User Manual

PCL5 ZD PCL5 SHD

A.R.C. Laser GmbH

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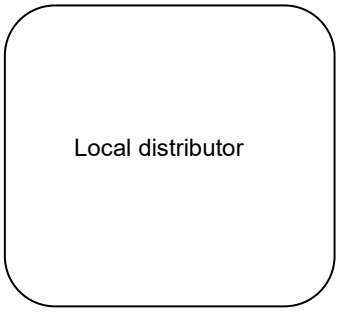

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1 Introduction

We thank you for having chosen our PCL5 SHD/ZD and wish you every success in using this slit lamp.

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, 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.

1.2 Intended use

The PCL5® is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. With lenses or contact glasses the examination area can be extended right up to the retina. It is used to aid in the diagnosis of diseases or trauma which affects those areas of the eye.

1.3 General contraindications

A T T E N T I O N

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

1.4 Characterization of the User

1.4.1 Physician

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

1.4.2 Medical assistant

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

1.4.3 A.R.C. Laser Service Technician and medical technician

Typical job title	A.R.C. Laser Service technician, Medical technician
Provided education	Vocational training, Training by experienced A.R.C. employees
Demographic particularity	Not necessarily native speakers, speaks language of the organization at least at B2 level
Provided work experience	N/A
Typical work environment	Examination room, service department A.R.C.
Typical work	Installation, Servicing, Safety Check
Provided training	Training for PCL5

1.5 Characterization of the Patients

The *PCL5* can be used independent of patients age or gender. Restrictions occur, when the patient is not able to place his eyes in front of the slit lamp, respectively to place his head and chin on the chin rest. This can be the case for disabled patients, patients with a need to lay and babies.

1.5.1 Indications and contraindications

Medical Application indicated	**Indication** from clinical data	**Side and adverse effects**	**Contraindications**
ophthalmic diagnosis	preventive eye examinations or a specifically diagnostic examination in case of an existing disease to work out a diagnose	Glare, in case of unintended overexposure of light to the eye: vision loss	-
ophthalmic diagnosis: tonometry	the PCL5 slip lamp can be used to set the tonometer at the right position to measure the intra ocular pressure	Glare, in case of unintended overexposure of light to the eye: vision loss	-
ophthalmic diagnosis: gonioscopy	the PCL5 slip lamp can be used to allow a view via the gonioscope into the chamber angle of the anterior chamber of the eye	Glare, in case of unintended overexposure of light to the eye: vision loss	-
ophthalmic therapy: laser therapy	the PCL5 slit lamp can be used with a laser to treat eye diseases when light and laser radiation are parallel adjusted to allow easier laser radiation application	Glare, in case of unintended overexposure of light to the eye: vision loss – other side effects are related to the laser use	-
ophthalmic diagnosis: adjustment of contact lenses	the optimal adaptation of contact lenses can be observed with the help of the magnification of the PCL5 slit lamp	Glare, in case of unintended overexposure of light to the eye: vision loss	-

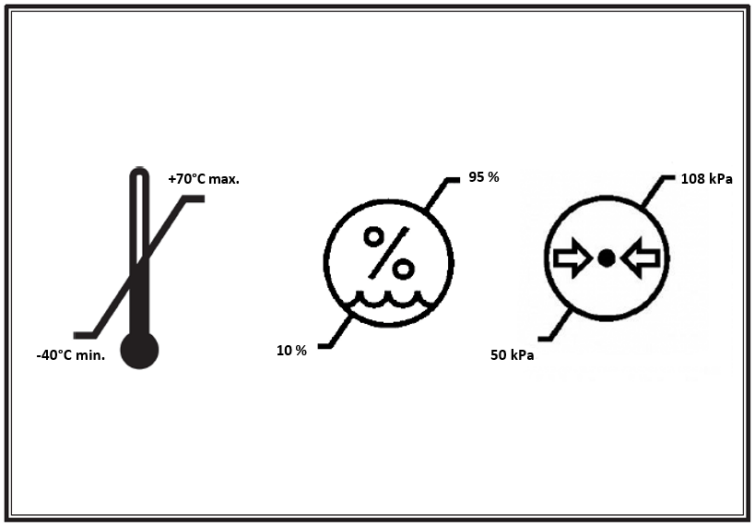
1.6 Theory and technical set-up

The PCL5 SHD/ZD slit lamp is an optical device which allows the user to direct a sharply defined slit-shaped beam of light to the eye of the patient, where the width of the slit can be changed by the user. Furthermore, the eye can be inspected by the use of a binoculars. The binocular has a magnification of 12.5x and can be adapted between +8 and -8 diopters. The optical zoom of the slit lamp can be adjusted from 6.3x to 40x. The optics within the slit lamp are illuminated from above. Different filters are included to adjust the slit lamp according to the application use. Also, the illumination intensity through the slit and its orientation can be adjusted . For directing the patients visual axis and eye orientation, a light is mounted on the slit lamp which facilitates the patient looking at this adjustable target.

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 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 -40° C and 70° C. The air pressure during transport must be between 500 hPa and 1080 hPa. During storage, a temperature range of -10° C and 55° C must be maintained. The environment/air must be dry and clean. The relative humidity during transport and storage must be between 10 % and 95 %.

ATTENTION

If the device is transported or stored at a temperature below -40°C, it can be damaged when starting. Unpack and leave it for at least 12 hours at normal room temperature so that the system reaches room temperature.

2.1 Shipping and unpacking the device

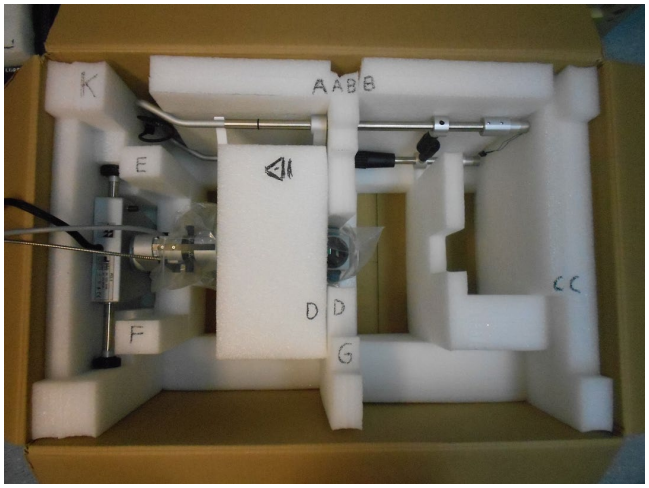
Unpacking and installation of the device is normally done by an authorized technician. After installation and the correct connection of the device, the technician will put the device into operation and explain the function of the device. All functions and safety procedures are discussed and demonstrated here.

If you wish to install the device by yourself, a description for installation can be found in chapter 4.

2.2 Return shipment

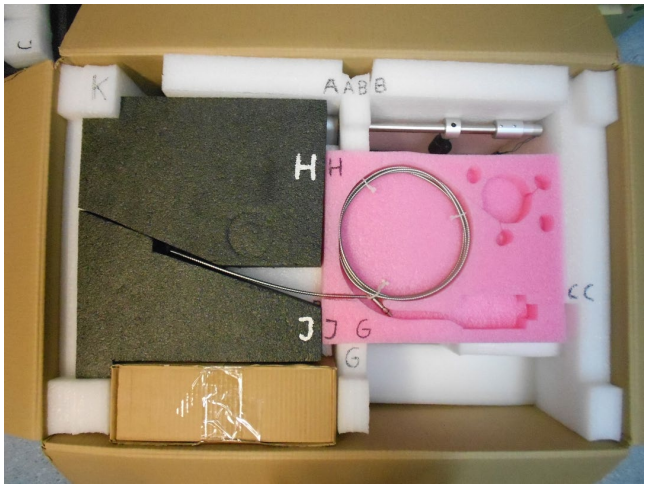
The device will be shipped in a specially developed transport packaging. Please keep this. If you ship the device back to A.R.C. Laser GmbH, be sure to use the intended transport packaging.

The transport packaging is designed so that the device fits snugly into the foam parts.



All accessories are stowed in an extra padding inside the transport packaging.

If all foam parts are in the right place and the box is closed, the device is ready for shipping.



3 Set-up and installation

3.1 Installation Site

Before the device is delivered, it must be ensured that the slit lamp can be set up in a suitable location.

The slit lamp is attached to a lifting table. The table should be positioned and operated in an easily accessible place. In order to protect the internal optics of the slit lamp and prevent permanent damage to it, the working temperature should be between 10° C and 35° C

The device should be operated in a dust-free room. There should be no carpets on the floor or walls. When the device is not in used, it should be covered with the dust protection cover.

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 must be between 30 % and 90 %.

3.2 Electrical connection

The power is supplied by an external power supply, which is permanently fixed to the slit lamp table. The power supply unit may only be connected to an earthed wall socket and can be operated from 100 V – 240 V (50/60 Hz) AC voltage.

Make sure that the plug is accessible at any time so that the device can be disconnected from the mains after use.

4 Safety Information

The PCL5 SHD/ZD has been carefully developed to meet the requirements of ISO 10939 and ISO 15004 standards.

Also, to the best knowledge of A.R.C. Laser GmbH, our products do not contain any substances in concentrations whose placing on the market is prohibited according to the applicable requirement of Directive 2015/863/EU (RoHS3).

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

With regard to the instrument table, reference is only made here to the danger from improper use as a seat or storage area. When operating the height adjustment, make sure that no one can be harmed.

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

4.1 CE-Marking

The PCL 5 bears a CE mark in accordance with Regulation (EU) 2017/745. The device has been checked for electrical and mechanical safety. All parts used comply with the CE regulations.

Additional devices that are attached to the device require approval from an official test center. Changes to the device or intervention on your part will void the approval and warranty.

4.2 Electrical protection

Never remove any parts of the device. Work on the device may only be carried out by authorized technician.

The room in which the PCL5 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 device or its accessories if you notice any visible defect on it.
Never use the device if you notice any visible defect on the power plug, wires or when the supply lines are exposed.

4.3 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 (RoHS3).

4.4 Labels and markings

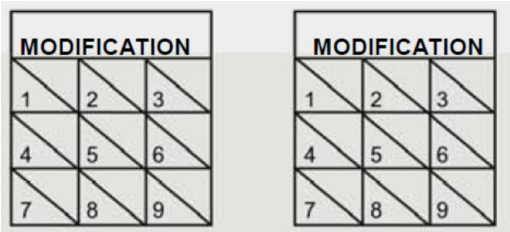
The PCL5 bears labels and markings in accordance with European and worldwide guidelines.

4.4.1 Type plate

PCL5 ZD

PCL5 SHD

4.4.2 Modification Label



4.4.3 Warning signs

4.5 Operating conditions

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 800 hPa.

The following environmental conditions must be met:

- Ambient temperature: 10° C to 35° C
- Relative humidity: <90 %

4.6 Electromagnetic compatibility

The PCL5 meets the EMC requirements according to EN 60601-1-2. Guidelines and the manufacturer's declaration are described in chapter 10.

ATTENTION

Avoid using the 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.

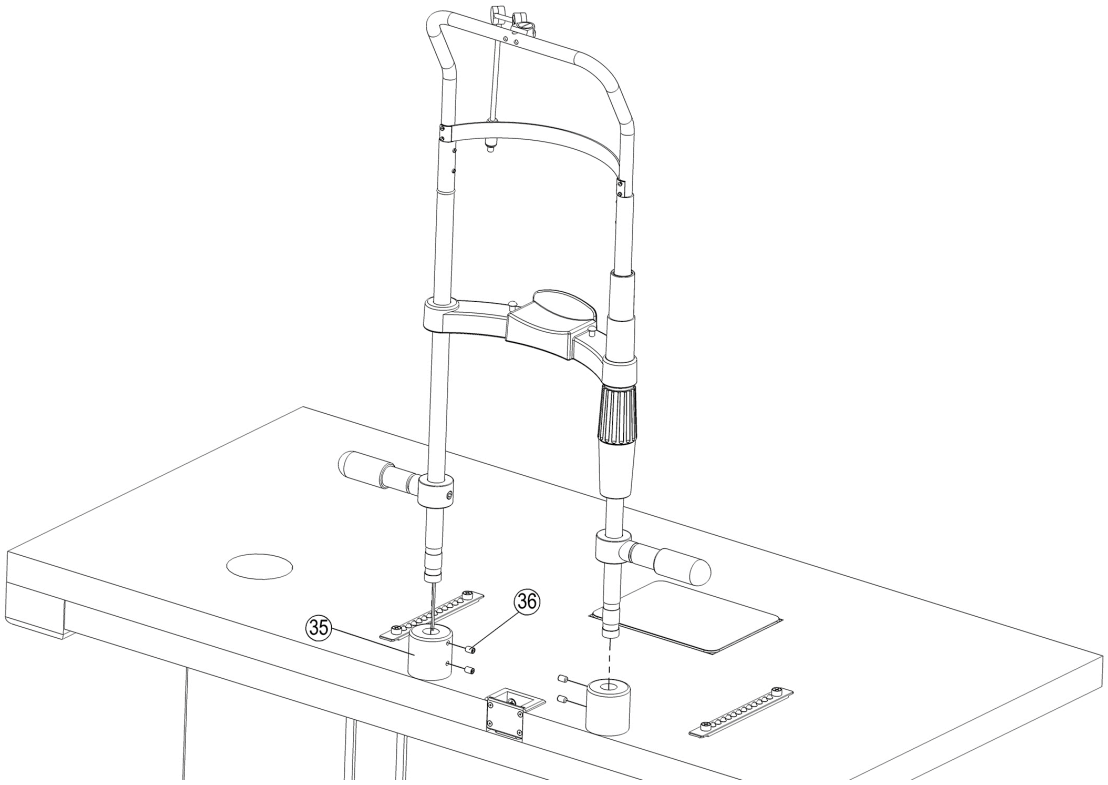
5 Installation

5.1 Installation PCL5 SHD

Typically, the slit lamp is installed by an authorized technician of A.R.C. Laser or a representative. Nevertheless, there is the possibility to install the device independently by the user. For that the following steps should be respected. The following images are for illustrative purposes only and do not represent the exact appearance of the device.

5.1.1 Installation of the chin rest

- Take out the chin rest from the package.
- Fasten the chin rest using the provided discs (35) which are preinstalled at the slit lamp table using the screws (36).

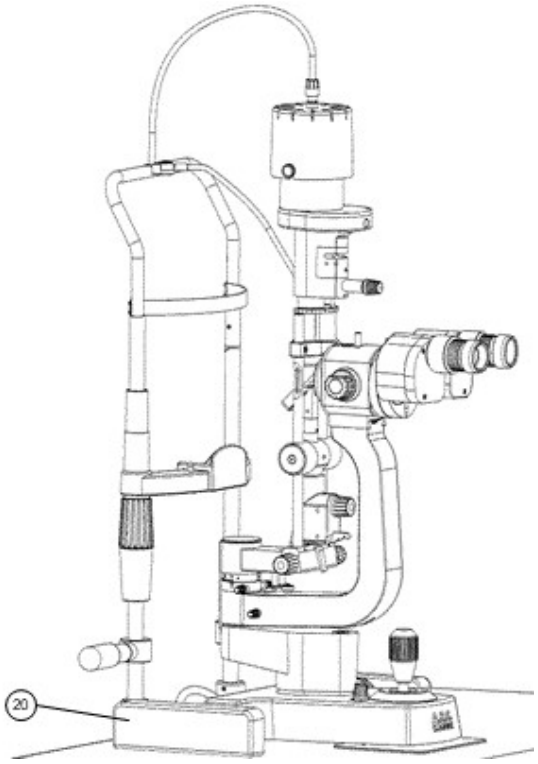


ATTENTION

Ensure that the electrical connection cable for the fixation lamp will not be damaged when it is passed through the left fixation hole (35).

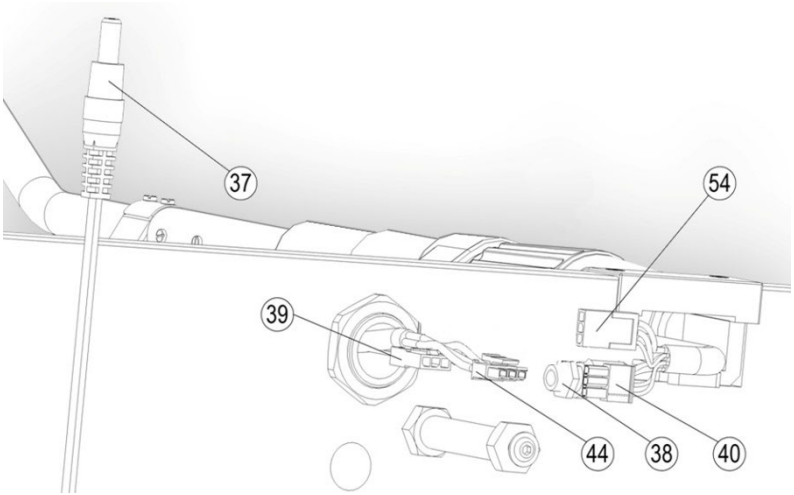
5.1.2 Installation of basic device

- Take out the main device and put it on the rails
- Put the left and right cover for the toothed racks (20). Those covers prevents the device to fall over



5.1.3 Connection of electrics

- Connect the main plug (37) with the socket (38)
- Connect the plug from the chin rest (39) with the socket (40)
- Connect the plug (44) for the illumination with the socket (54)
- Connect the power supply with the socket using the power cable

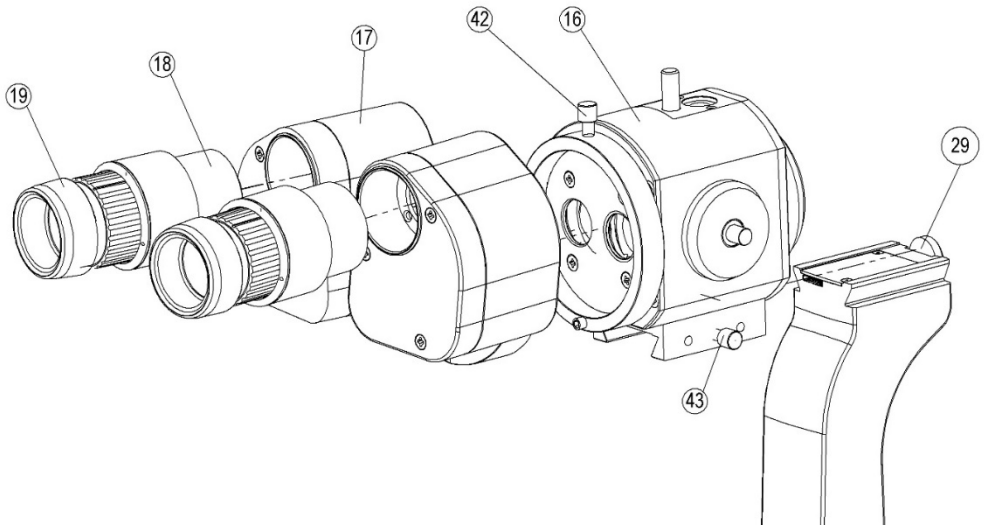


ATTENTION

Please check if the connections are properly fixed.

5.1.4 Installation binocular

- Put the oculars (18) into the binocular tube (17)
- Mount the binocular (17) with the clamping screw (42) on the binocular coupler (16)
- Move the binocular to the stopper screw (29) which is on the dovetail of the binocular arm and fasten it with the clamping screw (43).



ATTENTION
Never look into the sun with the binocular of the slit lamp.

5.2 Installation PCL5 ZD

Typically, the slit lamp is installed by an authorized technician of A.R.C. Laser or a representative. Nevertheless, there is the possibility to install the device independently by the user. For that the following steps should be respected. The following images are for illustrative purposes only and do not represent the exact appearance of the device.

Preparation of slit lamp table – OEM Version

- Take out the chin rest from the package.
- Transfer with the chin rest angle (31) the position of the mounting holes on the table base and drill with a 1.5 mm drill six holes about 15mm deep. Fasten the chin rest, then use the attached screws (30)
- Drill as displayed in picture 3 with a 1,5 mm drill four approx. 15 mm deep holes into the table base and attach it to the power supply (32) using the attached screws. Take care during positioning of the power supply the available cable lengths for in- and output. If a power supply for direct connection of the bulb already exists you can skip this step.

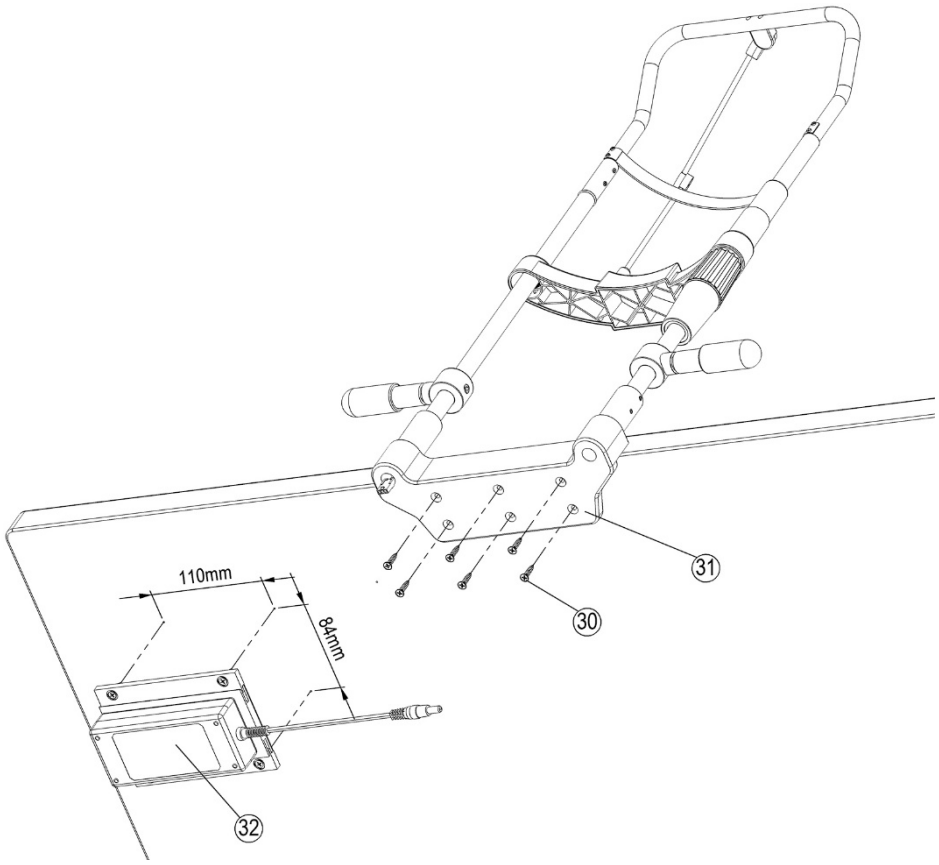


Image 4: Mounting of power supply and chin rest

- Drill with the help of attached mounting template with a 1.5 mm drill four 15 mm deep holes into the tabletop and fasten the two racks (33). Ensure that the spacers (34) are not forgotten.
- Stick to the gliding plate (10) using the mounting template on the tabletop. Please make sure that the tabletop is clean and free of grease.

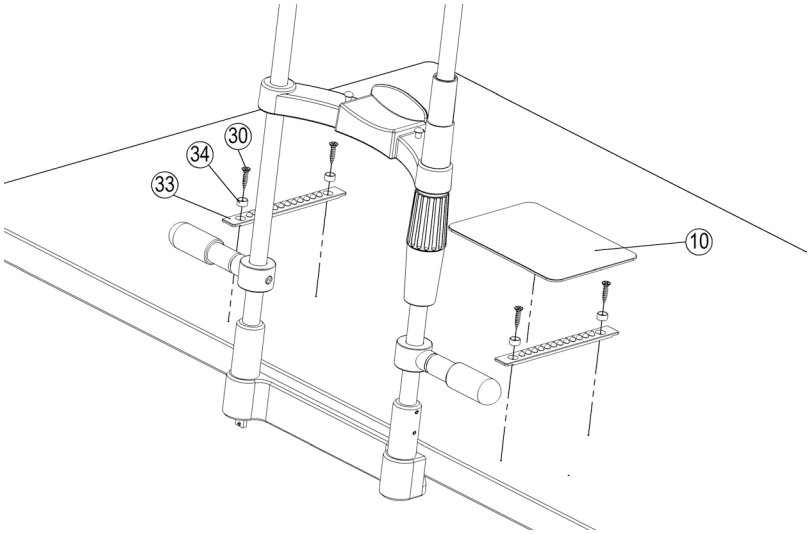


Image 5: Mounting of racks and gliding plate

5.2.1 Preparation of slit lamp table

- Remove the chin rest from the package
- Fasten the chin rest with the attached discs (35) preinstalled at the slit lamp table using the mounting screws (36).
- Pay attention while inserting the chin rest that the electrical connection cable for the fixation lamp will not be damaged during feed through at the fixation hole (35).

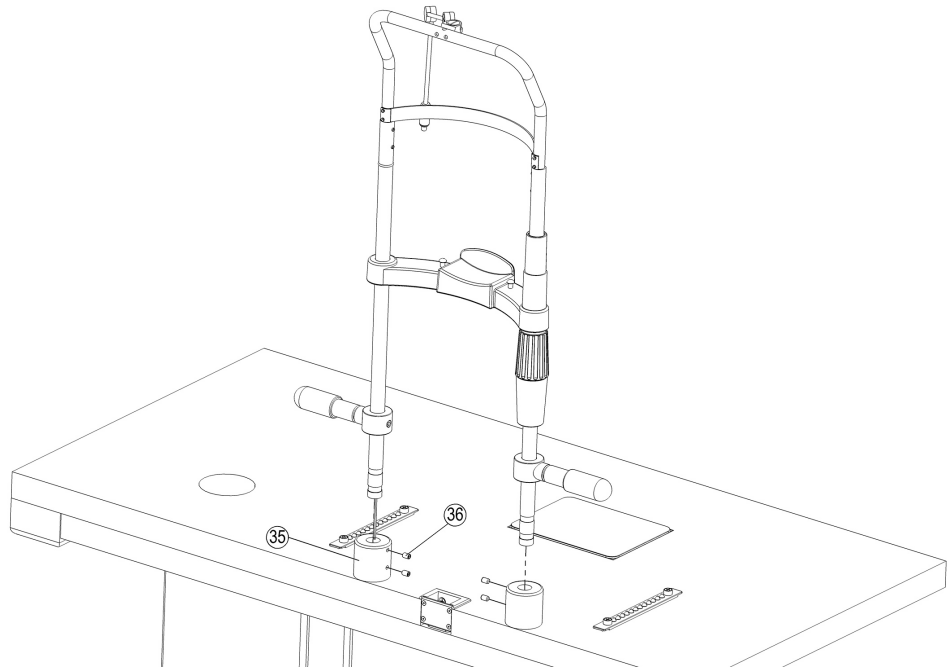


Image 6: Mounting of chin rest on prefabricated slit lamp table

5.2.2 Installation basic device

- Pull out the main device and put it on the rails
- Fix the cap (20) to the left and right rack

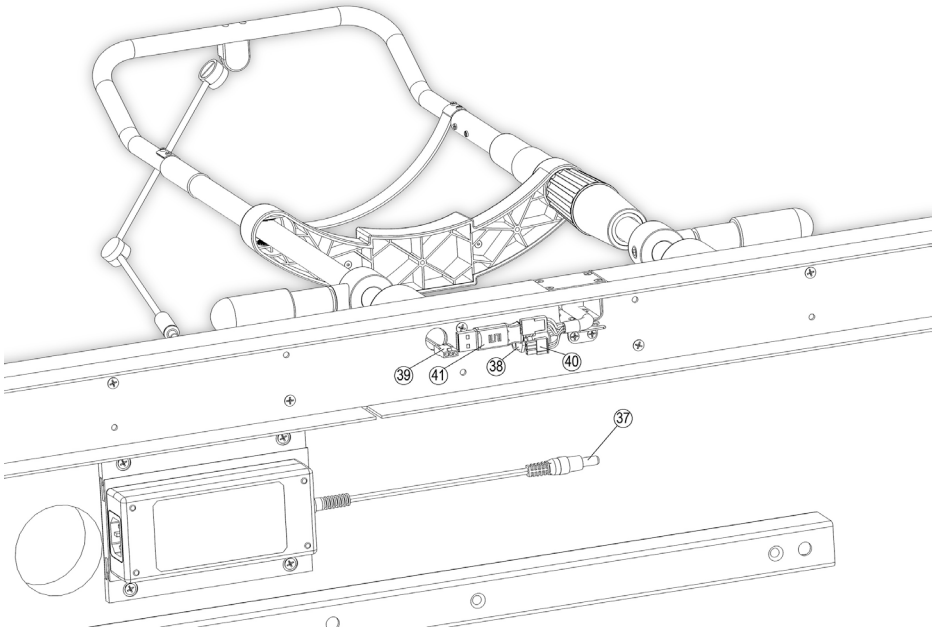


Image 7: Connection of supply cable

- Connect the main plug (37) with the socket (38)
- Connect the plug from the chin rest (39) with the socket (40)
- The plug (41) is only to be used with a Camera adapter (accessory) The Plug 55 is used only for operating the PCL5 SHD. It is not necessary for the slit lamp described here.
- Connect the power supply with the socked using the power connection cable

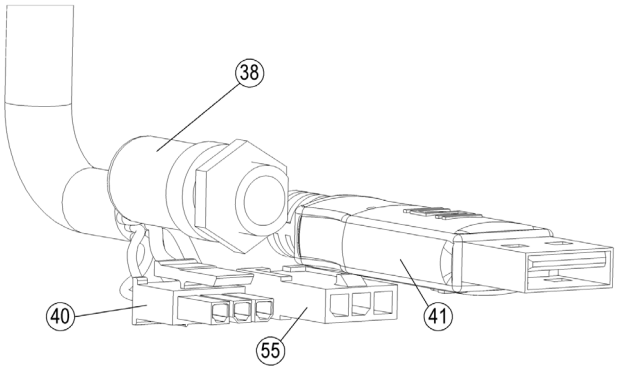


Image 7: Connection of supply cable

5.2.3 Installation of slit lamp microscope

To install the slit lamp microscope put the oculars (18) into the binocular tube (17)

- Mount the binocular (17) with the clamping screw (42) on the microscope coupler (16)
- Slide the microscope until it stops at the screw on the microscope arm and attach it with the help of the clamping screw (43)

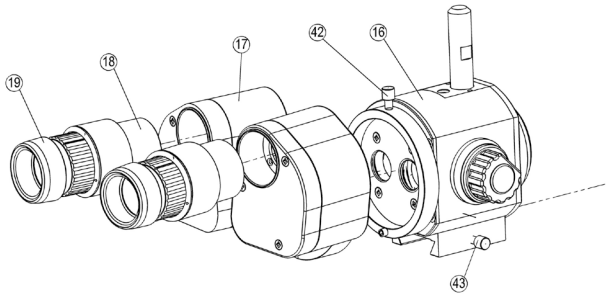


Image 8: Installation of slit lamp microscope

A T T E N T I O N
Never look into the sun with the binocular of the slit lamp.

5.2.4 Installation of diffuser attachment

If the provided diffuser (44) is to be used, fix this with the screws as shown in Figure 8

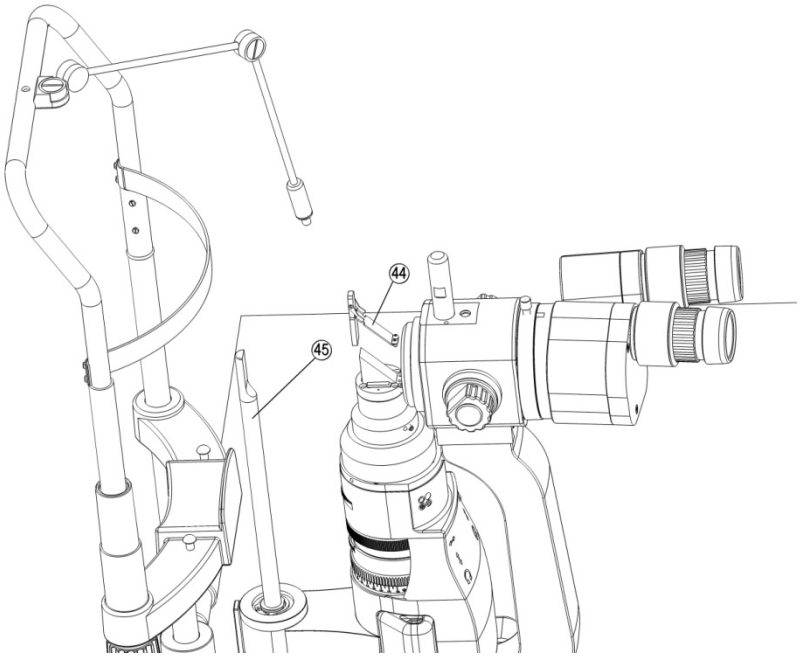
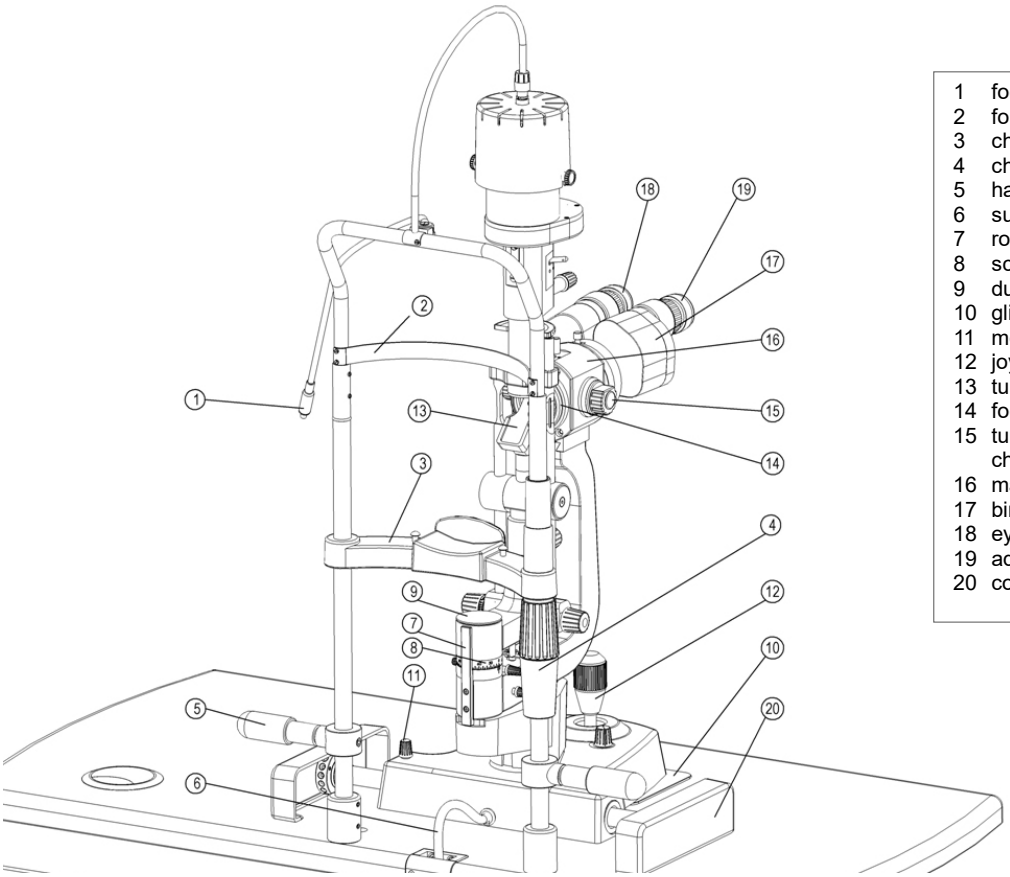


Image 9: Mounting of diffuser attachment; adjustment of eyepieces

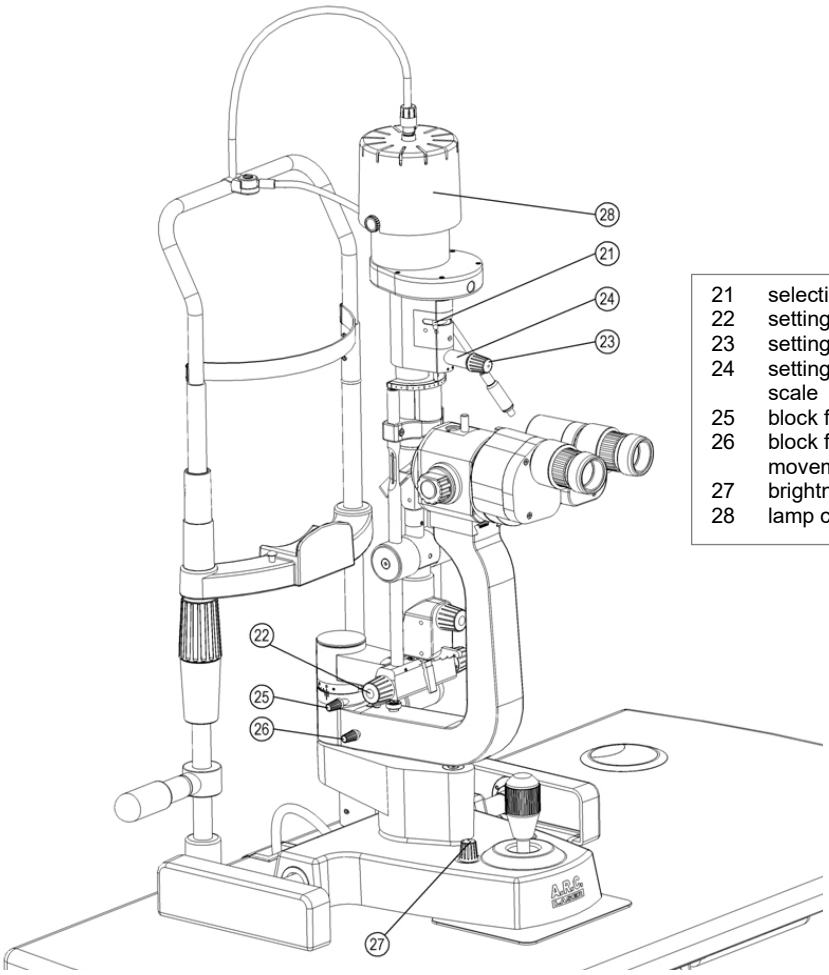
6 Operation

6.1 Operation SHD

The PCL5 SHD consists of following parts The following images are for illustrative purposes only and do not represent the exact appearance of the device.:



1	focusing target
2	forehead band
3	chin rest with paper rivets
4	chin rest height adjustment
5	hand-grip patient
6	supply cable
7	rotation block
8	scale lamp arm rotation
9	dust cover
10	gliding plate
11	movement stopper
12	joystick
13	turning mirror
14	focusing objective
15	turning knob magnification changer
16	magnification changer
17	binocular tube
18	eyepieces
19	adjustable eyepiece cups
20	cover toothed racks



21	selecting wheel color filter
22	setting wheel slit width
23	setting wheel slit height
24	setting wheel slit rotation with scale
25	block for lamp arm movement
26	block for binocular arm movement
27	brightness controller
28	lamp cover

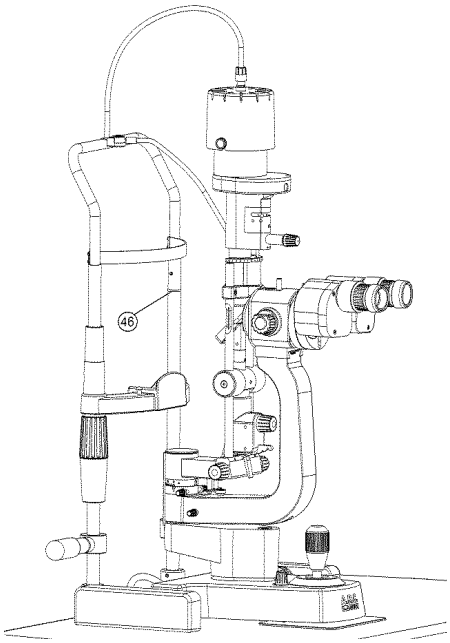
A T T E N T I O N

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

6.1.1 Adjusting the Eyepieces

Turn on the slit lamp with the brightness controller and look at the focus rod through the slit lamp binocular. Pull the sliding eyecup (19) out until it stops, if you're not wearing glasses. Spectacle wearers push them in up to the stop. Adjust each eyepiece separately, by turning the knurled ring with the diopter scale separately, until the projected slit is seen in focus. Adjust from (+) to (-) at low magnification.

6.1.2 Preparing the Patient



To obtain a firm support for forehead and chin, the height of the table has to be adjusted in such way that the patient is sitting in a slightly forward-bent position. Move the chin rest up or down with the height adjustment (4) until the eyes of the patient are on the same level as the black mark (46) on the right side of the chin rest.

In order to ensure that only that part of the eye is illuminated which is to be examined and to avoid disturbing glare, the height of the light beam must be appropriately adjusted.

Those parts of PCL5, which have contact with the patient should disinfected before each examination.

6.1.3 Operating the instrument

Turn on the slit lamp with the brightness controller (27). Move the slit lamp by gently pushing it to adjust the slit on the eye. Afterwards the fine adjustment can be done by using the joystick (12).

It is recommended to first adjust the height position of the slit by rotating the joystick. Thereafter the lateral position and distance to patient can be adjusted by moving the joystick in the desired direction.

The slit lamp can be blocked turning the movement stopper (11) clockwise. Also, the illuminating arm of the slit lamp with the slit can be rotated by ± 90 ° around the vertical axis manually and blocked with rotating wheel (25). The arm with the optics and binocular can be rotated by ± 30 ° around the vertical axis and blocked with rotating wheel (26).

The magnification of the slit lamp can be adjusted by the knobs at the side (15). The slit height and width can be adjusted with the setting wheels (22) and (23). Through the setting wheel (24) the slit can be rotated around the optical axis.

If an illumination with reduced brightness but at the same time with constant colour temperature of the slit image should be necessary, a grey filter can be used with the setting wheel (21). In addition, a green or a blue filter can be chosen.

After treatment, the slit lamp should be switched off. If the device should not be used for a longer time, the PCL5 should be covered with the provided dust protection.

A T T E N T I O N

Before using the dust cover, the device should cool down for 30 minutes to avoid damage on the device.

6.2 Operation PCL5 ZD

The following images are for illustrative purposes only and do not represent the exact appearance of the device.

6.2.1 Prepare the patient

- For the comfort of your patient please adjust the height of the table to enable a firm rest for the forehead and chin.
- In order to ensure that only that part of the eye to be examined is illuminated and to avoid disturbing glare, the height of the light beam should be appropriately adjusted.
- Those parts of the equipment coming into contact with patients should be disinfected before each examination.
- Move the chin rest up or down with the height adjustment (4) until the eyes of the patient are on the level with the black mark (46) on the headrest column.

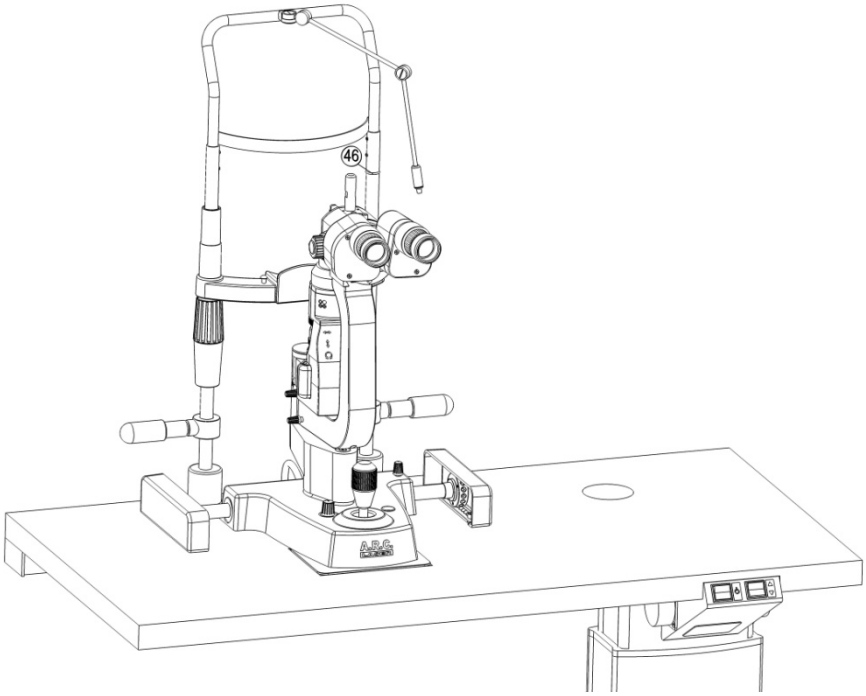


Image 10: Adjustment of the chin rest

6.3 Device parts and accessories

The basic parts of the PCL5 SHD/ZD include the following:

Part	Description	Article number
Power supply cable	EU cable – Type E/F, 5m	KB13003
	UK cable – Type G, 5m	KB13004
	US cable – Type B, 5m	KB13005
Dust protection	Dust protection cover	KB03005
Chin rest paper	Chin rest paper for patient	SL01115
Spare LED module	Spare module for the LED	BG06565
Cover toothed racks	Cover for the toothed racks	ME06544
User Manual	User manual PCL5 SHD/ZD	
Transport box	Wooden transport box	VP01081
Transport carton	Slit lamp carton	VP01066

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

The following accessories are available:

Part	Description	Article number
Adapter plate for tonometer	Adapter plate for tonometer	BG06576

ATTENTION

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

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

6.3.1 Instrument table

The PCL5 SHD/ZD is supplied with an instrument table as standard. The instrument table on which the slit lamp is mounted is height adjustable. This allows the user to adjust the optimal working height comfortably for each patient. Please note that the table can only take an additional load of 2.0 kg. This means that no objects heavier than 2.0 kg in total may be placed on the table. Also, no persons may sit on the table or support themselves with their entire body weight on it.

If the table is inclined, you can calibrate it. To calibrate the table, move it all the way down while holding the down arrow button pressed until it comes to a complete stop. After calibration, the table is horizontal again.

6.3.2 Combinations

The PCL5 SHD/ZD can be used as a stand-alone product or in combination with the A.R.C. Laser laser devices Q-Las, Cito; Classic. If the slit lamp is part of a laser device, increased security measures must be taken into account. Respect the provided user manual of the respective laser device for more information.

7 Technical data

7.1 PCL5 SHD

7.1.1 General information

Model PCL5 SHD	Slit lamp
Weight	12.7 kg
Dimensions	H 45 cm / W 33 cm / D 34 cm
Max. weight allowed on table	2 kg
Filters	grey, blue, green

7.1.2 Specifications

7.1.3 Slit illumination

Slit width	0 – 8 mm
Slit image	0.5 – 8 mm
Illumination fields	ø0.2, 1, 2, 3, 4, 5, 6, 8 mm Test mark with fixation
Slit image radial range	± 90 ° (0°-180°)
Vertical movement of slit illumination	± 90 °
Mode of operation	continuous
LED module	14 V, 5 W
Illumination intensity	220lm-780lm

7.1.4 Binocular

Stereo angle	10 °
Magnification changer	6.3x / 10x / 16x / 25x / 40x
Eyepiece magnification	12.5x
Range of adjusting eyepiece	+8 to -8 diopters
Interpupillary distance	52 – 78 mm
Horizontal rotation	± 30 °

7.1.5 Electrical connection data

Power supply connection values 110 – 240 V, 50/60 Hz,

7.1.6 Classification

Classification to MDR	I, Rule 1
Electrical safety class Classification IEC 60601-1	Class II, Type B
IP safety class	IPX0

7.2 PCL5 ZD

7.2.1 General information

Model PCL5 ZD	Slit lamp
Weight	12.7 kg
Dimensions	H 67 cm / W 33 cm / D 34 cm (with table at lowest position)
Max. weight allowed on table	2 kg
Filters	grey, blue, green

7.2.2 Specifications

7.2.3 Slit illumination

Slit width	0 – 16 mm
Slit image	1 – 16 mm
Illumination fields	Ø: 1 mm Test mark
Slit image radial range	± 90 ° (0°-180°)
Vertical movement of slit illumination	± 90 °
Mode of operation	continuous
LED module	14 V, 5 W
Illumination intensity	220lm-780lm

7.2.4 Binocular

Stereo angle	10 °
Magnification changer	6.3x / 10x / 16x / 25x / 40x
Eyepiece magnification	12.5x
Range of adjusting eyepiece	+8 to -8 diopters
Interpupillary distance	52 – 78 mm
Horizontal rotation	± 30 °

7.2.5 Electrical connection data

Power supply connection values	110 – 240 V, 50/60 Hz,

7.2.6 Classification

Classification to MDR	I, Rule 1
Electrical safety class Classification IEC 60601-1	Class II, Type B
IP safety class	IPX0

8 Maintenance

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.

ATTENTION

There is no need for the user to perform service work within the slit lamp. All adjustments and calibration that require to open the protective housing must be carried out by trained service personnel. This also include cleaning of optics within the slit lamp.

8.1 Care by the user

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

For cleaning and disinfection, the power supply must be disconnected. First clean the device with clear water and neutral detergent to remove coarse and visible contamination. Make sure that no moisture penetrates into the device. Furthermore, wipe disinfection is possible. When choosing the disinfectant, pay attention to the following:

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

When doing wipe disinfection, the manufacturer's instructions for the disinfectant must be respected. Following possible disinfectants meet the above-mentioned 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.

Please check if any screw has loosened after cleaning and tighten it if necessary.

8.1.1 Cleaning of slit lamp mirror

If necessary, clean the slit lamp mirror with a suitable lens brush. After dedusting, clean the mirror with Kodak lens cloths and a few drops of pure acetone. Do not use the cloth dry, otherwise the mirror will be scratched. Press only lightly so that the mirror is not misaligned. Do not rub more than once or twice. Heavy rubbing only spreads the dirt and causes scratches.

ATTENION

Do not open any part of the slit lamp to clean the inside.

8.1.2 Inspection and cleaning of external optics

Check the accessible surfaces of the optics for possible contamination. The surfaces of the slit lamp can be cleaned with a soft cloth and distilled water or a mixture of distilled water and approx. 10 % alcohol.

ATTENTION

Always wipe the optical surface in one direction. Never go back in the other direction with the same cotton swab. Any particles that have already settled in the cotton swab would scratch the optical surface again when moving back and thus cause irreparable damage to the optics.

8.1.3 Chin rest

The disinfectant used for the slit lamp can also be used for the chin rest. This also includes the forehead band. The chin rest should be covered with the chin rest paper which is delivered with the device. The paper may be changed after each patient.

8.2 Replace the LED module PCL5 SHD

ATTENTION

Before changing the light bulbs, switch off the slit lamp and disconnect the supply cable from the socket. Allow the slit lamp to cool down for 30 minutes, if it was used before.

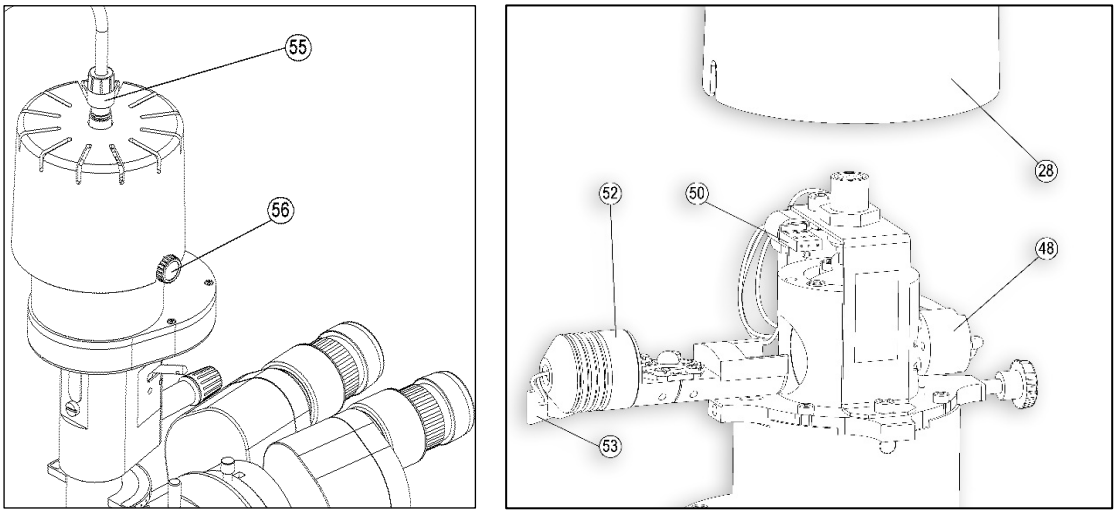
Avoid touching the LED lens of the illuminant and use original illuminants only!

- Loose both locking screws (56) by turning them 2-3 times. Remove the connection cable (55) from the lamp cover and the lamp cover (28) itself.
- Pull out the lamp socket (48) from the LED storage tray.
- Remove the socket (53) of the LED module from the connector (50)
- Replace the old LED module by the new one by pulling it out of the lamp housing
- Connect the socket of the new LED module with connector.

ATTENTION

Mind the alignment of the illuminant. The illuminant has to lock into place at the bottom

- Insert the lamp socket and fasten the lamp cover with the locking screws
- Put the connection cable back into the socket


55
56
28
52
50
48
53

8.3 Changing the light bulbs

8.3.1 Changing the Light Bulbs PCL5 SHD

Before changing the light bulbs, switch off the slit lamp and disconnect the supply cable from the socket. Allow the slit lamp to cool down for 30 minutes, if it was used before.

- Loose both locking screws (56) by turning them 2-3 times. Remove the connection cable (55) from the lamp cover. Now you can take away the lamp cover (28).
- Remove the lamp socket (48) from the illuminant (47) and pull out the bulb thereafter as well
- Unpack the new bulb and put it into the light arm. Please make sure that the notch of the bulb at the side shows to the left. The bulb has to lock into place at the upper and underside.
- Push the lamp socket (48) back onto the contact up to the stop and fasten the lamp arm again with the two locking screws (56), then put the connection cable back into the jack.

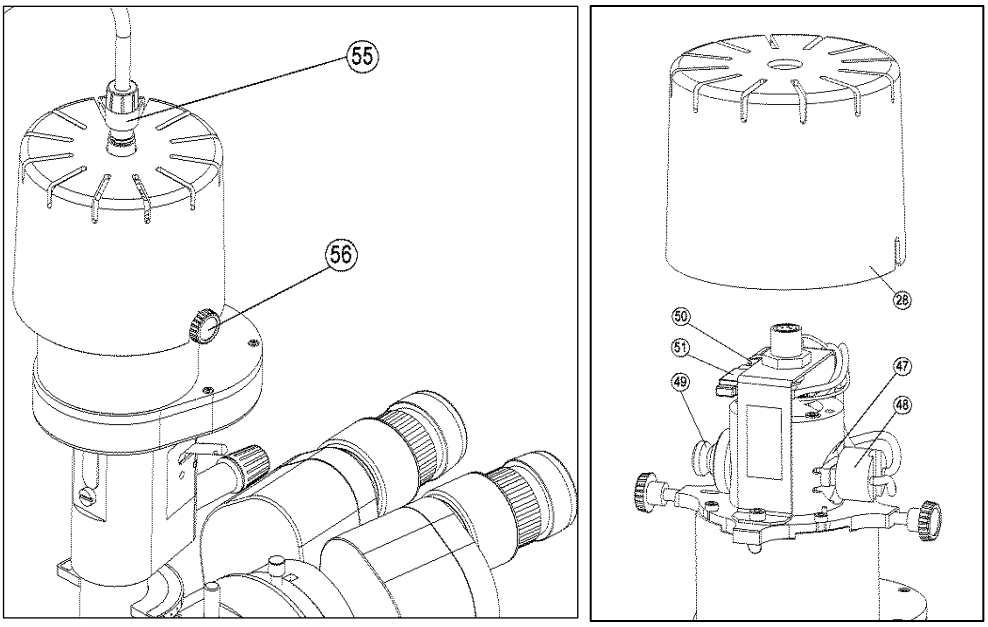


Abbildung 11: Changing of light bulbs

8.3.2 Changing the light bulbs PCL5 ZD

Before changing the light bulbs switch off the slit lamp and disconnect the supply cable from the socket. Allow the slit lamp to cool down for 30 minutes, if it was used before.

Avoid touching the glass bulb of the illuminant (47) with your fingers!

- Loose the lamp cover (13) by pressing vertically
- Pull out the dummy plugs (49) from the lamp housing and store them for possible re-use
- Now remove the dongle (51) from the connector (50) and store it for possible re-use.
- Loose the lamp cover (28) by pressing vertically
- Remove the lamp socket (48) from the illuminant (47) and pull out the bulb thereafter as well. In case that the illuminant (47) is still functional store it for possible re-use.
- Push the LED module into the lamp housing and mind the alignment of the bulb. Make sure that the bulb locks into place at the underside.

- Connect the jack (52) of the LED module with the connector (50)
- Reinsert the lamp cover (13) by pressing vertically
- Put the alignment for the new LED module (48) into the foreseen place
- Reinsert the lamp cover (28) by pressing vertically

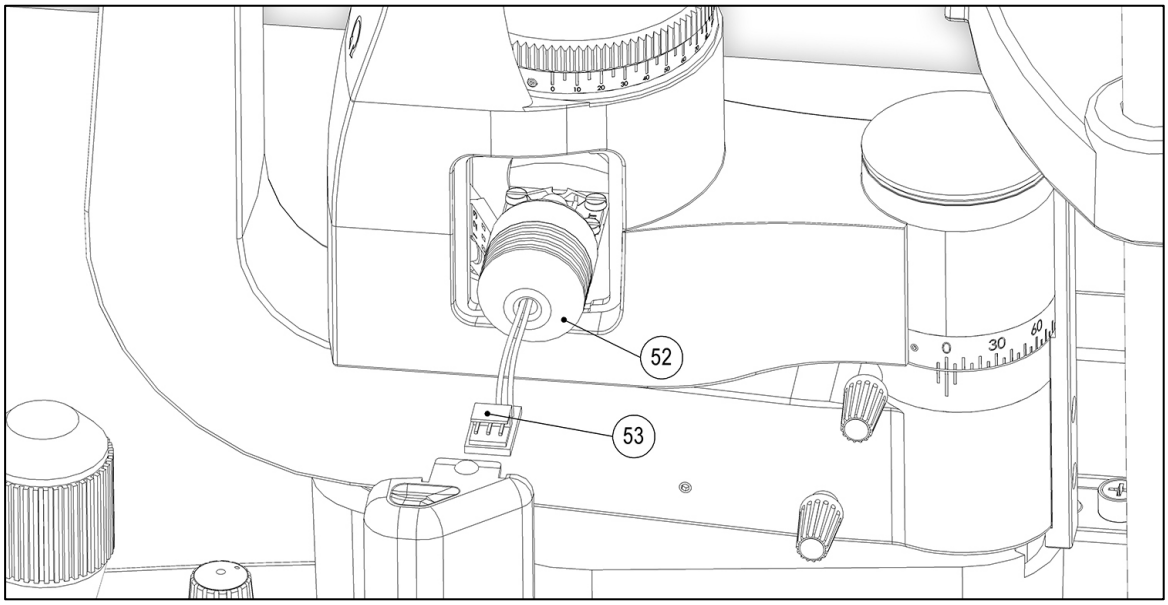
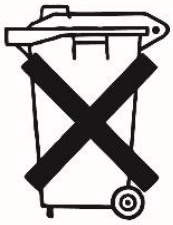


Image 12: Changing of light bulbs

8.4 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 owner. Please contact our service department.

9 Customer service

9.1 Warranty information

A.R.C. Laser GmbH grants 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 A.R.C. Laser and 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 and are 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

Please contact A.R.C. Laser GmbH or your local distributor for sales and service information.

10 Guidelines and manufacturers declaration

10.1 Electromagnetic Emission

The slit lamp is intended for use in an environment as specified below. The customer or user of the slit lamp should ensure that it is operated in such an environment.

Immunity tests	Compliance	Electromagnetic environment - guideline
RF-Emissions CISPR 11 150 kHz – 30 MHz	EN 55011 Group 1/Class B	The laser uses RF energy exclusively for its internal function. Hence, RF emission is very low and not likely to cause any interference in nearby electronic equipment
RF- Emissions CISPR 11 30 MHz - 1 GHz	EN 55011 Group 1/Class B	The device is only suitable for the environment in professional healthcare facilities.
Harmonic emission	IEC 61000-3-2 Class A	
Voltage fluctuations/flicker	IEC 61000-3-3	

10.2 Electromagnetic Immunity (1)

The slit lamp 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 discharge (ESD)	± 2 kV, ± 4 kV, ± 6, ± 8 contact discharge; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air discharge	IEC 61000-4-2	Floors should be made of wood, ceramic or stone. If the floor is covered with a synthetic material, the relative air humidity should be at least 30%.
Radiated RF electromagnetic field	3 V/m 80 MHz to 2.7 GHz	IEC 61000-4-3	Only the voltage of a typical professional healthcare facility may be used.
Proximity fields from RF wireless communications equipment	(see Table 10.4)	IEC 61000-4-3	-
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 disturbances induced by RF fields	3 V 0.15 MHz to 80 MHz 6 V in ISM-frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	IEC 61000-4-6	Only the voltage of a typical professional healthcare facility may be used.
Rated power frequency magnetic field	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.
Power interruption	0% UT; 250/300 cycles at 0 and 180 level	IEC 61000-4-11	-

10.3 Electromagnetic Immunity (2)

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

Immunity tests	IEC 60601-Test level	EMV standard	Electromagnetic environment – guidelines
Voltage dips and variations	0 % UT; ½ cycle at 0, 45, 90, 135, 180, 225, 270 and 315 level 0 % UT;1 cycle at 0 and 180 level And 70 % UT; 25/30 cycles at 0 and 180 level	IEC 61000-4-11	Only the voltage of a typical professional healthcare facility may be used. It is recommended to use an uninterruptible power supply.
Radiofrequency electromagnetic fields in the immediate vicinity of wireless communication devices	0% UT; 250/300 cycles at 0 and 180 level	IEC 61000-4-11	Only the voltage of a typical professional healthcare facility may be used. It is recommended to use an uninterruptible power supply.
NOTE: UT is the AC mains voltage prior to application of the test level.			

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

The slit lamp is intended for use in an electromagnetic environment in which the RF disturbances are controlled. The customer or the user of the device can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device - 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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