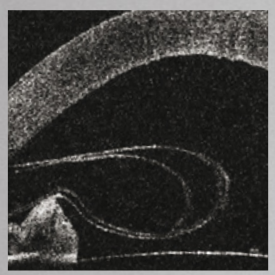
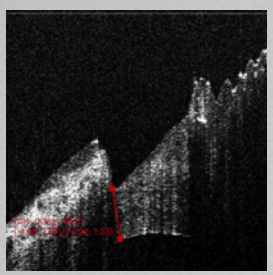
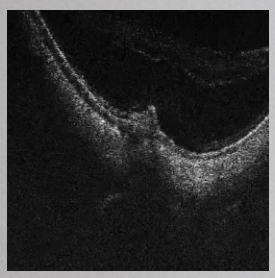
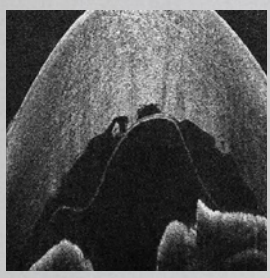
From Eye to Insight

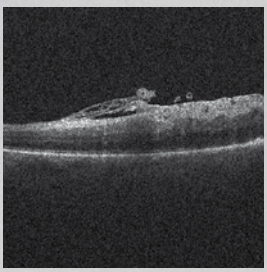
Leica
MICROSYSTEMS











OCT system for anterior & posterior segment surgeries

FOCUS ON PERFECTION

EnFocus intraoperative optical coherence tomography (OCT)

Optimized Design for Enhanced Performance*

*Compared to the previous generation of EnFocus intraoperative OCT for Proveo 8

FOCUS ON PERFECTION

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

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.

Page 4-5

Immediate confirmation
Confirm in real-time how occular 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.

Page 6-7

Maximum freedom
EnFocus OCT is fully integrated into your Proveo 8 and 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.

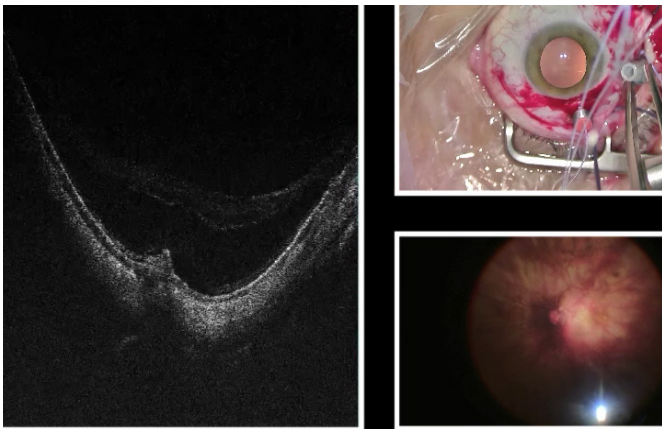
Page 8-9

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.

*Compared to the previous generation of EnFocus intraoperative OCT for Proveo 8

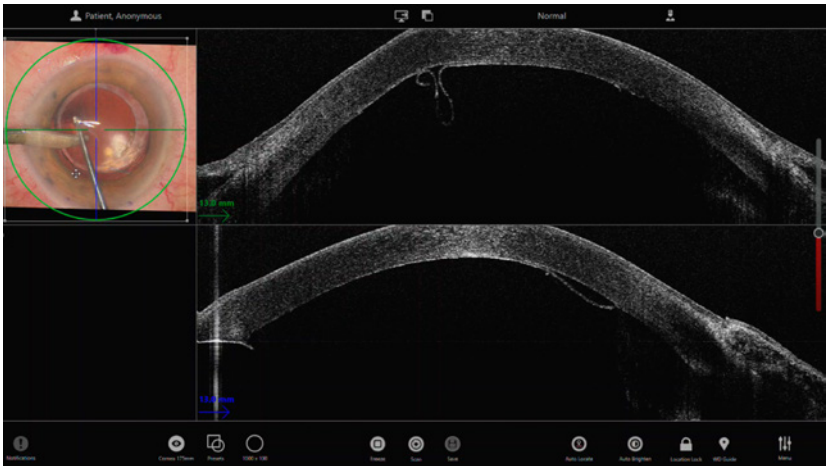
Your benefits in retina surgery

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

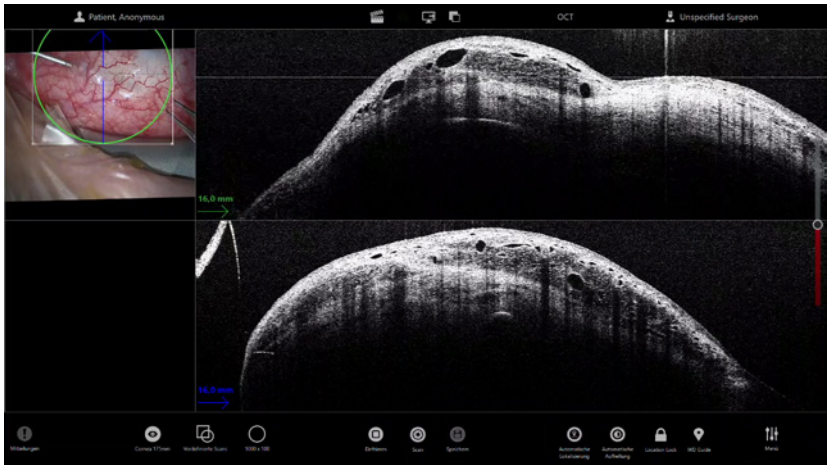
Easily view the whole cornea and the anterior chamber with a scan range of 20 mm x 20 mm. In advanced lamellar corneal surgeries such as DMEK and DSAEK, this helps you to confirm the correct orientation and adhesion of donor tissue.



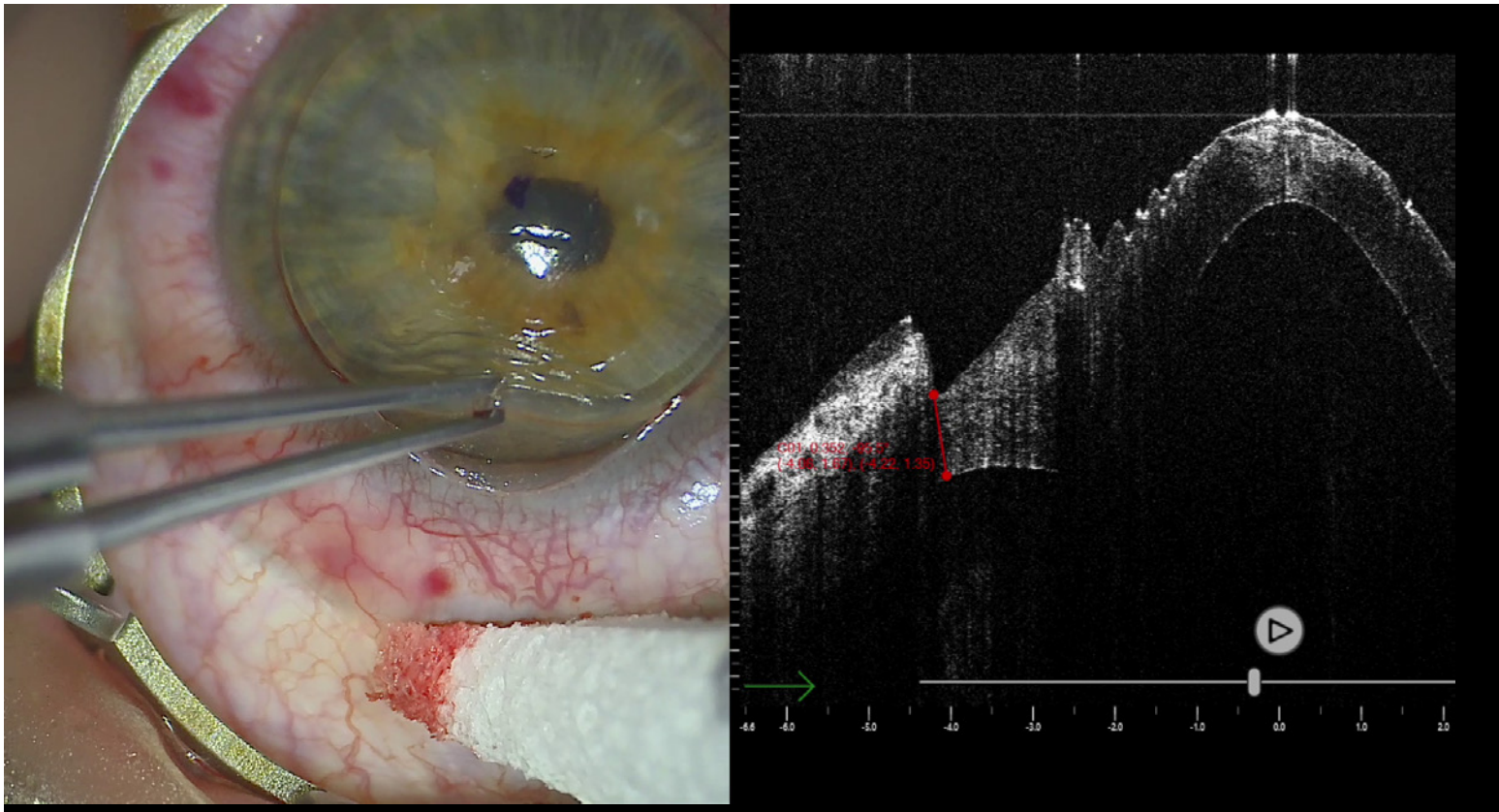
Thin Manual Descemet Stripping Endothelial Keratoplasty (TM-DSEK): The intraoperative OCT clearly shows the Descemet membrane peeling and the endothelium. Image courtesy of Mr. David Anderson, MB BS FRCOphth PhD FEBO, University Hospital Southampton NHS FT, United Kingdom.

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

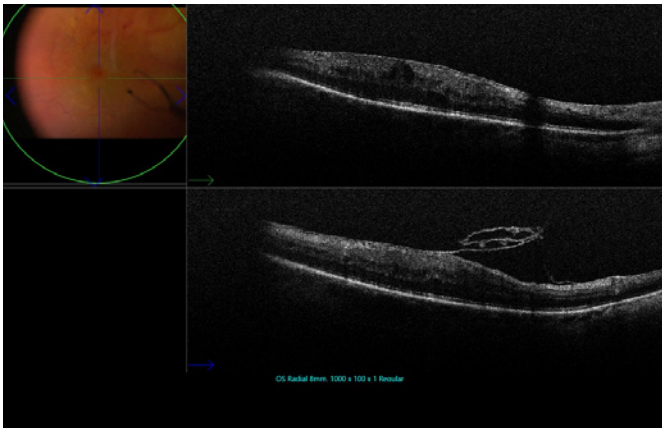
Confirm in real-time how ocular tissue is reacting intraoperatively to your surgical maneuvers. Immediately adjust your plan if needed for greater confidence in the surgical outcome.

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 microscope, 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 Pournaras, 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

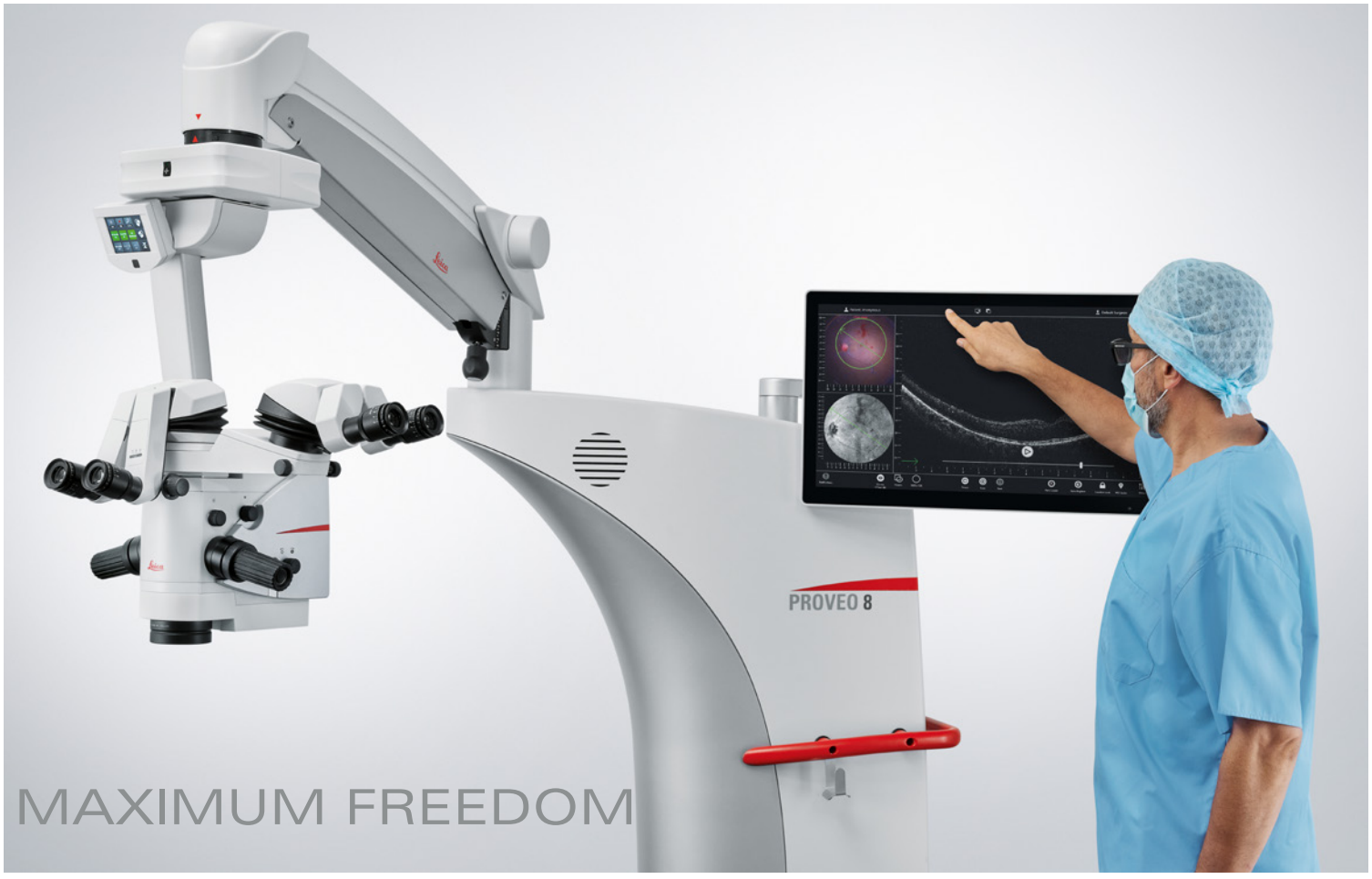
Simply activate via the wireless footswitch

As the Proveo 8 with EnFocus OCT is 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 footswitch's joystick

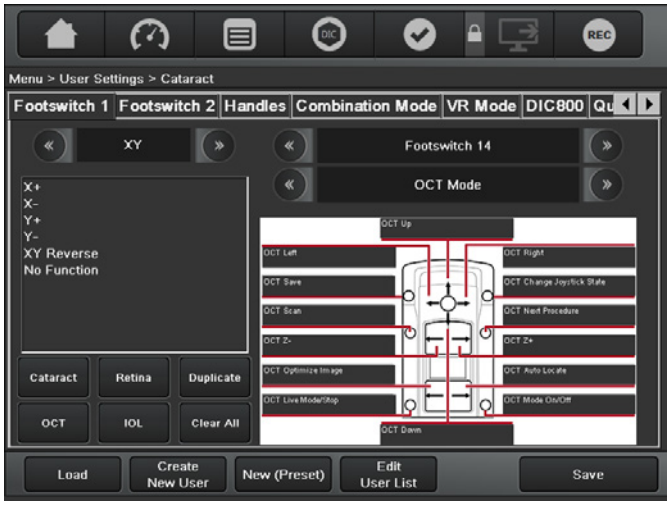
"Measurements with EnFocus OCT during deep anterior lamellar Keratoplasty for Keratoconus help me to quantify exactly how deep I cut into the stroma and I can judge if the incision is deep enough."

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



EnFocus intraoperative OCT is built into your Proveo 8 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.



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*

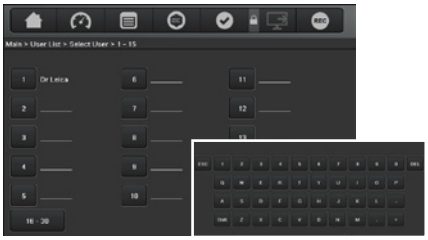
*Compared to the previous generation of EnFocus intraoperative OCT for Proveo 8

Work comfortably

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

Get a bigger picture

Display your microscope and intraoperative OCT-image on the 27" touch-screen monitor. For even larger screen projections for you and your team, four video outputs are available.



Start surgery quickly

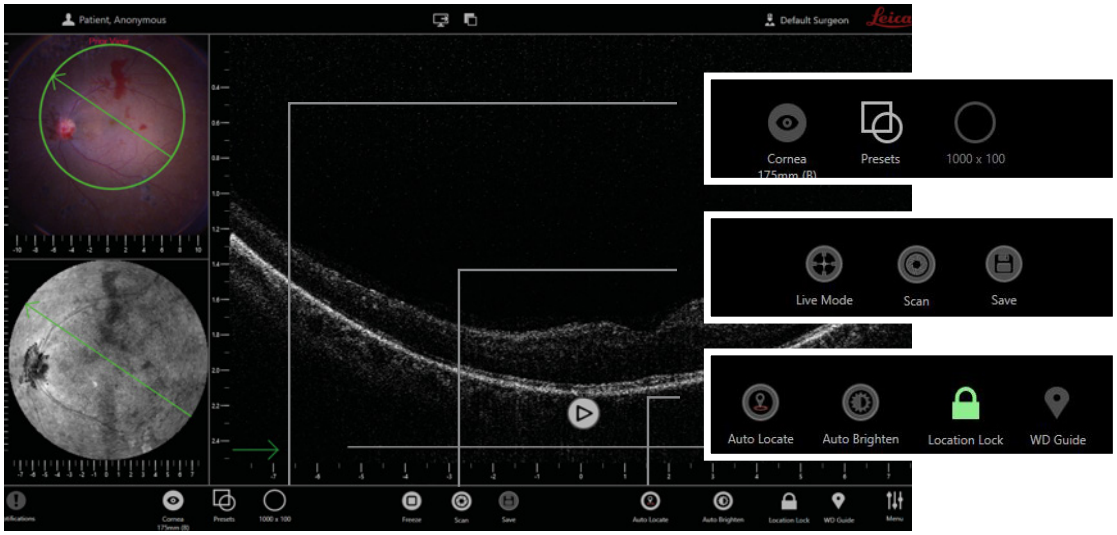
Select, modify, and load surgeon preferences before surgery using the intuitive touch screen user interface.

Switch your view with one tap

Switch easily between the microscope view an intraoperative OCT view at any point yourself without interrupting surgery. Whether you use the footswitch, handle or the touchscreen monitor it's just a single tap. Review acquired scans and recordings in the same way.

Record and document with ease

For optimized visualization and documentation use the Evolution4K recording system from Med X Change. Record images and video easily via footswitch, handles, and touchscreen.



Control via intuitive touch-screen

Multi-touch gesture control can be used by you or your assistant during surgery to adjust the scan position in the z-axis, the image size and rotation. You can also activate the recording and replay.

TECHNICAL SPECIFICATIONS PROVEO 8 WITH BUILT-IN ENFOCUS OCT

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 > Floor stand approx. 390 kg with built-in EnFocus OCT > CT42 telescope mount total approx. 200 kg

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 persons wearing glasses 8.3×, 10× and 12.5× dioptric 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

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, individually programmable touch-screen (up to 30 surgeons) for control of motor functions and light intensity > Menu selection based on unique software for user-specific configuration > 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

EnFocus OCT Optical Performance

Axial resolution in tissue	4.0 µm
Lateral resolution	31 µm for 175 mm objective 35 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	> 36000 scans/s, 30Hz B-scan display refresh rate
OCT optical power	< 750 µW
Imaging center wave-length	860 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
OCT scanner dimensions	5.43 cm (h) x 11 cm (w) x 24.53 cm (l)
Scan head weight	1.3 kg (2.9 lbs)

EnFocus OCT Configurations

Proveo 8 floor stand	Built-in EnFocus OCT system with optimized scan head design
Proveo 8 with CT42 ceiling mount	External EnFocus OCT system unit on cart, standard* scan head design

*The technical specifications differ slightly, please ask your local Leica representative for more detailed information.

Proveo 8 is a Class I surgical microscope

EnFocus OCT is a class IIa medical device

CE 0123

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