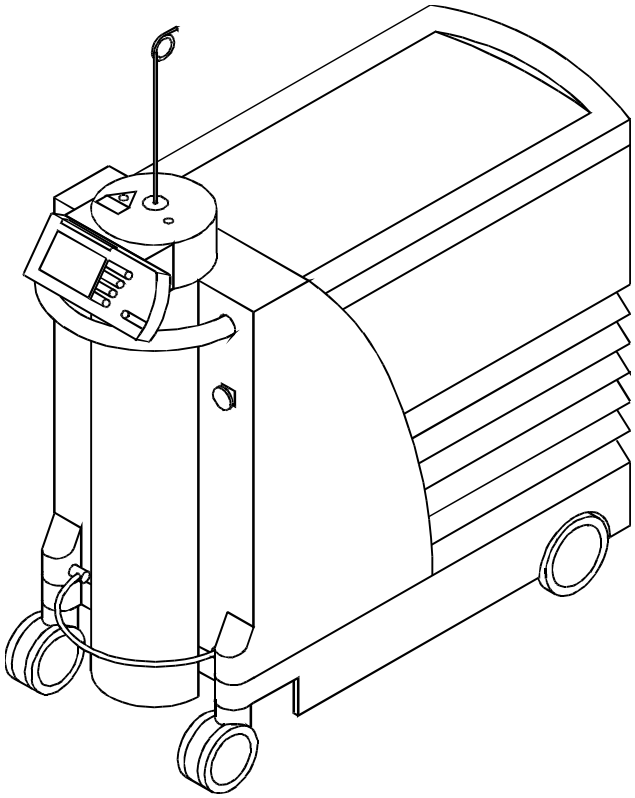
LISA
laser products

Medical Pulse Laser

SPHINX

25 W / 30 W / 45 W / 60 W / 80 W Holmium-YAG Laser



User Manual

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1 Items included

The Holmium-YAG SPHINX laser device is supplied without medical accessories. Laser fibres, applicators and other accessories must be ordered separately from the device manufacturer or his representative.

Included with the laser device's basic equipment are:

SPHINX laser system	**qty.**	**items included**
SPHINX Holmium-YAG medical laser	1	SPHINX Holmium-YAG medical laser
	1	Foot switch
	1	Door-interlock dummy connector
	1	User manual
	2	Laser warning signs

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2 About this manual

This manual provides important information concerning the safe handling of the medical pulse Holmium-YAG laser system SPHINX.

This manual must be carefully read and comprehended before using the laser system for the first time!

Safety instructions and symbols used in this manual

The safety instructions in this manual are intended to prevent possible injuries, material damage and operational faults. The fact that, before operating the laser for the first time, you should read through this manual carefully and keep it for future reference is also considered to be part of the safe operation of this product.

In this manual a distinction is made between the safety instructions used to warn of possible injury (DANGER) and instructions warning against operational faults (WARNING):

DANGER: **Risk of injury**! This instruction concerns the safety of patients, operators and other persons, who are in the room, in which the laser is being operated or maintained.

In this manual the following symbol is used to warn of the **risk of injury** from laser radiation (Fig. 1):

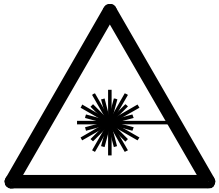

Fig. 1: **Symbol for Danger**

WARNING: Danger of **operational fault**! Failure to observe this instruction can lead to damage to the laser device, the applicator or the laser fibre.

In this manual the following symbol is used to indicate a possible **operational fault** and the damage to the laser device, which might result from it (Fig. 2).

Fig. 2: **Symbol for Warning**

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3 Manufacturer

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4 Important customer information

This manual describes the Holmium-YAG laser series. Within this series there are various power classes. The power class of the device in question can be seen from the name plate and the indications on the display control. The operation of these devices is uniform.

The laser systems belong to the following classifications/nomenclatures:

Medical product class according to MDD 93/42/EEC (Medical Device Directive)	Class IIb
Medical Device Class according to Title 21 of CFR, Parts 862-892	Class II
Medical product nomenclature according to UMDNS	17-769
Laser class according to IEC 60825	Class 4 / IV
Protection class according to IEC 60601	Class I
Protection group according to EN 60529	IP20

The SPHINX laser system complies with the ”Essential Requirements of the European Medical Devices Directive 93/42/EEC”

Observe the applicable guidelines of your employer’s liability insurance association and equal ranking organizations. The responsibilities, relevant safety measures and personal protective gear are described in these regulations.

Observe the specific national laws and regulations on operation and safety of medical devices and laser equipment.

The installation of a laser system must be according to the instructions given in this manual.

The documents referred to and this manual must be read carefully before operating the laser system.

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5 General description

The SPHINX laser device is a surgical cutting laser. The wavelength is invisible and infrared (2.1 µm). The laser radiation is given off in pulses. Because it is possible to transmit the laser beam via a laser fibre it is particularly applicable for endoscopic use.

Operation of the device is user-friendly via the display control.

5.1 Basic physico-technical principles

The SPHINX Holmium Laser is a so-called Holmium-YAG laser. Holmium is an element of the rare earths. Trivalent Holmium ions in a crystal matrix of synthetic Yttrium-Aluminum-Garnet (YAG) are the optically active ions in this laser, i.e. Ho^{3+} ions in the YAG crystal emit the laser radiation.

Apart from Holmium the laser crystal is also doped with optically active chrome (Cr^{3+}) and thulium (Tm^{3+}) ions. These two additional dopings are responsible for the efficient excitation of the Holmium ions with the light of a xenon flash lamp. The complete description of this laser type is as follows:

YAG:Cr,Tm,Ho solid state laser

The laser crystal, which has the shape and dimensions of a cigarette, is arranged parallel to the rod-shaped Xe flash lamp. The end surfaces of the laser rod are polished. The axis of the laser rod forms the optical axis of the laser.

As a result of optical excitation by the light from the flash lamp the Holmium ions spontaneously emit light with a wavelength of 2.1 µm. Photons, which emerge by chance from the laser rod onto the optical axis and are reflected back into the crystal, experience optical amplification when there is sufficient optical excitation of the laser crystal by the flash lamp, i.e. the intensity of the light beam increases within the laser rod like an avalanche. The emission of the laser radiation is therefore stimulated by spontaneously emitted light. The acronym LASER was formed from this relationship:

LASER = Light **A**mplification by **S**timulated **E**mission of **R**adiation

A part of the light beam emerges through the output mirror as a working beam and is focussed from a focussing optic into a laser fibre made from quartz glass. This fibre, provided with a suitably shaped handpiece serves the operator as working instrument.

5.2 Basic physico-medical principles

This section will deal with the underlying principles of laser-tissue interaction. More detailed information about special medical applications will follow lower down in the section on “Clinical applications”.

The Holmium-YAG laser emits invisible pulsed laser radiation of the 2.1 µm wavelength. Aqueous tissue absorbs radiation of this wavelength particularly well, i.e. laser radiation affecting the tissue is absorbed in a particularly short path distance and converted into heat. At 2.1 µm wavelength this so-called absorption length amounts to c. 0.3 mm.

For the efficient removal of tissue it is necessary that the absorption process (duration of one laser pulse) dissipates as quickly as the removal of the heat created within the tissue by thermal conduction and convection. The output capability of the laser device in question is based upon the relatively short pulse duration of less than 170 µs (see “Technical data” section).

With a significantly longer pulse duration heat would dissipate into the surrounding area during the laser pulse and would then no longer be available for tissue removal.

5.2.1 Intended use of the laser device

The SPHINX Holmium laser is used for cutting, removal and coagulation of soft and hard tissue. The laser is transmitted through a laser fibre of high quality material. The distal end of the fibre is enclosed in an appropriate applicator. Various applicators are available, each of which is designed for a specific purpose (see sections on “Accessories” and “Clinical applications”). Use, cleaning, care and if necessary re-sterilization of the individual applicators is explained in the appropriate user manuals.

Operation of the laser device is carried out using an operating console, which may be turned through 270 degrees about the laser outlet. Switching-on and setting the operating parameters is explained in the section “Operating the laser device”.

5.2.2 Tissue interaction

The tissue-removing effect of the Holmium laser is based upon direct heating of aqueous tissue during the absorption of a laser pulse. The effective zone within the tissue is limited by the absorption length.

The absorption length describes the path length, upon which a weak laser beam, which causes no change in the tissue, is attenuated to 1/e = 37% of its initial intensity. After a further 0.3 mm the intensity then amounts to only 37% x 0.37% = 14%; etc.

In practical use a greater intensity is chosen, because a tissue change or tissue removal is the purpose of using the laser. Removal is attributed to the direct heating of the tissue to above boiling point. The resultant vaporization leads to the removal of the vaporized tissue.

The effect of the laser is at its maximum directly in front of the fibre tip. Because of the divergence of the laser beam, the diameter of the laser beam increases continuously with the distance from the fibre tip. At the same time the intensity and, consequently, the effect of the laser beam decreases.

The extent of what is removed depends upon the amount of pulse energy used and the area irradiated with one pulse. As a rule of thumb one can say: The closer the fibre tip is brought to the tissue surface the narrower though deeper is the removal. The greater the pulse energy used, the deeper is the effect.

The damage zone is not limited to the visible removal of tissue, since the individual laser pulse penetrates beyond the excision further into the tissue. In addition there is heating of the tissue through thermal conduction, because heat flows out into the surrounding area through heat conduction from the area, in which the laser pulse was absorbed.

Depending upon the treatment technique, the actual damage zone can become larger than 2 mm. As a rule of thumb one can say: The greater the set frequency or the longer the applicator is held in one place, the wider is the thermal damage zone. The greater the pulse energy used and the lower the frequency, the narrower is the thermal damage zone.

5.2.3 Irrigation liquid

The Holmium-YAG laser is extremely suitable for applications using aqueous irrigation liquids. Such circumstances occur, for example, in arthroscopy and transurethral urology. The use of the Holmium-YAG laser on tissue in the air can easily lead to overheating and carbonization of the tissue and the throwing out of tissue particles.

Any medically approved water-based irrigation liquid may be used. It does not matter whether the aqueous medium is a Glycine or Sodium Chloride solution. Both media will provide very similar absorption and cooling characteristics. In contrast with HF surgery, the conductivity of the irrigation liquid has no effect upon the operation of the laser.

When used with the laser the irrigation liquid assumes the following functions:

1. efficient removal of the heat generated by the laser.
2. the irrigation fluid limits the effective zone to the vapour bubble, which builds up in front of the fibre tip during the laser pulse.

6 Installation of the laser device

The laser device and the relevant regulations place specific demands upon the place where it is set up. These refer to the safety precautions, the electricity supply and the place where it is positioned.

The installation of the laser device is carried out by an expert authorized by the device manufacturer, who will also carry out a functional test after the laser device has been installed in the designated place.

6.1 Marking the operating room

The room, in which the laser device is to be operated (generally the OR) must be designated as a laser area, in accordance with the relevant guidelines. The sign to be used for this purpose is shown in the section “Marking the entrance doors”.

6.2 Laser warning light

The operator must install a laser warning lamp above the entrance door to the operating room. This lamp must then always be switched on when the laser is in operation.

The manufacturer or his representative will be happy to provide appropriate suggestions for the electric wiring.

6.3 Mains connection

The requirements regarding the mains connection for the types of laser device described here are a little different, depending upon the power class of the device. Please note the maximum current consumption from the name plate. The manufacturer recommends, if possible, a 3-phase 32 Amp CEE type wall socket with its own fuse.

In any case only mains connectors with a locking mechanism are approved by the manufacturer to be used with the laser. Apart from the laser device, no additional electrical loads should be connected to this fuse.

3-phase equipment is fitted with an acoustic monitoring device, indicating the failure of one phase or an erroneous rotational direction:

Single tone every 5 seconds	one or two phases have failed
Double tone every 5 seconds	erroneous rotational direction

Should a fault occur call your house technician or the service department

6.4 Cooling

SPHINX lasers are fitted with an integrated compressor cooling system.

While the laser is being operated this active cooling system draws off the resultant dissipation power into the room air. Because of the efficiency of the laser device, the dissipation power is almost identical with the consumption power.

In rooms, which are not air-conditioned, one should take account of a corresponding warming of the room air. The laser may be operated continuously at an ambient temperature of up to about 26 °C. The device switches off automatically if the ambient temperature becomes too high. (see section “Fault messages”).

When operating the laser device please ensure that the ventilation grilles on each side of the laser device do not become covered. During operation the device must not be placed with one of its longer sides directly against a wall!

An additional cooling water or gas connection is not necessary.

6.5 Connecting the foot switch

The plug at the free end of the foot switch cable is inserted into the first socket on the left at the back of the device and screwed tight. The plug will only fit in one particular way. All electrical connections to the laser device are designed so that they are not interchangeable. See also further in this section on the drawing of the laser device.

6.6 Connecting a door-interlock switch

A door-interlock switch can be plugged into the second socket from the right (back of the device) and screwed tight. Installation of the door-interlock must take place in collaboration between one of the device manufacturer's service technicians and your house technician. See also further in this section on the drawing of the laser device.

If no door-interlock switch is used, the dummy plug supplied must be plugged into the free socket. The dummy plug is fitted with a bridge between pin 1 and pin 3.

When the door-interlock switch circuit is broken – or the bridge between pin 1 and pin 3 – the laser is immediately de-activated. Once the door-interlock switch has been closed again the laser can only be operated again after pressing the 'release' button.

6.7 Transportation and storage of the laser device

The laser device may only be transported and stored upright, otherwise cooling water can leak out.

During transportation care must be taken to ensure that the device is not subjected to severe jolts or vibrations. For example, the laser must not be placed hard on the floor or pushed too quickly over non-skid floor surfaces. In extreme cases those kinds of stresses can lead to de-adjusting of the laser resonator.

The laser device can be lifted at the front using the pushing handle and at the back under the frame (see section on "Front of the device"). For design reasons the device should **never** be lifted with the handle used to activate the **wheel brake**.

The room temperature at the installation and storage locations must be at least + 3 °C.

7 Laser and device safety

The SPHINX Holmium laser uses as its working beam a pulsed Ho:YAG laser with an emission wavelength of 2.1 µm. The laser device is allocated to laser class 4 in accordance with IEC 60825. Accidental irradiation of persons can cause injuries to the skin and the eyes.

A semiconductor laser with an emission wavelength of 635 nm and an output of 0.95 mW is used as a target beam (pilot laser). Although this laser is classified in laser class 2 as a laser light pen, non-intentional irradiation of persons is to be avoided.

Observe the applicable national guidelines of your employer's liability insurance association and equal ranking organizations and your national guidelines / regulations on the safe use of medical laser devices. The responsibilities, relevant safety measures and personal protective gear are described in these regulations.

Follow the instructions in this manual and those in the laser accessory manual.

DANGER

Only use the laser for the purpose, for which it was designed!

Never point the laser beam at a person!

Irradiation of persons can cause injuries to the skin and eyes.

All persons in the laser area must wear appropriate laser safety eyewear.

DANGER

Irradiation of flammable materials or liquids can cause them to ignite.

The laser system must not be used in an explosive atmosphere.

DANGER

Smoke generated by laser tissue interaction may contain viable tissue particles or toxic substances!

Use an appropriate smoke evacuation.

DANGER

The function of the SPHINX may be affected by mobile or cordless phones and other HF–communication devices.

Do not use mobile or cordless phones and other HF–communication devices during operation of the SPHINX.

7.1 Marking of entrance doors to laser areas

All entrance doors to the operating theatre (=laser area), in which the laser system is set up and operated, are to be marked on the outside with the following warning sign in accordance with

IEC 60825 (or the relevant local regulation) (original black on yellow).

If a laser is used the operating theatre becomes the laser area.

Fig. 1: Warning sign for marking of entrance doors

A laser warning light above the entrance door to the operating room is compulsory. This light always has to be illuminated when the laser is in operation.

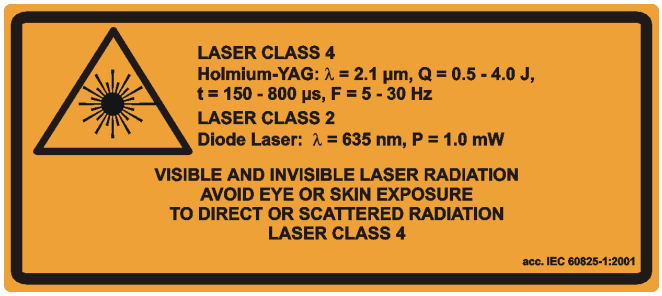
7.2 Marking of the laser system

This Chapter describes the type and the location of the danger and regulatory compliance labels of the SPHINX laser. From the labelling of the system the user gets important information regarding the device and the safety of laser devices. The labelling has to follows the applicable standards and regulations.

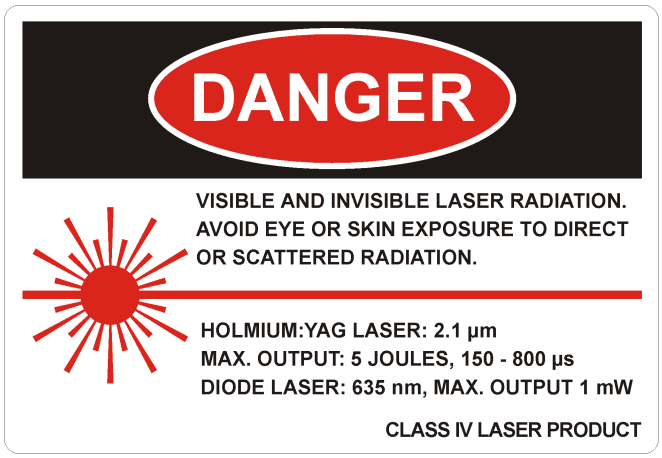
7.2.1 Laser Warning Labels

The following signs are is attached to the back of the laser (original black on yellow). They shows the laser class and output. (Fig. 2)

Warning Label Laser Class



Warning Label Laser Output



Warning Label Laser Output (USA only)

Fig. 2: Laser Danger Label

7.2.2 Beam outlet (fibre port)

The beam outlet is marked with the following sign (original black on yellow)

Fig. 3: Warning Labels Beam outlet

7.2.3 Laser-Stop

The Laser Stop-Button is marked with the following sign (original black on yellow)

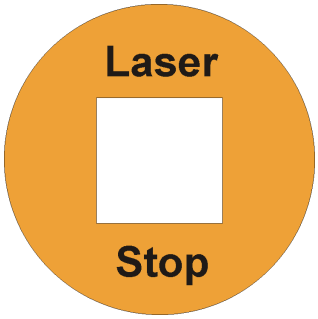


Fig. 4: Marking of the Laser-Stop Button

7.2.4 Danger Label Electric Energy

Parts of the device where danger from High Voltage electric energy may occur are labeled with the following sign:

Fig. 5: Danger Label Electricity

7.2.5 Name Plate

The name plate is attached to the outside of the back door. It comprises all the necessary data for the identification of your laser system (Fig. 6).

Fig. 6: SPHINX Name Plate (Example SPHINX 80 Watts)

SN XXX	200X		IP20	CE 0123	!
Serial Number	Manufacturing date	Type BF Applied part	Ingress protection	CE Marking	Attention, read manual

7.2.6 Position of Labels

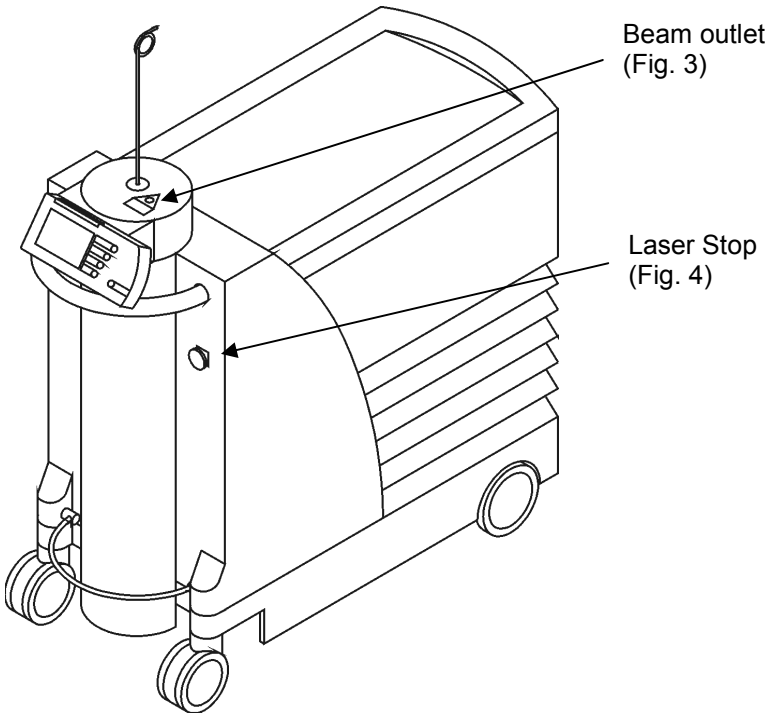


Fig. 7: Labels at the front of the device

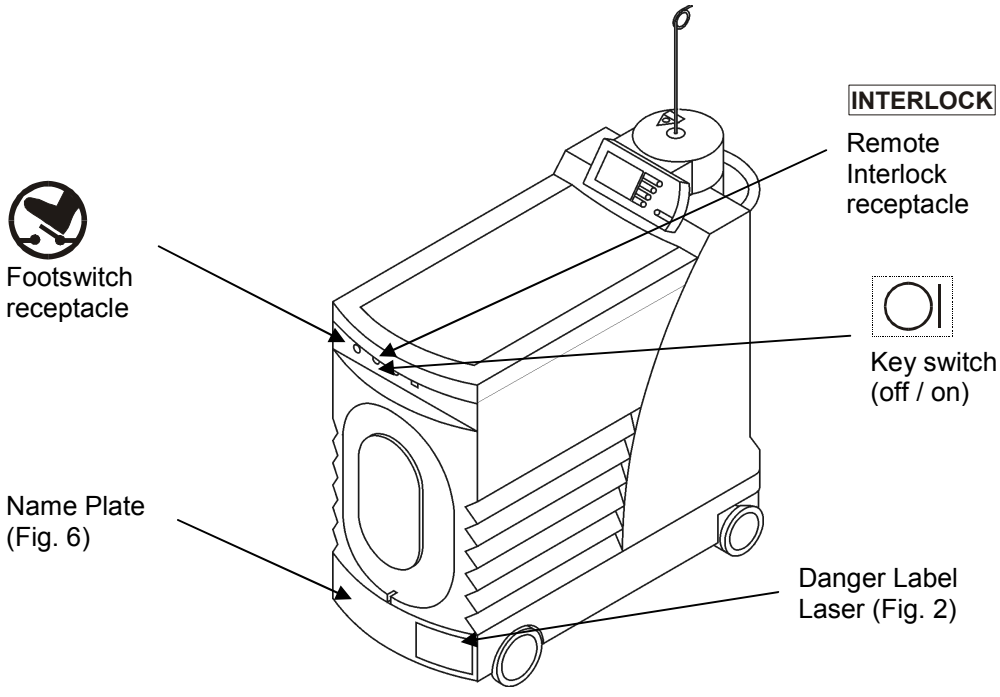


Fig. 8: Labels at the back of the device

	INTERLOCK	
Key switch (off / on)	Remote Interlock receptacle	Footswitch receptacle

7.3 Laser safety eyewear

7.3.1 NOHD - "Nominal Ocular Hazard Distance" for SPHINX Laser

As laser radiation is more or less divergent the energy density decreases with increasing distance from the laser source. The NOHD marks the distance were the energy density of the laser radiation is equal to the MPE (Maximum Permissible Exposure Limit).

The NOHD is calculated according to the European standard DIN EN 60825-1:2001-11 „Safety of laser devices“.

Wavelength	λ = 2,1 µm
Numerical aperture of fibre	NA = 0,22 ϕ = 25,4° = 0,443 rad
Fibre diameter	a = 200 µm
Pulse energy	E_{Puls} = 4 J
Average power	P_p = 80 W
Pulse length	t_{min} = 150 µs
Pulse frequency	f = 30 Hz
Pulse peak power	$P_p = E_{Puls} / t_{min}$ = 4 J / 150 µs = 2,7*10^4 W

The calculation of the NOHD follows either the calculation of single pulses or the calculation of a cumulated series of pulses what ever leads to a higher restriction.

The calculation of the NOHD of the SPHINX Holmium laser follows the assessment of the average power.

Average energy of irradiation

According to Cap.13.3b of DIN EN 60825-1 the mean value of the radiation of a series of pulses is (MPE limit):

$$E_{series} = 5600 \cdot t^{-0,75} Wm^{-2} = 5600 \cdot (10s)^{-0,75} Wm^{-2} = \underline{995,83 Wm^{-2}}$$

The actual power of a series of pulses is:

$$P_{mean} = P_P \cdot t_{\min} \cdot f = 2,7 \cdot 10^4 W \cdot 150 \mu s \cdot 30 Hz = \underline{121,5 W}$$

The NOHD (**r_{NOHD}**) is than calculated as:

$$r_{NOHD} = \frac{\sqrt{\frac{4 \cdot 2,5 \cdot P_{mean}}{\pi \cdot E_{series}}} - a}{\phi} = \frac{\sqrt{\frac{4 \cdot 2,5 \cdot 121,5 W}{\pi \cdot 995,83 Wm^{-2}}} - 200 \cdot 10^{-6} m}{0,443 rad} = \underline{1,41 m}$$

Therefore the NOHD for the SPHINX Holmium laser is: 1,41 m.

7.3.2 Required eye protection

The laser area is considered to be that area, in which the amount of radiation or the radiation can exceed the current maximum permitted radiation of the cornea of the eye (MPE), including the possibility of a random unintended deviation of the laser beam. Usually the laser area is identical to the room, in which the laser is installed. The worst case Nominal Ocular Hazard Distance (NOHD) of the SPHINX laser is 1.4 m.

All personnel who are within the NOHD are considered to be within the laser area and shall wear suitable eye protection supplied by the manufacturer/distributor of the laser system with a minimum protection class (acc. to EN 207) of: **L2** (at 2.1 µm)

7.4 Laser safety officer

According to most of the national regulations the operator – in most cases the hospital administration or the qualified doctor – has to appoint in writing a proficient person to act as the laser safety officer for the operation of the laser system.

The laser safety officer is regarded as proficient if, during his professional training or experience he has acquired sufficient knowledge about the use of the laser, which is to be brought into use, and is thoroughly informed about the effect of laser radiation, about safety measures and safety regulations, so that he is able to assess the necessary safety precautions and check their effectiveness.

Make sure that you fulfill you national regulation on the safety of medical laser devices before operating the system.

7.5 Authorized users of the laser device

The laser system may only be used by such persons who have been instructed by the manufacturer or by an authorized representative of the manufacturer in the correct operation of the system taking the manual into account. Only those people may receive instruction who, because of their knowledge or practical experience, are suitable for instruction in the operation of this system. The SPHINX laser system is intended solely for physicians trained in the use of the laser system.

7.6 System book, medical systems book

Due to regulation in some countries a medical systems book is to be kept with the laser system. The medical systems book is to be kept both by the operator as well as by the maintenance and servicing personnel and it has to be shown on request to the competent testing and supervisory authorities.

The following is to be specially entered into the medical systems book:

1. Training of the personnel responsible for the laser system
2. Training of skilled operators
3. Technical safety controls
4. Maintenance measures and
5. Functional errors.

The medical systems book is to be kept without gaps until the system is finally taken out of service and to be kept for a further 5 years beyond that time.

Please make sure that you follow the applicable regulation in your country.

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8 Operation of the laser device

In the first part of this section the operating components of the laser device will be explained, without the laser device having to be operated in order to understand the text.

The actual “Starting-up and switching-on routine” will be described further on in a separate sub-section. In that sub-section it will also be shown how the correct state of the laser device can be ascertained.

Before using the laser device make sure that all safety measures have been taken.

8.1 Operating and display components

The operating and display components are arranged in two groups, which are to be found on the back of the device and the operating console.

8.1.1 Back of the device

All electrical connections and the key switch to switch on the device are located on the back of the device (Fig. 9).

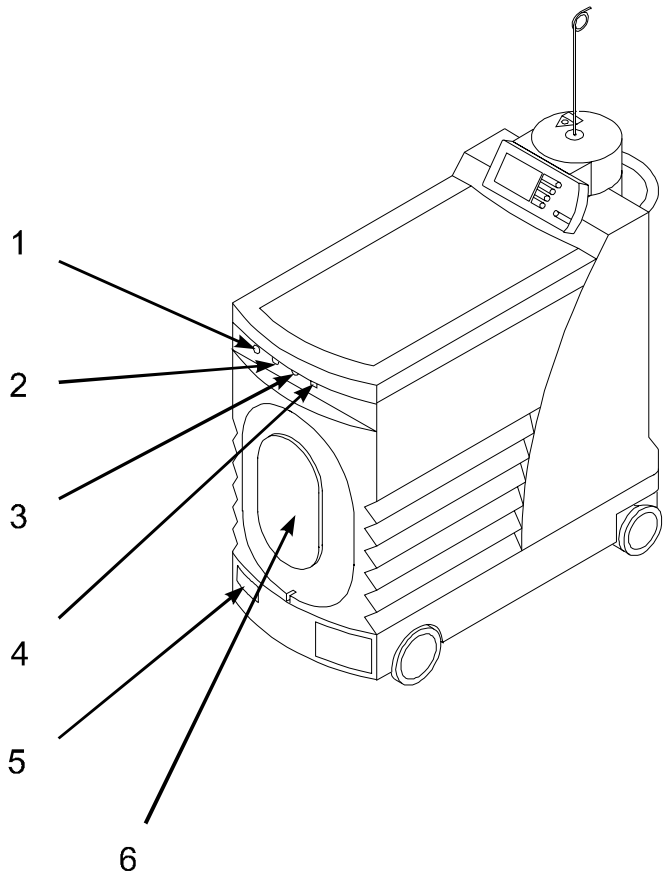


Fig. 9: Back view of the device

1	Foot switch connection	4	Computer interface
2	Door-interlock connection	5	Name plate
3	Key switch	6	Mains cable holder

8.1.2 Front of the device

The most important operating and indicating components are brought together on the front of the device (Fig. 10).

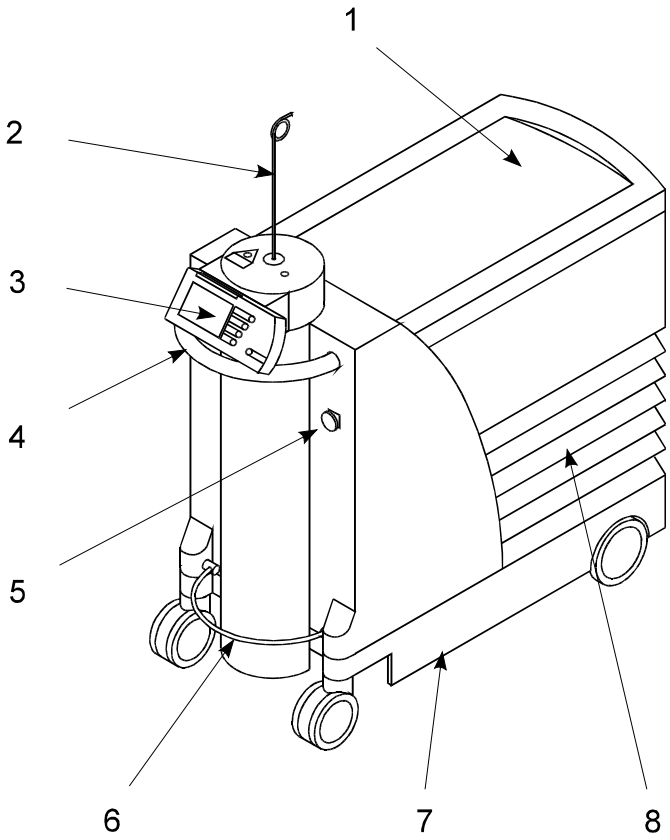


Fig. 10: Front view of the device

1	Place of deposit	5	Emergency off button
2	Fibre holder	6	Wheel brake
3	Operating console	7	Frame
4	Pushing handle	8	Ventilation grille

8.1.3 Operating console

All communication between operator and laser device passes through the operating console, which may be turned through 270 degrees. The fibre holder is located at the turning center. The beam outlet (circular black area) is immediately adjacent (Fig. 11).

The output components of the laser device are the colour monitor, the laser warning lamp and a loudspeaker. The input elements are the four function buttons and the release button.

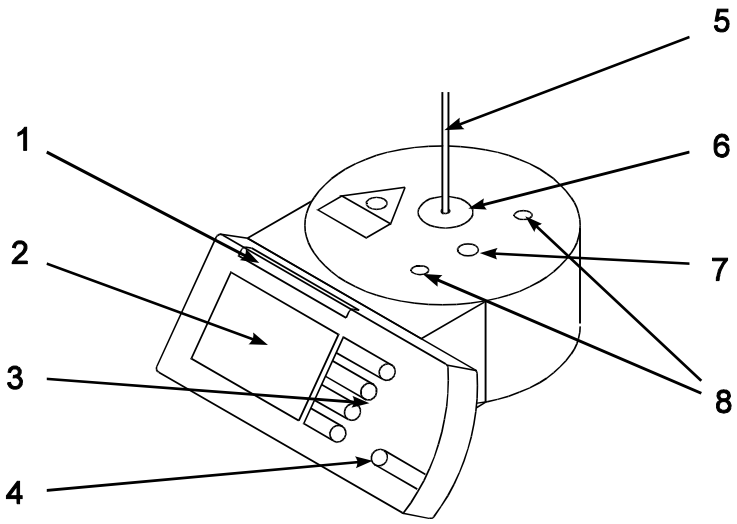


Fig. 11: Operating Console

1	Laser warning lamp	5	Fibre holder
2	Color monitor	6	Guide for the fibre holder
3	Four function buttons	7	Fibre port
4	Release button	8	Screws for securing the console cover

8.2 Starting-up and switching-on routine

Before switching on it is necessary to check whether:

1. the necessary safety precautions have been taken (e.g. wearing laser safety goggles, the arrangement of the laser safety area and of what is to be observed in it)
2. the foot switch is attached and the laser device is connected to a suitable power supply.
3. if necessary the door-interlock dummy plug is inserted and
4. the necessary laser fibres and laser applicators are to hand.

   On the use of laser fibres and laser applicators please consult the manual for the accessory in question.

   You will find a list and explanation of “Clinical applications” in a separate section later on.

Switching-on routine:

1. Switch the laser device on using the key switch on the back of the device (1/4 turn to the right). The cooling water pump and the compressor cooler will immediately start to work.
2. The microprocessor control carries out various checks on the device during the first 70 seconds after switching-on (start-up). At first the laser warning lamp stays permanently on and the colour monitor screen is dark. After approx. 40 seconds the manufacturer’s logo appears on the screen, the laser warning lamp blinks and during the course of a test routine the laser emits an audible internal laser pulse. After approx. 50 seconds the warning lamp goes out and the selection menu appears (see section on “Operation of the display control”).
3. Possible fault messages during the Start-up routine appear on the screen in clear text (see section on “Fault messages”).
4. The desired mode is selected either directly or as a pre-setting (memo) (see section on “Operation of the display control”).
5. Remove the fibre holder and insert the fibre.
6. Pressing the release button opens the fibre port. Attach the laser fibre as instructed in this manual (see section on “Connecting the laser fibre”) and the laser fibre’s manual. The fibre port will close automatically after about 10 seconds.

7. Take care when attaching the laser fibre that dust, dirt or liquids never penetrate into the beam outlet on the laser device!

WARNING	Dust, dirt or liquid penetrating into the beam outlet can severely damage the fibre coupling blast shield and the focussing cell. Please observe the instructions in the section on “Care and maintenance” relating to the checking and replacement of the fibre coupling blast shield.

8. By pressing the release button a second time the laser is switched from **“Stand By”** to **“Ready”**. The “**Ready**” mode is indicated by the illumination of the laser warning lamp and the pilot laser being switched on. Should the pilot laser not be visible at the distal end of the fibre then the setting for the brightness of the pilot laser should be adjusted (see section on “Altering the pulse duration and the brightness of the pilot laser”).
9. The laser device can now be brought into use by pressing on the foot switch. In so doing, note that the foot switch has a clearly tangible action point. The first laser pulse will not be emitted until a few tenths of a second after the action point has been passed, simultaneously with an acoustic signal.

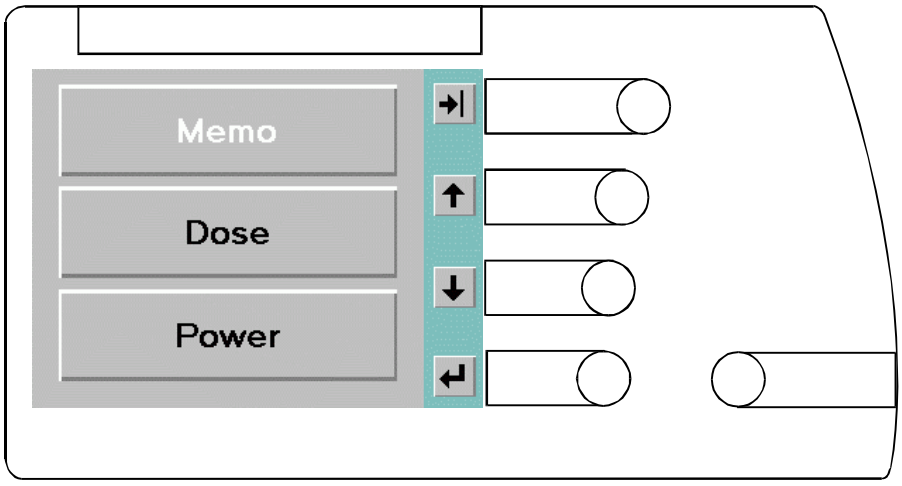
DANGER	There is a danger of injury from an uncontrolled emission of laser radiation. Only use the laser device and the laser radiation for intended purposes.

10. Before the laser is used for the purpose for which it was designed, the user must acquaint himself with the correct condition of the laser device (see section on “Care and maintenance”).

8.3 Operating the display control

Altering the laser parameters is achieved using the display control – just like using a cash-point machine.

After the laser device is switched on the following graphic appears on the color monitor, which is called the selection menu.



At this stage by using the ↑-button or the ↓-button either the “**Power**” or “**Dose**” mode is selected or pre-set parameters are called up from the “**Memo**” mode. Your selection appears in **red lettering** and you can then call it up with the ↵-button.

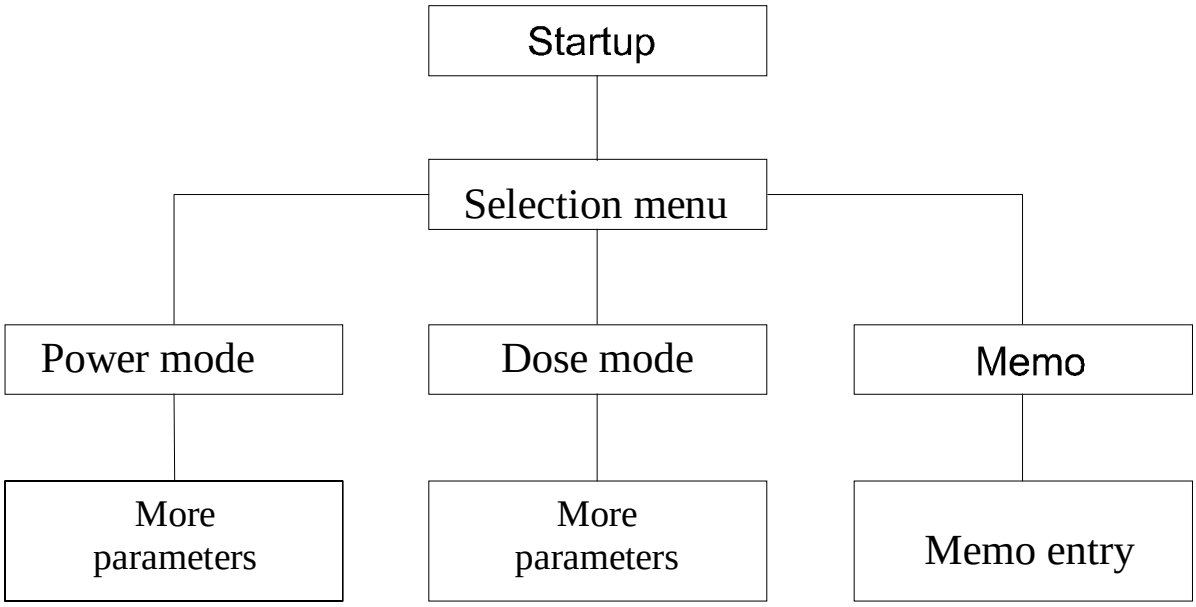
The operation of the “**Power**” and “**Dose**” modes is characterized by the following features:

“Power”	Control of the radiation emitted by the laser device according to the formula: power = energy x frequency, i.e. the energy and frequency of the emitted radiation can be varied. The laser emits laser pulses as long as the foot switch is depressed. See sections on “Alteration of the parameters in the power mode” and “Clinical applications.
“Dose”	Control of the radiation emitted by the laser device according to the formula: Partial dose x positions = dose, i.e. a selected dose is divided up into a certain number of partial doses. Once this dose is reached, the laser device stops. See sections on “Variation of parameters in the dose mode” and “Clinical applications”.

8.4 Modes and menu structure

Each of the laser device's modes (e.g. "power" or "dose") is allocated a separate so-called menu. The totality of all possible menus is described as the menu structure.

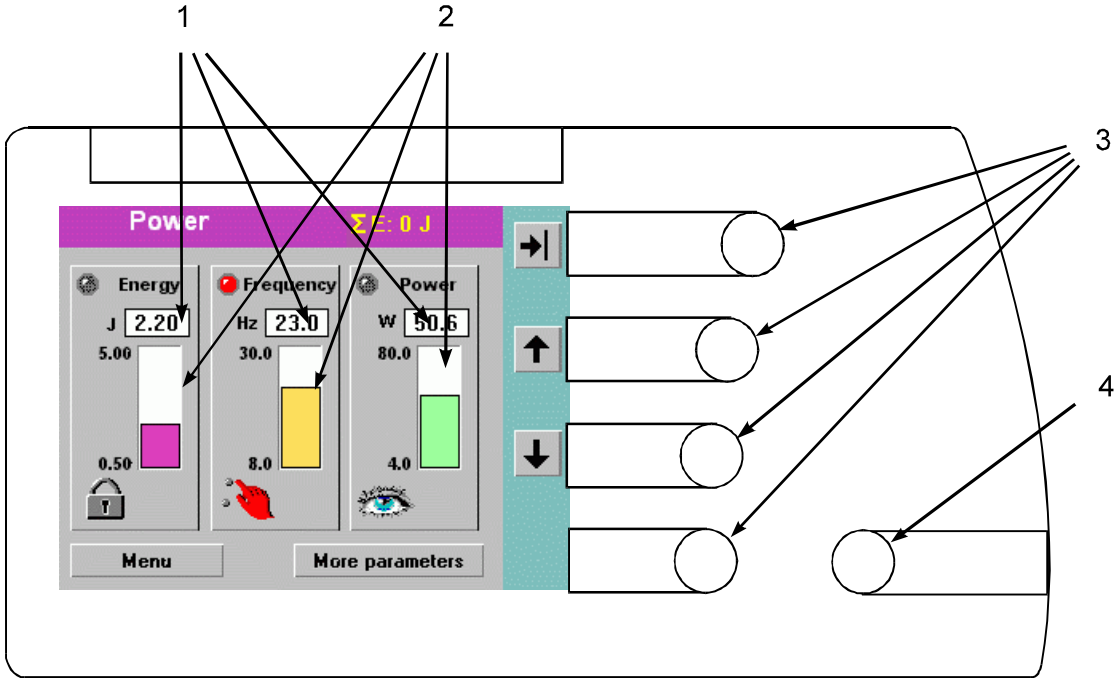
8.4.1 Menu structure of the display control



Depending upon the parent menu, the menu's "More parameters" are easily variable. Using the "Return" function from one menu "More parameters" can be exclusively returned to the previously selected mode.

8.4.2 Functions of the menu control

In the following illustration of the function buttons it is assumed that the "power" mode was selected in the menu. Obviously the "dose" mode can equally well be selected from the menu (see section on "Dose operation – percutaneous laser nucleotomy").



1	Current set parameters
2	Bar graph displays with the setting range (e.g. frequency: 10 – 25 Hz) shown on the left.
3	Four function buttons

4	Release button (READY)

Altering the parameters such as (laser pulse) energy, frequency and power is carried out exclusively by means of the four function buttons on the operating console. What the function buttons do depends upon the display shown (menu). In the right display border each menu has a toolbar, determining the meaning of the function buttons specific to that menu.

The possible meanings of the function buttons are (see next page):

 Increase the parameter indicated by the hand symbol and red dot.

 Decrease the parameter indicated by the hand symbol and red dot.

 Change the hand symbol and the red dot to the next parameter or change to the next item on the menu. In all menus the menu items are arranged below the bar graph displays. As soon as a menu item is selected its labelling changes from **grey** to **red**.

 Entry confirmation, change to the selected menu.

The display symbols have the following meaning:

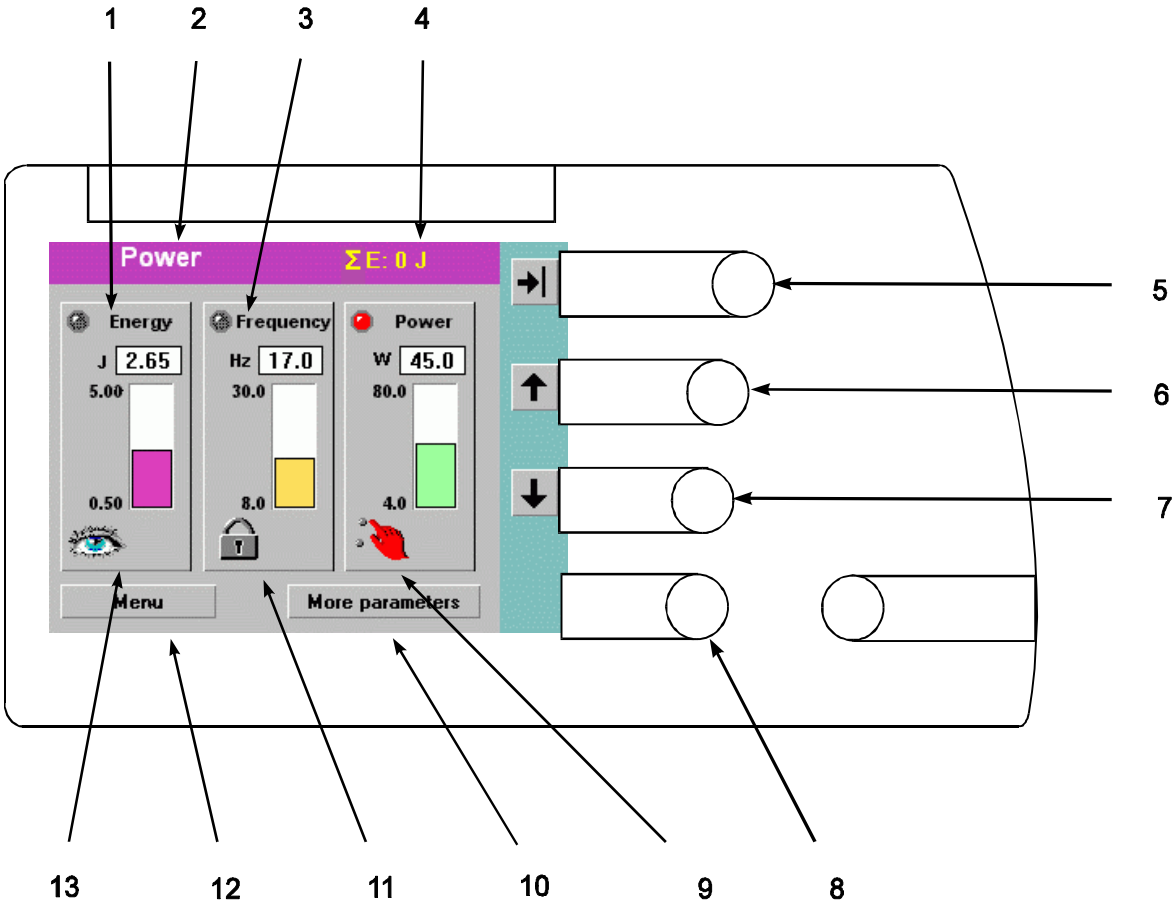
 The hand symbol and red dot  appear on each occasion in the parameter field, which has been selected by the user and is ready to be altered.

 The eye indicates the parameters monitored during variation of the parameters (see also section on “Variation of parameters in the power mode”).

 The lock symbol marks the parameter, which was last set and is to be maintained within the technically possible limits during parameter variation (see also section on “Variation of parameters in the power mode”).

8.5 Power mode

When the “power” mode is selected the following menu appears (together with other readings):

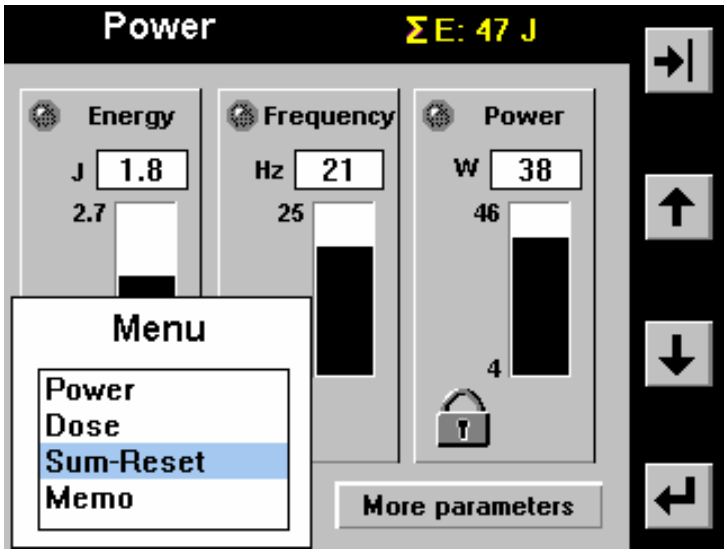


#	Meaning
1	Red spot off, in this case the “**Energy**” parameter is not ready to be adjusted
2	Menu bar, describes the function of the menu, in this case: “**Power**” mode
3	Red spot on. Frequency parameter is ready to be adjusted
4	Σ E indicates how much energy has been emitted since the last summation-reset
5	By pressing the button the hand symbol is changed to the next adjustable parameter or the next item on the menu.
6	By pressing the button the parameter indicated by the hand symbol and the red spot is increased. In this case the frequency was increased
7	By pressing the button the parameter indicated by the hand symbol and the red spot is decreased. In this case the frequency was decreased.
8	In this mode the fourth button from the top has no function
9	Eye, indicates the parameter being monitored (see section on “Variation of parameters in power mode”).
10	Behind the menu item “**More parameters**” are hidden setting of the pulse duration and the intensity of the pilot laser.
11	The hand symbol and the red spot indicate the parameter, which can be altered with the arrow keys.
12	The other modes can be selected with the menu item “**Menu list**”.
13	Lock symbol, this parameter was the last to be set and will be adhered to during parameter variations.

8.5.1 Menu list – resetting the Joule display

While in “power” mode the summation of the energy emitted is shown in the top right corner of the colour monitor screen (in this case 46 J).

This number can be reset to zero by using the  button to change to the menu item “**Menu list**” and selecting “**Summation reset**” with the  key.



8.5.2 Variation the parameters in power mode

In the power mode the parameters power, energy and frequency are combined in the formula:

Power = energy x frequency

Here “power” means the average power of the laser device, which can be adjusted over a range of some 10 watts. This value is not to be confused with the peak pulse output of the individual pulse, which is in the range of several kilowatts.

The values shown for power and energy presuppose perfect focussing in the fibre, a perfect fibre coupling blast shield and the laser fibre being in perfect condition. If the laser fibres are not in a perfect condition the transmission can drop considerably. The calibration of the indicated value with the emission from the fibre is explained in the section on “Calibration of the energy and power display”.

WARNING

A dirty or damaged blast shield or a dirty or damaged fibre connector absorbs laser power. The absorbed laser power leads to heating of the dirty or damaged place and can lead to further damage through overheating.

In the power mode the laser device’s computer control system permits the variation of parameters within the limits set by the design of the laser device. For example, at the maximum frequency setting the maximum pulse energy is no longer available.

The maximum average power is achieved at a specific repetition rate. At higher and lower frequencies the maximum average attainable power decreases.

The setting range of each parameter is shown at the side of the setting bar.

If the parameter identified with  is varied by the user, the computer control system automatically calculates the parameter marked with the  symbol. During this the parameter marked with  is kept constant.

The choice of the correct parameters for different medical applications is imparted in the laser training sessions, which are offered by the manufacturer. Section “Clinical applications” provides guidelines.

8.5.3 Power mode – more parameters

A special feature of SPHINX lasers is the adjustability of the laser pulse duration. When the laser pulse duration is altered the set pulse energy remains constant. The result is an increased peak pulse output for short laser pulses and a lower peak pulse output for long pulses.

This special technical feature is particularly useful, for example, in lithotripsy and during the removal and cutting of soft tissue.

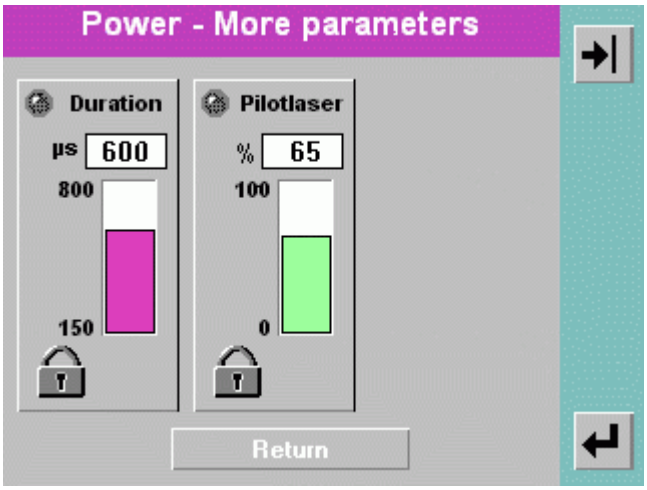
For the same amount of pulse energy a short laser pulse is more effective for removing hard tissue than a longer laser pulse of similar energy, because of its higher peak pulse output. On the other hand the coagulating effect of the long laser pulse is better than the coagulating effect of the short laser pulse.

The laser-tissue interaction can be summarized as follows:

	Removal of hard tissue, lithotripsy	Removal of soft tissue, coagulation
Short laser pulse	+	-
Long laser pulse	-	+

In order to alter the pulse duration, the menu item "**More parameters**" is selected with the button (script then changes from grey to red) and activated with the button.

Thereupon the following menu appears:



In order to adjust the pulse duration setting the button must be used to put the symbol and the red dot on the pulse duration. Then the desired duration can be set with the and buttons.

The pilot laser power (brightness) is set in a similar way:

... until the symbol and the red are placed on the pilot laser. Then press and until the desired brightness is set.

In this menu using the button again it is possible to change between the variable parameters (pulse duration and pilot laser) and the menu item "**Return**" + .

8.6 Dose mode – percutaneous laser nucleotomy

The dose mode was specially designed for the application of the laser device in percutaneous laser nucleotomy. During this application a specific total amount of energy (= dose) is to be emitted. For this application the laser device provides the possibility of dividing this dose into a pre-selected number of partial doses. The dose is calculated using the simple formula:

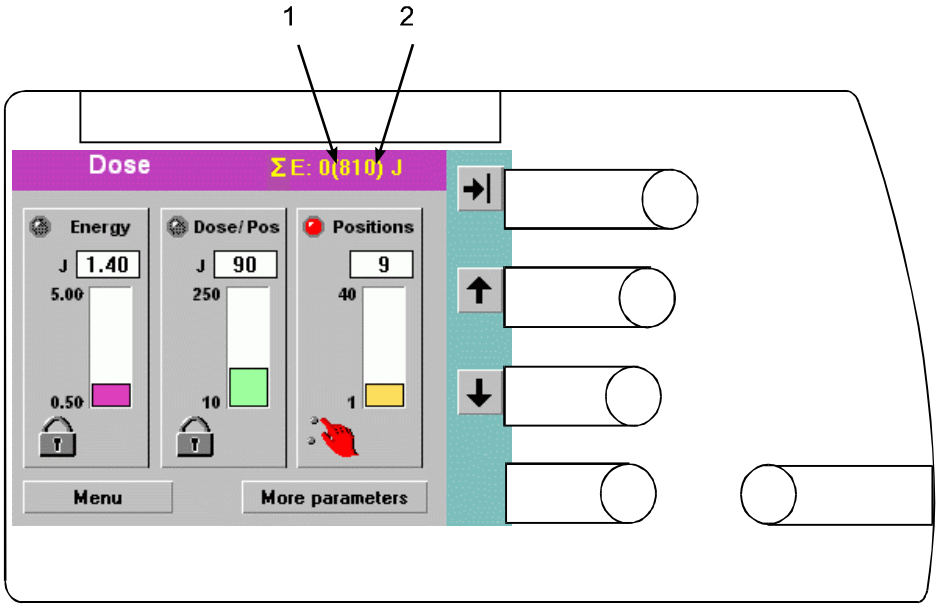
Partial dose x positions = dose

The following parameters must be set in the dose menu:

1. Energy of the individual laser pulse
2. Energy of the partial dose
3. Number of positions

The number of laser pulses per partial dose is calculated automatically. The frequency can be set in the **"More parameters"** menu.

After switching on the laser device the "**Dose**" mode is either selected directly from the selection menu or via the menu list in the "**Power**" mode. The following display then appears:



#	Meaning
1	Energy emitted in this application
2	Dose to be applied

In addition to the "**Σ** E:", already mentioned in relation to the power mode, the **dose to be applied appears in brackets** in the header.

During the **selection** of the parameters the value directly behind " **Σ** E:" is zero, that is to say, that up to this point no energy has been emitted. During the application the energy emitted up until that point is shown in joules in this position.

Variation of the adjustable parameters in the dose mode is carried out according to the same method as in the power mode.

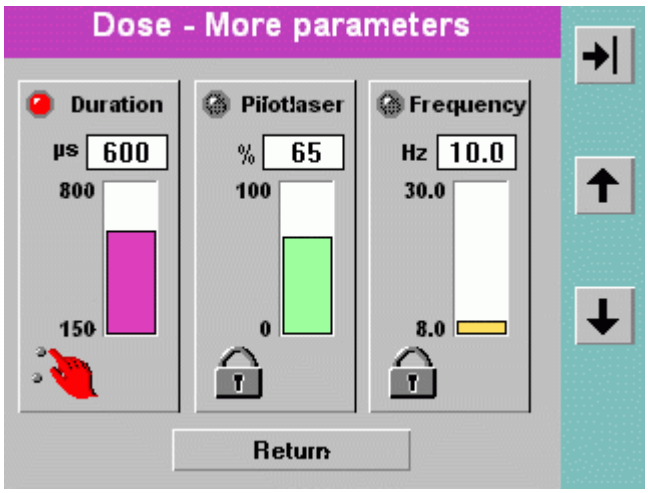
In the dose mode the frequency is set in the "**More parameters**" menu below the dose mode.

The laser can in the dose mode – without affecting the energy summation – be stopped at any time for as long as you like and then be reactivated.

Every time a partial dose is reached a gong is heard, which tells the operator that a partial dose has been emitted. This gives the operator the opportunity to deactivate the foot switch and to place the laser applicator in a different spot, in order to give the next partial dose in a new position.

8.6.1 Dose – More parameters

In the menu item "**Dose – More parameters**", pulse duration, pilot laser brightness and frequency are set for the dose mode in the same way as the procedures in the power mode.

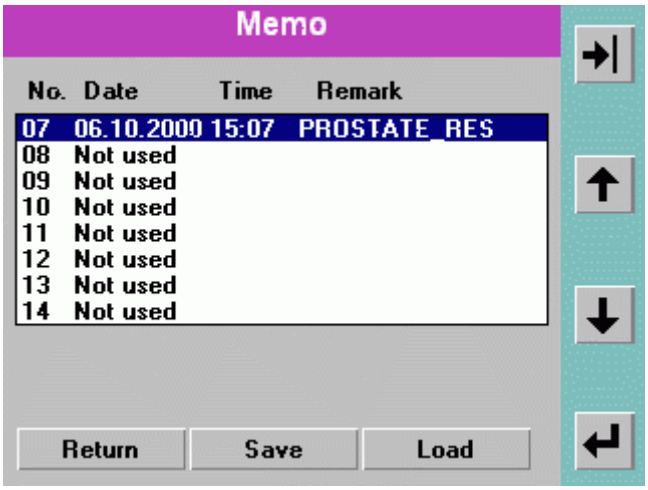


8.7 Memo – Saving settings

The "**Memo**" menu can be accessed either from the selection menu or from any other mode. It is used for saving and loading operational settings.

After selection of the "**Memo**" menu the following screen image appears.

The remark "PROSTATE_RES" is merely an example for other appropriate labels.



8.7.1 Loading of pre-selected settings

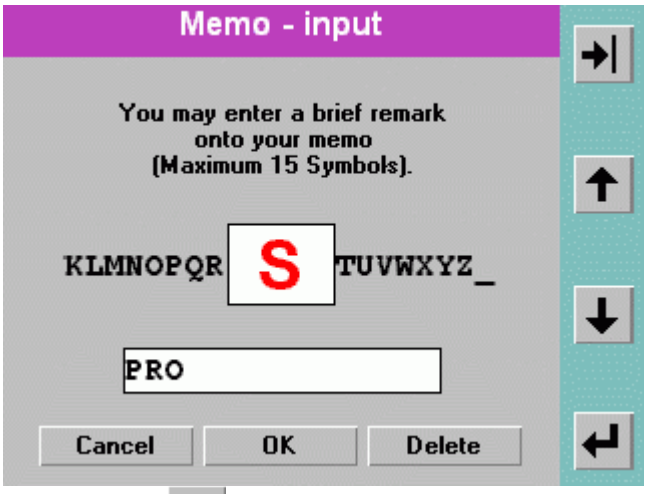
By pressing the ↑ and ↓ buttons the desired "**No. ..Remark**", which is to be loaded, is selected and loaded by pressing twice the ↵ button.

8.7.2 Saving pre-selected settings

As soon as a preferred operating mode is found this can be stored for later use.

To do so the menu item "**Menu list**" is selected in the respective operational menu using the →| button and from it "**Memo**" is selected using the ↑ and ↓ buttons. Thereupon an image appears similar to the one above, in which the menu item "**Save**" is selected with the →| button and loaded with the ↵ button.

The remark for the setting to be saved is written in the free field, the relevant letters being selected with the ↑



and ↓ buttons and activated with the ↵ button.

The completed remark will be saved, together with the setting data by pressing "**OK**". The device then returns immediately to the saved operational mode.

8.8 Checking the laser fibre

Before connecting the following points must be checked on each fibre:

1. The free-standing fibre end in the fibre connector (approx. 0.5 mm in diameter) must be smoothly reflective and free from damage and dirt. The hollow area within the fibre connector surrounding the fibre end must be free of any sign of blackening or burning. If necessary a magnifying glass of something similar must be used for checking.
2. The fibre must be free from external damage.
3. Test the laser fibre to see if the optical transmission is perfect: hold the distal end to a light source. The fibre end in the fibre connector must appear as a bright spot. In case of doubt it must be compared with a new fibre.

Please note the instructions for checking the laser fibres in the laser fibre manual. **Damaged fibres cannot be used any longer!**

WARNING	If laser fibres with a dirty or damaged fibre connector are used, laser output will be absorbed in the dirt and damage. This leads to overheating and can cause severe damage to the fibre coupler's blast shield and the focussing cell. Please note that the focussing cell can be damaged if the fibre connector is handled roughly.
DANGER	The use of damaged laser fibres can lead to injuries because the laser radiation emerges at the point where the laser fibre is damaged and not at the distal fibre end.

Instructions for cleaning and sterilizing the fibres can be found in the relevant accessory handbook.

8.9 Visual checking of the fibre-coupler's blast shield

To protect the focussing cell, which focuses the laser beam in the laser device and images it in the proximal fibre end, a specially-coated small plate, made from an IR-transparent glass, is located in the laser device between the fibre connector and the focussing cell. This small glass plate, which is enclosed in a "drawer" and pushed sideways into the fibre coupler, is the fibre coupler's blast shield.

Even the smallest particles of dirt, which detach themselves from the fibre connector and remain lying on the blast shield, can be burnt into the blast shield by the effect of the intense laser radiation and absorb a part of the radiation. In extreme cases this can lead to a significant reduction in power and to overheating of the blast shield.

The SPHINX lasers make use of a special blower, which blows filtered air onto the fibre coupler's blast shield while the laser fibre is being changed and while the laser is being operated. The stream of air makes it difficult for dust particles to settle on the fibre coupler's blast shield. At the same time the air-flow cools the fibre coupler's blast shield.

Visual checking of the blast shield should always be undertaken when the fibre used last shows signs of damage on the fibre connector (see "Checking the laser fibre") or if the fibre connector becomes hot during operation of the laser.

In order to check the blast shield visually, the beam outlet is opened with the release button. In this situation no laser radiation can be emitted. Nevertheless remember to wear laser protective goggles at this point. When the beam outlet is opened in a bright room a small circular section of the ceiling is reflected in the blast shield. Large pieces of dust or dirt on the blast shield may clearly be recognised as dots and specks in the reflection.

A dirty fibre-coupler blast shield must be replaced (see section on "Care and maintenance").

If in doubt the fibre-coupler blast shield must be checked as described in the instructions in the section on "Care and maintenance". A dirty blast shield can be replaced by trained operating personnel (see chapter on "Care and maintenance").

WARNING	Operating the laser device with a dirty or damaged blast shield or operating the laser device without the blast shield can cause severe damage to the focussing cell.

8.10 Replacing the fibre

1. Unscrew the connected fibre connector from the SMA-receptacle (turn to the left) and carefully take it out. Screw protective cap onto the fibre connector.
2. Check the cleanliness of new fibres and the connector (see above). Press the release button if the fibre port is closed. Put the new fibre into the SMA-receptacle, screw it in and tighten it **finger-tight**.
3. Press the release button a second time in order to activate the laser.

8.11 Switching-off routine

1. Unscrew the fibre connector (leftwards) from SMA-receptacle and pull it out. Screw protective cap onto the fibre connector.

2. Push the fibre-holder back in. To do this squeeze the area around the fibre-holder outlet.
3. Switch off the laser device with the key switch. The fibre port is closed automatically. All settings are retained for the next time it is used.
4. Take off laser safety goggles.
5. Pull out the mains plug and wind the mains cable back into the cable drum.

8.12 Correct state of the laser device

The laser device is therefore in the correct state if:

- after switching on the selection menu appears,
- the maximum adjustable power in the power mode (see section on "Power mode") which corresponds with the power class shown on the first screen (see section on "Starting-up and switching-on routine").
- the fibre coupler's blast shield is in the correct state (see section "Visual checking of the fibre-coupler's blast shield" and “Dismantlement, checking and installing the fibre-coupler’s blast shield”).
- a fibre which is in a correct state emits power during operation of the laser (see section "Checking the laser fibre").

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9 Clinical applications

The following text is based upon the experiences of users of SPHINX Holmium lasers and international publications concerning the medical use of Holmium lasers. This literature is available to interested parties on request. Please make yourself aware of the content of this section before you use the laser clinically. Start your experience of lasers with low power settings.

Note the relevant safety regulations (see section on “Laser safety”) and follow the instructions of your establishment’s laser safety officer.

9.1 Arthroscopy

The Holmium-YAG laser can be used in arthroscopy for the following clinical applications:

(Partial-)resection of the meniscus

Smoothing of cartilage lesions

Treatment of synovia

Lateral release

Particularly advantageous in arthroscopy is the combination of the specific ablation from tissue, the haemostatic effect and the slim laser applicator.

LISA laser products OHG supplies all the laser accessories for arthroscopic applications.

The laser fibres and applicators are re-usable. Information about sterilization of the instruments can be found on the packaging (and in the laser fibre’s instruction manual). It is preferable to choose a sterilization process for the fibres, which operates at the lowest possible temperatures (< 90°C). It is also advantageous if there is not the slightest oxidization of the fibre connector, which is unavoidable with autoclaving. The applicators themselves can be autoclaved without hesitation.

The laser fibres described in this section radiate forwards. The fibres must be checked to see they are intact before each time they are used (see section on “Replacing fibres”) and shortened at the distal end after use with the fibre tool. After shortening the radiation quality should be checked with the pilot laser.

Danger !

With all arthroscopic applications using the Holmium laser there is a danger of thermal damage. Start with low power settings. Therefore the laser may only be switched on if the effect of the laser – that is the distal fibre end – can be observed. Start with low power settings.

9.1.1 (Partial-)resection of the meniscus

Laser accessories: VarioFib laser fibre,
VarioLas NT or SlimLas laser applicator.

Laser setting:

Pulse energy	0.8 – 2.0 J
Repetition	10 -30 Hz
Duration	650 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the applicator to be used. Check the fibres for external damage. Satisfy yourself that the fibres were shortened at the distal end with the fibre tool after the last operation. Take care that the fibre can be easily inserted into the applicator and taken out again.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Attach the fibre to the applicator. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the applicator. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the applicator, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.8 joule, 12 Hz.
5. Use the “near contact” method of working.
6. Since a pure laser resection is time-consuming, usually a combined mechanical treatment is undertaken, first with the punch and/or shaver followed by laser treatment.
7. Afterwards smooth the edges of the incision with the laser.
8. Smooth the meniscus surface with the laser as if sealing tissue.
9. Possible staunching of bleeding in the area rich in blood vessels at the base of the meniscus using the laser.

Sole use of the laser is recommended in narrow joint compartments. Because of the small dimensions of the laser instrument and the laser effect, which is solely directed forwards, it is possible to avoid iatrogenic damage to the cartilage surface.

Adjust the power setting in the light of your experience.

In order to avoid thermal damage, during use the laser applicator is always held at a tangent to the tissue at a angle of < 30°, so that the laser radiation cannot strike the tissue vertically.

9.1.2 Smoothing of cartilage lesions

Laser accessories: VarioFib laser fibre,
VarioLas NT or SlimLas laser applicator.

Laser setting:

Pulse energy	0.5 -1.5 J
Repetition	8 -15 Hz
Duration	650 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the applicator to be used. Check the fibres for external damage. Satisfy yourself that the fibres were shortened at the distal end with the fibre tool after the last operation. Take care that the fibre can be easily inserted into the applicator and taken out again.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Attach the fibre to the applicator. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the applicator. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the applicator, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.5 joule, 8 Hz.
5. The working distance of the distal end of the fibre should be 1 – 1.5 mm from the cartilage surface.
6. Use the “near contact” method of working:
7. With large surface areas preliminary work can be done with a mechanical instrument and then smoothed with the laser. Small lesions should be solitarily treated with the laser.
8. Working on the damaged areas with mechanical instruments, principally with scalpel and shaver.
9. Afterwards smooth the edges of the area with the laser.
10. Smooth the cartilage surface with the laser as if sealing tissue.

Sole use of the laser is recommended in narrow joint compartments. Because of the small dimensions of the laser instrument and the laser effect, which is solely directed forwards, it is possible to avoid iotragenic damage to the cartilage surface.

Adjust the power setting in the light of your experience.

In order to avoid thermal damage, during use the laser applicator is always held at a tangent to the tissue at an angle of < 30°, so that the laser radiation cannot strike the tissue vertically.

9.1.3 Treatment of synovia

Laser accessories: VarioFib laser fibre,
VarioLas NT or SlimLas laser applicator.

Laser setting:

Pulse energy	1 -2 J
Repetition	10 -30 Hz
Duration	650 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the applicator to be used. Check the fibres for external damage. Satisfy yourself that the fibres were shortened at the distal end with the fibre tool after the last operation. Take care that the fibre can be easily inserted into the applicator and taken out again.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Attach the fibre to the applicator. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the applicator. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the applicator, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 1 joule, 10 Hz.
5. The working distance of the distal fibre end from the tissue surface should be 1 – 1.5 mm. Should bleeding occur, the laser probe is aimed directly at the vessel in question and the bleeding stopped with a few pulses.
6. Use the “near contact” method of working:
7. With large synovial areas, inflamed and proliferative tissue is removed with the shaver and then worked on with the laser. Punctual bleeding is controlled very well with the laser.

Adjust the power setting in the light of your experience.

9.1.4 Lateral release

Laser accessories: VarioFib laser fibre,
VarioLas NT or SlimLas laser applicator.

Laser setting:

Pulse energy	1.5 -2.0 J
Repetition	10 -30 Hz
Duration	650 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the applicator to be used. Check the fibres for external damage. Satisfy yourself that the fibres were shortened at the distal end with the fibre tool after the last operation. Take care that the fibre can be easily inserted into the applicator and taken out again.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Attach the fibre to the applicator. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the applicator, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 1.5 joule, 10 Hz.
5. During this treatment the distal end of the applicator is held as vertically as possible to the tissue surface. The working distance of the distal fibre end from the tissue surface should be 1 – 1.5 mm. For shrinkage the laser probe is held 2-3 mm away.
6. Use the “near contact” method of working:
7. Lateral release with the laser
8. Shrinkage of the collagen tissue in the area of the medial reticulum and the medial capsule with less laser power (1 J/ 10 Hz).

Adjust the power setting in the light of your experience.

9.2 Urology

The Holmium-YAG laser is used in urology in the following clinical applications:

Removal of urethral strictures

Removal of ureter strictures

Resection of the prostate

Bladder neck incisions

In-situ ablation of bladder tumours

Lithotripsy of bladder stones

Lithotripsy of urethral calculi and of kidney stones

The haemostatic effect of the Holmium laser is particularly advantageous in the ablation of soft tissue.

For urological applications LISA laser products OHG supplies the necessary laser fibres as standard accessories. The endoscopic urological instruments, which are required in addition, must have a working channel to take the laser fibre and be authorized by the manufacturer for laser use. Please allow us to advise you.

The laser fibres described in this section are reusable. Information about sterilization can be found on the packaging and in the laser fibre's instruction manual. It is preferable to choose a sterilization process, which operates at the lowest possible temperatures (< 90°C). It is also advantageous if there is not the slightest oxidization of the fibre connector, which is unavoidable with autoclaving.

The laser fibres described in this section radiate forwards. The fibres must be checked to see they are intact before each time they are used and shortened at the distal end after use with the fibre tool. After shortening the radiation quality should be checked with the pilot laser.

Danger !

With all applications of the Holmium laser in the urogenital tract there is a danger of perforation. Therefore the laser may only be switched on if the effect of the laser – that is the distal fibre end – can be observed. Start with low power settings.

9.2.1 Removal of urethral strictures

Laser accessories: PowerFib or RigiFib laser fibre
Laser resectoscope

Laser setting:

Pulse energy	0.5 -1.2 J
Repetition	15 -20 Hz
Duration	700 µs

Preparation:

Make sure before the OP that the existing fibres are compatible with the endoscopic instrument to be used.

Take care that the fibres can easily be fitted into the endoscopic instrument and taken out again. Check that the laser fibre can be fixed in the applicator. The distal fibre end must be able to be brought into the field of vision of the optic.

Procedure:

1. Start the laser as described in the section on "Operation of the laser device".
2. Insert the fibre in the endoscopic instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.5 joule, 12 Hz. Set the pulse duration to the maximum value.
5. Use the "near contact" method of working. Activate the laser with the footswitch while pulling the fibre end back across the tissue surface. It is advantageous to do so, because in this way the fibre end cannot remain hanging in the tissue.

Adjust the power setting in the light of your experience.

9.2.2 Resection of the prostate

Laser accessories: PowerFib or RigiFib laser fibre,
Laser resectoscope
sterile fibre tool or 2-3 spare fibres

Laser setting:

Pulse energy	2 -4 J
Repetition	20 -30 Hz
Duration	700 µs

Preparation:

Make sure before the OP that the fibres are compatible with the endoscopic instrument to be used.

Take care that the fibres can easily be fitted into the instrument and taken out again. Check that the laser fibre can be fixed in the applicator. The distal fibre end must be able to be brought into the field of vision of the optic.

The cladding of the laser fibre acts as mechanical reinforcement and protection against kinking at the distal end of the laser resectoscope. For this reason the cladding removed from the fibre for resection of the prostate should be only 3 – 5 mm. When the fibre is inserted the cladding at the distal end of the resectoscope should be visible.

It is important that the fibre is fed right up into the field of vision by the instrument. In this way vibration of the fibre will be prevented.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Insert the fibre into the instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 2 joule, 30 Hz. Set the pulse duration to the maximum value.
5. You will find a detailed description of the technique of the operation in: Peter J. Gilling, “The Technique of Holmium-Laser Resection of the Prostate (HOLRP)”. A systematic method of working is a good prerequisite for a successful resection.
6. Use the “near contact” method of working. Activate the laser with the footswitch while pulling the fibre end back across the tissue surface. It is advantageous to do so, because in this way the fibre end cannot remain hanging in the tissue.
7. A usable setting is 2 joules, 30 Hz.
8. From experience allow about one gram of tissue per minute to be resected.

Adjust the power setting in the light of your experience.

Because of the high average power and the amount of the total energy applied during the application a small amount of burning off occurs at the fibre tip. This burning off causes the reduction of the radiation quality and so the cutting capability. In order to be able to work at full power throughout the OP either a sterile fibre tool for intra-operative repair of the fibres or suitable replacement fibres should be to hand.

During the laser application the operator becomes aware of the burning off through increasing diffusion of the pilot laser’s beam. The pilot laser’s light, which is diffused by the roughening end surface of the laser fibre, may be seen by looking through the optic.

As a rule of thumb one can say: the more visible the distal end of the laser fibre in the color of the pilot laser, the further the burning off has progressed and therefore the less efficient is the cutting power.

9.2.3 Bladder neck incisions

Laser accessories: PowerFib or RigiFib laser fibre
Laser resectoscope

Laser setting:

Pulse energy	0.5 -1.2 J
Repetition	10 -20 Hz
Duration	700 µs

Preparation:

Make sure before the OP that the existing fibres are compatible with the endoscopic instrument to be used. Take care that the fibres can easily be fitted into the instrument and taken out again. Check that the laser fibre can be fixed in the applicator. The distal fibre end must be able to be brought into the field of vision of the optic.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Insert the fibre into the instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.8 joule, 15 Hz. Set the pulse duration to the maximum value.
5. Use the “near contact” method of working. Activate the laser with the footswitch while pulling the fibre end back across the tissue surface. It is advantageous to do so, because in this way the fibre end cannot remain hanging in the tissue.

Adjust the power setting in the light of your experience.

9.2.4 In-situ ablation of bladder tumors

Laser accessories: PowerFib or RigiFib laser fibre
Laser resectoscope

Laser setting:

Pulse energy	0.5 -1.2 J
Repetition	10 -15 Hz
Duration	400 µs

Preparation:

Make sure before the OP that the existing fibres are compatible with the endoscopic instrument to be used. Take care that the fibres can easily be fitted into the instrument and taken out again. Check that the laser fibre can be fixed in the applicator. The distal fibre end must be able to be brought into the field of vision of the optic.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”. Insert the fibre into the instrument. The non-sterilized OP assistant attaches the fibre to the laser.
2. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
3. At the begin use a low power setting; e.g. 0.8 joule, 10 Hz. Set the pulse duration to a middle value.
4. Use the “near contact” method of working. Activate the laser with the foot switch, while holding the fibre end above the tissue to be removed.
5. Bear in mind the laser’s depth effect. It depends upon the working technique. If the laser is continuously brought over the tissue to be removed, the depth effect is limited to 0.5 – 1.0 mm. On the other hand if the laser is held in stationary contact with the tissue at one place, tissue will be damaged up to a depth of 2 mm.

Adjust the power setting in the light of your experience.

9.2.5 Removal of ureter strictures

Laser accessories: PercuFib laser fibre
Ureterorenoscope

Laser setting:

Pulse energy	0.5 -1.2 J
Repetition	15 -20 Hz
Duration	700 µs

Preparation:

Make sure before the OP that the existing fibres are compatible with the endoscopic instrument to be used.

Take care that the fibres can easily be fitted into the endoscopic instrument and taken out again. Check that the laser fibre can be fixed in the applicator. The distal fibre end must be able to be brought into the field of vision of the optic.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Insert the fibre in the endoscopic instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.5 joule, 17 Hz. Set the pulse duration to the maximum value.
5. Use the “near contact” method of working. Move the fibre back and forth in the area of the stricture. Activate the laser with the footswitch while pulling the fibre end back across the tissue surface. It is advantageous to do so, because in this way the fibre end cannot remain hanging in the tissue.

Adjust the power setting in the light of your experience.

9.2.6 Lithotripsy of bladder stones

Laser accessories: PowerFib, RigiFib or PercuFib laser fibre
Laser resectoscope

Laser setting:

Pulse energy	0.8 -1.5 J
Repetition	8 -12 Hz
Duration	150 µs

Preparation:

Make sure before the OP that the existing fibres are compatible with the endoscopic instrument to be used. Take care that the fibres can easily be fitted into the instrument and taken out again. Check that the laser fibre can be fixed in the applicator. The distal fibre end must be able to be brought into the field of vision of the optic.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Insert the fibre into the instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.8 joule, 10 Hz. Set the pulse duration to the shortest value.
5. Place the fibre directly onto the stone. The stone will immediately react to the first pulse. Hard stone material will break up into smaller fragments. Soft stone material will be perforated by the laser. In this case with larger stones the pulse energy can be increased, in order to increase the working speed.
6. Work with short bursts of pulses and wait for the field of vision to clear before you commence the next burst of pulses.

Adjust the power setting in the light of your experience.

9.2.7 Lithotripsy of urethral calculi and of kidney stones

Laser accessories: PercuFib, FlexiFib or LithoFib (only SPHINX litho) laser fibre
flexible or rigid or semi-rigid ureterorenoscope with a suitable working channel.

Laser setting:

Pulse energy	0.8 -1.5 J
Repetition	8 -12 Hz
Duration	150 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the instrument to be used. Take care that the fibres can easily be fitted into the instrument and taken out again. The instrument must have a device, with which the fibre may be attached. The distal fibre end must be able to be brought into the field of vision of the optic.

Find out before the OP how the flexible ureterorenoscope behaves with the fibre inserted. Bear in mind that the distal fibre end has a sharp edge. If you push the fibre end into the flexed ureterorenoscope, internal damage can be caused to the ureterorenoscope.

WARNING

While attempting to push the distal fibre end into the flexed ureterorenoscope, internal damage can be caused to the ureterorenoscope.

The laser fibre can easily be inserted into the ureterorenoscope when stretched, until it projects just beyond the utreterorenoscope. While positioning the ureterorenoscope inside the patient the distal fibre end must be kept just outside the ureterorenoscope.

The frictional forces between the fibre and the fully flexed ureterorenoscope can be so great that it is hardly possible to move the fibre. In this case the work must be so arranged that the fibre tip can just be seen in the field of vision throughout the whole positioning of the fibre tip.

In no circumstances may the laser be activated when the distal fibre end is inside the flexible ureterorenoscope. Otherwise the flexible ureterorenoscope can be completely destroyed and the patient subjected to injuries.

WARNING

Do not activate the laser when the distal fibre end is withdrawn inside the ureterorenoscope.

DANGER

The patient can suffer injuries if the laser is activated when the distal laser fibre end is withdrawn inside the ureterorenoscope.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Insert the fibre into the instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.8 joule, 10 Hz. Set the pulse duration to the shortest value.
5. Make sure that the laser fibre is protruding from the instrument.
6. Place the fibre directly onto the stone. The stone will immediately react to the first pulse. Hard stone material will break up into smaller fragments. Soft stone material will be perforated by the laser. In this case with larger stones the pulse energy can be increased, in order to increase the working speed.
7. Work with short bursts of pulses and wait for the field of vision to clear before you commence the next burst of pulses.

Adjust the power setting in the light of your experience.

9.2.8 Open resection of penis tumours

Laser accessories: PowerFib or PercuFib laser fibre,
SlimLas laser handpiece

Laser setting:

Pulse energy	0.5 J
Repetition	20 Hz
Duration	700 µs

Preparation:

Make sure before the OP that the fibres are compatible with the instrument to be used.

Take care that the fibres can easily be fitted into the instrument and taken out again. Check that the laser fibre can be fixed in the applicator.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Insert the fibre into the instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. Use a low power setting; e.g. 0.5 joule, 20 Hz. Set the pulse duration to the maximum value.
5. Use the “near contact” method of working. The closer the fibre end is to the tissue, the stronger is the cutting effect. When the distance from the tissue is increased, the laser beam widens and the cutting effect decreases to the advantage of the coagulating effect.
6. Cut around the tumour as with a scalpel. Make sure that you do not dwell too long on once place with the laser. As a rule of thumb one can say:

Slower working = more coagulation and deeper necrosis

Quicker working = less coagulation and flatter necrosis

7. Use the “near contact” method of working. Activate the laser with the footswitch while pulling the fibre end back across the tissue surface. This method of procedure is advantageous, because this way the fibre end cannot remain hanging in the tissue.

Adjust the power setting in the light of your experience.

9.2.9 Open resection of tumours in the cortex of the kidney

Laser accessories: PowerFib or PercuFib laser fibre,
SlimLas laser handpiece

Laser setting:

Pulse energy	1.0 -1.5 J
Repetition	20 Hz
Duration	700 µs

Preparation:

Make sure before the OP that the fibres are compatible with the instrument to be used.

Take care that the fibres can easily be fitted into the instrument and taken out again. Check that the laser fibre can be fixed in the applicator.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Insert the fibre into the instrument. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the instrument. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. Use a medium power setting; e.g. 1.0 joule, 20 Hz. Set the pulse duration to the maximum value.
5. Use the “near contact” method of working. The closer the fibre end is to the tissue, the stronger is the cutting effect. When the distance from the tissue is increased, the laser beam widens and the cutting effect decreases to the advantage of the coagulating effect.
6. Cut around the tumor as with a scalpel. Make sure that you do not dwell too long on once place with the laser. As a rule of thumb one can say:

Slower working = more coagulation and deeper necrosis

Quicker working = less coagulation and flatter necrosis

7. Use the “near contact” method of working. Activate the laser with the footswitch while pulling the fibre end back across the tissue surface. This method of procedure is advantageous, because this way the fibre end cannot remain hanging in the tissue.

Adjust the power setting in the light of your experience.

9.3 ENT

The Holmium laser is used for the following clinical applications in ENT:

Reduction of turbinates (mucosa) cha

Ablation of bones and cartilage (turbinates and septum)

Shrinkage of nasal polyps

Shrinkage of benign tumours of the larynx

Because of the combination of the following features the Holmium-YAG laser is particularly advantageous for working in ENT:

- directional, ablation effect on mucous membrane, cartilage and bones
- excellent haemostasis
- necrosis confined to narrow area
- slender laser applicators
- flexible fibre guide
- little post-operative pain
- very good healing of the wound
- preservation of the mucosa.

LISA laser products OHG supplies the laser accessories listed in the section on “Accessories for SPHINX Holmium YAG lasers” for use in ENT.

The laser fibres and applicators are re-usable. Information about sterilization of the instruments can be found on the packaging (and in the laser fibre’s instruction manual). It is preferable to choose a sterilization process for the fibres, which operates at the lowest possible temperatures (< 90°C). It is also advantageous if there is not the slightest oxidization of the fibre connector, which is unavoidable with autoclaving. The applicators themselves can be autoclaved without hesitation.

The laser fibres described in this section radiate forwards. The fibres must be checked to see they are intact before each time they are used (see section on “Replacing fibres”) and shortened at the distal end after use with the fibre tool. After shortening the radiation quality should be checked with the pilot laser.

DANGER

During all applications of the Holmium laser in ENT there exists the danger of thermal damage. Start with low power settings. Space out your work in order to allow the area directly around the place where treatment is being given to reach a thermal balance. The laser may then only be activated if the effect of the laser – that is the distal fibre end and the irradiated tissue – can be observed.

9.3.1 Reduction of turbinates (mucosa)

Laser accessories: PercuFib laser fibre
ENTLas or SlimLas ENT laser applicator

Laser setting:

Pulse energy	0.5 -1.0 J
Repetition	5 -10 Hz
Duration	650 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the applicator to be used. Check the fibres for external damage. Satisfy yourself that the fibres were shortened at the distal end with the fibre tool after the last operation. Take care that the fibre can be easily inserted into the applicator and taken out again.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Attach the fibre to the applicator. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the applicator. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the applicator, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.5 joule, 8 Hz.
5. Use the “near contact” method of working. Move the fibre tangentially backwards in the fibre direction directly above the mucous membrane.
6. Work in strips, so that untreated strips remain between the treated zones. This procedure reinforces the subsequent healing process.

Any type of surface anaesthetic can be used.

Adjust the power setting in the light of your experience.

9.3.2 Reduction of turbinates and nasal septum (bone)

Laser accessories: PercuFib laser fibre
ENTLas or SlimLas ENT laser applicator

Laser setting:

Pulse energy	0.5 -1.0 J
Repetition	5 -10 Hz
Duration	150 µs

Preparation:

Preparation is the same as that for the reduction of mucosa.

For ablation bones in accordance with the above-mentioned information only the setting of the laser pulse duration may be altered. That reinforces the ablation effect and reduces the penetration of heat into the surrounding tissue.

Procedure:

1. The procedure is similar to that for the reduction of mucous membrane.
2. After exposing the bony spur the duration of the laser pulse is altered to the above-mentioned value (see section on “Operation of the laser device”).
3. Remove the bone using the “near contact” method.

Any type of surface anaesthetic can be used.

Adjust the power setting in the light of your experience.

9.3.3 Shrinkage of nasal polyps

Laser accessories: PercuFib laser fibre
ENTLas or SlimLas ENT laser applicator

Laser setting:

Pulse energy	0.5 -1.0 J
Repetition	5 -10 Hz
Duration	650 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the applicator to be used. Check the fibres for external damage. Satisfy yourself that the fibres were shortened at the distal end with the fibre tool after the last operation. Take care that the fibre can be easily inserted into the applicator and taken out again.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Attach the fibre to the applicator. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the applicator. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the applicator, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.5 joule, 8 Hz.
5. Use the “near contact” method of working. Place the distal fibre end directly onto the tissue to be removed and switch the laser on.
6. Activate the laser only as long as you can observe the effect directly.
7. Work in short periods of time in order to give the surrounding tissue time to reach thermal balance.

Any type of surface anaesthetic can be used.

Adjust the power setting in the light of your experience.

9.3.4 Shrinkage of benign tumors of the larynx

Laser accessories: PercuFib laser fibre
Flexible ENT laser endoscope with suitable working channel

Laser setting:

Pulse energy	0.5 -0.8 J
Repetition	5 -10 Hz
Duration	650 µs

Preparation:

Before the OP make certain that the existing fibres are compatible with the applicator to be used. Check the fibres for external damage. Satisfy yourself that the fibres were shortened at the distal end with the fibre tool after the last operation. Take care that the fibre can be easily inserted into the applicator and taken out again.

Procedure:

1. Start the laser as described in the section on “Operation of the laser device”.
2. Attach the fibre to the applicator. The non-sterilized OP assistant attaches the fibre to the laser.
3. Check if the red pilot laser is emitted at full strength from the fibre. If it seems weak to you it could be that the fibre was damaged during insertion into the applicator. In that case the fibre should be prepared again using the fibre tool or another fibre should be used. If a fibre, which is broken inside the applicator, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 0.5 joule, 8 Hz.
5. Use the “near contact” method of working. Place the distal fibre end directly onto the tissue to be removed and switch the laser on.
6. Activate the laser only as long as you can observe the effect directly.
7. Work in short periods of time in order to give the surrounding tissue time to reach thermal balance.

Any type of surface anaesthetic can be used.

Adjust the power setting in the light of your experience.

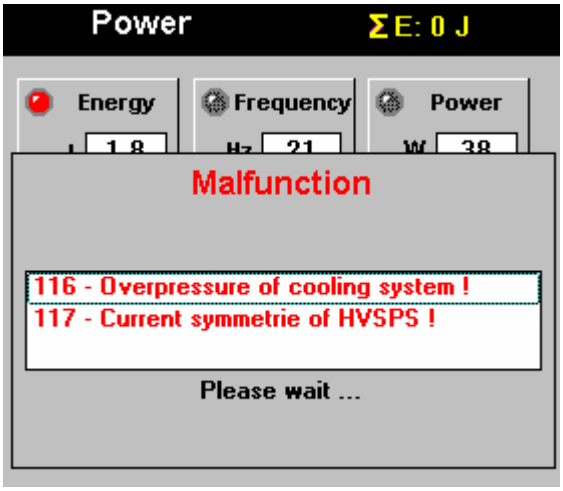
10 Fault messages

10.1 Fault menu

The laser device is equipped with two computer systems for operating, controlling and monitoring purposes. During the whole operation a series of checks on the device is being undertaken continuously, which, if they prove negative, give rise to warnings or fault messages. Each of the irregularities recognized by the system processor is indicated in clear text on the colour monitor display, together with a three-digit number. Warnings must be confirmed by the user. Faults clear themselves once the cause is removed. Subsequently the laser must be cleared again with the release button.

If it is not possible to correct a fault, the service technician must be informed.

The fault messages look like this:



You will find the telephone number of your service technician in the section “Technical Data”.

10.2 List of fault messages

The following faults are recognized by the system and displayed. In cases of repetition the service technician should be informed about the fault messages, which have appeared, before his visit.

All faults are to be listed in the medical devices book and passed on to the manufacturer.

We should be grateful if you would let us know your experiences with our device. We can deduce valuable information for the further development of our devices particularly from difficulties you may have encountered during use and the possible solutions you have found.

10.2.1 System faults

Fault message in the display	**Cause**	**Remedial measure**
100 Specified energy not reached	During the start-up phase the laser did not attain at least one pulse energy value.	The manufacturer’s service technician must check the laser resonator and switching power supply.
101 Overvoltage capacitor bench	The capacitor bank was charged at too high voltage	The service technician must check the electronic controls of the HV switching power supply.
102 Drift energy sensors > 20%	The energy measurement of one detector deviated from the measurements of the other detectors by at least 20% for at least one laser pulse	The service technician must check the laser pulse energy measuring device for optical, mechanical and electrical defects.
103 Instability of pulse frequency	The pulse frequency is unstable.	The service technician must check the pulse frequency.

104 Overtemperature of Laser cavity	The temperature of the coolant is either too low or too high.	The laser should be run for a few minutes in “stand-by” mode. If the fault message disappears, work can proceed. If it does not, the manufacturer’s service technician must be informed.
105 Low voltage power supply	The voltage supply is insufficient for the internal electronic controls.	The service technician must check the voltage supply of the internal electronic controls.
106 Number of errorpulse per time	More than one out of ten laser pulses exceeds the set energy value by more than 50% or by more than 100%.	The service technician must check the laser resonator and the internal energy measuring device.
107 Flow through of cooling water	The flow of cooling water is too little.	The service technician must check the cooling water level and the flow meter.

10.2.2 Operational faults

Fault message in the display	**Cause**	**Remedial measure**
110 Overtemperature of HVSPS	The temperature of the switching power supply has exceeded one limit.	The laser should be run for a few minutes in “stand-by” mode.
111 Synchronisation laserresonator	The synchronization of the frequency and phases of the beam deflection is insufficient.	Should this recur the service technician must check the laser head. As long as this fault message can be reset the laser may continue to be used.
112 Interlock loop open	The bridging in the interlock plug is missing or the interlock is open.	See section in this manual on “Connecting a door-interlock switch”
113 Fibre connector missing	The monitoring system for the fibre coupler cannot detect a fibre connector.	Screw the fibre in **finger tight** up to the mechanical back stop.
114 Error in shutter position	The internal beam lock is not responding to the control signals.	Should this recur the service technician must check the laser head. As long as this fault message can be reset the laser may continue to be used.
115 Clock of systemprocessor	The system computer is not working properly.	The service technician must check the system computer.
116 Overpressure of cooling system	The pressure in the coolant circuit is too high because it is operating at too high a temperature.	Lower the ambient temperature.
117 Input line voltage	The supply voltage is either momentarily or generally too low.	The mains voltage must be checked at the mains plug while the laser device is running by a specialist with an oscilloscope.

10.2.3 Warning messages

Fault message in the display	**Cause**	**Remedial measure**
120 Ignition or simmer	One or more flash lamps do not ignite.	Wait a few minutes – if the warning reappears the manufacturer’s service technician must check the flash lamps and the simmer

121 HVSPS not ready	The HV switching power supply is not ready.	There is an electrical fault, which can only be corrected by the service department.
122 Deviation of energy > 100%	More than one out of ten laser pulses exceeds the set energy value by more than 50% or by more than 100%.	The service technician must check the laser resonator and the internal energy measuring device.
123 Foot switch	The foot switch's twin-channel signalling system is not synchronized.	There is an electrical or mechanical fault in the foot switch, the foot switch cable or the signal processing in the laser device. Get in touch with the service technician.
124 Waterlevel cooling system	The level of the cooling water is below the minimum.	The cooling water system must be topped up by an expert trained by the manufacturer.
125 Deviation of energy > 20%"	One laser pulse is deviating more than 20% from the set value.	If this warning keeps recurring the service technician must check the laser resonator and the internal energy measuring system. As long as this fault message can be reset the laser may continue to be used.
126 Overtemperature of heat sink!	The cooling system of the HV switching power supply is inadequate.	The laser should be run for a few minutes in "stand-by" mode.

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11 Accessories for SPHINX Holmium-YAG lasers

The laser device should only be used with the following accessories:

Description	LISA order designation	Article no.
Personal protective equipment		
Color neutral laser safety glasses for SPHINX with earpieces		101 503 142
Colour neutral laser safety goggles for SPHINX without earpieces		101 503 143
Arthroscopy:		
Hand applicator with fibre feed	VarioLas NT	101 503 101
0° tip for VarioLas NT length = 100 mm	0° tip, length = 100 mm	101 503 132
0° tip for VarioLas NT length = 160 mm	0° tip, length = 160 mm	101 503 102
15° tip for VarioLas NT length = 160 mm	15° tip, length = 160 mm	101 503 103
30° tip for VarioLas NT length = 160 mm	30° tip, length = 160 mm	101 503 104
60° tip for VarioLas NT length = 160 mm	60° tip, length = 160 mm	101 503 105
Standard hand applicator, straight	SlimLas	101 503 106
Standard hand applicator, 15°	SlimLas 15°	101 503 107
Standard hand applicator, 30°	SlimLas 30°	101 503 136
Cleaning wire for VarioLas and SlimLas tips	0.7 mm cleaning wire	101 503 111
Fibre for arthroscopy 400 µm optical core	VarioFib	101 503 108
Percutaneous laser disc decompression (PLDD):		
PLDD instrument set, straight	PercuSpine, straight	101 503 120
PLDD instrument set, bend	PercuSpine, bend	101 503 121
Spine Surgery (Formaninoplasty):		
Self bending handpiece	AutoFlex	101 503 220
Spare cannula for PercuSpine, straight	Spare cannula, straight	101 503 122
Spare cannula for PercuSpine, bend	Spare cannula, bend	101 503 123
Fibre for PLDD, 365 µm optical core	PercuFib	101 503 128
Urology:		
Accessory for Holmium laser prostate resection (HoLRP)	Holmium laser prostate resectoscope (Olympus compatible)	101 503 135
Accessory for Holmium laser prostate resection (HoLRP)	Holmium laser prostate resectoscope (STORZ conpatible)	101 503 212
Fibre for HoLRP 400 µm optical core	PowerFib	101 503 139
Fibre for transurethral laser lithotripsy, 365 µm optical core	PercuFib	101 503 128
Fibre for transurethral laser lithotripsy, 200 µm optical core	LithoFib (only for use with SPHINX litho)	101 503 188
Fibre for transurethral laser lithotripsy, 273 µm optical core	FlexiFib	101 503 189
ENT:		
ENT laser applicator	ENTLas	101 503 167
Standard hand applicator, straight	SlimLas	101 503 106

Description	LISA order designation	Article no.
Standard hand applicator, 15°	SlimLas 15°	101 503 107
Fibre for ENT applications, 365 µm optical core	PercuFib	101 503 128
Fibre tool:		
Stripping tongs for VarioFib	Fibre-Stripper 0.8	101 503 109
Stripping tongs for PowerFib	Fibre-Stripper 0.6	101 503 119
Stripping tongs for PercuFib	Fibre-Stripper 0.5	101 503 129
Stripping tongs for FlexiFib	Fibre-Stripper 0.3	101 503 249
Stripping tongs for LithoFib	Fibre-Stripper 0.2	101 503 187
Special cutter for fibre preparation	Fibre cutter	101 503 110
Inspection microscope for fibre connector	Inspection microscope (magnification 200 times)	101 503 230
Inspection microscope for fibre connector	Inspection microscope (magnification 50 times)	101 503 210

Attention is specifically drawn to the fact that only laser fibres supplied by the device manufacturer (LISA laser products OHG) may be connected to the laser device. So-called SMA compatible products made by other manufacturers could cause costly damage to the focussing cell. Other accessories being used must be specially certified by the manufacturer as being suitable for use with a Holmium-YAG laser.

Please ask the device manufacturer about additional accessories available for the device.

12 Care and maintenance

This section will be devoted solely to measures, which appertain to the maintenance of the laser device's functional capability. This section is not a repair or service manual!

The laser device does not require any particular maintenance on the part of the user. Surface cleaning can be carried out with light suds or an alcohol solution. When doing so, take care that no moisture can penetrate the beam lock.

Every 12 months the laser device must undergo a technical safety control by a service technician authorised by the manufacturer.

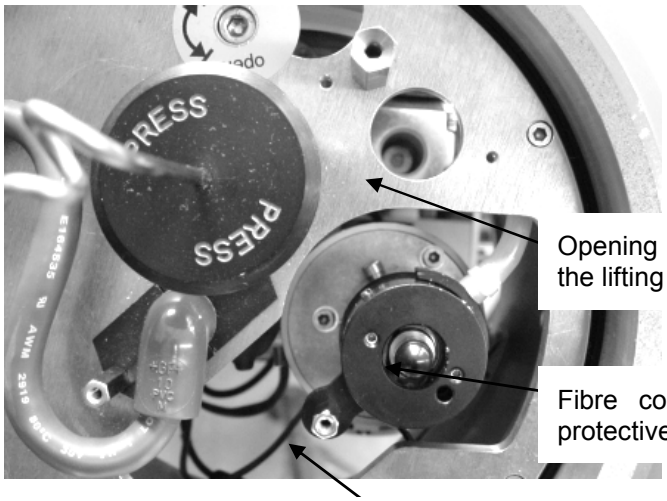
12.1 Dismantlement, testing and installation of the fibre-coupler's blast shield

Slight dirt on the fibre coupler's blast shield only has an insignificant effect upon the laser's available capacity. Nevertheless the fibre coupler's blast shield should be subjected to a visual inspection on a regular basis (e.g. once on each OP day, when the first fibre is connected) (see section on "Visual inspection of the fibre coupler's blast shield").

If the visual inspection of the fibre coupler's blast shield does not lead to the definite conclusion that the blast shield is clean, then it must be dismantled in accordance with the instructions in the following sub-section, tested and, if necessary, replaced.

12.1.1 Dismantling the fibre coupler's blast shield

To replace the fibre coupler's blast shield the console cover must be removed.



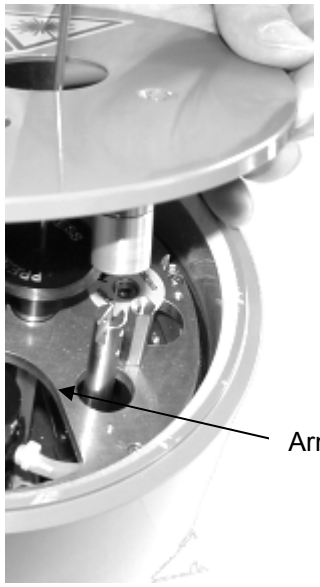
1. Switch the laser off with the key switch and pull out the mains plug.
2. Unscrew the two bolts securing the console (see section on "Front of the device") with a 3 mm Allen key.
3. Lift the console cover upwards – away over the fibre holder – (mind the armature of the lifting magnet).
4. Cover the fibre connector socket with a protective cap.
5. The "drawer" with the fibre coupler's blast shield can be pulled out sideways from the fibre coupler by grasping with the fingertips on the hexagonal bolt.

12.1.2 Checking the fibre coupler's blast shield

Lift the fibre-coupler's blast shield up to the light or place it against a clean, bright background (e.g. clean, white writing paper). A clean blast shield is colourless and transparent. A clearly dirty fibre coupler's blast shield decreases the laser by about 50%. (That means that half of the power emitted by the laser is absorbed in the blast shield and converted there into heat). A few dots mean only a slight loss in power. A dirty fibre coupler's blast shield must be replaced (see accessories' list).

12.1.3 Installing the fibre coupler's blast shield

1. The new fibre coupler's blast shield is pushed back into the fibre coupler in the way that the old one was pulled out.
2. Before the console cover is put back on the protective cap must be removed from the fibre connector socket and put to one side.
3. When replacing the console cover, take care that the lifting magnet armature is in its correct position. That may easily be checked by switching the laser on with the key switch before fastening the two bolts and pressing the release button. If the beam lock opens the solenoid armature is correctly positioned.



4. Replace the two bolts in the console cover and tighten them lightly.

12.2 Calibration of the energy and power displays

The displayed value for power shown on the screen display are based on values, taken directly from the laser resonator. The values are reduced by a fixed factor, which takes into account for the transmission loss of an optimum transmission system (fibre). Below will be described how the power reading on the screen display can be calibrated. In normal use this calibration is unnecessary.

With the external laser power meter it is possible to determine the power emitted from the fibre tip by a given fibre. The calibration factor for the power reading on the screen display is determined as follows:

Calibration factor = Reading of the external laser power meter / Power reading on laser display

If the power deviation is greater than 20% then call your authorized LISA service centre in order to arrange a calibration of the laser system.

The power emitted from the transmission system is corrected for each setting in accordance with the following formula:

*Power = Calibration factor * Power reading on laser display*

The transmission properties of a fibre are highly dependent upon the condition of both ends of the fibre. The unavoidable burning off of the distal fibre end can reduce the transmission to 50%. Evaluation and, if necessary, shortening of the distal fibre end are explained in the relevant accessory's manual.

12.3 Use of the external power meter

The pilot laser should be set to maximum brightness (see section on "Power mode – More parameters") and a functional fibre attached to the laser (see section on "Replacing fibres"). The laser is activated by a foot switch, whilst the laser outlet is pointed downwards. In doing this care must be taken that persons are not endangered and that the laser beam does not cause unnecessary or dangerous heating of material.

With your free hand press the reset-knob on the power meter for 2 seconds, after which the black absorbent surface is brought into the laser beam. The red spot of the pilot laser should cover about 2/3 of the absorbent surface. If the measuring device gives out a series of some three signal tones, the measurement is complete and the absorbent surface is removed from the beam. The power meter displays the measurement obtained in watts for several seconds. Then, after a more rapid tone sequence, it returns to its rest position. The external power meter can be obtained from the manufacturer (see list of accessories).

13 Technical data

The following pages contain technical data relating to the laser device supplied with this manual.

Manufacturer: LISA laser products OHG
Max-Planck-Str.1
D-37191 Katlenburg-Lindau
Germany
Fon +49 (0) 5556-9938-0
Fax +49 (0) 5556-9938-10
e-mail: info@lisalaser.de
web: www.lisalaser.com

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Technische Daten / Technical Data
SPHINX (25, 30, 45, 60, 80 W)

	Technische Größe / Specification	**Ausführung / Data**
1	Laserart / Laser System	YAG:Cr,Tm,Ho Festkörperlaser YAG:Cr,Tm,Ho Solid State Laser
2	Laserschutzklasse / Laser Class	4 & 2
3	Emissionswellenlänge / Wavelength	2,1 µm
4	Pulsenergie / Pulse Energy	0.5 - 2.3 J (25 W System) 0.5 - 2.7 J (30 W System) 0.5 - 2.8 J (45 W System) 0.5 - 3.8 J (60 W System) 0.5 - 4.0 J (80 W System)
5	Pulswiederholrate / Repetition Rate	5 - 15 Hz (25 W System) 5 - 20 Hz (30 W System) 8 - 25 Hz (45 W System) 8 - 25 Hz (60 W System) 8 - 30 Hz (80 W System)
6	Mittlere Leistung / Average Power	max. 25, 30, 45, 60, 80 Watt
7	Pulsdauer / Pulse Duration	150 - 800 µs
8	Pulsspitzenleistung / Pulse Peak Power	> 15 kW
9	Pilotlaser / Aiming Beam	Halbleiterlaser / diode laser, 635 nm, 1 mW
10	Netzspannung / Utilities	230 V, 50/60 Hz, 30 A (max.), einphasig / single phase (~, N, PE) (nur / only 25, 30, 45 und / and 60 W System) **oder / or** 400 V, 50/60 Hz, 16 A (max.), dreiphasig / three phase (3~, N, PE) (25, 45, 60 und / and 80 W System)
12	Kühlsystem / Cooling	interner Kompressor, geschlossener Kreislauf / internal compressor cooling *externe Wasserkühlung optional /* *optional external water cooling*
13	Kältemittel / Cooling Agent	R 404 A
14	Abmessungen (H x B x T) / Dimensions	ca. 850 x 450 x 1050 mm
15	Gewicht / Weight	ca. 165 kg

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14 Conformity declaration

The following pages contain the conformity declaration, with which the manufacturer states that the laser device described in this manual conforms with the 93/42/EEC guideline on medical products.

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LISA
laser products

CE
0123

EU-Konformitätserklärung

EU-Declaration of Conformity

UE-Déclaration de Conformité

Hersteller: LISA laser products OHG
Manufacturer:
Entreprise:

Anschrift: Max-Planck-Str. 1
Address: D-37191 Katlenburg-Lindau
Adresse: Germany

erklärt in eigener Verantwortung, daß das Produkt mit der Bezeichnung
declares at its own risk the designated product
explique dans propre responsabilité que le produit avec la désignation

Produktbezeichnung: SPHINX
Product Designation:
Désignation du produit:

die Forderungen folgender Europäischer Richtlinien erfüllt:
to comply with the following European Directives:
accomplit les demandes des directives européennes suivantes:

93/42/EWG Medizinprodukte-Richtlinie

LISA laser products OHG

Katlenburg-Lindau, 16.01.2003 Dr. H.-O. Teichmann

(Ort) (Datum) (Geschäftsführer)

KE	Konformitätserklärung	04	**geprüft**	von HT	am 15.08.99
Bezug	MPL40		**freigegeben**	von HT	am 15.08.99
erstellt	von FSimon	am 8.8.99	**gesperrt**	von	am

KEmpl04KonformitaetsErklaerung.doc gespeichert am 05.12.00

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15 ISO certificates

The following pages contain photocopies of the DIN EN ISO 9001 and DIN EN 13485 ISO certificates issued by the TÜV Product Service, Munich for *LISA laser products OHG*.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

TÜV PRODUCT SERVICE

No. Q1Z 02 11 11426 010

TÜV PRODUCT SERVICE GMBH certifies that the company

LISA laser products OHG

Max-Planck-Straße 1
D-37191 Katlenburg-Lindau

in the facility:

LISA laser products OHG, D-37191 Katlenburg-Lindau

within the scope:

Design, manufacture and distribution of laser systems for medical applications and related components and accessories

has established and is maintaining a quality system which meets the requirements of:

EN 46001: 1996
EN ISO 13485: 2000

Quality Systems - Medical Devices -

Particular Requirements for the Application of

DIN EN ISO 9001: 1994

as documented in audit report no. 70029614.

This certificate is valid until 10/2005.

Munich, 11-20-2002

TÜV PRODUCT SERVICE GMBH
ACCREDITED CERTIFICATION BODY
FOR QUALITY SYSTEMS

Akkreditiert durch
ZLG vertreten im DAR
ZLG-ZQ-999.98.12-46

TÜV PRODUCT SERVICE GMBH · Zertifizierstelle · Ridlerstrasse 65 · 80339 München · Germany

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