ziemer
OPHTHALMOLOGY

FEMTO LDV
Z Models

Operator Manual

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1 General

We would like to thank you for your decision to purchase this Ziemer product.

If the instructions in this manual are carefully followed we are confident that this product will give you reliable and trouble-free usage.

1.1 Indications for use

Ziemer's **FEMTO LDV™ Z Models** are medical instruments exclusively designed for use in ophthalmic surgery. The **LDV** is a precision manufactured instrument indicated for the creation of corneal incisions in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

1.2 About this Manual

Title	**FEMTO LDV™ Z Models**: Operator Manual
Part number	REF 510.951.500
Document number	FL5940-0500
Revision	Version 1.3
Release date	March 29, 2012
Product	**Ziemer**'s Femtosecond Surgical Lasers: • **FEMTO LDV Z2** • **FEMTO LDV Z4** • **FEMTO LDV Z6**
Author	EBA/DPA
Disclaimer	Please note that while every effort has been made to ensure that the data provided in this document is accurate, it is the policy of **SIE** to continuously improve the operating performance and overall quality of its medical devices. Accordingly, the information, figures, illustrations, tables, specifications and schematics herein are subject to change without notice.
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Trademarks	**FEMTO LDV™** is a trademark of **Ziemer Group**. Other trademark names are used in an editorial fashion only with no intention of infringement of the trademark of the respective owner.
Manufacturer	**SIE Surgical Instrument Engineering AG**, a **Ziemer Group Company** Allmendstrasse 11, CH-2562 Port, Switzerland CE 0297
Licensee and distributor	**Ziemer Ophthalmic Systems AG**, a **Ziemer Group Company** Allmendstrasse 11, CH-2562 Port, Switzerland www.ziemergroup.com

1.3 How to use this manual

This Operator Manual provides important information regarding the use of the systems:

- **FEMTO LDV Z2**
- **FEMTO LDV Z4**
- **FEMTO LDV Z6**

The three systems will be referred to in this document as "**LDV**" as most of the information comprised in this manual is common to the three systems. All features being different between the systems will be explicitly indicated.

Physicians using the **LDV** should read the manual thoroughly prior to operating the device. The Operator Manual serves only to provide the surgeon and medical assistants with general operating instructions and areas where special attention is required to avoid instrument damage or patient injury.

This manual is about using the **LDV**; it does not provide instructions on clinical procedures to perform keratectomies. References and information concerning the surgical procedure found in this manual are intended to serve as recommendations or guidelines only. The attending physician and/or surgeon must decide which surgical techniques and procedures are to be followed. The manufacturer or its representatives cannot be held responsible or liable for the techniques chosen and used during the surgery.

If there are questions, unclear points or uncertainty remaining after reading this Operator Manual, then the **LDV** should not be used. In this case, please consult a **Ziemer Customer Service** representative.

This manual is only applicable for **LDV** software versions #4.0 or higher.

Caution: Federal (U.S.) law restricts this device to sale by, or on the order of, a physician.

1.4 Maintenance & Customer Service information

No part of the **LDV** may be serviced by users. All service must be carried out by a **Ziemer** Customer Service specialist or an authorized service center. Do not implement any modifications on the **LDV** yourself.

Only spare parts, components, accessories and disposables obtained from **Ziemer** and manufactured by **SIE** may be used with the **LDV**. Use of any non-**SIE** parts will void all warranties.

For service assistance and to order accessories or replacement parts, contact the Ziemer Customer Service department. For each instrument, an individual service contract will be signed between **Ziemer** or its Distributor and the customer, detailing the conditions of response.

Please direct all inquiries and correspondence regarding Support to:

Ziemer Ophthalmic Systems AG
Allmendstrasse 11
CH-2562 Port / Switzerland

Phone: +41 848 943 637
E-mail: customer-support(at)ziemergroup.com

Refer to section 11 Service and Maintenance for more details.

1.5 Supporting manuals

The following documents are to be used in conjunction with this manual:

	Part number	Document number
Installation Planning Manual	REF 510.951.101	FL5910-000-0058
External Power Meter	n/a	FL5910-300-0565
Surgical Procedure Manual	510.951.502	FL5940-0502
Surgical Procedure Manual – Advanced Settings	510.951.503	FL5940-0503

1.6 Notes on safety and icons

Throughout this manual, icons are used to alert the reader of special situations. The following symbols are defined:

Symbol	Name and significance
	**Warning** A warning indicates an action or procedure which, if not performed correctly, can result in injury or a safety hazard. Comply strictly with the instructions and proceed with care.
	**Caution** A caution indicates an action or procedure which, if not performed correctly, can result in incorrect operation or destruction of the device. Comply strictly with the instructions.
	**Note** A note indicates an action or procedure which, if not performed correctly, can have an indirect effect on operation or trigger an unexpected response on the part of the instrument. The word 'Note' may be replaced by a meaningful title

1.7 Icons on labels

Symbol	Name and significance
	**Electrical shock** Type B applied part.
	**Waste Electronic and Electrical Equipment** Symbol is based on European Union Directive 2002/96 EC. The disposal to municipal waste is prohibited for electronic equipment subject to this directive; this equipment must be collected separately and treated or recycled.
	**Attention** Attention symbol: follow instructions for use.
	**Warning label:** Laser aperture
	**Warning label:** Invisible Laser radiation Max. 1300mW at 1020-1060nm, Pulse duration 200-350fs Class 4 Laser Product, **avoid exposure to beam.**
	**Warning label:** Class 4 invisible radiation when open and interlock defeated. Avoid eye or skin exposure to direct or scattered radiation
	**Laser Warning:** Signals possible exposure to laser beam
	**UPS Connection Warning:** The UPS (Uninterruptible Power Supply) is designed for exclusive use with the FEMTO LDV Systems. Do not connect any other electrical device to the UPS System.

1.8 Terms and Abbreviations

Abbreviation	Meaning
ANSI	American National Standards Institute
Cornea	The clear, front surface of the eye that bends or refracts light rays as they enter the eye. For clear vision, light rays must be focused by the cornea and lens to fall precisely on the retina.
FDA	Food and Drug Administration (USA)
Femtosecond	Measure of time; 1 fs = 10^{-15} seconds
Flap	Corneal lenticle created during the initial step of a LASIK procedure.
FMAA	Fixed Mirror Articulated Arm
FS	Fast Scan
HP	Handpiece
HPC	Handpiece Casings
IS	InterShield spacer
IOP	Intraocular Pressure
LASIK	Laser Assisted In-Situ Keratomileusis
LK	Lamellar Keratoplasty
LED	Light Emitting Diode
MPE	Maximum Permissible Exposure
NOHD	Nominal Ocular Hazard Distance
PK or PKP	Penetrating Keratoplasty
PP	Procedure Pack
Retina	A layer of light-sensing cells that lines the back of the eye
SBK	Sub-Bowman Keratomileusis
SR	Suction Ring
SRG	Surgeon
SS	Slow Scan
STER	Sterile Assistant
Trajectory	Path followed by the laser during resection
UNST	Non-sterile Assistant
UPS	Uninterruptible Power Supply

2 Safety instructions

2.1 General

Do not use the **LDV** system without having a thorough understanding of instrument assembly, sterilization procedures, operation and all components, functions, controls and limitations of the instrument.

2.2 Operational user qualification

The **LDV** should only be operated by, or under the direct supervision of an ophthalmic surgeon with training in laser safety and in the use of the **LDV**.

All users (surgeons, nurses and surgical or technical assistants) operating or working with the **LDV** must undergo formal training by a **Ziemer Customer Support** specialist or a certified **Ziemer** representative and must be fully familiar with this Operator Manual and associated supporting documents (see section 1.4) before attempting to use the **LDV**. Each individual trained will receive a training certificate issued by **Ziemer Customer Service**.

2.3 System installation

Instructions for site preparation are provided prior to shipment in the Installation Planning Manual (see section 1.5).

Warning: Only trained **Ziemer** service representatives should perform unpacking and installation of the **LDV**.

Ports for input and output signals

Warning: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standard (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

2.4 General warnings

Radiation

Caution - use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Warning: Observe the yellow Laser radiation warning labels (see section 1.7) on the instrument and on the entrance door(s) to the room in which the **LDV** is operated.

Fire

While the risk of fire is extremely low, the **LDV** should not be operated in the presence of flammable anaesthetic, volatile substances (e.g. solvents or anaesthetic substances), or oxygen flow lines.

Warning: Do not use cell phones, pagers or radio frequency devices of any kind that do not comply with medical environment radio frequency standards, in the same room as the **LDV**.

Electrical shock

Warning: High voltage electrical circuits are accessible if the side covers are removed. Only trained **LDV** service representatives should attempt to open the side covers. Serious injury or death may occur as a result of exposure to electrical circuits in the unit interior.

Water

Warning: The LDV system is not protected against contact and ingress of water (IPX0).

Portable phones

Warning: Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Adjacent equipment

Warning: The LDV system shall not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system shall be tested to verify normal operation in the configuration in which it is being used.

Accessories

Warning: The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

3 System hazards

3.1 Precautions

Intraocular pressure (IOP) is increased during surgery; care must be taken to minimize applanation and suction times.

Incomplete applanation may result in thin or non-uniform flap thickness and in smaller than intended flap size.

Poor or otherwise unacceptable resections may result if the laser is improperly operated.

Observe procedures detailed in the applicable Surgical Procedure Manual (see section 1.5).

3.2 Unauthorized use

The **LDV** is a precision instrument. The instrument may be damaged if not handled properly.

If you intend to leave the **LDV** unattended for short periods of time, always log off to prevent unauthorized use.

When not in use, switch off the power supply of the **LDV** and ensure that the wheel brake is activated.

3.3 Electrical

The **LDV** uses the following electrical services:

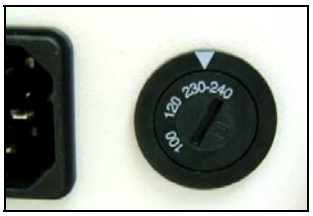
Line voltage:..... 100/120/230-240 VAC, 50…60 Hz (switchable)

Protection class:.... I Protection type:..... B

IP..... X0 Laser Class: 4

Warning: High voltage electrical circuits are accessible if the side covers are removed. Only trained **LDV** service representatives should attempt to open the side covers with a specially designed key. Serious injury or death may occur as a result of exposure to electrical circuits in the unit interior.

Warning: Switch to appropriate line voltage before attempting to switch the **LDV** on.



3.4 Eye safety (Nominal Ocular Hazard Distance)

The **LDV** generates a high peak power laser pulse specifically designed to produce micro-photodisruption in corneal tissue. The Nominal Ocular Hazard Distance (NOHD) is defined as that distance from the laser aperture within which exposure to the eye may exceed the Maximum Permissible Exposure limit (MPE) as per ANSI standard Z136.1-2000 and per IEC 60825-1 Annex A.5.

The NOHD for a direct beam exposure from the **LDV** is 10 cm (4 inches). This means that only the patient's operative eye will be exposed to laser radiation exceeding the MPE. Protective eyewear for operating suite personnel is not required.

Standard laser safety protocol requires that a warning sign be placed on the door of the room where the laser is operated, to warn personnel of laser usage in progress before they enter the controlled area. The door should remain closed during the operation of the laser.

For more details see section 13.1.

3.5 Single-use disposable accessories

The **LDV** can be operated only with the pre-sterilized single-use original **Ziemer LDV Procedure Packs**, containing all required single-use, sterile disposable components (see section 5.7).

Warning: Using other manufacturers' accessories or re-using Ziemer's single-use disposable accessories could result in injury to the cornea or in damage to the instrument.

Terms of warranty: Should any non-**Ziemer** disposables be used or **Ziemer** disposables be re-used, any warranty will become invalid.

3.6 Environmental and chemical

Ensure that the **LDV** does not come into contact with any liquid or gaseous chemical substances. Sensitive components could be affected and become defective.

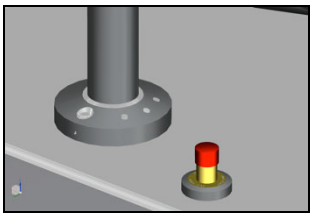
The **LDV** must not be employed in a wet environment or used in contact with liquids. Disregarding this warning may result in electric shock.

Regardless of whether the HP is locked to the BS or not, do not pull the cable too tight, and never pull on the cables connecting the HP to the BS (e.g. when cleaning). Always handle the HP with care, and do not drop the HP.

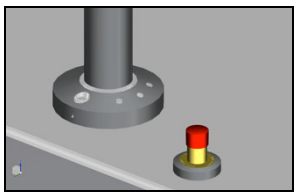
If components of the **LDV** such as the Base Station, the HP or the FMAA are exposed to excessive mechanical shock during transportation, proper functioning cannot be guaranteed any more, and Customer Service should be contacted (see section 11, Service and Maintenance).

3.7 Emergency OFF

In the event of an emergency, the **LDV** should be immediately shut down by pressing the red Emergency OFF button located on top of the table of the BS working surface.



4 Safety features

Master ON Switch 	The BS is turned on by Master ON and by depressing the start button (see section 5.2). Caution: Switch to appropriate line voltage before attempting to switch the **LDV** on. 
Safety System	The entire electronic system is permanently checked by an independent system. If any component does not respond in less than 4 seconds, then the system will automatically shut down.
Laser Enabling	When the master switch is turned to the ON position, the **LDV** System Window appears on the touch screen and requests a login name and password. Laser emission is disabled until the user selects appropriate treatment parameters, the Handpiece is fixed on the eye with the suction ring and all internal control parameters are checked.
Interlock Key	The Interlock Key is a Key Plug which, when removed, opens the safety interlock system, thus making it impossible to start the laser head. It is located on the bottom back of the unit. To prevent the device from being activated accidentally, the interlock key must be removed between uses. 
Laser Aperture	The device has a single aperture located in the HP (see picture in section 5.3) for the laser beam.
Laser Emission Indicator	Laser emission is indicated by blue LED indicators located at the base of the touch screen monitor.
Protective Housing	The **LDV** has a protective housing that prevents unintentional access to laser radiation. This housing is to be opened only by a qualified **Ziemer** Customer Service representative.
Labels	Warning labels are mounted in appropriate locations on the system to indicate conditions under which the user could be subjected to laser radiation (see section 13.3 of this manual).
Laser Module / Safety Shutter	The Laser module is activated during the start up of the system but a shutter, controlled by the safety system, will prevent any laser emission. The shutter will only be opened after the fixation, by suction, of the eye to the HP or during an external power measurement (see section 10.3).
Footswitch Control	The footswitch cannot be activated unless all steps in preparation for resection have been completed.
Emergency OFF Button	The Emergency OFF Button is a red button located on top of the table of the base station and reachable from all operating positions. When pressed, the button closes the shutter and shuts off the main system power. This control should be used only in the event of an emergency. 
Unauthorized Use	Unauthorized use is prevented (1) by the software, which requires a password for Login, and (2) by a special hardware key needed for opening the base station. A special key should also be used to make the device functioning.

5 System description

5.1 Main functional units

The complete **LDV** system consists of the following functional units:

- Base Station (BS), integrating the Laser Unit, Fast Scan Unit (FS), Fixed Mirror Articulated Arm (FMAA), Power Supply, Computer, Touchscreen Monitor, Suction Unit, and Safety System
- Handpiece[1] (HP), integrating the Slow Scan Unit (SS) and the Cutting Lens
- External wireless keyboard and mouse

The **LDV** is movable on four wheels. Two wheels can be locked by a mechanical brake. The other two wheels can be locked in driving direction with the smaller pedal. For movement inside the clinic, HP and FMAA must be locked in their park position for secure movement.

The working position of the HP is located in the focus of the operating microscope of the Excimer Laser. During laser resection, the Handpiece is in a horizontal position and approximately perpendicular to the patient's body axis. Interfering contours within the environment of the eye are thus largely avoided.

In the working position all joints of the fixed-mirror Articulated Arm are aligned roughly at right angles (±30°). During resection, the elbow of the FMAA is positioned above the torso of the patient. These positions allow optimal control of the FMAA with the HP.

To prevent uncontrolled rotation around the shoulder joint, the upper arm of the FMAA can be inserted in a clamp, from where it can be removed by a tractive force of < 5 N. The limitation of the tractive force allows the operator to remove the FMAA from the clamp by holding the HP. During transportation, the

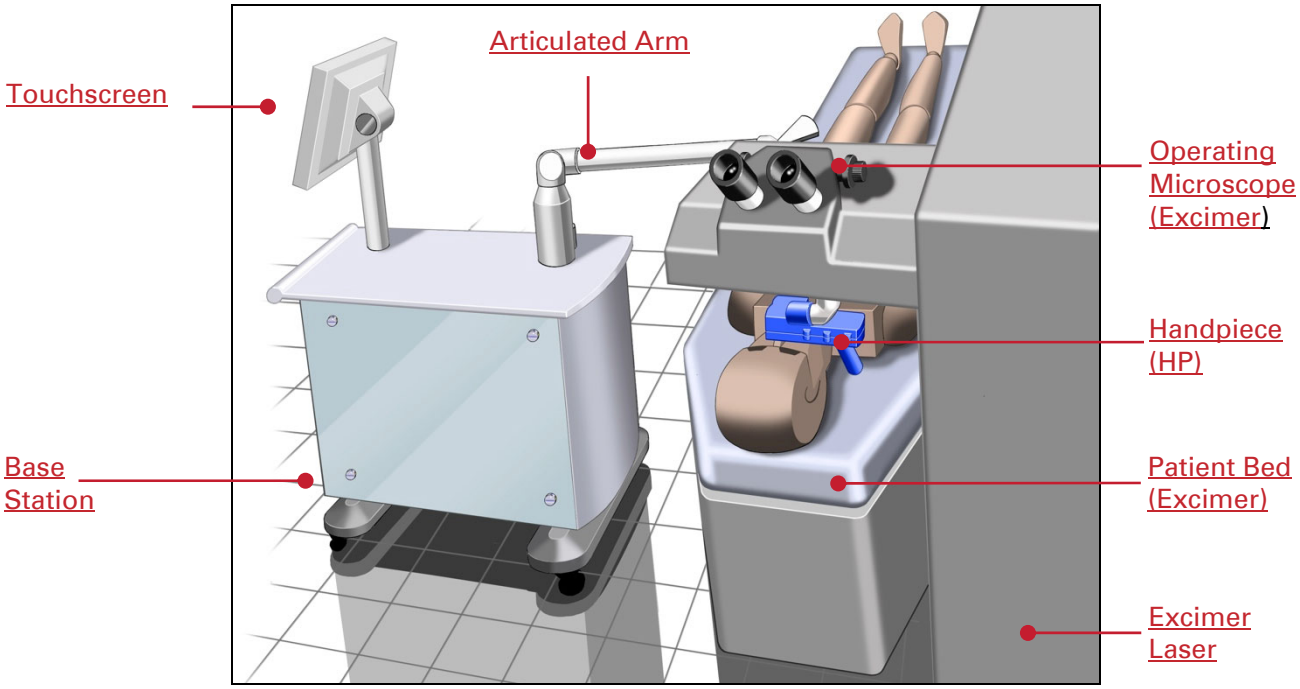
[1] FEMTO LDV Z2: MkII-Handpiece; FEMTO LDV Z4 and Z6: Z-Handpiece. For more details see section 5.3.

clamp protects the FMAA from excessive strain and vibration. The clamp further provides vertical support of about 50 N to the FMAA.

The BS is in a position perpendicular to the patient's body axis, allowing manipulation of the FMAA from both sides of the BS. The BS is height adjustable in a way as to allow fixation of the shoulder (middle) joint at 890-1190 mm above ground. This allows the adjustment of the system to different types of patient couch within a range of 300 mm. The nominal reference height is 1000 mm.

On the table of the BS there is a park position where HP and forearm of the FMAA are locked when the system is not in operation.

The system is balanced in a way as to hold the residual net force, i.e., without external force on HP or of FMAA on eye, within a limit of < ±2 N.

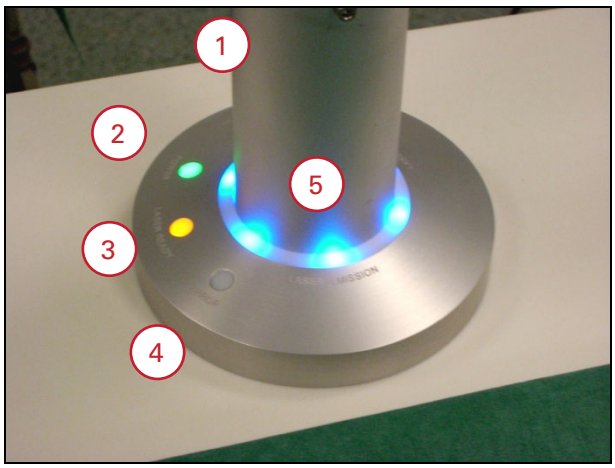


5.2 Operating interface

Most of the **LDV** user interface items (switches, signals, warnings and errors) are implemented on the touchscreen monitor. Nevertheless, some essential functions are duplicated in the **BS** hardware for safety reasons.

5.2.1 Monitor base

1. Start button: switches the **LDV** unit on and off (not visible in picture).
2. Power: **LDV** is switched on (green LED).
3. Laser ready: laser system is switched on yellow LED).
4. Error: a watchdog error occurred (red LED).
5. Laser emission: laser is emitting, shutter is opened (blue LED).



5.2.2 System dimensions

Base station footprint: 95 cm (L) x 70 cm (W) + 76 cm (H).

For further details please refer to Installation Manual (see section 1.5).

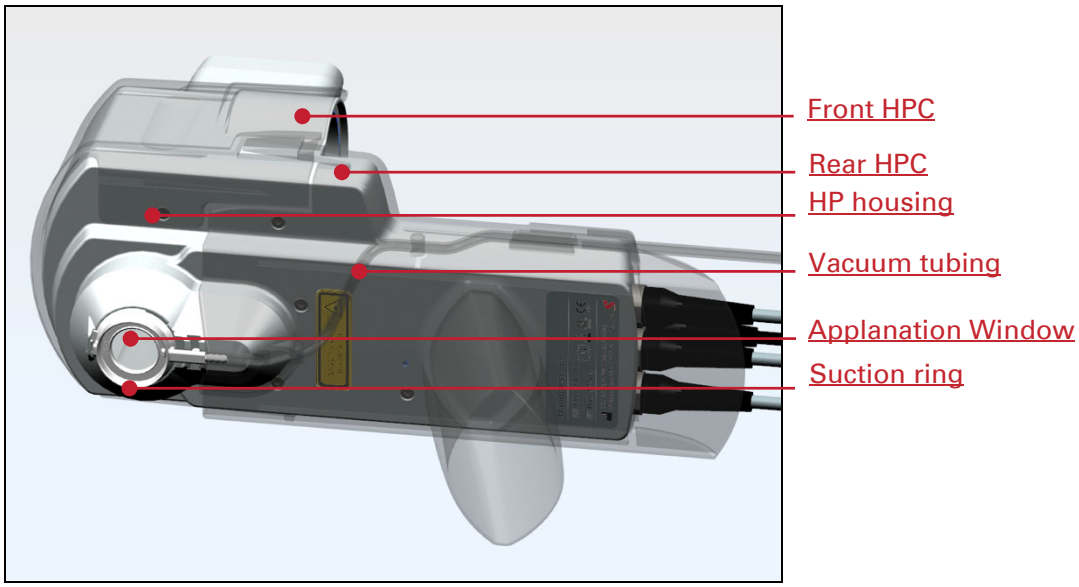
5.3 Handpiece

FEMTO LDV Z2 systems are equipped with MkII-Handpiece with a fixed-focus (250 µm) objective, which is moved in two dimensions (xy) to create the corneal resection.

FEMTO LDV Z4 and **Z6** systems are equipped with a Z-Handpiece which, additionally to the movement in the xy-plane, features the possibility of resection in the third axis (variable from 50 to 850 µm) allowing for further advanced applications.

During operation the HP is, in all cases, fixed with the SR to the patient's eye. The HP is covered with disposable, sterilized HPCs.

The exact positioning of the Handpiece relative to the patient's eye is determined by the surgeon and not by the system or the software. Accordingly, the position of the different resection trajectories in respect to the patient's anatomy has not been validated (e.g. alignment of elliptical flap angle with respect to the cylinder settings of the LASIK ablation pattern).



5.4 Footswitch

The footswitch is an UL 2601.1, DIN EN and CAN/CAS conforming, off-the-shelf product.

The main steps of the surgical procedure are fully controlled by the surgeon and can be activated by the footswitch. As an alternative, footswitch actions may also be activated by touching appropriate buttons on the touchscreen monitor.

The functionalities of the footswitch are described in section 8.15.

5.5 Brake system

1. Mechanical brake pedal: locks two wheels by a mechanical brake to prevent the device from moving.
2. Driving direction pedal: locks two wheels to orientate the device in a particular driving direction. It is especially useful when the device should be driven straight forward.

5.6 Starter kit

The **LDV** is provided with a Starter Kit. The Starter Kit contains one titanium Suction Ring of each type (8.5, 9.0, 9.5 and 10 mm diameter) and the basic instruments, as recommended by **Ziemer**, for Z-LASIK surgery: 2 Thorlakson Z-LASIK Flap Lifters and 2 Thorlakson Z-LASIK Specula.

Surgical Instruments

For cleaning and sterilization instructions of these instruments please refer to the "Surgical Instruments Handling Instructions" delivered with each Starter Kit.

Suction Rings

The titanium SRs may be used as an alternative to the disposable SRs contained in each PP, for example if the surgeon decides, just before resection, to change the SR diameter after considering the patient's symptoms.

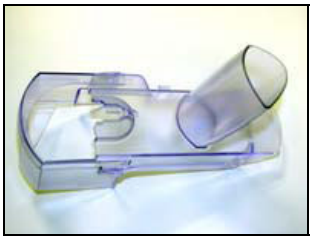
When working with Titanium SRs, it is the user's responsibility to make sure the SR is cleaned and sterilized as recommended (see section 9.3) and the correct SR size is manually entered into the Resection Parameter list (see section 8.12).

Do not touch the applanation window with the titanium SR, otherwise titanium may be deposited on the window causing reduced laser transmission.

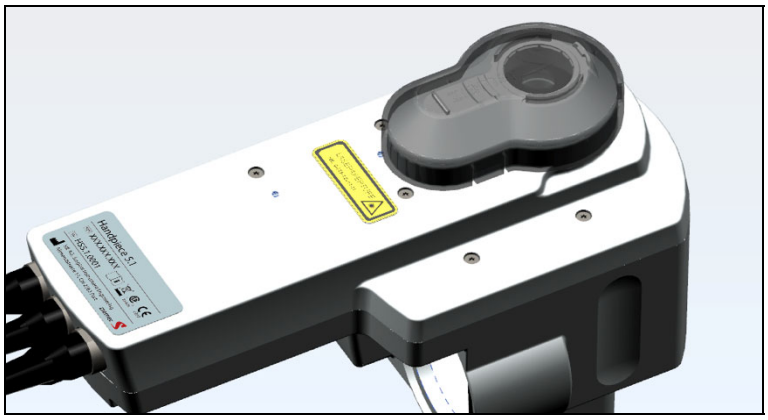
To obtain a complete list of materials required for surgery, please contact your Distributor or a **Ziemer** sales representative. See also the Installation Planning Manual and the Surgical Procedure Manual (see section 1.5).

5.7 Procedure Packs

The **Procedure Pack** provided by **Ziemer** for the **LDV** contains the single-use sterile disposable items detailed below:

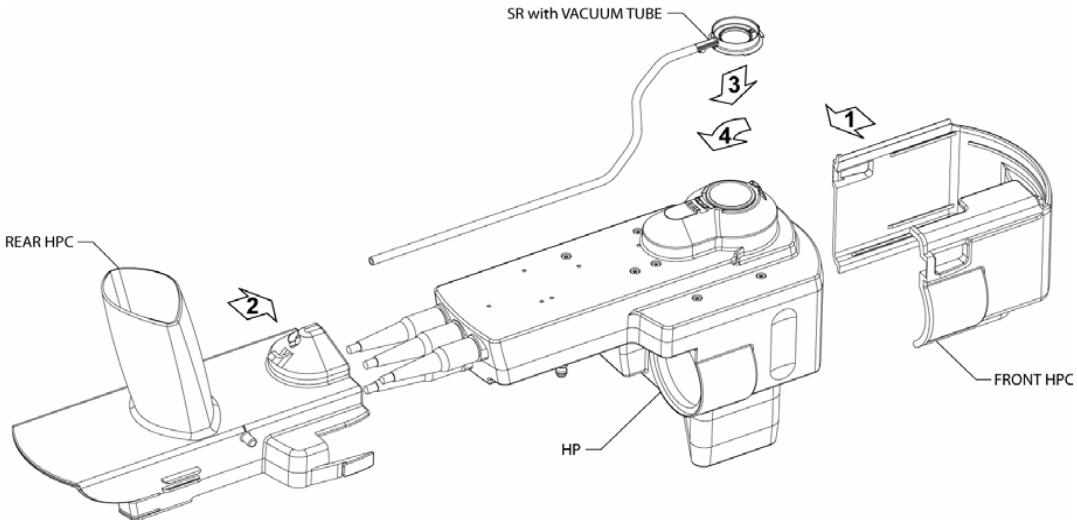
Drape	The Sterile Drape is used to cover the top of the **LDV** working surface so that it can be used to prepare sterile accessories. A self-adhesive strip on the back secures the drape on the working surface.	
Handpiece Casings	The two HPCs ensure the sterility of the handgrip on the HP. They slide over the HP body and are mechanically interlocked.	
InterShield spacer	The IS spacer ensures sterility of Laser Exit Window surface. Handle the IS with sterile, un-toothed forceps. Avoid scratching the IS or the HP window with the forceps. By **FEMTO LDV Z2** systems with MkII HP (fixed-focus) the thickness of the IS spacer also serves to determine the flap thickness. The flap thickness achieved with the IS is indicated on the packaging.	
Suction Ring and **Suction Ring applicator**	The SR connects, by the force of a vacuum, the HP to the eye during resection. Due to the suction, the corneal surface is applanated and, depending on the resection method, it also determines the flap diameter (see Surgical Manual). The SR applicator serves to hold the SR for applying it to the HP. It also serves as a holder for two IS spacers (one IS serves as reserve).	
Vacuum Tubing with Strainer	The vacuum tubing connects the SR to the vacuum pump inside the BS.	

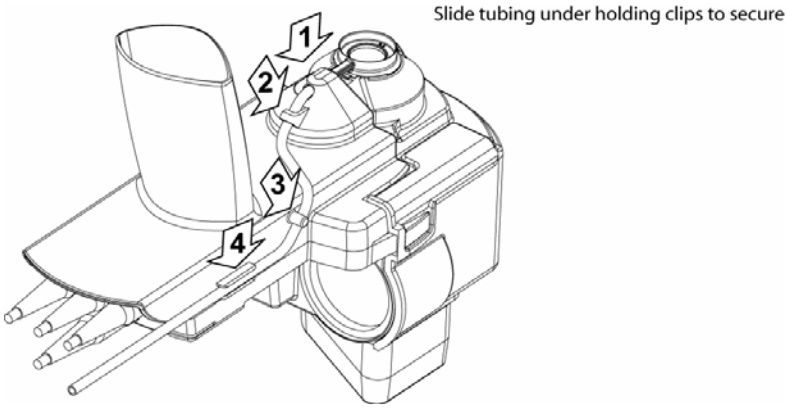
5.8 Handpiece protection cap



It is recommended to use the Handpiece protection cap to protect the applanation window whenever the system is not in use.

5.9 Handpiece assembly





For a more detailed procedure to mount the IS and SR with its applicator, refer to the corresponding Surgical Manual (see section 1.5).

Verify proper assembly of Suction Ring and InterShield. There must be no gap between Suction Ring and hand piece cone. Any gap may lead to an incorrect flap size.

6 System specifications

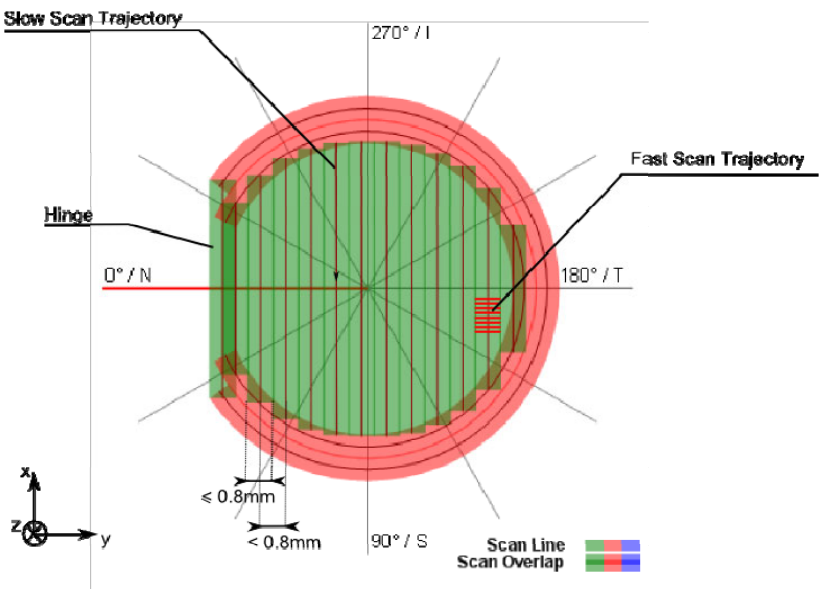
System Parameter	Specifications
Laser Type	Mode-locked, diode-pumped Yb oscillator
Mode	Fundamental (TEM_{00})
Central Laser Wavelength	1020 - 1060 nm
Laser Pulse Duration	200 - 350 fs
Laser Class	4
Remote Interlock	Yes
Base Station Footprint	95cm (L) x 70cm (W) x 76cm (H)
System Height	100cm (floor to fixed mirror Articulated Arm) 139cm (floor to top of screen)
System Weight	215 kg
Input Voltage & Maximum Current	100/120/230-240 VAC, 50-60 Hz 700 VA
Interfaces	USB 2 / Ethernet / ext. interlock / footswitch
Ambient Operating Conditions	18 to 24° C (65 to 75° F), 20 to 70% rH
Recommended Storage Conditions	10 to 50°C (50 to 122° F), 20 to 70% rH
Recommended Transport Conditions	-20 to 60°C (-4 to 140° F), 10 to 90% rH not condensed
Atmospheric pressure range	500 hPa to 1060 hPa.

7 Method of resection

The general method of resection will be described in this section. The exact resection method varies slightly depending on the chosen procedure but is based on similar methodologies.

Prior to resection, the eye is applanated against the applanation window. In order to create the flap, the **LDV** uses ultra-short light pulses. By accurately focusing the laser beam, sufficient energy density can be achieved inside the cornea. This leads to a photodisruption process that generates microscopic bubble-shaped dissection points at a desired depth inside the cornea, without damaging nearby tissue outside the laser focal point area. Fixation of the eye is achieved by a vacuum that is generated inside the SR. The resulting applanated surface, and for some procedures the flap diameter, are determined by the geometry of the SR. For more details refer to Surgical Procedure Manual (see section 1.5).

One part of the corneal resection (see image below) is created by the software-controlled xy-scanner (Slow Scan), which moves a lens inside the HP over the applanated surface following a meander-like scanning pattern (Slow Scan trajectory). Simultaneously to this Slow Scan motion, the laser beam oscillates perpendicularly to this trajectory within an amplitude ≤ 0.8 mm (Fast Scan). To provide a contiguous surface treatment, the distance between the lines of the Slow Scan trajectory is < 0.8 mm. The movement of the Fast Scan is adjusted perpendicular to the y-axis of the slow scan within ± 5° by a rotator prior to laser resection. Additionally by **FEMTO LDV Z4** and **Z6** systems resection in the z-axis is allowed, if required for the selected method.



8 Software

The software of the **LDV** is configured in such a way as to prevent errors and maladjustments to a large extent. Access via a graphical user interface is restricted to the program level. The operator cannot see the operating system level of the controls.

The text on the graphical user interface is available in English and other languages (see section 8.21). The main steps of the procedure are confirmed by acoustic signals.

Start up screen of the FEMTO LDV program

8.1 Screen structure

The **LDV** user interface is structured in a sequence of windows that display parameter settings, accept user entries and display system status and procedure progress information. In all screens, a status bar is visible at the bottom of the window.

8.2 Status bar

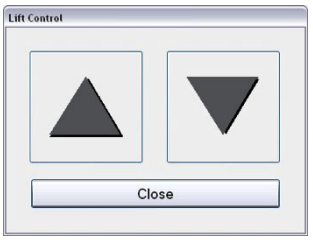
1. Status of system components: color of the LED provides level of errors occurred:
   - Green: all subsystems are functional.
   - Orange: warnings that will not affect the resection process. However, this kind of warning should be checked and validated by the user. Click on the button to view details.
   - Red: errors occurred which prevent user to perform a new resection. Click on the button to view details.
2. Mode: current status of the software is displayed
   - Start-up and shutdown: on start and shutdown.
   - Idle and running: screen update or while running resection process.
   - Preparation and post cut: on setting and status screens before or after resection.
3. User: current user logged in (rights may be different for each user).
4. Laser: current laser power output in %.

5. Keyboard: with this button, the visual on-screen keyboard is enabled when alphanumeric inputs are required. Use by tapping on screen with a finger or a touch pen. Click in a text field before typing

6. Eye illumination: available during preparation of the resection procedure process, this slider changes the eye illumination brightness inside the Handpiece. Default value is medium.

The light emitted by the Handpiece is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to the light of the Handpiece when operated at maximum output will exceed the safety guideline after approx. 7 minutes. Therefore, the LEDs are automatically switched off by the software after 400 sec.

7. Adjust height: with this button, the BS height adjustment window as shown is opened.
   Height of top surface may be adjusted from 890 to 1190 mm. This control is not available during resection procedure.



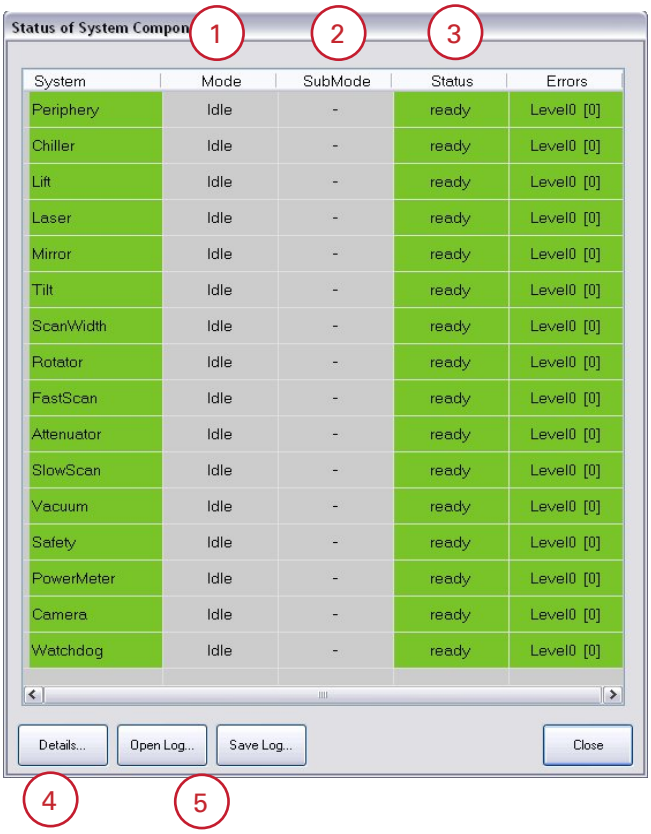
8.3 Status Window

The Status Window is activated by clicking on the Status of System Components button in the status bar.

Status of System Components

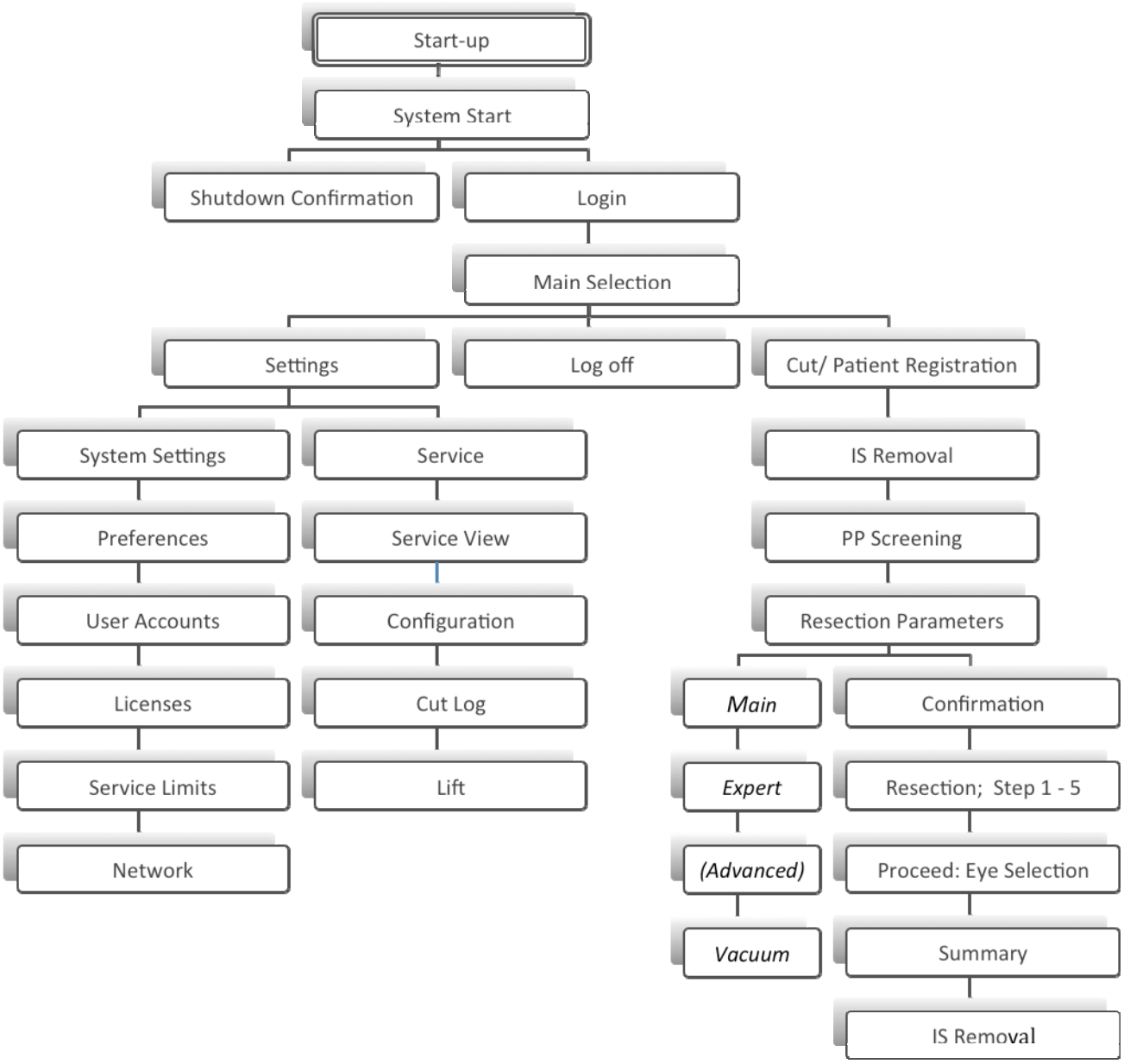
The status of each system component may be checked in this window. If one of those components is not ready or working, it is not possible to initiate a resection process.

1. Mode: same mode as displayed in main screen.
2. SubMode: resection process mode (Standby, ApplyVacuum, FlapCut, ReleaseVacuum).
3. Status: ready, starting, working, testing, warning, error, stopped. Colors depend on the error level, from level 0 in green to level 3 (critical error) in red.
4. Details: display a more detailed window regarding the item selected in the list.
5. Open and Save Log: these buttons deal with log files. In these formatted text files, events are recorded in a timetable. In case of error or warning events, these files are be useful for servicing. Open Log button retrieves event files for reading while Save Log button saves the up-to-date files for export.



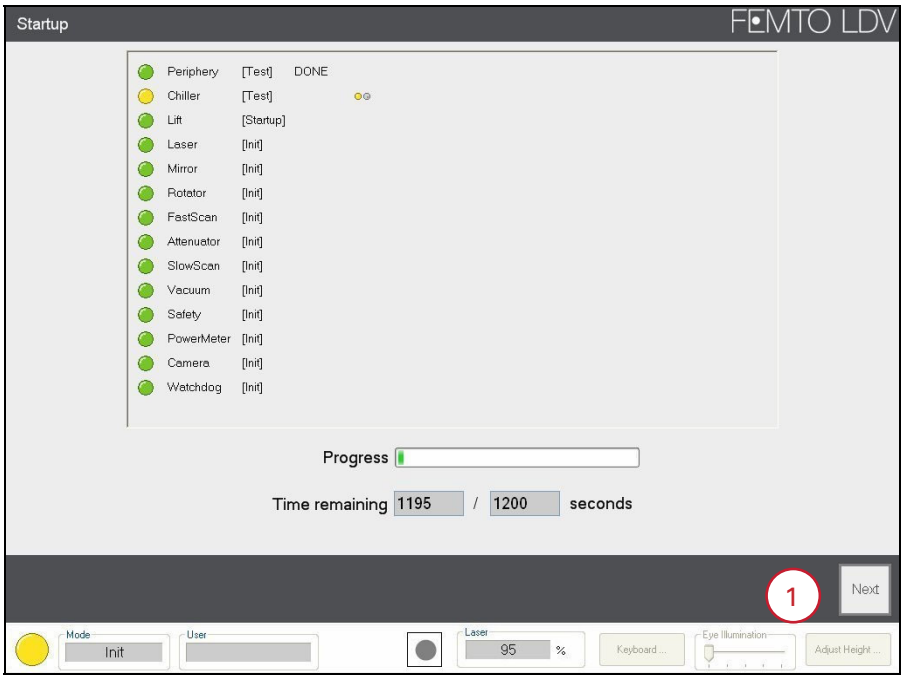
System	Mode	SubMode	Status	Errors
Periphery	Idle	-	ready	Level0 [0]
Chiller	Idle	-	ready	Level0 [0]
Lift	Idle	-	ready	Level0 [0]
Laser	Idle	-	ready	Level0 [0]
Mirror	Idle	-	ready	Level0 [0]
Tilt	Idle	-	ready	Level0 [0]
ScanWidth	Idle	-	ready	Level0 [0]
Rotator	Idle	-	ready	Level0 [0]
FastScan	Idle	-	ready	Level0 [0]
Attenuator	Idle	-	ready	Level0 [0]
SlowScan	Idle	-	ready	Level0 [0]
Vacuum	Idle	-	ready	Level0 [0]
Safety	Idle	-	ready	Level0 [0]
PowerMeter	Idle	-	ready	Level0 [0]
Camera	Idle	-	ready	Level0 [0]
Watchdog	Idle	-	ready	Level0 [0]

8.4 Screen Sequence



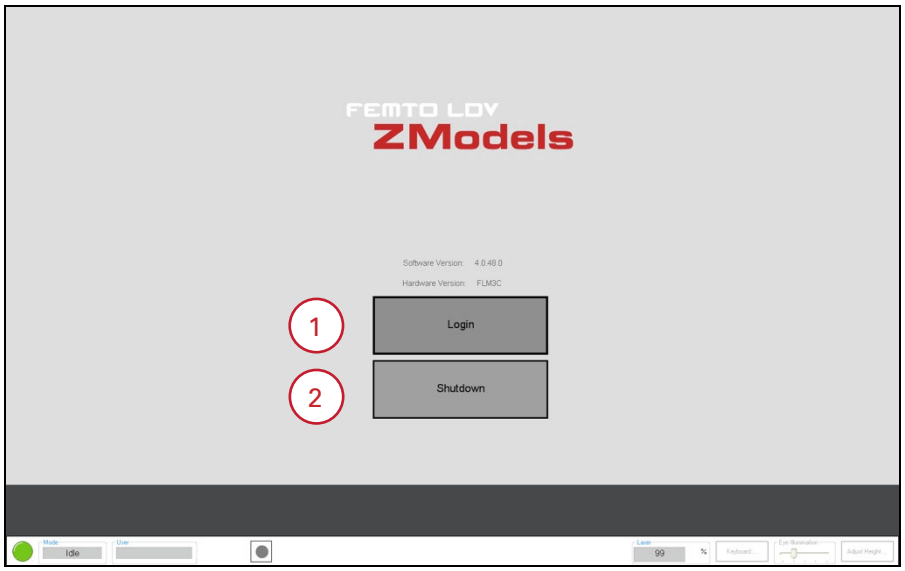
8.5 Start up

After operating system start-up (display of splash screen, see page 21), the start up screen will be displayed. It shows the progress of all subsystem start-up routines. This process will take approximately 20 minutes. No interaction is possible during the start-up process until the laser unit is ready.



1. Click on the **Next** button when active (**Time remaining** = 0 seconds).

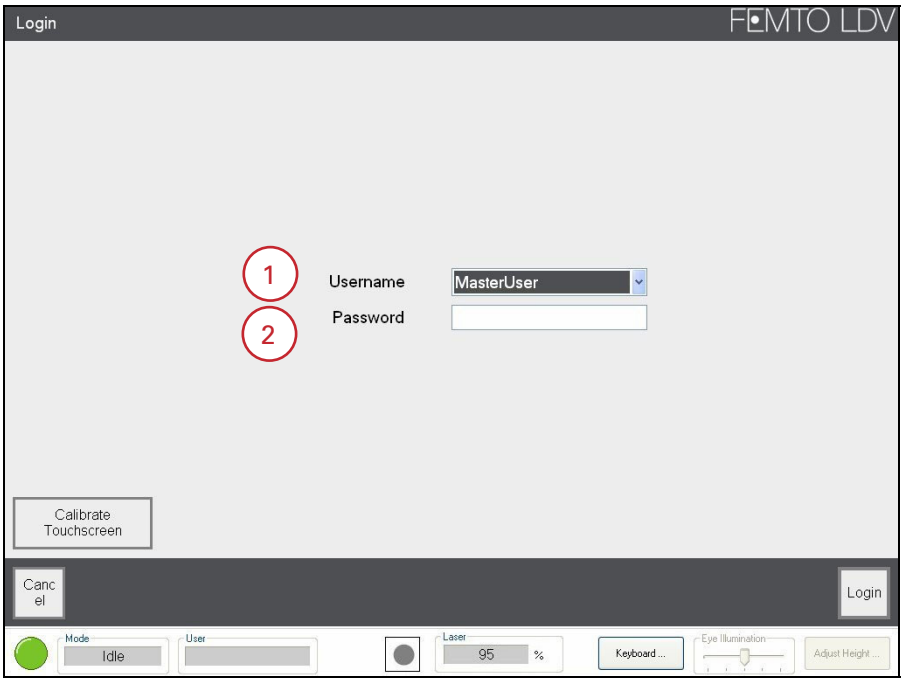
8.6 System start



1. Login: Click on the **Login** button to bring up the login display.
2. Shut Down: shut down the device.

Remember to lower table height before shutting down if you intend to transport the **LDV.**

8.7 Login

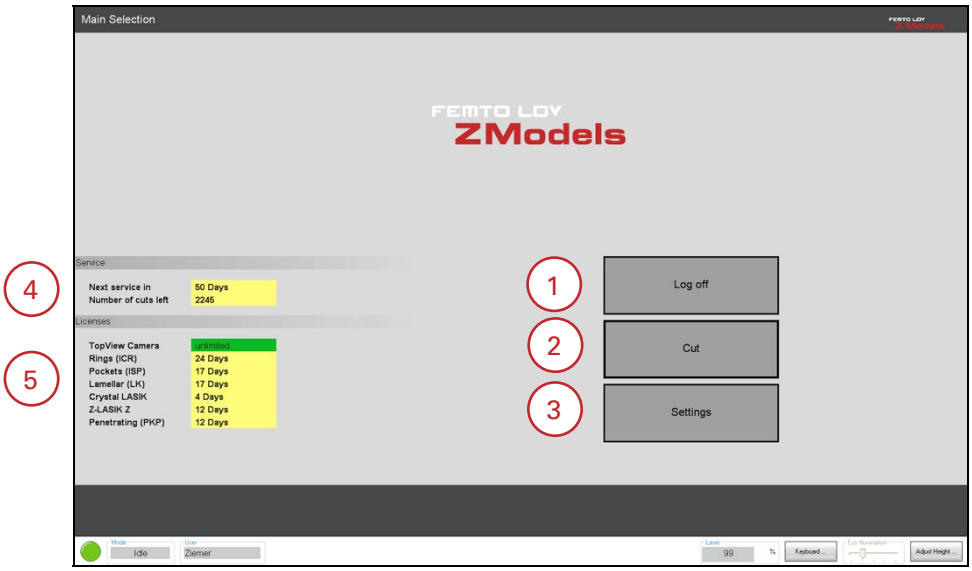


1. Username defines which rights will be granted, and will load the user's preferences (default parameters, trajectory). Trained guest user may use the generic “User” profile that covers most of the use cases needed.
   Other predefined usernames[2]:
   - Administrator: owns user accounts and service limit rights. This user cannot perform any resection.
   - Service engineer: this profile is defined to perform maintenance. However this user cannot perform any resection.
   - Ziemer: defined for **Ziemer** service engineers, this profile owns almost all rights.
   - Technician: this profile owns resection rights, some service rights and user account rights.
   - Master User: this enhanced profile owns resection rights.
2. Password: related to the username chosen.

Service Login for remote maintenance:
User may have to use a temporary service login to perform some tasks for servicing (see section 12.4 for more details). User will be directed by a Ziemer engineer to perform this operation.

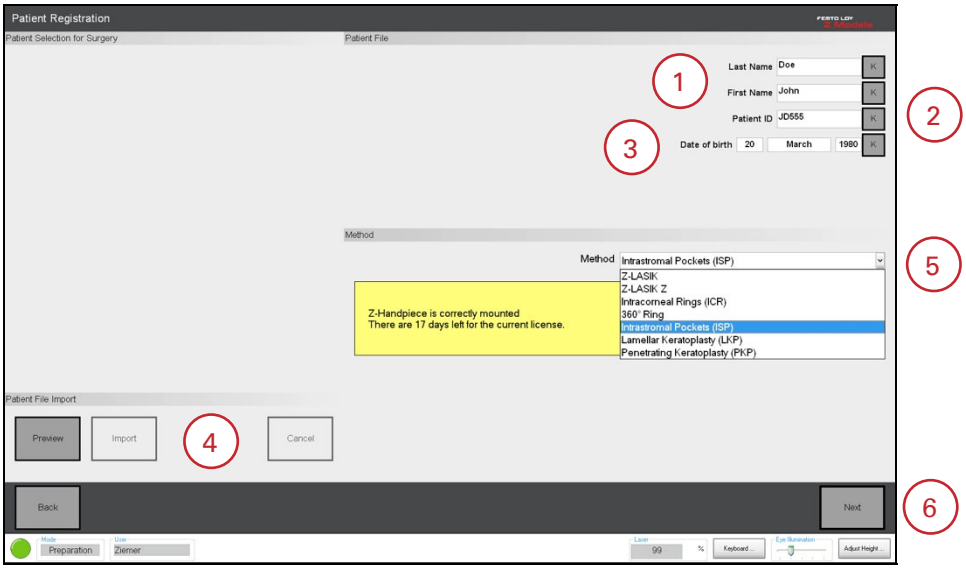
[2] Only Master User’s and User’s profiles can be modified. Others are locked.

8.8 "Main selection" screen



1. Log off: the current user will be logged off. System returns to System Start Screen.
2. Cut: if no components encountered any trouble, the **Cut** button is enabled. Cut may be disabled (grayed out) even though the status of the system components is safe while secure tests are performed (< 1 min).
3. Settings: User-adjustable System settings, default parameters and Service/Maintenance options are available here. See section 8.20.
4. Service: note that the number of cuts and days remaining till the next service are indicated on the left side of the screen.
5. Licenses: each application module can be released for a limited time on a device. This limit is displayed for each license that has been once activated.

8.9 "Patient registration" screen



1. Last and First Names: Enter patient names. Any uppercase and lowercase characters are accepted.
2. ID: Patient ID may be any combination of alphanumeric characters.

3. Date of birth: Patient date of birth (optional). Default value is the current day. The list box arrow displays a calendar for convenience, but the date can also be entered by using the numerical keys on the keyboard.

Note that either ID or the combination of First and Last Name are required to move to the next step. This will ensure that each data set is identified in a unique manner. However, the system will not test for uniqueness of names and IDs.

4. Patient List Import:

The **LDV** software allows to pre-record multiple patient names externally, to import a patient list, and to select the patient from this list.

- Preparing a patient list:
  Patient lists are created on an external PC, either by creating the list directly, e.g. as an excel list, or by exporting from an electronic medical record (EMR) database. The file must be in tab-separated csv format and must have the filename /filetransfer/patient_import.csv.
  The format of patient records in the list is:
  Firstname[tab]Lastname[tab]ID[tab]Birth_year[tab]Birth_month[tab]Birth_day
  Valid records must contain a valid date and at least either a **Lastname** or a patient **ID**. Example:
  John [] Doe [] Doe1965 [] 1965 [] 05 [] 15
- Importing a Patient List:
  Insert a USB Flash Memory Drive into the USB connector. On the Patient Selection Screen, touch **Preview**, to display the list. All entries on the USB drive will be displayed, with invalid entries marked in yellow. Touch **Import** to load the list. Note that invalid entries will not be imported.
- Selecting a Patient:
  Type the first few characters of the desired patient's last or first name or ID. Matching entries will be displayed. From the selection displayed, touch the desired entry. The selected patient's details will be displayed in the fields on the right hand side of the screen.

5. Method: choice list for the resection methods.
   Depending on system configuration, the following methods may be activated and can be selected:
   - Z-LASIK (available in all systems)
   - Z-LASIK Z
   - Intracorneal Rings (ICR)
   - Intrastromal Pockets (ISP)
   - Lamellar Keratoplasty (LKP)
   - Penetrating Keratoplasty (PKP)
6. Then touch **Confirm** if the correct HP is mounted and continue touching **Next**.

8.10 "InterShield removal" screen

This screen will appear after a new patient has been entered and before a Procedure Pack can be scanned:

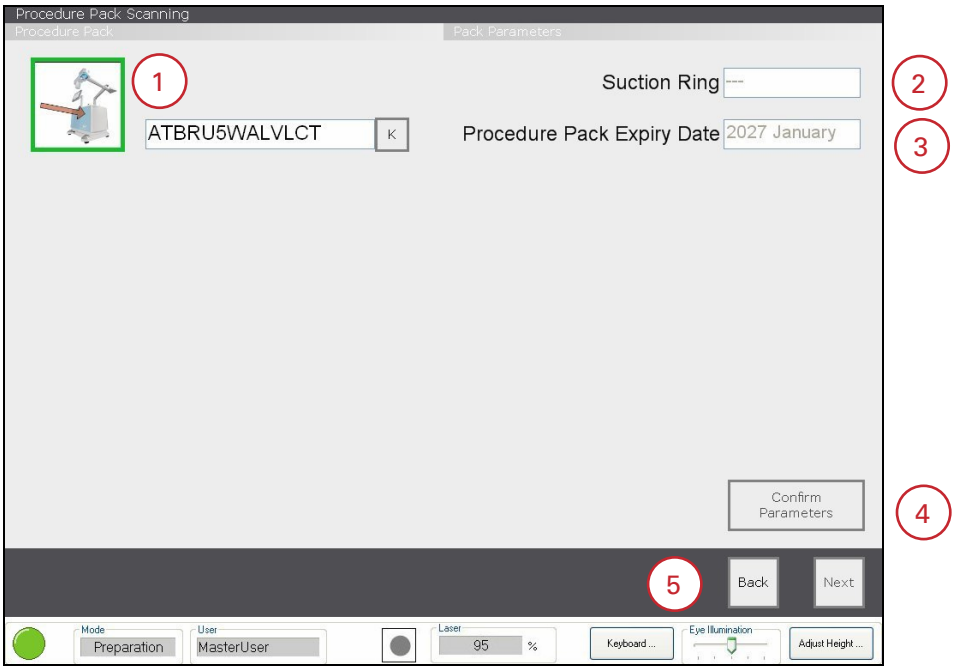
Have you removed the InterShield from applanation window? Please confirm.

Confirm removal of InterShield from applanation window. Remove by using moist cloth (cf. sections 8.19 and 9.3). Upon touching the button, the next screen will be presented.

Carefully check that there is no InterShield (IS) spacer left on the Handpiece from the previous procedure. DO NOT click **Confirm** unless you have positively confirmed that there is no transparent IS spacer on the applanation window.

8.11 “Procedure Pack scanning” screen

Select a PP that contains the IS/SR (for **FEMTO LDV Z2** systems) or the SR (for **FEMTO LDV Z4** and **Z6** systems) dimensions requested by the surgeon according to the procedure is going to be performed. When this screen is presented, hold the new, unused Procedure Pack against the designated area on the top right corner of the BS front panel. If the PP is identified as valid, its serial number will appear in the “Serial Code” window, and the dimensions of SR and InterShield will be displayed. A beep will indicate successful reading.

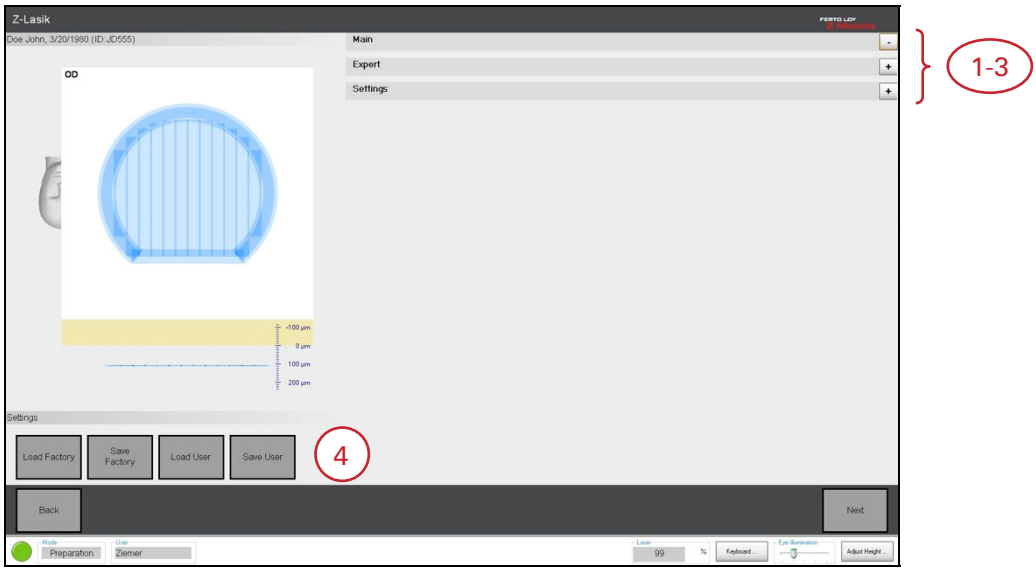


1. Serial Code: the Serial Code appears when the Procedure Pack is successfully scanned.
2. Suction Ring (InterShield): nominal dimension of the chosen Suction Ring (for Z4 and Z6 systems) or Suction Ring and InterShield (for Z2 systems) will be shown here. These values are automatically provided after scanning the Procedure Pack.
3. Expir. Date: expiration date (Year Month) of the Procedure Pack scanned.
4. Confirm Parameters: if displayed IS/PP dimensions are consistent with the procedure you intend to perform, touch the Confirm button. Then touch Continue.
5. Back: this button will take you back to the previous screen. You may scan the same PP again later if no resection has been performed in the meantime using this PP. Or you may scan another PP if the previous one was not accepted.

After touching the **Next** button, a specific base speed for the Fast Scan unit is already set to save time for the surgery.

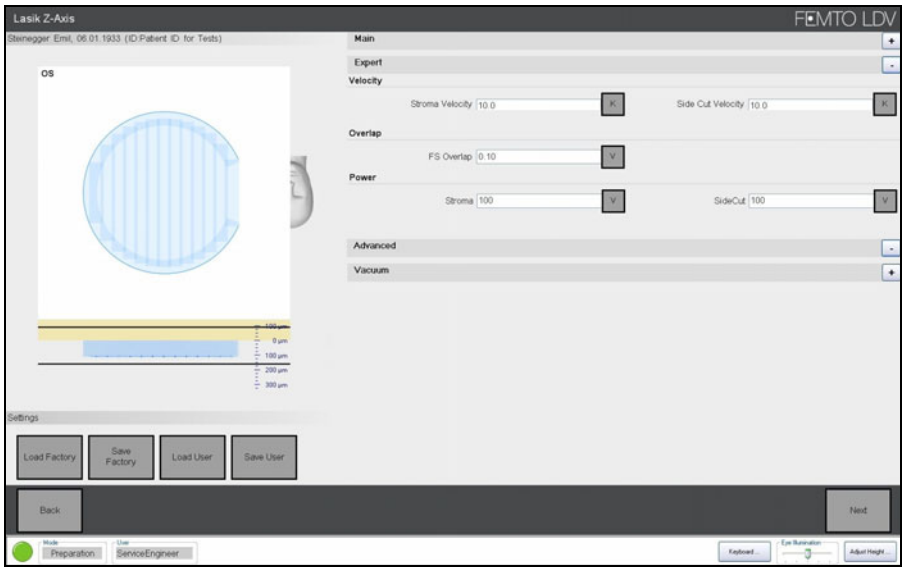
Keep any PP that was rejected if you feel it was rejected without a valid reason. Return the complete PP to your Distributor for verification and eventual refund.

8.12 “Resection parameters” screen (example screen)



Each method comprises different Main and Expert parameters. The meaning of each parameter as well as the complete instruction for programming of a method can be found in the corresponding Surgical Procedure Manual (see 1.5).

1. Main: this section is intended for the most used parameter e.g. eye, resection depth, etc. Every standard procedure not needing any special feature can be completely programmed in this section.
2. Expert: this section presents some special features intended for fine-tuning the procedure. They should be modified carefully since they may have a significant influence of resection performance.
   - Power and Velocity: For **FEMTO LDV Z4** and **Z6** the laser energy and the trajectory velocities (see image below) can be adjusted for optimization of the resection. A **Ziemer** Service Engineer or a specially trained **Ziemer** representative will provide you with an initial setting recommendation during installation and training.
     As a rule, a higher **Power** setting and a lower **Velocity** setting would result in easier tissue separation. For deeper cuts and cuts through corneas with scars or those with opacity, the **Power** setting should be increased to compensate for transmission loss.



3. Settings: this section is intended for the vacuum settings:
   - Vacuum mode: two modes are available, Controlled and Full. Typical setting is Controlled. In Controlled mode, the vacuum will be built up to the selected target value. After reaching target the vacuum pump will be switched off and the vacuum held. If the vacuum falls more than the set tolerance below the target value, it will be adjusted. In Full mode, after the selected vacuum value is reached, the operation will be unblocked. The vacuum pump however will keep running to maintain the maximal achievable vacuum.
   - Vacuum target value: values from 300 to 700 mbar are allowed. Values from 600 to 700 are typical settings.
   - Vacuum release mode: two modes are available, Automatic and Manual. Automatic is the typical setting, leading to an automatic vacuum release after completion of the resection process. If Manual is selected, suction must be released by depressing the footswitch or touching the [Suction off] button.

There is a hidden “Advanced” tab containing special advanced parameters for custom-made trajectories, which are not necessary for a standard procedure. Advanced parameters can be accessed, modified and enabled (upon appropriate training and for specific purposes) by a Ziemer Service Engineer only. Advanced parameters are described in the “Advanced Settings” Manual (see section 1.5)

4. Settings buttons: in this section, the current defined settings can be saved for future surgeries. To ensure a safe resection, the factory settings can be loaded.
   - Load Factory: loads the factory pre-set parameters.
   - Save factory: saves the new defined parameters as factory pre-set. This option is only available for a Ziemer Service Engineer.
   - Load User: loads the parameters as saved by the user. There is only one parameter set for each user. Temporary settings can always be used to perform a resection.
   - Save User: saves the new defined parameters for future procedures.

All expert and some other system parameters are factory pre-set or optimized for the system during installation and training. It is recommended for new users to work with these standard settings initially, until some experience has been acquired.

It is the surgeon's responsibility to use Expert settings that are appropriate and safe. Assistants and technicians should use Expert mode only as directed by the surgeon.

8.13 Resection Parameters

The most relevant resection parameters for the different methods are shown in the tables below:

5. Z-LASIK

Parameter	Definition	Range
Depth	Distance from cornea anterior surface to the resection plane	50 – 250 µm
Round flaps:		
Diameter	Flap anterior surface diameter	5 – 10 mm
Elliptical flaps:		
Diameter 1 & 2	Flap anterior surface major and minor axes	5 – 10 mm
Hinge:		
Position	Hinge position according to TABO system	0 – 359°
Width	Distance from the flap diameter to the uncut portion of the flap	0.3 – 0.8 mm
Border angle	Angle of the flap border related to a natural vertical position	30 – 150°

6. Rings

Parameter	Definition	Range
Depth	Distance from cornea anterior surface to the resection plane	50 – 850 µm
Tunnels:		
Inner diameter	Internal diameter of the corresponding tunnel resection	5.5 – 10 mm
Outer diameter	External diameter of the corresponding tunnel resection	5 – 10 mm
Arc length	Length of the tunnel resection measured in degrees, from the incision position until the end of the tunnel	0 – 359°
Incision position	Position of the insertion area for the rings, according to TABO system	0 – 359°

7. Pockets

Parameter	Definition	Range
Depth	Distance from cornea anterior surface to the resection plane	50 – 850 µm
Pocket:		
Outer diameter	External diameter of the pocket resection	5 – 10 mm
Access tunnel:		
Outer diameter	Outer diameter of the pocket resection	5 – 10 mm
Width	Width of the access tunnel	3 – 5 mm
Incision position	Position of the insertion tunnel for the inlay insertion, according to TABO system	0 – 359°

8. LK and PK

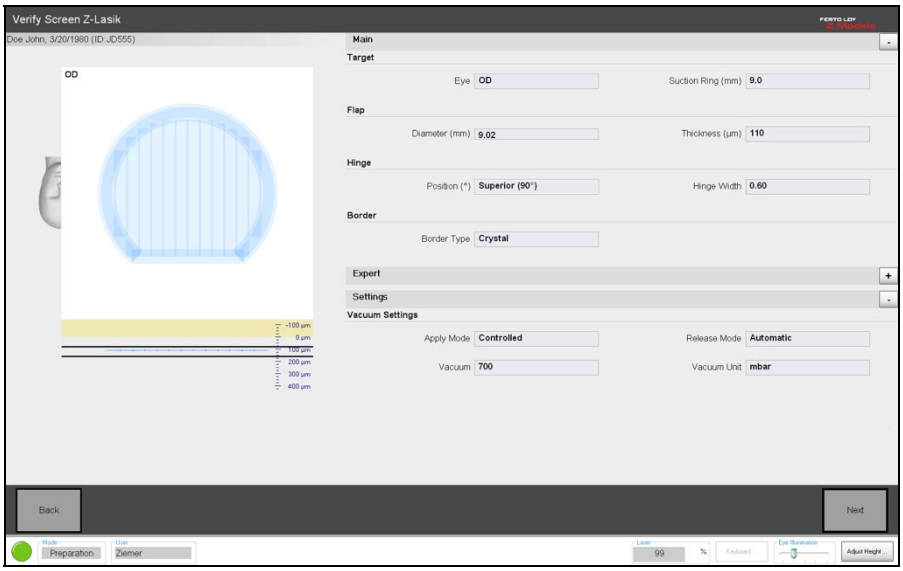
Parameter	Definition	Range
Depth	Distance from cornea anterior surface to the resection plane	50 – 850 µm
Round resections:		
Diameter	Resection anterior surface diameter	5 – 10 mm
Elliptical resections:		
Diameter 1 & 2	Resection anterior surface major and minor axes	5 – 10 mm
Border angle	Angle of the resection border related to a natural vertical position	30 – 150°

8.13.1 Parameter resolution

For the above-mentioned parameters, the following steps are selectable for the user:

- Resection dimensions (x and y axes): 10 µm
- Resection depths (z axis): 1 µm
- Resection position: 1°

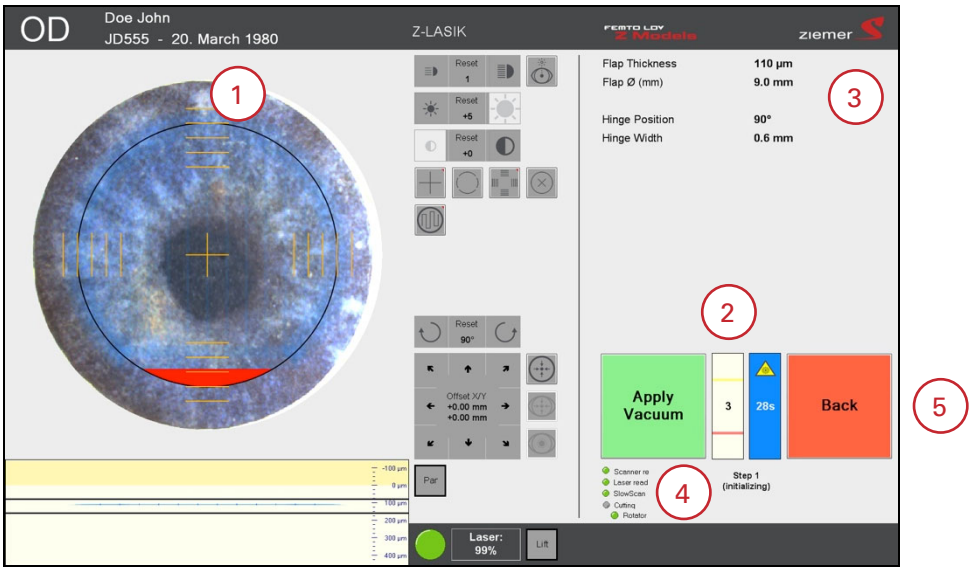
8.14 "Resection parameter confirmation" screen (example screen)



Verify entered parameter settings for the resection procedure. If you need to change any of the values, click on **Back** to return to the parameter entry screen. Confirm your parameter settings by clicking the **Continue** button – the cutting screen will then open.

It is recommended to read the selected parameters to the surgeon for confirmation.

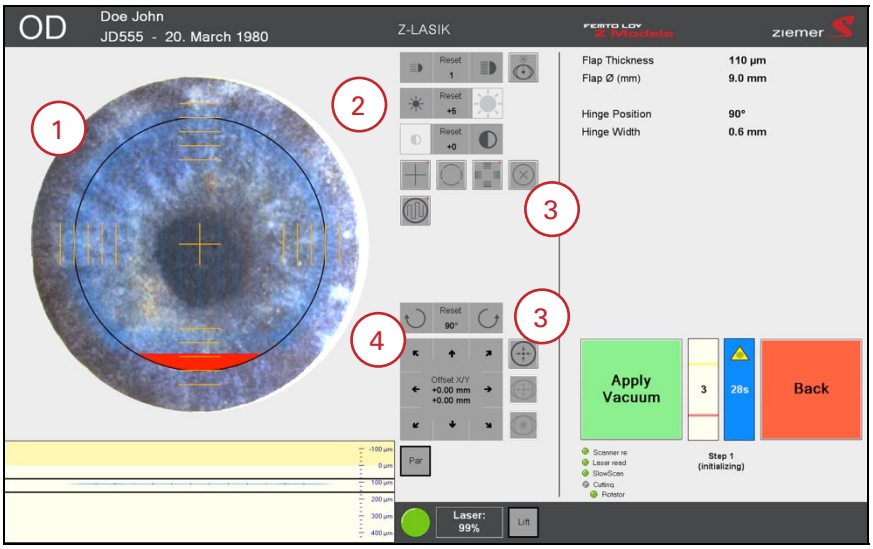
8.15 "Resection" screen (example screen)



1. Resection progress: eye cutting progress is displayed. Which eye, left or right, is indicated on the face diagram.
2. Vacuum: the gauge bar is composed of 3 ranges with a red arrow for the current value applied.
3. Parameters: parameters shown here are for confirmation only. They cannot be changed in this screen. If you detect an error on settings, touch the Back button.
4. Process: FastScan, Laser and SlowScan units are checked before enabling Apply Vacuum button. Wait for the three indications to change to green.
5. Control: control buttons to move to the next step, resume an action, stop the process or cancel the whole process.

8.15.1 Top View camera features

Images coming from the camera are displayed in real time (> 10 frames per second) until the resection process begins. Only the region of interest, inside the suction ring area, is displayed. When the image is touched, the normal view is hidden and an enlarged view (also in real time) is displayed on the right side and additional image controls may be accessed).



1. Top View enlarged image: this screen permits centering the trajectory on the eye. Indicators (marks, trajectory slow scan steps, and hinge) may be displayed to aid positioning the HP and the resection trajectory relative to the eye. The black ring shows the resection target diameter. Default marks displayed at the start may be set in the Preferences screen (see section 8.22).

Before displaying the resection screen, a camera test is performed, especially to check that the SR size is corresponding to the resection parameter settings. If not correct, a warning message is displayed.

During resection, the real time view is replaced by the last captured image; therefore the top view image will be static during the resection process.

2. Image settings:

	Eye illumination: the eye illumination inside the Handpiece may be adjusted for best visibility of the eye. Range of values: 0 to +4.
	Brightness: image brightness may be adjusted for best visibility or for improving pupil detection. Range of brightness values: -5 to +5.
	Contrast: image contrast may be adjusted for best visibility or for improving pupil detection. Range of contrast values: 0 to +7.

3. Mark settings: Shape or combination of shapes used to help positioning the resection trajectory. Marks available:

	Cross-hair.
	Circle (1.5 mm Ø).
	Ladder → Lines start 3 mm from center and are 0.5 mm apart.

Cross-hair, circle, and ladder all move when the trajectory center is shifted.

	Camera center mark (fixed position in center of applanation window).

Other options available:

	Trajectory Preview: press this button to show/hide the resection pattern. The preview may be displayed at the start as a default setting (see section 8.22).
	Centering button: recall the resection trajectory and marks to home position (x=0 and y=0, center of the camera and home position of the focus lens).
	Pupil identification: launches, if suction is applied above the red range, the pupil outline identification algorithm. Pupil identification button is grayed out when the normal view is displayed. When identified, pupil outline is shown in orange.
	Pupil center: press this button to center the resection pattern on the previously identified pupil.

	Fixation light: this button activates/deactivates the fixation light. This tool may be used to align HP and eye optical axes, and to facilitate patient's fixation. Fixation light automatically turns off as soon as the vacuum is applied. When the vacuum is released for any reason, the fixation light turns on again if it was initially on.
	Trajectory lock / unlock: this buttons lock / unlock the trajectory on the eye TopView image to avoid unwished shifting of the resection.
	Flap diameter: allows enlarging or reducing the flap diameter while the vacuum is applied.

When a mark is selected, its button displays a red mark on the right top corner: 

4. Centering / rotating arrows: With these 10 buttons, the position of the resection trajectory home position may be shifted within limits that will keep the resection trajectory inside the applanated area. Once a maximum shifted position is reached, control buttons are deactivated. Tapping on the buttons shifts the trajectory center in 25 µm increments. Touching a button continuously will shift quickly to the desired position. This control is available only in enlarged view.

   Offset position: displays the relative position of the resection trajectory from the camera center in µm (x- and y- axes).

   Other options available:

	Pocket: with this button the middle point of the pocket may be shifted within limits to keep the resection trajectory inside the applanated area. The tunnel will however remain in its position.
	Pocket tunnel: with this button the central point of the entry tunnel may be shifted within limits to keep the resection trajectory inside the applanated area. The pocket will however remain in its position.

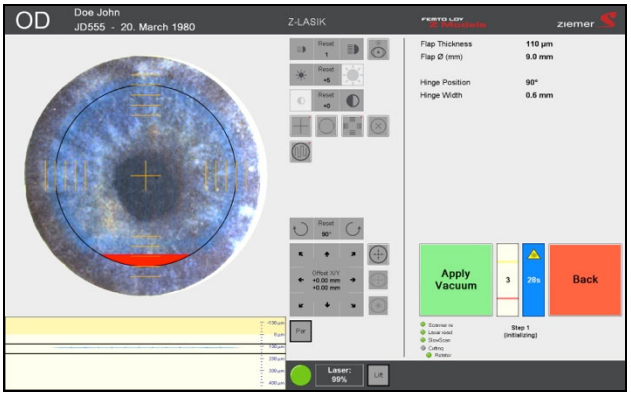
8.16 Resection steps (example screens)

Resection – Step 1

Apply vacuum to reach the target value.

Before applying vacuum, await the end of the vacuum test, and wait for Scanner, Laser and SlowScan to be ready (green spots). You may proceed by touching the **Apply vacuum** button when it turns green.

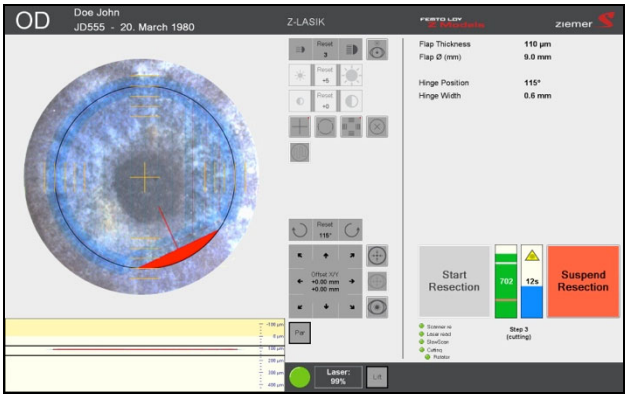
You may touch the **Back** button at any time to stop the procedure.



Resection – Step 2

When suction has reached target value, resection may be started when **Start Resection** button turns green and acoustic ready signal sounds.

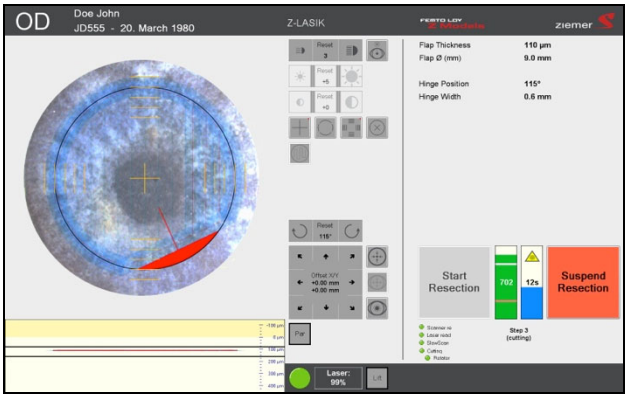
After an elapsed time (typically 60 s) without any action, vacuum is released and display returns to step 1.



Resection – Step 3

While resection is in progress, a blue laser warning label appears. The process may be suspended and then resumed or cancelled at any time.

To suspend the resection temporarily, touch the red **Suspend resection** button (or depress footswitch). The laser optics will recede, while suction remains active, to allow the surgeon to view the progress of the resection. To continue and complete resection, touch the **Resume resection** button. To abort the procedure, touch the **Cancel/Recut** button.



Suction remains on while resection is suspended. To avoid possible trauma through elevated IOP do not keep resection suspended for prolonged times.

If a partial loss of suction appears during the resection, re-pumping is automatically started. If suction decreases to a level in the yellow range, resection is suspended but may be resumed. If vacuum reaches the red range, resection is aborted.

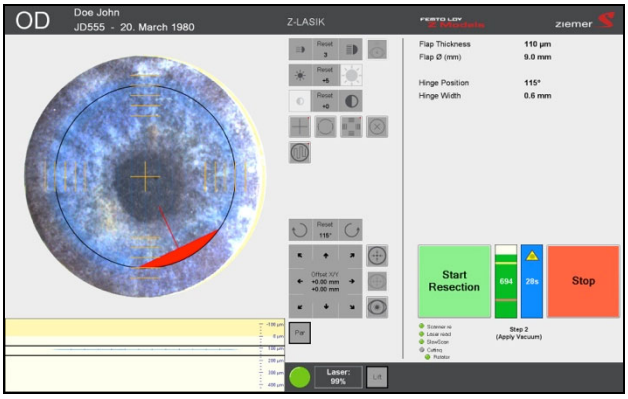
Note that a progression bar indicates the remaining time to completion of the resection.

Resection – Step 4

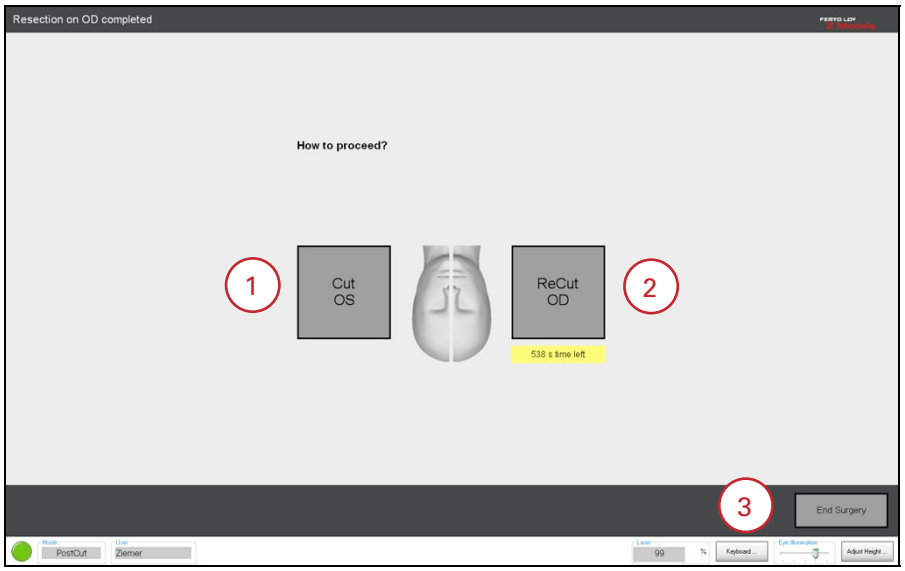
Upon completion of the resection process, suction can be released (if set to “automatic”, suction will be released automatically).

Resection – Step 5

Remove Handpiece from eye. Touching the Continue button will take you to the next step (section 8.17).



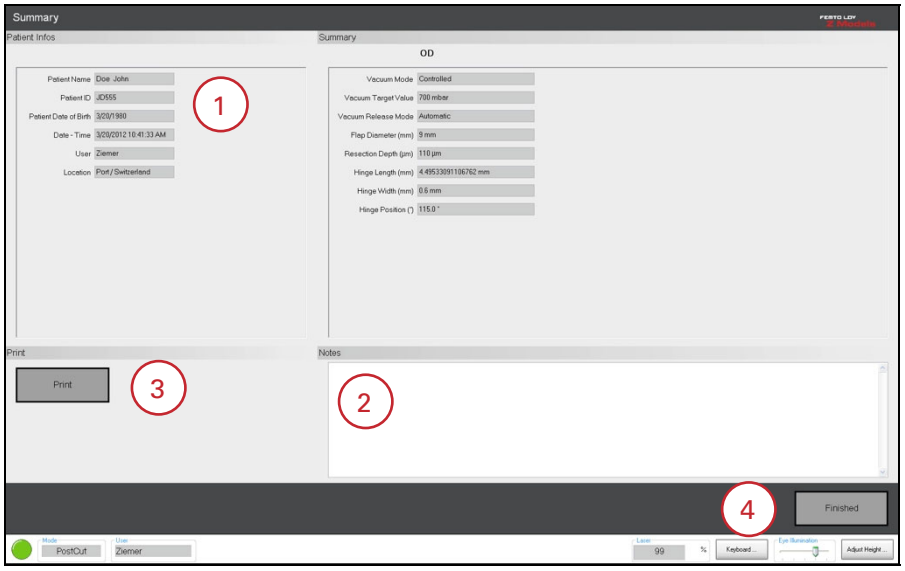
8.17 Eye selection screen (example screen)



1. Normally, if the resection process was successfully completed, you will proceed to performing a resection on the contralateral eye by touching the **Cut OS/OD** eye. This will take you back to section 8.12.
2. If the resection needs to be repeated (e.g. resection appears incomplete), touch the **Recut** button.
3. If no further resection is planned (i.e. monolateral procedure) touch the **End Surgery** button.

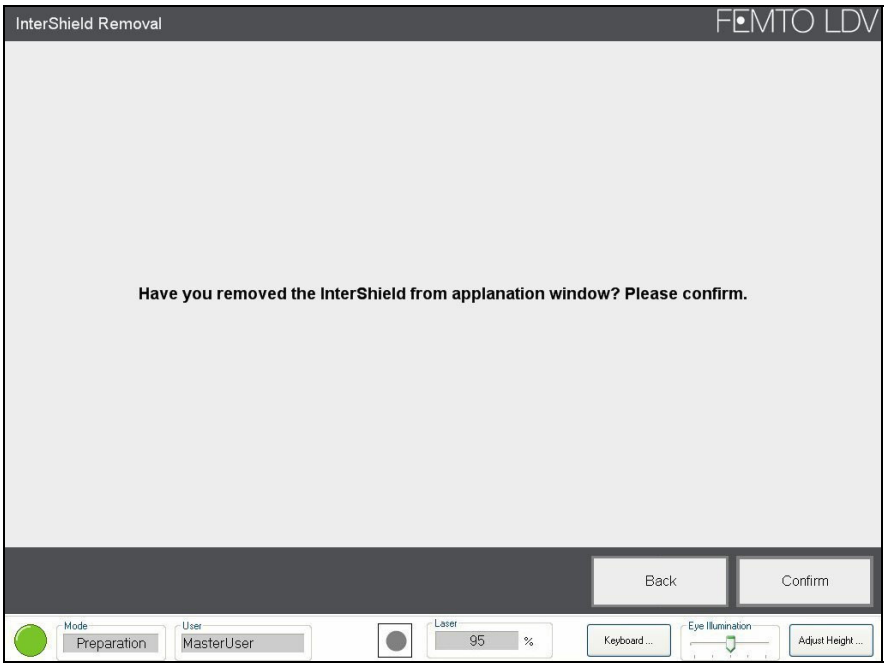
Note that a progression bar indicates the remaining time to completion of the resection.

8.18 Summary screen (example screen)



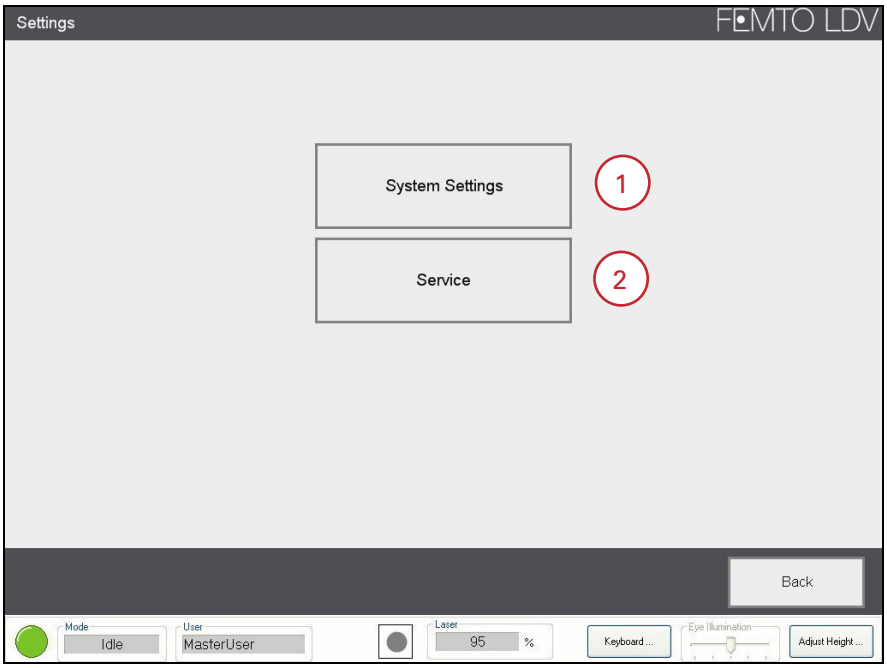
1. **Summary** of the cutting process.
2. **Notes** may be added here.
3. **Print** can be performed if a printer is installed. If no printer is installed, a PDF file will be generated. To export the PDF file, see section 13.2.
4. Select **Finished** once the procedure is completed.

8.19 InterShield removal



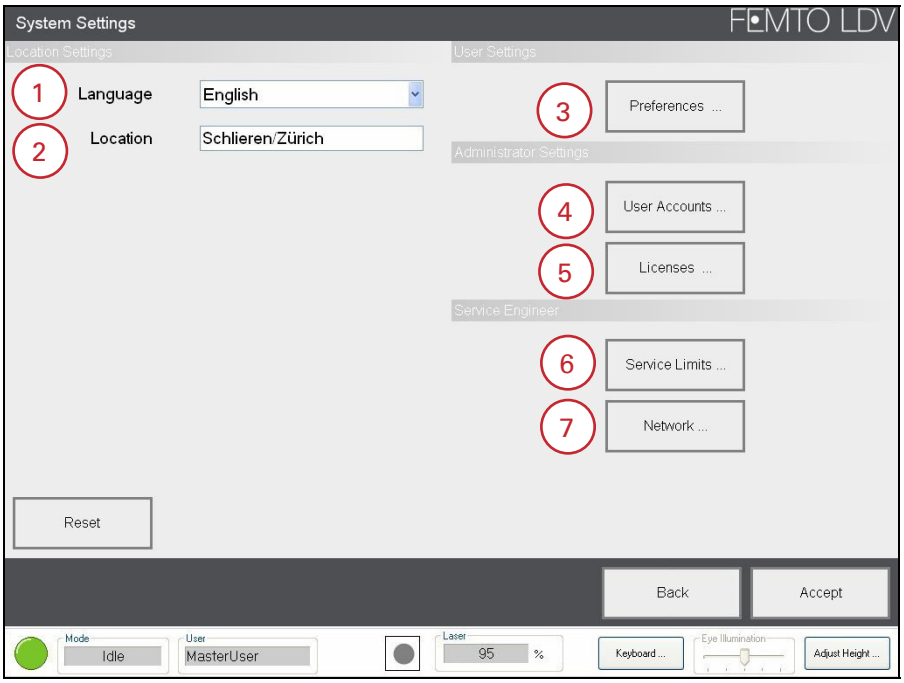
Remove by using moist cloth as described in section 9.3. Confirm the removal of the IS spacer from the applanation window.

8.20 Settings



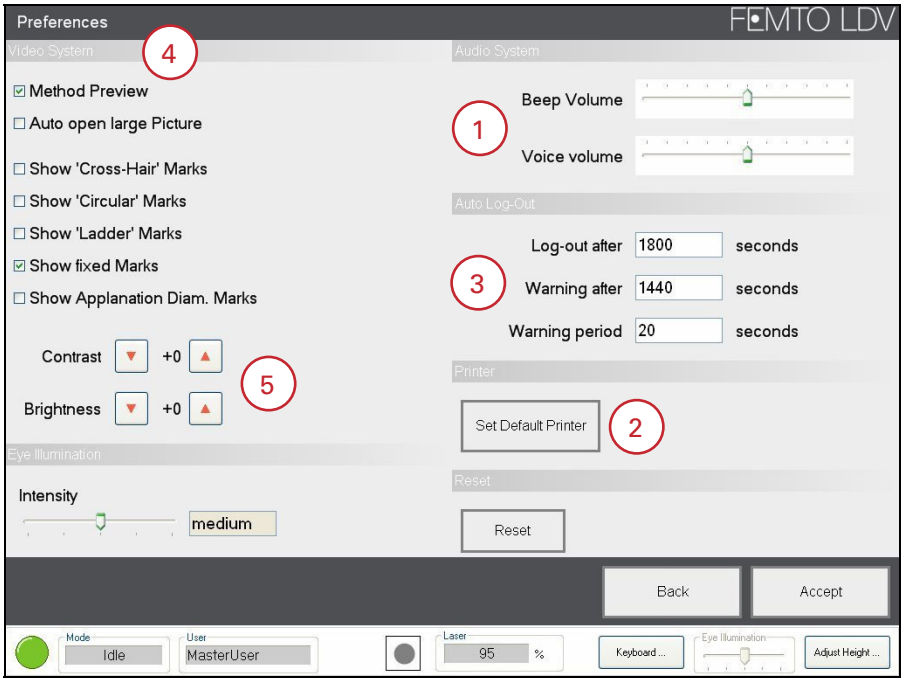
1. System Settings: set default system settings (section 8.21).
2. Service: reach some service options (section 8.24).

8.21 System settings



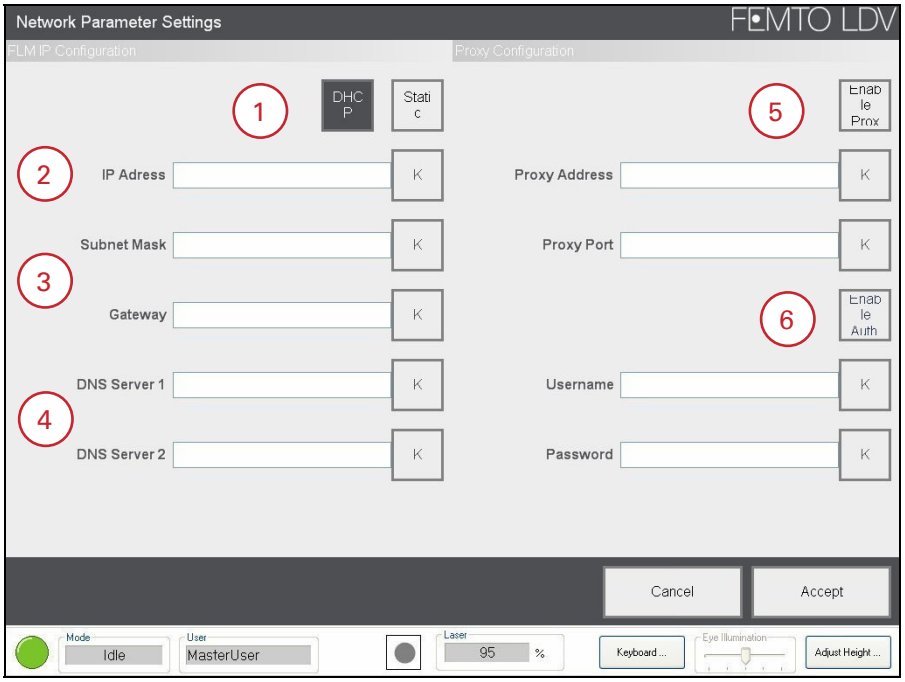
1. Language: select from available languages.
2. Location: set any descriptive text (city, clinic, etc.).
3. Preferences: some sound and interface settings (section 8.21).
4. User accounts: new user accounts can be created by users with admin privileges only.
5. Licenses: licenses for new applications can be released with the corresponding registration key.
6. Service: service limits may be modified by users with service privileges only.
7. Network: settings can be modified to connect the **LDV** to an Ethernet network.

8.22 Preferences



1. Audio system: adjust sound volume of acoustic signals and voice messages.
2. Printer: set the default printer on which reports will be printed. PDF is also possible.
3. Auto log-out: timers for Auto Log-out may be changed here: Log-out after sets the time of inactivity after which the user will be logged off automatically, Warning after and Warning period set the time before a warning message appears and the period of the warning, respectively. Warning after must be smaller than Log-out after.
4. Video system: the preferences for the Top View camera system may be changed here.
5. Contrast/Brightness: Set the brightness and contras default level for eye Illumination.

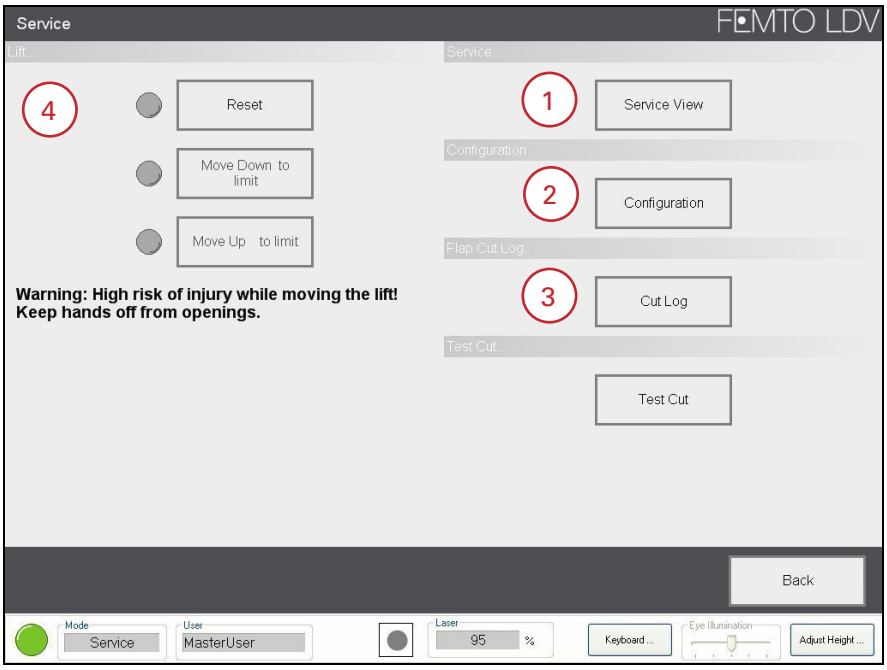
8.23 Network



1. DHCP (Dynamic Host Configuration Protocol): set a dynamic address for the **LDV** from the DHCP server.
   Static: instead of DHCP, a static address may be set.
2. IP address: when static address is set, this field is available for changes. Otherwise it would be created automatically.
3. Subnet Mask and Gateway: when static address is set, Subnet Mask and Gateway are available for changes. Otherwise default values are used.
4. DNS Server 1 and 2: IP address(es) of the DNS server(s).
5. Proxy: a proxy server may be used when other network configuration settings are unsatisfactory. If chosen, Proxy Address and Proxy Port used have to be set.
6. Enable authentication: a user authentication may be used in conjunction with the proxy server. If chosen, Username and Password have to be set.

([K]: displays an on-screen keyboard with a mask corresponding to the field).

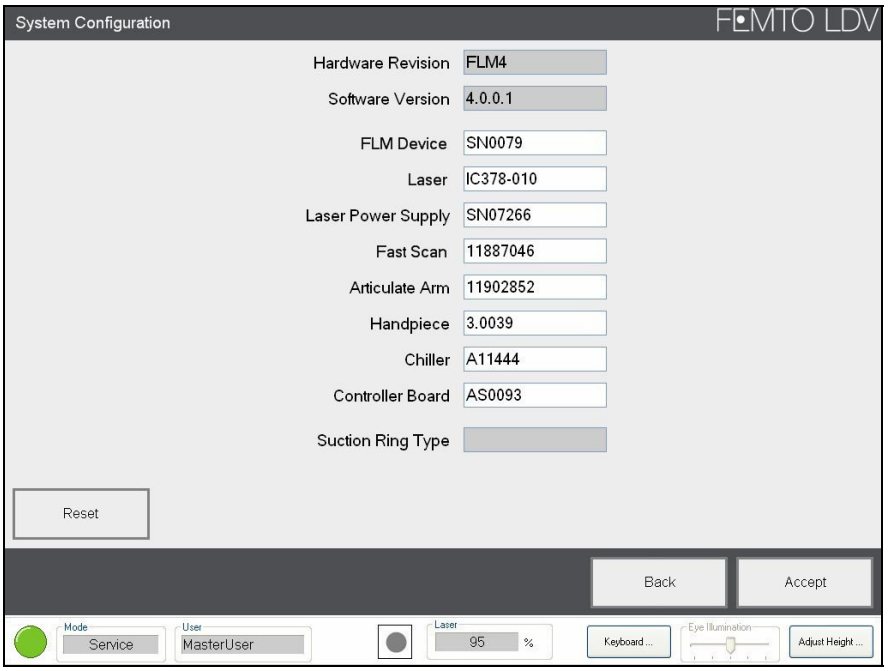
8.24 Service



1. Service view: service view is available to users with service privileges only.
2. Configuration: displays current system configuration (section 8.18).
3. Cut Log: to access the flap cut historical tool (section 8.26).
4. Lift: if a table lift error is pending, these buttons allows you to perform an initialization procedure. First, click on Reset button. This will shut off and on the lift control to execute a reference travel of the lift. This process takes approximately 15 seconds. During this time, the lift control cannot accept a new command. When enabled, click on Move Down to limit button to reach the lift lower limit and when target limit reached, click on Move Up to limit button to reach the upper limit.

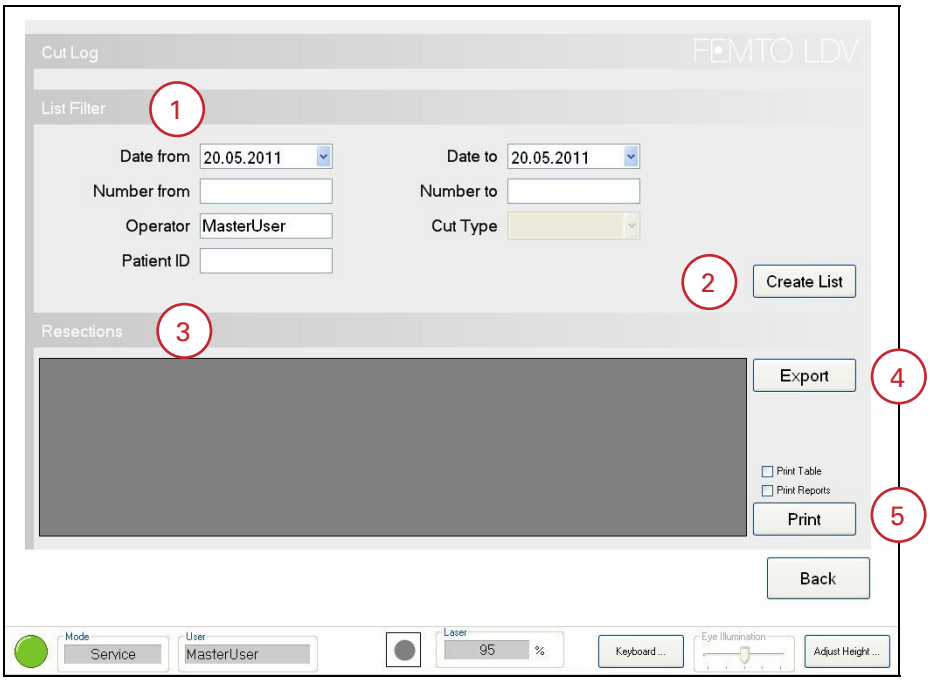
8.25 System configuration

All software and hardware configuration parameters are displayed here. These entries cannot be modified.



8.26 Resection procedure log

From this "Flap Cut Log" screen, detailed lists of performed procedures may be generated, viewed and printed.



1. List Filter: filter option used to create the flap cut list. Filtering options are by: surgery date range, flap cut ID, operator name, and Patient ID.
2. Create List: after filters are set, touch this button to create the list.
3. Resections: all the flap cut parameters are gathered here and may be rearranged similarly to a common Excel table: Arrange column order by pulling a column header into a new position; Set sort order (up or down) by clicking on any column header.
4. Export: the flap cut list may be exported to an USB storage device as formatted text (see 13.2).
5. Print: the displayed flap cut list and/or detailed reports may be printed by toggling checkboxes (Print Report: one detailed report for each selected procedure will be generated).

8.27 Shutdown confirmation

This confirmation window will appear when the Shut down button is touched (section 8.6).

Remember to lower table height before shutting down if you intend to transport the **LDV.**

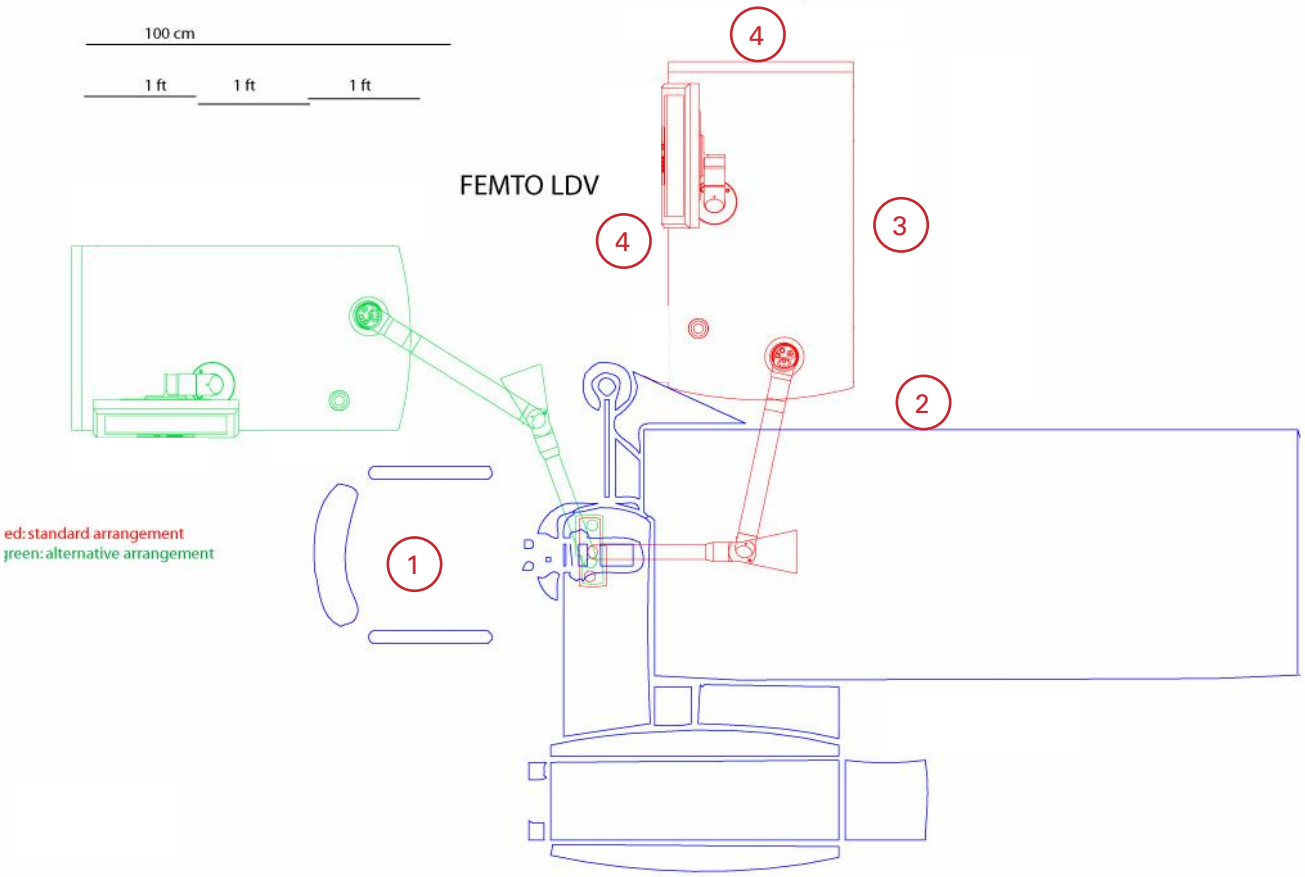
9 Surgical procedure

9.1 Primary decisions

Operation of the **LDV** normally involves three individuals:

1. Surgeon (SRG)
2. Sterile Assistant (STER)
3. Non-sterile Assistant (NSA)

If only one assistant is available, then it is in his/her responsibility to clearly separate sterile from non-sterile zones and procedures.



The surgeon (SRG) is sitting behind the patient's head during surgery (1).

The sterile nurse (STER) is in position (2) during surgery and assists the surgeon. Prior to surgery the STER can be in position (3) to prepare the surgical procedure.

To operate the **LDV**, the non-sterile assistant (NSA) is in position (3) or (4) during surgery.

The four sides of the BS are defined as shown on the schematic drawing above:

Front, facing the patient	**Left**, turned away from SRG
Back, turned away from patient	**Right**, facing the SRG

9.2 Step-by-step overview of surgery

Each surgical procedure is described in detail in the corresponding Surgical Manual (see 1.5).

9.3 Cleaning and sterilization

Component	Action
General	The outer surface of the entire system (BS, FMAA and HP) must be cleaned at least daily and wipe disinfected with a moist cloth (e.g., Microcide AF cloth by S&M or Meliseptol HBV cloth by B. Braun). All outer surfaces of the system, except the rubber rollers, are resistant to alcohol-based disinfectants (up to 80%). However, cleaning and disinfection must be done with a moist cloth. The rubber rollers of the BS can be cleaned with soap if required.
Handpiece	The HP is cleaned in its park position and without HP casings using the standard disinfection solutions of the operating room. Disinfection is performed with a moist cloth. Use of liquid should be avoided. The entire HP must be disinfected at least daily. The base portion of the HP must be disinfected following each patient and prior to mounting the sterile cover. Make sure, using a moist cloth, that InterShield is removed from the applanation window.
Single-use InterShield	The single-use disposable IS spacer acts as a sterile barrier between laser exit window and eye. It is shipped in a sterile package and is disposed after each patient.
Seals	HP and FMAA are sealed against dust and moist cleaning.
Single-use Casings	Disposable HPCs are shipped in a sterile package and disposed after each patient.
Single-use Suction Ring	Sterile disposable SRs are contained in the PP and disposed after each patient.
Strainer + suction tubing	The strainer is integrated into the suction tubing and therefore disposed after each patient.

Do not directly apply liquid disinfectants on the system. Do not use etching or abrasive agents.

9.3.1 Titanium Suction Ring[3]

The Titanium Suction Rings (SR) are supplied non-sterile and must be cleaned and sterilized as described below before being used for the first time.

Cleaning

Automatic mechanical treatment is recommended:

- This process takes place in an automatic machine for cleaning all types of medical products (we recommend the Miele G7733 Laboratory).
  - Prewash: 2 minutes with deionized water (room temperature).
  - Rinsing with an alkaline powder cleaner (we recommend Deconex 22 PF) at 70°C (= 158°F) during 3 minutes.
  - Rinsing with deionised water at 23°C (= 73°F) during 1.5 minutes.
  - Rinsing with deionised water at ca. 18°C (= 64 °F) during 1.5 minutes.
  - Hot water disinfection with deionised water at 75°C (= 167 °F) during 1.5 minutes.
- Drying at 60°C during 30 minutes in a drying chamber.

Sterilization

Steam autoclave sterilization is recommended. The titanium SR is designed to withstand the parameters of ANSI/AAMI and EN ISO standards for steam sterilization.

The sterilization/autoclave chamber should be cleaned, loaded and operated in accordance with manufacturer directions.

The Suction Ring must be free from any residual debris and thoroughly dried from water and cleaning agent prior to sterilization. If the Suction Ring is not clean enough then clean and dry it again following the Steps 1 - 7.

Sterilization procedure:

- There must be direct steam access to all surfaces including the vacuum channel.
- The recommended sterilization cycle is 132°C / 270°F for 18 minutes in a pre-vacuum type autoclave, followed by drying for 15 minutes at 70°C / 158°F. If necessary, adjust the drying time to ensure the instrument is completely dry.
- Local regulations may require more stringent sterilization conditions. The titanium SR withstands sterilization cycles of 134°C / 273°F for 18 minutes.
- Other steam sterilization cycles are possible. However, it is the user's responsibility to validate any alternative procedure.

Storage

Store the titanium Suction Ring clean, dry, and protected from mechanical damage.

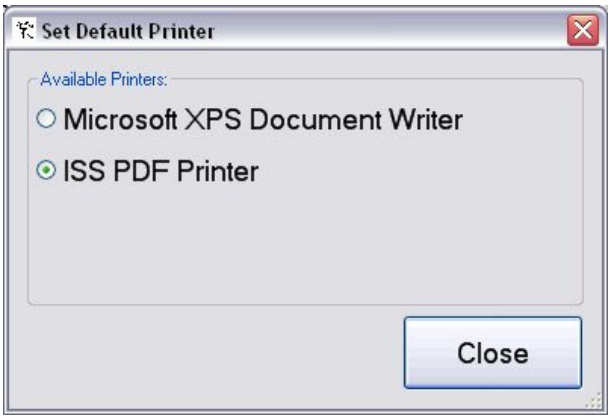
Visual inspection

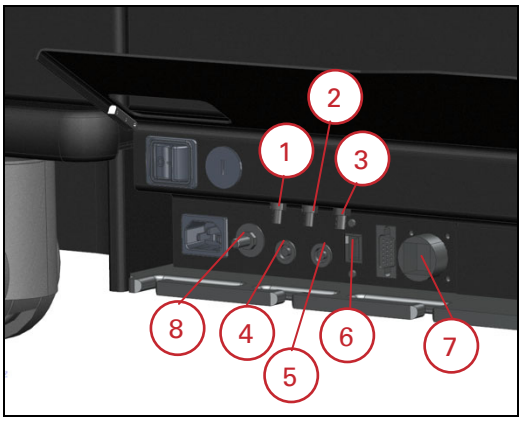
The titanium SR is reusable indefinitely unless mechanically damaged. Before each use, check visually for scratches, surface marks, cracks, or other signs of wear. If any damage is detected, the product is to be inspected by a Ziemer customer service center before further use.

[3] A set of reusable SRs made from titanium is available as part of the Starter Kit. These may be used as an alternative to the disposable SRs contained in each PP.

9.4 Printing

A printer can be connected via USB interface. Printouts are then obtained by touching the Print button on the Summary Screen (see section 8.18) or on the Resection Procedure Log screen (see section 8.26)[4]. Instead of printing, a PDF file may be created with the same procedure by choosing the ISS PDF Printer, and may be exported to an external USB storage device (see Appendix, section 13.2). The USB interface connector is located on the backside of the Base Station.





1. Fuse F1 (8 AT).
2. Fuse F2 (8 AT).
3. Fuse F3 (4 AT).
4. Footswitch connector.
5. Connector for door interlock.
6. USB connector.
7. Ethernet connector.
8. Connector for Potential Equalization Conductor

[4] The printer driver currently installed in the LDV supports printers of the HP-5700 family (printer not supplied by Ziemer).

10 Calibration and adjustments

10.1 Power check

The **LDV** contains an internal power sensor that monitors the laser power continuously. If the measured power exceeds or falls below the pre-set warning or safety limits, the device displays a warning and prevents starting or continuation of the operation with the **LDV** in order to guarantee the patient's safety. Additionally, the power is checked automatically by the software during the start-up phase of the **LDV**.

10.2 Power calibration

The correct calibration of the power sensor is checked by authorized **Ziemer** staff only. Prior to shipping and at each service the calibration of the power sensor is optimized. There is no need for the user to check or calibrate the power sensor.

10.3 External power meter

An external power meter is available as an option. The use of this power meter is recommended for users who mobilize their **LDV** system and for users who have their own technician trained in performing advanced system tests and alignments. Refer to the technical document FL5910-300-0565 for more details.

10.4 Scanner adjustment

The position of the laser beam in the **LDV** is governed by the motorized scanners – Slow Scan and Fast Scan – the positions of which are monitored by precision sensors. The scanners are factory adjusted. Customer service checks its adjustment during the service procedure.

Additionally, the scanner motors and sensors are checked automatically by the software during the start-up phase and online during the resection sequence. In case of malfunction, the **LDV** prevents further operation and displays the corresponding warning or error message. There is no need for the user to adjust the scanners.

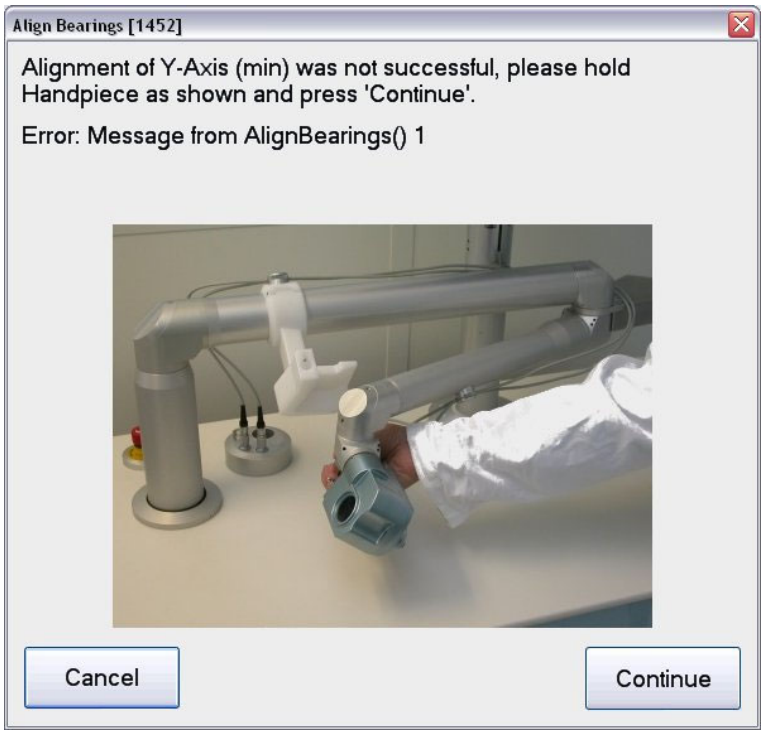
10.5 Automatic mirror adjustment

Laser Power output level is monitored continuously. The mirror adjustment routine automatically adjusts the power level in pre-determined intervals, attempting to keep the Output level always at 100 ±2%. Before the automatic adjustment process starts, an announcement appears on the touch-screen monitor. The user may stop the adjustment process by clicking on "cancel" within 15 seconds. If the process is not cancelled within 15 seconds, the adjustment will proceed, taking approx. 3 minutes to complete.

During the Mirror Adjustment process, a resection procedure cannot be started. During a resection procedure, no adjustment will be attempted by the system.

10.6 Handpiece bearings alignment

During the start-up procedure of the **LDV** and before every resection procedure, the internal alignment of the mechanical parts inside the HP is automatically checked and adjusted. During this automatic process, the software may prompt the user to hold the HP in a specific position and to push a button on the touchscreen monitor.



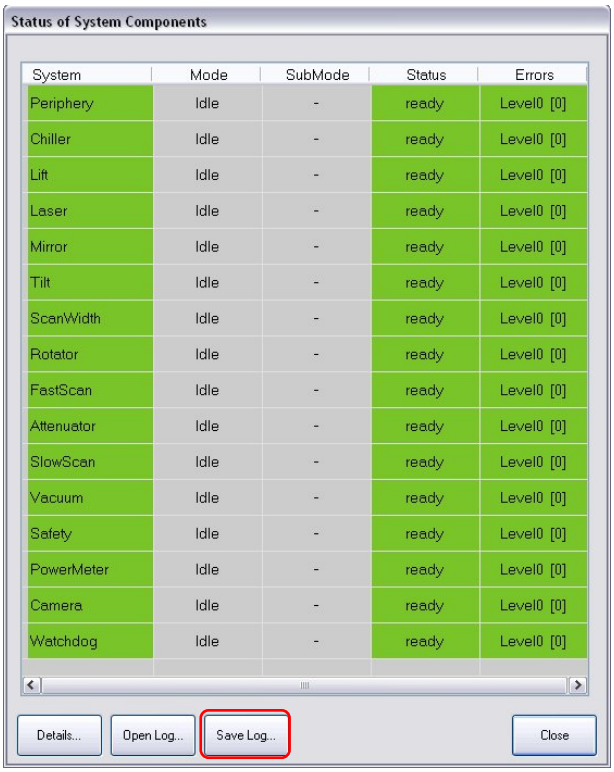
11 Service and Maintenance

The **LDV** is a solid-state laser, i.e., it requires essentially no maintenance or adjustments by the user. Maintenance service must be provided by a specially trained **Ziemer** representative every six months.

As your first point of contact for support we strongly recommend to always contact the distributor from whom you purchased your instrument. The list of distributors can be found at http://www.ziemergroup.ch/products/ldv/distributors.

If you need to contact **Ziemer Customer Support** directly, please visit our website: www.ziemergroup.com. Alternatively, you may also send us an email using the following email-address: customer-support@ziemergroup.com (worldwide).

In order to enable Customer Service to provide fast and efficient help, the LogFile containing details for every warning and error which occurred should be sent with the form or email (see section 8.3).



System	Mode	SubMode	Status	Errors
Periphery	Idle	-	ready	Level0 [0]
Chiller	Idle	-	ready	Level0 [0]
Lift	Idle	-	ready	Level0 [0]
Laser	Idle	-	ready	Level0 [0]
Mirror	Idle	-	ready	Level0 [0]
Tilt	Idle	-	ready	Level0 [0]
ScanWidth	Idle	-	ready	Level0 [0]
Rotator	Idle	-	ready	Level0 [0]
FastScan	Idle	-	ready	Level0 [0]
Attenuator	Idle	-	ready	Level0 [0]
SlowScan	Idle	-	ready	Level0 [0]
Vacuum	Idle	-	ready	Level0 [0]
Safety	Idle	-	ready	Level0 [0]
PowerMeter	Idle	-	ready	Level0 [0]
Camera	Idle	-	ready	Level0 [0]
Watchdog	Idle	-	ready	Level0 [0]

Touching Save Log, a file browser (see Appendix, section 13.2) opens to allow you to choose the destination for these files (as formatted texts).

If you need to contact **Ziemer Customer Support** by phone and during office hours, you may call our Helpline numbers as follows:

International Customer Support Center in Switzerland: phone +41 848 ZIEMER (943 637)

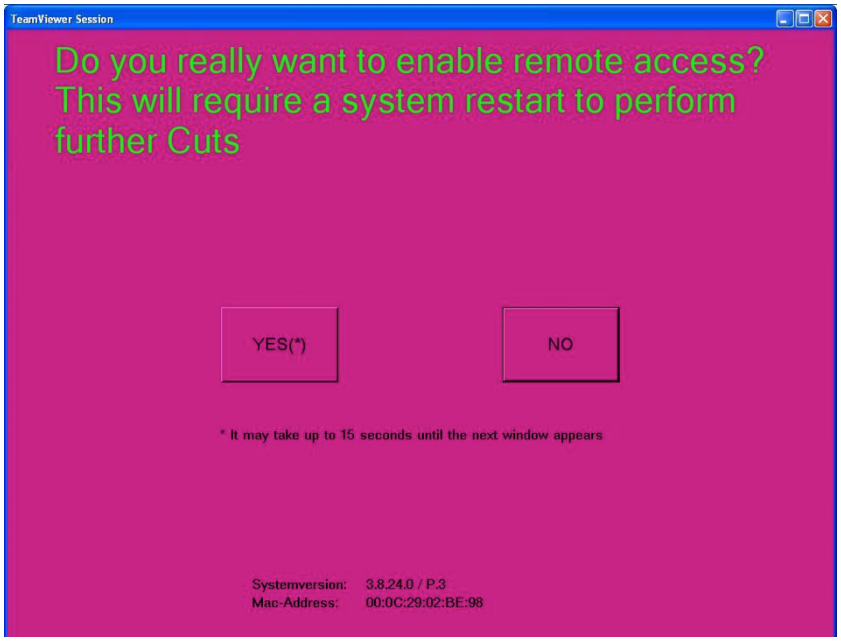
American Customer Support Center (USA and Canada): phone 866-708-4472

It is recommended that you keep your **LDV** connected to the Internet at all times. The **LDV**'s security features will prevent any potentially harmful interaction from the Internet while the **LDV** is performing resection procedures.

Remote maintenance is available on the **LDV**, using the TeamViewer application. By connecting the **LDV** to the Internet, **Ziemer**'s helpline can perform maintenance and troubleshooting tasks remotely without any contribution from the user side. It prevents the user from performing unrequested manipulations that may damage the system.

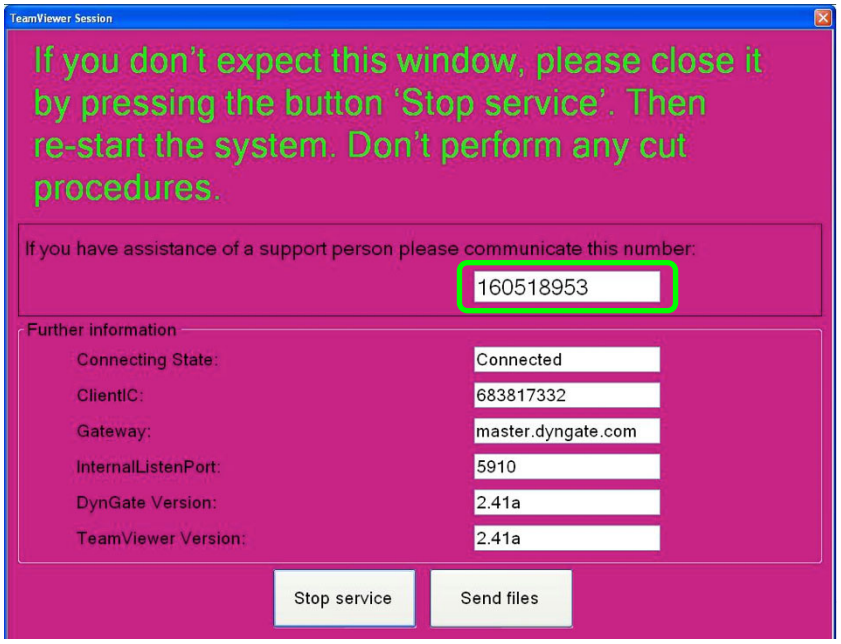
Connection can be established by connecting an Ethernet cable (network or directly to a cable/ADSL modem) using the Ethernet port located on the backside of the **LDV** (see picture in section 9.4).

In order to activate remote maintenance, use the key shortcut [ALT+T]. The validation screen below is then displayed to warn the user that a restart will be compulsory after servicing and before any resection process.



Note that the software version and the MAC address of the **LDV** are provided on this screen (the MAC address is a unique identifier that identifies any device connected to a network, in the present case, the Internet).

After clicking "Yes", the next screen provides the user with a number by which the support person will be able to access your **LDV** and perform any tests required.



12 Troubleshooting

This section is provided to assist the user in identifying and correcting certain problems that may arise prior to and during surgery.

Caution: Do not remove the cover of the Base Station. Do not attempt to service the Base Station. Maintenance must be conducted only by authorized **Ziemer**-trained service technicians

12.1 General problems

Problem	Cause	Solution
System does not start	Emergency Stop pressed	Release emergency stop.
	Power cord not connected.	Connect power cord.
	Main switch not ON.	Press main switch to ON at the bottom back of the unit. 
	Fuse1, F2 or F3 tripped.	Press F1, F2 or F3 (see photo on page 47).
Vacuum not reaching target value	Tube not connected.	Connect tube.
	Tube leaking.	Check tube.
	Hand piece not positioned properly on eye.	Adjust hand piece on eye to achieve complete applanation.
Laser does not start	Chiller temperature out of range.	Verify chiller functionality.
	Interlock open.	Check interlock switch (see photo in section 4).
Fast scan does not reach target value	Malfunction.	Contact Service.
Height adjustment does not work	Not allowed during flap cut process.	Leave flap cut window.
	Emergency stop pressed.	Release emergency stop and try again.
	Not initialized properly.	Restart **LDV**. If problem persists, contact Service.
System cannot be moved	Brakes set.	Release brakes (see drawing in section 5.5)

Flap cut does not start	Fast scan not within limits.	Contact Service.
	Laser power not within limits.	Check laser (see section 12.3.3).
	Vacuum not within limits.	Check vacuum (see section 12.3.3).
	Rotator not adjusted.	Ensure that suction ring is attached correctly to eye during adjustment process.
	Hand piece malfunction.	Contact Service.
	Test cut or service limit reached.	Perform test cut or contact Service.
Bearing adjust failed	Slow scan cannot reach target position.	1) Second bearing adjust in status of system components. 2) Contact Service.
Laser not between 95-102%	Not completely started up.	Wait one hour after switching on.
	Not mode- locked[5].	1) Perform mirror adjust after 1 h. 2) Wait one hour and then restart system. No mirror adjust!
Laser over 105%	Laser in double pulse[6].	Restart system.
Procedure Pack (PP) not readable	Moved PP to fast.	Hold PP against the glass again, do not move rapidly.
Cannot reach vacuum	Leak.	Contact Service.
	Target vacuum too high	Set Target to ≤ 700 mbar.
	LDV is installed high above sea level.	Set Target to 650 mbar.
Power meter is not working	First use.	Restart **LDV**.
	Communication error.	Reconnect power meter.
Footswitch is not working	Disconnected.	Connect footswitch.
External keyboard not working	Low batteries.	Replace batteries.
	Lost Bluetooth connection (only older keyboards, new ones are not Bluetooth).	Initialize keyboard (on login screen).
	Keyboard is inactive in flap cut screen.	Leave flap cut window.

[5] When mode-locked, laser is in pulsed operation. With low laser current, misaligned mirrors inside laser head or defective laser head, laser may switch to continuous-wave mode which implies that no pulse is generated.

[6] When too high laser power is produced, a circulating pulse may break into two undesired spaced pulses ("double pulse mode").

12.2 Error code list

Error code	Error message	Solution
Errors 1000 - 1340	Various Initialisation error messages	Reboot System. If error remains, please call the Helpline
Error 1350	Handpiece is not in Parkholder! Please place Handpiece into Parkholder.	Make sure the Handpiece is correctly placed into the Parkholder. Make sure the Parkholder has the correct position.
Errors 1400 - 1440	Various Slow Scan error messages	Check proper connection of hand piece cables. If error remains, reboot System. If error remains, please call the Helpline
Error 1452	Alignment of the bearings FAILED!	Perform a successful Align-Bearings Process (see Slow Scan in section Status of components12.2). There might be a hardware problem.
Error 1460	Slow Scan signaled BAD state!	Check proper connection of hand piece cables. If error remains, reboot System. If error remains, please call the Helpline
Error 1470	Trajectory point is out of limits!	Make sure that the parameters for profile calculation are correct (expert mode) Make sure the parameters inside the trajectory profile file are correct
Error 1471	Slow Scan limit check can NOT be performed!	Software problem: send Log-File to Customer Service for further analysis
Error 1500 - 1570	Various Vacuum error messages	Reboot System. If error remains, please call the Helpline
Error 1570	Vacuum Tube Test FAILED!	Make sure suction ring is connected and vacuum tube is unblocked
Errors 1600 - 1680	Various Laser and Shutter error messages	Reboot System. If error remains, please call the Helpline
Error 1690	Power too high!	Perform adjustment corresponding to section12.3.4. If error remains, reboot System. If error remains please call the Helpline
Error 1691	Power too low!	Perform adjustment corresponding to section 12.3.4. If error remains, reboot System. If error remains, please call the Helpline
Error 1700	Laser is not started – chiller is not ready!	See error “ChillerNotStable”
Error 1710	Laser is not stable!	Please wait, if error remains, please call the Helpline

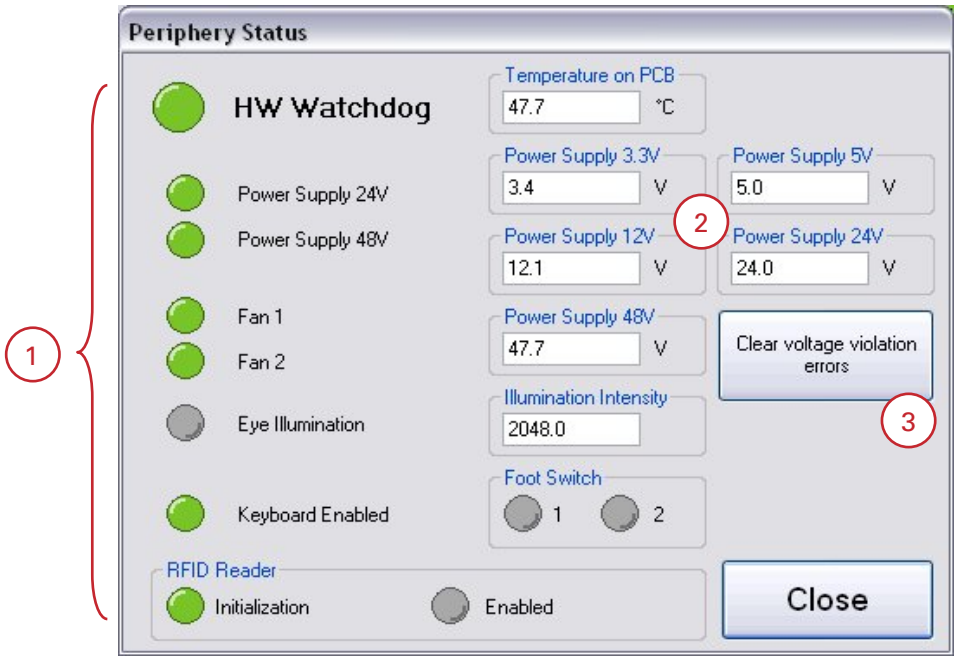
Error code	Error message	Solution
Error 1720	Laser temperature not yet stable!	Please wait, if error remains, please call the Helpline
Errors 1730 - 1731	Mode Lock error messages	Reboot System. If error remains, please call the Helpline
Error 1740	Laser Error received!	Check Log-File to get more detailed information (search for string “LaserControl” and status “Error” or for string “SubSystemLaser” and status “Error”) Using the status view of the **LDV**-application: Check all sub-systems for errors
Error 1800	Command to init Fast Scan Control FAILED!	Software problem → send Log-File to Customer Service for further analysis
Error 1810	Command to start Fast Scan FAILED!	Reboot System. If error remains, please call the Helpline
Error 1811	Command to stop Fast Scan FAILED!	Make sure fast-scan self-test is not running anymore
Errors 1820 - 1830	Fast Scan error messages	Reboot System. If error remains, please call the Helpline
Errors 1900 - 1950	Safety Control error messages	Reboot System. If error remains, please call the Helpline
Error 2000	Command to init Attenuator Control FAILED!	Software problem: send Log-File to Customer Service for further analysis
Error 2010	Attenuator adjust power FAILED!	Retry, if error remains, reboot System. If error remains, please call the Helpline
Error 2020	The Attenuator Adjust function failed! Laser Power II is X %.	Check that Laser is mode-locked and power of sensor I is within its target range. If not, try to adjust laser power at power sensor I using Mirror and Laser-Current Adjust functions.
Error 2030	The Attenuator Adjust function couldn't be started because the Attenuator Control was busy.	Wait until Attenuator adjustment finishes and try again.
Error 2040	Attenuator Adjust time out error!	Retry, if error remains, reboot System. If error remains, please call the Helpline
Error 2050	The automatic attenuator adjust is still busy. Please wait for a minute or two and try again.	Wait until the automatic attenuator adjustment has finished before trying to open any of the ‘Adjust’ dialogs.

Error code	Error message	Solution
Error 2100	Command to init Mirror Control FAILED!	Retry, if error remains, reboot System. If error remains, please call the Helpline
Error 2110	Mirror adjust max power FAILED!	Retry, if error remains, reboot System. If error remains, please call the Helpline
Error 2200	Watchdog HW test FAILED!	Reboot System. If error remains, please call the Helpline
Error 2210	Watchdog timeout error!	Reboot System. If error remains, please call the Helpline
Error 2300	Slow Scan failed during Flap Cutting!	Try to Recut, if error remains, reboot system, if error remains, please call the Helpline
Error 2310	Trajectory has no data!	Use a Trajectory file that contains data or use a calculated Trajectory.
Errors 2400 - 2451	Warning error messages	Note the Warning Code and please call the Helpline
Error 2452	The Data-Grabber is still running, cutting is not possible. Error code: [2452]	Reboot System. If error remains, please call the Helpline
Error 2500	RFID reader error. Please try again.	Try again. Restart the **LDV**. Analyze the logfile, look for the string “RFID reader error =” to find more information about the exception that caused the problem Please call the Helpline.
Error 2501	More than one RFID tags detected. Place one tag near the reader.	Use only one tag at a time. Make sure no other RFID-Tags (e.g., employee badges) are close to the reader while reading the RFID tag of the procedure pack
Error 2510	This is a test set and cannot be used for flap cuts. Please use a new Procedure Pack.	Use a regular procedure pack instead of the test set.
Error 2511	This is not a test set and cannot be used for test cuts. Please use a new Procedure Pack.	Use a test set instead of a regular procedure pack.
Error 2520	Shelf life has expired on dd.mm.yyyy. Please use a new Procedure Pack.	Use a different procedure pack that has not yet expired.
Error 2521	This Procedure Pack was recalled. Please use a new Procedure Pack.	Use a different procedure pack.

Error code	Error message	Solution
Error 2522	Invalid RFID tag. Please use a new Procedure Pack.	Try to read the tag again. Use a different procedure pack.
Error 2530	This Procedure Pack was already used in a previous procedure. Please use a new Procedure Pack.	Use a different procedure pack. Once a procedure pack has been scanned on a **LDV** it can only be used on exactly that **LDV**.
Error 2540	System not enabled for 90um Flaps.	Use a different procedure pack for a thicker flap.
Error 2600	Command to init Power-Meter FAILED!	Reboot System. If error remains, please call the Helpline
Errors 2700 - 2781	Z-Axis error messages	Check the proper connection of hand piece cables. If error remains, reboot System. If error remains, please call the Helpline
Errors 3000 - 3050	Camera error messages	Check the proper connection of hand piece cables. If error remains, try to reset camera in Status Of System Components. If error remains, please call the Helpline.
Errors 4000 - 4999	Application error messages	These errors are dependent from application. Check that all values are valid in Parameter Screen.
Error 5500 - 5999	Scan Width error messages.	Initialize the scan width axis in Status of System components. If error remains, please call the Helpline.

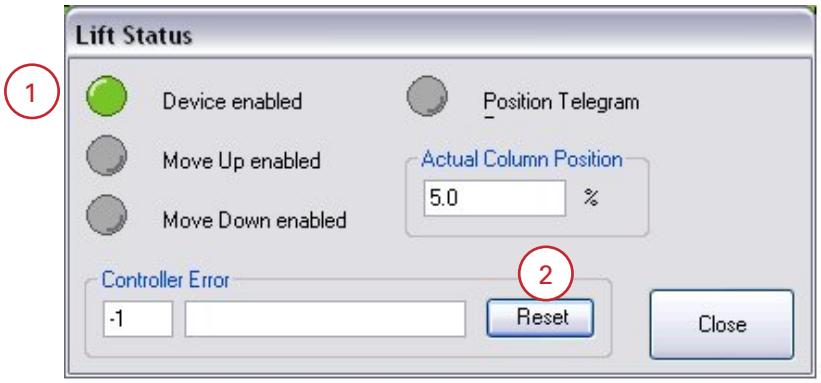
12.3 Status of components

12.3.1 Periphery status



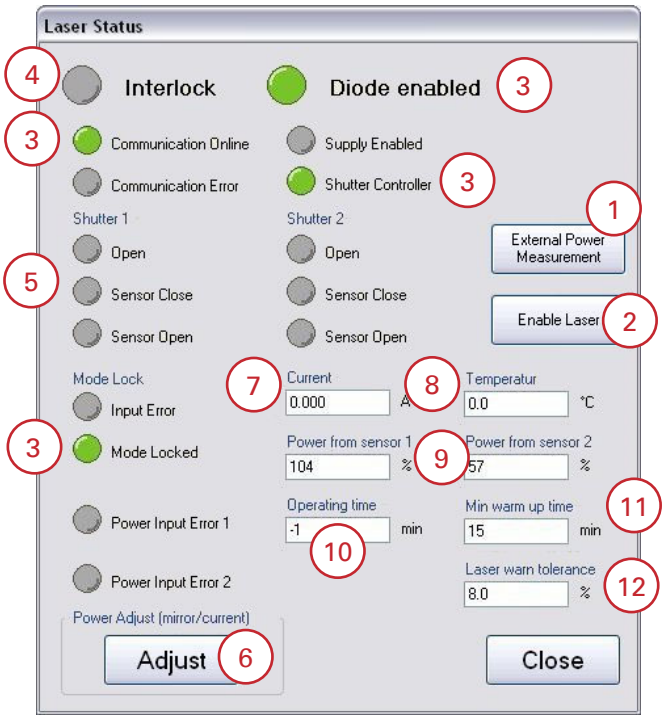
1. Status LED: all these LEDs must be green for the periphery system to be considered fully operational.
2. Supply Voltages: displays the current value of the internal available voltages.
3. Clear voltage violation errors: tries to clear all remaining voltage errors. If any error remains, please call the helpline.

12.3.2 Lift status



1. Status LED: this LED must be green for the lift to be considered fully operational.
2. Reset: tries to clear the last occurred error. If the error remains, please call the helpline.

12.3.3 Laser



1. External Power Meter Measurement: allows the user to perform an external power measurement by use of an optional Power Meter. Please refer to the technical document FL5910-300-0565.
2. Enable Laser: allows the user to manually enable the laser. This button is not available by initializing and with a running laser.
3. Status LED: all these LEDs must be green for the laser to be considered fully operational.
4. Interlock: if interlock circuit is opened, this LED shows red.
5. Shutter 1: two sensors control that the shutter is either closed or opened (respectively Sensor Close and Sensor Open). If both sensor LEDs Sensor Close and Sensor Open are green, it means that an error occurred; for normal operation either one or the other, but not both, must be green.
6. Adjust: reaches the Power Adjust window on which a complete adjustment procedure (mirror, current and attenuator) may be launched.
7. Current: displays actual pump laser diode current.
8. Temperature: displays actual temperature measure in the laser head.
9. Power from sensor 1 and 2: a photodiode (Power from sensor 1) in laser head constantly monitors the generated laser power. For normal operation, the laser power value must lie within the range displayed in the Laser warn tolerance field. A second measurement is performed in the Fast Scan unit (Power from sensor 2).
10. Operating time: displays time elapsed since the laser was started up.
11. Min. warm-up time: displays time required before the laser is fully operational. A mirror adjust cannot be performed before this time has elapsed.
12. Laser warn tolerance: displays the allowed deviation from 100% laser power (e.g. 8% means the range of 92%-108% is permitted before an error occurs).

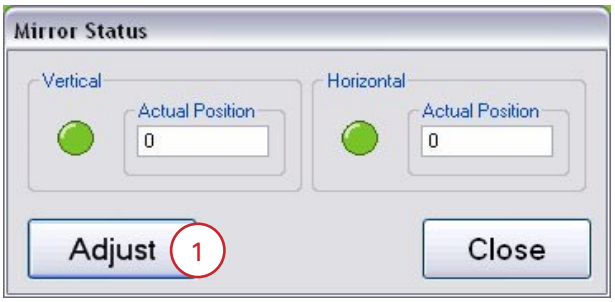
12.3.4 Power adjust window

1. Press this button to perform a power adjustment: mirror, current and attenuator adjustments.
2. Press this button to perform a power adjustment without mirror adjustment.
3. Every step is displayed with a green LED to indicate that the step has been completed successfully. After each adjustment, the power is checked to keep it within the permitted range.

When the laser is losing power, a mirror adjust should be performed (see section Mirror below). A complete power adjust procedure, which includes 2 more processes (current and attenuator adjustments), should normally not be performed.

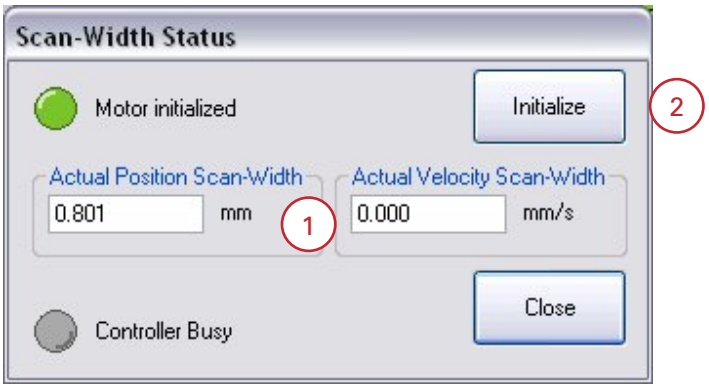
12.3.5 Mirror

A motor-driven mirror is integrated into the laser cavity. With its two motors, this mirror can be adjusted along two perpendicular axes.



1. Adjust: Adjusts automatically the laser mirror position (vertical and horizontal) to reach the optimum laser beam output power

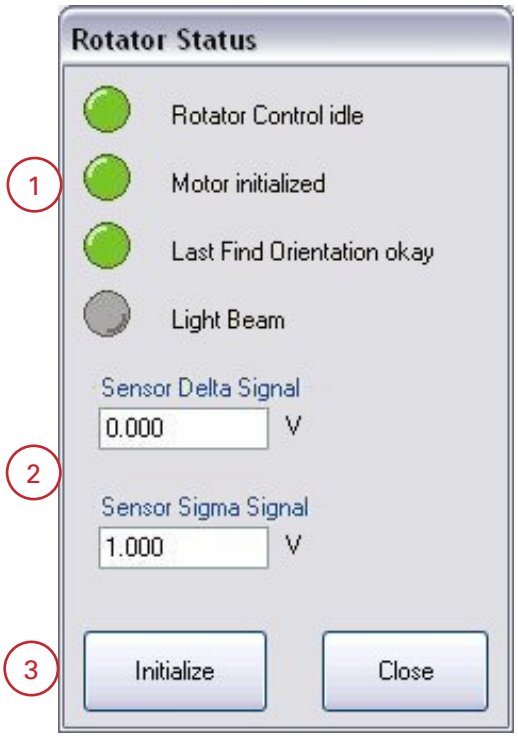
12.3.6 Scan-Width



1. Actual Position and Velocity: displays the current position and velocity of the Scan-Width axis.
2. Initialize: resets the scan-width axis and perform all required checks to consider it as fully operational.

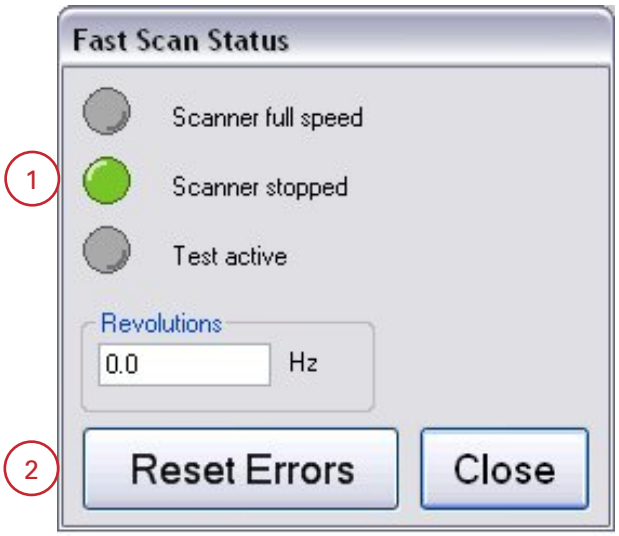
12.3.7 Rotator

As described in section 7, Fast Scan is adjusted perpendicular to the y-axis of the Slow Scan by means of an optical rotator. The correct position of the rotator is controlled by a rotator sender in the hand piece generating a rotation control beam, and a pair of rotator sensors in the base station.



1. Rotator Control Idle, Motor initialized, Last Find Orientation okay: all status LEDs must be green for the regular functioning of the laser.
2. Sensor Delta and Sigma Signals: to perform an accurate positioning, a pair of sensors measure sum (Sigma Signal) and difference (Delta Signal) of the light beam intensity coming from the rotator sender through the FMAA.
3. Initialize: reinitializes the rotator motor and corresponding sensors to reach the required orientation of the laser line.

12.3.8 Fast Scan



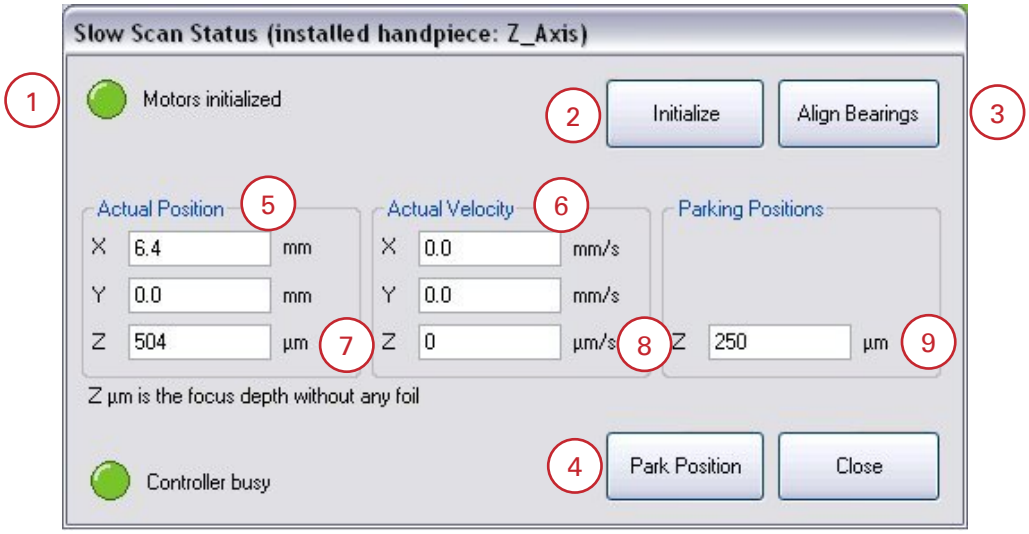
1. Status LED: this LED must be green for the Fast Scan to be considered fully operational.
2. Reset Errors: tries to clear all remaining errors. If any error remains, please call the helpline.

12.3.9 Attenuator Status

1. Status LED: this LED must be green for the Attenuator to be considered fully operational.
2. Initialize: resets the attenuator axis and perform all required checks to consider it as fully operational.

12.3.10 Slow scan

The Slow Scan unit moves the focusing lens across the applanated eye in a special scanning pattern, thereby generating a two-dimensional resection surface (three dimensional if the system is equipped with a Z-Handpiece).



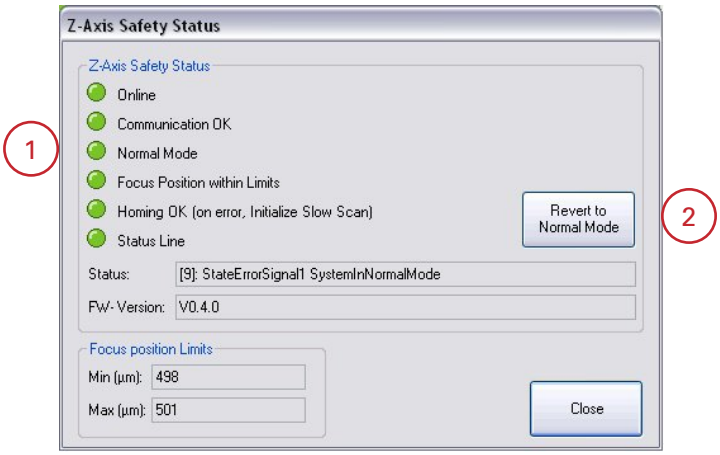
1. Motors initialized: motors are working properly (green LED).
2. Initialize: moves the focusing lens along the x and y axes to initialize limit positions according to sensors (if a Z-Axis Handpiece is mounted, the z axis is also initialized).
3. Align Bearings: same task as described in 10.6 is carried out.
4. Park Position: moves the focusing lens to the park position.
5. Actual position X and Y: actual position of the slow scan unit. Home position (0, 0) corresponds to the center of the laser aperture. X-drive range: -27 to 6.3 mm; y-drive range: -6.3 to 6.3 mm. Position X up to -27mm allow the slow scan unit to reach park position.
6. Actual Velocity X and Y: actual velocity of the slow scan unit. When default factory parameters are set, Velocity X and Velocity Y should respectively reach 25mm/s and 10 mm/s (5mm/s at the border) during resection process.

If the system is equipped with a Z-Handpiece (**FEMTO LDV Z4** and **Z6**), the following options are available:

7. Actual position Z: actual position of the slow scan unit along z-axis.
8. Actual velocity Z: actual velocity of the slow scan unit along z-axis.
9. Parking Position Z: current parking position used.

12.3.11 Z-Axis Safety

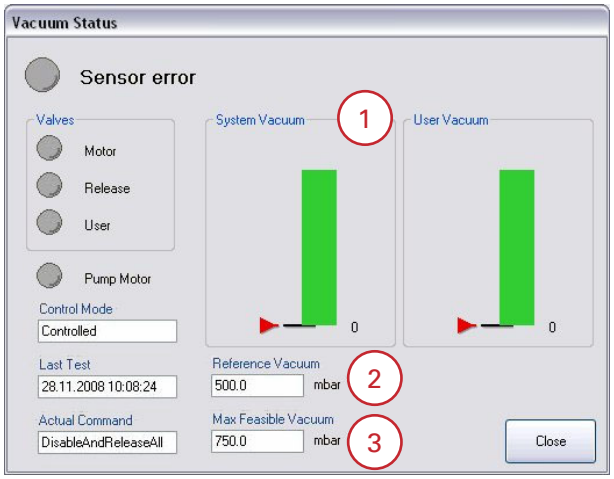
If the system is equipped with a Z-Handpiece, a safety system supervises the z-axis. A new status window is hence available.



1. Status LED: all LEDs must be green for the z-axis safety system to be considered fully operational.

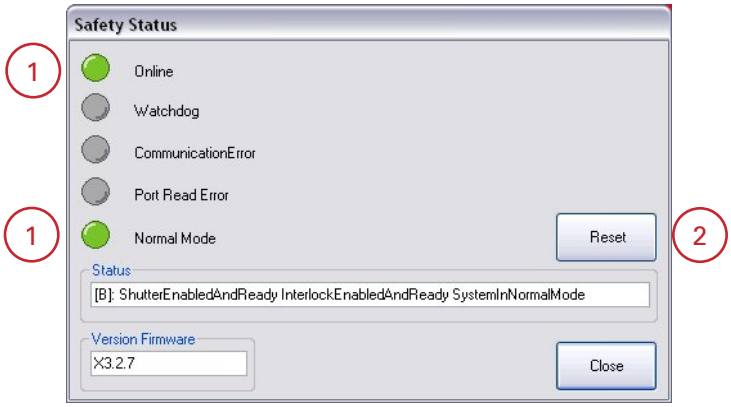
2. Revert To Normal Mode: tries to clear all remaining errors for z-axis safety system and reverts the safety system to normal mode.

12.3.12 Vacuum



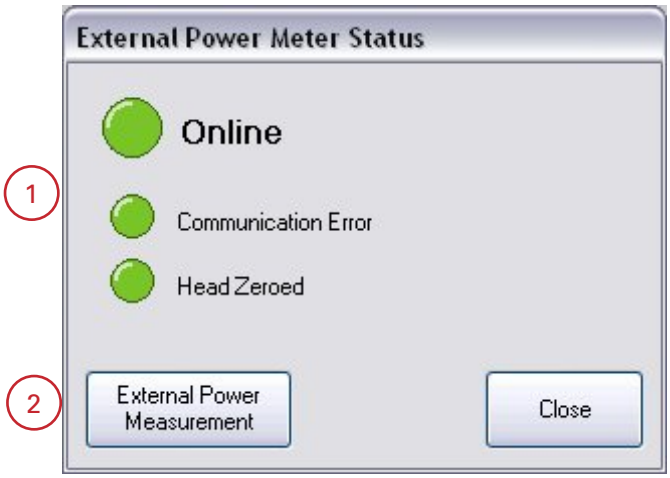
1. System Vacuum and User Vacuum: vacuum pressure is measured at 2 points in the vacuum system. The User Vacuum value corresponds to the vacuum applied on the SR.
2. Reference Vacuum: displays the target vacuum value.
3. Max Feasible Vacuum: displays maximum value allowed.

12.3.13 Safety



1. Status LED: both LEDs must be green for the safety system to be considered fully operational.
2. Reset: tries to clear all remaining errors for the safety system and reverts the safety system to normal mode.

12.3.14 Power meter



1. Status LED: all these LEDs must be green for the external power meter to be considered fully operational.
2. External Power Meter Measurement: allows the user to perform an external power measurement by use of an optional Power Meter. Please refer to the technical document FL5910-300-0565 for more details.

12.3.15 Camera

1. Status LED: this LED must be green for the camera to be considered fully operational.
2. Reset Camera: tries to clear all remaining errors for the camera.

12.3.16 Watchdog

1. Status LED: this LED must be green for the watchdog to be considered fully operational.
2. Reset Error: tries to clear all remaining errors for the watchdog.

12.4 Remote maintenance

If a problem that you have encountered still persists after checking solutions in the previous sections, then a remote diagnosis and maintenance should be performed.

Please proceed as follows:

- Contact the Customer Service helpline (see section 11). Make sure your **LDV** is connected to the Internet.
- Establish a Team viewer session as directed by your helpline engineer (see section 11).

If a Team viewer session cannot be established, Helpline will guide you through a series of diagnostic checks that you perform at the direction of the helpline engineer. To perform these checks, go to Login (section 8.7). Select username Service Engineer and check the box [Use Temporary Password]. A 10-digit number code will be displayed. Give this code to the engineer on the phone. He will give you a temporary password. Enter this password and touch Login. Proceed further as directed by the helpline engineer.

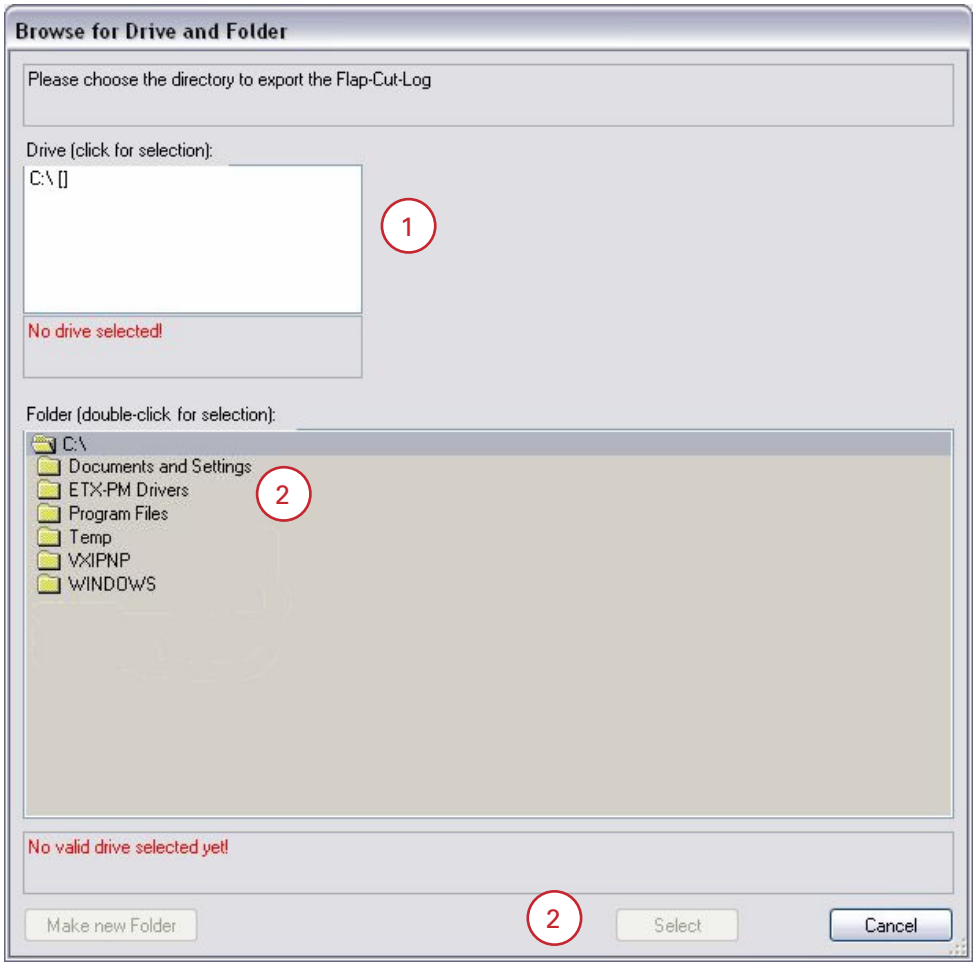
13 Appendix

13.1 Nominal Ocular Hazard Distance (NOHD)

The NOHD is defined according to the American National Standards Institute Z136.1-2000 “American National Standard for Safe Use of Lasers” and to IEC 60825-1 Annex A.5. The NOHD is computed in terms of the Maximum Permissible Exposure (MPE) allowed onto the eye. The NOHD calculated using this standard for the **LDV** is 4 inches (10 cm) due to the low pulse energies and very large beam divergence used.

The practical consequence is that surgeons and assistants are not in any optical radiation danger during normal and routine operation of the laser. Any service operation requiring the removal of any covers on the base station will require protective eyewear of OD > 9 at a wavelength of 1045 nm. Only authorized Ziemer service representatives should attempt to remove base station covers or to service the **LDV**.

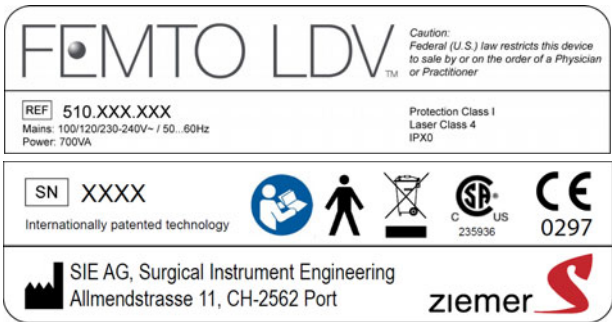
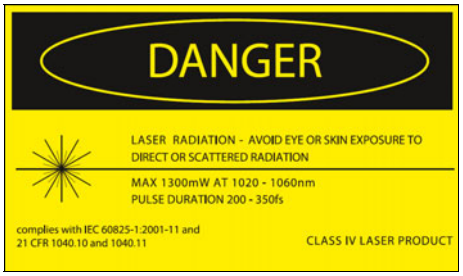
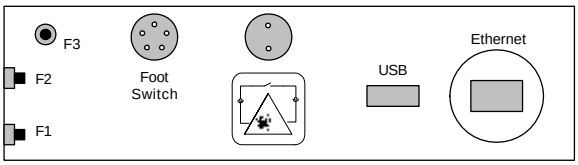
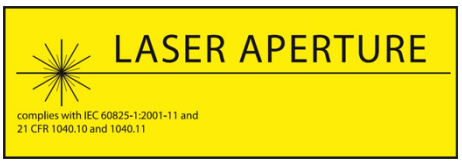
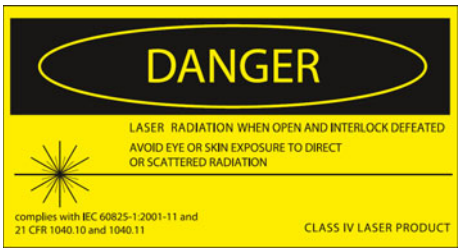
13.2 File browser



The file browser is displayed when a log file is saved or a PDF file is printed. Only external drives are permitted to save such files. Make sure an external USB storage device is connected.

1. Choose your external drive to save files. Note that access to the hard drive of the LDV is forbidden due to security issues.
2. Set the folder destination and push Select. If it is a permitted destination, this button is enabled.

13.3 Base station and Handpiece labels

Label No.	Label definition	Label name
1		Main identification label (front side of the undercarriage cover onto Base Station)
2		Warning label (front side of the undercarriage cover onto Base Station)
3		Label (adjacent to interfaces)
4		Warning label (bottom of Handpiece Unit)
5		Warning label (inside base station onto part of Laser Unit)
6		Laser radiation warning label (inside base station, different positions)
7		Protective Earth terminal (inside base station)

13.4 Limited warranty terms

1. General: Ziemer Ophthalmic Systems AG (hereinafter called "ZIEMER") warrants to the owner of a valid proof of purchase ("Consumer") that the products and all accessories provided by ZIEMER in the sales package, but excluding immaterial goods, ("Product") are free from material defects in materials, construction and workmanship, pursuant to the following terms and conditions, when installed and used normally and in accordance with operation instructions. This limited warranty extends only to the Consumer of Products purchased and used within the sales area covered by ZIEMER, other applicable agreements notwithstanding.

2. Limited Warranty: During the limited warranty period, ZIEMER's authorized service representatives will repair or replace, at written notice by the Consumer, at ZIEMER's option, without charge, a Product which is not free from material defects in construction, material or workmanship ("Materially Defective Product") and therefore is unusable or defective. If ZIEMER repairs this product, ZIEMER may use new or refurbished replacement parts. If ZIEMER chooses to replace this product, ZIEMER may choose to replace it with a new or refurbished product of the same or similar design. ZIEMER will return repaired or replacement Product to Consumer in working condition only, if not agreed otherwise in writing. Replaced parts, modules or equipment will be returned into ZIEMER's property. Repair or replacement of Product, at ZIEMER's option, is Consumer's exclusive remedy.

3. Duration of Limited Warranty Period: The Limited Warranty Period for the Product extends for one (1) year. The Limited Warranty period starts at the date of the delivery to the Consumer, at the latest with the date of issue of the delivery note (from Distributor to Consumer). The Limited Warranty ends at the latest two (2) years from the date shown on the note of delivery to the Distributor. If ZIEMER repairs or replaces the Materially Defective Product under the terms and conditions of this limited warranty, this limited warranty also applies to repaired or replacement Products for a period of either (a) 90 days from the date repaired or replacement Product is shipped to Consumer or (b) the time remaining on the original one-year warranty, whichever is longer. For consumable products carrying an expiration date, the Limited Warranty ends, at the latest, at the date of expiration printed on the product packaging.

4. Coverage of Limited Warranty: The limited warranty covers exclusively and only defects in material, construction or workmanship of the Products and does among others not cover:

a) Product that has been subjected to misuse, accident, incident, shipping or other physical damage, improper installation, abnormal operation or handling, neglect, inundation, fire, smoke, liquid intrusion in any form, chemical or electrolytic influences, normal indicated or excessive use; or

b) Product that has been used by a non-authorized user; or

c) Product that has been damaged due to repair, service, alteration, and use of parts other than ZIEMER's or modification by anyone other than an authorized service representative of ZIEMER; or

d) Consumable or Disposable Products or components;

e) Product to the extent that the problem experienced is caused by radiation in any form, signal conditions, network reliability or cable or antenna systems; or

f) Product to the extent that the problem is caused by use with electrical or electronic accessories not provided by ZIEMER; or

g) Product whose warranty/quality sticker, product serial number label or electronic serial number information have been removed, altered or rendered illegible; or

h) Product returned without valid RMA-Number (Return Merchandise Authorization Number) and valid proof of purchase; or

i) Charges for installation or set-up, adjustments of customer controls, and installation or repair of systems outside the unit, as well as

j) Any other reasons, which ZIEMER is not responsible for.

Furthermore ZIEMER does NOT warrant that the results obtained from the use of Product will be accurate or reliable.

5. Special Terms for Software and Firmware: ZIEMER warrants that software disks will be free from defects in materials and workmanship under normal use for ninety (90) days from the date Consumer receives the Software. ZIEMER does NOT warrant that the functions of the Software or Firmware will meet Consumers' specific requirements or that operation of the software will be uninterrupted or error-free.

6. Transfer of Title and Risk: Benefit from the Product and risk for loss and damage shall transfer to Consumer at the date of shipment to Consumer (FOB), unless otherwise agreed in writing. Transportation- and administration costs to the service location are to be paid by the Consumer. ZIEMER will return repaired or replaced Product under this limited warranty to Consumer, transportation, delivery administration costs prepaid by Consumer. ZIEMER assumes no risk for damage or loss of the Product in transit.

7. Inspection and Acceptance: If the Product failure is not covered by this limited warranty, or proof of purchase does not meet the terms of this limited warranty, ZIEMER will notify Consumer and will request that Consumer authorizes the cost of repair without warranty coverage prior to any further repair activity. Consumer must pay for the cost of repair and return shipping costs for the repair of Product that are not covered by this limited warranty.

8. Warranty Service: To obtain warranty service, Consumer must:

a) contact ZIEMER to obtain a RMA-Number and return shipping instructions. The RMA-Number is valid for thirty (30) days from date of issue;

b) return the entire original package and contents including the Product to the ZIEMER service location along with a description of the malfunction or difficulty and ensure that package is marked with the RMA-Number;

c) include "valid proof of purchase" (Sales receipt) identifying the Product purchase and the date of purchase or receipt; and

d) provide your name, complete and correct mailing address, and telephone number.

9. Disclaimer of warranty and Liability: ZIEMER provides no other warranty to this Product. The warranty exclusively describes all of ZIEMER's responsibilities regarding the Product. ZIEMER makes no representation or warranties, either expressed or implied, by or concerning any content of materials such as information, documents or software, and in no event shall be liable for any implied warranty of merchantability or fitness for any particular purpose or for any consequential, incidental or indirect damages (including but not limited to damages for loss of business profits, business interruption and loss of business information) arising from the use or inability to use these materials or Products. No one is authorized to make modifications to this limited warranty and Consumer should not rely on any such modification. In no case whatsoever shall Consumer be entitled to claim damages other than occurred on the Product itself. It does apply, however, to the unlawful intent or gross negligence of persons employed or appointed by ZIEMER to perform any of its obligations. Any liability of ZIEMER shall in any case be limited to the purchase value of the Product. Some countries may not allow the exclusion or limitation of liability for consequential or incidental damages, so the above limitations offending the above mentioned law may not apply to Consumer.

10. Place of Jurisdiction; Applicable Legislation: These Limited Warranty Terms are subject to Swiss law. The courts at the domicile of ZIEMER shall hold jurisdiction.

13.5 Manufacturer's Electromagnetic Compatibility (EMC) declaration

Changes or modifications to this system not expressly approved by SIE AG could cause EMC issues with this or other equipment. This system is designed and tested to comply with applicable regulations regarding EMC and needs to be installed and put into service according to the EMC information stated as follows:

Guidance and Manufacturer's Declaration – Electromagnetic Emissions:

Guidance and manufacturer's declaration – electromagnetic emissions		
Ziemer's **FEMTO LDV** is intended for use in the electromagnetic environment specified below. The customer or user of the **FEMTO LDV** should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1 Class B	The **FEMTO LDV** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1 Class B	The **FEMTO LDV** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Pst = 1 Plt = 0.65	

Immunity tests	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
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	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge 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.
Power frequency magnetic field immunity test IEC 61000-4-8	3 A/m	30 A/m	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	- 100% / 10ms - 60% / 100ms - 30% / 500ms - 100% / 5000ms	- 100% / 10ms - 60% / 100ms - 30% / 500ms - 100% / 5000ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **FEMTO LDV** requires continued operation during power mains interruptions, it is recommended that the **FEMTO LDV** be powered from an uninterruptible power supply or a battery.
Note: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The **FEMTO LDV** is intended for use in the electromagnetic environment specified below. The customer or the user of the **FEMTO LDV** should assure that it is used in such an environment.			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should

			be used no closer to any part of the **FEMTO LDV**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz outside ISM bands	3 V rms	d = 1,2 root P
Radiated RF IEC 61000-4-3	3 V/m	10 V/m	d = 0,35 root P 80 MHz to 800 MHz d = 0,7 root P 800 MHz to 2,5 GHz
			where P is the maximum output power rating in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 

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] Fixed 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 access 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 **FEMTO LDV** is used exceeds the applicable RF compliance level above, the **FEMTO LDV** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **FEMTO LDV**.

[b] over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the FEMTO LDV

The **FEMTO LDV** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **FEMTO LDV** can help prevent electromagnet interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **FEMTO LDV** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P) W	Separation distance according to frequency of transmitter (meters)		
	150 kHz to 80 MHz d= 1.2 root P	80 MHz to 800 MHz d= 0.35 root P	800 MHz to 2.5 GHz d= 0.7 root P
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.11	2.21
100	12	3.5	7

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 higher frequency range applies.

Note 1: At 80 MHz and 800 MHz, the separation distance for 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..

NOTES

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