LISA Laser PRODUCTS
An OmniGuide Company

Instructions for use

RevoLix HTL

2micron
Hybrid Thulium Laser

RevoLix HTL

RevoLix HTL cw

RevoLix HTL eco

Content

1 About these instructions for use

These instructions for use provide essential information about the safe handling of the laser devices ***RevoLix HTL***, ***RevoLix HTL cw,*** and ***RevoLix HTL eco*** of the company LISA Laser Products GmbH, Germany (LISA Laser Products).

Information and indications relating only to a specific model are marked.

The instructions for use, the documents mentioned in these instructions for use, and the instructions for use for the laser accessories (including fibres and handpieces) must be carefully read and followed **before the initial use of the laser device!**

Keep these instructions for use for your reference.

Before using the device, read and follow national regulations and instructions on the safe use of laser devices. The rules and notices define areas of responsibility, conditions of use, and occupational health and safety measures.

Subject to technical changes! The illustrations and technical specifications shown in these instructions for use may differ slightly due to further developments.

These instructions for use refer to devices with software from version 01Vxx onwards.

1.1 Signal words in these instructions for use

The safety instructions and warnings in these instructions for use warn of possible risks of injury to patients, users, or third parties or damage to property.

The signal words described below are found in safety-related information that warns the user of hazards and instructs how to avoid them. Warnings are usually given in the instructions for use, where tasks are described in which hazards may occur. Read the warnings carefully and follow the hazard prevention measures.

A collection of general safety instructions can be found in the following chapter.

DANGER	Hazardous situation with a high degree of risk which, if not avoided, will result in death or serious injury.
WARNING	Hazardous situation with a medium degree of risk which, if not avoided, may result in death or serious injury.
CAUTION	Hazardous situation with a low risk level which, if not avoided, may result in minor or moderate injury.
NOTICE	Indicates imminent damage to property.
INFORMATION	Highlights information and recommendations.

1.2 Precautions and safety information

The following section provides essential safety advice and information. Not following the instructions may injure patients, users, or third parties or damage the laser device.

Please also consider the special instructions in other chapters and other related instructions for use.

The ***RevoLix HTL*** laser device may only be used by persons who have a corresponding medical qualification and have been instructed by LISA Laser Products - considering the instructions for use - in the proper handling.

Any serious incident (i.e., the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat) occurring in relation to the device must be reported immediately to LISA Laser Products and the national competent authority responsible for medical device surveillance.

⚠ WARNING

Laser radiation

The working laser emits Class 4 invisible laser radiation. Direct, reflective or scattered laser radiation can cause severe eye injury and skin burns.

- Never look directly into the laser beam.
- Do not aim the laser beam at reflective surfaces or instruments.
- Never point the laser beam at other people.
- Wear suitable safety goggles.

⚠ WARNING

Flammable materials and gases

Flammable materials and gases (including endogenous gases) may ignite due to laser radiation and cause severe burns or poisoning and chemical burns.

- Do not use the laser radiation in an explosive atmosphere (oxygen-enriched air).
- Do not aim the laser radiation at flammable gases, liquids or other substances. The flammability of methane gas must also be considered when treating in or near the perianal area
- Do not aim the laser radiation at flammable material and tissue.
- Use suitable non-flammable tubes and drapes for laser surgery etc.
- When using flammable disinfectants, ensure adequate drying.

⚠ WARNING

Providing a wrong operating mode due to a malfunction of the laser device.

The delivery of laser radiation in the wrong operating mode can cause unexpected tissue interaction and result in serious injury and severe thermal tissue damage.

- Check the selection of the operating mode (CW / PULSED) before starting the laser application.
- Use the CW operating mode for soft tissue indications
- Use the PULSED operation mode for laser lithotripsy
- Only trigger the emission if the effect of the laser radiation - the distal end of the fibre and the tissue - can be observed.

⚠ WARNING

A modification of the constructional or functional characteristics of the ***RevoLix HTL*** laser device is not permitted.

The laser device must not be disposed of by household waste.

2 Delivery

2.1 Scope of delivery

RevoLix HTL laser devices are delivered with the following standard scope of supply:

Tab. 1: Standard scope of supply

Lot	Included items
1	***RevoLix HTL*** Laser Device
1	Door Interlock Dummy Plug (REF 101 600 166)
1	Instructions for use
2	Key (REF 101 610 002)
1	Single-pedal footswitch ***Kix*** (REF 101 630 147) Alternatively: Double-pedal footswitch ***Kix DUO*** (REF 101 630 144)

3 Product description

This chapter contains a description of the intended purpose, contraindications and side effects, the user requirements, and controls and features.

3.1 Identification of the model

The model name, the power range (max. power), and the wavelength of the emitted radiation can be found on the type plate (Fig. 15).

After starting the laser device, the model name is shown on the start image on the screen (Fig. 39).

An overview of the different models is given in the table below. A detailed technical datasheet can be found in Chapter 12.

Tab. 2: Description of the different models of the *RevoLix HTL* laser device

Model	***RevoLix HTL***	***RevoLix HTL cw***	***RevoLix HTL eco***
Wavelength	2013 ±10 nm	2013 ±10 nm	2013 ±10 nm
Average Power	5 - 150 W (±20 %)	5 - 150 W (±20 %)	5 - 75 W (±20 %)
Pulse peak power (PULSED)	max. 1300 W	N/A	max. 1300 W
Pulse energy (PULSED)	max. 4.5 J (±20 %)	N/A	max. 4.5 J (±20 %)
Pulse Repetition rate (PULSED)	5 - 300 Hz (±5 %)	N/A	5 - 300 Hz (±5 %)
Pulse duration (PULSED)	200 µs - 4750 µs Depending on the parameter setting	N/A	200 µs - 4750 µs Depending on the parameter setting

3.2 General description

The ***RevoLix HTL*** laser device is a Thulium:YAG laser emitting radiation of 2013 nm (±10 nm) in wavelength. This wavelength is in the invisible infrared range.

The ***RevoLix HTL*** laser device offers a combination of two operating modes. In the continuous-wave (CW) operation mode, laser radiation is emitted continuously. The CW mode is used for soft tissue indications. In PULSED mode, laser pulses are emitted at an adjustable frequency. The peak power of these individual pulses is higher than their average power over the same time interval. The PULSED mode is used for laser lithotripsy.

The laser radiation is transmitted through a fibre made of quartz glass, and its distal end is connected to a suitable applicator. Various applicators are available and tailored to serve specific clinical applications.

The laser device is operated via a control console equipped with a screen. Laser radiation can be emitted by pressing a foot pedal of a footswitch.

RevoLix HTL laser devices comply with the "General Safety and Performance Requirements" of the Regulation (EU) 2017/745 on Medical Devices.

3.2.1 Expected service life

RevoLix HTL laser devices are designed for a service life of 10 years if used as intended, regularly maintained, and tested under the specifications in these instructions for use.

3.3 Intended use / Intended purpose

RevoLix HTL is a surgical laser used in CW operation for non-invasive, invasive and surgically invasive incision, excision, resection, removal, evaporation (vaporization) and coagulation of soft tissue in the field of urology. The PULSED operation of the laser is used for the invasive and surgically invasive fragmentation and dusting of stones in the urogenital tract (bladder, ureter, kidney), and for laser enucleation of the prostate.

3.4 Indications for Use

RevoLix HTL is intended for soft tissue treatments and lithotripsy in the field of urology for the treatment of: Neoplasms of the urinary organs (kidney, ureter, urinary bladder and urethra); neoplasms of the male genital organs (penis); ureteral and urethral strictures; bladder neck obstructions; prostatic hyperplasia; condylomas; stones in the lower urinary tract and kidney and ureteral stones.

3.5 Contraindications

RevoLix HTL is not indented for direct application on the central nervous system and on the cardiovascular system and for ophthalmological applications.

The contraindications of surgical and endoscopic laser interventions generally correspond to those of conventional endoscopic or surgical procedures in the respective field of application.

Contraindications are intolerance to surgical or endoscopic procedures, intolerance to anaesthesia, untreated infections (e.g. the genitourinary tract), pregnancy, sepsis.

The user must decide based on the patient's condition whether an intervention can be performed with the ***RevoLix HTL*** laser device.

Treatments of patients with coagulation disorders or under anti-coagulation therapy are subject to special risks. The conduct of such treatment must be assessed on a case-by-case basis by the attending physician and taking into account current scientific findings. The final decision on the procedure is the responsibility of the attending physician.

3.6 Side effects

The side effects of surgical and endoscopic laser interventions generally correspond to those of conventional endoscopic or surgical interventions in the respective field of application.

The main complications are pain, infections, fever, bleeding, perforations, trauma and edema. Laser radiation can cause thermal tissue damage.

3.7 Authorised users

The ***RevoLix HTL*** laser device may only be used by persons who have a corresponding medical qualification and have been instructed by LISA Laser Products - considering the instructions for use - in the proper handling.

Only persons who, based on their knowledge and practical experience, are suitable for handling the laser device may be admitted. Records must be kept of the training.

The re-processing of the laser fibres and other accessories may only be carried out by trained professionals.

3.8 Classification

RevoLix HTL is a ‚medical device' according to the definition of 2017/745 Art. 2 (1) intended to be used for human beings for the treatment of disease.

The laser device is categorised into the following classifications and nomenclatures:

Tab. 3: Classifications

Medical device class according to Council Directive 93/42/EEC (MDD)	IIb
Medical device class according to Regulation (EU) 2017/745 (MDR)	IIb
Medical device nomenclature according to EMDN	Z12011006
Medical device nomenclature according to GMDN	36170
Basic UDI-DI	42503419RevoLixHTLCV
Laser class according to IEC 60825-1 (working laser)	4
Laser class according to IEC 60825-1 (aiming laser)	3R
Protection class according to IEC 61140	I
Degrees of Protection according to IEC 60529	IP20
Applied part according to IEC 60601-1	BF

3.9 Applied part

The applied part of the laser device is the distal end of the laser fibre, including the length of the laser fibre that is inserted into the instrument.

When the laser fibre is connected to the device, the laser has a Class BF applied part.

3.10 Controls and indicators

The controls and indicators are divided into three areas. They are located at the front (Fig. 1) and back (Fig. 2 and Fig. 3) of the device, as well as attached to the control console (Fig. 6).

3.10.1 Front

The fibre holder, fibre connector (fibre coupler), control console, light stripes, laser stop, key switch, footswitch connector, and parking brake are located at the front of the device.

Fig. 1: Front

3.10.2 Back

The back of the laser device features the type plate, the door interlock connector, the potential equalisation connector, another parking brake, the power cable, and the storage compartment for the footswitch.

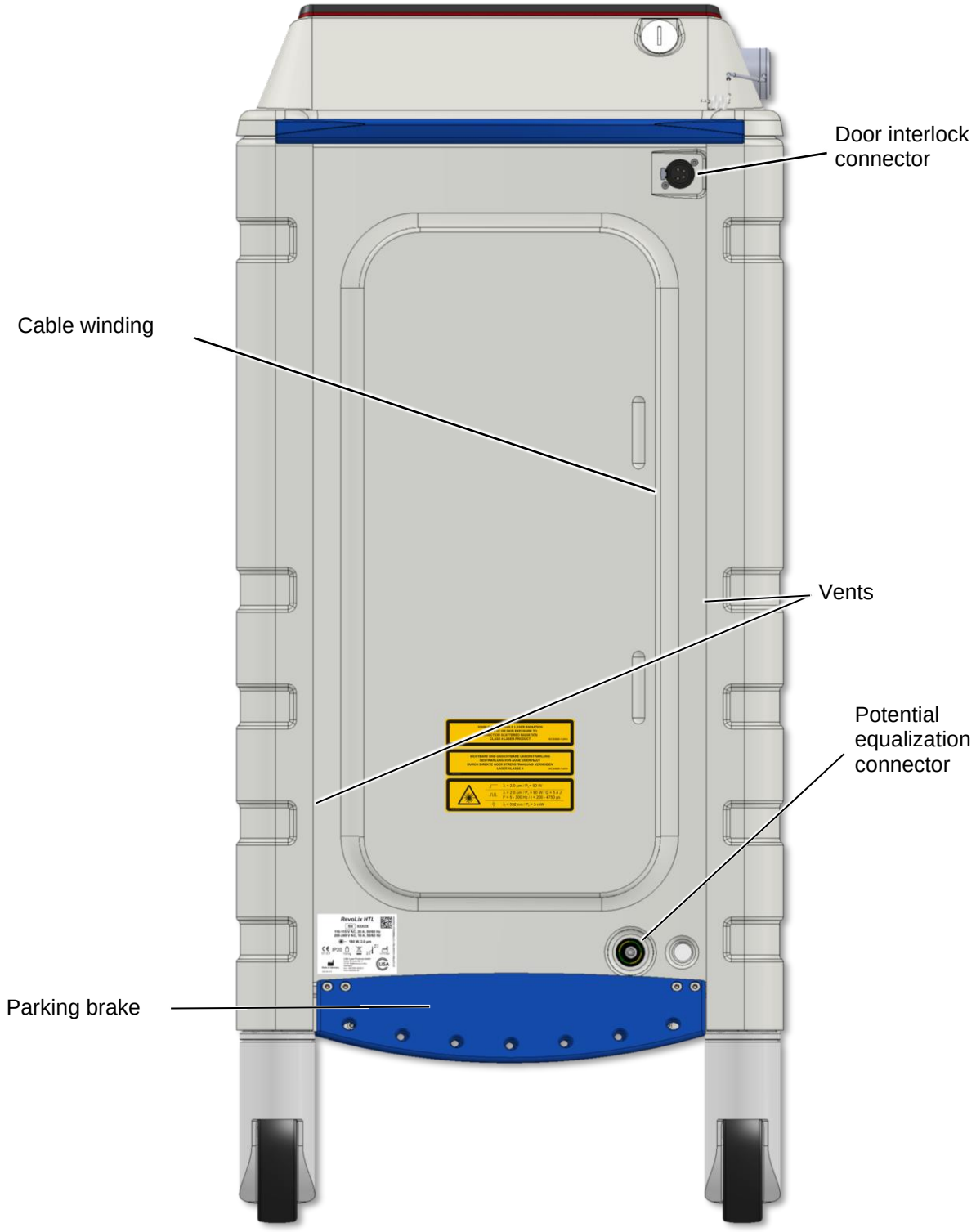


Fig. 2: Back

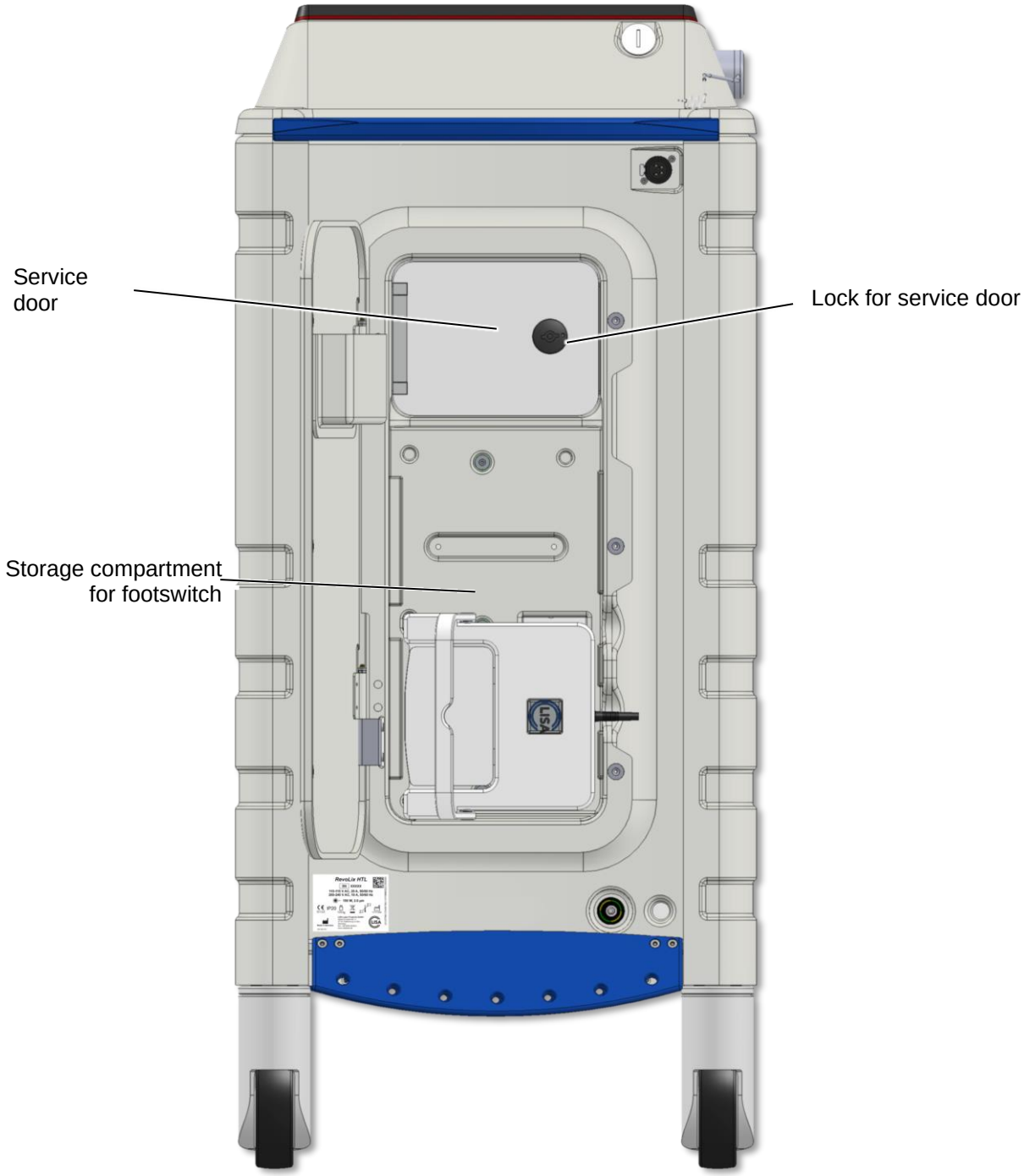


Fig. 3: Back (Laser housing with open footswitch storage compartment)

3.10.3 Footswitch

The footswitch is the control switch for laser emission. If the laser device is in the LASER READY mode, laser radiation can be emitted by pressing the footswitch pedal.

Two footswitch versions are available: the ***Kix*** single-pedal footswitch and the ***Kix DUO*** double-pedal footswitch. The double-pedal footswitch offers an extended range of functions.

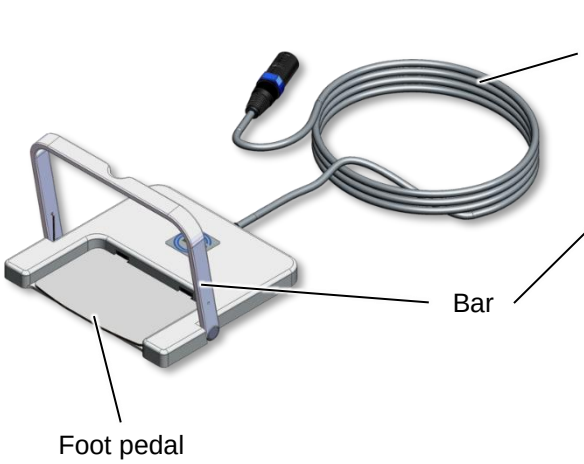


Fig. 4: Single-pedal footswitch *Kix*

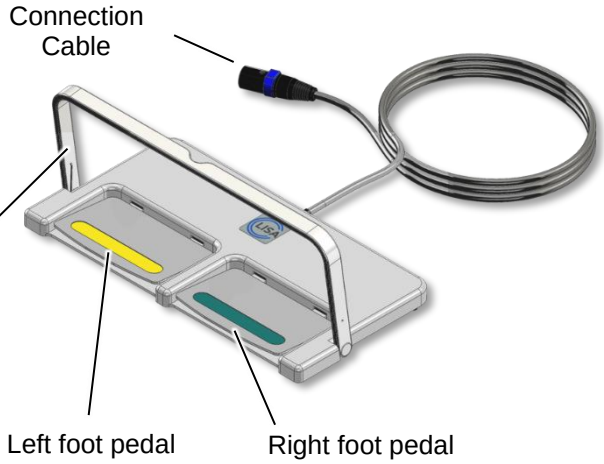


Fig. 5: Double-pedal footswitch *Kix DUO*

3.10.4 Control console

All communication between the user and the laser device is carried out using the control console.

Changing the laser parameter settings and switching between the different operating modes of the laser device are done using the touch screen and the ready-slider.

Fig. 6: Control panel

1	Fibre connector	3	Touch Screen
2	Status icons	4	Ready-Slider

3.10.5 Screen elements

The screen in Fig. 7 shows the laser parameters and is subdivided into four areas.

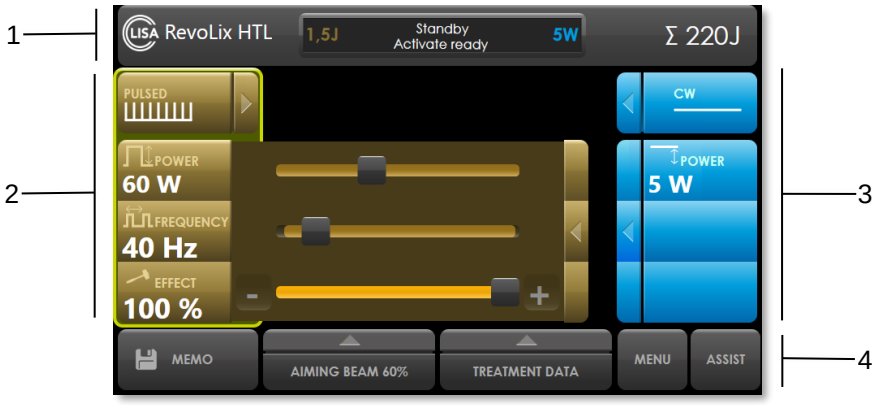


Fig. 7: Areas of the touch screen

1	A status bar containing the name of the laser device, the set power (CW) or pulse energy (PULSED), the system status, and a counter for the emitted energy (sums the emitted energy since the last reset [J])
2	The controls and display elements of the laser parameters of either the single-pedal footswitch *Kix,* or the left foot pedal of the double-pedal footswitch *Kix DUO*
3	The controls and display element of the laser parameters of the right foot pedal of the *Kix DUO* double-pedal footswitch. When a single-pedal footswitch is connected, this part is inactive.
4	Menus to change the brightness level of the aiming beam, obtain statistical information on the use of the laser device, to save and load laser setting using the MEMO function, device information and contact data of the manufacturer, to change the language to English (ASSIST)

3.10.6 Menu structure of the touch screen control

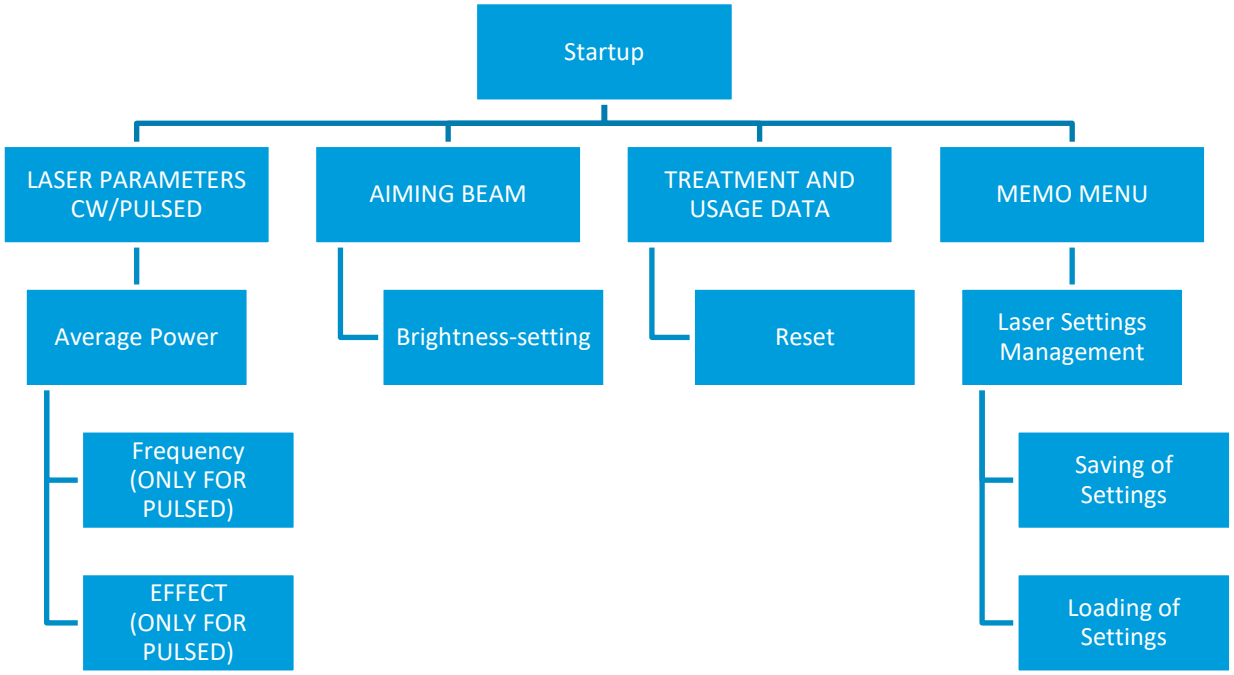


Fig. 8: Menu structure

3.10.7 Status icons

The status icons give detailed information about operating states or states of functions of the ***RevoLix HTL*** laser device.

Tab. 4: Status Icons

Icons	Function	Status	Colour
	Interlock	Interlock is open	Red
		Interlock is closed	Green
	Fibre	Fibre is connected	Green
	Billing	Billing system blocks the laser device	Red
		Billing system is active	Green
		Laser device is not equipped with a billing system.	-
	Device condition	Device is switched on	Green
	Device error	Device error	Red
	Left footswitch pedal	Single-pedal footswitch or left foot pedal of the double-pedal footswitch is connected	Green
		Footswitch pedal is pressed	Yellow
	Right footswitch pedal	Right foot pedal of the double-pedal footswitch is connected	Green
		Footswitch pedal is pressed	Yellow
	Laser emission	Laser is active	Green
		Maximum value of laser pump energy has been reached	Yellow

3.10.8 Optical and acoustic signals

The different operating states of the laser device can be recognized by various acoustic and optical signals.

The laser warning light ribbon around the control console indicates the device's operating state and the laser emission. Additionally, the light elements of the ready-slider and the light stripes located at the front at the lateral openings of the housing change colour depending on the device's operating state.

Moreover, the device's operating states are indicated by acoustic signals, such as a slowly and quickly periodically beeping sound, depending on the mode of emitted laser radiation. Additionally, switching from the STANDBY operating state to LASER READY can be noticed by a short confirmation sound.

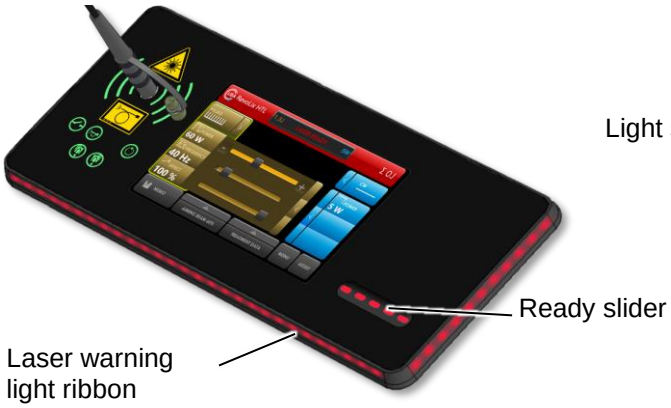


Fig. 9: Laser warning light ribbon

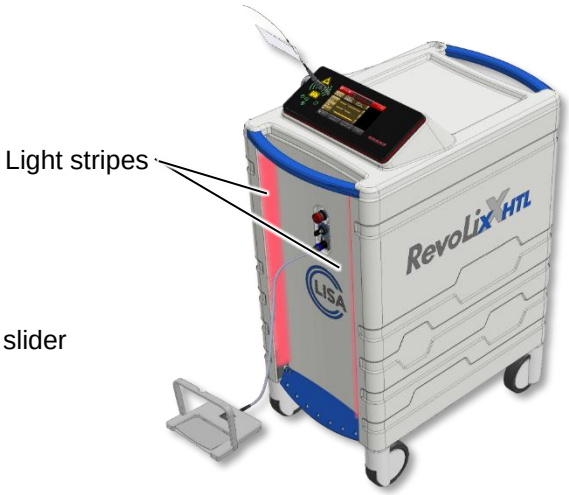


Fig. 10: Light stripes

Tab. 5: Optical and acoustic signals

Operating states	**optical/acoustic signals**
Startup	During the system test, the laser warning light ribbon lights up briefly due to the internal functional test. At the same time, the start-up melody of the laser device is playing.
Switching between STANDBY – LASER READY	By using the ready-slider on the control console, the laser device switches from the STANDBY to the LASER READY operating state, which is confirmed by a short beeping sound, and the laser warning light ribbon shines continuously in red (laser ready indicator).
EMISSION (PULSED)	The emission of pulsed laser radiation is signalled by a slowly periodically beeping sound and a red blinking laser warning light ribbon (laser emission indicator).
EMISSION (CW)	The emission of CW laser radiation is signalled by a quickly periodically beeping sound and a red blinking laser warning light ribbon (laser emission indicator).
Switching between the pedals of the *Kix DUO*	Switching between the different pedals of the ***Kix DUO*** double pedal footswitch is indicated and thus confirmed by a short clicking sound.

3.10.9 Emergency Laser Stop

The laser device is equipped with a laser stop button (laser stop) located at the front of the laser device (Fig. 1). By pressing the laser stop button, the emission of laser radiation interrupts immediately.

After the hazardous situation has been cleared, the laser stop can be released by turning it leftwards. Then follow the steps indicated in the display.

Ensure that the laser stop is always easily accessible during the operation of the laser device.

3.10.10 Key-switch

The key-switch (Fig. 1) turns the laser device on or off. In the OFF position, the key is removable, and thus the laser device can be secured against unauthorised use.

3.10.11 Aiming laser

The laser device is equipped with an aiming laser, whose beam is only visible in the LASER READY and LASER EMISSION operating states. The beam marks the emission area of the working laser.

The brightness of the aiming beam is adjustable (0 – 100 %).

CAUTION

Visible laser radiation

When looking directly into the aiming beam, glare, impairment of colour vision or irritation of the eyes can occur.

- Do not direct the aiming beam at persons.
- Avoid direct radiation to the eyes.
- In case of direct radiation, close your eyes immediately or turn your eyes out of the laser beam.

3.11 Laser fibre

The laser device and laser fibre are connected by a fibre coupler (Fig. 1). The laser fibre is made of quartz glass and guides the laser beam to the target.
Various laser fibres are available for the ***RevoLix HTL*** laser device (Chapter 9 "Accessories"). The laser fibres differ in core and outer diameter, mechanical flexibility, and beam direction.

The choice of a suitable laser fibre for a specific medical application depends on the compatibility of the laser fibre with the utilised instrument/applicator and the desired mechanical properties (e.g., flexibility) that are required to perform a particular treatment.

WARNING

Use of incompatible laser fibres

Incompatible or unsuitable laser fibres can be damaged during use. The breakage may cause unintended emission of laser radiation and may result in heat, tissue damage and burns.

- Only use laser fibres that are suitable for the ***RevoLix HTL*** laser device and are expressly approved by LISA Laser Products for use with this laser device.
- Consider possible performance limitations of the laser fibres.
- Consider the prescribed minimum bending radius for the laser fibre.

3.12 Fibre holder

Rotate the fibre holder [1.] to the desired position and then pass the laser fibre through the fibre holder [2.].

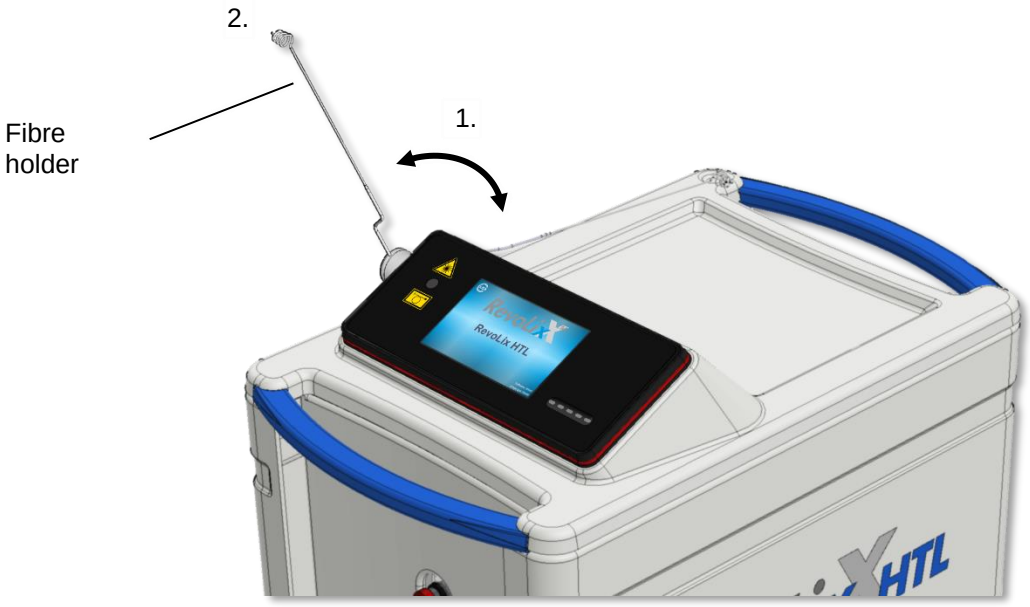


Fig. 11: Fibre holder

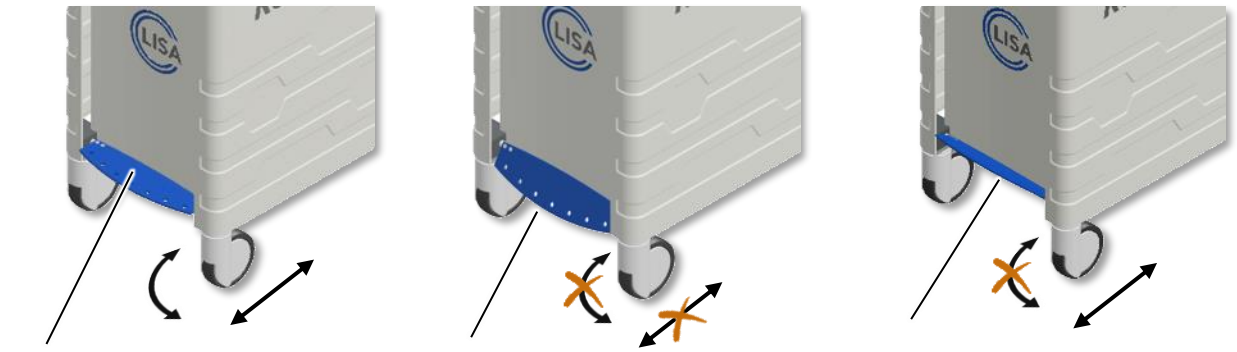
3.13 Parking brakes

The parking brakes are located at the front and back of the laser device. Each pedal only controls its corresponding pair of wheels.

If the pedal is in the centre position (Pos. A), the brakes are released, and the wheels roll and swivel freely.

If the pedal is pressed down (Pos. B), the brakes are activated, and the wheels are entirely blocked.

If the pedal is pushed up to the top (Pos. C), the brakes only block the swivel movement of the wheels, but the wheels can still roll.



Position A
Parking brake released
Wheels swivel and roll

Position B
Parking brake activated

Position C
Parking brake partially activated
Wheels do not swivel but roll

Fig. 12: Parking brakes

3.14 Fume extraction systems

In open laser surgery, potentially infectious material or cell debris can become airborne via laser fumes. The laser fumes should be extracted as close as possible to the source (recommended filter specification according to IEC/TR 60825-8 – ULPA filter with retention efficiency of at least 99.999 % for particle sizes of at least 0.1 µm).

4 Installation of the laser device

The laser device should only be installed by a trained and authorised professional.

The installation of the ***RevoLix HTL*** laser device needs to meet specific requirements for safety precautions, power supply, and air conditioning. Before operating the laser device, make sure to comply with the regulations for laser equipment and active medical devices and notify the relevant authorities, such as trade associations, responsible for occupational health and safety.

The relevant national regulations and health measures regarding the safe use of medical devices and laser equipment must be followed. Information on laser safety and necessary safety measures can be found in the chap. 5 “Laser safety.”

4.1 Unpacking

The laser devices are usually delivered unpackaged. Remove existing protective films, edge protection, and transport pads before operating the device.

The keys and the door interlock dummy plug that come with the device are packed separately.

If the laser device is delivered in a wooden transport box, you should unpack the laser device together with an authorised LISA Laser Products representative to avoid possible damage.

4.2 Mains supply

All ***RevoLix HTL*** laser devices require a single-phase mains connection. The connection may be made to a TN-S or IT system, which should not be used by an additional device consuming electricity to avoid overloading the circuit.

The exact requirements of the laser device can be found on the type plate.

WARNING

Danger from electric current

To avoid the risk of electric shock, this device may only be connected to a supply mains with protective earth.

The laser device internally monitors the supply voltage. If the supply voltage is outside the permitted range, a warning tone sequence sounds, and a message appears on the screen. In such a case, check the connection requirements and the electric installations of the building.

If you have any questions about the installation, please contact LISA Laser Products Customer Service.

Tab. 6: Requirements for the power supply

Mains supply	200 - 240 V, 50/60 Hz, max. 10 A, 1~/N/PE 110 - 115 V, 50/60 Hz, max. 20 A, 1~/N/PE *(Automatic switching)*
Power consumption	max. 2.2 kVA
Mains plug	country-specific

INFORMATION

The mains plug is used as the supply mains isolation device.

Place the laser device in such a way that access to the mains plug of the power supply cord is ensured at all times so that the laser device can be completely disconnected from the supply mains.

The laser device is equipped with a non-detachable power cord, which cannot be individually replaced by maintenance personnel. In case of a power cord defect, please contact LISA Laser Products Customer Service.

4.3 Door interlock switch

The socket for the door-interlock switch is located at the device's back (Fig. 2). If the door interlock is interrupted, the laser emission deactivates immediately. After closing the door interlock, the laser device can be operated again by using the ready-slider.

If no door interlock is used, plug in the complimentary dummy plug into the free socket to bridge PINs 1 and 3. LISA Laser Products Customer Service provides detailed information on connecting the door interlock switch.

4.4 Potential equalisation

The use of additional potential equalisation may be necessary to compensate for different electrical potentials or to minimise electric potential differences that may occur between medical electrical devices and conductive parts of other devices. Insert the appropriate potential equalisation cable into the potential equalisation port at the back of the laser device (Fig. 2).

In this context, also comply with the requirements of IEC 60601-1 for medical electrical systems.

4.5 Operating Conditions

During operation, the temperature should be between 15 °C and 28 °C, the relative humidity between 10 % and 90 % (non-condensing), and the air pressure between 700 hPa and 1060 hPa.

The laser device can be operated continuously at an ambient temperature of up to 28 °C. The laser source switches off automatically if the coolant temperature is too high.

If the laser device was stored or transported at a temperature outside its operating temperature (15 °C to 28 °C), the laser device must first adapt to the ambient temperature at the new operating location. At large temperature differences, this takes up to 3 hours.

During operation, ensure that the laser device is not exposed to strong shocks or vibrations.

4.6 Cooling

The ***RevoLix HTL*** laser device has an integrated cooling system.

During operation, the cooling system releases its excess heat to the surroundings by emitting an airstream from the laser device's ventilation openings located beneath the laser device. Thus, in rooms without air-conditioning, the temperature might increase accordingly.

No additional cooling water or gas connection is required.

INFORMATION

In case of insufficient air circulation, the laser device can heat up strongly.

- The ventilation openings at the front and back of the laser device (Fig. 13) must not be covered during the operation.

Fig. 13: Ventilation openings

4.7 Electromagnetic Compatibility (EMC)

Medical electrical equipment such as the ***RevoLix HTL*** laser device is subject to special precautions with regard to EMC and must be put into operation in accordance with the instructions in these instructions for use.

4.7.1 EMC - Operating Environment

The use of the ***RevoLix HTL*** laser device may only take place in professional healthcare facilities, including clinics, independent surgery centres, operating theatres and endoscopy rooms.

The ***RevoLix HTL*** laser device may also be operated in rooms where HF surgical devices are also used.

⚠ CAUTION

Use of the ***RevoLix HTL*** laser device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, ***RevoLix HTL*** laser device and the other equipment should be observed to verify that they are operating normally.

The ***RevoLix HTL*** laser device is not intended for use in home health care and should not be connected to a public supply network that also supplies buildings used for residential purposes. The characteristics of the ***RevoLix HTL*** laser device (CISPR 11, Class A) determined by dispatches may not provide adequate protection of radio services in the residential area. The ***RevoLix HTL*** laser device is only for use with original accessories and cables, as in Tab. 7 specified, determined.

Tab. 7: Cable lengths of the accessory

Accessories	**Ref**	**Length**
Potential equalization cable	101 630 123	5.0 m
Footswitch ***Kix***	101 630 147	2.9 m
Footswitch ***Kix DUO***	101 630 144	2.9 m

⚠ CAUTION

The use of accessories, transducers and cables other than those specified or provided by LISA Laser Products could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ CAUTION

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (or 12 inches) to any part of the ***RevoLix HTL*** laser device, including specified cables. Otherwise, degradation of the performance of this equipment could result.

4.7.2 Electromagnetic emissions and immunity

The ***RevoLix HTL*** laser device complies with the requirements of IEC 60601-1-2:2014 (Electromagnetic disturbances - requirements and tests) and additional standards. In the following, the test methods, classifications and test levels complied with as well as the compliance with basic EMC standards are listed in detail.

Tab. 8: Conformity of electromagnetic immunity

Testing requirement	Basic standard/test procedure	Ports	Test level
Immunity to electrostatic discharge (ESD)	IEC 61000-4-2:2008	Enclosure port	Contact discharge ± 8 kV Air discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
		SIP/SOP	Contact discharge ± 8 kV Air discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Immunity to high-frequency electromagnetic fields	IEC 61000-4-3:2006 + AMD1:2007 + AMD2:2010	Enclosure port	80 MHz to 2.7 GHz, 3V/m 80% AM at 1 kHz
	ETSI EN 301 489-3 V2.1.1 (2019-03)	Enclosure port	80 MHz to 6 GHz, 3V/m 80% AM at 1 kHz
Immunity to near fields of wireless RF communication devices	IEC 61000-4-3:2006 + AMD1:2007 + AMD2:2010	Enclosure port	385 MHz - 27 V/m, PM 18 Hz 450 MHz - 28 V/m, FM x 5 kHz 710 - 780 MHz - 9 V/m, PM 217 Hz 810 - 930 MHz - 28 V/m, PM 18 Hz 1720 - 2450 MHz - 28 V/m, PM 217 Hz 5240 - 5785 MHz - 9 V/m, PM 217 Hz
Immunity to fast transient electrical disturbances/burst	IEC 61000-4-4:2012	Power supply cord SIP/SOP	± 2 kV, 100 kHz frequency ± 1 kV, 100 kHz frequency
Immunity against surge voltages	IEC 61000-4-5:2005	Power supply cord	Line against line ± 0.5 kV, ± 1 kV Line against ground ± 0.5 kV, ± 1 kV, ± 2 kV
Immunity to conductive interference, induced by high-frequency fields	IEC 61000-4-6:2013	Power supply cord	0.15 MHz to 80 MHz - 3 V ISM Frequency Bands - 6 V 80 % AM at 1 kHz
		SIP/SOP	0.15 MHz to 80 MHz - 3 V ISM Frequency Bands - 6 V 80 % AM at 1 kHz
Immunity to magnetic fields with energy-related frequencies	IEC 61000-4-8:2009	Enclosure port	30 A/m, 50 Hz/60 Hz
	IEC 61000-4-39:2017	Enclosure port	134.2 kHz, 65 A/m, PM 2.1 kHz 13.56 MHz, 7.5 A/m, PM 50 kHz
Immunity to voltage drops, short-time interruptions and voltage fluctuations	IEC 61000-4-11:2004	Power supply cord	0 % U_T; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % U_T; 1 period at 0 degrees 70 % U_T; 25 periods at 0 degrees 0 % U_T; 250 periods U_T is the AC mains voltage before applying the test levels.

Tab. 9: Conformity of electromagnetic emissions

Testing requirement	Basic standard/test procedure	Accordance
Conducted and radiated emissions	CISPR 11:2009 + AMD1:2010	Class A Group 1
Electromagnetic compatibility of multimedia equipment - Emission Requirements	CISPR 32:2015 + AMD1:2019	Limits for the specified frequency range for class A (1 GHz to 6 GHz)
Distortions due to harmonics	IEC 61000-3-2:2005 + AMD1:2008 + AMD2:2009	n/a No limit is set for professional devices with power consumption > 1 kW.
Limitation of voltage changes, voltage fluctuations and flicker	IEC 61000-3-3:2013	Matches

Tab. 10: Performance conformity of radio equipment

Testing requirement	Basic standard/test procedure	Test level / Accordance
Performance and test requirements for radio Short Range Devices (SRD) in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz	ETSI EN 300 330 V2.1.1 (2017-02)	Matches

4.7.3 Electrosurgical interference

The use of the recommended tests in accordance with IEC 60601-2-2, Annex BB.4, has proven that the function of the ***RevoLix HTL*** laser device is not impaired by electrosurgical devices, and the ***RevoLix HTL*** laser device can be operated in rooms where HF surgical devices are also used.

Tab. 11: Electrosurgical interference

Testing requirement	Basic standard/test procedure	Port	Test level
Interference caused by HF surgical equipment	IEC 60601-2-2:2009 Annex BB.4	Enclosure SIP/SOP Power supply cord	Generation of strong E-fields and H-fields by monopolar cutting and coagulating with an electrosurgical device

4.8 Transport and storage

When transporting and storing the laser, the temperature must be between 0 °C and +70 °C, the relative humidity between 10 % to 90 % (non-condensing) and the air pressure 700 hPa to 1060 hPa.

If there is a risk of the ambient temperature falling below 0 °C, the coolant must be discharged from the laser unit by a service technician. Before commissioning the laser device, the cooling fluid must be replenished. Both the discharge and the filling of the laser device with cooling fluid may only be carried out by a specialist authorised by LISA Laser Products.

4.9 Functional test before the first commissioning

Before the first commissioning by the operator, a functional test according to the manufacturer's specifications must be carried out and recorded at the place of operation. A form is available and can be requested from LISA Laser Products.

5 Laser safety

The ***RevoLix HTL*** laser device emits laser radiation class 4. Irradiation of persons can cause injuries to the skin and eyes. Become familiar with laser safety protections.

⚠ WARNING

Laser radiation

The working laser emits Class 4 invisible laser radiation. Direct, reflective, or scattered laser radiation can cause severe eye injury and skin burns.

- Never look directly into the laser beam.
- Do not aim the laser beam at reflective surfaces or instruments.
- Never point the laser beam at other people.
- Wear suitable safety goggles.

5.1 General information

The ***RevoLix HTL*** laser device uses a DPSS **(D**iode **P**umped **S**olid **S**tate) laser with a wavelength of 2013 nm (2.013 µm) as a working beam.

The aiming laser is a semiconductor laser with 532 nm emission wavelength (green). This aiming laser corresponds to the laser Class 3R.

Please comply with national occupational health and safety regulations and accident prevention regulations, which may place additional requirements and specifications for laser protection measures and the designation of a laser safety officer to operate medical laser devices.

5.2 Safety Distance (NOHD, Nominal Ocular Hazard Distance)

Since the laser radiation emitted by the fibre is radiated divergently, the power density decreases with increasing distance from the laser beam source. The nominal ocular hazard distance (NOHD) is the distance at which the power density is equal to the maximum permissible irradiation. The maximum permissible exposure (MPE) is the relevant limiting value for the cornea of the eye, which is the basis for the calculation of the NOHD.

The NOHD is calculated according to the standard (IEC 60825-1, "Safety of Laser Devices").

The calculation of the MPE, in which the laser radiation is considered as a sequence of single pulses (pulse train), provides the most restrictive NOHD value.

Tab. 12: Calculation of the NOHD for the continuous-wave laser radiation of the *RevoLix HTL* laser devices

Wavelength	λ = 2013 nm
Numerical aperture of the fibre	NA = 0.2
Opening angle	Φ = 2 * arcsin (NA) Φ = 23.1° = 0.403 rad
Fibre core diameter	d = 200 µm
Average performance	P_0 = 150 W + 20 % = 180 W
Time base	t = 10 s (for wavelengths > 1400 nm)

MPE (maximum permissible exposure)	1000 Wm^{-2}
NOHD	$NOHD_{CW} = \frac{\sqrt{\frac{4P_0}{\pi E_{MPE}}} - d}{\Phi}$ $NOHD_{CW} = \frac{\sqrt{\frac{4 \cdot 180\ W}{\pi \cdot 1000\ Wm^{-2}}} - 200 \cdot 10^{-6}\ m}{0.403\ rad} = 1.19\ m$
The NOHD (safety distance) for the continuous-wave laser radiation of the *RevoLix HTL* laser devices is 1.19 m.	

Tab. 13: Calculation of the NOHD for the pulsed laser radiation of the RevoLix HTL laser devices

Wavelength	λ = 2013 nm
Numerical aperture of the fibre	NA = 0.2
Opening angle	Φ = 2 * arcsin (NA) Φ = 23.1° = 0.403 rad
Fibre core diameter	d = 200 µm
Maximum energy	E_0 = 4.5 J + 20% = 5.4 J
Frequency at maximum energy	33 Hz
MPE (maximum permissible exposure)	$MPE = 10^3 \times (33\ Hz \times 10\ s)^{-0.25} \left[J/m^2 \right]$ $MPE = 235\ J/m^2$
NOHD	$NOHD = \frac{\sqrt{\frac{4E_0}{\pi MPE}} - d}{\Phi}$ $NOHD = \frac{\sqrt{\frac{4 \cdot 5.4\ J}{\pi \times 235\ Jm^{-2}}} - 200 \cdot 10^{-6}\ m}{0.403\ rad} = 0.38\ m$
The NOHD (safety distance) for the pulsed laser radiation of the *RevoLix HTL* laser devices is 0.38 m.	

5.3 Laser safety eyewear

As soon as the laser device is laser emission ready, all persons present in the area surrounding the laser must wear suitable laser safety eyewear.
The laser safety eyewear must have at least the DLB3 protection level for continuous-wave mode laser emission and the ILB3 protection level for pulsed laser emission at the wavelengths of the laser device. The laser safety eyewear should be specified and tested in accordance with EN 207 and must have a CE mark.

Tab. 14: Laser safety eyewear

Protection level	Wavelength
minimum DLB3 + ILB3	2013 nm

For safety reasons, we recommend using only laser safety eyewear supplied by LISA Laser Products. It is not recommended to use other laser safety eyewear as it may not provide the necessary protection.

5.3.1 Identification of laser safety eyewear in accordance with EN 207

Laser safety eyewear that meets the requirements of EN 207 is marked with the appropriate protection level.

Tab. 15: Example of marking laser safety eyewear

Element	Description
DI	Laser type D = continuous-wave / I = pulse
<1400nm – 1000µm	valid wavelength range
LB3	Protection Level (LB1 – LB10) LB3 = maximum spectral transmittance of 10^{-3}
XXX	Identification of the manufacturer
DIN CE	Signifies conformity to EN 207

5.4 Laser area

The laser area is surrounding the laser device in which the laser radiation might exceed the maximum permissible exposure of the eye's cornea (MPE), including the possibility of accidental deflection of the laser beam.

In general, the laser area encompasses the entire room in which the laser device is operated.

Laser areas of Class 4 laser devices must be delimited during laser operation and marked by warning signs (laser warning symbol W004 - ISO 7010). Additionally, warning lamps indicating the operation of the laser should be installed at the entrance to laser areas.

Fig. 14: Warning sign intended for entrance doors to mark laser areas

6 Labelling of the laser device

The following symbols label the ***RevoLix HTL*** laser device and therefore provide the user with important information. The positions of the individual labels can be found in the illustrations in Chapter 6.4.4.

6.1 Symbols used

The following symbols are used on the outside of the laser device:

Tab. 16: Symbols on the outside of the laser device

						
Follow instructions for use	Application part BF	Footswitch	Potential equalisation	Key switch (ON / OFF)	OFF	ON

6.2 Type plate - Laser device

The type plate is attached to the back of the device (Fig. 24). It contains all essential information for identifying the laser device and the specifications of the mains supply.

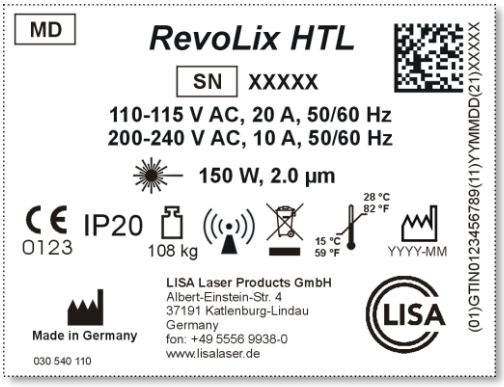


Fig. 15: Type plate of the laser device (example – *RevoLix HTL*)

The following symbols are used on the type plate:

Tab. 17: Symbols on the type plate

	 YYYY-MM			
Manufacturer	Date of manufacture (YYYY-MM)	Serial number	Laser output	Operating temperature

 xxx kg	IP20				
Mass of the device	Degrees of Protection	Medical Device	Do not dispose of in the domestic waste	CE-mark	Non ionizing electromagnetic radiation

6.3 Type plate - Footswitch

The type plate of the footswitch is located at its rear side and contains the necessary information to identify the footswitch.

Fig. 16: Type plate of the footswitch (example – *Kix DUO)*

The following symbols are used:

Tab. 18: Symbols on the type plate of the footswitch

REF	SN	CE	MD	IPX6 / IPX8			YYYY-MM
Order No.	Serial number	CE-mark	Medical Device	Degrees of Protection	Do not dispose of in the domestic waste	Manufacturer	Date of manufacture

6.4 Laser safety labels

6.4.1 Warning signs for the laser beam aperture

The laser beam is emitted from the distal tip of the connected laser fibre. The laser beam exits the laser device at the laser beam aperture, which is marked as follows:

Fig. 17: Laser warning symbol

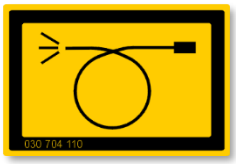


Fig. 18: Aperture label

6.4.2 Labelling of the Emergency Laser Stop

The laser stop is labelled as follows:

Fig. 19: Emergency Laser Stop

6.4.3 Labelling of laser radiation

The following labels describe the laser radiation and the laser class. The model-specific laser markings are described in Chapter 12.1:

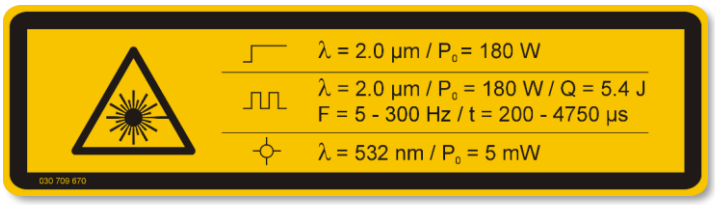


Fig. 20: Labelling of the emitted laser radiations (example – *RevoLix HTL*)

Fig. 21: Labelling of the laser class

Tab. 19: Symbols of the markings

Continuous Operation (CW)	Repeat Exposure (PULSED)	Aiming Beam

6.4.4 Positions of warning signs and labels

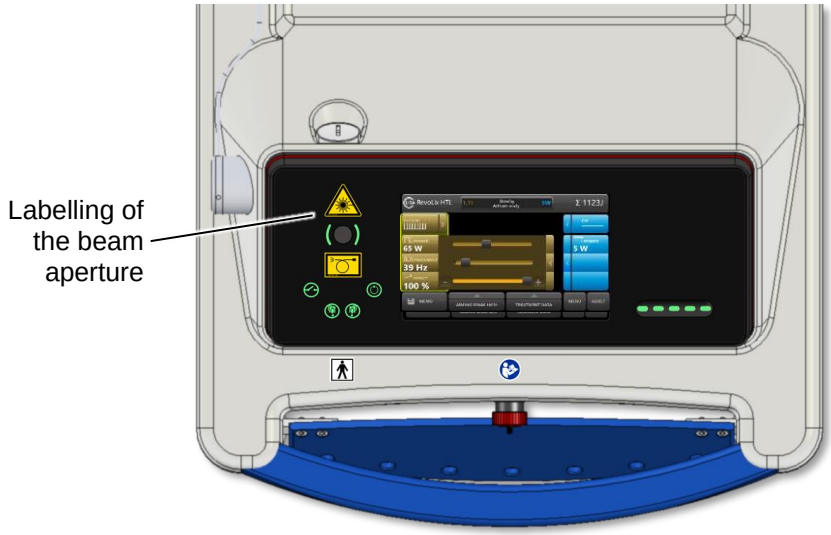


Fig. 22: Labels on the control console

Fig. 23: Labels at the front of the device

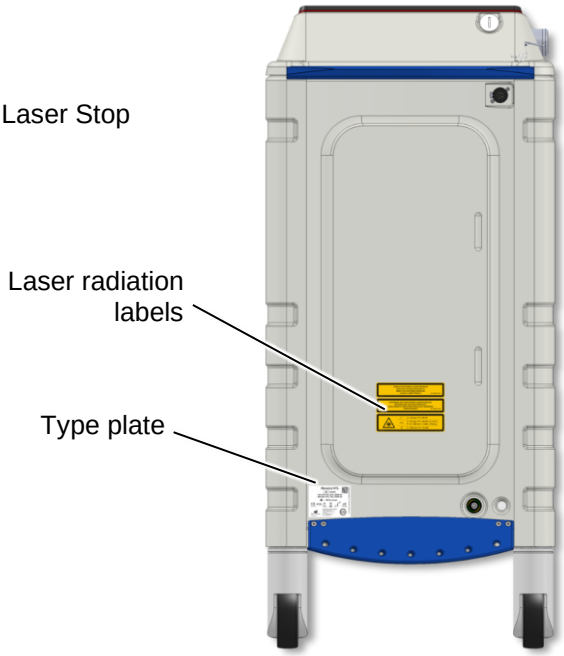


Fig. 24: Labels at the back of the device

7 Operation of the laser device

This chapter describes how to operate the ***RevoLix HTL*** laser device and contains information about the different operating states (STANDBY, LASER READY), operating modes (CW or PULSED), usage of the laser device, and how to configure the laser parameters.

WARNING

Use of controls or adjustments in ways other than those described in this manual may result in hazardous radiation exposure and skin and eye injury.

7.1 Operating states of the system

During operation, three different operating states are possible:

1. **STANDBY:**
   The system is fully operational, but it is not ready to emit laser radiation. The laser warning light ribbon and the aiming laser are not active. The STANDBY operating state is active after the START-UP phase is finished or after the laser switched back from the LASER READY state to the STANDBY state.
2. **LASER READY:**
   By activating the ready-slider (Fig. 6[4]), the device switches from the STANDBY to the LASER READY state. The device is now ready to emit laser radiation. The laser warning light ribbon shines continuously (laser ready indicator), and the aiming beam becomes visible. By touching the ready-slider, the device switches back to the STANDBY operating state. The device does not switch from the STANDBY to LASER READY state as long as one of the foot pedals of the footswitch is pressed.
3. **EMISSION:**
   Pressing the foot pedal of the footswitch activates the laser emission, which is indicated by a flashing laser warning light ribbon accompanied by a beeping sound.

7.2 Operating modes

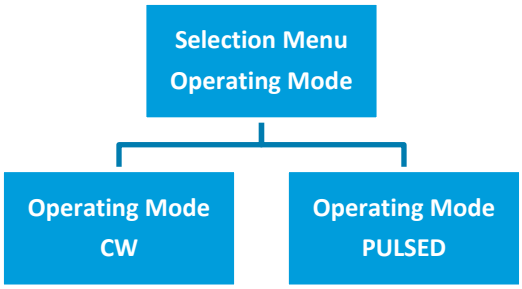


Fig. 25: Menu structure: The selection contains the operating modes CW and PULSED

The currently active operating mode is displayed on the upper tile of the left or right display panel, coloured in yellow or blue, respectively.

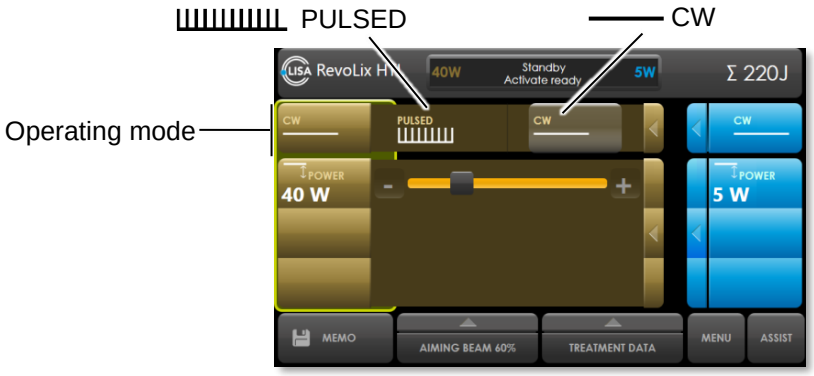


Fig. 26: Selection of the operating mode

WARNING

Emission of laser radiation in the wrong operating mode

The emission of laser radiation in the wrong operating mode may cause unexpected tissue interaction and result in severe injury and severe thermal tissue damage.

- Check the selection of the operating mode (CW / PULSED) before starting the laser emission.
- Only activate the laser emission if the effect of the laser radiation at the distal end of the fibre and the tissue can be monitored.

7.3 Laser parameters

The configuration of the laser parameters can only be carried out in the operating states STANDBY and LASER READY. As soon as laser parameters are being changed in the LASER READY operating state, the laser device is switched to the STANDBY state but switches back again shortly after automatically.

During laser emission, the display panels are locked; thus, the laser parameters cannot be changed.

The settings are made via display elements. The set values are displayed graphically by bar ranges and numerically.

Each specific laser parameter setting becomes accessible by pressing the corresponding field and can be changed by using slider bars. The number of adjustable laser parameters depends on the selected operating mode: CW or PULSED.

The set values of the laser parameters are displayed numerically and graphically by the position of a bar slider.

Fig. 27: Setting of the laser parameters; here in CW mode

7.3.1 Laser parameters of the operating modes

The laser emits continuously with the set parameters as long as the pedal of the footswitch is pressed.

In CW mode, only the average power is adjustable. In the PULSED mode, the power, frequency (pulse repetition rate), and pulse effect are adjustable. The settings are made using the display elements.

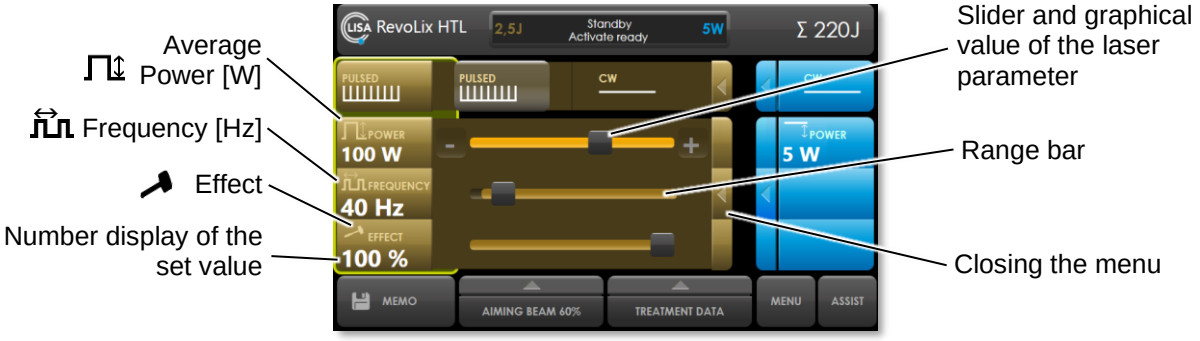


Fig. 28: Setting of the laser parameters; here in the PULSED operating mode

Both laser parameters are influenced by each other. When increasing the average laser power, the maximum possible frequency for the laser energy setting is calculated and, if necessary, adjusted. The average laser power limits the maximum possible frequency (pulse repetition rate).

The effect-setting influences the duration and peak power of a laser pulse. The pulse peak power ranges from approx. 300 W (Effect 50 %) up to 1000 W (Effect 100 %). The laser pulse duration is automatically adjusted according to the selected effect-value, therefore keeping the pulse energy constant.

7.3.2 Pulse effect setting

A unique feature of the ***RevoLix HTL*** laser device is the adjustable pulse effect setting, which changes the duration and the peak power of the laser pulse. The effect setting ranges between 50 % and 100 %.

The pulse shapes (x-axis ≙ time, y-axis ≙ pulse peak power) shown in Fig. 29 and Fig. 30 are influenced by the selected effect setting. The power and frequency scale is identical in both charts.

The pulse effect setting of "100 %" emits a short laser pulse (in the example: 1050 µs) with a high pulse peak power.

The pulse effect setting of "50 %" emits long laser pulses (in the example: 4500 µs) featuring a low pulse peak power.

Fig. 29: Pulse shape of a short laser pulse with a high pulse peak power

Fig. 30: Pulse shape of a long laser pulse with a low pulse peak power

When the laser pulse duration is changed by adjusting the effect setting, the set average power remains constant. Therefore, when the laser pulse duration is reduced, the pulse peak power increases, or when the laser pulse duration is increased, the pulse peak power reduces.

This pulse shape behaviour is particularly useful, e.g., in lithotripsy and removing and cutting soft tissue.

With the same pulse energy, a short laser pulse removes hard tissue more effectively than a longer laser pulse due to a more substantial impact of the laser pulse on the tissue at higher pulse peak powers. In turn, the coagulating effect of longer laser pulses is better than of short laser pulses.

Laser-tissue interactions can be summarised as follows:

Tab. 20: Use of the pulse effect setting

Pulse effect	Pulse duration	Pulse peak power performance	Removal of hard tissue	Removal of soft tissue, coagulation
100 %	short laser pulses	high peak power	+	-
50 %	long laser pulses	low peak power	-	+

To adjust the pulse effect setting, touch the hammer icon, and the parameter bar appears. Then, touch the setting button and move it to the desired value.

7.4 Settings when using a *Kix DUO* double pedal footswitch

Using the ***Kix DUO*** double pedal footswitch, custom-selectable operating modes with the corresponding laser parameters can be assigned to the left and right foot pedal.

The laser parameter sets are shown on the left and right display panel. A yellow frame marks the currently active laser parameter set of the corresponding foot pedal.

The settings for the operating mode and laser parameters can be made independently for footswitch pedals.

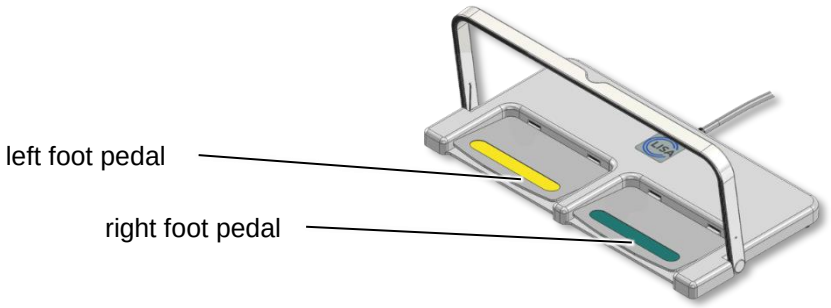


Fig. 31: Double-pedal footswitch *Kix DUO*

Fig. 32: Touch screen of a laser device connected to a double-pedal footswitch, left foot pedal settings are currently active

Both footswitch pedals with the corresponding laser parameter settings can be activated by a one time pressing and releasing step. A clicking sound confirms this switching process, and the active laser setting, which is marked by a yellow surrounding frame, changes from one panel to the other.

In the LASER READY operating state, laser radiation is not emitted until the foot pedal is pressed again. Pressing both footswitch pedals at the same time does not emit laser radiation.

A change of the active foot pedal can be done in the STANDBY and LASER READY operating state.

A change in the brightness level of the aiming beam affects both footswitch pedals regardless of which one is currently active.

7.5 Brightness level adjustment of the aiming beam

The brightness of the aiming beam can be set between 0 and 100 % using the "Aiming Beam" selection menu. Adjust the brightness setting in the LASER READY operating state, as in this state, the aiming beam becomes visible.

By restarting the laser device, the brightness level of the aiming beam sets automatically at 60 % if it was below 60 % before restarting. Higher brightness level settings are saved and remain set after a reboot.

Fig. 33: Aiming beam brightness setting

7.6 Memo, treatment, and usage data menus

7.6.1 Treatment and usage data menus

The treatment or usage data can be viewed in the treatment data menu containing the following records:

Tab. 21: Recorded data

Usage	Description	Format / Unit
START	Date and time (UTC) of the first laser activation	DD MMM YYYY - hh:mm:ss
LASER ACTIVE	Total time duration of laser emission	hh:mm:ss
TOTAL ENERGY	Sum of emitted energy (also displayed in status line in the upper right corner “Σ“)	J

The usage data is recorded for the entire system. The device does not record the usage data of both footswitch pedals separately.

Pressing the RESET button resets all data to zero.

Fig. 34: Usage data

7.6.2 Memo menu

The “MEMO” menu allows the saving and loading of laser parameter settings.

By tapping on the “**MEMO**” menu button, the following screen image appears.

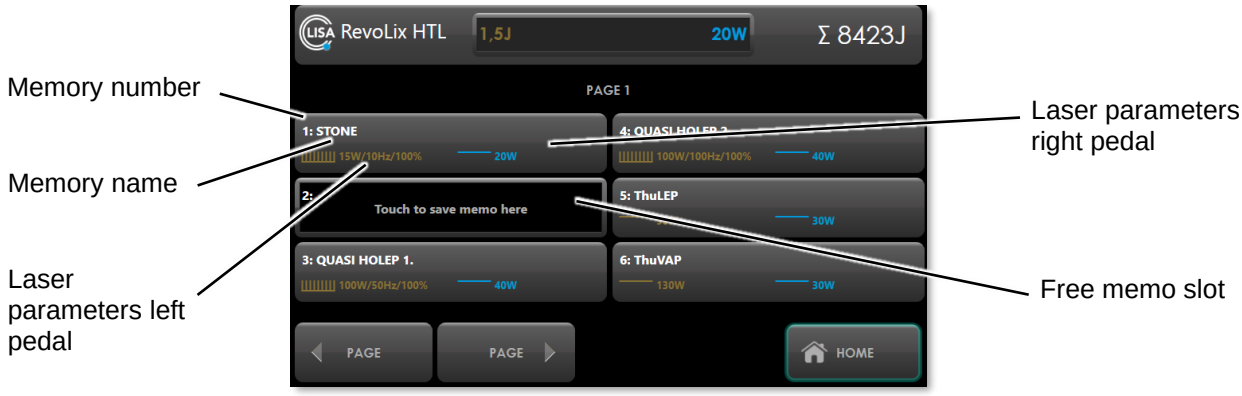


Fig. 35: MEMO menu

Tab. 22: Display and laser parameters

Display	Laser parameters	
15W/10Hz/100%	Yellow colour: Laser parameters for the left footswitch pedal:	PULSED MODE: Average power: 15 W Frequency: 10 Hz Effect: 100 %
20W	Blue colour: Laser parameter for the right footswitch pedal:	CW MODE: Average power: 20 W

Loading of saved settings

By tapping on the memory name (e.g. “1: STONE”), this setting is selected, and the following image (Fig. 36) appears. Please confirm the selection by pressing the “load” button or the memory name.

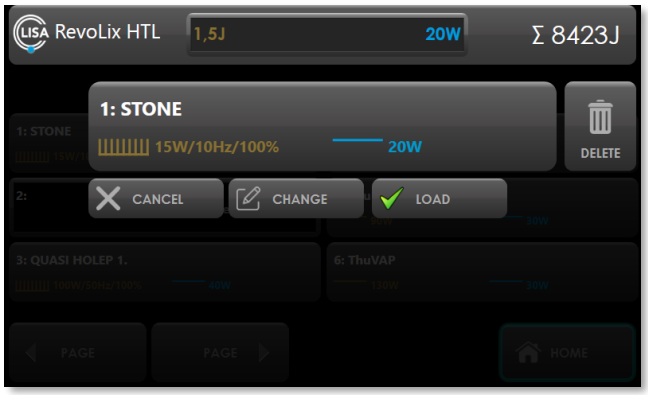


Fig. 36: Loading of the laser parameter settings

Pressing the “DELETE“ button deletes the laser parameters previously saved in the selected memo slot.

Saving of settings

The laser parameter settings can be saved by pressing a free memory slot, which can be recognised by a black background (Fig. 35). In case no free memory slot is shown on the page, please scroll the pages until an available one appears.

In the following sample, the memory slot number 2 was selected, and the name “2: TISSUE” was typed and chosen as the memory name. To delete a single letter within the name, press the back-arrow key. The laser settings are saved by pressing the “save” button.

Fig. 37: The save menu

7.7 Commissioning

7.7.1 Before switching on

The laser device must be positioned at an optimal spatial distance from the operating field. Ensure that the ventilation openings are not blocked and that the exhaust air is not directed at the patient.

The footswitch of the device must always be directly accessible and easily operated by the operating person. The connecting cable between the footswitch and the laser device shall be laid so that no stumbling block or obstruction arises. The laser stop must be accessible immediately and at any time.

Deploy the parking brakes to prevent an unintentional movement of the laser device.

Before switching on the device, make sure that

- the necessary laser safety measures have been implemented (Ch. 5)
- the laser device is connected to a suitable and adequate power supply.
- the door interlock is connected or use the complementary door-interlock dummy plug. Ensure that the entrance doors to the laser area are closed.
- laser fibres and laser applicators are available
- all persons in the laser range wear suitable laser safety eyewear. Ensure that the laser safety eyewear is suitable for the emitted wavelength and has no damage (Ch. 5.3).

Do not operate the ***RevoLix HTL*** laser device if the device is damaged.

7.7.2 Connecting a door interlock switch

Plug the door interlock switch in its socket at the back of the laser device (Fig. 2). If you are not using a door interlock switch, you must plug the complementary door interlock dummy plug into the available socket. Without a connected interlock switch or dummy plug, the status icon "Interlock" (Tab. 4) lights in red, and the laser device cannot be used.

7.7.3 Connecting the footswitch

Carefully remove the footswitch from its holder at the back of the device. Please note that the handle opens automatically as soon as the footswitch is taken out of its bracket.

Connect the footswitch to the laser device. The socket is located below the laser stop button at the front of the device (Fig. 1).
Please ensure a stable position of the footswitch in a non-slippery area.

An adequately connected single-pedal footswitch ***Kix*** is confirmed by the green shining status symbol "Left footswitch pedal" (Tab. 4). In case a double-pedal footswitch ***Kix DUO*** is connected, the left and the right footswitch pedal symbols shine in green.

The following message is shown on the screen of the control console if no footswitch is connected to the laser device.

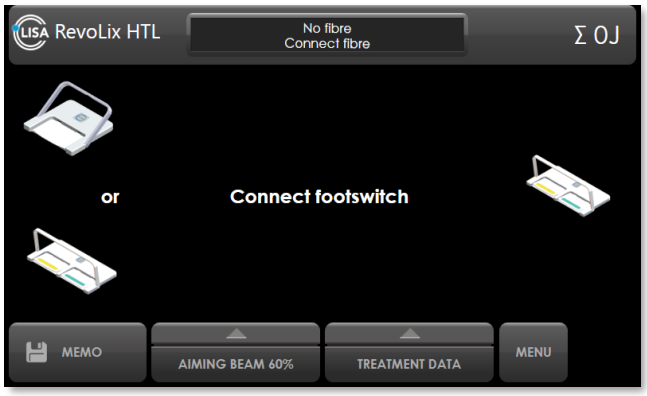


Fig. 38: Connecting footswitches

7.7.4 Switching-on routine of the laser device

Turn on the laser device using the key switch (¼ turn to the right). A power-on process is immediately initiated, including an automated system test (start up).

The start image appears on the screen shortly after (Fig. 39).

As part of the test routine, the laser device triggers laser pulses internally that can be heard by clicking sounds, and the laser warning light ribbon flashes. After the system test is completed, the laser parameter menu appears.

Now select the operating mode and the laser parameters (Ch. 7.2 ff).

Fig. 39: Start image

7.8 Testing the laser fibre

The following section describes important tests that you must perform before using the laser fibre.

Detailed test descriptions can also be found in the respective instructions for use of the laser fibres.

- Check the laser fibre label for readability. Do not use the laser fibre if the information is illegible or missing.
- Make sure that the selected laser fibre is suitable and approved for the laser device. Pay particular attention to power limitations.

CAUTION

Absorption of laser radiation in the fibre connector caused by using incompatible laser fibres or exceeding maximum power limits

Absorption of laser power in the fibre connector may heat up the fibre connector and may cause burns when touching the hot fibre connector.

- Prior to use consult labelling and instructions for use of the laser fibres for information on laser compatibility and power limitations
- Use only fibres that are compatible with the laser device
- Use only power settings permitted for the fibre

- For single-use laser fibres, inspect the packaging for damage that could affect sterility. If the packaging is damaged or the sterility is to be questioned, then do not use the product.
- For single-use laser fibres, make sure that the expiry date is not exceeded.
- Inspect the laser fibre for kinks, fractures, and other damage. The laser fibre must not have any damage along the entire length.
- The integrity of the distal laser fibre end is tested by applying a lateral load, a procedure like making a dot with a ballpoint pen.
- Check the laser fibre plug and the end of the laser fibre in the laser fibre plug for damages and contamination.
- The front surface of the laser fibre in the laser fibre plug must be flat, optically shiny, and free of damage.
- Check the light transmission of the laser fibre from the distal end to the laser fibre plug. Align the distal end of the laser fibre with a bright light source and observe the laser fibre end in the laser fibre plug. There must be a clear and bright light point from the laser fibre end in the plug.

CAUTION

Absorption of laser radiation in defective fibre connector

A defective or dirty fibre connector may heat up. Touching the hot fibre connector may result in burns. Likewise, damage may occur to the coupling optics of the laser device.

- Check the laser fibre as instructed above prior to use.
- Do not use a laser fibre with dirty or damaged fibre connector.

7.9 Connecting the laser fibre

Remove the protective cap of the laser fibre plug - the free-standing fibre end in the laser fibre plug is very sensitive and must not be damaged or soiled.

Carefully guide the laser fibre plug to the laser fibre connector socket. The socket opens automatically and is internally illuminated. Alternatively, you can open the socket by touching the ready-slider. Please note that the fibre connector socket closes automatically after a few seconds. Make sure that when connecting the laser fibre, dust, dirt, or liquids never enter the connector socket.

The laser fibre plug should be plugged into the fibre connector without any effort. Thus, screw the fibre into the connector finger-tight.

As soon as the laser fibre is connected to the device, the green light next to the fibre connection lights up continuously.

Fig. 40: Guide fibre to beam aperture

Fig. 41: Beam aperture opens automatically

Fig. 42: Insert the fibre into the beam aperture and carefully screw it in tightly

Fig. 43: The laser fibre is successfully connected

7.9.1 RFID Fibre Identification

Devices equipped with a RFID fibre identification only accept compatible LISA Laser Products laser fibres equipped with RFID fibre identification tag.

Fig. 44 shows the initial screen in case no RFID fibre is connected. After connecting a compatible fibre the fibre is recognized by the laser device and information about the connected fibre are displayed as shown in Fig. 45. Depending on the fibre model this information may include the Model Name, Use-by date, Number of remaining cases and other information about possible limitations.

After connecting the fibre, check if the displayed information, the expiry date, and the power limitations automatically set by the laser device are in compliance with the information given on the fibre label.

CAUTION

Absorption of laser radiation in the fibre connector caused by using incompatible laser fibres or exceeding maximum power limits

Absorption of laser power in the fibre connector may heat up the fibre connector and may cause burns when touching the hot fibre connector.

- Check that power limitations set by the laser device comply with the information given on the labelling of the fibre
- Use only power settings permitted for the fibre

WARNING

Use of fibres after use-by date has expired.

The integrity of the sterile barrier system and the sterility of the laser fibre cannot be ensured after the use-by date has expired. This can cause infection by insufficient sterility.

- Check the use-by date given on the labelling before use
- Check that the expiry date displayed by the laser device complies with the information given on the labelling of the fibre
- Do not use the fibre, if the use-by date has expired

In case the fibre is not compatible or number of cases or use by date are expired, the laser device recognizes the fibre as invalid and displays a message shown in Fig. 46.

Fig. 44: Initial screen in case no RFID fibre is connected

Fig. 45: Information about the connected fibre

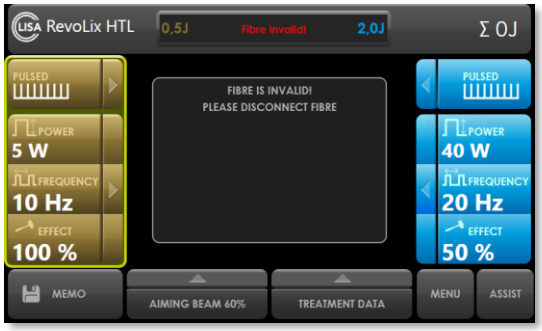


Fig. 46: Information about invalid fibre

As soon as the laser fibre is connected to the device and identified as compatible and valid, the green light next to the fibre connection lights up continuously.

7.10 Switching the device to LASER READY operating state

Set the desired operating mode and laser parameters as described. For the aiming beam, you should initially choose a brightness level of 100 %. Bring the laser device from the STANDBY to the LASER READY operating state by swiping over the ready-slider with your thumb or finger from left to right.

Fig. 47: Switch to LASER READY operating state

Fig. 48: Active laser warning light ribbon in LASER READY state

The change of the operating state is confirmed by a short beeping sound, a red shining laser warning light ribbon, and lateral light stripes illuminated in red. Additionally, the aiming beam becomes visible, and the status bar on the screen changes to red. The laser device is now ready to emit laser radiation.

Fig. 49: The red status line indicates the LASER READY operating state

WARNING

Laser radiation

The working laser emits Class 4 invisible laser radiation. Direct, reflective or scattered laser radiation can cause severe eye injury and skin burns.

- Never look directly into the laser beam.
- Do not aim the laser beam at reflective surfaces or instruments.
- Never point the laser beam at other people.
- Wear suitable safety goggles.

Point the distal end of the laser fibre at a white surface. Do not look directly into the aiming beam. Check that the radiation of the aiming beam is emitted only from the fibre's distal end and not from anywhere else. A properly working laser fibre projects a circular image of the aiming beam onto the white surface. Do not use the laser fibre if the aiming beam is faint or barely visible, or visible along the laser fibre or the stripped fibre end.

7.11 Emission of laser radiation

Make sure you have selected the correct laser parameters.

Insert the distal fibre end into the handpiece/endoscope. To start the laser emission, press the foot pedal. Please note that the footswitch should only be operated by the person who performs the laser intervention.

The emission of laser radiation is indicated by the red flashing laser warning light ribbon (laser emission indicator), a signal tone, and the operating state "LASER EMISSION" (Fig. 50) shown on the screen.

During laser emission, the laser pulse shape, the laser pulse duration, and the pulse peak power are shown on the screen.

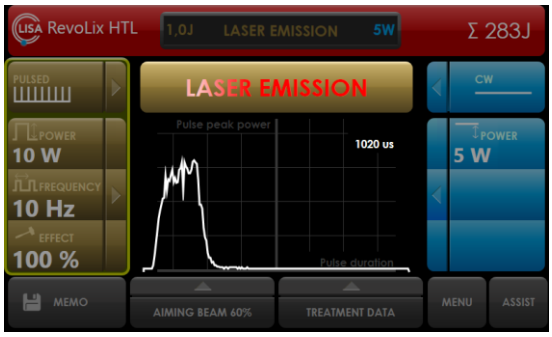


Fig. 50: Display of the laser pulse shape

Laser radiation is emitted as long as the footswitch pedal is pressed.

7.12 Switching the laser device to STANDBY

During lengthy interruptions or after the application has been completed, switch the laser device back to STANDBY by pressing the ready-slider (Fig. 51).

Fig. 51: Switching to the STANDBY operating state

7.13 Removing or replacing the laser fibre

Switch the laser device to the STANDBY operating state. Unscrew the laser fibre plug and detach it from the fibre coupling. Put the protective cap back on the fibre plug.

Reusable laser fibres can now be reprocessed. Single-use laser fibres must be disposed. Detailed information is provided in the instructions for use of the laser fibres.

7.14 Switch-off routine

Switch the laser device to the STANDBY operating state and remove the laser fibre from the laser device as described.

The laser device can now be switched off using the key switch (Fig. 2). Then pull the power plug out of the socket. The power cord is wound up at the back of the laser device.

To prevent unauthorised use of the laser device, unplug the key from the key-switch.

7.15 Cleaning and disinfection

Turn off the device and unplug the power plug. Always carry out the cleaning work with activated parking brakes to prevent the device from moving.

The laser device and its control console can be cleaned with a soft cloth soaked with cleaning solution. Disinfection can be carried out with an alcohol-free or low-alcoholic surface disinfectant.

Always clean and disinfect the wheels of the laser device.

Clean the footswitch and its cable with commercially available disinfectants and a damp cloth. The footswitch is waterproof and can be rinsed under running water.

WARNING

Hazard of Infection

The laser device and its accessories may be contaminated with biological materials after use. In case of improper cleaning / disinfection, these materials can enter the environment and represent a potential source of infection.

- Clean and disinfect the laser device, footswitch and other accessories carefully after each use.
- Clean and disinfect the laser device before relocating to eliminate cross-contamination.

NOTICE

The laser device is not protected against the ingress of liquid.

- Switch off the laser device and disconnect it from the mains supply before cleaning and disinfection.
- Make sure that no liquid penetrates the laser device through the beam aperture or the ventilation openings.

7.16 Reprocessing of laser fibres, applicators and handpieces

For the preparation and reprocessing of reusable laser fibres, applicators and handpieces, follow the detailed instructions in the respective instructions for use. If missing, please request the instructions for use from LISA Laser Products.

8 Clinical applications

Please refer to clinical literature, training events, and medical society guidelines on a regular basis for the latest status and recommendations on indications and practices.

8.1 Warnings and Precautions

This section contains warnings and precautions that are applicable to surgical procedures specifically related to the use of the ***RevoLix HTL*** laser device.

Laser fume

Hazard of infection / poisoning by viable tissue particles or toxic components in the laser fume or the laser fume plume.

- Use appropriate smoke evacuation for the particular application.

Using a wrong operating mode.

The delivery of laser radiation in the wrong operating mode can cause unexpected tissue interaction and result in serious injury and severe thermal tissue damage.

- Check the selection of the operating mode (CW / PULSED) before starting the laser application.
- Use the CW operating mode for soft tissue indications
- Use the PULSED operation mode for laser lithotripsy

Laser radiation

Uncontrolled delivery of laser radiation risks causing tissue damage and severe thermal damage.

- Check the settings (laser parameters and operating mode) of the laser device before starting the laser application.
- Always start with low power settings. If necessary, increase the laser power gradually to the required level.
- Only trigger the emission if the effect of the laser radiation - the distal end of the fibre and the tissue - can be observed.

Unexpected effect of the laser radiation

Unexpected effect of the laser radiation due to mix up of the foot pedals of the ***Kix DUO*** double pedal foot switch.

- Check the selection of the laser parameters and their assignment to the footswitches before starting the laser application.
- Only trigger the emission if the effect of the laser radiation - the distal end of the fibre and the tissue - is visible.

WARNING

Perforations caused by laser radiation

In all endoscopic and laparoscopic applications there is a risk of perforation.

- Always start with low power settings. If necessary, increase the laser power gradually to the required level.
- Only trigger the laser emission if the effect of the laser radiation - the distal end of the fibre and the tissue - can be observed. Do not use the laser if the desired target is not visible. All available measures to visualize the target tissue (e.g. sufficient irrigation, haemostasis) should be taken.
- Use caution when treating patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.

WARNING

Strong bleeding

In highly vascularised anatomical structures haemostasis of the laser may not be sufficient, which can lead to heavy bleeding.

- Make sure that conventional methods of haemostasis are available if a bleeding vessel cannot be coagulated with the laser.
- Consider that the risk of bleeding is higher for patients with coagulation disorders or under anti-coagulation therapy.

WARNING

Thermal tissue damage

In surgical laser applications there is a risk of unwanted thermal tissue damage.

- Always start with low power settings. If necessary, increase the laser power gradually to the required level.
- Use of the laser on anatomical structures in proximity to known critical structures, such as large arteries, veins, bowel, ureter, bladder, nerves, etc., should be performed carefully to avoid inadvertent or unintended damage of such structures. If applicable, maintain irrigation in the treatment area to reduce heat accumulation
- Only trigger the emission if the effect of the laser radiation - the distal end of the fibre and the tissue - can be observed. Do not use the laser if the desired target is not visible. All available measures to visualize the target tissue (e.g. sufficient irrigation, haemostasis) should be taken.

WARNING

Flammable materials and gases

Flammable materials and gases (including endogenous gases) may ignite due to laser radiation and cause severe burns or poisoning and chemical burns.

- Do not use the laser radiation in an explosive atmosphere (oxygen-enriched air).
- Do not aim the laser radiation at flammable gases, liquids or other substances. The flammability of methane gas must also be considered when treating in or near the perianal area
- Do not aim the laser radiation at flammable material and tissue.
- Use suitable non-flammable tubes and drapes for laser surgery etc.
- When using flammable disinfectants, ensure adequate drying.

WARNING

Improper handling of laser fibres

Mechanical damage or excessive bending of the laser fibre as a result of improper handling. At the damaged or excessively curved location of the laser fibre, laser radiation may cause heat to develop, causing tissue damage and burns.

- Consider possible performance limitations of the laser fibres.
- Do not bend the laser fibre too much. Consider the prescribed minimum bending radius.
- Fix the laser fibre securely on / in the handpiece / endoscope.
- Do not use laser fibres that are kinked or otherwise damaged.

WARNING

Insufficient fixation of the laser fibre

In case of insufficient fixation, the laser fibre may slip back into the handpiece / endoscope. Laser radiation which is released inside the handpiece / endoscope may heat the handpiece / endoscope and cause tissue damage and burns.

- Fix the laser fibre securely on / in the handpiece / endoscope.
- Use only fixings suitable for the outer diameter of the laser fibre. Consider the technical data of the laser fibre (outer diameter) and the intended fixation.

WARNING

Detachment of damaged laser fibre components

Fragments can detach from damaged laser fibres. Unretrieved device fragments (UDF) can cause injuries or diseases in the human body.

- The outer plastic sheath of the laser fibre (jacket) serves at the distal end as a mechanical reinforcement and as a kink protection. To prevent the fibre tip from breaking off, the stripped fibre length must not exceed 2 - 5 mm.
- Direct contact of the stripped glass fibre with the metal fibre guide may cause the fibre to break.
- Use only compatible handpieces / endoscopes in combination with the laser fibre. Consider the requirements of the laser fibre on the bending radius and the necessary working channel.
- Use only instruments / endoscopes that do not have sharp corners and edges. Check the handpiece / endoscope before use.
- Only use laser fibres that are compatible with the ***RevoLix HTL*** laser device and are expressly approved by LISA Laser Products for use with this laser device.
- Consider possible performance limitations of the laser fibres.
- Consider the prescribed minimum bending radius for the laser fibre.

NOTICE

Improper handling

In an attempt to advance the distal tip of the fibre within a deflected endoscope, it can cause extensive damage that is not immediately recognized.

- Do not insert the laser fibre into a deflected endoscope.

8.2 Laser tissue interactions

8.2.1 Physical-technical basics

The ***RevoLix HTL*** laser is a diode-pumped solid-state laser (DPSS). The laser radiation is generated by the excitation of a solid-state laser crystal using a laser diode and emitted continuously or pulsed.

The emitted laser radiation has a wavelength of 2013 nm (±10 nm). The laser can be operated in “CW” operation with continuous emission of laser radiation and in “PULSED” operation with pulsed laser output.

The laser radiation is focused into a flexible silica laser fibre. The fibre guides the laser radiation to the surgical site.

8.2.2 Physical-medical basics

The principle of the laser tissue interaction in both operational modes “CW” and “PULSED” is the strong absorption of 2 µm laser radiation by water molecules in tissue and in stones (Fig. 52). Water molecules are omnipresent in tissue and stones disregarding their colouration or the blood circulation.

As shown in Fig. 52 at 2 µm wavelength the depth of penetration into water-containing tissue is approximately 0.5 mm, assuming that the optical properties of the tissue are not changed by the irradiation. A synonym of the depth of penetration is the so-called absorption length. The absorption length defines the optical pathway along which (1 - 1/e) or 63 % of the incident laser energy is absorbed. The effect of the laser radiation within the tissue is limited by the absorption length.

For 2 µm radiation the density of absorbed power in aqueous irrigant and/or in tissue is high and results in an immediate increase of the temperature. The generated heat may be used for coagulation or ablation of tissue or stone disintegration depending on the procedure.

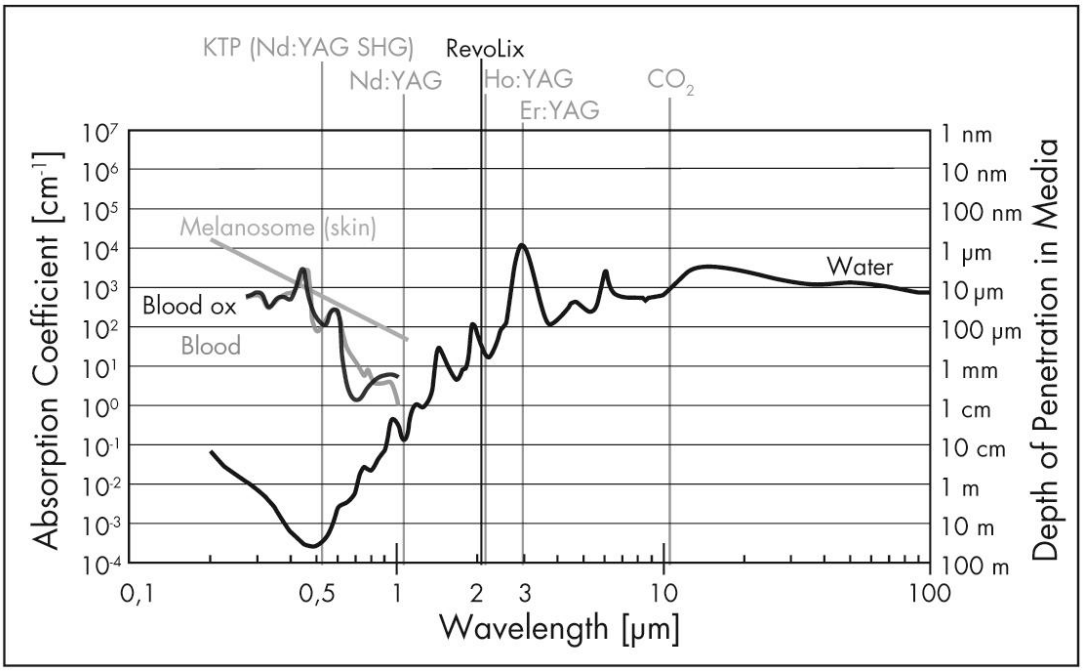


Fig. 52: Absorption spectrum of water and laser wavelengths

The tissue effect of the 2 µm laser is related to the intensity (defined as laser power per area) of the laser radiation on the tissue. The intensity can be varied with the setting of the power of the laser and/or with the distance of the fibre tip to the tissue.

The laser beam emitted by the laser fibre diverges in form of a cone with an opening angle of about 25° (divergence of the laser radiation from the laser fibre), i.e. the beam diameter increases continuously with increasing distance of the laser fibre tip to the tissue. Thus, the intensity and consequently, the effect of

laser radiation on the tissue decreases. The effect (intensity) of the laser radiation is maximal directly at the beam exit of the laser fibre. The intensity increases with increasing laser power and decreases with increasing distance of the laser fibre tip to the tissue.

For cutting and ablation of tissue and for stone disintegration, the laser fibre is used in the "contact". For coagulation, the distance between the tissue and the fibre tip is increased to reduce the laser beam intensity.

Due to its strong absorption, the 2 µm laser radiation beam has a very short optical path in aqueous media. If the power is sufficiently high and the distance to a tissue surface is small, a vapor bubble forms, which is almost stationary at a small distance of the fibre tip to the tissue surface and establishes optical contact with the tissue for the laser radiation and allows the laser radiation to act effectively on the tissue. If the distance between the fibre tip and the tissue increases to about 1 to 4 mm, the laser radiation is completely absorbed by the water and the beam is thus shielded. The tissue is not vaporized.

At low intensities (low power setting and/or greater distance of the laser fibre from the tissue), the effect on the tissue is mainly coagulative. In this case, the density of the absorbed laser power is lower than required for vaporization of water in the tissue (ablation threshold I_s in Fig. 53). In this case, the temperature rise in the tissue leads to tissue coagulation. Even prolonged irradiation does not lead to vaporization, since the absorbed laser power is released into the surrounding medium (tissue, surrounding gas or liquid) just as quickly. In other words, the cooling effect due to heat conduction into the surrounding tissue exceeds the heat generation due to absorption (I in in Fig. 53).

With increasing intensity (higher laser power and/or smaller distance of the laser fibre tip to the tissue (smaller spot diameter), the temperature of the tissue increases. At some point, so much heat has built up in the irradiated tissue that the vaporization temperature of the water in the tissue is reached and the tissue evaporates (I_s in Fig. 53).

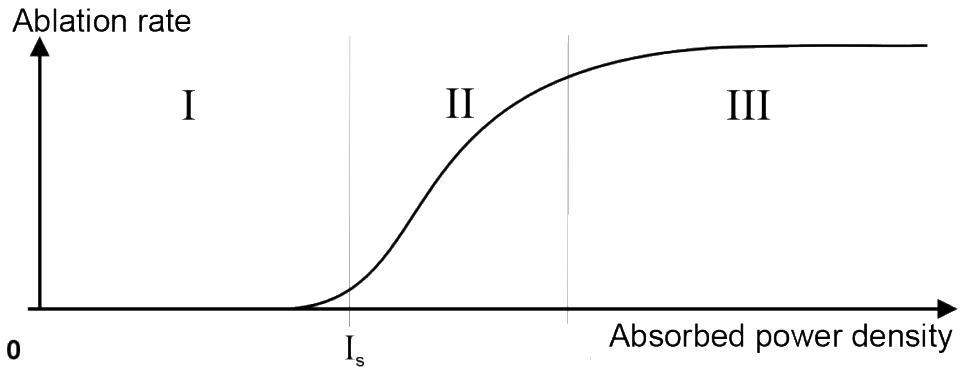


Fig. 53: Tissue effect depending on power density

The ablation rate (ablation rate in Fig. 53) can be controlled to a certain extent by variation of the power density (area II in Fig. 53).

Further increase in power density (area III in Fig. 53) does not lead to a further increase in the ablation rate, because the tissue is protected from laser radiation by the evaporating ablation products. If the fibre is kept in place the vaporization of tissue will continue until the critical intensity for ablation is not reached any more. Some carbonisation of the tissue will occur when using the laser in open surgery. In aqueous medium charring is strongly reduced.

The tissue effect is also influenced by the surrounding medium, whether gaseous (open surgery) or water (endourology). A gaseous medium (air, CO_2) dissipates less heat from the surgical sites so that overheating of the tissue and undesirable carbonisation can occur. Any smoke that may arise must be removed by appropriate means (smoke evacuation).

An aqueous medium (irrigation liquid) ensures much better cooling of the tissue, carbonisation is mostly avoided, and visual tissue identification is facilitated. And in addition, in an aqueous medium, any tissue that is more than 5 mm away from the tip of the fibre is protected from the laser effect by the strong absorption of 2 µm of laser radiation in the aqueous medium. This can be understood as an additional safety aspect.

8.2.3 Tissue interaction

The tissue-ablating effect of the thulium laser is achieved by the immediate heating of water-containing tissue when the laser energy is absorbed. The generated heat leads to tissue coagulation or ablation or stone disintegration depending on the procedure.

CW operation

The continuous wave laser radiation of the CW operation mode is applied for the treatment of soft tissue. In CW operation mode, the coagulation and ablation properties are mild compared to the pulsed laser radiation of Holmium pulsed lasers. The tissue is coagulated or dissected with no trauma, visibility is not affected by bubbles and no tissue fragments including living cells sputter lenses or masks.

The absorption of laser power is limited to a layer of app. 0.5 to 1 mm depth below the surface. Tissue damage to deeper tissue areas may occur due to heat conduction when the fibre or beam is moved slowly or held in place.

The damage zone is not limited to visible tissue ablation, as the laser energy penetrates into the tissue beyond the ablation (optical penetration depth is greater than cutting depth). In addition, heating of the surrounding tissue occurs because heat is dissipated via thermal conduction from the volume in which the laser energy was absorbed.

The actual damage zone also depends on the treatment technique. At a power density that allows cutting of the tissue, the damage zone is less than 1 mm. As a rule of thumb, the longer the fibre is held in one place, the greater the thermal damage zone.

PULSED operation

The pulsed laser radiation of the PULSED operation mode is applied for the removal and fragmentation of stones and hard tissue. The high pulse peak power evaporates the water contained in the stone or tissue and as a result tears or disintegrates the tissue or stone.

When the laser radiates into aqueous liquid, a vapour bubble builds up at the end of the laser fibre. The bubble, in combination with the effects of the laser beam, removes and ablates stones and hard tissue very effectively.

The disadvantage of pulsed radiation may be tearing and trauma to the surrounding tissue; also, bubble formation may occur, which hinders vision. When pulsed lasers are used in open surgical procedures, splashes of tissue parts can contaminate the endoscope lenses. For soft tissue applications, the CW operation should be used.

The following variable treatment parameters are available to the user:

Tab. 23: Treatment parameters

Treatment parameter	Variation	Effect
Laser power	High or low power	• Absorbed power density • Ablation rate
Contact or non-contact procedures	Beam diameter on the tissue	• Absorbed power density • Ablation rate
Laser fibre, optical core	Different core and sheath diameters	• Fibre flexibility • Beam intensity
Medium	Open surgery (gaseous medium) or surgery in an aqueous medium	• Cooling • Shielding

8.2.4 Laser surgery in a gaseous medium

The cooling of the tissue is low when the laser is applied in a gaseous medium, i.e. vaporization occurs as soon as the absorbed power density has reached the ablation threshold. Carbonization is almost inevitable, especially for larger cuts performed during open surgery. Under a carbon dioxide atmosphere, less carbonization occurs because of the missing oxygen.

For the use of the ***RevoLix HTL*** laser device in a gaseous medium, it is recommended to drip water or saline solution over the laser fibre at the application sites. This prevents carbonization and makes it possible to differentiate the tissue visually.

Smoke must be removed using smoke extraction.

⚠ WARNING

Thermal tissue damage

For applications in gaseous media, there is a greater range of the laser beam. The lower tissue cooling can lead to a stronger carbonization of the tissue and unwanted thermal damage.

- Always start with low power settings. If necessary, increase the laser power gradually to the required level.
- Only trigger the emission if the effect of the laser radiation - the distal end of the fibre and the tissue - can be observed.

8.2.5 Laser surgery in an aqueous medium

An aqueous medium cools the application site intensively. Therefore, carbonization occurs only very limited because the temperature increase is limited by the evaporation enthalpy of the aqueous medium (about 100 °C) and the tissue.

For the following reasons, aqueous media allows higher power settings compared to gaseous media:

1. Compared to open surgery, the cooling effect is larger and, therefore, more laser power is needed to achieve the desired effect.
2. Compared to open surgery, there is less carbonisation.

All standard rinsing solutions such as Aqua dest., 0.9 % NaCl solution, Purisol (Mannit/Sorbite) solution, ringer solution and 1.5 % glycine solution can be used as a rinsing solution. When using the rinsing solutions, check the manufacturer's user information. Glycine solution reacts under laser radiation at the fibre tip which might reduce the fibre's durability, especially of sideways emitting laser fibres.

8.3 Procedures during application

The optimal distance between the distal end of the laser fibre tip and the tissue to be treated depends on the intended application. Different methods were developed, which differ in the distance of the distal laser fibre tip to the tissue.

1. **Near-contact procedure:** This procedure is used in the vaporization of tissue with simultaneous coagulation (haemostasis). The fibre end is held close to the tissue to remove it. Immediate bleaching of the tissue indicates the coagulation of it.
2. **Contact procedure:** When cutting tissue (incisions), the laser fibre must be guided to the tissue surface in slight contact, while pulling the fibre end over the tissue surface. This is advantageous because, in this way, the fibre end cannot get stuck in the tissue.

8.4 Preparation

8.4.1 Handpieces and endoscopes

Before the surgery, ensure that the existing laser fibres are compatible with the endoscopes or handpieces to be used. Also, ensure that the laser fibre can be inserted into and pulled out of the endoscope or handpiece without any effort. Additionally, check whether the laser fibre can be fixed securely.

It is essential to guide the laser fibre in the instrument precisely to its distal end. Always choose a fibre guiding tube from the selection of available tubes for the instrument that fits closest to the deployed laser fibre. Thus, the outer diameter of the laser fibres is noted on the label of the laser fibre and the packaging.

The outer plastic sheath of a laser fibre serves as mechanical protection. The underlying coating of the quartz fibre serves for mechanical stabilization and strengthens the breaking strength of the laser fibre. To prevent the tip of the fibre from breaking off, the stripped fibre length shall not exceed 5 mm. Direct contact of the stripped laser fibre with the fibre guiding instrument can damage the laser fibre.

In the case of endoscopic instruments, the distal fibre end must be brought into the field of vision of the optics.

Please note the instructions and information in the instructions for use of the laser fibres.

Use of incompatible instruments

Mechanical damage or excessive bending of the laser fibre as a result of combination with incompatible handpieces / endoscopes. At the damaged or excessively bent location of the laser fibre, laser radiation may cause heat to develop, causing tissue damage as well as burns and property damage to the handpiece / endoscope used.

- Use only compatible handpieces / endoscopes in combination with the laser fibre. Consider the requirements of the laser fibre on the bending radius and the necessary working channel.
- Use only handpieces / endoscopes without rough edges. Check the handpiece / endoscope prior to use.
- Do not go below the minimum bending radius of the laser fibre.
- Use only laser fibre fixations which prevent mechanical damage to the laser fibre.
- Insert the laser fibre carefully into the handpiece / endoscope.

Insufficient fixation of the laser fibre

In case of insufficient fixation, the laser fibre may slip back into the handpiece / endoscope. Laser radiation which is released inside the handpiece / endoscope may heat the handpiece / endoscope and cause tissue damage and burns.

- Fix the laser fibre securely on / in the handpiece / endoscope.
- Use only fixings suitable for the outer diameter of the laser fibre. Consider the technical data of the laser fibre (outer diameter) and the intended fixation.

8.4.2 Step by step

1. Put the laser device into operation as described in Chapter 7 “Operation of the laser device".
2. Remove the laser fibre from the packaging in accordance with sterile procedures and inspect the laser fibre for damage as described in Chapter 7.8 “Testing the laser ”. Damaged laser fibres must not be used.
3. Before laser use, the sterile surgical nurse hands the end of the fibre with the plug to the non-sterile surgical nurse who operates the laser device. The non-sterile surgical nurse removes the protective cap from the laser fibre plug and connects the laser fibre to the laser device (Chapter 7.9)
4. Switch to LASER READY operating state on the laser device. This turns on the green aiming beam.
5. Set the aiming beam to a high brightness level. Check that the aiming beam is only emitted at the distal fibre end and is easily visible. Do not use the laser fibre if the aiming beam is weakly visible or leaks in the area of the fibre sheath.
6. Insert the laser fibre into the instrument to be used. Make sure the two are compatible. Bring the instrument to the desired position.
7. Make sure the fibre tip protrudes from the instrument.
8. Position the instrument together with the laser fibre so that the aiming beam is directed at the tissue to be treated.
9. Set the laser parameters. The emission of laser radiation from the working laser is triggered by pressing the footswitch pedal. Trigger the emission of laser radiation only if the distal fibre end and the target tissue are visible.
10. During laser use, a low burn-back of the fibre tip may occur depending on the selected parameters and the application. During laser application, the surgeon perceives the burn-back as an increasing scattering of the aiming beam at the distal fibre end. The burn-back of the fibre tip reduces the beam quality and thus impairs the cutting performance.
11. During the operation, the distal end of the laser fibre must be continuously observed. Make sure that the end of the fibre always stands at least one millimetre out of the instrument to protect it from damage.
12. Remove the laser fibre immediately after the end of the operation. For reusable laser fibres, immediately screw the protective cap onto the fibre plug. To reprocess the laser fibre, follow the instructions for use. Laser fibres for single use must be disposed.
13. To turn off and clean the laser device, please follow the instructions in Chapter 7.14 “Switch-off routine” and 7.15 “Cleaning and disinfection.”

8.5 Urology

8.5.1 Patient target group

Adult patients with one of the medical indications described in Chapter 3.4.

8.5.2 Clinical Benefits

In Thulium laser treatment of benign prostate obstruction (BPO), the patient benefits from significant improvements in the IPSS, Qmax, PVR and QoL. Compared to conventional procedures (TURP), laser treatment results in less serum haemoglobin decrease, shorter time of catheterization, shorter length of hospital stay, and less transfusion.

For the treatment of urothelial cancer, the patient benefits from a high kidney preservation rate.

In ureteroscopic laser lithotripsy with the pulsed Thulium laser the patient benefits from high stone free rates (SFR). Compared to laser lithotripsy with Ho-YAG lasers, stone retropulsion is less and fragment sizes are smaller.

8.5.3 Urology – Indications in CW operating mode

The ***RevoLix HTL*** laser device is used in the CW operating mode in urology in the following clinical soft-tissue indications:

- VapoResection of the prostate (ThuVARP)
- VapoEnucleation of the prostate (ThuVEP)
- Blunt enucleation of the prostate (ThuLEP)
- Vaporization of the prostate (ThuVAP)
- Opening of urethral strictures
- Elimination of ureter strictures
- Bladder neck incisions
- Resection of bladder tumours
- Ablation of tumours in the ureter
- Ablation of tumours in the kidney
- Condyloma and penis tumour excision

8.5.3.1 VapoResection of the prostate (ThuVARP)

The VapoResection of the prostate is carried out with frontal emitting laser fibres.

A laser resectoscope serves as an instrument for the application. The laser fibre is guided via a guiding tube to the distal end of the instrument.

Use the contact procedure for resection and start with a low power setting. Change the power settings according to your observations and experiences.

8.5.3.2 VapoEnucleation of the prostate (ThuVEP)

Use the contact procedure for resection and start with a low power setting. Change the power settings according to your observations and experiences.

One possible treatment technique is the enucleation technique in which the lobes are cut into only a few parts. The implementation is essentially in line with the HoLEP.

8.5.3.3 Blunt enucleation of the prostate (ThuLEP)

The blunt enucleation of the prostate is carried out with frontal emitting laser fibres.

A laser resectoscope serves as an instrument for the application. The laser fibre is guided via a guiding tube to the distal end of the instrument.

The enucleation takes place entirely mechanically by pushing out the adenoma from the prostatic capsule.

Use the contact procedure for the first incisions and coagulation. Begin with a low power setting, change the power settings according to your observations and experiences.

8.5.3.4 Vaporization of the prostate with SideFib-SU (side emitting laser fibre)

The vaporization of the prostate is carried out with a side-emitting laser fibre ("sidefire" fibre), which emits the laser radiation on the side to the fibre direction (approx. 70°).

A special laser cystoscope for the "sidefire" laser fibre is used as an instrument. The laser fibre is guided via a guiding tube to the distal end of the instrument. There is no fixation in the instrument, as the steering of the laser beam during application is primarily carried out by rotation and translation of the laser fibre.

INFORMATION

The laser light emerges laterally from the laser fibre at a 70° angle. Note that the exit window protrudes from the distal end of the instrument and that the laser beam is not radiating towards the optics.

First, insert the shafts with the help of an obturator. Then switch the obturator to the laser cystoscope. Then insert the laser fibre into the instrument, set the laser device to LASER READY and direct the aiming beam at the tissue to be vaporized. Control the laser fibre with the handling aid of the ***SideFib-SU*** laser fibre. Use a low power setting at the beginning, then activate the emission with the footswitch and use the non-contact procedure for the vaporization of the prostate.

At the contact point where the laser radiation beam encounters the water, a steam bubble forms at the fibre tip. The vaporization begins when the vapour bubble bridges the gap between the laser fibre and the tissue. The optimal distance between the laser fibre and the tissue is about 1 mm. If the distance between the tip of the fibre and the tissue becomes too large, the vapour bubble becomes unstable, and the vaporization rate decreases drastically.

The laser radiation is directed over the tissue surface by slightly turning the laser fibre back and forth in slow fan movements ("sweeping technique").

Tissue adhesion is possible at the exit point of the laser radiation, which must be removed regularly. These tissue adhesions lead to accelerated erosion of the laser fibre. The adhesion of tissues can be prevented if an optimal distance (approx. 1 mm) to the tissue surface is always maintained. If the vaporization effect does not return after cleaning the laser fibre, then the laser fibre should be replaced.

Change the power settings according to your observations and experiences.

8.5.3.5 Vaporization of the prostate with frontal emitting laser fibres

The vaporization of the prostate is carried out with a frontal emitting laser fibre with large fibre core diameter. These laser fibres can be reprocessed and thus have an advantage over side firing laser fibres.

A special laser resectoscope serves as an instrument for the application. The laser fibre is guided via a guiding tube to the distal end of the instrument.

First, insert the sheaths and an obturator before inserting the laser guiding instrument containing the laser fibre. Switch the laser device to the LASER READY state. Then direct the aiming beam towards the tissue to be vaporized. The instrument is only moved as far as it is necessary to get an overview of the surgical field. Use a low power setting at the beginning and then activate the emission of laser radiation by pressing the respective pedal of the footswitch. When the laser radiation hits the water, a steam bubble is created in front of the fibre tip. Vaporization begins when the steam bubble bridges the gap between the laser fibre and the tissue. The optimal distance between the laser fibre and the tissue is about 1 mm. If the laser radiation does not strike the tissue surface directly, the steam bubble becomes unstable, and the vaporization rate decreases drastically.

The laser radiation is directed by gently rotating the laser fibre back and forth in slow fan movements over the tissue surface ("sweeping technique").

Tissue adhesion is possible at the exit point of the laser radiation, which must be removed regularly. The adherence of tissue can be controlled if an optimal distance (about 1 mm) to the tissue surface is always maintained.

Change the power setting according to your observations and experiences.

8.5.3.6 Opening of urethral strictures

The opening of urethral strictures is carried out with frontal emitting laser fibres.

A special laser resectoscope serves as an instrument for the application. The laser fibre is guided via a guiding tube to the distal end of the instrument.

In the beginning, use a low power setting and use for incisions the contact-type procedure. Change the power setting according to your observations and experiences.

8.5.3.7 Opening of ureter strictures

The opening of ureter strictures is carried out with frontal emitting laser fibres.

Use a rigid (or flexible) ureterorenoscope in which the laser fibre is guided through its working channel to the distal end of the instrument.

Use a low power setting at the beginning and use the contact-type procedure to perform incisions. Change the performance setting according to your experience.

8.5.3.8 Bladder neck incisions

The Bladder neck incisions are carried out using frontal emitting laser fibres.

A special laser resectoscope serves as an instrument for the application. The laser fibre is guided via a guiding tube to the distal end of the instrument.

Use a low power setting at the beginning. For incisions, use in the contact-type procedure. The surgical procedure is identical to the "Turner-Warwick" procedure. Change the power setting according to your observations and experiences.

8.5.3.9 Vaporization of urothelial carcinomas of the upper urinary tract (UTUC)

The vaporization of urothelial carcinoma of the upper urinary tract is carried out with frontal emitting laser fibres.

Use a rigid (or flexible) ureterorenoscope in which the laser fibre is guided through its working channel to the distal end of the instrument.

Use a low power setting at the beginning. Use the near-contact technique to perform tissue ablation. Change the performance setting according to your observations and experiences.

Keep in mind that laser radiation also heats the surrounding fluid in the kidneys and urinary tract. Work at intervals.

8.5.3.10 Removal of bladder tumours (en bloc resection of bladder tumors)

The removal of bladder tumours is carried out with frontal emitting laser fibres.

Use a laser resectoscope and use its guiding tube to guide the laser fibre to the distal end of the instrument.

Use a low power setting at the beginning and use the contact method for resections. Change the power settings according to your observations and experiences.

8.5.3.11 Partial nephrectomy

Partial nephrectomy is performed with frontal emitting laser fibres.

A special laser handpiece serves as an instrument for the application. The laser fibre is guided via a guiding tube to the distal end of the instrument.

Use a low power setting at the beginning. Use the contact procedure for resection. Use irrigation to remove blood from the surgical site and reduce smoke. Change the power setting according to your observations and experiences.

Strong bleeding

In a partial nephrectomy, blood vessels with a diameter greater than 1.5 mm cannot be cut with sufficient haemostasis, which can lead to heavy bleeding.

- Prepare the temporary clamping of the renal artery to perform temporary ischemia in case of bleeding.
- Note that the ischemia time must not exceed 30 minutes.
- Then use the conventional methods of haemostasis.

8.5.3.12 Condyloma and penile tumour excisions

Condyloma and penile tumour excisions are performed with frontal emitting laser fibres.

A special laser handpiece serves as an instrument for the application. The laser fibre is guided via a guide tube to the distal end of the instrument.

Use a low power setting at the beginning. Work on the excision of tumours in the near-contact procedure. Wipe off the carbonized and coagulated tissue to assess the result. Change the power setting according to your observations.

8.5.4 Urology – Indications in PULSED operating mode

The ***RevoLix HTL*** laser device is used in the PULSED operating mode in urology for the following clinical indications:

- Lithotripsy of bladder stones
- Lithotripsy of ureter stones and kidney stones

.

8.6 Reference values of laser parameters for different applications

The treatment parameters in the tables may only be regarded as a guide. The effect of the settings cannot be determined in advance for each case. The settings must be checked individually and adjusted if necessary. Always assess the setting based on the observed laser effects on the target tissue. Start with low power settings and increase if necessary.

Please comply with the safety and warning instructions in the relevant chapters.

8.6.1 Settings for tissue applications

Tab. 24: Applications and Settings for Tissue Applications

Application	Power	Frequency (Pulse repetition rate)	Operational Mode	Laser fibre	Accessories or endoscope	Distance to the tissue
Urology						
VapoResection of the prostate	50 - 150 W		CW	*RigiFib, RigiFib 800*	Laser-resectoscope	Contact
Enucleation of the prostate	50 - 90 W		CW	*RigiFib*	Laser-resectoscope	Contact
	100 W	50 Hz	PULSED			
Vaporization of the prostate	70 - 150 W		CW	*SideFib-SU, RigiFib 800, RigiFib 1000*	Laser-resectoscope or laser-cystoscope	Near-Contact
Opening of ureter strictures	5 - 15 W		CW	*PercuFib*	Ureterorenoscope	Contact

Application	Power	Frequency (Pulse repetition rate)	Operational Mode	Laser fibre	Accessories or endoscope	Distance to the tissue
Opening of urethra strictures	10 - 15 W	-	CW	*PercuFib, RigiFib*	Laser resectoscope	Contact
Bladder neck incisions	15 - 30 W	-	CW	*RigiFib*	Laser resectoscope	Contact
Bladder tumour resections	5 - 20 W	-	CW	*RigiFib, PercuFib*	Laser resectoscope	Near-contact Contact
Partial nephrectomy Kidney tumour ablation	15 - 30 W	-	CW	*RigiFib, PercuFib, FlexiFib, SureFib*	Laser-handpiece *SurgiLas,* Smoke Evacuation	Contact
Condyloma	5 - 15 W	-	CW	*RigiFib, PercuFib*	Laser-handpiece *SurgiLas,* Smoke Evacuation	Near-contact
	5 - 15 W	10 - 15 Hz	PULSED			
Penile tumour excision	5 - 15 W	-	CW	*RigiFib, PercuFib*	Laser-handpiece *SurgiLas,* Smoke Evacuation	Near-contact
Ureter tumour ablation	5 - 15 W	-	CW	*PercuFib*	Ureterorenoscope	Contact

8.6.2 Settings for lithotripsy (PULSED mode)

Tab. 25: Applications and settings for lithotripsy (PULSED mode)

Application	Power	Effect [%]	Frequency (Pulse repetition rate)	Laser fibre	Accessories or endoscopes
Urology					
Lithotripsy of bladder stones	15 - 30 W	75 - 100	10 - 20 Hz	*PercuFib*, *RigiFib*	Cystoscope or comparable endoscope
Lithotripsy of ureter stones	10 - 15 W	75 - 100	10 - 15 Hz	*LithoFib, FlexiFib, SureFib*, *PercuFib*	Rigid URS, flexible URS
Lithotripsy of Kidney Calix Stones (URS)	10 - 15 W	75 - 100	10 - 15 Hz	*LithoFib, FlexiFib, SureFib*	Flexible URS
Lithotripsy of Kidney Calix Stones (PCNL)	15 - 25 W	75 - 100	10 - 15 Hz	*PercuFib*, *RigiFib*	Nephroscope
Lithotripsy of Renal Pelvis Stones (URS)	10 - 15 W	75 - 100	10 - 15 Hz	*LithoFib, FlexiFib, SureFib*	Rigid URS, flexible URS
Lithotripsy of Renal Pelvis Stones (PCNL)	15 - 40 W	75 - 100	10 - 15 Hz	*PercuFib*, *RigiFib*	Nephroscope
Lithotripsy ("Dusting")	10 - 20 W	50 - 100	25 - 100 Hz	*LithoFib, FlexiFib, SureFib*, *PercuFib*, *RigiFib*	Rigid URS, flexible URS, Nephroscope

9 Accessories

The products listed below are standard accessories for use with ***RevoLix HTL*** laser devices. In addition, accessories to be used must be indicated as suitable for use with ***RevoLix HTL*** laser devices. Please contact LISA Laser Products if you would like to use accessories not listed here together with a ***RevoLix HTL*** laser device.

Please check with LISA Laser Products for additional available equipment accessories.

9.1 Laser fibres

Note that only laser fibers supplied by LISA Laser Products may be connected to the laser device. Products from other manufacturers and suppliers may impair product safety and performance and may also result in costly damage to the laser optical system and instruments.

Tab. 26: Laser fibres

Product	Description	Order Number
LithoFib	Reusable laser fibre, 200 µm core diameter	101 503 188
LithoFib-SU	Laser fibre for single use, 200 µm core diameter	101 503 576
SureFib-SU	Laser fibre for single use, 272 µm core diameter	101 503 513
SureFib-SU 5m	Laser fibre for single use, length 5 m 272 µm core diameter	101 503 569
SureFib	Reusable laser fibre, 272 µm core diameter	101 503 364
FlexiFib	Reusable laser fibre, 272 µm core diameter	101 503 189
FlexiFib 5m	Reusable laser fibre, length 5 m, 272 µm core diameter	101 503 118
FlexiFib-SU	Laser fibre for single use, 272 µm core diameter	101 503 387
PercuFib	Reusable laser fibre, 365 µm core diameter	101 503 128
PercuFib-SU	Laser fibre for single use, 365 µm core diameter	101 503 384
RigiFib	Reusable laser fibre, 550 µm core diameter	101 503 213
RigiFib-SU	Laser fibre for single use, 550 µm core diameter	101 503 289
RigiFib 800	Reusable laser fibre, 800 µm core diameter	101 503 287
RigiFib-SU 800	Laser fibre for single use, 800 µm core diameter	101 503 385
RigiFib 1000	Reusable laser fibre, 940 µm core diameter	101 503 284
RigiFib-SU 1000	Laser fibre for single use, 940 µm core diameter	101 503 386

Tab. 26: Laser fibres

Product	Description	Order Number
SideFib-SU	Side-emitting laser fibre for single use, 550 µm core diameter	101 503 138
SureFib-SU smart connect	Laser fibre for single use, 272 µm core diameter, with RFID connection	101 503 650
FlexiFib-SU smart connect	Laser fibre for single use, 272 µm core diameter, with RFID connection	101 503 651
RigiFib-SU smart connect	Laser fibre for single use, 550 µm core diameter, with RFID connection	101 503 652
PercuFib smart connect	Reusable laser fibre, 365 µm core diameter, with RFID connection	101 503 665
FlexiFib smart connect	Reusable laser fibre, 272 µm core diameter, with RFID connection	101 503 666
RigiFib smart connect	Reusable laser fibre, 550 µm core diameter, with RFID connection	101 503 667

The use of laser fibers other than those listed in this manual together with this laser device poses a risk of injury to the patient.

9.2 Laser safety eyewear

Tab. 27: Laser safety eyewear

Product	Description	Order Number
Laser safety eyewear	Lightweight plastic basket glasses, suitable for wearers of glasses	101 503 141
Laser safety eyewear	Glasses with earpieces	101 503 399
Laser safety eyewear	Glass basket glasses, suitable for wearers of glasses	101 503 400

9.3 Other accessories

Tab. 28: Other accessories

Product	Description	Order Number
Kix	Single-pedal footswitch with connection cable	101 630 147
Kix DUO	Double-pedal footswitch with connection cable	101 630 144
Interlock connector	Dummy plug for the door interlock socket	101 600 166
Key	Key for the key-switch to turn on the laser devices	101 610 002
Fibre coupler shield	Protective shield for fibre connection	101 610 001
Potential equalization cable	Connection cable for potential equalization Length 5 m	101 630 123

10 Care and maintenance

Maintain and check the laser device regularly. The work described below is a preventive measure to ensure that the ***RevoLix HTL*** laser device is always ready for use.

WARNING

Infection risk

The laser device and its accessories may be contaminated with biological materials after use and present a potential source of infection.

- Clean and disinfect the laser device and its accessories before performing any maintenance.

WARNING

Laser radiation and electric current

Do not carry out any work on the laser device other than described in this maintenance manual. Opening housing parts can provide access to voltage or current-carrying parts as well as invisible laser radiation.

WARNING

Improper or inadequate maintenance / inspection

An improper or inadequate maintenance / inspection may result in a hazard to patients and users by electric power or laser radiation.

- Service/maintain the laser only as described in this chapter.
- All maintenance work must be carried out only by well trained and authorized personnel who is familiar with the unit and the associated risks.
- Do not attempt to make any maintenance actions, such as repairs, adjustment and inspections, yourself! Those work may only be performed by qualified and trained service technician authorized by LISA Laser Products!

10.1 Visual and functional check

The following tests should be carried out at regular intervals to ensure safe operation of the laser device:

Tab. 29: Maintenance/Inspection Schedule

Check	Recommended frequency
Housing parts Housing parts, handles and doors have no sharp corners and edges or other visible damage.	Monthly
Power and footswitch cables The cables and their strain reliefs do not show any damage. The transition points between the cable and connector/device should be checked very thoroughly.	Before each use
Parking brakes and wheels All wheels are smooth-running. After pressing the parking brakes, the device cannot be moved.	Monthly
Fibre coupler protective shield The fibre coupler shield has no damage. The optical window is clean and also free of damage (see chap. 10.2).	Upon need
Laser Stop The laser stop is pressed during the LASER READY operating state. The laser device responds with an error message.	Monthly
Door Interlock An error message is displayed when the door interlock switch is interrupted, or the interlock dummy plug is removed from the laser device.	Monthly
Laser fibre detection An error message is displayed when the laser fibre plug is loosened in the LASER READY operating state.	Monthly
Display The display in the control console is legible and has no errors. The displayed values in the display are plausible.	Monthly
Laser power (see chap. 10.4)	Annually or as needed
Aiming beam The quality of the aiming beam at the distal end of the laser fibre is uniform and circular. No dark shadows, stray light, or smears are visible. A slight inhomogeneous intensity distribution is possible.	Before any treatment or when changing the laser fibre
Special accessories Other accessories used during the operation of the laser device, such as smoke evacuators, should also be checked for damage and proper functioning.	Upon need
Laser safety eyewear The laser safety eyewear does not have scratches or damaged frames. The marking is legible.	Monthly

10.2 Checking and changing the fibre coupler shield

The coupled optics are protected from damage and contamination by a fibre coupler shield (REF 101 610 001). This shield must be checked regularly for damage and contamination. A check is always required if damage to the laser fibre plug has occurred. A dirty fibre coupler shield significantly weakens the laser power. This means that a large part of the emitted laser power is absorbed in the shield and converted into heat, which can cause damage to the fibre coupler or laser fibre.

To remove the fibre coupler shield, the cover [1.] is turned out. You can now pull out the fibre coupler shield [2.] with the help of pliers or tweezers on the cable hanger.

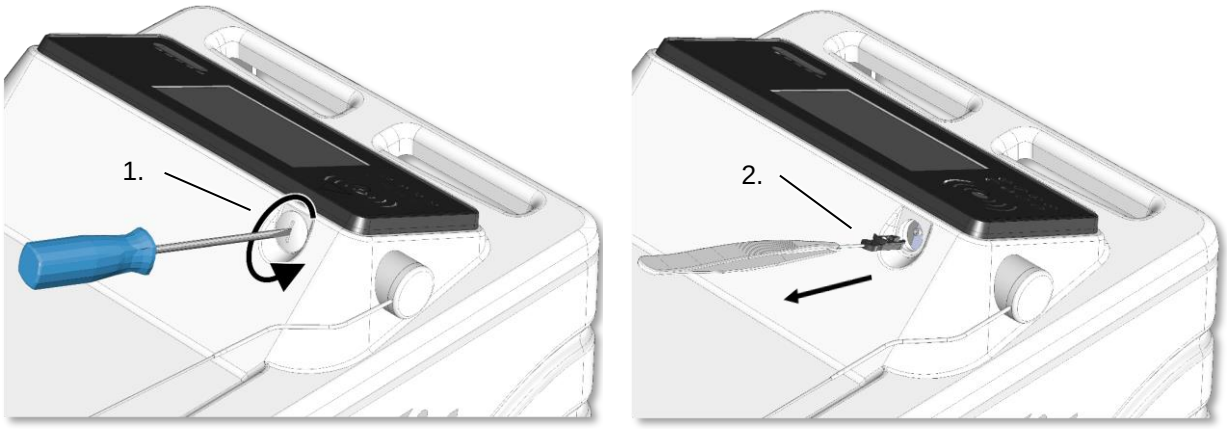


Fig. 54: Removal of the fibre coupler shield

To check the fibre coupler shield, hold it against the light or place it on a clean, bright surface. The optical window must be colourless transparent and free of damage and contamination. In the case of a damaged or dirty optical window, the fibre coupler shield must be replaced.

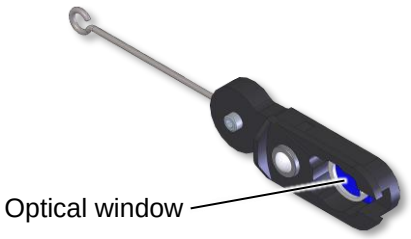


Fig. 55: Fibre coupler shield

INFORMATION

A soiled or damaged fibre coupler shield can absorb laser radiation and overheat. This can lead to a functional failure of the laser device and cause severe damage to the coupling optics.

- Check the fibre coupler shield regularly.
- Do not operate the laser device with a dirty or damaged fibre coupler shield.
- Never operate the laser device without a fibre coupler shield.

10.3 Cooling fluid

The level of the cooling fluid in the laser unit is automatically recorded. If there is insufficient cooling liquid, a corresponding message appears on the screen. The laser device must not be operated without cooling fluid. If necessary, have the coolant refilled by LISA Laser Products Customer Service.

10.4 Calibration and verification of laser power

The laser device is equipped with a control system that keeps the emitted laser power constant directly in the laser head and monitors it. This ensures that the emitted laser power is in line with the set laser power.

The accuracy and conformity of the displayed and emitted laser radiation is part of the periodic safety check, which must be carried out at least annually.

If you suspect that the emitted laser power no longer corresponds to the set value, you can control this by measuring the laser power with a suitable external laser power meter at the distal end of the laser fibre.

If the difference between displayed and measured performance is greater than 20%, LISA Laser Products customer service should be contacted to recalibrate the laser device.

Please note that the measured laser power may depend on the properties and condition of the laser fibre used for the measurement. The transmission of the radiation can be significantly reduced due to wear, damage, or contamination of the laser fibre.

10.5 Recurrent safety check

Every 12 months, a periodic safety check should be carried out.

The exact scope of the safety inspection can be found in the test specifications available on request from LISA Laser Products.

INFORMATION

The safety check should only be carried out by LISA Laser Products or a trained and authorized LISA Laser Products Customer Service.

10.6 Decommissioning and disposal

The laser device must not be disposed of in the household waste. The device contains substances that must be recycled or disposed of in accordance with the legal provisions. Clean and disinfect the laser device and its accessories before disposal.

LISA Laser Products also offers the return of the device after decommissioning.

Hazard of Infection

The laser device and its accessories may be contaminated with biological materials after use. Improper disposal may cause these materials to contaminate the environment and constitute a potential source of infection.

- Clean and disinfect the laser device and its accessories before disposing.

11 Error diagnosis

This chapter provides information on how to resolve malfunctions of ***RevoLix HTL*** laser devices. The customer service address can be found at the end of this chapter.

If a functional fault makes it necessary to carry out service or repair work on the laser device, in order not to endanger your and the safety of your patients, let this work be carried out only by a trained service technician authorized by LISA Laser Products. In such cases, contact LISA Laser Products Technical Customer Service.

⚠ WARNING

Improper maintenance

Improper maintenance can endanger patients, users and third parties from electrical current or laser radiation. Opening of housing components can open access to live parts as well as invisible laser radiation.

- Do not attempt to make any maintenance actions, such as repairs, adjustment and inspections, yourself! Those work may only be performed by qualified and trained service technician authorized by LISA Laser Products.
- For any repair work, contact LISA Laser Products' customer service.

11.1 Error messages

During the system test and the entire operation, device checks are performed continuously, which trigger warnings or error messages in the event of an error. Each irregularity detected by the system processor is displayed on the display together with a three-digit number in plain text, and instructions are given.

Please record all errors in the medical device book and also inform LISA Laser Products customer service. Contact details can be found in Chapter 11.2.

The error messages appear on the display as follows:

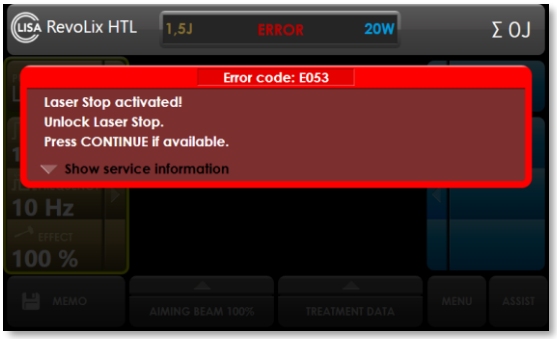


Fig. 56: Error message (example: error code E053)

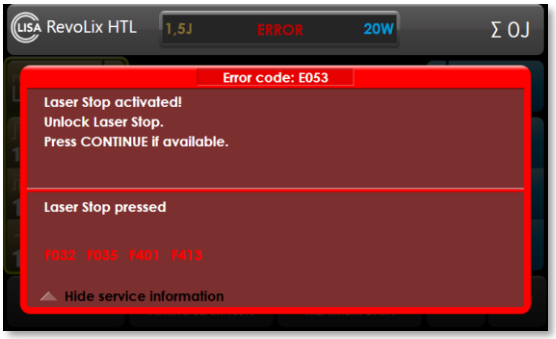


Fig. 57: Error message - service information with F-code

You can view additional service information by pressing the triangle in the lower-left edge of the error message.

If an error cannot be fixed, contact LISA Laser Products. If you receive an error message, please enter the error code and the F code from the service information for the error message.

Errors automatically reset after the error is no longer present (Fig. 58). The device is then in the STANDBY operating state.

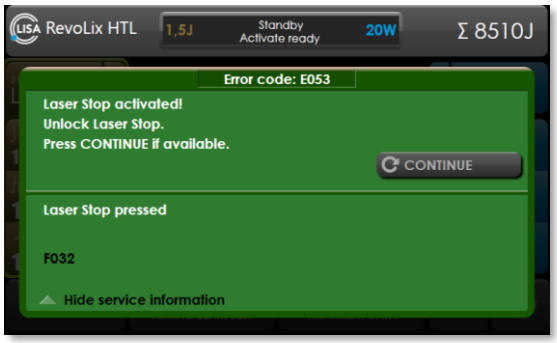


Fig. 58: Message after fixing the error

11.2 Information messages

Information messages indicate special settings or states of the laser device. The messages are hidden after confirmation of the displayed keypad or independently, after changing the state of the laser device.

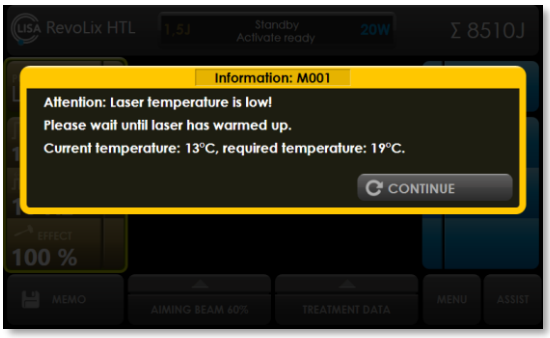


Fig. 59: Information message

11.3 Customer service

If you have any technical problems with the ***RevoLix HTL*** laser equipment, please contact our technical customer service:

LISA Laser Products GmbH

Albert-Einstein-Str. 4
37191 Katlenburg-Lindau
Germany
☎ +49 5556 9938-77
🖷 +49 5556 9938-10
service@lisalaser.de
www.lisalaser.de

11.4 Returns

Devices and their accessories that are returned to LISA Laser Products for maintenance or repair must first be thoroughly removed from possible pathogens with suitable cleaning and disinfectants. If you have any questions, please contact LISA Laser Products or your local contact person.

⚠ WARNING

Hazard of Infection

The laser device and its accessories may be contaminated with biological materials after use and present a potential source of infection.

- Clean and disinfect equipment and accessories before shipping.

12 Technical specifications

Tab. 30: Technical specifications

Technical Specifications	Laser Device Versions		
Model	***RevoLix HTL***	***RevoLix HTL cw***	***RevoLix HTL eco***
Dimensions (H x W x D)	1025 x 450 x 740 mm		
Weight	108 kg		
Degree of protection (IEC 60529)	IP 20		
Mains supply			
Electrical requirements	200 V - 240 V, 50/60 Hz, Max. 10 A (1~, N, PE) 110 V - 115 V, 50/60 Hz, Max. 20 A (1~, N, PE) *Automatic change-over*		
Mains plug	country specific		
Power supply cord	5.90 m		
Power consumption	Max. 2.2 kVA		
Protection against electrical shock (IEC 61140)	I		
Earth leakage current N.C.	Max. 0.5 mA @ 264 V AC (60 Hz)		
Working laser			
Type	Tm:YAG DPSS laser		
Laser class (IEC 60825-1)	4		
Wavelength	2013 nm (±10 nm)		
Operating mode PULSED			
Average power	5 - 150 W (±20 %)	n/a	5 - 75 W (±20 %)
Pulse peak power	max. 1300 W	n/a	max. 1300 W
Pulse energy	max. 4.5 J (±20 %)	n/a	max. 4.5 J (±20 %)
Pulse repetition rate	5 - 300 Hz (±5 %)	n/a	5 - 300 Hz (±5 %)
Step size	1 Hz	n/a	1 Hz
Pulse duration	200 µs - 4750 µs, Depending on laser settings	n/a	200 µs - 4750 µs, Depending on laser settings
Operating mode CW			
Power	5 - 150 W (±20 %)	5 - 150 W (±20 %)	5 - 75 W (±20 %)
Operation	Continuous-wave (CW)		
Aiming Laser			
Type	Diode laser		
Laser class (IEC 60825-1)	3R		
Wavelength	532 nm (green)		
Power	max. 3 mW (adjustable)		
Applied part			
Type (IEC 60601-1)	BF		
Beam delivery	All silica low OH multimode fibre (use LISA fibres only)		
Fibre connector	LISA F-SMA		
User panel	Colour LCD display, touch sensitive		

Technical Specifications	Laser Device Versions
Connectors	
Interlock	Neutrik female connector, type XLR, 4-pin
Footswitch	Neutrik female connector, type XLR, 7-pin
Cooling system	Air-Cooling fluid
Cooling fluid	Deionised water
Environmental conditions	
Operation	
Air temperature	+15 °C - +28 °C +59 °F - +82 °F
Rel. air humidity	10 - 90 % Non-condensing
air pressure	700 - 1060 hPa
Heat emission	0.47 kW up to 2.20 kW Depending on laser settings
Storage / Transport	
Air temperature	0 °C - +70 °C +32 °F - 158 °F
Acceleration	Max. 25 g
Transport position	Upright, lateral
Manufacturer	LISA Laser Products GmbH Albert-Einstein-Str. 4 37191 Katlenburg-Lindau Germany ☎ +49 5556 9938-0 🖷 +49 5556 9938-10 ✉ info@lisalaser.de 🌍 www.lisalaser.de

The device contains an RFID reader, with an RF transmitter. The RFID system has the following characteristics (Tab. 31).

Tab. 31: Technical RFID specifications

Description	Characteristic
Carrier frequency	13,56 MHz +/- 7kHz
Number of channels	1
Standard	ISO 15693
Communication data rate	19.2 kBaud
Reading distance	0 – 15 mm
Current with HF field	150 mA
Current without HF field	25 mA
Power with HF field	0.6 W
Power without HF field	0.1 W
Magnetic field	200 µT

12.1 Model specific laser marking

The following markings describe the laser radiation of the various ***RevoLix HTL*** versions:

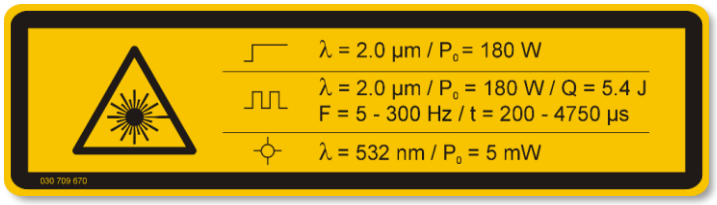


Fig. 60: *RevoLix HTL*

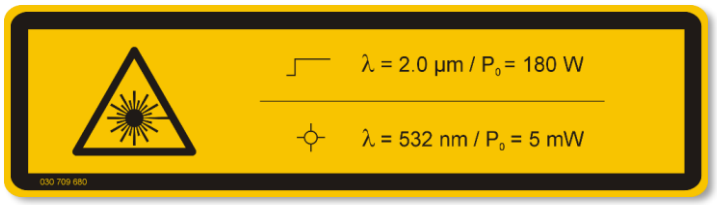


Fig. 61: *RevoLix HTL cw*

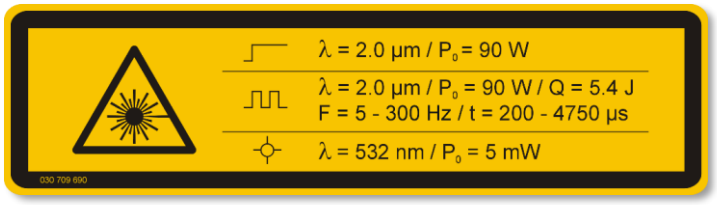


Fig. 62: *RevoLix HTL eco*

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