# User Manual

# Q-LAS


**PHOTODISRUPTOR**
**Q-Switch Nd:YAG Laser**
With Slit Lamp

**A.R.C. Laser GmbH**

| | | | |
|---|---|---|---|
| CE 0483 | Bessemerstr. 14<br>90411 Nürnberg | Tel.: +49 911 21779-0<br>Fax: +49 911 21779-99 | info@arclaser.de<br>www.arclaser.de |

Please contact for Service:

A.R.C. LASER GmbH
Bessemerstr. 14
D-90411 Nürnberg

Tel.: +49 911 21779-0
Fax: +49 911 21779-99
service@arclaser.de

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| Autor: | Markus Barten, Markus Graf |
| Inspected: | Dr. Walker |


PHOTODISRUPTOR
Q-Switch Nd:YAG Laser

With Slit Lamp

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# 1 Introduction

We appreciate your decision to purchase the Q-Las Laser and wishing you a productive and successful usage with this multi-functional laser system.

The Q-Las Laser generates a high-intensity laser beam which may induce injuries in improper handling. Therefore, this User Manual should be read carefully before using the device. Should you have any further questions regarding safety, the use of the device, or concerning laser and laser radiation, please contact A.R.C. Laser GmbH or your local authorized dealer (see Section 10.3 "Sales and Service - Information").

**A T T E N T I O N !**

We are obliged by local laws to sell this device only to licensed physicians, through our local authorized dealer which holds a valid MDEL (Medical Device Establishment License).

## 1.1 Copyright



## 1.2 Marking and Symbols

The international sign **"Attention"** is attached to all surfaces, which are hazardous for the user. Before carrying out any further works at such marked parts, please read the user manual or contact your local dealer or contact directly to A.R.C. Laser GmbH service department.

The laser radiation sign warns the user against aiming laser beams to undesired surfaces by improper handling. The laser beams of this device are not visible. When using the protection goggles filtering such beams, the user can neither identify nor see the beams.

## 1.3 Intended Use

The Nd:YAG Laser is emitting a wavelength of 1064 nm. This laser-light is modified by a Q-Switch to create short pulses with 4 to 10 ns. These pulses have a power of ca. 40 mJ and can create an optical breakthrough after focusing.

This laser goes through a slit lamp and will be focussed by a short lens or guided through a contact glass.

**Capsulotomy**

The intention is to create an optical breakthrough in the case of posterior cataract. A posterior subcapsular cataract starts as a small, opaque area that usually forms near the back of the lens, right in the path of light on its way to the retina.

Prof. Aron Rosa, Paris and Prof. Fanckhauser, Bern described this technology first. Opening the capsule (secondary Cataract) has been practiced since 1990. It is an elegant way to open the capsule and the preferred method by ophthalmologists all around the world.

**Indications for Capsulotomy:**

- The loss of function for the individual visual requirements (eg, office or home) caused by posterior cataract, or eligibility requirements interfere with or endanger (eg roadworthiness) of the patients.
- Compelling medical reasons (obstruction fundus view). In general an optical breakthrough will be created.

**Iridotomy**

With several pulses will be made with puncture-like openings through the iris without the removal of iris tissue. It is typically used to decrease intraocular pressure in patients with angle-closure glaucoma.

**Indicationen for Iridotomy:**

- Non efficient control of the intraocular pressure by any other means
- Closed angle glaucoma

**Contraindications**

- Eyes that have no potential visual function
- Eyes with corneal defects such as lesions, scars, edema or a cloudy cornea
- Cloudy intra-ocular media or opacities within the eye. Focussing might become impossible or the laser could be absorbed with harmful side effects.
- Ocular inflammations
- If the device is not focussing
- Eyes that have a glass intraocular lens as there is a risk of fracture of the glass
- Disability of the patient to sit in front of the slit lamp, open the eye and keep the position and the eye open for minimum 2 minutes

**CAUTION -** The device may only be used by physicians that undergone appropriate training and have extent knowledge of the medical effects and risks involved in using this device, as well as the understanding for using this device in accordance with this manual.

# 2 Theory and Technical Options

This Laser is a Nd:YAG Laser with a Wavelength of 1064 nm. The radiation generated in the laser head uses a flash lamp. The laser beam of the device has a small diameter, this less than 10µm in the patients eye.

The word laser means „light amplification by stimulated emission of radiation“.

All laser types include three fundamental elements:

The **lasing medium** (providing atoms), or molecules allowing to amplify the light.

An **excitation source** (the abovementioned molecules or atoms are excited with), and an optical **resonator** which, similar to a resonant circuit, supports or generates the radiation stimulated by the internal reflection.

Atoms and molecules may have different energy states, which can generate electromagnetic phosound radiation changing from one state to the next by means of absorption and consequently by radiation. In their normal state, the electrons of an atom are in the so-called basic or normal state.

By supplying energy through light – or though plasma formation, as inert gas lasers do – electrons are transported into the higher state. The dwell time in the higher state is very short though. and the electrons sink back into their original state. During this short phase, the previously stored energy is released again by sending out photons.

The consequently emitting photons have the same wavelength and the same direction within the laser. Inside the resonator cavity, the photons between the two mirrors are compelled to pass through the cavity several times. During this time, they hit further photons thus generating a monochromatic light. To make the light built up this way in the resonator also accessible outside, the initial mirror of the laser is made permeable in parallel.

The Q-Las is a pulsed laser, which generates short pulses with high energy. It is equipped with an internal Q-switch. This switch opens the resonator for a very short time only, as soon as significantly more atoms has been stimulated by the excitation source than it would be the case with a continuous laser operation. In this way, short and high-energy laser pulses are generated.

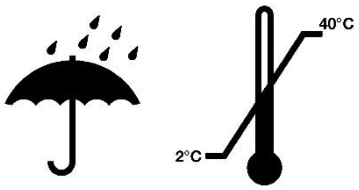
The wavelength depends of the laser light emitting medium. In this case, it is an IR beam. A special **crystal** cuts the emitted wavelength by half. So the pulses are modified into green laser pulses with high energy.

The Q-Las laser beam path is superposed on the observation beam path of the slit lamp. The desired position can be accurately determined in advance with the aid of the aiming beam.

Utilising a knob at the Laser unit one can shift the laser Focus in two steps.

# 3 Transport / Storage

Prior to delivery this instrument has been packed with special care in order to minimize transport risks.
However, before unpacking your laser, check the packaging for signs of damage. If you discover any contact the shipping company immediately and only remove the packaging in the presence of a representative of the company. Draw up a list of all damaged parts and make sure it is signed by the transport company's representative.




The device should never be exposed to temperatures below 2°C. or above 40°C The ambient air must be dry and clean. A humidity above 80% can result in the destruction of the Q-LAS when switching on the device.

**Protect the device against water and moisture!**

**WARNING**

If the instrument is at a temperature below 15°C switching on the instrument may cause serious damage. Unpack the instrument and leave it at normal temperature for at least half a day to ensure that the internal components warm up gradually.

# 4 Installation

## 4.1 Installation Site

Prior to delivery, however, the user need to make sure a suitable location was prepared for the installation.

The Q-Las Laser System should be installed at a readily accessible place not too close to a heater or next to a sink. The laser should not be operated close to a heater as its air cooling system works best when the ambient temperature does not exceed 21°C.

Higher ambient temperature may result in shorter working times as the device will be switching off earlier to prevent overheating.

If the ambient temperature is too low (below 15°C), the device cannot be started, in order to avoid possible condensation on its internal optics as this might cause a permanent damage.

- The unit should be positioned that the laser beam of the slit lamp is not directed onto a door, a window or reflective material.
- The unit should be installed in a dust-free room. No carpets should be on the floor or mounted on the walls.
- If the unit is not in use, it should be covered to avoid contamination.

The cables have to be placed that as there occur no tripping hazards or other hazards.

The air humidity in the treatment room should be monitored and kept below 75%.

## 4.2 Room Requirement

Legislation imposes the following requirements to any room in which a class 4 laser (according to EN 60825-1) is operated.

### 4.2.1 Warning Signs

All ingresses shall be clearly marked to prevent an outside person from entering as this might be hazardous.

- Please attach the laser warning sign (triangle with laser symbol) as well as the wavelength marking at each access door.
- Please mount a warning lamp above each access door which always has to light up, when the laser is in operation.
  This ensures warning to prevent accidental entry to the room without protective goggles.
- Please store the laser protective goggles at the entrance of the room and make sure they are readily accessible.

### 4.2.2 Window Shielding

Windows need to be covered with suitable masking or shielding to prevent laser radiation leakage. For any question or in case of any doubt, please contact your local A.R.C. Laser authorized dealer, or contact directly to A.R.C. Laser GmbH at any time.

### 4.2.3 Reflecting Surfaces

To avoid possible danger caused by reflected radiation direct or scattered, reflecting surfaces must not be present in the room during operation. Such surfaces may include

- mirrors
- pictures with front glass
- chrome surfaces
- windows

These surfaces must be either removed or covered with suitable matt type material. Even at the area around the laser fiber port, use only matted, non-reflecting as well as non-combustible instruments and materials.

## 4.3 Electrical Connection

The laser must be connected only with the provided power supply. In case of violation damage to the unit can result, further any approval will be withdrawn.

The power supply can be connected to 110 V or at 240 V AC.

The mains plug is considered as a disconnecting device. This plug must be reachable by the operator after use of the laser.

## 4.4 Transport and unpacking the device (Only Germany)

The device will be unpacked and installed by an authorized technician from ARC Laser GmbH or a distributor of A.R.C. Laser. After the installation and the correct connection of the device, the technician will put the device into operation and explain the function of the device. All functions and security features will be discussed and demonstrated. If the laser shipment arrives at your premise, you should ensure, before the arrival of the service technician that the shipping packaging has arrived undamaged. Any damage at the packaging should immediately be reported to ARC Laser GmbH and to the carrier.

# 5 Safety Information and Technical Certification

## 5.1 General

The Q-Las Laser is a precision instrument for medical applications. A.R.C. Laser has paid the utmost care for safety aspects during its design and manufacturing as well as implementing intensive testing procedures prior shipment, to ensure the device you are receiving is safe to use.

Following the "*Radiation Emitting Devices Act* " of your Country, it is highly advisable to keep with the device, detailed laser safety instructions and inform the person using the device on their location..

The Q-Las Laser is classified according to EN 60601-2-22 and EN 60825-1 as a Class 3B Laser Product.

Class 3B of the standard describes high-energy laser and therefore special actions must be taken before using the device to ensure safe and proper use. In particular, it is important to protect the eyes and the skin of the operator, the patient and accompanying persons. Laser safety goggles must be used, and to carry out appropriate actions to clothing. In particular, you have to protect yourself from reflected laser light. Additionally in the room - in which the laser is operated - no flammable materials are to be stored.

The following comments are very extensive, but do not claim to be complete. All users of the laser devices should therefore attach regulations, which are available during the time the device is used and inform the staff accordingly. We refer in particular to the rule "operation of laser equipment and laser radiation safety regulations," which is also available from our side. Additionally, controls can be accessed from the technical surveillance of the individual countries. Should the device be operated outside Germany, even rules of American National Standard ANSI Z136.3-1996 office "American National Standard for the Safe Use of Lasers in Health Care Facilities," and ANSI Z136.1-1995 "American National Standard for the Use of Lasers" can be used. In addition, our technicians are available for questions and our office at any time.

This user manual is limited to the use, maintenance and control of the device. The user manual is not a manual for the treatment of diseases, which can be done with the laser.

Regarding the supplied equipment such as slit lamp or instrument table, the safety, operating and maintenance instructions in the manuals must be followed. Do not use the instrument table as a seat or storage. When you operate the height, adjustment is important to ensure that no one will be injured.

A.R.C. Laser cannot be held responsible for damage or loss resulting from improper use.

The warranty on the unit expires if the laser (even partially), was opened, modified or repaired by unqualified personnel.

## 5.2 Eyewear Protection

**A T T E N T I O N !**

Never look directly into the laser beam or to the light reflected by the laser beam as this will cause serious eye injury.

As a safety measure against direct or indirect laser radiation within the laser room, it is necessary - clearly defined by the accident prevention regulations for laser radiation - that all personnel in the room must wear laser safety goggles.

When using the laser only such laser safety goggles must be used, which are designed for the wavelength of 532 nm and in which the CE mark and the Class L6 or DLB6 is noted. Goggles according to approval are available at ARC Laser GmbH.

Goggles for the specific wavelength are included. For subsequent orders, please contact A.R.C. Laser GmbH, indicating the wavelength or the article number of the Goggle. If you have further questions regarding safety goggles, please contact us.

There are different types of goggles that also allow eyeglasses wearers to wear tight goggles on all sides. In particular, scattered radiation, which does not directly hit the front of the eye, may present risks resulting from internal reflections in the glasses themselves. We strongly recommend wearing the goggles, which also guarantee full side protection.

The treatment room should not be opened from the outside during the treatment. Outside the treatment room of a warning light should be installed. During the operation, this laser warning light must be switched on. In addition, adequate safety goggles should be available in the room to provide accompanying person with glasses. For the patient, a patient-compliant eye protection must be applied.

A door interlock is required by the accident prevention regulations. The standard unit is equipped with an interlock connector to which a door interlock switch can be connected directly. Open the door and the unit switches off. Here we suggest as an alternative, to close the door from inside so that accidental opening from the outside cannot be done.

## 5.3 Electrical Protection

Do not disassemble the unit. Never remove any housing parts as this can cause a serious risk hazard as it may immediately destroy the laser diodes.

Authorized personnel from A.R.C. Laser GmbH only, should carry out any service to the unit or its accessories.

The room in which the laser is operated should be kept dry. Rooms that need to be cleaned with the use of water, please make sure the floor has dried out before using the laser.

**A T T E N T I O N !**

Never work with the device if you notice any visible damage to the device.

**A T T E N T I O N !**

Never work with the device if you notice any visible damage to outlet plug, or notice the wires have become exposed because of improper handling**.**

The device needs to undergo a safety inspection every 24 months carried out by qualified service personnel to ensure continued safe use of the laser. In the equipment book any faults during service should be noticed.

## 5.4 Explosion and Fire Hazard

**A T T E N T I O N !**

Never work with the laser near easily flammable anesthetics, easily flammable solutions or material. In particular, please remove combustible plastic or paper elements from and around the working area of the laser. Focusing the green or IR laser beam on flammable materials may ignite these and cause a fire or expulsion!

When working with the laser, make sure the laser is switched from READY mode to STAND-BY mode, in case the treatment has to be interrupted. This will assure that no laser radiation will be emitted due to unintentional stepping on the pedal switch.

## 5.5 Protection against Undesired Radiation

The foot switch controlling the laser pulse should never be outside the range of the operator. It is prohibited that any person other than the operator controls the foot switch.

In operating rooms in which several pedal switches are available, it is particularly important to make sure that the laser pedal switch is in within the operator vicinity.

**A T T E N T I O N !**

During a laser treatment, the system is in "Ready" mode. Should the operator need to pause the treatment for any reason; the laser must be switched back to "Stand-by" mode. The device must be turned off when left without supervision, to prevent usage by unauthorized individuals. Installing and/or operating the Laser in any other way differing from the one described herein may cause hazardous exposure to radiation.

## 5.6 NOHD Safety Distance

The calculation is based on:

BGI 832 – Operation of laser equipment

Application of safety regulations

„Laser radiation“ BGV B2 for new laser classifications and MZB-values according to DIN EN 60 825-1 (VDE 0837-1): 2001-11
Professional Association of Precision Mechanics and Electrical Engineering BGFE dated April 2003 (ZH1/405)

$$NOHD = \frac{\sqrt{\frac{4P}{MZB * \pi}} - Diameter\ Beam\ Bundle}{Beam\ Divergence}$$

Valid for Q-Las:

| | |
|---|---|
| Wavelength in nm: | 1064 |
| Diameter Beam Bundle in m: | 0,00001 |
| Beam Divergence in rad: | 0,279 rad |

| | |
|---|---|
| **Burst I** | |
| **NOHD:** | **1,98 m** |

| | |
|---|---|
| **Burst II** | |
| **NOHD:** | **3,06 m** |

| | |
|---|---|
| **Burst III** | |
| **NOHD:** | **3,94 m** |

However, this hazard distance is irrelevant as the access to the laser radiation is blocked by the marked operation room for the laser device.

*(See also "Room Requirements" Section 4.2 and "Eyewear Protection" Section 5.2).*

## 5.7 CE-Regulations

The Q-Las Lasersystem was accredited by the notified body in accordance with the European directive 93/42 for medical equipment. Therefore the device is labeled with the CE mark CE 0483.

The device was tested for electrical compliance as well as for mechanical safety. All parts used by A.R.C. Laser for the Q-Las Laser comply with CE regulations.

Any additional equipment that needs to be attached to the device must require the official approval of the local inspection authority. No modifications for the device are allowed as these may have a serious risk potential and will void the regulatory approval as well as the warranty.

An Equipment book and an regulatory approval number is included to the device.

## 5.8 External Interlock-Plug

At the rear of the console, a removable plug is inserted. The plug when fully inserted, enables main power to the console internal circuitry. Should this plug pulled out, the laser will instantly shut down.


The plug is intended to be used as an additional safety switch by connecting it to the door of the treatment room. Should the door be unexpectedly opened, laser radiation will immediately drop to zero.

Please be advised that the laser can only operate when the plug is fully inserted into the socket.

## 5.9 Console Protecting Housing

The Q-Las Lasersystem has a protection housing to prevent laser radiation leakages, and is electrically isolated. Housing should never be opened or modified. Non-authorized personnel should never attempt to carry out any type of service to the console. Console parts should only be removed and replaced by trained A.R.C. Laser GmbH service technicians.

## 5.10 Safety Shutter / Aiming Beam

The Q-Las has an internal safety switch (safety shutter). Pressing the ready button opens this shutter and releases laser radiation. However, this can only occur if the laser has passed the internal tests and calibrations. The red LED on the Ready button indicates whether the laser is in standby mode and the internal safety shutter is open.

The aiming beam is visible only when the laser is in the READY mode. This aiming beam is a laser with extremely low power.

As mentioned above, the system includes a shutter, which is opened by the following actions

- Ready-Button pushed and system check passed successfully

## 5.11 Manual Reset

When an error occurs (e.g. power instable etc.), the device changes into the STAND-BY mode. Switch the laser with the key off and on to see if a new automatic calibration at startup will solve the error. If this does not work, trained personnel only can correct it. Please contact the service A.R.C. Laser GmbH in this case.

## 5.12 Stickers, Labels and Markings

The Q-Las Laser has various warning labels in accordance with the European directives, intended to prevent any laser users to become exposed to laser radiation as a result of improper use. You can identify the arrangement of these labels with the following drawings.

### Identification Plate on Device

(located under the switch box)


Bild 1: Label under the switch box

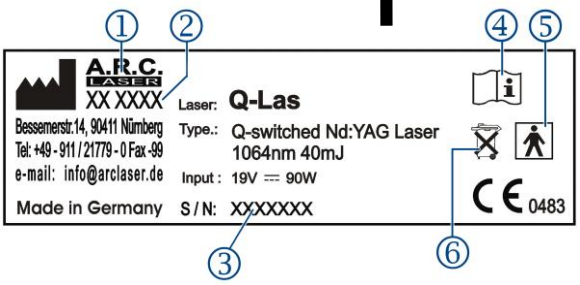



Bild 2: Label under the switch

① Manufacturer

② Date of manufacturing

③ Serial number

④ See manual

⑤ Applied Part Type BF

⑥ no disposal in domestic waste

## Connections

- Interlock Connector
- Warning Light
- Foot switch/
  Manual Remote
- Laser Connector
- Power supply


Bild 3: Labels at the rear

## Warninglabel



Pic 3: Label on Laserhead


Pic 4: Label Laser Aperture

Pic 6: Switch Box


Pic 7: Warning Label Laser radiation

## 5.13 Operating Conditions:

- The Q-Las laser system is not suitable for use with combustible gas mixtures.
- The laser system has not been tested for operation in heights exceeding 2,000 m above sea level.
- To ensure steady operation following ambient conditions must be ensured:
- Ambient temperature: 15 to 35 °C
- Air humidity: < 75%

## 5.14 Electromagnetic Compability

The Q-Las laser system complies with the EMV requirements to DIN EN 60601-1-2:2007-12. Guidelines and manufacturers declaration are described in Chapter 12

# 6 User Information and System Introduction

## 6.1 Technical Introduction Training

Upon installation, a staff member from A.R.C. Laser or the local authorized dealer will provide introductory training for the Laser system. The introductory training will cover the device technical abilities as well as overall safety associated with the installation and use of lasers in general. All individuals working at the vicinity of the laser should attend this introductory training. One individual with the training and experience to knowledgeably administer a laser safety program, will be chosen as the person responsible for monitoring and overseeing the control of laser safety.

This person is entitled to instruct other people on the unit. These must be recorded in the equipment book also.

To complete the enclosed documents correctly the operating instructions should be read carefully before initial start.

## 6.2 Laser-Safety-Training

The Q-Las laser system is designed for medical applications. It may only be used by a physician who received training by an authorized personal. In addition to the trainings offered by A.R.C. Laser, we recommend to attend seminars offered by us. These seminars contain topics like “working with different laser systems”. Moreover, introductions into the laser safety and the use of lasers in general will be covered in these seminars. We recommend you to make sure that only the person who was trained will use the laser. We recommend to ensure that only the person which is trained on the device and noted into the equipment book is using the laser.

The fact that even personnel not working directly with the laser should attend the "laser safety” or "laser application” courses, has proven to be very useful. Laser safety, the basic principles of the laser and of laser treatment is mainly discussed in these courses. It is particularly important that the operating personnel attend the laser safety courses. In these courses, extensive training is given to master precautionary measures when working with lasers (e.g. caution in case of combustible material, the importance of laser protective goggles etc.) are dealt with in detail.

Training for the accompanying personnel is offered in addition to the introductory, and is given by the local A.R.C. authorized dealer service person when installing the device.

In this training, special attention is given for safety in general like the laser protective goggles. It also covers clinical information as well as references to the indication but does not intend to be complete and to be used as is, since each patient may require different parameters.

A.R.C. Laser GmbH holds a list of recommended courses as well as laser safety courses available, and can be retrieved from us through our local dealer at any time.

## 6.3 Medical Introduction Training

The scope of the device medical introduction training is to provide basic information on selected medical applications for the users' specific intended use.

Where required, it is possible to attend a comprehensive training course held by an experienced physician. Upon request, please contact your local A.R.C. Laser authorized dealer, or contact us directly.

Do not attempt to perform any type of service or maintenance work to the device. A service technician trained by A.R.C. Laser GmbH should, only carry out any calibrations or adjustments that require opening the protective housing. This includes also any type of optics cleaning within the laser system.

## 6.4 List of Medical Device

The medical device equipment book is attached to the device documentation. This should be carefully kept and submitted to the engineer in the event of service or regular technical security control (STK)

## 6.5 Medical Device Parts and Accessories

Hereunder is a list of the components included with the basic console:

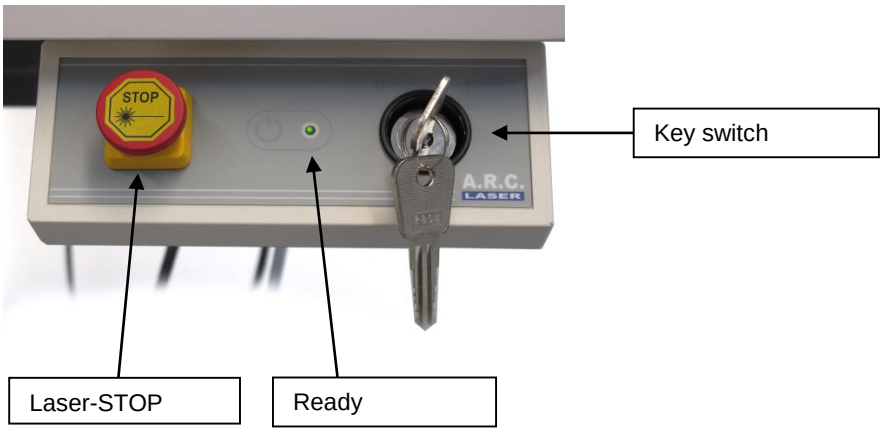
| | |
|---|---|
| Laser head with slit lamp | Keys |
| Power supply with power cord (Laser) | Motoric table |
| Power supply with power cord (Slit lamp) | Footswitch |
| User manual | |

For Information of availability of other accessories, please contact ARC Laser GmbH or your local distributor.

**A T T E N T I O N !**

Only the parts and applications as specified by A.R.C. Laser GmbH can be used with the Laser. Any use of other non approved accessories may pose a serious risk hazard to the operator and/or patient; As well as not provide the expected result**.** A.R.C. Laser GmbH undertakes no liability in this case.

### 6.5.1 Front Panel



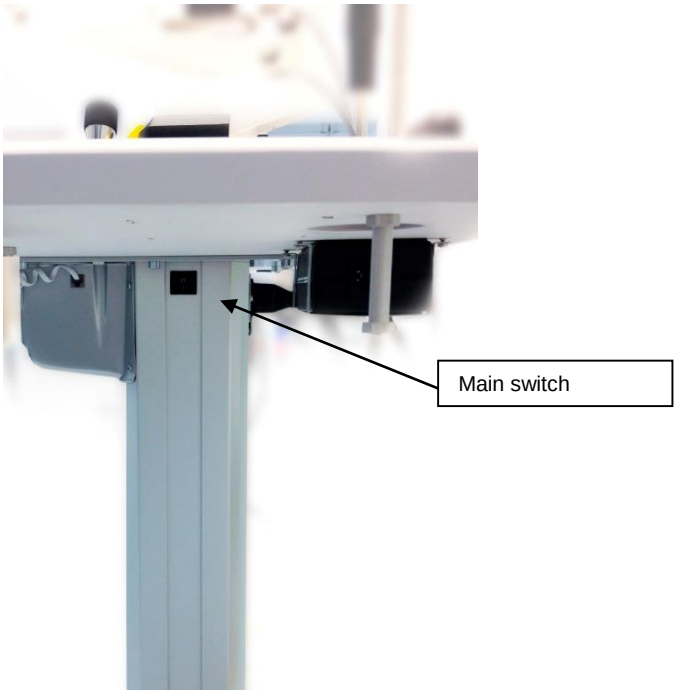

**Key switch**

The key switch is used to turn off on the laser and protects it against unauthorized third-party use. The Ready light turns off when the unit is switched off with the key switch.

**Laser-STOP, Panic switch**

The large red STOP button will instantly stop all laser functions when pressed.

### 6.5.2 Power Supply Rear



## 6.6 Door Switch Installation

The user must provide the actual door switch.

It may be a magnetically or mechanically actuated switch which will close its contact when the door is closed and open its contact when the door is open. The switch and its wiring must be rated for at least 24 VAC and 50 mA. The wires should terminate with a standard male connector.

The order of polarity is not important.

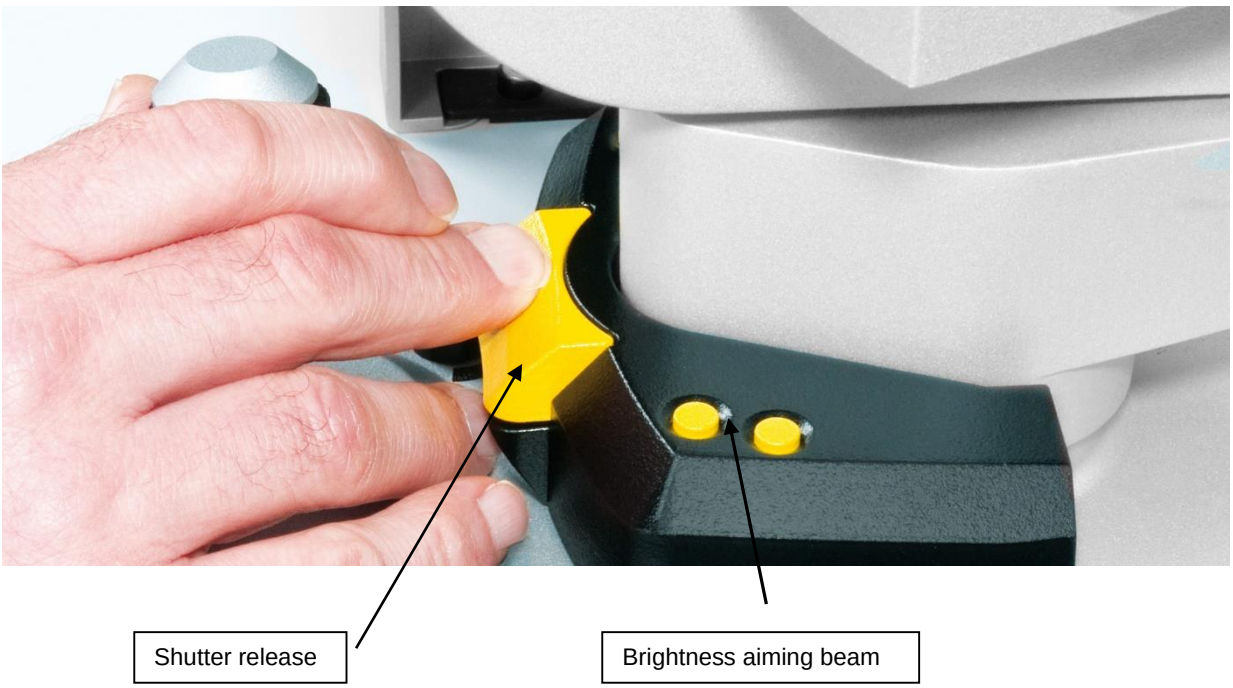
Insert your door switch connector in its place.

Be sure to seat it firmly to avoid unexpected interlock problems of the system.

## 6.7 Manual Remote (optional)

With your Q-Las an optional hand switch is available to trigger the laser.

Two other buttons are controlling the brightness of the aiming beam.



# 7 Operation

**A T T E N T I O N !**

The Q-Las Laser may only be operated by personnel that undergone relevant training for the device and that proves the necessary knowledge for the laser's applications.

This part of the manual describes mainly the technical aspect of the device functionality without providing extensive details on its medical use. A more elaborated medical use is detailed at A.R.C. Laser application manuals, which can be obtained through your local authorized distributer.

Device settings as well as various parameters adjustments should only be carried out in compliance with the operating instructions manuals. Any modifications or settings not indicated in the operation manuals may cause malfunctions.

**A T T E N T I O N !**

A warning lamp/s outside the treatment room door/s must be switched on as soon as the laser starts to operate; the doors have to be marked as laser rooms, visible from outside (with the warning signs).

**A T T E N T I O N !**

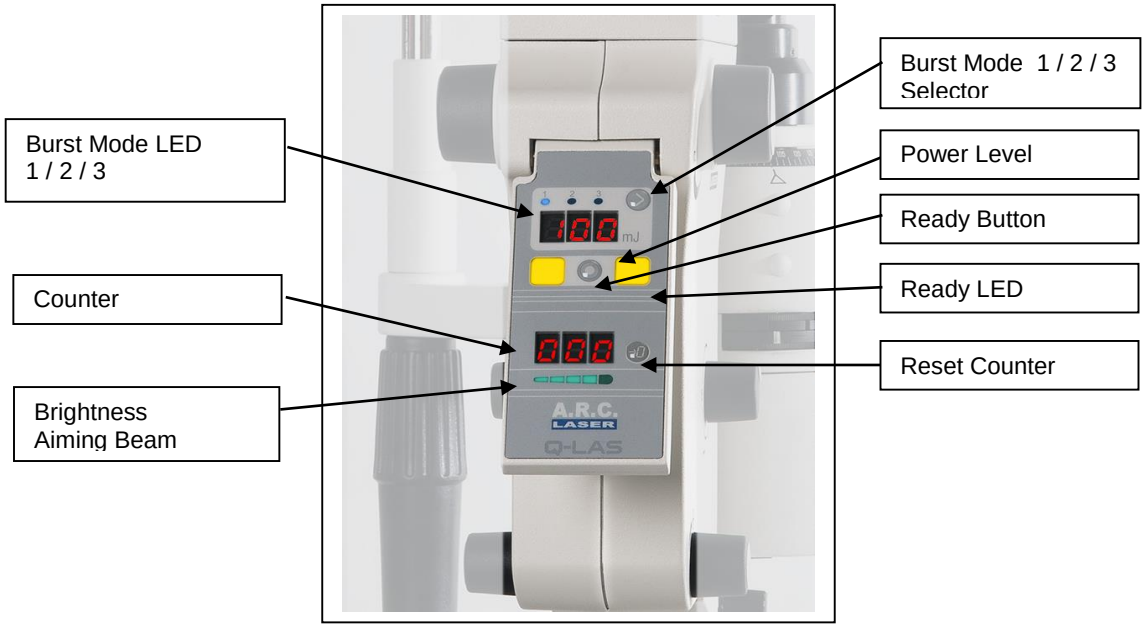
Since the aiming beam shares with the infrared laser beam, the same optical delivery system, it provides a very good indication for checking the intactness of the laser optical delivery system.

If the target spot does not appear at the distal end of the laser delivery system, or if it has low intensity, or appears to be diffused, this may indicate a damaged or not properly installed delivery system of the unit.

## 7.1 Laser Console Adjustment

- Ensure that the power cable is connected.
- Verify that the panic stop button is not pressed. If it is pressed pull it out
- Turn on the Main switch on the Table (see 6.5.2)
- Turn the key switch (see 6.5.1)
- The LED next to the panic button is lit.

## 7.2 DISPLAY




The LCD display of the control box displays different screens depending on the state of the unit. The screen shows up as soon as the unit is turned ON (when the key switch is ON).

The Display will show:


- During the Warm-up it counts down from 100 to 0
- Then the laser will perform 3 simulation shots
- The READY LED flashes
- The Counter will show 000
- The current output is displayed in the upper display.

**Possible Errors:**

The Slit lamp is not turned on (green button)

The main switch is not turned on

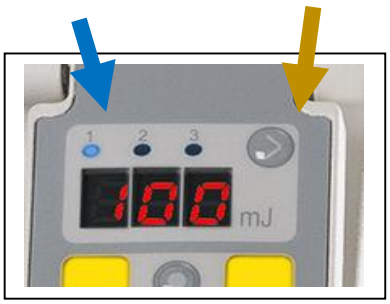
### 7.2.1 Energy Selection

Use the Energy selection button to change the values. The energy ranges from 1.0 mJ to maximum with steps of 0.1 mJ

### 7.2.2 Burst Mode (Number of Pulses)

You can modify the amount of pulses. According to the number (1, 2, 3) the energy is changing (mJ).

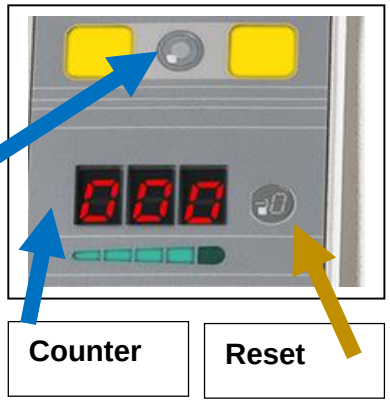
**Burst mode (Pulses): 1, 2 or 3 Pulses.** The Energy is changing according to the following table.




| | Energy (mJ) according to the Burst Mode (1,2 or 3 Pulses) |
|---|---|
| **1 Pulse** | **1.0 to max with steps of 0.1 mJ** |
| **2 Pulses** | **2.0 to max with steps of 0.2 mJ** |
| **3 Pulses** | **3.0 to max with steps of 0.3 mJ** |

### 7.2.3 Reset Counter

To reset the counter to 0, pulse the Reset-button on the remote control.




**Laser Stand-by / Ready**

This button enables or disables the treatment beam.

Green LED is lit: Laser Standby

Yellow LED is lit: Laser Ready

**Note:**
If the laser is in Ready Mode and the laser is not used for 3 minutes, the unit switches automatically into standby mode.

### 7.2.4 Tristar-Focus

The Q-LAS is equipped with 3 aiming beams.

All 3 beams intersect in the focal plane to form a single spot. The laser exerts its effect on the focal plane. An exception is the focus shift, see chapter 7.3

In the default state of the laser the three target have been determined. These can also be put into rotation.

**Rotation of the aiming beam**

Simply press the reset button for at least 4 sec. The aiming beams start rotating as long as you again push the Reset button (at least 4s). The Q-Las will memorize this setting and will restart with the rotating aiming beam.

Note: The counter will not be affected/reset by this change.

| Aiming Beam | | | |
|---|---|---|---|
|  |  |  |  |
| The focus layer is inside the lens | The focus layer is at the capsule | Focus layer behind the lens | Push the reset button for a least 4s and toggle the rotation of the aiming beam. |

## 7.3 Adjustments at the Laser Head


**Power Selection**

Use the energy knob to increase or decrease the energy values.

**Focus Shift**

The Focus of the Nd:YAG will be moved posterior :
0: Focus Position 30 µm is behind

1: Focus Position 150 µm moves behind

2: Focus Position 300 µm moves behind

**Aiming Beam**

Turn the knob to increase or decrease the brightness of the Aiming Beam.

Adjustments on the laser head

## 7.4 Footswitch

To trigger the laser press the Footswitch. The Remote control has to be in ready mode.

## 7.5 Treatment

Prepare and seat the patient, his chin and forehead resting on the chinrest.

Adjust the slit lamp position, illumination and focus as required.

Select your initial values for energy, pulse(s) level. It is always best to begin at an energy level below the anticipated treatment level and then increase the energy as required during the treatment

Fixate the patient's eye with a lens and focus the aiming beam into the eye to be treated.
Press the „READY" mode button to enable the laser: the yellow light turn ON.
Treatment can be started.

Between two patients
At the end of treatment press the STANDBY mode: the green light goes ON.
In this position the footswitch is not active.

## 7.6 Shut down

1. Turn the key switch to position „OFF“ (see Chapter **6.5.1**) to turn the laser OFF
2. Remove the key.
3. Switch OFF the unit with the main switch at the table**.**

**A T T E N T I O N !**
REMEMBER TO TURN OFF THE SLIT LAMP and the system should be covered to avoid dust setting on the optics.

## 7.7 Laser-STOP / Panic-switch

Re-Starting the device after pushing the Laser-STOP:

1) Turn the key switch to position „OFF“
2) Pull out the red knob on the right side
3) Start the device again

Timing and counter settings will return to their default values.
Energy will display the selected value by the energy knob.

**WICHTIG:**
The panic switch must be used only in case of emergency. It is located on the front of the Power supply.

# 8 SPECIFICATIONS

## 8.1 General

| | |
|---|---|
| Modell | Q-Las |
| Cooling | Air cooling |

## 8.2 Laser-Data

| | |
|---|---|
| Wavelength | 1064 nm |
| Lasersource | Nd:YAG |
| Energy | 1.0 mJ to Maximum - Single Pulse |
| Energy Setting | Adjustment in steps with 0.1 mJ from 1.0 mJ to its maximum |
| Pulse width | 4 ns |
| Burst Mode | 1, 2 or 3 Pulses |
| Spot size | < 10 µm |
| Cone angle | 16 º |
| Aiming beam | 635 nm red < 1mW |

## 8.3 Electrical Requirements

| | |
|---|---|
| Electrical connection | 100-240 V ~, 50-60 Hz |
| Electrical power | 50 VA / 19 V, 90 W |

## 8.4 Laser Specifications

| | |
|---|---|
| Laser classification Therapy Beam | 3B |
| Laser classification Aiming Beam | 2 |
| Classification per MPG | IIb Rule 9 |
| Electrical class of protection per IEC 60601-1 | II |
| Certification | CE 0483 |

Safety:
Internal monitoring of all critical systems including safety circuit monitor shutter system, power control system and microprocessor control system

## 8.5 Compliance:

- This laser product complies with 21 CFR 1040 as applicable
- Electrical leakage below UL 544 limits
- Power supply and enclosures designed per IEC 601-1
- Safety of laser products: IEC 825-1
- Safety of therapeutic laser equipment IEC 601-2-22
- European Directive 93/42/EWG
- Electromagnetic compatibility IEC 601-1-2

# 9 SERVICE

## 9.1 Introduction

The device was designed, developed and tested according to research based on state-of-the-art technology. As a rule, similar devices have a service life exceeding 5 years. This product service life is defined to be 10 years in order to guarantee the availability of its spare parts during this period of time. However, to make sure the product is in good working order, the device can display its internals working status through the display.

**A T T E N T I O N !**

Do not attempt to perform any type of service or maintenance work to the device. Any calibrations or adjustments that require to open the protective housing, should only be carried out by a service technician trained by A.R.C. Laser GmbH. This includes also any type of optics cleaning within the laser system.

## 9.2 Safety Check (STK)

**A T T E N T I O N !**

The entire device needs to undergo a preventive inspection and maintenance every 24 months carried out by qualified service personnel to ensure continued safe use of the laser.

In the event where the device is out of order and/or not safe to operate, remedial maintenance is required and/or the operator shall be informed of the hazard originating from this device.

The device must not be operated any longer as soon as it reveals any faults which may pose hazard to the patients, to the operating personnel or third persons. In this case, the operator shall immediately inform the responsible regulatory authority thereof.

**A T T E N T I O N !**

Please note that the laser device may only be operated by people who can guarantee proper handling due to their training and knowledge as well as due to their practical experience. Responsible people have to be instructed at the place of operation when the device is installed.

## 9.3 Care and Maintenance by the User

**A T T E N T I O N !**

Disconnect AC power completely before cleaning the case (turn off the main switch).

The following care and maintenance can be done by the user.

This helps to ease the work.

Before cleaning the Q-Las disconnect the system completely from power. The housing may be cleaned with a damp cloth. Clear water or a neutral cleaning solution (e.g. mild common cleaning solution for household) may be used. Pay attention to never use a wet cloth, because water must not enter the device in any case!

A disinfection of the surface by wiping the surface is possible: Disinfection solutions like DescoseptAF* or a comparable disinfectant (e.g. Mikrozid AF) can be used (*DescoseptAF: Dr. Schumacher GmbH (www.schumacher-online. de))

DescoseptAF solution contains about 42% Ethanol and about 0,05% Didecyldimethylammoniumchlorid.

Also other disinfectants can be used, as if they are not aggressive or contain acids, which affect the material surfaces of medical devices. Following the guidelines of the manufacturers also agents on the basis of quaternary ammonium compounds, as e.g. TPH protect (company Schülke), or Mikrobac® forte from Bode are suitable. According to the manufacturers, these agents can be used on sensitive surfaces (e.g. acrylic glas), or metal (stainless steel (V2A), aluminium, copper, brass) and plastic (PA, PE, PP, PS, PU, PVC, ABS, silicon, rubber, latex, Makrolon®, Plexiglas®, Teflon®).

The manufacturers regulation for combined devices – e.g. Slit lamp – have to be followed!

**Protect the device against water!**

Penetrating water may cause a serious malfunction. Do not drop or rinse in any solution or water. Please avoid wet cloths in all cases.

**Do not use any chemicals or aggressive agents!**

Chemicals or aggressive agents can lead to damage at the surface of the device and damage inside if they penetrate the device.

**A T T E N T I O N !**

Never look directly into the laser beam emitted from the slit lamp once the foot switch has been activated, as this will cause a severe eye injury. Always switch off the laser and disconnect it from the power cable when cleaning the console and components.

### 9.3.1 Inspection and Cleaning of external Optics

Check accessible surface areas of the optics for possible contamination. The surfaces of the slit lamp can be cleaned with a soft cloth and distilled water or a mixture of distilled water and 10% alcohol

### 9.3.2 Inspection and Cleaning of internal Slit lamp Optics

Regularly check all optics at the slit lamp - especially the mirror and lens above - for contamination

If the lens seems dirty, it could lead to greater losses during passage of the laser beam. The following problems may occur:

When testing and calibration, the capacity is no longer achieved. The device will not release the laser beam.

A change in behavior of the laser beam and therefore a change to the focal spot during operation.

Following actions may help:

1. Use alcohol-free, non-soaked cotton swab and try to clean the lens from the outside with distilled water. If this is not successful, please continue with step number 2
2. Take a few drops of 100 % alcohol and sprinkle it gently the end of the cotton swab and then proceed as in step number 1

3. Always wipe only in one direction of the optical surface. Never run with the same swab back in the other direction. Any particles that have already been fixed in the cotton swab would scratch the optical surface upon return again and this may lead to irreparable damage to optics

## 9.4 Slit lamp

Detailed instructions for care and maintenance of the slit lamp can be found in the supplied User Manual. These instructions must be followed strictly.

### 9.4.1 Slitlamp Mirror

When necessary, remove dust from the slit lamp mirrors with an appropriate lens brush. After dusting, clean the mirrors with Kodak lens tissue and a few drops of pure acetone. Do not use the tissue dry as this will scratch the mirror. Use a very light pressure to avoid disalignement of the mirrors. Do not rub the mirrors for more than one or two passes. Excessive rubbing will only redistribute the dirt and cause scratches.

### 9.4.2 Dust Cover

After each use, place the dust cover over the slit lamp to keep all optical surfaces clean – after the device is cooled down.

### 9.4.3 Test the Slit lamp focus

1) Use the focus stick which is supplied with the unit and place it into the hole of the slit lamp axis. Refer to the slit lamp manual which is supplied with the unit.

**A T T E N T I O N !**

Press the oculars firmly into their mounting so they are fully inserted into the binocular piece. Adjust each ocular to your accommodation so that the single slit on the target paper is in sharp focus to avoid straining your eyes.

2) Turn on the laser. Do not press the foot switch to trigger the laser, leave in STANDBY mode. Center the Aiming Beam in the visual field on the Focus stick.
3) Check the two aiming beams are superimposed when you are on the Focus stick
4) A disturbed Aiming beam may be an indication of a faulty system; the Aiming beam can be a tool to check the integrity of the system.

## 9.5 Error Messages

| Possible Error | | Messages and solutions | |
|---|---|---|---|
| F01 | Reduced output -20% | Permanently checked by test shots during the system start-up and during the operation | Hardware error<br>Please restart the system |
| F02 | Higher output +20% | Permanently checked by test shots during the system start-up and during the operation | Hardware error<br>Please restart the system |
| F04 | Optokoppler Safety Shutter Time Out | Permanently checked by test shots during the system start-up and during the ready phase | Please contact your local sales & service-representative of A.R.C. Laser |
| F06 | Foot switch short circuit – pre / post | Checked during the system start | Please contact your local sales & service-representative of A.R.C. Laser |
| F11 | Unable to set power | Checked during the system start | Please contact your local sales & service-representative of A.R.C. Laser |
| F38 | DA converter | Checked during the system start | Please contact your local sales & service-representative of A.R.C. Laser |
| F47 | Performance check, Checksum error | Checked during the system start | Please contact your local sales & service-representative of A.R.C. Laser |
| F50 | I2C-error | Checked during the system start | Please contact your local sales & service-representative of A.R.C. Laser |
| F51 | keys error | User interface error | Please contact your local sales & service-representative of A.R.C. Laser |
| F58 | Pulse Threshhold Voltage | Checking the maximum charge voltage at the charge controller | Please contact your local sales & service-representative of A.R.C. Laser |
| F0C | Knob Position Error | Permanently checked. Needs to be placed in a locked position. | Please check knob position of the Focus Shift. |

## 9.6 Disposal

The unit should be disposed according to the valid laws, rules and guidelines of your country. Contact your local government's recycling or solid waste management department to learn more about the services it provides. This laser must not be disposed in your garbage. A.R.C. Laser would be very happy to assist you in the question of how to dispose the device properly. Costs and responsibility for the proper return of the laser to ARC Laser has to be beard by the customer. Please contact our Service department for further information.

# 10 Customer Service

## 10.1 Warranty-Information

A.R.C. Laser GmbH provides a two-year warranty. Within these two years, any parts showing a defect will be replaced free of charge. This does not include any purchased parts acquired from a third party. Our warranty covers the repair works and the replacement of defective parts. However, we reserve the right to renew even complete units and to adjust them to the technical progress.

Refer any claims or defects to

**A.R.C. LASER GmbH** Bessemerstr. 14, D-90411 Nuremberg

Phone: +49 911 21779-13 (-0), Fax: +49 911 21779-99, Email: service@arclaser.de

Repair works carried out by third parties or modifications of the device void the warranty claim. The use of parts other than those approved together with the device or purchased from other suppliers also voids the warranty for the complete device. Any parts, units or modifications of the device require the explicit written consent of A.R.C. Laser GmbH.

## 10.2 Warranty Consignments, Packaging

A warranty claim for defective parts, malfunction or damage of the housing of the device shall be passed on to A.R.C. Laser GmbH within 24 hours. Parts returned during the warranty period (upon the explicit request of A.R.C. Laser GmbH), are subject to the written confirmation by A.R.C. Laser GmbH. Detailed packaging instructions and information on how to return the device will be provided by A.R.C. The return consignment shall be insured and the costs arising hereof from shall be borne. A.R.C. will notify the customer of the return consignment opted for. Any changes as well as the change of the transporter or the type of dispatch may result in delays in transport and handling. Any other components covered by the warranty claim will be renewed by A.R.C. free of charge within the warranty period. We reserve the right to modify the design of the device – if necessary – thus increasing the safety or the functioning of the device. The responsibility for the design as well as any modifications of the device is exclusively incumbent on A.R.C. Laser GmbH. The customer will be informed about any changes that will be carried out on the premises of A.R.C. Laser GmbH.

## 10.3 Sales and Manufacturer's Declaration

For information, about sales and service please contact: A.R.C. Laser main office:

**A.R.C. LASER GmbH**

Bessemerstr. 14, D-90411 Nuremberg
Phone : +49 911 21779-0, Fax : +49 911 21779-99
Email : info@arclaser.de, www.arclaser.de

# 11 Guidelines and Manufacturer's Declaration

## 11.1 Electromagnetic Emissions

| Guidelines and Manufacturer's Declaration – Electromagnetic Emissions | | |
|---|---|---|
| The laser is intended for use in an environment as specified below. The customer or the user of the laser should ensure that it is used in such an environment. | | |
| **Immunity tests** | **Compliance** | **Electromagnetic environment – guideline** |
| RF emissions CISPR 11 | Group 1/Class B | The laser uses RF energy exclusively for its internal function. Hence, RF emission is very low and not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The laser is suitable for use in any and all establishments including establishments in residential areas and those directly connected to the public power supply network which also supplies buildings used for domestic purposes |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Complies | |

## 11.2 Electromagnetic Immunity I

| Guidelines and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should ensure that it is used in such an environment | | | |
| **Immunity tests** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidelines** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact discharge<br>± 8 kV air discharge | Complies with IEC 60601 | Floors should be wood, concrete or ceramic tiles. Where floors are covered with synthetic material, the relative air humidity should be at least 30%.. |
| Fast transient electrical /burst IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input and output lines | Complies with IEC 60601 | The supply voltage quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode voltage<br>± 2 kV common mode voltage | Not applicable | The supply voltage quality should be that of a typical commercial or hospital environment. |

| Immunity tests | IEC 60601-test level | Compliance level | Electromagnetic environment – guidelines |
|---|---|---|---|
| Voltage dips, short interruptions and variations on power supply input lines IEC 61000-4-11 | < 5 % $U_T$ (>95 % dip in $U_T$) for ½ cycle<br><br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br><br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><br><5 % $U_T$ >95 % dip in $U_T$) for 5 s | Complies with IEC 60601 | The supply voltage quality should be that of a typical commercial or hospital environment. When the user of the laser requires continued operation during power mains interruptions, it is recommended that the laser is powered from its battery or an uninterruptible power supply or an external battery.. |
| Magnetic field with power frequency (50/60 Hz) IEC 61000-4-8 | 3 A/m | Complies | Magnetic fields in mains frequency should be those of a typical commercial or hospital environment. |
| NOTE: $U_T$ is the A.C. mains voltage prior to the application of the test level. | | | |

## 11.3 Electromagnetic Immunity II

| Guidelines and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should ensure that it is used in such an environment. | | | |
| **Immunity tests** | **IEC 60601-test level** | **Compliance level** | **Electromagnetic environment – guidelines** |
| Conducted RF<br>IEC 61000-4-6 | 3 $V_{eff}$<br>150 kHz to<br>80 MHz | Complies with<br>IEC 60601 | Portable and mobile RF communications equipment should be used no closer to the laser, including cables, than the recommended separation distance calculated for the equation applicable to the frequence of transmitter.<br><br>**Recommended separation distance:**<br><br>$d = [\ 3{,}5 : V_1\ ]\ \sqrt{P}$<br><br>$d = [\ 3{,}5 : E_1\ ]\ \sqrt{P}$<br>for 80 MHz to 800 MHz<br><br>$d = [\ 7 : E_1\ ]\ \sqrt{P}$<br>for 800 MHz to 2,5 GHz<br><br>where *P* maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer and *d is the* recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br><br>Interference may occur in the vicinity of equipment marked with the following symbol.. |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to<br>2,5 GHz | Complies with<br>IEC 60601 | |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br><br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| a) The field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with battery. To determine to electromagnetic environment resulting from the fixed RF transmitters, an electromagnetic site survey should be considered. Where the measured field strength in the location in which the laser is used exceeds the applicable RF compliance level indicated above, the laser should be observed to verify the normal operation. Where abnormal power is observed, additional measures may be necessary, such as reorienting or relocating the laser.<br>b) Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m. | | | |

## 11.4 Recommended Separation Distance

| **Recommended Separation Distance between Portable and Mobile RF Telecommunications Equipment and the Laser** | | | |
|---|---|---|---|
| The laser is intended for use in an electromagnetic environment in which radiated RF are controlled. The customer or the user of the laser can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the laser as indicated below – according to the maximum output power of the communication equipment | | | |
| **Maximum output power rating of the transmitter [W]** | **Separation distance according to frequency of transmitter in meter [m]** | | |
| | 150 kHz tos 80 MHz<br>$d = [\,3{,}5 : V_1\,]\,\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = [\,3{,}5 : E_1\,]\,\sqrt{P}$ | 800 MHz to 2,5 GHz<br>$d = [\,7 : E_1\,]\,\sqrt{P}$ |
| 0,01 | 0,12 | 0,12 | 0,23 |
| 0,1 | 0,37 | 0,37 | 0,73 |
| 1 | 1,17 | 1,17 | 2,33 |
| 10 | 3,69 | 3,69 | 7,30 |
| 100 | 11,66 | 11,66 | 23,30 |
| For transmitters with a maximum output power rating not listed above, the recommended separation distance *d* in meters (m) can be determined by using the equation applicable to the frequency of the transmitter where *P* is the maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer list.<br><br>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br><br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people | | | |

A.R.C. LASER GmbH

Bessemerstr. 14
D-90411 Nürnberg

Tel: +49 911 21779-0
Fax: +49 911 21779-99

www.arclaser.de