

User Manual

CLASSIC 514



Medical Diode Laser System for Photocoagulation

In case service is required please contact:

A.R.C. LASER GmbH

Bessemerstr. 14

D-90411 Nürnberg/Germany

TEL +49 911 21779-0

FAX +49 911 21779-99

Address/Contact of your local sales representative:

.
.
.
.
.
.

Revision:

Date	Sept 12 2017
File	User-Manual_Classic514_EN.docx
Revisions-Date	June 2020
Author	Markus Barten, Markus Graf
Revised	Dr. R. Walker



CONTENT

1	Introduction.....	6
1.1	Copyright.....	6
1.2	Marking and Symbols	6
1.3	Intended use	7
1.4	Indications	7
1.5	Contraindications:	7
2	Theory and Technical Background of a Diode Laser	8
3	Transport / Storage.....	9
4	Set-up / Installation.....	10
4.1	Location.....	10
4.2	Requirements for the treatment room	10
4.3	Electrical connection	11
4.4	Dispatching and unpacking the device	11
5	Safety Information and Technical Acceptance	12
5.1	General	12
5.2	Eyewear Protection	12
5.3	Electrical Protection	13
5.4	Explosion and Fire Hazard.....	14
5.5	Protection against Undesired Radiation	14
5.6	Nominal Ocular Hazard Distance (NOHD)	15
5.7	CE regulations.....	15
5.8	RoHS2 Regulations	15
5.9	External interlock Plug	16
5.10	Protective housing	16
5.11	Safety shutter / Aiming Beam	16
5.12	Manual reset	16
5.13	Labels and stickers	17
5.14	Working condition:	18
5.15	Electromagnetic immunity	18
6	User Information and System Introduction.....	19
6.1	Shipping and Unpacking the Device	19
6.2	Technical Introduction Training.....	19
6.3	Laser Safety Training.....	19
6.4	Medical Introduction Training.....	20
6.5	Medical Device Book	20
6.6	Medical Device Parts and Accessories.....	20
6.7	Housing	27
6.8	Combinations	30



7	Operation	32
7.1	Preparation.....	32
7.2	START the device	33
7.3	Pin Code	33
7.4	Ready	37
7.5	Installation of the slit lamp and the table.....	37
7.6	Switch off.....	37
8	Specifications	38
8.1	In General	38
8.2	Laser specifications	38
8.3	Power supply.....	38
8.4	Classification	38
9	Maintenance.....	39
9.1	Introduction	39
9.2	Safety check (STK)	39
9.3	Care and Maintenance (by the user)	40
9.4	Error Detection	41
9.5	System Self Check.....	42
9.6	Troubleshooting	43
9.7	Power Calibration.....	43
9.8	Proper Disposal.....	43
10	Customer Service	45
10.1	Warranty Information	45
10.2	Warranty Consignments, Packaging	45
10.3	Sales and service information.....	45
11	Symbols Description	46
12	Guidance and manufacturer's declaration.....	47
12.1	Electromagnetic Emissions.....	47
12.2	Electromagnetic immunity (1)	48
12.3	Electromagnetic Immunity(2)	49
12.4	Recommended separation distances between portable and mobile RF communication equipment and the laser.....	50

1 Introduction

Congratulations that you have decided to purchase our medical laser system **CLASSIC 514**. It is a versatile tool in medicine.

The diode laser **CLASSIC 514** generates high-intensity laser beam, which may induce injuries in improper handling. Therefore, this User Manual should be read carefully before using the device. Should you have any further questions regarding safety, the use of the device, or concerning laser and laser radiation, please contact A.R.C. Laser GmbH or your local authorized dealer (see Section 10.3 „Sales and Service - Information“). head office in Germany at the following address:

A.R.C. Laser GmbH
Bessemmerstr. 14
90411 Nürnberg
GERMANY

Phone: +49 911 21779 - 0
Fax: +49 911 21779 - 99
info@arclaser.de
www.arclaser.de

1.1 Copyright

This user manual is protected under copyright. The copyright prohibit any duplication of parts or of the entire user manual without an explicit written consent by A.R.C. Laser GmbH.

Approved copy or parts extracted from this user manual, as licensed by A.R.C. Laser GmbH, shall include references to the original document and author as stated in this original document. Furthermore, this copyright applies to any translated copy of the user manual to other languages.

We would like to point out, that this user manual was prepared based on A.R.C. Laser proprietary data and to the best of our knowledge. A.R.C. Laser reserve the rights to revise, renew or modify any of the included drawings, images or text without further notice. In case of any content change, the revised document will be readily available for the regulatory authorities.

1.2 Marking and Symbols



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



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

1.3 Intended use

The CLASSIC 514 Ophthalmic Laser Photo coagulator is indicated for retinal photo-coagulation in the following conditions:

In particular diseases of the retina, which can be treated with coagulation and diseases in the anterior segment, which can be treated by coagulation, or partial evaporation of tissue - when indicated. These include most retinal diseases, glaucoma using iridotomy and trabeculoplasty.

For this purpose, the laser is used together with a slit lamp, which directs the laser radiation to the targeted tissue via optics and mirrors. The laser radiation can also be applied directly via hand pieces or through a LIO.

The laser effect is selectively tuned to treat the disease by means of a minimal impact on the patient's tissue. For this reason it is necessary to choose the laser parameters correctly. The treatments do cause minor injuries or pain only.

The use of the laser is superior to numerous treatments regards to trauma and efficacy, and is one of the most common treatments in modern ophthalmology.

The laser can be used both in a non-sterile environment, for example in a practice, a treatment room or in a sterile OR.

1.4 Indications

Retina coagulation

- Retinal tear
- Retinal detachment
- AMD (Age Related Macula Degeneration)
- choroidal neovascularization

Glaucoma-Treatment

- Iridotomy
- ALT: Laser-Trabeculoplasty

1.5 Contraindications:

are given in case the user is not trained to use laser radiation and is not able to correctly control the emission while guiding the laser beam. It should be fulfilled that the laser is only used in case the user does have experience either after guided surgeries by another experienced surgeon or after training on a model tissue like animal tissue or comparable.

All eye surgery where the visibility is not clear and the surgeon is not able to determine the exact dose of energy by watching the tissue reaction.

Others than defined by the Intended use.

2 Theory and Technical Background of a Diode Laser

This laser is a mere diode laser with a laser diode as the beam source. This laser diode can radiate light in the range of various wavelengths.

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

All laser types include three fundamental elements:

- The **lasing medium** (providing atoms), or molecules allowing to amplify the light.
- An **excitation or pump source** (the above-mentioned molecules or atoms are excited with), and an optical
- **resonator** which, similar to a resonant circuit, supports or generates the radiation stimulated by the internal reflection.

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

By applying a low voltage and a high power a diode laser is put into the state of the cast inversion to create and emit light. Forward electrical bias across the laser diode causes the emission by means of two species of charge carrier – holes and electrons – to be "injected" from opposite sides of the p-n junction into the depletion region. When an electron and a hole are present in the same region, they may recombine or "annihilate" producing an ongoing emission, emitting further photons. The avalanche effect of the stimulated emission arises.

To improve this effect the laser is equipped with a resonator – in our case the photon-emitting semiconductor itself. The plan parallel properties of the crystal with its high index of refraction take over the function of a resonator mirror. The end face of the semiconductor is covered with a highly reflecting mirror to force the photons to be reflected several times from each end face before they exit.

Through special manufacturing processes of the semiconductor material, A.R.C. Laser is able to provide this laser system in its specific wavelength property. The systems respective maximum output power varies in height and is set by the user via the display - just like the pulse length and pulse pause.

In general laser diodes are extremely sensitive towards voltage fluctuations. An internal microchip controller cushions and controls the high voltage to run the diode.

Via beam deflection mirrors and coupling ceramic elements the laser light is coupled into a silica glass fiber. The transmission of the various wavelengths is independent from the fiber. Transmissions ranging from 80 to 90 % of the laser power are possible. The laser source is cooled directly to maintain the mandatory operating. The cooling circuit is passive and controlled by fans.

3 Transport / Storage

The Laser is supplied in a custom made carrying case for ultimate protection during transportation. The device should never be transported or stored below -10 ° C or above 60 ° C. The ambient air must be dry and clean. Ambient air humidity exceeding 85% may result in destroying the laser when switching on the device.

Accessories such as fibers and hand pieces are fully protected as well, as they have dedicated spaces within the carrying case and can transported together with the laser console.

The laser is equipped with a bracket made of aluminum, which serves as a pure stand.

Always make sure that the bracket is firmly seated. Never lift the device by the strap if you are not sure that it is firm and stable.

ATTENTION!

The CLASSIC 514 Laser photo coagulator should be protected against water and moisture at all time.



We recommend transportation inside the available transportation case.

4 Set-up / Installation

Usually, A.R.C. Laser GmbH or its authorized dealer installs the CLASSIC Laser and you will be given full training for the device. Prior to delivery, the user needs to make sure a suitable location was prepared for the installation.

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

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

If the ambient temperature is too low (below 18°C), the device should not be switched on, to avoid possible condensation on its internal optics as this might cause a permanent damage.

All control elements need to be readily accessible. The fibers at the front must have sufficient space to avoid accidental bending. The air humidity in the treatment room should be monitored and kept below 75%.

CAUTION!

If the instrument is at a temperature below 18°C the instrument should not be switched on. It may cause serious damage. Unpack the instrument and keep it at normal temperature for at least half a day to ensure that the internal components will be warmed up gradually. An error message will inform you when switching on the device.

4.1 Location

- The instrument should be positioned in such a way, that the laser beam coming out of the slit lamp cannot be directed towards an opening (door, window, ...) or any reflecting material.
- The instrument should be installed in a dust free room like an doctors office and the use of carpets on either the walls or the floor should be avoided.
- When not in use, the system should be covered to avoid dust settling on the optics.
- If there is a main switch available in the room turn this off.

4.2 Requirements for the treatment room

4.2.1

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

Warning-Signs

- Please attach the laser warning sign (triangle with laser symbol) as well as the wavelength marking at each access door.
- Please mount a warning lamp above each access door, which always has to be lit up, when the laser is in operation.

This ensures warning to prevent accidental entry to the room without protective goggles.

- Please store the laser protective goggles at the entrance of the room and make sure they are readily accessible.

Windows

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

4.2.2

Cover of high reflective material in the room

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

4.2.3

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

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

4.3 Electrical connection

The CLASSIC 514 operates at 24 V DC, which is supplied by an external power supply unit. Only use power supplies made by A.R.C. Laser GmbH and obtained through the authorized dealer.

The above-mentioned power supply unit can be connected to an AC voltage ranging from 100V to 240V at 50Hz-60Hz. Specifications are as labelled. See also chapter 1.1.1

4.4 Dispatching and unpacking the device

In case unpacking and installing is done under the responsibility of the user:

Take care that the enclosed documents, included in the shipment with the Laser system, need to be completed and sent back to A.R.C. Laser GmbH.

Outside Germany, your local A.R.C. Laser dealer will complete the documents.

In the event where the device is transported to the user via a courier delivery services, the consignee should take special care that the parcel was delivered in a proper and undamaged condition. Any visible damage to the outer packaging shall immediately be reported to the transporter and your local A.R.C. Laser authorized dealer. In this case, warranty claims have to be addressed to the transporter only.

Before initial start-up, please read the user manual carefully to complete the enclosed documents correctly.

5 Safety Information and Technical Acceptance

5.1 General

This manual is designed to familiarize you with the normal operation and maintenance of the CLASSIC 514 Laser.

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

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

'CLASSIC 514' laser devices are classified according to **EN 60601-2-22** and **EN 60825-1**, as a **Class 4** laser product.

Class 4 of the standard describes high-energy laser and therefore special actions must be taken before using the device to ensure safe and proper use. In particular, it is important to protect the eyes and the skin of the operator, the patient and accompanying persons. Laser safety goggles must be used, and to carry out appropriate actions to clothing. In particular, you have to protect yourself from reflected laser light. Additionally in the room - in which the laser is operated - no flammable materials are to be stored.

Even though the safety information included in this manual is detailed, it is not intended to replace industry standards and guidelines for laser safety.

We would recommend keeping the document "Operation of Laser Facilities and Accident Prevention Regulations for Laser Radiation" which may be obtained through your local authorized dealer.

In addition, you can refer to the regulations of the American National Standard Agency ANSI Z136.3-1996 "American National Standard for the Safe Use of Lasers in Health Care Facilities" and ANSI Z136.1-1995 "American National Standard for the Use of Lasers".

Our local dealer's technical support department will gladly answer any questions you may have and provide you with appropriate training as well as assist with obtaining additional industry standards and guidelines for laser safety.

5.2 Eyewear Protection

ATTENTION!

Never look directly into the laser beam or to the light reflected by the laser beam. Never look directly into the exit of the fiber optics or into the exit of a laser optics (e.g. hand piece) as this will cause serious eye injury.

A.R.C. Laser cannot be held responsible for any damage or injury, which results from a failure to follow, or incorrect use of, the instructions contained in this manual.

Protective eyewear needs to be able to stop laser radiation coming from all directions from striking the eye. This is clearly defined by accident prevention regulations. All persons inside the room have to wear eye safety glasses.

When using the **CLASSIC 514** laser (green light) only the laser safety glasses may be used which are approved on the wavelength and on which the CE mark and the degree of protection D1RL5 bzw. DL5 (OD8+) is noted.

Goggles can be ordered - according the regulations - at ARC Laser GmbH.

The laser is used together with the A.R.C. Laser GmbH slit lamp, it must be ensured that the appropriate eye safety filter (514 nm) is properly installed within the optical path of the slit lamp and the treating physician. That makes sure that the physician is protected by the filter.

If you have further questions regarding the goggles or the wearing of the protective glasses, please contact us.



There are different types of goggles that allow spectacle wearers to wear tight goggles on all sides. In particular, the scattered radiation that does not directly come from the front of the eye may present risks resulting from internal reflections on the glasses. Therefore, we encourage you to wear the goggles, which also guarantee a full protection to the side parts.

The treatment space should not to be opened during the treatment from outside. In addition, a warning light should be attached outside. When operating with the laser this warning light must be turned on. In addition, sufficient goggles should be present in the room to be provided to the accompanying persons.

A door interlock is required from the regulations for accident prevention. The standard device is equipped with an interlock connector, for which the door interlock can be connected directly. When opening the door and the unit switches off. However, we recommend to close the door from the inside to avoid opening by mistake from outside.

5.3 Electrical Protection

Do not disassemble the unit. Never remove any housing parts as this can cause a serious risk hazard.

Any service to the unit or its accessories should only be carried out by an authorized personnel by A.R.C. Laser GmbH.

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

ATTENTION !

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

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

The WOLF Laser should undergo a safety inspection every 24 months, carried out by qualified personnel. The safety inspection has to be noticed into the device book in order to file every error during the service.

5.4 Explosion and Fire Hazard

ATTENTION !

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

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

5.5 Protection against Undesired Radiation

To avoid any unwanted triggering and dangerous situations, never focus the laser on flammables or onto skin. Green light is well absorbed in blood and could cause dangerous burns at the skin; do not focus the laser beam on easily flammable materials as this may cause a fire.

The pedal switch controlling the laser Pulse should never be outside the range of the operator holding the laser hand piece/fiber. It is prohibited that any person other than the operator controls the pedal switch.

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

ATTENTION !

During a laser treatment, the system is in "Ready" mode. Should the operator need to pause the treatment for any reason; the laser must be switched back to "Stand-by" mode. In case of pauses exceeding 1 minute, please press the "Ready" key.

The device must be turned off when left without supervision, to prevent usage by unauthorized individuals.

ATTENTION!

Installing and/or operating the laser in any other way differing from the one described herein may cause hazardous exposure to radiation

5.6 Nominal Ocular Hazard Distance (NOHD)

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

Wavelength λ:	514 nm
NOHD for 514 nm:	2,96 m

The access to the laser irradiation is shielded through the marked service room. (See therefore recommendations above and chapter 4.1, 4.2).

5.7 CE regulations

The CLASSIC 514 laser system was accredited by the notified body in accordance with the European directive 93/42 for medical equipment. Therefore, the device is labeled with the CE mark CE 0483.

The device was tested for electrical compliance as well as for mechanical safety. All parts used by A.R.C. Laser for the CLASSIC 514 laser comply with CE regulations.

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

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

5.8 RoHS2 Regulations

A.R.C. Laser operates worldwide and considers the protection of the environment and natural resources as a corporate obligation. Based on individual tests we can confirm that to the best of our knowledge, the products of A.R.C. Laser do not contain any substances in any concentration, the marketing of which is prohibited in accordance with the applicable requirement of Directive (RoHS2).

5.9 External interlock Plug

At the back side of the instrument you will find the female connector for the interlock plug . (see chapter 6.7.2)The plug when fully inserted, enables main power to the console internal circuitry. In case this plug is pulled out, the console will instantly shut down.

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

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

5.10 Protective housing

The **CLASSIC 514** Laser has a protective housing to prevent any unwanted laser radiation to leak through. In addition the housing protects the user from touching any electric components. Non-authorized personnel should never attempt to carry out any type of service to the console. Console parts should only be removed and replaced by trained A.R.C. Laser GmbH service technicians.

5.11 Safety shutter / Aiming Beam

The laser has an internal safety shutter installed. This safety switch enables the release of laser beam and will open when pressing the "READY key" followed by the pedal switch. When starting the laser internal tests begin. (After passing all the internal tests and calibrations) The yellow light at the ready button is not illuminated until the calibration is finished. The yellow light indicates the READY-Mode and the laser can be triggered to give way for the laser radiation.



The aiming beam is only visible in the case that the laser is set to Ready-Mode. This visible beam is a low-level laser.

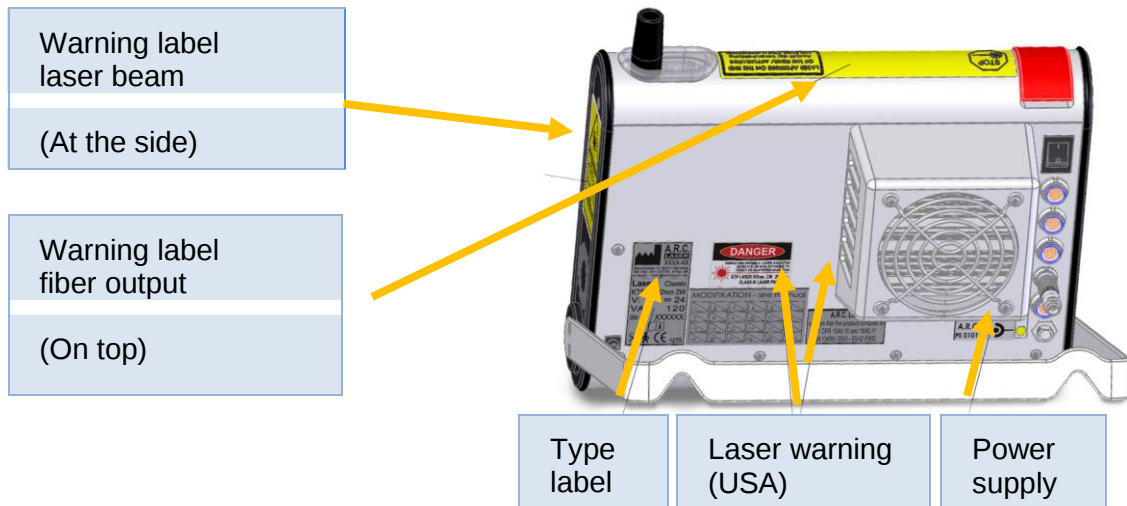
5.12 Manual reset



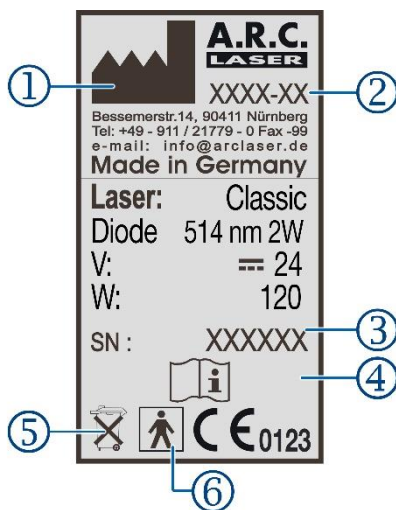
When an error occurs (e.g. power instable etc.), the device shows this symbol. Simply switch off the laser and restart it again, to make sure the device can reactivate itself. If the device cannot be started again, there is an error, which can only be re-solved by qualified personnel. Please contact your local A.R.C. Laser GmbH authorized dealer.

5.13 Labels and stickers

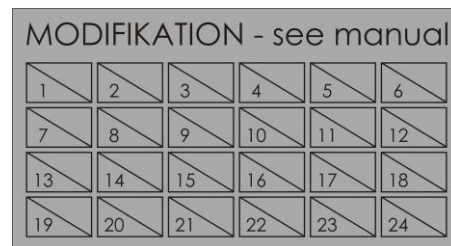
At the laser several warning labels are attached. All labels conform to the EN/US requirements. All warning logos are attached close to the dangerous output of the laser. Please see below the positions of the labels.



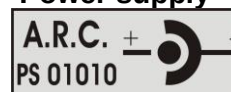
Type label (rear)



Modification label



Power supply



① Manufacturer	⑤ No disposal in domestic waste
② Date of manufacture	⑥ Applied Part: Type B
③ Serial Nr.	
④ See Manual	

Warning labels

Warning label laser beam



Warning label fiber output



Laser Warning (USA)



5.14 Working condition:

The medical laser CLASSIC 514 is not suited for the use in connection with any kind of flammable gas or gas mixtures.

It is not allowed to use the system in heights above 2.000 m above zero.

For its normal operation the system has to be able to receive appropriate cooling – The internal fan needs access to clean and almost dust free air around:

Temperature : 18 to 30 °C

Humidity : < 75%

There are no limitations in pulse (interval) mode.

5.15 Electromagnetic immunity

The laser system conforms to DIN EN 60601-1-2:2015-12. In order to avoid interferences with other electronic devices the information provided in chapter 12 should be considered.

6 User Information and System Introduction

Before initial start-up, read the operating instructions carefully.

6.1 Shipping and Unpacking the Device

In the case that the unpacking and installing of the device is made by the user:

Attached to the laser system you will receive documentation which has to be filled by the end-user and returned to A.R.C. Laser GmbH. Outside Germany your local dealer will handle this issue.

In the exceptional case, an on-site training takes place, the employee of A.R.C. Laser GmbH will fill out the accompanying documents together with the associated end-user customer.

If the device is transported by freight forwarder/post to the end customer, the beneficiary shall ensure that the package will be delivered in an orderly and undamaged condition. Any visible damage at the outer packaging must immediately be reported to the carrier or A.R.C. Laser. Warranty claims shall be made only to the transporter. The operating instructions should be read carefully before initial start-up, even to complete the accompanying documents correctly.

6.2 Technical Introduction Training

Upon installation, a staff member from A.R.C. Laser or the local authorized dealer will provide introductory training for the Laser system.

The introductory training will cover the technical features of the device as well as overall safety associated with the installation and use of lasers in general and the CLASSIC 514 Laser in particular.

All individuals working in the vicinity of the laser should attend this introductory training.

One individual having undergone the training and gathered the experience to knowledgeably administer a laser safety program will be chosen as the person responsible for monitoring and overseeing the control of laser safety.

6.3 Laser Safety Training

The CLASSIC 514 diode laser is designed for medical applications. Only physicians who received training by an authorized personal may only use it. In addition to the trainings offered by A.R.C. Laser, A.R.C. Laser GmbH recommends to attend seminars offered by us. These seminars contain topics like "working with different laser systems" such as the diode laser. Moreover, introductions into the laser safety and the use of lasers in general will be covered in these seminars. We recommend you to make sure that only the person holding the password will use the laser. The password should not be handed to other physicians unless they went through the recommended training for the device.

The fact that even personnel not working directly with the laser should attend the "laser safety" or "laser application" courses, has proven to be very useful. Laser safety, the basic principles of the laser and of laser treatment are mainly discussed in these courses. It is

particularly important that the operating personnel attend the laser safety courses. In these courses, extensive training is given to master precautionary measures when working with lasers (e.g. caution in case of combustible material, the importance of laser protective goggles etc.) are dealt with in detail.

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

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

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

6.4 Medical Introduction Training

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

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

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

6.5 Medical Device Book

The medical device book is included to the device. This is to be kept carefully and submitted to the engineer in case of service or execution of the Security Technical Control (STC).

6.6 Medical Device Parts and Accessories

The basic laser system includes the following parts (which can be ordered separately at any time):

Spare part	Type	Art. #
Power supply	PROTEK PMP120-14-B2 120 W Medical Switching Supply, 24V / 5 A	PS01010
Transport case	A.R.C. Transportation and storage case W 68cm x H 43cm x D 20 cm	VP04000
Goggles	Depending on the required size/wavelength	On request

Slit lamp adaption

With the assistance of slit lamp adaptations, it is possible to use the diagnosis slit lamps also for laser therapy with Classic 514 nm.

The Super View system of A.R.C. Laser offers a complete treatment unit inclusive slit lamp PCL 5 SH, laser Classic 514 and the beam combiner "super view". This is a ready to use unit. See: Chapter 6.6.1.1.

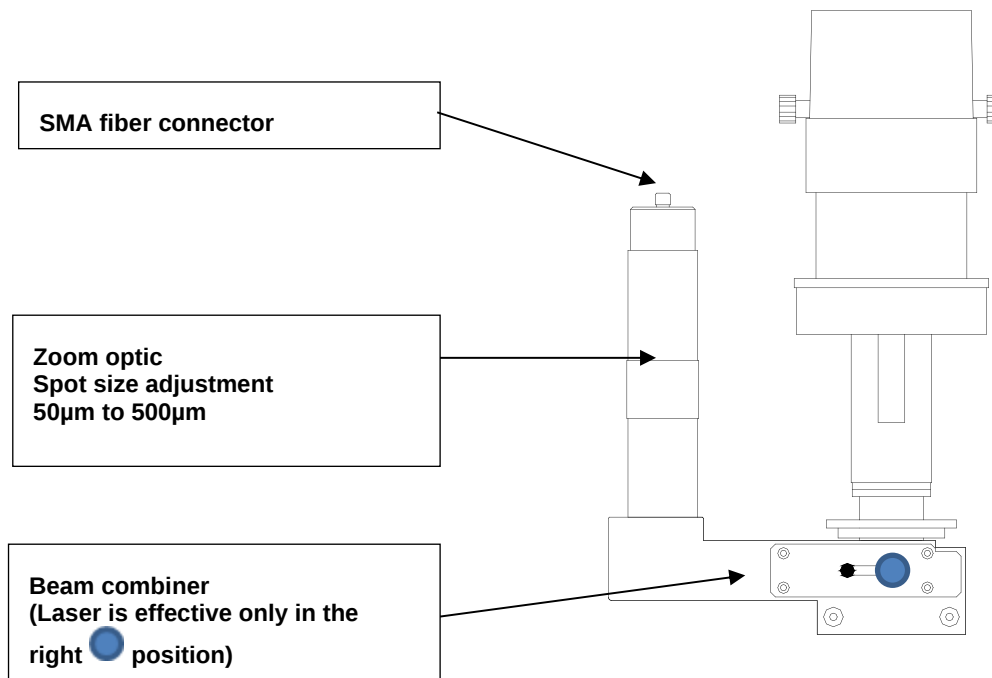
6.6.1

For the upgrade of an present diagnosis slit lamp to a treatment unit with Classic 514 the optic L-ORD is necessary. See chapter 6.6.1.2.

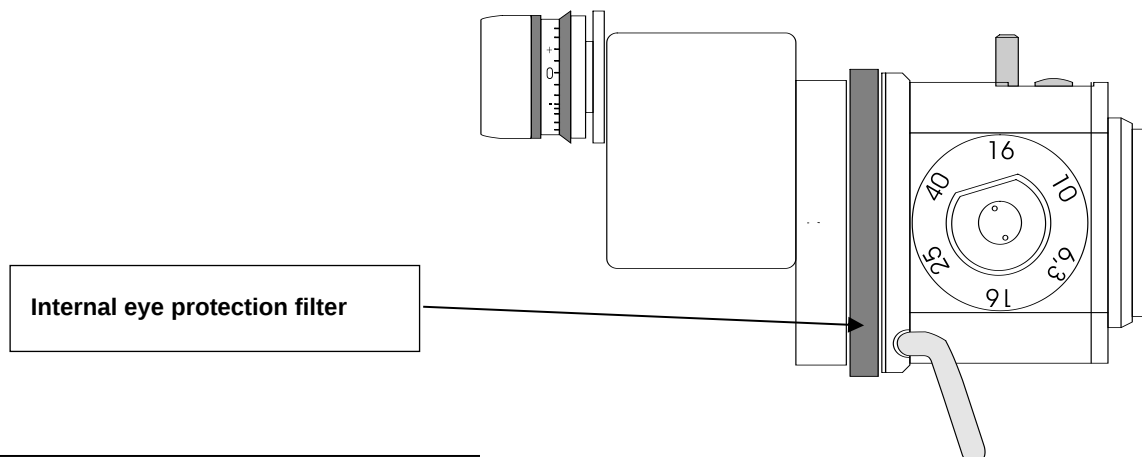
6.6.1.1 Classic 514 adapted at A.R.C. Laser slit lamp PCL 5 SH

Slit lamp – Beam combiner "Super View"

The adaption of Classic 514 to the A.R.C. Laser slit lamp PCL 5 SH is realized by the beam combiner "Super View".



Slit lamp – eye protection filter



In that case the laser system **CLASSIC 514** consists of 2 major components

- a) Laser system
- b) Slit lamp



Image: Classic 514 with A.R.C. Laser slit lamp

6.6.1.2 Classic 514 adapted at a slit lamp of a third-party manufacturer

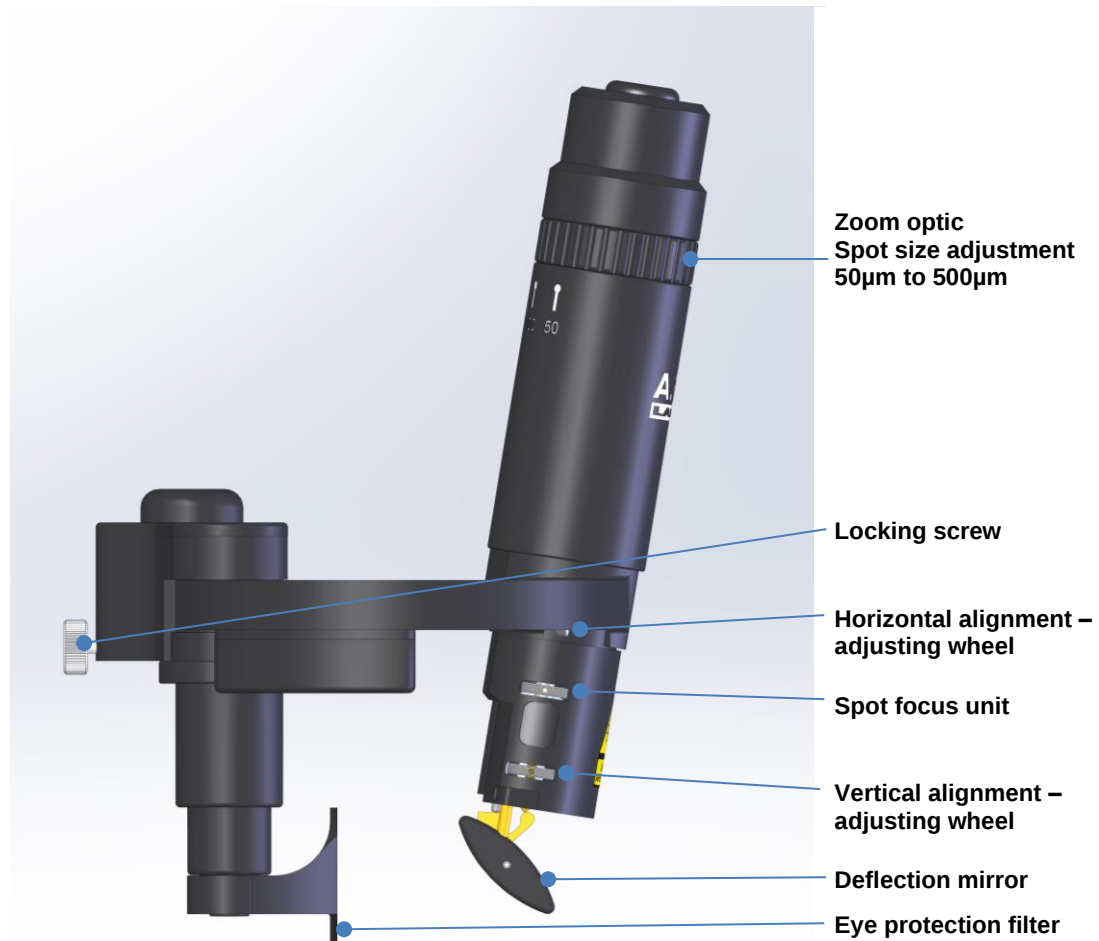
Slit lamp – Beam combiner “L-ord”

The adaption of Classic 514 to a slit lamp of third-party manufacturer (HS type only) is realized by the beam combiner “L-ord”.



L-ord is firmly attached to the Classic 514 and stored at a stand. The black connection cable contains the quartz fiber which is guiding the laser beam of Classic 514 and also the monitoring cable, for the position signal of L-ord.

Overview of operating elements



Spot size adjustment: The laser spot size can be adjusted from 50 to 500 µm with the adjustment ring.

Locking screw: L-ord is connected to the slit lamp via the pin of the tonometer mounting base at the slit lamp. The locking screw is used for fixation.

Spot focus unit: Adjustment of the beam focus.

Horizontal alignment – adjusting wheel: The horizontal position of the beam can be adjusted via this adjusting wheel.

Vertical Alignment – Adjusting wheel: The vertical position of the beam can be adjusted via this adjusting wheel.

Deflection mirror: The deflection mirror is used to bring the aiming beam as well as the laser beam in coincide to the observation beam path of the slit lamp microscope.

Eye protection filter: The coated filter glasses protect the operator's eyes from the laser beams. An additional eye protection filter for the slit lamp is not necessary.

Installation and Handling

Connect L-ord to the slit lamp

Place the L-ord on the pin of the tonometer mounting base at the slit lamp.
Turn the locking screw to fix the L-ord.



Connect L-ord to Classic 514

L-ord is firmly connected to Classic 514 at the Fiber port. Please do not manipulate this connection.



Make sure that the remote cable of L-ord, which is firmly fixed at the fiber port as well, is connected to the red marked socket (Interlock connector) at back side of Classic 514.

Put the L-ord in working position to apply the laser radiation under slit lamp view.



L-ord swung out – diagnosis position



L-ord swung in – working position,
laser application is possible



Attention:

If the L-ord is not in the correct working position it is no possible to set the laser in ready mode.

The Classic 514 will display the door symbol.

Please check the position.





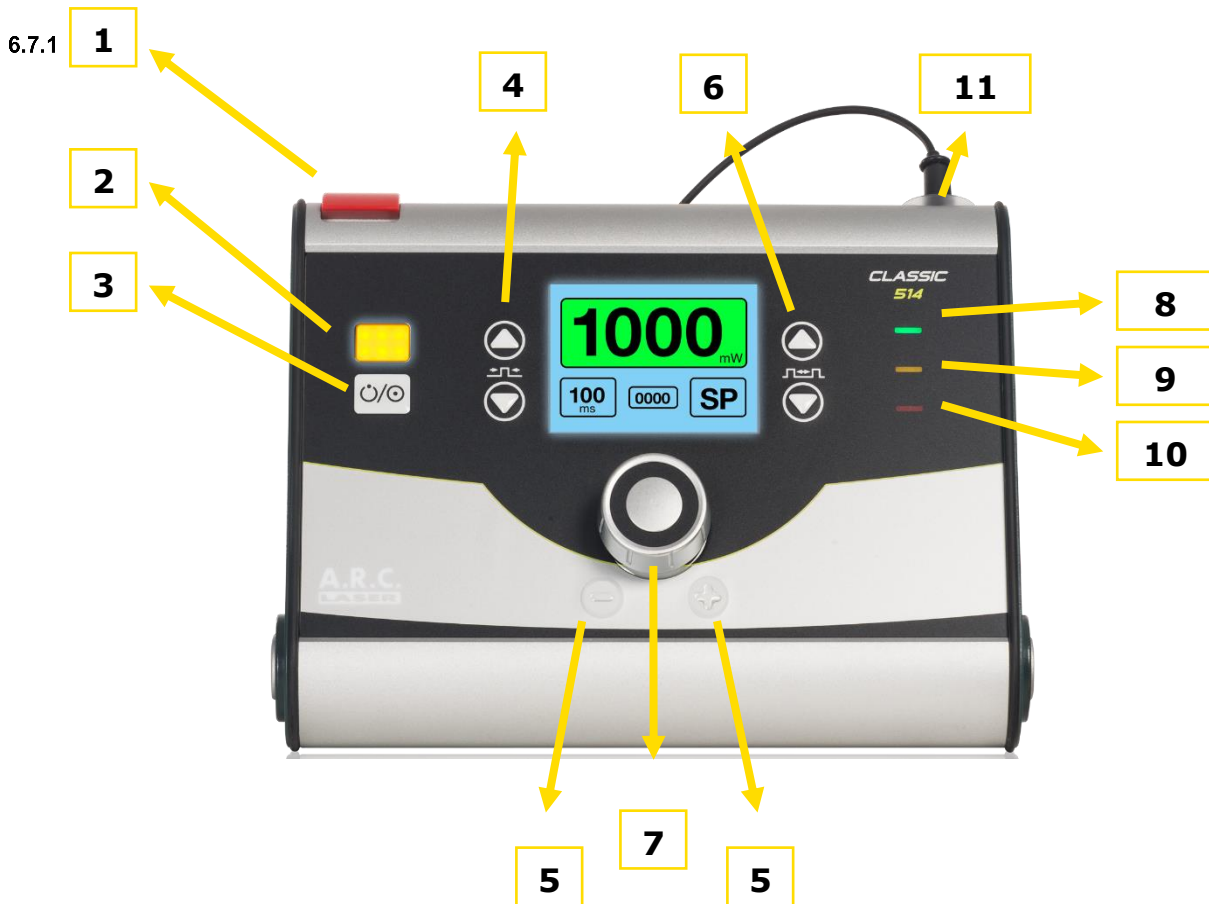
After Classic 514 with L-ord is installed, please fix the fiber at the head rest of the slit lamp (see markings in the picture).

6.7 Housing

The main body consists of the laser resonator, the power driver for the laser, safety shutter as well as all optical components for the beam guiding. The fiber coupler is also permanently attached to the main frame.

Front View of the device

The front view of the laser device consists of the main dial, the display and following buttons:



- | | |
|---|--|
| 1 Red laser stop button | 7 Power adjustment + confirmation button |
| 2 Yellow signal light "Laser ready" | 8 Green LED "Laser on mode" |
| 3 Ready push button | 9 No function |
| 4 Arrows up/down to adjust pulse length | 10 Red LED "Laser failure mode" |
| 5 - / + adjust aiming beam brightness | 11 Fiberport slit lamp attachment/ LIO |
| 6 Up/down to set repetition rate | |

6.7.1.1 Fiberport CLASSIC 514 for Slit Lamp

You will find the fiber port (11) at the top of the unit. The fiber with a diameter of 62.5 μm is attached to the unit and should not be removed under any circumstances.

CAUTION!

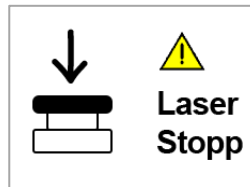
Do not use any tools to open or remove the fiber. Do not bend the fibers. Handle all fiber optics with care; the ends should be protected against soiling. Defective fibers should not be used – contact your local service provider of A.R.C. Laser.

6.7.1.2 Laser STOP



The laser stop button is at the upper left side corner of the device. In case the button is pressed during start-up of the device the following information on the display will be visible:

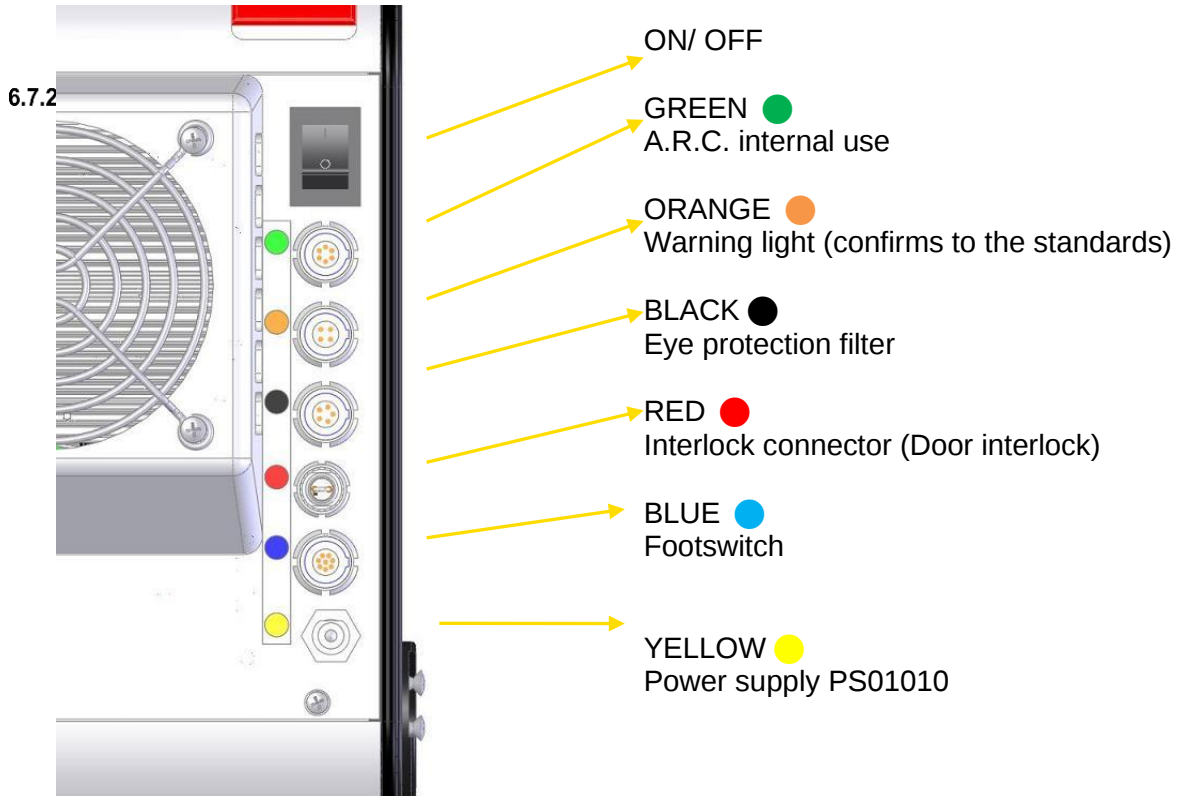
To continue the start up process pull laser stop button upwards - the unit will restart.



In case the laser stop button will be pressed accidentally during operation the same information on the display will be visible.

Back side of the device

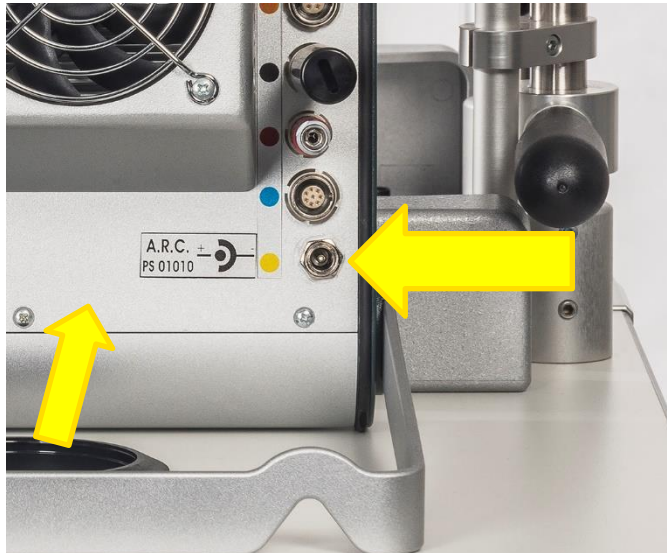
At the rear of the laser you will find following connectors:



Power Supply in combination with a slit lamp and a motorized table

When using the CLASSIC 514 according to the regular use in combination with a slit lamp, it is connected to the mains via the motoric table power supply.

6.7.3



The cables are guided through the table. The power supply is mounted under the table and will be connected to the tables power supply.

Switch on/off the laser by means of the standard power-switch at the motorized table and additionally via main switch at the back side of CLASSIC 514.



CAUTION!

When adapting the CLASSIC 514 to a different slit lamp or another motorized table the mounting may be different.

6.8 Combinations

A.R.C. Laser is providing the combination of a CLASSIC 514 with other medical devices:
CLASSIC 514 with slit lamp PCL5

A.R.C. Laser has checked and controlled the compatibility of the above according to the guidance of the respective manufacturers; the installation is done according to the guidance documents.

The systems are duly packed by A.R.C. Laser GmbH and supplied together with the corresponding accompanying documentation of the respective manufacturers. This accompanying information has to be respected.

Before delivery, each system is installed and validated thoroughly at A.R.C. Laser; corresponding test reports are archived together with other information in the device file provided by A.R.C. Laser.

7 Operation

CAUTION!

The laser should only be operated by trained personal.

This chapter of the manual describes the operation of the laser, without pointing out any medical details of photocoagulation.

The use of the device and the operation of this device should only be in accordance with this manual. Changes of parameters or adjustments not described in this manual can destroy the unit or can cause damage to the unit.

7.1 Preparation

Before starting the laser following steps should be obeyed to avoid any failures or damages to the laser or dangerous situation.

- Is the power supply plugged into the laser at the rear side?
- Is the power supply connected to the mains?
- Is the interlock door connector plugged in and/or connected to the door?
- Is the fiber securely connected to the laser?
- Are all cables and fibers without a damage?
- Do you have the safety goggles available for the persons in the room?

CAUTION!

The laser room has to be clearly marked from the outside. It is a law that the laser room has visible lights at the outside to indicate that a laser is in use. Warning logos need to be attached to the door.

CAUTION!

The aiming beam and the working beam follow the same path through the delivery system. Therefore the aiming beam may be used to check the integrity of the laser delivery system. If the aiming beam does not appear at the end of the delivery system, or if its intensity is low, or if it appears diffused this indicates potential defects or soiling of the laser delivery system.

7.2 START the device

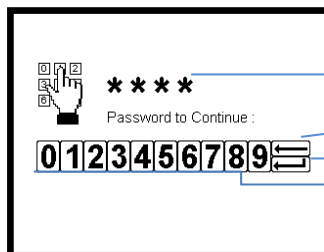
Press the mains switch at the rear of the unit to on (chapter 6.7.2)



At this time the laser will check all the internal safety features.

After successful finish of the self check the fiber port at the top side of the unit is illuminated in red and the main mask of the main menu is visible.

7.3 Pin Code



PIN CODE

BACK space (erases the last digit/input)

RETURN

Numbers (0 - 9)

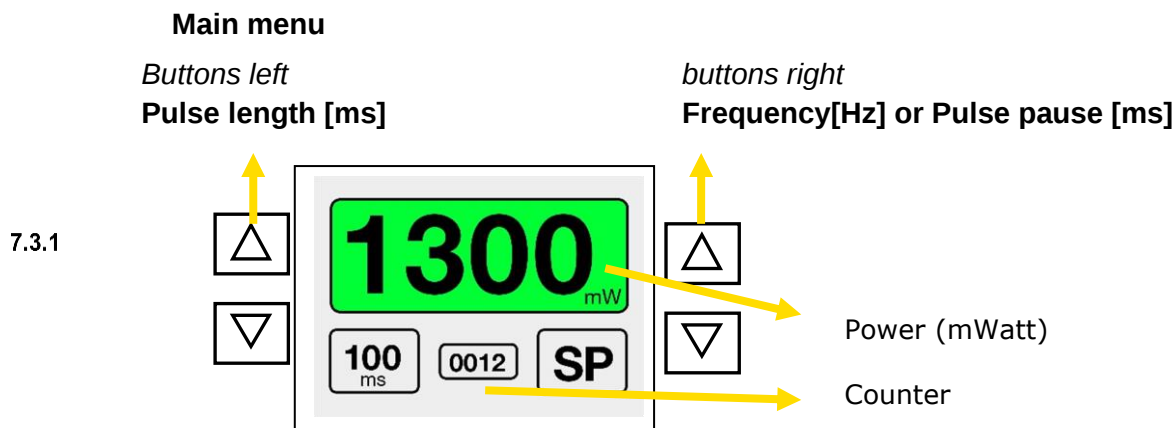


Turn the dial to the preselected number and confirm the digit by pressing the main dial. Each number pressed will be highlighted with a star. After finishing the preselect number scroll to the RETURN-arrow press the dial and allow the code to be entered.



NOTE!

At the time of installation, the code is 0000 - To change the Code see chapter 7.3.2.5



7.3.1.1 Power (mW)

The power is displayed in Milliwatt (mW) and can be changed by turning the main dial.

7.3.1.2 Pulse length

The pulse length is selected via the two arrows at the left hand side. Following pulse lengths are available.

10 ms, 25 ms, 50 ms, 75 ms, 100 ms, 150 ms, 200 ms, 300 ms, 400 ms, 500 ms, 600 ms, 700 ms, 800 ms, 900 ms, 1000 ms, 1,5 s, 2 s, CW

7.3.1.3 Frequency / Pulse pause

Frequency [Hz] mode is standard. On request a service technician can preselect pulse mode. Select via the right hand arrows beside the display.

Following values are available

1 Hz, 2 Hz, 3 Hz, 4 Hz, 5 Hz in steps with 1 Hz.

or

100, 200, 300, 400, 500, 600, 700, 800, 900ms, SP (Single pulse)

Note:

The frequency is depending on the pulse length and on the pulse pause selected. The following table below shows the possible selections.

Frequency (Hz) depending on pulse length and pulse pause										
		pulse on time in ms								
		15	25	50	75	100	150	200	400	800
Pulse Off time	100	9.09	8.00	6.70	5.70	5.00	4.00	3.30	2.00	1.10
	200	4.76	4.40	4.00	3.63	3.33	2.86	2.50	1.67	1.00
	300	3.23	3.08	2.86	2.67	2.50	2.22	2.00	1.43	0.91
	400	2.44	2.35	2.22	2.11	2.00	1.82	1.67	1.25	0.83
	500	1.96	1.90	1.81	1.74	1.67	1.54	1.43	1.11	0.77

7.3.1.4 Pulse counter

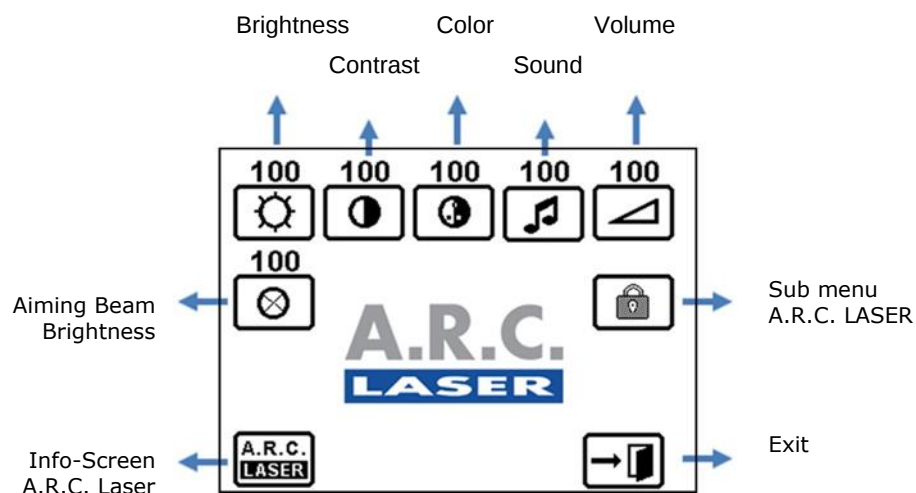
Each laser pulse triggered is accumulated at the counter. To set the counter to "0" press the main dial knob to reset the counter.

Sub menu

- 7.3.2 By pressing the right and left - / + key at the same time - while the laser is in standby - you will get in the submenu. Navigate through the menu with the + and – key to access each of the icons. A darkened icon is selected. By turning the main dial you alter the value of the selected function.

PLEASE NOTE

If you hear a constant beep, please press the main dial to stop the sound and fix the issue.



7.3.2.1 Brightness



Adjustment of brightness from 25-100%, step width 5

7.3.2.2 Sound frequency



Adjustment of the frequency of the tone from 0-100%, step width 5

7.3.2.3 Loudness



Adjustment of the loudness from 10-100%, step width 5

7.3.2.4 Aiming beam



Adjustment of the brightness of the aiming beam 0-100%, step width 1

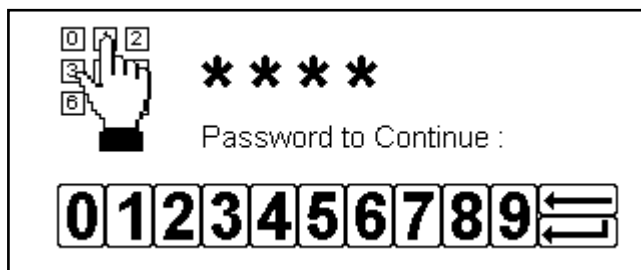
NOTE!

The aiming beam brightness can also be adjusted by using the arrow buttons on the left side of the display. At the time of adjustment, the aiming beam is active to control the brightness visually (works only in READY mode).

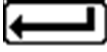
7.3.2.5 PIN CODE



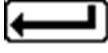
The PIN code can be changed individually,
Choose the „lock“ field to enter a new password:



To unlock the screen you have to enter the initial password first: **0000** (standard).

Select the return icon  and press main dial to confirm.

Enter New Password:

Input your new 4 digits code, by selecting your favorite numbers – they will be shown as “*****” only. Select the return icon  and press main dial to confirm.

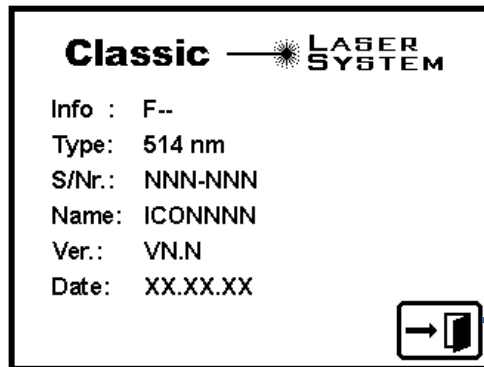
CAUTION!

Memorize this code, as there is limited access to reset the password. An incorrect password needs a service reset by an A.R.C. Laser representative.

7.3.2.6 Sub menu A.R.C.Laser



By choosing this field, you access the sub menu and the data for the laser will be displayed.



Choosing the door you will leave the sub menu.

7.3.2.7 Exit



You will exit the sub menu to go back to main menu

7.4 Ready



By pressing the ready button you will activate the Laser system and you will be able to trigger the laser via the foot switch. The yellow light above the button will blink for some seconds to verify the laser power and adjust the output to the pre-selected value. After the light shines continuously, the laser can be released via the footswitch. An early release might cancel the action.

After the treatment, press the ready button again to switch the laser to standby and avoid accidentally triggering the laser.

7.5 Installation of the slit lamp and the table

The installation of the table and the slit lamp should only be performed by a company trained technician.

7.6 Switch off

To turn the laser off, use the main button at the rear of the device (see chapter 6.7.2 and 6.7.3).

8 Specifications

8.1 In General

Model CLASSIC 514	DIODE Laser
Cooling	Ambient air
Weight	3,3 kg
Dimensions	WDH 25 cm, 22 cm with rest, 17 cm

8.2 Laser specifications

Output power	up to 1.3 Watt at distal end of fiber
Wavelength	514 nm (green)
Display	Digital at main console
Pulse length	10, 25, 50, 75, 100, 150, 200, 300, 400, 500, 600, 700 ms, 800 ms, 900 ms, 1000 ms, 1,5 s, 2 s, CW
Pulse pause	100/200/300/400/500/600/700/800/900 ms, SP
Rep. Rate (frequency mode)	1 to 5 Hz in 1 Hz steps
Laser transmission	Fiber 62.5 µm
Aiming beam	635 nm – Red < 1 mW

8.3 Power supply

Rated power laser	120 W
Input rating of laser	24 V DC, 5 A
External power supply	100-240V. 47/63 Hz. 1.4 – 0.6A

8.4 Classification

Class	
Laser class:	IV
European Medical Device Directive 93/42	class IIb / rule 9
Electric shock acc. IEC 60601-1:	II
applied part:	type BF
no protection against ingress of water:	IPX0
CE Certified	CE 0123

9 Maintenance

9.1 Introduction

Your laser was designed based on the latest technology and information available. The laser should have a life span of more than 5 years. The life time was fixed from the company to 10 years. During this time we will guarantee the availability of spare parts and service. To assure proper service and maintenance during operation we have incorporated a visual inspection from the outside via LED or inside the display.

In the rare situations when the device does not work, you can use the “Troubleshooting” section included in this manual, to isolate the problem. The solutions given therein will most likely allow you to solve the problem yourself. However if the problem cannot be solved, please contact your local A.R.C. Laser authorized dealer for technical support.

ATTENTION!

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

9.2 Safety check (STK)

No specific safety inspection interval is required. (2 years interval STK in Germany only).

If the unit shuts down during surgery or a failure is recognized, please inform your nearest distributor about the problem instantly. The unit should not be used further to avoid any dangerous situation for the user or accompanied personal, or even the patient. In case of a malfunction inform the distributor immediately.

ATTENTION!

The device needs to undergo a safety inspection every 24 months carried out by qualified personnel.

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

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

ATTENTION!

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

9.3 Care and Maintenance (by the user)

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

CAUTION!

Before cleaning the device. switch off the laser and disconnect it from all sockets and cables.

The housing of the CLASSIC 514 is made of aluminum and glazed plastic. The whole housing can be cleaned with standard cleaning detergents used in house holds. To avoid any particular smell do not use detergents with alcohol or special chemicals. We recommend using the same detergents which are used to clean spectacles in your office. Do not use pure water.

The housing may be cleaned with a damp cloth. Pay attention to never use a wet cloth, because water must not enter the device in any case!

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

DescoseptAF solution contains about 42% Ethanol and about 0,05% Didecyldimethyl.-ammoniumchloride.

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

Protect the device against water, do not expose to rain or splashes.

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

Do not use any chemicals or aggressive agents!

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

CAUTION!

Never look into the beam. Even if only the aiming beam is present. Eye injury can be caused by any of the laser beams available thru the slit lamp or the accessories. The laser has to be switched off completely when cleaning the console and components.

Inspection and cleaning of external optics (zoomoptics, mirrors etc. - external surfaces)

Please check the zoom-optics and the external surfaces of your optics if stained, dirty or contaminated. The optics surfaces can be cleaned using a clean, soft, lint-free cloth that has been moistened with distilled water or an 10% alcoholic solution.

9.3.1

Inspection and cleaning of internal optical slit lamp surfaces

When removing the fiber from the slit lamp zoom optic, be careful not to drop dirt or especially liquids into the open hole. Inspect the last lens of the zoom optics occasionally. Dirt or liquids can cause losses and consequently destroy the optics.

9.3.2

Following problems may occur:

- During test or during surgery the output power may not be the same as adjusted.
- The spot size may vary during surgery.

Following steps maybe required:

- 1) Use an alcoholic free cotton swop and clean the lens by carefully wiping across the surface. If the dust cannot be cleaned, see below.
- 2) Use Aceton or pure alcohol with the cotton swob and repeat step 1.

Never use the cotton swob after it has dried out. Reuse of this part may damage the lens. Do not press hard on the cotton swob to avoid any scratches on the lens. Be aware of any particles, use a small air blower to blow those particles away before cleaning with a cotton swob.

9.4 Error Detection

The **CLASSIC 514** laser electronic and laser driver is designed in modules. All components are tested against elevated temperatures and are also tested using a high frequency shaker. All components are also tested against shock.

Following this instruction some of the failures can be located and probably corrected. In case of service required from the company, get in contact with your local distributor first. We hope that you do not have to call on service during the next years. The system is designed to be trouble free for many years to come.



A failure in the system is indicated in cooperation with the symbol seen aside. (see chapter **Error! Reference source not found.Symbols**)

Other failures could be the following:

1. **Electrical connections.** The mains plug has to be plugged into the wall. and the switch at the rear of the laser has to be in the "I" position.
2. **Interlock.** The door is closed or in case the interlock is jumped, the connector has to be plugged in.

3. "**Laser stop**" is pressed down. It has to be pulled all the way up.
4. **Main switch** at the lifting table is not switched on.

9.5 System Self Check

In general, a system self check will be performed, every time the system is started, and intended to check all important functions. If a failure occurs, you will be informed immediately and the error detail shows up on the screen.

We distinguish between two types of errors:

1. Dynamic failures,

i.e. errors that can be easily resolved or resolved after ordering a spare part from A.R.C. Laser GmbH.

Such errors may include:

- o Laser STOP button was pressed down
- o Interlock plug missing, disconnected or defective
- o Pedal switch pressed down when turning on device, or defective

2. Static errors,

errors which require contacting A.R.C. Laser service department.

or the local authorized dealer). For these usually an error message will appear in the display and can assist to identify the problem when calling for service.

9.6 Troubleshooting

Problem	Potential Error	Troubleshooting
No aiming beam	Laser is in Stand-By	Aiming beam only visible when the laser is in ready mode
	Slit lamp coupling is not in the right position	Move the mirror of the beam combiner to the very right 6.6.1
	Aiming beam brightness is close to „0“	Increase value for aiming beam
	Aiming beam diode is defective	Contact your distributor
No treatment beam, but aiming beam visible	Foot switch not connected	Check whether foot switch is connected
	Foot switch defective	Contact your distributor
No treatment beam and no aiming beam	Slit lamp fiber not inserted	Check position of fiber into the optic
	Slit lamp fiber defective	Contact your distributor
	Slit lamp coupling is not in the right position	Move the mirror of the beam combiner to the very right 6.6.1
Laser beam at focus different	Check your spot size at optic	If yes, contact your distributor

9.7 Power Calibration

The power indicated at the display is measured and calibrated automatically inside the unit. The power indicated at the display is the power which is available “for treatment”.

However it is important to check the power, especially if the laser is extensively used.

However, if the values of the power do vary more than the $\pm 20\%$ during a routine check, the laser has to be recalibrated at the office of the distributor or at A.R.C. Laser directly (see address following).

9.8 Proper Disposal

When electronics and other potentially hazardous wastes are improperly disposed of, they can harm public health and the environment. Batteries and e-waste contain toxic heavy metals such as lead, mercury, and cadmium.

Many local governments are offering assistance to companies that wish to safely dispose of these products. Contact your local government’s recycling or solid waste management department to learn more about the services it provides. This laser must not be disposed in your garbage. A.R.C. Laser would be very happy to assist you in the question of how to dispose the device properly.



All the applicators and probes should be disposed according to the valid laws, rules and guidelines of your country. A.R.C. Laser will help you to find out which materials have been used to produce your specific probe/applicator.

A.R.C. LASER GmbH

Bessemerstr. 14

D-90411 Nürnberg

Tel: +49 911 21779-13 (-0)

Fax: +49 911 21779-99

E-Mail: service@arclaser.de

10 Customer Service

10.1 Warranty Information

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

Refer any and all claims or defects to

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

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

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

10.2 Warranty Consignments, Packaging

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

10.3 Sales and service information

For sales and service information please contact:

A.R.C. LASER GmbH

Bessemerstr. 14

D-90411 Nürnberg

TEL: +49 911 21779-0

FAX: +49 911 21779-99

E-MAIL: info@arclaser.de

www.arclaser.de

11 Symbols Description

The CLASSIC displays Symbols as follows:

	Aiming beam		A.R.C. INFO
	Display brightness		Exit, change menu
	Loudness		Password / PIN CODE
	Tone frequency		Enter Password / PIN CODE
	CAUTION		Humidity too high
CW	Continuous wave	SP	SP (Single pulse) in repetition rate
	Temperature too low		1) External interlock; 2) L-ORD not in correct working position
	Laser Stopp		Temperature too high
	Please wait		

12 Guidance and manufacturer's declaration

12.1 Electromagnetic Emissions

The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guideline
RF emissions CISPR 11	GROUP 2	The laser uses RF energy to fulfill its intended function. Its RF emissions can cause interference in nearby electronic equipment. The laser is suitable for use in all establishments including use in domestic and those directly connected to the low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	CLASS B	
Harmonics emissions IEC 61000-3-2	CLASS B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	PASS	

12.2 Electromagnetic immunity (1)

The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	complies with IEC 60601	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	complies with IEC 60601	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2 kV common mode ± 1 kV differential mode	complies with IEC 60601	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycle $70\% U_T$ (30% dip in U_T) for 25 cycle $<5\% U_T$ ($>95\%$ dip in U_T) for 5 sec	complies with IEC 60601	Mains power quality should be that of a typical commercial or hospital environment. If the user of the laser requires continued operation during power mains interruptions, it is recommended that the laser be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	PASS	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC main voltage prior to the application of the test level

12.3 Electromagnetic Immunity(2)

The laser is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should assure that it is used in such an environment

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-6	3 V _{eff} 80 MHz to 2500 MHz	3 V _{eff} (V ₁) conforms to IEC 60601	Portable and mobile RF communications equipment should be used no closer to any part of the laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5 : V_1] \sqrt{P}$ $d = [3.5 : E_1] \sqrt{P}$ 80 MHz to 800 MHz $d = [7 : E_1] \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-3	3V/m 150 kHz to 80 MHz	3 V/m (E ₁) conforms to IEC 60601	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the laser is used exceeds the applicable RF compliance level above, the laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the laser.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than (V₁) V/m.

12.4 Recommended separation distances between portable and mobile RF communication equipment and the laser

The laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the laser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the laser as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter <i>W</i>	Separation distance according to frequency of transmitter <i>m</i>		
	150 kHz bis 80 MHz $d=[3.5:V_1] \sqrt{P}$	80 MHz bis 800 MHz $d= [3.5:E_1] \sqrt{P}$	800 MHz bis 2.5 GHz $d= [7:E_1] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.73
1	1.17	1.17	2.33
10	3.69	3.69	7.30
100	11.66	11.66	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A.R.C. LASER GmbH
Bessemerstr. 14
D-90411 Nürnberg/Germany
TEL +49 911 21779-13 (-0)
FAX +49 911 21779-99
service@arclaser.de

