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<td>11.2 Operating conditions</td>
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<td>11.3 Laser specifications</td>
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13 Appendix
A General information

To order additional copies of this user manual:
If additional copies of this user manual are required, refer to the SKU number on the cover page and contact your Authorized Technolas Perfect Vision Representative.

A.1 Information about this user manual

This user manual enables safe and efficient handling of the product, its accessories and tools. It must be kept close to the product where it is permanently accessible to the personnel.

Before starting any treatments, the personnel must read the manual thoroughly and understand its contents. Users must comply with all specified safety instructions and operating instructions to ensure safe operation.

In addition, local accident prevention regulations and general safety instructions must be observed in the area where the product is used.

The product images in this user manual are intended to provide a basic understanding of the product and may differ from the actual design you have on site. Screenshots were created using an exemplary patient and exemplary values. Depending on your system’s configuration the depicted screenshots may not be identical to the screen shown on your system.

The software user interface may only be available in English. Where applicable, the Appendix section of the user manual contains a list of the English software texts together with the appropriate translation.

A.2 Explanation of symbols

Safety notes in this user manual are introduced with symbols and a signal word that describe the severity of the hazard.

Follow these safety notes and proceed with caution to avoid accidents, personal injury, damage to property, and to ensure patient safety.

- **DANGER**
  This symbol and the word "DANGER" indicate an imminent hazardous situation that, if not avoided, could cause death or serious injury.

- **WARNING**
  This symbol and the word "WARNING" indicate a possible hazardous situation that, if not avoided, could cause death or serious injury.

- **CAUTION**
  This symbol and the word "CAUTION" indicate a possible hazardous situation that, if not avoided, could result in minor or moderate injury.

- **NOTICE**
  This symbol and the word "NOTICE" indicate a possible hazardous situation that, if not avoided, could result in damage to property or the environment.
Hints, recommendations, and examples

This symbol emphasizes useful tips and recommendations as well as information for the efficient and trouble-free use of the product.

Example of ...

This field shows examples of previous instructions or information.

Safety notes in step-by-step instructions

Safety notes are included in step-by-step instructions. This format allows the user to be aware of safety issues while performing tasks. The safety symbols are also part of the step-by-step instructions.

Symbols in this user manual

The following symbols and markings are used in this manual to indicate guidelines, descriptions of results, lists, and references:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Indicates</th>
</tr>
</thead>
<tbody>
<tr>
<td>➡️</td>
<td>Step-by-step instructions</td>
</tr>
<tr>
<td>⇨</td>
<td>Condition or automatic sequence as a result of action</td>
</tr>
<tr>
<td>📚</td>
<td>References to chapters in this user manual</td>
</tr>
<tr>
<td>▪️</td>
<td>Lists or list entries without a certain sequence</td>
</tr>
<tr>
<td>[Ctrl]</td>
<td>Keys on the keyboard, mouse buttons, key switches, hardware switches, or hardware buttons</td>
</tr>
<tr>
<td>‘Start’</td>
<td>Active (clickable) GUI elements</td>
</tr>
<tr>
<td>‘Patient selection’</td>
<td>Passive elements</td>
</tr>
<tr>
<td>c:\Program..</td>
<td>Text input</td>
</tr>
<tr>
<td>‘Administration ➔ User Registry’</td>
<td>Menu path</td>
</tr>
</tbody>
</table>

A.3 Customer service

Our customer service division is available to provide technical support and information. If any questions arise that are not answered in this user manual, do not hesitate to contact your Authorized Technolas Perfect Vision Representative for assistance.
A.4 Product names used in this user manual

For the sake of better readability and depending on the context, product names may appear in abbreviated form.

<table>
<thead>
<tr>
<th>Complete product name</th>
<th>Name used in this user manual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Interface 125 Kit <strong>in general</strong></td>
<td>PI 125 Kit</td>
</tr>
<tr>
<td>Patient Interface 125 Kit (REF 90000115)</td>
<td>PI 125 Kit (REF 90000115)</td>
</tr>
<tr>
<td>Patient Interface 125 Kit (REF 90000145)</td>
<td>PI 125 Kit (REF 90000145)</td>
</tr>
<tr>
<td>Patient Interface 125 <strong>in general</strong></td>
<td>PI 125</td>
</tr>
<tr>
<td>Patient Interface 125 (REF 90000115)</td>
<td>PI 125 (REF 90000115)</td>
</tr>
<tr>
<td>Patient Interface 125 (REF 90000145)</td>
<td>PI 125 (REF 90000145)</td>
</tr>
<tr>
<td>Suction Clip 125 <strong>in general</strong></td>
<td>Suction clip</td>
</tr>
<tr>
<td>Suction Clip 125 (REF 90000115)</td>
<td>Suction clip (REF 90000115)</td>
</tr>
<tr>
<td>Suction Clip 125 (REF 90000145)</td>
<td>Suction clip (REF 90000145)</td>
</tr>
</tbody>
</table>
| VICTUS™ Femtosecond Laser Platform             | VICTUS™ Femtosecond Laser Platform or generic term 'laser system'

A.5 Reference documents to this user manual

The following reference documents are related to this user manual.

<table>
<thead>
<tr>
<th>Document number</th>
<th>Document title</th>
</tr>
</thead>
<tbody>
<tr>
<td>GFO-100012286</td>
<td>Product configuration for VICTUS™ Femtosecond Laser Platform</td>
</tr>
<tr>
<td>ADD-100011422</td>
<td>Addendum to the user manual “VICTUS™ Femtosecond Laser Platform, SW V3.3 SP02” (English)</td>
</tr>
</tbody>
</table>
1 Introduction

1.1 VICTUS™ Femtosecond Laser Platform

The VICTUS™ Femtosecond Laser Platform is an ophthalmologic system based on femtosecond technology and is used to treat a wide variety of ophthalmologic indications.

The following treatments are available:

Cataract treatments
The laser system is able to perform steps of a cataract treatment.
For this purpose, an additional OCT (optical coherence tomography) device is available to help plan the procedure and monitor the treatment.
For details refer to Chapter 5.3.1 ‘Cataract procedures’ on page 5 - 3.

Corneal treatments
The laser system allows very precise, preprogrammed, 3-dimensional patterns to be cut into the cornea of the human eye. These patterns are cut using infrared light pulses with spot sizes of approximately 10 μm and pulse duration of several hundred femtoseconds. The infrared light is focused into the cornea and induces optical breakdown or photodisruption with practically no heat. This results in the formation of gas bubbles.
The user can arrange these patterns in various ways, so that various surgical incisions are possible, for example, a laser-generated LASIK flap.
For details refer to Chapter 5.3.2 ‘Corneal procedures’ on page 5 - 4.

Therapeutic treatments
Furthermore, the laser system is able to perform various therapeutic treatments.
For details refer to Chapter 5.3.3 ‘Therapeutic procedures’ on page 5 - 4.

1.2 Scope of delivery

- VICTUS™ Femtosecond Laser Platform
- User manual "VICTUS™ Femtosecond Laser Platform, SW V3.3 SP02"
- Addendum to the user manual "VICTUS™ Femtosecond Laser Platform, SW V3.3 SP02" (English)
- Patient bed (delivered with 2 fuses)
- User manual "Laser Patient Bed LS Comfort" by AKRUS GmbH & Co KG
  - User manual "Patient Support System PSS S60" by AKRUS GmbH & Co KG
- Accessories and tools (refer to Chapter 7 ‘Accessories and tools’ on page 7 - 1)
  - Plug adapter
Connect only items that have been specified as part of the VICTUS™ Femtosecond Laser Platform ME system or specified as being compatible with the VICTUS™ Femtosecond Laser Platform ME system!

The following items form the VICTUS™ Femtosecond Laser Platform ME system:

- VICTUS™ Femtosecond Laser Platform
- Patient bed with swivel position 16.5°, 60° or 70°
- Uninterruptible power supply (UPS): see relevant customer configuration sheet (transient currents up to 16 A possible)

The following parts of the VICTUS™ Femtosecond Laser Platform ME system are suitable for use within the patient environment:

- VICTUS™ Femtosecond Laser Platform
- Patient bed with swivel position 16.5°, 60° or 70°

1.3 Use with other medical devices

Do not use VICTUS™ Femtosecond Laser Platform together with medical devices other than the devices described in this section.

Patient beds "LS Comfort" and "Patient Support System S60" by AKRUS GmbH & Co KG

These patient beds are medical devices that are approved in accordance with the Medical Device Directive. Technolas Perfect Vision GmbH has assessed their use in combination with VICTUS™ Femtosecond Laser Platform. Technolas Perfect Vision GmbH allows only specific versions of the "LS Comfort" or the "Patient Support System S60" patient bed to be used with VICTUS™ Femtosecond Laser Platform. It must be installed by an Authorized Service Technician. For information about how to operate the patient bed refer to the user manual "Laser Patient Bed LS Comfort" or "Patient Support System PSS S60" by AKRUS GmbH & Co KG. Refer to Chapter 4.1.1 'Interface of the patient beds "LS Comfort" and "Patient Support System S60" by AKRUS GmbH & Co KG’ on page 4-2 for the interface description.

1.4 List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACD</td>
<td>Anterior Chamber Depth</td>
</tr>
<tr>
<td>AI</td>
<td>Arcuate Incisions</td>
</tr>
<tr>
<td>BSS</td>
<td>Balanced Salt Solution</td>
</tr>
<tr>
<td>CXL</td>
<td>Crosslinking</td>
</tr>
<tr>
<td>D</td>
<td>Dioptr</td>
</tr>
<tr>
<td>EHD</td>
<td>Exit Height Difference</td>
</tr>
<tr>
<td>EMC</td>
<td>Electromagnetic Compatibility</td>
</tr>
</tbody>
</table>

SKU: 70005780TPV * Version 6 * UM-100010770 GB
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>fs</td>
<td>femtosecond</td>
</tr>
<tr>
<td>GUI</td>
<td>Graphical User Interface</td>
</tr>
<tr>
<td>H0</td>
<td>Height Zero</td>
</tr>
<tr>
<td>hPa</td>
<td>hecto Pascal</td>
</tr>
<tr>
<td>ICRS</td>
<td>Intracorneal Ring Segments</td>
</tr>
<tr>
<td>LASER</td>
<td>Light Amplification by Stimulated Emission of Radiation</td>
</tr>
<tr>
<td>LASIK</td>
<td>Laser-Assisted In Situ Keratomileusis</td>
</tr>
<tr>
<td>LCD</td>
<td>Liquid Crystal Display</td>
</tr>
<tr>
<td>LED</td>
<td>Light-Emitting Diode</td>
</tr>
<tr>
<td>LKP</td>
<td>Lamellar Keratoplasty</td>
</tr>
<tr>
<td>LPS</td>
<td>Laser Position Sensor</td>
</tr>
<tr>
<td>LRCS</td>
<td>Laser Refractive Cataract Surgery</td>
</tr>
<tr>
<td>LVC</td>
<td>Laser Vision Correction</td>
</tr>
<tr>
<td>ME</td>
<td>Medical Electronic</td>
</tr>
<tr>
<td>NOHD</td>
<td>Nominal Ocular Hazard Distance</td>
</tr>
<tr>
<td>OCT</td>
<td>Optical Coherence Tomography</td>
</tr>
<tr>
<td>PETG</td>
<td>Polyethylene Terephthalate Glycol</td>
</tr>
<tr>
<td>PI</td>
<td>Patient Interface</td>
</tr>
<tr>
<td>PIK</td>
<td>Patient Interface Kit</td>
</tr>
<tr>
<td>PKP</td>
<td>Penetrating Keratoplasty</td>
</tr>
<tr>
<td>UPS</td>
<td>Uninterruptible Power Supply</td>
</tr>
<tr>
<td>®</td>
<td>Registered trade mark</td>
</tr>
<tr>
<td>TM</td>
<td>Trade mark</td>
</tr>
</tbody>
</table>

1.5 Definitions

**LRCS** indicates a set of procedures that includes the following:
- capsulotomy
- lens fragmentation
- arcuate incisions
- corneal incisions
2 Safety

Please ensure that only the corresponding user manual with the correct software version (refer to the label "Installed software" in Chapter 2.10.2 'Labels on the laser system' on page 2 - 13) is used as a reference material!

2.1 Intended use

The VICTUS™ Femtosecond Laser Platform has been designed and constructed exclusively for the intended use described in this section.

The VICTUS™ Femtosecond Laser Platform is a femtosecond laser that is used to perform cataract and refractive surgery on human eyes (Chapter 5.1 'Medical indications' on page 5 - 1). Patients may be treated provided they do not exhibit any condition that may pose a contraindication as discussed in Chapter 5.2.1 'Contraindications' on page 5 - 2.

The laser system must only be used in dry, dust-free rooms that comply with the cleanliness standards for operating rooms.

The laser system must only be used with the installed software.

The laser system is also intended to be used only as described in the instructions in this user manual.

Any use that exceeds, or is different from, the specified intended use is considered to be misuse.

Danger of injury due to misuse!

Misuse of the laser system may lead to dangerous situations and severe injuries.

- Do not use the laser system on patients who come under the exclusion criteria (Chapter 5.2.1 'Contraindications' on page 5 - 2).
- Do not use the laser system with devices, accessories and tools that are not specified in this user manual.
- Do not use the laser system with software that is not authorized and certified by Technolas Perfect Vision GmbH.
- Connect only items that have been specified as part of the VICTUS™ Femtosecond Laser Platform ME system or specified as being compatible with the VICTUS™ Femtosecond Laser Platform ME system.

Claims of any type due to damage arising from misuse are excluded.

2.2 Complications (side effects)

Potential general complications resulting from VICTUS procedures include, but are not limited to the following:
2 SAFETY

- Corneal abrasion or defect
- Pain
- Bleeding
- Inflammation
- Elevated intraocular pressure
- Incomplete procedure resulting from treatment interruption caused for example by suction loss or insufficient contact pressure
- Hemorrhage
- Decentration of planned procedure

Potential complications resulting from anterior capsulotomy or lens fragmentation include, but are not limited to the following:
- Incomplete capsulotomy or lens fragmentation
  In this case, the surgeon may elect to complete the procedure using traditional surgery methods.
- Capsular tear and/or rupture
- Damage to intraocular structures
- Miosis

Potential complications resulting from creation of corneal flaps or corneal cuts / incisions include, but are not limited to the following:
- Corneal edema
- Epithelial ingrowth
- Incomplete flap or corneal cuts / incisions creation
- Flaps and LKP only:
  - Flap striae
  - Flap / graft tearing or incomplete lift
  - Photophobia
  - Thick or thin flap / graft
  - Vertical gas breakthrough
  - Anterior chamber gas bubbles
  - Opaque bubble layer
- LKP only:
  - Corneal perforation

ICRS tunnel incisions only:
- Anterior or posterior corneal penetration

*Potential complications are not limited to those included in this list. These complications may be surgically or medically managed using currently accepted techniques.*
2.3 Important safety considerations

**WARNING**

Danger of injury due to user negligence!
Always double-check the following before treatment:
- Are you treating the right patient?
- Did you select the correct treatment?
- Was the correct eye selected?
- Does the entered data match the patient to be treated?

Failure to verify any of the above-mentioned aspects may result in serious permanent patient injury.

**WARNING**

Danger of injury for persons with cardiac pacemakers!
Negative influence on the pacemaker, such as electromagnetic interference, could occur during laser operation.
- During laser operation, no person—medical personnel or patients—with a cardiac pacemaker should be present in the treatment room.

**WARNING**

Property damage due to improper stacking or locating of non-intended devices next to the product!
The product is very sensitive. Improper stacking or locating of non-intended devices next to the product may lead to equipment damage or influence concerning EMC. If adjacent or stacked use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
- Do not stack or locate any non-intended devices next to the product during operation.

- **The medical electrical equipment** implies special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Appendix A ‘EMC declaration’ on page 13 - 3.
- **The medical electrical equipment** may be affected by portable and mobile radio frequency communication equipment.

2.4 Responsible organization

The responsible organization can be, for example, a public hospital, a private person (ophthalmologist), or a private clinic.

Education and training is included in the term ‘use’.

- The responsible organization must ensure that hazards of network coupling of the device must be observed. Such hazards include, for example, virus protection, data security, network protection by firewall systems, and ensuring sufficient bandwidth.
- System modifications and use in combination with other equipment is limited to TPV-approved equipment. Otherwise, the responsible organization is in charge of proper risk management.
2.5 Customer responsibilities

The laser system is used for commercial purposes. Laser system users are therefore required to observe their obligations with regard to occupational health and safety.

In addition to the safety instructions provided in this manual, the safety, accident prevention, and environmental regulations applicable at the place of installation must be observed, particularly as follows:

- The customer must ensure that personnel who handle the laser system read and understand the manual.
- The customer must ensure that unauthorized persons do not have access to the operating room and the laser system.
- The customer must ensure that the service and calibration intervals specified in this manual are observed.
- The customer must provide all users with personal protective equipment, if necessary.
- The customer must ensure that all warning signs are prominently displayed on the access to the operating room.
- The customer must ensure that the entrance to the operating room is equipped with a light that shows if the operating room is in use.

2.6 Personnel requirements

**WARNING**

Danger of injury if persons are unauthorized or insufficiently qualified!

If unauthorized or unqualified persons perform work on the laser system or are in the danger zone of the laser system, hazards may arise that can cause serious injury and substantial damage to property.

- All treatments must be performed by appropriately qualified persons.
- Unauthorized persons must not use the product.

**Personnel in general**

All persons are expected to perform their work in a reliable manner. Persons with impaired reactions due to the consumption of drugs, alcohol, medication, or any other reason are prohibited.

2.6.1 Role definitions

**Assistant**

Assistants are trained for the special area of responsibility in which they are involved. Assistants know the content of all regulations, guidelines, and standards which are applicable for the safe use of the system and can implement the requirements mentioned in them.

Assistants have been trained by Technolas Perfect Vision GmbH staff or personnel authorized by Technolas Perfect Vision GmbH in proper handling of the system. Assistants can safely perform the work assigned to them and can recognize, evaluate, and avoid potential hazards to themselves or the patient because of their professional medical training and experience.
Assistants have the necessary technical knowledge of the application area of the system for which they are responsible and rigorously follow all hygiene requirements for operating rooms and the use of medical products.

Assistants have basic knowledge of Microsoft Windows®.

**Authorized Service Technician**
Based on their professional, product-related training, professional experience, and knowledge of all relevant regulations, Authorized Service Technicians can service ophthalmologic systems and detect and prevent possible hazards.

**User**
Users are medical providers who specialize in the diagnosis, treatment, and surgery of the eye.

Users have been trained by Technolas Perfect Vision GmbH staff or personnel authorized by Technolas Perfect Vision GmbH in proper handling of the system including special precautionary measures for working with laser-emitting systems. Users know the content of all regulations, guidelines, and standards that are applicable for the safe use of the system and can implement the requirements mentioned in them.

Users have the necessary technical knowledge of the application area of the system for which they are responsible and rigorously follow all hygiene requirements for operating rooms and the use of medical products.

Users have basic knowledge of Microsoft Windows®.

### 2.7 General hazards

This section specifies several risks that should be avoided based on a risk assessment. In order to reduce health risks and avoid dangerous situations, observe the safety instructions listed here and the safety instructions contained in other chapters of this user manual.

Failure to follow the directions and safety information given in this user manual may result in severe injuries.
2.7.1 Electrical hazard

**DANGER**
Life-threatening hazard due to electric shock!
There is an imminent life-threatening hazard of electric shock if live parts are touched. Damage to insulation or to specific components can pose a life-threatening hazard.
- Only a qualified electrician should perform work on the electrical equipment.
- Immediately switch off the device and have it repaired if the insulation of the power supply is damaged.
- Keep moisture away from live parts, for example, switch plugs or the computer system. Moisture can cause short circuits.
- Do not use multiple sockets or extension cables since this impacts the function of protective earth and may lead to electric shock.
- The laser system must only be connected to mains supply with proper protective earth connection.
- Do not touch the patient at the same time as live parts, for example, USB ports or connectors.

**WARNING**
Danger of injury due to the incorrect handling of rechargeable batteries!
If rechargeable batteries are handled incorrectly, there is a risk that they explode or that harmful liquid leaks from them. In case of skin contact, the liquid can cause chemical burns. The liquid is highly toxic if swallowed, and eye contact may cause blindness.
- Never allow unauthorized persons to have access to rechargeable batteries.
- If battery liquid makes contact with the eyes, immediately rinse the eyes with clean water for at least 15 minutes. Be sure to rinse under the eyelids by directing a gentle stream of water directly into the eye. Do not rub the eye. Seek medical attention immediately.
- Avoid skin contact with leaking rechargeable battery liquid. In case of accidental skin contact, wash the affected area using plenty of soap and water.
2.7.2 Laser radiation hazard

**DANGER**

Danger due to ocular or skin exposure to the laser beam!

If you do not follow the described instructions, an emitted class 3B laser beam may injure the retina of the eyes or burn the skin. The laser beam is invisible.

- Unauthorized persons must not enter operating rooms where laser equipment is used, and they are not permitted to operate laser-emitting equipment.
- When using laser equipment, always ensure that it is in perfect operating condition and that all safety devices function properly.
- Never look directly into the laser source.
- Do not dock any other accessories as described in Chapter 7.1 ‘Accessories’ on page 7 - 1 or Chapter 9 ‘Treatment’ on page 9 - 1.
- If you follow the instructions, no hazardous laser radiation will be emitted. Therefore no Nominal Ocular Hazard Distance (NOHD) needs to be applied.
- Safety goggles are only necessary for Authorized Service Technicians. For specifications of safety goggles the Authorized Service Technicians have to refer to field service note "FSN-1302 VICTUS, FEMTEC & EXCIMER Safety Goggles".

**WARNING**

Danger of serious injury due to incorrect operation or maintenance of the laser system!

Use of operating options, adjustments or performance of procedures other than those specified in this user manual may result in hazardous radiation exposure.

- Never operate the laser system other than specified in this user manual.

2.7.3 Fire hazard

**WARNING**

Danger of injury due to heavy objects or liquids!

The product is very sensitive. Heavy objects placed on the product may lead to dealignment. Liquids placed on the product may spill, which can cause a short-circuit or equipment damage.

- Do not put heavy objects on the product.
- Do not put liquids on the product.

Life-threatening hazard in the event of fire due to highly flammable substances!

Highly flammable substances, liquids, or gases may catch fire and cause serious or fatal injuries.

- Do not use flammable substances near the product.
- Be sure that suitable extinguishing agents are available such as a fire blanket and a fire extinguisher.
2 SAFETY

**WARNING**

Danger of fire and/or explosion due to flammable materials, solutions or gases, or in an oxygen-enriched environment!

There is a risk of fire and/or explosion when the laser output is used in the presence of flammable materials, solutions or gases, or in an oxygen-enriched environment.

The high temperatures produced in normal use of the laser system may ignite some materials, for example cotton wool when saturated with oxygen. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser system is used.

Attention should also be drawn to the danger of ignition of endogenous gases.

- Do not use flammable materials, solutions or gases near the product.
- Do not use the laser system in an oxygen-enriched environment.

**2.7.4 Mechanical hazard**

**CAUTION**

Danger of injury from tripping!

If the power cable is laid in the open, there is a risk that someone can trip over the cable and be injured. The power plug and the unit can also be damaged.

- Lay the power cable in a place where it cannot be tripped over by personnel.
- Always connect the power plug in a safe position where it cannot be damaged or destroyed.

**2.7.5 Damage to property**

**NOTICE**

Danger of property damage due to malicious software!

USB memory sticks connected to the product must not be infected with viruses or other malicious software. Malicious software and viruses may cause damage that cannot be repaired.

- Do not use USB memory sticks infected with viruses or other malicious software.
- Before connecting the product to a LAN interface, verify that connected equipment complies with the requirements for the LAN interface.
### 2.8 Warning signals and alarms

<table>
<thead>
<tr>
<th>Device</th>
<th>Event</th>
<th>Alarm frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser system</td>
<td>Running procedure</td>
<td>Two beeps per second with a frequency of 2 kHz and a volume of 55 dB</td>
</tr>
<tr>
<td>Laser chiller</td>
<td>Critical readings for flow, temperature, or water level</td>
<td>One beep per second</td>
</tr>
</tbody>
</table>

#### Visual signals
- Color-coded visual signals are displayed on the shear force display and in the software GUI on the monitors of the assistant workstation and the surgeon control screen. Every time the color of the symbols, signs, or LEDs changes to yellow or red, a fault has occurred in the corresponding system.
- The meaning of colors on the shear force display and in the software GUI follows the principle of traffic lights.
- A flashing visual signal may be displayed on the LED bar display of the vacuum pump unit if a serious error in the vacuum pump unit has occurred.

### 2.9 Safety devices

**WARNING**

Danger to life from non-functional safety devices!

If safety devices are not functioning or are disabled, there is a danger of severe injury or death.

- Ensure that all safety devices are fully functional and correctly installed before starting work.
- Never disable or bypass safety devices.
- Ensure that all safety devices are always accessible.
### ‘Laser Stop’ button with integrated ‘Bed Stop’

<table>
<thead>
<tr>
<th>Action</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>To <strong>activate</strong> the ‘Laser Stop’ button:</td>
<td>- Press the ‘Laser Stop’ button. Any possible laser emission stops immediately by cutting off the laser interlock.</td>
</tr>
<tr>
<td></td>
<td>- The patient bed cannot be moved upwards or downwards.</td>
</tr>
<tr>
<td></td>
<td>- The integrated illumination in the ‘Laser Stop’ button is no longer illuminated.</td>
</tr>
<tr>
<td></td>
<td>- The ‘Reset’ button is illuminated simultaneously.</td>
</tr>
<tr>
<td>To <strong>unlock</strong> the ‘Laser Stop’ button:</td>
<td>- After 2 seconds the ‘Reset’ button is no longer illuminated (normal operation).</td>
</tr>
<tr>
<td></td>
<td>- The integrated illumination in the ‘Laser Stop’ button is illuminated red (normal operation).</td>
</tr>
</tbody>
</table>

### Patient beds with headrests

*Depending on the headrest connected to the patient bed, please note the following warning!*

#### Headrest with external joysticks

- Red pushbutton at the headrest (at the patient bed ‘LS Comfort’)

#### Headrests with integrated joysticks

- Pushbutton at the headrest (at the patient bed ‘Patient Support System S60’)

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TPV Controlled Document / Status: Effective / Effective Date: Jun 14, 2017 2:38:46 PM

SKU: 70005780TPV * Version 6 * UM-100010770 GB
Danger of injury due to system abort!

In emergency cases the user is able to abort the laser system by pressing the 'Laser Stop' button (§ on page 2 - 10).

- If the system abort occurs during a treatment,
  - press the silver-coded function button (§ on page 2 - 10/Headrest with external joysticks/1) at the front of the headrest when using a patient bed with headrest and external joysticks, or
  - press the red pushbutton on the side of the headrest (§ on page 2 - 10) when using a patient bed with headrest and integrated joystick.

Now, you can manually tilt the headrest downwards to release the patient.
Refer to the respective patient bed user manual by AKRUS GmbH & Co KG.
- Ask the patient to leave the patient bed very carefully.
- Before unlocking the 'Laser Stop' button, ensure that the cause of the laser stop has been removed.
- Do not unlock the 'Laser Stop' button until there is no more danger and there is no patient lying on the patient bed!

2.10 Labeling

Danger of injury due to illegible labels!

Over time, labels and signs can become dirty or illegible due to wear and tear or fading. If labels become illegible, dangers cannot be recognized, necessary operating instructions cannot be followed, and injuries can occur.

- Always keep the labels in good condition so that they are always legible.
- If a label is damaged or has become illegible, contact an Authorized Service Technician.

SKU: 70005780TPV * Version 6 * UM-100010770 GB
2.10.1 Labels in the operating room entrance area

The following labels must be displayed in the operating room entrance area:

<table>
<thead>
<tr>
<th>Label name</th>
<th>Label</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No smoking</td>
<td>![No smoking icon]</td>
<td>Fire hazards exist from flammable or potentially explosive solid, liquid, or gaseous substances.</td>
</tr>
<tr>
<td>Unauthorized access prohibited</td>
<td>![Unauthorized access icon]</td>
<td>Only persons authorized by the customer may enter the operating room.</td>
</tr>
<tr>
<td>Laser beam</td>
<td>![Laser beam icon]</td>
<td>Unauthorized persons must not enter work places where laser beams are used and they are not permitted to operate laser emitting equipment. The equipment should only be operated when the user is sure that the laser output cannot damage eyes, burn skin or tissue, or result in damage to protective work clothing or other objects. Never look directly into the laser source!</td>
</tr>
</tbody>
</table>
| Invisible laser radiation (large) | ![Invisible laser radiation (large) icon] | INVISIBLE LASER RADIATION
AVOID EXPOSURE TO BEAM
LASER CLASS 3B
Wavelength: 1040 ± 25 nm
Pulse duration: 290 – 550 fs
Maximum pulse frequency: 160 kHz
Maximum output power: 0.86 W
IEC 60825-1:2014 |
2.10.2 Labels on the laser system

Fig. 1: Front view

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laser beam (small label); caution when cover is open</td>
</tr>
<tr>
<td>2</td>
<td>No heavy loads</td>
</tr>
<tr>
<td>3</td>
<td>Laser beam (small label); laser aperture</td>
</tr>
</tbody>
</table>
## SAFETY

**Fig. 2: Side view**

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laser beam (small label); laser aperture</td>
</tr>
<tr>
<td>2</td>
<td>Laser beam (small label); caution when cover is open</td>
</tr>
<tr>
<td>3</td>
<td>Consult operator's manual</td>
</tr>
<tr>
<td>Pos.</td>
<td>Label</td>
</tr>
<tr>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td>1</td>
<td>Laser beam (small label); caution when cover is open</td>
</tr>
<tr>
<td>2</td>
<td>High voltage (power supply of the laser system)</td>
</tr>
<tr>
<td>3</td>
<td>Power patient bed</td>
</tr>
<tr>
<td>4</td>
<td>‘Vacuum’ footswitch</td>
</tr>
<tr>
<td>5</td>
<td>Interlock patient bed (interlock cable)</td>
</tr>
<tr>
<td>6</td>
<td>‘Procedure’ footswitch</td>
</tr>
<tr>
<td>7</td>
<td>OP camera</td>
</tr>
<tr>
<td>8</td>
<td>Camera live image</td>
</tr>
<tr>
<td>9</td>
<td>Interlock external</td>
</tr>
<tr>
<td>10</td>
<td>Laser beam (large label); invisible laser radiation</td>
</tr>
<tr>
<td>11</td>
<td>Patent label</td>
</tr>
</tbody>
</table>
The following labels must be displayed on the laser system:

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>WEEE directive</td>
</tr>
<tr>
<td>13</td>
<td>Type plate</td>
</tr>
<tr>
<td>14</td>
<td>Installed software</td>
</tr>
</tbody>
</table>

**Laser beam**

Unauthorized persons must not enter work places where laser beams are used and they are not permitted to operate laser emitting equipment.

The equipment should only be operated when the user is sure that the laser output cannot damage eyes, burn skin or tissue, or result in damage to protective work clothing or other objects.

Never look directly into the laser source!

**Caution when cover open**

Caution - Class 4 Invisible laser radiation when open.

Avoid eye or skin exposure to direct or scattered radiation.

**No heavy loads**

Do not lean or put heavy loads on the designated component.

**Laser aperture**

Laser aperture - Avoid exposure - Invisible laser radiation is emitted from this aperture.
| **High voltage** | This sign warns that there are live parts with high voltage behind the cover to which the sign is attached. Unauthorized persons may not open covers that display this sign. |
| **Power Patient Bed** | This label shows the place of the power connection for the patient bed. |
| **‘Vacuum’ foot-switch** | This label indicates the connection for the ‘Vacuum’ footswitch. |
| **Interlock Patient Bed** | This label indicates the location of the plug for the patient bed interlock. |
| **‘Procedure’ foot-switch** | This label indicates the connection for the ‘Procedure’ footswitch. |
| **OP Camera** | This label indicates the location of the plug for the OP camera. |
| **Camera Live Image** | This label indicates the location of the plug for the video camera. |
| **Interlock external** | This label indicates the location of the plug for the interlock external. |
2 SAFETY

Invisible laser radiation (small)

INVISIBLE LASER RADIATION
AVOID EXPOSURE TO BEAM
LASER CLASS 3B
Wavelength: 1040 ± 25 nm
Pulse duration: 290 – 550 fs
Maximum pulse frequency: 160 kHz
Maximum output power: 0.86 W
IEC 60825-1:2014

Disposal of electronic equipment

The European Union's WEEE Directive requires manufacturers to label their electronic equipment properly and to provide for recycling at the end of its useful life. Technolas Perfect Vision GmbH fully complies with the WEEE Directive. This symbol on the product indicates that it must be separately collected and recycled in order to protect human health and the environment.

In that regard, Technolas Perfect Vision GmbH will arrange the collection and recycling of end-of-life Technolas Perfect Vision GmbH equipment.

To initiate the collection of end-of-life equipment, please contact an Authorized Service Technician.
Type plate for VICTUS™ Femtosecond Laser Platform with serial number ≤ TFW-0109 (see back side of the laser system)

The type plate contains the following information:
- Unit type
- Manufacturing date Year-Month-Day
- Serial number
- Supply mains
- Power consumption
- Mode
- Classification
- Manufacturer
- CE Mark with the number of the Notified Body

Type plate for VICTUS™ Femtosecond Laser Platform with serial number ≥ TFW-0110 (see back side of the laser system)

The type plate contains the following information:
- Unit type
- Manufacturing date Year-Month-Day
- Serial number
- Supply mains
- Power consumption
- Mode
- Classification
- Unique device identification (UDI)
- Manufacturer
- CE Mark with the number of the Notified Body

Installed software

This label is located next to the type plate. On the label you can find information about the software installed on the laser system.
Patent Label

This product, its manufacture, its use, or its components may be covered by US patents listed at www.TechnonasPV.com/patents/

This patent label is located next to the type plate and refers to the website where all patents are listed under which the VICTUS™ Femtosecond Laser Platform is manufactured or used.

'Vacuum' footswitch

The 'Vacuum' footswitch is labeled with the 'Vacuum' label and labels from the footswitch manufacturer.

'Procedure' label

The 'Procedure' footswitch is labeled with the 'Procedure' label and labels from the footswitch manufacturer.

Follow the instructions

Consult operator's manual.
3 Transport and storage

This chapter provides information regarding the delivery, unpacking, and storage of the laser system.

3.1 Transportation

The product will be delivered to you by a delivery company. Depending on the form of transportation, the product may be packed in wooden boxes, or the individual components will be transported with other protective material.

The packaging may be removed only by an Authorized Service Technician.

Do not move or transport the product yourself.

Hazards due to unauthorized transport!

The product is very sensitive to any changes in temperature, to shocks, or vibrations. Improper transport may result in property damage and impaired treatments, which can cause severe injuries.

The product must only be transported by a delivery company that is authorized by Technolas Perfect Vision GmbH. This requirement applies to delivery, to in-house transports, and to external transports.

3.2 Visual inspection after delivery

The product and the required documents are given to the carrier in perfect condition. The documents state the type and content of the delivered goods. Check the delivery note to ensure the completeness of the delivery. The carrier is responsible for delivering the product promptly and in perfect condition. Should a loss of parts or damage occur during transportation, the delivery company is responsible.

If there are defects or damage that have occurred during transport, perform the following steps:

- Inform the nearest service division immediately. A delay in reporting the damage may result in denial of the damage claim.
- Urge the delivery person to write down the kind of damage on the freight note immediately and sign the freight note as confirmation.
- Under certain circumstances, an expert’s opinion on the damage cost or the value of lost goods can only be provided by a representative of the transport insurance company.
- Fill in a form for the insurance company immediately. Payment for lost goods or for repair of damaged goods can only be obtained from the transport insurance company.
3.3 Storage before installation

After delivery to your clinic, hospital or practice, note the following:
- The individual parts of the shipment must be stored in a secure and dry place before installation and initial use.

3.4 Unpacking

After delivery, the product must be unpacked and installed by an Authorized Service Technician exclusively.

**WARNING**

Hazards due to unauthorized unpacking!
Removal of the transport safety device in the wrong sequence may result in damage.
- The product must only be unpacked by Authorized Service Technicians.
- The product must not be connected before Authorized Service Technicians have made sure that it is in proper working condition before initial operation.

Technolas Perfect Vision GmbH does not assume any liability for any damage to the product arising from unauthorized unpacking.
4 Installation, commissioning, service, calibration, decommissioning and disposal

4.1 Installation and commissioning

⚠️ CAUTION
Initial installation and commissioning are exclusively performed by Authorized Service Technicians. Unauthorized installation and commissioning will void the warranty.

⚠️ WARNING
Danger of serious injury in conjunction with improper service or maintenance!
The medical electrical equipment must not be serviced or maintained while it is in use with the patient.
- Never service or maintain the medical electrical equipment while it is in use with the patient.

⚠️ CAUTION
Hazards due to use of unauthorized accessories / tools / devices!
Only authorized accessories, tools or devices specified in this user manual are allowed for usage or replacement. Any damage caused by the improper usage of unauthorized accessories, tools or devices will void the certification and the warranty. Furthermore it may lead to increased emissions or decreased immunity of the equipment.
- Do not use other accessories / tools / devices than the ones specified in this user manual.

Longer periods out of operation
After longer periods out of operation, the conditions specified under "Chapter 11.4 'Transport and storage conditions' on page 11 - 4 must be observed.

After longer periods out of operation, the laser system can be started as described in "Chapter 6.2.3.1 'Switching the laser system on and off' on page 6 - 4 and in "Chapter 8.1.1 'Starting and closing the software' on page 8 - 1."
### 4.1.1 Interface of the patient beds "LS Comfort" and "Patient Support System S60" by AKRUS GmbH & Co KG

#### Interface ports at the VICTUS™ Femtosecond Laser Platform

![Interface ports at the VICTUS™ Femtosecond Laser Platform](image1)

**Fig. 4: Interface ports at the VICTUS™ Femtosecond Laser Platform**

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Interface port</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Power supply (laser system)</td>
</tr>
<tr>
<td>2</td>
<td>Main switch</td>
</tr>
<tr>
<td>3</td>
<td>Power patient bed</td>
</tr>
<tr>
<td>4</td>
<td>‘Vacuum’ footswitch</td>
</tr>
<tr>
<td>5</td>
<td>Interlock cable ‘Interlock Patient Bed’</td>
</tr>
<tr>
<td>6</td>
<td>‘Procedure’ footswitch</td>
</tr>
<tr>
<td>7</td>
<td>OP camera (optional)</td>
</tr>
<tr>
<td>8</td>
<td>Camera Live Image (optional)</td>
</tr>
<tr>
<td>9</td>
<td>Interlock external</td>
</tr>
</tbody>
</table>

#### Interface ports at the patient bed "LS Comfort"

![Interface ports at the patient bed "LS Comfort"](image2)

**Fig. 5: Interface ports at the patient bed "LS Comfort"**

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Interface port</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Interlock cable ‘INTERLOCK’</td>
</tr>
<tr>
<td>2</td>
<td>Joystick(s)</td>
</tr>
<tr>
<td>3</td>
<td>Power supply</td>
</tr>
<tr>
<td>4</td>
<td>Main switch</td>
</tr>
</tbody>
</table>

#### Interface ports at the patient bed "Patient Support System S60"

![Interface ports at the patient bed "Patient Support System S60"](image3)

**Fig. 6: Interface ports at the patient bed "Patient Support System S60"**

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Interface port</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Interlock cable</td>
</tr>
<tr>
<td>2</td>
<td>Not used</td>
</tr>
<tr>
<td>3</td>
<td>Power supply</td>
</tr>
<tr>
<td>4</td>
<td>Main switch</td>
</tr>
</tbody>
</table>
Danger of confusion due to identical-looking connectors at the interlock cable!
- Check for the labels on the cable to identify the connector that corresponds to the respective interface port.

1. Connect the laser system and the patient bed. Observe the cable labeling.
2. Verify that all cables are connected correctly and are seated firmly. The power cable must be snapped into place.
3. Verify the proper function of the interlock connection. To do so, apply a vertical force of >6 N. Observe the LED indicators on the force display. The patient bed must only be movable in the downward direction.

4.2 Service and calibration

Hazard due to improperly completed service or calibration!
Service or calibration that is completed by personnel other than Authorized Service Technicians may result in severe injuries to persons who perform the service, third parties or patients, and may damage the laser system.
- Service and calibration must only be performed by Authorized Service Technicians.

When do perform service and calibration

If system checks fail or other errors occur, service must be performed as soon as possible.
The service and calibration interval is 6 months.

Service life
The expected service life is 5 years.

4.3 Decommissioning and disposal

Danger of injury in conjunction with improper decommissioning and disposal!
Stored residual energies and components featuring edges, tips, and corners on and inside the laser system or on the required tools may cause injuries.
- Decommissioning and disposal must be performed by Authorized Service Technicians exclusively.

Technolas Perfect Vision GmbH will arrange for the collection and recycling of (a) end-of-life Technolas Perfect Vision GmbH equipment and (b) end-of-life equipment from other manufacturers when a Technolas Perfect Vision GmbH product is purchased to replace the older equipment and has identical functionality. To initiate the collection of end-of-life equipment, contact an Authorized Service Technician.
5 Clinical applications

The use of the laser system is the particular responsibility and is at the discretion of the user once the therapeutic benefits and possible complications and side effects have been considered.

**CAUTION**

Do not exceed a total exposure duration of one hour of the eye to the LED ring, as ophthalmic damage could occur.

5.1 Medical indications

This section provides information about the available procedures for specific indications.

<table>
<thead>
<tr>
<th>Medical indication</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract</td>
<td>Capsulotomy</td>
</tr>
<tr>
<td>Cataract</td>
<td>Lens fragmentation</td>
</tr>
<tr>
<td>Cataract</td>
<td>Corneal incisions</td>
</tr>
</tbody>
</table>

In addition, arcuate incisions are available as part of a cataract treatment.

<table>
<thead>
<tr>
<th>Medical indication</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>LASIK flap</td>
<td>Flap</td>
</tr>
</tbody>
</table>

**CAUTION**

Cataract procedures

**Corneal procedures**

<table>
<thead>
<tr>
<th>Medical indication</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>LASIK flap</td>
<td>Flap</td>
</tr>
</tbody>
</table>

**Therapeutic procedures**

<table>
<thead>
<tr>
<th>Medical indication</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miscellaneous diseases of the cornea</td>
<td>Penetrating keratoplasty (PKP)</td>
</tr>
<tr>
<td>Keratoconus</td>
<td>Intracorneal ring segments tunnel (ICRS tunnel), crosslinking (CXL)</td>
</tr>
<tr>
<td>Opacity of the cornea or superficial injury</td>
<td>Lamellar keratoplasty (LKP)</td>
</tr>
<tr>
<td>Keratectasia</td>
<td>Intracorneal ring segments tunnel (ICRS tunnel), crosslinking (CXL)</td>
</tr>
</tbody>
</table>
5.2 Patient selection criteria

⚠️ WARNING
Danger of injury due to the failure to observe the patient selection criteria!
Failure to observe the contraindications may result in serious permanent patient injury.

- Observe the contraindications in § Chapter 5.2.1 ‘Contraindications’ on page 5 - 2.

5.2.1 Contraindications

Limitations for usage of the laser system correspond to the exclusion criteria known to be associated with such applications.

Patients with pacemakers

The cover of the laser is designed in a way that electromagnetic fields are minimized. Nevertheless, special precaution must be taken when treating patients with pacemakers. Patients with pacemakers should only be treated in the presence of an anesthetist and after consultation with their cardiologist.

The following criteria apply to all procedures:

- Corneal opacity that would interfere with the laser beam.
- Pediatric surgery, patients under the age of 18 years or legal age.
- All valid exclusion criteria for the intended treatment like:
  - glaucoma and suspected glaucoma
  - diabetes mellitus
  - retinal disorders
  - rheumatic diseases
  - occlusion of retinal vessels
  - pellucid marginal degeneration
  - herpes zoster or herpes simplex keratitis
  - heavy vascularization of the ocular tissue
  - epilepsy
  - recurrent corneal erosion
  - severe basement membrane disease
  - patients who suffer from severe wound-healing disorders such as connective tissue disease, autoimmune illnesses, immunodeficiency illnesses, endocrine diseases, lupus, rheumatoid arthritis, collagenosis, or clinically significant atopy
  - patients suffering from AIDS or HIV.
- Valid exclusion criteria that complicate the docking procedure like:
  - chemosis
  - significant loss of stability of the conjunctiva
  - nystagmus
  - On a keratometric map of the cornea, the minimum and maximum K-values of the central 3 mm zone must not differ by more than 5 D.
  - The maximum K-values must not exceed 60 D. The minimum value must not be smaller than 37 D.
- Patients who are pregnant or nursing.
Patients who are blind in the fellow eye.
Known sensitivity to planned concomitant medications.
Patients with a recurrent or active ocular or uncontrolled eyelid disease.

In addition, the following applies to flap used in LASIK:
- Previous corneal surgery of any kind
- Dry eye diseases
- Cataract
- Patients with signs of progressive or unstable myopia in the eye that requires treatment.
- Keratoconus and suspected keratoconus.

In addition, the following applies to capsulotomy and lens fragmentation:
- Subjects with a poorly dilating pupil.
- Patients with an anterior chamber depth (ACD) < 1.5 mm or ACD > 4.8 mm as measured by ultrasonic examination.
- Presence of blood or other material in the anterior chamber.
- A history of lens instability (e.g. posterior polar cataract, traumatic cataract) or zonular instability.

In addition, the following applies to arcuate incisions and corneal incisions:
- Dry eye diseases
- Previous corneal surgery specifically incisions that might provide a potential space into which the gas produced by the procedure can escape.
- Corneal thickness requirements that are beyond the range of the system.
- Keratoconus and suspected keratoconus (only applicable for arcuate incisions).

In addition, the following applies to the therapeutic procedures:
- Previous corneal surgery of any kind.

5.3 Available procedures

**WARNING**

Danger of injury due to the failure to observe the patient selection criteria!
Failure to observe the contraindications may result in serious permanent patient injury.
- Observe the contraindications listed in the relevant chapter of this user manual.

5.3.1 Cataract procedures

The cataract treatment comprises the following procedures:
- Capsulotomy
- Lens fragmentation
- Arcuate incisions
- Corneal incisions
5 CLINICAL APPLICATIONS

Capsulotomy
With this procedure, the anterior capsulotomy is performed intraocularly by means of the laser system. The correct positioning of the capsulotomy cut on the anterior capsular surface can be verified by means of an integrated optical coherence tomography (OCT) device before starting the cutting process.

Lens fragmentation
This procedure generates precise cuts inside the cataractous lens, leading to a softening and fragmentation of the lens. The correct positioning of the cuts inside the lens can be verified by means of an OCT before starting the laser-assisted fragmentation process.

Arcuate incisions
With this procedure, the laser system is used for patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating cuts / incisions in the cornea.

Corneal incisions
This procedure creates cuts in the outer area of the cornea and very close to the sclera. These penetrating cuts / incisions are done at patients undergoing a cataract surgery for direct access into the eye. The correct position and shape of the cuts can be verified by the video image.

5.3.2 Corneal procedures
The corneal treatment comprises the following procedure:

- Flap

Flap
This procedure cuts a corneal flap. The flap is generated by cutting a bed parallel to the anterior surface of the cornea and a rim or side cut with a hinge. This procedure enables the user to define flap parameters such as the depth, the diameter of the bed, the position and the width of the hinge, and the angle of the rim cut in relation to the cornea.

5.3.3 Therapeutic procedures
The therapeutic treatment comprises the following procedures:

- Crosslinking
- Intracorneal ring segments tunnel
- Lamellar keratoplasty
- Penetrating keratoplasty

Crosslinking
The crosslinking software module provides certain advantages compared to the conventional method. By creating a bed and incisions for inserting Riboflavin, the Riboflavin does not have to be dripped onto the eye but can be inserted directly under the bed, and the cornea absorbs the Riboflavin faster. Furthermore, the epithelium does not have to be removed.
This procedure allows the user to set parameters such as depth, position, and number of the entrance incision(s).

**Intracorneal ring segments tunnel**

This procedure allows to create intrastromal channel incisions for nearly all types and sizes of ring segments. The results achieved are especially convincing in the treatment of keratoconus and ectasia. The incision follows the natural curvature of the cornea and enables optimal positioning of ICRS inside the stroma. The diameter, width, depth of the tunnel incisions and entrance incisions are individually adjustable.

**Lamellar keratoplasty**

Lamellar keratoplasty is usually performed when a superficial injury, opacity, or scarring of the cornea reduces visual acuity. The damaged cornea is removed and replaced by a healthy donor cornea. Lamellar keratoplasty has the advantage of being primarily extraocular and therefore preserves the recipient endothelium.

This procedure allows the user to cut the donor and recipient cornea with matching diameters and rim angles. This method facilitates better wound closure.

**Penetrating keratoplasty**

This procedure allows to cut a penetrating keratoplasty into the donor cornea as well as into the recipient's cornea. Diameter and depth are individually adjustable.
6 Hardware

6.1 Overview on the components

Depending of the laser system, the position of the surgical microscope illumination in the VICTUS™ Femtosecond Laser Platform can differ as described below.

<table>
<thead>
<tr>
<th>VICTUS™ Femtosecond Laser Platform with surgical microscope illumination on the top of the laser system</th>
<th>VICTUS™ Femtosecond Laser Platform with surgical microscope illumination integrated in the laser system</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Main unit</td>
<td>1 Main unit</td>
</tr>
<tr>
<td>2 Assistant workstation</td>
<td>2 Assistant workstation</td>
</tr>
<tr>
<td>3 Start-up panel</td>
<td>3 Start-up panel</td>
</tr>
<tr>
<td>4 Suction status controller and force display</td>
<td>4 Suction status controller and force display</td>
</tr>
<tr>
<td>5 Panel with knob for switching on/off laser ring light and another knob for shifting the camera focus between corneal and lens treatments</td>
<td>5 Panel with knob for switching on/off laser ring light and another knob for shifting the camera focus between corneal and lens treatments</td>
</tr>
<tr>
<td>6 Spacer cone with protection cover</td>
<td>6 Spacer cone with protection cover</td>
</tr>
<tr>
<td>7 Surgeon control screen</td>
<td>7 Surgeon control screen</td>
</tr>
<tr>
<td>8a Surgical microscope (optional)</td>
<td>8a Surgical microscope (optional)</td>
</tr>
<tr>
<td>8b Surgical microscope with illumination unit integrated in the laser system and footswitch for adjusting the illumination (optional)</td>
<td>8b Surgical microscope with illumination unit integrated in the laser system and footswitch for adjusting the illumination (optional)</td>
</tr>
<tr>
<td>9 Surgical microscope illumination</td>
<td>9 Surgical microscope illumination</td>
</tr>
</tbody>
</table>
6.2 Operating the hardware

6.2.1 Main unit

The main unit consists of the following components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistant workstation</td>
<td>Allows to perform the system tests, to enter and manage the patient data, to select and program procedures, to apply vacuum for PI 125 and suction clip, to adjust the procedure according to the patient’s eye and to export treatment records.</td>
</tr>
<tr>
<td>Chiller</td>
<td>Helps to ensure that the main components are kept at a steady temperature.</td>
</tr>
<tr>
<td>Controller</td>
<td>Checks the connectivity among all electronic components.</td>
</tr>
<tr>
<td>GUI PC</td>
<td>Interface between the user and the laser system.</td>
</tr>
<tr>
<td>Laser source</td>
<td>Generates the laser beam.</td>
</tr>
<tr>
<td>Optical unit</td>
<td>Controls the complete laser beam path.</td>
</tr>
<tr>
<td>Surgeon control screen</td>
<td>Shows a life camera image, a life OCT image, and all relevant parameters for the selected treatment.</td>
</tr>
<tr>
<td>Treatment illumination</td>
<td>Contains the laser ring light module. It illuminates the treatment area.</td>
</tr>
<tr>
<td>OCT</td>
<td>Monitors cataract, corneal and therapeutic treatments.</td>
</tr>
</tbody>
</table>

The core of the main unit is the laser source that generates the laser beam. All other components control and sustain the treatment process.

The following components are optional:

<table>
<thead>
<tr>
<th>Optional component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical microscope</td>
<td>Allows for centering the suction clip.</td>
</tr>
<tr>
<td>Surgical microscope illumination</td>
<td>Provides a uniform and adjustable illumination.</td>
</tr>
</tbody>
</table>
6.2.2 Assistant workstation / surgeon control screen

**Assistant workstation**

The assistant workstation (Fig. 7) consists of a monitor, a standard keyboard and a standard mouse. The monitor is mounted on a rotating arm and can be tilted. The mouse is also used for the surgeon control screen (Fig. 8).

**Surgeon control screen**

The surgeon control screen (Fig. 8) consists of a monitor and the standard mouse from the assistant workstation (Fig. 7). The monitor is mounted on a rotating arm and can be tilted. The surgeon control screen displays a live camera image and a live OCT image for cataract, corneal and therapeutic treatments. The screen also shows all relevant information about the main treatment parameters, vacuum and pressure status, as well as treatment progress.

6.2.2.1 Adjusting the monitor settings

For best visual accuracy it is recommended not to run the monitor in [ECO] mode.

Refer to the user manual of the monitor that you use.
6.2.3 Start-up panel

Fig. 9: Start-up panel

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USB ports</td>
</tr>
<tr>
<td>2</td>
<td>System key-operated ‘Off’ / ‘On’ switch</td>
</tr>
<tr>
<td>3</td>
<td>Indicator for the power supply</td>
</tr>
<tr>
<td>4</td>
<td>‘Laser Emission’ indicator during a running procedure.</td>
</tr>
<tr>
<td>5</td>
<td>‘Reset’ button to unlock the laser system if the ‘Laser Stop’ button has been pressed, or after a system error and also by starting the laser system.</td>
</tr>
<tr>
<td>6</td>
<td>‘Laser Stop’ button with integrated ‘Bed Stop’ function.</td>
</tr>
</tbody>
</table>

Property damage due to use of unauthorized accessories / tools / devices!

Only USB memory sticks specified in this user manual must be inserted into the USB ports.

– Do not insert other tools than the one specified in this user manual into the USB ports. Failure to observe these instructions may damage the laser system.

6.2.3.1 Switching the laser system on and off

Switching on

1. Turn the system key (Fig. 9/2) to the ‘On’ position. The ‘Power OK’ button (Fig. 9/3) lights up.

   ☑ A system self test runs for 5-10 minutes.
2. For initial start-up, wait at least 20 minutes to allow the cooling unit (chiller) to provide the required temperature. Press the blue ‘Reset’ button (Fig. 9/5) to start the laser source and wait for at least 20 minutes (automatic countdown).

Switching off

1. Turn the system key (Fig. 9/2) to the ‘Off’ position. The laser system shuts down with a safety delay of 5 minutes.
2. Remove the system key.

6.2.4 Suction status controller

The suction status controller (Fig. 10) allows the user to set the suction pressure for the suction clip. The vacuum decrease/increase is indicated by means of the LED bar display (Fig. 10/1). The range is from 350 mbar (1 LED illuminated) to 550 mbar (10 LEDs illuminated).

6.2.4.1 Adjusting the suction status

It is not possible to exceed the preset standard suction range in either direction.

Turn the controller (Fig. 10/2) clockwise to increase or counterclockwise to decrease the suction. The LED bar display (Fig. 10/1) indicates the suction pressure.
6.2.5 Force display

The force display (Fig. 11) is a control device that indicates important treatment parameters.

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘REGULAR PRESSURE’ LED</td>
<td>While docking the patient’s eye to the laser system with regular pressure, the ‘REGULAR PRESSURE’ LED (Fig. 11/1) gives the surgeon additional information about the pressure. If Fig. 11/1 is referred to, this LED will be stably illuminated when the docking pressure is correct. This is only valid for corneal treatments, therapeutic treatments, the arcuate incisions procedure and the corneal incisions procedure!</td>
</tr>
<tr>
<td>2</td>
<td>‘SOFT PRESSURE’ LED</td>
<td>While docking the patient’s eye to the laser system for cataract treatments, the ‘SOFT PRESSURE’ LED (Fig. 11/2) gives the surgeon additional information about the pressure. If Fig. 11/2 is referred to, this LED will be stably illuminated when the docking pressure is correct. This is only valid for cataract treatments, except for the arcuate incisions procedure and the corneal incisions procedure!</td>
</tr>
<tr>
<td>3</td>
<td>Shear force LEDs</td>
<td>25 LEDs display the shear forces that are exerted on the eye (Fig. 11/3). The LEDs are arranged in a circle.</td>
</tr>
<tr>
<td>4</td>
<td>‘WORKING’ control LED</td>
<td>After starting up the laser system, the force display performs a self check. Each of the shear force (x/y-) and vertical force (z-) LEDs blinks twice. When the check is completed, the control LED (Fig. 11/4) is illuminated green.</td>
</tr>
<tr>
<td>5</td>
<td>Position of the patient</td>
<td></td>
</tr>
</tbody>
</table>

6.2.6 Laser ring light illumination switch

The laser ring light illumination switch (Fig. 12/1) allows the user to switch the illumination of the laser ring light on/off.
6.2.6.1 Switching the laser ring light illumination on and off

1. Switch on the laser ring light illumination by turning the knob as follows (Fig. 12/1):
   - Position ‘2’: 2 LEDs are illuminated (for less reflection while centering the pupil)
   - Intermediate positions between ‘2’ and ‘OFF’
   - Intermediate positions between ‘OFF’ and ‘10’
   - Position ‘10’: 10 LEDs are illuminated (for centering the pupil while docking)

2. Switch off the laser ring light illumination by turning the knob to the ‘OFF’ position.

6.2.7 Camera focus switch

The camera focus switch (Fig. 12/2) allows to shift the camera focus for corneal and lens treatments.

6.2.7.1 Adjusting the camera focus

By turning the switch ‘CAM FOCUS’ (Fig. 12/2) clockwise the OP camera focuses on the lens, and by turning the switch counterclockwise the OP camera focuses on the cornea.

6.2.8 Spacer cone

Property damage due to an unprotected spacer cone!
The spacer cone is very delicate and may be damaged when it is not protected.
- Always protect the spacer cone with its protection cover when the laser system is not in use.

The spacer cone is the exit aperture of the laser beam. During treatment, the PI 125 and the patient are docked to the spacer cone via a vacuum.
Depending on the configuration of your laser system, the appropriate spacer cone (on page 6 - 7) is installed which works only with the corresponding PI 125.

"Spacer cone 9,5 + 10,5" (REF 14078) to be used for the PI 125 (REF 90000115):

"Spacer cone V4" (REF 14540) to be used for the PI 125 (REF 90000145):

6.2.8.1 Protecting the spacer cone

1. Slide the protection cover (Fig. 13) into the slot.
2. Turn the protection cover clockwise until it engages.

6.2.9 Surgical microscope and its illumination

The surgical microscope and the surgical microscope illumination are optional components.

The surgical microscope allows the surgeon to center the suction clip on the patient’s eye.
Surgical microscope components

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ocular lenses, adjustable</td>
</tr>
<tr>
<td>2</td>
<td>Ocular distance adjustment</td>
</tr>
<tr>
<td>3</td>
<td>Magnification displays</td>
</tr>
<tr>
<td>4</td>
<td>Magnification adjustment (5 different magnification settings)</td>
</tr>
<tr>
<td>5</td>
<td>Filter selection</td>
</tr>
<tr>
<td>6</td>
<td>Tilting joint</td>
</tr>
<tr>
<td>7</td>
<td>Fiber optics entry</td>
</tr>
<tr>
<td>8</td>
<td>Unlocking fiber optics</td>
</tr>
</tbody>
</table>

Surgical microscope filters

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Filter</th>
<th>Filter description</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘UV’</td>
<td>UV filter</td>
<td>Yellowness of the light; recommended for ophthalmology</td>
</tr>
<tr>
<td></td>
<td>Wide aperture: 5 mm</td>
<td>Optimum color fidelity</td>
</tr>
<tr>
<td></td>
<td>Spot: 2.65 mm</td>
<td>Optimum color fidelity</td>
</tr>
<tr>
<td></td>
<td>Mini spot: 0.25 mm</td>
<td>Optimum color fidelity</td>
</tr>
<tr>
<td>‘DF’</td>
<td>Daylight filter</td>
<td>Adaptation of halogen light to daylight</td>
</tr>
<tr>
<td>‘Blue’</td>
<td>Blue filter</td>
<td>Stimulation of fluorescence; temporary application with fluorescein</td>
</tr>
</tbody>
</table>

SKU: 70005780TPV * Version 6 * UM-100010770 GB
6.2.9.1 Adjusting the surgical microscope illumination

Depending on the position of the surgical microscope illumination, adjust the illumination as described below.

For surgical microscope illuminations that are positioned on the top of the laser system:

1. Remove the cover of the surgical microscope illumination (Fig. 15).

2. Switch on the ‘I/O’ power switch at the rear panel of the surgical microscope illumination (Fig. 16).

3. Adjust the illumination with the finger touch slider at the front panel (Fig. 17).

4. Close the cover of the surgical microscope illumination.
The illumination unit is positioned inside the laser system. It will be automatically switched on when the laser system is started.

The footswitch (Fig. 18) adjusts the brightness of the surgical microscope. The left pedal of the footswitch is used to darken the picture or to switch off the surgical microscope; the right pedal is used to increase the brightness. The brightness increment is more finely graduated and no longer linear.

The cable at the footswitch is connected to the surgical illumination unit.

If the laser system is running over night, remember to switch off the surgical microscope illumination by pressing the left footswitch (Fig. 18)!

6.2.10 Footswitches

<table>
<thead>
<tr>
<th>‘Procedure’ footswitch</th>
<th>‘Vacuum’ footswitch</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ‘Procedure’ footswitch has a red label and starts and controls the procedures.</td>
<td>The ‘Vacuum’ footswitch has a blue label and activates/deactivates the vacuum of the suction clip.</td>
</tr>
</tbody>
</table>

It is impossible to deactivate the vacuum of the suction clip with the ‘Vacuum’ footswitch during the treatment in order to avoid suction loss, which would lead to procedure abort.

Aborting the treatment by pressing the ‘Stop’ button in the GUI will automatically deactivate the vacuum.
6.2.11 Patient bed

**WARNING**

Danger of injury due to overloading the patient bed!
The patient bed is designed for a maximum patient weight of 135 kg. Overloading the patient bed may result in serious and permanent patient injury.

- Do not overload the patient bed!

**WARNING**

Risk of non-compliance of the ME system safety due to connecting the power supply of the patient bed to another equipment than the laser system!
The power supply for the patient bed may only be supplied from the laser system. Connecting the power supply of the patient bed to another equipment than the laser system may result in the loss of the ME system safety.

- Ensure that the power cable at the patient bed is connected to the interface port ‘Power patient bed’ at the laser system.

This figure (Fig. 19) shows an example of a patient bed that can be combined with the VICTUS™ Femtosecond Laser Platform.

---

6.2.11.1 Referencing the patient bed

If the patient bed "LS Comfort" or "Patient Support System S60" by AKRUS is used, this patient bed must be referenced at every time the laser system is switched on or after a power failure.

Refer to the user manual "Laser Patient Bed LS Comfort" or "Patient Support System PSS S60" by AKRUS GmbH & Co KG.
6.3 Cleaning instructions

Danger of property damage due to the use of improper cleaning agents!
The product may be damaged if it is cleaned with improper cleaning agents or scratching cleaning materials, such as cloths.

- Do not use solvents or lubricants.
- Do not use ether, acetone, concentrated acids, or bases.
- Do not use abrasive cleaning agents or cleaning agents with ammonia or other possibly caustic products.
- Do not use any steel wool or metal brushes.
- Before using a cleaning agent, test it on an inconspicuous area to check if the cleaning agent damages the material.

Use disinfectants recommended by local institutes for hygiene or microbiology.

You can use any standard neutral to slightly alkaline cleaning agent.

Use only soft lint-free cleaning cloths.

<table>
<thead>
<tr>
<th>Part of the laser system</th>
<th>Cleaning agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>All matte surfaces</td>
<td>Neutral or slightly alkaline cleaning agent</td>
</tr>
<tr>
<td>All lacquered surfaces</td>
<td>Neutral or slightly alkaline cleaning agent</td>
</tr>
<tr>
<td>Spacer cone</td>
<td>Alcohol</td>
</tr>
<tr>
<td>Oculars of the microscope</td>
<td>Alcohol</td>
</tr>
<tr>
<td>LCD screens</td>
<td>Commercially available cleaning kits for computers</td>
</tr>
<tr>
<td>Keyboard and mouse of the assistant workstation</td>
<td>Neutral or slightly alkaline cleaning agent</td>
</tr>
</tbody>
</table>

**Cleaning the laser system**

1. Switch off the laser system.
2. Ensure that no moisture enters the laser system.
3. Dilute the cleaning agent with water.
4. Soak a cleaning cloth in the diluted solution.
5. Wring out the cleaning cloth very well.
6. Wipe the laser system with the damp cleaning cloth.
7. Wipe the laser system with a dry cloth.
Cleaning the spacer cone

*NOTICE!* Contamination of the spacer cone lens occurs if alcohol enters the spacer cone!

Contaminations of the spacer cone lens can only be removed by Authorized Service Technicians.

- Do not spray alcohol into the spacer cone.
- Wipe the spacer cone with a lint-free cleaning cloth and some alcohol.

Cleaning the oculars of the surgical microscope

Wipe the oculars with a lint-free cleaning cloth and some alcohol.

Cleaning the assistant workstation and the surgeon control screen

1. Switch off the laser system.
2. Use a soft dry cleaning cloth to wipe the keyboard.

*NOTICE!* Danger of property damage due to aggressive cleaning agents and moisture!

The assistant workstation and surgeon control screen are electronic devices and are made of plastics.

- Do not use cleaning agents or abrasive powders that dissolve plastics.
- Ensure that no moisture enters the assistant workstation or the surgeon control screen.
- Ensure that the ventilation slots of the monitors remain open.
3. Follow the instructions on the cleaning kit for computers to clean the assistant workstation and the surgeon control screen.

Cleaning the patient bed

1. Switch off the laser system.
2. Wipe the mattress of the patient bed with a damp soft cloth.
3. Wait until the patient bed is dry before using it.

Refer to the user manual of the patient bed that you use.
7 Accessories and tools

The Patient Interfaces 125 and the Suction Clips 125 are accessories and the other items are additional tools.

7.1 Accessories

Patient Interface 125 of the Patient Interface 125 Kit (REF 90000115)
The PI 125 (REF 90000115) must only be used with the VICTUS™ Femtosecond Laser Platform (software version 2.7 and higher).

The PI 125 (REF 90000115) resembles a contact lens. The wider side (1) is sucked to the spacer cone of the laser system. The smaller side (2) contacts the corneal surface of the patient’s eye.

The product is sterile and for single use only!

WARNING! Ensure that the PI 125 (REF 90000115) is only used together with the suction clip (REF 90000115)!

Patient Interface 125 of the Patient Interface 125 Kit (REF 90000145)
The PI 125 (REF 90000145) must only be used with the VICTUS™ Femtosecond Laser Platform (software version 3.3 and higher).

The PI 125 (REF 90000145) resembles a contact lens. The wider side (1) is sucked to the spacer cone of the laser system. The smaller side (2) contacts the corneal surface of the patient’s eye.

The product is sterile and for single use only!

WARNING! Ensure that the PI 125 (REF 90000145) is only used together with the suction clip (REF 90000145)!

Suction Clip 125 of the Patient Interface 125 Kit (REF 90000115)
The suction clip (REF 90000115) must only be used with the VICTUS™ Femtosecond Laser Platform (software version 2.7 and higher).

The suction clip (REF 90000115) consists of a suction clip and a tube with a suction reservoir.

The product is sterile and for single use only!

WARNING! Ensure that the suction clip (REF 90000115) is only used together with the PI 125 (REF 90000115)!
Suction Clip 125 of the Patient Interface 125 Kit (REF 90000145)
The suction clip (REF 90000145) must only be used with the VICTUS™ Femto-second Laser Platform (software version 3.3 and higher).

The suction clip (REF 90000145) consists of a suction clip and a tube with a suction reservoir.

The product is sterile and for single use only!

WARNING! Ensure that the suction clip (REF 90000145) is only used together with the PI 125 (REF 90000145)!

7.2 Tools

User key
The user key stores and manages licenses for treatment procedures. The user key uses patented embedded encryption hardware and works exclusively with the VICTUS™ Femtosecond Laser Platform system software.

Detector head
The detector head is a part of the power meter and is used to perform the power test.

Digital scale
The digital scale is used to perform the pressure test. It is delivered with 2 batteries.
**Long adapter**
The long adapter is used to perform the depth test.

**Power meter**
The power meter is used to perform the power test.

**Round plate holder**
The round plate holder is a holder for the adapters used to perform the pressure test and the depth test.

**Short adapter**
The short adapter is used to perform the pressure test.

**Suction reservoir**
The suction reservoir is used to perform the vacuum test and is inserted into the suction port of the laser arm.
Support block
The support block is used during all system tests.
8 Software

8.1 Working with the software

Navigation and editing of elements within the graphical user interface are identical to a Microsoft® Windows operating system.

Operating the software

The laser system software can be operated from either of the two locations:
- Assistant workstation
- Surgeon control screen

The laser system software can be operated and managed by different personnel (see Chapter 2.6 ‘Personnel requirements’ on page 2-4).

Error messages

Problems are indicated by error messages.

8.1.1 Starting and closing the software

Danger of property damage due to aborted warm-up of the laser system!

The laser system must only be used after the warm-up has been completed. If you do not allow the laser system to warm up properly, the entire laser system may be permanently damaged.

- Do not abort warm-up.
- For initial start-up, wait at least 20 minutes after having turned the system key to the ‘On’ position. Only after waiting that 20 minutes, press the blue ‘Reset’ button. After having pressed the ‘Reset’ button, wait for at least 20 minutes (automatic countdown).

Precondition:
- The laser system and the monitors are switched on (see Chapter 6.2.3.1 ‘Switching the laser system on and off’ on page 6-4).
The startup screen appears and the system self test is performed automatically. The status of the system self test is displayed in the 'System state' dialog box (Fig. 21).

**System self test performed successfully:**
- If the system self test has been performed successfully, you can login after a few seconds (Fig. 22).

**System self test failed:**
- If the system self test failed, the ‘Startup menu’ dialog box appears (Fig. 24).
1. Click the ‘Status check’ (Fig. 24/4) button to repeat the system self test.

   Ensure that a USB memory stick is inserted in the USB port at the start-up panel!

2. If the system self test fails again, click the ‘Download logs’ button (Fig. 24/3).

   The log files are saved on the USB memory stick.

3. Contact your local Authorized Service Technician and send the log files.

Once the problem/fault has been rectified and the system self test has been performed successfully, log in the software (☞ ‘Log in the software’ on page 8 - 4).

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘Login’ button</td>
<td>The ‘Login’ button is disabled. Click to log in the software once the problem/fault has been rectified.</td>
</tr>
<tr>
<td>2</td>
<td>‘Open Tool Box’ button</td>
<td>Opens the ‘Tool Box’ software to perform troubleshooting, system modifications and/or adjustments at the laser system by an Authorized Service Technician.</td>
</tr>
<tr>
<td>3</td>
<td>‘Download logs’ button</td>
<td>Click to save the log files on a USB memory stick at the start-up panel. After the log files have been exported successfully, a message appears. The log files enable a fast problem/fault diagnosis.</td>
</tr>
</tbody>
</table>
### SOFTWARE

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>‘Status check’ button</td>
<td>Click to repeat the system self test.</td>
</tr>
<tr>
<td>5</td>
<td>‘System state’ dialog</td>
<td>Shows the system self test results.</td>
</tr>
</tbody>
</table>

#### Log in the software

![Login screen](image)

**Fig. 25: Login screen**

1. Enter your user name and password (Fig. 25/1).
2. Click ‘Log in’.
3. Click the ‘Select treatment mode LRCS / Corneal’ button (Fig. 27/4), if necessary.

**Fig. 26: ‘Select treatment mode’ screen**

- The ‘Select treatment mode’ screen (Fig. 26) opens.
4. Select ‘LRCS/Therapeutics (80 kHz)’ for cataract or therapeutic treatments, or ‘Flap (160 kHz)’ for flap procedures (Fig. 26).

Closing the software

Precondition:
- The patient bed is underneath the spacer cone.

1. Click ‘Log out’ (Fig. 27/15).
2. Then click ‘Quit’ (Fig. 25/2).

8.1.2 Elements of the ‘Main menu’ screen

![Main menu screen](image)

*Fig. 27: Elements of the ‘Main menu’ screen after login (example with ‘Flap (160 kHz)’)*

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Information header</td>
<td>Shows information about the name of the relevant menu or screen, the surgeon’s name, the patient’s name, the patient’s date of birth and the patient’s ID.</td>
</tr>
<tr>
<td>4</td>
<td>‘Select treatment mode LRCS / Corneal’ button</td>
<td>Opens the ‘Select treatment mode’ screen (refer to Fig. 26).</td>
</tr>
<tr>
<td>5</td>
<td>‘System test’ button</td>
<td>Opens the ‘System test’ screen (refer to Fig. 45).</td>
</tr>
</tbody>
</table>
### Elements of the treatment screens

The following illustrations show these elements using the flap treatment screens as an example. The elements are identical for all treatment types. Treatment-specific elements are described in Chapter 8.1.3.1 ‘Treatment-specific elements’ on page 8 - 11.
Fig. 28: Elements of the ‘Treatment planning’ screen (example)

Fig. 29: Elements of the ‘Treatment summary’ screen (example)
Fig. 30: Elements of the ‘Regular docking and treatment alignment’ screen (example)

Fig. 31: Elements of the ‘Treatment’ screen (example)
### ‘Treatment result’ screen

![Image of the ‘Treatment result’ screen](image)

**Fig. 32: Elements of the ‘Treatment result’ screen (example)**

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description / Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘Grid:’ drop-down selection</td>
<td>Select to fade in or to fade out the grid in the real-time video and have the choice of different grid patterns.</td>
</tr>
<tr>
<td>2</td>
<td>Position / treatment overlay</td>
<td>Activates the position overlay / treatment overlay to fade in or to fade out the schematic presentation of the pupil margin or limbus margin, the planned cuts/incisions and the circular arrangement in degrees in steps of 30 degrees in the real-time video.</td>
</tr>
<tr>
<td>3</td>
<td>Video (live) image</td>
<td>First displays a schematic eye image and later on the real-time video of the patient’s eye.</td>
</tr>
<tr>
<td>4</td>
<td>Gain slide control</td>
<td>Adjusts the illumination contrast in the real-time video via the slide control.</td>
</tr>
<tr>
<td>5</td>
<td>‘OD’ or ‘OS’</td>
<td>Shows the eye that shall be treated.</td>
</tr>
<tr>
<td>6</td>
<td>OCT B scan image</td>
<td>Shows the real-time OCT B scan image of the patient’s eye.</td>
</tr>
<tr>
<td>7</td>
<td>Procedure parameters dialog boxes</td>
<td>Click to view or specify the procedures parameter values.</td>
</tr>
<tr>
<td>8</td>
<td>‘Approve’ button</td>
<td>Click to verify the procedures parameter values.</td>
</tr>
<tr>
<td>9</td>
<td>‘Back’ button</td>
<td>Click to return to the previous screen.</td>
</tr>
<tr>
<td>10</td>
<td>‘Treatment summary’ overview</td>
<td>Shows a summarized overview about the patient’s data and the treatment’s data before starting the treatment.</td>
</tr>
<tr>
<td>11</td>
<td>Pressure status display</td>
<td>Displays the range of the contact forcing pressure on a scale. This applies to the regular docking procedures (flap, PKP, LKP, CXL, ICRS, as well as arcuate incisions and corneal incisions as part of the cataract treatment) and the docking procedures with reduced applanation pressure for wrinkle-free docking (capsulotomy and lens fragmentation).</td>
</tr>
</tbody>
</table>
## SOFTWARE

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description / Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>‘PI suction’ status indicator: ‘PI suction’ disabled</td>
<td>Displays the status of the PI suction vacuum. To enable or disable the PI suction, click the blue button next to the ‘PI suction’ status indicator.</td>
</tr>
<tr>
<td>13</td>
<td>‘Eye suction’ status indicator: ‘Eye suction’ disabled</td>
<td>Displays the status of the eye suction clip vacuum. To enable or disable the eye suction, click the blue button next to the ‘Eye suction’ status indicator.</td>
</tr>
<tr>
<td>14</td>
<td>‘Start’ button, ‘Stop’ button</td>
<td>Click the ‘Start’ button to start a procedure. Click the ‘Stop’ button to abort a procedure.</td>
</tr>
<tr>
<td>15</td>
<td>‘Eye suction’ timer</td>
<td>Starts running after the ‘Eye suction’ is enabled and stops when eye suction clip vacuum is lost.</td>
</tr>
<tr>
<td>16</td>
<td>Treatment progress bar</td>
<td>Shows the progress during performing the treatment.</td>
</tr>
<tr>
<td>17</td>
<td>‘Continue’ button</td>
<td>Click ‘Continue’ to open the ‘Treatment result’ screen.</td>
</tr>
<tr>
<td>18</td>
<td>‘Procedures’ dialog box</td>
<td>Shows the treatment results.</td>
</tr>
<tr>
<td>19</td>
<td>‘Remaining licenses’ dialog box</td>
<td>Shows the available/enabled procedures and the respective number of available licenses.</td>
</tr>
<tr>
<td>20</td>
<td>‘Next patient’ button</td>
<td>Click to return to the ‘Patient selection’ screen.</td>
</tr>
<tr>
<td>21</td>
<td>‘Main menu’ button</td>
<td>Click to return to the ‘Main menu’ screen.</td>
</tr>
<tr>
<td>22</td>
<td>‘Save as template’ button</td>
<td>Click to save the performed treatment as a template.</td>
</tr>
<tr>
<td>23</td>
<td>‘Show treatment record’ button</td>
<td>Click to show the respective treatment record.</td>
</tr>
<tr>
<td>24</td>
<td>‘PI suction’ enabled</td>
<td>Disables the PI suction (% on page 8 - 9/12) after performing the relevant procedure.</td>
</tr>
</tbody>
</table>

SKU: 70005780TPV * Version 6 * UM-100010770 GB
8.1.3.1 Treatment-specific elements

Fig. 33: Elements of the ‘LRCS’ ‘Treatment planning’ screen (example)

Fig. 34: Elements of the ‘LRCS’ ‘Soft docking’ screen (example)
Fig. 35: Elements of the ‘LRCS’ ‘Treatment alignment - lens’ screen (example)

Fig. 36: Elements of the ‘LRCS’ ‘Treatment alignment - cornea’ screen (example)
## Elements of the ‘LRCS’ ‘Treatment result’ screen (example)

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description / Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arcuate incisions in the video (live) image</td>
<td>The schematic presentation of the arcuate incisions is color-coded displayed in the real-time video.</td>
</tr>
<tr>
<td>2</td>
<td>Corneal incisions in the video (live) image</td>
<td>The schematic presentation of the corneal incisions is color-coded displayed in the real-time video.</td>
</tr>
<tr>
<td>3</td>
<td>Capsulotomy in the video (live) image</td>
<td>The schematic presentation of the capsulotomy is color-coded displayed in the real-time video.</td>
</tr>
<tr>
<td>4</td>
<td>Circular/radial cuts in the video (live) image</td>
<td>The schematic presentation of the circular and/or radial cuts of the lens fragmentation is color-coded displayed in the real-time video.</td>
</tr>
<tr>
<td>5</td>
<td>‘LRCS’ parameter values dialog boxes</td>
<td>Open the relevant dialog boxes to view or edit the respective parameter values.</td>
</tr>
<tr>
<td>6</td>
<td>OCT B scan image</td>
<td>Shows the real-time OCT B scan image of the patient’s eye. The flashing camera symbol represents the periodical updating of the OCT B scan image.</td>
</tr>
<tr>
<td>7</td>
<td>‘Restart recognition’ button</td>
<td>To restart the OCT-supported identification of ocular structures, click the ‘Restart recognition’ button.</td>
</tr>
<tr>
<td>8</td>
<td>‘Mark pupil’ button</td>
<td>If you do not agree with the results of the automatic identification of the ocular structures, click the ‘Mark pupil’ button to determine the pupil margin manually.</td>
</tr>
<tr>
<td>9</td>
<td>‘Mark limbus’ button</td>
<td>To center the capsulotomy and the lens fragmentation procedures to the limbus, click the ‘Mark limbus’ button to determine the limbus margin manually.</td>
</tr>
<tr>
<td>Pos.</td>
<td>Button/Field</td>
<td>Description / Action</td>
</tr>
<tr>
<td>------</td>
<td>--------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>10</td>
<td>‘Linear scan 0°’ OCT B scan image</td>
<td>Shows the real-time OCT linear scan image in 0° position of the patient’s eye. The flashing camera symbol represents the periodical updating of the OCT B scan image. Click the ‘Edit’ button to manually mark the anterior lens 0° position and posterior lens 0° position.</td>
</tr>
<tr>
<td>11</td>
<td>‘Linear scan 90°’ OCT B scan image</td>
<td>Shows the real-time OCT linear scan image in 90° position of the patient’s eye. The flashing camera symbol represents the periodical updating of the OCT B scan image. Click the ‘Edit’ button to manually mark the anterior lens 90° position and posterior lens 90° position.</td>
</tr>
<tr>
<td>12</td>
<td>Ring scan image</td>
<td>Provides depth information of structures in the eye scanned in a circular manner at the location of the planned capsulotomy. Click the ‘Mark capsulotomy’ button to mark the highest and lowest point of the anterior lens surface in the ring scan to ensure a complete capsulotomy cut.</td>
</tr>
<tr>
<td>13</td>
<td>‘Confirm’ button</td>
<td>Click the ‘Confirm’ button to accept all workflow settings.</td>
</tr>
<tr>
<td>14</td>
<td>‘-’ / ‘+’ buttons</td>
<td>To increase the rim height of the capsulotomy, click the ‘+’ button. To decrease the rim height of the capsulotomy, click the ‘-’ button.</td>
</tr>
<tr>
<td>15</td>
<td>‘Center to lens apex’ button</td>
<td>To center the capsulotomy and the lens fragmentation procedures to the lens apex, click the button.</td>
</tr>
<tr>
<td>16</td>
<td>‘3-click-centration’ button</td>
<td>To mark the pupil margin, click the ‘3-click-centration’ button.</td>
</tr>
<tr>
<td>17</td>
<td>‘Cyclotorsion’ buttons</td>
<td>To rotate the arcuate incisions and the corneal incisions clockwise, click the button. To rotate the arcuate incisions and the corneal incisions counterclockwise, click the button.</td>
</tr>
<tr>
<td>18</td>
<td>‘AI @ 225°’ ‘AI @ 45°’ OCT B scan images</td>
<td>These OCT B scan images show the position of the arcuate incisions. To adjust the cutting depth of each arcuate incision, click the relevant ‘Edit’ button.</td>
</tr>
<tr>
<td>19</td>
<td>‘Incision @ 90°’ / ‘Incision @ 180°’ / ‘Incision @ 0°’ OCT B scan images</td>
<td>These OCT B scan images show the cross sections of the cornea where the corneal incisions are planned.</td>
</tr>
<tr>
<td>20</td>
<td>‘Continue with not performed procedures’ button</td>
<td>To proceed with skipped procedures, click the ‘Continue with not performed procedures’ button.</td>
</tr>
</tbody>
</table>
Fig. 38: Elements of the ‘Flap’ ‘Regular docking and treatment alignment’ screen (example)

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OCT B scan image</td>
<td>Shows the real-time OCT B scan image of the patient’s eye.</td>
</tr>
<tr>
<td>2</td>
<td>‘Parameters’ dialog box</td>
<td>Shows flap parameters that can be changed last minute before starting the procedure. All other flap parameters are unchangeable at this point. It is only possible to change these parameters in the respective ‘Treatment planning’ screen.</td>
</tr>
<tr>
<td>3</td>
<td>‘Center to pupil’ button</td>
<td>Click the ‘Center to pupil’ button to center the flap automatically to the center of the pupil as far as possible.</td>
</tr>
</tbody>
</table>
Fig. 39: Elements of the ‘PKP’ ‘Treatment alignment’ screen (example)

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Button/Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ring scan image</td>
<td>Shows the real-time OCT ring scan image of the patient’s eye at the diameter of the planned cut.</td>
</tr>
<tr>
<td>2</td>
<td>‘Parameters’ dialog box</td>
<td>Shows the respective therapeutic parameters that can be changed last minute before starting the procedure.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All other therapeutics parameters are unchangeable at this point. It is only possible to change these parameters in the respective ‘Treatment planning’ screen.</td>
</tr>
<tr>
<td>3</td>
<td>‘3-click-centration’ button</td>
<td>If you do not agree with the results of the automatic identification of the ocular structures, click the ‘3-click-centration’ button to determine the pupil margin or the limbus margin manually.</td>
</tr>
</tbody>
</table>
8.1.4 Checking and modifying common settings

1. Click the ‘Settings’ button (Fig. 27/8) in the ‘Main menu’ screen.

![Fig. 40: 'Settings' screen](image)

2. Manage the general settings as described in the following table.

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘Start-up mode’ drop-down selection</td>
<td>Select the treatment mode for starting up the laser system. You can select ‘LRCS/Therapeutics (80 kHz)’ for cataract or therapeutic treatments, ‘Flap (160 kHz)’ for flap procedures or ‘Last mode’ for starting up the laser system in the treatment mode that was last used.</td>
</tr>
<tr>
<td>2</td>
<td>‘Date format’ drop-down selection</td>
<td>Select the date format that applies to the patient data and treatment data.</td>
</tr>
<tr>
<td>3</td>
<td>‘Enable corneal incision previews’ check box</td>
<td>Activate this check box to enable or to disable the OCT B scan images of the corneal incisions during the treatment.</td>
</tr>
<tr>
<td>4</td>
<td>‘Perform post-op OCT scans of arcuate and corneal incisions for the treatment record.’ check box</td>
<td>Activate this check box to perform post-op OCT scans of arcuate incisions and corneal incisions for the treatment record.</td>
</tr>
<tr>
<td>5</td>
<td>‘Current language’ drop-down selection</td>
<td>Select the user interface language.</td>
</tr>
</tbody>
</table>
8 SOFTWARE

8.1.5 Checking treatment licenses

Special tool: User key

1. Insert the user key in the ‘User Key’ port (Fig. 41/1) at the start-up panel of the laser system.

2. Click the ‘Licenses’ button on the ‘Main menu’ screen (Fig. 27/7).

   The ‘Remaining licenses’ dialog box (Fig. 42) shows the available/enabled procedures and the respective number of available licences.

3. To close the ‘Licenses’ screen, click the ‘Main menu’ button.

8.1.6 Restarting the software after an emergency shutdown

Ensure that no patient or equipment are attached to the spacer cone!

1. If required, undock the patient or the equipment and click ‘Confirm’.

   The software will shut down. Wait for the forced shutdown to close all programs.

2. Press the ‘Reset’ button (Fig. 41/5) at the start-up panel.

3. Wait for approximately 30 minutes until the reconnection is completed.

4. Continue as described in Chapter 8.1.1 ‘Starting and closing the software’ on page 8 - 1.
## 8.2 User administration

### 8.2.1 User profiles and specific rights

<table>
<thead>
<tr>
<th>Action</th>
<th>‘User’</th>
<th>‘Admin’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform system tests ([% Chapter 8.3 'System test description' on page 8 - 21)]</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Check ‘FEMTOCLICK’ licenses ([% Chapter 8.1.5 'Checking treatment licenses' on page 8 - 18])</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>View patient data</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Add new patients ([% Chapter 8.4.1 'Adding patients' on page 8 - 24])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Edit patient data ([% Chapter 8.4.3 'Editing patient data' on page 8 - 26])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Delete patient data ([% Chapter 8.4.4 'Deleting patient data' on page 8 - 26])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>View treatments</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Create new treatments ([% Chapter 8.4.6 'Creating treatments' on page 8 - 28])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Edit treatment data ([% Chapter 8.4.7 'Editing treatments' on page 8 - 32])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Delete treatment data ([% Chapter 8.4.8 'Deleting treatments' on page 8 - 32])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>View user data</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Add new users ([% Chapter 8.2.2 'Adding users' on page 8 - 20])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Edit registered user accounts ([% Chapter 8.2.3 'Editing registered user accounts' on page 8 - 21])</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Reset passwords</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Execute procedures ([% Chapter 9 'Treatment' on page 9 - 1])</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
8.2.2 Adding users

1. On the main screen, click the ‘Users’ button (Fig. 27/9) to open the ‘User management’ screen (Fig. 43).

2. To add a new user, click the ‘Add user’ button (Fig. 43/1).

3. Enter the user data in the mandatory fields of the ‘Add user’ dialog box (Fig. 44) and add the corresponding user profile to the user.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Username:’</td>
<td>Specifies the user name for login (minimum 6 characters). <strong>Mandatory.</strong></td>
</tr>
<tr>
<td>‘Full name:’</td>
<td>Specifies the user’s full name. <strong>Mandatory.</strong></td>
</tr>
<tr>
<td>‘User type:’</td>
<td>Shows the registered user profiles. Select the corresponding user profile for the new user.</td>
</tr>
<tr>
<td>‘Admin’</td>
<td></td>
</tr>
<tr>
<td>‘User’</td>
<td></td>
</tr>
<tr>
<td>‘Password:’</td>
<td>Specifies the user’s password (minimum 6 characters). <strong>Mandatory.</strong> To confirm, enter the password twice.</td>
</tr>
</tbody>
</table>
4. Click the ‘OK’ button to save the new user account.

8.2.3 Editing registered user accounts

1. On the ‘Main menu’ screen, click the ‘Users’ button (Fig. 27/9) to open the ‘User management’ screen (Fig. 43).
2. Click the user account that you want to edit.
3. To edit the data, click the ‘Edit user data’ button (Fig. 43/2).
4. View or specify the corresponding user record data in the ‘Add user’ dialog box (Fig. 44).
5. Click the ‘OK’ button.

8.3 System test description

The system tests include the functionality test for system components, the ‘Laser position test’ and four startup tests that the user must perform manually.

‘System test’ overview

<table>
<thead>
<tr>
<th>System test</th>
<th>Explanation</th>
<th>Performing the system test:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functionality test</td>
<td>The laser system automatically performs a system self test regarding the functionality of the system components. The results of the functionality test for the chiller are displayed on the ‘Chiller’ screen.</td>
<td>automatically after the laser system has been switched on</td>
</tr>
<tr>
<td>(chiller)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Laser position test’</td>
<td>The laser position sensor (LPS) checks the proper function of the laser scanner mirrors, as well as the integrity and precision of the proper alignment of the whole optical system.</td>
<td>manually daily after a treatment mode has been changed</td>
</tr>
<tr>
<td>‘Vacuum test’</td>
<td>Startup test</td>
<td>manually daily</td>
</tr>
<tr>
<td>‘Pressure test’</td>
<td>Startup test</td>
<td>manually daily</td>
</tr>
<tr>
<td>‘Depth test’</td>
<td>Startup test</td>
<td>manually daily after a treatment mode has been changed</td>
</tr>
<tr>
<td>‘Power test’</td>
<td>Startup test</td>
<td>manually daily after a treatment mode has been changed</td>
</tr>
</tbody>
</table>
The result of each system test is displayed in the ‘System test’ screen next to the relevant status indicator (Fig. 46).

**Performing the ‘System test’**

How to perform these system tests is described in the Chapter 9.3 ‘Performing the daily system test’ on page 9 - 2.

**Opening the ‘System test’ screen**

1. Click the ‘System test’ button on the ‘Main menu’ screen (Fig. 27/5) to open the ‘System test’ screen (Fig. 45).

   ![](image)

   **Fig. 45: ‘System test’ screen**

2. Click the relevant button (Fig. 45) to open the dialog box for the associated system test screen.

   You can proceed as follows:
   - Perform the ‘Laser position test’
   - Perform the startup tests
   - Verify the results of the automatic functionality test for the chiller.

**Status indicators**

<table>
<thead>
<tr>
<th>Status indicator</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>gray</td>
<td>System test has not been performed yet.</td>
</tr>
<tr>
<td>green</td>
<td>Test parameters are within the acceptable range. You can proceed with the next test or procedure.</td>
</tr>
<tr>
<td>red</td>
<td>A system error has occurred. You will not be able to start with the procedure. Contact an Authorized Service Technician.</td>
</tr>
</tbody>
</table>
After a successful system test, all status indicators have turned green.

Closing the ‘System test’

Click the ‘Main menu’ button (Fig. 45/7).

8.4 Patient / treatment administration

1. Click the ‘Patients’ button (Fig. 27/6) in the ‘Main menu’ screen.

2. Manage the patients and treatments as described in the following table.

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘Patients’ dialog box</td>
<td>Manage patient data. You can select patient data, create new patient records, modify or delete patient data.</td>
</tr>
<tr>
<td>2</td>
<td>‘Treatments’ dialog box</td>
<td>Manage patient data. You can select treatment records, modify or delete data in selected treatment records. If treatments have already been performed, the treatment records can be viewed.</td>
</tr>
<tr>
<td>3</td>
<td>‘Add treatment’ dialog box</td>
<td>Create new treatments.</td>
</tr>
<tr>
<td>4</td>
<td>‘Back’ button</td>
<td>Return to the ‘Main menu’ screen.</td>
</tr>
</tbody>
</table>
8.4.1 Adding patients

The ‘Patients’ dialog box must be opened (Fig. 47/1) in the ‘Patient selection’ screen.

1. To add a new patient, click ‘Add patient’ (Fig. 48/3).

2. Enter the patient data (Table on page 8-24) in the fields described below:

All (mandatory) fields must be filled in, otherwise the ‘OK’ button will not be enabled.

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Field Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘First name:’</td>
<td>Specifies the patient’s first name.</td>
</tr>
<tr>
<td>2</td>
<td>‘Last name:’</td>
<td>Specifies the patient’s last name.</td>
</tr>
</tbody>
</table>
3. To save the new patient data, click the ‘OK’ button.
   ⇒ The new patient is added to the database.

8.4.2 Selecting patients

The ‘Patients’ dialog box must be opened (Fig. 47/1) in the ‘Patient selection’ screen.

1. To search for a specific patient, enter at least the first characters of the patient’s first name, last name, date of birth or identifier in the search box (Fig. 48/1) of the ‘Patients’ dialog box.
   ⇒ The search result is highlighted (Fig. 48/2).

2. Click in the row with the patient that you want to select.
   ⇒ The treatments assigned to the selected patient are displayed in the ‘Treatments’ dialog box (Fig. 47/2).
8.4.3 Editing patient data

1. Select a patient as described in Chapter 8.4.2 ‘Selecting patients’ on page 8 - 25.

2. Click the ‘Edit’ button (Fig. 48/4) to open the corresponding dialog box.

3. View or edit the corresponding patient data (Fig. 50).

4. Click the ‘OK’ button to apply any changes.

8.4.4 Deleting patient data

Only data from patients, who have not been treated yet, may be deleted.

1. Select the patient that you want to delete as described in Chapter 8.4.2 ‘Selecting patients’ on page 8 - 25.

2. Click the ‘Delete’ button (Fig. 48/5).

3. To delete the patient data, confirm with ‘Yes’ in the warning message.
8.4.5 Selecting treatments for execution

**Precondition:**

A patient must be selected as described in Chapter 8.4.2 ‘Selecting patients’ on page 8 - 25.

1. To select a treatment in the ‘Treatments’ dialog box (Fig. 47/2), click on the row with the appropriate treatment.

   ![Fig. 51: ‘Treatments’ dialog box](image)

   - The selected treatment is highlighted (Fig. 51/1).

2. Click the ‘Select’ button (Fig. 51/2).

   ![Fig. 52: ‘Treatment summary’ screen (example)](image)

   - The ‘Treatment summary’ screen (Fig. 52) opens. So you can verify the parameter values before starting the treatment.

3. Continue with Chapter 9 ‘Treatment’ on page 9 - 1.
8.4.6 Creating treatments

**Precondition:**

A patient must be selected as described in Chapter 8.4.2 'Selecting patients' on page 8 - 25.

1. Click the ‘OD’ or ‘OS’ button (Fig. 47/3).

   ![Fig. 53: ‘Add treatment’ dialog box](image)

2. Select ‘Flap’ (Fig. 53/1) to create a flap procedure, ‘LRCS’ (Fig. 53/2) to create a cataract treatment or ‘Therapeutics’ (Fig. 53/3) to create a therapeutic treatment.

   ![Fig. 54: ‘Flap’ Template selection’ screen (example)](image)

   - The ‘Template selection’ screen (Fig. 54) opens to create a new treatment based on determined parameter default values or on a designated template.
The following table describes the relevant screens for the treatment selection and the treatment planning.

<table>
<thead>
<tr>
<th>Pos.</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fig. 54</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>'Template selection' screen header</td>
<td>Shows information about the selected patient, the user (surgeon) and if designated, the template's name.</td>
</tr>
<tr>
<td>2</td>
<td>'New template' button</td>
<td>Creates new treatment templates based on determined parameter default values or on a designated template.</td>
</tr>
<tr>
<td>3</td>
<td>'Back' button</td>
<td>Returns to the ‘Patient selection’ screen.</td>
</tr>
<tr>
<td>4</td>
<td>'Exit treatment' button</td>
<td>Closes a treatment.</td>
</tr>
<tr>
<td>Fig. 55</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>'Default' button</td>
<td>Creates a new treatment template based on determined parameter default values.</td>
</tr>
<tr>
<td>6</td>
<td>Designated template</td>
<td>Creates a new treatment template based on a designated template.</td>
</tr>
<tr>
<td>7</td>
<td>'Cancel' button</td>
<td>Returns to the previous ‘Template selection’ screen (Fig. 54).</td>
</tr>
<tr>
<td>Fig. 57</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>'Save template...' button</td>
<td>Saves a treatment template.</td>
</tr>
<tr>
<td>9</td>
<td>Parameter values dialog boxes</td>
<td>Open the relevant dialog boxes to view or specify the parameter values.</td>
</tr>
<tr>
<td>10</td>
<td>'Back' button</td>
<td>Click the ‘Back’ button to return to the previous ‘Template selection’ screen (Fig. 55).</td>
</tr>
<tr>
<td>11</td>
<td>'Approve' button</td>
<td>Verify and confirm the parameter values before starting the treatment.</td>
</tr>
</tbody>
</table>
8.4.6.1 Creating treatments based on default values

1. To create a new treatment which is based on determined parameter default values, click the 'New template' button (Fig. 54/2).

Fig. 55: ‘Flap’ ‘Template selection’ screen (new template)

2. Click the 'Default' button (Fig. 55/5).

3. To save the new treatment template, enter a name in the entry field (Fig. 56) and confirm with the 'OK' button.

Fig. 56: ‘Add template’ dialog box

4. View or modify the corresponding treatment data (Fig. 57/9).

Fig. 57: ‘Flap’ ‘Treatment planning’ screen (new template)

 podría ser útil proporcionar un breve resumen o enunciado en español para aquellos que no hablan inglés. Por ejemplo:

1. Para crear un nuevo tratamiento basado en valores predeterminados de parámetros, haga clic en el botón 'Nuevo plantilla' (Fig. 54/2).

Fig. 55: Pantalla de selección de plantillas ('Flap'), pantalla nueva (fig. 55)

2. Haga clic en el botón 'Predeterminado' (Fig. 55/5).

3. Para guardar la nueva plantilla de tratamiento, ingrese un nombre en el campo de entrada (Fig. 56) y confirme con el botón 'Aceptar' (Fig. 56).

Fig. 56: Diálogo de 'Agregar plantilla'

4. Ver o modificar los datos de tratamiento correspondientes (Fig. 57/9).

Fig. 57: Pantalla de planificación de tratamiento ('Flap'), pantalla nueva (fig. 57)
5. To start the treatment, click the ‘Approve’ button (Fig. 57/11) to confirm the parameter values. To save the treatment, click the ‘Exit treatment’ button (Fig. 57).

8.4.6.2 Creating treatments based on a template

1. Select the treatment template in the ‘Template selection’ screen (Fig. 58) to create a new treatment which is based on determined parameter values for a particular patient.

2. In the ‘Treatment planning’ screen (Fig. 57) view or modify the corresponding treatment data.

3. To save the changed treatment template, click the ‘Save template …’ button.

4. Enter a new template name and confirm with the ‘OK’ button.
   ⇒ The treatment can now be executed.
8.4.7 Editing treatments

**Precondition:**

- A patient must be selected as described in Chapter 8.4.2 ‘Selecting patients’ on page 8 - 25.

1. Select the treatment that you want to edit Chapter 8.4.5 ‘Selecting treatments for execution’ on page 8 - 27.

2. Verify the procedure parameter values in the relevant ‘Treatment summary’ screen (Fig. 52).

3. If required, click the ‘Back’ button and modify the procedure parameter values.

4. To save any changes, click the ‘Exit treatment’ button and confirm with ‘Yes’.

8.4.8 Deleting treatments

Deleting a treatment is only possible if the treatment has not been performed yet.

**Precondition:**

- A patient must be selected (see Chapter 8.4.2 ‘Selecting patients’ on page 8 - 25).

1. Select the treatment that you want to delete as described in Chapter 8.4.5 ‘Selecting treatments for execution’ on page 8 - 27.

2. Click the ‘Delete’ button over the highlighted row (Fig. 51/3).

3. To delete the treatment, confirm with ‘Yes’ in the warning message.
8.4.9 Deleting treatment templates

1. To delete a treatment template, click the ‘Delete template’ button (Fig. 54).

   ![Delete template button](image)

   Fig. 60: ‘Template selection’ screen
   - All treatment templates are displayed with red highlighted frames (Fig. 60).

2. Click the treatment template you want to delete and confirm with ‘Yes.’

8.4.10 Treatment records

A treatment record contains the following information:

- GUI software version
- User (surgeon) name
- Patient data
- Intervention date
- Images from the OP camera before the intervention
- Images from the OCT B scan before the intervention
- Treatment status
- Parameter values
- Images from the OP Cam after the intervention
- Images from the OCT B Scan after the intervention
8 SOFTWARE

Viewing a treatment record

1. Select the treatment record that you want to view (see Fig. 51).
2. Click the ‘Treatment record’ button (Fig. 51/4) in the highlighted row.
4. To close the ‘Treatment record’ screen, click the ‘Back’ button.

Exporting a treatment record

1. Select the treatment record that you want to export (see Fig. 51).
2. Click the ‘Treatment record’ button (Fig. 51/4) in the highlighted row.
3. Insert a USB memory stick in the ‘USB’ port at the start-up panel.
4. Click the ‘Export...’ button in the ‘Treatment record’ screen.
   ⇒ The treatment record’s data is now saved on the USB memory stick.

8.5 Procedure parameters

For detailed information about the relevant procedure parameter values refer to the addendum ‘VICTUS Femtosecond Laser Platform, SW V3.3 SP02 (English)’ (document no. ADD-100011422)!!
Danger of injury due to incorrect treatment values!
All procedure parameters and values must be correct and appropriate for the intended treatment. The failure to verify such parameters may result in serious permanent patient injury.

- Verify that the selected procedure parameters are appropriate for the selected treatment and can be applied safely.
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8.5.1 Parameters for capsulotomy

Precondition:
- A capsulotomy procedure must be selected (Fig. 62).

1. To view or specify the capsulotomy parameters, click the arrow downwards symbol (Fig. 62).

2. To view or specify the optional parameters, click ‘Options’.

3. To close the ‘Capsulotomy’ ‘Options’ dialog box, click ‘Close’.

4. To close the ‘Capsulotomy’ dialog box, click the arrow upwards symbol.

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Diameter [mm]:’</td>
<td>The diameter is determined by the cutting circle rim.</td>
</tr>
<tr>
<td>‘Rim height [µm]:’</td>
<td>Height of the shot capsulotomy.</td>
</tr>
<tr>
<td>‘Energy [µJ]:’</td>
<td>Energy level of each single pulse when cutting the rim.</td>
</tr>
<tr>
<td>‘Spot spacing [µm]:’</td>
<td>Distance from spot to spot on the line.</td>
</tr>
</tbody>
</table>
8.5.2 Parameters for lens fragmentation

Precondition:

- A lens fragmentation procedure must be selected (Fig. 65).

Fig. 65: ‘Lens fragmentation’ dialog box

For general information about how to view or specify parameter values refer to Chapter 8.5.1 ‘Parameters for capsulotomy’ on page 8 - 36. Parameter-specific information are described below.

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Line spacing [µm]:’</td>
<td>Distance of the spots from line to line.</td>
</tr>
<tr>
<td>‘Safety distance to pupil margin [µm]:’</td>
<td>The safety distance defines the minimal horizontal distance from the pupil margin to the outer border of the resulting treatment zone (the most radial point of the capsulotomy pattern will have a minimal distance to the iris margin as given by the radial safety distance to pupil margin).</td>
</tr>
</tbody>
</table>
To view or specify the circular/radial cuts, circular cuts, radial cuts or grid parameters, click the appropriate symbol (§ Table on page 8-38) to open the associated dialog box.

<table>
<thead>
<tr>
<th>Type</th>
<th>Symbol</th>
<th>Dialog box</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Circular cuts’</td>
<td>![Symbol]</td>
<td>![Dialog box]</td>
</tr>
<tr>
<td>‘Radial cuts’</td>
<td>![Symbol]</td>
<td>![Dialog box]</td>
</tr>
<tr>
<td>‘Circular cuts’</td>
<td>![Symbol]</td>
<td>![Dialog box]</td>
</tr>
<tr>
<td>‘Radial cuts’</td>
<td>![Symbol]</td>
<td>![Dialog box]</td>
</tr>
<tr>
<td>‘Grid’</td>
<td>![Symbol]</td>
<td>![Dialog box]</td>
</tr>
</tbody>
</table>

**Parameters**

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Number of circles:’</td>
<td>Number of circular cuts.</td>
</tr>
<tr>
<td>Parameter dialog box</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------</td>
</tr>
<tr>
<td>‘Diameter [mm]:’</td>
<td>Diameter of the largest circle.</td>
</tr>
<tr>
<td>‘Number of radials:’</td>
<td>Number of radial cuts.</td>
</tr>
<tr>
<td>‘Diameter [mm]:’</td>
<td>Outer diameter of the radial cut.</td>
</tr>
<tr>
<td>‘Energy [µJ]:’</td>
<td>Energy level of each single pulse when cutting the rim.</td>
</tr>
<tr>
<td>*</td>
<td></td>
</tr>
<tr>
<td>‘Number of circles:’</td>
<td>Number of circular cuts.</td>
</tr>
<tr>
<td>‘Diameter [mm]:’</td>
<td>Diameter of the largest circle.</td>
</tr>
<tr>
<td>*</td>
<td></td>
</tr>
<tr>
<td>‘Number of radials:’</td>
<td>Number of radial cuts.</td>
</tr>
<tr>
<td>‘Diameter [mm]:’</td>
<td>Diameter of the largest circle.</td>
</tr>
<tr>
<td>*</td>
<td></td>
</tr>
<tr>
<td>‘Grid size [µm]:’</td>
<td>Grid size in the real-time video.</td>
</tr>
<tr>
<td>‘Diameter [mm]:’</td>
<td>Diameter of the largest circle.</td>
</tr>
</tbody>
</table>

* The other parameters values are identical to the ‘Circular cuts’ / ‘Radial cuts’ parameters.
To view or specify the common parameters, click ‘Common options’ (Table on page 8 - 38).

Fig. 66: ‘Lens Fragmentation’ ‘Common options’ dialog box

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Spot spacing [µm]’</td>
<td>Distance from spot to spot on the line.</td>
</tr>
<tr>
<td>‘Line spacing [µm]’</td>
<td>Distance of the spots from line to line.</td>
</tr>
<tr>
<td>‘Anterior safety distance [µm]’</td>
<td>Minimum distance between the lens fragmentation pattern and the anterior lens surface in a vertical manner.</td>
</tr>
<tr>
<td>‘Posterior safety distance [µm]’</td>
<td>Minimum distance between the lens fragmentation pattern and the posterior lens surface in a vertical manner.</td>
</tr>
</tbody>
</table>

8.5.3 Parameters for arcuate incisions

Precondition:
- An arcuate incisions procedure must be selected (Fig. 67).

Fig. 67: ‘Arcuate incisions’ dialog box

For general information about how to view or specify parameter values refer to Chapter 8.5.1 ‘Parameters for capsulotomy’ on page 8 - 36. Parameter-specific information are described below.
If you change the parameters for incision 1, the relevant parameters for incision 2 are changed simultaneously.

If you change the parameters for incision 2, it does not affect the parameters for incision 1.

Every parameter change of incision 1 and/or incision 2 updates the respective B scan image automatically (Fig. 68).

**Fig. 68: ‘Arcuate incisions’ dialog box**

### Parameters

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Incision 1’</td>
<td>Perform a first arcuate incision.</td>
</tr>
<tr>
<td>‘Incision 2’</td>
<td>Perform a second arcuate incision.</td>
</tr>
<tr>
<td>‘Diameter [mm]’ (‘Incision 1’)</td>
<td>Double distance from the center to where the first cut will be performed.</td>
</tr>
<tr>
<td>‘Diameter [mm]’ (‘Incision 2’)</td>
<td>Double distance from the center to where the second cut will be performed.</td>
</tr>
<tr>
<td>‘Pachymetry [µm]’ (‘Incision 1’)</td>
<td>Thinnest pachymetry measured at the site of incision 1.</td>
</tr>
<tr>
<td>‘Pachymetry [µm]’ (‘Incision 2’)</td>
<td>Thinnest pachymetry measured at the site of incision 2.</td>
</tr>
<tr>
<td>‘Depth ratio [%]’ (‘Incision 1’)</td>
<td>Ratio of the incision 1 depth to the thinnest pachymetry measured.</td>
</tr>
<tr>
<td>‘Depth ratio [%]’ (‘Incision 2’)</td>
<td>Ratio of the incision 2 depth to the thinnest pachymetry measured.</td>
</tr>
<tr>
<td>‘Resulting depth [µm]’ (‘Incision 1’)</td>
<td>Absolute depth of the incision 1 given in microns.</td>
</tr>
</tbody>
</table>
### Parameter dialog box

<table>
<thead>
<tr>
<th>Definition</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Resulting depth [µm]:' ('Incision 2')</td>
<td>Absolute depth of the incision 2 given in microns.</td>
</tr>
<tr>
<td>'Position [°]:' ('Incision 1')</td>
<td>Defines the position of the first cut.</td>
</tr>
<tr>
<td>'Position [°]:' ('Incision 2')</td>
<td>Position of the second cut, normally position angle from first cut + 180°.</td>
</tr>
<tr>
<td>'Size [°]:' ('Incision 1')</td>
<td>Length of the first cut in degrees, which determines the arc length.</td>
</tr>
<tr>
<td>'Size [°]:' ('Incision 2')</td>
<td>Length of the second cut in degrees, which determines the arc length.</td>
</tr>
</tbody>
</table>

To view or specify the common parameters, click ‘Common options’ (Fig. 68).

### 'Common options' dialog box

![Common options dialog box](image)

**Fig. 69:** 'Arcuate incisions' 'Common options' dialog box

### 'Common options' parameters

<table>
<thead>
<tr>
<th>Definition</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Energy [µJ]:'</td>
<td>Energy level of each single pulse of the rim cut.</td>
</tr>
<tr>
<td>'Side cut angle [°]:'</td>
<td>Angle of the incision in respect to the corneal anterior surface.</td>
</tr>
<tr>
<td>'Spot spacing [µm]:'</td>
<td>Distance from spot to spot on the line.</td>
</tr>
<tr>
<td>'Line spacing [µm]:'</td>
<td>Distance of the spots from line to line.</td>
</tr>
<tr>
<td>'Top bonus [µm]:'</td>
<td>Rim bonus at the top.</td>
</tr>
</tbody>
</table>
8.5.4 Parameters for corneal incisions

Precondition:
- A corneal incisions procedure must be selected (Fig. 70).

Fig. 70: ‘Corneal incisions’ parameters dialog box

For general information about how to view or specify parameter values refer to Chapter 8.5.1 ‘Parameters for capsulotomy’ on page 8 - 36. Parameter-specific information are described below.

‘Corneal incisions’ dialog box

The dialog box shows the automatically updated B scan images of the primary corneal incision (‘Primary’), the secondary incision 1 (‘Side port 1’) and/or the secondary incision 2 (‘Side port 2’) (Fig. 71).

Fig. 71: ‘Corneal incisions’ parameters dialog box

Parameters

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Primary’</td>
<td>Perform a primary corneal incision.</td>
</tr>
<tr>
<td>‘Outer width [mm]’ (‘Primary’)</td>
<td>Adjust the outer width of the primary incision according to the size of the selected IOL.</td>
</tr>
<tr>
<td>‘Inner width [mm]’ (‘Primary’)</td>
<td>Adjust the inner width of the primary incision according to the size of the selected IOL.</td>
</tr>
<tr>
<td>‘Axis [°]’ (‘Primary’)</td>
<td>Select the position of the primary incision. This value may be changed according to the cyclorotation of the eye after the patient has been docked.</td>
</tr>
</tbody>
</table>
### Parameter dialog box

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Chord length [µm]’ (Primary)</td>
<td>Length of the primary corneal incision from PI 125 level to the posterior end of the primary corneal incision (measured in chord length).</td>
</tr>
<tr>
<td>‘Side port 1’</td>
<td>Option to perform a secondary corneal incision 1.</td>
</tr>
<tr>
<td>‘Outer width [mm]’ (‘Side port 1’)</td>
<td>Adjust the outer width of the secondary incision 1.</td>
</tr>
<tr>
<td>‘Inner width [mm]’ (‘Side port 1’)</td>
<td>Adjust the inner width of the secondary incision 1.</td>
</tr>
<tr>
<td>‘Axis [°]’ (‘Side port 1’)</td>
<td>Select the position of the secondary incision 1. This position may be changed according to the cyclorotation of the eye after the patient has been docked.</td>
</tr>
<tr>
<td>‘Chord length [µm]’ (Side port 1)</td>
<td>Length of the secondary corneal incision 1 from PI 125 level to posterior end of the secondary corneal incision 1 (measured in chord length).</td>
</tr>
<tr>
<td>‘Side port 2’</td>
<td>Option to perform a secondary corneal incision 2.</td>
</tr>
<tr>
<td>‘Outer width [mm]’ (‘Side port 2’)</td>
<td>Adjust the outer width of the secondary incision 2.</td>
</tr>
<tr>
<td>‘Inner width [mm]’ (‘Side port 2’)</td>
<td>Adjust the inner width of the secondary incision 2.</td>
</tr>
<tr>
<td>‘Axis [°]’ (‘Side port 2’)</td>
<td>Select the position of the secondary incision 2. This position may be changed according to the cyclorotation of the eye after the patient has been docked.</td>
</tr>
<tr>
<td>‘Chord length [µm]’ (Side port 2)</td>
<td>Length of the secondary corneal incision 2 from PI 125 level to posterior end of the secondary corneal incision 2 (measured in chord length).</td>
</tr>
</tbody>
</table>

**Incision options’ dialog boxes**

Every parameter change updates the respective B scan image automatically (Fig. 72).

The parameter value of ‘Depth [µm]’ ‘Plane 1’ must be lower than the parameter value of ‘Depth [µm]’ ‘Plane 2’ and the parameter value of ‘Depth [µm]’ ‘Plane 2’ must also be lower than the parameter value of ‘Depth [µm]’ ‘Plane 3’.
Fig. 72: ‘Corneal incisions’ ‘Incision options: Primary incision’ parameters dialog box (example)

### Parameters

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘One plane’</td>
<td></td>
</tr>
<tr>
<td>‘Depth [µm]’ (‘Plane 1’)</td>
<td>Depth of the first plane of the primary incision, secondary incision 1 or secondary incision 2.</td>
</tr>
<tr>
<td>‘Angle [°]’ (‘Plane 1’)</td>
<td>Cutting angle for the first plane of the primary incision, secondary incision 1 or secondary incision 2.</td>
</tr>
<tr>
<td>‘Two planes’</td>
<td></td>
</tr>
<tr>
<td>‘Depth [µm]’ (‘Plane 2’)</td>
<td>Depth in which the second plane of the primary incision, secondary incision 1 or secondary incision 2 ends.</td>
</tr>
<tr>
<td>‘Length [µm]’ (‘Plane 2’)</td>
<td>Length of the second plane of the primary incision, secondary incision 1 or secondary incision 2.</td>
</tr>
<tr>
<td>‘Three planes’</td>
<td></td>
</tr>
<tr>
<td>‘Depth [µm]’ (‘Plane 3’)</td>
<td>Depth in which the final plane of the primary incision, secondary incision 1 or secondary incision 2 ends.</td>
</tr>
<tr>
<td>‘Angle [°]’ (‘Plane 3’)</td>
<td>Cutting angle for the third plane of the primary incision, secondary incision 1 or secondary incision 2.</td>
</tr>
<tr>
<td>‘Chord length [µm]’</td>
<td>Length of the corneal incision from PI 125 level to the posterior end of the corneal incision (measured in chord length).</td>
</tr>
</tbody>
</table>
### 8.5.4.1 Schematic overview on corneal incisions

Schematic view of planes 1, 2, and 3
Schematic view of the plane depths

Schematic view of the side cut angles
8.5.5 Parameters for flap

Precondition:
- A flap procedure must be selected (Fig. 74).

For general information about how to view or specify parameter values refer to Chapter 8.5.1 ‘Parameters for capsulotomy’ on page 8 - 36. Parameter-specific information are described below.

**Fig. 74: Dialog boxes for flap procedures**

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Flap thickness [µm]:’</td>
<td>Distance from the bed to the epithelium surface measured in µm.</td>
</tr>
<tr>
<td>‘Diameter [mm]:’</td>
<td>The diameter of the flap is determined by the cutting circle of the bed and the rim (measured in chord length).</td>
</tr>
</tbody>
</table>

**Fig. 75: ‘Flap size’ dialog box**

**‘Bed’ dialog box**

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Energy [µJ]:’</td>
<td>Energy level of each single pulse when cutting the bed.</td>
</tr>
<tr>
<td>‘Spot spacing [µm]:’</td>
<td>Distance from spot to spot on the line.</td>
</tr>
<tr>
<td>‘Line spacing [µm]:’</td>
<td>Distance of the spots from line to line.</td>
</tr>
<tr>
<td>‘Disable bed cut’</td>
<td>To disable the bed cut, click ‘Disable bed cut’.</td>
</tr>
</tbody>
</table>

**Fig. 76: ‘Bed’ dialog box**
### ‘Rim’ dialog box

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Energy [µJ]:’</td>
<td>Energy level of each single pulse of the rim cut.</td>
</tr>
<tr>
<td>‘Spot spacing [µm]:’</td>
<td>Distance from spot to spot on the line.</td>
</tr>
<tr>
<td>‘Line spacing [µm]:’</td>
<td>Distance of the spots from line to line.</td>
</tr>
<tr>
<td>‘Side cut angle [°]:’</td>
<td>Angle between the surface tangent and the rim cut. A rim angle above 90° tilts the rim towards the center.</td>
</tr>
<tr>
<td>‘Top bonus [µm]:’</td>
<td>Additional rim at the top. To ensure that the rim is extended past the cornea, it is best to use a positive value.</td>
</tr>
</tbody>
</table>

### ‘Hinge’ dialog box

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Position:’</td>
<td>Predefined position of the hinge.</td>
</tr>
<tr>
<td>‘Position [°]:’</td>
<td>Angle of the center of the hinge.</td>
</tr>
<tr>
<td>‘Size [°]:’</td>
<td>The length of the hinge width is measured as an angle or length in µm. The size of the hinge length can be determined by the angle or the hinge width.</td>
</tr>
</tbody>
</table>

---

**Fig. 77: ‘Rim’ dialog box**

**Fig. 78: ‘Hinge’ dialog box**

**Fig. 79: Rim cut angle**
### Parameters for penetrating keratoplasty

**Precondition:**
- A penetrating keratoplasty procedure must be selected (Fig. 80).

**Parameter dialog box**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Diameter [mm]'</td>
<td>Diameter of the PKP at the anterior surface of the cornea.</td>
</tr>
<tr>
<td>'Pachymetry [µm]'</td>
<td>Pachymetry of the thickest point of the cornea at the diameter of the PKP.</td>
</tr>
<tr>
<td>'Depth ratio [%]'</td>
<td>Ratio of cutting depth to pachymetry, should be above 100 % for PKP.</td>
</tr>
<tr>
<td>'Resulting depth [µm]'</td>
<td>Cutting depth resulting from pachymetry and depth ratio.</td>
</tr>
<tr>
<td>'Posterior diameter [mm]'</td>
<td>Diameter of the PKP at the posterior surface of the cornea resulting from entered pachymetry, diameter and side cut angle.</td>
</tr>
</tbody>
</table>

**'Size' dialog box**

Every parameter change updates the B scan image automatically (Fig. 80).
**8.5.7 Parameters for lamellar keratoplasty**

**Precondition:**

- A lamellar keratoplasty procedure must be selected (Fig. 83).

For general information about how to view or specify parameter values refer to Chapter 8.5.1 ‘Parameters for capsulotomy’ on page 8 - 36. Parameter-specific information are described below.

---

**Fig. 83: Lamellar keratoplasty dialog boxes**

---

**Fig. 82: ‘Rim’ dialog box**
### ‘Size’ dialog box

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Diameter [mm]:’</td>
<td>Diameter of the LKP at the anterior surface of the cornea.</td>
</tr>
<tr>
<td>‘Pachymetry [µm]:’</td>
<td>Pachymetry of the thinnest point of the cornea at the diameter of the LKP.</td>
</tr>
<tr>
<td>‘Depth ratio [%]:’</td>
<td>Ratio of cutting depth to pachymetry.</td>
</tr>
<tr>
<td>‘Resulting depth [µm]:’</td>
<td>Cutting depth resulting from pachymetry and depth ratio.</td>
</tr>
<tr>
<td>‘Posterior diameter [mm]:’</td>
<td>Diameter of the LKP bed resulting from entered pachymetry, diameter and side cut angle.</td>
</tr>
</tbody>
</table>

### ‘Bed’ dialog box

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Energy [µJ]:’</td>
<td>Energy level of each single pulse when cutting the bed.</td>
</tr>
<tr>
<td>‘Spot spacing [µm]:’</td>
<td>Distance between adjacent spots on a line when cutting the bed.</td>
</tr>
<tr>
<td>‘Line spacing [µm]:’</td>
<td>Distance between spots of adjacent lines when cutting the bed.</td>
</tr>
</tbody>
</table>

### ‘Rim’ dialog box

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Energy [µJ]:’</td>
<td>Energy level of each single pulse when cutting the rim.</td>
</tr>
<tr>
<td>‘Spot spacing [µm]:’</td>
<td>Distance between adjacent spots on a line when cutting the rim.</td>
</tr>
<tr>
<td>‘Line spacing [µm]:’</td>
<td>Distance between spots of adjacent lines when cutting the rim.</td>
</tr>
<tr>
<td>‘Side cut angle [%]:’</td>
<td>Angle between the corneal surface tangent and the rim cut. A side cut angle below 90° leads to larger anterior than posterior diameter.</td>
</tr>
<tr>
<td>‘Top bonus [µm]:’</td>
<td>Extension of the rim cut at the anterior side of the cornea to ensure exit of laser cut out of the eye.</td>
</tr>
</tbody>
</table>
8.5.8 Parameters for crosslinking

Precondition:
- A crosslinking procedure must be selected (Fig. 87).

For general information about how to view or specify parameter values refer to Chapter 8.5.1 ‘Parameters for capsulotomy’ on page 8 - 36. Parameter-specific information are described below.

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>’Bottom bonus [µm]’</td>
<td>Extension of the rim cut inside the cornea to ensure that rim and bed cut overlap.</td>
</tr>
<tr>
<td>’Arc length [°]’</td>
<td>Arc length of rim cut, normally 360°.</td>
</tr>
<tr>
<td>’Arc center position [°]’</td>
<td>Central position of rim cut in case it is not 360°.</td>
</tr>
<tr>
<td>’Posterior diameter [mm]’</td>
<td>Diameter of the LKP bed resulting from entered pachymetry, diameter and side cut angle.</td>
</tr>
</tbody>
</table>

Fig. 87: Crosslinking dialog boxes

<table>
<thead>
<tr>
<th>’Size’ dialog box</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth [µm]: 140</td>
</tr>
<tr>
<td>Diameter [mm]: 7.5</td>
</tr>
</tbody>
</table>

Fig. 88: ’Size’ dialog box

<table>
<thead>
<tr>
<th>’Size’ parameter values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameter dialog box</td>
</tr>
<tr>
<td>’Depth [µm]’</td>
</tr>
<tr>
<td>’Diameter [mm]’</td>
</tr>
</tbody>
</table>
8.5.9 Parameters for ICRS tunnel

Precondition:
- An intracorneal ring segments tunnel procedure must be selected (Fig. 91).
For general information about how to view or specify parameter values refer to Chapter 8.5.1 ‘Parameters for capsulotomy’ on page 8 - 36. Parameter-specific information are described below.

**‘Tunnel’ / ‘Incisions’ dialog boxes**

<table>
<thead>
<tr>
<th>Parameter dialog box</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Tunnel dialog box" /></td>
<td>Perform a full tunnel, i.e. a full circle.</td>
</tr>
<tr>
<td>‘Diameter [mm]’</td>
<td>Central diameter of tunnel in projection.</td>
</tr>
<tr>
<td>‘Tunnel width [µm]’ (‘Tunnel 1’)</td>
<td>Width of the tunnel 1.</td>
</tr>
<tr>
<td>‘Tunnel length [°]’ (‘Tunnel 1’)</td>
<td>Length of the tunnel 1.</td>
</tr>
<tr>
<td>‘Position [°]’ (‘Tunnel 1’)</td>
<td>Central position of the tunnel 1.</td>
</tr>
<tr>
<td>‘Pachymetry [µm]’ (‘Tunnel 1’)</td>
<td>Pachymetry of the thinnest point of the cornea at the diameter of the ICRS.</td>
</tr>
<tr>
<td>‘Depth ratio [%]’ (‘Tunnel 1’)</td>
<td>Ratio of cutting depth to pachymetry.</td>
</tr>
<tr>
<td>‘Resulting depth [µm]’ (‘Tunnel 1’)</td>
<td>Cutting depth resulting from pachymetry and depth ratio.</td>
</tr>
<tr>
<td>‘Energy [µJ]’ (‘Tunnel 1’)</td>
<td>Energy level of each single pulse when cutting the tunnel.</td>
</tr>
<tr>
<td>‘Spot spacing [µm]’ (‘Tunnel 1’)</td>
<td>Distance between adjacent spots on a line when cutting the tunnel.</td>
</tr>
<tr>
<td>‘Line spacing [µm]’ (‘Tunnel 1’)</td>
<td>Distance between spots of adjacent lines when cutting the tunnel.</td>
</tr>
</tbody>
</table>

**Fig. 91: ICRS tunnel dialog boxes - full tunnel**

**Fig. 92: ‘Tunnel’ dialog box - full tunnel**
### Parameters that remain unchanged are not listed in the table below.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Position of incision 1 [°]:’</td>
<td>Perform incision 1.</td>
</tr>
<tr>
<td>‘Position of incision 1 [°]:’</td>
<td>Position incision 1.</td>
</tr>
<tr>
<td>‘Position of incision 2 [°]:’</td>
<td>Perform incision 2.</td>
</tr>
<tr>
<td>‘Position of incision 2 [°]:’</td>
<td>Position incision 2.</td>
</tr>
<tr>
<td>‘Length of incision 1 [µm]:’</td>
<td>Length of incision 1.</td>
</tr>
<tr>
<td>‘Length of incision 2 [µm]:’</td>
<td>Length of incision 2.</td>
</tr>
<tr>
<td>‘Energy [µJ]:’</td>
<td>Energy level of each single pulse when cutting the incisions.</td>
</tr>
<tr>
<td>‘Spot spacing [µm]:’</td>
<td>Distance between adjacent spots on a line when cutting the incisions.</td>
</tr>
<tr>
<td>‘Line spacing [µm]:’</td>
<td>Distance between spots of adjacent lines when cutting the incisions.</td>
</tr>
<tr>
<td>‘Top bonus [µm]:’</td>
<td>Extension of the incision cut at the anterior side of the cornea to ensure exit of laser cut out of the eye.</td>
</tr>
<tr>
<td>‘Bottom bonus [µm]:’</td>
<td>Extension of the incision cut inside the cornea to ensure that incision and tunnel cut overlap.</td>
</tr>
<tr>
<td>Parameter</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>'Tunnel width [µm]:'</td>
<td>Width of the tunnel segment.</td>
</tr>
<tr>
<td>'Tunnel length [°]:'</td>
<td>Length of the tunnel segment.</td>
</tr>
<tr>
<td>'Position [°]:'</td>
<td>Central position of the tunnel segment.</td>
</tr>
</tbody>
</table>

Parameters that remain unchanged are not listed in the table below.

Fig. 95: 'Tunnel' dialog box - single tunnel segment

Fig. 96: 'Incisions' dialog box - single tunnel segment

Fig. 97: ICRS dialog boxes - two-tunnel segments
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform two tunnel segments.</td>
<td></td>
</tr>
<tr>
<td>'Tunnel width [µm]': (‘Tunnel 1’)</td>
<td>Width of the tunnel segment 1.</td>
</tr>
<tr>
<td>'Tunnel length [°]': (‘Tunnel 1’)</td>
<td>Length of tunnel segment 1.</td>
</tr>
<tr>
<td>'Position [°]': (‘Tunnel 1’)</td>
<td>Central position of tunnel segment 1.</td>
</tr>
<tr>
<td>'Tunnel width [µm]': (‘Tunnel 2’)</td>
<td>Width of the tunnel segment 2.</td>
</tr>
<tr>
<td>'Tunnel length [°]': (‘Tunnel 2’)</td>
<td>Length of tunnel segment 2.</td>
</tr>
<tr>
<td>'Position [°]': (‘Tunnel 2’)</td>
<td>Central position of tunnel segment 2.</td>
</tr>
<tr>
<td>'Position of incision 1 [°]':</td>
<td>Perform incision 1.</td>
</tr>
<tr>
<td>'Length of incision 1 [µm]':</td>
<td>Length of incision 1.</td>
</tr>
<tr>
<td>'Position of incision 1 [°]':</td>
<td>Position of incision 1.</td>
</tr>
<tr>
<td>'Position of incision 2 [°]':</td>
<td>Perform incision 2.</td>
</tr>
<tr>
<td>'Length of incision 2 [µm]':</td>
<td>Length of incision 2.</td>
</tr>
<tr>
<td>'Position of incision 2 [°]':</td>
<td>Position of incision 2.</td>
</tr>
</tbody>
</table>
8.5.9.1 Schematic overview on ICRS tunnel incisions

The ICRS tunnel procedure allows the user to select the diameter, width, and depth of the tunnel. Up to two entry incisions can be created. The incisions are radial to the tunnel. The length and position of the cuts are adjustable. A schematic view of an intrastromal tunnel dissection is shown. The entry incision, which is marked as the bold blue solid line, is the only opening to the corneal surface.
Schematic side view of width and bottom bonus

Overview on the incision axes for left and right eye
9 Treatment

Danger of injury due to user negligence!
The user is responsible for performing a treatment with the VICTUS™ Femto-second Laser Platform. The user must supervise the whole treatment process.

Only the user (surgeon) is allowed to start a treatment by pressing the ‘Start’ button in the GUI and to operate the ‘Procedure’ footswitch. Failure to observe this responsibility may result in serious permanent patient injury.

Patients with pacemakers

The cover of the laser is designed in a way that electromagnetic fields are minimized. Nevertheless, special precaution must be taken when treating patients with pacemakers. Patients with pacemakers should only be treated in the presence of an anesthetist and after consultation with their cardiologist.

In the case of emergency shutdown of the laser system or treatment abortion by the user, please refer to Chapter 10 ‘Troubleshooting chart’ on page 10 - 1.

9.1 Preparing the laser system for a treatment day

1. Disinfect the surgery environment.
2. Switch on the laser system (Chapter 6.2.3.1 ‘Switching the laser system on and off’ on page 6 - 4).
   
   While the laser system warms up, you can proceed with the following tasks.
3. Reference the patient bed (Chapter 6.2.11.1 ‘Referencing the patient bed’ on page 6 - 12).
4. Adjust the surgical microscope, if required (Chapter 6.2.9.1 ‘Adjusting the surgical microscope illumination’ on page 6 - 10).
5. When the laser system warm-up is finished, login to the software.
6. Select the treatment mode that you want to perform (Fig. 27/4).
7. Perform the system tests (Chapter 9.3 ‘Performing the daily system test’ on page 9 - 2).

9.2 Maintaining the laser system after a treatment day

1. Clean the spacer cone ( ‘Cleaning the spacer cone’ on page 6 - 14).
2. Protect the spacer cone with the protection cover (Chapter 6.2.8.1 ‘Protecting the spacer cone’ on page 6 - 8).
3. Clean the patient bed ( ‘Cleaning the patient bed’ on page 6 - 14).
4. Shut down the laser system (Chapter 6.2.3.1 ‘Switching the laser system on and off’ on page 6).

9.3 Performing the daily system test

Whenever you change the treatment mode from ‘LRCS/Therapeutics (80 kHz)’ to ‘Flap (160 kHz)’ or vice versa during a treatment day, you must always repeat the following tests:

- Select the treatment mode ‘LRCS/Therapeutics (80 kHz)’ for cataract/therapeutic treatments or ‘Flap (160 kHz)’ for flap procedures (Fig. 27/4) in the ‘Main menu’ screen.
- Perform the following tests:
  - ‘Laser position test’
  - ‘Depth test’
  - ‘Power test’

9.3.1 Chiller submenu

1. Click the ‘System test’ button (Fig. 27/5) on the ‘Main menu’ screen.

2. Click the ‘Chiller’ button (Fig. 45/1) to open the ‘Chiller’ screen.

Fig. 100: ‘Chiller’ screen after chiller functionality test

- The ‘Chiller’ screen (Fig. 100) opens.

The following information are displayed:

- ‘Connection’ status
- ‘Power’ status
- ‘Coolant level’ status
Current flow' status
'Supply temperature' status
'Current flow [l/min]'
'Supply temperature [°C]'

If the functionality test for the chiller has been performed successfully, the status indicators next to the parameters turn green.

If an error occurs, an error message will open. In the case of an error condition, the corresponding status indicator turns red.

9.3.2 Performing the laser position test

If the 'Laser position test' has been completed successfully, it is valid for one treatment or for 24 hours.

If you fail to execute a procedure within this time frame, the 'Laser position test' must be repeated!

1. Click the 'System test' button (Fig. 27/5) on the 'Main menu' screen.

2. Click the 'Laser position test' button (Fig. 45/4) to open the 'Laser position test' screen (Fig. 101).

3. Follow the instructions in the 'Laser position test' screen.
4. Click the ‘OK’ button to close the message ‘Laser position test successful.’.

\[\Rightarrow\] The ‘Laser position test’ screen closes and the status indicator turns green (Fig. 102).

9.3.3 Performing the vacuum test

Special tool: Suction reservoir

\textit{If the ‘Vacuum test’ has been performed successfully, it is valid for 24 hours!}

1. Click the ‘System test’ button (Fig. 27/5) on the ‘Main menu’ screen.

2. Click the ‘Vacuum test’ button (Fig. 45/2) to open the ‘Vacuum test’ screen.

3. Follow the instructions in the ‘Vacuum test’ screen.
4. Click the ‘OK’ button to close the message ‘Vacuum test successful.’.

The ‘Vacuum test’ screen closes and the status indicator turns green (Fig. 104).

5. Remove the suction reservoir dummy.

9.3.4 Performing the pressure test

Special tools:
- Digital scale
- Round plate holder
- Short adapter
- Support block

1. Click the ‘System test’ button (Fig. 27/5) on the ‘Main menu’ screen.

2. Click the ‘Pressure test’ button (Fig. 45/3) to open the ‘Pressure test’ screen.

3. Follow the instructions in the ‘Pressure test’ screen.
9. Click the ‘OK’ button to close the message ‘Pressure test successful.’.

♀ The ‘Pressure test’ screen closes and the status indicator turns green (Fig. 106).

9.3.5 Performing the power test

The following section describes how to perform the ‘Power test’ for cataract/therapeutic and corneal treatments.

Special tool:
- Detector head
- Power meter
- Support block

1. Click the ‘System test’ button (Fig. 27/5) on the ‘Main menu’ screen.

2. Click the ‘Power test’ button (Fig. 45/5) to open the ‘Power test’ screen.

3. Follow the instructions in the ‘Power test’ screen.
4. Click the ‘OK’ button to close the message ‘Power test successful.’.

→ The ‘Power test’ screen closes and the status indicator turns green (Fig. 108).

9.3.6 Performing the depth test

Special tool:
- Long adapter
- Round plate holder
- Support block

Materials:
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000115) or
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000145)

You can use a PI 125 for up to five depth tests. To use a PI 125 more than once, choose a different diameter in the ‘Diameter:’ field for each depth test.

1. Click the ‘System test’ button (Fig. 27/5) on the ‘Main menu’ screen.

2. Click the ‘Depth test’ button (Fig. 45/6) to open the ‘Depth test’ screen.
3. Follow the instructions in the ‘Depth test’ screen.

4. Click the ‘OK’ button to close the message ‘Depth test successful.’.

⇒ The ‘Depth test’ screen closes and the status indicator turns green (Fig. 110).

9.4 Daily routine
9.4.1 When performing a treatment

Infection hazard due to loss of sterility!
The following tasks must be performed by the sterile user to guarantee sterility of the instruments and accessories. Never perform these tasks in a non-sterile environment.

– Removing the suction clip from the package.
– Opening the suction clip.
– Placing the suction clip onto the patient's eye.
– Verifying that the suction is actually engaged.
– Docking the patient to the PI 125.
– Closing the suction clip.
– Performing the treatment.

1. Observe all hygiene regulations related to medical treatments.

2. Select the patient you want to treat (☞ Chapter 8.4.2 ‘Selecting patients’ on page 8 - 25).
   - If the patient is not already in the patient database, create a new patient record for this patient (☞ Chapter 8.4.1 ‘Adding patients’ on page 8 - 24).
3. Select the treatment you want to perform (§ Chapter 8.4.5 'Selecting treatments for execution' on page 8 - 27).
   - To view the respective procedure parameters, check the parameters in the relevant ‘Treatment summary’ screen.
     Click ‘Back’ to open the associated ‘Treatment planning’ screen where you can make necessary changes in the relevant parameter’s dialog boxes.
   - If the treatment is not already recorded in the database, create a new treatment for this patient (§ Chapter 8.4.6 'Creating treatments' on page 8 - 28).

   It is not possible to select a treatment that has already been executed. If you want to perform a similar treatment on the second eye, this treatment has to be defined separately.

⚠️ WARNING! Danger of injury due to incorrect parameters!
If parameters are illogical and not within the recommended range, the treatment results may differ from the desired outcome, which may cause severe patient injuries.

- Always enter and verify all parameters very carefully.

For detailed information about the relevant procedure parameter values refer to the ‘Addendum to the user manual “VICTUS Femtosecond Laser Platform, SW V3.3 SPO2” (English)’ (document no. ADD-100011422)!

4. Before starting a treatment, ensure that all parameters are within the recommended range.

5. Ask the patient to enter the operating room.

6. If patients have their hair in a knot or a ponytail, ask the patient to loosen their hair.

9.4.2 Positioning the patient on the patient bed

Depending on the headrest being used, position the patient on the patient bed as described in the following subchapters.
9.4.2.1 Using a headrest with integrated joystick

1. Press the red pushbutton (Fig. 111/2 or Fig. 112/3) on the side of the headrest and allow 3 seconds for the lock to engage and disengage to facilitate the smooth movement of the patient bed. Swing the patient bed out completely.

2. Ask the patient to lie down and ensure that the legs of the patient are not crossed.

3. Place the leg bolster under the patient’s knees to improve patient comfort and discourage crossing of legs.

4. Ask the patient to lay the arms alongside his body or fold them lightly clasped across the stomach.

5. Use the molded headrest to securely and comfortably fixate the patient’s head.

   ☐ The patient is positioned on the patient bed so that the cornea is in a horizontal plane.

Refer to the user manual "Laser Patient Bed LS Comfort" or "Patient Support System PSS S60" by AKRUS GmbH & Co KG for instructions on how to operate the patient bed.

The supplied leg bolster should always be used to reduce patient movement.
9.4.2.2 Using a headrest with external joysticks

1. Press the silver-coded function button (Fig. 113/1) at the front of the headrest and allow 3 seconds for the lock to engage and disengage to facilitate the smooth movement of the patient bed. Swing the patient bed out completely.

Refer to the user manual "Laser Patient Bed LS Comfort" for instructions on how to operate the patient bed.

2. Ask the patient to lie down and ensure that the legs of the patient are not crossed.

The supplied leg bolster should always be used to reduce patient movement.

3. Place the leg bolster under the patient’s knees to improve patient comfort and discourage crossing of legs.

4. Ask the patient to lay the arms alongside his body or fold them lightly clasped across the stomach.

5. Use the molded headrest to securely and comfortably fixate the patient’s head.

6. To secure the position of the patient and to minimize head movement during the procedure, fasten the Velcro strapping (Fig. 114/1) across the forehead.

The patient is positioned on the patient bed so that the cornea is in a horizontal plane.

9.4.3 Connecting the PI 125 to the spacer cone and positioning the suction clip

The VICTUS™ Femtosecond Laser Platform may be used

- with the Patient Interface 125 Kit (REF 90000115) as well as
- with the Patient Interface 125 Kit (REF 90000145)
9 TREATMENT

Patient Interface 125 Kit (REF 90000115)

Refer to the “Patient Interface 125 Kit (REF 90000115)” instructions for use.

Outer packaging

Inner packaging

Patient Interface 125 Kit (REF 90000145)

Refer to the “Patient Interface 125 Kit (REF 90000145)” instructions for use.

Outer packaging

Inner packaging

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Infection hazard due to loss of sterility!
The PI 125 Kit packaging must not be damaged or opened. The expiry dates must not be exceeded. Damaged or opened packaging may result in loss of sterility and increases the risk of infections and severe injuries.

- Always inspect the PI 125 Kit packaging and ensure that it is not damaged in any way.
- Do not use the PI 125 and the suction clip if packaging is damaged or already opened.
- Do not open the packaging until you are ready to use it.
- Do not touch the PI 125 and the suction clip with powdered medical gloves. Only open shortly before treatment.

Infection hazard due to loss of sterility!
The non-sterile person must not touch the PI 125 or the suction clip. If necessary, dispose of the PI 125 Kit and use a different one.
The sterile person must not touch the packaging of the PI 125 Kit.

Before connecting the PI 125 to the spacer cone, ensure that the contact surface of the spacer cone is absolutely clean.

- Clean the contact surface of the spacer cone, if necessary (‘Cleaning the spacer cone’ on page 6 - 14).

1. Inspect the PI 125 Kit packaging, and dispose of all materials if they are damaged or already open.
2. Follow the procedures below.

9.4.3.1 Connecting the PI 125 (REF 90000115) to the spacer cone and positioning the suction clip (REF 90000115)

**WARNING!** Ensure that the PI 125 (REF 90000115) is only used together with the suction clip (REF 90000115)!

**WARNING!** Ensure that the suction clip (REF 90000115) is only used together with the PI 125 (REF 90000115)!
The following tasks shall be performed by a non-sterile person only:

1. Open the aluminium bag and remove the blister (Fig. 115/1) containing the PI 125 Kit (REF 90000115).
   Open the protective cover, keep all components of the kit inside the blister (Fig. 115/1), and secure the inlay (Fig. 115/2) with your thumb.

2. Hold the blister (Fig. 115/1) with the PI 125 (REF 90000115) under the spacer cone so that the PI 125 (REF 90000115) can be sucked to the spacer cone.
3. Enable the ‘PI suction’ in the software to activate the vacuum of the spacer cone.

Fig. 117: ‘Regular docking and treatment alignment’ screen: ‘PI suction’ enabled (example)

The PI 125 (REF 90000115) is sucked to the spacer cone. The green ‘PI suction’ status indicator (Fig. 117) indicates that the vacuum is in the valid range.

The PI 125 (REF 90000115) must be properly connected to the spacer cone to prevent suction loss.

⚠️ WARNING! Danger of injury due to contamination of the PI 125 (REF 90000115)!

If the PI 125 (REF 90000115) is contaminated during the docking process, infection of the patient’s eye may occur.

- Do not open the PI 125 Kit (REF 90000115) packaging until you are ready to use it.
4. If there is a problem with the PI recognition (Fig. 118), click 'Repeat PI recognition' to restart the PI recognition process.

   If the problem persists, repeat step 4.

5. Connect the suction reservoir to the suction port.
   - The suction reservoir is connected to the suction port (Fig. 119).

6. Using the recess (Fig. 115/3), remove the inlay (Fig. 115/2) without touching the suction clip (REF 90000115). Hold the blister so that the sterile person can remove the suction clip (REF 90000115).

   ![Fig. 119: Suction reservoir connected](image)

   **WARNING! Infection hazard due to loss of sterility!**
   The following task must be performed by the sterile user only to ensure the sterility of the suction clip (REF 90000115).

7. Without touching the blister (Fig. 115/1), remove the suction clip (REF 90000115) carefully. Inspect it for any visible damage or contamination.

   - If the suction clip (REF 90000115) is damaged in any way, dispose of the suction clip (REF 90000115) and use a different one.
WARNING! Infection hazard due to loss of sterility!
The following task must be performed by the sterile user only to ensure the sterility of the suction clip (REF 90000115).

8. If the suction clip (REF 90000115) is not open, open it by pulling the snap-fit (Fig. 120/1) backwards.

9. Place the suction clip (REF 90000115) centrally onto the patient’s eye.
   ⇒ The suction clip (REF 90000115) is positioned correctly.

10. To activate the vacuum for the suction clip (REF 90000115), press the ‘Vacuum’ footswitch once. Alternatively enable the ‘Eye suction’ (Fig. 121) in the software.

11. If a suction loss has occurred, check the connection between the suction port and the suction reservoir. Adjust the connection, if necessary, and repeat steps 5 to 10.

12. To verify that the suction is actually engaged, gently lift the suction clip (REF 90000115).

13. Press the release button at the patient bed and wait 3 seconds for the lock to disengage, swing the patient bed completely in (under the laser system) and wait 3 seconds for the lock to engage.
9.4.3.2 Connecting the PI 125 (REF 90000145) to the spacer cone and positioning the suction clip (REF 9000145)

**WARNING!** Ensure that the PI 125 (REF 90000145) is only used together with the suction clip (REF 9000145)!

**WARNING!** Ensure that the suction clip (REF 9000145) is only used together with the PI 125 (REF 90000145)!

The following tasks shall be performed by a non-sterile person only:

1. Split the blister packs (Fig. 123) of the PI 125 Kit (REF 90000145) into two parts at the perforation line (Fig. 123/3).
2. Open the protective cover of the PI 125 blister pack containing the PI 125 (REF 90000145) (Fig. 123/1).
3. Keep the PI 125 (REF 90000145) inside the PI 125 blister pack.
4. Without touching the PI 125 (REF 90000145), hold the PI 125 blister pack (Fig. 123/1) under the spacer cone so that the PI 125 (REF 90000145) can be sucked to the spacer cone.

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**Fig. 123: PI 125 Kit (REF 90000145) blister packs**

1. Split the blister packs (Fig. 123) of the PI 125 Kit (REF 90000145) into two parts at the perforation line (Fig. 123/3).
2. Open the protective cover of the PI 125 blister pack containing the PI 125 (REF 90000145) (Fig. 123/1).
3. Keep the PI 125 (REF 90000145) inside the PI 125 blister pack.
4. Without touching the PI 125 (REF 90000145), hold the PI 125 blister pack (Fig. 123/1) under the spacer cone so that the PI 125 (REF 90000145) can be sucked to the spacer cone.
5. Enable the ‘PI suction’ in the software to activate the vacuum of the spacer cone.

![Fig. 124: ‘PI suction’ disabled]

**Fig. 124: ‘PI suction’ disabled**

**Fig. 125: ‘Regular docking and treatment alignment’ screen: ‘PI suction’ enabled (example)**

– The PI 125 (REF 90000145) is sucked to the spacer cone. The green ‘PI suction’ status indicator (Fig. 125) indicates that the vacuum is in the valid range.

– The PI 125 (REF 90000145) must be properly connected to the spacer cone to prevent suction loss.

**WARNING! Danger of injury due to contamination of the PI 125 (REF 90000145)!**

If the PI 125 (REF 90000145) is contaminated during the docking process, infection of the patient’s eye may occur.

– Do not open the PI 125 Kit (REF 90000145) packaging until you are ready to use it.
9. **TREATMENT**

**PI recognition does not work:**

6. If there is a problem with the PI recognition (Fig. 126), click ‘Repeat PI recognition’ to restart the PI recognition process.

   If the problem persists, repeat step 6.

7. Open the protective cover of the suction clip blister pack containing the suction clip (REF 9000145) (Fig. 123/2).

8. Keep all components inside the suction clip blister pack.

9. Hold the suction clip blister pack (Fig. 123/2) so that the sterile person can remove the suction clip (REF 9000145).
WARNING! Infection hazard due to loss of sterility!
The following tasks must be performed by the sterile user only to ensure the sterility of the suction clip (REF 90000145).

10. Without touching the suction clip blister pack (Fig. 123/2), take the suction reservoir (Fig. 127/1) of the suction clip (REF 90000145) and connect it to the suction port (Fig. 128).

   Remove the suction clip (REF 90000145) by using the handle (Fig. 127/4). Inspect it for any visible damage or contamination.

   ■ If the suction clip (REF 90000145) is damaged in any way, dispose of the suction clip (REF 90000145) and use a different one.

WARNING! Infection hazard due to loss of sterility!
The following task must be performed by the sterile user only to ensure the sterility of the suction clip (REF 90000145).

11. If the suction clip (REF 90000145) is not open, open it by pulling the snap-fit (Fig. 129) backwards.

12. Place the suction clip (REF 90000145) centrally onto the patient’s eye.

   ö The suction clip (REF 90000145) is positioned correctly.
13. To activate the vacuum for the suction clip (REF 90000145), press the ‘Vacuum’ footswitch once. Alternatively enable the ‘Eye suction’ (Fig. 130) in the software.

14. If a suction loss has occurred, check the connection between the suction port and the suction reservoir. Adjust the connection, if necessary, and repeat steps 10 to 13.

15. To verify that the suction is actually engaged, gently lift the suction clip (REF 90000145).

16. Press the release button at the patient bed and wait 3 seconds for the lock to disengage, swing the patient bed completely in (under the laser system) and wait 3 seconds for the lock to engage.

9.4.4 Docking the patient to the spacer cone

Depending on the headrest being used, dock the patient to the spacer cone as described in the following subchapters.
9.4.4.1 For capsulotomy and lens fragmentation procedures using a headrest with integrated joystick

1. Move the patient bed using the joystick (Fig. 132/1 or Fig. 133/1) of the patient bed control panel at the headrest until the suction clip and the PI 125 are aligned.

2. Instill a maximum of six drops of balanced salt solution (BSS) in the suction clip.

3. Slowly move the patient bed upward until the suction clip almost touches the PI 125.

4. Be aware that the reflection of the laser ring light is visible in the video camera image. Ensure that the laser ring light illumination switch is adjusted to position ‘10’ (Fig. 12/1). Align the reflection of the laser ring light on the cornea with the laser ring light and gently move the patient bed upward.

5. Slowly move the patient bed upward until the central cornea gently touches the PI 125. Ensure that there are no wrinkles visible in the OCT image.

⚠️ CAUTION!
Ensure that the pressure status display does not reach the upper red pressure display area! Otherwise there is a higher risk to have wrinkles in the posterior cornea.

⇒ The shear force display shows the lateral pressure that is exerted on the eye. The optimal position is achieved when the LEDs are illuminated green.
6. Check if there are air bubbles or impurities between the PI 125 and the cornea.
   - It may be useful to change the camera focus between the lens and the cornea to better recognize air bubbles.
   - If you see air bubbles or impurities between the PI 125 and the cornea, undock the patient.
   - If the PI 125 is clean, continue with step 9.

7. Clean the PI 125 with a Merocel® sponge to remove the impurities.
   - If the PI 125 is not clean, dispose of the product and use a new PI 125.

8. Repeat steps 1 to 7 until no air bubbles or impurities are visible between the PI 125 and the cornea.

9. Verify that the eye is correctly centered.

10. Verify that one of the (more central) green or yellow shear force LEDs on the force display is illuminated.
    - If not, correct the pressure by using the joystick (Fig. 132/1 or Fig. 133/1) until one LED is illuminated green or yellow.

11. Close the suction clip by pressing the ends of the suction clip together.
    - The patient is docked to the PI 125.

12. If the pressure status display does not turn green, move the patient bed until you reach the green pressure status display area. Ensure that there are no wrinkles visible in the OCT image.
    - CAUTION!
      Ensure that the pressure status display does not reach the upper red pressure status display area! Otherwise there is a higher risk to have posterior wrinkles.

13. Verify again that one of the (more central) green or yellow shear force LEDs on the force display is still illuminated.

14. If the docking was performed correctly, a thin fluid film is visible in the periphery between the cornea and the PI 125, and the cornea preserves its natural shape.
9.4.4.2 For capsulotomy and lens fragmentation procedures using a headrest with external joysticks

1. Move the patient bed using the X/Y-joystick (Fig. 134/1) of the patient bed control panel until the suction clip and the PI 125 are aligned.

2. Instill a maximum of six drops of balanced salt solution (BSS) in the suction clip.

3. Slowly move the patient bed upward using the Z-joystick (Fig. 134/2) until the suction clip almost touches the PI 125.

4. Be aware that the reflection of the laser ring light is visible in the video camera image.

   Ensure that the laser ring light illumination switch is adjusted to position ‘10‘ (Fig. 12/1). Align the reflection of the laser ring light on the cornea with the laser ring light and gently move the patient bed upward.

5. Slowly move the patient bed upward until the central cornea gently touches the PI 125. Ensure that there are no wrinkles visible in the OCT image.

   **CAUTION!**
   Ensure that the pressure status display does not reach the upper red pressure display area! Otherwise there is a higher risk to have wrinkles in the posterior cornea.

   ⇒ The shear force display shows the lateral pressure that is exerted on the eye. The optimal position is achieved when the LEDs are illuminated green.

6. Check if there are air bubbles or impurities between the PI 125 and the cornea.

   ⇒ It may be useful to change the camera focus between the lens and the cornea to better recognize air bubbles.

   - If you see air bubbles or impurities between the PI 125 and the cornea, undock the patient.
   - If the PI 125 is clean, continue with step 9.

7. Clean the PI 125 with a Merocel® sponge to remove the impurities.

   - If the PI 125 is not clean, dispose of the product and use a new PI 125.

8. Repeat steps 1 to 7 until no air bubbles or impurities are visible between the PI 125 and the cornea.
9. Verify that the eye is correctly centered.

10. Verify that one of the (more central) green or yellow shear force LEDs on the force display is illuminated.
   - If not, correct the pressure by using the X/Y-joystick (Fig. 134/1) for the shear force until one LED is illuminated green or yellow.

11. Close the suction clip by pressing the ends of the suction clip together.
   - The patient is docked to the PI 125.

12. If the pressure status display does not turn green, move the patient bed until you reach the green pressure status display area. Ensure that there are no wrinkles visible in the OCT image.
   
   **CAUTION!**
   Ensure that the pressure status display does not reach the upper red pressure status display area. Otherwise there is a higher risk to have posterior wrinkles.

13. Verify again that one of the (more central) green or yellow shear force LEDs on the force display is still illuminated.

14. If the docking was performed correctly, a thin fluid film is visible in the periphery between the cornea and the PI 125, and the cornea preserves its natural shape.

**9.4.4.3 For all other procedures using a headrest with integrated joystick**

1. Move the patient bed using the joystick (Fig. 132/1 or Fig. 133/1) of the patient bed control at the headrest until the suction clip and the PI 125 are aligned.

2. Slowly move the patient bed upward until the suction clip almost touches the PI 125.

3. Be aware that the reflection of the laser ring light is visible in the video camera image.
   - Ensure that the laser ring light illumination switch is adjusted to position ‘10’ (Fig. 12/1). Align the reflection of the laser ring light on the cornea with the laser ring light and gently move the patient bed upward.

4. If the pressure status display does not show green, move the patient bed until you reach the green pressure display area.
WARNING! Danger of injury due to contaminations!
There must be no air bubbles, excess fluids, etc. between the PI 125 and the corneal surface. This situation may impair the treatment and cause severe patient injuries.

5. Check if there are air bubbles, fluids, or impurities between the PI 125 and the cornea.

- It may be useful to change the camera focus between the lens and the cornea to better recognize air bubbles.
- If you see air bubbles, fluids, or impurities between the PI 125 and the cornea, undock the patient.
- If the PI 125 is clean, continue with step 8.

6. Repeat steps 1 to 5 until no air bubbles, fluids, or impurities are visible between the PI 125 and the cornea.

7. Verify that there is no water ring between the PI 125 and the cornea.

- If there is a water ring, undock the patient and use a Merocel® sponge to absorb excess fluids. Repeat steps 1 to 7.

8. Verify that the eye is correctly centered.

9. Verify that one of the (more central) green or yellow shear force LEDs on the force display is illuminated.

- If not, correct the pressure by using the joystick (Fig. 132/1 or Fig. 133/1) until one LED is illuminated green or yellow.

10. Close the suction clip by pressing the ends of the suction clip together.

- The patient is docked to the PI 125.

11. Verify again that one of the (more central) green or yellow shear force LEDs on the force display is still illuminated.

9.4.4.4 For all other procedures using a headrest with external joy-sticks

1. Move the patient bed using the X/Y-joystick (Fig. 134/1) of the patient bed control until the suction clip and the PI 125 are aligned.

2. Slowly move the patient bed upward using the Z-joystick (Fig. 134/2) until the suction clip almost touches the PI 125.

3. Be aware that the reflection of the laser ring light is visible in the video camera image.

Ensure that the laser ring light illumination switch is adjusted to position ‘10’ (Fig. 12/1). Align the reflection of the laser ring light on the cornea with the laser ring light and gently move the patient bed upward.
4. Slowly move the patient bed upward until the PI 125 aligns completely with the corneal surface.
   - The shear force display shows the lateral pressure that is exerted on the eye. The optimal position is achieved when the LEDs are illuminated green.

⚠️ WARNING! Danger of injury due to contaminations!
There must be no air bubbles, excess fluids, etc. between the PI 125 and the corneal surface. This situation may impair the treatment and cause severe patient injuries.

5. Check if there are air bubbles, fluids, or impurities between the PI 125 and the cornea.
   - It may be useful to change the camera focus between the lens and the cornea to better recognize air bubbles.
   - If you see air bubbles, fluids, or impurities between the PI 125 and the cornea, undock the patient.
   - If the PI 125 is clean, continue with step 8.

6. Repeat steps 1 to 5 until no air bubbles, fluids, or impurities are visible between the PI 125 and the cornea.

7. Verify that there is no water ring between the PI 125 and the cornea.
   - If there is a water ring, undock the patient and use a Merocel® sponge to absorb excess fluids. Repeat steps 1 to 7.

8. Verify that the eye is correctly centered.

9. Verify that one of the (more central) green or yellow shear force LEDs on the force display is illuminated.
   - If not, correct the pressure by using the X/Y-joystick for the shear force and the Z-joystick for the vertical force until one LED is illuminated green or yellow.

10. Close the suction clip by pressing the ends of the suction clip together.
    - The patient is docked to the PI 125.

11. Verify again that one of the (more central) green or yellow shear force LEDs on the force display is still illuminated.

### 9.4.5 Repositioning the suction clip

If you have to reposition the suction clip, proceed as follows:

1. Open the suction clip by pulling the snap-fit backwards.

2. Move the patient bed slowly downward until there is enough space to reposition the suction clip without touching the PI 125 or the spacer cone.

3. Release the vacuum of the suction clip by pressing the ‘Vacuum’ foot-switch once.
4. Place the suction clip centrally on the patient's eye.
   ⇒ The suction clip is positioned correctly.

5. Repeat the steps in Chapter 9.4.4 'Docking the patient to the spacer cone' on page 9 - 22.

9.4.6 Completing a treatment

Depending on the headrest being used, complete the treatment as described as follows:

1. Lower the patient bed very carefully.
2. Unfasten the Velcro strapping, if used.
3. Swing the bed out completely so that the patient can easily get up.
4. Ask the patient to leave the patient bed.

For using a headrest with external joysticks only:

5. Remove the PI 125 from the spacer cone carefully by clicking the blue button next to the ‘PI suction’ status indicator.
   ⇒ The ‘PI suction’ status indicator turns gray.

6. Remove the suction reservoir from the suction port.

7. □ WARNING! Infection hazard due to reuse of the PI 125 and suction clip!
   The PI 125 and the suction clip are single-use devices. They must not be refurbished or reused. Neglecting this rule may result in infections and severe patient injuries.
   - Never reuse or refurbish the PI 125 or the suction clip!
     ■ Dispose of the PI 125 and the suction clip after use.
     ■ Use the PI 125 and the suction clip exclusively on one eye.
9.5 Performing a cataract treatment

Materials:
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000115) or
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000145)
- Suction Clip 125 of the Patient Interface 125 Kit (REF 90000115) or
- Suction Clip 125 of the Patient Interface 125 Kit (REF 90000145)

The following chapter describe cataract treatments using the example of a cataract treatment (‘LRCS’) including a capsulotomy procedure, a lens fragmentation procedure, an arcuate incisions procedure and a corneal incisions procedure with regard to a workflow supported by a 2S-OCT (≠ Chapter 9.5.2 ‘Performing a cataract treatment supported by a 2S-OCT’ on page 9 - 31) and a workflow supported by a TD-OCT (≠ Chapter 9.5.3 ‘Performing a cataract treatment supported by a TD-OCT’ on page 9 - 44).

Depending on the OCT being used, follow the relevant workflow as described.

9.5.1 Preparing a cataract treatment

The user (surgeon) must observe the treatment via the video live image in order to detect potential problems.

Important note: An incomplete bubble pattern during a capsulotomy procedure may indicate an incomplete capsulotomy.

1. Position the patient on the patient bed (≠ Chapter 9.4.2 ‘Positioning the patient on the patient bed’ on page 9 - 9).
2. Connect the PI 125 to the spacer cone (≠ Chapter 9.4.3 ‘Connecting the PI 125 to the spacer cone and positioning the suction clip’ on page 9 - 11).
   - After activating the ‘PI suction’ button, wait until the ‘PI suction’ status indicator is illuminated green.
3. Position the suction clip (≠ Chapter 9.4.3 ‘Connecting the PI 125 to the spacer cone and positioning the suction clip’ on page 9 - 11).
4. Dock the patient to the spacer cone (≠ Chapter 9.4.4 ‘Docking the patient to the spacer cone’ on page 9 - 22).
5. If required, reposition the suction clip (≠ Chapter 9.4.5 ‘Repositioning the suction clip’ on page 9 - 28).
6. WARNING! Danger of injury due to movement of the patient during the treatment!
   - Instruct the patient not to move or talk during the treatment.

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7. Verify that the ‘PI suction’ status indicator, the ‘Eye suction’ status indicator and the pressure status display are all green.

Fig. 135: System parameters are verified

9.5.2 Performing a cataract treatment supported by a 2S-OCT

1. To confirm, click the ‘Approve’ button (Fig. 135). The automatic identification of ocular structures is performed.

Fig. 136: ‘LRCS’ ‘Treatment alignment - lens’ screen

- The yellow marking circle appears in the video camera image (Fig. 136). The pupil margin is determined.
- The yellow marking outlines appear in the linear scan images (Fig. 136). The lens margins are determined.
- The capsulotomy appears in the linear scan images and in the ring scan image (Fig. 136).
2. If you agree with the results of the automatic identification of ocular structures, click the ‘Confirm’ button (Fig. 136) and continue with step 23.
3. If the pupil margin has not been detected correctly or if you want to center the treatment either to the limbus or to the lens apex, proceed as follows:

The following step is mandatory, because the pupil margin defines the limit for the laser cuts. Please be aware that the laser cannot be focussed behind the iris!

- To determine the pupil margin, click the ‘Mark pupil’ button (Fig. 136) and mark three points on the pupil in the video camera image.

The following step is optional. In case the limbus centering is different to the pupil centering, the capsulotomy center will be shifted towards the center defined by the limbus marking. In any case the pupil margin including the minimum safety distance of 500 µm will be respected.

- To determine the limbus margin, click the ‘Mark limbus’ button (Fig. 136) and mark three points on the limbus in the video camera image.

- To center to the lens apex, click the ‘Center to lens apex’ button (Fig. 136) in the video camera image.

Fig. 137: Pupil margin is determined (example)

- The green marking circle appears in the video camera image (Fig. 137). The pupil margin is determined.
If the pupil margin is not in the right position, repeat the relevant part in step 3.

Fig. 138: Limbus margin is determined (example)

The purple marking circle appears in the video camera image (Fig. 138).
The limbus margin is determined.

If the limbus margin is not in the right position, repeat the relevant part in step 3.

Fig. 139: Centering to the lens apex (example)

The capsulotomy is centered to the lens apex in the video camera image (Fig. 139).

4. Check the lens fragmentation pattern regarding the number of respective cuts.
5. If the lens body has not been detected correctly or not detected at all, the anterior lens and the posterior lens can be marked manually.

To mark the anterior lens 0° position and the posterior lens 0° position, click the 'Edit' button in the 'Linear scan 0°' OCT B scan image (Fig. 137).

![Fig. 140: ‘Lens structures @0°’]

6. Click the button (Fig. 140). To mark the anterior lens 0° position, mark the anterior capsule of the lens with three points.

7. Click the button (Fig. 140). To mark the posterior lens 0° position, mark the posterior capsule of the lens with three points.

![Fig. 141: Lens margins are determined in 0° position]
8. Confirm with ‘Accept’ (Fig. 141).

If the anterior lens 0° position and the posterior lens 0° position are not in the right position, click the ‘Edit’ button again. Mark the anterior lens 0° position and the posterior lens 0° position to find the right positions.

9. To mark the anterior lens 90° position and the posterior lens 90° position, perform the steps as described in step 5 to 8 by using the 90° images.

The yellow marking outline representing the selected surface appears in both the ‘Linear scan 0°’ and ‘Linear scan 90°’ OCT B scan images if the positions have been marked in both images. If the positions have been marked in only one image, they are indicated by the green marking dots; the yellow outline is not displayed.

10. Click the ‘Mark capsulotomy’ button in the ring scan OCT B scan image (Fig. 137), if it is necessary to correct the capsulotomy.

Mark the highest point and the lowest point of the anterior capsule of the lens, if necessary.

11. To increase the rim height, click the ‘+’ button (Fig. 142).

To decrease the rim height, click the ‘−’ button (Fig. 142).
12. If you want to accept all procedure workflow settings, click the ‘Confirm’ button (Fig. 142).

The user must verify that the parameter setting has been performed correctly.

Fig. 143: Pattern alignment for the cataract treatment accepted

→ The color marking of the circle in the video camera image and the outlines in the linear scan images turn green. The ‘Start’ button becomes available (Fig. 143).

⚠️ **WARNING!** Risk of tissue bridges due to movement when laser is firing!

Tissue bridges may occur if vibrations from movement occur when the laser is firing.

– Do not walk around while the procedure is performed.
– Do not touch the patient bed or the patient’s head while the procedure is performed.
– Do not touch the suction clip.
13. Press the ‘Start’ button to start the treatment (Fig. 143). When the green highlighted frame appears in the ‘Treatment’ screen, finally press the ‘Procedure’ footswitch.

The ‘Procedure’ footswitch must be pressed from the start of the capsulotomy procedure until the end of the lens fragmentation procedure! If you release the ‘Procedure’ footswitch, the treatment will pause. Press the footswitch again to continue the treatment.

An acoustic signal is emitted during the procedures.

The progress is displayed in the ‘Capsulotomy’ progress bar (Fig. 144).

**WARNING! Risk of tissue bridges due to correction of vertical / shear force movement!**

The vertical force may change, or the applied shear force may change during the procedure. If you attempt to correct such changes, this may affect the alignment or the treatment result, which may cause severe patient injuries.

- Do not correct changing vertical force or shear force during the procedure.

When the capsulotomy procedure is finished, the lens fragmentation procedure starts automatically. The progress is displayed in the ‘Lens fragmentation’ progress bar (Fig. 144).
14. Before you can continue with the arcuate incisions procedure, open the suction clip and follow the steps in \textit{Chapter 9.4.4 'Docking the patient to the spacer cone' on page 9 - 22} and, if required the steps in \textit{Chapter 9.4.5 'Repositioning the suction clip' on page 9 - 28}.

![Fig. 145: Regular docking of the patient](image1)

15. After the suction clip has been closed and the parameter setting has been approved by clicking the ‘Approve’ button (Fig. 145), the ‘Start’ button becomes available (Fig. 146).

![Fig. 146: Treatment screen before starting the arcuate incisions procedure](image2)

16. If you agree with the parameter setting, continue with step 20.
If the parameter setting is not correct, click the ‘3-click-centration’ button (Fig. 147) and, in the video camera image, mark either the pupil margin or the limbus margin with three dots.

The color-coded circle appears in the video camera image. The pupil margin or the limbus margin is determined and the position of the arcuate incisions and/or the corneal incisions is centered. Minor adjustments can be done by dragging and dropping the blue circle in the center in the video camera image.

To compensate for cyclotorsion, click on (Fig. 147) to turn the positions counterclockwise or on (Fig. 147) to turn the positions clockwise. The cyclotorsion is displayed in degrees in the video camera image.

The center point of the arcuate incisions (Fig. 147) and the corneal incisions (Fig. 147) can be moved by dragging and dropping the dot which represents the center point in the video camera image.

The diameter of each corneal incision (Fig. 147) can be shifted by dragging and dropping of the individual corneal incision overlay in the video camera image. The corresponding OCT scan is then refreshed.
18. To change the preset pachymetry value, click the ‘Edit’ button in the ‘AK @ 225°’ OCT B scan image (Fig. 147).

Fig. 148: ‘Arcuate incision editor’ (example)

19. **CAUTION!**

Be aware that the pachymetry values can vary over the length of the arcuate incisions cut.

To change the pachymetry value to the patient’s actual pachymetry, left-click on the yellow dot (Fig. 148) and drag and drop it to the rear side of the cornea.

Fig. 149: Changing the pachymetry value

- The ‘Pachymetry [µm]:’ value changes. Simultaneously, the ‘Resulting depth [µm]:’ value changes based on the preset ‘Depth ratio [%]:’ percentage.
20. Click the 'Accept' button (Fig. 149).

21. To change the pachymetry value in the ‘AK @ 45°’ OCT B scan image, perform steps 19 to 21.

22. To start the arcuate incisions procedure, press the ‘Start’ button. When the green highlighted frame appears in the ‘Treatment’ screen, finally press the ‘Procedure’ footswitch. Remember to keep the footswitch pressed during the whole procedure.

The ‘Procedure’ footswitch must be pressed from the start of the arcuate incisions procedure until the end of the corneal incisions procedure! If you release the ‘Procedure’ footswitch, the treatment will pause. Press the footswitch again to continue the treatment.

An acoustic signal is emitted during the procedures.

The progress is displayed in the ‘Arcuate incisions’ progress bar.

23. After the arcuate incisions procedure is finished, the corneal incisions procedure starts automatically. The progress is displayed in the ‘Corneal incisions’ progress bar.

24. When the complete treatment is finished, all progress bars are highlighted blue, the information footer shows the message ‘Treatment completed’ (Fig. 150), the acoustic signal stops and the green highlighted frame disappears in the ‘Treatment’ screen.

Fig. 150: Cataract treatment completed
25. Click the ‘Continue’ button (Fig. 150) to open the ‘Treatment result’ screen that shows the procedure results and the number of remaining licenses.

Fig. 151: ‘LRCS’ ‘Treatment result’ screen

⚠ CAUTION! Danger of trauma due to lowering the patient bed without having released the vacuum of the suction clip!
When the vacuum is activated, lowering the patient bed leads to an abrupt loss of vacuum and causes pain to the patient.
- Do not lower the patient bed while the vacuum is activated and the patient is docked.

26. Do not remove the suction clip while the vacuum is activated.

27. Verify that the eye suction has been released after the procedure has been executed.

- The ‘Eye suction’ status indicator of the suction clip turns gray.

ℹ️ If a treatment is completed and the ‘Eye suction’ status indicator does not turn gray, you must manually pull off the suction reservoir from the suction port at the laser system.

28. Disable the ‘PI suction’ in the software to deactivate the vacuum of the spacer cone.

29. Complete the cataract treatment (☞ Chapter 9.4.6 ‘Completing a treatment’ on page 9 - 29).
9.5.3 Performing a cataract treatment supported by a TD-OCT

1. To confirm, click the ‘Approve’ button (Fig. 135). The pupil recognition is performed.

![Fig. 135: 'Approve' button]

Fig. 152: ‘LRCS’ ‘Treatment alignment - lens’ screen

- The yellow marking circle appears in the video camera image (Fig. 152). The pupil margin is determined.

2. If you agree with the result of the pupil recognition, continue with step 5.
3. If the pupil margin was not detected correctly or if you want to center the treatment either to the limbus or to the lens apex, proceed as follows:

The following step is **mandatory**, because the pupil margin defines the limit for the laser cuts. Be aware that the laser cannot be focussed behind the iris!

- To determine the pupil margin, click the ‘Mark pupil’ button (Fig. 152) and mark three points on the pupil in the video camera image.

The following step is **optional**. In case the limbus centering is different to the pupil centering, the capsulotomy center will be shifted towards the center defined by the limbus marking. In any case the pupil margin including the minimum safety distance of 500 µm will be respected.

- To determine the limbus margin, click the ‘Mark limbus’ button (Fig. 152) and mark three points on the limbus in the video camera image.

Note that centering to the lens apex is only possible once the marking of the anterior and the posterior lens surfaces have been done as described in steps 5 to 8!

- To center to the lens apex, click the ‘Center to lens apex’ button (Fig. 152) in the video camera image.

![Fig. 153: Pupil margin is determined (example)](image)

- The green marking circle appears in the video camera image (Fig. 153).
- The pupil margin is determined.
If the pupil margin is not in the right position, repeat the relevant part in step 3.

Fig. 154: Limbus margin is determined (example)

The purple marking circle appears in the video camera image (Fig. 154). The limbus margin is determined.

If the limbus margin is not in the right position, repeat the relevant part in step 3.

Fig. 155: Centering to the lens apex (example)

The capsulotomy is centered to the lens apex in the video camera image (Fig. 155).

4. Check the lens fragmentation pattern regarding the number of respective cuts.
5. Click the button next to the OCT B scan image (Fig. 153). To mark the anterior lens 0° position, mark the anterior capsule of the lens with three points.

![Image of OCT B scan with green marking lines and highlighted frame around button]

*Fig. 156: Anterior lens 0° positioning is performed*

- The green marking line representing the selected surface, appears in the OCT B scan image. The frame around the button is highlighted green (Fig. 156).

> If the anterior lens 0° is not in the right position, click once again on the button. Mark the anterior lens 0° position as described to find the right position.
6. Click the button next to the OCT B scan image (Fig. 156). To mark the posterior lens 0° position, mark the posterior capsule of the lens with three points.

Fig. 157: Posterior lens 0° positioning is performed

The green marking line representing the selected surface, appears in the OCT B scan image. The frame around the button is highlighted green (Fig. 157).

If the posterior lens 0° is not in the right position, click once again on the button. Mark the posterior lens 0° position as described to find the right position.
7. Click the button next to the OCT B scan image (Fig. 157). To mark the anterior lens 90° position, mark the anterior capsule of the lens with three points.

Fig. 158: Anterior lens 90° positioning is performed

- The green marking line representing the selected surface, appears in the OCT B scan image. The frame around the button is highlighted green (Fig. 158).

If the anterior lens 90° is not in the right position, click once again on the button. Mark the anterior lens 90° position as described to find the right position.
8. Click the button next to the OCT B scan image (Fig. 158). To mark the posterior lens 90° position, mark the posterior capsule of the lens with three points.

   The green marking line representing the selected surface, appears in the OCT B scan image. The frame around the button is highlighted green (Fig. 159).

   If the posterior lens 90° is not in the right position, click once again on the button. Mark the posterior lens 90° position as described to find the right position.

9. To activate the capsulotomy setting, click the button next to the OCT B scan image (Fig. 159).

   Capsulotomy in the ring scan OCT B scan image

Fig. 159: Posterior lens 90° positioning is performed
10. Perform steps 10 to 29 in Chapter 9.5.2 ‘Performing a cataract treatment supported by a 2S-OCT’ on page 9 - 31.

9.6 Performing a corneal treatment

9.6.1 Performing a flap procedure

Materials:
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000115) or
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000145)
- Suction Clip 125 of the Patient Interface 125 Kit (REF 90000115) or
- Suction Clip 125 of the Patient Interface 125 Kit (REF 90000145)

The surgeon must observe the treatment via the video live image in order to recognize possible problems.

1. Perform steps 1 to 6 in Chapter 9.5 ‘Performing a cataract treatment’ on page 9 - 30.

2. Verify that the ‘PI suction’ status indicator, the ‘Eye suction’ status indicator and the pressure status display are all green (Fig. 161).

The 'Start' button becomes available (Fig. 161).

Fig. 161: ‘Flap’ ‘Regular docking and treatment alignment’ screen

⇒ The ‘Start’ button becomes available (Fig. 161).
3. Before starting the procedure, the user must verify that the parameter values are correct.

Check the parameter values for ‘Flap thickness [µm]:’ , ‘Diameter [mm]:’ , ‘Bed energy [µJ]:’ and ‘Rim energy [µJ]:’ in the ‘Parameters’ dialog box (Fig. 161), and check the position of the flap. Change it, if necessary.

4. If you agree with the parameter setting, continue with step 7.

5. If the parameter setting is not correct, either click the ‘Center to pupil’ button (Fig. 161) to center the flap automatically based on an automatical pupil detection, or click within the red highlighted circle and shift it by dragging and dropping in the right position to center the orange marking circle manually.

Fig. 162: Centering is performed

- The flap is correctly positioned (Fig. 162).

⚠️ WARNING! Risk of rough beds or tissue bridges due to movement when laser is firing!

Rough beds or tissue bridges may occur if vibrations from movement occur when the laser is firing.
- Do not walk around while the procedure is performed.
- Do not touch the patient bed or the patient’s head while the procedure is performed.
- Do not touch the suction clip.
6. To agree, click the ‘Confirm’ button (Fig. 162).

7. If you have verified the parameter setting, press the ‘Start’ button (Fig. 163). When the green highlighted frame appears in the ‘Treatment’ screen, finally press the ‘Procedure’ footswitch. Remember to keep the footswitch pressed during the whole procedure.

- The ‘Procedure’ footswitch must be pressed from the start of the procedure until the end of the procedure! If you release the ‘Procedure’ footswitch, the treatment will pause. Press the footswitch again to continue the treatment.

- An acoustic signal is emitted during the procedure.

The progress is displayed in the ‘Flap’ progress bar (Fig. 164).

- **WARNING!** Rough beds or tissue bridges can occur due to correcting vertical shear force movement!

- Vertical force may slowly decrease, or the executed shear force may change while the procedure is being performed. If this decrease or the change is corrected, it can affect the alignment or the result of the treatment and cause severe patient injuries.
  - You must not correct slowly decreasing vertical force or changing shear force.
8. When the flap procedure is finished, the ‘Flap’ progress bar is highlighted blue, the information footer shows the message ‘Treatment completed’ (Fig. 164), the acoustic signal stops and the green highlighted frame disappears in the ‘Treatment’ screen.

![Flap procedure completed](image)

**Fig. 164: Flap procedure is completed**

9. Click the ‘Continue’ button (Fig. 164) to open the ‘Treatment result’ screen that shows the procedure results and the number of remaining licenses.

> **CAUTION!** Danger of trauma due to lowering the patient bed without having released the vacuum of the suction clip!

When the vacuum is activated, lowering the patient bed leads to an abrupt loss of vacuum and causes pain to the patient.

- Do not lower the patient bed while the vacuum is activated and the patient is docked.

10. Do not remove the suction clip while the vacuum is activated.

11. Verify that the eye suction has been released after the procedure has been executed.

> The ‘Eye suction’ status indicator of the suction clip turns gray.

> **If a treatment is completed and the ‘Eye suction’ status indicator does not turn gray, you must manually pull off the suction reservoir from the suction port at the laser system.**

12. Disable the ‘PI suction’ in the software to deactivate the vacuum of the spacer cone.

13. Complete the flap procedure (Chapter 9.4.6 ‘Completing a treatment’ on page 9-29).
9.7 Performing a therapeutic treatment

Materials:
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000115) or
- Patient Interface 125 of the Patient Interface 125 Kit (REF 90000145)
- Suction Clip 125 of the Patient Interface 125 Kit (REF 90000115) or
- Suction Clip 125 of the Patient Interface 125 Kit (REF 90000145)

The following chapter describes a penetrating keratoplasty procedure as an example for performing a therapeutic treatment.

The performing of a lamellar keratoplasty procedure, a crosslinking procedure or an ICRS tunnel procedure is similar to the penetrating keratoplasty procedure, except the differences in the respective procedures that are described in detail.

The surgeon must observe the treatment via the video live image in order to detect potential problems.

1. Perform steps 1 to 6 in Chapter 9.5 ‘Performing a cataract treatment’ on page 9 - 30.
2. Verify that the ‘PI suction’ status indicator, the ‘Eye suction’ status indicator and the pressure status display are all green (Fig. 165).

Fig. 165: System parameters are verified
3. To confirm, click the ‘Approve’ button (Fig. 165). The OCT-supported identification of ocular structures is performed.

Fig. 166: ‘Penetrating keratoplasty (PKP)’ ‘Treatment alignment’ screen

- The yellow marking circle appears in the video camera image (Fig. 166).

The pupil margin is determined.

- The ‘Start’ button becomes available (Fig. 166).

4. Check the pachymetry marking (yellow line) in the OCT B scan image (Fig. 166). Change it, if necessary.

   - For penetrating keratoplasty procedures: The yellow line should be below the lowest point of the cornea (for PKP only!).

   - For lamellar keratoplasty procedures, crosslinking procedures or ICRS tunnel procedures: The yellow line should be above the thinnest point of the cornea.

5. If you agree with the results of the OCT-supported identification of ocular structures, continue with step 8.
6. If the parameter setting is not correct, click the ‘3-click-centration’ button and mark three points on the pupil in the video camera image.

![3-click-centration button](image)

Fig. 167: Pupil margin is determined manually

- The green marking circle appears in the video camera image (Fig. 167).
  The pupil margin is determined.

  *If the pupil margin is not in the right position, repeat step 6.*

7. Before starting the procedure, the user must verify that the parameter values are correct.

  Check the parameter values in the ‘Parameters’ dialog box (Fig. 167). Change it, if necessary.
9  TREATMENT

⚠️ WARNING! Risk of tissue bridges due to movement when laser is firing!
Tissue bridges may occur if vibrations from movement occur when the laser is firing.

– Do not walk around while the procedure is performed.
– Do not touch the patient bed or the patient's head while the procedure is performed.
– Do not touch the suction clip.

8. When you have verified the parameter values, press the 'Start' button (Fig. 167). When the green highlighted frame appears in the 'Treatment' screen, finally press the 'Procedure' footswitch. Remember to keep the footswitch pressed during the whole procedure.

⚠️ The 'Procedure' footswitch must be pressed from the start of the procedure until the end of the procedure! If you release the 'Procedure' footswitch, the treatment will pause. Press the footswitch again to continue the treatment.

♫ An acoustic signal is emitted during the procedure.

The progress is displayed in the 'Penetrating keratoplasty' progress bar (Fig. 168).

⚠️ WARNING! Risk of tissue bridges due to correction of vertical/shear force movement!
Vertical force may change, or the applied shear force may change while the procedure is being performed. If you attempt to correct such changes, this may affect the alignment or the treatment result, which may cause severe patient injury.

– Do not correct changing vertical force or shear force during the treatment.
9. When the PKP procedure is finished, the ‘Penetrating keratoplasty’ progress bar is highlighted blue, the information footer shows the message ‘Treatment completed’ (Fig. 168), the acoustic signal stops and the green highlighted frame disappears in the ‘Treatment’ screen.

![Fig. 168: PKP procedure completed](image)

10. Click the ‘Continue’ button (Fig. 168) to open the ‘Treatment result’ screen that shows the procedure results and the number of remaining licenses.

   - **CAUTION! Danger of trauma due to lowering the patient bed without having released the vacuum of the suction clip!**
   - When the vacuum is activated, lowering the patient bed leads to an abrupt loss of vacuum and causes pain to the patient.
   - Do not lower the patient bed while the vacuum is activated and the patient is docked.

11. Do not remove the suction clip while the vacuum is activated.

12. Verify that the eye suction has been released after the procedure has been executed.

   - The ‘Eye suction’ status indicator of the suction clip turns gray.

   ![Eye suction status indicator](image)

   - When a treatment is completed and the ‘Eye suction’ status indicator does not turn gray, you must manually pull off the suction reservoir from the suction port at the laser system.

13. Disable the ‘PI suction’ in the software to deactivate the vacuum of the spacer cone.

14. Complete the PKP procedure (Chapter 9.4.6 ‘Completing a treatment’ on page 9 - 29).
### Troubleshooting chart

**Warning:**

**Danger of injury due to improper repair!**

Improperly executed work in conjunction with troubleshooting may lead to serious injuries and significant property damage.

- Perform only troubleshooting tasks that local personnel can perform according to the troubleshooting chart.
- If you are in doubt about how to perform the troubleshooting tasks that are described in the troubleshooting chart, contact an Authorized Service Technician.
- Troubleshooting tasks that are not described in the troubleshooting chart must be performed only by Authorized Service Technicians.

#### Laser system in general

<table>
<thead>
<tr>
<th>Fault description</th>
<th>Cause</th>
<th>Remedy</th>
<th>Personnel</th>
</tr>
</thead>
</table>
| Laser system cannot be started by turning the system key to the ‘On’ position.    | The main switch on the bottom side of the laser system is switched off (position ‘0’). | - Press the main switch to position ‘I’.  
- Turn the system key to the ‘On’ position.                                      | Assistant User                                                        |
| Laser system is not ready for operation, although power is on.                    | ‘Laser Stop’ button is activated.                                     | - Ensure that the cause of the laser stop has been removed before unlocking the ‘Laser Stop’ button. | Assistant User  
Authorized Service Technician |
|                                                                                 | ‘Reset’ button is illuminated blue.                                   | - Press the blue ‘Reset’ button until it is not illuminated anymore.   | Assistant User                                |
|                                                                                 | Patient bed has not been referenced.                                  | - Reference the patient bed.                                          | Assistant User                                |
| Laser system is not ready for operation. ‘System test’ status indicator is illuminated orange or gray. | Functionality tests have not been performed successfully.            | - Contact an Authorized Service Technician.                           | Authorized Service Technician                |
|                                                                                 | Startup tests have not been performed successfully.                  | - Contact an Authorized Service Technician.                           | Authorized Service Technician                |
|                                                                                 | Not all startup tests have been performed.                           | - Perform the missing startup tests.                                  | Authorized User                                |
| ‘Laser position test’ failed.                                                    | The laser source has not warmed up / stabilized yet.                 | - If the ‘Laser position test’ fails repeatedly, even after 20 minutes warm-up, contact an Authorized Service Technician. | Authorized Service Technician                |
## TROUBLESHOOTING CHART

<table>
<thead>
<tr>
<th>Fault description</th>
<th>Cause</th>
<th>Remedy</th>
<th>Personnel</th>
</tr>
</thead>
</table>
| ‘Depth test’ failed.    | The depth test has failed after selecting another diameter in the ‘Diameter:’ drop-down field. | ■ Try to perform the depth test again.  
■ If the ‘Depth test’ fails repeatedly, contact an Authorized Service Technician. | Authorized Service Technician             |

### For headrest with integrated joystick only:

<table>
<thead>
<tr>
<th>Fault description</th>
<th>Cause</th>
<th>Remedy</th>
<th>Personnel</th>
</tr>
</thead>
</table>
| Laser system has been aborted during a treatment. | Laser system has been aborted, for instance, by pressing the ‘Stop’ button in the GUI. | ■ If a system abort occurs or has been performed during a treatment, make sure the eye suction is automatically switched off. Otherwise switch it off.  
■ Lower the patient bed and swing it in the patient entry position.  
■ Refer to the user manual “Laser Patient Bed LS Comfort” or “Patient Support System PSS S60” by AKRUS GmbH & Co KG.  
■ Ask the patient to leave the patient bed very carefully.  
■ Solve the problem, if possible.  
■ Otherwise call an Authorized Service Technician, if necessary. | User Authorized Service Technician                              |
| Emergency shutdown in the laser system. | Emergency shutdown has been initiated automatically by failures. | ■ If an emergency shutdown occurs during a treatment, make sure the eye suction is automatically switched off. Otherwise switch it off.  
■ Lower the patient bed and swing it in the patient entry position.  
■ Refer to the user manual “Laser Patient Bed LS Comfort” or “Patient Support System PSS S60” by AKRUS GmbH & Co KG.  
■ Ask the patient to leave the patient bed very carefully.  
■ Call an Authorized Service Technician. | Authorized Service Technician                                   |

### For headrest with external joysticks only:

<table>
<thead>
<tr>
<th>Fault description</th>
<th>Cause</th>
<th>Remedy</th>
<th>Personnel</th>
</tr>
</thead>
</table>
| Laser system has been aborted during a treatment. | Laser system has been aborted, for instance, by pressing the ‘Stop’ button in the GUI. | ■ If a system abort occurs or has been performed during a treatment, make sure the eye suction is automatically switched off. Otherwise switch it off.  
■ Lower the patient bed and swing it in the patient entry position.  
■ Refer to the user manual “Laser Patient Bed LS Comfort” by AKRUS GmbH & Co KG.  
■ Unfasten the VELCRO® strapping, if used. | User Authorized Service Technician                              |
### Emergency Shutdown

**Emergency shutdown in the laser system.**

- Emergency shutdown has been initiated automatically by failures.
- If an emergency shutdown occurs during a treatment, make sure that the eye suction is automatically switched off. Otherwise switch it off.
- Lower the patient bed and swing it in the patient entry position.
- Refer to the user manual "Laser Patient Bed LS Comfort" by AKRUS GmbH & Co KG.
- Unfasten the VELCRO® strapping, if used.
- Ask the patient to leave the patient bed very carefully.
- Call an Authorized Service Technician.

### Chiller

- **Fault description**: ‘Supply temperature’ and/or ‘Current flow’ are not in the specified range.
- **Cause**: Room temperature and/or current flow are outside of the specified range.
- **Remedy**: Shut down the laser system and try to restart it.
- ** Personnel**: Authorized User

### Suction status controller

- **Fault description**: LED bar display flashes at regular intervals.
- **Cause**: Error in the vacuum pump unit.
- **Remedy**: Contact an Authorized Service Technician.
- ** Personnel**: Authorized Technician

### Assistant workstation, surgeon control screen

- **Fault description**: Monitors are blank although power is on.
- **Cause**: Monitors have been switched off separately.
- **Remedy**: Switch on the monitors.
- ** Personnel**: Authorized User

- **Cause**: Power cables / PC cables are not plugged in.
- **Remedy**: Plug in the cables.
- ** Personnel**: Authorized User
## Troubleshooting Chart

### Surgical Microscope

<table>
<thead>
<tr>
<th>Fault Description</th>
<th>Cause</th>
<th>Remedy</th>
<th>Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lighting defect</td>
<td></td>
<td>Contact an Authorized Service Technician.</td>
<td>Authorized Technician</td>
</tr>
<tr>
<td>Magnification defect</td>
<td></td>
<td>Contact an Authorized Service Technician.</td>
<td>Authorized Technician</td>
</tr>
<tr>
<td>Image through the surgical microscope is blurred.</td>
<td>Focus of oculars is not adjusted.</td>
<td>Adjust focus of the oculars.</td>
<td>Assistant User</td>
</tr>
<tr>
<td>All other causes.</td>
<td></td>
<td>Contact an Authorized Service Technician.</td>
<td>Authorized Technician</td>
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### User Key

<table>
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<tr>
<th>Fault Description</th>
<th>Cause</th>
<th>Remedy</th>
<th>Personnel</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the ‘Licenses’ screen opens the message ‘Key is for another laser!’</td>
<td>The wrong user key has been inserted.</td>
<td>Insert the correct user key.</td>
<td>Assistant User</td>
</tr>
</tbody>
</table>
11 Technical data

11.1 General specifications

Fig. 169: Dimensions of the laser system (top view) with patient bed "LS Comfort"
Fig. 170: Dimensions of the laser system (top view) with patient bed "Patient Support System S60"

Fig. 171: Dimensions of the laser system (side view)
### Data Value Unit

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Weight (without patient bed) depending on configuration</td>
<td>640 - 690</td>
<td>kg</td>
</tr>
<tr>
<td>Length (without patient bed)</td>
<td>208</td>
<td>cm</td>
</tr>
<tr>
<td>Length (with patient bed)</td>
<td>210</td>
<td>cm</td>
</tr>
<tr>
<td>Width (without patient bed)</td>
<td>83</td>
<td>cm</td>
</tr>
<tr>
<td>Height</td>
<td>168</td>
<td>cm</td>
</tr>
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</table>

### 11.2 Operating conditions

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<thead>
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<th>Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient temperature</td>
<td>18 – 24</td>
<td>°C</td>
</tr>
<tr>
<td>Relative humidity, maximum (non-condensing)</td>
<td>30 – 50</td>
<td>%</td>
</tr>
<tr>
<td>Air pressure</td>
<td>800 – 1060</td>
<td>hPa</td>
</tr>
<tr>
<td>Air purity</td>
<td>no dust; no smoke; no evaporating cleaning agents; no chemical or alcoholic liquids</td>
<td></td>
</tr>
<tr>
<td>Floor loading, minimum</td>
<td>0.9</td>
<td>kg/cm²</td>
</tr>
</tbody>
</table>

The room temperature has to be kept stable with a maximum change of 1 °C per hour. Therefore active air conditioning is required.

The lighting of the operating room must comply with lighting standards for operating rooms.

### Operating time

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<th>Unit</th>
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</thead>
<tbody>
<tr>
<td>Maximum operating time without shutdown of the laser system</td>
<td>If operating conditions are within the previously specified parameters, shut down the laser system if it will not be used for the next 24 hours.</td>
<td></td>
</tr>
<tr>
<td>Operating life</td>
<td>5</td>
<td>years</td>
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</table>
11.3 Laser specifications

Laser type: solid-state laser, laser class 3B

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<tr>
<th>Data</th>
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<tbody>
<tr>
<td>Pulse duration</td>
<td>290 – 550</td>
<td>fs</td>
</tr>
<tr>
<td>Wavelength</td>
<td>1040 ± 25</td>
<td>nm</td>
</tr>
<tr>
<td>Pulse frequency, maximum</td>
<td>160</td>
<td>kHz</td>
</tr>
<tr>
<td>Output power, maximum</td>
<td>0.86</td>
<td>W</td>
</tr>
<tr>
<td>Beam divergence</td>
<td>15</td>
<td>°</td>
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</table>

Essential performance

Energy and pulse positioning are considered as an essential performance of the VICTUS™ Femtosecond Laser Platform.

11.4 Transport and storage conditions

- Store the laser system in a dry and dust-free location.
- Protect the laser system from direct sunlight.
- Avoid mechanical vibration.

<table>
<thead>
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<tbody>
<tr>
<td>Ambient temperature</td>
<td>5 – 50</td>
<td>°C</td>
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<tr>
<td>Relative humidity, maximum (non-condensing)</td>
<td>10 – 95</td>
<td>%</td>
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<tr>
<td>Air pressure</td>
<td>800 – 1060</td>
<td>hPa</td>
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</table>

11.5 Electrical connection

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<td>230</td>
<td>V AC</td>
</tr>
<tr>
<td>Frequency</td>
<td>50/60</td>
<td>Hz</td>
</tr>
<tr>
<td>Power input, maximum</td>
<td>13</td>
<td>A</td>
</tr>
<tr>
<td>Power consumption, maximum</td>
<td>3</td>
<td>kW</td>
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APPENDIX

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A  EMC declaration
A EMC declaration

1. Guidance and Manufacturer’s Declaration – Electromagnetic Emissions

The VICTUS™ Femtosecond Laser Platform is intended for use in the electromagnetic environment specified below. The customer or user of the VICTUS™ Femtosecond Laser Platform should assure that it is used in such an environment.

<table>
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<tr>
<th>Emissions test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
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<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The VICTUS™ Femtosecond Laser Platform uses RF energy only for its internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>The VICTUS™ Femtosecond Laser Platform is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, under the provision that the following warning is observed:</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Class A</td>
<td>Warning: This device/system is solely intended for use by healthcare professionals. This is a class A device/system in accordance with CISPR 11. In a domestic environment this device/system may cause radio interference in which case the user may be required to take adequate measures such as reorienting, repositioning or shielding the VICTUS™ Femtosecond Laser Platform or filtering the connection to the site.</td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

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2. Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The VICTUS™ Femtosecond Laser Platform is intended for use in the electromagnetic environment specified below. The customer or user of the VICTUS™ Femtosecond Laser Platform should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
</table>
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 6 kV contact ± 8 kV air | ± 6 kV contact ± 8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
| Electrical fast transient / burst IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input / output lines | ± 2 kV for power supply lines ± 1 kV for input / output lines | Mains power quality should be that of a typical commercial or hospital environment.
| Surges IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | ± 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment.
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % U<sub>T</sub> (>95 % dip in U<sub>T</sub>) for 0.5 cycle 40 % U<sub>T</sub> (60 % dip in U<sub>T</sub>) for 5 cycles 70 % U<sub>T</sub> (30 % dip in U<sub>T</sub>) for 25 cycles <5 % U<sub>T</sub> (>95 % dip in U<sub>T</sub>) for 5 sec | <5 % U<sub>T</sub> (>95 % dip in U<sub>T</sub>) for 0.5 cycle 40 % U<sub>T</sub> (60 % dip in U<sub>T</sub>) for 5 cycles 70 % U<sub>T</sub> (30 % dip in U<sub>T</sub>) for 25 cycles <5 % U<sub>T</sub> (>95 % dip in U<sub>T</sub>) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the VICTUS™ Femtosecond Laser Platform requires continued operation during power mains interruptions, it is recommended that the VICTUS™ Femtosecond Laser Platform is powered from an uninterruptible power supply or a battery.
| Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8 Magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U<sub>T</sub> is the AC mains voltage prior to the application of the test level.
3. Guidance and Manufacturer’s Declaration – Electromagnetic Immunity

The VICTUS™ Femtosecond Laser Platform is intended for use in the electromagnetic environment specified below. The customer or user of the VICTUS™ Femtosecond Laser Platform should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the VICTUS™ Femtosecond Laser Platform, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducted RF IEC 61000-4-6</td>
<td>3 V$_{eff}$ 150 kHz to 80 MHz</td>
<td>3 V$_{eff}$ 10 V/m</td>
<td>Recommended separation distance $d = 1.2 \sqrt{P}$ (conducted) $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz (radiated) $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz (radiated) P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference is possible in the vicinity of devices bearing the label shown below.</td>
</tr>
<tr>
<td>Radiated RF IEC 61000-4-3</td>
<td>3 V/m 80 MHz to 2.5 GHz</td>
<td>10 V/m</td>
<td></td>
</tr>
</tbody>
</table>

Interference is possible in the vicinity of devices bearing the label shown below.
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the VICTUS™ Femtosecond Laser Platform is used exceeds the applicable RF compliance level above, the VICTUS™ Femtosecond Laser Platform should be monitored to verify normal operation. If abnormal performance is observed, additional measures may be necessary, for instance re-orienting or relocating the VICTUS™ Femtosecond Laser Platform.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

4. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the VICTUS™ Femtosecond Laser Platform

The VICTUS™ Femtosecond Laser Platform is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the VICTUS™ Femtosecond Laser Platform can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VICTUS™ Femtosecond Laser Platform as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter meters (m)</th>
<th>150 kHz to 80 MHz ( d = 1.2\sqrt{P} )</th>
<th>80 MHz to 800 MHz ( d = 1.2\sqrt{P} )</th>
<th>800 MHz to 2.5 GHz ( d = 2.3\sqrt{P} )</th>
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<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
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<tr>
<td>0.1</td>
<td>0.38</td>
<td>0.38</td>
<td>0.73</td>
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<td>3.8</td>
<td>7.3</td>
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<tr>
<td>Rated maximum output power of transmitter (W)</td>
<td>Separation distance according to frequency of transmitter meters (m)</td>
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<td>---------------------------------------------</td>
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<tr>
<td>100</td>
<td>12</td>
<td>12</td>
<td>23</td>
<td></td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note 1**: At 80 MHz and 800 MHz, the higher frequency range applies.

**Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.