User Manual

COBRA

A.R.C. Laser GmbH

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1 INTRODUCTION

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

Cobra Laser system 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 symbol **"Attention"** is attached to all surfaces that mean danger to the user. Before carrying out any further work on such marked parts, the operating instructions should be consulted or the service of A.R.C. Laser GmbH should be contacted.

The symbol **"Attention laser radiation"** is intended to warn the user against directing laser beams to unwanted areas through improper handling or improper operation of the device.

1.2 Intended use

Cobra is a dual platform laser device consisting of the CITO 532 and Q-Las, featuring full performance capabilities of both devices which are discussed in this manual. The Cobra only serves the purpose of switching back and forth between CITO 532 and Q-Las.

With the Cobra you can treat open-angle glaucoma (see intended use CITO 532) and apply laser iridotomy or laser capsulotomy (see intended use Q-Las).

1.2.1 Intended use CITO 532

The Cito 532 is an SLT laser that emits laser light at a wavelength of 532 nm. This light is pumped using diodes to produce pulses with a duration of <7ns.

The purpose of the CITO 532 is to treat open-angle glaucoma. This includes the treatment of all patients who have increased intraocular pressure and in whom an anterior chamber angle is wide enough to act directly on the trabecular meshwork with laser light. For this purpose, the laser is used together with a gonioscope, which directs the laser light directly onto the trabecular meshwork via a built-in mirror. The laser effect is adjusted so that the disease is treated by gently acting on the patient's tissue without destroying the tissue. Using the laser light in the patient's chamber angle does not cause injuries or pain. The use of the laser can increase the outflow of aqueous fluid from the patient and thus lower the intraocular pressure. The laser unit is for use in a non-sterile environment, e.g. provided in a treatment room to treat patients on an outpatient basis.

Indications for the treatment of patients with open-angle glaucoma

- non-response to drug treatment
- drug allergies
- insufficient medication to lower intraocular pressure
- a need for manual glaucoma surgery and the presence of contraindications to this surgery (e.g. intolerance to anesthesia)
- the desire to reduce glaucoma medication
- the requirement to improve the quality of life of the glaucoma patient
- The desire for an alternative treatment to medication in the early stages of glaucoma treatment

Contraindications for the treatment of patients with open-angle glaucoma

- Glaucoma that is not associated with increased intraocular pressure
- Flat anterior chamber, without direct gonioscope view of the trabecular mechanism
- Angular block glaucoma
- Patients who are unable to take a seat in front of a slit lamp, open or keep eyes open, or hold a stationary head position for 2 minutes

1.2.2 Side effects in the treatment of open-angle glaucoma

Measures to reduce or avoid possible side effects:

1. Glare:
   - Make sure that the patient's pupil is as small as possible during the treatment, this significantly reduces the incidence of light on the retina and thus the patient's glare caused by scattered radiation from the laser.
   - Only use contact lenses suitable for laser applications. This reduces reflections or scattered radiation and thus glare and non-targeted, i.e. not relevant for treatment, radiation in and around the eye.
2. Inflammation (inside of the eye, of the anterior chamber):
   - Always start the treatment with low energy levels and increase the energy level to the treatment level. Never start with high values or values above the estimated treatment level. This reduces the radiation exposure for the eye and minimizes the possible occurrence of inflammation.
3. Collateral damage to irradiated tissue (cornea) and to the eye:
   - Avoid non-therapeutically effective laser pulses and follow the instructions in point 2, which reduces the total energy delivered to the eye and thus reduces possible tissue damage outside the desired therapeutic area.

Drug therapy is indicated to prevent or reduce possible collateral damage to irradiated tissue, counteract inflammation or treat temporary increases in pressure after treatment and is therefore indicated.

1.2.3 Intended Use Q-Las

The Q-Las is a Nd: YAG laser that emits laser light at a wavelength of 1064 nm. This light is passively converted by a Q-switch to produce pulses with a duration of 4 to 10 ns. Those impulses reach energy of maximally 40 mJ. The short, high-energy pulses generate a plasma in the focal plane, which ensures an optical breakthrough. This effect can be used in ophthalmology for iridotomy or a capsulotomy.

In laser iridotomy, laser pulses are used to treat closed-angle glaucoma by creating small holes in the peripheral iris that allow the pressure between the anterior and posterior chambers to be equalized.

In laser capsulotomy, the posterior capsular bag is opened in order to treat a cataract that occurs after a cataract operation.

Indications for laser iridotomy

- Treatment of patients with closed-angle glaucoma
- Pressure relief required
- No response to drug treatment
- Allergies to medication
- Treatment for glaucoma is necessary, but anesthesia is not possible

Contraindications to laser iridotomy

- Glaucoma, which is not caused by an increase in pressure in the eye
- Presence of open-angle glaucoma

Indications for laser capsulotomy

- Occurrence of fibrosis after cataract surgery

Contraindications to laser capsulotomy

- Inflammatory processes
- Glass lenses: risk of breakage

1.2.4 Contraindications to Laser-Iridotomy / Laser-Capsulotomy

Measures to reduce or avoid possible side effects:

1. Glare:
   - Make sure that the patient is not blinded by the light of the slit lamp for longer than necessary for the treatment.
2. Collateral damage to irradiated tissues and the retina:
   - Always start the treatment with the energy setting most likely necessary for the treatment. At a visual breakthrough and a good treatment effect, reduce the energy value until you notice a decrease in the treatment efficiency. Now return to the smallest possible setting at which you observed a treatment effect. If there is no optical breakthrough, increase the energy value gradually until this is achieved together with a good treatment effect. Never start with high values or above the estimated treatment level. Avoid non-therapeutic laser pulses. This reduces the exposure to radiation to the eye and minimizes the potential for collateral damage.
   - Only use contact glasses suitable for laser applications. This reduces reflections or scattered radiation and thus glare and non-targeted, i.e. radiation in and on the eye that is not relevant for treatment.
3. Inflammation (inside the eye):
   - Equivalent to point 2.
4. Damage to the artificial lens from laser pulses:
   - The focus shift possible on the Q-Las in position 1 or 2 increases the distance from the lens to the laser focus (2> 1) and can thus prevent damage to the artificial lens from laser pulses.

Therapy with medication can also prevent or reduce possible collateral damage to the irradiated tissue after treatment, counteract inflammation or treat temporary increases in pressure and is therefore indicated.

ATTENTION

The device may only be operated by specially trained personnel who are experts in the medical effects and possible 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

Cobra is a dual platform laser device consisting of the CITO 532 and Q-Las, featuring full performance capabilities of both devices. The laser beam path is coincident with the observation path of the slit lamp. Using the aiming beam, the desired location of the treatment can be precisely positioned.

1.3.1 Theory and Technical Set-up CITO 532

The CITO 532 is a diode-pumped laser with a wavelength of 532 nm. The radiation in the laser head is generated with the help of a pump diode. The laser beam that leaves the device has a small diameter; this is 400 µm at the point action in the patient's eye.

The wavelength of the emitted laser light depends on the laser medium. In our case, infrared laser radiation is generated in the device. The wavelength of this infrared laser radiation is now halved with the help of a special **crystal** and generates a wavelength of 532 nm. The laser beam is converted into short, green laser pulses with high energy, which leaves the device through the laser beam path.

With the CITO 532, 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.

1.3.2 Theory and Technical Set-up Q-Las

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; this is less than 10 µm at the place of its effect in the patient's eye.

The wavelength of the emitted laser light depends on the laser medium. In our case, infrared laser radiation is generated. Attenuating optics enable the energy that should leave the device to be set. Internal control mechanisms compare the actual with the target state for the selected amount of energy.

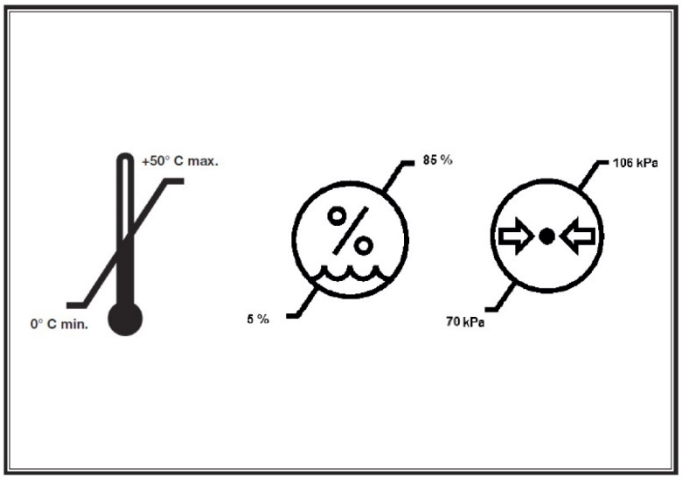
With the Q-Las, the laser beam path is overlaid with the observation beam path of the slit lamp. With the help of a target beam, the desired treatment position can be precisely determined in advance.

The focus of the laser can be shifted in 2 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 system, 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 -10°C and +60°C. The air pressure during transport must be between 1080hPa and 750hPa. 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%.

A T T E N T I O N

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.

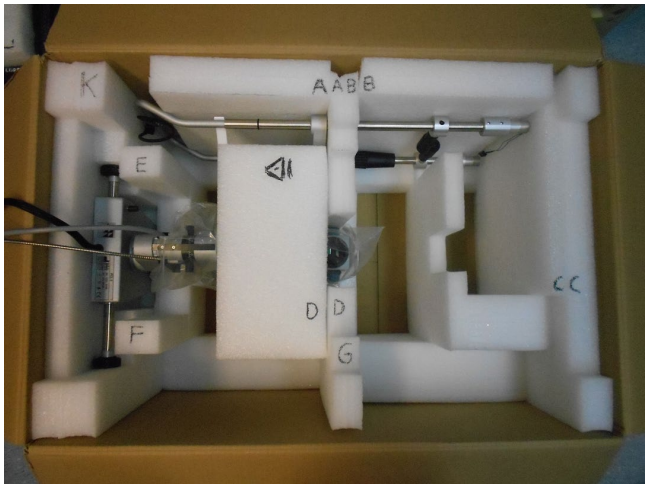
2.1 Shipping and unpacking the device

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

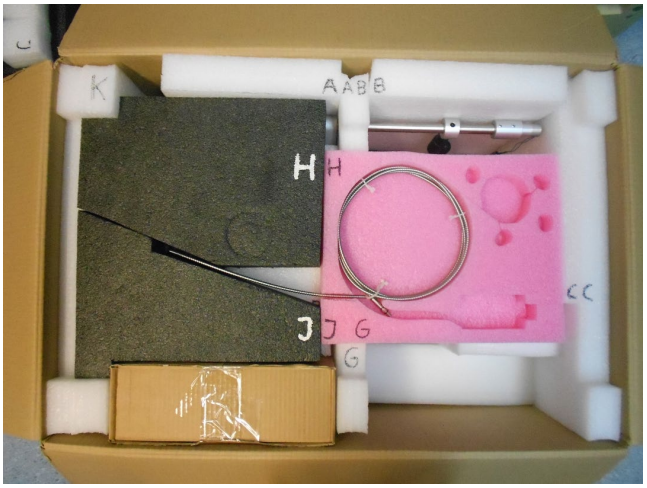
The device will be shipped in a specially developed transport packaging. Please keep this. If you ship the device back to A.R.C. Laser GmbH, be sure to use the intended transport packaging.

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

Before the device is delivered, it must be ensured that the laser can be set up in a suitable location.

The Cobra Laser should be operated in an easily accessible place. The laser should not be operated near a heater, since air cooling works best when the ambient temperature is not higher than 28°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 18°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 may only be operated on an earthed wall socket and 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 Cobra Laser system 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.

Der Cobra Laser falls under laser class 3B according to EN 60601-2-22 or rather EN 60825-1.

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.

With regards to the devices supplied, such as slit lamps or instrument tables, the safety, operating and maintenance instructions in the corresponding manuals must be observed. With regards to the instrument table, reference is only made here to the danger from improper use 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 Eye Safety

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 laser must be guaranteed for the patient.

When using the laser, please provide those safety goggles that are designed for the wavelength of, the treatment laser and on which at least the CE mark and protection class are marked

When using the CITO 532, you must use safety goggles for **532 nm** and provide safety class **DIR LB5 (OD 5+)**.

By using the Q-Las, you must use safety goggles for **1064 nm** and provide safety class **DIR LB6 (OD6+)**.

Alternatively, there are also laser protective goggles that are designed for both wavelengths.

Safety goggles are specially designed for these wavelengths and included in the scope of delivery. Please send reorders to the A.R.C. Laser GmbH stating the wavelength or the article number of the protective goggles.

The safety goggles also allow spectacle wearers to be protected on all sides. Scattered radiation that does not reach the eye directly from the front can harbor dangers due to internal reflections arising from glasses. Therefore, we recommend that you wear safety goggles that also ensure full side 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 will cause serious damage to your retina.

4.3 Electrical Protection

Never remove the housing parts of the laser. Work on the device may only be carried out by authorized A.R.C. Laser GmbH service personnel. If the mains have to be replaced, it must be carried out by authorized service personnel only.

The room in which the laser is operated should be kept dry. In the event that cleaning is necessary, make sure that 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 you notice any visible defect on the power plug, 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.

4.6 NOHD Sicherheitsabstand

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:

$$NOHD = \frac{\sqrt{\frac{4P}{MZB * \pi}} - Durchmesser\ Strahlbündel}{Strahldivergenz}$$

For the **CITO 532** applies:

Wavelength λ:	**532 nm**
NOHD:	**3.7 m**
Beam divergence $\alpha_{(full\ angle)}$:	**11.7°**
Permitted Maximum Radiation:	**6.7 x 10^{-3} Jm^{-2}**

For the **Q-Las** applies:

Wavelength λ:	**1064 nm**
NOHD:	**3.2 m**
Beam divergence $\alpha_{(full\ angle)}$:	**16°**
Permitted Maximum Radiation:	**2.5 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 Directive 93/42/EEC 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.

A device book and the test approval number are included with the device.

4.8 RoHS2- Regulation

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 2011/65/EU (RoHS 2).

4.9 Protecting Housing

Cobra laser system has a protective housing. It prevents radiation from the laser from escaping and protects users from touching live parts. This housing must not be removed.

1) Slit lamp PCL 5 and housing of the Q-Las
2) Controller / Touchscreen
3) Housing of the Cobra

4.10 Connectors and switches

The main switch under the table turns the entire system on and off.

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

You can connect a warning light to the orange marked connector. ● 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. ●You can replace it with a door interlock switch (see chapter 4.11).

There is a USB connection on the touch display. This is to be used for service purposes only! It is not possible to load or save files or programs via this port.

ATTENTION

To avoid the risk of electric shock, this device may only be connected to a supply network with a protective earth conductor.

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 is stucks firmly to prevent unexpected system interlock problems.

4.12 Safety-Shutter/Aiming Beam

The Cobra Laser has an internal safety shutter. This shutter is opened by pressing the READY button and then releases laser radiation. However, this can only be done if the laser has passed the internal tests and calibrations.

The aiming beam is only visible when the laser is in the READY mode. This aiming beam is a laser beam 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.

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.

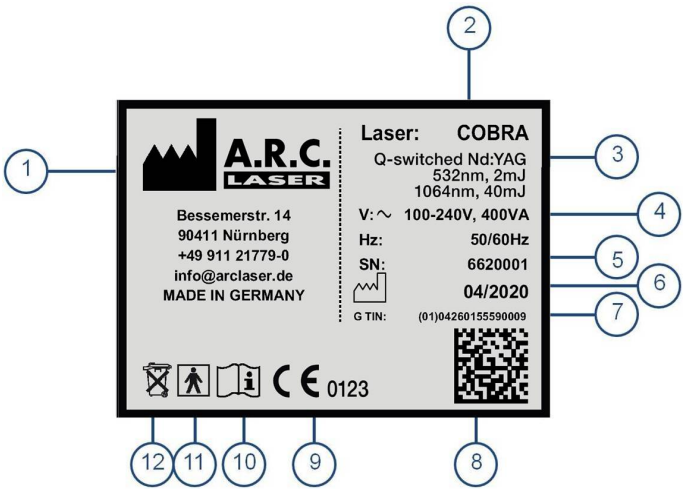
4.14 Reset by Power Failure

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

Cobra 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.

4.15.1 Typenschild

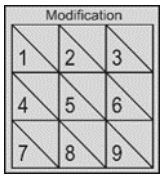


1) Manufacturer
2) Laser name
3) Laser specifications
4) Electrical connection data
5) Serial number (SN)
6) Production data
7) GTIN (Global Trade Item Number)
8) UDI (Unique Device Identification = GTIN + SN + production date)
9) CE-Mark
10) Follow instruction for use
11) Application part type BF
12)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

4.15.2 Fuse Label

Only use the predescribed fuses.

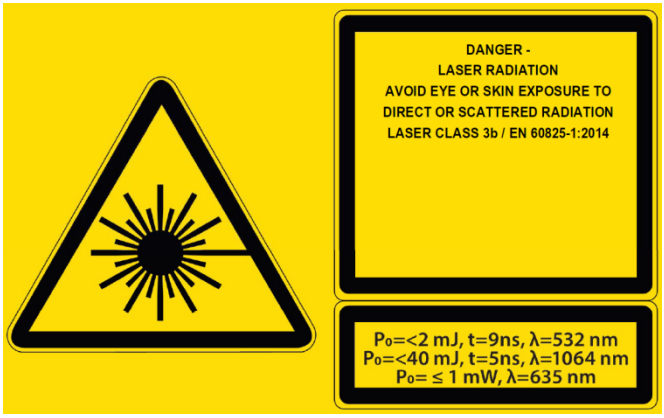
4.15.3 Modification Label



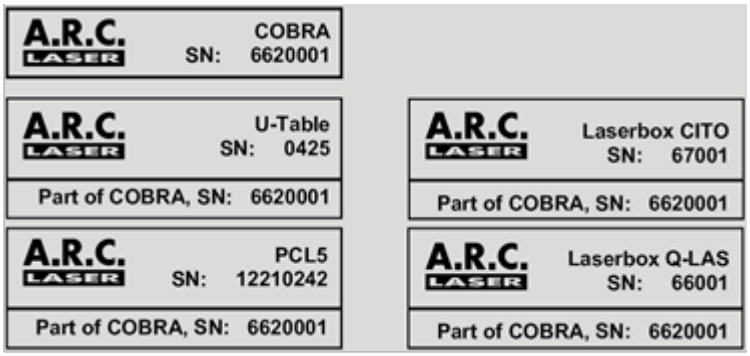
Shows the current device status based on the marked modification numbers.

4.15.4 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.



4.15.5 Serial Number



The Cobra consists of several subsystems, each with its own serial number.

4.15.6 Laser-Stop

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

4.15.7 Follow instructions for use

On the device,
You will again be reminded that the
instructions for use must be observed.

4.16 Operating Conditions:

The medical laser Cobra 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 1080hPa and 750hPa.

The following environmental conditions must be met:

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

4.17 Electromagnetic Compability

The 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

Avoid using this device next to other devices or with other devices in a stacked form as this could result in improper operation. If such use is still necessary, this device and the other devices should be monitored to ensure that they are operating properly.

5 ADVICE FO USERS

5.1 Technical Instruction

During the installation of the device, instruction is given by an A.R.C. Laser GmbH employee or an authorized representative.

This first instruction essentially relates to the technical use of the device. In addition, essential security-relevant points are dealt with. During the briefing, all persons working in the vicinity of the laser should be present.

After instruction, all instructed persons are noted in the device book, with one person being entered as the person responsible for safety. This person is later entitled to instruct other people on the device. These must also be noted in the device book.

5.2 Laser Safety Training

The Cobra laser is designed for medical users. It may only be used by personnel who have been instructed in its operation. The A.R.C. Laser GmbH recommends, in addition to the briefing, participation in seminars in which working with different laser systems is dealt with. In addition, instructions are given on laser safety and the use of lasers in general. It has also proven useful that people who do not work directly with the laser attend courses on laser safety.

Training for the accompanying staff is additionally accompanied by an instruction from an A.R.C. Laser GmbH employee or by an authorized representative when installing the device. During instruction, the use of laser safety glasses and laser safety will be specifically addressed.

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

In the context of device instruction, only the general medical application is addressed. The A.R.C. Laser GmbH only gives recommendations for applications.

If necessary, there is the possibility to take part in a training course with an experienced doctor. Please contact your responsible administrator or A.R.C. Laser GmbH directly.

5.4 Medical Device Book

The medical device book is included with the delivery documents. This must be kept in a safe place and presented to the technician in the event of servicing or when performing the technical safety check (STK).

Please note that a medical device book is not required in every country.

Note the local requirements and laws.

5.5 Device Parts and Accessories

The basic parts of Cobra include:

Lasersystem Cobra with slit lamp	User Manual (Cobra / PCL5)
Mains cable (Laser device)	Touch screen to operate the laser + cover
Power cord to connect the device to a wall outlet	Instrument table, height adjustable
A.R.C. dust cover	Door-Interlock-Plug

The system includes additional laser safety goggles (AS1003) to provide protection for third party individuals in the room at the time of treatment.

For information about other accessories, please contact A.R.C. Laser GmbH or the responsible sales partner.

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.

5.5.1 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.

6 OPERATION

This part of the manual only describes the technical application of the device, without going into the medical application. You will receive separate application manuals from A.R.C. Laser GmbH.

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.

The main switch under the table switches eht enire system on / off.

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.

A T T E N T I O N

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

6.1 Start the Cobra

- 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
- Switch on the Cobra via the remote-control Key Switch.

Position Key Switch:

← ON (1)

OFF (0)

↓

Rotary knob

To select either
CITO 532 or Q-Las

Energy Selector

Q-Las

A T T E N T I O N

The Cobra 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.

When the rotary knob on the side of the slit lamp is in the neutral position, i.e., neither the CITO 532 nor the Q-Las is selected, the laser starts normally, and the following image will appear on the display:

The following sequence then results:

- Upon initial turn on, the “Warm Up” phase appears on the slit lamp display as it counts down from 100 to 0. If the CITO 532 is already selected when the device is started, the warm-up phase will still appear on the slit lamp display.

  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 third at the latest, the device is at operating temperature (max. 180 sec).
- The LEDs at the slit lamp start to blink - - -
- Now turn the rotary knob upwards and select the Q-Las
- **Set the energy level to 5.0 mJ**
- The laser performs 3 simulation shots
- The yellow READY LED flashes
- The Counter will show 0 0 0

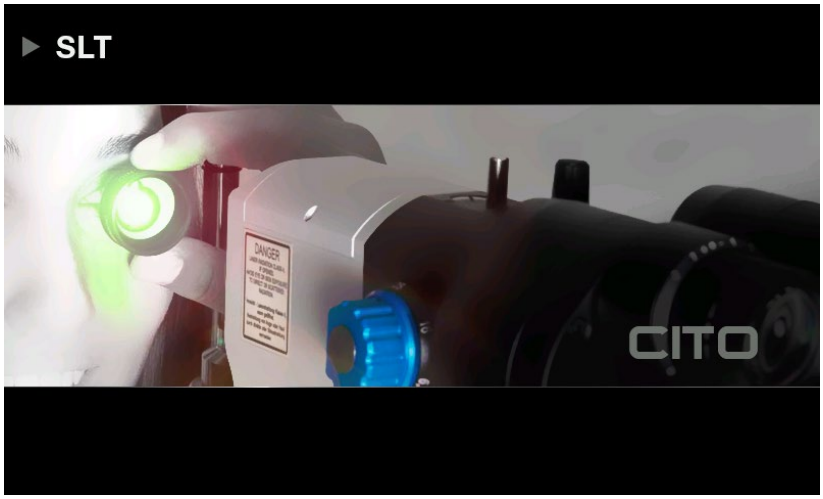
- The current output (5 mJ) is shown in the upper part of the display
- **Now reduce the energy and set your treatment value.**
  The laser cannot be switched to READY with 5.0 mJ.

Now Cobra is ready for operation.

6.1.1 Select Application

CITO 532:

To select the CITO 532, turn the rotary knob located on the side of the slit lamp in the counter clockwise direction (down) until it clicks into place. The following image will appear on the display:

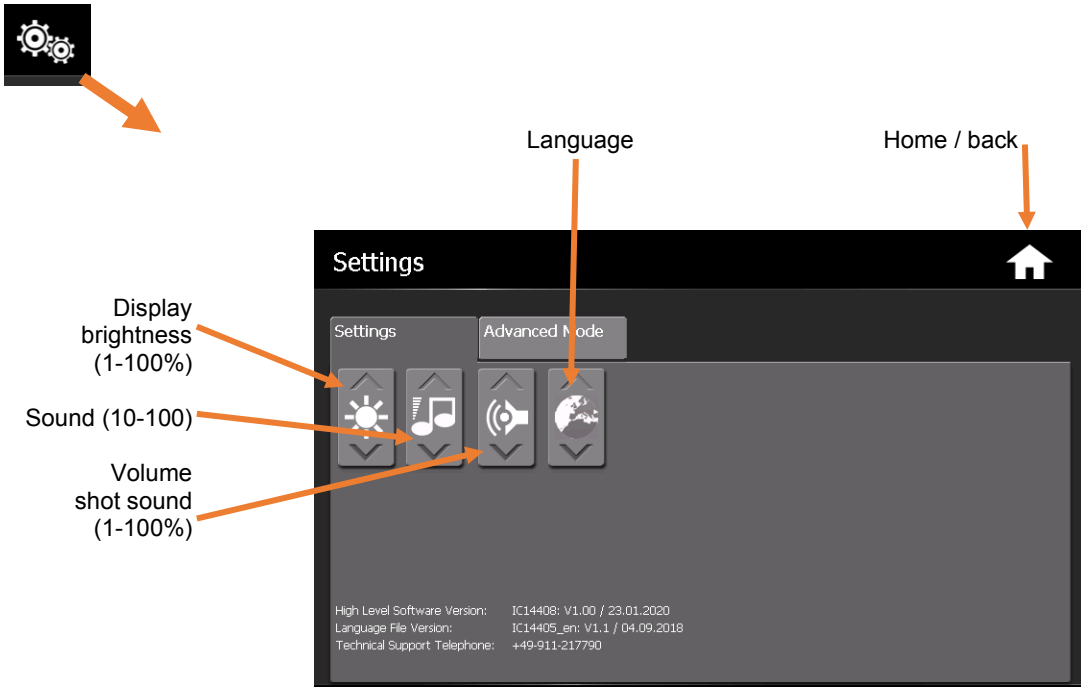


The main screen of the CITO 532 is then automatically displayed. Use the CITO as described in chapter *Kapitel 6.2 f*.

Q-Las:

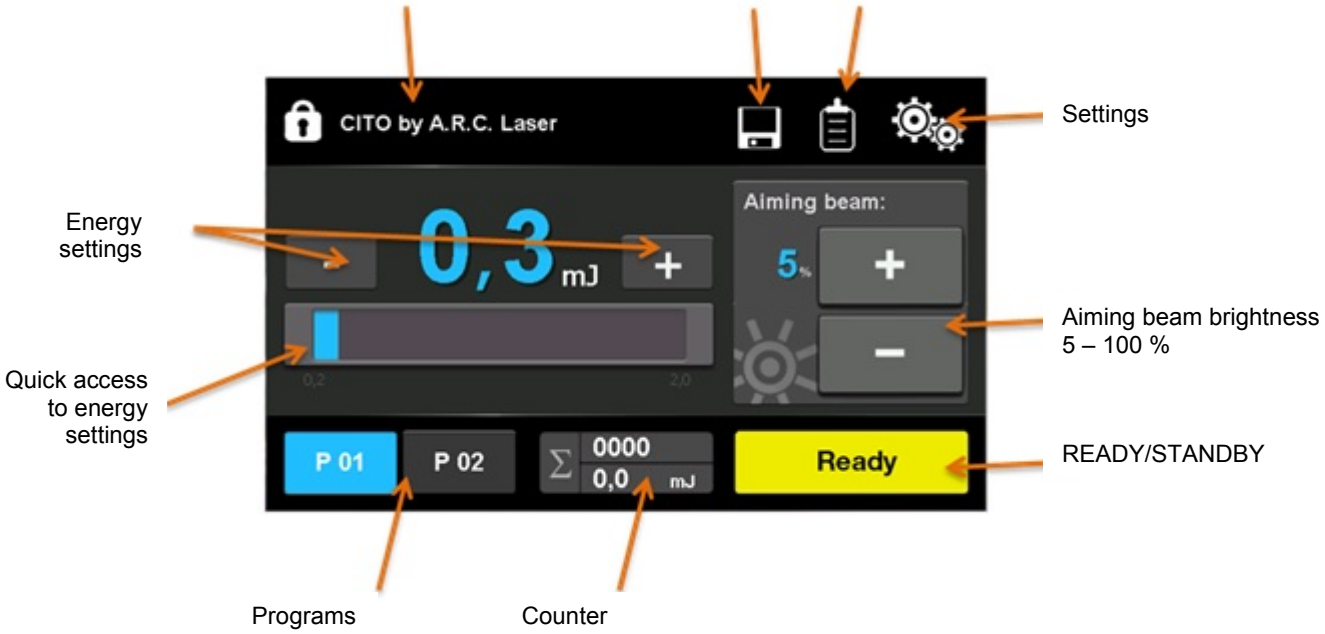
To select the Q-LAS, turn the rotary knob located on the side of the slit lamp in the clockwise direction (up) until it clicks into place. The following image will appear on the display:

Access the system settings for display brightness, sound and language via the gearwheel icon.



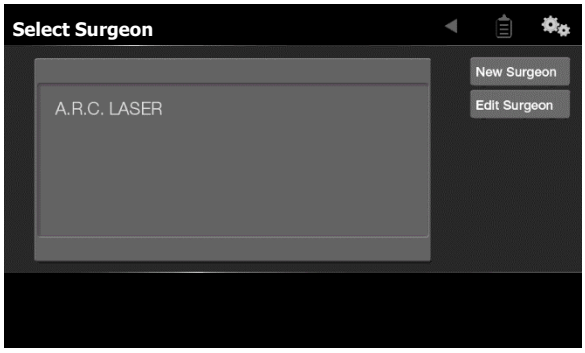
Further operation of the Q-Las is described in Chapter *6.3 f*.

6.2 Operation of CITO 532



6.2.1 Select doctor / Add doctor

Since it is possible to store multiple users, select a desired user by clicking on the doctor's name at the upper left of the control panel and it will automatically take you to the program stored for that selection. When logging in for the first time, it is necessary to click “New Surgeon” to create a new user.



Hinzufügen eines neuen Namens

As soon as several surgeons are entered, they appear in a selection list.

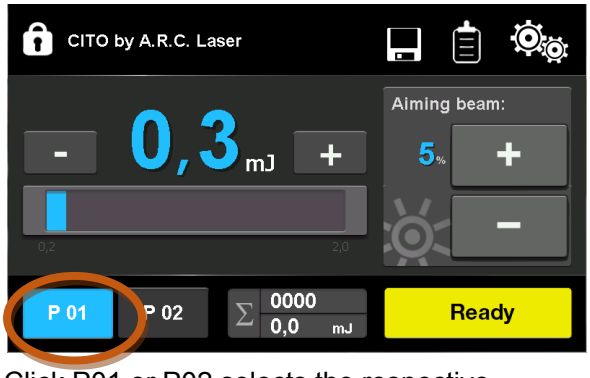
Surgeon List

Select the desired name from the list here.

 EDITING a surgeon

 DELETE from List
A security question prevents accidental deletion.

6.2.2 Selection of Programs

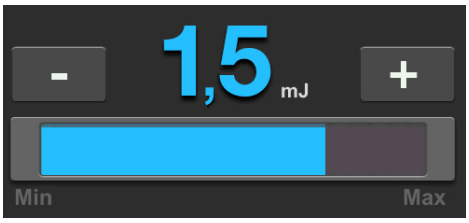


Both programs P01 and P02 can be individually defined and saved.

First set your desired energy and then press the disk symbol to save. The set energy value is now saved

Click P01 or P02 selects the respective program.

6.2.3 Energy Configuration



With Plus/Minus the Energie can be selected within small steps. Selection using the slider is suitable for larger steps or faster selection.

The following energy values are available:

0.2 till **1.4 mJ** in **0.1 mJ** steps

1.6 till **2 mJ** in **0.2 mJ** steps

6.2.4 Laser STANDBY / Ready

This button switches from STANDBY to READY and back.
A safety pause of 2 seconds is programmed before the first laser shot. The yellow READY field flashes three times

If a new energy value is set in READY mode that exceeds or falls below **1.4 mJ**, the laser recalibrates. The READY field flashes once and the touch screen cannot be operated. Once the internal calibration has been completed, the laser can be operated as usual.

A T T E N T I O N

If the laser is in the READY mode and is not used for more than 2 minutes, the laser automatically switches to the STANDBY mode.

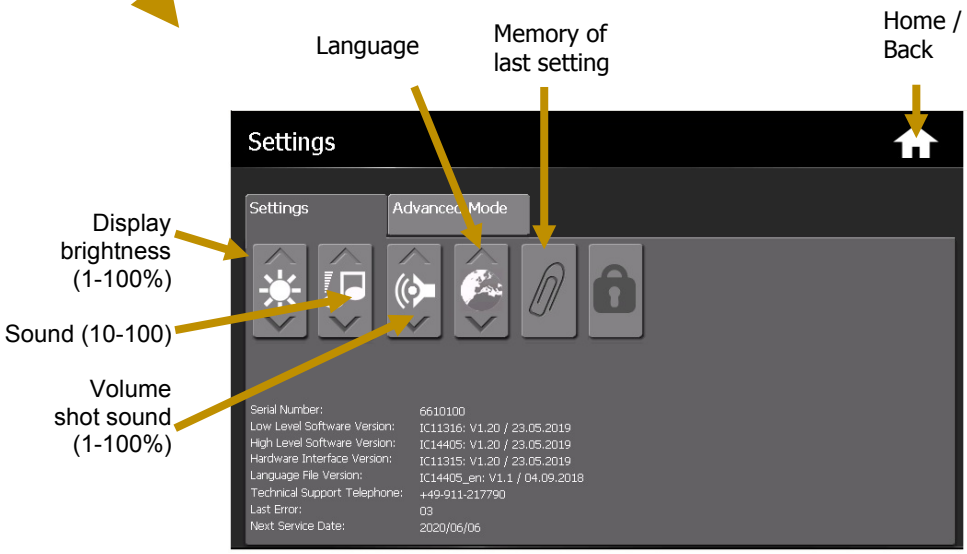
6.2.5 Counter

The number of shots fired, and the accumulated energy are shown in the lower part of the display (shot counter). To reset the counter to 0, press the sigma symbol (for at least 1s). This will reset the number of shots and the accumulated energy.

You can also access the recorded treatment data via the clipboard symbol (laser log). The system shows the serial number of the device and the average energy set. The total laser shots and the total energy output are displayed here. With the reset button, all counter readings in this and the main mask are reset.

6.2.6 Settings / Submenu

You can access the system settings via the gearwheel icon



Parameters are set using the up/down arrows  .

6.2.6.1 Select Language

While using the up/down arrows the system language can be selected: DE for German, EN for English

6.2.6.2 Reminder of the Doctor and Programs set

The system remembers the last selected setting when the paper clip is shown in white. The memory function applies to the doctor and treatment program. At the next start, the system automatically jumps to the last set routine. If the paper clip is dark, nothing is saved or preset.

6.2.7 Release Laser Beam

To trigger the laser, press the trigger on the vertical drive (joystick) of the laser slit lamp. To do this, the laser must be switched to the READY mode.

When a laser shot is fired, a simultaneous warning signal sounds and the red LED on the emergency stop button lights up.

6.2.8 Treatment

Position the patient´s chin 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, slit lighting, focus and contact glass as required. Choose your initial values for the laser energy. It is always good to start at a low level and then increase energy to the target 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 steel point is in focus with the microscope.

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

Treatment can start.

The software of the CITO 532 allows the energy delivered to be added up, which is permanently shown in the lower area of the display.

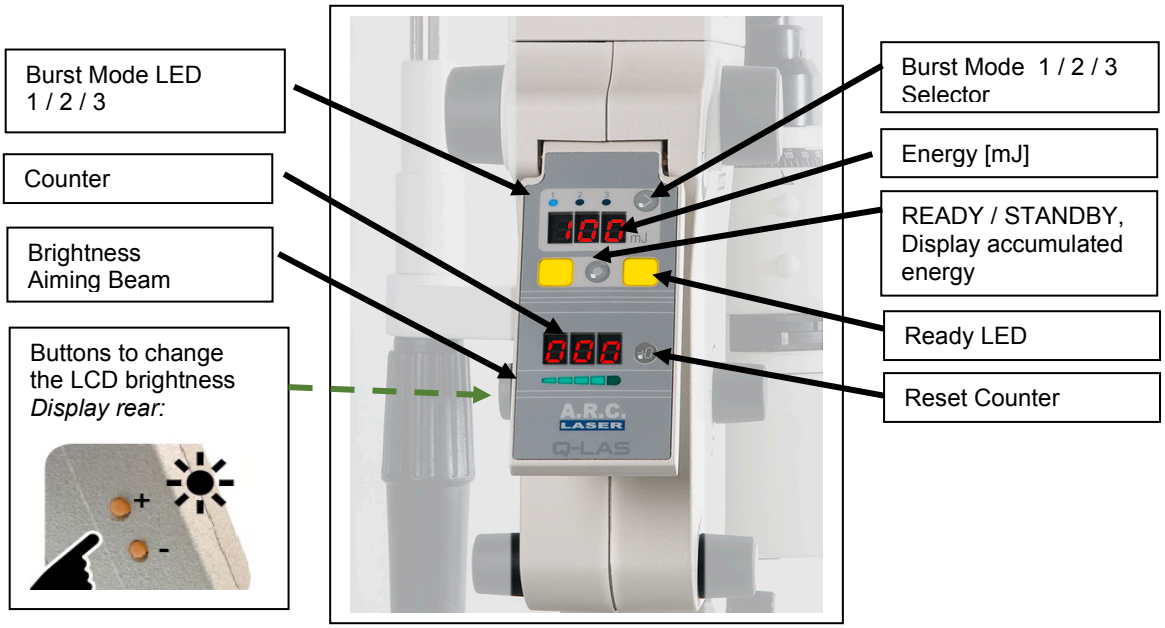
Change of Patient

At the end of a treatment, press the READY button, so you can document the total energy delivered. The trigger does not work in this position.

A T T E N T I O N

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

6.3 Handling the Q-Las



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:

6.3.1 Energy Selection

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

6.3.2 Burst-Modus (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 oder 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

6.3.3 RESET Counter

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

6.3.4 Laser STANDBY / READY

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

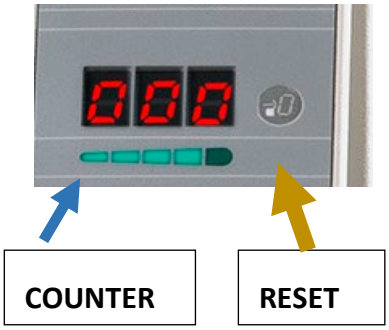
Yellow LED **lights up**: Laser READY

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.

6.3.5 Cummulated applied energy



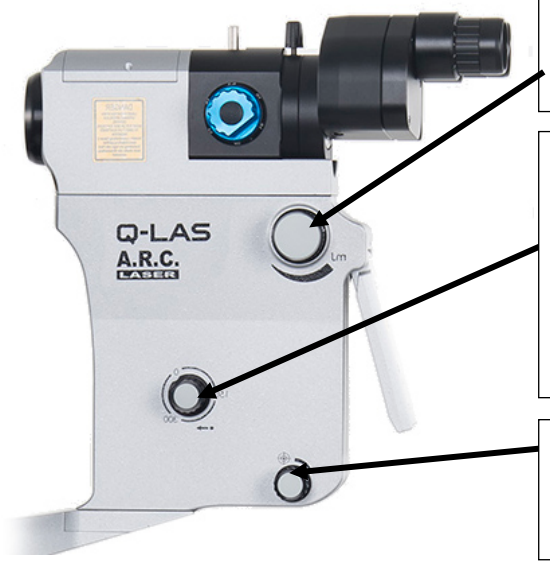
This function is an automatic calculation for the applied total energy – it is shown for a short time (2 to 3 s) when the user switches from READY mode to STANDBY mode. The total energy is accumulated until the reset button is pressed. It resets both the shot counter and the cumulated applied energy back to zero.

Note: Your service technician can activate or deactivate this feature.

6.3.6 DualSpot aiming beam

In the default state of the laser the DualSpot aiming beam is determined. The aiming beam is only visible in READY mode**.**
The 2 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).

6.3.7 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.

Adjustments at the laser head

6.3.8 Trigger Button at the Joystick

The aiming beam is only visible in READY mode. To trigger the laser, press the trigger on the elevator (joystick). To do this, the laser must be switched to READY mode and the lighting arm must be swiveled out approx. 12 ° to the right or left. An acoustic signal and the display (POS) warn that the arm is not swung out. The laser shot can only be triggered when this is swiveled out far enough. When a laser shot is fired, a warning signal sounds and the LED next to the joystick lights up.

6.3.9 Treatment

Position the patient´s chin 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 steel point is in focus with the microscope.

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

Treatment can start.

Change of Patient

At the end of a treatment, press the READY button, so you can document the total energy delivered. The trigger does not work in this position.

A T T E N T I O N

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

6.3.10 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 swiveled in. "POS" (swing out) appears as a warning in the display. There is also an acoustic warning (3x).

6.4 Switch Off your Cobra

1) Turn the key switch (see chapter 6.1) to the "OFF" position to switch off the laser.
2) Remove the key.
3) Switch off the device with the main switch on 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.

6.5 Laser-Stop / Not-Aus

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

CITO 532	Frequency-doubled Q-switched Nd:YAG Laser
Output	Single Pulse, maximum manual repetition rate 10 Hz, pulse duration <9 ns
Control Option	Digital Touch Screen
Q-Las	Passiver Q-switched Nd:YAG Laser
Output Q-Las	Einzelschuss Auslösung, Wiederholungsraten von 3 Hz, 2,4 Hz oder 1,8 Hz; Pulslänge < 5 ns
Kühlung	Luft intern
Gewicht	ca. 51 kg mit Tisch und Spaltlampe
Abmessungen	H 130 cm/B 69.2 cm/T 58.0 cm with Slit lamp, height adjustable table 72-94 cm
Kontrollmöglichkeit	7-segment display

7.2 Laser-Daten

CITO 532

Wavelength	Energy	Tolerance
532 nm	2 mJ max. Settings: 0.1 mJ Steps from 0.2 to 1.4 mJ 0.2 mJ Steps to 2 mJ	±20% of the shown energy according to IEC 60601-2-22

Q-Las

Wavelength	Energy	Tolerance
1064 nm	40 mJ max. Settings: 0.1 mJ Steps from 0.5 to 10 mJ BurstMode: 1,2 or 3 Pulses	±20% of the shown energy according to IEC 60601-2-22

Aiming beam	635 nm red < 1mW, variable brightness
Power transmission	coupled with a slit lamp

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, Regel 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, 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 must be subjected to a safety check (STK) by trained personnel. The execution of the STK and any faults are to be noted in the device book.

Please note that a medical device book and a regular technical safety check are not required in every country. Note the local requirements and laws.

Scope of Safety Check

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%)

A T T E N T I O N

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 by the user

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

It is recommended to disinfect all parts touched by patients in order to avoid the transmission of pathogens. Handles, headgear and chin rest can be disinfected at any time. Chinrest paper is used to further improve hygiene. The top sheet can be easily removed after use or before each new treatment. DescoseptAF * or a comparable disinfectant (e.g. Mikrozid AF) can be used for surface wiping disinfection. (* DescoseptAF: Dr. Schumacher GmbH (www.schumacher-online. De)) DescoseptAF * solution contains approx. 42% ethanol and approx. 0.05% didecyldimethylammonium chloride.

Other disinfectants can be used, as long as they are not aggressive or contain acids. For example, Agents based on quaternary ammonium compounds such as TPH protect (from Schülke) or Mikrobac® forte from Bode.

The manufacturer information for combined devices - for example slit lamps - must be observed!

A T T E N T I O N

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 Inspektion und Säuberung der internen Spaltlampenoptiken

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 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)

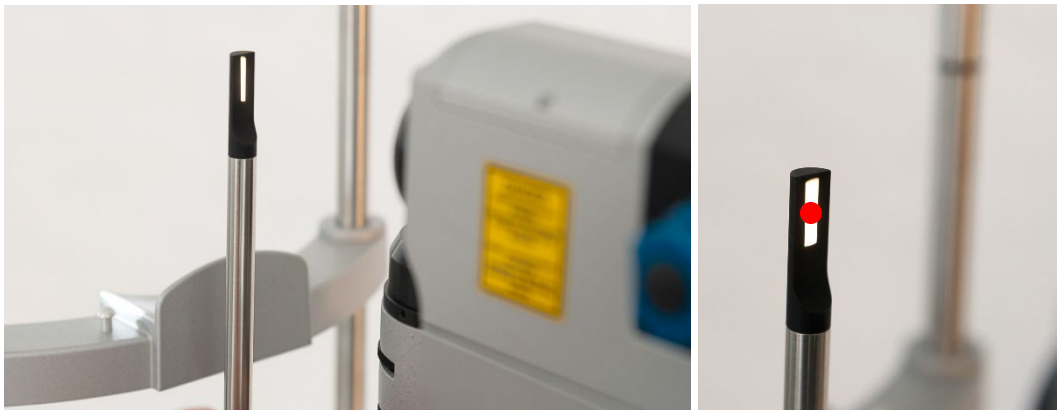
If necessary, clean the slit lamp mirror with a suitable lens brush. After dedusting, clean the mirror with Kodak lens cloths and a few drops of pure acetone. Do not use the cloth dry, otherwise the mirror will be scratched. Press only lightly so that the mirror is not adjusted. Do not rub more than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



A T T E N T I O N

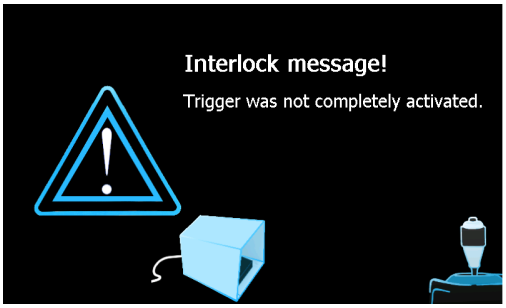
Press the eyepieces gently into the holder so that they are held completely in the binocular piece. Adjust each eyepiece to your satisfaction so that you can see a sharp image of the focus rod through each eyepiece.

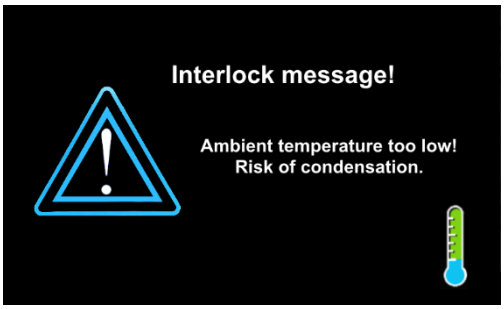
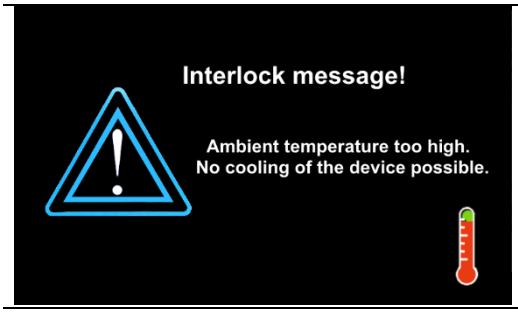
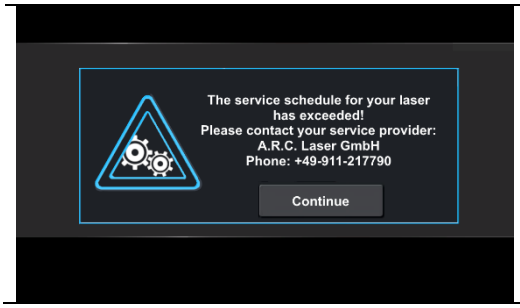
8.5 Troubleshooting

8.5.1 In case of an error, warnings will be displayed in the Touch Screen (CITO 532)

<table>
<tr><td rowspan="3"> 
</td><td colspan="2">F-errors are hardware errors
Common F-errors:</td></tr>
<tr><td>F01</td><td>F06, F07, F08</td></tr>
<tr><td>Sub-performance

Please restart the system.</td><td>Problems with the trigger.

Make sure that the trigger is not pressed continuously. Please restart the system if necessary.</td></tr>
<tr><td colspan="2">If the error cannot be remedied,
contact the service of A.R.C. Laser GmbH.</td></tr>
<tr><td> 
</td><td colspan="2">Door contact error
Close the door to the treatment room
or check the cable connection
to the door contact switch.</td></tr>
<tr><td> 
</td><td colspan="2">Joystick or footswitch pressed.
Release the switch to
to be able to continue working.</td></tr>
<tr><td> 
</td><td colspan="2">Joystick or footswitch
only half-pressed.
Release the switch to
to be able to continue working</td></tr>
</table>

	The ambient temperature is too low, the laser should be warmed up to continue working. There is a risk of damage to the laser.
	The ambient temperature is too high, the laser should be cooled in order to continue working.
	Please wait
	Contact Service of A.R.C. Laser GmbH

8.5.2 Fehlermeldungen, die im Display an der Spaltlampe angezeigt werden (Q-Las)

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 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	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 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
F0C	Position oft he 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.
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 buyer. Please contact our service department.

9 CUSTOMER SERVICE

9.1 Warranty Inforamtion

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 suitable for use in any and all settings including residential areas and those directly connected to the public power supply network which also supplies buildings used for domestic purposes.
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 discharce (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%.
Electrical fast transient /burst	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	IEC 61000-4-3	Only outlets that are usually available in domestic or clinical areas should be used.
Radiofrequency electromagnetic fields in the immediate vicinity of wireless communication devices	3 V/m 80 MHz to 2,7 GHz (see Table 10.4)	IEC 61000-4-3	Only outlets that are usually available in domestic or clinical areas should be used.
Magnetic fields with energetic design frequencies	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 should be used.
Electrical fast transient /burst	± 2 kV for power lines ± 1 kV for IO-lines 100 kHz repetition frequency	IEC 61000-4-4	Only outlets that are usually available in domestic or clinical areas should be used.
Surge voltages (Surges),Line against line	± 0.5 kV, ± 1 kV	IEC 61000-4-5	Only outlets that are usually available in domestic or clinical areas should be used.
Surge voltages (Surges),Line against grounding	± 0.5 kV, ± 1 kV, ± 2 kV	IEC 61000-4-5	Only outlets that are usually available in domestic or clinical areas should 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 outlets that are usually available in domestic or clinical areas should 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	Quality of the supply voltage that is usually available in domestic or clinical areas should 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	Quality of the supply voltage that is usually available in domestic or clinical areas should 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/m 150 kHz to 80 MHz	IEC 61000-4-6	Portable and mobile radio devices should not be used closer to the laser (including the lines) than the recommended protective distance, which is calculated according to the equation applicable to the transmission frequency. **Recommended protected distance:** d = [1.17 : $V1$] $\sqrt{P}$ d = [1.17 : $E1$] $\sqrt{P}$ for 80 MHz tos 800 MHz d = [2.33 m/V * vP for 80 MHz to 2.7 GHz with P as the nominal power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d as the recommended protective distance in meters (m). Die The field strength of stationary radio transmitters should be lower than the compliance level at all frequencies according to an on-site examination. Faults are possible in the vicinity of devices with the following symbol. 
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

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