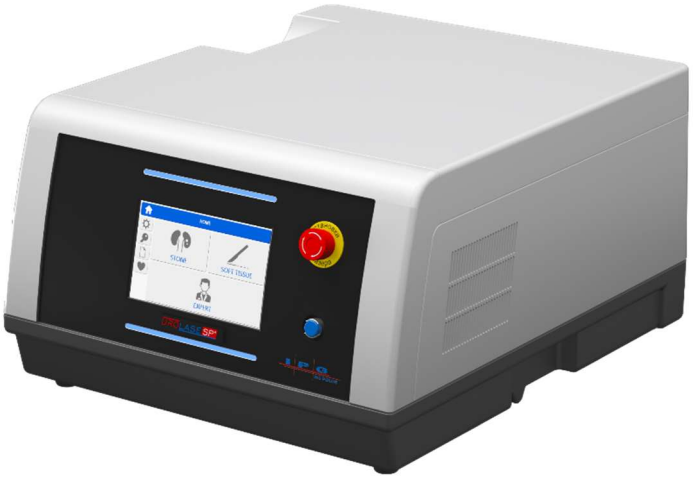
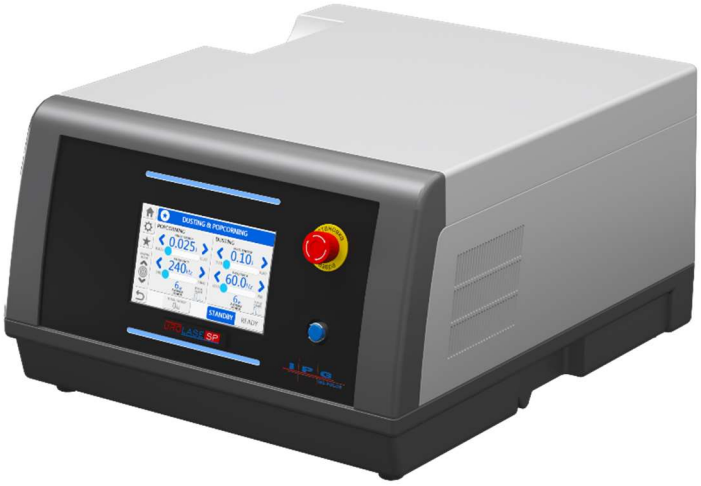
UROLASE SP+





UROLASE SP

USER MANUAL

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►PREFACE

This Operation Manual (hereinafter referred to as the Manual) provides technical information on the use and maintenance of the “Urolase SP+” and “Urolase SP” (hereinafter referred to as the Device), as well as information on safe operation of the Device. Do not start working without reading the Manual. Failure to comply with the requirements contained herein may result in accidents and may cause termination of the manufacturer's warranty. This Manual should be stored in an easily accessible place.

Maintenance information

For safe and stable operation of the Device, complete maintenance program works should be performed. This Manual contains maintenance procedures and schedules, which should be followed to ensure proper operation of the Device.

Safety requirements

This Manual describes safety measures, which should be taken when operating and maintaining the laser device.

CONTENTS

DEVICE PURPOSE

The principle of operation of the Device is based on the use of thermal effects of continuous, pulsed, and repetitively pulsed laser radiation for cutting, ablation, vaporization and coagulation of biological tissues during open and endoscopic surgical interventions.

The Device is intended for use in various areas of open and endoscopic surgery for dissection, resection, excision, ablation, vaporization, coagulation, and hemostasis, including the following procedures: ThuFLEP (Thulium Fiber Laser Enucleation of Prostate) — a laser enucleation of benign prostatic hyperplasia (adenoma) of prostate; resection of the bladder wall with a tumor; coagulation of non-muscular invasive bladder cancer; urethral stricture resection; dissection of the bladder neck; ablation and coagulation of a bladder tumor, a tumor of the urethra, and upper-urinal tract tumors; treatment of condylomas; lesions of the external genital organs; lithotripsy — the disintegration of various types of urinary tract stones: percutaneous lithotripsy; endoscopic fragmentation of stones in various localization.

CONTRAINDICATIONS

All clinical procedures performed using the Device are subject to the same clinical evaluation and should be performed with the same attention as procedures performed using traditional methods. Before clinical use of the Device, all possible risks for the patient should be considered and evaluated.

SYMBOLS AND DESIGNATIONS

The Manual as well as the Device uses the symbols shown in Table 1:

Table 1

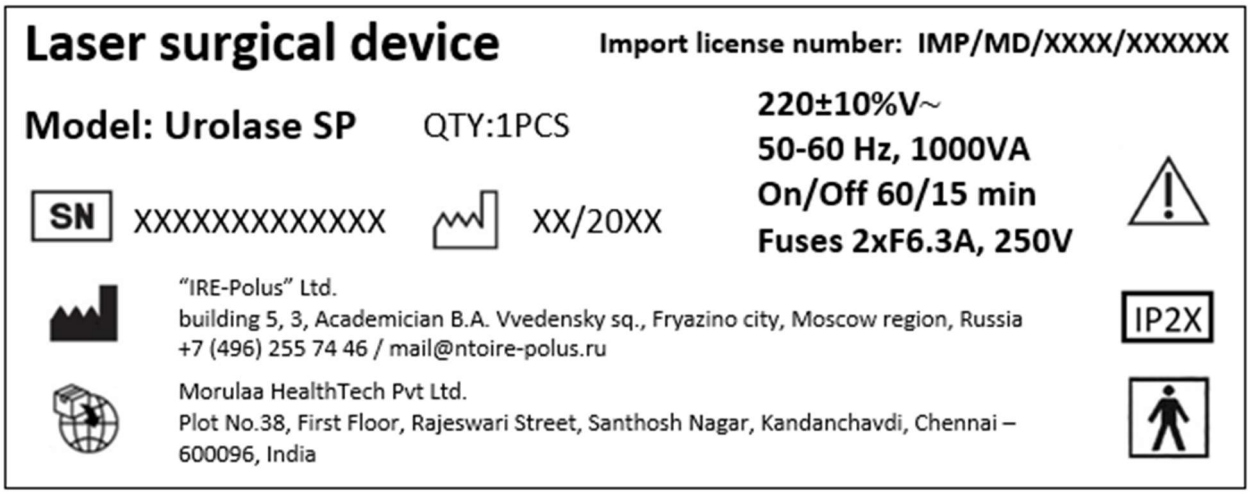
Symbol	*Value*
	*On/ Off*
	*Visible and invisible laser radiation*
	*Medical device of BF type, class 1 IEC (International Electrotechnical Commission)*
	*Foot switch*
	*Remote blocking*
	*Mark of conformity at conformity declaring*
	*Batch number*
	*Catalog number*
	*Serial number*
	*Stacking is prohibited**
	*Be careful, see accompanying documents*

** Symbol on transport container*

EXPLANATORY AND WARNING SIGNS

The following signs are used on Device and container:

Identification plate - contains information about manufacturer and the Device (Figure 1A – Layout of the Device's nameplate).



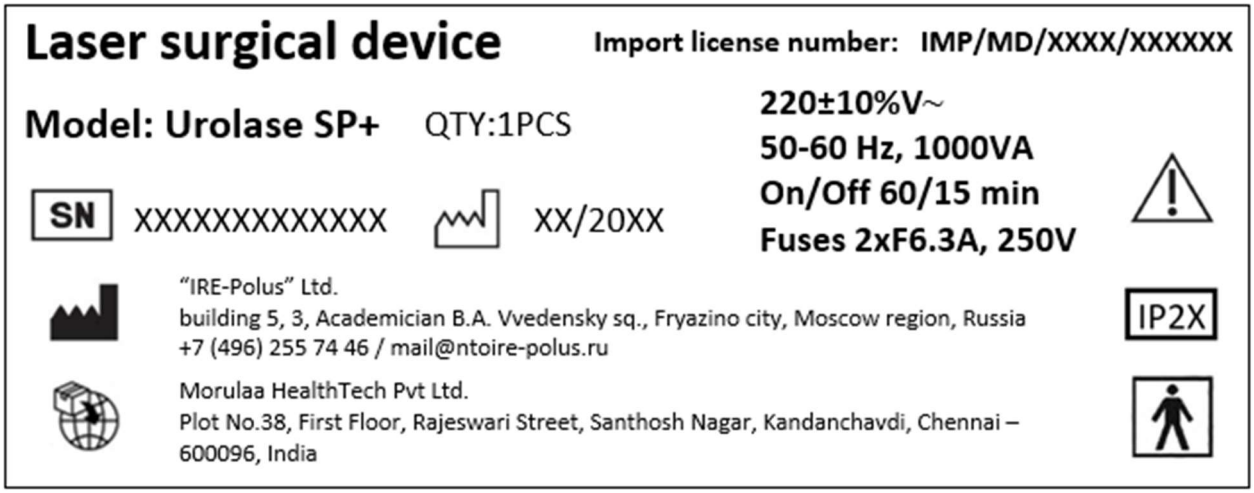


Figure 1a. Labels for Urolase SP and Urolase SP+

The nameplate contains the following information: product name; product number, year of manufacturing (or the last two digits), rated supply voltage, alternating current supply frequency, power consumption in rated operating condition, duty cycle as per IEC 60601-1, number and type of fusible elements (fuses) as per IEC 60601-1.

Laser hazard signs - contain information and warnings about laser radiation (Figure 1b). The plate contains the following information: wavelengths of radiation used in the Device, corresponding maximum values of radiation power and hazard class of the Device, and a sign indicating that the Device's radiation is output via a flexible optical fiber.

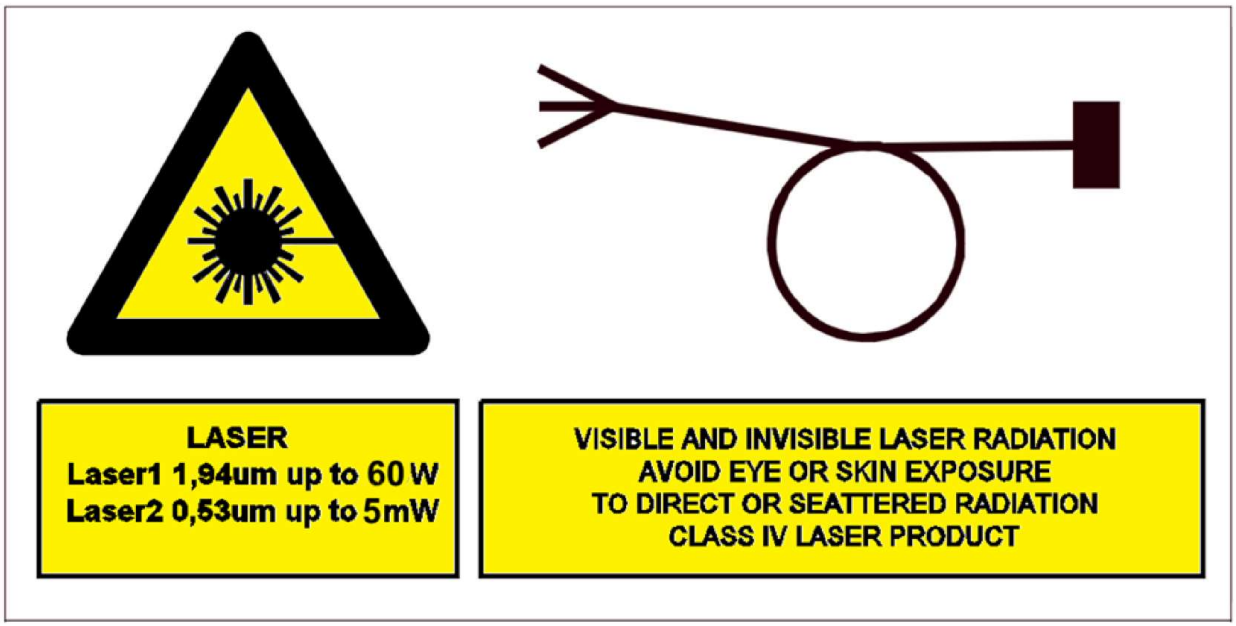


Figure 1b. Laser hazard signs for Urolase SP+

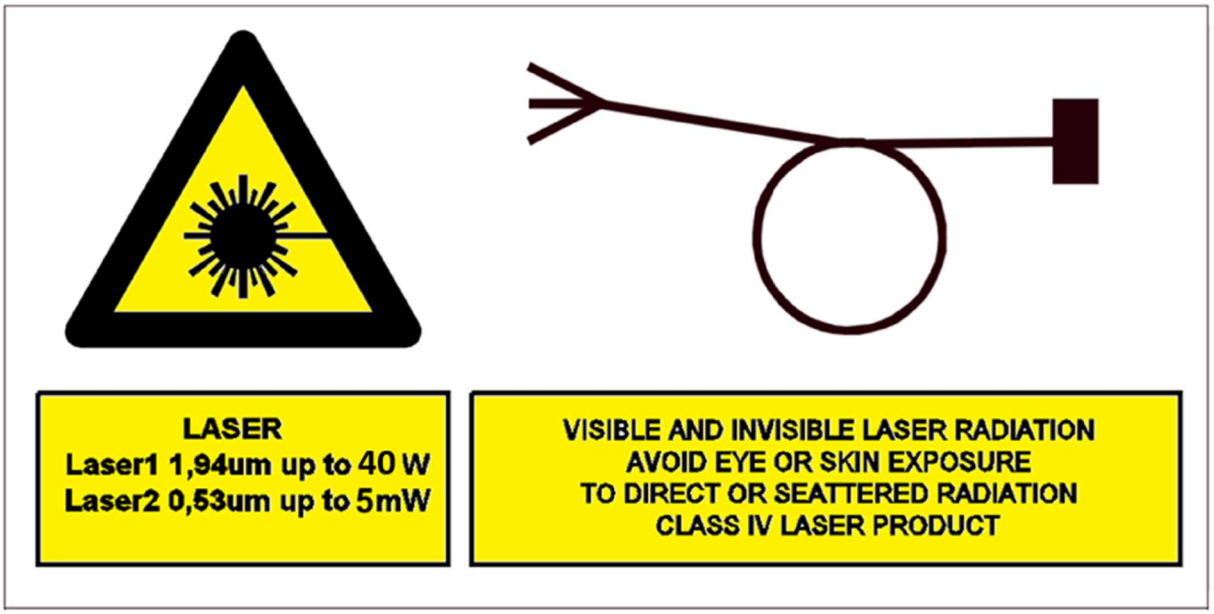


Figure 1c. Laser hazard signs for Urolase SP

BASIC SAFETY RULES

This Manual uses the following warning symbols and instructions:

DANGER	Indicates an unavoidably dangerous situation which, if not prevented, will result in serious injury or death.
CAUTION	Indicates a potentially dangerous situation which, if not prevented, will result in serious injury or death.

WARNING	Indicates a potentially dangerous situation which, if not prevented, will result in minor or moderate injury, and possible equipment damage.

NOTE	Contains additional useful information.

When working with the Device, take into account warnings about danger and follow precautionary measures. The following information is supplemented by warnings and safety rules which are described in each chapter.

DANGER

- The Device is a laser device which belongs to IV laser hazard class, and also includes 3R class laser pointer. Improper use may cause serious injury to the eyes, skin, and soft tissues of the patient and / or operator;
- Using the Device without eye protection is prohibited;
- Do not look directly at the end of the fiber when the Device is turned on and the fiber is connected. The Device emits visible and invisible laser radiation which is dangerous for the eyes and skin;
- During surgery operation, when the Device emits, do not direct fiber to the eyes of people, on the skin or any tissue other than the one which is to be affected by the Device radiation;
- Never leave the Device switched on or ready to turn on emission. Before leaving the operating room (office) where the Device is located, turn it off or press emergency stop button;
- Do not use the Device if the fiber is damaged or failed;
- The Device shall not be used in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide, or in the presence of volatile solvents such as alcohol or gasoline. Incombustible materials and tools are recommended to be used in the proximity of the Device. It is recommended to use fire-resistant surgical linen, overalls, etc;
- Do not allow liquids to get on the Device. If any liquid gets on or inside the Device, stop working immediately, disconnect the Device from the power supply, and contact the manufacturer for a complete cleaning and check of safety. Failure to do so may result in electric shock to the patient or doctor.

CAUTION

- The Device does not contain user-serviceable parts other than fuses and protective window. Do not disassemble, alter, or attempt to repair the Device except for replacing fuses and protective window. This can cause injury to patient or doctor, and damage to the Device;
- To avoid cross-infection of patients, sterilization of the fiber instrument is mandatory. During any surgical operations, be sure to keep the fiber instrument in a sterile field;
- Device meets requirements to patient and staff protection against electric shock according IEC 60601-2-22-2011, class 1, degree of protection against electric shock of BF type;
- Depending on potential risk of using medical devices, the Device belongs to class 2B;
- To avoid risk of electric shock, the product should only be connected to the mains with protective earth connection.

WARNING

- Only doctors who have been trained to work with laser surgical devices in medical institutions, are allowed to work with the Device. The Device should be serviced by trained personnel in accordance with the safety instructions and Operation Manual;
- Do not bend (twist) the fiber to a radius of less than 9 cm. Sharp bend may damage the fiber.
- Do not disconnect the fiber from the Device when the Device emits;
- Do not use the Device near heat sources. Make sure that the air vents at the back, side, and bottom of the Device are not blocked

WARNING

- Values of the Nominal Ocular Hazardous Distance (NOHD) when working with the open end of a fiber are shown in Table 2;

Table 2

NOHD, m
0.5

When operating medical electrical equipment, electromagnetic compatibility (EMC) precautions should be taken, and the following EMC requirements should be met when installing the equipment:

- Mobile and portable high-frequency communication equipment can have an impact on medical electrical equipment.
- Use of non-OEM accessories, fuses and cables may increase radiation power or reduce noise immunity of the equipment or the Device;

The Device is intended for use in the environment specified in Tables 3 (electromagnetic emission) and 4 (noise immunity).

Table 3 Manufacturer's Manual and Declaration - electromagnetic emission.

Electromagnetic emission test	Compliance	Electromagnetic environment - guidance
Radio interference as per CISPR 11	Group 1	The Device uses RF energy only to perform internal functions. RF emissions are low and probably will not disrupt nearby electronic equipment.
Radio interference as per CISPR 11	Class A	The Device is suitable for use in any location, except for residential buildings and buildings directly connected to the distribution mains that feeds residential buildings.
Harmonic emissions as per IEC 61000-3-2	Class A Complies	

Table 4 Manufacturer's Manual and Declaration - interference immunity.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance.
Electrostatic discharge (ESD) as per IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wooden, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Nanosecond disturb pulses as per IEC 61000-4-4	± 2 kV for power lines ± 1 kV for I/O lines	± 2 kV for power lines ± 1 kV for I/O lines	Mains power quality should be that of a typical commercial or hospital environment.
Microsecond high energy disturb pulses as per IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations in power supply input lines as per IEC 61000-4-11	< 5 % U_N (> 95 % drop in U_N) for 0.5 cycle 40 % U_N (60 % drop in U_N) for 5 cycles 70% U_N (30 % drop in U_N)	< 5 % U_N (> 95 % drop in U_N) for 0.5 cycle 40 % U_N (60 % drop in U_N) for 5 cycles 70% U_N (30 % drop in U_N)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Device requires continued operation during supply

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance.
	for 25 cycles < 5 % U_N (>95 % drop in U_N) for 5 sec	for 25 cycles < 5 % U_N (>95 % drop in U_N) for 5 sec	power interruptions, it is recommended that the Device be powered from an uninterruptible power supply or a battery
Mains frequency (50/60 Hz) magnetic field as per IEC 61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_N is the AC voltage prior to application of the test level.			

Table 5 Protection against electromagnetic field

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF as per IEC 61000-4-6 Radiated RF as per IEC 61000-4-3	3 Vrms 3 V/m in a band of 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ (80 to 800 MHz) $d = 2.3\sqrt{P}$ (800 MHz to 2.5 GHz) Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			in each frequency range.[b)] Interference may occur in the vicinity of equipment marked with the following symbol: 

[a)] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with sufficient accuracy. To assess the electromagnetic environment due to fixed RF transmitters, practical field strength measurements should be carried out. If the measured field strength in the location in which the Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Device.

[b)] Field strength should be less than 1 V/m when beyond the frequency range of 150 kHz to 80 MHz.

Notes

1) At frequencies of 80 MHz and 800 MHz, a higher field strength value is used.

2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 6 Recommended distances between portable and mobile RF communication equipment and the Device

Rated maximum output power of transmitter, W	Separation distance as per frequency of transmitter, m		
	$d = 1.2\sqrt{P}$ in the range from 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$ in the range from 80 MHz to 800 MHz	$d = 2.3\sqrt{P}$ in the range from 800 MHz to 2.5 MHz
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

Notes

1) At frequencies of 80 MHz and 800 MHz, a higher field strength value is used.

2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

TECHNICAL SPECIFICATIONS

Technical specifications of the Device are given in Table 7.

Table 7

Parameter	**Urolase SP**	**Urolase SP+**
Operational wavelength, µm	1.94±0.02	
Mode	Superpulsed /Continuous (CW)	
Output power adjustment range, W	2 - 40	2 - 60
Pulse Energy, J	0.025 … 6.0	0.025 … 6.0
Guidance laser wavelength, µm	0.53±0.05	
Maximum radiation power of the guidance laser, mW max	5	
Optical connector type	SMA	
Sound power level, dBA	55	
Supply voltage, V	220±10%	
Supply frequency, Hz	50…60	
Input power, VA max	1000	
Overall dimensions of the main unit, mm max	570 x 460 x 286	
Weight, kg, max	40	
Device body	IP2X	
Power cord length, m, minimum	2	
Maximum activation time (mode “on”), min	60	
Minimum deactivation time (mode “off”), min	15	
Fiber		
Divergence of radiation at the fiber output, rad	0.4	
Numerical aperture of replaceable fiber, minimum	0.22	
Core diameter of replaceable fiber, µm	150, 200, 365, 550, 940	
Light transmission of fiber, %, minimum	85	
Length of fiber, m, minimum	3	
Minimum allowable bending radius of fiber, mm	Core Diameter, µm: Minimum bending radius, mm 150: ≥ 9 200: ≥12 365: ≥20 550: ≥58 940: ≥73	
Foot switch		
Weight, kg, max	2	

Parameter	Urolase SP	Urolase SP+
Overall dimensions of the emission activation foot switch, mm	185 x 346 x 171±10	
Length of the connecting cable to the emission activation foot switch, m, minimum	3	
Press force of the emission activation foot switch, N, minimum	10	
Foot switch body	IPX8	
Touch panel display		
Overall dimensions, mm	154 x 93±10	
Screen resolution	800 x 480	
Brightness, cd/m^2, standard	308	
Contrast, standard	675	
Type of touch panel display	Capacitive	
Software (installed)		
Version, minimum	SWSP 2.1.0	SWSPP 3.1.0
Date of manufacture	03.2023	

COMPLETE SET

The Device is delivered in transport package. The transport package contains Device with all its accessories. Before opening the package, check the outer box for any signs of damage or deterioration during transport. Check the Device complete set.

Device complete set includes the following items:

Table 8

Description	Quantity
Laser device “Urolase SP+”/“Urolase SP”	1
Including:	
Power cord	1
Footswitch	1
Fuse	2
Interlock	1
IRE Surgical Fiber, bare fiber, type HP, 150 µm, reusable	1
IRE Surgical Fiber, bare fiber, type HP, 200 µm, reusable	1
IRE Surgical Fiber, bare fiber, type HP, 365 µm, reusable	1
IRE Surgical Fiber, bare fiber, type HP, 550 µm, reusable	1
IRE Surgical Fiber, bare fiber, type HP, 940 µm, reusable	1 (optional)
Laser safety goggles	3
Stripper for fiber 0.12 to 0.4 mm	1
Stripper for fiber 0.3 to 1.0 mm	1
Microscope for inspecting the fiber end in the connector	1
Fiber cleaver	1
Fiber holder (short)	1
Fiber holder (long)	1
Protective window	1
User Manual	1

DEVICE COMPONENTS AND THEIR IMAGES

Figures 2 through 9 show the Device and accessories. Images and descriptions of the components are shown below.

Following components are necessary for the Device operation (Fig. 2):

- Power cord.
- Fiber.
- Foot switch.
- Interlock.

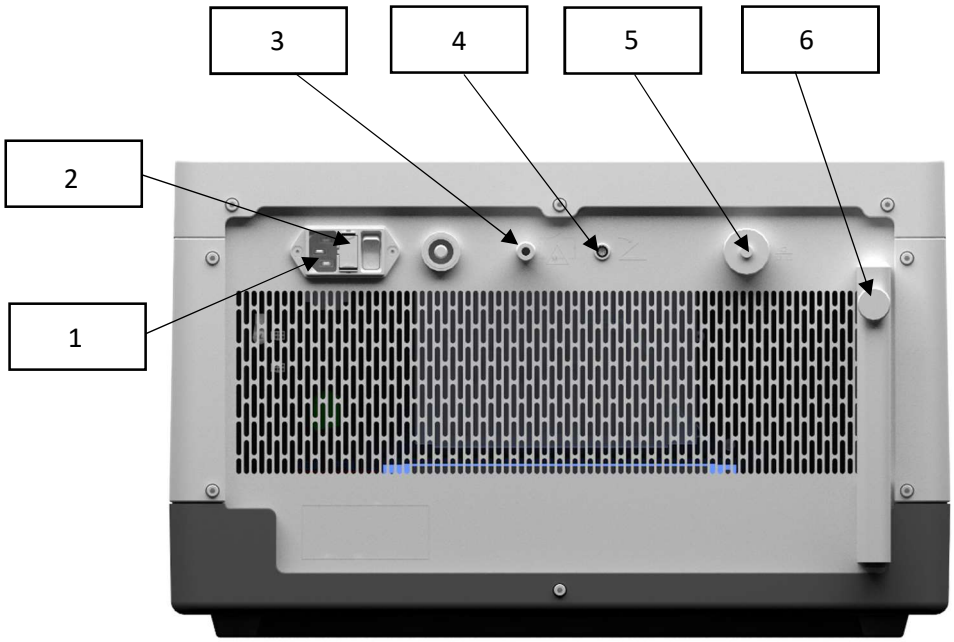


Figure 3. Laser device “Urolase SP+”/ “Urolase SP”- rear view

Rear panel of the Device:

- Power connector: (1);
- Fuse (2);
- Remote blocking: Connector for interlock (3);
- Connector of the foot switch (4);
- System port: Ethernet cable connector, used only by the manufacturer (5).
- Fiber holder lock: (6);

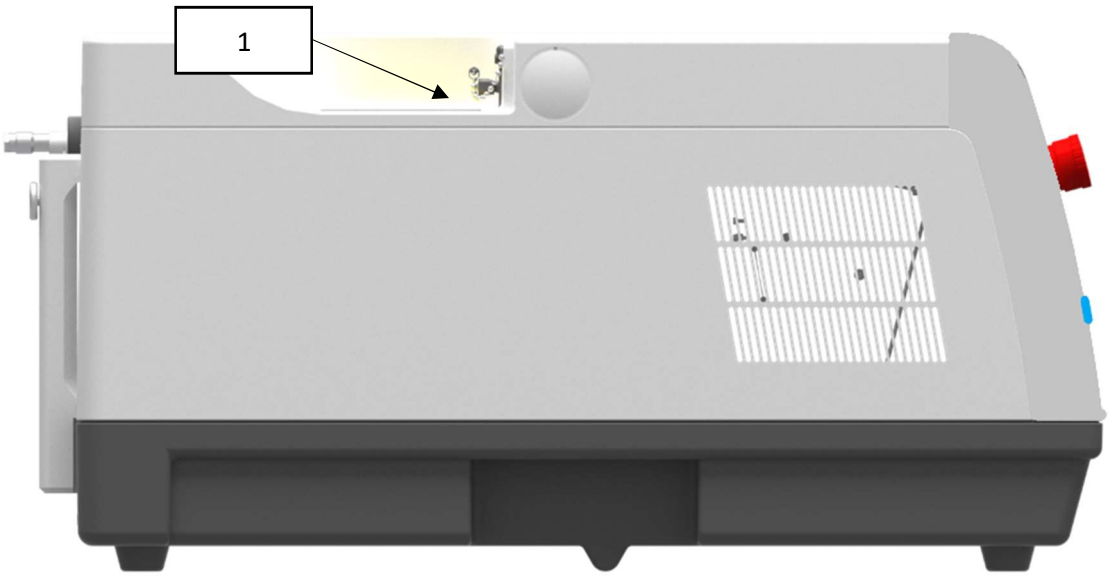


Figure 4. Laser device “Urolase SP+”/“Urolase SP” - side view (left)

- Optical connector for connecting fiber (1)

Figure 5. Laser device “Urolase SP+”/“Urolase SP” - side view (right)

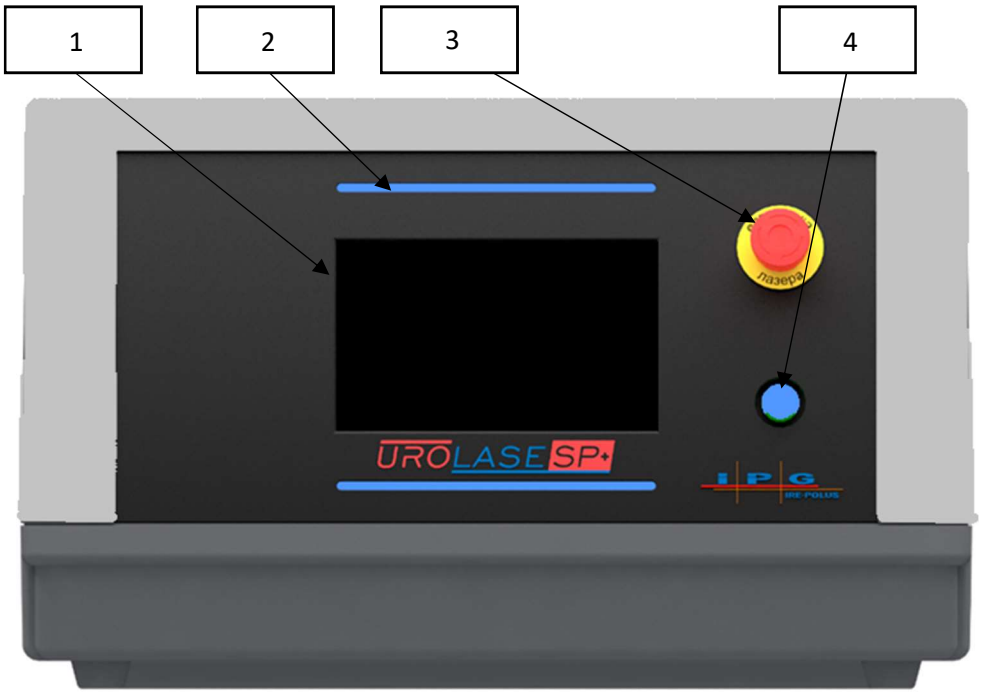


Figure 6. Laser device “Urolase SP+”/“Urolase SP” - front panel

Front panel elements:

• Graphic operator interface — an interactive touch screen with all the controls of the Device (1);
• Power indicators (2);
• Emergency stop button (3);
• On/off button of the Device (4).

FIBER

The IRE Surgical Fiber is a device designed to deliver laser radiation from a laser device at operating wavelengths ranging from 440 to 2200 nm to the surgical site.

The IRE Surgical Fiber consists of silica fiber and protective coating that is in direct contacts with patient and includes an SMA-905 connector for connection to the laser device. The IRE Surgical Fiber is sterilized with ethylene oxide and supplied sterile.

See IRE Surgical Fiber Instruction for Use to get more information.

DEVICE

The Device’s body includes a laser module with a fiber radiation output, a power supply unit, cooling fans, as well as electronic units to control and ensure safe operation of the Device. Also, the front panel has a touch-screen LCD monitor.

Danger of radiation from the fiber and optical connector on the Device (1) (Fig. 4) (when the fiber is disconnected):

DANGER	Laser radiation can cause damage to the eyes and skin. Despite the fact that the radiation is in the invisible wavelength range, laser radiation (direct or reflected) can cause permanent damage to the eyes. It is necessary to wear protective goggles every time when the Device is used.

INTERLOCK

The Device has remote blocking function which connects the door switch to the Device. Anyone entering the operating room when the Device is switched on opens the protective electrical circuit and the Device is switched off. This requires installation of a door switch and its connection to the Device via a connector for interlock.

Interlock (Fig. 7) is supplied together with the Device. This connector can be used in operating rooms where the door switch is not installed. To install this connector, insert it into the appropriate socket on the rear panel of the Device and turn clockwise to lock. To remove the connector, turn it counterclockwise and pull it out of the socket.

Figure 7. Interlock

NOTE

• In order to connect the door opening sensor to the Device, you need to contact the manufacturer (contact details for contacting the manufacturer are provided on the last page).

• If there is no door sensor, it is important for the operation of the device that the interlock is inserted into the appropriate slot. If you try to work on the device without installing the interlock, an error message is displayed on the screen

SETTING UP THE DEVICE

Install interlock in the connector (3) on the rear panel of the Device (Fig. 3). Connect power cable to power connector (1) on the rear panel of the Device (Fig. 3). Connect the foot switch to the connector (4) on the rear panel of the Device (Fig. 3).

PREPARATION OF THE FIBER

Figure 8. IRE Surgical Fiber, bare fiber, type HP, 150/200/365/550/940 µm, reusable

The complete set includes IRE Surgical Fiber – sterile reusable bare fiber (Fig. 8).

To clean the fiber distal end from ablation products during the operation, use a gauze swab moistened with water. Before wiping, wait 2-3 seconds after releasing the foot switch. Do not use flammable substances such as alcohol to clean the fiber end. As the end outlet fiber wears out, probability of its failure and getting debris into the patient's body increases. To avoid such hazard situation, it is necessary to cleave the fiber end face after each operation.

NOTE

To prepare for the next surgery, you should always cleave bare fiber and strip the protective coating before the surgery in accordance with IRE Surgical Fiber Instruction for Use.

Cleaving should be performed after stripping protective coating using a fiber stripper (Fig. 9) with approximately 4-5 mm of fiber exposed.

a) b)

Fig. 9 Fiber stripper 0.12 to 0.4 mm (a) and fiber stripper 0.3 to 1 mm (b)

Figure 10. Fiber cleaver

To fix the fiber position, hold the fiber down with index finger at the place of intended cleaving. Using the cleaver (Fig. 10), run one of its sides across the fiber with very light pressure to make a notch. Holding the fiber with your thumbs and index fingers about 1 mm on either side of the notch, break off the fiber along the notch. When working with optical fiber which protective shell was stripped, use protective goggles.

To prepare for the next operation, always cleave the end outlet fiber and clean protective coating before operation.

All small fragments of the end outlet fiber should be collected after cleaving. Keep them in a closed container.

The Device is supplied with the following fibers:

Standard: IRE Surgical Fiber, bare fiber, type HP, reusable, core diameter 150, 200, 365, 550 µm.

WARNING

- Do not allow bending (twisting) of the surgical fiber with a radius less than that specified in the IRE Surgical Fiber Instruction for Use. A sharp bend can damage the fiber instrument;
- To prevent damage, do not use excessive force when working with the fiber;
- If the cutting element breaks during the procedure, carefully remove the remnants from the operation site, rinse the place and repeat the procedure;
- Use only tools approved by the manufacturer and methods described herein for stripping the protective shell and cleaving the fiber;
- To prevent mechanical damage to the fiber, do not extend the end of the fiber more than 4-5 mm further than the end of the endoscope;
- Use only the original fiber supplied by the Device manufacturer. The manufacturer does not guarantee operation of the Device when using non-original fiber.

CONNECTING THE FIBER

After preparing the fiber, check the fiber connector using a microscope (Fig. 11) (supplied with the Device).

Fig. 11. Microscope for inspecting the fiber end in the connector

To inspect the fiber connector, insert the connector into the microscope (1) (Fig. 11). Adjust microscope sharpness (2) (Fig. 11) and check fiber end in the connector for any damage (dirt, cracks, black dots).

After inspection, connect the fiber to optical connector on the Device (1) (Fig. 4). Before surgery, make sure that the fiber is fixed on the Device.

On the top cover of the device there is a special connector for surgical fiber connection. When not in use, this special connector must be closed with a screw cap (Figure 11a).

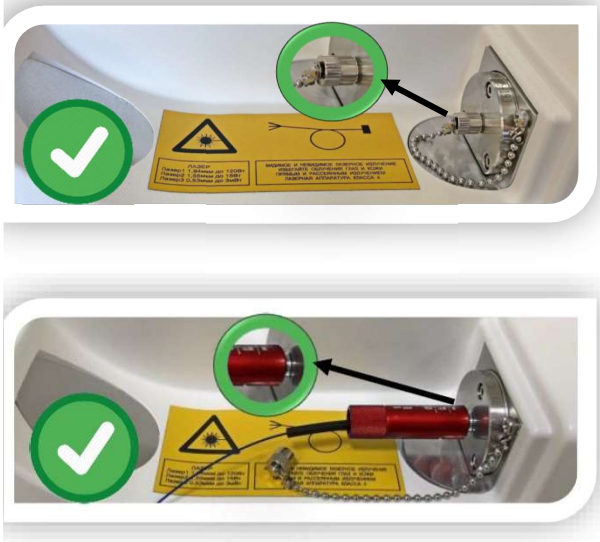


Figure 11a. Correct connection

Figure 11b. Wrong connection

Before turning on the 1.94 µm radiation, the surgical fiber recommend to check with an aiming beam laser (the spot of the green pilot laser should be round, no green light along the length of surgical fiber) (figure 11c).

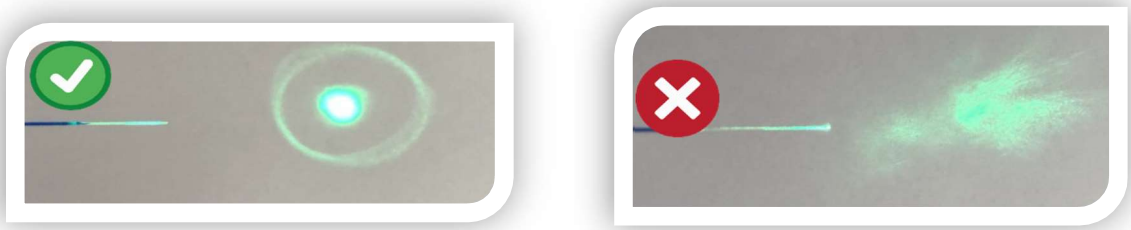


Figure 11c. Surgical fiber inspection

EYE PROTECTION EQUIPMENT

When 4 class laser device works, personnel and patients present should wear eye protection-safety goggles (Figs.12.1 through 12.5 (supplied with the Device)*. Degree of protection against laser radiation in the Device operation wavelength range at OD5+ optical density is as per EN 207:2009.

Fig. 12.1 Laser protective goggles, model - Eagle Pair EP-10-4, with lens cleaning cloth, in a case

Fig. 12.2 – Marking: name of goggles

Fig. 12.3 – Marking: goggles model

Fig. 12.4 – Marking: OD5+ optical density goggles, protection in the wavelength range from 980 to 2500 nm.

Fig. 12.5 – Case for goggles

**Use only protective goggles, which meet requirements for the Device working wavelength and power.*

CONTROLS

The Device can be turned on using the button on the front panel.
The Device is controlled using the touch screen.
The front panel also includes the **STOP** button for the Device emergency shutdown.

SCREEN ICONS

The interface icons that are used to control the Device are shown in Table 9.

Table 9.

Icon	Meaning
	Settings
	Favorites
	Log file
	Return to the password entry screen
	Home screen to choose the application area
❮ ❯	Step buttons

LAUNCHING THE DEVICE

After the Device has been assembled according to Section 2, you should turn it on by pressing the button on the front panel. Upon turning the Device on, the loading screen is displayed.

PASSWORD ENTERING

To start working with the Device, you should enter your password using the keypad (1): it is **1234** as shown in Fig. 13.

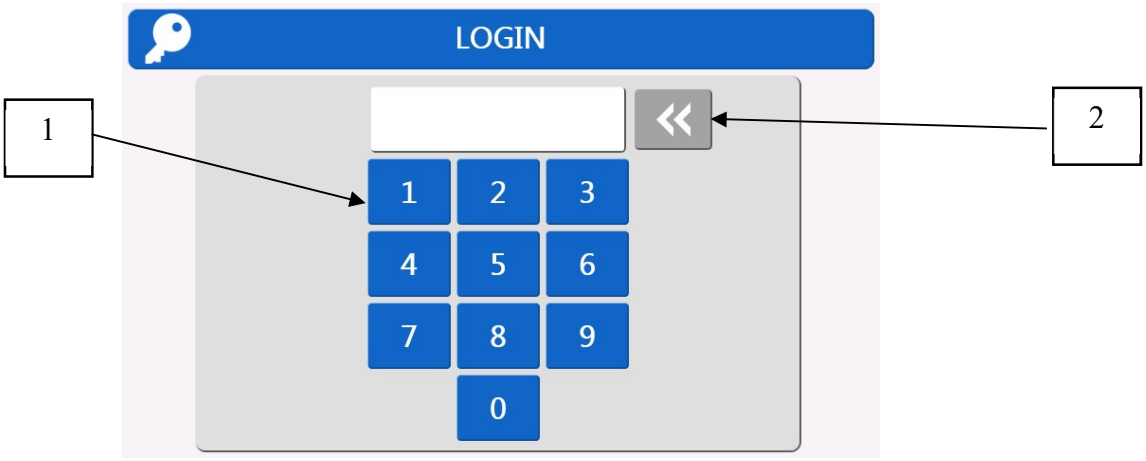


Figure 13. Password entry screen

If you have entered an invalid password, you will see a message error: “Invalid passcode.”. To delete wrong characters, please press the button (2).

CHOOSING THE APPLICATION AREA

After loading, the Device will display the Home Screen for choosing the application area (hereinafter referred to as the Home Screen) (Fig. 14).

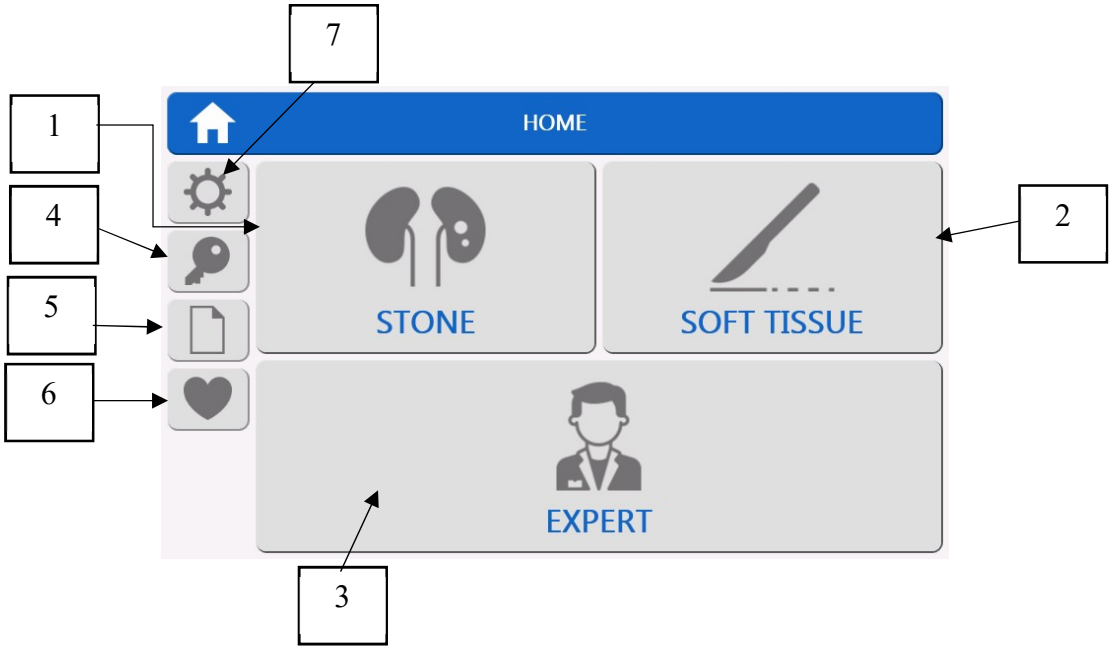


Figure 14. Home Screen to choose the application area

The Devices provides for preset modes (STONES (1) and SOFT TISSUES (2)) and the EXPERT mode (3), where the laser radiation parameters can be adjusted within the entire range.

The FAVORITE section (6) displays the modes saved by the user.

To adjust the screen brightness and beep volume, and to view the software version, press the button (7) (see the SETTINGS section).

To exist to the password entry screen, press the button (4) (see the PASSWORD ENTRY SCREEN section).

To view the log file (information about previously used modes of the Device), press the button (5).

STONES

The Device has preset modes for lithotripsy. By pressing the button (1) (Fig. 14), you will open the screen for setting the laser radiation parameters. Depending on the selected localization and lithotripsy method, you will be invited to use the appropriate range of parameters as well as recommended laser radiation parameters (Table 10).

Table 10.

Localization	Lithotripsy method		Recommended parameters	Parameter range
Kidney	Fragmentation	Energy	0.9 J	0.2 … 1.5 J
		Frequency	22 Hz	2 … 40 Hz
		Average power	19.8 W	2 … 24.2W
	Dusting	Energy	0.3 J	0.1 … 0.9 J
		Frequency	26 Hz	3 … 40 Hz
		Average power	7.8 W	2 … 24W
	Popcorning	Energy	0.4 J	0.1 … 0.7 J
		Frequency	38 Hz	20 … 250 Hz
		Average power	15.2 W	2 … 25W
Ureter	Fragmentation	Energy	0.9 J	0.2 … 1.4 J
		Frequency	8 Hz	2 … 15 (20**) Hz
		Average power	7.2 W	2 … 12W
	Dusting	Energy	0.3 J	0.1 … 0.9 J
		Frequency	10 Hz	3 … 20 Hz
		Average power	3.0 W	2 … 12W
Bladder	Fragmentation	Energy	3.0 J	0.5 … 6* J
		Frequency	9 Hz	2 … 80** Hz
		Average power	27 W	10 … 40* **W

*when connecting a fiber with a diameter of 150 μm, the maximum energy that can be set is 4 J, the maximum output power, 40 W.
**20 Hz – only for energy 0.1 J.

**for Urolase SP+: maximal frequency – 120 Hz, maximal average power – 60 W

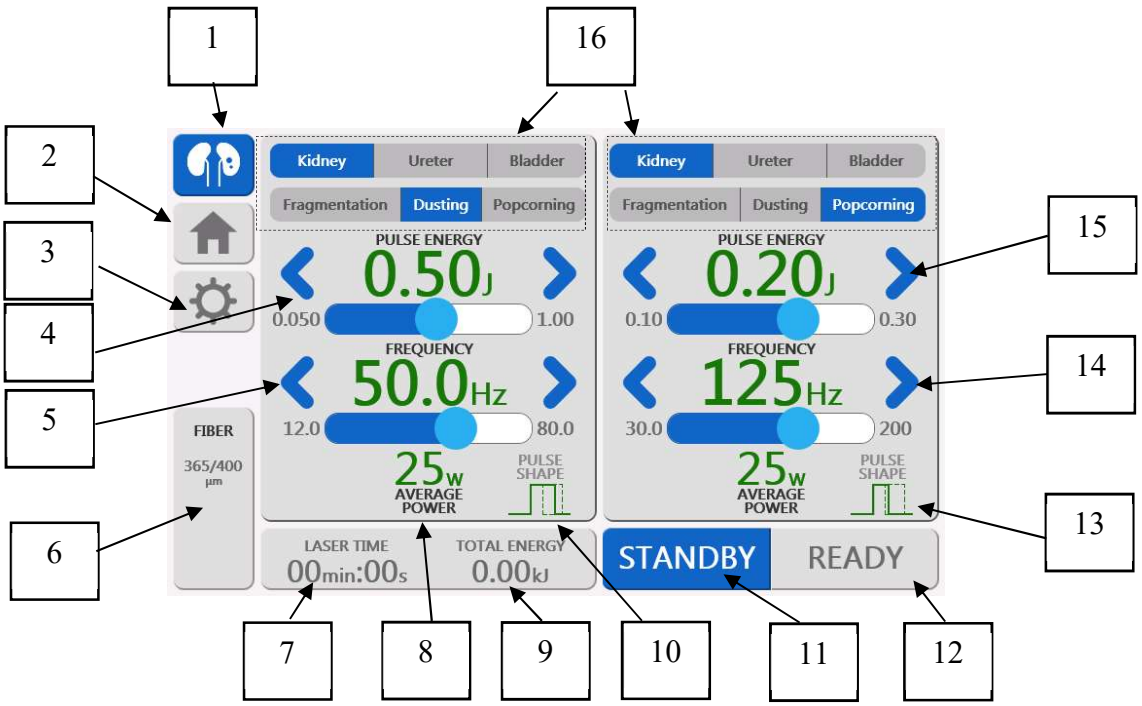


Figure 15. Screen for setting the laser radiation parameters for the STONE preset mode

The required localization and the lithotripsy method can be chosen by pressing the screen buttons (16) for left and right pedals.

The pulse energy can be set by pressing step arrows: (4) for the left pedal and (15) and for the right pedal. The pulse frequency can be set by pressing step arrows: (5) for the left pedal and (14) for the right pedal. Depending on the chosen pulse energy and pulse frequency values, the screen displays the average radiation power (8) calculated using the following formula:

$$Average\ power = Pulse\ energy \cdot Frequency \qquad (1)$$

Depending on the chosen pulse energy, the screen will display the laser radiation pulse type ("short pulse", "medium pulse", or "long pulse"): (10) for the left pedal and (13) for the right pedal.

The pilot laser radiation power can be adjusted on the SETTINGS screen (3) (see the SETTINGS section).

To return to the Home Screen, press the button (2).

The area (6) displays the selected fiber instrument type (before setup laser parameters Device suggest selecting fiber type) (Fig. 16).

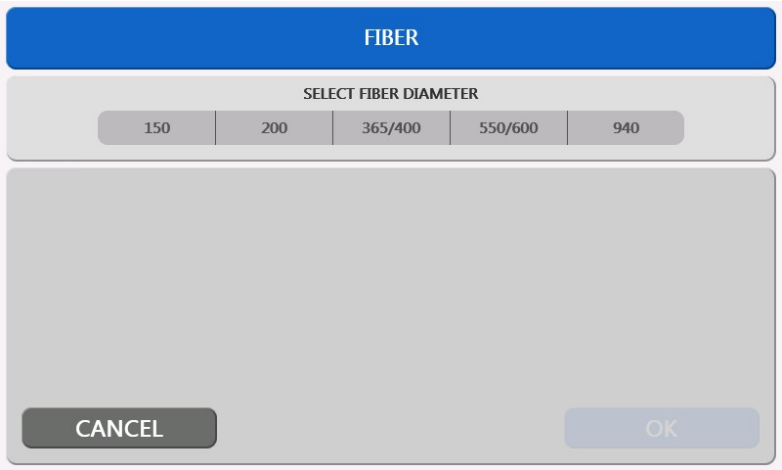


Figure 16. Fiber type selection

In the STANDBY mode, the laser radiation cannot be emitted by pressing the pedal. The laser radiation can be emitted only in the READY mode.

To switch to the READY mode, you should press the button (12).

You cannot switch to the READY mode in the following cases:

1. The pedal is pressed;
2. The cover plug for external locking on the rear panel is not installed;
3. The emergency stop button is pressed;
4. The fiber tool activation is not available.

ATTENTION

Before pressing the READY button, make sure that the fiber tool is connected to the Device, and the safety goggles are on.

DEVICE READINESS STATUS

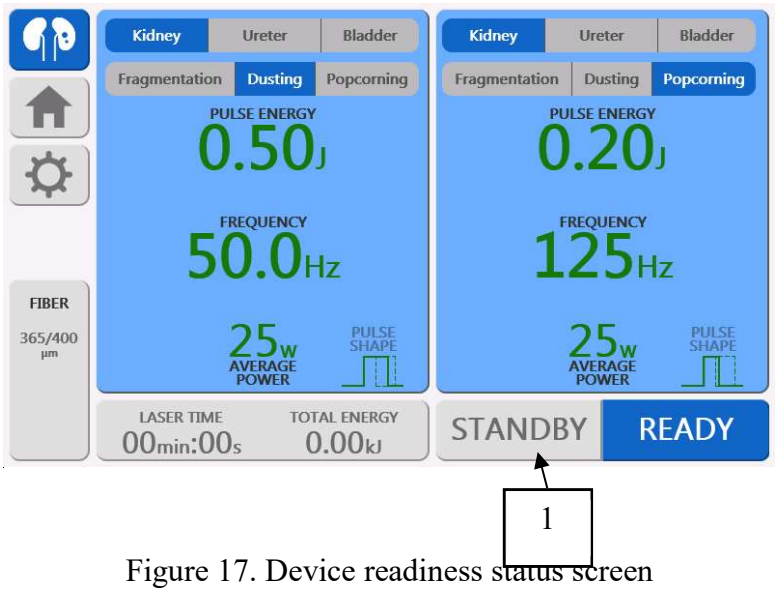


Figure 17. Device readiness status screen

When you press the pedal in the READY mode, the corresponding screen area is highlighted in yellow, the laser hazard icon flashes (Fig. 18 (1)), and a beep indicates the presence of laser

radiation. The system starts calculating the total energy emitted by the Device (2) and the emission time (3).

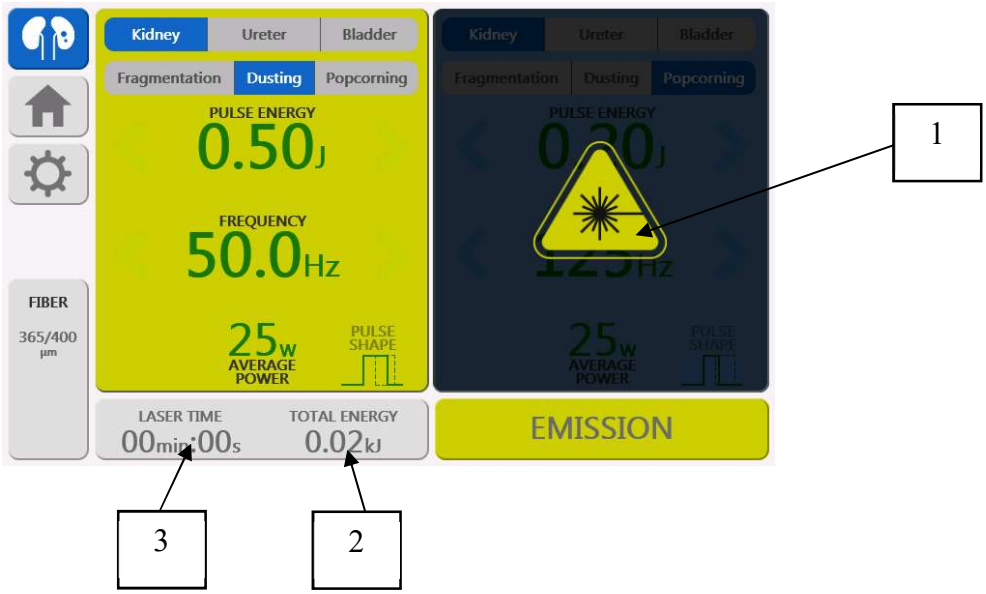


Figure 18. Laser screen upon pressing the pedal

When you press the left pedal, the laser radiation is emitted with the parameters set on the left side of the screen; when you press the right pedal, with the parameters on the right side of the screen.

NOTE

In the READY mode, changing the parameters of laser radiation is not available

To switch to the SETTING mode, release the pedal and press the button (1) (Fig. 17).

SOFT TISSUES

The Device has preset modes for soft tissue surgery. By pressing the button (2) (Fig. 14), you will open the screen for setting the laser radiation parameters. A special range of parameters will be suggested depending on the procedure you have selected, as well as the laser radiation recommended parameters (Table 11).

Table 11.

Localization	Recommended parameters		Parameter range	Pulse type
Enucleation (available only for Urolase SP+)	Energy Frequency Average power Pulse type	1.5 J 40 Hz 60 W Long	1 … 4 J 10 … 60 Hz 40 … 60 W*	Short Medium Long
Vaporization	Average power	60 W (Urolase SP+) 35 W (Urolase SP)	30 … 60 W* (Urolase SP+) 30 … 40 W* (Urolase SP)	Continuous mode

Localization	Recommended parameters		Parameter range	Pulse type
Incision	Energy Frequency Average power	1 J 10 Hz 10 W	1 … 1.5 J 7 … 30 Hz 10 … 30 W	Long
Hemostasis	Energy Frequency Average power Pulse type	0.3 J 10 Hz 30 W Long	0.1 … 1 J 10 … 400 Hz (Urolase SP) / 600 Hz (Urolase SP+)* 10 … 40 W (Urolase SP) / 60 W (Urolase SP+)*	Medium Long

*when connecting a fiber tool with a core diameter of 150 µm, the maximum energy that can be set is 4 J, the maximum output power, 40 W.

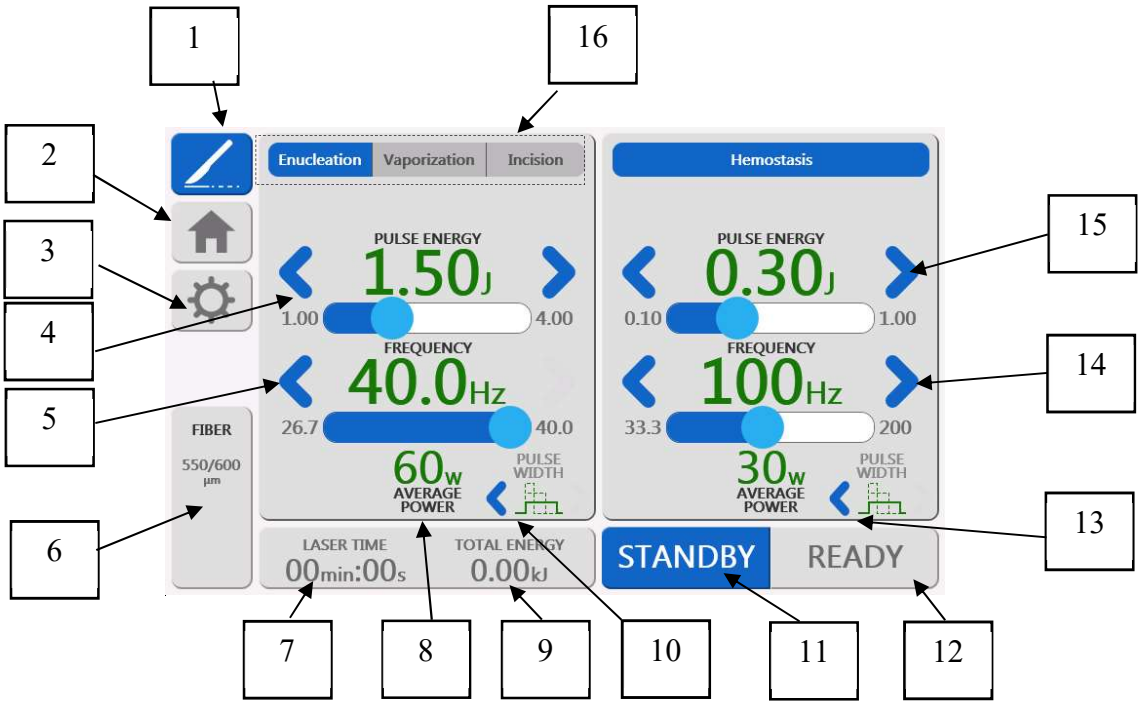


Figure 19. Screen for setting laser radiation parameters for the SOFT TISSUES preset mode
Note: Enucleation mode available only for Urolase SP+. Urolase SP have only Vaporization and Incision modes.

The procedure for setting the laser radiation parameters is described in the STONES section. The procedure can be selected by pressing the buttons (16) (Fig. 19).

To adjust the pulse length, press the buttons (10) for the left pedal and the buttons (13) for the right pedal (Fig. 19).

EXPERT

The EXPERT mode is provided to adjust the Device laser radiation parameters within the entire range. By pressing the button (3) (Fig. 14), you will open the screen for setting the laser radiation parameters (Fig. 20).

Figure 20. Screen for setting laser radiation parameters in the EXPERT preset mode

The procedure for setting the laser radiation parameters is described in the STONES/ SOFT TISSUES section. To choose an operating mode, press the buttons (16) (Figs. 15 and 19).

To save the laser radiation parameters, press the button (1) (Fig. 20). The mode saved will be displayed in the FAVORITES screen (6) (Fig. 14).

FAVORITES

On the EXPERT screen, the user can set the laser radiation parameters and save this mode that will be displayed in FAVORITES on the Home Screen.

To save the selected laser radiation parameters, press the button (1) in the SETTING mode (Fig. 20).

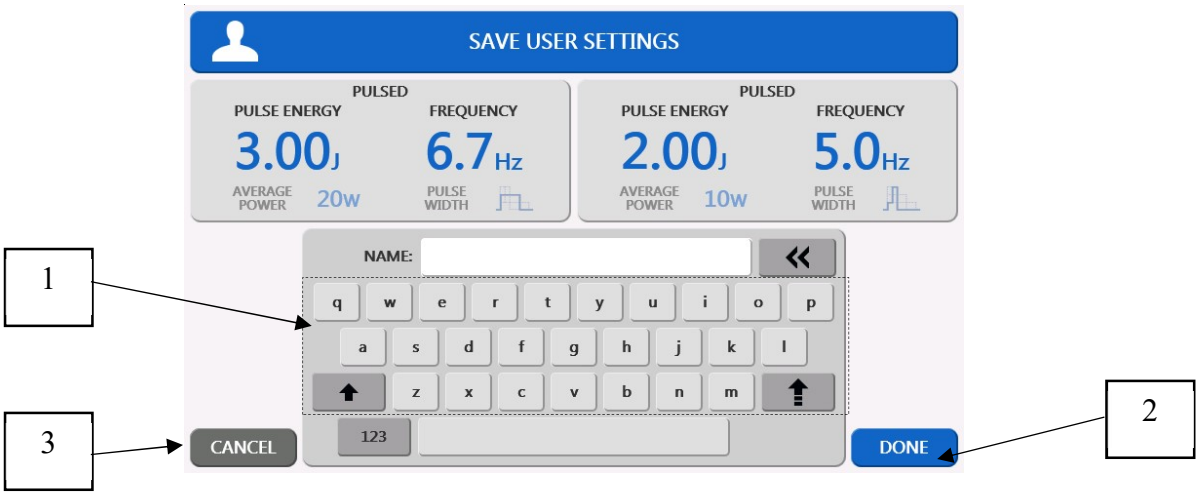


Figure 21. Screen for saving the laser radiation parameters

In the opened window (Fig. 21), enter the name of the mode to be set using the keypad (1). The number of characters in this name shall not exceed 10. After entering the name, press the button (2) to save the mode. To cancel saving, press the button (3).

ATTENTION

Before saving, please check the laser radiation parameters you have set.

SETTINGS

By pressing the button (7) (Fig. 14), you will open the screen for setting the screen brightness and the beep volume, for choosing the software language and the pilot laser power (Fig. 22):

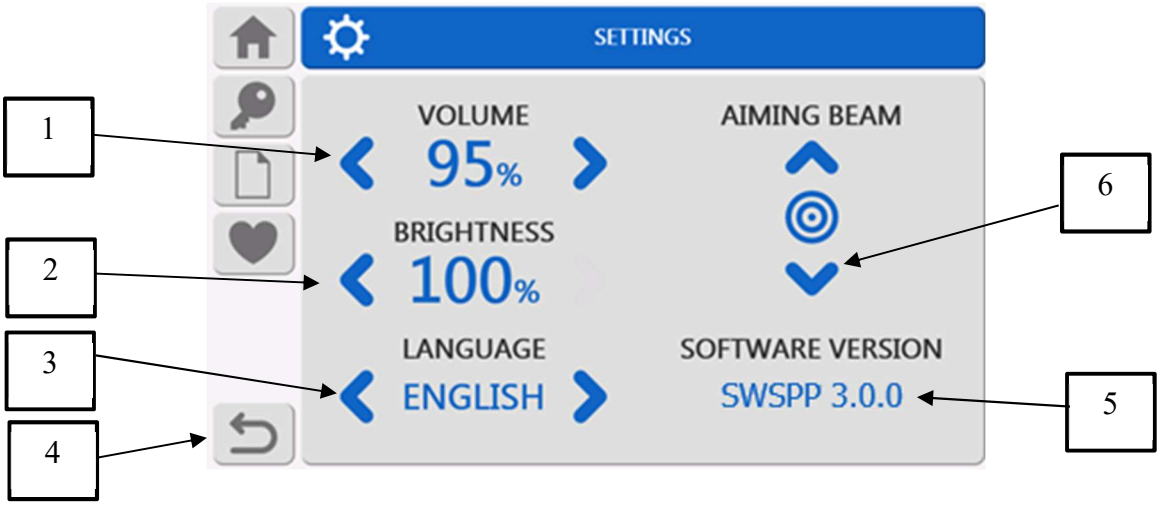


Fig. 22. Screen for setting the screen brightness and the beep volume

To set the beep volume, press the step arrows (1).

To set the screen brightness, press the step arrows (2).

To select the interface language (Russian/English), press the step arrows (3).

The software version is displayed in the field (5).

To set the pilot laser power, use the step arrows (6).

To return to the main menu, press the button (4).

PASSWORD ENTRY SCREEN

By pressing the button (4) (Fig. 14) to return to the password entry screen, you will see the following message (Fig. 23):

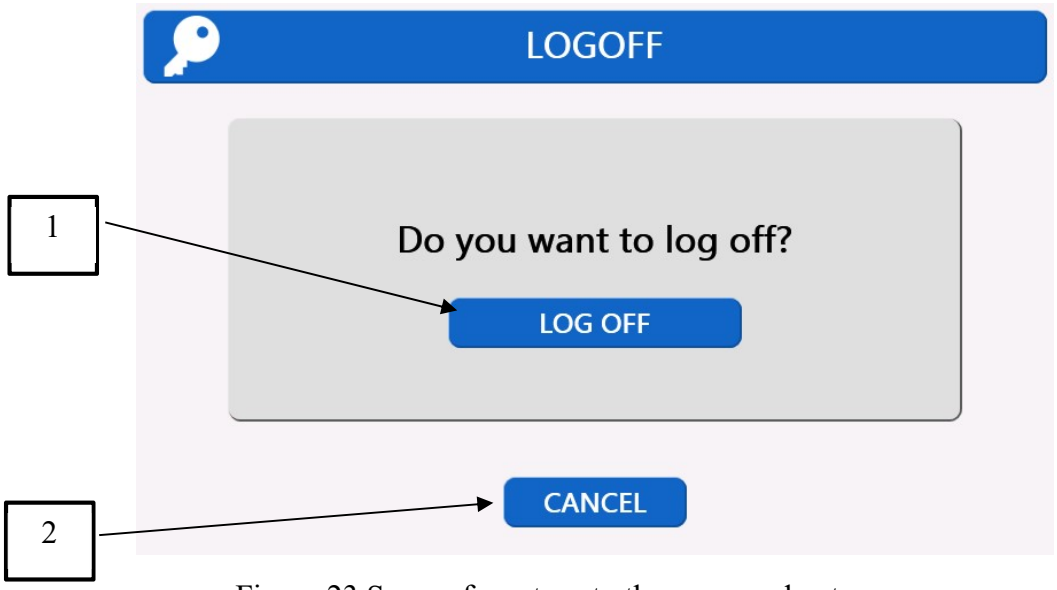


Figure 23 Screen for return to the password entry screen

By pressing the button (1), you will return to the password entry screen. To cancel, press the button (2).

LOG FILES

To view a log file (information about the previously used operating modes of the Device) (Fig. 24), you should press (5) (Fig. 14).

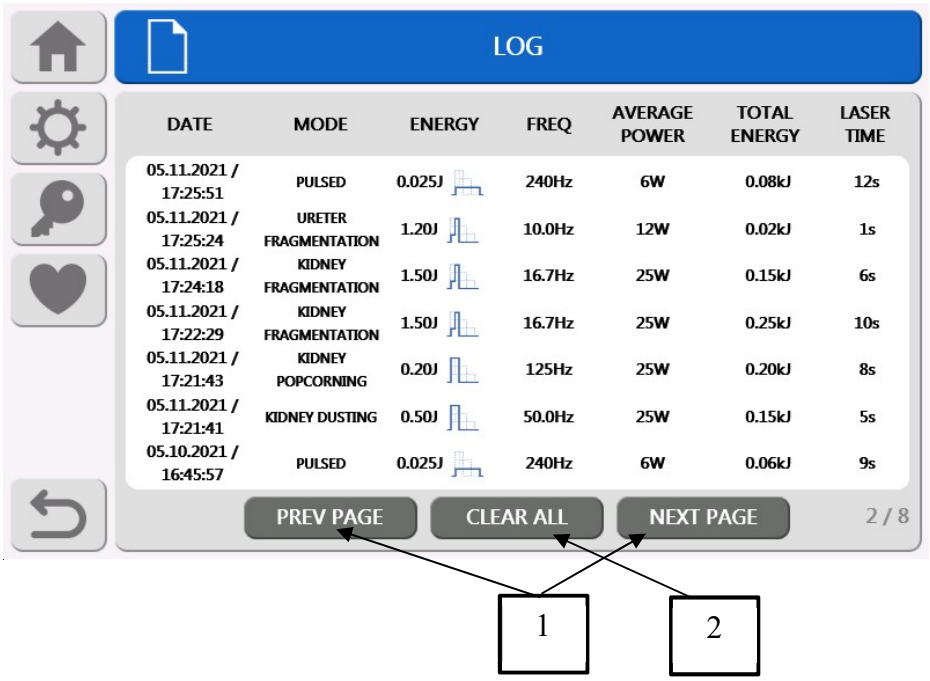


Figure 24. Log file screen

This screen displays the information about the date, mode, the laser radiation parameters used (the pulse energy, the pulse frequency, and the average power), the total energy and laser time emitted by the Device during a session.

To scroll through the list of records in log files, use the buttons (1). The maximum number of records that can be stored in LOG files is 50. To delete log files, press (2).

EMERGENCY SHUTDOWN

In case of an emergency, you must immediately press the emergency shutdown button (3) (Fig. 6). After pressing the emergency shutdown button, the Device will stop emitting the radiation.

To continue the work, you should:

- make sure that the emergency situation was eliminated;
- turn the Device off, by pressing the button on the front panel;
- rotate the emergency stop button clockwise by 90°;
- turn the Device on by pressing the button on the front panel.

TURNING THE DEVICE OFF (IN A NORMAL MODE)

Shut down the Device by pressing the button on the front panel.

ROUTINE MAINTENANCE

DAILY MAINTENANCE

Only qualified service personnels are allowed to perform maintenance of the Device.

To maintain the Device and its components in constant technical serviceability, it is recommended to carry out the following measures:

- carry out an external inspection of the Device and its components to check the absence of mechanical damage to the Device and connectors. If such damage is detected, further operation of the Device is prohibited and it is necessary to contact the manufacturer;

- remove dust and moisture from the external surfaces of the device;

- carry out pre-sterilization cleaning, disinfection and sterilization before each use

- check the presence and quality of the guide beam laser. Since the guide beam passes through the same transmitting optical system as the working radiation, this provides good results for testing the operability of the transmitting optical system. If the guide beam is not at the output of the transmitting optical system, its intensity is reduced or it looks scattered, this means that the transmitting optical system is damaged or is operating abnormally. If such damage is found, contact the manufacturer.

The list of possible malfunctions and errors in the operation of the Device, and recommendations for appropriate actions to eliminate them are given in section 5.

ATTENTION

WARNING - THE USE OF ADJUSTMENTS OR PERFORM ANY ACTIONS EXCEPT RECOMMENDED IN THIS MANUAL CAN RESULT IN EXPOSURE TO HAZARDOUS RADIATIONS

ATTENTION

IN CASE OF ANY MALFUCTIONS, CONTACT THE MANUFACTURER

CHECKING THE DEVICE'S FUNCTIONALITY

To check the Device's functionality, it is recommended to perform the following actions after each procedure of external surfaces disinfection and complete drying of the Device:

WARNING

When checking the Device's functionality, wear safety goggles.

Procedure	Description
Check for damage to the foot switch and power cord	Make sure that there is no visible damage to the emission activation foot switch or power cord. If there is a visible damage, replace the emission activation foot switch / power cord.
Checking the operation of the emergency stop button	Make sure that when the Device is turned on, after entering the password, a message appears on the screen when pressing the emergency stop button located on the front panel. If there is no message No. 2 (see Section 5) on the screen, contact the manufacturer.
Checking operation of interlock	Make sure that when the Device is turned on, after entering the password, a message appears on the screen when the interlock located on the rear panel is detached. If there is no message No. 4 (see Section 5) on the screen, contact the manufacturer.
Checking the Device's functionality	Make sure that in READY mode, when the fiber is connected, there are no messages on the screen when the foot switch is pressed, and laser radiation is emitted*. If there are messages on the screen, refer to Section 5. *when checking the Device's functionality, immerse the end of the fiber in a container with water, so that the end of the fiber is at least 4 cm away from the walls of the container. After checking, clean/disinfect/sterilize the fiber.

FIBER CONTAMINATION CONTROL

The IRE Surgical Fiber is intended for multiple usage (no more than 10 times). It is necessary before each use of the IRE Surgical Fiber to carry out its disinfection, cleaning and sterilization in accordance with the IRE Surgical Fiber Instruction for Use.

ATTENTION

READ THE IRE SURGICAL FIBER INSTRUCTION FOR USE BEFORE USING

DISINFECTION OF THE EXTERNAL SURFACES OF THE DEVICE AND ACCESSORIES

ATTENTION

DISINFECTION OF DEVICE AND ACCESSORIES MUST BE CARRIED OUT AFTER EACH USE

Make sure the Device is turned off. The outer surfaces of the Device, the pedal for switching on the radiation, the power cord, the interlock, the fiber strippers, the fiber cleaver, protective goggles, the microscope for checking the end of the fiber tool and the Surgical fiber holders should be disinfected by wiping with a napkin made of coarse calico or gauze moistened with a 3% solution of hydrogen peroxide with the addition of 0.5% detergent.

ATTENTION

DO NOT SPRAY DISINFECTANT DIRECTLY ON THE SURFACE OF THE DEVICE

Wipe the surfaces with a gauze swab or sponge. Do not use bleach or abrasive products for cleaning. When wiping, be careful not to get liquid inside the machine. After disinfection, allow to air dry at room temperature.

TRANSPORTATION AND STORAGE

The Device can be transported in the manufacturer's transport container by any covered means of transport, except for sea transport and non-heated, leaky compartments of aircraft, in accordance with the transport rules applicable to this type of transport.

Minimum temperature should not be less than -30°C. Maximum temperature shall be below +45°C.

There should be no corrosive agents (acid and alkali vapors) in the Device storage areas.

Unpacking and switching on the Device after its transportation or storage at a temperature below 10°C is allowed not earlier than in 12 hours.

PRODUCT OPERATING CONDITIONS

The product is intended for use in rooms specially equipped for laser device at an ambient temperature of +15°C to +30°C and relative humidity of not more than 80% at a temperature of not more than +25°C.

POST-WARRANTY MAINTENANCE

Post-warranty maintenance should be carried out by manufacturer or service organizations authorized by the manufacturer (with written permission).

REPLACEMENT OF FUSIBLE ELEMENTS

Fusible elements (fuses) are built into the Device. In case of burning out, the Device is supplied with 2 pieces of spare fuses. To replace the fuses:

- Disconnect the Device: disconnect power cord from the mains and wait for 5 minutes.
- Remove the fuses (2) from the electrical lead-in unit with the switch and fuse holder (Fig. 3).
- Replace them with new fuses.

REPLACEMENT OF THE PROTECTIVE WINDOW

If error No 11 appears on the screen (see Section 5), the protective window of the Device should be replaced. Unpack new protective window (1) from the packaging and remove the protective film (2) (Fig. 28).

Fig. 27. Protective window in the package

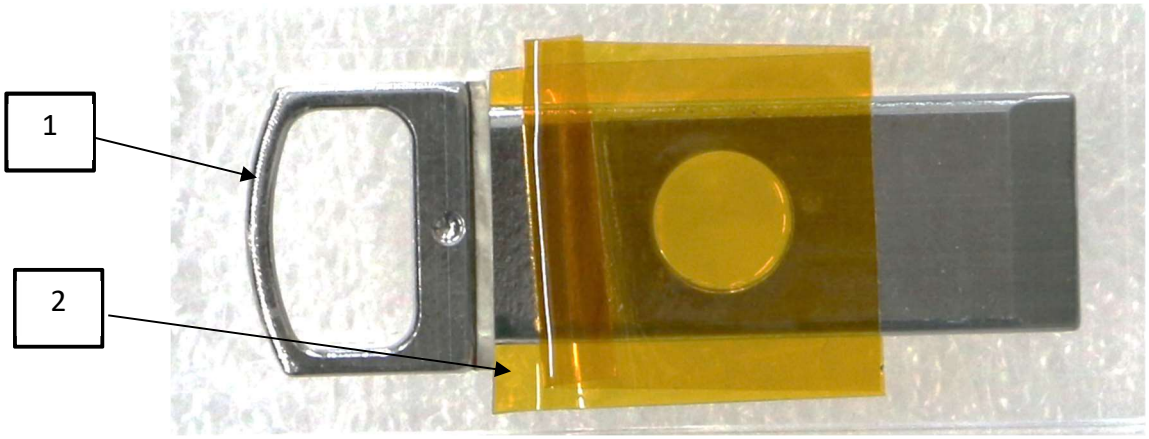
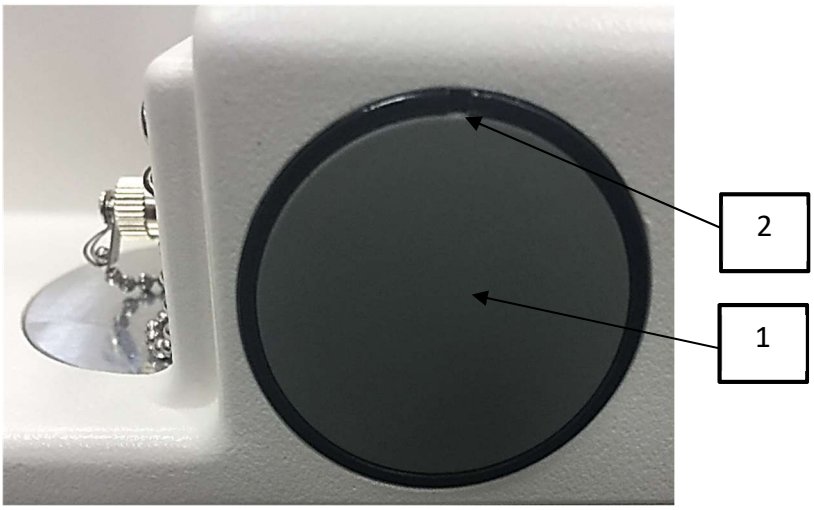


Fig. 28. Protective window with protective film

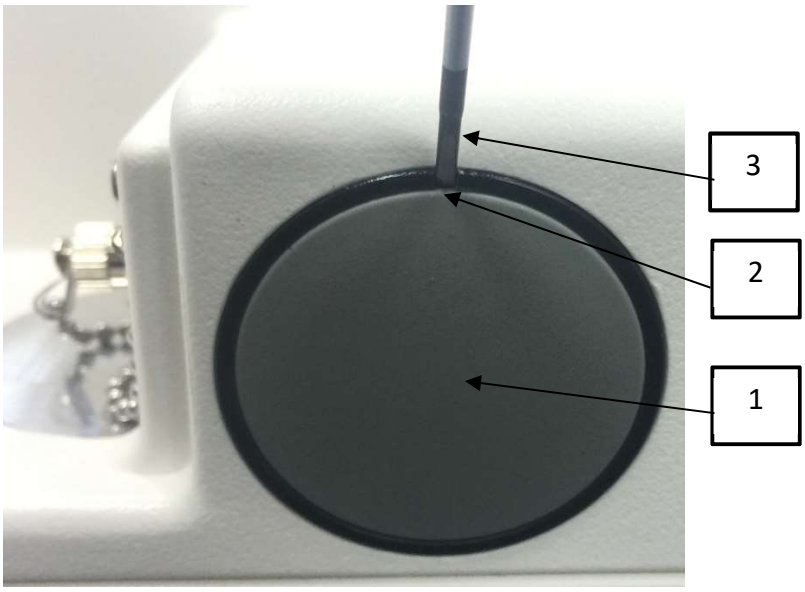
WARNING

- To avoid contamination of the protective window, do not touch its transparent part;
- The protective window should be replaced when the Device is switched on.

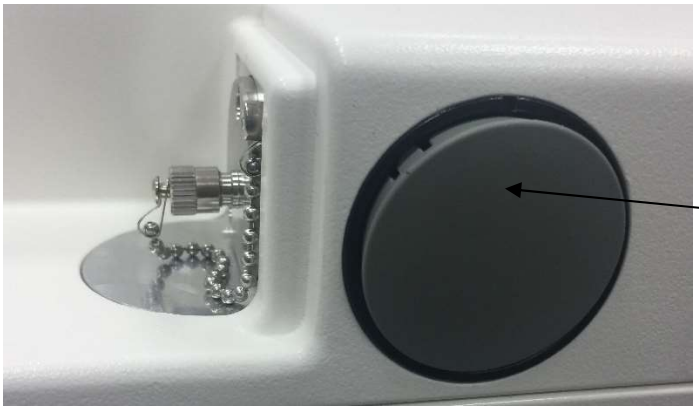
To replace protection window, carry out the following:



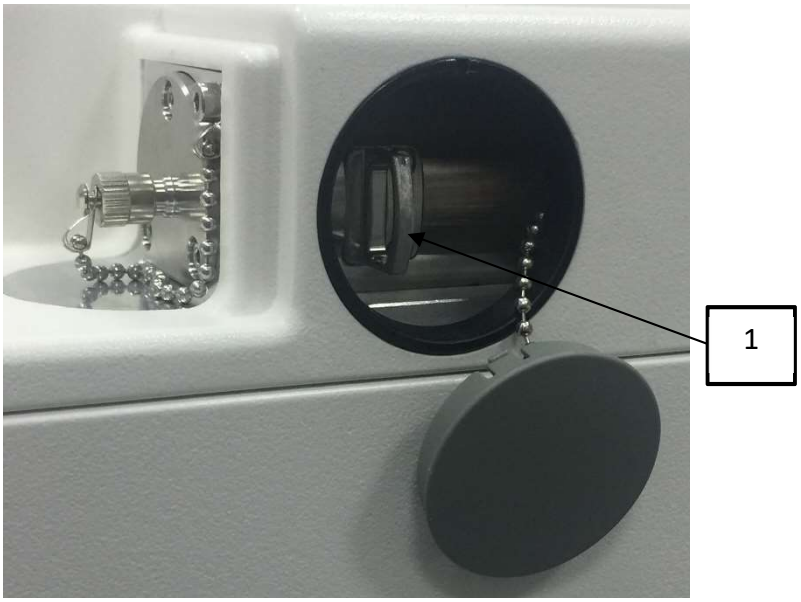
The protective window is located behind the cover (1). To access the protective window, open the cover (1). To do this, place a pointed item (such as a flat screwdriver, tweezers, etc.) in the hole (2).



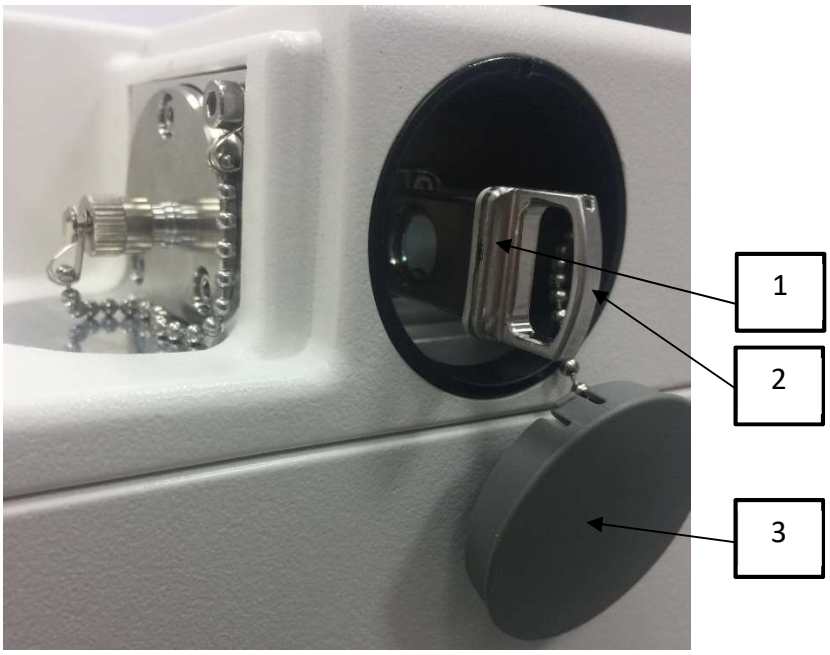
Slightly push the pointed item (3) away from yourself so that the cover (1) moves away from the Device body.



After the cover (1) has moved away from the Device, remove it.



Pull on the protective window (1) to remove it from the optical module of the Device.



Insert new protective window (2) until it stops (ledge (1) on the protective window should be located on the left when installing onto the Device) and close the cover (3). After installing a new protective window with the Device turned on, the error on the screen should disappear.

Possible malfunctions of the Device or fiber, possible causes of the malfunctions and methods of elimination are listed below. If additional assistance it troubleshooting is required, contact manufacturer.

TROUBLESHOOTING

Table 13.

Description of malfunction	Possible cause	Solution
The Device does not start.	• Incorrect connection of the power cord. • Emergency stop button is pressed. • Fuses are burned out.	•Check power cord connection. •Press out emergency stop button. •Replace the fusible elements on the rear panel.
The Device's software is not responding.	• An error occurred in the Device's software.	•Turn off and turn on the Device using the button on the front panel.
After turning on the laser and pressing the foot switch, no radiation is emitted.	• Foot switch cable is damaged or incorrectly connected. • The fiber is failed.	•Check foot switch connection. •Switching to Ready mode and check presence of the pilot laser at the output of the fiber. •If the pointing laser at the output of the fiber is available and connection to the foot switch is correct, contact the manufacturer.

ERROR MESSAGES

Table 14.

No.	A message on the screen	Action
1	Screen is locked. To exit, switch the laser into ‘Standby’.	Switch the Device from “Ready” mode to “Standby” mode.
2	Attention! ‘Red button’ is pressed. In order to continue work with laser, turn the ‘Red button’ clockwise.	Press out emergency stop button on the front panel of the Device.
3	In order to start emission release the pedal and set the device to the ‘Ready’ state.	Press out foot switch and switch the Device to "Ready" mode. Emission in the “Standby” mode is not possible.
4	Attention! The external interlock circuit is open. Connect the interlock to continue.	Interlock on the rear panel is not installed. Install this interlock. If it is lost, contact your Device supplier.
5	Attention! Error of turning on of the power supply. Press and release the emergency stop button.	Press and release emergency stop button. Turn off and turn on the Device using the key. If the error persists, contact your Device supplier.
6	Device failure. Turn off and turn on the device. If the message appears again, contact the manufacturer. Service information:	Turn off and turn on the Device using the button on the front panel. If the error persists, contact your Device supplier.
7	Case temperature (XX.X ˚C) below permissible.	The Device temperature is less than 15°C. It is necessary to warm up the Device to 15°C. If the Device temperature (XX °C) is more than 15°C, contact the Device supplier.
8	Overheating (XX.X ˚C).	The Device temperature is more than 53°C. It is necessary to cool the Device to 53°C. If the Device temperature (XX °C) is less than 53°C, contact the Device supplier.
9	Fiber instrument is missing or damaged. Connect or replace fiber instrument to continue.	Check fiber connection. Reconnect the fiber. Check the fiber connector with a microscope. If the error persists, contact your Device supplier.
10	Protective window is missing. Install protective window to continue.	Check whether the protective window is installed. If the protective window is inserted to full stop and the error persists, contact your Device supplier.
11	Protective window is damaged. Do not turn off the device and replace protective window to continue.	Protective window is damaged. Protective window should be replaced in accordance with Section 4 hereof.
12	Optical head malfunction. Further work may be dangerous. Please contact the manufacturer.	The Device optical module is damaged. Contact the supplier of the Device.
13	The left and right pedals are pressed simultaneously. Please release both pedals and press one pedal corresponding to the selected mode.	The left and right pedals are pressed simultaneously. Make sure there are no foreign objects near the pedal. Depress both pedals and press only one. If the error persists, contact the Device supplier

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