

# User Manual

# C-LAS



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# 1. Introduction

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

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

## 1.1 Marking and symbols



The "**General warning sign**" (ISO 7010 W001) indicates general risk. It encourages the user to take care regarding the hazard specified by the supplementary sign. Before carrying out any further 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 goggles.

## **1.2 Intended Purpose**

### **1.2.1 General purpose**

Coagulation and/or carbonization/vaporization of tissue, bony structures, or blood.

### **1.2.2 Medical purpose**

The C-Las is intended to be used for treatments requiring carbonization/vaporization (ablation) of tissue and bony structures. Tissue can be carbonized and removed or separated by vaporization.

The laser can be used together with micromanipulator C-Pro in non-contact mode.

The laser effect allows focused treatment of the disease area with minimal impact on the surrounding tissue.

The laser can be applied both in unsterile environment, for instance at a physician's examination room, and in a sterile environment e.g. operating theater. The carbon dioxide laser C-LAS is intended to be used for the following applications:

- Laryngology
- General Surgery
- Otology
- Oral and maxillofacial surgery
- Aesthetic and plastic surgery (lid surgery)
- Gynaecology

### 1.2.2.1 Indications and contraindications

Medical field	Indication	Side and adverse effects	Contraindication
Laryngology	<ul style="list-style-type: none"> <li>•Laryngeal surgery</li> <li>•Laryngeal cancer</li> <li>•Vocal cord cancer</li> <li>•Squamous cell carcinoma</li> <li>•Vocal fold benign lesions</li> <li>•Cordectomy</li> <li>•Laryngectomy</li> <li>•Glottic cancer</li> <li>•Leucoplakia</li> <li>•Zenker's Diverticulum</li> <li>•Recurrent Respiratory Papillomatosis RRP</li> <li>•Reinke Edema</li> <li>•Cricopharyngealmyotomy</li> <li>•Stenosis</li> <li>•Chondrosarcoma</li> <li>•Thyroglossal duct cyst</li> </ul>	<ul style="list-style-type: none"> <li>•Longer wound healing</li> <li>•Cuff rupture</li> <li>•Racheal perforation</li> <li>•Burns</li> <li>•Cautery artifacts on margins</li> <li>•Edema</li> <li>•Danger of perforating neck vessels</li> <li>•Scar formation</li> <li>•Voice change</li> <li>•Stenosis</li> <li>•Hypopharyngeal injury</li> <li>•Mediastinitis</li> <li>•Fistula formation</li> <li>•Airway fire</li> <li>•Thermal injury</li> <li>•Webbing</li> <li>•Emphysema</li> <li>•Swelling</li> <li>•Synechia</li> <li>•Bleeding</li> <li>•Pain</li> </ul>	<ul style="list-style-type: none"> <li>•Oxygen level can't be lowered below 30% due to previous illness if used nearby intubation tube.</li> <li>•Robotic surgery</li> </ul>
Otology	<ul style="list-style-type: none"> <li>• Stapedotomy / Stapedectomy</li> <li>• Tympanoplasty</li> </ul>	<ul style="list-style-type: none"> <li>• Thermal injury</li> <li>• Bleeding</li> <li>• Pain</li> <li>• Injury to inner ear structures</li> <li>• Heating of perilymph</li> <li>• Tinnitus</li> <li>• Footplate injury</li> <li>• Sensorineural hearing loss</li> <li>• Nystagmus</li> <li>• Vertigo</li> </ul>	<ul style="list-style-type: none"> <li>• Robotic surgery</li> </ul>
Oral and maxillofacial-surgery	<ul style="list-style-type: none"> <li>•Tonsillotomy / Tonsillectomy</li> <li>•Epulis fissuratum</li> <li>•Carcinoma</li> <li>•Laser assisted Uvulopalatoplasty</li> <li>•Soft Palate</li> <li>•Papilloma</li> <li>•Oral soft tissue</li> <li>•Frenectomy</li> <li>•Oral-maxillofacial surgery</li> <li>•Gingival hyperplasia</li> <li>•Hyperkeratotic lesions of mucosa</li> </ul>	<ul style="list-style-type: none"> <li>•Longer wound healing</li> <li>•Edema</li> <li>•Scar formation</li> <li>•Bleeding</li> <li>•Pain</li> </ul>	-



Aesthetic and plastic surgery	<ul style="list-style-type: none"> <li>• Blepharoplasty in case of dermatochalasis/ptosis at the eye</li> <li>• Benign tumour of eyelid</li> </ul>	<ul style="list-style-type: none"> <li>• Ectropion</li> <li>• Erythema</li> <li>• Bruising</li> <li>• Ecchymosis</li> <li>• Discomfort</li> <li>• Eyelid malposition</li> <li>• Bacterial conjunctivitis</li> <li>• Destruction of eyelash</li> <li>• Hypopigmentation</li> <li>• Edema</li> <li>• Scar formation</li> <li>• Swelling</li> <li>• Bleeding</li> </ul>	-
Gynaecology	<ul style="list-style-type: none"> <li>•Cervical dysplasia - cervical intraepithelial neoplasia (CIN)</li> <li>•Vaginal intraepithelial neoplasia</li> <li>•Tumour surgery of the Uterine Cervix</li> <li>•Laser conization</li> <li>•Genital warts/Condyloma (external anogenital and vaginal)</li> </ul>	<ul style="list-style-type: none"> <li>•Stenosis</li> <li>•Bleeding</li> <li>•discomfort</li> <li>•hypopigmentation</li> <li>•keloid formation</li> <li>•scar formation</li> <li>•haemorrhage</li> </ul>	-
General surgery	Treatments requiring coagulation or carbonization/vaporization of tissue, bony structures, or blood	<ul style="list-style-type: none"> <li>• Longer wound healing</li> <li>• Misalignment</li> <li>• Burns</li> <li>• Edema</li> <li>• Scar formation</li> <li>• Thermal injury</li> <li>• Swelling</li> <li>• Bleeding</li> <li>• Pain</li> </ul>	-

### 1.2.3 Principles of operation and mode of action

The power output of the C-Las can be adjusted peaking an output of 30 W. The laser radiation typically leave the cavity through a partially reflective mirror at one end; the optical energy can then be coupled into an optical system. The laser tube is controlled with electronics, which can be adjusted by the user on the touchscreen by means of output power, pulse length and width.

#### **ATTENTION**

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

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

### 1.3 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.

#### 1.3.1 Physician

Typical job title	Physician
Provided education	Medical degree,
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 (s. Chapter 4.4)
Typical work	Treatment of the patient
Provided training	No training provided. Training by a A.R.C. Laser specialist or person trained by a A.R.C. Laser specialist is recommended.

### 1.3.2 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 (s. Chapter 4.4)
Typical work	Cleaning the device, disinfect the device, prepare and assist the surgery
Provided training	No training provided. Training by a A.R.C. Laser specialist or person trained by a A.R.C. Laser specialist is recommended.

### 1.3.3 A.R.C. Laser Service Employee

Typical job title	A.R.C. Laser Service Employee, medical technician
Provided education	Vocational training, Training by experienced A.R.C. employees for COBRA
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 (s. Chapter 4.4) service department of A.R.C.
Typical work	Installation, Servicing, Safety Check
Provided training	Training for COBRA

## **1.4 Characterization of the Patients**

The C-Las laser device is used in the field of Laryngology, Otology, Oral and maxillofacial surgery, Aesthetic and plastic surgery (eye lid surgery), Gynecology, General surgery. In general, the C-Las can be used for all patients, where the indications meet. Please note the contraindications for the use of the C-Las.

## **1.5 Benefit Claims**

All patients can be treated unless there is no contraindication resulting from any pre-existing condition or the disease ought to be treated itself or from any device implanted having laser treatment as a contraindication.

Laser use can be beneficial as pressure to the tissue or bony structure is non-existent. In case of coagulation and carbonization/vaporization the laser can be controlled nicely as it interacts first on the surface of the treatment area resulting in a low necrosis.

Laser radiation is not applied in contact to the tissue surface; CO<sub>2</sub> Laser radiation is applied only in non-contact with no force or pressure to the tissue.

The pain level of a surgery can also be reduced by using a laser or it can even be completely painless compared to alternative modalities.

By the use of the accessory micromanipulator it is possible to connect the C-Las to the operation microscope and perform treatments in areas which are only accessible by the use of the microscope.

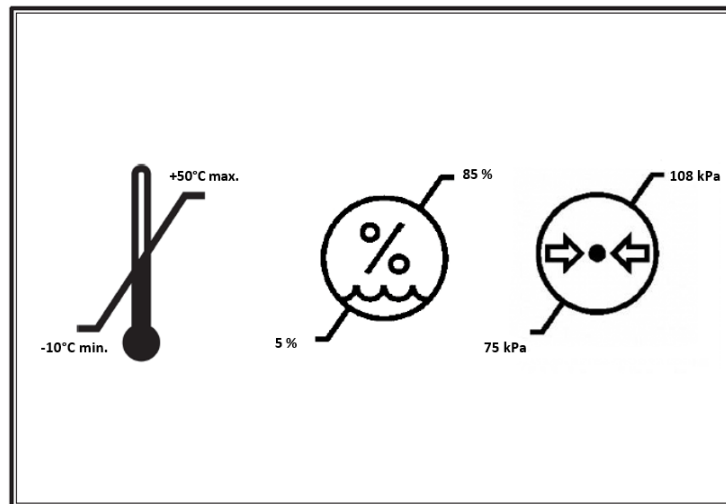
## **1.6 Theory and technical set-up**

RF energy acts as the excitation source and is supplied to the CO<sub>2</sub> gas to change the vibrational state of the molecule, from a lower to higher state i.e. the lasing medium is in an excited state. In the case of the CO<sub>2</sub> laser the change to a lower state of vibrational releases photons at 10.6µm. The period that the gas stays in this excited state is very short, however this can be influenced. By adding a cavity or optical resonator around the lasing medium, already existing photons can be used to further increase the supply of photons. Photons are absorbed by those atoms or molecules in an excited state, this then triggers the release of two photons, each of which have the same energy, travel in the same direction, and have the same phase - these are the unique properties of the laser. The cavity ensures that this happens many times over to increase the supply of photons and provides a steady state to give a constant optical output.

## 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  $-10^{\circ}\text{C}$  and  $50^{\circ}\text{C}$ . The air pressure during transport must be between 750 hPa and 1080 hPa. During storage, a temperature range of  $5^{\circ}\text{C}$  to  $40^{\circ}\text{C}$  must be maintained. The environment/air must be dry and clean. The relative humidity during transport and storage must be between 5% and 85% without condensation.

### **ATTENTION**

If the laser is transported or stored at a temperature below  $-10^{\circ}\text{C}$ , it can be damaged during start-up. Unpack the laser and leave it at least 8 hours at normal room temperature to allow the system to reach 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.

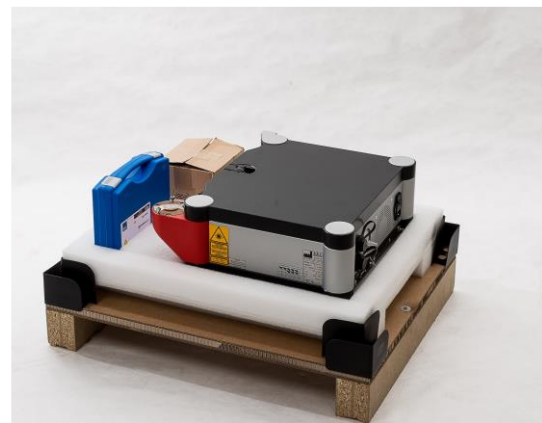
## 2.2 Return shipments

If you ship the device back to A.R.C. Laser GmbH, please use the carrying case for transportation and shipping.

The transport packaging is designed so that the unit fits exactly in the foam.



All accessories are stored in a suitable extra packaging inside the transport box.



If applicable, the C-PRO is placed on top of the foam. If all the foam parts are in the right place and the box is closed, the unit is ready for shipping.



The articulated arm must be carried in the ARC transport box. The dust protection caps must be used during transport at the socket and distal end.



The ARC transport box is secured with foam in the outer box.



## **3. Setup and installation**

### **3.1 Installation site**

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

The C-Las should be operated in an easily accessible place. The laser should not be operated near a heater as the air cooling works best when the ambient temperature does not exceed 28° C. Higher temperatures can cause the device to switch off due to prevention of 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 12 °C), the device cannot be started in order 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 wiring must be installed in such a way that there are no tripping hazards or other hazards.

The air humidity is monitored internally and must be below 75%.

### **3.2 Room requirements**

The C-Las is categorized as a class 4 laser. To provide the most possible safety, the following requirements must be met for any room a class 4 laser is operated in. (according to EN 60825-1)

#### **3.2.1 Marking of access points**

All entrances must be clearly marked to prevent unintentional or unauthorized entry, which can lead to hazards.

- Please attach the laser warning sign (triangle with laser symbol) as well as the wavelength marking at each access door.
- A warning lamp must be attached above each access door, which must always be turned on when the laser is in operation.
- Unintentional entry into the room without safety glasses shall be avoided.
- Please store the laser safety goggles at the entrance of the room and make sure they are readily accessible.

#### **3.2.2 Window shielding**

It must be ensured that no laser radiation can escape the room. In particular, windows need to be covered with suitable materials. For any questions or in case of any doubt, please contact your local A.R.C. Laser GmbH authorized dealer, or directly contact A.R.C. Laser GmbH at any time.



### 3.2.3 Reflective surfaces

To avoid any danger caused by reflected direct or scattered, reflecting surfaces must not be present in the room during operation.

Such surfaces may include:

- • mirrors
- • pictures behind glass
- • chrome surfaces
- • windows

Such surfaces should either be removed or covered with suitable matt-type material. In the area around the laser, use only matted, non-reflecting as well as non-flammable instruments and materials.

### 3.3 Electrical connection

The laser is operated by an external power supply. The power supply is approved by A.R.C. Laser GmbH especially for the C-Las; only this power supply is approved to be used. The power supply unit can be connected to 110V – 240V AC voltage (50Hz/60Hz).

#### ATTENTION

Different input voltages require different fuse values!

230 V 2x T 5A

115 V 2x T 10A

Do not use other than specified fuse value when operating the laser.

## 4. Safety information

### 4.1 General

The C-Las is a precise working instrument for medical applications. The system has been carefully developed and tested before shipping. In order to offer you and the operating personnel every possible protection, we recommend that you read this section of the operating manual carefully.

The C-Las is categorized as a class 4 laser according to EN 60601-2-22, EN 60825-1 respectively.

Class 4 in the standard describes high-energy lasers and therefore special measures must be taken prior to commissioning in order to ensure safe and trouble-free work with the device. In particular, it must be ensured that the eyes and skin of the operator, the patient and third parties are protected. Laser safety goggles are to be used for eye protection.

The following explanations are not exhaustive. All users of laser devices should enclose the applicable legal regulations and provisions with the device and inform the personnel accordingly. We refer here in particular to the publication "Operation of laser equipment and accident prevention regulations for laser radiation", which is also available from us. The Medical Device Operator Ordinance (MPBetreibV) also applies.

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

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

Regarding supplied accessories such as handpieces or applicators, the safety, operating and maintenance instructions in the relevant manuals must be respected.

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

The warranty of 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 all persons in the room wear laser safety glasses.

When using the laser, only laser safety glasses that are designed for the respective wavelength and on which the CE mark and the appropriate protection class are noted, may be used.

The protection level (LB) for laser safety glasses is determined by the standard EN 207 (personal eye protection). The optical density (OD) describes the attenuation of the radiation through the glasses.

There are different types of laser safety glasses 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 glasses. Therefore, we encourage you to wear laser safety glasses which also guarantee full protection to the side parts.

A.R.C. Laser GmbH offers laser safety glasses for the use of the C-Las. See chapter 5.5.3 for detailed information.

### ATTENTION

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

## 4.3 Electrical protection

Never remove any housing parts. Any service to the device or its accessories may only be carried out by authorized personnel of A.R.C. Laser GmbH.

The room in which the laser is operated should be kept dry. If cleaning is necessary, please make sure the floor is dry before using the laser.

### ATTENTION

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

Never work with the device if you notice any visible damage on the power plug, or if you notice, that the wires have become 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.

### ATTENTION

Laser radiation must not be applied if the oxygen concentration of the treatment environment is greater than 30% (e.g. during ventilation). There is a risk of fire! If an intubation tube is used for treatment in the pharynx/larynx and oral cavity, a laser-safe intubation tube is required. There is danger to life here!

## 4.5 Protection against undesired radiation

The foot switch should never be outside the area of the attending doctor. It is forbidden for anyone other than the attending doctor to trigger the foot switch.

Especially in operating theatres where there are multiple foot switches, it is important to ensure that the laser foot switch is close to the laser device.

## 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 thus identifies the danger area within which health damage to the eye is to be feared if the laser beam is directly and unprotected.

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:

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

Calculation of the maximum permissible irradiation (MPE) with an exposure time of 100s.

The result is:

### HS 11023

Wavelength  $\lambda$ : 10600 nm  
NOHD: 0,65 m  
Beam divergence  $\alpha_{(full\ angle)}$ : 18,9°  
Permitted Maximum Radiation: 1000 Wm<sup>-2</sup>

### HS11024

Wavelength  $\lambda$ : 10600 nm  
NOHD: 1,32 m  
Beam divergence  $\alpha_{(full\ angle)}$ : 9,3°  
Permitted Maximum Radiation: 1000 Wm<sup>-2</sup>

### Micromanipulator

Wavelength  $\lambda$ : 10600 nm  
NOHD: 4,4 m  
Beam divergence  $\alpha_{(full\ angle)}$ : 2,8°  
Permitted Maximum Radiation: 1000 Wm<sup>-2</sup>

## 4.7 CE-Regulations

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

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

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

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

## 4.8 RoHS3-Regulations

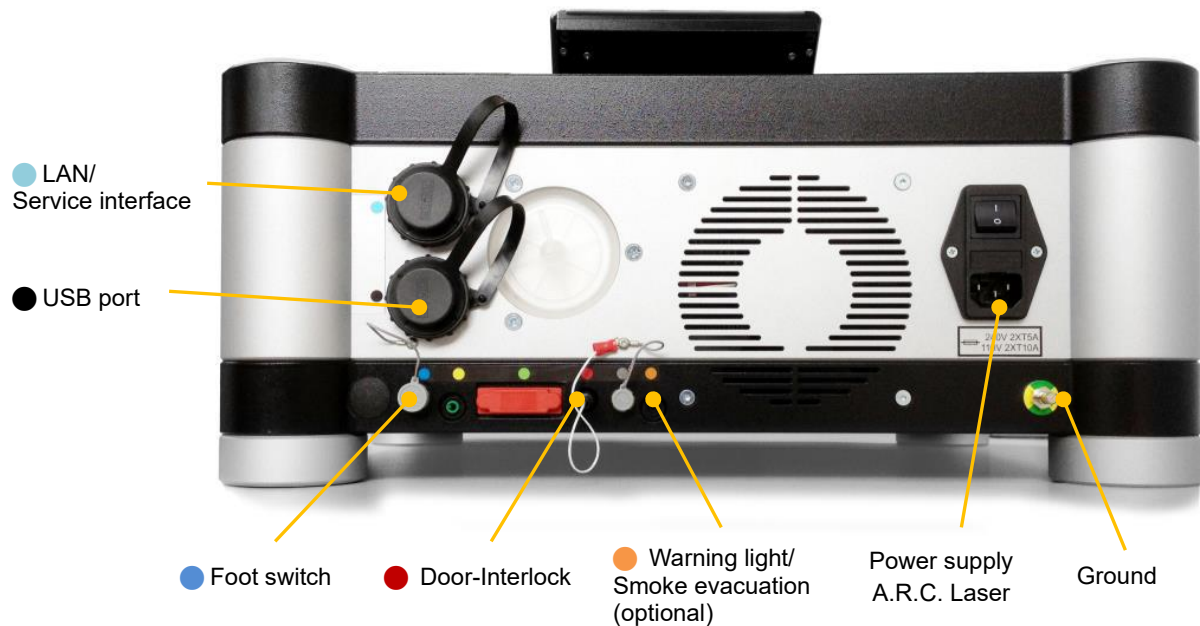
Our company operates worldwide and regards the protection of the environment and natural resources as an entrepreneurial obligation. Based on individual tests, A.R.C. Laser GmbH confirms that, to the best of our knowledge, our products do not contain any sub-stances in concentrations whose placing on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

## 4.9 Protective housing

The C-LAS has a protective housing which prevents radiation of the laser from penetrating to the outside and protects users from touching live electrical 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 Connector and plugs

Following connector sockets are located at the rear panel:



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

Port	Description	Note	Colour
Foot switch	Connector for the A.R.C. foot switch with cable	Use A.R.C. recommended and approved accessories only	Blue
Door interlock	Connector for the Door-Interlock plug	The Door-Interlock switch must be designed for at least 12V and 2mA.	Red
USB	USB connection for A.R.C. USB	Used only by service staff. Do not use any other USB-flash drive than supplied by A.R.C.	Black
Warning Light/Smoke Evacuation (optional)	Connector for the smoke evacuation.	The smoke evacuation is optional.	Orange
Power supply	Connection for medical approved power supply, A.R.C. Laser	Use A.R.C. supplied and approved accessories only	-

### ATTENTION

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

## **4.11 External interlock switch**

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

When installing a door interlock switch, note the following:

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

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

## **4.12 Safety shutter and aiming beam**

The C-Las has an internal safety shutter which only opens up when the laser is in READY mode and the footswitch is activated. This ensures that no radiation can leave the device accidentally.

As soon as the laser is set to READY mode, the aiming beam will appear. The aiming beam is a low-level laser.

## **4.13 Manual reset**

When an error occurs, the device changes into the STANDBY mode. In that case, you should switch the laser off and on by using the ON/OFF button on the left. The restart should fix the error due to automatic recalibration. Please refer to chapter 8.5 to identify the error messages.

If the error still occurs, this can only be resolved by qualified personnel. Please contact your local A.R.C. Laser GmbH authorized dealer.

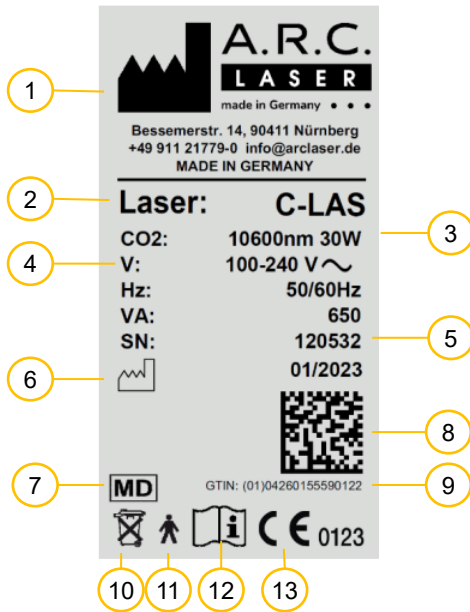
## **4.14 Reset due to power failure**

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

## 4.15 Stickers and labels

The C-LAS is provided with various warning labels in accordance with European and worldwide guidelines. This is to prevent the laser user from being exposed to laser radiation due to carelessness.

### 4.15.1 Type Plate



1. Manufacturer
2. Laser name
3. Wavelength and power
4. Electric connection
5. Serial number (SN)
6. Manufacturing date
7. Medical device
8. UDI (Unique Device Identification = GTIN + SN + production date)
9. Global Trade Item Number (GTIN)
10. Do not dispose in household waste
11. Applied part type B
12. See instructions for use
13. CE-Mark

### 4.15.2 Fuse label



Only use the described fuses

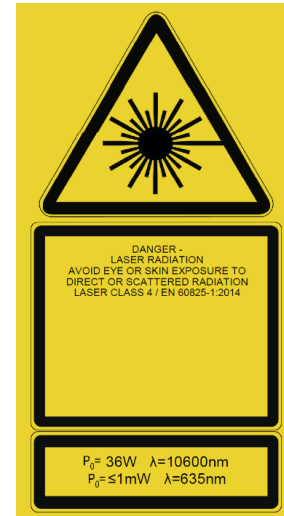
### 4.15.3 Modification label

MODIFICATION					
1	2	3	4	5	6
7	8	9	10	11	12
13	14	15	16	17	18
19	20	21	22	23	24

Shows the current device status based on the marked modification numbers



#### 4.15.4 Warning label laser



The warning labels provide information about the type and intensity of the laser system.

#### 4.15.5 Laser stop



This symbol indicates where the laser STOP button is located. See chapter 6.7 for further information.

#### 4.15.6 Follow instructions for use



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

## 4.16 Operating conditions

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

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

The following environmental conditions must be met:

- Ambient temperature: 12 bis 28°C
- Relative humidity: < 75%, non condensating

## 4.17 Electromagnetic Compatibility

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

### ATTENTION

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 instructions**

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

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

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

### **5.2 Laser safety training**

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

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

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

### **5.3 Medical introduction**

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 C-Las consists of the main body (1), the touchscreen (2) which is mounted on top of it, and the articulated arm (3).

### 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)	KB13003
	Type G (USA)	KB13004
	Type B cable	KB13005
Door interlock	Straight door interlock	KB02030
Footswitch	Surgery footswitch	BG04008
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 articulated arm	Transport box articulated arm	VP02003
Carton for VP02003	Carton for VP02003	VP02004
Shipment box C-LAS	Shipment box C-LAS	VP01092

Other equipment:

Part	Description	Article number
Dust protection cover	Dust protection cover	ZU01066
Display cover	Display cover	ME02040
Touch stick	Touch stick, disinfectable	ME03853
Lense cover	Dust protection lense cover	ME02818

### 5.5.3 Optional equipment

**Laser safety goggles** are not part of the basic equipment and are listed separately on the purchase order. We recommend ordering at least 3 laser safety glasses per laser (surgeon, nurse, patient, etc.).

An optional **smoke plume evacuation** system (e.g. ViroVac–Smoke Plume Evacuation System Manufacturer: CONMED) that can be connected to the laser (via KB01329) is also offered as additional equipment.

To guide the laser radiation to the application site, the **micromanipulator** C-Pro can be purchased and connected to the articulated arm.

Part	Description	Article number
Laser safety glasses*	Laser safety glasses 10600 nm	AS01023
C-Pro**	Micromanipulator	ZU12000

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

\*\* For the handling of the C-Pro please consult the quick guide which is attached to the device.

#### 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.

## 6. Operation

This part of the manual only describes the technical application of the device, without going into the medical application. Settings and adjustments should only be made in accordance with the operating instructions. Changes or settings that are not described in this manual can lead to malfunctions.

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

The front of the device consists of the following elements and buttons:



### Touch screen

The touch screen is used to change all necessary parameters for the treatment such as: output power, pulse duration and pulse pause duration. Furthermore, the system settings can be made via touchscreen. For more information see chapter 6.2.

### System status-LED

The System-Status-LED indicates the state of the device. If it is blinking green the device is booting. In case the LED is continuously green the booting process is finished, and the device is ready for use. If an error occurs the System-Status-LED flashes red.

### Laser stop switch

The Laser Stop switch interrupts the READY mode. If the Laser-Stop is activated the device cannot be used and a warning message appears. The laser is immediately deactivated and can only be activated if the laser stop switch is set back.

### ATTENTION

Use of the controls or adjustments other than those specified herein may result in hazardous radiation exposure.

## 6.1 Preparation

A power cable is included with shipment of the C-LAS device, which needs to be connected to the port at the rear panel. Input voltage ranges between 110 V and 240 V. Only use the power cable distributed by A.R.C. Laser GmbH.

Please refer to the following steps when preparing the device to operation in order to avoid unnecessary troubleshooting or even possible malfunctions.

- Is the laser connected to the mains?  
Connect the mains only if the device is switched off!
- Has the door interlock connector for the external interlock been plugged in?  
– or, if applicable: has the door interlock contact been connected to the laser?
- Has the footswitch been plugged in?
- Are enough protective goggles ready to be used?

### ATTENTION

All warning lights outside the treatment rooms must be switched on as soon as the laser starts to operate. The doors must be marked accordingly, visible from outside (with the warning signs).

Ensure a dry and solid surface with a stable stand for the laser system. We recommend placing the C-LAS on its cart.

## 6.2 Starting the device



To start the device, switch the On/Off-switch on the rear panel into position "I". The System Status-LED will begin to flash green. After about 30 seconds the startup screen will appear. Then the green System Status-LED will be lit permanently.



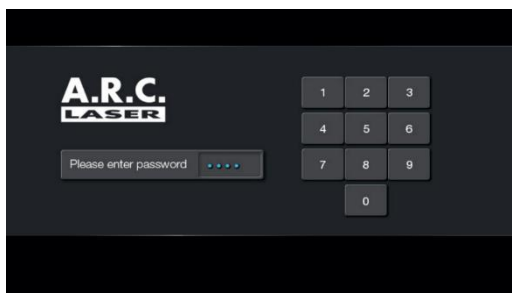
The C-LAS laser executes its system check automatically upon startup.

During the starting routine please do not activate the laser stop, remove the door interlock plug or press the foot switch. Otherwise, the device must be restarted.

### ATTENTION

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

### 6.2.1 Entering the password



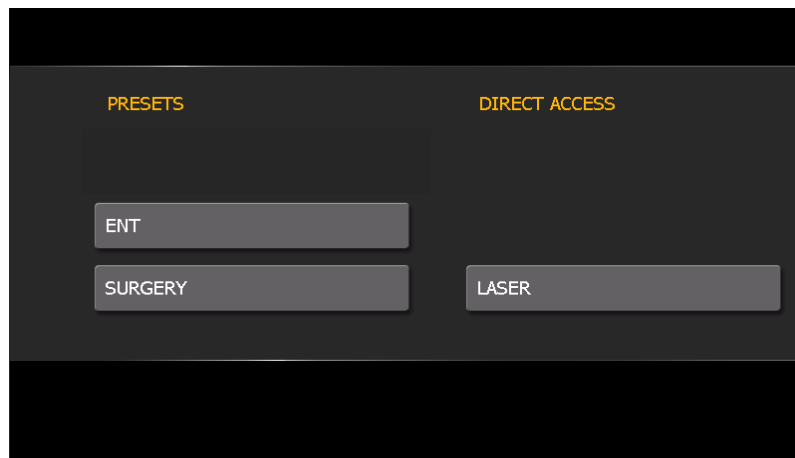
Once the system check has been completed, the locking screen will appear. To continue, the password has to be entered. In the factory setting the password is "0000". See chapter 6.3.3 to modify the password.

Since this password protects against unauthorized operation of the laser, it should be changed immediately.



## 6.2.2 Home screen

In the Home Screen the user can choose between manual operation and preset laser settings for different application fields.



### Presets:

Press the appropriate field to work with the predefined values for the specific field. All values are set on experiences of physicians working with A.R.C. lasers. After choosing your desired setting, you will be led to the profile management screen.

### Direct access:

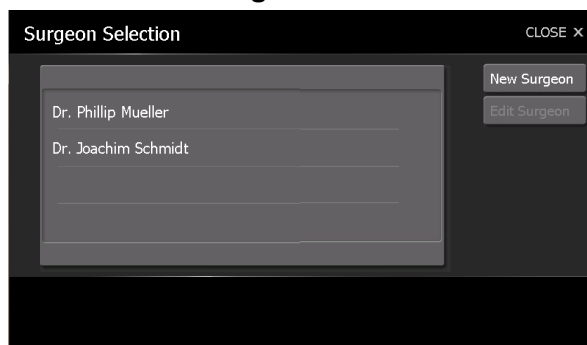
By pressing "LASER", the device will switch to the main operating screen. All laser parameters can be adjusted individually.

### ATTENTION

The pre-programmed laser parameters for the single applications have to be understood as mere recommendations. This does not exempt the surgeon from checking the values according to his knowledge and the desired interaction with the tissue. If necessary, the preset values must be adjusted.

## 6.2.3 Profile management

### 6.2.3.1 Surgeon Selection





After choosing the desired preset by clicking, the Surgeon Selection screen will appear. The appropriate surgeon can be chosen by touching the name. Then the main operation screen will be displayed. Every surgeon can adjust the settings according to the preferences and save those settings in his/her own user profile.

### 6.2.3.2 Edit Surgeon Selection

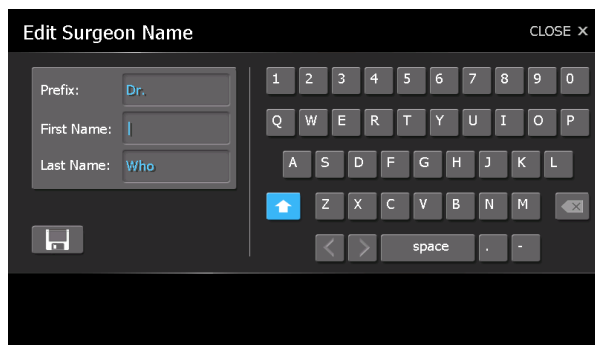


By pressing “Edit Surgeon” the device will lead to the “Edit Surgeon Selection”-screen where saved user profiles can be edited.


 Press the pen icon to edit the surgeon profile.

 Press the bin icon to delete the surgeon profile.

After pressing the pen icon, the Editing screen will be displayed:



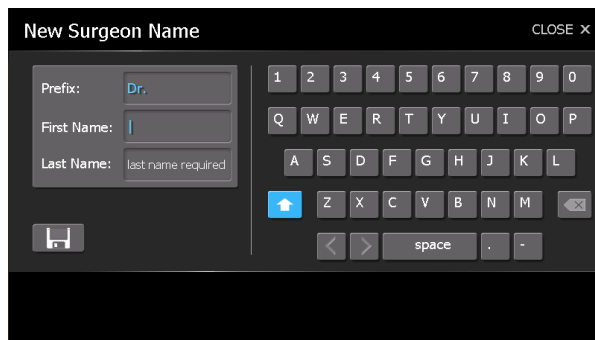
Make the desired changes to prefix, first and last name.

 Save your updated surgeon profile by pressing the save icon.


### 6.2.3.3 Add New surgeon



To create a new surgeon profile, select “New Surgeon”. The device will display a screen to enter the surgeon’s information.



Enter prefix, first and last name of the surgeon.

 Save your new surgeon profile by pressing the save icon.

## 6.2.4 Preset management

### 6.2.4.1 Preset Selection




After selecting the surgeon profile, the preset selection screen will appear.


Laser settings for different applications can be saved by the surgeon. When selecting a preset, the device will lead to the main operating screen with the stored laser settings.

### 6.2.4.2 Edit Preset

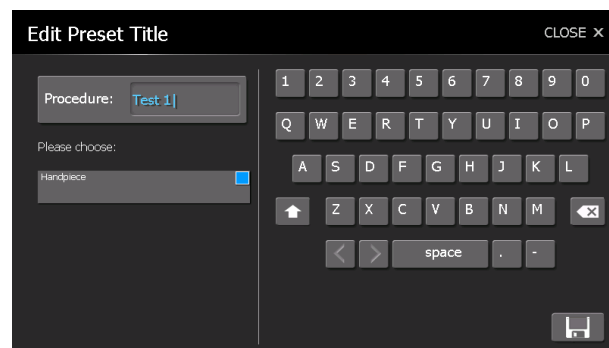


By pressing “Edit Preset” the device will lead to the “Edit Preset Selection”-screen.


 Press the pen icon to edit the preset.

 Press the bin icon to delete the preset.

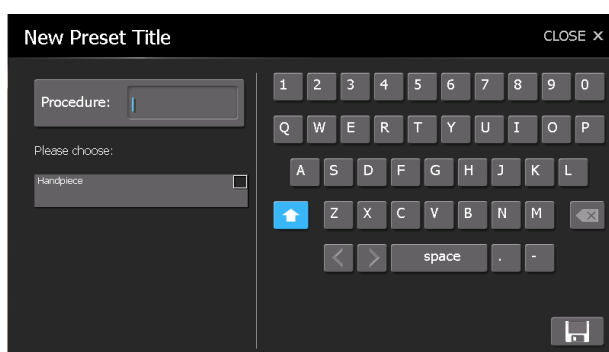
After pressing the pen icon the Editing screen will be displayed:



Make the desired changes to the procedure title and applicator checkbox.


 Save your updated preset by pressing the save icon.

### 6.2.4.3 New Preset



By pressing “New Preset” the device will lead to the “New Preset Title”-screen.

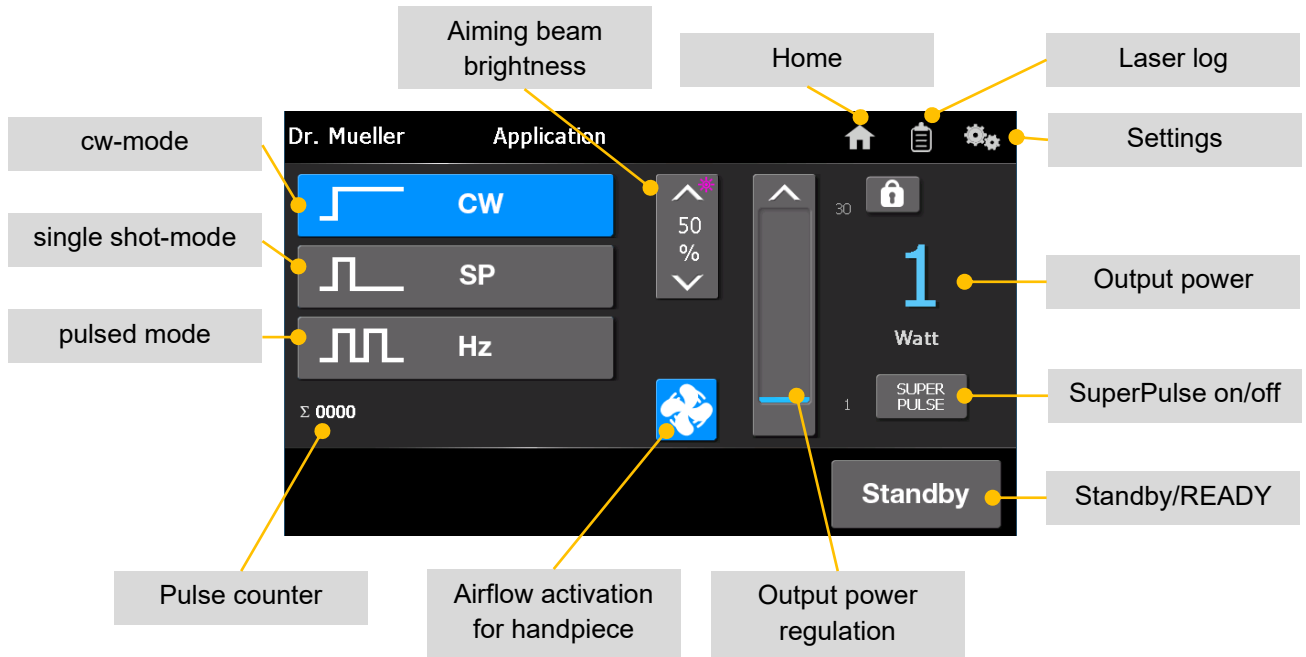
Enter the procedure title and select the applicator checkbox if the treatment should be executed with an applicator.

 Save your new preset by pressing the save icon.

## 6.3 Settings

### 6.3.1 Main operating menu

After selecting a preset or using direct laser access the following screen will appear:



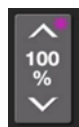
#### 6.3.1.1 Standby/READY-button



After starting the laser, the C-LAS is in standby mode. By pressing the button, the device changes into READY mode. The transition from STANDBY to READY takes a few seconds, which is accompanied by an acoustic signal and a blinking attention symbol. As soon as the C-LAS is in READY mode, if laser radiation is emitted by using the foot switch, the button will turn into a triangle with an exclamation mark.

By pressing the READY button again, the READY mode will be left, and the device returns to STANDBY.

#### 6.3.1.2 Aiming beam brightness



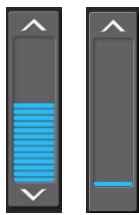
To regulate the aiming beam brightness, press the corresponding arrow key. The aiming beam brightness can be changed in steps of 10 %.

By pressing the number of the current setting (middle of the field) the aiming beam can be activated even when the laser is not in READY mode. This can be used to align the microscope.

#### 6.3.1.3 Airflow activation

The C-Las has an integrated pump which compresses air. This can be used to rinse the handpiece in use. When the micromanipulator is in use, this procedure is not needed and can be deactivated.

#### 6.3.1.4 Output power



The currently set output power is displayed on the right side of the screen. The maximum output power of the C-Las is 30 Watts in cw-mode respectively 10 Watts when SuperPulse mode is activated.

To set the desired output power, press the arrow keys or directly tap on the slide bar and swipe up or down.

The shown parameter for the power equals the power output at the distal end of the arm with a tolerance of  $\pm 20\%$ .

#### 6.3.1.5 Laser modes

To emit laser radiation, the C-Las must be in READY mode.

The C-Las can be used in three different laser modes:

- **Continuous wave (cw)**

Output power can be set.

The laser emits the set output power continuously, as long as the footswitch is pressed.

In addition to the standard cw-mode, SuperPulse mode can be activated.

- **Single pulse (SP)**



Pulse duration and output power can be set.

When pressing the footswitch, a single shot of laser radiation is released. To release another shot, the footswitch must be released and pressed again.

- **Pulsed (Hz)**

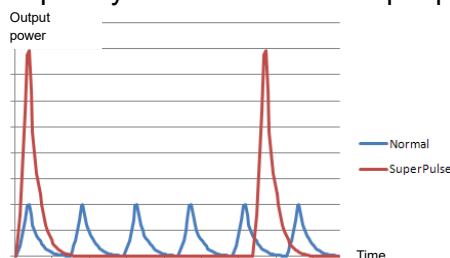


Repetition frequency and output power can be set.

The laser emits a series of laser pulses with equal pulse duration and pulse pause duration. The frequency of these series can be set in advance. The displayed output power equals the emitted power during the laser pulse.

#### 6.3.1.6 SuperPulse

When laser emission is generated in cw mode, the power oscillates with a very high frequency. This makes the output power appears constant during the treatment.



In addition to this standard cw mode, the SuperPulse mode combines several of the oscillation pulses into a super pulse. Those super pulses have a higher peak power than the standard ones (up to 80 W), due to the longer pause, the average power remains the same.

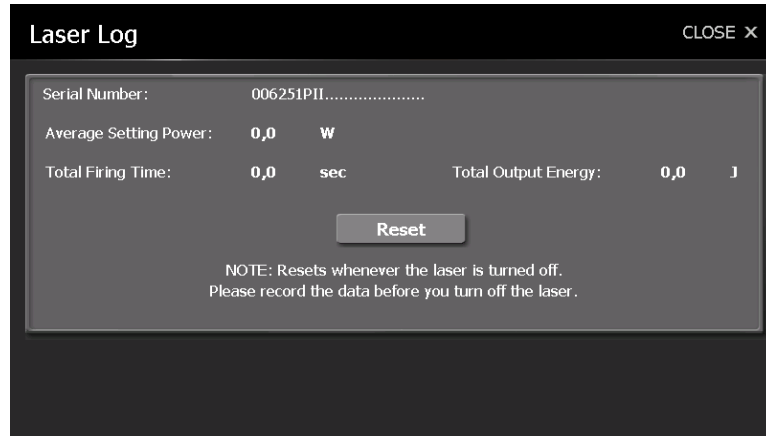
Some users prefer this type as it allows to cut a wide variety of tissue types with less carbonization.

The button "SuperPulse" switches between normal output and super pulse. If super pulse is selected, the button will be blue.

**NOTE:** If you are not familiar with the super pulse, try this mode on a tongue depressor or something alike before making any application on a patient.

### 6.3.2 Laser Log

The laser Log contains information about the emitted laser radiation. It resets every time the device is switched off. Press the X on the upper right corner to exit the Laser Log.



#### 6.3.2.1 Average Setting Power

This value is the adjustment of the average power while the laser is being triggered. For example, if the laser was fired for 10 seconds at 10 watts and 10 seconds at 5 watts, the setting of the average power is given as 7.5 watts.

#### 6.3.2.2 Total Output Energy

The total output energy is the set power multiplied by the time the laser is triggered.

#### 6.3.2.3 Total Firing Time

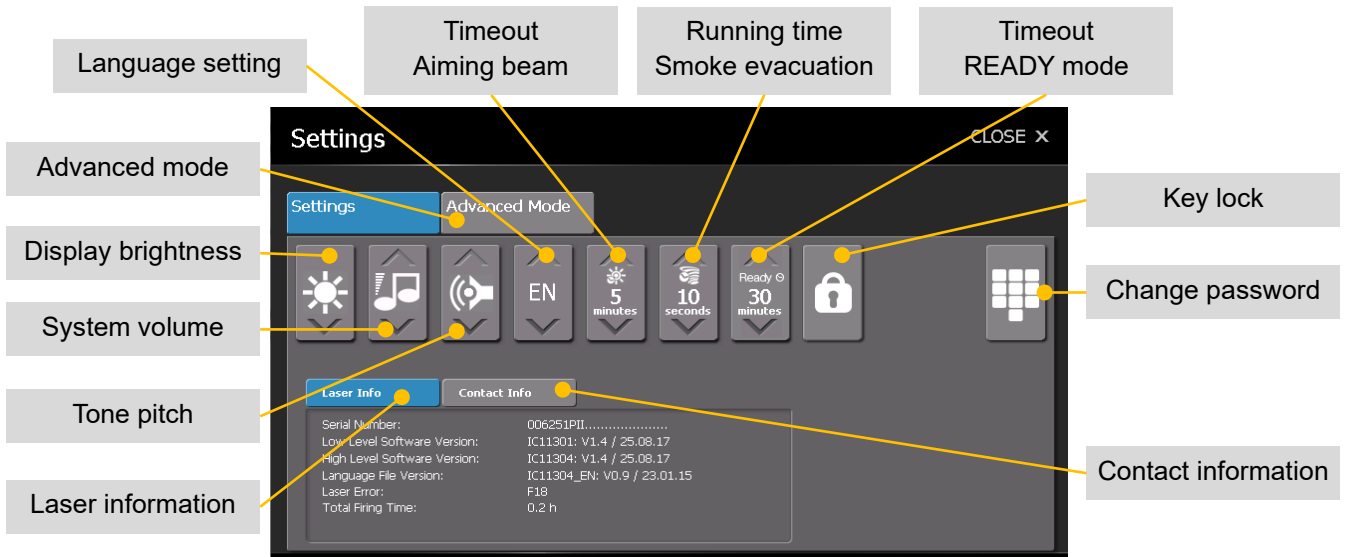
The total firing time is the time the laser has been fired since it was last turned on. If the laser is fired in repeat (pulsed) mode, the laser time is 50% of the time, during which the foot switch is pressed. If the laser is fired in the single pulse mode, the laser time is only the time during which the laser energy is emitted from the laser, but not the time during which the pedal is pressed.

#### 6.3.2.4 Reset

Press reset to restart counting and to reset the values.

### 6.3.3 Settings

To access the settings, press the gearwheel-symbol in the main operation mask.



#### Display Brightness



Setting the value of the brightness for the display from 5-100% in 5%-steps.

#### Tone volume



Setting the volume of the acoustic warning signal of the C-Las from 10-100% in 10%-steps.

The values can be changed by using the plus and minus-button of the touchscreen.

#### Tone pitch



Setting the tone pitch of the acoustic warning tone of the C-Las from 0-100 where 10 is the highest and 100 the lowest tone pitch.

#### Language



Choice between the different languages Spanish, English, German, French and Italian.

#### Timeout Aiming beam



This button sets the duration after which the aiming beam shuts down when activated in standby mode.

#### Running time smoke evacuation



When the smoke evacuation is activated, it will proceed to run for a short amount of time after the emission of the laser radiation is stopped, to get rid of the remaining smoke in the field of view. The time can be set to 5, 10, 20, 30, 40, 50 or 60 seconds.

#### Timeout READY-mode



When the laser is set to READY-mode but is not in use, it will switch back to standby mode after the set time period. This ensured that the laser is not triggered by accident.

### Key lock



When the key lock is activated, the password selection screen will be displayed. This prevents usage by third parties. To continue the work with the C-Las, enter the user password.

### Change password



When pressing this button, the password required for operating the device can be changed by the user. After pressing the button, the password can be changed in the lower area of the touch screen. The password consists of four digits (factory set is "0000").



The routine to change the password will guide you through the menu:

- (1) Enter old password
- (2) New password: Enter a new four-digit password
- (3) Confirm password: Repeat the new password

#### 6.3.3.1 Laser information

The following information appears in the laser information window:

- Laser serial number
- Software / language file revision numbers
- Latest error occurred
- Total operating time since commissioning

#### 6.3.3.2 Contact Information

The following information is available for you:

- Contact persons
- Contact – Technical Support
- Next service appointment

#### 6.3.3.3 Advanced Mode

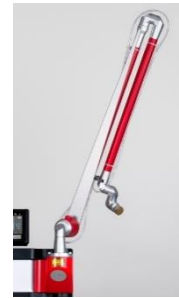
The advanced mode can only be activated by the service personnel with the corresponding password. Further system settings can be changed here.



## 6.4 Attaching the Articulated Arm

The packaging of the CO2 laser ensures that the laser cannot slip during transport. Normally, the articulated arm can be mounted without re-adjustment. During the first installation, the service technician will attach the articulated arm. When there are issues concerning the articulated arm, please contact your local distributor or A.R.C. laser.

For the handling of the arm please consult the quick guide which is attached to the device and is also included in the packaging of the arm.



## 6.5 Releasing the laser beam

The device will only emit laser radiation when it is set to READY mode. To trigger the laser radiation, press the foot switch.



When a laser shot is fired, a simultaneous warning signal sounds and a triangle with an exclamation mark is shown within the READY/Standby-Button on the screen.

## 6.6 Treatment

Select the necessary laser settings and position the patient. Make sure that all persons present wear laser safety goggles.

Press the READY/Standby button. It starts blinking and lights up yellow afterward. The device is now in READY mode, the aiming beam becomes visible.

During the treatment, the C-Las will count the emitted laser pulses/sum up the emitted energy. This value is displayed in the lower area of the screen.

After the treatment, press the READY/Standby button to set the device back to standby mode. No more laser radiation can be emitted. Document the total applied energy or display the laser log.

Make sure that only one person is operating the C-Las at the same time.

### ATTENTION

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

## 6.7 Laser Stop

The laser stop button is located on the left side of the laser front.

If the Laser-Stop is pressed while starting the device, the screen will remain black, no LED will light up.

**Solution:** Pull the Laser-Stop out and the device can be started.

If the Laser-Stop is pressed while working with the C-LAS, the device is completely shut down. The laser is deactivated immediately.

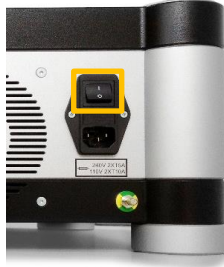
**Solution:** Pull out the Laser-Stop. The power supply is released and the device restarts if the on/off switch is turned on. If the on/off switch is turned off, you can switch on the laser as usual.



**ATTENTION**


























The Laser-Stop should only be used in emergencies.

## 6.8 Switch off your C-Las



The C-LAS can be turned off by pressing the on-/off-switch at the rear panel of the device.

## 6.9 Symbols

Symbol	Meaning	Symbol	Meaning
	Display brightness (5-100%)		Smoke evacuation, follow-up time
	Tone volume (5-100%)		Off, Standby
	Tone frequency		Key Lock
	Language		Input screen to access password
	OFF aiming beam		
	Settings, submenu		Next, change menu
	Home, main screen		Change to top
	Save		Call log file
	Continuous wave – mode (cw)		Laser in Standby Mode
	Single pulse - mode (SP)		Laser in Ready Mode
	Pulse mode (Hz)		Laser firing
	Edit Procedure / Name		Attention
	Delete		Brightness of aiming beam plus or minus

## 7. Technical data

### 7.1 General laser data

Laser type:	CO2 laser, sealed-in ceramic tube, RF excited
Cooling:	Air internal
Weight:	32 kg
Dimensions:	H 49 cm/ W 48 cm/ D 20 cm
Controlling:	Touch screen display
Power transmission:	Articulated arm
Laser output:	

Wavelength	Energy	Tolerance
10.6 $\mu\text{m}$	30 Watts max  Settings: 1 W to 30 W	$\pm 20\%$ of the shown energy  according to IEC 60601-2-22

#### Aiming beam:

Laser type:	diode laser
Wavelength:	638 nm nm red
Max. output power:	< 5 mW,
Brightness:	variable
Mode:	cw

### 7.2 Electrical connection data

Power supply connection values      100V – 240V, 50Hz/60Hz, 10 A - 5 A

### 7.3 Classifications

Laser class Laser Beam (Classification EN 60825-1)	4
Laser class Aiming Beam (Classification EN 60825-1)	2
Electrical protection class (Classification IEC 60601-1)	II
Classification according to MDD/MDR	IIb, Rule 9
Software safety classification	Class C
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 opening the protective housing must be carried out by trained service personnel. That includes cleaning the optics within the laser.

### 8.2 Safety Check (STK)

Once within 24 months, the laser must be subjected to a safety check (STK) by trained personnel. The execution of the STK and any faults are to be noted in the device book.

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

#### Scope of Safety Check

##### Visual Check

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

##### Functionality Check

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

##### Check the necessary monitoring/safety display and signaling unit

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

##### Electrical Safety Check

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

##### Output power measurements

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

**ATTENTION**

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

### 8.3 Cleaning and disinfection by the user

The following maintenance instructions can be carried out by the user. These serve to make your work easier.

**Before cleaning / disinfection:**

- Switch off the device and disconnected it from the mains
- Disconnect the applicator

**Cleaning and disinfection:**

Always use a damp, but never wet, soft cloth for cleaning and disinfecting.

**ATTENTION**

During cleaning, the device must always be switched off. Water or disinfectant should never be applied directly to the surface of the device. Make sure to dabble the cloth to then clean or disinfect the device.

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)

For wipe disinfection, the manufacturers instruction for the disinfectant must be respected. Following possible disinfectants that meet the above-mentioned requirements are listed:

<b>Manufacturer</b>	<b>Possible disinfectants*</b>
BODE Chemie GmbH	Mikrobac forte, Bacillol 30 Foam
ANTISEPTICA	Arcylan, Biguacid Liquid
Schülke & Mayr GmbH	Acryl-des, antifect AF (N)
Dr. Schuhmacher GmbH	CLEANISEPT; Descosept AF
Ecolab	Incidin Foam, Incidin Pro
Dr. Weigert	Neoform MED AF, neoform MED rapid

\*This list is not exhaustive.

## 8.4 Accessories cleaning

### 8.4.1 Laser safety goggles

Please follow the cleaning instructions provided with the laser safety goggles in any case. In general, you should never use chemicals for cleaning that can damage the coating of the glasses. Always use soft cloths that do not leave scratches on the surface.

### 8.4.2 Applicators

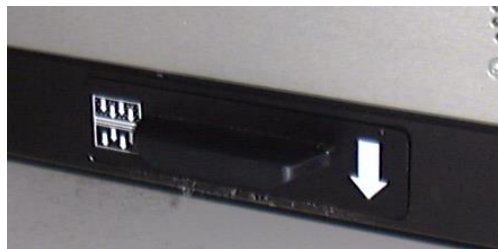
To ensure proper cleaning of the applicators, please consult the respective manual.

### 8.4.3 Foot switch

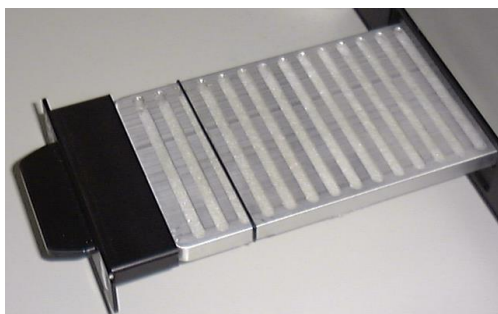
The general cleaning instructions (see above) must be respected in any case. When cleaning the foot switch, prevent the penetration of water or cleaning agents. Never immerse the foot switch in water or cleaning agents. This could lead to a short circuit.

### 8.4.4 Replacing the air filter

The air filter should be replaced every 3 months. For pulling it out, use the handle on the left side of the device.



Remove the filter holder completely from the device. The filter can be easily pulled out. The filter itself is clamped between the holder and has to be removed for cleaning.



Replace the filter with a new one. You can order the filter from A.R.C. Laser. It is important that a filter is always installed in the device.

After replacing the filter and correct inserting the filter cartridge, the laser can be switched on again.

#### ATTENTION

Never work with the laser without a filter.

Even in case of a short operation time, the laser may clog without filter and consequently break down. This would void the warranty.

## 8.5 Error detection

The C-LAS was designed and developed as a modular system. In addition, all components were subjected to a rough shaking and temperature test. In the event of a fault, you can use these instructions to isolate the problem and, in some cases, even rectify it yourself. Otherwise, please contact the service department of A.R.C. Laser GmbH or the local representative.

### 8.5.1 Error routine



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

#### Common errors might be:

- The red Laser-Stop needs to be pulled out.
- Interlock: The door interlock connector should be fully inserted into the device or the door contact switch should be closed.

### 8.5.2 System check

A system self-check will run when turning on the device, intended to check all important functions. If a failure occurs, you will be informed immediately, and the error detail shows up on the screen.

In general, it is distinguished between two types of errors:

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

Such errors may be:

- Laser-Stop-Switch is pressed down
- Door-Interlock connector missing, disconnected or defective
- Footswitch pressed down or defective when turning on device

**Static errors** are errors which require contacting A.R.C. Laser service department or the local representative. For these usually an error message will appear on the display and can assist to identify the problem when calling for service.



### 8.5.3 Troubleshooting

The following errors cannot be identified by the system self-check and have to be checked manually:






Problem	Potential Error	Troubleshooting
Laser does not start	Laser-Stop is pressed	Pull Laser-Stop out
	No power supply is connected	Check if the power supply is connected.
	On/Off switch is in position "O"	Switch the On/Off in position "I"
	Fuses are blown	Contact your local service representative
No aiming beam visible	Laser is in Standby-Mode	Aiming beam is only visible if the Laser is in READY mode and the yellow READY-LED is lit. Switch Laser in READY mode by pressing the Standby-Button.
	Aiming beam brightness is set to minimum	Increase aiming beam brightness (s. chapter 6.3.3)
	Aiming beam diode defective	Contact your A.R.C. Laser representative
No laser beam but aiming beam is visible	Footswitch not plugged in	Check if footswitch is correctly plugged in
	Footswitch defective	Contact your A.R.C. Laser representative

### 8.5.4 Error codes


Error message		Short Description	Solution
f00	Safety CPU	Failure in measuring the base frequency of 25KHz for the CPLD chip.	Restart device; Call customer service.
f01	Output Power -20%	Failure in comparison of the power during laser activation.	Restart device; Call customer service.
f02	Output Power +20%	Failure in comparison of the power during laser activation.	Restart device; Call customer service.
f03	Standby Power Too High	In Stand-by the TEC-element voltage is monitored to assure that there is no laser emission.	Restart device; Call customer service.
f04	Safety Shutter Overtime	Shutter position is monitored. If foot switch is pressed but shutter doesn't open, F04 is detected.	Restart device; Call customer service.
f05	Safety Shutter Open and Not Ready	Monitoring of the safety shutter with two opto-couplers. If Shutter is open in standby mode, F05 is displayed.	Restart device; Call customer service.
f06	Footswitch short circuit contact 1	Checking foot switch after system start. Contact 1 is short circuited.	Change foot switch.
f07	Footswitch short circuit contact 2	Checking foot switch after system start. Contact 2 is short circuited.	Change foot switch.
f11	Laser Light Test Error	Failed verification of the laser light during system test by measuring the voltage of a TEC element.	Restart device; when error persists call customer service.
f20	Watchdog error	Deetected failure state while monitoring the watch dog feature.	Restart device; when error persists call customer service.
f23	+12 V (+-0,5V) Test Error	Check after system start (during System-Check) if comparison of voltage is in permissible range on the PL11113	Restart device; when error persists call customer service.
f24	+5v Test Error	Check after system start (during System-Check) if comparison of voltage is in permissible range ( $\pm 0,15$ V)	Restart device; when error persists call customer service.
f44	Power Supply Error	Timeout error, if voltage-OK-signal is not set after 2 minutes during system check.	Restart device; when error persists call customer service.
f47	Laser Checksum Error	Failure of validation of the power data (checksum) during system-check: comparison with saved checksum.	Restart device; when error persists call customer service.
f49	IC-Chip Combination Error	Check after system start (during System-Check); Comparison if the software characteristic data are permissible (correct chip combination).	Call customer service.

f50	<i>I<sup>2</sup>C-Bus defective</i>	<i>Check of the I<sup>2</sup>C-Bus during System-Check: Failure in writing and reading of data into EEPROM.</i>	<i>Call customer service.</i>
f53	<i>Current sensor 1/2 Error</i>	<i>Error in redundant current monitoring: One current sensor signal is more than 10% higher than the other.</i>	<i>Call customer service.</i>
f57	<i>Internal storage full</i>	<i>Storage of embedded system is full, device switches off during System-Check and error message F57 appears on the display.</i>	<i>Call customer service.</i>


### 8.5.5 Error messages

Symbol	Meaning	Measure
	Door interlock not connected	Connect the interlock plug included with the system / close the door
	Temperature too low	The environment is too cold for operating the laser
	Operating temperature too high	Please wait until laser cools down to reach working temperature
	Air humidity too high	The laser should not be operated in this environment
	Ventilation fan blocked	Contact your A.R.C. Laser representative

### 8.5.6 Warning messages

Symbol	Meaning	Measure
	Foot switch pressed	Release the foot switch

### 8.5.7 Status messages

Symbol	Meaning
	Please wait

## 8.6 Disposal

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

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



## **9. Customer service**

### **9.1 Warranty 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 consignments, packaging**

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

### **9.3 Sales and service information**

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

**A.R.C. LASER GmbH**  
Bessemersstr. 14  
D-90411 Nürnberg  
Tel: +49 911 21779-0  
Fax: +49 911 21779-99  
E-Mail: [info@arclaser.de](mailto:info@arclaser.de)  
[www.arclaser.com](http://www.arclaser.com)

## 10. Guidelines and manufacturers declaration

The C-LAS has no essential performance.

### 10.1 Electromagnetic emission


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
Conducted RF-Emissions CISPR 11	EN 55011 Group 1/Class B	The laser uses RF energy exclusively for its internal function. Hence, RF emission is very low and not likely to cause any interference in nearby electronic equipment  The laser is only suitable for the environment in professional healthcare facilities.
Radiated RF- Emissions CISPR 11	EN 55011 Group 1/Class B	
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)	$\pm 2$ kV, $\pm 4$ kV, $\pm 6$ kV, $\pm 8$ kV contact discharge; $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air discharge	IEC 61000-4-2	Floors should be made of wood, ceramic or stone. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Radiated RF electromagnetic fields	3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used.
Proximity fields from RF wireless communications equipment	see Table 10.4	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used.
Rated power frequency magnetic fields	30 A/m 50 Hz or 60 Hz	IEC 61000-4-8	Magnetic fields at the grid frequency that are usually available in professional healthcare facilities may be used.
Electrical fast transients /burst	$\pm 2$ kV for power lines $\pm 1$ 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	$\pm 0.5$ kV, $\pm 1$ kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Surge voltages (Surges), Line against grounding	$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV	IEC 61000-4-5	Only the voltage of a typical professional healthcare facility may be used.
Conducted disturbances induced by RF 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; $\frac{1}{2}$ cycle at $0^\circ$ to $315^\circ$ 0 % UT; 1 cycle, $0^\circ$ and 70 % UT; 25/30 cycles at $0^\circ$	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.
Voltage interruption	0% UT; 250/300 cycles, $0^\circ$	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 disturbances induced by RF fields	3 V- 150 kHz to 80 MHz	IEC 61000-4-6	<p>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 C-Las, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p> <p>The field strength of stationary radio transmitters is, as determined by an electromagnetic site survey, at all frequencies smaller than the compliance level.</p>
Radiated RF electromagnetic fields and Proximity fields from RF wireless communications equipment	3 V/m 80 MHz to 2.7 GHz  resp. see Table 10.4	IEC 61000-4-3	<p style="text-align: center;"></p> <p>Interference may occur in the vicinity of equipment market with the following symbol:</p> <p>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).</p>

### 10.4 Recommended separation distances between portable and mobile RF telecommunication 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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MADE IN GERMANY



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