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OPTOPOL technology

User Manual

REVO HR

REVO FC 130

REVO FC

REVO nx 130

REVO nx

REVO 80

REVO 60

SOCT Copernicus REVO

SOCT Copernicus

SOCT Software Version 21.0.0

User Manual Rev. D

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REVISION CONTROL

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Service and Support

For Customer Service or Technical Support, contact your authorized OPTOPOL Technology representative or visit www.optopol.com for online support and resources.

Disclaimer

1. Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Proper procedures and techniques are the responsibility of the medical professional.
2. License and use of the REVO device is intended for trained operators in accordance with the license agreement – all other usage is prohibited – warranty restrictions and possible claim limitations apply.
3. If the device or its software is modified or serviced by someone other than an authorized service professional from OPTOPOL Technology or its official distribution network, the warranty will become void.

Conventions Used in this Manual

	**Warning** Indicates a hazardous situation which could result in severe injury or death.
	**Caution** Indicates hazards that may result in minor or moderate injury, equipment damage or impaired performance.
	**Important Note** Highlights important information about the operation of the REVO device.
	**Hint** Highlights important information to simplify operation of the REVO device.

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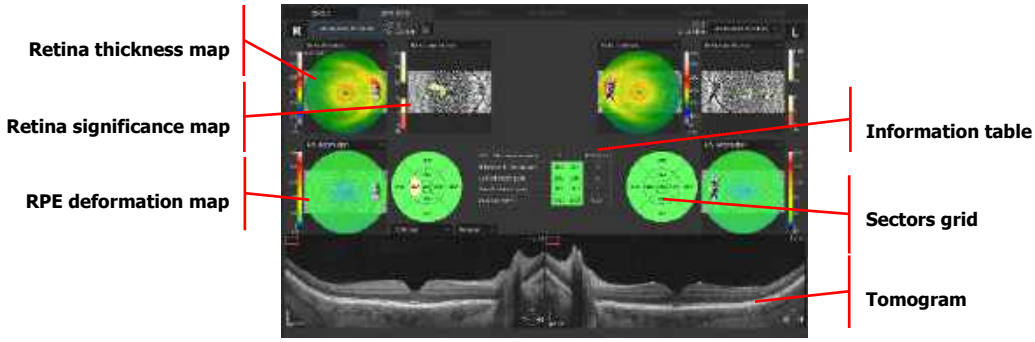

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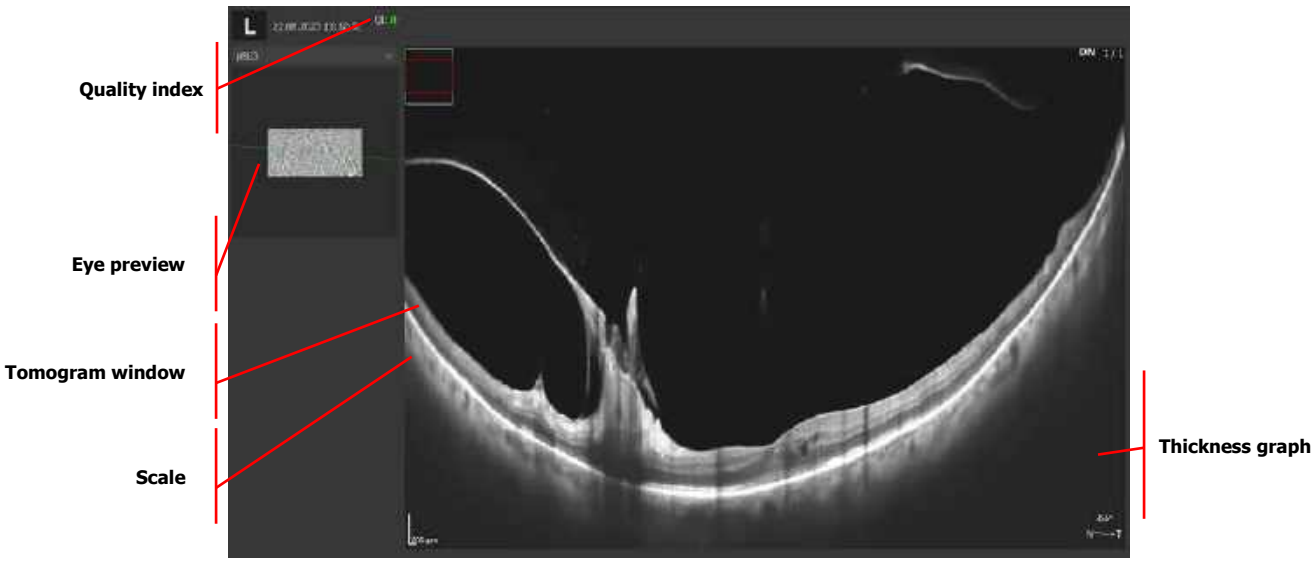

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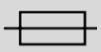
1.
Safety

1.1. Safety Symbols

	Caution
	Follow operating instructions
	Indicates a fuse is present near this symbol
	Power On and Off
	Type B Applied Parts
	Electrical and electronic Equipment waste. Do not discard the product with normal household waste.
	Sign of conformity with the general safety and performance requirements: The Medical Device Regulation 2017/745 (0197 - Notified Body Number)
	Class 1 Laser Product (IEC 60825-1:2014)
	Warning: Electricity

	General Warning Sign
	Warning: Laser Radiation

1.2. Product Label

A sample label from the REVO HR [REF 194-130] is presented below:

Figure 1.
A Sample Label from the REVO HR

A sample label from the REVO FC [REF 190-80] and the REVO FC 130 [REF 193-30], located on the rear of the device, is presented below:

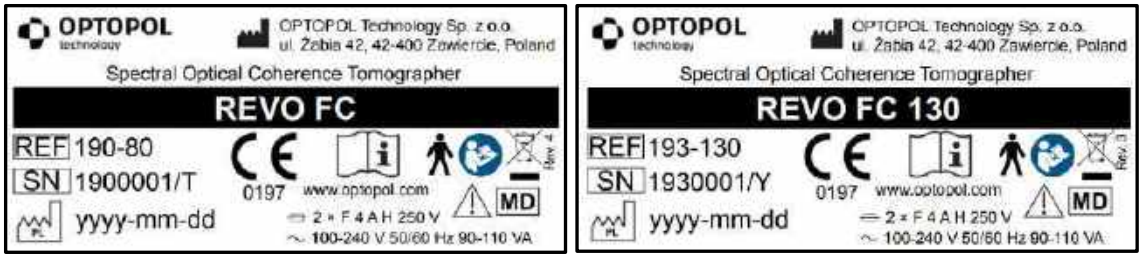


Figure 2.
A Sample Label from the REVO FC and the REVO FC 130

A sample label from the REVO nx [REF 192-110] and the REVO nx 130 [REF 192-130], located on the rear of the device, is presented below:

Figure 3.
A Sample Label from the REVO nx and the REVO nx 130

A sample label from the SOCT Copernicus REVO and SOCT Copernicus [REF 191-27], located on the rear of the device, is presented below:

Figure 4.
A Sample Label from the SOCT Copernicus REVO and the SOCT Copernicus

A sample label from the REVO 60 [REF 191-60] and REVO 80 [REF 191-80], located on the rear of the device, is presented below:

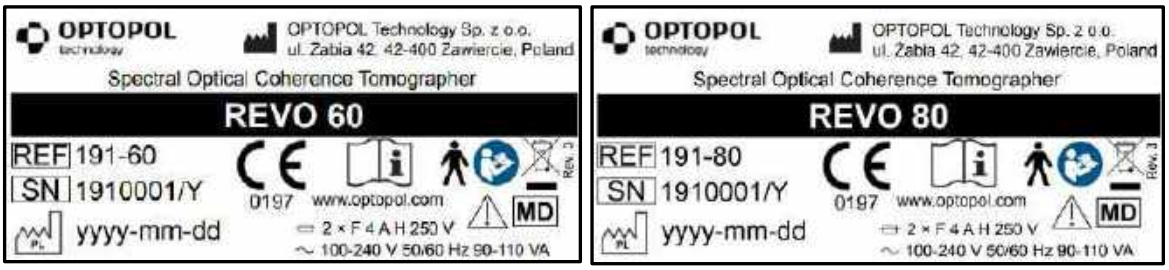
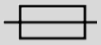


Figure 5.
A Sample Label from the REVO 60 and the REVO 80

1.2.1. Marks and Indications

	Manufacturer
	Date and country of manufacture (PL: Poland)
	Serial Number in eight digits and coded year of production
	Sign of conformity with the general safety and performance requirements: The Medical Device Regulation 2017/745 (0197 - Notified Body Number)
	Type B Applied Parts

	Follow operating instructions
	Caution
	Indicates a fuse is present near this symbol
	Alternating current
	Electrical and Electronic Equipment waste. Do not discard the product with normal household waste.
	Catalog Number
	Labeling: Prescription Use Only (USA)
	Medical Device: Indicates that the device is a medical device as defined in the MDR 2017/745.
	Unique device identification (UDI) - Unique numeric or alphanumeric code related to a medical device. It allows for a clear and unambiguous identification of specific devices on the market and facilitates their traceability.
	Distributor
	Importer

1.3. Safety Standards

CAUTION: Before using the device, the operator should be trained to operate the system efficiently and safely.

NOTE: The REVO system can only be connected to a power supply socket equipped with a properly connected grounding pin.

The system complies with all requirements of the Medical Device Regulation 2017/745 (MDR).

The REVO system has Type B applied parts (chin rest support and forehead support) and is classified as a Class I device in terms of protection against electric shock.

The REVO system can be a part of a larger Medical System, which consists of many other medical and non-medical devices. The Medical System in general and all its components must fulfill the requirements of the IEC 60601-1 standard.

To comply with the IEC 60601-1 standard, all non-medical devices must be connected to the isolating transformer. By connecting the devices to the isolating transformer, the leakage current is reduced to the level which is in line with the IEC standard. The isolating transformer supplies the power for non-medical devices connected to an electrical outlet and fulfills the requirements of the IEC 60601-1 standard for a medical electrical system. The isolating transformer can be installed in the patient environment in accordance with IEC 60601-1 standard.

OPTOPOL recommends connecting the system via an uninterruptible power supply (UPS) connected to the wall outlet.

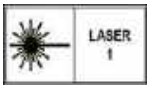
WARNING: Only the computer (All-in-One or Monitor + PC) and optional printer should be connected to the isolating transformer. Do not plug in any non-medical devices into the same wall supply socket as the REVO device. Connecting non-medical devices in any other way than presented in Chapter 1.3 Safety Standards can lead to electric shock or damage of the devices.

WARNING: It is strictly forbidden to connect any non-medical or medical devices which are not included with the system to the isolating transformer (e.g., lamp, vacuum cleaner, etc.), or to the Multiple Socket-Outlet.

WARNING: The REVO device must not be directly connected to the isolating transformer but should be connected directly to a mains power supply socket or to the dedicated supply socket on a dedicated table.

NOTE: The REVO device is connected to the PC using a USB 3.0 Type B cable.

NOTE: The light source is included inside the device. Removal of the device covers must be done only by authorized personnel. The maximum power of light radiation available outside of the covers is less than 1650 microwatts, providing safe operation of the device. The only output of light is from the front objective lens.



The REVO device is classified as a CLASS 1 laser device.

1.4. Safety Warnings

Warnings indicate hazards that may result in property damage, injury, or death:

WARNING: Do not scan patients who have been injected with photo-dynamic therapy (PDT) treatment drugs in the previous 48 hours. Failure to observe this warning could result in unintended exposure and uncontrolled treatment of neovascular vessels.

WARNING: Eye Care Professionals need to determine whether this device should be used for patients who may be photosensitive, including those with epilepsy.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a grounded main power supply. Ignoring safety rules can lead to electric shock.

WARNING: If the spectrum band height is too high the [ACQUIRE] tab will be blocked to avoid eye damage

WARNING: Multiple portable socket-outlets should not be placed on the floor.

WARNING: Any additional multiple socket-outlet or extension cord should not be connected to the system.

WARNING: It is strictly forbidden to connect any non-medical or medical devices which are not included with the system to the isolating transformer (e.g., lamp, vacuum cleaner, etc.), or to the Multiple Socket-Outlet.

WARNING: All internal maintenance of REVO hardware must be performed by the manufacturer or authorized personnel trained by the manufacturer.

WARNING: No modification of this equipment is allowed.

WARNING: OPTOPOL recommends that no accessories, other than those specifically described in this user manual, be connected to the system. Any customer accessory equipment connected to the interface ports must be certified according to the applicable IEC standards (for example, IEC 60950-1 or IEC 62368-1 for data processing equipment and IEC 60601-1 for medical equipment). Also, all configurations must comply with the system standard IEC 60601-1. Any person who connects or installs accessories to the system has the responsibility to verify this compliance. If in doubt, consult an authorized OPTOPOL representative.

WARNING: The system cannot replace clinical judgment and is intended to be used only in conjunction with other clinical tools for diagnosis of eye health and disease.

WARNING: The system is not intended to be used as the sole diagnostic aid in disease identification, classification, or management. The system provides data to be used in conjunction with other information intended to assist an eye care clinician in determining a diagnosis. Medical diagnosis is the sole domain of a licensed eye care clinician.

WARNING: This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

WARNING: The system has no special protection against harmful ingress of water or other liquids (classified IPX0). To avoid damage to the instrument and causing a safety hazard, cleaning solutions, including water, should not be directly applied to the device. Using a lightly dampened cloth (without dripping) is the proper method to clean the exterior surface of the enclosure. The table can be cleaned in the same manner as the system. Care should be taken to avoid excess fluid near any of the system components.

WARNING: While being examined, the patient must not touch any part of their body to an electrical device that is not powered by the system. In addition, while examining the patient, the system operator must not touch both the patient and any electrical device that is not powered by the system. Failure to observe these warnings could result in electrical shock to the patient and / or operator.

WARNING: The device cover housing should never be removed, with the exception of service repair by a trained OPTOPOL technician.

WARNING: If an examination is carried out when the cameras housing is removed from the device, the system operator must not touch the patient and uncovered parts of the device at the same time.

WARNING: Use an isolating transformer if non-medical external devices are located within 1.5 meters from the patient (patient environment). If the non-medical external devices are connected to the medical device and located outside the patient environment, a separation device must be used in the system or there shall be no electrical connection between the non-medical external devices and the device.

WARNING: The Real Corneal Power (RCP) value determined by the topography function is not interchangeable with the corneal power value determined by any other device. The Real Corneal Power determined by the topography function is not intended to be used in lieu of or to replace a value in your standard IOL calculation formula.

WARNING: Make sure that the patient does not put his head inside the headrest frame when the “up” or “down” chinrest elevation button is pressed.

WARNING: For biometry measurements, users must check the measurement readings for plausibility. This includes checking the detected position boundaries on the adjusted lines, which automatically adjust to the signal. The operator must also consider the type (e.g., posterior subcapsular cataract) and density of the cataract when evaluating scan.

WARNING: Remember that the user LOGIN and PASSWORD is the only means to open the software. In case of issues, please contact your authorized distributor.

WARNING: Make sure there is enough free space on HDD / remote folder before performing the backup process.

WARNING: Only the computer (All-in-One or Monitor + PC) and optional printer should be connected to the isolating transformer. Do not plug in any non-medical devices into the same wall supply socket as the REVO device. Connecting non-medical devices in any other way than presented in Chapter 1.3 Safety Standards can lead to electric shock or damage of the devices.

WARNING: The REVO device must not be directly connected to the isolating transformer but should be connected directly to a mains power supply socket or to the dedicated supply socket on a dedicated table.

WARNING: All hardware maintenance activities can only be done when the device is turned off and unplugged from power supply socket.

WARNING: There are no user serviceable parts inside the device. Any covers can be removed only by OPTOPOL authorized personnel.

WARNING: The main lens of the device should never contact the patient's eye or face.

WARNING: 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.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided and 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.

WARNING: Any imported IOL constant data must be reviewed and accepted by the operator prior to use. The full responsibility for using any imported IOL constant data from any source lies with the user. Imported IOL constant data must not be regarded as a recommendation in favor or against using any particular lens on a patient. IOL constant data obtained from IOL Con, ULIB, or any other source only presents an overview of available lenses. OPTOPOL is not responsible for the quality or correctness of data imported or manually entered into the system.

WARNING: The user chooses the IOL calculation parameters at their own discretion. The user has responsibility for the chosen parameters and the interpretation of results.

WARNING: The IOL calculation function is provided as an additional software module for physicians to aid in the selection of an appropriate IOL for a particular patient. The IOL calculation module is intended to be used in combination with accurate ophthalmic examination measurements. The results of calculations obtained with the IOL calculation tool do not serve as surgical or medical instruction and they are not conclusive. OPTOPOL cannot guarantee accuracy or correct functioning of the tool. The choice of a particular IOL model and surgical procedure lies exclusively with the Ophthalmologist who takes sole responsibility for the medical outcome of the procedure.

WARNING: The user is fully responsible for the verification of provided data when using for IOL implementation or any other medical procedure.

WARNING: The user is fully responsible for all data entered or changed manually in the IOL Calculation tab. Calculation parameters are determined at the user's discretion and it is the user's responsibility to make sure they guarantee obtaining a result optimized for a given case.

WARNING: Users should not rely solely on SOCT measurements in making decisions regarding the calculation and implantation of intraocular lenses or other therapeutic procedures and should rely on their own expertise and judgment.

WARNING: Do not use the Haigis L to calculate IOLs for eyes that were treated by RK (Radial Keratotomy).

WARNING: The user is fully responsible for all values entered or changed manually.

WARNING: The user is fully responsible for the verification of provided data when using for IOL implementation or any other medical procedure.

WARNING: The White-to-White (WTW) distance value is merely an indirect measurement of the inner lateral dimensions of the anterior ocular section. For this reason, it provides only approximate indications of the actual inner lateral dimensions of the anterior ocular section and of the size of the implant to be used.

WARNING: Ignoring or disregarding the statements above may lead to danger of death or serious injury.

WARNING: When using the adapter for the examination of the anterior segment of the eye, do not move the measuring head too fast and monitor its distance from the patient to prevent contact between the surface of the anterior adapter lens and the patient's eye.

WARNING: When using the adapter for the examination of the posterior segment of the eye, do not move the measuring head too fast and monitor its distance from the patient's eye to prevent contact between the surface of the UWF adapter lens and the patient's eye.

WARNING: When mounting the anterior adapter, make sure that the scanning head is in its maximum backward position and that the patient does not incidentally come into contact with the anterior adapter.

WARNING: When mounting the UWF adapter, make sure that the scanning head is in its maximum backward position and that the patient does not incidentally come into contact with the UWF adapter.

WARNING: This device is not designed, sold or intended for use except as indicated in this manual.

WARNING: Failure to use the safe lock functionality may result in physical contact between the adapter and the patient.

WARNING: The IOL Calculation function is provided as an additional tool in the hands of the physician to aid in the selection of an appropriate IOL for a particular patient. The tool is intended to be used in combination with a proper and comprehensive ophthalmic examination and diagnostic tests. The results of calculations obtained with the IOL Calculation tool do not serve as surgical or medical instruction and they are not conclusive. OPTOPOL Technology cannot guarantee accuracy or correct functioning of the tool. The choice of a particular IOL model and surgical procedure lies exclusively with the physician who takes the sole responsibility for the medical outcome of the procedure.

WARNING: Any imported IOL data must be reviewed and accepted by the operator prior to using it. The user takes full responsibility for using any imported IOL data from any source. Imported IOL data must not be regarded as recommendation in favor of or against using any particular lens on a patient. IOL data obtained from ULIB, IOL Con or any other source only represents an overview of available lenses. OPTOPOL Technology is not responsible for the quality or correctness of data imported into the system.

WARNING: Using data from ultrasound instruments requires the constant of every IOL to be optimized for that instrument. It is common to find online databases of lenses optimized for optical interferometry instruments.

WARNING: Do not forget user LOGIN and PASSWORD is the only way to open the software and enter this information. In case of problems, please contact your local OPTOPOL distributor.

WARNING: For optimal networking performance, the application on all of the PCs within the network should be upgraded to the latest version.

WARNING: Only scans with the "OK" status can be considred for a diagnosis. Scans with "!" status cannot be considered.

WARNING: Disc defragmentation is not recommended for SSDs.

1.5. Cautions

CAUTION: This manual does not provide guidance on interpretation of clinical results. The clinician must ensure that they have received appropriate medical training in such interpretation. OPTOPOL is not responsible for misdiagnosis of results.

CAUTION: OPTOPOL Technology does not offer advice or instruction in the diagnosis and interpretation of OCT images. It is the clinician's responsibility to diagnose and interpret OCT scans.

CAUTION: Do not use this instrument for purposes other than intended and specified.

CAUTION: Federal law restricts this device to be sold to or on the order of a physician or practitioner (CFR 801.109(b) (1)).

CAUTION: Before using the device, the operator should be trained to operate the system efficiently and safely.

CAUTION: Applicable Phototoxicity Statements (FDA CDRH Ophthalmologist Guidance #71): Because prolonged, intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the exposure time for the patient's eye be limited to the minimum time that is necessary for image acquisition.

Aphakic eyes, infants and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. When using this device the user must not perform any adjustments to the intensity of the incident light that falls on the retina.

CAUTION: Be extremely cautious (by minimizing scan exposure) when examining high-risk groups for optical radiation, including patients without a crystalline lens and patients who have photosensitivity.

CAUTION: The REVO device weighs approximately 23 kg (REF 155 and 156), 29 kg (REF 191 and 192) or 30 kg (REF 190, 193 and 194). It should be lifted by at least two persons. Use only the indicated positions for lifting.

CAUTION: Exercise caution when mounting the anterior adapter in order not to scratch the objective lens.

CAUTION: Exercise caution when mounting the UWF adapter in order not to scratch the objective lens.

CAUTION: Make sure the patient keeps their face away from the chinrest and the forehead rest when the Anterior Chamber Adapter is still attached. Otherwise, the patient may be injured by the Anterior Segment Adapter coming into contact with them if the scanning head moves in any direction.

CAUTION: Make sure the patient keeps their face away from the chinrest and the forehead rest when the UWF Adapter is still attached. Otherwise, the patient may be injured by the UWF Adapter coming into contact with them if the scanning head moves in any direction.

CAUTION: It is recommended to run the SOCT software from a Windows account with administrator privileges.

CAUTION: The Disc Damage Likelihood Scale (DDLS) is based on a publication by George L. Spaeth, MD in 2002[1]. The DDLS information provided is only as supplementary information and should not be used as disease confirmation. Use for reference only. The representation of the DDLS value by the REVO device is strictly a calculated value.

[1] Spaeth, George L et al. "The disc damage likelihood scale: reproducibility of a new method of estimating the amount of optic nerve damage caused by glaucoma." Transactions of the American Ophthalmological Society vol. 100 (2002): 181-5; discussion 185-6.

CAUTION: KPI is based on a publication by Naoyuki Maeda in 1994[2], and can only be treated as supplementary information and cannot be treated as disease confirmation. Use for reference only.

CAUTION: Calculation constants used in the IOL Calculation tab do not depend solely on the IOL type and calculation formula used. They can also be influenced by factors such as measurement technology and surgical technique, which is why the user is strongly advised to optimize the lens constants for their preferred conditions and method of practice.

CAUTION: While using an A-constant for IOL Calculations, remember that it is an estimate and should only be used for reference. Use only IOL constants optimized for optical biometers.

CAUTION: The software for taking measurements and performing IOL calculations must be operated only by appropriately trained and experienced staff. All members of the staff must read this User Manual thoroughly, with special attention given to the safety related points and instructions.

CAUTION: Prior to measurement, the user must verify that the patient is not wearing contact lenses. Patients wearing contact lenses during measurement will result in erroneous results.

CAUTION: The wearing of contact lenses (soft or hard) may have an effect on the surface geometry of the cornea and thus the optics of the eye. Therefore, for measurements conducted on wearers of contact lenses using SOCT topography module, a rest period should be observed from the time the contact lens is removed to the time of measurement. The required duration of the time from removal of the lens to the time of measurement may vary individually and must be determined by a qualified physician.

CAUTION: For patients with morphological changes of the retinal anatomy in the region of the fovea (e.g. retinal detachment, edema), the axial length measurement result may be erroneous and thus is not usable or only of limited use for IOL calculation. In case of retina segmentation errors, the user can perform a correction after verification of the region of interest.

CAUTION: Correct detection of boundaries should be checked with particular care during measurement, especially when measuring very long eyes, eyes with dense cataracts, pseudophakic or aphakic eyes, or eyes with any kind of pathology. Despite various plausibility checks, measuring errors can be manually excluded or corrected in individual cases.

[2] Automated Keratoconus Screening with Corneal Topography Analysis by Naoyuki Maeda, Stephen D. Klyce, Michael K. Smolek, and Hilary W. Thompson in 1994.

CAUTION: Measurements taken with the REVO device may serve as the central element for the calculation of intraocular lenses (IOL). A further important parameter in calculating the lens to be implanted is the IOL constant. When using the REVO device, only IOL constants optimized for optical biometers should be used. Please contact your IOL manufacturer for information on optimized IOL constants for optical biometry. An alternative source of information for IOL constants optimized for optical biometry is the website:

IOLCon.org: IOL Con is an international platform for characteristics of intraocular lenses and the optimization of lens constants. The IOLCon team is located at University of Saarland and working under the head of Steinbeis.

ULIB User Group for Laser Interference Biometry" (ULIB): http://ocusoft.de/ulib/c1.htm.

CAUTION: There is a risk due to measuring errors. Unstable patient fixation can lead to measuring errors and the calculation of incorrect IOL refractive powers. Make sure that the patient fixates correctly on all scans and that the corneal apex (with a visible central reflex) and the fovea are clearly visible on all tomograms. Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.

CAUTION: Using data from acoustic instruments also requires the constant of every IOL to be optimized for that type of instrumentation. At present, it is more common to find online only databases of lenses optimized for optical biometry instruments.

CAUTION: When using the data taken by this instrument for refractive correction surgery, thoroughly determine the selection by also examining surgery methods and exercising other inspections. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or other complications.

CAUTION: To ensure plausibility of biometry results, the operator should always use more than one calculation formula for a given IOL model and patient. This enables the user to exercise closer scrutiny of obtained results.

CAUTION: Pressure to the eyeball leads to a deformation of the cornea. Thus, the corneal curvature cannot be determined correctly and may result in the incorrect calculation of IOL refractive powers. When manually raising the patient's upper eyelid, ensure that no pressure is exerted on the eye.

CAUTION: Use of eye drops prior to topography measurement may lead to incorrect results in the measurement of corneal curvature. The use of artificial tear drops may impact the measured keratometry values.

CAUTION: Do not perform any contact measurements or examinations in which the eye is touched prior to measurement with the SOCT. Performing contact measurements prior may result in incorrect SOCT readings, particularly for biometry and corneal topography measurements. Contact measurements or examinations should only be performed after the patient has been measured with the SOCT.

CAUTION: For patients with a strong nystagmus, it may not be possible to take a reliable examination data.

CAUTION: Check for any damage to the package. Every transportation box is equipped with shock watches. If any shock watch is broken (red indicator), please contact OPTOPOL and file a complaint with the carrier.

CAUTION: After unpacking, check the unit and all accessories for mechanical damage, cables damage, etc. In case any damage is found, do not connect the device and contact OPTOPOL or your authorized distributor.

CAUTION: The REVO device should be placed in a room with a regulated temperature. Do not turn on the device if exposed to extreme temperatures. Always operate the device within operating ranges of temperature and humidity. For specific information on Environmental conditions, please refer to Chapter 27 Environmental Conditions.

CAUTION: Transportation position of the REVO device is to be set by turning it off and on – this will cause the device to go to the base position. Turn it off and pack in the box while securing with packing foams.

CAUTION: Always turn the PC ON first, and then after PC is fully loaded into Windows OS, turn ON the REVO device.

CAUTION: When using the data taken by this instrument to select intraocular lenses, thoroughly determine this selection by examining cataract surgery methods and exercising other inspections. If incorrect measurement data is used to select intraocular lenses, further surgery might be required.

CAUTION: Calculation constants do not depend solely on the IOL type and calculation formula used. They can also be influenced by factors such as measurement technology and surgical technique, which is why the user is strongly advised to optimize the constants for their particular circumstances, case, and practice.

To calculate the constants based on the A-constant of the manufacturer, enter the A-constant value in the [A-CONST] field and click [CALCULATE CONSTANTS].

CAUTION: The device may be used only by properly trained personnel.

CAUTION: The topography module may be used only by properly trained personnel.

CAUTION: Keep in mind that tomograms with very low signal level or low QI might degrade the performance of the AI DeNoise algorithm, potentially leading to an altered image. If you use these tomograms, always make sure the exported denoised images are identical to the original, unprocessed images.

CAUTION: Before replacing the fuses, make sure that there are no other visible reasons causing the device to not work (broken cables, disconnected cables etc.).

Before replacing the fuses, turn the device off and unplug it from the power supply socket.

CAUTION: The IOL calculation is valid only if the biometric measurement was correct, an appropriate IOL calculation formula was selected and the IOL constants were optimized for the specific application in advance.

CAUTION: Results from various SOCT software versions may differ. When comparing results on printouts to results in the software, make sure they were all obtained using the same software version.

CAUTION: If the PC on which the examination is being viewed loses connection to the database for longer than 60 seconds, the SOCT application automatically switches to the |PATIENTS| tab.

1.5.1. OCT-A Limitations

CAUTION: OCT-A is not a substitute for FA.

CAUTION: Vascular findings on FA (and / or ICG) may be poorly defined or absent on OCT-A.

CAUTION: Certain features visible with FA that involve slow or no flow of fluid, such as leakage, pooling or microaneurysms, may not be visible with OCT-A.

CAUTION: Artifacts such as decorrelation tails (projection artifacts) may cause false signals in layers below the vessels.

1.6. General Notes

IMPORTANT:

1. If the entire REVO System has been installed by the manufacturer of the REVO device or by authorized personnel, the manufacturer guarantees correct installation and compliance with all required standards and directives.
2. If the installation is not performed by the manufacturer or authorized personnel, the manufacturer of the REVO device is not responsible for any problems or risks that could be created by incorrect connections and violation of safety standards.

3. Operating personnel must be appropriately trained and instructed prior to operating the device. The REVO User Manual must be made available to operating personnel and they must read and understand the contents.
4. The manufacturer of the REVO device is not responsible for any incorrect medical diagnosis nor for the consequences of such incorrect medical diagnosis.

NOTE: The OCT image produced by the REVO device is a plot of optical path length. Depending on the optical design and scanning location, the image can be distorted from its actual physical shape.

NOTE: The OCT image can be affected by the optical pathway, which includes corneal opacity, cataract, and eye shape.

NOTE: The REVO is a medical device. The software and hardware have been designed in accordance with European, U.S. and other international medical device design and manufacturing standards. Unauthorized modification of the system software or hardware, or any addition or deletion of any application, may jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data.

NOTE: Any changes, additions or deletions to factory installed applications, the operating system or modifications to hardware in any manner, will void the manufacturer's warranty and may cause safety hazards.

NOTE: Incorrect segmentation of the anterior surface of the cornea or anterior chamber may lead to incorrect results.

NOTE: For corneal topography scanning, fully examine the measured tomograms for layer recognition and examination results. For bilateral acquisition, if the difference between measurement values for the left and right eye is significant or any problem is found in the anterior chamber during the preliminary examination, check the correctness of the tissue boundary recognition and / or reliability indices. For all corneal topography scanning, if the measurement result is not conclusive, repeat the measurement or further review the results.

NOTE: When using corneal topography or biometry data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking a minimum of three measurements and / or conducting manual measurements with other instruments.

NOTE: For topography and anterior scans, it may be difficult to recognize the boundaries when capturing an image of an eye with opacities or other malformation such as corneal disease or shallow anterior chamber. In this case, if required, manually correct the layers or reject the measurement values.

NOTE: Image artifacts may appear on the OCT image. This does not indicate imaging failure. An image artifact is any feature that appears in an image which is not present in the original, imaged object. An image artifact is sometimes the result of improper operation or a consequence of natural processes or properties of the human body.

NOTE: When the measurement light enters the cornea, sclera, conjunctiva, or intraocular lens perpendicularly, a bright vertical line appears.

NOTE: (Ghost images / noise) may occur in areas with strong reflection such as the cornea, sclera, conjunctiva, and iris.

NOTE: For corneal topography measurements, the operator should observe correct patient fixation and alignment centered on the cornea, as this is critical to obtaining a consistent corneal power measurement.

NOTE: The user should always seek to improve their IOL optimization. IOL personalized and optimized data should be created through the analysis of pre-operative data obtained with the device and the results of stable refraction tests performed three months after the surgery.

NOTE: The Anterior Chamber scan and Pachymetry scan include compensation for beam scanning geometry and reflection from the surface of the cornea. Therefore, during acquisition, it is important that the scan is centered on the vertex of the cornea so that a strong vertical reflex is visible through the corneal vertex. The compensation algorithm works with greatest accuracy when corneal scans are centered using this method.

NOTE: Low quality examination results can be expected in the following situations:

- **Patients with complete or partial coverage of the cornea, caused by palpebral fissure which is closed or too small.**
- **Patients which are unable to steadily fixate on the fixation target with the eye under examination**

NOTE: When measuring pseudophakic eyes, the auto-measurement of anterior chamber depth and lens thickness may be inaccurate. The measurement markers should be checked very carefully and corrected if necessary to ensure correct positioning.

NOTE: The Operator is to remain with the patient throughout the scanning process to oversee and guide them. The voice guidance feature is not intended to replace the Operator.

NOTE: The REVO system can only be connected to a power supply socket equipped with a properly connected grounding pin.

NOTE: Avoid the use of extension cords or a power strip.

NOTE: The REVO device is connected to the PC using a USB 3.0 Type B cable.

NOTE: The light source is included inside the device. Removal of the device covers must be done only by authorized personnel. The maximum power of light radiation available outside of the covers is less than 1650 microwatts, providing safe operation of the device. The only output of light is from the front objective lens.

NOTE: For graphical objects to be scaled correctly while using 4K resolution, it is necessary to set text scaling to 200% in the screen settings window of the operating system.

NOTE: Once opened, you can switch between the user manual and the SOCT application by pressing Alt+ Tab.

NOTE: To power off the device, turn OFF the power switch (Position O).

NOTE: The user should not remove the power cable without first switching the power switch to the OFF position (O).

NOTE: Regarding EMC (Electro-magnetic compatibility) standards all signal cables have to be put together.

NOTE: The REVO device must be directly plugged into a grounded main socket. Connect the PC, printer and monitor into the multiple portable socket-outlet, which is directly connected to the isolating transformer. By connecting the PC set to the isolating transformer, the leakage current is reduced to the level which is in line with the IEC standard. The isolating transformer is connected directly to the main power with a protective ground pin.

NOTE: Chemically induced pupil dilation is not typically needed, but can be used if necessary.

NOTE: The device is ready to use when the SOCT software is opened, and the status is indicated as READY.

NOTE: Fields “Last name”, “First name” and “Date of birth” are mandatory and must be properly filled in. Other fields are optional and can be left empty.

NOTE: In DEHS screening mode field “Patient ID” is mandatory and must be properly filled in. “Refraction” fields are optional and can be left empty.

NOTE: For patients with a spherical equivalent refractive error larger than ± 10 D, it is recommended to enter the patient’s spherical equivalent when adding the patient to the system. Entering data into the refraction fields transfers this information into the correction of focus in measurement mode.

NOTE: In the case of patients with spherical equivalent refractive error larger than ± 10 D, it may be challenging to use the automated retina detection.

NOTE: Disease field can use a user predefined dictionary of diseases as set up. The user can also set the obligatory fields in the Patient registering window to meet the regional regulations. For more information go to chapter 23.5.8 Input Settings Window.

NOTE: Make sure you have entered the correct patient’s name and date of birth. This will prevent data loss and help to avoid empty records in the Patient List.

NOTE: Once the patient is deleted, it is impossible to recover the deleted data. There will not be any patient data, including the patient file and any associated exams. Please make sure you are deleting the proper patient before accepting the warning.

NOTE: Use [CLEAR ALL] to reset the filter settings and disable filtering.

NOTE: Once the examination is deleted, it is impossible to recover the deleted data. Please make sure you are deleting the proper exam before accepting the warning.

NOTE: Only one exam or single visit can be cut and pasted at a time.

NOTE: To use the [AUTO FOCUS] function, the OCT signal must be visible in the tomogram live preview (eye open).

NOTE: In difficult conditions, such as:

- **Eyelashes or eyelid which block the beam of light**
- **Inability of subjects to maintain fixation**
- **Dense media opacities**
- **Strong nystagmus**
- **Rapid blinks**

the system can display a warning. In this case operator should decide whether to use the tips mentioned in the Chapter 8.6 Examination Tips or change the acquisition mode.

NOTE: Before performing the first retinal scan examination for an eye, if you set the focus value (refraction power compensation), the system will align the patient data according to the patient correction for the Left and Right eye.

NOTE: It is recommended to visually evaluate the focus after automatic focus is complete. If necessary, manually adjust the focus bar to optimize the scan.

NOTE: In cases when the [AUTO FOCUS] displays an error or a low QI value, try adjusting the refractive power above and below the initial value to obtain the best saturation of scans and a higher QI value.

NOTE: During the alignment of the OCT signal on the live tomogram preview, the pSLO image is frozen.

NOTE: Scan patterns in every scan program have different settings.

NOTE: Always check if the AccuTrack™ is on or off. Turning the AccuTrack™ on is under the operators discretion.

NOTE: The optimal pupil size for AccuTrack™ is 3.6 mm or bigger.

NOTE: The aperture of the optics for the scans of the posterior segment is 15 mm[3]. For this reason, when using the maximum scan width for 3D and Angio scans, the OCT signal is not visible in the corners.

[3] Additional width of 21 x 21 mm is available using the UWF adapter. Ultra-Wide Field is an optional software module available for REVO FC devices (OCT with Fundus Camera). If you do not have this feature and want to purchase it contact Optopol's local distributor.

NOTE: All marked examinations must have the same physical dimensions and the same number of A and B scans and the same exam type. Please note, if an artifact repeats in the same position on all scans, the system will not be able to eliminate the artifact from this area.

NOTE: The scans used for Motion Correction must be complete scans with sufficient data and quality necessary for correct motion artifacts reduction.

NOTE: When the system displays warning "Tomogram Alignment failed", the operator should manually adjust the tomogram to the relevant position. Improperly aligned tomograms will influence the quality of the acquired tomograms and the reliability of the analysis.

NOTE: Voice guide is on by default. The user can mute it or decide to turn it off in the Setup tab – See Chapter 23.5.4 Voice Support Guide Tab

NOTE: If the system cannot detect a pupil, the user must adjust the center of the patient's pupil manually. To set the working position properly, align the center of the pupil to the proper height.

NOTE: If the system is not able to maintain the correct position of the retina (for example if the patient is moving), the operator must switch off tracking and carry out the examination manually.

NOTE: Selecting the disc examination does not initially change the Fixation position.

NOTE: Adjust the position of the scan with slight left / right / up / down movement if there are any shadows on the edge of the tomogram. The optimal position is where the entire tomogram is properly saturated, and QI is as high as possible.

To obtain the best saturation of the OCT signal, verify the correct refraction and perpendicularity of the tomogram. The operator can drag the tomogram to the desired position on the live OCT window.

NOTE: The vertical dense line in the center of cornea is a natural reflection of laser light and has no negative influence on the measurement result. It can be used to assess if the tomogram is in the proper position.

NOTE: Only when the cornea / sclera tissue is parallel to the scanning window are the AOD (angle opening distance) and TISA (trabecular-iris space area) manual measurements accurate.

NOTE: Semi-Auto or Manual mode is useful when the system cannot acquire an optimal fundus image in Full-Auto mode, or when the operator wants to scan an area other than predefined fixation locations (e.g., peripheral area).

NOTE: When the IR preview is ON, the OCT signal is not visible.

NOTE: To improve patient compliance during the examination, and to reduce patient movement, it is important to be clear regarding patient instructions and the progress of the examination.

NOTE: By moving one tomogram, i.e., horizontal, the vertical tomogram will move as well.

NOTE: If, after scanning, the patient begins to drift, remind them to continue in this same position in case a repeat scan is necessary.

NOTE: Patients usually are more cooperative with detailed instructions during an exam. Therefore, it is advisable to be informative about the progress of the examination to minimize movement.

NOTE: It is recommended that results are reviewed carefully if the QI score is five or less to determine if auto segmentation is placed correctly.

NOTE: It can be helpful to ask the patient to look up then down to try and move the floater to a different location.

NOTE: Areas of the Retinal Thickness Map may be missing portions due to lack of layer segmentation detection.

NOTE: Make sure that the foveola marker which shows the center of macula in the retina analysis tab locates the fovea properly.

NOTE: Clinicians must exercise their judgment in the interpretation of the reference data comparison. For any measurement, 10% (e.g., two out of 20 normal eyes) will fall above or below green.

NOTE: If the Fovea-disc axis does not go through the center of the disc and foveola, repositioning of the fovea-disc axis is required. On the Significance Map object, the operator can grab and move the blue dashed line to correct the position of the axis.

NOTE: The user should visually evaluate the image to determine if the segmentation lines are correctly finding the analyzed boundaries.

NOTE: Be aware when evaluating the tomogram with different parameter settings and / or with different scan widths, the proportion of the retina shape may not be kept.

NOTE: Be aware when evaluating the tomograms on the Quick Printout, it is possible that scanned widths are different between examinations.

NOTE: If manual adjustments of the segmentation lines are made by the user, the system will automatically recalculate the ONH parameters.

NOTE: Epithelium thickness is measured from corneal anterior surface to the posterior boundary of the epithelium. The posterior boundary of epithelium is defined as the interface of Epithelium and Bowman's Layer. When the Bowman's layer is absent e.g. in Post Refractive eyes, the posterior boundary is defined as the interface of epithelium and the Stroma.

NOTE: In case of auto segmentation layer errors, it may be necessary to modify the layer boundaries manually.

NOTE: The cornea analysis tab is available only when the system classifies the scanned object as a cornea scan. See the letter in the top left corner. To change scan type, go to Tomogram tab-> Menu -> Change Analysis type. The anterior analysis type window will appear. Select [Cornea] type.

NOTE: Review the scan carefully to determine accuracy when lid is on a part of the scan.

NOTE: Quantitative analysis is available only if the scanned structure type is marked as Cornea.

NOTE: To properly measure the AOD (Angle Opening Distance) and TISA (Trabecular Iris Space Area), review the exam with layers enabled to ensure the system has properly positioned the surface of the sclera. Verify recognition before judging the Anterior Angle morphology.

NOTE: The proportion of the scan may be different between examinations.

NOTE: The [HIGHLIGHTS] function desaturates overexposed areas. It may affect the local color presentation.

NOTE: Ultra-Wide Field is an optional software module available only for REVO devices with the Fundus Camera. If you do not have this module and would like to purchase them, please contact your local OPTOPOL distributor.[4]

NOTE: Ultra-Wide Field Angio examination will be unavailable if OCT-Angiography module is not purchased.

NOTE: OCT-Angiography is an optional software module. If you do not have these modules and wish to purchase them, please contact your local OPTOPOL distributor.

NOTE: The final measurement depends on the brightness, contrast, and sensitivity adjustments. The user is responsible for the correct adjustments of the brightness, contrast, and sensitivity to highlight only the proper structure of the changes. OPTOPOL Technology Sp. Z o.o. is not responsible for misdiagnosis of results.

NOTE: Due to the method of calculating the pixel density there may be slight differences between the results for the examination with different size and/or density scanning.

NOTE: Both VAD and VSD can detect abnormal vasculature and provide repeatable quantitative results equally in normal and diseased eyes.

NOTE: Areas with large vessels may block the ability for the OCT-A to display flow signal.

NOTE: The signal intensity of the tissue underneath a large blood vessel will be obstructed by the blood flow signal of the large blood vessel. The obstruction will affect the visualization of the highly reflective layers such as IS / OS or RPE in those areas. Therefore, the angiogram images including IS / OS or the RPE layer appear to be similar to the angiogram of blood vessel structure of the inner retina. This effect is called a "Decorrelation Tail" or "Projection Artifact". In a healthy eye, there are no blood vessels in the outer retina.

NOTE: When PAR is turned off, the vessels from above are projected downwards. The ability to turn PAR off is included so the operator can evaluate the image without the filter.

NOTE: Verify the retina layer recognition boundaries and the layer offsets before evaluating an angiogram of the vascular layer.

NOTE: Due to projection artifacts of the retinal flow signal onto deeper layers, such as the retinal pigment epithelium and choroid, carefully evaluate the signal in the deeper vascular layer, particularly the RPE and choriocapillaris.

[4] There may be a need to update the device's hardware. For more information, please provide the serial number of the device to your local Otptopol representative.

NOTE: It is not possible to show the same boundary slab in two different angiogram objects at once.

NOTE: Biometry is an optional software module. If you do not have these modules and wish to purchase them, please contact your local OPTOPOL distributor.

NOTE: Since the device measures up to the retinal pigmented epithelium, the reading displayed is adjusted to the internal limiting membrane, as a function of axial length or manually.

NOTE: If the patient has previously undergone cataract surgery, available records should be consulted for a plausibility check of the measurement.

NOTE: It may not be possible, under certain circumstances, to carry out measurements on patients with fixation problems.

NOTE: In cases of thick cataracts and uncertain measurement of the axial length, ultrasound biometry should be performed as a control examination.

NOTE: Dense lenticular opacities may make it impossible to measure the axial eye length and lens thickness.

NOTE: Pronounced opacities of the central cornea can make it impossible to measure corneal thickness, anterior chamber depth, lens thickness or axial eye length.

NOTE: In the case of an extremely dense cataract, blood in the vitreous may make it impossible to measure the axial eye length.

NOTE: The user must check the tomograms when measuring anterior chamber depth in pseudophakic mode. If only one IOL boundary is visible, this may lead to errors. Uncertainty in this case can lead to the displayed reading for anterior chamber depth being inaccurate based on the thickness of the IOL.

NOTE: It is recommended that both of the patient's eyes are examined with at least 10 repeats. The user should subject the measurement readings to extra scrutiny if there is a notable difference between the right and left eye. The following are classified as notable differences:

1. **More than 1D with respect to central corneal refractive power.**
2. **=> 0.18 mm difference with respect to the corneal curvature radius.**
3. **More than 0.3 mm with respect to axial eye length**

NOTE: The precision of the axial length measurement may be different in eyes with cataracts.

NOTE: Users should check the Biometry OCT images to determine that the eye is not excessively tilted or decentered, which may result in inaccurate or implausible measurements.

NOTE: Users should verify measurement caliper positions on all tomogram images.

NOTE: Based on the patient's gaze at the fixation light, the optical path length of the visual axis is measured. Make sure that foveola is in the center of scan.

NOTE: All distance - thickness parameters (axial length, corneal thickness, anterior chamber depth, lens thickness, white-to-white, pupil size) are measured in sequence captured tomograms.

NOTE: An excessively tilted or decentered IOL may make it impossible to measure the anterior chamber depth, lens thickness and aqueous depth.

NOTE: The user must verify that the eye assignment (OD, OS) is correct for the entered data.

NOTE: If the IOL material is not known prior to measurement, the operator should select the [IOL Unknown] option under Lens.

NOTE: Collecting the data from both eyes is highly recommended.

NOTE: If an incorrect LVC mode has been selected this may lead to the calculation of incorrect IOL refractive powers.

NOTE: If the system does not detect the pupil, the user must manually adjust the center of the patient's pupil. To set the working position properly, align the center of pupil to the proper height.

NOTE: In a patient with a dense cataract, the user should try to achieve a Q Bar that is as high as possible.

NOTE: It is strongly recommended to review all biometry series. Verify that the desired eye structures are properly visible. During review of the exam, ask the patient to keep the examination position. The user may be required to repeat exam with corrected conditions.

NOTE: When in the Acceptance window, review the specific conditions for a repeat exam according to the below procedure:

1. **THE RETINA IMAGE IS NOT PROPERLY VISIBLE ON ALL TOMOGRAMS: Use the repeat function or double click on the retina image.**
2. **THE CORNEA IMAGE IS INCORRECT: Double click on the cornea tomogram. It will start the procedure from the cornea scan and will use retina data from the previous scan. After adjusting the alignment of the cornea, press the [NEXT] button to align the lens.**
3. **THE FRONT OR BACK OF THE LENS IS NOT CORRECTLY VISIBLE: Double click on the lens tomogram. It will start the procedure from the cornea scan and will use retina data from the previous scan. After adjusting the alignment to the cornea, press the [Next] button and manually align the lens position. Use the C-gate slider or scroll on the tomogram window until the lens image appears in the scan window. It may be required to use the focus tool to optimize the signal strength. In cases of very thick lenses, place the image of front of the lens, higher than on the originally dashed lines and lower for thinner lenses. The system behaves differently for natural and intraocular lenses.**
4. **It is recommended to use the [RESCAN] function to repeat the exam if blinks or eye movement cause errors during acquisition and cause half or more of the repeated scans to have errors or to be missing.**

NOTE: Only a biometry exam with a valid calibration allows the operator to open IOL Calculation tab.

NOTE: Fields “Treatments” and “Start date” and “Date of birth” are mandatory and must be properly filled in. “End date” optional and can be left empty.

NOTE: Reference lines are based on published researches and may be different than the real trends in the population. Operator should bases on own experience and adjusts reference lines to accurate population.

NOTE: Topography is an optional software module. If you do not have these modules and wish to purchase them, please contact your local OPTOPOL distributor.

NOTE: Layers recognition is used for tracing.

NOTE: Since the simultaneous use of multiple devices can cause misdiagnosis or result in a hazardous situation due to non-interchangeable data, exercise caution when using this instrument.

NOTE: Fully examine the measured data for tracing results. If the difference between measurement values for the left and right eyes is significant or any problem is found with the anterior chamber during the preliminary examination, check the tracing and / or reliability on the check screen. If the measurement result is not conclusive, it may be necessary to repeat the measurement.

NOTE: It may be difficult to trace the border when capturing an image of an eye with an opacity or malformation such as corneal disease, shallow anterior chamber, aphakic eye, pseudophakic eye or dense cataract eye and the data may not be reliable.

NOTE: Shaded areas indicate questionable data - such scans should be reviewed for determine accuracy. Data is often compromised by lid or ghost images from iris related issues.

NOTE: The system automatically selects C-gate mode from Top to Bottom. In cases when the ghost image touches the cornea (e.g., shallow anterior chamber) the user has to change the C-Gate mode from Bottom to Top.

NOTE: It is recommended for the user to take at least three topography scans and calculate the mean corneal curvature parameters further reduce measurement variability.

NOTE: Make sure the REVO calibration tool is well fitted to the frame.

NOTE: The system requires initial calibration.

NOTE: The initial calibration usually takes longer to complete. If the calibration ends in failure, verify if: the tool is properly installed, the testing surface inside the calibration tool is free from pollution, no strong light is reflected from the testing surface.

NOTE: [RECOVER] function does not copy data from the recovered location! Do not remove the folder after recovery.

NOTE: For the devices with serial numbers starting with 155xxxx and 156xxxx programs with Anterior Adapter are always on the bottom position of the Program list.

NOTE: When the operator acquires a tomogram using the protocol in Full-Auto mode, the system executes all programs from the protocol automatically.

NOTE: The language of voice guidance can be changed in the acquire tab.

NOTE: Make sure that the SCP host delivering the patient demographic data for tests is correctly configured and active. Otherwise, data collection will fail.

NOTE: It is not permitted to make any modifications of the REVO device.

NOTE: Periodically one must check that there is no mechanical damage to the device or to any of the cables and fuses.

NOTE: Since hard disk defragmentation usually requires several hours to complete, we recommend that defragmentation is started at the end of the day and let the process run overnight. If defragmentation is not complete in the morning, it does no harm to stop defragmentation and continue using the instrument.

NOTE: Configuring and administrating the network configuration in client-server environment requires an expertise and experience, therefore it is recommended for the internal network settings to be adjusted only by the IT personnel. They should possess the necessary skills to effectively administrate the safety, permissions and general network operations.

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

NOTE: U_T is the AC main voltage prior to the application of the test level.

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: When using the data taken by this instrument for refractive correction surgery, it is the clinician's responsibility to confirm the measurements by utilizing other instruments to measure. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or severe complication such as keratectasia.

NOTE: For PTS connection it is required to install the Firebird database components. For further details refer to the Installation manual REVO.pdf

1.6.1. Reporting adverse events

If any serious incidents occur, they must be reported to the manufacturer or the distributor and to a competent authority of the Member States in which the user is established.

1.7. Electronic User Manual Access

1. The REVO User Manual is provided with the instrument on the included SOCT USB drive.
2. To access the electronic version of the REVO manual on SOCT PC:
   - Press Win button and type SOCT or enter SOCT into search window.
   - Open the SOCT folder.
   - Click the icon for the PDF version of the REVO User Manual.

NOTE: Once opened, you can switch between the user manual and the SOCT application by pressing Alt+ Tab.

1.8. Before and After Usage

1.8.1. Before Use

1. Inspect the device daily. Make sure that the objective lens is free of foreign matter that could affect image readings or diagnoses.
2. Any dirt or scratches on the objective lens appear as black spots which may affect the image quality. Check and clean the objective lens before taking an image. You cannot obtain good images if the objective lens is not clear of debris.
3. Sudden heating of a room in cold regions may cause condensation to form externally and internally within the objective lens or on optical parts inside the device, resulting in an inability to obtain optimal images. In this case, wait until condensation disappears before taking images. Please refer to Chapter 24.1 Routine Cleaning.
4. Each day before performing a topography or biometry scan, the system will prompt the user to perform a calibration check.
5. Before turning the device on, make sure that anterior chamber adapter is not installed on the objective lens.

1.8.2. After Use

After using the REVO device, first close the SOCT software, properly shut down the PC, switch off the power to the OCT device, place the objective lens cap to protect the objective lens from dust and place the dust cover over the device.

1.9. Protective Measures for IT Systems

OPTOPOL recommends operating the REVO device only on password-protected systems. The device should only be operated on virus-protected computers / networks. The institution operating the device is responsible for the safety of the network. When using external storage media, the user is responsible for ensuring that the media is free from viruses. The consequences of virus attacks cannot be foreseen. OPTOPOL is not liable for damage due to a computer virus.

NOTE: User must periodically backup patient data. The manufacturer is not responsible for lost data.

The manufacturer recommends the use of an established antivirus software and / or firewall such as Norton or McAfee on the PC attached to the REVO. The REVO device and SOCT software has been tested by the manufacturer with anti-virus protection provided with Windows 11/Windows 10 “Microsoft Security Essentials”.

Make sure that the operating system, SOCT software, and antivirus software are working properly and up to date. Make sure that all changes, updates, and patches including operating systems, are validated prior to installation. For questions regarding cyber security, contact the manufacturer or authorized distributor.

1.10. Cybersecurity Functions

Cybersecurity risk management is a shared responsibility among stakeholders including the medical device manufacturer, the user, and the health care facility. Failure to maintain cybersecurity can result in compromised device functionality, loss of data or integrity or expose other connected devices or networks to security threats.

The purpose of this section is to summarize the cybersecurity controls for the REVO device with the Windows 11/Windows 10 operating system.

The REVO device complies with the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued October 2, 2014.

1.10.1. System Overview

The PC, with SOCT software installed, has the following interfaces that are critical for cybersecurity:

1. LAN ethernet port for the DICOM services.
2. USB ports for connecting to various USB devices.

1.10.2. Authentication of Users

CAUTION: It is recommended to run the SOCT software from a Windows account with administrator privileges.

The REVO device uses Microsoft Windows 11/Windows 10 as its operating system. The operating system itself allows the end user to establish and configure “User Accounts” and “User Passwords” so that authentication is performed by password.

The REVO PC running SOCT software can use LDAP. Please refer to Chapter 23.4.2 LDAP Settings for more information.

1.10.3. Auto Logoff

The user can select one of two available methods of automated logoff when working with the SOCT application:

1. The Windows operating system can prevent access and misuse by unauthorized users if the device is left idle. The length of inactivity time before auto-logoff / screen lock is user / administrator configurable. The auto-logoff / screen lock can be manually invoked by the user.
2. The SOCT application also comes with an automated logoff capability which the user can easily setup as explained in Chapter 23.4 User Accounts.

For questions regarding cybersecurity, contact the manufacturer or authorized distributor.

1.10.4. Ensure Trusted Content

Software and firmware updates are to be performed by an authorized OPTOPOL representative from a protected source. All updates require an admin password or authentication code. See Chapter 23.4 User Accounts.

1.10.5. Cybersecurity Event

In the event of a cybersecurity attack:

1. Disconnect the REVO device from any network.
2. Contact the IT Administrator at the user facility for an on-site evaluation.
3. Run a scan using the anti-virus software.
4. Quarantine and delete any identified threats using the anti-virus software.
5. Restore the database.
6. Reconnect to the network.
7. Contact an OPTOPOL representative if additional assistance is required.

1.10.6. Data Recovery

Methods for retention and recovery of the device configuration by an authenticated user:

1. The SOCT software provides the ability to perform data backup on internal and external storage.
2. The SOCT software has the option to perform automatic backup at the start or closing of the SOCT application. See Chapter 23.8 Backup for more information.

1.10.7. Other Implemented Mechanisms

1.10.7.1 Institutional IT Infrastructure

The SOCT software uses the Windows 11/Windows 10 operating system and supports integration into the IT infrastructure and domain at the institution or facility where the device is installed. Some facilities / institutions will have their own cybersecurity infrastructure, such as remote control of user accounts, firewalls, and encryption. The REVO device will support these site-specific IT systems, and this is verified during the installation process by an OPTOPOL representative.

1.10.7.2 Standalone Mode

The REVO device can be run without an internet connection. There is no specific requirement to be connected to the internet for the device to operate properly.

1.10.7.3 Cybersecurity and Data Backup Configurations

1. On the Windows 11/Windows 10 PC where the SOCT application will be installed, the “Windows Firewall” must be enabled.
2. The SOCT software was validated on computers with anti-virus protection provided by “Microsoft Security Essentials”.
3. Data encryption can be added through third-party tools.
4. The SOCT software provides an option for an external data backup.
5. OPTOPOL recommends that the customer regularly backup data on an external hard drive or networked drive.

1.11. Disposal

For disposal at the end of the product life cycle, please follow national regulations.

CAUTION: Do not use this instrument for purposes other than intended and specified.

2.
Technical Data

2.1. Technical Data of the REVO HR (Reference number 194-130)

FUNDUS CAMERA

Type:	Non-Mydriatic
Photography type:	Color
Camera:	Built-in 12.3-megapixel CMOS Camera
Angle of view:	45 × (1 ± 5.0 %)°
Light source:	White LED
Minimum pupil size:	3.3 mm
Working distance (Optimal):	Fundus Photo 37 mm Anterior Photo 72 mm

OCT IMAGING

Light source:	Super Luminescent Diode (SLED)
Wavelength:	870 nm, 93 nm bandwidth
Scanning speed:	130 000 A-Scans per second
Optical power:	1 575 × (1 ± 4.5 %) µW
Measurement technique:	Spectral Domain Optical Coherence Tomography

Scanning Programs:	3D, Line, Radial, Raster, Raster 21, Cross, Angio[5], Axial length[6], Topography[6]
Axial Resolution: Axial optical resolution:	3 µm in tissue (1.3 µm digital)
Transverse optical resolution: Lateral optical resolution:	Ideal 12 µm, typical 18 µm
Lateral range	Retina Scan Width: (3 to 15) mm, (18 to 21) mm with UWF Adapter[7] Angio Scan Width: (3 to 15) mm, (18 to 21) mm with UWF Adapter[7] Anterior Scan Width: (3 to 18) mm
Scan depth: Axial range	2.6 mm / ≈ 5.4 mm in Full Range mode
Minimum pupil size:	1.7 mm
Working distance (Optimal):	Posterior Segment 37 mm Anterior Segment 52 mm With the UWF adapter 15 mm[7]
Power supply:	(100 to 240) V, 50 / 60 Hz
Power consumption:	(90 to 110) VA
Fuse ratings:	2 x F 4 A H 250 V
Multiple socket outlet:	Maximum Load 500 VA
Dimensions:	477 mm (L) × 367 mm (W) × 494 mm (H)
Weight:	30 kg

[5] OCT Angiography is an optional software module available for the REVO device. If you do not have this feature and want to purchase it, contact OPTOPOL's local distributor.

[6] Biometry and Topography are available as optional software modules for the REVO device. If you do not have these features and want to purchase them, contact OPTOPOL's local distributor.

[7] Ultra-Wide Field is an optional module available for OCT with Fundus Camera camera only. If you do not have this feature and want to purchase it contact Optopol's local distributor.

2.2. Technical Data of the REVO FC 130 (Reference number 193-130)

FUNDUS CAMERA

Type:	Non-Mydriatic
Photography type:	Color
Camera:	Built-in 12.3-megapixel CMOS Camera
Angle of view:	45 × (1 ± 5.0 %)°
Light source:	White LED
Minimum pupil size:	3.3 mm
Working distance (Optimal):	Fundus Photo 37 mm Anterior Photo 72 mm

OCT IMAGING

Light source:	Super Luminescent Diode (SLED)
Wavelength:	850 nm
Scanning speed:	130 000 A-Scans per second
Optical power:	1 575 × (1 ± 4.5 %) µW
Measurement technique:	Spectral Domain Optical Coherence Tomography
Scanning programs:	3D, Line, Radial, Raster, Raster 21, Cross, Angio[8], Axial length[9], Topography[9]
Axial resolution: **Axial optical resolution:**	5 µm in tissue (2.8 µm digital)

[8] OCT Angiography is an optional software module available for the REVO device. If you do not have this feature and want to purchase it, contact OPTOPOL's local distributor.

[9] Biometry and Topography are available as optional software modules for the REVO device. If you do not have these features and want to purchase them, contact OPTOPOL's local distributor.

Transverse optical resolution: Lateral optical resolution:	Ideal 12 µm, Typical 18 µm
Lateral range Scan width:	Retina Scan Width: (3 to 15) mm, (18 to 21) mm with UWF Adapter[10] Angio Scan Width: (3 to 15) mm, (18 to 21) mm with UWF Adapter[10] Anterior Scan Width: (3 to 18) mm
Scan depth: Axial range	2.8 mm / ≈6 mm in Full Range mode
Minimum pupil size:	1.7 mm
Working distance (Optimal):	Posterior Segment 37 mm Anterior Segment 52 mm With the UWF adapter 15 mm[10]
Power supply:	(100 to 240) V, 50 / 60 Hz
Power consumption:	(90 to 110) VA
Fuse ratings:	2 x F 4 A H 250 V
Multiple socket outlet:	Maximum Load 500 VA
Dimensions:	477 mm (L) × 367 mm (W) × 494 mm (H)
Weight:	30 kg

2.3. Technical Data of the REVO FC (Reference Number 190-80)

FUNDUS CAMERA

Type:	Non-Mydriatic
Photography type:	Color
Camera:	Built-in 12.3-megapixel CMOS Camera

[10] Ultra-Wide Field is an optional software module available for REVO FC devices (OCT with Fundus Camera). If you do not have this feature and want to purchase it contact Optopol's local distributor.

Angle of view:	45 × (1 ± 5.0 %)°
Light source:	White LED
Minimum pupil size:	3.3 mm
Working distance (Optimal):	Fundus Photo 37 mm Anterior Photo 72 mm

OCT IMAGING

Light source:	Super Luminescent Diode (SLED)
Wavelength:	850 nm
Scanning speed:	80 000 A-Scans per second
Optical power:	1 200 × (1 ± 4.5 %) µW
Measurement technique:	Spectral Domain Optical Coherence Tomography
Scanning programs:	3D, Line, Radial, Raster, Raster 21, Cross, Angio[11], Axial length[12], Topography[12]
Axial resolution: Axial optical resolution:	5 µm in tissue (2.8 µm digital)
Transverse optical resolution: Lateral optical resolution:	Ideal 12 µm, Typical 18 µm
Lateral range Scan width:	Retina Scan Width: (5 to 15) mm, (18 to 21) mm with UWF Adapter[13] Angio Scan Width: (3 to 9) mm, (18 to 21) mm with UWF Adapter[13] Anterior Scan Width: (3 to 18) mm

[11] OCT Angiography is an optional software module available for the REVO device. If you do not have this feature and want to purchase it, contact OPTOPOL's local distributor.

[12] Biometry and Topography are available as optional software modules for the REVO device. If you do not have these features and want to purchase them, contact OPTOPOL's local distributor.

[13] Ultra-Wide Field is an optional software module available for REVO FC devices (OCT with Fundus Camera). If you do not have this feature and want to purchase it contact Optopol's local distributor.

Scan depth: Axial range	2.8 mm / ≈6 mm in Full Range mode
Minimum pupil size:	1.7 mm
Working distance (Optimal):	Posterior Segment 37 mm Anterior Segment 52 mm With the UWF adapter 15 mm[14]
Power supply:	(100 to 240) V, 50 / 60 Hz
Power consumption:	(90 to 110) VA
Fuse ratings:	2 x F 4 A H 250 V
Multiple socket outlet:	Maximum Load 500 VA
Dimensions:	477 mm (L) × 367 mm (W) × 494 mm (H)
Weight:	30 kg

2.4. Technical Data of the REVO nx 130 (Reference Number 192-130)

OCT IMAGING

Light source:	Super Luminescent Diode (SLED)
Wavelength:	850 nm
Scanning speed:	130 000 A-Scans per second
Optical power:	1 575 × (1 ± 4.5 %) µW
Measurement technique:	Spectral Domain Optical Coherence Tomography
Scanning programs:	3D, Line, Radial HD, Raster, Raster 21, Cross, Angio[15], Axial length[16], Topography[16]

[14] Ultra-Wide Field is an optional software module available for REVO FC devices (OCT with Fundus Camera). If you do not have this feature and want to purchase it contact Optopol's local distributor.

[15] OCT Angiography is an optional software module available for the REVO device. If you do not have this feature and want to purchase it, contact OPTOPOL's local distributor.

[16] Biometry and Topography are available as optional software modules for the REVO device. If you do not have these features and want to purchase them, contact OPTOPOL's local distributor.

Axial resolution: Axial optical resolution:	5 µm in tissue (2.8 µm digital)
Transverse optical resolution: Lateral optical resolution:	Ideal 12 µm, Typical 18 µm
Lateral range Scan range:	Retina Scan Width: (3 to 15) mm Angio Scan Width: (3 to 9) mm Anterior Scan Width: (3 to 18) mm
Scan depth: Axial Range	2.8 mm / ≈6 mm in Full Range mode
Minimum pupil size:	1.7 mm
Working distance (Optimal):	Posterior Segment 37 mm Anterior Segment 56 mm
Power supply:	(100 to 240) V, 50 / 60 Hz
Power consumption:	(90 to 110) VA
Fuse ratings:	2 x F 4 A H 250 V
Multiple socket outlet:	Maximum Load 500 VA
Dimensions:	477 mm (L) × 367 mm (W) × 494 mm (H)
Weight:	29 kg

2.5. Technical Data of the REVO 60 (Reference Number 191-60) and the REVO 80 (Reference Number 191-80)

OCT IMAGING

Light Source:	Super Luminescent Diode (SLED)
Wavelength:	850 nm

Scanning speed:	60 000 / 80 000 A-Scans per second
Optical power:	1 100 × (1 ± 4.5 %) / 1 200 × (1 ± 4.5 %) µW
Measurement technique:	Spectral Domain Optical Coherence Tomography
Scanning programs:	3D, Line, Radial HD, Raster, Raster 21, Cross, Angio[17], Axial length[18], Topography[18]
Axial resolution: Axial Optical Resolution:	5 µm in tissue (2.8 µm digital)
Transverse optical resolution: Lateral optical resolution:	Ideal 12 µm, Typical 18 µm
Lateral range Scan range:	Retina Scan Width: (5 to 15) mm Angio Scan Width: (3 to 6) mm Anterior Scan Width: (3 to 18) mm
Scan depth: Axial range	2.8 mm / ≈6 mm in Full Range mode
Minimum pupil size:	1.7 mm
Working distance (Optimal):	Posterior Segment 37 mm Anterior Segment 56 mm
Power supply:	(100 to 240) V, 50 / 60 Hz
Power consumption:	(90 to 110) VA
Fuse ratings:	2 x F 4 A H 250 V
Multiple socket outlet:	Maximum Load 500 VA
Dimensions:	477 mm (L) × 367 mm (W) × 494 mm (H)

[17] OCT Angiography is an optional software module available for the REVO device. If you do not have this feature and want to purchase it, contact OPTOPOL's local distributor.

[18] Biometry and Topography are available as optional software modules for the REVO device. If you do not have these features and want to purchase them, contact OPTOPOL's local distributor.

Weight:	29 kg

2.6. Technical Data of the REVO nx 130 (Reference Number 156-130) and the REVO nx (Reference Number 156-110)

OCT IMAGING

Light source:	Super Luminescent Diode (SLED)
Wavelength:	830 nm
Scanning speed:	130 000 / 110 000 A-Scans per second
Optical power:	1 575 × (1 ± 4.5 %) µW
Measurement technique:	Spectral Domain Optical Coherence Tomography
Scanning programs:	3D, Line, Radial HD, Raster, Raster 21, Cross, Angio[19], Axial length[20], Topography[20]
Axial resolution: Axial optical resolution:	5 µm in tissue (2.6 µm digital)
Transverse optical resolution: Lateral optical resolution:	Ideal 12 µm, Typical 18 µm
Lateral range Scan range:	Retina Scan Width: (5 to 12) mm Angio Scan Width: (3 to 9) mm Anterior Scan Width: (3 to 16) mm
Scan depth: Axial range	2.8 mm / 4.8 mm in Full Range mode
Minimum pupil size:	2.4 mm

[19] OCT Angiography is an optional software module available for the REVO device. If you do not have this feature and want to purchase it, contact OPTOPOL's local distributor.

[20] Biometry and Topography are available as optional software modules for the REVO device. If you do not have these features and want to purchase them, contact OPTOPOL's local distributor.

Working distance (Optimal):	Posterior Segment 23 mm Anterior Segment 52 mm
Power supply:	100 – 240 V, 50 / 60 Hz
Power consumption:	115-140 VA
Fuse ratings:	2 x F 3.15 A L 250 V
Multiple socket outlet:	Maximum Load 500 VA
Dimensions:	556 mm (L) × 382 mm (W) × 469 mm (H)
Weight:	23 kg

2.7. Technical Data of the SOCT Copernicus REVO and SOCT Copernicus (Reference Number 155-27), REVO 60 (Reference Number 155-60) and REVO 80 (Reference Number (155-80)

OCT IMAGING

Light source:	Super Luminescent Diode (SLED)
Wavelength:	830 nm
Scanning speed:	27 000 / 60 000 / 80 000 A-Scans per second
Optical power:	1 100 × (1 ± 4.5 %) / 1 100 × (1 ± 4.5 %) / 1 200 × (1 ± 4.5 %) µW
Measurement technique:	Spectral Domain Optical Coherence Tomography
Scanning programs:	3D, Line, Radial, Raster, Raster 21, Cross, Angio[21], Axial length[22], Topography[22]
Axial resolution: **Axial optical resolution:**	5 µm in tissue (2.6 µm digital)

[21] OCT Angiography is an optional software module available for the REVO device. If you do not have this feature and want to purchase it, contact OPTOPOL's local distributor.

[22] Biometry and Topography are available as optional software modules for the REVO device. If you do not have these features and want to purchase them, contact OPTOPOL's local distributor.

Transverse optical resolution: Lateral optical resolution:	Ideal 12 µm, Typical 18 µm
Lateral range Scan range:	Retina Scan Width: (5 to 12) mm Angio Scan Width: (3 to 6) mm Anterior Scan Width: (3 to 16) mm
Scan depth: Axial range	2.8 mm / 4.8 mm in Full Range mode
Minimum pupil size:	2.4 mm
Working distance (Optimal):	Posterior Segment 23 mm Anterior Segment 52 mm
Power supply:	(100 to 240) V, 50 / 60 Hz
Power consumption:	(115 to 140) VA
Fuse ratings:	2 x F 3.15 A L 250 V
Multiple socket outlet:	Maximum Load 500 VA
Dimensions:	556 mm (L) × 382 mm (W) × 469 mm (H)
Weight:	23 kg

2.8. Device Classification

Classification:	Class 1 Laser Device (IEC 60825-1:2014)
Protection against Electric Shock:	Class 1
Degree of Protection against Shock:	Type B applied parts (chin rest, forehead rest) and ground
Degree of Protection against Ingress of Water:	IPX0

Mode of Operation:	Continuous operation

2.9. Minimum System Requirements

2.9.1. REVO Connected PC

Processor:	12th Generation Intel® Core™ i7 *
RAM:	64 GB** for REVO FC 130 and REVO HR 32 GB for REVO FC, REVO nx 130, REVO 80, REVO 60
Operating System:	Windows 11 Professional 64-bit, Windows 10 Professional 64-bit
Storage capacity:	500 GB (a 256 GB SSD for the OS and a 1TB SSD for Patient Data recommended)
Graphics Card:	NVIDIA GeForce GPU with at least 4 GB of memory (6 GB or more recommended) CUDA support (version 11.2.0 or higher) NVIDIA Studio graphics drivers (version 461.92 or higher)
Screen Resolution:	1920 x 1080 (Full HD), 3840 x 2160 (4K)***
Communication Ports:	1 available USB 3.0 port 2 available USB 2.0 ports
Network card	1GB/s (2.5 GB/s or higher recommended)
Mouse:	Mouse with a wheel
Touchscreen:	Optional

*Desktop type processors are supported (Standard, K, F, S, T, X, XE) only. Learn more from https://www.intel.com/content/www/us/en/processors/processor-numbers.html

**64GB of RAM it is required when OCT-A module is used on REVO FC 130 and REVO HR.

***For graphical objects to be scaled correctly when using 4K resolution, it is recommended to set text scaling to 200% in the screen settings window of the Windows operating system.

2.9.2. SOCT Software Review Station

Processor:	Intel® Core™i5 2.4 GHz or higher
RAM:	32 GB or more recommended (64 GB recommended if examinations reviewed were conducted on the REVO FC 130 or REVO HR)
Operating System:	Windows 11 Professional 64-bit, Windows 10 Professional 64-bit
Storage capacity:	256 GB (a 256 GB SSD recommended)
Graphics Card:	NVIDIA GeForce RTX with CUDA version 11.2.0 or higher support and NVIDIA Studio graphics drivers (version 461.92 or higher) or an Intel graphics chipset e.g., Intel 630
Screen Resolution:	1920 x 1080 (Full HD), 3840 x 2160 (4K)*
Communication Ports:	2 available USB 2.0 ports
Network card:	Network card supporting 1GB/s (2.5 GB/s or higher recommended)
Mouse:	Mouse with a wheel

* For graphical objects to be scaled correctly while using 4K resolution, it is recommended to set text scaling to 200% in the screen settings window of the Windows operating system.

2.10. Device Scan Types and Programs

Scan Mode	Scan Program
Retina	1. Retina 3D (up to 12mm x 12mm) 2. Retina Raster (up to 12mm 3. Retina Raster 21 (up to 12 mm) 4. Retina Line (up to 15mm) 5. Retina Cross (up to 15mm x 15mm) 6. Retina Radial (up to 15mm diameter) 7. Retina Angio 3x3 (3mm x 3mm)[23] 8. Retina Angio Wide 6x6 (up to 15mm x 15mm)[23] 9. Angio Mosaic 10x6 (6mm x 6mm)[23] 10. Angio Mosaic 12x5 (5mm x 5mm)[23] 11. Angio Mosaic 10x10 (6mm x 6mm)[23] 12. Angio Mosaic 7x7 (4mm x 4mm)[23]
Disc	1. Disc 3D (up to 7mm x 7mm) 2. Disc Line (up to 7mm) 3. Disc Radial (up to 7 mm diameter) 4. Disc Angio (up to 6mm x 6mm)
Widefield	1. Widefield 3D (up to 15mm x 15mm) 2. Widefield Raster (up to 15mm) 3. Widefield Full Range Line (14mm)
Ultra-Wide Field[23]	1. Ultra-Wide Field 3D[23] 2. Ultra-Wide Field Radial[23] 3. Ultra-Wide Field Angio[23] 4. Ultra-Wide Field Line[23] 5. Ultra-Wide Field Full Range Radial[23]
Anterior	1. Anterior Radial (8mm diameter) 2. Anterior 3D (up to 18mm x 18mm) 3. Anterior Raster (up to 18mm) 4. Anterior Line (up to 18mm) 5. Anterior Cross (18mm x 18mm) 6. Anterior Chamber Line Full Range (up to 18mm) 7. Anterior Chamber Radial Full Range (up to 18mm diameter) 8. Anterior Chamber Cross Full Range (up to 18mm x 18mm)
Topography[23]	1. Topography (8mm diameter) [23]
Biometry[23]	1. Biometry AL (3mm x 3mm x auto) [23]

[23] Mode is available as optional software module.

3.
Setup and Installation

CAUTION: Check for any damage to the package. Every transportation box is equipped with shock watches. If any shock watch is broken (red indicator), please contact OPTOPOL and file a complaint with the carrier.

The REVO set consists of the following components:

1. REVO device
2. External fixation adapter.
3. Anterior adapter (not applicable to the devices with reference number REF 190, 191, 192, 193 and 194).
4. UWF adapter (applicable to the devices with reference number REF 190, 193 and 194)[24]
5. Dust cover.
6. Power supply cable.
7. Lens cover.
8. USB 3.0 communication cable.
9. USB flash drive with the SOCT software, PC drivers and the REVO User Manual PDF.
10. Calibration tool (provided with the optional OCT Biometry and Topography modules only).
11. Chinrest papers.

3.1. Unpacking

This section describes how to unpack the device shipped from the factory. Remove the safety tapes. Remove the top of the box and side walls. Remove transport foams. The figures indicate where to grab the device while moving it. It should be lifted by at least two persons. Firmly hold the instrument body **at the base of the device** as indicated below and put it on the automatic instrument table. DO NOT lift the device holding it by the headrest assembly nor the indentation area located at the back of the device above the rear panel.

[24] Ultra-Wide Field is an optional software module available only for the REVO OCT models with Fundus Camera. If you do not have this feature and want to purchase it contact Optopol's local distributor.

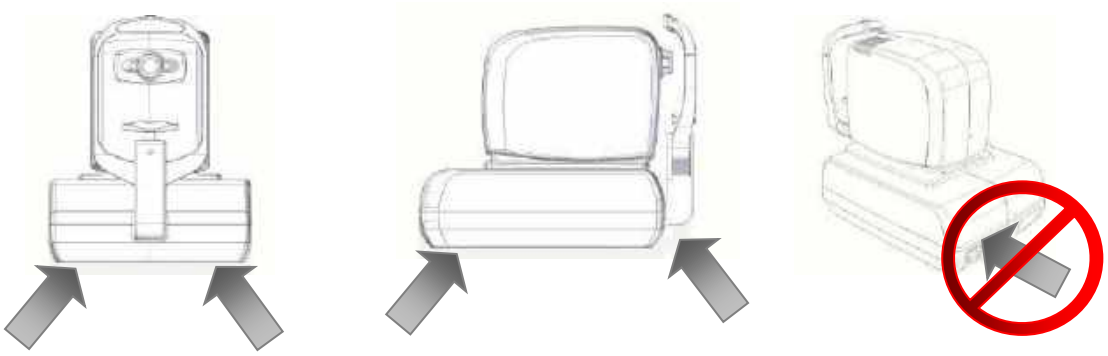


Figure 6.
Proper Location to Hold the Chassis of the devices with REF 155 and 156

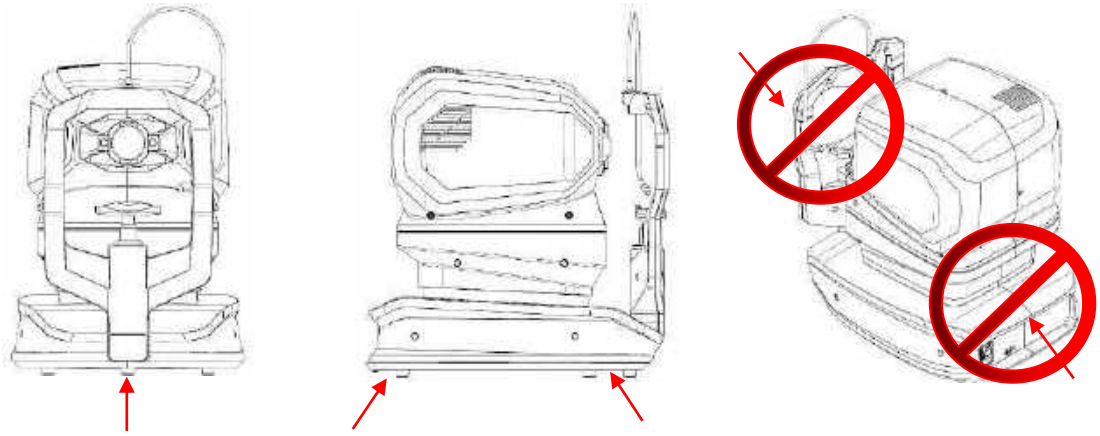


Figure 7.
Proper Location to Hold the Chassis of the devices with REF 190, 191, 192, 193 and 194

CAUTION: The REVO device weighs approximately 23 kg (REF 155 and 156), 29 kg (REF 191 and 192) or 30 kg (REF 190, 193 and 194). It should be lifted by at least two persons. Use only the indicated positions for lifting.

CAUTION: After unpacking, check the unit and all accessories for mechanical damage, cables damage, etc. In case any damage is found, do not connect the device and contact OPTOPOL or your authorized distributor.

CAUTION: The REVO device should be placed in a room with a regulated temperature. Do not turn on the device if exposed to extreme temperatures. Always operate the device within operating ranges of temperature and humidity. For specific information on Environmental conditions, please refer to Chapter 27 Environmental Conditions.

CAUTION: Transportation position of the REVO device is to be set by turning it off and on – this will cause the device to go to the base position. Turn it off and pack in the box while securing with packing foams.

3.2. Connecting Cables

The REVO device is connected to the PC running the SOCT software with the included USB 3.0 (Type B) cable.

Figure 8.
USB cable

Power supply cables are provided by local distributor.

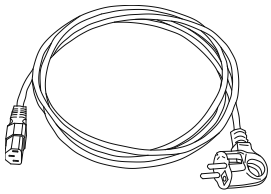


Figure 9.
Power supply cable

An AC power supply cable is provided as well. All power cords and plug assemblies must be certified and suitable for use in the given country based on the IEC 60601-1:2005, AMD1:2012, AMD2:2020 standard.
All sockets and plugs are specific, so it is not possible to connect plugs improperly. The figure below shows the rear panel view of the REVO devices.

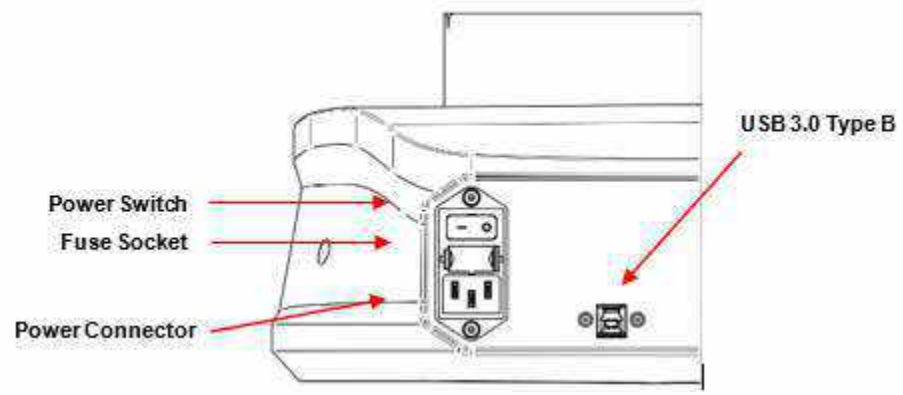


Figure 10.
Rear Panel of the devices with REF 190, 191, 192, 193 and 194

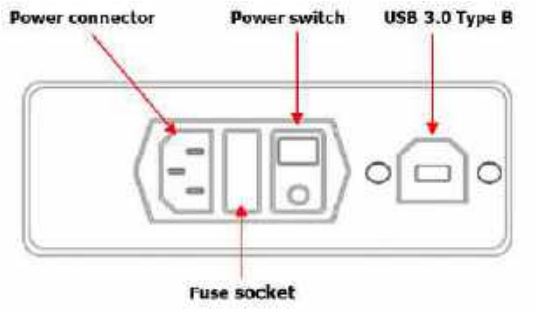


Figure 11.
Rear Panel of the devices with REF 155 and 156

First connect the USB cable, then connect the power supply cables.

The power switch has two positions:

1. **(I):** The device is ON.
2. **(O):** The device is OFF.

NOTE: To power off the device, turn OFF the power switch (Position O).

NOTE: The user should not remove the power cable without first switching the power switch to the OFF position (O).

NOTE: Regarding EMC (Electro-magnetic compatibility) standards all signal cables have to be put together.

3.3. Device Diagram and Connections

The REVO device is connected to the PC using a USB 3.0 cable.

NOTE: The REVO device must be directly plugged into a grounded main socket. Connect the PC, printer and monitor into the multiple portable socket-outlet, which is directly connected to the isolating transformer. By connecting the PC set to the isolating transformer, the leakage current is reduced to the level which is in line with the IEC standard. The isolating transformer is connected directly to the main power with a protective ground pin.

The diagram below shows how to connect all elements of the system.

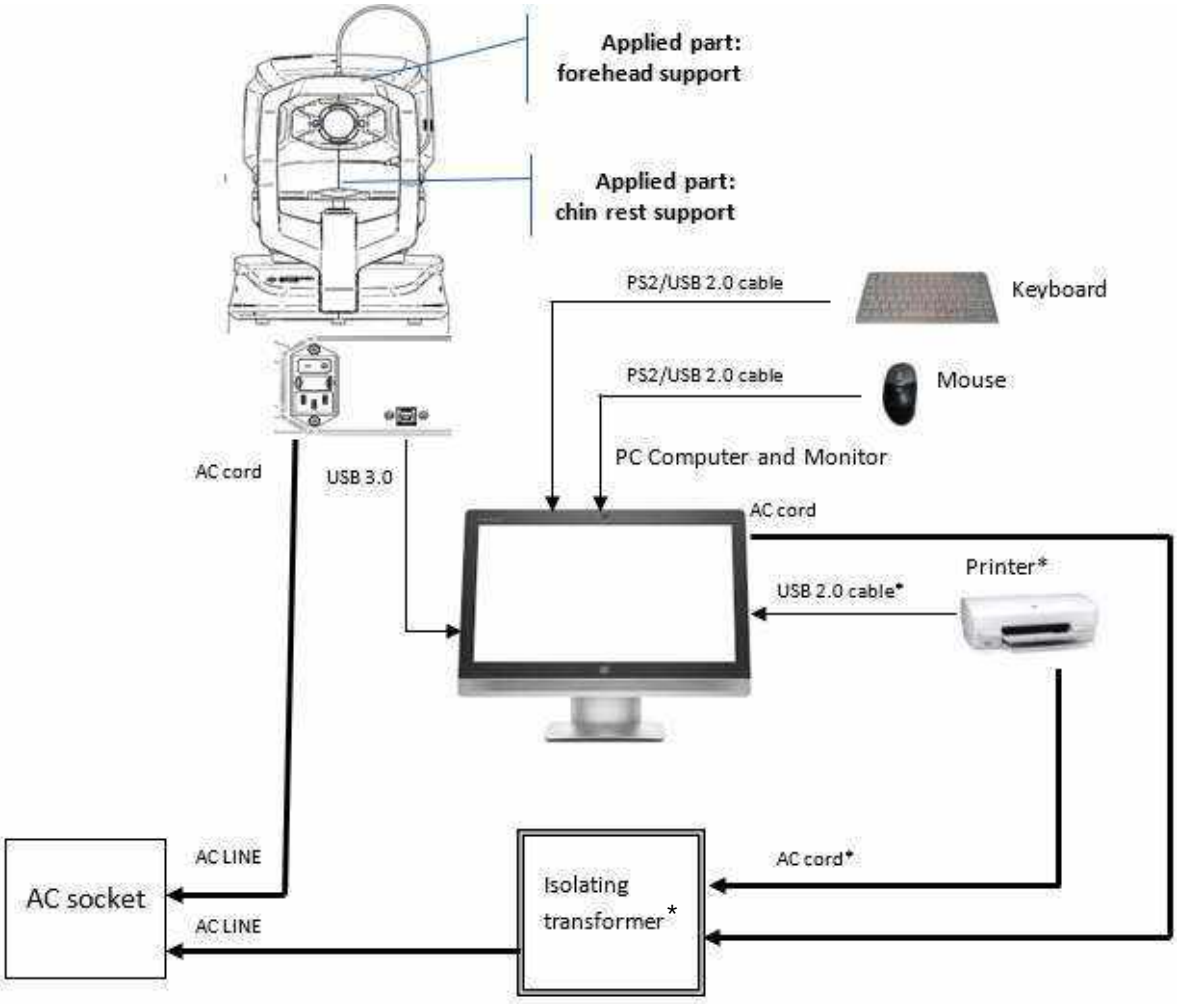


Figure 12.
Electrical Connections Diagram

*Components of a REVO system which are not provided by OPTOPOL Technology.

3.4. REVO Hardware Design

Hardware design of the REVO HR (REF 194), REVO FC 130 (REF 193); REVO FC (REF 190); SOCT Copernicus REVO (SOCT Copernicus)/REVO 60/REVO 80 (REF 191); REVO nx 130 (REF 192)

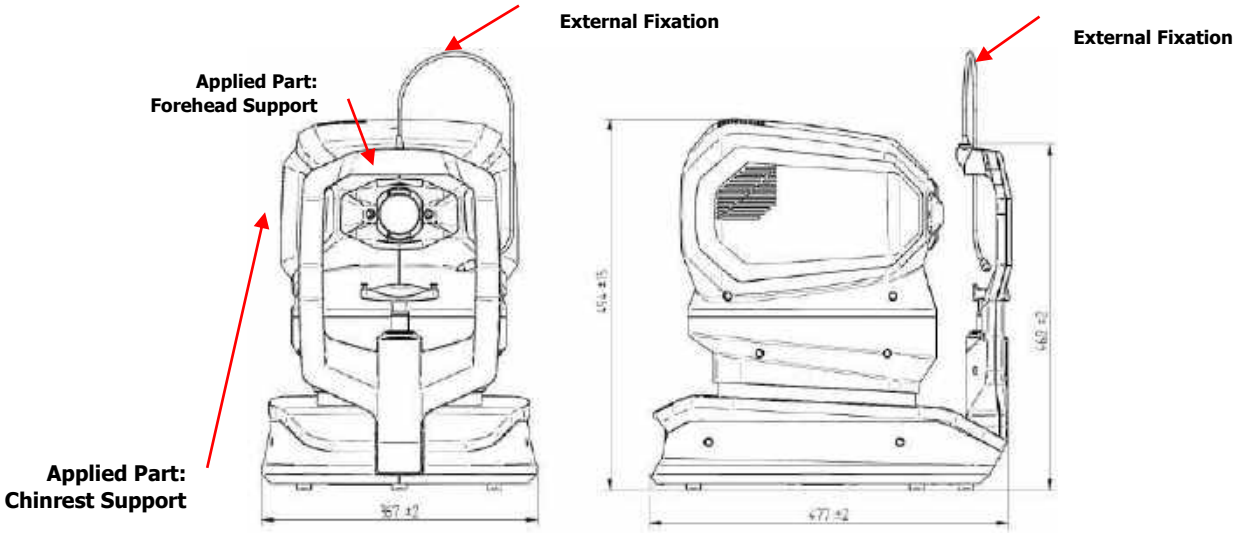


Figure 13.
Front and Sideview of the devices with REF 190, 191, 192, 193 and 194

SOCT Copernicus REVO (SOCT Copernicus)/REVO 60/REVO 80 (REF 155); REVO nx/REVO nx 130 (REF 156)

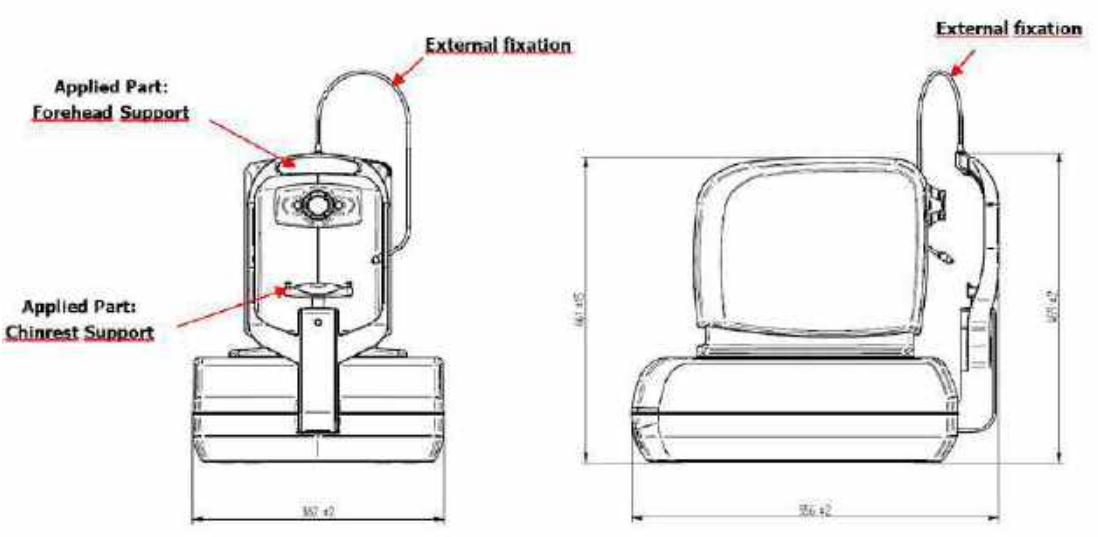


Figure 14.
Front and Sideview of the devices with REF 155 and 156

3.5. Factory Default Calibration and Configuration

The system is delivered fully installed and configured by the local OPTOPOL representative. No user installation or configuration is needed.

On the computer connected to the device, the Windows screen saver and power options on the computer must be set as shown in the table below:

Item	Setting
Screen Saver	None
Turn Off the Display	Never
Put the Computer to Sleep	Never
Turn Off Hard Disks	Never
When the Power Button is Pressed	Shutdown
Start Menu Power Button	Shutdown

4. Introduction

4.1. Purpose of this Manual

OPTOPOL designed this user manual to serve as a reference guide for training and usage of the REVO device and SOCT software. Read the entire user manual to gain a full understanding of proper scanning and operation. This does not replace the need for on-site training. The operator must have access to the User Manual. The User Manual also provides chapter links and references for easier navigation.

4.2. Device Description

SOCT uses Spectral Domain Optical Coherence Tomography method to obtain 3-dimensional and cross-sectional images of the retina.

SOCT is an optical coherence tomography system indicated for the in vivo imaging and measurement of the retina layers, retina nerve fiber layer, and optic nerve head as an aid in the diagnosis and management of posterior segment diseases as well as imaging of anterior segment structure.

The SOCT contains features including: Retina Thickness, Optical Nerve Head, Retinal Nerve Fiber Layer, Angle assessment, Cornea measurement, Blood vessels visualization, measuring distances along the visual axis.

The SOCT software with optional OCT Angiography visualization functionality is indicated as an aid in the visualization of vascular structures of the retina and choroid.

The SOCT software with optional Corneal Topography function is intended to measure and visualize anterior and posterior corneal curvatures.

The SOCT software with optional OCT Biometry function is intended for biometric measurements and visualization of ocular structures and performing IOL power calculations based on the patient's biometric data and a selection of recognized IOL calculation formulas.

REVO OCT models with Fundus Camera allow non-contact biomicroscopic imaging that incorporates a high-resolution digital camera for photographing, displaying and storing images of the retina and surrounding parts of the eye to be examined under Mydriatic and non-Mydriatic conditions. REVO OCT models with Fundus Camera provide images which are display only and the device does not provide any diagnostic, pathological analysis or classification of ocular health based on the acquired images.

4.2.1. Intended Use

The SOCT is intended for use as a diagnostic device to aid the detection and management of ocular diseases, including but not limited to, age-related macular degeneration, macular holes, diabetic retinopathy, macular edema and glaucoma.

With optional OCT Biometry software feature the device is intended to measure ocular structure along the eye axis. It measures the following parameters: Axial Length (AL), Central Corneal Thickness (CCT), Anterior Chamber Depth (ACD), Lens Thickness (LT), Pupil Diameter (P), White-to-White distance (WTW). The measurement and visualization assist in the determination of the appropriate power and type of intraocular lens.

With optional OCT Topography software feature the device is intended to quantify curvatures of the anterior and posterior surfaces of the cornea. It measures the following parameters: Corneal curvature (K1 and K2 keratometry values), Cylindrical power (CYL) and Axis, Average and Total corneal power (ACP and TCP), anterior and posterior power and Keratoconus prediction index (KPI).

With optional OCT Angiography software feature the device is indicated as an aid in the visualization of vascular structures of the retina and choroid.

REVO OCT models with Fundus Camera provide the images of the retina and external area of the eye and are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.

WARNING: The system is not intended to be used as the sole diagnostic aid in disease identification, classification, or management. The system provides data to be used in conjunction with other information intended to assist an eye care clinician in determining a diagnosis. Medical diagnosis is the sole domain of a licensed eye care clinician.

CAUTION: OPTOPOL Technology does not offer advice or instruction in the diagnosis and interpretation of OCT images. It is the clinician's responsibility to diagnose and interpret OCT scans.

4.3. Technical Description

4.3.1. Optical Coherence Tomography (OCT)

The REVO device uses a spectrometer based partial coherence interferometric technique that provides three-dimensional imaging based on backscattered infrared light. Tissue structure contrast is primarily provided by differences in refraction index. The device produces a light beam, which is focused on human eye tissue. The image of the tissue (retina or anterior segment) is obtained using the principle of optical interference in where emitted light is separated into two portions that are reflected onto the fiber coupler and re-joined, forming a low interference wave that is then separated by the diffraction grating converted into an electric signal for analysis. The raw data is processed by a computer to obtain data of cross-sectional tissue structure. This data is then processed, resulting in a tomogram which can be observed, recorded, and allows clinical assessment.

4.3.2. OCT Qualitative Imaging

REVO OCT models with Fundus Camera provide color fundus images as "display only" and the device does not provide any diagnostic, pathological analysis or classification of ocular health based on the acquired images.

4.3.3. Color Fundus Photography (CFP)[25]

REVO OCT models with Fundus Camera integrate a digital fundus camera that allows non-contact biomicroscopic imaging that incorporates a high-resolution digital camera for photographing, displaying,

[25] Programs available only for the REVO OCT models with Fundus Camera.

and storing images of the retina and surrounding parts of the eye to be examined under mydriatic and non-mydriatic conditions. The fundus camera includes color imaging, digital red-free imaging, and infrared light imaging (IR imaging) capabilities for fundus observation.

4.3.4. OCT-Angiography (OCT-A) (Optional)

The SOCT software has an optional OCT-A module available. The OCT-A module provides several OCT Angiography scan programs. These scans provide a view of the retinal vasculature, which allows for manual measurement of the delineation of the foveal avascular zone (FAZ).

4.3.5. Corneal Topography (T-OCT™) (Optional)

The REVO device has an optional software based Corneal Topography (T-OCT™) module available. The T-OCT™ module provides one additional Topography scan program. This scan provides corneal curvature parameters.

4.3.6. Biometry (B-OCT®) (Optional)

The REVO device has an optional software-based Biometry (B-OCT®) module available. The B-OCT® module provides one additional Biometry scan program. The device is used for visualization and measurements along the axis of the eyeball, which can be utilized for the calculation of the refractive power of the intraocular lens (IOL) to be implanted.

4.3.7. Ultra-wide Field (UWF-OCT) (Optional)

The REVO device has an optional software Ultra-Wide (UWF-OCT) module available for the OCT models equipped with a fundus camera. The UWF-OCT module provides several Ultra-Wide scan programs. With UWF adapter attached, the device provides much wider scans up to 21 mm width and height. If OCT-Angiography is bought, there is also Ultra-Wide Angiography program available.

4.4. Intended User

The REVO device is intended for use by Eye Care Professionals including Ophthalmologists, Optometrists, Opticians, Orthoptists, and other trained health personnel.

4.4.1. Qualification of Personnel

The user must be able to distinguish between the right eye and the left eye, chin, and forehead, and be able to read and understand the language and the functionality used in the SOCT software.

The device is intended for persons who are experienced and trained in the operation of ophthalmic imaging and diagnostic equipment. These include Eye Care Professionals such as Ophthalmologists, Optometrists, Nurses, Medical Technicians, Ophthalmic Assistants, Ophthalmic Technicians, Ophthalmic Imagers, Ophthalmic Imaging Specialists, and Retinal Angiographers.

4.4.2. Operating Skills

For instrument operation, the user should be able to perform the following functions:

1. Power on and power off the device.
2. Disinfect surfaces which interact with the patient.
3. Enter and modify the patient data.

4. Adjust the position of the patient, position of the instrument, the table height, and the patient's chair.
5. Set the examination parameters.
6. Acquire examination results.
7. Select or create the required type of printout.
8. Verify the printout for completeness of data.
9. Print, export and save the selected report.
10. Archive and recover the patient database.

4.4.3. Occupational Skills

The operator must possess the following skills:

1. Computer literacy.
2. Basic knowledge of the eye.
3. Ability to work with children, elderly patients and those with disabilities.

4.4.4. Data Interpretation

DEMOGRAPHIC

1. Ophthalmologist
2. Optometrist or equivalent
3. Other Eye Care Professional

REQUIREMENTS

1. Eye care professionals must have training and certification as required by the governing bodies to interpret the analysis in the treatment of ophthalmic diseases or other eye-related medical issues.
2. Users must be suitably trained and be familiar with the instructions, cautions, and warnings contained in this User Manual.

CAUTION: This manual does not provide guidance on interpretation of clinical results. The clinician must ensure that they have received appropriate medical training in such interpretation. OPTOPOL is not responsible for misdiagnosis of results.

4.5. Places of Use

The REVO device is intended for use in hospitals, eye care centers / clinics and surgery / operating rooms.

4.6. Patient Population

The patient must be capable of sitting up straight and keeping their head still. They must be physically and mentally capable and willingly cooperate to follow direction to execute the examination. The patient must be at least 5 years old.

4.7. Proper Instrument Use

1. Always enter patient information first.
2. Clean surfaces which make contact with patient (forehead and chin rest) with dedicated disinfectant substance.
3. Check the patient's head position before raising the chin rest.
4. Clean the ocular lens, if necessary, to ensure good image quality. Refer to Chapter 24 Maintenance and Cleaning Procedure for more information.
5. Adjust the power table height properly to ensure patient comfort during the examination.
6. Raise or lower the patient's head so the eye aligns with the canthus mark on the chin and forehead rest assembly.
7. Warn others not to sit or stand on any part of the table, including the base and the tabletop.
8. When lowering the table, make sure the patient is clear of the table
9. Do not store articles on the table base and tabletop.

NOTE: Chemically induced pupil dilation is not typically needed, but can be used if necessary.

4.8. Contraindications

Do not use the REVO device for those patients who:

1. Have a history of photo sensitivity disorders.
2. Have had PDT therapy in the past 48 hours (refer to the product document of administered photosensitizer about the prohibition period).

WARNING: This device is not designed, sold or intended for use except as indicated in this manual.

WARNING: The system is not intended to be used as the sole diagnostic aid in disease identification, classification, or management. The system provides data to be used in conjunction with other information intended to assist an eye care clinician in determining a diagnosis. Medical diagnosis is the sole domain of a licensed eye care clinician.

4.9. Instruction Manual Availability

The Instruction Manual for the REVO device is available in PDF format on the computer with SOCT software installed. To open the file, press **START → Application → SOCT → User Manual**. The

manual is included on a USB flash drive delivered with the standard package of the SOCT software. Install the .pdf file viewer (e.g., free Adobe Reader, from the www.adobe.com website or flash drive to open and read the manual in PDF format.)

A hard copy of the user manual may be available upon request, please contact an authorized OPTOPOL representative.

4.10. Instruction Manual Applicability

This document applies to the REVO device with software version 20.0 or higher, unless superseded.

5. Getting Started

The SOCT software has been developed to provide a smooth user experience. The software provides access to the three main functions: **Patient Tab - patient database, Acquire Tab - exam acquisition screen**, and **Results Tab - results analysis screen**.

The dedicated REVO device capture station running SOCT software allows users to capture from the attached REVO device. Any SOCT software review station software only allows for review of examinations and disables the exam **Acquire** tab option.

5.1. System Startup

Follow these instructions, in order, to properly turn on the REVO device system:

1. Power on the attached PC.
2. Login into the Windows.
3. Power on REVO device.
4. Open SOCT software.

CAUTION: Always turn the PC ON first, and then after PC is fully loaded into Windows OS, turn ON the REVO device.

5.2. SOCT Software Settings Initial Setup

The SOCT software must be set up before the first use.

1. From the Login screen enter Login name and Password.
2. Click **[SETUP]** button at upper right of Login Window.

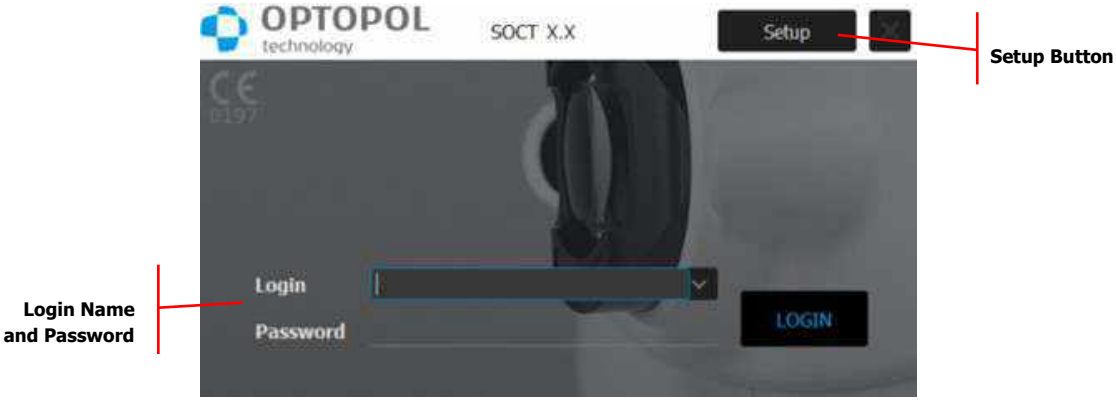


Figure 15.
Login Screen

3. Set all necessary settings. See Chapter 23 Settings and Setup Window.

5.3. System Shutdown

Follow these instructions to properly turn off the REVO device system:

1. Click the **[X]** button in the top right corner of the SOCT software to perform auto backup (Backup must be configured) and SOCT software will shut down.
2. Switch off power for the REVO device.
3. Click Windows **Start** button and choose '**Power > Shut down**'.

5.4. SOCT Application Structure

The application has been created to be user-friendly. The buttons are clear and ergonomically located.

The Login screen will appear after starting the SOCT software application.

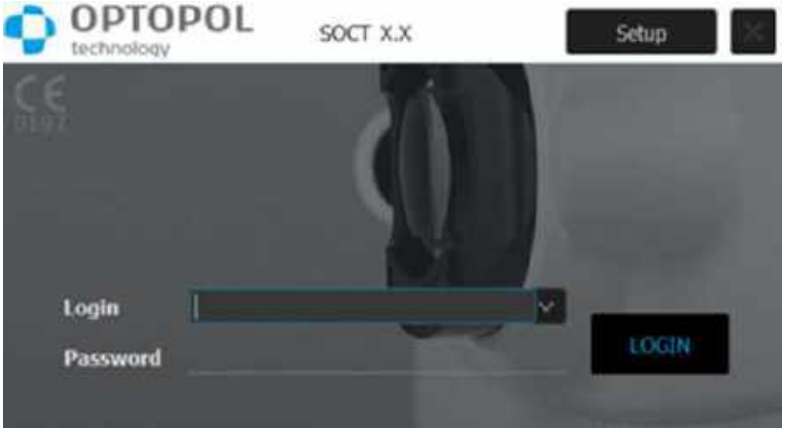


Figure 16.
Login Screen

Enter the User Login and Password then press **[LOGIN]** to go into the application or **[SETUP]** to change settings.

NOTE: The device is ready to use when the SOCT software is opened, and the status is indicated as READY.

5.5. Software Screen Tabs

The SOCT software has three main tabs for navigation, **PATIENTS**, **ACQUIRE**, and **RESULTS**.

Figure 17.
Software Application Tabs

1. **PATIENTS**

   Displays Patients and Exam lists and enables navigation of the patient database. This is the main screen of the SOCT software.

2. **ACQUIRE**

   Contains all controls necessary for performing a new examination.

3. **RESULTS**

   Enables user to review previously taken examinations, make quantitative analysis and compare results.

5.6. Title bar

The SOCT software has four general controls in the title bar: **Analysis of examinations, Logout, Minimize** and **Close**, which are localized in the top-right corner of the window.

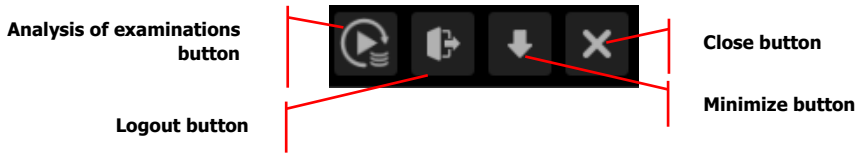


Figure 18.
General controls

5.6.1. Analysis of examinations

Analysis of examinations button is able only in the **PATIENTS** tab and opens the window which allows to manage analysis of the examinations in the database. Available functions allows to analyze unanalyzed examinations and reanalyze examinations analyzed by the older algorithm than the current one.

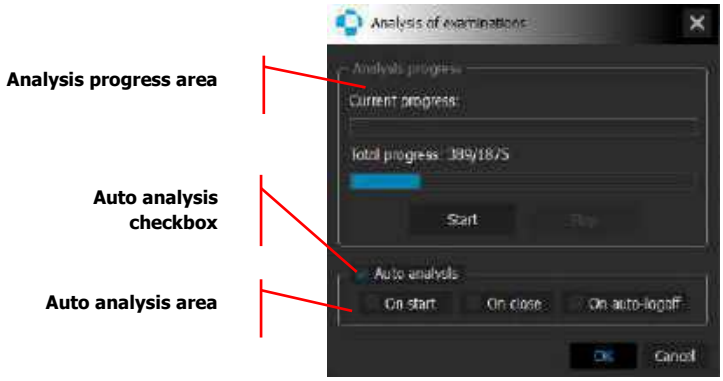


Figure 19.
Analysis of examinations window

5.6.1.1. Analysis progress area

Analysis progress area displays actual status of the analysis of the examinations. Current progress shows the actual process of the analysis of the current examination. Total progress informs about the number of the examinations analyzed by the latest algorithm compared to the all examinations in the database.

[Start] button allows to begin the analysis of the examinations.

[Stop] button allows to stop the current analysis.

5.6.1.2. Auto analysis area

Auto analysis area is possible to turn on/off by clicking the checkbox next to the name of the area.

[On start] checkbox causes start of the analysis after the first login to the application.

[On close] checkbox causes start of the analysis right after the closing application.

[On auto-logoff] checkbox causes start of the analysis after auto-logoff and manual logout.

[OK] button saves changes and closes the window.

[Cancel] and **[X]** buttons do not save the changes and do close the window.

If the Auto Backup is on, the application at the begging does the backup, then does the analysis of the examinations. Examinations of the blocked patients are not analyzed.

5.6.1.3. Algorithm version

After analysis, the user can check with which algorithm version the examination has been analyzed- hovering the mouse cursor over the examination thumbnail while holding the **[Shift]** button displays the information hint. The information hint includes: for version 11.5.3: structure, mode (chorioretinal/vitreoretinal), file storage path, device service number, software version on which the examination has been done and from version 20.0.0 additionally the algorithm version number. Algorithm number can be identified:

- Precise: identification number starts with P
- Fast: identification number starts with F
- For biometry 3 components are calculated: retina, lens and cornea
- For 11.5.3: identification number starts with 0

Analysis type	Ordinal number	AiMode	Version
Retina	5	**Fast**	2
Retina	5	**Precise**	2
Disc	7	**Fast**	2
Disc	7	**Precise**	2
Widefield	6	**Fast**	2
Widefield	6	**Precise**	2
Cornea	8	**Not affected**	2
Biometry lenses	3	**Not affected**	1
Angle	9	**Not affected**	0
AngleWide	10	**Not affected**	0
Sclera	13	**Not affected**	0
AnteriorFRLens	18	**Not affected**	0
AnteriorChamber	17	**Not affected**	0

For the unanalyzed examination in the algorithm field the “-.-.-.-“ is displayed.

5.6.2. Logout

Logout button allows user to manual logout from the SOCT software. Closes the application and opens the Login screen. Button is disabled during the processes like: analysis of the examinations, import/export of the examinations, output and acqusition.

Figure 20
Manual logout button

6.
Patients Tab

The main screen of the SOCT Software, the **PATIENTS** tab screen, appears once a user is logged into the system. This screen allows the user to easily manage the patient database by providing the following functions:

1. Add New Patient to the Database
2. Proceed to Acquire or Results Tab Screen

3. Search / Filter Existing Patients
4. Import / Export Data
5. Edit Patient Data
6. Delete Patient from the Database

All the controls of the main window are shown below:

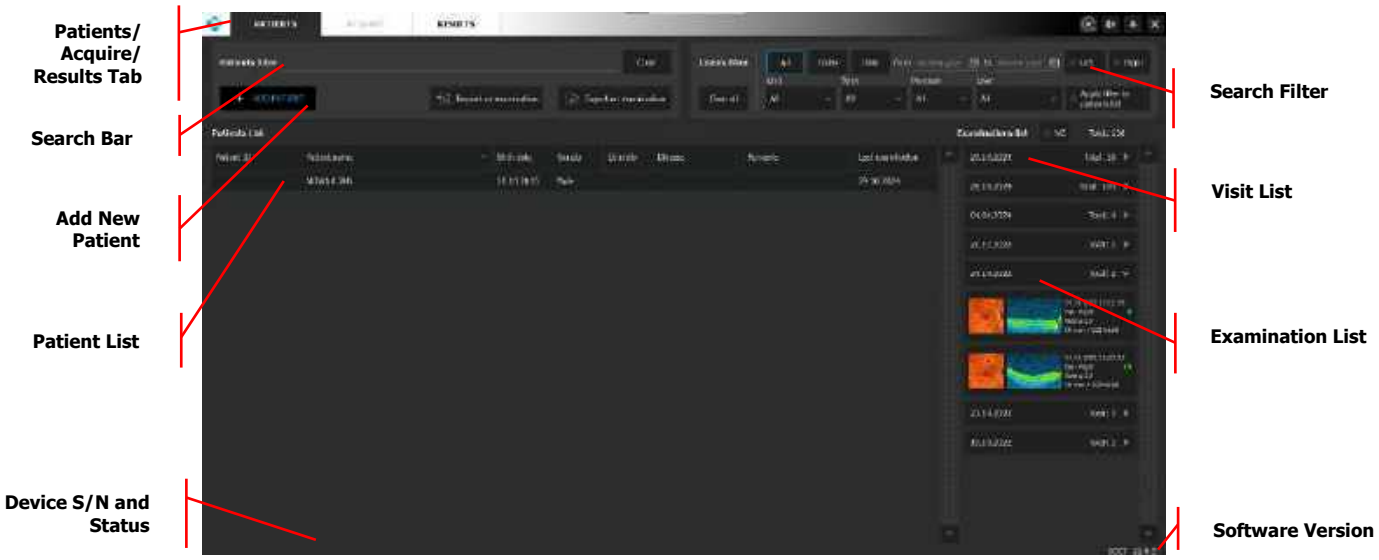
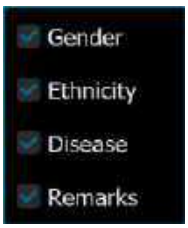


Figure 21.
Patient Tab Screen

6.1. Patients List View

To search a specific patient in the list, you can enter the first few letters of the name in the patients filter box. The system will show the closest matching-record. Customization of the patient list is available.

By default, patients are sorted in the Patient List alphabetically by **patient name (first and last name)**. Click the **[PATIENT ID]** header to sort by ID number. It is also possible to sort by other columns. Click each column header to sort in descending order and click again to sort in ascending order.



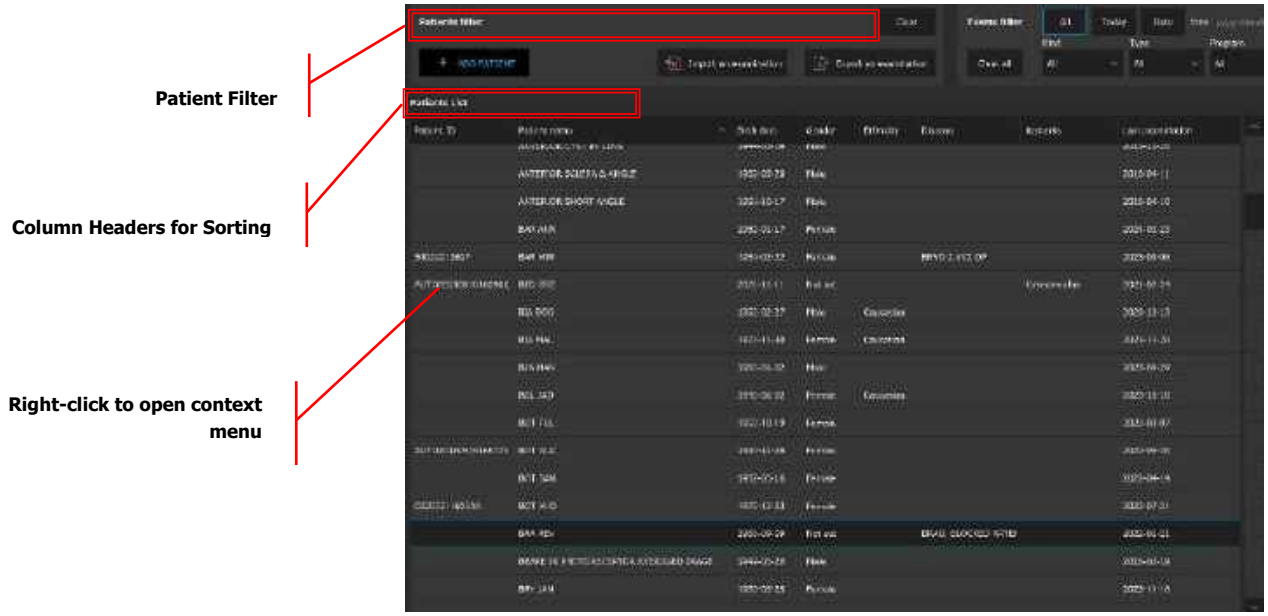


Figure 22.
Patient List View

6.1.1. Customization of the Patient List View

It is possible to customize the Patient List View. To **hide** columns: Gender, Ethnicity, Disease and / or Remarks, **right click** over the header to open the menu. Uncheck the unwanted column(s) from the menu. To **unhide**, recheck the mark next to the column name. To customize the width of each column, grab the end of the column header and move to the desired position.

6.2. Creating a New Patient File

To create a new patient file, click the button **[ADD PATIENT]** 

in the main window. The **Patient Registration** screen will open. Patient's first name, last name, and date of birth are required for registration of a patient file (required fields indicated by *).

The date format is adjusted to the one set in the operating system.

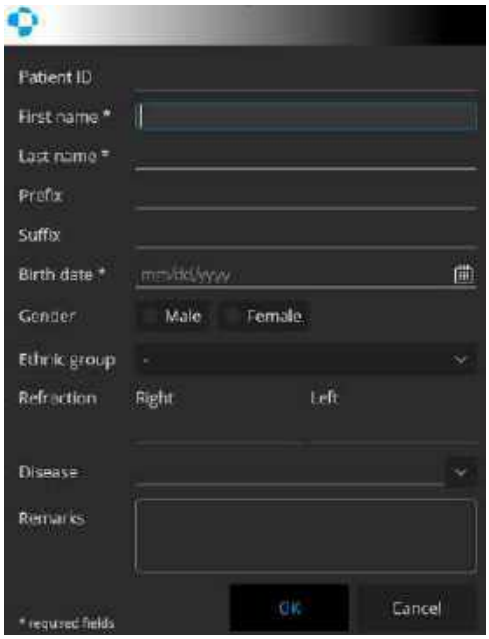


Figure 23.
Patients' Registration Edit Screen

NOTE: Fields "Last name", "First name" and "Date of birth" are mandatory and must be properly filled in. Other fields are optional and can be left empty.

Double-clicking on the refractive value resets the value to 0.00 D.

NOTE: For patients with a spherical equivalent refractive error larger than ± 10 D, it is recommended to enter the patient's spherical equivalent when adding the patient to the system. Entering data into the refraction fields transfers this information into the correction of focus in measurement mode.

NOTE: Disease field can use a user predefined dictionary of diseases as set up. The user can also set the obligatory fields in the Patient registering window to meet the regional regulations. For more information go to chapter 23.5.8 Input Settings Window.

After all the registration data are entered, click **[OK]** to confirm the registration. The system will check if the data are correctly entered. If not, the system will ask for a correction to be made.

NOTE: Make sure you have entered the correct patient's name and date of birth. This will prevent data loss and help to avoid empty records in the Patient List.

DUPLICATE PATIENTS

If the system detects that the patient entered is already registered in the database, a warning message will appear:

Figure 24.
Patient Data Conflict Window

MESSAGE: A patient with the same name, birth date and an unspecified Patient ID is already registered.

If the system detects that the name of the currently entered patient is already in the database, but the Patient ID is different, a warning message will be displayed.

MESSAGE: Patient with same Name, Last Name, DOB with different Ref No. is already registered. Do you want to register a new one? [Yes], [Cancel]

This means that there is a suspicion that the patient already exists, but the Patient ID was entered incorrectly. The operator should make sure the data is correct and then decide whether to continue to register the patient or cancel the registration.

6.2.1. DEHS screening [26]

To activate DEHS screening mode check the **[Screening capture mode]** checkbox, see Chapter 23.5.3 Parameters Tab. SOCT application in the DES Screening Capture Mode allows the user to conduct examinations and output the results to an external folder without storing them in the database. Examinations are removed after being added or selected.

Check the **[Screening mode]** checkbox in the **[ADD PATIENT]** window. Every field becomes inactivated except form “Patient ID” and “Refraction” field.

[26] Available only for the REVO OCT models with Fundus Camera.

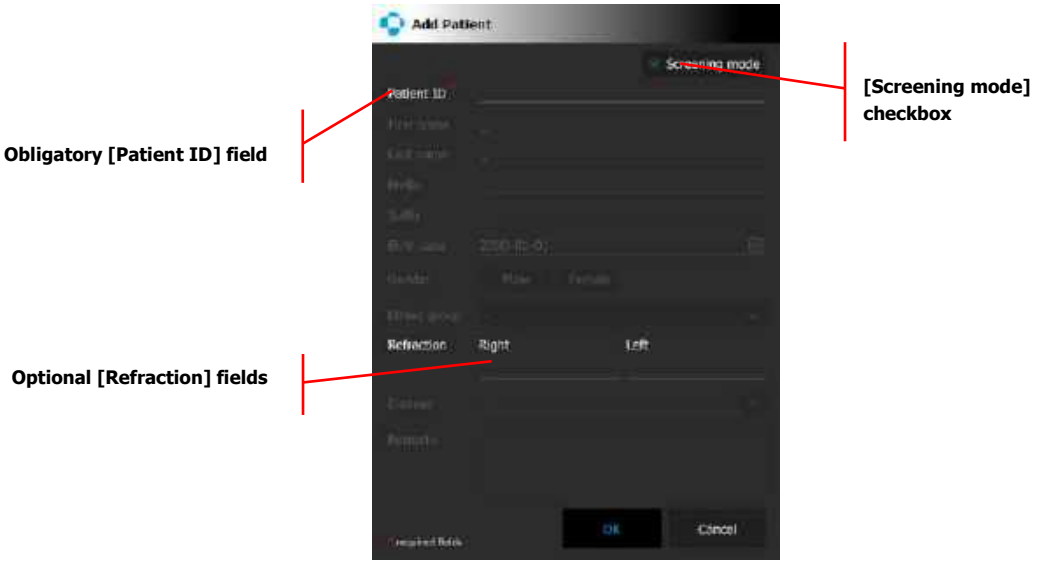


Figure 25.
Patients' Registration Edit Screen with Screening mode selected

NOTE: In DEHS screening mode field "Patient ID" is mandatory and must be properly filled in. "Refraction" fields are optional and can be left empty.

After "Patient ID" is entered, click **[OK]** (The *Refraction* fields are optional and can be left empty). **[ACQUIRE]** tab opens with the Screening mode active (See Chapter 8.3.6.3 Screening mode). The patient data is not saved in the database.

6.3. Editing Patient Demographic Data for an Existing Patient

To edit a patient file, find the patient in the Patient List, **right-click** over patient record and select **[EDIT]** from the popup menu. The patient registration screen will appear. After editing any patient data, click **[OK]** to confirm the changes.

6.4. Erase Patient File (All Data)

To delete an entire record of a selected patient, **right-click** on the patient's file and select **[DELETE]** from the popup menu. An accept / warning message will be displayed before deletion.

MESSAGE: [Are you sure you want to delete patient: Patient Last Name, First Name, DOB, Ref and all their data?]

After pressing **[YES]** the second confirmation window will be displayed.

MESSAGE: [All examination data of the selected patient will be lost. This action cannot by undone.]

After choosing **[YES]** for the second time, the patient and all examination results will be deleted irreversibly.

NOTE: Once the patient is deleted, it is impossible to recover the deleted data. There will not be any patient data, including the patient file and any associated exams. Please make sure you are deleting the proper patient before accepting the warning.

6.5. Examination Filter

The filter window helps to find examinations easily in the database. The system filters examinations according to all-patients meeting the filter criteria. To apply the filter, select the desired criteria.

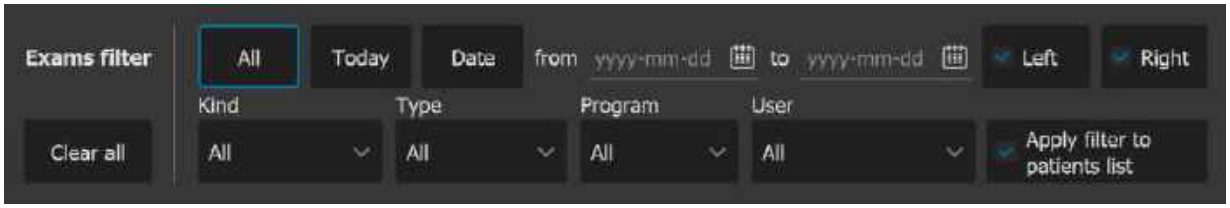


Figure 26.
Filter Panel

1. **ALL**

   All examinations are displayed.

2. **TODAY**

   Displays patient examination(s) which have been acquired on that same day - all others will be hidden.

3. **DATE FROM / TO**

   Displays all examinations acquired on days between (and including) the selected start **[FROM]** date and end **[TO]** date.

4. **EYE**

   To hide the examinations of the Left or Right eye, unmark the check box labelled “Left eye” or “Right eye”.

5. **KIND**

   Allows the user to filter by kind of exam: OCT, Photo, Biometry.

6. **TYPE**

   Allows the user to filter by type of scanned area: Retina, Disc, Widefield, Anterior. Different views are available depending on the scan program.

7. **PROGRAM**

   Allows the user to filter by scan program: 3D, Line, Line Full Range, Cross, Cross Full Range, Radial, Radial Full Range, Raster, Topography.

8. **USERS**

   Filters patients by the operator who performed the examination.

NOTE: Use [CLEAR ALL] to reset the filter settings and disable filtering.

6.6. Examination List

The **[EXAMINATION LIST]** contains detailed information regarding the saved exams. The exam preview for an exam displays an image of the anterior or posterior view during acquisition, a single tomogram, exam date and time, eye tested, scan program, and scan details. The thumbnail exam information is presented, such as the date and time of the examination, Right or Left eye, scan program, scan width, scan dimension and number of A-scans and B-scans. Double click on the thumbnail to open chosen examination in the **[RESULTS]** window

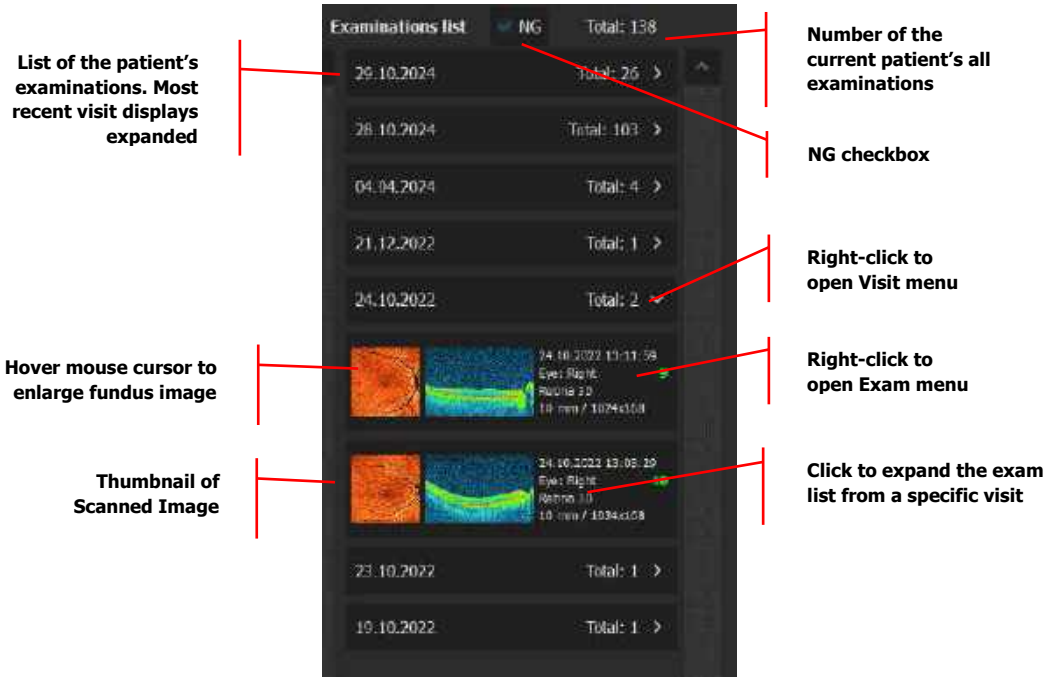
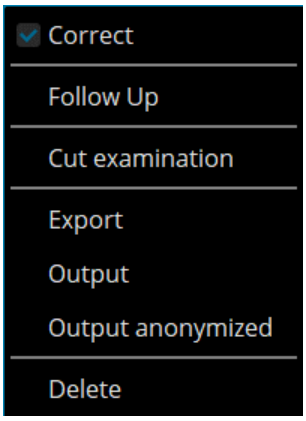


Figure 27.
Examination List

Examinations on the Examination List are shown in order of visit date. Multiple examinations acquired during the same visit are sorted by the visit date. The default display presented is the last visit. To display exams for each exam date, click the arrow to the right of each exam date to expand.**[NG]** checkbox allows to display (when is on) or hide (when is off) examinations with the NG status. Total shows the number of current patient's all examinations (the number depends whether the checkbox **[NG]** is turned on/off)

6.6.1. Exam Menu

Right-click the mouse button over the **visit date** to open the menu displaying the following options:



1. **CORRECT**

   When enabled, the results tab can display the exam automatically in **Both**, **Comparison** and **Progression** tabs.

2. **FOLLOW UP**

   Allows the user to repeat the selected examination. Opens **Acquire** tab and loads the previous settings for the repeat exam.

3. **CUT EXAMINATION**

   Allows the user to 'cut' an examination that was assigned to the wrong patient file in order to paste it into the correct patient file.

4. **EXPORT**

   Saves the *.oct examination file in raw *.opt file format. This format is for export to other devices with REVO SOCT software.

5. **OUTPUT**

   Outputs the exam results in a predefined file format. Configured in SOCT Setup Output Settings.

6. **OUTPUT ANONYMIZED**

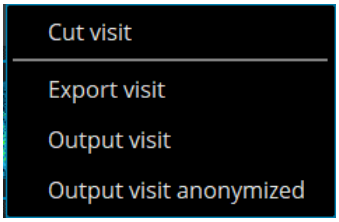
   Print or save the exam results without patient data.

7. **DELETE**

   Removes the examination from the database.

6.6.2. Visit Menu

Right-click the mouse button over the **visit date** to open the menu displaying the following options:



1. **CUT VISIT**

   Allows the user to 'cut' all examinations from the visit that were assigned to the wrong patient file in order to paste it into the correct patient file.

2. **EXPORT VISIT**

   Saves all OCT examinations files in raw *.opt file format from the visit. This format is for export to other devices with REVO software.

3. **OUTPUT VISIT**

   Print or save the results from the entire visit.

4. OUTPUT VISIT ANONIMIZED

Print or save the results from the entire visit without patient data.

6.7. Deleting Exams

Right-click on exam thumbnail and select **[DELETE]**.

NOTE: Once the examination is deleted, it is impossible to recover the deleted data. Please make sure you are deleting the proper exam before accepting the warning.

6.8. Reassigning Scans to the Correct Patient

The user has the option of moving the examination(s) from an incorrect patient record to the correct patient record. It is possible to move a single exam or move an entire visit:

1. Select desired Examination or Visit from Examination List.

NOTE: Only one exam or single visit can be cut and pasted at a time.

2. Hover over the selected thumbnail then right-click to show context menu, and press **[CUT EXAMINATION]** or **[CUT VISIT]**.
3. Select the patient on the “Patient List” where you wish to move the examination(s). (If the patient’s name does not exist, create a new patient record.)
4. Click the right mouse button and choose **[PASTE EXAMINATION(S)]**.

6.9. Exporting Examinations

The SOCT software offers the ability to export examination data in a raw format as *.opt file or *.dcm (DICOM). An examination exported in the *.opt format can be imported into the SOCT application.

EXAMINATION EXPORT PROCEDURE

1. Select the examination(s) to export from the “Examinations List”. Hold the **[Ctrl]** key to select multiple exams.
2. Press the right mouse button on the selected examination and choose from the context menu **[EXPORT]**.
3. Choose the folder and press **[SAVE]**:
   - When export is complete the following message appears: **All examinations have been exported**:

4. Press **[OK].** The procedure is completed.

6.9.1. Export with Anonymization

REVO SOCT software allows the user to export examinations with anonymization. Before exporting with anonymization, the user must define the anonymization settings in the setup window. See Chapter 23.5.6 Anonymization.

1. Select the examination(s) to export from the “Examinations List”. Hold the **[Ctrl]** key to select multiple exams.
2. Press the right mouse button on the selected examination and choose **[EXPORT ANONYMIZED]** from the contextual menu.
3. Choose the folder and press **[SAVE]**.
4. At the end, the following message appears: **All examinations have been exported**.

5. After **[OK]** is clicked, the procedure is completed.

6.10. Importing Examinations from Another REVO OCT

The **[Import an examination]** button allows import of the examination files from the chosen location. The system only accepts *.oct and *.opt formats.

6.11. Output (Print or Export)

From the Patient tab, it is possible to output (print or export) results from:

1. A single exam – right-click on the exam thumbnail.
2. All examinations from a single visit – right-click on the visit bar.
3. All patient results – right-click on the patient record.

Select the Output or Export option from the menu. It is possible to output Reports, a single Tomogram, or series of Tomograms. More details can be found in Chapter 23.7.1 Output Set Window.

6.12. Patient Work List

The SOCT software integrates with DICOM systems or third party software (via CMDL protocol) to provide work list functionality.

[USE A WORK LIST] tab appears only when the SOCT software is configured to work with external software via a Command Line (CMDL) or Modality Work List (MWL) interface. On the Work List, a list of patient orders appears. With the Patient List, the operator can receive the examination request. In this case the software will load the required exam or protocol. The SOCT software retrieves the Work List from the server periodically or on demand via user request - it is required to then click **[UPDATE]**.

To begin an examination from the Work List, the user double-clicks the patient order from the list. If the patient exists, the system will find the patient. If the patient does not exist, the system will add the patient to the database.

7.
Acquire Tab

The **[ACQUIRE]** tab is used to perform an examination. To open the examination window, click the **[ACQUIRE]** tab at the top-left of the Main Window. An example of the examination window is shown below:

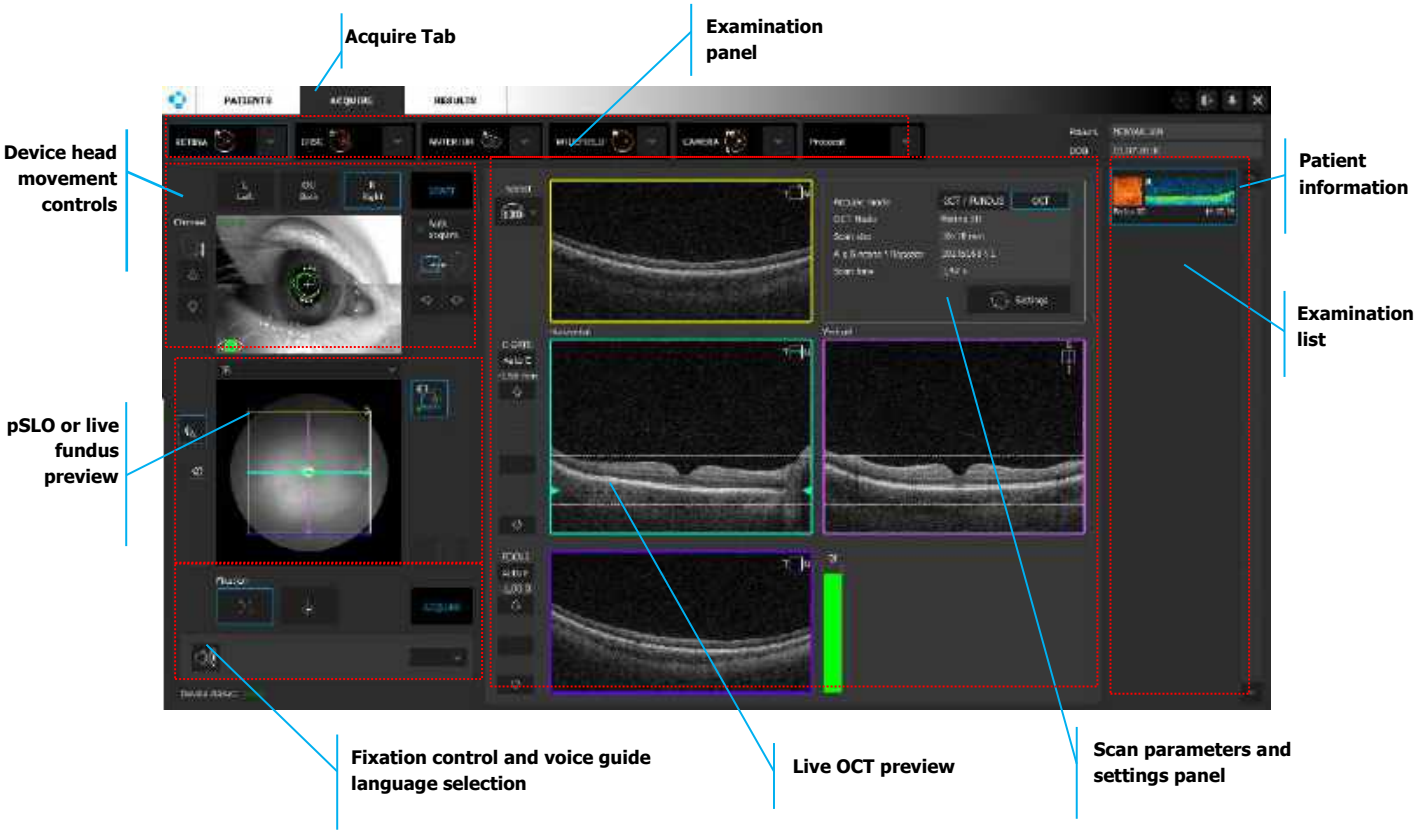


Figure 28.
Examination Screen View (Acquire Tab)

7.1. Examination Panel

1. **SCAN TYPE**

   Enables the user to choose the mode of scanning. For each Scan type (Retina, Disc, Anterior, Widefield) a set of scan programs is available. Each scan program has its own predefined settings

2. **SCAN PROGRAM**

   Expands to show the list of scan programs. To load a program, press its icon.

3. **CAMERA (REVO FC ONLY)**

   Allows the user to take a color fundus photo without performing an OCT examination.

4. **SCAN PROTOCOL**

   Click to expand the list of protocols. This enables the user to select a protocol with a predefined set of exams.

7.1.1. Movement Control

Detailed instructions on the operation of the movement control panel can be found in Chapter 7.5 Device Head Movement Controls.

7.1.2. Fundus Preview Type

The live Fundus Preview can be adjusted between three available types: IR (Infrared), pSLO / IR and pSLO (Pseudo Scanning Laser Ophthalmoscope). The pSLO live image displays the enface view of the fundus.

Detailed instructions on all available fundus preview types (pSLO, IR, pSLO / IR) can be found in Chapter 7.7 Fundus Preview.

7.1.3. Fixation Control and Voice Guide Control

ASSISTED VOICE GUIDE

Voice guidance guides the patient through the process of acquiring the examination. In the Setup Sound tab, you can customize or disable the voice guidance function. For more details see Chapter 23.5.4 Voice Support Guide Tab

1. **MUTE / UNMUTE**

Click **[SPEAKER ICON]** to mute / unmute the REVO device.

2. **FIXATION CONTROL**

Click the **[FIXATION]** Control button to change the shape (small or large) of the fixation target or select external fixation.

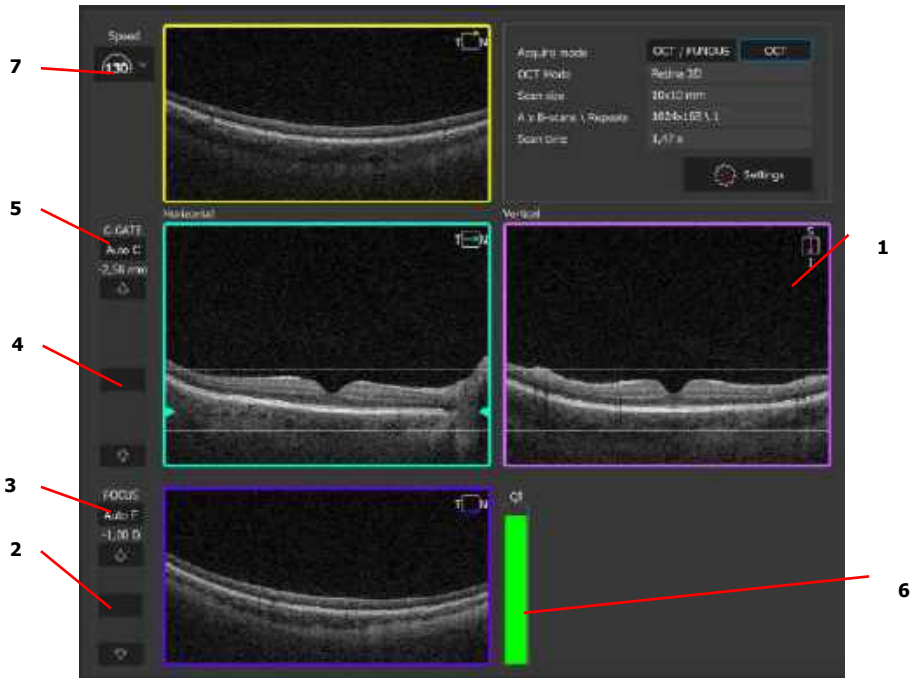
3. **ACQUIRE**

Click **[ACQUIRE]** to start data acquisition.

4. **VOICE GUIDANCE LANGUAGE**

Click the dropdown arrow to open the list of available languages. This allows the operator to change the language of voice guidance directly from the Acquire window. The language interface remains unchanged. Open the list from the message area and select the desired language.

7.1.4. Live OCT Preview



1. **LIVE OCT (TOMOGRAMS) PREVIEW**

Displays horizontal and vertical live OCT images. The live tomograms correspond to the arrow within the fundus preview window with the same color as the live OCT preview window border. Indicator Lines on the vertical and horizontal windows display the location and proper position of the tomograms. Note that poorly aligned tomograms have influence on quality of tomograms and reliability of analysis.

2. **FOCUS SLIDER**

Adjusts to compensate for the patient's refractive error. When the cursor is placed over the Focus Control Panel, the mouse scroll enables change the focus value (compensation of the refraction).

3. **AUTO FOCUS**

   Automatically focuses the OCT signal to compensate for the patient's refractive error.

4. **C-GATE SLIDER**

   Adjusts the position of the object displayed in the tomogram window.

5. **AUTO C (GATE)**

   Automatically aligns the OCT image in the tomogram window.

6. **QI INDEX BAR**

   Displays the signal to noise ratio. The user should adjust the focus to achieve the highest image saturation to try to achieve a QI value as high as possible. If the patient has dry eye, artificial tears may help to improve the signal.

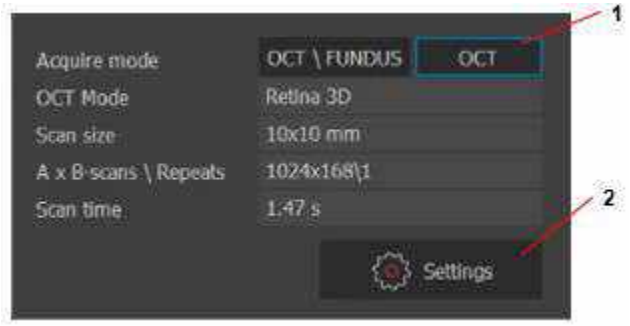
7. **SCANNIG SPEED SELECTOR**

   Allows to choose scanning speed of the device

NOTE: To use the [AUTO FOCUS] function, the OCT signal must be visible in the tomogram live preview (eye open).

7.1.5. Scan Parameters Panel

The Scan Parameters panel shows the parameters of the loaded examination.



1. **OCT + FUNDUS OR OCT**

   Allows the user to choose to perform both the OCT exam and a Fundus photo or just an OCT exam.

2. **SETTINGS**

   Enables the user to change the parameters of the exam such as width, number of A-scans, number of B-scans or C-gate mode (vitreous or choroid).

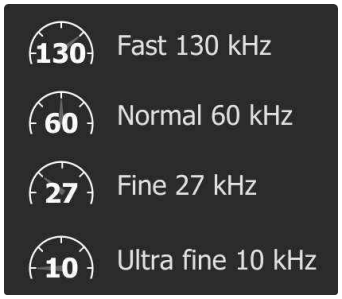
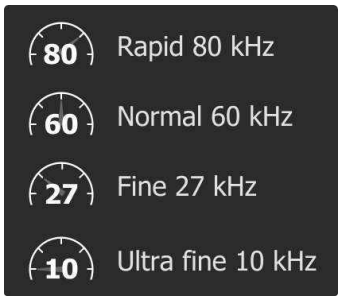
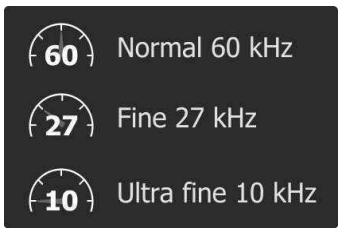
7.1.6. Cataract mode[27]

Cataract switch button allows to change the scanning speed of the OCT. Depending on the scanning speed there are 4 or 3 scanning speeds to choose from listed in the table below.

[27] Cataract mode is not available for devices with the reference number 155-XX and 156-XX.

Through the change of the scanning speed it is possible to manipulate the saturation of the OCT image. Lower scanning speed causes higher saturation of the image which helps capture the eye with opacity e.g. cataract. It is important to keep in mind the lowering scanning speed causes the prolongation of the examination time.

Default scanning speed is the nominal speed of the device. Scan parameters in the cataract mode for 60 kHz, 27 kHz and 10 kHz[28] are not adjustable. Table below contains examinations available in the cataract mode.

Device	Available scanning speeds
REVO HR **REVO FC 130** **REVO NX 130**	
REVO FC **REVO 80**	
REVO 60	

[28] Scanning parameters cannot be changed while working with decreased scanning speed in the Cataract mode.

Scan type	Fast – 130 kHz[29]	Normal – 60 kHz[29]	Fine – 27 kHz[29]	Ultra fine – 10 kHz[29]
Retina	3D Angio Angio Wide Angio Mosaic Cross Line Radial Raster 21 Raster	3D Angio Angio Wide Cross Line Radial Raster 21 Raster	3D Cross Line Radial Raster	Cross Line Radial Raster
Disc	3D Angio Line Radial Raster	3D Angio Line Radial Raster	3D Line Radial Raster	Line Radial Raster
Widefield	3D Line Full Range Line Radial Raster UWF[30]	3D Line Full Range Line Radial Raster	3D Line Full Range Line Radial Raster	Line Radial Raster
Anterior	3D Line Full Range Line Radial Full Range Radial Raster Topography	3D Line Full Range Line Radial Full Range Radial Raster	3D Line Radial Raster	Line Radial
Biometry	Axial Length	Axial Length	Axial Length	Axial Length

7.1.7. List of Examinations

Detailed information of the options provided by the list of examinations can be found in Chapter 6.6 Examination List.

[29] In the Cataract mode, the frequency of 60 kHz is available for devices with the nominal speed of 130 kHz, the frequencies of 80 kHz and 27 kHz are available for devices with the nominal speed of 130 kHz, 80 kHz and 60 kHz, the frequency of 10 kHz is available for devices with the nominal speed of 130 kHz, 80 kHz and 60 kHz.

[30] Ultra-Wide Field is an optional module available for OCT with Fundus Camera camera only. If you do not have this feature and want to purchase it contact Optopol's local distributor. Ultra-Wide Field examination types are described in chapter 18 Ultra-Wide Field (Optional Function)

7.1.8. Patient information

PATIENT INFORMATION SECTION

Displays the personal data of the patient.

1. **PATIENT**

   Presents the name of the patient.

2. **DOB**

   Presents the patient's date of birth is adjusted to the one set in the operating system.

NOTE: In difficult conditions, such as:

- **Eyelashes or eyelid which block the beam of light**
- **Inability of subjects to maintain fixation**
- **Dense media opacities**
- **Strong nystagmus**
- **Rapid blinks**

the system can display a warning. In this case operator should decide whether to use the tips mentioned in the Chapter 8.6 Examination Tips or change the acquisition mode.

NOTE: For patients with a spherical equivalent refractive error larger than ± 10 D, it is recommended to enter the patient's spherical equivalent when adding the patient to the system. Entering data into the refraction fields transfers this information into the correction of focus in measurement mode.

NOTE: Before performing the first retinal scan examination for an eye, if you set the focus value (refraction power compensation), the system will align the patient data according to the patient correction for the Left and Right eye.

NOTE: It is recommended to visually evaluate the focus after automatic focus is complete. If necessary, manually adjust the focus bar to optimize the scan.

NOTE: In cases when the [AUTO FOCUS] displays an error or a low QI value, try adjusting the refractive power above and below the initial value to obtain the best saturation of scans and a higher QI value.

7.2. Selection of Scan Pattern Type

When the Acquire tab is opened, the Retina 3D scan pattern is presented by default. Any scan type or scan program can be selected. Depending on the scan pattern, different result analysis views are available. The operator can combine more than one type of scan program and protocol to be used. The System will automatically change the working distance if necessary.

Scan Type	Description
Retina 	Fixation position is on the Macula. This result displays the tomogram image of the macula, the retinal analysis, and ganglion cell layer analysis.
Disc 	In Disc mode, the fixation target is offset to allow the center of the optic nerve to move to the center of the scan area. The scan pattern overlay assists in the alignment of the optic disc in the center of the scan area. The result displays the tomogram images of the optic disc, results of the thickness of the NFL (Nerve Fiber Layer) analysis, and quantification of the morphology of the optic disc.
Anterior 	Fixation position is centered. This result displays the tomogram image of the anterior segment with the result of the cornea analysis or anterior segment imaging and biometry. This section has three groups of scan programs: 1. [Anterior] group: 3mm to 18 mm scan programs. 2. [Biometry] (optional): AL program. 3. [Topography] (optional): Topography scan.
Widefield 	Fixation position is offset to align the placement of the macula and the optic disc to the center of the scan area. This mode is useful for peripheral observation. 1. [Widefield] 2. [Ultra-Wide Field] examinations can be selected from this list (optional).
Protocol 	Protocol allows the user to perform a predefined set of examinations of different types sequentially. This option saves overall visit time because the user does not have to manually select multiple scan programs during the visit.
Camera 	The Fundus Camera mode allows the user to perform fundus photography in the following programs: Central, Disc and Retina.

7.3. Selection of Scanning Programs

The user can select the scan program from the Scan Programs panel by clicking the mouse on the desired scan pattern from the icon list (R-Retina, D-Disc W-Widefield, A-Anterior). Scan parameters are different depending on selected scan type and program. The operator can reconfigure and save desired settings as the default.

NOTE: The aperture of the optics for the scans of the posterior segment is 15 mm[31]. For this reason, when using the maximum scan width for 3D and Angio scans, the OCT signal is not visible in the corners.

[31] Additional width of 21 x 21 mm is available using the UWF adapter. Ultra-Wide Field is an optional software module available for REVO FC devices (OCT with Fundus Camera). If you do not have this feature and want to purchase it contact Optopol's local distributor.

Scan Icon	Scan Program	Description
	**3D**	Consists of a series of equally-spaced parallel line scans over a square or rectangular region, the size of which is determined by the operator. This enables precise and three-dimensional reconstruction of the retina.
	**Radial**	Consists of a series of two to 32 equally-spaced line scans through a common central axis. This program enables taking scans in high resolution tomograms in a star shaped pattern. The default pattern has 12 lines of 15 mm length. The operator can adjust the length of the scan lines by adjusting the scan width and number of scans.
	**Line**	Enables capture of a single B-scan in the highest resolution. The operator can adjust the length and placement of the B-scan. If averaging is selected, the scanning program scans in one place a pre-defined number of times. This allows for enhancement of the data captured at the single location and can be helpful for patients with a gaze problem.
	**Cross**	Enables the taking of two tomograms (horizontal (0°) and Vertical (90°) of 10 mm length. The user can adjust the length and placement of the scans. This program acquires B-scans with the highest resolution.
	**Raster**	Obtains five B-scans with the highest resolution. The default pattern is five horizontal lines of various lengths depending on the scan program. The user can adjust the length, tomogram spacing and angle of the scan.
	**21 Raster**	Takes 21 B-scans with the highest resolution. The default pattern is 21 horizontal lines of various lengths depending on the scan program. The user can adjust the length, tomogram spacing and angle of the scan.

FULL RANGE PROGRAMS

Scan Icon	Scan Program	Description
	**Line Anterior Chamber Full Range**	Generates an extended depth ≈ 6mm deep single B-scan in high resolution of the anterior chamber.
	**Anterior Chamber Radial Full Range**	Generates an extended depth ≈ 6mm deep scan in a star shaped pattern of the anterior chamber.
	**Posterior Full Range**	Enables capture of a ≈ 6 mm deep single B-scan in high resolution. The operator can adjust the length and placement of the B-scan. The scan is designed to show detail in the vitreous and the choroid especially in high myopic and long eyes.

7.3.1. OCT-B Biometry Programs (Optional Module)

Scan Icon	Scan Program	Description
	**AL Biometry**	Measurement of axial length distances and anterior image analysis. Scan provides: AL, CCT, ACD, LT.

7.3.2. OCT-T Topography Programs (Optional Module)

Scan Icon	Scan Program	Description
	**OCT Topography**	Obtains radial cornea scans. Based on corneal surfaces, provides the analysis of anterior, posterior, and real corneal power.

7.3.3. OCT Angiography Programs (Optional Module)

Allows the operator to perform a 3D scan. This dye free method allows visualization of retina microvasculature, retinal morphology. For REVO FC 130 examinations available from width of 3x3 mm to 15x15 mm, and 18x18mm or 21x21 for Ultra-Wide FIeld Angio program.[32]

Scan Icon	Scan Program	Description
	**Retina Angio (3x3)**	Provides the highest resolution of OCT Angiography scan. By default, it is set to visualize the 3 mm x 3 mm volume scan program.
	**Retina Angio Wide (6x6)**	Displays a larger view. By default, it is set to a 6 mm x 6 mm volume scan program.
	**Ultra-Wide Field Angio**	Displays largest view. Scanned area is 21mm x 21mm by default.[32]

[32] Additional width of 21 x 21 mm is available using the UWF adapter. Ultra-Wide Field is an optional software module available for REVO FC devices (OCT with Fundus Camera). If you do not have this feature and want to purchase it contact Optopol's local distributor.

OCT-A mosaic programs combine multiple 5mm x 5mm or 6mm x 6mm scans at different locations to create a single high-resolution montage image of a larger area.

Scan Icon	Size	Description
	**10 mm x 6 mm**	Captures two 6mm x 6mm Retina and Disc scans one after another.
	**12 mm x 5 mm**	Captures three 5mm x 5mm scans one after another. Retina, disc, and Nasal scans.
	**7 mm x 7mm**	Captures five scans. Four side scans and one central scan.
	**10 mm x 10 mm**	Captures four side scans.

7.3.4. Ultra-Wide Field Programs (Optional Module)

The Ultra-Wide Field program is currently the widest examination possible to perform on Revo devices with a fundus camera. They enable scanning width of 18x18 mm or 21x21 mm.

Scan Icon	Scan Program	Description
	**Ultra-Wide Field 3D**	Consists of a series of equally-spaced parallel line scans over a square or rectangular region, the size of which is determined by the operator. This enables precise and three-dimensional reconstruction of the retina and disc areas
	**Ultra-Wide Field Line**	Enables capture of a single B-scan in the highest resolution. The operator can adjust the length and placement of the B-scan. If averaging is selected, the scanning program scans in one place a pre-defined number of times. This allows for enhancement of the data captured at the single location and can be helpful for patients with a gaze problem.
	**Ultra-Wide Field Radial**	Consists of a series of two to 32 equally-spaced line scans through a common central axis. This program enables taking scans in high resolution tomograms in a star shaped pattern. The default pattern has 12 lines of 15 mm length. The operator can adjust the length of the scan lines by adjusting the scan width and number of scans.
	**Ultra-Wide Field Line Full Range**	Enables capture of a ≈ 6 mm deep single B-scan in high resolution. The operator can adjust the length and placement of the B-scan. The scan is designed to show detail in the vitreous and the choroid especially in high myopic and long eyes.
	**Ultra-Wide Field Radial Full Range**	Enables capture of a ≈ 6 mm deep of two to 32 equally-spaced line scans through a common central axis. This program enables taking scans in high resolution tomograms in a star shaped pattern. The default pattern has 12 lines of 15 mm length. The operator can adjust the length of the scan lines by adjusting the scan width and number of scans. The scan is designed to show detail in the vitreous and the choroid especially in high myopic and long eyes.
	**Ultra-Wide Field Angio**	This dye free method allows visualization of retina microvasculature, retinal morphology. Displays largest possible OCT-A view. It requires the Angio module.[33]

7.3.5. Fundus Camera Programs [34]

	Central Fundus Photo
	Disc Fundus Photo
	Retina Fundus Photo

[33] Additional width of 21 x 21 mm is available using the UWF adapter. Ultra-Wide Field is an optional software module available for REVO FC devices (OCT with Fundus Camera). If you do not have this feature and want to purchase it contact Optopol's local distributor.

[34] Programs available only for the REVO OCT models with Fundus Camera.

	Anterior Photo[35]

7.3.6. OCT + Fundus Photography [34]

	3D Scanning Program+ Fundus Photo
	Radial Scanning Program + Fundus Photo
	Line + Fundus Photo
	Cross-Scanning Program + Fundus Photo
	Raster + Fundus Photo

OCT Angiography programs with Fundus Photo are included with the optional OCT-A module:

	Retina Angio 3x3 + Fundus Photo
	Retina Angio Wide 6x6 + Fundus Photo
	OCT-A Mosaic 10x6 + Fundus Photo

[35] Program available only for REVO FC 130 and REVO FC with REF 1905xxx.

7.4. Selection of Protocol

The Protocol function enables operators to create and use a set of predefined scan programs to capture tomograms according to disease and anatomy. After acquisition of a tomogram, the system automatically loads the next scan program from the selected protocol. Review the scan programs included within the saved protocols and select a protocol that is appropriate for the eye being imaged.

Upon opening the Acquire tab, the Retina 3D scan pattern is selected by default. The user may change the default to a different protocol. It is possible to edit, create or remove protocols. Up to 10 configured protocols is possible. To learn more about configuring the Protocol function settings, see Chapter 23.5.2.1 Protocol Tab.

The user can select a desired protocol from the protocol panel by clicking on **[PROTOCOL]** and by selecting the desired protocol from the list. Three default protocol sets are provided in the SOCT software. Users may add / remove / edit these protocols in system settings. Types of proposed Protocols:

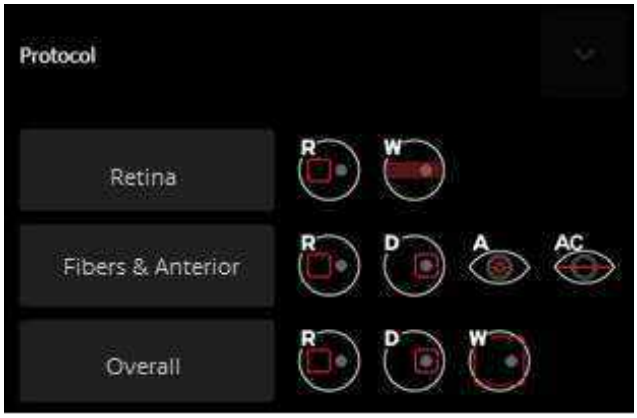


Figure 29.
Protocol Selection Tab

1. **RETINA**

   This program set captures tomograms by performing a 3D scan of the macula and Raster of the central region of retina. Scan programs: **[Retina 3D]** and **[Widefield Raster]**.

2. **FIBERS & ANTERIOR**

   This program set captures tomograms of macula and optic disc, cornea, and the angle. Scan programs: **[Retina 3D]**, **[Disc 3D]**, **[Anterior Radial]** and **[Full Range Anterior Line]**.

3. **OVERALL**

   This examination set captures tomograms of the macula, disc, and central region of the retina. Scan programs: **[Retina 3D] [Disc 3D] [Widefield 3D]**.

7.5. Device Head Movement Controls

The REVO device is controlled by the SOCT software and is operated via mouse or touch screen[36]. Press Left or Right Eye button to move the device to the patient eye to be scanned.

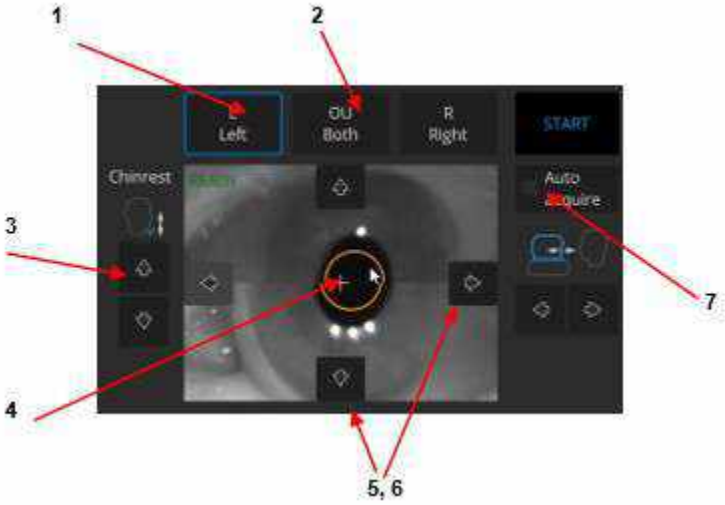


Figure 30.
Device Movement Controls

1. [LEFT] [RIGHT] BUTTONS

The **[LEFT]** or **[RIGHT]** button, when clicked, causes the device to move to the selected eye for examination. The device will be set at the starting position on the Z-axis.

2. OU BOTH

When **[OU BOTH]** button is **ON**, after the **[START]** button is pressed, the device will acquire an examination of both eyes. It will automatically adjust the device in to the second eye once the scanning of the first eye is complete.

3. CHINREST CONTROL

The Chinrest Control, when pressed, aligns the patient's head position. The canthus must be positioned at the level of the reference mark on the headrest.

4. EYE PREVIEW

The Eye Preview displays a single anterior segment image created from two cameras. Click on the pupil to correct the objective lens position. When the cursor hovers over the Eye Preview window: scrolling of the mouse wheel moves the device head back and forth. In the Eye Preview, the device indicates the end of range movement by the display of a red symbol and a 'Prompt' sound.

5. MOVEMENT CONTROLS

Movement Controls appear when the Eye Preview panel is active and can be operated via mouse or touch screen.

[36] Touch screen control is optional. For availability, contact your OPTOPOL distributor.

6. UP / DOWN & LEFT / RIGHT CONTROLS

Device Head Movement Control buttons appear when the field is active (click or place the mouse cursor over it). They control the movement of the device in the Left, Right, Up, and Down directions.

7. AUTO ACQUIRE

If Auto Acquire is checked, after the operator clicks the **[START]** button, the system will auto align and capture a scan.

7.6. Anterior Eye Preview

The Eye Preview window displays views from two cameras. In the working distance position, the image is composed as a single anterior view. The system detects the patient's pupil and then a status of READY is visible and the **[START]** button is active. The device must be positioned on the LEFT or RIGHT side as the central position will not allow the user to acquire a proper exam. The white circle indicates the minimum pupil size (1.7 mm for the devices with REF 190, 191, 192, 193 and 194; 2.4 mm for the devices with REF 155, 156), the cross should be placed directly over the center of the pupil:

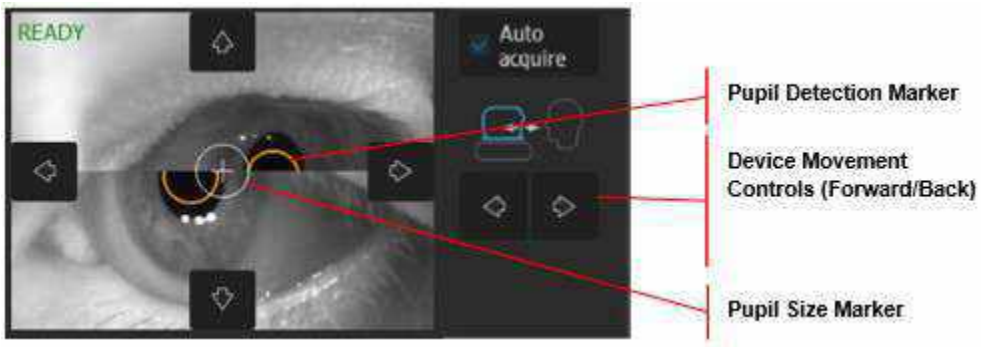


Figure 31.
Device Movement Control Buttons

When the cursor is hovered over the Eye Preview window, Movement Control buttons (Up / Down / Right / Left) are displayed. Scrolling the mouse wheel or pressing the movement buttons moves the scanning head backward and forward. In the working position X, Y, Z axis, the white cross must be in the center of the aligned pupil. When the scanning head is in the working distance position, click on the pupil to move the scanning head across the center of the pupil (shift in X, Y axis):

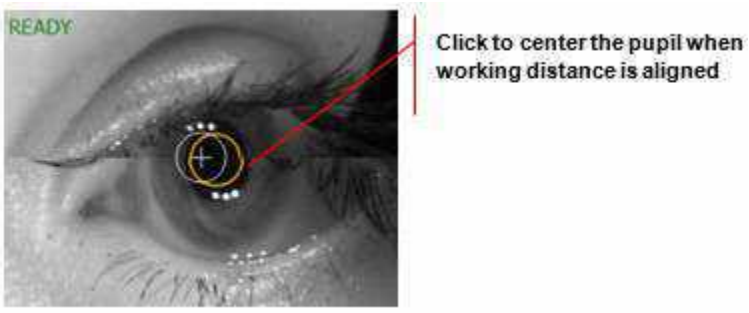


Figure 32.
Device Aligns to the Place in Which You Click on the Preview

Properly align the pupil to start searching for the OCT signal:

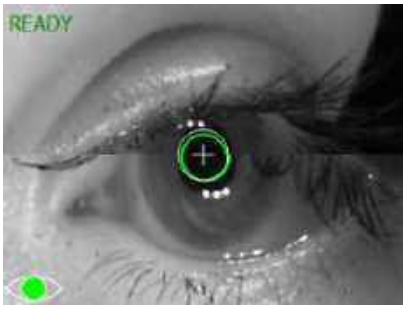


Figure 33.
Properly Aligned Measurement Head Position

7.7. Fundus Preview

7.7.1. IR Preview

To optimize the image on the IR preview, move the scanning head to the optimal fundus position in one of the following ways:

1. Scroll the mouse wheel over the eye preview window, or click the Device Movement Control buttons (Up, Down, Right, Left).
2. In the Live Preview Window, move the fixation target or scroll the mouse wheel over the window to change the working position.
3. Grab and move the horizontal and / or vertical tomogram windows.

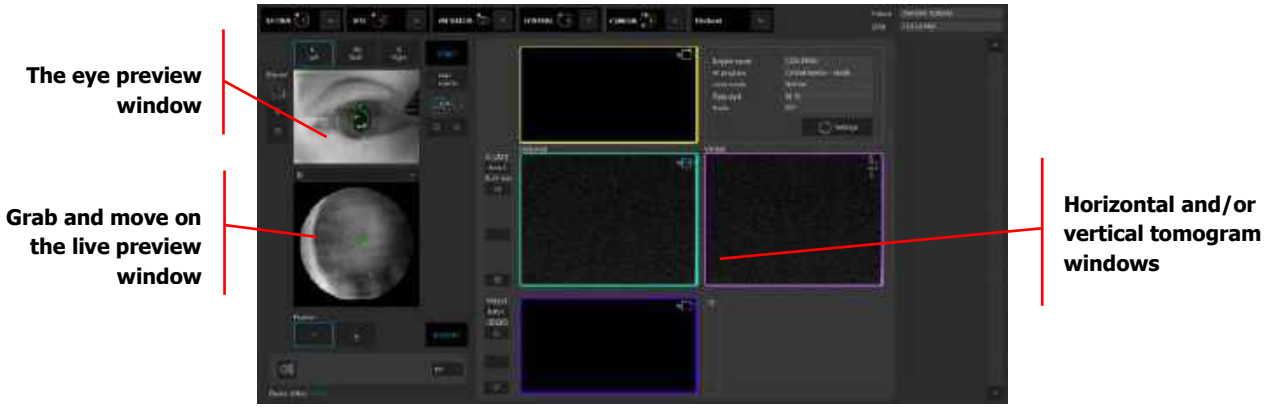


Figure 34.
IR mode in the acquire window

When the IR mode is selected in the Live Fundus preview, a context menu becomes available. To open the menu, right-click on the IR preview window:

Figure 35.
IR Preview Window Context Menu

ENHANCE MODE

The Enhance Mode processes the IR image to enhance the fundus signal. This is useful for patients with a cataract or a small pupil.

Enhance Off

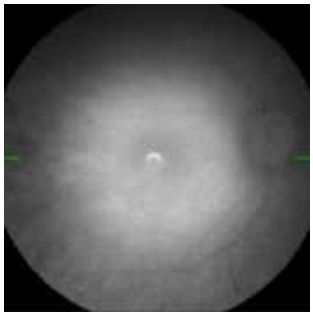


Figure 36.
IR Preview with the Enhance Mode OFF

Enhance On

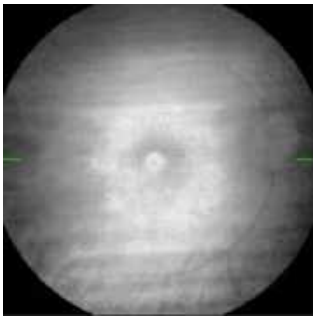


Figure 37.
IR Preview with the Enhance Mode ON

1. **Color IR**

   This feature places a pseudo-color mask on the IR image.

   The Auto IR function offers automatic control of the IR illumination and gain and is described in detail in the next section.

2. **FUNDUS PREVIEW SWITCH**

   IR / pSLO IR / pSLO modes are available.

3. **LIVE IR**

   Live fundus preview in Infra-red mode (changed in the **[SETTINGS]** button).

7.7.1.1. Auto IR Function

The Auto IR function controls the parameters of the IR preview in real time and keeps the brightness of the fundus image stable, regardless of the pigmentation or opacity level of the patient's eye.

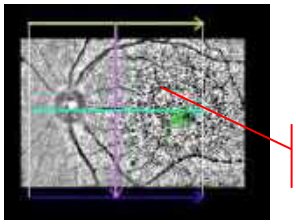
To turn the function on or off, click the  or  button on the left side of the acquisition window. The Auto IR buttons present the current state of the function:

	Auto IR function ON (IR Preview Gain and IR Illumination are adjusted automatically). The IR Gain and Illumination Sliders in the scan parameters window are disabled.
	Auto IR function OFF (IR Preview Gain and Illumination can be adjusted manually only). The bars above the letter M indicate the IR Gain Level ranging from 1 bar (the lowest level) to five bars (the highest level), as set by the user in the Scan Parameters Window.

The Auto IR settings can be modified in the scan parameters window as described in Chapter 7.10 Customizing Scan Parameter Settings.

7.7.2. pSLO Live Fundus Preview

The Pseudo SLO (pSLO) live image displays the enface view of the fundus. The pSLO image appears when the OCT signal is properly aligned. The view is overlaid with a box indicating the location of the scan pattern on the fundus and with a green cross indicating the location of the fixation target. You can adjust the patient's fixation by moving the fixation target and by changing the scanner offset position. Scrolling the mouse wheel over the pSLO can change the Working Position (to compensate for edge shadows created by a small pupil diameter during the wide and peripheral scans of retina). Left-click and drag the box to adjust the scan placement. Right-clicking allows the user to select a higher resolution or a higher refresh rate from the menu.



NOTE: During the alignment of the OCT signal on the live tomogram preview, the pSLO image is frozen.

ENHANCE PSLO

Changes the contrast to modify the visualization of the structure.

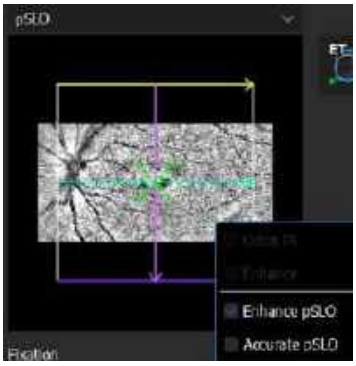


Figure 38.
Enhance pSLO selected.

ACCURATE PSLO

Increases resolution.

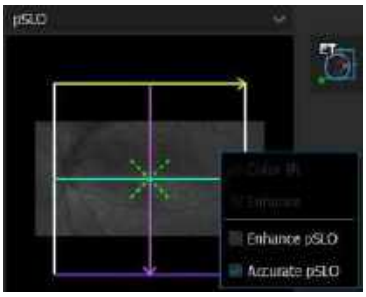


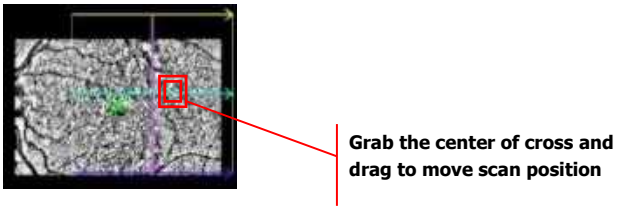
Figure 39.
Accurate pSLO selected.

Accurate pSLO and enhance pSLO can be selected simultaneously.

7.8. Operation of the Fundus Preview

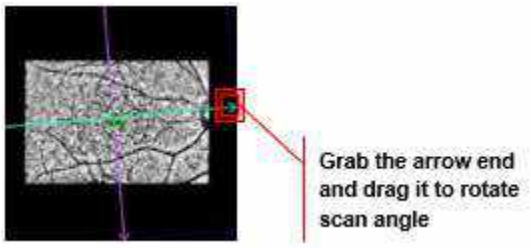
7.8.1. Moving the Scanning Area

Drag the scanning area on the pSLO Live Fundus Preview and the fixation target will not move. This changes the scanner offset. To reset the offset to the center of the fundus preview, double-click on the scanned area and the fixation target will come back to the default position.



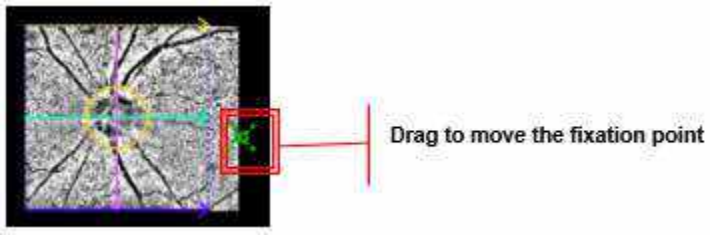
7.8.2. Rotation of the Scanning Angle

For Raster and Line programs, it is possible to rotate the scan angle. The adjustment angle range is -90º to 90º with 1º steps. Double click on the scanned area to reset the scan angle.



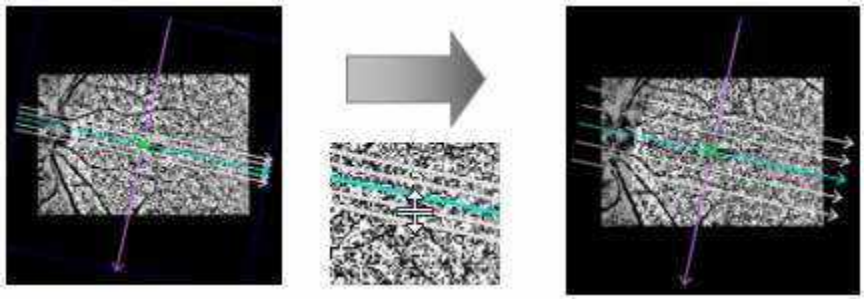
7.8.3. Moving the Internal Fixation Target

Drag the internal fixation target mark in the live Fundus Preview. When the retina / disc cross-section is visible in the OCT live preview, the system displays the pSLO image of the fundus. Now the operator may move the internal fixation position by dragging the green cross into the desired position. Ask the patient to follow the moving point. To reset the scanning area to the center of the Fundus Preview, double click on the Fundus Preview and the fixation target will come back to the default position.



7.8.4. Changing the Raster Scan Step Distance

To change the distance between the parallel tomograms in a raster scan, place the cursor over the line representing the scan area, grab the line and move the mouse to change the distance between the lines.



7.8.5. Changing the Scan Width

Drag the corner of the scanning area on the pSLO live Fundus Preview to change the scan width. The step increments of the scan width are 1 mm.

7.9. Fixation Target Adjustment

There are two sizes of the internal eye fixation target available (small or large). The option for the external fixation target allows for external fixation positioning. Choose either the small or large target by clicking the desired appearance. The active fixation target button is highlighted with a blue border. Choose the external fixation target icon to use the external fixation.

Figure 40.
Fixation Target Selection

7.10. Customizing Scan Parameter Settings

In the SOCT software, there are different scan parameter settings for each scan pattern and scan area. These scan parameter settings depend on the Type (Retina, Disc, Anterior, Widefield, Fundus Camera) and Scan Program (3D, Radial, Line, Raster, Angio*, Cross, Topography* and Full Range). The control panel allows the user to adjust the parameters of the examination. The user can change the predefined scan settings. It is possible to save user chosen settings as a default for each operator. To change the parameters, press the 

[SETTINGS] button in the Acquire window.

*Optional modules.

7.10.1. OCT + Fundus Scan Parameters

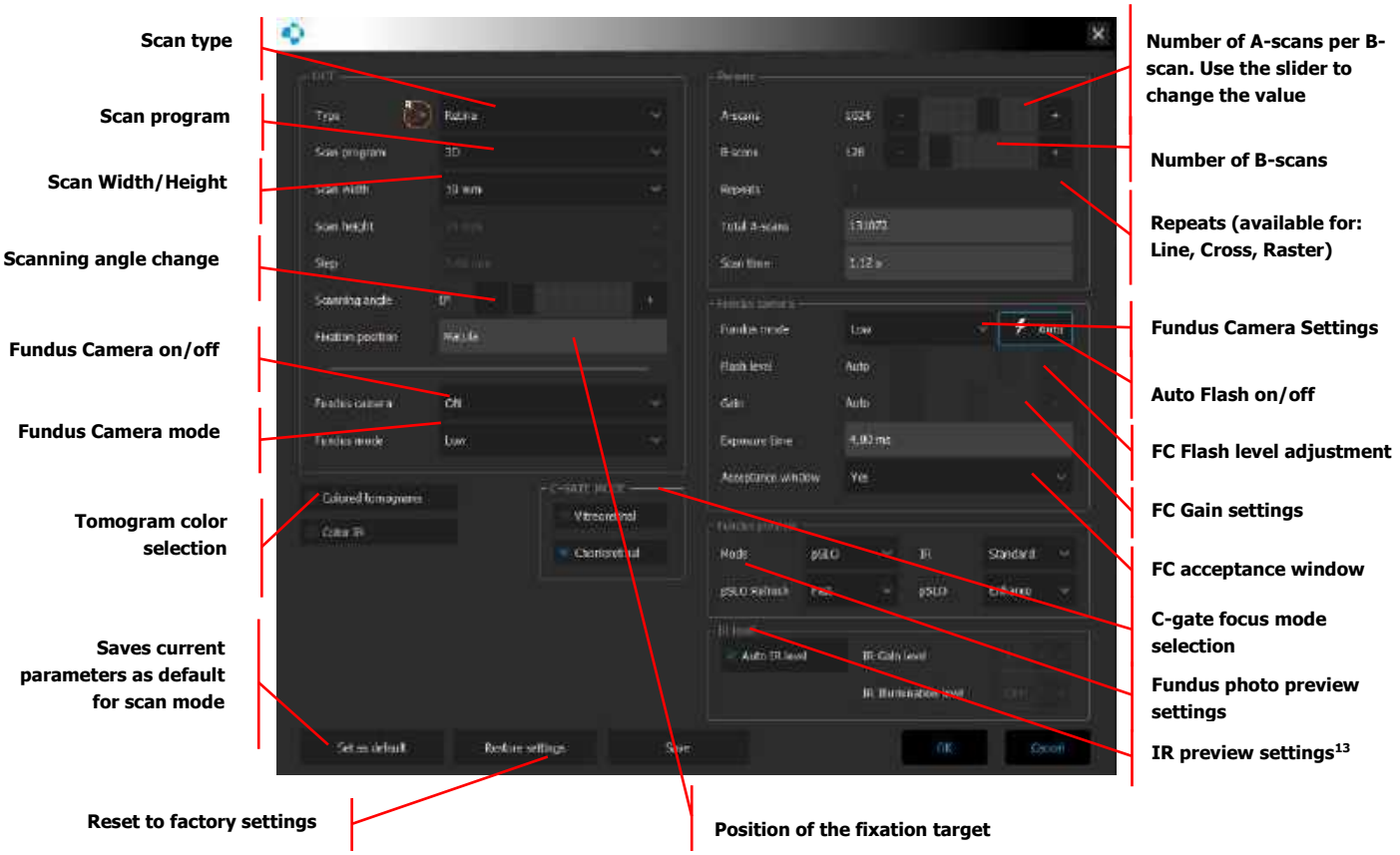


Figure 41.
OCT + Fundus Examination Settings Panel

7.10.2. OCT Scan Parameter Window

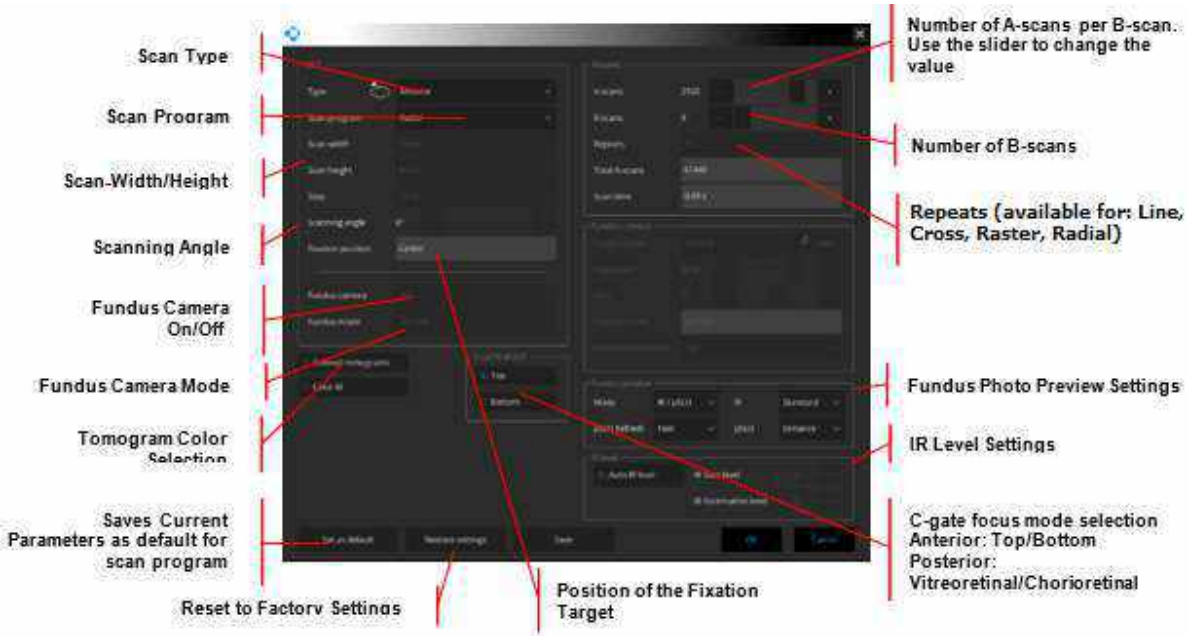


Figure 42.
OCT Examination Settings Panel

The system calculates the total number of A-scans and the examination time. After the changes have been made, the user must press **[OK]** to transfer new scan parameters to the SOCT software or **[SAVE]** to save modified parameters as a new default value.

NOTE: Scan patterns in every scan program have different settings.

1. Increasing the number of B-scans improves fundus reconstruction and map reliability and increasing the number of A-scans improves the quality of tomograms.
2. The operator can save their own settings as a default program to reduce examination time or to obtain a more detailed reconstruction of the retina.
3. By selecting **[RESTORE SETTINGS]**, it is possible to restore the default factory settings and eliminate any saved defaults.
4. To optimize the image on the IR preview, see Chapter 7.7.1 IR Preview.

7.10.3. Fundus Camera (FC) Parameter Window[37]

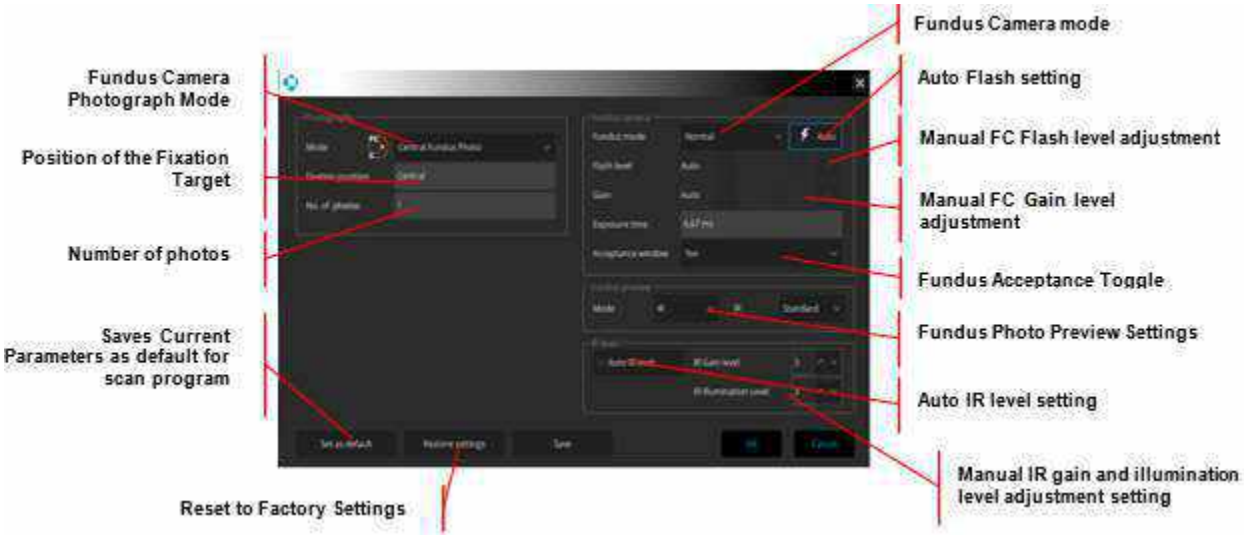


Figure 43.
Fundus Camera Mode Examination Settings Panel

1. FUNDUS CAMERA MODE

Set the level of the flash – increase the value when the photo is too dark or decrease the value when the photo is overexposed. there are three modes available: high, normal and low. Choose the mode suitable for color of the eye and the size of the pupil.

2. AUTO FLASH

Controls the Fundus Camera (FC) flash and gain levels automatically and disables the manual flash and gain sliders. To turn the function on / off, click the icon. When enabled, a blue border will surround the Auto button.

[37] Programs available only for the REVO OCT models with Fundus Camera.

3. **FUNDUS CAMERA FLASH LEVEL**

Sets the level of the flash – increases the value when the photo is too dark or decreases the value when the photo is overexposed. This adjustment is not available if the Auto Flash function is on.

4. **FUNDUS CAMERA GAIN SETTING**

Sets the gain level – increases the gain when the photo is too dark or decreases the gain when the photo is overexposed.

5. **FUNDUS CAMERA ACCEPTANCE WINDOW**

Toggles the display of an acceptance window on or off after capturing the fundus image.

6. **FUNDUS PREVIEW MODE**

Sets the live preview display type.

7. **PHOTOGRAPH MODE**

Offers three programs: Central Fundus Photo, Disc Fundus Photo, and Retina Fundus Photo.

8. **FIXATION POSITION**

Sets the fixation target.

9. **NUMBER OF PHOTOS**

Sets the number of photos captured.

10. **AUTO IR**

Adjusts the IR gain and illumination levels automatically and disables the manual gain and illumination controls. To turn the function on / off, check / uncheck the checkbox.

7.10.4. Parameter Window Options

OCT + FUNDUS PARAMETER SETTINGS

OCT

Type:	**Retina**, **Disc**, **Anterior**, **Widefield**
Scan Program:	**3D**, **Raster**, **Raster 21, Line**, **Cross**, **Radial**, **Full Range**
Scan Width:	Select from available scan width options based on scan type and program.
Scan Height:	Select from available scan height options for Raster scans.
Step:	Select from available spacing options for Raster scans.
Scanning Angle:	Adjust the slider to select scanning rotation angle.

Fixation Position:	Displays **Macula**, **Disc**, or **Widefield** depending on the Scan Type.
Fundus Camera[38]:	**ON** or **OFF**
Fundus Mode[38]:	**Low**, **Normal** or **High**. Choose the mode suitable for the color of the eye and the size of the pupil.
Color Tomographs:	**ON** or **OFF**
Color IR:	**ON** or **OFF**
C-Gate Mode:	**Vitreoretinal** or **Chorioretinal** mode (Posterior Scans). **Top** or **Bottom** mode (Anterior Scans). To learn more about C-Gate mode, see Chapter 8.5 C-Gate Modes.

Parameters

A-Scans:	Adjust the slider to select the number of A-scans per B-scan.
B-Scans:	Adjust the slider to select the number of B-scans (not available for single B-scan, cross and raster scan programs).
Repeats:	Select from the available number used for B-scan averaging. This defines how many times a B-scan is repeated in one location. It is used to create an averaged image. It is available for the B-scan and the raster scans.
Total A-Scans:	Displays the total number of A-scans for current parameter settings.
Scan Time:	Displays the total time needed to complete the current scan. Displays a warning for a long examination time in red.

Fundus Camera[38]

Fundus Mode:	Choose: **Low**, **Normal** or **High**. Use low for photophobic patients, and **Normal** or **High** for the best quality image.
Auto Flash:	**ON** or **OFF**. Controls the camera flash and gain levels automatically and disables the manual flash and gain sliders. To toggle the function on / off, click on the icon.
Flash Level:	If **Auto Flash** is turned off, use the slider to adjust the flash level.

[38] Available only for REVO FC 130 and REVO FC with REF 1905xxx.

Gain:	If **Auto Flash** is turned off, use the slider to adjust the gain.
Exposure Time:	Displays the exposure time in milliseconds. Changes based on the Fundus Mode.
Acceptance Window:	Switches acceptance window **ON** or **OFF**.

Fundus Preview

Mode:	**IR, IR / pSLO**[39], or **pSLO**
IR[39]**:**	**Standard** or **Enhance**
pSLO Refresh:	**Fast** or **Accurate**. Adjusts the refresh rate of the fundus preview. **Fast** displays smooth movement of the retina but decreases the number of details displayed.
pSLO:	**Standard** or **Enhance**

IR Level[39]

Auto IR Level:	**ON** or **OFF**
IR Gain Level:	If the **Auto IR Level** is off, use up / down to adjust the **IR Gain** level.
IR Illumination Level:	If the **Auto IR Level** is off, use up / down to adjust the **IR Illumination level**.

7.11. Live OCT Preview

The Live OCT Preview has four tomogram previews for the 3D scan types and two for other scan types. For 3D scans, each viewport includes a color-coded scan marker on the upper right to identify each

[39] Available only for REVO FC 130 and REVO FC with REF 1905xxx.

scan line. The color and orientation of each marker corresponds to the color and orientation of the lines that make up the scan pattern overlay in the pSLO preview.

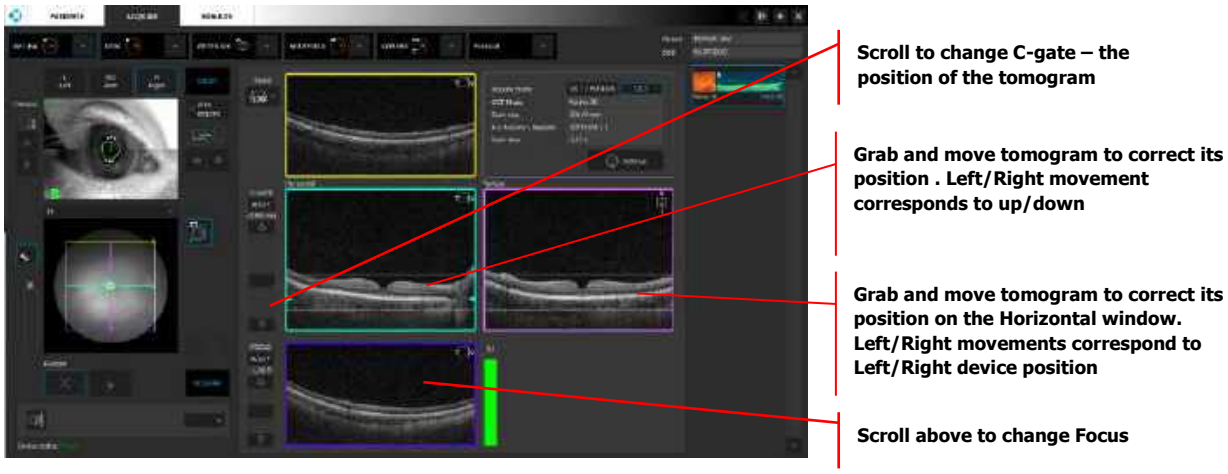


Figure 44.
Tomogram Preview Images (Manual Position Adjustment)

On the horizontal and vertical image, it is possible to correct the position of the tomogram. Grab and move the OCT image (e.g., retina) to the desired position. On the horizontal preview, the left / right movement corresponds to the left / right scan head movement. On the vertical preview, the left / right movement corresponds to the up / down scanning head movement.

AUTO C (GATE)

Automatic C-gate function compensates for the position of the object on the OCT live window preview (length of coherence gate). These buttons help to place the tomogram in the proper position vertically. To change the default height of the retina tomogram move one of the green triangles to the desired position.

C-GATE

Displays position of the length of coherence gate. These sliders help to improve the scan image quality and place it in the optimal position vertically.

7.12. Pupil Size Indicator

The Pupil Size Indicator (Figure below) shows if the measured diameter of the pupil is suitable for Eye Tracking. There are three levels of pupil size indicators:

	The diameter of the pupil is below the minimum allowable pupil diameter of 1.7 mm (for the devices with REF 190, 191, 192, 193 and 194) or 2.4 mm (for the devices with REF 155, 156). Eye tracking with AccuTrack™ is not available.
	The diameter of the pupil is equal to or greater than 1.7 mm (for the devices with REF 190, 191, 192, 193 and 194) or 2.4 mm (for the devices with REF 155, 156), but is smaller than the optimal pupil diameter of 3.6 mm. The performance of eye tracking with AccuTrack™ may be affected.

	The diameter of the pupil is equal to or greater than the optimal 3.6 mm.

7.13. AccuTrack™ (Hardware Eye Tracking)

The hardware eye tracking technology (AccuTrack™)[40] based on IR fundus preview, when enabled, automatically compensates for involuntary eye movements and blinks during an examination. The AccuTrack™ system reacts during eye movement to maintain alignment of the scan to the original position of the scan.

The AccuTrack™ is available for Posterior scans in all acquisition modes

NOTE: Always check if the AccuTrack™ is on or off. Turning the AccuTrack™ on is under the operators discretion.

NOTE: The optimal pupil size for AccuTrack™ is 3.6 mm or bigger.

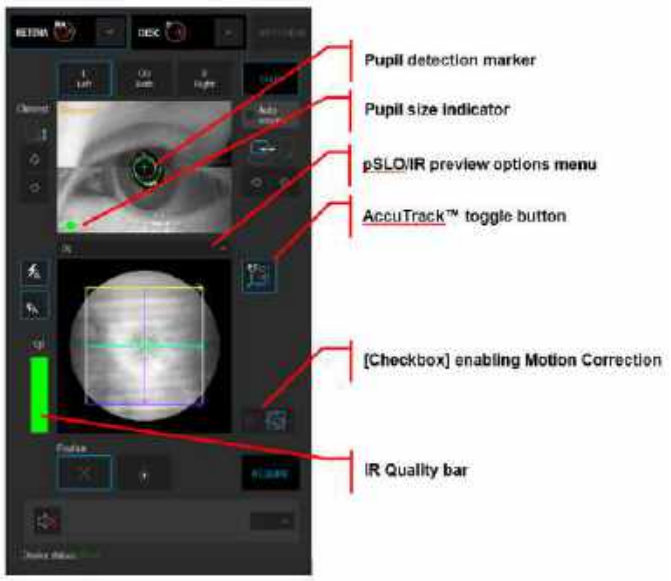


Figure 45.
Eye Preview with Tracking Controls

[40] Available only for REVO HR, REVO FC 130 and REVO FC with REF 1905xxx

1. PSLO / IR PREVIEW OPTIONS MENU

Allows the user to choose from the following preview modes: pSLO (the default setting for devices without IR), IR (the default setting), and IR / pSLO

2. ACCUTRACK™ BUTTON

Click to turn the eye tracking function on or off. Once the function is enabled, the state of the function is indicated as seen below:

	All requirements for performing a scan with AccuTrack™ have been met and the green status is displayed.
	Poor image quality and / or a small pupil: AccuTrack™ is disabled and the red status is displayed.

ACCUTRACK™ BUTTON QUALITY

The quality of an IR image is indicated by a green or red symbol. If the image quality is too low, the red symbol is shown, and AccuTrack™ is disabled.

If the user is working in Full-Auto or Semi-Auto mode, and the image quality is too low for the eye tracking functionality, the following message is displayed:

"No condition for Eye Tracking. Press OK to continue examination without Eye Tracking or press Cancel to stop examination."

The user can choose to either continue to scan without eye tracking or to go back to the Acquire window by clicking Cancel.

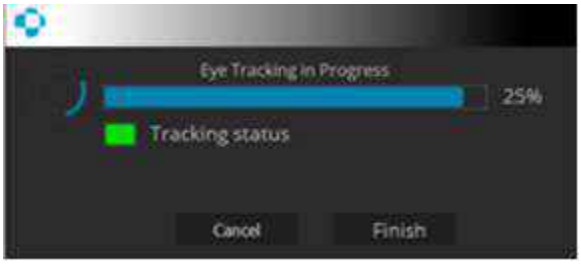
If the user is working in Manual mode and the conditions for using Eye Tracking have not been met, the following message is displayed:

"No condition for Eye Tracking."

When eye start tracking fails, this message is displayed. Click **[OK]** to close it and continue examination without the Eye Tracking. Verify condition and try again or continue scanning without tracking.

The message disappears after three seconds, and the user can continue to manually acquire an exam with the Eye Tracking function off.

Once scanning has started, a progress bar window with the tracking status indicator is displayed. The indicator is green if scanning is progressing normally. If scanning conditions deteriorate (due to blinking, poor IR image quality, etc.) or if the device is repositioning the lens, the tracking status indicator turns red.



After conducting an examination with Eye Tracking, the system displays an acceptance window with the result of a scan.

AccuTrack™ button stores status separately for Angio OCT and 3D scans.

7.14. Motion Correction Acquisition

[iTracking] is available only for examinations with the scan width equal to or less than 7 mm.[41]

To enable **[iTracking],** click on the [Checkbox] shown in Fig. 29. With the motion correction feature checked, the system conducts a motion corrected examination.

Figure 46.
Motion correction enabled

Prior to a OCT-A exam, if the operator expects a patient will be unable to maintain position or fixation, they can enable **[iTracking]** to capture two identical exams one after another by pressing the **[ACQUIRE]** button. The system will then generate a third, motion corrected, exam which will eliminate or minimize eye movement artifacts.

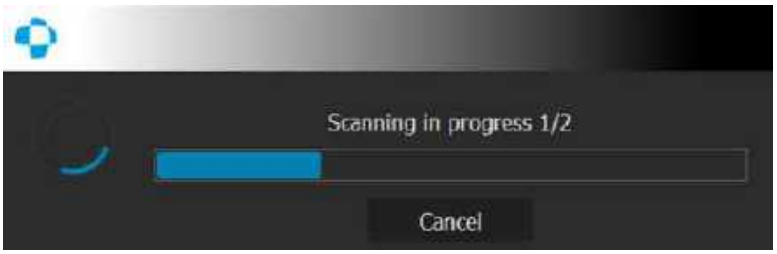


Figure 47.
Scanning process

After conducting an examination, the user decides if the Motion Correction analysis will be performed immediately in the **[ACQUIRE]** tab or later in the **[RESULTS]** tab.

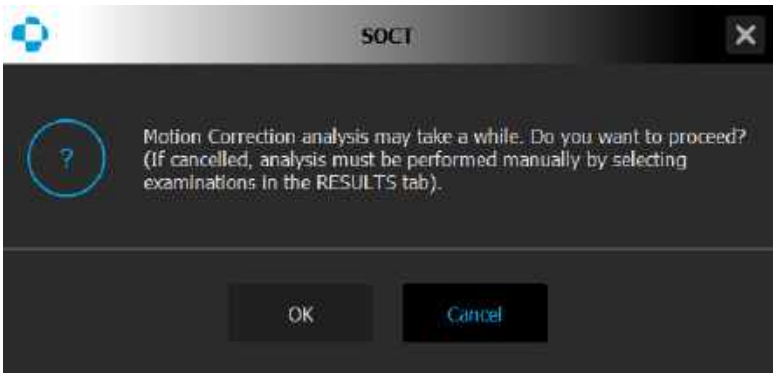


Figure 48.
A dialog for choosing when the analysis is to be performed

After an exam, if the user determines it is necessary to rescan (as explained in Chapter 7.14.1 Acceptance of the scan with the iTracking function.), the user can select the **[RESCAN]** option and the

[41] Motion Correction is not available for Angio scans with a resolution of 768x768 on PCs with less than 32 GB of RAM.

system will repeat the exams. Then, if the operator selects **[MOTION CORRECTION]** in the **[RESULTS]** tab, the system will use up to four repeated exams to generate the motion corrected image. A single exam may provide sufficient data. If there is enough data, the algorithm will generate a correct result.

To perform Motion Correction on completed exams:

1. Mark the desired examinations (one to six identical exams) on the Exam List in Results view (hold the **CTRL** key and click on each exam).
2. Click the right mouse button and select “Motion Correction” from the Menu. The system will generate a new image with reduced motion artifacts.

NOTE: All marked examinations must have the same physical dimensions and the same number of A and B scans and the same exam type. Please note, if an artifact repeats in the same position on all scans, the system will not be able to eliminate the artifact from this area.

NOTE: The scans used for Motion Correction must be complete scans with sufficient data and quality necessary for correct motion artifacts reduction.

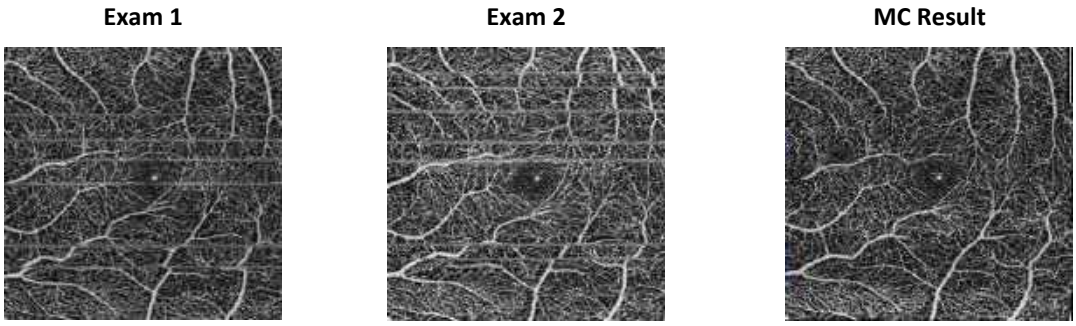


Figure 49.
Example of Motion Corrected OCTA Examination

[iTracking] button stores status separately for Angio OCT and 3D scans.

7.14.1. Acceptance of the scan with the iTracking function.

If the system does not recognize any motion artifacts, it will not create a Motion Corrected scan. In this situation, instead of the Motion Corrected label in the top left corner of the window, the system will display the time of the exam without the label.

If the user does not accept the Motion Corrected results, they can **[RESCAN]** the exam. If the new Motion Corrected results are still unacceptable, the user can choose the Motion Correction function based on four or more original scans from the Result tab.

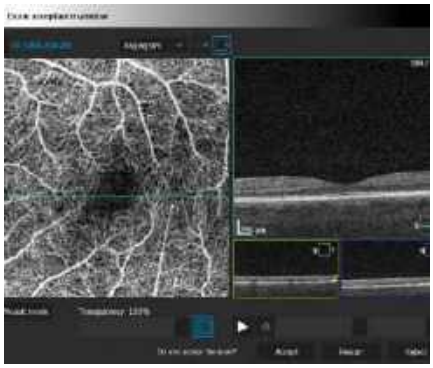


Figure 50.
Angio Scan Acceptance Window

1. **ACCEPT**

   Button [ACCEPT] accepts conduted scans:

   - If after pressing [ACCEPT] the Motion Correction (MC) algorithm does not detect movement artifacts and / or blinks in two acquired scans, the device software will save the two scans without movement artifacts and / or blinks.

   - If after pressing [ACCEPT] the Motion Correction (MC) algorithm detects movement artifacts and / or blinks in two acquired scans, the device software will save the third scan without artifacts.

2. **RESCAN**

   Saves the two scans and returns to the acquisition window to repeat a poor scan due to movement artifacts and / or blinks. If the second or further scans yield no satisfactory result, the user can either try again or use the Motion Correction function based on scans from two or more iTracking attempts from within the Results tab.

3. **REJECT**

   If clicking **[REJECT]**, the system will only save the two basic scans if iTracking had been enabled. If not, the system will not save any scans.

4. **MOSAIC MODE**

   In Mosaic mode, when selected, the system goes into mosaic acquisition mode.

See details in Chapter 8.3.8.2 Manual Mosaic Acquisition Mode.

After scan acquisition, the Angio Scan Acceptance Window will appear. For more on Acceptance Windows see Chapter 9.2 Exam Acceptance Windows.

At the top of the exam list, a Motion Corrected scan is shown and is selected as the active scan.

For Angio exams, the component description is corresponding to those carried out with Mosaic and those will not be analyzed, but instead marked as one, two and MC on the list. When identical exams are performed again (i.e., same location, number of A and B scans, width, and angle of scan), those will be marked as three and four.

7.15. Too high spectrum band height warning

WARNING: If the spectrum band height is too high the [ACQUIRE] tab will be blocked to avoid eye damage

When the spectrum band height will exceed a certain value (4000), the warning presented below will appear and the **[ACQUIRE]** tab will be blocked.

To unlock the **[ACQUIRE]** tab go to Setup -> Preferences -> Setup(Device) -> Parameters and click [**Unlock ACQUIRE**] button. The window presented below will appear:

Click on the [**Check the spectrum band height**] button. If the spectrum band height will be at a correct (less than 3800) value, the **[ACQUIRE]** tab will be unlocked and the window presented below will appear:

In case the spectrum band height remains above the correct (3800 or more) value please contact an authorized Optopol representative immediately to have the power output of the device verified and adjusted.

8. Performing the OCT Examination

The SOCT software provides several different scan types and programs. The table of all scans is found in Chapter 2.10 Device Scan Types and Programs.

1. There are six **Scan Types**: Retina, Disc, Anterior, Widefield, Fundus Camera and Protocol (See details in Chapter 8.3 Description of the scanning programs.)
2. There are several **Scan Programs**: 3D, Line, Cross, Raster, Radial, Widefield. Optional modules include: Angio, Topo, and Biometry.
3. There are three **Acquisition Modes**: Full-Auto, Semi-Auto and Manual mode. (See details in Chapter 8.2 Description of Acquisition Modes.)

8.1. Preparing for an Examination

To prepare for an examination, have the patient sit comfortably in a stable chair in front of the REVO device. Clean the chinrest and forehead rest with dedicated disinfectant substance. It is helpful to explain general instructions and a summary of the examination procedure to the patient:

> **"Today we will be performing an OCT and taking images of the inside or back of your eyes. There will be blinking lights and I will instruct you where to look during the exam."**

When taking a Fundus photo with an OCT device, let the patient know they are going to experience a flash, for example in these words:

> **"At the end of the exam, there will be a bright flash to capture a photo."**

Check the patient's pupil size. The pupil of the eye to be examined must be at least 1.7 mm (for the devices with REF 190, 191, 192, 193 and 194) or 2.4 mm (for the devices with REF 155, 156) in diameter. **Dilation is optional.** Attempting acquisition of tomograms through a pupil with a diameter <1.7 mm (for the devices with REF 190, 191, 192, 193 and 194) or 2.4 mm (for the devices with REF 155, 156) will result in dark edges and lack of signal peripherally.

Perform the following steps to begin an examination in the SOCT software:

1. From the **[PATIENTS]** Tab, create / select the patient to be examined. The **[PATIENTS FILTER]** can be used to quickly filter existing patients in the database. See Chapter 6.2 Creating a New Patient File.

2. Verify the patient refraction data. If the refraction value is higher than ± 10 D, add spherical equivalent information to the patient's data by clicking **[EDIT PATIENT].** See Chapter 6.3 Editing Patient Demographic Data for an Existing Patient.

3. Click the **[ACQUIRE]** tab from the main window. Make sure that the proper patient is selected (look at the upper right corner of examination window). See Chapter 7 Acquire Tab.

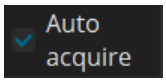
4. Select the desired scan type (**RETINA, DISC, ANTERIOR, WIDEFIELD)** (see Chapter 7.3 Selection of Scanning Programs) or Protocol. See Chapter 23.5.2.1 Protocol Tab in the examination panel and acquisition mode. See Chapter 8.2 Description of Acquisition Modes. The type of Acquisition mode should be selected (Full-Auto, Semi-Auto, or Manual).

5. **Patient Positioning:** Ask the patient to sit facing the chinrest. Adjust the chair height to allow the patient to sit comfortably. Adjust the table to allow the patient to place their chin on the chinrest and ask the patient to rest their head against the forehead support. Check if the patient head touches the forehead support and the patient chin is placed on the chinrest. If necessary, adjust the Chinrest height with up / down control buttons to adjust the height alignment. Align the patient's canthus to the canthus reference marker on the headrest of the REVO device. Advise the patient to look straight ahead and to focus on the blinking fixation target only and not to follow the scanning beam.

WARNING: Make sure that the patient does not put his head inside the headrest frame when the "up" or "down" chinrest elevation button is pressed.

6. On the acquisition screen, press the **[L]**, **[R]** or **[BOTH]** button to choose the desired eye(s) for testing. When the system recognizes the pupil, the **[START]** button becomes available. If the pupil is not visible on the eye preview, the user should move the scanning head to the left / right and / or forward / backward slightly to allow for pupil detection. It is also possible to click on the eye preview (left mouse button or by tapping the touch screen) to move the device to the desired location. See Chapters 7.5 Device Head Movement Controls and 7.6 Anterior Eye Preview.

8.2. Description of Acquisition Modes

The user can check or uncheck the 

[AUTO ACQUIRE] button to set Acquisition Mode configurations:

1. FULL-AUTO CAPTURE MODE

Auto-alignment, auto-optimization and auto-capture are enabled. The system performs an auto-alignment of the scanner position to the patient, optimizes the OCT signal (optimizes the C-gate position, OCT focus position, adjusts tomograms within horizontal alignment lines) and then automatically captures an examination once the automatic alignment procedure has been successful. **[AUTO ACQUIRE]** button is **checked**.

2. SEMI-AUTO CAPTURE MODE

Auto-alignment and auto-optimization are enabled. Operator presses **[START]** button to align and optimize the OCT signal automatically, and then the operator initiates the acquisition of the examination by pressing the **[ACQUIRE]** button. **[AUTO ACQUIRE]** button is **unchecked**.

3. MANUAL CAPTURE MODE

Fully manual alignment, optimization of the tomogram and manual capture. The operator manually aligns and optimizes the OCT signal position of the tomograms and initiates the acquisition of the examination by pressing the **[ACQUIRE]** button. **[AUTO ACQUIRE]** button is **unchecked**.

NOTE: When the system displays warning "Tomogram Alignment failed", the operator should manually adjust the tomogram to the relevant position. Improperly aligned tomograms will influence the quality of the acquired tomograms and the reliability of the analysis.

8.2.1. Full-Auto Capture

1. Prepare the patient for examination, see Chapter 8.1 Preparing for an Examination.
2. Press the [**START]** button. Ask the patient to follow voice guidance instructions. Wait until the system finishes the examination. The patient will be voice guided by the software.

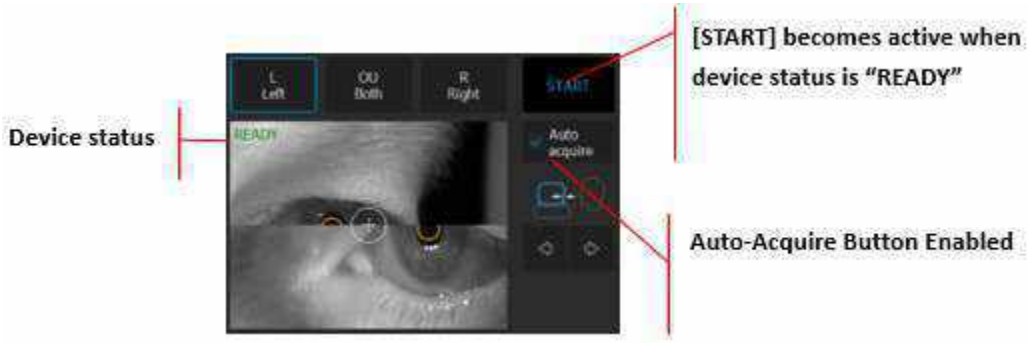


Figure 51.
Full-Auto Examination Configuration

NOTE: In difficult conditions, such as:

- **Eyelashes or eyelid which block the beam of light**
- **Inability of subjects to maintain fixation**
- **Dense media opacities**
- **Strong nystagmus**
- **Rapid blinks**

the system can display a warning. In this case operator should decide whether to use the tips mentioned in the Chapter 8.6 Examination Tips or change the acquisition mode.

NOTE: The Operator is to remain with the patient throughout the scanning process to oversee and guide them. The voice guidance feature is not intended to replace the Operator.

NOTE: Voice guide is on by default. The user can mute it or decide to turn it off in the Setup tab – See Chapter 23.5.4 Voice Support Guide Tab

8.2.2. Semi-Auto Capture

1. Uncheck **[AUTO ACQUIRE]** and press **[START]**. The system will automatically align and optimize the tomogram:

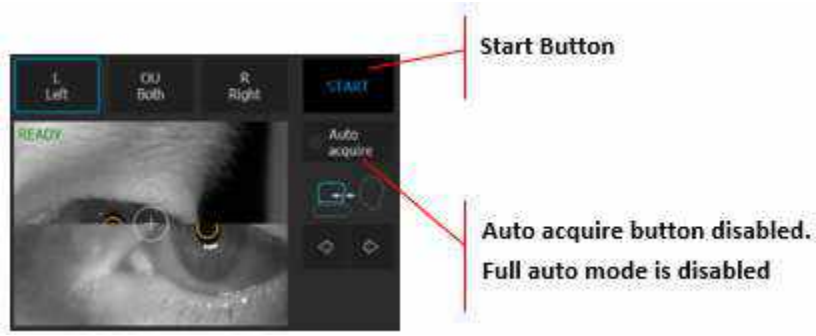


Figure 52.
Semi-Auto Examination Configuration

2. The OCT scan will be placed between the horizontal lines in the OCT tomogram preview.

Figure 53.
Semi-Auto Examination Acquire Screen

3. The user can start the examination by double-clicking on the tomogram or clicking the **[ACQUIRE]** button.

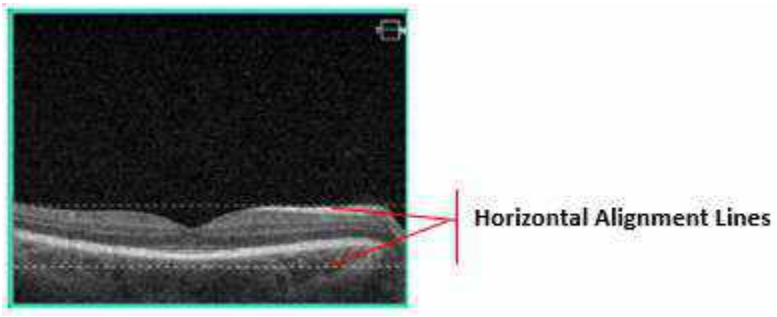


Figure 54.
Correct Position of Tomogram between Horizontal Alignment Lines

4. If the OCT signal is weak, manually optimize the signal, and if the OCT preview has low intensity or shadows around the edges, reposition the scanner head or scan placement in the Fundus Preview.

5. If it is required to scan areas other than the default (macula / disc), change the position of the scan area.

6. Ask the patient to keep looking at the fixation target to avoid any shadowed edges. The OCT cross-section should be visible in the OCT live preview window. Click and drag the tomogram to move the position between the horizontal alignment hash lines on the OCT live preview. To visualize other retinal structures of interest, the user can choose the Vitreoretinal or Chorioretinal C-gate mode.
7. Entering the refractive correction may be necessary to obtain the best quality tomogram. Observe the Quality Index (QI) bar to obtain the best signal while changing the **[FOCUS]** bar position. See Chapter 7.1.4 Live OCT Preview.
8. Once the scan location is aligned, ask the patient to blink. Double click on the tomogram or press the **[ACQUIRE]** button. The device will initialize the examination immediately and a full scan will be performed.
9. When the examination is over, the system transfers the captured image into the database.

NOTE: If the system cannot detect a pupil, the user must adjust the center of the patient's pupil manually. To set the working position properly, align the center of the pupil to the proper height.

NOTE: If the system is not able to maintain the correct position of the retina (for example if the patient is moving), the operator must switch off tracking and carry out the examination manually.

8.2.3. Manual Capture

1. Uncheck the **[AUTO ACQUIRE]** button.
2. Align the position of the pupil using the **[UP / DOWN]** and **[FORWARD / BACKWARD]** buttons. Move forward until the top and bottom align the orange half circles merging into one green circle.

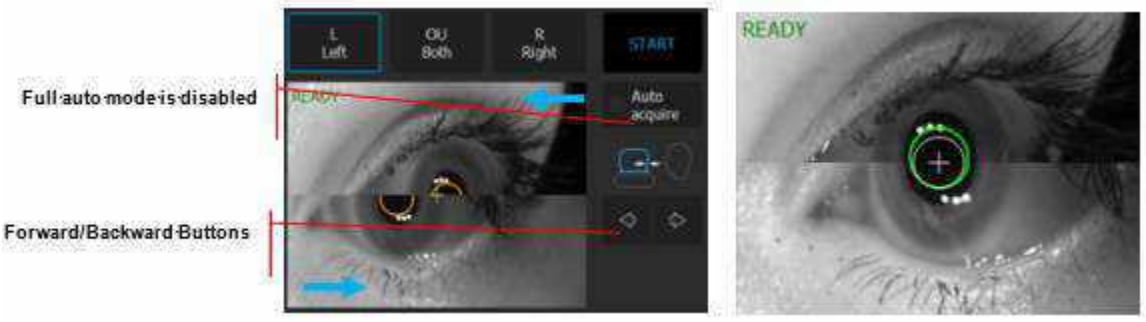


Figure 55.
Manual Examination Mode

3. Click / Press in the center of the pupil to align the image in the center of the pupil.

4. The B-scan image will appear in the OCT preview. Adjust the C-GATE manually by dragging the slider, or by scrolling the mouse wheel while hovering on the slider bar or swiping on the touchscreen. Clicking on **[AUTO C]** button automatically optimizes the C-Gate position.

Figure 56.
Manual Examination Process

Scan optimization and tomogram position alignment. The Left image shows tomograms that are too low and need to be adjusted. The Right image shows a properly align Retina.

5. If the Quality (Q) Bar color is green and the position of the B-Scan is within the horizontal alignment hash lines, proceed to Step 6. If not, reposition the scan area, adjust the focus and / or adjust the C-Gate position until Q bar is green. For optimal quality, the Q Bar (Signal to Noise ratio) should be as high as possible.

6. See Chapter 7.1.4 Live OCT Preview

Figure 57.
Proper Position and Quality of the Tomogram

7. Manually optimize the signal if the preview has low saturation or shadows on the edges, and if required, change the scan area (e. g., peripheral area):

   - Move the position of the internal fixation target. Ask the patient to follow the fixation target. The OCT tomogram should be visible in the OCT live preview window. Drag the preview to move the tomogram to the correct position.
   - Change the offset of the scanners.
   - Choose between Vitreoretinal or Chorioretinal C-Gate mode, for improved visualization of retinal or choroidal structures.

8. Adjust the **[FOCUS]** slider to improve tomogram quality. Observe the Quality Bar to obtain the best signal while adjusting the **[FOCUS]** slider position. Clicking **[AUTO F]** button will automatically adjust the focus.

9. Once the scan location is aligned, ask the patient to blink. Double click on the tomogram or press the **[ACQUIRE]** button. The device will initialize the examination immediately and a full scan will be performed.
10. When the examination is complete, the system saves the image to the database.

8.3. Description of the scanning programs

8.3.1. Retina Examination

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. If voice guidance is switched off, inform the patient to look at the center of the green cross (the fixation target) and to blink freely. If voice guidance is required, use the large fixation target. See Chapter 7.9 Fixation Target Adjustment.
3. Verify scan program and change to **[RETINA]** if required.
4. Follow the procedure depending on the Acquisition mode (Full-Auto, Semi-Auto, Manual). See Chapter 8.2 Description of Acquisition Modes.

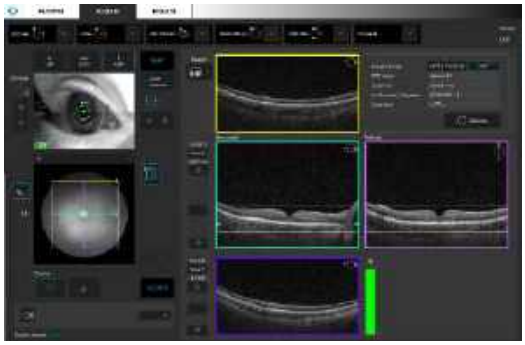


Figure 58.
Proper Alignment of Retina Tomogram

8.3.2. Widefield Examination

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. If the voice guidance is disabled, ask the patient to look at the center of the green cross (the fixation target) and let them know they can blink freely. If required, use the large fixation target. See Chapter 7.9 Fixation Target Adjustment.
3. Verify the scan program and change to WIDEFIELD if required.

4. Follow the procedure depending on Acquisition mode (Full-Auto, Semi-Auto, Manual). See Chapter 8.2 Description of Acquisition Modes.

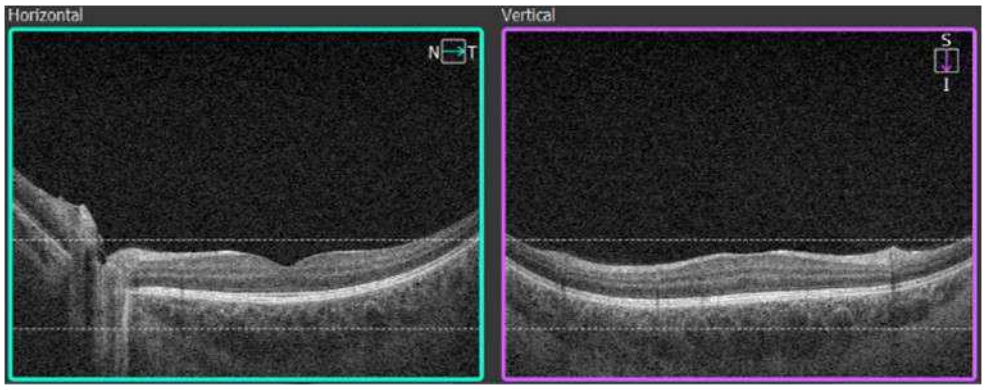


Figure 59.
Widefield Examination Proper Scan Alignment

8.3.3. Disc Examination

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. Select Disc mode and scan type from program panel.

NOTE: Selecting the disc examination does not initially change the Fixation position.

3. If voice guidance is switched off, inform the patient to look at the center of the green cross (the fixation target) and to follow it as it moves in the nasal direction.
4. Press the **[START]** button for Full-Auto or Semi-Auto mode.
5. In Semi-Auto or Manual mode, after the OCT signal is aligned properly, the pSLO or in IR fundus preview image of the Optic Nerve appears in view.
6. The center of the scanning area should be placed in the center of the Optic Nerve Head.

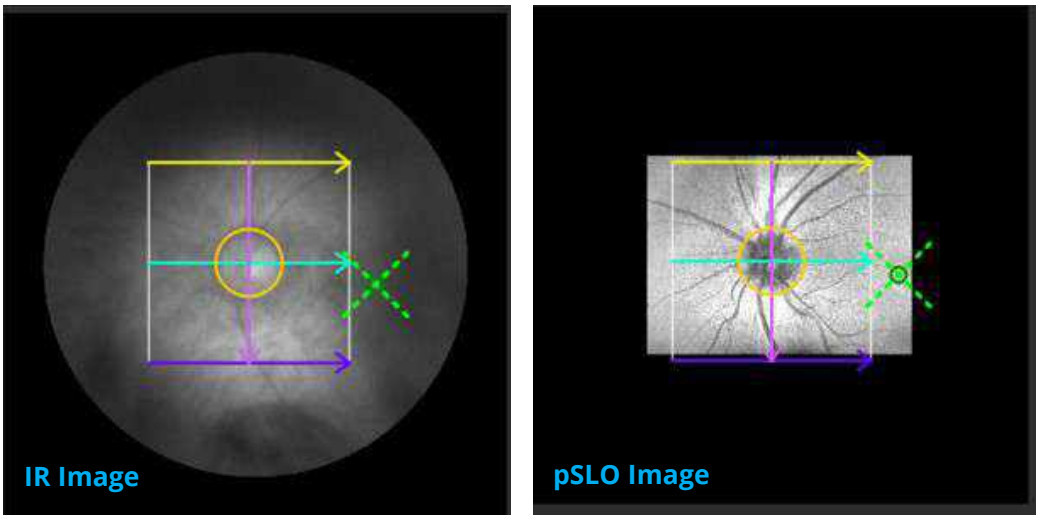


Figure 60.
Proper Positioning of the Scanning Area over the Optic Nerve Head.

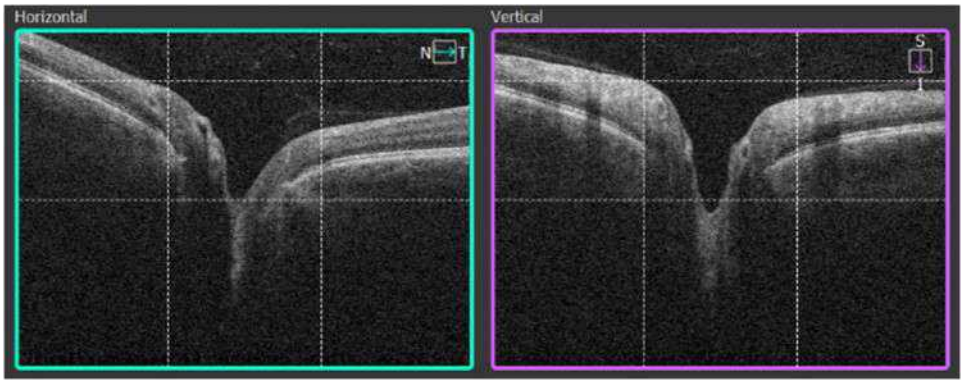


Figure 61.
Proper Disc Examination Alignment (Live View)

If correction of the scanning area is required drag and move the scanning area to the center of Optic Nerve Head. See details in Chapter 7.8.1 Moving the Scanning Area. Dashed vertical lines on the live tomogram preview correspond to the circle on the pSLO fundus preview. The scan is positioned correctly when the vertical lines on the live OCT windows are equally placed from Bruch Membrane Opening

NOTE: Adjust the position of the scan with slight left / right / up / down movement if there are any shadows on the edge of the tomogram. The optimal position is where the entire tomogram is properly saturated, and QI is as high as possible.

To obtain the best saturation of the OCT signal, verify the correct refraction and perpendicularity of the tomogram. The operator can drag the tomogram to the desired position on the live OCT window.

7. Once the scan location is set on the selected area of the disc, double click on the tomogram preview window or press the **[ACQUIRE]** button. The device will begin the acquisition process.

8.3.4. Anterior Examination

The devices with reference number REF 190, 191, 192, 193 and 194 come with an internal anterior lens and does not require the installation of an external adapter for examination of the anterior segment. When the user selects an anterior scan program, the internal lens is automatically positioned.

To conduct an Anterior Segment examination, follow these instructions:

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. Select the dropdown arrow next to **[ANTERIOR]** and select a scan program. (Hover over each icon to display the Scan name).
3. Press the **[START]** button to begin Full-Auto or Semi-Auto capture mode.
4. In Semi-Auto or Manual mode, verify the position of the OCT signal before pressing the **[ACQUIRE]** button.

CORNEA SCAN

(For acquisition of the Pachymetry Map, select the Anterior Radial scan). For optimal corneal imaging, place the cornea image between the two horizontal dashed lines. Use the center reflex from the cornea

to identify the vertex and align it with the vertical reference line. Center the scan in the middle of the scan window.

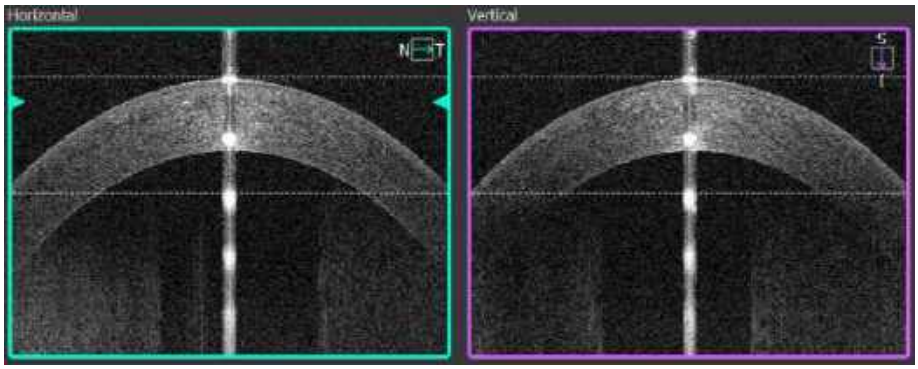


Figure 62.
Proper Anterior Measurement Alignment

ANGLE SCAN

There are two techniques available to acquire the single Angle scan:

Method I:	Ask the patient to look to the side (edge of device head) or use the external fixation target to guide the patient until the cornea and sclera are parallel to the scanning window. Grab and move the cornea image until the anterior angle is in the center of the scan window. (See the image below for reference).

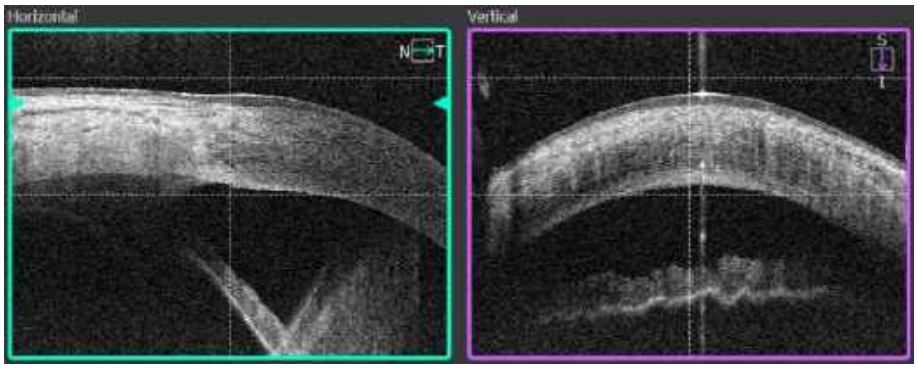


Figure 63.
Single Angle Measurement Proper Alignment

Method II:	Ask the patient to look straight ahead. Move the scanning head until the anterior angle appears in the scan window. For this method, it is recommended to scan in Bottom mode. See Chapter 8.5.2 Anterior Top / Bottom C-Gate Mode.

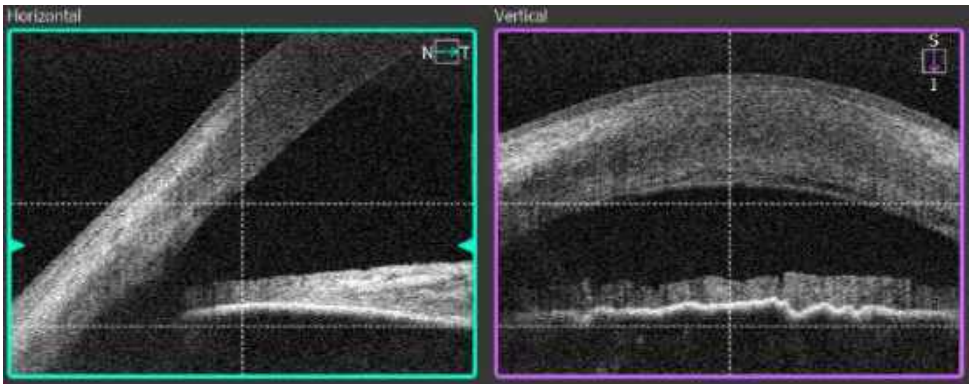


Figure 64.
Proper Alignment of a Single Angle Measurement (Live Preview)

5. Once the scan location is selected, click twice on the tomogram, or press the **[ACQUIRE]** button. The device will initialize the measurement process and then the full scan will be performed.

NOTE: The vertical dense line in the center of cornea is a natural reflection of laser light and has no negative influence on the measurement result. It can be used to assess if the tomogram is in the proper position.

NOTE: The Anterior Chamber scan and Pachymetry scan include compensation for beam scanning geometry and reflection from the surface of the cornea. Therefore, during acquisition, it is important that the scan is centered on the vertex of the cornea so that a strong vertical reflex is visible through the corneal vertex. The compensation algorithm works with greatest accuracy when corneal scans are centered using this method.

NOTE: Only when the cornea / sclera tissue is parallel to the scanning window are the AOD (angle opening distance) and TISA (trabecular-iris space area) manual measurements accurate.

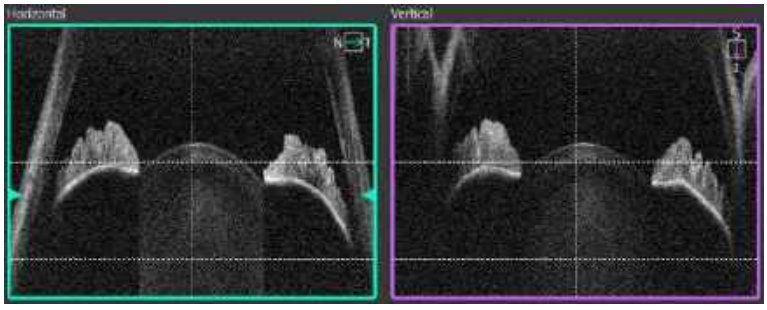


Figure 65.
Preview of Proper Alignment of an Angle-to-Angle Scan

8.3.5. Anterior Wide Examination

8.3.5.1. Anterior Wide programs for REVO, REVO NX and REVO FC

The devices with reference number REF 190, 191, 192, 193 and 194 come with an internal anterior lens and does not require the installation of an external adapter for examination of the anterior segment. When the user selects an anterior scan program, the internal lens is automatically positioned.

In order to conduct examination of anterior segment, follow the instructions below:

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination
2. Select one of Wide Anterior scan program. The scanning head has moved back. The built-in lens will slide out.
3. Press the **[START]** button to begin Full-Auto or Semi-Auto capture mode.
4. In Semi-Auto or Manual mode, verify the position of the OCT signal before pressing the [ACQUIRE] button. Some slight left/right/up/down movements may be needed to find the correct position. Drag the tomograms to optimize the scan position.

8.3.5.2. Anterior Wide programs for REVO and REVO NX (REF 155 and 156)

The anterior chamber adapter for the SOCT is an easy-to-install hardware attachment to allow wide scanning of anterior segment structure. The lens adapter is attached and removed by a trained operator.

When using the adapter for the examination of the anterior segment of the eye, do not move the measuring head too fast and monitor its distance from the patient to prevent contact between the surface of the anterior adapter lens and the patient's eye.

Figure 66.
Side views of Anterior Adapter

In order to conduct examination of anterior segment, prepare the anterior adapter and follow the instructions below:

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. Grab the anterior chamber adapter as shown in the image (with two fingers close to the insertions positioned horizontally.)

Figure 67.
Anterior chamber adapter mounting

3. Get the anterior chamber adapter to the objective and rotate 90º clockwise.

Figure 68.
Anterior chamber adapter rotation

WARNING: When mounting the anterior adapter, make sure that the scanning head is in its maximum backward position and that the patient does not incidentally come into contact with the anterior adapter.

CAUTION: Exercise caution when mounting the anterior adapter in order not to scratch the objective lens.

4. Press the **[START]** button to begin Full-Auto or Semi-Auto capture mode.
5. In Semi-Auto or Manual mode, verify the position of the OCT signal before pressing the [ACQUIRE] button. Some slight left/right/up/down movements may be needed to find the correct position. Drag the tomograms to optimize the scan position.

WIDE CORNEA SCAN

For acquisition of the Pachymetry Map, select the Anterior Radial scan. For optimal corneal imaging, place the cornea image between the two horizontal dashed lines. Use the center reflex from the cornea to identify the vertex and align it with the vertical reference line. Center the scan in the middle of the scan window.

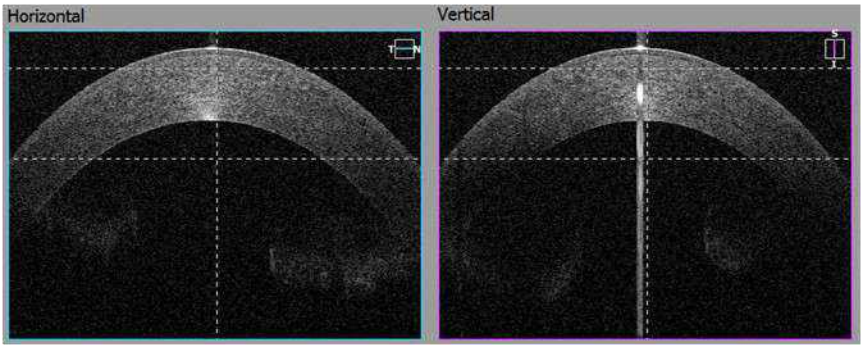


Figure 69.
Proper Wide Cornea Measurement Alignment

ANGLE TO ANGLE SCAN

Ask the patient to look at the center of the green cross. Place the scan in the middle of the iris. Use the pSLO view and the dashed vertical line on the live OCT window for reference. Both angles have to be visible on the live OCT window

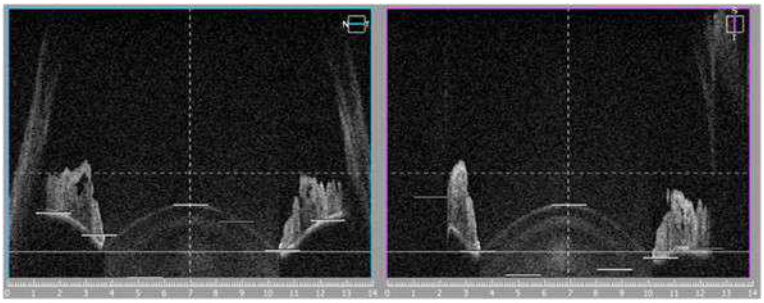


Figure 70.
Proper Angle to Angle Measurement Alignment

6. Once the scan location is selected, click twice on the tomogram, or press the **[ACQUIRE]** button. The device will initialize the measurement process and then the full scan will be performed

NOTE: Only when the cornea / sclera tissue is parallel to the scanning window are the AOD (angle opening distance) and TISA (trabecular-iris space area) manual measurements accurate.

CAUTION: Make sure the patient keeps their face away from the chinrest and the forehead rest when the Anterior Chamber Adapter is still attached. Otherwise, the patient may be injured by the Anterior Segment Adapter coming into contact with them if the scanning head moves in any direction.

8.3.6. Fundus Image (available for REVO FC only)

8.3.6.1. Fundus Only Mode

8.3.6.1.1. Fundus Full-Auto Mode

The Full-Auto mode fundus exam provides a color fundus photo without any OCT scan.

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.

2. If voice guidance is switched off, inform the patient to look at the center of the green cross (the fixation target). If required, use the large fixation target.
3. Choose FUNDUS only mode (Disc, Retina or Central).
4. Follow the procedure for each type of Acquisition mode.

8.3.6.1.2. Fundus Photo Semi-Auto Mode

NOTE: Semi-Auto or Manual mode is useful when the system cannot acquire an optimal fundus image in Full-Auto mode, or when the operator wants to scan an area other than predefined fixation locations (e.g., peripheral area).

1. Prepare the patient's position as explained in Chapter 8.1 Preparing for an Examination.
2. Choose one of the desired Fundus Camera modes: Central (C), Disc (D), or Retina (R).

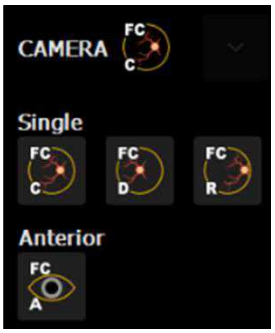


Figure 71.
Fundus Camera Modes

3. To perform Semi-Auto mode, uncheck **[AUTO ACQUIRE]** and press **[START]**. The system will automatically align and optimize the device position (align X-Y-Z head position, optimize focus based on OCT signal) and then correct the position based on the IR preview window and optimize focus base on the OCT signal.

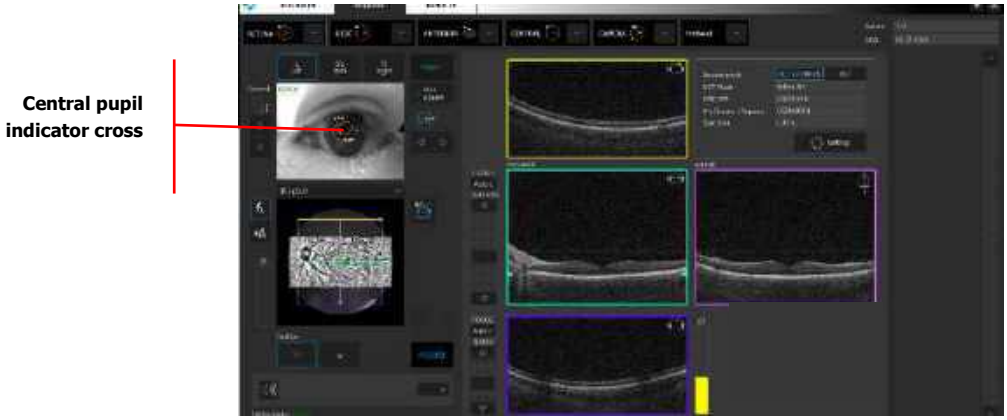


Figure 72.
Correctly Aligned Pupil Position in Fundus Camera Mode

4. The software aligns the position of the scanning head. The operator must perform the following:
   - Verify the position of the scanning head in the Z direction. The two pupil images should create one aligned image.

- Verify the pupil size (a white circle identifies the minimum pupil size). If the pupil is too small, dim the room light or, optionally, dilate the pupil.
- If necessary, correct the alignment of the pupil position. Make sure that the cross on the Eye preview window is in the center of the pupil. You may correct the pupil position as described in Chapter 7.6 Anterior Eye Preview.

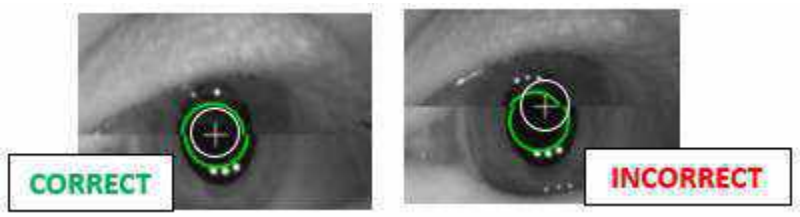


Figure 73.
Eye Preview Window and Pupil Position

- To verify the fundus alignment position, change the live fundus preview to IR to verify the optimal fundus alignment.

NOTE: When the IR preview is ON, the OCT signal is not visible.

Figure 74.
Live Fundus Preview Modes

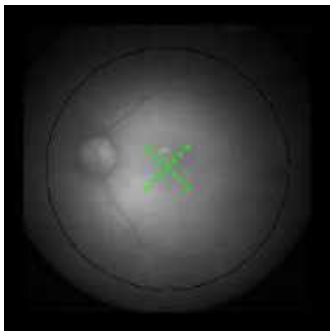


Figure 75.
Live Fundus Preview IR Mode

5. Optimize the visibility and exposure of the retina in the live preview window:
   - The retina must be uniformly exposed. Make sure there are no reflexes on the live preview window, and you will reach the best exposure possible.
   - We recommend optimizing the visibility and exposure of the retina in the live preview window by grabbing and moving the tomogram windows.

- When the reflex is on the left or right side of the retina preview, as shown in Figure 76, grab and move the horizontal tomogram so that the fundus image is centered with no crescent artifacts (reflex).

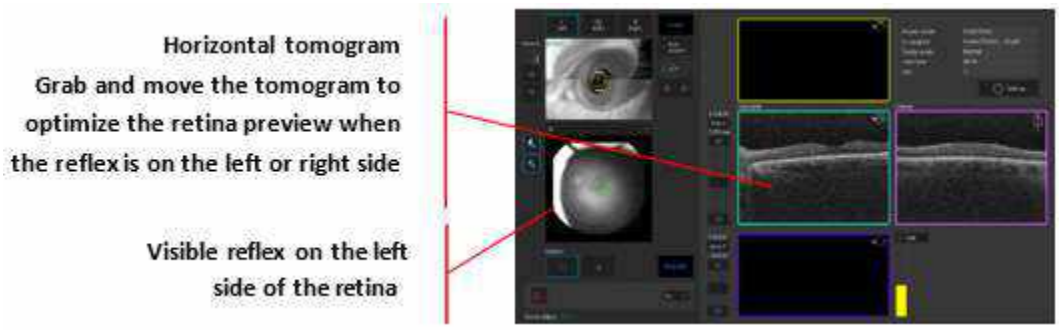


Figure 76.
Fundus Photo Mode Acquire Window

- To eliminate the reflex at the top or at the bottom of the retina preview, grab and move the vertical tomogram so that it sits in the bottom half of the window.

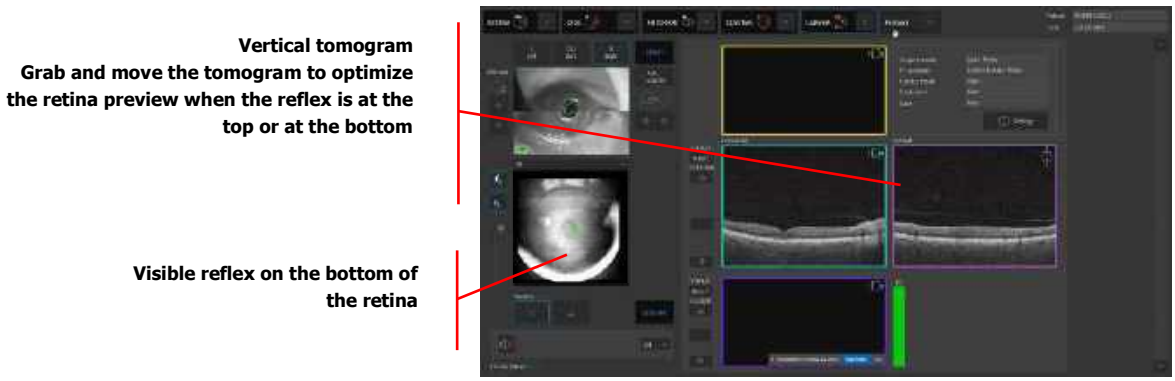


Figure 77.
Fundus Photo Mode Acquire Window

- Try to reach the best possible image of the retina. In case of a weak fundus preview image (i.e., small pupil size, use the enhance mode.) See Chapter 7.7.1 IR Preview.
- Once you reach the best retina exposure, ask the patient to blink. Double click on the tomogram or press the **[ACQUIRE]** button. The device will acquire a photo of the fundus.

8.3.6.1.3. Fundus Photo Manual Mode

1. The Manual mode for Fundus exam provides only a color fundus photo without any OCT scan.
2. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
3. If voice guidance is muted or disabled, ask the patient to look at the center of the green cross and blink freely. If required, use the large fixation target.
4. Choose FUNDUS only mode (Disc, Retina or Central).
5. Move scanning head to working position by scrolling forward:
   - Verify the position of the scanning head in the Z direction. Two pupil images should create one aligned image.

- Verify the pupil size (a white circle identifies the minimum pupil size). If the pupil is too small, dim the room light or dilate the pupil.
- If necessary, correct the alignment of the pupil position. Make sure that the cross on the Eye Preview Window is in the center of the pupil. You may correct the pupil position as described in Chapter 7.6 Anterior Eye Preview;

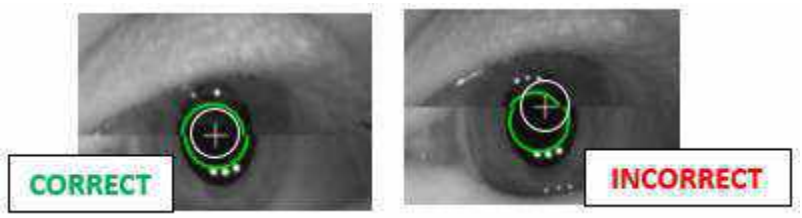


Figure 78.
Eye Preview Window and Pupil Position

- To verify the correctness of the fundus alignment position, change the Live fundus preview to IR to verify the optimal fundus alignment.

NOTE: When the IR preview is ON, the OCT signal is not visible.

Figure 79.
Live Fundus Preview Modes

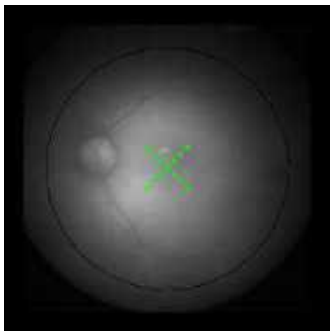


Figure 80.
Live Fundus Preview IR Mode

6. Optimize the visibility and exposure of the retina in the live preview window. The retina must be equally well exposed. Make sure there are no reflexes on the live preview window, and you will reach the best exposure possible.
7. We recommend optimizing the visibility and exposure of the retina in the live preview window by grabbing and moving the tomogram windows.

8. When the reflex is on the left or right side of the retina preview, grab and move the horizontal tomogram so that the fundus image is centered with no crescent artifacts (reflex).

Figure 81.
Fundus Photo Mode Acquire Window

9. To eliminate the reflex at the top or at the bottom of the retina preview, grab and move the vertical tomogram up or down so that it appears in the bottom half of the window.

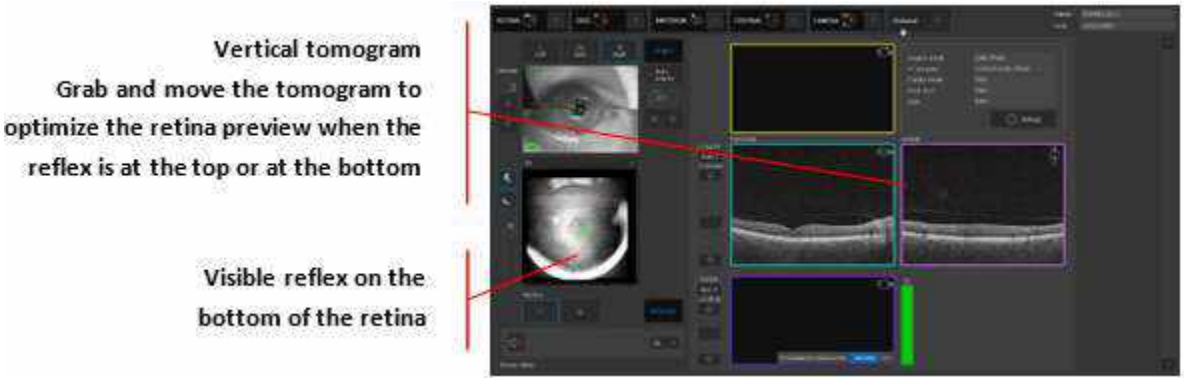


Figure 82.
Fundus Photo Mode Acquire Window

10. Try to reach the best possible exposure of the retina. In case of a weak fundus preview image (i.e., if small pupil size) use the enhance mode. See Chapter 7.7.1 IR Preview.

11. Once you reach the best retina exposure, ask the patient to blink. Double click on the tomogram or press the **[ACQUIRE]** button. The device will acquire a photo of the fundus.

8.3.6.2. Auto Flash

The flash level and gain settings are controlled by the software. The flash level and gain sliders in the scan parameters window are disabled. To turn the function off, click the button.

AUTO FLASH ON

The flash level and gain settings are controlled by the software. The flash level and gain sliders in the scan parameters window are disabled. To turn the function off, click the button.

AUTO FLASH OFF

The user can now adjust the flash level and gain manually in the scan parameters window as described in Chapter 7.10 Customizing Scan Parameter Settings. To turn the function on, click the button.

8.3.6.3. Screening mode

The **[ACQUIRE]** tab with DES mode allows the user to take only Fundus Photo Central, Retina Fundus Photo and Disc Fundus Photo.

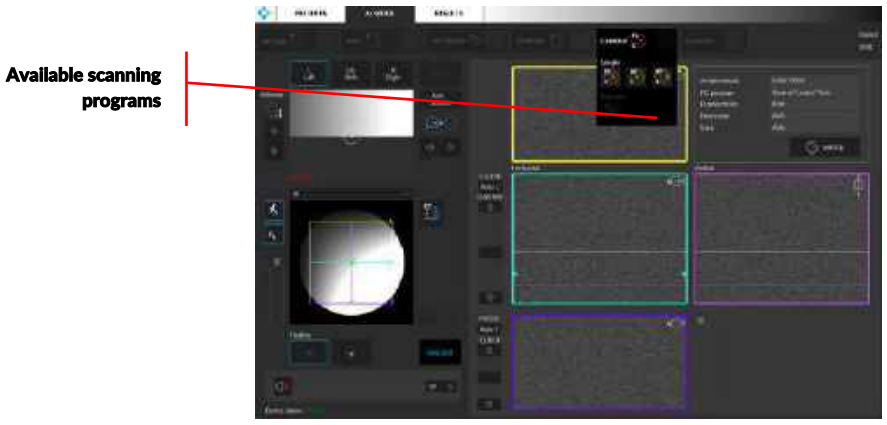


Figure 83.
DEHS Screening Acquire Window

After conducting and accepting the examination the result is automatically generated as a .JPEG file to desired location. Concucted examination can be viewed in the **[RESULTS]** tab but entering **[PATIENTS]** tab removes all patient data from the SOCT database.

8.3.6.4. Fundus Image Acceptance Window

After taking a Fundus photo, with or without OCT, the fundus acceptance window is displayed.

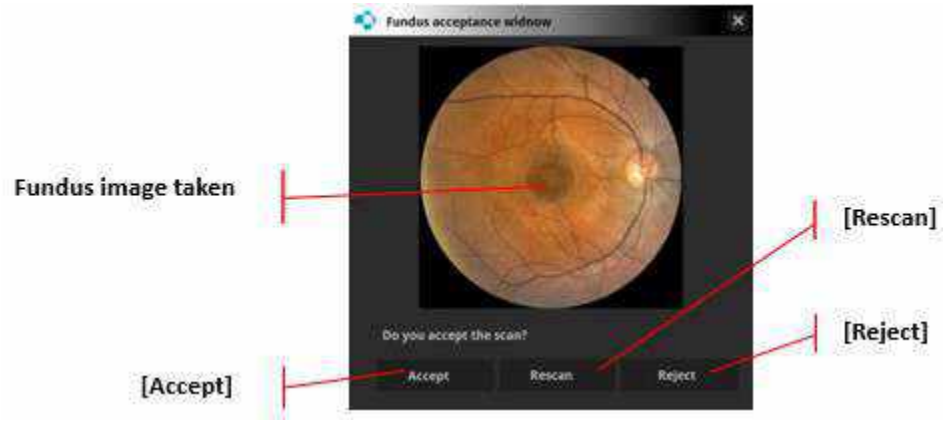


Figure 84.
Fundus Image Acceptance Window for Fundus Picture Mode

1. **[ACCEPT]**

   The exam is saved and the Acquire window is reopened. The operator can continue capturing images or leave the Acquire window. If the operator is using a Protocol, the system moves to the next exam.

2. **[RESCAN]**

   The exam is saved and the Acquire window is reopened for the operator to repeat the scan. If the operator is using a Protocol, the system continues with the current exam type.

3. **[REJECT]**

   The exam is not saved (it is rejected). The Acquire window is displayed to repeat the exam. If the operator is using a Protocol, the system continues with the current exam type.

The X in the upper right corner of the information window closes it and initiates the same action as the **[RESCAN]** button.

8.3.6.5. OCT / Fundus Mode

The OCT + Fundus exam mode provides an OCT scan and captures a flash fundus photo at the end of the OCT scan.

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. If voice guidance is switched off, inform the patient to look at the center of the green cross (the fixation target) and to blink freely. If required, use the large fixation target.
3. Verify the scan program selected.
4. Follow the procedure depending on Acquisition mode. See Chapter 8.2 Description of Acquisition Modes.

8.3.7. OCT Angiography Examination

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. If voice guidance is switched off, inform the patient to look at the center of the green cross (the fixation target) and to blink freely. If required, use the large fixation target. See Chapter 7.9 Fixation Target Adjustment.
3. Select one of the Angiography scan programs.
4. Follow the procedure depending on the Acquisition capture mode selected. See Chapter 8.2 Description of Acquisition Modes.
5. After the scan has been acquired, verify the result on the acceptance screen.

8.3.7.1. OCT-A Acceptance Screen

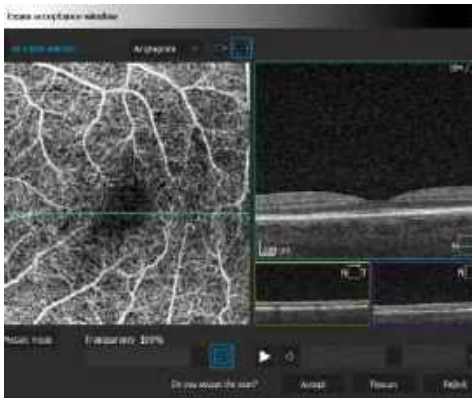


Figure 85.
Angio Acceptance Window

1. RESCAN

The exam is saved and localization is marked. This marker can be used for motion correction values. The Acquire window is reopened for the operator to repeat the scan.

2. **ACCEPT**

   The exam is saved and the Acquire window is reopened for the operator to repeat the scan. If mosaic mode is checked, the system loads the next examination and starts the procedure of shifting the fixation target and tomogram.

3. **REJECT**

   The exam is not saved (it is rejected). The Acquire window is reopened for the operator to repeat the exam.

The option to check **[MOSAIC MODE]** allows the user to capture an additional area to merge with the original scan, generating a montage of a larger area.

For more information on OCT-A Acceptance Window, see Chapter 9.2.3 OCT-A Scan Acceptance Window

8.3.8. OCT Angiography Predefined Mosaic Examination

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. Instruct patient that several scans will be taken.
3. If a scan is repeated, roman numerals indicative of the repeat number will be shown at the top of the exam on the list. If the repeated scan is carried out in a different location, this repeat indication will not be shown.

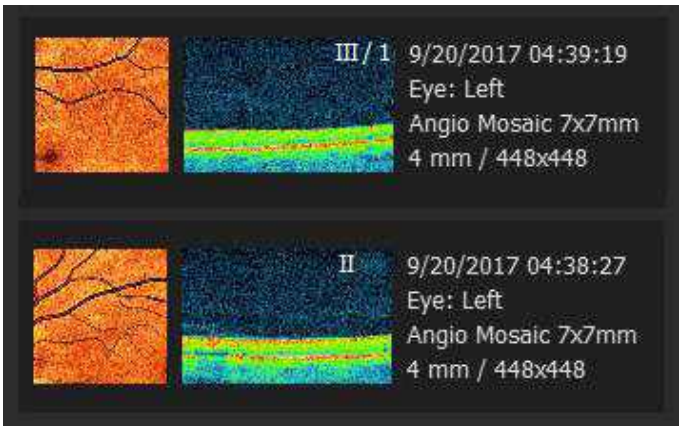


Figure 86.
Exam List: Angio Mosaic Scans

8.3.8.1. Predefined Mosaic Modes

1. Select one of the Angiography Mosaic programs.
2. Perform the scan. After scan acquisition, verify the result on the acceptance screen.

   If the result is accepted, the system will outline the scanned area in the pSLO window.

   If the user chooses to **[RESCAN]** the examination, the system, by default, will use the latest examination for the mosaic. If Motion Correction is performed the Motion Corrected exam will be used.

3. The system will load the next area to scan and shift the fixation position and the scanner position.

4. On the fundus preview window, the system displays the area which has already been scanned in a blue outline.
5. If voice guidance is switched off, inform the patient to follow the fixation target.
6. When the tomogram is correctly positioned, press **[ACQUIRE]** to capture the next image.
7. After the last examination for the mosaic, the system will not automatically load an additional scan program.

8.3.8.2. Manual Mosaic Acquisition Mode

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. Instruct the patient that you are going to take a few examinations and that the fixation target may change positions.
3. Select one of the Angiography mode programs. If desired, the operator can change the default parameters.
4. After acquisition of the first Angio scan, on the confirmation screen check **[MOSAIC MODE]** to activate the mosaic mode.

   Verify the result. If you accept the result, the system will outline the scanned area with a blue box on the pSLO preview.
5. If the user chooses to **[RESCAN]** the examination, the system, by default, will use the latest examination for the mosaic. If Motion Correction is performed the Motion Corrected exam will be used. If voice guidance is switched off, inform the patient to follow the fixation target.
6. If required, adjust the position of the scan area and / or tomogram and acquire the image.
7. When the user shifts the fixation target and / or the scanner frame, the system will change the color of the frame from green to orange when not on the border of the ideal area. It will change to red if moved outside of the acceptable range.

Green:	The newly presented scan area has enough coverage to allow for automatic superimposition.
Orange:	The newly presented scan area touches the previously scanned area, but it will not guarantee enough data for automatic superimposition.
Red:	The newly selected scan area does not have any common area with the already scanned area.

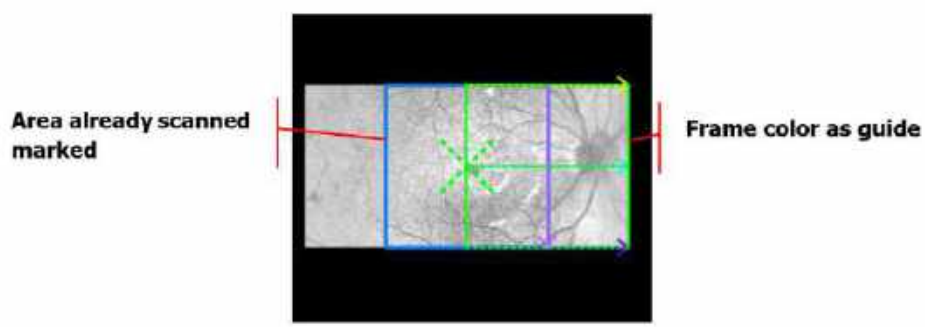


Figure 87.
Scanned Area Marked on fundus preview (pSLO mode) Window

8.3.9. Anterior Full Range Programs Examination

For the devices with reference number REF 155 and 156 in order to perform a Full Range scan of the Anterior segment of the eye it is necessary to install the anterior chamber adapter on the lens. The installation process is described in detail in 8.3.5 Anterior Wide Examination.

The Anterior Full Range programs allow users to visualize the entire Anterior Chamber. The system automatically optimizes the signal for the Anterior Chamber; however, the operator can move the position of the scanner head forward to optimize the signal for viewing the intraocular lens.

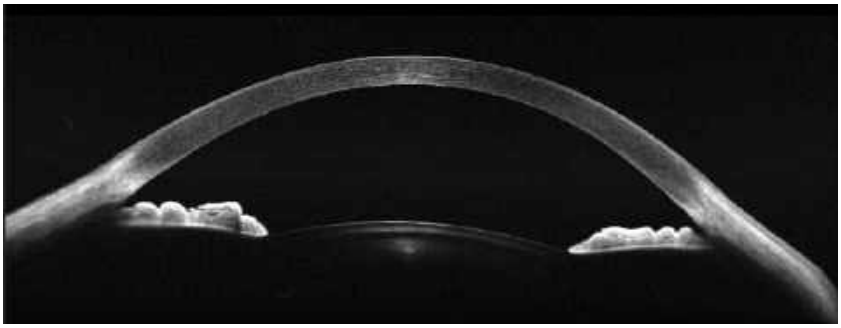


Figure 88.
Anterior Line Wide Full Range (Tomogram of Anterior Chamber)

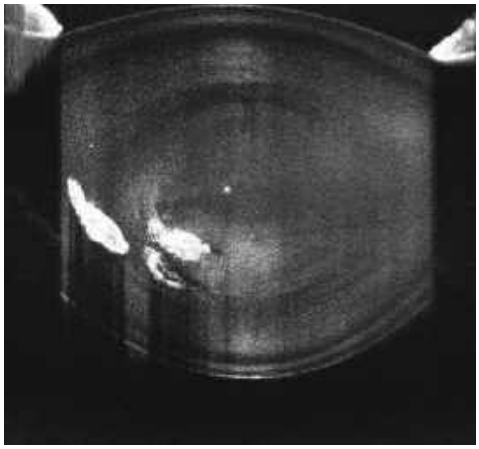


Figure 89.
Anterior Line Wide Full Range Tomogram of the Intraocular Lens)

There are two modes of displaying the tomogram preview during acquisition: simple and complex.

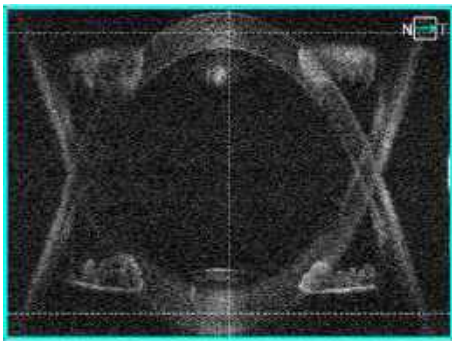
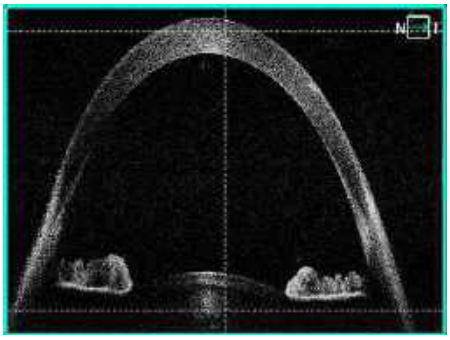
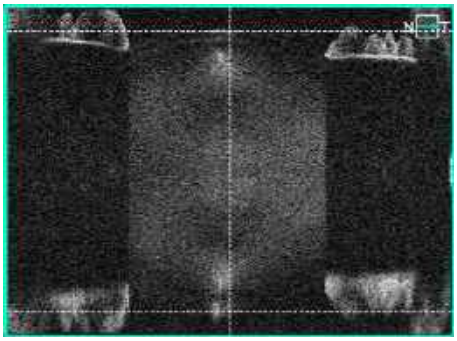
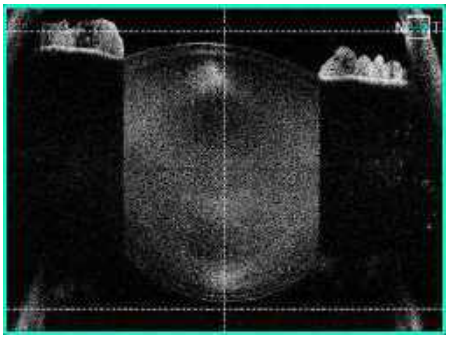
In the Semi-Auto and Manual modes, the image visible in the tomogram window can be displayed in two modes:

1. **SIMPLE MODE**

   In Simple Mode the user can see the original image together with its inverted reflection. This mode has a faster refresh rate of the Tomogram view and allows faster positioning.

2. **COMPLEX MODE**

   In the Complex Mode the original and inverted images are coupled to form a detailed, homogenous image. This mode has a slower refresh rate of the Tomogram view and shows a more accurate Tomogram preview.

Description	Simple Mode	Complex Mode
Anterior Chamber		
Lens		

The Simple Mode is active in the following situations:

1. During the automatic or manual alignment.
2. During adjustments of parameters (Focus, C-Gate, Scan position, Scanner position).

The Complex Mode is active in the following situations:

1. When the system finishes alignment.
2. After manual alignment.
3. When the operator moves the mouse cursor over the eye preview window.

8.3.10. Biometry Program

OCT Biometry (B-OCT®) is an optional feature. It is available as an upgrade and purchased separately. For more information go to Chapter 20 Biometry OCT (Optional Function).

8.3.11. Topography Program

OCT Topography (T-OCT™) is an optional feature. It is available as an upgrade and purchased separately. For more information go to Chapter 21 Topography (Optional Function).

8.3.12. Ultra-Wide Field Program

Ultra-Wide Field (UWF-OCT) is an optional feature. It is available as an upgrade and purchased separately. For more information go to chapter 18 Ultra-Wide Field (optional Function).

8.4. Full Range Examination Mode

Full Range examination mode offers an increased scanning depth of 6 mm (for the devices with reference number REF 190, 191, 192 and 193) ≈5.6 mm (for the device with reference number REF 194) or 4.8 mm (for the devices with reference number REF 155 and 156), compared to the standard scanning depth is 2.8 mm. Before conducting a Full Range examination, prepare the patient as explained in Chapter 8.1 Preparing for an Examination.

A Full Range scan in the simple mode (described below in Chapter 8.3.9 Anterior Full Range Programs Examination) normally displays an inverted mirror image of the scanned structure. The inverted image can be oriented to overlay and match the original image. As a result, the two images become coupled to form a highly detailed image of the structure.

8.4.1. Posterior Widefield Full Range Examination

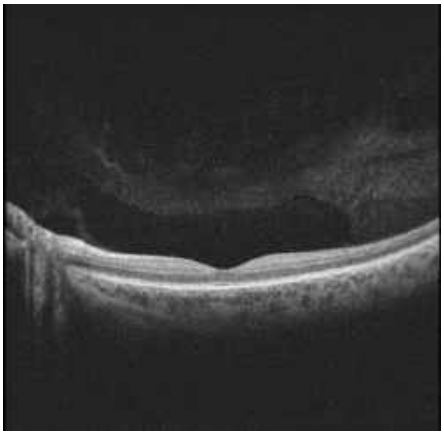
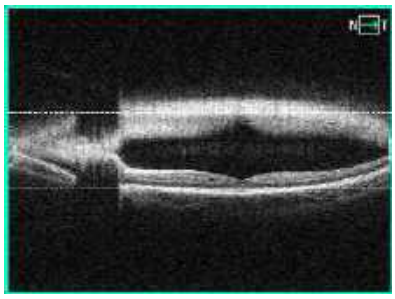


Figure 90.
Full Range Posterior Line Examination Window

In the Semi-Auto and Manual modes, the tomogram can be displayed in SIMPLE or COMPLEX mode.

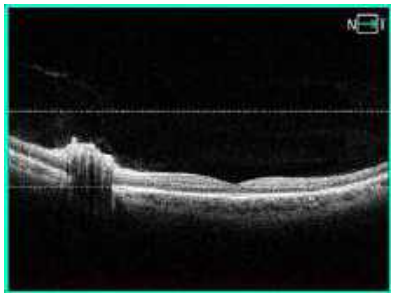
1. SIMPLE MODE

In the Simple Mode the user can see the original image together with its inverted reflection. This mode has a faster refresh rate of the Tomogram view and allows faster positioning.



2. COMPLEX MODE

In the Complex Mode the original and inverted images are coupled to form a detailed, homogenous image. This mode has a slower refresh rate of the Tomogram view and shows a more accurate Tomogram preview.

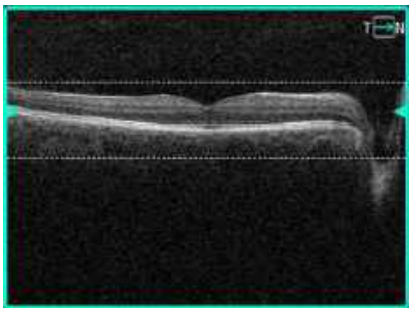


8.5. C-Gate Modes

8.5.1. Vitreoretinal / Chorioretinal C-Gate Mode

In the Vitreoretinal / Chorioretinal C-Gate mode, settings are programmed based on the user scan preference such as whether to improve signal above the RPE (Vitreoretinal) or to improve signal beneath the RPE to enhance choroidal visibility (Chorioretinal). Press **[SETTINGS]** and select C-Gate mode to change the mode. Press **[OK]** to change the scan program.

Vitreoretinal Positioning



Chorioretinal Positioning

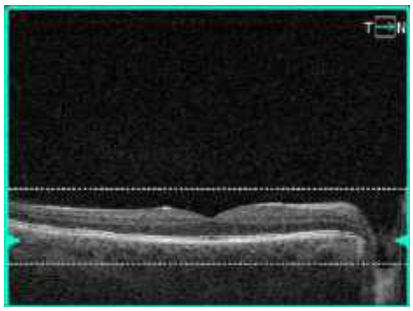
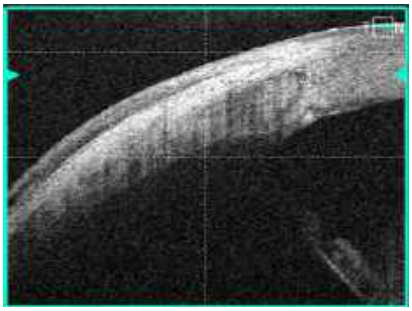


Figure 91.
Difference in Vitreoretinal and Chorioretinal C-Gate Modes

8.5.2. Anterior Top / Bottom C-Gate Mode

In the Top / Bottom C-Gate mode, settings are programmed based on the user scan preference such as whether to improve signal in the upper part of the scan (Top) or to improve signal in the lower part of the scan (Bottom). Press [SETTINGS] and select C-Gate mode to change the mode. Press [OK] to change the scan program.

Top Positioning



Bottom Positioning

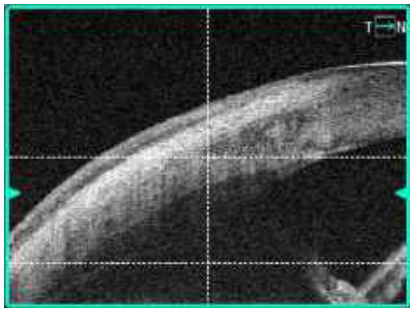


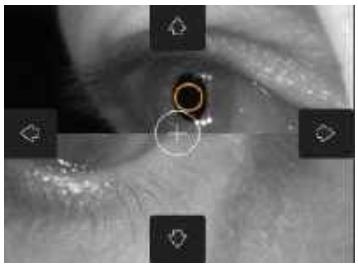
Figure 92.
Difference in Top and Bottom C-Gate Mode for the Angle

8.6. Examination Tips

NOTE: To improve patient compliance during the examination, and to reduce patient movement, it is important to be clear regarding patient instructions and the progress of the examination.

8.6.1. Tips for Automatic Eye Alignment

TIPS IN CASE OF THE [START] BUTTON BEING UNAVAILABLE

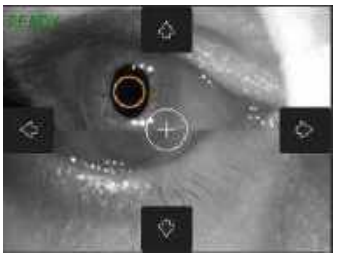


1. Verify the chinrest height.
2. Verify the head position.
3. Verify the pupil recognition.
4. Check for obstructions such as eyelids or eyelashes.
5. If necessary, adjust the device position using Movement Controls **[UP / DOWN AND LEFT / RIGHT]** when hovering over the live eye preview. Red arrows indicate incorrect patient position.
6. Click on the pupil to align the pupil to the center of the image. If necessary, repeat a click on the pupil to refine the position.

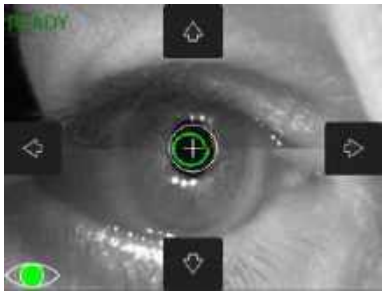
8.6.2. Tips for Manual Eye Alignment

1. To align the working distance, move the device using the **[FORWARD / BACK]** buttons until both halved images (top and bottom half) create a single continuous image (final result image). The correctly aligned pupil will have a white cross in the center of the pupil.

2. If the white cross is not in the center, **click** in the center of the pupil. The white cross will be automatically moved to the center of the pupil.



- The final result shows the white cross centered inside the pupil across the two halved images creating a continuous image.



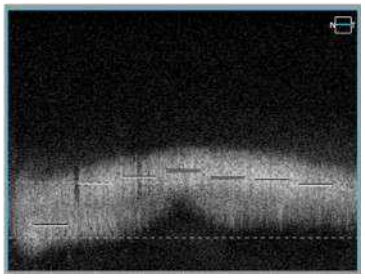
8.6.3. Tips for C-Gate Issues

IN CASE OF ISSUES WITH C-GATE

1. Check if the pupil is centered.
2. Verify the patient refraction data.

   If the refraction value is higher than ± 10 D, it is recommended to add spherical value (refraction error) information to the patient's data by entering or clicking data in the *Refraction* field in [Add Patient] window. In other cases, OCT focus adjustment may need to be optimized by operator.
3. If the issue persists, check for eyelids or eyelashes obscuring the scan area.
4. Verify that the OCT focus is set correctly.

5. If the issue remains unresolved, verify that the patient's forehead is still fully against the headrest frame and set correctly.
6. When a "ghost image" is displayed, move the C-Gate position and check if the pupil is centered.
7. The proper examination position can be obtained by scrolling the mouse wheel or dragging it to the desired position.



8.6.3.1. Tips to Optimize the OCT Signal

8.6.3.1.1. Focus Alignment

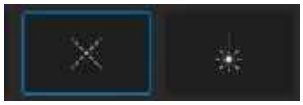
1. To ensure successful automated eye focus alignment, it is important to assess the following conditions:
    - Eyelashes or eyelids are not blocking the beam of light.
    - Patient fixation.
    - Patient steady head position.
    - Rapid blinks

NOTE: In difficult conditions, such as:

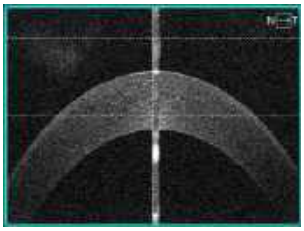
- **Eyelashes or eyelid which block the beam of light**
- **Inability of subjects to maintain fixation**
- **Dense media opacities**
- **Strong nystagmus**
- **Rapid blinks**

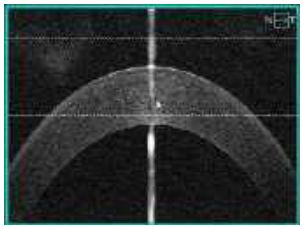
the system can display a warning. In this case operator should decide whether to use the tips mentioned in the Chapter 8.6 Examination Tips or change the acquisition mode.

2. In cases where automated functions are not working, it may be necessary to:
    - Optimize the OCT signal manually.
    - Align the Tomogram manually.
    - Acquire the exam manually.
3. To manually compensate for a patient's refractive error, scroll over the focus slider.
4. Simultaneously observe the Quality (Q) Bar and scan intensity to receive the best results. The Q Bar displays the signal to noise ratio as GREEN / YELLOW / RED.
5. If the Q Bar signal strength is low (yellow or red), adjust the focus manually to achieve best possible signal.
6. Artificial tears may be used.
7. For patients with poor central fixation, use the large fixation target.

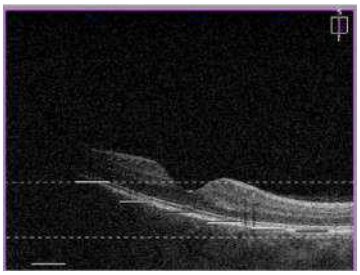


8. Focus correction may improve the saturation of the tomogram.





9. If shadows are displayed on tomogram edges, check whether the pupil is centered. To eliminate the shadows, drag the tomogram in the direction of the shadow.

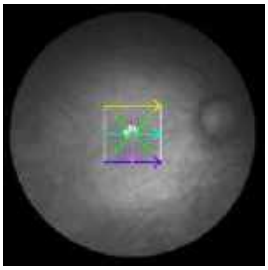


8.6.3.2. Quality IR Preview

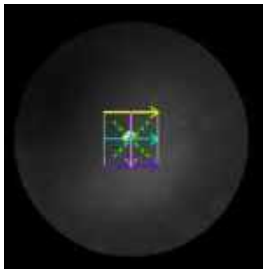
TO OPTIMIZE IR PREVIEW IMAGES

1. Adjust the position of the device working distance to ensure even illumination around the edges (see Chapter 8.6.2 Tips for Manual Eye Alignment).
2. Ensure proper alignment to the center of the pupil by using the brightest area of the pupil to avoid any media opacities.
3. Move the fixation target or scroll the mouse wheel over the live preview window to change the working position.

Good IR Image



Poor IR Image



IR PREVIEW OPTIMIZATION TIPS

1. AccuTrack™ depends on the IR preview quality.
2. To improve IR preview (if needed):
   - Dim the room lights to allow natural dilation of the patient's pupil, and to reduce glare and provide comfortable visualization of the fixation target.

- If glare occurs, drag and move the IR preview toward the glare to avoid it, as it may interfere with AccuTrack™
- Verify the tomograms position after IR corrections. In some cases the tomogram may stay slightly tilted.

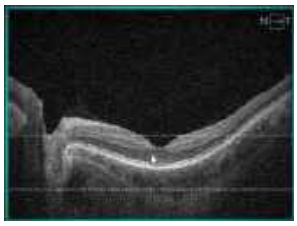
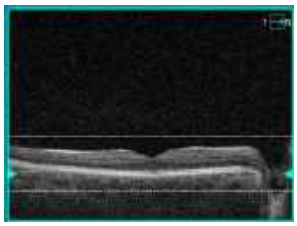
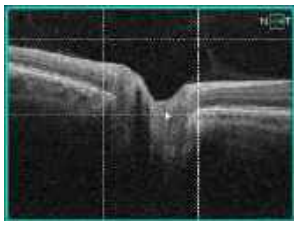
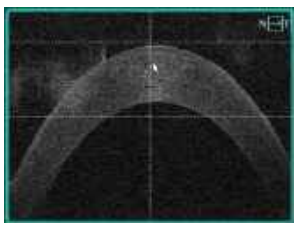
8.6.3.3. Tomogram Alignment within Horizontal Lines

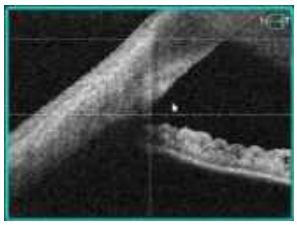
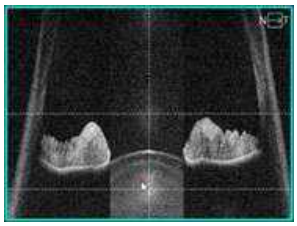
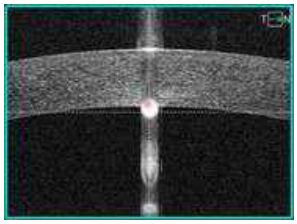
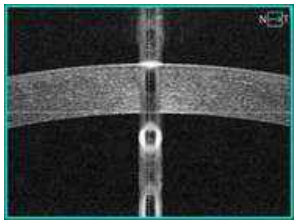
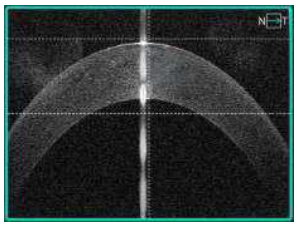
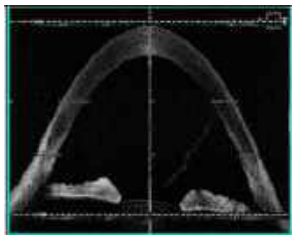
To align the position of the tomogram within the horizontal hash lines:

1. For precise movement, click and drag the tomogram vertically and horizontally.
2. For general movement, scroll the mouse wheel over the tomogram.

NOTE: By moving one tomogram, i.e., horizontal, the vertical tomogram will move as well.

Below are examples of correctly aligned horizontal tomograms.

Example	Horizontal Tomogram
Retina Raster. The retina is aligned between the two dashed horizontal lines.	
Retina 3D. The retina is aligned between the two dashed horizontal lines.	
Disc 3D. Align the retina between the dashed lines and set BMO (Bruch's membrane opening) evenly spaced to the vertical lines.	
Widefield 3D. The retina is aligned between the two dashed horizontal lines.	
Widefield 3D, Peripheral area. The retina is aligned between the two dashed horizontal lines. Manually shifted fixation.	
Anterior Wide Line Cornea, align the desired structure between the dashed horizontal lines.	

Example	Horizontal Tomogram
Anterior Line Angle, C-gate top. Place the angle structure between the two dashed horizontal lines.	
Anterior Wide Line with Angle to Angle, align the two angles between the dashed horizontal lines.	
Biometry Axial Length. The central cornea reflex is aligned with the dashed vertical line.	
Biometry ACD, align the central cornea reflexes with the dashed vertical line.	
Topography. The desired structure is aligned between the dashed horizontal lines and the central cornea reflex with the vertical dashed line.	
Full Range Anterior. The cornea is aligned with the dashed vertical line, and aligned between the dashed horizontal lines.	
Full Range Posterior. The retina is aligned between the two dashed horizontal lines indicating the area with the highest scanning sensitivity. The image can be aligned below or above the dashed lines to broaden the visualization range above or below the retina.	

8.6.4. Tips to Successfully Scan Difficult Patients

A PATIENT WITH POOR SIGHT MAY HAVE DIFFICULTY FOLLOWING THE FIXATION, RESULTING IN AN IMPROPERLY ALIGNED SCAN

Utilize the large fixation or external fixation (see Chapter 7.9 Fixation Target Adjustment) as an aid in keeping the eye in the scanning area. If the eye moves outside of the scanning area, stop the scan, and help the patient relax and focus on the fixation. Re-scan the patient.

NOTE: In the case of patients with spherical equivalent refractive error larger than ± 10 D, it may be challenging to use the automated retina detection.

In this case, the refractive error must be compensated for manually with the C-Gate scrolling until the retinal structure is recognized. If the issue persists, assess the pupil position, and adjust if necessary. Utilize the large fixation target. It is important to enter the patient refractive error for each patient eye with a high refractive error so that the system can automatically adjust the C-Gate in further scans.

PATIENTS WHO MOVE EXCESSIVELY DURING A SCAN ARE LIKELY TO HAVE POOR SCANS

Patient movement will not necessarily affect the ability to capture a scan but will always affect the quality (observe Q Bar). Action is required if excessive patient movements occur. Try asking the patient to minimize movement during scan acquisition.

Also, try moving the device head slightly towards or away from the patient to stabilize the scan window.

Lastly, the height of the table should be raised or lowered to adjust to the patient position. If possible, position the table low enough so that the patient can rest their head firmly in the headrest. This will place the patient in a firm and secure position and minimize movements.

NOTE: If, after scanning, the patient begins to drift, remind them to continue in this same position in case a repeat scan is necessary.

NOTE: Patients usually are more cooperative with detailed instructions during an exam. Therefore, it is advisable to be informative about the progress of the examination to minimize movement.

PATIENTS WHO HAVE SMALL EYE FISSURES OR CANNOT OPEN THEIR EYES WIDE

When a patient's eyelid is blocking the pupil or obstructing the anterior view of the eye, it may be necessary to use cotton swab or a gloved hand to move and hold eyelids out of the way. It is also possible to use tape in order to manually elevate the eyelid during scan acquisition.

The figures below show proper alignment for scan acquisition. Tomograms should be placed within the horizontal dashed lines.

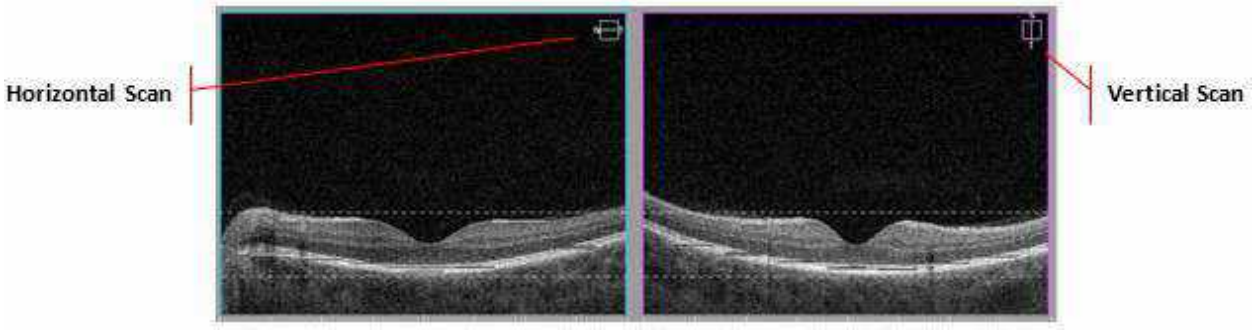


Figure 93.
Properly Aligned Retina between Dashed Lines

In the figure below, the tomogram is upside down due to the C-Gate position being too low. Adjust the C-Gate by scrolling the mouse wheel or dragging it to the desired position.

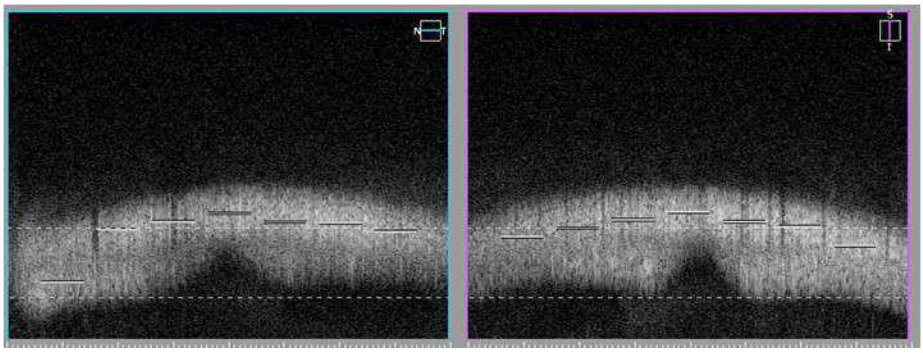


Figure 94.
Upside down tomogram

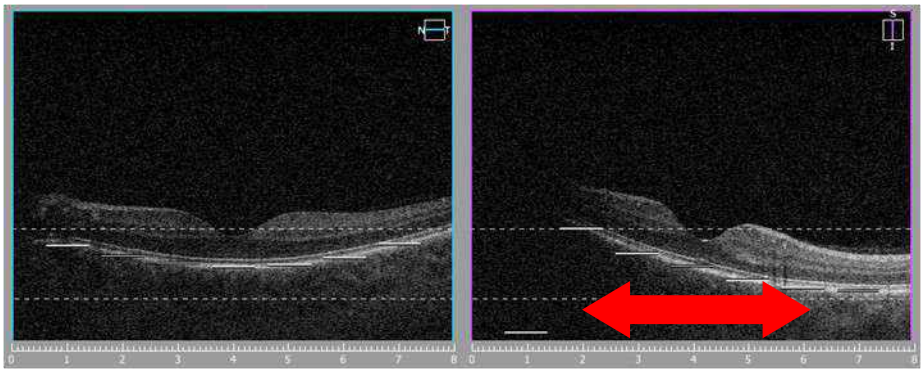


Figure 95.
Shadow on the Tomogram. Grab and drag towards the shadow (left side).

The vertical line in the fundus preview window is related to the right figure view of the scan preview window. This line shows the position of the scan in the eye. The scan should lie flat horizontally. To achieve the correct horizontal scan orientation, drag the tomogram and move it left / right. (Click and

drag Left / Right movement on the vertical OCT live window corresponding to up / down movement of the head. In the case above, the device is too high, so it should be dragged to the left (move down).

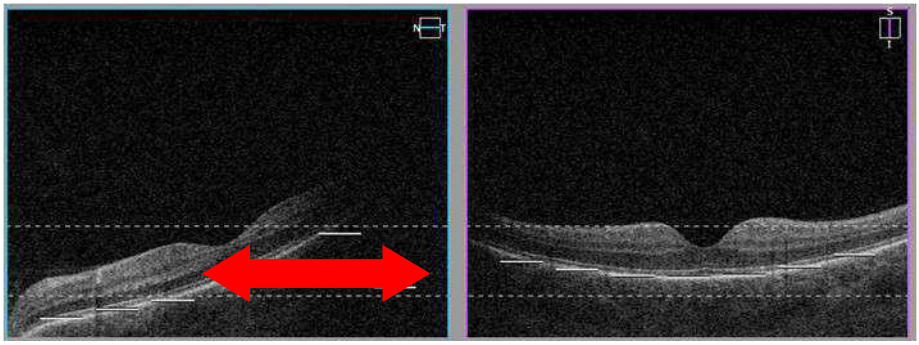


Figure 96.
Shadow on the Tomogram. Grab and drag towards the shadow (right side).

The horizontal line in the fundus preview window relates to the left figure view of the scan preview window. This scan also should be horizontal. In the case above, the tomogram should be dragged right towards the shadow (the head movement device should be moved right to align the scan and remove the shadow).

The easiest way to align the tomogram is to click and drag it to the proper position in the window. If it is required to manually align the working position across the center of the pupil, first move the scanning head (usually forward) to the correct working distance. At the correct working distance, images created from the two preview cameras create one combined view. Then click on the pupil or use up / down and right / left buttons to adjust the scanning head to place the white cross in the center of equally aligned pupil or click on the center of the pupil to center the pupil in the window.

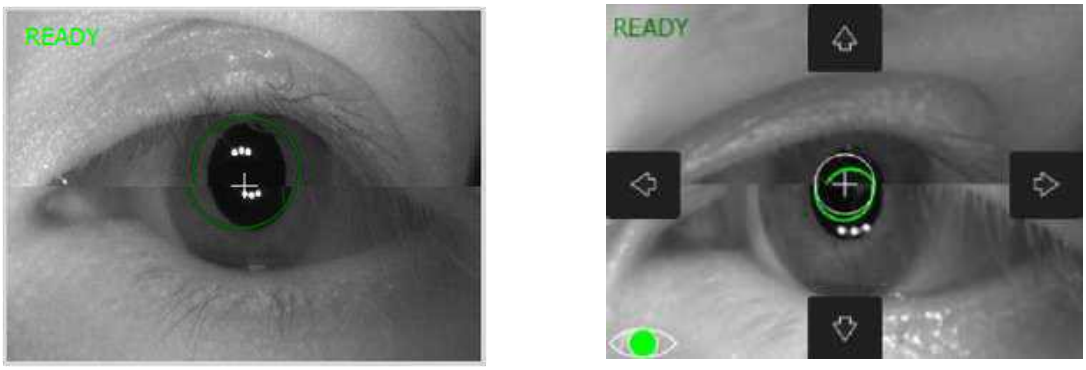


Figure 97.
(Left) Proper Eye Alignment (Right) Movement Control Buttons. Tap the pupil to auto center.

8.7. External Fixation

With the External Fixation, the patient uses the second eye to fixate on an external target light. First place the external fixation target arm onto the REVO device. It is attached at the top of the forehead support. Its position is set manually. When the user selects the External Fixation target, the user should instruct the patient to look at the flashing light at the end of the external fixation arm.

9. Evaluating Scan Quality

9.1. Overview

Once OCT data is acquired, the **Exam Acceptance Window** appears. The acceptance window shows results and information for the selected scan type. These will be discussed in the following sections.

9.2. Exam Acceptance Windows

9.2.1. 3D OCT Scan Acceptance Window

Figure 98.
OCT Acceptance Window

1. **FUNDUS PREVIEW IMAGE**

   Displays the IR / Fundus Reconstruction image with the Scan Overlay.

2. **SCAN SLIDER (BLUE LINE)**

   Displays the location of the current scan image. Click on fundus to display specific location. Mouse scroll allows to move the line and review tomograms.

3. TRANSPARENCY SLIDER

Adjust the slider to change the transparency of the Scan Overlay.

4. TRANSPARENCY BUTTON

Set the transparency to 0 or 100%.

5. SCAN VIEW SELECTOR

Choose: Fit OCT Scan to Fundus Image or Maximize OCT Scan in Window.

6. QUALITY INDEX SCORE (QI)

OCT scan signal strength value.

7. OCT SCAN DISPLAY

Blue (Displays scan from location of blue line), Yellow (Top scan), Purple (Bottom scan).

8. PLAY MOVIE BUTTON

Plays through all scans automatically in the Blue Scan Display window.

9. ACCEPT / RESCAN / REJECT BUTTON

- Accept saves scan and moves to next scan.
- Rescan saves scan and repeats scan.
- Reject does not save scan and repeats scan.

9.2.2. 3D OCT Scan + Fundus Photo Acceptance Window[42]

Figure 99.
OCT + Fundus Photo Acceptance Window

[42] Programs available only for the REVO OCT models with Fundus Camera.

1. **FUNDUS PREVIEW IMAGE**

   Displays the Color Photo / IR / Fundus Reconstruction image with the Scan Overlay.

2. **SCAN SLIDER (BLUE LINE)**

   Displays the location of the current scan image. Move the slider to change the tomogram display.

3. **TRANSPARENCY SLIDER**

   Adjust the slider to change the transparency overlay.

4. **TRANSPARENCY BUTTON**

   Set the transparency to 0 or 100%.

5. **SCAN VIEW SELECTOR**

   Choose: Fit OCT Scan to Fundus Image or Maximize OCT Scan in Window.

6. **QUALITY INDEX (QI)**

   OCT scan signal strength value.

7. **OCT SCAN DISPLAY**

   Blue (Displays scan from location of blue line), Yellow (Top scan), Purple (Bottom scan).

8. **PLAY MOVIE BUTTON**

   Plays through all scans automatically in the Blue Scan Display window.

9. **ACCEPT / RESCAN / REJECT BUTTONS**

   - Accept saves scan and moves to next scan.
   - Rescan saves scan and repeats scan.
   - Reject does not save scan and repeats scan.

9.2.3. OCT-A Scan Acceptance Window

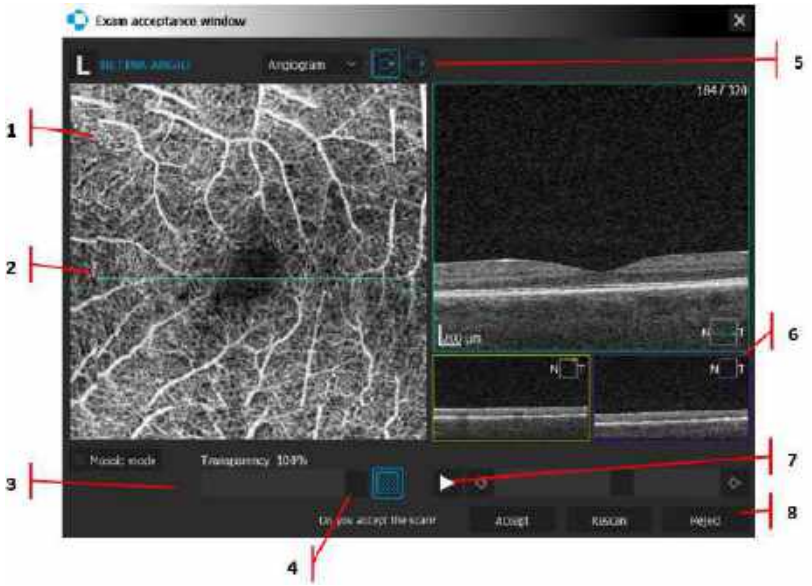


Figure 100.
OCT-A Acceptance Window

1. **FUNDUS PREVIEW IMAGE**

   Displays the IR / Fundus Reconstruction image with the Scan Overlay.

2. **SCAN SLIDER (BLUE LINE)**

   Displays the location of the current scan. Move the slider to change the tomogram display.

3. **TRANSPARENCY SLIDER**

   Adjust the slider to change the transparency overlay.

4. **TRANSPARENCY BUTTON**

   Set the transparency to 0 or 100%.

5. **SCAN VIEW SELECTOR**

   Choose: Fit OCT Scan to Fundus Image or Maximize OCT Scan in Window.

6. **OCT SCAN DISPLAY**

   Blue (Displays scan from blue line), Yellow (Top scan), Purple (Bottom scan).

7. **PLAY MOVIE BUTTON**

   Plays through all scans automatically in the Blue Scan Display window.

8. **ACCEPT / RESCAN / REJECT BUTTONS**

   - Accept saves scan and moves to next scan.
   - Rescan saves scan and repeats scan.
   - Reject does not save scan and repeats scan.

9.2.4. OCT-A + Fundus Photo Acceptance Window[43]

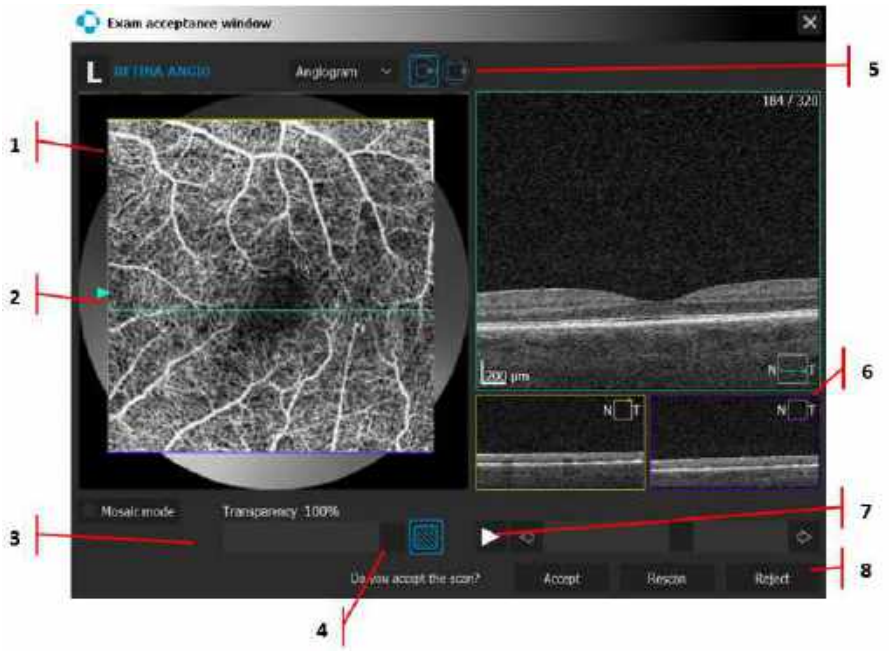


Figure 101.
OCT + Fundus Photo Acceptance Window

1. **FUNDUS PREVIEW IMAGE**

   Displays the Color Photo / IR / Fundus Reconstruction image with the Scan Overlay.

2. **SCAN SLIDER (BLUE LINE)**

   Displays the location of the current scan slice.

3. **TRANSPARENCY SLIDER**

   Adjust the slider to change the transparency overlay.

4. **TRANSPARENCY BUTTON**

   Set the transparency to 0 or 100%.

5. **SCAN VIEW SELECTOR**

   Choose: Fit OCT Scan to Fundus Image or Maximize OCT Scan in Window.

6. **OCT SCAN DISPLAY**

   Blue (Displays scan from blue line), Yellow (Top scan), Purple (Bottom scan).

7. **PLAY MOVIE BUTTON**

   Plays through all scans automatically in the Blue Scan Display window.

8. **ACCEPT / RESCAN / REJECT BUTTON**

   - Accept (Saves scan and moves to next scan).

[43] Programs available only for the REVO OCT models with Fundus Camera.

- Rescan (Saves scan and repeats scan).
- Reject (Does not save scan and repeats scan).

9.3. Quality Index (QI) Score

The Quality Index Score is displayed only after the image has been processed. The Quality Index (QI) is a numerical value based on a combination of image intensity and signal to noise ratio. The QI is a quantitative measurement of signal strength, where a greater intensity corresponds to a higher QI. The QI is a major component of image acceptability, however additional points must be taken into consideration. Recommended cut-off range for each 3D examination is shown below:

Description of the QI value range

Examination	QI Score Range
Retina 3D	≥4
Disc 3D	≥5
Widefield 3D	≥4

The QI equal to 0 is marked in Red as ”Not Good” (NG). The user can open the scan, but they will likely see only a signal on the noise level. Scans with the status NG are rejected from automatic selection (in the tabs: both eyes, cromparison, progression).

The QI in the range from 1 to the recommended cut-off is marked in Red. A tomogram of worse quality. The operator should exercise caution when interpreting the thickness map. The quality of the tomogram may be bad. The layer recognition result may possibly be incorrect.

The QI in the range from the recommended cut-off to 10 is marked in Green. A tomogram of good quality. The layer and thickness recognition algorithms should work correctly.

The operator should repeat the exam to obtain a better level of the QI parameter if possible. If it is not possible, the user should carefully evaluate the exam and verify segmentation along the scan.

The Quality Index (QI) is a global examination index, which represents an average quality of all tomograms in an exam. QI uses all tomograms for 3D scans. When image averaging is used (Line, Cross, Radial, Raster), the system calculates the QI only from averaged tomograms.

NOTE: It is recommended that results are reviewed carefully if the QI score is five or less to determine if auto segmentation is placed correctly.

9.4. Posterior: Criteria for Image Acceptance

During the scan review, use the following criteria to ensure that the exam data is acceptable for posterior scans.

9.4.1. OCT

Prior to accepting an OCT exam, the user must verify:

1. Signal strength (by Quality Index value):
    - For Retina 3D and Widefield 3D and Ultra-Wide Field 3D examinations – QI ≥ 4
    - For Disc 3D examinations – QI ≥ 5

In addition, the user should take the following points into consideration as it pertains to the area of interest:

1. The scan should be centered on the fovea, optic nerve head or area of interest.
2. OCT scans should be complete without missing data (e.g., no blinks).
3. The OCT Enface (Fundus Reconstruction) image should have minimal saccades and no saccades through the area of interest (macula or optic disc, for example).
4. Scan saturation should be consistent across the entire tomogram.

9.5. Anterior: Criteria for Image Acceptance

Prior to accepting an Anterior OCT exam, the user must verify:

1. The central part of the scan should be centered on the apex of the cornea, anterior angle, or the area of interest.
2. Only when the cornea / sclera tissue is parallel to the scanning window are the AOD (angle opening distance) and TISA (trabecular-iris space area) manual measurements accurate.

In addition, the user should take the following points into consideration as it pertains to the area of interest:

1. OCT scans should be complete and without missing data.
2. Verify the position of the retina or the cornea in the tomogram window. If the C-Gate position is too low or too high, then part of the signal will be overlaid by a “ghost signal”.
3. The brightness of the scan (signal strength) should be uniform from one end of the tomogram to the other.
4. The scan should have well defined posterior and anterior surfaces.

5. The scan should not have excessive motion artifacts or strong reflections from the anterior surface.
6. Operator should center the scan on the pupil for centrally taking cornea scan. For the angle scan it should be centered on the nimbus.
7. Operator should make sure that the eyelid or eyelashes are not blocking or shadowing a significant portion of the image in vertical tomogram. If there is blocking or shadowing, the scan should be excluded and then repeated if possible.

Figure 102.
Anterior Exam Acceptance Window

9.6. OCT-A: Criteria for Image Acceptance

Prior to accepting an OCT Angiography exam, the user must verify:

1. Signal Quality (by Quality Angio value) – QA ≥ 4.

In addition, the user should take the following points into consideration as it pertains to the area of interest:

1. The scan should be centered on the fovea, optic nerve head or area of interest.
2. The vascular structure should be sharp and clear.
3. The scan area should be complete without missing data.
4. The region of interest should not contain any movements, blinks or other types of imaging artifacts such as:
    - Significant clipping
    - Decorrelation tails
    - Proper tomogram alignment
    - Segmentation errors.

9.6.1. Signal Quality and Imaging Artifacts

OCT Angiography is far more sensitive to signal quality than structural OCT imaging. Poor signal quality will have great effect on image quality and may lead to dark areas, which can affect interpretation of the exam. OCT Angiography may therefore occasionally display dark spots that are not a result of capillary dropout, but rather due to poor local signal. See examples below.

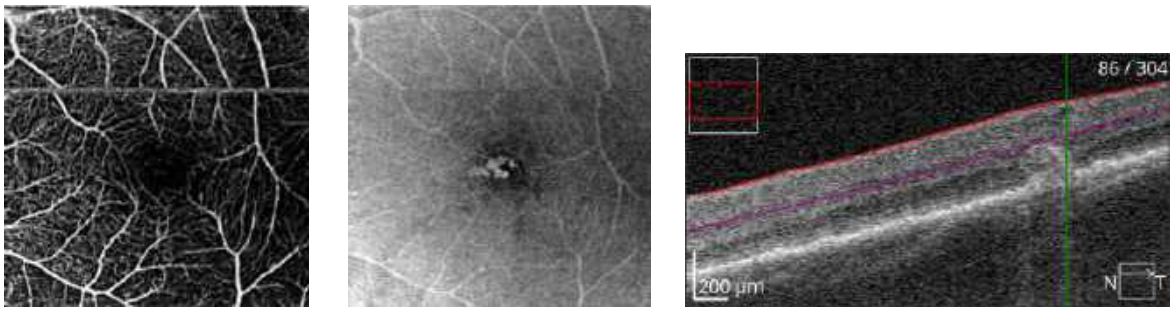


Figure 103.
Example of Poor Image Quality Caused by Saccadic Motion

The issue in this example is caused by saccadic motion. In other cases, floaters or other media opacities are causes for concern when accepting an OCT Angiography exam. The operator may also examine the B-scan and the structural enface image.

In an eye with pathology, the OCT Angiography image may appear dark, but the B-scan and enface image will not. In these cases, it is recommended to perform the exam again.

9.6.2. Segmentation Errors

These errors may result in incorrect interpretation of angio (blood) flow. On the active slab, the two boundary lines overlying the B-scan are used to verify the proper segmentation of a particular angio or enface image. It is important to confirm the presence or absence of angio flow and whether it is associated with the layers of interest. It may happen that angio flow is present in areas where it should not be.

For example, the image below (left) should be avascular, but shows a few bright areas. Examination of the B-scan shows an area that has pushed the segmentation up into the hyper-reflective outer plexiform layer. This may be caused by drusen, therefore any bright signal detected at this location is likely not due to ordinary inner retinal vasculature and should be regarded as an error and automatic segmentation should be corrected.

In the examples below, the segmentation is not correctly passing through the avascular outer retinal layer. Consequently, the image seems to show vasculature in an area that should be free of signal.

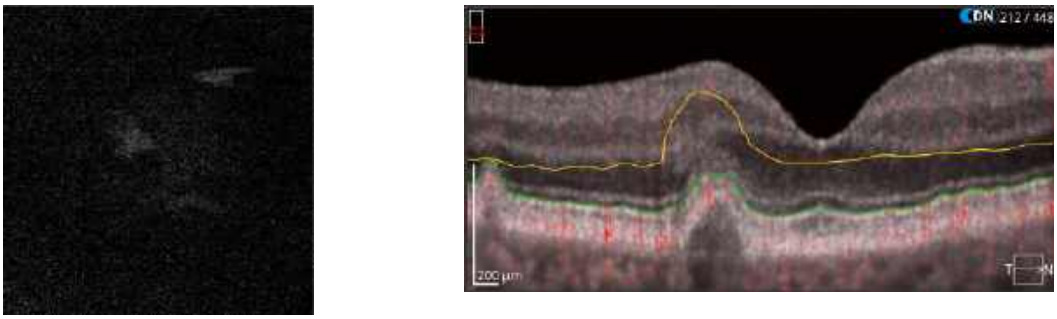


Figure 104.
Example of a Segmentation Error in OCT Angiography

9.6.3. Decorrelation Tails

Seen as bright shadows of more superficial vessels that appear in posterior layers, decorrelation tails result from light that passes through the moving blood cells and returns to be detected. This creates a signal that is below the original motion, but caused by the motion, and therefore is always found posterior to the original signal.

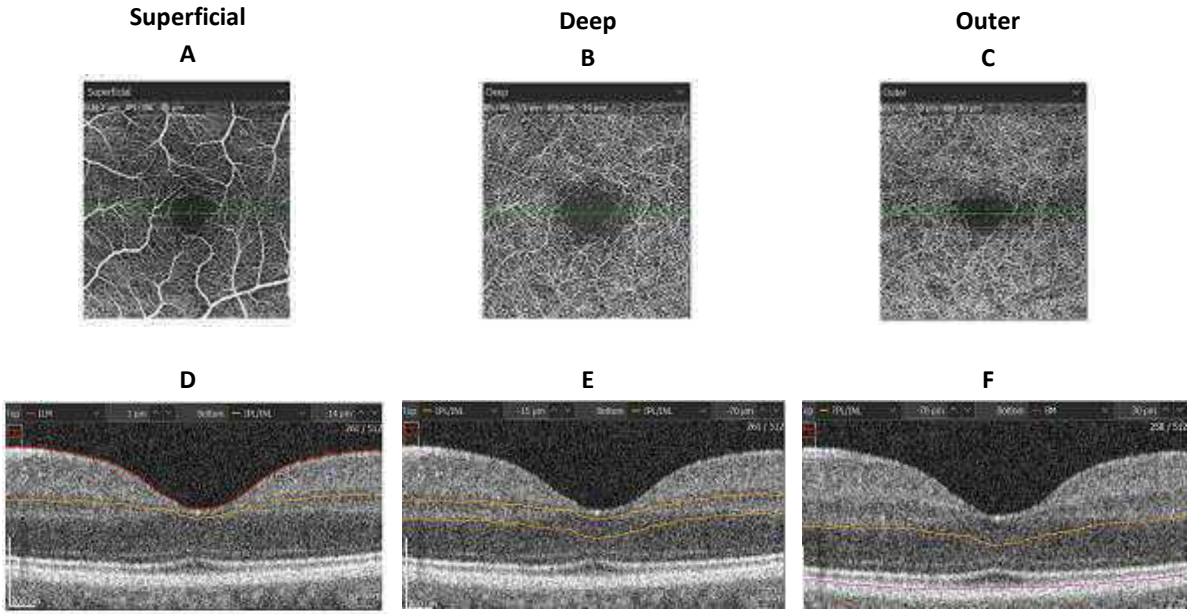


Figure 105.
OCT-A Decorrelation Tails (Enface and Slab Views)

This effect is always weaker than the original signal and is also correlated with the brightness of the reflecting layer. Therefore, decorrelation tails may appear to have disappeared within the outer nuclear layer, but then appear strongly again in the brightly reflecting RPE. The figure above clearly shows that an enface image collected only around the RPE includes vasculature very similar to the overlying Superficial Retinal Layer. There are two potential methods to determine whether a signal is due to decorrelation tails or due to motion in the layer observed. One is the characteristic of the vasculature itself, even if it is disrupted. A typical normal eye demonstrates that the deeper retinal layer (Figure 104 - B, E) has a different characteristic appearance than the Superficial Retinal Layer (Figure 105 - A, D). Another way is to note when the vessel of interest has exactly the same shape as a layer superior to it. The area around the RPE is not expected to have any vasculature, so the enface image shown in Figure 82-C, F is clearly due to decorrelation tails.

9.7. Biometry: Criteria for Image Acceptance

Prior to accepting a Biometry OCT exam, the user must verify:

1. All measured structures (Cornea, Anterior Surface of the Lens, Posterior Surface of the Lens, Retina with Foveola) must be visible on the tomogram's series preview and easily identifiable. In cases with a weak signal, operators can manually correct the caliper placement.
2. Signal Quality (by Quality Index value) ≥ 7.

In addition, the user should take the following points into consideration:

1. Verify if the biometry scan was performed along the optical axis (apex of the cornea and foveola are in the center of the horizontal and vertical preview scans).
2. Verify that more than half of the series is properly visible.
3. In case of a low QI score, carefully examine the visibility of each structure's boundaries.

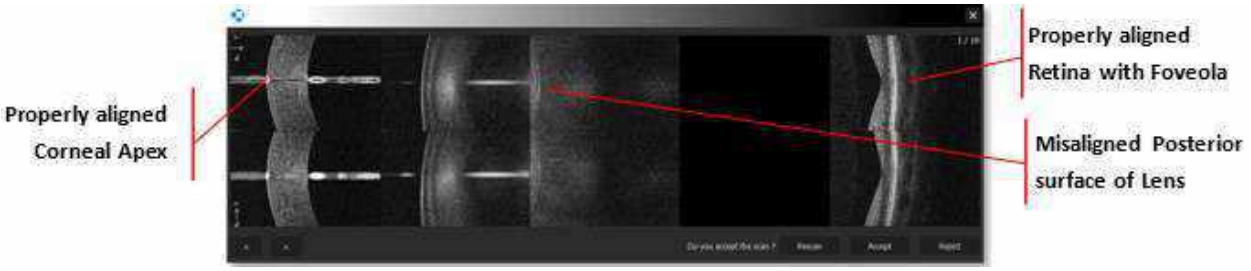


Figure 106.
Biometry Acceptance Preview Window with Incorrectly Placed Posterior Surface of the Lens

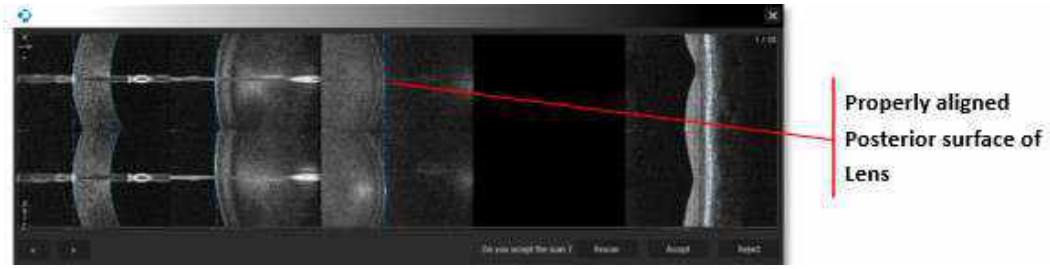


Figure 107.
Biometry Acceptance Preview Window with Correctly Placed Scans

9.8. Topography: Criteria for Image Acceptance

Prior to accepting a Topography OCT exam, the user should verify:

1. After completing the exam, the system evaluates the quality of the examination and displays the Topo Quality Factor (TQF).
2. Topo Quality Factor (TQF) should be ≥ 7.
3. In cases where the quality is borderline (yellow !), inspect the scan for completeness and repeat the examination if necessary. In cases where the quality is no good (red NG), repeat the examination.

4. If a blink is detected, a warning message is displayed, and the operator should repeat the exam.

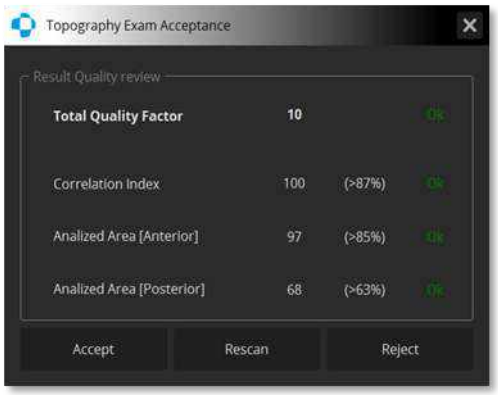


Figure 108.
Topography Acceptance Preview Window with Topo Quality Factor

9.9. Examples of Artifacts

The following examples display artifacts or poor image quality that should be evaluated, and the operator should perform additional scans to minimize or resolve the issues.

9.9.1. Saccades (Movement Artifacts)

A saccade is movement of the eye. They are shown in the fundus reconstruction image as discontinuities in the appearance of the blood vessels, usually visible as a horizontal shift of the image. For 3D or Angio program scans, it is important to ensure that there is minimal saccadic motion. There should be no protrusion into or through the areas of interest, such as the macula or optic disc. AccuTrack™ assists with minimizing the effect of saccadic motion or other artifacts during acquisition. Below is an example of multiple horizontal shifts due to saccades and is not acceptable for analysis.

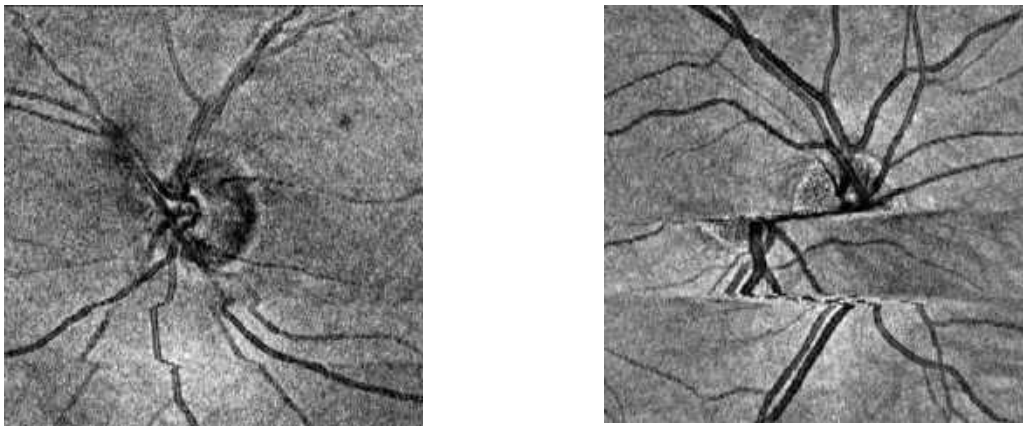


Figure 109.
Example of Eye Movement Artifacts in Fundus Reconstruction

9.9.2. Banding

Carrying out 3D exams with iTracking™ enabled may lead individual B-Scans being acquired at different horizontal positions (banding). Due to banding, there may be vertical tissue variations in the B-scan window. Although AccuTrack™ is also meant to correct for this motion, it may nevertheless cause the OCT images to contain intensity artifacts. These artifacts appear as horizontal lines or form bands in the OCT image, as shown in the examples below:

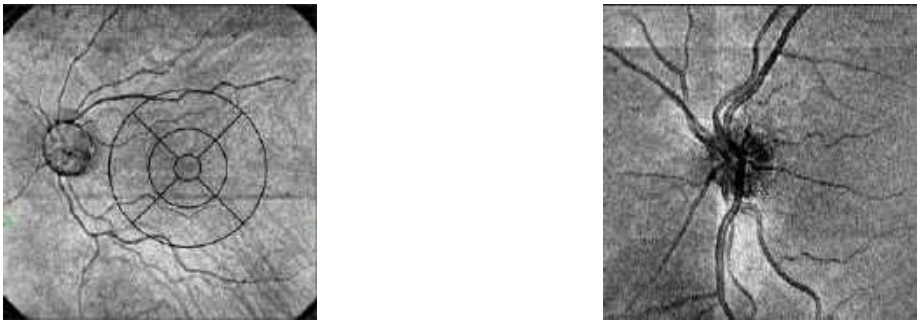


Figure 110.
Examples of Banding in Fundus Reconstruction

Given that there are no saccades, exams with OCT images like these should be sufficient for analysis as there is no protrusion into or through the areas of interest.

9.9.3. Cropped Image

In cases where the scan is placed too high or too low in the OCT tomogram preview window, it will usually lead to image cropping. These can be recognized in the reconstruction image as dark areas and cross-checked against corresponding B-scan images as being too high or too low in the window.

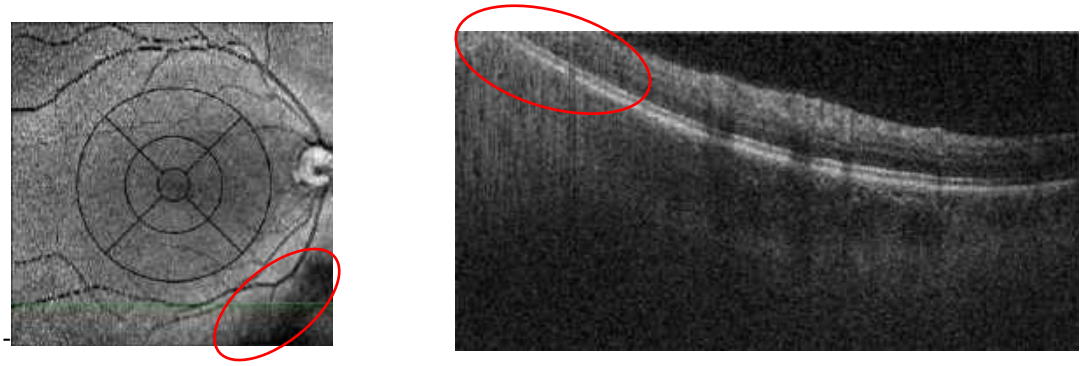


Figure 111.
Example of a Cropped Image

These artifacts can also be identified as a local signal reduction. Although this type of local signal reduction is not analyzed by the Quality Index calculations, it may significantly affect results analysis. These examinations should therefore be analyzed carefully or repeated without artifacts. The figure below is an OCT image that was placed too high in the preview window. The entire scan is out of the scan window.

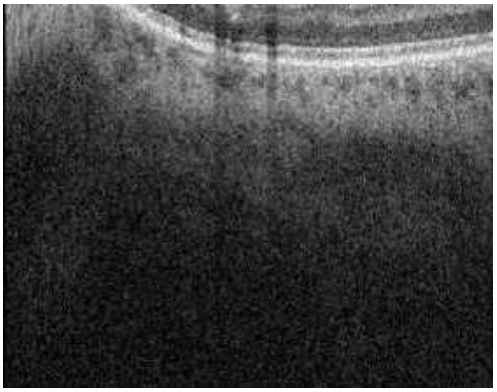


Figure 112.
Example of an OCT Image Placed High and Outside of the Scan Window

Figure below is an OCT image that was placed too high in the tomogram preview window with a part of the scan out of range. A part of the retina cross-sectional OCT image is cropped. A part of the OCT structure is out of the scan window.

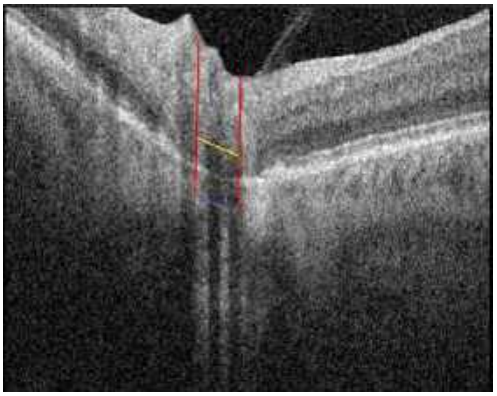


Figure 113.
Example of an OCT Image Placed too High

9.9.4. Blinks

Blink artifacts are obstructions of the OCT scan beam during acquisition that cause an absence of information while the eye is closed. These artifacts appear as straight black lines without any structure within the lines. These lines are easily visible and can also be recognized due to the loss of image. Motion Correction is designed to prevent these artifacts from forming, however it may still be possible

for blinks to be visible in exams without AccuTrack™ enabled. Below is an example of a blink in the OCT image.

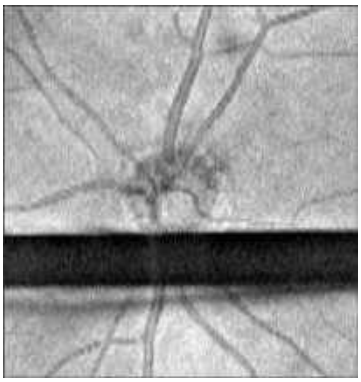


Figure 114.
Example of an Uncorrected Blink

The following images show an example of blinks in two exams of the same location corrected by Motion Correction and acceptable for analysis.

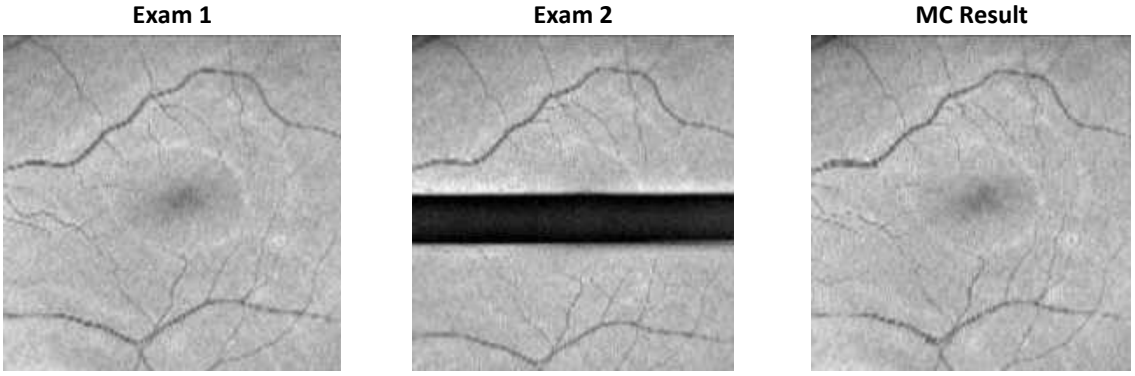


Figure 115.
Blink Artifacts Corrected to an Acceptable Standard

Blinks can also be identified as a local signal reduction. Although this type of local signal reduction is not analyzed by the Quality Index (QI) calculations, it may significantly affect results analysis. These examinations should therefore be analyzed carefully or repeated without artifacts.

9.9.5. Floaters

As with blinks, floaters are obstructions to the OCT scan beam, thereby reducing the signal strength reflected from the tissue beneath the obstruction. If a floater has sufficient density and size, the vessels

below can appear as weak or missing completely as in the example below. This example also shows saccadic motion.

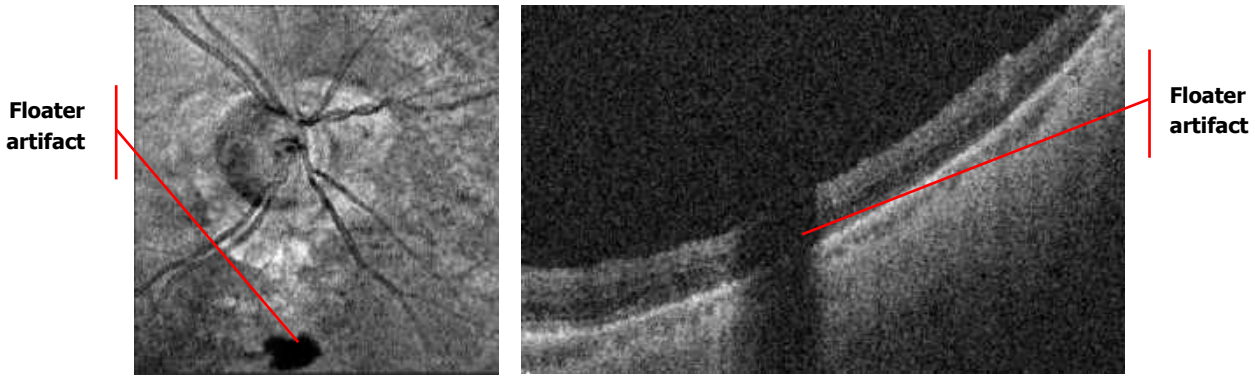


Figure 116.
Examples of Floaters with Saccadic Motion

The “shadows” displayed in the above figures can be identified as floater artifacts by cross-checking for the same pattern of shadows across the enface scan and B-scan. The above example displays a shadow that starts in the vitreous and proceeds through the retina, which effectively shows that there was an opacity between the light source and the tissue. This can further be identified as a local signal reduction. Although this type of local signal reduction is not analyzed by the Quality Index (QI) calculations, it may significantly affect results analysis. These examinations should therefore be checked for artifacts and repeated if necessary. The above example also has motion artifacts and should be repeated without movement if possible.

NOTE: It can be helpful to ask the patient to look up then down to try and move the floater to a different location.

9.9.6. Media Opacities

Regional drop of the signal, either caused by floaters in the vitreous or by other media opacities (e.g., cataract) can be recognized in the fundus reconstruction image and confirmed in corresponding B-scans.

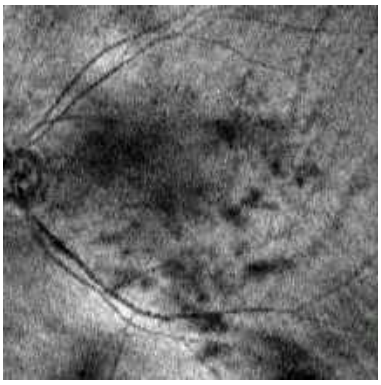


Figure 117.
Example of a Cataract Patient with a Loss of Saturation

9.9.7. Small Pupil

A pupil under the minimum size of 1.7 mm (for the devices with REF 190, 191, 192, 193 and 194) or 2.4 mm (for the devices with REF 155, 156) will result in a dark area on the edges of the fundus image and tomogram.

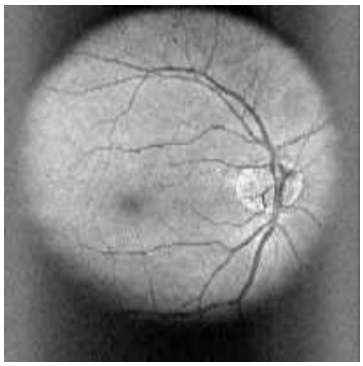


Figure 118.
Fundus Image with Pupil below the miminum size.

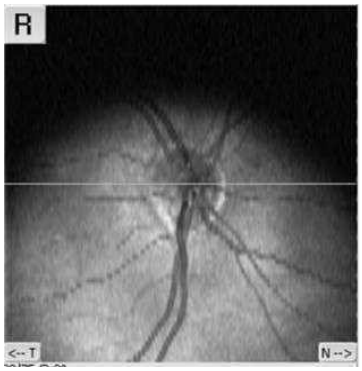


Figure 119.
Fundus Image with Small Pupil

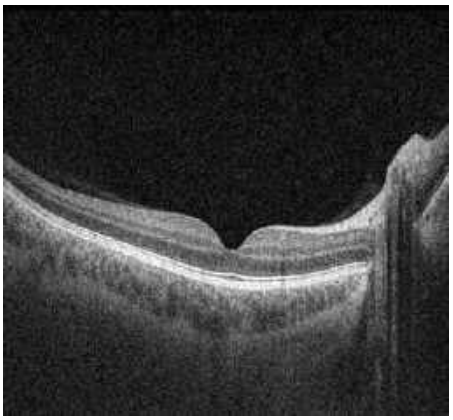


Figure 120.
Example of a Strong Signal and Properly Centered and Aligned Tomogram

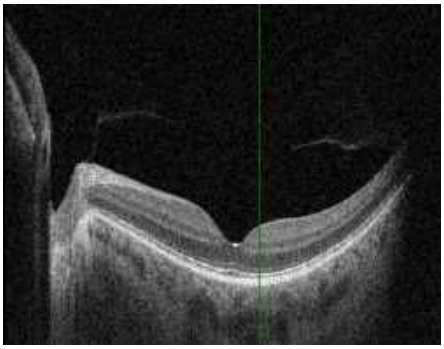


Figure 121.
Example of a Scan with Shadowing Visible on the Side (Edge of Pupil)

9.9.8. Cataract (Media Opacity)

The figure below shows an image with poor signal quality on part of the tomogram. On the left side of the tomogram, a properly saturated structure is brightly visible. On the right side of the tomogram, the retinal layers are not visible on all A-scans.

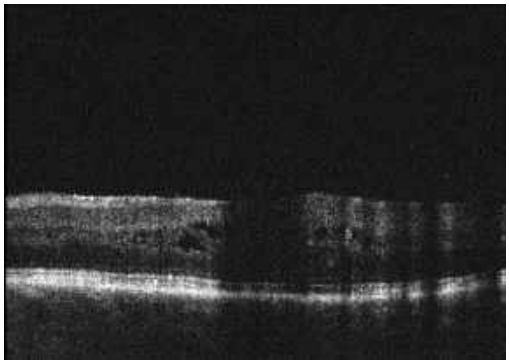


Figure 122.
Example of a Scan with Cataract

9.10. Color Fundus Photo: Criteria for Image Acceptance

During scan review, use the following criteria to ensure that the exam data is acceptable for posterior scans.

9.10.1. Color Fundus Photo

Prior to accepting a fundus image, the user must verify that the correct area of interest is in the image. In addition, the user should take the following points into consideration as it pertains to the area of interest:

1. The focus should be sharp and clear, preferably with good visibility of the branching blood vessels.
2. The fundus image should have uniform illumination without vignetting (dark corners).
3. There should be few, if any, artifacts that may cast shadows on the OCT scan.

10. Results Tab

This chapter describes the Results Tab screen and the different available reports which display the analysis results of acquired examinations. The analysis displayed depends on the scan program and diagnostic purpose of the analysis.

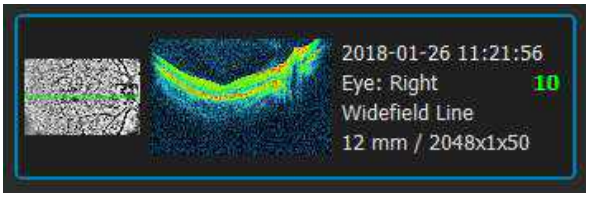
The Results Tab window enables the operator to browse all the stored examination results for a selected patient. This window contains all the tools for analysis of acquired data. The main window contains tabs: **[SINGLE]**, **[BOTH EYES]**, **[COMPARISON]**, **[PROGRESSION]**, **[3D]**, **[ADVANCED]** and **[COMBINED]**.

Figure 123.
Results Screen

10.1. Exam List

10.1.1. Examination Thumbnail

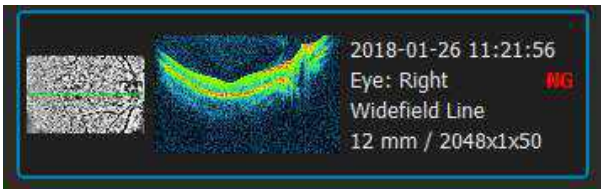
Each examination thumbnail provides details of the exam displayed. As displayed in the image below, examination thumbnails display the fundus preview, tomogram preview, date and time, eye tested, Quality Index (QI), scan program and scan details.



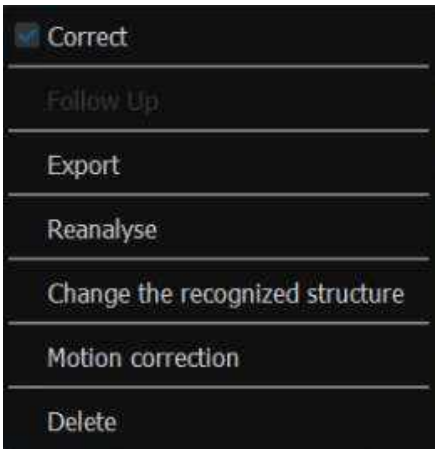
The **QI** should be displayed in the thumbnail area under the exam date in **[SINGLE]**, **[BOTH EYES]**, **[COMPARISON]**, **[PROGRESSION]** Tab views.

NG (NOT GOOD)

If the examination has been marked as not correct, or if the examination has **QI=0,** it is automatically labelled **NG**, and the NG mark is displayed instead of QI on the examination list. If an exam has an **NG** label, it will be excluded from being automatically selected for **[BOTH EYES]**, **[COMPARISON]**, **[PROGRESSION]** views.



10.1.2. Exam List Menu



Right-click on an exam in the exam list to display the menu below:

1. **CORRECT**

   When enabled, the results tab can display the exam automatically in the **Both**, **Comparison** and **Progression** tabs.

2. **FOLLOW UP**

   Allows the user to repeat the selected examination. Opens Acquire tab and loads previous settings for a repeat exam.

3. **EXPORT**

   Saves the exam as *.opt file format or *.dcm DICOM file format.

4. **REANALYZE**

   The system will process the examination data.

5. **CHANGE THE RECOGNIZED STRUCTURE**

   To change the type of the structure, select this option. In the new window, select the desired structure from the list. Press [**OK]** to accept.

6. **MOTION CORRECTION**[44]

   Select exam(s) from the list. Select this option in the menu to generate a motion corrected exam.

[44] Option only available for 3D examinations (with scan width of less than 7 mm) and Angio examinations.

7. **DELETE**

Removes the examination from the database.

10.2. Type of Results Views

Depending on the type of examination selected, the system will display different analysis views. Not all views are available for each scan.

10.2.1. [Single] Tab Screen

The **[SINGLE]** screen shows the analysis results of a single eye exam.

10.2.2. [Both Eyes] Tab Screen

The **[BOTH EYES]** screen shows the analysis results displaying both Right (R) and Left (L) eyes in the same scan program on the same date. It is possible to switch exam dates for the same scan program.

10.2.3. [Comparison] Tab Screen

The **[COMPARISON]** screen shows the analysis results comparing two examinations of one eye using the same scan program from different dates. The **[COMPARISON]** tab also features the lock function for common manipulation of tomograms. More information on the lock function can be found in Chapter 10.2.5 Lock Function.

10.2.4. [Progression] Tab Screen

The **[PROGRESSION]** screen shows the analysis results comparing six examinations arranged in chronological order for a single eye. The scans must be the same scan program and same size of scanning area to display in the progression screen.

10.2.5. Lock Function

10.2.5.1. Standard Lock Function

The **[LOCK FUNCTION]**  enables simultaneous and synchronized manipulation of several tomograms. Available operations include: scrolling examination, zooming in / out, moving tomograms, changing display parameters (i.e., brightness / contrast), display method. The **[LOCK FUNCTION]** is available for synchronized operation on the following tabs: Both Eyes, Comparison and Progression tabs for Posterior scans. To lock tomograms, click the arrow next to the lock button  to unfold a drop-down menu and click to  lock.

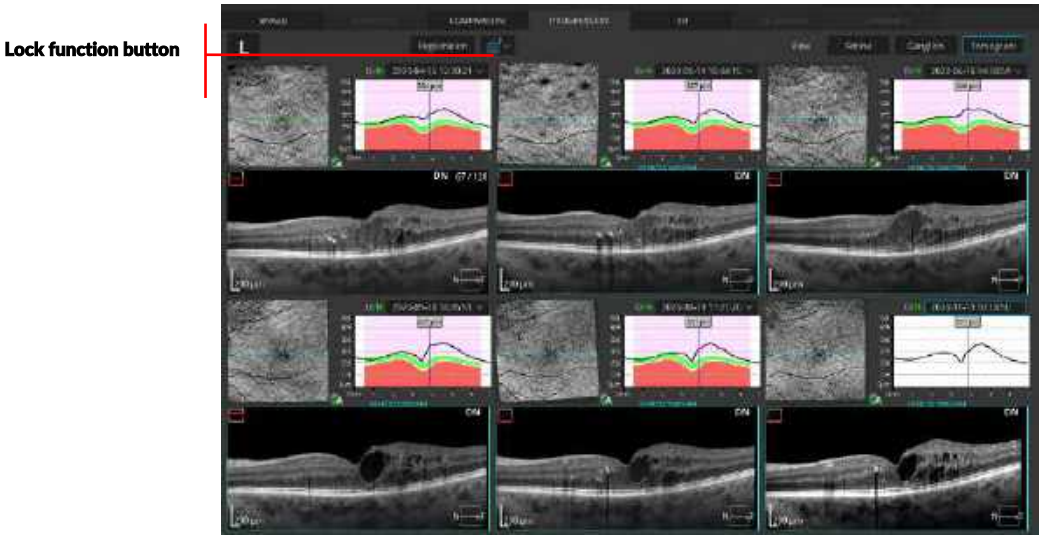


Figure 124.
Progression View (Lock Function On)

10.2.5.2. Lock Function with Extracted Tomograms

The **[LOCK FUNCTION]** is also available in conjunction with the function of **[EXTRACTING TOMOGRAMS]** described in detail in Chapter 11.2.1 Tomogram extraction from a 3D Exam.

To both lock and extract location correlated tomograms click the arrow next to the lock button  to view the drop-down menu and choose **[LOCK BUTTON]**. 

10.2.6. AI DeNoise

The AI DeNoise function offers the ability to capture an individual scan and improve the result without the need to acquire and merge multiple images. The AI DeNoise algorithm uses a neural network to deliver images with greatly reduced image noise, increased detail, and improved visibility with the push of a button. The **[DN]** button is available for any tomogram in the software and is activated by default on non-averaged scans. On averaged tomograms the function is off by default. Non-averaged tomograms using the AI DeNoise function look similar to an averaged tomogram.

When the software loads a tomogram the AI DeNoise function is initiated. After a short moment the original raw tomogram is replaced with a noise-free image. This process is started each time you load or scroll to display a new tomogram.

The figure below presents the same tomogram with the AI DeNoise function off (left) and on (right).

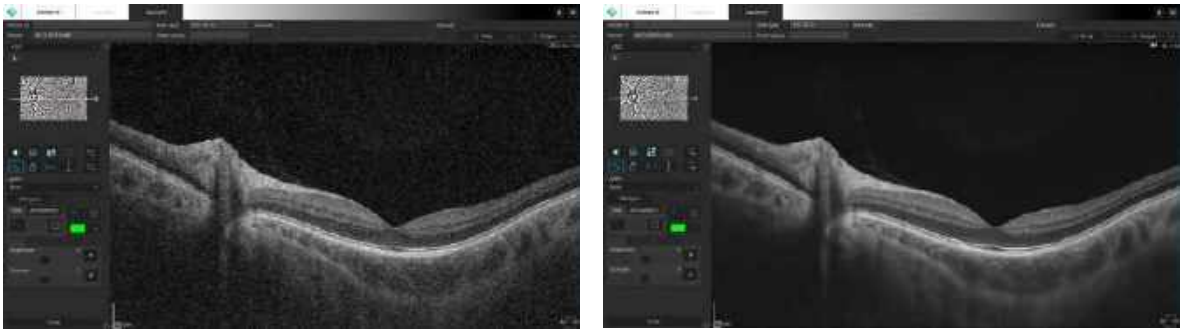


Figure 125.
AI DeNoise OFF (Left) and ON (Right)

CAUTION: The AI DeNoise algorithm works to enhance the visibility of morphological structures by processing the original image. However, tomograms with very low signal level may be challenging to process correctly. When working with such tomograms, it is recommended that the user always compares the denoised processed image with the raw unprocessed image to make sure there is no variance between the morphological structures presented on both tomograms.

TURNING AI DENOISE ON AND OFF

When the AI DeNoise function is ON, it is indicated by the DN sign in the upper right-hand corner of the tomogram.

You can turn the function OFF and return to the original image. To do this, hover your mouse over the DN sign. It will change into the DN switch for you to click the function OFF. Clicking the switch again turns the function back on.

The state of the switch on shutdown is saved and restored when you launch the software again.

For more on 3D view AI DeNoise features, see Chapter 10.2.7 3D Tab.

10.2.7. 3D Tab

The AI DeNoise function in the 3D tab is available in both the **[SOLID]** and **[VOLUME]** 3D tab. To turn the AI DeNoise **ON**, go to the settings section inside the tab and click **[DISPLAY]**. At the bottom of the **[DISPLAY]** tab there is an AI **[DeNoise]** checkbox. Select it to apply the AI DeNoise algorithm to the

image. If you deselect the checkbox, the AI DeNoise function is turned **OFF**. The state of the checkbox inside the 3D tab does not influence the AI DeNoise switch in other tabs.

Figure 126.
AI DeNoise Checkbox in the 3D Tab

11. Posterior Analysis

At the top of the Results window, choose between different analysis tabs to provide different views of the exam data.

Single / Both Eyes / Comparison / Progression / 3D / Advanced / Combined

11.1. Retina Thickness Analysis

11.1.1. Single Tab

The Single tab analysis shows the results from a single examination.

On the **[SINGLE]** tab, a single eye retina analysis is presented. For each examination, retina charts and maps used for assessment are calculated. It is possible to scroll through single tomograms from a 3D scan.

NOTE: The REVO will not display quantification if the user has changed the default scan parameters.

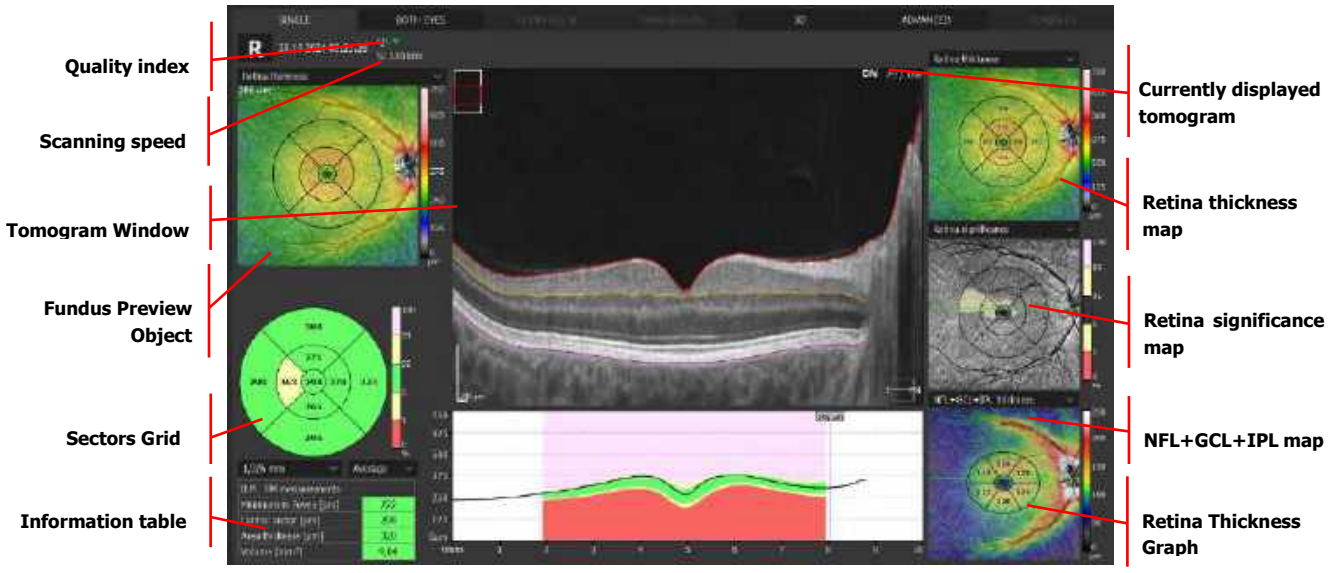


Figure 127.
Single Tab Retina 3D Analysis

11.1.1.1. Tomogram Window

1. Scroll the mouse wheel to change the displayed tomogram.
2. Double click to open the Tomogram full screen window.
3. Right-click to display the Functional menu.
4. Hold the right mouse button and move it right / left and up / down to change the brightness and contrast.

11.1.1.2. Fundus Preview Object

The fundus preview object can be changed between several options. The fundus reconstruction image is created from all A-scans acquired in the scanned area.

Right-click on the fundus preview to select the image overlay from the menu.

The following images are available:

1. Fundus Photo
2. Fundus Reconstruction
3. pSLO
4. IR

To change the transparency level, move the mouse wheel on the fundus reconstruction image.

A right-click over the eye preview window opens the following display and actions menu.

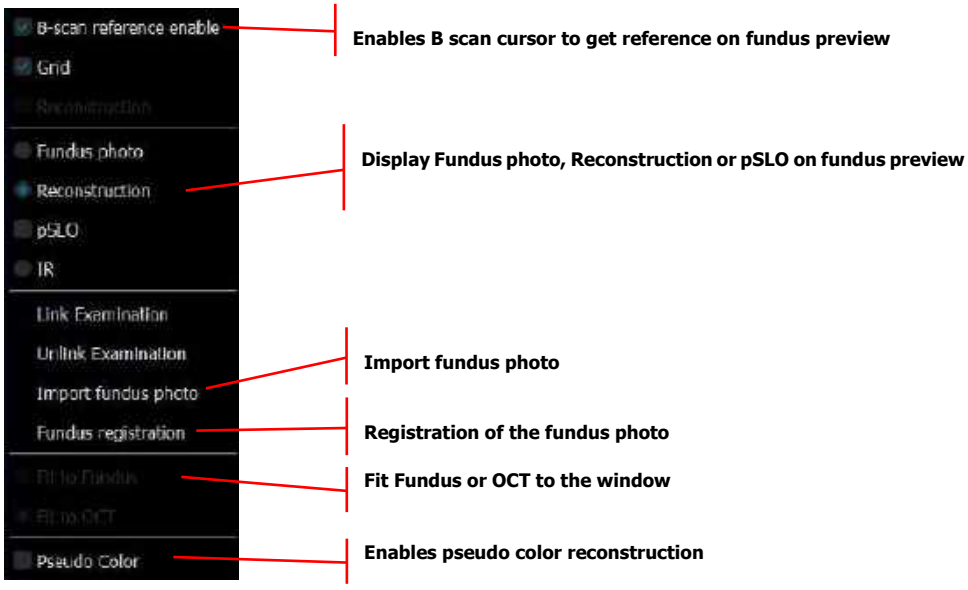


Figure 128.
Eye Preview Window Context Menu

11.1.1.3. Sectors Grid

The Sectors Grid corresponds to the grid overlaid on the Retina Thickness Map. In each sector of the grid, the retinal thickness of each sector appears.

It is possible to show sector grids with diameters: 1 / 3 / 6 mm or 0.6 / 2.22 / 3.45 mm. When the “Grid” option is selected, the entire map is covered by a grid of numbers. Each number represents the retinal thickness at each selected point.

The following values can be selected to be viewed in the sectors: Mean, Maximum, Minimum or Volume of the zone. The Thickness Map is further organized and presented in the nine ETDRS-like zones.

11.1.1.4. Information Table

The Information Table displays the average thickness of the central sector, volume of the scanned cube and average retinal thickness of the scanned cube.

11.1.1.5. Retinal Thickness Graph

The Retinal Thickness Graph displays the retinal thickness contour of the currently displayed scan overlayed on color coded reference data ranges. The ranges appear using **light red, light yellow, green, yellow, red** described in the legend below. The reference data is applicable to scans acquired with the 3D scan program.

NOTE: Areas of the Retinal Thickness Map may be missing portions due to lack of layer segmentation detection.

NOTE: Make sure that the foveola marker which shows the center of macula in the retina analysis tab locates the fovea properly.

White areas on the retina thickness graph identify areas not covered by reference data (e.g., scan length higher than 10 mm and fovea are not centered.)

11.1.1.6. Macula Reference Distribution

Color Code for Retina Parameters (Used in Retina 3D and Widefield 3D)

Above Normal	**1%**	1% falls within the light red band, considered outside the RDB limit. (Thickest 1% Higher than 99%)
Suspected above normal	**5%**	5% falls within or above the light-yellow band. (Thickest 5% Higher than 95%)
Normal	**90%**	90% falls within the green band. (Middle 90%)
Suspected Below Normal	**5%**	5% falls within or below the yellow band. (Thinnest 4% lower than 95%)
Below normal	**1%**	1% falls within the red band, considered outside the RDB limit. (Thinnest 1% lower than 99%)

NOTE: Clinicians must exercise their judgment in the interpretation of the reference data comparison. For any measurement, 10% (e.g., two out of 20 normal eyes) will fall above or below green.

CAUTION: This manual does not provide guidance on interpretation of clinical results. The clinician must ensure that they have received appropriate medical training in such interpretation. OPTOPOL is not responsible for misdiagnosis of results.

11.1.1.7. Foveola marker position

The system automatically detects the fovea and marks it with a green fovea marker.

If the system does not detect the fovea position, and the ”Fovea: not found” hint is displayed at the bottom of the eye preview window, and the fovea marker in the center of the scan turns orange. In this case the operator must set the fovea position manually.

On the tomogram window, hover the cursor over the fovea and select ‘Set foveola’ from the context menu or grab and move the center of the sector over the thickness map and the grid on the map. The foveola marker is used to superimpose the reference data area and thickness measurements on the grid and the table. Upon manual corrections the ”Fovea: manual” hint is displayed at the bottom of the eye preview window, and the fovea marker is displayed in white.

If the SOCT does not find the fovea, it set is in the center of the scan for the Retina 3D map.

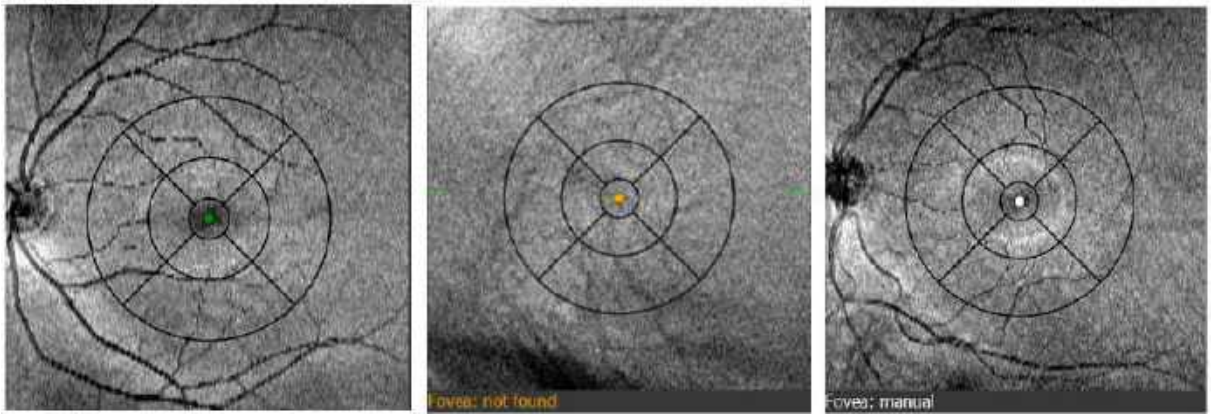


Figure 129.
Possible states of the fovea marker. From the left - the fovea found automatically, the fovea not found, and the fovea position changed manually.

11.1.1.8. Retina Thickness Map

Scroll over the tomogram to scroll through each tomogram. The REVO device measures retinal thickness at each point on the map. Place the mouse cursor over any point on the map and click the left mouse button. Detailed values will be displayed in the panel in the upper left corner of every map.

The macula location is detected automatically. Correction of the fovea detection is available. To correct the fovea detection, move the mouse cursor over the center of a central sector. Click and hold the left mouse button on a white dot at “Retina Thickness Map” and move the pointer to the desired position.

11.1.1.9. Retina Significance Map

The Retina Significance Map compares the measured value to the corresponding reference value. See Chapter 11.1.1.6 Macula Reference Distribution

11.1.1.10. Retina Deviation Map

The Retina Deviation Map shows the percentage loss of retinal thickness from the reference database. Each super pixel value on the map is calculated as a percentage value by the following formula: (Thickness value – mean reference value) / (mean reference value) * 100.

The range of the color-coding of the map corresponds to -50% to 50% deviation.

The color-coding is displayed as below:

Red:	Maximum (+50%)	
Yellow:	Upper Middle	
Green:	Middle (0%)	
Cyan:	Lower Middle	
Blue:	Minimum (-50%)	

11.1.1.11. Thickness Maps

The user can select the following options from the Thickness Maps dropdown menu:

1. Retina Significance
2. Retina Deviation
3. RPE Deformation
4. NFL Thickness
5. MZ / EZ-RPE Thickness
6. Inner Retinal Thickness
7. Outer Retinal Thickness
8. NFL+GCL+IPL Thickness
9. GCL+IPL Thickness
10. Central Cone Map[45]
11. Photoreceptor Map[45]
12. RPE Thickness[45]
13. COST Map[45]
14. Inner photoscreen[45]

11.1.1.12. RPE Deformation Map

The RPE deformation compares the outer boundary of RPE layer against a BM layer. The color-coded RPE Deformation Map displays the variance.

[45] Available for examinations conducted on the REVO HR device or newer.

11.1.2. Both Eyes Tab

In the tab **[BOTH EYES]**, it is possible to compare the analyses of the left and right eyes. This produces a symmetry analysis.

11.1.2.1. Retina View

Retina view on the **[BOTH EYES]** tab displays the output of the Retinal Thickness Map, Thickness / Volume Sectors Map, and two additional custom maps selected by the user. It is possible to choose either **Retina Thickness / Retina Significance / Retina Deviation / Fundus Preview**. This analysis tab requires one right and one left examination performed with the 3D Retina Scan.

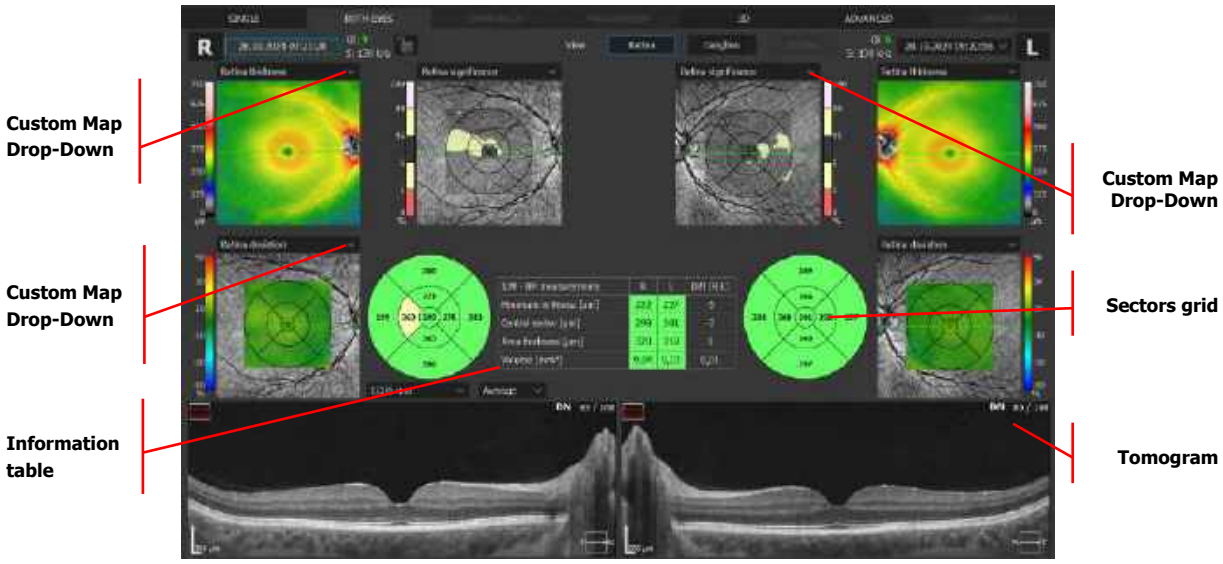


Figure 130.
Both Eyes Retina Analysis

The Sectors Map shows either average, maximum, minimum retinal thickness (in microns) or volume (in mm^3) in each area. From the Sector Map Dimension base on circle diameters 1 / 3 / 6 mm (ETDRS).

11.1.2.2. Ganglion View

Ganglion view is enabled only with Retina 3D scan.

The Ganglion view results offer indirect measurement of the Ganglion Cells layer. This function can analyze the thickness of NFL thickness (between ILM and NFL / GCL), GCL+IPL (between NFL / GCL and IPL / INL) or NFL+GCL+IPL (between ILM and IPL / INL):

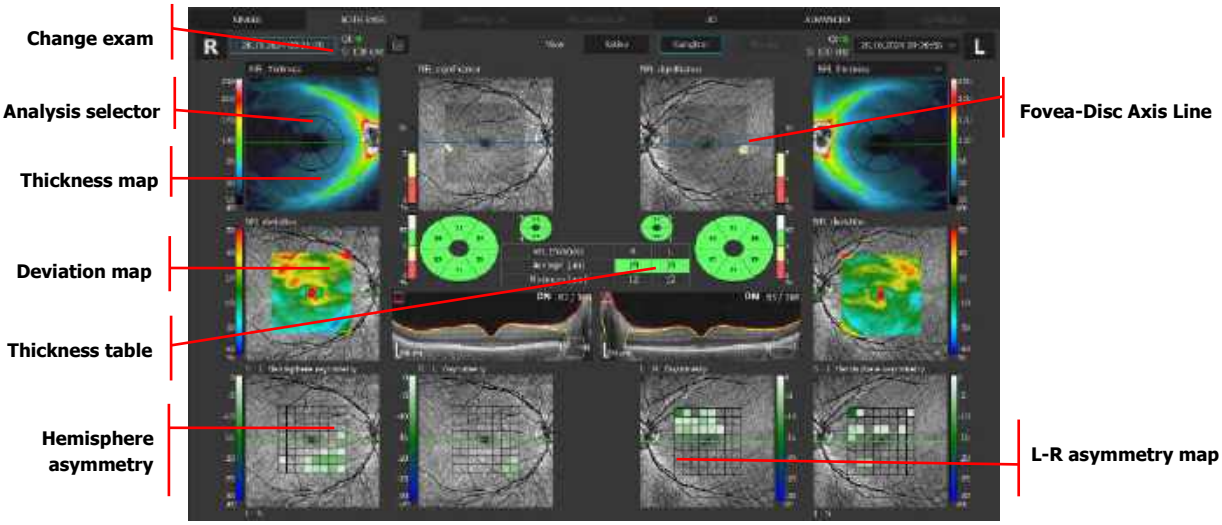


Figure 131.
Ganglion Cell Analysis (GCC)

The thickness map to overlay on the fundus reconstruction can be selected from the drop-down menu:

1. NFL+GCL+IPL Thickness Map
2. GCL+IPL Thickness Map
3. NFL Thickness Map

VISUAL FIELD STIMULUS LOCATIONS

The OPTOPOL PTS Perimeter can interface with the OPTOPOL REVO device to create a “Structure and Function” Report. Right-click on any of the above maps to view the context menu from which VF locations display can be enabled. See Chapter 11.5 Structure and Function: Combined OCT and VF Report.

NFL+GCL+IPL RDB / GCL+IPL / NFL SIGNIFICANCE MAP (RDB REFERENCE)

This color map shows a comparison of NFL+GCL+IPL, GCL+IPL or NFL thickness with the reference database (RDB).

The Fovea-Disc axis presented by the blue dashed line shows the symmetry axis used for the Asymmetry Map analysis (see below). To modify the Fovea-Disc axis, place the cursor over the dashed line, press and hold the left mouse button, and move the line to the desired position.

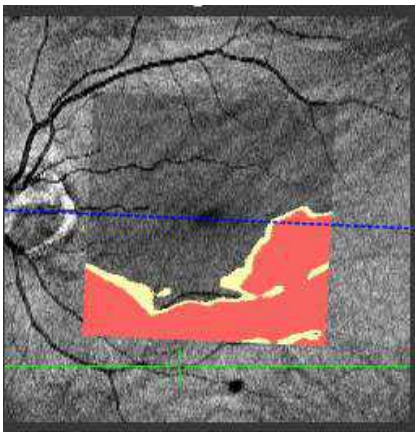


Figure 132.
Fovea Disc Axis

NFL+GCL+IPL / GCL+IPL / NFL DEVIATION MAP

This color map shows the deviation between the thickness of the analyzed layers and the reference database.

ASYMMETRY (RELATIVE THINNING) MAPS

Hemisphere Asymmetry S-I (Superior – Inferior) and I-S (Inferior – Superior) Maps present thickness subtraction on a 6 mm x 6 mm area of the Ganglion cell layer (NFL+GCL+IPL, GCL+IPL or NFL when selected). The subtraction is performed between two grids or points (with super grid selected) which are positioned symmetrically in relation to the center of the fovea-disc axis within the same eye. The fovea-disc axis is presented as a blue, dashed horizontal line.

For example, The Hemisphere Asymmetry S-I (Superior – Inferior) Map takes the value of a particular point on the superior grid and subtracts the value of the corresponding point (positioned symmetrically in relation to the fovea-disc axis) on the inferior grid. Where the resulting value is negative, the area is colored. Where the resulting value is positive, the area is not shaded.

Right-click the Asymmetry Map and select **[SET STANDARD GRID RESOLUTION]** or **[SET SUPER GRID RESOLUTION]** to change the display method.

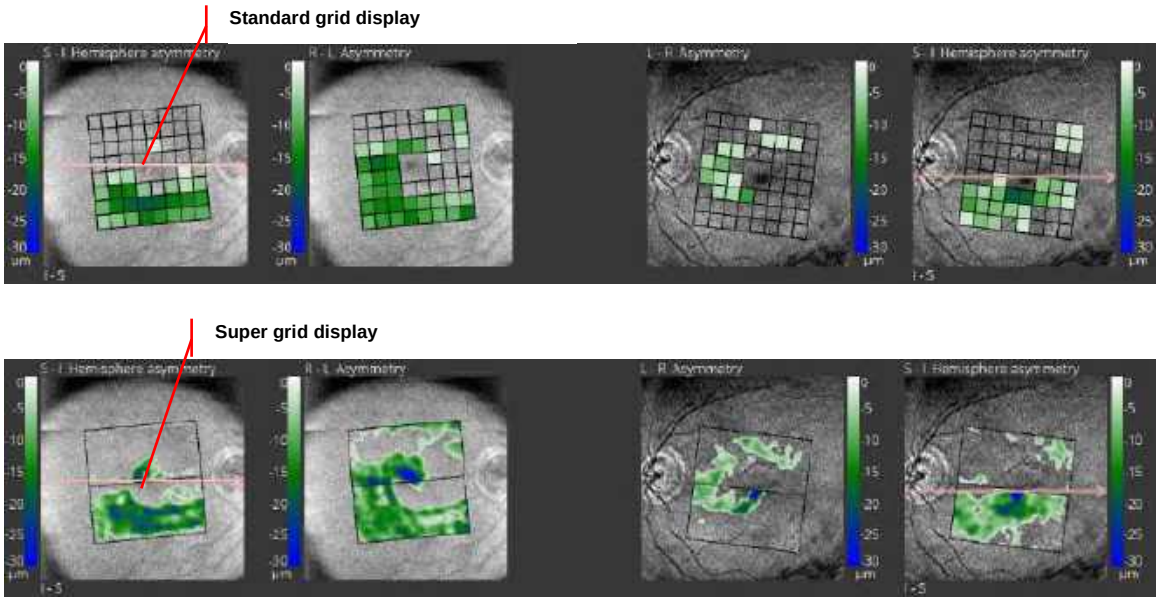


Figure 133.
Asymmetry Maps

NOTE: If the Fovea-disc axis does not go through the center of the disc and foveola, repositioning of the fovea-disc axis is required. On the Significance Map object, the operator can grab and move the blue dashed line to correct the position of the axis.

INTER EYE ASYMMETRY MAPS

Inter eye Asymmetry Maps: Right minus Left (R- L) and Left minus Right (L-R) subtract the thickness value of cells (or super pixels) which are positioned symmetrically with respect to the axis between the eyes by highlighting on a color scale all cells that are thinner than the corresponding cells in the other eye.

If the difference between the "Right minus Left eye" or “Left minus Right eye" is a negative value, the background is colored. The areas with positive values are transparent.

TOMOGRAM

Use the mouse-wheel to scroll (or swipe on touchscreen) through the displayed tomogram. Press and hold the **CTRL** key to change the zoom level while turning the mouse-wheel.

Double click the tomogram to open it in full screen mode.

THICKNESS TABLE

The Table contains the average and minimum thicknesses of the as NFL+GCL+IPL, GCL+IPL or NFL which are measured in an elliptical annulus.

SECTORS

Sectors in the middle portion of the screen divide the elliptical annulus of the Thickness Map into six regions: three equally sized sectors in the superior region and three equally sized sectors in the inferior region. The vertical inner and outer diameters of the sectors are, respectively, 1 mm and 4.2 mm. The horizontal inner and outer diameters are, respectively, 1.2 mm and 4.8 mm. The values within the sectors are compared to reference data.

The size and shape of the annulus are the result of an analysis of a reference thickness of GCL+IPL layers.

Color Code for the NFL parameters and Ganglion parameters

Suspected thick	**5%**	Thicker than 95% in the RDB
Normal	**Middle 90%**	90% falls within the green band.
Suspected thin	**Thinnest 5%**	Thinner than 95% in the RDB
Thin	**Thinnest 1%**	Thinner than 99% in the RDB

NOTE: The user should visually evaluate the image to determine if the segmentation lines are correctly finding the analyzed boundaries.

CAUTION: This manual does not provide guidance on interpretation of clinical results. The clinician must ensure that they have received appropriate medical training in such interpretation. OPTOPOL is not responsible for misdiagnosis of results.

11.1.2.3. Fundus View

The Fundus View tab is only available for examinations that capture a fundus photo. This view presents the fundus image in a large format for viewing.

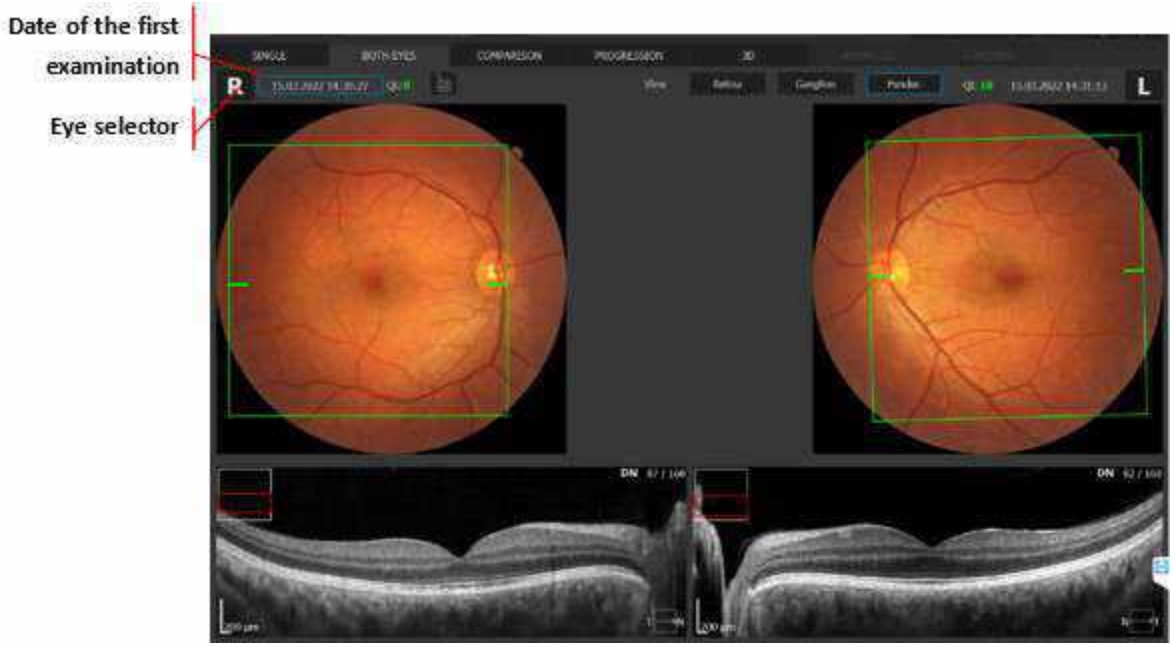


Figure 134.
Both Eyes Fundus View

11.1.3. Comparison Tab

The Comparison Tab is used to observe follow up changes in the eye.

The SOCT software automatically selects the oldest and the most recent exams for comparison. The user can manually choose other examinations from the drop-down list, depending on the chosen comparison protocols.

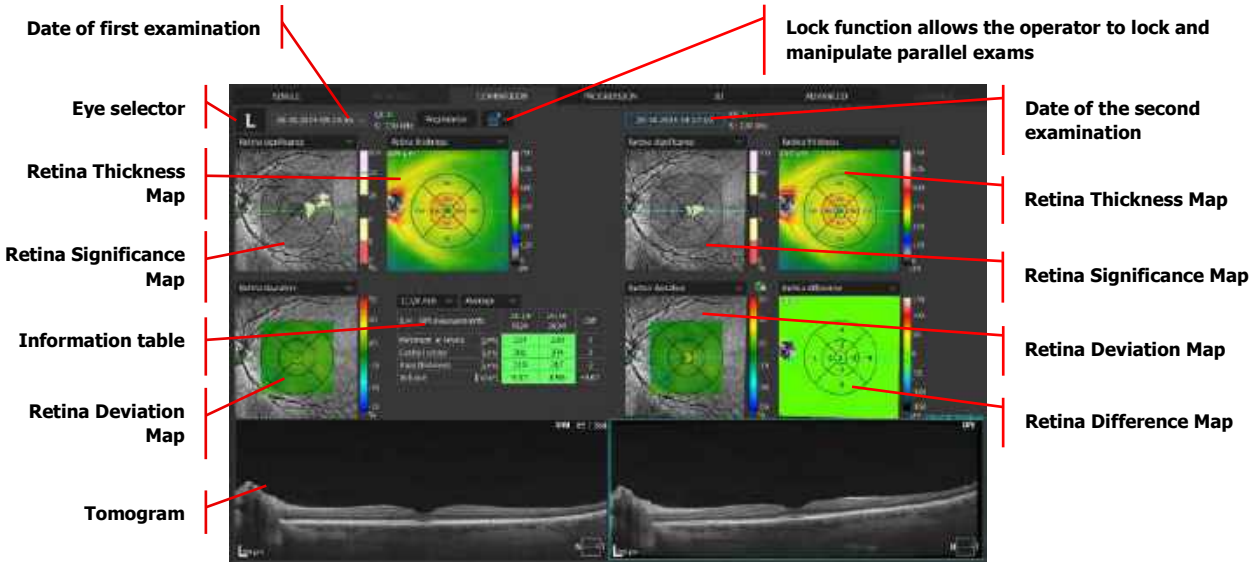


Figure 135.
Follow Up Comparison of the Two Retina Examinations

In the **[COMPARISON]** tab, it is possible to compare maps from different visits. The user can choose Retina Thickness, Significance, and Difference maps.

The user can also change the way the measurements are displayed.

Two options are available:

1. Rings: 1, 3 and 6 mm (standardized ETDRS testing)
2. Grid

The Lock Function  enables locking or locking and extracting tomograms for synchronized manipulation of exams and is available in the Both Eyes, Comparison and Progression tabs. This function is described in detail in Chapter 11.2 Lock Function.

1. In the COMPARISON view, after clicking the Examination selector button, the options **[EQUAL INTERVAL]** or **[LATEST SCANNED]** are available. **[EQUAL INTERVAL]** chooses examinations for the COMPARISON view scanned in equal intervals between the baseline and the current examination.
2. **[LATEST SCANNED]** chooses the current and the latest scanned examinations.
3. For the Disc examination, the **[EQUAL INTERVAL]** is set as the default.
4. For the Retina and Widefield examinations, the **[LATEST SCANNED]** is set as default.
5. The system stores information about the selection method separately for Disc, Retina and Widefield. This information is stored globally (remains unchanged after restarting the software).

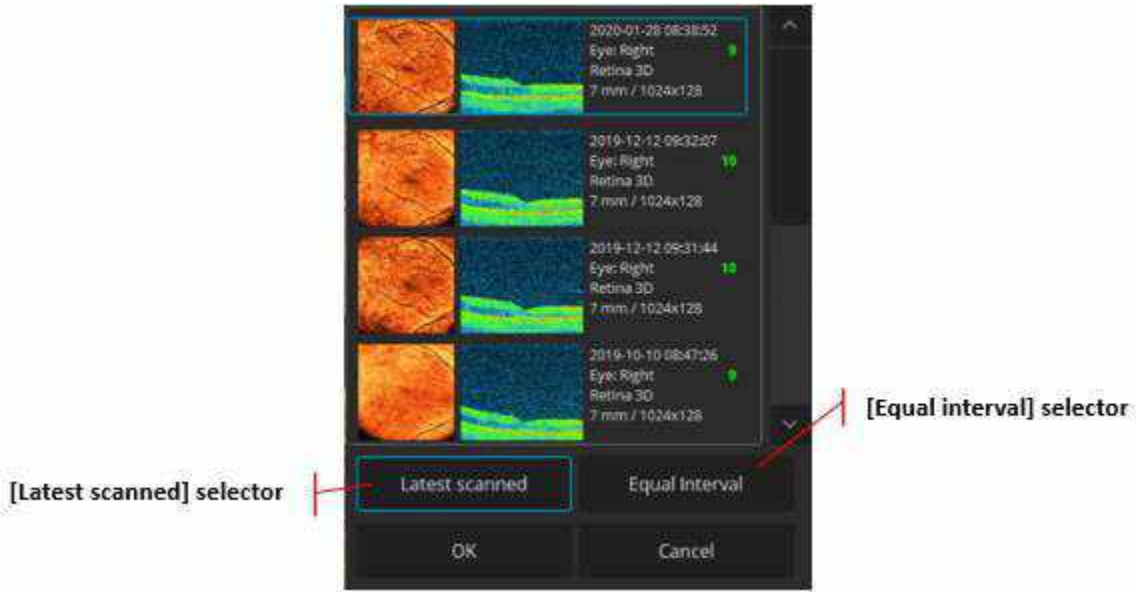


Figure 136.
Latest Scanned and Equal Interval Selector for COMPARISON View

11.1.4. Progression Tab

In the **[PROGRESSION]** tab, it is possible to see differences in up to six exams.

11.1.4.1. Retina View

The Retina View allows the user to compare the retinal thickness, retina difference, retina significance and retina deviation between all the examinations selected, sector by sector.

The single sector plot shows the differences in a graph regarding the selected sector. It is possible to select which zones are compared: Central sector, Full retina thickness or Total retina volume.

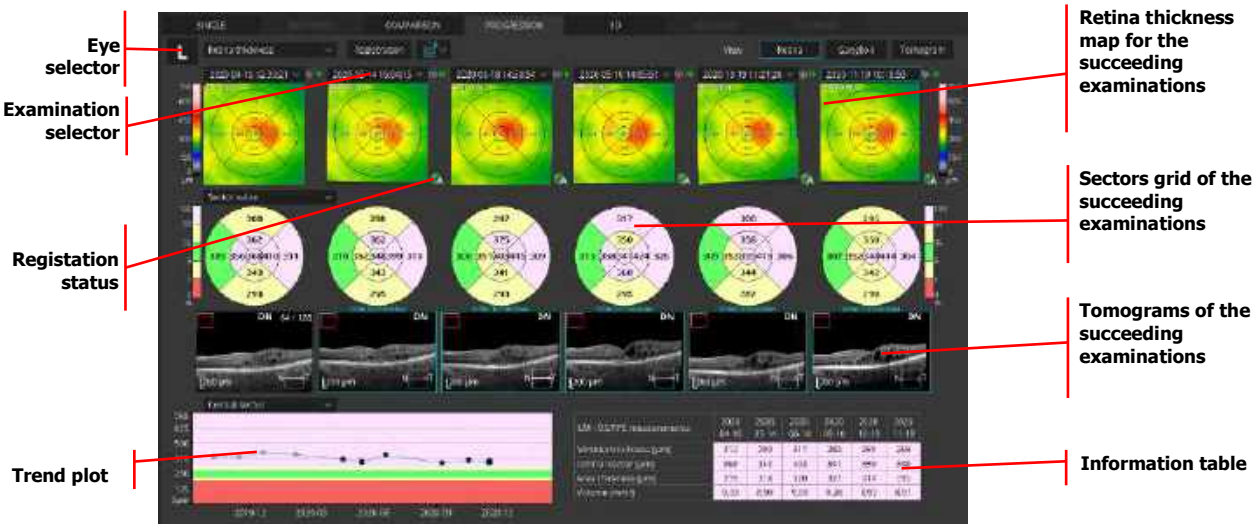


Figure 137.
Follow Up of the Selected Retina Examination

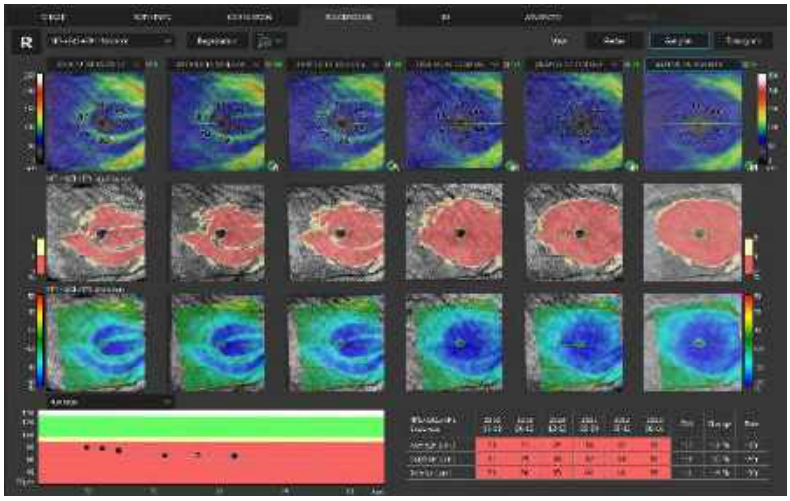


Figure 138.
Retina 3D Progression tab

1. The trend plot shows the differences in each zone on one plot.
2. For the **[PROGRESSION]** view after clicking the Examination selector button, the options **[EQUAL INTERVAL]** and **[LATEST SCANNED]** are available. **[EQUAL INTERVAL]** chooses examinations for the **[PROGRESSION]** view scanned in equal intervals between the baseline and the current examination.

3. **[LATEST SCANNED]** chooses the current and the latest scanned examinations.
4. For Disc examination, the **[EQUAL INTERVAL]** is set as the default.
5. For Retina and Anterior examinations, the **[LATEST SCANNED]** is set as the default.

11.1.4.2. Ganglion View

The Ganglion view is available for the 3D Retina scan only.

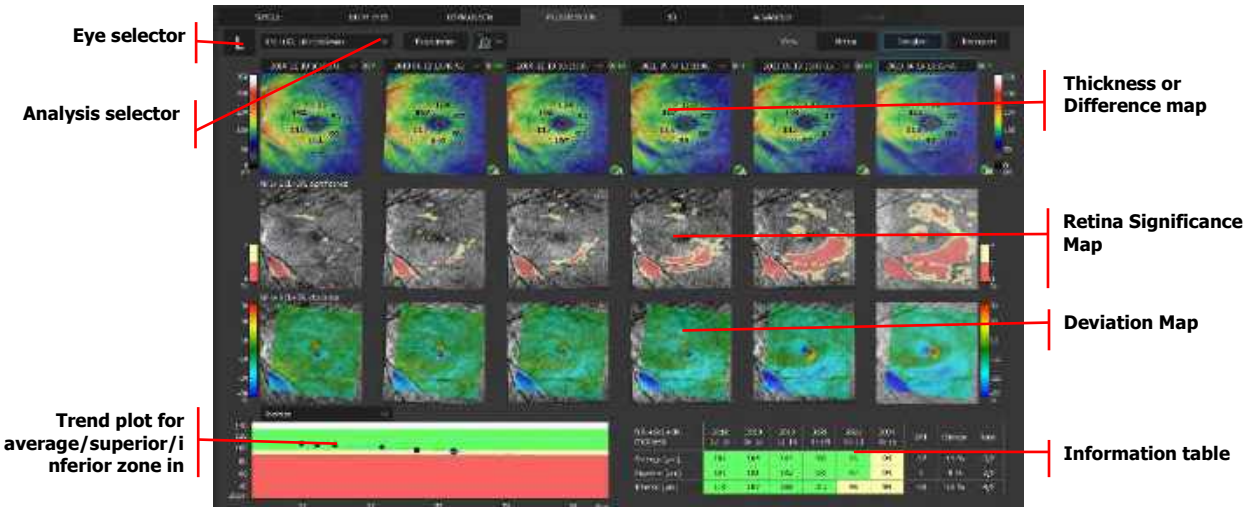


Figure 139.
Follow Up of the Changes in Ganglion Cell Analysis

The Thickness or Difference Map can be selected from the list box and overlaid on the reconstruction image.

Values corresponding to the map are shown on the NFL+GCL+IPL , GCL+IPL or NFL Grid:

1. **NFL+GCL+IPL / GCL+ IPL / NFL THICKNESS**

   Shows the thickness map for four examinations.

2. **NFL+GCL+IPL / GCL+ IPL DIFFERENCE**

   Shows the difference between the Baseline (oldest examination) and the displayed examinations as a color map with values. For the Baseline examination, the Thickness Map is shown instead of the Difference Map.

3. **NFL+GCL+IPL / GCL+IPL / NFL TREND PLOT**

   This plot shows changes in the analyzed thickness over time in a graph based on the analysis selector. It is possible to decide which zones are compared. Linear regression analysis is performed to fit a straight line through the longitudinal data to estimate the rate of change.

4. **SUMMARY TABLE**

   This table shows the overall average value of annulus ring and the average values of the superior and inferior sectors for the analyzed thickness. The last column presents the rate of change in the year. The rate value appears only if the time interval between the baseline and

next exams is at least three months. Background colors are color-coded according to the reference database.

11.1.4.3. Tomogram View

When viewing the **[TOMOGRAM]** View, the software displays tomograms and fundus reconstruction of each compared examination. The user can manually select examinations from the list. Press the drop-down menu near the date & time of examination to expand the exam selection list. This view shows the tomogram image from the macula up to the optic disc, and analysis results of retinal thickness.

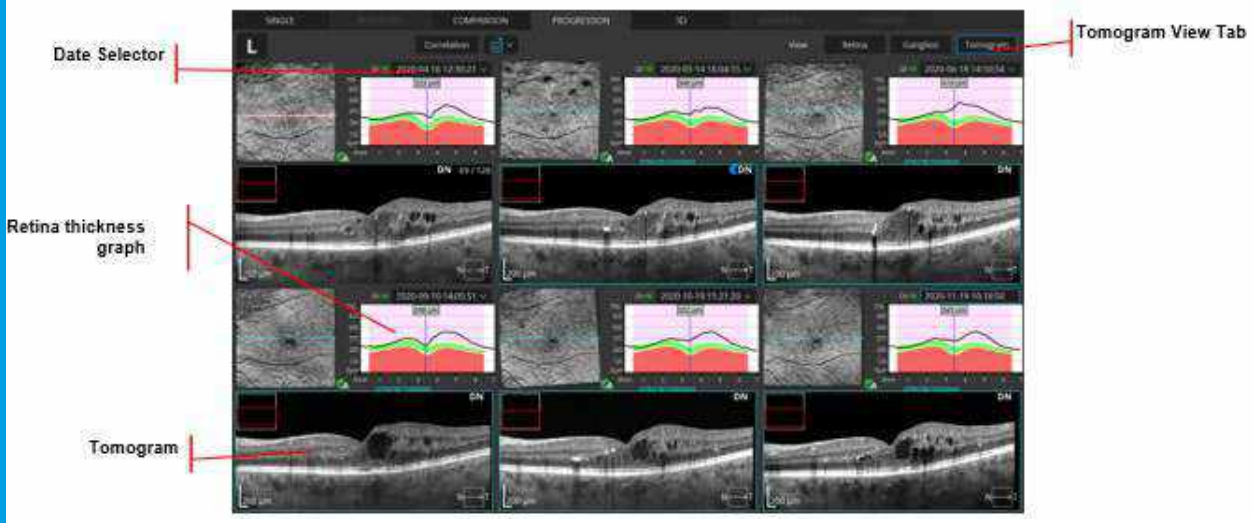


Figure 140.
Comparison of the Tomograms from Succeeding Examinations

NOTE: Be aware when evaluating the tomogram with different parameter settings and / or with different scan widths, the proportion of the retina shape may not be kept.

NOTE: Be aware when evaluating the tomograms on the Quick Printout, it is possible that scanned widths are different between examinations.

11.1.5. Examination Registration

11.1.5.1. Registration Status

The SOCT automatically registers examinations of the same eye to align the equivalent location of the retina for each image. The software displays the registration status to the baseline exam displayed with the set of maps on the right. Available statuses include:

A:	Automatically registered.
M:	Manually registered.
Not Registrated:	Not registered. In this case press the [Registration] **[REGISTRATION]** button to correlate the exams manually.

To learn more about Exam Registration, see Chapter 17.1.2 Manual Registration.

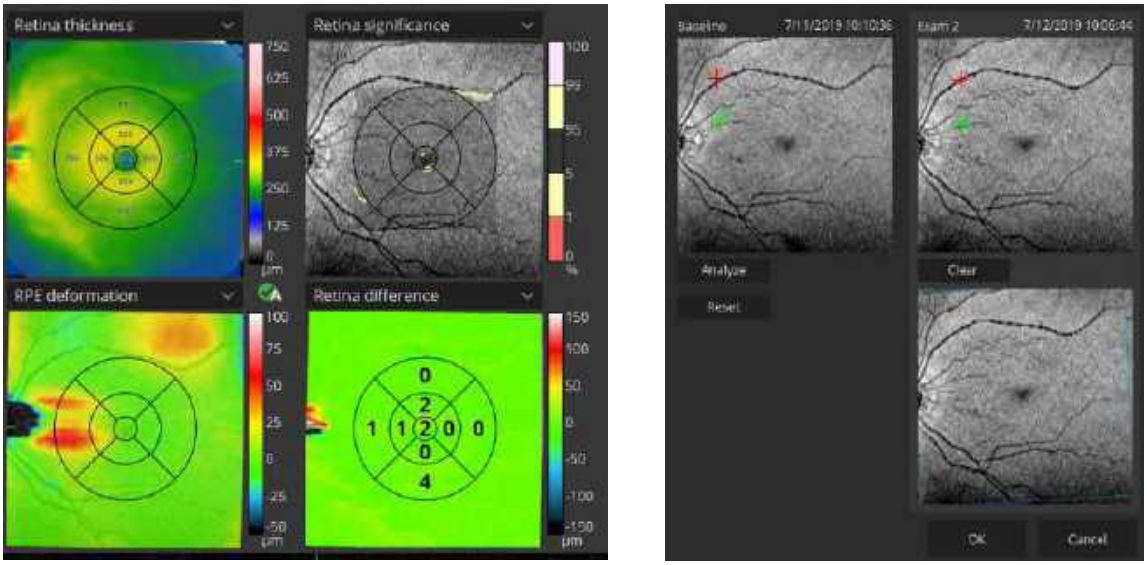


Figure 141.
Progression Analysis / Registration of Exams

11.2. Lock Function

11.2.1. Tomogram extraction from a 3D Exam

The SOCT Lock Extraction function enables a user to display the same position that is viewed on the baseline tomogram in the X, Y, Z axes and rotation of the exam. Once locked, all tomograms will present the equivalent location of the patient's retina for precise comparison or tracking of disease progression. In order to reach the correct alignment of all tomograms, the software adjusts the images for differences in scan positioning and rotation that have occurred during acquisition.

Before the function can be used, examinations must be correlated automatically or manually. The registration of examinations is explained in the Chapter 17 Examinations Registration. An extracted tomogram is created by extracting A-scans of the follow-up tomogram based on the registration with the reference tomogram.

To display an extracted tomogram, go to the Comparison or Progression tabs. Make sure the examinations have been correlated. Click the arrow next to the lock button  to drop down a context menu and choose the extraction function by clicking.  (If the examinations are not correlated, the extraction function is not available). The extracted tomogram is displayed in the bottom right-hand corner. From now on, scrolling over either of the tomograms (or swiping on the touchscreen) causes both to act in sync, always presenting the same location of the patient's retina.

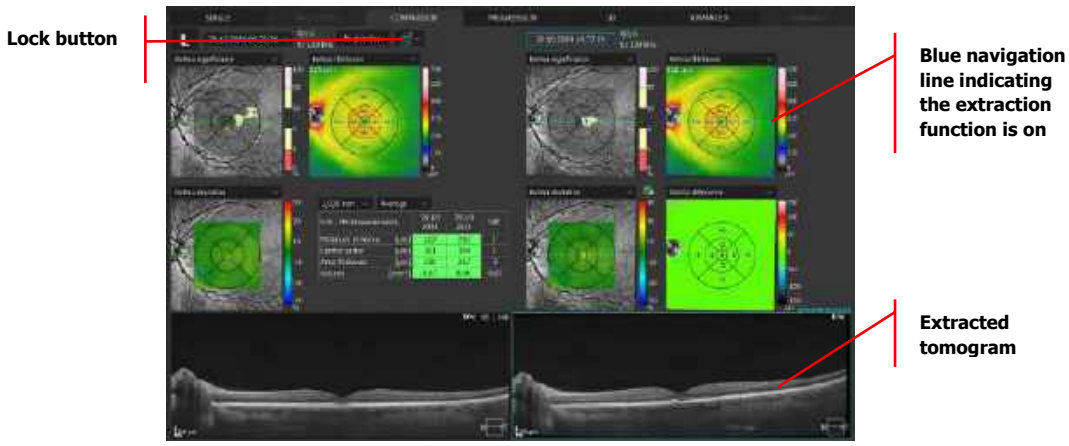


Figure 142.
Comparison Tab with an Extracted Tomogram Displayed in the Bottom Right-Hand Corner

Different options in the lock button drop down menu indicate the following:

	Lock is off, no registration.
	Lock is on, no registration.
	Extracted tomogram, function is on.

11.3. Optic Nerve Head Analysis

The Optic Nerve Head analysis shows the thickness of NFL (Retinal Nerve Fiber Layer) and analysis results of the shape of the optic nerve head. The compatible scan program is **[DISC 3D]**.

The measurement result of the optic disc and NFL region is analyzed based on the captured OCT image of the optic disc in the **[DISC 3D]** mode. The results of NFL analysis are shown, for example, as a map relating to the NFL thickness, NFL profile indicating the thickness of locations through which a measurement circle passes (diameter 3.45 mm centering on the optic disc), and NFL grid indicating the thickness of the region inside the measurement circle. The results of shape analysis of the optic disc are shown in Disc, Cup, Rim, and other ONH parameters.

These analysis results can be shown on the **[SINGLE], [BOTH EYES]** and **[PROGRESSION]** tab screens.

11.3.1. Both Eyes Tab

The **[BOTH EYES]** tab presents the results of the optic nerve head, NFL thickness, and NSTIN region analyses based on the captured OCT data for both eyes. It is the default view for the **[DISC 3D]** scan. In this view, the results of NFL analysis displays the NFL thickness map, NFL NSTIN profile, (indicating the thickness of locations through which a measurement circle passes), and NFL grid (indicating the

thickness of the region inside the measurement circle). The results of the optic disc analysis are displayed in the table as ONH parameters.

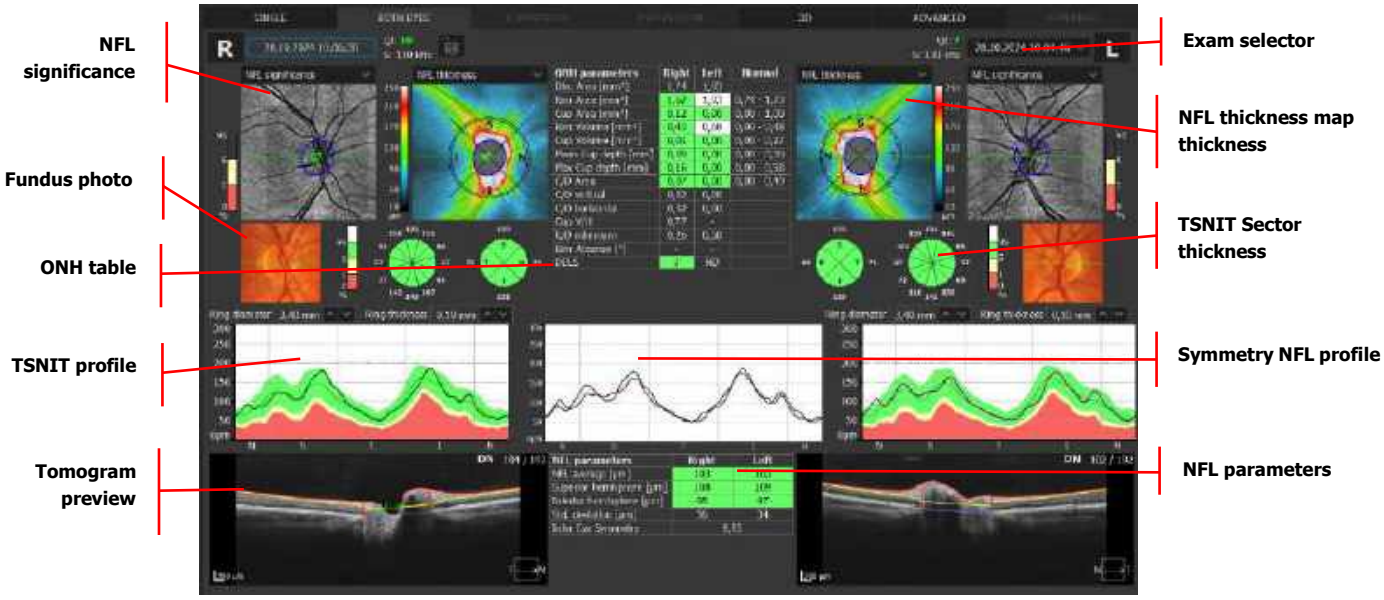


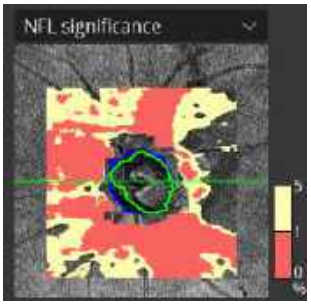
Figure 143.
Disc 3D Both Eyes

11.3.1.1. NFL Reference Distribution

Color Code for the NFL parameters and Ganglion parameters

Suspected thick	**5%**	Thicker than 95% in the RDB
Normal	**Middle 90%**	90% falls within the green band.
Suspected thin	**Thinnest 5%**	Thinner than 95% in the RDB
Thin	**Thinnest 1%**	Thinner than 99% in the RDB

11.3.1.2. NFL Significance Map



The NFL Significance Map compares the measured value to the corresponding reference value. The optic disc outline is indicated with a blue line and the cup outline with a green line. The RDB color code presents only the thinnest 5% and 1%. The middle and above values are presented as transparent.

The displayed map to overlay on the fundus reconstruction can be selected from the list box:

1. NFL Significance
2. NFL Deviation
3. NFL Thickness

To change the transparency level, scroll over the object.

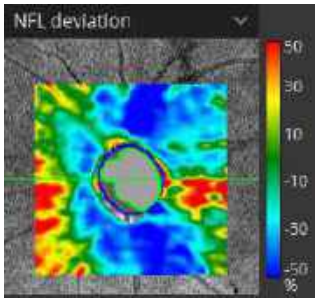
11.3.1.3. NFL Deviation Map

The NFL Deviation Map shows the percentage loss of NFL thickness from the norm determined from the reference database. Each pixel value on the map is calculated as a percentage value by the following formula: : (Thickness value – mean reference value) / (mean reference value) * 100.

The range of the color-coding of the map corresponds to -50% to 50% deviation.

The color-coding is displayed as below:

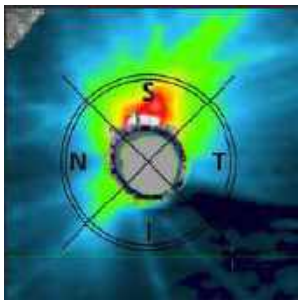
Red:	Maximum (+50%)	
Yellow:	Upper Middle	
Green:	Middle (0%)	
Cyan:	Lower Middle	
Blue:	Minimum (-50%)	



VF LOCATIONS DISPLAY

Right click on any of the above maps to view the context menu from which the OPTOPOL PTS Visual Field locations display can be enabled. See more in Chapter 11.5 Structure and Function: Combined OCT and VF Report.

11.3.1.4. NFL Thickness Map



The NFL thickness map displays a color representation of the thickness of the NFL layer for the scanned area. The map presents the TSNIT ring position and disc and cup outline.

11.3.1.5. Fundus Photo

A fundus photo of the right and / or left eye is displayed if the user has imported or linked a photo. To do this, click the right mouse button over the fundus preview image to open a context menu (shown below) and choose **[IMPORT FUNDUS PHOTO]** as described in Chapter 16.1 Import Fundus Image to an Examination or **[LINK EXAMINATION]** as described in Chapter 16.2 Linking a Fundus Photo to an Examination.

1. To zoom the photo in-or-out, hold the **CTRL** key and scroll with your mouse over the image.

2. To move the image, hold your left mouse button over the image and move it.
3. To change the brightness / contrast of the image, hold the right mouse button and move it over the image.
4. To open the photo in the **[FUNDUS PHOTO]** tab, double-click on the image.

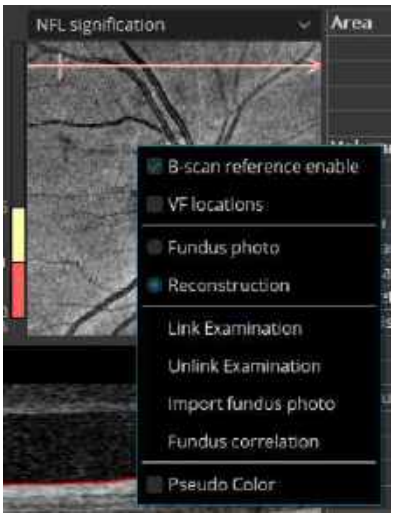


Figure 144.
Context Menu of the Disc Reconstruction Image

11.3.1.6. ONH Table

The ONH Table displays selected ONH parameters for Right and Left eye.

11.3.1.6.1. ONH Reference Distribution

SOCT compares the patient ONH parameters to the reference data

Color code parameters: Rim Area, Rim Volume, R/D minimum

No indicator	No comparison	For patients with lower and higher disc size (exceed collected limit)
Suspected large	**Largest 5%**	Larger than 95% in the RDB
Normal	**Middle 90%**	90% falls within the green band. (Middle 90%)
Suspected thin	**Smallest 5%**	Smaller than 95% in the RDB
Thin	**Smallest 1%**	Smaller lower than 99% in the RDB

ONH parameters Color code parameters: Cup Area, Cup Volume, C/D area, C/D Horizontal, C/D vertical.

No indicator	No comparison	Disc size has no reference parameters
Suspected small	**Smallest 5%**	Smaller than 95% in the RDB
Normal	**Middle 90%**	90% falls within the green band. (Middle 90%)
Suspected large	**Largest 5%**	Larger than 95% in the RDB
Large	**Largest 1%**	Larger than 99% in the RDB

11.3.1.7. NFL NSTIN Profile

The NFL NSTIN Profile displays the NFL thickness at the NSTIN region for the right or left eyes.

11.3.1.8. Tomogram Preview

The Tomogram Preview displays the OCT image in the selected location with marked ILM, NFL layer.

11.3.1.9. Exam Selector

If there are more than one exam from the same location and the same date, the operator can change the displayed exam. Click the exam date and select the desired scan from the list.

11.3.1.10. NFL Symmetry Profile

The NFL thickness at the NSTIN region for the right and left eye is shown. Reference Database (RDB) background may be switched on / off by right-clicking on the NFL symmetry profile chart and selecting or deselecting the RDB background.

11.3.1.11. NFL Sector

The inside of the NFL measurement circle is divided into 4 or 12 sectors, and the NFL thickness from NSTIN is shown. Background colors are color-coded based on comparison to the reference database.

11.3.1.12. NFL Parameters Table

The NFL Parameters table summarizes the measurement values relating to the NFL thickness at the NSTIN region for the right and left eyes. Background colors are color-coded based on comparison to the reference database.

1. NSTIN Average Standard Deviation of Nerve Fiber layer of NSTIN region Symmetry.
2. Average value of NFL thickness of the NSTIN region (µm).
3. Inter Eye Symmetry of both eyes relating to the NSTIN region.

11.3.2. Single 3D Tab

The 3D view for a single eye is automatically open only in cases in which there is no **[DISC 3D]** scan of the opposite eye from that same visit. This view shows Fundus reconstruction with a preview of the selected tomogram, the NFL thickness map for the scan area, a table with ONH data information, and the NFL thickness graph.

Figure 145.
Disc 3D Single Tab

11.3.2.1. Fundus Photo

A fundus photo is displayed if the user has captured a photo with the REVO FC exam, imported, or linked a fundus photo. To manually add a fundus image, right-click the mouse button over the disc reconstruction image to open a context menu (shown below) and choose **[IMPORT FUNDUS PHOTO]** or **[LINK EXAMINATION]**.

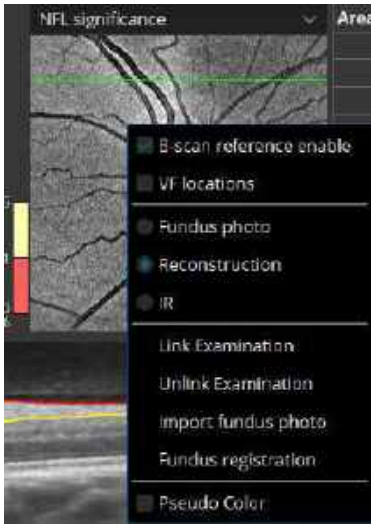


Figure 146.
Context Menu of the Disc Reconstruction Image

1. To zoom the photo in or out, hold the **CTRL** key and scroll with your mouse over the image.
2. To move the image, hold your left mouse button over the image and move it.
3. To change the brightness / contrast of the image, hold your right mouse button and move the mouse over the image.
4. To open the photo in the **[FUNDUS PHOTO]** tab, double click on the image.

11.3.2.2. NFL Significance Map

This color map shows singular points by comparing the NFL thickness with the RDB. The disc contour is displayed in blue color, the cup contour is displayed in green color.

11.3.2.3. Tomogram Image of the Optic Disc

The tomogram preview image displays the selected tomogram. Markers point to the left and right edge of Bruch's Membrane on the actual scan (if the actual scan crosses the disc). If necessary, the marker points can be moved. To move the marker points:

1. Double click to open full screen image.
2. Press **[EDIT DISC]**.
3. Click on a marker and drag it to the proper location. (Changes in a single scan will occur on the shape of the disc and cup and will take effect in all analyses.)

On the tomogram preview image, the yellow line displays the Cup Offset Line (parallel to the purple line which represents the disc surface.) The distance between the Cup Offset Line and the disc surface line may be changed by editing the value on the Cup Offset Panel or moving the slider. It is possible to change the default cup offset value in the setup mode.

11.3.2.4. NFL Thickness Map

The NFL thickness map displays the thickness of the NFL layer for the scanned area. This map displays the rings around the disc in which the NFL thickness data are used for NSTIN analysis. This ring is divided into four zones representing, Nasal, Superior, Temporal, Inferior, and Nasal.

1. If the operator clicks anywhere in the map, the thickness of the NFL at the chosen point will be displayed.
2. The black rings around the disc represent the edges of the ring used to calculate the NSTIN NFL thickness displayed on the NFL thickness graph.
3. The dimensions of the ring (diameter and thickness) are shown below the map.
4. It is possible to manually change the dimensions of the ring by moving them to the desired position.
5. Contours of the Disc (in blue) and Cup (in green) are drawn on the map.
6. The shape of the cup and disc can be manually modified by the operator.
7. The green horizontal line on the thickness map indicates the position of the displayed tomogram.
8. To display the measured value from a specific location, left click the location from the display.

11.3.2.5. Optic Nerve Head (ONH) Parameters

Optic Nerve Head (ONH) parameters describe the quantified morphology of the optic disc. Data is calculated from the ILM, Disc, and Cup parameters for all scans. All ONH data is based on automatic recognition of ILM surface, BMO (Bruch's Membrane Opening), Cup Offset, and layer segmentation on the scanned cube.

NOTE: If manual adjustments of the segmentation lines are made by the user, the system will automatically recalculate the ONH parameters.

1. The operator can manually modify automatic recognition.
2. The operator can modify the following: (Layers segmentation - ILM surface and BMO position).
3. All ONH data is automatically recalculated if the ILM surface or BMO open edge factors change.
4. It is possible to restore the default analysis by pressing **[REANALYZE]**.

11.3.2.6. Disc Damage Likelihood Scale (DDLS)

The Disc Damage Likelihood Scale (DDLS) score is based on the DDLS scale introduced by George L. Spaeth, MD in 2002[46], [47]. The DDLS relies on the optic nerve as a direct indicator of disease. It classifies the appearance of the neuroretinal rim of the optic disc, corrected for disc diameter, into 10 stages. This scale can only be utilized as supplementary information and should not be used to determine any disease confirmation.

46 Spaeth, George L et al. "The disc damage likelihood scale: reproducibility of a new method of estimating the amount of optic nerve damage caused by glaucoma." Transactions of the American Ophthalmological Society vol. 100 (2002): 181-5; discussion 185-6.

47 Spaeth GL, Henderer J, Steinmann W. The Disc Damage Likelihood Scale (DDLS): Its use in the diagnosis and management of glaucoma. Highlights of Ophthalmology. 2003; 31:4-19.

How DDLS score is determined with the REVO device:

1. To determine the DDLS score, the software first measures the vertical height of the optic nerve head.
2. It then selects the proper column from the DDLS table for a small, average, or large disc.
3. Next, the software calculates the rim-to-disc ratio by comparing the width of the neuroretinal rim with that of the disc diameter using the same axis ratio around the disc in 360 degrees.
4. The software determines the narrowest rim-to-disc ratio (R/D) and uses this value to classify the DDLS stage. When R/D is > 0, the DDLS score is displayed. When R/D = 0, the software counts the number of degrees on the edge of the disc where the R/D = 0 (rim absence in degrees).
5. The rim absence (number of degrees with R/D = 0) is used to select the score from the DDLS table.

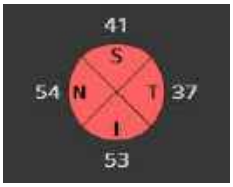
Disc Damage Likelihood scale						
	Narrowest width of rim (rim/disc ratio)			Examples		
DDLS Score	For Small Disc < 1.5 mm	For Average Size Disc 1.5 – 2.0 mm	For Large Disc > 2.0 mm	1.25 mm optic nerve	1.75 mm optic nerve	2.25 mm optic nerve
1	.5	.4 or more	.3 or more			
2	.4 to .49	.3 to .39	.2 to .29			
3	.3 to .39	.2 to .29	.1 to .19			
4	.2 to .29	.1 to .19	less than .1			
5	.1 to .19	less than .1	0 for less than 45°			
6	less than .1	0 for less than 45°	0 for 46° to 90°			
7	0 for less than 45°	0 for 46° to 90°	0 for 91° to 180°			
8	0 for 46° to 90°	0 for 91° to 180°	0 for 181° to 270°			
9	0 for 91° to 180°	0 for 181° to 270°	0 for more than 270°			
10	0 for more than 180°	0 for more than 270°				

Figure 147.
DDLS Score Table

CAUTION: The Disc Damage Likelihood Scale (DDLS) is based on a publication by George L. Spaeth, MD in 2002[48]. The DDLS information provided is only as supplementary information and should not be used as disease confirmation. Use for reference only. The representation of the DDLS value by the REVO device is strictly a calculated value.

[48] Spaeth, George L et al. "The disc damage likelihood scale: reproducibility of a new method of estimating the amount of optic nerve damage caused by glaucoma." Transactions of the American Ophthalmological Society vol. 100 (2002): 181-5; discussion 185-6.

11.3.2.7. NFL NSTIN Profile



The NFL thickness graph shows the mean values of NFL thickness, which are calculated as mean values in the selected ring for each angle from 0 to 360 degrees.

The vertical blue line in the graph is correlated with the angle on the NFL map. The value on the top shows the mean of NFL thickness, expressed in microns. Ring Diameter (RD) is 3.4 mm, and Ring Thickness (RT) is 0.1 mm.

11.3.2.8. NFL Sector

The inside of the measurement circle is divided into four or 12 sectors and the NFL thickness is shown. The background colors are color-coded based on the reference database. The mean NSTIN value and NSTIN SD are displayed above.

CAUTION: OPTOPOL Technology does not offer advice or instruction in the diagnosis and interpretation of OCT images. It is the clinician's responsibility to diagnose and interpret OCT scans.

11.3.3. Progression

The **[DISC 3D]** Progression displays a selection of up to six scans from the same eye displayed chronologically to help track NFL and ONH changes over time. The system automatically selects exams equally spread over time, and displays them, beginning with the baseline exam.

On the side of each NFL Thickness map of an examination, registrstion status (A (automatic), registrstion, M (manual), NG (not good)) is indicated. Press the **[REGISTRATION]** button to verify or correlate the examination manually if required. See details in Chapter 17 Examinations Registration.

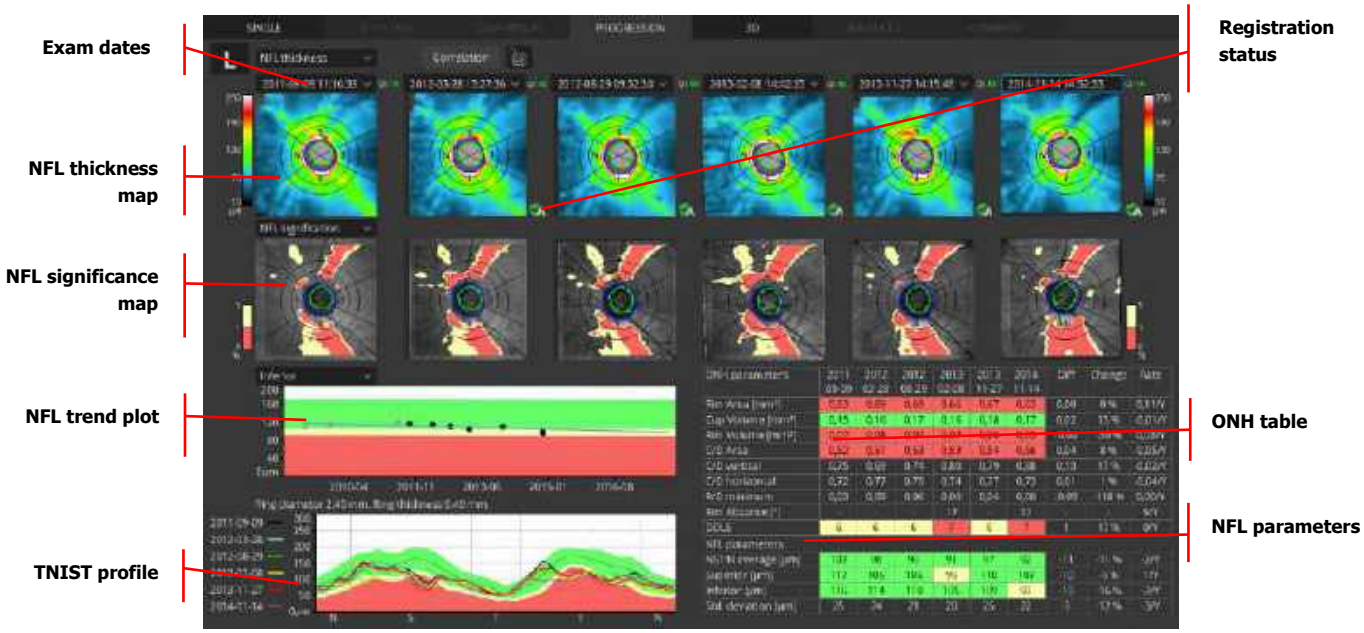


Figure 148.
Progression 3D Disc

11.3.3.1. NFL Thickness Map

Select the map that is displayed from the drop-down menu.

1. **NFL THICKNESS**

   The NFL thickness map displays a color representation of the thickness of the NFL layer for the scanned area.

2. **NFL DIFFERENCE**

   Color map with values that show the difference between the baseline exam (on the far left) and the current examination.

3. **NFL SIGNIFICANCE**

   Color map which displays a comparison of NFL thickness with the reference database.

4. **NFL DEVIATION**

   Color map which displays the deviation between the NFL thickness and the reference database.

The disc contour blue color and cup contour green color and measurement circles are shown.

11.3.3.2. NFL Significance

Select the map that is displayed from the drop-down menu.

1. **NFL DIFFERENCE**

   Color map with values that show the difference between the baseline exam (on the far left) and the current examination.

2. **NFL SIGNIFICANCE**

   Color map that displays a comparison of NFL thickness and the reference database.

3. **NFL DEVIATION**

   Color map that displays the deviation between the NFL thickness and the reference database.

RDB COMPARISON NFL MAP

Select the map that is displayed from the drop-down menu. Disc (gray), Cup (light gray) and Measurement Circle (yellow) are shown.

NFL TREND PLOT

This plot shows examinations performed for the same patient to display changes in the NFL thickness in the NSTIN region over time. Select the map that is displayed from the drop-down menu.

1. **NSTIN AVERAGE**

   Average value for entire measurement circle.

2. **SUPERIOR AVERAGE**

   Average value for superior semicircle.

3. INFERIOR AVERAGE

Average value for inferior semicircle.

The regression line is shown on the graph. Placing the cursor over any point on the graph displays the value from the selected point.

NSTIN PROFILE

The NSTIN graph provides an overlay displaying the NFL thickness results along the NSTIN as different color lines.

ONH PARAMETERS

Displays the most important parameters of ONH for each examination. The column on the far right is the rate of change. Background colors are color-coded based on the reference database.

NFL PARAMETERS

This is the same as the **[BOTH EYES]** tab screen. This table displays the values for each examination. The far-right column is the rate of change. Background colors are color-coded based on the reference database. The NFL parameter contains a difference column (from baseline) and rate of regression slope (the rate value appears only if the time between the baseline and the next exams is at least three months).

11.4. Advanced View (-Retina and Optic Nerve Head Analysis)

The **[ADVANCED]** tab displays the glaucoma summary report for 3D exams of retina and disc scans for both eyes from the same visit. This view is available for one **[RETINA 3D]** examination of one eye.

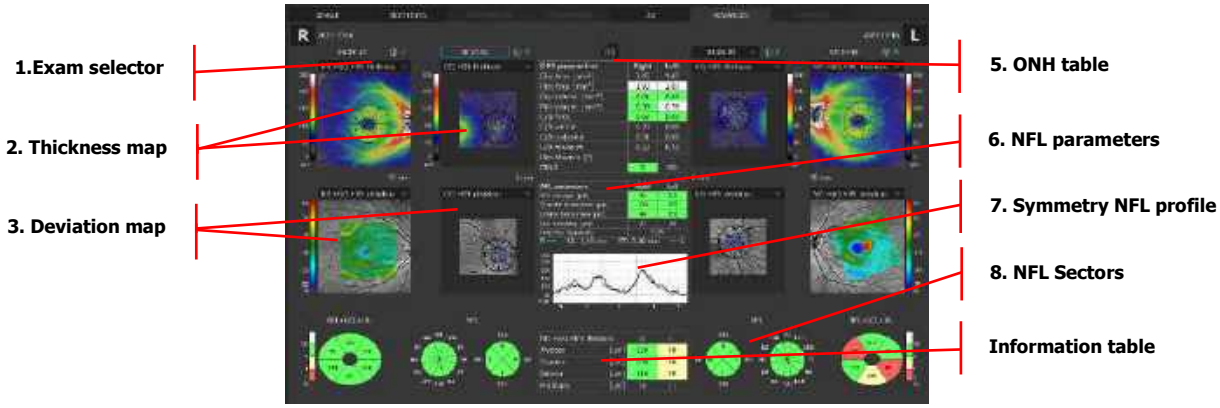


Figure 149.
Advanced View: Retina and Optic Nerve Head Analysiss

1. EXAM SELECTOR

If there are two or more exams of the same location from the same date, the operator can select the exam to be displayed. Click the exam date and select the desired scan from the list.

2. THICKNESS MAP

A map to overlay the fundus reconstruction can be selected from the drop-down menu:

- NFL+GCL+IPL thickness

- GCL+IPL thickness
- NFL thickness

To change the transparency level, turn the mouse wheel over the object.

3. DEVIATION MAP

A map to overlay the fundus reconstruction can be selected from the drop-down menu. Options depend on the map selected in the Thickness Map object above it:

If NFL+GCL+IPL thickness was selected:

- NFL+GCL+IPL Significance
- NFL+GCL+IPL Deviation

If GCL+IPL thickness was selected:

- GCL+IPL Significance
- GCL+IPL Deviation

If NFL thickness was selected:

- NFL Significance
- NFL Deviation

4. VF LOCATIONS DISPLAY

Right-click on any of the above maps to view the context menu from which Visual Field locations can be enabled. See more in Chapter 11.5 Structure and Function: Combined OCT and VF Report.

5. ONH TABLE

Displays selected ONH parameters for the Right and Left eye.

6. NFL PARAMETERS

This table summarizes the measurement values for the right and left eye relating to the NFL thickness at the NSTIN region. The background is color-coded based on the reference database.

7. SYMMETRY NFL PROFILE

Shows the NFL thickness at the NSTIN region for the right and left eye.

There is an option to switch the RDB background on / off by right-clicking on the NFL symmetry profile chart and selecting or deselecting the RDB background.

8. NFL Sectors

The inside of the NFL measurement circle is divided into four or 12 sectors, and the NFL thickness from NSTIN is shown. Background colors are color-coded based on comparison to the reference database.

11.5. Structure and Function: Combined OCT and VF Report

This report combines information about the patient's functional vision derived from the OPTOPOL PTS Visual Field device and comprehensive data on Retinal Ganglion Cells, NFL and Optic Nerve Head data from Retina and Disc OCT scans. Both eyes are represented on a single, combined report page. This view is accessible only if the Visual Field (VF) database connection has been configured in the setup[49]. For more information on setting up VF database go to Chapter 23.5.7 Visual Field

Figure 150.
Combined Structure and Function Report

1. SENSITIVITY MAP

Sensitivity map from Visual Field examination test patterns 24-2, 30-2 or 10-2.

2. TOTAL DEVIATION MAP AND PATTERN DEVIATION MAP

Probability graphs for VF results.

3. VF PARAMETERS

Reliability and global indices for Visual Field results.

4. RETINA / DISC THICKNESS MAP

A map to overlay the fundus reconstruction can be selected from the drop-down menu:

- NFL+GCL+IPL Thickness
- GCL+IPL Thickness
- NFL Thickness

[49] Structure and function is available only for customers using PTS automated perimeters from OPTOPOL with software version 3.7 and above and with configured SOCT applications. See more in Chapter 25 PTS Remote Connection and requirements, and in Chapter 11.5.2 Perimetry Requirements for SOCT Software.

5. **TRANSPARENCY**

   To change the transparency level, turn the mouse wheel over the object.

6. **RETINA / DISC SIGNIFICANCE / DEVIATION MAP**

   A map to overlay the fundus reconstruction can be selected from the drop-down menu. Options depend on the map selected in the Thickness Map object above it:

   If NFL+GCL+IPL thickness was selected:

   - NFL+GCL+IPL Significance
   - NFL+GCL+IPL Deviation

   If GCL+IPL thickness was selected:

   - GCL+IPL Significance
   - GCL+IPL Deviation

   If NFL thickness was selected:

   - NFL Significance
   - NFL Deviation

7. **KEY FOR VISUAL FIELD**

   Key for Visual Field information on the OCT map.

8. **VF LOCATIONS / RESULTS**

   Right-click on any of the above maps to view the context menu from which VF locations and / or VF results display can be enabled.

9. **COMBINED MAP OF STRUCTURE AND FUNCTION**

   An overlay of information from the PPD field of a vision map on the map of sectors from the OCT image (the Significance map).

10. **ONH TABLE**

    Displays the selected ONH parameters for the Right and Left eye.

11. **NFL PARAMETERS table**

    Summarizes the measurement values for the Right and Left eye relating to the NFL thickness at the NSTIN region. Background color based on RDB.

12. **NFL SYMMETRY PROFILE CHART**

    Shows the NFL thickness at the NSTIN region for the Right and Left eye.

Once a user selects the **[COMBINED]** tab, the system will search the VF database for the patient by name, DOB., or ID (Name and DOB must match, ID does not need to match). If the data matches and corresponding exams from the same day are found, the results are displayed. By default, the system presents one retina, disc, and VF exam for each eye. If any of these exams is missing for a given eye, the system displays results for the eye for which a full set of exams is found.

If the VF database features a patient with the same name and DOB., but a different ID, the patient selection window pops up. In the window, there is a list of patients with the same first name, last name, and DOB., but a different Patient ID. After a patient is chosen, the system displays the list of their exams. If there is only one patient, their name is highlighted automatically.

If the VF database features a patient record with matching data, but lacking a VF exam with the same date as the OCT exam, the system displays a selection window allowing the choice of a VF exam to be displayed.

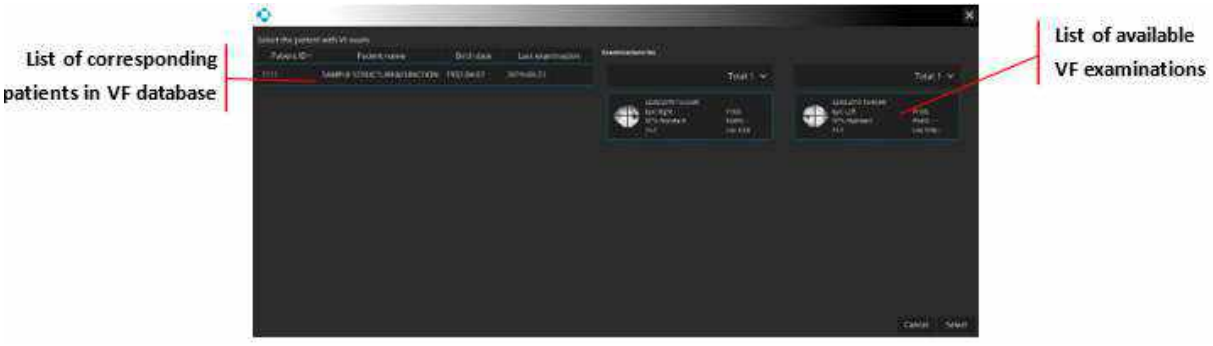


Figure 151.
Selecting the Patient and VF Examination Window

11.5.1. Relationships between Visual Field and RNFL / Ganglion maps

Structure and Function relationship is measured by eight corresponding regions of neuroretinal rim area, peripapillary retinal never fiber layer and visual field[50]. This concept is based on Structure and Function map introduced by Garway-Heath et al.[51]

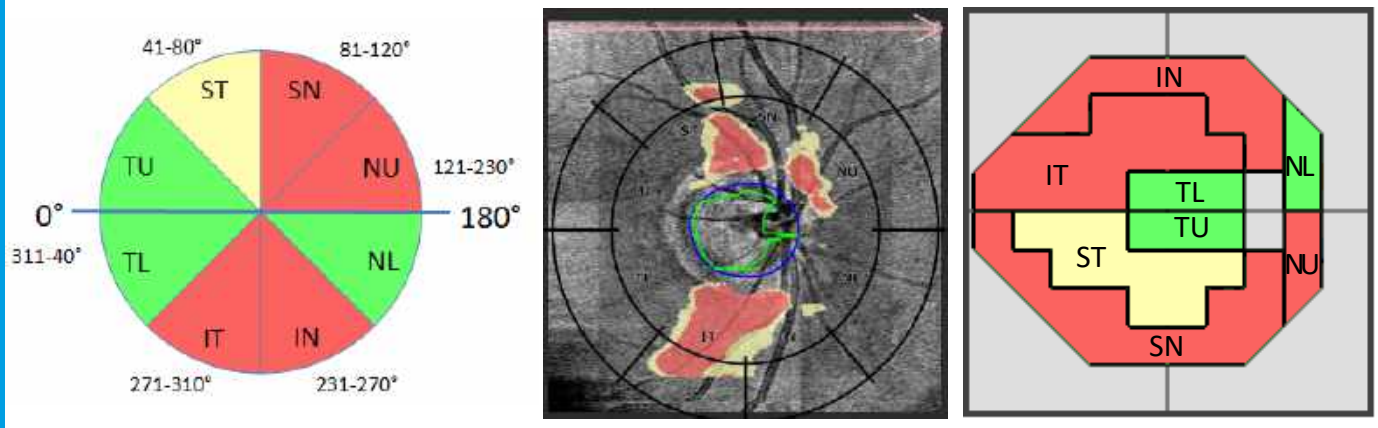


Figure 152.
Relationships between OCT and VF by Garway-Heath et al.

11.5.2. Perimetry Requirements for SOCT Software

1. PTS perimetry software version 3.7.0 or higher.
2. Configured connection between the SOCT and PTS software.
3. Input data from the SOCT: at least one Retina 3D or Disc 3D examination.

[50] Concept adaptation based on a publication by Garway-Heath et al., after own modification. Source below.

[51] Structure–Function Relationships between Spectral Domain OCT and Standard Achromatic Perimetry Naveed Nilforushan , Nariman Nassiri, Sasan Moghimi, Simon K. Law, JoAnn Giaconi, Anne L. Coleman, Joseph Caprioli and Kouros Nouri-Mahdavi. Investigative Ophthalmology & Visual Science, May 2012, Vol. 53, No. 6

4. A patient record in the SOCT application with the same personal details as the patient record in the PTS application (first name, last name, date of birth).

An exception is the patient ID which can differ between the SOCT and PTS applications. If the patients IDs are identical, only the patient record from the PTS application is used. Otherwise, the SOCT application loads the list of all patient records with the same personal data without taking into account the patient ID - the list of the patients and their exams is then displayed. If there is a full correspondence of patient data (the same name, surname, date of birth, id) all test data, if they meet the conditions of the automatically selectable test, will be added to the [**COMBINED]** tab automatically without displaying the list of tests. Otherwise, a list of the patient's tests will be displayed for the selection of the test/tests of the left and/or right eye. The test for a given eye will not be automatically added if there is no consistence between the SOCT and PTS tests, e.g., when there is a test for both the left and the right eye in the SOCT software, but in the PTS software the test for only one eye is 100% consistent.

The following conditions must be met for the compatibility of a test with Structure and Function:

1. Eye correspondence in both tests - for a given perimetric test, there must exist an SOCT test of the same eye.
2. The size of the stimulus used in the perimetric test: Goldman Size III.
3. The color of the stimulus used in the perimetric test: white or green.
4. Strategy of the perimetric test: any threshold strategy (Threshold, Fast threshold, Dynamic, Advance, ZETA, ZETA Fast, ZETA Faster, TOP, TOP+).
5. A fully finished perimetric test.
6. **Test Field:** Arbitrary (a thumbnail of the original field on the list of tests. After adding the test to the Combined tab, the field is interpolated to one of three visual field patterns with a maximum radius of 10, 24 or 30).

The following conditions must be met for a full compatibility of tests from the OPTOPOL PTS application (automatically selected) with tests from the REVO SOCT application:

1. The difference between the dates of tests cannot exceed 182 days (half a year).
2. The perimetric test must be accompanied by reliability indices such as H-K (Heijl-Krakau), FPOS (False Positive Errors), FNEG (False Negative Errors).
3. The result of each reliability test (H-K, FPOS, FNEG) should be lower than 25% (error / test ratio).

11.5.3. Structure and Function – VF Results Layer in Combined View

This additional layer provides the ability to overlay OCT Structure & Function maps with Visual Field (VF) Results and VF Locations.

VF Results overlay is available only in [Combined] view. VF Locations overlay is available in Retina 3D **[BOTH EYES]** Ganglion view, Disc 3D **[BOTH EYES]**, **[ADVANCED]** and **[COMBINED]** views.

The VF Results layer displays the Pattern Deviation probability (PPD) results of Visual Field points, at appropriate locations adjusted to foveola and disc area in the Retina and Disc maps.

The VF Results layer can be enabled in the context menu of any of NFL+GCL+IPL significance map and NFL+GCL+IPL deviation maps. This functionality requires an active connection with PTS software,

otherwise the **[COMBINED]** tab will be inaccessible and VF results will not be loaded. PTS software version later than 3.4 is required for this functionality.

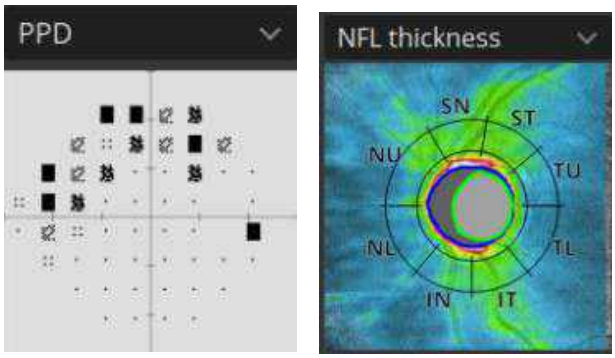


Figure 153.
Probability Results (on the left) and Disc area (on the right)

PPD results of 10-2 and 30-2 Visual Field are arranged in a way that takes into account the non-linear relationship of distance on the VF maps and the distance on the retina (only when connection is established with PTS version 3.4 or higher)

The PPD results for the combined view with the Disc sectors never take into account the nonlinearity of the relationship, as seen below.

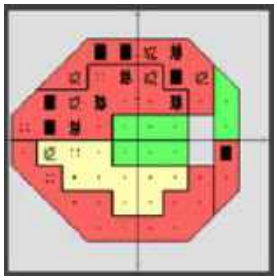


Figure 154.
PPD Combined view results

If you select PD result, it is presented with numerical values as shown below.

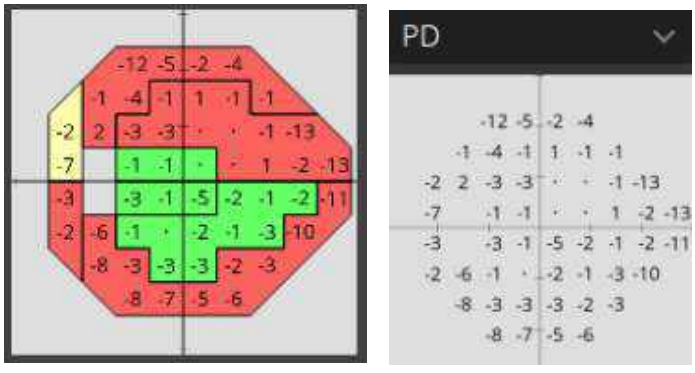


Figure 155.
PD result with numerical values

VF results are also visible in the enlarged windows available by double-clicking on the selected view with the VF results displayed.

11.5.3.1. Availability of VF results

VF results layer is available in the **[COMBINED]** tab:

1. In Retina maps if a Macula or Central visual field test is currently loaded (displayed as either point 10-2, point 24-2 or 30-2) for a given eye.
2. In Disc maps if a Macula or Central visual field test is currently loaded (displayed as either point 24-2, point 30-2 or 10-2) for a given eye.

It can be toggled on and off by selecting **[VF results]** in the context menu from select views. Context menu can be accessed by right-clicking on a suitable preview.

Figure 156.
Enable VF results from Context menu

If the VF results layer is available and enabled, the VF locations layer for the map is hidden (if enabled). Enabling VF results in one view enables it in all views for which VF locations can be displayed.

Printouts from individual views reflect the display state of the VF locations function in the user interface. The VF results display state is saved to the specific user and the state is saved after the application restart.

11.5.4. Structure and Function – VF Locations Layer

The VF Locations layer displays the position of points of Visual Field, at appropriate locations adjusted to foveola hole and disc area in the Retina and Disc maps. VF points of 10-2 and 30-2 test fields are arranged in a way that takes into account the non-linear relationship of VF results and retina OCT imaging.

The VF Locations layer can be enabled in the context menu in any of NFL thickness, NFL Signification and NFL deviation maps.

This functionality does not require an active connection with PTS software.

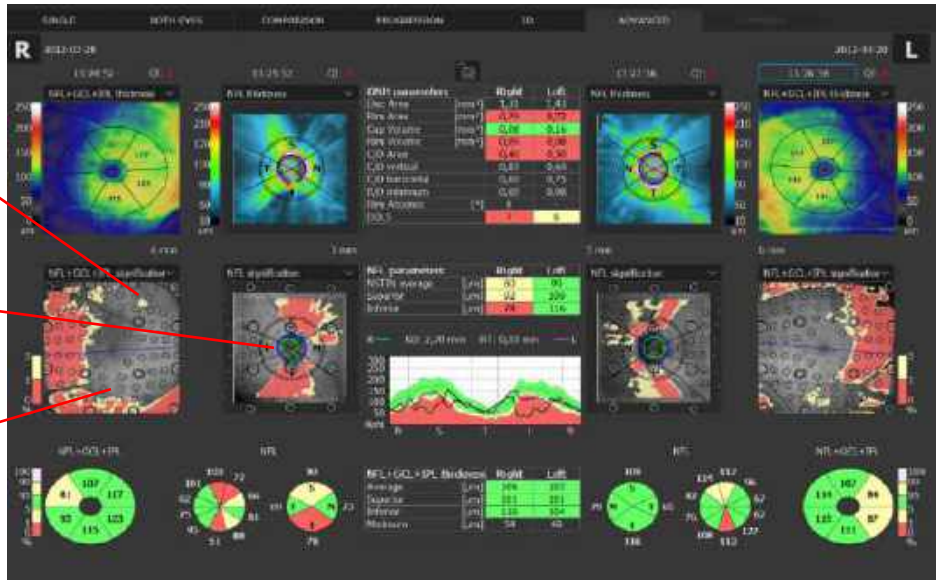


Figure 157.
Enabled VF results from Context menu

Example points of visual field 10-2 and 30-2 are arranged in a way that takes into account the non-linear relationship of distance on visual field maps and distance on the retina, shown below.

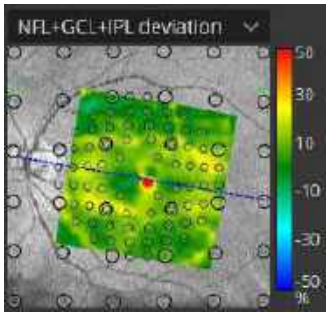


Figure 158.
Non-linear relationship

11.5.4.1. Availability of VF Locations layers

It can be toggled on and off by selecting **[VF locations]** in the context menu from select views. Enabling VF locations in one view, will enable this functionality for all views that can display VF locations. Context menu is brought up by right-clicking on a suitable view, shown below.

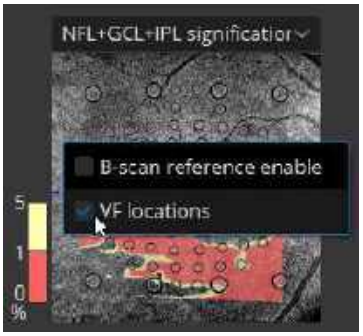


Figure 159.
Enable VF locations from context menu

The context menu with the option to enable VF locations is available for Retina 3D and Disc 3D examinations when viewing:

1. Retina 3D examination **[BOTH EYES]** Ganglion view
2. Disc 3D examination **[BOTH EYES]**
3. Retina 3D and Disc 3D examination **[ADVANCED]**
4. Retina 3D and Disc 3D examination **[COMBINED]**

The VF locations layer is also visible on the enlarged windows after double clicking select view with VF locations displayed, as seen from the example below.

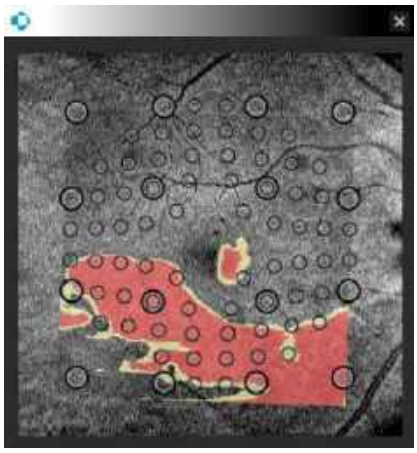


Figure 160.
Enlarged window

Printouts from individual views reflect the display state of the VF locations function in the user interface, so printouts are the same.

The display state of VF locations is saved to the specific user and the state is remembered after the application restart. This setting is enabled by default.

11.6. Widefield 3D Examination

A Widefield examination can display the options below depending on the type of examination.

11.6.1. Single Tab

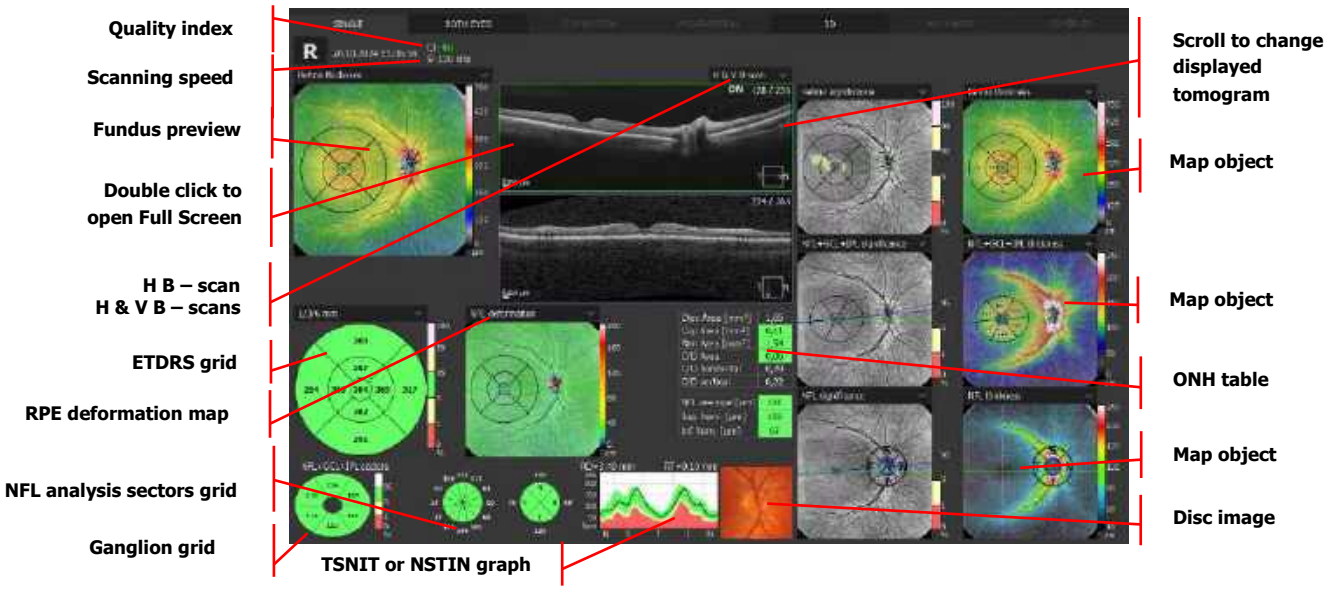


Figure 161.
Single Eye Widefield 3D Horizontal

In “Single Tab”, single eye **[WIDEFIELD 3D]** analysis is presented. For each examination, central charts and maps used for assessment are calculated.

Figure 162.
Single Eye Widefield 3D Single Horizontal and Vertical

11.6.1.1. Fundus Preview

1. Retina Thickness
2. Fundus Photo
3. Retina Significance

The fundus reconstruction image is created from all A-scans acquired in the scanned area.

Right-click to select the image to overlay.

The following images are available:

1. Fundus reconstruction
2. pSLO
3. Fundus photo
4. IR

To change the transparency level, turn the mouse wheel on the fundus reconstruction image.

A right click over the eye preview window opens the following display and actions menu.

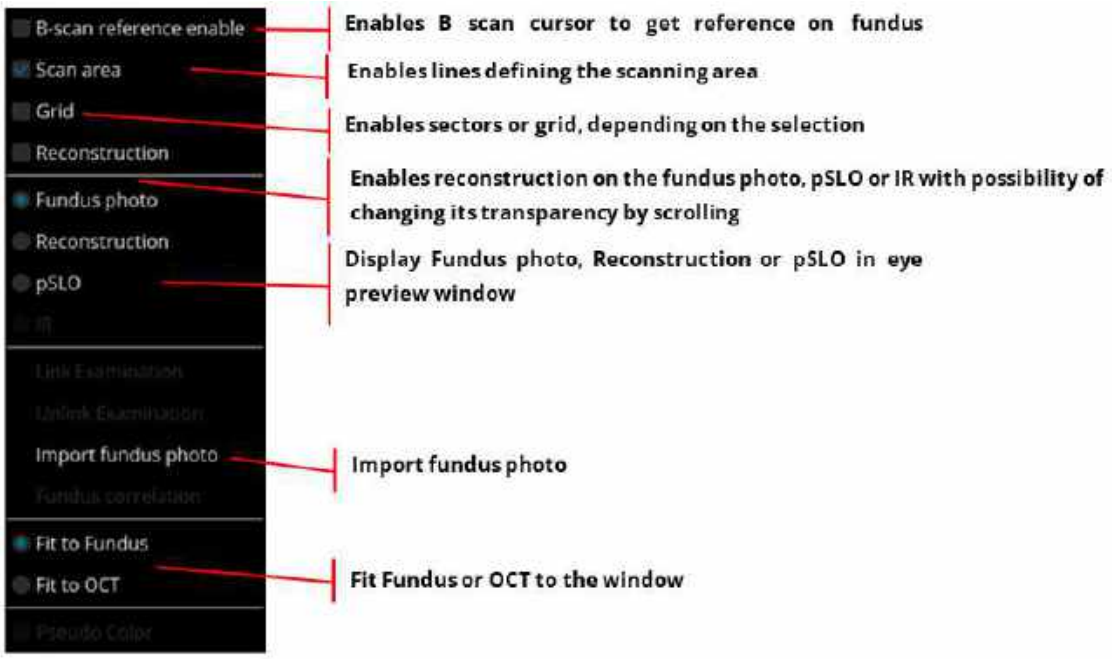


Figure 163.
Eye Preview Window Context Menu

11.6.1.2. Ganglion Cells Sector

Figure 164.
Dimensions of Sectors for Ganglion Cells

11.6.1.3. TNSIT or NSTIN Graph

Shows the NFL thickness at the NSTIN region.

11.6.1.4. ETDRS Grid

1. Retina sector value

In each sector of the grid, the retinal thickness of each sector appears. Background colors are color-coded based on comparison to the reference database.

Sector grids show with diameters: 1mm / 3mm / 6mm. When “Grid” option is selected, the whole map is covered by a grid of numbers. Each number represents the retinal thickness at each selected point.

The following values can be selected to be viewed in the Average sectors. The thickness map is further organized and presented in the nine ETDRS-like zones.

For RPE deformation maps values in the sectors are not available.

11.6.1.5. RPE Deformation Map

1. RPE deformation
2. Retina sector value

For RPE deformation maps values in the sectors are not available.

11.6.1.6. Retina Thickness Map

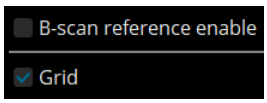
1. Retina Thickness
2. Retina Significance
3. Retina Deviation
4. RPE Deformation
5. Retina sector value
6. Central cone map[52]
7. Photoreceptor map[52]
8. RPE thickness[52]
9. COST map[52]
10. Inner photoscreen[52]

11.6.1.7. NFL+GCL+IPL Map

1. NFL+GCL+IPL Thickness
2. NFL+GCL+IPL Significance
3. NFL+GCL+IPL Deviation
4. NFL+GCL+IPL sectors
5. GCL+IPL Thickness
6. GCL+IPL Significance
7. GCL+IPL Deviation
8. GCL+IPL sectors

[52]Available for examinations conducted on the REVO HR device or newer.

11.6.1.8. NFL Map



1. NFL Thickness
2. NFL Significance
3. NFL Deviation

Contextual menus are available for every type of map display. Right-click to view the contextual menu.

11.6.1.9. Disc Image

The disc image appears once an exam is linked to a fundus image (Fundus Photo – default, Reconstruction – if photo isn't available or IR).

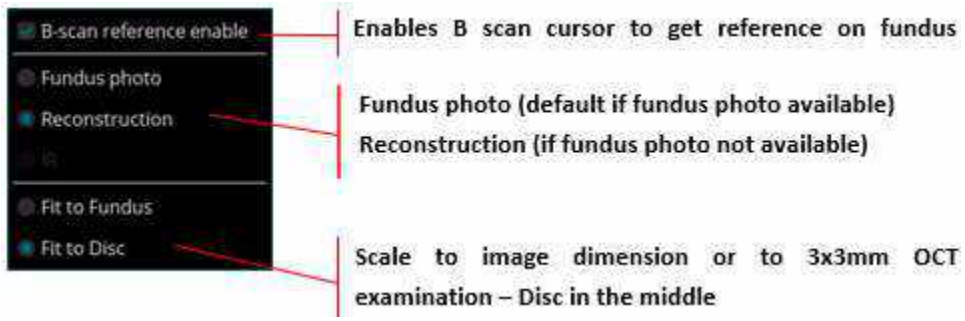


Figure 165.
Disc Image Window Context Menu

Hold the **CTRL** key and use the mouse scroll to zoom in / out on the disc tomogram image.

Hold left mouse button to move the image.

Hold right mouse button and the **CTRL** key and move to change brightness or contrast of the image.

11.6.1.10. NFL Sectors

The inside of the measurement circle is divided into four or 12 sectors and the NFL thickness is shown. The background colors are color-coded based on the reference database. The mean NSTIN value and NSTIN SD are displayed above.

11.6.1.11. ONH Table

The Information Table displays the: Disc Area, Cup Area, Rim Area, Cup / Disc, C/D horizontal, C/D vertical, NSTIN average, Superior NFL and Inferior NFL of the scanned cube.

11.6.1.12. Tomogram Window

Scroll the mouse wheel to change the displayed tomogram.

Double click to open the Tomogram Full screen window.

Press the right mouse button to display the Functional menu.

Hold the right mouse button and move right / left and up / down to change the brightness and contrast.

11.6.2. Both Eyes Tabs

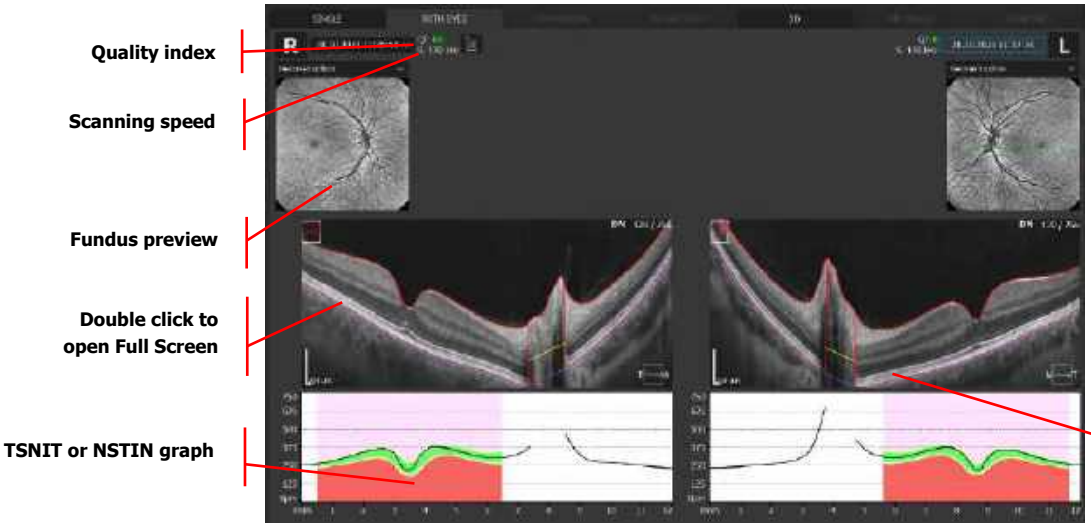


Figure 166.
Both Eyes Tab Widefield 3D

11.6.3. Comparison Tab

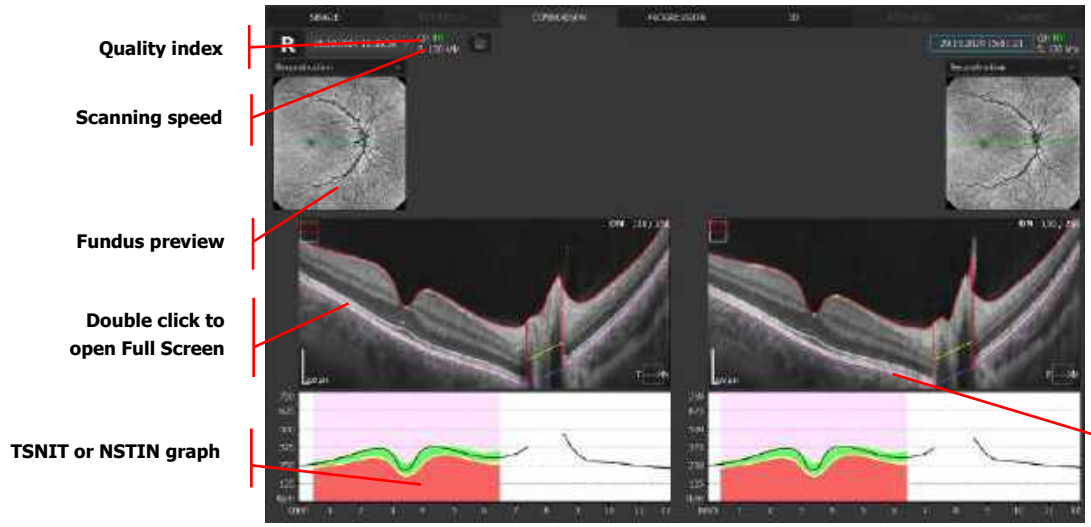


Figure 167.
Comparison Tab Widefield 3D

11.6.4. Progression Tab

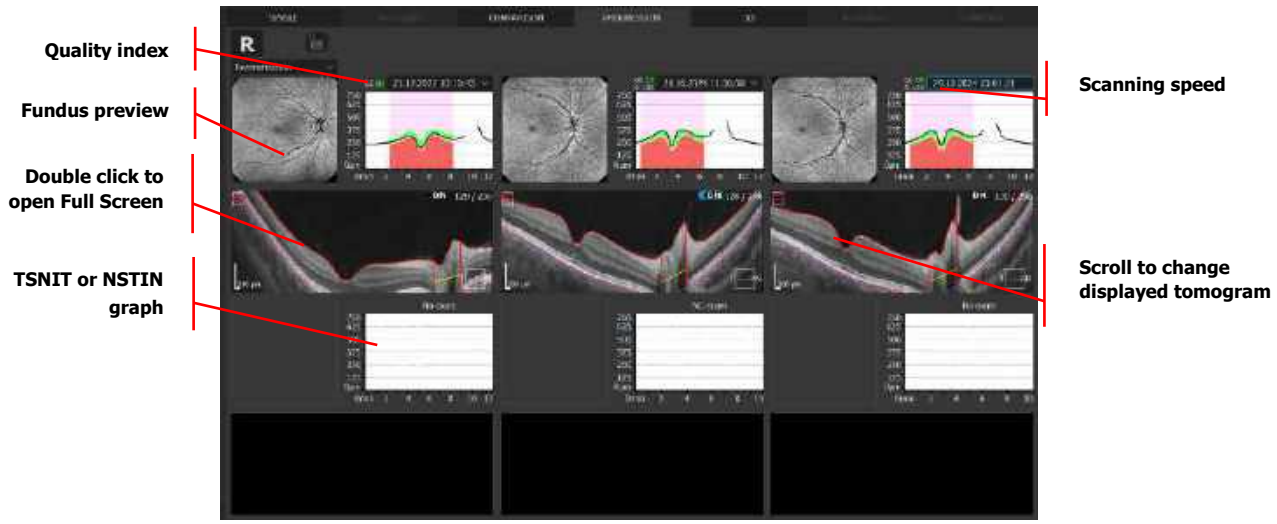


Figure 168.
Progression Tab Widefield 3D

11.7. Widefield Line

Widefield Line examination has the same views as Retina Line or Disc Line examinations, described in the Chapter 11.9.1 Single Line Examination Review.

11.8. Widefield Radial

Widefield Radial examination has the same views as Retina Radial examination, described in the Chapter 11.1 Retina Thickness Analysis.

11.9. 2D Scan Programs Results Review

Depending on scanned area (Retina, Disc, Anterior segment). This chapter will describe the available results. Below is the list of options:

For a more detailed description of scan programs, refer to Chapter 7.3 Selection of Scanning Programs.

RETINA

1. Raster
2. Radial
3. Single line
4. Cross

DISC

1. Raster
2. Single line
3. Cross

4. Radial

WIDEFIELD

1. Line
2. Radial

ANTERIOR

1. Raster
2. Single line
3. Radial

11.9.1. Single Line Examination Review

Single Line scans provide a quick and efficient method to scan a single B-scan in an area. Averaging is possible. Viewing Options:

SINGLE SCAN

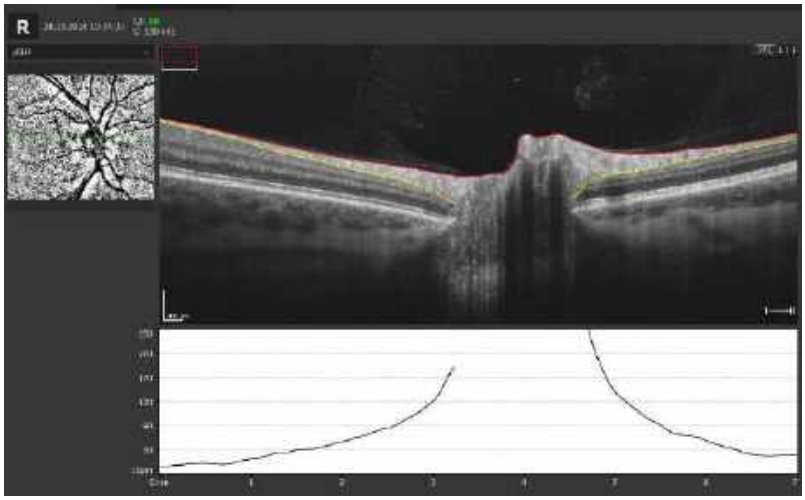


Figure 169.
Disc Single Line Scan View

BOTH EYES

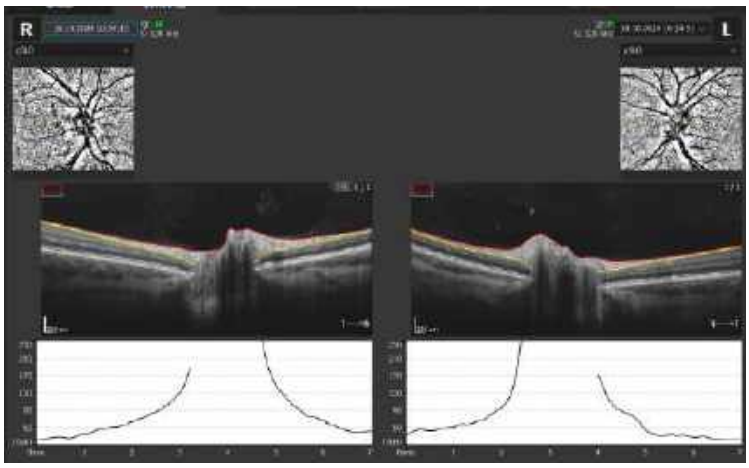


Figure 170.
Single Line Scan (Both Eyes View)

COMPARISON

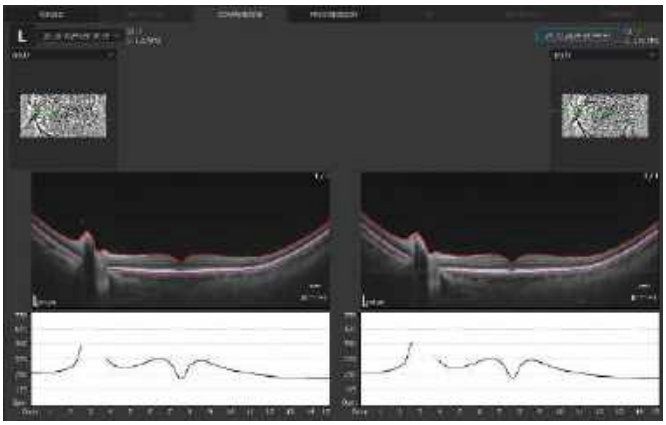


Figure 171.
Single Line Scan (Comparison View)

PROGRESSION

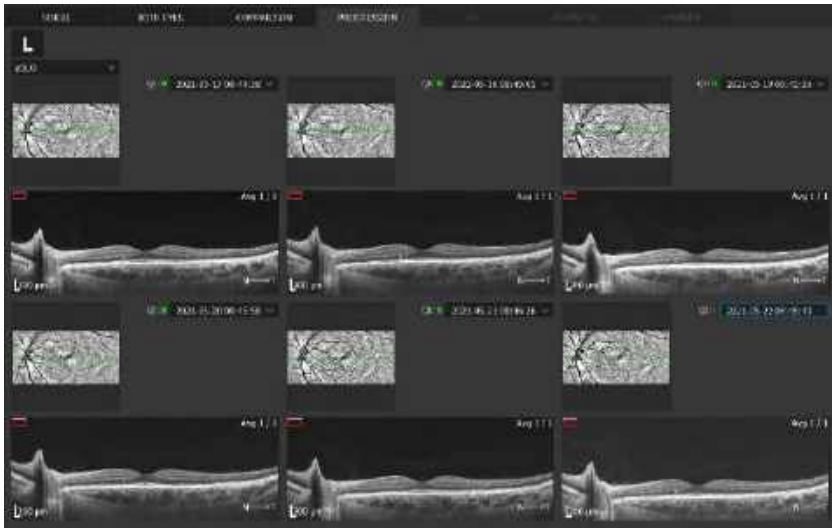


Figure 172.
Single B Scan (Progression Window)

11.9.2. Raster Examination Results Review

The raster examination provides the averaged image with enhanced resolution. The five raster tomograms are displayed. Below are examples:

SINGLE SCAN

Figure 173.
Retina Raster (Single Scan View)

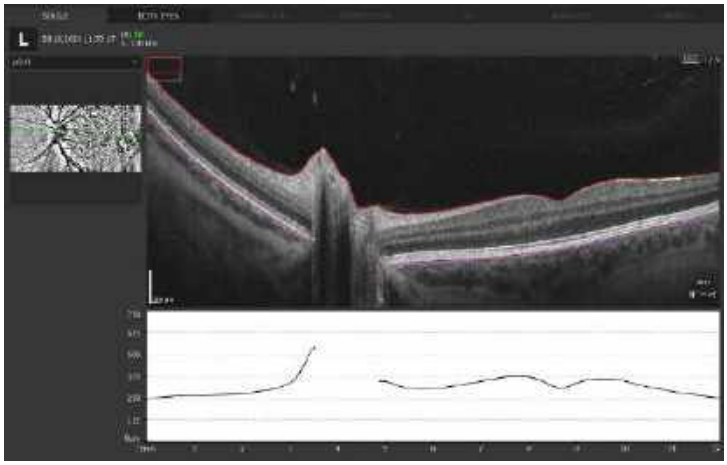


Figure 174.
Widefield Raster (Single B-Scan View)

BOTH EYES

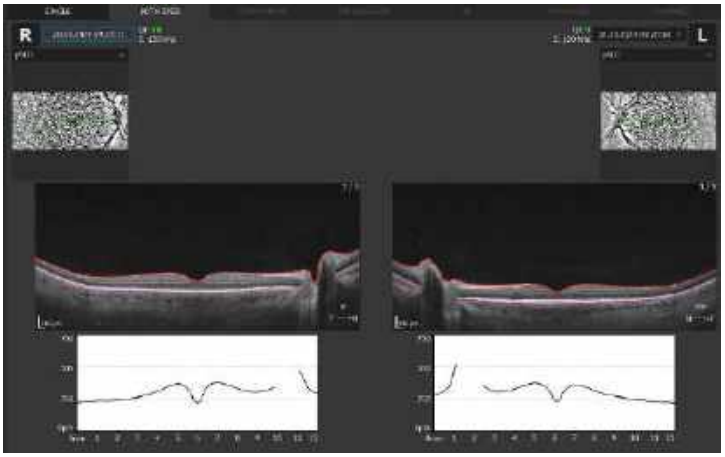


Figure 175.
Retina Raster Both Eyes view

COMPARISON

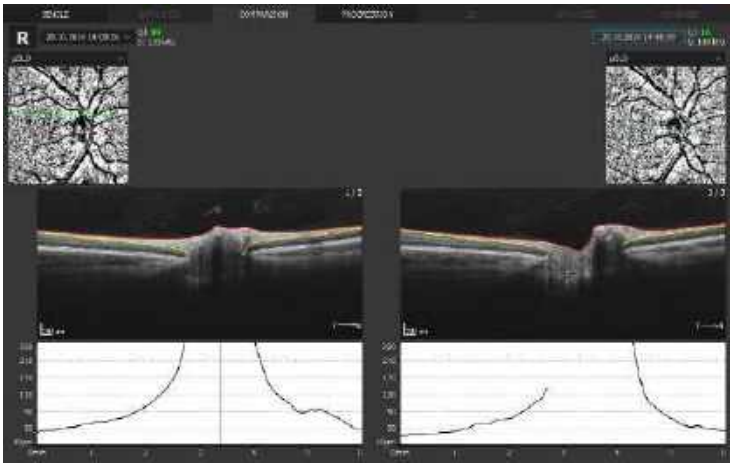


Figure 176.
Raster Comparison view

PROGRESSION

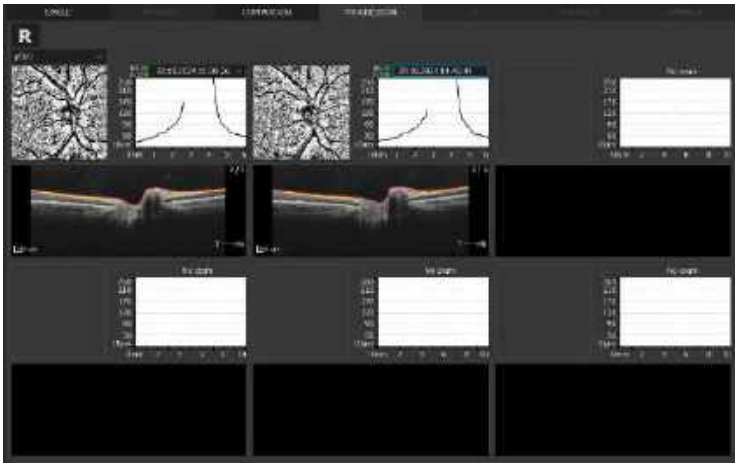


Figure 177.
Raster Progression view

11.9.3. Retina Raster 21

The Retina Raster 21 examination provides the averaged image with enhanced resolution. A maximum 5 out of 21 tomograms can be displayed, fundus reference image, TSNIT (or NSTIN) graph and Retina Thickness map.

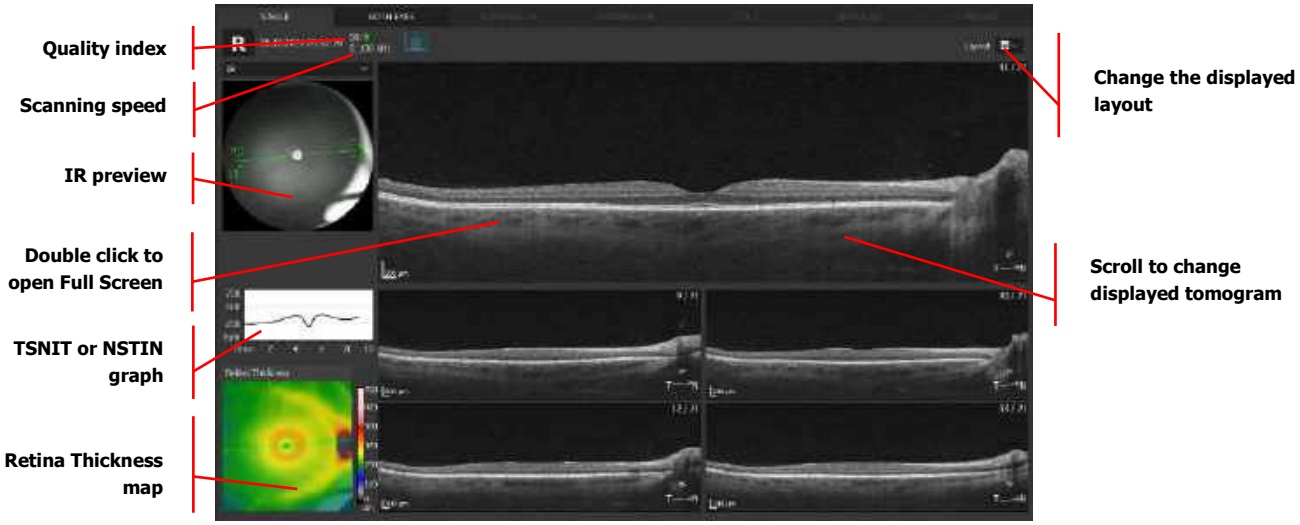


Figure 178.
Retina Raster 21 . Single exam view. Layout 1x4.

Figure 179.
Retina Raster 21 . Single exam view. Layout 1x1.

11.9.4. Radial Examination Results Review

Radial examination for all tomograms (number of B-scans taken here can be adjusted). Single B-scan is displayed. By clicking on fundus preview, it is possible to select a different B-scan. Tomograms are displayed depending on the scanned region. Below are examples:

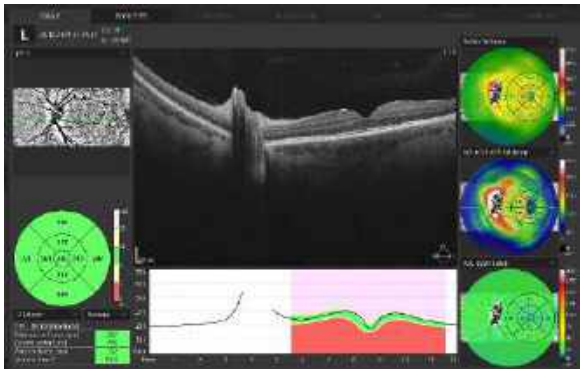


Figure 180.
Widefield Radial Examination Single View

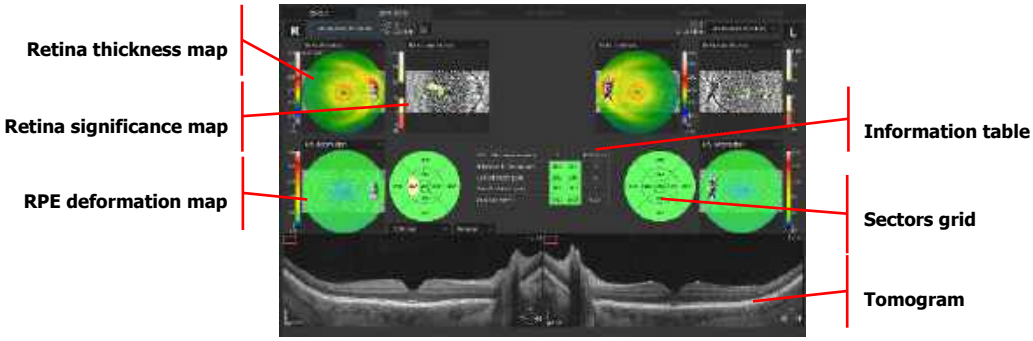


Figure 181.
Radial Examination (Both View)

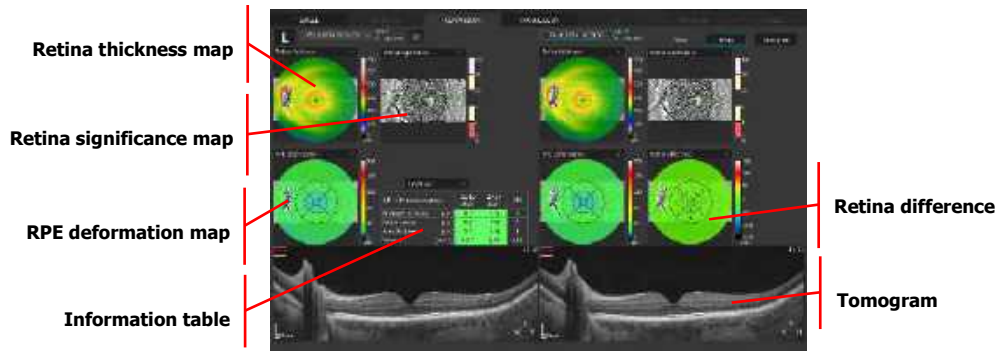


Figure 182.
Radial Examination (Comparison – Retina View).

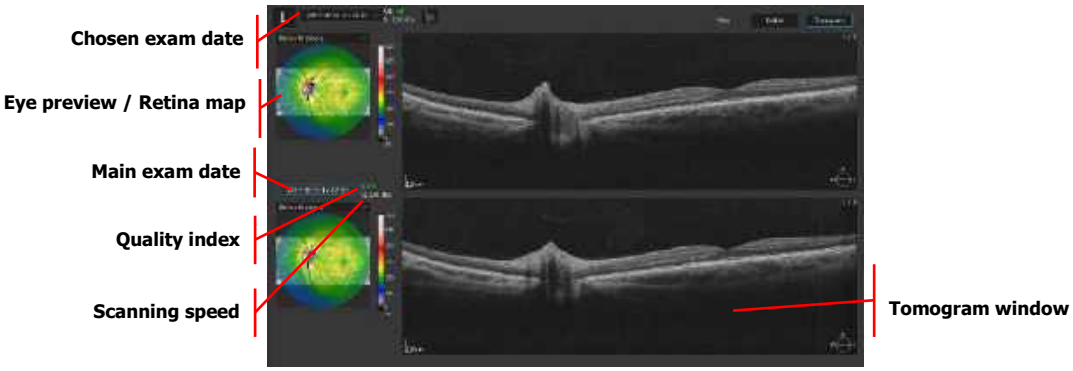


Figure 183.
Radial Examination (Comparison – Tomogram View).

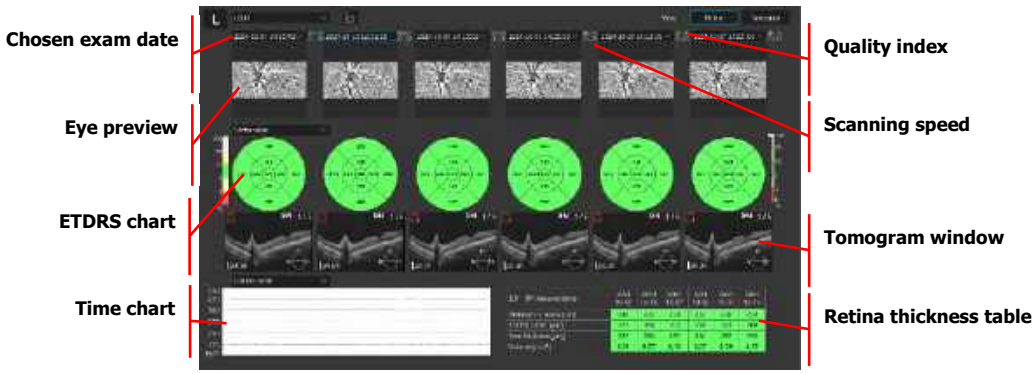


Figure 184.
Radial Examination (Progression – Retina View).

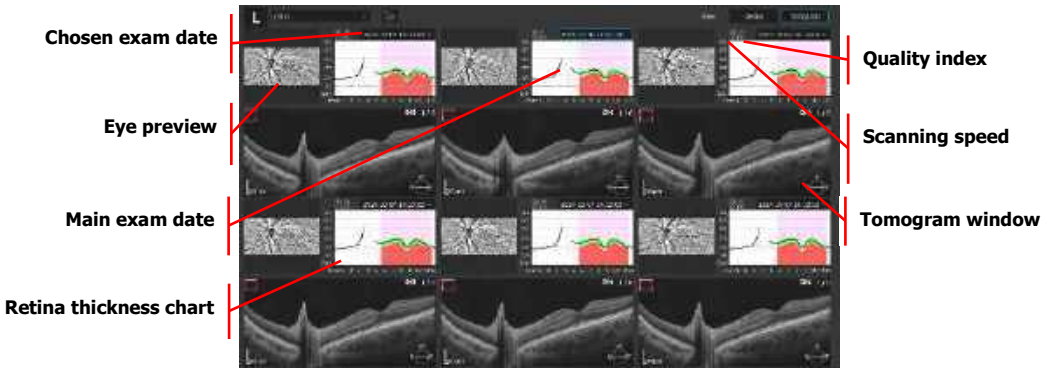


Figure 185.
Radial Examination (Progression – Tomogram view).

11.9.5. Cross Examination Results Review

Cross examination result provides image similar to Single Line. Averaging is possible. Single B scan is displayed and by clicking on fundus preview it is possible to select different B-scan (vertical or horizontal). Example below:

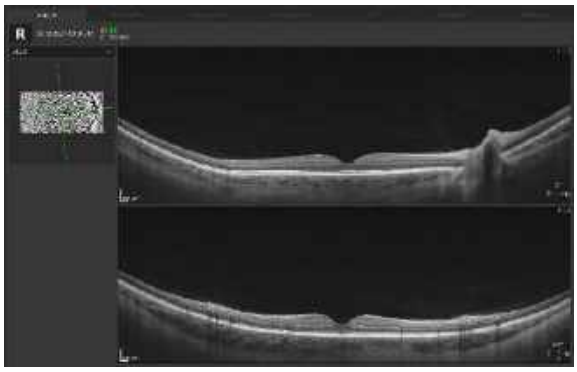


Figure 186.
Cross Scan Horizontal View

Both Eyes, Comparison and Progression displays are available for previously presented examples.

11.10. 3D Visualization

The 3D visualization tab is enabled only for posterior scans which have been taken using the 3D and Angio scanning programs. The window shows the 3D reconstruction of the retina structure. The software offers two 3D visualization modes: Solid and Volume.

11.10.1. [Solid] View

Shows the surface, layers of the retina, and choroid as non-transparent images.

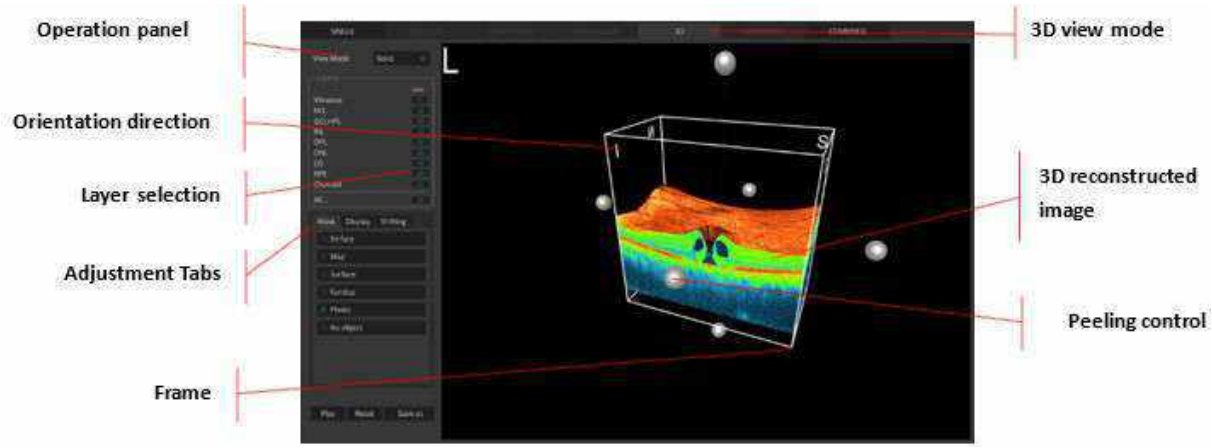


Figure 187.
3D Solid View

1. **3D TOMOGRAM IMAGE**

   This 3D image is constructed from B-scan tomograms.

2. **ORIENTATION DIRECTION**

   Letters (S, N, I, T) show the orientation or view direction of the 3D tomogram image.

3. **"PEELING" CONTROL BALL**

   Right-click to activate control balls. The front view of the cube image corresponds to the position of the balls.

4. **FRAME**

   This is the boundary of the 3D tomogram cube.

5. **3D VIEW MODE**

   Select the format for viewing 3D tomogram images. **[Volume]** or **[Cross-Section]** view.

6. **LAYER SELECTION**

   - **[VISIBLE]:** Shows selected layers in the 3D tomogram image.
   - **[PEELING]:** Controls selected layers by using the peeling ball. The position of the layer is maintained when this is deselected.
   - **[SELECT ALL]:** Clicking this item selects all layers.

7. **OPERATION TABLE**

   The display operation table allows the user to modify the initial view.

11.10.2. [Volume] View

Shows the surface, layers of the retina and choroid as semi-transparent images.

Tuning tab is available for the Volume view.

On the mask tab, it is possible to shift position of specific layers and change brightness and contrast level.

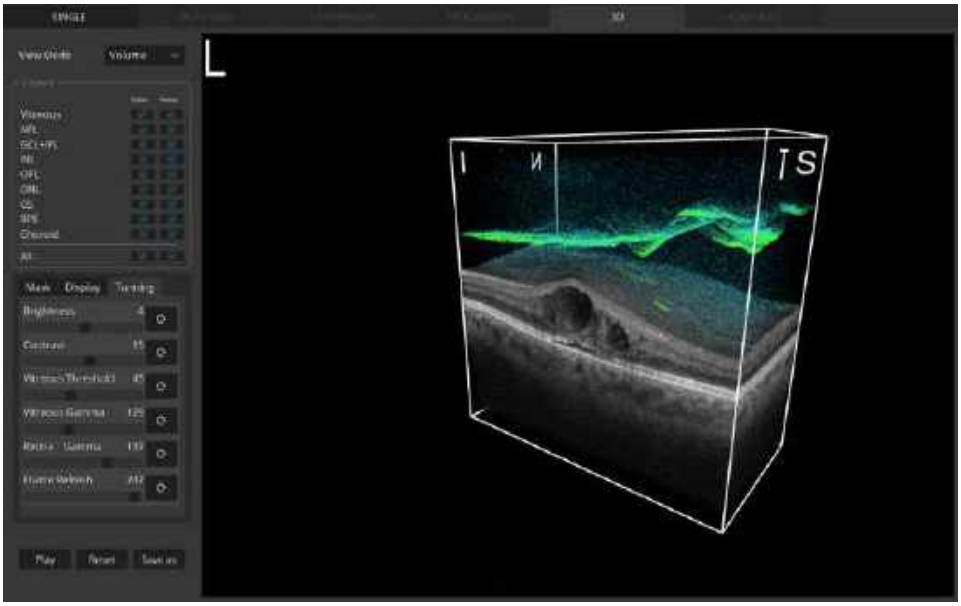


Figure 188.
Volume View

1. **BRIGHTNESS**

   Change Brightness level.

2. **CONTRAST**

   Change Contrast level.

3. **VITREOUS THRESHOLD**

   Change threshold of displayed points in the vitreous.

4. **VITREOUS GAMMA**

   Change gamma of displayed points in the vitreous.

5. **RETINA GAMMA**

   Change gamma of displayed points on the retina.

6. **FRAME REFRESH**

   Change the number of times per second the view is being updated.

11.10.3. Manipulation of the 3D Cube

The following describes an example of how to operate the 3D view:

1. **ROTATING**

   Drag the 3D tomogram image in any direction. 3D reconstruction can be rotated by 360° around the vertical axis and from -90 to +90 around the horizontal axis.

2. **SLICING**

   To enable slice reconstruction, press the right mouse button and gray balls appear. The direction of layered images is chosen by balls placed on the proper axis. Click one of six balls to make one active (clicked ball changes from gray to red) and then the user can slice tomograms by dragging the ball along the axis line or use the mouse scroll button to slice the tomograms.

3. **MOVING**

   Drag the 3D tomogram image in any direction with the shift key held down.

4. **RESIZING**

   Hold down the **CTRL** key and turn the mouse wheel.

5. **RESET**

   Resets the 3D tomogram image to its original state.

11.10.4. Selection of Displayed Layers

Selection of layer that is shown:

1. **VISIBLE**

   Shows selected layers in the 3D tomogram image. Uncheck ‘Visible’ checkbox to hide the selected retina layer.

2. **PEELING**

   Marked layers will be peeled during movement of the red ball over the tomograms. The operator can peel each layer separately. The easiest way to restore your view is to use the **[RESET]** button.

3. **SELECT ALL**

   Mark this item to select all layers.

11.10.5. Operation Panel

11.10.5.1. Mask Tab

The mask tab allows the user to change the item overlay on the surface of the cube:

1. **ENFACE**

   Displays enface image of the displayed layer.

2. **MAP**

   Displays the thickness map of the retina or selected layer.

3. **SURFACE**

   Displays the non-transparent, color-coded layers on the surface of each retina layer.

4. **FUNDUS PHOTO**

   This option is enabled only when a fundus image has been imported to the examination. This displays the common part of the imported fundus image on the surface of the retina.

11.10.5.2. Shifting Layers Tab

It is possible to separate the layers displayed in 3D visualization. The **[SHIFTING]** tab is available in the 3D **[SOLID]** view and allows the user to view each segmented layer separately with space in between.

On the **[SHIFTING]** tab, it is possible to adjust the position of specific layers and change the brightness and contrast levels.

1. **SHIFTING**

   Separate the position of the layers.

2. **BRIGHTNESS**

   Change Brightness level.

3. **CONTRAST**

   Change Contrast level.

11.10.5.3. Tuning Tab

The tuning tab is available for Volume view.

On the mask tab, it is possible to shift the position of specific layers and change the brightness and contrast levels.

1. **BRIGHTNESS**

   Change brightness level.

2. **CONTRAST**

   Change contrast level.

3. **OPACITY**

   Change opacity level.

4. **THRESHOLD**

   Change the threshold of displayed points in the retina.

5. **VITREOUS**

   Change the threshold of displayed points in the vitreous.

11.10.5.4. Display Tab

The display options allow the user to change the visualization of the 3D cube:

1. **B-SCAN ALIGNMENT**

   Aligns B-scans displayed on the 3D visualization to facilitate the view in 3D reconstruction.

2. **THICKNESS MARKER**

   Displayed boards with Retina, NFL and RPE thicknesses for a selected point. To display thickness, double-click on any point on the surface of the retina. A popup will appear with values from the selected point. All the values are expressed in microns. The software displays up to four measurements.

3. **COLOR**

   Displays the 3D reconstruction in color or black and white.

4. **INVERSE**

   Inverses the color of tomograms.

5. **WHITE BACKGROUND**

   Changes the background color.

6. **FLATTENING**

   Adjusts tomogram view so that RPE layer is flattened. This is used for the C-scan view.

7. **DISPLAY DETAILS**

   Displays a detailed tomogram on the front surface of the cube.

8. **FUNDUS**

   This option is enabled only when a fundus camera photo has been added to the examination. It displays the fundus image on the bottom of scanned cube. The user can drag this image to the desired position.

9. **DENOISE**

   Activates AI DeNoise for 3D view. Only available for **[SOLID]** 3D view.

10. RESET

Resets all parameters of the displayed image (angle of rotation, scale, displayed maps, tuning settings) to the default settings.

11. PLAY / STOP BUTTON

Enables automatic tomogram slicing. After clicking this button, control elements appear on the screen. Choose one direction to start automated slicing. It is possible to rotate the reconstruction during slicing. To finish, click the **[STOP]** button, which replaces the **[PLAY]** button during the automated process.

12. SAVE AS

Saves the currently displayed image in JPEG format.

12. Anterior Segment

The REVO device was designed to obtain corneal and anterior segment images using Anterior Scan programs. Anterior scans for 3-5 mm width do not require anterior lens.

For the devices with reference number REF 155 and 156, performing a wide anterior scan with a scan width of up to 16 mm requires the anterior adapter being installed on the objective lens for better segmentation processing.

The devices with reference number REF 190, 191, 192, 193 and 194 come with an internal anterior examination lens, which means that no external anterior adapter is necessary to perform anterior scans.

12.1. Anterior Radial

The corneal thickness analysis is performed based on the recognized structure of OCT images of the anterior segment captured in **[ANTERIOR RADIAL]** and **[WIDE ANTERIOR RADIAL]** modes.

The analysis results are shown on maps, corneal grids, and tables. These analyses can be shown on the **[SINGLE]**, **[BOTH EYES]**, **[COMPARISON]**, and **[PROGRESSION]** tab screens.

12.1.1. Single Tab Screen

This screen shows the analysis results for one eye.

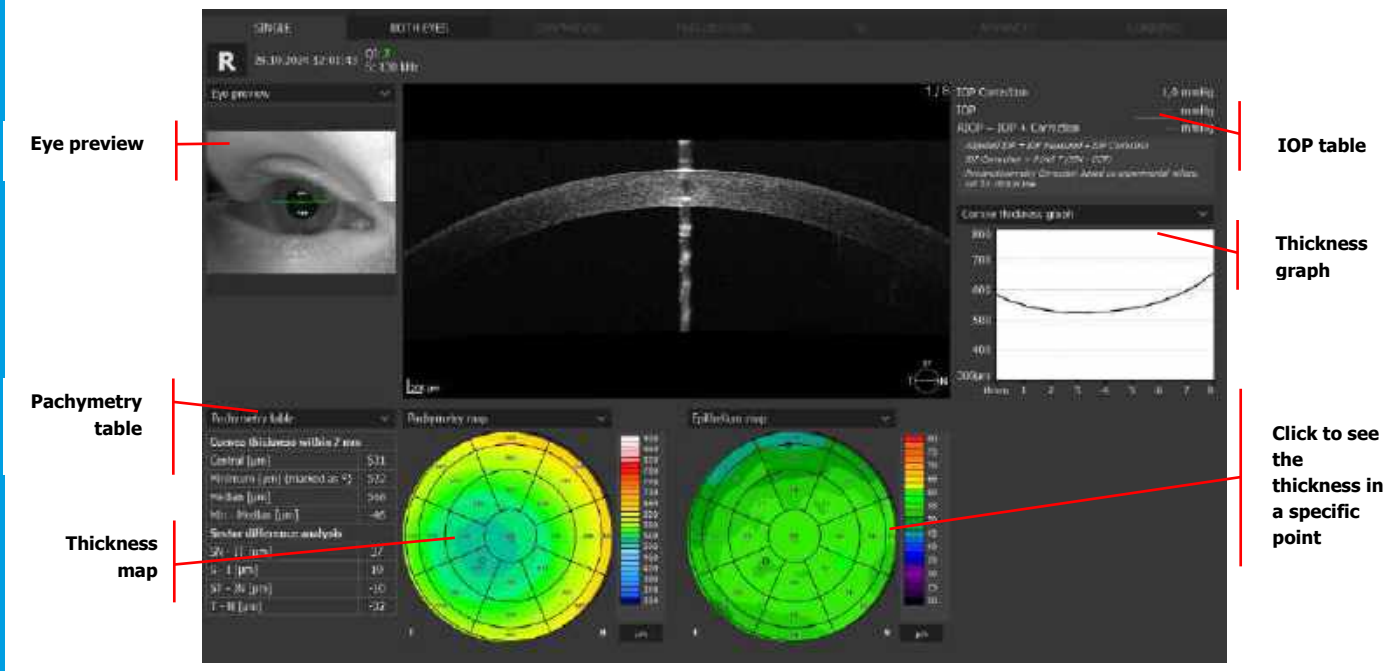


Figure 189.
Single Anterior Radial

1. EYE PREVIEW

It shows the location of the scan on the image. It can be selected from the list:

- **Eye Preview:** Captured image from front cameras
- **pSLO:** Pseudo SLO image

2. INFORMATION TABLE

The table displays a summary of pachymetry data.

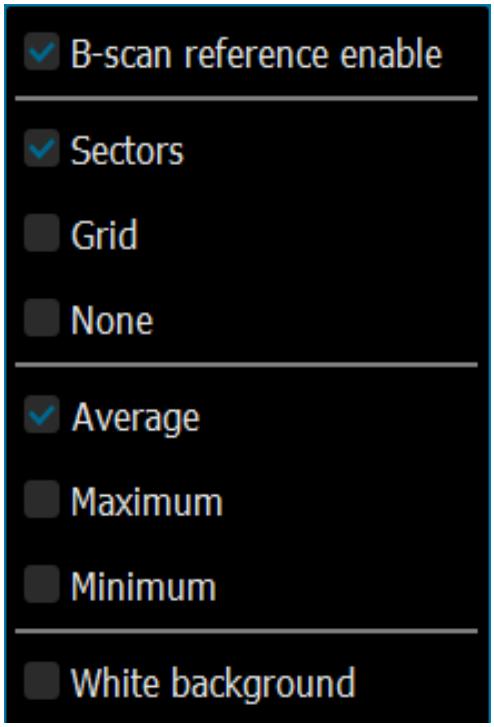
3. THICKNESS MAP

Pachymetry or Epithelium maps are color coded for thickness. Overlay values correspond to displayed settings.

- **Color Scales:** To change the scale, click one of the scale descriptions in the bottom corner of the map. The scale settings window pops up. The user can change the scale type and units.
- **Color Scales Available for the Pachymetry Map:** O style Scale, American style and REVO style Scale.
- **Color Scales Available for the Epithelium Map:** O style Scale and REVO style Scale.

For more information on scales, go to Chapter 21.6 Color Scale (Standards).

To change the display settings right click to open the menu.



B-SCAN REFERENCE ENABLE

Enable / disable the reference B-scan on the map.

SECTORS

The Sectors Grid corresponds to the grid overlaid on the map. In each sector of the grid, the thickness of each sector appears. It shows sector grids with diameters: 2 / 5 / 7 mm.

GRID

When the “Grid” option is selected, the entire map is covered by a grid of numbers. Each number represents the thickness at each selected point.

VALUES

Select the displayed values: average, maximum or minimum.

WHITE BACKGROUND

Enable / disable the white background for the map.

4. IOP FORMULA

Displays IOP correction. Enter the patient’s IOP into the form to see the adjusted IOP. The SOCT software can calculate the correction of IOP (Intraocular Pressure) reading from pneumo-tonometer on the basis of the corneal thickness. After obtaining a complete tonometry value the program calculates the level of correction (Correction) and the corrected IOP value (Adjusted IOP) for the examined eye. The calculation formula is predefined.

NOTE: Epithelium thickness is measured from corneal anterior surface to the posterior boundary of the epithelium. The posterior boundary of epithelium is defined as the interface of Epithelium and Bowman’s Layer. When the Bowman’s layer is absent e.g. in Post Refractive eyes, the posterior boundary is defined as the interface of epithelium and the Stroma.

NOTE: In case of auto segmentation layer errors, it may be necessary to modify the layer boundaries manually.

NOTE: The corneal analysis tab is available when the cornea scan is displayed. If another scan analysis type is displayed, change the analysis type as follows: Examination list in the [RESULTS] tab -> Right-click -> Change the recognized structure. Anterior analysis type window will appear. Select the [Cornea] type.

NOTE: Review the scan carefully to determine accuracy when lid is on a part of the scan.

NOTE: Quantitative analysis is available only if the scanned structure type is marked as Cornea.

12.1.2. Both Eyes Tab Screen

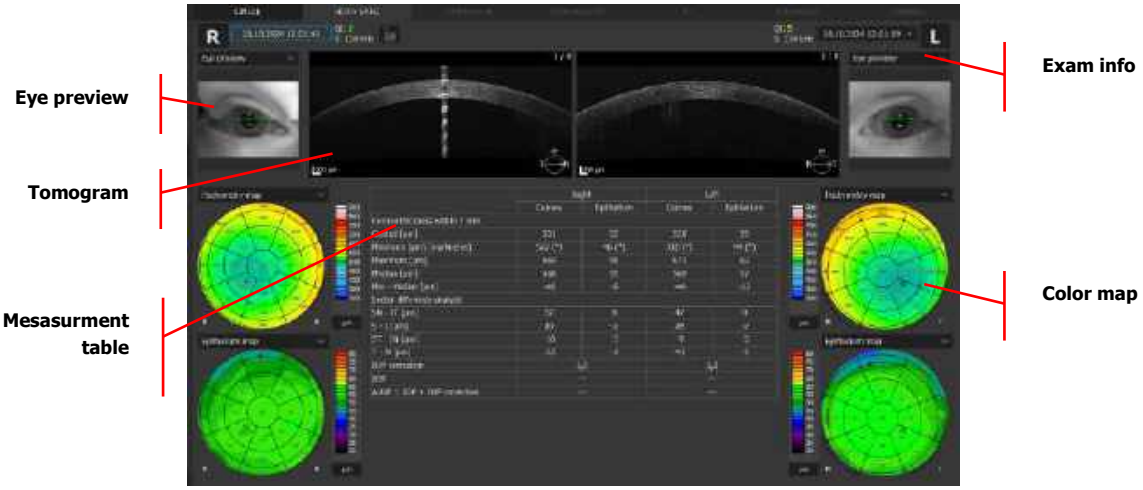


Figure 190.
Both Eyes Anterior Radial

This screen shows the analysis results comparing examinations of both eyes in the same scan mode and on the same date.

12.1.3. Comparison Tab Screen

This screen shows the analysis results comparing two examinations of one eye on the same side in the same scan mode, from different dates.

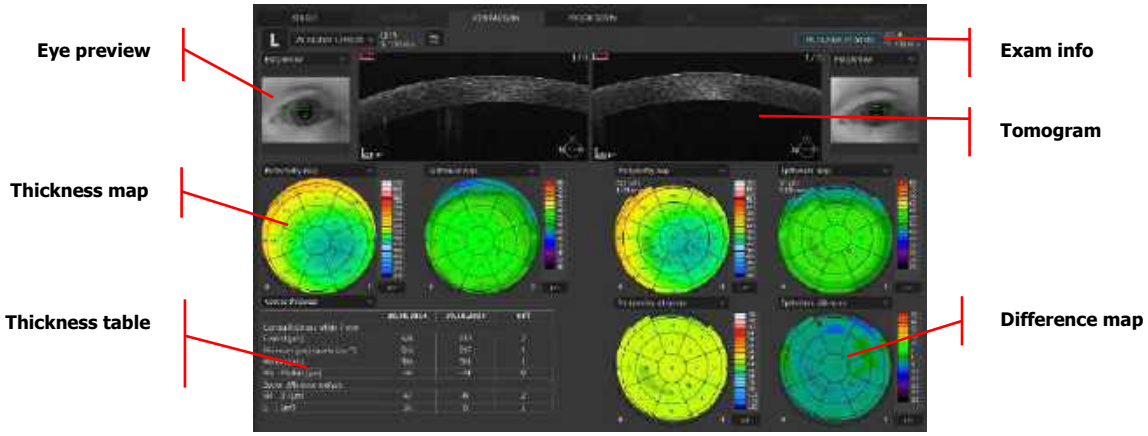


Figure 191.
Comparison Anterior Radial

1. EYE PREVIEW

It shows the location of the scan on the image. It can be selected from the list:

- **Eye Preview:** Captured image from front cameras.
- **pSLO:** Pseudo SLO image.

2. THICKNESS MAP

Pachymetry or Epithelium maps are color coded for thickness. Overlay values correspond to displayed settings.

- **Color Scales:** To change the scale, click one of the scale descriptions in the bottom corner of the map. The scale settings window pops up. The user can change the scale type and units.
- **Color Scales Available for the Pachymetry Map:** O style Scale, American style and REVO style Scale.
- **Color Scales Available for the Epithelium Map:** O style Scale and REVO style Scale.

3. THICKNESS PARAMETERS TABLE

These options are the same as on the **[SINGLE]** tab screen. This table shows the values for each examination. The column on the far right is the difference between the two examinations.

4. DIFFERENCE MAP

This color maps show the differences in corneal thickness and corneal epithelium thickness between both examinations. Values for the differences between both examinations are shown on the grids.

12.1.4. Progression Tab Screen

This screen shows the analysis results comparing six examinations arranged in chronological order for the same eye, in the same scan program, and same sized scanning area.

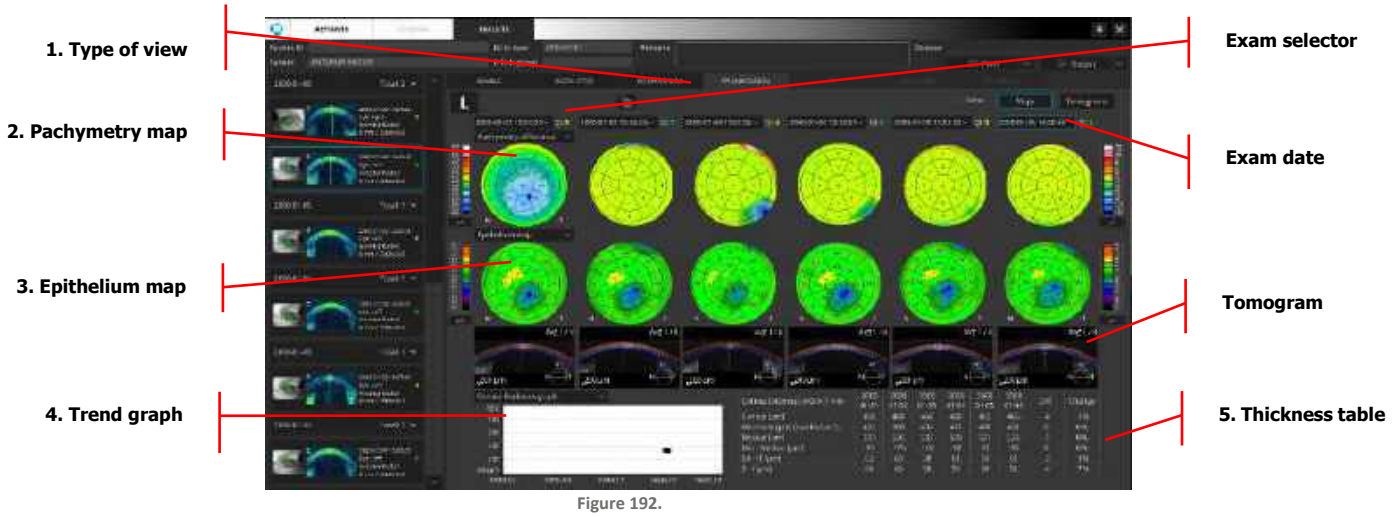


Figure 192.
Progression Anterior Radial Map

12.1.4.1. Progression Maps View

1. TYPE OF VIEW

- **Maps:** This view enables the user to evaluate scans quantitatively.

- **Tomograms:** This view enables the user to evaluate the morphology of scanned tissue.

2. PACHYMETRY MAP

The values overlay on the color-coded thickness map. Values corresponding to the map are shown on the corneal grid.

3. EPITHELIUM MAP

Shows the corneal epithelium thickness map for consecutive exams.

4. THICKNESS GRAPH

This graph plots all examinations of the same type performed for the same patient to show changes in corneal thickness over time. The selected examinations that are displayed on the reports are indicated in black and other examinations not displayed on the progression tab are indicated in gray.

Select what is shown from the drop-down box:

- Cornea thickness graph
- Epithelium thickness graph
- Stroma thickness graph

5. THICKNESS TABLE

This table shows the values for each examination. The column on the far right is the rate of change.

Value	Rate of Change
Central Corneal Thickness	Central corneal thickness
Minimum Thickness	Minimum corneal thickness in the measured area
Maximum Thickness	Maximum corneal thickness in the measured area
Minimum – Maximum	Difference between the minimum and maximum corneal thicknesses
SN-IT	Difference between SN sector and IT sector within the corneal grid
S-I	Difference between S sector and I sector within the corneal grid
Minimum – Maximum	Difference between the minimum and maximum corneal thicknesses
SN-IT	Difference between SN sector and IT sector within the corneal grid
S-I	Difference between S sector and I sector within the corneal grid

12.1.4.2. Progression Tab Tomograph View

Tomogram view enables review of the morphology of the anterior structure on consecutive visits.

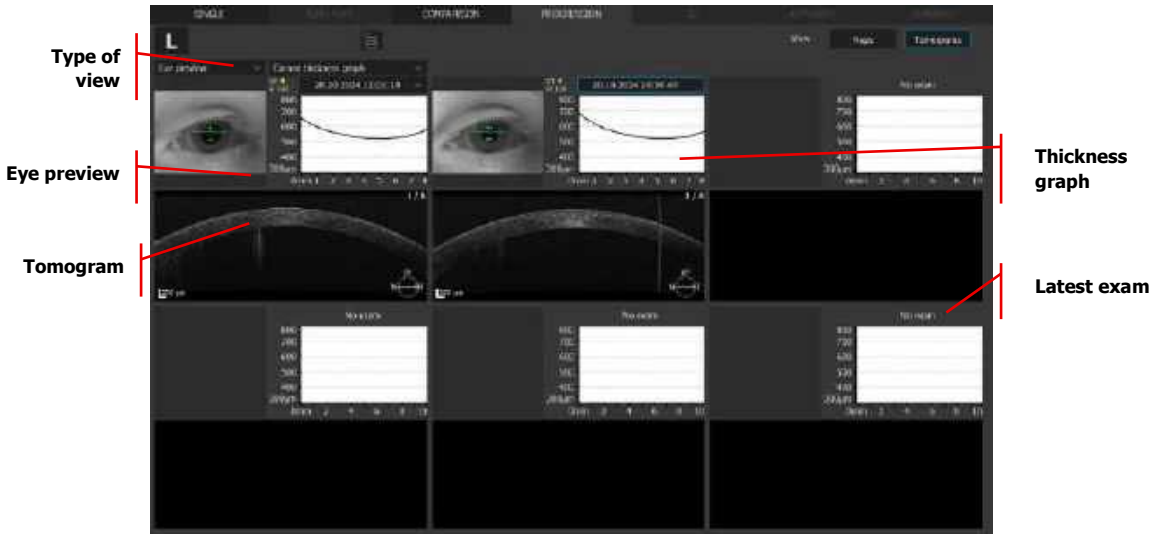


Figure 193.
Anterior Progression Tomogram View

NOTE: In case of auto segmentation layer errors, it may be necessary to modify the layer boundaries manually.

NOTE: The corneal analysis tab is available when the cornea scan is displayed. If another scan analysis type is displayed, change the analysis type as follows: Examination list in the [RESULTS] tab -> Right-click -> Change the recognized structure. Anterior analysis type window will appear. Select the [Cornea] type.

12.1.5. Caliper Tool

The caliper tool is used to measure structures within the anterior chamber. To activate this tool, click the caliper tool button.  Next, click and hold the left mouse button on the location within the

image to start the measurement. Then extend it by moving the mouse to the end-point to which to extend the measurement.

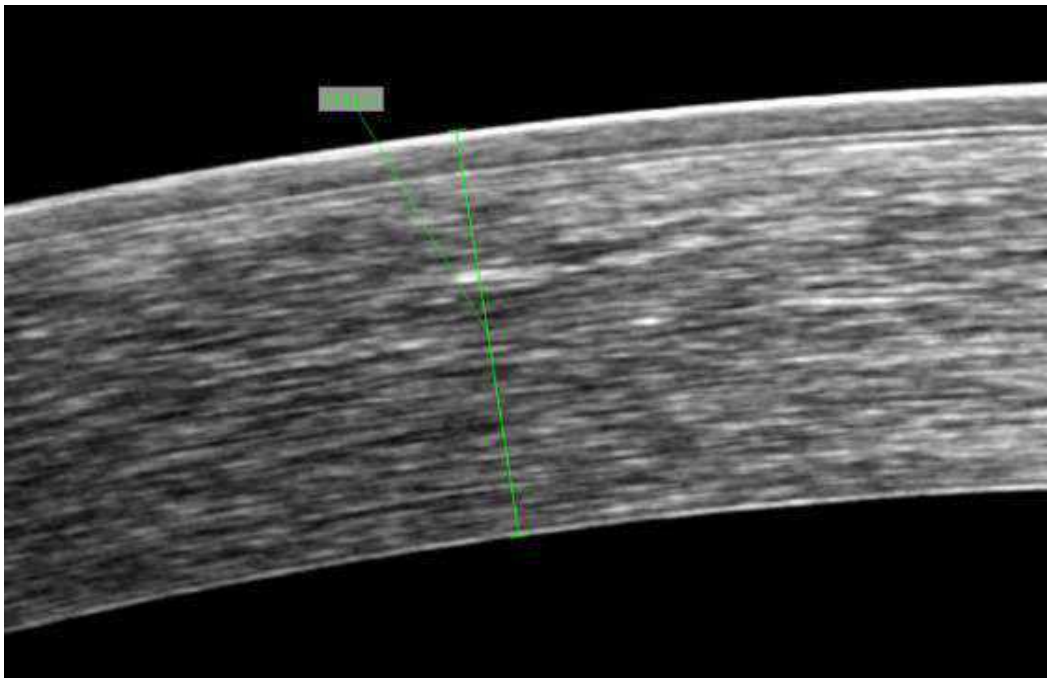


Figure 194.
Example of a Caliper Measurement

Each of the three variants of the tool is optimized for measuring a specific structure type. To choose a variant, click the button to open the tools menu and choose the desired tool.

C:	Caliper tool for measuring the thickness of the cornea.	
AQ:	Caliper tool for measuring distances within the Aqueous Depth.	

12.1.6. Area Tool

The area tool is used to measure structure areas. To activate this tool, click the area tool button. Next, click and hold the left mouse button on the location within the image to start the measurement. Then extend it by moving the mouse to the next point and repeat until the desired area will be selected.

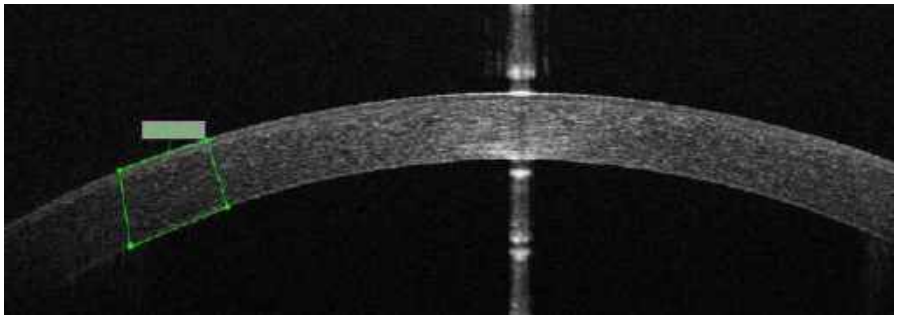


Figure 195
Example of an Area Measurement

12.1.7. AOD Measurement Tool

The AOD measurement tool is used to measure the **Trabecular Iris Surface Area** (TISA) and the **Angle Opening Distance** (AOD) in the anterior chamber angle. The value 500 or 750 is the distance in microns measured from a point in the scleral spur along the posterior corneal surface. The AOD is the distance from the cornea at the 500 or 750 mark to the iris. The area is measured as the trapezoidal area enclosed by these distances and the structure of the iris.

The Trabecular Iris Angle is an angle measured between the point on the posterior corneal surface 500 µm from the scleral spur and the point perpendicular to it on the iris surface.The Trabecular Iris Angle is an angle between the apex (place in sclearar spur) and the extreme vertices of the AOD 500 line.

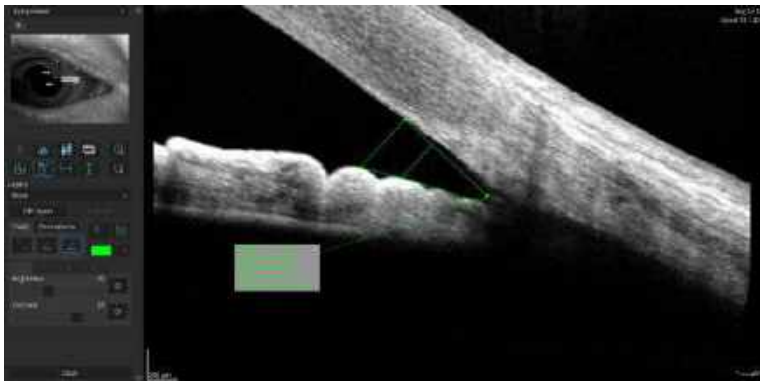


Figure 196.
Example of an AOD Measurement

AOD500:	Angle Opening Distance at 500 microns.
AOD750:	Angle Opening Distance at 750 microns.
TISA 500:	Trabecular Iris Space Area 500 (mm2):
TISA 750:	Trabecular Iris Space Area 750 (mm2):
TIA:	Trabecular Iris Angle.

1. To use this tool, click the  [AOD] button, position the mouse cursor over the scleral spur and press the left mouse button.
2. The system will draw a line of up to 750 µm from the scleral spur, following the mouse cursor. Click where you want to place the second apex on the posterior surface of the cornea.
3. Place the rest of the markers on the posterior surface of the iris.
4. To replace any created apex, move the cursor over the area of interest, press and hold the left mouse button and point to the areas you wish to measure. You can replace the position of the information table in the same way.

The mouse cursor will changes to **Move** ✣ . Press and hold the left mouse button and move the tool to the desired position.

12.1.8. Angle Measurement Tool

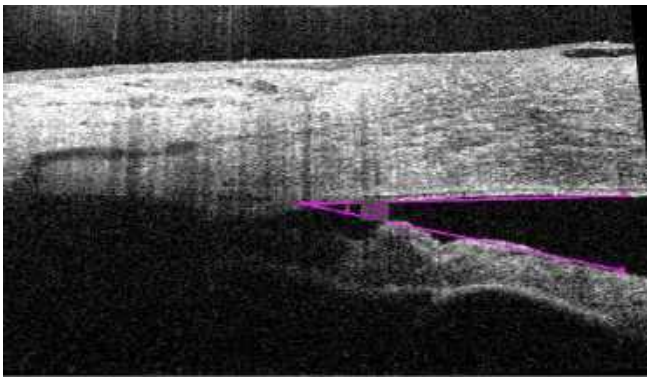


Figure 197.
Example of an Angle Measurement

This tool enables the user to measure an angle. Click the **[ANGLE MEASUREMENT]** button, put the mouse cursor over the desired point of the apex of the angle and click the left-mouse button. Next set one of the arms by clicking the desired location, and then place the cursor of the angle to the desired position and click a second time. Information about the angle will be displayed between the angle sides. Measurements are expressed in degrees. It is also possible to move the position of the angle and its measurement by dragging and dropping its apex and the two points of measurement. The measurement checkbox will also affect the angle visibility in the tomogram window. Select or deselect this to display or hide the angle measurement.

12.1.9. Editing the Anterior Surface

The device finds the anterior (outer) and posterior (inner) surfaces of the cornea automatically. Dewarping calculation (a form of image processing) is conducted for all Anterior scans used to transfer the OCT image from “optical distance space” to “physical distance space”. The algorithm requires a properly recognized boundary intersecting the Anterior structure of the eye.

NOTE: To properly measure the AOD (Angle Opening Distance) and TISA (Trabecular Iris Space Area), review the exam with layers enabled to ensure the system has properly positioned the surface of the sclera. Verify recognition before judging the Anterior Angle morphology.

In some cases, the corneal surface lines clearly do not fit the corneal contours, due to anomalies in the scan image which may be caused by the interference of eyelids or eyelashes.

To edit the surface boundary lines, double click on the tomogram window. Press the **[EDIT LAYERS]** button and select the desired boundary. Then draw the correct shape of the anterior structure.

12.1.9.1. Angle or Angle to Angle Scan

When you edit the layers, if required remove unnecessary data to change the portion of image data included into mathematic model of ray tracing analysis in which that image is used. Automatically, SOCT excludes portions of the image to which ray tracing correction model (a form of image processing) cannot be confidently applied. The size of the excluded margin can be larger when the processing algorithm cannot detect the corneal surfaces due to poor image quality.

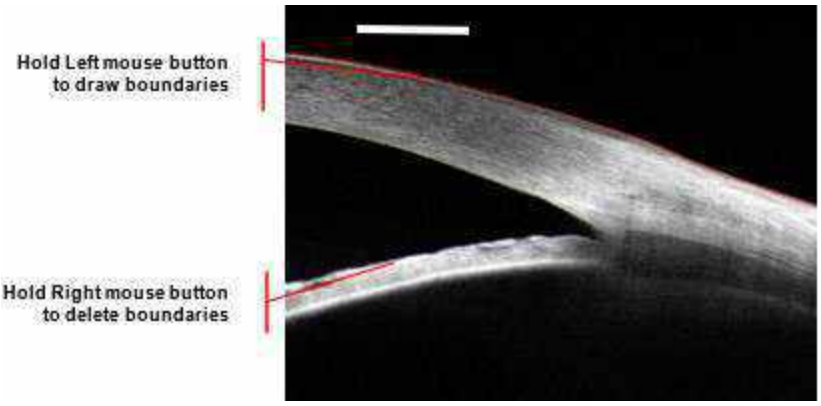


Figure 198.
Edit Anterior Angle Layer

12.1.10. Tomogram Review Analysis

This displays the tomogram image and the defined thickness for the specified area. The compatible scan programs are **[RASTER]**, **[LINE]**, **[CROSS]** and **[RADIAL]**. These tomogram images can be averaged.

12.2. Anterior Image Type

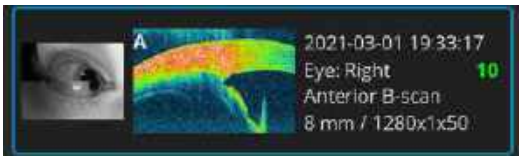
During analysis, the system classifies recognized structures on the image as:

Cornea
Cornea **L**ens
Angle
Angle to **A**ngle
IOL
Iris
Lens **F**ront
Lens **B**ack
Sclera
Anterior **S**egment

In the case of a Full Range examination, the system classifies recognized structures as

Anterior **C**hamber
Lens
Angle
Cornea
Sclera

Recognition status is displayed in the top left corner of the Anterior scan tomogram thumbnail. Depending on the scan classification, proper analysis is displayed as seen below:



To change the classification of the scanned object, press the right mouse button on the examination thumbnail and select **[CHANGE THE RECOGNIZED STRUCTURE]** from the list. Choose the structure classification type. Once the type is selected, the system reprocesses the examination using a different algorithm based on the selected type.

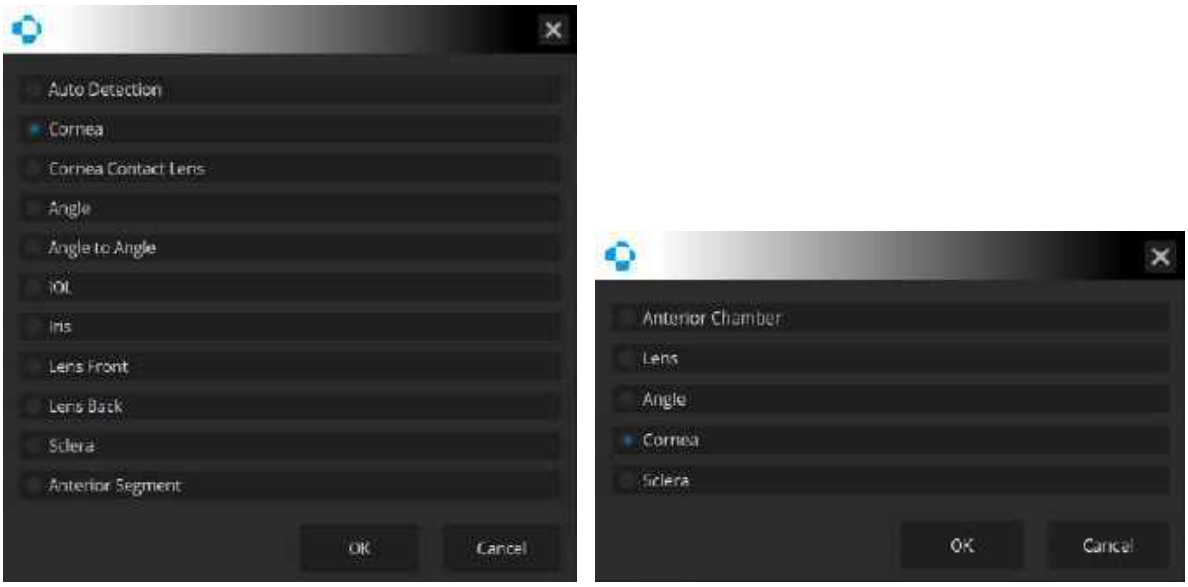


Figure 199.
Structure Classification Menus for Anterior (Left) and Full Range (Right)

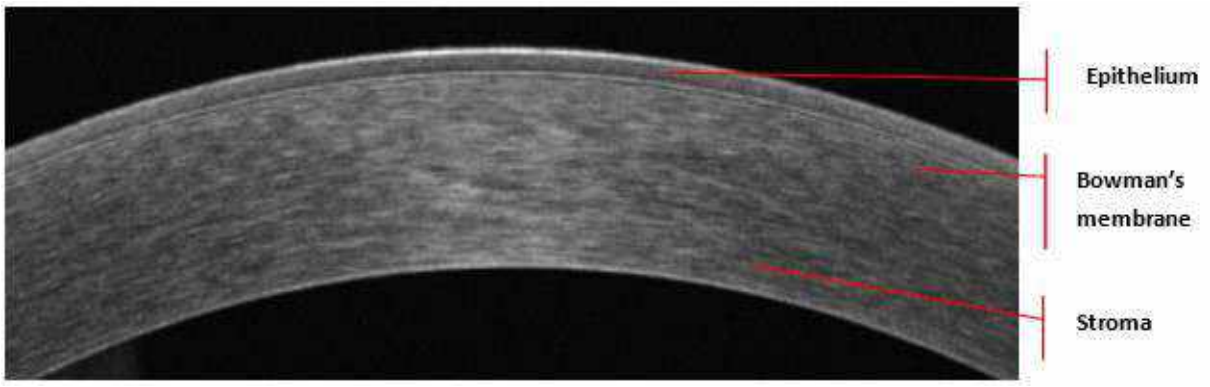


Figure 200.
Cornea Scan

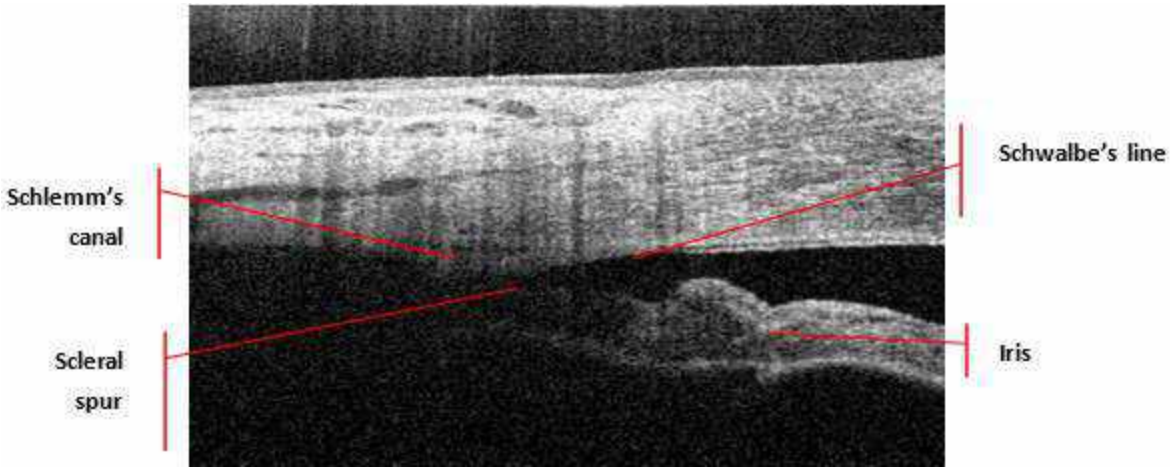


Figure 201.
Short Anterior Angle Scan

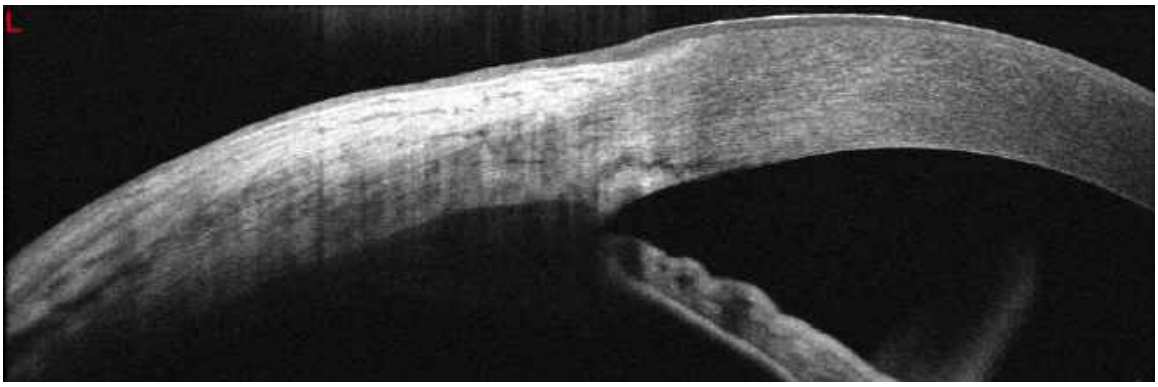


Figure 202.
Sclera and Cornea Wide Anterior 11 mm Scan

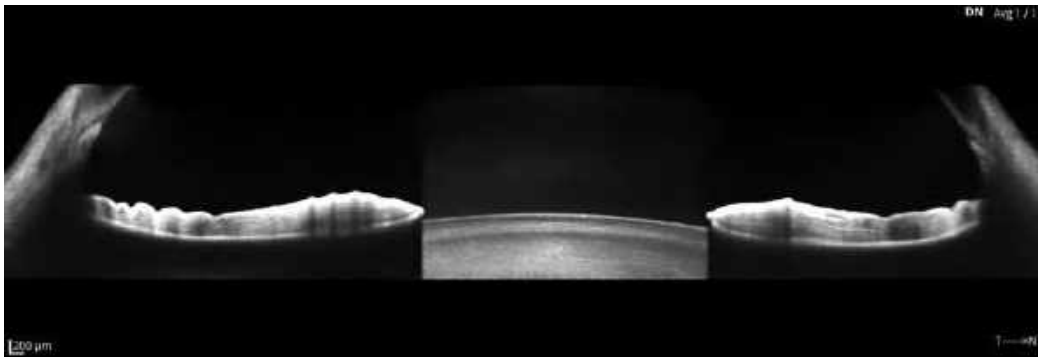


Figure 203.
Angle-to-Angle View (Example of Wide Anterior Line)

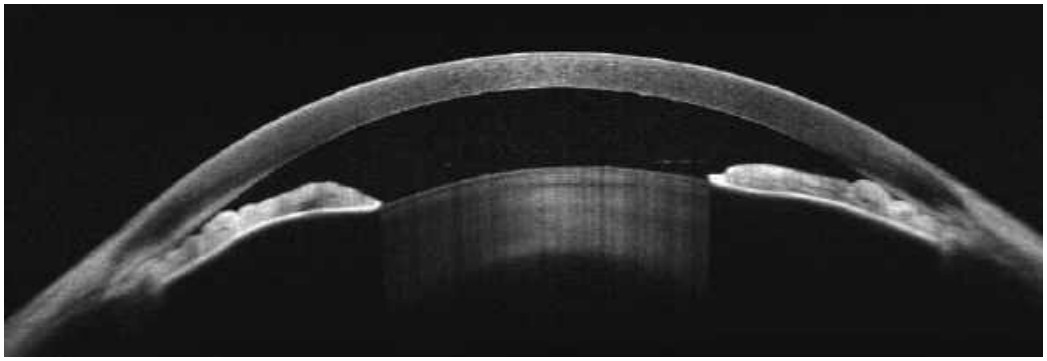


Figure 204.
Full Range Anterior Chamber

13.
Full Screen Window

To open Full screen tomogram window, double click on the tomogram window. The full screen window enables the operator to browse all the stored examination results. It contains all tools for editing of the layers, manual measurements and comments or descriptions in the tomogram.

Figure 205.
Full Screen Tomogram

13.1. Eye Preview Modes (Fundus Reconstruction or pSLO)

A drop-down list allows the user to toggle between fundus reconstruction, eye preview, pSLO or fundus photo.

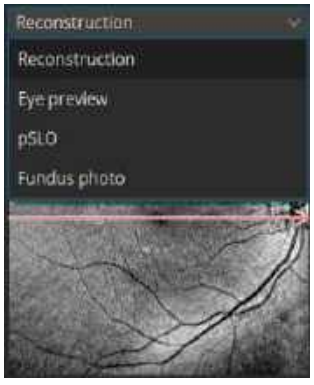


Figure 206.
Eye Preview Type Selection

The fundus photo is set as default.

13.2. Imaging Tools

In the full screen window, there are several imaging tools available for adjusting, such as: brightness / contrast, color, or grayscale tomogram visualization, etc.

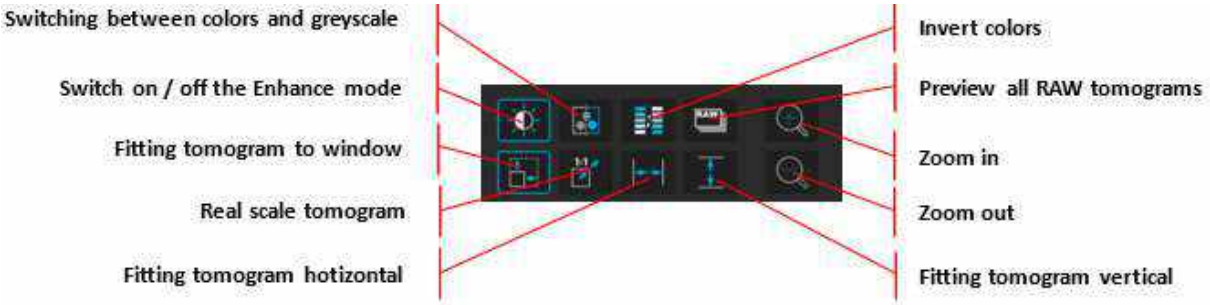


Figure 207.
Imaging Tools

The function to preview all raw tomograms is enabled as the default when the examination contains averaged tomograms. When it is unselected, the user can display and review only averaged images. When enabled, first the current averaged tomogram is displayed and after scrolling, the corresponding series of raw tomograms for that averaged tomogram are displayed, until the next averaged tomogram is reached, after which the corresponding series of raw tomograms will be displayed for that next averaged tomogram. Scroll down to go to the next tomograms and scroll up to go to the previous ones.

13.3. Measurement Tools and Annotations

On the fundus reconstruction object and on the tomogram, tools may be used to perform a measurement of an area and to perform a measurement of the distance between two points or the angle between two sections.

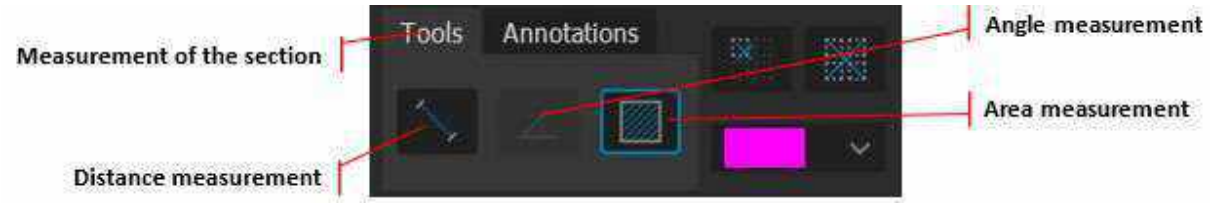


Figure 208.
Measurement Tools

The annotation tab enables inputting a text field with operator comments, as well as an arrow symbol pointing exactly to the area that the comment concerns. The operator can also choose the color in which the marking will be displayed on tomogram. An additional two buttons allow the user to delete a single marking or all markings on a particular tomogram.

Figure 209.
Tab of Tomogram Annotations

The above tools and annotations remain enabled and will continuously insert additional measurements and markings until disabled by clicking on them again.

13.4. Brightness and Contrast Adjustment

Brightness and contrast adjustments are done with the sliders presented below. The adjustment is sometimes necessary because of the difference in the optical transparence of the examined eyes. To the right of each slider, there is a button restoring the default brightness and contrast settings.

Figure 210.
Brightness and Contrast Manipulation

The recommended method to adjust brightness and contrast is to click the right mouse button and move the cursor over the tomogram or angiogram window and drag the cursor up / down or right / left:

1. **Dragging Up and Down:** Adjusts the brightness.
2. **Dragging Right and Left:** Adjusts the contrast.
3. **Resetting Brightness and Contrast After Adjustment:** Right-click the OCT image and select **[RESET BRIGHTNESS / CONTRAST]** from the menu.

Enhanced mode highlights the details of the morphological structures above and below the retina. While in this mode, it is possible to adjust the brightness and contrast in one of three zones: Vitreous, Retina and Choroid. The vitreous mode adjusts the brightness and contrast above the ILM layer. The retina mode adjusts the brightness and contrast between the RPE / BM and ILM layers. The choroid mode adjusts the brightness and contrast below the RPE / BM layer.

13.5. Full Screen Mode Exit

[CLOSE] button enables a full screen mode exit and entry to the exam analysis. The same result is achieved by double clicking on tomogram.

13.6. Tomogram Window Manipulation

Right-click over the tomogram preview to open the display and actions menu. Moving the mouse up or down with the right button pressed continuously adjusts brightness and contrast. The list of options is presented below:

1. Auto fit function has been modified.
2. Auto fit – it fits tomogram horizontally.

NOTE: The proportion of the scan may be different between examinations.

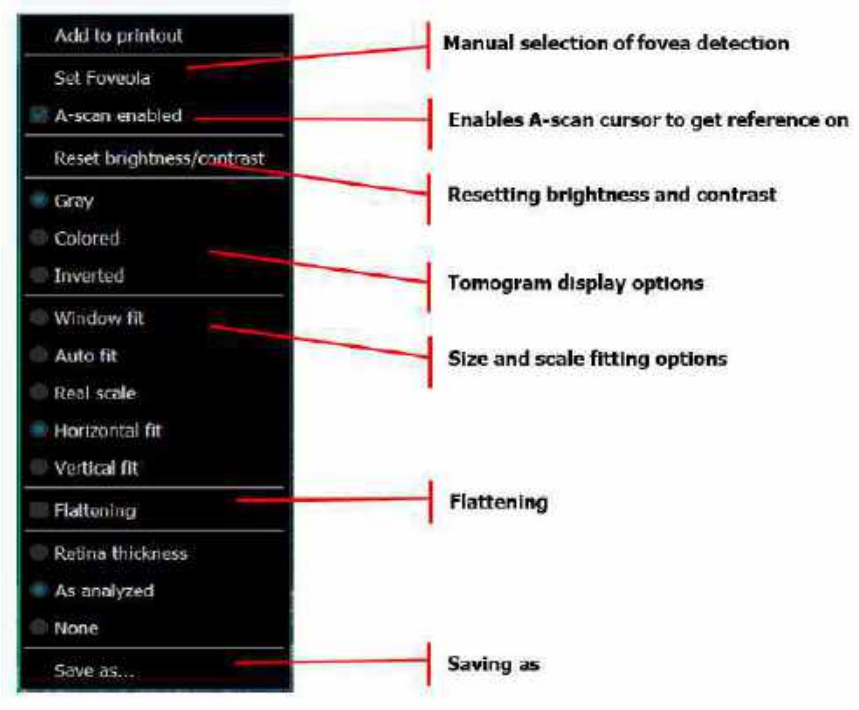


Figure 211.
Tomogram Display Options Window

Double clicking on the tomogram preview switches the view to full screen and allows the user to edit layers recognition in the same way as in the Retina examination viewing tab.

Tomogram window context menu offers:

1. **Add to printout** – adds the tomogram to the multi B-scan printout buffer.
2. **Set Foveola**– place the fovea marker on the indicated A-scan.
3. **A-scan enabled** – display the vertical line indicating the A-scan.
4. **Reset brightness / contrast** – reset the brightness and contrast values.
5. **Angio Flow*** – overlay images of blood flow on the tomogram.
6. **Gray** – display a tomogram in a grayscale.
7. **Colored** – display the tomogram in pseudo-colors.
8. **Inverted** – display a tomogram in an inverted color scale.
9. **Window fit** – fit the tomogram to the display window.
10. **Auto fit** – stretch the tomogram horizontally to the display window and vertically to the point at which Retina fills 75% of the displays window.
11. **Real scale** – 1:1 μm, the actual tomogram scale.
12. **Horizontal fit** – display the tomogram in its original proportions, in a scale fit to the width of the window, and with the area of recognized layers is displayed in the center of the window.
13. **Vertical fit** – display the tomogram in original proportions, in a scale fit to the height of the window.

14. **Flattening** - flatten all layers by matching the RPE to a flat surface.
15. **Vertical scan / Horizontal scan*** – switch between Vertical or Horizontal tomogram.
16. **Save as…** – open a dialog Window to save the tomogram as a .png fie
17. **Save anonymized as…** – open a dialog Window to save the tomogram as an anonymized .png fie. Available only when anonymized output is configured. See details in Chapter 23.5.6 Anonymization

*Available for OCT-A examinations only

13.7. Editing Segmentation Layers

The software automatically recognizes and performs segmentation of layers. Should the recognition of layers be incorrect, manual correction can be performed. This feature is especially useful in cases where the retina or cornea has structural anomalies or pathology that may cause the algorithms to incorrectly trace the actual boundaries.

Figure 212.
Selection and Edition of Layers and Disc

In order to correct the recognized layers, press the **[EDIT LAYERS]** button. In order to correct the layers, choose the layer from the list and draw its outline on the tomogram.

To draw the layer place the cursor over the desire boundary. Press and hold mouse button and draw the corrected shape of the boundary.

After correction of tomogram/s press **[ACCEPT]** option. The software will automatically recalculate all the data on the basis of the user modifications. This correction can be used for fovea and disc analysis. It is enabled only after analysis is done.

Pressing the **[H]** button on the keyboard will hide all of the layers. This functionality works both when editing layers and when only viewing. Pressing **[H]** again will make the layers visible. This tool is used to toggle the layers on and off when reviewing the examinations.

[REANALYZE] function is used to recover default recognition of layers. It is recommended to make reanalysis of examinations taken with previous software versions.

Retina Layers

ILM:	Inner Limited Membrane (surface of the retina)
NFL / GCL:	Outer boundary of Retina Nerve Fiber Layer
GCL / IPL:	Outer boundary of Ganglion layer
IPL / INL:	Outer boundary of Inner Plexiform Layer

INL / OPL:	Outer boundary of Inner Nuclear Layer
OPL / ONL:	Outer boundary of Outer Plexiform Layer
ELM:	External Limiting Membrane
MZ / EZ:	Junction of Myoid and Ellipsoid Zones
EZ/OS:	Junction of Elipsoid Zone and Outer Segment of Photoreceptors
IZ / RPE:	Junction in Interdigitation Zone and Pigment Epithelium
RPE / BM:	Outer boundary of RPE
BM:	Bruch's Membrane modeling based on outer boundary of RPE
BM Fit:	Parabolic fit for end of RPE Layer

The abbreviations and names of the layers and boundaries shown in analysis are as follows:

ILM:	Internal Limiting Membrane
NFL:	Nerve Fiber Layer
GCL:	Ganglion Cell Layer
IPL:	Inner Plexiform Layer
INL:	Inner Nuclear Layer
OPL:	Outer Plexiform Layer
ONL:	Outer Nuclear Layer
ELM:	External Limiting Membrane
IZ:	Interdigitation Zone
EZ:	Elipsoid Zone
OS:	Photoreceptor Outer Segment
RPE:	Retinal Pigment Epithelium

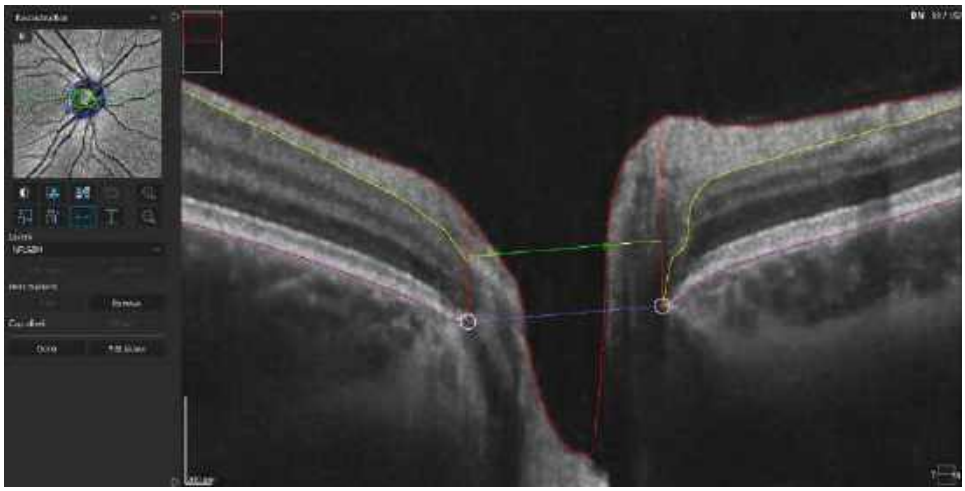
BM:	Bruch's Membrane

Cornea Layers

Anterior Surface	Anterior surface of the Cornea
Epithelium	Corneal Epithelium posterior Boundary.
Endothelium	Posterior boundary of the Cornea

13.8. Manual Disc Contour Editing for Disc Examinations

It is possible to edit the position of the recognized end of the BM membrane, which defines the disc shape. Press the **[EDIT DISC]** button to adjust the markers.



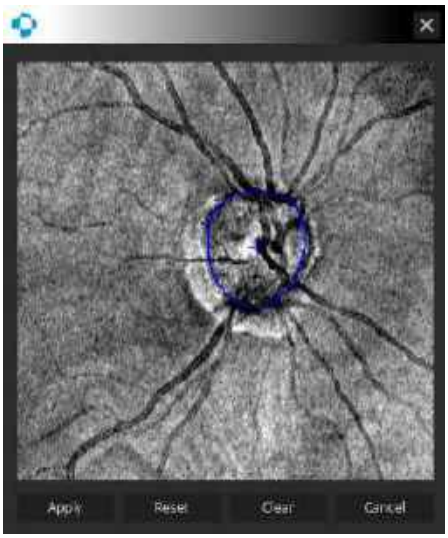
On the tomogram preview windows, white marker points will appear on left and right edge of Bruch's Membrane on the actual scan (if the actual scan crosses the disc). If necessary, marker points can be moved by clicking and dragging them on the tomogram image area to the proper location. (Changes in a single scan will occur on the shape of the disc and cup and will take effect in all analysis). A yellow line displays the Cup Offset Line (parallel to the purple disc which represents the disc surface).

After analyzing the disc, the operator can manually edit the position of the BMO markers. To adjust the marker which identifies the edge of the BM, click the white marker, hold the button, and drag it to the proper location in the disc profile (for each scan). It is possible to change the position of the edge by drawing the shape of the disc in the **Manual disc contour option**.

Changing the Cup Offset will move the cup closer or further from disc, this will be visible in the cup shape on the fundus reconstruction. All ONH data are automatically recalculated if the Cup Offset or RPE edge factors change. It is possible to restore the default analysis by using the **[REANALYZE]** option. Right-click on the preview exam.

1. **[EDIT SHAPE]**

   Opens “Manual disc contour editing” window, which allows the user to manually redefine the shape and position of the disc.



2. **[APPLY]**

   Applies the changes to the disc and closes the window.

3. **[CANCEL]**

   Exits the window without changes.

4. **[RESET]**

   Resets the disc shape to previous settings.

5. **[CLEAR]**

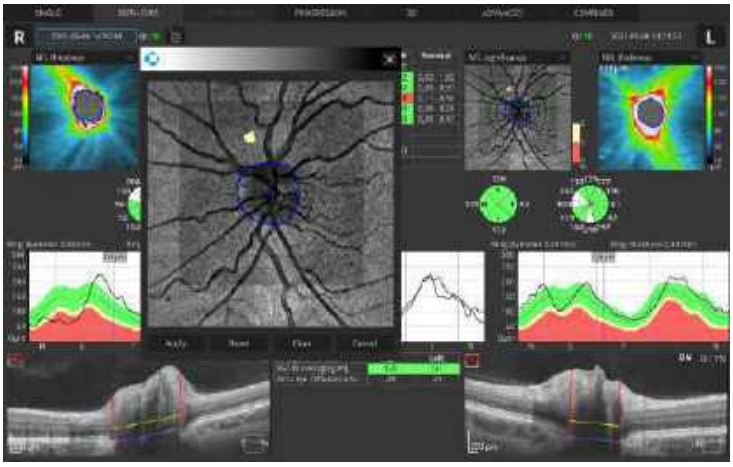
   Clears the disc’s factors. New shape of disc should be drawn manually.

There are two ways to correct the shape of the disc.

One is to remove the contour of the disc by using the **[CLEAR]** button and drawing it again. To draw a new shape of the disc, click on the center of a disc and at least two points on the edge of it. Recognition of the disc will be automatically circled between selected points around the disc center. All other points will be automatically added after the **[APPLY]** button is used. If the operator decides to draw the disc contour more accurately (with a non-elliptic shape), it is possible to add more disc points manually by clicking on the image.

The second method is to redraw the existing shape.

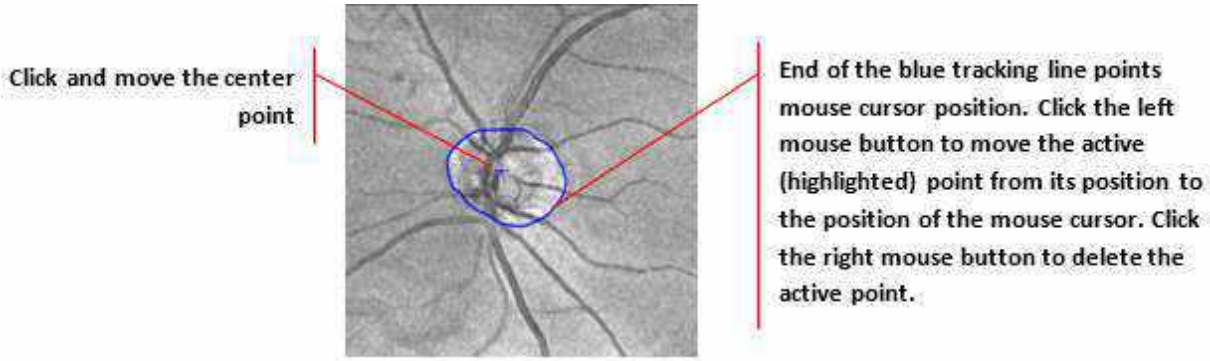
The disc shape adjustment window can be opened by double-clicking on the NFL Significance map in either the SINGLE or BOTH EYES view.



13.8.1. Redraw the Disc Contour

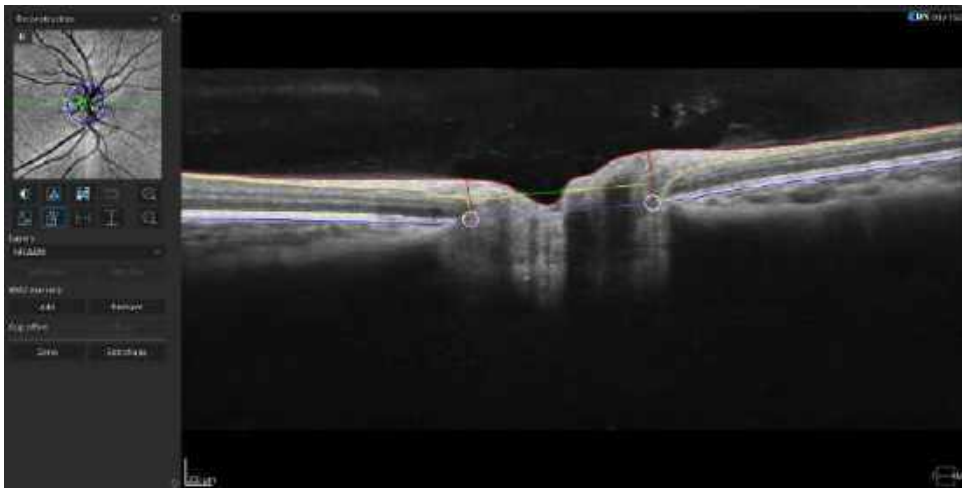
The operator can redraw the disc contour position in two ways:

1. Click and hold left mouse button and draw the desired shape.
2. Put the cursor over the blue point to activate it. The point will highlight. To move the active point to a new position, click the left mouse button and move the mouse. To delete an active point, click the right mouse button on it and the point will disappear. The white disc contour line will be updated to connect the two neighboring points.



Disc contour lines are always restricted to image margins.

If the manual analysis is not helpful to draw the shape of the disc, the user can fix the manual analysis by correction of BMO Bruch Member Opening markers (two white circle markers) in the tomogram preview. To remove or add a pair of markers press **[REMOVE]** or **[ADD]** buttons.



CAUTION: OPTOPOL Technology does not offer advice or instruction in the diagnosis and interpretation of OCT images. It is the clinician's responsibility to diagnose and interpret OCT scans.

14. Print

Press the [Print] button to print the displayed report.

CAUTION: Results from various SOCT software versions may differ. When comparing results on printouts to results in the software, make sure they were all obtained using the same software version.

14.1. Posterior Segment Examination Reports / Outputs

14.1.1. Retina 3D

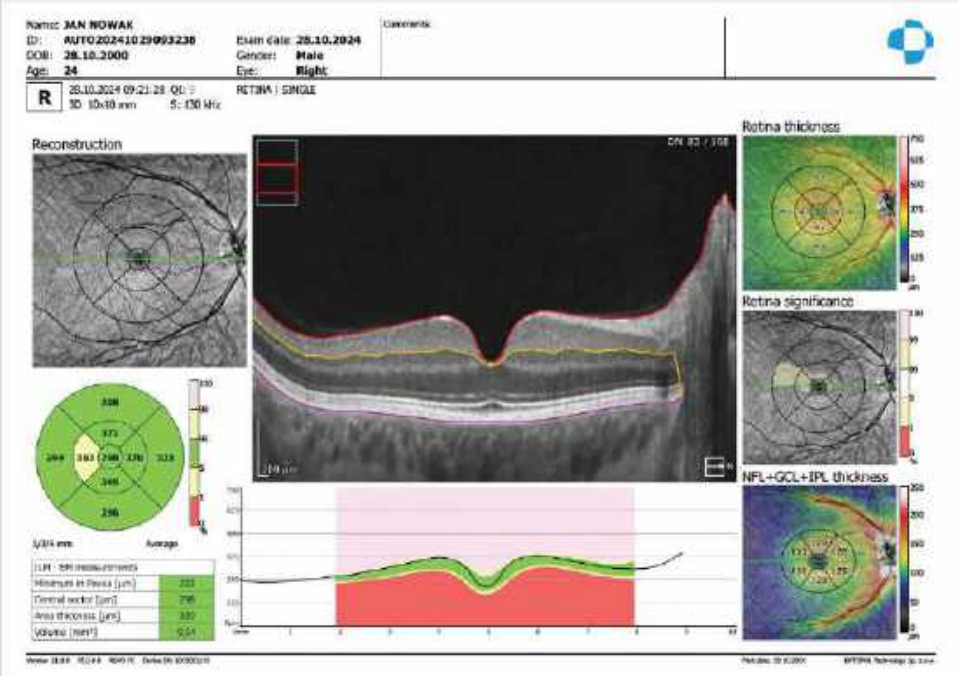


Figure 213.
Examination Report for Retina 3D (Single Output)

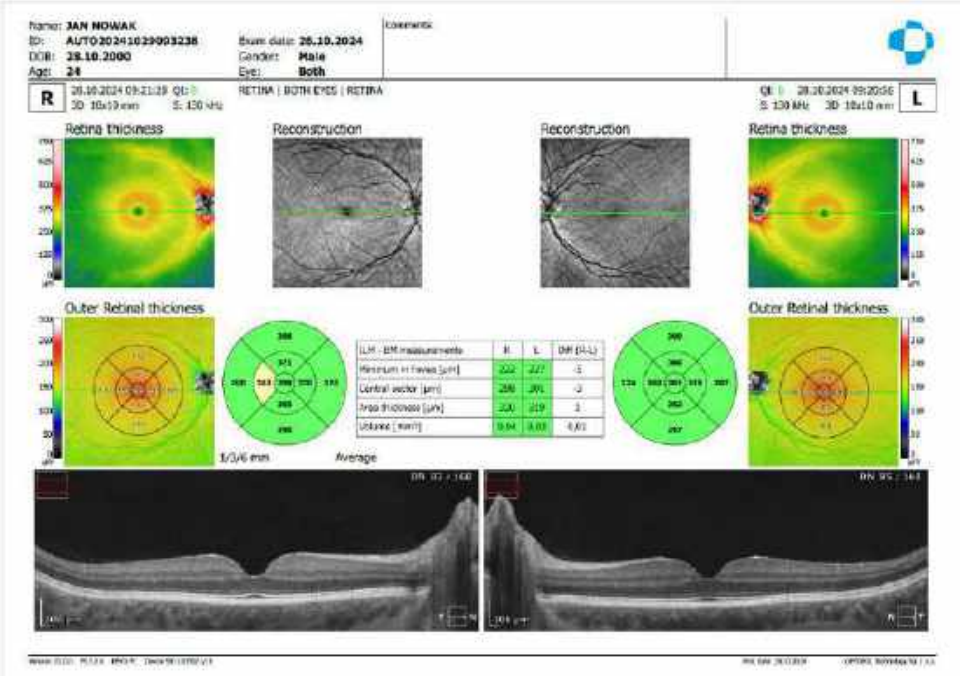


Figure 214.
Examination Report for Retina 3D (Both Output)

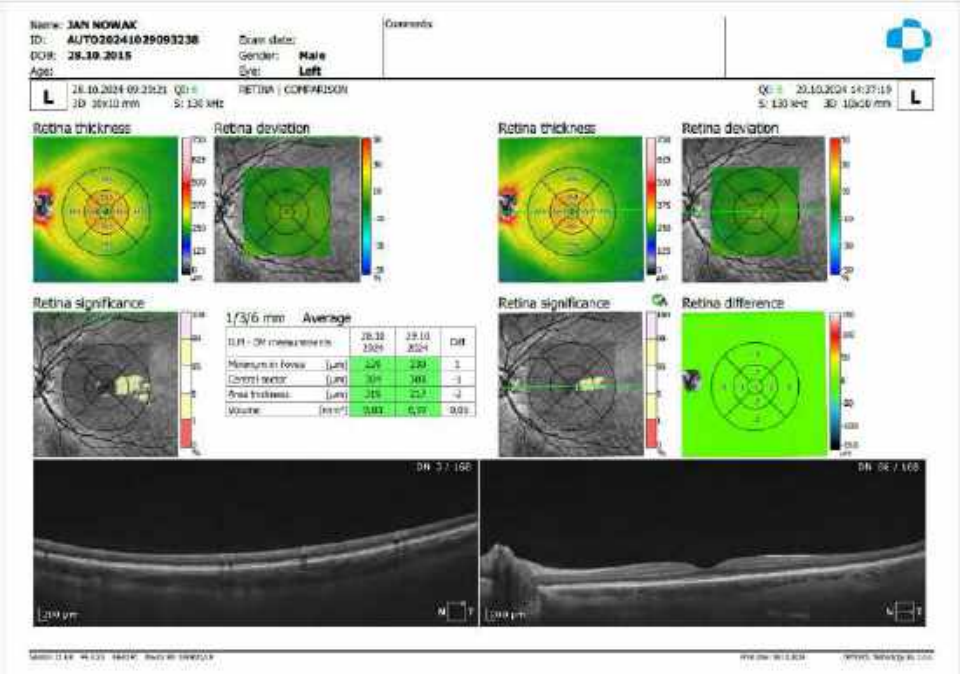


Figure 215.
Examination Report for Retina Comparison (Comparison View)

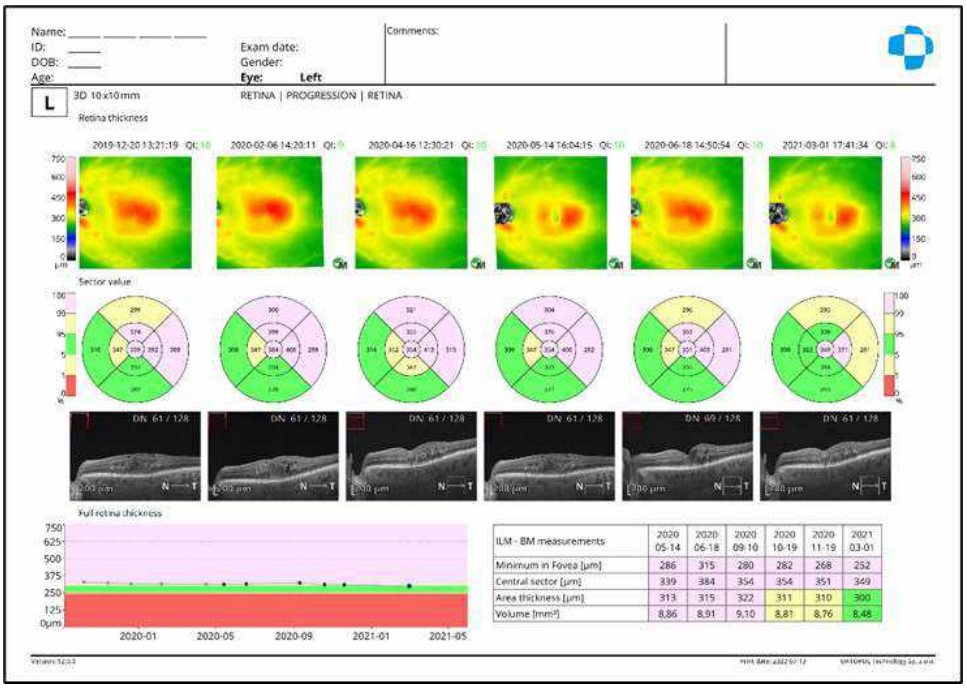


Figure 216.
Examination Report for Retina Progression (Progression View)

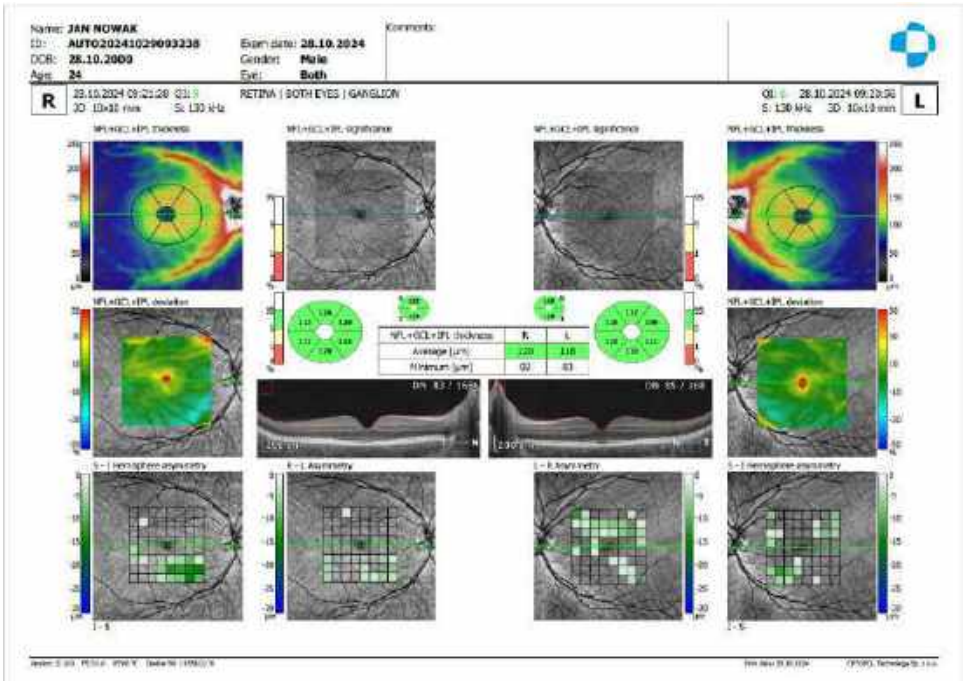


Figure 217.
Examination Report for Retina Ganglion (Both View)

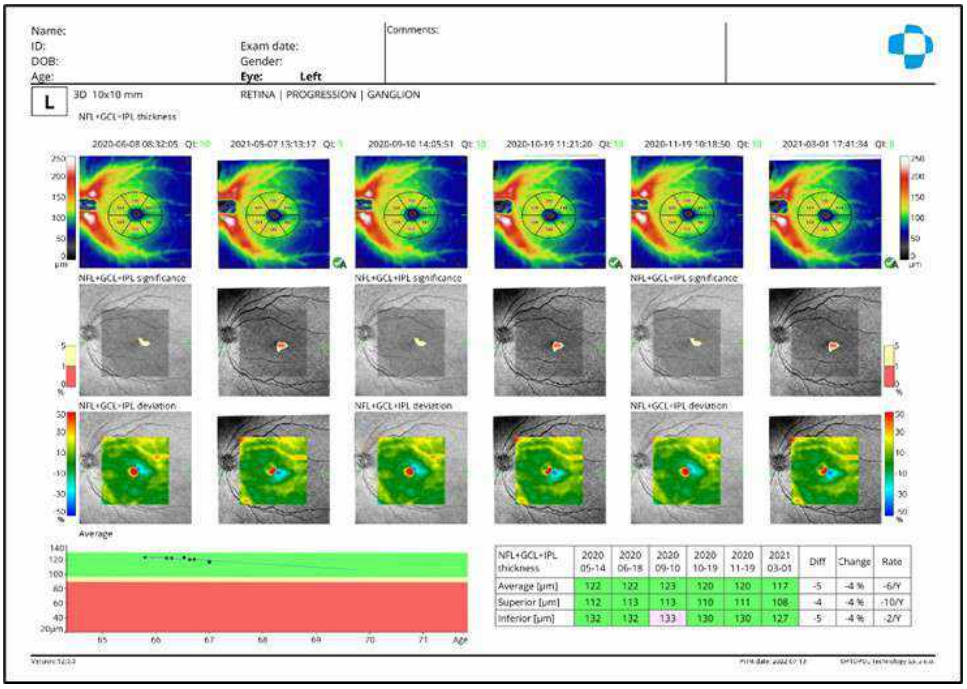


Figure 218.
Examination Report for Retina Progression Ganglion (Progression View)

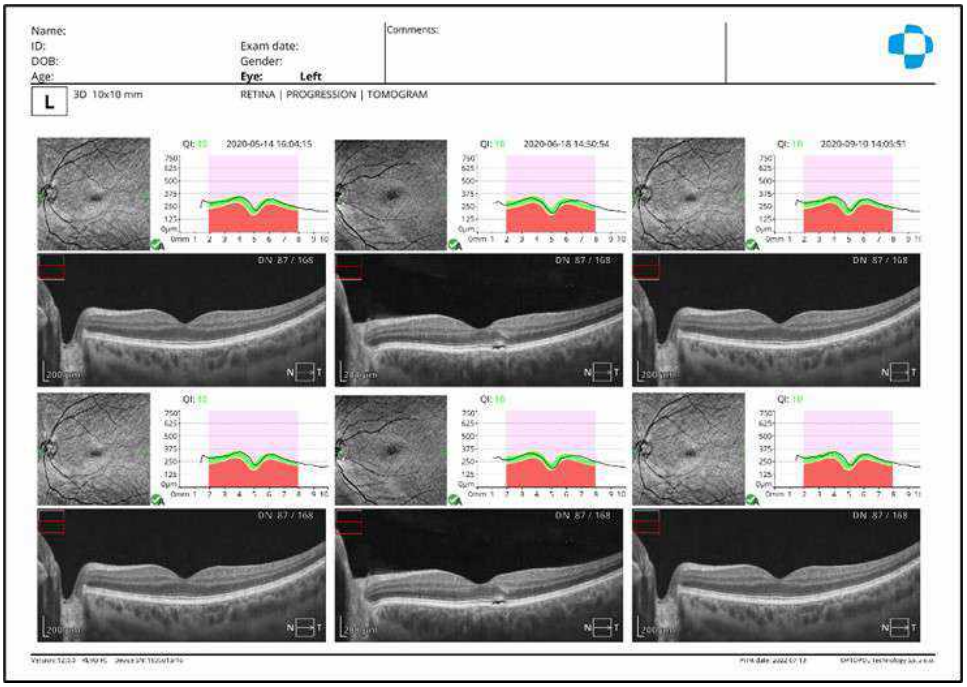


Figure 219.
Examination Report for Retina Progression Tomogram (Progression View)

14.1.2. Disc 3D – Optic Nerve Head Analysis Reports

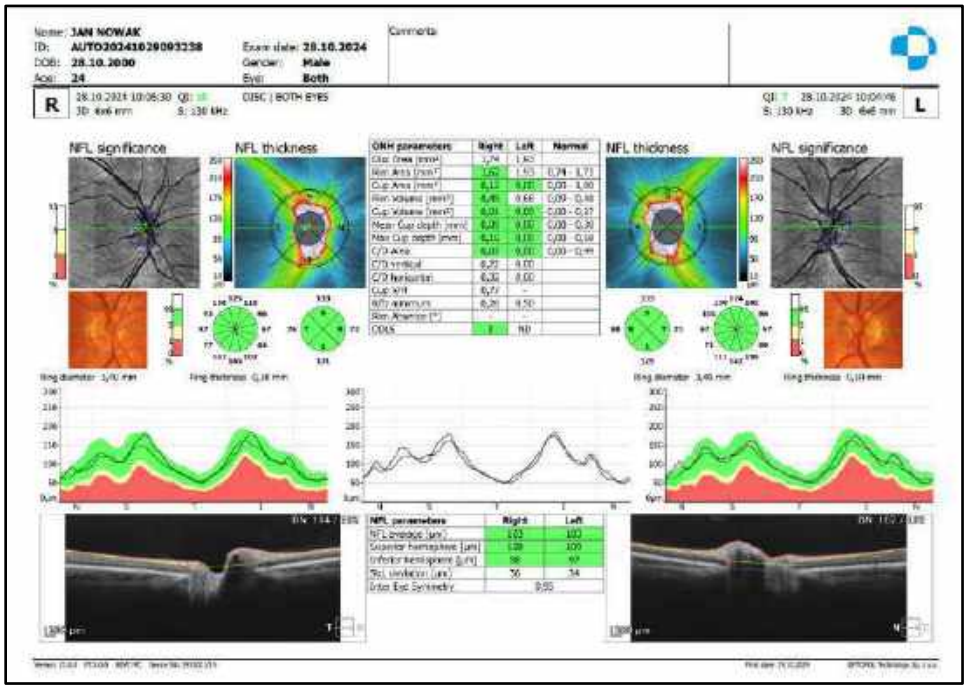


Figure 220.
Examination Report for Both Disc View

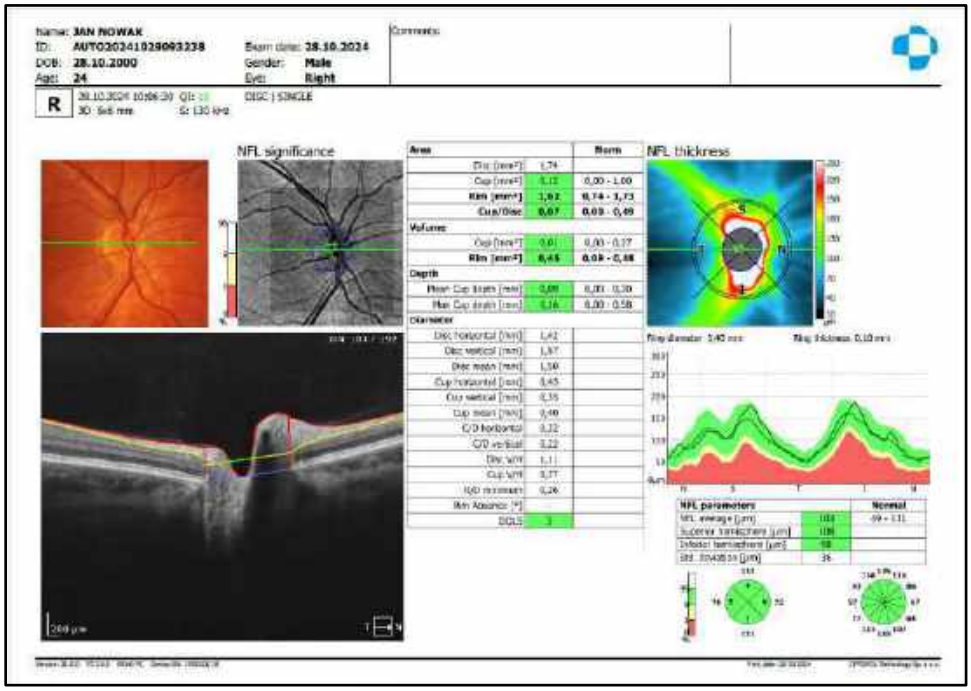


Figure 221.
Examination Report for Single Disc View

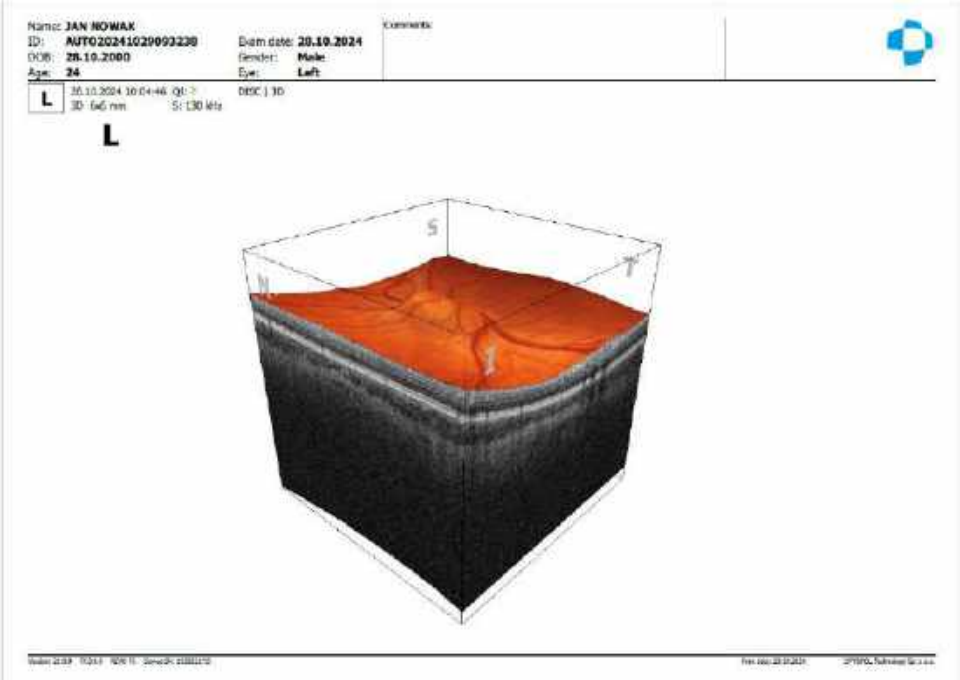


Figure 222.
Examination Report for 3D Single Disc View

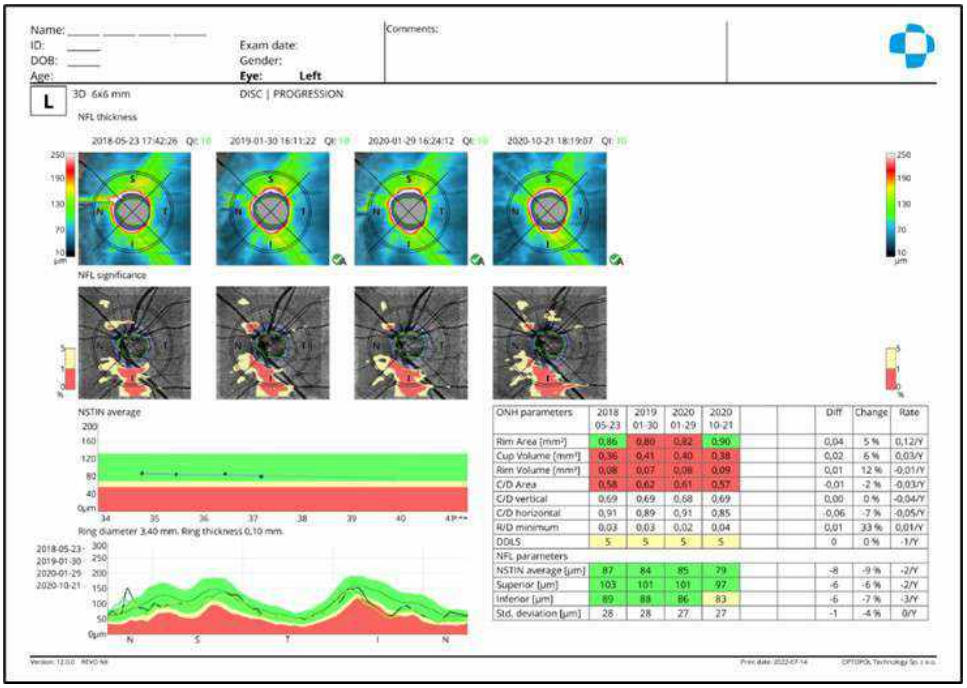


Figure 223.
Examination Report for Single Disc Progression View

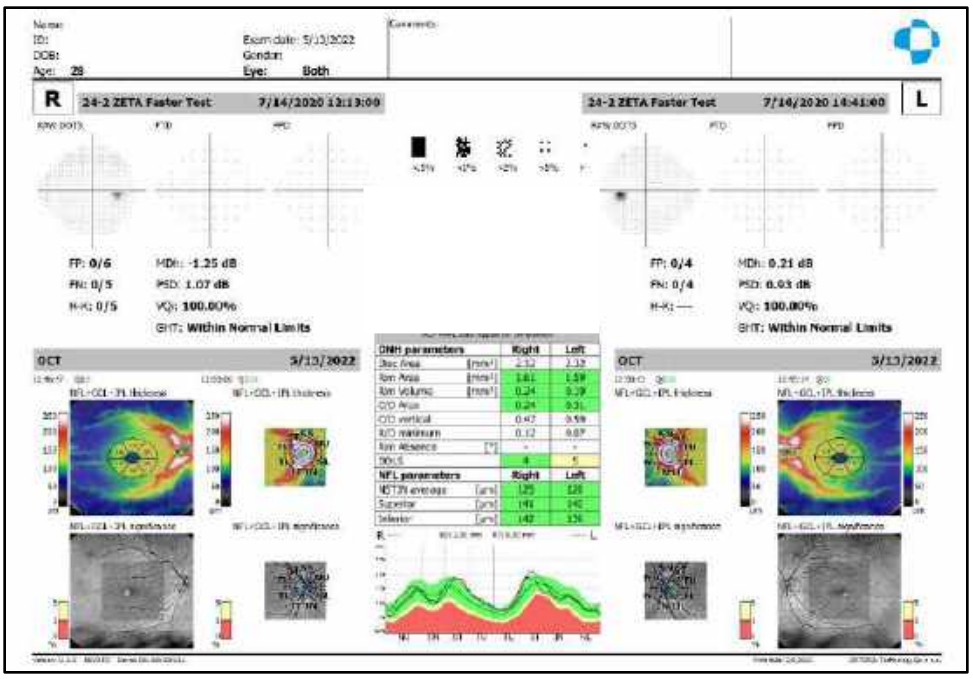


Figure 224.
Structure and Function Examination Report

14.1.3. Advance tab Retina 3D + Disc 3D

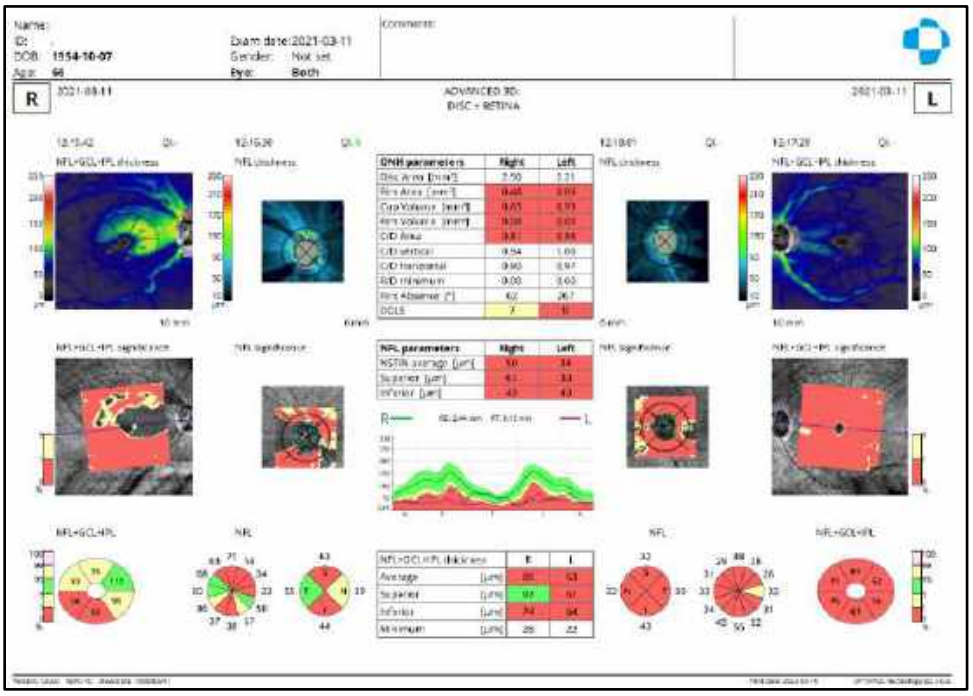


Figure 225.
Examination Report for Retina + Disc Advanced

14.1.4. Widefield 3D

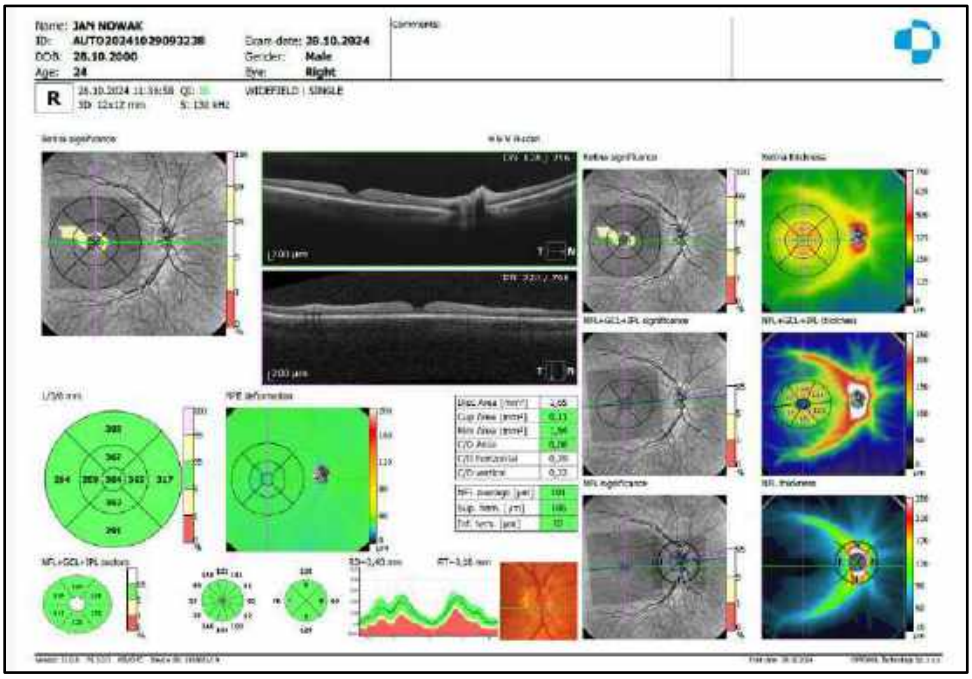


Figure 226.
Examination Report for Widefield 3D

14.2. Anterior Reports

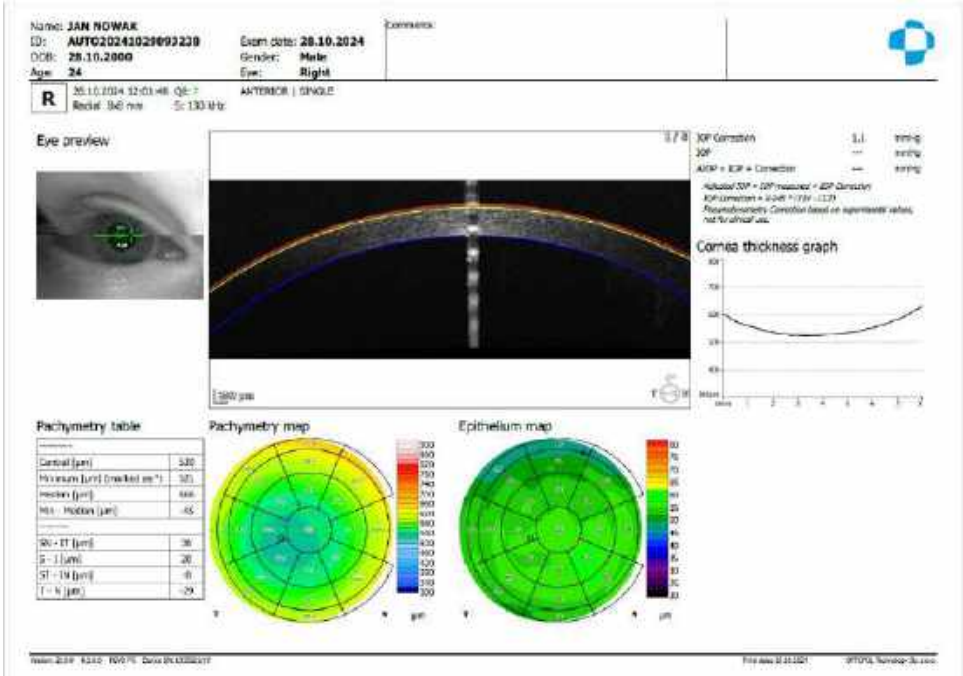


Figure 227.
Examination Report for Anterior Radial (Single View)

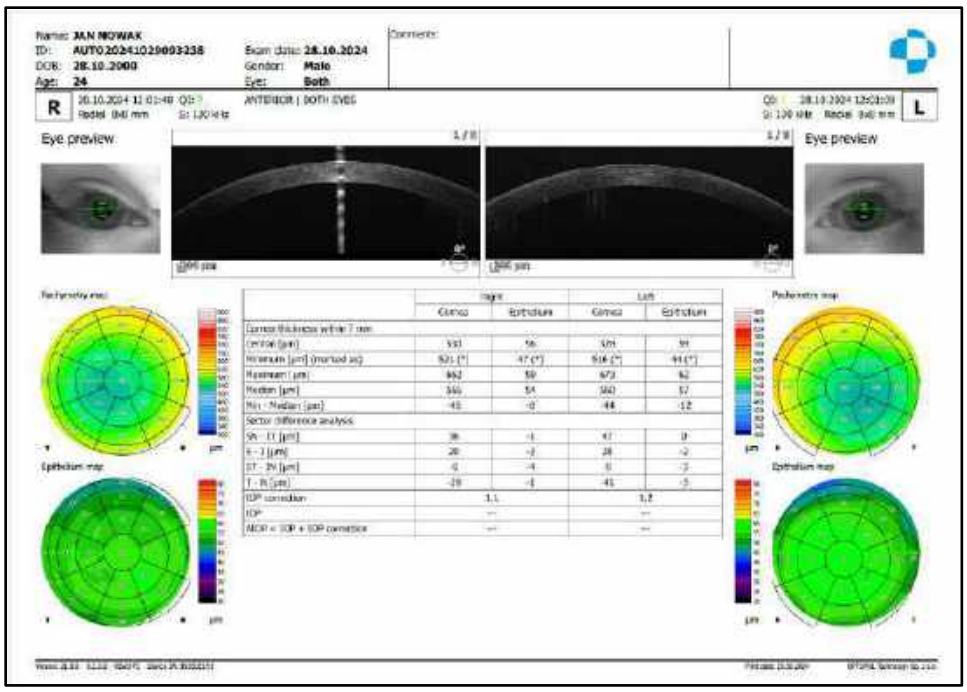


Figure 228.
Examination Report for Anterior Radial (Both View)

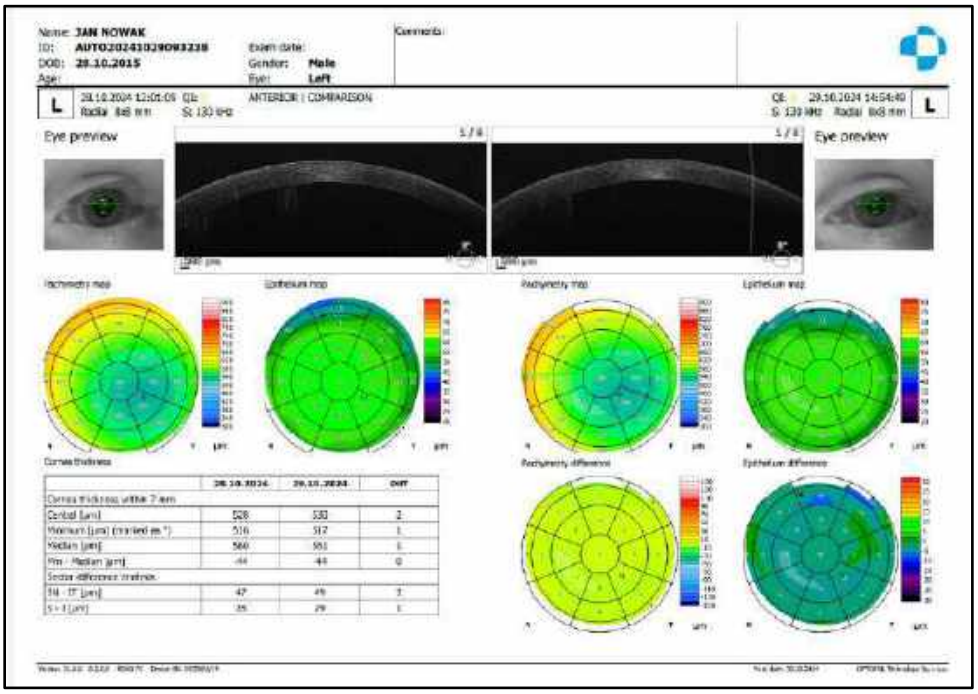


Figure 229.
Examination Report for Anterior Radial (Comparison View)

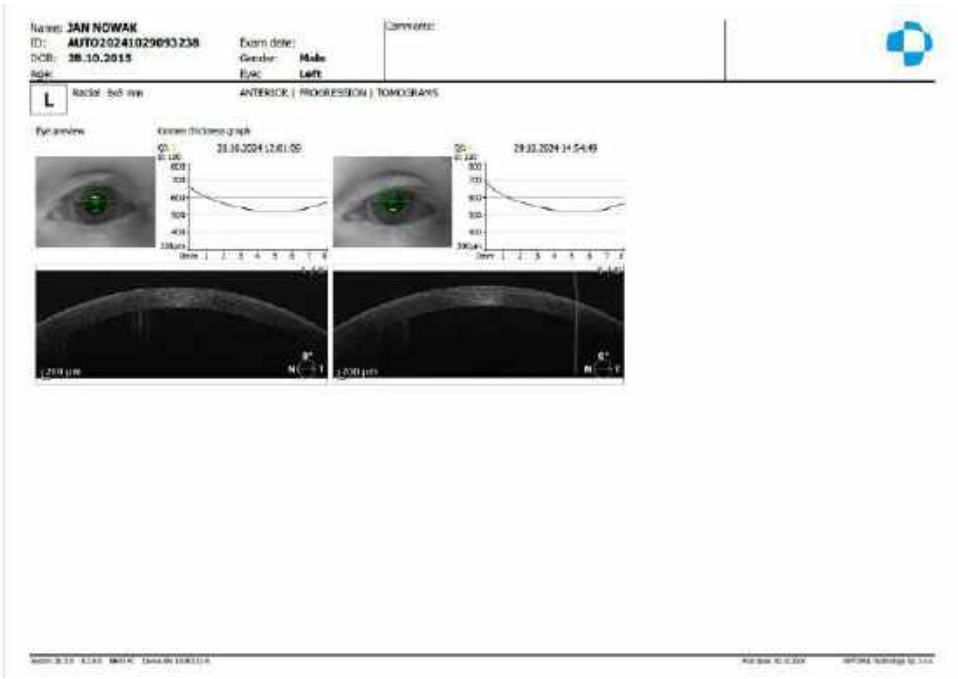


Figure 230.
Examination Report for Anterior Radial (Progression View)

Figure 231.
Examination Report for Anterior Line (Single View)

Figure 232.
Examination Report for Anterior Line (Both View)

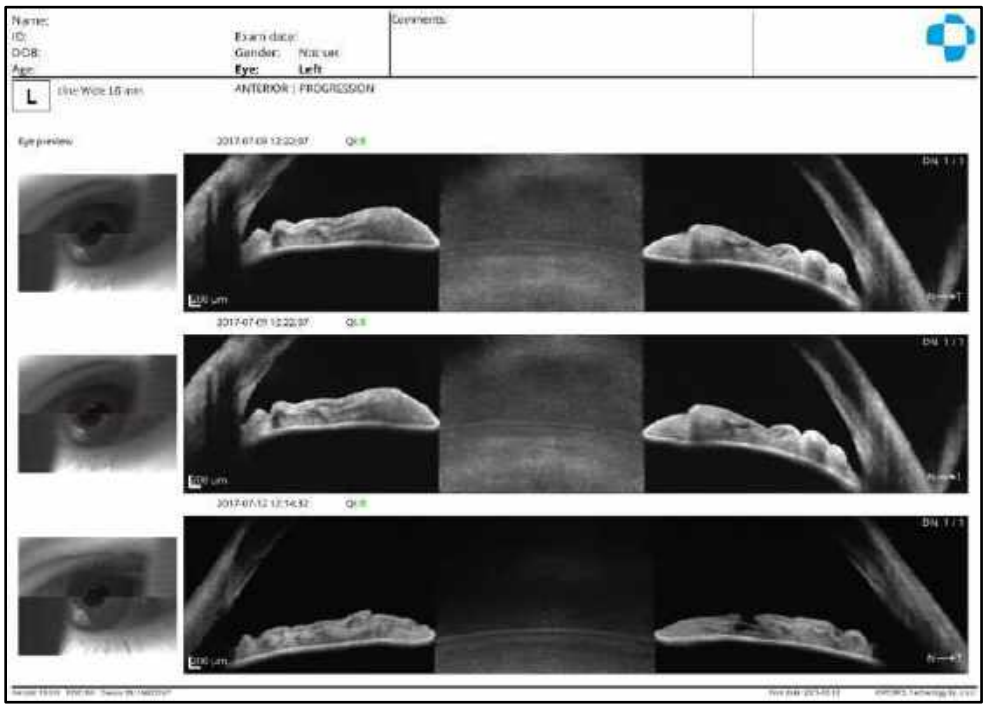


Figure 233.
Examination Report for Wide Anterior Segment Progression (Progression View)

14.3. Retina OCT-A Examination Reports

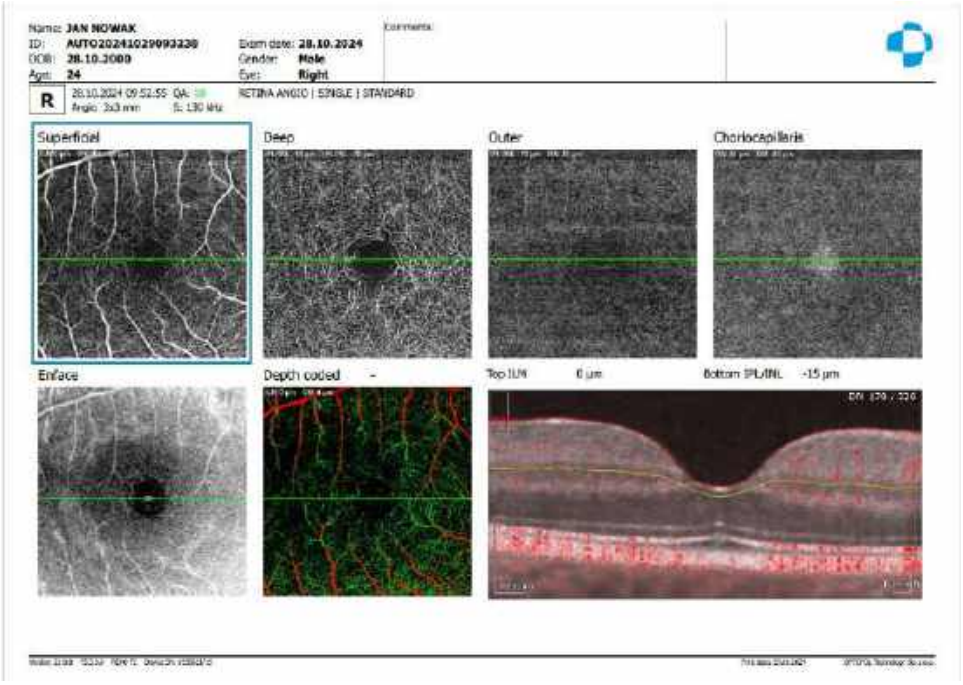


Figure 234.
Examination Report for Angiography (Single Standard View)

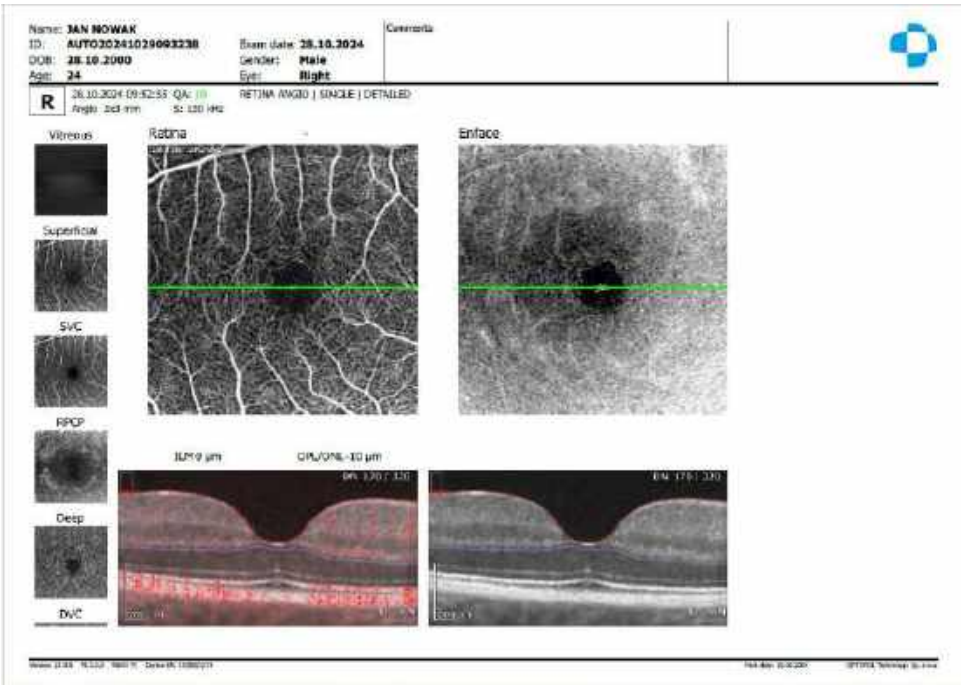


Figure 235.
Examination Report for Angiography (Single Detailed View)

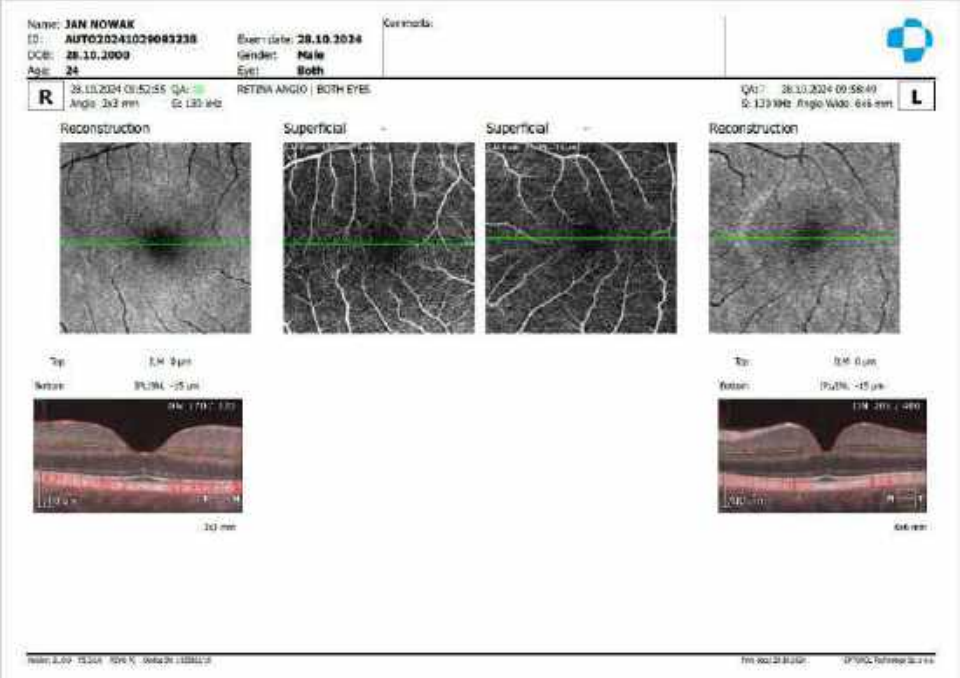


Figure 236.
Examination Report for Angiography (Both View)

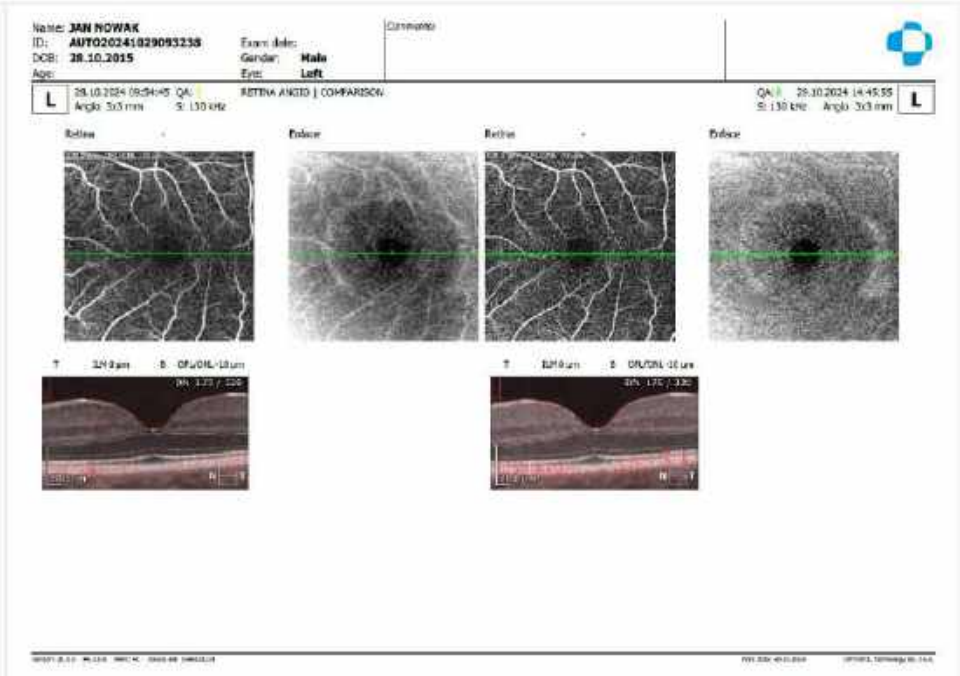


Figure 237.
Examination Report for Angiography (Comparison View)

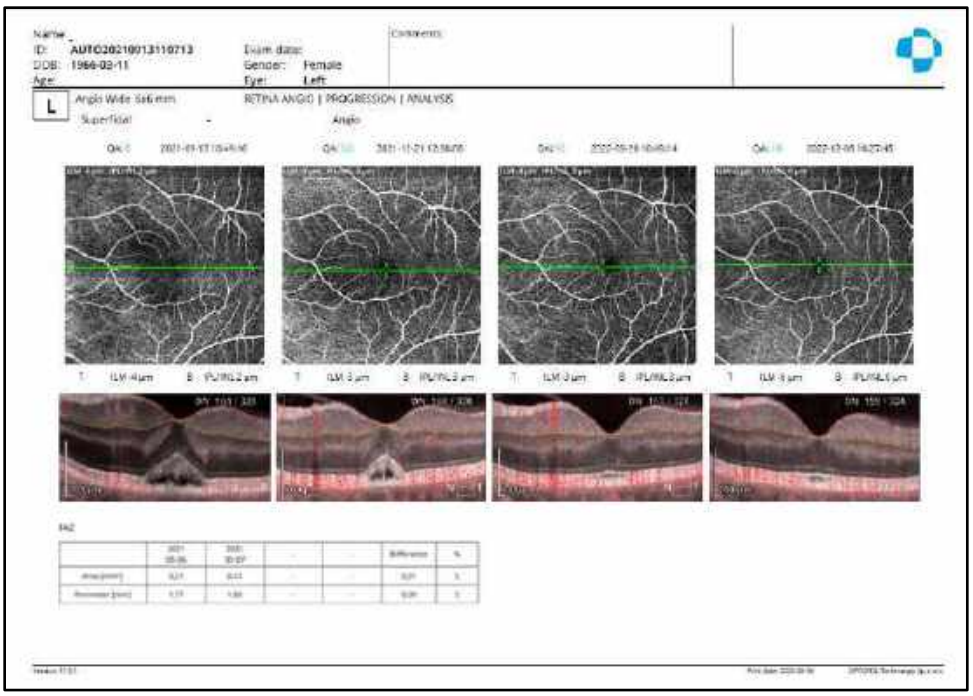


Figure 238.
Examination Report for Angiography (Progression Analysis View)

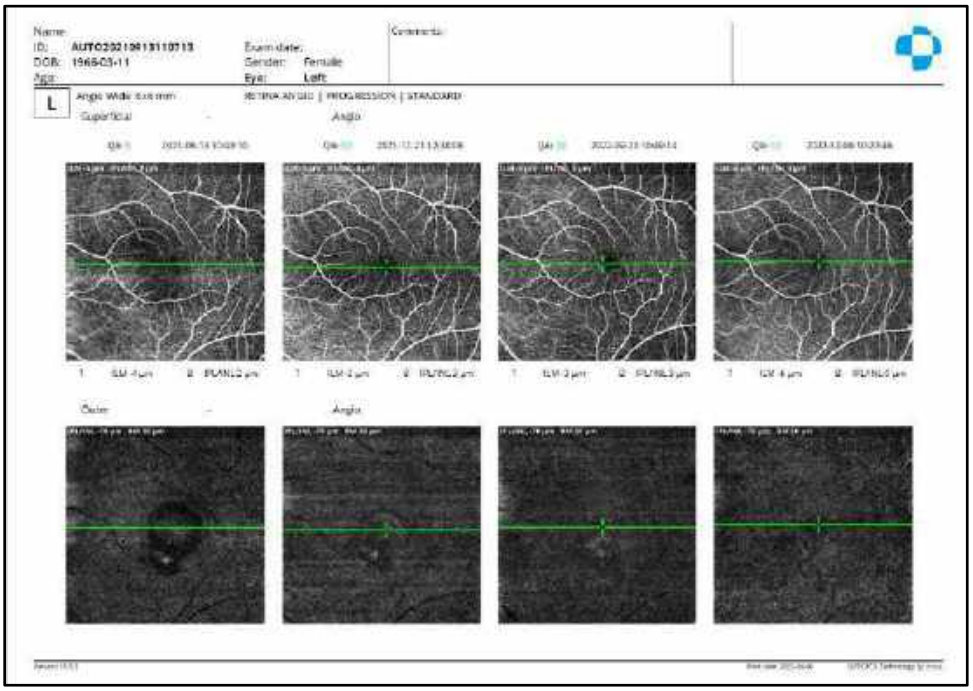


Figure 239.
Examination Report for Angiography (Progression Standard View)

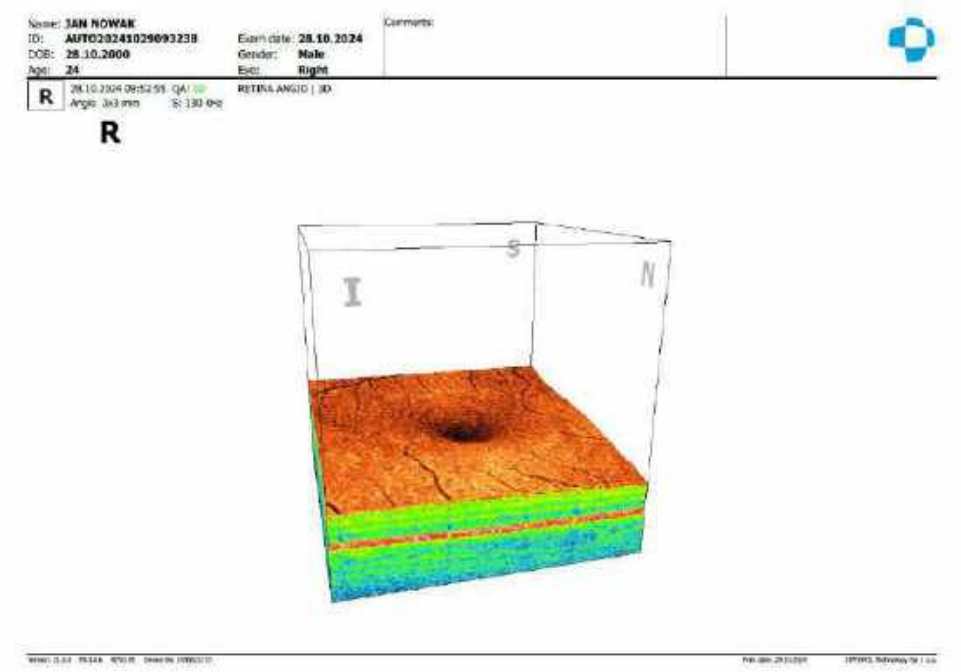


Figure 240.
Examination Report for Angiography (3D View)

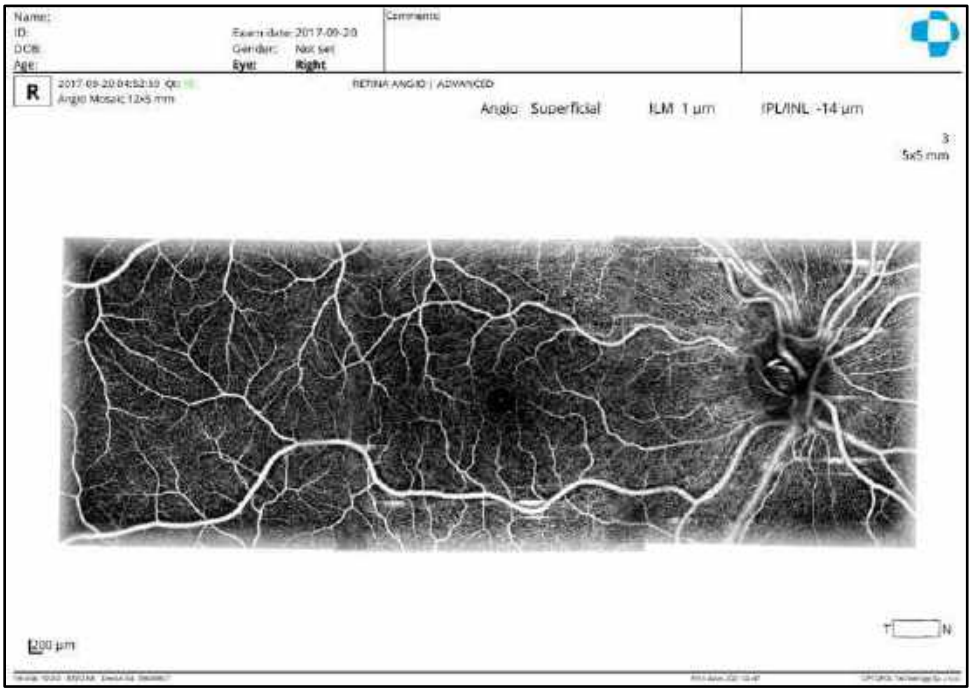


Figure 241.
Examination Report for Angiography 12x5 Mosaic VO View

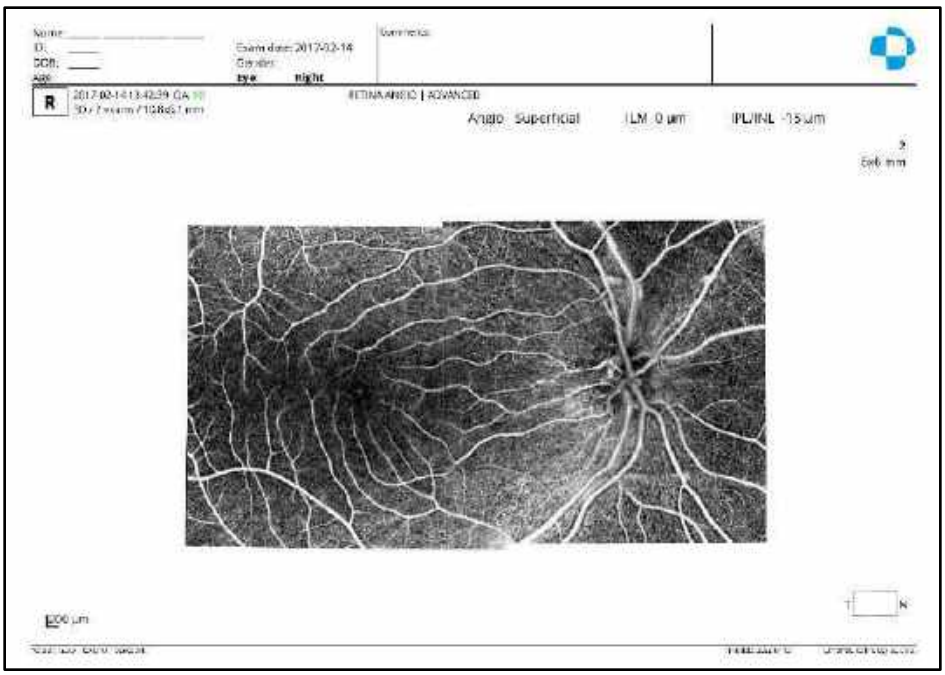


Figure 242.
Examination Report for Retina/Disc Angio Mosaic 10x6 VO View

14.4. Disc OCT-A Examination Reports

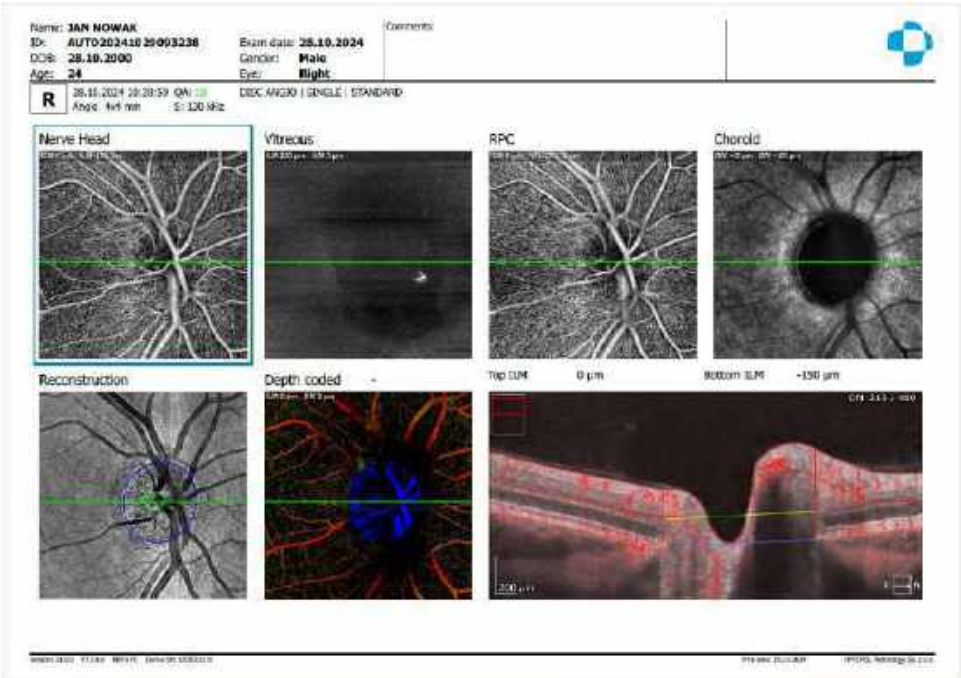


Figure 243.
Examination Report for Disc OCT-A (Single Standard View)

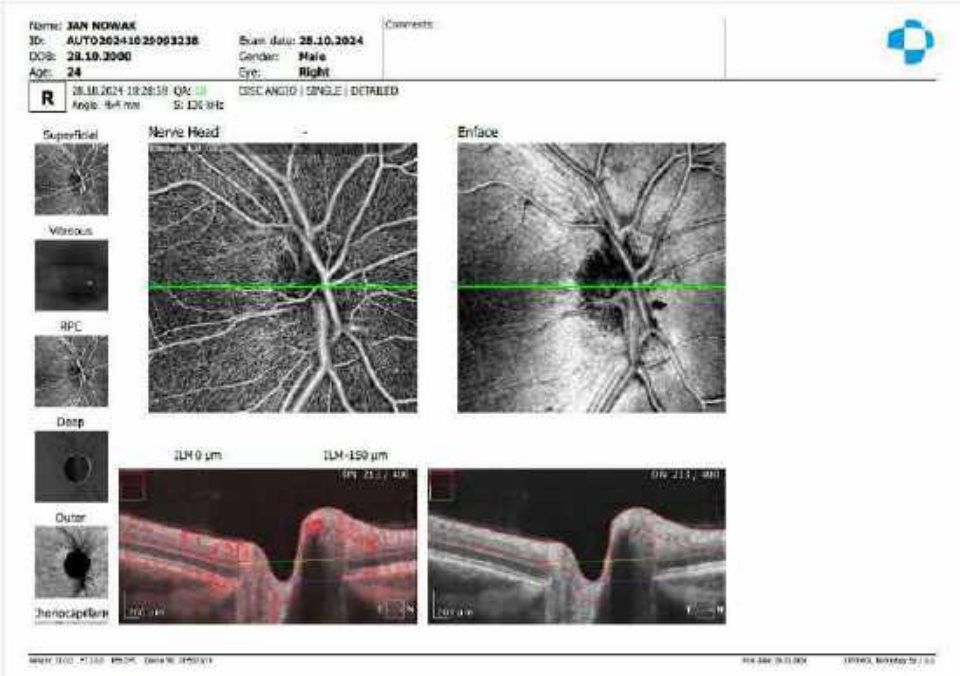


Figure 244.
Examination Report for Disc OCT-A (Single Detailed View)

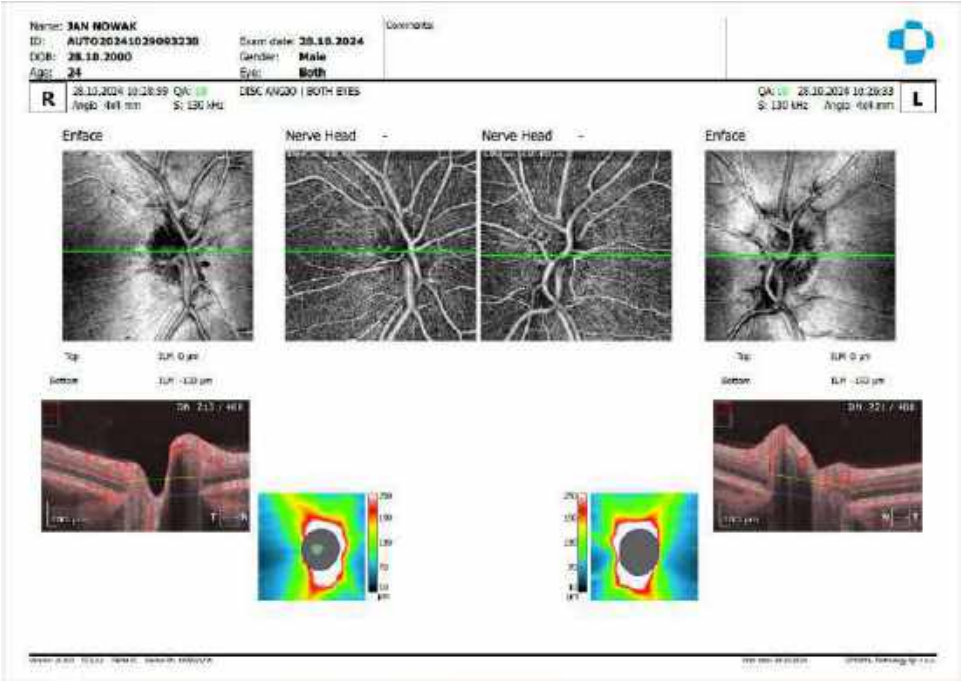


Figure 245.
Examination Report for Disc OCT-A (Both View)

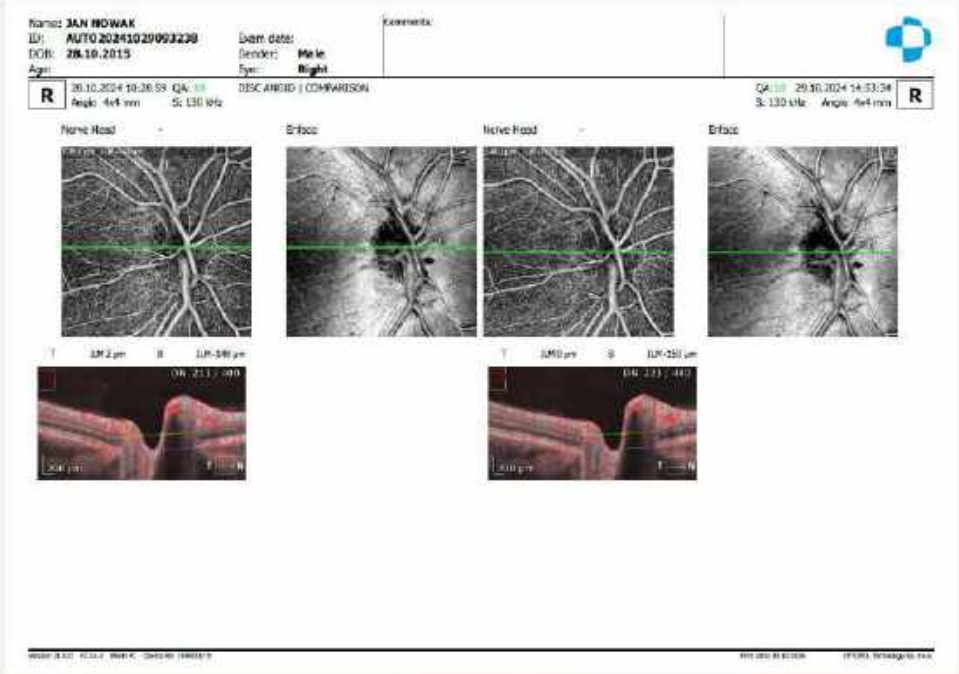


Figure 246.
Examination Report for Disc OCT-A (Comparison View)

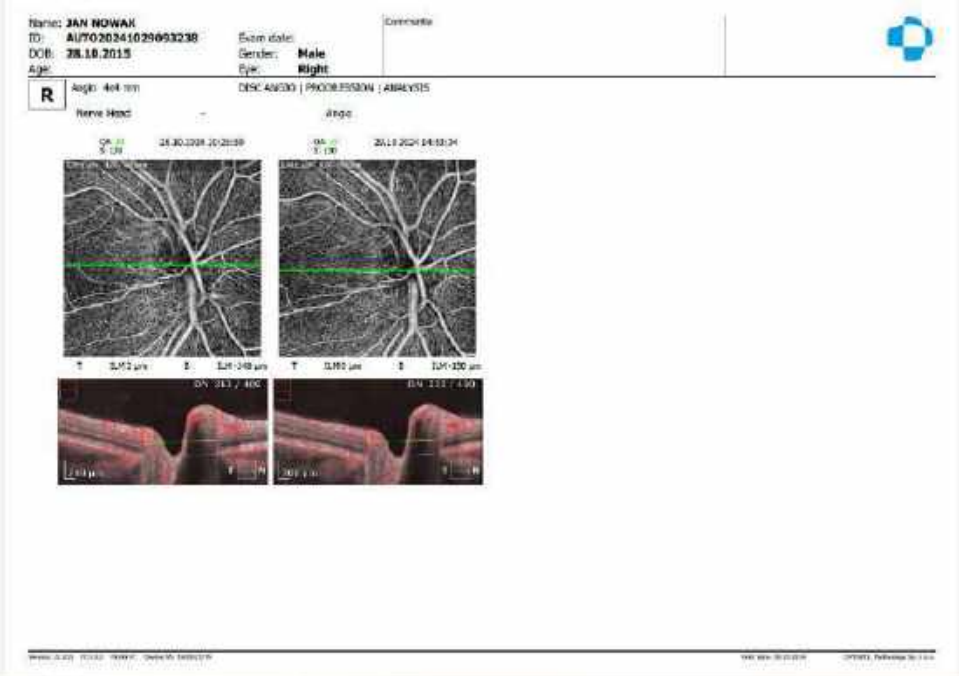


Figure 247.
Examination Report for Disc OCT-A (Progression Analysis View)

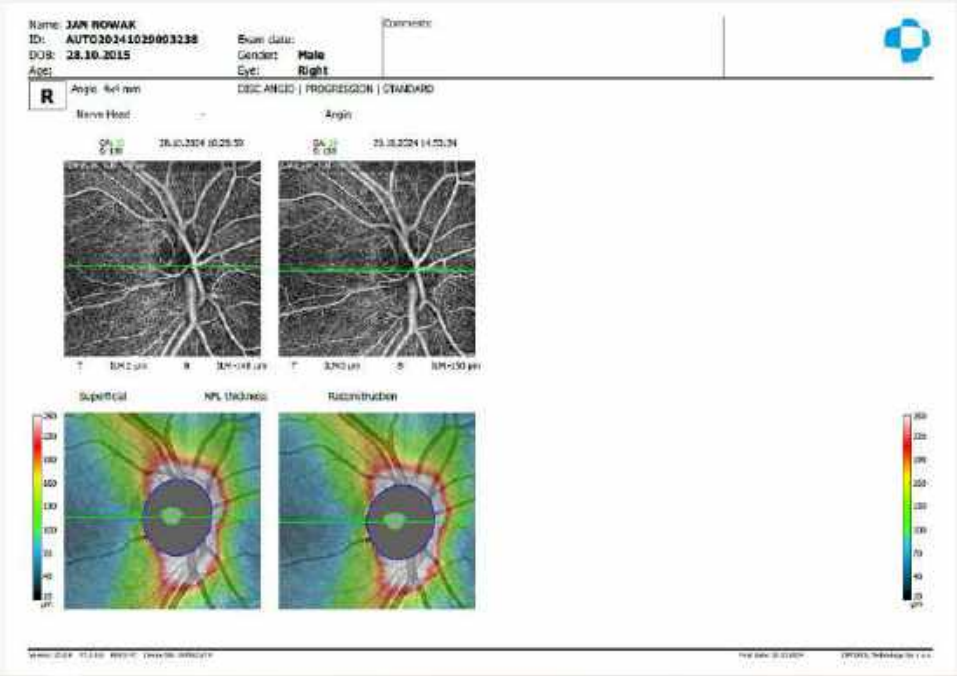


Figure 248.
Examination Report for Disc OCT-A (Progression Standard View)

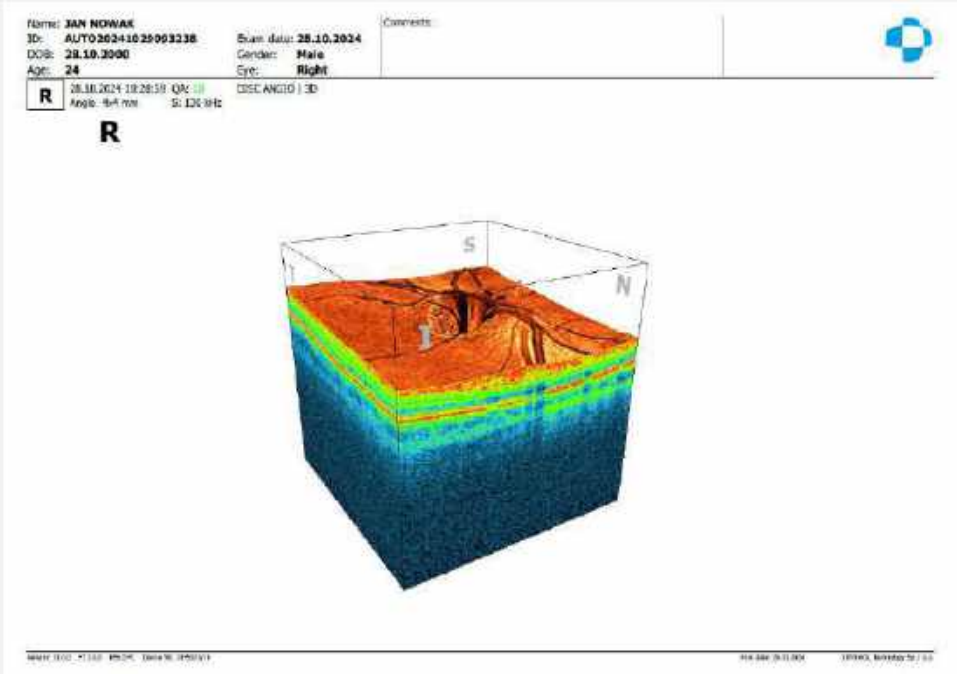


Figure 249.
Examination Report for Disc OCT-A 3D (Volume View)

14.5. Topography Examination Reports

14.5.1. Topo View

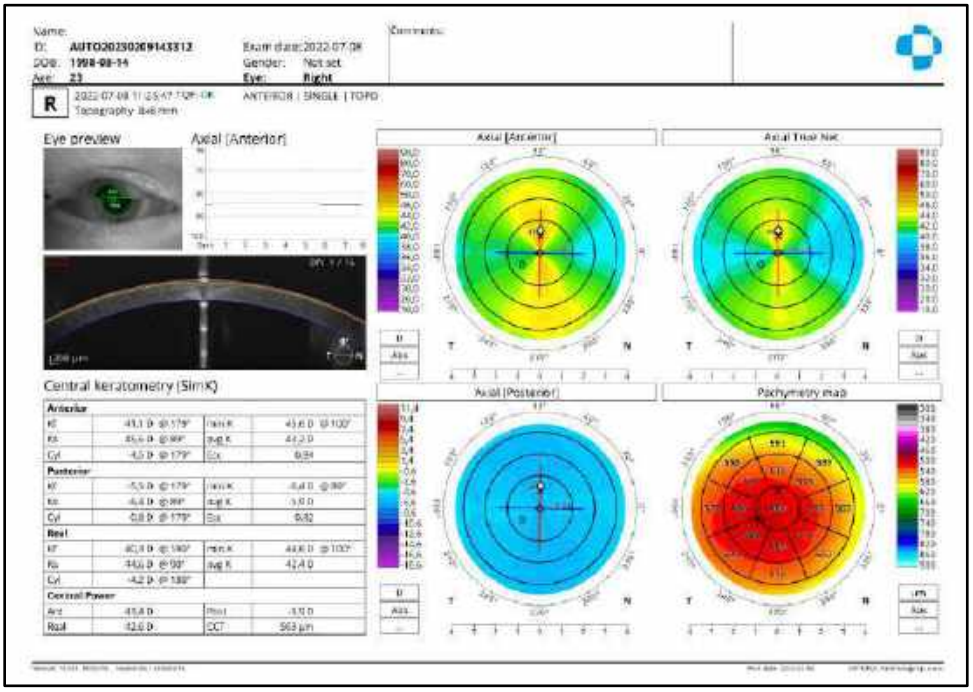


Figure 250.
Examination Report for Topography (Single Topo View)

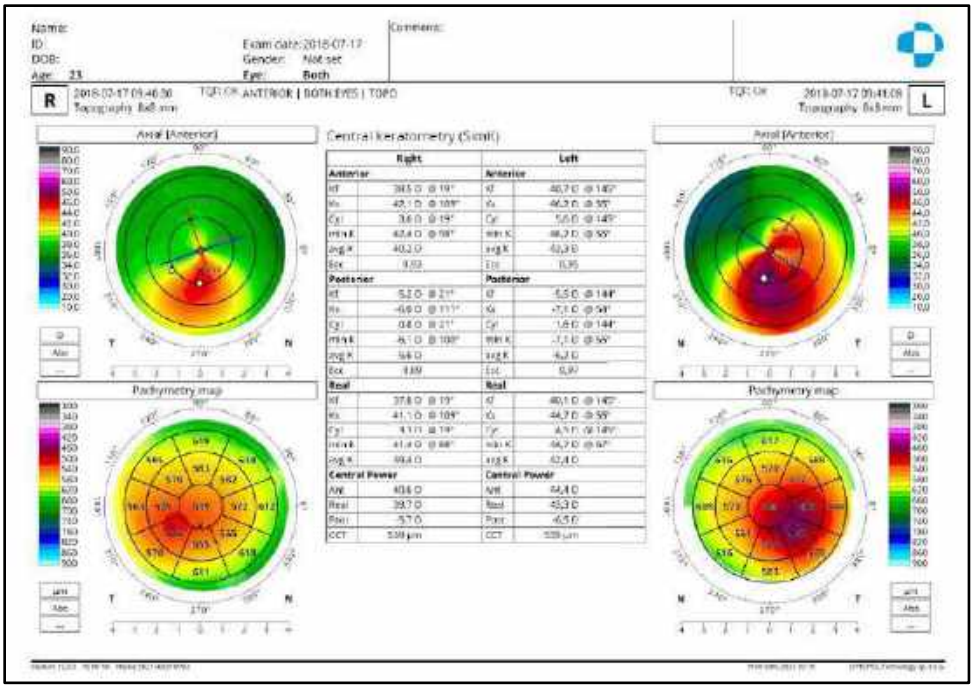


Figure 251.
Examination Report for Topography (Both Topo View)

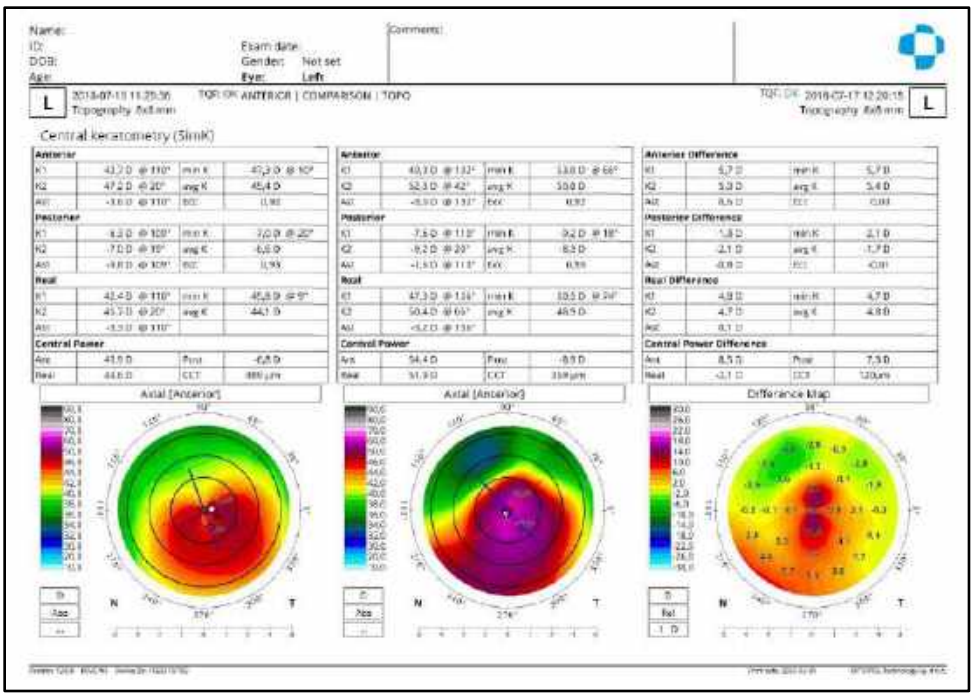


Figure 252.
Examination Report for Topography (Comparison Topo View)

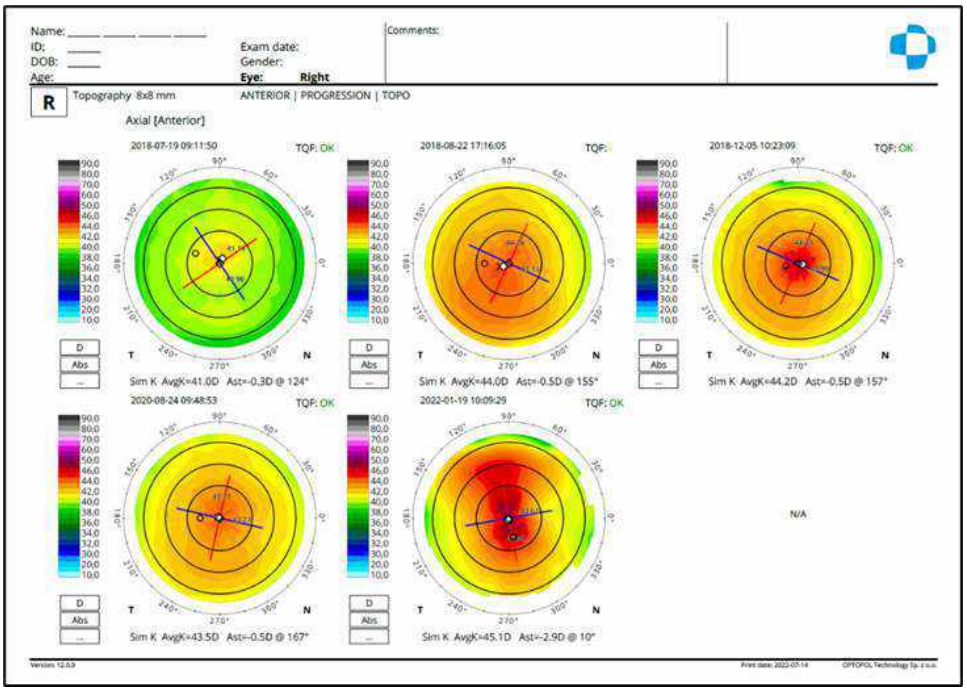


Figure 253.
Examination Report for Topography (Progression Topo View)

Figure 254.
Examination Report for Topography (Progression Tomograms View)

14.5.2. Pachy View

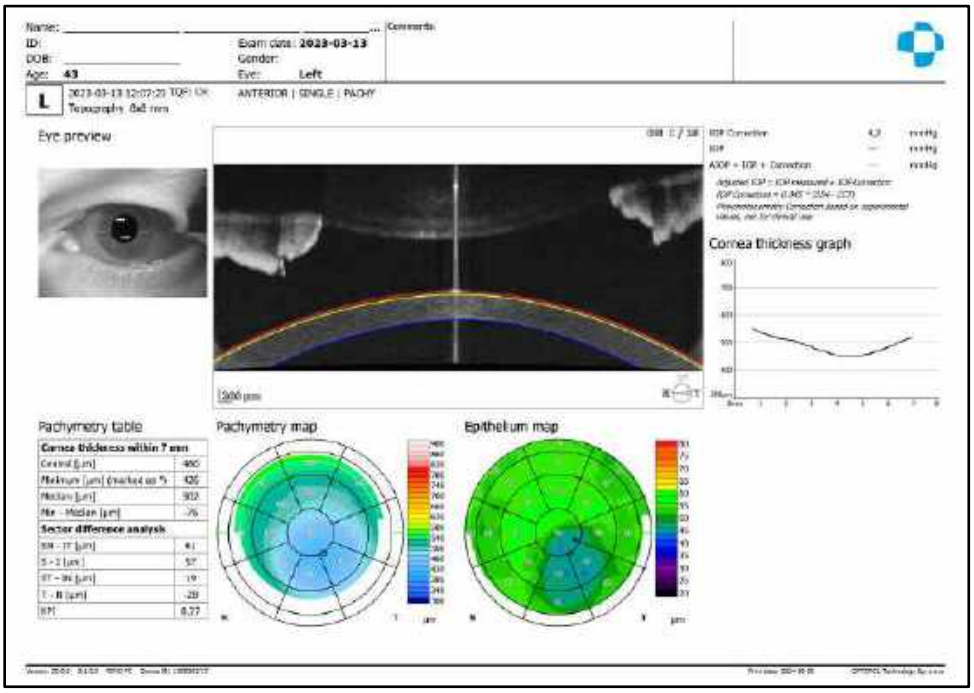


Figure 255.
Examination Report for Topography (Single Pachy View)

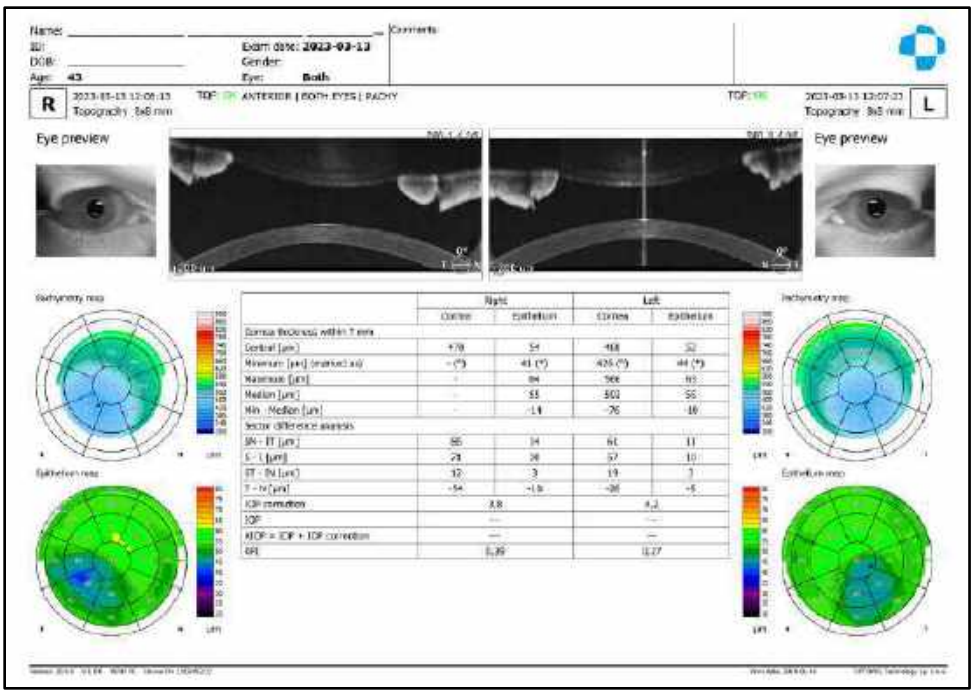


Figure 256.
Examination Report for Topography (Both Pachy View)

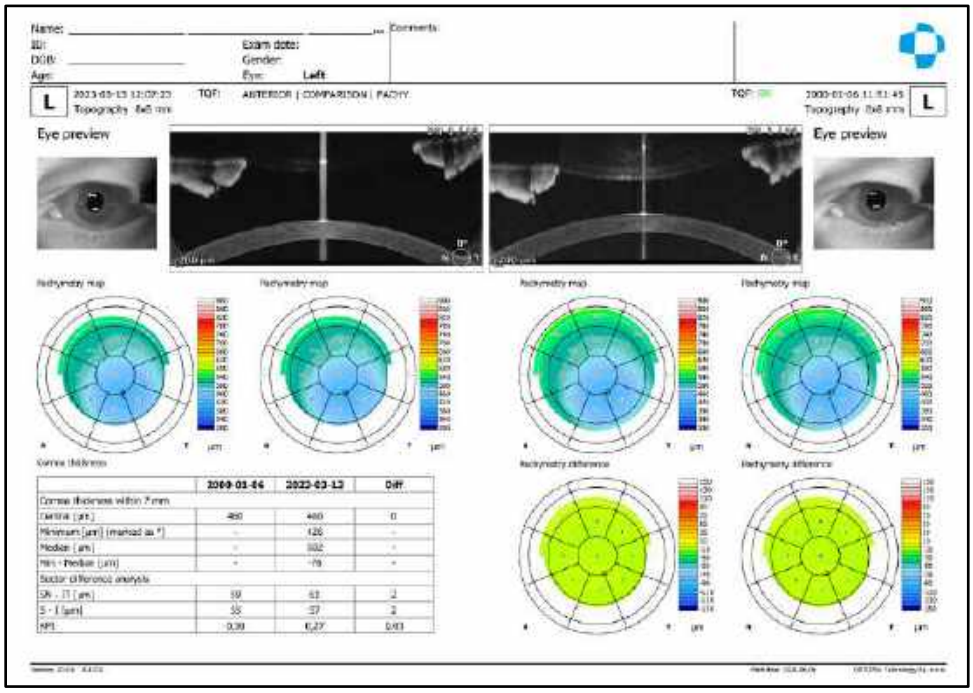


Figure 257.
Examination Report for Topography (Comparison Pachy View)

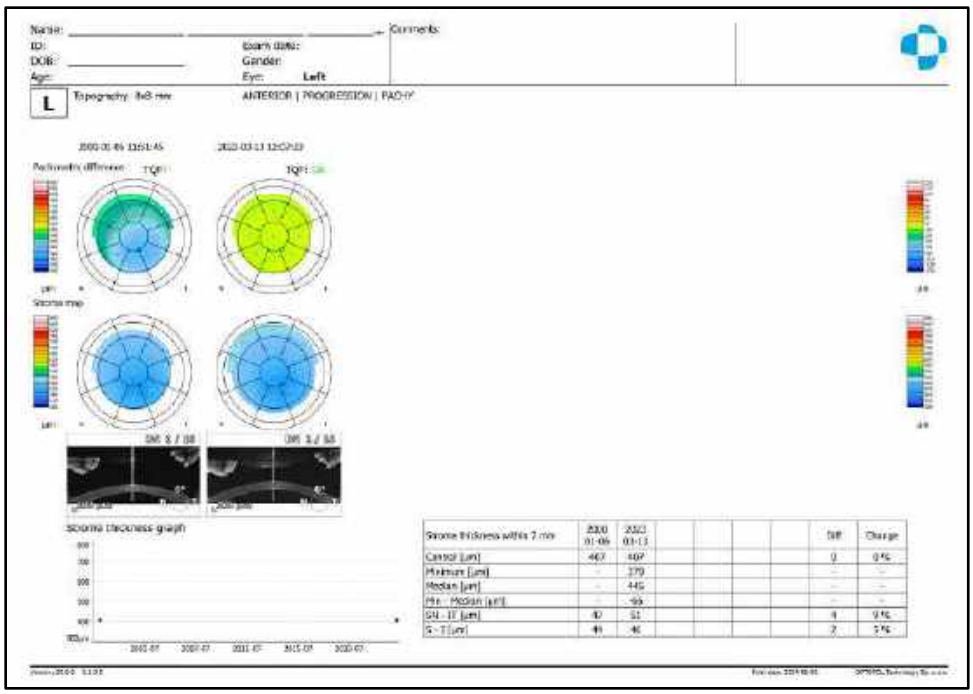


Figure 258.
Examination Report for Topography (Progression Pachy View)

14.6. Biometry Examination Reports

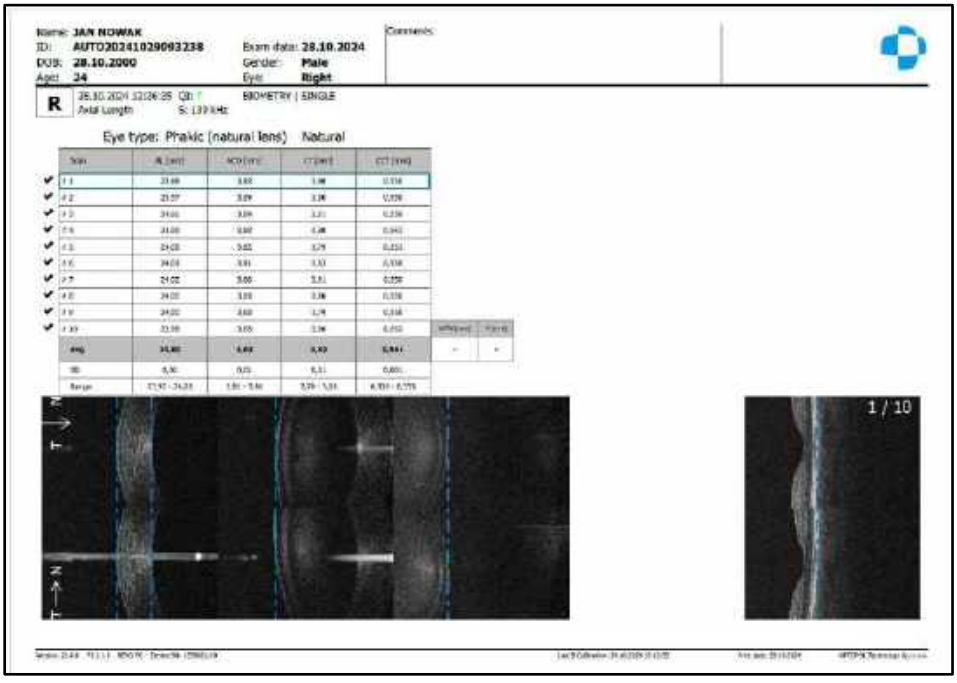


Figure 259.
Examination Report for Biometry (Single View)

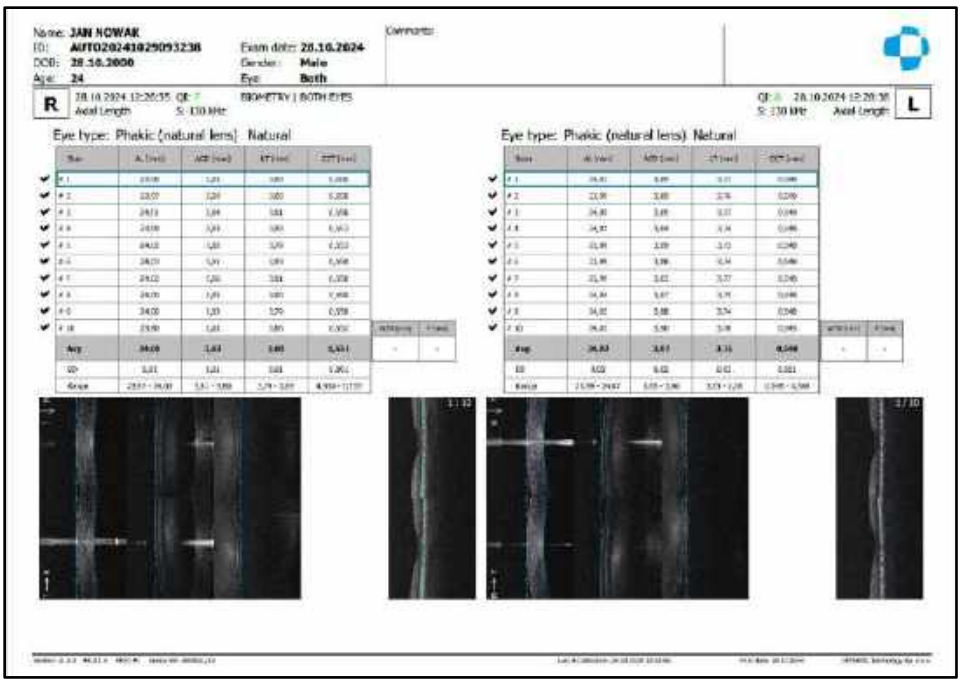


Figure 260.
Examination Report for Biometry (Both View)

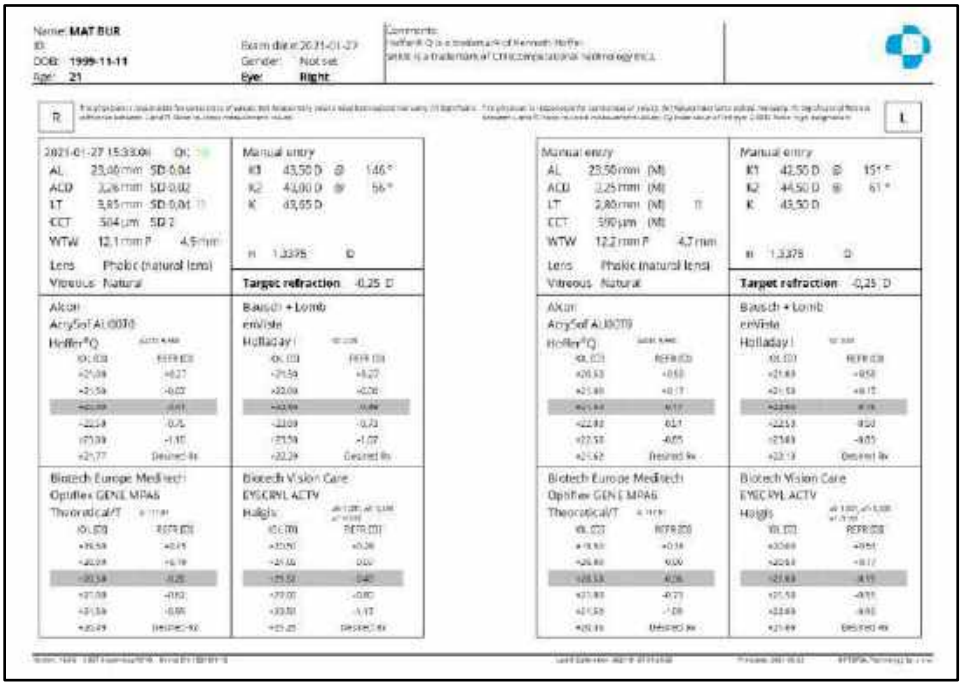


Figure 261.
Examination Report for IOL Calculation

Figure 262
Examination report for Myopia Forecast

14.7. Multi B-Scan Report

The Multi B-scan procedure allows the user to print 4 tomograms on one printout. Press v on the **[PRINT]** button and select Multi B-scan from menu. The REVO places four tomograms on printout. Tomograms can be automatically selected by the system or by the user.

Tomograms are added to the multi B-scan printout buffer on the first in, first out basis.

New Multi B-scan acceptance window allows the user to verify, save, output and print Multi B-scan reports. The Multi B-scan acceptance window appears after selecting Multi B-scan from the menu.

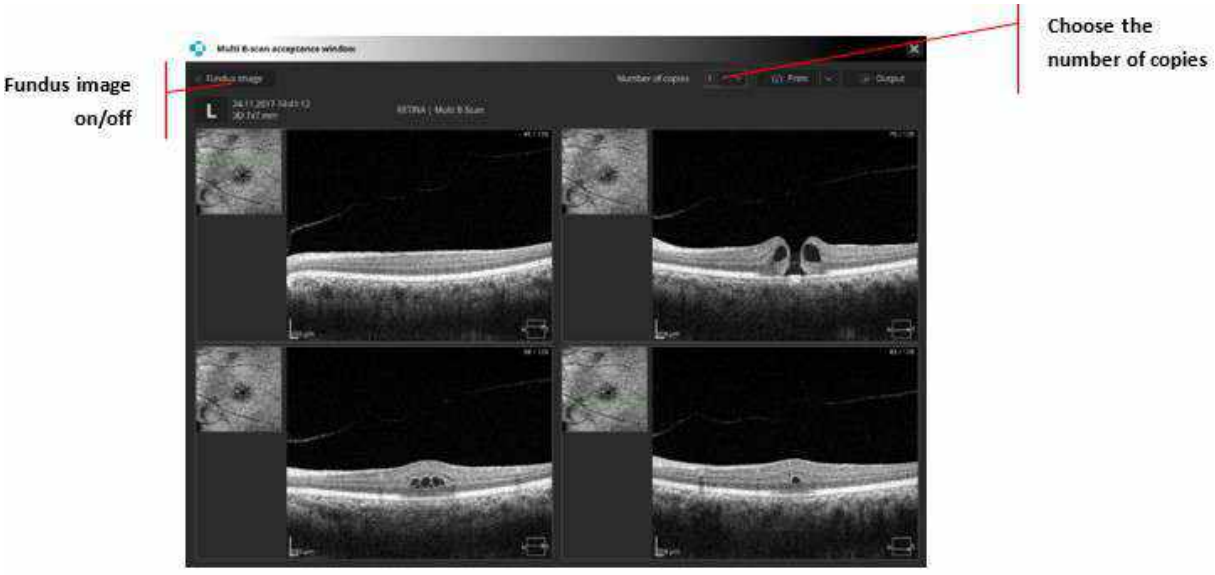


Figure 263.
Multi-B-Scan Acceptance Window

14.7.1. Manually Select Tomograms

It is possible to select tomograms individually for the Multi B-scan report. To select the desired tomogram for the Multi B-scan printout, press Right-click and select 'Add to printout' from the menu or hold the **CTRL** key and Left-click anywhere in a printout preview. On the tomogram, in the right-top corner, the letter P will appear. If more than 4 tomograms are selected, the last selected tomogram replaces the first selected tomogram. Press P on the tomogram to unselect the tomogram from the Multi B-scan printout.

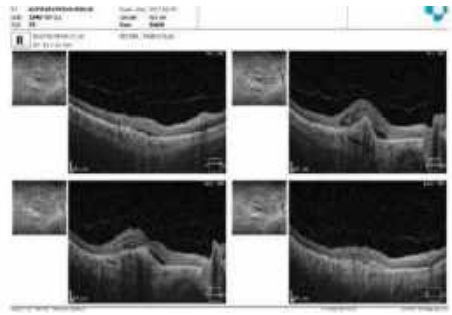
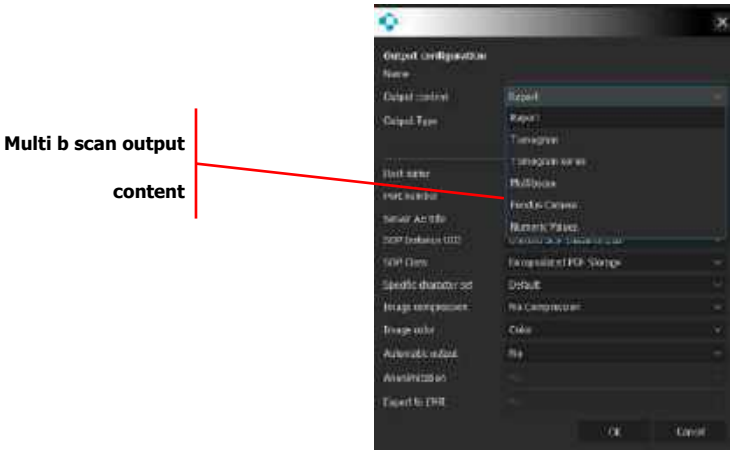


Figure 264.
Multi B-Scan Report

14.7.2. Multi B-Scan Report for Both and Comparison View

Figure 265.
Multi B-Scan Report for Both Eyes and Comparison View

The Multi B-scan report output settings are available in the SETUP / Preference / Output settings window. For more information, see Chapter 23.7.1 Output Set Window.



14.8. Single Tomogram Report

To print one tomogram on the page, go to the full screen view (double click on the tomogram window) and press the Print button.

Figure 266.
Single Tomogram Printout

14.9. Color Fundus Photo Examination Reports

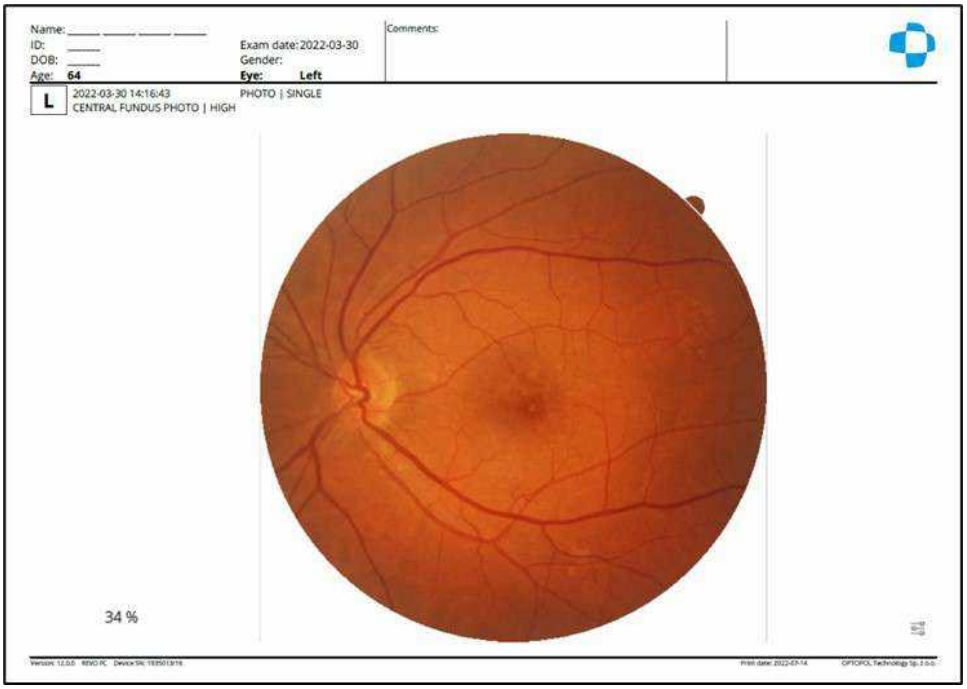


Figure 267.
Examination Report for Fundus (Single View)

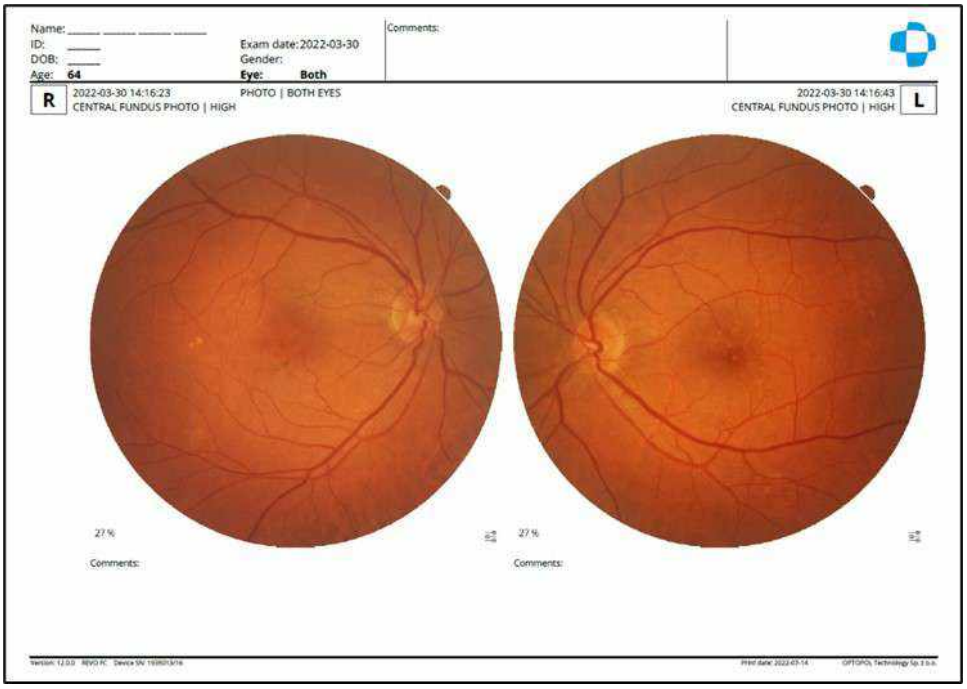


Figure 268.
Examination Report for Fundus (Both View)

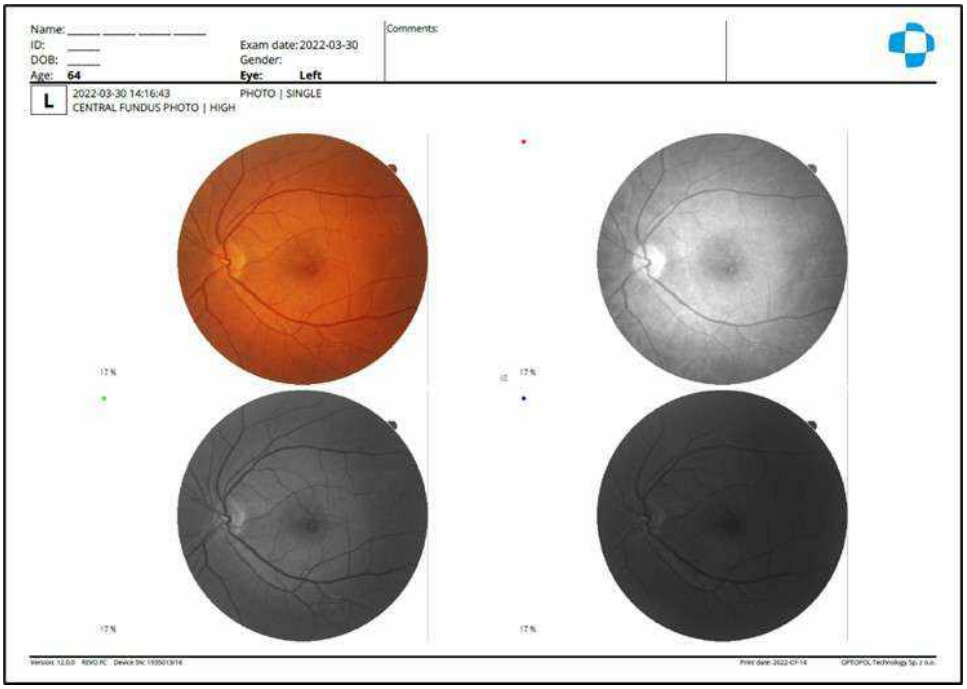


Figure 269.
Examination Report for Fundus (Single View x4)

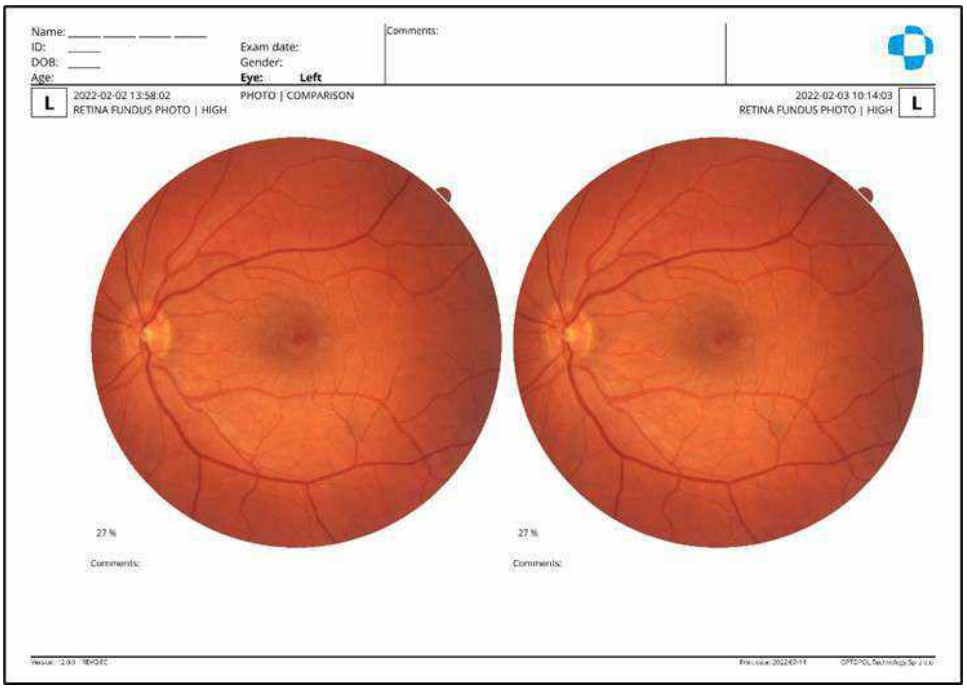


Figure 270.
Examination Report for Fundus (Comparison View)

14.10. Select the Desired Printer

It is possible to select the desired printer before printing. Press “v” on the Print button and **[SELECT PRINTER AND PRINT]** option from the list. Choose the desired printer and press the **[OK]** button.

15.
Output

The output function allows the user to save the examination results in several ways. When the output set is not created, the system saves the report to the file. When a set is created, the output window appears after pressing print. The user can select the desired set(s) and then press **[OK]**. When the set is marked, the output examination data are displayed on the right. If the Automatic output setting is set to **[WHEN PRINTING]**, the system saves the output when the user presses **[PRINT]** button.

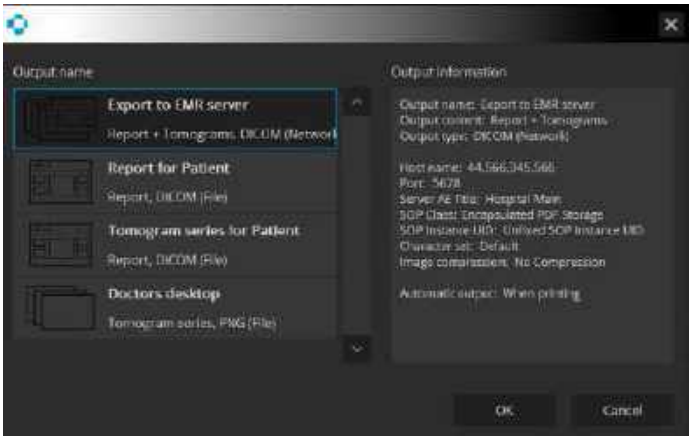


Figure 271.
Output Screen

The user can define the output sets. This makes it possible to specify the kind of data (tomogram, series of tomograms, reports, or tomogram plus report), location of saving data, the type of data (graphic format or SOP class) and moment of exporting. The Output function can be sent to the DICOM, EMR server, or to any other specified location.

More details on how to define output sets can be found in Chapter 23 Settings and Setup Window.

16.
Importing / Linking Color Fundus Image to the OCT Exam

Fundus images captured by another device such as an SLO or retinal camera can be imported to the REVO exam and shown instead of the fundus reference image (Fundus reconstruction / IR / pSLO). A fundus image may be overlaid onto any REVO retinal OCT exam to display the scan position on the fundus image.

Available image formats include *.png, *.tiff, *.jpeg, *.gif, *.bmp and *.jpg. When a fundus image is imported into a patient file, the image is added to the visit as separate exam or can be displayed as a reference image instead of fundus reconstruction.

The **right-click** context menu is available in the following views:

1. Retina 3D
2. Retina Raster
3. Retina Raster 21
4. Retina Line
5. Retina Cross
6. Retina Radial
7. Retina Angio
8. Disc Radial
9. Disc Raster
10. Disc Angio
11. Widefield 3D
12. Widefield Raster
13. Widefield Line
14. Widefield Radial

15. Ultra-Wide Field Line
16. Ultra-Wide Field Radial
17. Ultra-Wide Field 3D
18. Ultra-Wide Field Line Full Range
19. Ultra-Wide Field Radial Full Range

16.1. Import Fundus Image to an Examination

1. **Right-click** on the fundus reconstruction image and select **[IMPORT FUNDUS PHOTO...]** from the context menu.

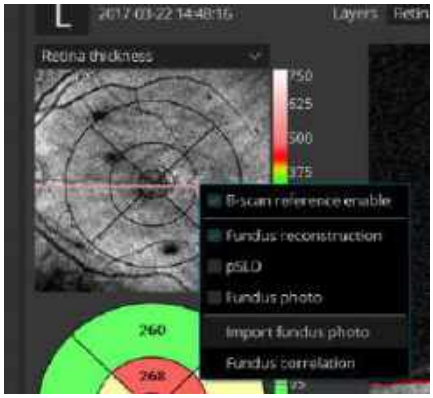


Figure 272.
Context Menu

2. In the window that opens, select a fundus photo to import. Directories from which photos should be displayed can be easily changed in the **[LOOK IN]** field. In case of a directory with many files, use the View selection menu to see previews that can be changed in size. See below.

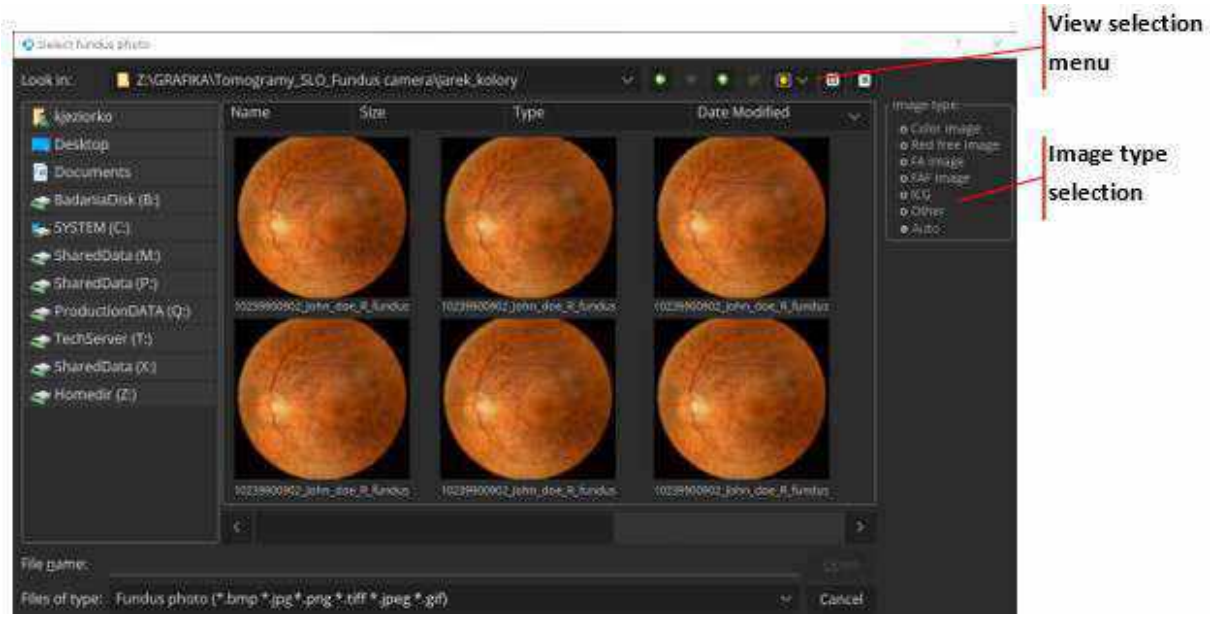


Figure 273.
Fundus Import Selection Screen

3. The user can indicate the type of fundus photo that is to be imported in the **[IMAGE TYPE]** selection field on the right side of the window. Indicating the type of the image allows the system to apply an image-optimized registration algorithm.

4. Once the desired file has been selected, click **[OPEN]**. A Fundus and OCT registration window will now open.

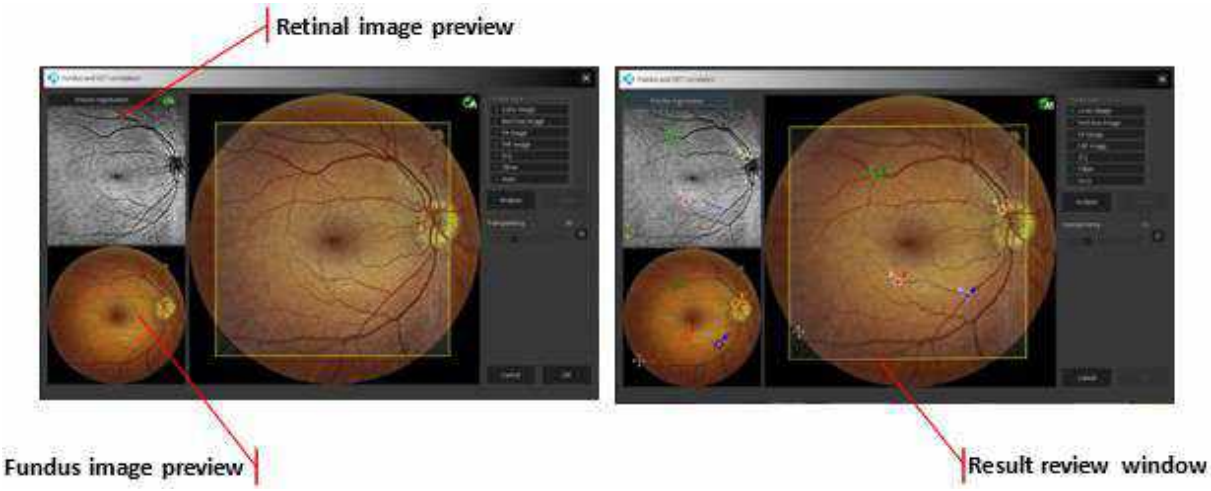


Figure 274.
Fundus Registration before Registration (Left) and Marked after Registration (Right)

In cases in which the automatic registration is not correct, the operator can perform manual registration using the following methods:

1. **COURSE**

   Allows the user to quickly move, change dimension or rotate image:

   - **Change Size (both dimension):** Grab and move the border line.
   - **Change Size X or Y:** Grab the corner of the image.
   - **Rotate:** Grab the corner of the image.

2. **PRECISE REGISTRATION**

   This allows a more precise method to perform manual registration.

Click a minimum of three points and up to five points on both exams.

In the place the markers on any characteristic points of the retina i.e., blood vessels on both fundus (1) and retinal* (2) image previews, right-click anywhere to view more options such as to reset all markers. Use standard controls to zoom and move the previews.

5. Verify whether selected points are placed precisely on both previews. Right-click a point to remove it. Closing the window will not import the photo and will discard any changes. Registration between the imported fundus image and retinal preview may be reviewed by moving the transparency over the result review window (3). Clicking **[OK]** will save the registration and import the fundus photo.

*For Angio OCT scans, the preview can be changed to other vascular layers such as superficial, SVC, depth coded etc. if they are selected in the top left window.

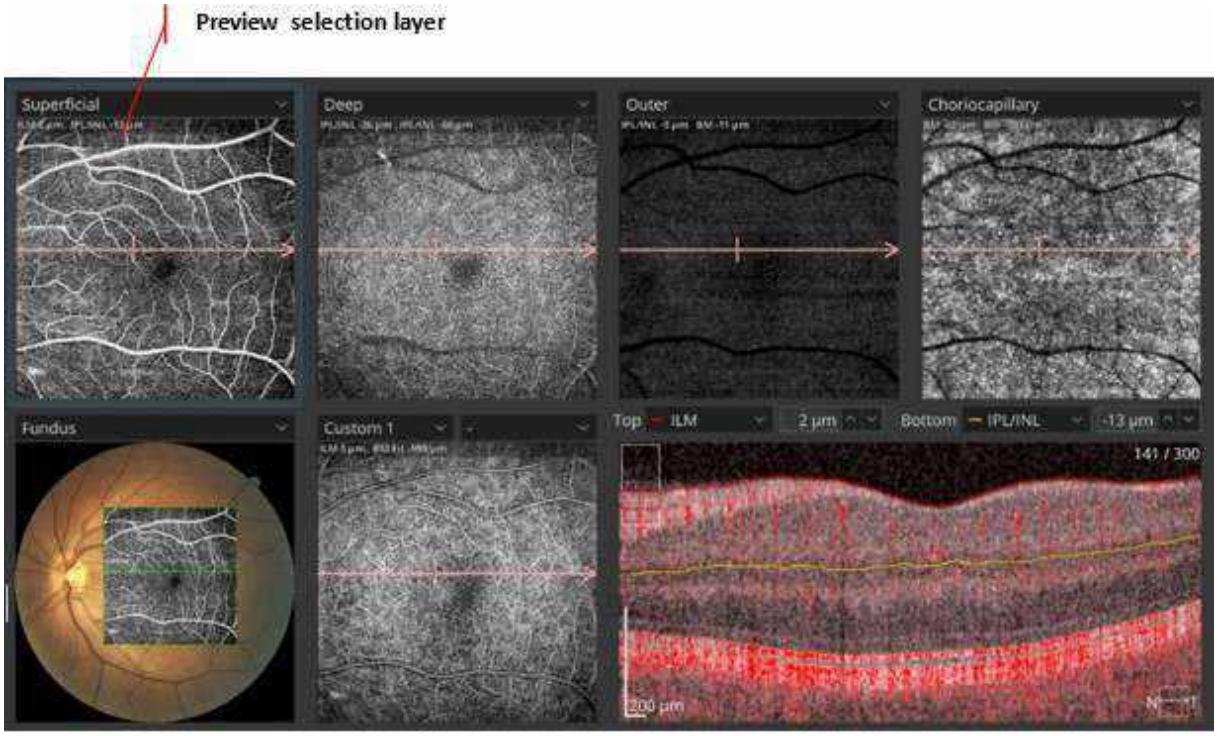


Figure 275.
Vascular Layer Previews

16.2. Linking a Fundus Photo to an Examination

The user can link a single fundus photo to several OCT exams. Every OCT exam can be linked to only one photo. It is always recommended to perform this operation to reduce the number of photos per eye.

To link a photo to an exam, click the right mouse button on the reconstruction image to open the context menu as shown below. Choose **[LINK EXAMINATION]**.

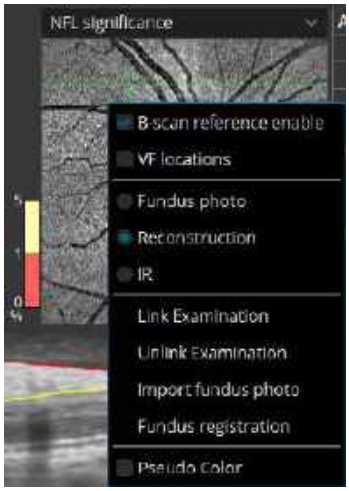


Figure 276.
Context Menu

A list of available photos that can be used for linking opens. If the user marks the **[NG]** checkbox, all available photos, including the ones with an NG status, are listed. To go to the Fundus and OCT registration window, double click on a selected image.

Figure 277.
Fundus Photo Selection for Linking with an Examination

16.3. Fundus Image Registration

Right-click on the fundus reconstruction window. From the context menu, select **[FUNDUS REGISTRATION]** option.

The Fundus registration screen will open. To correct the position, proceed as described in Chapter 16.1 Import Fundus Image to an Examination.

17.
Examinations Registration

17.1. OCT-OCT Registration

The SOCT software automatically correlates examinations by matching the unique blood vessel pattern. If the operator uses artifact-free examinations for analysis, then the dense scanning provides enough data for precise overlays which eliminate X, Y and rotation shifts between compared examinations. When the above conditions are met, then this function serves as post processing tracking.

Exams with artifacts can be marked by the operator as not good – NG examination status appears on the scan. Exams with NG status are not included in any analysis (e.g., comparison, progression, etc.).

17.1.1. Automatic Registration

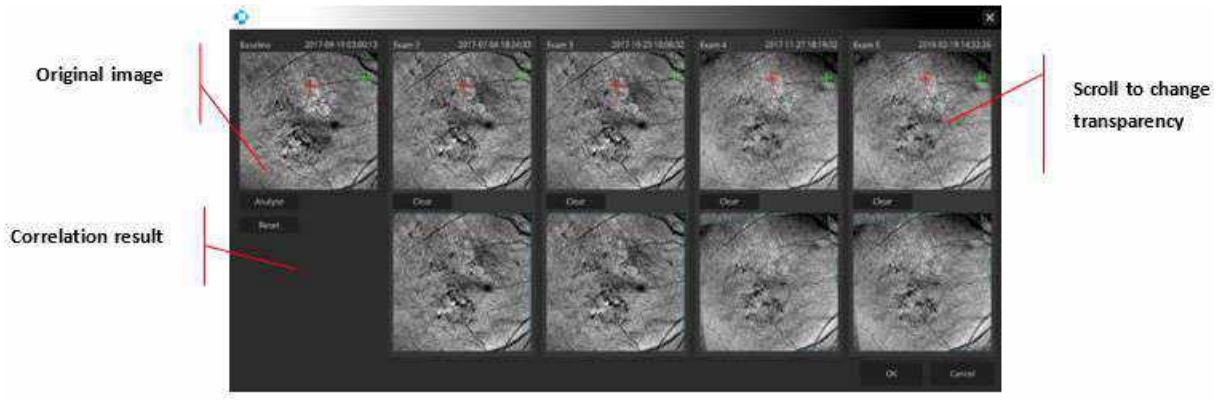


Figure 278.
The Result of OCT Registration

The system displays registration status (A - Automatically registration, M - Manually registrated, - Manual registration required). If automatic registration is not possible, the system displays the status “Registration failed”. To verify automatic registration or to correlate exams manually, Press the **[REGISTRATION]** button. The results are displayed on a pop-up screen, as shown above.

In this screen, images in the top row are the original fundus reconstruction images. The bottom images are results images. The reconstruction images from each examination that has been registered are overlaid on the baseline exam.

Registration accuracy between the exams and the baseline can be verified. Place the mouse cursor over one of the results images and scroll the mouse wheel to change the transparency.

17.1.2. Manual Registration

If the examinations cannot be automatically registered, the user can align and register the data manually. Place each point marker on any characteristic points of the retina (e.g., characteristic retina blood vessels) that appear in baseline and registered scans. It is required to select from two to five corresponding points on the baseline image and compared examination image by using the mouse.

Use the mouse scroll as needed to change the transparency of the Exam Image overlayed on the Baseline Image. Changing the transparency allows visual confirmation of alignment of blood vessels and other features of the two exams.

To return the registration to the original settings, press the **[RESET]** button.

If the positioning of the points is not satisfactory, delete the selected points by right-clicking over the desired marker. To delete all markers, press **[CLEAR]** and make new point selections.

It is possible to correct the marker position. Press and hold the left mouse button and drag the point to desired position. Corresponding markers on other images highlight during dragging.

To bring up automatic registration, press **[ANALYZE]**.

To see the final registered image, move the transparency slider over the result object. If the resulting overlay is satisfactory, select **[OK]**. To reset the values to the original registration, click **[CANCEL]**.

17.2. Fundus Photo Registration

The REVO SOCT software can automatically register fundus photographs with OCT examinations by recognizing patterns in the shape of vessels. To open the Fundus and OCT Registration window, click the right mouse button on a reconstruction image or a fundus photo and choose **Fundus registration** from the drop-down menu.

17.2.1. Automatic registration

To perform automatic registration, choose the type of the image in the **Image type section** and click **[ANALYZE]**. The result of the registration will be shown in the registration preview. If automatic registration is not possible, the system displays the symbol  meaning that manual registration is required. If the Image type is set to Auto and the result of the registration is not satisfactory, the user can indicate the image type manually to further optimize the performance of the algorithm. If the result of the automatic registration is still not acceptable, the user can perform manual registration. This procedure is described in Chapter 17.2.2 Manual Registration.

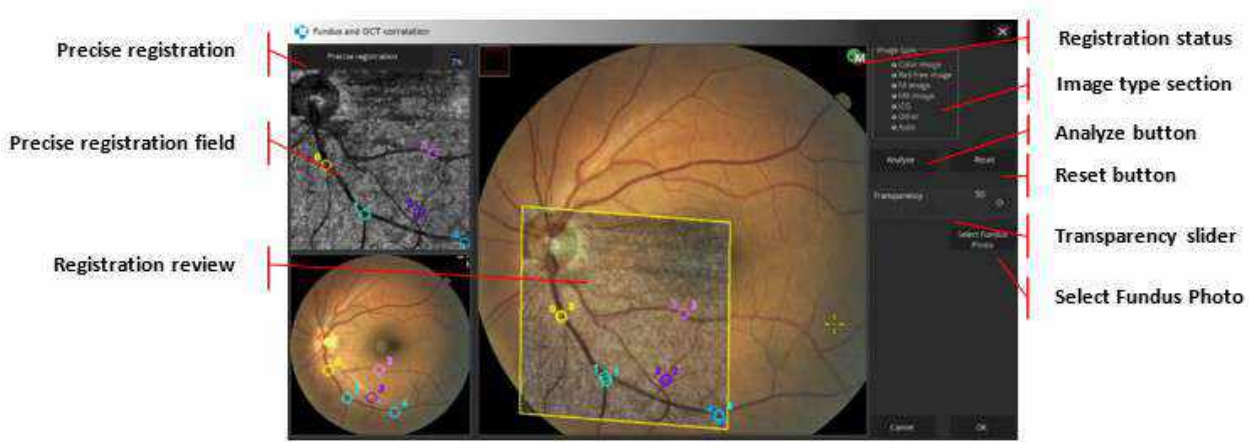


Figure 279.
Fundus and OCT Registration Window

1. **PRECISE REGISTRATION**

   Activates the precise registration field for manual registration.

2. **PRECISE REGISTRATION FIELDS**

   In this field, the user can manually correlate the fundus photo with the OCT image. To do this, place markers on any characteristic points of the retina such as blood vessels on both the fundus and the OCT image. Right-click anywhere to view more options.

3. **REVIEW WINDOW**

   Shows the result of automatic registration and allows the user to correct it manually. The OCT image is overlaid on the fundus image with 50% transparency. The level of transparency can be changed with the **Transparency slider**.

4. **REGISTRATION INDICATORf**

   Indicates the status of registration with three icons:

	Automatic Registration completed successfully.
	Unable to complete Automatic Registration.
	Manual Registration complete.

5. **IMAGE TYPE**

   Allows the user to indicate the type of imported image used to optimize the performance of the registration algorithm.

6. **ANALYZE**

   Software attempts to perform automatic registration.

7. **RESET**

   Rejects all actions performed by the operator and restores the initial state of the registration window.

8. **TRANSPARENCY SLIDER**

   Allows the user to adjust the level of transparency of the OCT image overlaid on the fundus photo from 0% to 100%. Transparency can also be adjusted by scrolling over the result preview section.

9. **SELECT FUNDUS PHOTO**

   Allows the user to select a fundus photo for registration.

10. **OK**

    Clicking **[OK]** closes the window and saves the result of the registration with changes introduced by the user.

11. **CANCEL**

    Clicking **[CANCEL]** closes the window without saving changes.

ADDITIONAL OPTIONS

For more options, click the right mouse button over the **Precise registration** field or **Registration preview** to open the following context menu:

1. **REMOVE POINTS**

   Removes all markers form the Precise registration field and Registration preview.

2. **RESET ZOOM**

   Restores the original zoom.

3. **RESET ALL**

   Removes all markers and restores the original zoom.

4. **RESET BRIGHTNESS / CONTRAST**

   Resets brightness and contrast to default levels.

17.2.2. Manual Registration

If the result of automatic registration is not satisfactory, it can be manually corrected. To enter manual mode, click **[PRECISE REGISTRATION]**. Place markers on any characteristic morphological structures such as blood vessels on the OCT image. Then place markers on the fundus image by replicating the positions of markers on the OCT image. When the first pair of corresponding points is set, the preview image changes to show the current state of registration. Continue adding markers until accurate alignment is achieved. The results can be further fine-tuned in the result preview by moving individual points.

Use the mouse scroll as needed to change the transparency to see more of the OCT or fundus image. By scrolling the mouse wheel back and forth, alignment of blood vessels and other features can be verified with identical features in the other image.

To return the registration to the original setting, press **[RESET ALL]** in the context menu.

If the positioning of the points is not satisfactory, delete a selected point by right-clicking over the desired marker. To delete all markers, choose **[CLEAR ALL MARKERS]** from the context menu.

17.2.2.1. Coarse Manual Registration

When registering a fundus image, a user can quickly match and register an OCT preview image with a color fundus image using “coarse manual registration”. With this method a user can manually stretch, move, and rotate the OCT image over the fundus photo until the vessel pattern matches. To stretch the OCT image, place the mouse cursor over any of the edges of the image or on the corner. The cursor icon will change into a double ended arrow ⟺ indicating the direction of stretching. Press and hold the left mouse button and drag the edge of the image until the desired length is achieved. Similarly, to rotate the image, place the cursor over any corner of the image. The cursor icon will change into a bent arrow  . Press and hold the left mouse button to rotate the image.

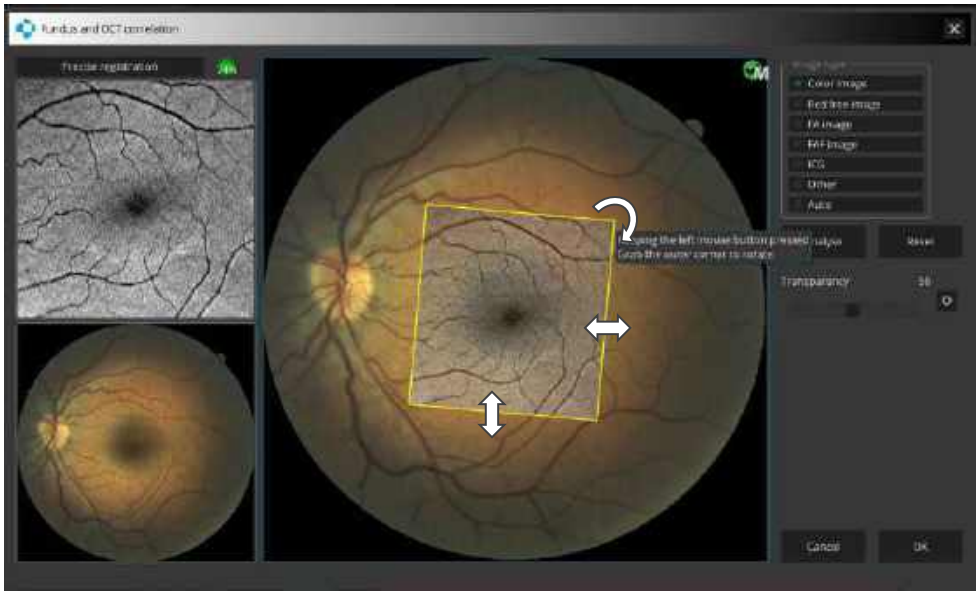


Figure 280.
Registration Screen with Arrows Indicating the Direction of the Manipulation of the Image

17.2.3. Moving the OCT Fundus Image Overlay

DRAGGING THE IMAGE

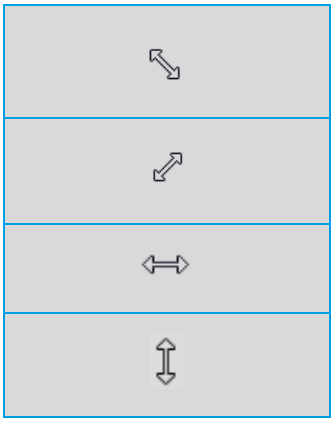
The OCT image overlaid over the fundus photo can be dragged to the desired position by holding the left mouse button and moving the mouse.

ROTATING THE IMAGE

The image can be rotated in relation to its center. To do this, hover the mouse cursor over any of the corners of the image until the cursor changes into the “rotate” sign. Click and hold the left mouse button and rotate the image right or left.

CHANGING THE SIZE OF THE IMAGE

To change the size of the OCT image, hover the cursor over any of the corners of the image until it changes into one of the following symbols indicating the direction of change:



Click and hold the left mouse button and move the mouse to change the size of the image.

17.2.4. Closing Fundus and OCT Registration Window

To exit the window and save the registration results click **[OK]**. Clicking **[CANCEL]** rejects any changes to the images and closes the window without saving the results of the registration.

17.3. Fundus Camera (Result Review)

This functionality is available for fundus camera photos acquired with the REVO FC device or photos imported to the SOCT application from an external device.

17.3.1. Color Fundus Photo ([Single] View x1)

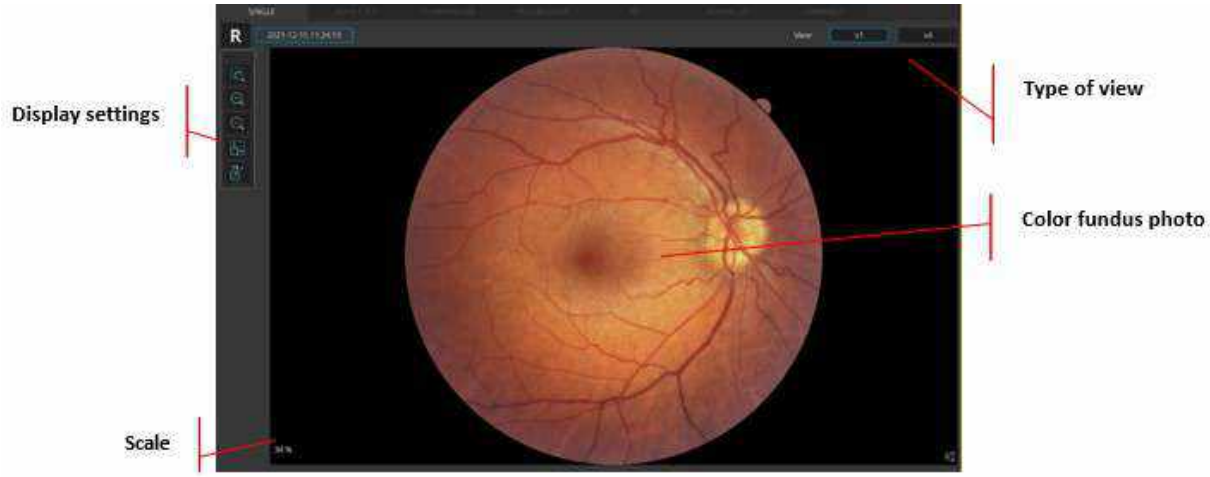


Figure 281.
Single Eye Color Fundus Photo (x1 View)

17.3.2. Color Fundus Photo ([Single] View x4)

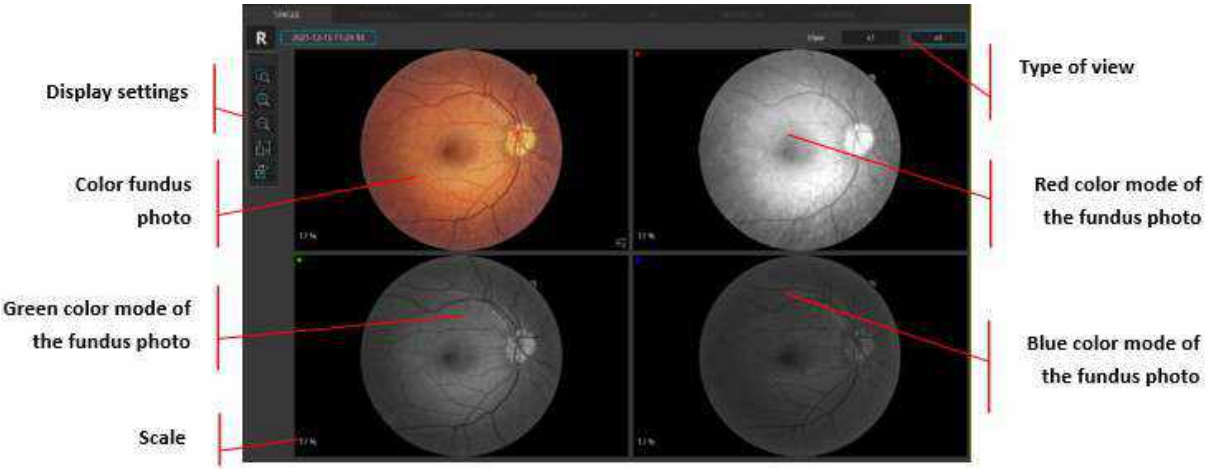


Figure 282.
Single Eye Color Fundus Photo (x4 View)

17.3.3. Color Fundus Photo (Full Screen View)

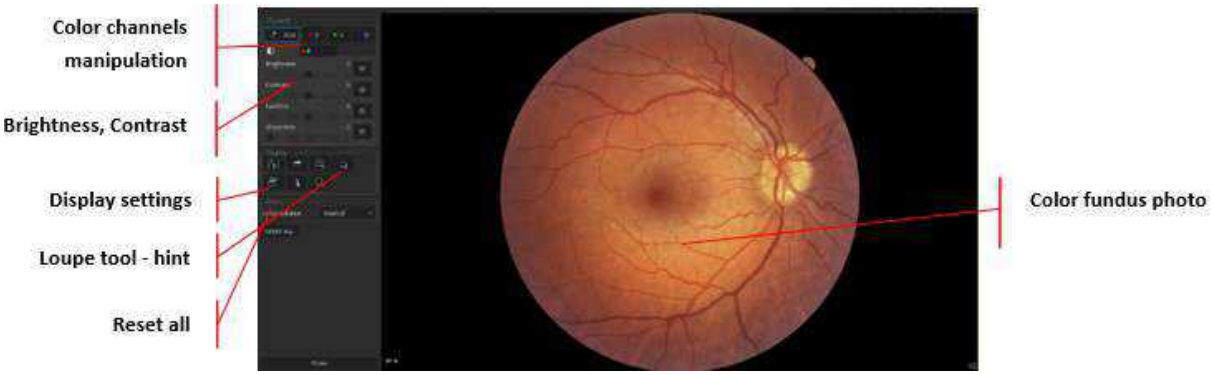


Figure 283.
Single Eye Color Fundus Photo (Full Screen View)

The user can choose the all-channels tab (RGB) or a single channel (R, G or B).

The RGB tab allows the operator to adjust each channel separately or all channels simultaneously. Also, the adjustment of brightness and contrast is available.

When the user chooses a single channel (R, G or B), it is only possible to manipulate brightness and contrast of the selected channel.

COLOR CHANNELS MANIPULATION

The user can choose only one option at a time.

THE RGB BUTTON CONTROLS THREE CHANNELS

R – only red channel, G – only green channel, B – only blue channel. When the button is pressed, the image is displayed in one of the channels or in the RGB. With the button selected, the user can adjust the Brightness, Contrast, Gamma, and Sharpness sliders, which affect only the displayed channel. The RGB button is selected by default. Choosing a different channel for the display closes the previously chosen channel. Displaying multiple channels simultaneously is not possible. Deactivating all the channels' results in displaying the image in grayscale. If the RGB button is engaged, the tab with the sliders for all individual channels is available with three sliders respectively for the three channels (R, G, B).

GAMMA SLIDER

The user can set the gamma value

SHARPNESS SLIDER

Affects the contrast at a pixel level - makes the contrast between each pixel more or less pronounced. Adjusting the sharpness slider can add or reduce perceived texture in a photo.

COLOR BALANCE FIELD[53]

Allows to change predefined color balance setting for **Neutral** and **Standard**.

[53] Available only for REVO HR, REVO FC 130 and REVO FC with REF 1905xxx

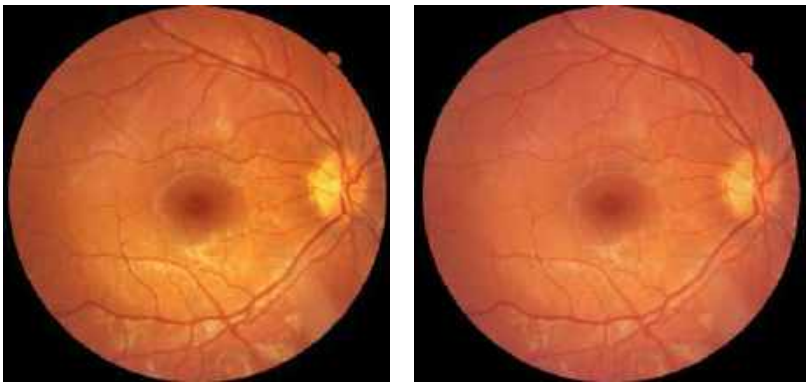


Figure 284.
Neutral Color Balance (on the left) and Standard Color Balance (on the right).

HIGHLIGHTS BUTTON

A function that darkens highlights on the photo. Useful for disc observation.

NOTE: The [HIGHLIGHTS] function desaturates overexposed areas. It may affect the local color presentation.

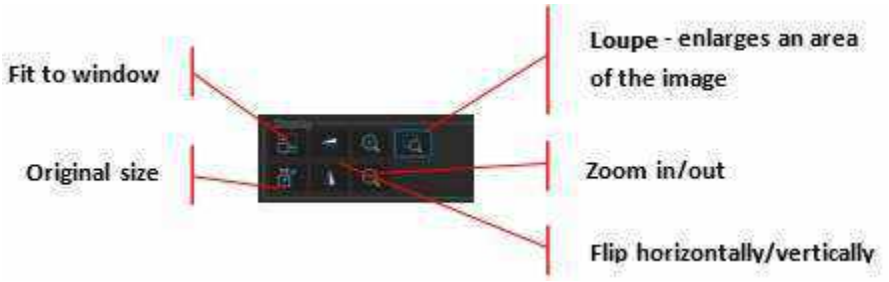


Figure 285.
Display Settings in Single Eye Color Fundus Photo (Full Screen View)

17.3.4. Color Fundus Photo ([Both] View)

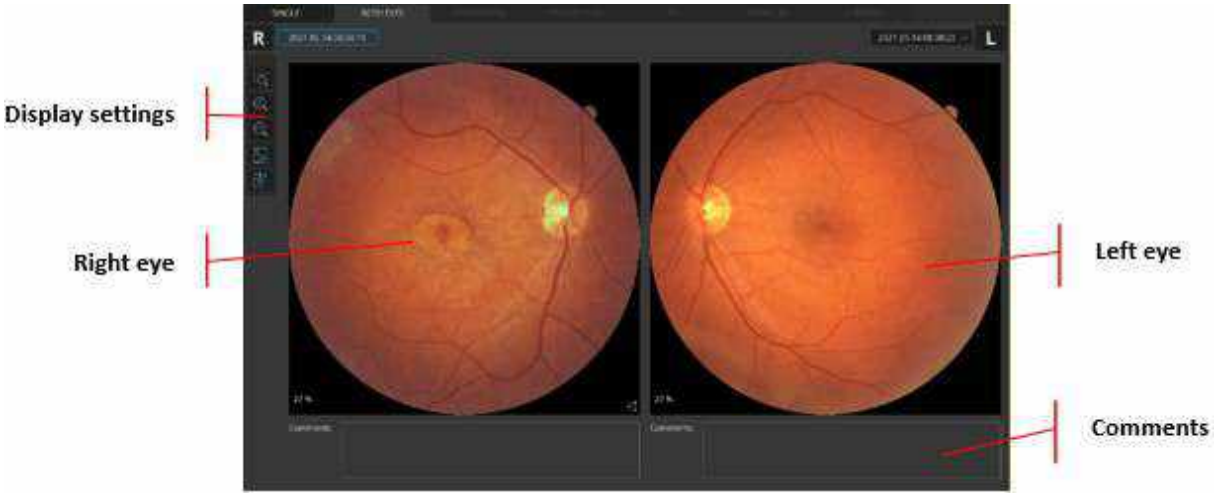


Figure 286.
Both Eyes (Color Fundus Photo View)

17.3.5. Color Fundus Photo ([Comparison] View)

Figure 287.
Comparison (Color Fundus Photo View)

18. Ultra-Wide Field (Optional Function)

NOTE: Ultra-Wide Field is an optional software module available only for REVO devices with the Fundus Camera. If you do not have this module and would like to purchase them, please contact your local OPTOPOL distributor.[54]

18.1. UWF adapter

18.1.1. UWF adapter installation

The UWF adapter for OCT devices with a fundus camera is intended to increase OCT scanning width in posterior segment imaging.

Scan width for Ultra-Wide Field examinations have 21 or 18 mm width.

WARNING: When using the adapter for the examination of the posterior segment of the eye, do not move the measuring head too fast and monitor its distance from the patient's eye to prevent contact between the surface of the UWF adapter lens and the patient's eye.

WARNING: When mounting the UWF adapter, make sure that the scanning head is in its maximum backward position and that the patient does not incidentally come into contact with the UWF adapter.

CAUTION: Exercise caution when mounting the UWF adapter in order not to scratch the objective lens.

In order to conduct ultra-wide examination of posterior segment, prepare the UWF adapter and follow the instructions below:

1. Grab the UWF adapter with two fingers placing them on grooves of the adapter's surface.

[54] There may be a need to update the device's hardware. For more information, please provide the serial number of the device to your local Otptopol representative.

Figure 288.
UWF adapter attachment.

2. Make sure that the “I” mark on the UWF adapter coincides with the mark on the device (as shown in the image).

Figure 289
UWF Adapter inserted into device’s head.

3. Get the UWF adapter to the objective and rotate 90° clockwise until “II” mark on adapter will cover with “I” mark of the device.

Figure 290.
UWF Adapter rotated properly.

CAUTION: Make sure the patient keeps their face away from the chinrest and the forehead rest when the UWF Adapter is still attached. Otherwise, the patient may be injured by the UWF Adapter coming into contact with them if the scanning head moves in any direction.

4. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
5. Use [Safe Lock] functionality explained in Chapter 18.2 Safe Lock (optional).

1. Press the **[START]** button to begin Full-Auto or Semi-Auto capture mode.
2. Head of the device will find eye’s position and start moving forward to the eye.

3. In Semi-Auto or Manual mode, verify the position of the OCT signal before pressing the **[ACQUIRE]** button. Some slight left/right/up/down movements may be needed to find the correct position. Drag the tomograms to optimize the scan position.
4. After finishing work, make sure to put the UWF adapter back into the packaging properly (as shown below).

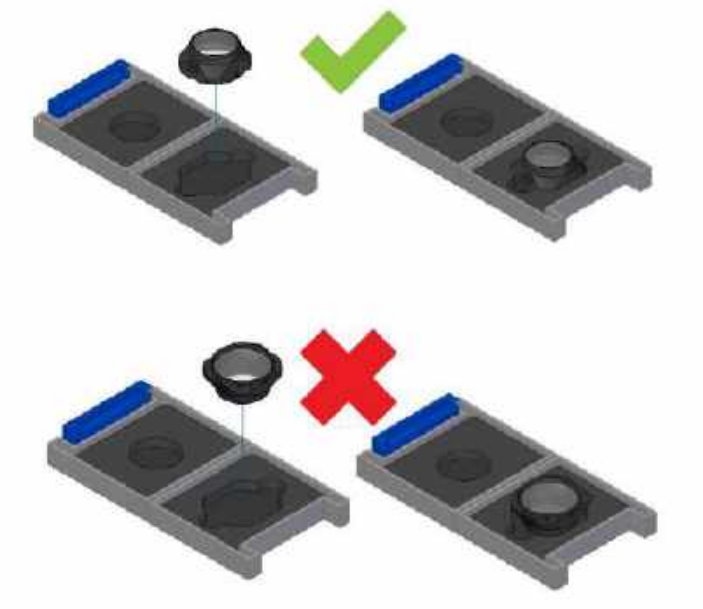


Figure 291.
Proper placement of the adapter.

18.1.2. UWF adapter cleaning

CLEANING OF THE UWF ADAPTER LENS

1. Inspect the adapter lens each time you would to use it, make sure the lens is free of foreign matter that could affect image readings or diagnoses.
2. Any dirt or scratches on the adapter lens appear as black spots which may affect the image quality. Check and clean the lens before taking an image. You cannot obtain good images if the adapter lens is not clear of debris.
3. For easier dirt check you can use flashlight on the UWF adapter, each unclean part will be easier to spot.

For cleaning UWF adapter go to Chapter 24.1 Routine Cleaning [Cleaning of the lens].

18.2. Safe Lock

Safe lock allows you to block the forward movement of the device's head, to prevent the adapter from colliding with the patient's eye.

The user should monitor the distance between the lens and the eye. Click [Safe lock] button (shown below) if you want to block forward movement of the device head, and lock it at a minimum safe distance. Device head won’t move closer than set location.

	Safe Lock is off. The UWF adapter can come in physical contact with the patient.
	Safe Lock is on. The device head will not exceed the given position. After turning on, Safe Lock icon will be framed by blue color.
	Safe Lock is on. The device head has reached the given limit. If operator will try to cross safe lock location, icon will turn red.

WARNING: Failure to use the safe lock functionality may result in physical contact between the adapter and the patient.

18.3. Ultra-Wide Field Acquisition Mode

1. Install the UWF adapter as shown in Chapter 18.1 UWF adapter.

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.

2. If voice guidance is switched off, inform the patient to follow the fixation target and to blink freely.

   If required, use the large fixation target. See Chapter 7.9 Fixation Target Adjustment.

3. Select the Ultra-Wide Field scan program.

   Motion Correction can be used during the Ultra-Wide Field acquisition. For more details see Chapter 7.14 Motion Correction Acquisition.

   Once the scan program is selected, the topography acquire window is available.

Figure 292.
Topography Acquire Window

   While capturing the scan, the following steps should be observed:

   - Disc and Retina areas should be positioned between top and bottom line on Horizontal and Vertical tomogram preview
   - The operator should make sure that the lids of the eye are not blocking or shadowing a significant portion of the image in the vertical meridians.

4. After the result is acquired, it is displayed in the acceptance window. The operator should verify the measurement reliability indices. A measurement with poor reliability indicates an increased risk of variability. Measurements with poor reliability should be replaced.

5. Follow the procedure depending on the acquisition mode.

18.3.1. Full-Auto Mode

1. Enable the **[AUTO ACQUIRE]** checkbox and press the **[START]** button.
2. In this mode eye preview is disabled, eye can be observed in pSLO/IR preview window.
3. Wait until the system finishes the examination. The patient will be voice guided by the software unless it is muted or disabled.

NOTE: In difficult conditions, such as:

- **Eyelashes or eyelid which block the beam of light**
- **Inability of subjects to maintain fixation**
- **Dense media opacities**
- **Strong nystagmus**
- **Rapid blinks**

the system can display a warning. In this case operator should decide whether to use the tips mentioned in the Chapter 8.6 Examination Tips or change the acquisition mode.

NOTE: If the system does not detect the pupil, the user must adjust the center of the patient's pupil manually. To set the working position properly, align the center of the pupil to the proper height.

NOTE: The Operator is to remain with the patient throughout the scanning process to oversee and guide them. The voice guidance feature is not intended to replace the Operator.

NOTE: If the system is not able to maintain the correct position of the retina (for example if the patient is moving), the operator must switch off tracking and carry out the examination manually.

18.3.2. Semi-Auto Mode

1. Uncheck **[AUTO ACQUIRE].**
2. Press **[START].**
3. Device head will find middle of the Cornea and will get slowly closer to the patient's eye, it is possible that lens will touch patient's eyebrow or eye socket.
4. The Disc and Retina area OCT signal should appear in the tomogram preview. If it does not, adjust C-Gate manually by moving the sliding bar or scrolling over the tomogram window. If the cornea OCT signal cannot be located, adjust the patient refraction value, and try to find the signal again.
5. Some refraction correction may be needed to obtain the best tomogram quality. Observe the Q Bar to obtain the best signal while changing **[FOCUS]** the bar position.
6. Verify the position of the Retina and Disc area, which should be placed on the dashed horizontal line. The Retina and Disc areas for the best scan quality, should be between the horizontal lines.

7. Once the position is aligned, ask the patient to blink and start the final Ultra-Wide Field acquisition. Double click on the tomogram or press the **[ACQUIRE]** button. The device will initialize the measurement immediately and perform a full scan.

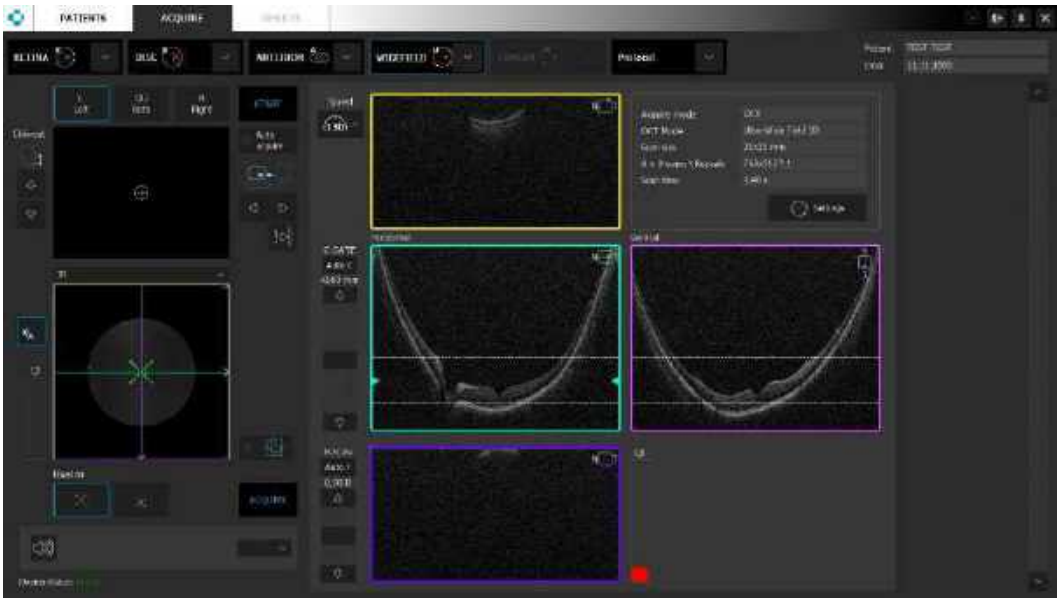


Figure 293.
Manual Examination Process

8. After the examination is over, the system will display an acceptance screen.

18.3.3. Manual Mode

1. Uncheck **[AUTO ACQUIRE]**.
2. Align the tomogram between the two horizontal dashed lines in the Horizontal and Vertical (cyan and magenta) panels.
3. Adjust the **[FOCUS]** manually by using the slider under focus, or the up / down arrows. Observe the Q bar and signal strength saturation of the tomogram image to obtain the best signal.
4. If a ghost signal (reflected image of iris) appears, it may be necessary to open the **[SETTINGS]** and switch C-Gate mode.
5. Adjust the position of the Retina and Disc tomogram in the blue and magenta panels and click to drag the position between the two horizontal dashed lines in the top portion of the panels.
6. Once aligned properly, ask the patient to blink twice.
7. To begin acquisition, click the **[ACQUIRE]** button or double-click on a tomogram panel.

18.4. ETDRS Grid

In each sector of the grid, its retinal thickness is shown. Background colors are based on comparison to the reference database.

Sector grids can be displayed as 3 / 6 / 12 / 18 mm sectors or as total grid size 18x18 (6x6 grid, 3x3 mm squares).

For RPE deformation maps, values in the sectors are not available.

18.5. Ultra-Wide Field 3D

An Ultra-Wide Field examination can display the options below depending on the type of chosen tab.

18.5.1. Single Tab

In the “Single Tab”, a single eye [Ultra-Wide Field 3D] analysis is presented. For each examination, central charts and maps used for assessment are calculated.

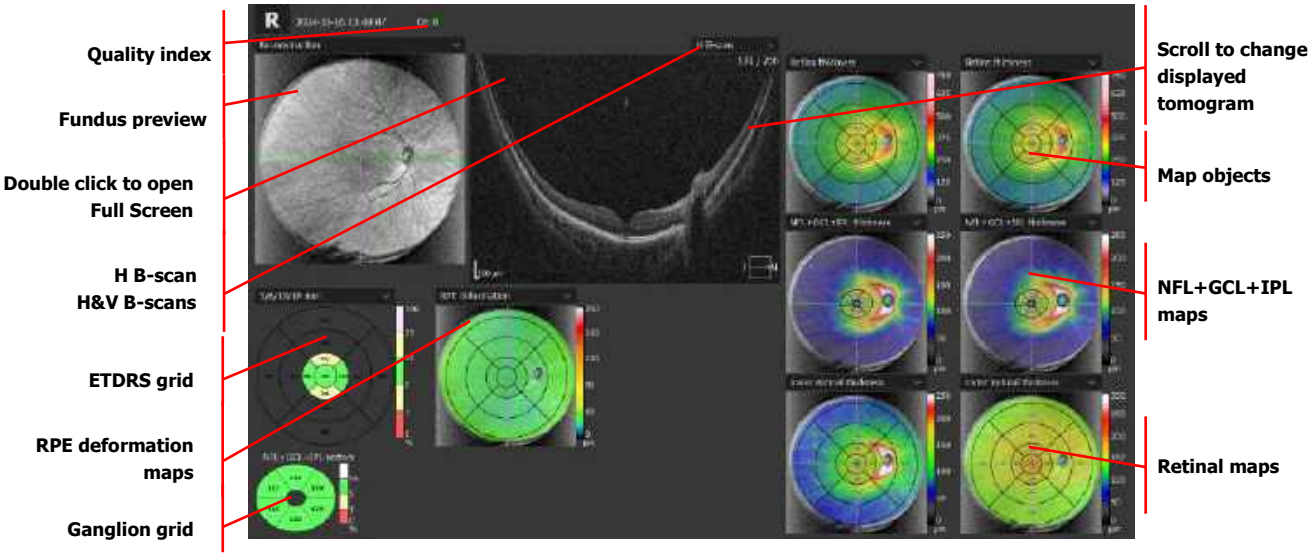


Figure 294.
Ultra-Wide Field 3D Single Tab with Horizontal B-scan view.

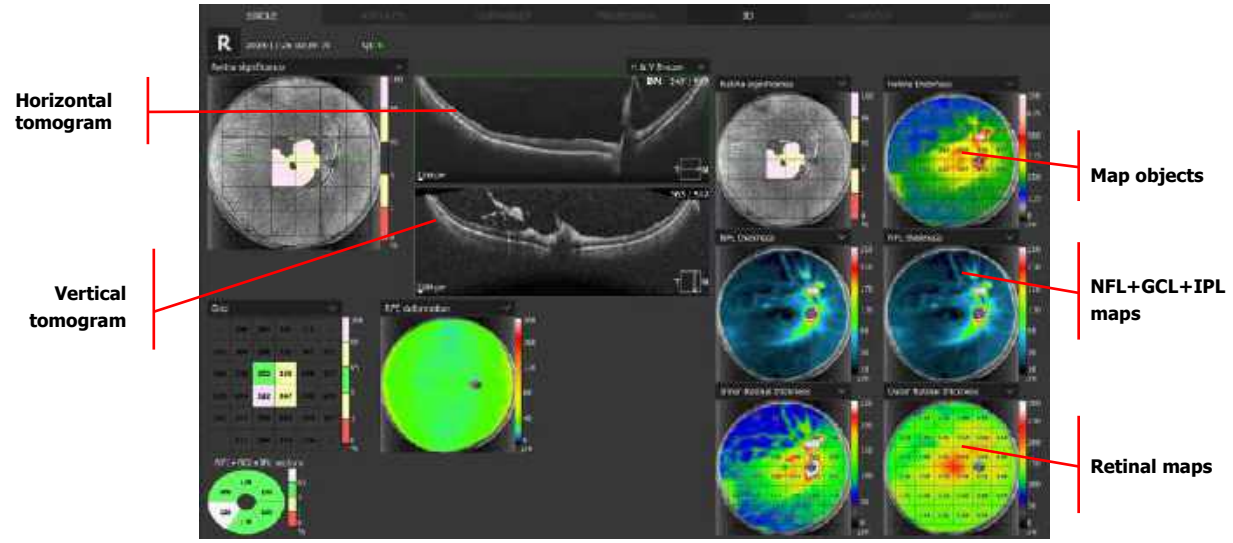


Figure 295.
Ultra-Wide Field 3D Single Tab with Horizontal and Vertical B-scan view.

18.5.2. Both Eyes Tab

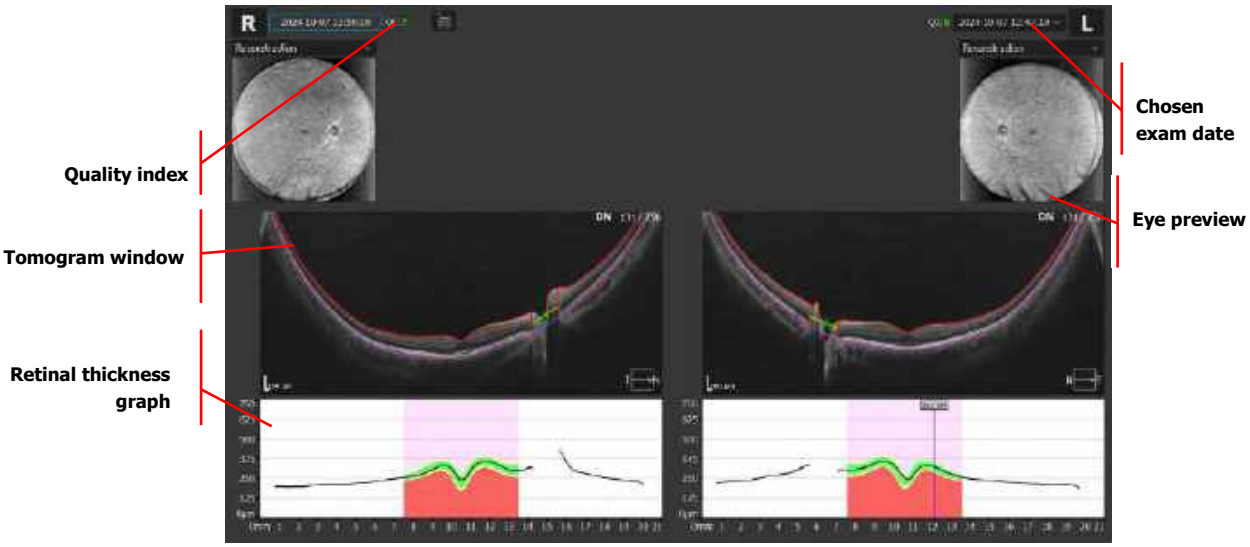


Figure 296.
Ultra-Wide Field 3D Both Tab View.

18.5.3. Comparison Tab

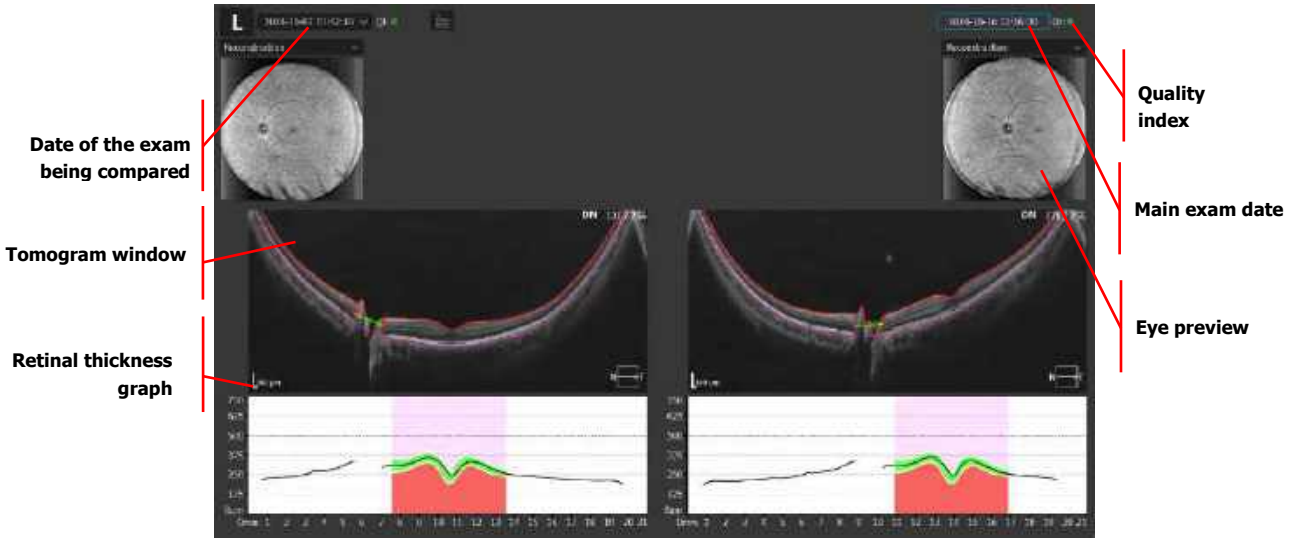


Figure 297.
Ultra-Wide Field 3D Comparison Tab View.

18.5.4. Progression Tab

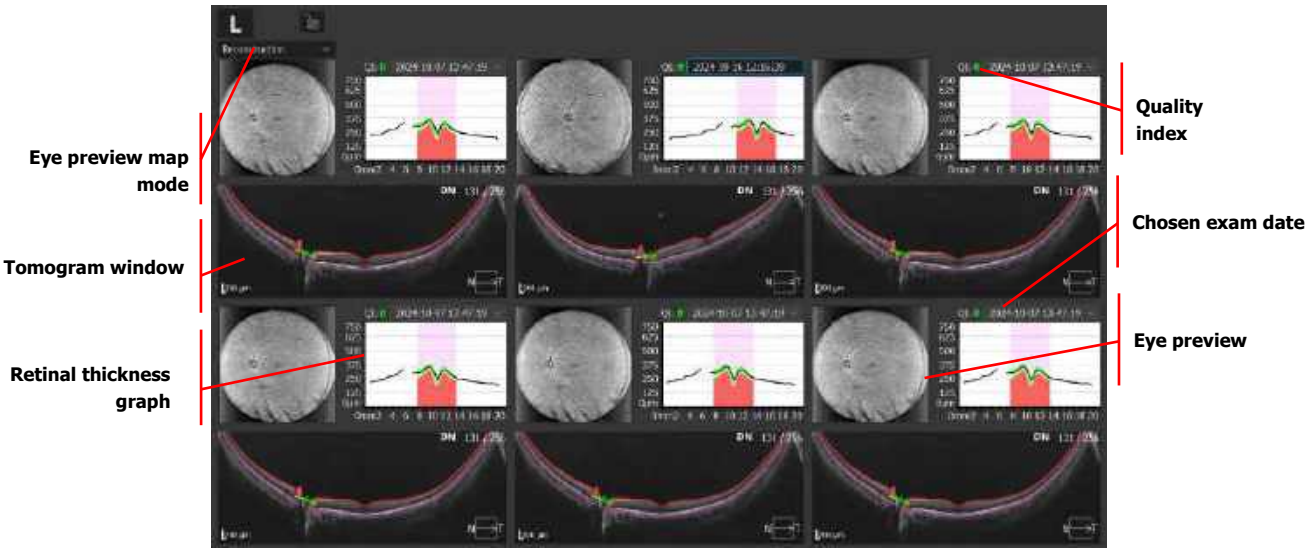


Figure 298.
Ultra-Wide Field 3D Progression Tab View.

18.5.4.1. Fundus Preview Object

The fundus preview object can be changed between several options.

1. Retina Thickness
2. Retina Significance
3. Reconstruction

The fundus reconstruction image is created from all A-scans acquired in the scanned area.

Right-click on the fundus preview to select the image overlay from the menu.The following images are available:

1. Fundus Photo
2. Fundus Reconstruction
3. pSLO

To change the transparency level, move the mouse wheel on the fundus reconstruction image.

A right-click over the eye preview window opens the context menu.

18.5.4.2. Sectors Grid

The Sectors Grid corresponds to the grid overlaid on the Retina Thickness Map. In each sector of the grid, its retinal thickness is shown.

Sector grids can be displayed as 3 / 6 / 12 / 18 mm sectors or 6 x 6 mm grid (3 mm x 3 mm squares). Each number represents the retinal thickness from particular square.

18.5.4.3. Ganglion Cells Sector

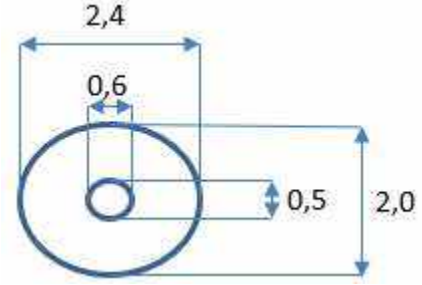


Figure 299.
Dimensions of Sectors for Ganglion Cells

Figure 300.
Ganglion Cells Sectors

18.5.4.4. Available maps

18.5.4.4.1. RPE Deformation Maps

1. RPE Deformation
2. Retina Sector Value

18.5.4.4.2. RPE Deformation Maps

1. Retina Significance
2. Retina Thickness
3. Retina Deviation
4. Retina Sector Value

18.5.4.4.3. NFL+GCL+IPL Maps

1. NFL+GCL+IPL Thickness
2. NFL+GCL+IPL Sectors
3. NFL Thickness

18.5.4.4.4. Retinal Maps

1. Inner Retinal Thickness
2. Outer Retinal Thickness
3. RPE Deformation

Context menu is available for every type of map display. Right-click to view the context menu.

18.5.4.5. NFL Sectors

The NFL measurement circle is divided into 6 sectors and the NFL thickness is shown.

18.5.4.6. Tomogram Window

Scroll over the tomogram window to change the displayed tomogram.

Double click to open the Tomogram Full screen window.

Press the right mouse button to display the Context menu.

Hold the right mouse button and move right / left and up / down to change the brightness and contrast.

18.6. Ultra-Wide Field OCT-A

NOTE: Ultra-Wide Field Angio examination will be unavailable if OCT-Angiography module is not purchased.

Prepare the patient as explained in Chapter 8.1 Preparing for an Examination. To capture OCT-A scans, see Chapter 8.3.7 OCT Angiography Examination. OCT-A technique is further described in Chapter 19.2 OCT-A Results Screen

The Ultra-Wide Field OCT-A 21x21 mm scan, which serves as the basis for the construction of angiography data, is acquired with 400 A-scans and 400 B-scans as the default (for REVO FC) or with 448 A-scans and 448 B-scans as the default (for REVO FC 130 or newer). The widths available for each device are 512x512, 600x600, 640x640 and maximum of 768x768 A-scans to B-scans.

18.6.1. Sectors Grid

In Ultra-Wide Field OCT-A Results there is a possibility to show same grid layouts as in Ultra-Wide Field 3D exam described in Chapter 18.5.4.2 Sectors Grid.

18.6.2. Standard tab view

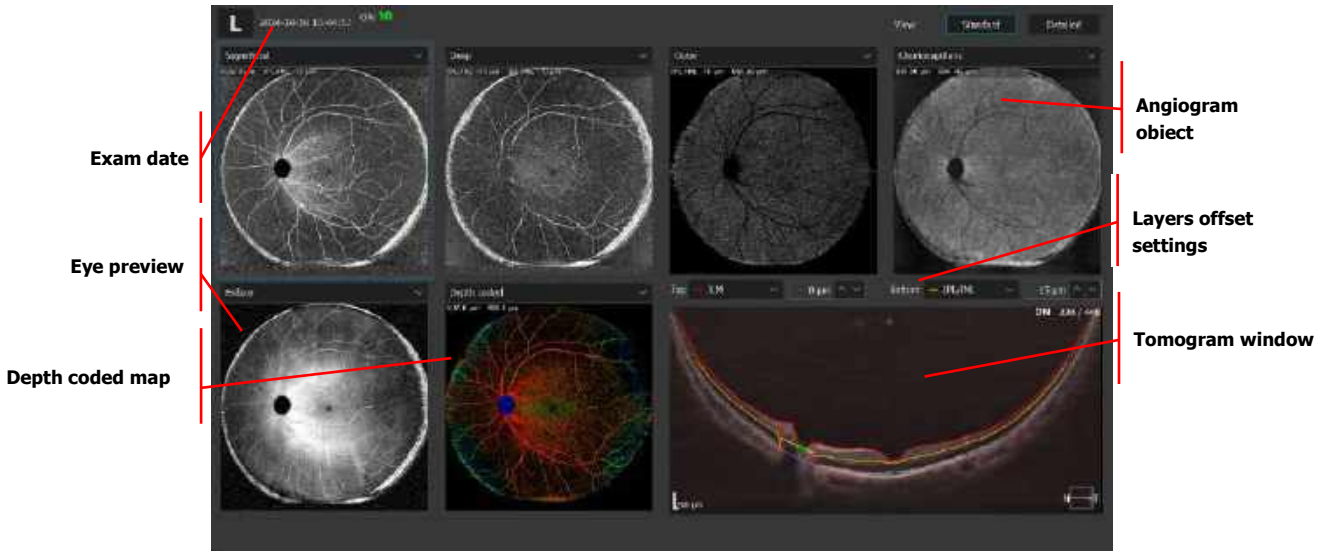


Figure 301.
Ultra-Wide Field OCT-A Single Tab Standard View.

18.6.3. Detailed view

Ultra-Wide Field Angio is based on Retina Angio exam layout with exceptions described below. See chapter 19 OCT-Angiography (Optional Function).

The results view and available Vascular layers are described in the chapter 19.2 OCT-A Results screen. The results view is similar to Retina OCT-A, apart from the detailed view, which is described below.

Except, in UWF OCT-A there is no disc measurement, which means that FAZ is unavailable.

18.6.3.1. Ultra-Wide field OCT-A detailed view

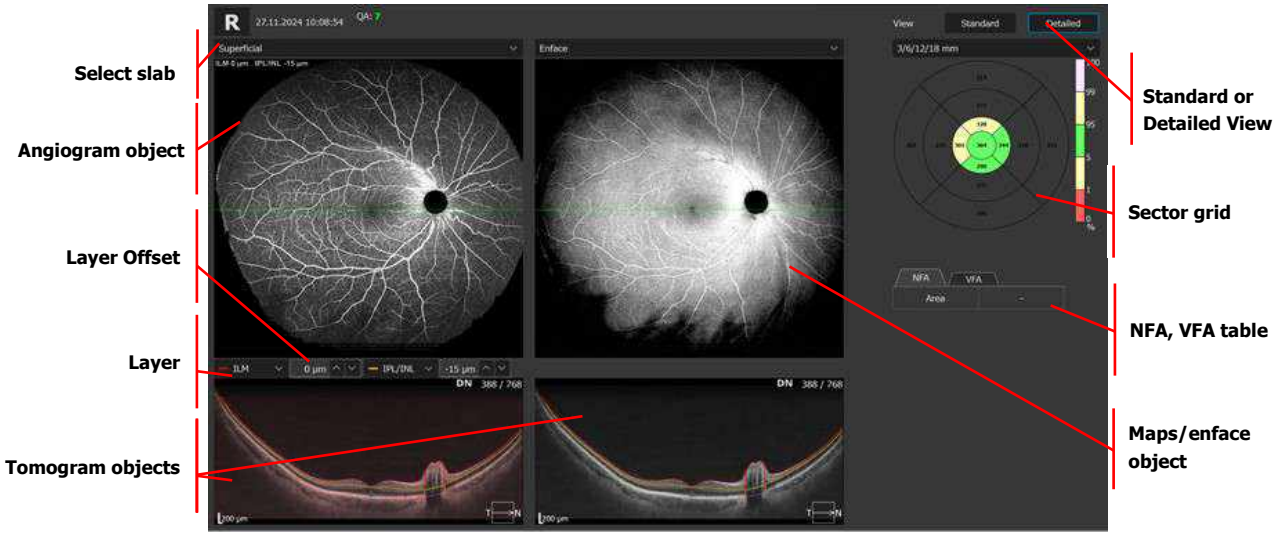


Figure 302.
Ultra-Wide Field OCT-A Single Tab Detailed View.

18.6.4. Both tab view

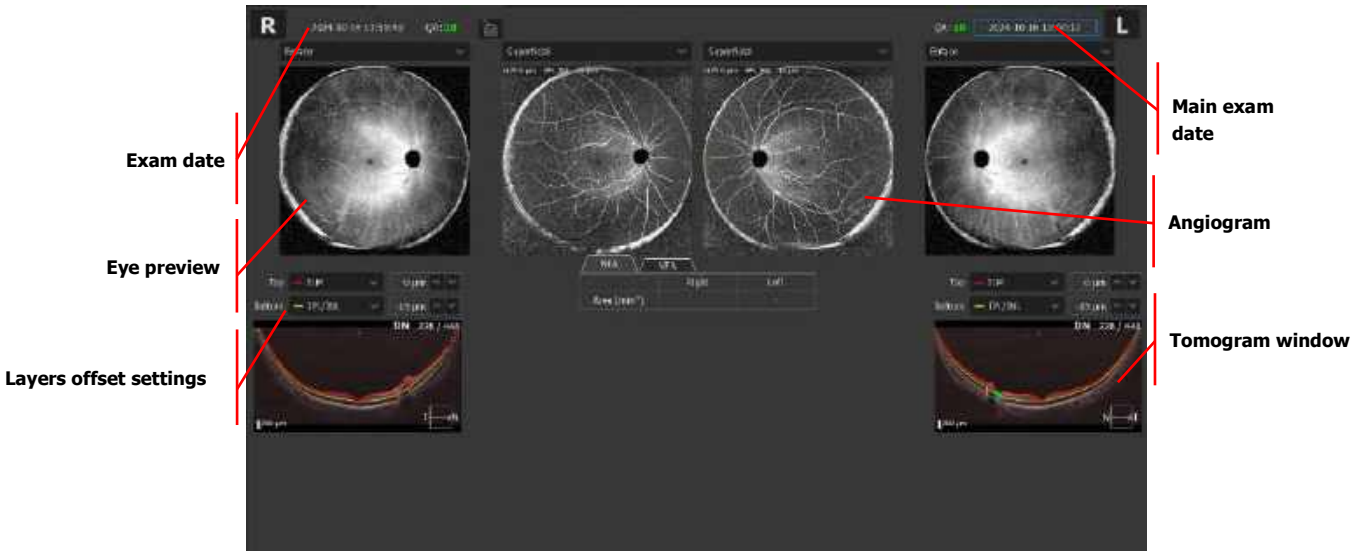


Figure 303.
Ultra-Wide Field OCT-a Both Tab View.

18.6.5. Comparison tab view

Figure 304.
Ultra-Wide Field OCT-a Comparison Tab View.

18.6.6. Progression tab view

18.6.6.1. Progression analysis view

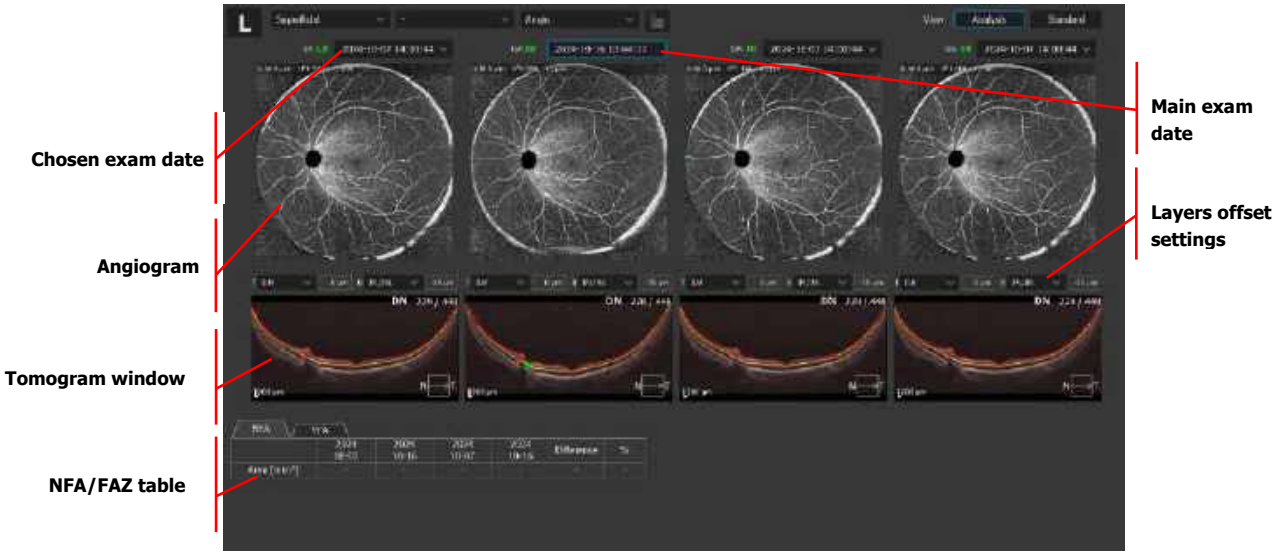


Figure 305.
Ultra-Wide Field Progression Tab Analysis View.

18.6.6.2. Progression standard view

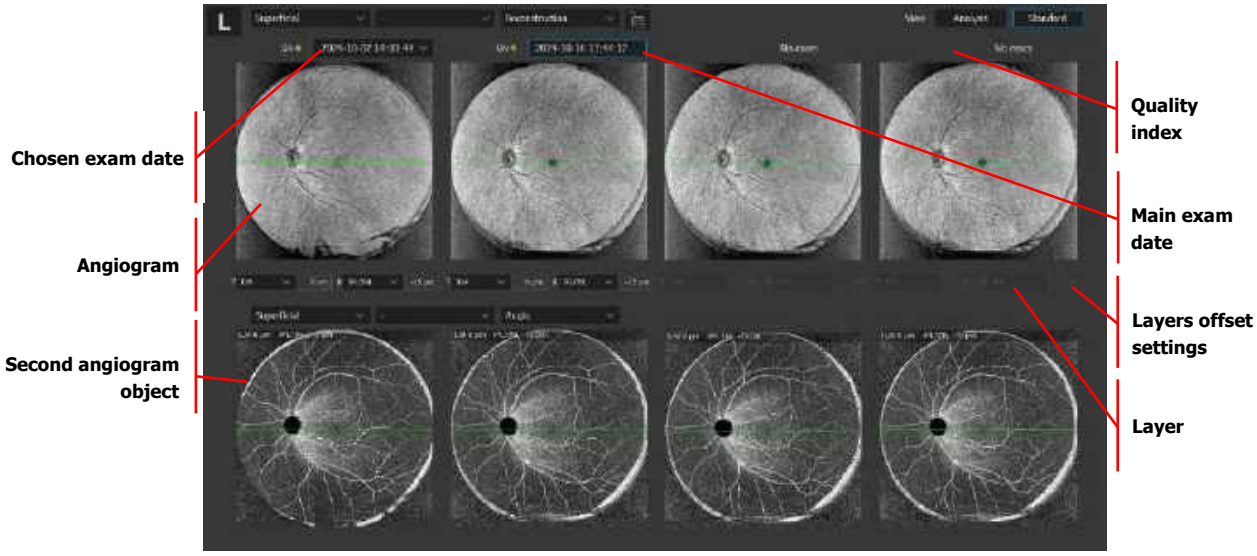


Figure 306.
Ultra-Wide Field OCT-a Progression Tab Standard View.

18.7. Scan programs Results Review

This chapter describes the available results view.

For more detailed description of scan programs, refer the Chapter 7.3 Selection of Scanning Programs.

18.7.1. Ultra-Wide Field Line

Single Line scans provide a quick and efficient method to scan a single B-scan in an area. (Averaging is possible). Viewing Options:

18.7.1.1. Single Tab

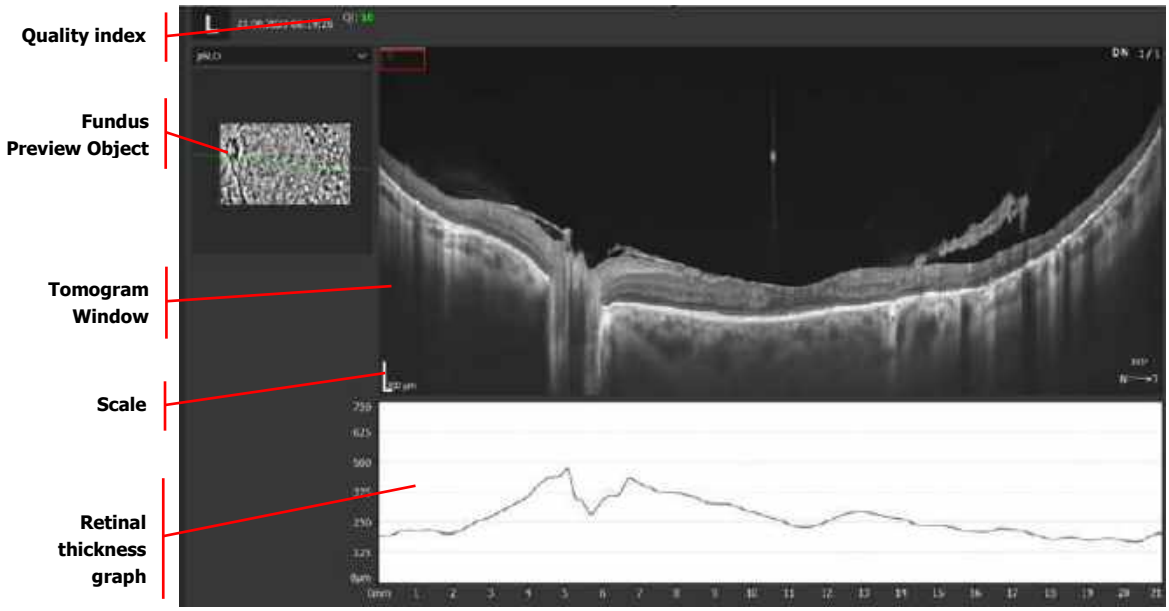


Figure 307.
Ultra-Wide Field Line Single Scan View

18.7.1.2. Both Eyes Tab

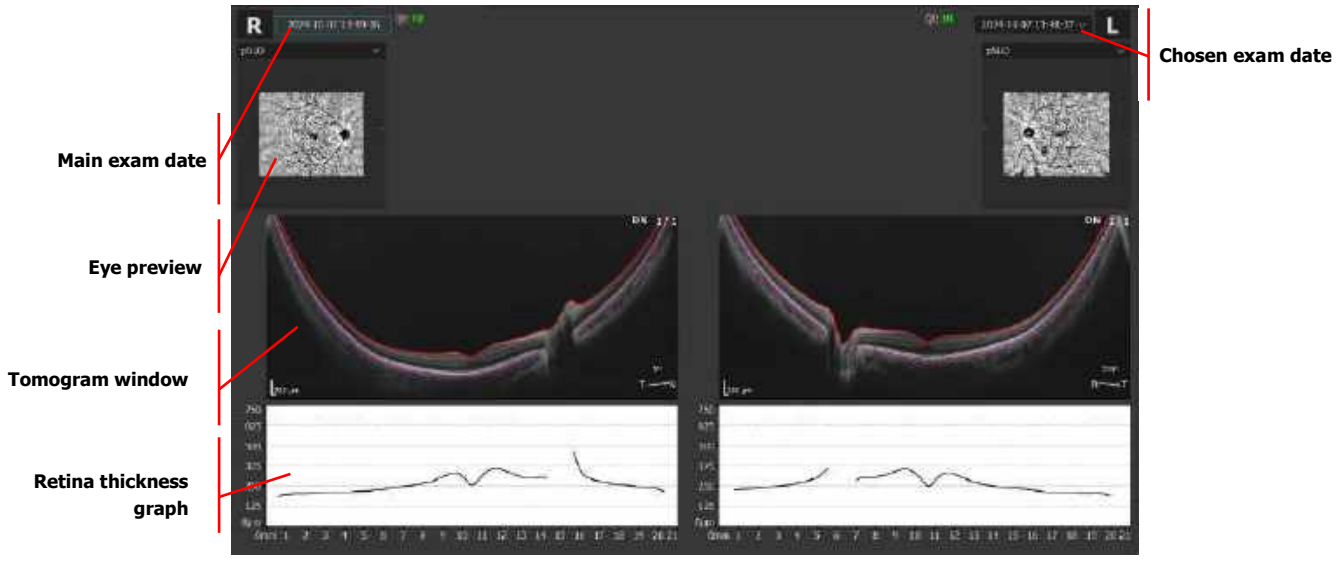


Figure 308.
Ultra-Wide Field Line Both Tab View.

18.7.1.3. Comparison Tab

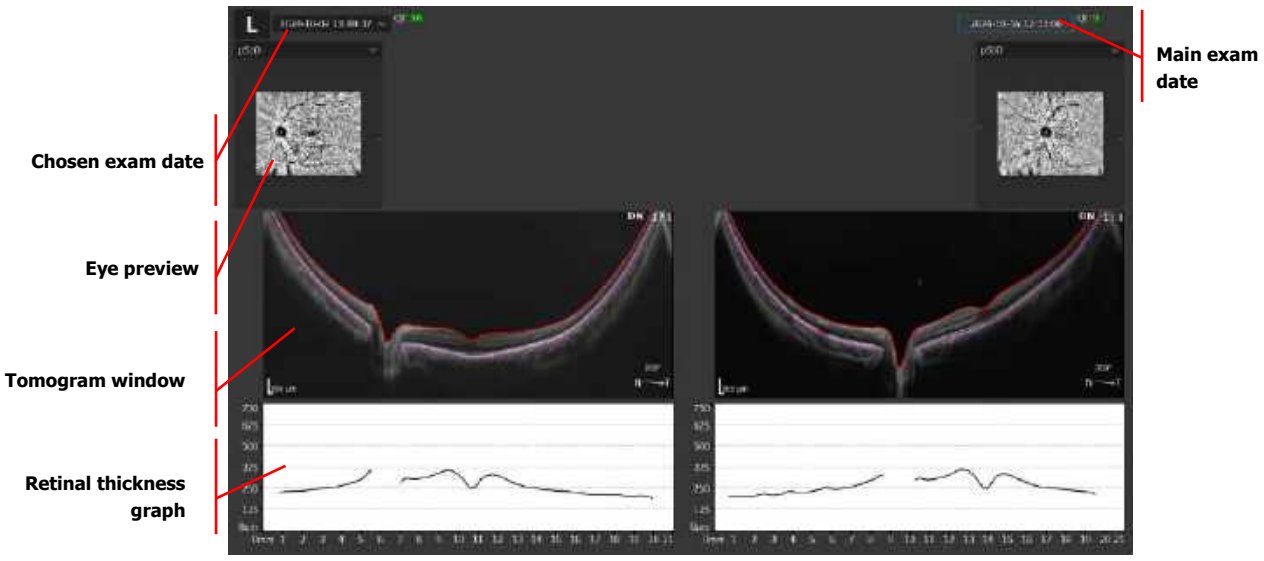


Figure 309.
Ultra-Wide Field Line Comparison Tab View.

18.7.1.4. Progression tab view

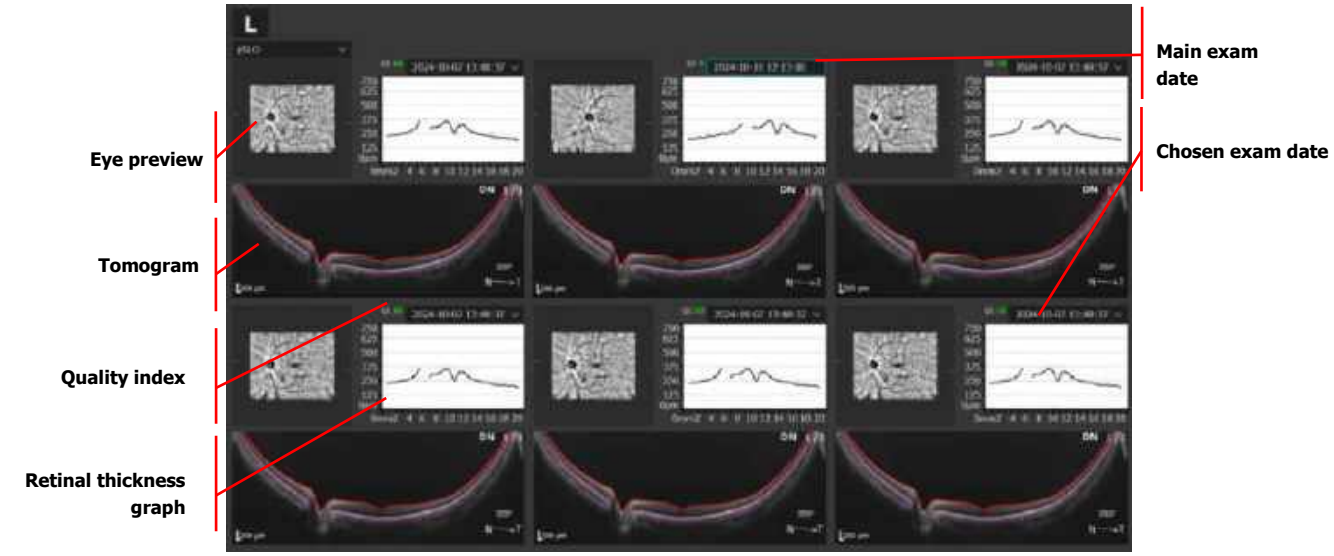


Figure 310.
Ultra-Wide Field Line Progression Tab View.

18.7.2. Ultra-Wide Field Radial

In tomogram window single B-scan is displayed. It is possible to select a different B-scan by scrolling or clicking on the reconstruction / pSLO image.

18.7.2.1. Single tab view

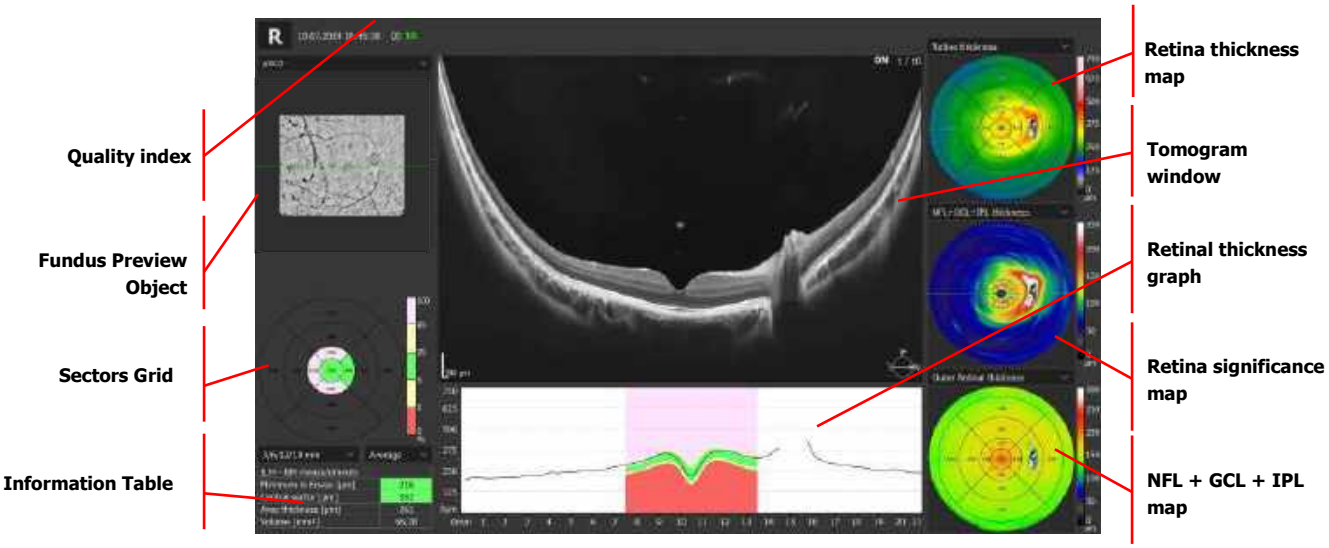


Figure 311.
Ultra-Wide Field Radial Single Tab View.

18.7.2.2. Both tab view

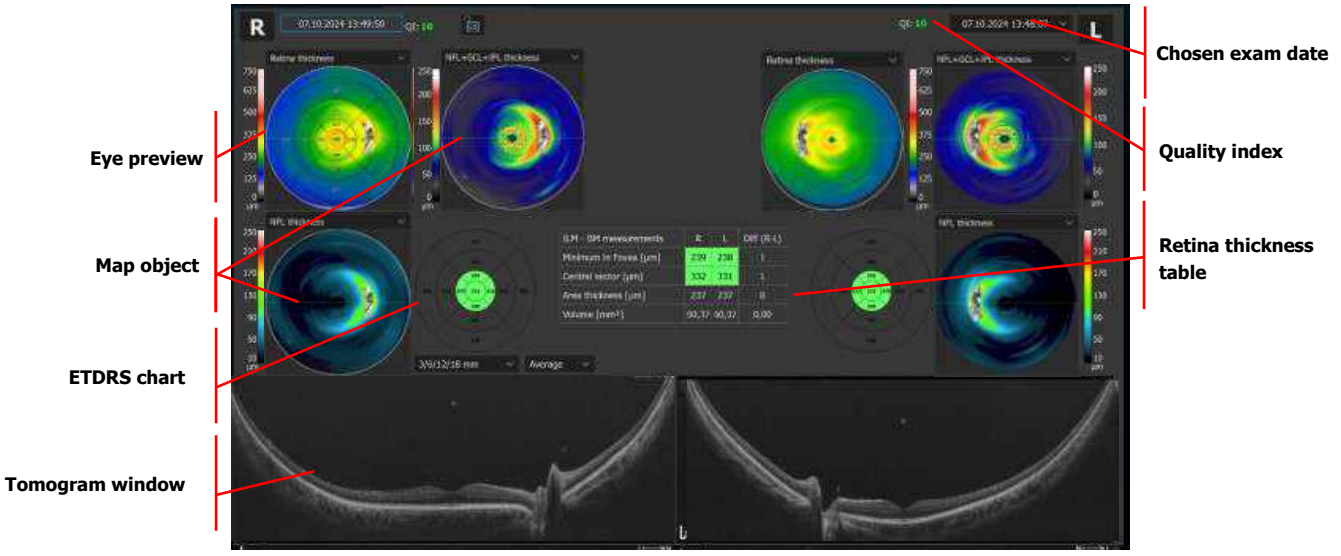


Figure 312.
Ultra-Wide Field Radial Both Tab View.

18.7.2.3. Comparison tab view

18.7.2.3.1. Retina view

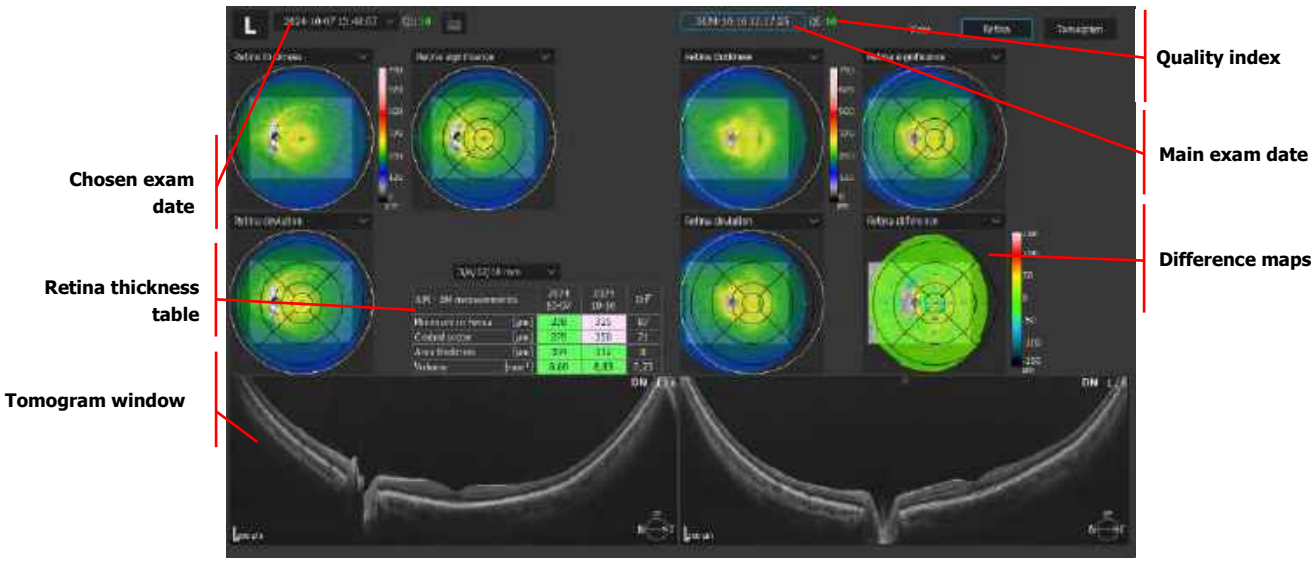


Figure 313.
Ultra-Wide Field Radial Comparison Tab Retina View.

18.7.2.3.2. Tomogram view

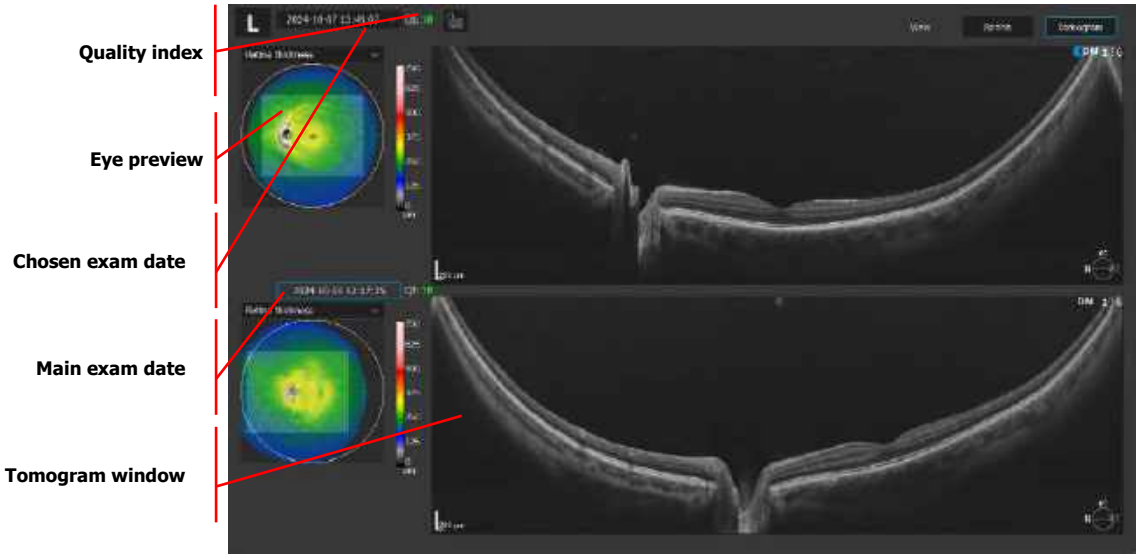


Figure 314.
Ultra-Wide Field Radial Comparison Tab Tomogram View.

18.7.2.4. Progression tab view

18.7.2.4.1. Progression retina view

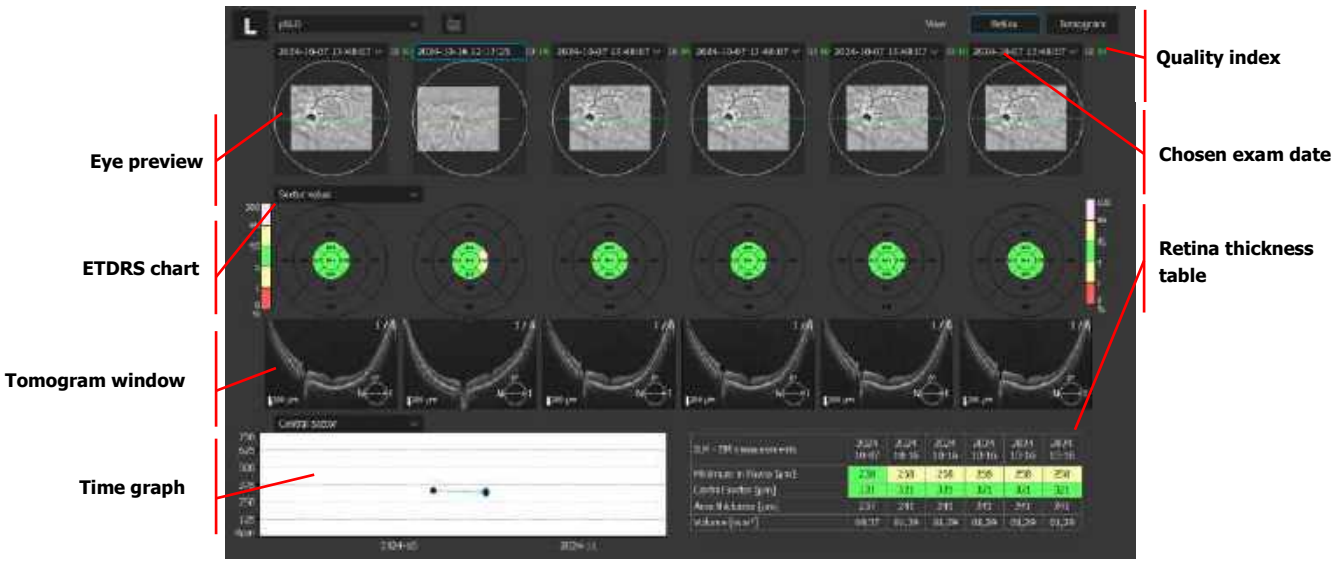


Figure 315.
Ultra-Wide Field Radial Progression Tab Retina View.

18.7.2.4.2. Progression tomogram view

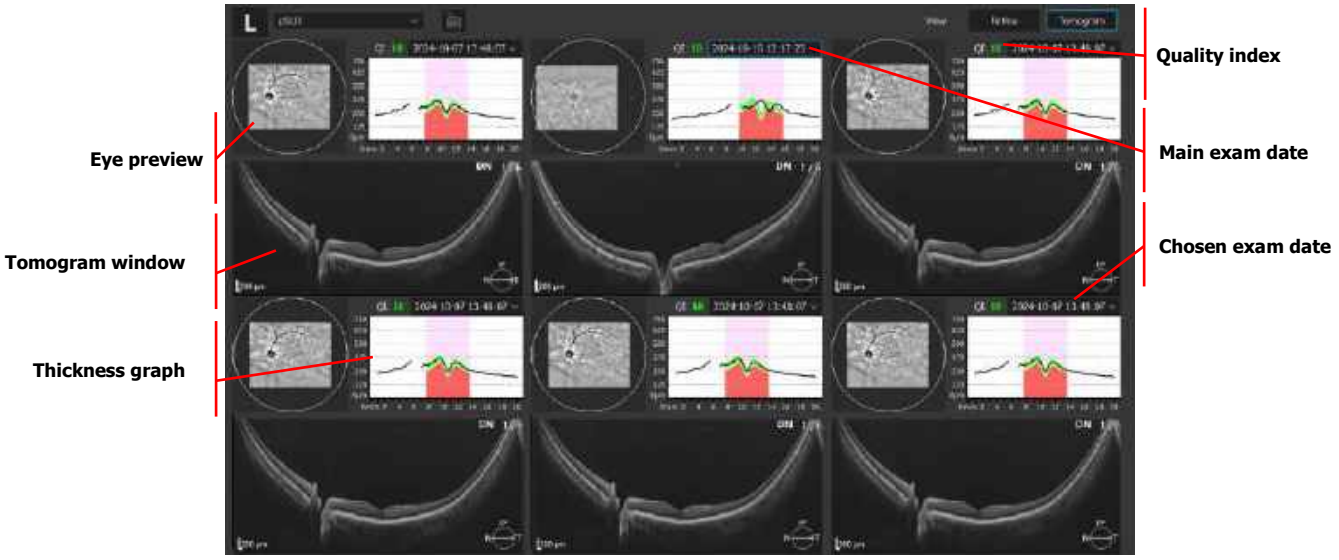


Figure 316.
Ultra-Wide Field Radial Progression Tab Tomogram View.

18.7.2.5. Object description

For an Ultra-Wide Field Radial Single Scan View description go to Chapter 11.1.1 Single Tab.

18.7.2.6. Sectors grid exception

The Sectors Grid corresponds to the grid overlaid on the Retina Thickness Map. In each sector of the grid, the retinal thickness of each sector appears.

It is possible to show sectors with diameters 3 / 6 / 12 / 18 mm or 18x18 mm grid.

The following values can be selected to be viewed in the sectors: Average, Maximum, Minimum or Volume of the zone. The Thickness Map is further organized and presented in the nine ETDRS-like zones.

18.7.3. Ultra-Wide Field Full Range Line

Full Range examination mode offers an increased scanning depth of ≈6 mm, comparing to the standard scanning depth. Before conducting a Full Range examination, prepare the patient as explained in Chapter 8.1 Preparing for an Examination.

Examination modes are described in Chapter 7.3 Selection of Scanning Programs.

18.7.3.1. Single tab view

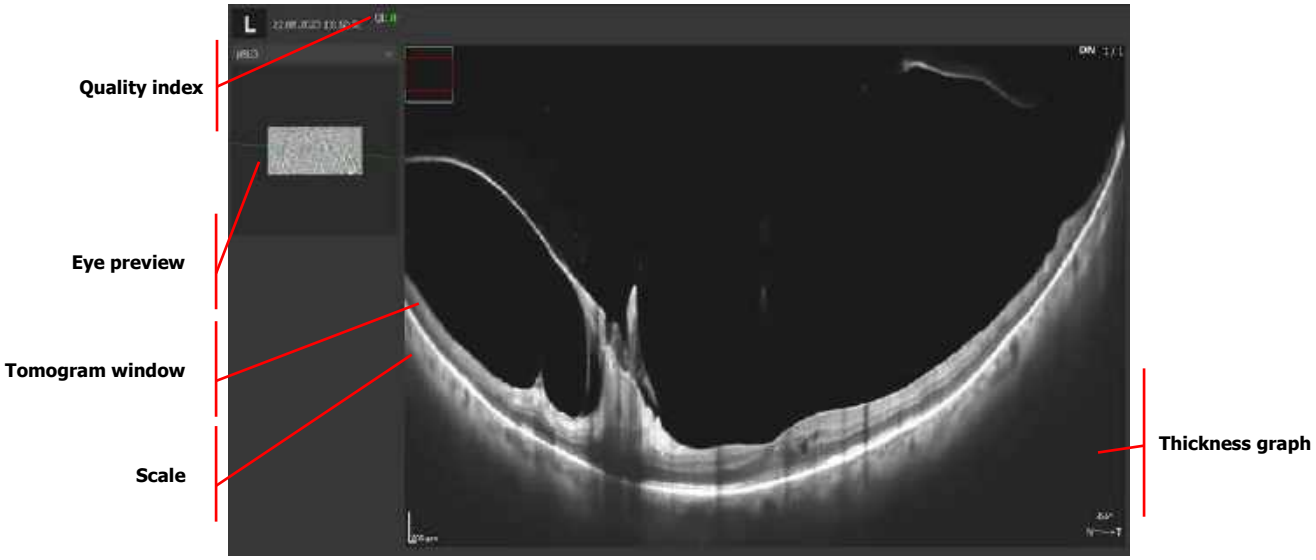


Figure 317.
Ultra-Wide Field Full Range Line Single Tab View.

18.7.4. Ultra-Wide Field Full Range Radial

Full Range examination mode offers an increased scanning depth of ≈6 mm. Before conducting a Full Range examination, prepare the patient as explained in Chapter 8.1 Preparing for an Examination.

A Full Range scan in the simple mode (described below in Chapter 8.3.9 Anterior Full Range Programs Examination) normally displays an inverted mirror image of the scanned structure. The inverted image can be oriented to overlay and match the original image. As a result, the two images become coupled to form a highly detailed image of the structure.

Examination modes are fully described in Chapter 7.3 Selection of Scanning Programs.

Radial examination for all tomograms (number of B-scans taken here can be adjusted). Single B-scan is displayed. By clicking on fundus preview, it is possible to select a different B-scan. Tomograms are displayed depending on the scanned region. Below are examples:

18.7.4.1. Single tab view

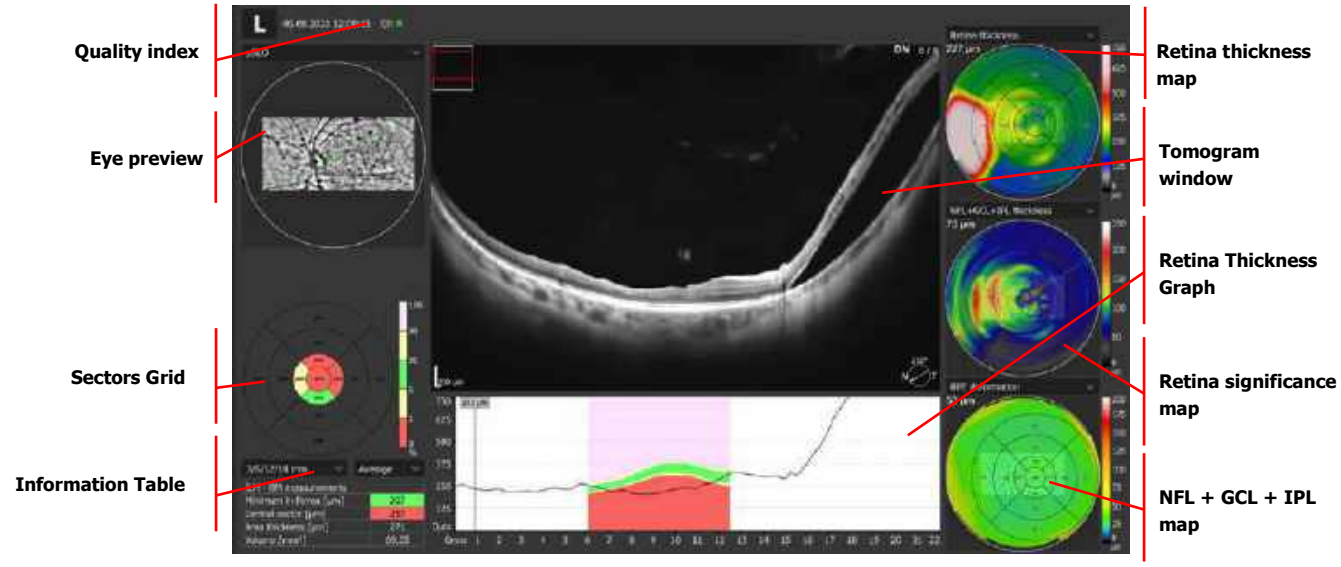


Figure 318.
Ultra-Wide Field Full Range Radial Single Tab View.

18.7.4.2. Both tab view

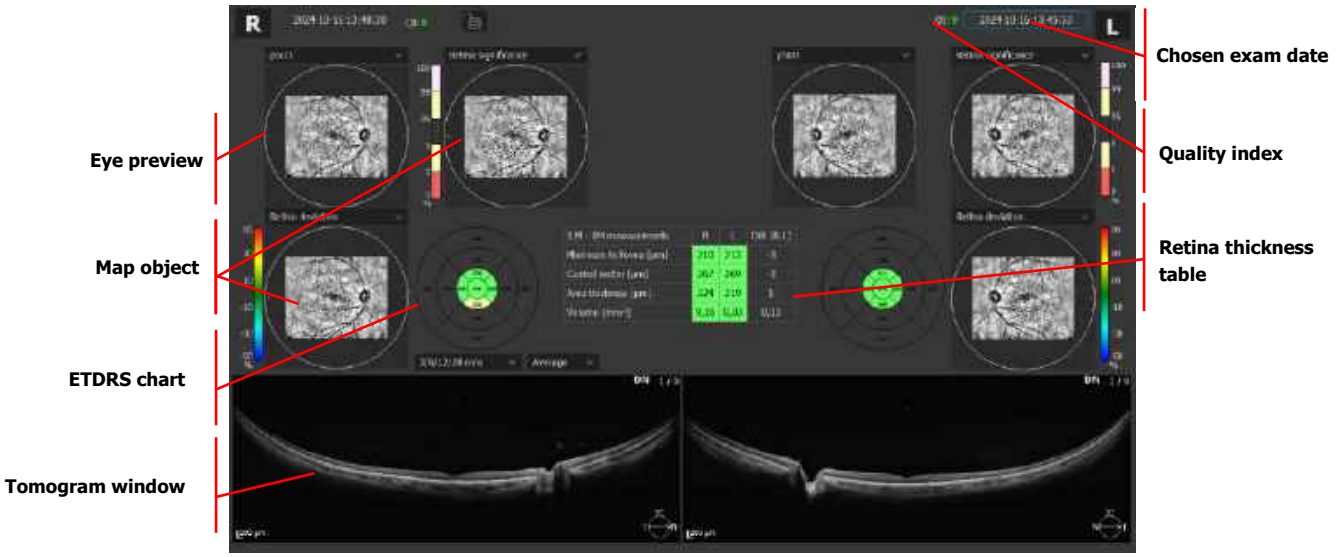


Figure 319.
Ultra-Wide Field Full Range Radial Both Tab View.

18.7.4.3. Comparison view

18.7.4.3.1. Retina view

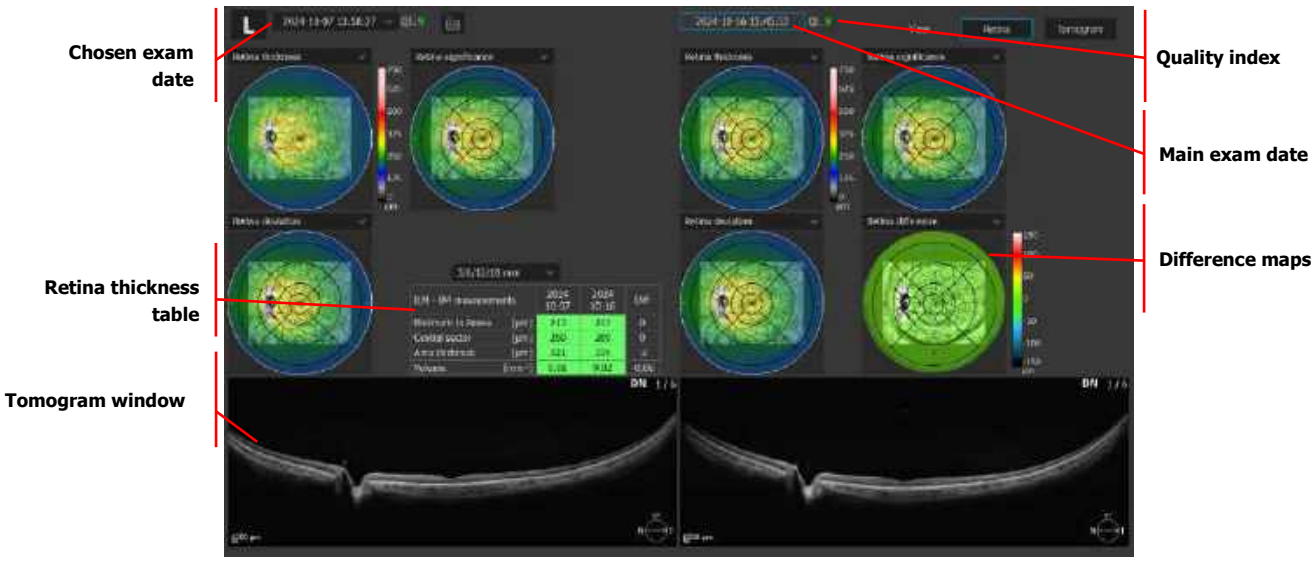


Figure 320.
Ultra-Wide Field Full Range Radial Comparison Tab Retina View.

18.7.4.3.2. Tomogram view

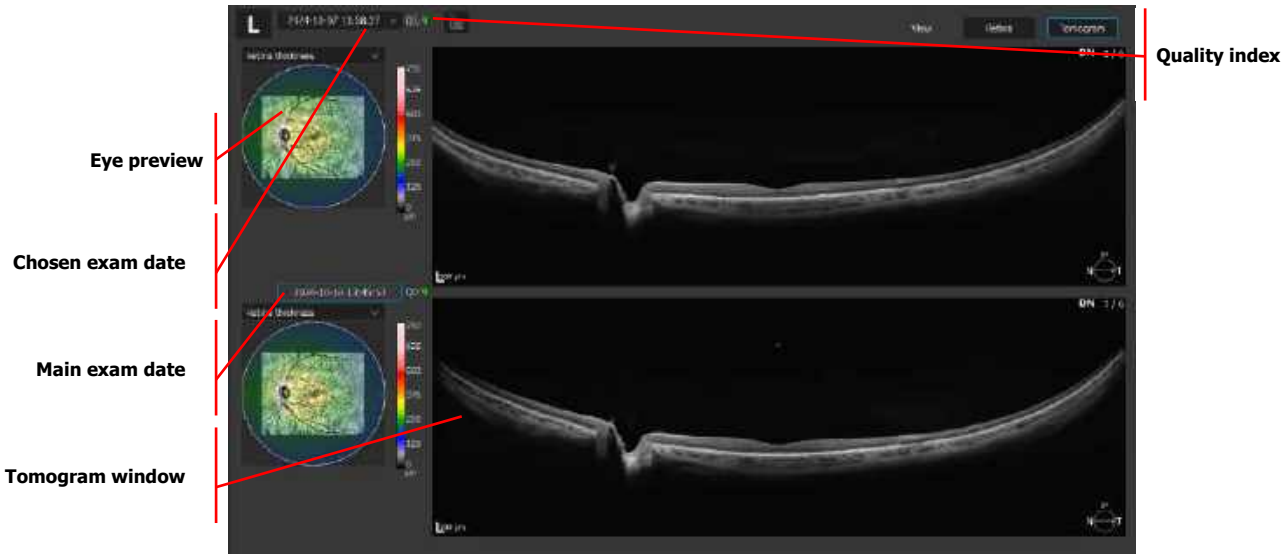


Figure 321.
Ultra-Wide Field Full Range Radial Comparison Tab Tomogram View.

18.7.4.4. Progression tab view

18.7.4.4.1. Retina view

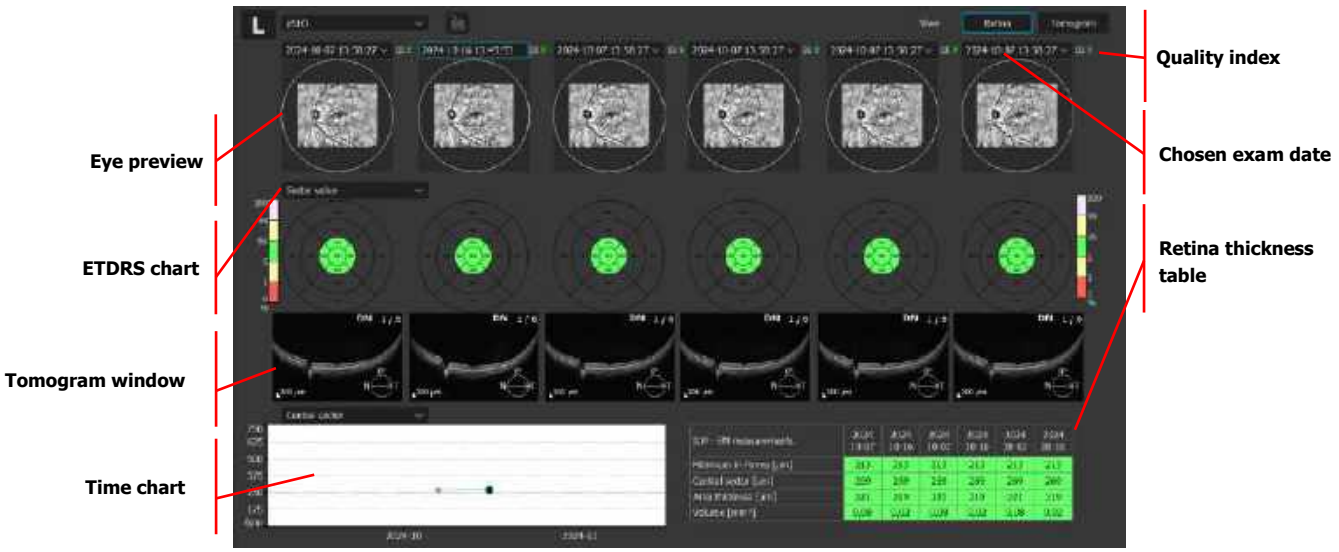


Figure 322.
Ultra-Wide Field Full Range Radial Progression Tab Retina View.

18.7.4.4.2. Tomogram view

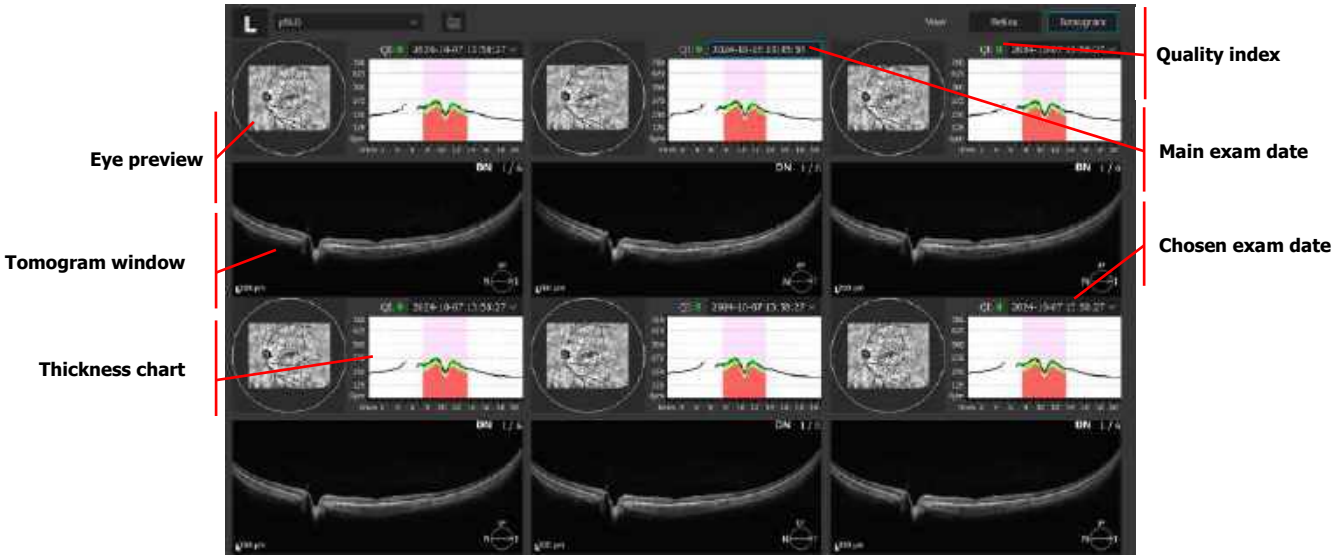


Figure 323.
Ultra-Wide Field Full Range Radial Progression Tab Tomogram View.

19. OCT-Angiography (Optional Function)

NOTE: OCT-Angiography is an optional software module. If you do not have these modules and wish to purchase them, please contact your local OPTOPOL distributor.

The optional REVO OCT-Angiography (OCT-A) feature is indicated as an aid in the visualization of vascular structures of the retina and choroid in normal subjects and in subjects with glaucoma and retinal diseases for the angiographic visual assessment of vascular density and the foveal avascular zone (FAZ). It is also indicated to perform manual measurement of the foveal avascular zone and the non-flow area.

19.1. Quality Angio Index (QA)

QA (Quality Angio) can have 11 statuses represented by numerical values ranging from 0 to 10, where 0 is expressed as NG (Not Good). The numerical values of the QA coefficient are color coded to inform the operator about the quality of the captured exam.

Description of the QA value range

QA Value Ranges	Color	Description
<10-7>	Green	Signal of the angiogram and tomogram is well saturated
<6-4>	Yellow	Signal of the tomogram and angiogram is moderately saturated. The quality of the angiogram may be decreased. The operator should repeat the exam in order to attempt a higher level of the QA parameter. The operator should exercise caution when interpreting the angiograms.
<3-1> / 0 (NG)	Red	Signal of the tomogram and angiogram is not well saturated. Exams with QA = 3 or lower are likely difficult or not possible to interpret. The exam must be repeated in order to obtain higher QA parameter if possible.
		Scans classified as 0 (NG) are the worst quality. The operator must repeat the exam. Scan with status NG are

		rejected from automatic selection (in the tabs: both eyes, comparison, progression).

19.2. OCT-A Results Screen

Prepare the patient as explained in Chapter 8.1 Preparing for an Examination. To conduct OCT-A scans, see Chapter 7 Acquire Tab.

OCT-A exams can be used to detect flow within ocular tissue. The algorithm uses the variation information in the repeated B-scans to detect locations of flow within ocular tissue. The OCT-A scan protocol creates a 3D scan data set that combines the results of repeated B-scans in the same location. The OCT-A results graphically represents the results from OCT images by contrasting areas of flow and static tissue. The Retina OCT-A 3x3 mm scan, which serves as the basis for the construction of angiography data, is acquired with 320 A-scans and 320 B-scans as the default.

19.2.1. Operation on the Angiogram object

1. **ENLARGE**

   Double-click on the angiogram – in the Retina OCT-A examination only for RPCP layer, in the Disc OCT-A examination for Nerve-Head, Retina, Vitreous, Outer, Choroid, Choriocapillaris and Depth Coded layer.

2. **FAZ + NFA + VFA TOOL**

   Double-click on the angiogram – in the Retina OCT-A examination for every layer except RPCP, in the Disc OCT-A examination for Superficial, RPC and Deep layer. See Chapter 19.2.5 OCT-A Manual Tools.

3. **BRIGHTNESS AND CONTRAST**

   Hold the right-mouse button on angiogram. Move the cursor up / down for brightness and left / right for contrast adjustments.

4. **MODIFY BOUNDARY**

   Click on desired angiogram. Hover the mouse cursor over the image. Scroll the mouse wheel up / down to move top and bottom boundaries on the tomogram.

5. **EXPORT IMAGE**

   Right-click on the desired angiogram to export *.png. Select **[SAVE AS..]** from the context menu.

6. **ZOOM IN / OUT**

Hover the mouse cursor over the desired angiogram. Hold the **CTRL** key and scroll mouse wheel up / down to zoom in / out.

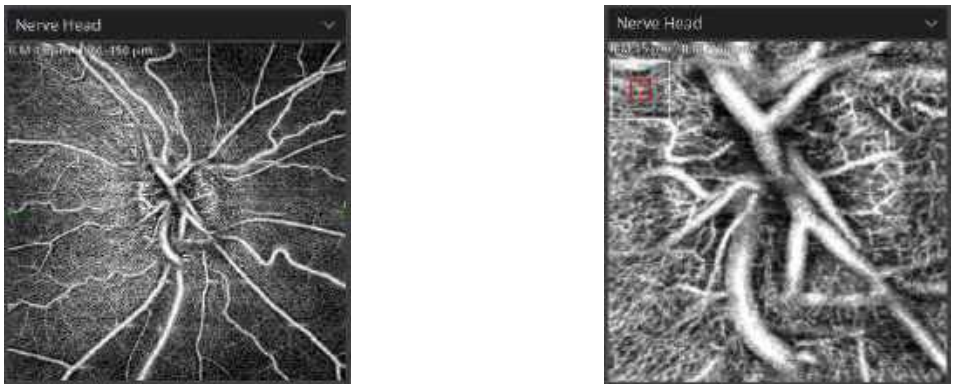


Figure 324.
Zoom Out / In Over the Angiogram Window

The Angiogram context menu includes:

1. **RESET BRIGHTNESS / CONTRAST**

Restore the brightness / contrast default.

2. **B-SCAN REFERENCE ENABLE**

Enable / disable the reference B-scan on the angiogram.

3. **SAVE AS…**

Save the angiogram.

4. **PROJECTION REMOVAL**

Enable / disable the projection Artifact removal algorithm.

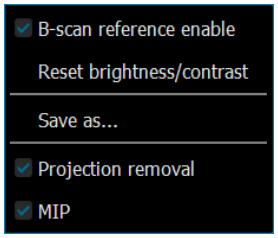
Left Click to the desired position to see the tomogram from a specific location. Hold the left mouse button and move it to change the position.

5. **MIP - MAXIMUM INTESITY PROJECTION**

Enable Maximum Intensity Projection of the OCT-A slab. When disabled the Average Intensity Projection is used.

19.2.2. MIP – Maximum Intensity Projection

By default, the angiogram (OCT-A slab) is calculated using the Average Intensity Projection (AIP) algorithm (the average value of vessels at a given x, y position over a given depth range).



With the Maximum Intensity Projection (MIP) enabled the overlap of multiple vessels or projection (shadow) artifacts is ignored resulting in a cleaner angiogram as shown below.

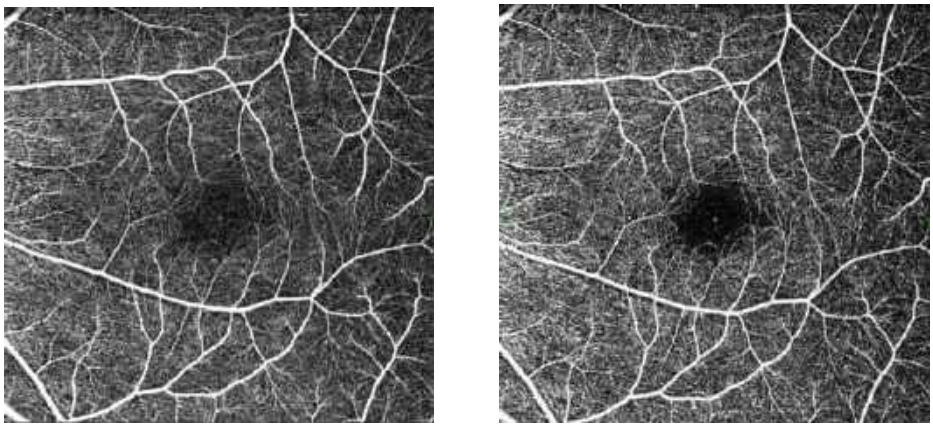


Figure 325.
Example of Outer layer with AIP (on the left) and MIP (on the right) enabled

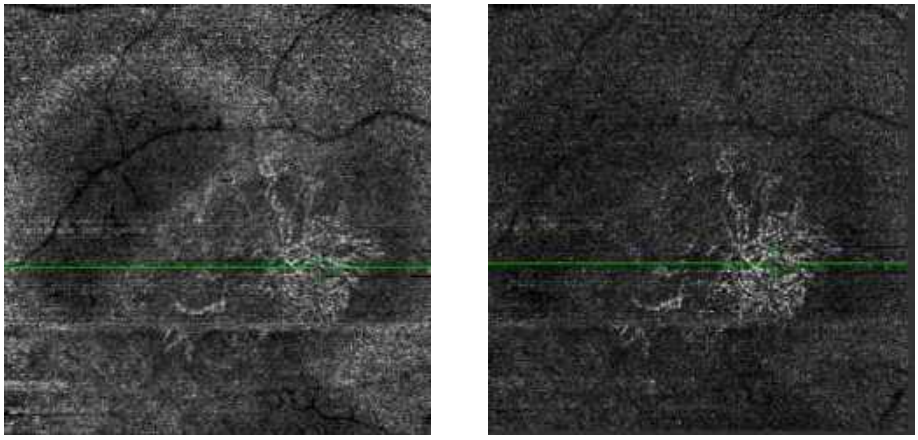


Figure 326.
Example of Outer layer with AIP (on the left) and MIP (on the right) enabled

19.2.3. Enface Window

THE OCT-A SINGLE TAB

Standard View Enface window is located on the bottom left of the screen. The object displayed can be selected from the drop-down menu.

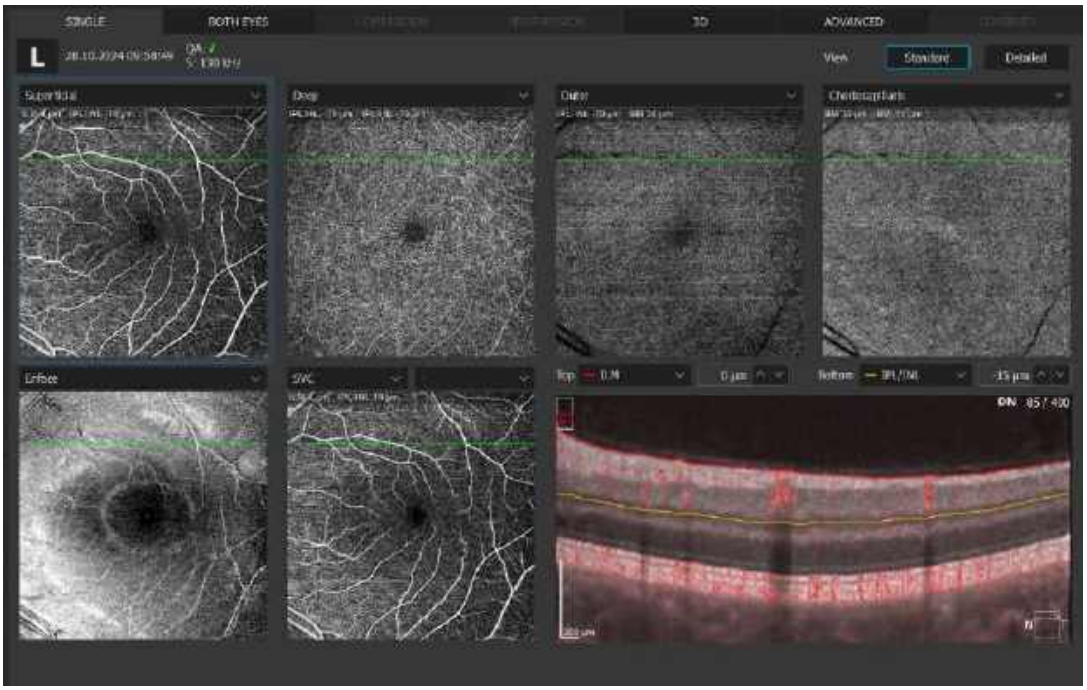


Figure 327.
OCT-A Enface Window in the Results Tab

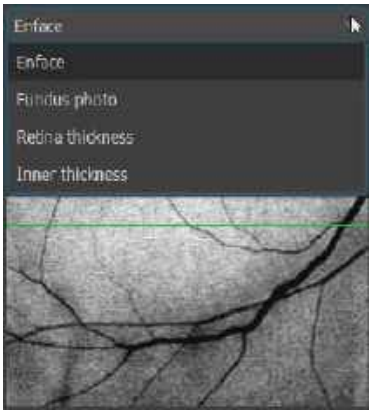


Figure 328.
Enface Window Drop-Down Menu

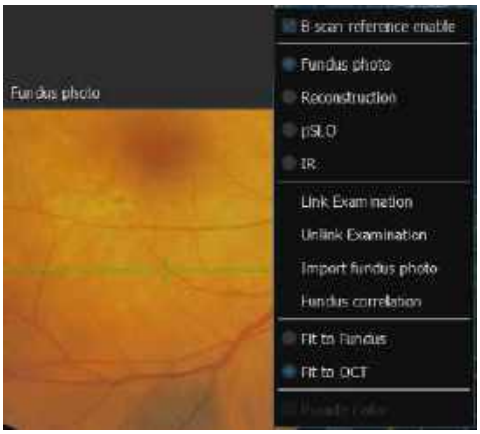


Figure 329.
Enface Window (Right-Click Context Menu)

1. **ENFACE**

   Displays an enface image generated between the boundaries from the active angiogram window.

2. **FUNDUS PHOTO**

   Displays a color fundus photo (if available).

3. **RECONSTRUCTION**

   Displays OCT reconstruction image.

4. **pSLO**

   Displays pSLO image.

5. **IR**

   Displays IR image.

6. **RETINA THICKNESS**

   Displays the Retina Thickness map.

7. **INNER THICKNESS**

   Displays the Inner Retina Thickness map.

When the Structure map is selected, it is possible to hide the thickness sectors. To hide the sector, position the mouse cursor over the Structure map, press the right button and uncheck the **[SECTORS]**.

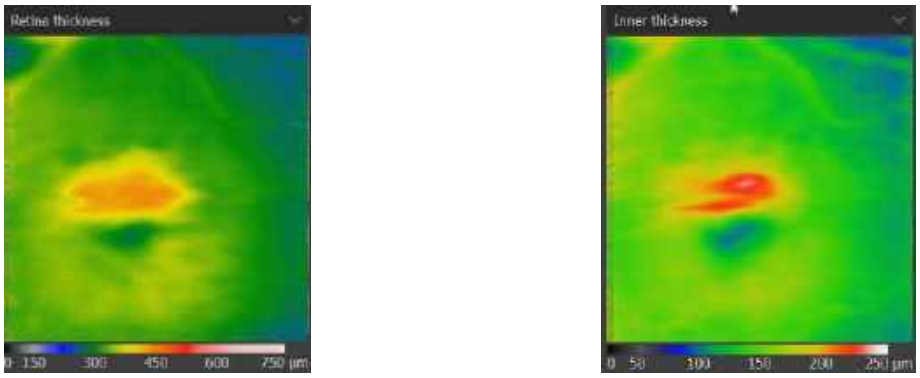


Figure 330.
Enface Structure Map

Enface Image context menu offers:

1. **RESET BRIGHTNESS / CONTRAST**

   Restore brightness / contrast default.

2. **B-SCAN REFERENCE ENABLE**

   Enable / disable the reference B-scan on the angiogram.

3. **INVERT**

   Invert the colors of the enface image.

4. **SAVE AS…**

   Save enface image.

INVERT

Inverts the grayscale in enface images. When the invert function is used for the choroidal layer, it displays dark on white regions where the choroidal blood vessels are, instead of the standard white on black appearance.

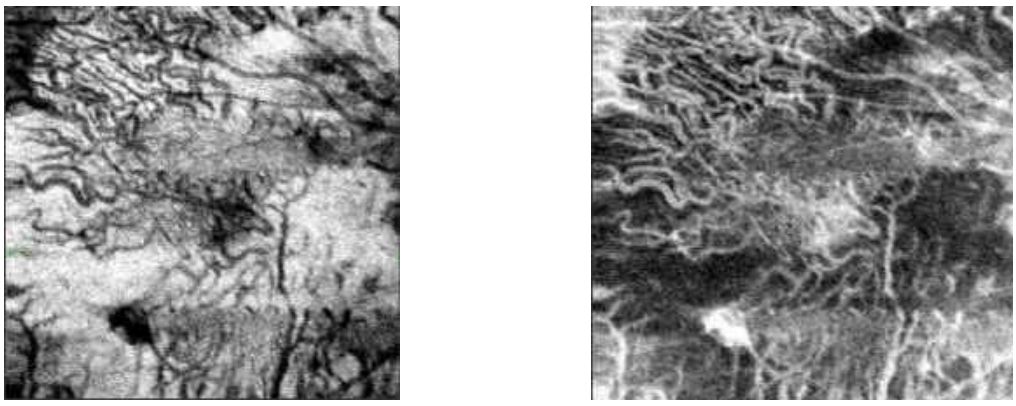


Figure 331.
Enface Image for the Choroid Layer (Invert OFF / ON)

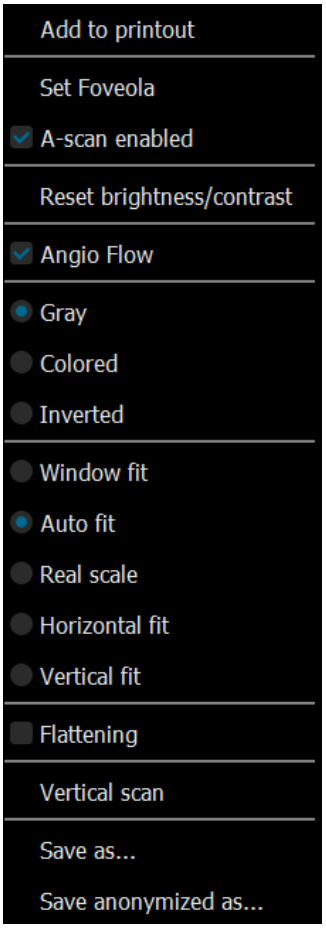
19.2.4. Tomogram Window

This shows the selected tomogram overlaid with layer boundaries from the active angiogram window. On the tomogram a semi-transparent, red decorrelation mask is overlaid. It is possible to change the position of the desired layer by typing in the offset over the tomogram window or grabbing and moving the selected layer. The offset is expressed as microns from the original position of the recognized retinal layer. A negative offset value describes the position below the original position.

19.2.4.1. Operation of the Tomogram Object

Standard manipulation of the tomogram window is described in Chapter 13.6 Tomogram Window Manipulation. Additionally, it is possible to modify the position of the boundary layers that create the angiogram view. Select the boundary from the list box. Grab the desired layer and move it to the desired position. It is possible to change the depth position of any boundary.

Tomogram window context menu offers:



1. Add to printout
6. Set Foveola
7. A-scan enabled
8. Reset brightness / contrast
9. Angio Flow
10. Gray
11. Colored
12. Inverted
13. Window fit
14. Auto fit
15. Real scale
16. Horizontal fit
17. Vertical fit
18. Flattening
19. Vertical scan
20. Save as…
21. Save anonymized as…

When vertical scan is marked:

1. The system displays a composed vertical tomogram (created from B-scans) with layer boundaries.
22. On the enface and angiogram object, an additional green, vertical reference line appears.
23. The B-scan alignment function is turned on (the same function as used in 3D Scans).

24. Scrolling vertical tomograms is not synchronized with the horizontal tomogram.
25. On the context menu (RMB), the B-scan alignment function is available (it is turned on by default). When it is off, B-scans are not aligned along the Z axis.

[ANGIO FLOW OVERLAY]

This option is checked by default. When the operator selects the angio flow option, they can adjust the brightness and contrast of the red color of the Angio flow areas. To adjust the brightness and contrast of the flow mask, right-click and hold the right mouse button, place the cursor over the tomogram and move it up / down or right / left.

Dragging up and down adjusts the brightness. Dragging right and left adjusts the contrast.

Right-clicking the OCT image and selecting **[RESET BRIGHTNESS / CONTRAST]** from the menu resets the brightness and contrast adjustments.

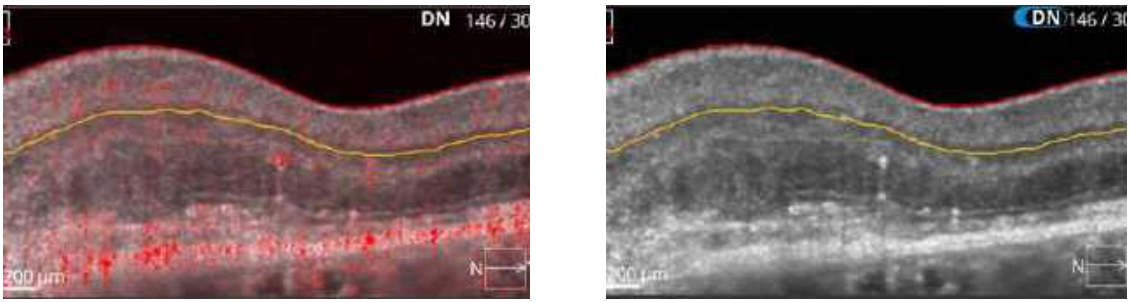


Figure 332.
Tomogram Window with Angio Flow Overlay ON (Left) and OFF (Right)

19.2.5. OCT-A Manual Tools

19.2.5.1. FAZ Tool

In OCT-A analysis of the retina, the center of the macula is generally capillary-free and named the “foveal avascular zone” (FAZ).

Foveal Avascular Zone (FAZ) measurements are based on OCT-A scans and are available only on the Retina layer. Only one measurement per scan is possible.

FAZ TOOL

Foveal avascular zone manual tool is available with the optional angiography module. It can be open by double clicking on the angiogram object. FAZ is not available on the enface view and the depth coded map.

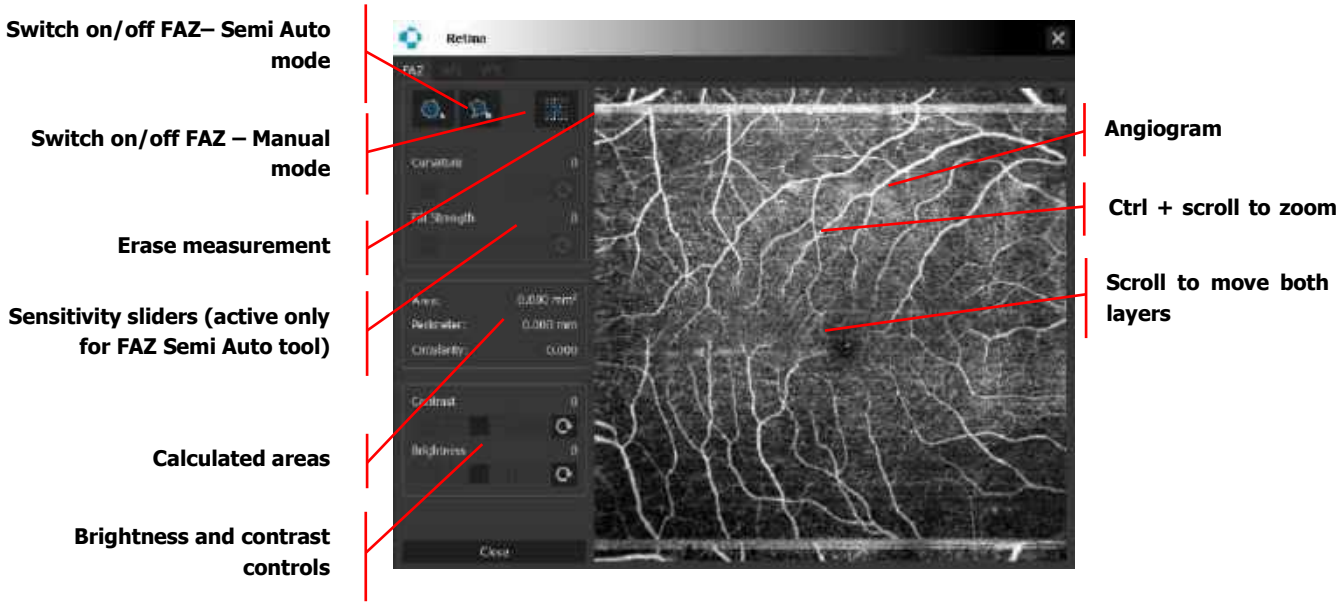


Figure 333.
Foveal Avascular Zone (FAZ) Tool

1. ERASE MEASUREMENTS

Clear all measurements.

2. CALCULATED AREAS

The following parameters are provided:

- **Area:** FAZ area in mm^2.
- **Perimeter:** FAZ perimeter in mm.
- **Circularity:** ratio between the measured perimeter and the perimeter of a circular area of the same size.

3. BRIGHTENESS AND CONTRACT ADJUSTMENT

Two sliders for brightness and contrast adjustment.

19.2.5.1.1. Foveal Avascular Zone (Semi Auto)

Figure 334.
Foveal Avascular Zone Tool (Semi Auto)

FAZ (SEMI AUTO)

Curvature and fill strength sliders allow to manually adjust the automatic FAZ area detection. For best results it is recommended to click on the measured area and set the value of the strength slider to 0. Then adjust the curvature value to get the best shape of the measured area. Adjust the strength sliders for the best coverage of the measured area.

19.2.5.1.2. Foveal Avascular Zone (Manual)

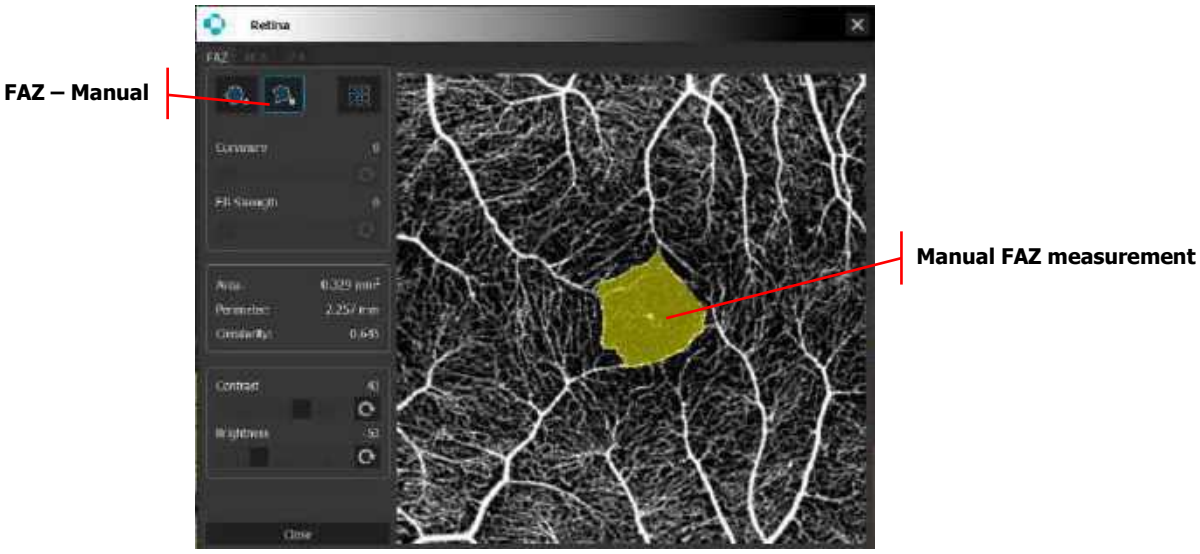


Figure 335.
Foveal Avascular Zone Polygon Tool (Manual)

FAZ (MANUAL)

Select and click the location for the first node and click again to select the position for the next node to begin. Continue clicking to create further nodes. The **CTRL + Z** key combination cancels the last change that was made.

Close the selection border by doing either of the following:

1. Position the pointer over the starting point and click. The mouse pointer changes to a hand icon when over the starting point.

26. If the pointer is not over the starting point, click the right mouse button.

27. After closing to polygon, the user can correct the position of each node by grabbing and moving it. The user may also grab and move the polygon. When hovering over the node with the mouse pointer, it changes to a hand icon. The area inside the polygon has a yellow mask.

NOTE: The final measurement depends on the brightness, contrast, and sensitivity adjustments. The user is responsible for the correct adjustments of the brightness, contrast, and sensitivity to highlight only the proper structure of the changes. OPTOPOL Technology Sp. Z o.o. is not responsible for misdiagnosis of results.

19.2.5.2. VFA Tool

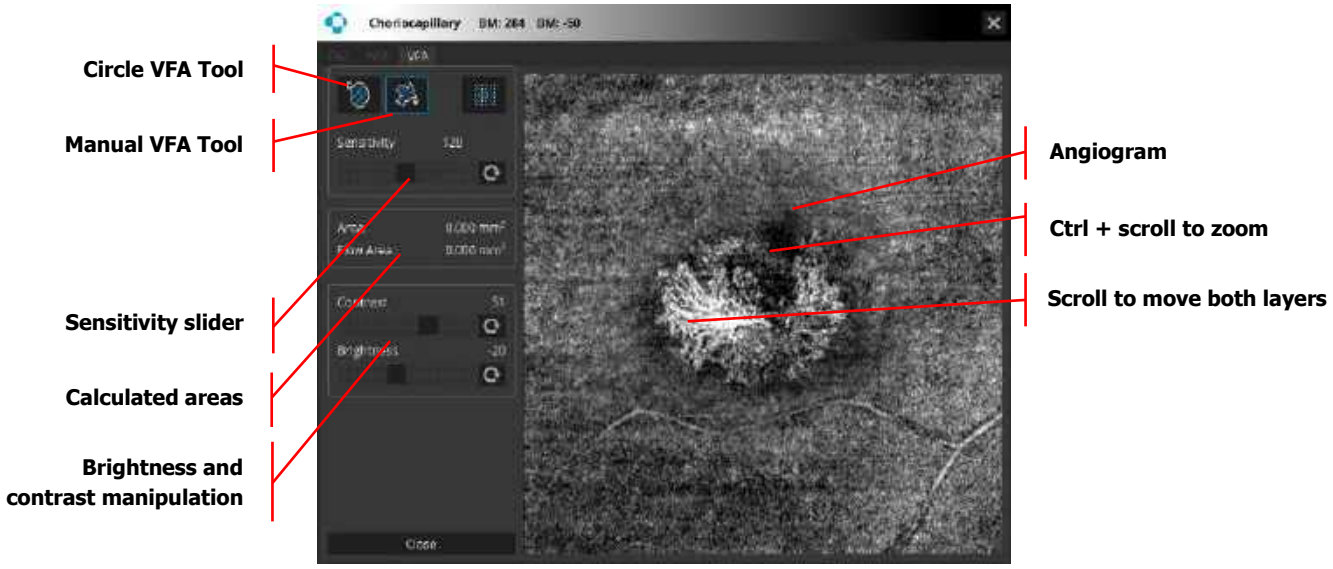


Figure 336.
Vascular Flow Area Tool

Vascular Flow Area (VFA) measurement is based on Angio scans detecting the white vessels which usually run in the pre-defined layers. To use VFA double click on the Angiogram object. This tool is available only for Outer retina and Choricapillary, Vitreous and Choroid layers and allows to measure the area of vasculature inside the selected area. The flow detection can be performed either by using the circle tool or the manual pointer. In the selected space the area and the flow area parameters will be provided [mm^2].

19.2.5.2.1. Vascular Flow Area (Circle Area Tool)

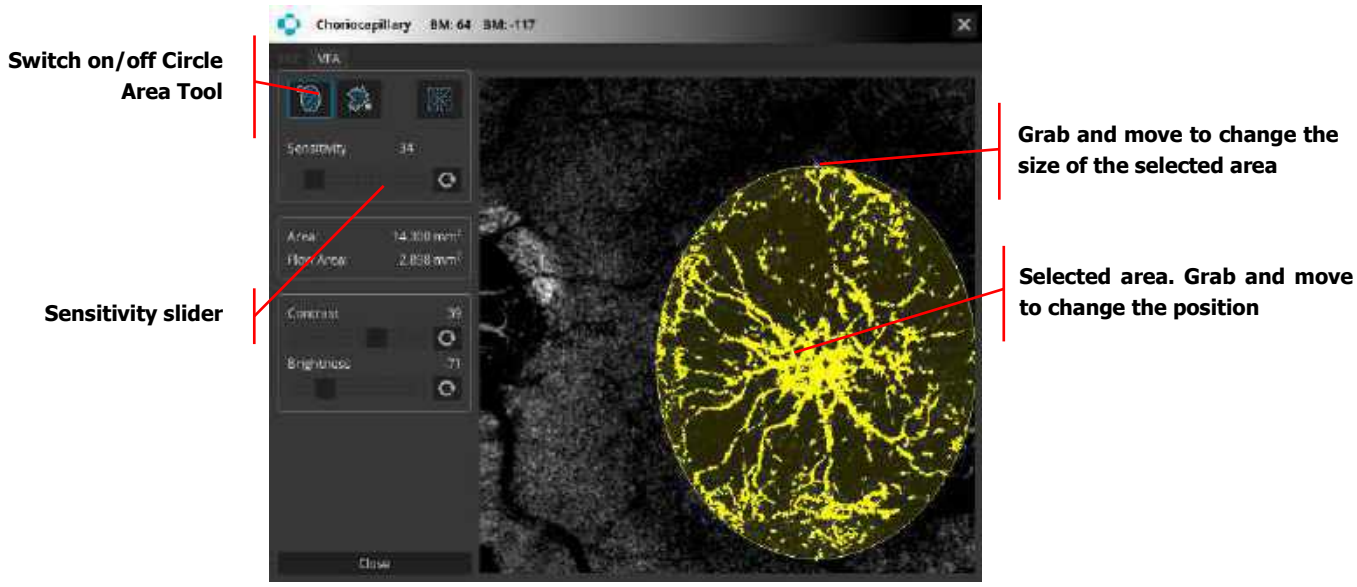


Figure 337.
Vascular Flow Area Tool – Circle Area Tool

To draw an oval selection click at the point to position the middle of the selection, then hold your mouse button down and move it in the desired direction until the object or area is surrounded by the selection outline. Release the mouse button to complete the selection. The selection may be corrected by grabbing the oval and moving it to the proper position. The shape and size of the selected area can be changed by grabbing and moving individual nodes. Sensitivity slider changes the tolerance of the tool.

19.2.5.2.2. Vascular Flow Area (Manual Pointer Area Tool)

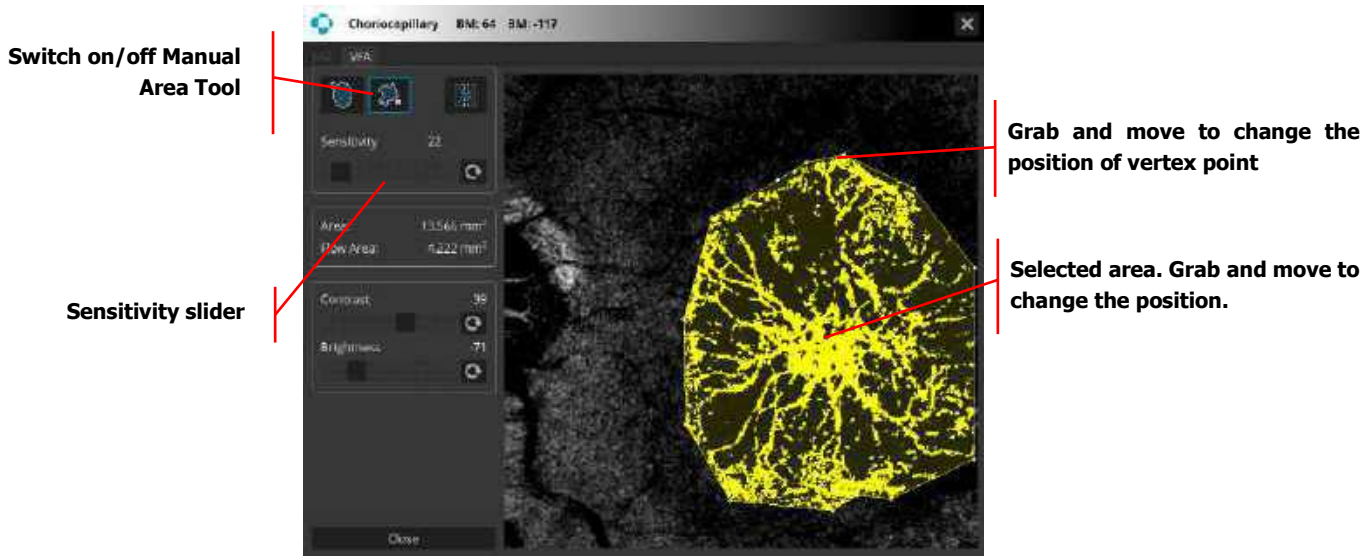


Figure 338.
Vascular Flow Area Tool – Manual Pointer Area Tool

Manual Pointer Area Tool creates irregularly shaped selections defined by a series of line segments. To create a polygon selection, click repeatedly with the mouse to create line segments. When finished,

click at the starting point (or double click), and the software will automatically draw the last segment. The vertex points that define a polygon selection can be moved and deleted. **CTRL + Z** – removes the last change that was made.

To move a vertex, grab and move the chosen point. To delete the vertex point, click the right mouse button and chose one of the following two options: **Delete Current Polygon** or **Delete Current Node**. To cancel click any other place.

User can modify thresholding using sensitivity slider.

NOTE: The final measurement depends on the brightness, contrast, and sensitivity adjustments. The user is responsible for the correct adjustments of the brightness, contrast, and sensitivity to highlight only the proper structure of the changes. OPTOPOL Technology Sp. Z o.o. is not responsible for misdiagnosis of results.

19.2.5.3. NFA Tool

Non-Flow Area (NFA) measurement allows the user to manually quantify the Non-flow Area on the OCT-A examination. To use NFA (Non-Flow Area tool), double click on the angiogram object. This tool is available only for Superficial, SVC, Deep, DVC, ICP and DCP layers. For the selected space, the area of the nonflow area will be provided [mm^2].

The NFA Tool provides:

1. Area of as a sum of all marked spots.
28. Up to 30 spots available to be analyzed.

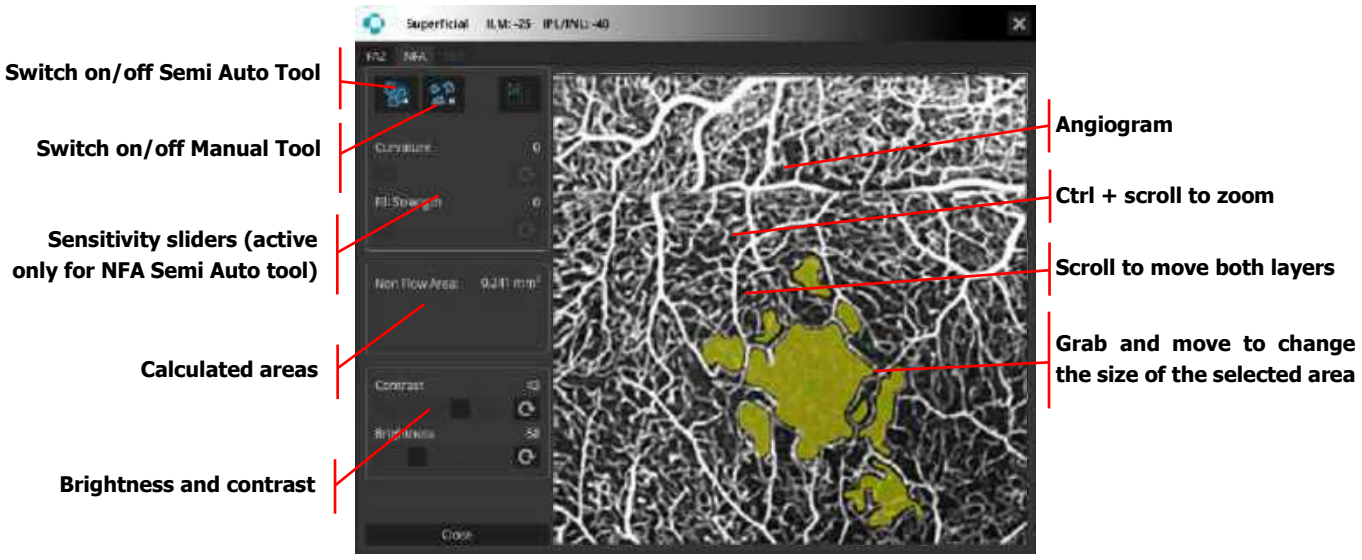


Figure 339.
Non-Flow Area Tool

19.2.5.3.1. Non Flow Area (Semi Auto)

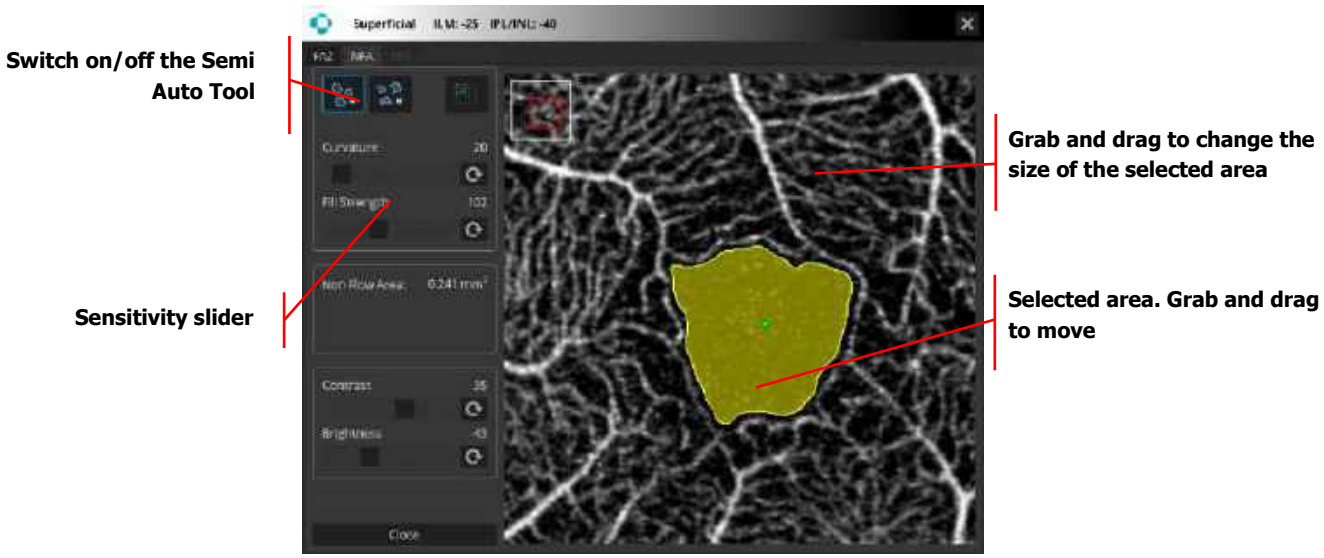


Figure 340.
Non-Flow Area Tool (Semi Auto)

For best results it is recommended to click on the measured area and set the value of the strength slider to 0. Then adjust the curvature value to get the best shape of the measured area. Adjust the strength sliders for the best coverage of the measured area.

19.2.5.3.2. Non Flow Area (Manual)

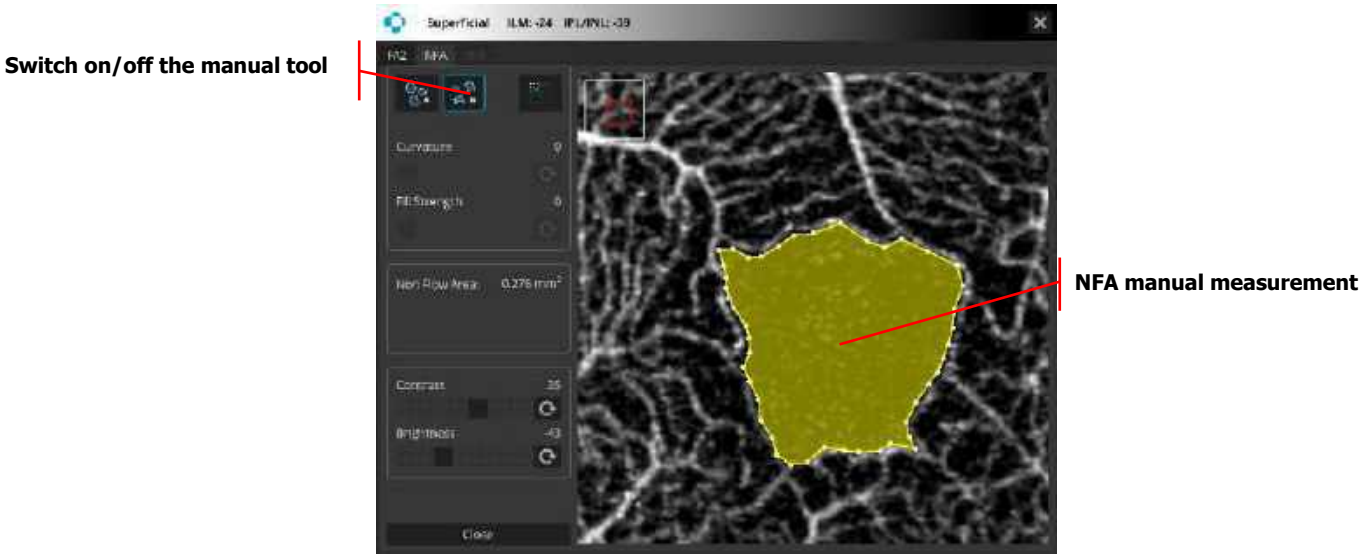


Figure 341.
Non Flow Area Tool (Manual)

Select and click the location for the first node, then move the mouse to the position to place the next node and click again. Continue in this fashion to create further nodes. The **CTRL** + **Z** combination cancels the last change that was made.

19.2.5.4. Layer Segmentation Correction

Layer segmentation can be corrected in the Full Screen View – See Chapter 13.7 Editing Segmentation Layers

19.2.6. Quantification Maps (Density and Skeleton)

Quantification of vasculature in specific sectors and heat map corresponding to the vasculature. It is available for Retina Angio layers:

- Superficial
- Deep

And Disc Angio layer:

- RPC

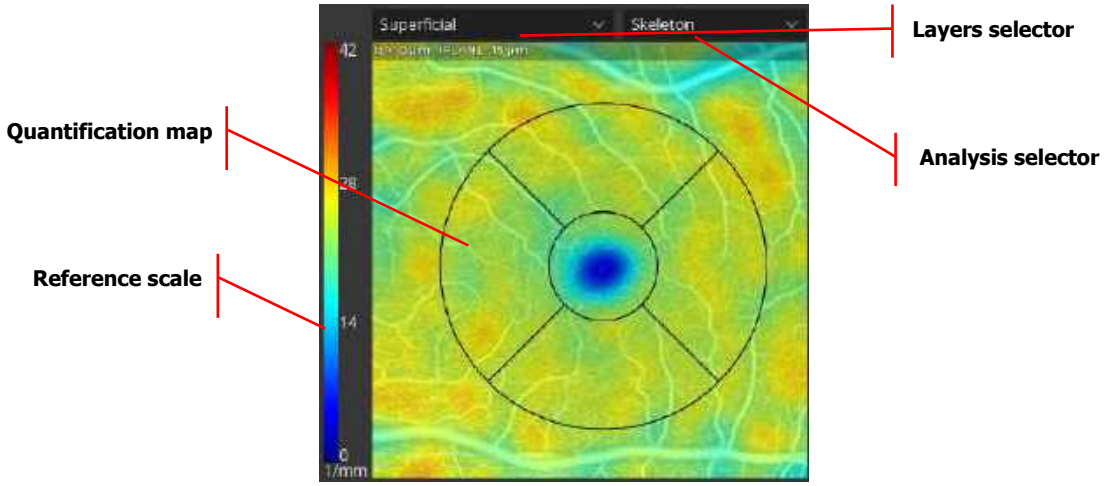


Figure 342.
Quantification data field in Angio [SINGLE] Standard and Detailed View

1. LAYERS SELECTOR

Allows to select the layer. The quantification is not available for all layers.

2. ANALYSIS SELECTOR

In the **[SINGLE]** and [**BOTH EYES]** tab in both Standard and Detailed view there are two analysis available:

- Density
- Skeleton

In the **[COMPARISON]** and **[PROGRESSION]** tab in both Standard and Detailed view there are four analysis available:

- Density
- Density Difference
- Skeleton
- Skeleton Difference

3. QUANTIFICATION HEAT MAP

The results of the quantification are displayed in the form of a mask over the analyzed area, with values according to the selection. In order to change the transparency of the quantification mask scroll over the quantification map.

The results can be presented as values in the table acquired in the specific folder.

DENSITY DISPLAY

Vessel Area Density (VAD) - is defined as the total area of perfused vasculature per unit area in a region of measurement. This metric is calculated by summing up the number of pixels which contain perfused vasculature, and dividing the sum by the total number of pixels in the considered region. The result is a unitless number ranging from 0 (no perfusion) to 100 (fully perfused) [mm²/mm²].

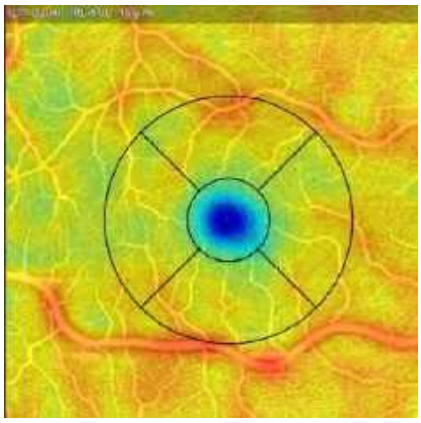


Figure 343.
Vessel Density Map

SKELETON DISPLAY

Vessel Skeleton Density (VSD) – it is defined as the total area of skeletonized vasculature per unit area in a region of measurement. Skeletonization performs thinning of all vessels down to 1 pixel width and thus makes analysis more sensitive to small vasculature (as the large vessels lose more area than the thin ones in the skeletonization process). This metric is calculated by summing up the number of pixels that represent the skeleton of the vasculature, and dividing the sum by the total number of pixels in the considered region. The result is a unitless number ranging from 0 (no perfusion) to 100 (fully perfused) [mm²/mm²].

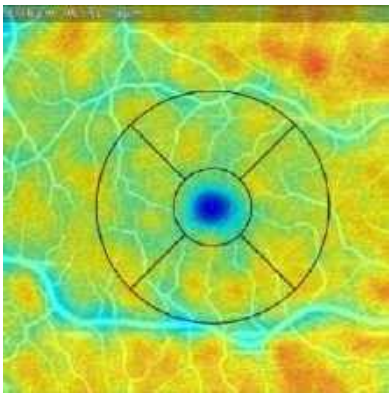


Figure 344.
Skeleton Density Map

NOTE: Due to the method of calculating the pixel density there may be slight differences between the results for the examination with different size and/or density scanning.

NOTE: Both VAD and VSD can detect abnormal vasculature and provide repeatable quantitative results equally in normal and diseased eyes.

QUANTIFICATION TABLE

Presents the results of the quantification. The table in the **[COMPARISON]** and **[PROGRESSION]** can only display a comparison of exams which meet the following criteria: they are identical width and the difference in their scanning densities does not exceed 30%. If the exams do not conform to these criteria, N/A is displayed in the difference column.

Measurement Zones for Retina (3 to 5 mm scan)

Region	Density
Total	56.1
Superior	56.2
Inferior	56.3
Central	56.4
Inner	56.5
Superior Inner	56.6
Inferior Inner	56.5
Full	56.6

Figure 345.
Retina Measurement Zones – 3 to 5 mm

	Total
	Superior
	Inferior
	Central
	Inner
	Superior Inner

	Inferior Inner
	Full

Measurement Zones for Retina (6 mm scan)

Region	Density
Total	56.1
Superior	56.2
Inferior	56.3
Center	56.4
Inner	56.5
Superior Inner	56.6
Inferior Inner	56.5
Outer	56.6
Superior Outer	56.7
Inferior Outer	56.8
ETDRS	56.9

Figure 346.
Retina Measurement Zones – 6 mm

	Total
	Superior
	Inferior
	Central
	Inner
	Superior Inner

	Inferior Inner
	Outer
	Superior Outer
	Inferior Outer
	ETDRS

Measurement Zones for Disc

Region	Density
Total	56.1
Superior	56.2
Inferior	56.3
Inside disc	56.4
Peripapillary	56.5
Superior Peripa	56.6
Inferior Peripa	56.5

Figure 347.
Disc Measurement Zones

	Total
	Superior
	Inferior
	Inside Disc

	Peripapillary
	Superior Peripapillary
	Inferior Peripapillary

19.2.7. OCT-A Analysis Table

If the measurements are performed on exams differing in size and / or on different layers, the "!" symbol is displayed in the table next to the result. The difference is calculated as: newer scan - baseline scan. The percentage value is the percentage change compared to the baseline (change / baseline) *100%.

If the operator uses only one analysis tool, the tab with the measurements results is activated.

19.2.7.1. Single View

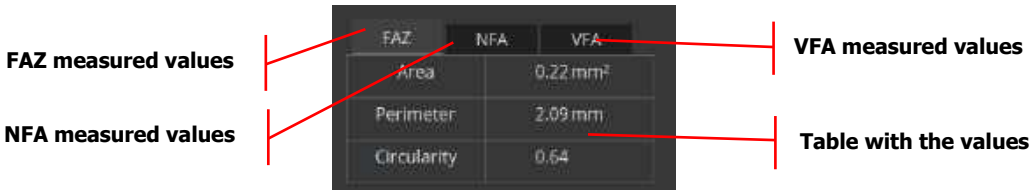


Figure 348.
Angio OCT Analysis Table (Single View)

19.2.7.2. Both Eyes View

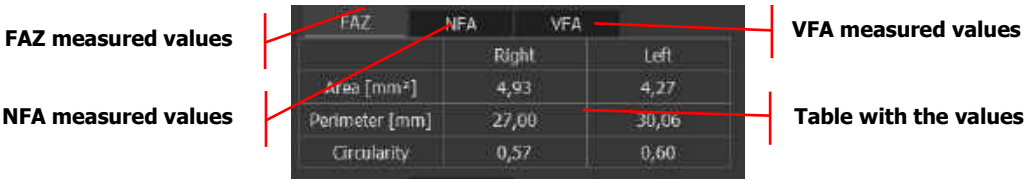


Figure 349.
Angio OCT Analysis Table (Both Eyes View)

19.2.7.3. Comparison View

Figure 350.
OCT-A Analysis Table for Comparison View

19.2.7.4. Progression View

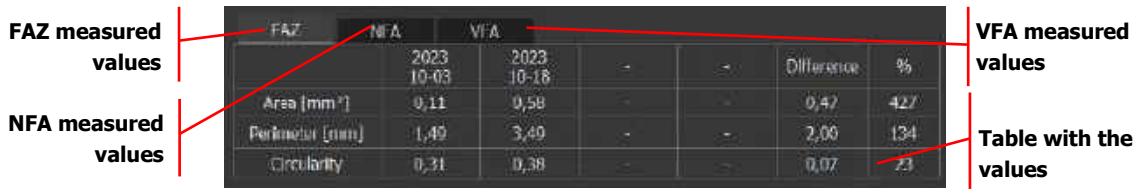


Figure 351.
OCT-A Analysis Table for Comparison View

19.3. Retina OCT-A

19.3.1. Retina OCT-A Results View

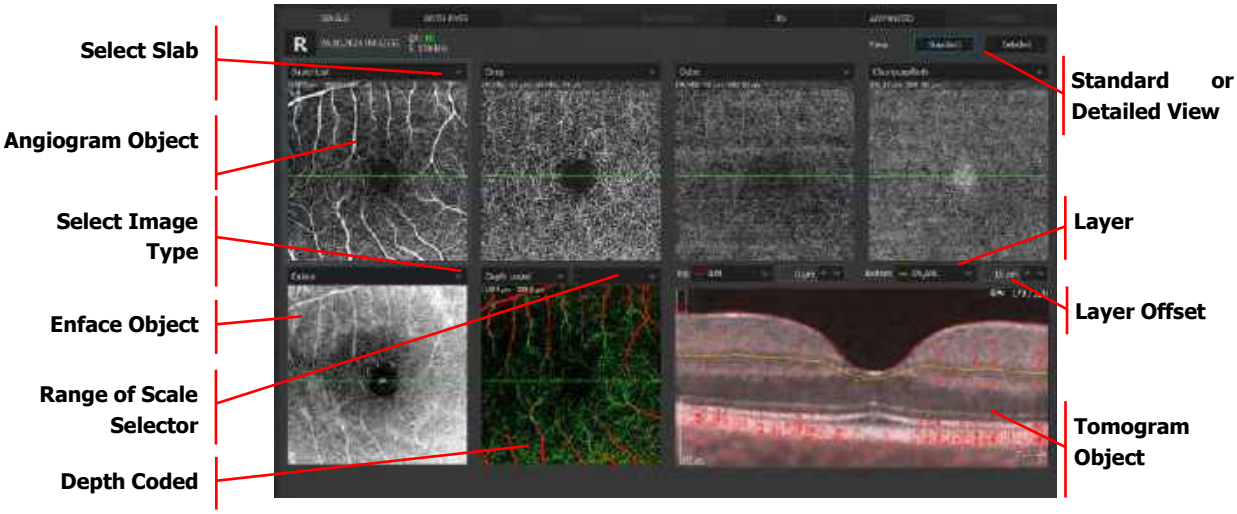


Figure 352.
Retina OCT-A Single Tab (Standard View)

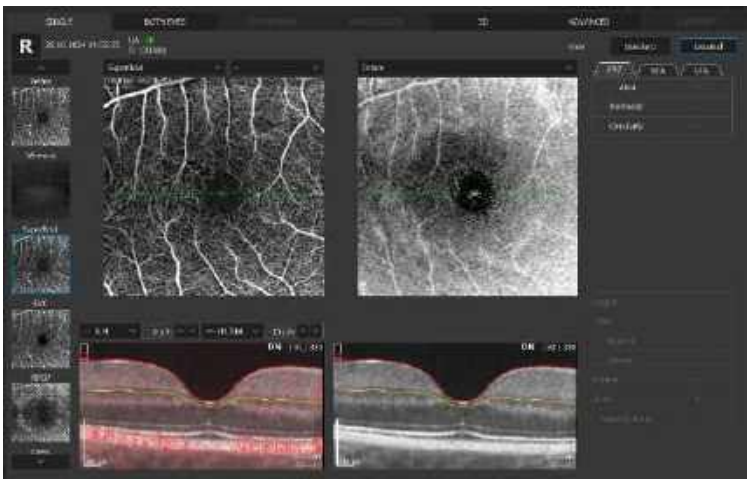


Figure 353.
Retina OCT-A Single Tab (Detailed View)

Right-click on the tomogram window to open the context menu and turn on / off the **Angio Flow** on the tomogram.

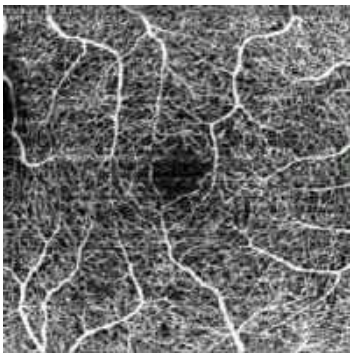
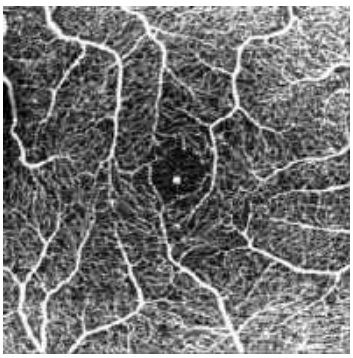
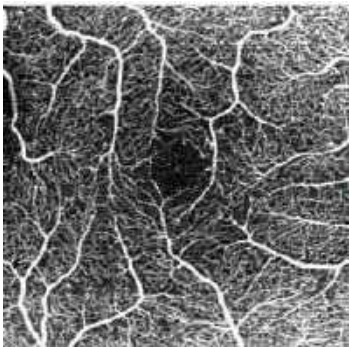
The SOCT algorithm calculates the decorrelation value for each pixel in the B-scan by comparing the OCT signal intensity variations across the B-scans in each set. Static tissue locations, without flow,

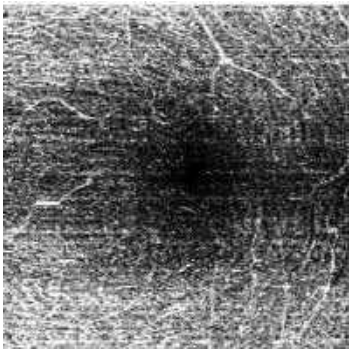
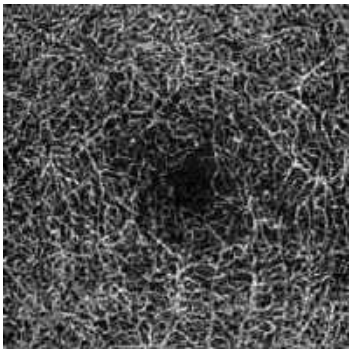
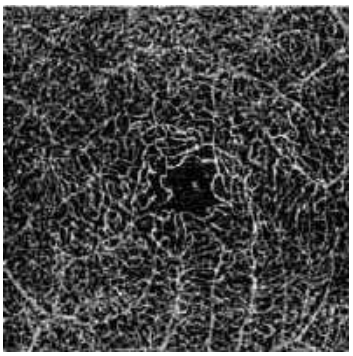
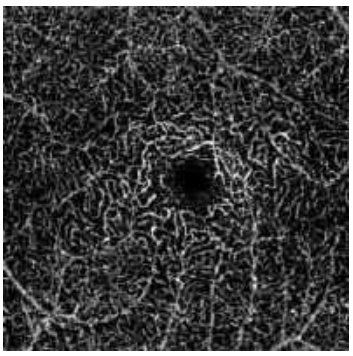
exhibit little variation in OCT signal intensity over the repeated B-scans; therefore, the decorrelation values will be low.

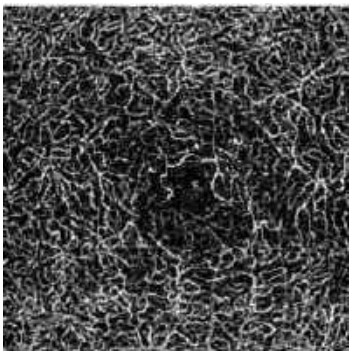
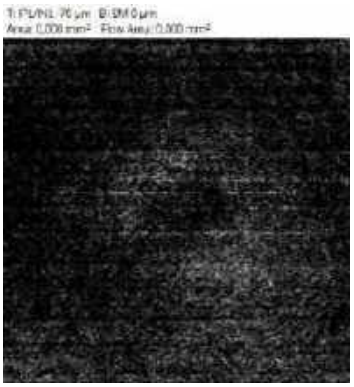
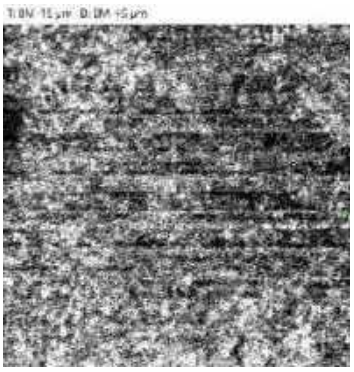
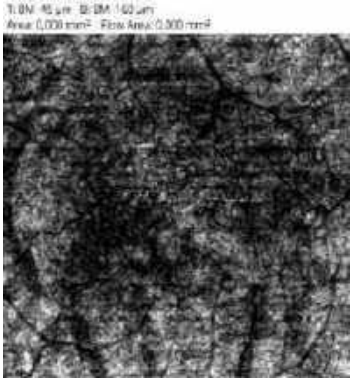
NOTE: Areas with large vessels may block the ability for the OCT-A to display flow signal.

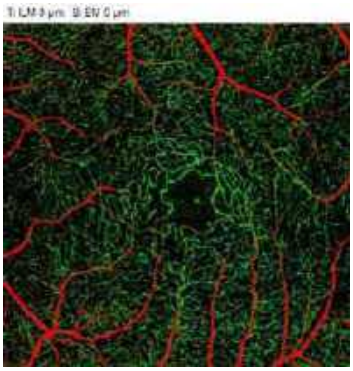
Information displayed on the angiogram object is extracted from the space limited by the position of the top (selected retina layer and their offset) boundary and bottom (retina layer and their offset) boundary.

By selecting the dropdown above each angiogram object, the user can select one of the predefined vasculature layers based on the position of the recognized retina layer. The vascular layer can be selected from the list box of available layers:

Vascular Layer	Slab Preview	Description of Layer	offset
Retina		Retinal vasculature angiogram	ILM 0µm OPL/ONL -10µm
Vitreous		Vitreous structure (above ILM layer) No vasculature is present	ILM 250 µm ILM 3 µm
Superficial		Superficial capillary plexus	ILM 0 µm IPL / INL -15 µm
SVC		Superficial vascular complex	ILM 0 µm IPL / INL 10 µm

Vascular Layer	Slab Preview	Description of Layer	offset
RPCP		Radial peripapillary capillary plexus	ILM 0 µm NFL / GCL 0 µm
Deep		Deep capillary plexus	IPL / INL -15 µm IPL / INL -70 µm
DVC		Deep vascular complex	IPL / INL 10 µm OPL / ONL -10 µm
ICP		Intermediate capillary plexus	IPL / INL 10 µm INL / OPL 10 µm

Vascular Layer	Slab Preview	Description of Layer	offset
DCP		Deep capillary plexus	INL / OPL 10 µm OPL / ONL -10 µm
Outer		Outer retina layers (avascular zone)	IPL / INL -70 µm BM 30 µm
Choriocapillaris		Choroidal capillary	BM 30 µm BM -45 µm
Choroid		Choroidal vessels	BM -45 µm BM -220 µm

Vascular Layer	Slab Preview	Description of Layer	offset
Depth Coded		Color coded retinal vasculature angiogram	ILM 0 µm BM 0 µm

Exact information about boundaries used to generate angiogram for active object is displayed in the upper part of the tomogram window.

NOTE: The signal intensity of the tissue underneath a large blood vessel will be obstructed by the blood flow signal of the large blood vessel. The obstruction will affect the visualization of the highly reflective layers such as IS / OS or RPE in those areas. Therefore, the angiogram images including IS / OS or the RPE layer appear to be similar to the angiogram of blood vessel structure of the inner retina. This effect is called a "Decorrelation Tail" or "Projection Artifact". In a healthy eye, there are no blood vessels in the outer retina.

19.3.2. Projection Artifact Removal Algorithm

Angio OCT techniques are based on the principle of motion contrast. Visualization of the deeper vascular layers is affected by flow projection artifacts from fluctuating shadows of the flowing blood cells in the more superficial blood vessels that create "false flow" in the deeper layers. These are called "projection artifacts". On cross-sectional Angio OCT, projection artifacts are seen as an elongated signal tail. On enface OCT-A images, the higher layer blood vessels network gets duplicated on the deeper slabs.

Turn on / off the projection artifact removal by **right-clicking** in the context menu over the angiogram. As the default, PAR is activated for the Outer, Choriocapillaris, Choroid and Deep layers.

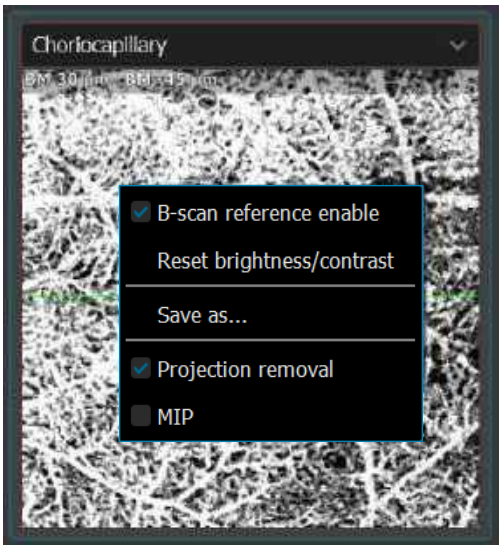


Figure 354.
OCT-A Enface Right-Click Context Menu

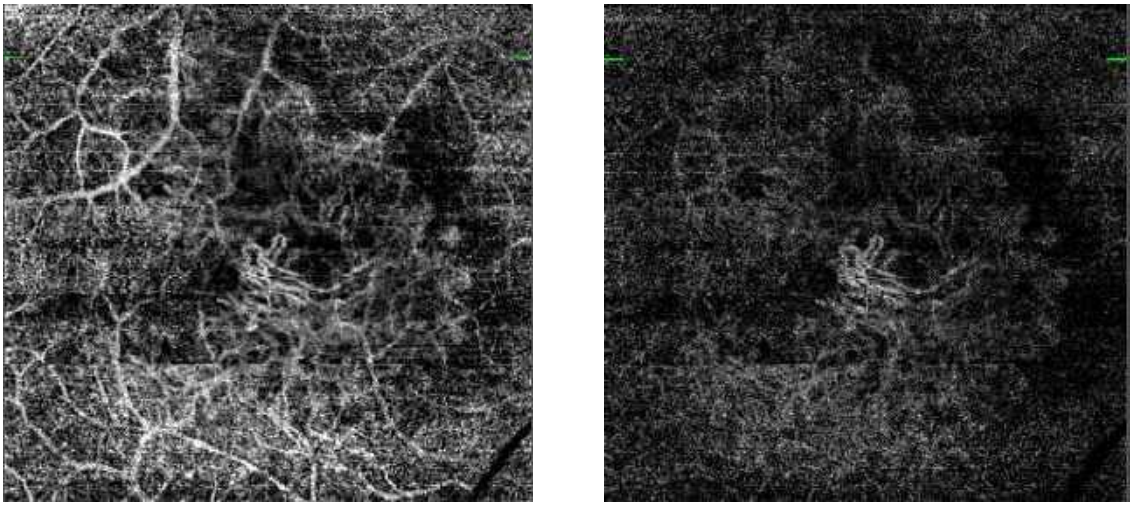


Figure 355.
Projection Artifact Removal Algorithm OFF / ON

NOTE: When PAR is turned off, the vessels from above are projected downwards. The ability to turn PAR off is included so the operator can evaluate the image without the filter.

NOTE: Verify the retina layer recognition boundaries and the layer offsets before evaluating an angiogram of the vascular layer.

NOTE: Due to projection artifacts of the retinal flow signal onto deeper layers, such as the retinal pigment epithelium and choroid, carefully evaluate the signal in the deeper vascular layer, particularly the RPE and choriocapillaris.

19.3.3. [Single] Tab (Standard View)

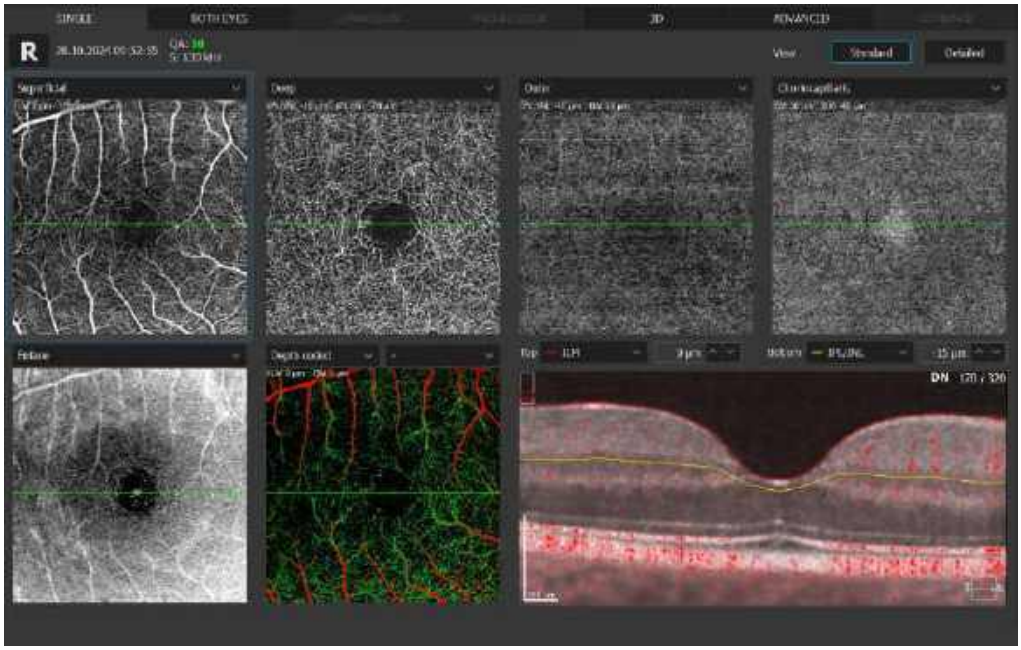


Figure 356.
Single (Standard View)

The Single - Standard View includes:

1. Four angiogram objects of different predefined retina layers depths (slabs).
29. OCT enface object.
30. Depth coded color map.
31. Tomogram with [Angio Flow] overlay.

FUNCTIONS OF THE SINGLE STANDARD VIEW

1. Each object has a green (horizontal) line that indicate the current tomogram location. Reposition these lines to display a tomogram from a desired location.
32. Each angiogram object has a dropdown menu, that switches between several predefined boundary slabs or custom slabs.

NOTE: It is not possible to show the same boundary slab in two different angiogram objects at once.

33. The user can customize the layer boundaries and offset positioning in the tomogram window. The customized segmentation is saved with each examination.
34. It is possible to import a fundus image into the enface object. Right-click on the enface object and choose import fundus photo from the context menu.
35. To reset all settings to the default segmentation and the customized angiogram enface slab settings, right-click on the exam list thumbnail to display the context menu options and press the **[REANALYZE]** button.

Figure 357.
OCT-A Tomogram Window Right-Click Context Menu

19.3.4. [Single] Tab (Detailed View)

Detailed view allows to see large objects and quantify results.

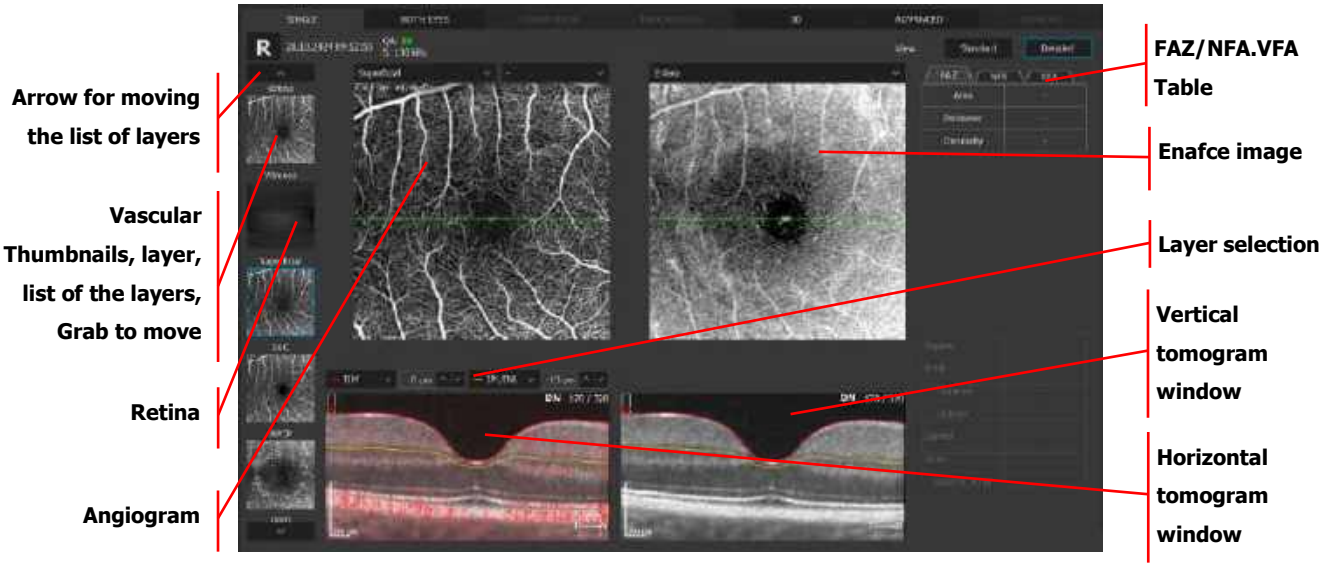


Figure 358.
Single Detailed View for Retina OCT-A

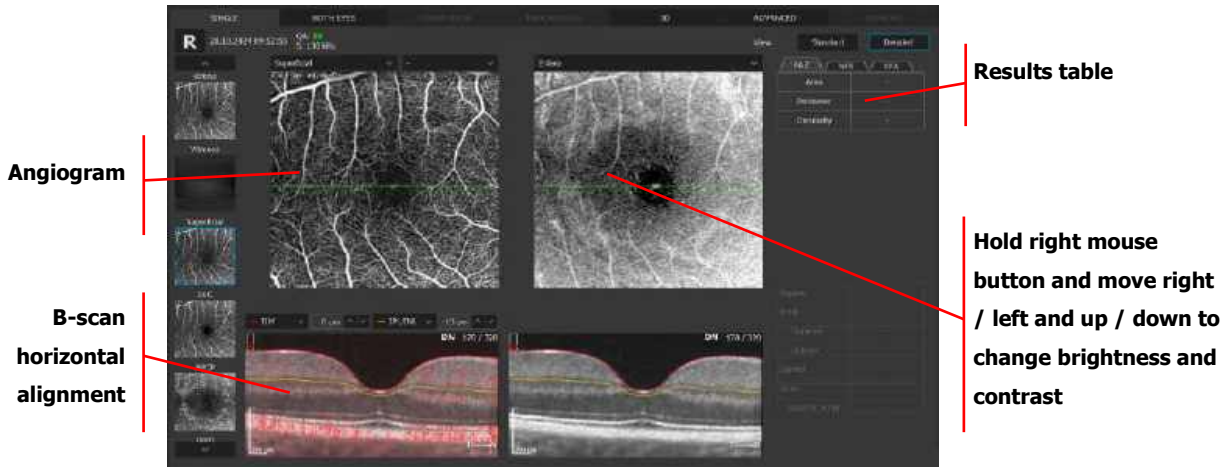


Figure 359.
Single Detailed View (Vertical and Horizontal Alignment)

THUMBNAILS OF VASCULAR LAYERS

1. Click on the thumbnail to display the object in the large window.
36. The user can move the list by clicking on the arrows or by scrolling over the list.
37. The user may also change the thumbnails order by grabbing and moving them to a new position.

Angiogram and enface images respond to manipulations and changes in offsets and layers.

The enface image displays an image generated between the boundaries of the active angiogram window.

The tomogram window shows the selected tomogram overlaid with layer boundaries from the active angiogram window. It is possible to change the position of the desired layer. It is possible to change the position of the desired layer by typing in the offset over the tomogram window or grabbing and moving the selected layer. The offset is expressed in microns from the original position of the recognized retinal layer. A negative offset value indicates the position below the original position.

The tomogram is overlaid with a semi-transparent, red decorrelation mask. The user can change the level of the decorrelation mask on the B-scan. Simultaneously hold the **CTRL** key on the keyboard and the right mouse button and move the mouse up / down and left / right to change the intensity level. To switch off the Flow, press the right mouse button and uncheck Flow from the menu.

The context menu is initiated with a mouse right-click.

The angiogram context menu offers:

1. **RESET BRIGHTNESS / CONTRAST**

   Restore brightness / contrast default.

2. **B-SCAN REFERENCE ENABLE**

   Enable / disable the reference B-scan on the angiogram.

3. **SAVE AS… / SAVE ANONYMIZED AS…**

   Save angiogram.

4. **PROJECTION REMOVAL**

   Enable / disable the projection artifact removal algorithm.

The enface Image context menu offers:

1. **RESET BRIGHTNESS / CONTRAST**

   Restore brightness / contrast default.

2. **B-SCAM REFERENCE**

   Enable / disable the reference B-scan on the angiogram.

3. **INVERT**

   Invert the colors of the enface image.

4. **SAVE AS… / SAVE ANONYMIZED AS…**

   Save the enface image.

19.3.5. [Both] View

In the **[BOTH EYES]** tab it is possible to make a comparison of both eyes (i.e., left, and right eye), which can be followed by asymmetry analysis of both eyes.

This analysis protocol operates only on one Right and one Left OCT-A examinations from the same visit.

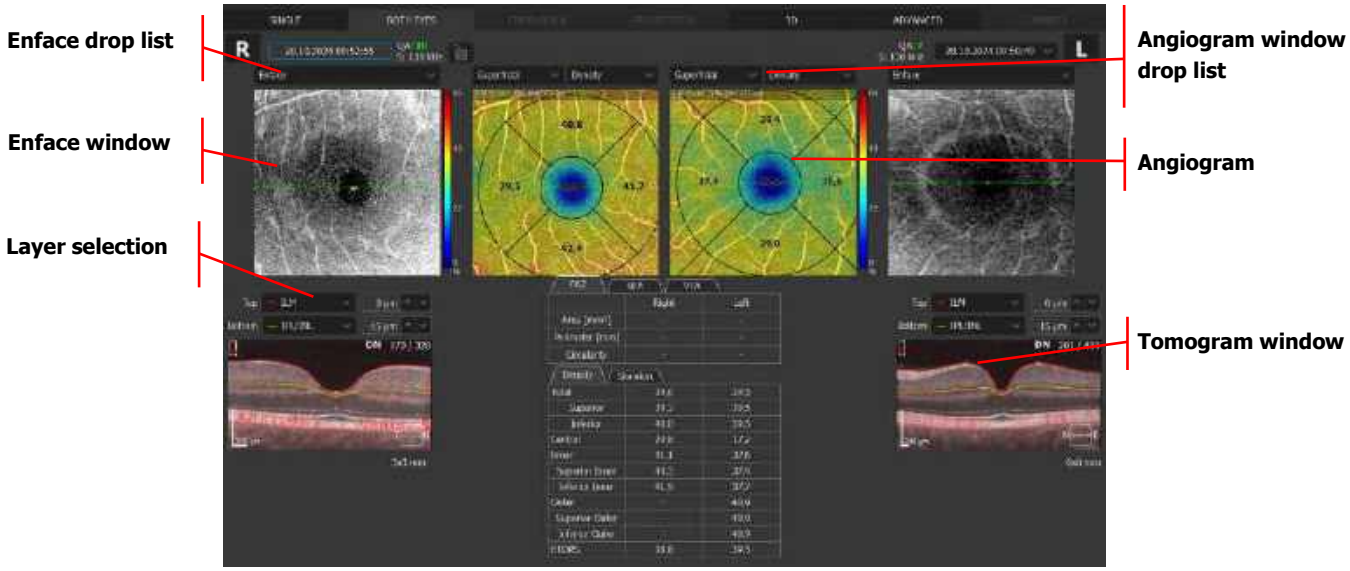


Figure 360.
Both Eyes (Retina Angio View)

ENFACE WINDOW

The object displayed can be selected from the enface drop list.

1. **ENFACE**

   Displays an enface image generated between the boundaries from the active angiogram window.

2. **STRUCTURE**

   Shows a color-coded thickness map of the retina. Sector dimension on the map is 1/3 mm in diameter.

3. **pSLO**

   Shows the location of OCT-A scan on the pSLO image of the retina.

In the angiogram window, the user can select one of predefined vasculature layers which are based on the position of the recognized retina layer. The vascular layer can be selected from the following angiogram drop list box:

Retina:	Retinal vasculature angiogram.
Vitreous:	Structure above ILM layer

Superficial:	Superficial capillary plexus.
SVC:	Structure between ILM and IPL / INL layers.
RPCP:	Structure between ILM and NFL / GCL layers
Deep:	Deep capillary plexus.
DVC:	Structure between IPL / INL and OPL / ONL layers.
ICP:	Structure between IPL / INL and INL / OPL layers.
DCP:	Structure between INL / OPL and OPL / ONL layers.
Outer:	Outer retina layers (avascular zone).
Choriocapillaris:	Choroid choriocapillaris visualization.
Choroid:	Choroid visualization.
Depth Coded:	Color coded Retinal vasculature angiogram.
Custom View:	User defines top and bottom boundaries to generate angiogram.

The tomogram window shows the selected tomogram overlaid with the boundaries of layers from the active angiogram window. On the tomogram, a semi-transparent, red colored decorrelation mask is overlaid. It is possible to change the position of the desired layer by typing in the offset over the tomogram window or grabbing and moving the selected layer. The offset is expressed in microns from the original position of the recognized retinal layer. A negative offset value describes the position below the original position.

Changing the type of the vascular layer on one object affects both eyes and both objects (angiogram and enface). The FAZ tool can be used only on the Superficial, Deep, ICP, DCP layers. VFA tool is available only for Outer, Choriocapillaris, Vitreous and Choroid layer.

19.3.6. [Comparison] View

This screen shows the analysis results comparing two examinations of one eye, on the same side, in the same scan program, from different dates.

The comparison view is used to observe follow up changes in the eye structure. The software automatically selects the outermost examinations (the oldest and the newest) to compare them. The user can manually choose examinations from the list, depending on the chosen comparison protocols that are highlighted.

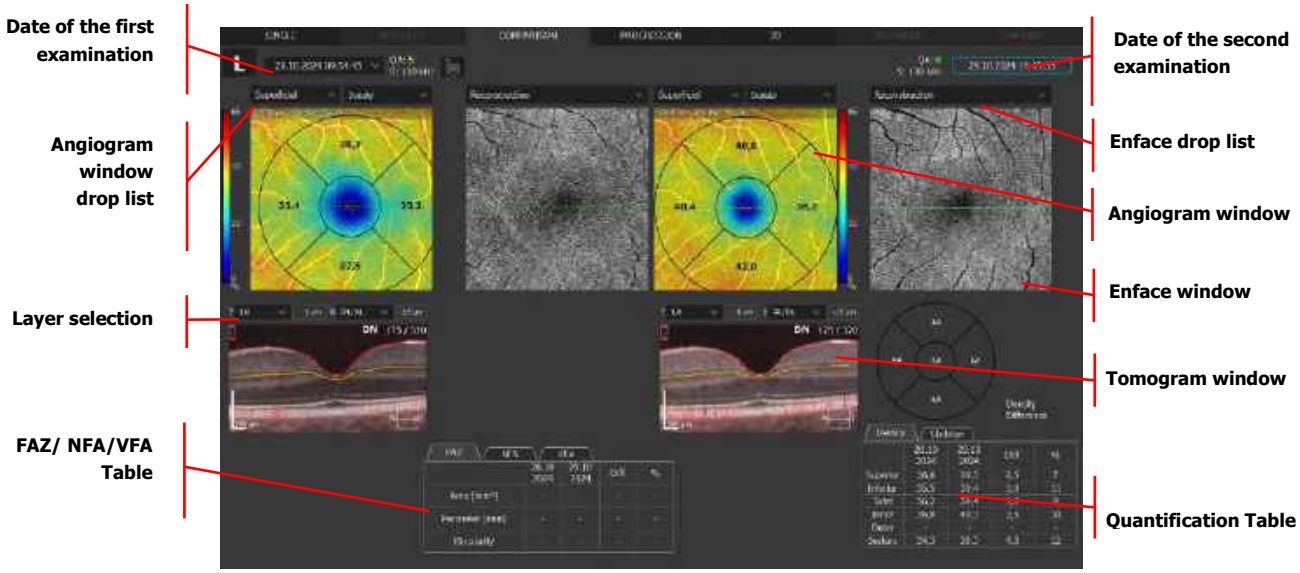


Figure 361.
Comparison Retina (Angio View)

In the Comparison tab, it is possible to compare different kinds of vasculature layers which are based on the position of the recognized retina layer (Retina, Depth Coded, Superficial, Deep, Outer, Vitreous, Choriocapillaris, Choroid). In the Enface window, it is possible to display Enface, Structure or pSLO.

The tomogram window displays the selected tomogram overlaid with the boundaries of layers from the active angiogram window.

19.3.7. [Progression] View

This screen shows the analysis results comparing four examinations, done on the same side in the same scan program, and on the same size of scanning area, arranged in a time sequence.

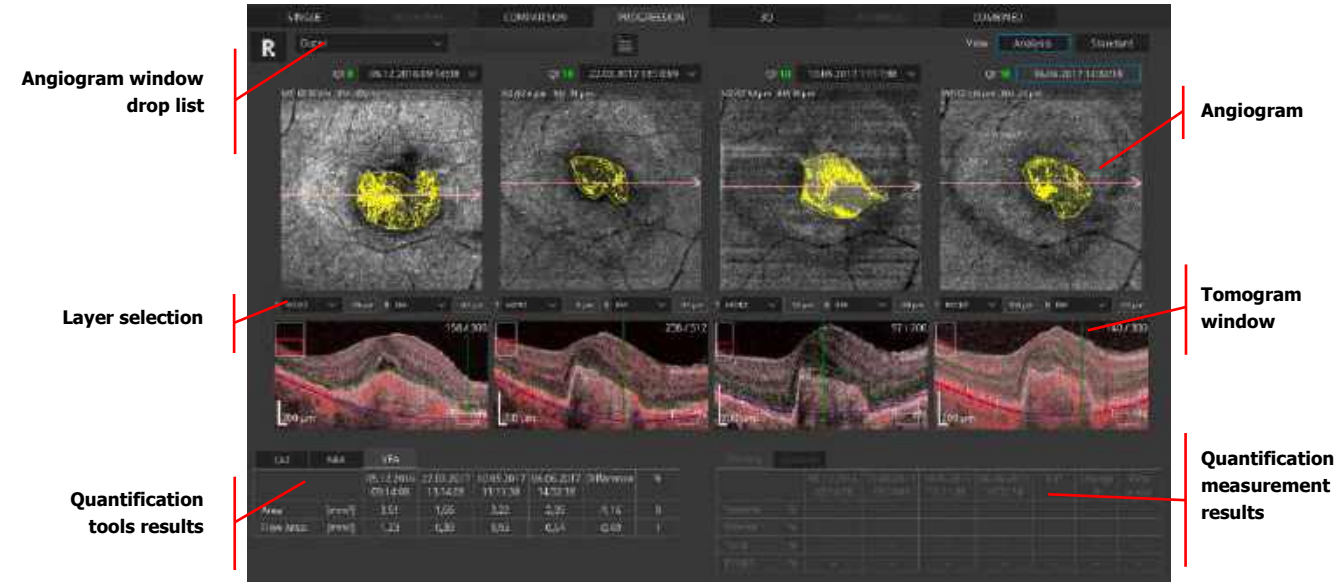


Figure 362.
Progression Retina (Angio Analysis View)

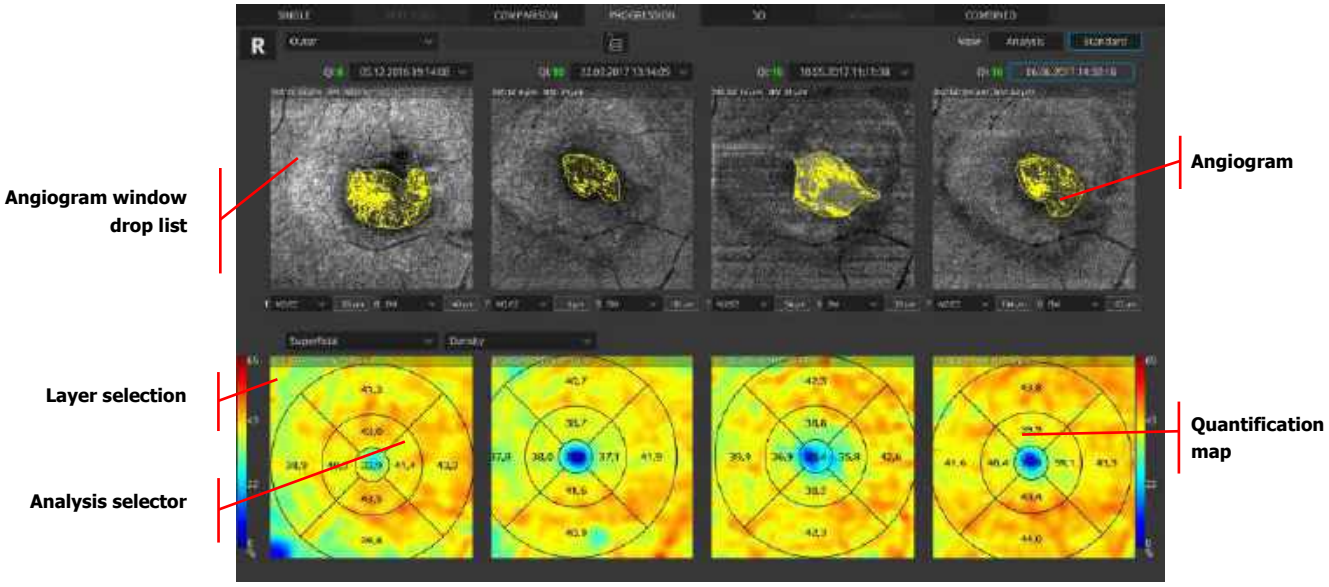


Figure 363.
Progression Retina Angio (Standard View)

In the angiogram window, the user can select one of the predefined vasculature layers based on the position of the recognized retina layer. Vascular layers can be selected from the angiogram drop list box with the following options:

Retina:	Retinal vasculature angiogram.
Vitreous:	Structure above ILM layer

Superficial:	Superficial capillary plexus.
SVC:	Structure between ILM and IPL / INL layers.
RPCP:	Structure between ILM and NFL / GCL layers
Deep:	Deep capillary plexus.
DVC:	Structure between IPL / INL and OPL / ONL layers.
ICP:	Structure between IPL / INL and INL / OPL layers.
DCP:	Structure between INL / OPL and OPL / ONL layers.
Outer:	Outer retina layers (avascular zone).
Choriocapillaris:	Choroid choriocapillaris visualization.
Choroid:	Choroid visualization.
Depth Coded:	Color coded Retinal vasculature angiogram.
Custom View:	User defines top and bottom boundaries to generate angiogram.

TOMOGRAM WINDOW

This displays selected tomograms overlaid with the boundaries of layers from the active angiogram window. On the tomogram, a semitransparent, red color decorrelation mask is overlaid. It is possible to change the position of the desired layer by typing in the offset over the tomogram window or grabbing and moving the selected layer. The offset is expressed in microns from the original position of the recognized retinal layer. A negative offset value describes the position below the original position.

TABLE WITH MANUAL MEASURMENT RESULT

The FAZ Table shows difference between measurement.

19.4. Disc OCT-A

19.4.1. [Single] View

19.4.1.1. Standard Disc OCT-A

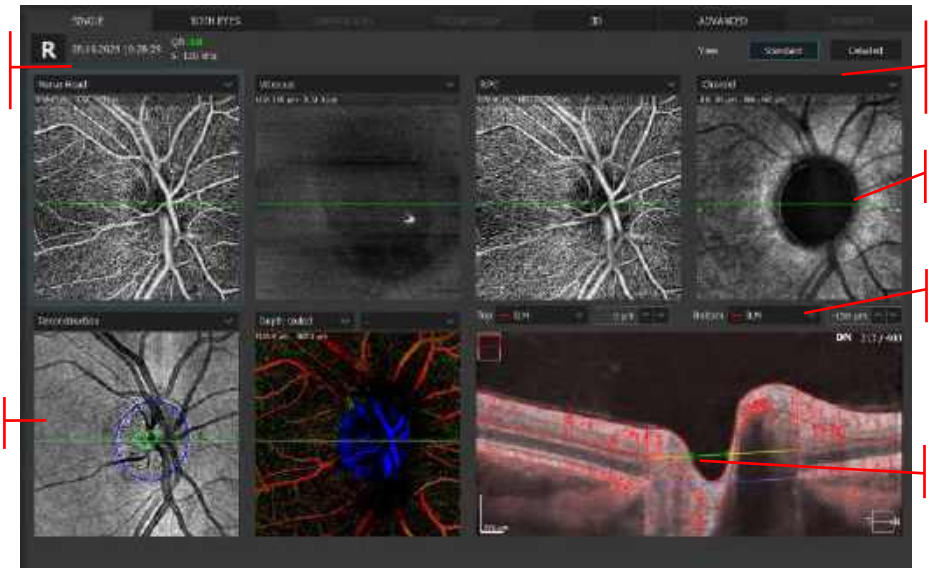


Figure 364.
Single Standard View for Disc OCT-A

In the angiogram window for Optic Nerve Head (ONH), the user can select one of the predefined vasculature layers based on the position of the recognized retina layer. The vascular layer can be selected from the list box:

Vascular Layer	Description of Layer	Offset
Nerve Head	Nerve Head	ILM 0 µm, ILM -150 µm
Vitreous	Vitreous Structure (above ILM layer)	ILM 250 µm, ILM 3 µm
Superficial	Superficial Capillary Plexus	ILM 0 µm, IPL / INL -15 µm
RPC	Radial Peripapillary Capillary Plexus	ILM 0 µm, NFL / GCL 0 µm
Deep	Deep Capillary Plexus	IPL / INL -15 µm, IPL / INL -70 µm
Outer	Outer Retina Layers (Avascular Zone)	IPL / INL -70 µm, BM 0 µm
Choroid	Choroidal Vessels	BM -45 µm, BM -160 µm
Choriocapillaris	Choroid choriocapillaris visualization	BM 30 µm, BM -45 µm
Depth Coded	Color Coded Retinal Vasculature Angiogram	ILM 0 µm, BM 0 µm
Retina	Retina	ILM 0 µm, OPL/ONL -10 µm,
Custom View	User defined top and bottom boundaries to generate angiogram	

19.4.1.2. Detailed

The detailed view allows the user to view large objects and quantify results.

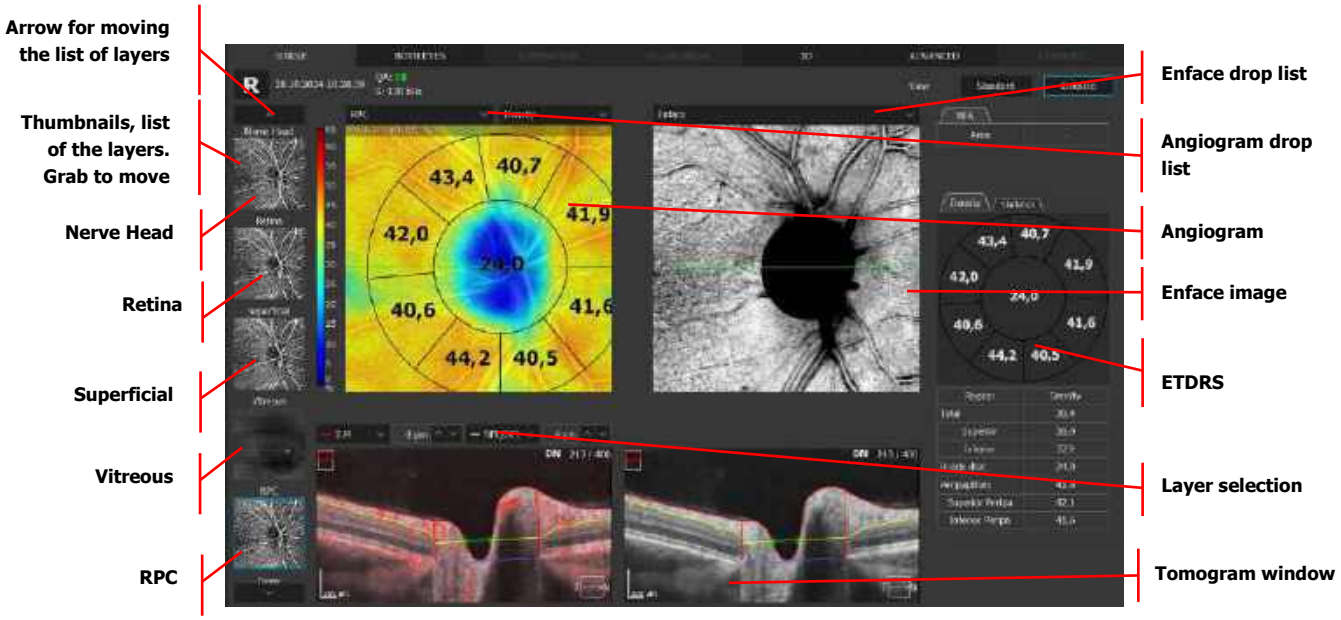


Figure 365.
Single Detailed View for Disc OCT-A

List of the layers: Click on the thumbnail to display the object in the large window. The user can move the list by clicking on the arrows or by scrolling over the list. The user may also change the thumbnail order by grabbing and moving them.

Angiogram and enface images respond to manipulations and changes in offset and layers.

The enface image displays the enface image generated between the boundaries from the active angiogram window.

The tomogram window shows the selected tomogram overlaid with the outlines of layers from the active angiogram window. On the tomogram, a semitransparent, red colored decorrelation mask is overlaid. It is possible to change the position of the desired layer by typing in the offset over the tomogram window or grabbing and moving the selected layer. The offset is expressed in microns from the original position of the recognized retinal layer. A negative offset value describes the position below the original position.

19.4.2. [Both] View

In the **[BOTH EYES]** tab, it is possible to make a comparison of the analysis of both eyes (i.e., the left and right eye), which can be followed by the asymmetry analysis of both eyes.

This analysis protocol operates only on one Right and one Left Disc Angio examinations from the same visit.

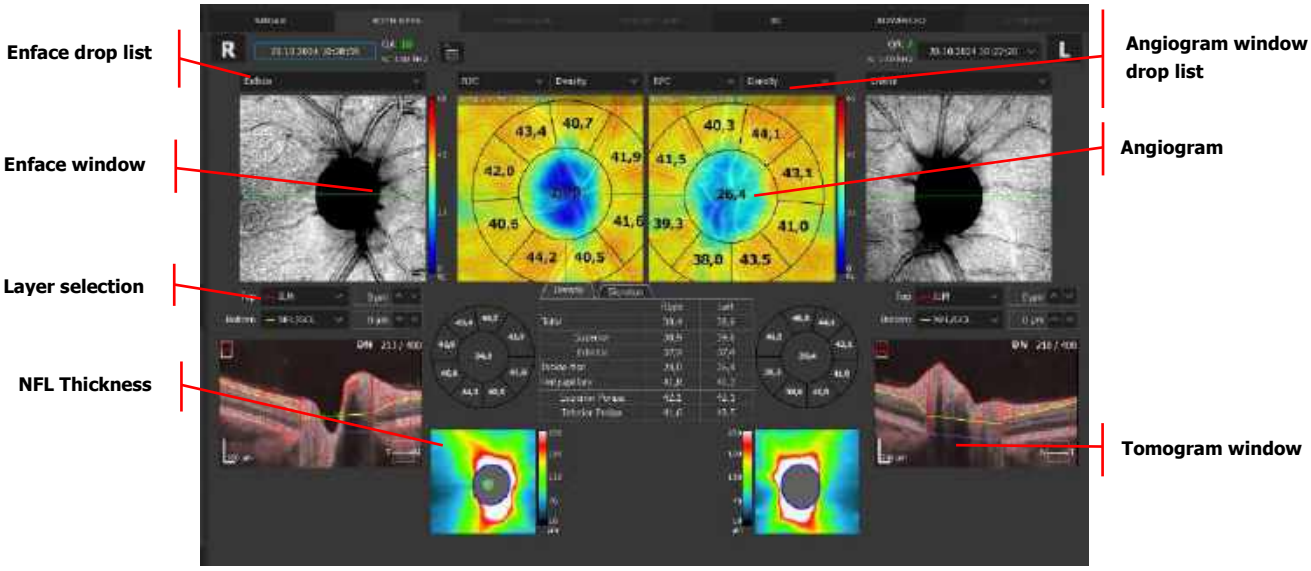


Figure 366.
Both Discs (Angio View)

ENFACE WINDOW

To display an object, select it from the enface drop down menu.

1. **ENFACE**

   Displays an enface image generated between the boundaries from the active angiogram window.

2. **STRUCTURE**

   Displays a color-coded thickness map of the retina. The sector dimension on the map is 1/3mm in diameter.

3. **pSLO**

   Displays the location of the OCT-A scan on the pSLO image of the retina.

In the angiogram window, the user can select one of the predefined vasculature layers which are based on the position of the recognized retina layer. The vascular layer can be selected from the drop list box.

1. Nerve Head
2. Retina
38. Superficial
39. Vitreous
40. RPC

41. Deep
42. Outer
43. Choroid
44. Choriocapillaris
45. Depth Coded
46. Custom view

The tomogram window shows the selected tomogram overlaid with the boundaries of layers from the active OCT-A window. On the tomogram, a semi-transparent, red overlay mask displays OCT-A flow details. It is possible to change the position of the desired layer by typing in the offset over the tomogram window or grabbing and moving the selected layer. The offset is expressed in microns from the original position of the recognized retinal layer. A negative offset value describes the position below the original position.

Changing the type of vascular layer on one object affects both eyes and both objects (angiogram and enface).

NFL thickness map shows the thickness of the NFL on the scanned area.

To change the transparency level, turn the mouse wheel over the object.

19.4.3. Angio Disc (Comparison View)

This screen shows the analysis results comparing two examinations of one eye, on the same side, in the same scan program, from different dates.

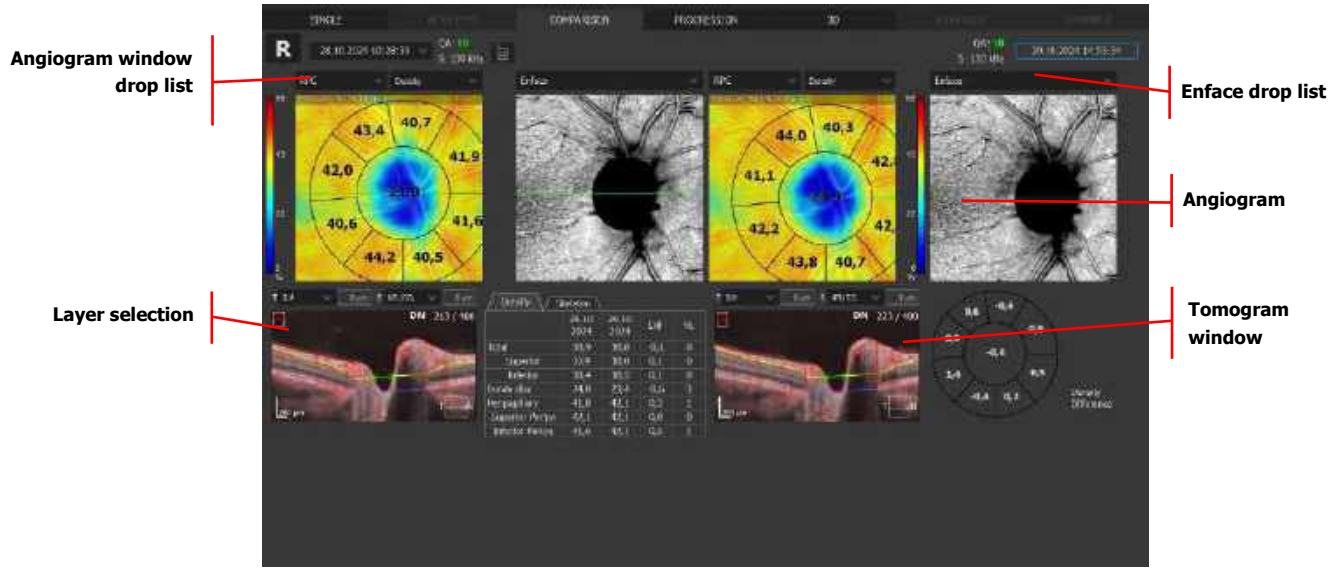


Figure 367.
Comparison Disc (Angio View)

The NFL thickness map shows the thickness of the NFL on the scanned area. A map to be overlaid on the fundus reconstruction can be selected from the Enface drop list:

1. NFL thickness
47. NFL significance

To change the transparency level, turn the mouse wheel over the object.

19.4.4. [Progression] View

This screen shows the analysis results comparing four examinations done on the same eye, in the same scan program, and the same size scanning area, arranged in a time sequence.

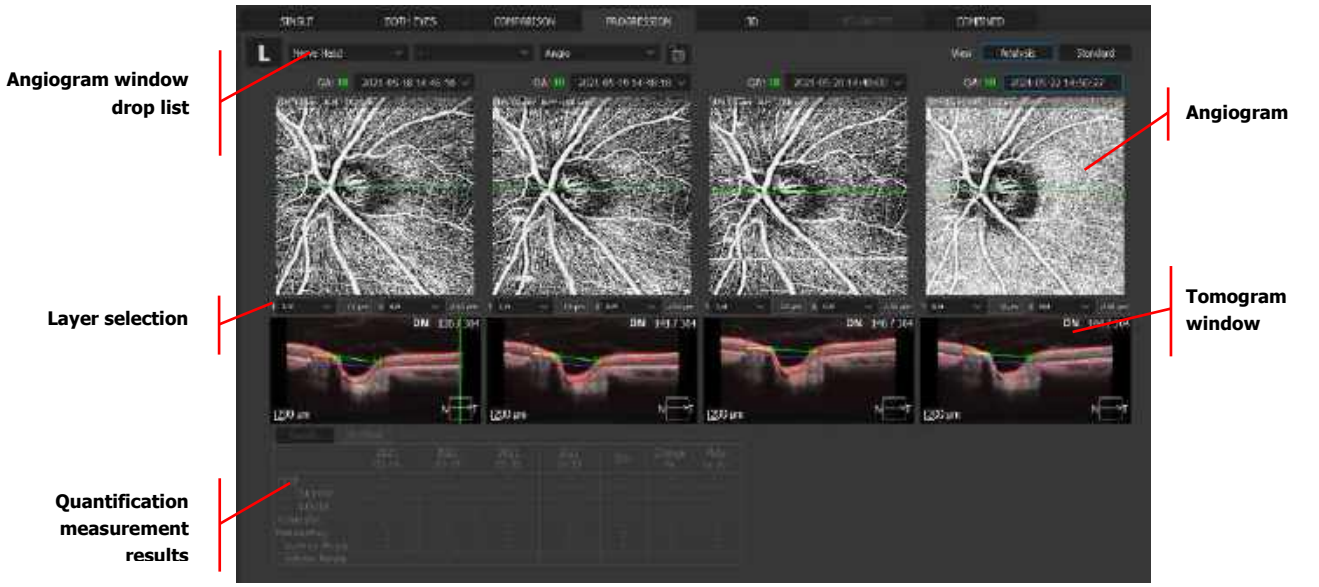


Figure 368.
Progression Disc (Angio Analysis View)

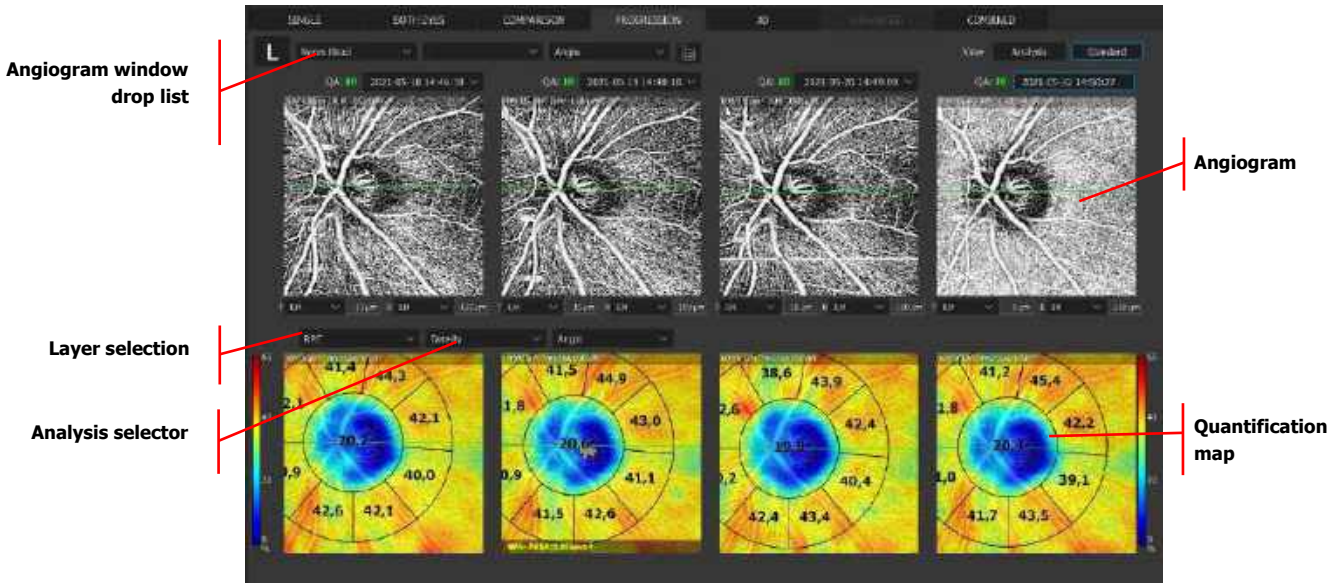


Figure 369.
Progression Disc (Angio Standard View)

In the angiogram window, the user can select one of the predefined vasculature layers based on the position of the recognized retina layer. The vascular layer can be selected from the drop-down list.

TOMOGRAM WINDOW

This shows the selected tomogram overlaid with the boundaries of layers from the active angiogram window. On the tomogram, a semi-transparent, red decorrelation mask is overlaid. It is possible to

change the position of the desired layer by typing in the offset over the tomogram window or grabbing and moving the selected layer. The offset is expressed in microns from the original position of the recognized retinal layer. A negative offset value describes the position below the original position.

Changing the type of vascular layer on one object affects both eyes and both objects (angiogram and enface).

19.5. OCT-A Mosaic

The angio mosaic feature can be used to present a wider field of view with that same level of details. The algorithm uses examination from predefined sets of data of at least two examinations to superimpose the mosaic image. An angio mosaic view can be created from two to 12 images. Open the **[ADVANCED]** tab to see superimposed images. The user can modify the initial position of the images.

The SOCT software can create a mosaic from the examinations included from a predefined set or a manually created set (activated by Mosaic mode button). It is also possible to create the set from examinations with the same parameters of scan (size, A&B scan number, same date). If a scan is carried out again, roman numerals indicative of the repeat number will be shown at the top of the exam on the list. If the repeated scan is carried out in a different location, this repeat indication will not be shown.

Figure 370.
Advance Tab (Angio Mosaic)

In the mosaic window, the user can select one of the predefined vasculature layers based on the position of the recognized retina layer. The vascular layer can be selected from the list box:

Vitreous:	Structure above the ILM layer
Retina:	Retinal vasculature angiogram
Superficial:	Superficial capillary plexus
RPC:	Radial Peripapillary Capillaries
Deep:	Deep capillary plexus
Outer:	Outer retina layers (avascular zone)

Choriocapillaris:	Choroid choriocapillaris visualization
Choroid:	Choroid visualization

The type of displayed data can be selected from the list box:

Angio:	Vascular angiogram from selected vascular layer
Enface:	Enface structure from selected vascular layer
Depth Coded:	Color coded retinal vasculature angiogram
Retina Thickness:	Retina thickness map
NFL Thickness:	NFL thickness map

19.5.1. Registration Status

This feature informs the user about the method of superimposition used:

	Automatically superimpose
	Manually superimposed (by the operator)

19.5.2. Select Screen

On the select screen, the user can change, remove or add exams used in mosaic composition.

Once the user selects or unselects the exams, the **[ANALYZE]** button becomes active. Press **[ANALYZE]** to start the automatic superimpose process.

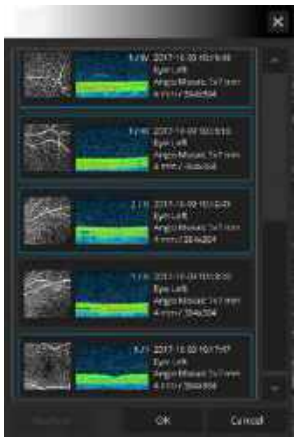


Figure 371.
Select Screen

19.5.3. Operation of the Mosaic

19.5.3.1. OCT-A Mosaic Display

1. **ZOOM IN / OUT**

   Press the **CTRL** key and mouse scroll.

2. **MOVE ZOOMED IMAGE**

   Hold the left mouse button and move to change the position.

3. **BRIGHTNESS AND CONTRAST**

   Press and hold the right mouse button and move the mouse up / down and left / right to adjust the brightness and contrast of the angiogram image.

4. **TRANSPARENCY**

   When enface view or the thickness map is selected, a mouse scroll will change the transparency level.

The user can modify the depth position of the top and bottom boundaries at once. Scroll the mouse wheel to go deeper or upper from the initial position.

RIGHT MOUSE MENU

1. **INVERSE**

   Inverses the color of tomograms.

2. **SAVE AS**

   Right-click the mouse button and select **[SAVE AS...]** from the menu to save the mosaic image.

Figure 372.
Advance Tab (Manipulation of Entire Mosaic)

19.5.3.2. Operation of a Single Exam

The operator can modify the original position of the superimposed images. Only selected exams can be manipulated.

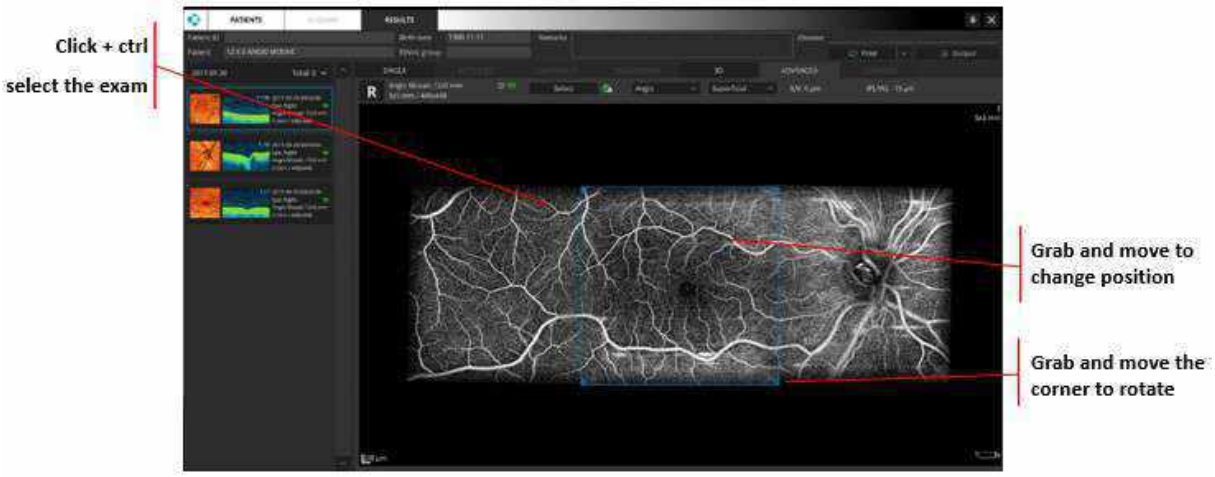


Figure 373.
Advance Tab (Manipulation of Single Image)

1. **SELECT**

   To select an exam, hold the **CTRL** key and click on the desired image(s). It is possible to select more than one examination.

2. **MOVE**

   Grab and move to the desired position. For precise alignment, use **[UP]** / **[DOWN]**, **[RIGHT]** / **[LEFT]** arrows on the keyboard.

3. **ORDER**

   Use **[PAGE UP]** and **[PAGE DOWN]** on the keyboard to change the angiogram layer order to the front or back of the layers.

4. **ROTATE**

   Grab and move the corner to rotate.

20. Biometry OCT (Optional Function)

NOTE: Biometry is an optional software module. If you do not have these modules and wish to purchase them, please contact your local OPTOPOL distributor.

The SOCT software with an optional Biometry OCT function is intended for biometric measurements and visualization of ocular structures. It is also capable of performing IOL power calculations based on the patient's biometric data and a selection of recognized IOL calculation formulas.

Measurements and visualization of the eye provided by the REVO device with the SOCT software, assist in the determination of the appropriate power and type of intraocular lens for implantation (IOL).

Axial length (AL) is the distance from the corneal apex to the fovea or more specifically, to the RPE (Retinal Pigment Epithelium). The calculation is performed as the sum of the thicknesses of the cornea, aqueous humor, lens, vitreous humor, and neurosensory retina.

Central Corneal Thickness (CCT) is the distance between the anterior and the posterior surface of the cornea.

Anterior Chamber Depth (ACD) is the distance between the anterior surface of the crystalline lens (anterior capsule) and the outermost stratum of the cornea (epithelium).

Lens Thickness (LT) is the distance between the anterior and the posterior surfaces of the lens, divided by its refractive index.

White to White (WTW) is the distance from limbus to limbus of the eye.

Pupil diameter (PD) is measured horizontally through the center of the pupil.

WARNING: Users should not rely solely on SOCT measurements in making decisions regarding the calculation and implantation of intraocular lenses or other therapeutic procedures and should rely on their own expertise and judgment.

WARNING: The user is fully responsible for all data entered or changed manually in the IOL Calculation tab. Calculation parameters are determined at the user's discretion and it is the user's responsibility to make sure they guarantee obtaining a result optimized for a given case.

WARNING: The user is fully responsible for the verification of provided data when using for IOL implementation or any other medical procedure.

WARNING: For biometry measurements, users must check the measurement readings for plausibility. This includes the checking of the detected position boundaries on the B-scan and the adjusted lines, which automatically adjust to the signal, whenever one of the measurements displays an unusually high standard deviation. The operator must also consider the type (e.g., posterior subcapsular cataract) and density of the cataract when evaluating plausibility.

CAUTION: The IOL calculation is valid only if the biometric measurement was correct, an appropriate IOL calculation formula was selected and the IOL constants were optimized for the specific application in advance.

CAUTION: Do not perform any contact measurements or examinations in which the eye is touched prior to measurement with the SOCT. Performing contact measurements prior may result in incorrect SOCT readings, particularly for biometry and corneal topography measurements. Contact measurements or examinations should only be performed after the patient has been measured with the SOCT.

CAUTION: For patients with morphological changes of the retinal anatomy in the region of the fovea (e.g. retinal detachment, edema), the axial length measurement result may be erroneous and thus is not usable or only of limited use for IOL calculation. In case of retina segmentation errors, the user can perform a correction after verification of the region of interest.

CAUTION: Correct detection of boundaries should be checked with particular care during measurement, especially when measuring very long eyes, eyes with dense cataracts, pseudophakic or aphakic eyes, or eyes with any kind of pathology. Despite various plausibility checks, measuring errors can be manually excluded or corrected in individual cases.

CAUTION: There is risk due to measuring errors. Unstable fixation can lead to measuring errors and the calculation of incorrect IOL refractive powers. Check that the patient fixates correctly on all scans and the fovea is visible in all tomograms. Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.

CAUTION: Prior to measurement, the user must verify that the patient is not wearing contact lenses. Patients wearing contact lenses during measurement will result in erroneous results.

CAUTION: There is a risk due to measuring errors. Unstable patient fixation can lead to measuring errors and the calculation of incorrect IOL refractive powers. Make sure that the patient fixates correctly on all scans and that the corneal apex (with a visible central reflex) and the fovea are clearly visible on all tomograms. Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.

NOTE: Since the device measures up to the retinal pigmented epithelium, the reading displayed is adjusted to the internal limiting membrane, as a function of axial length or manually.

NOTE: If the patient has previously undergone cataract surgery, available records should be consulted for a plausibility check of the measurement.

NOTE: It may not be possible, under certain circumstances, to carry out measurements on patients with fixation problems.

NOTE: In cases of thick cataracts and uncertain measurement of the axial length, ultrasound biometry should be performed as a control examination.

NOTE: Dense lenticular opacities may make it impossible to measure the axial eye length and lens thickness.

NOTE: Pronounced opacities of the central cornea can make it impossible to measure corneal thickness, anterior chamber depth, lens thickness or axial eye length.

NOTE: In the case of an extremely dense cataract, blood in the vitreous may make it impossible to measure the axial eye length.

NOTE: The user must check the tomograms when measuring anterior chamber depth in pseudophakic mode. If only one IOL boundary is visible, this may lead to errors. Uncertainty in this case can lead to the displayed reading for anterior chamber depth being inaccurate based on the thickness of the IOL.

NOTE: It is recommended that both of the patient's eyes are examined with at least 10 repeats. The user should subject the measurement readings to extra scrutiny if there is a notable difference between the right and left eye. The following are classified as notable differences:

4. **More than 1D with respect to central corneal refractive power.**
5. **=> 0.18 mm difference with respect to the corneal curvature radius.**
6. **More than 0.3 mm with respect to axial eye length**

NOTE: The precision of the axial length measurement may be different in eyes with cataracts.

NOTE: Users should check the Biometry OCT images to determine that the eye is not excessively tilted or decentered, which may result in inaccurate or implausible measurements.

NOTE: Users should verify measurement caliper positions on all tomogram images.

NOTE: Based on the patient's gaze at the fixation light, the optical path length of the visual axis is measured. Make sure that foveola is in the center of scan.

NOTE: All distance - thickness parameters (axial length, corneal thickness, anterior chamber depth, lens thickness, white-to-white, pupil size) are measured in sequence captured tomograms.

NOTE: An excessively tilted or decentered IOL may make it impossible to measure the anterior chamber depth, lens thickness and aqueous depth.

NOTE: The user must verify that the eye assignment (OD, OS) is correct for the entered data.

The measured axial eye length depends on the measuring mode selected. The SOCT software corrects the measurement, if necessary, with a "constant" defined in the tables below.

Two conditions of the eye that can alter the measurement of axial length are taken into consideration:

1. Vitreous body filled with silicone oil

48. Implanted IOL (intraocular lens)

The difference in the measurement is caused by a different group refraction index considered in the formula. According to bibliographic data, the calculations have been performed to assess the amount of correction that must be applied to correct the measurement in these special cases.

The correction values (in mm) of the natural vitreous body:

Natural Vitreous Body	Correction Values (in mm)
Phakic (natural lens)	0
Aphakic (no lens)	0.21
IOL PMMA	0.1
IOL Silicone	0.12
IOL Acrylic	0.1
IOL Unknown Material	0.11
Dense cataract	0

The correction values (in mm) of the vitreous body filled by Silicon Oil:

Vitreous Body Filled by Silicon Oil	Correction Values (in mm)
Phakic (natural lens)	-0.74
Aphakic (no lens)	-0.86
IOL PMMA	-0.75
IOL Silicone	-0.74

IOL Acrylic	-0.76
IOL Unknown Material	-0.75
Dense cataract	-0.74

20.1. Biometry Acquisition

CAUTION: When using the data taken by this instrument to select intraocular lenses, thoroughly determine this selection by examining cataract surgery methods and exercising other inspections. If incorrect measurement data is used to select intraocular lenses, further surgery might be required.

CAUTION: When using the data taken by this instrument for refractive correction surgery, thoroughly determine the selection by also examining surgery methods and exercising other inspections. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or other complications.

Before the first biometry examination of each day can begin, the operator is required to perform the initial calibration of the device. The calibration procedure is described in Chapter 22 Calibration Test.

1. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
2. If voice guidance is switched off, inform the patient to follow the fixation target. If required, use the large fixation target. See Chapter 7.9 Fixation Target Adjustment.

49. Select the Biometry scan program from the Anterior tab group. AL program provides AL, CCT, ACD and LT.

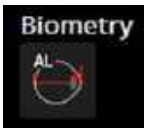


Figure 374.
Biometry program in the Anterior tab group.

50. Once the scan program is selected, the operator must confirm the type of eye to be scanned, based on the type of lens currently present:

    - **Phakic (Natural Lens):** The patient has a natural crystalline lens.
    - **Aphakic (No Lens):** The patient does not have any crystalline lens or intraocular lens implant.

    A pseudophakic eye is one in which the patient has an IOL (intraocular lens) that has been implanted as a substitute for their natural crystalline lens. In this case, it is very important to determine the type of material used for the implant and to select one of the following options:

    - IOL PMMA
    - IOL Silicon
    - IOL Acrylic
    - IOL Unknown

- User (the user must determine and enter the refractive index of the patient's IOL)

NOTE: If the IOL material is not known prior to measurement, the operator should select the [IOL Unknown] option under Lens.

51. Select type of vitreous in the eye:
    - **Natural:** The vitreous body has never been operated on or treated such as to alter its composition.
    - **Silicon Oil:** The vitreous body has been filled, even if only partly, with silicon oil.

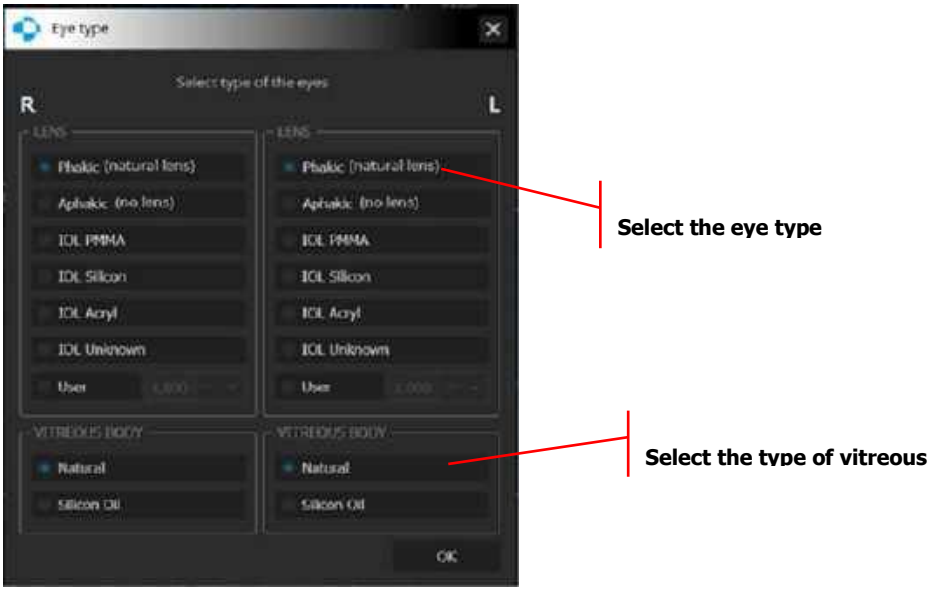


Figure 375.
"Type of Eye" Selection Window

52. The SOCT will find and optimize the signal from the retina, cornea, and intraocular lens. Then the system automatically acquires a series of tomograms. Each series contains four tomograms at predefined positions for each type of measurement. A single measurement can repeat each measurement 5, 10 or 15 times. Acquisition time of five series is approximately three seconds.

NOTE: Collecting the data from both eyes is highly recommended.

NOTE: If an incorrect LVC mode has been selected this may lead to the calculation of incorrect IOL refractive powers.

20.1.1. Full-Auto Mode

1. Select the desired biometry scanning program. If required, change the number of repeats.

53. Mark the Auto Acquire checkbox and press the **[START]** button.

54. Wait until the system finishes the examination (alignment and capturing).

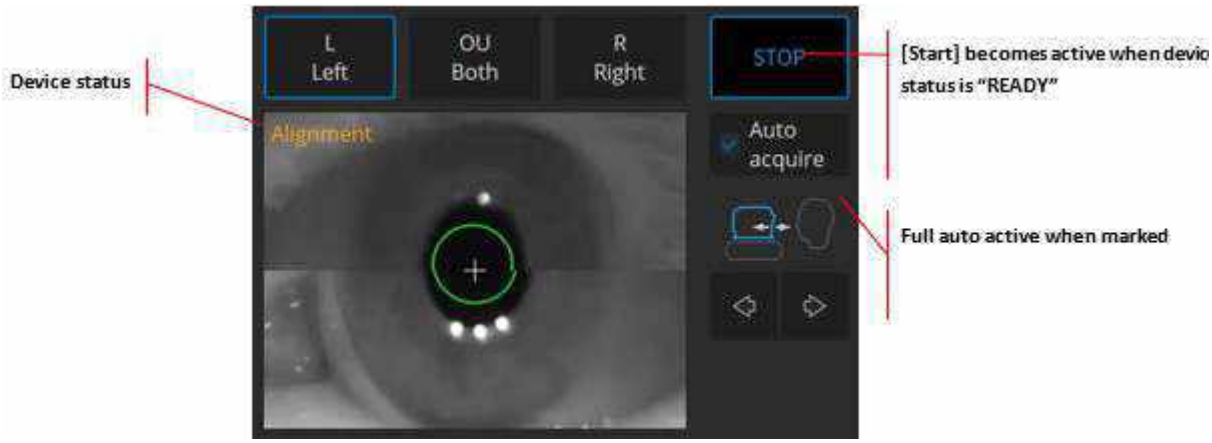


Figure 376.
Full-Auto Mode Examination

NOTE: In difficult conditions, such as:

- **Eyelashes or eyelid which block the beam of light**
- **Inability of subjects to maintain fixation**
- **Dense media opacities**
- **Strong nystagmus**
- **Rapid blinks**

the system can display a warning. In this case operator should decide whether to use the tips mentioned in the Chapter 8.6 Examination Tips or change the acquisition mode.

NOTE: If the system does not detect the pupil, the user must manually adjust the center of the patient's pupil. To set the working position properly, align the center of pupil to the proper height.

NOTE: If the system is not able to maintain the correct position of the retina (for example if the patient is moving), the operator must switch off tracking and carry out the examination manually.

NOTE: The Operator is to remain with the patient throughout the scanning process to oversee and guide them. The voice guidance feature is not intended to replace the Operator.

20.1.2. Semi-Auto Mode

In non-typical and dense cataract cases it will be required for the operator to optimize the signal manually. The operator is guided along the examination by text messages displayed in the tomogram preview window.

1. Uncheck the Auto acquire checkbox.

Figure 377.
Manual Examination Mode

2. The retina OCT signal should appear in tomogram preview. If not, adjust C-Gate manually by moving the sliding bar or scroll over the tomogram window. The operator can also adjust the patient's refraction value and try to find the signal one more time.

55. Some refractive correction may be needed to obtain the best quality tomograms. Observe the Q Bar to obtain the best signal while changing the **[FOCUS]** bar position.

56. Verify the position of the retina which should be placed on the one dashed horizontal line. If possible, the center of the foveola should be set on the vertical dashed line.

57. Once the retina position is aligned, press the **[NEXT]** button.

NOTE: In a patient with a dense cataract, the user should try to achieve a Q Bar that is as high as possible.

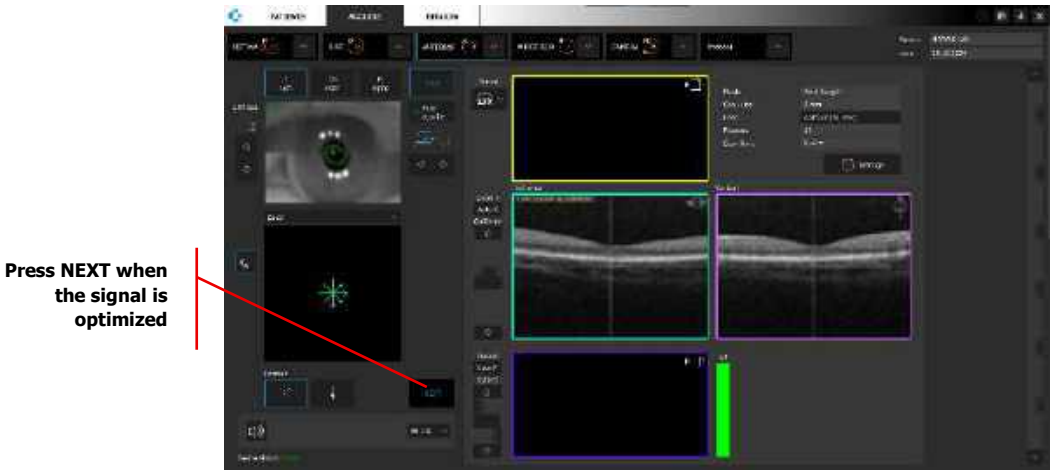


Figure 378.
Manual Examination Process

58. The system will move to align the cornea signal. The operator can press the **[START]** button for automatic cornea alignment or align and optimize the cornea manually as explained in Chapter 8.3.4 Anterior Examination. Once the cornea OCT image is optimized, press the **[NEXT]** button.

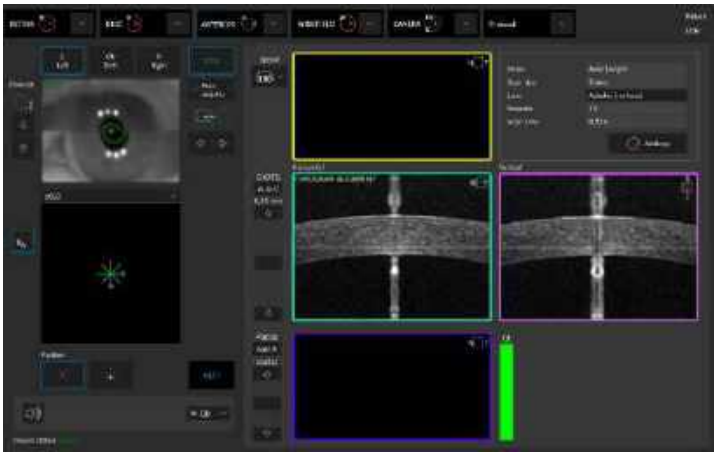


Figure 379.
Proper Position of the Cornea

59. The operator can press the **[START]** button for automatic optimization of the lens image, or can align and optimize the lens position manually as explained in Chapter 8.3.4 Anterior Examination.

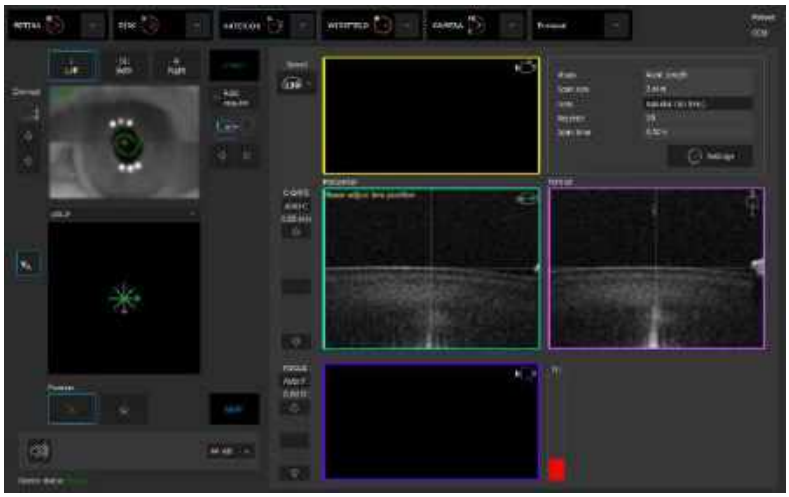


Figure 380.
Proper Position of the Intraocular Lens

60. Once the lens image is optimized, start the final biometry acquisition. Ask the patient to blink, double click on the tomogram or press **[ACQUIRE]**. During biometry series acquisition, the patient can blink. The system will reject improper measurements (due to blinks) from the calculation.

20.1.3. Biometry Acceptance Window

After completing a biometry examination, the system displays an acceptance window. Choose either to **[RESCAN]**, **[ACCEPT]**, or **[REJECT]** the scan. The operator must verify if the desired ocular structure has been scanned.

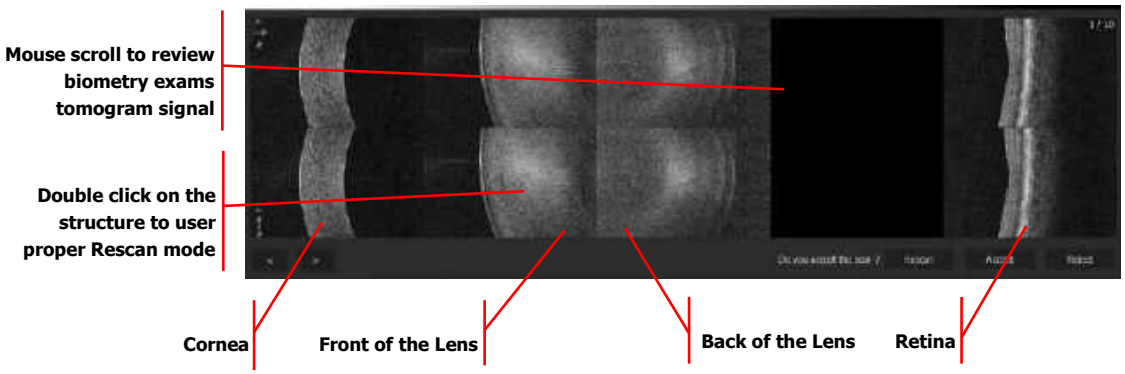


Figure 381.
Biometry Acceptance Window

NOTE: It is strongly recommended to review all biometry series. Verify that the desired eye structures are properly visible. During review of the exam, ask the patient to keep the examination position. The user may be required to repeat exam with corrected conditions.

NOTE: When in the Acceptance window, review the specific conditions for a repeat exam according to the below procedure:

5. **THE RETINA IMAGE IS NOT PROPERLY VISIBLE ON ALL TOMOGRAMS: Use the repeat function or double click on the retina image.**
6. **THE CORNEA IMAGE IS INCORRECT: Double click on the cornea tomogram. It will start the procedure from the cornea scan and will use retina data from the previous scan. After adjusting the alignment of the cornea, press the [NEXT] button to align the lens.**
7. **THE FRONT OR BACK OF THE LENS IS NOT CORRECTLY VISIBLE: Double click on the lens tomogram. It will start the procedure from the cornea scan and will use retina data from the previous scan. After adjusting the alignment to the cornea, press the [Next] button and manually align the lens position. Use the C-gate slider or scroll on the tomogram window until the lens image appears in the scan window. It may be required to use the focus tool to optimize the signal strength. In cases of very thick lenses, place the image of front of the lens, higher than on the originally dashed lines and lower for thinner lenses. The system behaves differently for natural and intraocular lenses.**
8. **It is recommended to use the [RESCAN] function to repeat the exam if blinks or eye movement cause errors during acquisition and cause half or more of the repeated scans to have errors or to be missing.**

1. **[<] [>]**

   Press the arrow buttons to change the displayed image.

2. **ACCEPT**

   The exam is saved and the Acquire window is reopened. The operator can continue capturing images or leave the Acquire window.

3. **RESCAN**

   The exam is saved and the Acquire window is reopened for the operator to repeat the scan.

4. **REJECT**

   The exam is not saved (it is rejected). The Acquire window is reopened for the operator to repeat the exam.

20.1.4. White-to-White

White-to-White (WTW) is a measurement of the distance from limbus to limbus. The measurement yields two values:

White-to-White:	The distance from limbus to limbus, measured horizontally through the center of the pupil.
P:	The diameter of the pupil measured horizontally through the center of the pupil.

The software automatically recognizes the edge of the pupil and the edge of the limbus. The diagram below presents the concept of the WTW measurement:

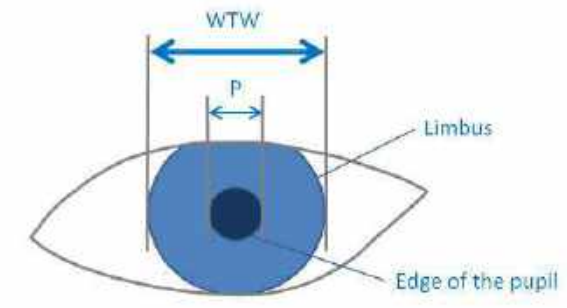


Figure 382.
WTW and P Measurement Ranges

WARNING: The White-to-White (WTW) distance value is merely an indirect measurement of the inner lateral dimensions of the anterior ocular section. For this reason, it provides only approximate indications of the actual inner lateral dimensions of the anterior ocular section and of the size of the implant to be used.

The results of the WTW measurement are presented in the Biometry and IOL calculation tabs in a form of a WTW measurement table as shown below:

WTW [mm]	P [mm]
12.4	2.4

Figure 383.
WTW and P Measurement Result Table

The user can adjust WTW and P results. After the circular WTW and P indicators are modified manually, the results in the WTW and P table are marked by the * symbol.

20.2. Result Review

The user should check the validity of the results and it is recommended to review all series of measurements and their values with the corresponding boundary detection of the signal on the tomograms. To make a manual correction of the boundaries, open full screen by double clicking on tomogram from the Single or Both views.

20.2.1. Single Eye Biometry Results

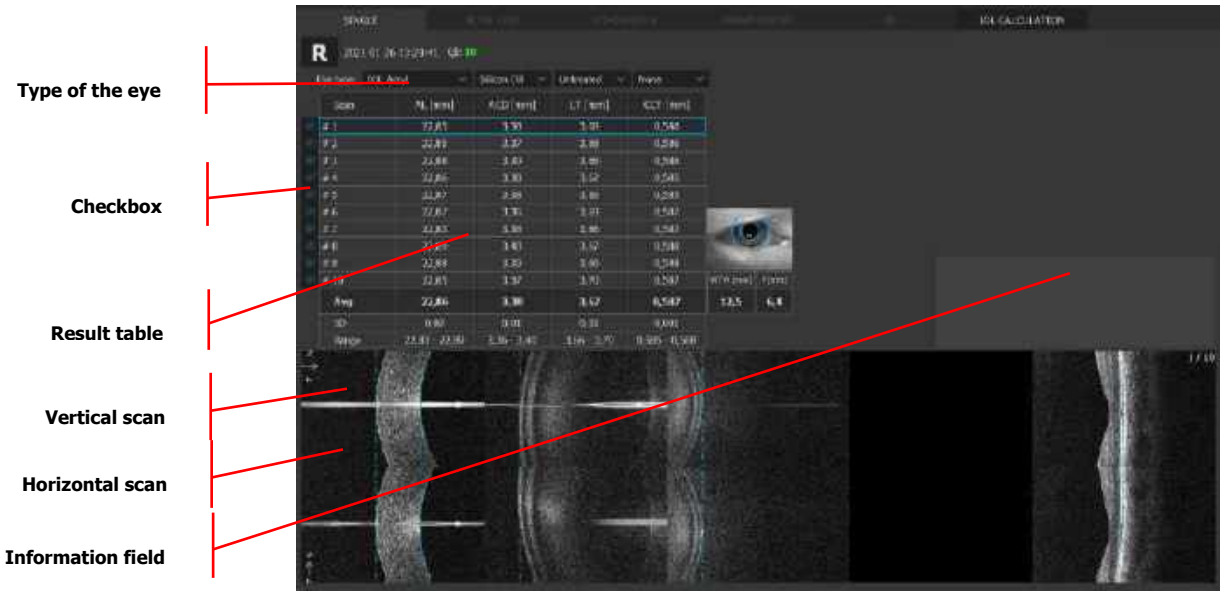


Figure 384.
Biometry (Single View)

1. **TYPE OF EYE**

   Provides drop-down menu for selection of type of eye (Phakic, Aphakic, etc.). Analysis results will vary depending on the type indicated.

2. **TABLE**

   Displays results of each scan in the biometry series, the standard deviation, the average, and range for AL, ACD, LT and CCT thickness.

3. **CHECKBOX**

   Allows selection of measurements to be included in, or excluded from, the calculations. Unchecked scans are excluded from the average (AVG) and standard deviation (SD) values.

4. **HORIZONTAL / VERTICAL TOMOGRAMS**

   Functions in the same manner as a standard tomogram window.

5. **ZOOM IN / OUT, BRIGHTNESS AND CONTRAST MANIPULATION, COLOR DISPLAY MODE, RIGHT-CLICK MENUS**

   Are available as on the standard tomogram window.

6. **RESET BRIGHTNESS / CONTRAST**

- Gray
- Colored
- Inverse

7. **SAVE AS…**

Saves the composed image.

20.2.1.1. Biometry Results Table

In the table below, the system displays result of each measurement.

In each row, the data from each measurement are displayed.

In each column, there are results of each parameter (AL, ACD, LT, CCT).

AVG:	Calculated averaged value for specific parameters. Only highlighted examinations are included for this calculation.
SD:	Standard deviation values of several individual measurements.

In the table, the system offers alerts for the measurements:

(!):	Indicates an uncertain measurement value.
(*):	Indicates that this value has been edited.
---:	Indicates a measurement failure.
(!!):	Significant difference between L and R.
(N/A):	Measurement in this type of eye not available.

Clicking the right mouse button on the results table enables exporting the data as a .txt file.

Right click on the Biometry results shows [Save as txt...]

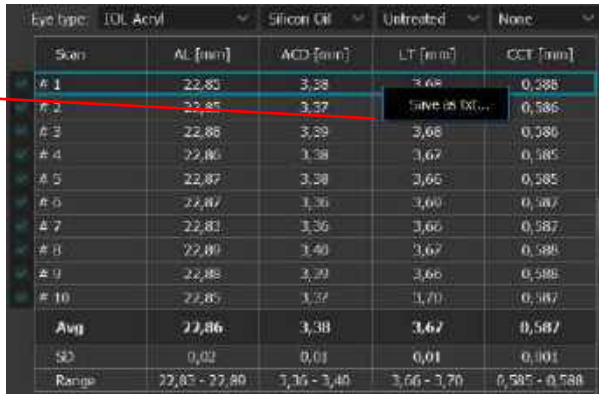


Figure 385.
Biometry Results Table

20.2.2. Both Eyes Biometry Results

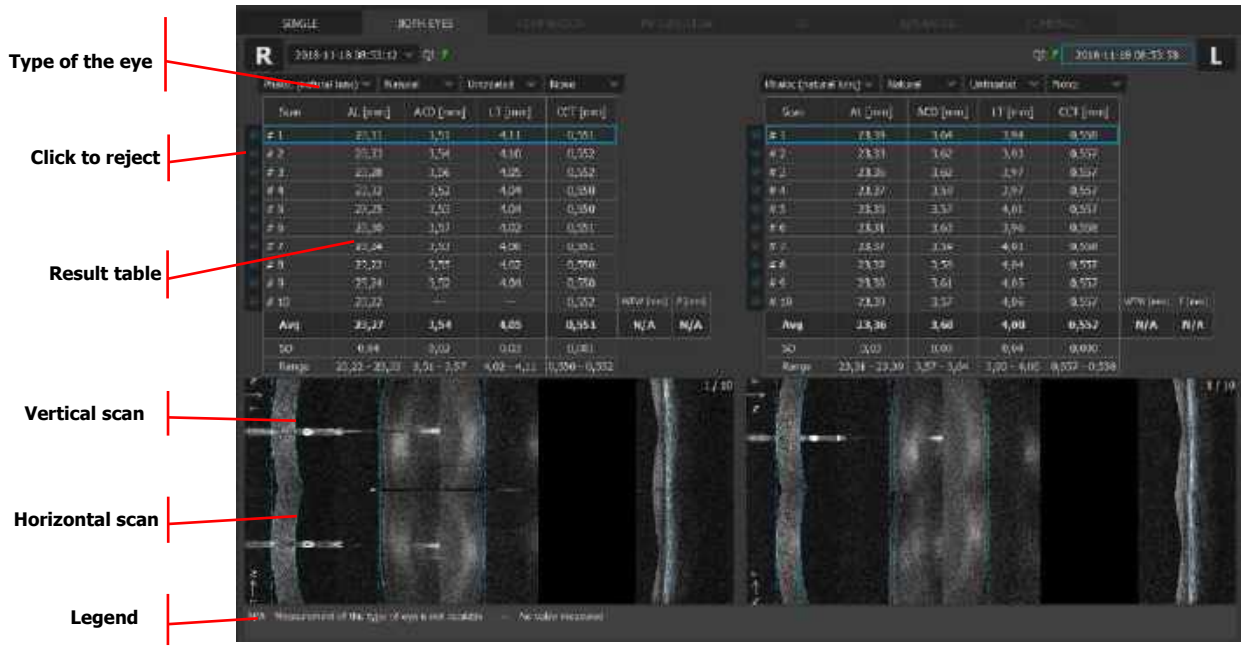


Figure 386.
Biometry Both Eyes

20.2.3. Full Screen

The SOCT software provides a full screen view, in which it is possible to manually reposition the calipers to refine obtained values of each structure. There may be instances of detecting the wrong boundaries, particularly in the posterior of the lens, as well as the retinal position. The user can visually adjust the value by positioning the line-markers on the tomogram image and signal graph. The signal graph shows the value marked by a horizontal line. An asterisk (*) will be displayed for any manually adjusted value.

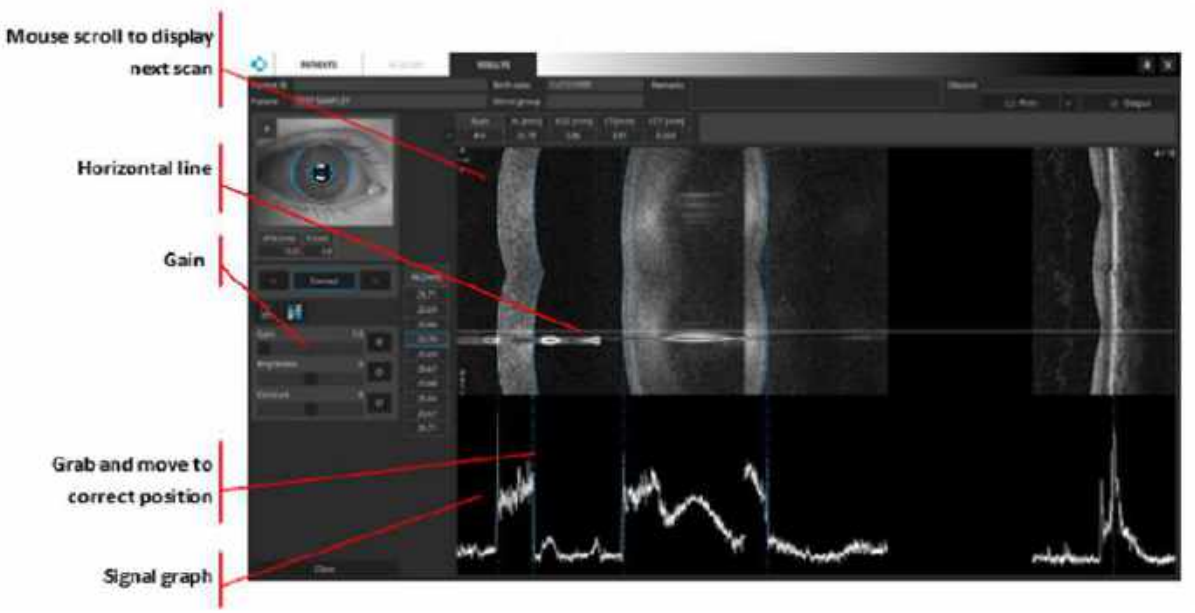


Figure 387.
Biometry (Full Screen Window)

1. **[<] [>]**

   Press the arrow buttons to display the previous or next image.

2. **GAIN**

   Amplifies the strength of intensity signal graph.

3. **SIGNAL GRAPH**

   Displays the intensity of A-scans along the composed tomogram (similar as echogram in ultrasound technique). It displays the result from the place identify by a horizontal line on the tomogram preview.

20.2.3.1. Editing Distances

The operator can edit the distance measurement by dragging the line markers to the desired location.

Moving the line-markers automatically adjusts the values for distance calculation for all the related parameters and their SD and average value. The adjusted parameters will be shown with a caution (*) notation. To provide more control to the operator, a zoom-in and zoom-out is available.

20.2.3.2. Editing White-to-White (WTW) and Pupil Size (P)

Double click on the eye preview window to open the editor. To edit WTW and / or P distance, grab any one of the blue squares, as seen in the Figure, and move it to increase or decrease the diameter of the circles. Zoom the eye preview in and out with the **CTRL** key + scroll combination. Grab and move ‘x’ marker to change position of the center of the pupil.

Figure 388.
White-to-White Distance Measurement Window

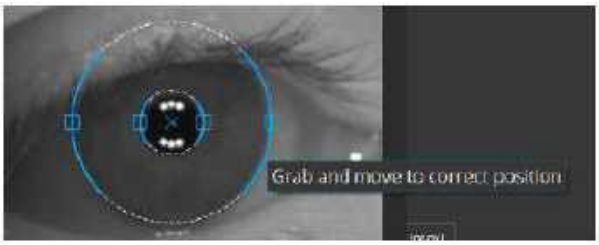


Figure 389.
Editing WTW and P Results

20.3. IOL Calculation Tab

The IOL Calculation tab allows the user to calculate the lens power of a selected IOL model based on the patient's morphological data (AL, Ks, ACD) and an IOL formula selected by the user.

Before starting work with the calculation tool, the user needs to enter IOL lens data as discussed in Chapter 20.6 IOL Settings Editor.

Running IOL calculations requires an optional biometry module installed in the system as well as valid licenses for using IOL calculation formulas. The function is available only for exams which were carried out on a properly calibrated device. Detailed information on the calibration of the device can be found in Chapter 22.3 Axial Length (Biometry) Calibration.

WARNING: The IOL Calculation function is provided as an additional tool in the hands of the physician to aid in the selection of an appropriate IOL for a particular patient. The tool is intended to be used in combination with a proper and comprehensive ophthalmic examination and diagnostic tests. The results of calculations obtained with the IOL Calculation tool do not serve as surgical or medical instruction and they are not conclusive. OPTOPOL Technology cannot guarantee accuracy or correct functioning of the tool. The choice of a particular IOL model and surgical procedure lies exclusively with the physician who takes the sole responsibility for the medical outcome of the procedure.

WARNING: Biometry measurements must always be checked for plausibility, which entails checking the following: keratometry values, A and B-scans, the cursors automatically adjusting to the signal, pupillometry and the white-to-white distance values. Performing a plausibility check is particularly important if any of the measurements show an unusually high standard deviation. Also, the characteristics of the cataract such as the type (for example, posterior subcapsular cataract) and density, must be considered.

WARNING: The user is fully responsible for all values entered or changed manually.

WARNING: Using data from ultrasound instruments requires the constant of every IOL to be optimized for that instrument. It is common to find online databases of lenses optimized for optical interferometry instruments.

CAUTION: Measurements taken with the REVO device may serve as the central element for the calculation of intraocular lenses (IOL). A further important parameter in calculating the lens to be implanted is the IOL constant. When using the REVO device, only IOL constants optimized for optical biometers should be used. Please contact your IOL manufacturer for information on optimized IOL constants for optical biometry. An alternative source of information for IOL constants optimized for optical biometry is the website:

IOLCon.org: IOL Con is an international platform for characteristics of intraocular lenses and the optimization of lens constants. The IOLCon team is located at University of Saarland and working under the head of Steinbeis.

ULIB User Group for Laser Interference Biometry" (ULIB): http://ocusoft.de/ulib/c1.htm.

NOTE: Only a biometry exam with a valid calibration allows the operator to open IOL Calculation tab.

Biometry results with an NG status are not available in the IOL Calculation tab.

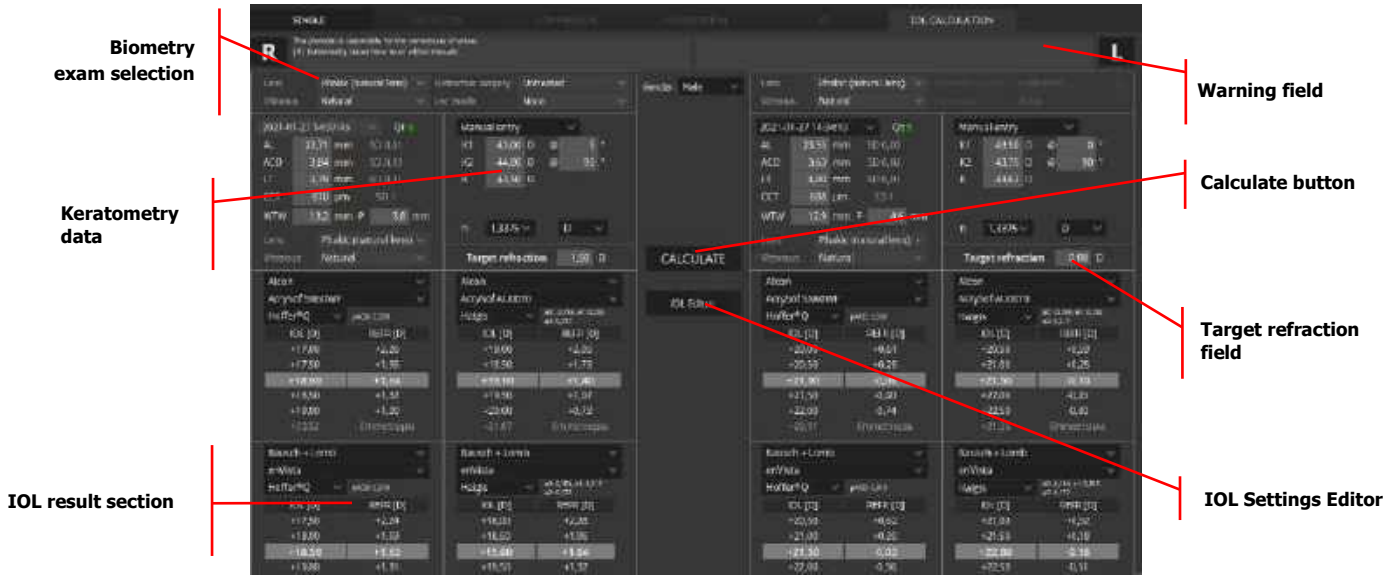


Figure 390.
IOL Calculations Tab

20.4. Performing IOL Calculations

Click on the **[BIOMETRY EXAM SELECTION]** field to open a drop-down menu and choose a biometry exam by date. If any of the loaded biometry data is changed by the user, the name of the data set is replaced with "Manual entry". Next, enter the keratometric data. To calculate IOL parameters, it is also

necessary to provide the target refraction value after the IOL implantation procedure. Click on the target refraction value field and enter the target value.

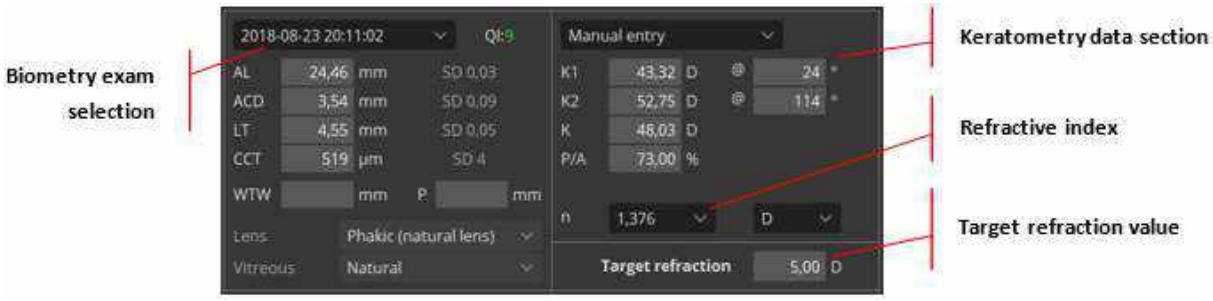


Figure 391.
Entering Biometry and Keratometry Data

Choose the IOL manufacturer and model by clicking on the drop-down menus as shown below. Similarly, specify the calculation formula.

20.4.1.1. Available IOL Calculation Formulas

You can choose from the following IOL power calculation formulas:

1. Hoffer®Q[55]
61. Holladay I[56]
62. Haigis[57]
63. Theoretical/T[58]
64. Regression II[59]

For each eye, the user can choose up to four formulas at the same time. Then click **[CALCULATE]** in the center of the calculation tab. The result of the calculation will be displayed in the results table in the following six lines: the third line presents the value closest to the target refraction; the two lines above

[55] Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. J Cataract Refract Surg 1993; 19(6):700–712; errata 1994; 20(6):677 and 2007; 33(1):2-3.

[56] Holladay JT, Praeger TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS. A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg 1988; 14(1):17–24.

[57] Haigis W. The Haigis formula. In: Shammas HJ ed. Intraocular Lens Power Calculations. Thorofare, NJ: Slack, Inc.; 2004:41–57.

[58] Based on the idea of the Development of the Theoretical intraocular lens implant power calculation.

[59] Second generation IOL formula which is now expired.

and below the third line show lower and higher values respectively; the line at the bottom presents the value of Emmetropia.

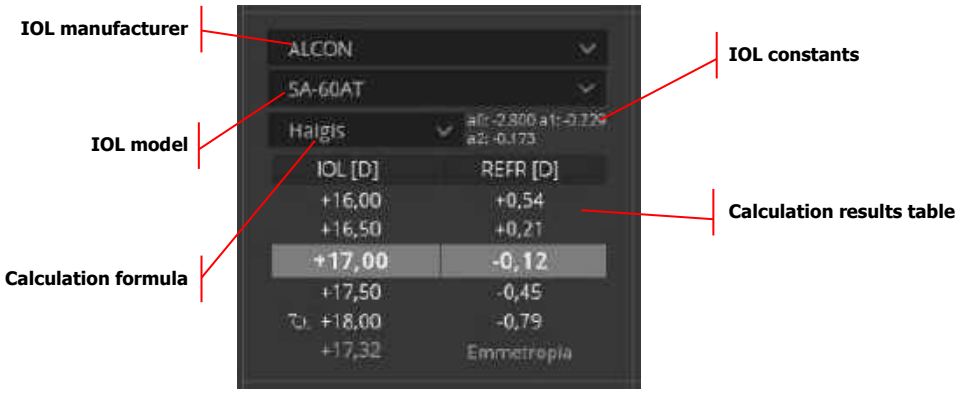


Figure 392.
IOL Calculation Results Table

WARNING: The user chooses the IOL calculation parameters at their own discretion. The user has responsibility for the chosen parameters and the interpretation of results.

CAUTION: To ensure plausibility of biometry results, the operator should always use more than one calculation formula for a given IOL model and patient. This enables the user to exercise closer scrutiny of obtained results.

20.5. Marking IOL Selected

The user can mark two lenses, one for each eye. To do this, right-click on the value to mark and a drop-down menu will open. Click **[SELECT IOL]**. Clicking **[REMOVE IOL]** removes the selection. The marked lens is identified by the sign, which is also present on the printout.

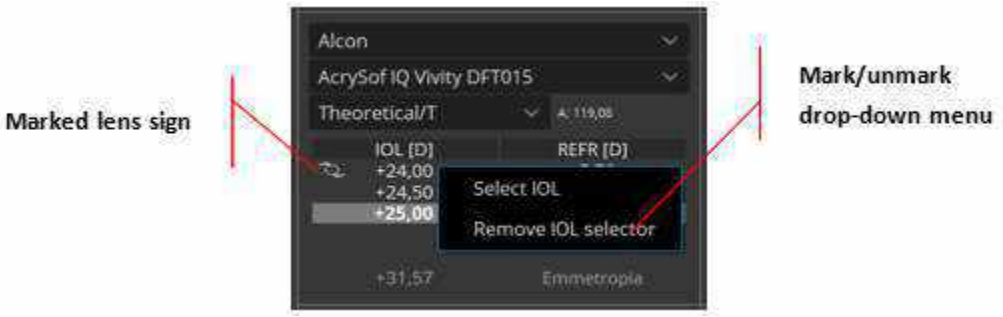


Figure 393.
Marking Lenses

20.6. IOL Settings Editor

The IOL Settings Editor allows a user to import / export IOL data or edit any IOL data in the system. To go to the window, click the **[IOL EDITOR]** button in the center of the IOL window. The list of lenses is

displayed on the left side of the window, showing all available lenses sorted by manufacturer. The right-side of the window contains the IOL constant editing section.

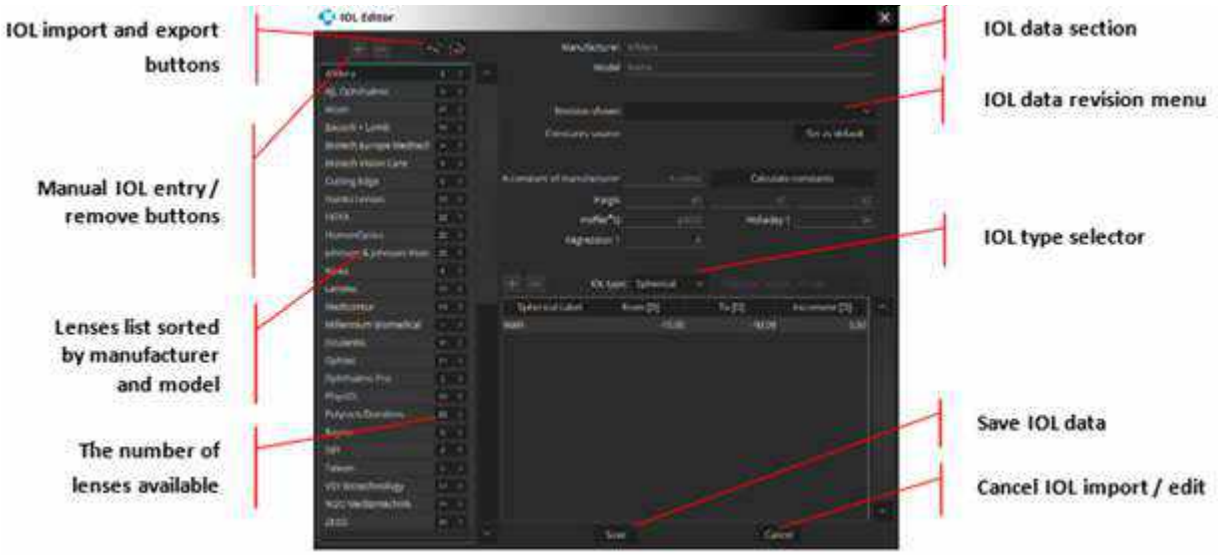


Figure 394.
IOL Editor Windows

20.6.1. Importing IOL Data

WARNING: Any imported IOL data must be reviewed and accepted by the operator prior to using it. The user takes full responsibility for using any imported IOL data from any source. Imported IOL data must not be regarded as recommendation in favor of or against using any particular lens on a patient. IOL data obtained from ULIB, IOL Con or any other source only represents an overview of available lenses. OPTOPOL Technology is not responsible for the quality or correctness of data imported into the system.

CAUTION: Measurements taken with the REVO device may serve as the central element for the calculation of intraocular lenses (IOL). A further important parameter in calculating the lens to be implanted is the IOL constant. When using the REVO device, only IOL constants optimized for optical biometers should be used. Please contact your IOL manufacturer for information on optimized IOL constants for optical biometry. An alternative source of information for IOL constants optimized for optical biometry is the website:

IOLCon.org: IOL Con is an international platform for characteristics of intraocular lenses and the optimization of lens constants. The IOLCon team is located at University of Saarland and working under the head of Steinbeis.

ULIB User Group for Laser Interference Biometry" (ULIB): http://ocusoft.de/ulib/c1.htm.

To import IOL constant data in the *.mdb (ULIB), *.xml (IOLCon) or *.odb (Optopol Database) format, click the import button and choose the data file to be imported.

20.6.2. Exporting IOL Data

To export the full database or a single lens in the *.odb (Optopol Database) format, click the export button.

20.6.3. Adding Lenses Manually

To add a new lens manually, click the + button in the upper left-hand corner of the editor window and enter the details of the lens.

20.6.4. Deleting Lenses Manually

To delete a single lens, highlight its name by clicking on it and then click the delete button. − Similarly, to delete all lenses by the same manufacturer, click on the manufacturer's name and then click the delete − button. In either case, after clicking the delete button, a dialogue box is displayed to confirm the deletion.

20.6.5. Viewing the List of Lenses

To display the list of lenses by a chosen manufacturer, double click the manufacturer's name. The list shows the available lenses and their details.

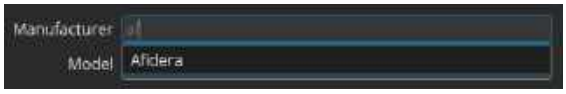
To choose a lens for editing, simply click on its name. The data of the selected IOL will be displayed in the IOL editing section to the right of the lenses tree.

Figure 395.
List of Lenses in the IOL Editor Window

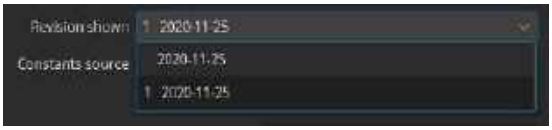
20.6.6. Editing IOL Data

The IOL data section to the right of the lenses tree allows the user to optimize or personalize IOL data.

The manufacturer and model of the lens can be entered manually in their respective fields at the top of the section. This triggers the auto-suggest function to speed up the IOL selection process.



Revision shown drop-down menu allows the user to choose the revision of IOL data they wish to use for the calculation. A new revision is created whenever the user introduces changes to the data and saves them by clicking **[SAVE]** at the bottom of the window. Consecutive IOL revisions are indicated by a number next to the date. By default, the system uses the latest revision of data.



WARNING: The user is fully responsible for all data entered or changed manually.

The **Constants source** field shows the source of the constants. The user can set the constant source displayed as the default source by clicking **[SET AS DEFAULT]**.

CAUTION: Calculation constants do not depend solely on the IOL type and calculation formula used. They can also be influenced by factors such as measurement technology and surgical technique, which is why the user is strongly advised to optimize the constants for their particular circumstances, case, and practice.

To calculate the constants based on the A-constant of the manufacturer, enter the A-constant value in the [A-CONST] field and click [CALCULATE CONSTANTS].

CAUTION: While using an A-constant for IOL Calculations, remember that it is an estimate and should only be used for reference. Use only IOL constants optimized for optical biometers.

CAUTION: The software for taking measurements and performing IOL calculations must be operated only by appropriately trained and experienced staff. All members of the staff must read this User Manual thoroughly, with special attention given to the safety related points and instructions.

NOTE: The user should always seek to improve their IOL optimization. IOL personalized and optimized data should be created through the analysis of pre-operative data obtained with the device and the results of stable refraction tests performed three months after the surgery.

20.6.7. Adding Additional Power Ranges and Increments

The default power range in the IOL Editor window is -10 to +40 diopters in increment of 0.5 diopters. It is possible to create additional power ranges and increments. To add a new power range, click the + button. To modify the range and increment values, double click on the value to modify and enter a new value. To remove a power range, click on it to highlight it and then click −.

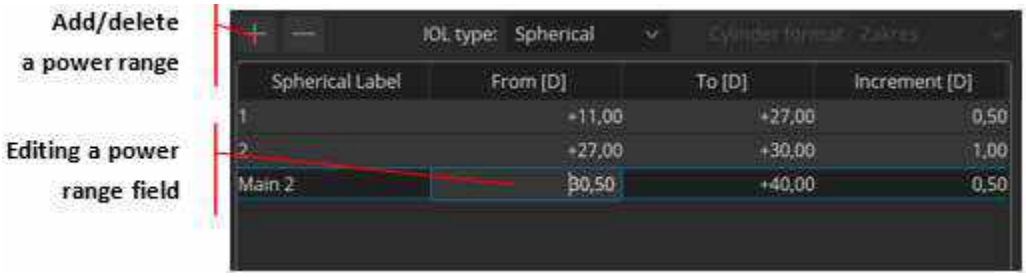


Figure 396.
Adding Additional Power Ranges and Increments

Using a Toric IOL requires the user to provide both the corneal astigmatism range and the cylinder power.

20.7. Myopia Forecast

The Myopia Forecast tab allows the user to collect and manage all necessary data related to myopia based on biometry, topography and refraction parameters.

Running the Myopia Forecast requires an optional biometry module with IOL installed in the system. The function is available only for exams which were carried out on a properly calibrated device. Detailed information on the calibration of the device can be found in Chapter 22.3 Axial Length (Biometry) Calibration.

To use Myopia Forecast tab there is no need to have optional topography module. However, if you have topography module you can use topography examinations to load parameters like: K1, K2 and K avg to Myopia Forecast tab and analyze them for myopia.

20.8. Myopia Protocol

When user has the optional biometry and topography modules, it is possible to run Myopia Protocol which allows to perform the biometry and topography examinations one by one. To run the protocol click on the **[PROTOCOL]** button and select “Myopia protocol”.

Before the start of the examinations software checks whether the calibration for biometry and topography has been done. If not, the SOCT will display a warning and ask to perform the calibration. When device is calibrated, the SOCT will start a biometry examination. After the biometry examination an acceptance window will appear. After accepting the biometry examination a topography examination will start. Also after the topography examination an acceptance window will appear.

20.9. Myopia Forecast tab

Myopia Forecast tab is available for every biometry examination, which was performed with the biometry module calibrated on the day of the examination, before the scan was taken (with the exception of the examinations performed on the versions earlier than SOCT 21.0.0, which are available on the Myopia Forecast tab).

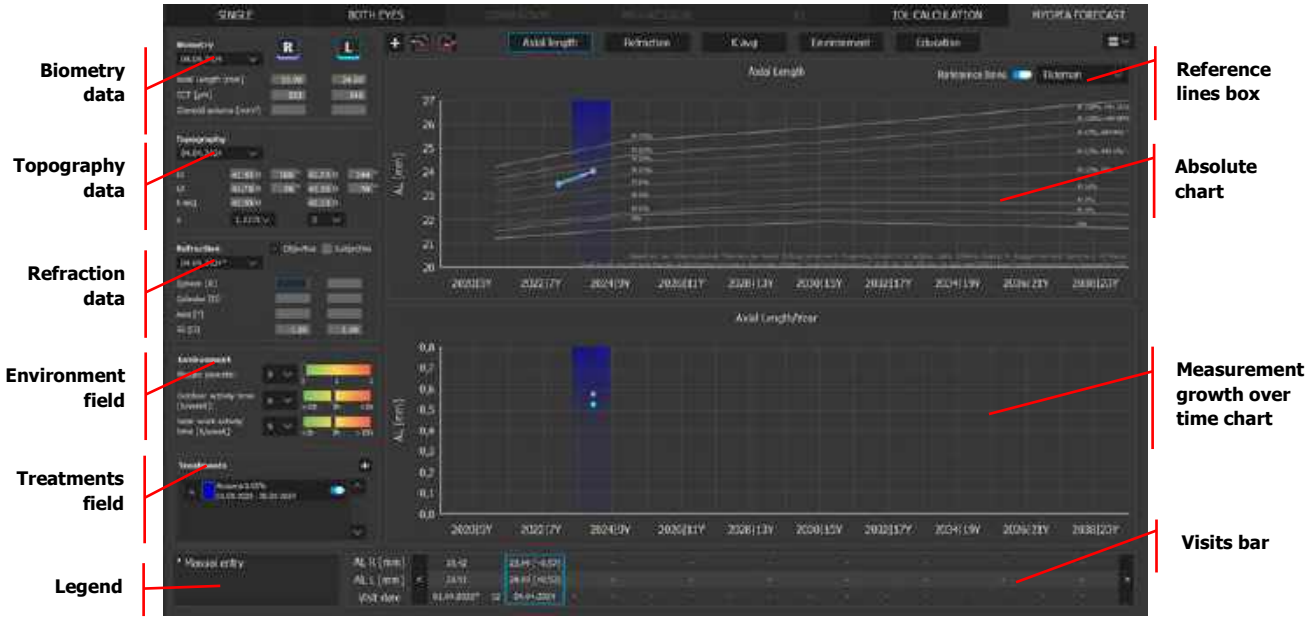
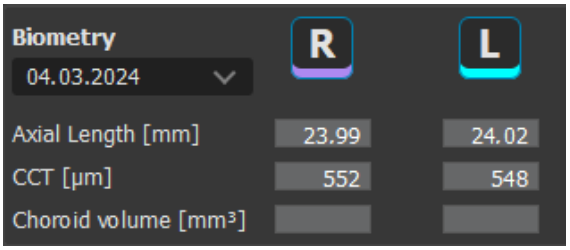


Figure 397
Myopia Forecast tab

20.9.1. Parameters

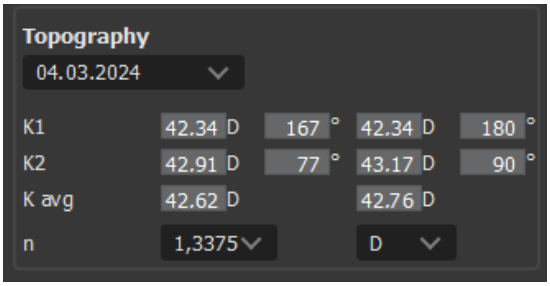
The left side of the Myopia Forecast tab contains parameters from examinations related to myopia: biometry, topography and refraction. In addition to the parameters each field displays visit date. If the measurements were added manually, the visit date will be marked with the asterisk (*****). In case when one eye has more than one examination in one day program will load parameters from the examination with the highest quality index. If more examinations have the same QI, program will load the last one.

20.9.1.1. Biometry field



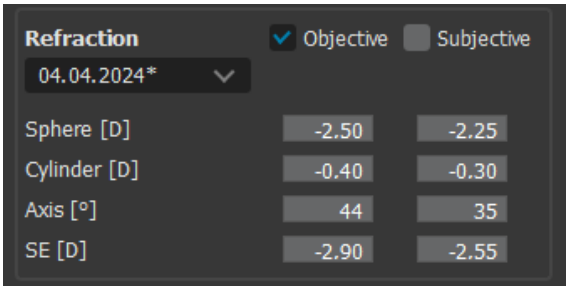
Contains biometrical parameters for both eyes like: Axial Length [mm], Central Cornea Thickness [µm] and Choroid volume [mm]. Values can be loaded from the biometry examinations or added manually as Manual Entry or by “Add Visit”.

20.9.1.2. Topography field



Contains topographic parameters for both eyes: K1 [D and °], K2 [D and °] and K avg [D], which could be changed to R1 [mm and °], R2 [mm and °] and R avg [mm]. Additional as in IOL Calculator, has refractive index. Values can be loaded from the topography examinations or added as Manual Entry or by “Add Visit”.

20.9.1.3. Refraction field



Contains refractive parameters for both eyes: Sphere [D], Cylinder [D], Axis [°] and SE [D]. Values can be added as Manual Entry or by “Add Visit”. It is mandatory to choose whether the measured values are Objective or Subjective by choosing the adequate checkbox.

20.9.1.4. Environment

Contains 3 factors influencing myopia: number of myopic parents, outdoor activity time [h/week] and near work activity time [h/week]. Values are selected from the dropdown list next to the factors. Single set of factors is assigned to a single visit, except “Myopic parents” factor, once set, is assigned to all visits. A change in this factor in one visit will be equivalent to a change in the rest of the visits.

20.9.1.5. Legend

Contains the explanations of the signs used in Myopia Forecast tab

- Manual entry (*) asterisk,
- No value measured (---) three dashes.

20.9.2. Treatments

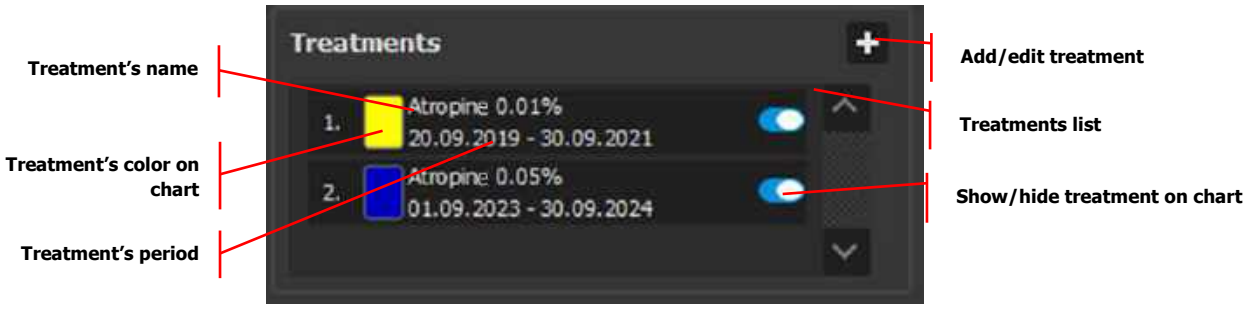


Figure 398
Treatments field

Treatment's list is displayed in the left bottom corner of the Myopia Forecast tab. Every treatment has own number and color. The numbers are assigned from the oldest to the latest treatments.

To add, edit or delete treatments click the **[+]** button. The Treatments window will open. The date format is adjusted to the operating system format.

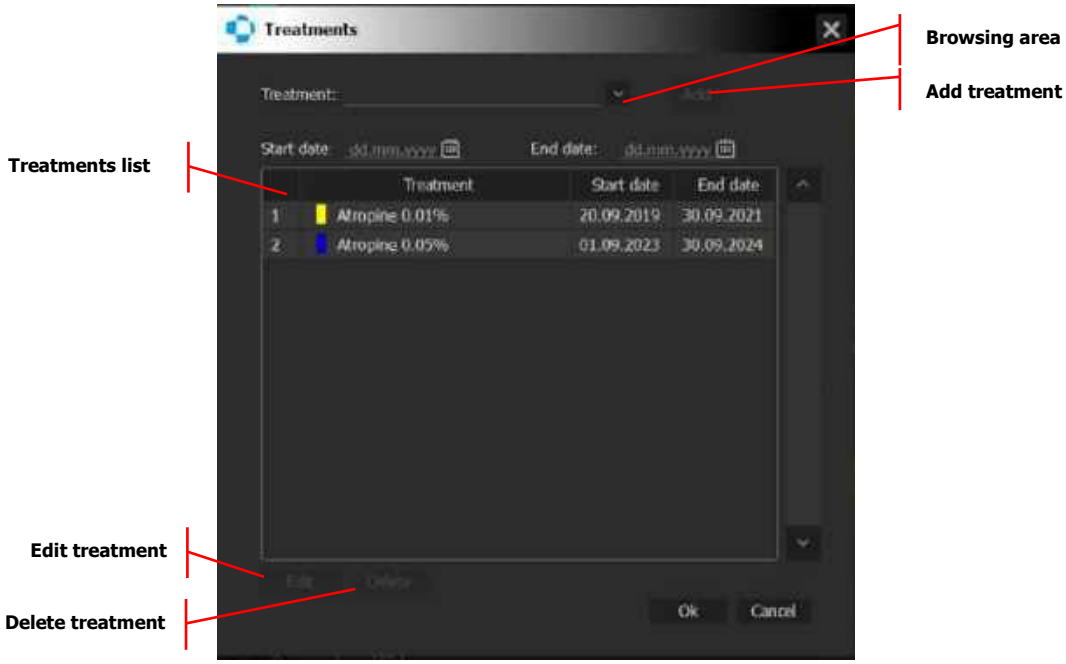


Figure 399
Treatments window

Sorting treatments is available by name and start date throughout clicking on the headlines.

NOTE: Fields "Treatments" and "Start date" and "Date of birth" are mandatory and must be properly filled in. "End date" optional and can be left empty.

List of treatments has fundamental types of treatments:

- Atropine 0.01%,
- Atropine 0.05%,
- Atropine 0.1%,

- Soft multifocal contact lenses,
- Rigid multifocal contact lenses,
- Ortho keratology contact lenses,
- Executive lenses,
- Progressive lenses,
- Bifocal lenses,
- Myopia lenses.

To add new type of treatment type it in the browsing area, select start date and end date (optionally) and click the **[Add]** button.

It is possible to add more than one treatment with the same name. The only condition is that the start and the end dates must be different from the already added treatment period.

To edit treatment, select one from the treatments list and click the **[Edit]** button. The treatment name, start date and end date (if was set) will appear in the fields above the treatment's list and they will be able to edit. To exit edit mode unclick the **[Edit]** button.

To delete treatment select one from the treatments list and click the **[Delete]** button.

To save changes and close Treatments window click the **[OK]** button. To discard changes and close Treatments window click the **[Cancel]** button.

20.9.3. Charts

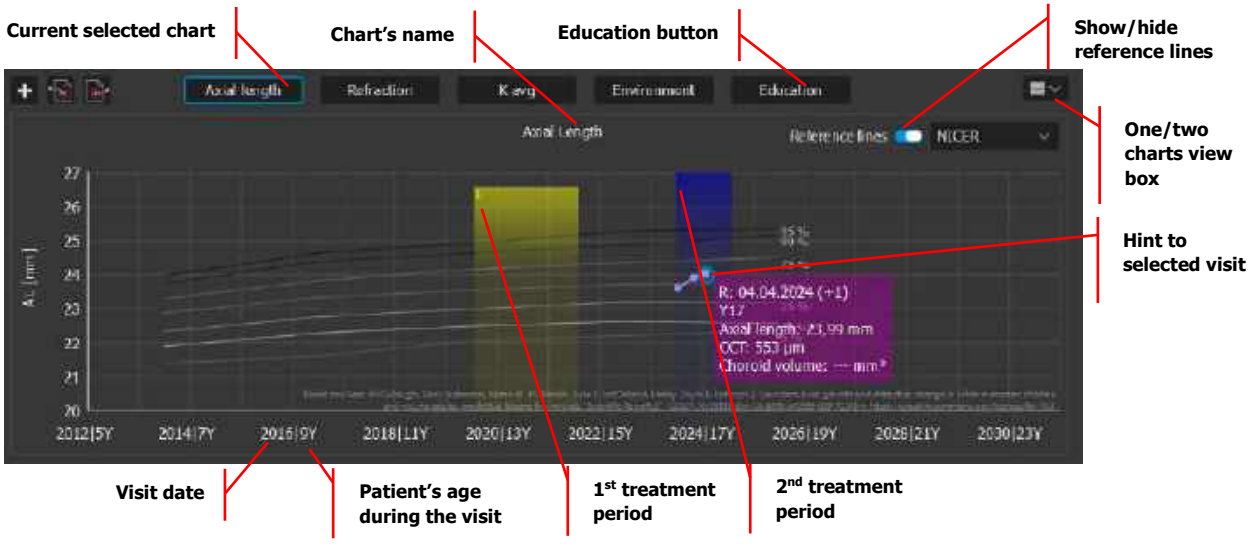


Figure 400
Charts section

Charts section is in the center of the Myopia Forecast tab. Allows to display the progress of the most important myopic parameters: Axial length, SE and K avg. In the top right corner is a box, where user can choose between one chart view and two charts view.

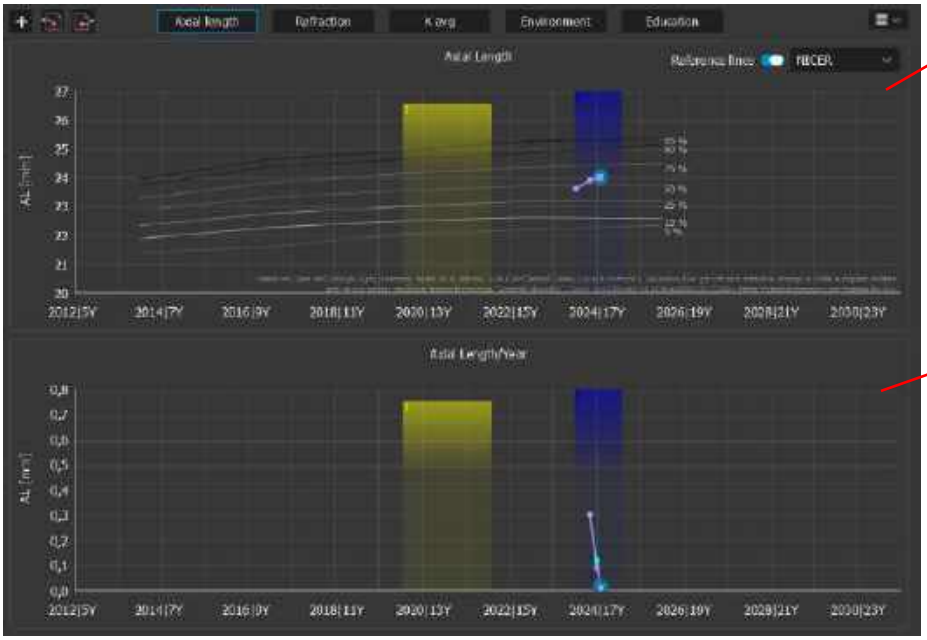


Figure 401
Example of two chart view

Two charts view displays absolute chart and measurement growth over time chart.

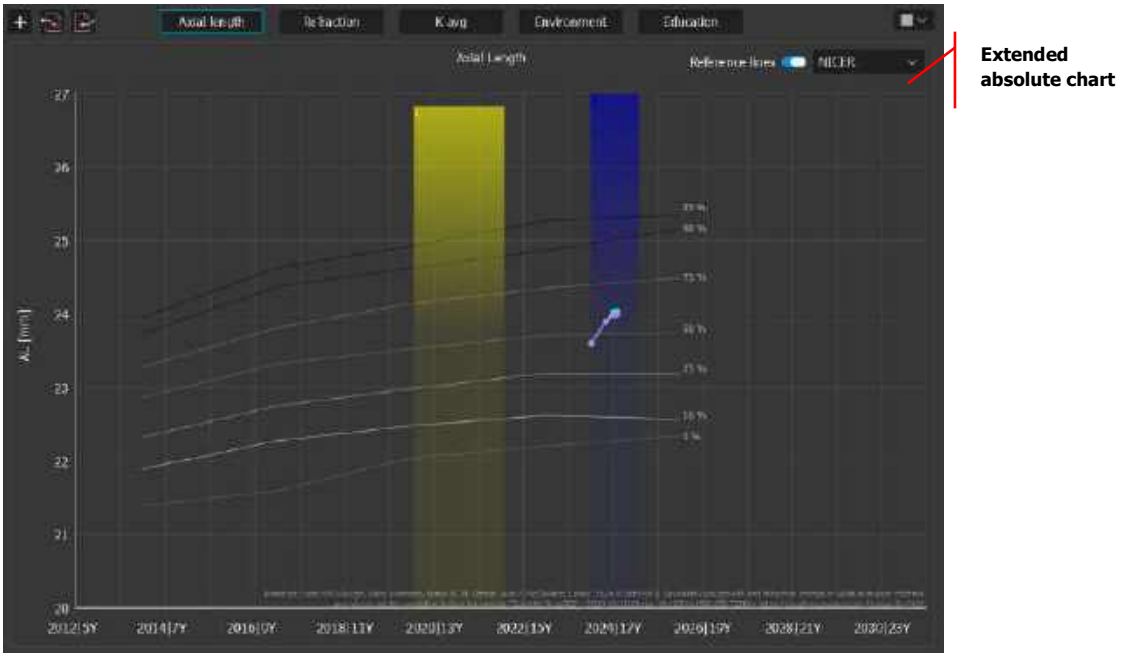


Figure 402
Example of one chart view

One chart view displays extended absolute chart.

On the X axis values of the chosen parameter are presented. On the Y axis visit dates and patient's age during those visits are presented.

User can display or hide chosen treatments on the charts by using the slide next to the treatments in Treatment's list (see Chapter 20.9.2 Treatments).

One click on the point on the chart displays the hint which contains the information:

- date of the visit with,
- patient's age during the visit,
- all parameters from the selected section.

Double click on the point on the chart displays the same hint as mentioned above and additionally changes the displayed visit date to the chosen one.

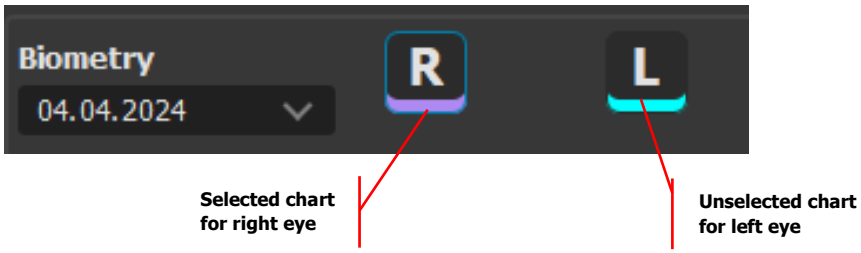


Figure 403
Right and left eye chart buttons

By clicking the **[R]** and **[L]** buttons in Biometry section user can decide whether the chart will present the values for only right, only left or for both eyes.

20.9.3.1. Reference lines

It is possible to choose the references line for the charts. In top right corner in chart's section is a slide button which show/hide chosen reference lines. Next to the slide button is a drop-down list with reference lines. Every chart has different reference line.

Axial length chart has:

- Tideman[60], which is based on research done on the European children and young adults (divided into males and females) in age 6-25,
- Sanz Diez[61], which is based on research done on the Chinese children (divided into males and females) in age 6-15,
- NICER[62], which is based on research done on the white European children (divided into males and females) in age 6-18.

Refraction chart has:

- NICER[62], which is based on research done on the white European children in age 6-18.

K avg chart has no reference lines.

Environment chart has:

[60] Axial length growth and the risk of developing myopia in European children Jan Willem Lodewijk Tideman, Jan Roelof Polling, Johannes R. Vingerling, Vincent W. V. Jaddoe, Cathy Williams, Jeremy A. Guggenheim, Caroline C. W. Klaver DOI: 10.1111/aos.13603

[61] Growth curves of myopia-related parameters to clinically monitor the refractive development in Chinese schoolchildren Pablo Sanz Diez, Li-Hua Yang, Mei-Xia Lu, Siegfried Wahl, Arne Ohlendorf DOI: doi.org/10.1007/s00417-019-04290-6

[62] Northern Ireland Childhood Errors of Refraction study; Axial growth and refractive change in white european children and young adults: predictive factors for myopia Sara McCullough, Gary Adamson, Karen M. M. Breslin, Julie f. Mcclelland, Lesley Doyle, Kathryn J. Saunders

- Tideman[60], which is based on research done on the European children (divided into girls and boys) in age 6-25,
- Sanz Diez[61], which is based on research done on the Chinese children (divided into males and females) in age 6-15,
- NICER[62], which is based on research done on the white European children (divided into males and females) in age 6-18.

NOTE: Reference lines are based on published researches and may be different than the real trends in the population. Operator should bases on own experience and adjusts reference lines to accurate population.

20.9.3.2. Charts types

There are 4 types of charts: **Axial length**, **Refraction**, **K avg** and **Environment**. Each type might be displayed as a one chart view (extended absolute chart) and two charts view (absolute chart and measurement growth over time chart).

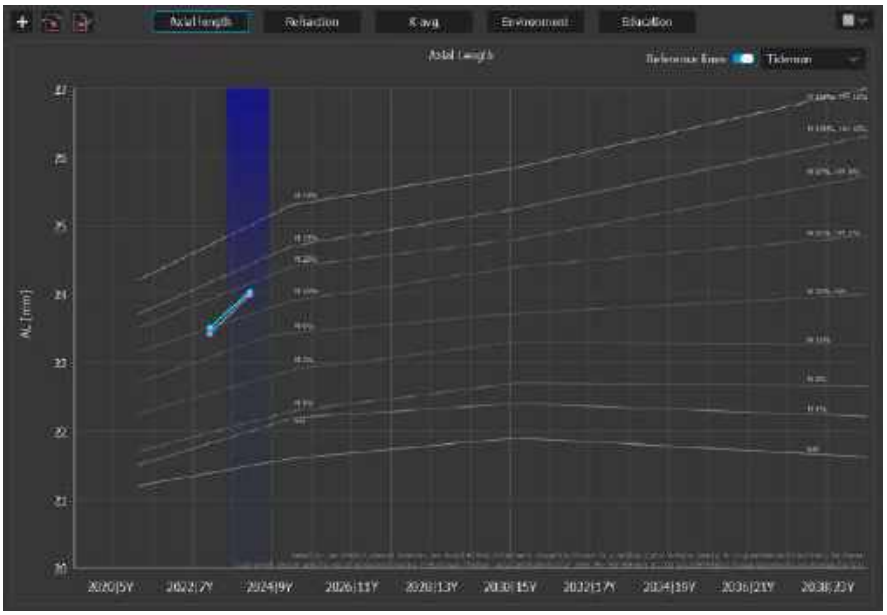


Figure 404
Axial length chart displays the progression of the Axial length [mm] value.

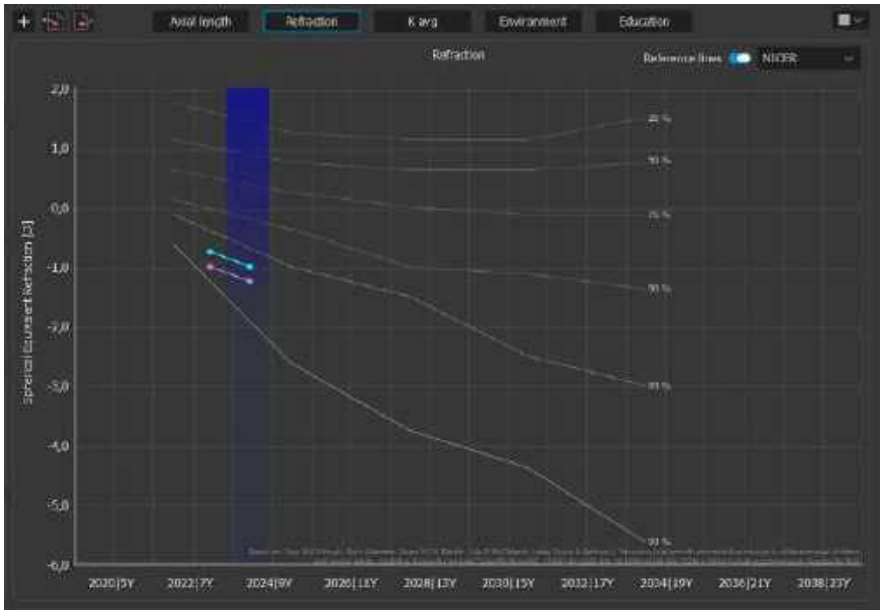


Figure 405
Refraction chart displays the progression of the SE [D] value.

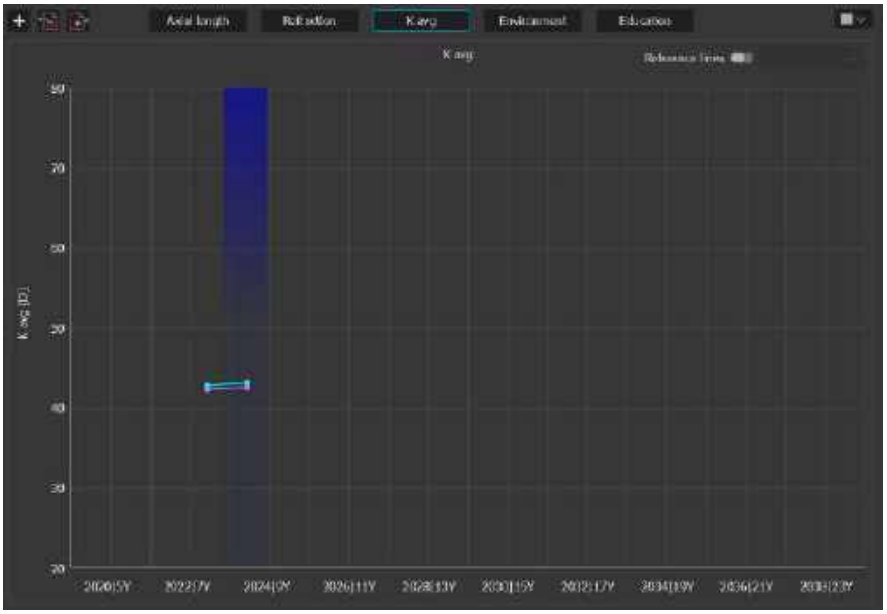


Figure 406
K avg chart displays the progression of the K avg [D] value

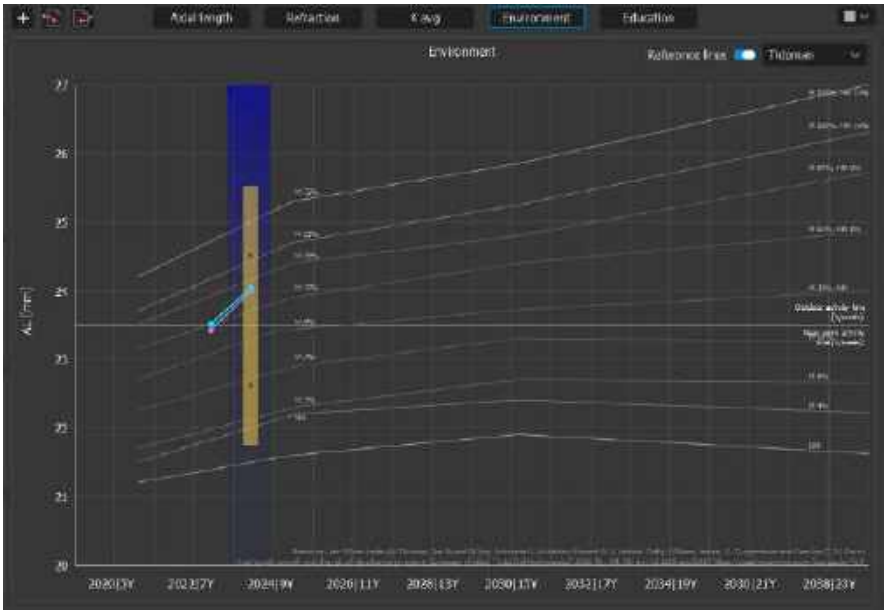


Figure 407
Environment chart base on the Axial length chart and additionally displays the impact of the environmental factors on the Axial length.

20.9.4. Visits bar

Visit bar is chart dependent. Contains in each column the values of the presented on the chart parameters from each visit for both eyes. For the Axial length chart and Environment chart presents Axial length [mm] values, for the refraction chart presents the SE [D] values, for the K avg chart displays K avg [D] values.

In the brackets next to the parameter's value are the values of the parameter growth relative to the previous visit.

The values between each column, which appears in the Visit date row inform about the period between visits (in months).

Double click on the column change a current displayed visit to the chosen one from the column.

20.10. Data management

Data can be entered in three ways: loading myopic parameters from the examinations (only for biometry and topography), entering them manually and adding a visit.

One visit date includes biometric, topographic and refractive parameters for both eyes and environment data.

20.10.1. Parameters from examinations

The program assigns to the visit date parameters from the latest biometric and topographic examinations with the best quality index.

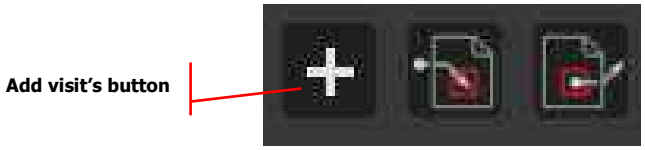
20.10.2. Parameters from Manual entry

To add parameters from different sources by manual entry type new values in interested field (refers to biometry, topography and refraction field). Each change will be automatically saved as a visit date with the asterisk (*).

Figure 408
Example of the visit with manually added parameter

To display values loaded form the examinations expand drop list and choose the date without asterisk

20.10.3. Parameters from add visit



To add visit press **[+]** button localized next to the **[Import]** and **[Export]** buttons.

Visit date is necessary to add visit. Each section has the same field to fill as in the main tab. The exception is Topography section where the parameters are presented in diopters.

If the chosen visit date coincides with the visit which already has manual entry the values from that manual entry appears in the empty fields.

Click **[Add]** button to save changes/new visit. Click **[Cancel] or [X]** button to cancel editing/adding a new visit.

20.10.4. Export/Import

It is possible to import and export patient's visit. The **[Import]** and **[Export]** buttons are localized next to the **[+]** (Add visit) button. By clicking the **[Import]** button user can import Manual entry data

The **[Export]** button allows to export current displayed visit as:

- separate biometry examinations for each eye with all parameters from the visit,
- manual entry as ".myopia" file which contains all parameters (biometric, topographic and refractive) for both eyes from the visit without biometry examinations. It also includes information about environmental parameters and treatments related to that visit.

The **[Import]** button allows as the only one in the SOCT import ".myopia" file.

20.10.5. Delete examination

Deleting biometry and topography examinations removes all parameters loaded from those examinations from Myopia Forecast tab. Manual entries with the date of removed examinations remain in the tab.

20.10.6. Output

It is possible to output to CSV file myopic parameters from current displayed visit. The output contains parameters for both eyes (loaded from examinations and added by manual entry) like:

- Axial Length [mm],
- CCT [µm],
- Choroid volume [mm^3],
- K1 [D] and [°],
- K2 [D] and [°],
- K avg [D],
- Sphere [D],
- Cylinder [D],
- Axis [°],
- SE [D].

Additionally contains information's related to the visit like:

- Myopic parents,
- Outdoor activity time [h/week],
- Near work activity time [h/week],
- Treatments prescribed to the patient,

More information about the output can be found in Chapter 23.7. Output Settings

21. Topography (Optional Function)

NOTE: Topography is an optional software module. If you do not have these modules and wish to purchase them, please contact your local OPTOPOL distributor.

The topography module provides the analysis of anterior and posterior corneal surfaces based on Corneal Curvature, Dioptric power, Elevation and Real power analysis of both surfaces and local corneal thickness (Ray tracing).

The topography scanning program is available in the Anterior scanning program list. The scanning parameters are fixed: 16 B-scans, 8mm width. Scan time:

- approximately 0.17 sec. for REVO HR / REVO FC 130 / REVO NX 130
- approximately 0.22 sec. for REVO FC / REVO 80
- approximately 0.29 sec. for REVO 60

21.1. Topography (Safety Notes)

WARNING: When using the adapter for the examination of the anterior segment of the eye, do not move the measuring head too fast and monitor its distance from the patient to prevent contact between the surface of the anterior adapter lens and the patient's eye.

WARNING: When mounting the anterior adapter, make sure that the scanning head is in its maximum backward position and that the patient does not incidentally come into contact with the anterior adapter.

CAUTION: Use of eye drops prior to topography measurement may lead to incorrect results in the measurement of corneal curvature. The use of artificial tear drops may impact the measured keratometry values.

CAUTION: Do not perform any contact measurements or examinations in which the eye is touched prior to measurement with the SOCT. Performing contact measurements prior may result in incorrect SOCT readings, particularly for biometry and corneal topography measurements. Contact measurements or examinations should only be performed after the patient has been measured with the SOCT.

CAUTION: Exercise caution when mounting the anterior adapter in order not to scratch the objective lens.

CAUTION: Prior to measurement, the user must verify that the patient is not wearing contact lenses. Patients wearing contact lenses during measurement will result in erroneous results.

CAUTION: The topography module may be used only by properly trained personnel.

NOTE: Layers recognition is used for tracing.

NOTE: For corneal topography scanning, fully examine the measured tomograms for layer recognition and examination results. For bilateral acquisition, if the difference between measurement values for the left and right eye is significant or any problem is found in the anterior chamber during the preliminary examination, check the correctness of the tissue boundary recognition and / or reliability indices. For all corneal topography scanning, if the measurement result is not conclusive, repeat the measurement or further review the results.

NOTE: When using corneal topography or biometry data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking a minimum of three measurements and / or conducting measurements with other instruments.

NOTE: Since the simultaneous use of multiple devices can cause misdiagnosis or result in a hazardous situation due to non-interchangeable data, exercise caution when using this instrument.

NOTE: Fully examine the measured data for tracing results. If the difference between measurement values for the left and right eyes is significant or any problem is found with the anterior chamber during the preliminary examination, check the tracing and / or reliability on the check screen. If the measurement result is not conclusive, it may be necessary to repeat the measurement.

NOTE: It may be difficult to trace the border when capturing an image of an eye with an opacity or malformation such as corneal disease, shallow anterior chamber, aphakic eye, pseudophakic eye or dense cataract eye and the data may not be reliable.

NOTE: When the measurement light enters the cornea, sclera, conjunctiva, or intraocular lens perpendicularly, a bright vertical line appears.

NOTE: Artifacts (Ghost images / noise) may occur in areas with strong reflection such as the cornea, sclera, conjunctiva, and iris.

NOTE: The Anterior Chamber scan and Pachymetry scan include compensation for beam scanning geometry and reflection from the surface of the cornea. Therefore, during acquisition, it is important that the scan is centered on the vertex of the cornea so that a strong vertical reflex is visible through the corneal vertex. The compensation algorithm works with greatest accuracy when corneal scans are centered using this method.

NOTE: Low quality examination results can be expected in the following situations:

- **Patients with complete or partial coverage of the cornea, caused by palpebral fissure which is closed or too small.**
- **Patients which are unable to steadily fixate on the fixation target with the eye under examination**

NOTE: When using these instruments measurements for selecting intraocular lenses, thoroughly determine the selection by also examining cataract surgery methods and performing measurements on other devices. If incorrect measurement data is used to select intraocular lenses, further surgery might be required.

NOTE: When using the data taken by this instrument for refractive correction surgery, it is the clinician's responsibility to confirm the measurements by utilizing other instruments to measure. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or severe complication such as keratectasia.

NOTE: Shaded areas indicate questionable data - such scans should be reviewed for determine accuracy. Data is often compromised by lid or ghost images from iris related issues.

21.2. Topography Acquisition Mode

1. Before the first topography examination of each day, it is recommended to perform the initial calibration of the device. The calibration procedure is described in Chapter 22 Calibration Test.
2. Prepare the patient as explained in Chapter 8.1 Preparing for an Examination.
3. If voice guidance is switched off, inform the patient to follow the fixation target and to blink freely.

   If required, use the large fixation target. See Chapter 7.9 Fixation Target Adjustment.

3. Select the Topography scan program.

   Once the scan program is selected, the topography acquire window is available.

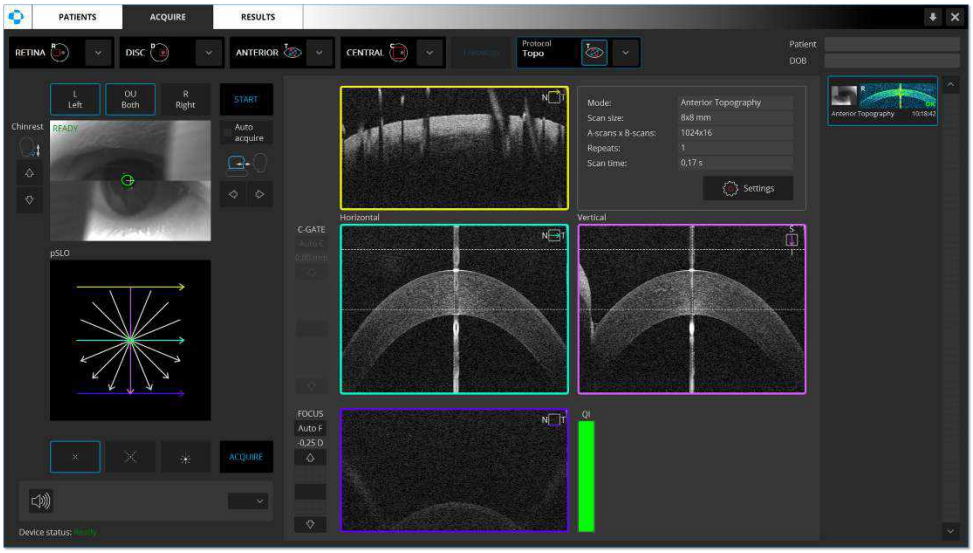


Figure 409.
Topography Acquire Window

While capturing the scan, the following steps should be observed:

- The cornea tomogram should be positioned within the range defined by the two horizontal dashed lines.
- The operator should make sure that the lids of the eye are not blocking or shadowing a significant portion of the image in the vertical meridians.

4. After the result is acquired, it is displayed in the acceptance window. The operator should verify the measurement reliability indices. A measurement with poor reliability indicates an increased risk of variability. Measurements with poor reliability should be replaced.

5. Follow the procedure depending on the acquisition mode.

NOTE: The system automatically selects C-gate mode from Top to Bottom. In cases when the ghost image touches the cornea (e.g., shallow anterior chamber) the user has to change the C-Gate mode from Bottom to Top.

21.2.1. Full-Auto Mode

4. Enable the **[AUTO ACQUIRE]** checkbox and press the **[START]** button.
2. Wait until the system finishes the examination. The patient will be voice guided by the software unless it is muted or disabled.

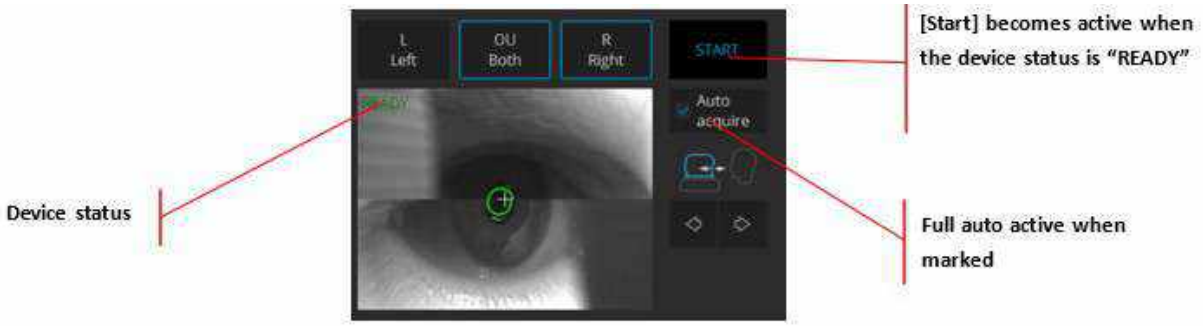


Figure 410.
Full-Auto Examination

NOTE: In difficult conditions, such as:

- **Eyelashes or eyelid which block the beam of light**
- **Inability of subjects to maintain fixation**
- **Dense media opacities**
- **Strong nystagmus**
- **Rapid blinks**

the system can display a warning. In this case operator should decide whether to use the tips mentioned in the Chapter 8.6 Examination Tips or change the acquisition mode.

NOTE: If the system does not detect the pupil, the user must adjust the center of the patient's pupil manually. To set the working position properly, align the center of the pupil to the proper height.

NOTE: The Operator is to remain with the patient throughout the scanning process to oversee and guide them. The voice guidance feature is not intended to replace the Operator.

NOTE: If the system is not able to maintain the correct position of the retina (for example if the patient is moving), the operator must switch off tracking and carry out the examination manually.

21.2.2. Semi-Auto Mode

5. Uncheck **[AUTO ACQUIRE]**.

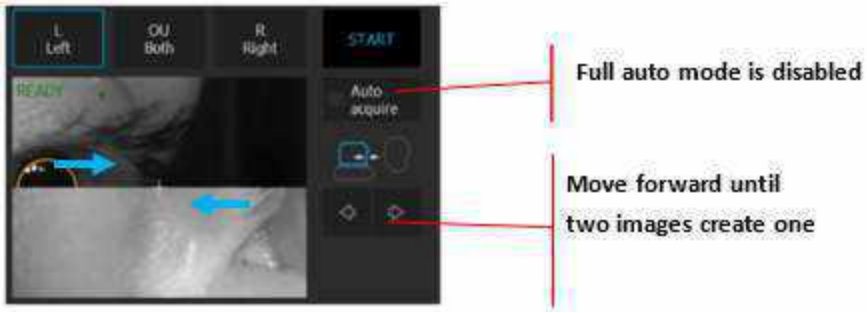


Figure 411.
Manual Examination Mode

6. The cornea OCT signal should appear in the tomogram preview. If it does not, adjust C-Gate manually by moving the sliding bar or scrolling over the tomogram window. If the cornea OCT signal cannot be located, adjust the patient refraction value, and try to find the signal again.

3. Some refraction correction may be needed to obtain the best tomogram quality. Observe the Q Bar to obtain the best signal while changing **[FOCUS]** the bar position.

4. Verify the position of the cornea which should be placed on the dashed horizontal line. The center of the cornea should be on the vertical dashed line.

5. Once the cornea position is aligned, ask the patient to blink and start the final topography acquisition. Double click on the tomogram or press the **[ACQUIRE]** button. The device will initialize the measurement immediately and perform a full scan.

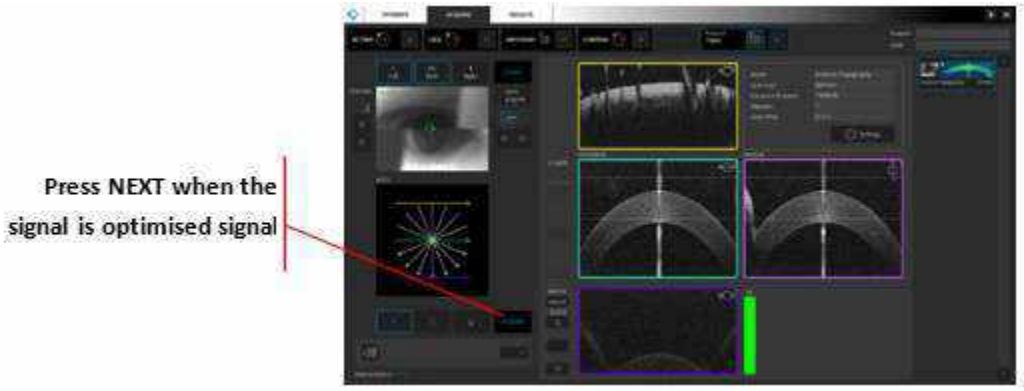


Figure 412.
Manual Examination Process

6. After the examination is over, the system will display an acceptance screen.

21.2.3. Manual Mode

7. Uncheck **[AUTO ACQUIRE]**.

8. Align the tomogram between the two horizontal dashed lines in the Horizontal and Vertical (cyan and magenta) panels.

9. Adjust the **[FOCUS]** manually by using the slider under focus, or the up / down arrows. Observe the Q bar and signal strength saturation of the tomogram image to obtain the best signal.

10. If a ghost signal (reflected image of iris) appears, it may be necessary to open the **[SETTINGS]** and switch C-Gate mode.

11. Adjust the position of the corneal tomogram in the blue and magenta panels and click to drag the position between the two horizontal dashed lines in the top portion of the panels.
12. Once aligned properly, ask the patient to blink twice.
13. To begin acquisition, click the **[ACQUIRE]** button or double-click on a tomogram panel.

21.2.4. Topography Acceptance Screen

After capturing a topography examination, the system checks if all measurement parameters are on an acceptable level. If any of them are not, the system displays an acceptance window as seen in the figure below.

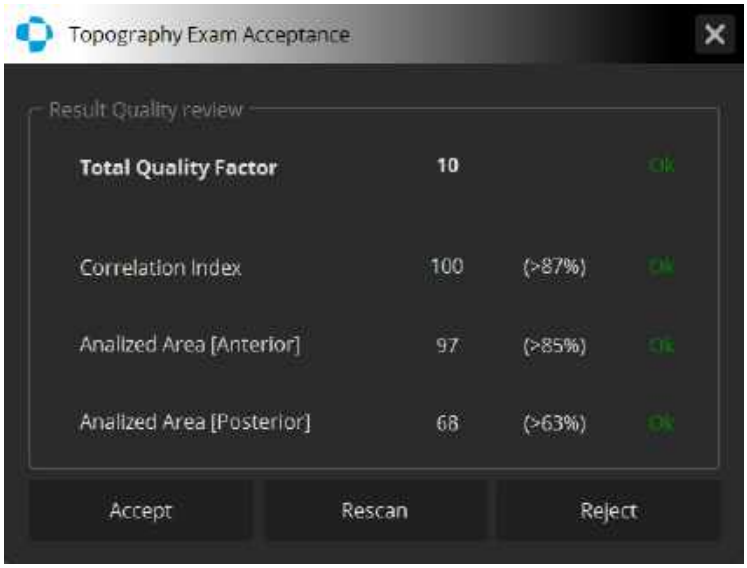


Figure 413.
Topography Exam Acceptance Window

1. **[RESCAN]**

   The examination is saved. The system is ready to repeat the examination.

2. **[ACCEPT]**

   The examination is saved.

3. **[REJECT]**

   The examination is not saved, and the system returns to the acquire window.

If **[RESCAN]** is selected, pressing the right mouse button on the tomogram in the acquire window initiates automatic alignment of tomograms along the X and Y axis. The Z axis remains the same. If the Auto Acquire check is selected, the system automatically acquires a scan.

21.2.5. Topo Quality Factor (TQF)

WARNING: Only scans with the "OK" status can be considred for a diagnosis. Scans with "!" status cannot be considered.

TOPO QUALITY FACTOR

A summary factor that determines whether the operator can trust the measurement. The TOPO quality factor is based on the values of all individual factors: QI, CI, AAA, APA.

CORRELATION INDEX

Information about tomograms correlation in the measurements.

OK	[Accepted]	Not correlated	>87%
!	[Borderline]	Unreliable	>86% to >70%
NG	[Not correlated]	Not correlated to	<69%

ANALYZED AREA

Information about the relation of the scanned area in ideal conditions to the recognized area in the anterior and posterior. It is expressed in %.

AAA [Anterior Analyzed Area]

OK	[Accepted]	>85%	
!	[Borderline]	>84% to >65%	
NG	[Not correlated]	Not correlated to	<64%

PAA [Posterior Analyzed Area]

OK	[Accepted]	>63%	
!	[Borderline]	>63% to >41%	
NG	[Not correlated]	Not correlated to	<40%

ARTIFACT

This warning appears when on three consecutive scans, the system detects sections in which the recognition algorithm has uncertainty. This problem makes it possible to detect artifacts related to a closed eyelid, ghost signal from the iris, lack of signal due to long eyelashes or decreasing signal due to opacity in the cornea.

Results for the topography scan are not displayed for scans with poor quality in which an algorithm has failed. In this case, the scan should be repeated.

NOTE: It is recommended for the user to take at least three topography scans and calculate the mean corneal curvature parameters further reduce measurement variability.

21.3. Results Review

21.3.1. [Single] Topo View

The overview display is a compilation of several evaluations and offers the user a quick overview of the anterior eye segment.

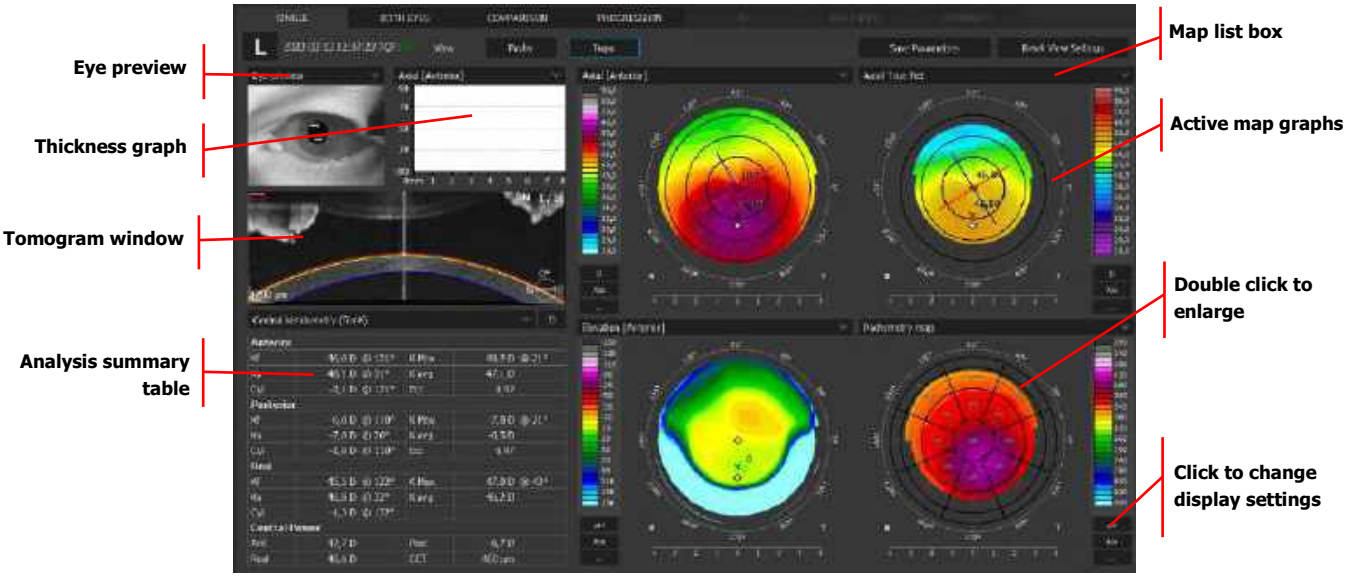


Figure 414.
Single Topography Topo View

At the topography window, the user can select one of the predefined maps from the list box:

1. Axial [Anterior]
2. Axial [Posterior]
3. Refractive Power map [Kerato]
4. Refractive Power map [Anterior]
5. Refractive Power map [Posterior]
6. Refractive Power map [Total]
7. Tangential map [Anterior]
8. Tangential map [Posterior]
9. Net Map
10. Axial True Net
11. Equivalent Keratometer
12. Elevation Map [Anterior]
13. Elevation Map [Posterior]
14. Height map
15. Pachymetry map

16. Epithelium map

Clicking the right mouse button on the results Topography and Biometry table enables exporting the data as a .txt file.

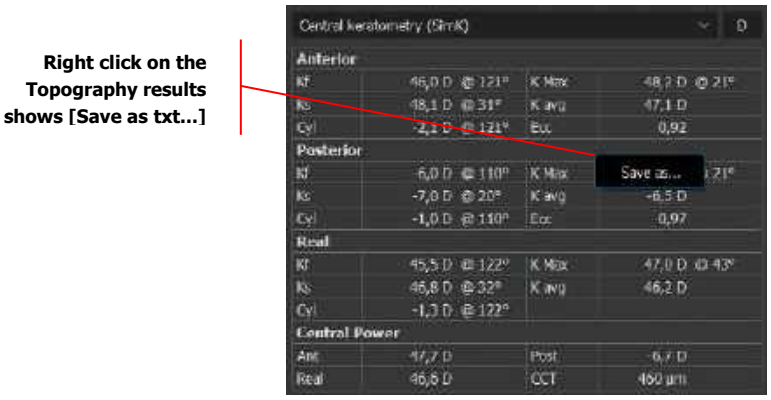


Figure 415.
Topography table

21.3.1.1. Enlarged Detailed Map View

Double click on the active map for a new window with an enlarged detailed map.

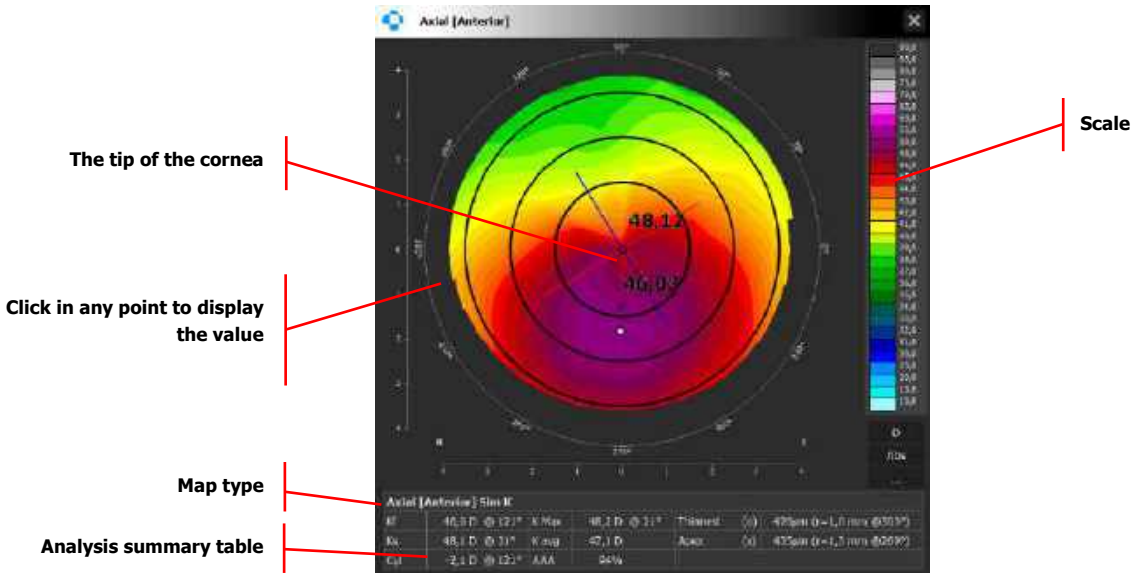


Figure 416.
Enlarged Detailed Topography (Map View)

Markers on maps:

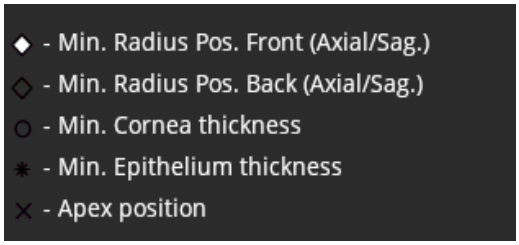


Figure 417.
Enlarged Detailed Topography (Map View)

After pressing the right mouse button on the map, a context menu appears with the following options:

B-SCAN REFERENCE ENABLE

Enable / disable the reference B-scan on the map. Changes are visible on all maps. Inactive for enlarged map.

SECTORS

It allows sectors to be superimposed on the map.

GRID

When the “Grid” option is selected, the entire map is covered by a grid of numbers. Unavailable for Height and Elevation maps.

NONE

It allows to show map without Sectors and Gird.

MARKERS

It enables the display of corneal markers. Changes are visible on all maps.

WHITE BACKGROUND

It changes the background illumination of all maps to white. Changes are visible on all maps.

SAVE AS

Saving the current map to a file.

21.3.2. [Both] Topo View

This screen shows the analysis results comparing exams of both eyes, performed in the same scan mode and on the same date.

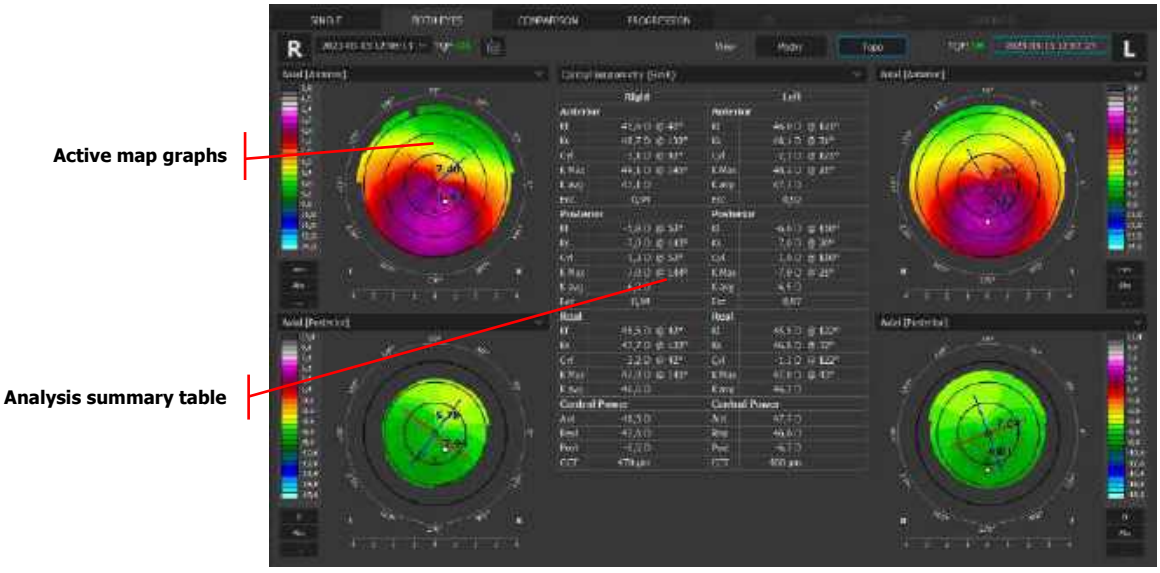


Figure 418.
Both Topography Topo View

21.3.3. [Comparison] Topo View

This screen shows the analysis results comparing two examinations of one eye on the same side, in the same scan mode, from different dates.

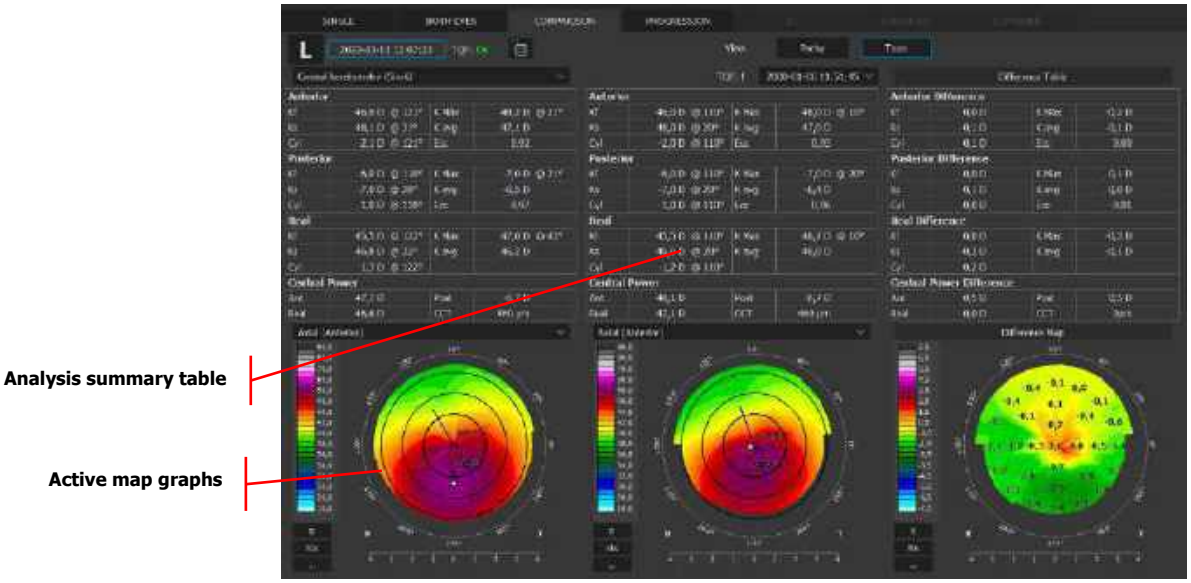


Figure 419.
Comparison Topography Topo View

21.3.4. [Progression] Topo View

This screen shows the analysis results comparing six examinations of eyes on the same side in the same scan mode, and the same size of scanning area, arranged in a time sequence.

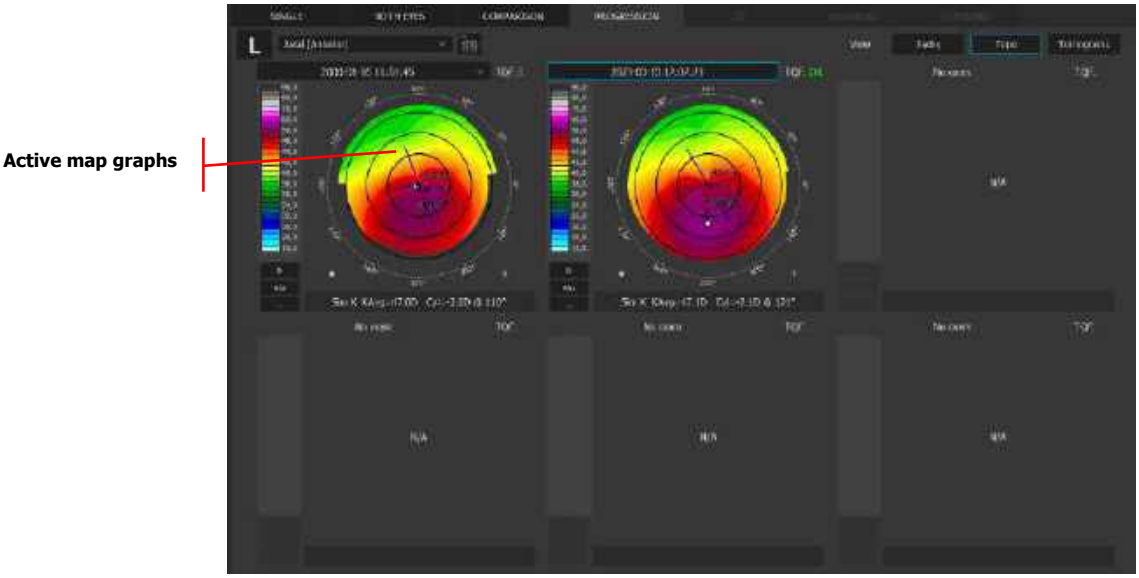


Figure 420.
Progression Topography Topo View

21.3.5. [Single] Pachy View

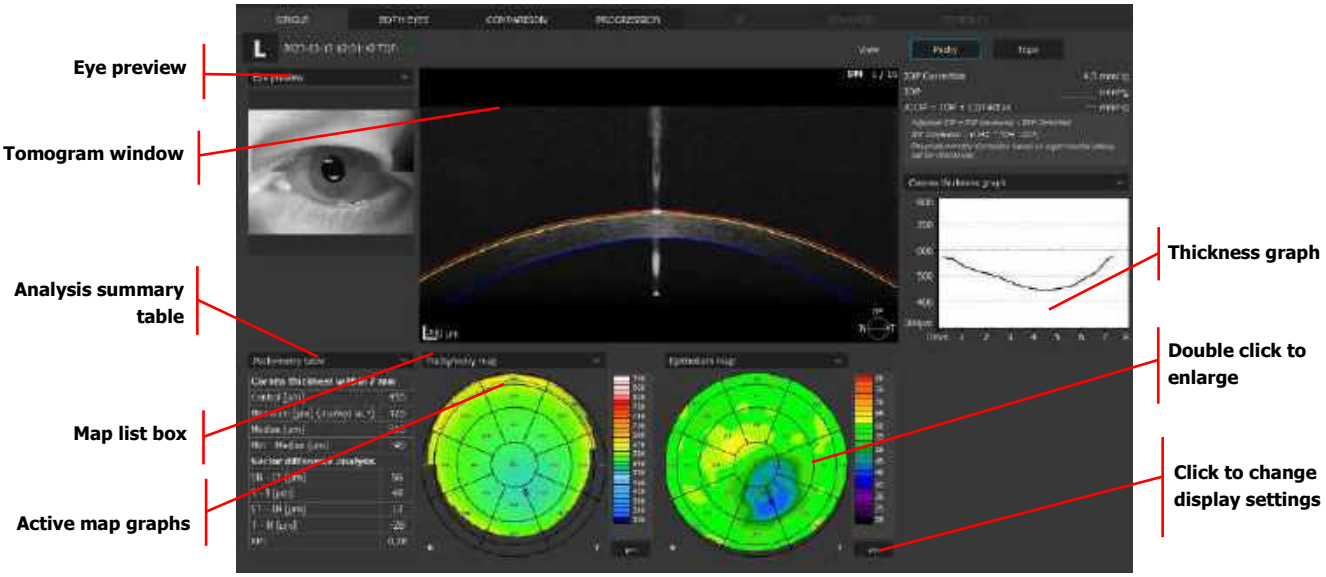


Figure 421.
Single Topography Pachy View

At the topography window, the user can select one of the predefined maps from the list box:

1. Pachymetry map
2. Epithelium map
3. Strona map

After pressing the right mouse button on the map, a context menu appears with the following options:

B-SCAN REFERENCE ENABLE

Enable / disable the reference B-scan on the map. Changes are visible on all maps. Inactive for enlarged map.

SECTORS

It allows sectors to be superimposed on the map.

GRID

When the “Grid” option is selected, the entire map is covered by a grid of numbers. Unavailable for Height and Elevation maps.

NONE

It allows to show map without Sectors and Gird.

AVERAGE

Average thickness within the area.

MAXIMUM

Maximum thickness within the area.

MINIMUM

Minimum thickness within the area.

WHITE BACKGROUND

It changes the background illumination of all maps to white. Changes are visible on all maps.

21.3.6. [Both] Pachy View

Figure 422.
Both Topography Pachy View

21.3.7. [Comparison] Pachy View

Figure 423.
Comparison Topography Pachy View

21.3.8. [Progression] Pachy View

Figure 424.
Progression Topography Pachy View

21.4. Analysis

21.4.1. Definitions of basic keratometry values

ANT

The average power of the central 3 mm front sector, displayed only as refractive power [D].

APEX

Corneal thickness from the epithelium to endothelium at the anterior corneal apex position.

CCT

Central Corneal Thickness; displayed in micrometers [µm].

CYL

The Cylinder power (Astigmatism). The amount of the anterior/posterior/true net corneal astigmatism, calculated as a difference between K1/Kf and K2/Ks; displayed only as refractive power [D]. The tilt angle of the astigmatism axis is equal to the K1/Kf tilt angle.

ECC

Eccentricity, calculated according to the mathematical definition as a difference between the corneal model and the best-fitting sphere in the range of 7 mm. Eccentricity is calculated according to the formula:

$$\varepsilon = \frac{\sum_0^n \frac{\sqrt{\left|R_i^2 - r^2\right|}}{d_i}}{n}$$

R – the value of the radius of curvature (ant or post at a given point),

r – the radius of the best-fit sphere,

d – flat distance to the tested point,

K1/KF

The anterior/posterior/true net, simulated keratometer reading obtained from a circle with the K diameter value chosen in the Setup, and a width of 1 mm. K1 - flat meridian (blue) is displayed as the refractive power [D]. The tilt angle of the astigmatism axis is equal to the K1/Kf tilt angle.

K2/KS

The anterior/posterior/true net, simulated keratometer reading obtained from a circle with the K diameter value chosen in the Setup, and a width of 1 mm. K2 - steep meridian (red) is displayed as the refractive power [D]. The tilt angle of the astigmatism axis is equal to the K2/Ks tilt angle.

K AVG

The arithmetic average of the central keratometry (SimK), calculated as an arithmetic mean from K1/Kf and K2/Ks; displayed as the refractive power [D].

K MAX

The steepest radius of the curvature of the anterior/posterior/true net corneal surface, displayed in [mm] or the largest value of refractive power of the anterior/posterior/true net corneal surface, displayed in [D].

POST

The power of the posterior surface ranging 3 mm; displayed only as refractive power [D].

REAL

The power of the cornea is calculated from the sagittal curvature values of the anterior and the posterior surface. Anterior sagittal power is calculated using refractive indices of n=1 for air and n=1.376 for corneal tissue, whereas posterior sagittal power is calculated using refractive indices of n=1.376 for corneal tissue and n=1.336 for the aqueous, and the results are then aggregated; displayed only as refractive power [D].

THINNEST

Corneal thickness at the thinnest location.

21.4.2. Central Keratometry (SimK)

Displays the Simulated Keratometry values from the central area bases on the **Axial** maps.

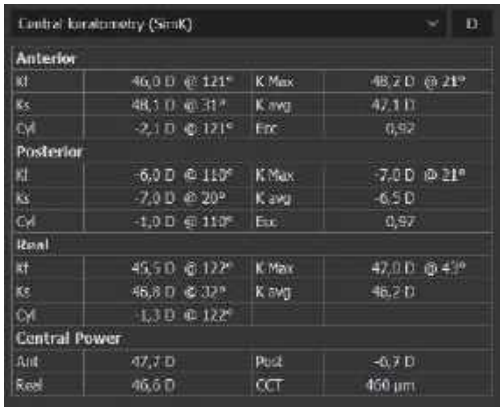


Figure 425.
Central Keratometry table

Keratometry values are distinguished:

1. Anterior – Anterior Corneal Surface. Values are calculated based on the **Axial [Anterior]** map.
2. Posterior – Posterior Corneal Surface. Values are calculated based on the **Axial [Posterior]** map.
3. Real – The power of the cornea. Values are calculated based on the **Axial True Net** map.
4. Central Power – the central power of the cornea. Values are calculated based on the **Axial [Anterior]**, **Axial [Posterior]**, **Axial True Net** and **Pachymetry** map.

21.4.3. Keratometry (Meridian)

This calculates the astigmatism based on the mean diameter in each zone. A steep axis is read as a 90^0 shift from a flat axis. Calculation based on the **Axial [Anterior]** and **Axial [Posterior]** maps.

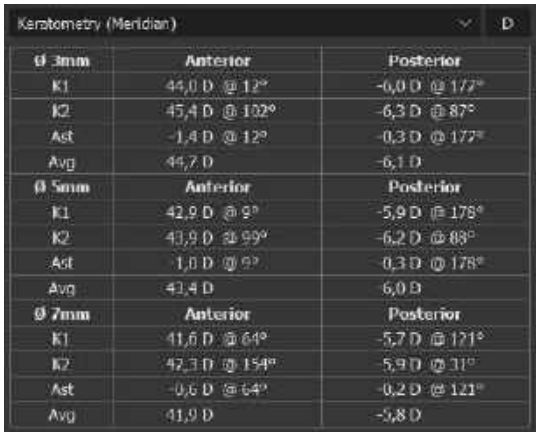


Figure 426.
Keratometry (Meridian) table

21.4.4. Keratometry (SemiMeridian)

This calculates irregular astigmatism bases on the mean radius in each zone. Calculation based on the **Axial [Anterior]** and **Axial [Posterior]** maps.

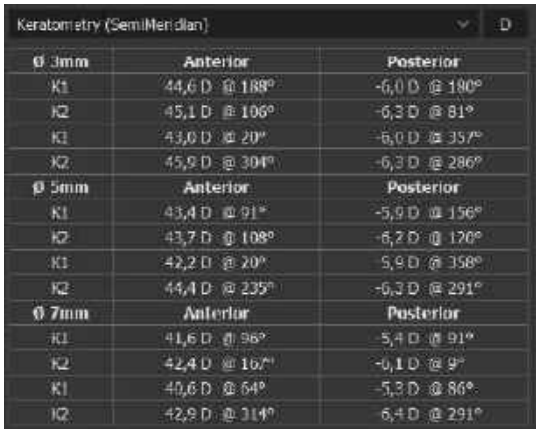


Figure 427.
Keratometry (SemiMeridian) table

21.4.5. Keratoconus screening

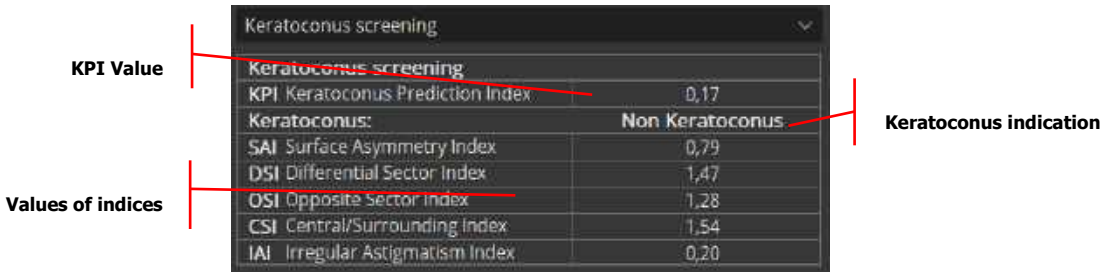


Figure 428.
Keratoconus screening table

To classify the keratoconus occurrence in the examined cornea, a Keratoconus Prediction Index (KPI) is calculated by the software after the examination is completed. KPI Result is displayed in a table and it will determine whether keratoconus had been detected based on the indices.

21.4.5.1. KPI Result

This system can be used as a screening procedure to distinguish clinical keratoconus from other corneal topographies. It may also aid in refining the clinical interpretation of topographic maps. If the system detects a result a calculated KPI value greater than 0.23 or K2 greater than 38.5, it is indicative of keratoconus, which later is distinguished by the method of elimination. See Figure 429Figure 428.

Keratoconus prediction index (KPI) is calculated by a combination of 8 topographic indices and relies on a linear discriminant function. The indices DSI, OSI, CSI, SAI, K1, K2, IAI and AA are described in detail in Chapter 21.4.5.2 Definition of Quantitative Indices.

CAUTION: KPI is based on a publication by Naoyuki Maeda in 1994[63], and can only be treated as supplementary information and cannot be treated as disease confirmation. Use for reference only.

KPI is a result of linear function, calculated according to the following formula:

KPI = 0,30 + 0,01(–41,23 – 0,15DSI + 1,18OSI + 1,49CSI + 4,13SAI – 0,56K1 + 1,08K2 – 3,74IAI + 0,10AA)

KPI value is calculated on the basis of Quantitative Indices, which are the components of the formula.

21.4.5.2. Definition of Quantitative Indices

Classification of the keratoconus screening is performed according to the following graph.

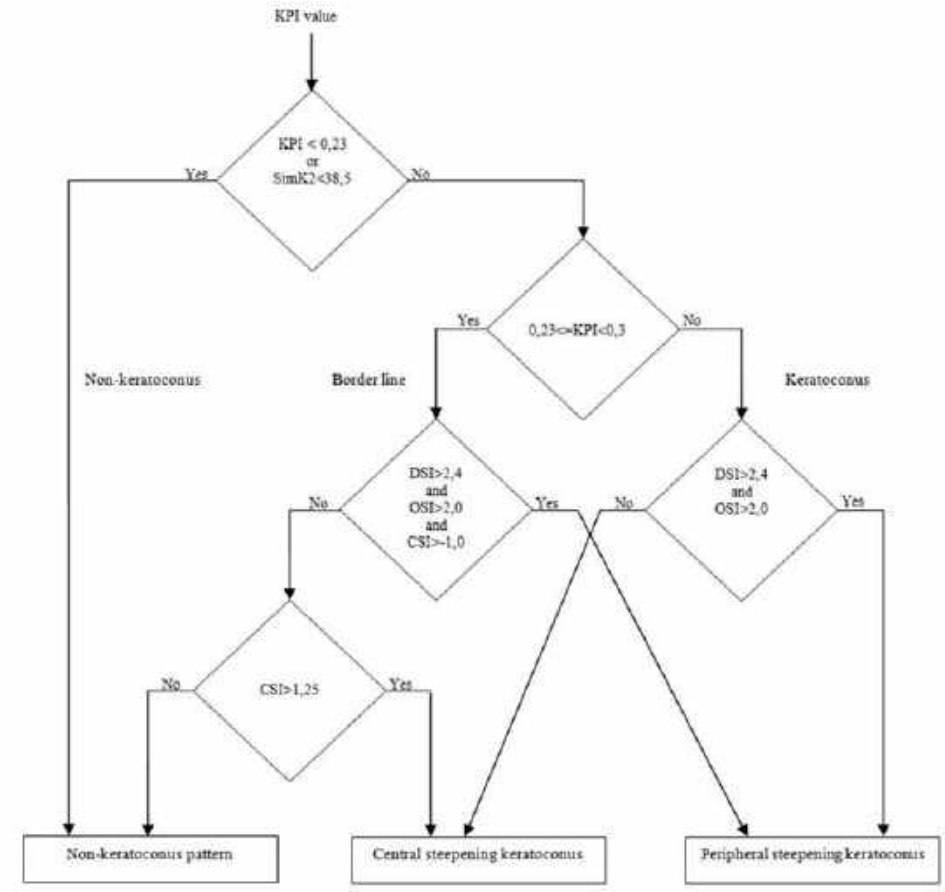


Figure 429.
Keratoconus screening classification

1. DSI AND OSI

DSI (Differential Sector Index) - the greatest difference in average power between any two (out of eight) sectors.

$$DSI = D_{max} - D_{min}$$

OSI (Opposite Sector Index) - the greatest difference of the average power in opposite sectors.

[63] Automated Keratoconus Screening with Corneal Topography Analysis by Naoyuki Maeda, Stephen D. Klyce, Michael K. Smolek, and Hilary W. Thompson in 1994.

$$OSI = D_{max} - D_{opposite}$$

To calculate Differential Sector Index and Opposite Sector Index, the analyzed area is divided into eight equal sectors. One of the sectors covers the area with the greatest power. Each sector has a specific average power calculated by the system (Figure 430).

Before the calculation of Differential Sector Index and Opposite Sector Index, the sectors are rotated at an angle, until the average power of one of the sectors reaches the highest value (D_{max}).

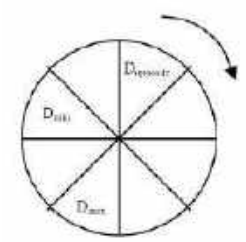


Figure 430.
Sectors (DSI, OSI)

D_{max} – average power value of the sector with maximum power

$D_{opposite}$ – average power value of the sector which is opposite to the sector with maximum power

D_{min} – average power value of the other sector with minimum power

2. CSI

CSI (Central / Surrounding Index) - difference in the average area-corrected corneal power between the central area and an annulus surrounding the central area ().

$$CSI = D_{central} - D_{surround}$$

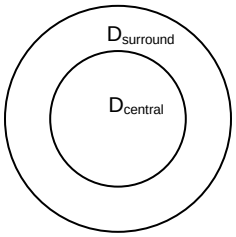


Figure 431
Sectors (CSI)

3. SAI

SAI (Surface Asymmetry Index) - difference in corneal powers at every ring (except for 180º) over the entire cornea surface.

4. K1

K1 (Keratometry K1) – average maximum radius in 3 mm zone.

5. K2

K2 (Keratometry K2) – average minimum radius in 3 mm zone.

6. IAI

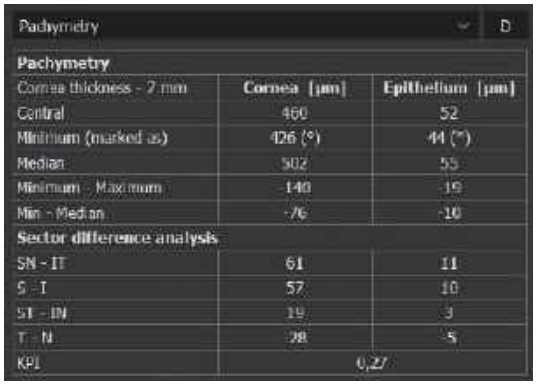
IAI (Irregular Astigmatism Index) – experimentally selected value based on examinations from a test database, within the normal range for healthy eyes.

7. AA

AA (Analyzed Area) – analyzed area of the examined cornea.

21.4.6. Pachymetry

The table displays a summary of pachymetry data. Calculation bases on **Pachymetry** and **Epithelium** maps.



Pachymetry		
Cornea thickness - 7 mm	Cornea [µm]	Epithelium [µm]
Central	460	52
Minimum (marked as)	426 (°)	44 (°)
Median	502	55
Minimum - Maximum	-140	-19
Min - Median	-76	-10
Sector difference analysis		
SN - IT	61	11
S - I	57	10
ST - IN	19	3
T - N	28	5
KPI	0,27	

Figure 432.
Pachymetry table

21.4.6.1. Definitions of pachymetry parameters

CENTRAL THICKNESS

The corneal/epithelial thickness at the central point of the Pachymetry / Epithelium Grid; displayed in micrometers [µm].

MINIMUM

Minimum corneal / epithelial thickness within the area; displayed in micrometers [µm].

MEDIAN

Median thickness; displayed in micrometers [µm].

MINIMUM – MAXIMUM

The difference between the minimum and median corneal / epithelial thicknesses within the area; displayed in micrometers [µm].

MIN – MEDIAN

The difference between the minimum and median corneal / epithelial thicknesses within the area; displayed in micrometers [µm].

21.4.6.2. Definitions of sector difference analysis parameters

SN – IT

The difference between the average thickness in the Superior-Nasal and Inferior-Temporal parts of the grid.

S – I

The difference between the average thickness in the Superior and Inferior parts of the grid.

ST – IN

The difference between the average thickness in the Superior-Temporal and Inferior-Nasal parts of the grid.

T – N

The difference between the average thickness in the Temporal and Nasal parts of the grid.

21.5. Map Types

The formula for converting the geometrical radius [mm] values into optical power values in Diopters [D]. Diopter: D = [(Ref index-1) *1000] / Rmm.

AXIAL MAPS

Axial Power map is a curvature radius map that defines the center of curvature on the measurement axis. It is converted to refractive power using the refractive index for conversion based on a paraxial calculation. This map represents the sphericity of the entire cornea, which can be a useful indication of the refractive power of the cornea and the corneal shape. The spherical cornea without astigmatism is displayed in one color in this map, which makes it easy to identify the normal cornea.

The picture below describes this solution graphically. Unlike the tangential radius, the axial map always ends at the optical axis, and therefore the surface of the cornea should be considered as one lens with a different radius at each point. The alternative name of the sagittal map is axial map.

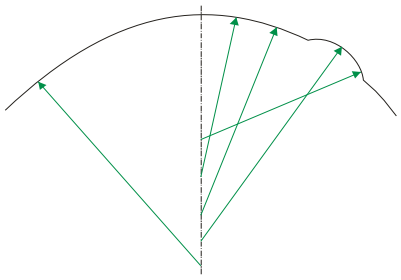


Figure 433.
Axial Power Map

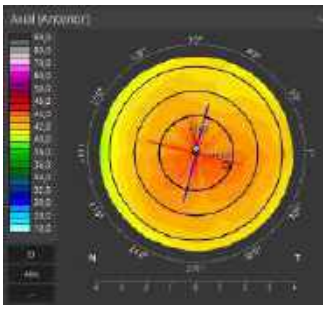


Figure 434.
Axial Power Map of the Anterior Surface

1. **AXIAL [ANTERIOR]**

   An axial power map of the anterior surface. Refractive index: 1.3375.

2. **AXIAL [POSTERIOR]**

   An axial power map of the posterior surface. Refractive index: 1.376.

TANGENTIAL MAPS

Clearly defines small or “instantaneous” curvature changes. It calculates each measured point of data at a 90° “tangent” to its surface. Tangential maps provide a more detailed description of the corneal shape and provide a clearer view of the size and shape of the cone in a keratoconus patient, for instance. The ability to measure the size of the cone is very helpful in determining the ideal lens design and optic zone size. Additionally, tangential maps define the position of the treatment or effect of corneal reshaping and refractive surgery.

The tangential map is calculated based on a digitally recognized ring pattern reflected from the surface of the cornea. It calculates the local curvature radius, which provides very accurate information about the shape of the cornea. In the case of spherical surface, all radii end at the optical axis at the same point. If the surface has defects, then the radii can end at any point and not on the axis.

From this point the cornea should be treated as an infinite set of small spherical lenses, in which each of them has a different radius length and origin.

The picture below shows the calculation of the tangential map graphically.

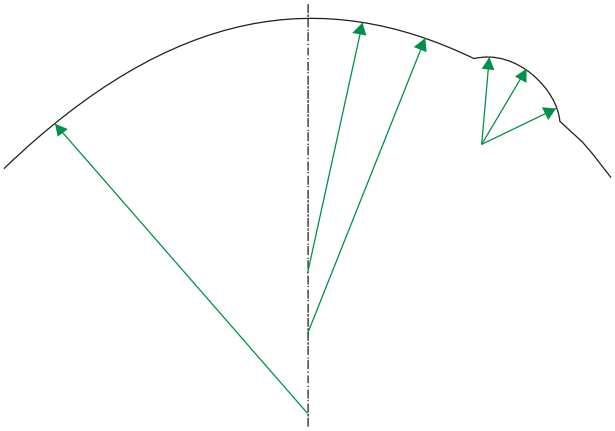


Figure 435.
Tangential Power Map of the Anterior Surface

1. **TANGENTIAL MAP [ANTERIOR]**

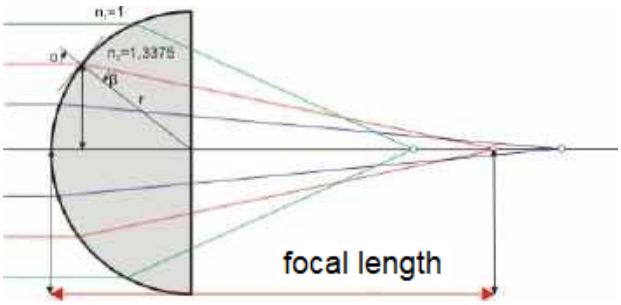
   A tangential power map of the anterior surface. Refractive index: 1.3375.

2. **TANGENTIAL MAP [POSTERIOR]**

   A tangential power map of the posterior surface. Refractive index: 1.376.

REFRACTIVE POWER MAP [KERATO]

Calculates the focal length from Snell's law and the corneal refractive power. This map uses only values from the anterior surface, but it also takes refractive effect into account. It calculates corneal power according to Snell's law of refraction, assuming a refractive index of 1.3375 to convert curvature into refractive power.



1. **REFRACTIVE POWER MAP [ANTERIOR]**

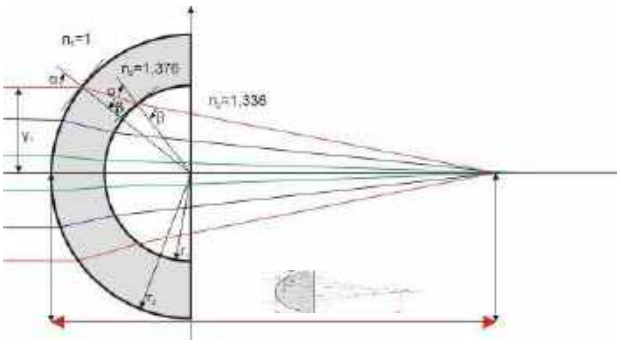
   Refractive index of the cornea: 1.376. Calculated based on Snell's law.

2. **REFRACTIVE POWER MAP [POSTERIOR]**

   Is calculated as difference between the refraction equivalent power map and the refraction power anterior. Refractive index of the cornea: 1.376.

REFRACTIVE POWER MAP [TOTAL]

This map uses ray tracing to calculate the refractive power of the cornea and the lens thickness formula. It considers how parallel light beams are refracted according to the relevant refractive indices (1.0, 1.376 and 1.336), the exact location of refraction and the slope of the surfaces. The location of refraction is a determinant of the surface slope, since the anterior and posterior surfaces have slightly different principal planes due to corneal thickness. In this way, the map takes the refractive effect, inclusion anterior / posterior surface, and the location of the principal planes, into account. Its results are more realistic than any other, but they will deviate from normal Simulated K values so they cannot be used in conventional IOL formulas.



NET MAP

This map shows the optical power of the cornea based on two different refractive indices, one for the anterior n=1.376 and for the posterior surface aqueous humor: 1.336, as well as the sagittal curvature of each. These results are aggregated.

The equation used:

Net power = $[(1.376-1)/R_{Ant}] *1000+[(1.336-1.376)/R_{Pst}]*1000$

AXIAL TRUE NET

A total power map of the anterior and posterior surfaces is calculated by the lens thickness formula. It is calculated by adding the corneal thickness correction to the sum of the refractive powers of the anterior and posterior surfaces. It considers how parallel light beams are refracted according to the relevant refractive indexes 1.0, 1.376 and 1.336.

The equation used:

$k_A=[(1.376-1)/R_{Ant}]$ $k_P=[(1.336-1.376)/R_{Pst}]$

CTP- Corneal Thickness at the Point

$K = k_A + k_P –[(CTP/1.376) * k_A *k_P$

EQUIVALENT KERATOMETER

This map was designed to consider the refractive effects of both the anterior and the posterior surfaces. The map considers how parallel light beams are refracted according to the relevant refractive indexes 1.0, 1.3375 and 1.336. The equivalent keratometer map considers refractive effect, inclusion anterior / posterior surface, and the corneal refractive index. The map calculates power according to Snell`s law using the refractive indices of the corneal tissue and aqueous humor and aggregating the values for anterior and posterior power. In this way, it provides equivalent K-values that can be used in IOL formulas that correct for n=1.3375.

ELEVATION MAP

Indicates the difference obtained by subtracting the height of the reference sphere (Best Fit Sphere) from the height of the cornea in a 6 mm radius with the least square method.

Positive Value:	The measurement point of the cornea is above the reference sphere.
Negative Value:	The measurement point of the cornea is below the reference sphere.

1. **ELEVATION MAP [ANTERIOR]**

   Difference maps between the best-fit sphere in the anterior layer and this layer.

2. **ELEVATION MAP [POSTERIOR]**

   Difference maps between the best-fit sphere in the posterior layer and this layer.

HEIGHT MAP

Is a difference from the tangent surface to the highest point of the cornea.

PACHYMETRY MAP

Displays the corneal thickness with a vertical direction to the anterior surface of the cornea. It allows visual capturing of the thin part of the cornea, providing extremely useful information for refractive surgery.

EPITHELIUM MAP

Shows the corneal epithelium thickness map for examination. It provides information for refractive LASIK and Keratoconus patients.

21.6. Color Scale (Standards)

SWITCHING THE SCALE

To change the color scale, click one of the scale descriptions in the bottom corner of the map. The scale settings window appears. The user can change the scale type, step, and units. Only the steps available for the chosen scale will appear. The system remembers maps chosen for each view position. After closing the examination, the settings are saved and used for future examinations.

Scales, steps and units available for:

Axial [Anterior], Tangential [Anterior]

Available Scales	Steps	Units
O Scale	Absolute	D
		mm
	0.25 D	D
	0.05 mm	mm
	0.5 D	D
	0.1 mm	mm
	1 D	D
	0.25mm	mm
	Normalized	D
		mm
ISO	Absolute	D
		mm
	0.5 D	D
	0.1 mm	mm
	1 D	d
	0.2 mm	mm
	Normalized	D
		mm
	Absolute	D

American		mm
	0.25 D	D
	0.05 mm	mm
	0.5 D	D
	0.1 mm	mm
	1 D	D
	0.25 mm	mm
	Normalized	D
		mm
Atlas	Absolute	D
		mm
	Normalized	D
		mm
S-K USS (Smolek Klyce)	Absolute	D
		mm
	Normalized	D
		mm

Axial [Posterior], Refractive Power [Kerato], Tangential [Posterior]

Available Scales	Steps	Units
O Scale	Absolute	D
		mm
	0.25 D	D
	0.05 mm	mm
	0.5 D	D
	0.1 mm	mm
	1 D	D
	0.25 mm	mm
	Normalized	D
		mm
American	Absolute	D
		mm
	0.25 D	D
	0.05 mm	mm
	0.5 D	D
	0.1 mm	mm
	1 D	D

	0.25 mm	mm
	Normalized	D
		mm
Atlas	Absolute	D
		mm
	Normalized	D
		mm
S-K USS (Smolek Klyce)	Absolute	D
		mm
	Normalized	D
		mm

Refractive Power [Anterior], Refractive Power [Posterior], Refractive Power [Total], Net Map, Axial True Net, Equivalent Keratometer

Available Scales	Steps	Units
O Scale	Absolute	D
	0.25 D	D
	0.5 D	D
	1 D	D
	Normalized	D
American	Absolute	D
	0.25 D	D
	0.5 D	d
	1 D	D
	Normalized	D
Atlas	Absolute	D
	Normalized	D
S-K USS (Smolek Klyce)	Absolute	D
	Normalized	D

Elevation [Anterior], Elevation [Posterior]

Available Scales	Steps	Units
O Scale	Absolute	µm
	25 µm	µm
	10 µm	µm
	2.5 µm	µm
	Normalized	µm

Height Map

Available Scales	Steps	Units
O Scale	Absolute	µm
	Normalized	µm

Pachymetry Map

Available Scales	Steps	Units
O Scale	Absolute	µm
	5 µm	µm
	10 µm	µm
	20 µm	µm
American	Absolute	µm
	5 µm	µm
	10 µm	µm
	20 µm	µm
RevoScale	Absolute	µm
	5 µm	µm
	10 µm	µm
	20 µm	µm

Epithelium Map

Available Scales	Steps	Units
O Scale	Absolute	µm
RevoScale	Absolute	µm

22.
Calibration Test

To ensure system stability over time, before the first examination, the topography module automatically prompts the user to perform a daily validation test. The validation test is performed with the REVO calibration tool. The result of the validation test is compared with the stored value obtained during the initial calibration to verify system stability. The limit of acceptable difference is ±0.15 D; if this is exceeded, the software will not allow the acquisition of topography scans. A warning message with instructions for further action is displayed on the screen.

22.1. Entering Biometry Calibration Parameters

Before starting calibration, it is necessary to enter the calibration parameters provided with the REVO calibration tool. To do that go to SETUP / Preferences / Device Setup / Parameters.

Figure 436.
Entering Biometry Calibration Parameters

Enter the parameters provided with the calibration tool (Length AL and Length ACD) in their respective fields in the calibration parameters section. To perform a common calibration for both the Biometry and Topography module, select the **Common Biometry and Topography calibration** checkbox. If the checkbox is not selected, the system will perform two separate calibration tests, each for the individual module. To learn more about common calibration, go to Chapter 22.3.4 Common Calibration.

22.2. Calibration Procedure Preparation

Before the calibration, the REVO calibration tool must be installed.

Figure 437.
REVO Calibration Tool

Take the tool out of the box and open as it is shown on the following images.

Figure 438.
Opening the REVO Calibration Tool

Put the opened REVO calibration tool on the forehead frame as shown on the image below. Mount the upper hooks first, then push the lower hooks on to the frame. Make sure there is no free space between the frame and the hooks of the REVO calibration tool.

Figure 439.
Mounting the REVO Calibration Tool

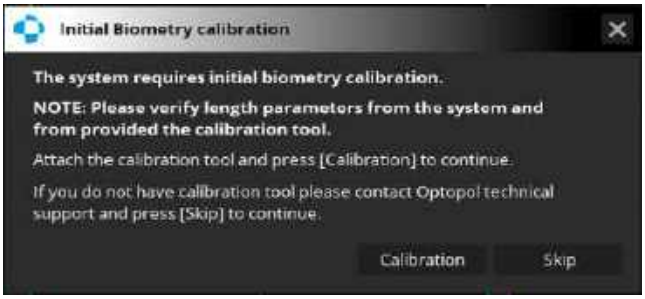
NOTE: Make sure the REVO calibration tool is well fitted to the frame.

22.3. Axial Length (Biometry) Calibration

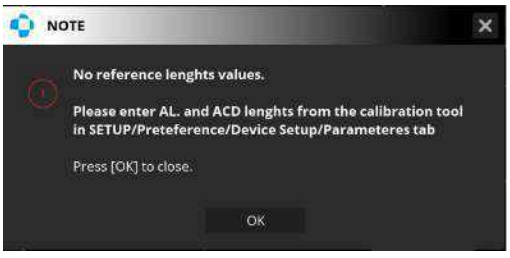
Performing calibration of the biometry module is necessary to check the precision of measurements. It is not possible to perform biometry scans without first performing calibration once per day.

22.3.1. Biometry Calibration with the IOL Calculation Tab Inactivated

Once the biometry module is opened for the first time, the system prompts the user to perform the initial calibration. A year after the initial calibration the user will be prompted every day to perform calibration.



To skip calibration, click **[SKIP]**. The calibration prompt will be displayed on the next day. To start calibration, click **[CALIBRATION]**. If the calibration parameters provided with the REVO calibration tool have not been entered, the system prompts the user to do this, as shown below.



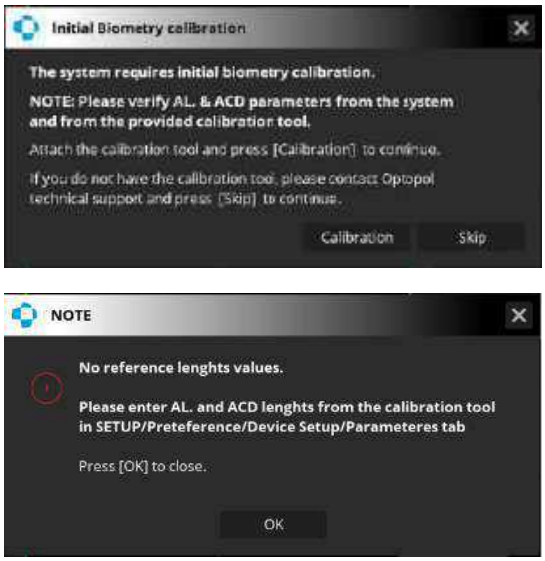
To close the window, click **[OK]**.

When the calibration process starts, the system displays the calibration procedure window.

22.3.2. Biometry Calibration with the IOL Calculation Tab Activated

The user is prompted daily to perform calibration at the first attempt to take a biometry measurement. Carrying out biometry exams is not possible if the calibration of the biometry module fails. If the user skips calibration, it is still possible to perform exams, but the IOL Calculation tab will not be available

for exams performed after skipping calibration. The tab is available only for exams carried out on the day of calibration (after calibration).



If the calibration parameters provided with the calibration tool have not been entered, the system prompts the user to do that, as shown below. Entering biometry calibration parameters is described in Chapter 22.1 Entering Biometry Calibration Parameters.

22.3.3. Calibration Process

The calibration process can be started from within the biometry or topography acquire window by choosing **[SETTINGS]** and clicking **[START CALIBRATION]**. The calibration procedure starts with the window presenting calibration details and the calibration tool test parameters, as shown below.

Figure 440.
Calibration Procedure Window

The user is asked to install the calibration tool (the installation procedure is described in Chapter 22.2 Calibration Procedure Preparation) and to verify the correctness of the tool parameters with the values provided displayed in the window. If the values are correct, the user can start calibration by clicking the **[TEST]** button. To cancel calibration and close the window click **[CANCEL]**.

Once the calibration begins, information in the window shows the progress of the process.

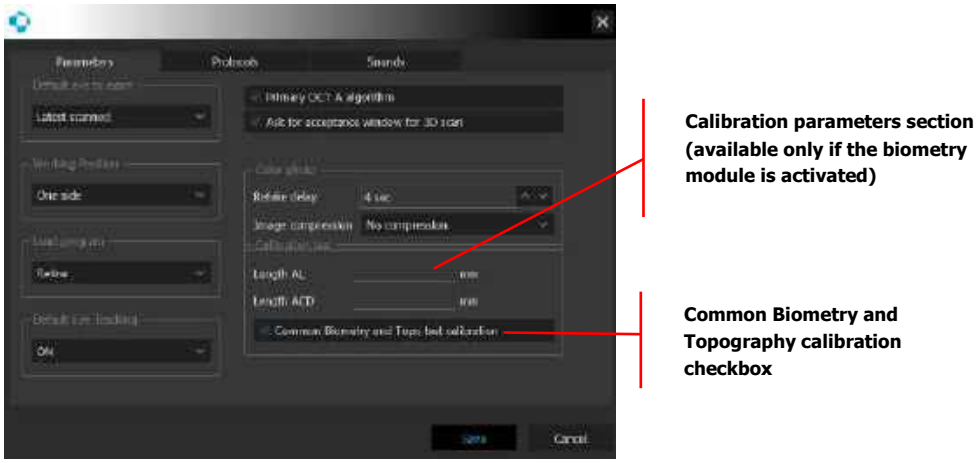
Figure 441.
Calibration Procedure in Progress

A successful calibration is indicated by a **Calibration successful** message inside the window. From now on, every examination performed on the day of the calibration can be used for IOL calculations.

If calibration fails, performing biometry examinations is not possible.

22.3.4. Common Calibration

Common calibration allows the user to perform biometry, topography and WTW calibration all at one time. To enable common calibration, go to SETUP / Preferences / Device Setup / Parameters and select the **Common Biometry and Topography calibration** checkbox as shown below. If the checkbox is not selected, the common calibration function is off.



With common calibration enabled in the Preferences tab, each time a calibration is required, the system displays the common calibration window presented below.

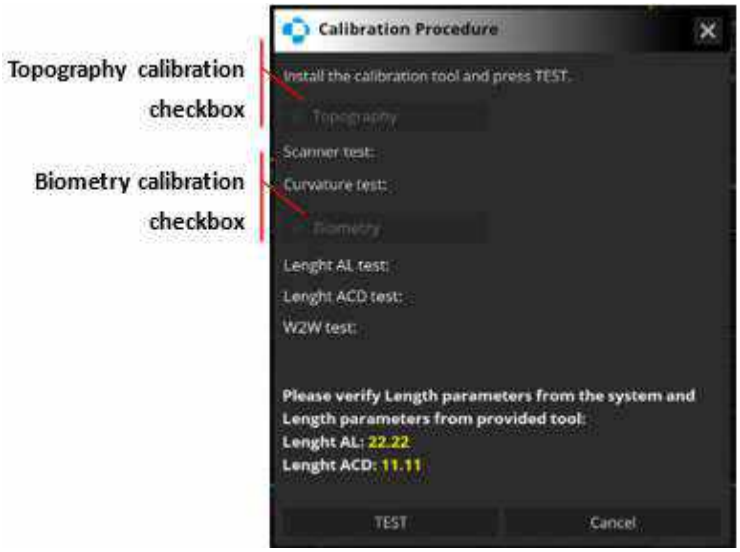
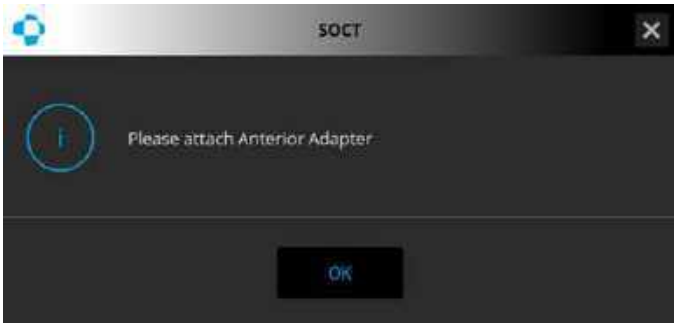


Figure 442.
Common Calibration Window

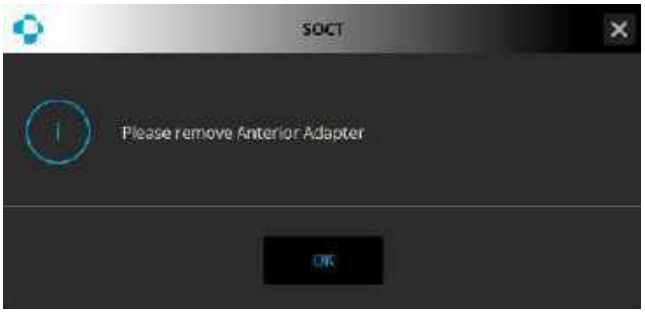
To calibrate the topography and biometry modules simultaneously, make sure that their respective checkboxes are selected. To exclude either of the modules from calibration, deselect its checkbox. The system will then perform calibration of the module that remains selected.

The window presents the calibration tool parameters. The user is asked to install the calibration tool and verify the correctness of the tool parameters with the values provided displayed in the window. If the values are correct, the user can start calibration by clicking the **[TEST]** button. To cancel calibration and close the window click **[CANCEL]**.

For devices with serial numbers starting with 155xxxx and 156xxxx if the Topography checkbox is selected, after clicking the **[TEST]** button, the user is prompted to attach the Anterior Adapter.



Once the adapter has been installed click [OK] to start calibration. To cancel the process and close the window click [x]. When Topography calibration is over the user is prompted to remove the Anterior Adapter and continue with WTW and Biometry calibration



Once the adapter has been removed click [OK] to continue. To cancel the process and close the window click **[X]**.

Follow the progress of the calibration in the common calibration window. To stop the process at any time, click **[CANCEL]**.

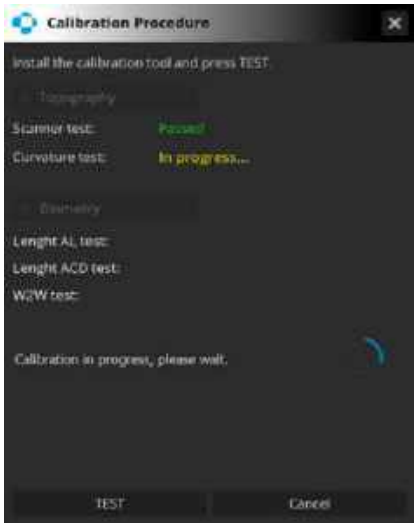


Figure 443.
Common Calibration in Progress

Figure 444.
Common Calibration Results Window

A successful calibration is indicated by a **Calibration successful** message inside the window. From now on, every examination performed on the day of the calibration can be used for IOL calculations.

If calibration of any of the modules fails, performing examinations with the module is not possible

22.4. Topography Calibration

22.4.1. Initial Topography Calibration Procedure

If the following information pops up, the device needs to go through the initial calibration procedure.

NOTE: The system requires initial calibration.

Attach the calibration tool and press **[OK]** to continue.

If you do not have the calibration tool, please contact OPTOPOL technical support.

1. **[TEST]**

   Starts the calibration process.

2. **[SKIP]**

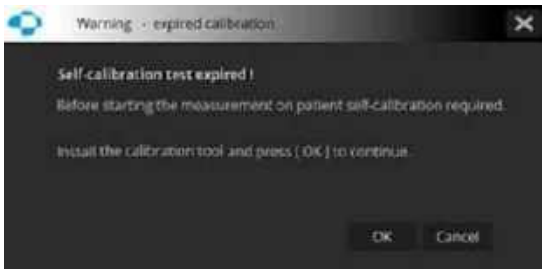
   Skips the calibration and closes the information window.

If the device has gone through the initial calibration successfully, the system starts to display the information for standard calibration.

NOTE: The initial calibration usually takes longer to complete. If the calibration ends in failure, verify if: the tool is properly installed, the testing surface inside the calibration tool is free from pollution, no strong light is reflected from the testing surface.

22.4.2. Standard Calibration

When the calibration is not required, after selecting the topography examination, no information is displayed. When the calibration is required, the system displays the following information:



1. **[OK]**

   Starts the calibration process.

2. **[CANCEL]**

   Skips the calibration and closes the information window.

Instead of standard calibration, the user can choose to perform common calibration of biometry, topography and WTW all at once. The common calibration procedure is described in Chapter 22.3.4 Common Calibration.

Before the examination the system checks when the device was calibrated for the last time and display the following information:

“Last calibration X days ago. Before starting a measurement on a patient, self-calibration is recommended. Press OK to continue”.

1. **[SKIP]**

   Goes to the acquire window.

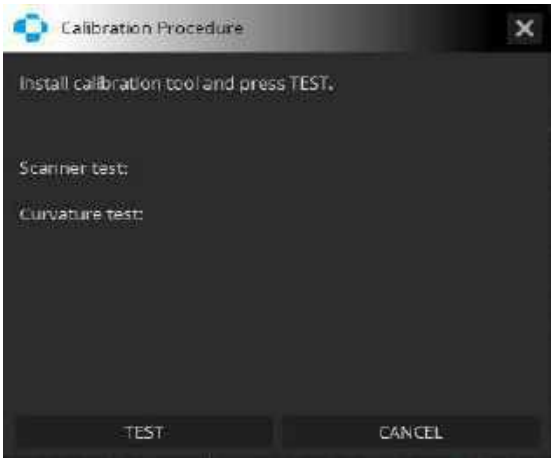
2. **[OK]**

   Starts the calibration process.

22.4.3. Calibration Process

At the start of the calibration process, the user will be asked to:

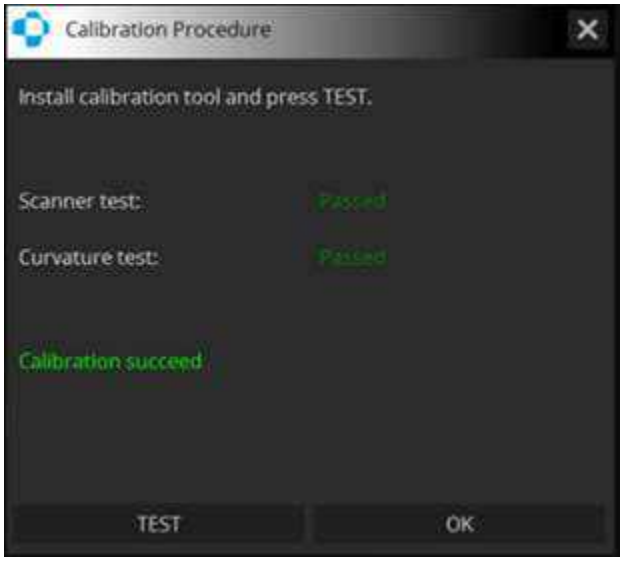
“Install the calibration tool on the chinrest and press Test.”



1. **[TEST]**

   Starts an automatic calibration process.

After calibration, the system displays a calibration summary:



If the system passes calibration, the following message is displayed in the calibration window:

“Calibration succeed”.

If the system fails calibration, the following message is displayed in the calibration window:

“NOTE: Topography analysis will be DISABLED due to the failure of the validation test. Please re-run the test. If failure persists, please contact the Service support.”

1. **[CANCEL]**

   Close the window.

2. **[TEST]**

   Repeat calibration.

If the device does not pass the software calibration, it is impossible to test and analyze in the topography mode.

If both the topography and biometry modules have been activated in the system, the user can calibrate them both at once. This procedure is described Chapter 22.3.4 Common Calibration.

23.
Settings and Setup Window

The REVO SOCT software setup window is used to set various parameters of the software. To enter the setup window, from the SOCT login screen, enter the admin username and password and select the **[SETUP]** button. When using the software for the first-time, a new user should be created in **[USERS]** tab.

Figure 445.
Entering the Device Settings Tab

23.1. General

This tab allows the user to enter clinic details, change language or software skin layout.

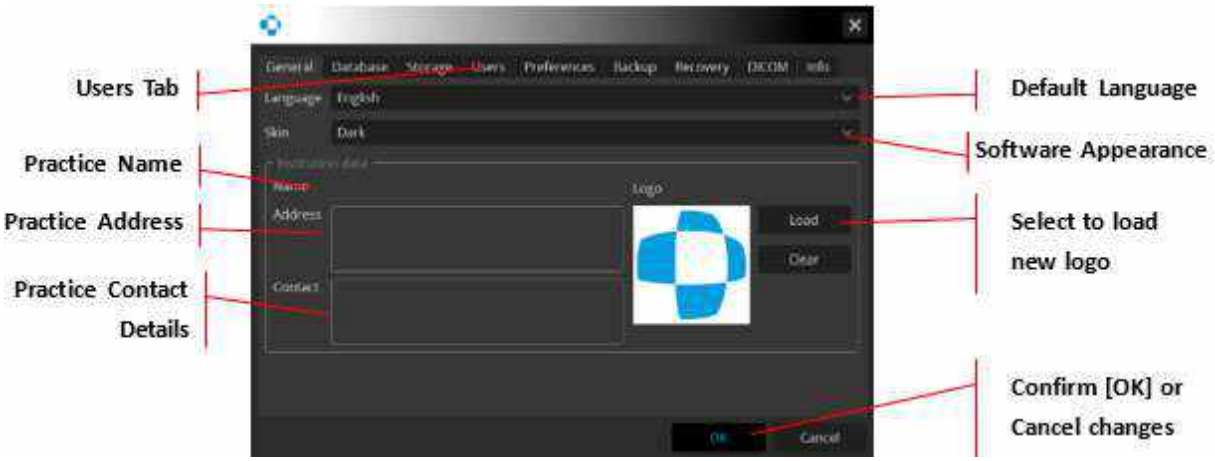


Figure 446.
General Setup Window

In this tab, the user can select the desired language, select application skin (layout) and type, practice details and add the practice logo. Practice details and logo will be visible on the printout header.

23.2. Database

Select **[DATABASE]** tab to be able to access all the tools needed to handle the database and set networking parameters. There is a path to the folder containing database tables. It can be typed manually or selected using the **[SELECT]** button. The connection with remote database can be tested. The storage of examination data is described below.

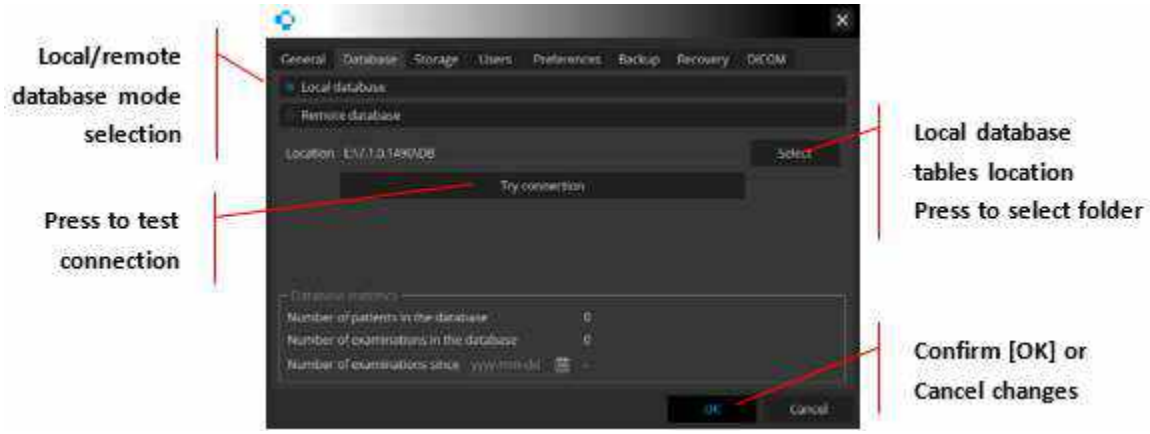


Figure 447.
Database Tab

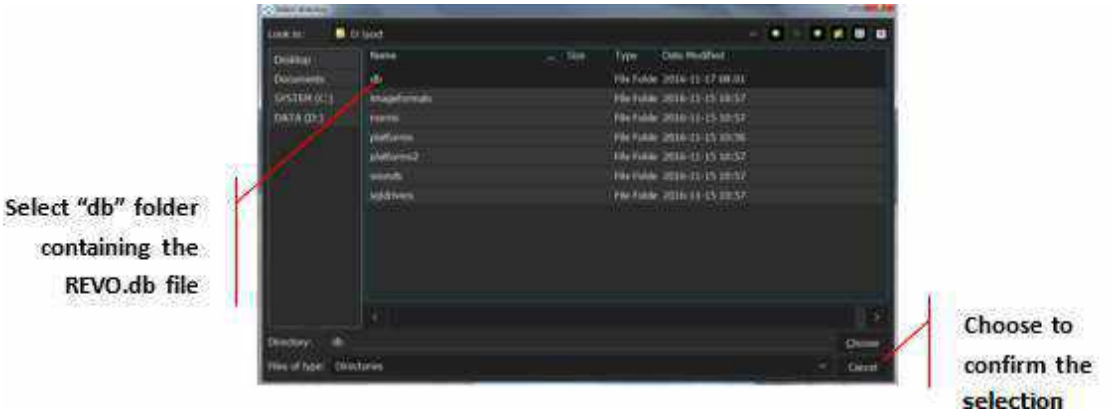


Figure 448.
Selecting Database Table Location

Information appears in case “db” folder is not present in indicated directory. Make sure to select the correct folder. Do not mark the SOCT folder location only.

Figure 449.
Example of Connection Error

This message appears in case of a wrong path indication or a mistake in the folder name.

Figure 450.
Lack of Directory Error

Confirmation of proper connection with database tables file.

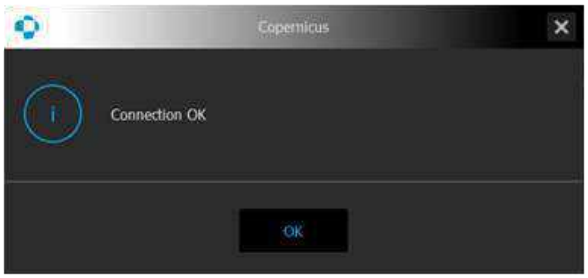


Figure 451.
Confirmation of Proper Connection

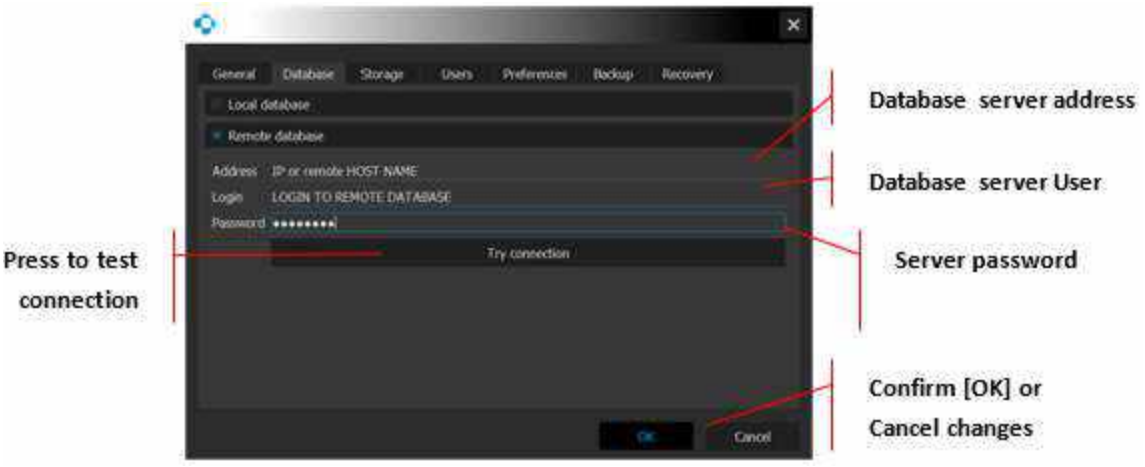


Figure 452.
Remote Server Connection Settings

LOCAL DATABASE

This mode should be selected if the database tables file is located on the PC connected to the REVO device. Storage of examination data can be in a different location (HDD or network location folder).

REMOTE DATABASE

Mode used when connecting viewing stations to the external database (server application that is storing data on a server, e.g., MySQL). There is no limit in the number of users connected to a remote database. In that case, all software applications as well as the REVO SOCT PC should have the same settings of the host and the same login to the server application.

It is obligatory to enter **login** and **password** of the database server software operating as the host and being connected to. For more details see Chapter 25.1.1 REVO SOCT Network.

The viewing station PC should have access to storage locations containing examination data (all folders should be shared and visible to all users).

23.3. Storage

REVO SOCT software allows the user to locate the database in various combined folders. It is possible to add more space for data storage if required and simply indicate the additional folder.

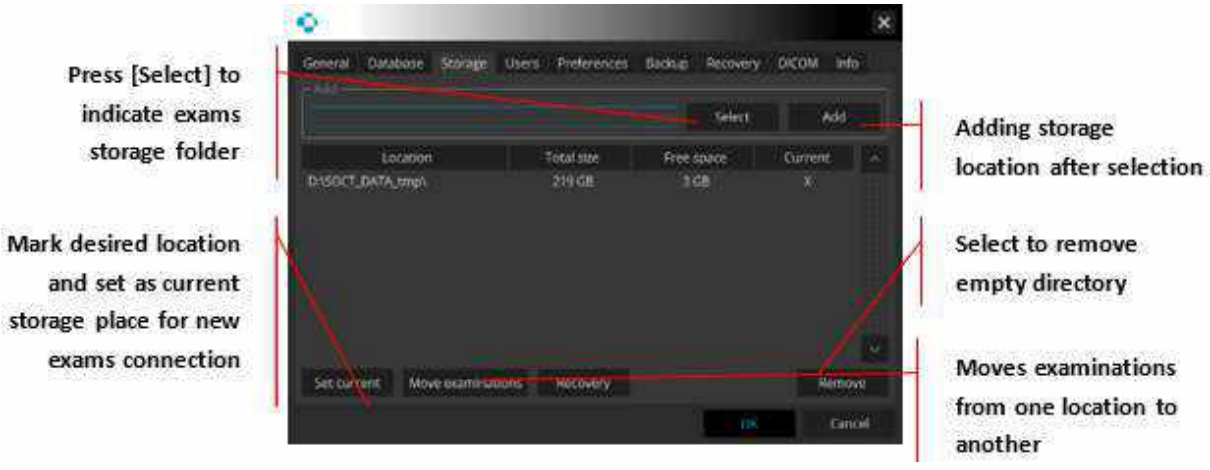


Figure 453.
Storage Administration Tab

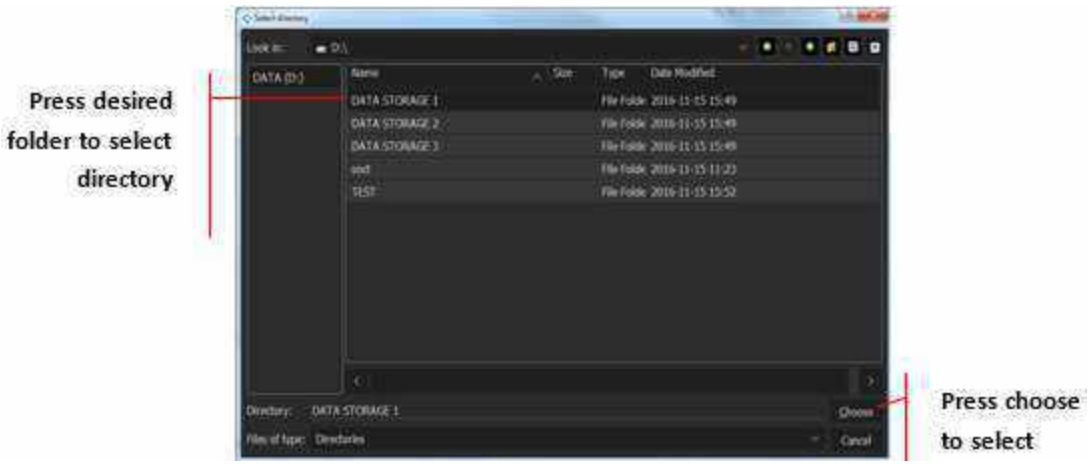


Figure 454.
Selection of an Additional Storage Folder

REVO SOCT software will display all examinations from indicated folders. Folders marked as “Current” will become storage for new examinations taken by the device.

1. **[MOVE EXAMINATIONS]**

   Allows a user to move examinations from one location to another. Allows a user to move latest examinations from the main HDD to another location and maintain high performance of the system. Click to open a new window and select the destination folder to move examinations.

2. **[RECOVER]**

   This allows the user to connect the examinations from the existing folder (.opt files) to the current database. Use **[ADD]** storage function to add a new location to the existing database.

NOTE: [RECOVER] function does not copy data from the recovered location! Do not remove the folder after recovery.

In cases in which the viewing station connections storage locations should be shared in the network, review the details in Chapter 25 Network Configuration

23.4. User Accounts

It is possible to have different operators log in into the system. This tab allows users to manage all REVO SOCT software users. Here user accounts can be added, removed, or edited. It is mandatory to create at least one user to use the software. The first user should have admin rights.

In the **[AUTO-LOGOFF TIME]** field, the user can select the time of inactivity after which they will be automatically logged off to prevent unauthorized access to the software. For example, setting of 30 minutes will mean that if the software is not being used for 30 minutes, it will automatically log the user out.

WARNING: Do not forget user LOGIN and PASSWORD is the only way to open the software and enter this information. In case of problems, please contact your local OPTOPOL distributor.

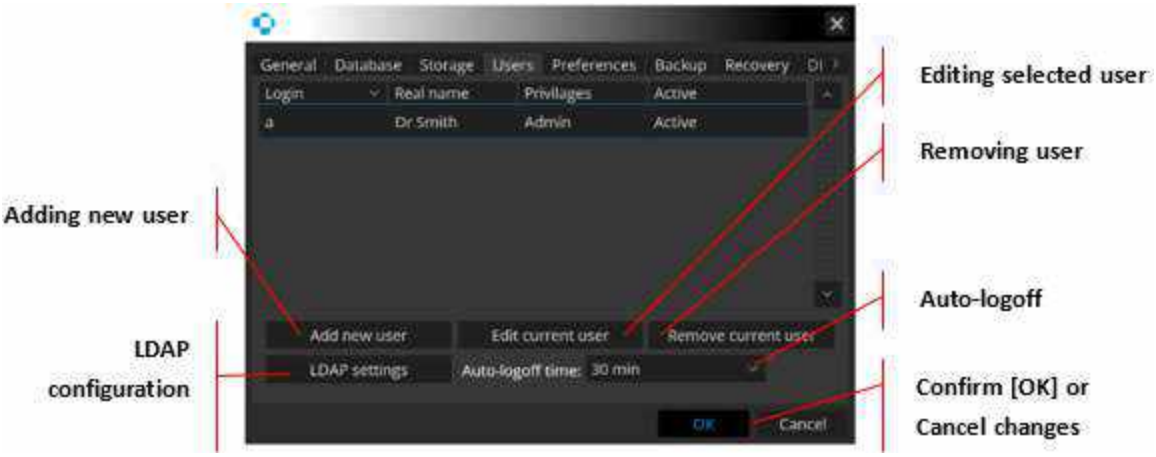


Figure 455.
Users Tab

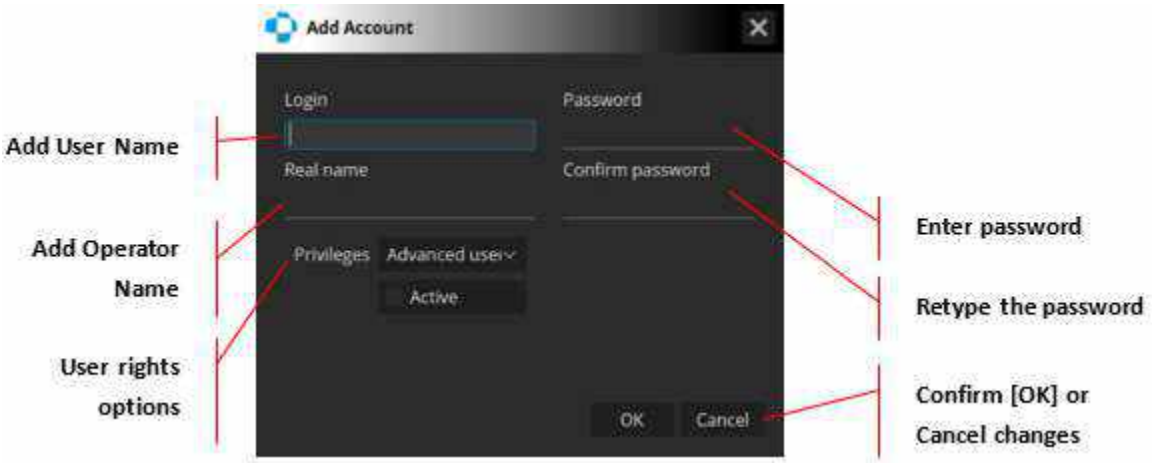


Figure 456.
Users Tab (Creating a New User)

23.4.1. Creating User Accounts

To create a new user account, press “add new user” and the window **[ADD ACCOUNT]** will pop up. The required fields to successfully create a user are: Login, Password, Confirm Password, and Privileges. A real name is not necessary to proceed. When the password is being typed in, it will show as asterisks, therefore ensure that the password is entered correctly. The privileges drop-down list allows the practice to set user rights. It is then possible to search for patient records by association with users. The REVO software automatically and permanently associates saved scans with the current user when saving. Each operator can have their own default scan parameters and printouts styles.

1. **ADMIN**

   Entitles the user to perform, review and analyze all results. Also, this user can remove and / or edit patient data. It also allows the creation of additional modified user accounts and management of the application global setup.

2. **ADVANCED USER**

   Entitles the user to perform, review and analyze all results with the option to export and import examinations.

3. **OPERATOR**

   Entitles the user to perform, review and analyze all results with the option to export examinations. This user is unable to enter application setup, delete patients, move patient exams, modify patient data, and import images, as well as patient examinations.

The last field is a checkbox **[ACTIVE]** which, if left unchecked, will disallow the user to login. This is useful to disable specific user accounts for any reason.

23.4.2. LDAP Settings

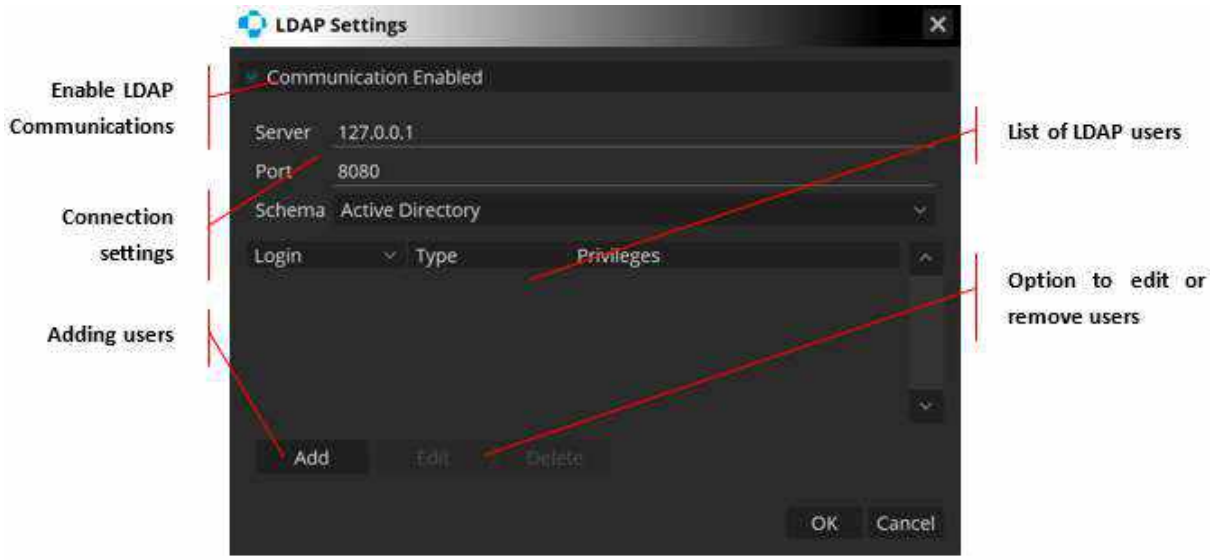


Figure 457.
LDAP Settings

A common use of LDAP (Lightweight Directory Access Protocol) is to provide a central account management to store usernames and passwords. This allows many different applications and services to connect. It allows the server owner to directly control all users, require periodic password updates, lock or close accounts that are unused, or to set a password difficulty requirement.

1. **[SERVER]**

   Correctly configured host server address / domain.

2. **[PORT]**

   Host server port.

3. **[SCHEMA]**

   Protocol to be used with a choice of active directory, Apache directory or custom.

To correctly setup the LDAP, a server address with a port must be entered. Logins and passwords must already be entered within the server for the application to fetch any users. The **[SCHEMA]** field allows the user to select the query / response protocol to be used by the software. Users will only be allowed to log in if their account exists on the host server.

23.5. Preferences

The preferences tab allows the user to customize the device and software settings.

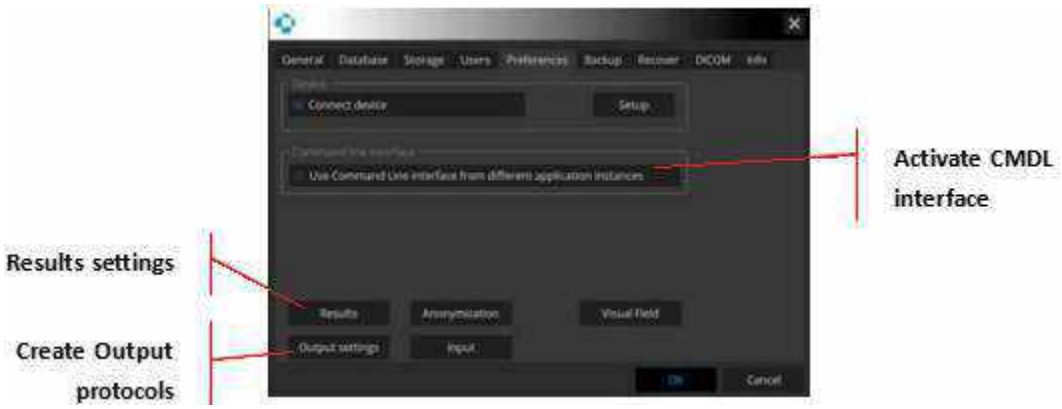


Figure 458.
Preferences Tab

23.5.1. CMDL Interface

This application was designed as an independent system to operate the device and to manage examination and patient data.

Use the Command Line Interface for different instances and activate CMDL communication. This features data exchange interfaces with external applications and the EMR systems.

When the CMDL checkbox system creates the Output Set – 'Export to EMR'. The 'Export to EMR' protocol can be customized, but the name cannot be changed. Find more details regarding how to customize this protocol in Chapter 23.7.1 Output Set Window. If the Export to EMR is selected for the patient without the Patient ID, the following warning is displayed:

Figure 459
Warning for a patient with no ID.

If [Yes] is selected, the application automatically assigns the Patient ID and generates the Export to EMR output. If [No] is selected, no Patient ID is assigned and no Export to EMR output is generated.

The application can be ordered to run various orders (tasks) by external EMR system. All tasks are queued in the "Worklist" when the application operates. The following tasks can be performed, based on data collected from the data exchange interface:

1. Adding patient to one day Worklist.
2. Registering patients in a local database.

3. Displaying the examination results belonging to a patient.
4. Preparing to acquire examination or protocols according to a received order from the EMR system.
5. Exporting output as report or tomogram file, to a predefined directory.

Receiving worklist is accepted from one active modality. Outputting interfaces are independent and can be used in parallel.

*Interface exchange protocol is available on request. The document allows your Electronic Medical Record provider to implement communication protocol. Please contact your local OPTOPOL Technology representative to receive the communication interface document.

23.5.2. Device Setup

When the device checkbox is marked, the **[SETUP]** button is available. Press to open the device configuration tabs.

23.5.2.1. Protocol Tab

This feature allows the user to create a preset combination of scans that can automatically be performed on a patient visit. To change the protocol settings, from the SOCT Software login screen, enter the username and password and press the **[SETUP]** button in the top right corner. Select the protocol tab in the setup window. In the protocol tab the user can create, edit, and delete a set of examinations. Up to 12 protocols can be registered. Up to seven scan programs can be registered in a single protocol set. Six protocols have been registered in the REVO SOCT software by default. These examination sets can be edited and deleted, but they cannot be returned to their default once they are edited or deleted.

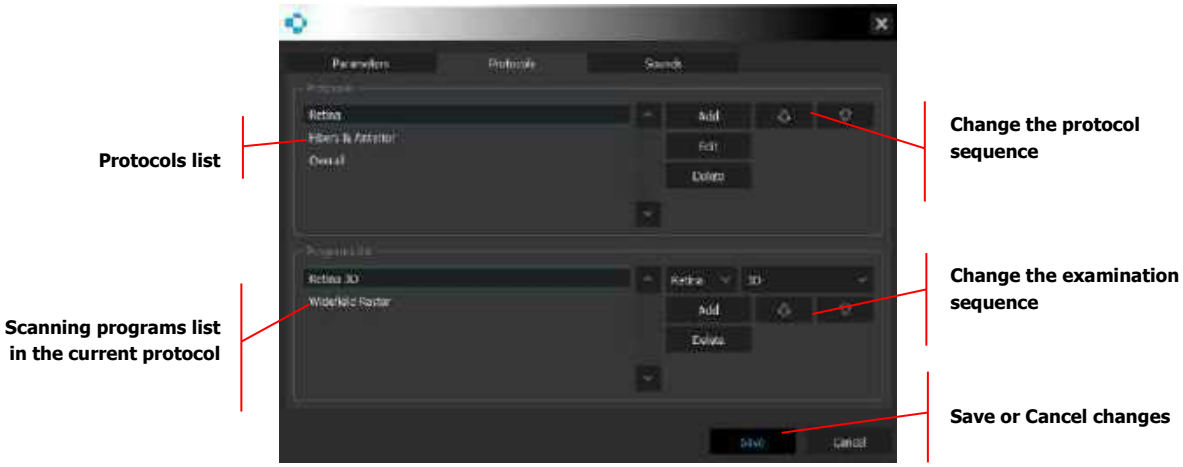


Figure 460.
Protocol Editor Tab

PROTOCOLS

1. **[ADD PROTOCOL]**

   Add a new protocol to the list.

2. **[EDIT PROTOCOL]**

   Allows editing of the existing protocol.

3. **[DELETE PROTOCOL]**

   Removes the protocol from the list.

4. **[UP AND DOWN ARROW]**

   Moves the position of selected protocol down or up on the list.

PROGRAMS LIST

Each protocol contains a set of scanning programs / exams. The operator can add or remove a scanning program on the list. It is possible to change the sequence of a scanning program.

1. **[ADD]**

   Add new exam for the selected protocol.

2. **[DELETE]**

   Remove the examination from the protocol.

3. **[SAVE]**

   Save changes in the protocol.

Exam setting parameters (scan width, number of A-scans, number of B-scans) are the same as settings as in the acquire window.

The user can add “Fundus Image” to the protocols.

23.5.2.2. Creating a New Protocol

1. Click **[ADD PROTOCOL]**, a new window appears, type the desired protocol name.
2. Input the name of the protocol and press **[OK]** to register the protocol.
3. Select the scan program from the program list box and then click **[ADD]**.
4. The selected scan program name appears on the program list.
5. To add another scan program, repeat the Step #3.

To change the display order of protocols or tomogram on the list, select the desired item and then click **[UP ARROW]** or **[DOWN ARROW]**.

NOTE: For the devices with serial numbers starting with 155xxxx and 156xxxx programs with Anterior Adapter are always on the bottom position of the Program list.

NOTE: When the operator acquires a tomogram using the protocol in Full-Auto mode, the system executes all programs from the protocol automatically.

23.5.2.3. Editing a Protocol

Use the protocol management screen to edit the protocol, add and delete a scan program, or change the order of the scan programs to be executed.

1. Select a protocol, then click **[EDIT]** to change the name.

2. On the program list, add a scan program by selecting the desired program from the list box and pressing the **[ADD]** button.
3. To delete the scan program from the protocol: select protocol, on the programs list, select the scan program to remove and click **[DELETE]**.
4. To delete the protocol, select the desired protocol from the protocol list and click **[DELETE PROTOCOL]**.
5. To change the display order of the protocols or scan programs, select the desired item on the list and then click **[UP ARROW]** or **[DOWN ARROW]**.

23.5.3. Parameters Tab

In order to change parameters, press the **[SETUP]** button in Preferences tab.

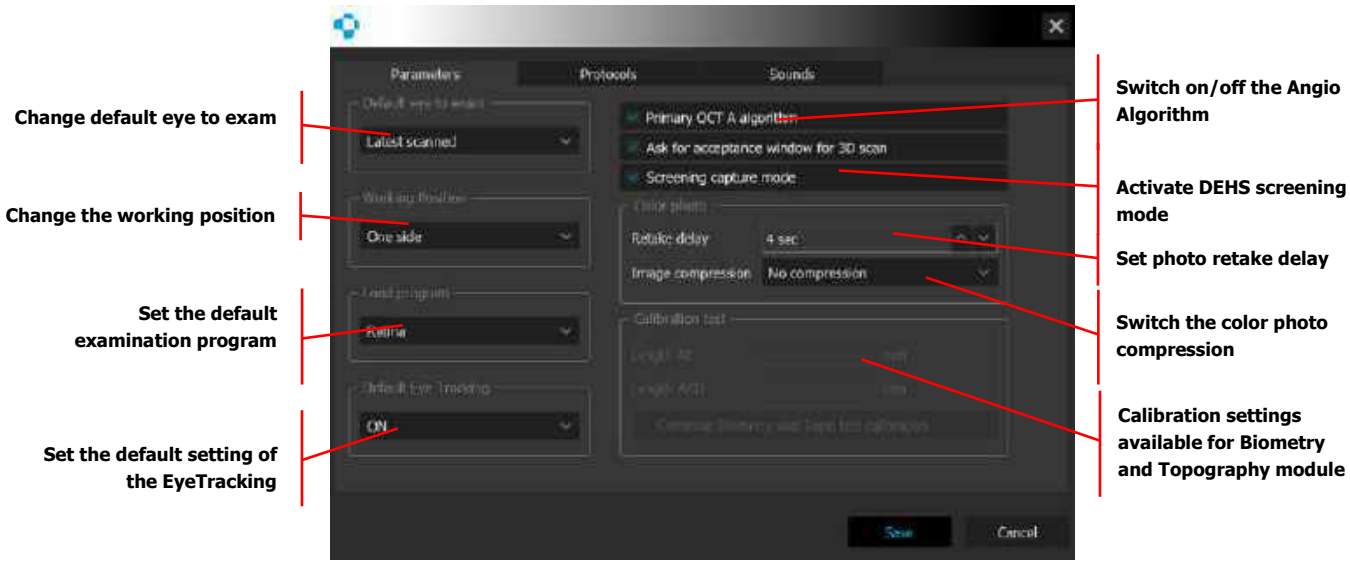


Figure 461.
Preference Tab

1. [DEFAULT EYE TO EXAM]

Set the initial position of the scanning head. The scanning head moves to the eye which will be examined for a new patient. When latest scan is selected, the unit does not move from the previous examination position.

2. [WORKING POSITION]

Change to Opposite if the patient and operator working positions are face to face. In this mode, direction Left / Right movement is changed.

3. [LOAD PROGRAM]

Allows the user to select the first loaded scan program when opening the acquire tab. When 'Protocol' is selected, the first protocol from the list is loaded.

4. [PRIMARY OCT ANGIOGRAPHY]

Allows the user to use an original when checked or enhances the Angio algorithms when unchecked.

5. **[SCREENING CAPTURE MODE]**

   Allows the user to use the DEHS screening. See Chapter 6.2.1 DEHS screening.[64]

6. **[CALIBRATION TEST]**

   In this field, the user enters the calibration parameters provided with the calibration tool and / or turns on / off the function of the common calibration of the biometry and topography modules.

For devices with serial numbers starting with 155xxxx and 156xxxx for Topography and Biometry module calibration, while using the new curvature target (TYPE: 155-4507) select it from the Topography Calibration Tool field by choosing the option “White”:

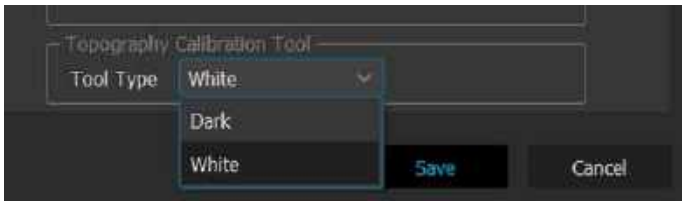


Figure 462.
Topography Calibration Tool field

For devices with serial numbers starting with 190xxxx, 191xxxx, 192xxxx, 193xxxx for Topography and Biometry module calibration, while using the new curvature target (TYPE: 155-4507) it is processed automatically but the new 11.5.3 software version (or higher) is required.

23.5.4. Voice Support Guide Tab

To change voice guidance settings, press the **[SETUP]** button in preferences tab. Voice guide is on by default in the **|ACQUIRE|** tab. The user can mute it or decide to turn it off in the **|SETUP|** tab.

The **[SOUNDS]** tab contains options enabling customization of voice guidance or disabling it.

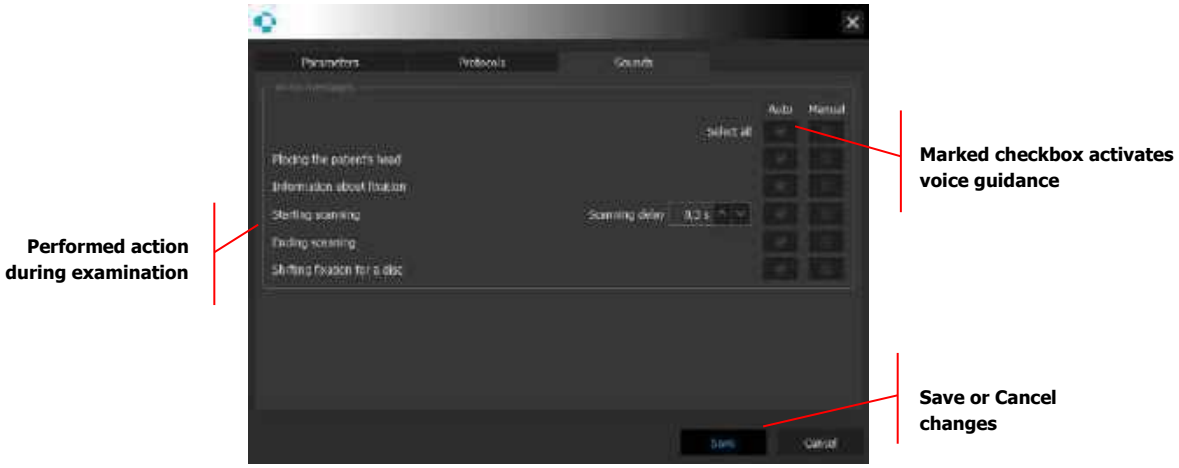


Figure 463.
Voice Support Guide Message Settings

The system uses synthesized sentences to assist the patient during the alignment and acquisition processes. The user can decide to customize the voice guidance sound when the device is working on

[64]Available only for the REVO OCT models with Fundus Camera.

fully auto mode (alignment with automatic data acquisition) or when the operator decides to press **[START]** to optimize the signal and acquire the examination by pressing the **[ACQUIRE]** button.

1. **AUTO**

   When 'Auto Acquire' function is checked.

2. **MANUAL**

   When 'Auto Acquire' in unchecked.

Uncheck field to disable playing voice guidance sound in situations described below. The system voice guide plays the following sentences:

Patient Head Positioning:	Sound "Please, place the head on the chinrest and blink freely" when acquire tab is open. The sound plays once per acquire session.
Patient Fixation:	Sound "Please look at the center of the green cross and blink freely." – when the operator presses the **[START]** button and the objective lens is moving closer to the front of the eye. The sound plays once for the selected eye.
Start of Scanning:	Sound "Please blink then keep your eyes open" plays before starting the acquisition of the examination.
Delay:	The time period counted from the end of playing the sound to the start of the acquisition of the examination. When it has a negative value, scanning starts before the end of the message.
Ending of Scanning:	"Thank you, you can blink freely" – when system finishes the acquiring the examination.
Shifting Fixation for a Disc:	Sound "Follow the green cross" – when system is changing the internal fixation target during the disc examination.

NOTE: The language of voice guidance can be changed in the acquire tab.

23.5.5. Results Settings

To change the setting of the results display, press the **[RESULTS]** button in the preferences tab.

Figure 464.
Results Review Settings Tabs

REVIEW TAB

1. **EYE IDENTIFIER**

   R/L or OS / OD can be selected to determine which eye is tested.

2. **MAP INTERPOLATION**

   This selects the method of how interpolated areas are presented on the maps. Semitransparent, dashed, regular or none can be selected.

3. **OUTPUT FUNDUS MASK**

   Allows the operator to enable or disable fundus mask display.

4. **COLOR BALANCE**

   Enables selection of the color balance used for Fundus Photos.

ANALYSIS TAB

1. **ALGORITHM TYPE**

   Sets one of the two segmentation algorithm types: *Precise* or *Fast*. *Precise* type requires a graphics processing unit and necessary CUDA files to run. *Fast* type uses central processing unit. If the computer has GPU, *Precise* is the default set and *Fast* is available to choose. If the computer has not GPU, *Fast* type is the default set and *Precise* is not available.

2. **NFL RING DIAMETER**

   Sets default ring diameter on NFL map to calculate NSTIN plot.

3. **NFL RING THICKNESS**

   Sets the default ring thickness on the NFL map to calculate the NSTIN plot.

4. CUP OFFSET

Defines the default value to calculate the cup and rim parameters.

5. USER IOL REFRACTION INDEX

Type of refraction index for the IOL lens being used. The parameters will be used calculate IOL lens thickness.

6. RETINA THICKNESS

Measured retina thickness definition. Select from the available retina thickness measurement definition.

7. SELECT THE NFL THICKNESS PROFILE GRAPH

TSNIT or NSTIN methods are available.

TOPOGRAPHY

1. KERATOMETRY

It sets the default topography summary table (SimK; Meridians; Semi meridians).

2. K PRESENTATION

It sets the default method of displaying values in the tables (K1 / K2 or K steep / K flat).

3. K DIAMETER

It defines the diameter values for SimK calculation (ø center of ring 2.5 mm +/- 0,5 mm thick ring or center ø3.0 thick ring mm).

4. SHOW SIGN OF ASTIGMATISM

Select **[Yes]** or **[No]** to decide which standard is used.

5. ASTIGMATISM AXIS

Select K flat / K1 or K steep / K2 to decide how the astigmatism axis is displayed.

23.5.6. Anonymization

To configure the anonymization, press **[ANONYMIZATION]** in the Setup / Preferences tab. Pressing **[ANONYMIZATION]** initiates the anonymization settings window where the user can adjust the settings for the anonymization of personal information when outputting data. The anonymization function can be set for personal data and the items to be anonymized while printing, exporting data, saving images or text files.

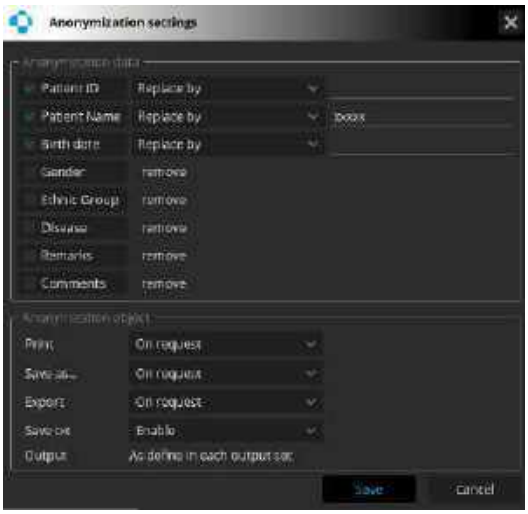


Figure 465.
Anonymization Settings Window

The anonymization settings window has two main fields: Anonymization data and Anonymization object.

The user can select which information will be anonymized and choose the method of anonymization.

Patient ID:	Replace by / Encrypt / Random
Patient Name:	Replace by / Encrypt / Random
Birth Date:	Replace by / Encrypt / Random
Gender:	Removed when checked.
Ethnic Group:	Removed when checked.
Disease:	Removed when checked.
Remarks:	Removed when checked.

ANONYMIZATION METHODS

1. **REPLACE BY**

   Replaces the information with a specified text string typed in the text field. The text field is active. The user can enter the text string in the field.

2. **ENCRYPT**

   Information is always coded in the same way (using only letters and numbers).

3. **RANDOM**

   Information is converted randomly (using only letters and numbers).

4. **REPLACE BY YYYY-00-00**

   The day and month of birth is changed to 00.

5. **REMOVE WHEN CHECKED**

   Information is removed.

The user can select anonymization action for Print, Save as…, Export, Save txt.

Print

1. Disable.
2. Enables data on the printout header to be anonymized as defined in anonymization data.
3. On Request: Displays a new position on the list box.

Anonymization affects Print and multi-B-scan print.

Save as…

1. Disable.
2. Enable.
3. On Request: Displays "save anonymized as…" in the RMB context menu below Export in all menus when export is available.

In this situation the system does not include personal information in the name of the file.

The system saves the item without the personal information of the selected patient.

Export

1. Disable.
2. Enable.
3. On Request Displays "Export anonymized" in the RMB context menu below “Export in all menus” when export is available.

Save as...

1. Disable.
2. Enable.
3. On Request: Displays "save anonymized as..." in the RMB context menu below “Export in all menus” when export is available.

In this situation the system does not include personal information in the name of the file. The system saves the item without information concerning the selected patient.

Text Files[65]

1. Disable
2. Enable

[65] Saving numerical data from the Topography Table and the Biometry Table.

OUTPUT

Each output can have the anonymization function enabled or disabled. By default, it is disabled (unchecked). The settings for the output are taken from the anonymization tab.

For example, if the output is set to printout – the system anonymizes the information and method according to the 'anonymization data' group.

For more details go to Chapter 23.7 Output Settings.

23.5.7. Visual Field

The configuration with the OPTOPOL PTS perimeter database is done by pressing **[VISUAL FIELD]** in the Setup\Preferences tab.

The system displays the Visual Field window where the user adjusts the settings necessary for the configuration of the data transfer between the OPTOPOL PTS software and REVO SOCT software.

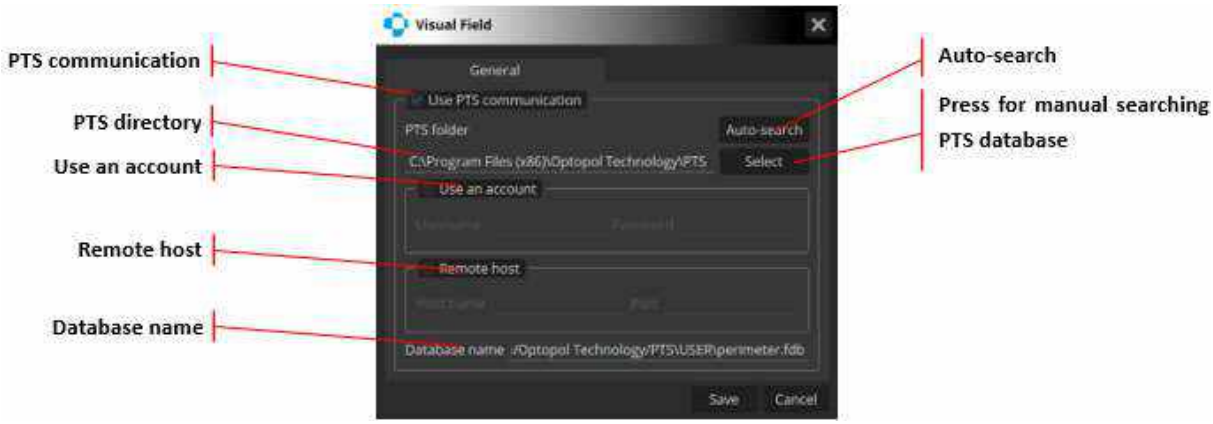


Figure 466.
Visual Field Settings Window

1. **PTS COMMUNICATION**

   Checking this field activates the other VF settings fields, the COMBINED tab, and the PTS-SOCT data transfer mechanism.

2. **AUTO SEARCH**

   Upon clicking this field, the application searches the system registry for an instance of the OPTOPOL PTS software. If it is found, the field **[PTS FOLDER]** is filled automatically and the **[DATABASE NAME]** is derived from the OPTOPOL PTS application settings located in the **[PTS FOLDER]**.

3. **PTS DIRECTORY**

   Location of the Use an account folder - checking this field activates with the PTS.exe file.

4. **SETTINGS FOR THE OPTOPOL PTS USER ACCOUNT**

   Checking the field is necessary if the PTS software is configured with user accounts. Otherwise, access to the PTS result database will not be granted. If this is the case, the user must enter the Username and Password.

5. **REMOTE HOST**

Checking this field activates the remaining two settings of the PTS database. If the application is to transfer VF data from an external database (not localhost), the user should check this field and configure **[HOST NAME]** and **[PORT]**.

6. **DATABASE NAME**

Location of the folder with the PTS database.

23.5.8. Input Settings Window

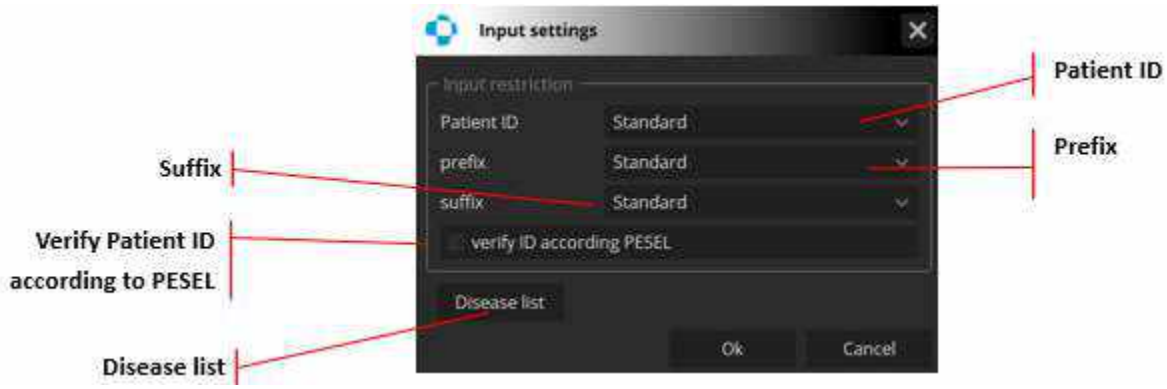


Figure 467.
Input Settings Window

1. **PATIENT ID**

Mandatory, standard or disable.

2. **SUFFIX**

Standard or disable.

3. **PREFIX**

Standard or disable.

4. **VERIFY PATIENT ID ACCORDING TO**

Checks the compatibility of entered data with the PESEL system (i.e., whether the date of birth has been entered correctly.)

5. DISEASE LIST

The user can set and manage the disease list.

The Disease list is stored in the disease.xml file. The Disease list can be edited in external software and copied to the SOCT installation folder. The disease list can be enabled on the patient registration screen. The user can select a disease from the examination list.

Figure 468.
Disease List Window

23.6. Edit Disease List Window

On the Output screen, perform the settings to output the examination data. Up to 10 output destinations can be registered. When the output destination is created, a list appears on the left side of the screen.

23.7. Output Settings

23.7.1. Output Set Window

This section describes how to create, modify, and remove sets of output data.

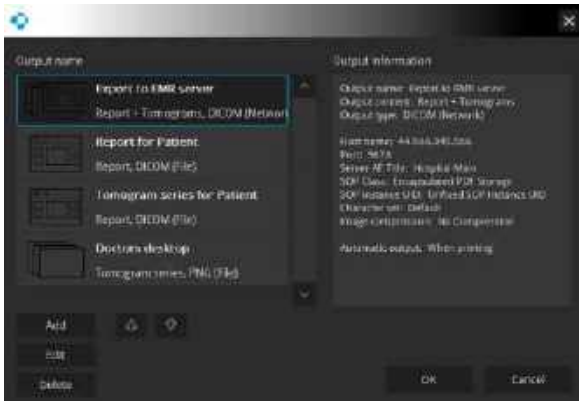


Figure 469.
Output Set Window

1. **[ADD]**

   Press to create a new output set.

2. **[EDIT]**

   Press to Edit a currently existing set.

3. **[DELETE]**

   Remove an existing set.

4. **[UP AND DOWN ARROW]**

   Move the position of the selected output set up or down on the list.

5. **[ARROWS]**

   Change the sequence position of the desired set on the list.

23.7.2. Exporting Tomograms with or without AI DeNoise

The user can decide if the tomograms are exported with the AI DeNoise function on or off. To determine the export manner, go to Setup → Preferences → Output Settings. In the output configuration window, find the **Image Denoise** section. Click on the drop-down menu in that section to unfold it. Choose **AI DeNoise** to export tomograms denoised or click **[NO AI DENOISE]** to export tomograms with the denoise function off.

The choice between the two export manners is always there, regardless of the selected output type (DICOM, JPG, BMP).

Figure 470.
AI DeNoise Export Settings

CAUTION: Keep in mind that tomograms with very low signal level or low QI might degrade the performance of the AI DeNoise algorithm, potentially leading to an altered image. If you use these tomograms, always make sure the exported denoised images are identical to the original, unprocessed images.

23.7.3. Creating an Output Set

The output configuration window has two views. One view for the DICOM storage configuration and the other for different file types.

23.7.4. Graphic File Standard

Outputted data can be viewed in a standard graphic file.

Figure 471.
Output Configuration Screen

1. **NAME**

   Input the Output set name.

2. **OUTPUT CONTENT**

   Tomogram, Series of tomograms and Report is available,

3. **OUTPUT TYPE**

   Select from one of graphic standard files .jpg, .png, .bmp, .pdf and .avi for the tomogram series.

4. **ADD FUNDUS IMAGE**

   The reference fundus reconstruction image will be added on the side of the tomogram object.

5. **OUTPUT FOLDER**

   Location to save data. It can be local or network location.

6. **FOLDER CREATION**

   Saved files can be placed automatically in the folder. The folder name is the date the report was prepared (Output Date folder) or the examination date (Study Date folder).

7. **AUTOMATIC OUTPUT**

   Select the moment when system data can be outputted.

   When Printing

   System output data when operator initiates printing the report.

After Capture

This option is available for tomogram/s only.

The output destinations are used to send DICOM files with the network or to write results to DICOM / JPEG / BMP / PDF / Movie in a specified location (local or network).

NO

User must press Output and select the desired set.

8. ANONYMIZATION

By default, this feature is disabled. Anonymization can be enabled or disabled for each output file.

9. EXPORT TO EMR

Available only if the checkbox *[Use Command Line interface from different application instances]* in the *Setup* tab → *Preferences* tab is checked. See chapter 23.5.1 CMDL Interface.

10. IMAGE COMPRESSION

The available image compressions are:

- Small
- Medium
- Large

23.7.5. Numeric Values Output Set

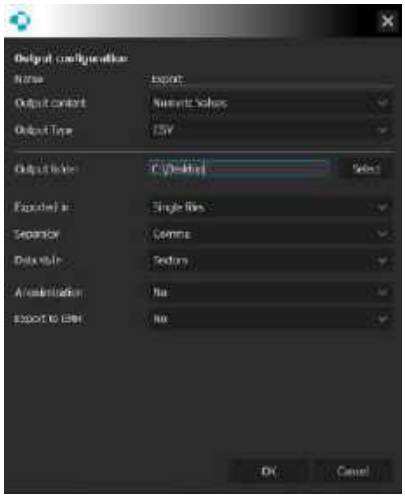


Figure 472.
Numeric Values Output Configuration Screen

1. NAME

Input the Output set name.

2. OUTPUT CONTENT

Numeric Values

3. **OUTPUT TYPE**

   CSV

4. **OUTPUT FOLDER**

   Location to save data. It can be local or network location.

5. **EXPORTED IN**

   Data can be saved in a Single file or in one Batch file for one type of examination.

6. **SEPARATOR**

   Select type of data`s separator.

7. **ANONYMIZATION**

   By default, this feature is disabled. Anonymization can be enabled or disabled for each output file.

8. **EXPORT TO EMR**

   Available only if the checkbox *[Use Command Line interface from different application instances]* in the *Setup* tab → *Preferences* tab is checked. See chapter 23.5.1 CMDL Interface.

23.7.6. DICOM C-Storage Output Set

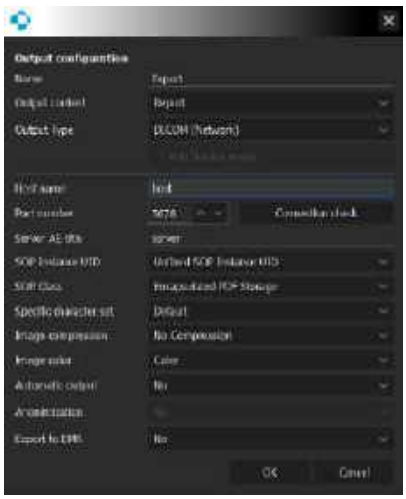


Figure 473.
DICOM Output Configuration Screen

1. **NAME**

   Input the Output set name.

2. **OUTPUT CONTENT**

   Tomogram, Report + tomogram, Series of tomograms and Report, Series of tomograms + Fundus photography examinations, Fundus photo, tomograms from – are available.

3. **OUTPUT TYPE**

   DICOM file – it can be saved in any location on a DICOM Network.

4. ADD FUNDUS IMAGE

The side of the tomograms will reference fundus reconstruction. The image will be attached.

5. HOST NAME

Enter the host name or the IP address (IPv4).

6. PORT NUMBER

Enter the port number.

7. CONNECTION CHECK

Check the connection with the DICOM server.

8. SERVER AE TITLE

Enter the server AE title. Be sure to input the value.

9. SOP INSTANCE UID

Fixed or Unfixed SOP Instance UID is available.

10. SOP CLASS

Select an SOP class for the model to be configured. Secondary Capture Encapsulated PDF Storage, Multi-frame True Color Secondary Capture Image Storage, Multi-frame Grayscale 8bit Secondary Capture Image Storage, Ophthalmic Tomography Image Storage, Fundus Image Storage.

11. SPECIFIC CHARACTER SET

Select the specific character set. Default Unicode.

12. IMAGE COMPRESSION

The available image compressions are:

- No Compression
- JPEG (Lossy)
- JPEG (Lossless)

13. AUTOMATIC OUTPUT

Select the moment when system data can be outputed:

WHEN PRINTING

System outputs data when operator initiates printing the report.

NO

User must press Output and select the desired set.

14. ANONYMIZATION

This is disabled by default. Anonymization can be enabled or disabled for each specific output file.

15. EXPORT TO EMR

Available only if the checkbox *[Use Command Line interface from different application instances]* in the *Setup* tab → *Preferences* tab is checked. See chapter 23.5.1 CMDL Interface.

23.8. Backup

Database and examinations backup can be performed on the external HDD or in network server location.

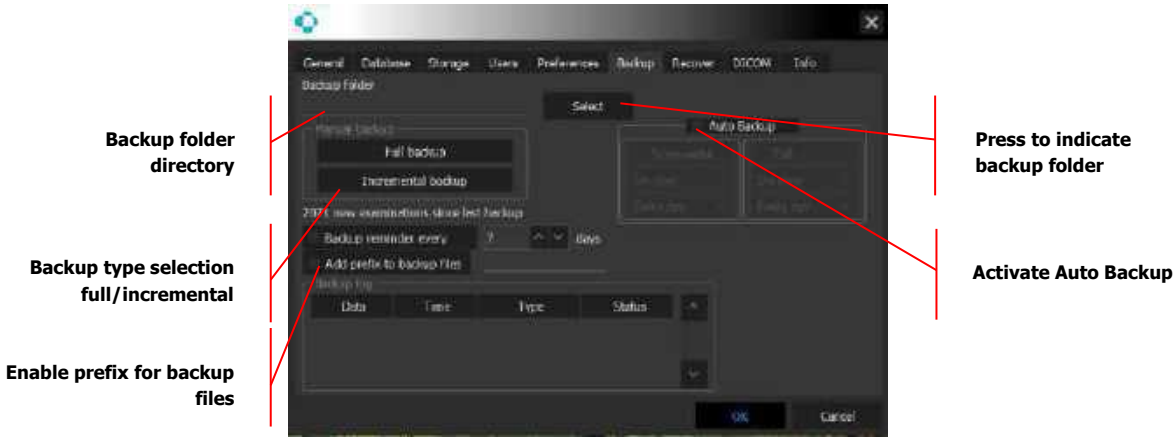


Figure 474.
Backup Tab

MANUAL BACKUP OPTIONS

Full Backup:	The complete database will be saved as a spare copy.
Incremental:	Only new exams are added to previously archived exams.

AUTOMATIC BACKUP OPTIONS

Auto Backup:	1. Activates automatic backup process. 2. **On Close or On Start:** As selected system backup after opening or prior close SOCT application. 3. **Types of Backups:** Full or Incremental.
Backup Reminder:	When backup is not performed, the system displays a backup reminder after a specified time.
Add Prefix to Backup Files:	When a backup is performed, files will have a prefix added for the user to easily distinguish an original file from a backup.

WARNING: Make sure there is enough free space on the HDD / remote folder before performing the backup process.

In case this window appears, please select backup folder location or check the external HDD connection.

Figure 475.
Backup Error Message

23.9. Recovery Tab

The REVO SOCT software provides an option for data recovery from the internal and external storage.

Figure 476.
Data Recovery Tab in Application Settings

Database recovery from software 6.1 or earlier - after pressing the Select button, an additional window opens, allowing selection of the folder from which the database will be imported. Before this is done, the function checks the list of patients for any Patient ID conflicts (this field in version 6.1 was not unique). If the conflicts occur, the program adds a random string sign to the **[PATIENT ID]** field. When all the conflicts are solved, it imports all examinations to the database.

23.10. DICOM

The DICOM Interface consists of two client modules (SCU):

1. Result Storage (Reports, Tomograms)
2. Modality Work List

DICOM client modules are based on communication with service providers (SCP hosts) within LAN TCP / IP. DICOM identifies the application based on the unique ID (AE Title) and the TCP / ID address. The AE Title and TCP / ID address should be saved in the application settings and in all SCP.

Figure 477.
DICOM Tab

23.10.1. System Settings

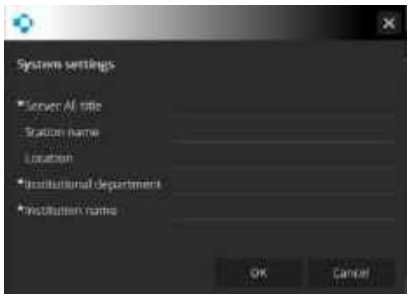


Figure 478.
System Settings Window

1. **AE TITLE**

   Enter the server Application Entry (AE) title. Mandatory field.

2. **STATION NAME**

   Input the station name.

3. **LOCATION**

   Enter the location.

4. **INSTITUTIONAL DEPARTMENT NAME**

   Enter the name of the institutional department. Mandatory field.

5. **INSTITUTION NAME**

   Enter the name of the practice or institution. Mandatory field.

23.10.2. MWL Settings

This module communicates with the Modality Work List whose ID (AE Title) and TCP / IP address can be configured in the MWL screen settings.

The Modality Work List client module collects demographic data of patients registered for tests from an external Modality Work List. Orders are created from the patient data which, together with orders from other data exchange systems, are added to the Work Manager list.

When the MWL settings is selected a new window will appear.

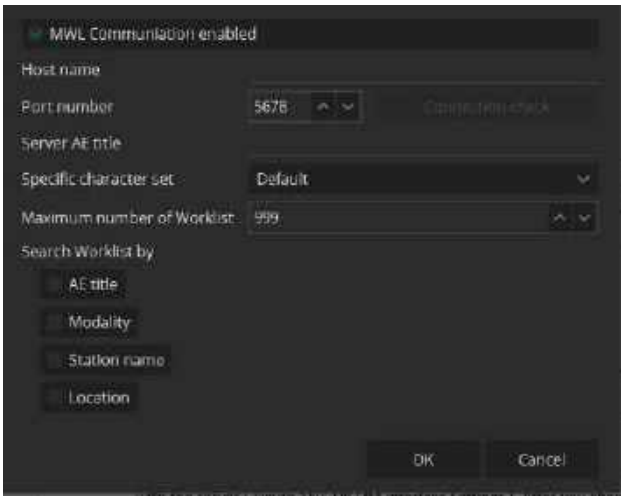


Figure 479.
MWL Interface Settings Window

MWL Communication enable Activate Work list. When selected, the application will monitor the work list on the configured host on a continuous basis. Order records are created from the identified patient data and are added to the Work Manager list.

1. **HOST NAME**

   Enter the Host name.

2. **PORT NUMBER**

   Enter the port number.

3. **SERVER AE TITLE**

   Enter the server AE title. Be sure to input the value.

4. **SPECIFIC CHARACTER SET**

   Select the specific character set.

5. **MAXIMUM NUMBER OF WORKLIST**

   Maximum length of worklist.

6. **SEARCH WORKLIST BY**

Retrieve the records from the Worklist sort by AE Title, Modality, Station name, Location.

7. **[CONNECTION CHECK]**

Check the connection with the DICOM server. After checking the communication and compatibility of the settings, a message will be presented indicating successful completion of the order or a list of errors.

NOTE: Make sure that the SCP host delivering the patient demographic data for tests is correctly configured and active. Otherwise, data collection will fail.

23.10.3. C-Storage

Examination results can be sent to a DICOM network or a DICOM file.

The REVO SOCT software saves files in the following standard: Encapsulated PDF Storage, Multi-frame True Color Secondary Capture Image Storage, Multi-frame Grayscale 8bit Secondary Capture Image Storage, Ophthalmic Tomography Image Storage.

The system can output in DICOM format: Tomogram, Series of tomograms, Series of tomograms + report, Report.

Series of tomograms + fundus photography examinations can be exported to DICOM.

See details in DICOM statement on file provided with the instrument **"SOCT DICOM Conformance Statement.pdf"** or contact OPTOPOL Technology support.

Detailed explanation how to configure DICOM storage can be found in Chapter 23.7.6 DICOM C-Storage Output Set.

23.11. Info Tab

Figure 480.
Information Label

23.12. Patient Record Change Traceability and LogReader Software

The LogReader.exe is located in the REVO SOCT application directory. Only users with Admin rights can log in the LogReader tool. Each login to the SOCT application and patient data modification is recorded in a Log file. This application will allow the administrator to have a recorded history of any changes and logins made by all users. For more information, please contact your local OPTOPOL distributor.

24. Maintenance and Cleaning Procedure

WARNING: All hardware maintenance activities can only be done when the device is turned off and unplugged from power supply socket.

WARNING: There are no user serviceable parts inside the device. Any covers can be removed only by OPTOPOL authorized personnel.

WARNING: The main lens of the device should never contact the patient's eye or face.

NOTE: It is not permitted to make any modifications of the REVO device.

The outside surfaces of the device should be kept tidy and free of dust and cleaned using mild cleaning solutions.

Take care not to get water or any other liquid inside the device. For hygienic reasons, after each examination, the chinrest and forehead support should be disinfected.

24.1. Routine Cleaning

CLEANING OF THE DEVICE CASING AND EQUIPMENT OF THE ME SYSTEM (PC, MONITOR LCD, PRINTER, KEYBOARD AND MOUSE PC)

Clean the casing with a soft cloth. Use only cleaners dedicated for cleaning of electronic equipment. Clean periodically or when needed.

CLEANING OF THE APPLIED PARTS (FOREHEAD AND CHINREST SUPPORT)

The applied parts should be disinfected after examination of each patient. Use a soft cloth, wet with an alcohol-free solution for cleaning and disinfection of alcohol-sensitive medical-equipment surfaces or alcohol-free wipes for disinfecting of alcohol sensitive medical-equipment surfaces.

The applied parts are to be disinfected also after long periods of no use.

CLEANING OF THE LENS

The lens should be cleaned only when contamination of lens surface is observed. For lens cleaning, use only cleaners that are made for optics, that do not cause scratching of the lens. Clean the lens softly with little force. The REVO device comes with a lens cap to protect it when not in use. The lens should be inspected periodically for dust and oily smudges and cleaned if necessary to ensure proper tomogram images are obtained. For the lens cover, an alcohol prep swap or cotton swap dipped in isopropyl alcohol may be used. Wipe it dry with a soft, non-lining cloth or tissue.

DUST PREVENTION

When the device is not used, make sure the cloth dust cover is placed over the unit.

NOTE: Periodically one must check that there is no mechanical damage to the device or to any of the cables and fuses.

24.2. Software Maintenance Activities

To keep the software in good condition, the user should perform activities below as minimum:

1. Windows automatic updates should be checked periodically at least once a month. To do the update: Enable automatic updates, wait until system finishes the update process. During the process, do not conduct an examination. Once the system finishes the update process, disable automatic updates.
2. If it is not possible to have automatic updates turned on (for security reasons or internet availability), the system administrator should manually keep the operating system updated. The system administrator should check regularly for new updates.
3. Installed antivirus software should be updated at least once a week.
4. For periodic software upgrades and updates, OPTOPOL will inform users through its distributors.

24.3. Hard Disk Defragmentation

WARNING: Disc defragmentation is not recommended for SSDs.

Defragmentation of the OCT PC hard disk becomes necessary when old scans are deleted and analyzed regularly. The process of recalculation, deleting data and then writing again to the hard disk fragments the hard drive, which degrades system performance over time. To maintain peak performance, we recommend that the hard disk is defragmented regularly.

NOTE: Since hard disk defragmentation usually requires several hours to complete, we recommend that defragmentation is started at the end of the day and let the process run overnight. If defragmentation is not complete in the morning, it does no harm to stop defragmentation and continue using the instrument.

To defragment the hard drive, follow these steps:

1. Close the REVO SOCT software.
2. Click Windows Start > Programs > Accessories > System Tools > Disk Defragmenter. The Select Drive dialog appears.
3. Select the desired drive (e.g., D:) and click **[OK]** to begin defragmentation.

24.4. Ordering Consumables

Article Name	Article Code	Description
Single use chinrest labels	R C003P	
Fuses 2 x F 4 A H 250V[66]	R B006P	
Fuses	R018	2 x F 3,15 A L 250 V
Dust cover	R C005 FC	
External fixation with an LED (interchangeable)	R024F	
USB 3.0 cable	R035	
Lens cover	R037	
USB Flash drive with the SOCT software, drivers and the User manual	R042	

[66] Applicable to REVO FC models.

24.5. Fuses

24.5.1. Replacing Blown Fuses

If the device does not work when the power is on, a blown fuse may be the reason.

CAUTION: Before replacing the fuses, make sure that there are no other visible reasons causing the device to not work (broken cables, disconnected cables etc.).

Before replacing the fuses, turn the device off and unplug it from the power supply socket.

The fuses are located in the power supply receptacle assembly at the back of the device. To replace the fuses, unplug the power supply cable, press the small plastic levers on the sides of the fuse casing and pull the casing out. Replace the fuses and slide the casing back in until it clicks in place.

25.
Network Configuration

The Installation Manual for the REVO device is available in PDF format on the computer with SOCT software installed - search for ***Installation manual REVO.pdf***. The manual is included on a USB flash drive delivered with the standard package of the SOCT software.

Install the .pdf file viewer (e.g., free Adobe Reader, from the www.adobe.com website or flash drive to open and read the manual in PDF format.)

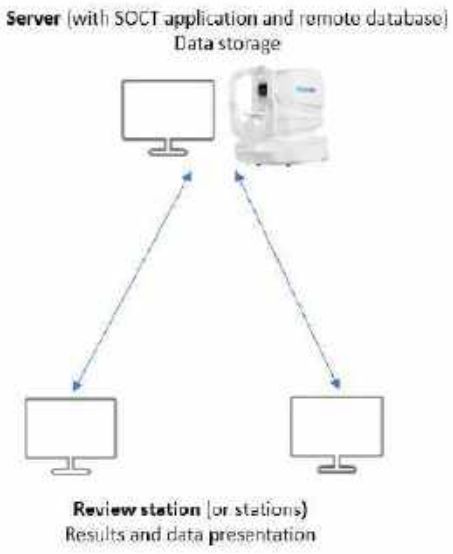
If the document is not available, please contact an authorized OPTOPOL representative.

WARNING: For optimal networking performance, the application on all of the PCs within the network should be upgraded to the latest version.

25.1. Network Connection Configuration

25.1.1. REVO SOCT Network

REVO SOCT software allows the user to locate examination data on external network locations or HDD. It is possible to work on multiple posts, where one PC acts as a server and others as clients receive or send data. Database as well as the data is stored on the server. Servers role can be assigned to the PC with installed SOCT software and connected REVO device. Servers role can also be assigned to any intended computer. Clients role can be assigned to any PC connected to the device or a working station in the Viewers mode.



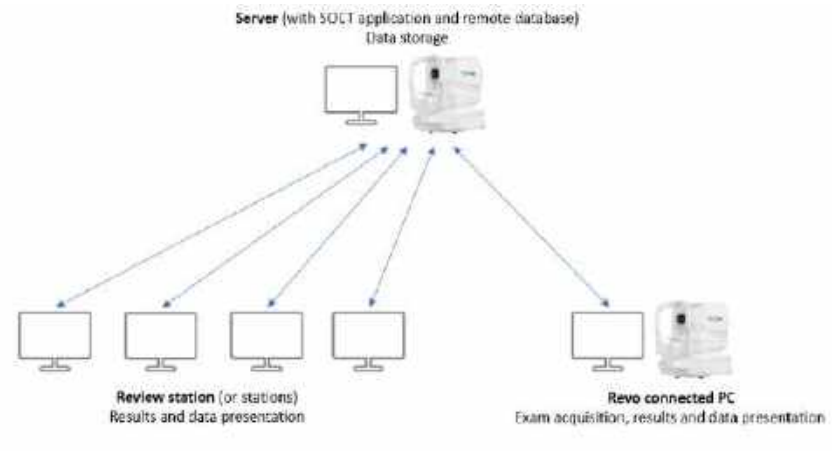


Figure 481.
Client-server model of the SOCT software

NETWORKING FUNCTIONALITY RESTRICTIONS

When the software is configured as a client, there are some limitations applied to its functionality:

1. Only the client connected to REVO device can perform new examinations.
2. In case specific a patient file is used on any PC connected to the database, there is no possibility to access this patient's data from any other PC. **'Selected patient is occupied by another user'** message is displayed. It means it is not possible to edit, review, perform, remove, analyze, import, export patients on more than one PC at that same time.
3. There is an unlimited number of PCs connected to the same LAN that can have access to the same server, however its work efficiency is restricted by network speed and processing power of the server PC and the client PC.

NOTE: Configuring and administrating the network configuration in client-server environment requires an expertise and experience, therefore it is recommended for the internal network settings to be adjusted only by the IT personnel. They should possess the necessary skills to effectively administrate the safety, permissions and general network operations.

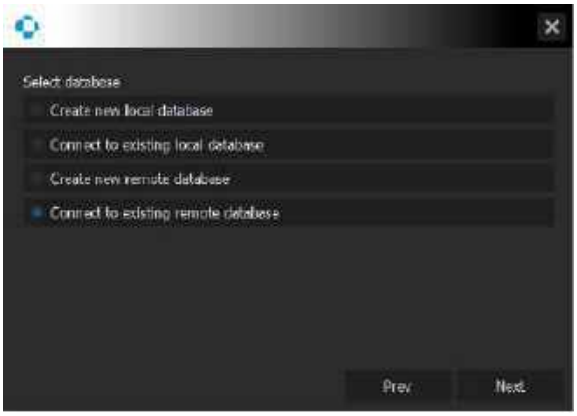


Figure 482.
Window After Login to New System

User can choose the type of the database in the Setup Wizard or later in the Setup tab – See Chapter 23.2 Database. Local database refers to the database located on the same PC. Remote database refers to the database located on the server.

The [Refresh] button allows the user to update the database if any changes in one of the review/workstations working remotely have occurred.

Figure 483
[Refresh] button

Hints to the [Refresh] button:

- Hint {No updates in database}: button in white
- Hint {Database updated, refresh}: button in blue

If there have been changes in the database, and the data needs to be updated, the [Refresh] button text is displayed in blue and the [Refresh] button has to be used.

25.2. Database connection

When connected to a network, the SOCT application displays the database connection status: **Database connected** or **Database disconnected**.

If the patient data which the user wants to view is currently opened on another PC, the following message is displayed:

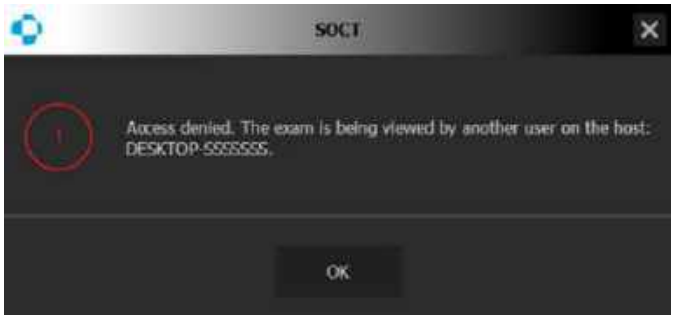


Figure 484
The examination being viewed on a different host warning.

CAUTION: If the PC on which the examination is being viewed loses connection to the database for longer than 60 seconds, the SOCT application automatically switches to the |PATIENTS| tab.

26.
PTS Connection

The Installation Manual for the REVO device is available in PDF format on the computer with SOCT software installed - search for ***Installation manual REVO.pdf***. The manual is included on a USB flash drive delivered with the standard package of the SOCT software.

Install the .pdf file viewer (e.g., free Adobe Reader, from the www.adobe.com website or flash drive to open and read the manual in PDF format.)

If the document is not available, please contact an authorized OPTOPOL representative.

AVAILABLE CONNECTIONS WITH THE PTS SOFTWARE:

NOTE: For PTS connection it is required to install the Firebird database components. For further details refer to the Installation manual REVO.pdf

1. Connection of the SOCT program to the local PTS application database configured using user accounts.
2. Connection of the SOCT program to the local PTS application database configured without using user accounts.

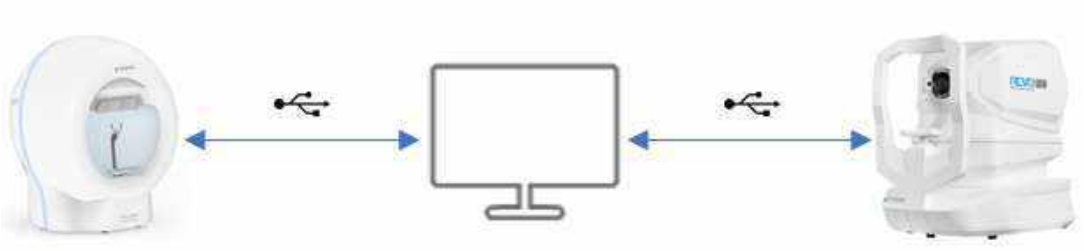


Figure 485.
3.Connection – SOCT and PTS software on one PC (with and without using the users accounts)

3. Configuring the connection of the SOCT software to the remote PTS database

   This model consists of 3 elements: a server, a working station and a viewing station. Requirements and options for each of the components:

   - **Sever:**
     - o Must have the PTS software with the database installed
     - o May be connected to a PTS or an SOCT device

   - **Working station:**
     - o Must have PTS software installed

- Must have SOCT software installed
- Must be connected to a PTS or a REVO device (if examinations are going to be performed)

27.
Environmental Conditions

ENVIRONMENTAL CONDITIONS OF USE

Criteria	Environmental Conditions
Temperature	+ 10°C to + 35°C
Relative humidity	30% to 75%
Atmospheric pressure	800 hPa to 1060 hPa
Dust in the air	No visible particles

STORAGE CONDITIONS

Criteria	Environmental Conditions
Temperature	-10°C to + 55°C
Relative humidity	10% to 95%
Atmospheric pressure	700 hPa to 1060 hPa

TRANSPORT CONDITIONS

Criteria	Environmental Conditions
Temperature	-10°C to + 55°C
Relative humidity	10% to 95%
Atmospheric pressure	500 hPa to 1060 hPa
Shock	30 g, duration 6 ms
Bump	10 g, duration 6 ms

PATIENT ENVIRONMENT

The patient environment is described as the place in which the patient / examiner may contact the equipment (including the connected devices) or where the patient / examiner may contact the person who touches the equipment (including the connected devices). The REVO devcide comes with an optional power table that requires an approximate area of (1,5 m by 2,4 m) for installation and patient comfort during use.

MEASUREMENT UNIT

All units on the SOCT are measured in the SI format. Unless noted otherwise, measurements are made in micrometers

28.
Warranty and Service

In case of problems contact your local OPTOPOL distributor:

Upon request, the supplier may make available circuit diagrams, components part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated by the manufacturer as repairable. The OPTOPOL distributor may require trained technical personnel to attend a certified service training program which may involve a fee and a non-disclosure agreement.

SERVICE LIFE

The service life of this product is approximately ten years, under normal conditions.

Performing an annual periodic inspection of the device is recommended. This includes checking optical power, spectrum height, polarization, cleanliness of the optics, a visual check of the optics and the housing for mechanical damage, as well as visual inspection of the power cable and the control cables in the device.

ABOUT REPAIRS

If a problem cannot be solved even after taking the measures indicated in Chapter 30 Troubleshooting, contact your OPTOPOL distributor for repairs.

When requesting repair, please provide the following information:

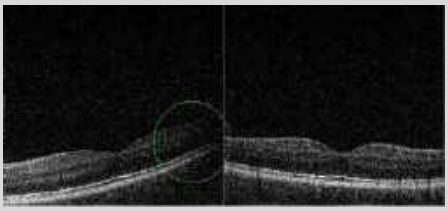
Full Name of the Device and Serial Number:	Number on the product label.
Description of Malfunction:	Report as much detail as possible

29.
Disposal

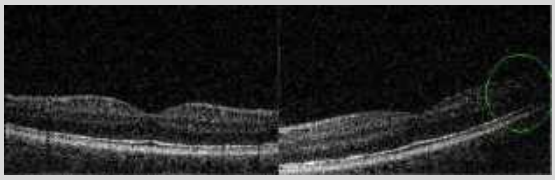
DISPOSAL: When the usage period is over, contact your distributor for instructions on the proper disposal of the device.

Maximum Lifetime of the Device:	Ten years from the date of manufacture.

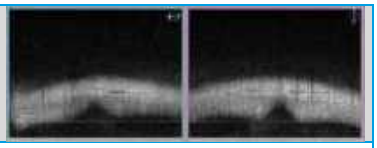
30.
Troubleshooting

Q1	**The tomogram images have good quality, but there is a shadow at the horizontal tomogram image (left image) on the left or right edge and the image is diagonal.** 
A1	The scanning beam is not centered on the pupil in the horizontal direction. This effect is observed mostly for very small pupils and wide scanning ranges. Grab and move the tomogram to left or right to obtain the best image quality.

Q2	**The tomogram images have good quality, but the horizontal retina cross section image is diagonal.**
A2	See A1.

Q3	**The tomogram images have good quality, but there is shadow at the vertical tomogram image (right image) on the left or right edge and image is diagonal.** 
A3	The scanning beam is not centered on the pupil in the vertical direction. This effect is observed mostly for very small pupils and wide scanning ranges. Grab and slightly move the tomogram (in this case, to the right) on the vertical window right to obtain equal image saturation.

Q4	**The tomogram images have good quality, but the vertical tomogram image (right image) is diagonal.**
A4	See A3.

Q5	**Live tomogram images are visible, but the image is fuzzy and upside down.** 
A5	This means the C-gate position is too far from the optimal position. Move the C-gate position (scroll or grab) closer to the patient. The retina cross section image will go down on the window and then up again in a straight orientation.

Q6	**After starting the REVO, software communication errors are displayed.**
A6	Make sure that the scanning head finished its self-test before the application is started.

Q7	**Software displays message “No signal detected”.**
A7	Run the “Skantest_lt” (START / ALL PROGRAMS / SOCT / Skantest_lt) application [Open] communication and run [STRAT] calibration procedure.

Q8	**The tomograms images have bad quality.**
A8	Check cleanliness of the objective lens. Clean with a lens wipe if necessary. Make sure that the system calibrates itself before the first examination.

Q9	**The SOCT application is connected to the device, but I get error messages when I open the acquire tab or while working in the acquire tab.**
A9	If the Fast Speed USB 3.0 Connection is not available in the system, the REVO camera is not able to work in the required mode. Verify the points below: 1. Make sure that the REVO SOCT USB cable is connected to 3.0 USB port. 2. Verify that the USB cable is protected from any unintentional tension, movement, or push. Make sure the USB plug is not loose. 3. Unplug the USB cable and plug it in again. Make sure there is no play (slack) on the port. Wait until system recognizes the devices again. 4. Verify if the system has properly installed Universal Serial Bus controller 3.0 hub Start->Control panel->System->Device manager->Universal Serial Bus controller. 5. Verify if the system has properly installed all devices Control panel->System->Device manager. There should not be any exclamation sign.

Q10	**During acquisition of tomograms, the REVO device live windows become black.**
A10	See the status of the device in the left bottom corner of the OCT image. In case of error, restart the application. If the problems occur again see A9.

Q11	**I have no connection to the remote database.**
A11	Verify the connection procedure according to the REVO User Manual again. Make sure network settings are proper. Verify if the host name /IP is properly entered in all software applications connected to the server.

Q12	**The analyze window is displayed only on a quarter of the screen.** 
A12	Verify the screen and Windows resolution. Go to Control Panel=>Appearance and Personalization=>Display and select "*Larger – 150%".*

31.
Glossary

A-Scan	Axial Scan
AC	Anterior Chamber
ACD	Anterior Chamber Depth
AL	Axial Length
AMD / ARMD	Age-Related Macular Degeneration
Applied Parts	As stated
Artifact	As stated
B-Scan	A 2-D image comprised of a series of A-scans
BCVA	Best Corrected Visual Acuity
CATARACT	As stated
CCT	Central Corneal Thickness
Choroid	As stated
CME	Cystoid Macular Edema
CNV	Choroidal Neovascularization
COAG	Chronic Open Angle Glaucoma
Cornea	As stated
CRAO	Central Retinal Artery Occlusion
CRVO	Central Retinal Vein Occlusion
CSCR	Central Serous Chorioretinopathy
C/D	Cup to Disc
CWS	Cotton Wool Spot
D / M / V / P	Disc / Macula / Vessels / Periphery

Diabetic Retinopathy	As stated
DICOM	Digital Imaging and Communications in Medicine
EMR	Electronic Medical Records
ERM	Epiretinal Membrane
FA	Fluorescein Angiogram
FAZ	Foveal Avascular Zone
Floater	As stated
Fovea	As stated
FUNDUS	As stated
GCC	Ganglion Cell Complex
Glaucoma	As stated
HDD	Hard Disk Drive
ILM	Internal Limiting Membrane
INL	Inner Nuclear Layer
IOL	Intraocular Lens
IOP	Intraocular Pressure
IPL	Inner Plexiform Layer
IR	Infrared
K	Unit of Measurement for Corneal Curvature
L	Lens
LT	Lens Thickness
ME System	Medical System
Microperimetry	As stated
NFL	Nerve Fiber Layer
NSTIN	NFL Thickness Measurement Orientation (Nasal, Superior, Temporal, Inferior, Nasal).
OCT	Optical Coherence Tomography
OCT-A	Optical Coherence Tomography Angiography

OD / OS / OU	Right / Left / Both Eyes
ONH	Optic Nerve Head
P	Pupil Size
PDR	Proliferative Diabetic Retinopathy
PDT	Photodynamic Therapy
pSLO	Pseudo Scanning Laser Ophthalmoscope
QI	Quality Index
QIS	Quality Index Score
Real Corneal Power	As stated
Retina	As stated
RPE	Retinal Pigment Epithelium
S & F	Structure and Function
SLO	Scanning Laser Ophthalmoscope
SOCT	Optopol REVO Software
TSNIT	NFL Thickness Measurement Orientation (Temporal, Superior, Nasal, Inferior, Temporal).
TQF	Topo Quality Factor
ULIB	User-Group for Laser Interference Biometry
VA	Visual Acuity
VF	Visual Field
WTW	White to White

32.
Product Compliance

32.1. Radio Interference

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
4. Consult the Optopol dealer or an experienced radio / TV technician for help.

32.2. EMC Information

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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

Emission Test	Compliance	Electromagnetic Environment (Guidance)
RF Emissions **CISPR 11**	Group 1	The REVO device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF Emissions **CISPR 11**	Class A	The REVO device 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 use, provided the following WARNING is heeded:
Harmonic Emissions **IEC 61000-3-2**	Class A	
Voltage Flicker / Flicker emissions **IEC 61000-3-3**	Complies	

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

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment (Guidance)
Electrostatic discharge (ESD) **IEC 61000-4-2**	± 8 kV contact ± 2,4,8,15 kV air	± 8 kV contact ± 2,4,8,15 kV air	Floors should be made 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 **IEC 61000-4-4**	± 2 kV for power supply lines	± 2 kV for power supply lines	Main power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	± 0,5; 1kV line(s) to line(s) ± 0,5; 1; 2 kV line(s) to earth	± 0,5; 1kV line(s) to line(s) ± 0,5; 1; 2 kV line(s) to earth	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines **IEC 61000-4-11**	0% Ut, 0,5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% Ut, 1 cycle. 70% Ut, 25 / 30 cycles Singe phase at 0°	0% Ut, 0,5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% Ut, 1 cycle 70% Ut, 25 / 30 cycles Singe phase at 0°	Main power quality should be that of a typical commercial or hospital environment. If the user of the REVO device requires main power supply interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field **IEC 61000-4-8**	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the AC main voltage prior to the application of the test level.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment (Guidance)
Conducted RF **IEC 61000-4-6**	3 Vms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the REVO device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **RECOMMENDED SEPARATION DISTANCE** $d = [1{,}17]\sqrt{P}$ $d = [1{,}17]\sqrt{P}$ 80 MHz to 800 MHz $d = [2{,}33]\sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz to 2,5 GHz	3V/m	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,* should be less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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

*Field strength 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 REVO device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the REVO device.

**Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE REVO SOCT

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

Rated Maximum Output Power of Transmitter W	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER m		
	150 kHz to 80 MHz $d = [1,17]\sqrt{P}$	80 MHz to 800 MHz $d = [1,17]\sqrt{P}$	800 MHz to 2,5 GHz $d = [2,33]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3

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

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

WARNING: 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.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided and 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.