User Manual

Q-LAS

A.R.C. Laser GmbH

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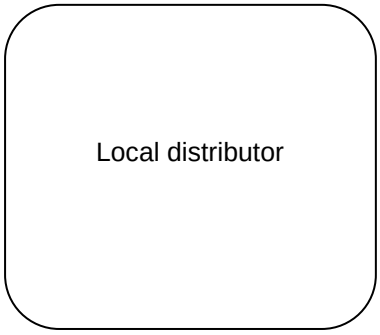

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Content

1 Introduction

We thank you for having chosen our Q-LAS and wish you every success in using this versatile laser system.

The Q-LAS laser generates a laser beam of high intensity, which can cause injuries if handled improperly. The user manual should therefore be read carefully before starting up the device. If you have any further questions regarding the safety or the use of the device or regarding the laser and laser radiation, please contact A.R.C. Laser GmbH.

1.1 Marking and Symbols

The "**General warning sign**" (ISO 7010 W001) indicates general risk. It encourages the user to take care regarding the hazard specified by the supplementary sign. Before carrying out any further works at parts with such marks, please read the user manual or contact your local dealer or the A.R.C. Laser GmbH service department.

The sign "**Warning; Laser beam**" (ISO 7010 W004) indicates laser hazards. It encourages the user to take care to avoid exposure to a laser beam. The laser beam of this device may not be visible to the naked eye nor through protecting googles.

1.2 Intended Purpose

1.2.1 General Purpose

Tissue disruption by plasma shockwave in the human eye

1.2.2 Medical Purpose

The Q-LAS is a medical laser device intended to be used in ophthalmic applications particularly for the treatment of glaucoma (closed angle glaucoma) and posterior cataract opacification (PCO) patients. The Q-switched Nd:YAG laser delivers very short but high energetic laser pulses. The pulse duration is in the nano-second regime with adjustable pulse energies. The short, high-energy pulses generate a plasma in the focal plane, which provides an optical breakthrough. Regarding to the medical indication (closed angle glaucoma or PCO) the Q-Las provides the treatments of iridotomy or capsulotomy.

Indications and contraindications

Medical Application indicated	**Indication** from clinical data	**Side and adverse effects**	**Contraindications**
Iridotomy	Prevention or treatment of high intraocular pressure related to angle closure glaucoma	- IOP rise (non-permanent) - inflammation - bleeding - change of endothelial cell density - cystoid macular edema - retinal complications - discomfort (mild/moderate) - pain - scotoma	- open angle glaucoma - congenital glaucoma - inflammatory/ uveitis glaucoma - acute intraocular inflammation - acute reduced optical transparency of the cornea
Capsulotomy	reduced visual acuity related to PCO	- inflammation - change of endothelial cell density - cystoid macular edema - retinal detachment - IOP rise - bleeding - lens damage/pitting lens	- acute intraocular inflammation - acute reduced optical transparency of the cornea

General Contraindications

Floater treatment is not intended with Q-Las, as the floater cannot be illuminated in a sufficient way due to technical setup. Further Trabeculoplasty is also a common procedure with Nd:YAG laser but not intended with the Q-Las.

A T T E N T I O N

The device may only be operated by specially trained personnel who are experts in the medical effects and dangers of the device. You must have the necessary skills to use the laser in accordance with this instruction manual.

When not in use, the device should be protected against unauthorized use.

1.3 Theory and Technical Set-up

The Q-LAS is a Nd:YAG laser with a wavelength of 1064 nm. The radiation in the laser head is generated with the help of a flash lamp. The laser beam that leaves the device has a small diameter with less than 10 µm at the place of its effect in the patient's eye.

Due to attenuating optics, the power of the emitted laser radiation can be varied. Internal control mechanisms compare the actual with the desired amount of energy and adjust the output.

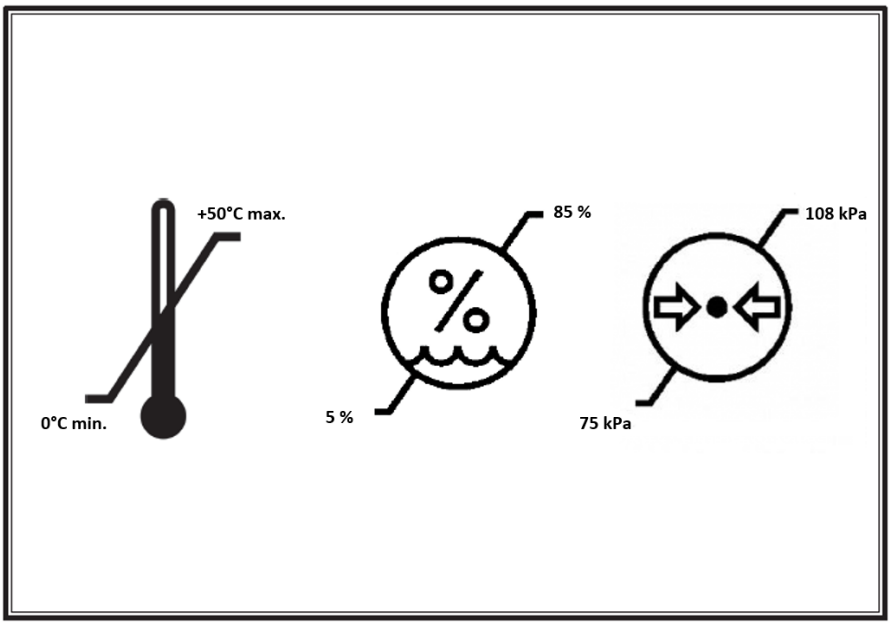
With the Q-LAS, the laser beam path is overlaid with the observation beam path of the slit lamp. With the help of a target beam, the desired treatment position can be precisely determined in advance.

The focus of the laser can be shifted in two steps using a dial on the laser unit.

2 Transport and Storage

We at A.R.C. Laser GmbH will make sure that the device is packed and transported with the greatest possible care.

Before unpacking the laser, please check the packaging for damage and report any damage immediately to the shipping agent and A.R.C. Laser GmbH. Only remove the packaging in the presence of a representative of the carrier. Make a list of the damaged parts and have this list signed by the courier.



The device must be transported at temperatures between 0°C and +50°C. The air pressure during transport must be between 1080 hPa and 750 hPa. During storage, a temperature range of 5°C to 40°C must be maintained. The environment/air must be dry and clean. The relative humidity during transport and storage must be between 5% and 85%.

ATTENTION

If the laser is transported or stored at a temperature below 5 °C, it can be damaged when starting. Unpack the laser and leave it for at least half a day at normal room temperature so that the system reaches room temperature.

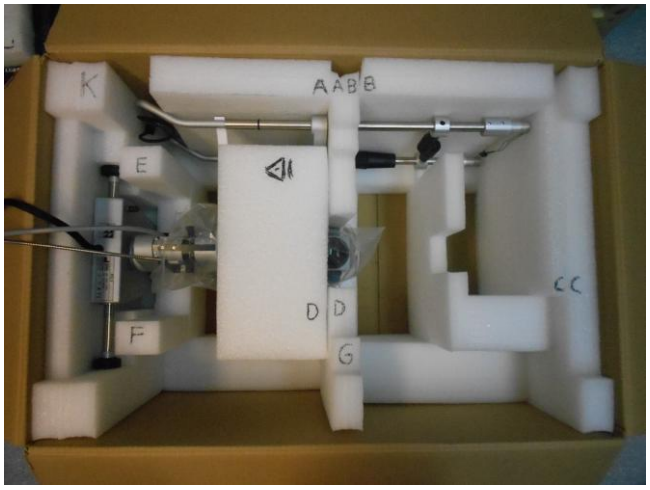
2.1 Shipping and Unpacking the Device

Unpacking and installation of the device must be carried out by an authorized technician or authorized representative of A.R.C. Laser GmbH. 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 safety procedures are discussed and demonstrated here.

2.2 Return Shipment

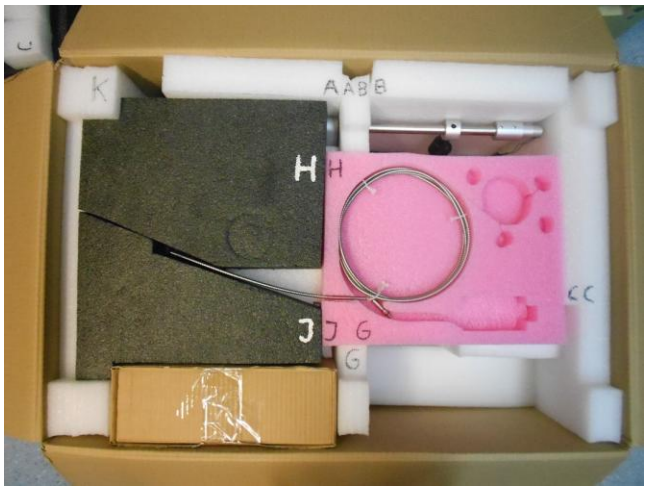
The device will be shipped in a specially developed transport packaging. Please keep this. If you ship the device back to A.R.C. Laser GmbH, be sure to use the intended transport packaging.

The transport packaging is designed so that the device fits snugly into the foam parts.



All accessories are stowed in an extra padding inside the transport packaging.

If all foam parts are in the right place and the box is closed, the device is ready for shipping.



3 Set-up and Installation

3.1 Installation Site

Ensure to provide a suitable location for the device before it is set up.

The Q-LAS should be operated in an easily accessible place. The laser should not be operated near a heater, since the device only works when the ambient temperature is not higher than 35°C. Higher temperatures can cause the device to switch off due to overheating. A place of installation in direct sunlight can cause an early shutdown and must be avoided in any case.

If the temperature is too low (below 15°C), the device cannot be started to prevent condensation on the internal optics; this could result in permanent damage to the laser.

- The device should be set up so that the laser beam is not aimed directly at a door, window or reflective material.
- The device should be operated in a dust-free room. There should be no carpets on the floor or the walls.
- When the device is not in use, it should be covered to prevent contamination. For this purpose, a suitable dust cover is included.

The wiring must be installed so that there are no tripping hazards or other hazards.

All control elements must also be free and easily accessible. The air humidity is monitored internally and must be below 75%.

3.2 Room Requirement

The legislation imposes the following requirements to any room in which a class 3B laser according to IEC 60825-1 is operated.

3.2.1 Marking Access Points

All entrances must be clearly marked so that unintentional or unauthorized entry, which can lead to a hazard, is avoided.

- Laser warning signs (triangle with laser symbol) and the wavelength labeling must be attached to each access door.
- A warning lamp must be attached above each access door. This must always light up when the laser is in operation. Unintentional entry into the room without safety glasses is avoided.
- The laser safety goggles must be easily accessible at the entrance.

3.2.2 Window Shielding

It must be ensured that no laser radiation can escape the room. In particular, the windows must be secured with suitable materials. If you have any questions, your contact person at A.R.C. Laser GmbH is available to assist you.

3.2.3 Reflecting Surfaces

To avoid danger from reflected direct and scattered radiation, there must be no reflective surfaces in the room.

These can be:

- Mirrors
- Pictures behind glass
- Chrome surfaces
- Windows

These surfaces must be removed or suspended or matted. In the area of laser use, only matted, non-reflective and non-flammable instruments and materials should be used.

3.3 Electrical Connection

The laser can be operated from 100 V - 240 V (50 Hz/60 Hz) AC voltage.

The power connection is made via the table column and the supplied IEC connector.

Make sure that the plug is accessible at any time so that the laser can be disconnected from the mains after use.

4 Safety Information

4.1 General

The Q-LAS laser is a precision instrument for medical applications. The system has been carefully developed and tested through intensive testing before shipping. In order to offer you and the operating personnel all possible protection, we recommend that you read this section of the operating instructions carefully.

According to EN 60601-2-22, respectively EN 60825-1 the Q-LAS is categorized into laser class 3B.

Class 3B in the standard describes high-energy lasers and therefore special measures must be taken before commissioning in order to ensure safe and trouble-free working with the device. It is particularly important to protect the eyes and skin of the operator, the patient and third parties. Laser safety glasses must be used for eye protection.

The following explanations are not exhaustive. All users of laser devices should enclose applicable legal regulations and provisions with the device and inform the staff accordingly.

If the device is operated outside Germany, provisions of the American National Standard Office ANSI Z136.3-2018 "American National Standard for the Safe Use of Lasers in Health Care Facilities" and ANSI Z136.1-2014 "American National Standard for the Use of Lasers" must be respected.

This manual is limited to the operation, maintenance and control of the device. The manual is not a guide for the treatment of diseases that can be remedied by laser.

Regarding the additionally supplied devices, such as slit lamps or instrument tables, the safety, operating and maintenance instructions in the corresponding manuals must be followed. Regarding the instrument table, reference is only made here to the danger from improper use of the table as a seat or storage area. When operating the height adjustment, make sure that no one can be harmed.

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

The warranty for the device expires if the laser has been opened (even partially), modified or repaired by unqualified personnel.

4.2 Eyewear Protection

As a safety measure against direct or indirect laser radiation, it is necessary that everyone in the room wear laser safety glasses. The treating doctor is protected from radiation by the laser protection integrated (eye safety filter) into the slit lamp. Eye protection appropriate to the patient must be guaranteed for the patient.

When using the laser, only those laser safety goggles that are designed for the wavelength of 1064 nm may be used. The safety goggles should bear a CE mark as well as the appropriate protection class.

The following laser safety goggles from A.R.C. Laser GmbH are suitable for the Q-LAS:

- AS01033: Protection class D LB 6 + IR LB8 + M LB10 / optical density OD10+ (Wavelength 1064 nm)

The safety goggles also allow spectacle wearers to be protected on all sides. In particular, scattered radiation that does not reach the eye directly from the front may present risks resulting from internal reflections on the glasses. Therefore, we recommend that you wear safety goggles that also ensure full side protection. The safety glasses offered by A.R.C. are suitable as over-glasses for spectacle wearers and also provide lateral protection.

A T T E N T I O N

Never look directly at the laser beam or the light reflected by the laser beam. This may cause serious damage to your eye.

4.3 Electrical Protection

Never remove the housing parts of the laser. Only authorized A.R.C. Laser GmbH service personnel is allowed to modify the device. If the mains have to be replaced, the replacement must be carried out by authorized service personnel.

The room in which the laser is operated should be kept dry. After cleaning the room, make sure the floor is dry before starting up the device.

A T T E N T I O N

Never use the laser if you notice any visible defect on the device.

Never use the device if wires or supply lines are exposed.

4.4 Explosion and Fire Hazard

Never work with the laser near flammable anesthetics, flammable solutions or other flammable materials. Flammable plastic parts or paper parts in particular should also be removed from the working area of the laser. There is a fire or explosion hazard if the laser is used in the presence of flammable materials, solutions, or gases or an oxygen-enriched environment.

4.5 Protection against Undesired Radiation

If a footswitch is used, it should never be outside the area of the attending doctor. It is forbidden for anyone other than the attending doctor to trigger the footswitch.

Especially in operating theaters where there are multiple footswitches, it is important to ensure that the laser footswitch is close to the laser device. Also, the hand trigger of the slit lamp may only be used by the attending surgeon.

4.6 NOHD Safety Distance

The NOHD (Nominal Ocular Hazard Distance) is the distance at which the irradiance is equal to the exposure limit value of the cornea of the eye. The NOHD identifies the danger area within which there is a risk of damage to the health of the eye if you look directly into the laser beam without protection.

The NOHD is calculated according to EN 60825-1 and taking into account the permitted power fluctuations (+/- 20%) according to EN 60601-2-22 using the following equation:

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

For the Q-LAS applies:

Wavelength λ:	**1064 nm**
NOHD:	**3.6 m**
Beam divergence $\alpha_{(full\ angle)}$:	**16°**
Permitted Maximum Radiation:	**2 x 10^{-2} Jm^{-2}**

4.7 CE-Regulations

The laser system Q-LAS has been approved by the notified body in accordance with the European Regulation 2017/745/EU for medical devices. Accordingly, the device bears the CE mark **CE 0123**.

The device has been checked for electrical and mechanical safety. All parts we use comply with the CE regulations or have been tested for approval or suitability by the notified body.

Additional devices that you attach to the device require approval from an official test center. Changes to the device or interventions on your part will void the approval and warranty.

The test approval number is included with the device.

4.8 RoHS3-Regulations

Our company operates worldwide and regards the protection of the environment and natural resources as an entrepreneurial obligation. Based on individual tests, A.R.C. Laser GmbH confirms that, to the best of our knowledge, our products do not contain any substances in concentrations whose placing on the market is prohibited according to the applicable requirements of Directive 2015/863/EU (RoHS3).

4.9 Protecting Housing

The Q-LAS laser system has a protective housing. It prevents radiation from the laser from escaping and protects users from touching energized parts. This housing must not be removed.

4.10 Connectors and Switches

Main switch

Thermal fuses

- O Door interlock
- O Warning light
- O Foot switch/ hand release
- O Connection laser device
- O Power supply
- O Connection of the laser shot LED

Laser stop and key switch

The main switch under the table turns the entire system on and off. The key switch is used to turn the laser on. The stop button is used to switch off the laser in emergencies.

To prevent a defect in the unit - caused by the power supply unit - the Q-LAS has two thermal fuses under the table. When the thermal fuses are tripped, they are pushed down and the red LED on the main switch fades out. As a result, no more voltage is passed on to the Q-LAS and you cannot continue treatment. In this case, please contact the service department of A.R.C. Laser GmbH or their local representative.

The sockets of the device are located on the bottom of the instrument table.

You can connect a warning light to the orange marked connector O. This indicates to third parties whether the laser is currently in operation. The switch and wiring must be designed for at least 12 V and 100 mA.

The red marked connector is the interlock connector O. You can replace it with a door interlock switch (see chapter 4.11).

The manual release or the foot switch is connected to the blue marked connection O.

The Q-LAS is connected to the table at the green marked connection O.

The yellow marked connection is the power supply for the Q-LAS O.

The purple connector O is used for the laser shot LED.

During the installation of the device, the authorized technician or representative of A.R.C. Laser GmbH will connect all needed wires. The user does not need to change any connections. If problems arise, please contact the A.R.C. Laser GmbH or the local representative.

4.11 External Interlock Switch

A door interlock switch is required by the accident prevention regulations. The device is equipped with an interlock connector as standard, which can be replaced by a door interlock switch. The laser switches off when the door is opened. In addition, the laser cannot be switched to the READY mode when the door is open. An error message appears on the control panel. When the door is closed, the error message disappears and the laser can be switched READY again.

When installing a door interlock switch, note the following:

The switch and wiring must be provided for at least 12 V and 20 mA. The wires should end with a standard male connector. The choice of polarity is expedient in both variants. The socket for connecting the door switch can be found underneath the table. Insert the door switch connector there.

Make sure the socket sticks firmly to prevent unexpected system interlock problems.

4.12 Safety Shutter/Aiming Beam

The Q-LAS has an internal safety shutter. This safety switch enables the release of the laser beam mechanically. As soon as the laser has passed its internal tests and calibrations, the laser can be set to READY mode by pressing the READY button. As soon as the laser is set to READY mode, the aiming beam will appear. The aiming beam is a low-level laser with very low power.

4.13 Manual Reset

If an error occurs, the system switches into STANDBY mode. You should then switch the laser off and on again. The restart should fix the error due to the automatic recalibration. Please refer to chapter 8.5 or a description of possible errors.

If the error still occurs, this can only be remedied by trained personnel. Please contact the service of A.R.C. Laser GmbH in this case.

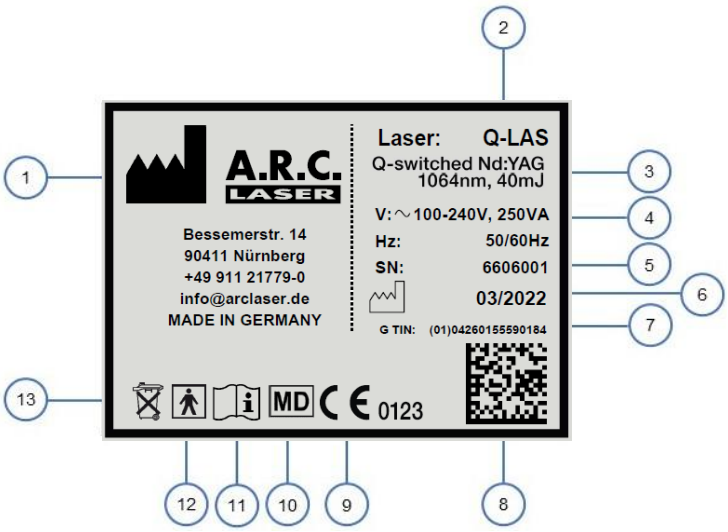
4.14 Reset by Power Failure

If the device is disconnected from the power grid accidentally - e.g. due to a power failure - it usually restarts automatically. The system recalibrates and deletes all unsaved settings. If there is still an error, it can only be corrected by trained personnel. Please contact A.R.C. Laser GmbH service department should this occur.

4.15 Labels and Markings

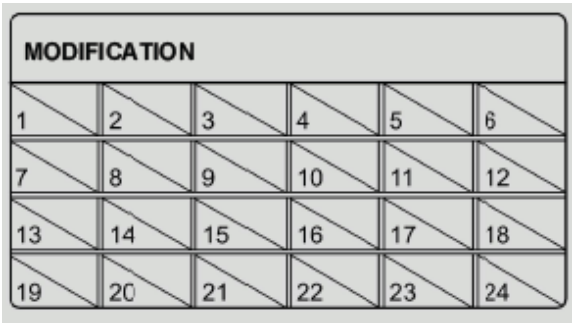
The Q-LAS is provided with various warnings in accordance with European and worldwide guidelines. This is to prevent the laser user from being exposed to laser radiation due to carelessness. Following labels are attached on the Q-LAS:

4.15.1 Type plate



1) Manufacturer
2) Laser name
3) Laser specifications
4) Electrical connection data
5) Serial number (SN)
6) Production date
7) GTIN (Global Trade Item Numer)
8) UDI (Unique Device Identification = GTIN + SN + production date)
9) CE mark
10) Medical Device
11) Follow instructions for use
12) Application part type BF
13) Do not dispose in household trash

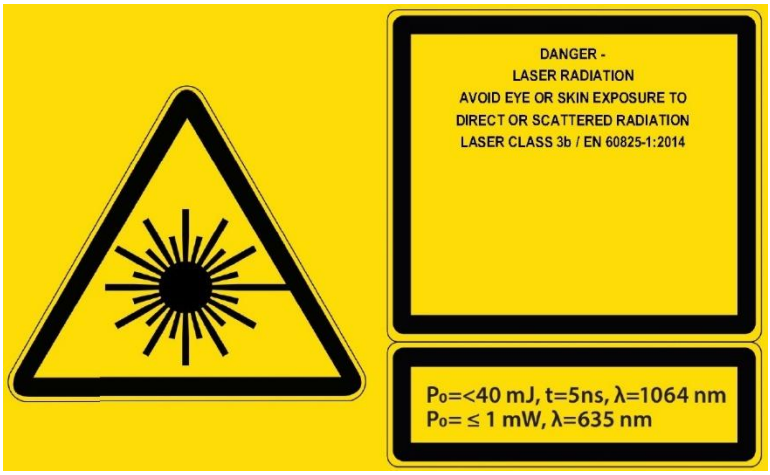
4.15.2 Modification Label



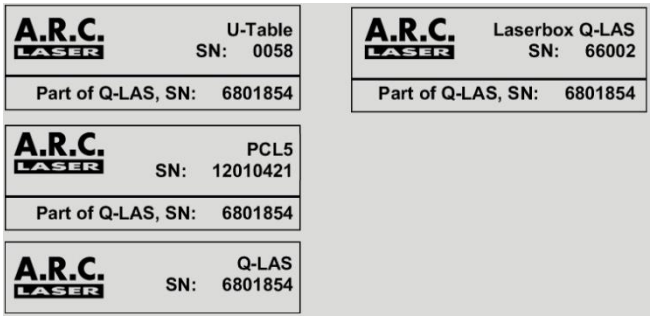
Shows the current device status based on the marked modification numbers.

4.15.3 Warning label laser

The “Laser Aperture” label marks the laser output. The other labels provide information about the type and intensity of the laser system.



4.15.4 Serial number



The Q-LAS consists of several subsystems, each with its own serial number.

4.15.5 Laser Stop

This symbol indicates where the laser stop button (see chapter 6.5)

4.15.6 Follow instruction for use

On the device, you will again be reminded that the instructions for use must be respected.

4.16 Operating Conditions

The medical laser Q-LAS is not suitable for use in connection with combustible gas mixtures of all kinds.

The device is not approved for operation at altitudes above 2,000 m above sea level. and only for an air pressure between 1080 hPa and 750 hPa.

The following environmental conditions must be met:

- Ambient temperature: 15°C to 35°C
- Relative humidity: < 75%

4.17 Electromagnetic Compatibility

The Q-LAS laser system meets the EMC requirements according to EN 60601-1-2. Guidelines and the manufacturer's declaration are described in chapter 10.

A T T E N T I O N

This device should not be operated immediately adjacent to or stacked with other devices.

This device should not be operated immediately adjacent to portable or mobile wireless communication devices or stacked with portable or mobile wireless communication devices.

For recommended separation distances from portable or mobile wireless communication devices, please refer to Chap. 10.3 (Electromagnetic Immunity - II) and 10.4 (Recommended separation distances).

RFID systems shall not be used at separation distances less than 0.15 m from the device. Otherwise, degradation of the performance of this device could result.

5 Advice for Users

5.1 Technical Instruction

During the installation, the A.R.C. Laser employee or local authorized representative will give a briefing. It contains the technical use of the device and essential security-relevant points. During the briefing, every person working in the vicinity of the laser should be present.

5.2 Laser-Safety-Training

The Q-Las laser is designed for medical users. It may only be used by personnel who have been instructed in its operation.

A.R.C. Laser GmbH recommends attending additional seminars to train working with different laser systems.

The A.R.C Laser employee or authorized representative who installs the device will also offer additional training for accompanying personnel. Subject of this briefing are the usage of laser safety goggles and laser safety in particular.

A.R.C. Laser GmbH has a list of recommended courses as well as laser safety courses. These can be obtained from us at any time.

5.3 Medical Instruction

During the instruction of the device, the A.R.C. Laser employee or authorized representative will only give a general overview of the medial applications.

If necessary, there is the possibility to take part in a training course with an experienced physician. Please contact your local A.R.C. Laser authorized representative, or contact us directly.

5.4 Device Parts and Accessories

5.4.1 Basic equipment

Additionally to the device itself, the basic parts consists of functional parts that are necessary for the operation of the device, as well as additional equipment for safety and functionality.

Necessary parts for operation:

Part	Description	Article number
Mains cable*	Type E/F (EU)	KB13003
	Type G (UK)	KB13004
	Type B (US)	KB13005
Door interlock	Door interlock plug, angular	KB03005
Chin rest paper**	Chin rest paper for the patient	SL01115
User Manual	User manual Q-LAS	

*The type of the mains cable depends on the destination country. One cable is included in the standard scope of delivery.

**Only chin rest paper provided by A.R.C. laser is allowed to be used with the Q-LAS. When the enclosed chin rest paper is used up, refills can be obtained from A.R.C. laser.

Additional equipment included:

The packaging equipment consists of:

Part	Description	Article number
Transport carton	Shipping box incl. distance foam	VP06028
Transport box***	Wooden shipping box	VP01081

***Lasers that are not delivered via freight transportation may not include a wooden shipping box.

other equipment:

Part	Description	Article number
Dust protection cover	Dust protection cover for the device	ZU01046
Cover for toothed racks	Cover for toothed racks to adjust the slit lamp position	ME06544
Spare LED Modul	Spare module for the LED	BG06565
Focus rod	Focus rod for adjustment of binoculars	ME06883

5.4.2 Optional accessories

Optional accessories are marketed separately. The products listed can, but do not have to, be purchased from A.R.C. laser.

A.R.C. laser offers **laser safety googles** for eye safety of additional people in the operating room.

Part	Description	Article-No.
Laser safety glasses	D LB 6 + IR LB8 + M LB10 / optical density OD10+, 1064 nm	AS01033

Contact glasses* required for Iridectomy or capsulotomy procedures can also be obtained from A.R.C. laser:

Application	Description**	Article-No.
Iridectomy	Ocular Abraham Iridectomy YAG Laser Lens	WE01243
Capsulotomy	Ocular Abraham Capsulotomy YAG Laser Lens	WE01244

*All offered contact glass forms are well established for their respective treatment. For further information about the medical treatments or the recommended devices consult the application manual or your medical device consultant. When buying contact glasses for use with Q-LAS, make sure that they are suitable for laser treatment.

**The listed designations are the trade names by ocular instruments. They may differ for different providers.

For the personal comfort of the physician and the stabilization of the arm while holding a contact glass, any comfortable **elbow rest** can be used. A.R.C. offers a stackable elbow rest made of foam. (ZU11056, diameter 116mm, height 28mm).

A T T E N T I O N

Only spare parts and applicators which are approved by A.R.C. Laser GmbH are to be used with the device. Accessories that have not been approved can significantly impair the safety and reliability of the device.

The use of accessories, transduce and services other than those which the A.R.C. Laser GmbH has determined or provided, may result in increased electromagnetic interference or reduced electromagnetic immunity of the device and lead to incorrect operation.

5.4.3 Instrument Table

The instrument table on which the slit lamp is mounted is height adjustable. This allows you to adjust the optimal working height comfortably for each patient. Please note that the table can only take an additional load of 2.0 kg. This means that no objects heavier than 2.0 kg in total may be placed on the table. Also, no persons may sit on the table or support themselves with their entire body weight on it.

If the table is tilted, you can calibrate it. To calibrate the table, move it all the way down and press and hold the button (down arrow) until it comes to a complete stop. After calibration, the table is horizontal again.

5.4.4 Foot Switch (optional)

An optional footswitch is available for your Q-LAS. This enables to emit laser radiation via the footswitch.

5.4.5 Lowering prism (optional)

A lowering prism can also be installed in the Q-LAS. This enables treatment by lowering the prism, without swinging out the lightning arm. A rotational prism is installed as standard.

6 Operation

This part of the manual only describes the technical application of the device, without going into the medical application.

Settings and adjustments should only be made in accordance with the operating instructions. Changes or settings that are not described in this manual can lead to malfunctions.

The laser is in the READY mode during treatment. If you interrupt, the laser must be returned to STANDBY mode. The device must always be switched off when unattended to prevent operation by an unauthorized third party.

ATTENTION

Since the aiming beam takes the same way through the laser transmission system as the working beam, it is a good way to check the integrity of the laser transmission system. If the aiming beam does not appear at the distal end of the laser transmission system, its intensity is weak or if it looks diffuse, this is a possible indication of a damaged or malfunctioning laser transmission system.

ATTENTION

The use of the controls or adjustments for performing procedures other than those specified herein may result in hazardous laser radiation exposure.

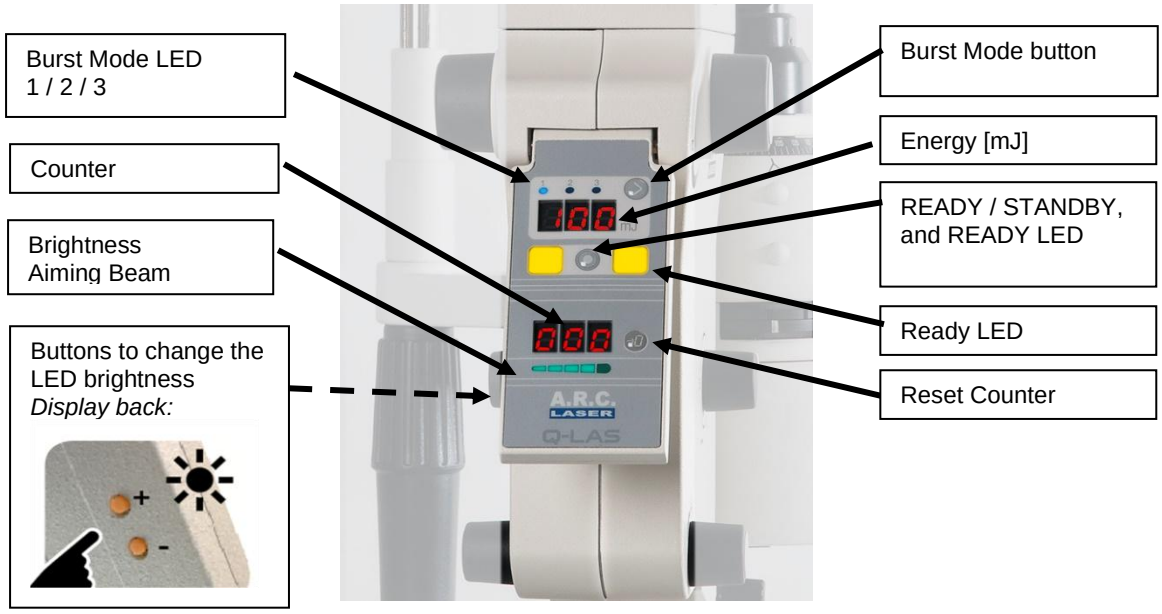
6.1 Starting the Laser

- Make sure the power cord is plugged in.
- Make sure the door contact switch is connected.
- Check that the Laser-Stop button is not pressed.
  If it is pressed, pull it up.
- Are third parties present who need safety glasses?
- Activate the main switch at the table.
- Turn the key switch.

ATTENTION

The Q-Las should not be operated for longer than 5 hours at a time. Restart the laser after 5 hours at the latest so that it can carry out the system check during the start routine. This ensures that undetected errors cannot occur.

6.2 Display



The display shows different information depending on the state of the unit.

When the Q-LAS is started by turning the key switch, the following sequence occurs:

- Warm-up phase: the system counts from 100 to 0. If the system has not yet reached the required operating temperature after the warm-up phase (approx. 60 seconds), it counts again from 100 to 0. A total of three warm-up phases are possible. After the warm-up phase, the device is at operating temperature (max. 180 s).
- The LEDs start to blink - - -
- **Set the energy level to 5.0 mJ**
- The laser performs 3 simulation shots
- The yellow READY LED flashes
- The Counter displays 0 0 0
- **Reduce the energy and set your treatment value.** (The laser cannot be switched to READY with 5.0 mJ.)

6.2.1 Energy Selection

Use the energy selection wheel to change the values. The available energy values can be continuously adjusted from 0.5 mJ to 10 mJ.

6.2.2 Burst Mode (Number of pulses = pulses per shot)

The number of pulses can be varied between 1, 2 or 3. The total energy output (mJ) changes depending on the number of pulses.

By changing the burst mode, the total energy changes as follows:

Energy (mJ) according to burst mode (1,2 or 3 pulses)	
1 Pulse	0.5 mJ to max. in 0.1 mJ steps
2 Pulses	1.0 mJ to max. in 0.2 mJ steps
3 Pulses	1.5 mJ to max. in 0.3 mJ steps

6.2.3 Reset Counter

To reset the counter to 0, pulse the Reset-button on the remote control: 000 is displayed again.

6.2.4 Laser STANDBY / READY

This button switches from STANDBY to READY and back. There is a safety break of 2 seconds programmed before the laser fires the first shot. The time flashes yellow LEDs.

Yellow LED **lights up**: Laser READY

Yellow LED **does not light up**: Laser STANDBY

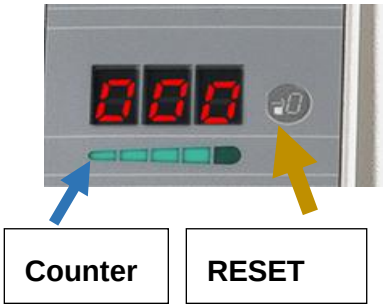
A T T E N T I O N

If the laser is in READY mode and is not used for more than 3 minutes, the laser automatically switches to STANDBY mode.

6.2.5 Counter and cumulated applied energy

In general, the sum of laser shots is displayed. However, it is also possible to display the applied energy. Therefore, the READY LED has to be pressed. The cumulated energy in Joule is displayed for a short time (2-3s) and the devices changes to STANDBY. The total energy is accumulated until the reset button is pressed. It resets both the shot counter and the cumulated applied energy back to zero.

Note: Your service technician is able to activate or deactivate this feature.



6.2.6 DualSpot Aiming Beam

The Q-LAS is equipped with a DualSpot aiming beam. The aiming beam is only visible in READY mode

The two 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 6.3).

6.3 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 the aiming beam

1: Focus position 150 µm behind the aiming beam

2: Focus position 300 µm behind the aiming beam

Aiming Beam

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

6.4 Trigger Button at the Joystick

6.4.1 Standard version with rotating prism

To trigger the laser, press the trigger on the elevator (joystick) or optionally the foot switch. To do this, the laser must be switched to READY mode and the lighting arm must be rotated approx. 12° to the right or left. An acoustic signal and the display (POS) warn if the arm is not fully rotated out.

The laser shot can only be triggered when the arm is fully rotated out.

When a laser shot is fired, a warning signal sounds simultaneously and the LED next to the joystick lights up.

6.4.2 Version with lowering prism

To trigger the laser, press the trigger on the elevation (joystick) or optionally the foot switch. The laser must be switched to the READY mode for this. The prism must then be lowered by turning the adjustment wheel on the prism. An acoustic signal and the display indicator (POS) will be noticeable to warn the operator if the prism is not lowered.

Alternatively, the procedure described in Chapter 6.4.1 can be used.

When a laser shot is fired, a warning signal sounds simultaneously and the LED next to the joystick lights up.

raised prism | retracted prism

6.5 Treatment

Position the patient on the chin rest. Make sure that the patient only touches the application parts. The application parts are the chin rest including handles. Make sure that you and the patient do not touch any other parts at the same time.

Adjust the position of the slit lamp, illumination and focus so that the visible aiming beam points merge into one point.

Choose your initial values for energy and burst mode. It is always good to start with a low energy level and then increase the energy during treatment.

Fix the patient's eye with a contact glass and focus the target beam into the eye to be treated.

Select the necessary beam intensity. At this point, you should see that the target point is in focus with the microscope.

Press the READY button: the yellow LED flashes for 2 seconds and then changes to steady light. The treatment can start.

Focusing too close to the intraocular lens can lead to its surface being damaged by the laser pulse. The patient may notice this after the treatment and find it disturbing. The focus shift can increase this distance. Furthermore, it is advisable to set the pulses circularly around the visual axis and not centrally.

A T T E N T I O N

Any serious incident that occurs with this laser must be reported to the A.R.C. Laser GmbH and the responsible state authority.

6.6 Variation for the Q-LAS PCL5-SH

If the Q-LAS is equipped with an SH-slit lamp, the laser leaves the READY mode when the arm is swung in. "POS" (swing out) appears as a warning in the display. Additionally, an acoustic warning signal is emitted three times.

6.7 Switch Off

1) Turn the key switch to position „OFF“ (see chapter 4.10) 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

Do not forget to turn off the system. It should be covered with a dust cover to avoid dust deposits on the optics.

6.8 Laser-Stop

Restart the device after pressing the laser stop (red button):

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

The counter is reset automatically. The energy display shows the selected energy value.

A T T E N T I O N

The **Laser-Stop** should only be used in emergencies.

It is located next to the key switch.

7 Specifications

7.1 General

Laser type	Q-switch Nd:YAG Laser
Cooling	passive with ambient air
Weight	53 kg with table and slit lamp
Dimentions	130 cm x 86 cm x 57 cm with slit lamp, height adjustable table 72-94 cm
Control Option	7-segment display

7.2 Laser Data

Wavelength	Energy	Tolerance
1064 nm	40 mJ max. Settings: 0,1 mJ Steps from 0,5 to 10 mJ BurstMode: 1,2 or 3 Pulse	±20% of the shown energy according to IEC 60601-2-22

Output	Single pulse, repetition rate 3 Hz, 2.4 Hz or 1.8 Hz
Pulse duration	< 5ns
Power transmission	coupled with a slit lamp
Aiming beam	
Lasertype	Diode laser
Wavelength	635 nm red
Optical output power	< 1mW
Brightness	variable

7.3 Electrical Connection Data

Power supply connection values	100-240 V, 50Hz/60 Hz, 250 VA

7.4 Classification

Laser class Laser Beam (Classification EN 60825-1)	3B
Laser class Aiming Beam (Classification EN 60825-1)	2
Classification according to MDR	IIb Rule 9
Electrical protection class (Classification IEC 60601-1)	II
Certification	CE 0123

8 Service

8.1 Introduction

The device was designed, developed and tested according to the latest technical knowledge. We have set the product life to 7 years. In addition, the availability of spare parts is guaranteed by us within a period of 10 years. However, in order to ensure that everything works properly, we have made it possible for you to carry out a visual check of the status indicators from the outside.

A T T E N T I O N

There is no need for the laser user to perform routine or service work within the laser system. All adjustments and calibrations that require the protective housing must be carried out by trained service personnel. This also includes cleaning and cleaning the optics within the laser.

8.2 Safety Check (STK)

Once within 24 months, the laser should be subjected to a safety check (STK) by trained personnel.

Scope of Safety Check (STK)

Visual Check

- Laser marking (laser class, max. Power, wavelength)
- Information signs/warning signs; properly and completely attached
- Instructions for use/medical device book
- Condition of the supply line
- Condition of the goggles/protective device
- Overall condition

Functionality Check

- Footswitch/joystick
- Beam guidance system/coupling/decoupling/pilot laser
- Check operating foil (touch screen)

Check the necessary monitoring/safety display and signaling unit

- Laser safety glasses
- Emission controls (acoustic, visual)
- Power meter (comparison internal, external)
- Key switch
- Laser stop switch (check for function)
- Interlock device (check for function)

Electrical Safety Check

- According to IEC 62353 or DIN VDE 0751, Part 1

Output power measurements

- Check the set power with an external power meter (permissible tolerance + 20%)

ATTENTION

If one or more safety-related points are objected to after the safety-related inspection (STK), the device may no longer be operated.

8.3 Care and Maintenance by the User

The following care instructions can be carried out by the user. These serve to make your work easier. For cleaning, the system must be disconnected from the mains. Always use a damp, but never wet, soft cloth for cleaning and disinfecting.

For cleaning and disinfection, the power supply must be disconnected. First clean the device with clear water and neutral detergent to remove coarse and visible contamination. Make sure that no moisture penetrates into the device.

Furthermore, wipe disinfection is possible. When choosing the disinfectant, pay attention to the following:

- according to the manufacturer of the disinfectant, the disinfectant should be suitable for non-invasive medical devices
- according to the manufacturer of the disinfectant, the disinfectant should be suitable for wipe disinfection of surfaces
- the disinfectant should be based on alcohol and/or quaternary compounds
- the disinfectant should be suitable for lacquers
- aldehyde-free disinfectant (recommended)

When doing wiping disinfection, the manufacturer's instructions for the disinfectant must be observed. Following possible disinfectant that meet the above mentioned requirements are listed:

Manufacturer	**Possible disinfectants***
BODE Chemie GmbH	Mikrobac forte, Bacillol 30 Foam
ANTISEPTICA	Acrylan, Biguacid Liquid
Schülke & Mayr GmbH	acryl-des, antifect AF (N)
Dr. Schumacher GmbH	CLEANISEPT, Descosept AF
Ecolab	Incidin Foam, Incidin Pro
Dr. Weigert	neoform MED AF, neoform MED rapid

*This list is not exhaustive.

ATTENTION

When cleaning, the device must always be switched off and disconnected from the mains.

Wet wipes should be avoided in any case. Exposure to water can lead to defects.

8.3.1 Inspection and cleaning of external optics

Check the accessible surfaces 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 approx. 10% alcohol.

8.3.2 Inspection and cleaning of internal Slit lamp optics

Regularly check all optics on the slit lamp - especially the plug-in mirror and the lens above it - for contamination.

A contaminated or dirty lens, mirror (both in PCL SH slit lamp) or prism (in PCL Z slit lamp) could lead to a reduction of energy when the laser beam passes through. The following problems can result:

- The set performance is no longer achieved during the test and calibration.
- A change in the beam behavior and the associated active beam during the operation.

Remedial Action:

1) Use non-alcoholic, not soaked cotton swabs and try to clean the outside of the lens with distilled water. If this does not lead to success, please continue with step number 2.
2) Take a few drops of methanol and gently drizzle the end of the cotton swab, then do as in step number 1.

A T T E N T I O N

Always wipe the optical surface in one direction. Never go back in the other direction with the same cotton swab. Any particles that have already settled in the cotton swab would scratch the optical surface again when moving back and thus cause irreparable damage to the optics.

8.4 Slit lamp

You can find detailed information on the care and maintenance of the slit lamp in the accompanying manual. It is essential to follow these instructions.

8.4.1 Slitlamp Mirror (only with SH-Slit lamp variant)

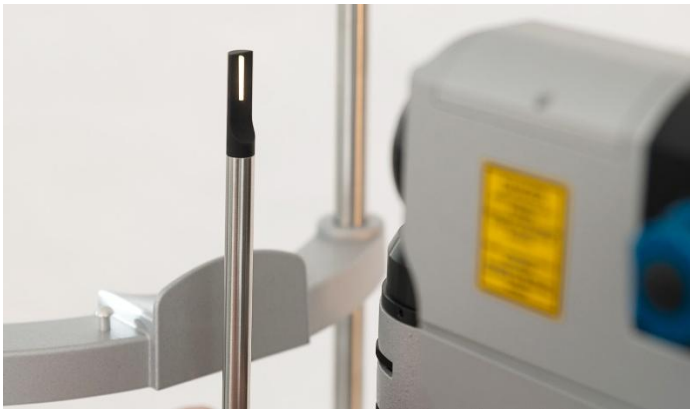
If necessary, clean the slit lamp mirror with a suitable lens brush. After dedusting, clean the mirror with Kodak lens cloths and a few drops of pure acetone. Do not use the cloth dry, otherwise the mirror will be scratched. Press only lightly so that the mirror is not adjusted. Do not rub more than once or twice. Heavy rubbing only spreads the dirt and causes scratches.

8.4.2 Dust Cover

After each use, the dust cover and the red display protective cover should be replaced to keep the surfaces clean.

8.4.3 Test the Slit lamp focus

1) Use the focus rod and insert it into the hole in the slit lamp axis. Follow the slit lamp manual that comes with the device.
2) Turn on the laser. Make sure that the laser is not triggered during this time. The laser must be in the READY mode. Center the aiming beam in the middle of the visual field on the focus rod.
3) Check that the aiming beam is circular and symmetrical.
4) A disturbed target beam can be an indication of a faulty system; thus the aiming beam can be a tool to check the integrity of the system.



ATTENTION

Press the eyepieces gently into the holder so that they are held completely in the binocular piece. Adjust each eyepiece to your satisfaction so that you can see a sharp imager of the focus rod through each eyepiece.

8.5 Troubleshooting

Possible Error		Messages and solutions	
F00	Watchdog error	Device is hanging during system check	Hardware Error Please restart the system. If the error occurs regular, contact your local sales & service-representative of A.R.C. Laser
F01	Reduced output -20%	Permanently checked by test shots during the system start-up and during the operation	Hardware error Please restart the system
F02	Higher output +20%	Permanently checked by test shots during the system start-up and during the operation	Hardware error 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 **F07** **F08**	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
F21	Error READY button	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
F44	Charging regulator of power supply without function	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 at the front panel	Please contact your local sales & service-representative of A.R.C. Laser
F58	Pulse Threshhold Voltage	Checking the maximum charge voltage at the internal charge controller	Please contact your local sales & service-representative of A.R.C. Laser
F61	Low voltages at the charging regulator	Checking the permissible voltage at the charging regulator	Please contact your local sales & service-representative of A.R.C. Laser
F62	Energy test error or burst mode voltage monitoring error	Checking if the energy or the burst voltage monitoring is function properly (d)	Please contact your local sales & service-representative of A.R.C. Laser
F63	Temperature/ humidity error	Checking the temperature, humidity respectively	Decrease the temperature, humidity respectively.
F0C	Position of the focus shift dial	Position of the focus shift is constantly checked	Check the position of the focus shift. It should be locked.
IL1	Internal Temperature	The internal temperature is out of permitted range. The laser should be allowed to cool down.	Please press the Reset-Button to delete the message.
IL2	Time Delay Trigger	Pressing the trigger only half way down or too slowly may cause this error message.	Please press the Reset-Button to delete the message. You immediately can proceed working afterwards.

Possible Error		Messages and solutions	
IL3	Internal power monitoring	Error when changing the energy while the device changes from STANDBY to READY	Device goes to STANDBY. Press the counter reset button to clear the display.
A or POS	Position of the arm: PCL5-SH and Z-version	The position of the lighting arm is constantly checked	Swing out the arm

8.6 Disposal

The relevant, locally applicable laws and regulations must be observed during disposal. Under no circumstances should the device be disposed of with domestic waste.

A.R.C. Laser GmbH is happy to assist with the disposal of the system; Costs for the proper return of the laser to A.R.C. Laser GmbH is the responsibility of the customer. Please contact our service department.

9 Customer Service

9.1 Warranty Information

A.R.C. Laser GmbH grants you a two-year guarantee. Parts that have a defect will be replaced free of charge within two years. All add-on and purchased parts are exempt from this guarantee. Our guarantee extends to the repair or replacement of defective parts. However, we reserve the right to renew entire assemblies and adapt them to technical progress.

Repairs by third parties or changes to the device will void the warranty. The use of other parts that have not been accepted with the device or obtained from other suppliers will also void the warranty. The attachment of parts or assemblies or other changes to the device requires the express written confirmation by A.R.C. Laser GmbH.

9.2 Warranty, Shipment, Packing

A warranty claim for defective parts, malfunction or damage to the housing of the device must be submitted to A.R.C. Laser GmbH within 24 hours. Parts that are returned during the warranty period (at the express request of A.R.C. Laser GmbH) must be confirmed in writing by A.R.C. Laser GmbH. Detailed packaging instructions and information on how to return the device are provided by A.R.C. Laser GmbH. The return must be insured and paid for by shipper. The insurance and transportation costs are not covered by A.R.C. Laser GmbH. The choice of the return is made by the A.R.C. Laser GmbH communicated to the customer. Changes and amendments in the carrier or the shipping method can lead to delays in transport and processing. All components to be changed under the warranty claim are manufactured by A.R.C. Laser GmbH renewed free of charge within the guarantee period. We reserve the right to make changes to the design of the device - if it appears necessary - to increase the safety or the functionality of the device. The responsibility for the design as well as for changes in the device lies solely with A.R.C. Laser GmbH. Changes will be communicated to the customer and accordingly carried out at A.R.C. Laser GmbH.

9.3 Sales and Service Information

For sales and service information, please contact A.R.C. Laser GmbH or our local distributor.

10 Guidelines and Manufacturers Declaration

10.1 Electromagnetic Emissions

The laser is intended for use in an environment as specified below. The customer or user of the laser should ensure that it is operated in such an environment.

Immunity tests	Compliance	Electromagnetic environment - guideline
RF-Emissions CISPR 11	EN 55011 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	EN 55011 Group 1/Class B	The laser is only suitable for the environment in professional healthcare facilities
Harmonic emission	IEC 61000-3-2 Class A	
Voltage fluctuations/flicker	IEC 61000-3-3	

10.2 Electromagnetic Immunity (1)

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)	± 2 kV, ± 4 kV, ± 6, ± 8 contact discharge; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	IEC 61000-4-2	Floors should be made of wood, ceramic or stone. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Radiated RF electromagnetic fields	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used..
Proximity fields from RF wireless communications equipment	3 V/m 80 MHz to 2,7 GHz (see Table 10.4)	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used..
Rated power frequency magnetic fields	30 A/m 50 Hz or 60 Hz	IEC 61000-4-8	Magnetic fields at the grid frequency that are usually available in domestic or clinical areas may be used.
Electrical fast transients /burst	± 2 kV for power lines ± 1 kV for IO-lines 100 kHz repetition frequency	IEC 61000-4-4	Only the voltage of a typical professional healthcare facility may be used..
Surge voltages (Surges), Line against line	± 0.5 kV, ± 1 kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Surge voltages (Surges), Line against grounding	± 0.5 kV, ± 1 kV, ± 2 kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Conducted disturbance variables, induced by high-frequency fields	3 V 0.15 MHz to 80 MHz 6 V in ISM-frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	IEC 61000-4-6	Only the voltage of a typical professional healthcare facility may be used.
Voltage dips	0 % UT; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 level 0 % UT;1 cycle at 0 and 180 level And 70 % UT; 25/30 cycles at 0 and 180 level	IEC 61000-4-11	Only the voltage of a typical professional healthcare facility may be used. It is recommended to use an uninterruptible power supply.

Power interruption	0% UT; 250/300 cycles at 0 and 180 level	IEC 61000-4-11	Only the voltage of a typical professional healthcare facility may be used. It is recommended to use an uninterruptible power supply.
NOTE: UT is the AC mains voltage prior to application of the test level.			

10.3 Electromagnetic Immunity (2)

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	EMV standard	Electromagnetic environment – guidelines
Conducted disturbance variables, induced by high-frequency fields	3 V 150 kHz to 80 MHz	IEC 61000-4-6	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CLASSIC 514, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. The field strength of stationary radio transmitters is, as determined by an electromagnetic site survey, at all frequencies smaller than the compliance level. Interference may occur in the vicinity of equipment market with the following symbol:  If higher IMMUNITY TEST LEVELS than those specified in Table 9 (IEC 60601-1-2) are used, the minimum separation distance may be lowered. Lower minimum separation distances shall be calculated using the equation specified in 8.10 (IEC 60601-1-2).
Radiofrequency electromagnetic fields in the immediate vicinity of wireless communication devices	3 V/m 80 MHz to 2.7 GHz	IEC 61000-4-3	

10.4 Recommended separation distances between portable and mobile RF telecommunications equipment and the laser

The laser is intended for use in an electromagnetic environment in which the RF disturbances are controlled. The customer or the user of the laser can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the laser - depending on the output power of the communication device, as stated below.

Test frequency **MHz**	**Frequency band** **MHz**	**Radio service**	**Modulation**	**Maximum performance** **W**	**Distance** **m**	**Immunity test level** **V/m**
385	380 to 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 to 470	GMRS 460 FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0.3	28
710 745 780	704 to 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 801.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Notes:

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