

2  $\mu\text{m}$  Medical Continuous Wave Laser

# *RevoLix*

User manual



**CE**  
0123

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<b>Prepared</b>	by HT	On 26.09.02	<b>withheld</b>	by	on

## 1 About this manual

This manual provides important information concerning the safe handling of the medical 2  $\mu\text{m}$  continuous wave lasers (MCL) of the RevoLix product group.

For internal use only the manufacturer created the denominator MCL for the identification of this product group.

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

### 1.1 Safety instructions and symbols used in this manual

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

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

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

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

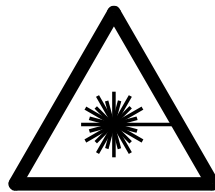


Fig. 1: **Symbol for Danger**

**WARNING:** Danger of **operational fault!** Failure to follow this instruction can lead to damage to the laser system, the applicator or the laser fiber.

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

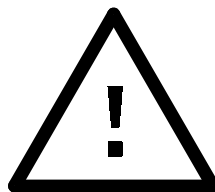


Fig. 2: **Symbol for Warning**



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### 3 Scope of this user manual

<b>RevoLix laser system</b>	<b>qty.</b>	<b>items included</b>
RevoLix 2 $\mu\text{m}$ cw medical laser	1	RevoLix 2 $\mu\text{m}$ cw medical laser
	1	Foot switch
	1	Door-interlock dummy connector
	1	User manual
	2	Laser warning signs

## 4 Important customer information

This manual describes the medical 2  $\mu\text{m}$  continuous wave lasers of the RevoLix series. The power range (max. power) and the name of the laser in question is to be found on the name plate (Fig. 7). The name of the laser appears on the start display (Fig. 14) after switched on.

The laser systems belongs to the following classifications/nomenclatures:

Laser protection class according to EN 60825	Class 4
Medical product class according to MPG	Class IIb
Medical product nomenclature according to UMDNS	17-447
Protection class according to IEC 601	Class I
Protection group according to EN 60529	IP20

The RevoLix laser system complies with the "Basic Requirements of the European Medical Products' Guideline 93/42/EEC"

In Germany operation of laser equipment is regulated by the Medical Products' Operating Regulation (Medizinprodukte-Betreiberverordnung = MPBetriebV), the VBG 93 Accident Prevention Regulation on "Laser Radiation" and the associated implementation instructions. These documents may be obtained from the Carl Heymanns Verlag KG, Luxemburger Str. 449, 50939 Köln, Germany. The responsibilities, relevant safety measures and personal protective gear are described in these regulations.

The installation of a laser system must be according to the instructions given in this manual. The locally competent trade association or the authority responsible for industrial safety must be informed.

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

## 5 General description

The RevoLix medical 2  $\mu\text{m}$  continuous wave laser is a high-performance, fiber coupled, diode pumped solid state (DPSS) laser for medical use in surgery (Chap. 9 "Clinical applications"). The wavelength is invisible infrared.

The RevoLix emits radiation at a wavelength of 2013 nm (equal to 2.013  $\mu\text{m}$ ). The radiation is given off in the continuous wave (cw) mode. The cw emission may be chopped as well (Pulsed mode). However the maximum pulse peak power remains the same as the set cw power.

The laser radiation is transmitted through a quartz glass fiber. The distal end of the fiber is attached to a suitable applicator. Various applicators are available for clinical use, which are designed for a specific purpose. The use and maintenance of the individual applicators is described in the respective manuals.

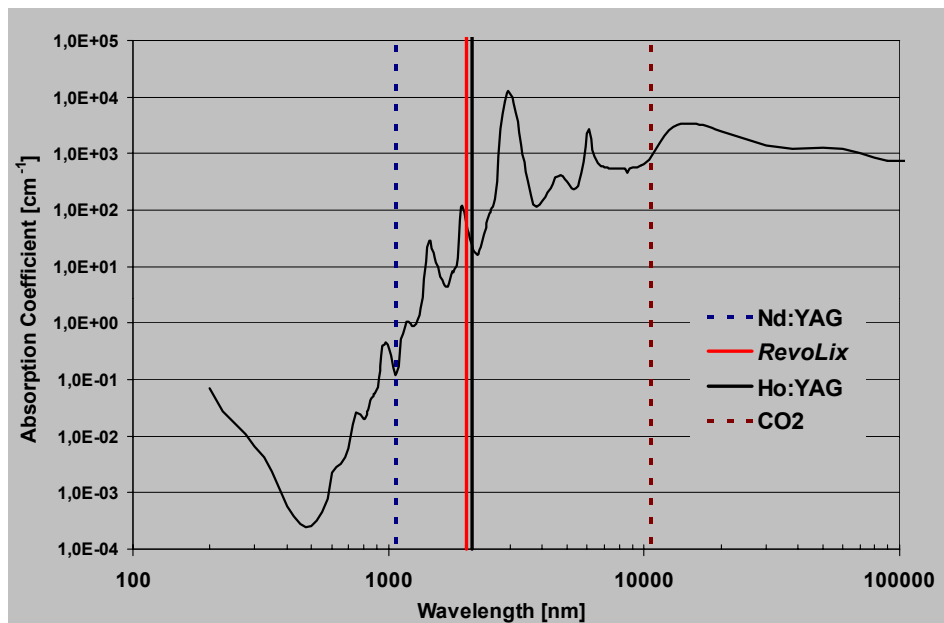
Operation of the laser system is undertaken from an operating console using a display. Activating and setting the operating parameters is described in Section 8 "Operation of the laser system".

### 5.1 Basic physico-technical principles

The RevoLix laser systems are high-performance lasers. The solid state laser crystal is excited by laser radiation emitted from a stack of semiconductor laser diodes. The diode laser radiation is directed at the solid state laser crystal which emits the 2  $\mu\text{m}$  laser radiation. The 2  $\mu\text{m}$  laser beam is focused into a fiber. The 2  $\mu\text{m}$  laser radiation emitted from the fiber – guided by a suitable applicator or focussing hand-piece – serves as the surgical instrument.

The laser-tissue-interaction is based on the strong absorption of 2  $\mu\text{m}$  radiation by water molecules, which are omnipresent in tissue disregarding coloration or circulation. The penetration of the RevoLix laser beam into tissue is less than 0.5 mm assuming no change of the optical properties of the irradiated tissue. The absorbing (= effected) volume of tissue is always within the visual reach of the surgeon. This property makes this laser a safe and universal surgical tool for soft tissue surgery.

**Fig. 3:** Absorption spectra of water with laser wavelengths



### 5.2 Basic physico-medical principles

The effect of the 2  $\mu\text{m}$  cw laser radiation to tissue depends on the intensity of the laser radiation. Intensity is defined as power per area. Another common word for the same is power density. The

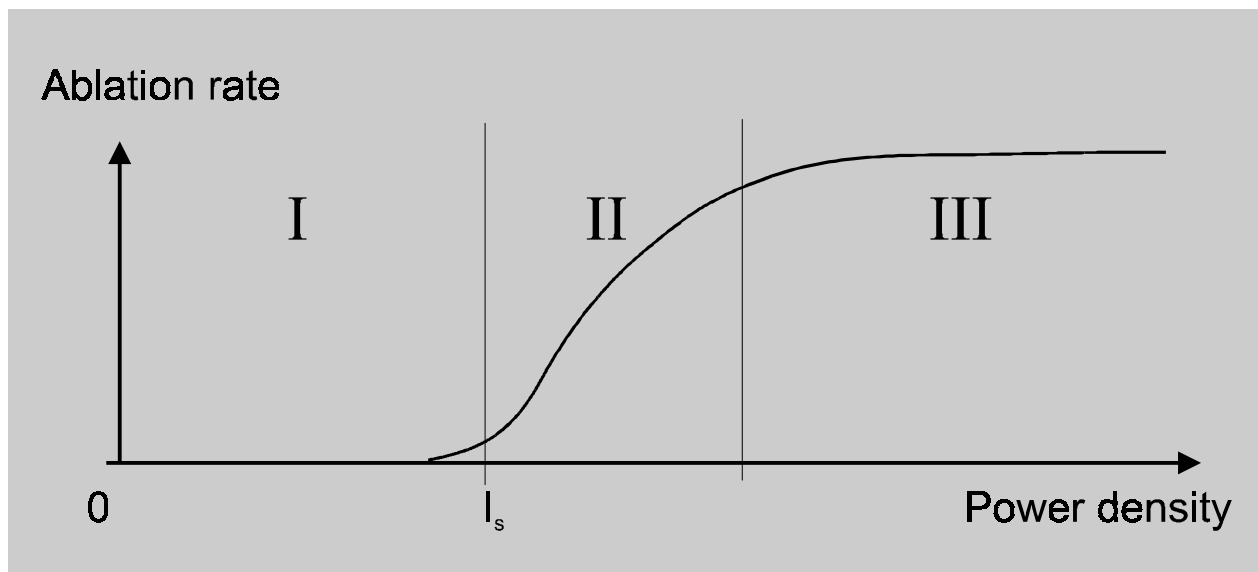
intensity may be varied by setting the power of the laser and/or selecting the distance from the tip of the fiber to the tissue. The distance dependence is due the fact that the radiation diverges considerably on emerging from the fiber.

Additionally the tissue effect depends on whether the procedure is carried out in open surgery (ambient = gas) or in an aqueous medium. In a gaseous medium the generated heat is converted into evaporation and dissipates into the adjacent tissue. Only very little heat is taken away by the ambient gaseous medium. Some smoke may be generated which is easily removed by a smoke evacuator.

An aqueous medium is advantageous twofold: There is much better cooling provided to the treated tissue which prevents charring. Furthermore any tissue which is more than 5 mm distant from the tip of the fiber is shielded off by the strong absorption of the laser radiation into the aqueous medium.

At low intensities (low power setting and/or larger spot diameter at tissue) the effect to tissue is mainly coagulative because the density of the absorbed power is less than required for the evaporation of water within the tissue. The effect to the tissue will be limited to a noticeable blanching. Even prolonged irradiation does not lead to evaporation, because the absorption process of the laser radiation is superimposed by the dissipation of heat into the surrounding medium (tissue, ambient gas or medium). In other words: the cooling effect by heat conduction into the ambient overcomes the heat build up due to absorption (I in Fig. 4).

With the intensity increasing (higher power setting and/or smaller spot diameter) the temperature of the irradiated tissue increases. At some point the heat build up inside the irradiated tissue reaches a point where the water in the tissue evaporates and takes it away ( $I_s$  in Fig. 4).



**Fig. 4: Tissue effect depending on power density**

The evaporation may be controlled to some extent by varying the power density (II in Fig. 4).

However at some point (III in Fig. 4) further increase of the power density does not lead to an increase of evaporation because the tissue is shielded off by evaporation products.

If the fiber is kept in place the evaporation of tissue will continue until the tissue has retracted and the critical intensity for ablation is under passed. Some charring of the tissue will occur when using the laser in open surgery. In aqueous medium charring is strongly reduced.

### 5.2.1 Comparison to flashlamp pumped lasers

Flashlamp pumped lasers like Holmium lasers by nature emit laser radiation in a pulsed mode. The average power of these lasers is defined as the product of the pulse energy [Joules] multiplied by the pulse repetition rate [Hertz].

However the pulse peak power of free running flashlamp pumped lasers like Holmium YAG always is in the kilowatt range [kW] - even at the lowest power setting of the laser which may be a few watts only. The high intensity generated by each laser Holmium laser pulse evaporates all kinds of tissue - regardless if soft or hard like bone or stone. The downside of the pulsed radiation are ruptures and traumas to the surrounding tissue, bubble formation impairing the visibility, sputtering of tissue fragments and soiling of endoscope lenses when used in open surgery.

The RevoLix 2  $\mu\text{m}$  cw laser emits laser radiation in a continuous mode. The available power range depends on the specific model. As a result the coagulative and ablative tissue effects are gentle compared to the flash lamp pumped laser. The tissue is coagulated or dissected with no trauma, visibility is not affected by bubbles, no tissue fragments including living cells sputter lenses or masks.

### 5.2.2 RevoLix pulsed mode

The RevoLix may be operated in a pulsed mode as well. However the pulse peak power of the 2  $\mu\text{m}$  cw laser always is of the same power [Watts] as indicated of the display of the console. The single and repetitive pulsed mode is included into the specification of the laser in order to give a better control on the laser emission to the surgeon.

Different to the pulsed Holmium YAG laser bubble formation in an aqueous medium in front of the fiber, which guides the divergent beam to tissue (Moses effect) does not occur.

The pulsed mode of the 2  $\mu\text{m}$  cw laser radiation is incapable of ablating hard tissue like bone and stone.

## 5.3 Intended use of the RevoLix medical 2 $\mu\text{m}$ continuous wave laser

The RevoLix is a surgical laser, which is used in the contact and non-contact mode for the incision, excision, removal and coagulation of soft tissue. The underlying principle is the absorption of 2  $\mu\text{m}$  laser radiation by water molecules in tissue. The generated heat may be used for coagulation or ablation of tissue depending on the treatment method applied.

The absorption of laser power is confined to a volume between the surface and a layer app. 0.5 to 1 mm below tissue. Tissue damage to lower lying tissue may occur due to heat conduction when the fiber or beam is moved slowly or held in place.

The damage zone exceeds the visible excision by the optical penetration depth, which is of the order of 1 mm, since the laser energy penetrates beyond the excision further into the tissue. In addition there is heating of the surrounding tissue, because heat is being dissipated by thermal conduction from the area, in which the laser energy was absorbed.

The actual damage zone depends on the treatment technique. At a power density, which allows to cut the tissue, the damaged zone is less than 1 mm. As a rule of thumb one can say: the longer the applicator is held in one place, the more extensive is the zone of thermal damage.

The following treatment parameters are to the surgeon's disposal:

Parameter	Range	Effect
Power setting	High or low power	Speed
Beam diameter at tissue	Contact or non-contact mode	Beam intensity
Fiber selection	Different core and cladding diameter	Beam intensity and fiber flexibility
Atmosphere	Open surgery (gaseous) or in aqueous medium	Cooling and shielding

### 5.3.1 Power setting

The power setting determines how much tissue may be coagulated or evaporated per unit of time. Because the RevoLix lasers show a very strong tissue effect the power should not be set too high for a start. Please refer to the settings in the section “Clinical applications”.

### 5.3.2 Beam diameter at tissue

The laser beam emerging from the fiber / handpiece is divergent at a full cone angle of app. 25°. The beam diameter increases with distance. As the laser beam intensity equals laser power divided by beam cross section the beam intensity decreases with distance.

The laser intensity is highest at the distal tip of the fiber / handpiece and decreases with distance.

Evaporation of tissue requires high beam intensity. Reduced intensity is used for coagulation.

In aqueous medium the laser beam is strongly absorbed. Depending of the power setting tissue more than 1 to 4 mm from the tip of the fiber is shielded or completely from the laser radiation. This feature may be understood as a safety feature.

### 5.3.3 Fiber selection

A range of laser fibers is available for this laser (Section accessories). These fibers differ in core diameter and in the outer (cladding) diameter.

The diameter of the optical core determines the highest achievable intensity at the distal tip of the fiber. The smallest fibers achieves the highest intensity. However this effect is superimposed by the divergent characteristic of the beam emerging from the fiber – meaning that after a short distance the intensity from a 356 µm fiber is at the same level as the beam emerging from a 600 µm fiber. Additionally it needs to be understood that small diameter fibers mechanical are more delicate than “larger” fibers.

Most important for fiber selection is the compatibility with the instrument / applicator to be used and the mechanical properties required for a special treatment. Please refer to the section “Clinical applications”.

### 5.3.4 Contact versus non-contact mode

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

Generally spoken the laser fiber will be used in contact mode if cutting or evaporation of tissue is intended. For coagulation the fiber is retracted in order to decrease the intensity. It should be

understood that in an aqueous medium the optical pathway of the laser is very short because of the strong absorption of the 2  $\mu\text{m}$  radiation in water.

### **5.3.5 Open surgery (gaseous medium)**

In an air or gaseous medium there is very little cooling to the tissue despite conduction cooling by adjacent tissue. Evaporation will take place rapidly as soon as the beam intensity reaches evaporation threshold. Charring may be inevitable mainly with larger cuts in air. In Carbon Dioxide charring is less because of the lack of Oxygen.

In a gaseous medium the diameter of the laser beam – and its intensity – can be controlled by the distance between fiber tip and tissue because the gaseous atmosphere does not absorb the 2  $\mu\text{m}$  laser radiation. The full range between contact mode and non-contact mode is available in open surgery.

Generated smoke may be controlled by means of a smoke evacuator.

### **5.3.6 Laser surgery in aqueous medium**

In an aqueous medium there is ample cooling to the tissue surface under laser irradiation. Charring will only be very limited, because the temperatures increase will be capped by the evaporation temperature of the tissue and the aqueous medium (app. 100°C). Therefore higher power settings can be applied in an aqueous medium compared to gaseous media for two reasons:

1. Compared to open surgery cooling is stronger, more power is required to achieve the desired effect;
2. Compared to open surgery charring is less.

In a aqueous medium the 2  $\mu\text{m}$  laser radiation is strongly absorbed. Different to the pulsed Holmium YAG laser bubble formation in front of the fiber, which guides the divergent beam to tissue (Moses effect), does not occur.

The control on the beam diameter by the distance between fiber tip and tissue is limited because of the strong absorption of the 2  $\mu\text{m}$  laser radiation in the aqueous medium.

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.

## 6 Laser safety

The RevoLix laser uses as the working beam a DPSS laser with an emission wavelength of 2  $\mu\text{m}$ . According to IEC 825 this laser is class 4. Irradiation of persons can cause injuries to the skin and eyes.

Internally a high power diode laser is used as an excitation source for the 2  $\mu\text{m}$  cw laser. Several technical precautions are provided to keep the accessible laser diode radiation at harmless level even under fault condition.

A semiconductor laser with an emission wavelength of 635 nm and an output of < 1.0 mW is used as an aiming beam (pilot laser). Although this laser is class 2, one should refrain from irradiating persons when they are not undergoing treatment.

In Germany operation of laser equipment is regulated by the Medical Products' Operating Regulation (Medizinprodukte-Betreiberverordnung = MPBetriebV), the VBG 93 Accident Prevention Regulation on "Laser Radiation" and the associated implementation instructions. These documents may be obtained from the Carl Heymanns Verlag KG, Luxemburger Str. 449, 50939 Cologne. The responsibilities, relevant safety measures and personal protective gear are described in these regulations.



**DANGER**

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

Never point the laser beam at a person!

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

All persons in the laser area must wear laser safety goggles.



**DANGER**

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

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

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

### 6.1 Marking of entrance doors to laser areas

All entrance doors to the operating theatre (=laser areas), in which the laser system is set up and operated, are to be marked on the outside with the following warning sign in accordance with DIN VDE 0837 (or the relevant local regulation)(original black on yellow).

If a laser is used the operating theatre becomes the laser area in accordance with VBG 93 (or the relevant local regulation).

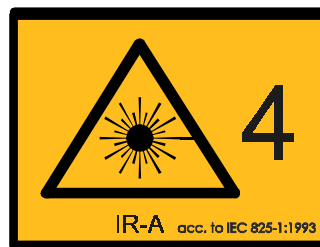


**Fig. 5: Warning sign for marking of entrance doors**

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

## 6.2 Marking the laser system

The following sign is attached to the back of the laser, (original black on yellow). It shows the laser class. (Fig. 6)



**Fig. 6: Marking the laser class**

The name plate is attached to the inside of the front door. It comprises all the necessary data for the identification of your laser system (Fig. 7).



Fig. 7: RevoLix name plate

### 6.3 Beam outlet (fiber port)

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

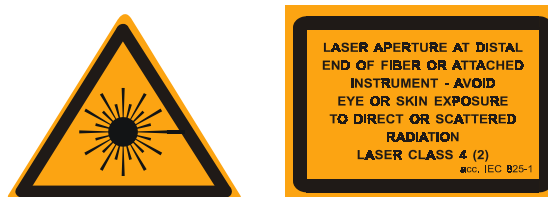


Fig. 8: Warning sign for beam outlet

With a fiber properly connected to the laser the interlock mechanism allows the aiming beam and the working beam to pass through the fiber and handpiece.

### 6.4 Laser safety officer

The operator – in most cases the hospital administration or the qualified doctor – has (according to VBG 93 or other local regulations) to appoint in writing a proficient person to act as the laser safety officer for the operation of the laser system.

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

The duties of the laser safety officer are laid down in the implementation instructions to the VBG 93 accident prevention regulation on "laser radiation".

### 6.5 Authorized users of the laser system

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

The names of the persons instructed must be entered in the medical systems book accompanying the system.

## **6.6 Laser area and laser safety goggles**

The laser area is considered to be that area, in which the amount of radiation or the radiation can exceed the current maximum permitted radiation of the cornea of the eye (MZB), 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.

As soon as the laser system is switched on, all persons present in the laser area must wear suitable laser safety goggles, supplied by the manufacturer of the laser system.

## **6.7 System book, medical systems book**

A medical systems book is to be kept with the laser system, in accordance with § 7 of the MPBetreibV (Medical Products' Operating Regulation or other local regulations). The medical systems book is to be kept both by the operator as well as by the maintenance and servicing personnel and it has to be shown on request to the competent testing and supervisory authorities.

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

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

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

## 7 Installation of the laser system

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

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

The expert will also check and take care that all latches connecting the laser modules are orderly connected and attached.

### 7.1 Transportation and storage of the laser system

During transportation and operation of the RevoLix, care must be taken to ensure that the system is not subjected to severe jolts or vibrations.

If there is danger that the ambient temperature may drop to below +3°C, the cooling water must be drained from the system and the laser head has to be purged with clean pressurized air of no more than 3 bars for at least 5 minutes.

Before putting the laser back in operation new cooling water supplied by the laser manufacturer must be filled up. Both the draining as well as the filling of the laser system with cooling water may only be undertaken by an expert authorized by the system manufacturer. Operating the laser system without cooling water may lead to severe damage to the laser diode.

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



**WARNING**

Severe jolts, vibration and ambient temperature of below + 3 °C, as well as operating the laser system without cooling water can cause severe damage.

### 7.2 Orderly state of the module latches

The laser system consists of three modules, which separate at the seams visible at the side faces. The modules interlock by 4 module latches at each end of the laser system. The module latches are accessible, after opening the storage and service hatch. All latches have to be orderly locked at all times. If the latches are open the hatches will disconnect from the laser system and the modules may disconnect resulting into severe injuries to persons or serious damage.



**WARNING**

Severe injuries and serious damage may occur if module latches are not properly secured.

Fig. 9 shows the order state of the module latches. Fastening the module latches should be done only by authorized personnel.



**Fig. 9: Orderly state of the module latches**

### **7.3 Marking the operating room**

The room, in which the laser system is to be operated, must be marked as a laser area in accordance with the valid local regulation. The sign to be used for this is shown in section 6.1 "Marking of entrance doors".

### **7.4 Laser warning light**

The operator must install a laser warning light above the entrance door to the operating room. This light must always be illuminated when the laser is in operation.

The manufacturer of the laser system or his representative will help with the electric wiring.

### **7.5 Mains connection**

The RevoLix requires single phase mains supply (230 Volts, -13 %, +10 %, 16 Amps, 50/60 Hz). The exact requirements for the laser system in question can be seen from the name plate.

### **7.6 Cooling**

The RevoLix medical 2  $\mu\text{m}$  continuous wave lasers are equipped with integrated refrigerant cooling systems.

During operation of the laser the cooling system draws off the excess heat into the ambient air. The heat load is specified in the section "Technical data".

In rooms, which are not air-conditioned, one should take account of a corresponding warming of the ambient air. The laser may be operated continuously at an ambient temperature of up to about 28 °C. The system switches off automatically if the ambient temperature becomes too high (section 9.1.1 "Error messages"). There is no danger to the laser unless it switches off automatically.

The ventilation openings at the side faces of the laser system - must not be covered during operation of the laser system.

An additional cold water or gas connection is neither necessary nor provided.



## **7.7 Connecting the foot switch**

The connector at the free end of the foot switch cable is plugged into the lower socket next to the Laser Stop button at the front of the system (Fig. 11) and screwed tight. The storage hatch may be opened for the operators ease. The connector will fit in only one orientation. All electrical connections to the laser system are designed so that they are not interchangeable.

For safety and ease of control the foot switch and the distal end of the laser fiber always should be as close as possible to each other and under control of the same person.

## **7.8 Connecting a door interlock**

A door interlock may be plugged into the socket on the back side of laser system (Fig. 1: Back of the system) and screwed tight. 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 on delivery must 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 open – or pin 1 and pin 3 are not bridged – 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 (Fig. 12).

## 8 Operation of the laser system

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

The actual "Start-up and switch-on routine" is described below in sub-section 8.2. In that sub-section it will also be shown how the orderly state of the laser system can be ascertained.

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

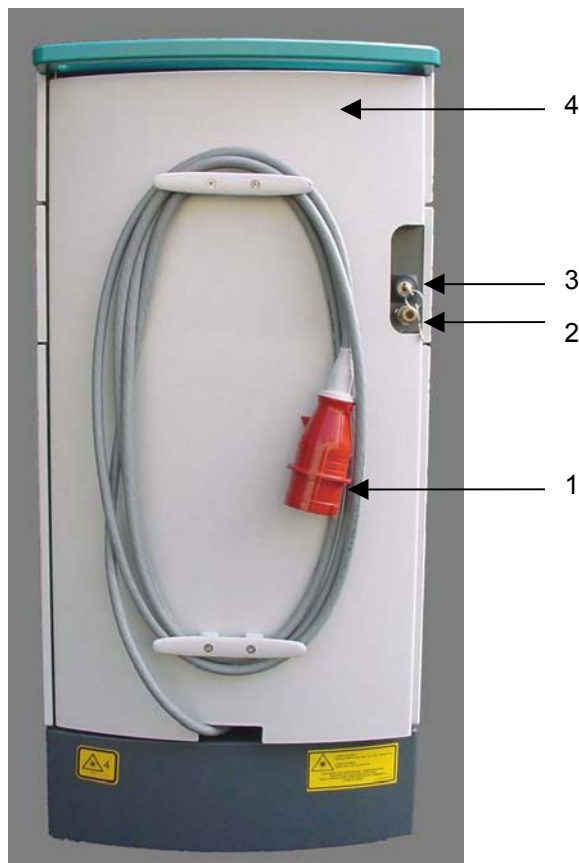
If laser has been stored at an ambient temperature outside the "Operational ambient temperature" range the laser needs to be stored at "Operational ambient temperature" for at least 3 hours.

### 8.1 Operating and display components

The operating and display components are arranged in three groups, which are to be found at the front and at the back of the system and on the operating console.

#### 8.1.1 Back of the system

Mains supply, door-interlock and the service hatch is located at the back of the system.

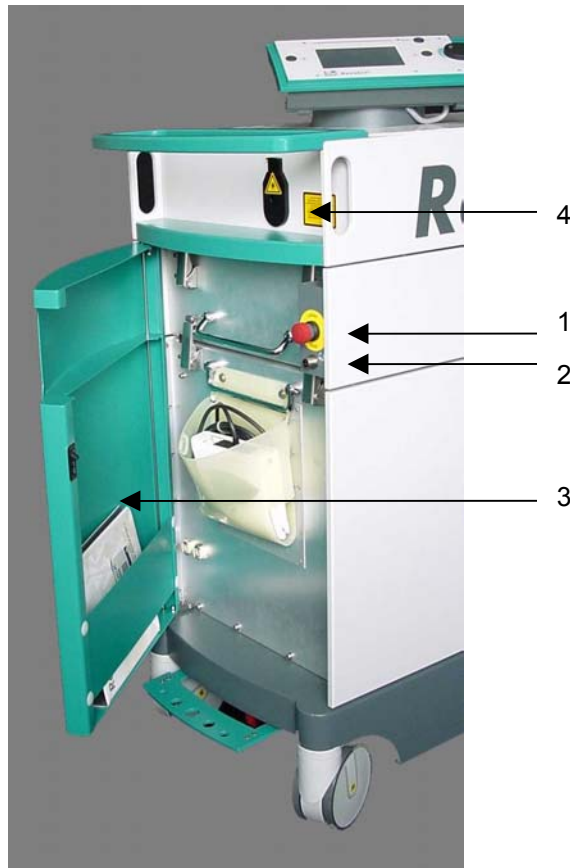


**Fig. 10:** Back of the system

1	Mains cable	3	Key switch
2	Door-interlock connection	4	Service hatch

### 8.1.2 Front of the system

Beam outlet, foot switch connection, Laser Stop button and the storage hatch are located at the front of the system. The storage hatch opens just by pulling the opening close to the Laser Stop button.



**Fig. 11:** Front of the system

1	Laser Stop button	3	Storage hatch (open)
2	Foot switch connection	4	Beam outlet with beam lock

With the storage hatch open there is access to the pigeon-hole for the foot switch and this "User manual" inside the door.

### 8.1.3 Operating console

All communication between the operator and the laser is accomplished via the adjustable operating console. The operating console swivels 180°.

The operating console comprises a b/w display, the laser warning lamp and a loudspeaker.

The input components are the two function buttons (menu button (1) and parameter selection button (5)), the adjusting wheel (4) and the ready button (3).



**Fig. 12: Operating console**

1	Menu button	4	Adjusting wheel
2	Laser warning lamp	5	Parameter selection button
3	Ready button	6	Display

## 8.2 Attaching the laser fiber to the fiber port

### 8.2.1 Checking the laser fiber for orderly state

Before connecting the fiber the following points must be checked:

1. The free-standing fiber tip in the fiber connector (ca. 0.5 mm in diameter, depending on fiber type) must be smoothly reflective and free from damage and dirt. The hollow space within the fiber connector surrounding the fiber tip must be free of any sign of blackening or burning. If necessary a magnifying glass must be used for checking.
2. The fibers must be undamaged and without kinks throughout the entire length.

### 8.2.2 Connecting the fiber to the laser

1. Check the orderly state of new fibers and the connector (see above).
2. Open the beam lock (Fig. 11) by gently pushing the top downwards until the fiber port is fully opened. Carefully insert the fiber connector without applying force, feel the insertion, screw it in until it is **finger-tight** (Fig. 7).



**Fig. 13:** Connecting the fiber

### 8.2.3 Disconnecting the fiber from the laser

1. Unscrew the connected fiber connector from the beam outlet (turn to the left) and carefully take it out.
2. Check the orderly state of the fiber (see above).
3. Replace the protective cap to the connector and **finger-tighten** it.



**WARNING**

Prevent all damage to the fiber connector. Damage to the fiber can lead to absorption of laser power, heat build-up and destruction of the fiber connector and the laser optics.

Please read the instructions for checking the laser fiber in the laser fiber manual. **Damaged fibers cannot be used any longer !**



**WARNING**

Replacing the fibers must **not** take place in the 'ready' operational state (laser warning lamp is switched on)!



**DANGER**

The use of damaged fibers can lead to injuries because the laser radiation can be emitted at the damaged point and not at the distal end of the fiber.

### 8.3 Start-up and switch-on routine

**Before switch on of the laser it is necessary to check whether:**

1. the necessary safety precautions (section 6 "Laser safety") have been taken
2. the foot switch is attached and the laser system is connected to a suitable power supply.
3. if necessary the door-interlock dummy connector is connected,

4. a laser fiber is connected or the beam lock is closed,
5. the necessary laser fibers and laser applicators are to hand and
6. all persons present in the laser area are wearing appropriate laser safety goggles. Take care that the laser safety goggles are suitable for the emitted wavelength and do not show signs of damage.



Irradiation of the eyes by direct or indirect laser radiation can lead to injuries and irreversible damage to the eyes. All persons present in the laser area must wear appropriate laser safety goggles.

**DANGER**

Concerning the use of laser fibers and laser applicators please consult the manual for the accessory in question.

#### Switch-on routine:

1. Switch on the laser system using the key switch on the back of the laser (1/4 turn to the right (clockwise)). It takes about 3 seconds for the first pumps and fans to start.
2. The microprocessor control carries out various checks on the system during the first few seconds after switch-on (start-up). The start display (Fig. 14) appears on the monitor displaying the brand name. After completion of the start-up a tune is heard and the laser parameter menu appears on the screen (Fig. 15) (section 26 "Setting the laser parameters").



**Fig. 14:** Start display after switch on the laser system

3. Possible error messages during the start-up routine appear on the screen in clear text (Section 10 "Error messages").
4. The desired operational mode or the system menu is selected with the menu button (Section 8.1.3 "Operating console").
5. After activating the 'Ready' button the laser is switched from "**Stand by**" state to "**Ready**" state. The "**Ready**" state is indicated by the illumination of the laser warning lamp on the console and the pilot laser being switched on. Should the pilot laser on the distal fiber end not be visible, then the setting for the brightness of the pilot laser (Section 8.4 "Setting the laser parameters") should be adjusted.
6. There is a safety delay of 2 seconds after pressing the "**Ready**" button, until the laser gets in the "**Ready**" state. Only then it is possible to activate laser emission by activating the foot switch. Before activating the foot switch, make sure that the displayed parameter settings conform with

the desired treatment parameters. Immediately on pressing the foot switch laser radiation will be emitted from the fiber. At the same time an audible signal is activated.



**DANGER**

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

Only with a laser fiber connected the "Ready state" can be activated.

- Before the laser is used on a patient, the user must become conversant with the orderly state of the laser system (Section 8.7 "Orderly state of the laser system").

### 8.3.1 Operational states of the system

During operation two different operational states are possible:

- Stand-By:** The system is fully operational but is not yet ready to emit laser radiation. The laser warning lamp (No. 2 in Fig. 12) and the pilot laser are not yet switched on. This state is reached after the start-up.
- Ready:** By activating the 'ready' button once (No. 3 in Fig. 11) the system is switched from the Stand-By state to the Ready state (takes 2 seconds waiting). The system is now ready to emit laser radiation. The laser warning lamp is lit and the pilot laser is switched on. By pressing the foot switch laser radiation is emitted. Activating the 'ready' button again switches the system back into Stand-By state.

### 8.4 Setting the laser parameters

Setting the laser parameters is done by using the buttons and the adjusting wheel. After the laser system has been switched on and completion of orderly start-up, the parameter menu appears on the display Fig. 15..



**Fig. 15:** Parameter menu after switch on the laser system

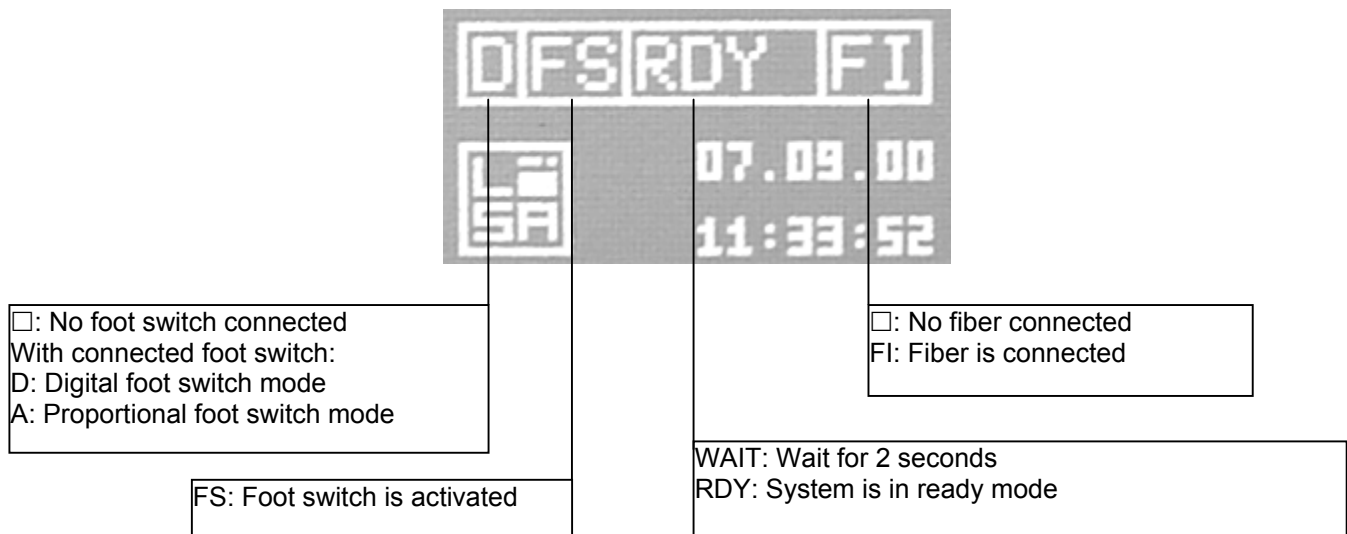
The following abbreviations are used:

- Power (or Max.Power)** Power of the 2  $\mu\text{m}$  laser power available from the distal end of the handpiece or the fiber at this setting.
- CONTINUOUS** = continuous The laser power is emitted continuously.
- PULSED** The laser power is not continuous but given off at set intervals.
- SINGLE** Only one single pulse given off.

<b>Duration</b>	Pulse duration at this setting (ON TIME).
<b>Repetition</b>	Pulse repetition rate at this setting (how often the pulse is emitted per second)
<b>Counter</b>	Shows the number of the pulses emitted so far
<b>Time</b>	Shows how long laser power has been emitted.

## 8.5 Status display on the monitor

As part of the parameter menu in the lower left corner the status display (Fig. 16) shows details of the operational status of the system, together with the system time and date.



**Fig. 16:** Status display (extract from the display)

### 8.5.1 Operational mode selection

The RevoLix laser may be operated in continuous mode, pulsed mode and single pulse mode.

By pressing the menu selection button (No.1 in Fig. 12) left to the display, it is possible to toggle between CONTINUOUS operation (Fig. 17), PULSED operation (Fig. 18), SINGLE pulse operation (Fig. 19) and the SYSTEM menu (Fig. 20). The selected mode is highlighted in white.



**Fig. 17:** Parameter menu for continuous mode



Fig. 18: Parameter menu pulsed mode



Fig. 19: Parameter menu for single pulse operation



Fig. 20: RevoLix system menu

#### 8.5.1.1 Setting the treatment parameters for continuous operation

In continuous wave (cw) operation the output power is set by adjusting the wheel between minimum and the maximum power. These values depend on the model and are listed in the specifications. Turning the adjusting wheel (No. 4 in Fig. 12) to the right (clockwise) increases the maximum power; turning the adjusting wheel to the left (counter-clockwise) decreases the maximum power.

On adjusting the POWER the system falls back to “**STAND BY**”. After setting the power the “Ready Button” has to be presses again for “**READY**”.

### **8.5.1.2 Setting the treatment parameters for pulsed and single-pulse operation**

Repeated pulsed mode operation is selected by pressing the parameter selection button (Fig. 12, No. 5) until PULSED is highlighted. In this mode POWER (pulse peak power), Duration (pulse duration) and Repetition can be selected. The parameter selected is highlighted in white and can be altered with the adjusting wheel. Turning the adjusting wheel to the right (clockwise) increases the selected parameter; turning the adjusting wheel to the left (anti-clockwise) decreases the selected parameter. By turning the adjusting wheel to the left (counter-clockwise) the counter is set to zero. The pulse duration can be adjusted from 50 -1000 ms in 10 ms intervals. The repetition rate can be set from 0.5 – 10 Hz in steps of 0.5 Hz.

The pause between two pulses must be at least as long as the pulse, the repetition rate is automatically adjusted to take account of this.

The emitted pulse peak power, the overall number of pulses emitted (Counter) and the total energy emitted (Energy) are shown in the display.

### **8.5.1.3 Setting the brightness of the pilot laser**

The brightness of the pilot laser (635 nm emission wavelength) can be adjusted in the SYSTEM menu by turning the adjusting wheel between 0 and 100%. Maximum setting is 0.95 mW from the orderly fiber. The pilot laser is ON in the Ready state (No. 3 in Fig. 12).

## **8.6 Switch-off routine**

1. Switch off the laser system with the key switch. The fibers may remain connected. All settings are retained for the next time it is used.
2. Take off laser safety goggles.
3. Pull out the mains connector.
4. Remove the key, to prevent unauthorized use of the system.

## **8.7 Orderly state 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. a fiber which is in a orderly state emits power during operation of the laser.

## 9 Clinical applications

The following text is based on the experiences of users of RevoLix medical 2  $\mu\text{m}$  continuous wave lasers and international publications concerning the use of medical 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 for safety reasons.

Take note of the relevant safety regulations (section 6 “Laser safety”) and follow the instructions of your establishment’s laser safety officer.



**DANGER**

Whenever a laser or specifically a RevoLix system is used there is a potential risk of thermal damage. Start with low power settings. The laser should only be activated if the fiber tip and the tissue at which the laser is directed is within sight.

### 9.1 Urology

The RevoLix 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**

**Condylomata**

The tissue effects of the RevoLix medical 2  $\mu\text{m}$  continuous wave laser are particularly advantageous in endourological application.

LISA laser products OHG supplies the necessary laser fibers as standard accessories. The endoscopic urological instruments, which are required in addition, must have a working channel to take the laser fiber and need to be authorised by the manufacturer for the use together with lasers or At best with the RevoLix product. Please allow us to advise you.

The laser fibers described in this section are reusable. Information about sterilisation can be found on the packaging and in the laser fiber user manual. It is preferable to choose a sterilisation process, which operates at the lowest possible temperatures (< 90°C) in order to exclude oxidation of the fiber connector. By principle autoclaves operate at 121°C minimum temperature. Therefore this method of sterilisation should not be used as standard if repeated use of fibers is intended.

The laser fibers described in this section emit the laser radiation forwards. The fibers must be checked if they are in orderly state before they are used. If the tip of the fiber is not in orderly state the distal end needs to be cut with the fiber tool. After shortening the beam quality should be checked with the pilot laser.



**DANGER**

With all applications of the RevoLix laser in the urogenital tract there is a danger of perforation. Therefore the laser may only be switched on if the distal tip of the fiber and its effect to tissue is under visual control of the surgeon controlling the foot switch. Start with low power settings.

### 9.1.1 Opening of urethral strictures

**Laser accessories:** PercuFib laser fiber  
Laser resectoscope

**Laser setting:**

Power setting	5 - 15 W
Mode	Continuous

**Preparation:**

Prepare the laser system according to section “Operation of the laser system”.

Make sure before the procedure that the existing fibers are compatible with the endoscopic instrument to be used.

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

**Procedure:**

1. Start the laser as described in the section on “Operation of the laser system”.
2. Insert the fiber in the endoscopic instrument. The non-sterile nurse attaches the fiber to the laser.
3. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak it could be that the fiber was damaged during insertion into the instrument. In this case the fiber should be prepared again using the fiber tool or different fiber should be used. If a damaged fiber is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 5 – 10 Watts.
5. Use the “contact” method for incision. Activate the laser with the foot switch while pulling the fiber tip backwards across the tissue surface. It is advantageous to do so, because in this way the risk to perforate the tissue is minimum.
6. Adjust the power setting in the light of your experience.

### 9.1.2 Opening of ureter strictures

**Laser accessories:** PercuFib laser fiber  
Ureterorenoscope

**Laser setting:**

Power setting	5 – 10 W
Mode	Continuous

**Preparation:**

Prepare the laser system according to section “Operation of the laser system”.



Make sure before the procedure that the existing fibers are compatible with the ureterorenoscope to be used.

Take care that the fibers can easily be introduced into the ureterorenoscope and taken out again. Check that the laser fiber can be fixed. The distal fiber end must be able to be brought into the field of vision of the optic.

**Procedure:**

1. Start the laser as described in the section on “Operation of the laser system”.
2. Insert the fiber in the endoscopic instrument. The non-sterile nurse attaches the fiber to the laser.
3. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak it could be that the fiber was damaged during insertion into the instrument. In this case the fiber should be prepared again using the fiber tool or different fiber should be used. If a damaged fiber is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 5 Watts.
5. Use the “contact” method for incision. Activate the laser with the foot switch while pulling the fiber tip backwards across the tissue surface. It is advantageous to do so, because in this way the risk to perforate the tissue is minimum.
6. Adjust the power setting in the light of your experience.

**9.1.3 Resection of the prostate**

**Laser accessories:** PowerFib laser fiber,  
Laser resectoscope,  
sterile fiber tool or 2-3 spare fibers

**Laser setting:**

Power setting	20 – 40 W
Mode	Continuous

**Preparation:**

Prepare the laser system according to section “Operation of the laser system”.

Make sure before the procedure that the existing fibers are compatible with the laser resectoscope to be used.

Take care that the fibers can easily be introduced into the laser resectoscope and taken out again. Check that the laser fiber can be fixed. The distal fiber tip must be able to be brought into the field of vision of the optic.

The cladding of the laser fiber acts as mechanical reinforcement and protection against kinking and breaking at the distal end of the laser resectoscope. For this reason only the cladding protruding from the fiber guidance tube should be removed, i.e. only 3 – 5 mm. When the fiber is inserted into the resectoscope the cladding at the distal end of the guidance tube must be visible.

**Procedure:**

1. Start the laser as described in the section on “Operation of the laser system”.

2. Insert the fiber into the instrument. The non-sterilised nurse attaches the fiber to the laser.
3. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak to you it could be that the fiber was damaged during insertion into the instrument. In that case the fiber should be prepared again using the fiber tool or another fiber should be used. If a fiber, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 20 to 30 W.
5. Use the “near contact” method for resection. Activate the laser with the foot switch while pulling the fiber end back or sideways across the tissue surface. It is advantageous to do so, because in this way the fiber end cannot remain hanging in the tissue.
6. Today different methods of resection of prostate are applied. You will find a detailed description of the technique used with Holmium lasers in: Peter J. Gilling, “The Technique of Holmium-Laser Resection of the Prostate (HOLRP)”. These guidelines may be used with the RevoLix as well. A different approach is the enucleation of the prostate where the lobes are enucleated with a remaining connection to the bladder neck. some contact to the until they are connected Later the lobes are removed with help of a mechanical punch. A systematic method of working is a good prerequisite for a successful resection.
7. Adjust the power setting in the light of your experience.
8. Change or cut the fibers when you feel the cutting effect is impaired.

#### 9.1.4 Bladder neck incisions

**Laser accessories:** PowerFib laser fiber,  
Laser resectoscope

**Laser setting:**

Power setting	15 – 25 W
Mode	Continuous

#### Preparation:

Prepare the laser system according to section “Operation of the laser system”.

Make sure before the procedure that the existing fibers are compatible with the laser resectoscope to be used.

Take care that the fibers can easily be introduced into the laser resectoscope and taken out again. Check that the laser fiber can be fixed. The distal fiber tip must be able to be brought into the field of vision of the optic.

The cladding of the laser fiber acts as mechanical reinforcement and protection against kinking and breaking at the distal end of the laser resectoscope. For this reason only the cladding protruding from the fiber guidance tube should be removed, i.e. only 3 – 5 mm. When the fiber is inserted into the resectoscope the cladding at the distal end of the guidance tube must be visible.

#### Procedure:

1. Start the laser as described in the section on “Operation of the laser system”.
2. Insert the fiber into the instrument. The non-sterilised nurse attaches the fiber to the laser.



3. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak to you it could be that the fiber was damaged during insertion into the instrument. In that case the fiber should be prepared again using the fiber tool or another fiber should be used. If a fiber, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 15 W.
5. Use the “near contact” method for incision. Activate the laser with the foot switch while pulling the fiber end sideways across the tissue surface. It is advantageous to do so, because in this way the fiber end cannot remain hanging in the tissue.
6. The surgical procedure is identical to the regular “Turner Warwick” procedure.
7. Adjust the power setting in the light of your experience.

### 9.1.5 In-situ ablation of bladder tumours

**Laser accessories:** PowerFib laser fiber,  
Laser resectoscope

**Laser setting:**

Power setting	10 – 20 W
Mode	Continuous

#### Preparation:

Prepare the laser system according to section “Operation of the laser system”.

Make sure before the procedure that the existing fibers are compatible with the laser resectoscope to be used.

Take care that the fibers can easily be introduced into the laser resectoscope and taken out again. Check that the laser fiber can be fixed. The distal fiber tip must be able to be brought into the field of vision of the optic.

The cladding of the laser fiber acts as mechanical reinforcement and protection against kinking and breaking at the distal end of the laser resectoscope. For this reason only the cladding protruding from the fiber guidance tube should be removed, i.e. only 3 – 5 mm. When the fiber is inserted into the resectoscope the cladding at the distal end of the guidance tube must be visible.

#### Procedure:

1. Start the laser as described in the section on “Operation of the laser system”.
2. Insert the fiber into the instrument. The non-sterilised nurse attaches the fiber to the laser.
3. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak to you it could be that the fiber was damaged during insertion into the instrument. In that case the fiber should be prepared again using the fiber tool or another fiber should be used. If a fiber, which is broken inside the instrument, is used, this can lead to severe damage and burns.
4. At the begin use a low power setting; e.g. 10 W.
5. Use the “near contact” method for incision. Activate the laser with the foot switch while pulling the fiber end sideways across the tissue surface. It is advantageous to do so, because in this way the fiber end cannot remain hanging in the tissue. It is possible to undercut or to ablate the tissue.



6. Adjust the power setting in the light of your experience.

### 9.1.6 Condylomata

**Laser accessories:** PercuFib laser fiber  
SlimLas laser handpiece

**Laser setting:**

Power setting	5 - 15 W
Mode	Pulsed, 100 to 400 msec, or Continuous

**Preparation:**

Prepare the laser system according to section “Operation of the laser system”.

Make sure before the procedure that the existing fibers are compatible with the laser handpiece to be used.

Take care that the fibers can easily be introduced into the laser handpiece and taken out again. Check that the laser fiber can be fixed in the applicator.

**Procedure:**

1. Start the laser as described in the section on “Operation of the laser system”.
2. Insert the fiber in the laser handpiece. The non-sterile nurse attaches the fiber to the laser.
3. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak it could be that the fiber was damaged during insertion into the instrument. In this case the fiber should be prepared again using the fiber tool or different fiber should be used. If a damaged fiber is used, this can lead to severe damage and burns.
4. Understand this procedure is carried out in an gaseous medium (air) and charring will be stronger compared to endourological cases. At the begin use a low power setting; e.g. 5 – 10 Watts.
5. Use the “contact” method for ablation of condylomata. Activate the laser with the foot switch while pointing in near contact at the tissue to be ablated. Immediate blanching indicates the coagulation of the tissue.
6. Adjust the power setting in the light of your experience.

## 9.2 Gynecology

The RevoLix laser is used in Gynecology in the following clinical applications:

### Incisions and excisions to the outer female genital

#### Condylomata

Laparoscopic procedures are under investigation.

The tissue effects of the RevoLix medical 2 μm continuous wave laser are particularly advantageous in gynecological application.

LISA laser products OHG supplies the necessary laser fibers and handpieces as standard accessories. All instruments must have a working channel to guide the laser fiber properly and need to be authorised by the manufacturer for the use together with lasers or at best with the RevoLix product. Please allow us to advise you.

The laser fibers described in this section are reusable. Information about sterilisation can be found on the packaging and in the laser fiber user manual. It is preferable to choose a sterilisation process, which operates at the lowest possible temperatures (< 90°C) in order to exclude oxidation of the fiber connector. By principle autoclaves operate at 121°C minimum temperature. Therefore this method of sterilisation should not be used as standard if repeated use of fibers is intended.

The laser fibers described in this section emit the laser radiation forwards. The fibers must be checked if they are in orderly state before they are used. If the tip of the fiber is not in orderly state the distal end needs to be cut with the fiber tool. After shortening the beam quality should be checked with the pilot laser.

### **Danger !**

With all applications of the RevoLix laser in the urogenital tract there is a danger of perforation. Therefore the laser may only be switched on if the distal tip of the fiber and its effect to tissue is under visual control of the surgeon controlling the foot switch. Start with low power settings.

#### **9.2.1 Incisions and excisions to the outer female genital**

**Laser accessories:** PercuFib laser fiber  
SlimLas laser handpiece

#### **Laser setting:**

Power setting	15 – 25 W
Mode	Continuous

#### **Preparation:**

Prepare the laser system according to section “Operation of the laser system”.

Make sure before the procedure that the existing fibers are compatible with the laser handpiece to be used.

Take care that the fibers can easily be introduced into the laser handpiece and taken out again. Check that the laser fiber can be fixed in the applicator.

#### **Procedure:**

1. Start the laser as described in the section on “Operation of the laser system”.
2. Insert the fiber in the laser handpiece. The non-sterile nurse attaches the fiber to the laser.
3. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak it could be that the fiber was damaged during insertion into the instrument. In this case the fiber should be prepared again using the fiber tool or different fiber should be used. If a damaged fiber is used, this can lead to severe damage and burns.
4. Understand this procedure is carried out in an gaseous medium (air) and charring will be stronger compared to endourological cases. At the begin use a low power setting; e.g. 15 Watts.

7. Use the “near contact” method for incision. Activate the laser with the foot switch while pulling the fiber end sideways across the tissue surface. It is advantageous to do so, because in this way the fiber end cannot remain hanging in the tissue. It is possible to undercut or to ablate the tissue.
5. Adjust the power setting in the light of your experience.

### 9.2.2 Condylomata

**Laser accessories:** PercuFib laser fiber  
SlimLas laser handpiece

**Laser setting:**

Power setting	5 - 15 W
Mode	Pulsed, 100 to 400 msec, or Continuous

**Preparation:**

Prepare the laser system according to section “Operation of the laser system”.

Make sure before the procedure that the existing fibers are compatible with the laser handpiece to be used.

Take care that the fibers can easily be introduced into the laser handpiece and taken out again. Check that the laser fiber can be fixed in the applicator.

**Procedure:**

7. Start the laser as described in the section on “Operation of the laser system”.
8. Insert the fiber in the laser handpiece. The non-sterile nurse attaches the fiber to the laser.
9. Check if the red pilot laser is emitted at full strength from the fiber. If it seems weak it could be that the fiber was damaged during insertion into the instrument. In this case the fiber should be prepared again using the fiber tool or different fiber should be used. If a damaged fiber is used, this can lead to severe damage and burns.
10. Understand this procedure is carried out in an gaseous medium (air) and charring will be stronger compared to endourological cases. At the begin use a low power setting; e.g. 5 – 10 Watts.
11. Use the “contact” method for ablation of condylomata. Activate the laser with the foot switch while pointing in near contact at the tissue to be ablated. Immediate blanching indicates the coagulation of the tissue.
12. Adjust the power setting in the light of your experience.

## 10 Error messages

### 10.1 Error menu

Throughout the period that the system is in operation continuous checks are carried out which, should they prove negative, give rise to warnings or errors. Every irregularity recognized by the system processor is displayed in clear text on the screen with a three-digit number, together with information on how to deal with it. 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 a error, the service technician must be informed. You will find the telephone number of your service technician in the section "Technical Data".

The error messages look like this:



Fig. 21: System menu with error message 012 (Fiber is missing)

### 10.2 List of error messages

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

All errors are to be listed in the medical systems book and passed on to the manufacturer.

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

No.	Error message	Explanation	Remedial measure
001	High temperature of cooling system Please wait for cool down !	High temperature of the cooling water.	Allow the laser to cool down – do not switch off. Be sure to operate the laser at no more than 28°C ambient temp. Do not cover air vents.
002	High temperature of laser power supply. Please wait for cool down !	High temperature of the laser power supply.	Allow the laser to cool down – do not switch off. Be sure to operate the laser at no more than 28°C ambient temp. Do not cover air vents.
003	Error message of microprocessor. Please restart system !	Internal error	Restart laser system.



004	Failure of pulse generator Please call service engineer !	Internal error	Restart laser system or call service engineer if error condition persists.
005	Failure of low voltage power supply Please call service engineer !	The low voltage power supply for microprocessors and electronics may be defective.	Restart laser system or call service engineer if error condition persists.
006	Power line failure Please check power line !	Mains supply may be out of range or the power line is defective.	Please have the mains supply checked by an electrician or call service engineer if error condition persists.
007	Cooling water flow failure Please call service engineer !	The cooling water flow rate is low.	Restart laser system or call service engineer if error condition persists.
008	Cooling water level failure Please call service engineer !	The level of the cooling water is low. Reason may be leakage or evaporation.	The laser should continue to operate. However the service engineer should be called immediately to check the system.
009	Chiller failure Please restart system !	Error condition in the chiller module.	Restart laser system or call service engineer if error condition persists.
010	Detector failure Please call service engineer !	Error condition in the power detectors.	Restart laser system or call service engineer if error condition persists.
011	Laser Stop button pressed Please release Laser Stop button !	Laser Stop button was activated.	Release Laser Stop button by turning it anti-clockwise.
012	No fiber Please connect fiber !	The laser fiber connector is detected if fully inserted. The laser will not operate until fiber is orderly connected.	Attach the laser fiber and secure the connector finger tight. Call service engineer if error condition persists.
013	Interlock open Please check interlock circuit !	Interlock circuit open or dummy connector missing.	Check interlock circuit or attach dummy connector.
014	Footswitch failure Please check the footswitch connector !	Footswitch signals not synchronized.	Check footswitch connector. May be the footswitch was depressed extremely. Press faster.
015	Footswitch not connected Please connect footswitch !	Footswitch not detected by laser system.	Connect footswitch.

## **11 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!

### **11.1 Cleaning**

The laser system does not require any particular maintenance on the part of the user. Surface cleaning using a damp cloth with suds or an alcohol solution may be undertaken. When doing this take care that no moisture can penetrate into the fiber port.

### **11.2 Technical safety control (STK=Sicherheitstechnische Kontrolle)**

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

### **11.3 Use of the external power meter**

The external power meter can be obtained from the manufacturer of the RevoLix (Section 14 "Accessories for RevoLix").

The pilot laser should be set to maximum brightness and an orderly fiber attached to the laser (section 8.2.2 "Connecting the fiber"). Before activating the laser all persons present in the laser area must wear appropriate safety goggles. The laser is activated by a foot switch, whilst the laser fibers pointed downwards. In doing this care is taken that persons are not endangered and that the laser beam does not cause unnecessary or dangerous heating of material.

With your free hand press the reset-knob on the power meter for 2 seconds, after which the black absorbent surface is brought into the laser beam. The red spot of the pilot laser should cover about 2/3 of the absorbent surface. If the measuring system gives out a series of three signal tones, the measurement is complete and the foot switch is released. The power meter displays the measurement obtained in watts for several seconds. Then, after a more rapid tone sequence, it returns to its rest position.



## 12 Technical data

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

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

### 13 Technical data RevoLix 50

Technical entity	Type
Laser type	Diode pumped solid state laser (DPSS)
Laser safety class	4 & 2 (pilot laser)
Emission wavelength	2 $\mu\text{m}$
Maximum power	50 W
Operational mode	Continuous wave (cw), pulsed (chopped)
Duration	50 ms to cw
Aiming beam (pilot laser)	Semiconductor laser, 635 nm, < 1 mW
Mains voltage	230 VAC, -13 %, +10 %
Mains current at 230 VAC	Max. 13 A
Earth leakage current	< 0.5 mA
Patient leakage current	< 0.1 mA
Storage ambient temperature	+3°C to 45°C
Operational ambient temperature	+18°C to 28°C
Cooling system	Integrated, refrigerant
Refrigerant	R134 A
Heat emission (peak)	3 kW
Heat emission (average)	App. 2 kW
Dimensions (Depth x width x height)	0.89 x 0.42 x 0.95 m
Weight	App. 140 kg

## 14 Accessories for RevoLix

The laser system may only be used with the following accessories:

Description	LISA order designation	Article no.
<b>Personal protective equipment</b>		
Colour neutral laser safety glasses for RevoLix with earpieces		101 503 142
Colour neutral laser safety goggles vfor RevoLix without earpieces		101 503 143
<b>General Surgery</b>		
Standard hand applicator, straight	SlimLas	101 503 106
Standard hand applicator, 15°	SlimLas 15°	101 503 107
Standard hand applicator, 30°	SlimLas 30°	101 503 136
Cleaning wire for SlimLas	Cleaning wire 0.7 mm	101 503 111
Laser handpiece for ENT	ENTLas	101 503 167
PercuFib fiber (365 µm optical core)	PercuFib	101 503 128
<b>Fiber repair tools</b>		
Stripping tongs for PercuFib	Fiber-Stripper 0.5	101 503 129
Fiber cutter for fiber cleaving	Fiber cutter	101 503 110
<b>Laser accessories:</b>		
Inspection microscope for fiber connector	Inspection microscope	101 503 145
Laser power meter	PED	101 503 140

Attention is specifically drawn to the fact that only laser fibers supplied by the laser manufacturer (LISA laser products OHG) may be connected to the laser system. So-called SMA compatible products made by other manufacturers could cause costly damage to the laser optics in the fiber coupler.

Additional accessories to be used must be specifically certified by the accessory manufacturer as being compatible for use with the RevoLix

Please ask the laser manufacturer about additional accessories available for the system.



## **15 Conformity declaration**

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



## 16 ISO certificates

The following pages contain photocopies of the DIN EN ISO 9001 and DIN EN 46001 ISO certificates issued by the TÜV Product Service, Munich for *LISA laser products OHG*.

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