User Manual

CETUS

A.R.C. Laser GmbH

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1 Introduction

We appreciate your decision to purchase the CETUS and wishing you a productive and successful usage with this system.

The CETUS may induce injuries in improper handling. Therefore, this User Manual should be read carefully before using the device. If you should have any further questions regarding safety, the use of the device, please contact A.R.C. Laser GmbH or your local authorized dealer (see Section 10.3 „Sales and Service - Information").

1.1 Marking and Symbols

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

1.2 Intended Use

The CETUS is intended to be used for cataract surgery. It allows photofragmentation of the cataractous crystalline lens as an alternative to mechanical break up of the lens nucleus structure. Shockwaves are generated inside the CETUS hand piece by a plasma, initiated by strong absorption of the laser radiation onto a titanium surface. The surgery is performed in the operation theater, in general with the anesthetized patient lying and the surgeon looking through a magnifying microscope. The hand piece of the CETUS system is inserted into the eye through a 2.4-2.5 mm parazenthesis. or sometimes larger (up to 2.8 mm) depending on the surgeons plan for implanting the artificial intraocular lens and the surgery design. The parazenthesis is performed by a sharp surgical knife. The capsular bag is opened before surgery performing the so called rhexis, an about 5.5 mm diameter round opening which serves as entrance to the capsular bag for the surgery. After completion of the rhexis the surgeon mobilizes the lens nucleus by hydro dissection. The next step is the cataract removal procedure with the hand piece touching the nucleus. The nucleus is photofragmented by the shock waves and aspirated through the hand piece by means of the suction power from the phaco machine attached to the CETUS system. For the operation, some hundreds of laser pulses are used to fragment the lens. One laser pulse has an energy of 3 – 8 mJ, whereas normally 4 – 5 mJ per pulse are used for ordinary cases. Hard, respectively mature cataracts require more energy than soft ones. As the CETUS system is designed to be really atraumatic and gentle to the eye with only low energy release, harder cataracts (LOCS IV or more) are not the preferred type of cataracts to be treated with the CETUS system.

Medical Application	Indication	Side and adverse effects	Contraindications
Ophthalmology	Cataract	- Infection/ inflammation, corneal edema, trauma, discomfort and pain - Side effects which may occur from cataract surgery in general are also macular edema, infection/ inflammation and corneal edema or folds - Capsular rupture	- any condition which does not allow to operate the patient in a lying position and anesthetize the eye. - health condition of the patient which prohibits an operation at the eye - non- transparent cornea - inflammation (intraocular or at/ around the eye)

1.3 General Contraindications

The CETUS should not be used in case of cloudy corneas causing reduced visual access and therefore no easy possibility for operating the lens a cataract surgery with the CETUS system is not intended. Non transparent corneas are a contraindication. Mature or hard cataracts (LOCS IV or more) may lead to a surgeon's decision not to use the CETUS system to perform the cataract removal.

A T T E N T I O N
The device may only be used by specially trained personnel who are experts in the medical effects and possible dangers of the device. You must have the necessary skills for using the laser in accordance with this instruction manual.
When not in use, the device should be protected against unauthorized use.

1.4 Theory and Technical Set-Up

This device has a Nd:YAG beam source with a wavelength of 1064 nm. For the application, this light is converted to a shock wave.

The laser diode is operated with high current up to 35 amperes and low voltage. Current drivers generate the current running through the laser diode in the electronic system thus allowing the user to control the output power through the touch screen display.

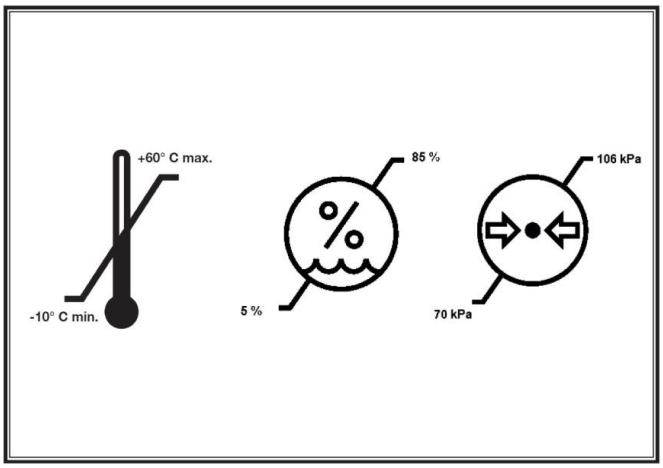
Via beam deflection mirror elements, the laser light is coupled into a silica glass fiber and converted to shock waves. Transmissions ranging from 70 to 80 % of the laser power are possible. The laser diode is controlled by internal electronic system that is adjustable through the device control monitor. The CETUS output power as well as pulse frequency can be controlled individually.

The emitted laser beam is polarized and therefore very easy to adjust.

2 Transport and Storage

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

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



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

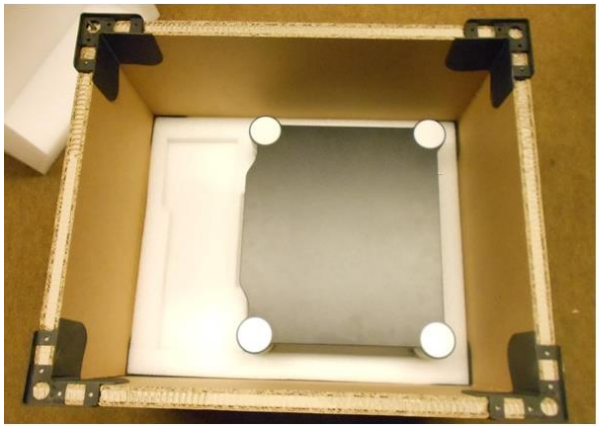
A T T E N T I O N
If the laser is transported or stored in temperatures below 5°C, it can be damaged when starting. Unpack the CETUS and leave it at least five hours at normal room temperature so that the system reaches room temperature.

2.1 Shipping and unpacking the device

Unpacking and installation of the device must be carried out by an authorized technician or authorized representative of A.R.C. Laser GmbH. After the installation and the correct connection of the device, the technician will set the device into operation and explain the function of the device. All functions and safety procedures are discussed and demonstrated here.

2.2 Return Shipment

The device is shipped in a specially designed transport box. If you ship the device back to A.R.C. Laser GmbH, please use the box for transportation and shipping, which is developed so that the device fits exactly in the foam parts.



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 CETUS should be used in an easily accessible place. The device should not be operated near a heater, since the device only works if the ambient temperature is not higher than 30° C. Higher temperatures can cause the device to switch off due to overheating. Also, 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 16° C), the device cannot be started to prevent condensation on the internal optics; this could result in permanent damage to the device.

The device should be operated in a dust-free room. There should be no carpets on the floor or the walls. 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%.

The CETUS has to be operated in connection to a cataract surgery system. Please take care, that the CETUS is standing close to the phaco system, as a connection tube needs to be plugged into the vitrectomy module of your phaco machine.

3.2 Room Requirements

Legislation does no prescribe any requirement for rooms in which a class 1 laser is operated. A.R.C. Laser GmbH imposes to use the CETUS within an operating theater.

3.3 Electrical Connection

The CETUS is operated with24 V DC. The integrated power supply unit complies with the information on the label. It can be connected to an AC voltage ranging from 100 V to 240 V (50/ 60Hz).

4 Safety Information

4.1 General

The CETUS 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 CETUS device is classified according to EN 60825-1 as a Class 1 laser.

Class I in the standard describes a laser in an enclosed housing The laser does not pass through the associated hand piece directly and thus does not represent a danger to users and patients.

The following information 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" should be respected.

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

With regard to the accessories supplied with the device, e.g. the CETUS probe, the safety, operating and maintenance instructions in the corresponding manual must be observed.

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

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

4.2 Eyewear protection

During the treatment no harmful radiation can escape from the device. Irradiation of the skin and the eyes is not present. During treatment, no special eye protection is necessary.

4.3 Electrical Protection

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

The room in which the CETUS is operated should be kept dry. In the event that cleaning is necessary, make sure that the floor is dry before starting up the device.

A T T E N T I O N

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

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

4.4 Explosion and Fire Hazard

The plasma should not come in contact with easily flammable materials. Never work with the CETUS 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 device. There is a fire or explosion hazard if the laser is used in the presence of flammable materials, solutions, or gases or an oxygen-enriched environment

4.5 Protection against Undesired Radiation

The device is operated with the foot switch of the phaco system. The foot switch should never be outside the range of the operator. It is forbidden that anyone other than the attending operator triggers the foot switch.

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

4.6 NOHD Safety Distance

Since this is an encapsulated laser system and no radiation can exit from the fiber optics into the environment, there is no need for a protection of doctor and patient through goggles. A minimum distance also is not required.

4.7 CE-Regulations

The CETUS system was accredited by the notified body in accordance with the European directive 93/42/EEC for medical equipment. Therefore, the device is labeled with the CE mark CE 0123.

The device was tested for electrical compliance as well as for mechanical safety. All parts used by A.R.C. Laser for the CETUS comply with CE regulations or have been tested for approval or suitability by the notified body.

Any additional equipment that is attached to the device must require the official approval of the local inspection authority. Changes to the device or interventions on your part will void the approval and warranty.

The test approval number are included with the device.

4.8 RoHS3 regulations

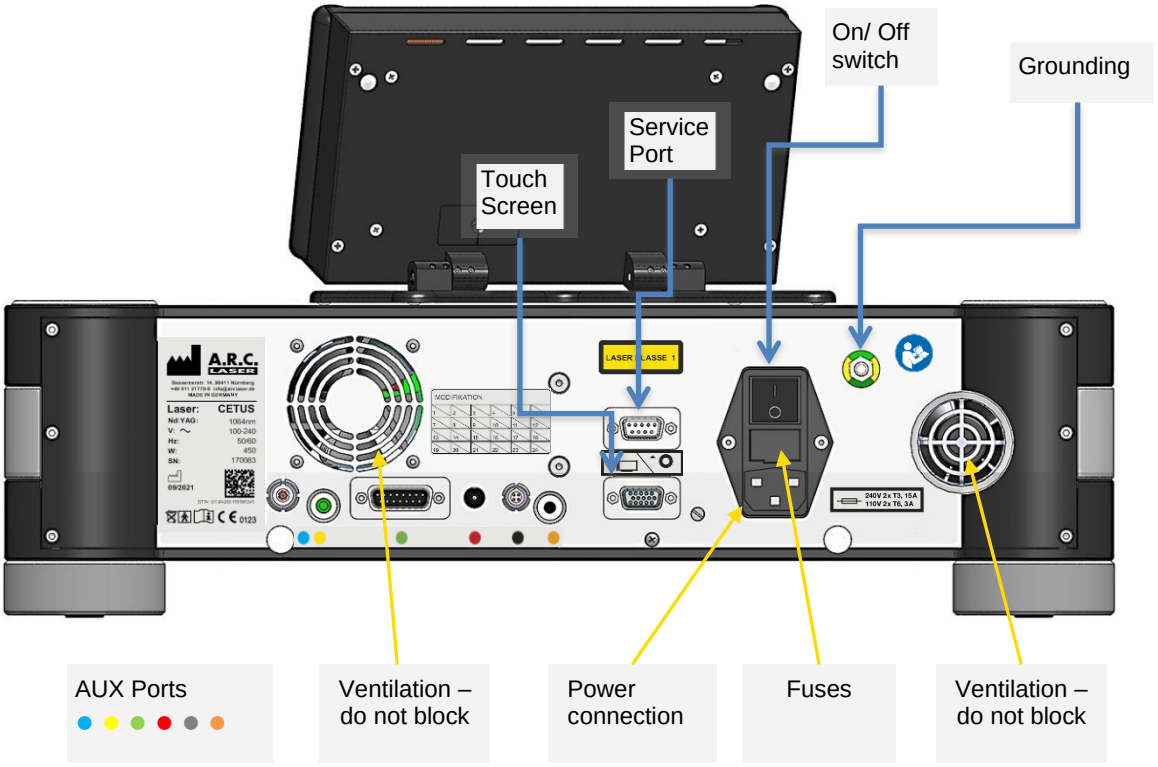
Our company operates worldwide and considers the protection of the environment and natural resources as a corporate obligation. Based on individual tests we can for the products of ARC Laser GmbH confirm that these substances are not present in concentrations according to our knowledge, the marketing of which is prohibited in accordance with the applicable requirement of Directive 2015/863/EU (RoHS3).

4.9 Protective Housing

The CETUS has a protection housing. It prevents that radiation escapes from the laser and protects the users from touching live parts. The housing must not be removed. Housing parts should only be removed and replaced by trained A.R.C. Laser GmbH service technicians.

4.10 Connector and Switches

Following connector sockets are located on the back of the device.



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

Ports	Description	Usage	Color
External foot switch	Connector for the A.R.C. foot switch with cable connector	12 V, only for service personnel	Blue
Grounding	Connector for grounding	Used for electrical grounding, protects the device from static discharge	Yellow-Green
Power connection	Connector for the power cable	Only use power cable approved by A.R.C. Laser	-
AUX Ports	Currently without use	Do not insert any plug	Yellow, green, red, silver and orange

A T T E N T I O N
To avoid the risk of electric shock, this device must only be connected to a supply network with a protective earth conductor.

4.11 Safety Switch

The CETUS has an internal fiber switch. This switch is enabled by inserting the probe. Only, if the probe is inserted properly, the device can be used.

4.12 Manual Reset

If an error occurs, the system shows an error message. You should switch the device off and on again. The error should be eliminated by the restart due the automatic re-calibration. Please refer to chapter 8.5.3 to identify the error messages.

If the device cannot be started again, only qualified personnel can resolve an error. Please contact your local A.R.C. Laser GmbH authorized contact person.

4.13 Reset by Power Failure

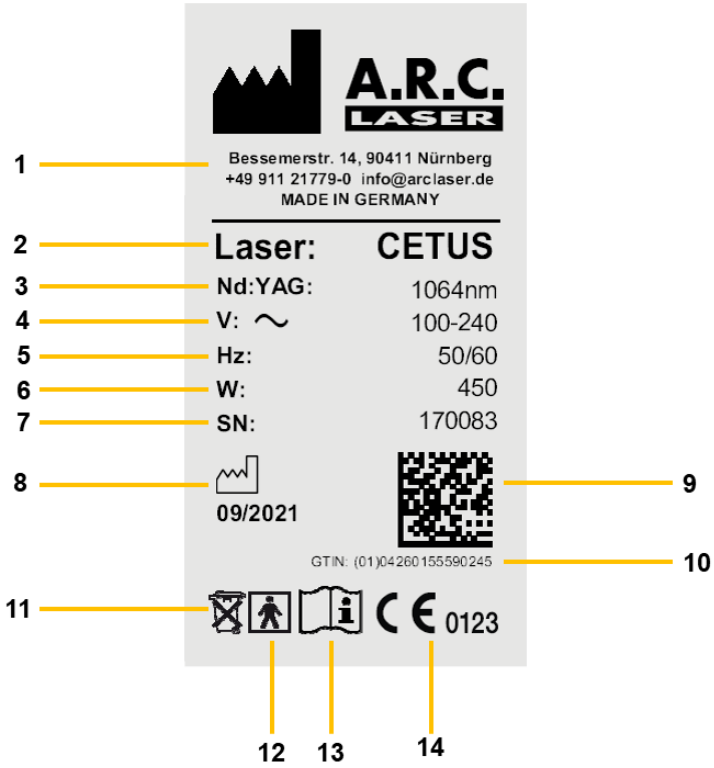
If the device is disconnected from the power supply network, e.g. due to a power failure, the CETUS usually restarts automatically. The system recalibrates and deletes all un-saved settings. If there is still an error, it can only be corrected by trained personnel. Please contact A.R.C. Laser GmbH service department if such an issue occurs.

4.14 Labels and Markings

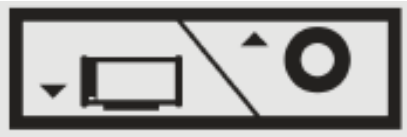
The CETUS has various warning labels in accordance with the European directives, intended to prevent any laser users to become exposed to laser radiation because of improper use. Following labels are used for the CETUS:

IDENTIFICATION LABEL
at the back side

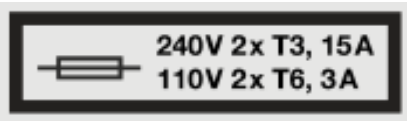
1 Manufacturer
2 Name
3 Wavelength and medium
4 Power input in volt
5 Power input in frequency
6 Power device
7 Serial number (SN)
8 Manufacturing date
9 Unique Device Identifier (UDI = Datum + SN + GTIN)
10 Global Trade Item Number (GTIN)
11 Do not dispose in household waste
12 Applied part BF
13 Follow user manual
14 CE sign



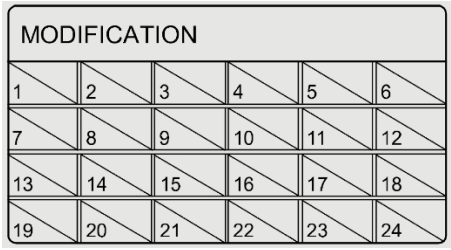
OTHER LABELS



Plugs for service work (above) and for display (below)



Fuse sticker



Modification label

Label for identification of the display

Label of laser class 1

Read manual

4.15 Operating Conditions

The CETUS is not suitable for use with combustible gas mixtures of all kind.

The device has not been tested for operation in altitudes exceeding 2,000 m above sea level. It is only released for an air pressure between 1080 hPa and 750 hPa.

The following ambient conditions have to be provided:

- Ambient temperature: 16˚ C to 30˚ C
- Air humidity: < 75%

4.16 Electromagnetic Compatibility

The CETUS Laser complies with the EMV requirements according to DIN EN 60601-1-2:2015. Guidelines and manufacturer's declaration are described in Section 10.

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

5 Advice for Users

5.1 Technical Introduction Training

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

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

5.2 Laser-Safety Training

The CETUS is designed for medical applications. It may only be used by personnel who have been instructed in its operation. Since the CETUS is a laser of class I laser safety training is not required. Nevertheless, A.R.C. Laser GmbH recommends to attend seminars in which working with different system is explained. We also recommend to visit users who have the system in use and can provide information on its effects and use. A.R.C. Laser GmbH holds a list with contacts for which you can ask for.

5.3 Medical Introduction

In the context of the 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 user. Please contact your responsible administrator or A.R.C. Laser GmbH directly.

5.4 Medical Device Parts and Accessories

The basic version of the CETUS contains following items that can be reordered at any time:

Part	Description	Article-No.
Power Cable	EU power cable 5.0 m UK power cable 5.0 m US power cable 5.0 m	KB13003 KB12004 KB13005
Display	Display for operation	BG07020
Cable	Cable to connect the display	KB07003
Connection tube	Connection tube to connect the device with the phaco system	WE07000
Probe	Laser probe (CETUS probe)	LY11004s
User Manual	User Manual	-
Transport box	Transport box for CETUS	VP01092

For further information about accessories, please contact A.R.C. Laser GmbH or your local distributor.

A T T E N T I O N

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

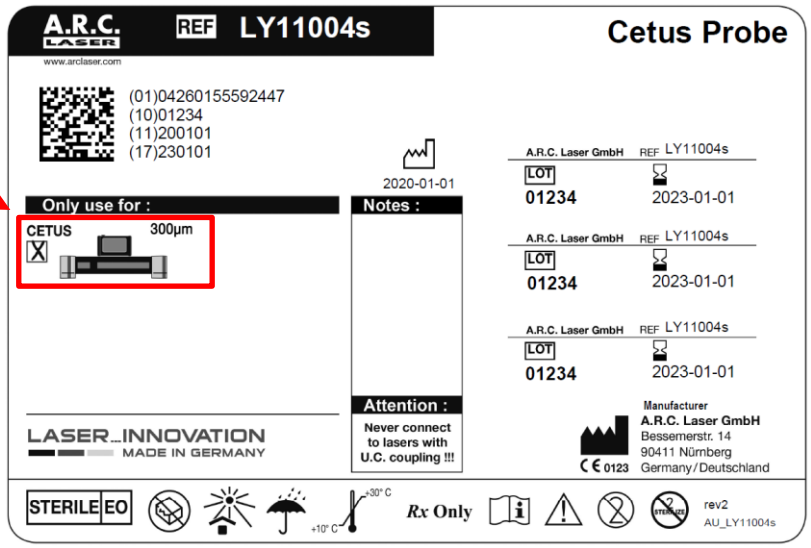
The use of accessories, transduce and services other than those which the A.R.C. Laser GmbH has determined or provided, may result in increased electromagnetic interference or reduced electromagnetic immunity of the device and lead to incorrect operation.

Probes / Applicators

The CETUS is a fiber guided device. It consists of a fiber port at the front of the device. The fiber port is used to insert the patented A.R.C. Laser GmbH probes. A dust protection cover is integrated, to protect the fiber port.

The CETUS can only be used with the corresponding CETUS probe. The labels of the CETUS probe indicate the use with the CETUS laser device.

Suitable for CETUS



A T T E N T I O N

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

6 Operation

This part of the user manual only describes the technical application of the device, without taking medical application into consideration.

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.

If the treatment shall be interrupted, unplug the CETUS probe.

A T T E N T I O N
If the CETUS probe is removed and reconnected again, the sum of shots and energy emitted is deleted.

The front of the device consists the following elements:

Error LED

If the system detects an error, the error LED lights up. The device should be re-started.

Ready LED

If the fiber is connected to the coupling, the Ready LED lights up. If the fiber is removed again, the LED fades.

Fiber port

The CETUS consists of a fiber port at the front of the device. The fiber port is used to connect the patented A.R.C. fiber coupling for the CETUS probe. To protect it, the fiber port is provided with a dust protection.

Connection phaco system

Used to connect the CETUS with your phaco system

Start LED

The start LED shows if your device is switched on

Touch Screen

By using the touch screen, the user can change all settings like power, frequency or setting on the system.

A T T E N T I O N
Never use an applicator if its packaging is damaged or kinked.

A T T E N T I ON
The use of the control panel, settings or adjustments for performing procedures other than those specified herein may result in hazardous laser radiation exposure.

6.1 Preparation

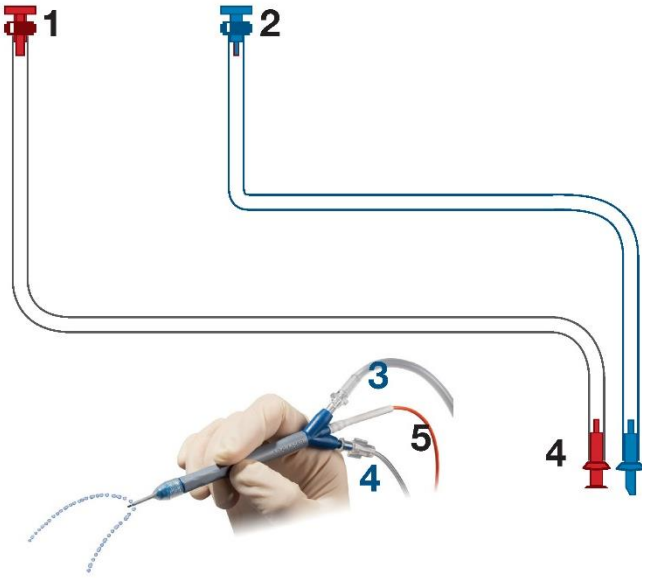
A power cord is sent with the CETUS device, which needs to be connected to the port at the rear panel. Input voltage range is between 100V and 240V. Due to security reasons, your CETUS can only be operated with the power supply distributed by A.R.C. Laser.

Please be aware of the following information, to avoid unnecessary troubleshooting or even possible failures:

- Is the laser connected to the power supply? The power supply should only be connected if the device is switched off.
- Do the probes have any damage?
- Is the system connected to the phaco system surgery system?

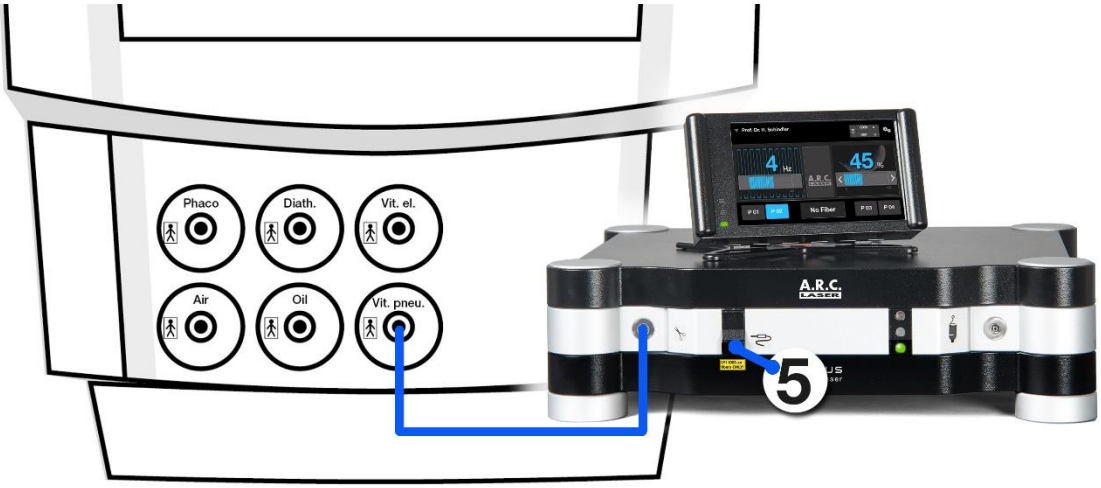
It is recommended to place the CETUS on a dry and solid surface. Ensure a stable stand for the laser system.

Connection to probe with the CETUS:

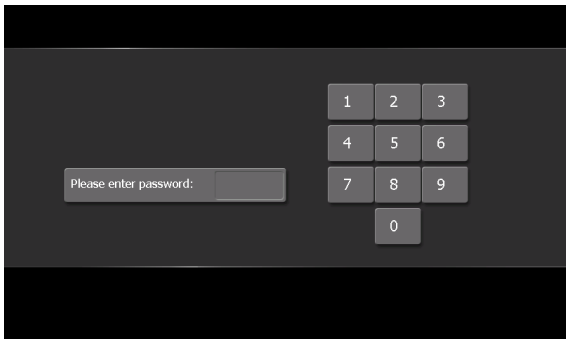


1) Connector to the cassette system
2) To infusion-set
3) To hand piece irrigation
4) To hand piece aspiration
5) CETUS fiber port

Connection to a symbolic phaco system:



6.2 Switch on the Device



To start the device, push the On/Off switch on the rear panel.

The green Start-LED starts to flash. It takes some seconds until the start screen shows up. The green status-LED will be lit permanently.

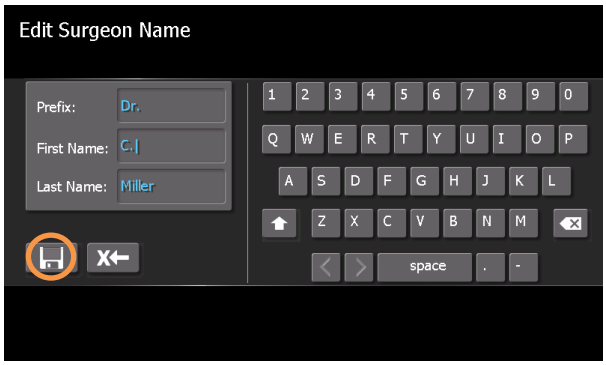
The CETUS Laser executes its system check automatically upon startup.

Once the system check has been completed, the password entry mask appears. By default, the password is "**0000**". Chapter 6.5.8 describes how to change the password, if wished.

6.3 Select/ add/ edit/ delete user

Select surgeon:

After entering the password, you can select the user. After choosing the desired name on the display, you will be redirected to the main menu.

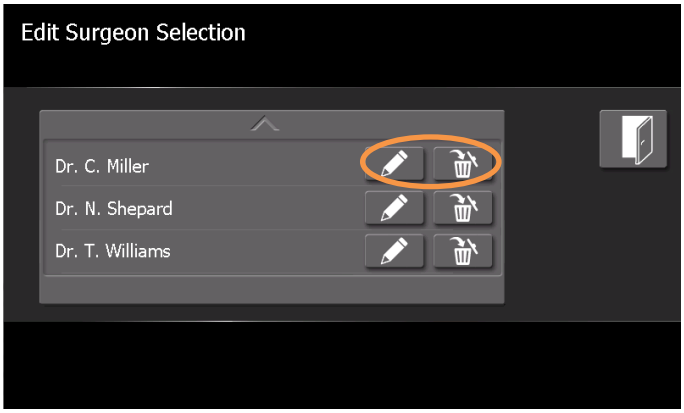


Add surgeon:

You can add a new user by selecting the Add surgeon field. After entering the name, it can be saved using the field for saving (floppy disk).

Change or delete surgeon:

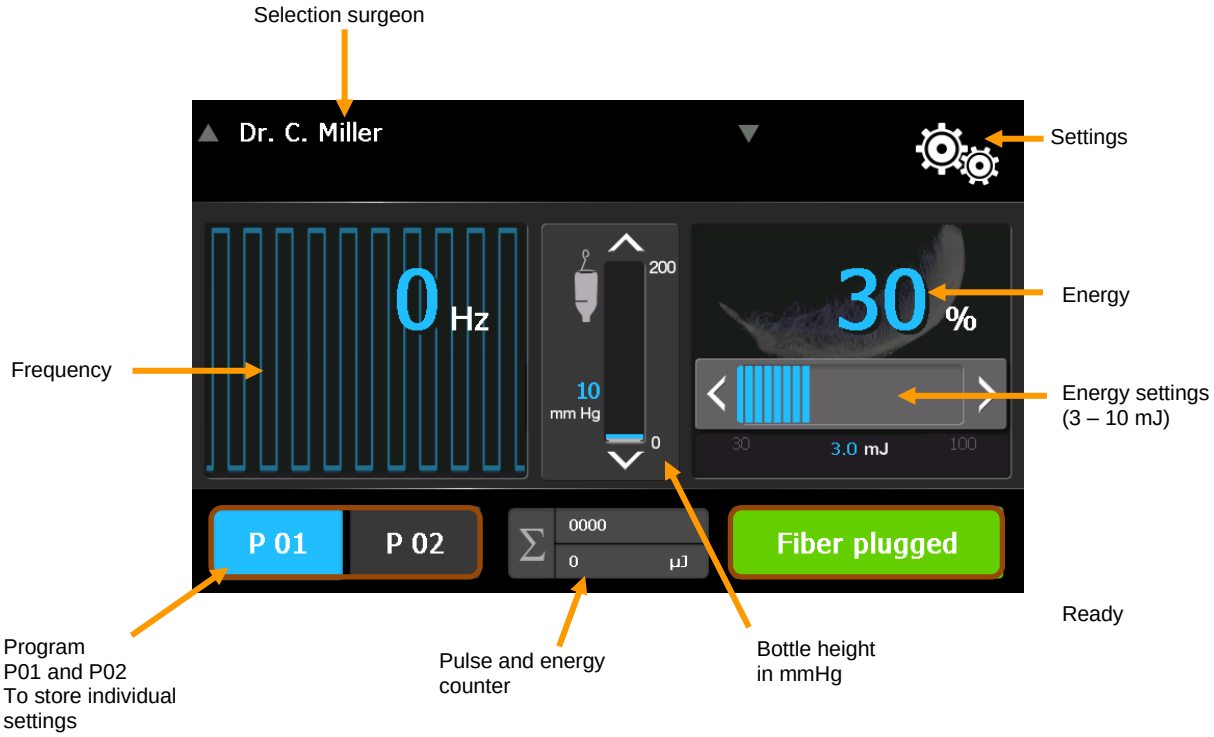
To change a name, select the field. By using the pen symbol, you can change the respective name. Using the delete symbol, the chosen name can be deleted. To return to the main menu, use the door symbol.



As soon as multiple doctors are entered, they appear in the selection list. By using the arrow keys you can scroll through the names. By choosing a name, you will be redirected to the main menu.

6.4 Program and Settings

6.4.1 Display / Main Menu



6.4.2 Energy

The energy is shown in per cent. By changing the energy, you can adjust the generated shock wave used for the treatment individually. The energy can be adjusted using the left and right arrows. Furthermore, the energy set is shown in mJ.

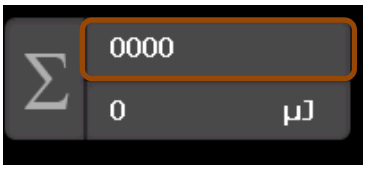
6.4.3 Saving parameters

Parameters can be stored for the next treatments. Press one of the program buttons for at least 2 seconds. After that, the parameters are safed under the chosen programm and can be used at any time.

6.4.4 Standby / Ready

If no probe is plugged in the CETUS is in stand by and the ready field shows “Insert fiber”. Inserting a fiber changes the field to “Fiber plugged”. Additionally, the yellow LED at the front of the device indicates that a fiber is plugged in.

6.4.5 Counter

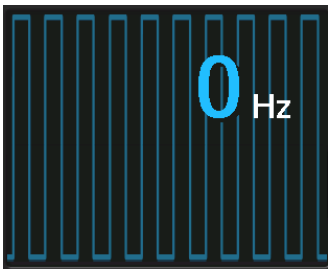


The triggered pulses are accumulated. The device automatically counts thepulses triggered by means of the foot switch. The maximum number of pulses registered is 1.500. When reaching the maximum number of pulses, a sound is audible and a warning message is shown, which signalizes that the probe has to be changed. By changing the fiber, the counter is reset to zero when inserting a new fiber.

6.4.6 Cumulated energy

The displayed energy value is the product resulting from the set power and the actual time of exposure as well as the number of pulses triggered. By changing the fiber, the energy-counter is reset to zero.

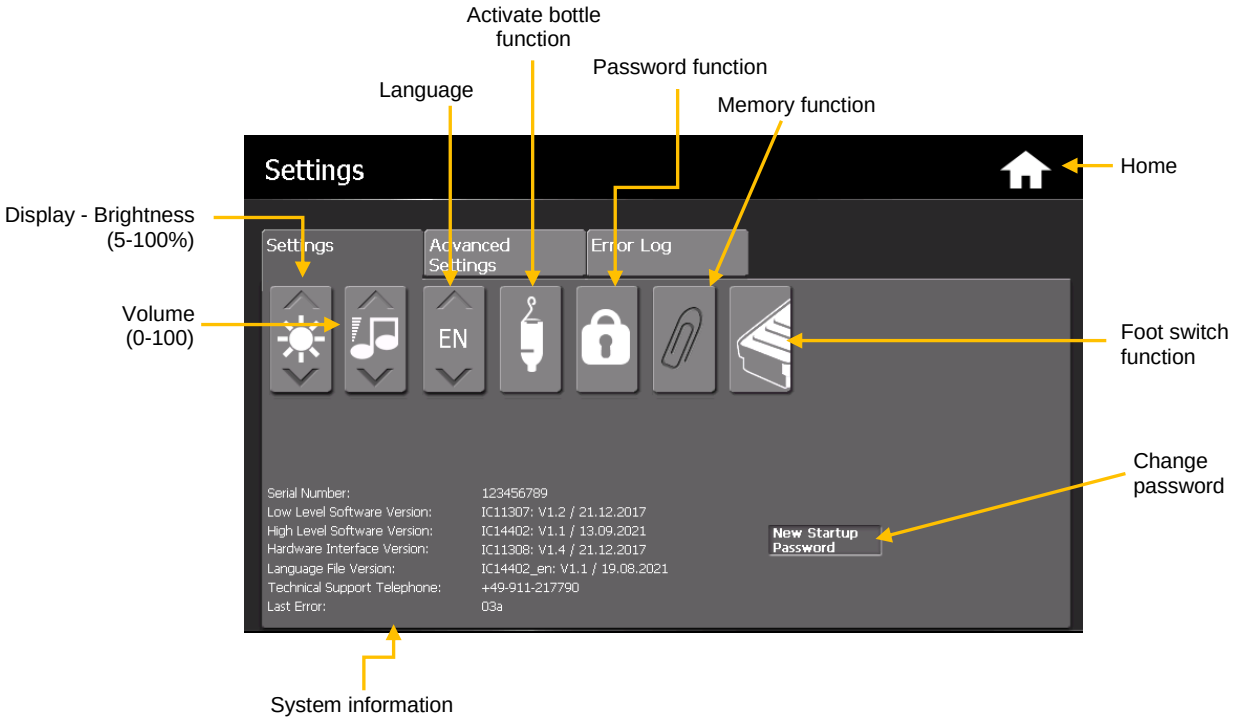
6.4.7 Frequency



The frequency value depends on the settings of the phaco system and is set to the number of pulses per second.

6.5 Submenu

Leave the main menu to enter the submenu by pressing the gear wheels.



6.5.1 Display brightness

The display brightness can be set darker or brighter according to your preferences and to the lighting conditions. Use the arrow buttons to increase or decrease the brightness.

6.5.2 Volume

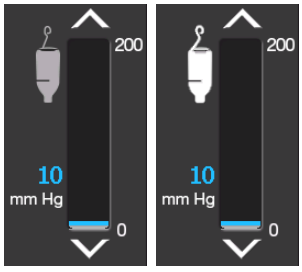
Furthermore, you can set the volume of the tone signals individually.

6.5.3 Language

Set the language to your wishes, using the arrow buttons.

6.5.4 Activate bottle function

Please be aware that the bottle function can only be activated if a pressurized pump is installed with the corresponding order. When the function is activated in the submenu, the air for the pressurized infusion can be set on the display of the CETUS. Within the main menu you can now activate and deactivate the pumping function by pressing the bottle. When activated, the bottle appears in white.



6.5.5 Deactivate password function

For easy and fast operation of the device, it is possible to deactivate the password after system check. For that, deselect the lock (appears in grey). After selection, leave the submenu to safe the setting.

6.5.6 Memory function

The memory function helps to safe the settings of the device. When the CETUS is switched on, the parameters, like language, user or volume, stay the same as when it was switched off. The function is signalized with a bright paper clip. If the paper clip is deselected and therefore dark, the CETUS starts with the user login. Leave the submenu after selection to change the settings.


dark


bright

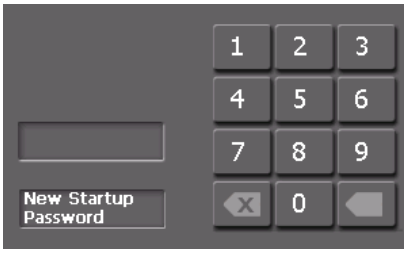
6.5.7 Foot switch function

The foot switch function is only used in service cases and has no function for the CETUS user.

Make sure that the foot switch symbol is dark to use the CETUS.

6.5.8 Change password

This tool is used to change the user password, which is entered after the start routine.



You can change the password according to your wishes. The password consists of four numbers (standard is **0000**). The menu guides you through the routine for changing the password:

(1) Insert old password

(2) New password: Please insert your desired four-digit password

(3) Confirm password: Repeat the new password

6.5.9 System information

The system information shows the actual software version. Additionally, it consists information about the serial number as well as the last error shown on the device.

6.5.10 Advanced settings

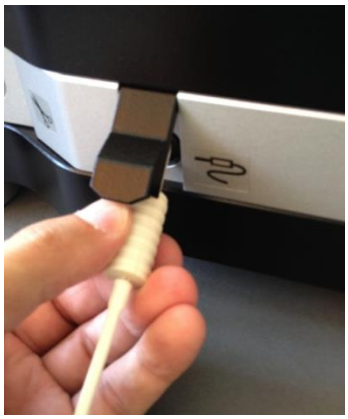
Next to the user settings, the CETUS also holds advanced settings. Those settings are secured with a special password and are only to be used or set by briefed service personnel.

6.5.11 Error log

The error log is used for the service personnel to read out previous errors and is also not accessible for the user.

6.6 Inserting the applicator

After the energy is set, the CETUS probe can be connected to the device. To do this, insert the fiber plug into the opening until it locks into place.



If the plug is not connected properly, the device does not change into “Ready” mode (Fiber plugged). Please pay attention to the clearly perceptible "click" when plugging in the fiber!

After the plug is properly connected, the device is ready to use. Pulses can be emitted through the handpiece, when using the foot switch. It must therefore be ensured that the applicator is in the eye in accordance with the medical application and is not directed at flammable material.

6.7 Treatment

Positioning the patient and select the necessary settings. Insert the Fiber to change to “Ready” mode. The treatment can be started.

The CETUS is now waiting for the pneumatic pulses of the phaco system, which are emitted by the foot switch of the phaco system. When the CETUS is connected to the pressure signal of the phaco system, the frequency is set analogous to that of the phaco system.

The software of the CETUS permanently sums up the energy, which is shown in the lower part of the display.

Remove the probe after use to set the CETUS back into the “Standy by” mode. No more energy can be released and the total energy can be noted.

Be aware that not more than one person touches the device at a time.

A T T E N T I O N
Any serious incident that occurs with this device must be reported to A.R.C. Laser GmbH and the responsible state authority.

6.8 Switch off

The CETUS is switched off by using the On/Off switch on the rear panel of the device.

6.9 Symbol Description

	Display brightness (5-100%)		Select language
	Ton volume (0-100%)		Safe last settings
	Main menu		Change foot switch function
	Settings		Edit name
	Change password function		Delete user
	Change bottle function		Leave screen
	Warning		Safe user
Insert Fiber	No fiber plugged, Stand-By Mode	Fiber plugged	Fiber plugged, Ready Mode

7 Technical Data

7.1 General

Model	CETUS
Cooling	Air, internal
Weight	12 kg
Dimensions	H 13.5 cm / W 47.8 cm / L 42.1 cm
Touch-Screen	H 13.8 cm / W 21.6 cm / L 14.2 cm
Control	Digital touch screen

7.2 Device Data

Energy	3 – 10mJ
Pulse length	5 ns
Shot frequency	variable 1 Hz to 25 Hz
Power Transfer	Fiber 300 µm with hand piece
Operation Mode	pulsed

7.3 Power Requirements

External power requirement	100 - 240 V AC, 50/60 Hz, 5A

7.4 Classifications

Laser class: (Classification: EN 60825-1)	1
Electrical protection class: (Classification: IEC 60601-1)	I
Classification according to MDD/MDR:	IIb Rule 9
Certification:	CE 0123

8 Service

8.1 Introduction

The device was designed, developed and tested according to research based on state-of-the-art technology. The product life has been set to 7 years. In addition, the availability of spare parts is guaranteed by A.R.C. Laser GmbH 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.

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

8.2 Safety inspection

Once within 24 months, the laser should 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.

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
- Overall condition

Functionality check

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

Electrical Safety Check

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

Output power measurements

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

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

8.3 Care by the user

The following maintenance instructions can be carried out by the user. These serve to make your work easier. The system must be disconnected from the mains for cleaning. 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. 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.

A T T E N T I O N
Please only clean the device with a damp cloth. Penetrating humidity increases the risk to damage the display

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

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

*This list is not exhaustive.

A T T E N T I O N
When cleaning the device, it must always be switched off and disconnected from the mains. Wet wipes should be avoided in any case. The penetration of water or disinfectant can lead to defects.

8.4 Cleaning of accessories

8.4.1 Hand pieces

The CETUS handpieces are single use sterile products. It is not allowed to re-sterilize the probes. Please refer to the user manual of fibers and probes for more information.

8.4.2 Connection tube

Cleaning the connection tube of the phaco system shall be done according to cleaning of the device, see chapter 8.3

8.5 Error Detection

The CETUS was developed and designed as a modular system. In addition, all its components had undergone a rough shake test as well as temperature testing. In case of an error, you can use these instructions to isolate the problem. In most cases, you should be able to resolve the problem yourself. If the problem persists, please contact your local A.R.C. Laser authorized dealer for technical support.

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

8.5.1 System Self Check

In general, a system self check will run after turning on the device, to check all important functions. If a failure occurs, you will be informed immediately about the detailed error on the screen, see chapter 8.5.3.

8.5.2 Troubleshooting

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

Problem	Potential Error	Troubleshooting
Black screen	Monitor-cable is loose / not connected	Check if the monitor cable is firmly inserted. You might plug it off and in again.
No Nano pulse	Fiber optic is not connected correctly, or is defective	Check the connection and position of the fiber connector. You might have to change the hand piece. In case of a defective hand piece and ask our A.R.C. Laser representative for replacement
	Connecting tube is not connected	Check and correct the connection of the tube.
	Wrong program set on the phaco system	Check the program, which has to release the pneumatic pressure pulses (vitrectomy mode)

8.5.3 Error codes

Following error will be identified during the system check or during use. If such an error occurs, restart the device. Please contact service, if the error persists anyway.

Error message	Short Description	Error message	Short Description
F00	Error system start	F38	DAC error
F08	Short circuit foot switch	F47	Error check sum
F18	Error Q-Switch driver	F49	Error IC-Chip combi
F23	Error system voltages (+ 12V)	F50	Error I²C-Bus
F24	Error system voltages (+ 5V)	F65	Communication error
F25	Error system voltages (+ 24V)		

8.5.4 Error messages

	Attention	Consider Error message or wait

8.5.5 Status messages

	Please wait

8.6 Disposal

The relevant, local applicable laws and regulation must be respected during disposal. The device must not be disposed with domestic waste under any circumstances.

A.R.C. Laser GmbH will help you with disposal of the system. Costs for proper return of the device to A.R.C. Laser GmbH is under the responsibility of the customer. Please contact our service department.

9 Customer Service

9.1 Warranty Information

A.R.C. Laser GmbH provides a two-year warranty. Within these two years, any parts showing a defect will be replaced free of charge. This does not include any add-on parts or purchased parts. Our warranty covers the repair works and the replacement of defective parts. However, we reserve the right to renew entire assemblies and adapt them to the 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 explicit written confirmation of A.R.C. Laser GmbH.

9.2 Warranty Consignments, Packaging

A warranty claim for defective parts, malfunction or damage of the housing of the device shall be passed on to A.R.C. Laser GmbH within 24 hours. Parts returned during the warranty period (upon the explicit request of A.R.C. Laser GmbH), are subject to the written confirmation by A.R.C. Laser GmbH. Detailed packaging instructions and information on how to return the device will be provided by A.R.C. Laser GmbH. The return consignment shall be insured and the costs arising hereof are not covered by A.R.C. Laser GmbH. A.R.C. will notify the customer of the choice of return. Any changes as well as the change of the transporter or the type of shipping may result in delays in transport and handling. Any other components covered by the warranty claim will be renewed by A.R.C. free of charge within the warranty period. We reserve the right to modify the design of the device – if necessary – thus increasing the safety or the functioning of the device. The responsibility for the design as well as any modifications of the device lies exclusively with A.R.C. Laser GmbH. Changes will be communicated to the customer by A.R.C. Laser GmbH.

9.3 Sales and Service Information

For information about sales and service please contact A.R.C. Laser GmbH or your local sales representative.

10 Guidelines and Manufacturer's Declaration

10.1 Electromagnetic Emissions

<table>
<tr><td colspan="3">The CETUS is intended for use in an environment as specified below. The customer or the user of the laser should ensure that it is used in such an environment.</td></tr>
<tr><td>Immunity tests</td><td>Compliance</td><td>Electromagnetic environment – guideline</td></tr>
<tr><td>RF emissions CISPR 11</td><td>EN 55011
Group 1/Class B</td><td>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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>EN 55011
Group 1/Class B</td><td rowspan="3">The device is only suitable for the environment in professional healthcare facilities.</td></tr>
<tr><td>Harmonic emissions</td><td>IEC 61000-3-2
Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker</td><td>IEC 61000-3-3</td></tr>
</table>

10.2 Electromagnetic Immunity (1)

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

Immunity tests	IEC 60601-Test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharce (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 usuallty 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.

Power interruption	0% UT; 250/300 cycles	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 device is intended for use in the electromagnetic environment specified below. The customer or the user of the laser should ensure that it is used in such an environment.

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

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

The device 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

Notes:

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