

2 Micron Surgical Continuous Wave Laser

RevoLix Jr.

User Manual





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1 About this manual

This manual contains important information concerning the safe handling of the medical 2 micron continuous wave laser, RevoLix Jr.

This manual must be read carefully before using the laser device 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 device for the first time, you should read through this manual carefully and keep it for future reference, is also considered to be part of the safe operation of this product.

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

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

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

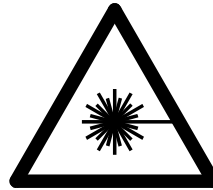


Fig. 1: Symbol for Danger

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

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



Fig.2: Symbol for Warning



2 Manufacturer

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



3 Distributor in the United States of America

AllMed Systems, Inc.
9232 Klemetson Drive
Pleasanton CA 94588
USA
Tel: +1 - 925 468 0433
Fax: +1 - 925 399 5984
e-mail: pallen@allmedsys.com
web: www.allmedsys.com

CAUTION: US federal law restricts this device to sale by or on the order of a physician!



4 Scope of this user manual

The regular scope of supply includes:

RevoLix Jr. laser system	qty.	items included
RevoLix Jr. 2 micron cw medical laser	1	RevoLix Jr. 2 micron cw medical laser
	1	Foot switch
	1	Door-interlock dummy connector
	1	User manual
	2	Laser warning signs
	3	Laser safety glasses



5 Important customer information

This manual describes the medical 2 micron continuous wave lasers of the RevoLix Jr. series. The power range (max. power) and the name of the laser in question is to be found on the name plate (Fig. 8). The name of the laser appears on the start display (Fig. 19) after switched on.

The laser systems belongs to the following classifications/nomenclatures:

Medical product class according to MDD 93/42/EEC (Medical Device Directive)	Class IIb
Medical Device Class according to Title 21 of CFR, Parts 862-892	Class II
Medical product nomenclature according to UMDNS	17-447
Laser class according to IEC 60825	Class 4 / IV
Protection class according to IEC 60601	Class I
Protection group according to EN 60529	IP20

The RevoLix Jr. laser system complies with the "Essential Requirements of the European Medical Devices Directive 93/42/EEC"

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

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

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

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

6 General description

The RevoLix Jr. medical 2 micron continuous wave laser is a high-performance, fiber coupled, diode pumped solid state (DPSS) laser for medical use in surgery (Chap. 10 “Clinical applications”). The wavelength is invisible infrared.

The RevoLix Jr. emits radiation at a wavelength of 2013 nm (equal to 2.013 micron). 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 the Section “**Error! Reference source not found.**”.

6.1 Basic physico-technical principles

The RevoLix Jr. 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 micron laser radiation. The 2 micron laser beam is focused into a fiber. The 2 micron laser radiation emitted from the fiber – guided by a suitable applicator serves as the surgical instrument.

The laser-tissue-interaction is based on the strong absorption of 2 micron 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.

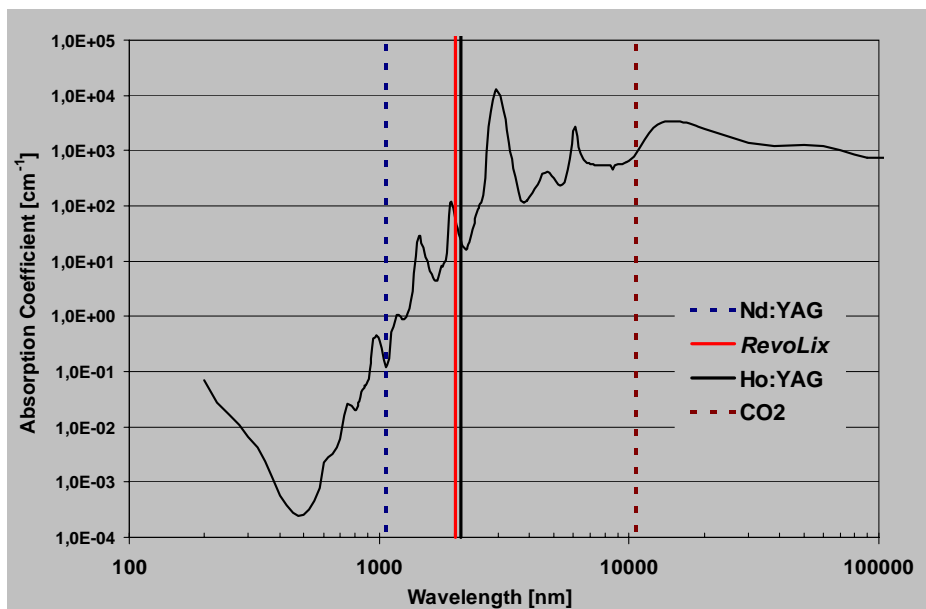


Fig. 1: Absorption spectra of water with laser wavelengths

6.2 Basic physico-medical principles

The effect of the 2 micron 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).

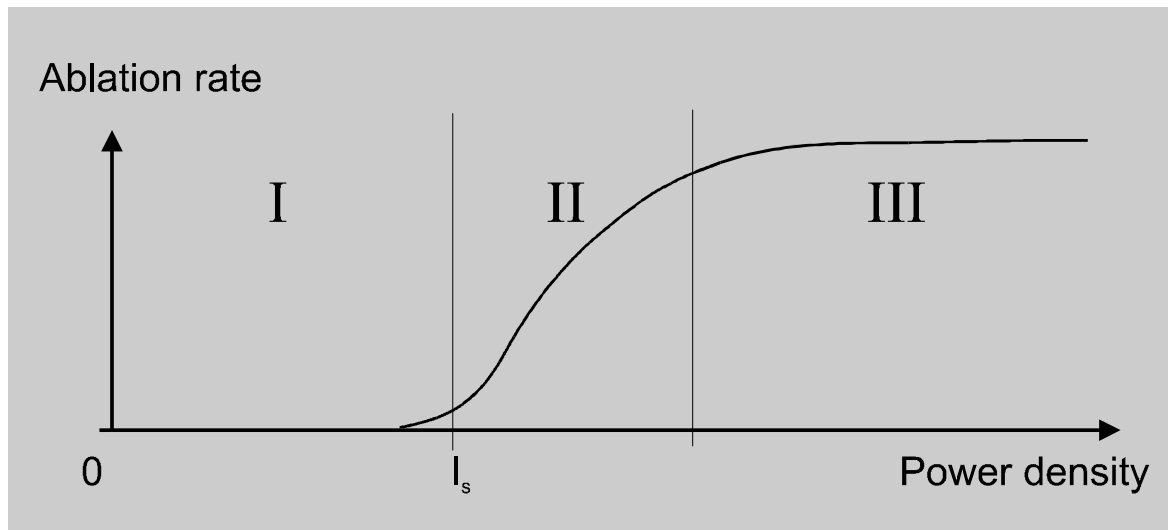


Fig. 2: Tissue effect depending on power density

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.

6.2.1 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 Jr. 2 micron 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.

6.2.2 RevoLix Jr. pulsed mode

The RevoLix Jr. may be operated in a pulsed mode as well. However the pulse peak power of the 2 micron 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 micron cw laser radiation is incapable of ablating hard tissue like bone and stone.

6.3 Intended use of the RevoLix Jr. medical 2 micron continuous wave laser

The RevoLix Jr. 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 micron 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, 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

6.3.1 Power setting

The power setting determines how much tissue may be coagulated or evaporated per unit of time. Because the RevoLix Jr. 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".

6.3.2 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.

6.3.3 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 micron fiber is at the same level as the beam emerging from a 600 micron 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”.

6.3.4 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 near contact mode if cutting or ablating tissue. 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 micron radiation in water.

6.3.5 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 micron 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.

6.3.6 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 micron 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 micron 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.

7 Laser and device safety

The RevOLix Jr. laser uses as the working beam a DPSS laser with an emission wavelength of 2 micron. According to IEC 60825 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 micron 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.

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.



DANGER

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

Never point the laser beam at a person!

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

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



DANGER

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

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



DANGER

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

Use an appropriate smoke evacuation.



DANGER

The function of the RevOLix Jr. may be affected by mobile or cordless phones and other HF-communication devices.

Do not use mobile or cordless phones and other HF-communication devices during operation of the RevOLix Jr.

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

7.1 Marking of entrance doors to laser areas

All entrance doors to the operating theatre (=laser area), in which the laser system is set up and operated, are to be marked on the outside with the following warning sign in accordance with IEC 60825 (or the relevant local regulation) (original black on yellow).

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



Fig. 3: 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. Marking of the laser system

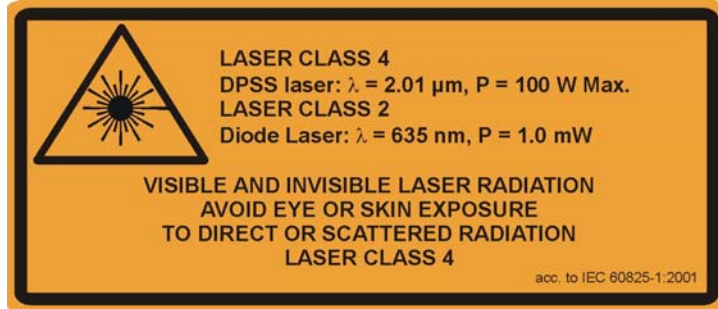
This Chapter describes the type and the location of the danger and regulatory compliance labels of the RevoLix Jr. laser. From the labeling of the system the user gets important information regarding the device and the safety of laser devices. The labeling has to follow the applicable standards and regulations.

7.1.1 Laser Warning Labels

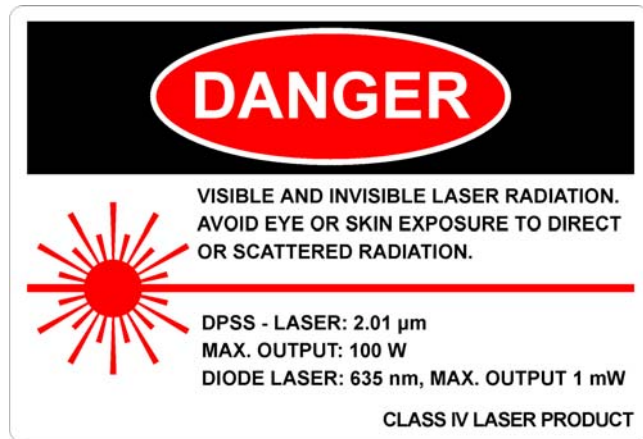
The following signs are attached to the back of the laser, (original black on yellow). They show the laser class and output. (Fig. 4)



Warning Label Laser Class



Warning Label Laser Output



Warning Label Laser Output (USA only)

Fig. 4: Laser Danger Label

7.1.2 Beam outlet (fiber port)

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

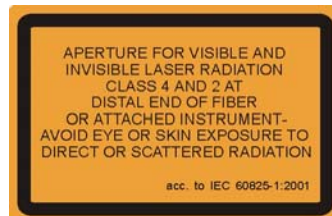
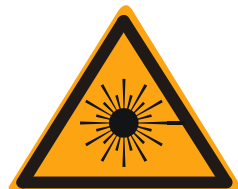


Fig. 5: Warning Labels Beam outlet

7.1.3 Laserstop

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

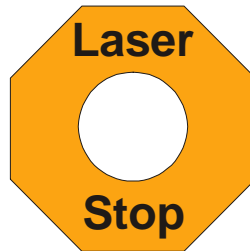


Fig. 6: Marking of the Laser-Stop Button

7.1.4 Danger Label Electric Energy

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



Fig. 7: Danger Label Electricity

7.1.5 Name Plate

The name plate is attached to the outside of the back door. It comprises all the necessary data for the identification of your laser system (Fig. 8).



Fig. 8: RevoLix Jr. Name Plate

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

Fig. 9: Marking of the Modules

7.1.6 Distributor Label (USA)



Fig. 10: Distributor Label (USA)

7.1.7 Position of Labels

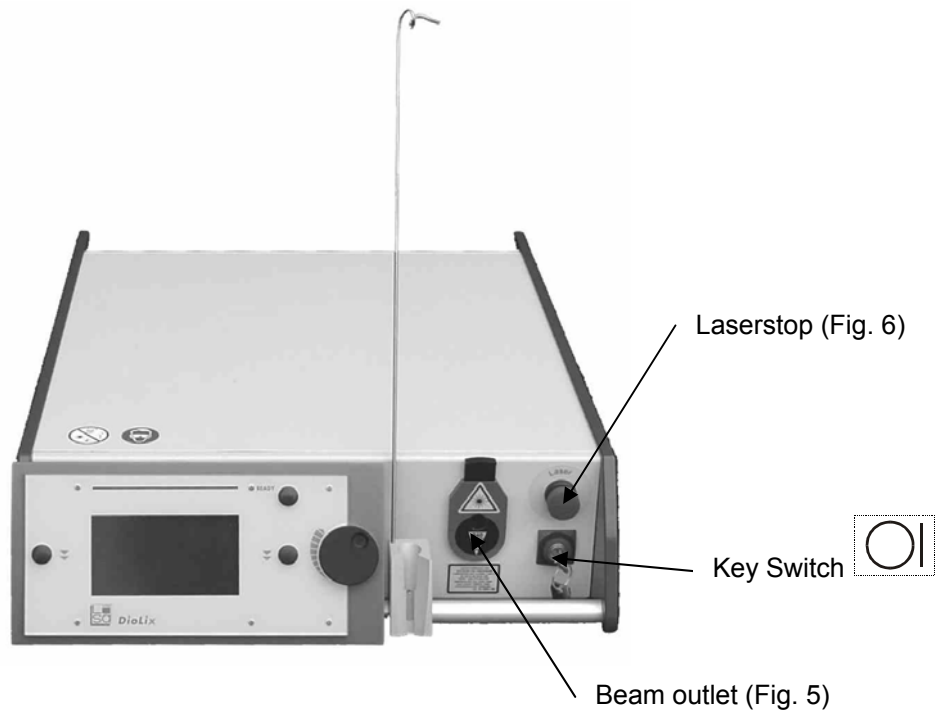


Fig. 11: Labels at the front of the device

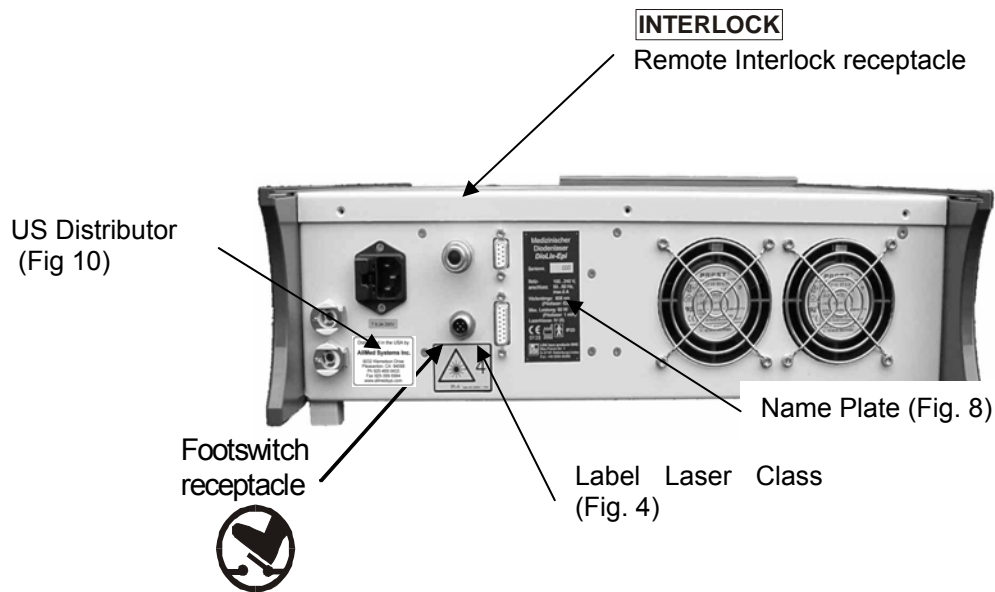


Fig. 12: Labels at the back of the device

7.2 Laser safety eyewear

7.2.1 NOHD - "Nominal Ocular Hazard Distance" for RevoLix Laser

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

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

Wavelength	$\lambda = 2,01 \text{ micron}$
Numerical aperture of fiber	NA = 0,22 $\phi = 25,4^\circ = 0,443 \text{ rad}$
Fiber diameter	a = 365 micron
Average power	$P_0 = 100 \text{ W}$
time basis	t = 10 s
MPE (Maximum Permissible Exposure Limit)	$5600 t^{0,25} \text{ J m}^{-2}$

$E_{MPE} =$	$5600 (10 \text{ s})^{-0,75} \text{ W m}^{-2} = \underline{995.83 \text{ W m}^{-2}}$
-------------	--

$$NOHD = \frac{\sqrt{\frac{4P_0}{\pi E_{MPE}} - a}}{\Phi}$$

NOHD = 0,81 m

Therefore the NOHD for the RevoLix is: 0.81 m.

7.2.2 Required eye protection

The laser area is considered to be that area, in which the amount of radiation or the radiation can exceed the current maximum permitted radiation of the cornea of the eye (MPE), including the possibility of a random unintended deviation of the laser beam. Usually the laser area is identical to the room, in which the laser is installed. The worst case Nominal Ocular Hazard Distance (NOHD) of the RevoLix laser is 0.8 m.

All personnel who are within the NOHD are considered to be within the laser area and shall wear suitable eye protection supplied by the manufacturer/distributor of the laser system with a minimum protection class (acc. to EN 207) of: **L2** (at 2.01 micron)

7.3 Laser safety officer

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

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

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

7.4 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 RevoLix laser system is intended solely for physicians trained in the use of the laser system.

7.5 System book, medical systems book

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

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

1. Training of the personnel responsible for the laser system

* MERGEFORMAT REVOLIX JR. USER MANUAL.DOC

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2. Training of skilled operators
3. Technical safety controls
4. Maintenance measures and
5. Functional errors.

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

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

8 Installation of the laser device

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.

8.1 Transportation and storage of the laser device

During transportation and operation of the RevoLix Jr., care must be taken to ensure that the device 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.

8.2 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 7.1 "Marking of entrance doors".

8.3 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.



8.4 Mains connection

The mains connection is via a standard plug (voltage 100 – 240 V AC, current 6 A maximum, 50/60 Hz), the exact requirements for the laser device in question can be seen from the name plate.

8.5 Cooling

The RevoLix Jr. medical diode lasers have an integrated air/water cooling system.

While the laser is being operated this cooling system draws off the resultant dissipation power into the room air.

In rooms, which are not air-conditioned, one should take account of a corresponding warming of the room air. The laser may be operated continuously at an ambient temperature of up to about 28 °C. The device switches off automatically if the ambient temperature becomes too high. (section 11).

The ventilation grilles on the bottom and at the rear of the laser device must not be covered during operation of the laser device.

An additional cold water or gas connection is not necessary.

8.6 Connecting the foot switch

The plug at the free end of the foot switch cable is plugged into the lower socket on the back of the device (Fig.) and screwed tight. The plug will only fit in one particular way. All electrical connections to the laser device are designed so that they are not interchangeable.

For ease of control the foot switch and the distal end of the laser fibers attached to the laser device should be as close as possible to each other.

8.7 Connecting a door-interlock switch

A door-interlock switch can be plugged into the upper socket (Fig.12) 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 plug supplied must be plugged into the free socket. The dummy plug is fitted with a bridge between pin 1 and pin 3.

When the door-interlock switch circuit is broken – or the bridge between pin 1 and pin 3 – the laser is immediately de-activated. After the door-interlock switch has been closed again the laser can only be operated again after pressing the 'ready' button (No. 3 in Fig.17).

9 Operation of the laser device

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

The actual "Start-up and switch-on routine" is described below in sub-section 9.3. In that sub-section it will also be shown how the correct state of the laser device can be ascertained.

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

9.1 Operating and display components

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

9.1.1 Back of the device

All the electrical connections and the connection for filling and draining the water cooler are to be found on the back of the device.

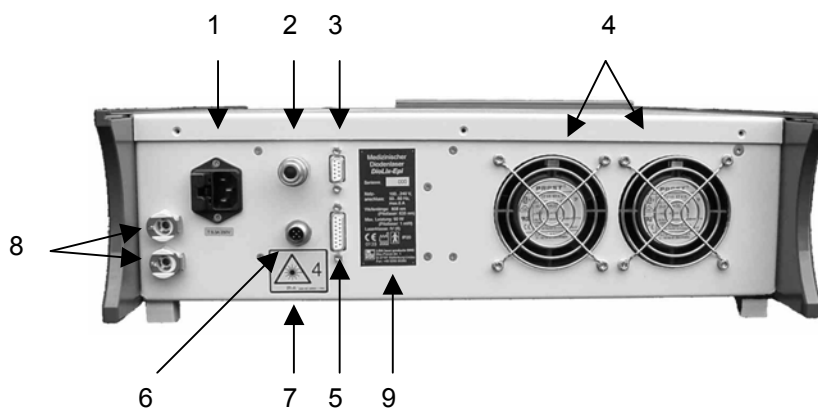


Fig.15: Back of the device

1	Mains connection	6	Foot switch connection
2	Door-interlock connection	7	Marking of the laser
3	Serial interface	8	Connection for draining and filling the cooling water
4	Venting	9	Name plate
5	Expansion interface		

9.1.2 Front of the device

All the important operating and display components, together with the emergency off button and the key switch for operating the laser, are located on the front of the device. (Fig.16 shows the RevoLix Jr. laser).

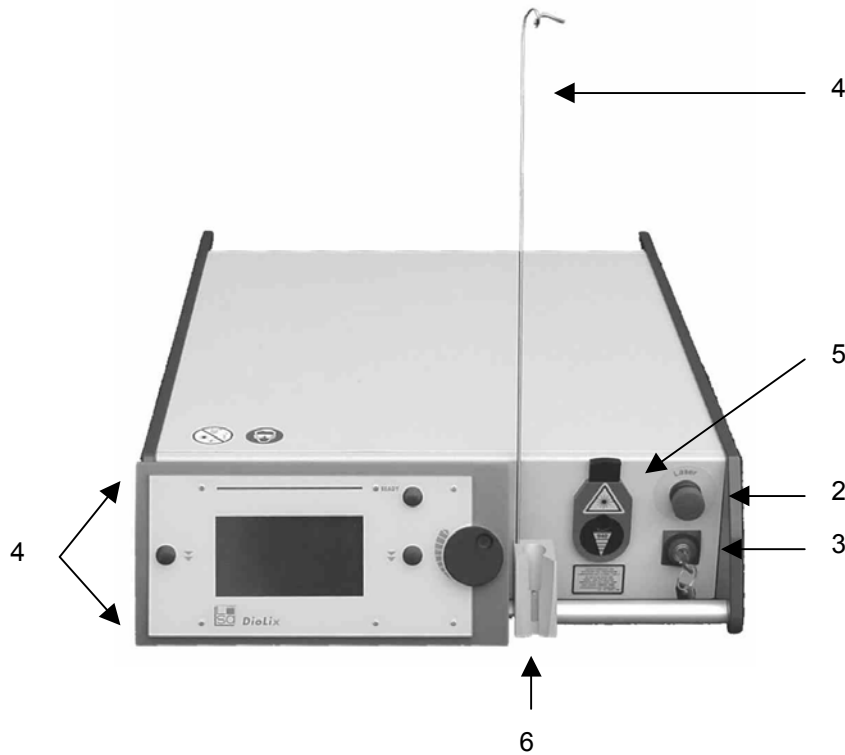


Fig.16: Front of the device

1	Operating console	4	Fiber holder (may be put into a handpiece holder)
2	Emergency off button	5	Beam outlet with beam lock
3	Key switch	6	Handpiece holder

9.1.3 Operating console

All communication between the operator and the laser device runs via the adjustable operating console.

The output units of the laser device are the 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.17: Operating console

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

9.2 Attaching the laser fiber to the fiber port

9.2.1 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.

9.2.2 Connecting the fiber to the laser

1. Check the orderly state of new fibers and the connector (see above).
2. Open the beam lock (**Error! Reference source not found.**) 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 18)**



Fig. 18: Connecting the fiber

9.2.3 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.


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

9.3 Start-up and switch-on routine

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

the necessary safety precautions (section 7 “Laser and device safety”) have been taken

4. the foot switch is attached and the laser system is connected to a suitable power supply.
5. if necessary the door-interlock dummy connector is connected,
6. a laser fiber is connected or the beam lock is closed,
7. the necessary laser fibers and laser applicators are to hand and
8. 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.

	<p>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.</p>
<p>DANGER</p>	

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 front 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.) 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.) (section 9.4 “Setting the laser parameters”).

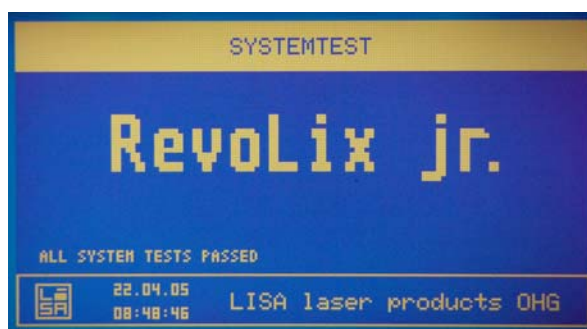


Fig. 19: Start display after switch on the laser system

Possible error messages during the start-up routine appear on the screen in clear text (Section 11 “Error messages”).

3. The desired operational mode or the system menu is selected with the menu button (Section 9.1.3 “Operating console”).



4. After activating the 'Ready' button the laser is switched from "**Standby**" 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 9.4 "Setting the laser parameters") should be adjusted.
5. 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.

6. Before the laser is used on a patient, the user must become conversant with the orderly state of the laser system (Section 9.7 "Orderly state of the laser system").

9.3.1 Operational states of the system

During operation two different operational states are possible:

1. **Stand-By:** The system is fully operational but is not yet ready to emit laser radiation. The laser warning lamp (No. 2 in Fig 17) and the pilot laser are not yet switched on. This state is reached after the start-up.
2. **Ready:** By activating the 'ready' button once (No. 3 in Fig 17) 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.

9.4 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.).



Fig. 20: Parameter menu after switch on the laser system (Power setting 15 W)

The following abbreviations are used:

- Power (or Max. Power)** Power of the 2 micron laser power available from the distal end of the handpiece or the fiber at this setting.
- 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.
- Duration** Pulse duration at this setting (ON TIME).
- Repetition** Pulse repetition rate at this setting (how often the pulse is emitted per second)

9.5 Status display on the monitor

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

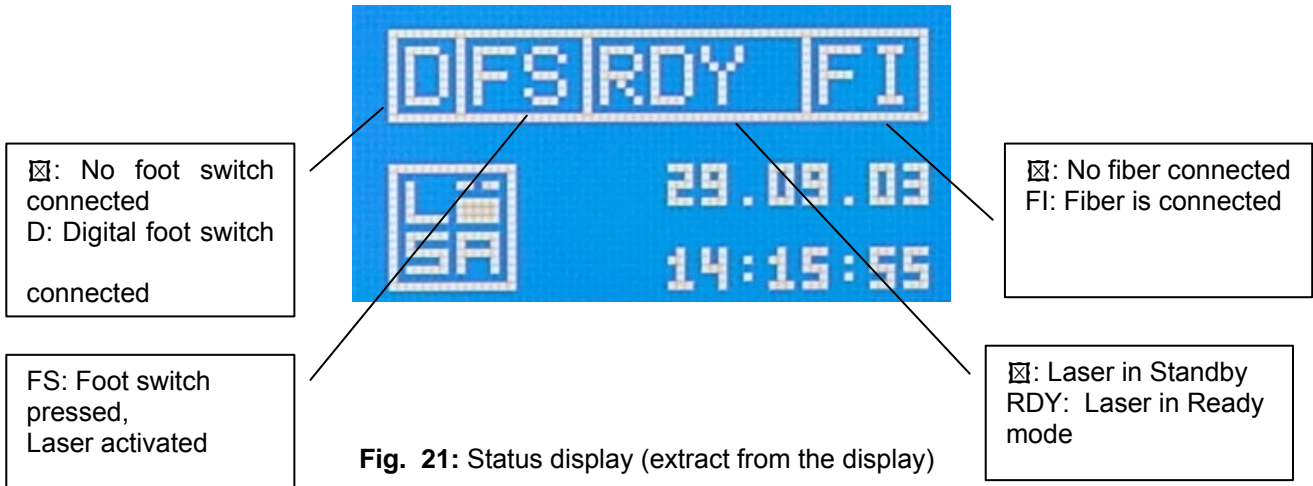


Fig. 21: Status display (extract from the display)

9.5.1 Operational mode selection

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

By pressing the menu selection button (No.1 in Fig 17) left to the display, it is possible to toggle between CONTINUOUS operation (Fig.), PULSED operation (Fig. 23), SINGLE pulse operation (Fig. 24) and the SYSTEM menu (Fig. 25). The selected mode is highlighted in white.



Fig. 22: Parameter menu for continuous mode

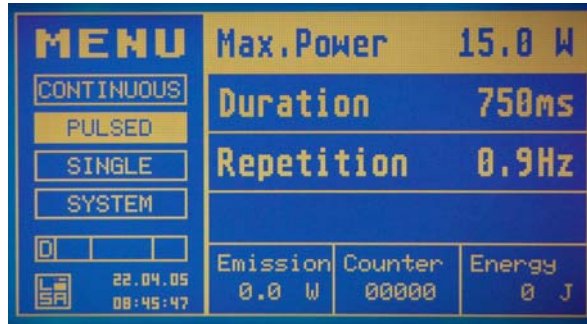


Fig. 23: Parameter menu pulsed mode

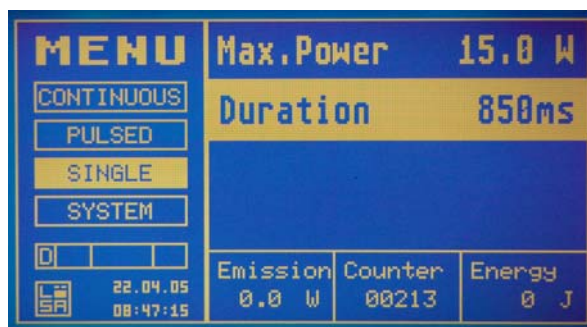


Fig. 24: Parameter menu for single pulse operation



Fig. 25: RevoLix Jr. system menu

9.5.1.1 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 17) 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 “**STANDBY**”. After setting the power the “Ready Button” has to be pressed again for “**READY**”.



9.5.1.2 Setting the treatment parameters for pulsed and single-pulse operation

Repeated pulsed mode operation is selected by pressing the parameter selection button (Fig 17, No. 1) until PULSED is highlighted. In this mode POWER (pulse 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.

9.5.1.3 Setting the brightness of the pilot laser / aiming beam

The brightness of the pilot laser / aiming beam (635 nm emission wavelength) can be adjusted in the CONTINUOUS, PULSED or SINGLE menu by choosing aiming beam and turning the adjusting wheel between 0 and 100%. Maximum setting (= 100 %) is 0.95 mW from the orderly fiber. The pilot laser is ON in the Ready state. After switching on the system the brightness of the pilot laser is automatically set to 30 % whenever the setting was below 30 % before switching off the system. Otherwise the set value is kept.

9.6 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.

9.7 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.

The following text is based on the experiences of users of RevoLix Jr. medical 2 micron 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.

The given parameters are provided as a guide. Adjust the parameters individually according to your treatment experiences, clinical observations and the laser-tissue interaction.

Take note of the relevant safety regulations (section 7 "Laser and device safety") and follow the instructions of your establishment's laser safety officer.



DANGER

Whenever a laser or specifically a RevoLix Jr. 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.

10 Clinical applications

The following text is based on the experiences of users of RevoLix medical 2 micron 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.

The given parameters are provided as a guide. Adjust the parameters individually according to your treatment experiences, clinical observations and the laser-tissue interaction.

Take note of the relevant safety regulations (section 7 "Laser and device safety") and follow the instructions of your establishment's laser safety officer.



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.

DANGER

10.1 Urology

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

Removal of urethral strictures

Bladder neck incisions

In-situ ablation of bladder tumors

Condylomata



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 fibre and its effect to tissue is under visual control of the surgeon controlling the foot switch. Start with low power settings.

DANGER

The tissue effects of the RevoLix medical 2 micron 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 authorized 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 sterilization can be found on the packaging and in the laser fiber user manual. It is preferable to choose a sterilization process, which operates at the lowest possible temperatures (< 90°C) in order to exclude oxidization of the fiber connector. By principle autoclaves operate at 121°C minimum temperature. Therefore this method of sterilization 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.

10.1.1 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.

10.1.2 Bladder neck incisions

Laser accessories: PowerFib laser fiber,
Laser resectoscope

Laser setting:

Power setting	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 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-sterilized 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.
6. The surgical procedure is almost identical to the regular "Turner Warwick" procedure.
7. Adjust the power setting in the light of your experience.



10.1.3 In-situ ablation of bladder tumors

Laser accessories: PowerFib laser fiber,
Laser resectoscope

Laser setting:

Power setting	10 – 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 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-sterilized 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.



10.1.4 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 a 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.

10.2 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 micron 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 authorized 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 sterilization can be found on the packaging and in the laser fiber user manual. It is preferable to choose a sterilization process, which operates at the lowest possible temperatures (< 90°C) in order to exclude oxidization of the fiber connector. By principle autoclaves operate at 121°C minimum temperature. Therefore this method of sterilization 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 fibre and its effect to tissue is under visual control of the surgeon controlling the foot switch. Start with low power settings.



10.2.1 Incisions and excisions to the outer female genital

Laser accessories: PercuFib laser fiber
SlimLas laser handpiece

Laser setting:

Power setting	10 – 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 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. 10 Watts.
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.

10.2.2 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:

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.

11 Error messages

11.1 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:

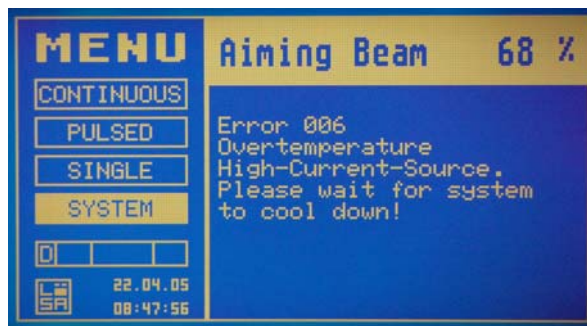


Fig. 26: System menu with error message 006 (Overtemperature High-Current-Source)

11.2 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	Overtemperature of cooling system. Please wait for system to cool down!	Overtemperature of the cooling water ($T > 32^{\circ}\text{C}$).	Machine must cool down – do not switch off.
002	Fail Detector. Please call a service engineer!	Relative deviation of the two mutually monitoring detection channels.	Note the fault number and operational conditions and ring the service department.



No.	Error message	Explanation	Remedial measure
003	Laser-Stop-Button pressed. Please release Laser-Stop-Button!	Laser-Stop-Button pressed.	Release the Laser-Stop-Button by twisting it.
004	Fiber is missing. Please check fiber!	Fiber not inserted (or incorrectly inserted) when switching to 'ready' mode.	Attach fiber correctly.
005	Interlock. Please check interlock circuit!	Interlock contact open.	Connect interlock plug or close door.
006	Overtemperature High-Current-Source. Please wait for system to cool down!	Mains supply unit not ready, since the cooling element temperature is over 65°C.	Note the fault number and operational conditions and ring the service department.
007	Fail Laser-Head-Controller. Please call a service engineer!	Fault in the power supply to the laser head controller (LHC)	Check the cabling or note the fault number and operational conditions and call the service department.
008	Fail pulse generation. Please call a service engineer!	Fault in the generation of the pulse signal at the control board (SCU)	Note the fault number and operational conditions and ring the service department.
009	Fail ground connect footswitch. Please check the footswitch connector!	Fault in the ground connection to the footswitch input.	Check connections to the analogue input as well as the maximum input voltage.
010	Fail flow of cooling-water. Please call a service engineer!	Too little flow in the cooling system.	Note the fault number and operational conditions and ring the service department.
011	Fail water-level. Please call a service engineer!	Water level in the tank too low.	Note the fault number and operational conditions and ring the service department.
012	Internal fail message of processor. Please restart the system!	Unexpected software fault.	Restart the system Note the fault number and operational conditions and ring the service department.
013	Fail Pump-Power-Supply. Please call a service engineer!	Fault in the power supply to the cooling pump.	Note the fault number and operational conditions and ring the service department.



No.	Error message	Explanation	Remedial measure
014	Fail System-Control-Unit. Please restart the system!	Fault in the control board (SCU).	Restart the system Note the fault number and operational conditions and ring the service department.
015	Fail clock generation. Please restart the system!	Fault in the generation of the processor clock on the control board (SCU).	Note the fault number and operational conditions and ring the service department.
016	Fail power line. Please check power line!	Interruption of MVS supply.	Check the mains connection at the output voltage on the PFC.
017	Fail Low-Voltage-Supply. Please call a service engineer!	Defect on one of the low voltage supply units (LVM).	Note the fault number and operational conditions and ring the service department.
018	Hardware message of external system:	Fault message relating to an external accessory.	Note the fault number and operational conditions and ring the service department.
019	Hardware	Unexpected hardware fault.	Note the fault number and operational conditions and ring the service department.
020	Fail Control-System. Please restart the system!	Notification of an SCU fault by the hardware monitoring system.	Restart the system Note the fault number and operational conditions and ring the service department.
021	Chiller fault. Please restart the system!	Temperature of the cooling system outside the operational specifications.	Restart the system Note the fault number and operational conditions and ring the service department.
022	Laser-Stop-Button pressed. Shut down System and release Laser-Stop-Button!	Laser-Stop-Button pressed.	Switch off system, release Laser-Stop-Button and restart system.
023	Fail Activate-RELEASE. Please call a service engineer!	The system's fault processing is faulty.	Note the fault number and operational conditions and ring the service department.
024	Undertemperature of cooling system. Please wait for system to warm up!	System at too low a temperature (i.e. below 12°C) caused, e.g. by the ambient conditions.	Switch on the cooling system and wait for the operation of the pump to warm it up.



No.	Error message	Explanation	Remedial measure
025	Footswitch not connected. Please connect footswitch!	Footswitch not connected or incorrectly connected	Check the footswitch plug
026	Fail Deactivate-RELEASE. Please call a service engineer!	The system's fault processing is faulty.	Note the fault number and operational conditions and ring the service department.
027	Fail activate flow error. Please call a service engineer!	Fault in the cooling system.	Note the fault number and operational conditions and ring the service department.



12 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!

12.1 Cleaning

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

12.2 Technical safety control and maintenance

Every 12 months the laser system should undergo a technical safety control and maintenance by a service technician authorized by the manufacturer to ensure proper laser performance.

12.3 Calibration of the energy and power displays

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

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

$$\text{Calibration factor} = \text{Reading of the external laser power meter} / \text{Power reading on laser display}$$

If the power deviation is greater than 20% then call your authorized LISA service center 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:

$$\text{Power} = \text{Calibration factor} * \text{Power reading on laser display}$$

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

12.4 Use of the external power meter

The external power meter can be obtained from the manufacturer of the RevoLix Jr. (Section 16 "Accessories for RevoLix Jr.").

The pilot laser should be set to maximum brightness and an orderly fiber attached to the laser (section 9.2.2 "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.



13 Decontamination of Returned Equipment

To comply with the U.S. postal and transportation laws, equipment shipped to AllMed Systems Inc 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 (provided at the end of this section) must be enclosed in the package.

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

Any inquiries should be directed to AllMed Systems Medical Service Department.

**AllMed Systems Inc.
9232 Klemetson Dr.
Pleasanton, California
94588 USA
Fon: (925) 469 0433
Fax: (925) 399 5984**

For service assistance and to order replacement parts or accessories, call AllMed Systems Service / Customer Relations at the following telephone number: 925 468 0433



DECONTAMINATION CERTIFICATION

Under the provisions of Postal Law, Title 18, United States Code, Section 1716, and Department of Transportation rules contained in CFR 49, Section 173.386 and 173.387, "etiologic agents, diagnostic specimens and biological products... are non-mailable..."

The undersigned therefore certifies that the AllMed Systems equipment being returned herein by

Individual/Institution

City/State

has undergone decontamination with a commercially available germicide cleared for use as a "Hospital Disinfectant" and is clean and free from biohazards, including, but not limited to, human or animal blood, tissue or tissue fluids or components thereof.

The undersigned also agrees to reimburse AllMed Systems for any costs incurred in cleaning the enclosed equipment, in the event said item(s) is/are received by AllMed Systems in a contaminated condition.

Model

Serial Number

AllMed Systems RMR Number

Printed Name

Position/ Title

Signature

Date



14 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
web: www.lisalaser.com

15 Technical data RevoLix Jr.

Technical entity	Type
Laser type	Diode pumped solid state laser (DPSS)
Laser safety class	4 & 2 (pilot laser)
Emission wavelength	2.01 micron
Maximum power	30 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	100 - 240 VAC,
Mains current at 230 VAC	Max. 6 A
Storage ambient temperature	+3°C to 45°C
Operational ambient temperature	+18°C to 30°C
Cooling system	Air / water heat exchanger
Coolant	Distilled Water
Dimensions (Depth x width x height)	approx. 58 x 48 x 15 cm
Weight	App. 20 kg

16 Accessories for RevoLix Jr.

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

Description	LISA order designation	Article no.
Personal protective equipment		
Colour neutral laser safety glasses for RevoLix with earpieces		101 503 142
Colour neutral laser safety goggles for RevoLix without earpieces		101 503 143
General Surgery		
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 micron optical core)	PercuFib	101 503 128
Fiber repair tools		
Stripping tongs for PercuFib	Fiber-Stripper 0.5	101 503 129
Fiber cutter for fiber cleaving	Fiber cutter	101 503 110
Laser accessories:		
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



17 Conformity declaration

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



EU-Konformitätserklärung
EU-Declaration of Conformity
UE-Déclaration de Conformité



Hersteller: LISA laser products OHG
Manufacturer:
Entreprise:

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

erklärt in eigener Verantwortung, dass die Produkte mit den Bezeichnungen
declares at its own risk the designated products
explique dans propre responsabilité que le produits avec la désignations

Produktbezeichnung: RevoLix
Product Designation:
Désignation du produit:

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

93/42/EWG Medizinprodukte-Richtlinie

LISA laser products OHG

Katlenburg-Lindau,

(Ort)

(Datum)

(Geschäftsführer)

LISA laser products OHG, D-37191 Katlenburg-Lindau, Max-Planck-Straße 1, Germany
Tel. +49 (0)5556-9938-0, Fax +49 (0)5556-9938-10
KEmdl01KonformitaetsErklaerung.doc - gedruckt am 28.03.03



18 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*.

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

CERTIFICATE



No. Q1Z 02 11 11426 010

TÜV PRODUCT SERVICE GMBH certifies that the company

LISA laser products OHG

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

in the facility:

LISA laser products OHG, D-37191 Katlenburg-Lindau

within the scope:

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

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

EN 46001: 1996

EN ISO 13485: 2000

Quality Systems - Medical Devices -

Particular Requirements for the Application of

DIN EN ISO 9001: 1994

as documented in audit report no. 70029614.

This certificate is valid until 10/2005.

Munich, 11-20-2002

TÜV PRODUCT SERVICE GMBH
ACCREDITED CERTIFICATION BODY
FOR QUALITY SYSTEMS



Akkreditiert durch



vertreten im **ZLG-ZQ-999.98.12-46**



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



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