LISALaser PRODUCTS
An OmniGuide Company

**Instruction for Use**

# *Sphinx*

2micron **Holmium Laser**


***Sphinx 45 litho -***
***Sphinx 60 - Sphinx 80 – Sphinx 100***

# Inhalt

# 1 About these Instruction for Use

These instruction for use provide important information concerning the safe handling of the ***Sphinx*** Holmium YAG laser.

These instructions for use describe the models:

| ***Sphinx 45 litho*** | ***Sphinx 60*** | ***Sphinx 80*** | ***Sphinx 100*** |
|---|---|---|---|

The information and remarks referring only to a designated model, option or version is emphasised specially.

You will find the name of the specific model and the power range (max. power) on the name plate (Fig. 5). In addition the name of the laser model appears on the start display (Fig. 17) after switched on.

**Before using the laser device for the first time read and comprehend these instructions for use, referred documents and instructions of the accessories (e.g. fibres and applicators) carefully and follow the instructions! Please keep the instructions for use for future reference.**

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

**Subject to technical modifications and amendments!** Due to enhancements images and technical data may vary slightly.

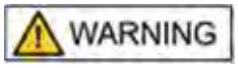
## 1.1 Safety instructions and symbols used in these Instructions for Use

The safety messages described in this section will be listed at the start of any chapter containing instructions that carry a particular risk. Please take the time to read these safety messages carefully and bear them in mind when performing the activities concerned.

| | |
|---|---|
| DANGER | Indicates a highly hazardous situation which if not avoided will result in death or serious injury |
| WARNING | Indicates a hazardous situation which if not avoided could result in death or serious injury |
| CAUTION | Indicates a fairly hazardous situation which if not avoided could result in minor or moderate injury |
| NOTICE | Indicates imminent material damage and suggests ways to avoid possible material damage. |
| INFORMATION | Provides recommendations, information, and advice for efficient use |

## 1.2 Safety instructions

This section includes a summary of the basic danger and safety instructions. Failure to observe any of these instructions may lead to the injury of patients, users or third parties or could cause damage to the laser device by operator error. Please also refer to the specific safety instructions in the other sections and the related instructions for use.




**Injury** to the patients, users and third parties and / or product damage **by non-authorized personnel.**

The *Sphinx* laser is intended only for personnel who have the appropriate medical qualification and who are trained in the correct handling of the laser system to exclude injury risks for patients, users or third parties. Make absolutely sure that the laser system may only be operated by qualified personnel who have been appropriately trained.

- Lock device by removing key of key switch to prevent unauthorized use of laser device.


Installation and service of the device should only be performed by trained experts who are authorized by LISA Laser Products.

These persons are capacitated:

- to carry out proper service and maintenance work
- to give LISA Laser Products GmbH approved clearance for operational use at a specific site, along with the accompanying documentation of a successful functional test
-

INFORMATION

Properly carried out service reports, successful yearly functional tests, and timely maintenance work help to guarantee a faultlessly functioning laser device and support warranty claims.
Please make sure that the installation and service are only provided by an authorized expert.


**Injury** to the patients, users and third parties and /or product damage **by user's inability to make proper use of the laser system.**

Before use, please make sure that all required documents, such as safety regulations and the instructions for use are present, along with the required safety glasses, and that they are in a usable condition. Please make sure that the door interlock device is functioning properly before use.

Follow the specific national laws and regulations on operation and safety of laser equipment to exclude the possibility of injury or infection risks for patients, users or third parties.

INFORMATION

Other sources of information are:

- the instructions for use of devices used during operation, of the accessories, of the endoscopes, of the instruments and
- the instructions, given by safety regulations and safety training and/or courses or in-house schooling, which have to be observed.

INFORMATION

Check the laser system and its suitable accessories for visible damage on the outside, on cables and wires before every use. Please consult the indicated sources of information for further instructions. Do not use a defective laser system to avoid preventively potential hazard during treatment.

CAUTION

**Malfunction:** consequential damages by unsuitable **location / installation site and storage conditions:**

Before use of the laser device, ensure that the laser has been positioned properly and in an optimum spatial separation in the operation area to avoid malfunction and failure by space constraints during treatment.

- The footswitch of the device is always directly available to the operating person and easy to operate, along with the connecting cable being placed so that no tripping hazard or obstruction shall arise
- The distance of the laser device from the operation field is of a length that coordinates to the laser fibre being used so that no tensile load on the laser fibre or undercutting of the bend radius of the laser fibre could occur during the operation.
- The unsterile person that operates the laser device for the operating person must be able to use the laser device unimpeded and direct. They must be able to have a direct overview of the operation field and the laser device from their point of view. The laser device should be positioned so that the laser stop button always is directly available without hindrance.

INFORMATION

To avoid malfunctions and disturbances through spatial limitations during operational usage,

the following requirements at the operations site and storage site guarantee a properly functioning laser device:

- The device must be in the upright position
- Do not turn the laser device upside down or place the laser device on its side.
- Make sure the device is in a stable position. Use the locking brakes to prevent the device from rolling.
- Ensure adequate and secure mounting and storage of the laser device. Further information is available in the instructions for use.

INFORMATION

The shutdown process, deliberately induced or caused by failure of the laser device, does not lead to risk to the patient, user or third party.

- Procedures with the laser device can easily be stopped again and be repeated.
- The risk assessment of an extension of the operating time for the patient is up to the treating physician.

CAUTION

**Functional impairment**, hazards by injuries and delay during treatment caused by incorrect assembling and insufficient preparation for medical use:

The device must be connected / assembled properly with all required components and accessory parts.

- Therefore, observe the notes in the Instructions for Use and
- make sure, that the laser device and its accessories work properly


**Possible hazard of the eyes by direct eye contact with the aiming / pilot laser beam.**

The pilot / aiming beam is classified as a laser of:

Laser class according to IEC 60825-1:2007 (pilot laser) 3R
Laser classification US FDA CDRH (21CFR1040.10) (pilot laser) IIIA

- Do not look directly into the pilot laser beam.


**Hazards** and **injuries which may happen during treatment.**

**Severe injury of the eyes by direct eye contact with the working beam**

The working beam is classified as a laser of:

Laser class according to 60825-1:2007 (working laser) 4
Laser classification US FDA CDRH (21CFR1040.10) (working laser) IV

- Do not look directly into the working laser beam
- Keep the safety distance for laser radiation class 4 ref. to chapter 5 et seqq.
- Use appropriate eye protection ref. to chapter 5.6


**Hazards for patients, users and third parties by fibre breakage / instrument damage.**

- Therefore observe the relevant notes of the instructions for use for all devices used the accessories and the instruments.
- Keep the laser safety standards ref. to chapter 5 et seqq.


**Hazard to patients by tissue damage**

During treatment with class 4 laser radiation, thermal damage of the tissue is possible.

- Always start with low parameters.
- Laser radiation may only be activated, if the fibre tip and the tissue are clearly visible.


**Hazards for patients, users and third parties by the laser smoke under open surgery conditions.**

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

- Use an appropriate smoke evacuation.
- Observe the further notes in chapter 8et seqq.: “Safety instructions”.


**Hazards to patients by laser treatment under oxidizing environmental conditions by way of an explosive atmosphere (flammable gases, oxygen-enriched air, flammable material, and flammable liquids).**

Irradiation with the *Sphinx* laser of flammable materials, gases or liquids (e. g. produced naturally in the body) can cause them to ignite and lead to serious injury to the patients.

- Make sure that the laser radiation does not impinge on inflammable substances or inflammable tissue.
- Observe the further notes in chapter 8.1: “Safety instructions”.


**Infection:**

Insufficiently sterilized accessories may be hazardous to patients

- Observe the sterilization regulations for authorized trained personnel prior to every use and sterilize the accessories as such as laser fibres, endoscope and other instruments before and after laser treatment to avoid risk of infection.
- Therefore read the instructions for use of the respective accessories and keep the cleaning and sterilization regulations.


**Contamination:**

Endangering persons through potential contamination related to location.

Note, that the laser device and its accessories may possibly be contaminated with biological material in the operating room. Protect yourself and others from potential harm and

- ensure a suitable decontamination, e. g. before disposing / recycling the laser device.
- Therefore, read the notes in these instructions for use.


**Disposal:**

The laser device may not be disposed of as domestic waste. It contains valuable and hazardous material which should be recycled or disposed of according to local regulations. LISA Laser offers to recycle the device at the end of its life.

- Please contact your local representative or contact directly LISA Laser Products GmbH.

# 2 Delivery

## 2.1 Regular scope of delivery

The Sphinx laser is usually delivered with the following minimal scope of delivery. The exact scope of delivery refers to the shipment.

**Tab. 1: Scope of delivery**

| ***Sphinx* laser system** | **qty.** | **Items included** |
|---|---|---|
| *Sphinx* Holmium-YAG medical laser | 1 | *Sphinx* Holmium-YAG laser |
| | 1 | Footswitch Kix (REF 101 600 215) |
| | 1 | Door-interlock dummy connector (REF 101 600 166) |
| | 1 | User manual |
| | 2 | Keys (REF 101 600 237) |

## 2.2 Software-Version

This manual refers to the laser software version OSCF04Vxx. You can see the software version on the desktop (Fig. 17) and in the service mode.

# 3 Product description

This section provides important information about the device. The section contains a general description of the *Sphinx* laser, its intended use and authorized users, the contraindications and side effects. You will learn how to identify your specific model and get information about the device classification.

Subchapter 3.8 “overview” shows you the most important items of the laser device.

You will find information about the laser fibres that are approved for the *Sphinx* in the section 3.9 ”Fibre selection” and the fibre instructions for use.

## 3.1 Identifizierung des Modells

You can find name of the model, the power range (max. power) and the character of the emitted laser radiation on the name plate (Fig. 5).

After switching on the device the model designation is indicated on the start picture (Fig. 17).

Tab. 2 gives a short overview about the technical specifications. For detailed technical date refer to section 12 “Technical Data”.

**Tab. 2: Discription of different models of Sphinx**

| | ***Sphinx 45 litho*** | ***Sphinx 60*** | ***Sphinx 80*** | ***Sphinx 100*** |
|---|---|---|---|---|
| Wavelength | 2120 ± 3 nm | | | |
| Power | 2.0 - 45 W | 2.0 - 60 W | 2.0 - 80 W | 2.0 - 100 W |
| Energy | 0.5 – 4.0 J | 0.5 – 4.5 J | 0.5 – 4.5 J | 0.5 – 4.5 J |
| Pulse duration | 150 - 800 µs | | | |
| Repetition rate | Single pulse;<br>4 – 30 Hz | Single pulse;<br>4 – 30 Hz | Single pulse;<br>4 – 30 Hz | Single pulse;<br>4 – 30 Hz |

## 3.2 General description

The *Sphinx* Holmium laser devices are surgical laser systems. The laser radiation is solely delivered in pulses. The *Sphinx* laser has the wavelength 2.120 nm (±3 nm) (equal to 2.1 micron). This wavelength is invisible infrared.

The laser radiation is focused by a fibre coupler into a flexible silica laser fibre. The laser radiation is delivered by this silica fibre to the surgical site. The distal end of the fibre is attached to an appropriate applicator which serves as the surgeon’s working instrument. Various laser fibres and applicators designed for specific purposes are available at LISA Laser Products for clinical use.

The laser system is operated from an operating panel with a display and control elements. The laser is activated by a footswitch. Setting of operating parameters and activating the laser device is described in the section 7 “Operation of the laser device”.

## 3.3 Contraindications

Contraindications, related directly to the *Sphinx,* are not known. The contraindications of surgical or endoscopic laser procedures meet the common ones for classical surgeries like:

General inability to receive surgical or endoscopic procedures, pregnancy, sepsis, anticoagulation or bleeding disorders are contraindications to use the laser device.

The medical professional should decide on the laser usage depending on the patient’s situation.

INFORMATION

The mentioned contraindicated treatment methods mentioned can be supplemented or minimized by recent findings in research, literature and science. Considering the current literature, the risk and the advancing surgical technique, all applications should be assessed on a case-by-case basis, including those listed in the contraindications. The final decision on the procedure is up to the attending physician.

- Please also refer to chapter 8 "Clinical Applications and Tissue Interactions".

## 3.4 Intended use

The *Sphinx* surgical laser is used together with the suitable laser fibre and applicator for the invasive and surgically invasive incision, excision, vaporisation, ablation, resection and coagulation of soft tissue and the ablation of hard tissue and laser lithotripsy.

Please refer to the applications in section 8 ”Clinical applications and tissue interaction”.

Direct application of the *Sphinx* on the central nervous system and on the cardiovascular system is not intended. The *Sphinx* laser is not indented for ophthalmological applications.

## 3.5 Side effects

The potential complications, which may result from a surgical laser procedure, are the same as those normally encountered in conventional surgery and may include but are not limited to pain, perforation, entrapment, evulsion, haemorrhage, infections, sepsis, tissue trauma, bleeding and oedema.

## 3.6 Authorized Users

The *Sphinx* laser is designed for professional users. It may only be used by qualified persons who have been trained by the manufacturer or by an authorised representative of the manufacturer in the correct and safe operation of the laser on basis of the manual. Only those people may receive a training who have an appropriate medical knowledge or professional clinical experience.

Re-processing of laser fibres, applicators and accessories should be performed by trained professionals only.

Maintenance and service of the device should only be performed by trained and authorised experts approved by LISA Laser Products and based on these and related instructions for use.

## 3.7 Classification

The *Sphinx* laser systems belong to the following classifications/nomenclatures:

| | |
|---|---|
| Medical product class according to MDD 93/42/EEC (Medical Device Directive)<br>Medical Device Class according to Title 21 of CFR, Parts 862-892 | Class IIb<br>Class II |
| Medical product nomenclature according to UMDNS | 17-769 |
| Laser class according to IEC 60825 (working laser)<br>Laser classification US FDA CDRH (21CFR1040.10) (working laser) | Class 4<br>Class IV |
| Laser class according to IEC 60825 (pilot laser)<br>Laser classification US FDA CDRH (21CFR1040.10) (pilot laser) | Class 3R<br>Class III |
| Protection class according to IEC 60601<br>Protection group according to EN 60529 | Class I<br>IP20 |
| Applied part | BF |

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

The laser device is classified as class BF when a fibre is connected.

The applied part of the laser device is the distal end of the laser fibre incl. the length of the laser fibre inside of an instrument.

## 3.3 Overview

### 3.3.1 Front view

The beam outlet, the laser-stop, the access for the fibre coupler protection shield, the foot break and the fibre holder are at the front side of the device.

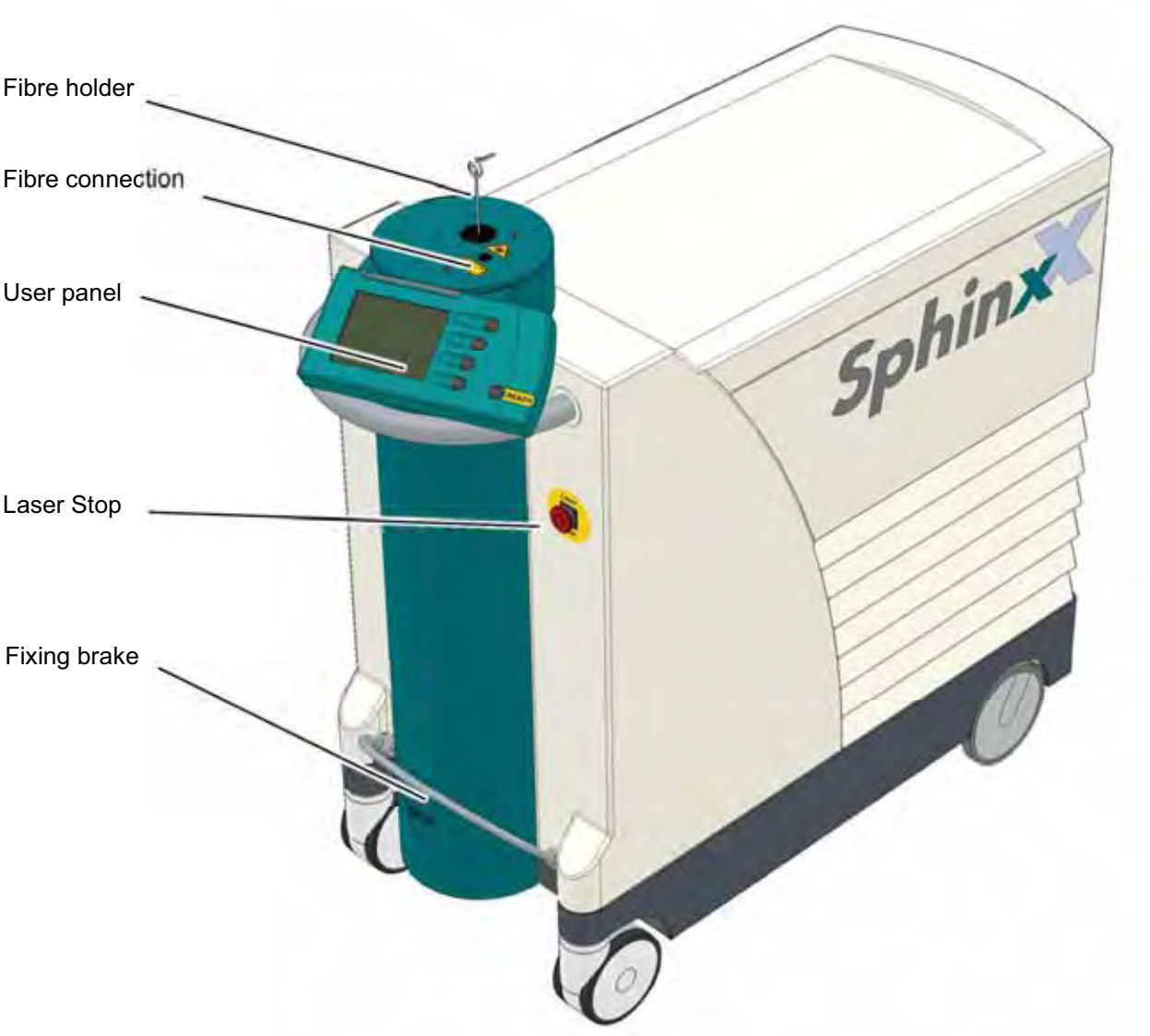



**Fig. 1: Front side and top side view**

### 3.8.2 Rear view

At the rear side of the device you will find the key switch, the door interlock connection, the power cord and the receptacle for the footswitch.

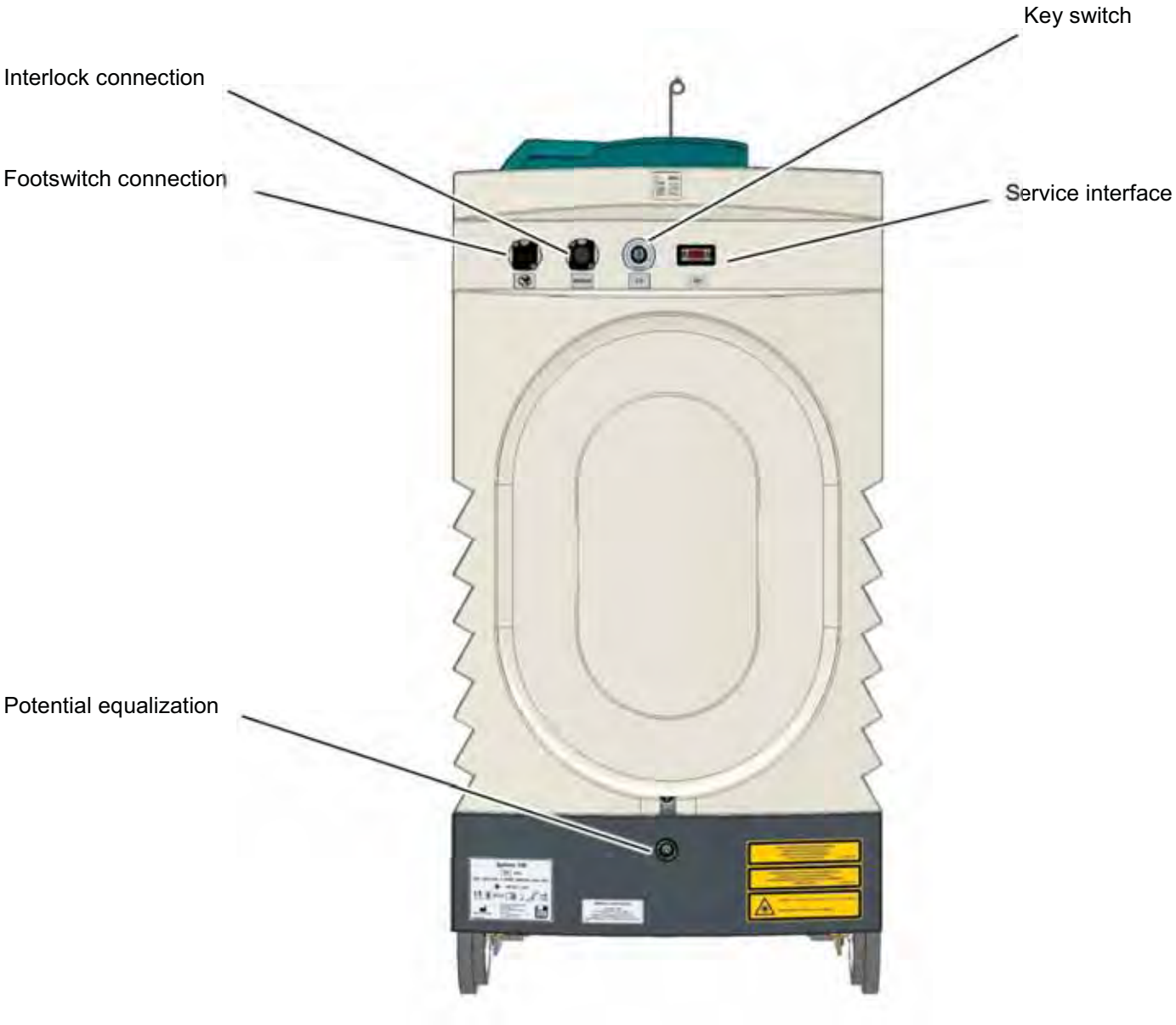



**Fig. 2: Rear view**

## 3.9 Fibre selection

A range of laser fibres is available for the *Sphinx*. These fibres differ in core and in the outer (cladding) diameter, in mechanical flexibility and in direction of radiation.

Select the fibre according to the application, the compatibility with the used instrument / applicator and the mechanical properties required for the treatment.

In general small core diameter fibres are more flexible than fibres with larger core diameter but also less mechanically stable. The smaller the core diameter of a fibre is the higher is the intensity of the laser beam at the distal tip of the fibre

INFORMATION Be sure to observe that the chosen fibre is compatible with the used instrument / applicator.

For more information about the laser fibres please refer to the information in the instructions for use chapter 10 and the packaging of the fibres.

⚠ WARNING **Injuries** and product damage by usage error **if the laser system is not properly used.**

- Observe the instructions for use of the laser fibres to handle properly the laser fibres and to avoid usage error.

⚠ CAUTION **Injuries** and product damage by usage error if **incompatible accessories** are used.

Only use laser fibres, which are suitable for the respective laser system *Sphinx* and approved for the use of the laser device by LISA Laser Products GmbH

- Observe the minimum bend radius of the laser fibre.
- Observe restrictions concerning the maximum permissible laser power.
- Using unsuitable fibres or setting to high parameters may damage the laser fibre or the laser system.

# 4 Installation of the laser device

This section gives important information about the safe installation of the device.

You will get information about the specific regulations for operators of medical devices, about the requirements regarding the electrical installation, the environmental conditions. You will get notes regarding the EMI conditions.

## 4.1 General remarks

The laser system and the relevant local regulations impose specific requirements upon the installation site. These requirements concern the safety precautions, electrical supply and heat management.

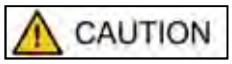
The installation of the laser system has to be carried out by an expert authorized by LISA Laser Products. This person will also carry out a functional test after the laser system has been installed at the designated site.

### 4.1.1 Unpacking

The devices are usually shipped in a wooden transport crate. To avoid damages to the system, the unpacking should be done only by a LISA Laser Products service representative. Before operation remove all packaging material and transport cushions from the system.

The keys and the door interlock dummy connector are packed separately.

For the specific scope of delivery refer to the shipping documents.




**Injuries** caused by a damaged during the transportation laser device. Cutting injuries through cracked housing parts, injuries to damaged power lines or plug connections**.**

- Check the laser system for damage to the housing or cables.
- Do not use a damaged laser system.

### 4.1.2 Before first use

Prior to the first use of the laser, the system needs to be tested for safety at the site of operation. The test should follow the manufacturer's instruction and needs to be performed by qualified and authorized service personnel. The results of the test shall be reported to the manufacturer.

The results on the proper function of the laser device are recorded in a form. This form must be signed by both parties and returned to LISA Laser Products GmbH as proof of the correct delivery condition of the laser device.

## 4.2 Electrical installation

The Sphinx laser is intended to be used in a medical location. The electrical installation should follow the specific requirement for these locations and should be in accordance with the IEC 60364-7-710 and referenced standards.

NOTICE

During operation an unexpected shut-down of the *Sphinx* does not endanger the patient if the operation times for the patient are not prolonged disadvantageously.

- Surgeries with the *Sphinx* can be interrupted, repeated or continued with alternative devices without any problems
- The risk assessment of an extension of the operating time for the patient is up to the treating physician.

Please contact LISA Laser Products or your LISA representative for any questions.

## 4.3 Permitted medical areas

Due to the purpose, it can be concluded that the application of the Sphinx may only be made in the areas of GROUP 1 and GROUP 2 (definition according to DIN VDE 0100-710) on the TN-S or IT system.

A failure or shutdown of the sphinx does not endanger the patient when used as intended.

## 4.4 Mains supply

The requirements regarding the main connections for the types of laser device described here might differ slightly, depending upon the power class of the device can be found on the name plate (Fig. 5). Please consider the maximum current consumption stated on the name plate. The manufacturer recommends, if possible, a wall socket with its own fuse. Apart from the laser device, no additional electrical loads should be connected to this fuse.

The connection of the Sphinx laser should be done with the plug type that is given in the related datasheet. In case you need another plug/receptacle combination please contact your LISA Laser Products representative.

⚠ CAUTION

Exposure to overloading of the mains connection, extension of operating times, loss of function and consequential damage can occur if several electrical consumers are connected to a protected mains connection with the Sphinx Laser.

- Protect the mains connection with the Amper number given below for the respective device version (see Tab. 3, Tab. 4, Tab. 5)
- This mains connection should not be additionally burdened by other consumers, so that the protection cannot be overloaded.

⚠ WARNING

Risk of electric shock

In order to avoid the risk of electric shock, this device may only be connected to a mains connection with a protective conductor.

**Tab. 3: Power requirements of the Sphinx 45 litho - Sphinx 100 (single phase)**

| | ***Sphinx 45 litho*** | ***Sphinx 60*** | ***Sphinx 80*** | ***Sphinx 100*** |
|---|---|---|---|---|
| **Supply** | 200-230V, 50/60Hz, 25A 1~/N/PE | 200-230V, 50/60Hz, 30A 1~/N/PE | 200-230V, 50/60Hz, 30A 1~/N/PE | 220-230V, 50/60Hz, 30A 1~/N/PE |
| **Plug type** | CEE-plug (1P+N+PE, 6h), 400V, 32A, blue (acc. IEC 60309-2) | | | |

**Tab. 4: Power requirements of the Sphinx 45 litho - Sphinx 100 (three phase models)**

| | *Sphinx 45 litho* | *Sphinx 60* | *Sphinx 80* | *Sphinx 100* |
|---|---|---|---|---|
| **Supply** | 400V, 50/60Hz,<br>16A<br>3~/N/PE | | | |
| **Plug type** | CEE-plug (3P+N+PE, 6h), 400V, 16A, red (acc. IEC 60309-2) | | | |

The laser system has an internal monitoring of the line voltage. If the line voltage is out of the acceptable range, an acoustic warning signal sounds. In this case check the electrical house installation.

For uncertainties on the electrical installation please contact LISA Laser Products GmbH representatives.

INFORMATION

The power plug serves as a power disconnecting device.

Place the laser device in such a way that access to the mains plug of the mains cable is always ensured, so that the laser device can be completely disconnected from the power supply.

The laser device is equipped with a not removable mains cable which needs to be changed by an authorizes technician. Instruction for exchange or the use of components and fuse are described in the service instruction.

## 4.5 Connecting a door interlock

A door interlock may be plugged into the socket on the back side of laser system (Fig. 2) and locked. The installation of the door-interlock must be done in collaboration between one of the manufacturer's service technicians and your house technician.

If no door-interlock switch is used, the dummy connector supplied with the laser should be plugged into the free socket. The dummy connector is fitted with an electrical bridge between pin 1 and pin 3. When the door-interlock switch circuit is broken the laser is immediately de-activated. After the door-interlock switch has been closed again the laser can only be operated again after pressing the 'ready' button.

## 4.6 Connecting a potential equalization cable

The potential equalization cable comply with the IEC 60601-1. The use of an additional potential equalization is necessary to balance electrical potentials during simultaneous contact or to minimize potential differences which can occur between other medical devices or conductive parts of other devices. Plug the suitable potential equalization cable into the potential equalization connection located at the rear side of the laser device.

## 4.7 Medical devices book

Due to regulation in some countries the operator of the medical device is obliged to keep records of the device history in a medical devices book. The medical device book has to be shown on request to the competent authorities.

The following records are kept:

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 period beyond that time. The duration of this period is subject to national regulation. Please make sure that you follow the applicable regulation in your country.

## 4.8 Environment Conditions

NOTICE

**Possible function failure** and **longer operation times**, if the device has been exposed improper ambient conditions during transport, storage or operation.

Observe the notes in the Instructions for Use.

- Avoid severe jolts or vibration during transport, storage and operation.
- Make sure that there is sufficient anti-freeze in the cooling liquid during transport and storage.
- Freezing of the cooling liquid may cause severe damages to the device.
- Never operate the device without cooling liquid.
- The temperature conditions for storage and transport are indicated in the Technical Data (chapter 11).

### 4.8.1 Transportation and Storage

⚠ CAUTION

**Injuries** from tipping over the laser device during transport.

Bruises, cuts and broken housing parts can be the result of transport damage due to inadequate transport safety.

- Operate the parking brakes of the laser device when you want to transport the device on a pallet or in a vehicle.
- Secure the laser device with suitable transport safety devices to prevent the laser device from tipping over or slipping during transport.
- If possible, the laser device should be in its original packaging, (wooden outer packaging on delivery).
- Comply with the statutory regulations for load securing.

During transportation of the *Sphinx*, take care that the device is not subjected to severe jolts or vibrations.

The ambient temperature should be between -15 °C to +70 °C, the relative humidity 10 % to 90 % (non-condensing) and the air pressure 700 hPa to 1060 hPa.

At delivery the laser system is freeze protected down to -15 °C. If there is danger that the ambient temperature may drop to below 0 °C, the anti-freeze of the cooling liquid must be checked by an authorized expert.

### 4.8.2 Operation conditions

The *Sphinx* is designed for continuous operation (definition acc. IEC 60601-1) at an operational ambient temperature between 15 °C to 28 °C, relative humidity 30 % to 75 % (none condensing) and air pressure 700 hPa to 1060 hPa.

If laser has been stored at a temperature outside this operational ambient temperature range the laser needs to adjust its temperature. For large temperature difference it should be kept in the operation room at the operational temperature for at least 3 hours to achieve a temperature adjustment. During operation of the *Sphinx*, take care that the device is not subjected to severe jolts or vibrations.

## 4.9 Cooling

The *Sphinx* laser device is equipped with integrated active cooling system. While the laser is operated the cooling system discharges the waste heat into the ambient air. The maximum heat load is in the range of the totally consumed electrical power.

In rooms, which are not air-conditioned, take into account that the ambient temperature rises. The laser may be operated at an ambient temperature of up to about 28 °C. The device switches off automatically if the internal temperature of the laser becomes too high. (chapter 9: error messages and malfunctions)

An additional cooling water or gas connection is not necessary.

NOTICE

Do not cover the ventilation in- and outlets at the side frames of the laser device during operation of the laser device.

Do not place the device with one of its longer sides directly against a wall!

The air flow from the laser device has to be directed away from the patient!

CAUTION

Danger of infection: the exhaust air flow which the laser device generates for its cooling must not be directed towards the surgical field. The exhaust air could carry directly dangerous particles to the operating field due to contaminated ambient air, which can lead to infections in the patient.

- Position the laser device so that the air flow from the laser device is not directed at a patient or the surgical field. The exhaust air flow exits through the openings on the right side in the lower part of the laser device when you are in front of the laser device, Fig. 1

## 4.10 Electromagnetic compatibility (EMC)

Medical Electrical Equipment like the *Sphinx* needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.

CAUTION

**Malfunction**

The Sphinx Laser is intended for use in the electromagnetic environment specified below with accessories and cables as supplied and / or approved by LISA Laser Products GmbH for this laser device. The use of other accessories or cables may result in increased electromagnetic emissions or less interference immunity of the laser device.

- The Sphinx Laser should not be connected or stacked with other equipment. If necessary, it should be checked whether the Sphinx Laser can be operated properly.

Further information can be found in the guidelines and manufacturer's declaration.

### 4.10.1 Guideline and Manufacturer´s declaration – Electromagnetic emissions

**Tab. 5: Electromagnetic emission**

| Electromagnetic emission | | |
|---|---|---|
| The Sphinx is intended for use in the environment specified below. The customer or user of the Sphinx should assure that the product is used in such an environment. | | |
| **Emission test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions CISPR 11 | Group 1 | The Sphinx uses RF energy for its internal function. Therefore, the RF emission is very low and is not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class A | The Sphinx is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |

## 4.10.2 Guidance and manufacturer's declaration - electromagnetic immunity

**Tab. 6: Electromagnetic immunity**

| Electromagnetic immunity | | | |
|---|---|---|---|
| Essential performances<br>The essential performances of the Sphinx in normal and single fault conditions are:<br>1. no unintended emission of laser radiation,<br>2. Cut-off of laser emission, if the laser radiation output deviates by more than 20% from the set laser power / energy,<br>3. no unintended changes of the user set parameters,<br>4. a locking device for preventing unwanted movement of the device,<br>5. Cut-off of laser emission, if the laser-stop was pressed,<br>6. Prevention of use by unauthorized persons. | | | |
| The ***Sphinx*** is intended for use in the environment specified below. The customer or user of the Sphinx should assure that the product is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 – test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | ± 6 kV contact<br>± 8 kV air | Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient/burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input / output lines | ± 2 kV for power supply lines<br>± 1 kV for input / output lines | Mains/line power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode<br>± 2 kV common mode | ± 1 kV differential mode<br>± 2 kV common mode | Mains/line power quality should be that of a typical commercial or hospital environment. |

| | | | |
|---|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | < 5 % UT<br>(> 95 % dip in UT)<br>for ½ cycle<br>40 % UT<br>(60 % dip in UT) for 5 cycles<br>70 % UT<br>(30 % dip in UT) for 25 cycles<br>< 5 % UT<br>(> 95 % dip in UT)<br>for 5 s | Not complies | Mains / line power quality should be that of a typical commercial or hospital environment. If the user of the Sphinx requires continued operation during power mains/line interruptions it is recommended that the Sphinx should be powered from an uninterruptible power supply or battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment. |
| NOTE: $U_T$ is the a. c. mains voltage prior to application of the test level. | | | |

## 4.10.3 Guidance and manufacturer's declaration - electromagnetic immunity for equipment and systems that are not life-supporting

**Tab. 7: Electromagnetic immunity for equipment and systems that are not life-supporting**

The ***Sphinx*** is intended for use in the environment specified below. The customer or user of the ***Sphinx*** should assure that the product is used in such an environment.

| **Immunity test** | **IEC 60601 – test level** | **Compliance level** | **Electromagnetic environment - guidance** |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Sphinx, including cables, than the recommended separation distance calculated from equation applicable to the frequency of the transmitter. |
| Conducted RF<br>IEC 61000-4-6 | 3 $V_{rms}$<br>150 kHz to 80 MHz | complies<br>$V_1$=3 $V_{rms}$ | Recommended separation distance<br>$d = 1.2\sqrt{P}$ |
| Radiated RF<br>IEC 6100-4-3 | 3 V/m<br>80 MHz to 2,5 GHz | complies<br>$E_1$=3 V/m | Recommended separation distance<br>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>where P is the maximum power output rating of the transmitter in watts [W] (according to the transmitter manufacturer) and d is the recommended separation distance in meters [m]<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of devices with the following symbol:<br>  |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies

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

[a] The field strength of fixed transmitters, such as base stations for radio (cellular/cordless) telephones, land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the EMC environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the product is used exceeds the applicable compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or relocating the product.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## 4.10.4 Recommended separation distances between portable and mobile RF communications equipment and devices that are not life-supporting

**Tab. 8: Recommended separation distance**

The Sphinx is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Sphinx as recommended below.

| Rated nominal output power of the transmitter [W] | Separation distance as a function of transmitter frequency [m] | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a nominal output power not listed in the table above, the recommended separation distance (d) in meters [m] can be determined using the applicable equation (observe frequency). P = nominal power of the transmitter in Watt [W].

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies

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

### 4.10.5 List of cables and their length

**Tab. 1: List of cables**

| Article description and cable length | | |
|---|---|---|
| **Cable** | **REF** | **Length** |
| Power supply cable | n/a | 5.90 m |
| Potential equalisation lead | 101 630 123 | 5.00 m |
| Footswitch Kix for Sphinx | 101 600 215 | 2.90 m |


Danger of malfunctions and injuries due to modifications.

It is not allowed to change the laser device and / or its accessories. Changes to the laser device and / or accessories may result in malfunction, injury to patients, users, and others. Changes are changes to the laser device and / or accessories that are not described in the instructions for use.

# 5 Laser safety

This section provides important information and guidelines about the laser safety.

Regulations regarding laser safety for the safe installation and operation of a medical laser are described. You will get guidelines for the protective measures and the marking for the operation room. The Nominal Ocular Hazardous Distance (NOHD) is calculated and you will get information about the required laser safety eyewear.

## 5.1 General information

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 a class 4 laser device 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 (red) or 532 nm (green) (see labelling of the device) and an output of max. 1.3 mW is used as aiming beam (pilot laser) . This laser is class 3R. Thus, one must refrain from irradiating persons when they are not undergoing treatment.

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 these instructions for use and those in the laser accessory instructions for use.**

## 5.2 Notes about your safety


**Hazard by laser radiation:** if the device is used in an inappropriate manner and / or incorrect operation.

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure and may lead to injuries of skin and eyes.

- Only use the laser for the intended use.
- Never point the laser beam at a person.

  Irradiation of persons can cause injuries to skin and eyes.
- All persons in the laser area must wear appropriate laser safety eyewear.
- Irradiation of flammable materials, liquids or gases (as well as the body's own!) can cause them to ignite.
- Smoke generated by laser tissue interaction may contain viable tissue particles or toxic substances. Use an appropriate smoke evacuation.
- Do not use laser treatment under oxidizing environmental conditions by way of an explosive atmosphere. (Flammable gases, oxygen-enriched air, flammable material, and flammable liquids).
- Do not use laser radiation in an explosive atmosphere.
- The laser should only be activated if the desired target is clearly visible.
- Before use, always make sure that the laser fibre is undamaged. The use of a damaged laser fibre may cause accidental laser exposure and injury to the personnel or patient.

## 5.3 Laser safety officer

According laser safety regulations in most countries the operator of a laser, usually the hospital administration, has to appoint in writing a proficient person as the laser safety officer of the organization. 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 fulfil your national regulation on the safety of medical laser devices before putting the system into operation.

## 5.4 Laser area

The laser area is considered to be that area, in which the amount of radiation can exceed the current **m**aximum **p**ermissible **e**xposures limit 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.

## 5.5 Sicherheitsabstand (NOHD, Nominal Ocluar Hazadous Distance)

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 maximum permissible exposures (MPE) for the eye cornea are the relevant limit defining the NOHD.

The NOHD is calculated according to the European standard (EN 60825-1, „Safety of laser products“).

The calculation of the MPE regarding the laser emission as a pulse train leads to the most restrictive NOHD value.

**Tab. 9: Calculation of the MPE**

| | |
|---|---|
| | *Sphinx 45 litho*<br>*Sphinx 60*<br>*Sphinx 80*<br>*Sphinx 100* |
| Wavelength: | λ = 2.1 µm |
| Numerical aperture of fibre: | NA = 0.22 |
| Opening angle: | Φ = 2 * arcsin(NA)[°] converted into radians<br>Φ = 25.4° = 0.4436 rad |
| Fibre diameter: | $d$ = 200 µm |
| Maximum energy (plus margin of error): | $E_0$ = 4.5 J * 1.2 = 5.4 J |
| Frequency at maximum energy | 22 Hz |
| MPE (engl.): maximum permissible exposures | $MPE_{Pulse\_train} = 10^3 \times (22Hz \times 10s)^{-0.25}$ $\left[J/m^2\right]$<br>$MPE_{Pulse\_train} = 260\, J/m^2$ |

**The NOHD is than calculated as:**

$$NOHD = \frac{\sqrt{\frac{4 \times E_0}{\pi \times MPE_{Pulse\_train}}} - d}{\Phi} [m]$$

**for Sphinx 45 litho, Sphinx 60, Sphinx 80, Sphinx 100:**

$$NOHD = \frac{\sqrt{\frac{4 \times 5.4J}{\pi \times 260 J/m^2}} - 200\mu m}{0.4436 rad} [m]$$

$$NOHD = 0.37m$$

**The NOHD for the Sphinx 45 litho, Sphinx 60, Sphinx 80, Sphinx 100 Holmium laser is 0.4 m.**

## 5.6 Required eye protection

All personnel who are within the NOHD are considered to be within the laser area and shall wear suitable eye protection . The protection glasses should be specified and approved according EN 207 and must have CE-marking.

For safety reasons we recommend to use only safety eyewear that is supplied by LISA Laser Products GmbH or your LISA representative. Please contact us for further information.

### 5.6.1 Required eye protection for *45 litho, Sphinx 60, Sphinx 80 and Sphinx 100*

The eye protection for the laser devices *Sphinx 45 litho* and *Sphinx 60* must supplied with the minimum protection class/optical density **LB3** (EN 207:2010), respectively, at I (pulse) mode at the wavelength of the laser device 2.1 µm.

**Tab. 10: Eye Protection for *Sphinx 45 litho, Sphinx 60, Sphinx 80 and Sphinx 100***

| Referenced Standard | Remark | Protection level / Optical Density (OD) | Wavelength |
|---|---|---|---|
| EN 207:2010-04 | | LB3 | 2.123 nm |
| ANSI Z136.1 | US Norm | OD3 | 2.123 nm |

### 5.6.2 Eye protection markings according to EN 207

This standard specifies requirements for laser safety goggles. Filters that are used in laser safety goggles and that comply with this standard are marked with the appropriate protection level (LB). On the glasses, the following information is included:

DI >1400-2200 L2 XXX DIN CE

| | |
|---|---|
| DI | Laser type D = Continuous wave/ I = Pulsed |
| >1400-2200 | valid wavelength range |
| LB3 | Scale number (protection level) (LB1 – LB8)<br>LB3 = maximum spectral transmittance of $10^{-3}$ |
| XXX | Manufacturer designation |
| DIN CE | Signifies conformity according to EN 207 |

## 5.7 Marking of entrance doors to laser areas

All entrance doors to the laser area (e.g. the operating theatre), in which the laser system is set up and operated, have to be marked on the outside with the following laser hazard symbol in accordance with IEC 60825-1 (or the relevant local regulation) (Fig. 3).

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

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


**Fig. 3: Warning Sign (hazard symbol) for entrance doors of laser area**

# 6 Labeling of the device

This section 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 follow- the applicable standards and regulations.

The position of the labels is given in Fig. 10, Fig. 11 und Fig. 12.

## 6.1 Used Symbols

The following symbols are used:

| | | | | | | |
|---|---|---|---|---|---|---|
|  |  YYYY-MM |  |  |  |  |  |
| Manufacturer | Date of manufacture | Serial Number | Laserradiation | Applied part type BF | Off | ON |

| | | | | | | |
|---|---|---|---|---|---|---|
|  | IP20 |  |  0123 |  |  |  |
| Operating temperature | Degrees of protection | Potential equation | CE-Mark | Do not dispose in domestic waste | Follow instructions for use | Pay attention to user manual |

| | | | |
|---|---|---|---|
|  |  |  INTERLOCK |  COM |
| Receptacle for footswitch Fig. 11 | Key switch (ON / OFF) Fig. 11 | Interlock connection Fig. 11 | Receptacle for footswitch Fig. 11 |

**Fig. 4: Pictograms**

## 6.2 Name plate

The name plate (Fig. 5) of *Sphinx l*aser is attached to the back of the device (Fig. 11). It comprises all the necessary data for the identification of your laser system.


Example:
Sphinx 100 (1~+N+PE)

Example:
Sphinx 100 (3~+N+PE)

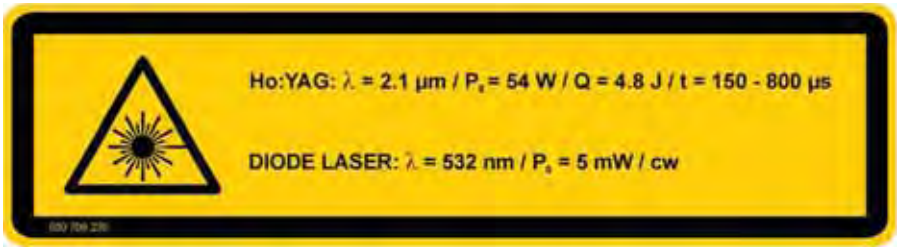
**Fig. 5: Name plate**

## 6.3 Laser warning lables

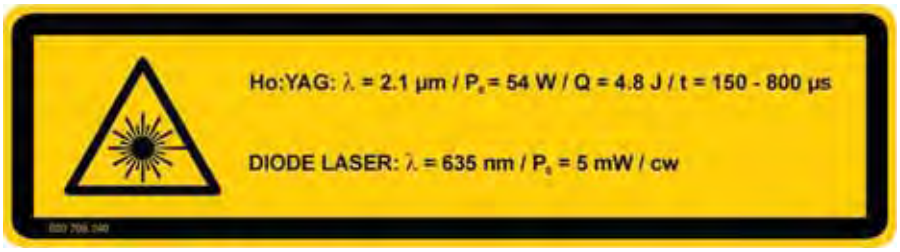
This section describes the type and the location of the danger and regulatory compliance labels of the *Sphinx* laser. From the labelling of the system the user gets important information regarding the device and the safety of laser devices. The labelling follows the IEC 60825-1 standard.

### 6.3.1 Explanatory label

The following signs are attached at the rear side of the laser. They describe the laser radiation (position F - Fig. 11) and the laser class (position E - Fig. 11).


(Example: *Sphinx 45 litho* with green pilot laser)




(Example: *Sphinx 45 litho* with red pilot laser)

Labelling laser class and output values
L and K in **Fehler! Verweisquelle konnte nicht gefunden werden.**

**Fig. 6: Labelling laser radiation**

The deviation in the marking of the aforementioned laser types is the value of the indicated power $\mathbf{P_0}$ of the laser. Here, the maximum possible power plus the allowed maximum positive deviation of 20% is given.

Performance and deviation

| *Sphinx 45 litho* | *Sphinx 60* | *Sphinx 80* | *Sphinx 100* |
|---|---|---|---|
| $\mathbf{P_0 = 54\ W}$ | $\mathbf{P_0 = 72\ W}$ | $\mathbf{P_0 = 96\ W}$ | $\mathbf{P_0 = 120\ W}$ |

### 6.3.2 Labelling of the beam outlet (fibre coupler)

The beam outlet is marked with the following signs (original black on yellow) (A and B in Fig. 10)

**Laser warning**
**A in Fig. 10: Position warning signs / labelling front side**


warning beam outlet
B in Fig. 10: Position warning signs / labelling front side

**Fig. 7: Explanatory beam outlet**

### 6.3.3 Laser-Stop

The Laser Stop-Button is marked with the following sign (original black on yellow) (D in Fig. 11).


**Label laser-Stop**
**D in Fig. 10: Position warning signs / labelling front side**

**Fig. 8: Label Laser-Stop**

## 6.4 Certification lable acc. to 21 CFR 1040.10

The marking indicates that the device complies with the specified standards / guidelines of the "Code of Federal Regulation" of the USA (for positioning see Fig. 11). This marking only exists on laser devices that are intended for delivery to the USA.

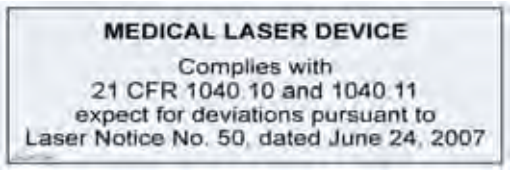



**Fig. 9: Certification label**

## 6.4 Position of warning signs and labels on the front side


**Fig. 10: Position warning signs / labelling front side**

| | Labelling and warning signs |
|---|---|
| **A** | Laser warning |
| **B** | warning beam outlet |
| **C** | Ready button |
| **D** | Laser Stop |

## 8.6 Position of warning signs and labels on the rear side

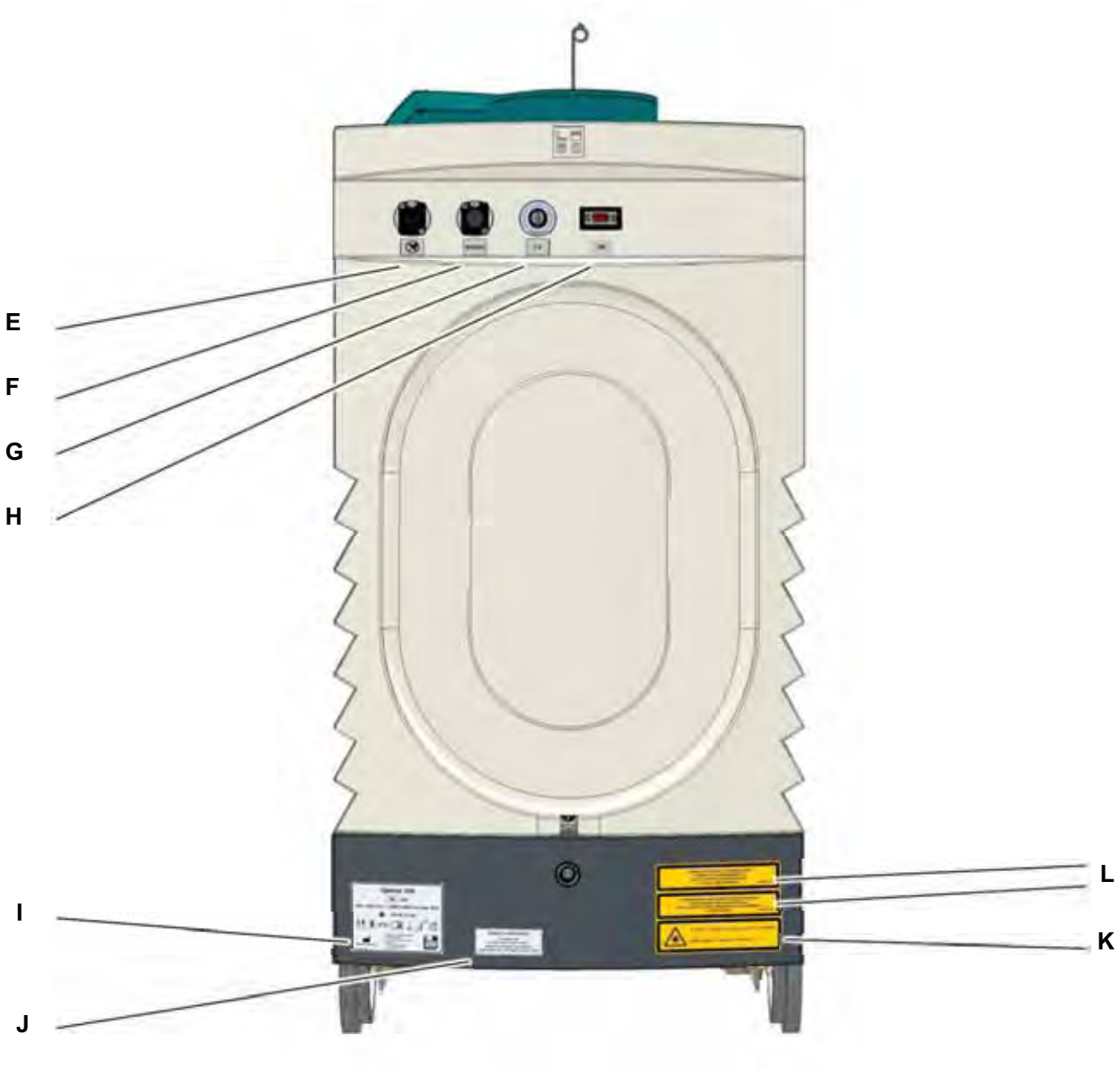



Fig. 11: Labeling and warning signs rear

| | Labelling and warning sign |
|---|---|
| E | Receptacle for footswitch |
| F | Interlock connection |
| G | Key switch (ON / OFF) |
| H | Service Interface |
| I | Name plate |
| J | Certification label |
| K | Laser radiation |
| L | Explanatory lettering |


**Fig. 12: Information sign instruction for use**

| | Labelling |
|---|---|
| **M** | Follow instruction for use |

## 6.7 Nameplate of the footswitch

The name plate of the footswitch is attached to the back of the footswitch. It comprises all the necessary data for the identification of the footswitch.

The following symbols are used:

| | | | | | | |
|---|---|---|---|---|---|---|
| REF | SN | CE | IPX8 | | | YYYY |
| Order Number | Serial Number | CE-Mark | Protective class | Do not dispose in domestic waste | Manufacturer | Date of manufacture |

**Fig. 13: Pictograms footswitch**


**Fig. 14: Name plate Kix (Example)**

# 7 Operation of the laser device

This section describes the operation of the laser device. You will get information about the different operating elements. The different operational modes are described.

You will learn how to set the laser parameters and how to check the orderly state of the device and the laser fibres. The procedures are described step-by-step.

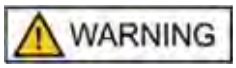
You will get important safety information.

## 7.1 Notes about safety


**Hazards to the eyes by direct or deflected laser radiation.**

Injuries by laser radiation can lead to serious damage to the eyes.

- All persons present in the laser area must wear appropriate laser safety goggles.
- There is a danger of injury from uncontrolled emission of laser radiation. Only use the laser system and the laser radiation for intended purposes.
- Inspect laser system and the footswitch for damage on housing or cables. Do not use a defective laser device.
- Lock device by removing key of key switch to prevent unauthorized use of laser device.
- For your safety, the "ready" mode can only be activated with the fiber connected.




**Risk of infection by particles in laser smoke which can be inhaled.**

Laser smoke might contain viable tissue particles or toxic components.

Watch out for a suitable smoke evacuation.


**Risk of burns by defective fibre plug**: a defective fibre plug can rise up to 60 °C.

If the fibre plug heats up about 60 °C, the laser emission will be interrupted by an error message.

- Check the fibre connector on heating during operation of laser device. If temperature of the fibre connector rises above approximately 50 °C switch off laser device, to prevent damage to the fibre or connector.
- Let the fibre plug cool down before you touch it.
- Shut down device immediately if smoke of cable fire is recognized and call service engineer.
- If you hear unusual loud operating noise shut down device immediately and call service engineer.

## 7.2 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 (Fig. 15). All electrical connections and the key switch to switch on the device are located on the back of the device (Fig. 2). The most important operating and indicating components are brought together on the front of the device (Fig. 1).

### 7.2.1 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 centre. The beam outlet (circular black area) is immediately adjacent

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.

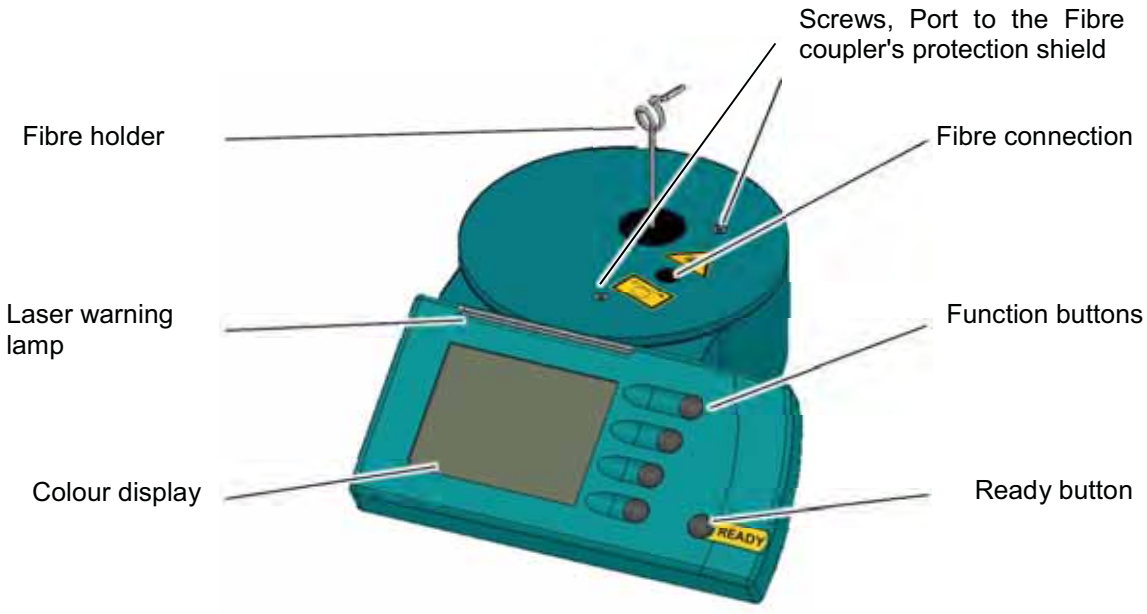



**Fig. 15: Operating console**

## 7.3 Starting-up and switch-on routine

### 7.3.1 Prearrangement

If laser has been stored at an ambient temperature outside (15 °C to 28 °C) the laser needs to adjust its temperature.

For large temperature difference it should be kept in the operation room for at least 3 hours to let adjust the temperature.

**Before switch on of the laser check if:**

1. The necessary safety measures have been taken (Section 7.1).
2. The laser system is connected to a suitable power supply (Section 6.2).
3. The door-interlock or the dummy connector is connected and the entrance doors are closed. (Section Connecting a door interlock)
4. The footswitch is attached (Section 7.3.2)
5. The necessary laser fibres and laser applicators are available. Concerning the use of laser fibres and laser applicators please consult the relevant instructions for use.
6. All persons in the laser area are wearing appropriate laser safety glasses. Take care that the laser safety glasses are suitable for the emitted wavelength and do not show signs of damage.

### 7.3.2 Connecting the footswitch

The connector at the free end of the footswitch cable is plugged into the socket at the back side of the system (Fig. 2) and locked. (Notice: devices built before 2007 have a plug type which is secured by screwing). The connector will fit in only one orientation. For safety and ease of control the footswitch and the distal end of the laser fibre always should be as close as possible to each other and under control of the same person.


**Fig. 16: Footswitch Kix**

### 7.3.3 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 passive cooling system will immediately start to work.

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. The start display (Fig. 17) appears on the monitor displaying the brand name of the model. After approx. 50 seconds the warning lamp goes out and the selection menu appears (see section 7.5 "Operation of the display control").


**Fig. 17: Start display after switching-on the laser system (Example Sphinx 80)**

2. Possible fault messages during the Start-up routine appear on the screen in clear text (see section 9 "Error messages and malfunctions").
3. The desired mode is selected either directly or as a pre-setting (memo) (see section on "Operation of the display control").
4. Remove the fibre holder and insert the fibre.

5. 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.
6. Take care when attaching the laser fibre that dust, dirt or liquids never penetrate into the beam outlet on the laser device!
7. By pressing the Ready button (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.
8. 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 emission is activated by pressing on the footswitch. Note that the footswitch has a clearly tangible pressure point. The first laser pulse will not be emitted until a few tenths of a second after the action point has been passed.
10. Before the laser is used on a patient, always make sure that the laser device and used accessories are in a proper state (Section 7.4").

CAUTION

**Absorption of laser radiation in defective fibre connector**

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

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

NOTICE

Dust, dirt or liquid penetrating into the beam outlet can severely damage the fibre coupling protection shield and the focusing cell. Please observe the instructions in the section 10 “Care and maintenance” relating to the checking and replacement of the fibre coupling protection shield.

## 7.4 Proper condition of the laser system

The laser system is in its orderly state if:

1. after switch on first the start display and then the parameter menu appears,
2. the maximum adjustable power corresponds with the value on the name plate,
3. the readings on the display are clearly legible.
4. the displayed parameters are plausible and the graphical and numerical readout correspond.
5. a fibre that is in an orderly state emits power during operation of the laser.

## 7.5 Display operating console

Altering the laser parameters is achieved using the operating control.

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

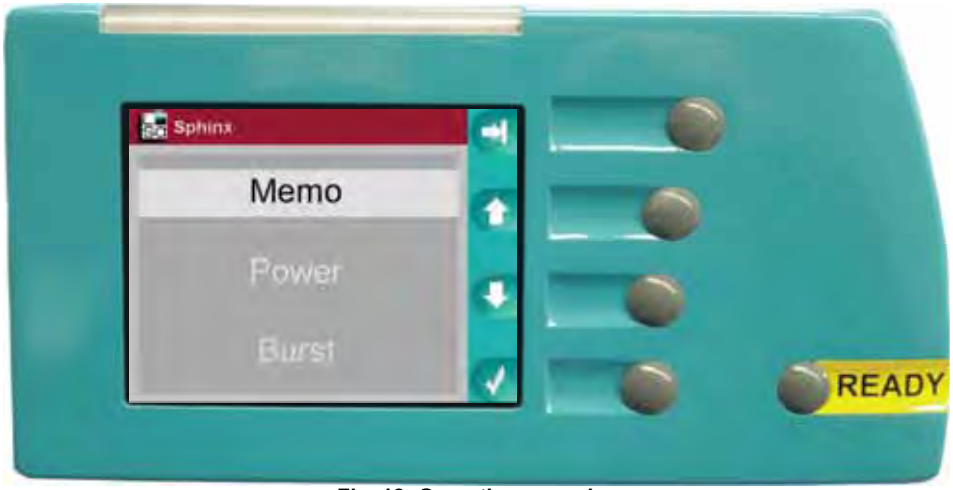



**Fig. 18: Operating console**

At this stage by using the -button or the -button either the "**Power**" or "**Burst**" (or optionally "**Dose**") mode is selected or pre-set parameters are called up from the "**Memo**" mode . Your selection appears highlighted and you can then call it up with the -button.

The operation of the "**Power**", "**Burst**" and "**Dose** (optionally)" 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 footswitch is depressed. |
| "Burst" | Control of the radiation emitted by the laser device according to the parameters energy and number of pulses. A burst of pulses is emitted at set pulse energy and repetition rate. Once a pre-set number of pulses is reached, the laser device stops. |
| optional: | |
| "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. |

## 7.6 Modes and menu structure

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

### 7.6.1 Menu structure of the operation console

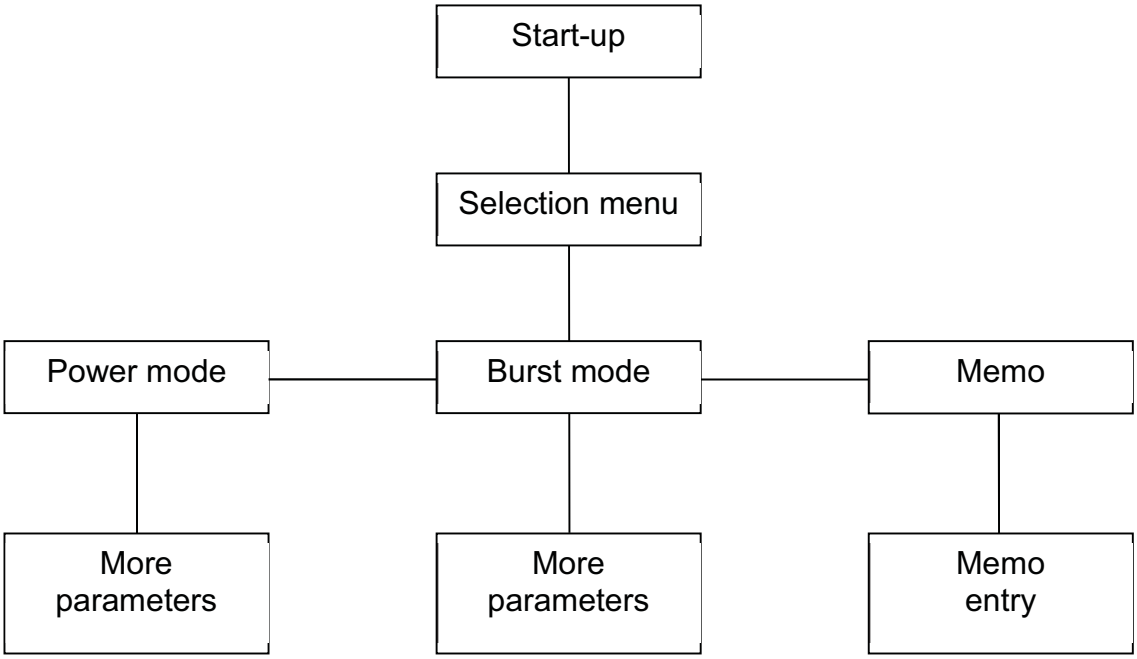



**Fig. 19: Menu structure**

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.

### 7.6.2 Functions of the menu operating console

In the following illustration of the function buttons it is assumed that the “power” mode was selected in the menu. Obviously the “burst” mode can equally well be selected from the menu (see section on “Burst operation”).

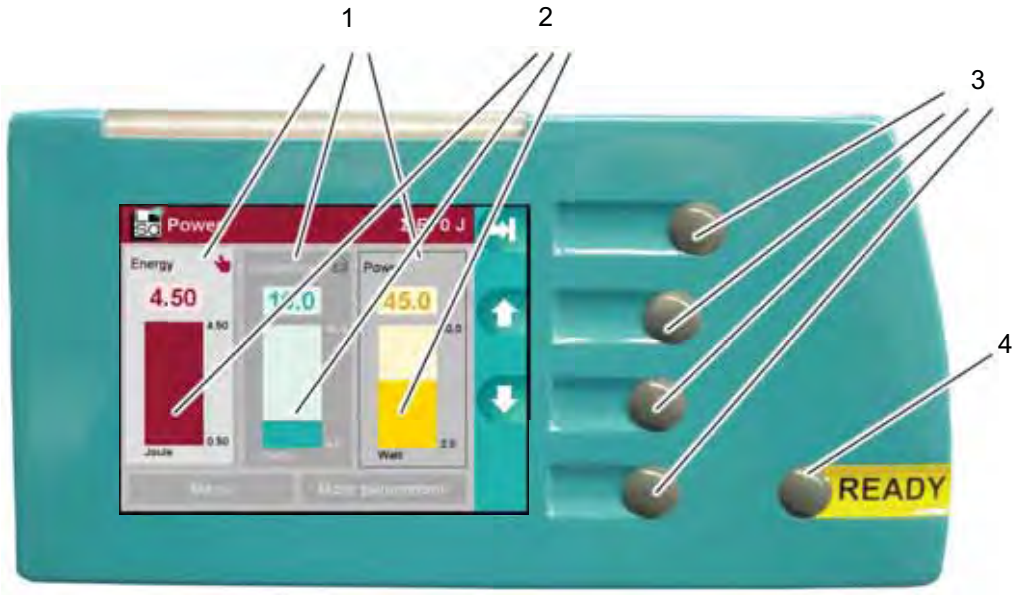



**Fig. 20: Operating console**

| | |
|---|---|
| 1 | Current set parameters |
| 2 | Bar graph displays with the setting range shown on the right. |
| 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:

Increase the selected parameter highlighted and marked by the hand symbol.

Decrease the selected parameter highlighted and marked by the hand symbol.

Change the selected parameter which has a black font, a highlighted background and the hand symbol 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 font colour changes from grey to back and its background is highlighted.

Entry confirmation, change to the selected menu.

**Fig. 21: Function buttons**

The display symbols have the following meaning

The hand symbol appears at the selected parameter which 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 padlock 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”).

## 7.7 Power mode

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

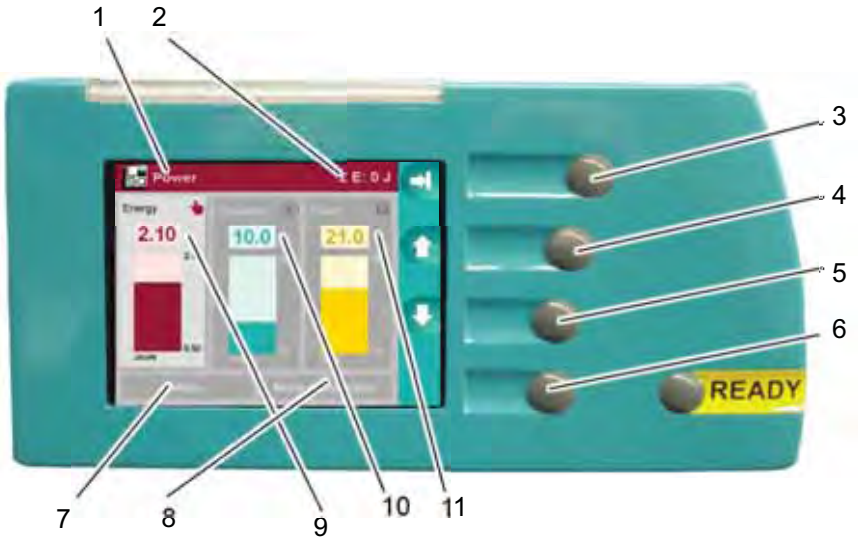



Fig. 22: Fur uttons and there meanings

| # | Meaning |
|---|---|
| 1 | Menu bar, describes the function of the menu, in this case: “**Power**” mode |
| 2 | Σ E indicates how much energy has been emitted since the last summation-reset |
| 3 | By pressing the  button the hand symbol is changed to the next adjustable parameter or the next item on the menu. |
| 4 | By pressing the  button the parameter indicated by the hand symbol and the red spot is increased. In this case the frequency was increased |
| 5 | By pressing the  button the parameter indicated by the hand symbol and the red spot is decreased. In this case the frequency was decreased. |
| 6 | In this mode the fourth button from the top has no function |
| 7 | The other modes can be selected with the menu item “**Menu list**”. |
| 8 | Behind the menu item “**More parameters**” are hidden setting of the pulse duration and the intensity of the pilot laser. |
| 9 | **“Energy”** parameter is selected and can be adjusted. The hand symbol indicates the parameter, which can be altered with the arrow keys. |
| 10 | **“Frequency”** parameter is not ready to be adjusted. The eye, indicates the parameter is being monitored |
| 11 | **“Power”** parameter is not ready to be adjusted, it is locked. This parameter was the last to be set and will be adhered to during parameter variations. Sphinx lasers manufactured after 2010-09 on will not have the possibility to adjust the power. |

### 7.7.1 Menu list – resetting the energy counter 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 1005 J).

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


**Fig. 23: Display**

### 7.7.2 Setting 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 protection 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”.

NOTICE

A dirty or damaged protection 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.

### 7.7.3 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.

**Tab. 11:** Laser-Tissue interaction

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

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

Thereupon the following menu appears:

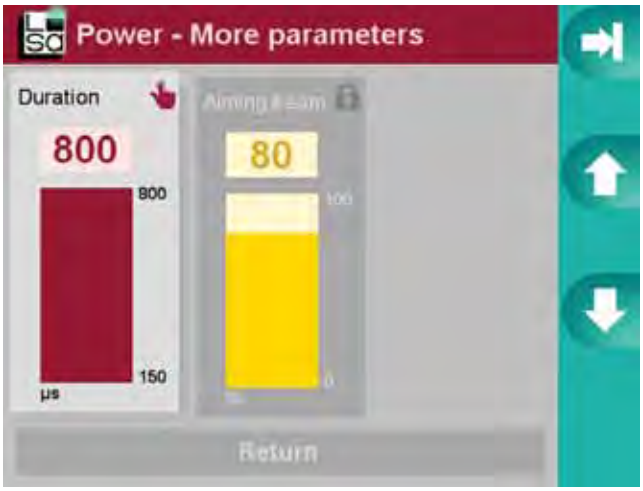



**Fig. 24: Display more parameter**

In order to adjust the pulse duration setting the button must be pressed until the pulse duration is selected and marked by the symbol and the highlighted background. Afterwards, the desired duration can be set with the and buttons.

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

... until the symbol are placed on the pilot laser. Then press or 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**" + .

## 7.8 Burst mode

The burst mode was specially designed for the application of the laser device in lithotripsy.

During this application a single pulse or a pre-set series of pulses is emitted. You can set the number of pulses and the repetition rate. The laser emission stops automatically when the specified number of pulses is reached or when you release the footswitch.

The following parameters must be set in the dose menu:

1. Energy of the individual laser pulse
2. Repetition rate (frequency)
3. Number of pulses

The pulse duration can be set in the **"More parameters"** menu.

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

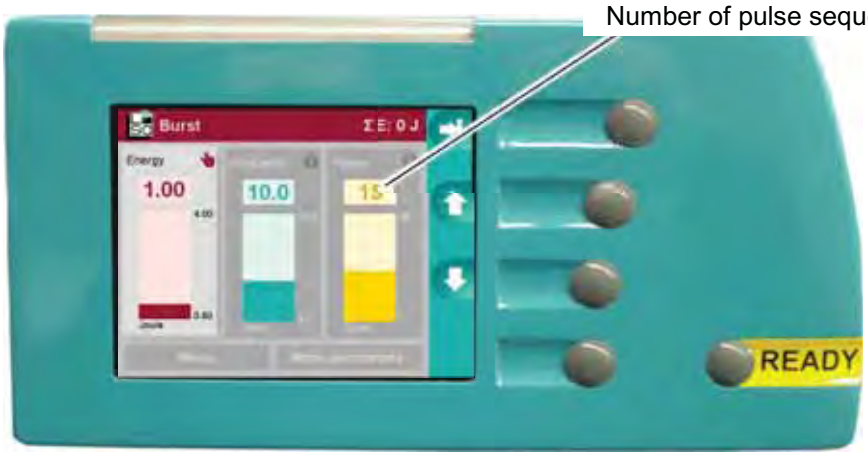



**Fig. 25: Display Burst**

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

You can stop the laser emission during the burst sequence at any time by realising the footswitch. When you activate the footswitch again a new burst sequence starts.

### 7.8.1 Burst – More parameters

In the menu item “**Burst – More parameters**”, the pulse duration and the pilot laser brightness are set in the same way as the procedures in the power mode.

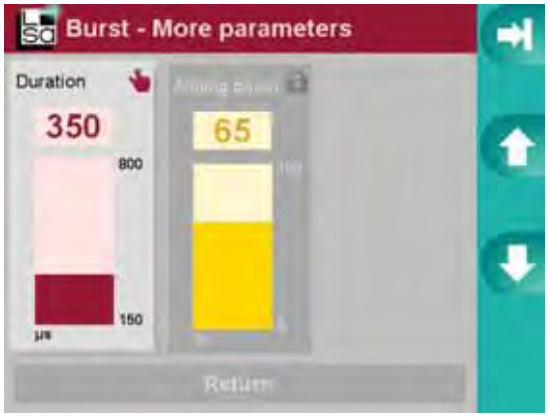



**Fig. 26: Burst – More parameters**

## 7.9 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 “NORMAL” is merely an example for other appropriate labels.

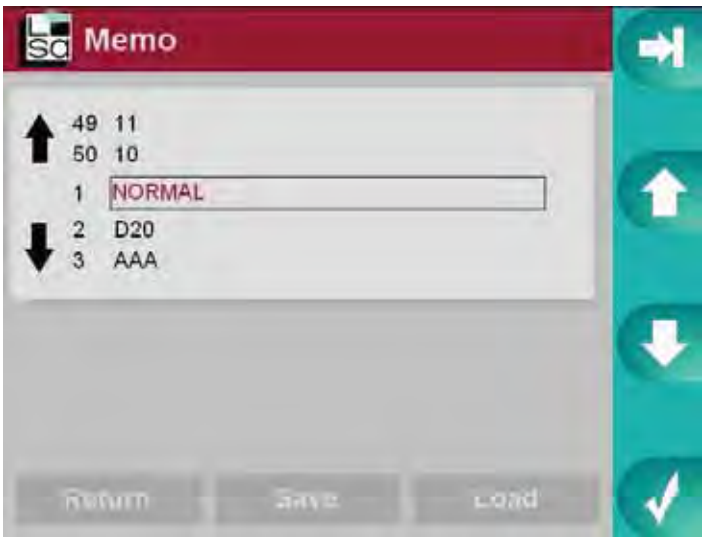



**Fig. 27: Memo menu**

### 7.9.1 Loading of pre-selected settings

By pressing the  and  buttons the desired “**No. ..NORMAL**”, which is to be loaded, is selected and loaded by pressing twice the  button.

### 7.8.2 Saving pre-selected settings

As soon as a preferred operating mode is found it 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. There upon an image appears similar to the one above, in which the menu item “**Save**” is selected with the button and loaded with the button.

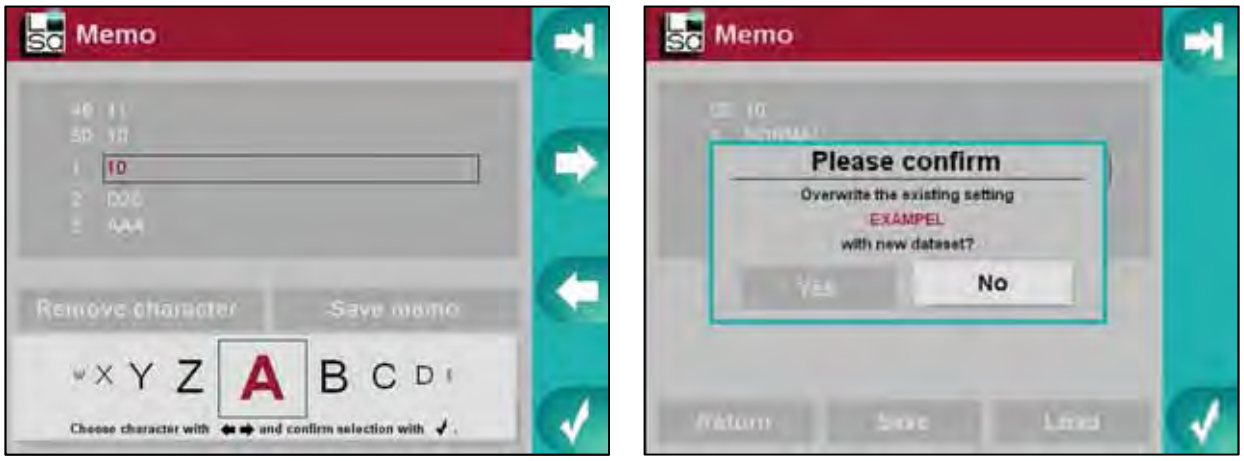



**Fig. 28: Memo menu**

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 last character can be removed by pressing the button to select “remove character” and the button

The completed remark will be saved, together with the setting data by selecting “Save memo” with the button and press the button. After selecting “Yes” with button and pressing the button the actual laser setting is stored and the previous settings of this single dataset are overwritten. The device then returns immediately to the saved operational mode.

## 7.10 Optional: Dose mode - percutaneous laser nucleotomy

The dose mode is available optionally on order and is not installed in the standard configuration of the Sphinx.

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, afterwards the following display appears:

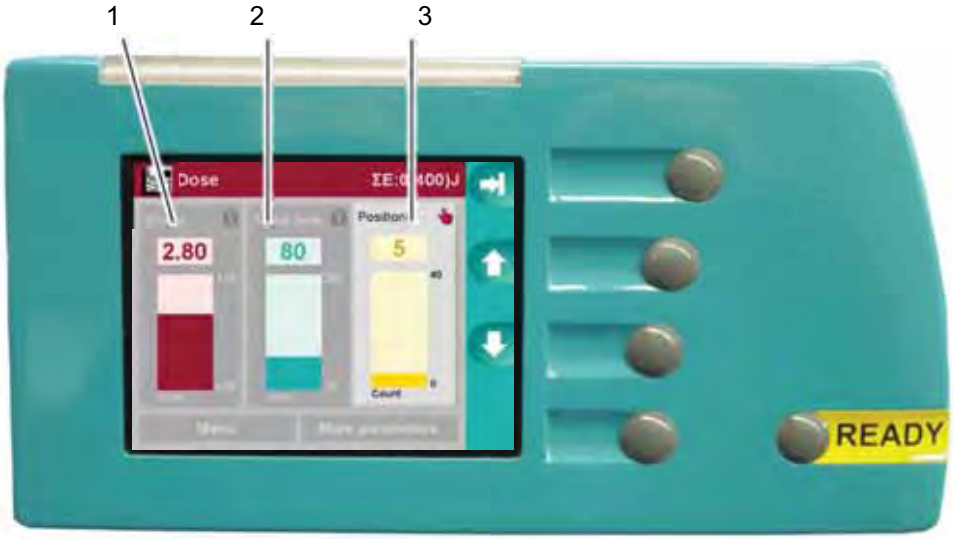



**Fig. 29: Parameter adjustment**

| # | Meaning |
|---|---|
| 1 | Pule energy emitted in this application |
| 2 | Dose to be applied |
| 3 | Number of positions |

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 footswitch and to place the laser applicator in a different spot, in order to give the next partial dose in a new position.

### 7.10.1 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.

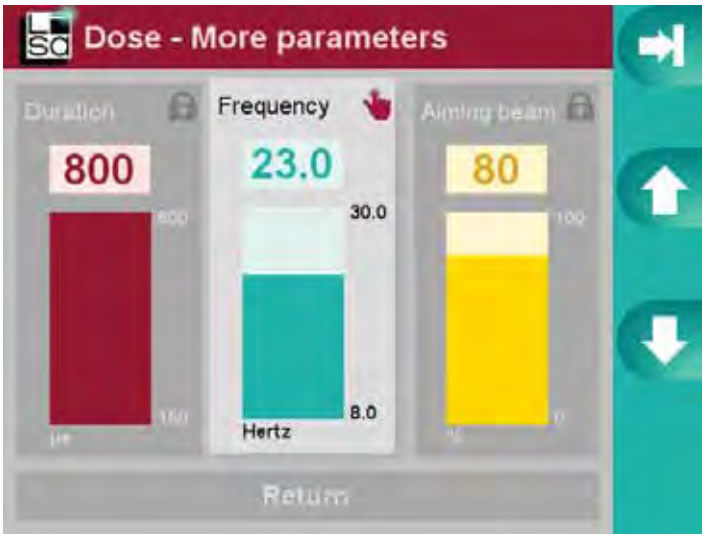



**Fig. 30: Dose**

## 7.11 Connecting a laser fibre to the laser

### 7.11.1 Notes about your safety

CAUTION

**Hazard by improper use.** Avoid any danger for your patients, personnel or yourself and protect the device from damages.

Before using the laser fibres, read the safety instructions in the additional fibre instructions carefully.

If these instructions for use of laser fibres are needed, please contact your LISA Laser Products representative.

WARNING

**Risk of infection** by using **non-sterile** fibres.

Check the laser fibre before every use for functionality and if the fibre is correctly cleaned and sterilized.

WARNING

**Risk of injuries** to patients, users and third parties as well as risk of product damage.

It is not allowed to use damaged laser fibres. There is the danger that the laser fibre breaks at the damaged position during the laser process.

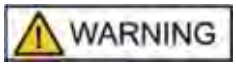
NOTICE

**Hazard of property damage**

Laser fibres may be overloaded due to incorrect power settings and be destroyed or damaged by improper handling.

- Be aware the fibre restrictions due to maximum laser power.
- The use of not qualified laser fibres or the use of too high laser power can lead to damages of the laser fibre or the laser system.
- Unscrew the protecting cap of the fibre connector only for checking the fibre and connecting the laser fibre to the laser system.
  During storing and preparation of the laser fibre the protecting cap must be screwed on the fibre connector to avoid damage or soiling of the distal fibre tip.
- When coiling up / storing the laser fibres do not fall below the minimum bending radius.

Never use a haemostat or similar instruments to clamp the fibre. The fibre could be damaged.




**Hazard** for users, patients and third parties **by uncontrolled emission of laser radiation when the fibres are damaged.**

It is not allowed to use laser fibres with a damaged buffer. There is the danger that the laser fibre breaks at the damaged position during the laser process.

A break of the laser fibre can lead to injuries of the patient or user such as burns of skin and tissue on patients, users and third parties and/or may lead to damage to instruments.

- Only use laser fibres, which are suitable for the respective laser system. Using laser fibres that are not approved by LISA Laser Products will result in a loss of the manufacturer's warranty for the system. Observe the notes in the additional fibre instructions.
- During the laser process the laser fibre must not be kinked or strongly bended.
- Observe the minimum bend radius (note the label of laser fibres), since otherwise the danger exists, that the laser radiation can possibly emerge at the kinked or bended position and the fibres break during the laser process. A break of the laser fibre can lead to injuries of the patient or user.
- The distal fibre tip emits laser radiation which can lead to eye and skin injuries. Do not look into the laser beam.
- Do not focus the laser beam on inflammable materials and solutions as these may ignite.

The power and energy values shown on the screen assume proper radiation from the laser fiber, a clean and undamaged fiber coupler protective window and proper laser fiber. If the laser fiber is not optimal, the transmission can be much lower than specified. The calibration of the displayed value with the radiation from the fiber is described in Chap. 10.6.

In the pulsed 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.

The choice of the correct parameters for different medical applications is imparted in the laser training sessions, which are offered by the manufacturer. Section 7 "Clinical applications and Tissue interaction" provides guidelines.

### 7.11.2 Checking and connecting the laser fibre

Before connecting the fibre check the following:

1. The free-standing fibre tip in the fibre connector (ca. 0.5 mm in diameter, depending on fibre type) must be smoothly reflective and free from damage and dirt. The hollow space within the fibre connector surrounding the fibre tip must be free of any sign of blackening or burning. If necessary, use a magnifying glass for checking.
2. The fibres must be undamaged and without a kink throughout the entire length.
3. Check the laser fibre for proper optical transmission: Hold the distal fibre end against a light source. The fibre end in the fibre connector must appear as a bright point of light. If you are not sure, compare it with a new fibre.

INFORMATION

When using laser fibers with dirty or damaged fiber connectors, laser power is absorbed in the dirt or the damaged area. This leads to overheating and can cause severe damage to the coupling optics in the laser device.

WARNING

Damaged or kinked fibers should not be used as there is a risk of the fibers breaking at the damaged area during operation.

A break in the fiber can result in injury to the patient or user

INFORMATION

Please note the instructions for testing the laser fiber in the instructions for use of the laser fiber.

WARNING

Avoid damage to the fiber connection. Damaged fibers can result in absorption, overheating, and damage to the fiber connector and laser optics.

The fiber change must not take place in the "ready" operating state (laser warning lamp is switched on)!

INFORMATION

The connection of the laser fiber can only be done with the device switched on, otherwise the fiber connection cannot be opened.

1. Check the laser fibre for functionality and if the fibre is correctly cleaned / sterilized.
2. Press the release (READY) button to open the fibre port. Note that the fibre port will close automatically after about 10 seconds. Take care that no dirt or liquids penetrate into the beam outlet
3. Remove protection cap of the fibre.
4. Place the fibre into the SMA-receptacle, screw it in and tighten it **finger-tight**.
5. Press the release button a second time in order to activate the laser (Ready-mode). The "**Ready**" mode is indicated by the illumination of the laser warning lamp and the pilot laser being switched on. In case the aiming beam is not visible at the distal end of the fibre, first check and adjust the brightness of the aiming beam. If the aiming beam is still not visible inspect the fibre again for damages.
6. The laser emission is activated by pressing on the footswitch. Note that the footswitch has a clearly tangible pressure point. The first laser pulse will not be emitted until a few tenths of a second after the action point has been passed

### 7.11.3 Disconnecting the fibre from the laser

1. Unscrew the connected fibre connector from the SMA-receptacle (turn to the left) and carefully take it out.
2. Check the proper state of the fibre.
3. Screw protective cap onto the fibre connector.

Observe the additional fibre instructions for use for cleaning and sterilizing of the fibres.

## 7.12 Switching-off routine

1. Push the fibre-holder back in. To do this push down the area around the fibre-holder outlet.
2. 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.
3. Take off laser safety goggles.
4. Pull out the mains plug and wind the mains cable back into the cable drum.
5. Lock device by removing key of key switch to prevent unauthorized use of laser device.
6. Clean the device like mentioned in chapter 10.3 "Cleaning the laser system".


Shut off the laser device by removing the key switch key. This will prevent the use of lasers by unauthorized persons.

# 8 Clinical applications and tissue interaction

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.

## 8.1 Notes about your safety

WARNING

If you use a broken fibre, an incorrect inserted fibre or a non-fixed fibre in the applicator / instrument, the fibre might slide out of the applicator or irradiation occurs in the instrument. This might result in injuries of the patient or yourself or could damage the applicator / instrument or fibre.

Whenever a *Sphinx* laser system is used there is a potential risk of thermal damage. Irradiation of flammable materials, liquids or gases can cause them to ignite (even by gases produced by the human body (e. g. methane)). Risk of serious injury of the patient.

Make sure that the laser beam does not hit flammable tissues or substances.

When using the laser device in an oxygen-enriched atmosphere the carbonised tissue may ignite and lead to injury.

Observe the carbonized tissue during irradiation by the laser device and reduce, if necessary, the oxygen content of the atmosphere around the surgical site.

For all endoscopic applications with the *Sphinx* laser there is a risk of injury of the tissue or parts of the tissue of the patient, which can cause irreversible damage. The laser should only be activated if the fibre tip and the tissue, at which the laser is directed, are within sight. Start with low power settings.

Laparoscopic or open laser procedure, are the same as those normally encountered in conventional surgery. Bleeding, perforation, sepsis and air embolism are very serious complications and can lead to a severe aggravation of the health state or to death of the patient.

Firing the laser while the fibre tip is inside the applicator may lead to injuries of the patient and damages of the applicator / instrument.

Continuously inspect the fibre tip with the dismantled area during the application because the laser fibre is being consumed during operation. The fibre tip must protrude from the surgical instrument at least 1 mm to make sure that laser radiation does not impair the instrument. If there is only 1 mm to the distal end of the instrument left, the laser fibre should be repositioned to restore a safety distance to 2-5 mm to the distal end of the instrument.

## 8.2 Preparation

Before you start the procedure and before induction of the anaesthesia follow the described preparation procedure.

1. Make sure that all persons involved in the operation of the laser have read and understood the safety instructions and warnings in this and in referred manuals.
2. Evaluate the risk of the laser surgery and its potential side effects and contraindications (see section 8.4 and 8.5)
3. Prepare the laser system and the accessories according to the instructions mentioned in section 7 “Operation of the laser device”.
4. **Before** induction of the anaesthesia make sure that the laser system is fully functioning (see section 7.4), and that all necessary instruments, fibres and accessories are available (section 7.11).
5. **Before** you start with the procedure make sure that the selected fibres are compatible to instruments used. Good fibre guidance inside the instrument is very important for the treatment control. Make sure that the inner diameter of your instrument and the outer diameter of the fibre match closely. Make sure that the fibres can easily be introduced into the instrument and check that the laser fibre can be fixed properly. During operation the distal end of the fibre should always be inside the field of vision of the optic.

The jacket of the laser fiber serves the fiber at the distal end as a mechanical reinforcement and as a kink protection. To prevent the fiber tip for brakage, the stripped fiber length must not exceed 3 to 5 mm. Direct contact of the silica fiber with the metal fiber guide may cause the fiber to break. With fiber inserted into the instrument / handpiece / applicator, the jacket must protrude from the distal end of the instrument / handpiece / applicator to avoid direct contact between the glass fiber and the fiber guide of the instrument. For endoscopic instruments, the distal end of the fiber must be placed in the field of view of the optic. Please note the instructions and information in the separate operating instructions for the laser fibers.

## 8.3 Step-by-step procedure

1. Switch-on the laser according to the procedure described in section 7.
2. Remove the sterilized fibre from the pouch or box using aseptic technique. Inspect the fibre for damages as described in section 7.12.
3. Before the laser application starts, the sterile operation nurse (scrub nurse) hands over the fibre end with the fibre connector to the circulating nurse, who operates the laser system. The circulating nurse removes the protective cap of the fibre connector, opens the beam outlet of the laser system, and inserts the connector in straight line and screws in the fibre connector carefully into the fibre coupler. The expansion nut of the fibre connector is fixed tightly, until you feel a resistance (section 7.11).
4. Set the aiming beam to a high intensity. Check if the red aiming beam is transmitted from the distal end of the fibre and if the beam is clearly visible on a white target. If the aiming beam is weak or poorly visible or the appearing somewhere on the entire length of the fibre, do not use; discard the fibre or return it to the supplier.
5. Introduce the fibre into the applicator, hand piece or endoscope. Make sure that the fibre fits to the chosen instrument and that the inner diameter of your instrument and the outer diameter of the fibre match closely to have good fibre guidance.
6. Position the aiming beam to the target tissue. Make sure the fibre tip extents out of the instrument.
7. Set the laser parameters as instructed in sections 7.7 (Power mode), 7.8 (Burst Mode) and 7.10 (Dose Mode). The laser is activated by pressing the footswitch. Make sure that the targeted tissue and the distal tip of the fibre are always visible when firing the laser.
8. You should always take into account a minimum consumption of the fibre during an operation. The surgeon recognises this erosion of the fibre tip during the laser application as an increasing scattering of the aiming beam at the distal fibre tip. The burn-up of the fibre tip reduces the beam quality and cutting efficiency of the working laser beam. The laser fibre tip should be inspected continuously during the operation. In all cases the laser fibre tip has to protrude from the surgical instrument at least half a millimetre.
9. After the procedure disconnect the fibre from the laser and immediately screw on the protection cap (section 7.13). For re-processing, follow the instructions in the particular fibre instructions for use.
10. Switch off and clean the laser as described in section 10.3.

## 8.4 Applications

The table shows an overview about the parameter settings for the different applications. A detailed description of the procedures is available on request.

**Tab. 12: Applications and adjustment**

| Application | Pulse energy | Frequency | Pulse duration |
|---|---|---|---|
| ***Urology*** | | | |
| Ureter Strictures | 1.2 J | 12 Hz | 700 µs |
| Urethra Strictures | 1.5 J | 15 Hz | 700 µs |
| Prostate resection | 2.0 J | 30 Hz | 700 µs |
| Prostate resection | 4.0 J | 20 Hz | 800 µs |
| Bladder neck incision | 1.5 J | 20 Hz | 800 µs |
| Bladder tumor ablation | 1.0 J | 10 Hz | 400 µs |
| Open tumor excision | 1.0 J | 20 Hz | 800 µs |
| Open penis tumor resection | 0.8 J | 20 Hz | 800 µs |
| Fragmentation of Bladder Stones | 1.5 J | 10 Hz | 150 µs |
| Fragmentation of Ureter Calculi | 1.2 J | 10 Hz | 150 µs |
| Fragmentation of Kidney Stones | 1.0 J | 10 Hz | 150 µs |
| Fragmentation of stones in the renal pelvis | 1.0 J | 10 Hz | 150 µs |
| Fragmentation of stones (dusting) | 0.5-0.8 J | 20 - 30 Hz | 150 µs |
| ***Orthopedics*** | | | |
| Meniscectomy | 1.2 J | 15 Hz | 450 µs |
| Smoothing of cartilage lesions | 0.8 J | 10 Hz | 650 µs |
| Lateral release | 1.5 J | 10 Hz | 650 µs |
| Capsular shrinkage | 1.0 J | 10 Hz | 650 µs |
| Synovectomy | 1.2 J | 15 Hz | 650 µs |
| ***ENT*** | | | |
| Reduction of turbinates | 0.8 J | 8 Hz | 650 µs |
| Reduction of nasal septum (cartilage / bone) | 0.8 J | 8 Hz | 150 µs |
| Shrinkage of polyps | 0.8 J | 8 Hz | 650 µs |
| ***Spine*** | | | |
| Foraminoplasty (soft tissue) | 1.5 J | 12 Hz | 500 µs |
| Foraminoplasty / (bone) | 2.5 J | 12 Hz | 350 µs |
| PLDD | 0.6 J<br>insg ca. 1200 J | 10 Hz | 600 µs |

The mentioned settings should be regarded as a guideline and should be individually modified depending on the conditions.

### 8.4.1 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 GmbH supplies all the laser accessories for arthroscopic applications.


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.

### 8.4.2 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 GmbH 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 approved by the manufacturer for laser use. Please allow us to advise you.


**Danger of perforation** at the patient by laser radiation.

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.


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


**Risk of malfunction** of the instrument can lead to longer operation times and /or heating of the instrument can lead to thermal tissue damage at the patient.

If the distal laser fibre end is inside the instrument and the laser is activated, the ureterorenoscope may be damaged and destroyed. Furthermore the patient can suffer injuries by heating of the endoscope.

- Only activate laser if the laser fibre is clearly visible outside of the instrument.

## 8.4.3 ENT

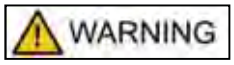
The Holmium laser is used for the following clinical applications in ENT:

- **Reduction of turbinates (mucosa)**
- **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 GmbH supplies the laser accessories for use in ENT.




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.

## 8.5 Laser-tissue interaction

### 8.5.1 Basic physico-technical principles

The *Sphinx* Holmium Laser is a so-called Holmium-YAG laser.

As a result of optical excitation by the light from the flash lamp the Holmium laser crystal spontaneously emit light with a wavelength of 2.1 µm. Photons, which emerge by chance from the laser crystal 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 = L**ight **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.

### 8.5.2 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 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 approximately 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 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.

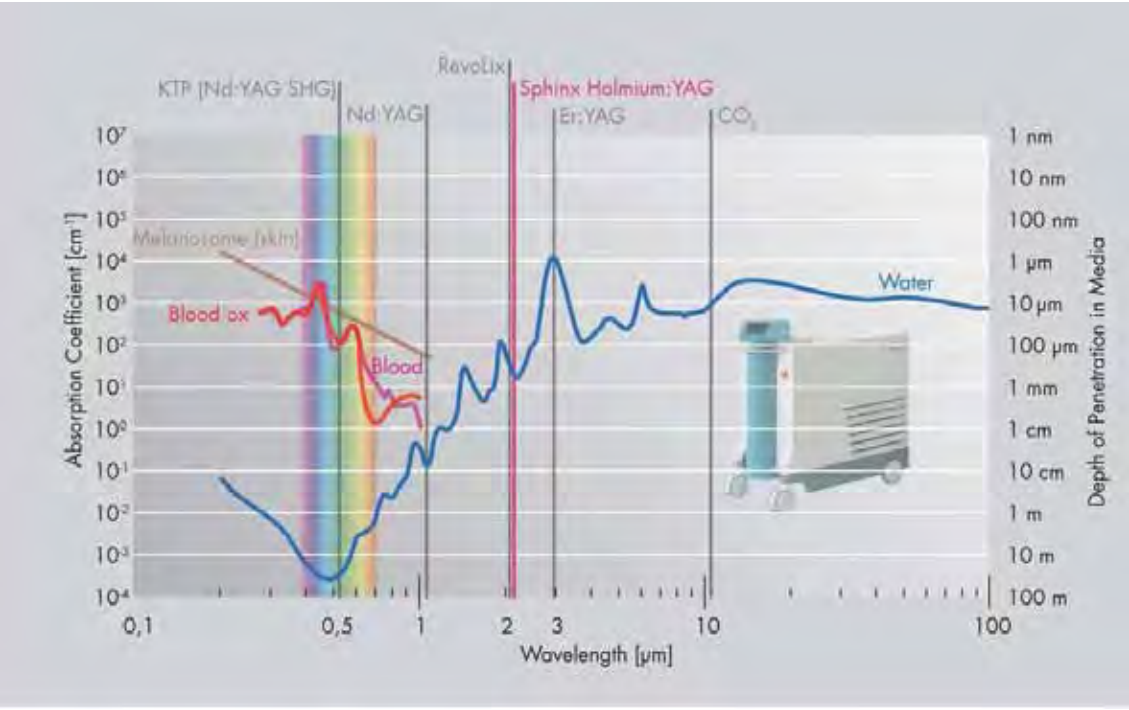



**Fig. 31: Absorption spectrum**

### 8.5.3 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.

### 8.5.4 Irrigation liquid

The Holmium 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 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.

# 9 Error messages and malfunctions

This section provides information how to deal with malfunctions of the laser. The different error and warning messages are explained and you will get recommendation how to solve the error.

You will find the address of our customer service.

## 9.1 Error messages

During operation the system continuously monitors its function and safety. Every irregularity detected by the laser is displayed in clear text on the screen with a three-digit number, together with information on how to deal with it (Fig. 12). Errors clear themselves once the cause is removed. Afterwards the laser must be released with the 'ready' button.

If it is not possible to correct an error, inform an authorised service technician. You will find the telephone number of your service technician in the section 9.2. Please mention the error code together with the F-Code and details when reporting a malfunction.

The messages look like this:

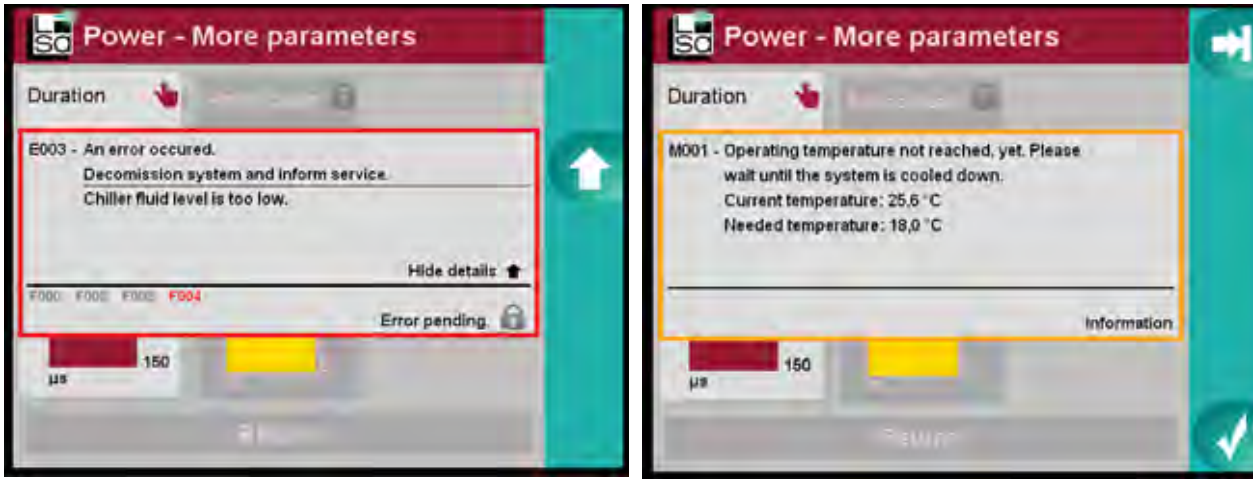



**Fig. 32: Info and error message**

## 9.2 Technical customer support

For technical service and support please contact the technical service department of LISA Laser Products or your local representative Service.

LISA Laser Products GmbH
Albert-Einstein-Str. 4
37191 Katlenburg-Lindau
Germany
fon: +49 5556 9938 0
fax: +49 5556 9938 10
service@lisalaser.com
www.lisalaser.de

# 10 Care and Maintenance

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

You will get information about cleaning and maintenance of the Sphinx.

## 10.1 Notes about your safety

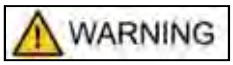

Danger due to incorrect maintenance:

The installation, maintenance and care of the laser device may only be performed by trained professionals based on this instruction for use.

Observe the regular maintenance, such as inspection and cleaning, of the laser device and its accessories. Consider this manual and the instructions for the accessory.

Never open the protective covers of the footswitch to avoid disturbing the function of the footswitch, as moisture could penetrate inside the footswitch.

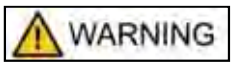
Pay attention to a stable stand of the device. Use the parking brake to prevent unwanted rolling of the laser device.




Infection:

Danger to patients due to insufficiently sterilized accessories.

- Before each use, observe the sterilization instructions for the authorized specialist and sterilize the accessories, such as laser fiber, endoscope and other instruments before and after laser use, to avoid a risk of infection.
- Read the instructions for use of the respective accessories and follow the cleaning and sterilization instructions.




Contamination:

Danger to persons due to possible site-related contamination.

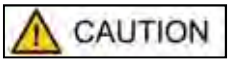
Note that the laser device and its accessories may be contaminated with biological materials in the operating room. Protect yourself and others from potential dangers.

- ensure suitable decontamination before using, eg. store the laser device, send for repair and dispose of or recycle.
- Additionally, read the instructions in the instructions for use.


Danger of electric shock:

Never open the housing of the laser device as its opening will allow access to voltage parts or live parts that could cause a life-threatening electric shock. Further disassembly can lead to the release of laser radiation.

- Only carried out assembly and repair work by a trained and authorized specialist.
- Special high-voltage parts inside the laser device are specially marked.




Property damage due to the escape of coolant:

Never turn the laser device upside down or lay it on its side. Liquid could escape from the cooling circuit and severely damage the laser device and cause a malfunction. Carry out the recommended maintenance in good time, so that the cooling system is also checked frequently.

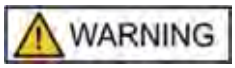
- Always carry out the cleaning work in the normal standing position with the parking brake activated in order to prevent the laser device from rolling away.

## 10.2 Regular safety check

Every 12 months the laser system should undergo a technical safety inspection and maintenance by a service technician authorized by the manufacturer to ensure proper and safe laser performance. This inspection will include a test for accuracy and calibration of the laser output. The inspection shall follow a procedure as described in IEC 62353.

The detailed instruction for the safety check and the test report form is available in the relevant service manual.

## 10.3 Cleaning the device




**Danger of electrical shock**

The laser device is not protected against incoming liquids. There is the danger of an electrical shock.

Switch off the laser and disconnect the laser from the mains supply before cleaning the device.

1. Switch off the laser device and pull out the mains connector.
2. Disconnect the fibre, the footswitch cable and the interlock
3. Wear protection gloves for disinfection and cleaning
4. Disinfect and clean the surfaces of the laser device except the display and the operating console with a non-caustic cleaning solution, an alcohol solution or a disinfectant. Take care that no moisture can penetrate into the device neither through the cooling grilles nor the fibre port.
5. Disinfect the footswitch and its cable with common disinfectant and clean it with a damp cloth containing non-caustic mild cleaning solutions. The footswitch is water resistant and can be rinsed with water. No moisture should penetrate the footswitch connector.

## 10.4 Re-processing the accessories

To re-process accessories like fibres, hand pieces and applicators please refer to the particular instructions for use for detailed descriptions. You can order these instructions for use from LISA Laser Products or your LISA representative.

## 10.5 Check and exchange of fibre coupler protection shield

NOTICE

When using a damaged or dirty fibre coupler protection shield laser power is absorbed by the dirt or the broken parts. This may lead to an overheating of the connector or the coupler and may destroy them.

Do not operate the laser without or with a damaged laser coupler protection shield.

The fibre connector and its coupler is protected against dirt and damage by the fibre coupler protection shield

Slight dirt on the fibre coupler's protection shield only has an insignificant effect upon the laser's available capacity. Nevertheless the fibre coupler's protection 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 protection shield").

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

**Fig. 33: Fibre coupler protection shield**

### 10.5.1 Dismantling the fibre coupler's protection shield

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

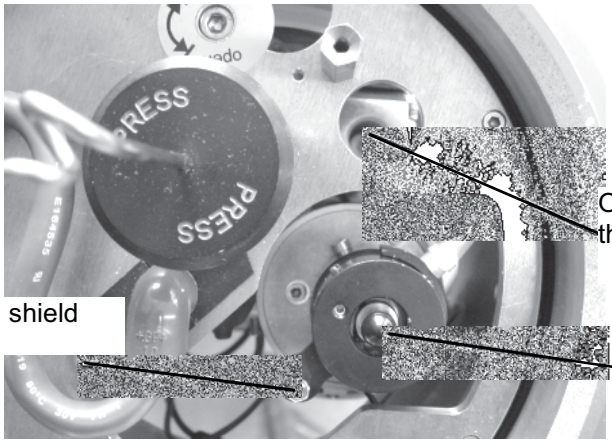



**Fig. 34: Dismantling the fibre coupler's protection shield**

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 protection shield can be pulled out sideways from the fibre coupler by grasping with the fingertips on the hexagonal bolt.
6. Lift the fibre coupler's protection shield up to the light or place it against a clean, bright background (e. g. clean, white paper). A clean protection shield is colourless and transparent. A significantly dirty fibre coupler protection shield decreases the laser by about 50 %. That means that half of the power emitted by the laser is absorbed in the protection shield and converted there into heat. A dirty fibre coupler's protection shield must be replaced immediately.

### 10.5.2 Checking the fibre coupler's protection shield

Gross contamination can be easily recognized without dismantling the fibre coupler's protection shield. Open the beam lock with the release button. No laser radiation can leak in this situation. Nevertheless and for your safety protective eye glasses should be worn. In a light room while opening the beam lock a small circular cut-out of the room ceiling is reflected in the fibre coupler's protection shield. Gross contamination of the fibre coupler's protection shield can be clearly recognized as spots or blotches in the reflection.

If - after visual control - a proper fibre coupler's protection shield cannot be confirmed, it has to be dismantled, checked and replaced in accordance with the following subchapter (10.5.3).

### 10.5.3 Installing the fibre coupler's protection shield

1. The new fibre coupler's protection 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.

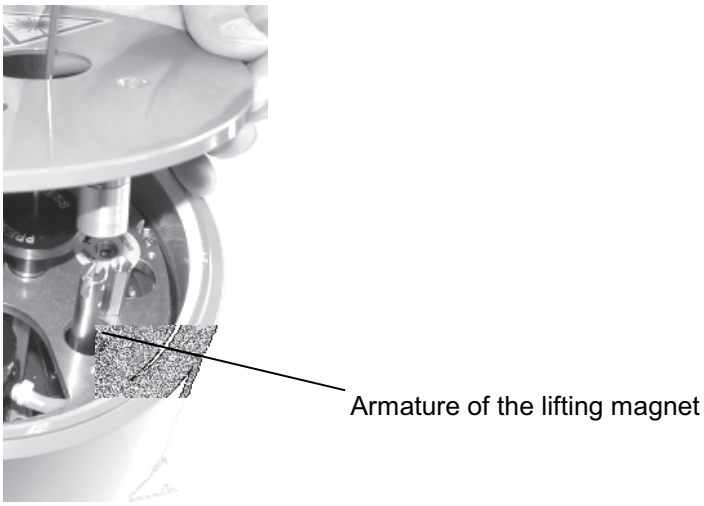



**Fig. 35: Lifting magnet**

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

## 10.6 Calibration of the laser output

The values for energy and 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 the transmission loss of an optimum transmission system (fibre) into account. Below you will find a description of the accurate calibration of the power reading on the screen display, although in normal use this calibration is unnecessary. Calibration procedures should be performed annually by a properly trained and authorized service representative.

### 10.6.1 Test of accuracy

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 between the reading on the power meter and the set value (reading on the display) 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, the shortening of the distal fibre end are explained in the relevant accessories' instructions for use.

### 10.6.2 Use of the power meter

The external power meter (REF 101 503 140) can be ordered from LISA Laser.

1. Ensure that all personnel in the area are wearing the appropriate protective eyewear.
2. Attach a laser fibre and set the aiming beam to maximum brightness
3. Hold the power meter so that the LCD display is in your hand with the black anodized target facing away from you
4. Press and hold the RESET/POWER button for at least two seconds. This activates the power meter
5. Release the RESET/POWER button to begin the six-second measurement sequence. The LCD display should read 00.0 Watts (± 00.3 W). If the reading is not within this range, repeat step 5.
6. Quickly insert the target area of the power meter into the beam path. Position the power meter so the beam is centred in the middle of the target. The red spot of the pilot laser should cover about 2/3 of the absorbent surface. Activate the laser.
7. The final value of the laser output is shown on the display within a few seconds after insertion into the beam. Remove the power meter from the beam path when you hear a series of five beeps. This indicates the measurement sequence is complete.
8. The power meter shuts down automatically after a 15 second hold sequence.

## 10.7 Exchange or refilling of cooling liquid

While the laser is being operated the cooling system draws off the resultant dissipation power into the room air. The cooling system needs sufficient amount of cooling liquid. Before putting the laser in operation cooling liquid supplied by the laser manufacturer must be filled up. The instrument automatically checks the cooling liquid's level and displays a message code onto the operation panel when the level is low. Both the draining as well as the filling of the laser system with cooling liquid may only be conducted by an expert authorized by the system manufacturer. Please contact LISA Laser Products or its representative. Operating the laser system without cooling water may lead to severe damage to the laser device.

## 10.8 Disposal of the device and the accessories

Before disposal disinfect the surfaces of the laser device and the accessories.


**Disposal:**

The laser device may not be disposed of as domestic waste. It contains valuable and hazardous material which should be recycled or disposed of according to local regulations. LISA Laser offers to recycle the device at the end of its life.

- Please contact your local representative or contact directly LISA Laser Products GmbH.

# 11 Accessories for Sphinx Holmium Laser

Please note that the safety and performance of the laser system is only guaranteed with accessories approved by LISA Laser Products. Please contact LISA Laser Products or your LISA Laser Products representative if the accessory part is not mentioned in the following list.

NOTICE

The use of other laser fibers with this laser device than the laser fibers listed in this manual.

- violates the declaration of conformity of this laser device,
- may cause damage to endoscopes.

CAUTION

The use of other laser fibers with this laser device than the laser fibers listed in this manual.

- presents a risk of injury to the patient,
- and assigns the liability risk of using laser fibers other than the laser fibers listed in this manual to the user.

Only laser fibres that are supplied by the LISA Laser Products may be connected to the laser system. So-called SMA compatible products supplied by other manufacturers may cause costly damage to laser optics in the fibre coupler.

Use the accessories only for their intended application and make sure that they are approved for the use with the Sphinx.

## 11.1 Laser fibres

**Tab. 13: Laser fibres**

| Name | Description | Part No. |
|---|---|---|
| *SureFib-SU* | ***For Sphinx 45, max. 30W/4J***<br>Single use laser fibre, sterile,<br>272 µm core diameter | 101 503 513 |
| *SureFib-SU 5m* | ***For Sphinx 45, max. 30W/4J***<br>Single use laser fibre, sterile,<br>272 µm core diameter | 101 503 569 |
| *SureFib* | ***For Sphinx 45, max. 30W/4J***<br>Reusable laser fibre,<br>272 µm core diameter | 101 503 364 |
| *SureFib 5m* | ***For Sphinx 45, max. 30W/4J***<br>Reusable laser fibre, Length 5 m<br>272 µm core diameter | 101 503 580 |
| *FlexiFib* | Reusable laser fibre,<br>272 µm core diameter | 101 503 189 |
| *FlexiFib-SU* | Single use laser fibre, sterile,<br>272 µm core diameter | 101 503 387 |
| *FlexiFib 5m* | Reusable laser fibre, Length 5 m<br>272 µm core diameter | 101 503 118 |
| *PercuFib* | Reusable laser fibre,<br>365 µm core diameter | 101 503 128 |
| *PercuFib-SU* | Single use laser fibre, sterile,<br>365 µm core diameter | 101 503 384 |
| *RigiFib* | Reusable laser fibre,<br>550 µm core diameter | 101 503 213 |

| Name | Description | Part No. |
|---|---|---|
| *RigiFib-SU* | Single use laser fibre, sterile,<br>550 µm core diameter | 101 503 289 |
| *RigiFib 800* | Reusable laser fibre,<br>800 µm core diameter | 101 503 287 |
| *RigiFib-SU 800* | Single use laser fibre, sterile,<br>800 µm core diameter | 101 503 385 |
| *RigiFib 1000* | Reusable laser fibre,<br>940 µm core diameter | 101 503 284 |
| *SideFib* | Side firing laser fibre, single use, sterile,<br>550 µm core diameter | 101 503 138 |

## 11.2 Laser safety eyewear

**Tab. 14: Laser eyewear**

| Name | Description | Part No. |
|---|---|---|
| Laser protective Eyewear | Plastic goggle fits over glasses | 101 503 141 |
| Laser Protective Eyewear, Glasses | Glasses with earpieces | 101 503 399 |
| Laser Protective Eyewear, Goggle | Goggle fits over glasses | 101 503 400 |
| Steel goggles | steel, non-transparent, for patient | 101 503 184 |

## 11.3 Additional accessories

**Tab. 15: Additional accessories**

| Name | Description | Part No. |
|---|---|---|
| Footswitch Kix | Footswitch | 101 600 215 |
| Interlock connector | Door-Interlock dummy connector | 101 600 166 |
| Key | Switch-on key | 101 600 237 |
| Fibre coupler protection shield | Protection window for fibre coupler | 101 600 210 |

# 12 Technical Data

**Tab. 16: Technical data**

| | **Technical Detail** | **Data** | |
|---|---|---|---|
| 1 | **Device** | ***Sphinx 45 litho* (Art.-Nr.: 103 014 xxx) /<br>*Sphinx 60* (Art.-Nr.: 103 015 xxx) /<br>*Sphinx 80* (Art.-Nr.: 103 016 xxx) /<br>*Sphinx 100* (Art.-Nr.: 103 017 xxx)** | |
| 2 | Dimensions (H x W x D) | approx. 1040 x 450 x 1070 mm | |
| 3 | Weight | ca. 180kg (*Sphinx 45 litho; Sphinx 60, 80, 100*) | |
| 4 | Degree of protection<br>(acc. IEC 60529) | IP 20 | |
| 5 | Medical device class<br>(acc. MDD Annex IX) | IIb | |
| 6 | Classification | 17 - 769 | |
| | Mains supply | | |
| | Electrical requirements | *Sphinx 45 litho* | 230 V, 50/60 Hz,<br>30 A (1~, N, PE)<br>or<br>400 V, 50/60 Hz,<br>16 A (3~, N, PE) |
| | | *Sphinx 60* | 230 V, 50/60 Hz,<br>30 A (1~, N, PE)<br>or<br>400 V, 50/60 Hz,<br>16 A (3~, N, PE) |
| | | *Sphinx 80* | 230 V, 50/60 Hz,<br>30 A (1~, N, PE)<br>or<br>400 V, 50/60 Hz,<br>16 A (3~, N, PE) |
| | | *Sphinx 100* | 210-240 V, 50/60 Hz,<br>30 A (1~, N, PE)<br>or<br>400 V, 50/60 Hz,<br>16A (3~, N, PE) |
| 8 | Mains plug | *Sphinx 45 litho* | CEE-plug (1P+N+PE, 6h)<br>(acc. IEC 60309-2)<br>230 V, 32 A, blue<br>or<br>CEE-plug (3P+N+PE, 6h)<br>(acc. IEC 60309-2)<br>400 V, 16A, red |
| | | *Sphinx 60* | |
| | | *Sphinx 80* | |
| | | *Sphinx 100* | |
| 9 | Power supply cord | approx. 5.9 m | |

| | | | |
|---|---|---|---|
| 10 | Power consumption | *Sphinx 45 litho* | max. 6.5 kVA |
| | | *Sphinx 60* | max. 6.5 kVA |
| | | *Sphinx 80* | max. 6.5 kVA |
| | | *Sphinx 100* | max. 6.5 kVA |
| | | | |
| 11 | Protection against electrical shock (acc. IEC 61140) | class I equipment | |
| 12 | Earth leakage current N.C. | *Sphinx 45 litho* | max. 1.5 mA @ 253 V (60 Hz)<br>max. 1.5 mA @ 440 V (60 Hz) |
| | | *Sphinx 60* | max. 1.5 mA @ 253 V (60 Hz)<br>max. 1.5 mA @ 440 V (60 Hz) |
| | | *Sphinx 80* | max. 1.5 mA @ 253 V (60 Hz)<br>max. 1.5 mA @ 440 V (60 Hz) |
| | | *Sphinx 100* | max. 1.5 mA @ 253 V (60 Hz)<br>max. 1.5 mA @ 440 V (60 Hz) |
| | Working laser | | |
| 13 | Type | YAG:Cr,Tm,Ho solid state laser | |
| 14 | Laser class (acc. IEC 60825-1: 2007) | 4 | |
| 15 | Wavelength | 2120 nm ±3 nm | |
| 16 | Avarage power | *Sphinx 45 litho* | max. 45 W |
| | | *Sphinx 60* | max. 60 W |
| | | *Sphinx 80* | max. 80 W |
| | | *Sphinx 100* | max. 100 W |
| 17 | Pulse energy | *Sphinx 45 litho* | 0.5 – 4.0 J |
| | | *Sphinx 60* | 0.5 – 4.5 J |
| | | *Sphinx 80* | 0.5 – 4.5 J |
| | | *Sphinx 100* | 0.5 – 4.5 J |
| 18 | Pulse repetition rate | *Sphinx 45 litho* | Single pulse; 4 – 30 Hz |
| | | *Sphinx 60* | Single pulse; 4 – 30 Hz |
| | | *Sphinx 80* | Single pulse; 4 – 30 Hz |
| | | *Sphinx 100* | Single pulse; 4 – 30 Hz |
| 19 | Pulse duration | 150 - 800 µs | |

| | | | |
|---|---|---|---|
| | Aiming beam | | |
| 20 | Type | diode laser | |
| 21 | Laser class (acc. IEC 60825-1: 2007) | 3R | |
| 22 | Wavelength | 635 nm (optional 532nm) | |
| 23 | Power | max. 5 mW | |
| | Applied part | | |
| 24 | Type (acc. IEC 60601-1) | BF | |
| 25 | Beam delivery | silica – silica multimode fibre(LISA fibres only) | |
| 26 | Fibre connector | FSMA LISA | |
| 27 | User panel | colour LCD Display, 5 buttons | |
| | Connectors | | |
| 28 | Interlock | connector Serie / type XLR,<br>at the backside of the device | |
| 29 | Foot switch | connector Serie / type XLR,<br>at the backside of the device<br>2.9 m cable length | |
| 30 | Cooling system | internal refrigeration, closed circuit | |
| 31 | Coolant | R 404 A | |
| 32 | Cooling fluid | deionised water (85 v/v %)<br>+ monoethyleneglycol (15 v/v %) | |
| | Environmental conditions | | |
| | Operation | | |
| 33 | Air temperature | +15 °C - +28 °C / +59 °F - +82 °F | |
| 34 | Rel. air humidity | 10 – 90 %, non-condensing | |
| 35 | Heat emission | *Sphinx 45 litho,*<br>*Sphinx 60,*<br>*Sphinx 80,*<br>*Sphinx 100* | 2.08 kW to 6.5 kW<br>depending on laser<br>setting |
| | Storage / Transport | | |
| 36 | Air temperature | +5 °F - +158 °F | |
| 37 | Acceleration | max. 25 g | |
| | Manufacturer | | |
| 38 | LISA Laser Products GmbH<br>Albert-Einstein-Str. 4<br>37191 Katlenburg-Lindau<br>Germany | fon: +49 (0) 5556 9938 0<br>fax: +49 (0) 5556 9938 10<br>info@lisalaser.de<br>www.lisalaser.de | |

# 13 Decontamination of Returned Equipment

To comply with the postal and transportation laws, equipment shipped to LISA laser products for repair or return must be properly decontaminated with a chemical germicide that is commercially available and cleared for use as a "Hospital Disinfectant." To ensure that all equipment has been properly decontaminated, a signed Decontamination Certificate must be enclosed in the package.

If equipment is received without a Decontamination Certificate, LISA Laser Products will assume that the product is contaminated and will assess the customer with cleaning costs.

Any inquiries should be directed to the technical service department of Lisa Laser Products or the local representative.

LISA Laser Products GmbH
Albert-Einstein-Str. 4
37191 Katlenburg-Lindau
Germany
fon: +49 5556 9938 0
fax: +49 5556 9938 10
service@lisalaser.com
www.lisalaser.de

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LISA Laser Products GmbH
Albert-Einstein-Str. 4
37191 Katlenburg-Lindau
Germany
☎ +49 5556 9938-0
🖷 +49 5556 9938-10
info@lisalaser.de
www.lisalaser.de

CE
0123