From Eye to Insight

Leica
MICROSYSTEMS

MEDICAL DIVISION

EnFocus OCT

User Manual

9054-10063_EN - Revision M

4.2025

Thank you for purchasing an EnFocus OCT system. In developing our systems, we have placed great emphasis on simple, self-explanatory operation. This user manual contains important information related to the device, safety, operation, and cleaning. In order to avoid injury to persons or damage to the system this user manual, including indications, warnings and precautions, must be read and understood before performing any procedure.

Thank you for choosing our products. We hope that you will enjoy the quality and performance of your EnFocus OCT system.

For inquiries regarding sales, service, or support contact Leica Microsystems by either visiting

http://www.leica-microsystems.com/service/

or by calling the One Call support number closest to your facility:

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Austria: +43 1 486 80 50 27
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China: +86 400 650 6632
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Germany: +49 64 41 29 44 44
Hong Kong: +852 800-969-849
India: 1800 313 2339
Italia: +39 02 57486.1
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United Kingdom: +44 845 604 9095
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For issues concerning the manufacturing center please contact:

Leica Microsystems NC, Inc.
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Suite 390
Durham, NC 27703
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Phone: +1 800-248-0223

CAUTION

Federal law restricts this device to sale by or on the order of a physician or practitioner.

Leica Microsystems CMS GmbH
Ernst-Leitz Strasse 17-37
35578 Wetzlar, Germany

CE marking

Leica Microsystems (Schweiz) AG
Max Schmidheiny-Strasse 201
9435 Heerbrugg, Switzerland

Legal disclaimer

All specifications are subject to change without notice.
The information provided by this manual is directly related to the operation of the equipment. Medical decision remains the responsibility of the clinician.
Leica Microsystems has made every effort to provide a complete and clear user manual highlighting the key areas of product use. Should additional information regarding the use of the product be required, please contact your local Leica representative.
You should never use a medical product of Leica Microsystems without the full understanding of the use and the performance of the product.

Liability

For our liability, please see our standard sales terms and conditions. Nothing in this disclaimer will limit any of our liabilities in any way that is not permitted under applicable law, or exclude any of our liabilities that may not be excluded under applicable law.

Contents

1 Introduction

1.1 About this user manual

In addition to notes on the use of the instruments this user manual gives important safety information (see chapter "Safety notes").

► Read this user manual carefully before operating the product.

This revision of the EnFocus User Manual includes the instructions for use for multiple EnFocus models. The following table provides a cross reference for EnFocus brand names, material numbers, and model numbers that are covered by this manual.

Brand Name	Material #	Model #
EnFocus 2300 System, 100 V	90-C2350-V2-100	9070-10084
EnFocus 2300 System, 120 V	90-C2350-V2-120	9070-10070
EnFocus 2300 System, 230 V	90-C2350-V2-220	9070-10071
EnFocus 2300 Integrated OCT System	90-C2350-V4	9070-10088
EnFocus 2300 Integrated OCT System	900C23550V5	9070-10100

Read manual addendum prior to reading other sections of manual. Within this manual, references to EnFocus, EnFocus OCT, EnFocus OCT device, and EnFocus OCT system all refer to the applicable system that was delivered with this manual.

1.2 Symbols in this user manual

The symbols used in this user manual have the following meaning:

Symbol	Warning word	Meaning
	**Warning**	Indicates a potentially hazardous situation or improper use that could result in serious personal injuries or death.
	**Caution**	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in minor or moderate injury.
	Notice	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in appreciable material, financial and environmental damage.
		Information about use that helps the user to employ the product in a technically correct and efficient way.
►		Action required; this symbol indicates that you need to perform a specific action or series of actions.

1.3 Optional product features

Different product features and accessories are optionally available. The availability varies from country to country and is subject to local regulatory requirements. Please contact your local representative for availability.

2 Product Identification

The model and serial numbers of your product are located on the identification label on the illumination unit.

► Enter this data in your user manual and always refer to it when you contact us or the service workshop regarding any questions you may have.

Type	Serial no.
...	...

3 Safety notes

Always follow the instructions in this user manual, and in particular the safety notes.

3.1 Intended use

The EnFocus OCT device is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SDOCT).

- The EnFocus OCT system is indicated for use as an aid in the visualization of physiologic and pathologic conditions of the eye through non-contact optical imaging.
- The EnFocus OCT system is indicated for use on patient populations from premature and neonatal infants to adult.
- The EnFocus OCT system is indicated for use in supine imaging, mounted to a surgical microscope, with cooperative patients or patients under anesthesia.

Contraindications

The EnFocus device is not for use with the following surgical microscopes:

- Microscopes contra-indicated for pediatric use or restricted to adult use only.
- Microscopes with illumination systems that do not independently conform to ISO 15004-2:2007 Group 2.

WARNING

Risk of injury to the patient.

Images from the EnFocus OCT device are to serve only as supplementary information.

► Ensure that the images from the EnFocus OCT are not used as the sole basis for any diagnosis.

CAUTION

Danger of eye injury due to laser radiation.

This device is a Class 1 Laser Product product in accordance with the IEC 60825-1 standard.

► Make sure that exposure to the direct output of this device is limited to the minimum duration necessary for images.

3.2 General directions

- The EnFocus OCT system may be used only in enclosed rooms and must be placed on a solid floor.
- The EnFocus OCT system is subject to special precautionary measures for electromagnetic compatibility: It must be installed and commissioned in accordance with the guidelines and manufacturer's declarations and recommended safety distances (according to EMC tables based on IEC 60601-1-2).
- Portable and mobile as well as stationary radio communications equipment can have a negative effect on the reliability of the EnFocus OCT system's functionality.

CAUTION

Risk of EM Compatibility Issues.

► The EnFocus System should not be operated near active HF SURGICAL EQUIPMENT or near magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

- The EnFocus is intended for operation in the hospital environment.

3.3 Directions for the person responsible for the instrument

The intended users of the EnFocus OCT system are physicians or technicians with professional training or experience in the use of ophthalmic imaging equipment. Nurses and other clinical staff will interact with the system by performing setup and shut down functions, and may also run the software during the procedure.

► Read and understand the entire user manual before operating this system. If there are any questions concerning the use of this system, contact your Leica customer service representative.

► Ensure that the EnFocus OCT system is used only by persons qualified to do so.

► Ensure that this user manual is always available at the place where the EnFocus OCT system is in use.

► Inform your Leica Microsystems representative or customer service immediately about any product defect that could potentially cause injury or harm.

► Service on the EnFocus OCT system may be carried out only by technicians who are explicitly authorized by Leica Microsystems to do so.

► Only original Leica Microsystems replacement parts may be used in servicing the product.

► After service work the device must be readjusted in accordance with our technical specifications.

► If the instrument is serviced by unauthorized persons, is improperly maintained (as long as maintenance was not carried out by us), or is handled improperly, Leica Microsystems will not accept any liability and any warranty will be void.

► The effect of the system on other instruments has been tested as specified in IEC 60601-1-2. The system passed the emission and immunity test and complies with the usual precautionary and safety measures relating to electromagnetic and other forms of radiation.

► The electric installation in the building must conform to the applicable national standards, e.g., current-operated ground leakage protection (fault-current protection).

3.4 Directions for the operator of the instrument

- ► Read and understand the entire user manual before operating the EnFocus OCT system. If there are any questions concerning the use of the EnFocus OCT system, contact customer service.
- ► Follow the instructions described in this user manual.
- ► Follow the instructions given by your employer regarding the organization of work and safety at work.

3.5 Expected service life

The expected service life of the EnFocus OCT system is 7 years. After 7 years, please contact Leica customer service to arrange for further servicing.

3.6 Dangers of use

3.6.1 Overall system

WARNING

Danger of injury for pediatric patients.

- ► Do not image pediatric patients with devices that are contraindicated for pediatric use or that are indicated for use only in adult populations.

WARNING

Danger of fatal electrical shock.

- ► To reduce risk of electrical shock, do not open enclosures. There are no serviceable parts inside.
- ► Ensure that only authorized service personnel performs installation, assembly, service, and maintenance.

WARNING

Danger of fatal injury and burns.

- ► Do not operate the EnFocus OCT in potentially explosive areas.
- ► Do not operate the EnFocus OCT within 25 cm of flammable anesthetics or volatile solvents, benzene or similar flammable materials.

WARNING

Risk of Performance Degradation.

- ► 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.

CAUTION

Risk of injury to the patient.

- ► Ensure the EnFocus OCT scan head is securely attached to the microscope prior to moving it into position above the patient.
- ► Do not attempt to remove the scan head while a patient is underneath the microscope. The scan head could fall on the patient resulting in injury.

CAUTION

Risk of injury to the patient.

- ► Do not perform the balancing procedure while a patient is underneath the microscope.
- ► To avoid unintentional movement of the microscope make sure that the arm system is properly balanced before starting an operation.

CAUTION

Risk of infection.

- ► Leica recommends that the EnFocus OCT system be draped during surgical procedures consistent with draping of the surgical microscope.

CAUTION

Risk of injury to the operator.

- ► Do not remove glare masks from microscope without waiting 30 seconds after turning off main illumination as there is a potential to be burned.

CAUTION

Risk of allergic reactions.

- ► Individuals that are allergic to system materials with which they come in contact should limit skin exposure.

CAUTION

Risk of injury due to contact with the device.

- ► Ensure that the optical working distance of the scanner is sufficient to avoid contact with the patient.
- ► The operator should take care that the patient does not come into contact with the device.

CAUTION

Tripping Hazard.

Transporting the system is performed by pushing the system cart in the forward direction.

- ► Do not pull the cart as this may cause it to tip over.

CAUTION

Tripping Hazard.

- ► Do not create a tripping hazard with the cord of the EnFocus OCT device.

NOTICE

Risk of System Overheating.

System requires proper ventilation.

- ► Do not block the front, back or sides of the system during operation.

NOTICE

Risk of damage to the lens.

- ► Never use the same lens cleaning tissue twice to avoid scratching the lens.

NOTICE

Risk of damage to the EnFocus OCT scan head during transportation.

- ► When carrying the scan head, hold the scan head by the extension tube and keep the cover on the objective lens.

NOTICE

Risk of damage to the EnFocus OCT system.

- ► Only connect items that have been specified as part of or compatible with the EnFocus OCT System.

NOTICE

Risk of damage to the EnFocus OCT system due to a computer virus.

- ► Use caution when connecting the system to a network, thumb drive, or other device as the connection could result in the introduction of a computer virus to the system.

NOTICE

Risk of damage to the EnFocus OCT system.

- ► Do not expose this equipment to rain or moisture.

NOTICE

Risk of damage to the EnFocus OCT scan head due to immersion in a liquid.

- ► Do not immerse the scan head in any liquid. Immersion will result in damage to the electronics in the scan head.

NOTICE

Risk of damage to the EnFocus OCT system due to use in humid environments.

This device is not designed for use in damp or high humidity environments.

- ► Do not allow condensation to form on any component.
- ► Do no place fluid-filled containers on any surface of the device.

NOTICE

Risk of damage to the EnFocus OCT system due to incorrect assembling.

- ► System must be assembled and calibrated by a Leica service representative prior to initial use.

NOTICE

Obstruction of the view.

- ► If the objective lens becomes scratched or damaged and obstructs the view through the scope, remove the OCT scan head from the scope.

NOTICE

Risk of damage to the system.

- ► Do not use the system adjacent to or stacked with other equipment.
- ► If adjacent or stacked use is necessary, observe the system to verify normal operation in this configuration.

NOTICE

Risk of damage to the device.

- ► Do not use the foot pedal if any damage is found.
- ► Contact Leica customer service to order a replacement foot pedal.

3.6.2 Laser Safety

WARNING

Danger of eye injury due to laser radiation.
This device is a Class 1 Laser product.
Use of controls or adjustments or performance of procedures other than those specified herein and any companion documents may result in hazardous radiation exposure.

- ► Do not operate the system when the fiber optic cable is removed from the optical fiber port.
- ► Do not look directly in to the optical fiber port.
- ► Do not remove the optical fiber while the system is powered on.
- ► Turn off power before removing the optical fiber.

The following Photo toxicity cautions are mandatory text as defined in the CDRH guidance document #1241, "Ophthalmoscope Guidance (Direct and Indirect).

CAUTION

Photo toxicity.
Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device does not emit optical radiation outside of the near infrared wavelength region 770 nm – 1100 nm.

CAUTION

Photo toxicity.
The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

CAUTION

Photo toxicity.
While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, persons with aphakia and other diseases of the eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

The following cautionary statement is mandatory text as defined in ISO 15004-2:2007 for Group 2 ophthalmic instruments.

CAUTION

Photo toxicity.
The light emitted from this instrument presents a potential thermal hazard to the cornea and lens. The longer the duration of exposure, the greater the risk of ocular damage. The maximum corneal and lenticular infrared radiation irradiance emitted from this instrument is 95 mW/cm^2 when operated at worst case conditions (i.e., no eye movement and with non-scanning beam). This value is 5% below the safety guideline (100 mW/cm^2) specified in ISO 15004-2: 2007.

The EnFocus™ Spectral Domain Ophthalmic Imaging System (SDOIS) complies with the Group 2 instrument requirements of ISO 15004-2:2007.

CAUTION

Risk of injury to the retina due to prolonged light exposure.

- ► Do not unnecessarily prolong the use of the device for ocular examination.

CAUTION

Thermal hazard to the cornea and lens.

- ► To limit the risk of ocular damage do not unnecessarily prolong the duration of exposure.

3.6.3 Electrical Safety Precautions

WARNING

Danger of fatal electrical shock due to high voltage.

- ► Do not remove component covers. There are no serviceable parts inside.
- ► Only authorized service personnel may perform installation, assembly, service, and maintenance.

WARNING

Risk of electrical shock.

Not correctly connecting the system may result in injuries to the patient or operator, or in damage to the equipment.

- ► Ensure that the system always is connected to a protective earth when in operation.

WARNING

Danger of fatal electrical shock.

This equipment receives power from more than one source. The output receptacles may be energized even when the unit is unplugged. Unplugging the UPS puts it into backup mode and does not remove the electrical charge.

- ► To ensure that the UPS is off, turn the power switch “OFF” before unplugging the UPS from the wall outlet.

WARNING

Risk of electrical shock.

- ► Do not simultaneously touch the patient and the computer.

WARNING

Risk of electrical shock due to improper grounding.

- ► To achieve grounding reliability connect this equipment to matching receptacle marked "Hospital Only" or "Hospital Grade".

WARNING

Risk of electrical shock due to interrupted grounding.

- ► Periodically check grounding continuity.

WARNING

Risk of reduced electrical safety.

Connecting electrical equipment to an extension cable can result in a reduced level of safety.

- ► Plug the system directly into the wall outlet.
- ► Do not connect additional equipment to the UPS of the system.
- ► Do not add an additional multiple socket-outlet or extension cord to the system.

WARNING

Risk of electrical shock.

The rear video input ports are not electrically isolated.

- ► Only use the rear video input ports with medical grade microscope cameras.

WARNING

Risk of electrical shock.

The USB ports are not electrically isolated.

- ► Only use the USB ports with bus-powered devices such as flash drives.
- ► Do not use the USB ports with any device that connects to an external power source.

WARNING

Fire danger.

- ► Do not use the UPS in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

WARNING

Danger for the patient health due to changes to the equipment.

- ► Do not modify or adulterate this equipment.

CAUTION

Electrical or optical hazards.

- ► Never attempt to repair or disassemble the system yourself. Only a qualified service representative can service the system or perform maintenance.

CAUTION

Risk of electrical shock for the patient or the operator, or damage to the equipment.

- ► Never use a converter adapter to connect the three-pronged AC plug into a two-pronged, ungrounded wall outlet.

CAUTION

Risk of electrical shock for the patient or the operator, or damage to the equipment, due to insufficient inspection procedures.

- ► Routinely inspect all components, including the power cord, before using the system.
- ► Never use any component that appears damaged.

CAUTION

Risk of injury due to improper disposal of the UPS battery.

The UPS contains a sealed lead-acid battery.

- ► Refer to UPS Manufacturer's Instructions For Use document for information on battery replacement, recycling, and disposal.
- ► Battery replacement should only be performed by qualified service personnel.

CAUTION

Risk of electrical shock and device damage.

Many important parts of the system are not water resistant.

- ► Do not use any spray or liquid solution on the system in a manner that is not specifically defined in cleaning and disinfection procedures of this manual.
- ► Do not allow any fluid to drip or run down surfaces of optical engine or computer.
- ► Always shut down the system and unplug the power cord prior to wiping surfaces.

NOTICE

Risk of damage to the UPS battery.

- ► To avoid permanent loss of capacity of the UPS battery, do not unplug a UPS from its AC utility power source for an extended period of time.
- ► If equipment is not likely to be used for several months, follow the instructions included in this manual (see "9.5 Storage for cart configuration" on page 55).

NOTICE

Special precautions for Medical Electrical Equipment.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

- ► Only install and put into service this Medical Electrical Equipment according to the EMC information provided in this manual.

NOTICE

Risk of damage to the UPS.

- ► Do not plug the UPS into itself.

NOTICE

Risk of damage.

- ► Periodically check the UPS to ensure its working condition.

3.6.4 Security and Patient Privacy Precautions

CAUTION

Risk of breach to patient's personal information.

Breach of patient identifying information is a HIPAA violation. Steps must be taken to ensure its integrity.

- ► Take precautions to protect patient data and patients personal information from unauthorized access and/or use.
- ► Do not leave the system unattended when patient identifying information is displayed.
- ► When exporting patient data to external storage devices, take steps to ensure the security of the device
- ► Patient data should be regularly archived to a secure long-term storage location.

CAUTION

Risk of intended or unintended malware infection of the system.

A malware infection can corrupt the OCT system and render it unusable and/or corrupt patient data.

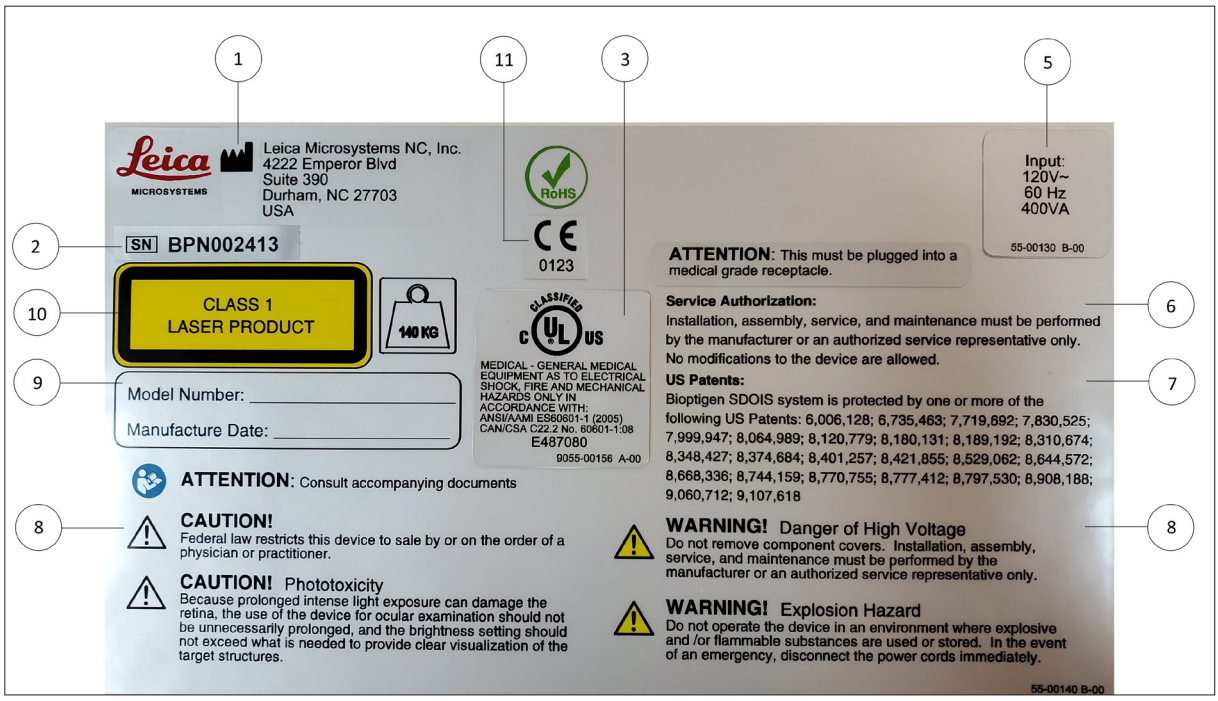
- ► The system should be protected, at all times, from unauthorized users. When the system in not in use it should be shut down.
- ► This device is only intended for connection to a secure IT network for the purposes of data transfer and service support. Do not leave the device permanently connected to a network.
- ► The device is not intended for wireless connectivity.

3.7 Signs and labels

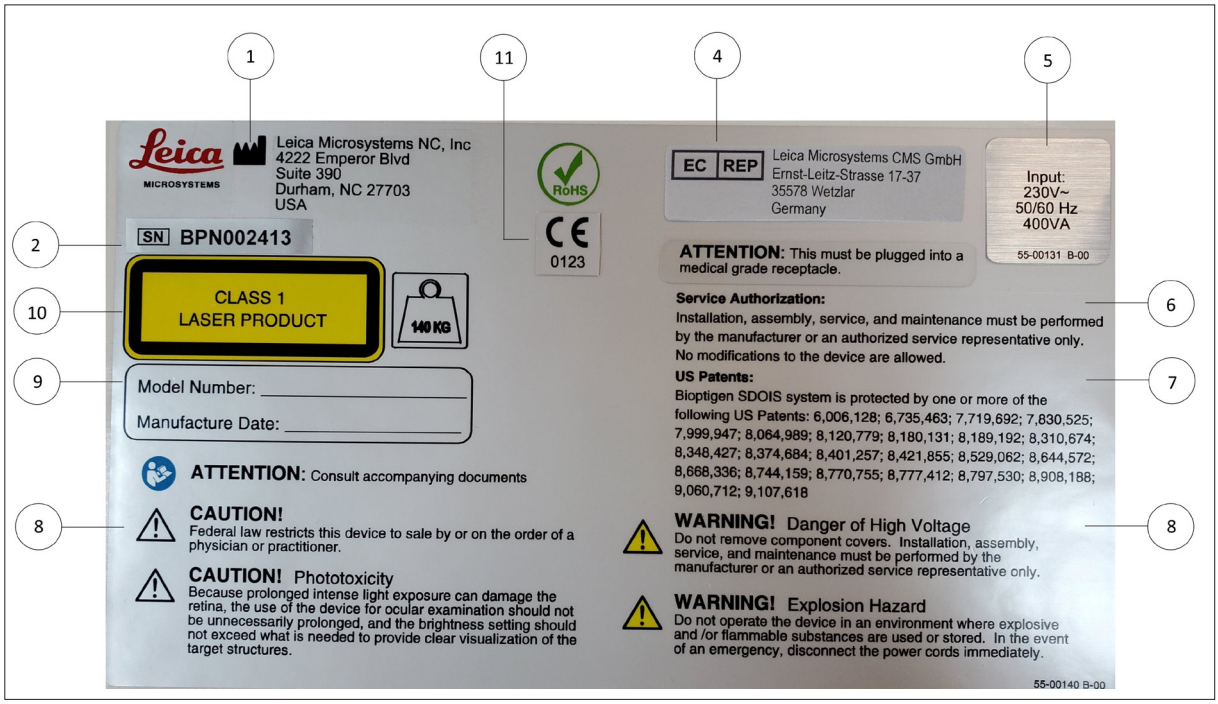
3.7.1 EnFocus Cart Installation

The following labels are affixed to the back panel of the EnFocus system:

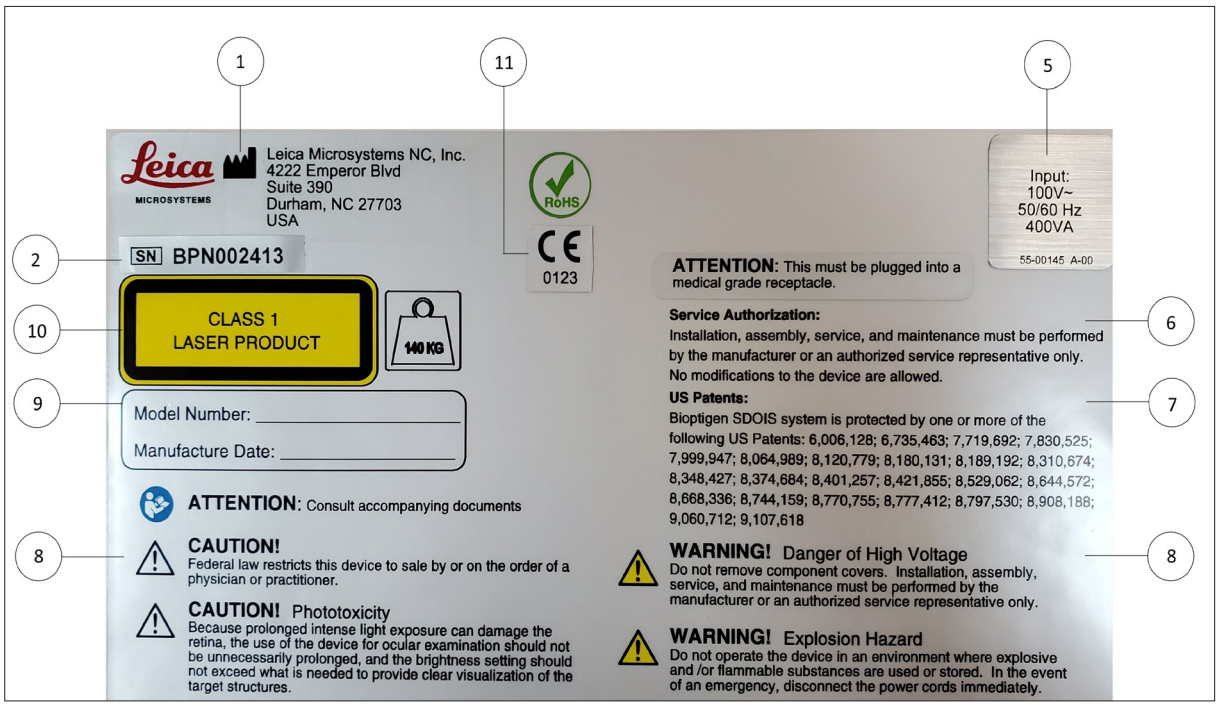
EnFocus Cart Installation Systems with 120 V (e.g. for USA)



EnFocus Cart Installation Systems with 230 V (e.g. for Europe)



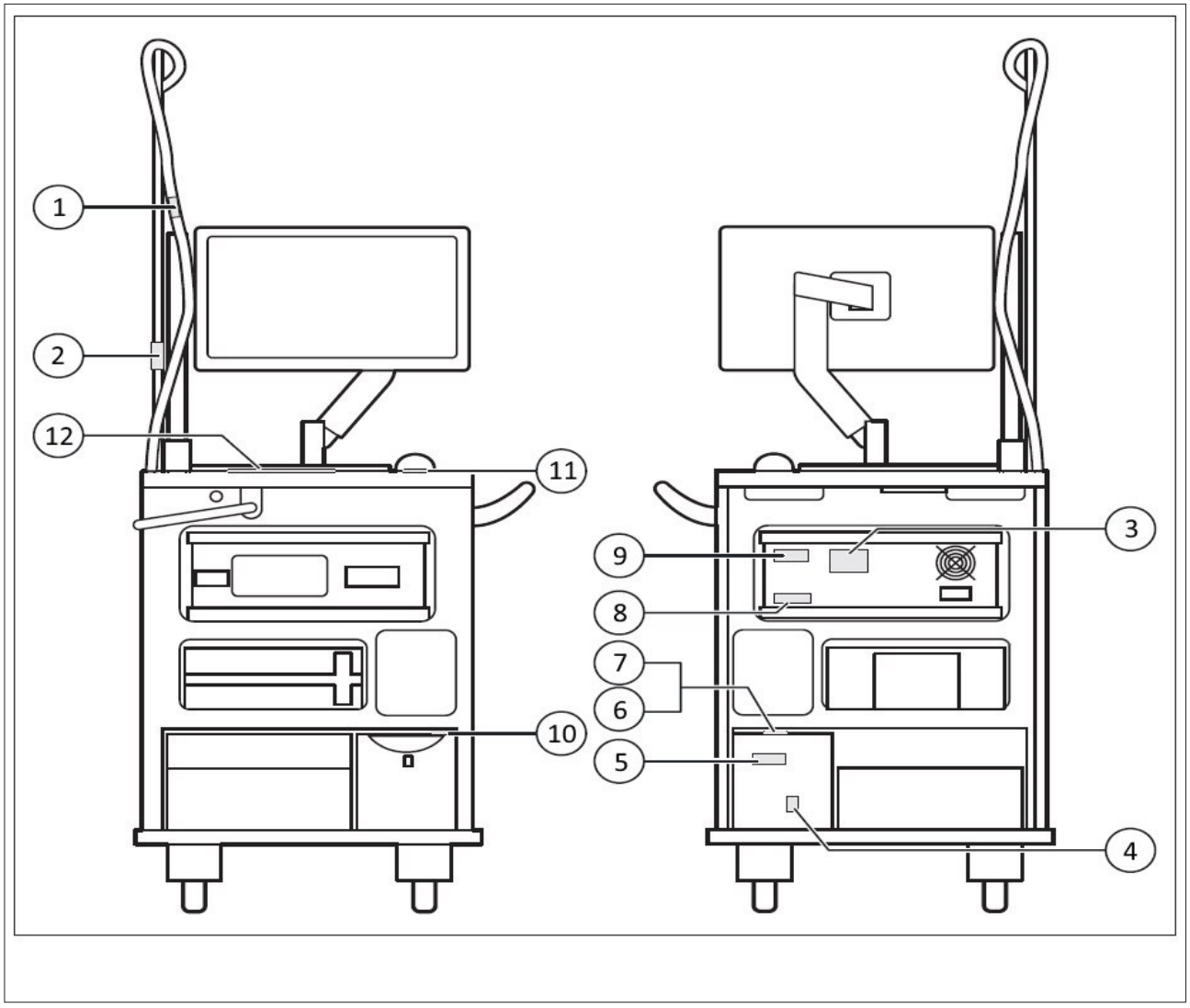
EnFocus Cart Installation Systems with 100 V (e.g. for Japan)



Label Description

1 Manufacturer's information
2 System Serial Number
3 UL certification label (only on 120V systems)
4 European authorized representative (only on 230V systems)
5 Electrical Input Information
6 Service Authorization
7 Patent Information
8 Cautions and Warnings
9 Model Number and Date of Manufacture
10 Product Optical Output Classification
11 CE marking

Engine and Interface box rear panels are not visible with the system back panel in place.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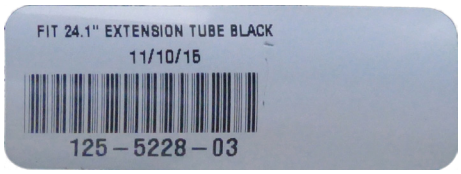

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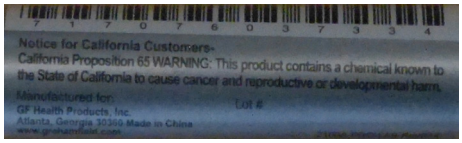

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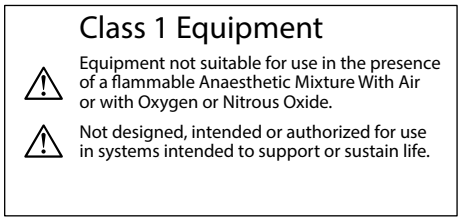

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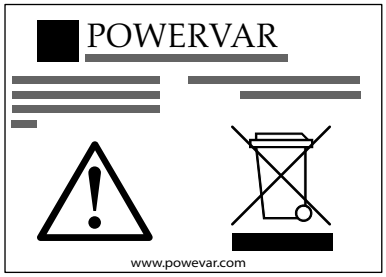

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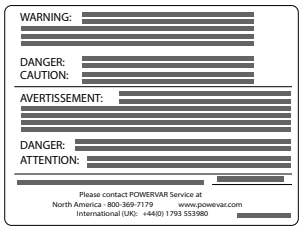

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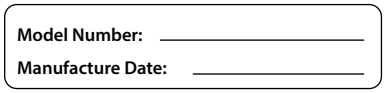

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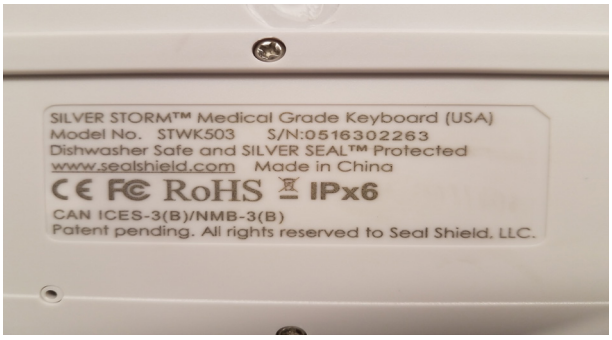
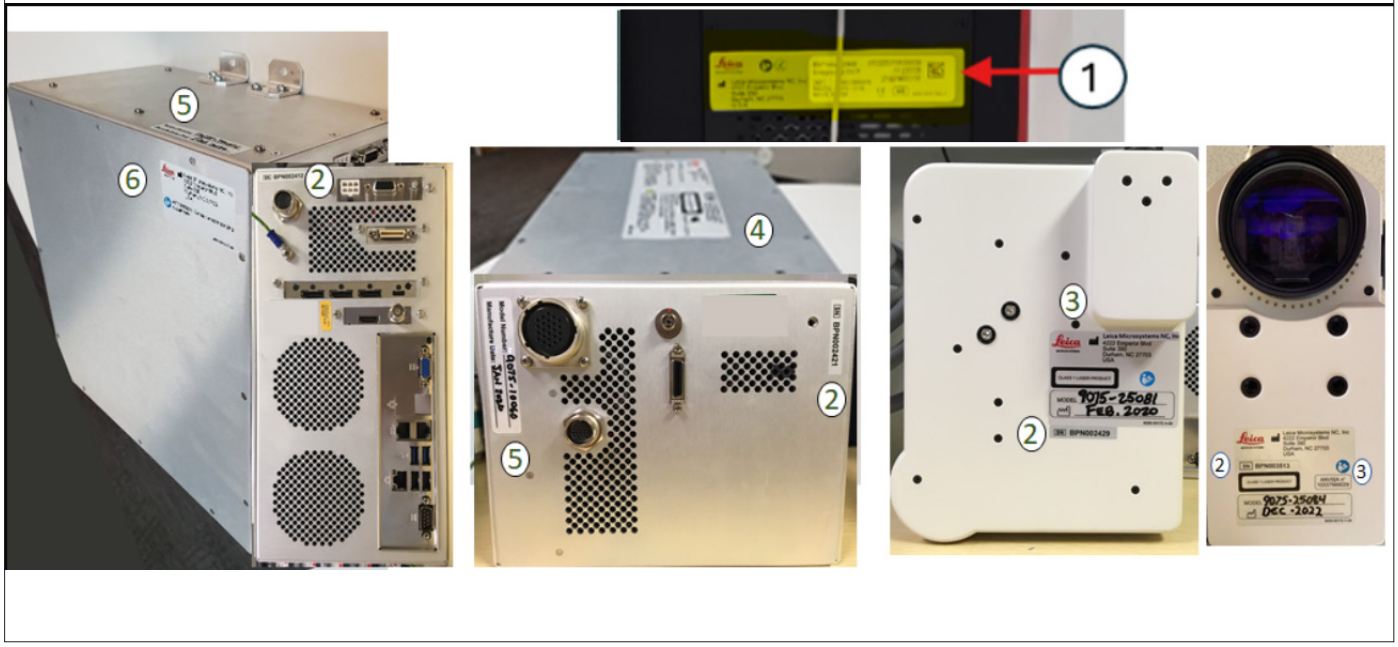


3.7.2 EnFocus Configuration for Microscope Integration

EnFocus configuration for microscope integration with 48 Volt DC Input Voltage has the following labels are located on the EnFocus subsystems and system label on the integrating microscope.



1	System Serial Number, UDI & Manufacturer Information Leica Microsystems NC, Inc. 4222 Emperor Blvd, Suite 390 Durham, NC 27703 U.S.A. EnFocus 2300 Integrated OCT System SN BPN123456 REF 900C23550V5 MODEL 9070-10100 (01)00857691006039 (11)160101 (21)BPN123456 MD MADE IN USA 9055-20041 Rev B
2	Module Serial Number SN BPN000000
5	Module Model Number and Manufacturing Date Model Number: _____ Manufacture Date: _____

4	System Information

3	Scanner Model Number, Manufacturing Date, and Manufacturer Information

6	Manufacturer Label

4 EnFocus Components

4.1 EnFocus Cart Installation

The EnFocus OCT cart configuration includes the following components:

1 Screen
2 Keyboard / Mouse
3 Mobile Security Cart
4 Optical Engine
5 Scanner Storage Case
6 Computer
7 Scanner (not shown)
8 Pole for conduit routing (not shown)

Accessories

- Filter mask M844
  circle
  modified bar
- Filter mask Proveo 8
- Video Cables

4.1.1 Optical Engine

The EnFocus OCT engine contains the optical and electrical components associated with signal acquisition, detection and processing. A fail-safe circuit that monitors the scanner is also included inside the engine. If a scanner fault signal is detected or the system is not scanning, the fail-safe circuit shuts down power to the OCT light source, a superluminescent diode (SLD).

The engine contains a power indicator light showing that the system is on or off.

4.1.2 Scanner

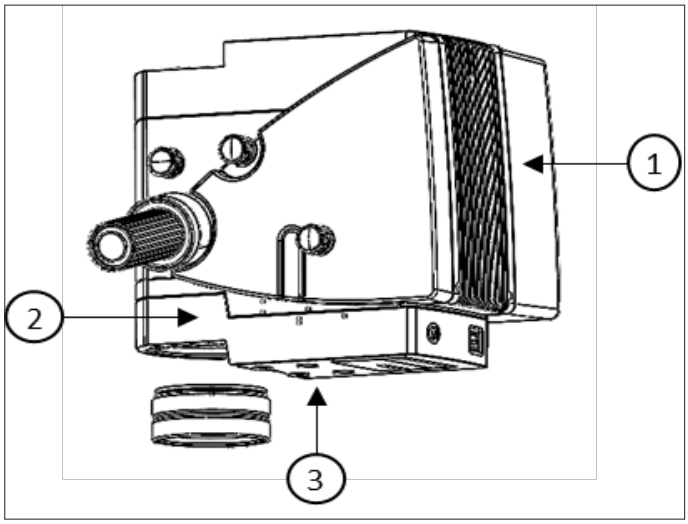
The scan head of the EnFocus OCT system is intended to be mounted to the optics carrier of compatible surgical microscopes for imaging during surgical procedures.

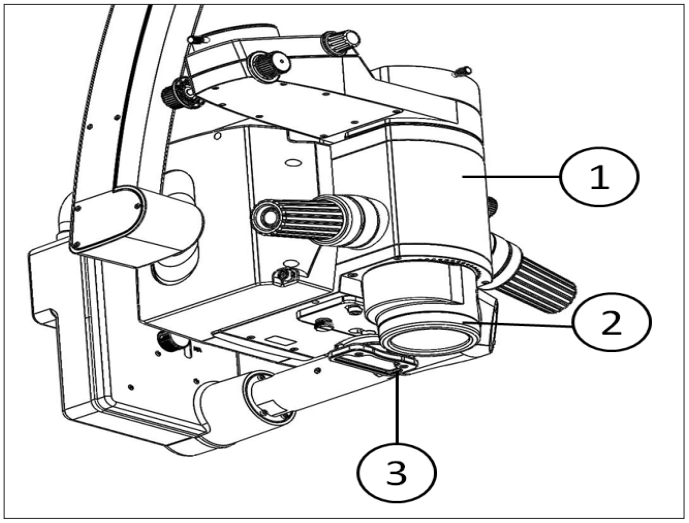
The scan head includes an aperture, allowing undisturbed transmission of visible optical signals during concurrent OCT scans while viewing through the microscope oculars. The OCT signal is coupled into the microscope path with a dichroic filter reflective in the OCT wavelength and transmissive in the visible waveband.

The scan head works with objective lenses that operate with a working distance approximately equal to the focal length of common surgical objective lenses.

The scanning OCT beam may be used with supplementary optics (such as wide angle viewing systems for vitreoretinal procedures) between the objective lens and the patient, as long as the supplementary optics are transparent in the OCT waveband.

There are two versions of the scanner depending on the system model that has been purchased. The first image below shows the scanner for system model 9070-10100 and all other models use the scanner in the second image.





1 Microscope
2 Scanner
3 Mounting Interface

4.1.3 Computer

The computer has 1 TB of storage capacity on mirrored disks (RAID 1), 16 GB RAM and a video card with 2 GB of dedicated RAM. The computer operates on a Windows platform installed on a dedicated hard drive that is separate from the data drives, and supports Computer System recovery, and data integrity in case of an operating system corruption.

The system includes a computer monitor, keyboard, and mouse.

The monitor is secured to the mobile cart with an adjustable mounting arm that moves fluidly in X, Y, and Z directions.

The IEC 60601-1 compliant keyboard is sealed in water-proof silicone which may be disinfected.

4.1.4 Foot Pedal

Microscope Integrated Foot Pedal

If the EnFocuss connected to a microscope with an integrated communications interface, the microscope's foot pedal can be used to execute OCT functions. Please refer to the associated microscope user manual for details.

4.1.5 Cables

WARNING

Risk of Unspecified Accessories/Cables.

- ► 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.

Standard System Cables

The system uses the following cables for operation:

Cable	Length	Description
Mains	16' [5 m]	Permanently attached mains input power cable
EnFocus 2-button Foot pedal	8.8' [2.7 m]	Foot pedal USB cable to the system
Scan head	27' [10 m]	Fiber optic cable, connection between the scan-head module and cart

Only Leica approved and provided cables are to be used for these connections. Use of unapproved cables may degrade the performance of your system displays.

4.1.6 Cart

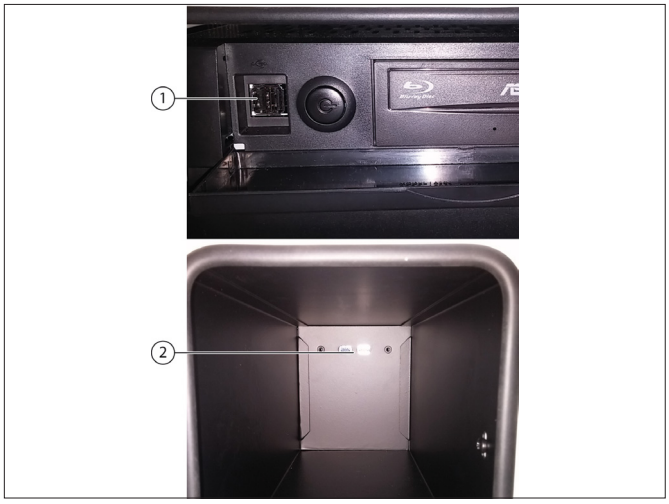
The EnFocus Cart Configuration has the Optical Engine and Scanner installed on a mobile cart with lockable casters to prevent unwanted movement.

The cart provides cable management and contains a UPS that is for the use of the EnFocus system only. All cables are provided with the system and are not user interchangeable.

The cart computer has a front panel with a system power switch and data ports.

4.1.7 USB ports

The computer installed in the cart provides access to bus-powered memory devices. The panel behind the front of the computer has two 2.0 USB ports for accessing data on the system and a power switch. There are two 3.0 USB ports at end of the glove box.



WARNING

Risk of electrical shock.

The USB ports are not electrically isolated.

- ► Only use the USB ports with bus-powered devices such as flash drives.
- ► Do not use the USB ports with any device that connects to an external power source.

4.1.8 Video Input Ports

WARNING

Risk of electrical shock.

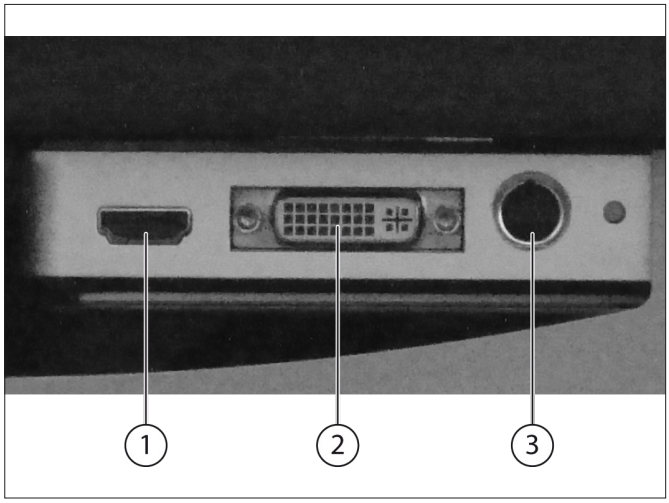
The rear video input ports are not electrically isolated.

- ► Only use the rear video input ports with medical grade microscope cameras.

EnFocus supports the ability to stream microscope video into the OCT software.

The system provides video input ports for DVI, HDMI, and S-video formats at the back of the cart to interface to a medical grade microscope camera only. The incoming video is used to co-register the OCT scan with the surgical microscope field of view. Note that only one port may be used at any given time. The appropriate video cable, as determined at the time of purchase, is provided with the system.

The following camera controllers are compatible with the Enfocus system: Leica HDC100, Leica HDC300, Panasonic GP-US932, and Sony PMW-10MD.



1 HDMI
2 DVI
3 S-video

Only Leica approved and provided cables are to be used for these connections. Use of unapproved cables may degrade the performance of your system displays.

If after your initial order, your microscope camera input requirements have changed, please contact your Leica sales or service representative for consultation on cables that are needed.

4.1.9 Video Output Connections

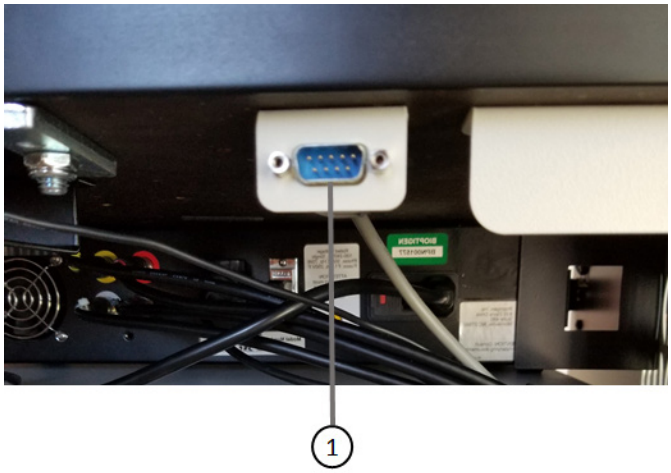
EnFocus supports the ability to connect to additional video outputs such as a secondary display or a DIC 800 in-ocular display. The supported connection type for these display's is via HDMI, DVI, or a VGA connection.

The cables associated with your display needs, as determined at the time of system purchase, have been shipped with the system and installed by your Leica representative.

If after your initial order, your video output requirements have changed, please contact your Leica sales or service representative for consultation on cables that are needed.

4.1.10 Proveo-EnFocus Communication Port

The EnFocus system can make use of the microscope footswitch to control select EnFocus imaging functions, if desired.
Communication is made using a serial communication cable connected between the Proveo microscope and the EnFocus. A DB9 connector is located on the back of the EnFocus cart for this purpose.
To make the connection, plug the DB9 female connector on the end of the Microscope communication cable (p/n 10747122) into the DB9 male connection port on the back of the Enfocus system



1 DB9 male Connection port

WARNING

Risk of electrical shock.
The DB9 connection port on the back of the EnFocuss only to be used with the microscope communication cable supplied with the system.

Note: This feature is only available with the Proveo microscope.

4.1.11 Uninterruptible power supply

The system uses an uninterruptible power supply (UPS) to provide sufficient power to safely shut down the system in the event of a power failure.
The UPS is not intended to fully support the system for use during a procedure. The UPS is a medical grade device that complies with IEC 60601-1 and is available in 100/120/230 V, 50/60 Hz, 600 VA (single-phase). The make and manufacturer of the UPS may change.

Depending on the version of the system and the country where the system is to be used, there are different UPS systems available. The system may be equipped with any of the following UPS devices:

Manufacturer	Model Number	Description
Powervar	50060-202R	120 V 60 Hz
Powervar	51060-200R	230 V 50/60 Hz (frequency auto set)
Powervar	50060-201R	100 V 50/60 Hz (Frequency auto set)

Refer to the manufacturer's Instructions For Use for usage instructions, safety warnings, service, and battery replacement. The battery full load runtime is 20 minute and the recharge time to 60% is 6-10 hours.

Restoration of charge to maximum capacity requires 24 – 48 hours.

The UPS is not designed for constant use, but only to compensate for a power loss during a procedure.

► Before moving from room to room, power down the system.

WARNING

Risk of injury due to inaccessible power connection!

The UPS can only be directly disconnected from the mains by unplugging the power cable from the wall socket.

► Make sure that the power plug is accessible at all times during system operation.

Powervar UPS

Elements on the front of the UPS:

1 Status display
2 Test/silence button
3 On/off button

On/off button

► To turn the UPS system on or off press and hold the power switch for at least 2 seconds.

► To turn on the UPS system in battery backup mode, while the UPS system is off and not connected to the mains press and hold the power switch for at least 2 seconds.

Status display

UPM LED display	UPS status
	UPM output on
	Battery charge status in 20% increments
	UPM load status in 20% increments
	UPM in battery operation due to improper incoming AC
	UPM overloaded
	Battery fault or battery disconnected
	High incoming AC: UPS has to reduce the output compared to the incoming power level
	Low incoming AC: UPS has to increase the output compared to the incoming power level
	Fault/error
	UPM temperature too high

4.1.12 EnFocus OCT system component table

This table lists components, accessories, and detachable parts for use with the EnFocus OCT system.

Description	Part Number
System	9070-10070 EnFocus 2300, VHR Source, 120 V 9070-10071 EnFocus 2300, VHR Source, 230 V 9070-10084 EnFocus 2300, VHR Source, 100 V (see model number on back of system cart)
Optical Engine	9075-10039, 23 Spectrometer, VHR
Scanner	9075-25074 9055-10078 (Scan Head case)
Computer	9075-70025
Cart	9075-80026

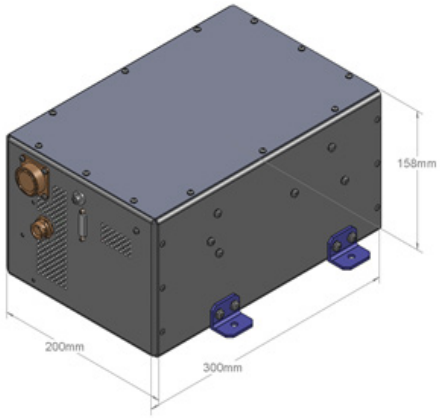
Description	Part Number	
EnFocus 2-button Foot pedal	9025-00400	
UPS	9039-00543 (100 V) 9039-00544 (120 V) 9039-00545 (230V)	
Proveo mask	9038-00667	
M844 mask kit	9085-10502	
Power cords with country-specific plugs	USA: EU: UK: Switzerland: AU: India: JP:	9039-00178, 6.1 m 9039-00230, 6.1 m 9039-00231, 6.1 m 9039-00225, 6.1 m 9039-00467, 6.1 m 9039-00229, 6.1 m 9039-00488, 4.6 m
Cable conduit	F40 F20	9085-10550 9085-10551

4.2 EnFocus Configuration for Microscope Integration

EnFocus configuration for microscope integration utilizes the same internal components as the cart based system to provide the OCT imaging performance. Man of the components used by the cart system are removed and are provided by built-in functionality of the integrating microscope. This allows the components of EnFocus to be repackaged and embedded within the surgical microscope.

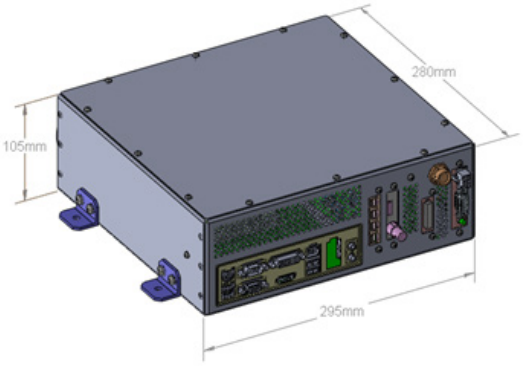
4.2.1 Optics Module

The Optics Module for the microscope integrated enFocus configuration contains the optical and electrical components associated with signal acquisition and signal detection. A fail-safe circuit that monitors the scanner is also included inside the engine. If a scanner fault signal is detected or the system is not scanning, the fail-safe circuit shuts down power to the OCT light source, a superluminescent diode (SLD). Connectors will vary based upon model number (90-C2350-V4 shown below).



4.2.2 CPU Module

The CPU Module provides all of the required processing capability and generates views that may be displayed on connected monitors. The CPU Module has a video input/output, serial, USB, and Ethernet signal connections that are connected when installed in the integrating microscope.



4.2.3 Scanner

EnFocus configuration for microscope integration utilizes a similar scanner as described in section 4.1.2. Differences are in the conduit length, end point connections, and communication protocol used; which are not noticeable in daily use

4.2.4 Keyboard

EnFocus configuration for microscope integration utilizes a wireless keyboard that is connected via Bluetooth to the CPU module. The keyboard is a sealed keyboard that may be washed for decontamination. It uses rechargeable batteries and may be recharged by connecting to a powered USB.

NOTICE

National Limitations on Use of Radio Devices

- Bluetooth adapter is not approved for use in Japan, Taiwan, Brazil, or Mexico as the device is not a registered radio device in those countries.
- Keyboard may only be used in wired configuration in Japan, Korea, Taiwan, Brazil, Mexico, and China as the device is not a registered radio device in those countries.

4.2.5 Interface Panel

The EnFocus when integrated within a microscope includes an interface panel to make 2 USB ports, 1 HDMI video Output and power switch accessible. The panel, located on the on a user accessible surface of the integrating microscope, contains a USB 3.0 port for accessing data on the system. The panel contains a second USB port for connecting a Bluetooth adapter to allow the keyboard to be used wirelessly or for the keyboard to connect via USB cable for control. The panel also contains an HDMI port for displaying OCT data on an external monitor. The panel also includes a power switch to turn off EnFocus power without cycling power of the microscope.

4.2.6 Integrating Microscope Dependencies

EnFocus configuration for microscope integration is dependent on the microscope to provide a monitor for visualizing the OCT data; controlling the EnFocus via the microscope inputs (foot pedal, handles, touch screen, etc); providing power; and providing microscope video input. The microscope integrator is provided with the cable kit required to integrate Enfocus into the microscope; no additional cabling should be required for use. Once integrated, EnFocus will power on or off with the power cycling of the microscope. If you desire to turn the OCT off, the power switch on the interface panel provides this capability.

4.2.7 EnFocus Configuration for Microscope Integration Components

This table lists components, accessories, and detachable parts for use with the EnFocus Configuraion for Microscope Integration.

Description	Part Number	
System	9070-10088	9070-10100
Optics Module	9075-10060	9075-10061
Scanner **Scanner Case**	9075-25081 9075-50053	9075-25084 9075-50112
CPU Module	9075-70031	9075-70031
Proveo mask	9038-00667	9038-00667
Kit, EnFocus Cables for Proveo Microscope Integration	9085-10549	9085-10553
Keyboard Assembly	9075-70032	9075-70032

4.3 InVivoVue Software

The EnFocus uses software developed by Leica Microsystems called InVivoVue to control the OCT engine and analyze data collected from the scan head. The software works with the system controller to offer intuitive, flexible system control with advanced functionality. Images can be saved in several different formats for use with other applications.

For description of functionality and instructions on the use of the InVivoVue system software see "8 InVivoVue Software" on page 35.

5 Device overview

The EnFocus OCT is a non-contact, noninvasive ophthalmic imaging device that uses Spectral Domain Optical Coherence Tomography (SD-OCT) and a Class 1 laser product near infrared light source to image ocular tissue microstructures. The system hardware includes an OCT Engine and a Scan Head. System when configured for sale in Cart configuration include computing peripherals (mouse, keyboard, monitor, and foot pedal) and an Uninterruptible Power Supply (UPS) organized on mobile Security Cart for ease of transport. The system software, InVivoVue, works with the hardware and the hardware controller to provide flexible system control, high-speed volume data acquisition and imaging.

The EnFocus OCT 2300, commonly referred to as the EnFocus Ultra-HD, acquires, processes and displays cross sectional image data at 32,000 A-scans / second, with a nominal 1000 A-scans per image frame (B-scan) a maximum 2000 A-scans per B-scans, and up to 1,000,000 A-scans per volume. Volumetric image data is projected into an en face view, called a Volume Intensity Projection, orthogonal to the depth resolved view, providing for direct cross-sectional image registration with an en face view of the imaged structure. Images are saved into a system format for review on Leica Microsystems systems and can be saved by the user into several different formats for subsequent visualization.

The scan head is mounted to the undercarriage of a surgical microscope's optical carrier for supine patients. The system is compatible with microscope objective lenses, including 175mm and 200mm working distance objectives. The objective lens aperture is 70mm in diameter and transparent and anti-reflection coated across the visible and near infrared wavebands, allowing for undisturbed transmission of visible optical signals through the optical train of the microscope. The OCT signal is coupled into the transmission path with a dichroic mirror that is reflective at the OCT wavelength and transmissive across the visible waveband for concurrent OCT scanning while viewing through the microscope oculars.

The scanning OCT signal beam of the EnFocus OCT is telecentric with respect to the microscope objective, and is therefore compatible with third party retinal viewing lenses particularly useful for viewing the posterior of the eye.
The EnFocus OCT device allows for both anterior and posterior imaging of ocular tissue .

5.1 Anterior segment imaging

The telecentric scanning of the OCT beam through the microscope main objective offers a depth resolved view of anterior surfaces, such as a cornea or sclera, to complement the user's stereoscopic view as observed through the oculars. The user controls the microscope, including focus and zoom controls, as he/she would normally. When the target structure is aligned and focused, the OCT is also aligned.

A real-time cross-hair scanning mode is enabled to identify the scanning location. The OCT system has independent controls for setting the scan dimension, scan centration, and scan orientation (angular rotation). These settings are controlled through "one-click" presets using the InVivoVue software interface.

InVivoVue for EnFocus OCT allows user control over the following additional parameters:

- The Z-control (reference arm control) allows continuous or jogged adjustment of the z-position (depth) of the target structure within the OCT display window.
- The focus control allows adjustment of the OCT focus and OCT image brightness in the region of interest.
- The polarization control allows adjustment of the OCT polarization and OCT image brightness in the region of interest.
- Automatic optimization functions, Auto Locate, Auto Brightness and Auto Sharpen adjust these parameters to provide optimal imaging conditions.

5.2 Posterior segment imaging

The telecentric scanning of the OCT beam through the microscope main objective is centered in the optical axis of the main objectives and readily images through supplemental lenses such as a wide angle viewing system (i.e., a fundus viewing system or microscope camera feed) or a surgical contact lens.

A fundus viewing system operates by imaging the retina to an intermediate plane above the eye, and relaying this image through a reduction lens, the microscope objective, and the oculars to the viewer. The user controls the microscope, including focus and zoom controls, as he/she would normally. When the target structure is aligned and focused, the OCT is also aligned. When using an adjustable fundus viewing system it is important to get the microscope into focus on the anterior, then flip the viewing system into place and use that adjustment, not the microscope focus, to sharpen the fundus image. If the microscope focus is adjusted, this will change the working distance of the OCT which will yield degraded images.

6 Installation & removal

6.1 Receiving and inspection

- ► Upon receipt, inspect the exterior of shipping containers for damage.
- ► If the shipping container is damaged, do not open it. Notify the

shipping carrier and your sales or service representative immediately.

6.2 Initial set-up

- ► Do not use the EnFocus OCT system until a service technician has completed installation and verified system operation is fully functional.
- ► The system will be calibrated at the factory prior to shipment and verified on-site by the technician.
- ► Upon installation the system will be assessed for the presence of glare (visible microscope illumination that is reflected from the EnFocus OCT objective lens into the oculars of the microscope) and the microscope illumination path adjusted accordingly. See "17.1 Glare Management" on page 85<DT> for details on Glare management.
- ► If there is residual glare present at the time of installation at a level determined by the surgeon to be interfering, installation can be discontinued. The EnFocus OCT can be removed, and the microscope can be reverted to its original state.

This phenomenon only occurs when viewing the anterior of the eye through the microscope, using the built-in microscope illumination. For posterior segment applications, where endo-illuminators are used for illumination, and for any other illumination system that is not directed through the main objective to the patient, there is no potential for glare originating from the EnFocus OCT system.

6.3 System connections

WARNING

Risk of Degradation from Portable RF Equipment.

- ► 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 EnFocus OCT system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

6.3.1 Cart Configuration

All electrical and optical signal connections will be secured at the time of installation and secured behind the system's back panel.

The operator will only be required to connect the system input power cord to an appropriate electrical outlet.

No other connections are required by the operator.

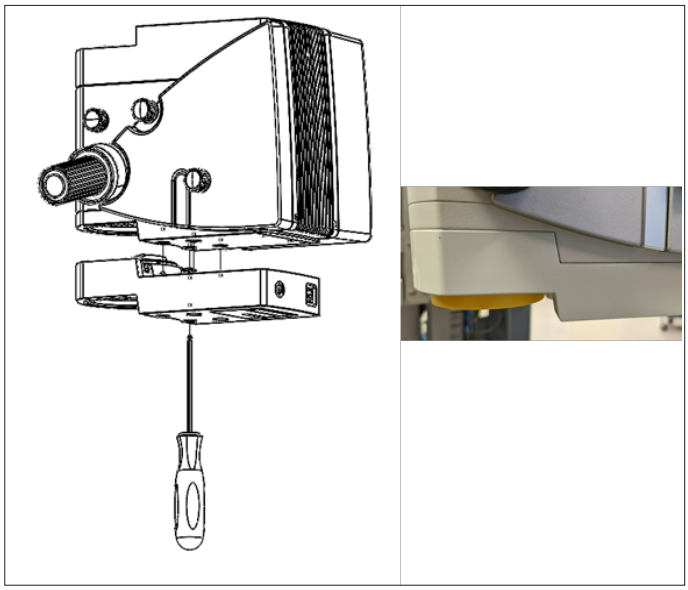
6.4 Installing the scanner

Installation of the scan head is the same for both the Leica M844 and the Proveo microscopes. To install the scan head:

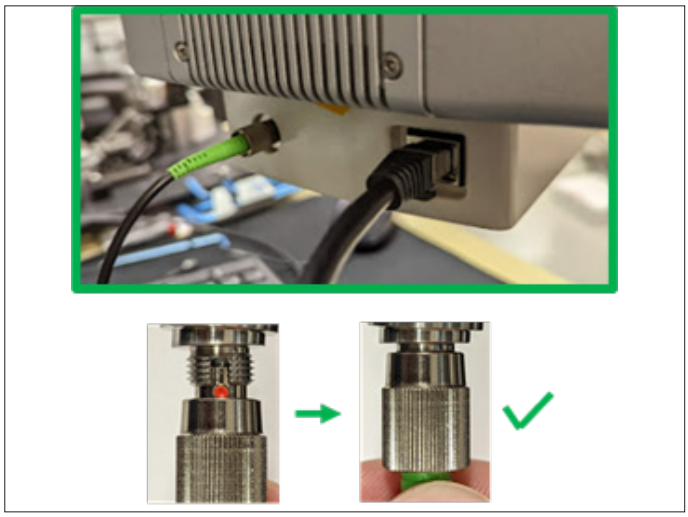
- ► Determine the work station layout of the microscope and the EnFocus cart before you begin. Ensure that adequate floor space and a power source can accommodate the EnFocus cart alongside the microscope
- ► Clear the area around the desired location of the EnFocus cart.
- ► Technician should wear nitrile gloves when conducting installation or removal
- ► Remove any microscope accessories from the work station that may interfere with the EnFocus device installation, including any fundus viewing system. If any of the accessories must remain sterile, be sure to follow sterile technique when handling them.
- ► If a sterile drape has been pre-installed, remove and discard the drape.
- ► Remove any installed mounting accessories from the base of the optics carrier, placing them in storage cases when available. Make sure the bolt holes on the under body of the microscope are clear.
- ► Remove the original microscope objective from the microscope optics carrier. If it is available, place the objective in its original case for protection
- ► Position the EnFocus cart in the desired location:
  - Close enough to the surgeon's chair for the screen to be visible to the surgeon.
  - On the side of the patient gurney opposite to the scrub nurse and sterile instrument cart.
  - The EnFocus must not be in the way of anesthesia or other critical surgical staff functions.
  - Once the cart is positioned in the correct location, lock the wheels on the EnFocus cart
- ► Remove the EnFocus scan head case from the bottom of the cart and place it on the EnFocus cart work surface, moving the keyboard and mouse out of the way, if necessary.

6.4.1 Mounting scanner model 9075-25084

- ► Remove the dust cap from the upper aperture of the scan head.
- ► Align the scan head underneath the optics carrier as shown such that the 4 captured screws at visible on the lid of the scan head align with the 4 mounting holes on the underside of the optics carrier.
- ► Use an M5 hex driver to hand tighten each of the 4 captured screws into the optics carrier

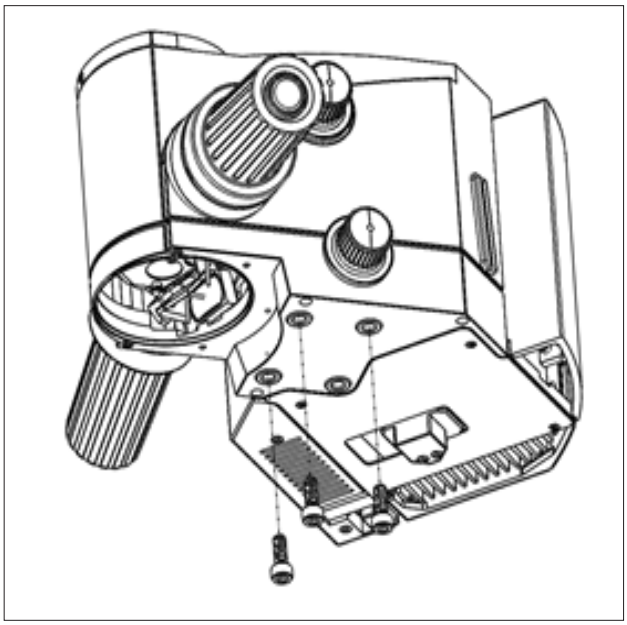


- ► Connect the optical fiber and ethernet cables at the back of the scan head as shown, being careful not to touch the exposed tip of the optical fiber.



6.4.2 Mounting scanner model 9075-25081

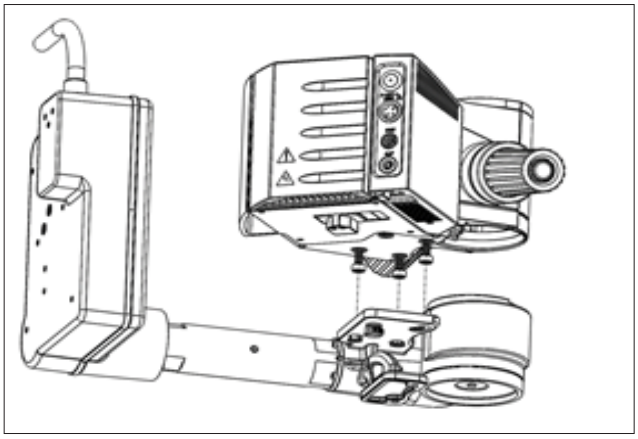
- ► Insert 3 screws into optics carrier at the locations shown in the figure (if standing in front of optics carrier use front-left, front-right and back-right screw holes), until red on the end of each screw cannot be seen
- ► While standing behind the optics carrier, place large holes of Scanner mount over the 3 screws inserted into the microscope and push the scanner up until it looks like the picture below.



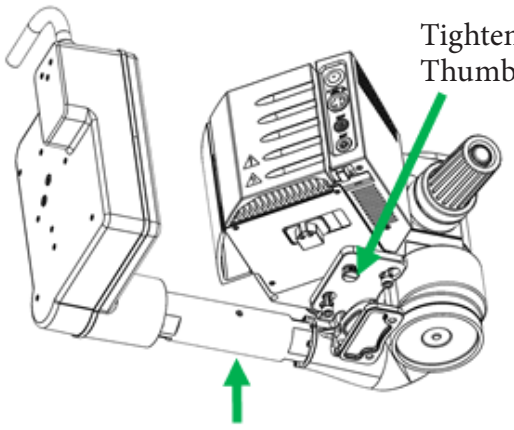
NOTICE

Risk of damage to the EnFocus OCT scan head during transportation.

- ► When carrying the scan head, grip the tube of the scan head.



- ► While standing behind the optics carrier, rotate Scanner counter clockwise to align the screws with the small holes of the Scanner mount.
- ► While standing behind the optics carrier, use one hand to tighten the thumbscrew 4 turns while second hand is used to push the scanner upwards.



- ► While standing behind the optics carrier, use ball head Allen key with one hand to tighten the 3 screws until firmly secured while second hand is used to push the scanner upwards.
- ► While standing behind the optics carrier, tighten the thumb screw until firmly secured but do not overtighten.

6.4.3 Common Instructions to complete

- ► Route the cables or conduit using the instructions of section 6.5.
- ► Once the cable has been routed and is secured, re-wind any excess cable onto the cable wraps on the side of the cart and fasten the cable loop with a cable tie for EnFocus cart systems.
- ► Test the routing of the cable to ensure there is enough slack, and it does not bind when the microscope is rotated or moved. The microscope must be able to rotate 270 degrees and move 1 meter in any direction from its nominal location without the cable binding or becoming tight. You may need to adjust the microscope stand spring tension to balance the microscope with the additional weight of the scan head. (See microscope manufacturer's instructions.)
- ► If required, install a sterile drape around the microscope and EnFocus device. Follow instructions provided by the drape manufacturer and the microscope manufacturer
- ► Re-install any accessory devices that are required for the surgical procedure and compatible with the EnFocus device (e.g. wide-angle fundus viewing lens, etc.). If the accessories are required to be sterile, be sure to follow sterile techniques as per the accessory device manufacturer.
- ► The bolt pattern from the optics carrier has been reproduced underneath the scanner mount, allowing accessories that were originally bolted to the microscope to be installed on the receiver, exactly as if they were installed directly on the base of the optics carrier.

CAUTION

Tripping Hazard.

- ► Do not create a tripping hazard with the cord of the EnFocus OCT device.

CAUTION

Risk of injury for the patient.

- ► Ensure the EnFocus OCT scan head is securely attached to the microscope prior to moving into position above the patient.
- ► Do not attempt to remove the scan head while a patient is underneath the microscope. The scan head could fall on the patient resulting in injury.

6.5 Mounting the EnFocus OCT cable

Once the scan head has been installed onto the microscope, the EnFocus OCT system cable must be mounted onto the microscope arm.
This is necessary to:

- Avoid tripping hazards for the operators,
- Avoid hindering the movement of the operators,
- Avoid contact of the cable with the patient.

The cable mounting procedures are different for the following configurations:

- Leica M844 F40, C40, or CT40 with EnFocus Cart Installation
  The cable duct is pre-mounted to the microscope arm and does not have to be mounted or removed again.
- Leica M844 F20, or Proveo 8 with EnFocus Cart Installation
  The cable cover is mounted over the cable.
- Leica Proveo 8 with EnFocus Microscope Integration Configuration
  The cable cover is mounted over the cable and is routed into the Proveo tower.

6.5.1 Mounting the cable onto the Leica M844 F40, C40, or CT40, microscope

- ► When mounting the cable, make sure that the remaining cable above the microscope arm's joint has the correct length:
  - The remaining cable must be long enough to allow free movement of the microscope arm.
  - The remaining cable must be short enough to prevent it from getting in the way or trapped in the joint.
- ► Route the cable along the cable duct.
- ► Secure the cable with the bracket and the knurled screw, located on the tilted side of the microscope arm.

6.5.2 Mounting the cable onto the Leica M844 F20 OR Proveo 8 microscope

Preparing the cable cover

Since the cable cover will stay on the cable, this procedure has to be done only once before mounting the cable for the first time.

► When routing the cable through the cable cover, make sure that the remaining cable above the microscope arm's joint will have the correct length:
  - The remaining cable must be long enough to allow free movement of the microscope arm.
  - The remaining cable must be short enough to prevent it from getting in the way or trapped in the joint.

► Route the cable through the cable cover.

Mounting the cable

► Mount the cable cover onto the microscope articulated arm with 3 knurled thumb screws.

! In the absence of a cable duct the EnFocus OCT cable may be secured using cable ties.

6.5.3 Mounting and routing the conduit of the EnFocus Integrated Configuration on the Leica Proveo 8 microscope

Mounting and Routing for Stationary Proveo

In most hospitals, the Proveo optics carrier will be in a fixed position relative to the tower,patient bed, and other items in the operating room. In these cases, the Proveo optics carrier only needs 180 degrees of motion so the conduit is able to be routed cleanly with no loops follow this routing procedure.

Scanner Model 9075-25084(Left Side of Image)

- Route the fiber and the cable through the cable channel then pass through the cable tie and two cable clips on the Proveo.
- Remove the fiber tip protector and connect the fiber and cable to the scanner. Cable wraps are provided to keep the fiber and cable connected in the routing.

Scanner Model 9075-25081 (Right Side of Image)

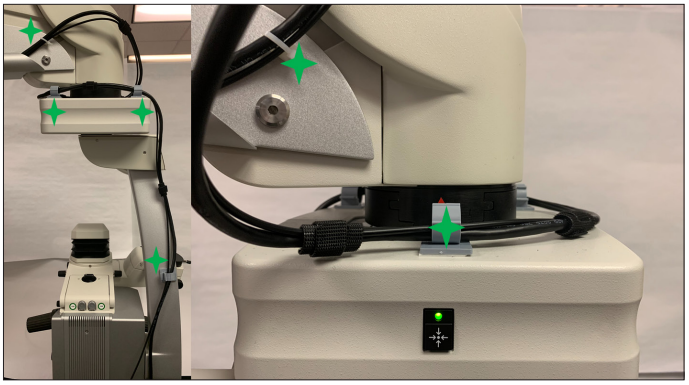
- Disconnect the cable channel from the Proveo parallelogram by removing the 2 thumbscrews.
- Route the conduit from the scanner through the two cable clips on the Proveo.
- Place the cable channel over the conduit such that the first marking on the conduit is at the end of the channel closest to the optics carrier.
- Connect channel guide to the parallelogram.

Mounting and Routing on Multiple Position Proveo

In cases where the Proveo will be moved between multiple operating rooms and the orientation of the room may be varied, the full degrees of maneuverability of the Proveo optics carrier is required. For these cases the conduit must be routed to provide the additional degree of freedom, follow this conduit routing procedure.

Scanner Model 9075-25084

- Setup the Proveo so that the optics carrier is at the maximum distance from the control unit.
- Route the fiber and the cable through the cable channel then pass through the cable tie just outside the channel. Leave a loop of cable at the base of the parallelogram at the tower to allow for movement throughout the range of motion.
- Route the conduit through the clip on the front of the XY coupler first. Wrap the cable and fiber loosely around the front of the XY coupler and then through the cable clips on the back.
- Route the cable and fiber through the cable clip on the side of the Prove and connect to the scanner. Cable wraps are provided to keep the fiber and cable connected in the routing.



CAUTION

Risk of compromised sterile field by loose cables.

The Ethernet and fiber optic cables on configuration 9075-00100 must be properly connected into the scanner. Failure to proerly connect the cables may result in the cables falling into the sterile field..

Scanner Model 9075-25081

- Setup the Proveo so that the optics carrier is at the maximum distance from the control unit.
- Adjust conduit to minimize the loop around the XY coupler but providing enough so it may turn 300 degrees without tension.
- Adjust conduit to minimize the amount looping around the parallelogram base but providing enough so it may turn 180 degrees with minimum tension.
- Place the cable channel over the conduit such that conduit remains loose. Connect channel guide to the parallelogram using the thumb screws.
- Route the conduit through the clip on the rear of the XY coupler and route loosely around the front of the XY coupler as shown.
- Route the conduit from the scanner through the lower cable clip on the side of the Proveo. Skip the cable clip located behind the surgeon screen.

6.6 Glare Mask Install and Remove

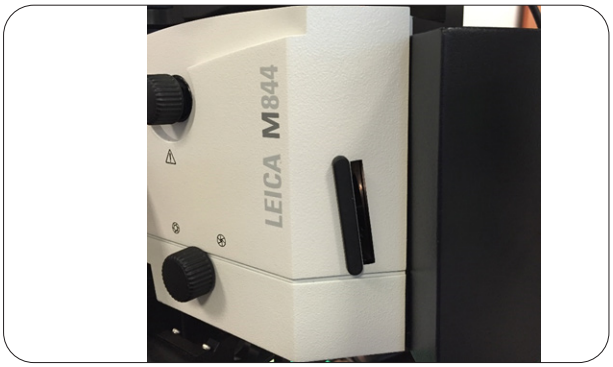
See "17 Glare" on page 85 for information on when to use a glare mask and "17.2 Glare Mask Selection" on page 90 on how to select which glare mask to use.

6.6.1 Leica M844

There are 2 glare mask options for use on the Leica M844 microscope - the circle mask and the bar mask.

To install a glare mask in the microscope do the following:

- ► Locate the two filter slides on the side of the M844 optics carrier
- ► Remove the protective dust cover from the rear slide and set aside.



- ► Insert the glare mask with the handle facing upwards until it is fully seated in the filter slide. You will hear a click when it is fully engaged.

- ► To remove the mask, simply pull it out of the slide, gripping the handle firmly. Be sure to replace the dust cover.

6.6.2 Proveo

There is 1 glare mask for use on the Proveo microscope.
To install a glare mask in the microscope do the following:

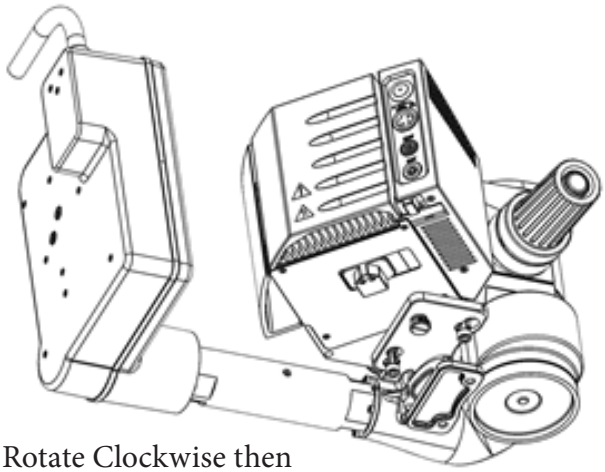
- ► Locate the two filter slides on the side of the Proveo optics carrier
- ► Remove the protective dust cover and set aside
- ► Insert the glare mask into the right most slot with the handle facing downwards until it is fully seated in the filter slide.
- ► To remove the mask, simply pull it out of the slide, gripping the handle firmly. Be sure to replace the dust cover.

6.7 Removing the scanner

- ► Remove any accessories that were installed on the EnFocus scanner mount and set them aside. If any of the accessories must remain sterile, be sure to follow sterile handling technique when handling them.
- ► Rotate the optics carrier away from the sterile field, then remove and discard the sterile drape.
- ► Remove the EnFocus scan head case from the bottom of the cart and place it on the EnFocus cart work surface, moving the keyboard and mouse out of the way, if necessary. Open the case and remove the toolkit.
- ► Remove the microscope objective from the scanner.
- ► Unfasten the cable ties that secure the cable to the microscope boom and IV pole.

6.7.1 Removing scanner model 9075-25081

- ► While standing behind the optics carrier, unscrew the thumb screw until completely loose.
- ► Use ball head Allen key to loosen each of the 2 screws that are closest to the objective lens (if standing in front of optics carrier front-left and front-right screws shown in the figure) until the green line on each screw is visible. Once the green line is visible, the screw heads will be under the plate with enough clearance to allow for the scanner to be rotated.
- ► While standing behind the optics carrier, use ball head Allen key with one hand to loosen the final screw until the green line on the screw is visible while second hand is used to push the scanner upwards. Once the green line is visible, the screw heads will be under the plate with enough clearance to allow for the scanner to be rotated.
- ► While standing behind the optics carrier, rotate Scanner clockwise to align the screws in the Optics Carrier with the large holes of the Scanner mount. Then pull the Scanner down, allowing holes of the scanner mount to pass over screws.

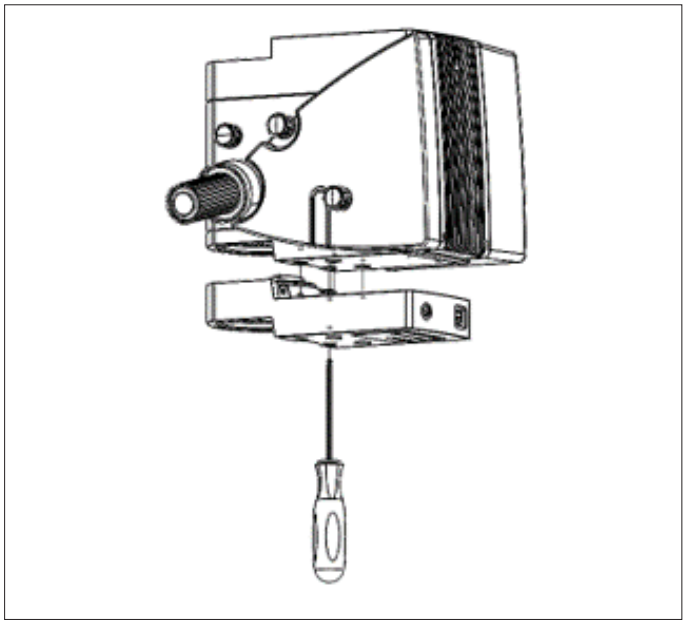


Rotate Clockwise then
Pull Down

- ► Remove 3 screws from the optics carrier.
- ► Reinstall the vinyl protection caps on the scan head and place it in the scan head case.
- ► Wind the slack in the cable around the cable wrap on the side of the EnFocus cart.
- ► Uninstall three screws that held the scanner to the microscope and place the screws in the scan head case. Close the scan head case, being careful not to pinch the cable.
- ► Reinsert the scan head into the EnFocus cart with the cable facing outwards. Wind any remaining slack in the cable around the cable wrap and secure the cable wrap with the remaining cable tie.
- ► Shut down the EnFocus device by powering down the computer. While the computer is shutting down, unplug the EnFocus power cord. The UPS will beep to indicate power has been removed, but the system will continue to operate on reserve power.
- ► While the computer continues to shut down, wind the power cable around the cable wrap, then push the EnFocus cart out of the surgical area to a secure location.
- ► Once the computer has powered down, turn off the EnFocus device by flipping the switch on the UPS.

6.7.2 Removing scanner model 9075-25084

- ► Hold the scanner with one hand and use an M5 hex driver to loosen each of the 4 captured screws from the optics carrier
- ► Remove the EnFocus cables.
- ► Reinstall the vinyl protection caps on the scan head and place it in the scan head case.



6.7.3 Common steps to finish removal

- ► Reinstall the microscope objective lens by carefully threading it in underneath the microscope. Do not overtighten.
- ► If required, install a sterile drape around the microscope. Follow instructions provided by the drape manufacturer and the microscope manufacturer.
- ► Re-install any accessory devices that are required for the surgical procedure. If the accessories are required to be kept sterile, be sure to follow sterile techniques as per the accessory device manufacturer.
- ► Rotate the microscope back into the sterile field

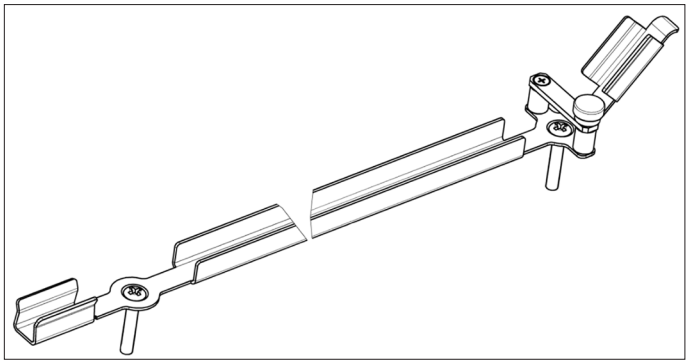
6.8

6.9 Removing the EnFocus

6.10 OCT cable

6.10.1 Removing the cable from the Leica M844 F40, C40, or CT40, microscope

- ► Loosen but do not remove the knurled screw of the bracket on the tilted side of the microscope arm.
- ► Open the bracket securing the cable to the cable duct.



- ► Remove the cable from the cable duct.

6.10.2 Removing the cable from the Leica M844 F20 or Proveo 8 microscope

- ► Loosen the 3 knurled screws.
- ► Remove the cable together with the cable cover.

6.11 Accessories Connections

6.11.1 Microscope Communication

Microscopes with serial communication ports may provide the ability to communicate status and commands between the 2 systems. Your service technician will make the necessary connections to enable this feature.
A status button at the bottom of the IVV window will indicate microscope communication status.
Once connected, the microscope input devices including the foot pedal and the handles may be programmed to control the actions of the EnFocus. The method for programming the input device can be found in the user manual of the microscope. The functions available and the effect that they have on the EnFocus behavior are provided here for your reference.

Function Name	Function Description
OCT mode on/off	Changes the controls of the foot pedal and handles to execute the functions programmed on the microscope for OCT Footswitch and OCT Handles or OCT Footswitch VR and OCT Handles VR if the microscope is in VR Mode.

Function Name	Function Description
OCT Change joystick state	Changes the state of the OCT control between DSC position and DSC size. During playback, the joystick state is automatically set to playback.
OCT up (joystick)	Multifunction button that has behavior dependent on the state of the joystick. If joystick state is in DSC position, this button moves the dynamic scan control window and location of the scan up in respect to the microscope video shown in IVV. If joystick state is in DSC size, this button increases the size of the scan. If joystick state is in playback, this button advances to the last collected frame.
OCT down (joystick)	Multifunction button that has behavior dependent on the state of the joystick. If joystick state is in DSC position, this button moves the dynamic scan control window and location of the scan down in respect to the microscope video shown in IVV. If joystick state is in DSC size, this button decreases the size of the scan. If joystick state is in playback, this button advances to the first collected frame.
OCT left (joystick)	Multifunction button that has behavior dependent on the state of the joystick. If joystick state is in DSC position, this button moves the dynamic scan control window and location of the scan left in respect to the microscope video shown in IVV. If joystick state is in DSC size, this button rotates the scan in a counter clockwise direction. If joystick state is in playback, this button advances to the previous collected frame in the collected scan.
OCT right (joystick)	Multifunction button that has behavior dependent on the state of the joystick. If joystick state is in DSC position, this button moves the dynamic scan control window and location of the scan right in respect to the microscope video shown in IVV. If joystick state is in DSC size, this button rotates the scan in a clockwise direction. If joystick state is in playback, this button advances to the next collected frame in the collected scan.
OCT Optimize Image	Single button combines auto locate, auto brighten and auto sharpen in a single button.
OCT Auto Locate	Automatically searches through the depth for the current procedure to find a sharp surface with high contrast from background and then sets the Z position at the setting where that condition is met.
OCT Focus +	Increases the position of where the OCT source is being focused, effectively drives the source to focus deeper into tissue.

Function Name	Function Description
OCT Focus -	Decreases the position of where the OCT source is being focused, effectively drives the source to focus shallower into tissue.
OCT Z +	Increase the depth location of where the OCT is being collected, effectively samples from a location deeper into tissue.
OCT Z -	Decrease the depth location of where the OCT is being collected, effectively samples from a location shallower in the tissue.
OCT Live Mode/ Stop	Initiates acquisition and display of orthogonal B-scans and upon stop makes the presented B-scan information and microscope video available for saving.
OCT Auto Sharpen	Finds optimal OCT processing coefficients in order to improve the sharpness of the image.
OCT Auto Brighten	Finds optimal conditions for OCT focus and polarization in order to provide the brightest image in the axial dimension.
OCT Scan	Captures a single volume with the specified B-scans per volume for playback or saving.
OCT Continuous Scan	Repeatedly captures volumes with the specified scan parameters over the volume set by the DSC.
OCT Save	Saves the volume captured by the scan command or orthogonal B-scan images during a stop from Live Mode into the file format specified in save preferences.
OCT Crosshair On/ Off	Crosshair and the DSC box appear/disappear from live video window and from oculars when injected.
OCT Reset DSC	Moves the dynamic scan control window back to the center of the microscope video view in InVivoVue with zero degrees of rotation.
OCT Previous Scan	Loads the previous scan collected into active memory.
OCT Next Workflow	Advance from current preset scan parameters to the next in the series of presets for the procedure.
Change View	Changes to next view in series (50:50, Full Screen).
OCT Toggle Image Lock	Turns Image lock function on/off.
OCT Toggle Image Contrast	Turns Image contrast function on/off.
OCT Frame backward	During playback, displays the previous frame in the collected scan.
OCT Frame forward	During playback, displays the next frame in the collected scan.
OCT First frame	During playback, displays the first frame in the collected scan.

Function Name	Function Description
OCT Last frame	During playback, displays the last frame in the collected scan.
OCT Next Procedure	Advances from current IVV procedure to the procedure nearest on the right. If at right most procedure, it cycles back to the left most procedure.

In addition to the programmable functions for the microscope control, EnFocus has several default behaviors associated with specific actions taken by the user with the microscope that occur when connected to the microscope.

1. When Magnification of the Microscope is changed, IVV automatically updates the field of view in the microscope video and the magnification value in the scan information.
2. When the Microscope is put into park position, IVV stops the system from acquiring OCT data.
3. When the Microscope is put taken out of park position, IVV begins acquiring OCT data in Live Mode.
4. When the Microscope is placed into VR mode, the IVV procedure changes to BIOM if the microscope states that a BIOM is in position or defaults to Flat Lens if a BIOM is not detected.
5. When microscope is communicating, status message stating "Microscope Communicating."
6. When view of B-scan overlay is active in surgeon oculars, status message stating "DIC 800: On" is reported.

6.11.2 Video Input and Output Connections

Your Leica service technician will make all necessary connections to the microscope video and to any secondary displays during system installation. If, however, you find it necessary to disconnect and/or reconnect you should do so by disconnecting and reconnecting the appropriate cable from the video output port on the microscope and from the video input port on secondary display devices.

6.11.3 Hot key Control

Hot key control provides an alternative method for controlling EnFocus functions using the keyboard.

Key	Function
F1	Toggle Aim/Freeze
F2	Scan
F3	Save
F4	Toggle Record On/Off
F5	Toggle Image Lock On/Off
F6	Toggle image Contrast On/Off
F7	Autolocate
F8	Autobrighten
F9	Autosharpen
F10	Next Procedure
F11	Change View
F12	Toggle Overlays On/Off
=	Increase Z Position
-	Decrease Z Position
Ctrl + =	Increase OCT Focus
Ctrl + -	Decrease OCT Focus
Spacebar	Toggle Playback/Stop
Left Arrow	Advance one frame backward in playback
Right Arrow	Advance one frame forward in playback
Ctrl + **Left**	Advance to first frame in playback
Ctrl + **Right**	To the last frame of playback

7 Operation

7.1 Training

A Leica associate will provide hands-on user training during the initial installation. In addition to the physicians, this training should include clinical staff, such as nurses and technicians, who will interact with the system by setting up and shutting down, and running the software during the procedure. If additional training is required after the initial setup, contact Customer Service to schedule an advanced training session.

7.2 Calibration

The system will be calibrated at the factory prior to shipment. Upon initial setup, a Leica service technician will verify operation and finalize calibration of system.

7.3 Draping

The EnFocus OCT device is compatible with standard off-the-shelf drapes used for surgical microscopes. Leica Microsystems recommends draping the EnFocus OCT device when using in a sterile environment. No unique draping specification is required to accommodate the EnFocus OCT scan head.

7.4 Device startup

7.4.1 EnFocus Cart Installation

- ► Prior to startup, inspect the system for damage, including the foot pedal.
- ► If damage is found, do not continue and contact customer service for repair.
- ► If required, install the scan head to the microscope per instructions (see "6.4 Installing the scanner" on page 2424).
- ► Connect the system's main power plug to a hospital grade wall outlet.
- ► When installed configuration includes a UPS, turn on the master power switch located on the front of the UPS.
- ► Once the system has completed the boot cycle, the InVivoVue image acquisition software will automatically start up.

7.4.2 Microscope Integrated Configuration

- ► Prior to startup, inspect the microscope for damage, including the foot pedal.
- ► If damage is found, do not continue and contact customer service for repair.
- ► If required, install the scan head to the microscope per instructions (see "6.4 Installing the scanner" on page 2424).
- ► Turn on power to the microscope, EnFocus will automatically be powered and InVivoVue will load.
- ► Once the system has completed the boot cycle, OCT mode and Change View functions will be active.

CAUTION

Risk of injury for the patient.

- ► Ensure the EnFocus OCT scan head is securely attached to the microscope prior to moving into position above the patient.
- ► Do not attempt to remove the scan head while a patient is underneath the microscope. The scan head could fall on the patient resulting in injury.

7.5 Standard Workflow

The following standard series of steps represents a typical workflow for surgeons, nurses, and hospital staff to follow to easily acquire and save OCT images during surgery. It does assume that the default preferences are being used. The user may find alternative workflows that achieve the same result using different combination of preferences and workflow step. These are provided as reference for new users.

- **Setup Microscope**

Ensure that all microscope setting are correctly configured. This should include verifying that the objective being used is selected and that the eye pieces on the binocular tubes are properly set for the surgeon or if unknown set to 0. Additionally ensure all settings associated with recording system are set as desired.

- **Select Surgeon Preference Set**

For microscope integrated configuration, select the surgeon on the microscope and the microscope tells Enfocus which surgeon is using the microscope. EnFocus automatically updates the preference based on this change. For cart integration configuration, select the surgeon preference to use for current surgery from Surgeon Preference Menu.

- **Add a Patient or a New Exam**

EnFocus may be used either in an anonymous mode where patient information is not stored or in a patient association mode.

If you are using the system in anonymous mode, add an exam under the anonymous patient. When you add he exam, ensure that the correct surgeon is selected. This will associate the exam with that surgeon and use that surgeon's preferences.

If you are using the system in patient association mode, select add patient. Enter the patient information, confirm the correct surgeon is selected and save. This creates the patient and an exam under that patient; the active exam is the exam that you just created.

- **Adjust Microscope into Position**

The surgeon should take the microscope out of the park position and adjust the microscope for the image to be parfocal. Taking the microscope out of park will automatically start EnFocus live imaging and as soon as the microscope stops moving EnFocus will find the target surface and report how far away from the working distance the surface is and allow the surgeon to make adjustments to be parfocal.

- **Optimize and Adjust Image**

Surgeon should choose to change the view being displayed to their preferred selection, 50:50 View is recommended for adjusting the OCT acquisition. Surgeon may choose to use the optimize functions to improve the image quality or with location lock enable just begin working and allow EnFocus to track the surface and automatically adjust the image. If the surgeon chooses to optimize locate will find a surface; z-position slider is used to adjust the depth in the eye where the OCT scan is being taken; auto-brighten to adjust the focus of the OCT laser to get a brighter image. User may also choose to change the location or orientation of the scan by adjusting the dynamic scan control; this is the shape that is overlaid on the microscope video in the 50:50 View. These functions may be done be entering OCT mode on the microscope and using the controls programmed on the foot switch or having an assistant activate the functions on the screen or keyboard.

- **Acquire Volumes, Playback, and Save**

In addition to the live OCT mode which provide two orthogonal scans in real time, the user may collect, review and save volume images. Select the scan icon to acquire a volume. Once acquisition is complete, the review controls become available to scan through the volume. At this point save the volume and a video of the volume is automatically saved and available for review.

For the remainder of the surgery, the user can alternate through the last two steps as desired. If additional optical instruments are used during the procedure, the system will automatically change procedures if the microscope has an actuator (VR mode or electrical BIOM); if not, the user should change the procedure button based on the current optical condition: Cornea for no optic; BIOM when using BIOM; flat lens when using a surgical contact lens; or RUV if using a RUV fundus viewing system. This may be done using the microscope foot switch or by having an assistant change the selection on the screen.

7.6 Shutting down the system

7.6.1 Cart Based Configuration

Leica Microsystems recommends shutting down the system at the end of each day.

► Close the InVivoVue software application.
► Shut down the system computer (Start button > Shut down).
► Once the computer has completed its shutdown sequence, turn off the master power switch on the front of the UPS. This will power down the imaging engine and interface box.
► Perform cleaning as necessary, see "9.1 Cleaning" on page 54.

7.6.2 Microscope Integrated Configuration

► Place microscope optics carrier into park position.
► Turn off the microscope power switch. This will begin a 45 second shutdown sequence that includes turning off EnFocus.

8 InVivoVue Software

Leica Microsystems' InVivoVue software enables a user to acquire, process, and display images acquired on Leica Microsystems' Spectral Domain OCT imaging systems.

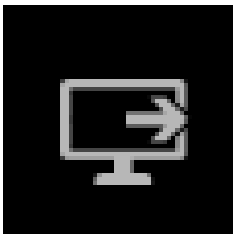
Image data is collected via defined scans. The data can be displayed in real-time and the scans are organized by patients, physician, and by exam session. The files are stored in a database that allows the user to browse through prior exams and to share data between InVivoVue systems. Images can be saved in several different formats for use with other applications.

InVivoVue supports a variety of hardware configurations providing software controls to command select hardware functions.

This user manual describes the use of the InVivoVue software together with the EnFocus OCT system.

8.1 Display Views

There are multiple viewing modes which control what information is displayed. The change view button (shown below) or change view function programmed on the microscope advances to the next display view in a predefined sequence.



The displayed view advances through a sequence determined by the EnFocus configuration, the microscope mode, and the user role.

Cart Installation Configuration Sequence

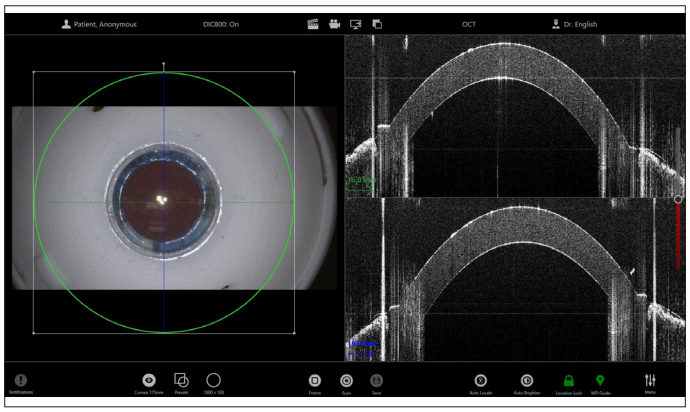
Independent of microscope mode, the sequence is 50:50 View, Quad View and then Microscope (if user role is Surgical Assistant) or Engineering View (if the user role is Hospital IT).

Configuration for Microscope Integration

For OCT mode on the microscope, the sequence is 50:50 View, Quad View and then Microscope (if user role is Surgical Assistant) or Engineering View (if the user role is Hospital IT). For all other microscope modes, the microscope view is followed by the 50:50 view.

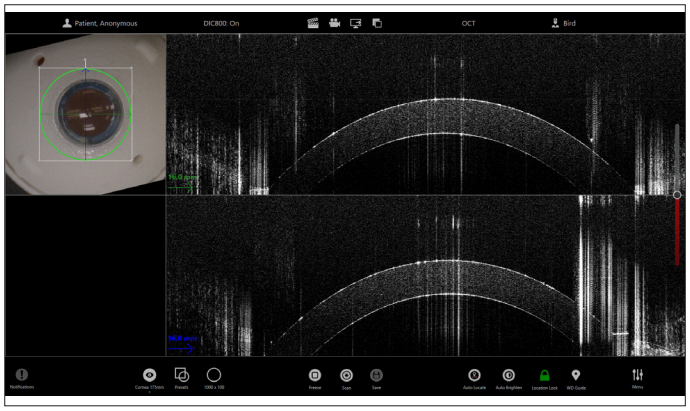
8.1.1 50:50 View

50:50 View uses half of the screen to show the microscope video and half of the screen to show OCT B-scans. OCT controls and notifications are located on the bottom of the screen with the exception of reference arm location which is a slider on the right side of the screen. Display controls, Patient Menu, a Surgeon Preference Menu are provided on the top of the screen.



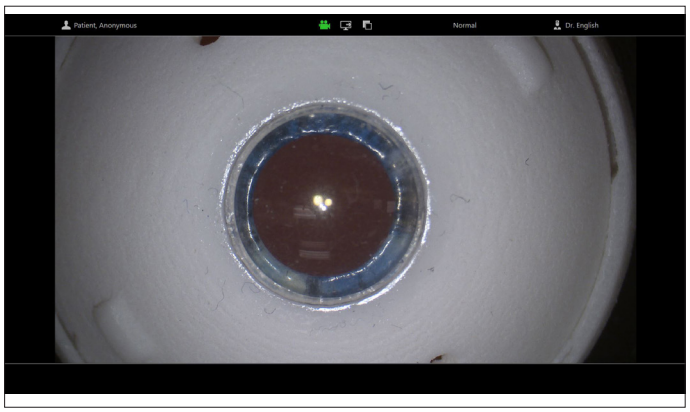
8.1.2 Quad View

Quad View uses 70% of the screen width to show OCT B scans. The left 30% of the screen is vertically split with microscope video on top and the volume intensity projection (VIP) on the bottom. The VIP provides an en face view of the acquired volume, where axial intensity is summed and displayed. While in live mode, no VIP image is displayed (as shown below). The same controls available in 50:50 are available on this view.



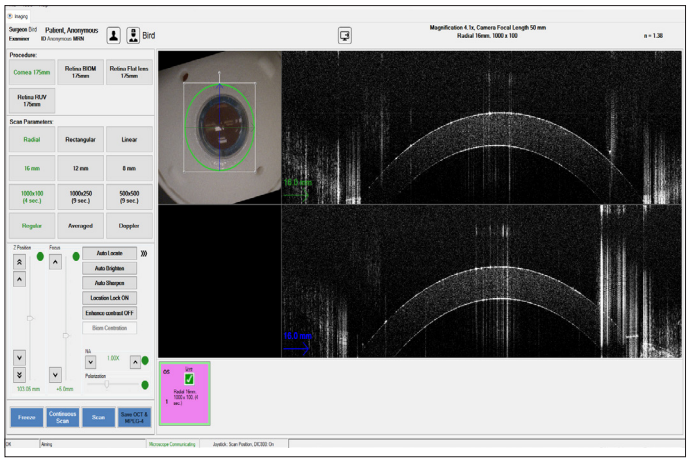
8.1.3 Microscope View

Microscope View shows the microscope camera view. It does not show any OCT controls but does show display controls on the top of the screen.



8.1.4 Engineering View

The Engineering View is where access to additional functions may be found.



Engineering View Sub-menus

▶ **File menu**

The file menu contains items for saving data in various formats and for printing images.

▶ **Tools menu**

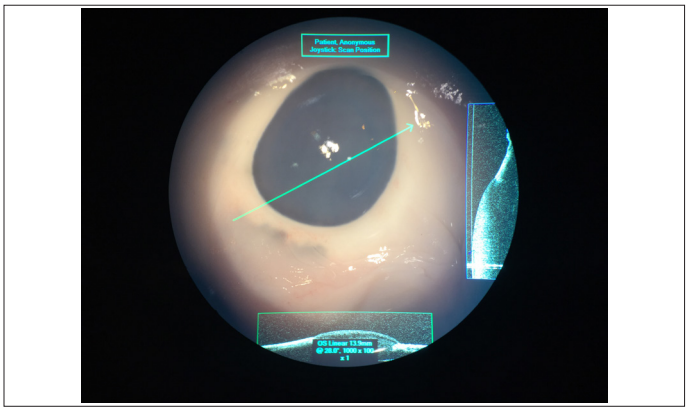
The tools menu has options for managing data files by importing and archiving/retrieving. There are also options for creating and loading custom configuration files and customizing system behavior. Advanced users may see options for interacting with the hardware at a low level.

▶ **Help menu**

The help menu has shortcuts for reviewing the user manual and release notes, as well as viewing dialogs with system and installation information.

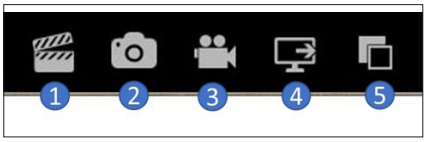
8.1.5 Intraocular Viewing

Users that want to see the OCT scans while looking into the microscope binoculars need to use an image injection binocular like the DI C800. In this case, the dynamic scan control is placed over the field of view and the OCT scans are placed on the side and bottom of the binocular view. Additionally patient information and scan information may be shown in this view or may be turned off by Leica Service personnel.



8.2 Primary Functions

8.2.1 Display Controls

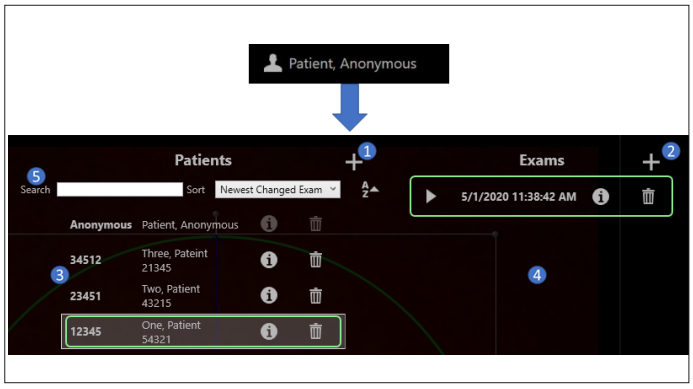


1. **Docusystem Control Screen:** This button transitions microscope to provide the Docusystem with touch screen control and displays the Docusystem user interface. Used for accessing functionality like patient setup, data export, or playback of recorded files on the system. Function is only present for specific docusystems where control is needed. Once entered, use Change View on the microscope to return to EnFocus views.
2. **Still Capture:** Use button to capture picture of current screen.
3. **Recording:** Use button to start or stop the recording of what is shown on the microscope monitor. Button flashes when recording and is solid when not recording.
4. **Change View:** Advance to next viewing screen in sequence.
5. **View Controls:** Stops displaying the controls in the view. Touch screen anywhere to display the controls again.

Next to these controls there are two information fields. On the left, between the Display Controls and the Patient menu, the status of the DI C800 (intraocular viewing) display is provided when installed. On the right, between the Display Controls and the

Surgeon Preference Menu, the mode of the microscope is shown.

8.2.2 Patient Menu



After selecting the patient icon from the main screen, user is presented with a list of existing patients on the left. The green border identifies which patient is associated with the active (currently loaded) exam. On the right, all exams associated with the active patient are displayed and the active exam has a green border. The labels in the menu image above have the following functions:

NOTICE

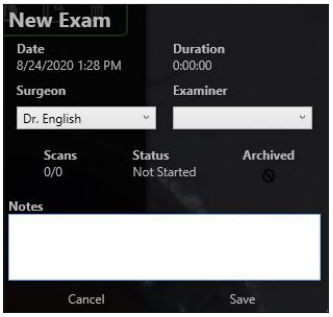
List of named patients and ability to add a named patient are only available to authenticated Surgical Assistant users or when user authentication is disabled.

1. **Add Patient:** Opens window to add a new patient. User may enter Name, identifying number, medical record number (MRN), date of birth, eye condition and notes. Adding a new patient creates an exam for that patient that is associated with the active surgeon preference .

NOTICE

Activating the user interface outside of an active menu will close the active menu. Any changes or data added that have not been saved or applied will be lost.

2. **Add Exam:** Opens window to add a new exam under the currently selected patient. An exam is a collection of scans associated with a specific patient on a specific day; it contains all the OCT data collected during a surgery. Surgeon associated with active Surgeon Preference is the default but may be changed from this window. Examiner field may be used if a dedicated assistant it collecting OCT scans and you want to record that data.

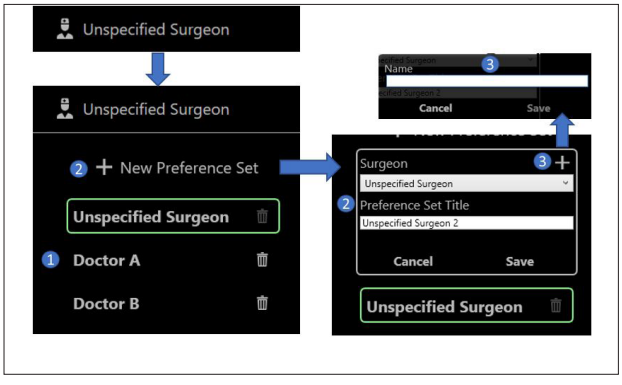


3. **Patient Selection:** List of patients previously entered into system. Select one to see the list of exams associated with that patient on the right or to add an exam under the selected patient. Green outline indicates which patient currently selected. Info button allows elevated users to edit patient information and all users to review data.
4. **Exam Selection:** List of exams associated with the active patient. Green outline indicates which patient currently selected.
5. **Search and Sort Patient:** User may enter a whole or partial patient name or identifier into the search field and reduce the number of patients shown to those with a match. May also choose to sort the displayed data by exam date, identifier or name in either ascending or descending order.

Information icon allows user to view or edit patient/exam details. Delete icon allows elevated users to delete the patient and all associated exams or delete specific exams.

8.2.3 Surgeon Preferences Menu

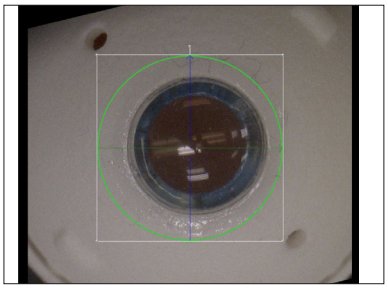
Surgeon preferences enable customization of the software for different users. The menu is located on the top right of the View and selecting the menu provides several functions.



1. **Surgeon Preference List:** List of available preferences to choose to activate; currently selected preference has green border.
2. **Add a New Preference:** Selecting the + icon opens a dialogue to add a new preference. First select the surgeon that will be associated with the preference. Every time the preference is used all collected exams will be associated with the named surgeon in the database. If the surgeon is not already entered into the system, select the add surgeon button. Second, give the preference a title that will be displayed; this may be the surgeon's name or provide something more descriptive if a surgeon has different preferences for different surgery types.
3. **Add a New Surgeon:** Add surgeon + button allows the user to add a surgeon to the database. Enter the surgeon's name in the format of your choice (first name last name recommended).

8.2.4 OCT Dynamic Scan Control

Dynamic Scan Control (DSC) is a graphical overlay placed over the microscope camera video to track the placement of the scan relative to specific locations in the eye. The dynamic scan control graphic reflects the pattern of the selected scan, including showing the orientation of two orthogonal scans used during Live mode. Adjustments can be made during Live mode but not while a volume scan is being acquired.



▶ Adjust Size

On touch screen, size may be adjusted by moving two fingers closer (to make smaller) or farther apart (to make larger). Using a mouse, select a corner of the overlay and move to the center of the DSC for a smaller scan and away for a larger scan. Using foot pedal, select the OCT Toggle Footpedal to change from location control to size and orientation then use OCT Up to increase size and OCT Down to decrease size. The size of the orthogonal scans are shown on the lower left corners in the B-scans.

▶ Adjust Location

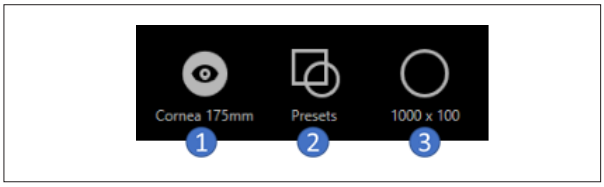
On touch screen, location may be adjusted by selecting within the scan and dragging the scan to desired location. Selecting outside the scan repositions the center of the scan to location where you touched. Using a mouse, select the overlay and drag the DSC to desired location. Using foot pedal, use the OCT Toggle Footpedal to have location control to then use OCT Up, Down, Left, or Right to position the scan.

▶ Adjust Orientation

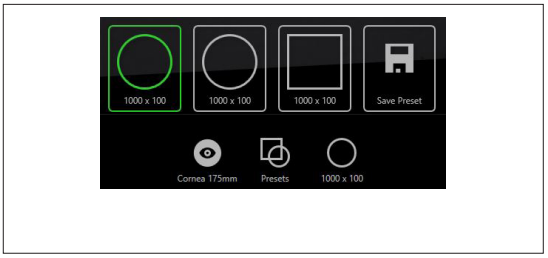
On touch screen, orientation may be adjusted by touching screen with two fingers and then rotating those fingers in the direction you want the scan to go. Using a mouse, select the top handle of the overlay and move clockwise or counter-clockwise to orient the scan. Using foot pedal, select the OCT Toggle Footpedal to change from location control to size and orientation then use OCT Left to rotate counter clockwise and OCT Right to rotate clockwise.

8.2.5 OCT Controls: Scan Configuration

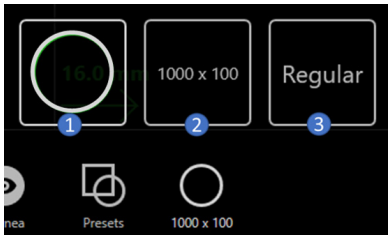
OCT Scan Configuration controls are found on the bottom left of the OCT Views. It is a group of controls that includes a method to select the procedure to use; select and save preset scans; and adjust the current scan shape, density, and special processing.



1. **Procedure:** Informs user what procedure is currently active: Cornea; Retina BIOM; Retina Flat Lens; or Retina RUV. Each time the icon is selected it advances to the next procedure in the list of active procedures as set in surgeon preferences. Each procedure adjusts the z-position range to match the expected optical setup, orientates the camera view, and access preset scans. In addition to manually changing the procedure, the procedure may be changed by a change in the microscope mode, engaging/disengaging electric BIOM, or by activating Change Procedure function through the footswitch.
2. **Presets:** Three options of scan configurations that define shape, density, scan specialty, scan size, and orientation of the scan to be use. Allow user to quickly change between preferred scan types throughout the surgery without independently configuring each setting. When a new preset is desired, setup the scan configuration desired as a preset; under Presets activate the **Save;** select the preset that will be replaced. Each surgeon preference preference has individual Presets and each Procedure has independent presets that may be configures. If a preset is currently active, the border is green. In addition to manually changing the preset, activating Next Workflow on the footswitch will advance to the next preset.



3. **Scan Settings:** When activated provides user options to change active scan settings.



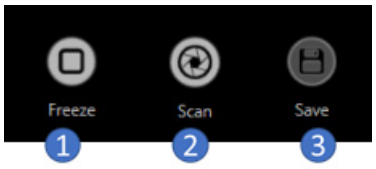
1. Shape: rectangular, radial, or linear (repeatedly acquires the same line over time)

2. Density: Number of points collected in a volume defined as the number of A-scans per B-Scan by the number of B-scans per volume

3. Scan specialty: Regular, Doppler (use false color to show qualitative axial motion of fluid), or Averaged (enhance signal to noise ratio by collecting multiple samples at each point and automatically register and average the points before displaying results)

8.2.6 OCT Controls: Acquisition

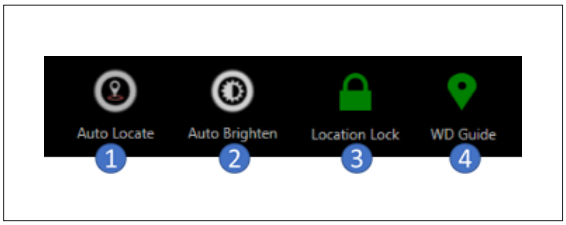
OCT acquisition controls are found on the bottom, center of the OCT Views. The controls are used to acquire and save scans. Each function may be controlled using the microscope footswitch or by the touchscreen.



1. **Live/Freeze:** Continuously acquire and display two cross sections; one along the blue and one along the green line. Allows user to scan anatomy to find target sites for OCT imaging by moving the dynamic scan control (DSC). Selecting freeze stops the acquisition and user may save the active frames that are on screen (with Save Icon). In Live mode, each B-scan has 1000 A-scans across each orthogonal dimension.
2. **Scan:** Capture a volume defined by the scan pattern and scan density. Once collected the scan data may be saved, reviewed, or discarded by overwriting.
3. **Save:** Saves the captured scan in the formats and locations defined by user preferences.

8.2.7 OCT Controls: Optimizations

OCT optmizations controls are found on the bottom, right of the OCT Views. It is a group of controls that includes a method to locate a surface, track a surface over axial movement, optimize signal, and be informed of relative offset of microscope from working distance.

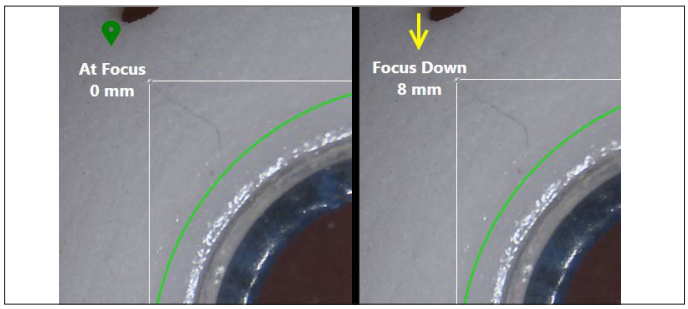


1. **Auto Locate:** Automatically adjusts the scan to find the brightest target surface in axial range for the selected procedure. May be activated from screen or footswitch; once activated icon will show option to Abort the function which will immediately cancel the search. If the position of the microscope is changed while activated, the function will automatically abort.
2. **Auto Brighten:** Automatically adjusts illumination settings (focus and polarization) to achieve maximum brightness of target image. May be activated from screen or footswitch; once activated icon will show option to Abort the function which will immediately cancel the search.
3. **Location Lock:** Automatically detects the brightest target surface in axial range and tracks that surface axially. First the function detects a surface then it will automatically adjust the Z-position and OCT focus to keep that target which is moving axially in view on the B-scan and maintain optimal brightness. May be activated from screen or footswitch; or configured to automatically start at startup. During use if the system does not find a target surface within 5 seconds of engagement, it will use the autolocate function to search a larger axial depth to find the surface. When the function is engaged, if the microscope axial position is changed and the microscope is communicating with EnFocus the function will stop until the microscope stops moving. When activated, the lock icon which turns green - light green indicates active but not tracking and dark green indicates that system is actively tracking a surface.

NOTICE

Location lock finds and tracks the brightest image in the active range. If the surface being imaged has low signal strength and a surface with high signal strength is nearby it is recommended to turn Location Lock off and manually adjust the Z-position using footswitch or screen controls.

4. **Working Distance Guide:** Working distance guide uses the location of a target surface to determine how close to the actual working distance of the objective, the microscope is currently positioned. This function may only be used when Location Lock is active and the microscope is in Normal mode. The function creates an overlay that is shown in the top left corner of the microscope video. When the system is within 2mm of the working distance the wording is green indicating that the microscope is correctly positioned. When the microscope is at the working distance, the microscope will be parfocal and all magnifications should remain focused for the surgeon without needing to readjust the microscope. When the difference is greater than 2mm, the direction and distance that microscope needs to move is displayed in yellow. If no surface is found over the Location Lock range, it reports no OCT image in red. When activated, the icon which turns green; May be activated from screen; or configured to automatically start at startup with an option for overlay to be persistent or fade after 5 seconds.

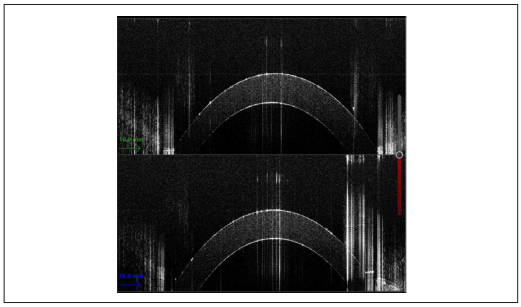


NOTICE

Working Distance Guide is dependent on the correct objective lens being selected on the microscope and the user having used Parfocality Guide to establish accurate diopter settings and having the binoculars configured to those settings.

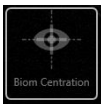
8.2.8 OCT Controls: Z-Position

Adjusts position where the OCT will collect its image in the depth of the eye. This can be adjusted by dragging the B-scan on the screen in the desired direction: up to move the imaging plane deeper and down to move the imaging plane towards the objective lens. It can also be adjusted by moving the red slider on the right side of the B-scan, or by using the OCT Z+ or OCT Z- functions on the footswitch.



8.2.9 OCT Menu

Menu icon on the OCT views provides access to additional functions used less frequently. Selecting the Menu icon displays a listing of icons that include immediate actions and access to submenus that have a collection of associated functions.

	**Display Axis:** Displays axes in millimeters on available views in axial and lateral dimensions of B-scan, VIP, and microscope image.
	**Auto Sharpen:** Adjusts processing to provide sharpest image of target layers. Automatically done in the background for EnFocus for Microscope Integration.
	**Continuous Scan:** Repeatedly captures a volume defined by the scan pattern and density. The scan sequence wraps to the beginning after collecting the specified number of lines in the scan density.
	**BIOM Centration:** With BIOM in place for imaging, function centers the OCT beam on the apex of the lower lens and adjusts video registration to align the scan and microscope video. Additional information in the **Advanced Functions > BIOM Centration** section of this manual
	**Data Management:** Provides submenu to access of help functions including file open, archive, and retrieve actions. Additional information in the **Data Management** section of this manual.
	**Help:** Provides submenu to access of help functions including user manual, changing user role, and service actions. Additional information in the **OCT Help Functions** section of this maual**.**
	**Preferences:** Launches window to access of preferences described in **Surgeon Preferences** section of this manual.
	**Calipers:** Provides a method to manually measure features in the image. Provides a submenu allowing for configuring or selecting calipers for use. Additional information in the **Advanced Functions > Calipers** section of this manual
	**Review Acquired Scans:** Opens submenu that allows selection of saved scans for playback. Each saved scan has the time it was collected to aid in selection.

8.2.10 OCT Notification: Messages, Errors and Warnings

EnFocus provides users with two types of notifications of system conditions: temporary notifications and user acknowledged notifications. Temporary notifications inform users of temporary

states or conditions; these messages are briefly shown above the OCT controls and then disappear without any user actions required.

User acknowledged notifications are warnings and errors that the user must acknowledge for the message to be cleared. These notifications are managed by the Notification Manager in the bottom, left of the OCT Views. When one occurs the color of the Notification Manager icon changes to Yellow for a Warning or Red for an Error. By selecting the Notification Manager, additional details on the error/warning message are provided to the user to take action. Messages and recommended actions are provided in the troubleshooting section of this manual.

8.3 Surgeon Preferences

EnFocus provides users the ability to customize their experience through Surgeon Preferences. Each Surgeon Preference defines preferences for saving, scanning, viewing, displaying data, workflow, behavior of automated functions, and is connected to a single surgeon. When EnFocus is communicating with a microscope, it coordinates the User ID of the microscope with the Surgeon Preference to minimize the steps required for a user.

8.3.1 Surgeon Preference Menu

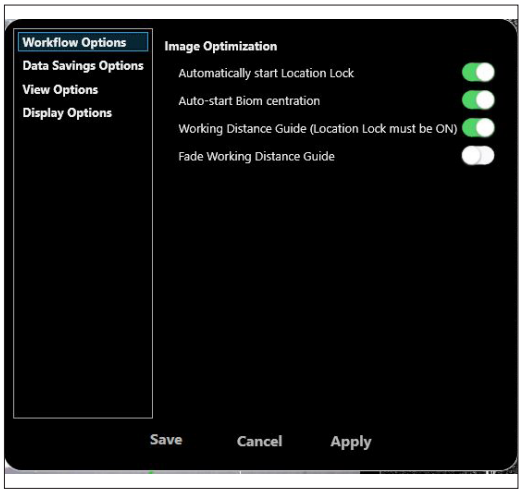
Surgeon Preference Menu provides the user the ability to add or select the preference to use. These directions are described in section 8.2.3 when discussing Primary Functions. A surgeon has a single entry in the metadata corresponding to their name but the surgeon may have multiple surgeon preferences. Having multiple surgeon preferences allows the system to be configured differently for different surgery types if that is desired. Each preference should be associated with a separate User ID on the microscope. The User ID of the microscope is only ever connected with one EnFocus Surgeon Preference at any time. This is what allows the User ID to automatically set the surgeon in the metadata. This relationship can be changed by the user at any time.

8.3.2 Preference Settings

The Configure Preference window opens with the ability to change four sets of options: Workflow Options; Data Saving Options; Display Options; and View Options. In this window, the option is immediately enabled when the slider is set green; it is made permanent to the active Surgeon Preference when "Save" is selected and selecting "Apply" applies the setting until InVivoVue is restarted.

> **!** Preference settings will only become persistent if they are saved to the User Configuration by selecting "Save Preferences" in the Preferences Window.

Workflow Options allows you to change the behavior of automated functions.

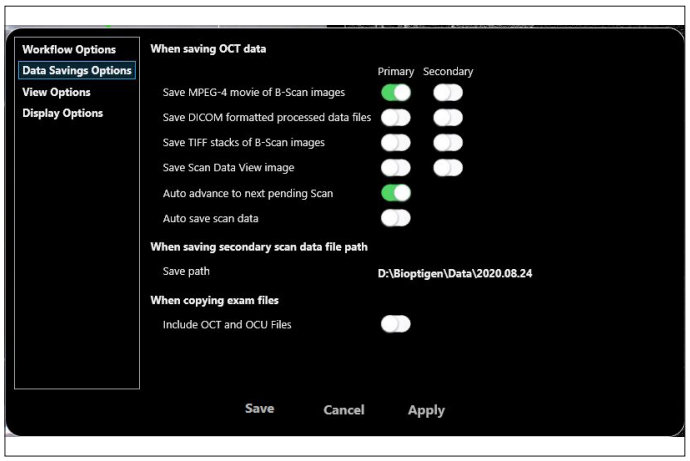


- Acquisition Control setting enables the system to start automatically average OCT data when an averaged scan is selected.
- Enabling Location Lock to start automatically at start-up, allows EnFocus to find an OCT image without any interaction.
- Auto-start BIOM centration when enabled runs the BIOM centration the first time the BIOM is flipped into place during an exam.
- If Autostart Location Lock is selected, user may also choose to have Working Distance Guide active on start-up.
- Enabling Fade Working Distance Guide causes the guide to disappear after 5 seconds of being displayed (when the value changes the counter is reset).

Data Saving Options

Allows user to configure which types of files are saved to saving locations and what data is copied when copy data function is used. It allow configuration of system behavior when a scan is saved and tells the Secondary Save path.

For Primary Saving, all data is saved to a fixed location in the embedded data drive of the EnFocus and has a fixed organization. You may choose to save scans as one or more transportable file formats to the primary location including MPEG-4, DICOM readable, and TIFF stack video formats and choose to save the scans in native OCT/OCU formats (high fidelity files that only InVivoVue can open but are needed for reprocessing data). For data collected in Scan Mode, you can choose to save an image of the Scan Data View which saves the view from the middle frame during acquisition. For data collected in Live Mode, you can choose to save an image of the Scan Data View which saves the view when the Live Mode is stopped.



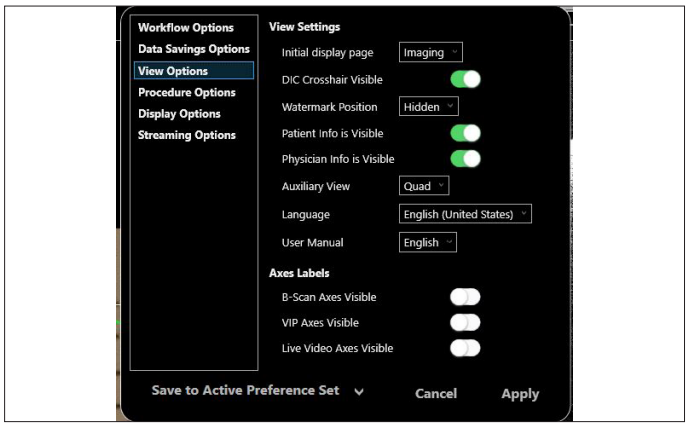
- InVivoVue may be set to automatically save every scan by enabling "Auto save scan data" on this page. It will save all selected data formats each time Scan Mode is activated.

- InVivoVue may be set to automatically advance to the next pending scan after every scan by enabling "Auto advance to next pending scan" on this page.

For Secondary Saving, the set of file format choices to save may be independently chosen from the primary save. These files will get saved to the secondary location. This function allows data to be saved to an external drive that is temporarily attached during surgery and disconnected at the end of the procedure.
This allows the operator to review the files away from the EnFocus without having to export the data.

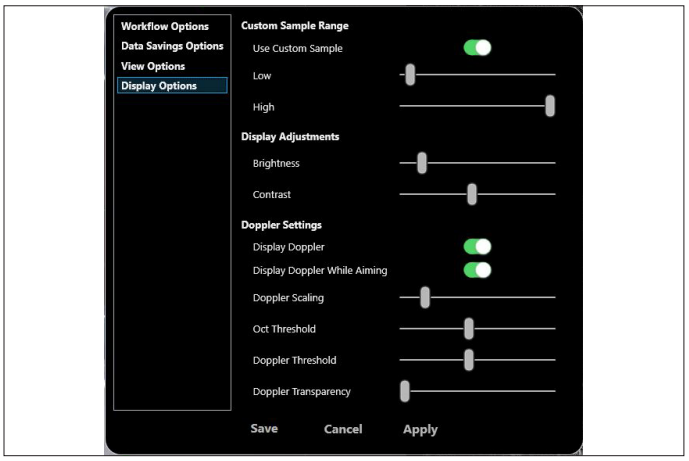
If secondary saving is enabled but an external drive is not connected, InVivoVue save will fail and a message indicating that the secondary storage device is not located will be displayed.

View Options allows the user to select what is viewed. The Leica log may be repositioned (or removed) with Watermark Position selection. Patient and Physician names are shown when enabled. Auxiliary View determines what view is shown on external HDMI output. The manual and user interface languages can be set. Can add presence of axis as a default.

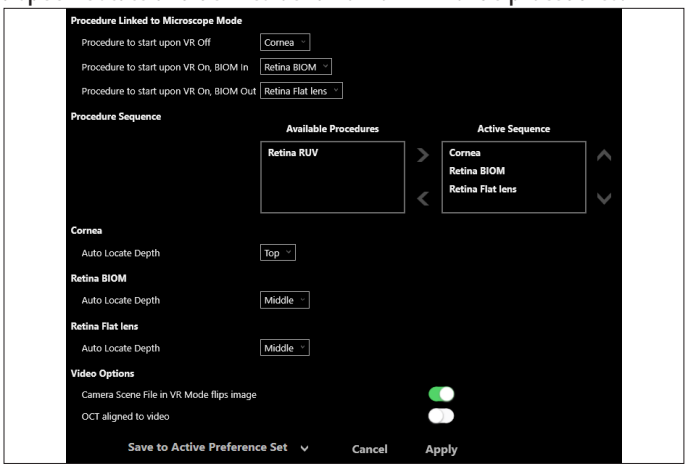


Display Options

- Adjust the amount and location of the axial depth being displayed in the B-scan by enabling **Custom Sample Range.** Slide the **Low** control from left to right to exclude depth from the top and the **High** control from right to left to include or exclude line samples from the bottom of the image.
- Use the slider controls to adjust the Brightness and Contrast of the image in the B-Scan window.
- Details of Doppler Display Settings are in the Doppler Scan Section in Advanced Functions



Advanced Procedure Options configures which Procedure should be used when a connected, communicating microscope is in a specific state and defines behavior for InVivoVue procedures.



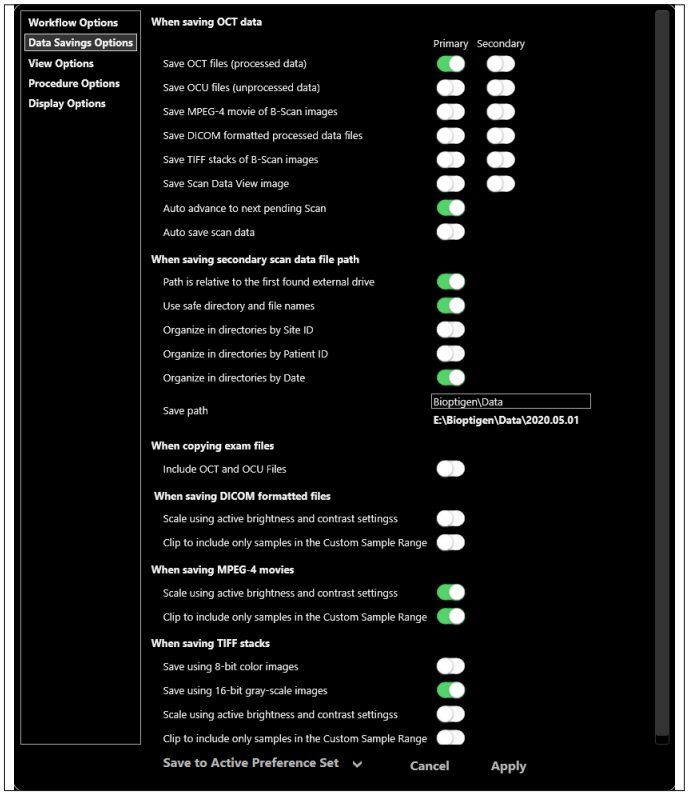
- Procedure Linked to Microscope Mode defines the InVivoVue procedure to be used for "VR Mode Off", "VR Mode On with BIOM In", and "VR Mode On with BIOM Out". For these options, the state of the BIOM expects an electrically connected BIOM and if a manual BIOM is being used it is equivalent to "VR Mode On with BIOM Out."
- Procedure Sequence allows the user to define the sequence of procedures that the procedure button cycles through when activated. Select a procedure and use left/right arrow to exclude/include in the sequence; once included use up/down to define the order of the sequence.
- Auto-locate location defines where (top or middle) in the

B-scan the auto-locate function will position the scan for each procedure.

- Video option has one setting used to match the configured behavior of the microscope video during vitreoretinal procedures (inverted or not). The second setting when disabled registers the microscope video to the EnFocus scan; when enable it registers the EnFocus scan to the video.

Advance Workflow Options includes the ability to select which parameters are optimized for Auto Brighten and which optimization functions are called by the Auto Optimization function (Auto Locate, Auto Brighten, and Auto Sharpen being the options).

Advanced Save Options



- For each of the transportable video formats, you can choose to save the videos to match the way they were seen during acquisition by enabling the settings "Scale using active brightness and contrast settings" and "Clip to include only samples in the Custom Sample Range." If these settings are not enabled then data is saved without any processing that makes the images easily viewable.
- Change the path where secondary files will be saved and the scheme of organization of those files. Changing the "Save Path" will change the location where file types enabled as secondary save files will be saved. The selection "Path is relative to the first found external drive" will set the drive portion of the path to be the first external drive letter when enabled and will be an absolute drive path defined in the save path if disabled. The selection for "Organize" establishes the organization of files in sub folders in the save path. Each selection creates a folder structure under the main save path and multiple selections creates a folder hierarchy with Date under patient which is under Site.
- Patient information is protected by default in the file names. If user prefers the file names to include defining information, disable "Use safe directory and file names" and the names will be descriptive.
- Enable "Include OCT and OCU Files" for the copy exam function to include those files when copying.
- May choose to save native OCT or OCU files on primary or secondary.

CAUTION

Risk of patient data not being saved.

- If all save options are disabled in the save preference, saving a scan will not report an error and will not save any data for the exam.
- It is recommended to leave Save OCT to Primary enabled at all times to mitigate the potential for this occurring. If an OCT file is available the other formats can be created at a later time.

8.3.3 Surgeon Preset Scan Configurations

Every Surgeon Preference has three preset scan configurations available for each procedure (Cornea, Retina BIOM, Retina Flat Lens, Retina RUV). The methods for using or modifying the presets are described in OCT Controls: Scan Configuration.

8.3.4 Microscope User Association

EnFocus Surgeon Preferences can be associated with microscope User ID such that selecting a User ID on the microscope automatically selects the surgeon preference used by EnFocus. To associate the Surgeon ID with the microsope User ID.

- Select the User ID on the microscope.
- Select (or create) the surgeon preference that should be associated with the microscope User ID from the surgeon preference menu.
- The User ID and surgeon preference are now associated. Selecting the microscope user ID will select the surgeon preference and this sets the surgeon in the exam metadata.

This procedure may be done when initially creating the preference or at any point selecting an alternate Surgeon Preference will associate that preference with the microscope User ID.

8.4 Patient Management

EnFocus provides a capability to manage collected scans as exams referenced to a patient. Patient information is collected and kept in a database. A patient has one or more exams; each exam is the series of scans collected during a specific imaging session (surgery).

The exams can then be searched using patient information to help find the desired exam. Alternatively, EnFocus may be used without adding specific patient information; scans may be collected and managed using the Anonymous Patient. The decision of collecting and storing patient information on EnFocus is the decision of the user and the user's institution.

Anonymous patient

The anonymous patient is a predefined patient record without any specific patient data and is used as a placeholder to quickly create exams without having to enter a new patient first. It is the default patient that is used when IVV is started after inactivity (opens with last named patient if period of inactivity short).

8.4.1 Add Patient

Opening the Patient Menu opens a window to add a new patient. User may enter Name, identifying number, medical record number (MRN), date of birth, eye condition and notes.

► Enter the data for the patient entry:
- ID (only letters and numbers, must be unique)
- First and Last name (duplicates are allowed but will trigger a warning message)
- DOB (date of birth)
- Select M or F for the patient's gender
- MRN (medical record number, must be unique if entered)
- Refractive Error and Axial Length. These values are records only and are not used by the program.
- Notes

► Adding a new patient creates an exam for that patient that is associated with the active surgeon preference .
► When all entries are made, select **Save**.

8.4.2 Link Exam to Patient

Exams can be associated to a patient after initial acquisition.

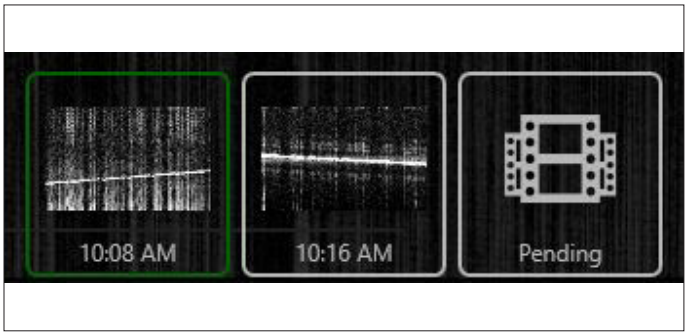
► If the patient doesn't exist, create the patient.
► Select patient to find the exam to be linked. With large database, the process is easier if you search for the patient name to minimize the number of patients shown on screen.
► Drag the exam from the Exam list to the patient on the left; release the exam when file is over the desired patient.
► Exam is now associated with the patient, select patient to see the exam in the exam list to the right. Note, if you mistakenly associate the exam with the wrong patient, repeat the process.

8.4.3 Review Exam Data

At any time, user can review saved scans of the active exam.

► If a scan has been acquired but not yet saved, this unsaved scan can be reviewed by using the **Playback** buttons.
► The current exam contains the pending, unsaved, and saved scans in the **Review Acquired Scans** submenu.
► To review a saved scan go to **Menu** > **Review Acquired Scans** and select the icon in the Scan queue corresponding to the scan time that you wish to review. The scan currently loaded has the green outline.

Reviewing scans from a previous exam



► Open the Patient Menu
► Select the patient record for which you want to review image scans. When you select the patient record, all exams for that patient are listed in the Patient Exams group box on the right.
► From the list of patient exams, select the exam for which you want to review scans. InVivoVue loads the scans for the selected exam into the scan menu.
► To review a saved scan, go to **Menu** > **Review Acquired Scans** and select the icon in the Scan queue corresponding to the scan time that you wish to review. The OCT scan is loaded and ready for review.

8.4.4 Edit Patient

The patient record can be changed when an exam for the patient exists.

- ► Select the Info button of the patient record to be edited.
- ► Click the **Edit** button. The information fields become editable.
- ► Enter new information and update existing information as needed for the record.
- ► To save the patient record when all changes are made, click the **Save** button.

8.4.5 Delete Patient or Exams

Surgical Assistant users can delete patients including all personal information and scan data or delete specific exams for a patient.

To delete a patient, select the **Patient Menu**. Selectt the delete icon on the patient to be deleted**.** This will launch a window to confirm deletion, select **Yes** and all exams associated with that patient will be deleted and the data from those exams will also be deleted. If files associated with the exam are missing, confirm the desire to continue by selecting a check box and selecting Yes.

To delete an exam enter the **Patient Menu.** Find the exam to be deleted and select the delete icon. This will launch a window to confirm deletion, select **Yes** and the exam data will be deleted but the patient will remain in the database. If files associated with the exam are missing, confirm the desire to continue by selecting a check box and selecting Yes.

CAUTION

Risk losing patient's data.

Using the functionality to delete patient will remove all identifying information and data for the selected patient. Be certain that you want to delete the data as it will not be recoverable after taking this action.

- ► Take precautions to protect patient data and patients personal information from unintentional deletion.
- ► Do not leave the system unattended when logged into your account.
- ► Double check that you have highlighted the correct patient before deleting the entries.

8.5 Data Management

Data management functions provide methods for sharing data and increasing disk space on the local drive. Functions are located under Menu > Data Management or the Tools Menu in the Engineering View.

8.5.1 File Types

InVivoVue uses files of several file types, including proprietary and common use, to store data and images for the software. The following is a list of each of the possible file types along with a brief definition of each:

- .OCT: A Leica Microsystems file format containing processed, viewable images with a file header.
- .OCU: A Leica Microsystems file format containing the raw spectral data in an array of bytes without a header.
- .BMP: A device-independent file for storing and rendering viewable images, especially on the Microsoft Windows operating system. InVivoVue uses .BMP files to store single-frame images of the B-Scan, Volume Intensity Projection, Video Image windows, and Scan Data View, as well as thumbnails used in the UI.

After InVivoVue saves an image scan, the user can also save image data into the following device-independent formats:

- .DCM: DICOM is a format and protocol for storing and handling medical images.
- .MP4: MPEG-4 is a graphics and video compression format.
- .TIFF: Tagged Image File Format for digital imaging.

8.5.2 Local Data

EnFocus saves two types of data to the local hard drive: metadata and scan data. Metadata is all information entered about a patient, an exam, and the sequence of scans within an exam. Metadata is contained in an encrypted database that is accessed when InVivoVue is running. Scan data includes all of the images and videos collected when acquiring scans. This data is saved in the Data folder on the system. All of these files have file names obfuscated so that the names do not provide details that connect the image to the patient or exam (this may be changed in Save preferences). Over time the scan data will fill the drive and the archive function must be used to remove data from the drive.

8.5.3 Secondary Save

Secondary Save provides an option to have EnFocus automatically save data to an external drive while acquiring scans. This removes a step of copying scans at the end of the procedure. Within the Save Preference, user may select what data is saved to the external drive. When the user connects the drive and a scan is saved the selected data are saved onto the external drive. There are additional options for the organization of the data into folders and the inclusion of native file (OCT and OCU).

8.5.4 Saving Transportable Files

The easiest way to save data as a transportable file type is to set the preference to always save data in the transportable format. It is not the only way. If a scan has been saved and a transportable file of that scan is needed, load the scan and right-click the B-scan window; this opens a dialogue where **Save Data As** should be selected. This brings up a window that allows the data to be saved as a transportable file. Additionally, the File Menu in the Engineering View provides options to save data as transportable file types.

8.5.5 Data Copy

Data Copy function copies the files from an exam to an attached external drive. User selects the Data Copy icon (yellow highlight) on one or more exams for one or more patients and the data is coppied to the external drive. By default, the function only copies transportable files that are viewable anywhere (JPG, BMP, MP4, TIFF, or DICOM) but the function may be configured to also make a copy of native files. The organizational structure of files copied using this function follow the folder structure created for secondary save. When using Data Copy no patient information is transferred with the files, nor is the relationship relative to a specific exam. When an exam has a significant amount of data to copy, a green progress bar under the Data Copy function will provide status on the copy progress.

8.5.6 Archive & Restore Archive

Archiving data is the process of physically removing the data files from your computer. Restoring archived data places previously archived files back on the system for review. These functions can only be done on the same system, user cannot archive from one system and restore on a second system; Export/Import is required for that function.

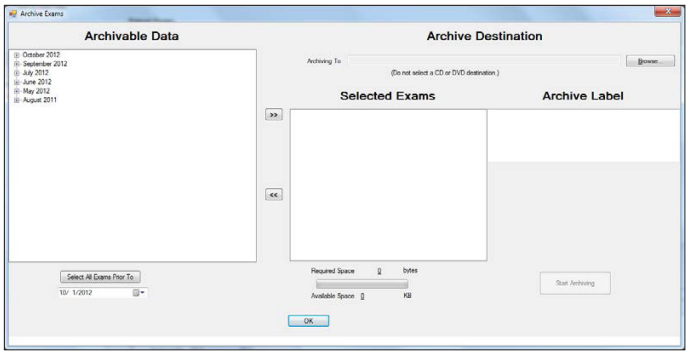
The data files InVivoVue collects are quite large, and without archiving them from the system, the computer's hard drive will eventually fill up.

Leica Microsystems strongly recommends archiving regularly. When available disk space falls below 10% of total capacity, you will receive a warning every time you click the **Save** button. Since you are running out of hard disk space, you must archive exams to increase available disk capacity.

Because of the large size of images, archiving requires a storage location with a large amount of available space, such as a server or secondary storage devices, such as one or more external drives.

While archiving is going on, InVivoVue will not allow you to perform other tasks. The duration of the archiving process will depend heavily upon how many exams you archive at once. It is best to schedule archiving for a quiet time that the system is not needed for examining patients. Once the exams to archive have been selected and archiving initiated, the system does not need to be attended; InVivoVue will complete the archiving activity on its own (unless it runs out of space on the archiving destination).

► To archive exams, from the **Menu**, select **Data Management** then select **Archive Exams.**



All exams that are not already archived are listed in the Archivable Data group box by date, with the most recent exams appearing at the top. The exams are grouped by month and date, to make it easier to select entire sets of exams for archiving together.

► Double-click each date to add all exams to the Selected Exams group box. Alternatively, expand the month nodes to show individual dates, and the date nodes to show individual patients.

► Double-click the items you wish moved off your system.
As you do so, the exams affected will appear in the Selected Exams group, with text indicating how many files and their relative size.
The bar underneath reflects how much of the available space on the archiving destination will be used up by archiving.

► To select all exams prior to a given date enter a date and click the **Select All Exams Prior To** button.
All exams in your system that took place before the date you

selected will be added to the Selected Exams group.
At the bottom of the window, the Required Space field shows how much storage space is required to store the selected exams.

► Use the **Browse** button at the top of the dialog to select the location to which you want files archived.
The Available Space field will be updated to show how much storage space is available on the volume (network drive, external device, etc.) selected.

► Click the **Start Archiving** button.
InVivoVue begins moving the image files for the exams you selected to the archiving location.

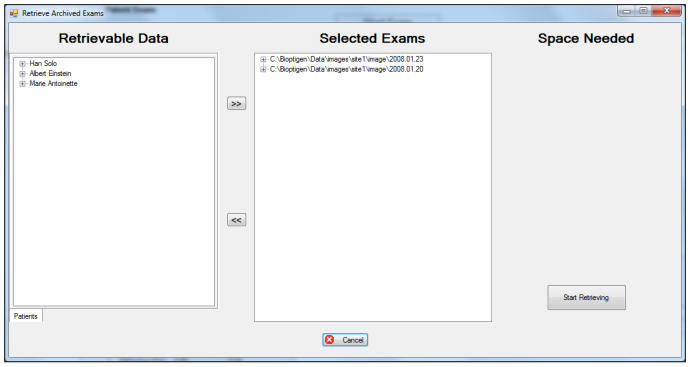
The process can take many minutes to complete, so be sure you have enough time available without interrupting patient exams.

Retrieving archived scans

Archived scans are removed from the system and stored in another location. If you find that you need to refer to archived scans, InVivoVue allows you to retrieve them. The Retrieve Archived Scans function moves selected scans from the archive and restores them to the original location on your system.

Retrieving scans locks InVivoVue, preventing you from performing any other tasks, and depending upon how many scans you retrieve, the process can take quite a while.
You should not retrieve scans at any time that you need your system for other tasks, such as examining patients.

► From Menu select Data Management then **Retrieve Archives** option.



In the Retrievable Data group box, all data available for retrieving is listed alphabetically by patients' names.

► Select each patient for whom you want to retrieve data.

► Double-click the name or click the >> button to move it to the list in the Selected Exams group box.

► If you only want to retrieve data for individual exams, click the + button to drop down a list of exams by date for each patient, and select the ones to retrieve.
Exams you select for retrieval are moved to the Selected Exams list and are shown along with the file path to the original location where the data will now be restored.
In addition, the Space Needed field shows how much total space is needed for the retrieved images and how much is available on your system.

► Click the **Start Retrieving** button.
InVivoVue begins moving the image files for the exams you selected to the original location.

The process can take many minutes to complete, so be sure you have enough time available without interrupting patient exams.

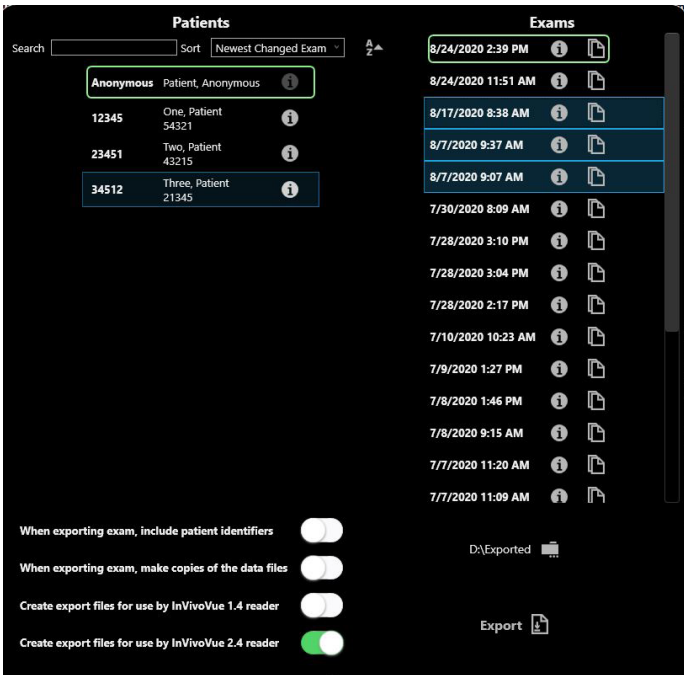
Some users use multiple network locations for archiving, others use a series of external drives, and after some time, it can be difficult to remember to where data was archived.
If you find you cannot remember where an exam is archived and need to know to make sure a device is connected before retrieving, select the exam, navigate to the Engineering View, and mouse over one of the scan tiles. The archive path will be shown on the tooltip.

8.5.7 Open File

File Open allows user to open a file with an OCT extension under an anonyomus function. No patient information is available with this function. The relationship in time that exists within an exam between multiple scans is not maintained. The file allows a single scan from any EnFocus system to be opened and reviewed. To access the function go to the **Menu**, select **Data Management** then select **Open File;** this provides a file browser to select the file to open.

8.5.8 Export / Import

Exporting data creates a copy of exams that can be read on a second EnFocus. The process is initiated by opening Menu/Data Management/Export Exam which opens the Export exams Window. This opens a windows to select the patient in the left column then select each exam that should be exported in the right column. Exams from multiple patients may be selected and exported together by repeatedly selecting a patient, select exams and then select another patient.



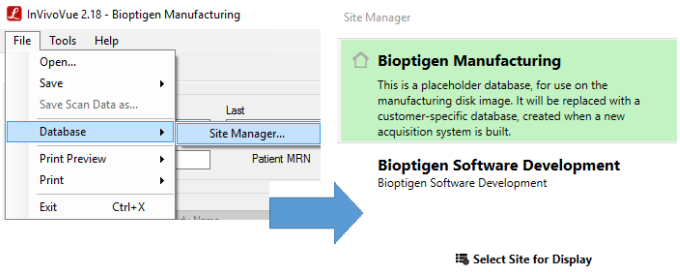
Once all exams to be exported are selected, configure the export settings on the lower left:

- Choosing to include patient identifiers provides all patient metadata
- Choosing to make copies of the data files to copy the scan data as part of the export; with it disabled only the patient metadata will be exported
- Choosing IVV reader 1.4 or 2.4 allows those versions of the reader to open the exported file

Then choose the Export location by selecting the file folder on the right hand side. Once all selections have been made, select the Export Icon and the files will be exported to the export folder and are ready for moving to a secondary system.

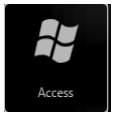
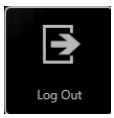
Importing is the complimentary function to Export. Import Exam brings an exported exam into the local database. To import, elevate user role and access to Engineering View; then go to **Menu > DataManagement > Import Exam.** This opens a window to select the folder and the patient exam to import.

Files collected on a secondary system are associated with that system's location and even once imported they remain associated with the collection site. To be able to view the data from different sites, you need to select the site from where you want to access data: Select File> Database> Site Manager from Engineering view or Menu> Data Management> Site Manager from main view and a dialogue window with your local site and all sites from which you have imported data. Select the location that you want to review and then choose "Select Site for Display." When done reviewing the data, use site manager to change back to your local site. You will not be able to acquire new exam data until you return to your local site.



8.6 OCT Help Functions

Located under Menu> Help the following functions provide user support.

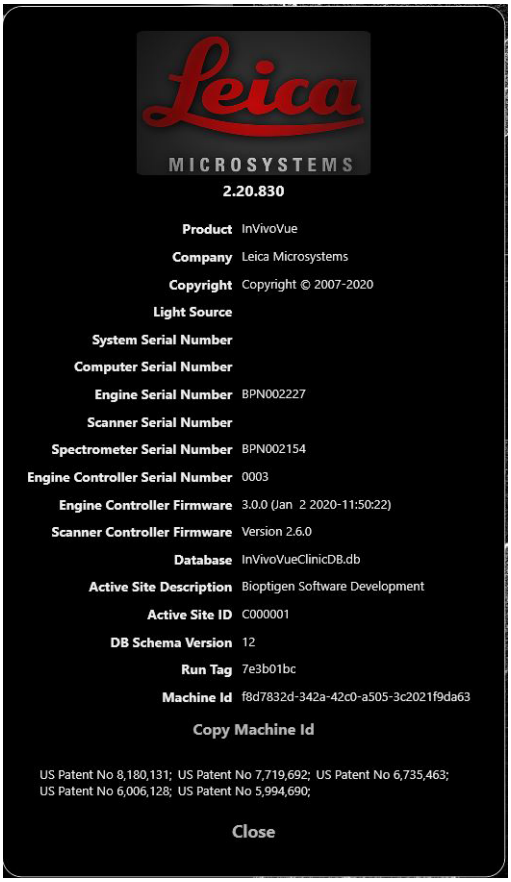
	**User Manual:** Opens user manual in the language matched to surgeon preference language.
	**Release Notes:** Opens document that documents known limitations of current release and advises on potential solutions (English only).
	**System Information:** Opens window that provides details on the system including serial numbers and software versions.
	**User Role:** Opens dialogue window to change user role to access elevated functionality.
	**Remote Support:** Opens internet browser and attempts to connect to Leica remote support website. Function only available to Hosptal IT Users..
	**Line Spectra:** Toggles acquisition to provide an unprocessed view of the spectrometer signal. Useful to understanding system health when working with Leica Service personnel.
	**Parfocality Guide:** Instructs user through a detailed process to ensure microscope oculars are set to correct diopter to ensure that microscope will be in focus over all magnifications without the need for refocusing.
	**Software Update:** Opens window that allows application and operating system updates from Leica to be installed. Function only available to Hospital IT Users..
	**Software Restart:** Activating button closes and reopens software. Use this button if system is not responsive to specific actions.
	**Windows Access:** Provides credentials to open Windows account with administrative privileges.. Function only available to Hospital IT Users.
	**Tools Menu:** Opens window that provides system troubleshooting functionality. Function only available to Hospital IT Users.
	**Log Out**: Ends the session of any user currently authenticated by the system..

8.6.1 Change User Role Window

The window opens, select desired from user role drop down menu, add user name "Name" entry, enter user specific password in password entry and select "Ok" to change the role. Contact the local administrator with Hospital IT access on the system if an account is needed

8.6.2 System Information

Product information as captured in the System Information window.



8.7 Advanced Functions

The functions in this section are used in specific situations and not required for typical daily use.

8.7.1 InVivoVue User Roles

InVivoVue (IVV) User roles provide different user classes with access to different functionality. There are three user roles available to you.

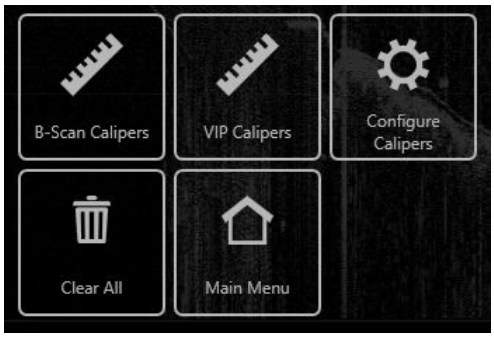
Basic
This role is the default user role that is active when IVV is started. Operation in this role allows the user to acquire and save data under the anonymous patient when user authentication is enabled. Access to named patient data is not allowed.

Surgical Assistant
This role provides authenticated users with access to patient information and all the functionality previously described in this manual.

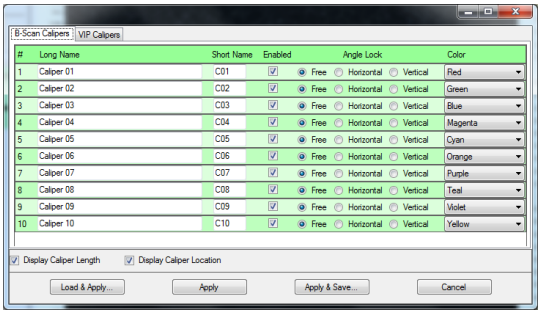
Hospital IT
Ths role enables certain functionality surrounding product security and product management including user management and active security functionality. These function are described in the product security section.

8.7.2 On-screen Measurements: Calipers

Calipers provide a method to measure distance and angle between two points in the scan. Calipers may be placed on stationary scans and are only active on the frame where they are placed. Calipers may be placed on the B-scan or the VIP, so user must select which type is being used prior to use. Caliper submenu is accessible through the main menu.

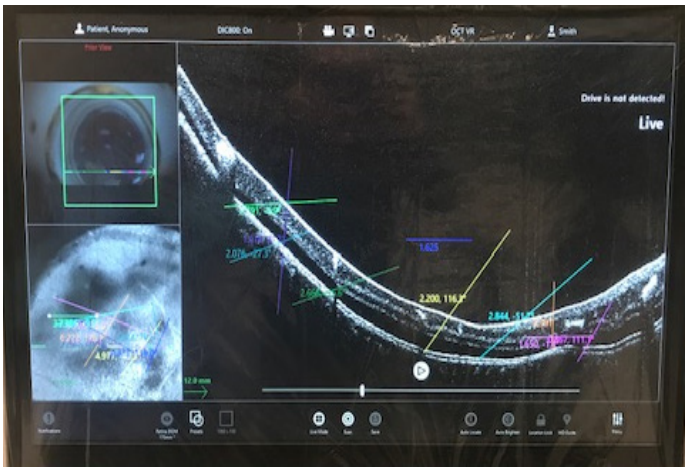


- **B-scan Caliper** opens submenu to select which caliper to apply on the B-scan.
- **VIP Caliper** opens submenu to select which caliper to apply on the VIP. Ensure you are on the Quad or Engineering view to be able to place this caliper.
- **Configure Calipers** opens window where the calipers can be configured to measure horizontal, vertical or free (vertical and horizontal at the same time).



- **Clear All** removes all the caipers currently present on the image.

To place a caliper click on the first point to place the caliper, then the second point and a line between the two points is created. To move the line, select it in the middle and drag it to desired location. To move one end of the line, select the end to adjust then drag that point to the desired location and the other point will stay in its position. To remove a single caliper, enter the caliper submenu and all active calipers have green borders, select the one to remove and it is taken off the screen.



NOTICE
Calipers are not saved.
- Calipers are not saved with the exam on EnFocus; they are only shown on the screen when placed.

CAUTION

Caliper Measurement Limitations

- Axial dimension of calipers is using the refractive index of 1.38 (average healthy eye, cornea to retina) to scale the dimension. If the refractive index is something else, it will cause the axial values to be incorrect.
- Aspect ratio of axial to lateral dimensions will cause the measured angle and reported angle to seem inconsistent due to a non 1:1 aspect ratio.
- Measurement reported based on calculated value, not rounded to the optical resolution of an A-scan which sets the limit on measurement accuracy .

8.7.3 BIOM Centration

When BIOM is placed in the optical path for imaging, BIOM centration function aligns the OCT scan and microscope video so the Dynamic Scan Controller (DSC) is accurately providing the location of the OCT scan in the eye.

BIOM centration may be programmed to automatically activate the first time the BIOM is engaged during the exam in the Workflow Options of the Preferences. Additionally, the function can be run manually from the Menu. The function will attempt to run but it will disengage and later restart if there is microscope or BIOM movement. While running, no B-scan is shown but a window to abort the function is provided. The function takes 20-30 seconds to complete.

If the BIOM is significantly off-center to the microscope axis or the lensholder is substantially bent; the function will not be able to properly align the system and will report that centration has failed. In this case there will be an offset between the DSC and the actual scan. Move to the Quad View, acquire a rectangular volume and compare the VIP to the DSC to have an understanding of the size of the offset. As you are scanning keep this offset in mind when positioning the scan to counter the offset. After the surgery, consider having the BIOM evaluated for repair.

NOTICE

BIOM movement and misalignment.

- When BIOM is not centered on the microscope optical axis, rotating the BIOM will translate the center of the lower lens.
- Recommending starting the procedure with BIOM positioned at a 12 o'clock position relative to the surgeon or whichever position the surgeon intends to have the BOM during most of surgery.
- Movement of greater than 20 degrees can induce an offset that will be noticeable to the surgeon. May manually activate BIOM centration or note the offset.
- IF BIOM is replaced during the surgery, the alignment will likely not be correct for the replacement BIOM. May manually activate BIOM centration or note the offset.

8.7.4 Continuous Scan

Continuously captures a volume defined by the scan pattern and density. The scan sequence wraps to the beginning after collecting the specified number of lines in the scan density. During continuous scan, select scan button to capture a single volume to be saved or reviewed or select Abort to stop scanning. Function may be activated by selecting under **Menu** then **Continuous Scan.**

8.7.5 Doppler Scan

Doppler scan provides qualitative visualization of fluid flow in the scanned volume. Doppler data for images comes in the form of acquiring multiple A-Scans at each position and calculating the doppler shift. Doppler data is then overlaid on the B-Scan image.

To acquire Doppler data:

- Select scan parameter.
- Toggle the special scan button until Doppler is displayed

Alternatively, use Custom Scan Editor from Engineering View

- Set the number of Doppler intervals you want to acquire per A-Scan in the **Number of Intervals** text box.

Leica Microsystems recommends setting the Number of Doppler Intervals to no more than 5.

InVivoVue displays Doppler data when a scan has acquired it, provided the Display Doppler option has been selected. Doppler data is displayed in the B-scan window along with the OCT image. The direction of blood flow is assigned a color:

- Red: Indicating flow away from the transducer.
- Blue: Indicating flow towards the transducer.

You can adjust the display of the Doppler data by changing the scaling, transparency, and threshold for OCT and Doppler data. You can turn off the Doppler display or reset the Doppler display settings to their original values.

Adjusting the Doppler data display

- Acquire a volume with Doppler activated.
- Open Preferences> Display Options.
- Verify that the **Display Doppler** check box is selected.
- De-select the check box if you wish to turn off the Doppler display.
- Use the **Playback** buttons to view the scan on a scan acquired with Doppler settings.
- Allow the scan to play continuously while adjusting the Doppler display.
- Use the Doppler Scaling slider:
  - To adjust the signal scaling.
  - To intensify or diminish the Doppler display.

Setting the threshold of OCT data

► Use the OCT Level Threshold slider to set the threshold of OCT data that must be present in order to display Doppler data.

This adjustment is used to suppress Doppler noise on a B-scan. It controls where you see Doppler and requires the OCT data level to be above the percentage of the maximum level in order for the Doppler data to be displayed.

Setting the threshold for the Doppler signal

► Use the Doppler Level Threshold slider to set the threshold for the Doppler signal.

This adjustment requires the Doppler level to be above the threshold in order to display Doppler data.

Setting the transparency of the OCT and Doppler signals

► Use the Doppler Transparency slider to set the relative transparency of the OCT and Doppler signals so that both OCT and Doppler data may be seen, depending on the transparency setting and the relative values of each.

8.7.6 Averaged Scan

The software has an option to allow for the registration and averaging of frames within a B-scan or volume. This mode is enabled by the acquisition of a scan with more than one frame/B-scan. Acquiring an averaged scan improves the signal to noise of the image creating a more defined image.

To acquire Averaged scan:
► Select Scan Parameter Icon.
► Toggle the special scan button until Averaged is displayed.
► Acquiring a scan will acquire 3 frames to be registered and averaged.

Alternatively, use Custom Scan Editor from Engineering View
► Click on the **Add a Custom Scan** button in the Imaging tab.
► Increase the number of frames/B-scan to greater than 1.
► Choose the number of frames you would like averaged to create each B-scan.
► Enter the number in the box.

Running the registration and averaging

By default, the Workflow Options in Preferences has automatic averaging enabled. In this case, the raw scans are not saved; the system immediately begins to register and average the frames and displays the averaged frames as soon as they are available. When saving, only the averaged view is saved for later use.

If automatic averaging is disabled in the Workflow Options in Preferences, averaging must be manually done from the Engineering View. Once you have acquired a scan with more than one frame/B-scan, you have the option of running the registration and averaging the algorithm before and after saving using the Average right click context menu on the Scan in the Scan queue. Be aware that the process will take time.

Once registration and averaging has taken place, a new file with the processed data is saved, and can be accessed through the context menu by right clicking the scan tile. The context menu contains a new option to Load data.

Number of Frames Averaged

This setting is adjustable under Edit Custom Scan and is set to 3 when selecting Average on the Special Scan under Scan Parameters. The number of times the same frame will be acquired for each B-scan may be increased from the default of one, although such multi-frame data must be registered and averaged as a separate step.

Adding more A-scans, B-scans, and frame repeats will increase the precision of the images acquired, but will take longer to acquire and require more memory to buffer during acquisition.

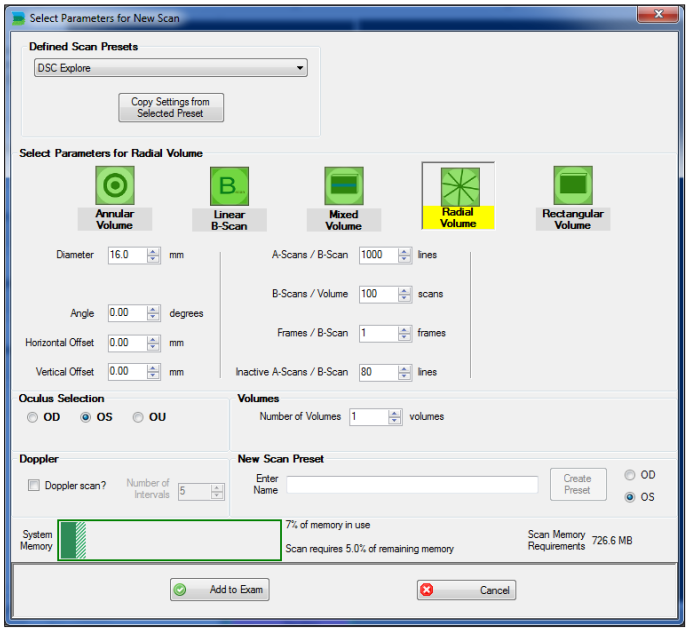
8.7.7 B-Scan Windowing

The en face image for volume scans is displayed in the Volume Intensity Projection (VIP) window. By default, this image is produced by projecting or summing the image intensities through the entire range of depth as displayed in the B-Scan window. However, you can change the settings to sum through a narrower range at any chosen depth of scan.
► To change the sample summation range, use the Windowing Lines in the B-Scan.
► To display the Windowing Lines, right-click on the B-Scan window and select Windowing Display On.
► A pair of horizontal lines are displayed on the B-scan window. They denote the sample width.

These lines can be dragged to adjust the range of line samples used to generate the VIP image.

8.7.8 Additional Scan Options

If you want more precise control over the scan definition, or no option that corresponds directly to what you want is present in the grid, you may use the scan editor to enter exact details. With the scan editor you can either change the currently selected scan definition or create a new scan definition. Go to Engineering View, right click on the bottom and select "Edit Custom Scan" in popup window.



Customizing the scan

- ► Select the desired scan pattern.
- ► Set the desired values of the scan pattern:
  - Length (how long/high the scan should be)
  - Width (how wide the scan should be)
  - Diameter (Radial only)
  - Min./ Max Diameter (Annular only)
  - Angle (tilt from the horizontal plane)
  - Offsets (from the center of the microscope video window)
  - Number of A-scans / B-scans acquired per frame
  - Number of B-scans (number of lateral scans per volume)
  - Frames per B-scan (Number of scans averaged)
  - Number of Volumes (How many times the same volume should be acquired during scan)

The scan is limited to the physical hardware limits of the galvos used to position the beam. InVivoVue does not allow the entry of values outside of allowable ranges. If you enter a value beyond the range, InVivoVue automatically reverts to the value at the nearest end of the range.

The **System Memory** bar in the scan editor shows how much memory a given scan requires, relative to the amount of RAM installed. While the memory bar is green, the given scan definition can certainly be executed. At around 70% of available memory, the bar will turn red. If you add this scan to the exam, the system may discover it is not able to actually run it. Scans that would require more than 90% of available memory cannot be added to the exam (the **Add to Exam** button is disabled).

Once the scan is created and active it can be added as a preset.

8.7.9 Operating System Access

EnFocus computer operates under a non-administrator level of the operating system. This prevents users from installing new software on EnFocus; running software on a connected external drive; or modifying operating system settings. It is our recommendation that users do not change the Operating System settings or add any additional software as it may result in system instability. This limitation also prevents users from installing Leica Mircosystems software updates. A Hospital IT account will be created on the system during system installation. It is the responsibility of the customer to retain the user name and password established at installation. In the event that the user name and password are forgotten, please contact Leica service personnel to have them reset it. Hospital IT users have the ability to change Windows accounts and access the operating system with administrator access.

8.7.10 Data Streaming

EnFocus has an option for continuously saving all OCT scans to the local hard drive. This provides an opportunity to continuously collect B-scans while there is space on the drive. The maximum amount of data is capped to prevent using more of the available hard drive then desired1

- Enable the functionality, in surgeon preference streaming option.
- Export the collected data by inserting portable USB drive and selectiing Menu > Data Management > Export Stream Data

9 Care and maintenance

9.1 Cleaning

9.1.1 Scan head optics cleaning

When necessary, the objective lens may be cleaned as follows:

► Obtain the following materials:
- Powder free latex or nitrile gloves.
- Lint-free lens tissue (a nonwoven rayon blend is recommended).
- Reagent-grade methanol.

► Wearing gloves, fold one piece of lens tissue in half 4 times in the same direction along the shorter side.
► Fold the lens tissue in half along the longer side.
► Apply one drop of ethanol or isopropyl alcohol to the tissue at the fold.
► Wipe the lens straight across and pull down off of the lens.
► Do not wipe lens in circular motions.
► Inspect the lens for residue. If the lens is not clean, repeat steps above using a new piece of lens tissue.

NOTICE

Risk of damage to the lens.

► Never use the same lens tissue twice to avoid scratching the lens.
► Avoid cleaning the lens too often to minimize the risk of scratching the lens.

9.1.2 Wiping system surfaces

WARNING

Danger of fatal electrical shock and device damage.
Many important parts of the system are not water resistant.

► Do not use any spray or liquid solution on the system in a manner that is not specifically defined in cleaning procedures of this manual.
► Do not allow any fluid to drip or run down surfaces of optical engine, computer, or foot pedal.
► Always shut down the system and unplug the power cord prior to wiping surfaces.

All other system component surfaces should be wiped down after each use with a damp cloth containing isopropyl alcohol.
The components consist of the OCT engine, scanner head, cart, and foot pedal (including cable).

► Inspect the foot pedal switch for wear, damage, or for unusual enclosure deterioration.
► Inspect the entire length of the connecting cord (wiring) from where it enters the foot pedal switch to where it enters the cart.
► Look for wear, cuts in the wiring insulation, or loose strain relief connections.

NOTICE

Risk of damage to the device.

► Do not use the foot pedal switch if any damage is found.
► Contact customer service to order a replacement foot pedal switch.

9.1.3 Cleaning table

Description	Cleaning
System	Alcohol wipe-down
Scanner	Cleaning required between uses.
Cart	Alcohol wipe-down
Foot pedal	Alcohol wipe-down
UPS	Alcohol wipe-down

9.2 EnFocus OCT system maintenance

The user should maintain cleanliness of the system. There is no preventive maintenance to be performed by the user.

WARNING

Danger of fatal electrical shock.

► Do not remove component covers.
► Let only the manufacturer or an authorized service representative may perform installation, assembly, service, and maintenance.

WARNING

Danger for the patient health due to changes to the equipment.

► Do not modify this equipment.

9.3 Periodic safety checks for cart configuration

The system components must be inspected periodically for integrity in order to ensure safety of the device.

► Every six months perform visual inspection of the power cord and any compatibility cables in use to ensure it is free from cracks and cuts.
► Verify the system enclosures are securely fastened on the system shelves and the back cover is securely in place.
► Inspect the cart casters to ensure they are rotating smoothly and swivel correctly.
► If any problems are observed, please contact customer service for further assistance.

9.4 UPS maintenance for cart configuration

The following is applicable for systems configured with a UPS.
The UPS does not require routine maintenance.

WARNING

Danger of fatal electrical shock.
This equipment services power from more than one source. The output receptacles may have voltages present even when the unit is unplugged. Unplugging the UPS puts it into backup mode and does not remove the electrical charge.

- ► To ensure that the UPS is off, turn the power switch "OFF" before unplugging the UPS from the wall outlet.

If the UPS will not be used for an extended period of time, follow the instructions for battery maintenance to prevent permanent damage.

The UPS is provided with its own Instructions for Use manual. Consult the UPS IFU manual for additional information regarding the use of the UPS device.

9.5 Storage for cart configuration

Short-term storage (less than 3 months)

- ► Shutdown system through Windows shutdown sequence (Start button > Shut down)
- ► Toggle the UPS power switch to the OFF position to deactivate the UPS.
- ► Leave the system plugged into a live AC outlet, if possible.
- ► If the system was not left plugged in, fully charge the UPS to maximum charge for 24 – 48 hours prior to the next use.

Long-term storage (more than 3 months)

- ► Shut down system through Windows shutdown sequence (Start button > Shut down)
- ► Toggle the UPS power switch to the OFF position to deactivate the UPS..
- ► Unplug the AC cable from the wall.
- ► Neatly coil the power cord around the cord wrap guides.
- ► Open the back of the cart.
- ► Turn off switch on OCT engine within cart.
- ► Disconnect cables from UPS to avoid battery drain.
- ► Reattach the cart's back panel being careful to avoid pinching the power supply cord.
- ► Route the power cord through the bottom cutout as shown below.

- ► For systems configured with a UPS, once every three months, fully recharge the UPS batteries by plugging the UPS into a live AC outlet and letting the UPS charge for 24 – 48 hours.

WARNING

Danger of fatal electrical shock.
This equipment services power from more than one source. The output receptacles may have voltages present even when the unit is unplugged. Unplugging the UPS puts it into backup mode and does not remove the electrical charge.

- ► To ensure that the UPS is off, turn the power switch "OFF" before unplugging the UPS from the wall outlet.

NOTICE

Risk of damage to the UPS battery.

- ► To avoid permanent loss of capacity of the UPS battery, do not unplug a UPS from its AC utility power source for an extended period of time.
- ► If equipment is not likely to be used for several months, refer to supplier's documentation of the UPS.

9.5.1 Transport

Cart Configuration

The EnFocus OCT Cart Configuration has been designed and tested to withstand transfer between rooms including over thresholds. If your system needs to be transferred to another facility that requires the system to be loaded on a vehicle, contact customer service for assistance.
Transport of the system by vehicle without support from Leica Microsystems will void the warranty.

CAUTION

Tripping Hazard.
Transporting the system is performed by pushing the system cart in the forward direction.

- ► Do not pull the cart as it may experience instabilities that could cause it to tip over.

10 Disposal

The respective applicable national laws must be observed for disposal of the products, with the involvement of corresponding disposal companies.

The EnFocus OCT system consists of mechanical, electrical, and optical components, including a camera and superluminescent diode (SLD) source. In the event that the customer wishes to dispose of the system, follow the instructions below:

- ► Notify customer support that the device will be disposed of.
- ► Remove all personal files, videos, emails, and pictures from the computer.
- ► Reformat the hard drive to return the system to its original state and ensure all patient data is removed.
- ► In the US, Deliver to an EPA-approved recycling center. Visit the Environmental Protection Agency eCycling site at www.epa.gov for more information.
- ► In Canada, Australia and the EU, waste batteries and equipment should be delivered to a designated collection point for the recycling of batteries, electrical and electronic equipment. For more information, please contact your local waste disposal service.
- ► In all other regions and countries, follow local laws for recycling or disposal of batteries, electrical and electronic equipment.

11 Troubleshooting

The following potential failure modes for the EnFocus OCT system have been identified. Refer to the charts below to identify the possible causes and actions to correct.

If your instrument has a malfunction that is not described here, please contact your Leica representative.

11.1 Hard shutdowns

If the shutdown process does not execute or system is not responding, perform a hard shutdown by pressing and holding the power button for 5 seconds.

11.2 Hardware malfunctions

When system is operating properly, the green power light will be lit on engine and scanner interface box.

Malfunction	Cause	Remedy
When master power on UPS is turned on, nothing happens.	Unit not plugged into the wall.	▶ Reconnect plug to wall.
	Plug on back of UPS loose.	▶ Remove back panel. ▶ Reconnect the plug.
When master power on UPS is turned on, system alarms.	Same as above, but because of battery backup, UPS is alerting you of the problem.	▶ Reconnect plug to wall. ▶ Remove back panel. ▶ Reconnect the plug.
UPS alarms while system is in operation.	Loss of power at the outlet.	▶ Restore wall power.
	Plug at wall has come loose.	▶ Reconnect plug to wall.
UPS turns on, but other components do not.	Plug on back of UPS is loose.	▶ Remove back panel. ▶ Verify all connections from UPS.
Green light on either Interface Panel, Scanner, or UPS does not turn on.	Switch on back of component is not turned on.	▶ Remove back panel. ▶ Verify switch on OCT engine is switched to on position.
	Plug is loose.	▶ Remove back panel. ▶ Verify plugs are installed.
	Fuse is blown.	▶ Contact customer service or have qualified service personnel replace a blown fuse in the OCT Engine.
Objective lens is scratched or damaged.	Incorrect cleaning method or scratched inadvertently with another object.	▶ Remove scan head if needed to continue procedures. ▶ Contact customer service for repair.

11.3 Scanning malfunctions

Malfunction	Cause	Remedy
Scan Head makes loud clicking sounds or high pitched sound while scanning.	Scan size is too large.	▶ Make scan size smaller and recheck.
	Inactive Scans setting is too small on the scan parameters.	▶ Check the scan parameters to make sure that "inactive scans" is set to at least 50. ▶ Delete current scan and add new scan from quick start grid.
	Damage to scanning mirrors.	▶ Contact customer service for repair.
Scan only works in one direction.	Cables between engine and the scanner are damaged.	▶ Contact customer service for repair.

11.4 Image malfunctions

There are many causes for this, some equipment, and some imaging technique.
This section identifies the equipment issues only.

► For tips on imaging technique, contact customer service for advanced training.

Malfunction	Cause	Remedy
Image is too bright.	Display settings incorrect.	► Change display brightness and contrast in the software. ► If problem remains, contact customer service.
Image is too dim.	Display settings incorrect.	► Change display brightness and contrast in the software. ► If problem remains, contact customer service.
	Lens is dirty.	► Clean lens as per instructions in this user manual.
	Reference Arm (RA) position is not optimized for the patient. OCT focus and microscope focus are not coincident.	► Adjust microscope to Z. ► Adjust IBZ focus.
	Obstructions in the patient's tissue, such as clouding or cataract.	Not an equipment problem.
Image quality has degraded: Line spectrum has shifted from factory installation. ► Determine this by comparing with line spectrum on Test Patient.	No Reference Arm (RA) mirror adjustment.	► Contact customer service for verification of the issue, and repair.
	Spectrometer misalignment.	► Contact customer service for verification of the issue, and repair.

11.5 Software malfunctions

This topic describes several software problems and suggests ways to correct them.

For some symptoms, an advanced level of training is required for the necessary actions to resolve the problems.

Malfunction	Cause	Remedy
Image appears blurry.		▶ Change the focus and check to see if the reference arm position is correct
The depth seems inadequate.		▶ Change the image display scale in the application window. ▶ If this does not resolve the issue, adjust the path length of the reference arm.
Part of the scan image is not visible, or the image fades at the beginning or end of the scan.		▶ Expand the horizontal and vertical offset parameters that are associated with the scan.
"Ghost" images appear in the display.		▶ Change the path length of the reference arm.
No image appears in the display.		▶ Move the sample to see if an image comes into focus. ▶ If this does not resolve the problem, contact customer support.
The image is distorted or garbled.		▶ Move the sample to see if an image comes into focus. ▶ If this does not resolve the problem, optimize the line spectrum.
There is background noise.		▶ Work with the Brightness and Contrast settings in the Display dialog. ▶ If the problem persists, please contact customer support.
The scan image is either too small or too large.		▶ Change the image display scale.
The scan image oscillates abnormally.		▶ Close InVivoVue, and restart it. ▶ If this does not resolve the problem, contact customer support.
Vertical striations appear in the scan image.		▶ Adjust the focus and/or NA.

11.6 Software Notifications

Temporary Notifications

Message	Remedy
Shutdown will begin after contrast enhancement completes	▶ No action required. Item infroms user of background activities and the need to wait before the next action occurs.
InVivoVue is currently saving. Shutdown will begin after save completes.	
InVivoVue is currently saving. Scan data will be loaded after save completes.	
InVivoVue is currently saving. Aiming will begin after save completes.	
Please wait. Canceling contrast enhancement.	
InVivoVue is currently saving. Continuous Scan will begin after memory is available.	
InVivoVue is currently saving. Snapshot will begin after memory is available.	
InVivoVue is currently saving another scan. The scan will be saved after the previous save is finished.	
Opening Database	
Clearing read-only for database file	
Database backup is starting	
Generating report...	
Please wait... averaging data	
Database has been opened	
Database has been backed up	
Scan exceeds available memory	▶ User needs to decrease the size of scan to have less than 1,000,000 A-scans. ▶ Could indicate a memory issue if memory limitation occurs for normal scan dimension. Reboot system, if message persists look at potential for cleaning or replacing memory."
A scan cannot be deleted from a protected patient.	▶ Current User Role does not allow for deleting the data. Either elevate user role to a level that allows deleting data from that patient.
A scan actively being acquired or saved cannot be deleted.	▶ No action required. Cannot delete a scan that is in process of acquired or saved. Wait and then functionality will be available.
Insufficient permission to delete scans that have been imported.	
Insufficient permission to delete scans for which data have been collected and saved.	
Image Optimization Failed	▶ Algorithm could not find an optimum image. Ensure that the target is near the working distance of the objective and correct procedure is selected before reattempting.
Image Optimization aborted	▶ No action required. Item infroms user that the function was aborted by user.
Image Optimization aborted due to user activity	▶ No action required. Item informs user that the function was aborted due to microscope activity. Optimization requires system to be static during optimization function.

Temporary Notifications Continued

Message	Remedy
Image Optimization aborted due to microscope auto-reset	▶ No action required. Item informs user that the function was aborted due to microscope being in reset position. Optimization requires system to be static during optimization function.
R & A succeeded	▶ No action required. Informing user that registering and averaging was completed
R & A was aborted	▶ No action required. Informing user that registering and averaging was canceled during action.
Error occurred while performing R & A	▶ Initial attempt did not complete process. Retry registering and averaging on valid data set.
R & A failed	▶ Generally means that there is too much motion in the image to register the frames. Acquire a new scan taking precaution to minimize target motion during acquisition.
Cannot create Image Quality exam and scan	▶ System unable to complete the action. Please retry.
Unexpected error occurred during Image Quality	▶ System unable to complete the action. Please retry.
Cancelling Image Quality...	▶ No action required. Notification that function has been cancelled.
Scan is missing metadata (perhaps because it was collected with older software)	▶ No action required. Notification that exam is missing patient data.
Not enough frames in scan to perform image quality assessment	▶ Failure of the image quality acquisition. Close out of image quality dialogue window then retry.
Load from file was not successful	▶ Unable to load from requested file. Verify that it the correct file type, has content and then retry.
Unrecognized file extension	▶ Requested file extension is not one that is supported for current action.
Cannot find documentation file	▶ Requested documentation file (manual or release notes)cannot be found in the expected folder. Restart IVV, if problem persists contact Service about receiving Document Installer.
Import succeeded	▶ No action required. Notification that the import function has successfully imported data into the database.
Some files were not copied because they previously existed in the destination location	▶ No action required. Notification that some of the files requested to be copied were already found on the drive and were not copied.
Unexpected error occurred while copying exam files	▶ Something went wrong while copying files. Verify that external media is connected to EnFocus USB port and has available capacity then retry copy function.
No saved data file available	▶ There are no saved files to do the requested copy or export. Choose an exam with saved data available.
Failed to load data: File is missing	▶ While loading the requested file, one or more of files required to open the scan are not available. Check to ensure that the data is in the folder with the data being opened and retry.
Display reset due to change of user access	▶ Active user changed due to inactivity resulting in navigation away from prior screen.
Currently selected patient does not match microscope patient	▶ Notification that user has selected a patient on the system other than currently active patient on the microscope recorder
Failed to retrieve requested OS credentials	▶ There was an issue getting the credentials, retry and contact Leica service if issue persist
A user with this user name already exists	▶ Choose an alternate user name available.

Temporary Notifications Continued

Message	Remedy
Password cannot be the same as your previous {0} passwords. Please try a different password.	▶ Error - Creation of new user account has encountered an issue. Try again following specific advice in the message.
Passwords must contain the following five requirements to meet complexity requirements.	
An unknown error occurred while creating a new user	
The specified Name and Password combination is not valid, or the account is locked. Please retry or contact your administrator.	
Failed to successfully reset the user {0}"	▶ Error - . Hosptal IT user has attempted to reset a user password but was unsuccessful. Try again.
The user {0} has been reset and enabled. Use the temporary password {1} to login and create a new password	▶ Notification - Hospital IT user has reset user password and a temporary password has been created..
Login credentials will expire in {0} minutes	▶ Notification - Current authenticated user has been inactive and will be logged out of the system when inactivity monitor hits time limit

User Acknowledged Notifications

Message	Remedy
Database file not found	▶ Error - Cannot find or open database in program folder. This indicates the file has been deleted, corrupted, cannot be decrypted, or is an unsupported database. Software will attempt to use a backup version if one can be found. If a backup cannot be used, user is unable to add patients, add exams, or save data. Contact Leica Service for assistance.
Failed to clear read-only for database file	
Database file is encrypted or is not a database	
Database file uses an unsupported schema	
Error occurred while copying database backup file	▶ Error - while making a database backup an error occurred . As a result no backup has been made; restart IVV to attempt to make a backup.
Database was restored from backup dated {0}	▶ Warning - Software could not find or open database in program folder and used a backup version. Data collected between the date of the backup database and current session will not be available.
Database could not be opened nor restored from a backup	▶ Error - Cannot find or open database in program folder and cannot open backup version. Contact Service for assistance with obtaining a new database and restoring unaccessible data.
Error while creating report	▶ Error - unable to make a report. Retry and if problem persists try restarting IVV before retrying. If unresolved, contact Leica Service for assistance with obtaining a new database and restoring unaccessible data.
Error while deleting previous report. Make sure the report is not open in another application.	▶ Error - unable to delete report. Confirm the report is not open in another application then retry.
Disk space is running low on primary drive	▶ Warning - When disk drive has less than 10% of available space user is provided this notification. Find time to archive data to increase the available disk space.
Insufficient disk space on primary drive	▶ Error - When disk drive has less than 2% of available space user is provided this error. Immediately archive data to increase the available disk space to enable saving.
Insufficient disk space on secondary drive	▶ Error - When secondary drive has less than 2% of available space user is provided this error. Immediately remove files to increase the available disk space to enable saving.

User Acknowledged Notifications Continued

Message	Remedy
Drive missing or unavailable for secondary save	▶ Error - Cannot save to secondary drive. Please confirm that the secondary drive is connected to EnFocus USB port and retry. Try alternative USB connection or alternate external drive if reconnection unsuccessful. Use Windows button + E to see if drive is detected in Windows explorer. If unresolved, contact Leica Service for assistance with USB interface failure.
No external storage device available	
Path invalid for secondary save	
Insufficient registrations for selected device	▶ Warning - Video registration has not been done for the selected lens. In order to use an objective lens, Leica service Engineers must conduct video registration for the lens. Selecting an uncalibrated lens will result in the system not obtaining images. Contact Leica Service or change the microscope objective (physically and in software).
Error loading configuration settings	▶ Error- Unable to load one or more configuration setting. Select an alternate then retry selecting the desired configuration to load. If issue persists, restart IVV and retry before contacting Leica Service.
Error saving configuration settings	▶ Error- Unable to save one or more configuration setting. Select an alternate then retry selecting and saving to the desired configuration. If issue persists, restart IVV and retry before contacting Leica Service.
Hardware error	▶ Error - A hardware item is not responding as expected. Acknowledge the error, attempt to continue using system if acquisition or controls non-responsive, restart EnFocus. If issue persists contact Leica Service with a hardware failure.
Error allocating memory for scan	▶ Error - memory could not be allocated to acquire specified scan size. Retry scan acquisition, if issue persists attempt restarting EnFocus and retrying. If after restart the issue still persists, contact Leica Service Personnel to address computer issue.
Some data were not imported because they were changed in both the source and destination and the conflict was not resolved.	▶ Error - Failure importing data, get a new copy of the data that you are trying to import and retry.
Import failed because of a SQL format problem with import data file	▶ Error - Failure importing data, get a new copy of the data that you are trying to import and retry. If still unsuccessfull, use file open to open OCT files without importing.
Unexpected error occurred while importing	▶ Error - Failure importing data, get a new copy of the data that you are trying to import and retry.
Some files were not copied because they were not available to copy	▶ Error - Failure copying data as associated files were moved from data folder and are unavailable for copy.
Unexpected error occurred while exporting exams	▶ Error - failure exporting exams, retry first then try restarting IVV before contacting Leica service with an IVV problem.
No files were copied because none of the preferred files were available	▶ Error - Failure copying data as all associated files were moved from data folder and are unavailable for copy.
Failed to start the Parfocality Guide	▶ Error - Failure launching parfocality guide function retry starting function first then try restarting IVV before contacting Leica service with an IVV problem.
No visible calipers to save	▶ Warning - If try to save calipers when none are visible this error will alert that there is nothing to save.
Error saving caliper file	▶ Error - Failure to save caliper file. Retry save first then try restarting IVV and power cycle system before contacting Leica service with an IVV problem.
Error saving B-scan thumbnail file for calipers	▶ Error - Failure to save caliper image. Retry save first then try restarting IVV and power cycle system before contacting Leica service with an IVV problem.

User Acknowledged Notifications Continued

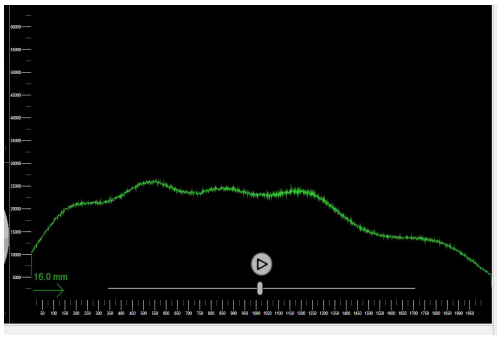
Message	Remedy
Error launching the installer	▶ Error - Issue launching the software installer. Try to launch again, ensure that you were launching as Administrator. If error persists, indicates the installer is damaged acquire a replacement IVV installer.
Failed to detect touch screen input	▶ Error - Touch screen input not working. Use physical keyboard until able to restart IVV. If problem persists, restart microscope before contacting Leica Service. Error only applicable for EnFocus for Microscope Integration.
Failed to navigate to the correct channel view	▶ Error - Issue ldisplaying desired view. Try again, if error persists, try restarting software if issue remains contact Leica Microsystems service. .
Control of NA not functioning	▶ Error - Issue where the system numerical aperture control is not responding. Try again, if error persists, power cycle the system if issue remains contact Leica Microsystems service..
Control of Focus not functioning	▶ Error - Issue where the system focus control is not responding. Try again, if error persists, power cycle the system if issue remains contact Leica Microsystems service...
Control of Polarization not functioning	▶ Error - Issue where the system polarization control is not responding. Try again, if error persists, power cycle the system if issue remains contact Leica Microsystems service..
Control of Z Position not functioning	▶ Error - Issue where the z-position control is not responding. Try again, if error persists, power cycle the system if issue remains contact Leica Microsystems service..r.
Failed to save Thumbnail image	▶ Error - Cannot save the specific file type. Try restarting IVV and EnFocus to resolve the issue. If error persists contact Leica Service to identify issue and reinstall InVivoVue.
Failed to save primary Scan Data View image	
Failed to save secondary Scan Data View image	
Failed to save Live Video still image	
Failed to save VIP image	
Failed to save OCT data file	
Failed to save OCU data file	
Failed to save TIFF stack files	
Failed to save MPEG-4 file	
Failed to save MPEG-4 file to secondary drive	
Failed to save DICOM file	
Path invalid for primary save	▶ Error - Primary save path cannot be found. Try restarting IVV and EnFocus to resolve the issue. If error persists contact Leica Service to identify issue with data path.
Preferences could not be saved because the physician is not uniquely identified	▶ Error - Need to have a surgeon under surgeon preferences to save preferences. Add a surgeon and then save the preference.

11.7 Checking the Line Spectrum

Checking the line spectrum allows the user to evaluate the quality of images being acquired by the system.
Possible problems that could occur when the spectrum is not optimized include:

- A dim image.
- Distorted or garbled images.
- Background noise.
- Vertical striations in the scan image.

► Select **Menu > Help > Spectrum**.
► Select **Menu >Display Axis**.
► Remove all items from being at or near working distance under objective lens.
► Select **Scan** from main screen .
A green curved line appears in the B-Scan window.



Depending upon certain properties of the optical source in your unit, the line may have a single peak, giving it the shape of a bell curve, or it may have more than one peak.

► Regardless of the particular shape of the curve, the peak should be within 20000 to 50000 intensity.
► Select Save from 50:50 or quad view will save the volume which can be sent to service. If Save Scan Data View is enabled in Preferences; this will save an bitmap image of the scan data view which may also be sent.
► If Save Scan Data view is not configured, go to Engineering View
► Select File > Save > B-scan image
► This image may be shared with Technical Support to assist with diagnosing imaging problems.
► Turn off Line Spectra mode. Either go to Tools and unselect Line Spectrum or select **Menu > Help > Spectrum**.

12 Service and Spares

There are several elements of the EnFocus Service and Spare program available to optimize your experience.

Service actions may only be performed by representatives qualified by Leica to perform the actions. Only original EnFocus replacement parts may be used in servicing the product. After service work the device must be readjusted in accordance with our technical specifications.

If the instrument is serviced by unauthorized persons, is improperly maintained or is handled improperly, Leica will not accept any liability.

12.1 Issue Escalation

If after following the troubleshooting section you are unable to return the system to operational status, please contact Leica service contacts for assistance. Global Leica service contact numbers and the website can be found on the first page of the manual. Once you have contacted the local service contact, a qualified service associate will be able to assist you in resolving the issue.

12.2 Basic Warranty

A general warranty period of one year exists for all newly purchased system. Repairs and maintenance has to be always carried out by an authorized and service trained person to maintain this warranty

12.3 Service Contracts and Extended Warranty

Leica Microsystems offers optional service contracts for your EnFocus system. By purchasing a service contract, a Leica service associate will conduct an annual visit where they will perform annual preventative maintenance which includes UPS battery replacement, update microscope video registration, optics cleaning, data archive, software and firmware updates, performance assessment and field adjustments to maintain imaging performance. Please contact Leica Customer Service through your local OneCall number or using the online form for additional information.

An Extended Warranty is offered through Leica Microsystems at the time of sale. The extended warranty includes all adjustments, alignments, and parts of the system, during the coverage period, in the event of a system failure. The warranty is only valid if instructions for use and maintenance are strictly followed.

If you are experiencing system issues and have an extended warranty or own a service contract, please have that information available when you contact Leica Microsystems for service escalation.

12.4 Replacement Accessories

Several EnFocus accessories available as replacement parts that will be sold and delivered directly to customers without the need for service intervention include the following:

9085-10502	**M844 EnFocus Glare Mask Kit**
9038-00667	**Proveo EnFocus Glare Mask Kit**
10448627	**Leica OCT ready Objective Lens 175mm**
10448626	**Leica OCT ready Objective Lens 200mm**
9041-00066 **9041-00067**	**EnFocus Scanner Caps**
9035-10348	**Scanner Mounting Screws**
9082-00242	**5mm Hex Driver**

12.5 Service and Repair

In the event that our service associates are unable to troubleshoot and repair the system there are two options: field repair or return for service. If the Service Associate believes that a field repair will return the system to a functioning condition, the associate will coordinate a visit to repair the system. If a field repair is not possible, determined either before a service visit or during a service visit, the service associate will coordinate shipment of the system for repair at a Leica Microsystems repair facility.

Once the repair facility evaluates the system, a repair quotation will be provided. Upon placement of a repair order, the facility will repair the system to working condition and return it to your facility. Upon return, the service associate will perform installation of the repaired system.

13 Specifications

13.1 Common Technical Specifications

Categories		Specifications
		2300 Model (Ultra-HD)
Method of operation		Spectral Domain Optical Coherence Tomography (SD-OCT)
Internal light source		800nm band SLD: Very High Resolution (VHR) ≥ 90nm bandwidth FWHM 860nm center ±5 nm
Patient interface		Non-patient contact
Optical power		≤ 750 µW
Scanner ergonomics		Microscope mounted
Scan patterns		Line, rectangular volume, circular volume, orthogonal cross sections
Field of view	Axial (air/tissue)	Model 9070-10100 6.8 ±0.1 mm / 5.0 ±0.1 mm All Other 2300 Models 3.4 ±0.1 mm / 2.5 ±0.1 mm
	Lateral	Up to 20 mm at any microscope magnification
Resolution	Axial (in tissue)	≤ 4 µm
	Lateral	175mm Objective: < 31.0 µm 200mm Objective: < 35.4 µm
Scan rate (aka acquisition speed)		≥ 32,000 A-scans/s
Scan pixels	Axial	Model 9070-10100 2048 pixels All Other 2300 Models 1024 pixels
	Lateral	User selectable, A-scans/B-scan: 2000 maximum
		Maximum A-scans/volume: ≥ 1,000,000
Calipers		Manual placement of on-screen calipers
Doppler		Qualitative blood flow visualization with color Doppler OCT

System has 2 modes of operation: Active and Standby.
Active Mode – A patient imaging procedure is being executed.
Standby Mode – The system is ready to start a new patient procedure or continue the previous procedure, but the scanner is not emitting light.
This device is considered a non-contact device and therefore there is no applied part.
There is no risk of harm associated with loss of function of the device.

13.1.1 Standards fulfilled

- Medical electrical equipment, Part 1: Generally defined for the security in IEC 60601-1; EN 60601-1; UL 60601-1
- Electromagnetic compatibility: IEC 60601-1-2; EN 60601-1-2; EN 61000-3-2; IEC 61000-3-2.
- Further applied harmonized standards: IEC 62366, EN 60825, IEC 62471, EN 62471, EN 980.
- Leica Microsystems NC, Inc. holds the management system certificate for the international standard ISO 13485 relating to quality management.

13.2 EnFocus Cart Configuration

13.2.1 Electrical data

Power connection	100 V, 120 V or 230 V Single Phase V AC, 50/60Hz, 400 VA max. Input via a Power entry module on UPS System. On/Off switch on front of UPS with indicator lights.
Power Cord	North America: Hospital grade NEMA 5-15 cord, 20' (6.1 m) Japan: Hospital grade cord 4.5 m based on country requirements International: Hospital grade cord 6.1 m based on country requirements
Fusing (UPS)	Resettable, linked dual pole (L & N) breaker
Fusing (Engine & Scan Head Interface Box)	F1.5AL 250V. Use Agency approved fuses only, 250V
Protection class	Class I Equipment

13.2.2 Physical Specifications

Dimensions	System: 31" (w) x 22" (d) x 37.5" (h) to top of cart top [79 x 56 x 94 cm] Total height of system cart (IN): 61" [155 cm] including monitor
Weight	System Cart: 250 lbs [125 kg] Scan Head: 5.7 lbs [2.6 kg]
Operating Temperature Range	+10°C to +35°C
Operating relative humidity range	30% to 90%, non-condensing
Storage	–10°C to +55°C
Transport	–40°C to +70°C

13.3 EnFocus Configuration for Micoscope Integration

13.3.1 Electrical data

Power Ratings (VA/ Watts)	400W, DC
Input Voltage Range	44-52V
Grounding	Modules must be connected to ground points during integration.

13.3.2 Physical Specifications

Dimensions	Components Incorporated into Microscope enclosure
Weight	System Modules: 26 lbs [<12 kg] Scan Head: & Conduit Model 9075-25081 5.7 lbs [<4.4 kg] Model 9075-25084 2.9 lbs (<1.3kg)
Operating Environment	+10°C to +50°C, 30% to 90% relative humidity, non-condensing, 800-1060 mbar
Storage & Transport Environment	-40°C to +70°C, 10% to 95% relative humidity, non-condensing, 500-1060 mbar

14 Compliance

This "Guidance and manufacturer's declaration" document is based on IEC 60601-1-2:2014 4th Edition.

14.1 EnFocus Cart Configuration

14.1.1 Electromagnetic emissions table

Guidance and manufacturer's declaration – electromagnetic emissions

The EnFocus OCT is intended for use in the electromagnetic environment specified below.
The customer or the user of EnFocus OCT should assure that it is used in such an environment

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.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions in accordance with CISPR 11	Group 1	The EnFocus OCT must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions in accordance with CISPR 11	Class A	The EnFocus OCT is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Complies	

14.1.2 Electromagnetic immunity table I

Guidance and manufacturer's declaration – electromagnetic emissions

The EnFocus Cart Configuration is intended for use in the electromagnetic environment specified below.
The customer or the user of the EnFocus Cart Configuration should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst immunity according to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	± 2 kV for power supply lines ± 1 kV for input and output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and power supply voltage fluctuations IEC 61000-4-11	0 % UT for 0,5 cycle at Sync Angle 0; 45; 90; 135; 180; 225; 270; 315 0 % UT for 1 cycle at Sync Angle 0 70 % UT (30 % dip in UT) for 25 cycles at Sync Angle 0 0 % UT for 5 second at and Sync Angle	0 % UT for 0,5 cycle at Sync Angle 0; 45; 90; 135; 180; 225; 270; 315 0 % UT for 1 cycle at Sync Angle 0 70 % UT (30 % dip in UT) for 25 cycles at Sync Angle 0 0 % UT for 5 second at and Sync Angle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EnFocus OCT requires that the instrument remain functional even after power interruptions, it is recommended that the EnFocus OCT be provided with an auxiliary power source such as an uninterruptible power supply (UPS) or battery back-up.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the EnFocus OCT further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note	U_T is the AC voltage prior to application of the test level.		

14.1.3 Electromagnetic immunity table II

Guidance and manufacturer's declaration – electromagnetic immunity

The EnFocus Cart Configuration is intended for use in the electromagnetic environment specified below.
The customer or the user of the EnFocus Cart Configuration should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF - Disturbance variables according to IEC 61000-4-6	3V RMS outside ISM band 6V RMS in the ISM and amatuer radio bands 150 kHz to 80 MHz	3V RMS outside ISM band 6V RMS in the ISM and amateur radio bands 150 kHz to 80 MHz	Portable and mobile RF communications should be used no closer to any part of the EnFocus OCT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ for 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].
Radiated RF - Disturbance variables according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Radiated RF - Wireless Communications Equipment according to IEC 61000-4-3	385MHz, 18Hz pulse, 27V/m 450MHz, 18Hz pulse modulation, 28V/m 710, 745, 780MHz, 217Hz pulse modulation, 9V/m 810, 870, 930MHz, 18Hz pulse modulation, 28V/m 1720, 1845, 1970MHz, 217Hz pulse modulation, 27V/m 2450MHz, 217Hz pulse modulation, 28V/m 5240, 5500, 5785 MHz, 217Hz pulse modulation, 9V/m	385MHz, 18Hz pulse, 27V/m 450MHz, 18Hz pulse modulation, 28V/m 710, 745, 780MHz, 217Hz pulse modulation, 9V/m 810, 870, 930MHz, 18Hz pulse modulation, 28V/m 1720, 1845, 1970MHz, 217Hz pulse modulation, 27V/m 2450MHz, 217Hz pulse modulation, 28V/m 5240, 5500, 5785 MHz, 217Hz pulse modulation, 9V/m	

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EnFocus OCT is used exceeds the applicable RF compliance level above, the EnFocus OCT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EnFocus OCT.

b Over the frequency range 120 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation amount is affected by absorption and reflection from structures, objects and people.

14.1.4 Recommended distances table

Recommended separation distances between portable and mobile RF communications equipment and EnFocus Cart Configuration

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

Rated maximum output power of transmitter in W	**Separation distance according to frequency of transmitter in m**		
	125 kHz up to 80 MHz $d = 1.2 \sqrt{P}$ in m	**80 MHz up to 800 MHz** $d = 1.2 \sqrt{P}$ in m	**800 MHz up to 2.7 GHz** $d = 2.3 \sqrt{P}$ in m
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

14.2 EnFocus Configuration for Micoscope Integration

14.2.1 Electromagnetic emissions table

Guidance and manufacturer's declaration – electromagnetic emissions

The EnFocus OCT is intended for use in the electromagnetic environment specified below.
The customer or the user of EnFocus OCT should assure that it is used in such an environment

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.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions in accordance with CISPR 11	Group 1	The EnFocus OCT must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions in accordance with CISPR 11	Class A	The EnFocus OCT is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

14.2.2 Electromagnetic immunity table I

Guidance and manufacturer's declaration – electromagnetic emissions

The EnFocus Configured for Microscope Integration is intended for use in the electromagnetic environment specified below.
The customer or the user of the EnFocus Configured for Microscope Integration should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Discharge of static electricity (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst immunity according to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	± 2 kV for power supply lines ± 1 kV for input and output lines	Use cables provided with system during integration.
Surges according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Not Applicable	System is DC powered from the integrating microscope and the test is not applicable to this configuration.
Voltage dips, short interruptions and power supply voltage fluctuations IEC 61000-4-11	0 % UT for 0,5 cycle at Sync Angle 0; 45; 90; 135; 180; 225; 270; 315 0 % UT for 1 cycle at Sync Angle 0 70 % UT (30 % dip in UT) for 25 cycles at Sync Angle 0 0 % UT for 5 second at and Sync Angle	Not Applicable	System is DC powered from the integrating microscope and the test is not applicable to this configuration.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the EnFocus OCT further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Note	U_T is the AC voltage prior to application of the test level.		

14.2.3 Electromagnetic immunity table II

Guidance and manufacturer's declaration – electromagnetic immunity

The EnFocus Configured for Microscope Integration is intended for use in the electromagnetic environment specified below.
The customer or the user of the EnFocus Configured for Microscope Integration should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF - Disturbance variables according to IEC 61000-4-6	3V RMS outside ISM band 6V RMS in the ISM and amatuer radio bands 150 kHz to 80 MHz	3V RMS outside ISM band 6V RMS in the ISM and amatuer radio bands 150 kHz to 80 MHz	Portable and mobile RF communications should be used no closer to any part of the EnFocus OCT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ for 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ for 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].
Radiated RF - Disturbance variables according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Radiated RF - Wireless Communications Equipment according to IEC 61000-4-3	385MHz, 18Hz pulse, 27V/m 450MHz, 1kHz sine modulation, 28V/m 710, 745, 780MHz, 217Hz pulse modulation, 9V/m 810, 870, 930MHz, 18Hz pulse modulation, 28V/m 1720, 1845, 1970MHz, 217Hz pulse modulation, 28V/m 2450MHz, 217Hz pulse modulation, 28V/m 5240, 5500, 5785 MHz, 217Hz pulse modulation, 9V/m	385MHz, 18Hz pulse, 27V/m 450MHz, 1KHz sine, 28V/m 710, 745, 780MHz, 217Hz pulse modulation, 9V/m 810, 870, 930MHz, 18Hz pulse modulation, 28V/m 1720, 1845, 1970MHz, 217Hz pulse modulation, 28V/m 2450MHz, 217Hz pulse modulation, 28V/m 5240, 5500, 5785 MHz, 217Hz pulse modulation, 9V/m	

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EnFocus Configured for Microscope Integration is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EnFocus OCT.

b Over the frequency range 120 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation amount is affected by absorption and reflection from structures, objects and people.

14.3 Common to Configurations

14.3.1 Recommended distances table

Recommended separation distances between portable and mobile RF communications equipment and the EnFocus OCT

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

Rated maximum output power of transmitter in W	**Separation distance according to frequency of transmitter in m**		
	125 kHz up to 80 MHz $d = 1.2 \sqrt{P}$ in m	**80 MHz up to 800 MHz** $d = 1.2 \sqrt{P}$ in m	**800 MHz up to 2.7 GHz** $d = 2.3 \sqrt{P}$ in m
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15 Compatibility with third party devices

15.1 Surgical microscope compatibility

A minimum requirement for compatibility with any microscope is that the combined exposure of both the microscope and the EnFocus OCT (installed) must conform to Group 2 limits of optical radiation safety (ISO 15004-2).

The EnFocus OCT device is not for use with the following surgical microscopes:

- Microscopes contra-indicated for pediatric use or restricted to adult use only.
- Microscopes with illumination systems that do not independently conform to ISO 15004-2:2007 Group 2.

When Use Includes Sterile Fields, The Following Applies For Compatibility:

- Microscope must be able to accommodate properly installed EnFocus OCT device without intrusion of EnFocus OCT into the sterile field. With the EnFocus OCT installed, the microscope can be draped using off the shelf drapes, without interfering with microscope functionality.
- With the EnFocus OCT installed and draping applied, the EnFocus OCT must be removable and the microscope revertible to an undraped state in less than 5 minutes.
- With the EnFocus OCT and a fundus viewing system installed EnFocus OCT must be removable and the microscope revertible to an undraped state in less than 10 minutes.

15.1.1 EnFocus Configuration for Microscope Integration

The EnFocus Configuration for Microscope Integration device has been validated for use with the following surgical microscopes:

- Leica Proveo 8 Ophthalmic Surgical Microscope, Models F42
- Leica Proveo 8x Ophthalmic Surgical Microscope 2D 4K and 3D 4K surgical microscope system

15.1.2 EnFocus Cart Configuration

The EnFocus Cart Configuration device has been validated for use with the following surgical microscopes:

- Leica M844 Ophthalmic Surgical Microscope
  - EnFocus and M844 are not approved for communication connection
- Leica Proveo 8 Ophthalmic Surgical Microscope, Models F42, C42, and CT42
  - EnFocus and these Proveo models may be connected for bidirectional communication by Leica serial cable 10747122

15.2 Fundus viewing systems

The EnFocus OCT has been validated for use with the following fundus/retina viewing lens system:

- OCULUS Surgical's Binocular Indirect Opthalmomicroscope (BIOM) fundus viewing system: BIOM Ready; BIOM 3, BIOM 4 and BIOM 5
- Flat surgical contact lens
- Leica RUV800 retinal wide-angle viewing system with an integrated inverter

Fundus viewing lens systems tend to be of similar but not identical construction and optical properties. Leica Microsystems cannot recommend or support accessories that have not been validated by Leica Microsystems. It is recommended to evaluate the compatibility of other imaging accessories with the EnFocus OCT prior to installation.

The recommended minimum requirements for compatibility are:

- Be compatible with Leica Microsystems 175mm or 200mm focal length objectives.
- Have mounting hardware compatible with the EnFocus OCT.

Select the retina viewing system appropriate for the focal length of the objective lens in use.

15.2.1 Using Adjustable Fundus Viewing Systems

While using an adjustable fundus viewing system (FVS), the focusing function of the microscope is intended to work like an aperture, only changing the field of view, not the sharpness of the image. Changing the microscope focus may degrade the OCT signal as it changes the working distance between objective and the retina. Please use the following workflow to achieve optimum retina images with an adjustable fundus viewing system:

- Setup the microscope to achieve proper focus and good image quality of the cornea.
- Swing the FVS into working position, without changing the microscope height. The front lens of the FVS should be centered in the field of view and perpendicular to the optical axis of the microscope.
- To get a sharp focused image of the retina, the focusing wheel of the FVS has to be used. It is helpful to start with a short length then the focusing wheel needs to be rotated until the image becomes sharp.
- After achieving a sharp image, do not adjust the microscope in order to change the field of view. Adjust the FVS focusing element while low magnification is engaged for focusing on specific detail looking to optimize sharpness of image. While the image is sharp, use highest magnification on the microscope and make fine focusing again using the rotating wheel on the FVS; then the image will become sharp and stay parfocal.

16 Product Security

This section of the user manual documents EnFocus connectivity; defines the set of cybersecurity controls used to secure the Leica Microsystems EnFocus and how a customer with elevated privileges (Hospital IT user role) may configure these controls.

16.1 EnFocus Connections

EnFocus is intended to be used within operating room in a hospital and is integrated within surgical microscope tower or installed on a mobile cart for use with ceiling mount microscopes. The system may be stored in the same room as where it will be used or moved to storage space (room or hallway) within the secure facilities. Hospital IT, nurses, and surgeons will regularly have access to the system.

The system has the following data interfaces which have been considered when evaluating system cybersecurity: it supports data transfer to external storage media and connections to 3rd party equipment to support interconnectivity and visualization in the operating room. Data transfer to external storage media is supported through USB 3.0 connections on the microscope. Connections to 3rd party equipment are connected by DVI and SDI connections for video distribution and CAN or Ethernet within an integrating microscope for control communications.

CAUTION

Microscope Network Connection .
Connecting the equipment to the hospital network exposes the equipment to additional risks of the network that could result in unidentified risks to patient, operator, or 3rd parties. Hospital organization responsible for the network should work with the microscope users to identify, analyze, evaluate and control these risks. .

EnFocus supports file transfer to external transportable media through USB 3.0. The system provides an export capability to copy images (JPG) and videos (MP4) to the external media. The external media is treated as a USB mass storage device class (MDC) and will support file transfer at up to 625 MB/s provided that the user is using an external media device that is USB 3.0 compatible. This connection is used to transfer data after surgery is complete, there is no risk to microscope use due to reduced bandwidth, this will simply slow transfer of the data. As such there are no hazardous situations that result from failure of the network to meet required bandwidth characteristics.

EnFocus includes several connections to additional equipment in the operating room. There are a video outputs that can be used to display the video on additional monitors or to be connected to an external recording or distribution system. There are a HDMI and SDI video input connection to allow video to be acquired by EnFocus and shown on output views. System supports communication to the microscope through a proprietary protocol supported by both a serial and ethernet connection.

16.2 EnFocus Cybersecurity Controls

Medical device security is a shared responsibility of all stakeholders: manufacturers, hospital employees, service providers and patients. Compromised cybersecurity can result in loss of data, system availability, system integrity or expose other connected devices or networks to security threats. The following lists the design controls that are in place to mitigate potential vulnerabilities and the associated threats.

Operating System Access: EnFocus users interact with the system configured with minimum permissions. Authenticated clinical users and unauthenticated users are limited in their use of Windows OS functions and are expected to only run the EnFocus application. Authenticated Hospital IT users and Leica Service users may use the system with elevated permissions and have access to full Windows OS functions; this access may be required for specific configuration actions.

Operating System Configuration: EnFocus runs Windows 10 IOT Enterprise LTSC 2019 (1809) with all unnecessary services and port access removed. EnFocus application launches at startup and the Windows account has restricted access.

Operating System Runtime Restrictions: EnFocus is configured with Windows Firewall, Windows AppLocker, and Trellix Application Control actively running to limit what software may execute and fiole permissions. This includes disabling Autorun functionality of USB ports; restricting the execution of unsigned software; restricting the location from which software may launch its execution.

Real-time Threat Protection: EnFocus is configured with Windows Defender activated providing real time protection against viruses and malware.

Encryption Measures: All protected health information, user authentication data, and auditable events are encrypted prior to being stored in local databases. This information is stored on the hard disc of the EnFocus. This ensures that no sensitive information is stored as plain text on the hard disc, and theft of the CPU Module or its hard disc will not compromise the sensitive information of the patients. All personally identifiable information stored on EnFocus

is encrypted prior to storage and decrypted for presentation to authenticated users.

User Management: EnFocus has implemented three user types for user operations and two user roles for Leica Microsystems personnel.

Unauthenticated Users: Use of the microscope does not require any user authentication, an unauthenticated user may use microscope including recording videos and pictures. The sole limitation is the inability to access or enter patient information for export or association with recorded imagery.

Authenticated Clinical User: Access to stored patient information, patient information from a modality worklist, or entering patient information that will be stored on the system requires Clinical users to login with their personally identifiable user name and password prior to accessing these system features.

Authenticated IT Users: These users have extensive rights to configure the security settings of the system. This includes resetting user passwords, creating new users, disabling users, configure security settings, configure connections, and generate audit reports. These users can exit the application and access the Operating System with elevated permissions to change Windows configuration and install software updates.

Leica Microsystems Accounts Limitation and Security: Leica Microsystems has specialized accounts, Service Engineer, Applications specialist and Manufacturing. These accounts allow Leica representatives system access to configure and troubleshoot the system. These accounts are only accessible by using of a hardware dongle that is managed by Leica Microsystems and is active for a predefined lifetime and are traceable to individual associates. These accounts do not have the ability to access patient information on the system.

User Authentication: Authenticated users are required to have usernames and passwords to manually be entered through the software interface. Authentication via credentials supplied over the network, using badge readers or biometrics is not possible. Usernames are expected to be unique to individuals to enable auditing to allow events to be traced to specific users.

Access Notification: EnFocus notifies users when they would have access to patient information. The EnFocus software reminds Clinical users that accessing patient information should only be done by authorized personnel and not to continue with login if unauthorized.

Secure Coding Practices: EnFocus software application has been developed by Leica Microsystems in accordance with development standards and practices. This includes requiring developers to complete secure coding training; conducting system cyber security risk assessment; conducting vulnerability assessments; implementing design controls to mitigate risks and vulnerabilities to achieve and acceptable level; conducting static code analysis during software development and deployment; and conducting 3rd party penetration testing and gap mitigation.

Digital Signatures: All software applications from Leica Microsystems are digitally signed. If the system detects that the digital signatures are either missing or incorrect, the application will not be launched. This ensures that the application being used is trustworthy, reducing the risk of unauthorized applications compromising the sensitive information stored on the machine.

Audit Logging: EnFocus provides IT users the ability to generate an audit log that reports all security events, identifies the user who initiated the event, and when the event occurred. Security events that are recorded include the following:

- Exporting images to file system
- Export audit logs to file system
- Export non-audit logs to the file system
- Retrieving and viewing OS elevated access credentials
- Initiating exports to file system
- Aborting exports to file system
- Viewing recorded surgeries (with patient names)
- Retrieving and viewing OS elevated access credentials
- License dongle insertion
- Automatic user activated on dongle insertion
- License dongle removal
- Being denied access to view requires more authorization
- Logging in successfully)
- Login failures
- Login failures (exhausted login attempts)
- Default user activation
- New user created
- User updated
- User passwords reset
- Patient Information Protection Option updated
- Auto delete option updated
- Unable to delete missing patient data file)
- Error deleting patient data file
- Deleting patient data file
- No record limit received from database
- Enabling/Disabling users from IT account
- Creating surgeon profiles
- Updating surgeon profiles
- Clearing of the audit log

Secure By Default: EnFocus security features are enabled by default. There are some security features that may be disabled at the discretion of IT users. These decisions on security configuration are applied to all system users once applied; these features include:

- Requiring clinical users to authenticate with user name and password prior to accessing or recording any patient health information.
- Require clinical users to have a unique, individualized user name and password. Generic user name and custom password
- Require clinical user passwords to meet minimum password requirements: one uppercase, one lowercase, one numeric, one special character and a minimum of 10 characters.
- Require clinical accounts to be changed when maximum password age is reached.
- Limit clinical user passwords from using repeated passwords from recent history.
- Automatic timeout of user account after inactivity.
- Automatically lockout users after specified number of invalid login attempts.

16.3 Product Security Software Features

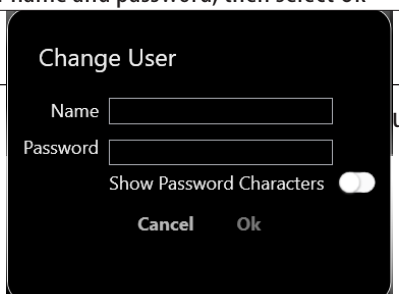
This section provides details for how Hospital IT users may change the system configuration. At the time of system installation, Leica Microsystems personnel will assist with initial setup of these functions. If no changes are required after installation, it is recommended to leave the system in the configuration established at installation. If the configuration must be changed, contacting Leica Microsystems Service teams to manage these changes is recommended. All the functions in the section require the user be authenticated as an IT user before proceeding with the instructions.

Caution: Risks Due to Changing System Configuration
Once the configuration that control potential cyber security risks is established, take care not to change the configuration without assessing the potential risk impact. These changes would include but are not limited to network configuration changes, connection of additional items to the microscope, disconnection of items from the microscope, update of equipment.

16.3.1 Authenticate as an IT User

Leica Microsystems associate will instruct Hospital IT on how to initially configure their user name and password during system installation. These instructions are how the user can authenticate after the initial setup.

- Select Menu then Help then Change User Role
- Enter user name and password, then select Ok



16.3.2 Logging Off Authenticated IT User

To prevent any unauthorized access, log out of your account when finished using the system.

- Select Menu then Help then Log Out

16.3.3 Configuring EnFocus Application Security Settings

The following steps allow you to configure security settings:
Authenticate as an IT User

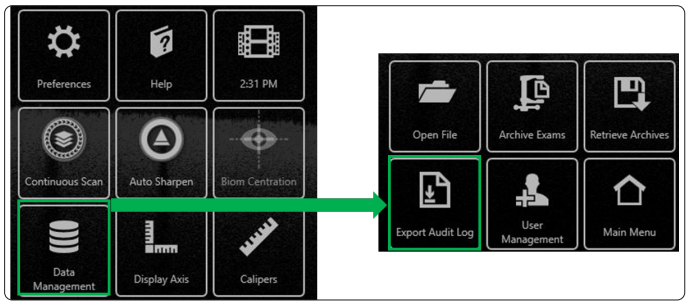
- Select Menu then Preferences
- Select Security Options from the Menu on the left

- Configure selections from this page
  - » Protect patient by Login: Choose to enable or disable function to require clinical users to authenticate with user name and password prior to accessing or recording any patient health information.
  - » Account lockout threshold: Select specified number of invalid logins attempts before lockout or disable the feature.
  - » Enforce Password Options: Choose to enable or disable function to require clinical user passwords to meet minimum password requirements: one uppercase, one lowercase, one numeric, one special character and a minimum of 10 characters.
  - » Maximum Password age: Choose frequency when accounts passwords need to be changed or disable the feature.
- Select Apply to have the changes take effect immediately and select save for these settings to be persistent over system power cycling.

16.3.4 Exporting Audit Reports

EnFocus maintains a record of all auditable activities. In the event of a suspected event, Hospital IT user may generate a report of these events and export it to a connected USB. Auditable events are maintained on the system for 180 days after this period the events will no longer be reported.

- Insert trusted USB into EnFocus USB connector for use as a location to export the audit log
- Authenticate as an IT User
- Select Menu then Data Management then Export Audit Log

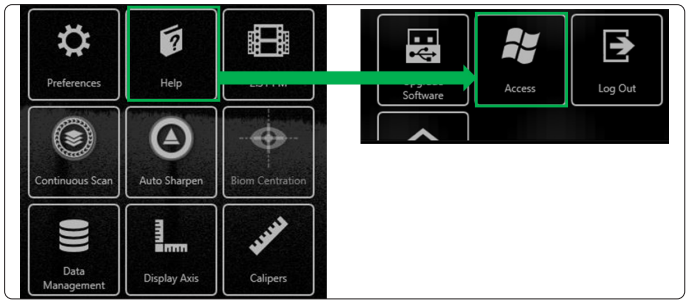


▶ Remove USB and review exported audit log on a secure computer

16.3.5 Elevating Windows Access

Hospital IT users may obtain elevated credentials to access Windows functionality with administrative privileges and to install software component.

▶ Authenticate as an IT User
▶ Open the Help Menu under the main Menu
▶ Select Access and record credentials for Windows login use



These credentials may be used to select when selecting "run as administrator" for installing software or accessing Windows searchable features. The credentials may also be used to access a Windows account with administrative credentials:

▶ Insert USB keyboard, Enter Control + Alt +Delete, Select switch user
▶ Select LeicaUser as User and enter credentials recorded in prior step

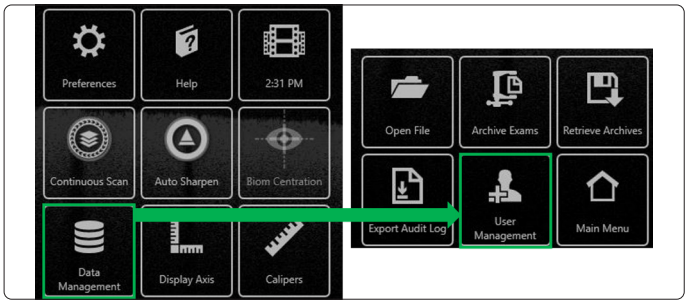
Note: Elevated credentials are only valid for 15 minutes. After that duration must restart system and elevate access again as the credentials have been changed.

Note: After elevating Windows access and completing the necessary changes, user should cycle power to the microscope to return to EnFocus application

16.3.6 User Management

Hospital IT has the ability to view which users have credentials; can add users, can enable or disable users; and may reset a user's password.

▶ Authenticate as an IT User
▶ Select Menu then Data Management the User Management



▶ This displays the list of users, their access level, and their access status

Disabling a user using the slider that system access will not be granted access. A user may either be disabled manually or if the incorrect password is entered too many time triggering the account lockout.

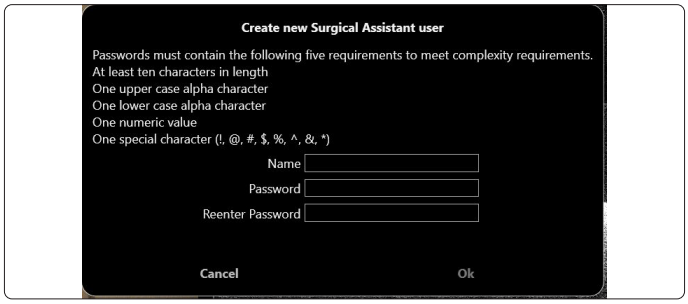
Selecting Reset will reset a user's password. A temporary password will be generated and shown. If a user is disabled and reset is selected, it will change the password and reset the users status to enabled.

Selecting the + icon will allow the Hospital IT user to add a new user from their account. The new user enters a user name and password and may then access the system after the Hospital IT user logs out of the system.

16.3.7 Alternative Method to Add Users

Leica Microsystems associate will instruct Hospital IT on how to initially configure a site specific password for the Surgical Assistant user role during system installation. These instructions are new surgical assistant user can be added.

- ▶ New user selects Menu then Help then User Role
- ▶ New user enters Surgical Assistant as the name and site specific password as the password
- ▶ New user is presented with dialogue window to enter their personal user name and password



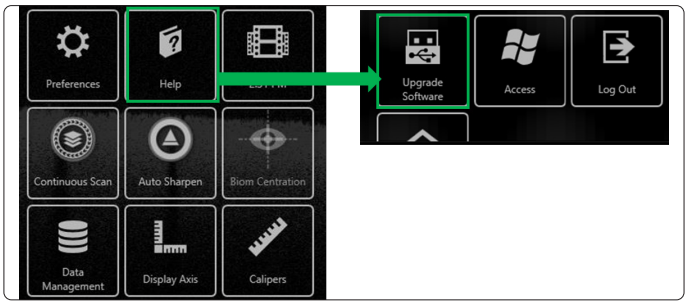
- ▶ After doing this the user should be instructed to use their new credentials when accessing the system

16.3.8 Resetting Hospital IT Password

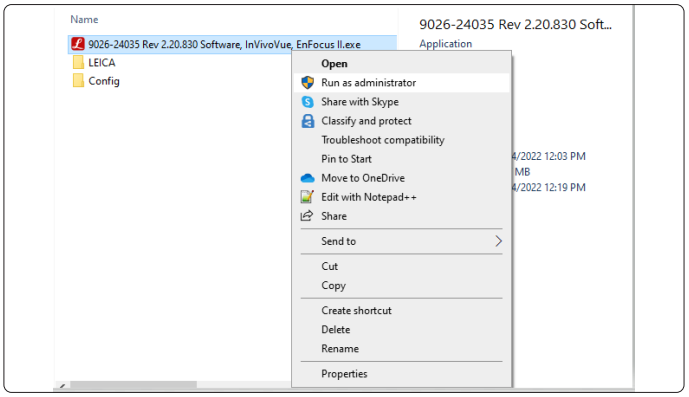
If an IT user needs their password reset, a Leica Microsystems Service Associate may login and reset the password. Contact local Leica microsystems service to schedule a visit.

16.3.9 Installing Software Updates

- ▶ Obtain or prepare a USB drive that is NTFS formatted and create a folder Leica\EnFocus on the USB
- ▶ Obtain software update from Leica Microsystems and copy the files to the Leica\EnFocus folder
- ▶ Follow procedure to authenticate as an IT User
- ▶ Follow procedure to Elevate Windows Access
- ▶ Go to Menu then Help then Update Software



- ▶ This will open a browser to allow you to select the software to install. Right select on the software (either with a mouse or highlight the file and hold down on touch screen with 2 fingers for 2 seconds) then select "Run as Administrator" and enter the credentials from Elevate Windows Access step.



- ▶ Follow instructions of installer to complete installation

16.4 Security Updates

Leica Microsystems develops products that help our customers to gain new insights. Insights that help to advance science, patient outcome, and gain insights for key questions concerning research, development, and engineering. To achieve this, we uphold core values that define our responsibility to those we serve. Among them are an unwavering commitment to the safety and security of our instruments and services. In response to potential threats to cybersecurity, Leica Microsystems is continually assessing vulnerabilities and determining responses. As part of the response, it is expected that EnFocus application software, operating system, antivirus definition files, and additional on product software will be regularly updated. For critical security vulnerabilities, Leica Microsystems will contact our customers and communicate the vulnerability, available short-term mitigations and when available provide the security update for installation. For non-critical security vulnerabilities, Leica will accumulate these changes into our patch release cycle and make them available at next scheduled service visit or upon customer request. In order to notify customers of these updates, it is important that we have accurate contact information for your institution. If the contact of record from your institution departs, please contact Leica Microsystems so we may update your contact information.

16.5 Cybersecurity Incident Reporting

Potential security vulnerabilities or privacy issues with a Leica Microsystems product should be reported to local Leica Microsystems customer service representatives. We ask that you please refrain from including sensitive information (e.g., PHI, PII, etc.) as a part of any submissions to Leica Microsystems. Please provide the following information in your submission:

- Contact information (e.g., name, address, phone number, and email)
- Date and method of discovery
- Description of potential vulnerability
- Product name
- Version number
- Configuration details
- Steps to reproduce
- Results or impact

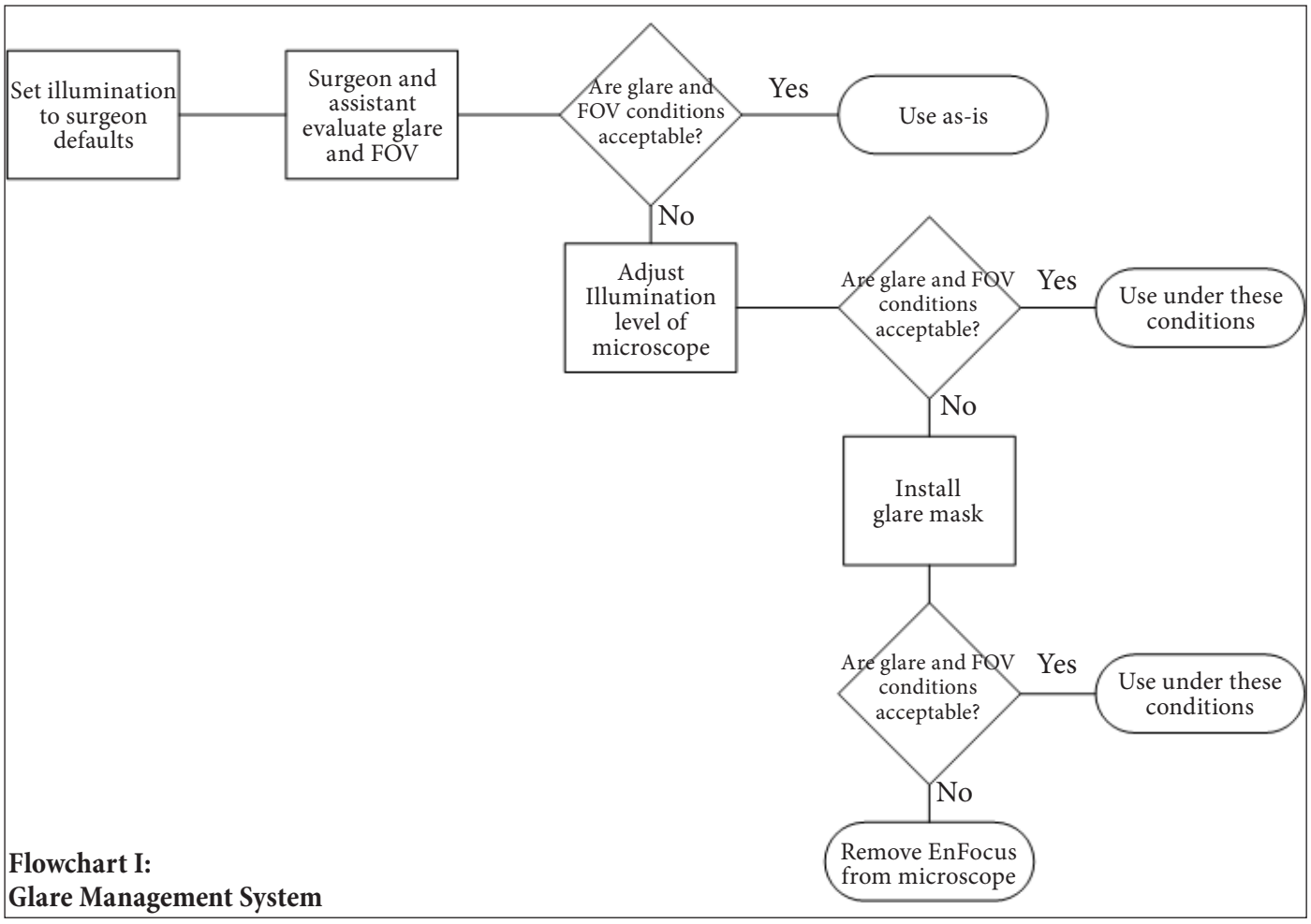
This incident report will be handled through Leica Microsystems Complaint Handling process. This includes investigating the incident or concern and determining corrective and preventative actions where needed and communicating those finding with the impacted customers.

17 Glare

17.1 Glare Management

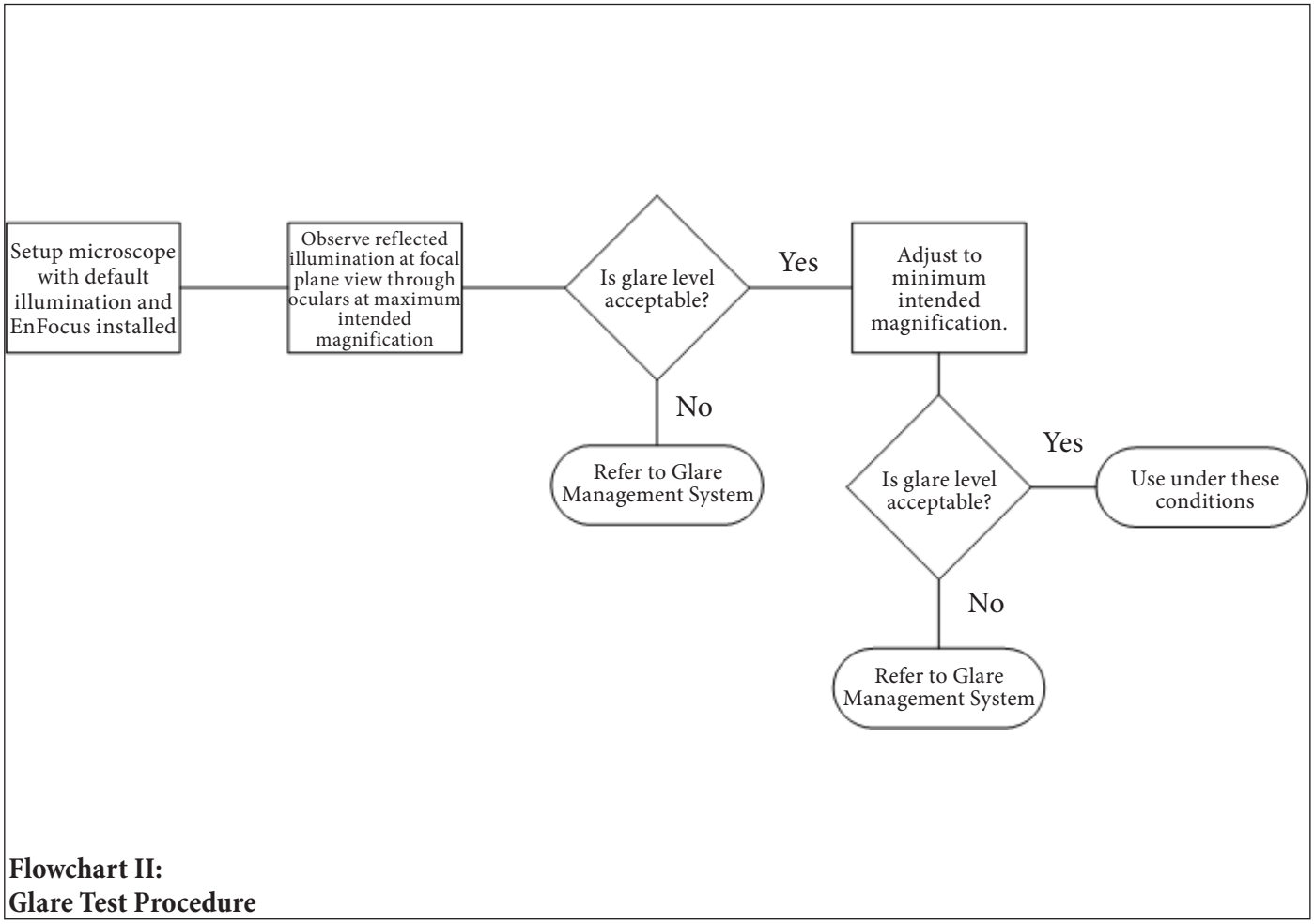
Installation of the EnFocus device on a microscope results in a vertical displacement of the microscope objective, which may cause glare to appear in the microscope oculars when the microscope's internal illumination system is used. The flowcharts on the following pages detail how this glare can be managed or eliminated, using either prescribed illumination settings or the supplied glare masks.

Flowchart I defines the **Glare Management System**, which details how glare can be evaluated and managed in general. First, the microscope illumination should be evaluated with the surgeon's preferred (default) illumination settings and evaluated for the presence of glare. If the illumination condition is acceptable, no further adjustments are required. If glare is present and distracting, the surgeon may adjust the illumination parameters per microscope-specific instructions, or install a microscope-specific glare mask, if available.



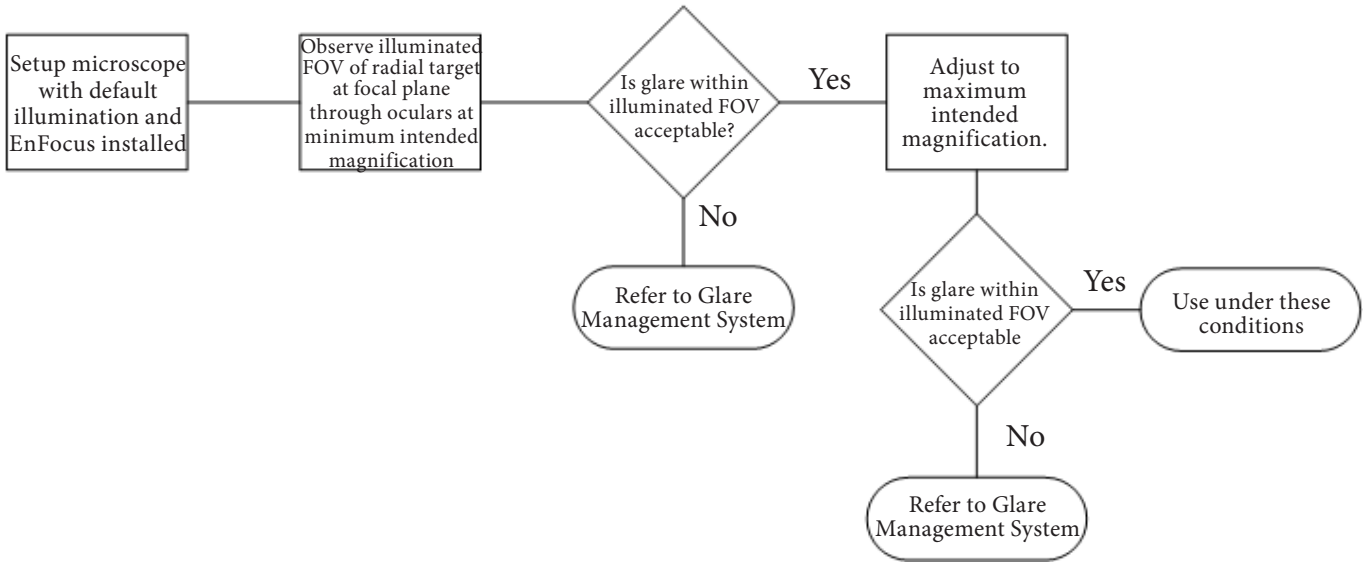
Flowchart I:
Glare Management System

Flowchart II is the **Glare Test Procedure.** It describes the procedure for evaluating the presence of glare. It corresponds to the "Evaluate Glare and FOV" step from Flowchart #1.



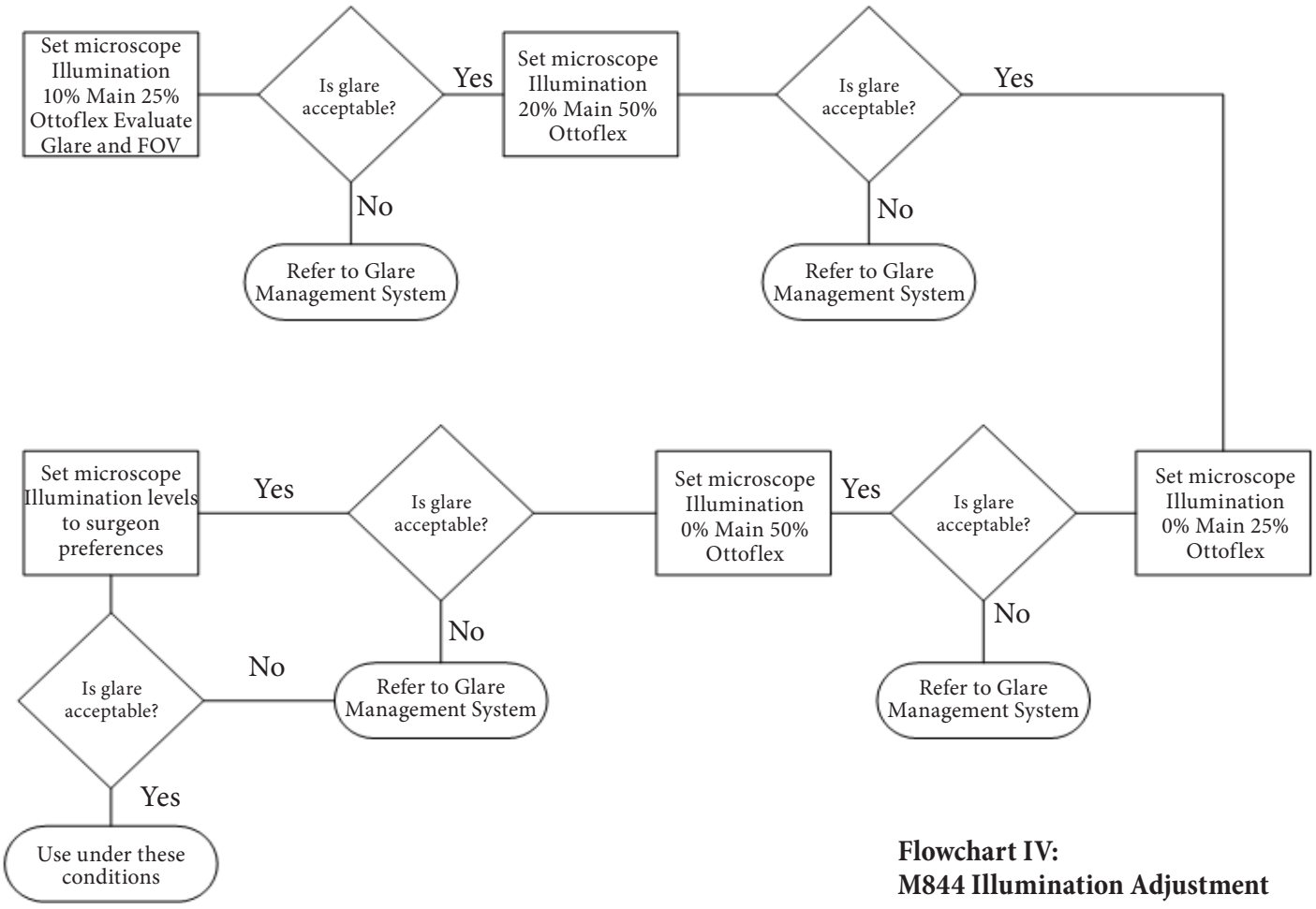
Flowchart II:
Glare Test Procedure

Flowchart III is the **Field of View Test Procedure.** It describes the procedure for evaluating the illuminated field-of-view and corresponds to the "Evaluate Glare and FOV" step from flowchart #1. These steps should be implemented when evaluating the microscope performance with a glare mask.



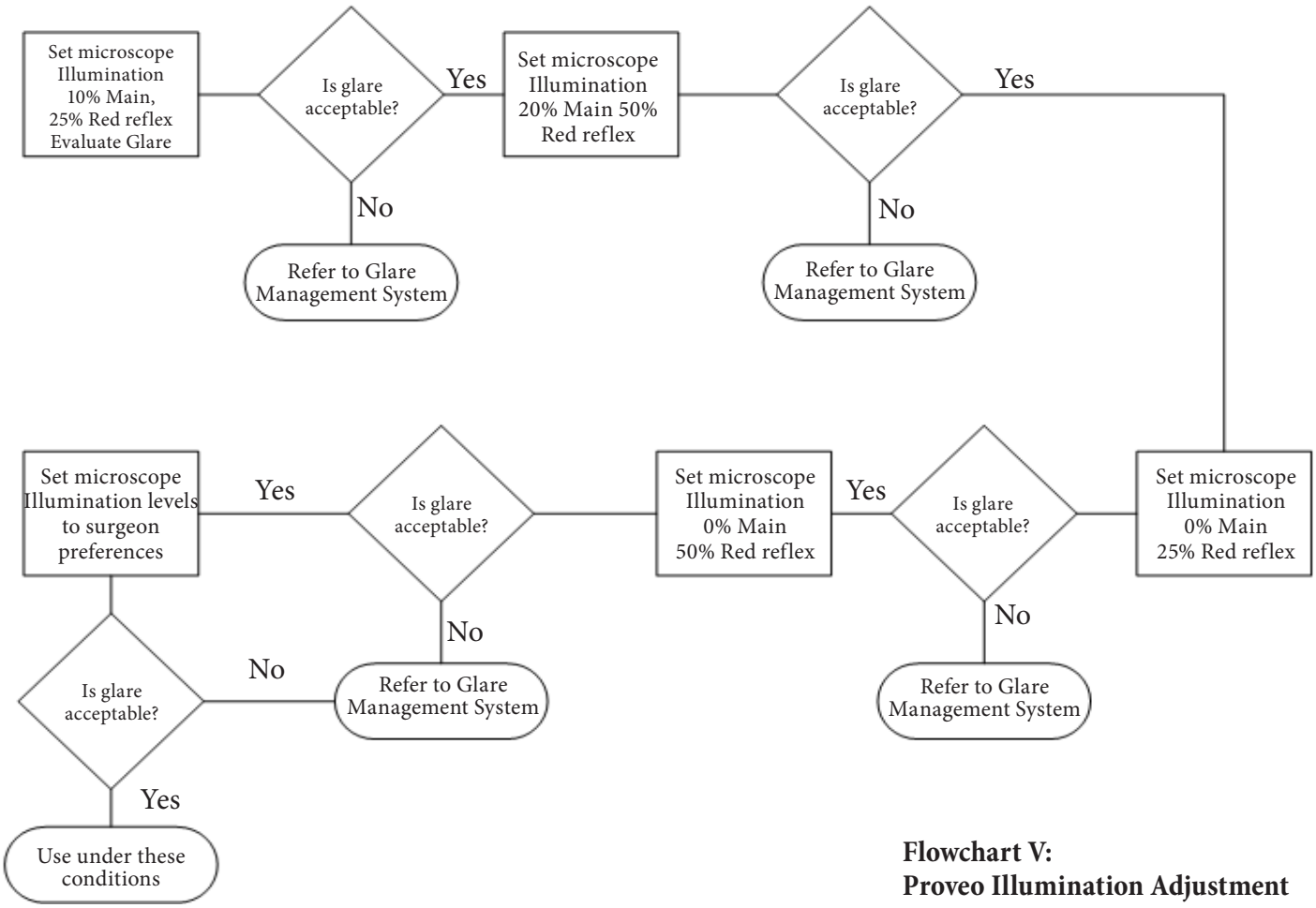
Flowchart III:
Field of View Test Procedure

Flowchart IV is the Illumination Adjustment Procedure specific for the Leica M844 microscope. It describes the recommended procedures for adjusting the illumination on a M844 microscope. It corresponds to the step from flowchart #1 on adjusting the illumination.



Flowchart IV:
M844 Illumination Adjustment

Flowchart V is the Illumination Adjustment Procedure specific for the Leica Proveo 8 microscope. It describes the recommended procedures for adjusting the illumination on a Proveo 8 microscope. It corresponds to the step from flowchart #1 on adjusting the illumination.



Flowchart V:
Proveo Illumination Adjustment

17.2 Glare Mask Selection

Leica M844:

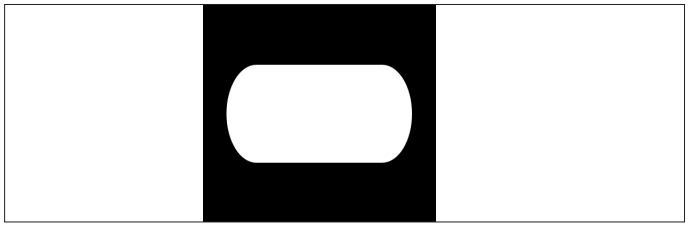
The EnFocus is supplied with two glare masks for use with the Leica M844: the circle and bar masks. Either of these masks will eliminate residual glare in the system by slightly altering the illumination shape. Masks should only be used if other glare mitigation strategies in the Glare Management System do not produce acceptable results.

While either of the masks will eliminate glare, each of the masks will produce a slightly different illumination shape at the microscope focal plane. Both masks will produce an illuminated FOV that includes a fully illuminated central circle of at least 38mm or 43mm in diameter (with the 175mm and 200mm objectives, respectively). However, outside of this central 38mm circle, some shadowing may be observed. The choice of mask depends entirely on the user's preference of illumination shape. A sketch of the expected illumination patterns is shown below.:

Illumination pattern sketches for circular (left) and bar (right) glare masks. The gray areas in the bar sketch denote areas that receive 50% illumination.

Leica Proveo 8

There is only one glare mask for the Leica Proveo 8 microscope. The illumination shape for the Proveo 8 glare mask is shown below:



18 Annex

18.1 Abbreviations

The following is a list of abbreviations used throughout this manual.

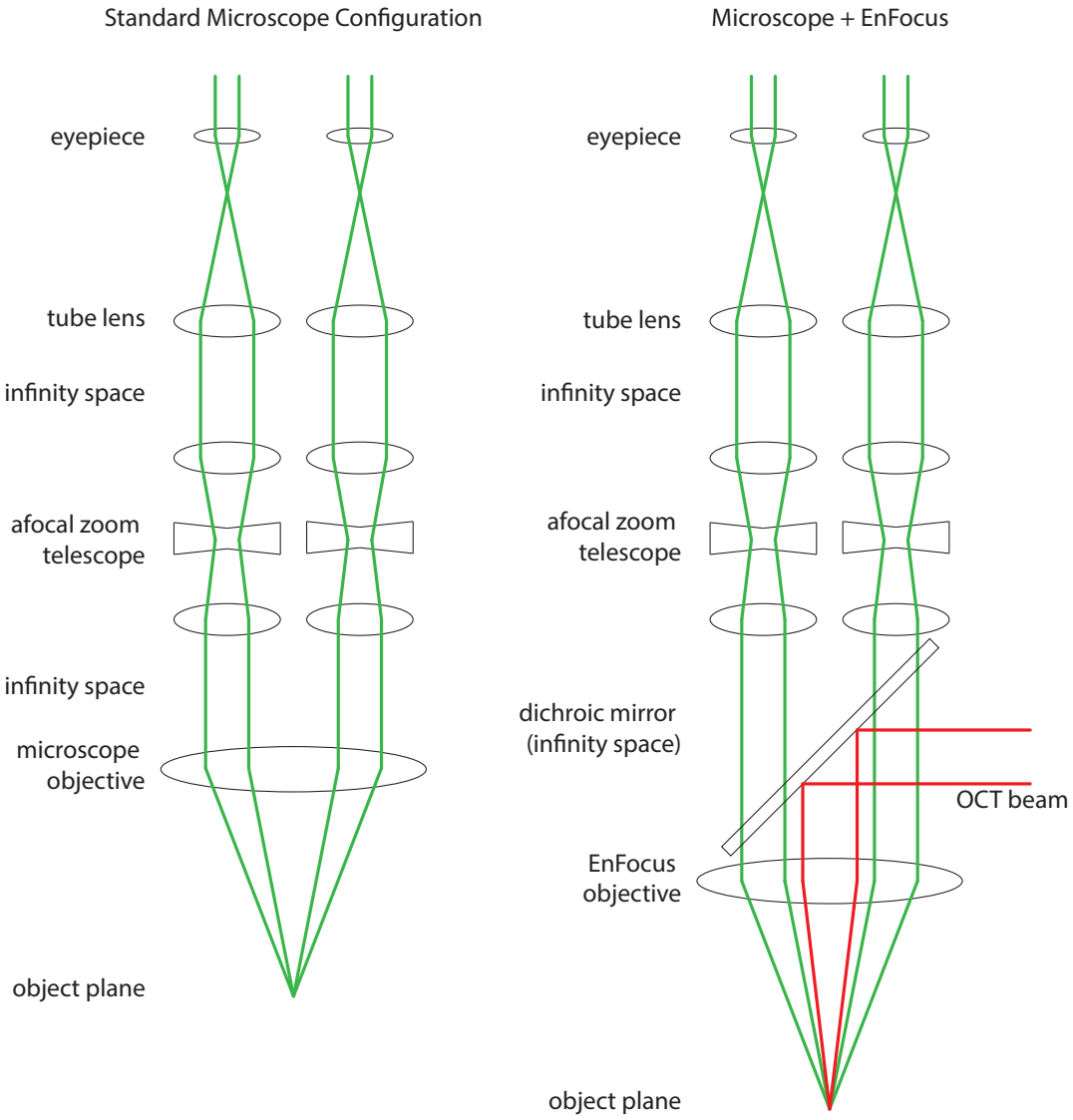
EMC	Electromagnetic Compatibility
FVS	Fundus Viewing System
IFU	Instructions For Use
IPA	Isopropyl Alcohol
LED	Light Emitting Diode
OCT	Optical Coherence Tomography
P/N	Part Number
RF	Radio frequency
SD-OCT	Spectral Domain Optical Coherence Tomography
SDOIS	Spectral Domain Ophthalmic Imaging System
SLD	Super Luminescent Diode
UPM	UPS module
UPS	Uninterruptible Power Supply

18.2 Glossary

A-Scan	A single line of OCT data along the axial (longitudinal) direction of an image..
Acquisition Rate	The rate at which image data is acquired and displayed, measured in A-scans per second. See also Scan Rate.
Axial	Referring to the direction that is parallel to the propagation of light in the system, i.e. parallel to the optical axis of the system. Equivalently referred to as "longitudinal."
Axial Field-Of-View (FOV)	The maximum display depth, or size of the OCT images in the axial direction. Also referred to as imaging depth or "Z_{max}".
Axial Optical Resolution (Δz)	The minimum distinguishable feature size of the OCT system in the axial direction. Equivalent to “longitudinal resolution” or LARRD (from sonography). May be shortened to "axial resolution" or "longitudinal resolution".
B-Scan	A cross-sectional plane of OCT image data is composed of a sequence of neighboring A-scans. A B-scan has one axial (longitudinal) dimension and one lateral dimension.
Image Depth (z_{max}".)	See Axial Field of View.
Lateral	Referring to a plane that is perpendicular to the optical axis of the system.
Lateral Field-Of-View (FOV)	The observable area of the imaging system in the lateral direction at the object plane, perpendicular to the axial direction (perpendicular to the direction of propagation of light in the system).
Lateral Resolution (Δr)	The optical resolution of the OCT system in the lateral plane, A higher numerical aperture yields finer lateral resolution.
Object Plane	The plane on which the objective lens focuses. This is the plane on which the sample being observed should be positioned.
Optical Coherence Tomography (OCT)	A medical imaging technique that uses light to create three-dimensional images from within biological tissue.
Scan Rate	The rate at which A-scan data is read from the spectrometer, measured in lines per second (one line corresponds to one A-scan).
Sensitivity	A measure of the weakest reflectivity that the OCT system can detect, relative to a perfect reflector (i.e. a mirror).
Sensitivity Roll-Off	A measure of the rate of change of signal quality as a function of axial depth in the OCT image, characterized by the reduction in sensitivity between the beginning and middle of the imaging range. Also called Fall-Off, Signal Fall-Off, or SNR Fall-Off.
Superluminescent Diode (SLD)	A semiconductor light source with brightness similar to a laser and the broad optical bandwidth of an LED. SLDs are well-suited light sources for OCT and are used in EnFocus OCT systems.
Tomography	The process for generating a volumetric image, or, a two-dimensional image of a slice through a three-dimensional object.
Volume Image	A three dimensional cube of OCT image data composed of a series of B-scans. A volume image has one axial (longitudinal) dimension and two lateral dimensions.
Volume Intensity Projection	A lateral cross sectional view of a volume of OCT data taken perpendicular to the B-scan direction. Creates an en face view of the subject volume being imaged. Sometimes referred to as a C-scan or C-slice.
Working Distance	The distance between the last (bottom) surface of the objective lens and the nominal object plane.

18.3 Principle of operation

The EnFocus OCT System provides OCT capability without impacting microscope function. When the EnFocus OCT system is attached to the microscope, the OCT is mounted onto the microscope by means of four mounting screw to the microscope optics carrier. The EnFocus OCT system sits below the microscope optics and the microscope objective is then attached to teh EnFocus. See the figure below for details of the EnFocus OCT optical path.



18.4 Sampling density and resolution

In anterior imaging mode, for the image resolution to match the optical resolution in a particular scan, the sampling density of that scan must be at least twice as fine as the optical resolution. This requirement is a consequence of the Nyquist-Shannon sampling theorem.

The sampling density of a particular scan can be computed by dividing the scan length by the number of A-scans per B-scan. For example, a 12mm B-scan with 1000 A-scans would have a sampling density of 12 microns. Denser scans can be achieved by either increasing the number of A-scans per B-scan, or by reducing the scan length.

Increasing the number of A-scans will improve lateral image resolution at the expense of the frame rate. Reducing the scan length will improve the lateral image resolution at the expense of the lateral field-of-view.

Note that in either case, the lateral image resolution can only be improved up to the optical resolution.

The following table lists the sampling densities for various scan patterns of commonly used scan lengths.

Sampling densities for common scan patterns			
Scan Type	**Scan Length**	**A-scans/B-scan**	**Sampling Density**
High Resolution	6mm	1000	6 µm
High Resolution	8mm	1000	8 µm
High Resolution	12mm	1000	12 µm
High Resolution	16mm	1000	16 µm

The next table lists the Nyquist sampling densities and nominal optical resolutions for anterior segment imaging:

Suggested sampling densities for anterior segment imaging			
Optical Resolution: 175mm objective	**Nyquist sampling density**	**Optical Resolution: 200mm objective**	**Nyquist sampling density**
31 µm	16 µm	34 µm	17µm

For posterior segment imaging, the optical resolution depends on several factors, including the IBZ setting, the fundus viewing system, and the quality of the patient optics.

The third table in this section lists the approximate best-case (diffraction-limited) optical resolutions for posterior segment imaging in common configurations. Note that for posterior segment imaging, it is recommended to operate the IBZ at the highest NA setting.

This table lists the suggested sampling densities and nominal optical resolutions for posterior segment imaging:

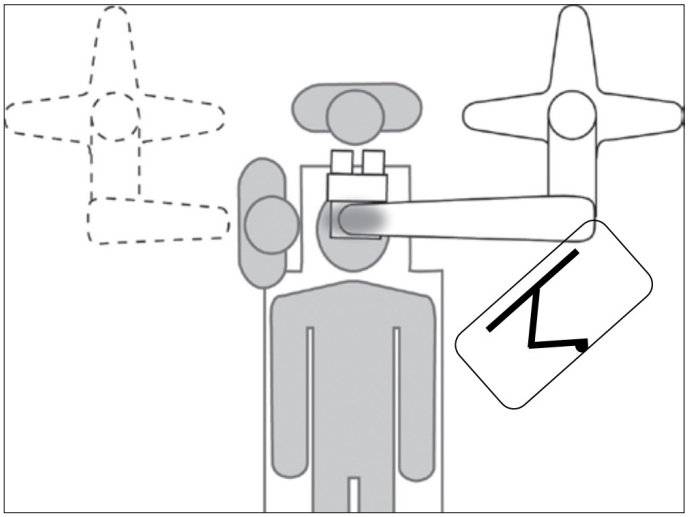
Suggested sampling densities for posterior segment imaging			
Objective Focal Length	**Fundus Viewing Lens FOV**	**Optical Resolution**	**Nyquist sampling density**
175mm	130 degrees	~40 µm	20 µm
200mm	130 degrees	~46 µm	23 µm

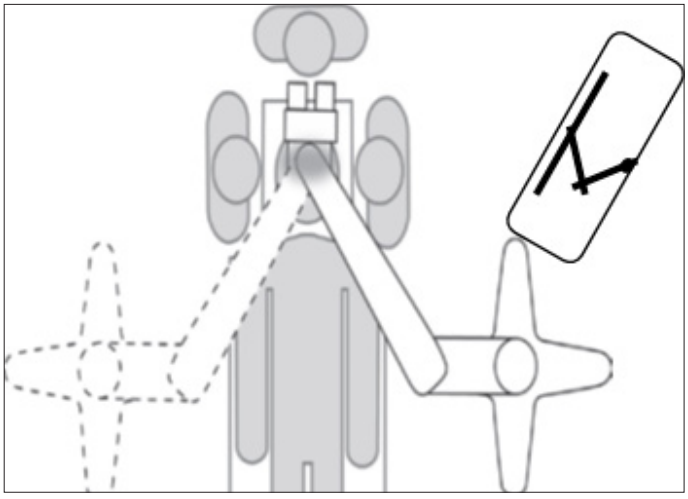
18.5 Expected positions of equipment and people

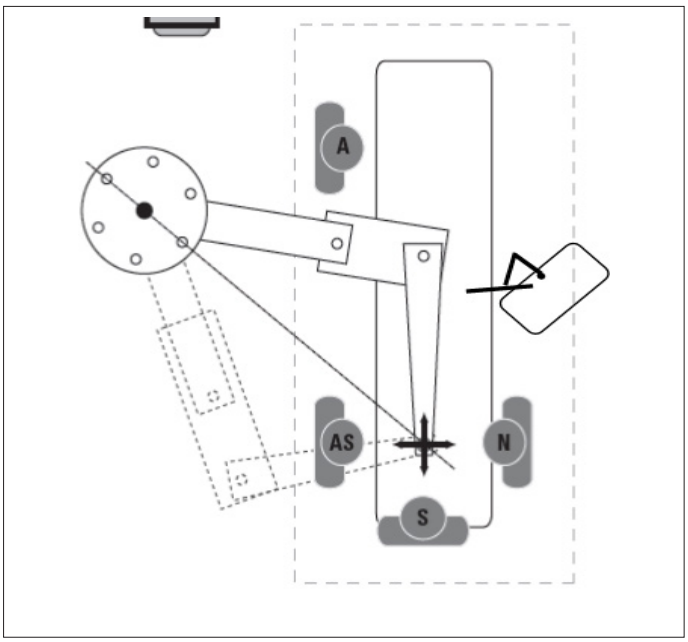
This section describes the most common positions of the patient, operator, and equipment in relation to the EnFocus OCT system in normal use. The setup may depend on the space available, personnel available, layout of the room, as well as the physician's preference.

When used during surgery, the patient is typically laid on their back, facing up underneath the microscope head. The surgeon may sit on either side of the patient or superior to the patient's head. The EnFocus OCT system has a 10m long tether and may be positioned where the surgeon can best see the monitor. The foot pedal has a cable length of 9 feet [2.7 m] which may impact the system location. The system needs to be within 9 feet [2.7 m] of the person performing data acquisition, whether that is the surgeon themselves or another staff member.

The following show typical positions of the systems in relation to the patient and the surgeons.







19 Quick Reference Guide

The following pages provide a quick reference guide for using EnFocus during surgery. Consider printing these pages and having them available for review prior to beginning surgery by the surgeon and any support personnel who may assit in the use of the product.

CAUTION

Read All Instructions Before Use

- ► Quick reference guide does not eliminate the need for training or for reading the manual in its entirety. The guide provides a reference to use the system for basic functionality.

Daily Start-up Checklist

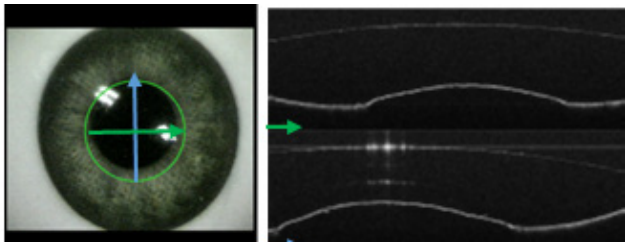
- ▶ Microscope positioned in OR to allow patient entry/exit and allow surgeon access.
- ▶ EnFocus Scanner is attached to microscope.
- ▶ Microscope monitor positioned so surgeon has clear line of sight from working position.
- ▶ Microscope video output connected to desired video connections
- ▶ Microscope and EnFocus are powered on.
- ▶ Surgeon ID on microscope selected corresponds with today's surgeon.
- ▶ Binoculars on microscope set to correct diopter value for surgeon (set to 0 if settings unknown).
- ▶ External drive connected to recording system for data transfer [if requested by surgical team].
- ▶ External drive connected to OCT for data transfer [if requested by surgical team].
- ▶ Microscope objective settings on microscope match what is being used.
- ▶ Fundus viewing system and microscope objective working distance compatibility confirmed.
- ▶ Patient added to recorder and case is started.
- ▶ Patient added to EnFocus or if using anonymous patient new exam is created.
- ▶ Handle covers and drapes required by facility are in place. Optics carrier and monitor have separate drapes available.

Next Case Checklist

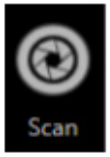
- ▶ Microscope moved to the reset position.
- ▶ Handle covers and drapes from previous surgery are replaced as required by facility.
- ▶ Previous case closed on recorder.
- ▶ Patient added to recorder and case is started.
- ▶ Patient added to EnFocus or if using anonymous patient new exam is selected.

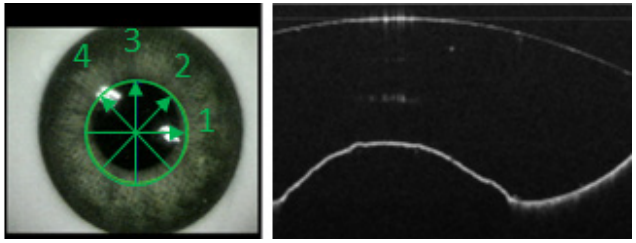
End of Day Checklist

- ▶ Previous case closed on recorder.
- ▶ Data finished recording to external drives.
- ▶ Remove external drives and provide to personnel handling the data transfer/storage.
- ▶ If storage limit warning was observed today notify personnel in charge of data management that space needs to be freed on the system. If you are responsible for data management, make space on EnFocus (Archive) or recorder as needed before powering off system.
- ▶ Handle covers and drapes from previous surgery are removed; system components cleaned with approved cleaning agents in accordance with facility policies.
- ▶ Microscope moved to the reset position.
- ▶ If microscope has to be moved, position microscope in transport positioning and disconnect external cables as needed to move the system.
- ▶ Turn off power to microscope (for cart based EnFocus, separately turn off its power).

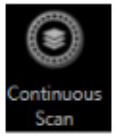


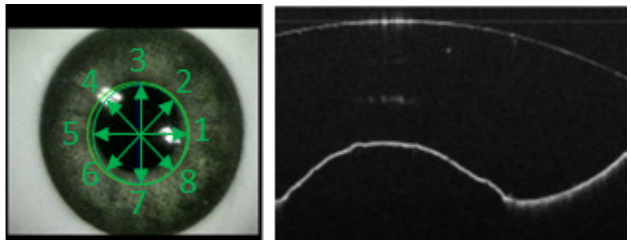
Continuously acquire and display two cross sections; one along the blue and one along the green line. Allows user to scan anatomy to find target sites for OCT imaging by moving the dynamic scan control (DSC).



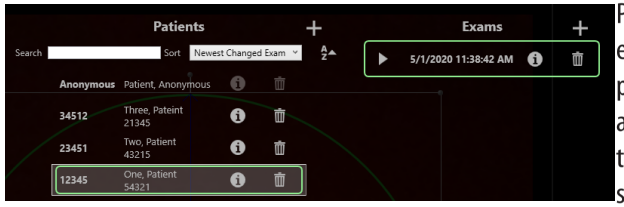


Capture a single volume defined by the scan pattern and scan density. Once collected the scan data may be saved, reviewed, or discarded by overwriting.

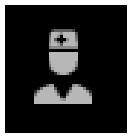




Continuously captures a volume defined by the scan pattern and density. The scan sequence wraps to the beginning after collecting the specified number of lines in the scan density. During continuous scan, select scan button to capture a single volume to be saved or reviewed or select Abort to stop scanning.

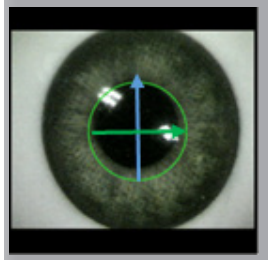


Patient Menu provides interface to add a patient; add an exam; copy exam data; search for a patient or review previously acquired scan data. The + to the right of Patient adds a new patient and automatically creates an exam. The + to the right of Exam adds a new exam for the currently selected patient.



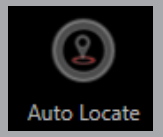
Surgeon Preference menu selects surgeon
That will be conducting surgery and loads their preferences. Each Surgeon ID on microscope is associated with a preference, selecting a different preference changes the association.

Changes view displayed on the monitor. Sequence depends on microscope mode and installed recorder.



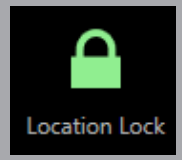
Dynamic Scan Control (DSC) is the overlay on the microscope video in InVivoVue. The crossing lines are where a Live Mode scan occurs, the shape around the crossing lines show the volume capture by a Scan. The overlay may be moved to change where EnFocus is imaging.

Saves the captured scan in the formats (BMP, MP4,TIFF, DICOM, Native) and locations defined by user preferences.



Adjusts the scan to find the brightest target surface in range for the selected procedure.

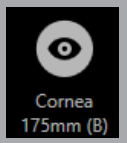
Adjusts laser settings (focus and polarization) to provide brightest image of target.



Adjusts scan settings (focus and z-position) to axially track brightest image of target.

Shows offset of current microscope from being at the working distance.

Provides warnings and errors/



Change settings to match current stage of procedure based on presence of fundus viewing system.

Select between 3 scan configurations or save current scan configuration as a preset

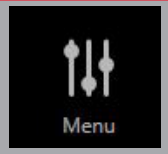
Configure active scan shape, density, or scan specialty: Doppler or Averaged.

Controls the playback of a captured or saved scan.

MICROSYSTEMS

Z-Position: Adjusts position where the OCT will collect its image in the depth of the eye. Smaller values are closer to the microscope objective and larger values are farther away. Best images are obtained when the light of the OCT is focused at the same point where z-position is imaging.

Menu Functions



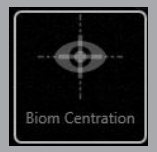
Displays dimensions on lateral and axial axes.

Allows acquired scans to be loaded and reviewed.

On-screen measurement of scan either on B-scan or VIP.

Provides access to options to customize surgeon experience.

Help functions including manual, software restart, and user role change.

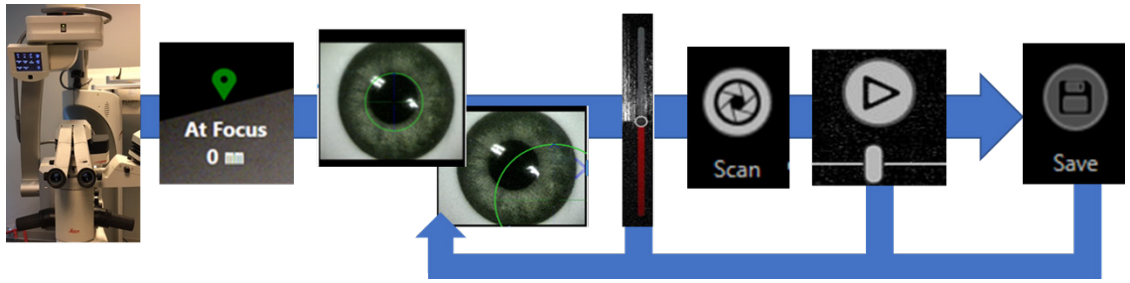


Aligns OCT scan and video to the optical axis of the BIOM.

Access function to archive data and open OCT files from secondary system.

Force adjustment of dispersion to sharpen image; executes automatically in background.

Workflow - Automated Functions On



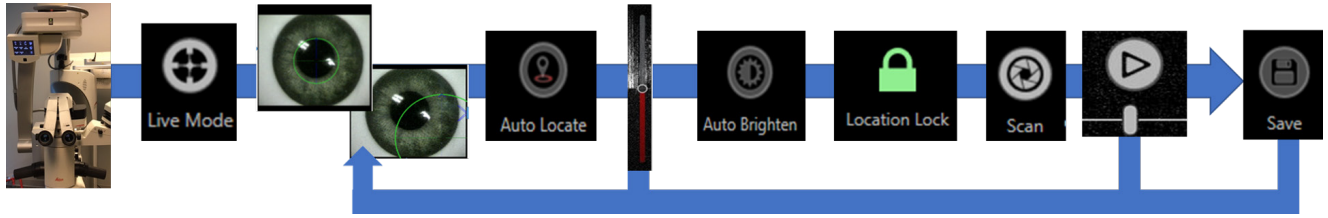
Move Microscope from Reset Position to Working Distance

Adjust the DSC to image targeted eye structure. Make minor adjustment to z-position as needed.

Capture a volume OCT scan; review scan and save scan as desired.

Automation settings enabled/disabled in Preferences > Workflow Options

Workflow - Automated Functions Off

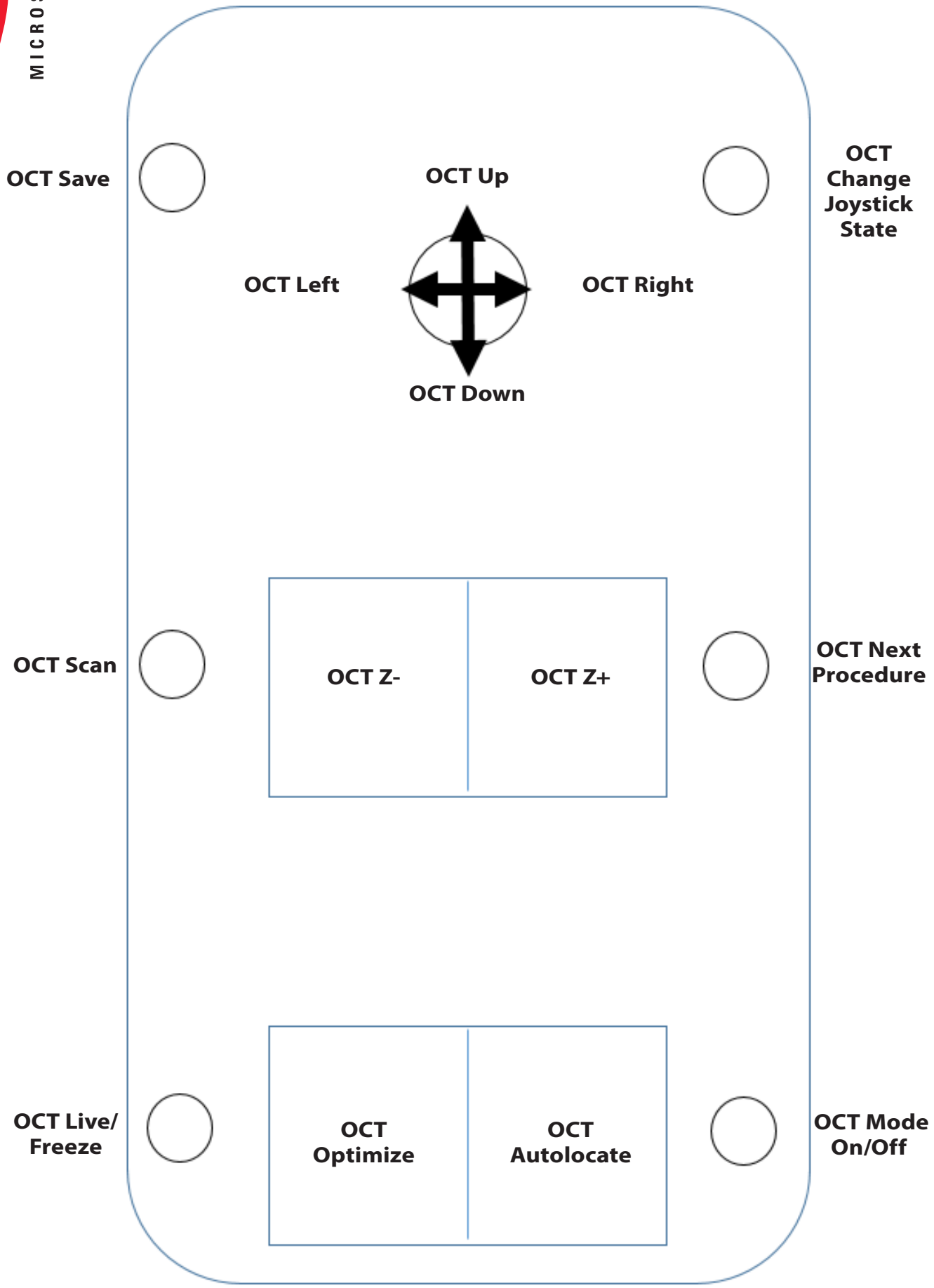


1. Move Microscope from Reset Position to Working Distance then turn on Live Mode to start OCT imaging.

2. Adjust the DSC to image targeted eye structure.

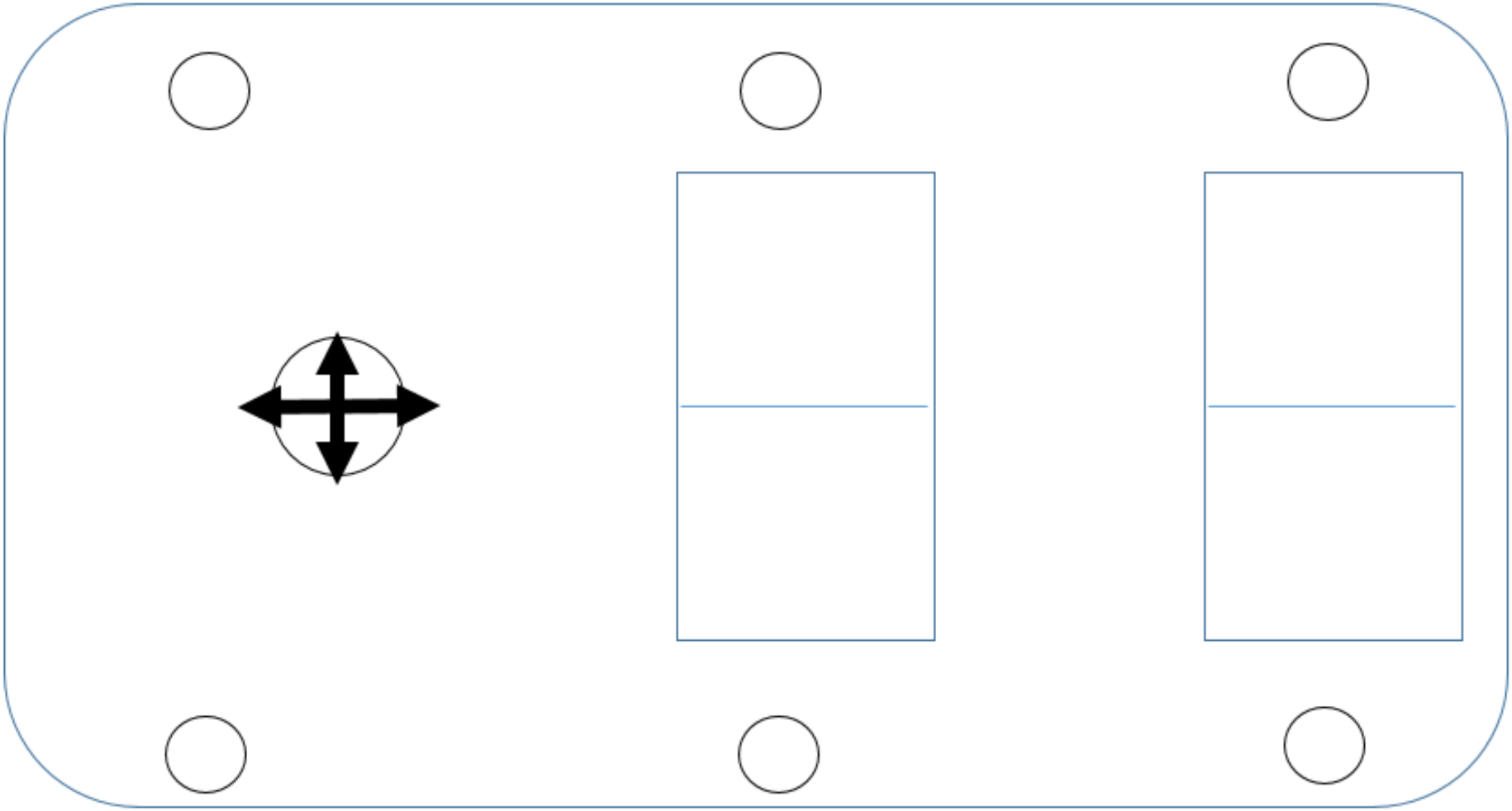
3. Activate Autolate to find the OCT image. Adjust Z-position to make minor adjustments of imaging depth. Activate Auto Brighten to obtain brightest image. Activate Location Lock to track the surface as eye and microscope adjust.

4. Capture a volume OCT scan; review scan and save scan as desired.



Recommended Foot Pedal Configuration

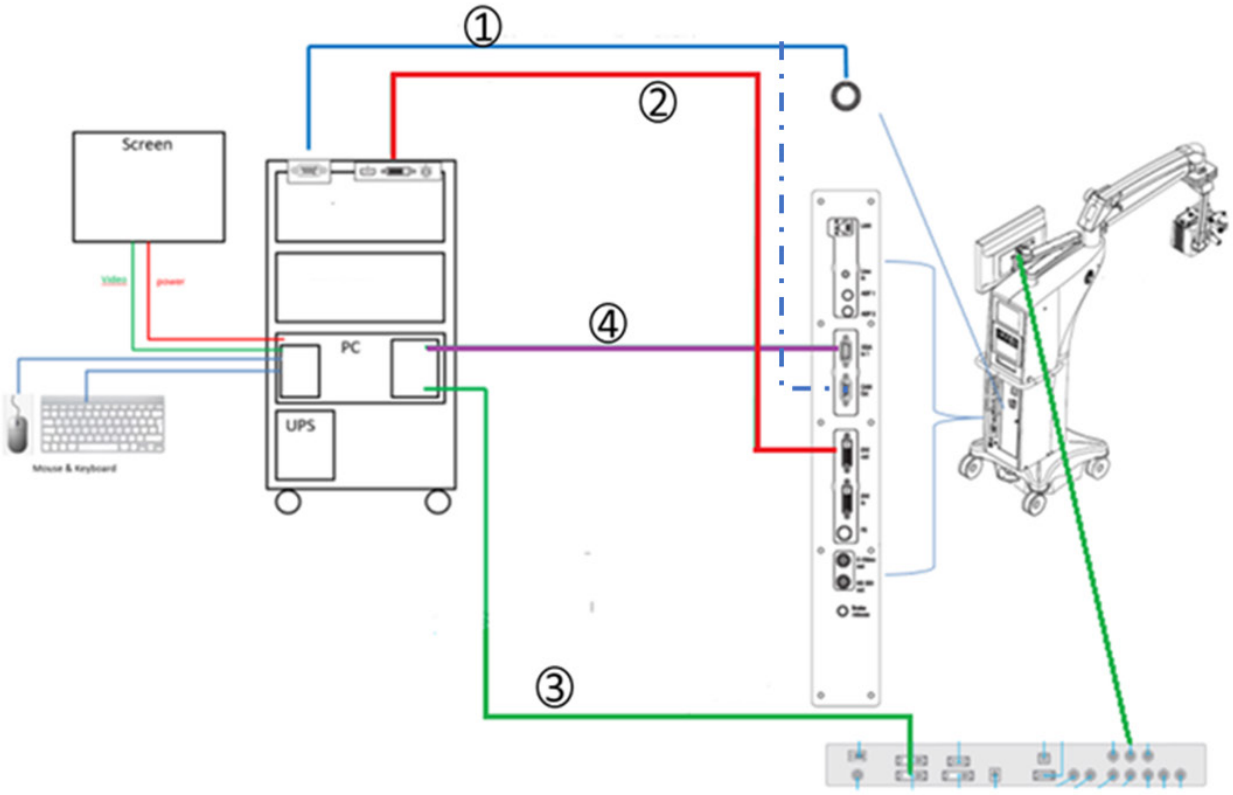
- Enable Auto advance to next pending scan in save preferences
- "Change View" programmed on left handle, turning towards surgeon



Personalized Foot Pedal Configuration

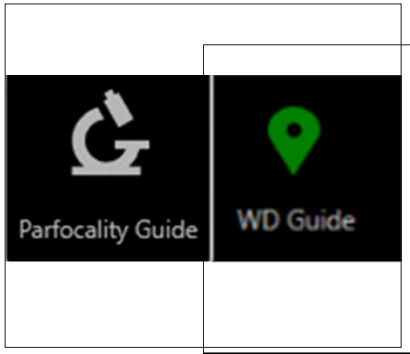
- Must have "OCT Mode On/Off" programmed on a button
- Must have "Change View" programmed on a button (Foot switch or handle)
- Program desired functions on the microscope and write them onto the corresponding locations for quick reference

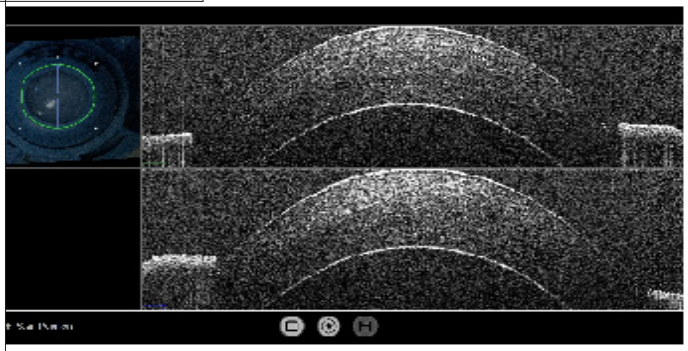
EnFocus, Cart Configuration – Proveo Cable Connections

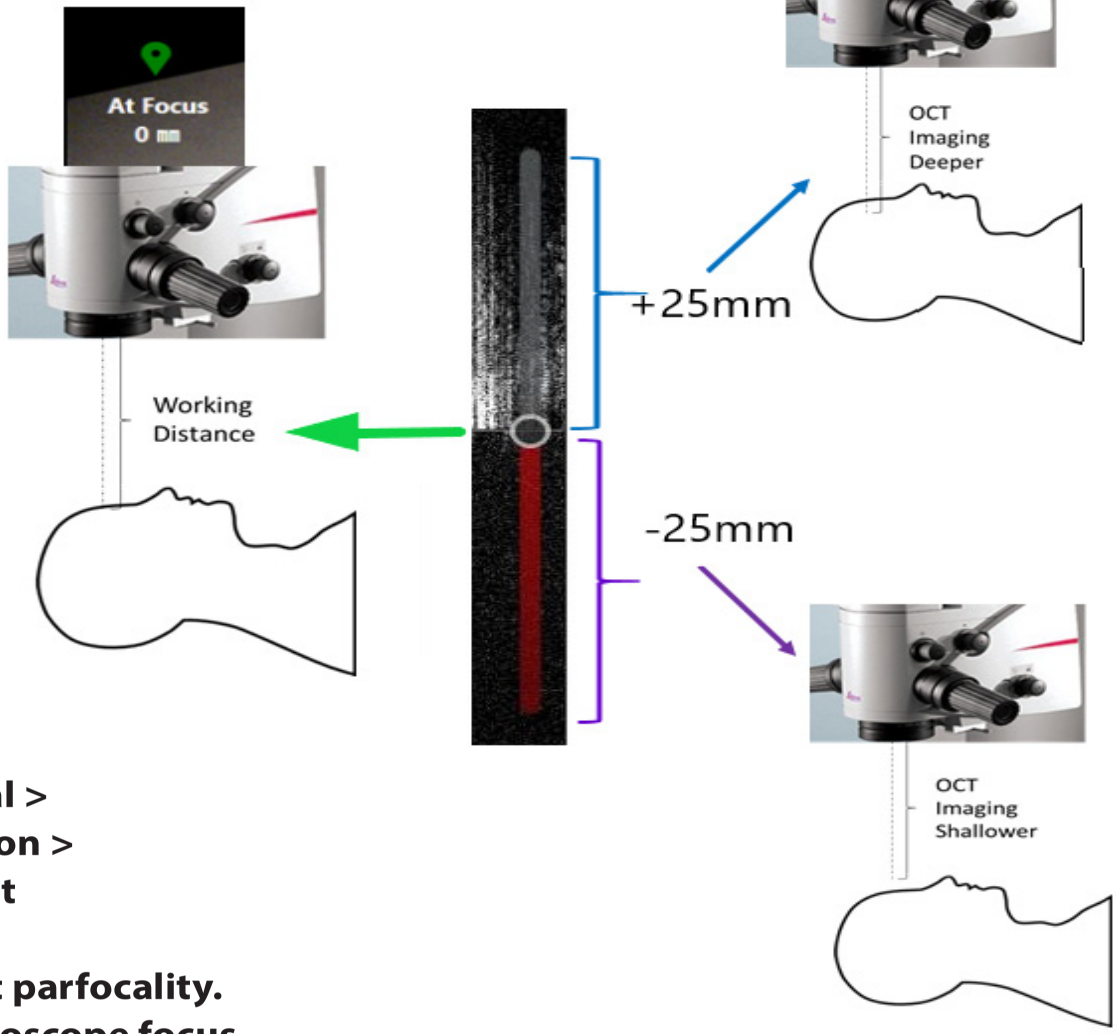


	Connection Description	EnFocus Connection	Proveo Connection
①	EnFocus-Proveo Communications cablle connects at EnFocus on left side underneath the cart tabletop to circle connector on Proveo door. Provides communication path between the devices. Newer Proveo have a serial connection labeled OCTon the connector board which should be used if available.		
②	EnFocus Microscope Camera Input cablle connects at EnFocus on right side underneath the cart tabletop to "DVI Out" connector on Proveo connector panel. Provides microscoep video to EnFocus.		
③	EnFocus Video Output for Proveo monitor allows OCT data to be shown on the Proveo monitor. An HDMI cable exits the bottom opening of the rear panel on the EnFocus cart and is connected to the DVI In 2 of the Proveo Monitor.		
④	EnFocus Video Output for DI C800 allows OCT data to be shown in the DI C800 when connected. A VGA cable exits the bottom opening of the rear panel on the EnFocus cart and is connected to XGA IN 1 on the Proveo Connector Panel.		

Best Workflow & Images When Operating Parfocal



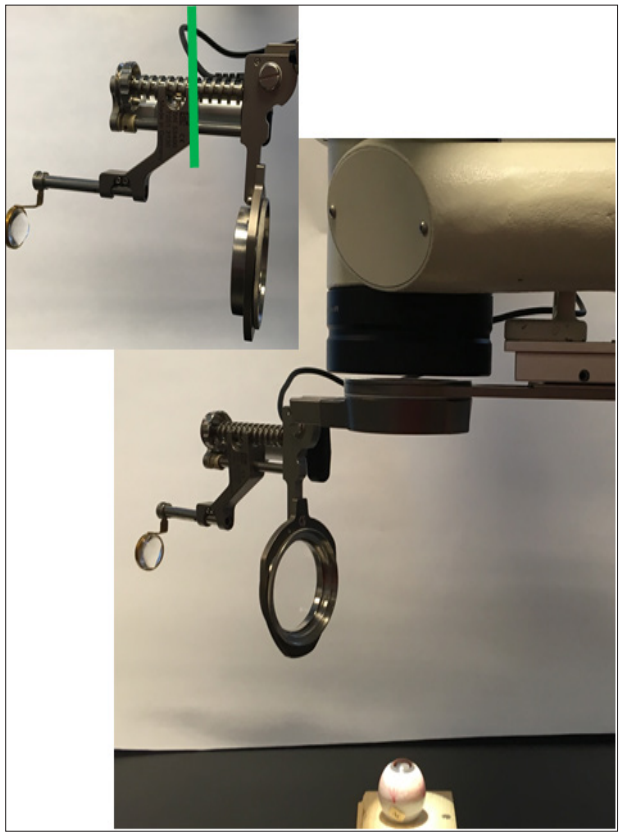




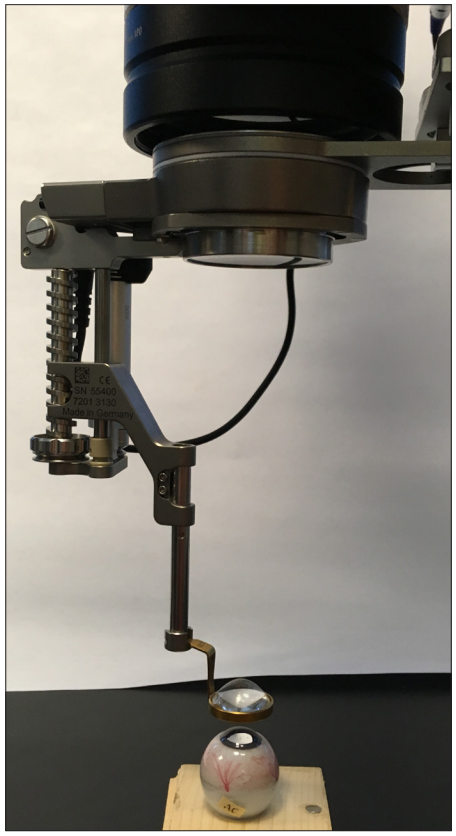
When Microscope Parfocal >
EnFocus at Central Z-position >
Best Images, Least Effort

Follow microscope procedure to set parfocality.
Watch OCT scan while adjusting microscope focus.
Stop when OCT scan is at top of window like picture.

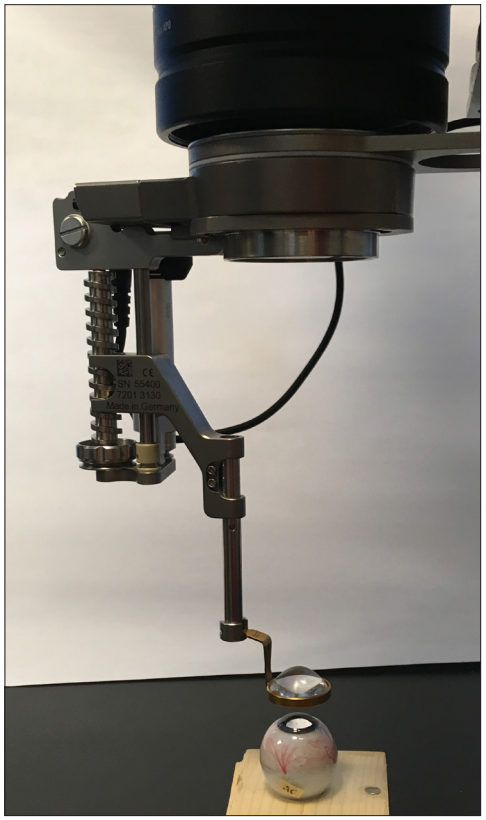
BIOM Workflow



- With BIOM flipped out verify microscope parfocal.
- Adjust microscope if necessary to be parfocal.
- Adjust BIOM relay lens so it is at 1/2 of its full range (marked in green).



- Flip BIOM into place.
- If BIOM is manual, change the procedure in InVivoVue to BIOM.

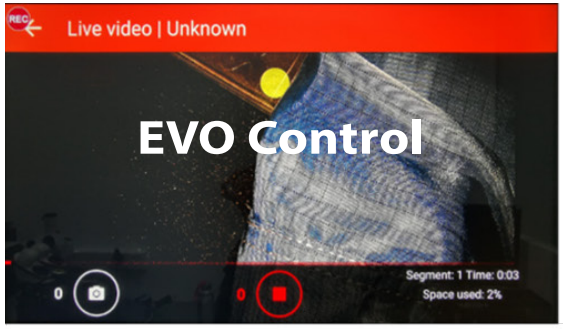


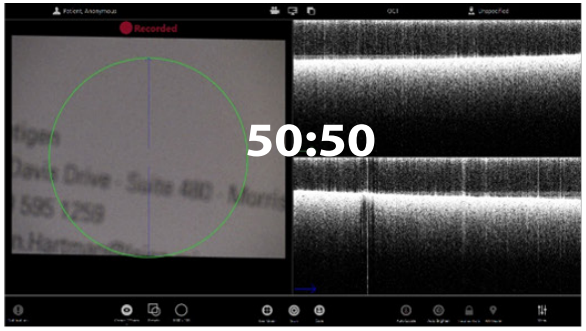
- Adjust the BIOM focus towards the eye to achieve good retinal image quality in the microscope.
  - Do not adjust microscope focus.
  - Use auto-locate to find the OCT image.
  - If OCT image not found adjust OCT focus to most negative value and retry.
- Largest field of view and best OCT images when bottom of relay lens 4-8mm from cornea.
- Microscope focus changes how much of the retina is viewable.

EnFocus for Microscope Integration - Sequence of Views

Docusystem	Normal & VR Mode	OCT Mode *Microscope replaced with Engineering for elevated user in OCT mode.	IOL Mode
EVO	Display: Microsccope | 50:50 Record: Same as Display	Display: 50:50 | Quad View | Microscope* Record: Same as Display	Not Applicable
Truevision	Display: IOL Main | 50:50 Record: Same as Display	Display: 50:50 | Quad View | Microscope* Record: 50:50 always	Display: IOL Main | 50:50 Record: Same as Display
HDR	Display: Microsccope | 50:50 Record: Same as Display	Display: 50:50 | Quad View | Microscope* Record: Same as Display	Not Applicable

Evo Control Icon changes to Evo control view





Change View Icon changes between views in the sequence