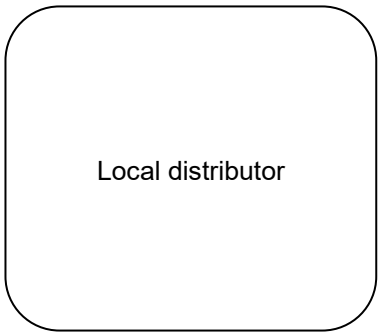
User Manual

A.R.C. Laser GmbH

CE 0123	Bessemerstr. 14 D-90411 Nürnberg	Tel.: +49 911 21779-0 Fax: +49 911 21779-99	info@arclaser.de www.arclaser.de

Please contact for service:



A.R.C. Laser GmbH Headquarters:

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

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

Content

1 Introduction

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

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

1.1 Marking and symbols

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

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

1.2 Intended Purpose

1.2.1 General purpose

Coagulation and or partial evaporisation of tissue of the eye.

1.2.2 Medical purpose

The Classic is intended to be used to treat diseases of the eye.

In particular, diseases of the retina, which can be treated with both coagulation and stimulation by applying microsecond pulses.
Other diseases in the anterior segment of the eye can be treated by coagulation or partial vaporisation of tissue, e.g. in glaucoma, by iridotomy.
For this purpose, the laser is used together with a slit lamp. The laser beam is directed onto the target tissue via imaging optics and mirrors.

The Classic is intended to be used for the following applications:

- coagulation of retinal tissue
- retina therapy (subthreshold treatment with microsecond pulses)
- iridotomy

1.3 Contraindications

The use of laser treatment for pregnant or breastfeeding women or children is NOT recommended because there do not exist clinical studies for these patients.

Patients with intransparent or partly intransparent or scattering media are not intended for the treatment.

Exceptions may be when the patient is not able to sit in front of the slit lamp, open the eye and keep it in the same position for the duration of the treatment.

A T T E N T I O N

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

1.4 Side effects

Complications can occur depending on the surgical procedure.

Generally speaking, they involve: infection, inflammation

1.5 Characterization of the User

Laser systems may only be operated by doctors and healthcare professionals. Each user must be trained in the operation of the laser by a specialist authorized by A.R.C. Laser or by someone trained by an authorized specialist.

1.5.1 Physician

Typical job title	Physician / Ophthalmologist
Provided education	Medical degree, specialist
Demographic particularity	Not necessarily native speakers, speaks language of the organization at least at B2 level
Provided work experience	Training with experienced doctor is recommended
Typical work environment	Treatment room
Typical work	Treatment of the patients eye
Provided training	No training provided. Training by a A.R.C. Laser specialist or person trained by a A.R.C. Laser specialist recommended.

1.5.2 Medical Assistant

Typical job title	Medical assistant
Provided education	Vocational training
Demographic particularity	Not necessarily native speakers, speaks language of the organization at least at B2 level
Provided work experience	N/A
Typical work environment	Treatment room
Typical work	Cleaning the device disinfect the device
Provided training	No training provided. Training by a A.R.C. Laser specialist or person trained by a A.R.C. Laser specialist recommended.

1.5.3 A.R.C. Laser Service technician and medical technician

Typical job title	A.R.C. Laser Service Employee, Medical Technician
Provided education	Vocational training, Training by experienced A.R.C. employee
Demographic particularity	Not necessarily native speakers, speaks language of the organization at least at B2 level
Provided work experience	N/A
Typical work environment	Treatment room, service department
Typical work	Installation, Service, Safety Check
Provided training	Training for Classic

1.6 Characterization of the Patients

The Classic laser device is used in ophthalmology to treat conditions such as retinal diseases or glaucoma. Exceptions may include cases where the patient's vision is decreased due to intransparent or partly intransparent or scattering media which make it difficult or impossible for the surgeon to see the target tissue (retina) clearly. Such situation also leads to radiation absorption or scattering which would make a treatment unpredict-able.

Other exceptions include situations where the patient is physically unable to undergo laser treatment, such as spasms or other contraindications.

Please note the contraindications (chapter 1.3) for the use of the Classic: The use of laser treatment for pregnant or breastfeeding women or children is NOT recommended because there do not exist clinical studies for these patients.

1.7 Characterization of the Use Environment

The Classic is designed exclusively for use in professional healthcare environments.

It should be operated in a location that is easily accessible. All accesses must be clearly marked so that unintentional or unauthorized entry is avoided. Each access door must have laser warning labels (triangle with laser symbol) as well as the marking of the wavelength. There must be a warning lamp above each access door. This must always light up when the laser is in operation. Laser safety googles must be located clearly visible at the entrance.

The laser should not be operated near a heater and direct sunlight should be avoided. The ambient temperature must be between 18°C and 32°C and the relative humidity less than 75%.

The device is not released for operation at altitudes above 2,000 m (SL). The device is released for an air pressure between 1080 hPa and 750 hPa.

The device should be positioned so that the laser beam is not aimed directly at a door, a window or reflective material. It must be ensured that no laser radiation can escape from the room. In particular, the windows must be protected with suitable materials.

To avoid the risk of reflected direct and scattered radiation, there should be no reflective surfaces in the room. These can be: mirrors, pictures behind glass, chrome surfaces or windows. These surfaces must be removed or covered. In the field of laser use, only mat, non-reflective and non-flammable instruments and materials should be used.

The device should be installed in a dust-free room. There should not be no carpets on the floor or on the walls. When not in use, it should be covered to prevent soiling.

The cabling must be installed in such a way that, as far as possible, no tripping hazards or other hazards arise.

1.8 Intended duration of use

The device is intended for use for less than 60 minutes. Therefore, the duration of use is “transient”. (European Union (EU) Medical Device Regulation 2017 / 745 (MDR) - Annex VIII - 1.1)

1.9 Benefit Claims

Benefit claims using the Classic are precise and without any alternative (e.g. retinal detachment) treatment options in ophthalmology to treat retinal diseases. Glaucoma treatments are also possible with minor side effects, non-contact, non-invasive and mostly pain free or with little pain and they can be performed atraumatic.

1.10 Exclusions from Intended Use

The intended use of Classic is the treatment of patients with retinal diseases or glaucoma. Other intraocular or other medical use is not intended.

In general, operations with little chance of success should be avoided. Also treatments which are not likely to improve the condition of the patient due to treatment with the laser should be avoided. The physician always has to weigh the benefits against non-improvement or failure of the procedure individually for each patient.

A further exclusion is the usage of accessories that are not intended to be used with Classic.

Please note the contraindications (chapter 1.3) for the use of the Classic: The use of laser treatment for pregnant or breastfeeding women or children is NOT recommended because there do not exist clinical studies for these patients.

Patients with intransparent or partly intransparent or scattering media are not intended for the treatment.

Exceptions may be when the patient is not able to sit in front of the slit lamp, open the eye and keep it in the same position for the duration of the treatment.

1.11 Theory and technical set-up

This laser device has a laser diode as the beam source which emits a wavelength of 514 nm.

The electrons of the atoms may have different energy states, which can generate electromagnetic radiation by stimulated emission of photons 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.

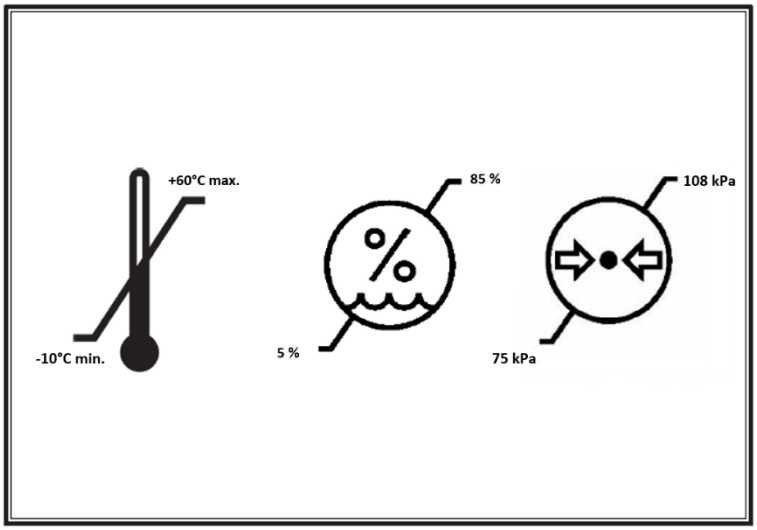
In general laser diodes are extremely sensitive towards voltage fluctuations. An internal microchip controller cushions and controls the high voltage to run the diode.

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.

2 Transport and storage

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

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



The device must be transported at temperatures between -10°C and +60°C. The air pressure during transport must be between 1080 hPa and 750 hPa. During storage, a temperature range of +5°C to +40°C must be maintained. The environment/air must be dry and clean. The relative humidity during transport and storage must be between 5 % and 85 %.

ATTENTION

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

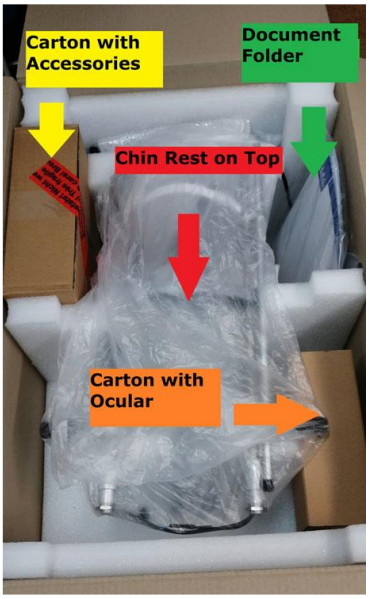
2.1 Shipping and unpacking the device

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. Normally, the Classic is delivered together with the slit lamp. For transportation the device is packed as follows:

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 Classic should be operated in an easily accessible place. The laser should not be operated near a heater, since the device only works when the ambient temperature is not higher than 32°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 4 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 goggles 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 is operated with a DC voltage of 24 V. The power is supplied by an external power supply. The power supply unit can be connected to an AC voltage ranging from 100 V – 240 V (50/ 60 Hz).

The power connection is made via the table column and the supplied 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 Classic laser is a precision instrument for medical applications. The system has been carefully developed and tested through intensive testing before shipping. In order to offer you and the operating personnel all possible protection, we recommend that you read this section of the operating instructions carefully.

The Classic laser falls under laser class 4 according to EN 60601-2-22, EN 60825-1 respectively.

Class 4 in the standard describes high-energy lasers and therefore special measures have to be considered before use 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 goggles 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. We refer here in particular to the publication “Operation of laser equipment and accident prevention regulations for laser radiation”. If the device is operated in Germany (oder Europe) the Medical Device Operator Ordinance (MPBetreibV) also applies.

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 treated with the laser.

With regard 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 regard 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 goggles. The treating doctor is protected from radiation by the laser protection integrated (eye safety filter) into the slit lamp. Eye protection appropriate to the patient must be guaranteed for the patient.

When using the laser, only those laser safety goggles that are designed for the wavelength of 514 nm and on which both the CE mark and the appropriate protection level are noted.

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

- AS01003 for 514 nm: Protection level D LB6+ I LB 6 + RM LB8 / Optical density OD8+

There are different types of laser safety goggles that also allow spectacle wearers to wear a tight goggle on top of their own which are protective to 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 goggles. Therefore, we encourage you to wear laser safety goggles which also guarantee a full protection to the side parts.

The eye safety of the operator is ensured by the eye safety filter which is firmly installed into the slit lamp. The eye safety filter is already included and may not be removed at any time.

ATTENTION

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

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. The mains may only be replaced by authorized service personnel.

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.

ATTENTION

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 anaesthetics, 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 theatres where there are multiple footswitches, it is important to ensure that the laser footswitch is close to the laser device.

Also, the hand trigger of the slit lamp may only be used by the attending doctor.

4.6 NOHD safety distance

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

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

$$NOHD = \frac{\sqrt{\frac{4P}{MZB * \pi}} - Diameter\ Laser\ Beam}{Beams\ divergence}$$

For the Classic with slit lamp the following applies:

Wavelength λ:	**514 nm**
NOHD:	**12.2 m**
Beam divergence $\alpha_{(full\ angle)}$:	**1.1°**
Permitted Maximum Radiation:	**$1.9*10^{-3}$ Jm^{-2}**

4.7 CE-Regulations

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

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

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

4.8 RoHS3-Regulations

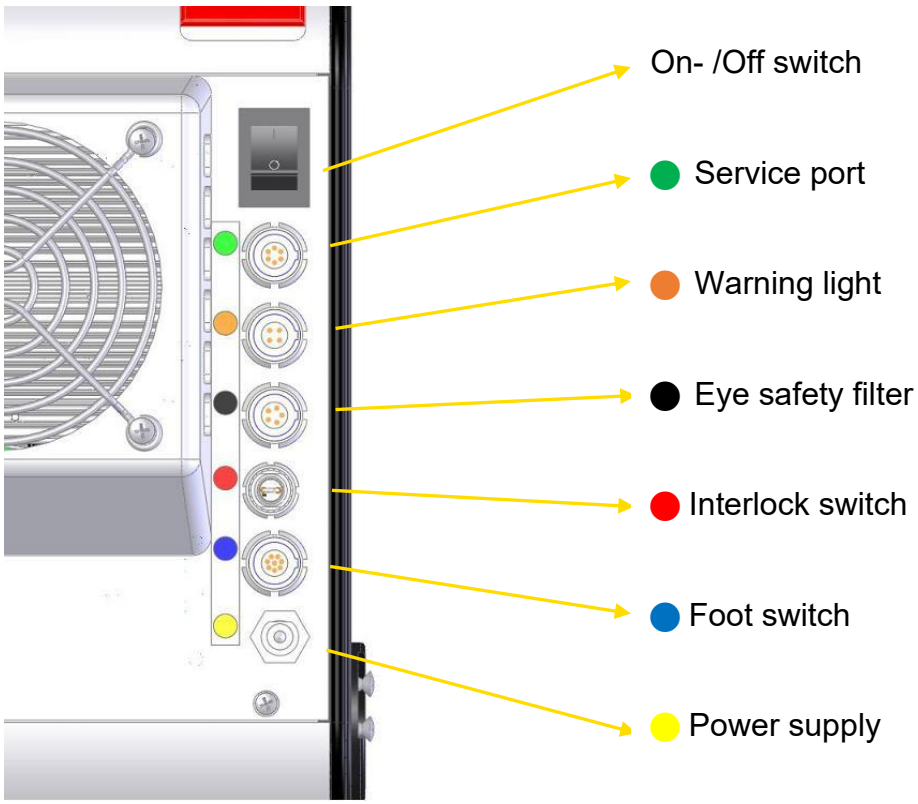
Our company operates worldwide and regards the protection of the environment and natural resources as an entrepreneurial obligation. Based on individual tests, A.R.C. Laser GmbH confirms that, to the best of our knowledge, our products do not contain any substances in concentrations whose placing on the market is prohibited according to the applicable requirements of Directive 2015/863/EU (RoHS 3).

4.9 Protective housing

The Classic laser 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. Any work carried out on the device must be performed by authorized personnel only. The housing parts should be removed by service personnel of A.R.C. Laser GmbH only.

4.10 Connectors and switches

At the rear panel of the laser following connector can be found:



It is prohibited to use the device's socket for other usages than those detailed here.

Connector	Description	Usage	Colour
Service Port	Service port, do not use	The service port may only be used by trained A.R.C. Laser service personal	Green
Warning light	Connection for the external warning light of the door	Only use the A.R.C. Laser GmbH connection for the Classic	Orange
Eye safety filter	Connector for the mechanical eye safety filter	Not in use anymore, please insert the dummy plug.	Black
Interlock switch	Interlock switch for the door interlock	The interlock switch can either be used for the door interlock	Red
Foot switch	Connector for the A.R.C. Laser GmbH footswitch	Only use the A.R.C. Laser GmbH foot switch for the Classic	Blue
Power supply	Connector for the medical certified A.R.C. Laser power supply	Only use the A.R.C. Laser GmbH power supply for the Classic	Yellow

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 to READY again.

The door interlock plug should be inserted instead of the dummy plug. Only connect plugs with 12V and 20mA.

Make sure the switch stuck firmly to prevent unexpected system interlock problems.

4.12 Safety-Shutter / Aiming beam

The Classic has an internal safety shutter. This shutter opens by pressing the READY button and allows the user to release laser radiation.

Thereafter, 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. In that case, you should switch the laser off and on again. Wait for 20 seconds when switching the device on again otherwise the error F00f is shown and you have to restart again. The restart should fix the error due to the automatic recalibration.

If the error still occurs, this can only be fixed 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 mains accidentally - e.g. due to a power failure - it usually restarts automatically. The system recalibrates. If there is still an error, it can only

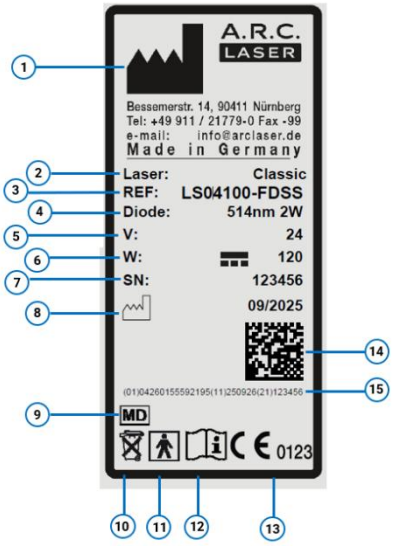
be corrected by trained personnel. Please contact A.R.C. Laser GmbH service department should this occur.

4.15 Labels and markings

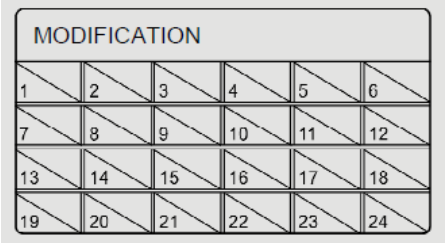
The Classic is provided with various warnings in accordance with European and worldwide guidelines to prevent the laser user from being exposed to laser radiation by negligence. The following labels can be found on the Classic:

Type plate

1) Manufacturer
2) Laser name
3) Reference Number (REF)
4) Wavelength and power
5) Power input
6) Power output
7) Serial number (SN)
8) Manufacturing date
9) Do not dispose with household waste
10) Applied part type BF
11) Follow user manual
12) CE sign
13) Unique Device Identifier (UDI = Manufacturing Date + SN + GTIN)
14) Unique Device Identifier human readable (UDI = Manufacturing Date + SN + GTIN)



Further Labels



The modification label shows the current state of the device.

Laser warning labels

(attached on the side)

Laser stop label and marking of the fiber exit
(attached on the device)

The device is marked with an additional label, which indicate to respect the user manual.

4.16 Operating conditions

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

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

The following environmental conditions must be met:

- Ambient temperature: 18°C to 32°C
- Relative humidity: <75 %

4.17 Electromagnetic compatibility

The Classic laser system meets the EMC requirements according to EN 60601-1-2. Guidelines and the manufacturer's declaration are described in Chapter 11.

A T T E N T I O N

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

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

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

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

5 User information and system introduction

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.

5.2 Laser-Safety-Training

The Classic 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 goggles 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

5.5.1 The device

The Classic device is shown above.

5.5.2 Basic equipment

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

Necessary parts for operation:

Part	Description	Article number
Mains cable*	Type E/F (EU) Type G (USA) Type B cable	KB13003 KB13004 KB13005
Power supply	Power supply	PS01010
Door Interlock	Door interlock	UG04022
Eye protection simulator plug	Eye protection simulator plug	BG01168
User manual	User manual	-

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

Additional equipment included:

The packaging consists of:

Part	Description	Article number
Transport box	Transport box for Classic consisting of the outer packaging, inner packaging, moulded foam and spacer corners for the packagings	VP04002

Additional equipment*:

Part	Description	Article number
Dust protection cover	Dust protection cover	ZU01046
Cover Turning Mirror	Cover Turning Mirror	ME12259
Footswitch*	Footswitch	BG04008
Eye safety filter	Eye safety filter type Zeiss 514nm Eye safety filter type Leica 514 nm	BG06076 BG06077

* Additional equipment is included in the standard delivery but is not part of the basic parts of the device. These items are not available separately as accessories.

** Optionally, the Classic can be used with a foot switch instead of the hand trigger of the joystick of the slit lamp.

5.5.3 Optional equipment

Laser safety googles are not part of the basic equipment and are listed separately on the purchase order. We recommend ordering at least 2 laser safety glasses per laser (nurse, patient, etc.).

Slit lamp: Classic can be used in combination with A.R.C. slit lamp PCL 5 SH. It is connected through a permanently installed adapter known as the “Super View”.

Instrument table: The *Classic* and the slit lamp are mounted on an instrument table which is height adjustable. This allows to adjust the optimal working height comfortably for each patient.

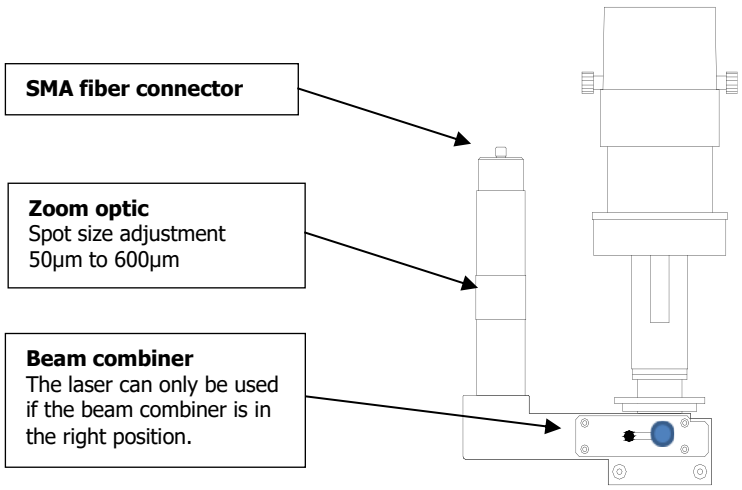
Part	Description	Article-No.
Laser safety goggles	Laser safety goggles >315-532 nm	AS01003
PCL5 SH	Slit lamp	SL01200
Instrument table	Adjustable table	SL11040

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

The image below shows the *Classic* connected with the PCL5 SH, positioned on the table. An eye safety filter (green in the picture) is installed in the slit lamp to protect the operator from hazardous laser radiation.

The Classic is connected to the slit lamp using a permanently installed adaption called "Super View". The Super View consists of an SMA fiber connector, a zoom optic and the beam combiner.

The slit lamp is connected through the fiber connector with a fiber to the Classic. The laser radiation which is coupled in the fiber connector is re-directed through the zoom optic into the beam combiner. For using the laser with the slit lamp, the beam combiner needs to be in the right position.



Additionally, the zoom optic has an integrated spot size adjustment with whom the spot size can be adjusted between 50 µm and 600 µm.

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ATTENTION

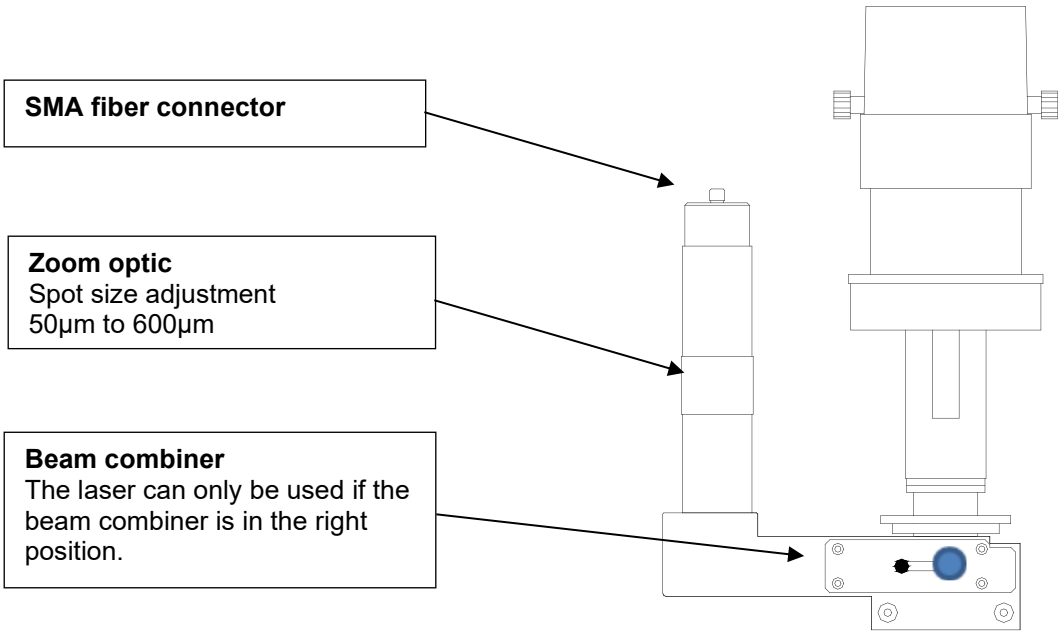
Only spare parts and applicators which are approved by A.R.C. Laser GmbH are to be used with the device. Accessories that have not been approved can significantly impair the safety and reliability of the device.

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.

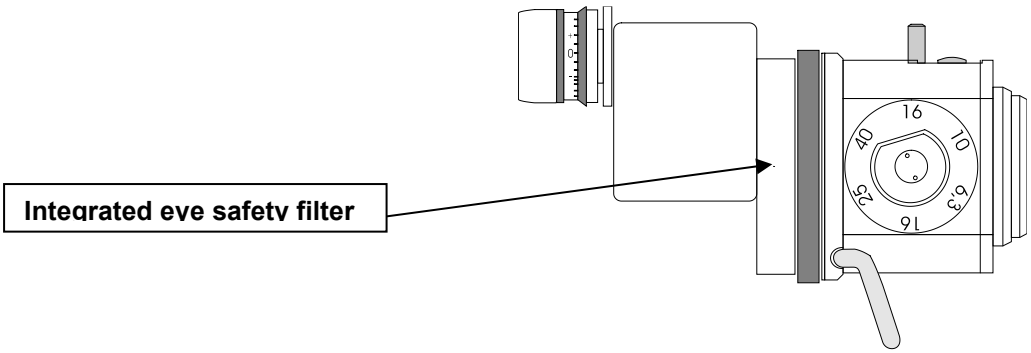
5.5.4 Slit lamp adaption of the laser

The Classic is delivered as standard with the slit lamp PCL 5 SH of A.R.C. Laser GmbH and is connected with the slit lamp via a permanently installed adaption, the “Super View”. The Super View consists of an SMA fiber connector, a zoom optic and the beam combiner. The slit lamp is connected through the fiber connector with a fiber to the Classic. The laser radiation which is coupled in the fiber connector is re-directed through the zoom optic into the beam combiner. For using the laser with the slit lamp, the beam combiner needs to be in the right position.

Additionally, the zoom optic has an integrated spot size adjustment with whom the spot size can be adjusted between 50 µm and 600 µm.



For safety, an eye safety filter is included in the slit lamp, which protects the operator for dangerous laser radiation.



5.5.5 Combinations

The Classic can be used with the slit lamp PCL 5 SH of A.R.C. Laser GmbH.

A.R.C. Laser has checked and controlled the compatibility of the products 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.

6 Operation

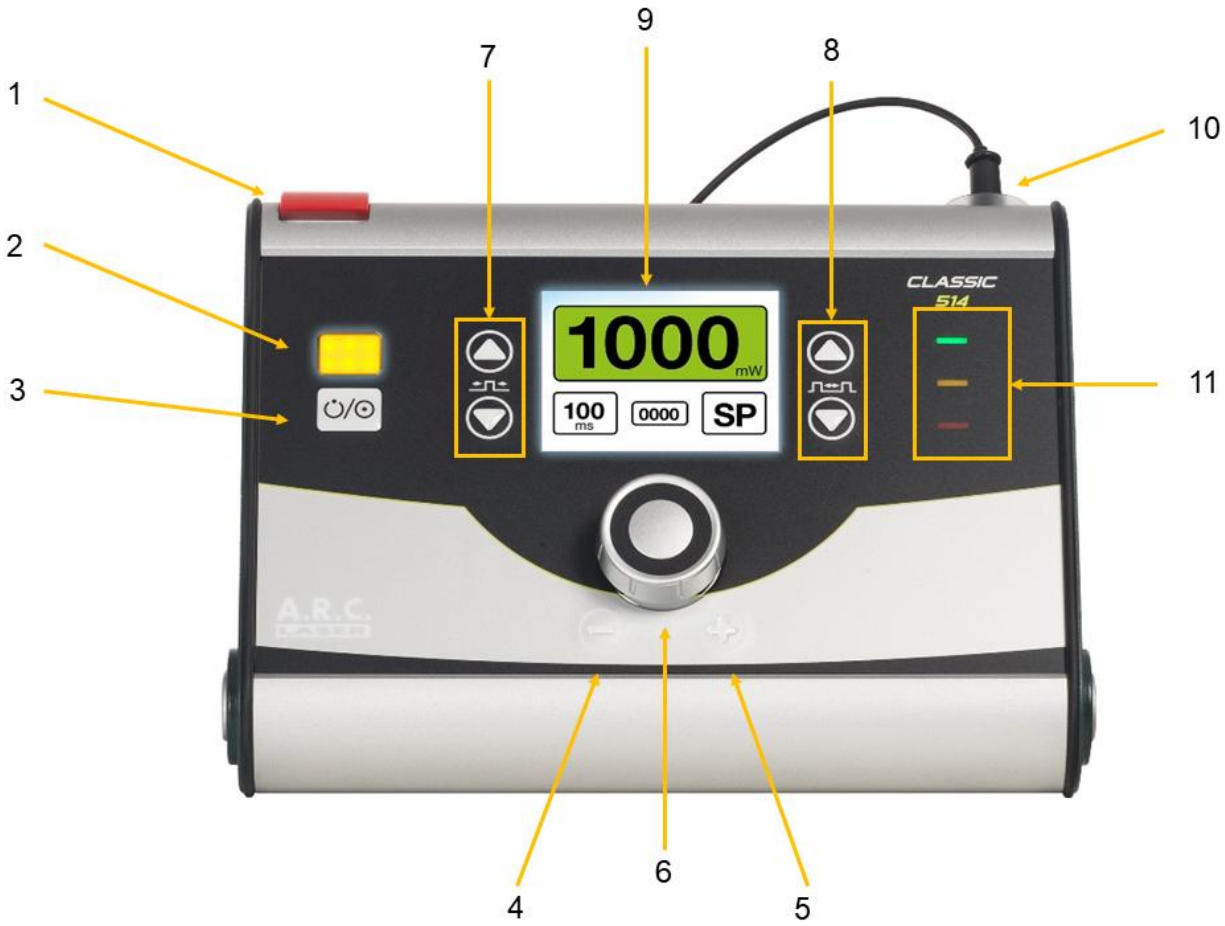
This part of the manual only describes the technical application of the device, without going into the medical application. You will receive separate application manuals from A.R.C. Laser GmbH, if needed.

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 need to interrupt, the laser must be returned to STANDBY mode. The device must always be switched off when unattended to prevent operation by an unauthorized third party.

ATTENTION

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



The front panel of the device consists of the following controls and keys:

1	Laser Stop
2	Laser READY LED
3	Laser READY button
4	Reduction of the aiming beam brightness
5	Increasing the aiming beam brightness
6	Regulation of the power and confirmation rotary knob.
7	Adjustment of pulse length with plus/minus
8	Adjustment of pulse pause with plus/minus
9	Display
10	Fiberport for the connection of the slit lamp
11	Status LED • Green: Laser on • Orange: without use • Red: Error LED

ATTENTION

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

6.1 Preparation

- Make sure the power cord is plugged in.
- Check that the Laser-Stop button is not pressed.
  If it is pressed, pull it up.
- Are third parties present who need laser safety goggles?

ATTENTION

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

6.2 Starting the device

The Classic is used together with a slit lamp. The device is connected via a power supply to the lifting table. To start the device and the slit lamp, switch on the main switch underneath the table. Afterwards, the device can be started using the On/Off switch on the back of the Classic.

ATTENTION

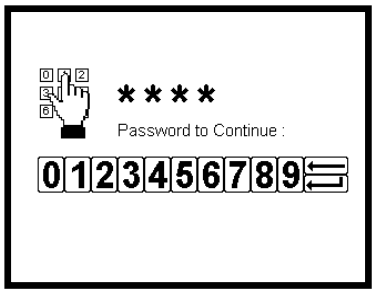
When using the Classic with another slit lamp, lifting table respectively, switching on may be differ from the previous description.

After the main switch at the lifting table and the device is switched on, the green status LED on the front starts to flash. The A.R.C. Laser GmbH logo is shown on the display and the system check starts.

Meanwhile the laser checks the internal safety functions. This may take a while.

The green LED stops blinking and lights up continuously after successfully performing the system check.

Password entry

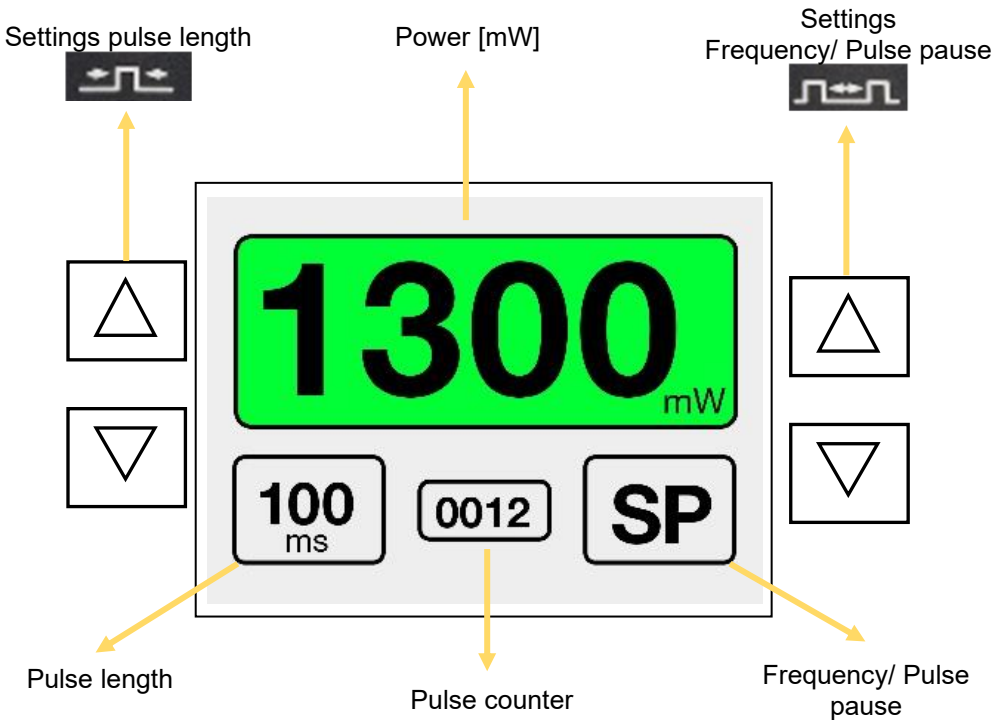


After the system check, you will be asked to enter a password. The factory set password is "**0000**". After first input the password should be changed individually. Refer to chapter 6.4.1 to change the password.

To enter the password, turn the rotating wheel to the right. The selected number is confirmed by pressing the rotating wheel. Afterwards a star in the upper code line marks the selection. After entering the four-digit code, you can confirm the password using the return button.

6.3 Programs and settings

6.3.1 Main menu



6.3.2 Energy settings

The energy can be set using the rotary wheel. The following energy values [mW] can be chosen by the operator:

50 mW bis **200 mW** in 10 mW steps

200 mW bis **500 mW** in 20 mW steps

500 mW bis **1000 mW** in 50 mW steps

1000 mW bis **1200 mW** in 100 mW steps

6.3.3 Pulse length settings

The pulse length [ms] can be changed up to 2000 ms using the left arrow keys. Following values are possible:

15	25	50	75						
100	150	200	300	400	500	600	700	800	900
1000	1500	2000							

6.3.4 Frequency/ pulse pause settings

In the factory settings, the right arrow keys can be used to change the frequency [Hz] up to 10 Hz. Following values are possible.

1 Hz to **5 Hz** in **1 Hz** steps

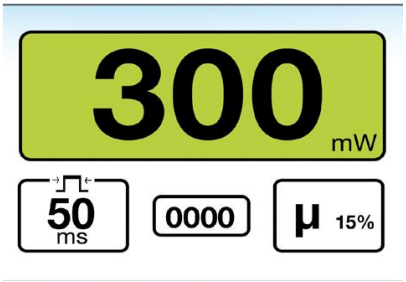
10 Hz and **SP** (single pulse)

If desired, the device can also display the pulse pause [ms] instead of the frequency. This can be set during installation by authorized service personnel. In pulse pause mode, the values range between **100 ms** and **900 ms** in **100 ms** steps. Also, the SP mode is available.

To protect the patient from too much laser energy, the combination of pulse lengths and frequency is limited. The following combinations are possible:

Pulse length [ms]	**Frequency** [Hz]	**Pulse length** [ms]	**Frequency** [Hz]
15 – 150	1 – 5, SP	400	1 – 2, SP
200	1 – 4, SP	500 – 900	1, SP
300	1 – 3, SP	1000 – 2000	SP

6.3.5 APL Mode (All Pulse Laser) (optionally)



The APL mode can be chosen after the SP settings. With the left arrow keys, the total pulse duration can be chosen as **50 ms, 100 ms, 150 ms, 200 ms** and **250 ms**. Using the right arrow keys the specific APL-Mode, **$\mu_{15\%}$, $\mu_{10\%}$ and $\mu_{5\%}$**, can be chosen.

By setting the APL mode, the pulse duration does not change for the moment. The change to this mode split the laser radiation into many small pulses. Those small pulses have durations of 100 µs (if set to 5 %), 200 µs (if set to 10 %) or 300 µs (if set to 15 %). The device emits 5 pulses per 10 ms which means 25 pulses when choosing 50 ms, 50 pulses when choosing 100 ms and so on. The percentual values (5 %, 10 %, 15 %) corresponded to the share of the delivered power to 100% (cw) also called DutyCycle. This results in the following values for the laser on and laser off times:

DC	t_{on}	t_{off}
5 %	0.1 ms	1.9 ms
10 %	0.2 ms	1.8 ms
15 %	0.3 ms	1.7 ms

The APL mode can be left when using the right arrow up key. A warning message appears to make sure that the operator wants to leave this mode. Navigate with the rotating wheel to the EXIT symbol, to leave the APL mode. When choosing the back symbol, the Classic remains in the APL mode.

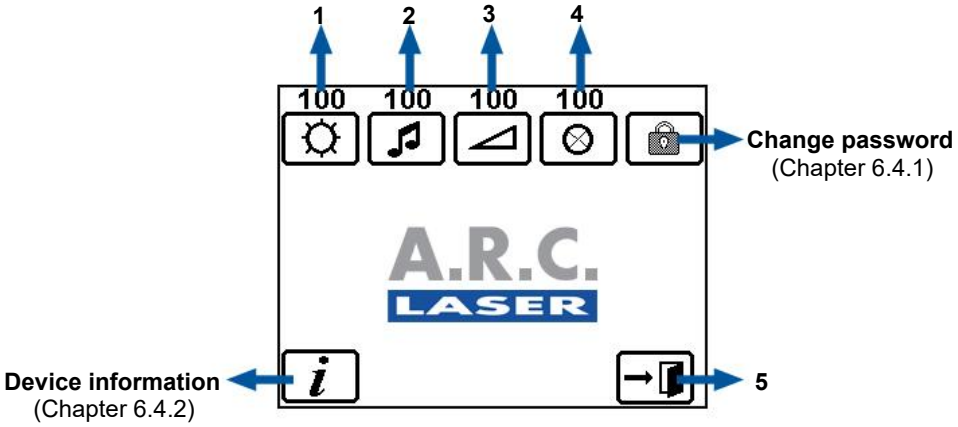
6.3.6 Pulse counter

The Classic sums up the triggered pulses. When pressing the rotary wheel, the counter will be set to 0 again.

6.4 Other settings

By pressing the right and left - / + key simultaneously will guide you into the submenu for the device settings. This is either possible in READY mode as well as in STANDBY mode. Please note, that the device will leave the READY mode, when the main menu is left.

Navigate through the menu with the + and – key. The rotary wheel changes the respective value. If an icon is darkened it is active and the values can be changed.



1 Display brightness can be adjusted from 25 – 100 % in 5 % steps.

2 Audio frequency can be adjusted from 0 – 100 % in 5 % steps.

3 Audio volume can be adjusted from 10 – 100 % in 5 % steps.

4 Aiming beam brightness can be adjusted 1 – 100 % in 1 % steps.

5 Using the door symbol, the current mask can be left.

Furthermore, the aiming beam brightness can be adjusted directly using the + and – keys next to the rotary wheel. For that, the device has to be in READY mode.

6.4.1 Password

The password can be changed individually. Choose the lock symbol for that.

The password consists of four digits (factory set is **0000**).

The routine for changing the password will guide you through the menu:

1) Old password: Insert the current password
2) New password: Insert your new desired password
3) Confirm Password: Repeat the new password.

6.4.2 Info menu

The information symbol redirects you into another sub menu. This menu contains information concerning your Classic. Furthermore, it informs about the last occurring error, which you can communicate to the service personnel in case of a service case.

6.5 Laser STANDBY / READY

Pressing the laser READY button activates the Classic and the READY LED is flashing for some seconds. When the LED lights up permanently, the laser is active and laser radiation can be emitted. If the hand trigger, food trigger respectively, is activated too early, the device does not change into READY mode.

After treatment the laser has to be returned to STANDBY mode by pressing the laser READY button again.

6.6 Release laser radiation

To trigger the laser, press the trigger on the vertical drive (joystick) of the slit lamp. For that, the laser must be switched to the READY mode. Alternatively, the Classic can be trigged by a foot switch.

When a laser shot is fired, a simultaneous warning signal sounds and the red LED of the Fiberport lights up.

6.7 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 point is in focus with the microscope.

Press the READY button: the yellow LED flashes for some seconds and then changes to steady light. Treatment can start.

The software of the Classic sums up the number emitted shots, which is permanently shown in the lower area of the display.

At the end of a treatment, press the READY button. The trigger does not work in this position.

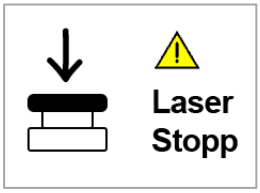
After setting the first treatment values, it is advisable to first set a laser pulse in the periphery of the retina, or the treatment area, in order to observe the laser effect. Under no circumstances should the first laser pulse be placed centrally or close to the macula.

A T T E N T I O N

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

6.8 Laser-Stop

The laser stop button is on top of the left side of the device. If the laser stop button is pressed during start-up, following error message is shown:



Pull the Laser stop button up to restart the device.

If the laser stop will be pressed during treatment, the same error message appears on the screen and the device cannot be used anymore.

ATTENTION

In general, the **Laser-Stop** should **only be used in emergencies**.

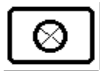
6.9 Switch Off

The Classic can be switched off on the back of the device using the On/Off switch. Afterwards you should also switch off the main switch on the lifting table.

ATTENTION

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

6.10 Symbols

	Display brightness (25 – 100%)		Attention
	Audio pitch (0 – 100)		Back (in APL Mode)
	Audio volume (10 – 100)		Delete (during entering password)
	Aiming beam brightness (1 – 100)		Accept (during entering password)
	Info menu		Temperature too high
	Leave menu		Temperature too low
	Change password		Humidity too high
	Laser Stopp pressed		Interlock Error
	Enter password		Foot switch/ Handtrigger pressed

7 Technical data

7.1 Classic

7.1.1 General

Model Classic	Diode laser
Cooling	Air internal
Weight	3,3 kg
Dimensions	H 17 cm/B 25 cm/T 22cm with stand
Control Option	Buttons and rotary wheel

7.1.2 Laser Data

Wellenlänge	Energie	Tolerance
514 nm	50 – 1200 mW	±20% of displayed energy according to IEC 60601-2-22

Pulse length	15 ms – 2000 ms
Frequency/ pulse pause	1-5 Hz, 100 ms – 900 ms

Aiming Beam

Laser type:	Diode laser
Wavelength:	635 nm red
Max. output power:	< 1 mW
Brightness:	variable
Mode:	CW

Power transmission	coupled in a slit lamp with 62.5 µm fiber

7.1.3 Electrical Connection Data

Power supply connection values	90-264 V, 47-63Hz, 1.06 – 0,8 A

7.1.4 Classification

Laser class working beam (Classification EN 60825-1)	4
Laser class Aiming Beam (Classification EN 60825-1)	2
Classification according to MDR	IIb, Rule 9
Electrical protection class (Classification IEC 60601-1)	II
Certification	CE 0123

8 Maintenance

8.1 Introduction

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

ATTENTION

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 are carried out by trained service personnel only. This also includes cleaning and cleaning the optics within the laser.

8.2 Safety Check (STK)

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

Scope of Safety Check (STK)

Visual Check

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

Functionality Check

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

Check the necessary monitoring/safety display and signaling unit

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

Electrical Safety Check

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

Output power measurements

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

ATTENTION

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

8.3 Care by the user

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

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

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

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

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

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

*This list is not exhaustive.

ATTENTION

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

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

8.4 Cleaning of Accessories

8.4.1 Foot switch

The general cleaning instructions (see above) must be respected in any case. When cleaning the foot switch, prevent the penetration of water or cleaning agents. Never place the foot switch in water or cleaning agent, this could lead to a short circuit.

8.4.2 Laser safety goggles

The cleaning instructions provided with the laser safety goggles must be respected.

In general, never use chemicals for cleaning that could damage the coating for the goggles. Always use soft cloths that do not leave scratches on the surface

8.4.3 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.

8.4.3.1 Slit Lamp mirror

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.

8.4.3.2 Dust Cover

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

8.4.3.3 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.

A disturbed target beam can be an indication of a faulty system; thus, the aiming beam can be a tool to check the integrity of the system.

ATTENTION

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

8.5 Error Detection

In case of an error, you can use this manual to isolate the problem and, in some cases, even solve it yourself the problem persists, please contact your local A.R.C. Laser authorized dealer for technical support.

When an error occurs in the system, the error will be displayed along with a symbol to identify the error.

Common causes of errors might be:

- Interlock Error: The contact plug should be plugged into the device or the door contact switch should be closed

Following errors are not detected during system check and have to be checked by the user

Problem	Probable error	Troubleshooting
No aiming beam visible	Laser is in STANDBY mode	Aiming beam is only visible, when the laser is in READY mode. Change to READY mode for use.
	Coupling of slit lamp (Beam Combiner) is not in the right position	Move the mirror of the beam combiner to the very right as described in chapter 5.4.3
	Aiming beam brightness too low	Increase aiming beam brightness
	Aiming beam diode defect	Please contact A.R.C. Laser GmbH service or your local representative
No working beam but an aiming beam is visible.	Foot switch defective	Check the connection of the foot switch.
	Foot switch/ hand trigger defect	Please contact A.R.C. Laser GmbH service or your local representative
No aiming beam and not working beam	Slit lamp fiber optic is not connected to the device	Check the fixation of the fiber to the device
	Slit lamp fiber optic defect/broken	Please contact A.R.C. Laser GmbH service or your local representative
Diameter of laser radiation different than before.	Spot size misaligned	Please contact A.R.C. Laser GmbH service or your local representative

8.6 Disposal

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

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

9 Customer service

9.1 Warranty Information

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

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

9.2 Warranty, Shipment, Packing

A warranty claim for defective parts, malfunction or damage to the housing of the device must be submitted to A.R.C. Laser GmbH within 24 hours. Parts that are returned during the warranty period (at the express request of A.R.C. Laser GmbH) must be confirmed in writing by A.R.C. Laser GmbH. Detailed packaging instructions and information on how to return the device are provided by A.R.C. Laser GmbH. The return must be insured and paid for by shipper. The insurance and transportation costs are not covered by A.R.C. Laser GmbH. The choice of the return is made by the A.R.C. Laser GmbH communicated to the customer. Changes and amendments in the carrier or the shipping method can lead to delays in transport and processing. All components to be changed under the warranty claim are manufactured by A.R.C. Laser GmbH renewed free of charge within the guarantee period. We reserve the right to make changes to the design of the device - if it appears necessary - to increase the safety or the functionality of the device. The responsibility for the design as well as for changes in the device lie 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 11 150 kHz – 30 MHz	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 30 MHz - 1 GHz	EN 55011 Group 1/Class B	The laser is only suitable for the environment in professional healthcare facilities.
Harmonic emission	IEC 61000-3-2 Class A	
Voltage fluctuations/flicker	IEC 61000-3-3	

10.2 Electromagnetic Immunity (1)

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

Immunity tests	IEC 60601-Test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD)	± 2 kV, ± 4 kV, ± 6, ± 8 contact discharge; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	IEC 61000-4-2	Floors should be made of wood, ceramic or stone. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Electrical fast transient /burst	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used.
Radiofrequency electromagnetic fields in the immediate vicinity of wireless communication devices	3 V/m 80 MHz to 2,7 GHz (see Table 11.4)	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may 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 professional healthcare facilities may 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 the voltage of a typical professional healthcare facility may be used.
Surge voltages (Surges),Line against line	± 0.5 kV, ± 1 kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Surge voltages (Surges),Line against grounding	± 0.5 kV, ± 1 kV, ± 2 kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Conducted disturbance variables, induced by high-frequency fields	3 V 0.15 MHz to 80 MHz 6 V in ISM-frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	IEC 61000-4-6	Only the voltage of a typical professional healthcare facility may be used.
Voltage dips	0 % UT; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 level 0 % UT;1 cycle at 0 and 180 level And 70 % UT; 25/30 cycles at 0 and 180 level	IEC 61000-4-11	Only the voltage of a typical professional healthcare facility may be used. It is recommended to use an uninterruptible power supply.

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

10.3 Electromagnetic Immunity (2)

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

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

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

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

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

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A.R.C. Laser GmbH

Bessemerstr. 14
D-90411 Nürnberg

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

www.arclaser.de