

User Manual

NUVOLAS



A.R.C. Laser GmbH

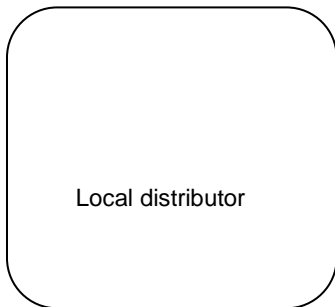
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1 Introduction

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

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



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

1.2 Intended Use

The NUVOLAS is intended to be used for treatments requiring coagulation or carbonization/vaporization of tissue, bony structures, or blood. At high power outputs, tissue can be carbonized and removed or separated by vaporization.

At low power output, heating of tissue or blood results in enzyme denaturation and coagulation e.g. of blood vessels. For this effect, the laser is used together with application fibers aiming the laser beam at the target tissue either directly in contact or non-contact or via further optics e.g. through handpieces.

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.

It can be used in conjunction with e.g. handpieces or endoscopes where the fiber is fed through the fiber/working channel to allow the physician to treat the desired area with the laser.

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

Laryngology

Otology

Rhinology

General Surgery

Medical field	Indication	Risks	Contraindication
Laryngology/ Oropharynx	<p>Treatments requiring coagulation or carbonization/vaporization of tissue, bony structures, or blood:</p> <ul style="list-style-type: none"> • Papillomatosis • Papillomatosis Varices • Reinke's Edema • Polyps • Vascular lesions • Ectasia Varices • Contact Granuloma • Leukoplakia • Dysplasia • Early Glottic Cancer • Microvascular angiomata • Cancer • Nodule • Stenosis • Granulation Amyloid • Hematomas • Tonsillectomy 	<ul style="list-style-type: none"> • edema • bleeding/hemorrhage • pain • scar formation/web formation • tissue injury (e.g. burning) • nerve injury • crusting • granulation • swelling • emphysema • synechia/stenosis • general or normal conventional (non-laser) operation collateral side effects 	<p>General contraindication: radiation exposure to the eye! (exception: Ophthalmology)</p> <p>Oxygen level can't be lowered below 30% due to previous illness if used nearby intubation tube.</p>

	<ul style="list-style-type: none"> • Palatoplasty / LAUP • Trismus • Cordotomy • Oral benign lesions 		
Rhinology	<p>Treatments requiring coagulation or carbonization/vaporization of tissue, bony structures or blood.</p> <ul style="list-style-type: none"> • Epistaxis • Turbinate surgery 	<ul style="list-style-type: none"> • dryness • edema • bleeding • pain • granulation • crust formation • scar formation • synechia • general or normal conventional (non-laser) operation collateral side effects 	-
Otology	<p>Treatments requiring coagulation or carbonization/vaporization of tissue, bony structures or blood.</p> <ul style="list-style-type: none"> • Tympanoplasty with and without ossicular reconstruction • Tympanoplasty with mastoidectomy • Glomus Tympanicum tumor 	<ul style="list-style-type: none"> • acoustic trauma • mechanical trauma (e.g. floating footplate) • vertigo • tinnitus • sensorineural hearing loss • general or normal conventional (non-laser) operation collateral side effects 	-
General Surgery	<p>Treatments requiring coagulation or carbonization/vaporization of tissue, bony structures or blood.</p>	<ul style="list-style-type: none"> • edema • bleeding • pain • scar formation • granulation • swelling • tissue injury • general or normal conventional (non-laser) operation collateral side effects. 	Oxygen level can't be lowered below 30% due to previous illness if used nearby intubation tube.

1.3 General Contraindications

The NUVOLAS is not intended to be used for interventions of the central circulatory system (arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior). Furthermore, the NUVOLAS is not intended to be used for treatments on the central nervous system (brain, meninges and spinal cord).

ATTENTION

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

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

1.4 Theory and Technical Set-up

The NUVOLAS is a diode laser with a wavelength of 514 nm. The laser radiation of the diode is collimated by optics and coupled into the applicator.

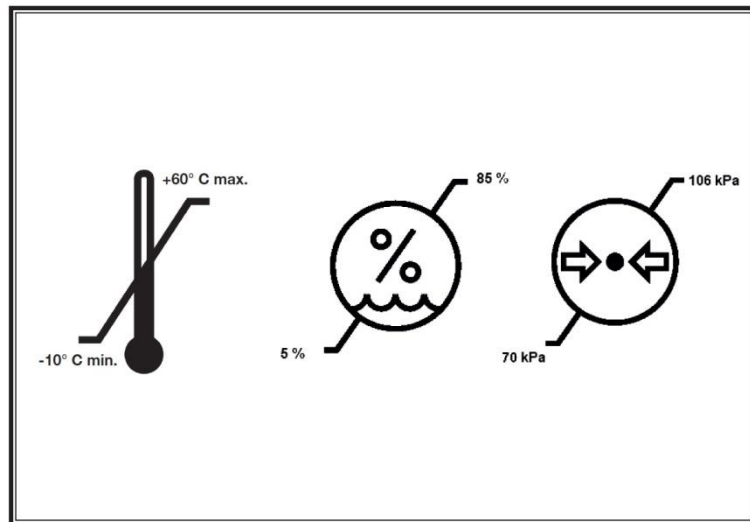
The laser light is coupled into a quartz fiber via deflection mirrors and coupling parts. The transmission of the different wavelength is independent for the fiber. Transmissions in the range of 80% to 90% of the laser power are possible. The laser source is brought to and maintained at the prescribed operating temperature via direct cooling. The passive cooling circuit is controlled via fans.

The laser beam of the diode is polarized and therefore very easy to control.

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 $+60^{\circ}\text{C}$. The air pressure during transport must be between 1080 hPa and 750 hPa. During storage, a temperature range of -10°C to 60°C must be maintained. The environment/air must be dry and clean. The relative humidity during transport and storage must be below 85 %.

ATTENTION

If the laser is transported or stored in temperatures below -10°C , it can be damaged when starting. Unpack the laser and leave it at least eight 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 will be carried out by an authorised technician or authorised 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

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.

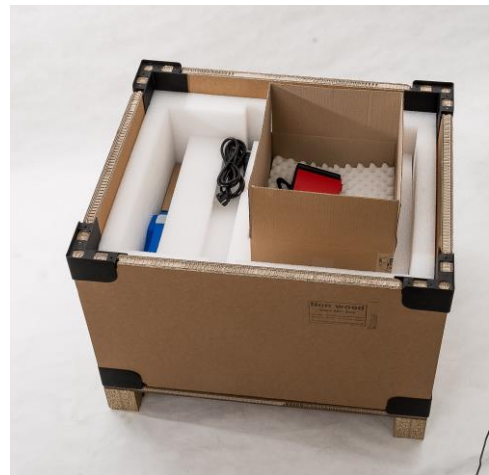


Distance holder
(VP01093)

All accessories are stored in a suitable extra packaging inside the transport box. A distance holder is placed between the laser and the display packaging.



If all the foam parts are in the right place and the box is closed, the unit 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 NUVOLAS should be operated in an easily accessible place. The laser should not be operated near a heater, since air cooling works best when the ambient temperature is not higher than 28° C. Higher temperatures can cause the device to switch off due to overheating. A place of installation in direct sunlight can cause an early shutdown and must be avoided in any case.

If the temperature is too low (below 18° C), the device cannot be started to prevent condensation on the internal optics; this could result in permanent damage to the laser.

- The device should be set up so that the laser beam is not aimed directly at a door, window or reflective material.
- The device should be operated in a dust-free room. There should be no carpets on the floor or the walls.

When the device is not in use, it should be stored in the carrying case. 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 Requirements

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 glasses is avoided.
- The laser safety goggles must be easily accessible at the entrance.

3.2.2 Window Shielding

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

3.2.3 Reflecting Surfaces

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

These can be:

- Mirrors
- Pictures behind glass
- Chrome surfaces
- Windows

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

3.3 Electrical Connection

The laser is operated with 230 V AC by an integrated power supply. The power supply is approved by A.R.C. Laser GmbH especially for the NUVOLAS; only this power supply is approved to be used.

The power supply unit can be connected to 100 V to 240 V AC voltage (50 Hz / 60 Hz).

ATTENTION

To protect against electric shock, the unit must be connected to a power supply with a protective earth conductor.

ATTENTION

Different input voltages require different fuse values!

230 V 2xT 3.15A

110 V 2xT 6.3A

Do not use excessive fuses when operating the laser.

4 Safety Information

4.1 General

The NUVOLAS 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 NUVOLAS 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 must be taken before commissioning in order to ensure safe and trouble-free working with the device. It is particularly important to protect the eyes and skin of the operator, the patient and third parties. Laser safety glasses must be used for eye protection.

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

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

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

With regard to the devices supplied, such as fibers or probes, the safety, operating and maintenance instructions in the corresponding manuals must be observed.

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

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

4.2 Eye Safety

As a safety measure against direct or indirect laser radiation, it is necessary that everyone in the room wear laser safety glasses.

When using the laser, only those laser safety glasses may be used which are designed for the respective wavelength, with the appropriate protection level and a CE mark.

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

- AS01003: Protection level D LB6 + I LB6 + RM LB 8 / Optical density OD8+

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 a full protection to the side parts.

When using a microscope, either laser safety glasses can be worn or it is possible to install an eye safety filter firmly into the beam path of the microscope. Please note that when using a beam splitter in the microscope, the eye safety filter is installed below the beam splitter to protect all outgoing beams above at the same time. Optionally, it is also possible to equip each individual beam path with an eye safety filter.

The following eye safety filters from A.R.C. Laser GmbH are suitable for the NUVOLAS and can be seen as external accessories of the laser system:

- BG06076/ BG06077: Optical density OD5+

The eye safety filters must be firmly installed in the respective microscope and checked by an employee of A.R.C. Laser GmbH or an authorized representative during delivery.

ATTENTION

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

ATTENTION

Third persons in the operating room, still have to wear laser safety goggles even if an eye safety filter is used.

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 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 anesthetics, flammable solutions or other flammable materials. Flammable plastic parts or paper parts in particular should also be removed from the working area of the laser. There is a fire or explosion hazard if the laser is used in the presence of flammable materials, solutions, or gases or an oxygen-enriched environment

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 treatments 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

By using a foot switch the NUVOLAS emits laser radiation. The foot switch should never be outside the area of the attending doctor. It is not allowed for anyone other than the attending doctor to trigger the foot switch.

Especially in operating theaters 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 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:

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

Wavelength λ:	514 nm
NOHD:	1.8 m
Beam divergence α(full angle):	25.4°
Permitted Maximum Radiation:	1.9x10³ Jm⁻²

4.7 CE Regulations

The laser system NUVOLAS has been approved by the notified body in accordance with the European Directive 93/42/EEC for medical devices. Accordingly, the device bears the CE mark **CE 0123**.

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

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

The test approval number is included with the device.

4.8 RoHS3 regulations

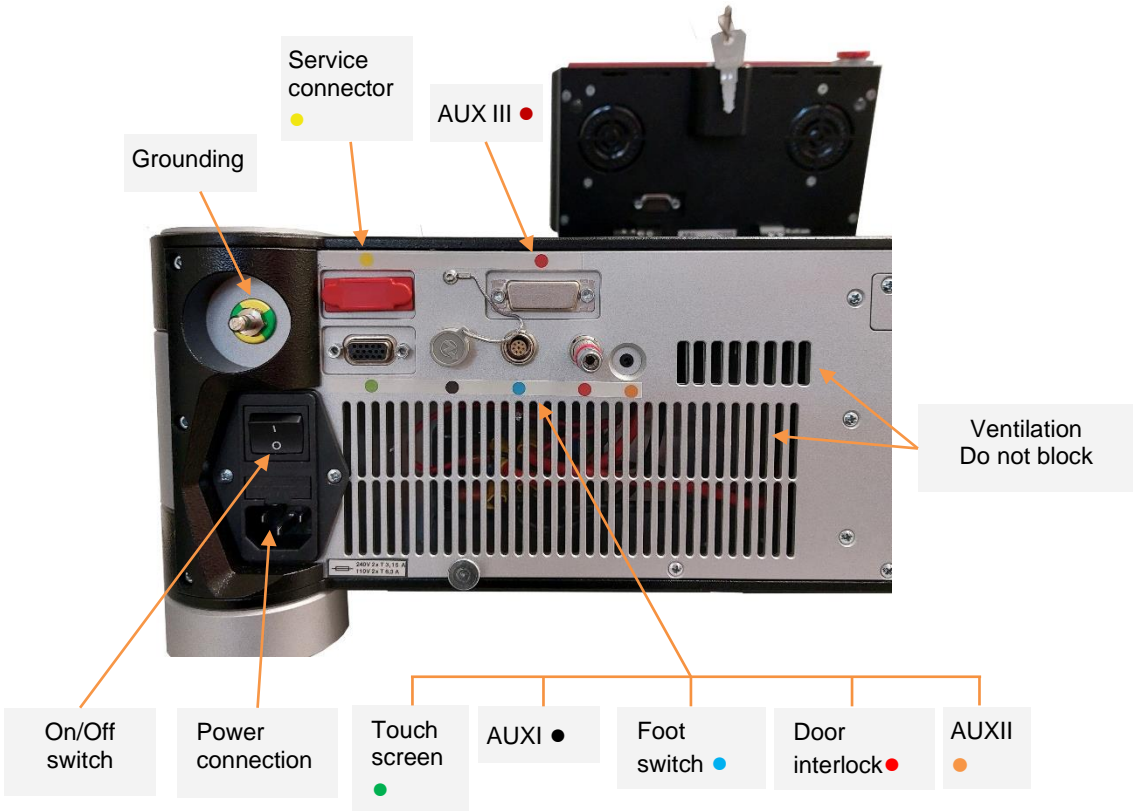
Our company operates worldwide and regards the protection of the environment and natural resources as an entrepreneurial obligation. Based on individual tests, A.R.C. Laser GmbH confirms that, to the best of our knowledge, our products do not contain any substances in concentrations whose placing on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

4.9 Protective Housing

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

4.10 Connectors and Switches

On the back of the device the following connect



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

Port	Description	Note	Color
Touch screen	Connector for the A.R.C. Laser touch screen	To control the NUVOLAS	Green
AUX 1	Currently without use		Black
Foot switch	Connector for the A.R.C. Laser foot switch	Only use accessories approved and tested by A.R.C. Laser.	Blue
Door interlock	Connector for the door interlock switch	The door interlock switch must be designed for at least 12V and 20mA.	Light red
AUX 2	Warning light / smoke evacuation	Optional	Orange
AUX 3	Currently without use		Dark red
Service port	Connector for service cable	The service port may only be used by A.R.C. Laser service personnel.	Yellow
Power Supply	Connection for medical approved power supply, A.R.C. Laser	Use A.R.C. supplied and approved accessories only	-

ACHTUNG

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 table. Insert the door switch connector there.

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

4.12 Safety shutter / Aiming Beam

The NUVOLAS has an internal safety shutter. This shutter is opened mechanically by inserting the fiber. Only if a fiber is properly plugged in, the laser can be switched into READY mode by pressing the READY button.

The aiming beam is only visible when a fiber is plugged in and 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 and an error message is shown. A restart should fix the error due to the automatic recalibration. Please refer to chapter 8.5.3 to identify the error messages.

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

4.14 Reset by Power Failure

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

4.15 Labels and Markings

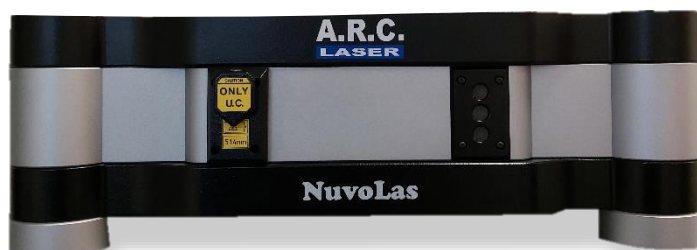
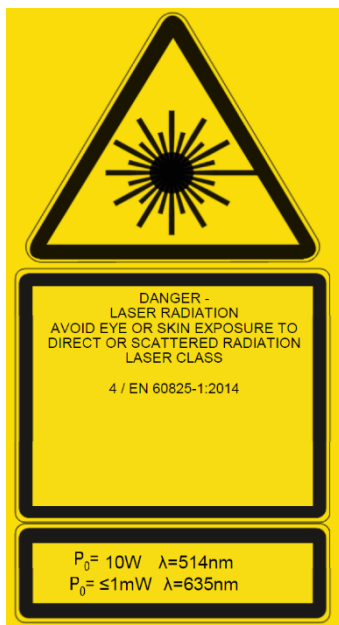
The NUVOLAS is provided with various warnings in accordance with European and worldwide guidelines. This is to prevent the laser user from being exposed to laser radiation due to carelessness.

TYPE PLATE

(on the backside of the device)

1. Manufacturer
2. Laser name
3. Wavelength, Power
4. Power consumption
5. Serial number (SN)
6. Manufacturing date
7. Medical device (MD)
8. No disposal in domestic waste
9. Unique Device Identification
(UDI = SN + GTIN + manufacturing date)
10. Global Trade Item Number (GTIN)
11. CE mark
12. Applied part type BF
13. See instructions for use

WARNING LABELS



Marks the laser exit and the used wavelength.



The NUVOLAS may only be used with Fibers and Probes which consists of an U.C. connector.

OTHER MARKINGS



Markings for fuse



Sticker for the display to identify the respective device



Please read the user manual

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

Modification label

4.16 Operating Conditions

The medical laser NUVOLAS 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 28° C
- Relative humidity: <75 % without condensation

4.17 Electromagnetic Compatibility

The NUVOLAS laser system meets the EMC requirements according to EN 60601-1-2:2015. Guidelines and the manufacturer's declaration are described in Chapter 10.

ATTENTION

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

5 Advice for Users

5.1 Technical Introduction

During the installation of the device, instruction is given by an A.R.C. Laser GmbH employee or an authorised 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 NUVOLAS 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 authorised 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 Device Parts and Accessories

The basic parts of the NUVOLAS include:

Part	Description	Article-No.
Footswitch	Footswitch, 4 m connection cable	BG08304
Power Supply	Power supply type E/F, 5 m	KB13003
Door Interlock	Door Interlock	UG08009
Display	Display with cover	BG08000
Connectin cable	Connecting cable for display	KB08035
User Manual	User Manual	-
Transport box	Transport box for NUVOLAS	VP01092
Distance holder	Distance holder for NUVOLAS transport box	VP01093

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

The NUVOLAS can be adapted to different surgical microscopes. For this purpose, various eye safety filters are available and can be ordered optionally:

Part	Description	Article-No.
Laser safety goggles	Laser safety goggles	AS01003
Eye safety filter for microscopes	Eye safety filer: 510 nm-522 nm	BG06076
		BG06077

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

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.

Fibers and Probes / Applicators

The NUVOLAS is a fiber guided laser. There are different fibers and hanpieces that are used to guide the laser radiation to the application side. The appropriate laser for the applicator is indicated on the label. For more information about suitable applicators, please contact A.R.C. Laser GmbH or the responsible sales partner.

Suitable for
NUVOLAS

A.R.C. LASER REF LL28068s

www.arclaser.com

(01)04260155592317
(10)12345
(11)211214
(17)241214

2021-12-14

HiFlex Fiber
600 µm, u.c.

A.R.C. Laser GmbH REF LL28068s
LOT 12345 2024-12-14

A.R.C. Laser GmbH REF LL28068s
LOT 12345 2024-12-14

A.R.C. Laser GmbH REF LL28068s
LOT 12345 2024-12-14

Notes :
OD < 0.9 mm
strip-off the coating ONLY with tool WE01441
size 0.75 / 1.40 - blue button

Only use for :

NUVO- & CHIROLAS u.c. FOX IV

WOLF FOX u.c. code@ SN-xWxx

LASER_INNOVATION
MADE IN GERMANY

Manufacturer
A.R.C. Laser GmbH
Bassamerstr. 14
90411 Nürnberg
Germany/Deutschland

CE 0123

STERILE EO rev4 AU_LL28068s

ATTENTION

The applicators are glass fibers that can break easily. Handle with the necessary care when taking them out of the packaging and during treatment to avoid fiber breakage. A broken fiber cannot be used for the treatment.

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 user manual. 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:



Fiber port

The NUVOLAS has a fiber port at the front of the device.

The fiber port is for connecting patented A.R.C. Laser fibers and probes only.

All fibers and probes which are marked with U.C. can be used without any restriction.

ATTENTION

Applicators for the NUVOLAS are labeled with U.C. (universal centering) on the product label on their packaging.

Laser emission LED

The laser emission LED indicates if laser radiation is emitted. If laser radiation is emitted the laser emission LED lights up red.

READY LED

The READY-LED lights up if the READY mode is activated via the touchscreen. If the READY mode is deactivated the READY-LED turns off.

Status LED

The status LED indicates the state of the device. If it is blinking 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.

Error LED

The error LED indicates if an error occurred. If it lights up in red, the device has to be restarted-

Touchscreen

The touchscreen the user can change parameters like power/pulse length/pulse pause or can change the settings of the system.

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.

Never use an applicator if its packaging is damaged, the fiber is kinked or the target beam is in irregular shape or not visible.

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

A power supply unit is integrated in the NUVOLAS, which needs to be connected to the mains. This is the standard power supply. Input voltage ranges between 100 V and 230 V. Only use the power supply 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 power supply?
The power supply only must be connected 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?
- Is a fiber or probe still connected?
- Are the fibers and probes free of any damage?
- Are there enough protective glasses ready to be used?
- Has the footswitch been plugged in?

We recommend placing the NUVOLAS on a dry and solid surface. Ensure a stable stand for the laser system.

ATTENTION

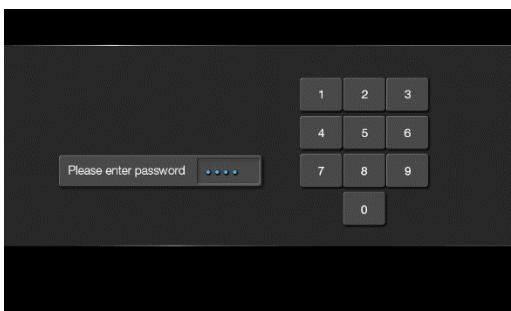
All warning lights outside the treatment rooms must be switched on as soon as the laser starts to operate. The doors have to be marked accordingly, visible from outside (with the warning signs).

6.2 Switch on the Laser

Switch on the device using the On/Off switch on the back of the device. The green status LED starts to blink. After approximately 30 seconds the start screen is visible. When the laser is ready to use, the green status LED now flashes continuously



The NUVOLAS performs a system-check during the start routine. During that, no fiber may be connected to the device.

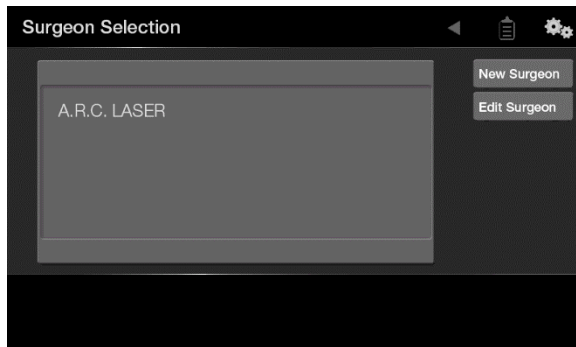


After system check, you will be asked to insert the password. In the factory settings the password is **0000**.

ATTENTION

The NUVOLAS 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 Select / Add / Edit / Delete a user

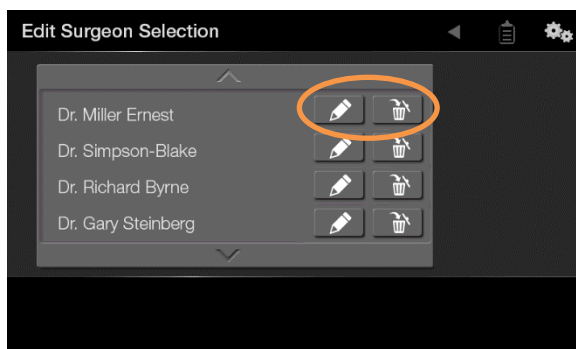
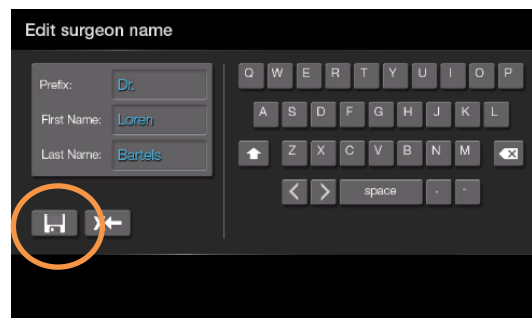


Select user:

The desired name can be chosen by directly touching it. Afterwards you will be automatically redirected to chose program. If you use the device for the first time, you should include your name.

Add user:

To add a user, chose "New Surgeon". Now you can insert the name and use the floppy disk to save it.

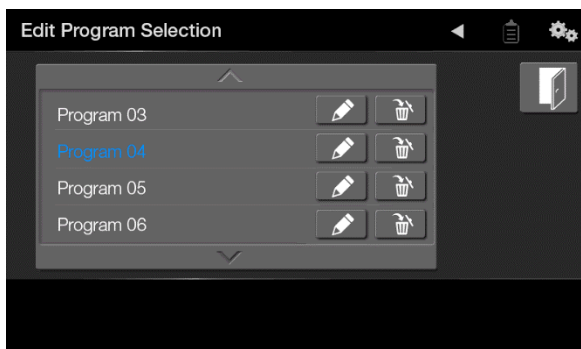


Edit or delete name:

Chose "Edit Surgeon" to change or delete a name. By the use of the pencil symbol you can change the name. If you use the delete symbol the name can be deleted.

In the drop-down list you can see all user names added. By using the arrow keys you can scroll through the list. By clicking on the name, the name is selcted and you will be re-directed.

6.2.2 Select / Add / Edit / Delete an application



In general, different application programmms are preset at the factory from which you can choose.

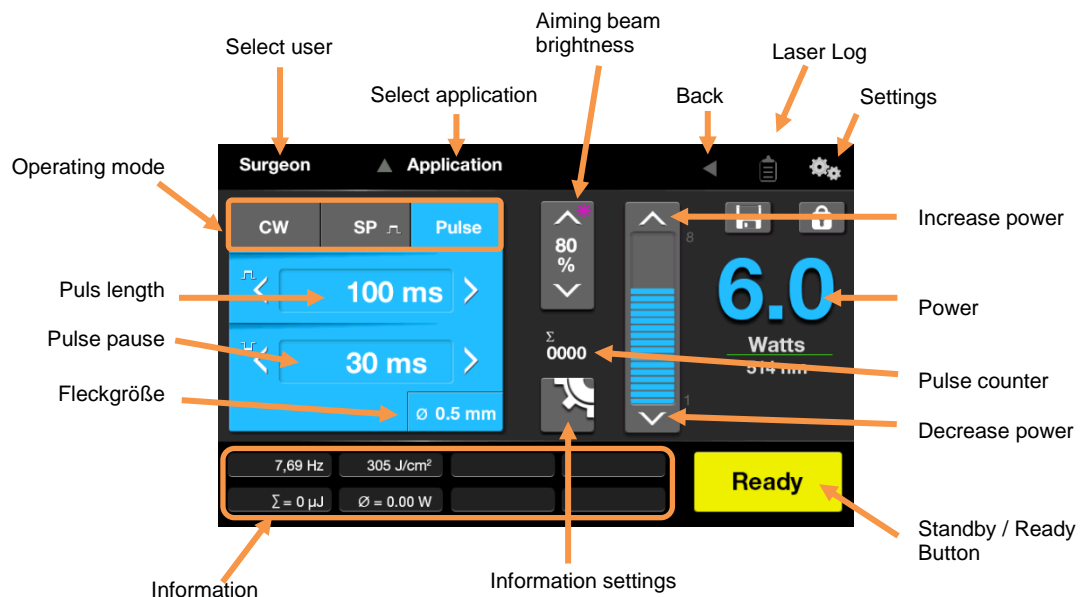
You can select, add, edit and delete application analogous to chapter 6.2.1.

6.3 Programs and Settings

ATTENTION

With some devices, programs and preset values are already stored. This does not release 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.

6.3.1 Display / Main Menu



6.3.1.1 Operating mode

You can choose between pulse mode, single pulse mode (SP) or continuous wave mode (CW) for the treatment. Just touch the desired tab. Afterwards you can select the parameters as needed.



6.3.1.2 Power (Watt)

The power controller is touch sensitive so that you can directly choose the correct value. Alternatively, you can change the power by using the arrow keys. The displayed power corresponds to the power at the fiber tip with a tolerance of $\pm 20\%$.



6.3.1.3 Safe values

To save changed values type on the floppy disc. The floppy disc is only visible, if the parameters (power, pulse length, pulse pause) of the application were changed. The following chapters explain in more detail how to change the pulse length and pause.

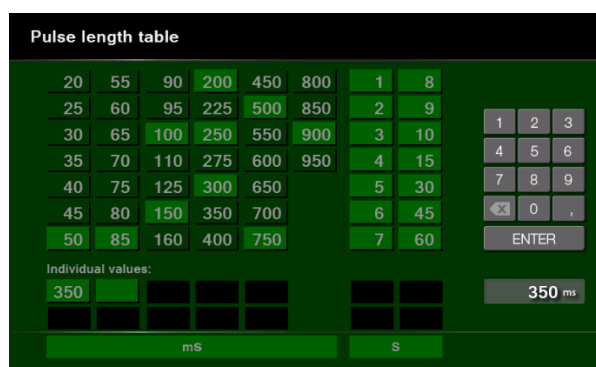


6.3.1.4 Pulse length



The pulse length can be changed using the arrow keys. Only the values selected in the pulse table are displayed. To change possible values for the pulse length that are available in the main screen press on the pulse length value for approx. 2 seconds. The pulse table opens and the desired values can be added.

Values which are already selected are highlighted in a light green. By clicking on a value, it can be selected or deselected. Boxes which are black highlighted can be used to add customized pulse lengths. To add a value just tap on a black box and use the number panel. Your customized pulse length can be changed at any time by selecting the value you want to change.



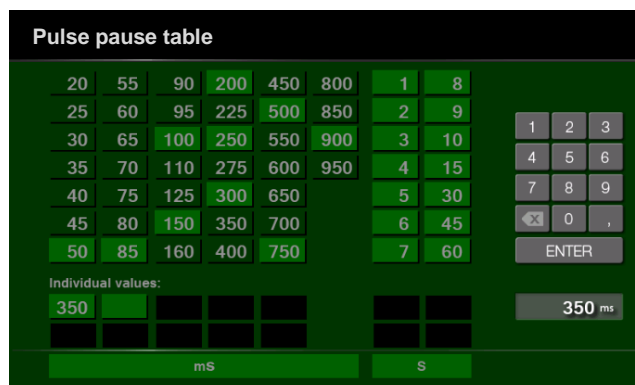
When you leave the pulse table, changed and selected values will be saved automatically. Light green highlighted values are now default values and can be chosen in the main screen.

6.3.1.5 Pulse pause



The pulse pause can be changed using the arrow keys. Only the values selected in the pulse pause table are displayed. To change possible values for the pulse pause that are available in the main screen press on the pulse pause value for approx. 2 seconds. The pulse table opens and the desired values can be added.

Values which are already selected are highlighted in a light green. By clicking on a value, it can be selected or deselected. Boxes which are black highlighted can be used to add customized pulse lengths. To add a value just tap on a black box and use the number panel. Your customized pulse pause can be changed at any time by selecting the value you want to change.



When you leave the pulse pause table, changed and selected values will be saved automatically. Light green highlighted values are now default values and can be chosen in the main screen.

6.3.1.6 Aiming beam brightness

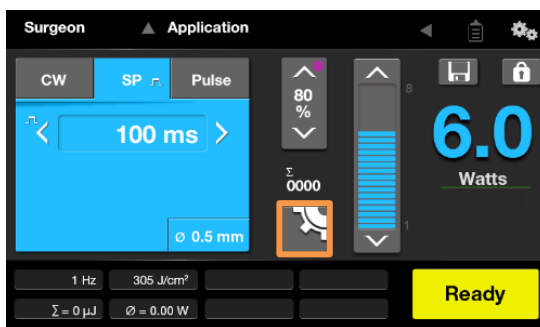
If a fiber is connected to the NUVOLAS the aiming beam brightness icon automatically changes to purple. The aiming beam brightness can be changed using the arrow keys. If the laser is in STANDBY-BY mode, the aiming beam brightness fades out after a few seconds.

6.3.1.7 Counter

The emitted pulses are cumulated. The device counts automatically pulses triggered by the footswitch or the number of pulses with the set frequency. The maximum number of pulses is 9999. By pressing the pulse counter box it will be reset to 0000.



6.3.1.8 Information settings



For your treatment with the NUVOLAS different statistical values can be used, to track the power, energy respectively, during the treatment. The information for the treatment can be found in the lower area of the main screen.

The parameters which should be displayed can be chosen by yourself. Therefore, the information setting icon has to be selected. The parameters are selected if the dot next to the parameter is colored white.

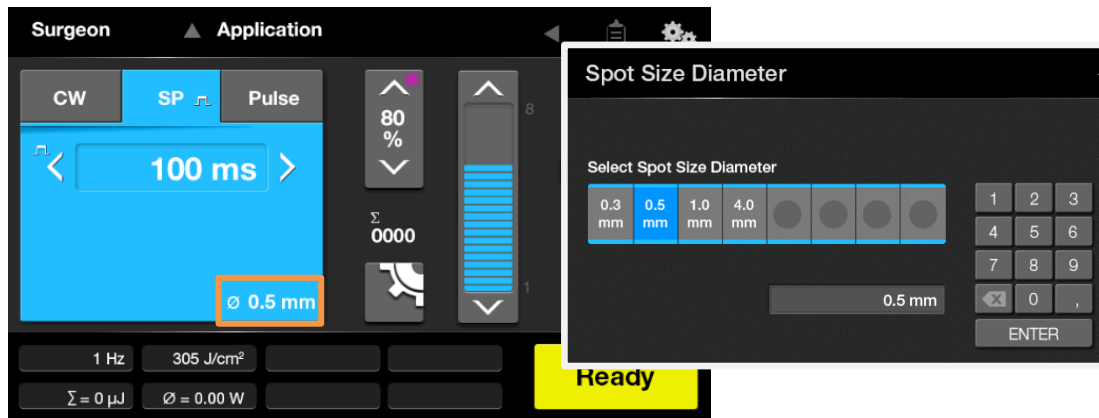
The following values can be selected:

- Frequency in Hz:** The shown frequency is generated by pulse length and pulse pause per second.
- Energy in Joule:** The shown energy value is the product of the set power and the actual set exposition time as well as the applied pulses. The displayed energy changes automatically from milli-Joule (mJ) to Joule (J) to Kilojoule (kJ).
- Ø Spot size:** Shows the current chosen spot size, which is used as basis for calculation for the density of energy. This option may only be used for probes.
- Energy density:** Depending on the spot size the system calculates the emitted density of energy in J/cm². This option may only be used for probes.
- Average power:** Shows the result of set power and actual exposition time in dependence of the pulse length and pulse pause. The displayed power changes automatically from micro-Watt (µW) to W.

6.3.1.9 Setting of the beam diameter to calculate the density of energy

The NUVOLAS offers the possibility to calculate the specific density of energy according to the used accessories. This parameter, similar to the mean power \bar{P} and the cumulated energy ΣE , can be displayed optionally for documentation reasons.

To calculate the correct values, the beam diameter which is defined by the accessory has to be selected or added. For that, just tap on the diameter shown. The values can be chosen by directly tapping on them. Alternatively, you can include the beam diameter by using the input field.



The following table provides information about the beam diameter for the accessories used with the NUVOLAS:

Fibers and Probes			Optic hand pieces		
Name	Article number	Beam diameter*	Name	Article number	Beam diameter**
HiFlex Fiber 300 μ m	LL28062s	0,3 mm	Focus hand piece blue	HS18002	0.3 mm
HiFlex Fiber 400 μ m	LL28066s	0,4 mm	Focus hand piece red	HS18003	0.6 mm
HiFlex Fiber 600 μ m	LL28068s	0,6 mm	Focus hand piece green	HS18004	1.0 mm
Otology Probe	LL28058s	0,3 mm	Therapy hand piece silver	HS18001	5.0 mm
	LL28059s				
DCR Probe	LL28067s	0,4 mm	Connector Fiber 300 μ m	LL28063	0.3 mm

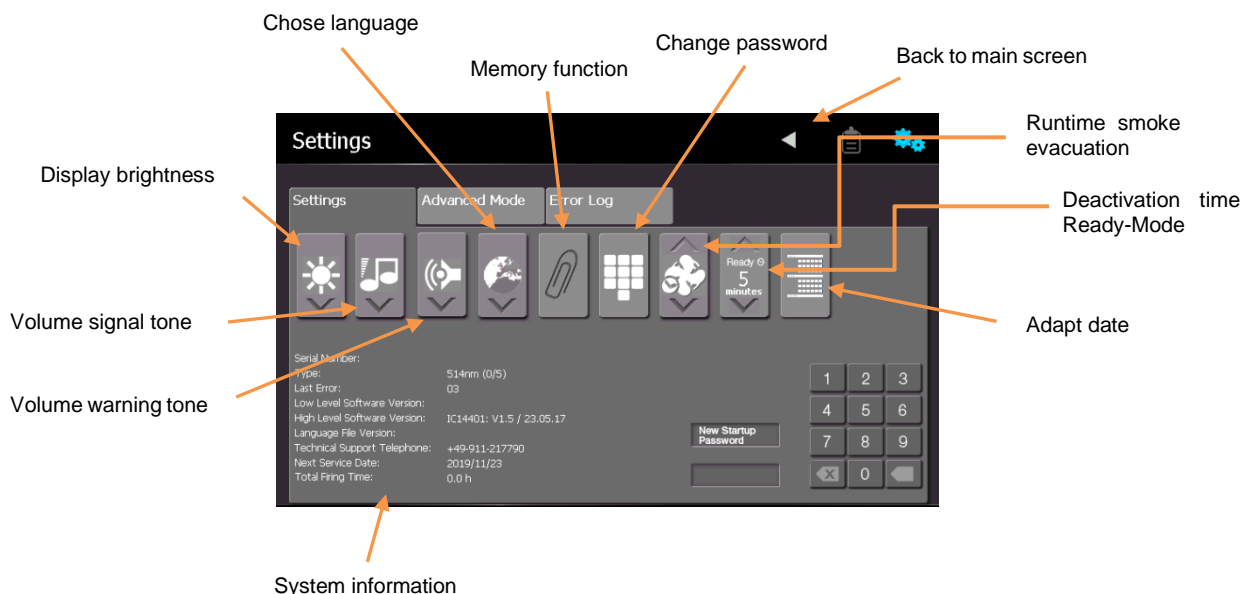
*Please note that the beam diameter for fibers and probes is only valid when using the applicator in contact. If you use the applicator in non-contact the beam diameter will increase due to the aperture angle of the fiber and the density of energy decreases.

**The beam diameter of the focus hand piece is only valid when the spacer of the hand pieces are in contact with tissue or if the therapy hand piece silver is used with a distance of 1-5 cm.

6.3.2 Settings



From the main menu you can enter the settings menu by tapping on the gear wheel symbol.



Display Brightness

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



Volume signal tone

Setting the volume of the acoustic signal tone of the NUVOLAS from 10-100 % in 10 %-steps.



Volume warning tone

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



Language

Choose between different languages, German, English, Spanish, Italian or French



Deactivation time Ready-Mode

Select the switch over time between READY and STAND-BY mode. 2-5 min in 1 min steps, 5 min-15 min in 5 min steps



Runtime smoke evacuation

Set the time the smoke evacuation is active after the release of the foot switch: 5 seconds, 10-60 seconds in 10 s steps. The smoke evacuation (ZU01049) can be used to remove the

All parameters can be changed by using the arrow keys.

6.3.2.1 Memory function

If the paper clip is highlighted bright, the laser remembers the last settings and starts the device with the same settings than it was switched off. Otherwise, the NUVOLAS will start again with the user request.



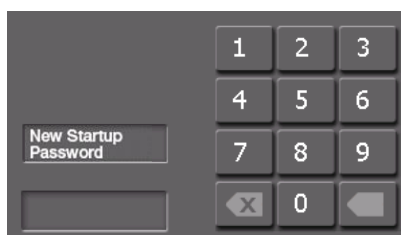
Not selected



Selected

6.3.2.2 Change user password

The user password, for which you will be asked after system check, can be changed by the user. Just tap on the change password icon. Afterwards, the password can be changed in the lower area of the touch screen. The password consists of four numbers (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

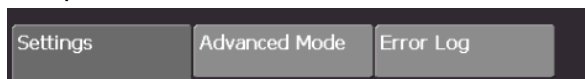
6.3.2.3 Calendar

With the calendar function you can change the date and time of the device.



6.3.3 Service settings

The service settings – which are the advanced mode and the error log – can only be activated by the service personnel with the corresponding service password. Further system settings can be changed here. Furthermore, the error memory of the device can be opened.



6.4 Inserting the applicator

If the device is ready and the treatment can be started, the applicator can be connected to the device.

All fibers and probes have a quick-release connector. The connectors are equipped with an anti-twist protection, recognizable by small notches in the connector.

This ensures an optimal fit in the fiber coupling for a reproducible power transmission. The connector has to snap in to use the laser device. In case the connector has not been properly connected, the device will not change into READY mode. Please pay attention to a clearly audible "click" when inserting the connector!



Once the connector has been locked in place, the treatment can start. At this point laser radiation can be emitted through the fiber if the foot switch is activated.

6.5 READY- / Standby-Button

After starting the laser, the NUVOLAS 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 NUVOLAS is in READY mode, you can emit laser radiation using the foot switch.

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



6.6 Release laser radiation

To emit laser radiation, press the foot switch. The laser must be switched to the READY mode to do so.

When a laser shot is fired, a simultaneous warning signal is audible and the red laser emission LED on the display lights up.

6.7 Treatment

Position the patient. Select the necessary laser settings. Press the READY button: The READY button in the display and the READY-LED light up yellow. The aiming beam is visible and the treatment can start.

The software of the NUVOLAS allows to sum up the energy emitted permanently.

Make sure that only one person at a time touches the NUVOLAS.

ATTENTION

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

6.8 Laser-Stop

If the Laser-Stop is pressed while starting the device, the device won't work, only the fan starts. The display will remain black and no LEDs will light up.

If the laser stop is activated during treatment with NUVOLAS, the device is deactivated immediately. The display and the LED will fade out.

Solution: Pull the Laser-Stop out. The power supply will be released again and the device can be started as usual, restarted respectively.

ATTENTION



The Laser-Stop should only be used in emergencies.

6.9 Switch Off

The NUVOLAS can be turned off by pressing the on-/off-switch at the back of the device. You should cover the display after each use, to prevent the display from damage.



6.10 Symbols Description

	Display brightness (5-100%)		Volume Signal tone (5-100%)
	Volume warning tone (10-100%)		Select language
	Memory function		Continue / Increase/ Decrease value
	Edit name		STANDBY time setting
	Delete value/ input		Symbol for changing date/ time
	Runtime smoke evacuation		Safe current settings
	Exit		Submenu settings
	Read treatment data		Information settings
	Pulse counter		Back
	Aiming beam brightness (5-100%)		Continous wave mode
	SP (Single pulse) in pulse pause field		Pulse length Pulse pause
	Fiber diameter/ spot size		Reduce or Increase time
	Attention		

7 Technical Data

7.1 General

Model NUVOLAS	Diode laser
Cooling	Air internal
Weight	24 kg
Dimensions	H 16.1 cm / W 47.8 cm / D 42.1 cm
Controlling	Touch screen display

7.2 Laser-Data

Wavelength	Power	Tolerance
514 nm	0.5 – 8 Watt	± 20% of displayed power According to IEC 60601-2-22

Wavelength	Pulse length	Pulse pause	Frequency
514 nm	20 ms – 60 s /CW	20 ms – 60 s /SP	0,008 Hz – 25 Hz /SP

Aiming Beam 635 nm red < 1 mW, variable brightness
continuous wave (CW)

Power transmission Fiber 300 µm, 400 µm, 600 µm
with or without handpiece

7.3 Electrical Connection Data

Power supply connection values 100V – 240V, 50Hz/60Hz, 6.3 A/ 3.15 A

7.4 Classification

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)	I
Classification according to MDD/MDR	IIb, Rule 9
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 to open 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 shall 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 laser safety glasses / eye safety filter / protective device
- Overall condition

Functionality Check

- Foot switch / Manual trigger

Check the necessary monitoring / msafety display and signaling unit

- Laser safety glasses / eye safety filter
- Emission controls (acoustic, visual)
- Laser-Stop (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 not 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 and the applicator must be disconnected. In addition, the red dust protection cap should also be inserted into the fiber connector. First clean the device with clear water and neutral detergent to remove coarse and visible contamination. Make sure that no moisture penetrates into the interior.

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 wiping disinfection, the manufacturer's instructions for the disinfectant must be observed. Below is a table of possible disinfectants that meet the above requirements:

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

*This list is not exhaustive.

ATTENTION

When cleaning, the device must always be switched off and disconnected from the mains. Wet wipes should be avoided in any case. Exposure to water can lead to defects.

8.4 Cleaning of accessories

8.4.1 Laser safety goggles

The cleaning instructions provided with the laser safety glasses must be observed.

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

8.4.2 Applicators

In most cases the applicators are single use products and must not be reprocessed. Please follow the instructions in the manual for fibers and probes.

8.4.3 Foot switch

The general cleaning instructions (see above) must be observed 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.

8.5 Error Detection

The NUVOLAS 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.



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 to the device or the door contact switch should be closed.
- The display is not connected correctly, the connecting cable is not connected or has loosened.

8.5.1 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: 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.

8.5.2 Troubleshooting

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







Problem	Potential Error	Troubleshooting
Display black	Display cable is losen / not connected	Check if the display cable is properly connected. You may have to disconnect and reconnect it again.
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 lights up.
	Aiming beam brightness is set to minimum	Increase aiming beam brightness
	Fiber or probe is not properly inserted	Twist the connector of the fiber or probe inside the socket with a slight movement inwards
	Aiming beam diode defective	Contact your A.R.C. Laser representative
No laser beam visible but aiming beam	Footswitch not plugged in	Check if footswitch is correctly plugged in
	Footswitch defective	Contact your A.R.C. Laser representative
	Laser is in STANDBY mode	Switch laser into READY mode
No aiming beam and no laser beam	Fiber not properly or not at all connected	Check the correct fitting of the applicator
	Applicator is broken	Replace the applicator

8.5.3 Error Codes

Following errors can be detected by the NUVOLAS during system check or use of the device. If such an error occurs, restart the device. If the error still occurs contact A.R.C. Laser service.

Error message	Short Description	Error message	Short Description
F00	Error system start	F23	Voltage test, error +12 V
F01	Power too low – 20 %	F24	Voltage test, error +5 V
F02	Power too high – 20 %	F25	Voltage test, error +24 V
F03	Laser radiation in STAND-BY	F32	Error diode current
F04	Time out of opto coupler	F33	Peltier, temperature too high
F06	Short circuit foot switch, left	F38	Error DA converter
F07	Short circuit foot switch, right	F47	Error check sum
F11	Power setting is not possibleh	F49	Error Chip combination
F15	Time out eye protection filter	F50	IC ² -Bus defect

8.5.4 Error Messages

	Door interlock not connected	Connect the interlock plug included with the system / close the door
	Attention	Note error message or wait
	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
	Fiber missing / or plugged incorrectly	Plug in fiber

8.5.5 Status message

	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 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, 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.

10 Guidelines and manufacturers declaration

The NUVOLAS does not have 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
RF-Emissions CISPR 11	EN 55011 Group 1/Class B	The laser is only suitable for the environment in professional healthcare facilities.
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)	± 8 kV 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 And 70 % UT; 25/30 cycles at 0	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.

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

10.3 Electromagnetic Immunity (2)

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

Immunity tests	IEC 60601-Test level	EMV standard	Electromagnetic environment – guidelines
Conducted disturbance variables, induced by high-frequency fields	3 V/m 150 kHz to 80 MHz	IEC 61000-4-6	<p>Portable and mobile radio devices should not be used closer to the laser (including the lines) than the recommended protective distance, which is calculated according to the equation applicable to the transmission frequency. If those information are not respected it may result in a reduction in the performance characteristics of the unit.</p> <p>Recommended protected distance:</p> $d = [1.17 : V1] \sqrt{P}$ $d = [1.17 : E1] \sqrt{P}$ <p>for 80 MHz to 800 MHz</p> $d = [2.33 \text{ m/V} * vP$ <p>for 80 MHz to 2.7 GHz</p> <p>with P as the nominal power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d as the recommended protective distance in meters (m).</p>
Radiofrequency electromagnetic fields in the immediate vicinity of wireless communication devices	3 V/m 80 MHz to 2.7 GHz	IEC 61000-4-3	<p>Die The field strength of stationary radio transmitters should be lower than the compliance level at all frequencies according to an on-site examination.</p> <p>Faults are possible in the vicinity of devices with the following symbol.</p> 

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	Frequency band	Radio service	Modulation	Maximum performance	Distance	Immunity test level
MHz	MHz			W	m	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

made in Germany ● ● ●

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