	1000 mW/cm <sup>2</sup>	800 mW/cm <sup>2</sup>	5 level	
Middle	10 sec	20 sec	60 sec	3 minutes	
L	1000 mW/cm <sup>2</sup>	500 mW/cm <sup>2</sup>	600 mW/cm <sup>2</sup>	1 level (min)	
Low	20 sec	30 sec	90 sec	3 minutes	

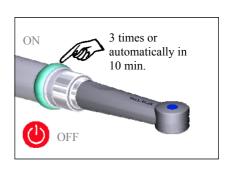
Changes of the working parameters in H, M, L modes are IMPOSSIBLE. Nevertheless when using "Estus Multi"\* control unit the additional working mode \( \frac{1}{2} \) ("Favorite") is activated which allows to change all working parameters of the photoactivator in a wide range of values.

The working parameters changing range is presented in section 5 "Technical specifications".

#### Step 5. Power off

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

All the indicators on the handpiece go out.

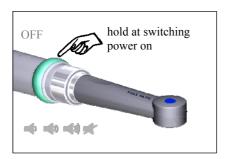


<sup>\*</sup> not included into the delivery set, could be purchased separately, additionally paid.

### Step 6. Audio volume adjustment

The handpiece acoustic emitter has 4 volume levels: low, normal, high and off

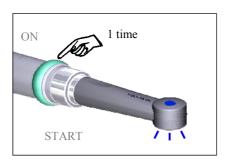
To select the required volume level hold the ring switch when switching the power on.



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

To choose the required volume level stop pressing the ring switch

Step 7. Turning the light source on



Press the ring switch to turn the light source on.

During the operation with the tips of BLUE and RED type the device signals every 5 sec.



- When working with tips of the "BLUE" or "RED" type, be sure

to use special orange or dark (sunglasses) glasses, respectively. In no case do not direct the light directly into the eyes of the doctor, patient and attendants, activate the photoactivator only directly in the patient's mouth.

- To avoid thermal injury to the patient, do not activate the light source with high-power polymerization tips "ESTUS LED BLUE 2500" and "ESTUS FULL BLUE" more than 4 times in a row.
- If it is impossible to exclude the effect of reflected blue light on the soft tissue of the patient, do not use the photoactivator with high-power polymerization tips, as such exposure may damage the soft tissue.
- When operating with the tip of BLUE type try to avoid any contacts of polymerizing material with the tip working surface (lens) during the first 5 seconds of the polymerization as it could cause material sticking on the lens, which leads to the light output decrease.

### Step 8. Turning the light source off

The turning off is automatic in a set period of time (see Step 4 of the table 6)

For the forced turning the light source off press the ring switch again.



- 1. If the STATUS indicator starts blinking ORANGE after turning off the light source, then the lens of the working tip has overheated. In this case, in order to avoid thermal injury to the patient, it is highly recommended to allow the tip to cool for at least 45 seconds (until the indicator stops blinking), after which you can continue to work.
- 2. If, after turning off the light source, the STATUS indicator starts blinking **RED**, it means that the radiator of the tip is overheated and the overheating protection of the product has been triggered. In this case, the operation of the light source is blocked by software. To continue the operation of the photoactivator, it is necessary to let the tip cool down for about 2 2.5 minutes (until the indicator stops blinking).

### Step 9. 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:



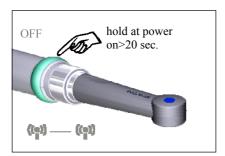
When the device is powered on, press the ring switch 3 times and hold it about 5 seconds after the device power is turned off. Release the button when the audio signal has sounded.

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

### Step 10. Pair creation mode activation

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

To activate pair creation 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 blin 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. CLEANING AND DISINFECTION

Use only cleaned and disinfected device components in accordance with the sanitary hygiene standards.

Disinfection must be conducted directly before the initial use of the device and between each patient use to avoid cross infection. Clean the contaminated surfaces prior to the used product disinfection.

Cleaning and disinfection of the product should be conducted chemically by wiping the surface of the product with a carefully wrung napkin soaked in a 70% solution of ethyl spirit.

To avoid entering the disinfectant into the product housing, it is strictly forbidden to carry out disinfection by immersing the product in any solution.

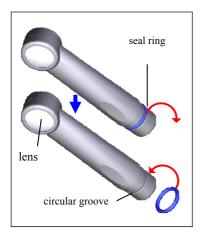
It is strictly forbidden to carry out any heat treatment of the product, including the working tip, in an autoclave, dry heat sterilizer, glass bead sterilizers, etc.

To avoid cross infection at the contact of the working tip with the patient mucosa it is recommended to use disposable sterile protective covers (are purchased separately).

#### 8. MAINTENANCE

#### 1. Working tip maintenance

- To avoid a decrease of the light output during the operation of the emitter, do not allow dirt and mechanical damage (scratches and chips) of the tips' lens. Wipe the lens with a gauze swab soaked in spirit.
- Replace the tip timely in case of serious mechanical damage or cloudiness of the lens surface



- In case of damage or significant loss of elasticity of the silicone seal ring, it must be replaced:
- A) Take the silicone ring from the circular groove on the tip housing and remove it.
- B) Take the new ring and place it in the circular groove.

A replaceable seal ring is not included in the delivery set and could be purchased separately, additionally paid (see section 3 "Accessories").

#### 2. Battery unit 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").

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### 9.TROUBLESHOOTING

Table 7.		
Problem	Possible cause	Solution
Handpiece does not switch on.	<ul> <li>The battery unit is discharged.</li> </ul>	• Charge the battery unit (see section 6, Step 1).
The handpiece switches off spontaneously.	• Energy saving function activates.	• See section 6, Step 5
	<ul> <li>The battery unit is discharged.</li> </ul>	• 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.
The battery unit does not charge	<ul> <li>Bad contact between the battery unit, charging station, cable, power adapter</li> </ul>	Check connections
	• Charging stand is failed	<ul> <li>Replace the charging stand or apply to the maintenance service</li> </ul>
	<ul> <li>Charger cable is damaged.</li> </ul>	<ul> <li>Replace the charger cable.</li> </ul>
	defective.	<ul> <li>Replace the power adapter</li> </ul>
	• Type-C socket on 4V battery unit is defective	Replace the battery unit
Sound problems	<ul> <li>Audio volume settings are incorrect</li> </ul>	• Check the settings (see section 6, Step 6)
The tip is fixed poorly or is put into the control unit barely	• Silicon seal ring of the working tip is damaged or lost its elasticity	• Replace the seal ring (see section 8– p.1)

Problem	Possible cause	Solution
Light intensity of the emitter is significantly	<ul> <li>The working lens is contaminated.</li> </ul>	• Wipe the lens with spirit solution
lower than the programmed value	<ul> <li>Mechanical damages of the working lens.</li> </ul>	• Replace the working tip
STATUS indicator flashes orange	Working tip lens overheating warning	• Let the tip cool down for 45 minutes
STATUS indicator flashes red	• The protection against overheating of the working tip has tripped	• Let the tip cool down for 2-2.5 minutes.

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  $\pm$  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 LIGHT" belongs to the medical waste hazard category of class A (non-hazardous waste of medical institutions).

# 12. SYMBOLS DESCRIPTION

Symbol	Description	
<u> </u>	Warning: Address to supporting documentation	
	Type of protection against electric-shock hazard. Device of the II class	
===	Direct current	
<b>†</b>	Protection level from electrical shock: Applied part B 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	Ingress Protection Rating dust and moisture	
<b>③</b>	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)	

#### ESTUS LIGHT

For notes	
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For notes

#### **APPENDIX**

#### 1. Electromagnetic Emissions and Immunity

#### Table 1

The device "Estus Light" 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 Light" 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 Light" in all establishments, including domest	
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 Light" 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 <sub>T</sub> for 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°)  0% U <sub>T</sub> for 1 cycle 70% U <sub>T</sub> for 25/30 cycles (at 0°)  Voltage interruptions:  0% U <sub>T</sub> for 250/300 cycle	Voltage dips:  0% U <sub>T</sub> for 0.5 cycle (at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°)  0% U <sub>T</sub> for 1 cycle  70% U <sub>T</sub> for 25/30 cycles (at 0°)  Voltage interruptions:  0% U <sub>T</sub> for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device "Estus Light" 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 <sub>T</sub> - level mains voltage prior to filing of the test exposure			

Table 3

The device "Estus Light" 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 Light", 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: ((w))

#### Table 4

Recommended working clearances between portable and mobile RF communication devices and the device "Estus Light"

The device "Estus Light" 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 $\sqrt{P}$	from 80 MHz to 800 MHz d = 1,2 $\sqrt{P}$	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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