

From Eye to Insight

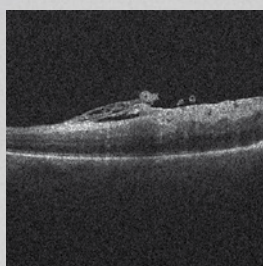
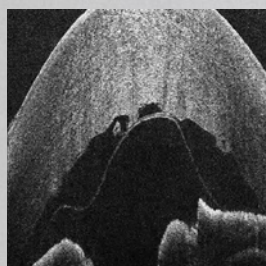
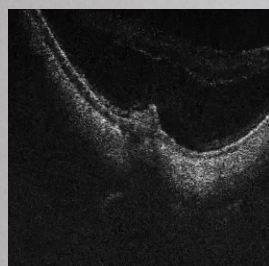
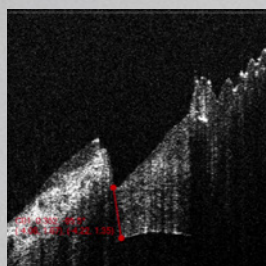
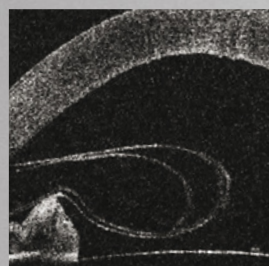
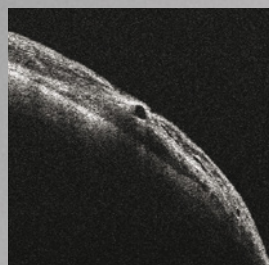
Leica
MICROSYSTEMS



OCT system for anterior & posterior segment surgeries

FOCUS ON PERFECTION

EnFocus intraoperative optical
coherence tomography (OCT)



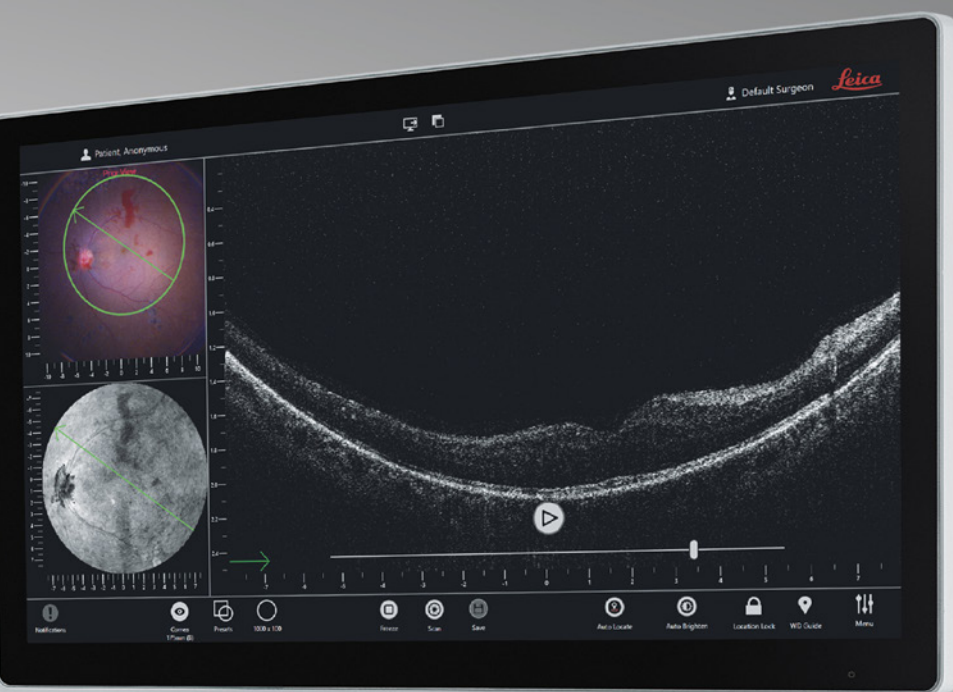
Now available for
Proveo 8x



FOCUS ON PERFECTION

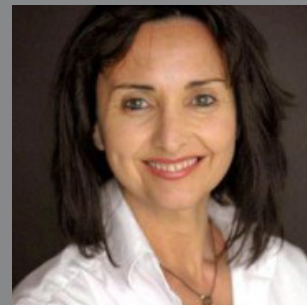
Apply your skills with even greater confidence during eye surgeries with EnFocus intraoperative OCT built into the Proveo 8 ophthalmic microscope and the Proveo 8x platform.

Intraoperative OCT allows you to see what lies underneath the surface, giving you additional information for a complete understanding of how subsurface tissue reacts to your surgical maneuvers in real-time. At any step during surgery you can simply enhance your microscope view and add intraoperative OCT imaging with just a few taps. You get an immediate visual confirmation on ocular tissue behaviour so you can focus on achieving an optimal surgical outcome. The optimized EnFocus design lets you work in a more comfortable and relaxed posture at the microscope.



"Having confirmation at every step during surgery is a huge advantage and helps enormously in surgical decision-making and diagnosis. In my experience intraoperative OCT makes the difference between compromise and perfection."

Dr. Barbara Parolini, Eyecare Clinic Brescia, Italy.



Greater insight

Supplement your microscope view with bright, sharp imaging of previously hidden subsurface details to better understand ocular pathology. EnFocus OCT imaging provides greater insights with additional information for your anterior and posterior segment procedures, you'll see more at once.

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Immediate confirmation

Confirm in real-time how ocular tissue is reacting intraoperatively to your surgical maneuvers. Adjust your plan as needed thanks to an immediate visual confirmation of subsurface tissue reaction, for more confidence in the surgical outcome.

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Maximum freedom

EnFocus OCT is fully integrated into your Proveo 8 or Proveo 8x, as well as into your workflow. Switch views and record effortlessly with the assurance that you will always have consistent, optimized OCT imaging available when you need it. The optimized design supports ergonomic work.

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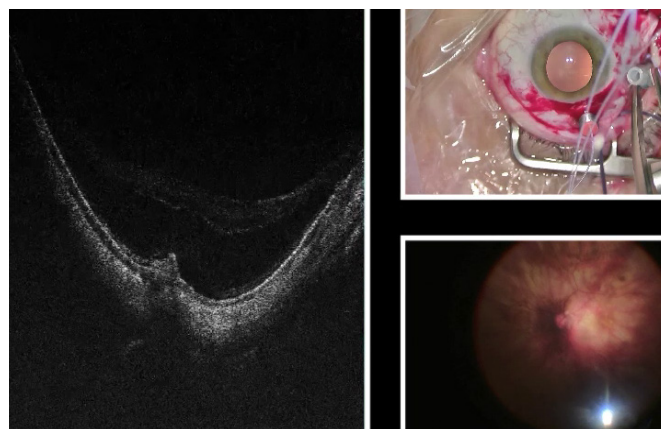


GREATER INSIGHT

Supplement your microscope view with bright, sharp imaging of previously hidden subsurface tissue details. EnFocus intraoperative OCT imaging provides additional information so you can get greater insights into ocular pathology during surgery.

See hidden details with bright, sharp OCT imaging

- > Clearly differentiate between artifacts and tissue due to the unique spectrometer technology including dispersion compensation software and a highly sensitive detector that captures more signal
- > See fine details with an axial resolution of 4 μm in tissue due to the patented Leica spectrometer design
- > Capture comprehensive area scans with high lateral resolution, due to a high scan density of up to 1000 A-scans x 1000 B-scans
- > See the full surgical field from the center to the periphery at all magnification levels thanks to a 20 x 20 mm lateral field of view
- > Obtain a complete image of the anterior chamber thanks to the increased scan depth of 5 mm in total*



Retinal detachment, image courtesy Dr. Barbara Parolini, Eyecare Clinic Brescia, Italy.

Your benefits in retina surgery

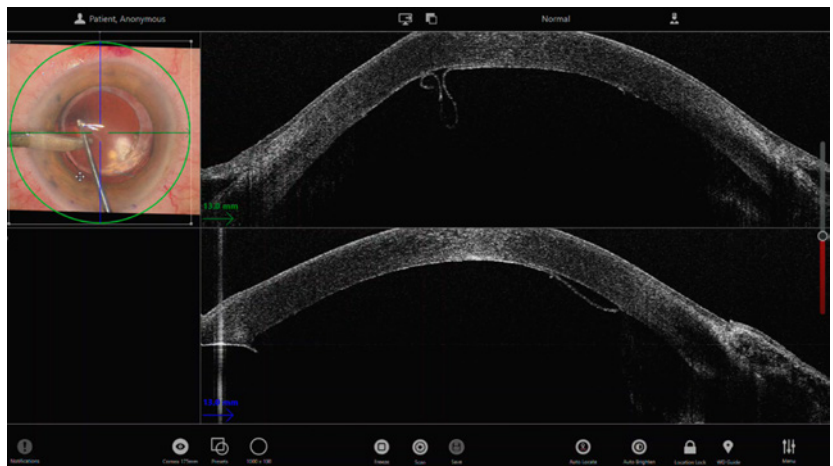
Assess the level of tension in a membrane peel to avoid potential tears and protect the integrity of underlying tissue. A high-resolution view aids examination of retinal morphology for residual membranes or complications such as a macular hole or sub-retinal edema. Built-in dynamic scan control via footswitch further supports your visualization by aligning the scan angle to the membrane tissue.



Microscope view of the retina (left) supplemented with EnFocus OCT (right) to visualize membrane layers during membrane peeling. Image courtesy of Dr. Massimo D'Atri, Cagliari, Italy.

Your benefits in cornea surgery

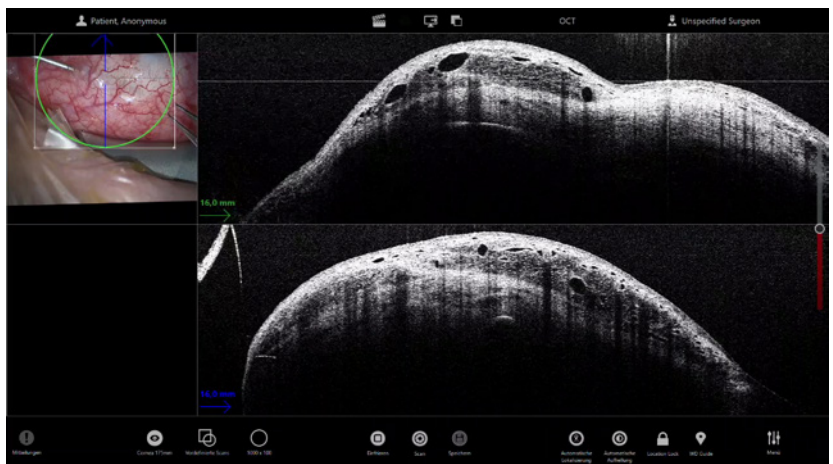
Easily view the whole cornea and the anterior chamber with a scan range of 20 mm x 20 mm. In advanced lamellar corneal surgeries such as DMEK and DSAEK, this helps you to confirm the correct orientation and adhesion of donor tissue.



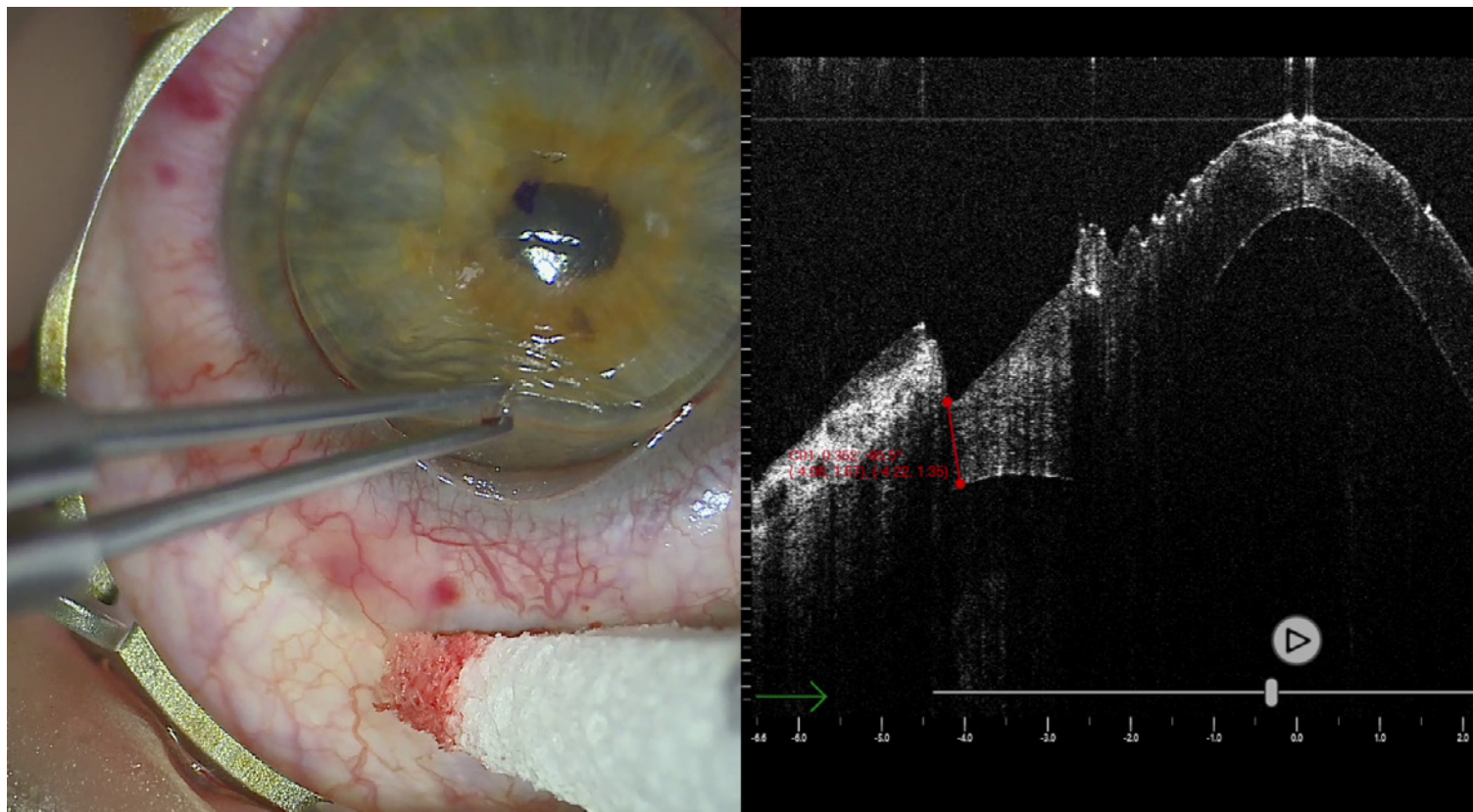
Thin Manual Descemet Stripping Endothelial Keratoplasty (TM-DSEK): The intraoperative OCT clearly shows the Descemet membrane peeling and the endothelium. Image courtesy of Mr. David Anderson, MB BS FRCOphth PhD FEBO, University Hospital Southampton NHS FT, United Kingdom.

Your benefits in glaucoma surgery

Visualize the position of a XEN gel stent to support accurate placement, with OCT scans of up to 20 mm wide. EnFocus OCT also supports visualization of shunt vessel placement and assessment of how much the tube should be tied off to control intraocular pressure.



Intraoperative OCT picture showing 5-Fluorouracil (5-FU) drug injection after trabeculectomy. Images courtesy of Prof. Gerd Geerling, MD, PhD, FEBO, Department of Ophthalmology, University Hospital Düsseldorf, Germany.



Measurement during corneal lamellar transplant surgery, courtesy of Dr. Enrico Bertelli, head of the ophthalmic department at Bolzano Hospital, Italy.

IMMEDIATE CONFIRMATION

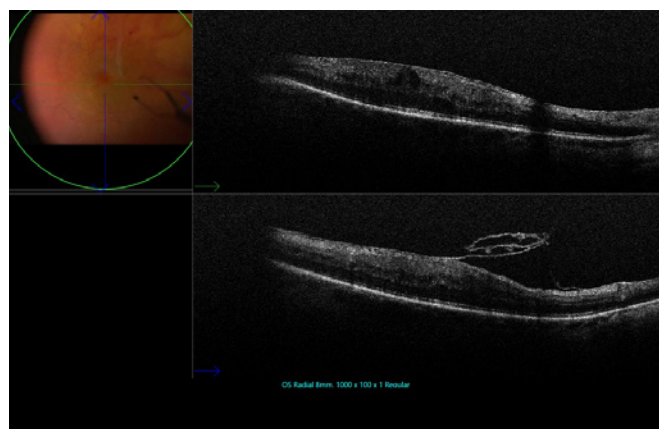
Confirm in real-time how ocular tissue is reacting intraoperatively to your surgical maneuvers. Immediately adjust your plan if needed for greater confidence in the surgical outcome.

During retina, cornea and glaucoma procedures, there is typically a point at which surgeons ask themselves whether they are really done or not? While the microscopic view delivers a precise picture of the operating field, subsurface tissue details are not easily visible.

Questions can arise, like:

- > Is there residual sub-retinal fluid?
- > Is the glaucoma drainage device in the correct position?
- > Is the corneal graft well opposed to the host cornea?

The EnFocus intraoperative OCT system built into the Proveo 8 and Proveo 8x microscopes can help surgeons overcome these uncertainties by providing immediate intraoperative confirmation.



OCT-guided 25G vitrectomy with Proveo 8 and EnFocus OCT, courtesy of Dr. med. Jean-Antoine Pourmaras, RétinElysée, Lausanne, Switzerland.

Surgical view

In the quad view you can see the white light microscope image from the microscope's video camera.

Enface view

The OCT B-scan composition provides a detailed anatomical surface view. Move the vertical line through the picture to review points of interest.



OCT B-scan view

The fast OCT scanner with a 30 Hz refresh rate delivers real-time subsurface details. Playback through acquired OCT scans frame by frame or in video mode for a careful review benefit from comprehensive scans of up to 1000 B-scans to not miss out on an important detail.

Observe real-time tissue changes and react instantly

- > Real-time display of 30 fps provides immediate feedback at each step e.g. to verify adherence of donor tissue in DMEK or DSAEK surgery
- > If OCT reveals a complication which wasn't visible via the microscope view, for example due to bleeding, you can instantly adapt your surgical plan
- > For additional confirmation you can easily review or playback through the acquired scans frame by frame or in playback video mode
- > On-screen live measurements provide additional confirmation e.g. cornea thickness and needle depth during DALK surgeries

Simply activate via the wireless footswitch

Proveo 8 and Proveo 8x with EnFocus OCT are fully interconnected, you can pre-program the footswitch to activate all EnFocus imaging and recording functions intraoperatively.

- > Switch from microscope to OCT view easily
- > Activate Autolocate to find for example the retina
- > Perform Image Optimization to improve image quality and contrast
- > Move the scan position, change the scan rotation and size via the footswitch joystick

"Measurements with EnFocus OCT during deep anterior lamellar Keratoplasty for Keratoconus help me to quantify exactly how deep I cut into the stroma and I can judge if the incision is deep enough."

Enrico Bertelli MD,
Head of the Ophthalmic Department,
Bolzano Hospital, Italy

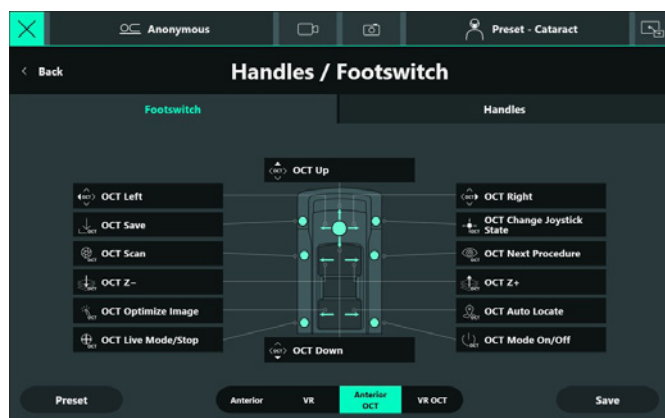




MAXIMUM FREEDOM

EnFocus intraoperative OCT is built into your Proveo 8 or Proveo 8x and into your workflow. Switch view and record at the touch of a button with the confidence you will always have an optimal image.

Our latest generation of EnFocus OCT was developed in collaboration with experienced ophthalmic surgeons for optimal workflow integration. No need to invest extra time and effort, or rely on a technician to activate OCT or to ensure you have the perfect image positioning and quality. Automatic image optimization and auto-locate functions do the job for you, with a single tap. You are free to concentrate on your procedure.



User interface of the Proveo 8x, showing footswitch and handle programming. Easily operated via a 27-inch 2D 4K touch screen monitor or 10-inch control panel on the tower.

Work smoothly, comfortably, and independently

- > For an uninterrupted workflow, your personal settings and modes can be pre-programmed into the footswitch and handle control, according to surgery type and workflow step
- > Preferences such as scan sizes, scan pattern, and scan density are fully customizable to your requirements
- > Auto-locate, auto-brighten, and auto-sharpness functions enable you to further optimize the image if needed, with just one tap of footswitch, handle or screen
- > Location Lock in z-direction keeps the OCT image centered automatically, no need for manual intervention
- > Work in a more relaxed posture thanks to the optimized EnFocus OCT scan head design with reduced stack height*

Work comfortably

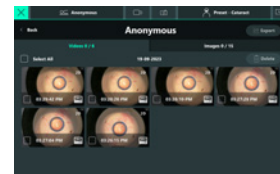
The optimized OCT scan head fits seamlessly into the optics carrier and allows for a comfortable posture.

Switch views with only one tap

Toggle between microscope and intraoperative OCT views via footswitch, handle, or touchscreen control. Review scans and recordings just as easily.

Intuitive touch screen user interface

Display your live microscope and intraoperative OCT images on the 27" 2D 4K microscope monitor, and select, modify, and load your preferences through the intuitive touch screen user interface.



Built-in imaging & documentation system

Record videos and images in 2D or 3D 4K quality, utilizing the high compression 4 TB storage space. Quickly store images and export via USB, and benefit from optimized data processing and connectivity for PACS and DICOM.

Multiply your visualization possibilities with the Proveo 8x 3D digital ophthalmic microscope and the MyVeo all-in-one surgical visualization headset.



A single view right in front of the eyes

MyVeo provides a live 3D view directly in front of your eyes. It frees you from oculars or monitors. Stay focused with a single-integrated view with seamless data integration from the phaco system and intraoperative OCT.

MyVeo benefits for you and your team

- > Work comfortably in an upright posture.
- > Share the same live 3D view as the main surgeon.
- > Enhance the teaching and learning experience.
- > Use up to three headsets simultaneously.

TECHNICAL SPECIFICATIONS

Proveo 8 ophthalmic microscope

CONSTRUCTION

Floor stand	Four 360° rotating castors (Ø150 mm), parking brake
Materials	- Conforming with RoHS - Coated with antimicrobial paint
Load	Floor stand max. 8.0 kg from microscope dovetail ring interface
Weight	Floor stand approx. 380 kg without load, without built-in EnFocus OCT; and 390 kg with built-in EnFocus OCT

TECHNICAL DATA

Power connection	- 600 VA 50/60 Hz - 100–240 V~ 50/60 Hz - 2 × T10 AH 250 V
Protection class	Class 1

OPTICS AND ILLUMINATION

FusionOptics	For increased depth of field and high resolution for main surgeon and assistant
OptiChrome optics	For high contrast, high resolution, natural colors without chromatic aberrations
Magnification	6:1 zoom, motorized
Total magnification	4.1× to 24.5× with 10× eyepiece 5.1× to 30.7× with 12.5× eyepiece
Focus range	75 mm
Objective / working distance	WD 175 mm/f = 200 mm WD 200 mm/f = 225 mm WD: Working distance, f: Focal length
Field of view	51.4–8.6 mm Ø with 10× eyepiece
Eyepieces	Wide-field eyepieces for people wearing glasses 8.3×, 10× and 12.5× dioptic adjustment, ± 5 diopter settings, adjustable eyecup
Direct illumination with 2 LED lamps	Main light - Integrated LED illumination system for intensive uniform illumination of the field of view - Continuously adjustable brightness with halogen-like color temperature CoAx 4 coaxial illumination - Illumination unit for generating a clear and stable Red Reflex, decreasing stray light through the sclera and increasing the image contrast
Adjustable CoAx 4	Diameter of coaxial illumination is adjustable between 4 and 23 mm via footswitch
Keratoscope	External adapter available for integrated Keratoscope illumination
Fine focus	Available for assistant and integrated camera or external 1/3 camera with C-mount interface

Fundus viewing systems	Compatible with BIOM 5, BIOM Ready, RUV800, and flat contact lens
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UPGRADEABILITY

OpenArchitecture	Prepared for integration of video camera systems, digital recording and imaging systems such as EnFocus OCT and monitors
Connectors	- Four built-in video connectors for transfer of video and control data (DIV Out, DIV In, C-video Out, HD-SDI Out) - Internal power supply 12 VDC, 19 VDC, 24 VDC and AC terminals
2D HD Video	Optional fully integrated 2D HD video and recording

MANEUVERABILITY

Optics	- 380° rotation - from -15° to + 105° motorized inclination tilt
XY speed	Zoom linked XY speed
XY range	62 × 62 mm
Balancing	Adjustable gas spring via balancing knob
Brakes	Floor stand with 4 electromagnetic brakes
Monitor arm	860 mm flexible arm with 4 axis for rotation and inclination, max. weight 15 kg for 27" monitors

CONTROL

Control unit	- User-friendly touch screen panel - Individually program up to 30 surgeon profiles for control of motor functions and light intensity - Built-in electronic auto-diagnosis and user support - Software independent hard keys and indicator for illumination - Data shown by means of LCD
Control elements	- Rotary handles - 14-function and 12-function wireless footswitch with optional back-up cable
IR sensor	Remote control of the HDR recorder
Indicators	- LED for video record status - Surgeon information panel for setting status

Proveo 8x 3D digital ophthalmic microscope

MODULAR CONFIGURATION OPTIONS

Proveo 8x 2D 4K IVC (Binocular-based configuration)	Optics carrier with integrated 2D 4K camera, integrated inverters, and binocular tubes for the main surgeon and the side assistant. Upgradeable to 3D.
Proveo 8x 3D 4K IVC (3D configuration)	Optics carrier with integrated 3D 4K camera, integrated inverters, and main surgeon binoculars for heads-up surgery and hybrid use. Compatible with MyVeo. Stereo attachment for second observer.

MONITORS FOR 3D-SURGERY AND OBSERVATION

32" 3D 4K cart-mounted monitor	Heads-up display for superior and temporal working positions - Flexarm allows for convenient positioning even over the OR bed - Viewing distance: 690-1380 mm - Models: Eizo LCD or Sony LCD
55" 3D 4K cart-mounted monitor	Heads-up display for superior and temporal working positions - Viewing distance: 1000-2000 mm - Models: FSN OLED or Sony LCD

MICROSCOPE FLOOR STAND

Power connection	- 1300 VA - 100–240 V~ 50/60 Hz
Protection class	Class 1
Material	- Use of RoHS conform materials - The Proveo 8x microscope is coated with a white paint which provides an antibacterial effect on surfaces
Base	770 × 770 mm with four 360° rotating castors with a diameter of 150 mm each, one parking brake
Weight	Approx. 380 kg without load
Load of optics carrier	Max. 8.0 kg from microscope dovetail ring interface
Max. height	1950 mm in parking position
Integrated imaging & documentation system	Built-in 2D/3D Leica Recording System: - Record in 2D or 3D quality utilizing a high-compression 4 TB storage space - Quickly store images and export via USB - Optimized data processing and connectivity for PACS and DICOM
Cybersecurity	Built-in security to protect patient data
RemoteCare	Designed with industry-leading security standards, RemoteCare detects system anomalies and alerts our Service team to proactively solve problems before they become critical.

Compatibility	- EnFocus OCT-system by Leica - EVA NEXUS phaco system of DORC (a Zeiss company) - Cassini Guidance System for toric IOL placement by Cassini Technologies
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OPTICS AND ILLUMINATION

OptiChrome optics	For high contrast, high resolution, natural colors without chromatic aberrations
Magnification	6:1 zoom, motorized magnification factor
Total magnification	4.1× to 24.5× with 10× eyepiece 5.1× to 30.7× with 12.5× eyepiece
Fine focus	Available for assistant and 2D 4K camera
Focus range	75 mm
Objective / working distance	OptiChrome WD 175 mm/f = 200 mm WD 200 mm/f = 225 mm WD 225 mm/f = 250 mm WD: Working distance f: Focal length
Eyepieces	Wide-field eyepieces for persons wearing glasses 8.3×, 10× and 12.5× dioptric adjustment, ±5 diopter settings, adjustable eyecup
Illumination	Main light: - Integrated LED illumination system for intensive, uniform illumination of the field of view CoAx 4 coaxial illumination: - Integrated LED illumination unit for generating a clear and stable Red Reflex, decreasing stray light through the sclera and increasing the image contrast - Continuously adjustable brightness with halogen-like color temperature
Adjustable Iris	Diameter of CoAx 4 coaxial illumination can be adjusted from 4 to 23 mm
Keratoscope	Adapter available
Integrated laser filter for camera	For laser filters from 532 nm to 810 nm. Integrated in Proveo 8x 3D; optional for Proveo 8x 2D
Fixation light	Allows patient to focus on a target in order to keep the eye stable during cataract surgery
Fundus Viewing System	Compatible with BIOM® 5, BIOM® Ready, RUV800, and flat contact lens

ENFOCUS OCT OPTICAL PERFORMANCE

Axial resolution in tissue	≤ 4.0 µm
Lateral resolution	< 31 µm for 175 mm objective < 35.4 µm for 200 mm objective
Imaging depth in tissue	5 mm +/- 0.1 mm
Lateral field of view (scan range)	up to 20 mm x 20 mm across entire range of microscope magnification
Image display resolution	1920 x 1080 pixels
Image acquisition speed	≥ 32,000 A-scans/s, 30Hz B-scan display refresh rate
OCT optical power	≤ 750 µW
Imaging center wave-length	860 nm ±5 nm
175 mm objective lens working distance	178 mm
200 mm objective lens working distance	203 mm
OCT compatible fundus viewing systems	Compatible with BIOM 5, BIOM Ready, and flat contact lens

ENFOCUS OCT PHYSICAL FEATURES

Workstation Operating System	64-bit, Windows 10
Removable scan head	Yes
Dimensions: EnFocus 2300 Integrated OCT System	5.43 cm (h) x 11 cm (w) x 24.53 cm (l)
Scan head weight	1.3 kg (2.9 lbs)

Any description of EnFocus mentioned in this document refers to the medical device EnFocus 2300 Integrated OCT System



Proveo 8 is a class I surgical microscope;
MyVeo is a class I medical device
accessory



Proveo 8x and EnFocus 2300 Integrated OCT System
are class IIa medical devices.



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