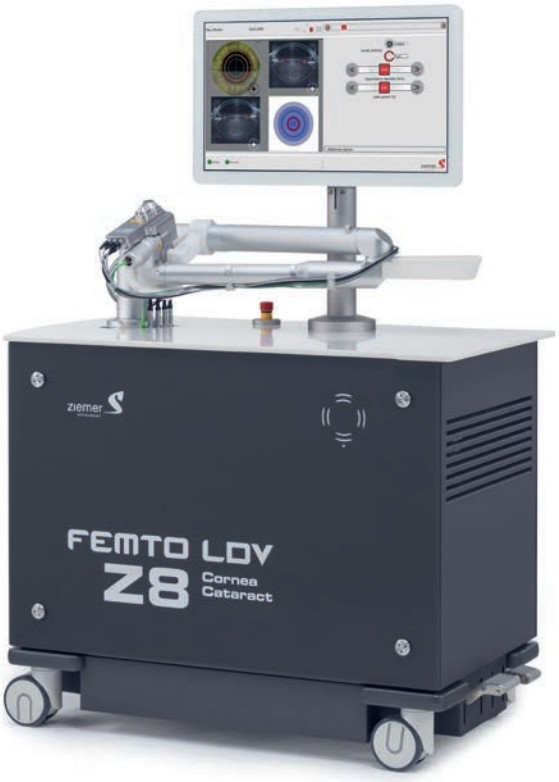
ziemer
OPHTHALMOLOGY

FEMTO LDV

Operator Manual

Z8 Models



LIST OF FIGURES

1 GENERAL

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

Please read this manual carefully and follow the instructions precisely.

1.1 Intended Use & Indications for Use

The FEMTO LDV Z8 Models[1] are ophthalmic surgical lasers intended for use in the creation of corneal incisions indicated for use in patients undergoing LASIK surgery, tunnel creation for insertion of implants, pocket creation for implantation of corneal implants, lamellar keratoplasty, penetrating keratoplasty or other treatment requiring lamellar resection of the cornea or of the ocular surface at a varying depth with respect to the surface.

In addition, the FEMTO LDV Z8 Models[1] are intended for use in the creation of capsulotomy, phacofragmentation and the creation of single plane, multi-plane, arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.

In addition, the FEMTO LDV Z8 Models[1] are intended for use in Curved Lamellar Resection (CLEAR) for the reduction or elimination of myopia from -0.50 D to -10.00 D, with astigmatism of 0 D to -5.00 D or without astigmatism, and MRSE of -0.50 D to -12.50 D in the eye to be treated in patients who are 18 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change in sphere and cylinder of ≤ 0.50 D in magnitude.

Caution: The intended use and indications for use may differ for some countries due to regulatory requirements. Please contact Ziemer for details.

1.2 Contraindications

Contraindications for **LASIK** with the FEMTO LDV Z8 Models include, but are not limited to the following:

- Corneal disease or pathology that precludes transmission of light at the laser wavelength or causes distortion of laser light.
- Corneal disease that precludes applanation of the cornea or transmission of laser light
- Corneal edema
- Corneal lesions
- Ocular hypotony or hypertension
- Glaucoma
- Existing corneal implant
- Fluctuating refractive error
- Residual thickness of stromal bed (after flap lift and ablation) < 250 µm

[1] According to 510(k) K150323 (FEMTO LDV Z8) and 510(k) K213559 (FEMTO Z8 NEO).

- Keratoconus and forme fruste Keratoconus

Contraindications for the creation of tunnel incisions for **intracorneal implants** with the FEMTO LDV Z8 Models include, but are not limited to, the following:

- Corneal disease or pathology that precludes transmission of light at the laser wavelength or causes distortion of laser light.
- Corneal disease that precludes applanation of the cornea or transmission of laser light
- Thin corneas, with thickness < 300 µm in the ring track
- Advanced keratoconus with curvatures > 60 diopters

Contraindications for the creation of **pocket incisions** for intrastromal inlays and corneal implants with the FEMTO LDV Z8 Models include, but are not limited to, the following:

- Corneal disease or pathology that precludes transmission of light at the laser wavelength or causes distortion of laser light.
- Corneal disease that precludes applanation of the cornea or transmission of laser light
- High myopia
- Severe dry eye
- Signs of early cataract
- Thin cornea (< 500 µm)

Contraindications for the creation of resections for **lamellar keratoplasty for therapeutic purposes** with the FEMTO LDV Z8 Models include, but are not limited to, the following:

- Corneal disease or pathology that precludes transmission of light at the laser wavelength or causes distortion of laser light.
- Corneal disease that precludes applanation of the cornea or transmission of laser light
- Unhealthy epithelium
- Corneal opacity that obscures visualization of the iris
- Stromal vascularization
- Descemetocele with impending corneal rupture
- Corneal thinning at the expected recipient-donor margin
- Previous corneal incisions intersecting with the planned incisions.

Contraindications for the creation of resections for **penetrating keratoplasty** with the FEMTO LDV Z8 Models include, but are not limited to, the following:

- Corneal disease or pathology that precludes transmission of light at the laser wavelength or causes distortion of laser light.
- Corneal disease that precludes applanation of the cornea or transmission of laser light
- Absence of corneal sensations
- Stromal vascularization

Contraindications for **corneal incisions** (clear corneal incisions, arcuate incisions) with the FEMTO LDV Z8 Models include, but are not limited to, the following:

- Corneal disease or pathology that precludes transmission of light at the laser wavelength or causes distortion of laser light.
- (If using Applanating Patient Interface) Corneal disease that precludes applanation of the cornea.
- Corneal disease that precludes transmission of laser light
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape.
- Corneal opacity that would interfere with the laser beam.
- Hypotony or hypertension, high IOP fluctuations that are not controlled under medications and continuous visual field damage.
- Presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal pathology (e.g., recurrent corneal erosion, severe basement membrane disease)

Contraindications for **capsulotomy** and crystalline **lens fragmentation** using the FEMTO LDV Z8 Models Laser include, but are not limited to the following:

- Corneal disease or pathology that precludes transmission of light at the laser wavelength or causes distortion of laser light.
- Descemetocele with impending corneal rupture
- Corneal opacity that would interfere with the laser beam.
- Presence of blood or other material in the anterior chamber
- Hypotony or hypertension, high IOP fluctuations that are not controlled under medications and continuous visual field damage.
- Presence of a corneal implant
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy.
- Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Residual, recurrent, active ocular or eyelid disease, including any corneal pathology (e.g., recurrent corneal erosion, severe basement membrane disease)
- A history of lens or zonular instability
- Any contraindications to cataract or keratoplastic surgery

Contraindications for **curved lamellar resection** for refractive purposes (CLEAR) with the FEMTO LDV Z8 Models include, but are not limited to the following:

- Residual thickness of stromal bed that is less than 250 microns from the corneal endothelium.
- Abnormal corneal topographic findings, e.g. keratoconus, pellucid marginal degeneration
- Ophthalmoscopic signs of progressive or unstable myopia or keratoconus (or keratoconus suspect)
- Irregular or unstable (distorted/not clear) corneal mires on central keratometry images
- Severe dry eye
- Active eye infection or inflammation
- Recent herpes eye infection or problems resulting from past infection.
- Active autoimmune disease or connective tissue disease

- Uncontrolled diabetes
- High IOP fluctuations that are not controlled under medications and continuous visual field damage.

Caution: Please follow specific recommendations of inlay/implant supplier regarding indications, contraindications, and inclusion and exclusion criteria.

Caution: The contraindications may differ for some countries due to regulatory requirements. Please contact Ziemer for details.

1.3 Patient Target Group

Patients aged 18 years and more, except pregnant or lactating patients, are eligible for the **FEMTO LDV Z8 Models** and their applications according to their intended use.

Paediatric patients are also eligible for **FEMTO LDV Z8 Models** with the following applications, but only in markets with regulatory approval for:

- Corneal Incisions (clear corneal incisions, arcuate incisions)
- Capsulotomy and crystalline lens fragmentation

1.4 About This Manual

Title	**FEMTO LDV™ Z8 Models**: Operator Manual
Document number	FL5940-0507
Revision	Version 19
Release date	August 2024
Product	**Ziemer**'s Femtosecond Surgical Lasers **FEMTO LDV Z8** and **FEMTO Z8 NEO**
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.
Copyright Notice	
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 AG, Surgical Instrument Engineering**, a **Ziemer Group Company**

	Allmendstrasse 11, CH-2562 Port, Switzerland
Licensee and distributor	**Ziemer Ophthalmic Systems AG**, a **Ziemer Group Company** Allmendstrasse 11, CH-2562 Port, Switzerland (www.ziemergroup.com)
European Authorized Representative and Importer	**Ziemer Ophthalmology (Deutschland) GmbH** Kronenstrasse 38, DE-79211 Denzlingen, Germany

1.5 How to Use This Manual

This Operator Manual provides important information regarding the use of the **FEMTO LDV Z8** and FEMTO Z8 NEO, referred to in this document as "**LDV**" or "**FEMTO LDV**".

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 instruction 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 any corneal or cataract surgery. 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.

Names, characters, birth dates and vacuum time are products of the author's imagination or are used fictitiously. Any resemblance to actual events or persons, living or dead, is entirely coincidental.

If there are questions 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 J.5939 or higher.

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

1.6 Intended Users

Clinical intended users are the following:

- Trained doctor (non-sterile / sterile)
- Trained healthcare professional (HCP) (non-sterile / sterile) (e.g. nurse, technical or surgical assistant)

1.7 Maintenance & Customer Service

No part of the LDV may be serviced by users. All service must be carried out by a Ziemer Customer Service representative or an authorized service center. Do not implement any modifications on the FEMTO 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 and all liabilities for resulting damages are refused.

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

a Ziemer Group company

Allmendstrasse 11

2562 Port (Switzerland)

Phone: +41 848 943 637

E-mail: support@ziemergroup.com

www.ziemergroup.com

Refer to section 10 (Service and Maintenance) for more details.

1.8 Supporting Documents

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

Title	Document number
FEMTO LDV Z8 Surgical Procedure Manual Neo App Suite	FL5940-0513
FEMTO LDV Z8 Surgical Procedure Manual Cornea SW Application	FL5940-0538
FEMTO LDV Z8 Procedure Packs for Corneal Surgery – Directions for Use	FL5940-8028
FEMTO LDV Z8 Procedure Packs for Cataract Surgery and Procedure Packs for Corneal Surgery Liquid – Directions for Use	FL5940-8027
FEMTO LDV Z8 Technical Specifications	FL5940-0509
External Power Meter – Directions for Use	FL5910-300-0565
Transport and Check LDV Z8 and Neo	FL5940-2034

1.9 Notes and Icons on Safety

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

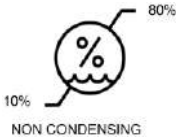
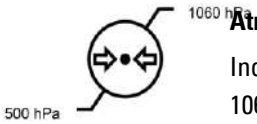
Symbol	Name and significance
	**Warning:** A warning indicates an action or procedure that, if not performed correctly, could result in serious injury or a safety hazard. Strict compliance with these instructions is required.
	**Caution:** A caution indicates an action or procedure that, if not performed correctly, might result in minor or moderate injury. Strict compliance with these instructions is required.
	**Note:** A note indicates an action or procedure that, if not performed correctly, can result in incorrect operation or damage to the device or trigger an unexpected response on the part of the instrument. Strict compliance with the instructions is required.
	**Hint:** Indicates tips and tricks for a successful handling of the device and its parameters.

1.10 Icons on Labels

On product labeling certain icons (symbols) are used. Their meaning is explained below:

Symbol	Name and significance
	**Certification mark** European certificate of conformity
	**Catalog Number** Manufacturer's catalog number
	**Manufacturer** Name and address of the manufacturer
	**Date of manufacture** Month of product manufacturing
	**EC-REP information** Name of authorized representative Adress
	**Importer information** Name and address of the European importing entity

Symbol	Name and significance
SN	**Serial Number** Manufacturer's serial number
UDI	**Unique Device Identification** Unique identifier to medical devices
	**Instructions for use** **Attention symbol**: Follow instructions for use.
MD	**Medical Device** Identifies as a medical device
	**Electrical shock** Type B applied part.
	**Waste Electronic and Electrical Equipment** Symbol is based on European Union Directive 2012/19/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.
	**Certification mark** Test symbol of MET with approval for USA and Canada
	**Rx only - US restricted sale symbol** Federal law restricts this device to sale by or on the order of a physician
Mains	**Mains**
Power	**Power**
Weight	**Weight**
Protection class I	**Protection class** Protection class indicates that the medical electrical equipment is supplied by an external electrical power source
IP 20	**Environmental code** Ingress Protection (IP) code indicates how well a device is protected against water and dust. First digit "2": Solid particle protection and protection against solid foreign objects > 12.5 mm. Second digit "0": No protection against ingress of water.
CAN ICES-001(A) /NMB-001(A)	**Canadian Interference-Causing Equipment Standard** Indicates a medical equipment highly unlikely to be used in a residential environment.

Symbol	Name and significance
	**Packaging orientation** Ensure the packaging orientation is upright.
	**Packaging weight** Indication of the weight (max. 0.00 kg) that can be placed on the shipment.
	**Fragile content** Indication that the device is fragile and should be handled with care.
	**Keeping dry** Indication that the device needs to be kept dry.
	**Temperature range** Indication of the storage temperature range between 0°C to +50°C.
	**Relative air humidity** Indication of the relative air humidity within the range of 10% to 80%.
	**Atmospheric pressure** Indication of the atmospheric pressure within the range of 500 hPa to 1060 hPa.
	**Warning label** Laser aperture
	**Warning label:** Visible and Invisible Laser radiation **Treatment Laser:** Max. 2000 mW at 1020-1060 nm, Pulse duration 200-500 fs Class 4 Laser Product, **avoid exposure to beam.** **Aiming Laser:** Max. < 1 mW at 650 nm, continuous wave (CW), Class 2 Laser Product **Optional OCT-Measure Laser:** Max. 5 mW at 880 nm, continuous wave (CW), **Class 3R Laser Product**
	**Warning label:** Class 4 invisible laser radiation when open and interlock defeated. Avoid eye or skin exposure to direct or scattered radiation
	**Laser Warning** Signals possible exposure to laser beam

Symbol	Name and significance
	**Electrical grounding** Indication of the grounding points of the system
	**Potential Equalization Conductor** Connector for Potential Equalization Conductor at the bottom of the device.

1.11 Terms and Abbreviations

The table below contains all abbreviations and technical terms used in this Operator Manual.

Abbreviation	Meaning
ANSI	American National Standards Institute
API	Applanating Patient Interface
ARC	Arcuate Incisions
BS	Base station
BSS	Balanced Salt Solution
CAN/CSA	Canadian Standards Organization
CCI	Clear Corneal Incisions
CLEAR	Corneal Lenticule Extraction for Advanced Refractive Correction
CLR	Curved Lamellar Resection; CLR for refractive use is called “CLEAR”. CLR for therapeutic use is called “Therapeutic Lamella”.
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.
Crystalline lens	The crystalline lens is a transparent, biconvex structure in the eye that, along with the cornea, helps to refract light to be focused on the retina. Upon aging, the lens hardens and turns opaque, a condition termed Cataract.
Capsulorhexis	A technique performed manually with a forceps to open the capsular bag by tearing a circle.
Capsulotomy	A technique performed with the femtosecond laser to open the capsular bag
CISPR	International Special Committee on Radio Interference
CW	Continuous-Wave
DIN	German Institute for Standardization
EN	European standard
FDA	Food and Drug Administration (USA)

Abbreviation	**Meaning**
Femtosecond	Measure of time; 1 fs = 10^{-15} seconds
Flap	Corneal lenticule created during the initial step of a LASIK procedure.
FMAA	Fixed Mirror Articulated Arm
FS	Fast Scan
HCP	Health care professional
HP	Handpiece
hPa	Hecto Pascal
HPC	Handpiece Casing
IEC	International Electrotechnical Commission
IOP	Intraocular Pressure
LASIK	Laser Assisted In-Situ Keratomileusis
LED	Light Emitting Diode
LPI	Liquid Patient Interface
MPE	Maximum Permissible Exposure
MRSE	Manifest Refraction Spherical Equivalent
NOHD	Nominal Ocular Hazard Distance
OCT	Optical Coherence Tomography
OR	Operating Room
PI	Patient Interface
PP	Procedure Pack
Retina	A layer of light-sensing cells that lines the back of the eye
rH	Relative Humidity
SRG	Surgeon
SS	Slow Scan
STER	Sterile Assistant
TABO	(derived from “Technischer Ausschuss für Brillen-Optik”, German technical board for spectacle optics) Counterclockwise coordinate system as used by LDV: OD: 0° = nasal; 90° = superior; 180° = temporal; 270° = inferior. OS: 0° = temporal; 90° = superior; 180° = nasal; 270° = inferior.
Trajectory	Path followed by the laser during resection
NSA	Non-sterile Assistant
UL	Underwriters Laboratories
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 and transport 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 Service representative or a certified Ziemer representative and must be fully familiar with this Operator Manual and associated supporting documents (see section 1.8) before attempting to use the LDV. Each individual trained will receive a training certificate issued by Ziemer Customer Service.

Warning: The device is intended to be used only by highly qualified personal.

2.3 System Installation

Warning: Only trained Ziemer Customer Service representatives should perform unpacking and installation of the LDV. Proper system installation is essential for the functionality of the LDV.

Warning: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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. The responsible organization is referred to this standard for the requirements applicable to ME systems. All USB devices need to be removed from the system while it is used for surgical procedures.

2.4 General Warnings

Radiation

Warning: The use of controls, 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 1.10) on the instrument and on the entrance door(s) to the room in which the LDV is operated.

Fire

Warning: The LDV should not be operated in the presence of flammable anesthetic, volatile substances (e.g. solvents or anesthetic substances), or oxygen flow lines, even the risk of fire is extremely low.

Electrical shock

Warning: High voltage electrical circuits are accessible if the side covers are removed. Only trained LDV Customer 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: 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.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the LDV, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Adjacent equipment

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Accessories

Warning: The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Electromagnetic Compatibility

Warning: This equipment/system is intended for use by healthcare professionals only. This is an equipment/system of Class A according to CISPR 11. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the LDV or shielding the location.

Warning: Magnets are used for the handpiece (HP) position detection. A safety distance of 20 cm from the HP is necessary for pacemaker.

Appliance Inlet

Warning: The appliance inlet and the power switch are at the bottom of the device. Do not position the LDV in a way that the inlet or the power switch cannot be accessed.

Modification

Warning: No modification of this equipment is allowed.

3 SYSTEM HAZARDS

3.1 Precautions

Warning: Intraocular pressure (IOP) is increased during surgery; care must be taken to minimize suction time.

Warning Corneal applications: Incomplete applanation in corneal surgery may result in thin or non-uniform resection thickness and in smaller than intended resection size.

Observe the procedures described in the applicable Surgical Procedure Manuals (see section 1.8).

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, remove and secure the key from the key switch, 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 (switchable), 50-60 Hz, 1000 VA		
Protection class:	I	Protection type:	B
IP	20	Laser Class:	4

Warning: High voltage electrical circuits are accessible if the side covers are removed. Only trained LDV Customer 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.

Caution: Mains power quality should be that of a typical commercial or hospital environment. Ensure that the current and the power of the line is sufficient and that the power supply is stable.

Caution: Select the 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. 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 mm (0.4 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.

For more details see section 12.1.

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.

3.5 Single-Use Disposable Accessories

The LDV can be operated only with the sterilized single-use original Ziemer LDV Procedure Packs, containing all required single-use, sterile disposable components (see section 5.10).

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, and all liabilities are refused.

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.

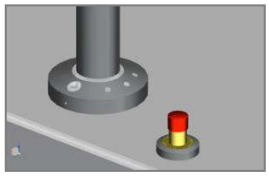
Warning: The LDV must not be employed in a wet environment or used in contact with liquids.
Disregarding this warning may result in electric shock.

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 (check the shock

indicators on the packaging), proper functioning cannot be guaranteed any more, and Ziemer Customer Service should be contacted (see section 10, Service and Maintenance).

4 SAFETY FEATURES

Master ON Switch	The LDV is turned on by Master ON and by depressing the **Start** button (see section 5.3.1). **Caution**: Switch to appropriate line voltage before attempting to switch the LDV on. 
Safety System	The entire electronic system is continuously checked by an independent safety system. This independent protection system (SW components "Safety System FW" and "Safety HP FW" and watchdogs WD1, WD2, WD3 and Main WD) runs in parallel. It monitors all status information and measured values of the hardware components and puts the system into a safe state in the event of a fault. By monitoring the status information and the measured values, the protection system is able to monitor the laser power and the cutting position of the laser.
Laser Enabling	When the master switch is turned to the ON position, the Module Selection Screen appears on the touchscreen and allows the user to select the desired application. Laser emission is disabled until the user selects appropriate treatment parameters, the HP is fixed on the eye with the suction ring and all internal control parameters are checked.
Interlock Dongle	The Interlock Dongle is a Key Plug which, when removed, opens the safety interlock system, thus making it impossible to start the laser. It is located at the rear of the unit, at the bottom. 
Key Switch	The laser system is enabled by a key switch. When the key is not present, the safety interlock system is open, thus making it impossible to start the laser.
Laser Aperture	The device has a single aperture located in the HP (see image in section 5.7) for the laser beam, aiming beam and OCT-imaging beam.
Viewing Window	The viewing window on top of the HP is optically coated to ensure that no laser light is emitted through the viewing window during surgery.
Laser Emission Indicator	Laser emission is indicated by blue LED indicators located at the base of the touchscreen monitor (see section 5.3.1).
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 12.4 of this manual).
Laser Module / Safety Shutter	The Laser cavity 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 vacuum system has reached appropriate suction to the eye or during an external power measurement (see section 9.3).
Footswitch Control	The footswitch is used in the workflow to confirm steps and navigate. The footswitch is only used in the cut screen to operate the laser and apply the

	laser pulses.
Emergency OFF Button	The **Emergency OFF** button is a red button located on top of the table of the base station and accessible 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 (Cornea SW Application), and/or (2) by a special hardware key needed for opening the base station. The key switch should also be used to make the device functioning.

5 SYSTEM DESCRIPTION

5.1 Description

The LDV is a solid-state femtosecond laser used in ophthalmology. It is used for producing cuts in ocular tissue and can be used in corneal and cataract surgery.

The LDV produces femtosecond laser pulses that are absorbed by the tissue, resulting in plasma formation. This plasma rapidly expands, creating a cavitation bubble separating the tissue. This process is known as photodisruption. Because of its very short pulse duration, femtosecond laser technology deploys low pulse energy that virtually eliminates damage peripheral to the incision site and can therefore be used to dissect tissue on a microscopic scale. Femtosecond laser systems may use closer spot spacing to overlap these cavitation regions, producing less tissue bridges.

The energy needed for photodisruption can be reduced with shorter pulse duration and smaller diameters of the spot. To achieve such a focused laser spot with a smaller diameter, a lens with a higher numerical aperture is required. Smaller spots enhance the accuracy and overall precision of cuts. The strategy of low pulse energy and small overlapping spots is employed by the FEMTO LDV technology, allowing the reduction of energy used.

5.2 Main Functional Units

The complete LDV system consists of the following functional units:

- Base Station (BS); integrating the Laser Cavity, Fixed Mirror Articulated Arm (FMAA), Power Supply, Computer, Touchscreen Monitor, Suction Unit, OCT Box and Safety System
- Handpiece (HP); integrating the Cutting Lens and the Topview Camera

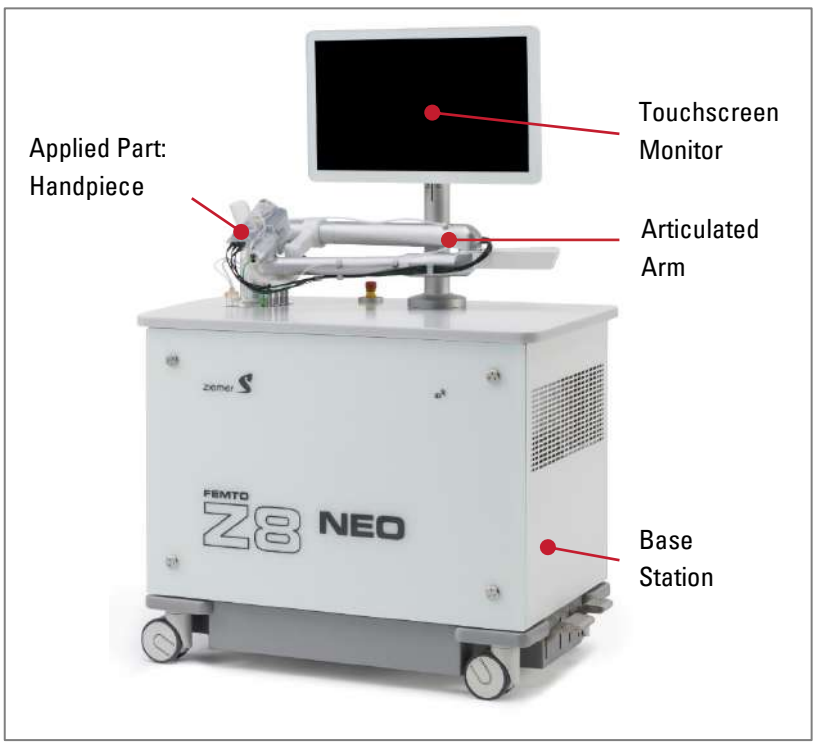


Figure 1: The FEMTO Z8 NEO System

The LDV is movable on four wheels and can be transported to different locations, also outside clean OR environments. 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, the table must be in the lowest position for secure movement and the front wheels must be locked in driving direction (see Figure 2).

Figure 2: HP and FMAA in park position.

Caution: It is fundamentally possible that the device might become contaminated during the transportation process. It is the responsibility of the user to perform professional decontamination and cleaning of the device and always ensure the proper application of sterile parts.

Note: If the LDV needs to be rolled over a step of up to 2 cm, please slightly lift the system manually. To do this, the system must be lifted on the underside (arrow in the image on the right).

Lifting the LDV system by holding on to the tabletop, the glass pane, the bumper, the pedals, the FMAA or other parts not shown in the illustration is not recommended and may cause damage to the system.

The working position of the HP is located in the focus of the surgical or ablation laser microscope. During laser resection, the HP 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 FMAA 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 clamp protects the FMAA from excessive strain and vibration.

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 positioning of the shoulder (middle) joint at 890-1190 mm above ground. This allows the adjustment of the system to different types of patient beds within a range of 300 mm. The nominal reference height is 1000 mm.

The FMAA should be placed and locked in the park position 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.

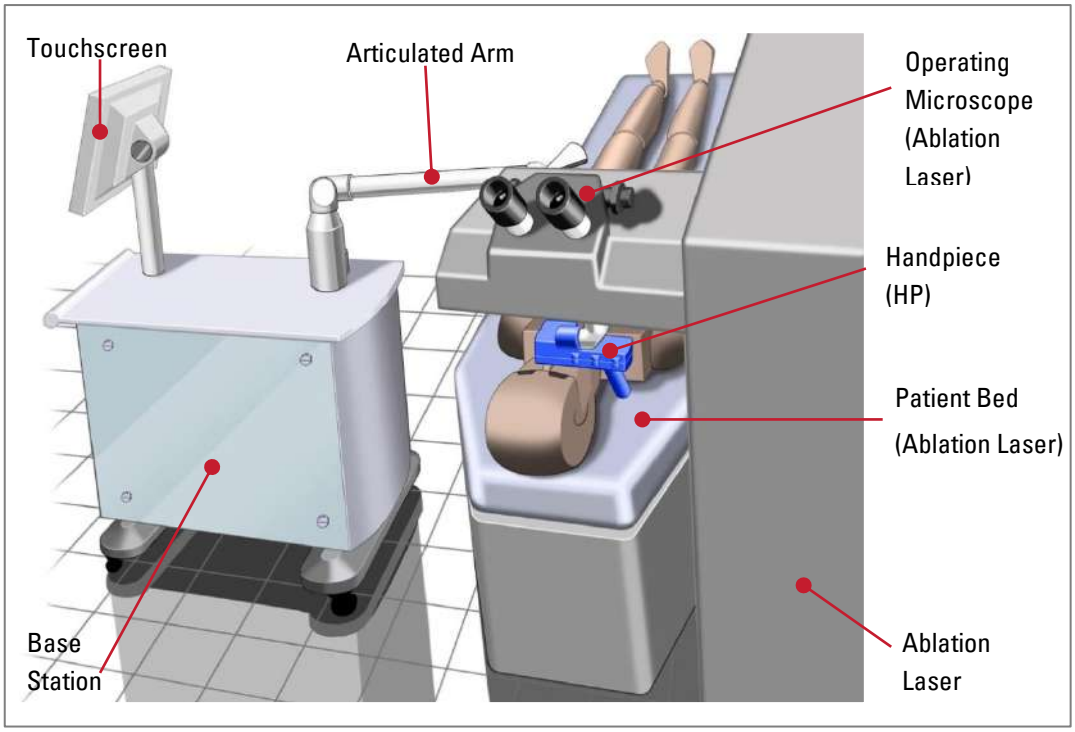
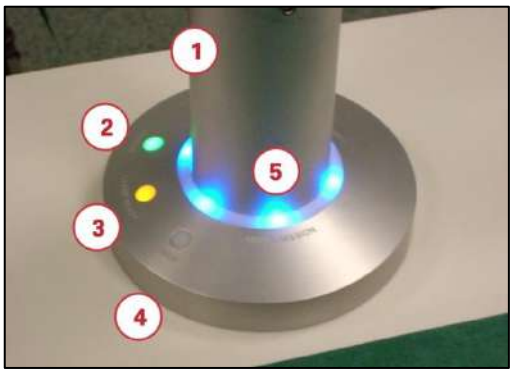


Figure 3: Example of LDV positioning when used with an ablation laser (LASIK)

5.3 Operating Interface

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

5.3.1 Monitor base



1 **Start button:** Switches the LDV unit on and off (not visible in image).

2 **Power:** LDV is switched on (green LED).

3 **Laser ready:** Laser system is switched on (yellow LED).

4 **Error:** A safety switch error occurred (red LED).

5 **Laser emission:** Laser is emitting, shutter is opened (blue LED).

5.3.2 System dimensions

Base station footprint: 102 cm (L) x 53 cm (W) x 78 cm (H).

5.3.3 RFID reader

The integrated RFID Reader complies with ISO 15693.

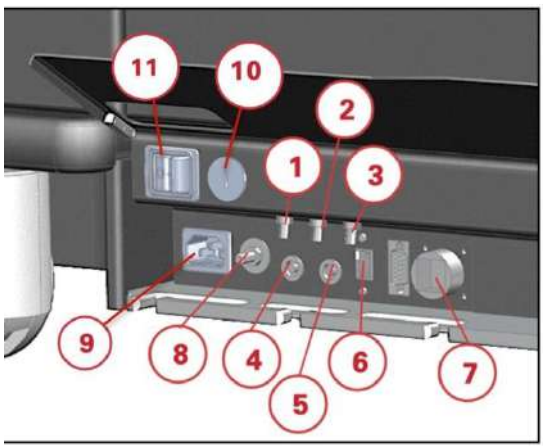
Frequency: 13.56 MHz

Effective Radiated Power: 0.5 W

Type of modulation: ASK

5.4 Hardware Interfaces

The interface connector panel is located on the backside of the base station.



1 Fuse F1 (push to reset)

2 Fuse F2 (push to reset)

3 Fuse F3 (push to reset)

4 Footswitch connector

5 Connector for door interlock

6 USB connector

7 Ethernet connector

8 Connector for Potential Equalization Conductor (see note below)

9 Appliance inlet

10 Line voltage selector switch

11 Master On switch

Note: The purpose of the additional potential equalization (8) is to reduce differences of potential which can occur during operation between the bodies of medical electrical devices and conductive parts of other objects. Connect this connector with a EN60601-1 conforming cable to the grounding connector.

5.5 System Start-Up

1 Change the line voltage switch to the appropriate position, if necessary.

2 Connect the power cable to the appliance inlet. Loop the cable through the base plate according to the following image to reduce the risk of unintended unplugging of the power cable.

3 Enable the Master On key switch by rotating it to (1).

4 Press the Start button.

5 Surgical planning and other tasks may be programmed by the software according to section 7.

5.6 System Power-Off

1 Shut the system down as described in section 7.1. Wait until all fans have turned off.

2 Switch the Master-On to position (0). The device is now completely isolated from the supply main.

Note: Never switch the FEMTO LDV off without the shutdown procedure described above. Switching off the Master On Switch or removing the cable can damage the system.

5.7 Handpiece

The FEMTO LDV Z8 and FEMTO Z8 NEO systems are equipped with the C2-Handpiece. The focal point of the laser beam can move in three dimensions (xyz) to create resections in any direction and in any position within the cornea or the crystalline lens. During operation the HP is, in all cases, fixed by means of the patient interface to the patient's eye. The HP is covered with a disposable, sterilized HP casing.

The exact positioning of the HP relative to the patient's eye is determined by the surgeon and not by the system or the software.

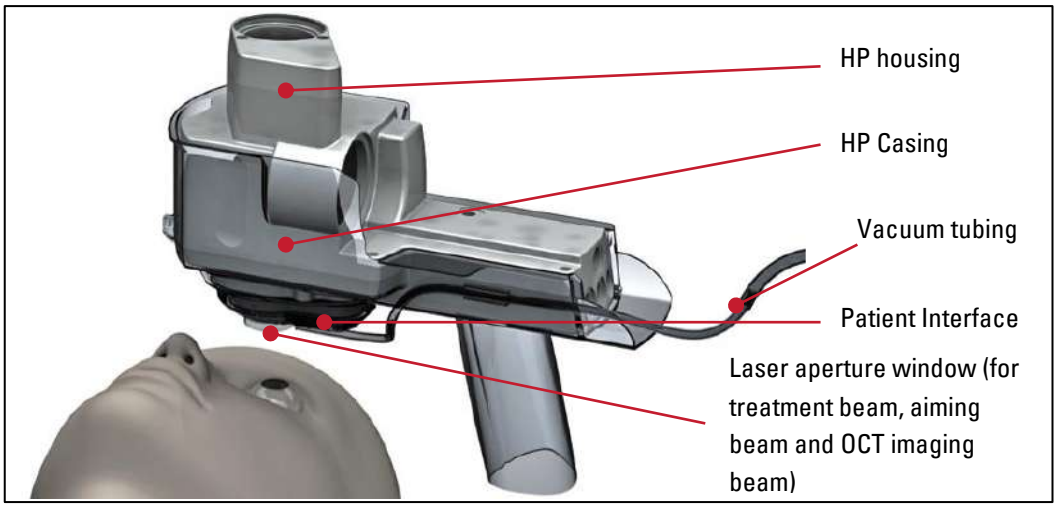


Figure 4: Handpiece with assembled casing and PI

5.8 Footswitch

The footswitch is an UL 2601.1, DIN EN and CAN/CSA conforming, off-the-shelf product. The recommended and tested foot switch for the system is listed in section 12.3.1.

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.

5.9 Brake System

Figure 5: Pedals on the LDV.

1 **Mechanical brake pedal:** Locks two wheels with a mechanical brake to prevent the device from moving.

2 **Driving direction pedal:** Locks two wheels in a forward orientation, allowing a greater sense of control when moving the device.

5.10 Procedure Packs

There are two different types of Procedure Pack provided by Ziemer for the FEMTO LDV Z8 and FEMTO Z8 NEO:

- Cornea PP: For corneal procedures, with applanating patient interface (API)
- Cataract and Corneal Liquid PP: For cataract and corneal procedures, with liquid patient interface (LPI)

5.11 Handpiece Assembly

The procedure for assembling the casing and patient interface to the HP is described in detail in the Directions for Use that are enclosed with each Procedure Pack:

- FEMTO LDV™ Surgical Laser Procedure Packs for Corneal Surgery: Doc No: FL5940-8028
- FEMTO LDV™ Surgical Laser Procedure Packs for Cataract Surgery and Procedure Packs for Corneal Surgery Liquid: Doc No: FL5940-8027

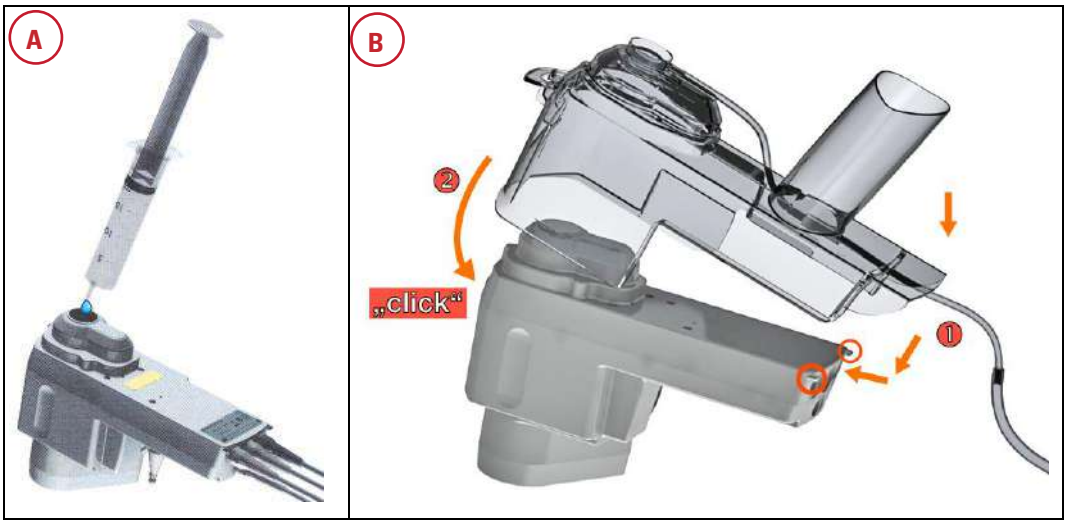


Figure 6: Handpiece assembly.

A: Moisten the laser exit window on the HP by applying one drop of sterile water (H_2O).

B:

1 Guide the casing at an angle of approx. 45° from above (cable side; ①) and into the pegs at the underside back of the HP. Lower the front end of the casing onto the HP (②) until the latch at the front snaps closed.

2 When mounting the sterile HP casing the latch must "click" in. Check and verify the latch position after mounting.

3 After scanning the procedure pack and before proceeding to the next screen, mount the sterile covers and suction tube.

In case of an error message indicating a suction tube fault, the patient interface (PI) must be exchanged.

After a successful suction tube test, the PI is ready to be handed over to the surgeon by the sterile assistant when requested.

Caution: Verify proper assembly of HP cover and patient interface.

Laser exit window of the HP and glass membrane of the casing should now be congruent, connected by a bubble-free water film.

Check that no particles, residue or bubbles are visible in the laser exit window.

HP, casing and patient interface must be properly and securely interlocked. Any misalignment may lead to an incorrect resection.

After use, remove the casing.

5.12 System Specifications

The specifications of the system components, the dimensions and the operating, transportation and storage conditions can be found in the Technical Specifications sheet of the LDV (see section 1.8).

6 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.

In order to create the resection, the LDV uses ultra-short light pulses. By accurately focusing the laser beam, sufficient energy density can be achieved inside the cornea, the crystalline lens, or the lens capsule. This leads to a photodisruption process that generates microscopic bubble-shaped dissection points at a desired depth, without damaging nearby tissue outside the laser focal point area. Fixation of the eye is achieved by a vacuum that is generated inside the patient interface. For more details refer to Surgical Procedure Manual (see section 1.8).

6.1 Slow and Fast Scan

In this section, the example of the LASIK resection is used to explain the cutting principle.

One part of the corneal resection (see LASIK example in Figure 7) is created by the software-controlled xy-scanner (Slow Scan), which moves a lens inside the HP following a raster-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 by a rotator prior to laser resection. In addition, resection in the Z-axis is permitted if this is necessary for the selected method.

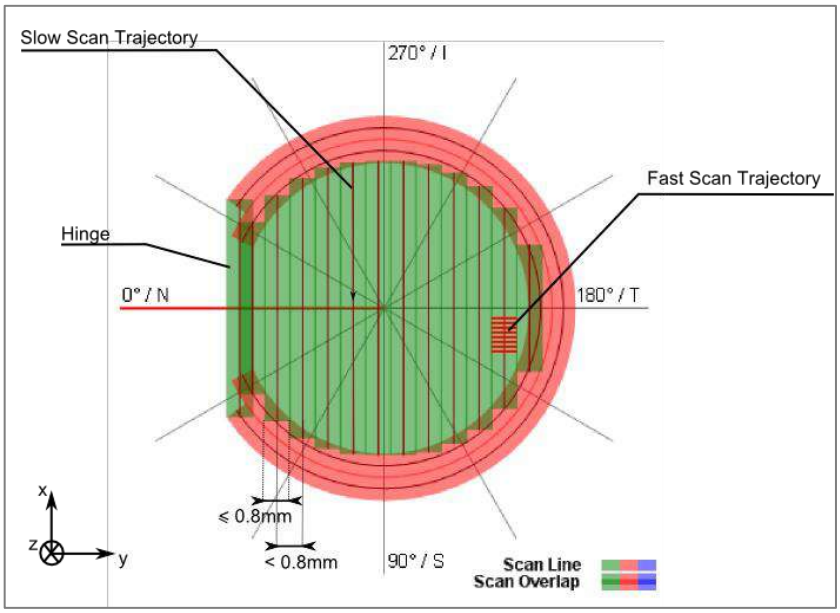


Figure 7: Slow and Fast Scan Lines (LASIK)

7 SOFTWARE

The LDV software is configured in such a way that errors and incorrect settings are avoided as far as possible. In case of detected risks, the software displays warning messages, which have to be acknowledged by the operator. These checks are designed to minimize the risks as far as technically possible. However, the operator is responsible for the correct interpretation of the information shown and for the ultimate decision where and how to position the cuts in the eye. Access via a graphical user interface is restricted to the program level. The operator cannot see the operating system level of the controls. The graphical user interface follows common graphical conventions and user actions.

The main steps of the procedure are confirmed by acoustic signals.

Refractive, Therapeutic and Cataract surgeries are performed and controlled by two separate application programs. All applications with the same button color (green or blue) will start the same program, meaning that an application change is still possible inside the program. After system start-up, the so-called “Module Selection” screen features the three treatment areas that are further divided by the Patient Interface required. On the lowest level each application has its own button. Only the buttons of the applications which are licensed on the system are active and selectable. Applications which are not licensed appear grey and are not selectable. Touch the desired application to proceed.

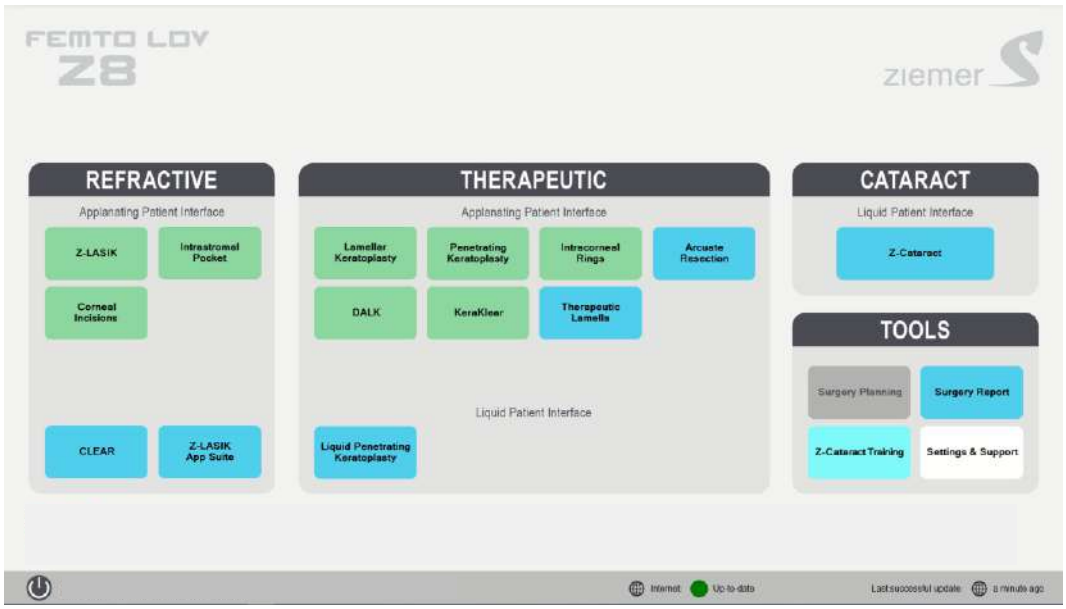


Figure 8: Module Selection screen of the FEMTO LDV

The information of the treatment area and the interface to be used for a specific module is easily available on the module selection screen. Table 1 additionally provides information on the corresponding application program and surgical procedure manual for a detailed explanation of the module.

Table 1: Overview of Module / Application program combinations

Module	Application Program / Surgical Procedure Manual	Patient Interface	Treatment Area
Z-LASIK	Cornea SW Application	API	Refractive
Intrastromal Pocket			
Corneal Incisions			
Lamellar Keratoplasty			Therapeutic
DALK			
Penetrating Keratoplasty			
Intracorneal Rings			
KeraKlear			
CLEAR	Neo App Suite	API	Refractive
Z-LASIK App Suite			
Therapeutic Lamella			Therapeutic
Arcuate Resection			
Liquid Penetrating Keratoplasty		LPI	
Z-Cataract			Cataract

Caution: For some countries, availability of applications may be restricted due to regulatory requirements. Please contact Ziemer for details.

Besides the three treatment areas, an additional area called "TOOLS" is available. In this area the "**Surgery Planning**", "**Surgery Report**", "**Z-Cataract Training**" (only if licensed) and "**Settings & Support**" buttons are accessible.

By selecting the "**Surgery Planning**" button (soon available), surgeries with the Neo App Suite can be preprogrammed on the system before the date of surgery.

The "**Surgery Report**" tool collects information of each surgery performed with in the Neo App Suite. The information can then be extracted to a PDF File, which can be saved on an external USB device. For further information on the "Surgery Report" Tool, proceed to section 7.4.

In the optional "**Z-Cataract Training**" module, the input of the parameters for the Cataract surgery

and the fine-tuning of the cuts can be trained. To start the training module, touch the corresponding button. A special cataract training tag and an artificial eye is needed. The workflow of the procedure is the same as in the cataract module, but no cut is performed in the training module.

The "**Settings & Support**" button opens a new page. On this page the button "Support (Remote Access)" can be found, which will start the Remote Access application. Proceed to section 10, Service and Maintenance for more information on remote maintenance. Additionally, the "module licenses" tab is available on this page. License keys can be entered in this tab to activate optional modules. With Software version J.5939 and higher, it is required to obtain cut licenses to be able to perform a Therapeutic Lamella or Arcuate Resection procedure. Those cut licenses are loaded on the device by internet or USB stick, and they are visible in the tab "Cut licenses" (see Figure 9).

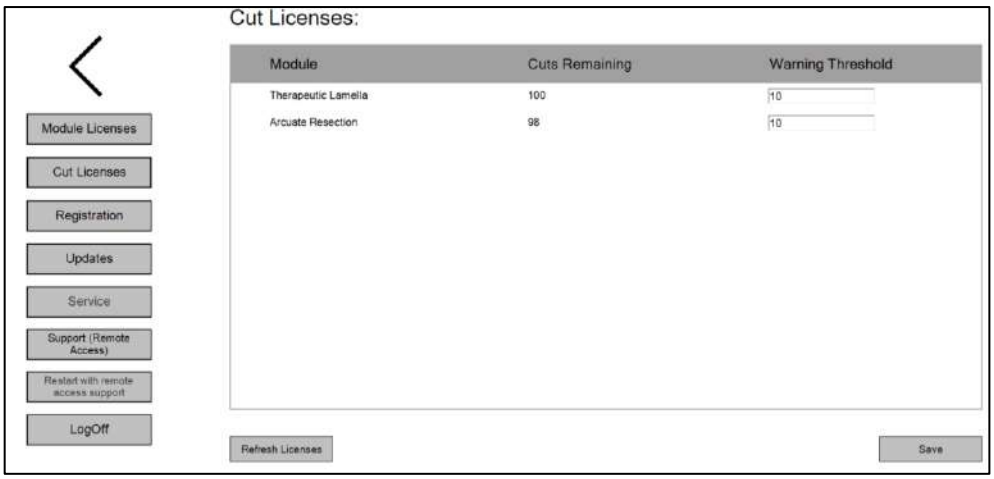


Figure 9: Cut Licenses tab.

Customizable warning thresholds for cut licenses can be activated in this tab by entering the desired minimum number of available cuts. The corresponding warning message will then appear on the Module Selection screen, whenever the available number of cut licenses is below the defined threshold.

Hint: If for a specific procedure no cut license warning is required, the threshold can be set to 0.

Hint: If a module license will expire within the next 30 days, a message box will be displayed on the "Module Selection" screen.

Hint: The database of the software program for the Neo App Suite has a capacity of 3000 patients (entries). A warning message appears on the “Module Selection” screen at every start-up of the system, when 2500+ patients (database entries) are reached. The message tells the user to export patient data with the “Surgery Report” tool to free capacity in the database by deleting the exported patient data. When the database is full (3000 entries) no additional surgery with Neo App Suite is possible.

7.1 System Shutdown

After closing the currently running module or tool, the “Module Selection” screen appears (see Figure 8). Touch the “Shut down” button to shut down the LDV.

7.2 Cornea Software Application

Refer to Table 1 for a list of all the modules available in the Cornea Software Application.

7.2.1 Screen structure.

The user interface of the Cornea SW Application 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.

7.2.2 Status bar

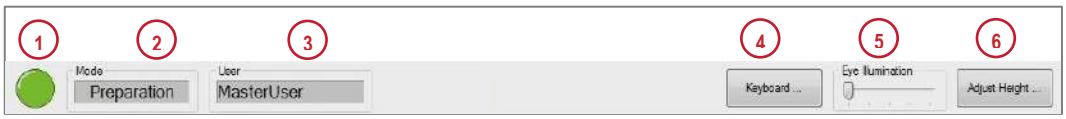


Figure 10: Status bar in the Cornea Software Module

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:** Status of the software is displayed.
- 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.

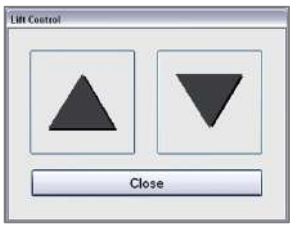
3 **User:** Current user logged in (rights may be different for each user).

4 **Keyboard:** With this button, the visual on-screen keyboard is enabled when alphanumeric

inputs are required. It is used by tapping on the screen with a finger or a touch pen. Click in a text field before typing.

5 **Eye illumination:** Available during preparation of the resection procedure process, this slider changes the eye illumination brightness inside the HP. Default value is medium.

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



7.2.3 Screen sequence

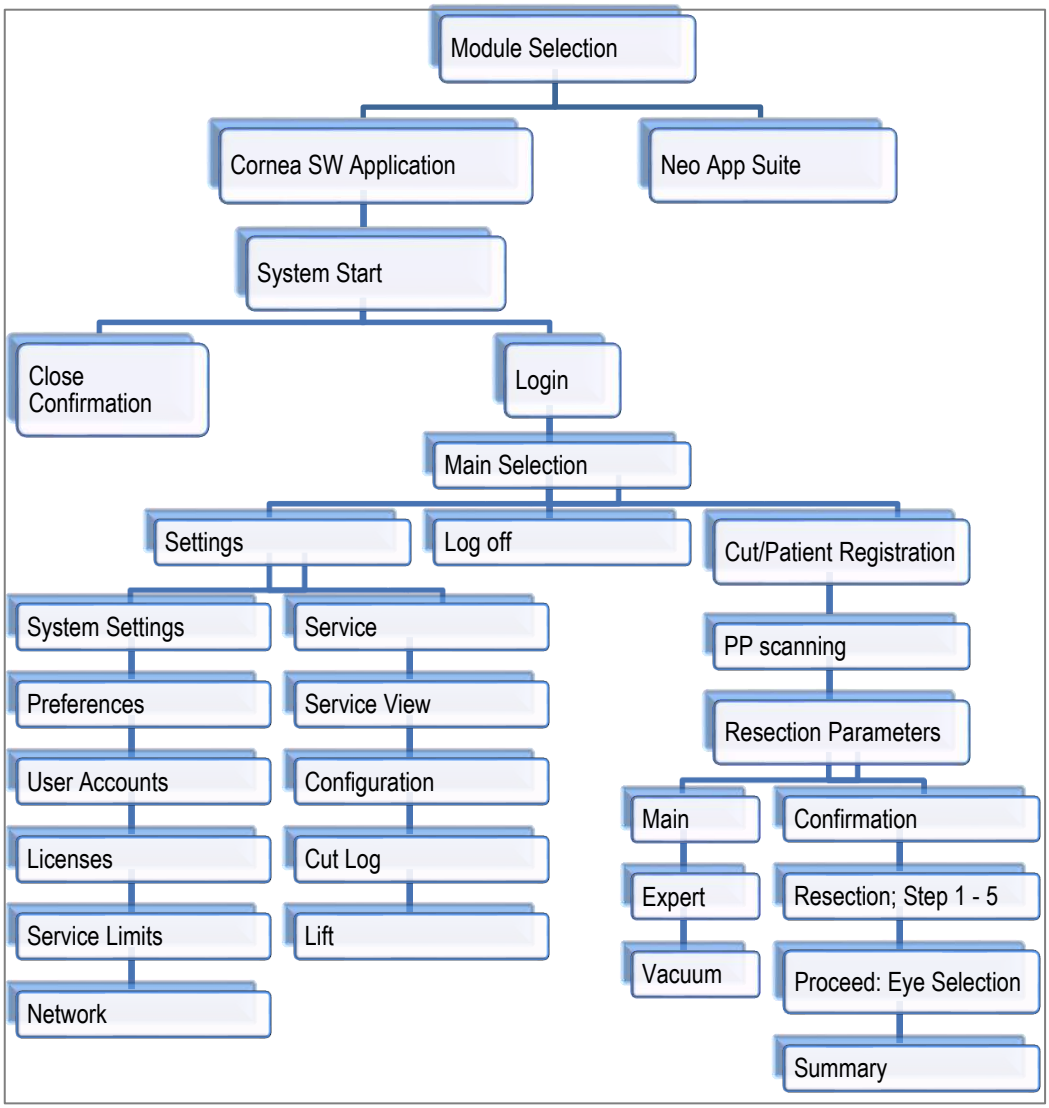


Figure 11: Screen sequence Cornea SW Application

7.2.4 Start-up of Cornea Software applications

After device start-up and selection of a Cornea SW Application method within a specific treatment area (“Module Selection” screen, see page 35), the “Start-up” screen (see Figure 12) will be displayed. It shows the progress of all subsystem start-up routines. This automatic process will take approximately 10 minutes. No interaction is possible during the start-up process until the laser cavity is ready.

Figure 12: Start-up screen.

1 Click on the **Next** button when active (time remaining = 0 seconds), to proceed to the "Start" screen of the Cornea SW Application (Figure 13).

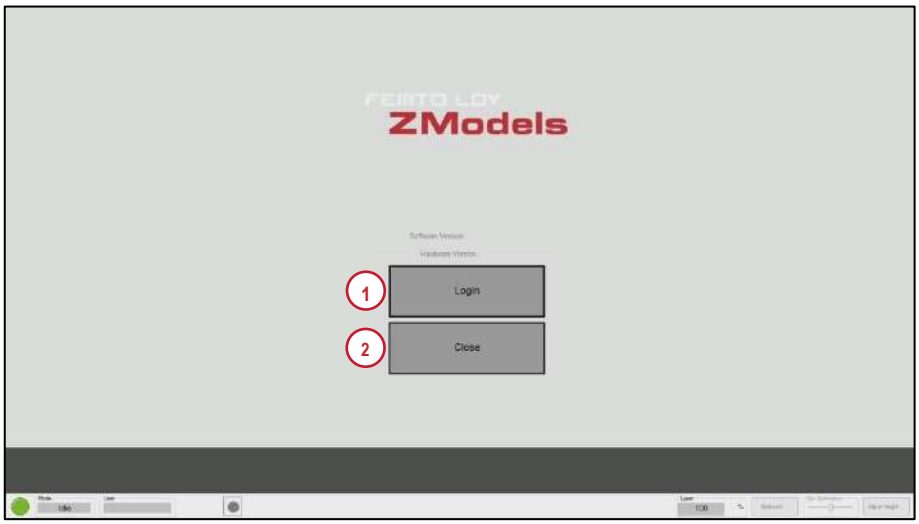


Figure 13: Start screen.

1 **Login:** Touch the Login button to bring up the login display.

2 **Close Application:** Touch the Close Application button to close the application Software. Closing the cornea software will not shut down the system but return to the "Module Selection" screen (see Figure 8).

Hint: Remember to lower table height before closing the application if you intend to transport the LDV. Lift cannot be activated once application is closed.

7.2.5 Login

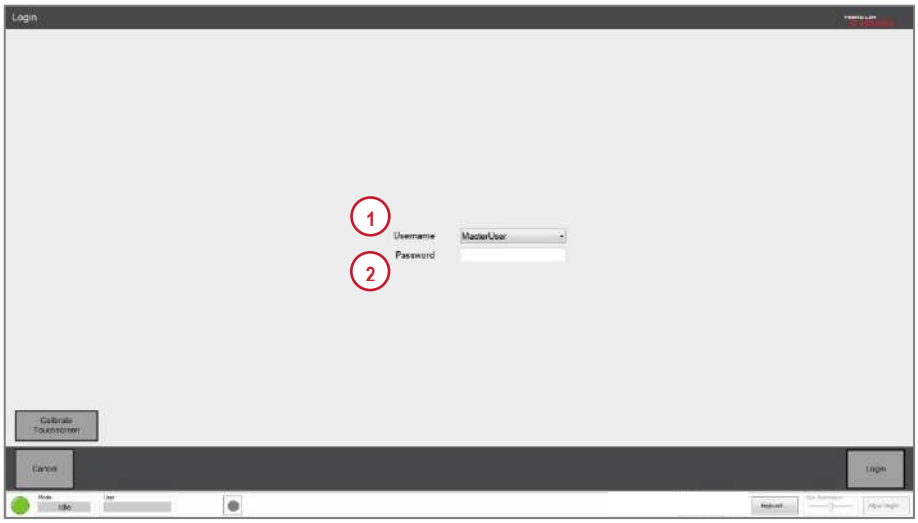


Figure 14: Login screen.

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.

2 Other predefined usernames[2]:

- Service: This profile is defined to perform maintenance and cannot perform any resection.
- MasterUser: This enhanced profile owns resection rights.

3 **Password:** Related to the username chosen.

Hint: Service Login for remote maintenance:

User may have to use a temporary service login to perform some tasks for servicing (see section 11.5 for more details). User will be directed by a Ziemer Customer Service representative to perform this operation.

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

7.2.6 "Main Selection" screen

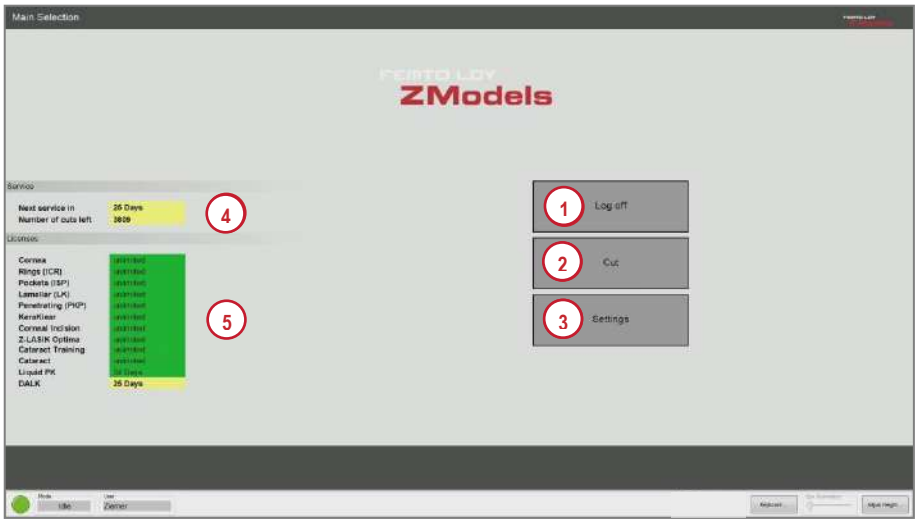


Figure 15: Main selection screen.

1 **Log off:** The current user will be logged off. System returns to "System Start" screen.

2 **Cut:** If no components encountered any level 3 errors, the Cut button is enabled. Cut may be temporarily 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 7.2.11.

4 **Service:** 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.

7.2.7 Patient registration

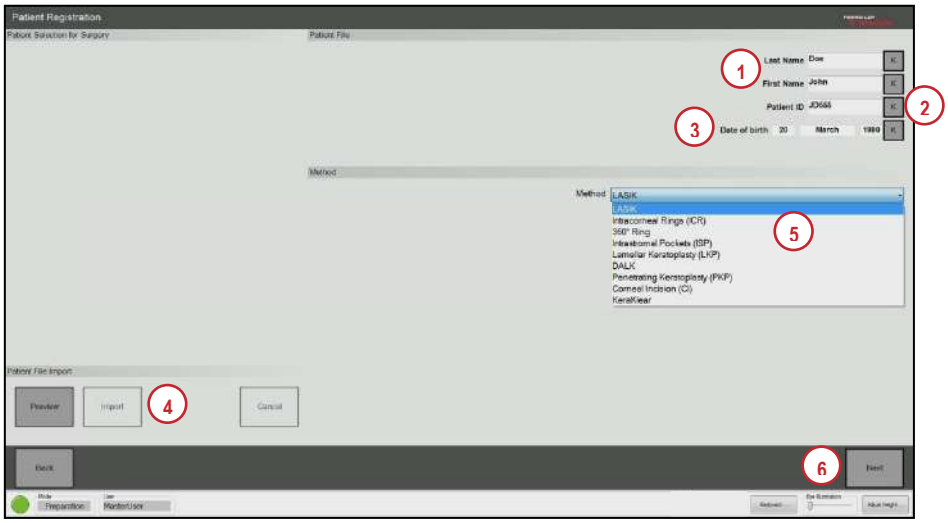


Figure 16: Patient registration.

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.

Hint: 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 Cornea SW Application 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, semicolon or coma-separated csv format and must have the filename /filetransfer/patient_import.csv.
- The format of patient records in the list is: LastName[tab]FirstName[tab]ID[tab]BirthYear[tab]BirthMonth[tab]BirthDay
- 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.
-

Hint: 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. The application that was selected on the “Module Selection” screen (see Figure 8) will appear as the preselected method when entering this screen.

6 Depending on system configuration, the following methods may be activated and can be selected:

- Z-LASIK
- Intrastromal Pockets (ISP)
- KeraKlear

- Intracorneal Rings (ICR)
- Lamellar Keratoplasty (LKP)
- Deep Anterior Lamellar Keratoplasty (DALK)
- Penetrating Keratoplasty (PKP)
- Corneal Incision (CI)

7 Continue by touching **Next**.

7.2.8 "Procedure Pack Scanning" screen

Select an applanating PP for Corneal Surgery, with SR dimensions requested by the surgeon according to the procedure 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 the SR will be displayed. A beep will indicate successful reading.

Figure 17: Procedure pack scanning (Cornea SW Application)

1 **Serial Code:** The serial code appears after the procedure pack has been successfully scanned.

2 **Suction Ring:** Nominal dimension of the chosen suction ring (for corneal applications) will be shown here. This value will be automatically displayed after scanning the procedure pack.

3 **Expiry Date:** Expiration date (Year Month) of the procedure pack scanned.

4 **Confirm Parameters:** If displayed PP type and SR 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 using this PP. Or you may scan another PP if the previous one was not accepted.

After touching the **Next** button, the "Resection Parameters" screen appears.

Hint: 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.

7.2.9 Resection parameters

The resection parameters are part of the Surgical Procedure Manual with API (see section 1.8).

7.2.10 Resection

The applanation and resection process is described in the Surgical Procedure Manual (section 1.8).

7.2.11 Settings

Figure 18: Settings.

1 **System Settings:** Set default system settings (see section 7.2.12).

2 **Service:** Access some service options (see section 7.2.15).

7.2.12 System settings

Figure 19: System settings.

1 **Language:** Select from available languages.

2 **Location:** Set any descriptive text (city, clinic, etc.).

3 **Preferences:** Interface settings.

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 Limits:** 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.

7.2.13 Preferences

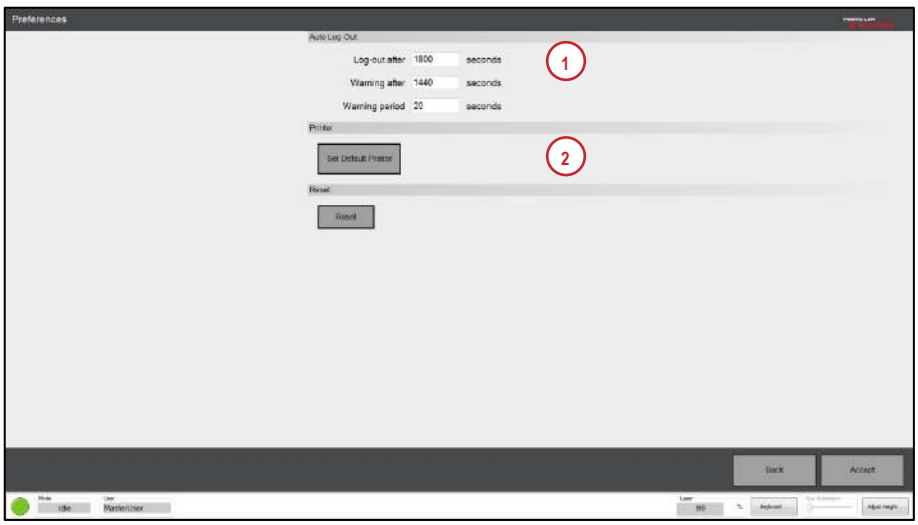


Figure 20: Preferences for the cornea application.

1 **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”.

2 **Printer:** Set the default printer on which reports will be printed. “Print to PDF” is also available.

7.2.14 Network

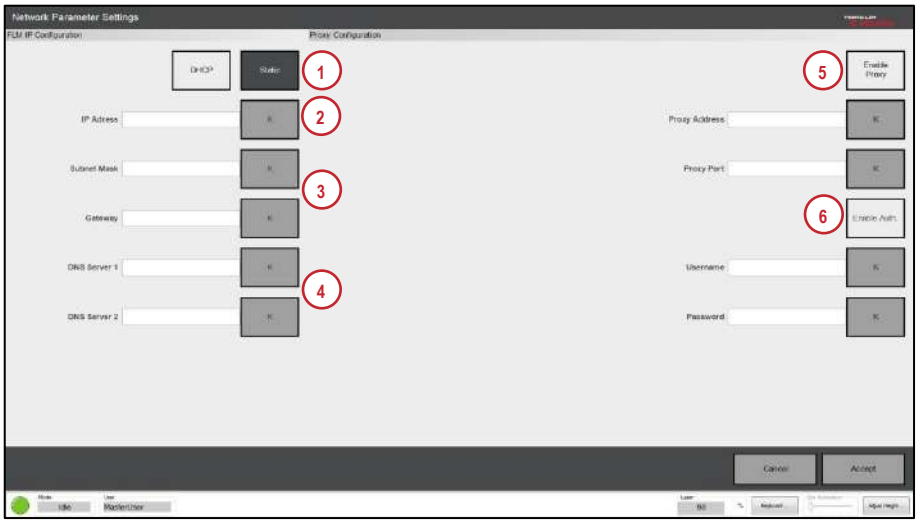


Figure 21: Network settings.

1 **DHCP** (Dynamic Host Configuration Protocol): Set a dynamic address for the LDV from the DHCP server.

2 **Static:** Instead of DHCP, a static address may be set.

3 **IP address:** When static address is set, this field is available for changes. Otherwise, it would be created automatically.

4 **Subnet Mask** and **Gateway:** When static address is set, Subnet Mask and Gateway are available for changes. Otherwise, default values are used.

5 **DNS Server 1** and **2:** IP address(es) of the DNS server(s).

6 **Proxy:** A proxy server can be used if other network configuration settings are not satisfactory. In this case, the proxy address and the proxy port used must be specified.

7 **Enable authentication:** User authentication can be used in conjunction with the proxy server. If selected, the username and password must be specified.

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

Warning: The integration of a Programmable Electronic Medical System into an IT network involving other devices may lead to risks for patients, operators or others that were previously unknown. The organization in charge must determine, analyze, evaluate and manage such risks. Note 3 IEC 80001-1:2010 contains instructions on how the organization in charge may address these risks. Modifications to the IT network that may lead to risks and require

analysis include: Changes to the configuration of the IT network, connection of additional elements to the IT network, removal of elements from the IT network, update of devices that are connected to the IT network, upgrade of devices that are connected to the IT network.

7.2.15 Service

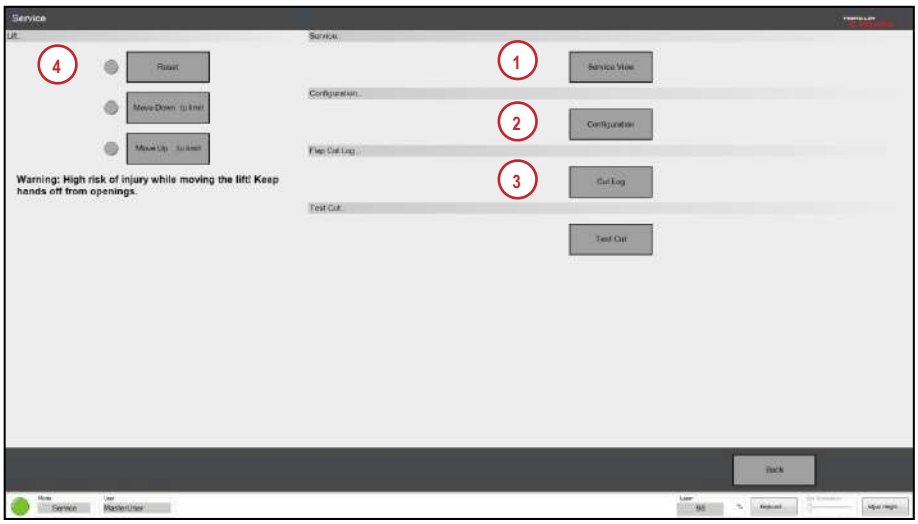


Figure 22: Service main screen.

1 **Service View:** Service view is only available to users with service privileges.

2 **Configuration:** Displays current system configuration (see section 7.2.16).

3 **Cut Log:** To access the flap cut history (see section 7.2.17).

4 **Lift:** If a table lift error is present, these buttons allow you to perform an initialization procedure. First, click on the **Reset** button. This will shut off and then turn 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** to reach the lift lower limit and when target limit reached, click on **Move Up to Limit** to reach the upper limit.

7.2.16 System configuration

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

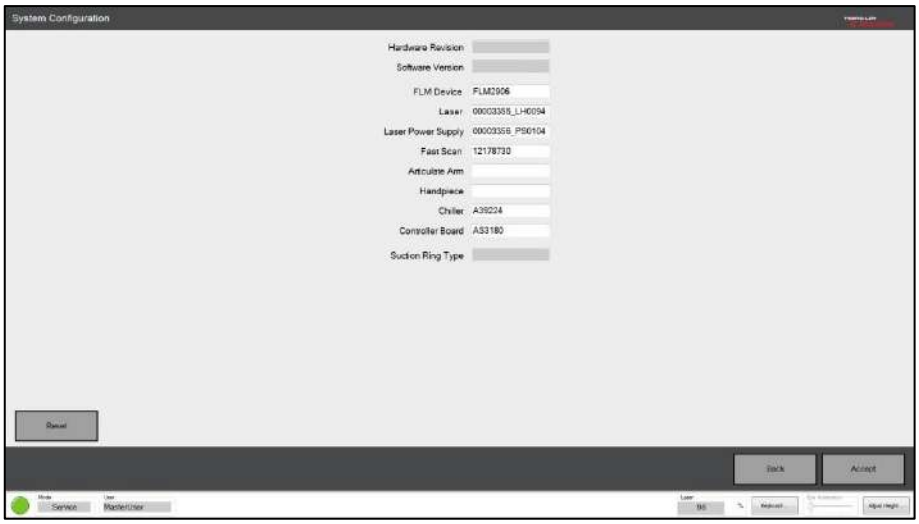


Figure 23: System Configuration

7.2.17 Resection procedure log

Detailed lists of the procedures performed can be created, displayed and printed from this "Flap cut log" screen.

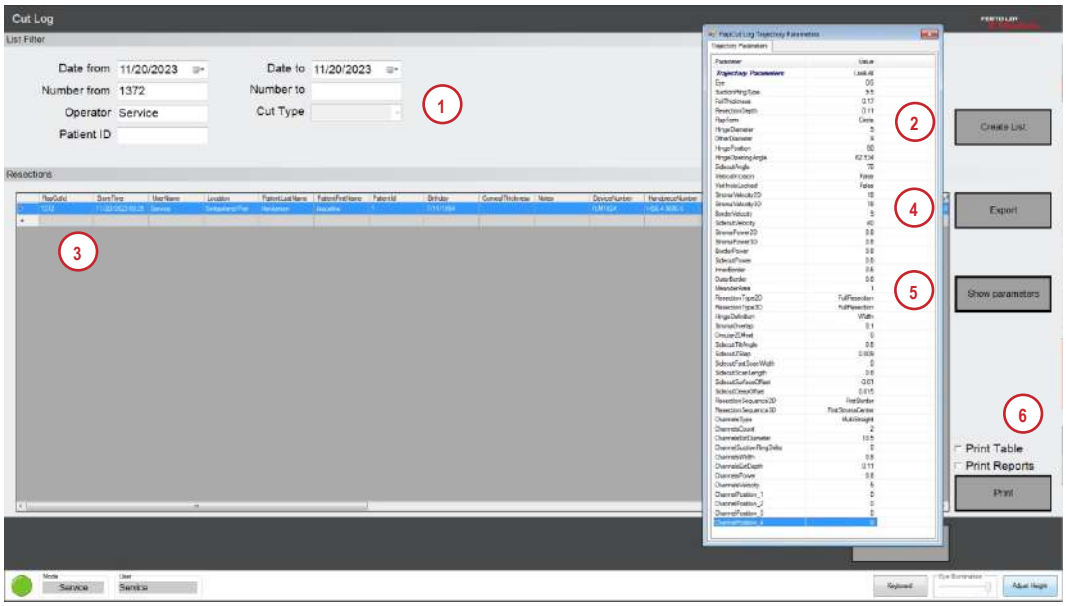


Figure 24: Resection procedure log.

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 section 12.2).

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).

6 **Show Parameters:** This option allows to see all parameters from PathParams column in a window.

7.2.18 Program shutdown

Exiting the Cornea SW Application will not shut down the system but return to the "Module Selection" screen (see section 7). Closing the Cornea SW application is only possible on the "Start" screen (Figure 13). The "Start" Screen can be reached by touching the **Back** button until the "Main Selection" screen appears (section 7.2.6), then press **Log off** and the "Start" screen appears. Press **Close** on the "Start" screen to shut down the Cornea SW Application. A reminder note and a confirmation window will appear.

7.3 Neo App Suite

Refer to Table 1 for a list of all the modules available in the Neo App Suite.

7.3.1 Screen structure

The user interface of the Neo App Suite is structured in four parts that display parameter settings, system status, procedure progress information, and user entries.

Top and bottom of all screens

In all screens, general context information is visible at the top of the window:

1 Patient name
2 Patient's birthdate
3 Suction time counter, displays time since suction was engaged
4 OD/OS indicator
5 Back button, returns to previous step
6 Progress indicator
7 Continue button, continues to next step

Status information is displayed at the bottom of all screens:

1 System status overview: Color of the LED provides level of errors occurred:

- Green: All subsystems are functional.
- Red: Errors occurred which prevent user to perform a new resection. Click on the button to view details.
- Clicking on the system status overview provides access to the following buttons:
- System: Opens the status of system components described in section 11.4.
- Camera: Opens the camera menu where the camera service can be restarted.
- Versions: Opens a list of all installed software versions
-

Note: The camera should only be restarted as long as it is not in use, for example on the planning screen.

2 Counter of currently active system or error messages. Click on the button to view details. Some error messages can be deleted by pressing on the message. Others will stay active and prevent the continuation of the procedure.

3 Abort button interrupts the current procedure. During an active resection, it stops the laser treatment and releases the vacuum docking.

4 Base station lift up/down buttons. Height of top surface may be adjusted from 890 to 1190 mm. This control is not available during resection procedure.

5 Exit button. It is followed by a confirmation dialog, and if the closing of the application is confirmed, the “Module Selection” screen appears after a short waiting period.

Note: The screen may go black for some seconds before the “Module Selection” screen reappears.

7.3.2 Start-up Neo App Suite applications

After device start-up and selection of an application of the Neo App Suite within a specific treatment area (“Module Selection” screen, see page 35), the operator/physician login Screen will be displayed. No Procedure Pack scanning is possible until the laser cavity is ready (Hardware status is green).

7.3.3 Login

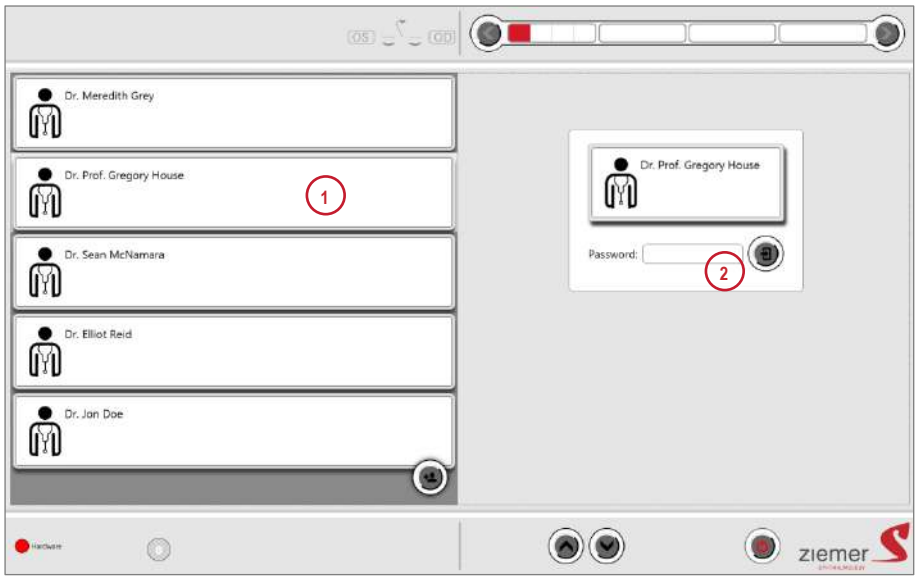


Figure 25: Login screen “Neo App Suite”

1 Select the operator/physician from the available list of operators who have been trained for operating the LDV, by touching the appropriate name.

2 Enter operator’s password and touch the Enter button.

7.3.4 Patient registration

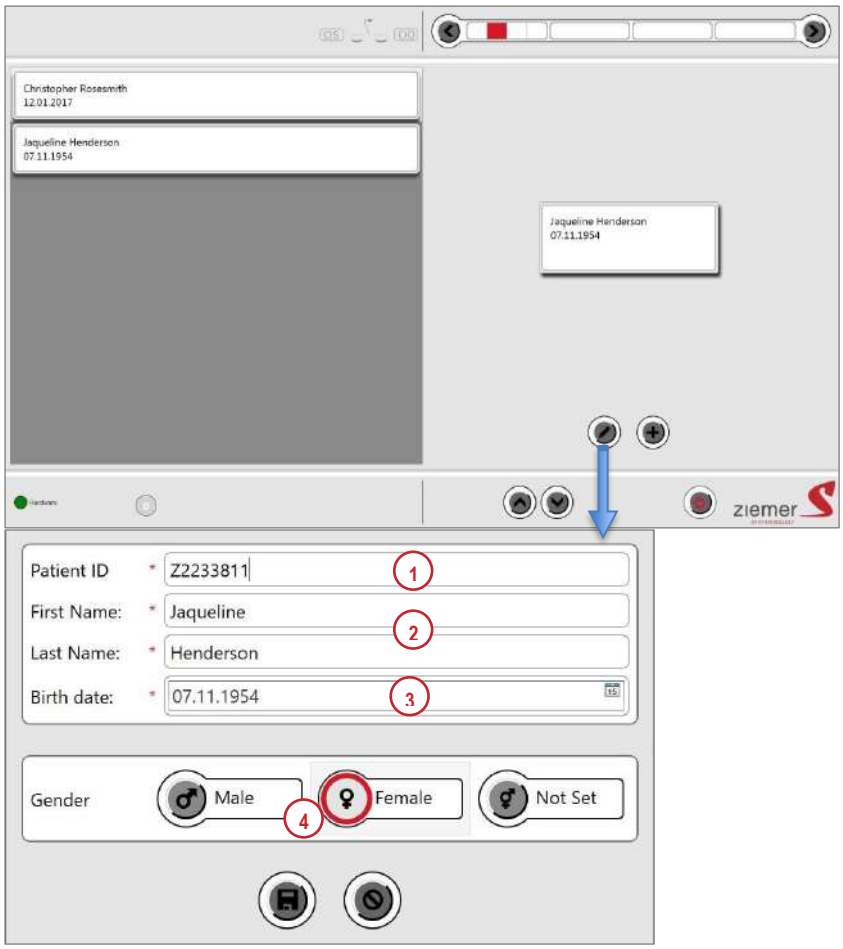


Figure 26: Patient registration.

To create a new patient entry, touch the “New Patient” button and enter all patient data.

1 **Patient ID:** Patient ID may be any combination of alphanumeric characters.

2 **First and Last Name:** Enter patient name. Any uppercase and lowercase characters are accepted.

3 **Birth date:** 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.

4 **Gender:** Enter patient gender (optional).

7.3.5 Method selection

Select the eye to be treated and the method(s) to be performed. At this point switching between applications of the Neo App Suite is still possible. After correct method selection, touch the Continue button.

7.3.6 Scanning a procedure pack

When the “Procedure Pack” screen is presented:

Figure 27: Procedure Pack Scanning (Neo App Suite)

1 Hold a new, unused procedure pack against the area marked ID on the front panel of the LDV base station. If the PP is successfully read, the message “Procedure Pack accepted” will be displayed.

2 Touch the **Continue** button in the progress bar (top right of screen) to continue to the planning parameters.

Hint: 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.

7.3.7 Planning screens

There is a planning screen for each method chosen. Initially the user’s default treatment parameters will appear. They can now be adjusted individually for the current patient.

For information on how to adjust the parameters, refer to the specific Surgical Procedure Manual (section 1.8).

7.3.8 Resection parameters

The resection parameters are explained in the specific Surgical Procedure Manual (see section 1.8). The manual provides the recommended standard values for all parameters.

7.3.9 Resection

Applying the patient interface to the patient eye, filling the interface with water, applying suction, and docking the HP to the patient interface. After these steps are performed, final adjustments can be done, as explained in the specific Surgical Procedure Manual (see section 1.8).

7.3.10 Program shutdown

Touch the **Exit** button (lower right of screen). A reminder note and a confirmation window will appear.

Exiting the software will not shut down the system but return to the “Module Selection” screen (see section 7).

Hint: Remember to lower table height before closing the application if you intend to transport the LDV. Lift cannot be activated once application is closed.

7.4 Patient Report (Cornea Software Application)

To access the Patient Report Tool for the Cornea Software Application, use the same surgeon login as in the specific application program. After the login a list of all the performed surgeries of the specific surgeon is displayed. The patient list on the left side can be filtered by editing the date range of the surgery. Each patient selected in this list can be added to the report list on the right side of the screen. For each patient added to the report list, an individual surgery report will be produced.

An external USB storage device needs to be connected to the device to be able to create reports.

After each procedure, it is possible to create a patient report with the most important parameters and information. To do this, click on "End Surgery" after the cut procedure to access the summary screen (see Figure 28: Patient Report Tool for Cornea Software Application). The patient report can be created using the "Print" button.

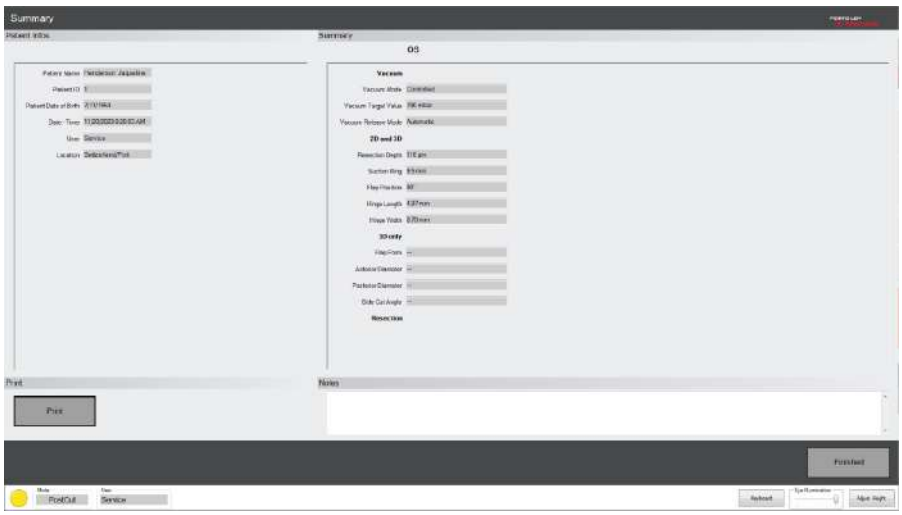


Figure 28: Patient Report Tool for Cornea Software Application

The patient report can also be created retrospectively for the desired patient. To do this, you can go to the settings in the "Main Selection" screen and then open the "cut log" under "Service" (see 7.2.15) and select the relevant patient(s).

7.5 Surgery Report (Neo App Suite)

To access the Surgery Report tool for the Neo App Suite applications, use the same surgeon login as in the specific application program. After the login a list of all the performed surgeries of the specific surgeon is displayed. The patient list on the left side can be filtered by editing the date range of the surgery. Each patient selected in this list can be added to the report list on the right side of the screen. For each patient added to the report list, an individual surgery report will be produced.

An external USB storage device needs to be connected to the device to be able to create reports.

Hint: Do not connect the USB storage device before entering the Surgery Report tool. Only USB storage devices connected to the system, while the tool is running, will be recognized by the system.

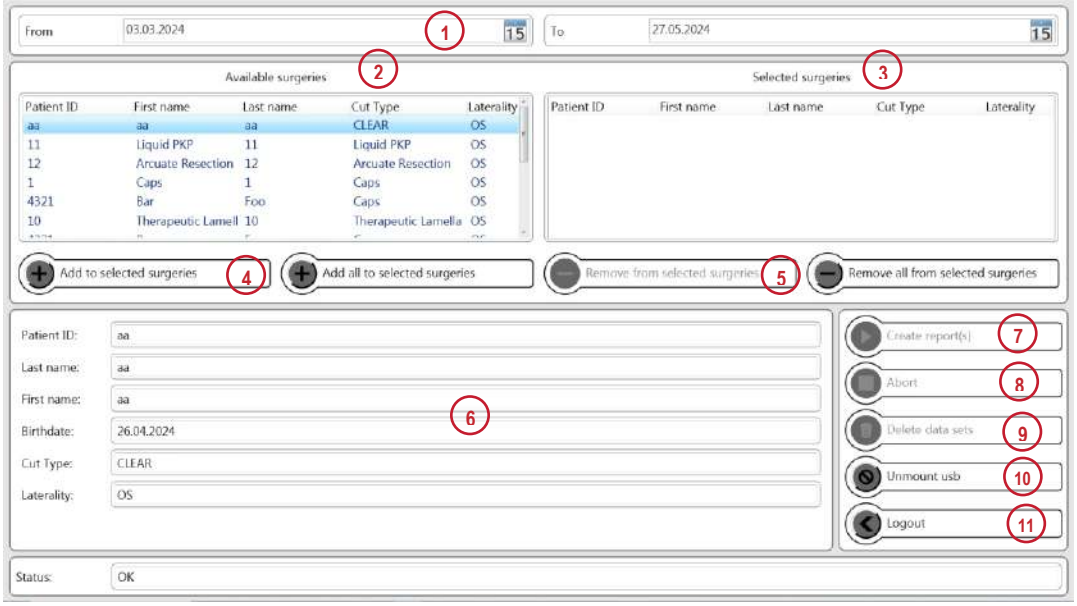


Figure 29:Surgery Report Tool for Neo App Suite

1 **Date:** The “available surgeries” list only displays surgeries performed in the chosen date range.

2 **Available surgeries:** List of all the performed surgeries (within the selected time span) of the surgeon currently logged in.

3 **Selected surgeries:** For each surgery added to this list, a surgery report will be produced.

4 **Add to selected surgeries:** To add a specific surgery to the “selected surgeries”, select the entry in the “available surgeries” list and click on ⊕ **add to selected surgeries**. To add all the surgeries to the “selected surgeries”, click on ⊕ **add all to selected surgeries**.

5 **Remove from selected surgeries:** To remove a specific surgery from the “selected surgeries”, select the entry in the “selected surgeries” list and click on ⊖ **remove from selected surgeries**. To remove all the surgeries from the “selected surgeries”, click on ⊖ **remove all from selected surgeries**.

6 **Patient information:** Patient information of the currently selected surgery.

7 **Create report(s):** Connect an USB device, then press this button to create the reports. For each surgery in the “selected surgeries” list, a separate report is created.

8 **Abort:** Press the “Abort” button to stop an active creation of reports. Already exported reports are not affected.

9 **Delete data sets:** When all selected surgery reports have been saved on the USB device, press this button to delete the selected data sets of all the exported surgeries. This will free hard disk space on your system for new surgery data sets. Deleting of each selected surgery takes about 5 seconds.

10 **Unmount USB:** When all surgery reports have been saved on the USB device, press this button for safe removal of the USB device.

11 **Logout:** After pressing the **logout** button, the “Module Selection” screen appears again. When all selected reports are exported, touch the **logout** button to close the Surgery Report tool. The “Module Selection” screen (see section 7) will reappear.

8 SURGICAL PROCEDURE

8.1 Primary Decisions

Operation of the LDV normally involves three individuals:

1 Trained doctor
2 Trained Healthcare professional (sterile)
3 Trained Healthcare professional (non-sterile)

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

Positioning of LDV relative to Excimer Laser (for LASIK surgery):

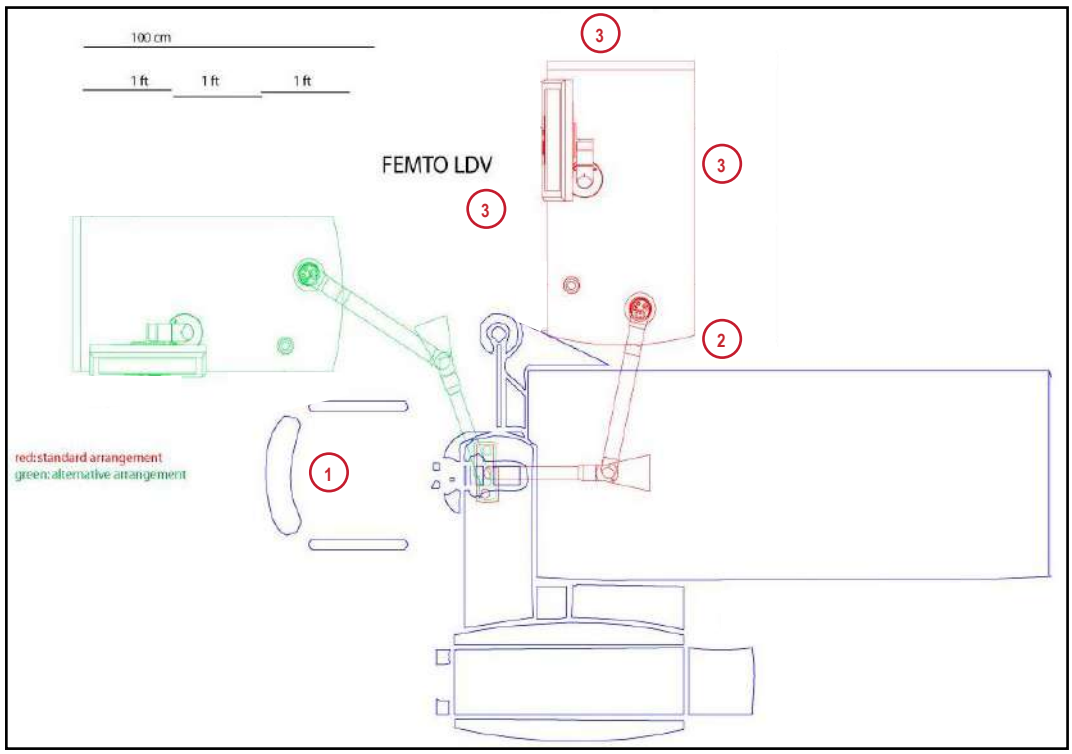


Figure 30: Schematic layout of an operating room for corneal surgery with the Femto LDV and ablation laser.

The trained doctor is sitting behind the patient's head during surgery (1).

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

To operate the LDV, the non-sterile HCP is in position (3).

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

Front, facing the patient **Left**, turned away from the doctor.

Back, turned away from patient **Right**, facing the doctor

8.2 Step-by-Step Overview of Surgery

Each surgical procedure is described in detail in the corresponding Surgical Manual (see section 1.8).

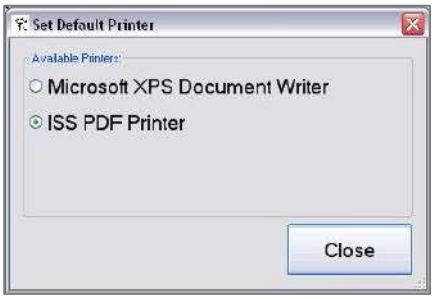
8.3 Cleaning and Disinfection

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.
Seals	HP and FMAA are sealed against dust and moist cleaning.
Single-use HP Casings	Disposable HPCs are shipped in a sterile package and disposed after each patient.
Single-use Patient Interface	Sterile disposable PI is 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.

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

8.4 Printing (for Cornea SW Application)

A printer can be connected via USB interface. Printouts are then obtained by touching the Print button on the “Summary” screen or on the “Resection Procedure Log” screen (see section 7.2.17)[3]. 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 12.2). The USB interface connector is located on the backside, under the cover on the bottom of the BS (see section 5.4, Hardware interfaces).



[3] The printer driver currently installed on the LDV supports printers of the HP-5700 family (printer not supplied by Ziemer). For installation of any other printer type, contact the Ziemer Customer Support.

9 CALIBRATION AND ADJUSTMENTS

9.1 Power Check

The LDV contains internal power sensors that monitor 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.

9.2 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.

9.3 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.

9.4 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. A Ziemer Customer Service representative 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 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.

9.5 Pulse Optimization Routine

Laser Power output level is monitored continuously. The pulse optimization routine adjusts the femtosecond pulses for best surgery results.

During the pulse optimization routine, a resection procedure cannot be started. During a resection procedure, no pulse optimization routine will be attempted by the system.

9.6 Handpiece Bearings Alignment

During the start-up procedure of the LDV and before every resection procedure, the internal alignment of the mechanical components 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 to start the routine.

Figure 31: Handpiece bearings alignment

10 SERVICE AND MAINTENANCE

The LDV is a mode-locked 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 Customer Service representative periodically.

This device is tested for 5 years of operation and a semi-annual preventive maintenance service must be provided by a specially trained Ziemer Customer Service representative. Upon successful maintenance and testing, the device is released for another semi-annual cycle.

As your first point of contact for support we strongly recommend to always contact the distributor from whom you purchased your instrument.

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

In order to enable Ziemer 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.

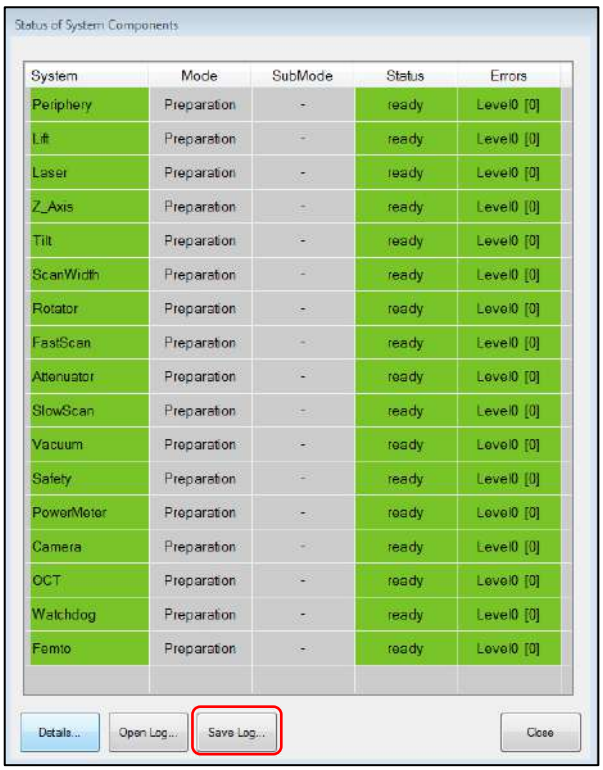


Figure 32: Status of system components.

Touching **Save Log**, a file browser (see Appendix, section 12.2) opens to allow you to choose the destination for these files (as formatted texts).

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

- International Customer Service Center in Switzerland: phone +41 848 943 637
- American Customer Service Center (USA and Canada): phone +1 866-708-4472

Remote maintenance is available on the LDV, using the Remote Access application. By connecting the LDV to the Internet, Ziemer's Customer Support can perform maintenance and troubleshooting tasks remotely without any contribution from the user side. This might help to reduce downtime.

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 image in section 5.4).

To activate remote maintenance, use the keyboard shortcut [ALT+T] or double-click on the "Femto" sub-system in the status of the system components. The "Access" screen below is then displayed to warn the user that a restart will be compulsory after servicing and before any resection process.

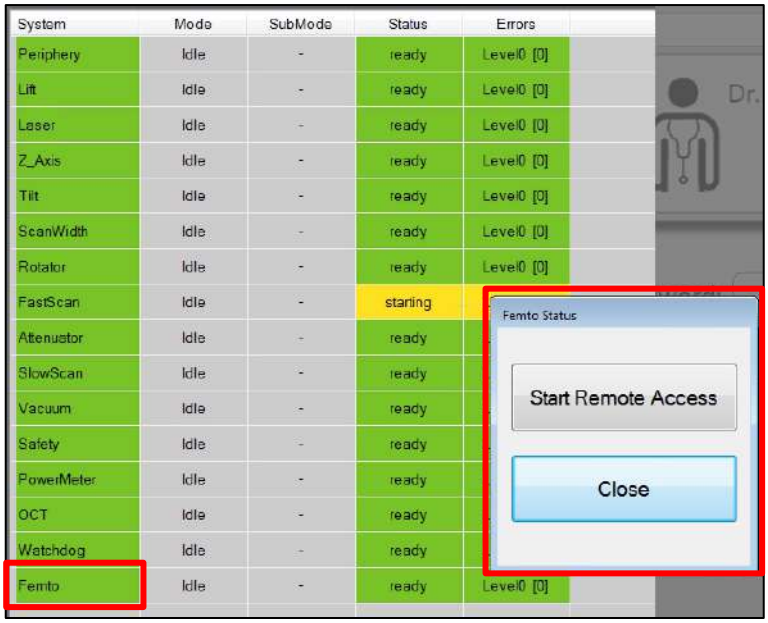


Figure 33: Status of the system components window with start button for remote access.

Figure 34: Remote access confirmation.

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.

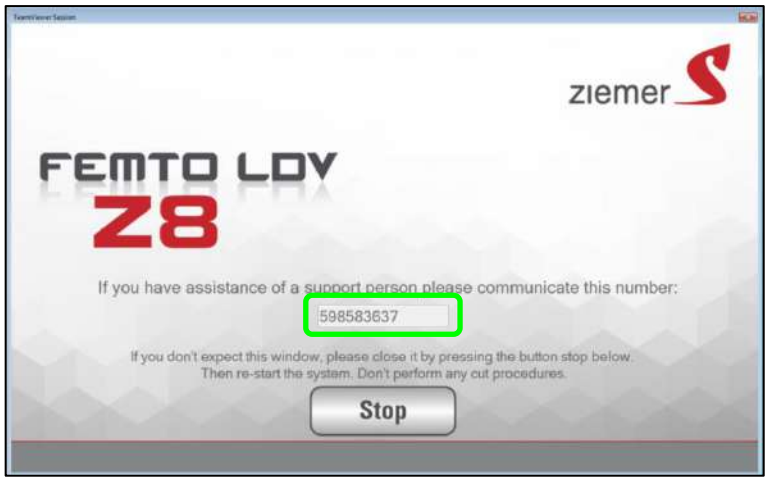


Figure 35: Example of remote access number.

10.1 Disposal

	In accordance with Directive 2012/19/EC of the European Parliament and of the Council of 4 July 2012, and in accordance with Swiss law governing marketing, return and environmentally compatible disposal of used electrical and electronic devices, such appliances must be recycled and may not be discarded as household waste. Dispose the LDV in a compliant manner.

10.2 Device Registration

Every device must be re-registered on an annual basis. The first and second warning appear about 3, respectively 2 months, before expiration. 30 days before the registration expires, the warning message is displayed daily. To perform the registration, click the “Settings & Support” button on the module selection screen (see Figure 8), then click on “Registration” (see Figure 36). Connect the device to the internet.

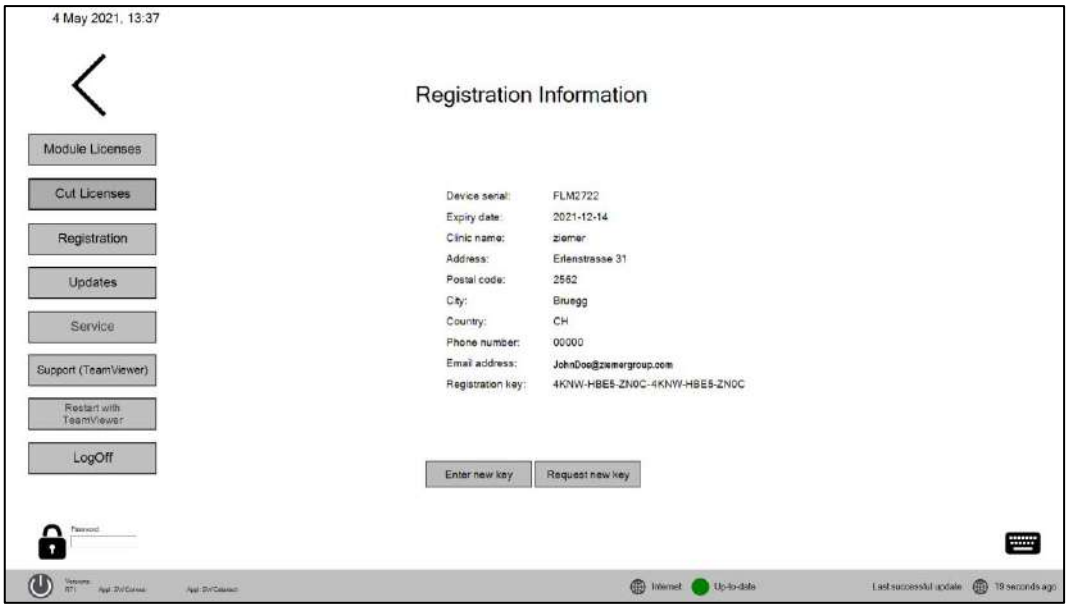


Figure 36: Registration Information

Click on “Request new key” and check or correct the registration information. Accept the Ziemer Privacy Policy and click “Submit”. Submitting the request requires a synchronization, which may require reconnecting the Ethernet cable. After submitting the request, a new registration key is sent to the Email address entered in the registration information. The new registration key should arrive within approximately 30 minutes after synchronization.

After receiving the new key, click on “Enter new key” (see Figure 36). Enter the key and click “Register” to register the device for another year (see Figure 37).

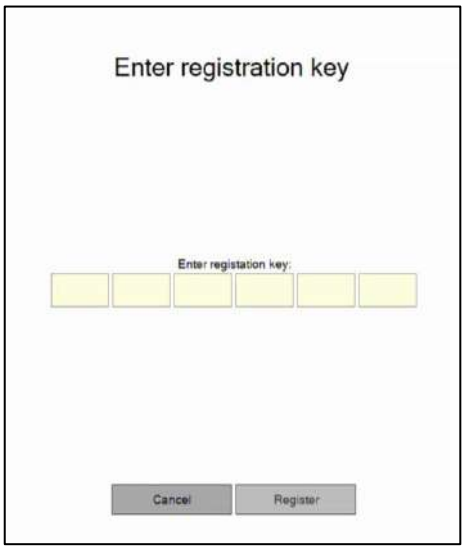


Figure 37: Enter registration key.

Note: If the device cannot be connected to the internet and must be registered by USB stick, contact your local representative.

11 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 an authorized Ziemer Customer Service representative.

Note: Any serious incident that occurred in relation to the LDV should be reported to the manufacturer and the competent authority of the member state in which the user is established.

11.1 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. 
	Key switch not enabled	Turn key switch.
	Fuse1, F2 or F3 tripped.	Press F1, F2 or F3 (see photo in section 5.4).
Vacuum not reaching target value	Tube leaking or defective.	Check or replace tube.
	HP not positioned properly on eye.	Adjust HP on eye to achieve complete applanation.
Cannot reach vacuum	Leak.	Check tube. Contact Ziemer Customer Support.
	Target vacuum too high.	Set Target to ≤ 700 mbar. (only Cornea SW Application)
	LDV is installed high above sea level.	Set Target to 650 mbar (only Cornea SW Application).
Laser does not start	Laser cavity not stable.	Occasionally, depending on internal conditions of the laser cavity or external ambient conditions, the cavity may require more time to reach stability. Wait for 15 minutes to see if error clears.
	Laser cavity defective.	Please contact your Ziemer Customer Support representative.
	Interlock open.	Check interlock switch (see photo in section 4)

Problem	Cause	Solution
		and press “Enable Laser” in the “Laser Status” (see section 11.4.3).
Fast Scan does not reach target value	Malfunction.	Please contact your support representative.
Height adjustment does not work	Not allowed during vacuum suction.	Press Abort to release vacuum and return to the “Docking” screen.
	Emergency stop pressed.	Release emergency stop and try again.
	Not initialized properly.	Restart LDV. If problem persists, contact Ziemer Customer Support.
System cannot be moved	Brakes set.	Release brakes (see drawing in section 5.9).
Flap cut does not start	Fast Scan not within limits.	Please contact your support representative.
	Laser power not within limits.	Check laser (see section 11.4.3).
	Vacuum not within limits.	Check vacuum (see section 11.4.11).
	Rotator not adjusted.	Ensure that suction ring is attached correctly to eye during adjustment process.
	HP malfunction.	Please contact your support representative.
	Service limit reached.	Contact Ziemer Customer Support.
Bearing adjust failed	Slow Scan cannot reach target position.	1) Perform bearing adjust in status of system components. 2) Please contact Ziemer Customer Support.
Laser not between 92% to 108 %	Not completely started up.	Wait one hour after switching on.
	Not mode locked.	Wait one hour and then restart system.
Procedure Pack (PP) not readable	Moved PP too fast.	Hold PP against the glass again, do not move rapidly.
Power meter is not working	Communication error.	Reconnect power meter.
Footswitch is not working	Disconnected.	Connect footswitch.
External keyboard not working	Discharged keyboard.	Recharge with included charging cable.
	Keyboard is active until vacuum button is pressed.	Leave flap cut window.

11.2 Problems Relating to OCT Imaging (Neo App Suite)

Problem	Cause	Solution
OCT image with poor contrast (weak signal).	The plug of the fiber – either at the base unit or at the FMAA – is not connected properly. Dirty fiber.	1) Be sure that the fiber plug is fixed correctly in the fiber connector of the base unit. 2) Be sure that the fiber plug is fixed correctly in the fiber connector of the FMAA. 3) Clean fiber at the base station connection.
No OCT image is visible.	The OCT-SW or the OCT-HW has not been correctly initialized.	1) Restart manually the OCT scanning process. 2) Reinitialize the OCT system by means of status of system component. 3) Switch off the LDV and restart the system.
Only the upper part of the OCT image is visible.	The image visualization did not work.	Make a rescan.
Cornea or lens is not properly recognized by the edge detection routine in the cataract software.	The image visualization did not work due to poor image quality.	1) Make a rescan. 2) Confirm the warning and manually shift the resection pattern to the desired position.

11.3 Error Code List

Hint: Error messages with numbered error codes apply to the Cornea SW Application only.

Error code	Error message	Solution
Errors 1000 - 1340	Various Initialization error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.
Error 1350	HP is not in Parkholder! Please place HP into parkholder.	Make sure the HP is correctly placed into the parkholder. Make sure the parkholder has the correct position.
Errors 1400 - 1447	Various Slow Scan error messages.	Check proper connection of HP cables. If error remains, reboot System. If error remains, please call the Ziemer Customer Support.

Error code	Error message	Solution
Error 1452	Alignment of the bearings FAILED!	Perform a successful Align-Bearings Process (see Handpiece Bearings Alignment in section 9.6). There might be a hardware problem.
Error 1460	Slow Scan signaled BAD state!	Check proper connection of HP cables. If error remains, reboot System. If error remains, please call the Ziemer Customer Support.
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.
1480-1491	Various Slow Scan Error messages for Z-Axis HP.	Check proper connection of HP cables. If error remains, reboot System. If error remains, please call the Ziemer Customer Support.
Error 1500 - 1569	Various Vacuum error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.
Error 1570	Vacuum Tube Test FAILED!	Make sure suction ring is connected and vacuum tube is unblocked.
Errors 1600 - 1744	Various Laser and Shutter error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.
Error 1800	Command to init Fast Scan Control FAILED!	Please contact the Ziemer Customer Support.
Error 1810	Command to start Fast Scan FAILED!	Reboot System. If error remains, please call the Ziemer Customer Support.
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 Ziemer Customer Support.
Errors 1900 - 1980	Safety Control error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.
Error 2000	Command to init Attenuator Control FAILED!	Software problem: Please call the Ziemer Customer Support.
2004-2005	Various Attenuator error messages.	Reboot System. If error remains, please call Ziemer Customer Support.
Error 2010	Attenuator adjust power FAILED!	Retry, if error remains, reboot System. If error remains, please call the Ziemer Customer Support.

Error code	Error message	Solution
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 Ziemer Customer Support.
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 2100	Command to init Mirror Control FAILED!	Retry. If error remains, reboot System. If error remains, please call the Ziemer Customer Support.
Error 2200	Watchdog HW test FAILED!	Reboot System. If error remains, please call the Ziemer Customer Support.
Error 2210	Watchdog timeout error!	Reboot System. If error remains, please call the Ziemer Customer Support.
Error 2300	Slow Scan failed during Flap Cutting!	Try to Recut. If error remains, reboot system. If error remains, please call the Ziemer Customer Support.
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 Ziemer Customer Support.
Error 2452	The Data-Grabber is still running, cutting is not possible.	Reboot System. If error remains, please call the Ziemer Customer Support.
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 Ziemer Customer Support.
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 code	Error message	Solution
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 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 2600	Command to init Power-Meter FAILED!	Reboot System. If error remains, please call the Ziemer Customer Support.
Errors 2700 - 2790	Z-Axis error messages.	Check the proper connection of HP cables. If error remains, reboot System. If error remains, please call the Ziemer Customer Support.
Errors 3000 - 3050	Camera error messages.	Check the proper connection of HP cables. If error remains, try to reset camera in “Status Of System Components”. If error remains, please call the Ziemer Customer Support.
Errors 4000 - 4999	Application error messages.	These errors are dependent from application. Check that all values are valid in “Parameter” screen.
Errors 5000 - 5999	Application error messages.	These errors are dependent from application. Check that all values are valid in “Parameter” screen.
Errors 6000 – 6006	Various Tilt error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.
Errors 6501 – 6506	Various Scan Width error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.
Errors 7000 – 7016	Various OCT error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.

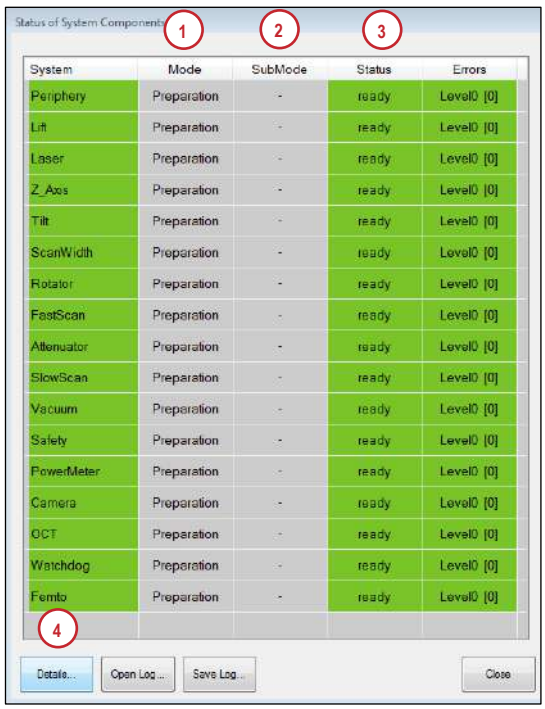
Error code	Error message	Solution
Errors 8000 – 8011	Various Low Level error messages.	Reboot System. If error remains, please call the Ziemer Customer Support.

11.4 System Status Overview

Via the system status overview in the lower left corner, detailed information on system components and basic tests can be performed if requested by Ziemer Customer Support.

System Status Overview

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



1 **Mode:** Same mode as displayed in main screen (of Cornea Software Application).

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 by clicking this button (only Cornea SW Application) or by double clicking the item.

11.4.1 Periphery

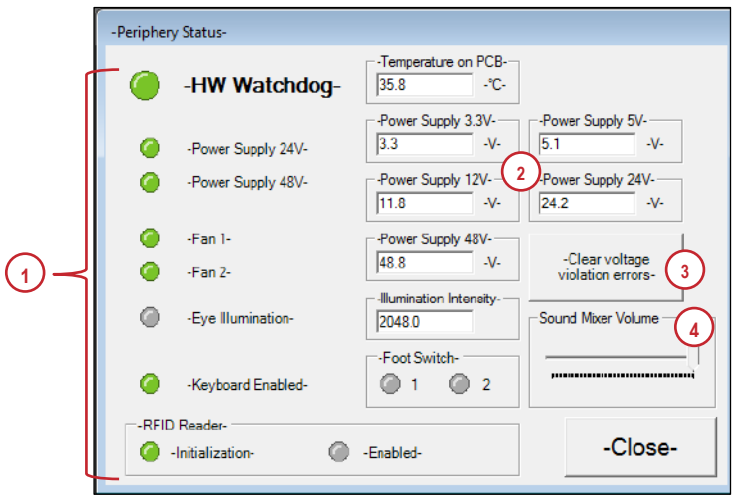


Figure 38: Periphery status screen.

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 Ziemer Customer Support.

4 **Sound Mixer Volume:** The volume of the system and the audio messages can be set here.

11.4.2 Lift

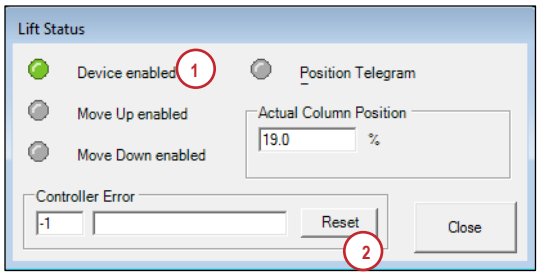


Figure 39: Lift status.

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 Ziemer Customer Support.

11.4.3 Laser

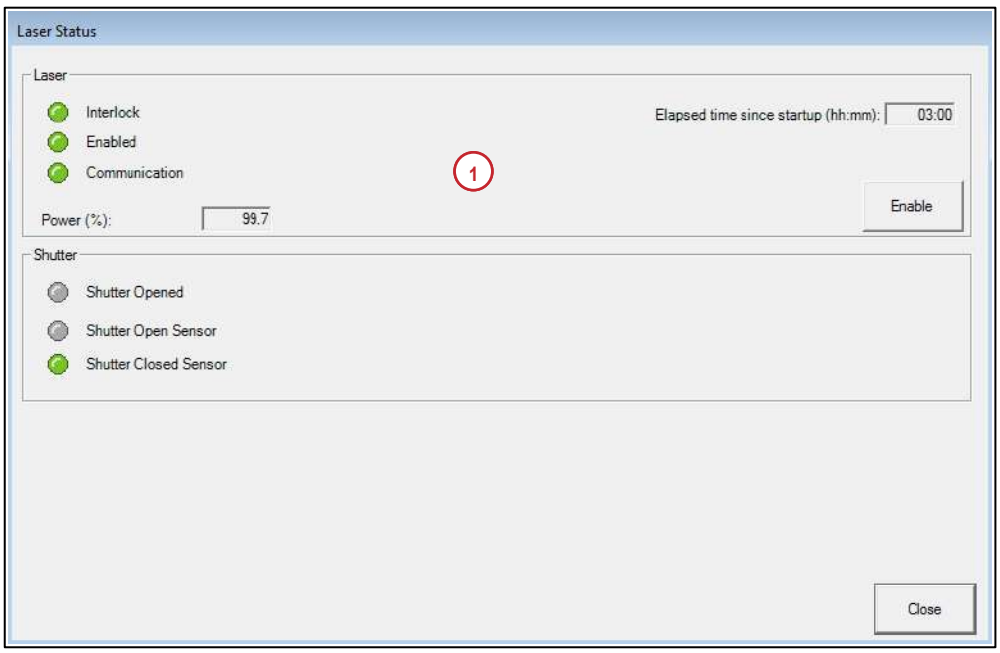


Figure 40: Laser status.

1 **Enable Laser:** Allows the user to manually enable the laser. This button is not available at initialization and with a running laser.

2 **Laser Status LED:** All these LEDs must be green for the laser to be considered fully operational.

3 **Power (%):** Mean value from measurements before the Fast Scan unit.

4 **Shutter Status LED:** Shutter LEDs indicating whether the shutter is open or closed.

11.4.4 Z-Axis

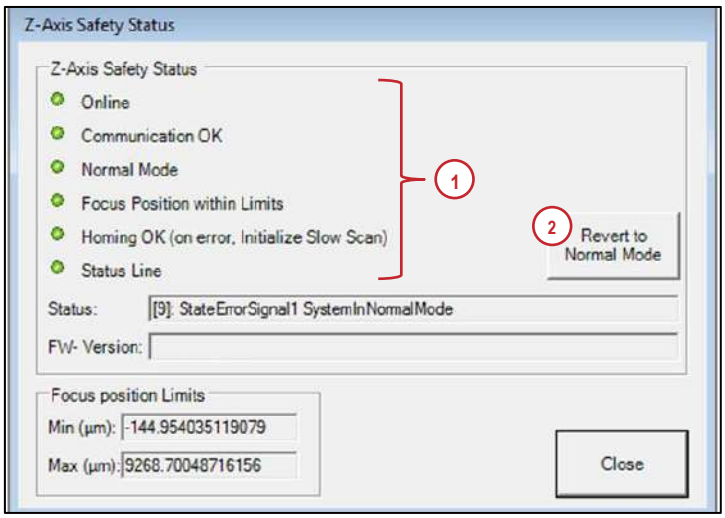


Figure 41: Z-Axis Safety status.

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.

11.4.5 Tilt

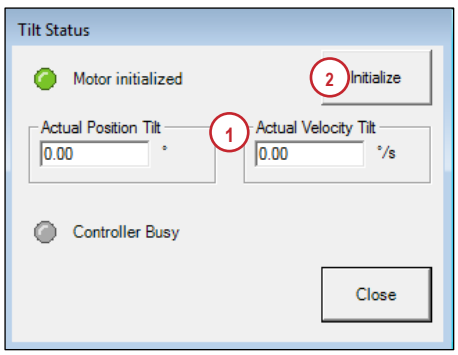


Figure 42:Tilt status.

1 **Actual Position** and **Velocity:** Displays the current position and velocity of the Tilt axis.

2 **Initialize:** Resets the Tilt axis and performs all required checks to consider it as fully operational.

11.4.6 Scan width.

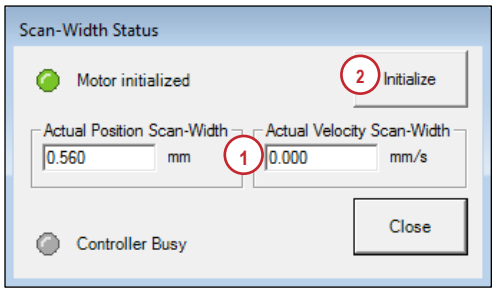


Figure 43: Scan-Width status.

1 **Actual Position and Velocity:** Displays the current position and velocity of the Scan-Width axis.

2 **Initialize:** Resets the Scan-Width axis and performs all required checks to consider it as fully operational.

11.4.7 Rotator

As described in section 6.1, 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 HP generating a rotation control beam, and a pair of rotator sensors in the base station.

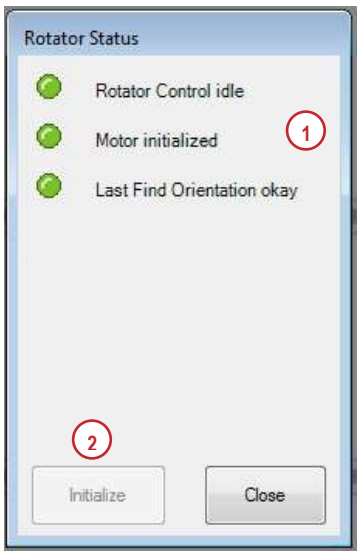


Figure 44: Rotator status.

1 **Rotator Control idle, Motor initialized, Last Find Orientation okay:** All status LEDs must be green for the regular functioning of the laser.

2 **Initialize:** Reinitializes the rotator motor and corresponding sensors to reach the required orientation of the laser line.

11.4.8 Fast scan

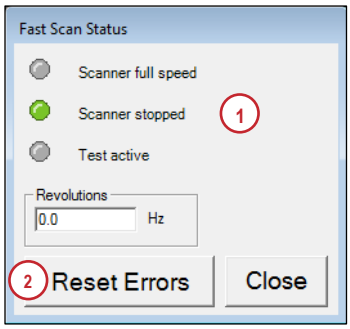


Figure 45: Fast scan status.

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 Ziemer Customer Support.

11.4.9 Attenuator

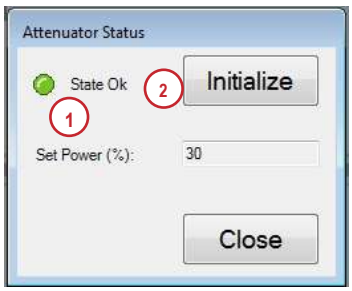


Figure 46: Attenuator status.

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.

11.4.10 Slow scan

The Slow Scan unit moves the focusing lens across the eye in a scanning pattern generated by the system software, thereby generating a three-dimensional resection surface.

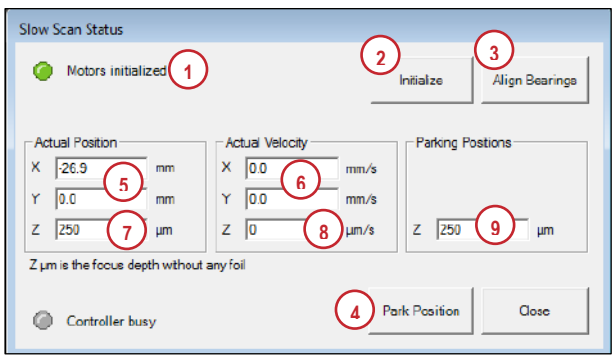


Figure 47: Slow Scan status.

1 **Motors initialized:** Motors are working properly (green LED).

2 **Initialize:** Moves the focusing lens along the x, y and z axes to minimum and maximum limit position. The inbuilt sensors monitor actual motor positions.

3 **Align Bearings:** Same task as described in section 9.6 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: -26.85 to 6.15 mm; y-drive range: -6.15 to 6.15 mm. Position X up to -27 mm 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 25 mm/s and 10 mm/s (5 mm/s at the border) during resection process.

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.

11.4.11 Vacuum

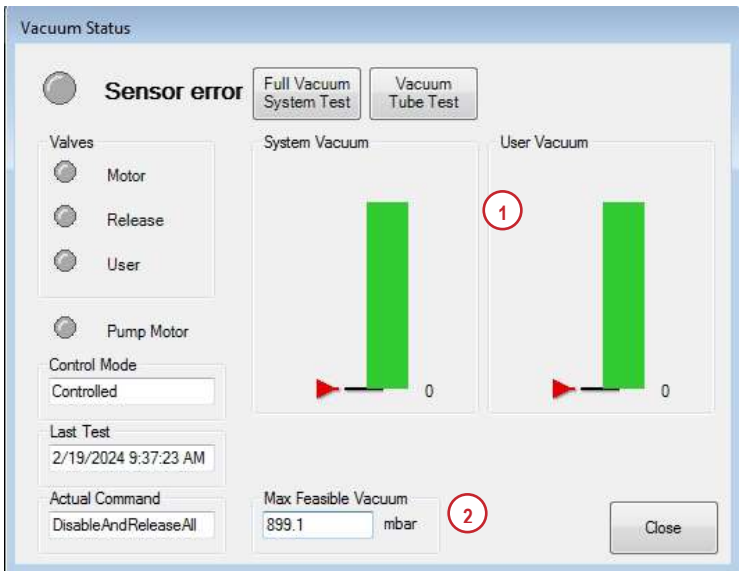


Figure 48: Vacuum status.

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 **Max Feasible Vacuum:** Displays maximum value allowed. This can be influenced by the altitude where the system is being used.

11.4.12 Safety

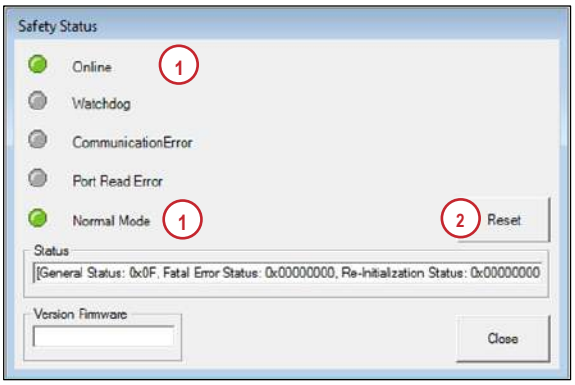


Figure 49: Safety status.

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.

11.4.13 External power meter

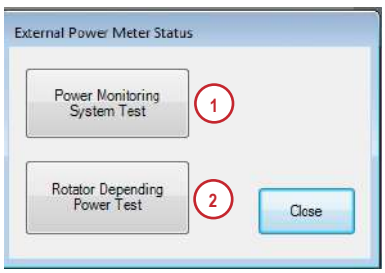


Figure 50: External power meter status.

1 **Power Monitoring System Test:** Press the button to perform a power measurement. To perform this test a power meter and a service dongle is required.

2 **Rotator Depending Power Test:** Press the button to perform a rotator depending power test. During this test the power will be measured in different handpiece positions. To perform this test a power meter and service dongle is required.

Refer to document FL5940-2034 “Transport and Check FEMTO Z8 and Neo” for more details.

11.4.14 Camera

This window is only available in the Cornea application SW. In the Neo App Suite the Camera is a separate button in the System Status Overview (see section 7.3.1)

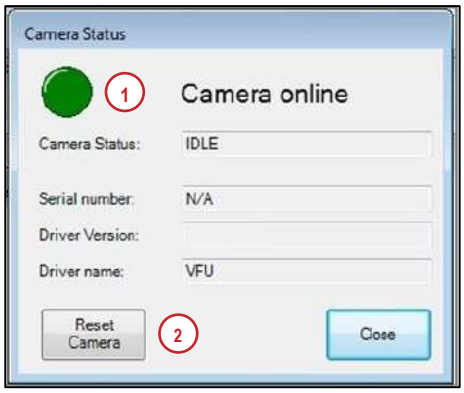


Figure 51: Camera status.

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.

11.4.15 OCT

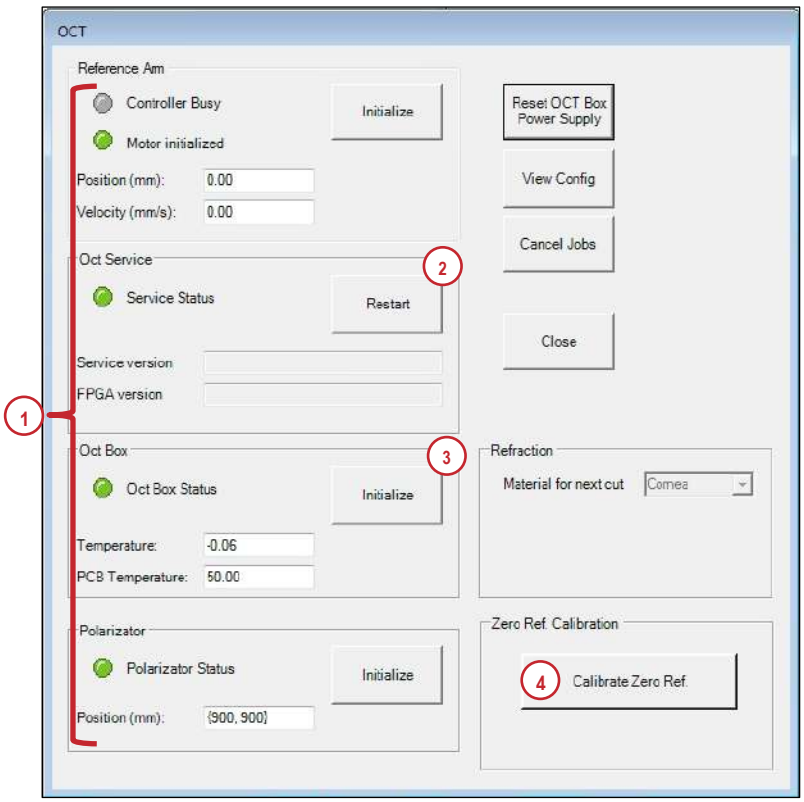


Figure 52: OCT status.

1 **Status LED:** All these LEDs must be green for the OCT system to be considered fully operational.

2 **Restart:** Restarts the OCT Service in case it was accidentally closed.

3 **Initialize:** Initializes the OCT Box.

4 **Zero Reference Calibration:** After successful calibration of the zero reference, the button turns green.

5 **Note:** This feature is only available for devices equipped with a handpiece with a structured laser exit window.

Note: The OCT system should only be restarted as long as it is not in use, for example on the planning screen.

11.4.16 Watchdog

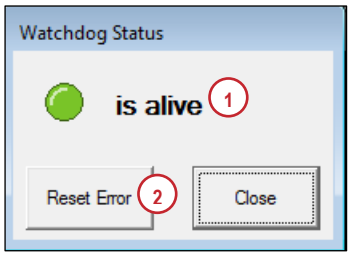


Figure 53: Watchdog status.

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.

11.5 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 Ziemer Customer Support (see section 10). Make sure your LDV is connected to the Internet.
- Establish a remote access session as directed by your Support engineer (see section 10).
- If a remote access session cannot be established, Ziemer Customer Support will guide you through a series of diagnostic checks that you perform at the direction of the Support engineer.

12 APPENDIX

12.1 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 10 mm (0.4 inches) 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 1020-1060 nm. Only authorized Ziemer Customer Service representatives should attempt to remove base station covers to service the LDV.

12.2 File Browser

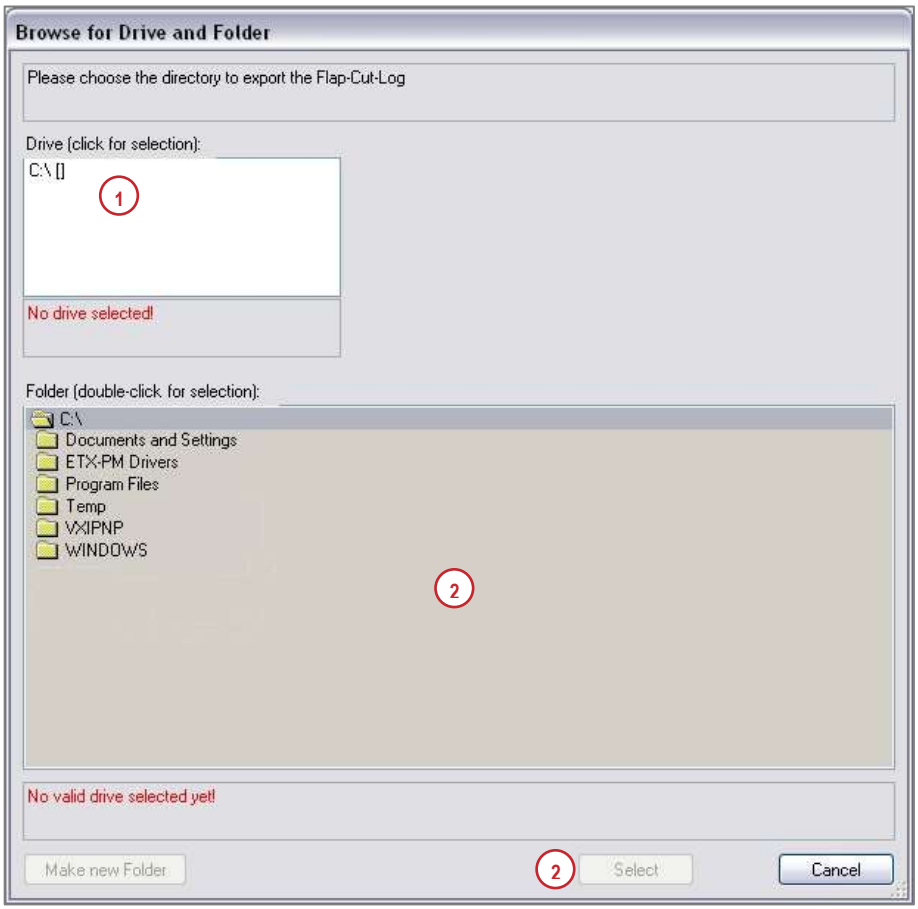


Figure 54: File browser.

The file browser in the cornea software application is displayed when a logfile 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 **Drive:** Choose your external drive to save files.

2 **Folder:** Set the folder destination and push **Select**. If it is a permitted destination, this button is enabled.

Note: The access to the hard drive of the LDV is forbidden due to security issues.

12.3 List of System Accessories

Item	Description	Part number
Procedure Packs for Corneal Surgery & Corneal Surgery SLIM	Box of 10 sterile procedure packs for all corneal procedures; suction ring diameter 8.5 mm, Applanating Interface	510.700.012
	Box of 10 sterile SLIM procedure packs for all corneal procedures; suction ring diameter 8.5 mm, Applanating Interface	510.700.020
	Box of 10 sterile procedure packs for all corneal procedures; suction ring diameter 9.0 mm, Applanating Interface	510.700.013
	Box of 10 sterile SLIM procedure packs for all corneal procedures; suction ring diameter 9.0 mm, Applanating Interface	510.700.021
	Box of 10 sterile procedure packs for all corneal procedures; suction ring diameter 9.5 mm, Applanating Interface	510.700.014
	Box of 10 sterile SLIM procedure packs for all corneal procedures; suction ring diameter 9.5 mm, Applanating Interface	510.700.022
	Box of 10 sterile procedure packs for all corneal procedures; suction ring	510.700.015

	diameter 10.0 mm, Applanating Interface	
	Box of 10 sterile SLIM procedure packs for all corneal procedures; suction ring diameter 10.0 mm, Applanating Interface	510.700.023
Procedure Packs for Cataract Surgery & Cataract Surgery SLIM	Box of 10 sterile procedure packs for cataract procedures, Liquid Interface	510.700.017
	Box of 10 sterile SLIM procedure packs for cataract procedures, Liquid Interface	510.700.019
Procedure Packs for Corneal Surgery Liquid	Box of 10 sterile procedure packs for corneal procedures; Liquid Interface	510.700.018

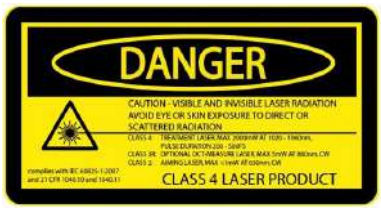
Note: SLIM Procedure Packs are only compatible with a SLIM handpiece.

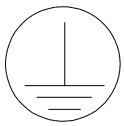
12.3.1 Detachable parts

Item	Description
Foot Switch	**Steute MGF 1NC / 1NO-MED-AP-Ziemer**

Note: Do not use detachable parts other than listed above without Ziemer's consent. Otherwise, any warranty will be voided.

12.4 Base Station and Handpiece Labels

Label definition	Label name
	Warning label (front side of the connector plate cover of the base station)

Label definition	Label name
	Warning label (bottom of HP unit)
	Warning label (inside base station on the optic box)
	Laser radiation warning label (inside base station, different positions)
	Protective Earth terminal (inside base station)

12.5 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		
The **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	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	Class A	The **FEMTO LDV** is suitable for use in Professional healthcare facility environment, except near HF surgical equipment, other than domestic. It may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

		Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2, 4, 8, 15 kV air	+/- 8 kV contact +/- 2, 4, 8, 15 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 100 kHz	+/- 2 kV for power supply lines 5 kHz & 100 kHz	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	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25 cycles 0 % UT for 250 cycles	0 % UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle 70 % UT for 25 cycles 0 % UT for 250 cycles	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.
Enclosure port immunity to proximity magnetic fields 61000-4-39	30 kHz, 8 A/m CW 134.2 kHz, 65 A/m PM 13.6 MHz, 7.5 AM PM	30 kHz, 8 A/m 134.2 kHz, 65 A/m 13.6 MHz, 7.5 AM	-
Note: UT is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity environment tested			
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.			
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.			
Immunity tests	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands and radio amateur band *	3 Vrms 150 kHz to 80 MHz outside ISM bands and radio amateur band *	If the measured field strength in the location in which the **FEMTO LDV** is used exceeds the applicable RF compliance level, 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**.
	6 Vrms 150 kHz to 80 MHz in ISM bands and radio amateur band *	6 Vrms 150 kHz to 80 MHz in ISM bands and radio amateur band *	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Minimum separation distance shall be calculated by following equation: $E = \frac{6}{d}\sqrt{P}$ E is the immunity test level in [V/m] d is the minimum separation in [m] P is the maximum power in [W]
Proximity field from RF wireless communication equipment IEC 61000-4-3	27 V/m 380-390 MHz 50 % PM 18 Hz 28 V/m 430-470 MHz FM ±5 kHz deviation, 1kHz sine 9 V/m 704-787 MHz 50 % PM 217 Hz 28 V/m 800-960 MHz 50 % PM 18 Hz 28 V/m 1700-1990 MHz 50% PM 217 Hz 28 V/m 2400-2570 MHz 50% PM 217 Hz 9 V/m 5100-5800 MHz 50% PM 217 Hz	27 V/m 380-390 MHz 50 % PM 18 Hz 28 V/m 430-470 MHz FM ±5 kHz deviation, 1kHz sine 9 V/m 704-787 MHz 50 % PM 217 Hz 28 V/m 800-960 MHz 50 % PM 18 Hz 28 V/m 1700-1990 MHz 50% PM 217 Hz 28 V/m 2400-2570 MHz 50% PM 217 Hz 9 V/m 5100-5800 MHz 50% PM 217 Hz	RF wireless equipment maximum output power and separation distance tested (at 30 cm) : TETRA 400: max 1.8 W GMRS 460, FRS 460: max 2 W LTE Band 13 and 17; max 0.2 W GSM 800/900: max 2 W TETRA 800: max 2 W iDEN 820: max 2 W CDMA 850: max 2 W LTE Band 5: max 2 W GSM 1800/1900: max 2 W CDMA 1900: max 2 W DECT: max 2 W LTE Band 1, 3, 4 and 25: max 2 W UMTS: max 2 W Bluethooth: max 2 W WLAN 802.11b/g/n: max 2 W RFID 2450: max 2 W LTE Band 7: max 2 W WLAN 802.11 a/n: max 0.2 W Interference may occur in the vicinity of equipment marked with the following symbol: 
*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz and 40.66 - 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz - 2 MHz, 3.5 - 4.0 MHz, 5.3 -			

5.4 MHz, 7 - 7.3 MHz, 10.1 - 10.15 MHz, 14 - 14.2 MHz, 18.07 - 18.17 MHz, 21.0 - 21.4 MHz, 24.89 - 24.99 MHz, 28.0 - 29.7 MHz and 50.0 - 54.0 MHz.

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**.

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

The **FEMTO LDV** is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **FEMTO LDV** can help prevent electromagnetic 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 communication equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz outside ISM and radio amateur bands *	**150 kHz to 80 MHz in ISM and radio amateur bands ***	**80 MHz to 2700 MHz (for define RF Wireless transmitters see table before)**
	$\boldsymbol{d} = 0.35\sqrt{\boldsymbol{P}}$ **	$\boldsymbol{d} = 1.20\sqrt{\boldsymbol{P}}$ **	$\boldsymbol{d} = 0.60\sqrt{\boldsymbol{P}}$
0.01 W	0.04	0.12	0.06
0.1 W	0.13	0.38	0.19
1 W	0.40	1.20	0.60
10 W	1.30	3.80	1.90
100 W	4.00	12.0	6.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres [m] can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

$$E = \frac{6}{d}\sqrt{P}$$

*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz and 40.66 - 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz - 2 MHz, 3.5 - 4.0 MHz, 5.3 - 5.4 MHz, 7 - 7.3 MHz, 10.1 - 10.15 MHz, 14 - 14.2 MHz, 18.07 - 18.17 MHz, 21.0 - 21.4 MHz, 24.89 - 24.99 MHz, 28.0 - 29.7 MHz and 50.0 - 54.0 MHz. **Formulas coming from Ed.4.1 of the IEC 60601-1-2

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