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User Manual

REVO nx

REVO nx 130

SOCT Copernicus REVO
SOCT Copernicus

REVO 60
REVO 80

REVO FC

Software Version 10.0

User Manual Rev. A

CE
0197

Make sure you read this manual before using the instrument. Keep this manual in a safe place so that you can use it in the future.

Copyright

User Manual Version 10.0 rev. A

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For Customer Service or Technical Service contact your authorized dealer of OPTOPOL Technology Sp. z o. o. Contact details are available on www.optopol.com.

Note: The SOCT Copernicus REVO/SOCT Copernicus/REVO 60/REVO 80/REVO nx REVO nx 130/REVO FC is hereinafter referred to as the “SOCT”.

The name of application which controls the scanning device is *SOCT.*

Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician. Proper procedures and techniques are the responsibility of the medical professional.

License and use of the SOCT is intended only for trained medical personnel in accordance with the license agreement – all other usage is prohibited – warranty restrictions and possible claim limitations apply.

1 DESCRIPTION OF THE DEVICE

This manual explains the details of the function and method of application to make a good use of the SOCT system. Before using the device, read this manual carefully to ensure that you operate it efficiently and safely. Always keep this manual at hand for reference.

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 device produces a light beam, which is focused on the human eye tissue. The light that reflects from internal structures of an eye is then interferometrically analyzed by the device. The raw data are processed by a PC to obtain images of eye tissue cross-sections.

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 FC version allows 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 FC version provides 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.

1.1 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.

FC version provides 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.

NOTE: The SOCT is not intended to be used as the sole diagnostic aid for disease identification, classification and management. A patient diagnosis is the sole domain of eye care clinician.

DISCLAIMER: OPTOPOL Technology is not offering and does not offer advice, instruction in the diagnosis and interpretation of SOCT images. It is the clinician's responsibility to make diagnosis and interpretation of OCT scans.

1.2 Intended User

The SOCT can be used by Ophthalmologists, Optometrists, Opticians, Orthoptists or other trained health personnel.

1.2.1 *The minimum knowledge*

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

1.2.2 *Education needed for operating the tomograph*

Ophthalmologist, Optometrist, Nurse, Certified Medical Technician, Assistant.

1.2.3 *Operating Skills*

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

- Power on and power off the device,
- Disinfect surfaces which interact with the patient,
- Enter and modify the patient data,

- Adjust position of the patient, position of the instrument, the table height, and the patient’s chair,
- Set the examination parameters, acquire examination,
- Select or create the required type of printout,
- Verify the printout for completeness of data,
- Print, export and save the selected report,
- Archive and recover the patient database.

1.2.4 *Occupational skills*

The user should be able to work with elderly patients, disabled patients and with children.

1.2.5 *Job requirements for the user*

The SOCT training in the scope of usage and operation is mandatory before the first use. The user should be also trained in the analysis and treatment of ophthalmic diseases or other eye-related medical issues, as it is stated by governing bodies. The user should be a computer literate person.

Users must be suitably trained and be familiar with the instructions, cautions, warnings contained in this user manual.

⚠ **CAUTION:** This manual does not provide guidance on interpretation of clinical results. The clinician must ensure that he or she has received appropriate medical training in such interpretation. OPTOPOL Technology Sp. z o. o. cannot be held responsible for misdiagnosis of results.

1.3 Places of Use

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

1.4 Patient population

The patient must be capable of sitting up straight and keeping his/her head still. They must be physically and mentally able to cooperate well and mentally capable of following the examination. Patients must be at least 5 years old.

1.5 Proper instrument use

- Always enter patient information first.
- Clean patient contact surfaces (forehead and chin rest).

- To avoid pinching the patient, check the patient’s head position before raising the chin rest

- Clean the ocular lens frequently to ensure good image quality.

- Adjust power table height properly to ensure patient comfort during the examination.

- Raise or lower the patient’s head so the eye aligns with the canthus mark on the chin and forehead rest assembly.

- Warn others not to sit or stand on any part of the table, including the base and the top.

- When lowering the table, make sure that pinch point areas are clear of people and articles; do not store articles in these areas.

Note: Chemically induced pupil dilation is not normally needed.

This device is not designed, sold or intended for use except as indicated.

1.6 Contraindication

Do not use the SOCT for those patients who:

- Have an anamnestic history of photodermatosis,
- Have undergone photodynamic therapy (PDT) within48 hours (refer to the product document of administered photosensitizer about the prohibition period),

1.6.1 *Instruction Manual Availability*

The SOCT Instruction Manual in PDF format is available on the computer with installed SOCT application. To open the file, press *START* → *Application* → *SOCT* → *User Manual*. The manual is included on USB flash drive delivered with the standard package of the SOCT. Install the .pdf file viewer e.g. free Adobe Reader from the www.adobe.com website or flash drive to read the manual in PDF format.

The Instruction Manual in paper form is available on request. To receive user manual in hardcopy please contact authorized OPTOPOL representative to receive it.

1.6.2 *Instruction Manual Applicability*

This document applies to the SOCT running with the application software version 8.0 or higher, unless superseded.

1.6.3 *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.

1.7 Protective Measures for IT Systems

Manufacturer recommends operating SOCT only on password-protected systems.

SOCT must 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.

Manufacturer will not accept any liability for damage due to a computer virus.

⚠ **NOTE**: User must periodically backup patient data. Manufacturer will not accept any liability for lost data.

Manufacturer recommends the use of an established antivirus software and/or firewall such as e.g. Norton, McAfee.

The SOCT is tested by the manufacturer with anti-virus protection provided with Windows 10 “Microsoft Security Essentials”.

Make sure that your operating system, your medical device software and your antivirus software are always 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 Manufacturer.

1.8 Cybersecurity Functions

The purpose of this section is to summarize the cybersecurity controls for the SOCT with Windows 10 operating system.

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 availability or integrity, or expose other connected devices or networks to security threats.

1.8.1 *System Overview*

The SOCT device has the following interfaces that are critical for cybersecurity:

- ETHERNET port /Wireless connection for DICOM interface

- USB ports for connecting to various USB devices

1.8.2 *Authentication of Users*

The SOCT device uses Microsoft Windows 10 as the 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.

1.8.3 *Auto-Logoff*

User can select one of two available methods of automated log-off when working with the SOCT application.

- The operating system has the ability to prevent access and misuse by unauthorized users if the device is left idle for a period of time. 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.

- The SOCT application also comes with an automated log-off capability which the user can easily setup in chapter 22.4 Users accounts.

For questions regarding cyber security contact the Manufacturer.

1.8.4 *Ensure Trusted Content*

Restrict Software of Firmware Updates to Authenticated Code. Software and firmware updates are performed by OPTOPOL representative from a protected source. All updates require a Privileged account.

1.8.5 *Cybersecurity event*

Provide information to the end user concerning appropriate actions to take upon detection of a cybersecurity event.

- Disconnect the SOCT device from any network
- Contact the IT Administrator at the user facility for on-site evaluation
- Run a scan using the anti-virus software
- Quarantine and delete any identified threats using the anti-virus software
- Restore the database
- Reconnect to the network
- Contact OPTOPOL Technology representative if additional assistance is required

1.8.6 *Recover*

Methods for retention and recovery of device configuration by an authenticated privileged user.

• The SOCT provides an option for a data backup on internal and externa storage

• The SOCT allows configuration to be backed up automatically at each launch or close of the SOCT application

1.8.7 *Other implemented mechanisms*

1.8.7.1 Institutional IT Infrastructure

The SOCT software uses the 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, encryption, and so forth. The SOCT device will support these site-specific IT systems and this is verified during the installation process by OPTOPOL representatives.

1.8.7.2 Stand Alone Mode

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

1.8.7.3 Cybersecurity and Data Back-up Configurations

- On the Windows 10 PC where SOCT will be installed the “Windows Firewall” has to be enabled.
- The SOCT was validated on computers with anti-virus protection provided by “Microsoft Security Essentials”
- Data encryption can be added by a third-party tool
- The SOCT provides an option for an external data backup
- OPTOPOL Technology recommend to backup data on the drive with RAID system

2 TECHNICAL DATA

2.1 Technical Data REVO nx 130 / REVO nx

OCT Image

Signal source	Super Luminescent Diode (SLED)
Wavelength	830 nm
Scanning speed	
REVO nx 130	130 000 measurements per second
REVO nx	110 000 measurements per second
Optical power	1575 µW ± -4,5%
Signal analysis	Spectral domain Optical Coherence Tomography
Scanning programs	3D, B-scan, Radial HD, Raster, Cross, Angio[1], Axial length[2], Topography[2]
Axial resolution	5 µm (in tissue)
Transversal resolution	ideal 12 µm
	typical 18 µm
Retina scan width	5 – 12 mm
Anterior scan width	3 – 16 mm
Scan depth	2.4 mm / 4.8 mm in Full Range mode
Working distance	Posterior segment 23 mm
	Anterior segment 52 mm
	Anterior segment with adapter 27 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	max. load 500 VA
Dimensions	556 mm L × 382 mm W × 469 mm H
Weight	23 kg

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

[2] - Biometry and Topography are optional software modules. If you do not have this feature and want to purchase it, contact Optopol's local distributor.

2.2 SOCT Copernicus REVO/ SOCT Copernicus / REVO 60/REVO 80

OCT Image

Signal source	Super Luminescent Diode (SLED)
Wavelength	830 nm
Scanning speed	
SOCT Copernicus REVO/ SOCT Copernicus	27 000 measurements per second
REVO 60/REVO 80	60 000/80 000 measurements per second
Optical power	
SOCT Copernicus REVO / SOCT Copernicus	1050-1150 µW
REVO 60/ REVO 80	1050-1150 µW/1150-1250 µW
Signal analysis	Spectral domain Optical Coherence Tomography
Scanning programs	3D, B-scan, Radial, Raster, Cross, Angio[3], Axial length[4], Topography[4]
Axial resolution	5 µm (in tissue)
Transversal resolution	ideal 12 µm
	typical 18 µm
Retina scan width	5 – 12 mm
Anterior scan width	3 – 16 mm
Scan depth	2.4 mm / 4.8 in Full Range mode
Working distance	Posterior segment 23 mm
	Anterior segment 52 mm
	Anterior segment with adapter 27 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	max. load 500 VA
Dimensions	556 mm L × 382 mm W × 469 mm H
Weight	23 kg

[3] - OCT Angiography is an optional software module available only for REVO 60/REVO 80. If you do not have this feature and want to purchase it, contact Optopol's local distributor.

[4] - Biometry and Topography are optional software modules. If you do not have this feature and want to purchase it, contact Optopol's local distributor.

2.3 Technical Data REVO FC

Fundus Camera REVO FC

Type:	Non-mydriatic fundus camera
Photography type	Color
Camera	Built-in 12,3-megapixel CCD camera
Angle of view	45 × (1 ± 5 %) °
Light source	White LED
Min. pupil size for fundus	3.6 mm

OCT image

Signal source	Super Luminescent Diode (SLED)
Wavelength	830 nm
Scanning speed	80 000 measurements per second
Optical power	1150-1250 µW
Signal analysis	Spectral domain Optical Coherence Tomography
Scanning programs	3D, B-scan, Radial, Raster, Cross, Angio[5], Axial length[6], Topography[6]
Axial resolution	5 µm (in tissue)
Transversal resolution	ideal 12 µm, typical 18 µm
Retina scan width	5 – 15 mm
Anterior scan width	3 – 16 mm
Scan depth	2.4 mm / 5 mm in Full Range mode
Min. pupil size for OCT	2.4 mm

Working distance	Posterior segment 37 mm, Anterior segment 52 mm
Power supply	100 – 240 V, 50 / 60 Hz
Power consumption	90-110 VA
Fuse ratings	2 x F 4 A H 250 V
Multiple socket-outlet	max. load 500 VA
Dimensions	479 mm L × 367 mm W × 493 mm H
Weight	30 kg

[5] - OCT Angiography is an optional software module available in REVO FC. If you do not have this feature and want to purchase it, contact Optopol's local distributor.

[6] - Biometry and Topography are optional software modules. If you do not have this feature and want to purchase it, contact Optopol's local distributor.

2.4 Device classification

Classification	Class 1 Laser Device
Protection against electric shock	Class 1
Degree of protection against electric shock	Type B applied parts (chin rest, forehead rest) and ground
Degree of Protection against ingress of water	IPX0
Mode of operation	Continuous operation

2.5 Minimum computer system requirements

2.5.1 *Capture station*

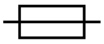
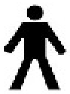
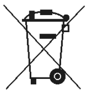
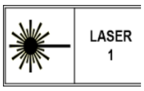
Processor	Intel® Core™ i7 3.0 GHz or higher
No. of cores	4 physical cores
RAM	minimum 16 GB, recommended 32 GB
Operating system	Windows 7 Professional 64-bit, Windows 10 PRO 64bit,
HDD	minimum 500 GB; recommended 256 GB SSD for OS 1TB SSD for Data
Graphic card	NVIDIA chipset, Intel 630
Screen resolution	1920 x 1080 (Full HD), 3840 x 2160 (4K) (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)
Communication ports	1 available USB 3.0 port
	2 available USB minimum 2.0 ports
Mouse	Mouse Wheel
Touch screen	Recommended

2.5.2 *Review station*

Processor	Intel® Core™ i5 2.4 GHz or higher
No of cores:	min. 2 physical cores, 4 logical
RAM	min. 16 GB
Operating system	Windows 7 Professional or Ultimate SP1 or later, Windows 10 Professional 64-bits
HDD	Minimum 256 GB
Screen resolution:	minimum 1920 x 1080 (Full HD), 3840 x 2160 (4K) (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)
Communication ports	2 available USB minimum 2.0 ports
Mouse	Mouse Wheel

3 SAFETY

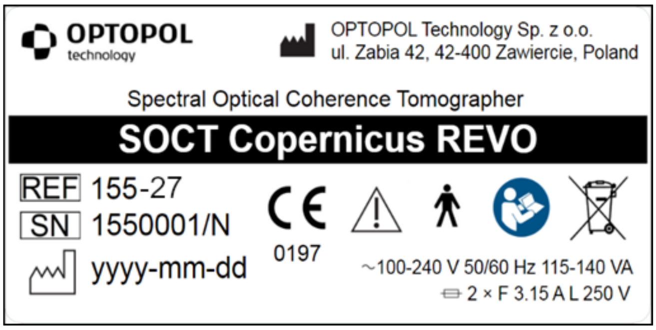
3.1 Safety information

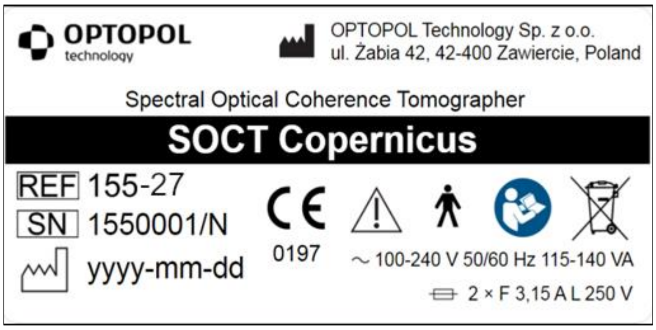
	CAUTION
	Follow operating instruction
	Indicates a fuse is present near this symbol
	On / Off
	Type B Applied Parts
	Date of manufacture
	Manufacturer
	Electrical and Electronic Equipment waste. Do not throw the product away with normal household waste at the end of its life
	Sign of conformity with essential requirements – The Medical Device Directive 93/42/EEC
	Class 1 Laser Product
	Warning: Dangerous voltage
	General warning sign
	Warning: Laser radiation

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

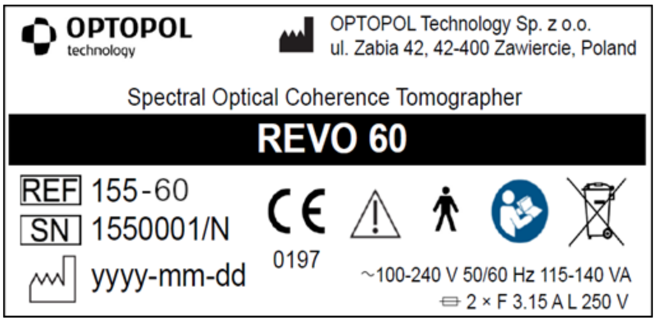
3.2 Product Label

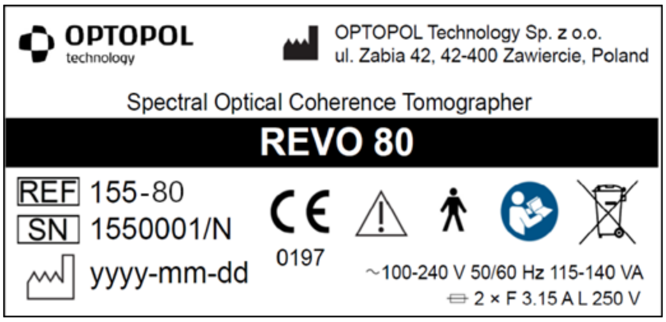
The sample label of the SOCT Copernicus REVO/SOCT Copernicus is presented below.



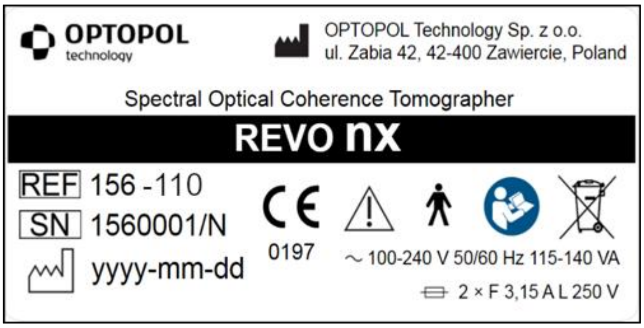


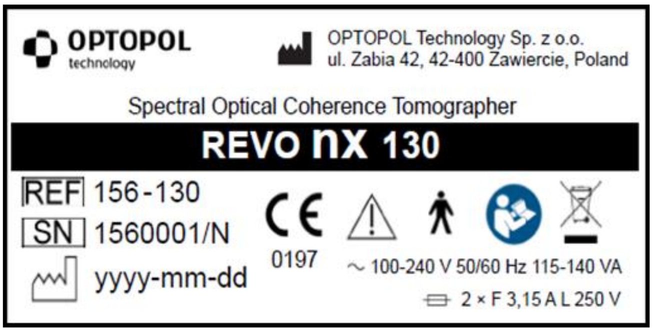
The sample label of the REVO 60/REVO 80 is presented below.

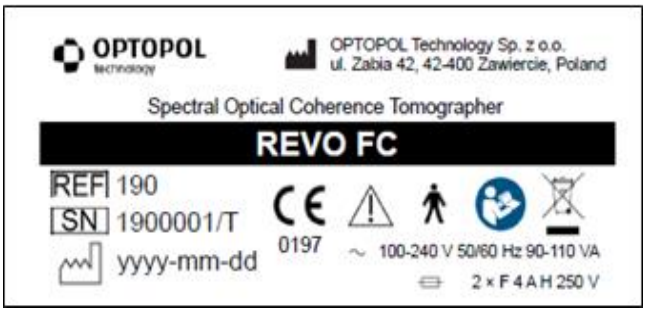




The sample label of the REVO nx is presented below.

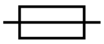
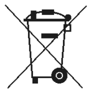






The sample label of the REVO FC is presented on the right.

The following table describes the marks and indications on the product label.

	Manufacturer’s name and address
	Year of manufacture
SN	Serial Number in eight digits and coded year of production
CE	Sign of conformity with essential requirements – The Medical Device Directive 93/42/EEC; 0197 - Notified Body Number
	Type B Applied Parts
	Follow operating instruction
	Caution
	Indicates a fuse and specification of the fuse
~	Alternating current
	Electrical and Electronic Equipment waste. Do not throw the product away with normal household waste at the end of its life
REF	Catalogue Number
R_x Only	Prescription Use Only (U.S.A)

3.3 Safety standards

CAUTION: Before the first use, the device operator should be trained how to use the system efficiently and safely.

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

The SOCT system complies with all requirements of the directive 93/42/EEC (MDD - Medical Devices Directive).

The SOCT is type B applied parts (chin rest support and forehead support) and class I protection against electric shock.

Usually SOCT is a part of larger Medical System, which consists of many other medical and non-medical devices. Medical system in general and all its components have to fulfill the requirements of IEC 60601-1 standard.

In order 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 fulfills requirements of IEC 60601-1 standard for medical electrical system.

The Isolating Transformer supplies the power for non-medical devices connected to electric not grounded mains in a room.

The Isolating Transformer can be installed in patient environment in accordance with IEC 60601-1 standard.

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

NOTE: Only the PC, monitor and printer have to be connected to the isolating Transformer. Connecting non-medical devices in other way than presented in chapter 3.3 Safety standards can lead to electric shock or damage of the devices.

NOTE: It is strictly forbidden to connect any non-medical or medical devices which are not included within the SOCT system to the Isolating Transformer e.g. lamp, vacuum cleaner, etc.

NOTE: The SOCT must not be connected to the Isolating Transformer, but directly to the main power supply socket or to the dedicated supply socket in the dedicated table.

NOTE: In situation when the cameras housing cover is removed, while examining the patient, the system operator must not touch at the same time the patient and uncovered parts of the device.

SOCT is connected to PC using USB 3.0 cable.

There are no user serviceable parts inside SOCT device. Light source is included inside the device. Removing the covers can be done only by authorized personnel.

The maximum power of light radiation available outside the covers is less than 1650 microwatts providing safe operation of the device.

Objective lens is the output of light.

SOCT has been classified as a CLASS 1 laser device.

IMPORTANT:

1. If the whole Medical System has been installed by Manufacturer of SOCT or Authorized Personnel, the manufacturer guarantees correct installation and compliance with all required standards and directives.

2. In case installation was made not by Manufacturer or Authorized Personnel, the manufacturer of SOCT takes no responsibility for any problems or risks that could be created by incorrect connection and violation of safety standards.

3. Understanding and following up of chapters 5 SOCT SOFTWARE, 6 PATIENT WINDOW, 7 EXAMINATION WINDOW, 8 CONDUCTING EXAMINATION and 9 RESULT REVIEW of this manual as well as PC experience are sufficient for operating the SOCT device.

4. Manufacturer of SOCT takes no responsibility for incorrect medical diagnosis of results and takes no responsibility for the consequences of such incorrect medical diagnosis.

3.4 Warnings

Warnings indicate hazards that, if not avoided, 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: Medical 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 mains supply with protective earth. Ignoring safety rules can lead to accidents.

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

WARNING: Any Additional Multiple Socket-Outlet or extension cord shall not be connected to the ME System.

WARNING: All activities that demand removing main body housing may be performed by Manufacturer or Authorized Personnel trained by Manufacturer only.

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

WARNING: No modification of this equipment is allowed.

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

WARNING: The system cannot replace clinical judgment and is intended to be used only in conjunction with other clinical tools considered to be the standard of care 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. A patient diagnosis is the sole domain of a licensed eye care clinician.

WARNING: 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 cause a safety hazard, the cleaning solutions, including water, should not be directly applied to the device. Using a dampened cloth (without dripping) is a good 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 his or her body to an electrical device that is not powered by the system. In addition, while examining the patient, the system operator must not touch at the same time 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 Real Corneal Power value determined by the topography 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 replace a value from another device into your standard IOL calculation formula.

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

WARNING: Users must check measurement readings for plausibility. This includes the checking of the detected position boundaries on 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 take into account the type (e.g., posterior subcapsular cataract) and density of the cataract when evaluating plausibility.

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

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

WARNING: All maintenance activities can only be made 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 authorized service staff.

WARNING: The main lens of the device should not 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 because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

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

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

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 at all times. 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.

3.5 Cautions

Cautions indicate hazards that, if not avoided, may result in property damage or injury.

CAUTION: This manual does not provide guidance on interpretation of clinical results. The clinician must ensure that he or she has received appropriate medical training in such interpretation. OPTOPOL Technology Sp. z o. o. cannot be held responsible for misdiagnosis of results.

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

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

CAUTION: Before the first use, the device operator should be trained how to use 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. Infants, aphakes, 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 with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography. This medical device has no user adjustable intensity settings for light incident on the retina, nor does it produce UV radiation or short wavelength blue light.

CAUTION: Be extremely cautious when examining high risk group of optical radiation, patient without crystalline lens, infants and patient who is insensitive to light for having ocular fundus disease with optical coherence topographer (OCT).

CAUTION: The SOCT weighs approximately 23 kg or 30 kg. It should be lifted by at least two persons. Use only the indicated positions for lifting.

CAUTION: Be careful when mounting anterior adapter in order not to scratch the objective lens.

CAUTION: Be sure to keep the patient's face away from the chin rest and forehead rest when the Anterior Chamber Adapter is still attached. Otherwise, a patient may be injured by the Anterior Segment Adapter making contact with him/her when the scanning head moves in any direction.

CAUTION: DDLS scale bases on a publication by George L. Spaeth, MD in 2002, and can only be treated as supplementary information and cannot be treated as disease confirmation. Use for reference only.

CAUTION: KPI bases on a publication by Naoyuki Maeda in 1994, 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 constants for their particular conditions and practice.

CAUTION While using an A-constant for IOL Calculations Remember that it is an estimate and should only be used for reference if no better constants are available. Use only IOL constants optimized for optical biometers.

CAUTION The software for taking measurements and performing IOL calculations must be operated only be appropriately trained and experienced staff with knowledge suitable for interpreting the results. All members of the stuff must read this user manual thoroughly, paying special attention to the safety related points and instructions.

CAUTION The white-to-white 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 used.

3.6 General notes

Please avoid the use of extension cords or a power strip.

IMPORTANT:

1. If the whole Medical System has been installed by Manufacturer of SOCT or Authorized Personnel, the manufacturer guarantees correct installation and compliance with all required standards and directives.
2. In case installation was made not by Manufacturer or Authorized Personnel, the manufacturer of SOCT takes no responsibility for any problems or risks that could be created by incorrect connection and violation of safety standards.
3. Understanding and following up of chapters 5 SOCT SOFTWARE, 6 PATIENT WINDOW, 7 EXAMINATION WINDOW, 8 CONDUCTING EXAMINATION and 9 RESULT REVIEW of this manual as well as PC experience are sufficient for operation of the SOCT device.
4. Manufacturer of SOCT takes no responsibility for incorrect medical diagnosis of results and takes no responsibility for the consequences of such incorrect medical diagnosis.

NOTE: OCT image 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. For example, a relatively flat retinal OCT image might not reflect the true curvature of the retina.

NOTE: The OCT image can be affected by the optical pathway, that is, by corneal opacity, cataract or eye shape.

NOTE: The SOCT 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 in any way, can 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 voids the warranty completely and can cause safety hazards.

NOTE: Cornea Layers recognition is used for tracing.

NOTE: For Corneal topography scan fully examine the measured tomograms for layer recognition and examination results. In particular, 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 layers recognition and/or reliability indices on the check screen. If the measurement result is not conclusive, review the inspection result by performing measurement again or performing another inspection.

⚠ **NOTE:** Allow only well-trained operators to use the instrument

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

⚠ **NOTE:** When using corneal topography or biometry data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking measurements multiple times and/or conducting other examinations.

⚠ **NOTE:** 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 severe complication such as keratectasia.

⚠ **NOTE:** Since simultaneous use of multiple devices can cause misdiagnosis or result in a hazardous situation, exercise caution when using this instrument

⚠ **NOTE:** For Topography and Anterior scan it may be difficult to recognize the boundaries when capturing an image of an eye with opacity or malformation such as corneal disease, shallow anterior chamber, aphakic eye, pseudophakic eye or dense cataract eye. In this case if required to correct the layers or reject measurement values. Oct image

⚠ **NOTE**: No SOCT is intended to be used as the sole diagnostic aid in disease identification of classification.

⚠ **NOTE**: The following artifact may appear on the OCT image, but this does not indicate any failure.

⚠ **NOTE**: When the measurement light enters the cornea, sclera, conjunctiva or intraocular lens perpendicularly, a bright line appears in the depth direction.

⚠ **NOTE:** Ghost noise may occur in areas with strong reflection such as cornea, sclera, conjunctiva and iris.

NOTE: Correct patient fixation and alignment centered on the pupil are both critical to obtaining a consistent corneal power measurement.

NOTE To ensure plausibility of IOL Calculation 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.

NOTE The user should always seek to ever 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 3 months after the surgery.

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

NOTE As the Anterior Chamber, wide Angle to Angle and Pachymetry scans are compensated for beam scanning geometry and reflection from the surface of the cornea, 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 this way.

3.7 Notes on Use

3.7.1 *Before use*

- Inspect the SOCT daily. Make sure that no foreign matter on the front lens is present that can affect image readings or diagnoses.
- 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 take good images if the objective lens is dusty.
- Sudden heating of a room during winter or in cold regions may cause condensation to form on the objective lens or on optical parts inside the SOCT, resulting in an inability to obtain optimal images. In this case, wait until condensation disappears before taking images.
- Before turning the device on, make sure that Anterior Chamber Adapter is not installed on the objective lens.

3.7.2 *After use*

After using the SOCT device, turn off the power, attach the objective lens cap to protect the objective lens from dust and place the dust cover over the device.

4 UNPACKING AND INSTALLATION

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

The SOCT set consists of the following components:

1. SOCT device,
2. External fixation adapter,
3. Anterior adapter (not applicable to REVO FC models),
4. Dust cover,
5. USB 3.0 communication cable,
6. Power supply cable,
7. USB Flash drive with the SOCT software, drivers and the User manual,
8. Calibration tool (option),
9. Chinrest papers.

4.1 Unpacking

This section describes how to unpack the device shipped from the factory. Remove the top of the box and side walls. Remove transport foams. The figures indicate where to grab the SOCT during moving. It should be lifted by at least two persons. Firmly hold the instrument body at the base of device as indicated below, and put it on the automatic instrument table. Do not lift the device holding it by indentation area located at the back of the device above the rear panel.

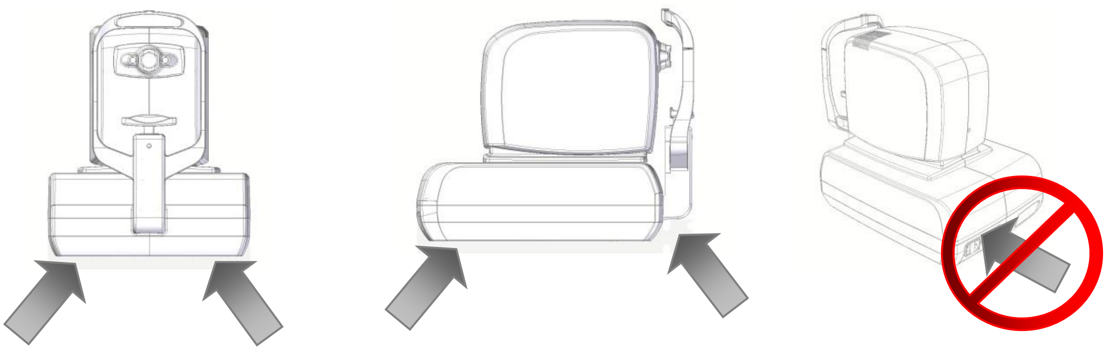


Figure 1. REF 155 and 156 series device

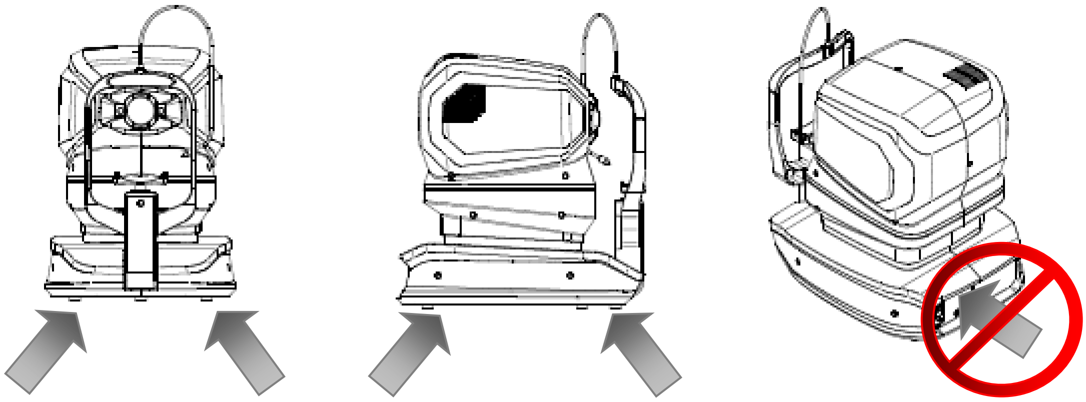


Figure 2. REF 190 and 193 series device

CAUTION: The SOCT weighs approximately 23 kg or 30 kg. It should be lifted by at least two persons. Use only the indicated positions for lifting.

After unpacking, one should check the whole set for any mechanical damages, cables damages, etc. In case any damage is found, don't connect the device and contact your local distributor.

IMPORTANT: Always let the device reach room temperature before it is powered up. This is particularly important if the device was exposed to extreme temperature. Always operate the device within operating ranges of temperature and humidity.

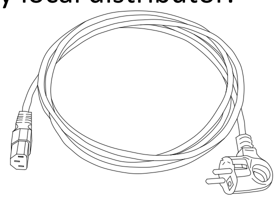
Transportation position of the SOCT device is to be set by turning it off and on – the device will go to base position. Turn it off and pack to the box securing with packing foams.

4.2 Connecting cables

To connect the SOCT to a PC, you need one USB 3.0 cable shipped with the device:

USB 3.0 cable to connect SOCT (type B) and PC (type A):

Power supply cables are provided by local distributor.



All sockets and plugs are different, so it is not possible to connect plugs improperly. The figure below shows the rear panel view of SOCT.

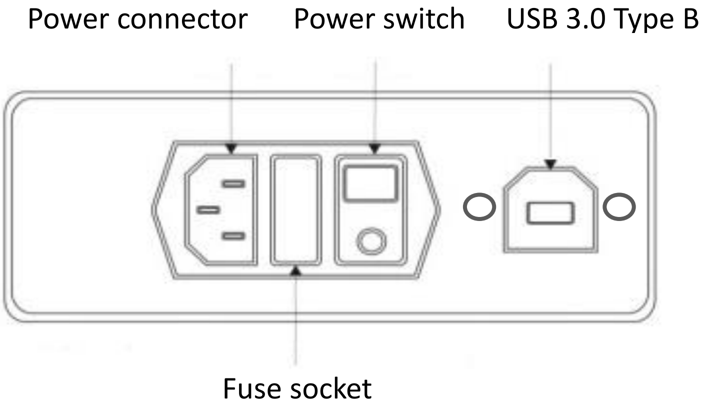


Figure 3. Rear panel of the REF 155 and 156 series device

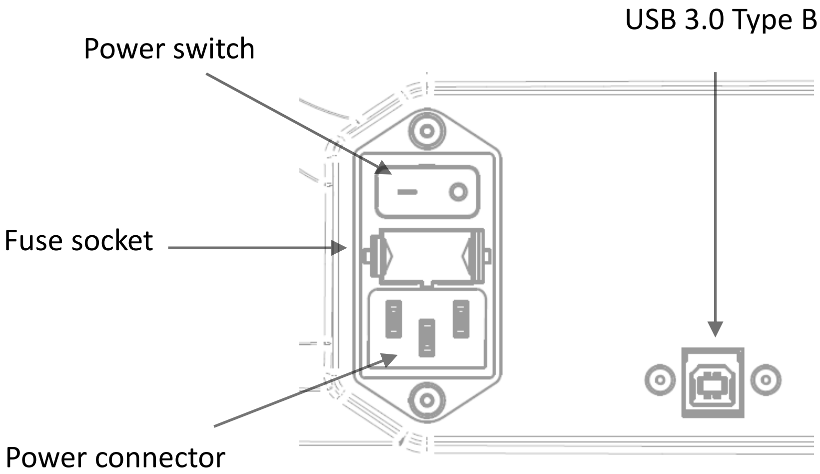


Figure 4. Rear panel of the REF 190 and 193 series device

First connect USB cable, in the next step connect power supply cables.

The power switch has two positions: I – the device is ON, O the device is Off.

⚠ **NOTE:** To remove power from the device turn OFF the power switch (Position O) or unplug the power cord from the wall or from the device.

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

4.3 Device connection

The SOCT is connected to the PC using USB 3.0 cable.

NOTE: The SOCT must be directly plugged into the mains with protective earth. 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 mains with protective earth pin.

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

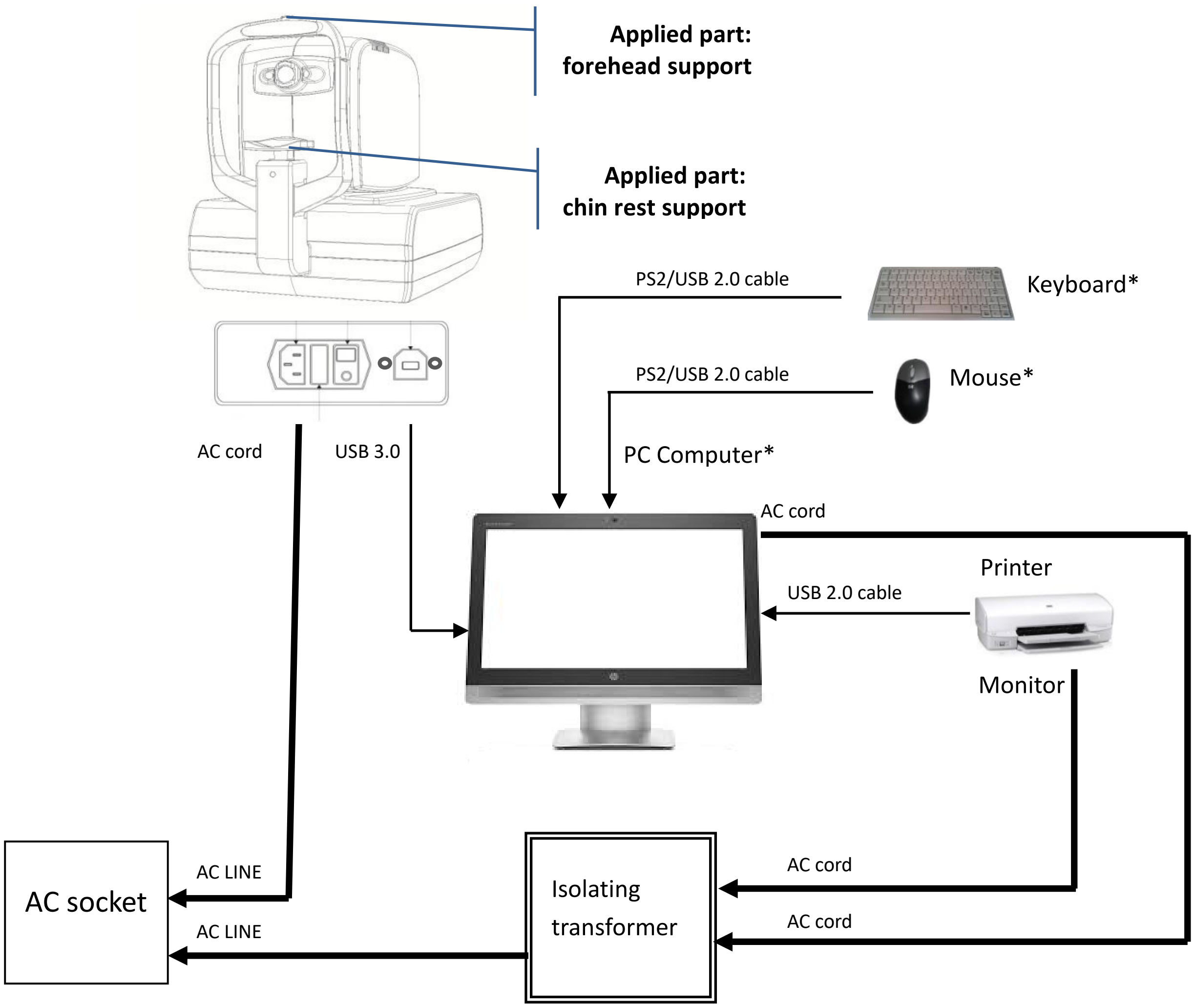


Figure 5 Electrical connection scheme

* - Elements of medical system are not provided by OPTOPOL Technology.

- REVO FC

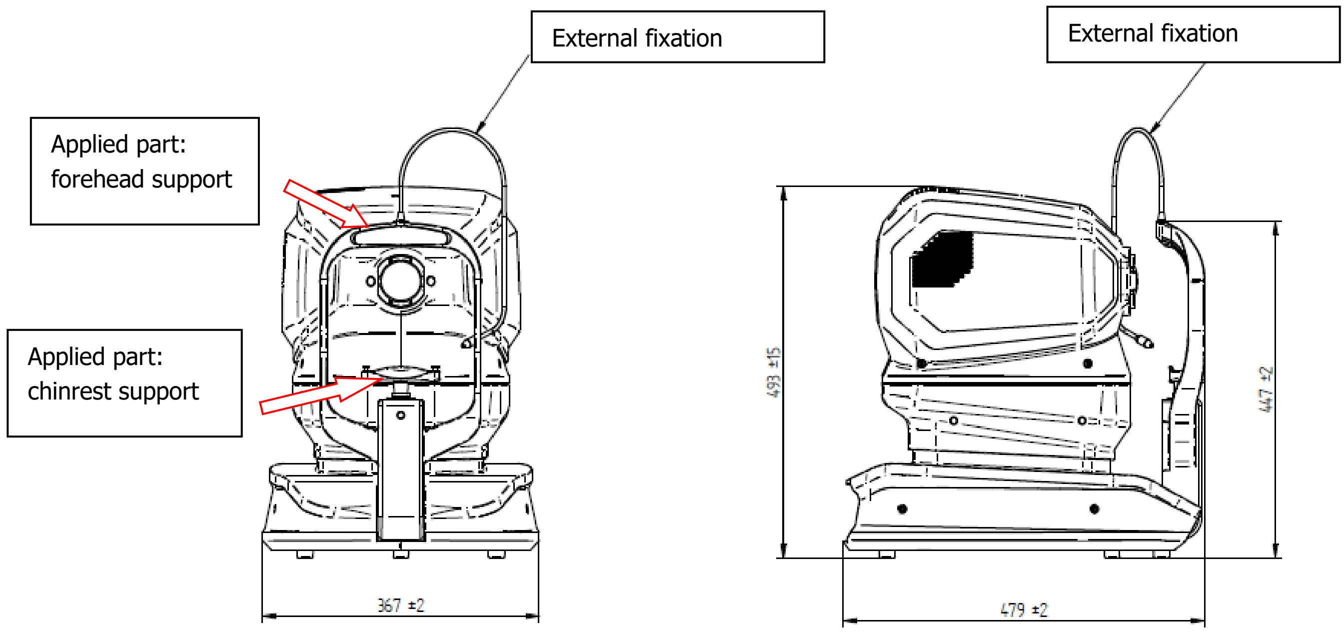


Figure 6. The chassis (front and side), applied parts and external fixation of the REVO FC

- REVO

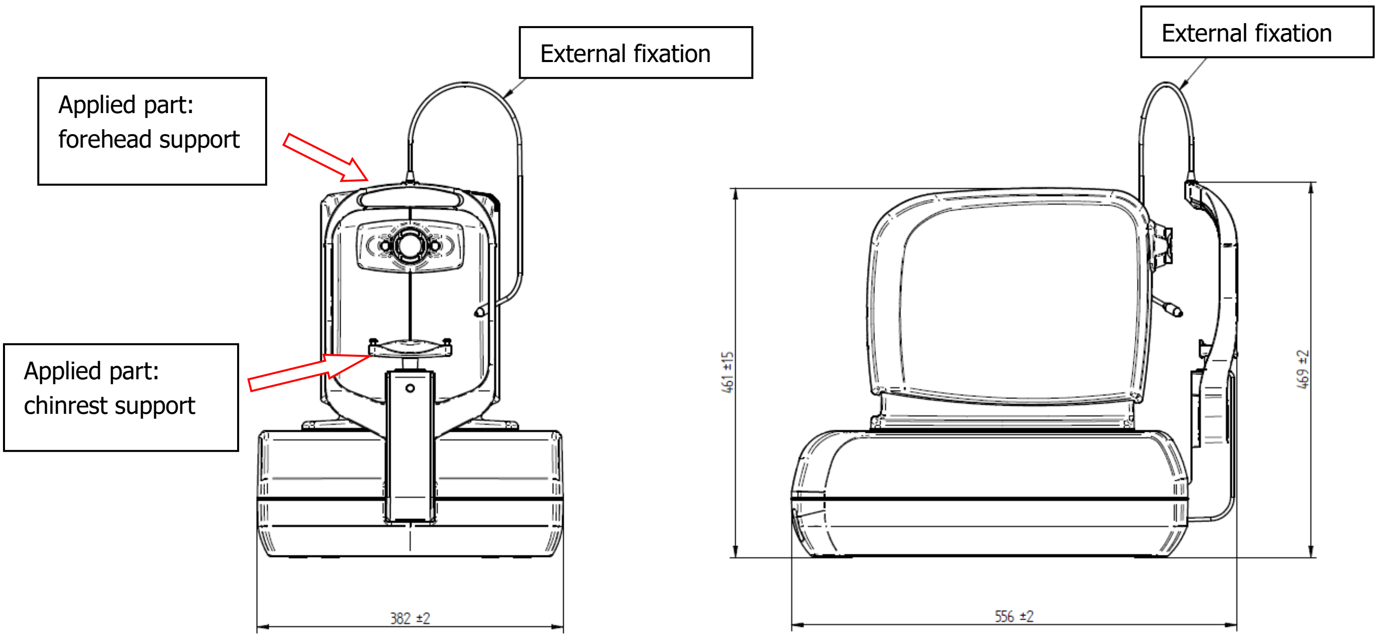


Figure 7. The chassis (front and side), applied parts and external fixation of the REVO

4.4 Factory default calibration and configuration

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

On the computer connected to the SOCT screen saver, power options on the computer have to be set as shown in the table.

Items	Settings
Screen saver	None
Turn off the display	Never
Put the computer to sleep	Never
Turn off hard disks	Never
When I press the power button	Shut down
Start menu power button	Shut down

5 SOCT SOFTWARE

IMPORTANT: Always turn ON the PC first and then turn ON the SOCT device.

5.1 Running SOCT application

After the Windows operating system is started and initialized, it is possible to run SOCT application: press *START* → *Application* → *SOCT* → *SOCT*. Click SOCT icon and the application will be loaded and activated.

NOTE: The device is ready to work when software is opened and the status is READY.

5.2 SOCT application structure

The application has been created to be user-friendly. The buttons are clear and located ergonomically what makes the usage very effective.

The Login screen will appear after starting the SOCT application.

Figure 8. Login screen

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

SOCT software is divided into three different modules which can be easily accessed from tabs:

PATIENTS	Patients and exams list appear after logging in the application. It enables to easily handle patients' database.
ACQUIRE	It contains all controls necessary for performing a new examination.
RESULTS REVIEWS	It enables to preview previously taken examinations, make quantitative analysis and compare results.

6 PATIENT WINDOW

The Patient tab will appear after login screen. Patient tab enables the user to easily manage patients' database:

- add new patients to the database,
- delete patients from the database,
- edit patients' personal data,
- enter remarks regarding patients,
- import/export data.

All the controls of main window with short description are shown in the picture below.

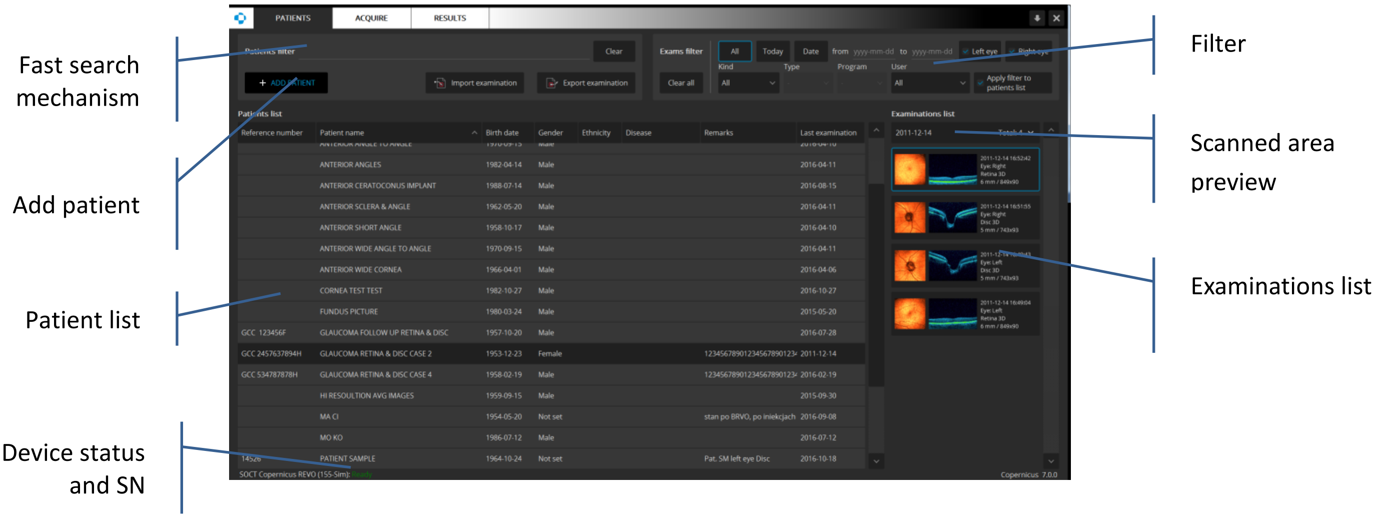


Figure 9. Patient tab

Result	It enables to preview and analyze taken examinations.
Software version	Version of application.
Device Status and SN	Device status (Ready, Busy or not connected) and Serial Number.

6.1 Patient list view

By default, patients are sorted in the list by **Patient name**. Click the **Reference number** header to sort them by ID number. It is also possible to sort by another column.

In order to search a specific patient in the list you can enter a few first letters of the name in patient filter-box. System will show the closest matching-record. Customization of the patient list is available.

It is possible to customize the patients list view. To hide columns: Gender, Ethnicity, Disease and remarks, Right Click over the header to open menu. Uncheck unwanted column from menu. To customize width of each column, grab the end of the column’s header and move to desired position.

Patient filter: use this field to quickly find a patient on the list.

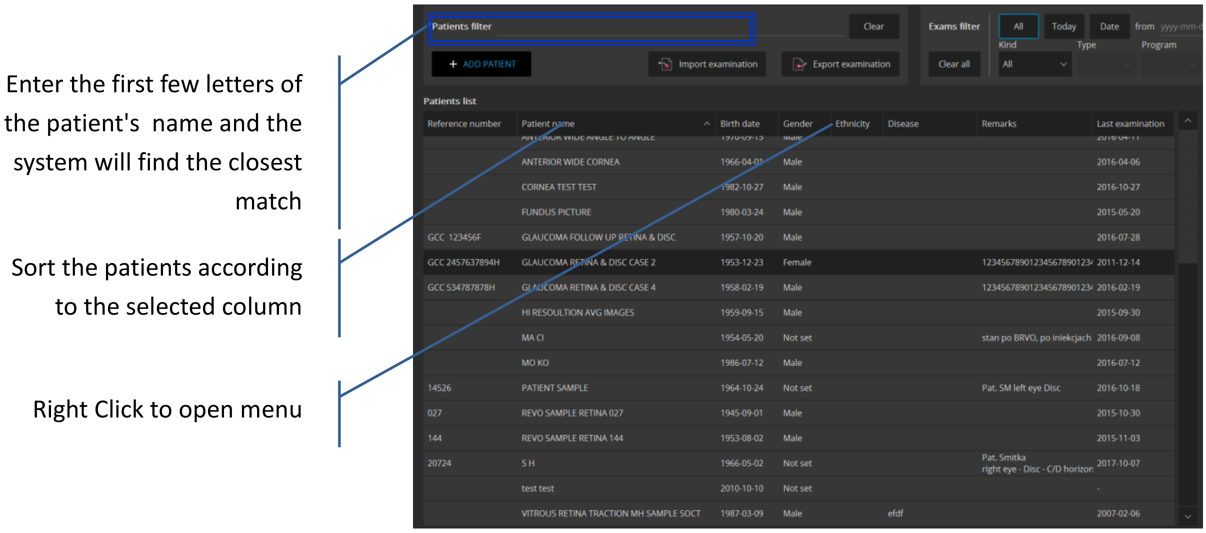
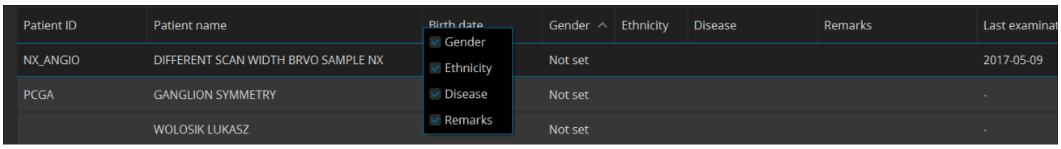


Figure 10. Patient list

6.1.1 *Customization of the patient list view.*

It is possible to customize the patients list view. To hide columns: Gender, Ethnicity, Disease and remarks, Right Click over the header to open menu. Uncheck unwanted column from menu. To customize width of each column, grab the end of the column’s header and move to desired position.



6.2 Registering new patients

In order to register a new patient, click button **[Add patient]** in the main window. Patient registration screen will open. Patient's first name, last name and date of birth must be entered in proper fields.

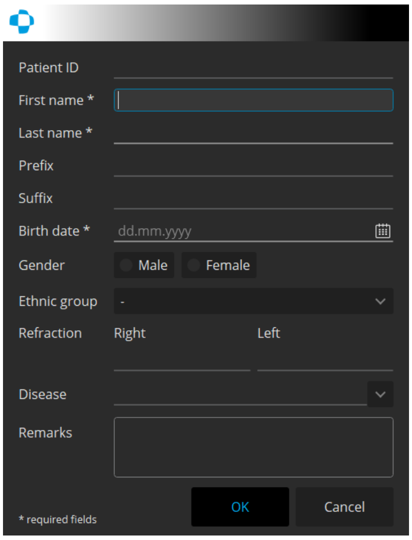


Figure 11. Patient edit screen

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

NOTE: For patients with refractive error bigger than -/+ 5D it is recommended to fill in refraction during adding patients to the system.

NOTE: Filling refraction fields transfers information into 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 22.5.8 Input settings window.

When all the data are entered, click [Enter] to confirm registration. The system will check if the data are correct. If not, it will ask for correction.

NOTE: Make sure you entered correct patient name and date of birth. It prevents you from data loss and helps to avoid empty records in the patients list.

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

> [Patient with same Name, Last Name, DOB and unspecified or different Ref No. is already registered. Do you want to [Edit details] or [Cancel].

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

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

It means that there is a suspicion, that the patient already exists, but the reference number was entered incorrectly. The operator should make sure the data is correct and can decide whether to register the patient or cancel registration.

6.3 Editing personal data

In order to edit currently selected patient's data, find the patient on the Patient list, Right-Click over patient record and select **[Edit]**. The patient registration screen will appear. After checking patient's data~~,~~ click [OK] button to confirm changes. System will check the data once again and display a warning message if entered data are incorrect. Then the same checking will be done as during the registration of a new patient.

6.4 Unregistering patients

In order to unregister currently selected patient, Right-Click and select **[Delete]** from the list. A warning message will be displayed.

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

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

> All examination data of 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. Please make sure you are deleting the proper patient.

6.5 Examination list

Examination list contains detailed information regarding the examinations. Thumbnail of scanned area – fundus reconstruction for posterior scans or eye preview for anterior and thumbnail of scanned image are displayed first. Behind thumbnails exam information such as date and time of examination, Eye, Analysis program, Scan width, Scan dimension and number of A-scans and B-scans are presented.

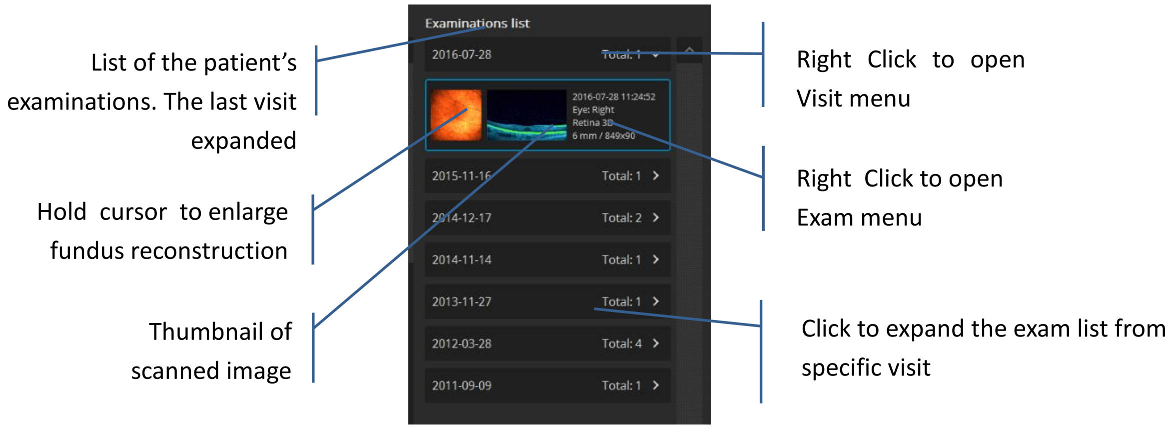


Figure 12. Examination list

Examinations on the examination list are shown in order of date. The examinations are sorted by visits. As default expanded is the Last visit.

Clicking the date panel stores the examination or shows it expanded.

Right-Click mouse button over the examination opens the menu:

Correct	When selected system can use examination for automatic display in Both, Comparison and Progression tab.
Follow up	Allows to repeat examination. Opens Acquire window and loads previous settings.
Cut exam	Select if you want to move examination assigned to wrong patient
Delete	Remove examination from the database.
Output	Output exam results. Configure Output set
Export	Save .oct examination in raw .opt format
Reanalyze	System processing examination data

Right-Click of mouse button over the visit date opens the menu:

Cut visit	Select if you want to move all exams from a visit assigned to a wrong patient
Output visit	Output results from whole visit
Export visit	Save all oct examinations in raw .opt format from the visit

6.6 Deleting Exam/s

Right-click on exam thumbnail and select [Delete].

6.7 Connecting scans connected to the wrong patient

The user has the option of moving examinations from an incorrect patient association, to the correct patient association. It is possible to move single exam or move whole visit.

1. Select the Examination/s or the visit from Examination list - examination you wish to move.
2. Press the right mouse button on and press [Cut examination or Cut visit].
3. Select patient on the "Patients list" where you wish to move examination.
4. Press the right mouse button and choose [Paste examination/s].

6.8 Exporting examinations

The SOCT offers the ability to export examinations data in raw format as .opt file. Exported examination in .opt can be imported to SOCT application. Export data procedure.

Examination/s export procedure:

1. Select the Examinations on "Examinations list - examination you wish to export.
2. Press the right mouse button on the selected examination and choose from the contest menu [Export].
3. Choose folder and press [Save].
4. At the end the following window appears.

   [Examination has been exported]

5. After pressing [Ok] the procedure is completed.

6.8.1 *Export with anonymization*

SOCT gives the possibility to export examinations with anonymization. Before exporting with anonymization, the user must define the anonymization settings in the setup window (see chapter 22.5.6 Anonymization).

1. Select the Examinations you wish to export on the "Examinations list".
2. Press the right mouse button on the selected examination and choose [Export anonymized] from the contest menu.
3. Choose the folder and press [Save].
4. At the end, the following window appears. [Examination has been exported]
5. After pressing [Ok] the procedure is completed.

6.9 Importing examinations

Allows to import examination from the desired location. The system accepts .oct and .opt format only.

6.10 Filter

The filter window helps to find examinations easily in the database. System filters examinations according to all-patients. In order to apply filter, select the desired criteria.

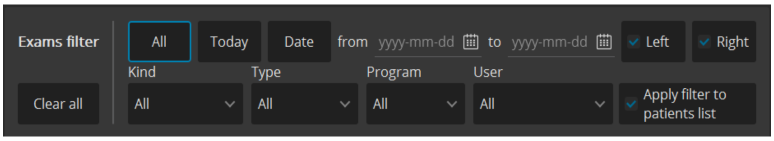


Figure 13. Filter panel

User can filter examinations by date:

All All examinations are displayed.

Today “Today’s” in the list of patients you will see only that/those examination/s which has/have been made today - all others will be hidden.

Date From - To Select specific Date range by selecting the start day [From] to last day [to]. In the list of all examinations you will see only that/those which has/have been scanned between selected days.

Eye If you want to hide examinations of Left or Right eye, unmark check box labeled “Left eye” or “Right eye”.

Kind The filter allows to filter by type exam. It can be oct result or imported examination.

Type Retina, Disc, Anterior, Central – depending on the analyzing program different views are available.

Program Raster, Radial, 3D, single B-scan etc.

Users Filter patient by operator who made examination.

Use [Clear all] to reset the filter settings and disable filtering.

6.11 Output

From the Patient tab it is possible to output results from the:

- Single exam
- All examinations from single visit
- All patient results.

Right Click on the exam thumbnail, visit identifier or on the patient record and select Output option from the menu. It is possible to output Reports, Tomogram or series of tomograms. More details can be found in chapter 22.7.1 Output set window.

6.12 **Work list**

Work list tab appears only when SOCT is configured to work with external software via CMDL or MWL interface with third companies' software. On the worklist a list of awaiting patients appears. User can select (double click) the record from the worklist and start examination. If patients exist, the system finds the patient, if patient does not exist, system adds the patient to the database. System retrieves work list from the server periodically or on the user request then it is required to press [Update]. With the patient lists operator can receive the examination request. In this case software will load required exam or protocol.

7 EXAMINATION ACQUSITION TAB

Examination acquisition tab is used to perform a new examination. In order to open the examination window, click the “Acquire“ tab at the top of the Main window. An example of the examination window is shown below:

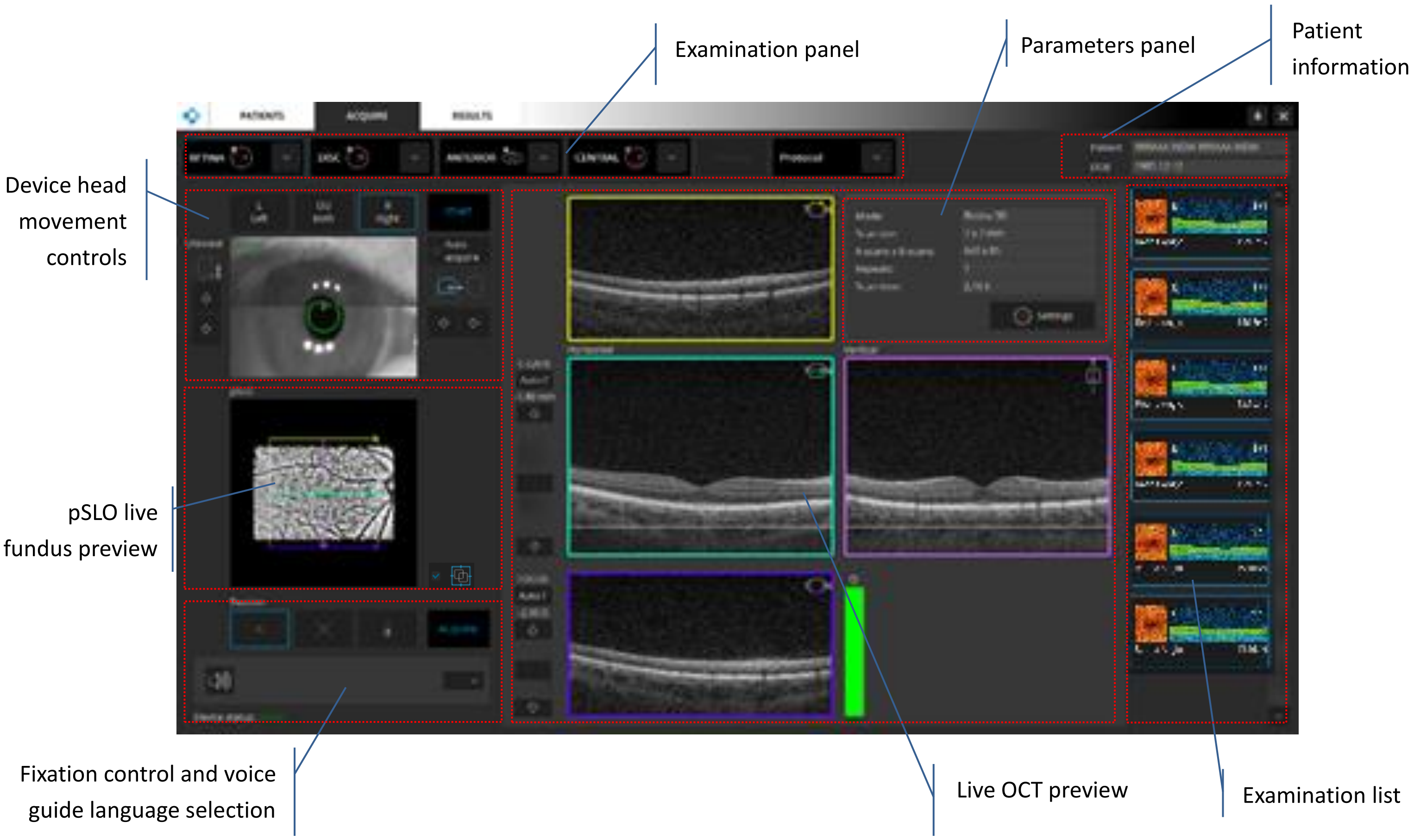


Figure 14.Examination window view for REVO nx / SOCT COPERNICUS REVO/ SOCT COPERNICUS / REVO 60/REVO 80

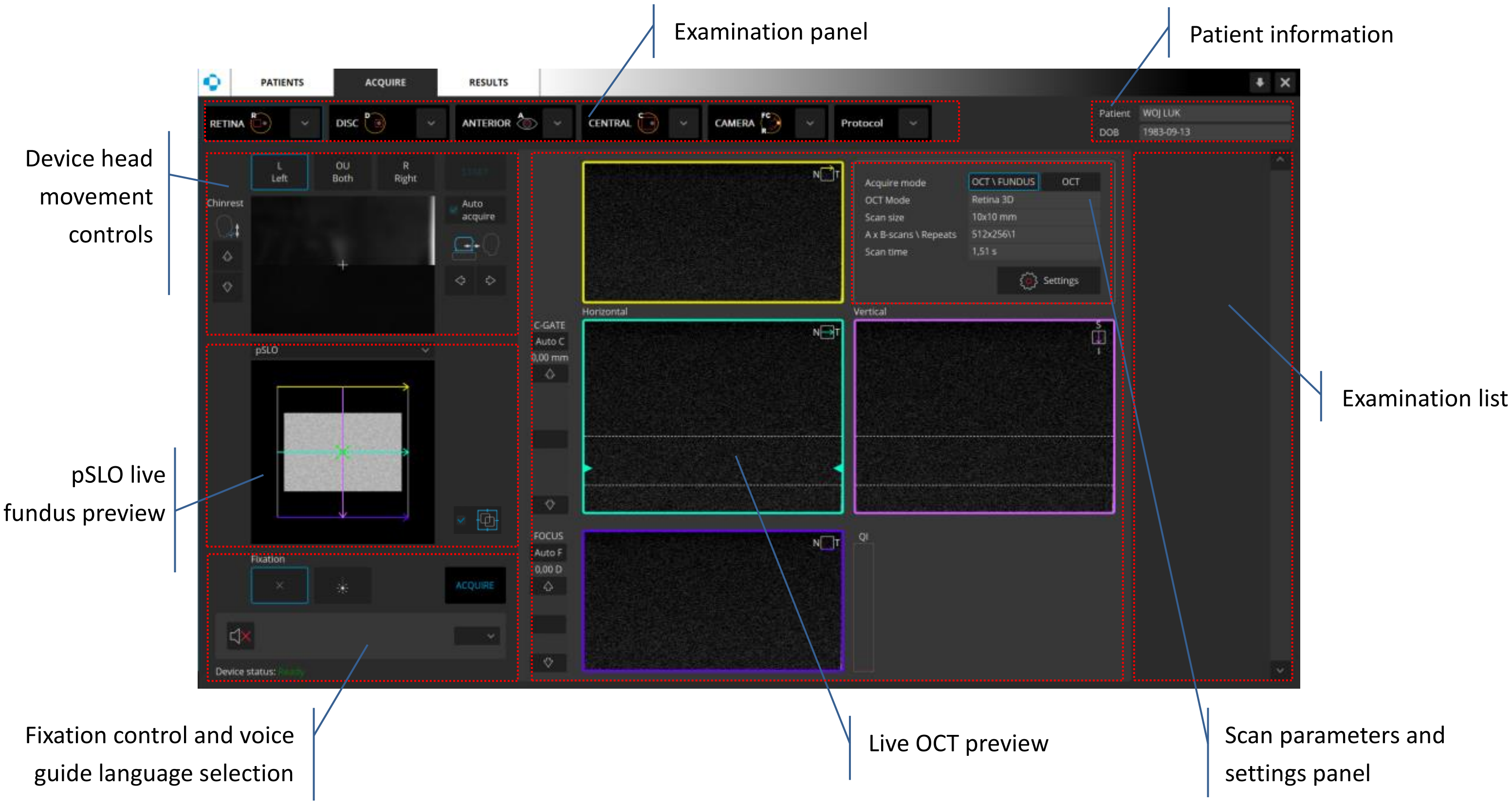


Figure 15. Examination window view for REVO FC

<u>Examination Panel</u>

1. Scan mode - enables the user to choose the mode of scanning. For each eye area (Retina, Disc, Anterior, Central) a set of examinations is available. Each examination has its own predefined settings.

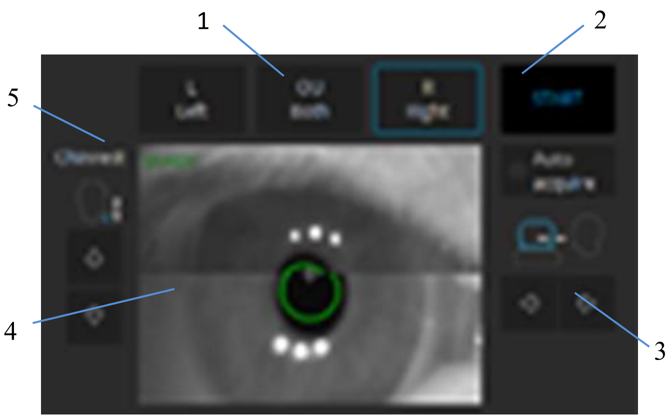
2. Scan program - press to expand the list of programs. Press the icon to load the desired program.

3. Camera (Revo FC only) - allows the user to take a color fundus photo without performing an OCT examination.

4. Fundus preview switch (Revo FC only) - IR/pSLO IR/pSLO mode are available. Live IR – Live fundus preview in Infra-red mode

5. Scan protocol - press to expand the list of protocols. It enables the user to select a protocol with predefined set of exams.

Movement control



1. Eye selector - the measurement unit moves to the patient's selected eye.

2. Start - press the start button to automatically align and optimize the scanning signal. When Auto Acquire is checked the system will capture an examination.

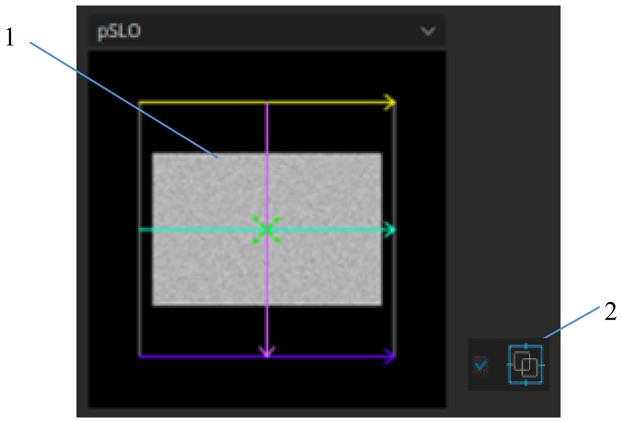
3. Forward/backward control - move the scanning head towards or away from the patient.

4. Eye preview - anterior segment image. The displayed view is created from two cameras.

5. Chinrest controls - buttons used to adjust chinrest height (patient’s head position).

Detailed instructions on the operation of the movement control panel can be found in section 7.4 Device head movement controls.

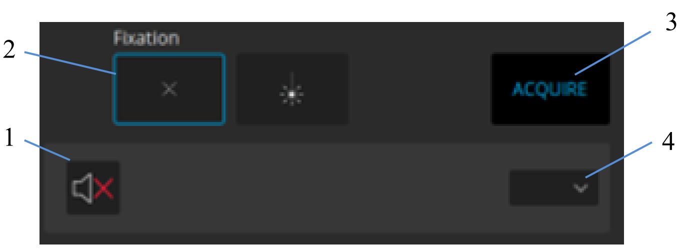
psLO preview



1. pSLO preview - the projection (enface) image of fundus will appear when proper alignment is achieved. On the preview it is possible to change fixation position, scanner offset and scan angle.

2. iTracking button - select checkbox to use the iTracking technology.

Fixation control and voice guide control



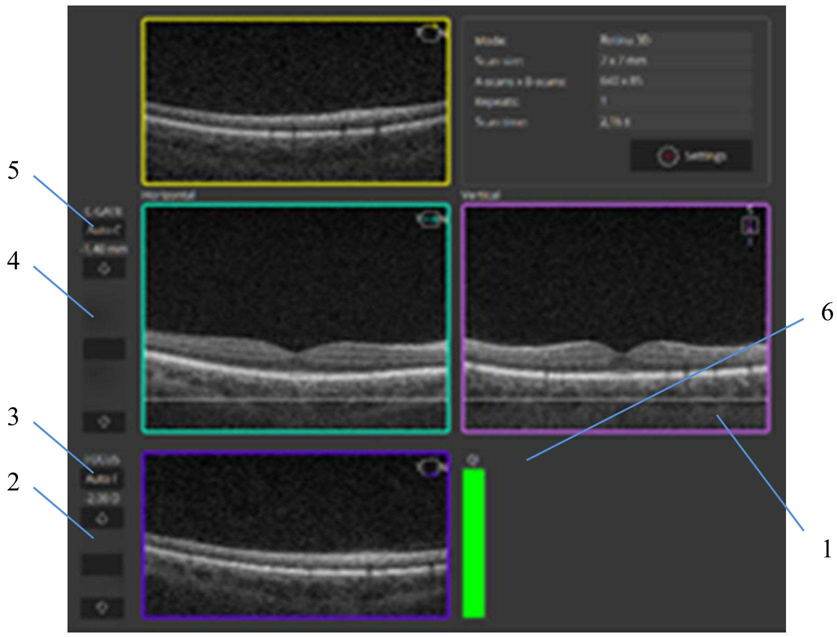
1. Voice guide – the icon shows the status of the voice guidance system. Press to mute/unmute. The voice guidance system guides the patient through the process of acquiring the examination. In Setup Sound tab you can customize or disable the voice guidance function. For more details see chapter 22.5.4 Voice messages.

2. Fixation control - changes shape of the fixation target or selects external fixation.

3. Acquire - press to start acquisition of data.

4. Voice guidance language - click to open the list. It allows the user to change the language of the voice guidance directly from the Acquire window. The language interface remains unchanged. Open the list from the message area and select the desired language.

<u>Live OCT preview</u>



1. Live OCT preview - preview window shows horizontal and vertical live OCT images. The tomograms correspond to the color cross on the pSLO fundus preview window. Note that poorly aligned tomograms have influence on quality of tomograms and reliability of analysis.

2. Focus slider - used to compensate for patient refraction.

3. Auto Focus - automatically compensates the patient refraction values.

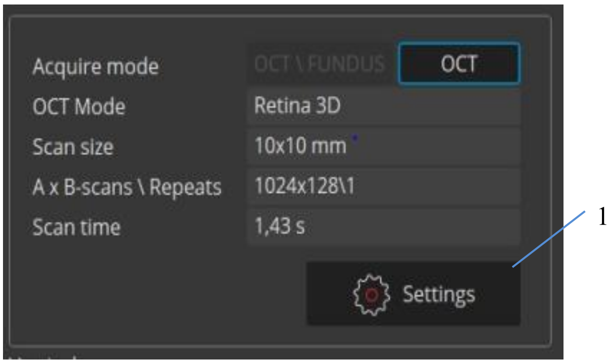
4. C – gate slider - adjusts position of object on the tomogram window.

5. Auto C - Auto C (coherence) gate button to automatically align the OCT image. For patients with refraction error bigger than -/+ 5D it is recommended to fill refraction value during adding patients to the system.

⚠ **Note** To call [Auto Focus] function OCT signal must be visible in tomogram live preview (eye opened).

6. QI index bar - shows signal to noise ratio. Compensate focus to achieve highest saturation of image – try to achieve QI value as high as possible.

Scan parameters panel



Scan parameters panel shows the parameters of the loaded examination.

1. Settings - enables the user to change the parameters of the exam such as width, number of A-scan, number of B-scan, exam mode (vitreous or choroid).

List of examinations

List of taken examinations - shows the previews of taken examinations.

1. Thumbnail - double click on the thumbnail to open chosen examination in the tomogram window.

Patient information

Patient information section - shows personal data of the patient

1. The field Patient presents the name of the patient

2. The DOB field presents the patient's date of birth

Note There are several conditions in which auto functions processes could fail. For example: dense media opacities, eyelashes or eyelid which block the beam of light, inability of subjects to maintain fixation, strong nystagmus. When adverse condition occurs optimize the OCT signal manually.

Note For patients with refraction error bigger than -/+ 5D it is recommended to fill rough refraction value during adding patients to the system.

Note Before first retina scan examination, if you set the rough focus value (refraction power compensation) the system will align the patient data form according to patient correction for Left and Right eye.

Note It is recommended to verify the refraction compensation set automatically. In case of Auto focus Error function or low QI identifier value try experimentally checking the refraction power above and under initial value in order to obtain the best saturation of scans and highest QI value.

Double click on the refraction value resets value to 0.00D.

When cursor is over focus control panel, mouse scroll enables to compensate refraction.

Lines on the vertical and horizontal window indicate proper position of tomograms.

7.1 Selection of scan pattern mode

On opening the Acquire tab, the Retina 3D scan pattern is selected by default. You may select any pattern mode or scan program by clicking it. Depending on scan pattern different result analysis views are available. In order to combine more than one type of scanning program a protocol can be used. System automatically changes the working distance.

Retina:

Fixation position central: The result shows the tomogram image of the macula and analysis results of retinal analysis for retinal disease and fibers analysis.

Disc:

The fixation target is offset to allow the center of the optic nerve to move to the center of the scanned area. The scan pattern overlay consists of concentric rings to assist in the alignment of the optic disc in the center of scanned area. The result shows the tomogram images of the optic disc, results of thickness of RNFL (Retinal Nerve Fiber Layer) analysis, and quantification of the morphology of the optic disc.

Anterior:

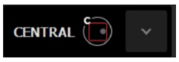
The result shows the tomogram image of the anterior segment and analysis result of the cornea analysis. This section has three groups of scan programs:

[Anterior] group - width of scan programs are 3 - 5 mm.

[Biometry] group – AL and ACD scan programs.

[Topography] group

Central:



The fixation target is offset to allow placing the macula and the optic disc in the center of the scanned area. Useful for peripheral observation.

Protocol:

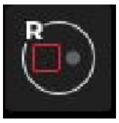
Protocol allows to perform predefined set of exams of different type one by one. This option allows to shorten time used for scanning program selection

CAMERA:

The Fundus Camera mode allows the user to perform fundus photography in the following programs: Central, Disc and Retina.

7.2 Selection of scanning program

User can select the desired scanning program from scan programs panel by clicking mouse cursor on the scan pattern and selecting program from the icon list (R-Retina, D-Disc C-Central, A-Anterior). Scanning parameters are different depending on scan modes and patterns. Operator can reconfigure and save personal settings as default.



3D scanning program consists of a series of equally spaced parallel line scans over a square or rectangle region, the size of which you determine. This program enables precise and three-dimensional reconstruction of retina. In the program, analysis modules give the most reliable and exact results.

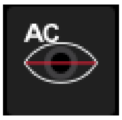
Radial scanning program consists of a series of 2 to 32 equally spaced line scans through a common central axis. This program enables taking scans in high resolution in a few directions. The default pattern has 15 lines of 7 mm length. Operator can adjust the length of scan lines by adjusting the scan width and number of scans.

B – scan Operator can adjust the length and placement of each scan. This program enables taking a single B scan in highest resolution. If averaging is selected, the scanning program scans one place defined number of times. It allows to enhance information and it can be helpful for patients with a gaze problem. A cine loop from scanned places can be observed.

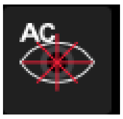
Cross scanning program Enables taking two tomograms (horizontal (0°) and Vertical (90°) of 10mm length. You can adjust the length and placement of scans. This program enables taking B-scans in highest resolution.

Raster This program enables taking 5 B scans in highest resolution. The default pattern is 5 horizontal lines whose length depends on the scan program. You can adjust the length, tomogram spacing and angle of scan.

Full range programs



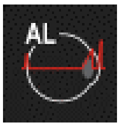
B-scan Anterior Chamber Full range scan of the anterior chamber



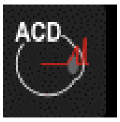
Anterior Chamber radial Full range scan of the anterior chamber

Central Full Range Posterior B – scan

7.2.1 *OCT Biometry programs*

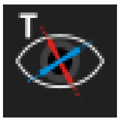


AL – scan provides: AL, CCT, ACD, LT



OCT Biometry[7] provides biometric axial lengths measurement. It is available in the Anterior tab group. ACD – scan program provides CCT, ACD

7.2.2 *OCT Topography programs*

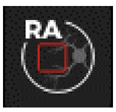


OCT Topography[8] provides the analysis of both surfaces based on Corneal Curvature, Dioptric power, Elevation and Real power analysis based on both surfaces and local cornea thickness.

7.2.3 *OCT Angiography programs**

Allows operator to perform 3D scan. This dye free method allows visualization of retina microvasculature, retinal morphology. For REVO FC 130 available from 3x3 mm to 9x9 mm.

Retina Angiography – This program is dedicated to presenting the highest angiography details. By default, it is set to visualize 3x3 mm scan program.



Retina Angiography – This program is dedicated to presenting the larger view. By default, it is set to 6x6 mm scan program .

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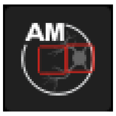
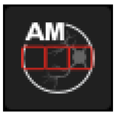
[7] **Biometry OCT** is an optional feature. It is available as an upgrade purchased separately.
[8] **Topography OCT** is an optional feature. It is available as an upgrade purchased separately

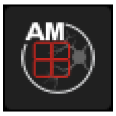
OCT Angiography mosaic programs – merge together 3x3 or 6x6 mm scans to create high resolution mosaics of a larger area.



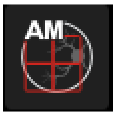
10x6** – This mode contains two examinations. Retina and Disc program.



12x5 – This mode contains 3 examinations. Retina, Disc and nasal side scan.



7x7 – This mode contains 5 examinations. 4 sides scan and one central.



10x10 - This mode contains 4 sides scan.

* **OCT Angiography** analysis is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Optopol's local distributor.
** 10x6 is the only Angiography mosaic mode available in SOCT Copernicus/REVO device.

7.2.4 *Fundus Camera programs**

Central Fundus Photo

Disc Fundus Photo

Retina Fundus Photo

7.2.5 *OCT + Fundus Photography**

3D scanning program + Fundus Photo

Radial scanning program + Fundus Photo

B – scan + Fundus Photo

Cross scanning program + Fundus Photo

Raster + Fundus Photo

OCT Angiography programs with Fundus Photo available with ANGIO module:

Retina Angiography + Fundus Photo

Retina Angiography + Fundus Photo

OCT Angiography mosaic 10x6 + Fundus Photo

* Programs available only for the REVO FC (OCT with Fundus Camera).

7.3 Selection of protocol

The Protocol function enables operators to use a set of predefined scanning programs to capture tomograms according to certain diseases and the anatomy being examined. After acquisition of a tomogram, the system automatically loads the next scanning program from the selected protocol. Check the contents full of the protocol beforehand and select one that is appropriate for tomogram captured.

On opening the Acquire tab the Retina 3D scan pattern is selected by default. You may change to load the protocol on opening the Acquire tab. It is possible to edit, add or remove protocols. See more details in chapter 22.5.2.1 Protocol tab.

User can select the desired protocol from protocol panel by clicking mouse cursor on the [Protocol] and selecting the required protocol from the list box.

Three protocols sets are registered in the SOCT by default. Types of proposed Protocols:

Figure 16. Protocol selection tab.

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

[Glaucoma] This program set captures tomograms of macula and optic disc, cornea and the Angle. Scan programs: [Retina 3D], [Disc 3D], and [Anterior Radial], [Anterior B-scan]

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

7.4 Device head movement controls

System is operated by mouse or touch screen[9]. Press Left or Right eye button to move the device to the desired patient's eye.

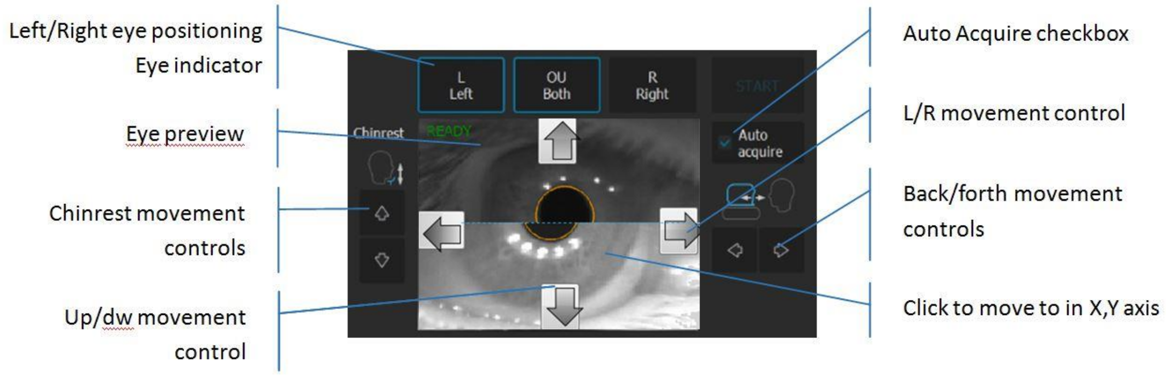


Figure 17. Device movement controls.

[Left] [Right] buttons

Shows examined eye. When clicked it moves the SOCT head across the chosen eye. When the user clicks on already selected eye the head will set for initial Z position across the patient's eye.

OU Both

When [OU Both] button is ON after pressing the [START] button the device will acquire examination of both eyes automatically.

Chinrest control

Press to align patient's head position. The canthus has to be set at level of reference mark.

Eye preview

Anterior segment image. Displayed view is created from two cameras. On the Z working distance, images create one view. Click on the pupil to correct the objective lens position.

[9] Touch screen control is an option. Contact Optopol representative for availability.

Up/Down Left/Right controls	Movement controls buttons appear when the field is active (click or place the mouse cursor over). They control movement of the device's head in Left, Right, Up, Down directions.
Movement controls	Movement controls buttons appear when eye preview panel is active e.g. the mouse cursor is over it or user touched the eye preview panel.
Auto Acquire	When checked system will start acquisition of data automatically after auto alignment of eye structure.

When the cursor is over Eye preview window: scrolling the mouse wheel moves the head back and forth.

On Eye preview the device indicates the end of range movement, by display of red symbol and playing 'Prompt' sound.

7.5 Eye preview

Eye preview window displays views from two cameras. In work distance position the image is composed as single anterior view. System is detecting patient's pupil. When pupil is detected, status READY is visible and [START] button is active. Device has to be positioned in LEFT or RIGHT side as central position will not allow to take proper exam.

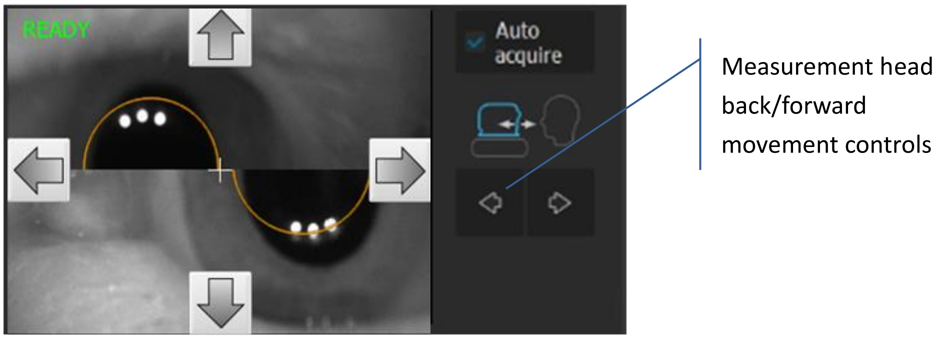
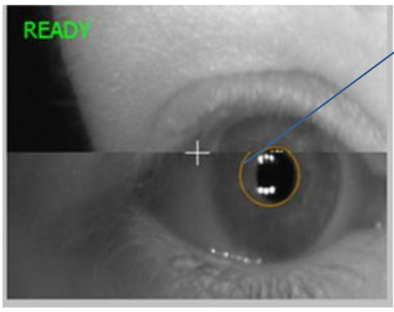


Figure 18. Movement control buttons.

When the cursor is over the eye preview window: movement control buttons (Up/Down/Righ/Left) are displayed, scrolling the mouse wheel or pressing movement buttons, moves the scanning head back and forward. In working position X, Y, Z axis the white cross has to be in the center of equally aligned pupil. When scanning head is in the working distance, click on the pupil to move the scanning head across the center of the pupil (shift in X, Y axis).



Click to center the pupil when working distance is aligned

Figure 19.Device aligns to the place of clicking on the preview

Properly align the pupil to start searching for the oct signal.

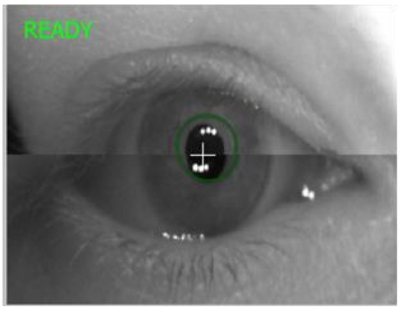
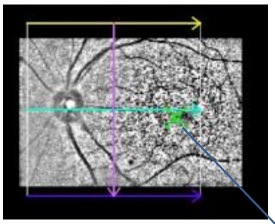


Figure 20. Properly aligned measurement head position

7.6 Fundus preview

7.6.1 *pSLO Live fundus preview*

Pseudo SLO (pSLO) live image shows the enface view of fundus. pSLO image appears when OCT signal is properly aligned. View is overlaid with a box indicating the location of the scan pattern on the fundus and a green cross indicating the location of the fixation target. You can adjust the patient’s fixation by moving the fixation target, and change scanner offset position.



Scrolling the mouse wheel over pSLO can change the working position (compensate edge shadows effected by small pupil during wide and peripheral scan of retina). Click and drag the box to adjust scan placement. Pressing the right mouse button allows to select higher resolution or higher refresh rate from the menu.

Scroll forward to compensate narrowest pupils size pupil

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

7.6.2 *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:

a. Over the eye preview window: by scrolling the mouse wheel or pressing the movement buttons (Up, Down, Right, Left)

b. Live preview window – you can move the fixation target or scroll the mouse wheel over the window to change the working position

c. Grab and move the horizontal and/or vertical tomogram windows.

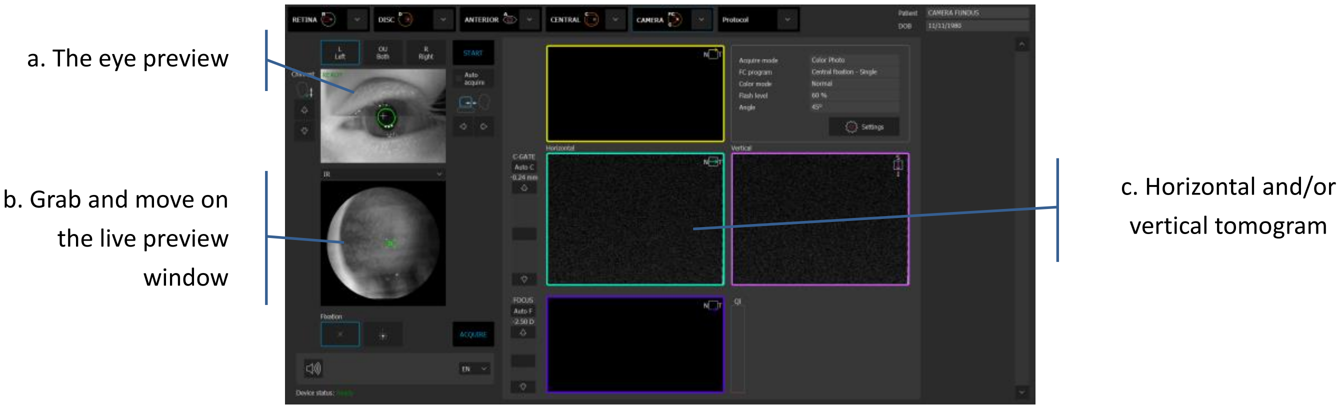


Figure 21 IR mode acquire window

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:

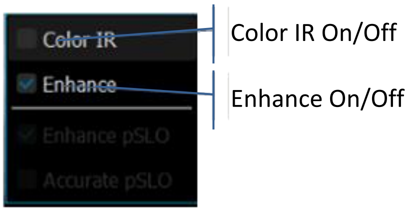


Figure 22. IR preview window context menu

Enhance mode – process the IR image to enhance fundus signal. Useful for patients with cataract or small pupil.

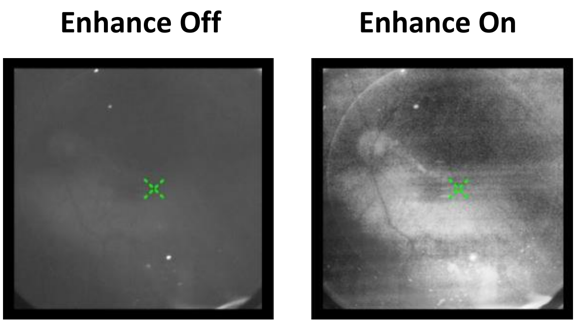
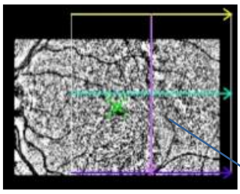


Figure 23. IR preview window display options with the Enhance mode OFF and ON.

Color IR – places a pseudo-color mask on the IR image

7.7 Operation on the fundus preview

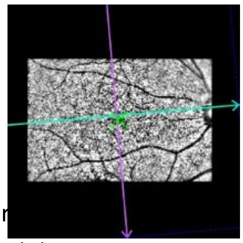
7.7.1 *Moving the Scanning Area*



Drag the scanning area on the pSLO Live fundus preview to change scanner offset. To reset the offset into the center of the fundus preview, double click on the scanned area and the fixation target will come back to default position.

Grab the cross and drag it to change

7.7.2 *Rotation of the Scanning Angle*

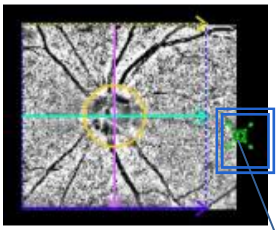


For Raster and B-scan programs it is possible to rotate the scan angle. Adjustment angle range is -90^0 to 90^0 with 1-degree step. Double click on the scanned area to reset scanners rotation.

Gr
and drag it to rotate

7.7.3 *Moving the Internal Fixation target*

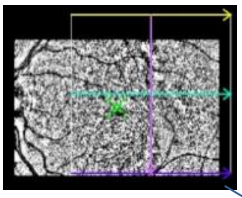
Drag the internal fixation target mark in the pSLO Live fundus preview. When retina/disc cross-section is visible in OCT live preview, system displays pSLO image of the fundus, then the



operator may move the internal fixation position. In order to do it, drag the green cross into the desired position. Ask patient to follow the moving point. To reset the scanning area into the center of the fundus preview, double click on the fundus preview, and the fixation target will come back to default position.

Drag to move the fixation point

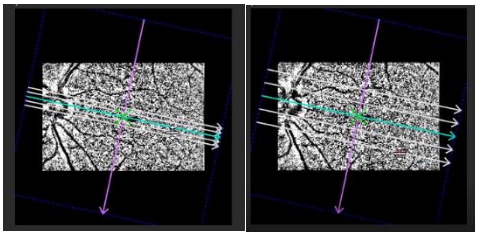
7.7.4 *Changing the scan width*



Drag the corner of scanning area on the pSLO Live fundus preview to change scan width. Scan width step is 1 mm.

Grab and move the corner to change the scan width

7.7.5 *Changing the scans distance*



To change the distance between consecutive tomograms, place the cursor over the line representing the scanned place, grab the line and move the mouse to change the distance between the lines.

7.8 **Fixation target change**

There are two sizes of internal eye fixation target available (small and large) and external fixation target. Click the icon to change it. Active fixation target button is highlighted.

Small fixation point

Large fixation point

External fixation point

See chapter 8.4 External

Figure 24. Fixation target selection

7.9 **Customizing scan parameters**

In the software there are prepared different settings of scan parameters for each pattern and area. Parameters depend on scanned area (Retina, Disc, Anterior, Central) and scanning program (3D, Radial, B-scan). This control panel allows the user to adjust the parameters of the examination. The user is able to change predefined scanning settings. It is possible to save own settings as a default by every operator. In order to change parameters, press [Settings] button at Acquire window.

Scan mode

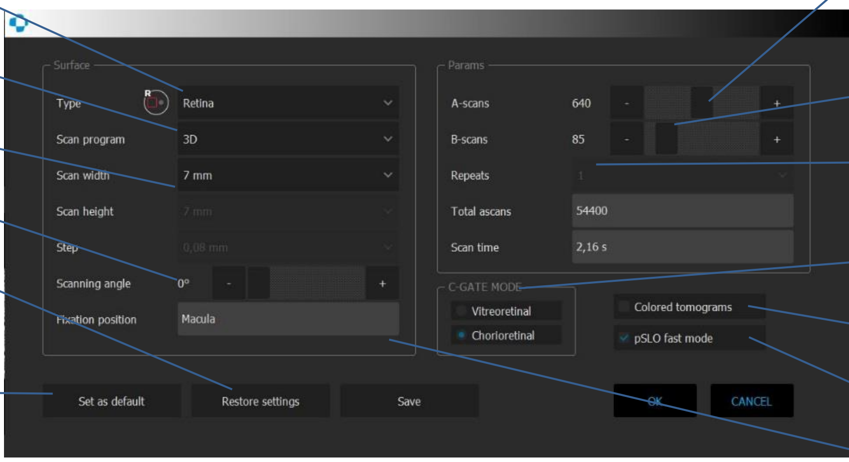
Scan program

Scanned area change

Scanning angle change

Reset to factory settings. Press [Save] to apply

Saves current parameters as default for scan mode



Number of A-scans per B-scan Use slider to change value

Number of B-scans

Averaging(available for: B-scan, Cross, Raster)

C gate focus mode selection

Tomogram color selection

pSLO mode selection

Position of fixation target

Figure 25. Examination settings panel

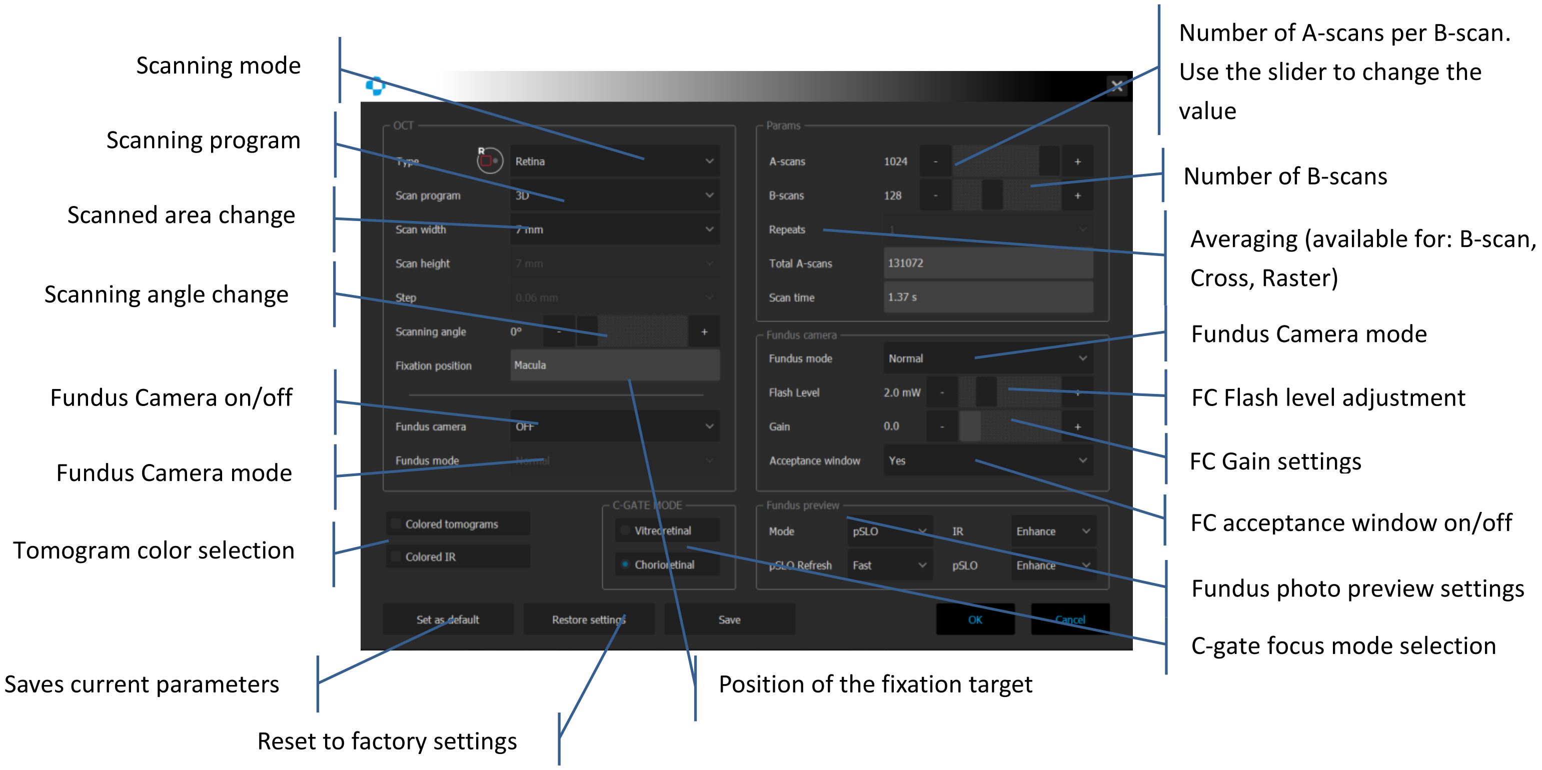


Figure 26. OCT examination settings panel

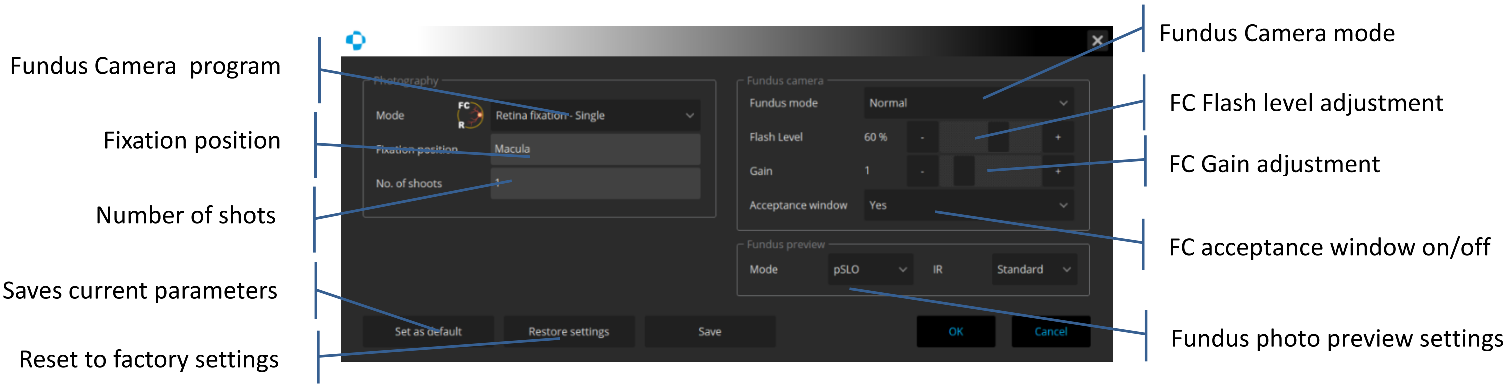


Figure 27. Fundus Camera mode examination settings panel

After the scanning program has been selected, the user is able to set the following parameters:

- Scan width depending on the scan mode.
- Scan height. It is available for Raster only.
- Spacing – Distance between consecutive tomograms. For Raster scan user can modify the distance, for all other programs the system displays the value automatically.
- Scan angle – change angle of scanning.
- Number of A-scans per B-scan.
- Number of B-scans (not available for single B-scan, Cross and Raster scanning program).

- No. of Averaging number defines how many times B-scan is repeated in one location. It is used to compose averaged image. It is available for B-scan and Raster.
- Color mask - Toggles live OCT preview in grey scale or color.
- C- gate mode, Vitreous and Choroid modes can be selected. It changes the sensitivity of the spectrometer on the bottom or top of the tomogram window helping to better visualize the observed structure.
- pSLO fast mode – user can change refresh rate on the retina fundus. Fast mode shows smooth movement of retina but decreases number of seeing details.
- Fundus Camera on/off – turns on/off the fundus imaging after each OCT examination.
- Fundus Camera mode – there are three modes available: high, normal and low. Choose the mode suitable for color of the eye and the size of the pupil. Each mode can be modified and saved as needed.
- Tomogram color selection.
- FC Flash level settings – set the level of the flash – increase the value when the photo is too dark or decrease the value when the photo is overexposed.
- FC Gain settings – set the gain level – increase the value when the photo is too dark or decrease the value when the photo is overexposed.
- FC acceptance window on/off – turns on/off the fundus photo acceptance window.
- Fundus photo preview settings – set the live preview display type.
- *Fundus Camera program* – there are three programs available: Central Fundus Photo, Disc Fundus Photo and Retina Fundus Photo.
- Fixation position – set the fixation target.
- Number of shots – set the number of shots.

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

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

Increasing the number of B-scan improves fundus reconstruction and map reliability, increasing the number of A-scan improves the quality of tomograms.

The operator is able to save their own settings as a default program for example in order to: reduce time of examination, obtain a more detailed reconstruction of the retina.

By selecting [Restore settings] it is possible to return to the default examination settings.

To optimize the image on the IR preview, see chapter 7.7.2 IR Preview.

7.10 Live OCT preview

OCT live preview has four tomogram previews for the 3D scan types and two for viewports for other type of scan. For 3D scans, each viewport includes a color-coded scan marker at upper right, to identify each scan line. The color and orientation of each marker correspond to the color and orientation of the lines that make up the scan pattern overlay in the pSLO preview.

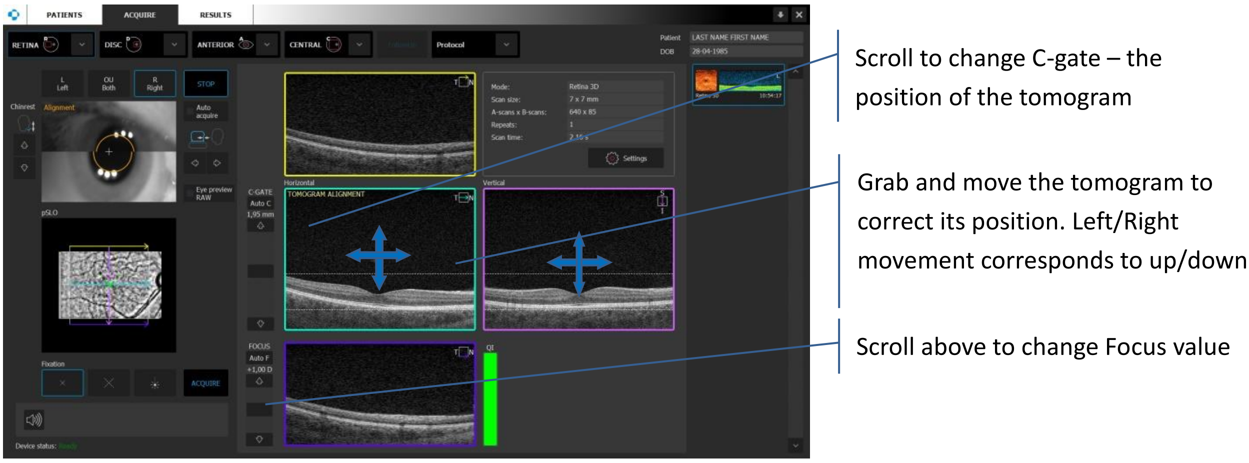
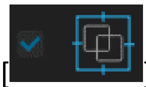


Figure 28. Tomogram preview images, manual position adjustment

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

[Auto C-gate] compensates position of object on the OCT live window preview (length of coherence gate) and [A-Focus] (Refraction compensation) buttons and sliders to the left help you improve the scan image quality and center it vertically.

7.11 iTRACKING

iTracking™ technology can compensate involuntary eye movements and blinks. If iTracking is enabled, each scan program is acquired twice and the system immediately creates an artifact-free MC examination using the Motion Correction Technology™. The system saves 3 examinations if artifacts are detected. Two exams will be saved if the system does not detect blinks and movements. iTracking is available for Angio OCT and 3D scans and can be enabled or disabled by pressing the [] iTracking button.

After conducting an examination with iTracking, the system will display an acceptance window with the results after Motion Correction. The windows for Angio OCT and 3D scans differ. A reconstruction from Motion Correction exam will be shown in the window.

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

7.11.1 *Acceptance window for a 3D scan*

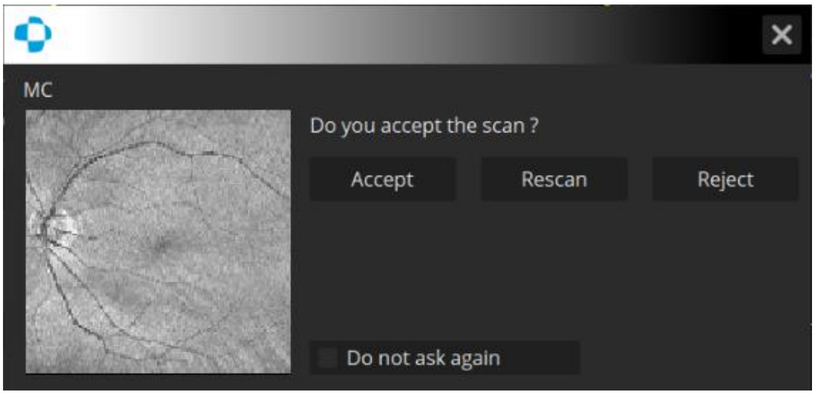


Figure 29 3D Scan Acceptance Window

[Accept] – On pressing [Accept] the system saves three scans. If after pressing [Accept] the MC algorithm does not detect movement artifacts or blinks in two acquired scans, it will save the two scans and will not generate any new MC scans.

[Rescan] – Saves the 2 scans and returns to the acquisition window in order to repeat the scan. 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. See chapter 17.3 Motion correction.

[Reject] – The system will not save any scans.

[Do not ask again] – When checked, it will always accept the scan for the user. This window will not be displayed again until being re-enabled.

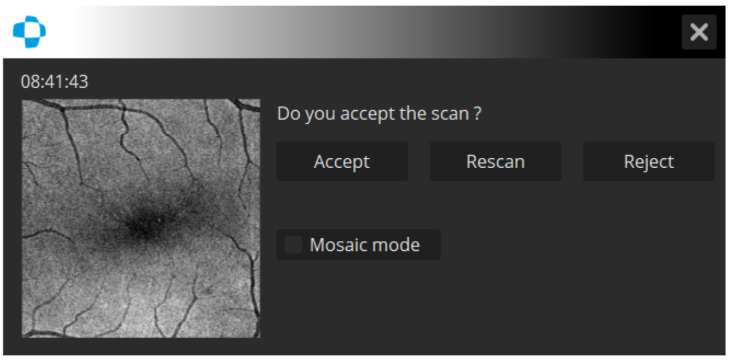
To enable the Acceptance window, head to **Setup\Preferences\[DEVICE TYPE] [Setup]\Parameters** Select **Checkbox Ask for acceptance window for iTracking 3D scan** under 22.5.3 Parameters tab.

When the system does not recognize any motion artifacts, it will not create an MC scan. In this situation, instead of the MC mark the system will display the time of the exam without artifacts.

If the user does not accept the MC results, they can [Rescan] the exam. If the new MC results are still unacceptable, the user can call the Motion Correction function based on 4 or more original scans from the Result tab. See details in chapter 17.3 Motion correction.

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

Figure 30 Angio Scan Acceptance Window



After scan acquisition, it will appear the top of the scan list, appear as an MC (Motion Correction) scan and be selected as the active scan. In case of opening the Result tab, the SOCT will only perform analysis on MC marked scans. The system only performs full analysis for MC marked scans.

In case of Angio exams, the component description is corresponding to those carried out with Mosaic and those will not be analyzed, but instead marked as 1,2 and MC on the list. In case identical exams are carried out again i.e. same location, amount of A and B scans, width and angle of scan, those will be marked as 3 and 4.

8 CONDUCTING EXAMINATION

There are three modes of acquiring the examination available: Full Auto, Semi Auto and Manual mode. See details in chapter 8.3 Acquisition modes description

8.1 Preparation for examination

Check patient's pupil size. In case of narrow pupil, it might be necessary to dilate the patient's eye. **Dilation is optional**. The pupils of the examined eyes must be at least 2.45 mm in diameter. Tomograms acquired through too small pupils may be dark on the edges, or the SOCT signal may be weak, leading to lack of image intensity and clarity.

1. From the main window, select the patient you want to examine. *Fast search* mechanism can be used to locate patients easily. If the patient is not on the list, perform the registration. See chapter 6. PATIENT WINDOW

2. Verify the patient refraction. If the refraction value is higher than -/+5D add this information to patient's data (Edit Patient). See chapter 6.2 Registering new patients

3. Click 'Acquire' tab from main window. Make sure that the proper patient is selected (look at the upper right corner of examination window). See chapter 7. EXAMINATION ACQUSITION TAB

4. Select the desired scanning program (RETINA, DISC, ANTERIOR, CENTRAL - see chapter 8.3 Scanning programs description) or Protocol (see chapter 7.3 Selection of protocol) and acquisition mode (see chapter 8.2 Acquisition modes description). The way of Acquisition mode should be selected (Full Auto-select checkbox, Semi Auto or Manual)

5. Tell the patient to sit in front of the device. Adjust the height of the table to seat the patient comfortably. Place patient's chin on the chinrest and ask the patient to rest his/her head firmly on chinrest and forehead support. Using the Chinrest control buttons adjust the elevation of patient's head. Canthus has to be on the reference position on the forehead frame. Advice the patient to look straight ahead then after its visible focus on blinking fixation point and do not follow the scanning beam.

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

6. Change the eye if required, press [L] or [R] button to choose the desired eye.

7. When the system recognizes the pupil [START] button becomes active. If the pupil is not visible on the eye preview, it is required to move the scanning head to left/right and/or back/forth slightly to allow pupil detection. It is also possible to click on the eye preview (left mouse button or touch screen press) to move the head to desired location. See chapter 7.4 Device head movement controls and 7.5 Eye preview).

8.2 Acquisition modes description

8.2.1 *Full auto mode*

1. Prepare patient's position, see chapter 8.1 Preparation for examination.
2. Press START button. Wait until the system finishes the examination. Patient will be voice guided by the software.

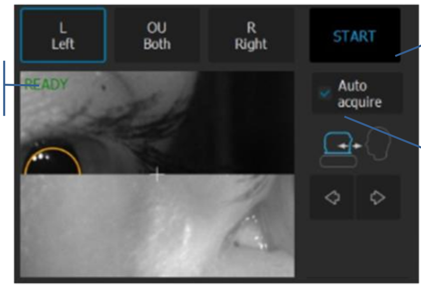


Figure 31. Full auto examination

NOTE: There are a number of conditions in which auto functions processes could fail. For example: dense media opacities, eyelashes or eyelid which block the beam of light, inability of subjects to maintain fixation, strong nystagmus. When adverse conditions occur, optimize the OCT signal manually.

8.2.2 *Semi Auto mode*

1. Uncheck [Auto Acquire] and press [START]. The system will automatically align and optimize tomogram [align XYZ head position, Optimize OCT signal (C-gate, Focus), align tomogram position].

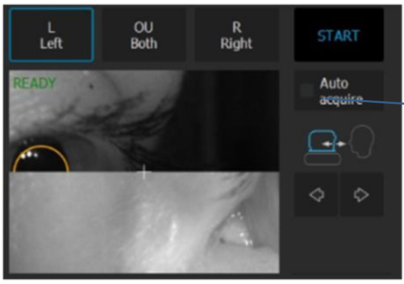


Figure 32. Semi auto examination

2. OCT signal will be placed between horizontal lines.

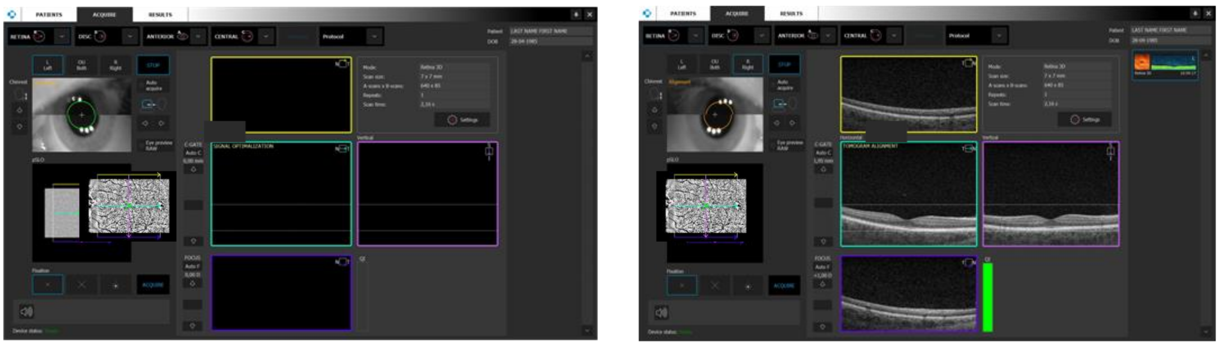


Figure 33. Semi-automatic examination mode

Scan optimization and tomogram position alignment. Double click or [Acquire] button starts measurement.

3. If QI and position of the tomogram are proper proceed to point 6.

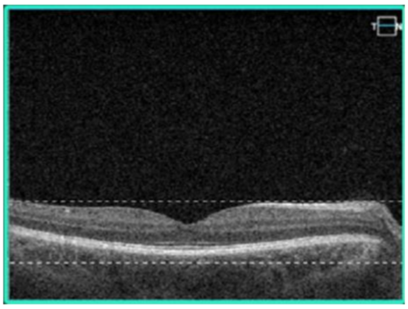


Figure 34. Proper quality and position of the tomogram

4. Manually optimize signal and if required (low saturation, shadows on edges), change the scanned area e.g. peripheral area.
   - Move position of the internal fixation target. Ask patient to follow fixation target, compensate shadow. The OCT cross-section should be visible in OCT live preview window. Drag the retina to move tomogram preview to correct position.
   - Change scanners offset.
   - In order to visualize the interesting retina structures better you can choose Chorioretinal and Vitreoretinal C-gate mode.
5. Some refracting correction may be needed to obtain the best quality of tomogram. Observe the QI bar in order to obtain the best signal while changing [FOCUS] bar position.
6. Once the scan location is aligned, ask patient to blink. Click twice on the tomogram or press [Acquire] button. Device will initialize measurement immediately and then full scan will be performed.
7. After examination is over the system transfers the captured image into database.

⚠ **NOTE**: If system does not detect the pupil, user has to adjust manually the center of the patient’s pupil. In order to set working position properly, align the center of pupil on proper height.

⚠ **NOTE**: In case the system is not able to keep proper position of retina (e.g. patient is shaking) operator has to switch off tracking and make examination manually.

8.2.3 *Manual mode*

1. Uncheck [Auto Acquire]
2. Align the pupil position. Move forward until both images create one. Then press the center of the pupil to align the lens across the center of the pupil.

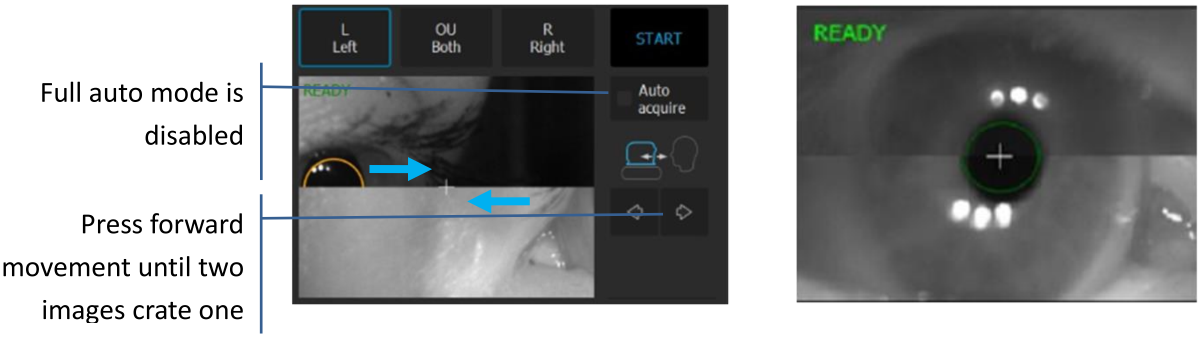


Figure 35. Manual examination mode

3. OCT signal should already appear in tomogram preview. Adjust C Gate manually by moving the sliding bar or use [Auto C] button or scrolling mouse wheel on the tomogram.

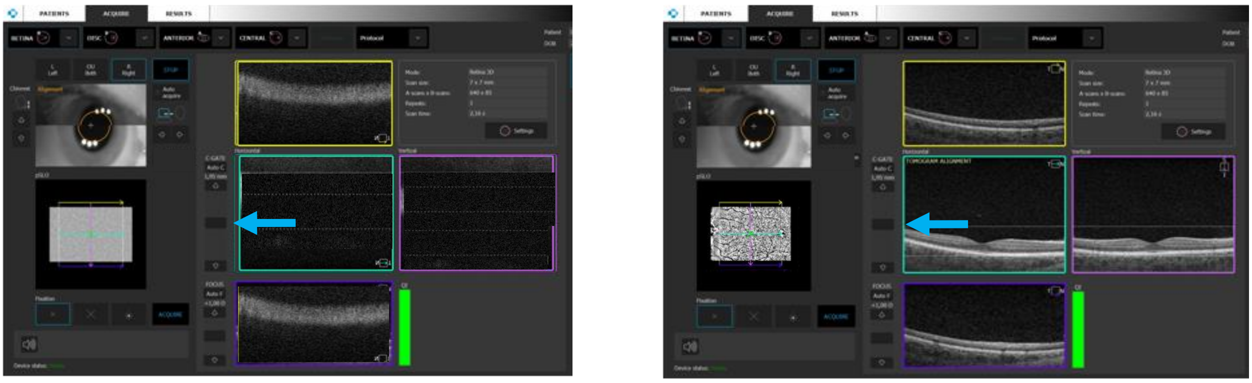


Figure 36. Manual examination process. Scan optimization and tomogram position alignment

4. In case QI and position of the tomogram is proper proceed to point 6.

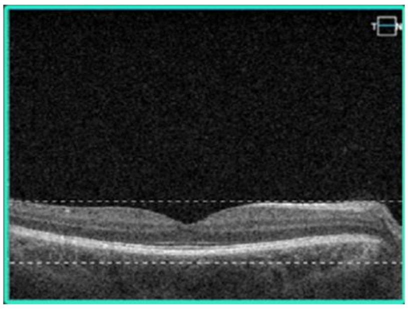


Figure 37. Proper position and the quality of the tomogram

5. Manually optimize signal (low saturation, shadows on edges), and if required change the scanned area e.g. peripheral area.

   - Move the position of the internal fixation target. Ask the patient to follow the fixation target, compensate shadow. The OCT cross-section should be visible in OCT live preview window. Drag the retina to move tomogram preview to correct position.

- Change scanners offset.
- In order to visualize the interesting retina structures better you can choose Chorioretinal and Vitreoretinal C-gate mode.

6. Some refracting correction may be needed to obtain the best quality of tomogram. Observe the QI bar in order to obtain the best signal while changing [FOCUS] bar position.
7. Once the scan location is aligned, ask patient to blink. Click twice on the tomogram or press [Acquire] button. Device will initialize measurement immediately and then full scan will be performed.
8. After examination is over the system transfers the captured image into database.

8.3 Scanning programs description

8.3.1 *Retina examination*

1. Ask the patient to look at the center of green cross and blink freely if the sound support is Mute or disabled. If required, use the large fixation target. See chapter 7.9 Fixation target change.
2. Verify scan program and change to RETINA if required.
3. Follow the procedure depending on Acquisition mode. See chapter 8.3 Acquisition modes description

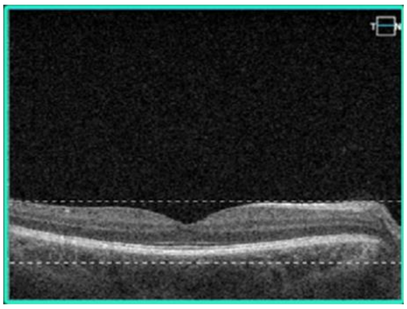


Figure 38. Proper Alignment of retina tomogram

8.3.2 *Central examination*

1. Ask the patient to look at the center of green cross and blink freely if the sound support is Mute or disabled. If required, use the large fixation target. See chapter 7.8 Fixation target change.
2. Verify scan program and change to CENTRAL if required.
3. Follow the procedure depending on Acquisition mode. See chapter 8.2 Acquisition modes description

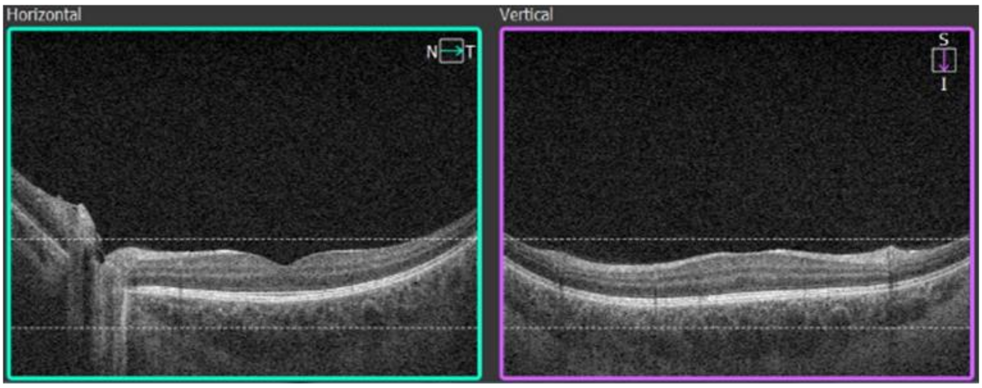


Figure 39. Central examination proper scan alignment

8.3.3 *Disc area examination*

1) Prepare the patient as explained in chapter 8.1 Preparation for examination.
2) Select Disc mode and scan type from program panel.

NOTE: Program settings do not change Fixation position.

3) When sound support system is not active instruct the patient to look at the fixation point and follow it when it moves. Inform that after a while the fixation target will move to the nasal direction. Ask the patient to follow when the fixation shifts.
4) Press [START] button for Full Auto or Semi Auto mode.
5) In Semi Auto or Manual when OCT signal is aligned properly, after a while the pSLO fundus preview image of the optic nerve appears.
6) The Optic nerve head has to be in the center of scanned area.

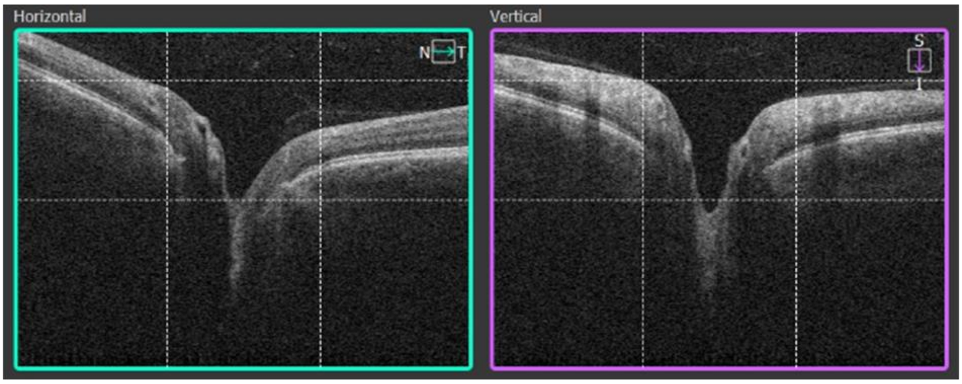


Figure 40. Proper Disk examination alignment

It may be required to correct the scanner position. Drag and move the scanner to the center of optic nerve head. See details in chapter 7.7.1 Moving the Scanning Area. Dashed vertical lines on the live tomogram preview correspond to the red circle on pSLO fundus preview. Scanners are positioned correctly when the vertical lines on the live OCT window are equally placed from RPE tips.

NOTE: If there is a shadow on the edge of the tomogram some slight left/right/up/down movement may be required to find the correct position (whole tomogram properly saturated and QI as high as possible)

In order to obtain the best saturation of OCT signal verify correct refraction and tilt of optic disc. Operator can drag the tomogram to desired position on the live OCT window.

7) Once the scan location is set on selected place in the disc, click twice on tomogram preview window or press [Acquire] button. Device will begin the acquisition process and then data calculation will be performed.

8.3.4 *OCT Angiography examination*

1. Prepare the patient as explained in chapter 8.1 Preparation for examination.
2. Ask the patient to look at the center of green cross and blink freely if the sound support is Mute or disabled. If required, use the large fixation target. See chapter 7.8 Fixation target change.
3. Select one of Angiography scan program.
4. Follow the procedure depending on the Acquisition mode. See chapter 8.2 Acquisition modes description
5. After the scan has been acquired, verify the result on the acceptance screen.

8.3.4.1 Acceptance screen

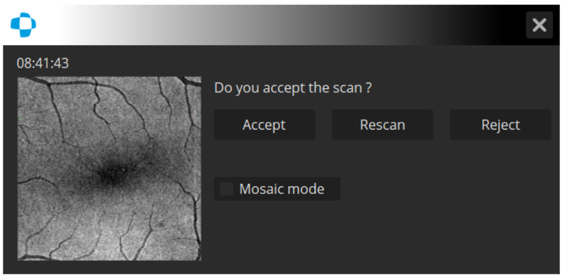


Figure 41. Angio acceptance window

Rescan Comes back to the Acquisition of scan. Examination is saved in database and localization is marked. This marker can be used for motion correction values.

Accept Saves examination. In mosaic mode system loads next examination and starts the procedure of shifting fixation and tomogram.

Reject Comes back to Acquisition window. Examination is not stored.

Mosaic mode When selected system goes to mosaic acquisition mode.

For REVO FC 130 the acceptance window presents MC Results provided by iTracking.

8.3.5 *OCT Angiography mosaic mode*

1. Prepare a patient as explained in chapter 8.1 Preparation for examination.
2. Instruct patient that in mosaic examination you are going to take a few scans.

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.

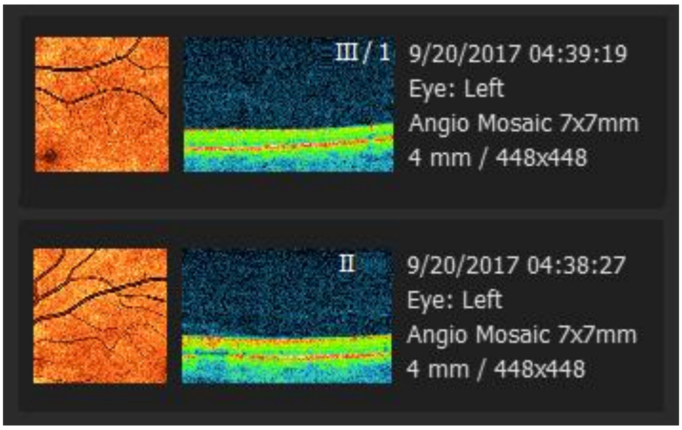


Figure 42 Exam List - Angio Scans

8.3.5.1 Predefined mosaic modes

3. Select one of Angiography Mosaic mode program.
4. After Acquire the scan on the confirmation screen verify the result.

   If you accept the result system will mark scanned area on pSLO window.

   If you Repeat the examination system as default will use newer examination in mosaic mode. If you use motion correction from specific location motion corrected exam will be used.
5. System will load next examination and start shifting the fixation and the scanners position.
6. On the upper part of window system shows which examination is already scanned. On the pSLO window system will draw by blue lines already scanned area.
7. If voice guide is switched off inform the patient to follow fixation target.
8. If required correct position of tomogram and press Acquire to capture next image.
9. After last examination system will not load the next scan program.

8.3.5.2 Manual mosaic acquisition mode

1. Prepare a patient as explained in chapter [8.1 Preparation for examination](#).
2. Instruct patient that you are going to take a few examinations and fixation target may change the position.
3. Select one of Angiography mode program. If required you can change default parameters.
4. After Acquire the first Angio scan on the confirmation screen check [Mosaic mode] to activate the mosaic mode.

   Verify the result. If you accept the result system will mark by blue lines scanned area on pSLO window.

   If you Repeat the examination system as default will use newer examination in mosaic mode. If you use motion correction from specific location motion corrected exam will be used.
5. If voice guide is switched off inform the patient to follow fixation target.
6. If required, correct the position of the tomogram and Acquire the image.
7. When you shift fixation and /or scanners frame change the color to guide you.

   Green frame The new showed scanned area has enough coverage to allow automatic superimpose.

   Orange frame The new showed scanned area touch previously scanned area but it will not guarantee enough data to automatic superimpose.

   Red frame The new selected scanned area does not have any common area with already scanned area.

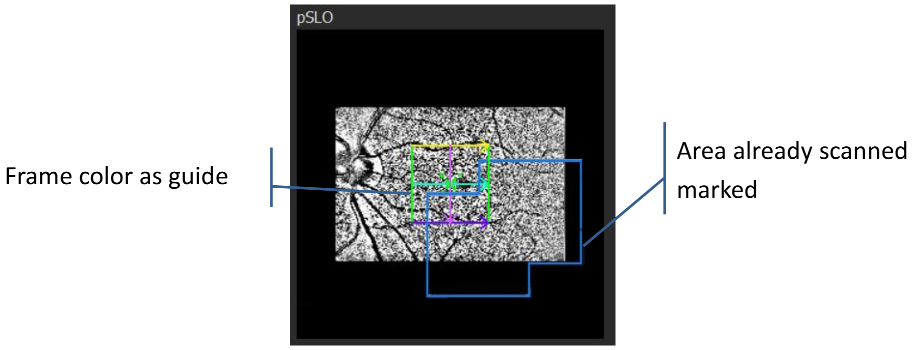


Figure 43. Scanned area marked on pSLO window

8.3.6 *Anterior measurement*

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

1) Select Anterior, and scan program if required.
2) Prepare the patient as explained in chapter 8.1 Preparartion for examination.
3) Press the [START] button to switch to the Full Auto or Semi Auto acquisition mode.
4) In Semi Auto or Manual verify the position of the OCT signal before pressing [Acquire] button.

   Cornea scan – (For pachymetry map use Anterior Radial scan). Locate the cornea in between two dashed lines to get the best cornea images. Use center reflex from cornea to locate the scan in the middle of scanned window. Use vertical dashed lines as reference.

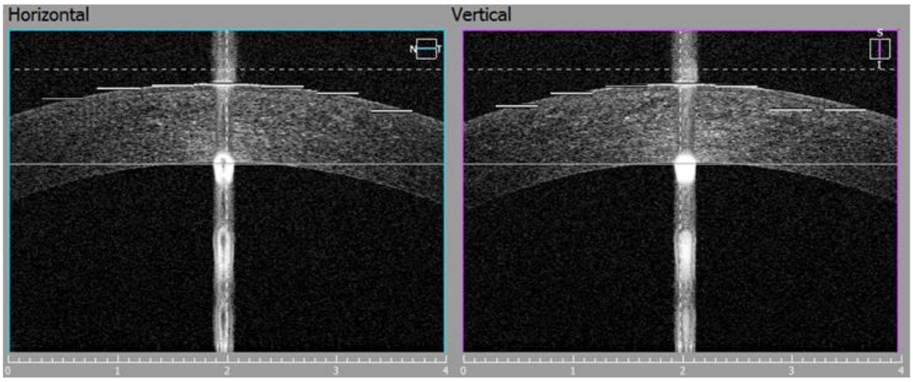


Figure 44. Proper Anterior measurement alignment

Angle scan – There are two techniques of acquiring single Angle scan. Use Single B scan

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

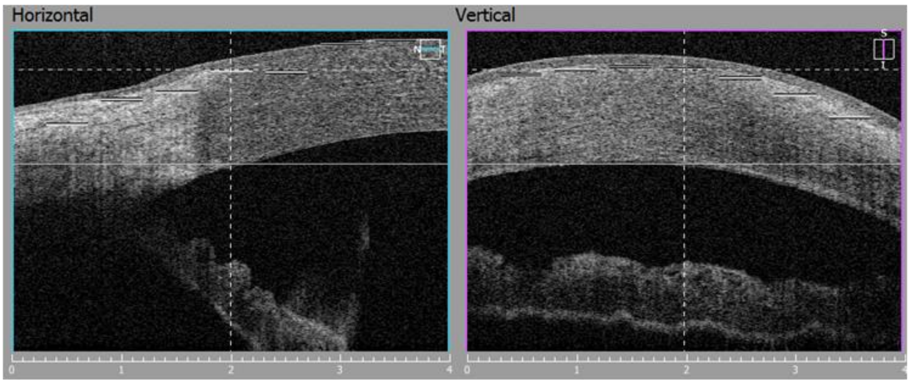


Figure 45. Single angle measurement proper alignment

Method II. Ask patient to look straight forward. Move the scanning head until Anterior angle appears in the scan window. In this method it is recommended to scan in Bottom mode.

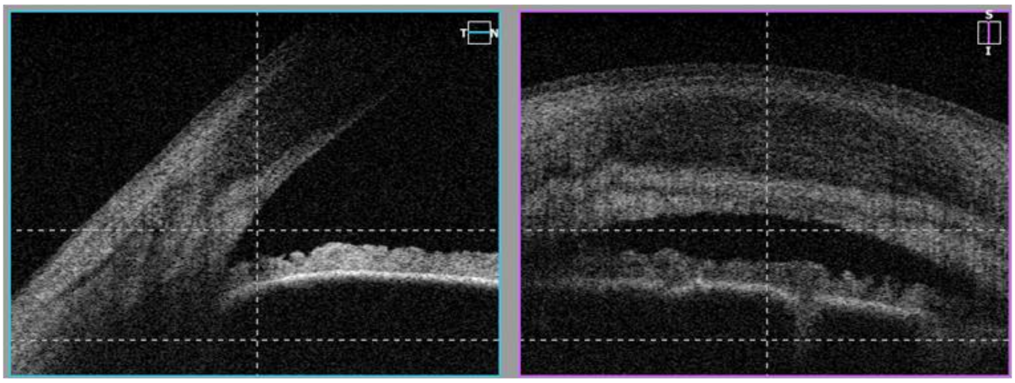


Figure 46.Single angle measurement proper alignment

5) Once the scan location is set in selected place, click twice on the tomogram or press [Acquire] button. PC will initialize measurement process and then full scan will be performed.

NOTE: Only when border air - anterior surface is correct are AOD and TISA measurements accurate. Verify recognition correction before judging the Anterior Angle morphology.

NOTE: Vertical dense line in the center of Cornea is a natural reflection of laser light and has no negative influence on measurement result. It can be used to locate the tomogram in proper position.

NOTE As the Anterior Chamber, wide Angle to Angle and Pachymetry scans are compensated for beam scanning geometry and reflection from the surface of the cornea, 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 this way.

8.3.7 *Wide Anterior programs*

8.3.7.1 Wide Anterior programs for REVO FC

The Anterior Chamber Adapter is not applicable for REVO FC models. It has an anterior lens built in. When a user selects anterior scan program, the lens will automatically install inside the device.

8.3.7.2 Wide Anterior programs for REVO & NX

The Anterior Chamber Adapter for the SOCT is an easy-to-install hardware attachment to allow wide scanning of anterior segment structure.

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

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

The lens adapter is attached and removed by a trained operator.

Note: When using the anterior adapter, do not move the head too fast and monitor proximity to patient in order to avoid incidentally hitting the patient's eye with the Anterior adapter lens surface.

Figure 47.Side views of Anterior Adapter

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

Select one of Wide Anterior scan program. The scanning head has moved back.

Install Anterior Chamber Adapter on the objective lens.

Grab the Anterior Adapter as shown on the image (two fingers are close to insertions positioned horizontally.

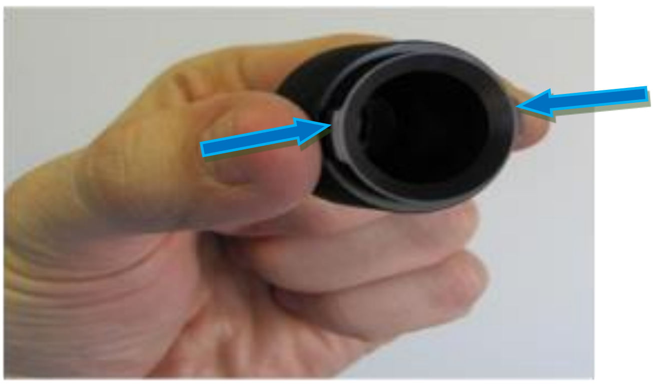


Figure 48. Anterior adapter mounting

5.1. Get the adapter to the objective and rotate 90^0 clockwise.

Figure 49. Anterior adapter mounting. Rotate to lock.

NOTE: Ensure that scanning head is in maximum backward position and patient will not incidentally hit the anterior adapter.

CAUTION: Be careful when mounting anterior adapter in order not to scratch the objective lens.

Prepare the patient as explained in chapter 8.1 Preparation for examination.

6) Press [START] button for Full Auto or Semi Auto acquisition mode.
7) In Semi Auto or Manual verify the position of the OCT signal before pressing [Acquire] button.
8) Some slight left/right/up/down movements may be needed to find the correct position. Drag tomograms to optimize scan position.

   – **Wide Cornea scan** – For pachymetry map use Anterior Radial scan. Locate the cornea in between two dashed lines to get the best cornea images. Use center reflex from cornea to locate the scan in the middle of scanned window. Use vertical dashed lines as reference.

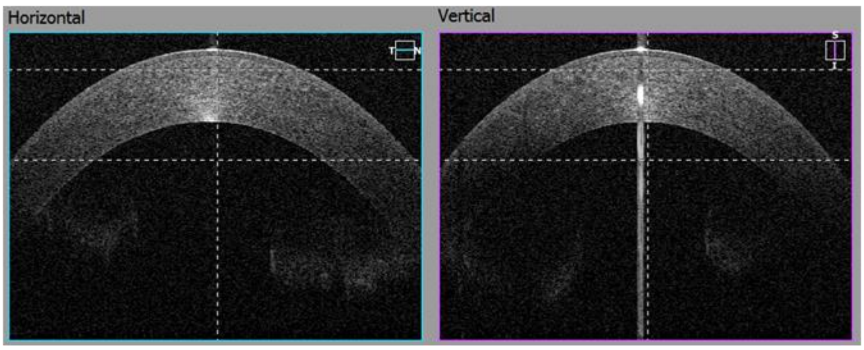


Figure 50. Wide Cornea scan proper alignment

– **Angle to Angle scan** – Ask patient to look at the green cross. Place the scan in the middle of the iris. Use pSLO view and dashed vertical line on live OCT window for reference. Both angles have to be visible on the live OCT window.

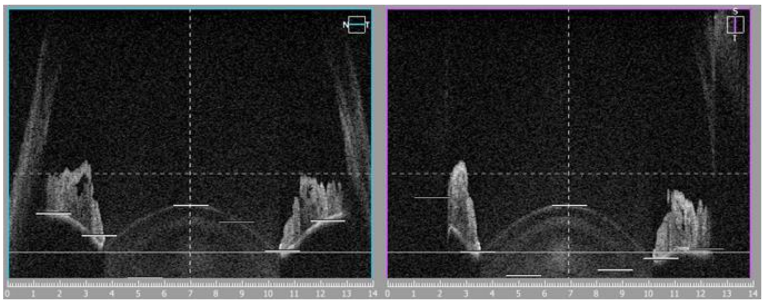


Figure 51. Angle to angle scan proper alignment

6) Once the scan location is set in selected place click twice on the tomogram or press [Start] button. PC will initialize measurement process and then full scan will be performed. Remove the Anterior Chamber Adapter after use.

NOTE: Only when cornea/sclera tissue is parallel to the scanning window are the AOD and TISA measurements accurate.

CAUTION: Be sure to keep the patient's face away from the chin rest and forehead rest when the Anterior Chamber Adapter is still attached. Otherwise, a patient may be injured by the Anterior Segment Adapter making contact with them when the scanning head moves in any direction.

8.3.8 *Biometry program*

OCT Biometry is an optional feature. It is available as an upgrade purchased separately. For more information go to chapter 18 BIOMETRY OCT.

8.3.9 *Topography program*

OCT Topography is an optional feature. It is available as an upgrade purchased separately. For more information go to chapter 20 TOPOGRAPHY OCT.

8.3.10 *Fundus Image REVO FC (REVO FC only)*

8.3.10.1 OCT/Fundus Mode

1. The OCT/FUNDUS exam mode is similar to standard OCT modes. The only difference is that the OCT exam is followed by a Fundus image capture. Prepare the patient as explained in chapter 8.1 Preparation for examination.

2. Ask the patient to look at the center of the green cross and blink freely if the sound support is Mute or disabled. If required, use the large fixation target.

3. Verify the scanning program and change it to the required mode.

4. Follow the procedure depending on Acquisition mode analogical to the OCT scanning modes. See chapter 8.2 Acquisition modes description

8.3.10.2 Fundus Mode

Fundus exam is similar to the examination of the posterior segment of the eye.

1. Prepare the patient as explained in chapter [8.1 Preparation for examination].

2. Ask the patient to look at the center of the green cross and blink freely if the sound support is mute or disabled. If required, use the large fixation target.

3. Verify the scanning program and change to the required FUNDUS mode.

4. Follow the procedure depending on the Acquisition mode similarly to the OCT scanning modes.

8.3.10.2.1 *Fundus Photo Semi Auto mode*

NOTE: With some patients the system may not take an optimal fundus image automatically. In this case use the Manual or the Semi Auto mode.

1. Prepare the patient's position chapter [8.1 Preparation for examination].
2. Choose one of the desired Fundus Camera modes.

Figure 52. Fundus Camera modes

3. Uncheck [Auto Acquire] and press [START]. The system will automatically align and optimize the device position (align XYZ head position, Optimize Focus based on OCT signal) and then correct the position on the basis of the OCT signal.

The cross identifies the centre of the lens and has to be place in the centre of the pupil.

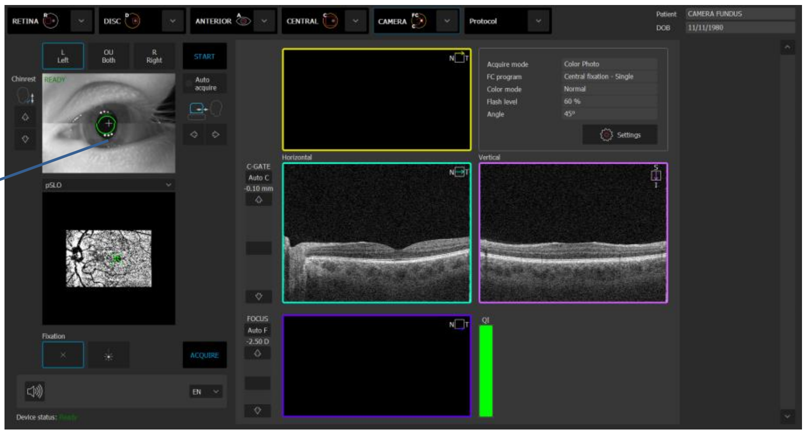


Figure 53. Aligned pupil position in Fundus Camera mode

4. The software aligns the position of the scanning head. The operator has to
   a) Verify the position of the scanning head in Z direction. Two pupil images should create one plane.
   b) Verify the pupil size (a white circle identifies the minimum pupil size). If the pupil is too small, dim the light or optionally dilate the pupil.
   c) 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 7.5 Eye preview.

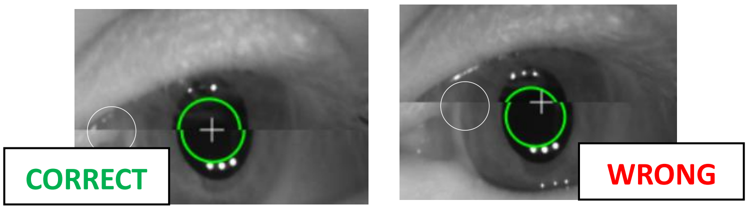


Figure 54. Eye preview window and pupil position

   d) 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.

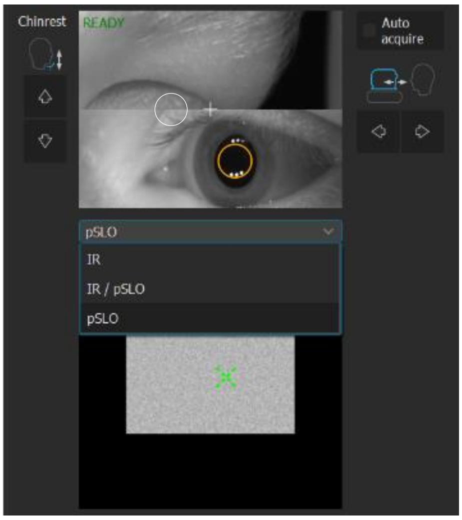


Figure 55. Live fundus preview modes

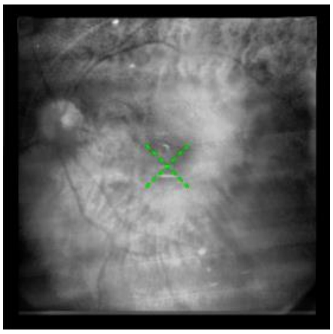


Figure 56. Live fundus preview IR mode

5. Optimize the visibility and exposure of the retina in the live preview window. The retina has to be equally well exposed. Make sure there are no reflexes on the live preview window and you will reach the best exposure possible.

We recommend to optimize the visibility and exposure of the retina in the live preview window by grabbing and moving the tomogram windows. That is the most accurate and precise way.

When the reflex is on the left or right side of the retina preview, grab and move the horizontal tomogram.

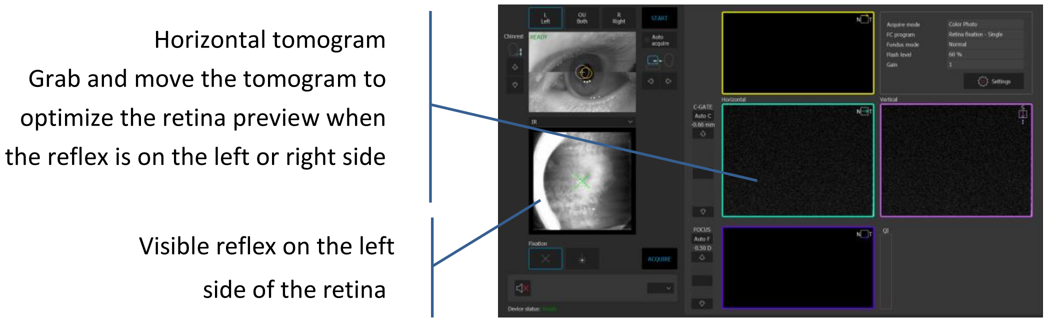


Figure 57. Fundus Photo mode acquire window

To eliminate the reflex at the top or at the bottom of the retina preview, grab and move the vertical tomogram.

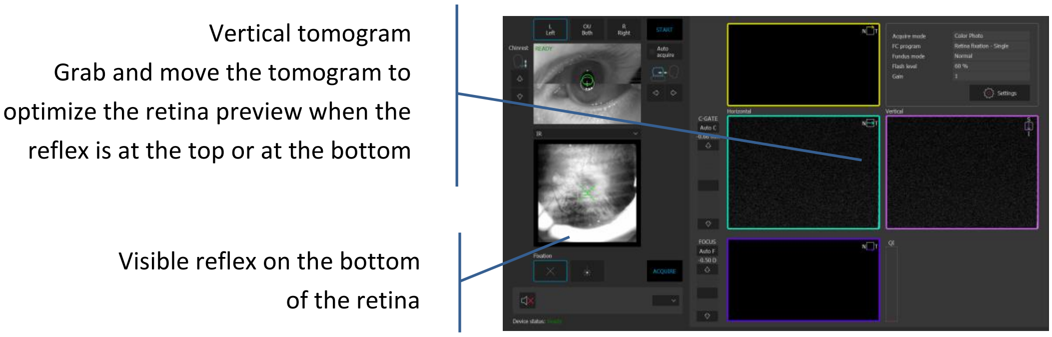


Figure 58. Fundus Photo mode acquire window

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 7.6.2 IR Preview.

Once you reach the best retina exposure, ask patient to blink. Click twice on the tomogram or press the [Acquire] button. The device will take a photo of the fundus.

8.3.10.3 Fundus Image Acceptance Window

After taking a Fundus photo with or without OCT, the fundus acceptance window is displayed.

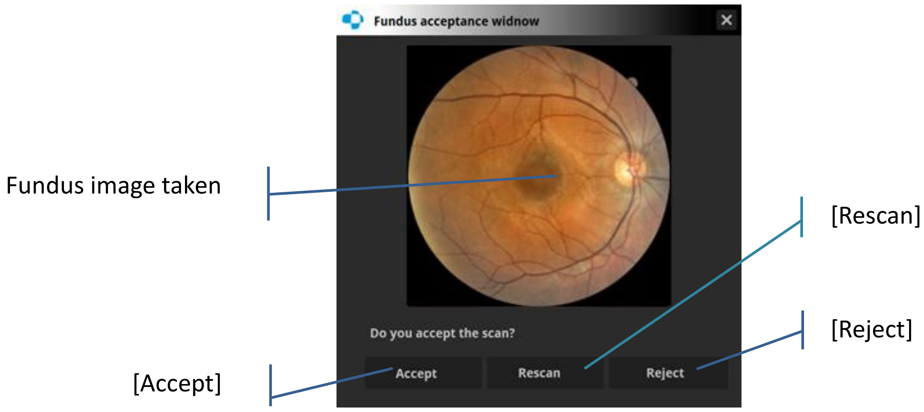


Figure 59. Fundus image acceptance window for Fundus mode

[Accept] – Closes the acceptance window and the Acquire window is displayed. The exam is saved. 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.

[Rescan] – The exam is saved and then repeated. If the operator is using a protocol, the system continues with the current exam type.

[Reject] – The file is not saved (it is rejected). If the user is using a protocol, the system continues with the current exam type.

The cross in the upper right corner of the information window closes it and initiates the same action as the [Rescan] button.

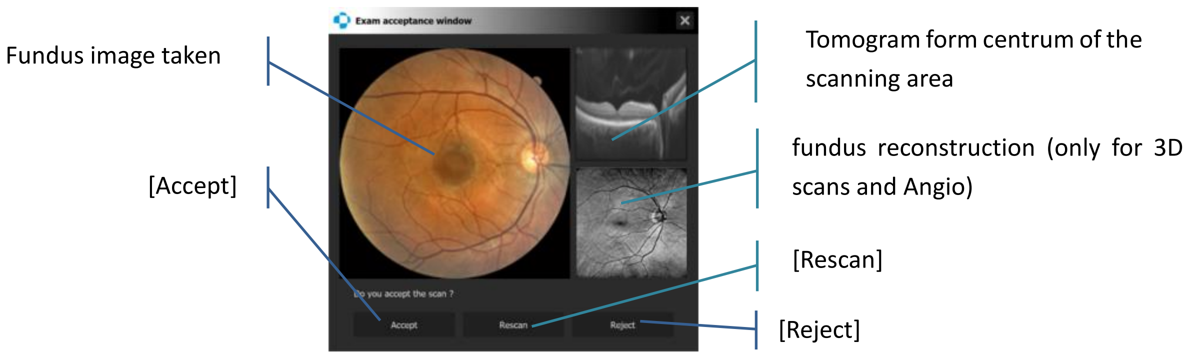


Figure 60. Acceptance window for FUNDUS/OCT mode

[Accept] – Closes the acceptance window and the Acquire window is displayed. The exam is saved. 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.

[Rescan] – The system saves the exam and displays the Acquire window in order to repeat the exam. If the operator is using a protocol, the system continues with the current exam type.

[Reject] – the file is not saved (it is rejected). The Acquire window is displayed in order to repeat the exam. If the operator is using a protocol, the system continues with the current exam type.

The cross in the top right corner of the information window closes it and initiates the same action as the [Rescan] button.

8.4 Full Range examination mode

Full Range examination mode offers scanning depth increased from the standard 2.4 mm to 5.0 mm (Revo FC) or 4.8 mm (SOCT Copernicus, SOCT Copernicus Revo, Revo 60, Revo 80, Revo nx, Revo nx 130). In order to perform a Full Range scan of the anterior segment of the eye it is necessary to install the anterior adapter on the lens of the SOCT device. Anterior adapter installation instructions can be found in section 8.3.7 Wide Anterior Programs. (The installation of the anterior adapter does not apply to the Revo FC which comes with a built-in, automatic anterior adapter).

Before conducting a Full Range examination, prepare the patient as explained in section 8.1 Preparation for examination.

A Full Range scan in the simple mode (described below in section 8.4.1 Anterior Full Range examination mode) normally displays an inverted mirror image of the scanned structure. The inverted image can be oriented to overlie 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 *Anterior Full Range examination mode*

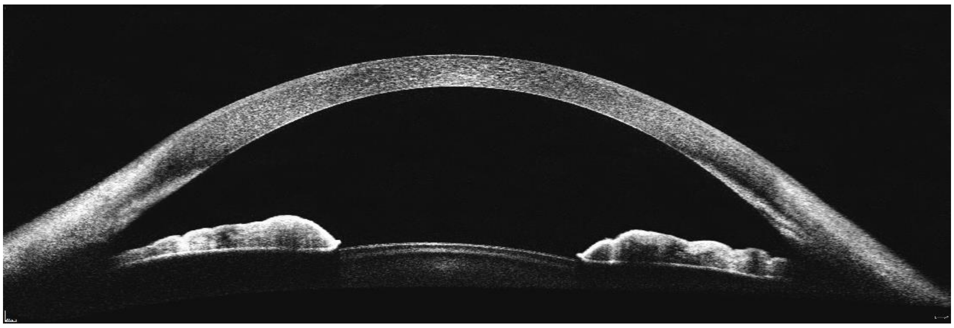


Figure 61. Anterior B-scan Wide Full Range examination view

There are two ways of displaying the tomogram: simple and complex.

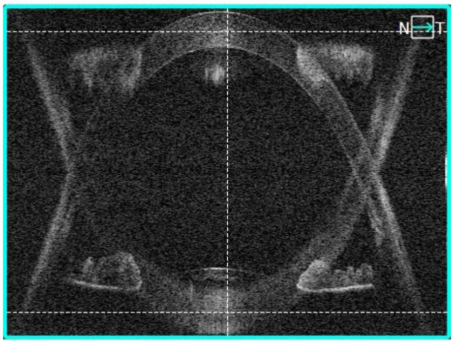
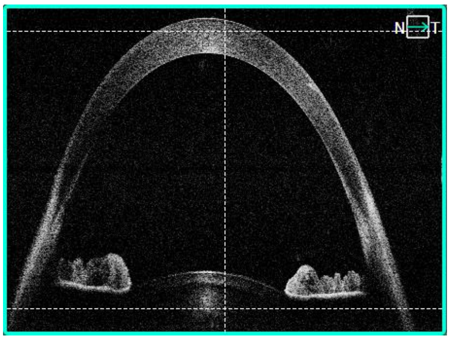
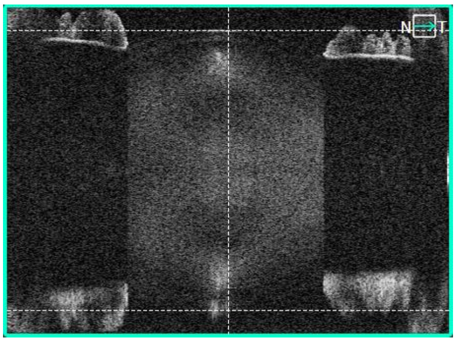
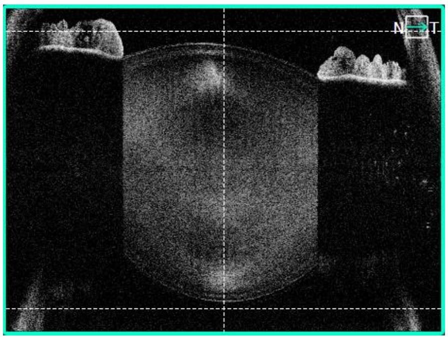
Simple mode is active in the following situations:

- During the automatic alignment.
- During manual alignment i.e. when using C-gate, Focus or Head movements, the eye is disengaged.

Complex mode is active in the following situation:

- When the scanners run slowly (if the user does not manipulate the system, the system shows a Full Range tomogram // scan with a density of 4096 B-scan).

In the semi-automatic and manual modes, the image visible in the tomogram window can be displayed in two modes:

Simple mode	Complex mode
Fast refresh Full Range discoupled – faster refresh. In the simple mode the user can see the original image together with its inverted reflection.	Full Range coupled mode – default – lower refresh. In the complex mode the original and inverted images are coupled to form a detailed, homogenous image.
	
	

8.4.2 *Central Full Range examination mode*

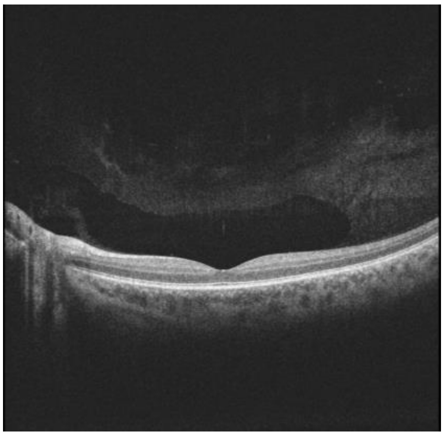
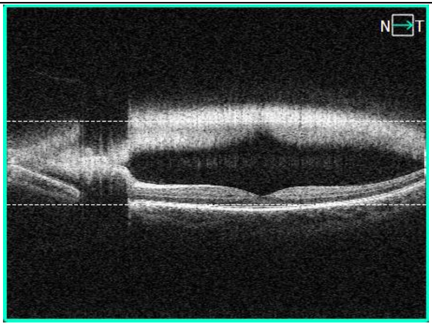
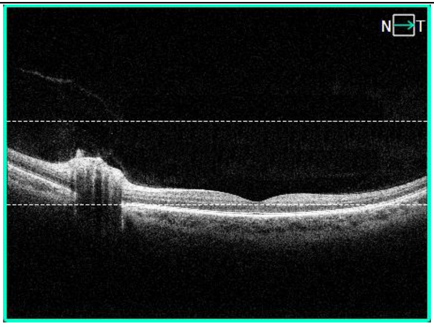


Figure 62.Full Range Posterior B-scan examination window

There are two ways of displaying the tomogram: simple and complex which are described in detail in section 8.4.1 Anterior Full Range examination mode.

In the semi-automatic and manual modes, the image visible in the tomogram window can be displayed in two modes:

Simple mode	Complex mode
Fast refresh Full Range discoupled – faster refresh. In the simple mode the user can see the original image together with its inverted reflection.	Full Range coupled mode – default – lower refresh. In the complex mode the original and inverted images are coupled to form a detailed, homogenous image.
	

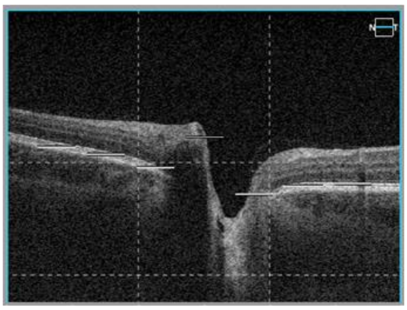
8.5 External fixation

With the external fixation method, the patient uses the second eye to fixate on an external target light. The SOCT may be equipped with an external fixation target arm. It is attached at the top of the forehead support. Its position is set manually. When you select external fixation target, instruct the patient to look at the blinking target light at the end of the external fixation arm.

8.6 Chorioretinal/Vitreoretinal mode

Vitreoretinal / Chorioretinal C-gate mode. Settings are programmed based on scan design to enhance either the information above the RPE (Vitreoretinal), or the choroid and overall information (chorioretinal). Press [Settings] and select C-gate mode to change mode. Press [OK] to change scan program.

Chorioretinal positioning



Vitreoretinal positioning

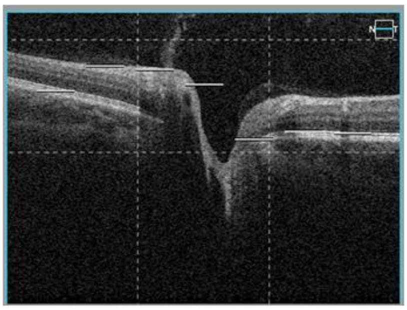


Figure 63. Difference in Chorioretinal and Vitreoretinal scanning mode

8.7 Examination tips

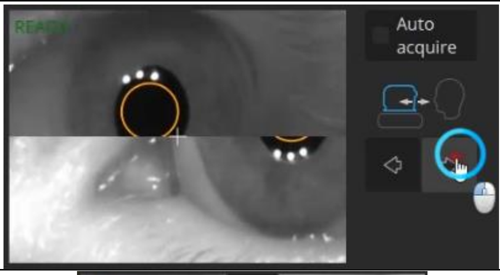
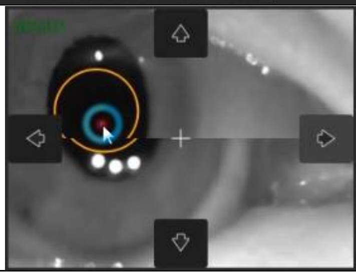
NOTE: Patients are usually nervous and stressed during an examination. Therefore, it is advisable to be informative about the progress of the examination to minimize unexpected movement.

8.7.1 *Tips for Automatic Eye Alignment*

Tips in case of the [START] button being inactive:

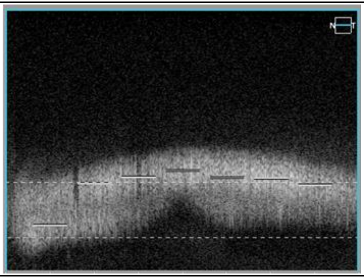
- verify pupil recognition;
- check for obstructions such as eyelids or eyelashes;
- verify chinrest height;
- verify head position;
- If necessary, adjust device position using Up/Down and Left/Right controls available when hovering over live eye preview. Red arrows indicate incorrect patient position.

8.7.2 *Tips for Manual Eye Alignment*

To align the pupil position, move the device forward using the back/forth controls until both halved images (top and bottom) combine. Correctly aligned pupil will have a white cross in the middle.	
If the white cross is not in the middle, click it into place after both halved images combine. The white cross has to be placed in the middle of the pupil.	

In case of issues with C-Gate:

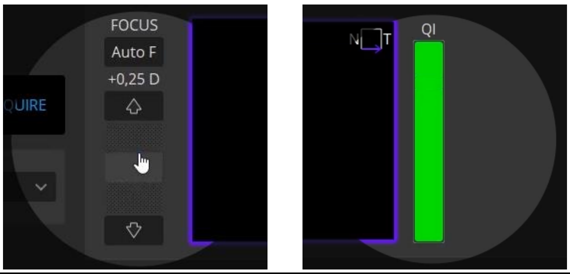
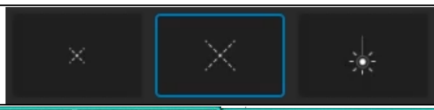
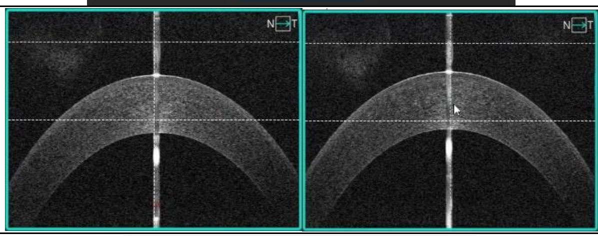
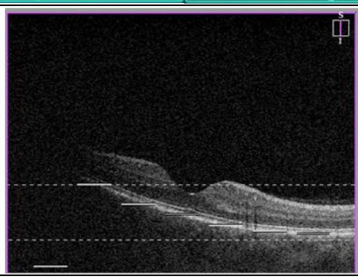
- check if the pupil is centered;
- verify whether the patient has a large refraction (if so, make a note in patient profile);
- if the issue persists, check for eyelids or eyelashes obscuring the scan area;
- verify whether focus is set correctly;
- if issue remains unresolved, verify whether the patient’s forehead is still fully against the frame and set correctly;
- manually scroll C-Gate;

If ghost tomograms are displayed, move C-Gate position and check if the pupil is centered. Proper examination position can be obtained by scrolling the mouse wheel or dragging to the desired position.	

8.7.3 *Auto C-Gate issues*

8.7.3.1 Tips to Optimize OCT Signal

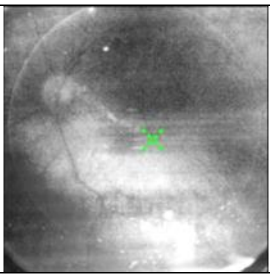
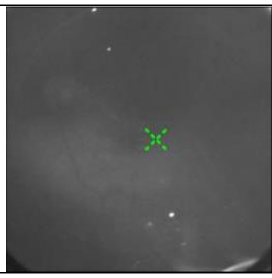
8.7.3.1.1 *Focus Alignment*

<table>
<tr><td colspan="2">There are a number of conditions in which automated function processes could fail, i.e.:
▪ dense media opacities;
▪ eyelashes or eyelids blocking the beam of light;
▪ inability of patients to maintain fixation;
▪ nervous and/or stressed patients with jerky movement;
▪ strong nystagmus.
In cases where adverse conditions occur, it may be necessary to:
▪ optimize the OCT signal manually;
▪ align the tomogram manually;
▪ carry out the exam manually.</td></tr>
<tr><td>To manually compensate patient refraction errors, scroll over the focus slider.
Simultaneously observe QI index bar and scan intensity to receive best results. The QI index bar displays the signal to noise ratio.</td><td></td></tr>
<tr><td colspan="2">If the signal strength is low, adjust the focus manually. Additionally, artificial tears may be used for dilated and dry eye patients.</td></tr>
<tr><td>For patients with severe sight problems, use a large fixation target.</td><td></td></tr>
<tr><td>Focus correction may improve the saturation of the tomogram.</td><td></td></tr>
<tr><td>If shadows are displayed on tomogram edges, check whether the pupil is centered.
To eliminate shadows, drag the tomogram into the shadow.</td><td></td></tr>
</table>

8.7.3.2 Quality IR Preview

To avoid poor quality images:

- Verify the device distance to ensure good illumination by alignment to the center of the pupil;
- Move the fixation target or scroll the mouse wheel over the live preview window to change the working position.

Good image	Poor image
	

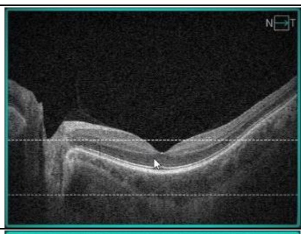
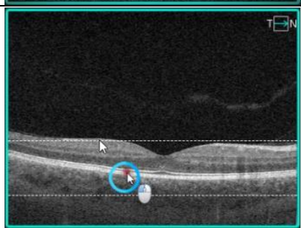
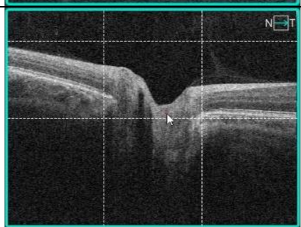
8.7.3.3 Tomogram Alignment

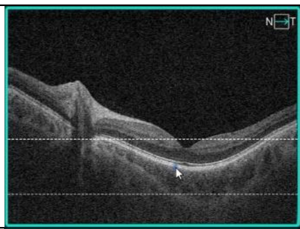
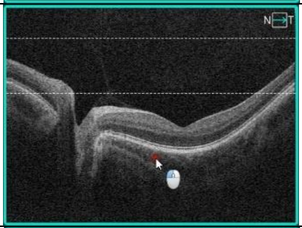
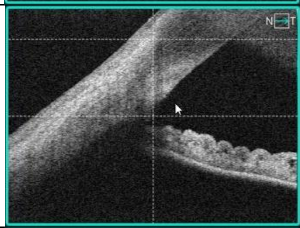
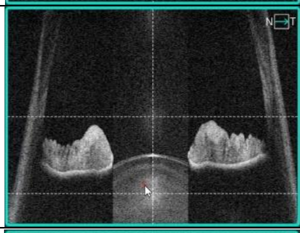
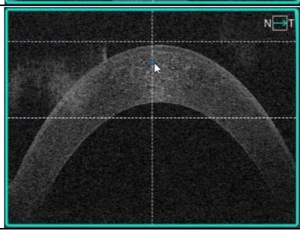
To align the position of the tomogram:

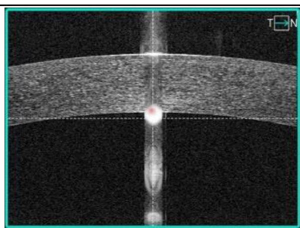
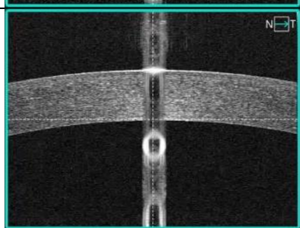
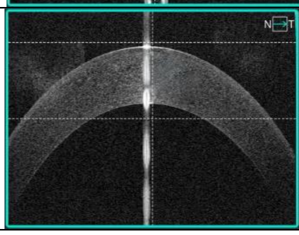
- For precise movement, click, hold and drag the tomogram vertically and horizontally;
- For large movement, scroll the mouse wheel over the tomogram.

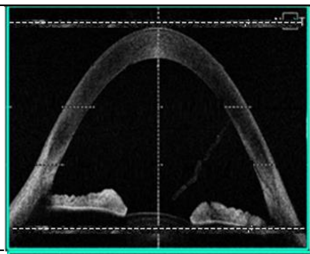
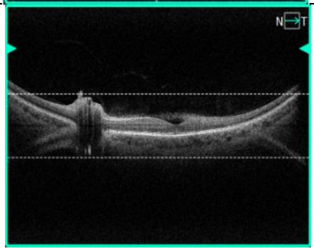
Note: By moving one tomogram i.e. horizontal, the vertical tomogram will move as well.

Below are examples of correctly aligned horizontal tomograms.

Example: Retina Raster, align the retina between the two dashed horizontal lines.	
3D Retina, align the retina between the two dashed horizontal lines.	
3D Disc, align the retina between the dashed lines and set foveola in the middle of the square.	
3D Central Peripheral, align the retina between the two dashed horizontal lines.	

3D Central, align the retina between the two dashed horizontal lines.	
For all Vitreous scans, align the Vitreous structure between the two dashed horizontal lines.	
Anterior B-Scan Angle C-Gate top, place the angle structure below the dashed horizontal lines.	
Anterior Wide B-Scan with Two Angles, align the two angles between the dashed horizontal lines.	
Anterior Wide B-Scan Cornea, align the desired structure between the dashed horizontal lines.	

Biometry Axial Length, align the central cornea reflexes with the dashed vertical line.	
Biometry ACD, align the central cornea reflexes with the dashed vertical line.	
Topography, align the desired structure between the dashed horizontal lines and the central cornea reflexes with the vertical dashed line.	

Full Range Anterior, make sure the cornea is aligned with the dashed vertical line, align the cornea between the dashed horizontal lines.	
Full Range Posterior, for the best image quality align the retina between the two dashed horizontal lines indicating the area with the highest scanning sensitivity. If, however, the user wants to broaden the visualization range above or below the retina, the image can be aligned below or above the dashed lines.	

8.7.4 *Tips to Successfully Scan Difficult Patients*

Problem: **A patient with poor sight has difficulty following the fixation, causing the scan to be invalid.**

Possible solution: Utilize the large fixation or external fixation (see chapter 8.4) as an aid in keeping the scanned 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.

Patients with large refraction error may be challenging for the automated processes to find the retina.

In this case, the refraction error has to be compensated manually with C-Gate scrolling until the retinal structure is recognized. If the issue still persists, verify pupil position and adjust if necessary. Utilize the large fixation target. It is important to enter patient refraction error to each patient so that the system can automatically adjust C-Gate in further scans.

Stressed, nervous or scared patients are likely to have excessive upward-downward movements in the scan window causing poor scans.

Patient movement will not necessarily affect scan sequence, but will always affect the quality (observe QI index bar). Action is required if such movements occur. Try asking the patient to minimize movement during scan.

Also, try moving the device head slightly towards or away from the patient to stabilize the scan window.

Lastly, the stability of the table can be utilized. If possible, position the table low enough so that the patient can rest their head firmly in the headrest and ask them to wrap their arms around the base of the device. This will place the patient in a firm and locked position and minimize movements.

Note: If after scanning the patient begins to drift, remind them to continue being in this same position in case a repeat would be necessary.

NOTE: Patients are usually nervous and stressed during an examination. Therefore, it is advisable to be informative about the progress of the examination to minimize movement.

The pictures below show how to make proper measurement and how to align the device. Dashed lines identify the right position of the retina in the live OCT window.

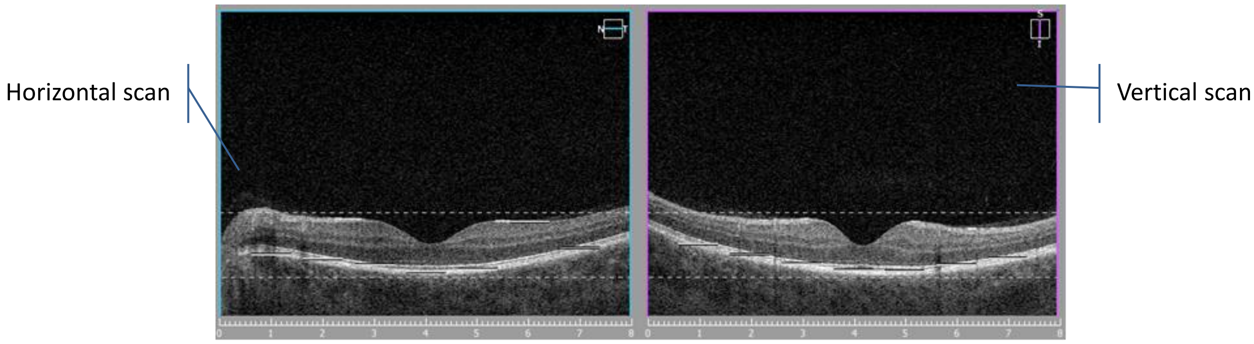


Figure 64. Properly aligned retina between dashed lines

In the picture below the tomogram is upside down, C-gate position is too low. Move C-gate. You can get a proper examination position by scrolling the mouse wheel or dragging to the desired position.

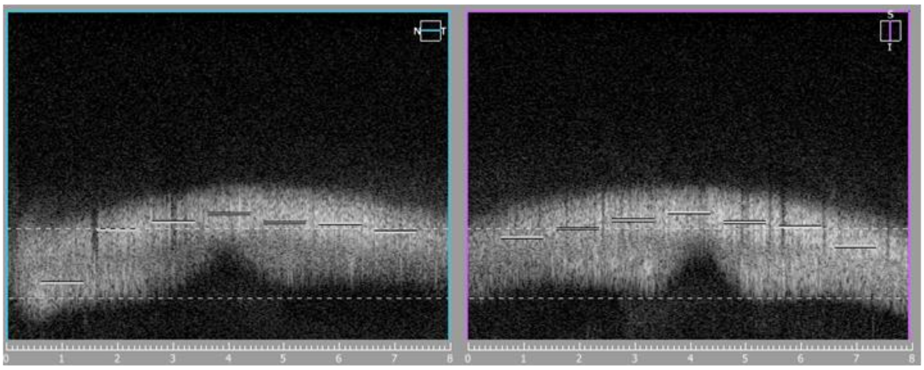


Figure 65. Improper-flipped tomogram preview

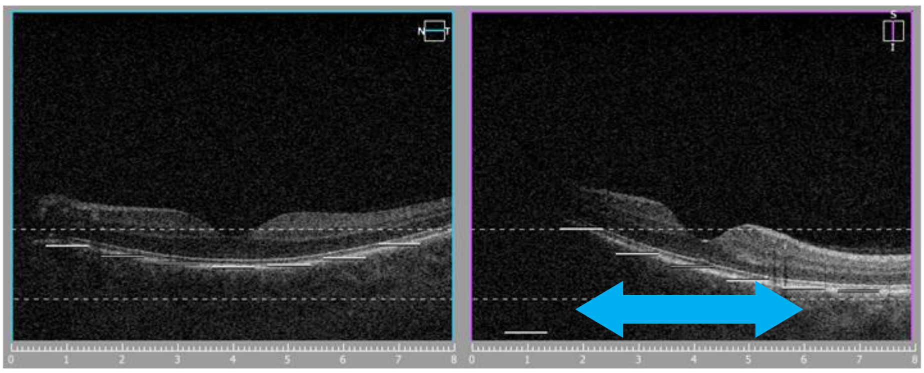


Figure 66. Shadow on tomogram, grab and drag towards left side

Vertical line in fundus preview window is related to the right part of scan preview window. This line shows the position of the scan in the eye. A scan should be horizontal, drag tomogram and move left/right. (Left/Right drag movement on the vertical OCT live window corresponds to up/down movement of the head. In the case here above the device is too high, so it should be dragged left (move down).

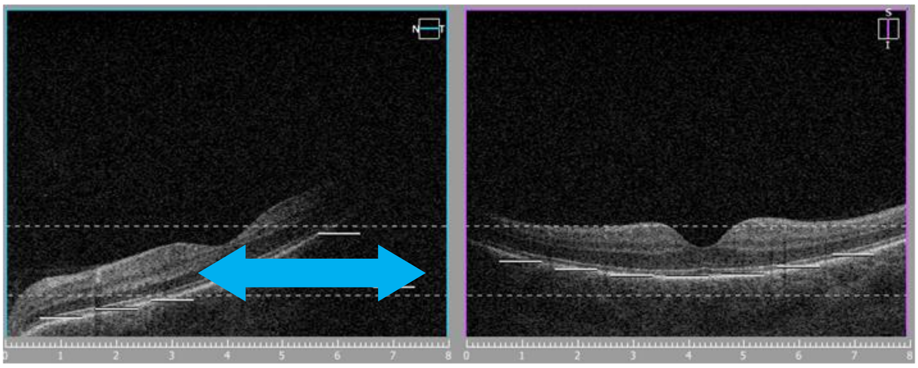


Figure 67. Shadow on tomogram, grab and drag towards right side

Horizontal line in fundus preview window relates to left part of scan preview window. This scan also should be horizontal. In the case here above the tomogram should be dragged right (head movement device should be moved right to align scan and remove shadow. The easiest way to align the tomograms is to drag a tomogram to the proper position. If it is required to manually align working position across the center of the pupil, move first the scanning head (usually forward) to working distance. At the working distance images created from two preview cameras create one equal view. Then click on the pupil or use up/dw and right/left movements to place the white cross in the center of equally aligned pupil.

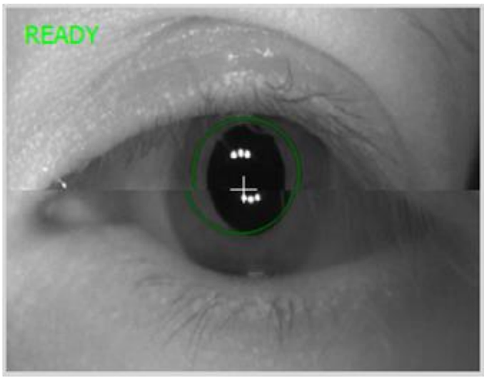


Figure 68. Proper live eye preview while manual acquire mode

8.8 Critera for Exam Acceptance

Use the following criteria to ensure that an OCT image you have captured is suitable. Evaluate Fundus reconstruction to see the quality of the OCT exam and then evaluate OCT images.

8.8.1 *Evaluation of OCT Fundus reconstruction for Posterior 3D exams.*

• The fundus reconstruction image should be sharp and clear, preferably with good visibility of the branching blood vessels

• The Fundus reconstruction image should have uniform saturation without dark corners

• The Fundus reconstruction image should have no or minimal saccades throughout the scan

The operator should review the Fundus reconstruction image to ensure that there are minimal saccades and no saccades in the area of interest (e.g. macula).

A saccade can be detected by discontinuities in the appearance of the blood vessels (for example, a horizontal shift of the vessel at a specific location).

• The Fundus reconstruction should have no blinks

• The Fundus reconstruction: there should be no, if any, artefacts that may cast shadows on the OCT scan. Shadows can come from media opacity such as e.g. cataract or floaters.

<u>Small pupil scan</u>

There is a visible dark area on the edges of the scan.

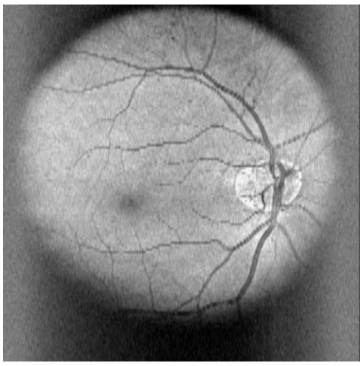


Figure 69. OCT scan through a very small pupil

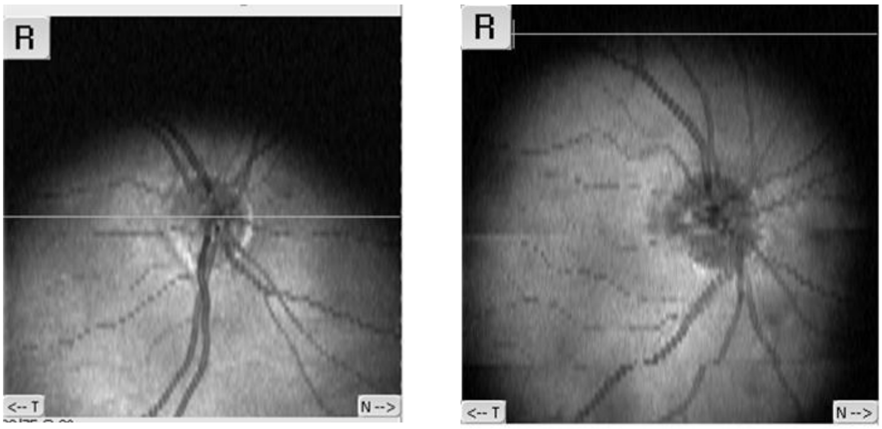


Figure 70. Examples of scans with dark corners

<u>Locally Weak Signal</u>

Regional drop of the signal, either caused by floaters or by media opacity e.g. cataract can be recognized in the fundus reconstruction image and confirmed in corresponding B-scans.

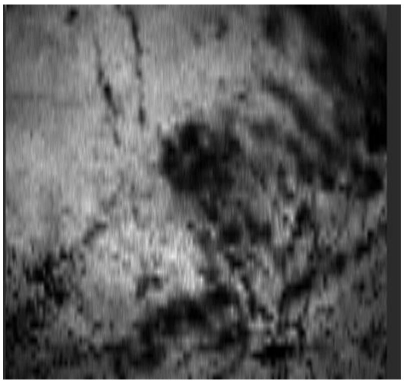


Figure 71. Example of a cataract patient with a loss of saturation

Floaters

Similar to blinks, floaters are obstructions of 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 visible in the example below. This example also shows saccadic motion.

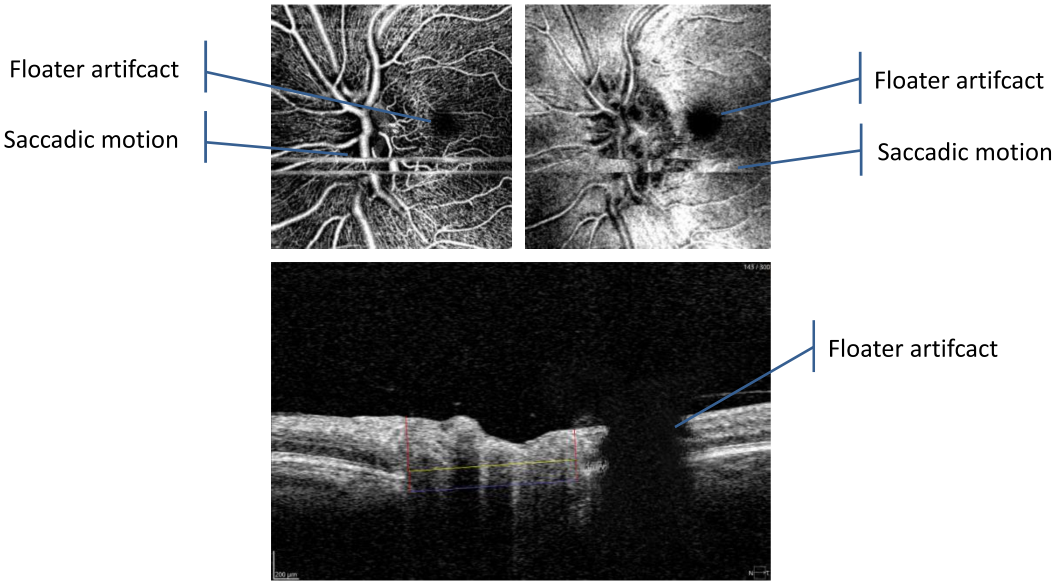


Figure 72. Examples of floaters with saccadic motion

These above “shadows” 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 the 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 calculations, it may significantly affect results analysis. These examinations should therefore be analyzed carefully or repeated without floaters. The above examination in particular also has saccadic motion, therefore it should be repeated regardless.

Blinks

Blink artifacts are obstructions of the OCT scan beam during acquisition causes 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 iTracking™ enabled. Below is an example of a blink in the OCT image.

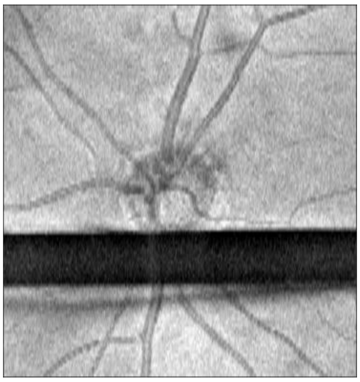


Figure 73 Example of an uncorrected blink

Example of blinks corrected by Motion Correction that is acceptable for analysis.

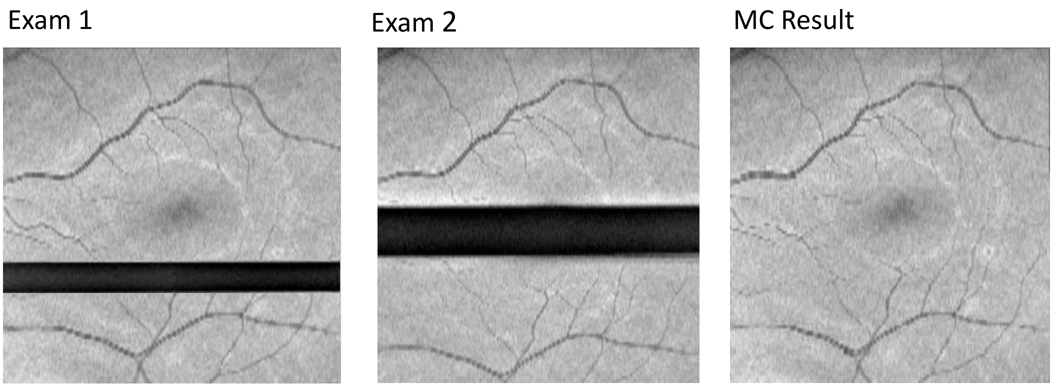


Figure 74 Blink artifacts corrected to an acceptable standard

Blinks can also be identified as a local signal reduction. Although this type of local signal reduction is not analyzed by the Quality Index calculations, it may significantly affect results analysis. These examinations should therefore be analyzed carefully or repeated without artifacts.

Saccades

A saccade can be detected by discontinuities in the appearance of blood vessels, usually visible as a horizontal shift of the image. For 3D exams it is important to ensure that there is minimal if any, saccadic motion. There should be no protrusion into or through the areas of interest, such as the macula or optic disc. iTracking™ is purposed with minimizing the possibility of saccadic motion being captured. Below is an example of multiple horizontal shifts known as saccades and is not acceptable for analysis.

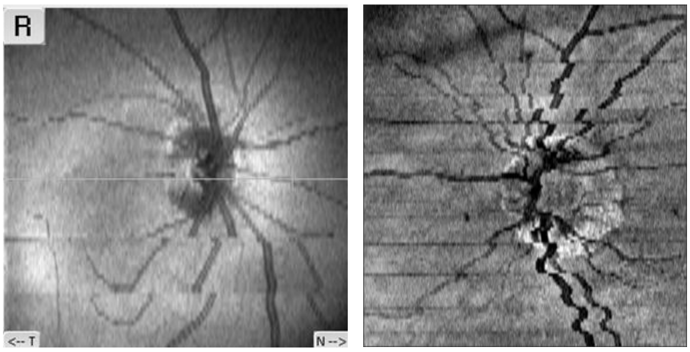


Figure 75. Example of a saccade

Example of saccadic motion corrected by Motion Correction that is acceptable for analysis after processing.

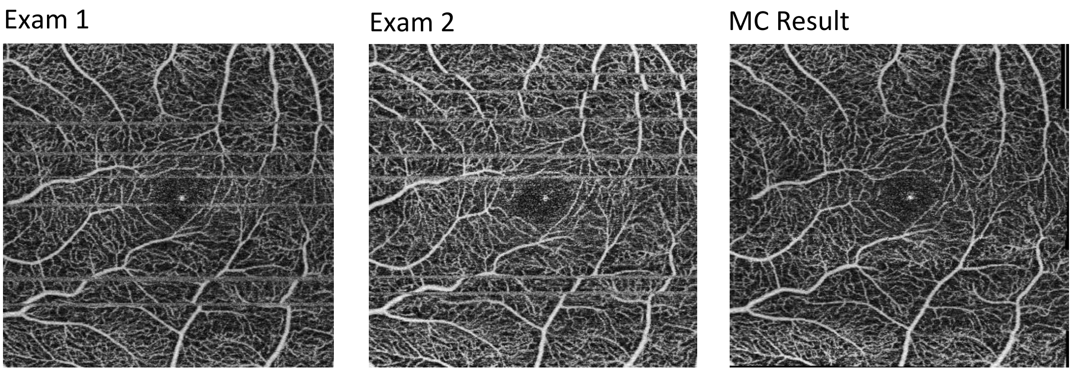


Figure 76 Saccadic Motion corrected to an acceptable standard

8.8.2 *Evaluation of OCT tomograms for Posterior and Anterior scans*

- The central part of the scan has to be centered on the fovea or the apex of the cornea or Anterior Angle has to be in the center
- OCT scans should be complete and without missing data
- Verify the position of the retina or the cornea in the scan window. No part of the signal can touch the upper or lower edge of the tomogram. If the tissue of the eye is captured too low or too high in the axial field of view of the scan, then part of the signal will be overlaid by a ghost signal and it can present an untrue structure
- The intensity of the signal has to be uniform from one end of the tomogram to the other

- The retinal image should be well-defined. Retina surface has to be strongly distinguished from the background and hiper-reflective layer. (ILM, OS/RPE) should not have excessive motion artifacts
- The corneal image should have well–defined posterior and anterior surfaces, should not have excessive motion artifacts
- The corneal image should have well–defined posterior and anterior surfaces, should not have excessive motion artifacts and strong reflections from anterior surface

If the image does not meet the criteria the operator has to retake it.

Example of a well saturated and centered tomogram with the fovea in the center.
The signal is equally saturated across the whole scan.

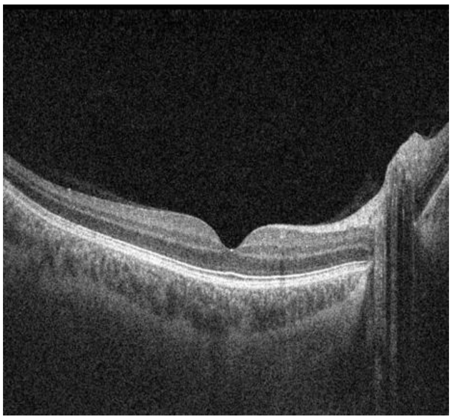


Figure 77. Example of a well saturated and properly centered tomogram

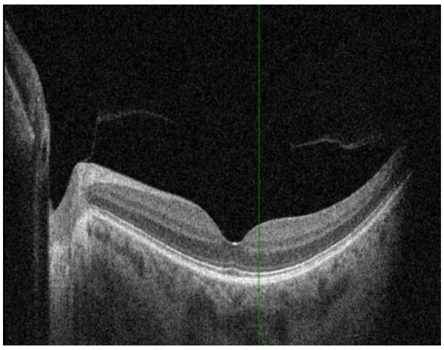


Figure 78. Example of a scan with shadowing visible on the side

Example of Cataract

Example shows an image with a poor signal quality throughout part of the OCT image. On the left side of the OCT image a properly saturated structure is brightly visible. The retinal layers on the right side are not visible on All A-scans.

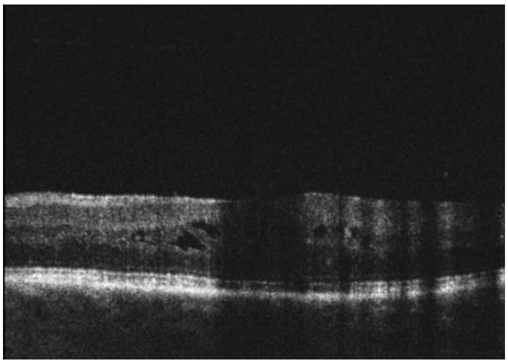


Figure 79. Example of a scan with cataract

Example of an OCT image placed too high 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.

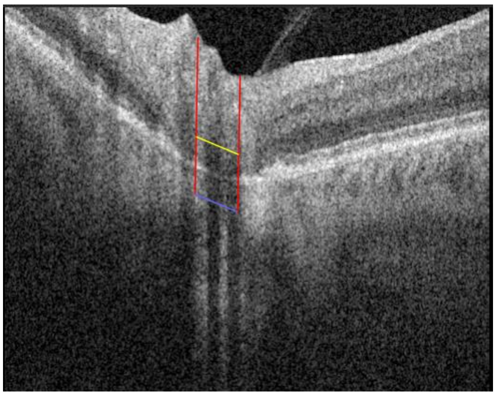


Figure 80. Example of an OCT image placed too high

Example of an OCT image placed too high. The whole scan is out of the scan window.

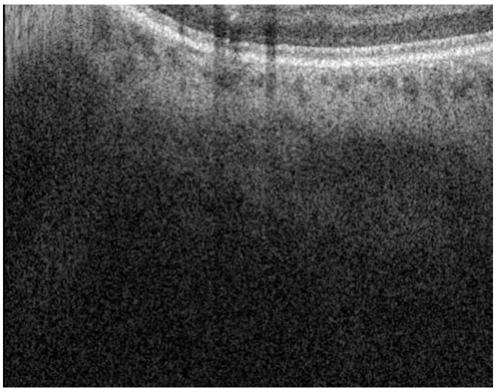


Figure 81. Example of an OCT image placed high and out of the scan window

8.8.3 *OCT images*

- For optimal quality, the signal strength should be rated 7 or more.
- Scans should be complete in all windows without missing fields.
- Density of color and features should be the same throughout.

8.8.4 *Fundus photography*

- The scan should be overlaid and centered directly on the fovea or optic nerve head.
- Photo focus should be sharp and clear. Branching blood vessels should be clearly visible.
- Artifacts that may cast shadows on the OCT scan should be kept to a minimum.

8.9 3D Examination Acceptance Criteria

Prior to accepting a 3D examination, the user must ensure that the acceptance criteria are met.

8.9.1 *Saccades*

Obstructions in the form of saccades are described in section 8.8.2 Evaluation of OCT tomograms for Posterior and Anterior scans

8.9.2 *Banding*

Carrying out 3D exams with iTracking™ enabled may lead individual B-Scans being acquired at different horizontal positions. Due to this, there may be vertical tissue variations in the B-scan window. Although iTracking™ is also purposed with correcting 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:

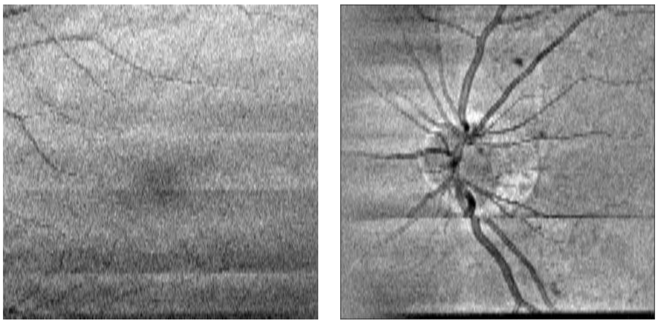


Figure 82. Examples of banding

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. The operator is therefore advised to save the exam.

8.10 **Weak local signal**

Weak local signal is often caused by media opacities between the OCT scan beam and the eye. There are several causes and sometimes carrying out an examination again will resolve the problem.

8.10.1*Blinks*

Visual obstructions in the form of blinks are described in section 8.8.2 Evaluation of OCT tomograms for Posterior and Anterior scans.

8.10.2*Floaters*

Visual obstructions in the form of floaters are described in section 8.8.2 Evaluation of OCT tomograms for Posterior and Anterior scans.

8.10.3*Cropped Image*

In cases where the retina is placed too high or too low in the OCT acquire window, it will usually lead to image cropping. These can be recognized in the reconstruction image and cross-checked against corresponding B-scan images.

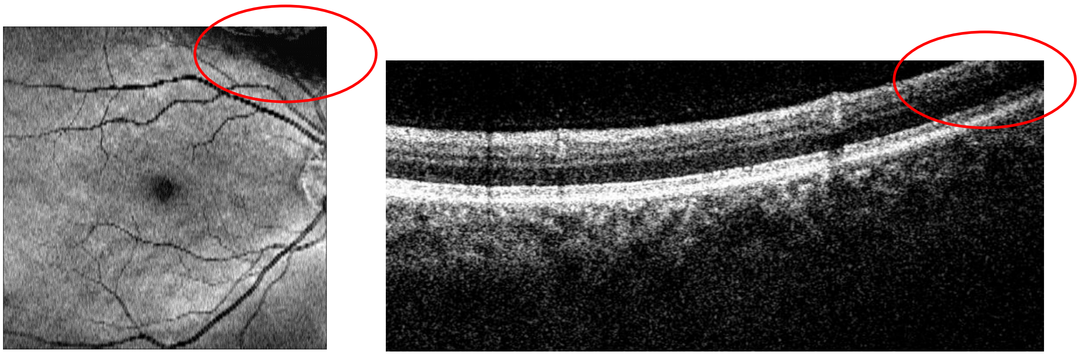


Figure 83. Example of a cropped image

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.

8.11 **OCT Angiography Acceptance Criteria**

Prior to accepting an Angiography exam, the user must take the following points into consideration:

- Segmentation errors
- Image quality

8.11.1 *Segmentation errors*

These errors may result in incorrect visualization of Angio flow. The two boundary lines are used to determine the particular enface image shown appear as purple and green lines overlying the B-scan. 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 shouldn't be.

For example, the below image that should be avascular shows several bright areas. Examination of the B-scan shows an area that has pushed the segmentation up into the hyper-reflective outer plexiform layer. This was caused by a drusen, therefore any bright signal detected at this location is likely due to ordinary inner retinal vasculature and should be regarded as an error.

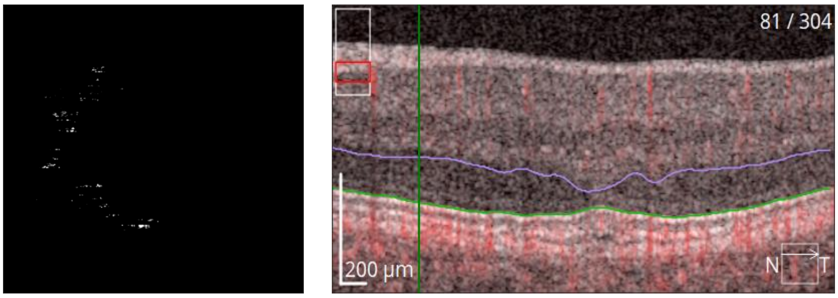


Figure 84. Example of a segmentation error in OCT Angiography

This example shows an avascular retinal layer which demonstrates that the segmentation is not correctly passing through the outer retinal layer that is expected to be free of signal.

8.11.2 *Image Quality*

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.

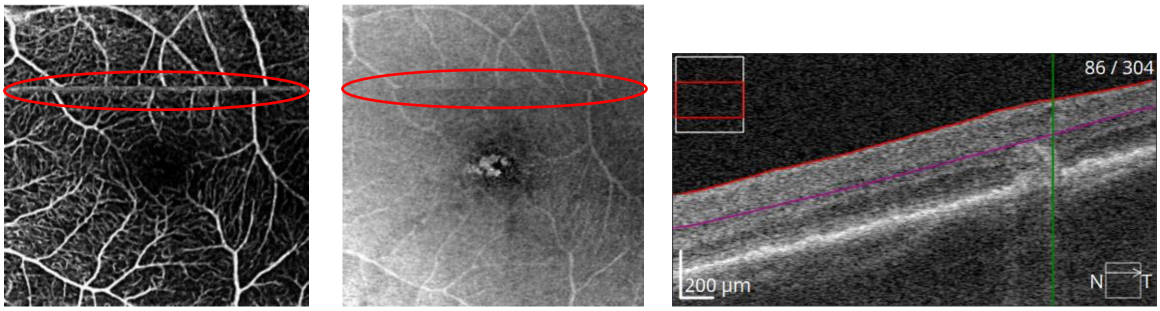


Figure 85. Example of poor image quality caused by saccadic motion

It is clear that 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 a real disease, the image will appear dark, but the B-scan and enface image will not. To cross-check this for errors, it is advisable to carry out more than one examination in cases where floaters or other media opacities may be an issue.

9 RESULT REVIEW

This chapter describes kind of reports which show the analysis results of examinations.

Analysis depends on the scan mode and diagnostic purpose of analysis.

Results review window enables operator to browse all the stored examination results. This window contains all tools for analysis of acquired data. The main window contains tabs: Tomogram, 3D-Imaging, Retina, Glaucoma or cornea analysis, Comparison, Fundus camera image.

9.1 Type of View Mode

Depending on the type of examination the system can display different analysis views.

Not all views are available for each scan.

9.1.1 *[Single] tab screen*

This screen shows the analysis results of one eye.

9.1.2 *[Both Eyes] tab screen*

This screen shows the analysis results comparing examinations of both eye in the same scan mode on the same date.

9.1.3 *[Comparison] tab screen*

This screen shows the analysis results comparing two examinations of one eyes on the same side in the same scan mode, 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 section 9.1.5 Lock function.

9.1.4 *[Progression] tab screen*

This screen shows the analysis results comparing six examinations arranged in time sequence of eyes on the same side in the same scan mode, and same size of scanning area.

9.1.5 *Lock function*

9.1.5.1 Standard Lock function

The *Lock* Function  enables simultaneous and synchronized manipulation of several tomograms. Available operation: scrolling examination, zooming in/out, moving tomograms, changing display parameters i.e. brightness/contrast, display method. The Lock is available in the 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 choose .

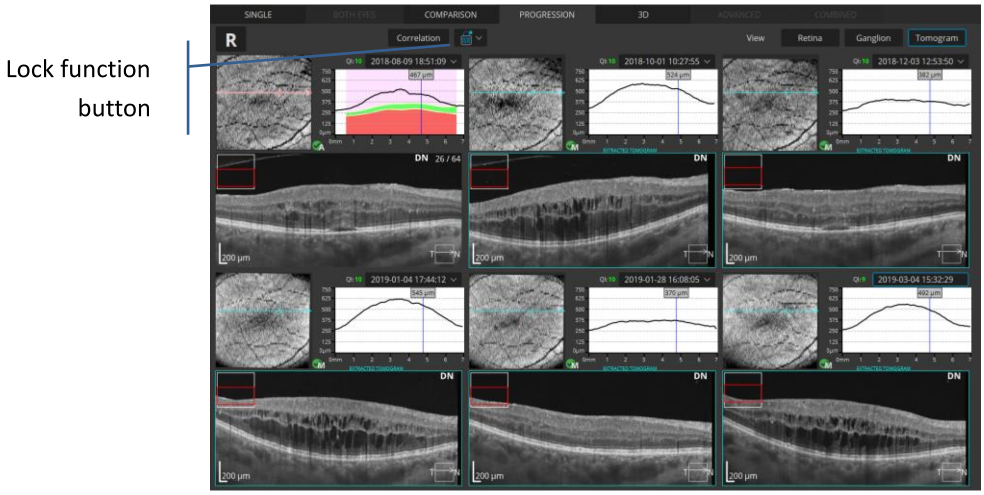


Figure 86. Progression view – Lock function on

9.1.5.2 Lock function with extracted tomograms

The Lock Function is also available in conjunction with the function of extracting tomograms described in detail in section 16.3 Extracting tomograms from a 3D exam. To both lock and extract correlated tomograms click the arrow next to the lock button  to unfold a drop-down menu and choose .

9.2 **Types of Analysis**

9.2.1 *Single Retina analysis*

This shows the tomogram image of the macula and analysis results of retinal thickness from Retina 3D scan. There are two analysis views available.

9.3 **AI DeNoise**

The AI DeNoise algorithm filters out noise form the tomogram for the highest and smoothest image quality. The function is available on all tomograms and in every tab featuring them, including the 3D tab. On averaged tomograms the function is on by default.

The moment a tomogram is loaded for review the software starts denosing it. After a short moment the original "undenoised" tomogram is replaced with a noise-free image.
This process is started each time you load or scroll to display a new tomogram.

The figures below present the same tomogram with the AI DeNoise function off (left) and on (right).

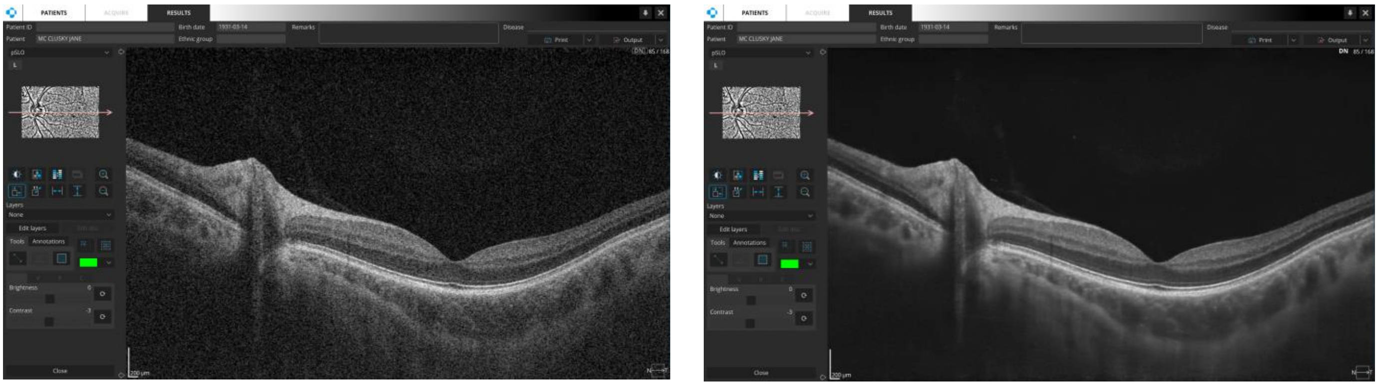
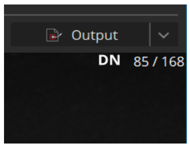


Figure 87. AI DeNoise off (left) and on (right)

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 or low QI may be challenging to be processed correctly. When working with such tomograms it is recommended that the user always compares the denoised image with the unprocessed image to make sure there is no variance between 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 always turn the function off and go back to the original image. To do that 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 remembered to be restored when you launch the software again.

9.3.1 *3D Tab*

The AI DeNoise function in 3D tab is available in both the Solid and the Volume view. To turn it 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 denoise function is turned off. The state of the checkbox inside the 3D tab does not influence the AI DeNoise switch in other tabs.

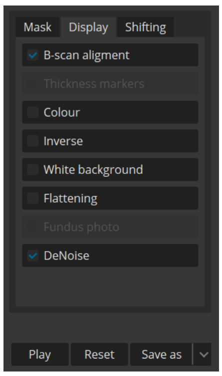


Figure 88. DeNoise checkbox in the 3D tab

10 POSTERIOR ANALYSIS

10.1 Retina Thickness Analysis

[Requirements that must be met for loading perimeter tests in the SOCT application](#).

10.1.1 *Single Tab*

In „Single Tab” single eye retina analysis is presented. For each examination retina charts and maps used for diagnosing are calculated. Except for maps interpretation it is possible to browse single tomograms that illustrate changes in the retina structure.

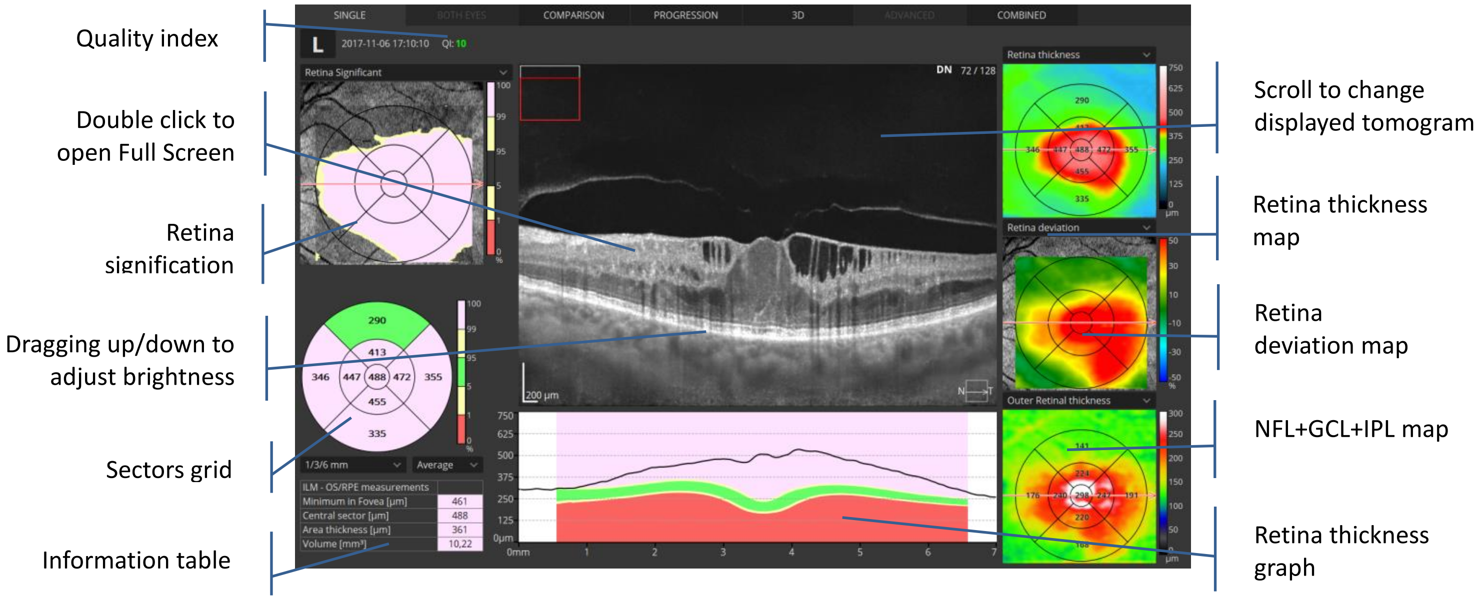


Figure 89. Single eye retina analysis

10.1.1.1 Tomogram window

Scroll the Mouse wheel to change displayed tomogram.

Double click to open Tomogram Full screen window.

Press right mouse button to display Functional menu.

Hold right mouse button and move right/left and up/down to change brightness and contrast.

10.1.1.2 Retina signification

The fundus reconstruction image is created from all A-scans made in the scanned area.

From the menu available by the right mouse button you can select the image to overlay.

The following images are available:

- Fundus reconstruction,
- pSLO,
- Fundus photo,
- Import fundus photo.

To change transparency level, turn the mouse wheel on the fundus reconstruction image.

Right Click (long press using touch screen) over the eye preview window opens the following display and actions menu.

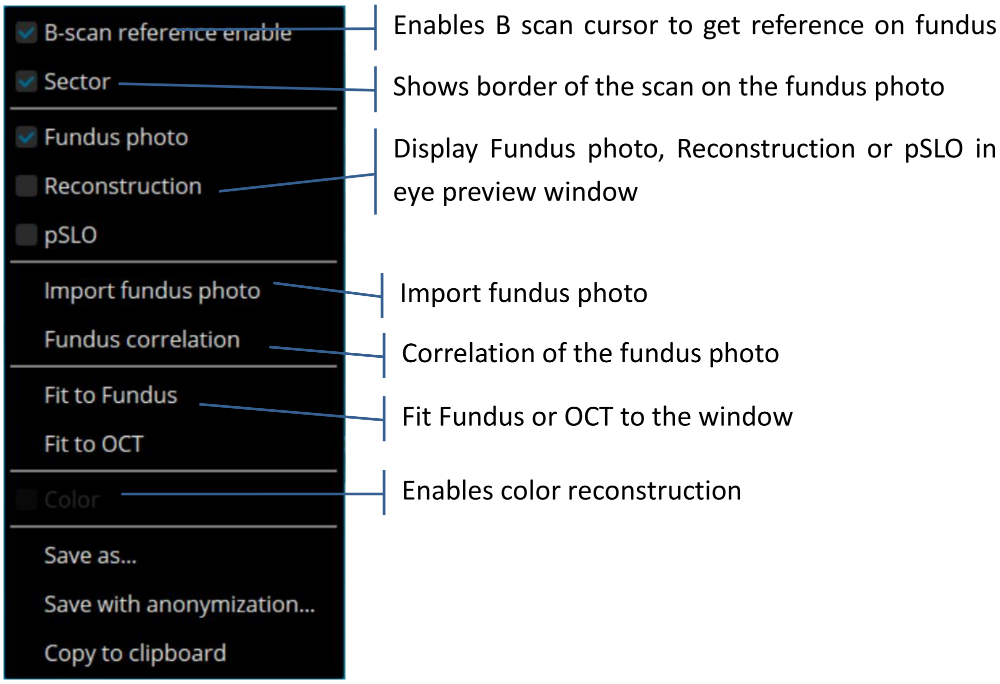


Figure 90. Eye preview widow context menu

10.1.1.3 Sectors grid

Sectors graph corresponds to the grid overlaid on the Retina thickness map. In the sectors graph the retinal thickness of each sector appears. Background colors are color-coded based on the normative database.

It is possible to show sector with diameter: 1 / 3 / 6 [mm] or 0.6 / 2.22 / 3.45 [mm]. When "Grid" option is selected, the whole map will be covered by grid of numbers. Each number represents thickness at a selected point.

You can choose which value you want to observe in sectors: Mean, Maximum, Minimum or Volume of the zone. The thickness map is further organized and presented in the nine ETDRS-like Zones.

10.1.1.4 Information table

In the information table there are: average thickness of central sector, volume of scanned cube and average retina thickness in scanned cube.

10.1.1.5 Retina thickness graph

Background of Retina Thickness graph shows the normative margin, the vertical blue line corresponds to the horizontal position of the pointer on the tomogram. These graphs are obtained only after detecting layers by means of Layers function.

The normative data are applicable to scans acquired with 3D scan mode. When the "Layers" checkbox is marked and 3D protocol is applied to an applicable scan, normative data ranges appear in the background. It uses a light red, light yellow, light green, yellow, red color codes like in the legend below, to indicate values. The color code applies to each particular A-scan location in the graph.

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

White area on the retina thickness chart identifies the area that is not covered by normative data. e.g. scan length higher than 7mm and fovea not in the center of a scanned area.

10.1.1.6 Macula Normative distribution:

1 %	1% falls within the light red band, considered outside the normal limit
4 %	4% fall within or above the light-yellow band
90 %	90% fall within the green band
4 %	4% fall within or below the yellow band
1 %	1% falls within the red band, considered outside the normal limit

NOTE: Clinicians must exercise judgment in the interpretation of the normative data. For any particular measurement, note that 2 out of 20 normal eyes (10%) will fall above or below green.

DISCLAIMER: OPTOPOL Technology Sp. z o.o. takes no responsibility for diagnostic interpretation of OCT images. It is the clinician's responsibility to make diagnostic interpretations of OCT scans.

10.1.1.7 Retina thickness map

Scroll over the tomogram to change the tomogram. Thickness at the single point of map can be measured. Place mouse cursor over any map at the desired point and click left mouse button. Detailed values will be displayed in the panel in the upper left corner of every map.

Macula location is detected automatically. There is possibility to correct fovea detection. Move mouse cursor over a center of central sector. Click and hold left mouse button on a white dot at "Retina thickness map" and move pointer to the desired position.

10.1.1.8 Quality index

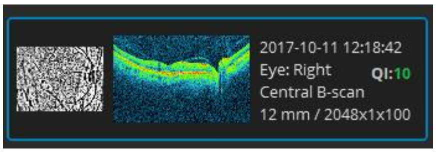
Quality Index is a numerical value which represents the OCT exam image intensity and signal coverage. The QI is a quantitative measure of signal strength, greater intensity corresponds to a higher QI. Quality index takes values in the range from 0 to 10, where:

0 - represents the noise level (i.e. examination scanned without any object)

10 - represents a scan of a healthy patient with high saturation of signal and lack of shadings in the boundary areas.

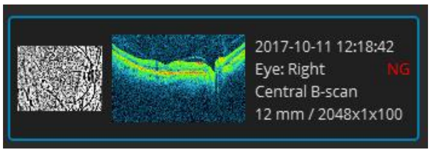
The Quality Index is a global examination index, which represents an average quality of all tomograms. Quality Index uses all b-scans for 3D scans. When averaging is used (b-scan, cross, radial, raster) the system calculates QI only from averaged images.

QI should be displayed on the thumbnails area under the exam date in single, both, comparison and progression views.

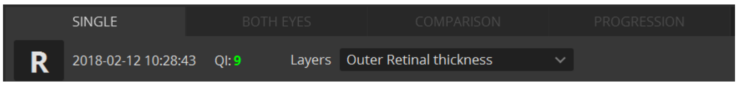


NG (Rejected Status): if the examination has been marked as rejected, the NG mark is displayed instead of QI on the examination list (only)

When the examination has QI=0 it is automatically labelled NG. If the NG label is not selected to be automatically displayed on the tomogram – the TQF window is displayed instead.



QI must be placed on every report printed or saved into a file. QI must be displayed below the exam date. Depending on the particular view the QI label position may differ.



Single view

10.1.1.9 Retina Deviation Map

Retina Deviation Map shows the percentage loss of the retinal thickness from the norm determined from the normative database. Each pixel value on the map is calculated as percentage value by the following formula: (Thickness value – Normal value)/(Normal Value) * 100.

The range of the color-coding of the map corresponds to -50% to 50% deviation.

The color-coding is roughly defined as below.

Red: Maximum (+50%)

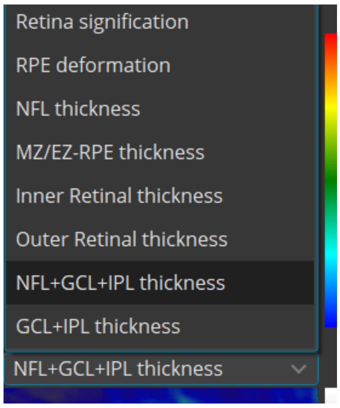
Yellow: Around Upper Middle

Green: Around Middle (0 %)

Cyan: Around Lower Middle

Blue: Minimum (-50%)

10.1.1.10 Thickness map



- Retina Significant
- Retina deviation
- RPE deformation
- NFL thickness
- MZ/EC-RPE thickness
- Inner Retinal thickness
- Outer Retinal thickness
- NFL+GCL+IPL thickness
- GCL+IPL thickness

10.1.1.11 RPE Deformation Map

This color-coded map displays the elevation of the RPE from a normalized plane.

The RPE deformation is a difference between a normalized RPE parabolic fit and an outer boundary of RPE layer.

10.1.2 *Both eyes tab*

In the tab „Both eyes" it is possible to make comparison of both eyes' analysis i.e. left and right eye. As a consequence, symmetry analysis of both eyes can be done there.

10.1.2.1 Retina view

Retina view on a Both eyes tab displays the output of the retinal thickness map, thickness/volume sectors map plus two other maps. It is possible to choose from the bottom Retina thickness/Retina signification/Retina deviation/Not overlaid.

This analysis protocol operates on one Right and one Left examination made with the 3D or Radial of Macula protocols.

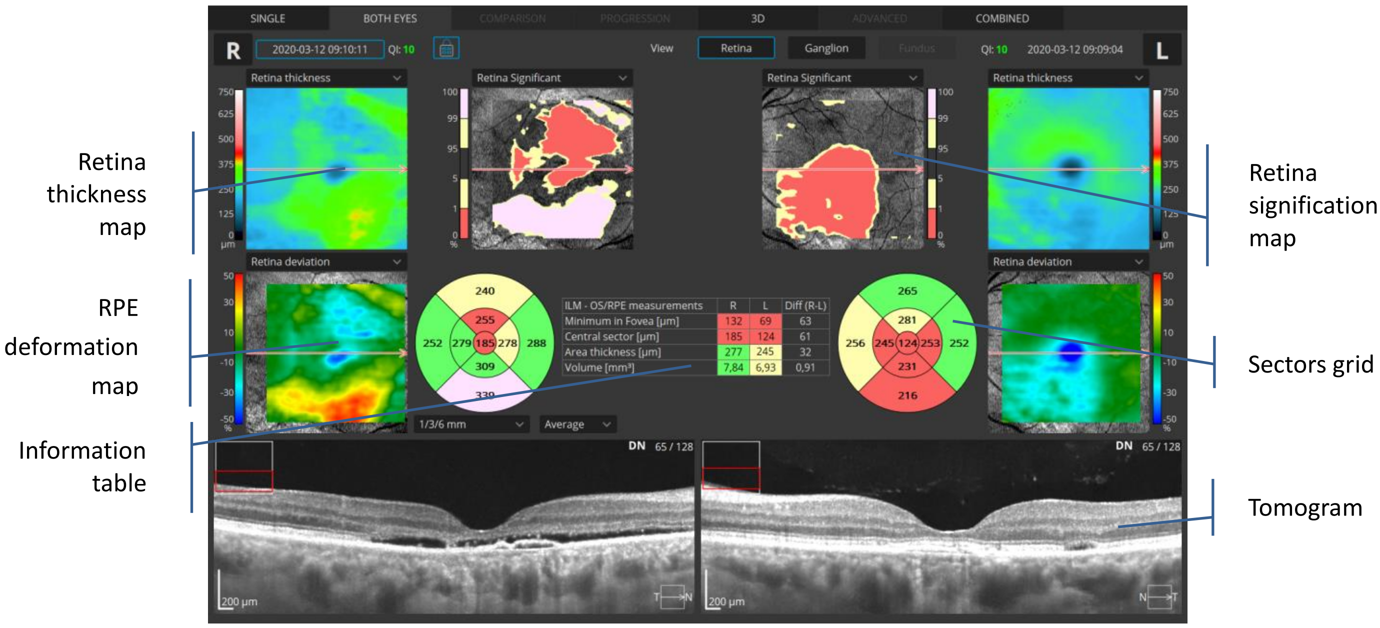


Figure 91. Both eyes retina analysis

Sectors Map shows either average, maximum, minimum retinal thickness (in microns) or volume (in mm^3) in each area. From Map Sector Dimension checklist choose circle diameters 0.6 / 2.22 / 3.45 mm or 1 / 3 / 6mm.

10.1.2.2 Ganglion view

This tab is enabled only with Retina 3D scan.

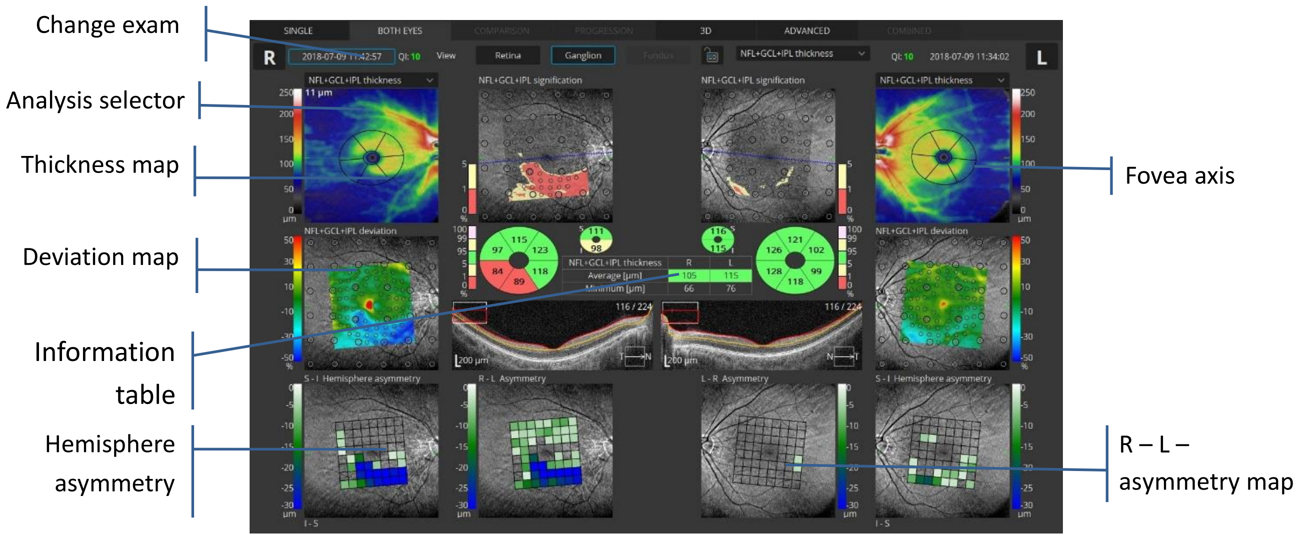


Figure 92. Ganglion Cell Analysis (GCC)

Software offers two methods of an indirect measurement of the Ganglion Cell layer:

- RNFL+GCL+IPL
- GCL+IPL

Thickness map to overlay on the fundus reconstruction can be selected from the list box:

- RNFL+GCL+IPL Thickness Map
- GCL+IPL Thickness Map

VF Locations - Right click on any of the above maps to view the context menu from which VF locations display can be enabled. See chapter 10.4.4 Structure & Function - VF Locations layers.

To change transparency level, turn the mouse wheel over the object.

RNFL+GCL+IPL NDB / GCL+IPL NDB Reference Map.

This color map shows a comparison of RNFL+GCL+IPL / GCL+IPL thickness with the normative database.

Blue dashed line shows axis used for asymmetry analysis. To modify the axis, place the cursor over the line, press and hold the left mouse button and move line to the desired position.

RNFL+GCL+IPL / GCL+IPL Deviation Map

This color map shows the difference between thickness of analyzed layers and the normative database.

S – I – asymmetry map

Asymmetry Maps – Asymmetry Maps compare the analyzed thickness of corresponding grid cells (or super pixel) within the same eye across the anatomic axis (Hemisphere Asymmetry). Mean thickness of corresponding cells is compared and displayed in a grayscale.

Right click the asymmetry map and select [Set standard grid resolution] or [Set super grid resolution] to change the display method.

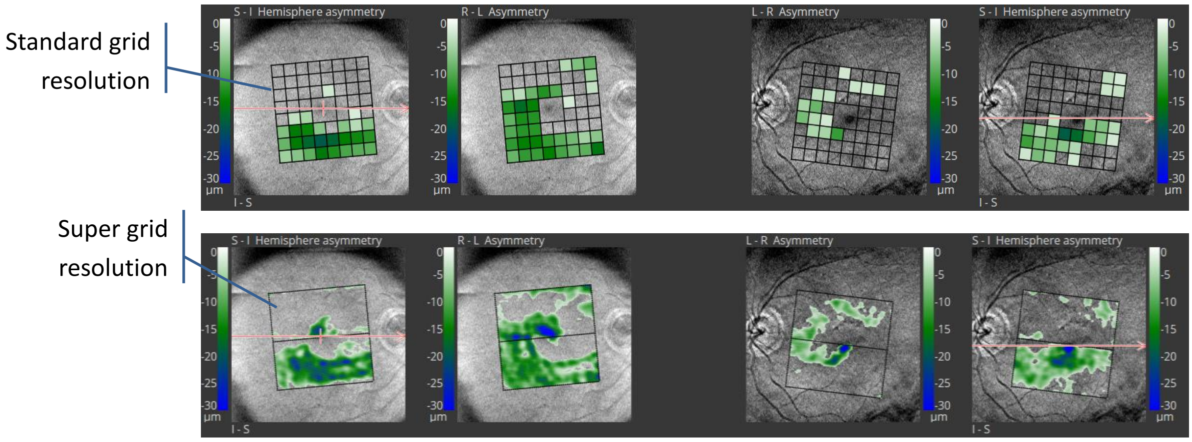


Figure 93. Asymmetry maps

If the difference between the "superior region” and “inferior region" is a negative value, the background color is shown. The background color is not shown for positive values.

NOTE: RNFL distribution in the macula depends on the individual anatomy, while the GCL+IPL appears regular and elliptical for most normal cases.

When RNFL+GCL+IPL method is used for some cases it may be required to make the manual correction of axis fovea-disc.

R- L – asymmetry map

R - L and L -R Asymmetry – Compares thickness of cells (or super pixels) between eyes by highlighting in color scale all cells, that are thinner than corresponding cells in the other eye.

If the difference between the "right eye” and “left eye" is a negative value, the background color is shown. The background color is not shown for positive values.

Tomogram

Use mouse scroll to change the displayed tomogram. Press and hold [CTRL] button to change the zoom level while turning the mouse wheel.

Double click the tomogram to open it on full screen.

Table

Table contains average and minimum thicknesses of the RNFL+GCL+IPL /GCL+IPL which are measured in an elliptical annulus.

Sector maps

Sectors divide the elliptical annulus of the Thickness Map into 6 regions: 3 equally sized sectors in the superior region and 3 equally sized sectors in the inferior region. Dimensions of sectors: vertical inner diameter 1 mm and vertical outer diameter 4.2 mm, horizontal inner diameter 1.2 mm and horizontal outer diameter 4.8 mm. Values are compared to normative data.

The size and shape of the annulus are the result of an analysis of a normative thickness of GCL+IPL layers.

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

⚠ **DISCLAIMER**: OPTOPOL Technology Sp. z o.o. takes no responsibility for diagnostic interpretation of OCT images. It is the clinician's responsibility to make diagnostic interpretations of OCT scans.

10.1.2.3 Fundus view

This tab is only available to examinations carried out along with a fundus photo. This view presents the results in a clear way.

Figure 94 Both Eyes Fundus View

10.1.3 *Comparison*

The comparison module is used to observe follow up changes in the eye structure.

System automatically tries to correlate examinations. System displays correlation status as a right side of exam time. Available statuses:

A - Automatically correlated

M - Manually correlated

Not correlated. In this case press [Correlation] button to correlate exams manually.

NOTE: In case when examinations are not correlated, evaluation of the quantified values has to be done carefully. For correlation, see chapter 16 EXAMINATIONS CORRELATION.

Software automatically selects outermost examinations (the oldest and the newest) in order to compare them. The user can manually choose examinations from the list depending on chosen comparison protocols that are highlighted.

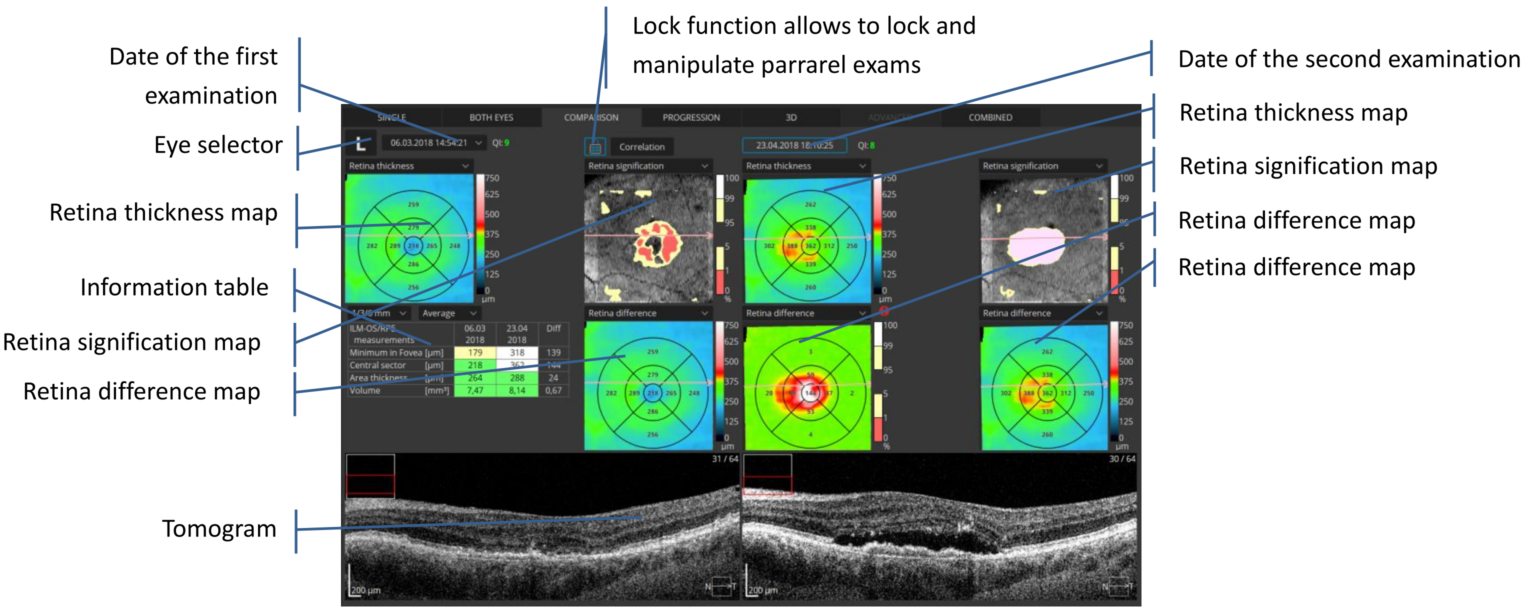


Figure 95. Follow up comparison of the two retina examinations

In the Comparison tab it is possible to compare different kinds of maps. The user can choose Retina thickness, signification and difference map.

The user can also change the way the measurements are displayed.

Two options are available:

- rings: 1; 3 and 6 mm (standardized ETDRS testing),
- grid.

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. The function is described in detail in section 9.1.5 Lock function.

For the COMPARISON view after clicking the Examination selector button the options [Equal interval] or [Latest scanned] are available. [Equal interval] chooses examinations for the COMPARIOSN view scanned in equal intervals between baseline and current examination.

[Latest scanned] chooses the current and the latest scanned examinations.

For Disc examination the [Equal interval] is set as default.

For Retina and Central examinations, the [Latest scanned] is set as default.

The system stores information about the selection method separately for Disc, Retina & Central. This information is stored globally (remains unchanged after restarting the software).

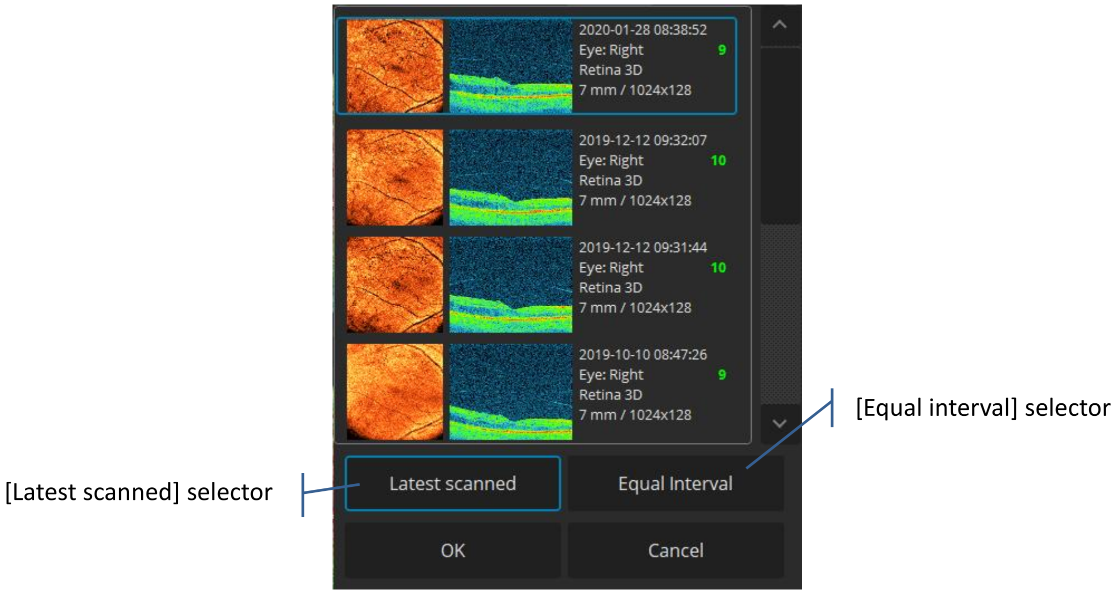


Figure 96. Latest scanned and Equal interval selector for COMPARISON view

10.1.4 *Progression*

In the Progression tab it is possible to see differences in the zones on the plots.

System automatically tries to correlate examinations. System displays correlation status as a right side of exam time. Available statuses:

 A - Automatically correlated

 M - Manually correlated

 Not correlated. In this case press [Correlation] button to correlate exams manually.

NOTE: In case when examinations are not correlated, evaluation of the quantified values has to be done carefully. For correlation, see chapter 16 EXAMINATIONS CORRELATION.

10.1.4.1 Retina view

The Retina View allows the user to compare Retina thickness, Retina difference, Retina Signification and Retina deviation between all the examinations selected, sector by sector.

Single sector plot shows differences in a graph regarding the selected sector. It is possible to decide which zone/s are compared: Central sector, Full retina thickness or Total retina volume.

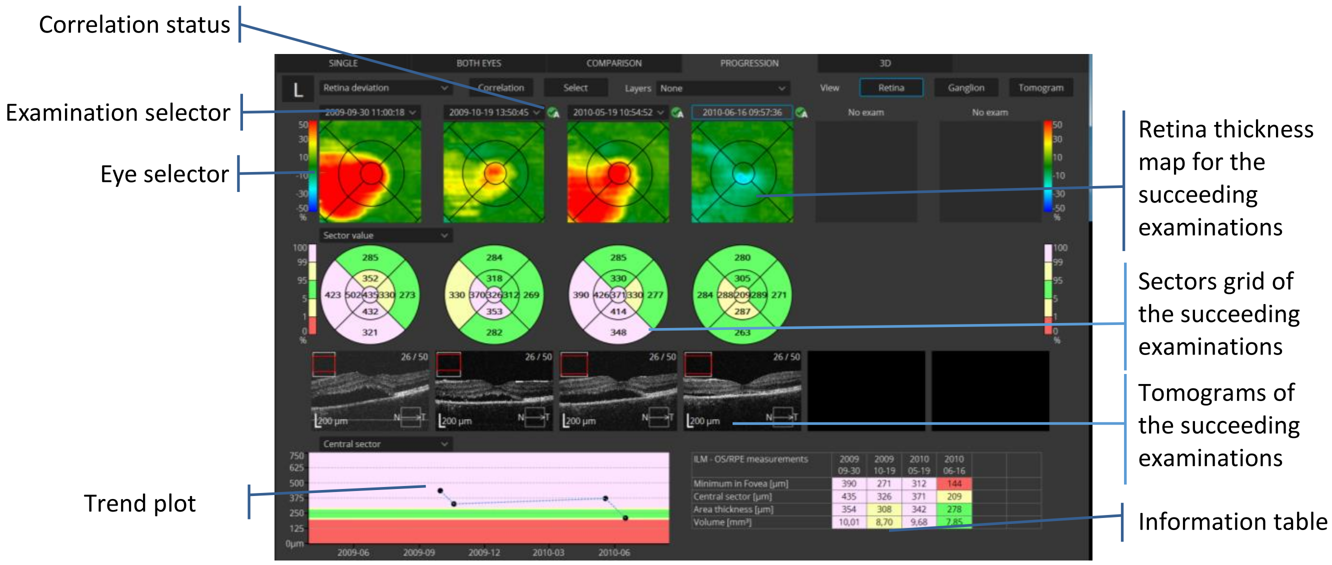


Figure 97. Follow up of the selected retina examination

Consolidated plot shows the differences in each zone on one plot.

For the PROGRESSION view after clicking the [Select] button the options [Equal interval] or [Latest scanned] are available. [Equal interval] chooses examinations for the PROGRESSION view scanned in equal intervals between baseline and current examination.

[Latest scanned] chooses the current and the latest scanned examinations.

For Disc examination the [Equal interval] is set as default.

For Retina and Anterior examinations, the [Latest scanned] is set as default.

10.1.4.2 Ganglion view

The Ganglion view is available for 3D Retina scan only.

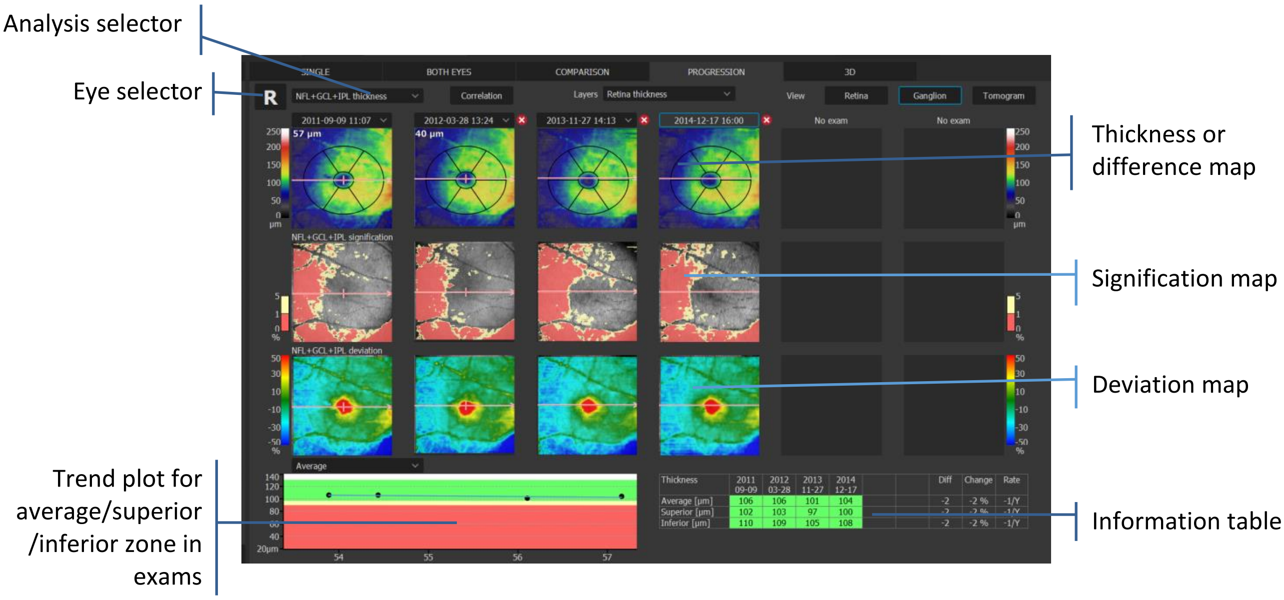


Figure 98. Follow up of the changes in ganglion cell analysis

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 RNFL+GCL+IPL or GCL+IPL grid:

- [RNFL+GCL+IPL/GCL+IPL Thickness]: shows the thickness map for four examinations,

- [RNFL+GCL+IPL Difference]: shows the difference between the Baseline (oldest examination) and displayed examinations as a color map and values. For the Baseline examination the Thickness Map is shown instead of difference.

RNFL+GCL+IPL/GCL+IPL Progression plot.

This plot shows changes in the analyzed thickness over time. Plot shows differences in a graph with regard to the analysis selector. It is possible to decide which zone/s are compared. Linear regression analysis is performed to fit a straight line through the longitudinal data to estimate the rate of change.

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 rightmost column is the rate of change. The rate value appears only if the time interval between baseline and next exams is at least three months. Background colors are color-coded according to the normative database.

10.1.4.3 Tomogram view

On the tomogram view tab, the software displays tomograms and fundus reconstruction of each compared examination. The user can manually select examinations from the list. Press "V" icon near the time of examination to open selection list.

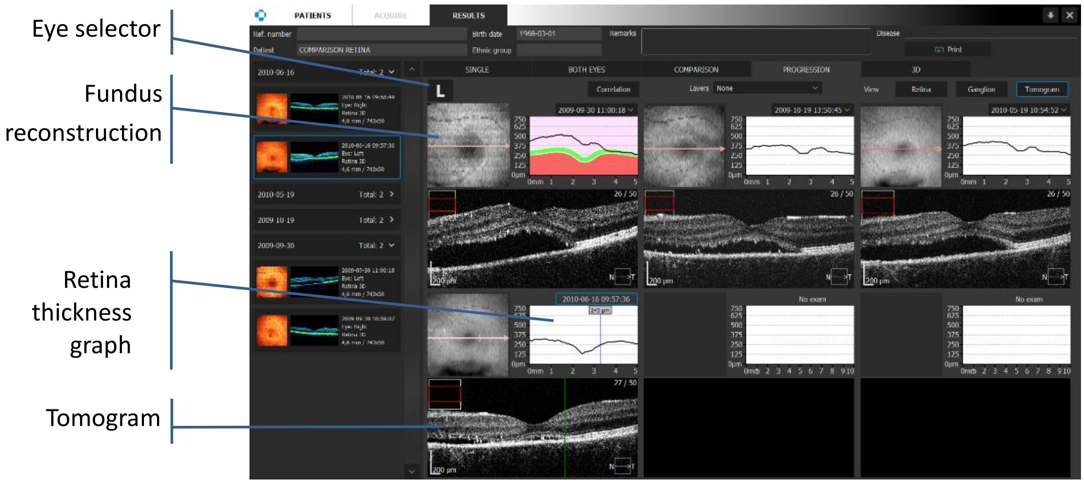


Figure 99. Comparison of the tomograms from succeeding examinations

NOTE: Pay attention when you evaluate the tomogram with different parameters setting and/or with different scanned widths, proportion of retina shape may not be kept.

NOTE: Pay attention when you evaluate the tomograms on the Quick Printout if scanned widths were different between examinations.

This shows the tomogram image from the macula up to the optic disc, and analysis results of retinal thickness.

10.2 OPTIC NERVE HEAD ANALYSIS

This shows the thickness of NFL (Nerve Fiber Layer) and analysis results of the shape of the optic nerve head. The compatible scan mode is [Disc 3D].

The measurement result of the optic disc and TSNIT region is analyzed based on the captured OCT image of the optic disc in the [Disc 3D] mode. The results of RNFL analysis are shown, for example, as a map relating to the RNFL thickness, RNFL profile indicating the thickness of locations through which a measurement circle (diameter 3.45 mm centering on the optic disc) passes, and RNFL 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.

10.2.1.1 [Both]

The Both tab is a default view for Disc 3D scan. It shows the measurement result of the optic nerve head, RNFL thickness and TSNIT region is analyzed based on the captured OCT data. The results of NFL analysis are shown as a map relating to the RNFL thickness, RNFL profile indicating the thickness of locations through which a measurement circle passes, and RNFL 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.

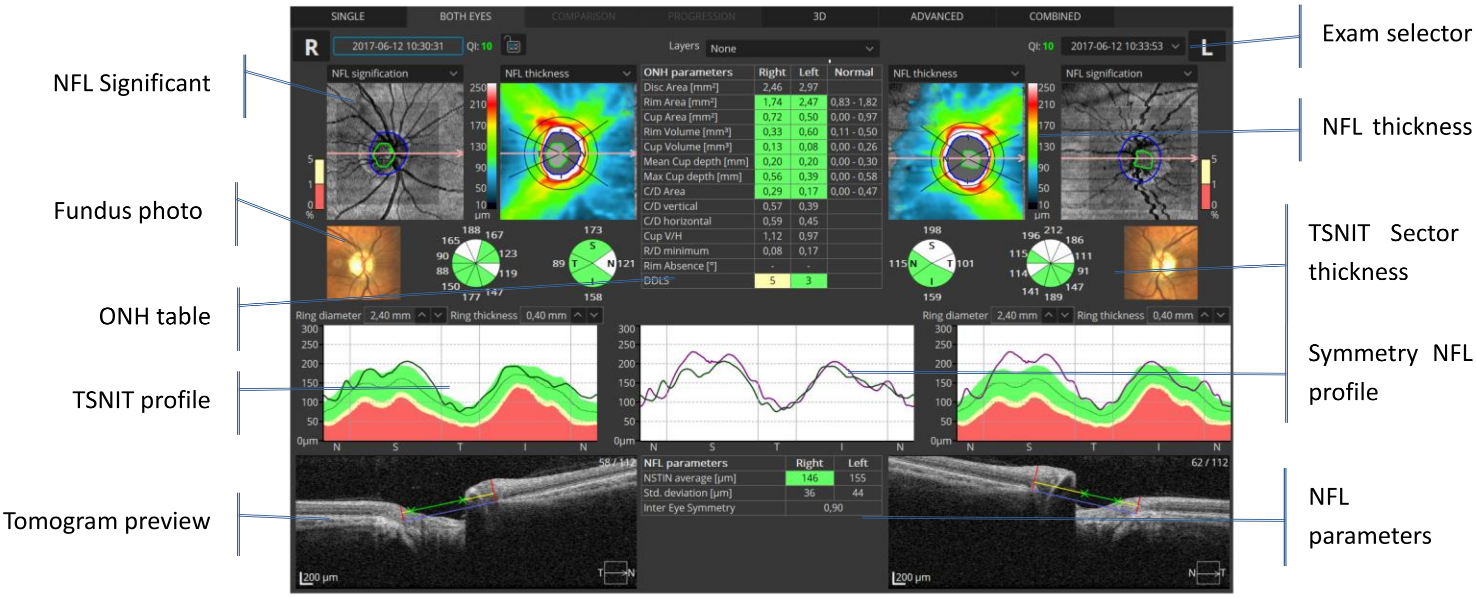


Figure 100. Disc [Both] tab

10.2.1.1.1 *1. NFL Significance map*

This color map shows singular points by comparing RNFL thickness with the normative database. Disc contour is marked as blue color, cup contour is marked as green color.

Displayed map to overlay on the fundus reconstruction can be selected from the list box:

- NFL Significant
- NFL Deviation
- NFL thickness

To change transparency level, turn the mouse wheel over the object.

VF locations display - Right click on any of the above maps to view the context menu from which VF locations display can be enabled. See more in chapter 10.4.4 Structure & Function - VF Locations Layer

10.2.1.1.2 *2. 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 that click the right mouse button over the reconstruction image to open a context menu shown below and choose [Import fundus photo] or [Link examination].

- To zoom the photo in or out hold the CTRL key and scroll with your mouse over the image.

- To move the image hold you left mouse button over the image and move it.
- To change the brightness/contrast of the image hold your right mouse button and move the mouse over the image.
- To open the photo in the Fundus Photo tab double click on the image.

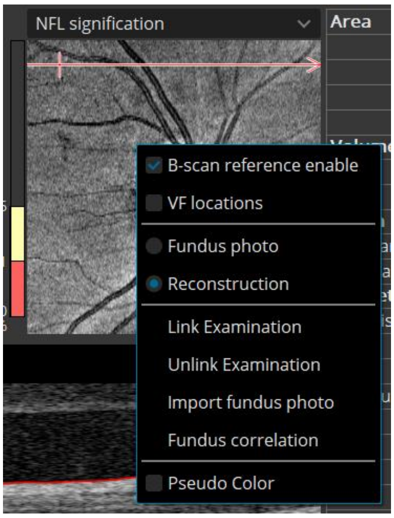


Figure 101. Context menu of the disc reconstruction image

10.2.1.1.3 *2. ONH table*

It displays selected ONH parameters for Right and Left eye.

10.2.1.1.4 *3. NFL TSNIT profile*

The NFL thickness at the TSNIT region for the right or left eyes is shown. Changes of Ring thickness and Ring diameter are implemented symmetrically to the opposite eye.

10.2.1.1.5 *Tomogram preview*

It shows OCT image in selected location with marked ILM, NFL layer.

10.2.1.1.6 *Exam selector*

If there are more exams of the same location from the same date, operator can change the displayed exam. Click the exam date and select desired scan from the list.

10.2.1.1.7 *NFL thickness map*

NFL thickness map shows thickness of NFL layer on scanned area. Detailed description of NFL thickness >> NFL thickness map

10.2.1.1.8 *NFL symmetry profile*

The NFL thickness at the TSNIT region for the right and left eye is shown. Changes in the Ring thickness and Ring diameter are implemented symmetrically to the opposite eye. There is a possibility to switch the NDB background on/off by right clicking on the NFL symmetry profile chart and selecting or deselecting the NDB background.

10.2.1.1.9 *NFL sector*

The inside of the measurement circle is divided into 4 or 12 sectors, and the NFL thickness from TSNIT is shown. Background colors are color-coded based on the normative database.

10.2.1.1.10 *NFL parameters table*

This table summarizes the measurement values relating to the RNFL thickness at the TSNIT region for the right and left eyes. Background colors are color-coded based on the normative database.

TSNIT Average Standard Deviation of retinal thickness of TSNIT region Symmetry

Average value of NFL thickness of TSNIT region (µm)

Inter Eye Symmetry of both eyes relating to TSNIT region

10.2.1.2 [Single] 3D

This view is automatically open only in case where is no Disc 3D scan of opposite eye from that same visit. Default view for Disc 3D scan is Both.

This view shows Fundus reconstruction with preview of selected tomogram, table with ONH Data information, RNFL thickness map in scan area and RNFL thickness graph.

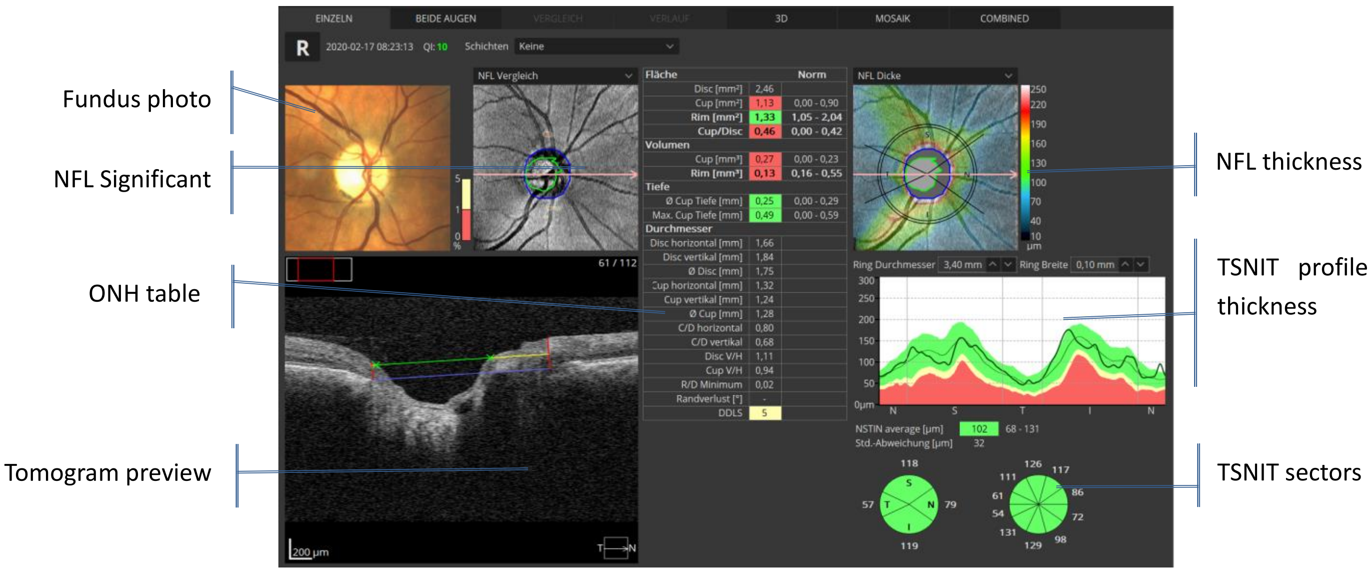


Figure 102. Disc 3D [Single] tab

1. Fundus photo

A fundus photo is displayed if the user has imported or linked a photo. To do that click the right mouse button over the disc reconstruction image to open a context menu shown below and choose [Import fundus photo] or [Link examination].

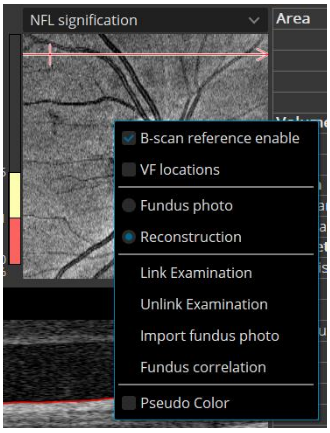


Figure 103. Context menu of the disc reconstruction image

- To zoom the photo in or out hold the CTRL key and scroll with your mouse over the image
- To move the image hold your left mouse button over the image and move it.
- To change the brightness/contrast of the image hold your right mouse button and move the mouse over the image.
- To open the photo in the Fundus Photo tab double click on the image.

2. NFL Significance map

This color map shows singular points by comparing RNFL thickness with the normative database. Disc contour is marked as blue color, cup contour is marked as green color.

3. Tomogram image of the optic disc

Tomogram preview image shows selected tomogram. Markers points left and right edge of BM on actual scan (if actual scan crosses disc). If necessary, marker points can be moved.

- Double click to open full screen image.
- Press [Edit disc].
- Dragging them on tomogram image area (changes in single scan will occur on shape of disc and cup and will take effect in all analysis) to proper location.
- Yellow line shows Cup Offset Line (parallel to purple disc which represents disc surface).
- Distance between Cup Offset Line and disc surface line may be changed by editing the value on Cup Offset Panel or moving the slider.
- It is possible to change default cup offset value in the setup.

4. NFL thickness map

NFL thickness map shows thickness of NFL layer on scanned area. Map has the rings around the disc, where the RNFL thickness data are used for TSNIT analysis. This ring is divided into four zones representing Temporal, Superior, Nasal and Inferior side.

- If operator clicks anywhere in the map, the thickness of the RNFL in the chosen point will be displayed.
- The black rings around the disc represent edges of ring used to calculate TSNIT RNFL thickness displayed on RNFL graph.
- Dimensions of ring (diameter and thickness) are shown below the map.
- It is possible to manually change the dimensions of the ring by grabbing them in desire position.
- On the map is drawn contours of the Disc (color: blue) and Cup (color: green).
- If you disagree with shape of the cup and disc operator can manually modify them.
- The red horizontal line on thickness map shows position of actual display tomogram.
- To display measured value from specific location left click to desire place and display from this place.

5. ONH (Optic Nerve Head) Data

ONH data show morphology quantification of papilla parameters. All the data from this part are calculated from Disc and Cup parameters on all scans. All ONH data base on automatic recognition of ILM surface, BM tips, Cup Offset and layers segmentation on all tomograms. Any manual modification of recognition causes ONH Data calculation.

DDLS (Disc Damage Likelihood Scale) score is based on DDLS scale introduced by George L. Spaeth, MD. It centers on the appearance of the neuroretinal rim of the optic disc corrected for disc diameter. It is a method for prognostic evaluation of the amount of optic disc damage in patients with glaucoma. This can be treated as supplementary information and cannot be treated as disease confirmation.

Caution: DDLS scale bases on a publication by George L. Spaeth, MD in 2002, and can only be treated as supplementary information and cannot be treated as disease confirmation. Use for reference only.

Source: “THE DISC DAMAGE LIKELIHOOD SCALE: REPRODUCIBILITY OF A NEW METHOD OF ESTIMATING THE AMOUNT OF OPTIC NERVE DAMAGE CAUSED BY GLAUCOMA” by George L. Spaeth, MD et al., 2002.

- Operator can manually modify automatic recognition.

- Operator has influence on default Cup offset and all other parameters (Layers segmentation, ILM surface, BM tips, Cup Offset)
- Changing the Cup Offset will move cup closer or further from disc, this will be also visible in cup shape on fundus reconstruction.
- All ONH data are automatically recalculated if Cup Offset or RPE edge factors change.
- It is possible to restore default analysis by pressing [Reanalyze].

6. TSNIT profile

The NFL thickness graph shows the mean values of NFL thickness which are calculated as mean value in selected ring for each angle from 0 to 360 degrees.

Normative range band can change from 2.4 to 5 mm. The vertical blue line in the graph is correlated with the angle on RNFL map. Value on the top shows the mean of RNFL thickness, expressed in microns. Operator can change RD - Ring Diameter from 2.0 to 4.5 mm, step 0.1mm; RT Ring thickness - from 0.1 to 0.9 mm, step 0.1 mm.

7. RNFL Sector

The inside of the measurement circle is divided into 4 or 12 sectors, and the RNFL thickness is shown. Background colors are color-coded based on the normative database. Mean TSNIT value and TSNIT SD are displayed above.

DISCLAIMER: OPTOPOL Technology is not offering and does not offer advice, instruction in the diagnosis and interpretation of SOCT images. It is the clinician's responsibility to make diagnosis and interpretation of OCT scans.

10.2.1.3 [Progression]

The Disc 3D Progression displays a selection of up to six scans of the same eye displayed chronologically to help track RNFL and ONH changes over time. On the side of each date of examination you can find correlation status. Press the [Correlation] button to verify or correlate examination manually if required. See details in chapter 16 EXAMINATIONS CORRELATION.

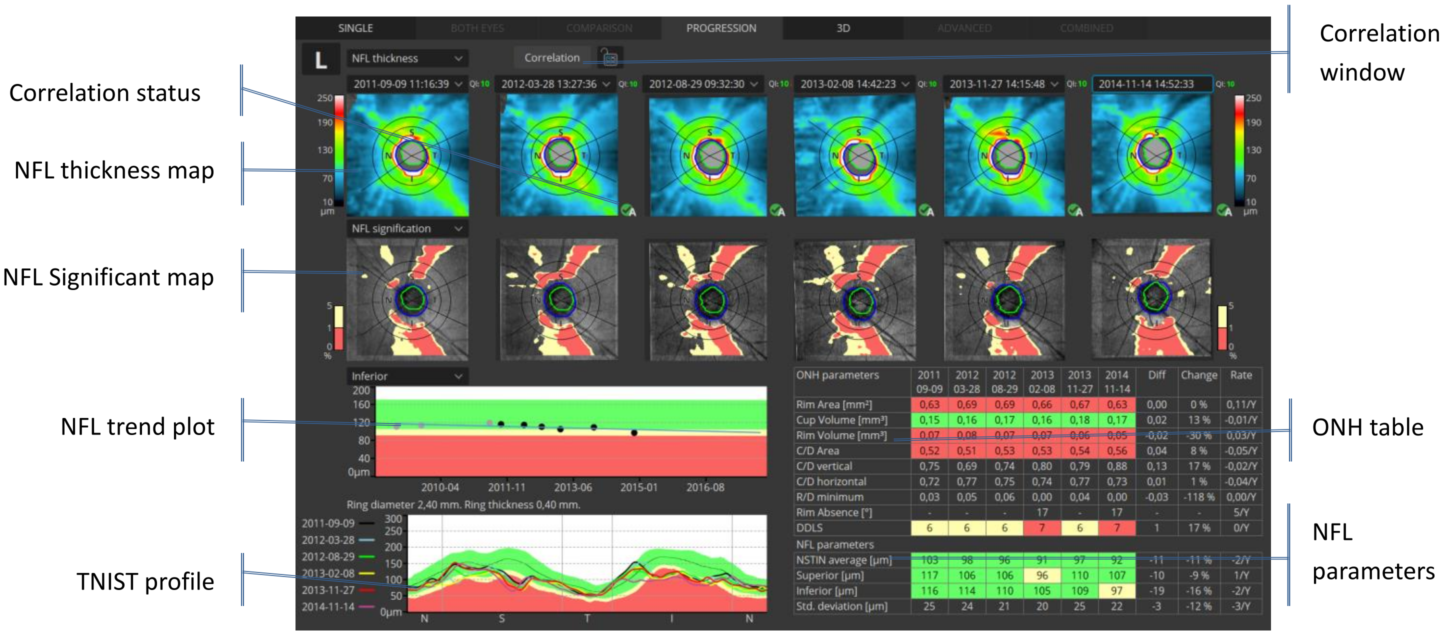


Figure 104. Progression 3D disc

1. NFL thickness map

You can select the map that is shown from the list box.

- NFL Thickness: Shows the RNFL thickness map for six examinations.
- NFL Difference: Shows the difference between the oldest examination (Baseline - leftmost examination) as a color map and values
- NFL Significance: Color map which shows result by comparing NFL thickness with the normative database
- NFL Deviation: Color map which shows differences between NFL thickness and the normative database.

Disc contour blue color, Cup contour green color and measurement circles are shown.

2. NFL Significance.

You can select the map that is shown from the list box.

- NFL Difference: Shows the difference between the Baseline (oldest) examination (Baseline - leftmost examination) as a color map and values
- NFL Significance: Color map which shows result by comparing NFL thickness with the normative database
- NFL Deviation: Color map which shows differences between NFL thickness and the normative database.

NDB comparison RNFL map

You can select the map that is shown from the list box. Disc (color: gray), Cup (color: light gray) and measurement circle (color: yellow) are shown.

3. RNFL trend plot

This plot displays examinations performed for the same patient to show changes in the RNFL thickness in the TSNIT region over time. You can select what is shown from the list box.

- TSNIT Average: Average value at entire measurement circle
- Superior Average : Average value at superior semicircle
- Inferior Average: Average value at inferior semicircle

The regression line is shown on the graph. Placing the cursor over any point on the graph displays value from selected point.

4. TSNIT profile

TSNIT graph provides an overlay showing the NFL thickness results along the TSNIT from the eye as different color lines.

5. ONH parameters

It shows most important parameters of ONH. This table shows the values for each examination. The rightmost column is the rate of change. Background colors are color-coded based on the normative database.

6. NFL parameters

The items are the same as on the [Both Eyes] tab screen. This table shows the values for each examination. The rightmost column is the rate of change. Background colors are color-coded based on the normative database. The NFL parameter contains a difference column (from baseline) and rate of regression slope (the rate value appears only if the difference between baseline and next exams is at least three months).

10.3 Advanced View – Retina and Optic Nerve Head analysis

The tab „Advanced” allows to view the glaucoma summary report for 3D exams of retina and disc scans for both eyes from the same visit. It can operate only on Right and Left 3D Retina and 3D Disc examinations.

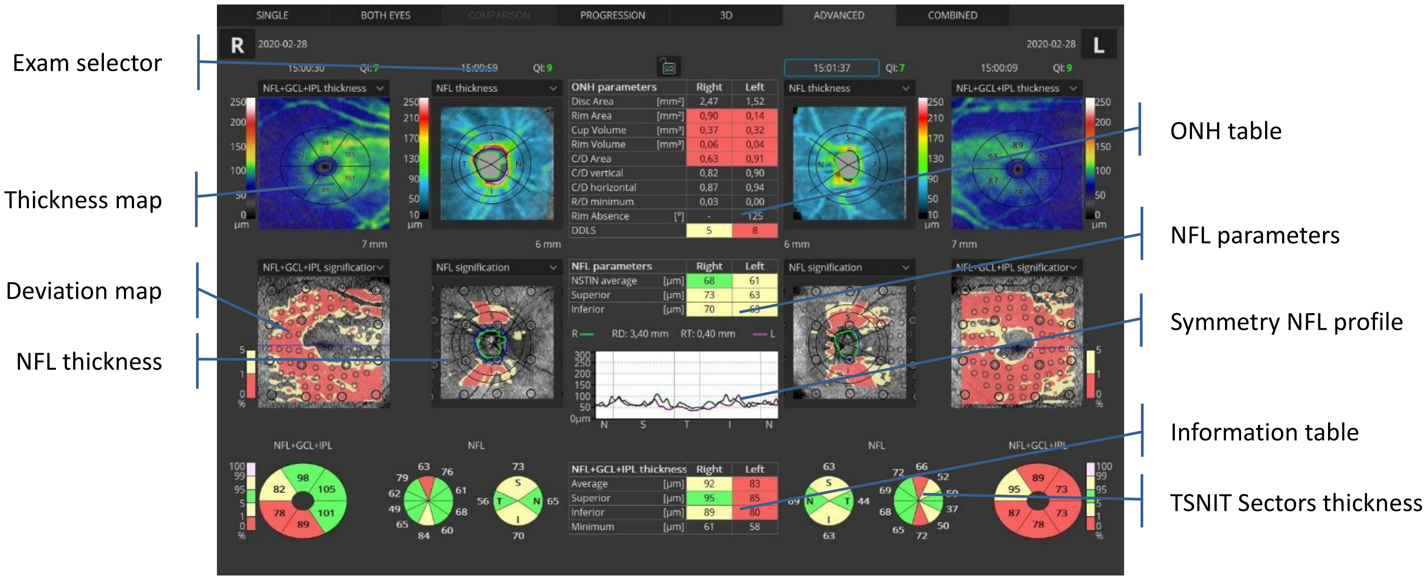


Figure 105. Advanced View - Retina and Optic Nerve Head analysis.

1. Exam selector

If there are more exams of the same location from the same date, the operator can change the exam 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 list box:

- 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 list box:

- NFL+GCL+IPL thickness
- NFL+GCL+IPL signification
- NFL+GCL+IPL deviation

4. NFL thickness

A map to overlay on the fundus reconstruction can be selected from the list box:

- NFL thickness
- NFL signification

- NFL deviation

VF locations display - Right click on any of the above maps to view the context menu from which VF locations display can be enabled. See more in chapter 10.4.4 Structure & Function - VF Locations Layer.

5. ONH table

It 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 RNFL thickness at the TSNIT region. The Background is color-coded based on the normative database.

7. Symmetry NFL profile

Shows the NFL thickness at the TSNIT region for the right and left eye. Changes of Ring thickness and Ring diameter are implemented symmetrically to the opposite eye.

8. SNITS Sectors thickness

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. Normative range band can change from 2.4 to 5 mm. The vertical blue line in the graph is correlated with the angle on the RNFL map. The value on the top shows the mean of RNFL thickness, expressed in microns. The operator can change RD - Ring Diameter from 2.0 to 4.5 mm, in 0.1 mm steps; RT Ring thickness - from 0.1 to 0.9 mm, in 0.1 mm steps.

There is a possibility to switch the NDB background on/off by right clicking on the NFL symmetry profile chart and selecting or deselecting the NDB background.

10.4 STRUCUTRE & FUNCTION – Combined OCT and VF Report

Combination of information about the functional quality of vision from Visual Field* device with comprehensive data on retinal Ganglion Cells, RNFL and Optic Nerve Head from Retina and Disc OCT scans for both eyes on a single combined report page, that compares in a natural way the anatomical relationship between VF and RNFL/Ganglion maps. Combined View is accessible only if the Visual Field (VF) database connection has been configured in the setup section[10]. For more information on setting up VF database go to chapter 22.5.7 Visual Field.

[10] Visual and structure is available only for customers using PTS 920, PTS 925 and PTS 2000 with software version 3.4 and have configured SOCT applications. See more in chapter 25 Remote Connection and requirements in chapter 10.4.2 Requirements that must be met for loading perimeter tests

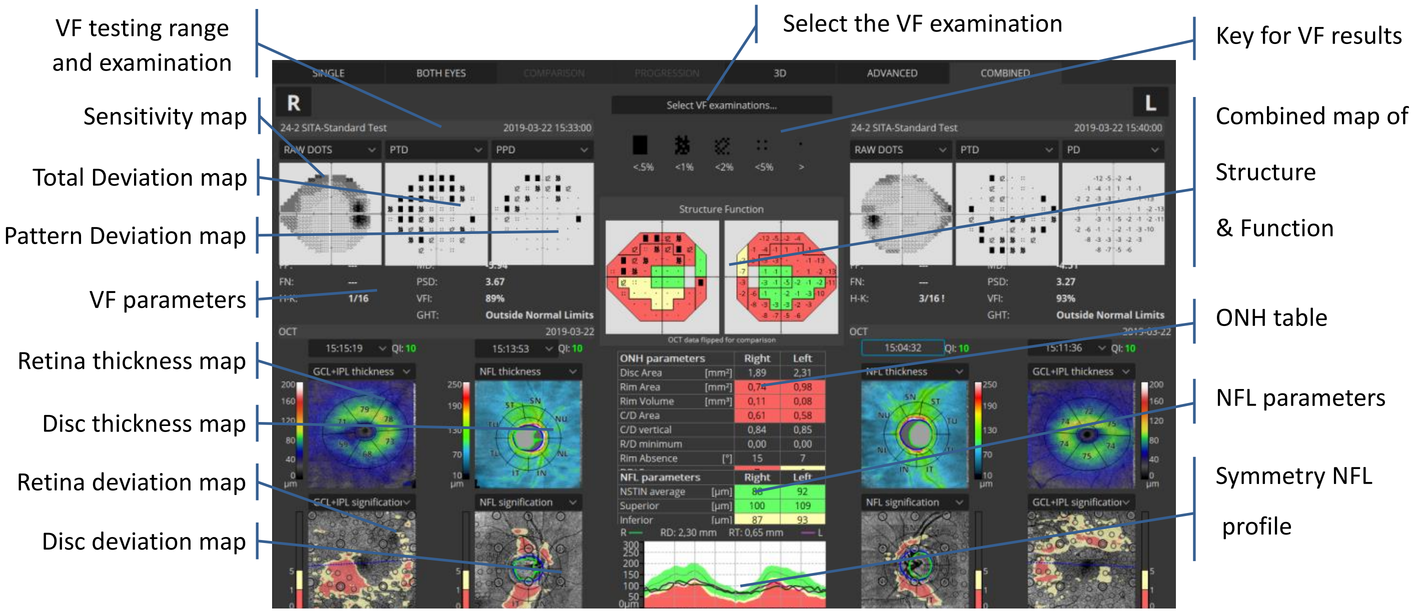


Figure 106 Combined View Structure & Function

- Select the VF examination - the operator can change the VF exam displayed by choosing from available examinations.
- Sensitivity map from examinations 24-2, 30-2 or 10-2
- Total Deviation map and Pattern Deviation map – probability graphs for VF results
- VF parameters – reliability and global indices for VF results
- Retina/Disc thickness map - a map to overlie the fundus reconstruction can be selected from the list box:
  - NFL+GCL+IPL thickness
  - GCL+IPL thickness
  - NFL thickness
- To change the transparency level, turn the mouse wheel over the object.
- Retina/Disc deviation map - a map to overlie the fundus reconstruction can be selected from the list box:
  - NFL+GCL+IPL signification
  - NFL+GCL+IPL deviation
- Key for VF information on the OCT map
- 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. See more in chapters

[10.4.4 Structure & Function - VF Locations Layer](#) and [10.4.3 Additional layer with VF Results](#).

- Combined map of Structure & Function – an overlay of information from the PPD field of vision map on the map of sectors from the OCT image (the Significance map)
- ONH table – displays the selected ONH parameters for the Right and Left eye
- NFL parameters – summarizes the measurement values for the Right and Left eye relating to the RNFL thickness at the TSNIT region. Background color based on NDB
- Symmetry NFL profile – shows the NFL thickness at the TSNIT 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 their name, DOB and ID. 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 name, surname and DOB but a different 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.

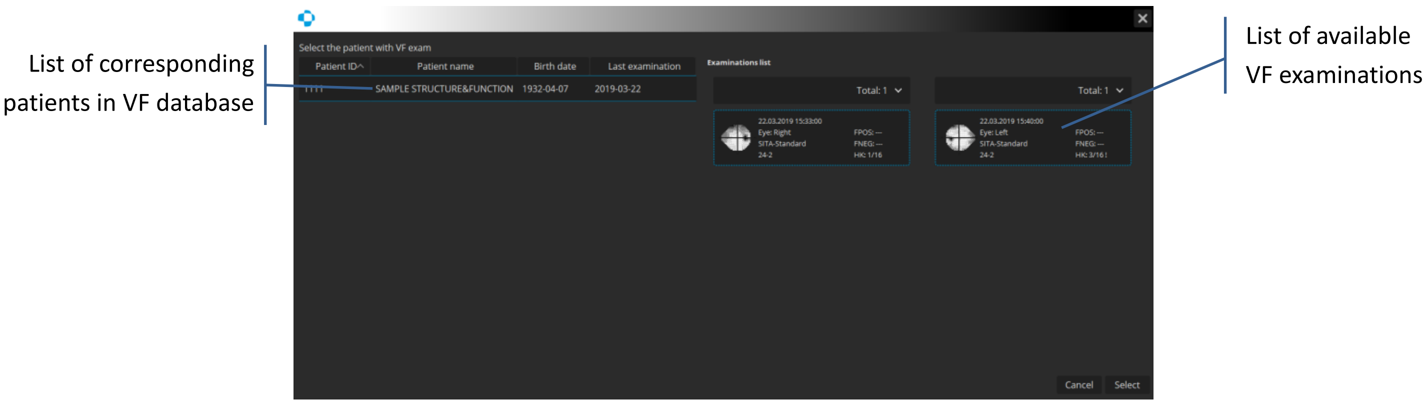


Figure 107 Selecting the patient and VF examination window

10.4.1 *Relationships between VF and RNFL/Ganglion maps*

Structure & Function relationship is measured by eight corresponding regions of neuroretinal rim area, peripapillary retinal never fiber layer and visual field.[11] This concept is based on Structure & Function map introduced by Garway-Heath et al.13.[12]

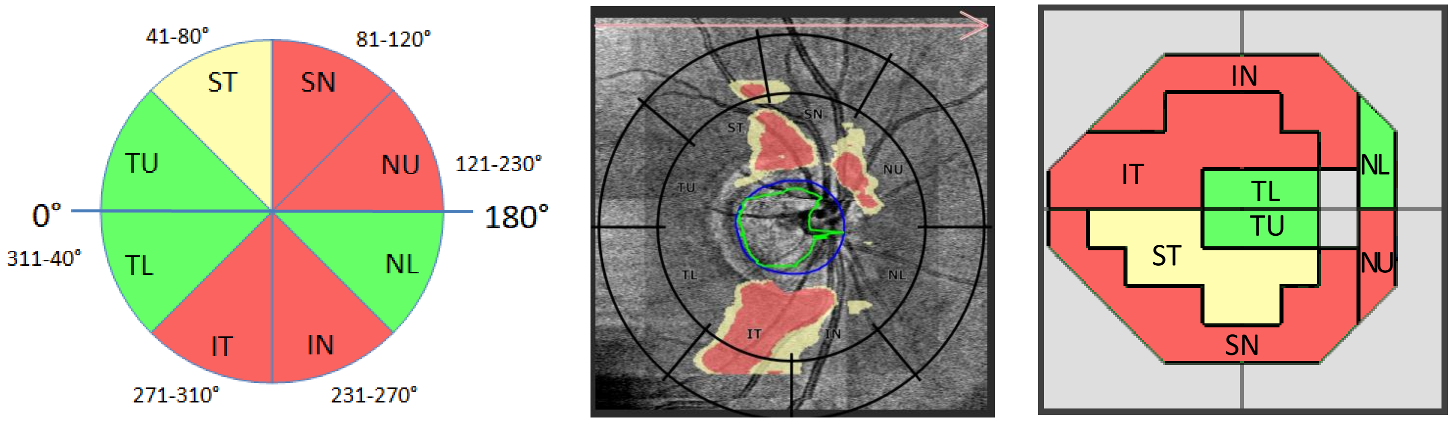


Figure 108 Relationships between OCT and VF by Garway-Heath et al.

10.4.2 *Requirements that must be met for loading perimeter tests in the SOCT application*

- PTS software version 3.4.0 or higher
- a configured connection between the SOCT and the PTS applications
- input data from the SOCT: at least one Retina 3D or Disc 3D examination
- a patient record in the SOCT application with the same personal details as the patient record in the PTS application (first name, second name, date of birth)

An exception is the patient id which can differ between the SOCT and PTS applications. If the patient's 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.

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[11] Concept adaptation based on a publication by Garway-Heath et al., after own modification. Source below.

[12] Structure–Function Relationships between Spectral Domain OCT and Standard Achromatic Perimetry Naveed Nilforushan ,1,2 Nariman Nassiri,1 Sasan Moghimi,1,3 Simon K. Law,1 JoAnn Giaconi,1 Anne L. Coleman,1 Joseph Caprioli,1 and Kouros Nouri-Mahdavi. Investigative Ophthalmology & Visual Science, May 2012, Vol. 53, No. 6

The following conditions must be met for the compatibility of a test with Structure & Function:

- eye correspondence in both tests - for a given perimetric test there must exist an SOCT test of the same eye.
- the size of the stimulus used in the perimetric test: Goldman 3
- the colon of the stimulus used in the perimetric test: white or green
- strategy of the perimetric test: any threshold strategy
- a fully finished perimetric test
- 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 orthogonal fields with a maximum radius of 10, 24 or 30)

The following conditions must be met for a full compatibility of tests from the PTS application (automatically selected) with tests from the SOCT application:

- the difference between the dates of tests cannot exceed 182 days (half a year)
- the perimetric test must be accompanied by reliability tests such as H-K, false positive errors, false negative errors.
- the result of each reliability test must be lower than 25% (error/test ratio)

10.4.3 *Structure & 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.

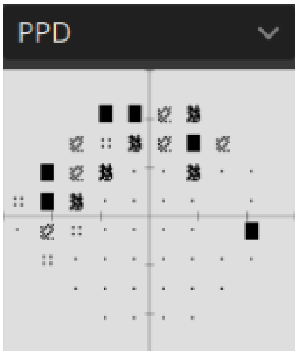


Figure 109 PPD Probability Results

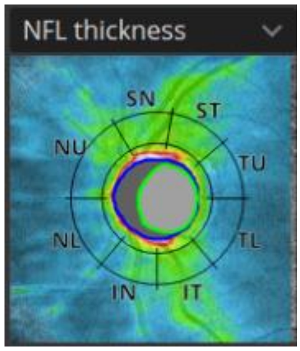


Figure 110 Disc area

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 v3.4 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:

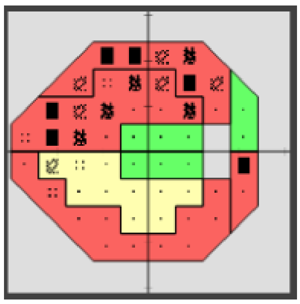
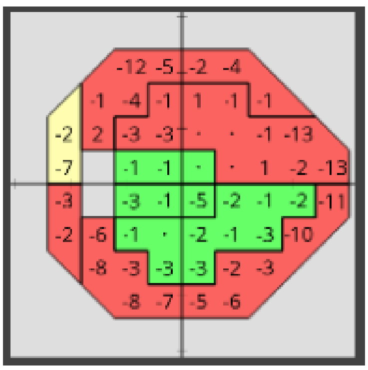
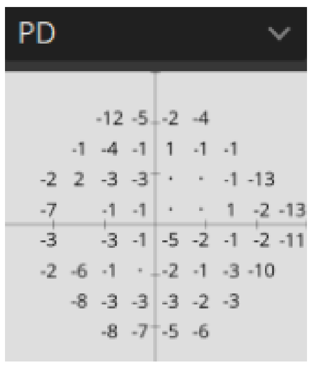


Figure 111 PPD Combined view results

If you select PD result, it is presented with numerical values as shown below.





VF results are also visible in the magnified windows available by double-clicking on the selected view with the VF results displayed.

10.4.3.1 Availability of VF results

VF results layer is available in the [Combined] tab:

- 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;
- in Disc maps if a central or macula 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.

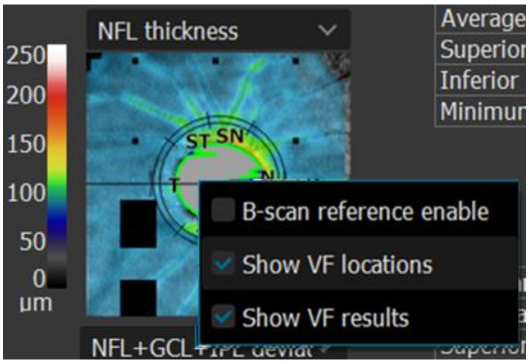


Figure 112 Enable VF results from Context menu

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.

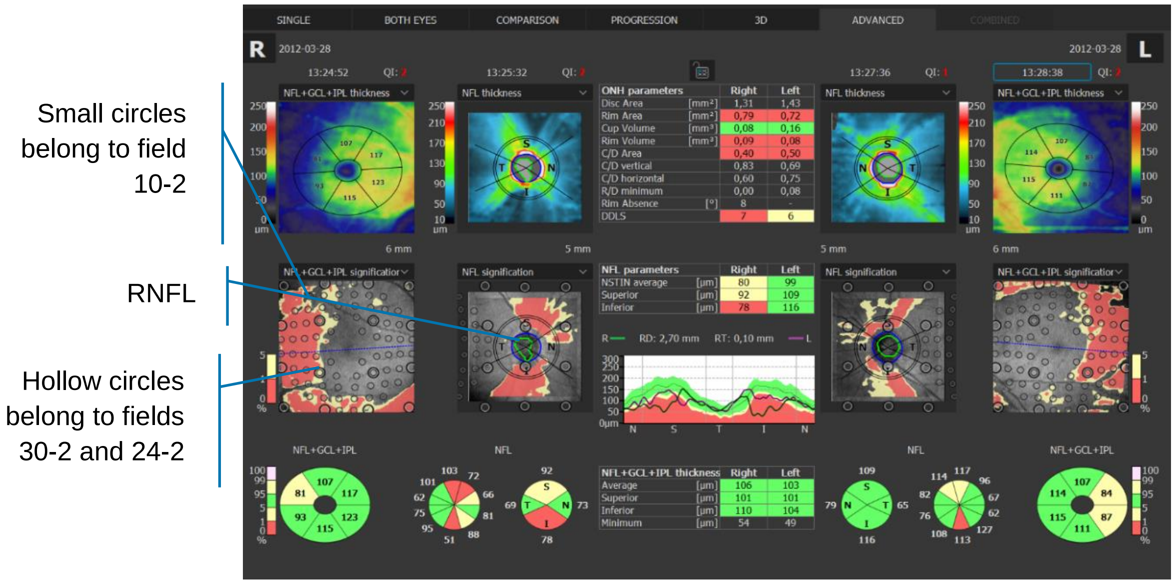
Printouts from individual views reflect the display state of the VF locations function in the user interface. The VF results display state is saved to the specific user and the state is saved after the application restart.

10.4.4 *Structure & 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.



An 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, see below:

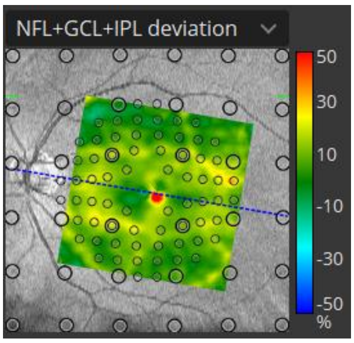


Figure 113 Non-linear relationship

10.4.4.1 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, see below:

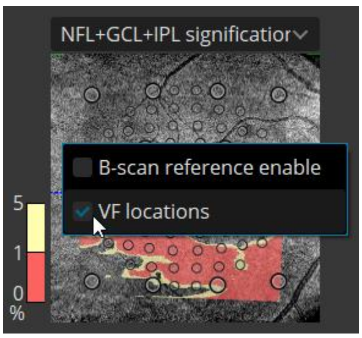


Figure 114 Enable VF locations from context menu

The context menu with the option to enable VF locations is available for Retina 3D and Disc 3D examinations when viewing:

- Retina 3D: Tab |Both| sub view [Ganglion]
- Disc 3D: Tab |Both|
- Retina 3D and Disc 3D: Tab | Advanced |
- Retina 3D and Disc 3D: Tab | Combined |

The VF locations layer is also visible when in magnification windows after double clicking select view with VF locations displayed, as seen from the example on the right:

Figure 115 Magnified view

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.

10.5 **Central examination**

Result review of Central examination can give below options of display:

- Depending on type of conducted examination:

10.5.1 *Central 3D examination.*

Display method depends on amount of taken examinations. It is the same as for retina 3D exam. We are able to display the following views:

- Single - displays single examination with possibility of editing layers recognition, this type of exam does not provide retina thickness maps.
- Both eyes - used to compare Left and right eye
- Comparison - to compare two exams on one sheet (no thickness maps available)
- Progression - used for treatment steps and compare up to 6 exams.
- 3D - three dimensional visualization of central exam

For more details refer to retina display modes.

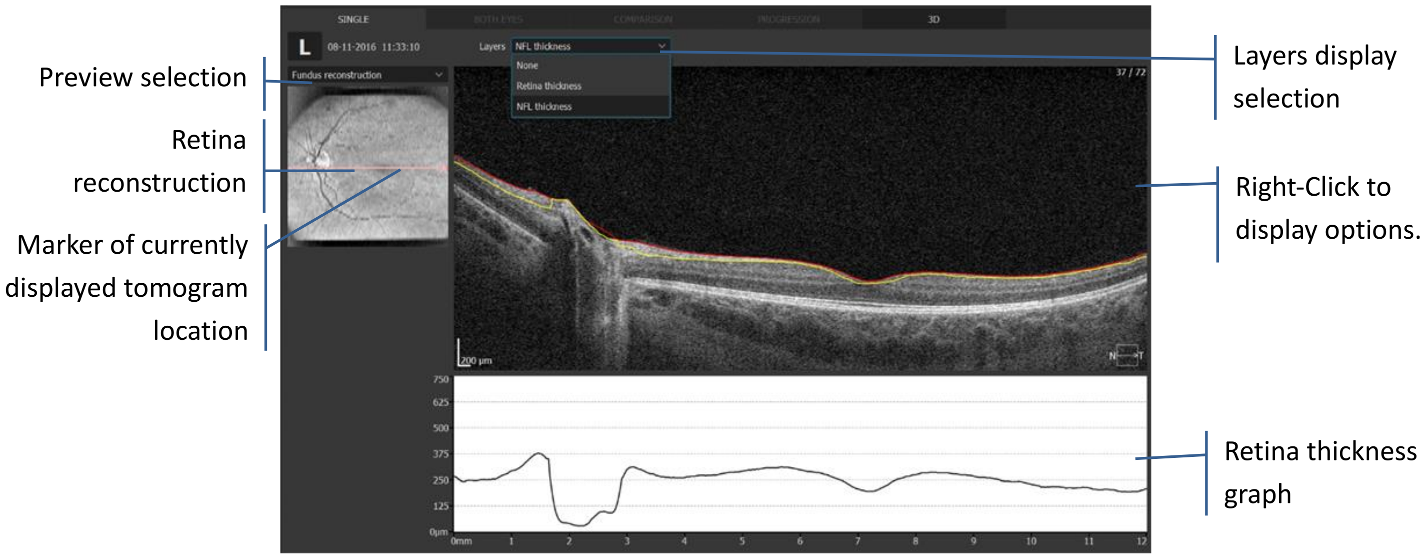


Figure 116. Central examination single scan review window.

Retina signification

The fundus reconstruction image is created from all A-scans made in the scanned area. From the menu available by the right mouse button you can select the image to overlay. The following images are available:

- Fundus reconstruction,
- pSLO,
- Eye preview,

Layers

Select the display options to present the desired layers recognition lines:

- NFL Thickness
- Retina thickness

- None

10.6 2D scan programs results review.

Depending on scanned area (Retina, Disc, Anterior segment) it is possible to use scanning programs other than 3D. This chapter will describe the possible results. Below is the list of possibilities:

Retina:

- Raster
- Single B-scan
- Cross scan

Disc:

- Raster
- Single B-scan
- Cross scan
- Radial

Anterior:

- Raster
- Single B-scan
- Radial
- Radial

For more detailed description of above scan modes refer to chapter [7.2 Selection of scanning program](#).

10.6.1 *Single B-scan examination review.*

Single B-scan exam allows to show detailed result and acquire it in a very short time (averaging is possible). Depending on amount of taken examinations it is possible to view:

- Single scan

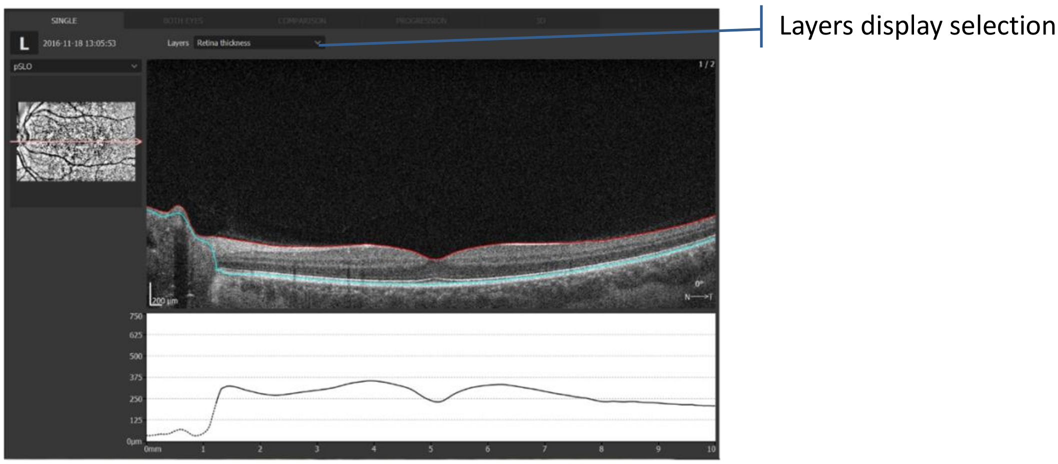


Figure 117. Single Scan view.

- Both Eyes

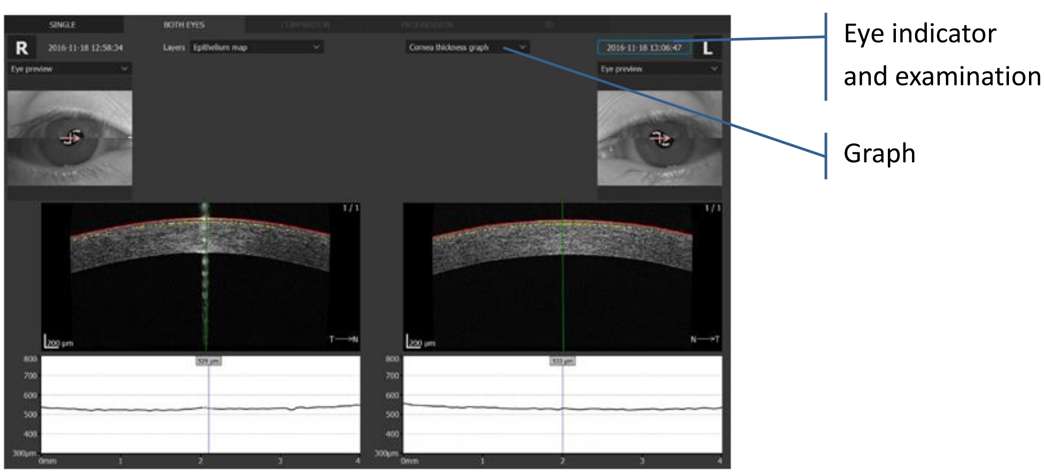


Figure 118. Single B-scan both eyes review.

- Comparison

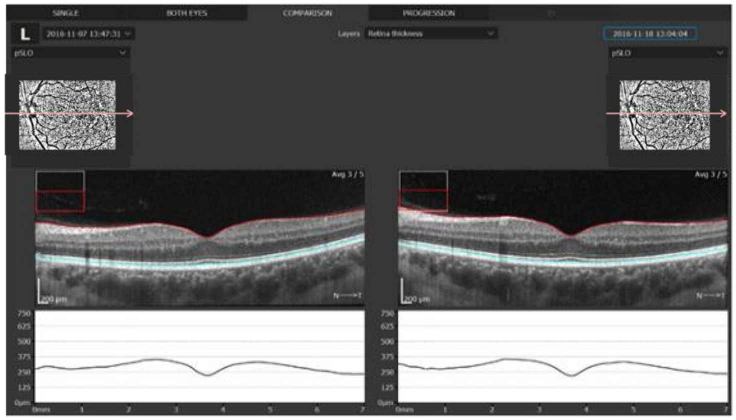


Figure 119. Single B-scan comparison window.

- Progression

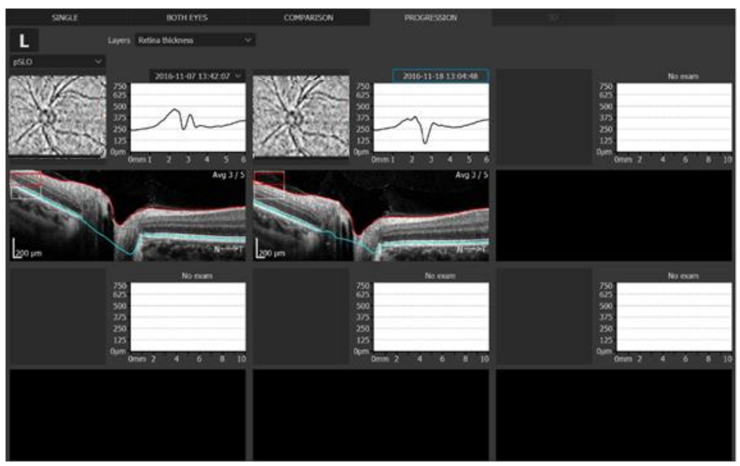


Figure 120. Single B scan progression window.

10.6.2 *Raster examination results review.*

Raster examination result provides averaged image with enhanced resolution. One/Five tomograms are displayed depending on scanned region. Below examples of views:

- Single scan

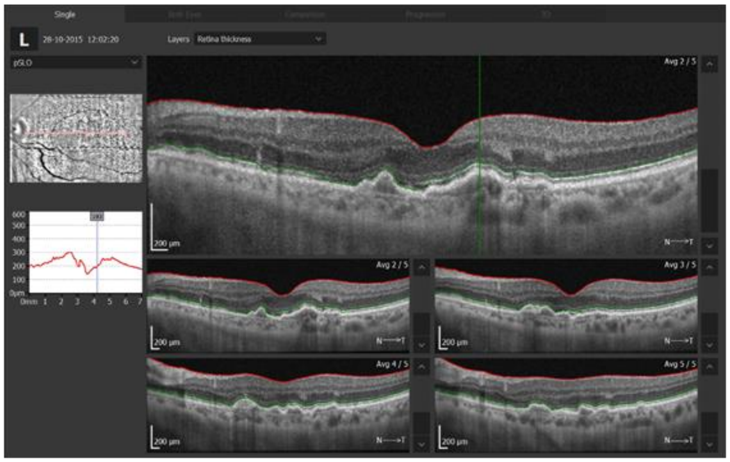


Figure 121. Retina raster, single scan view.

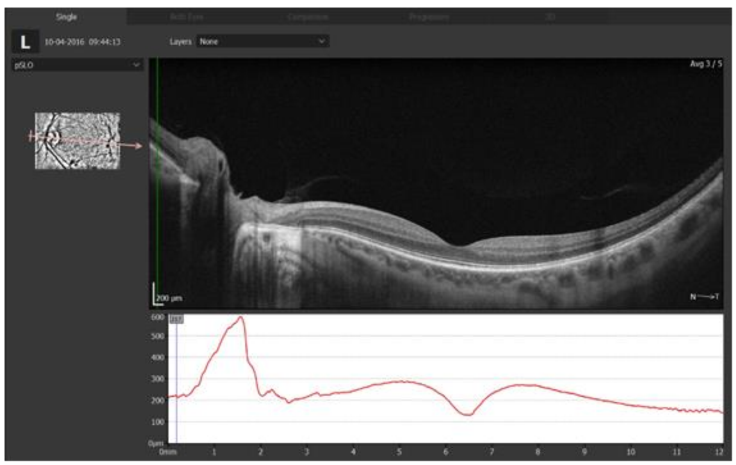


Figure 122. Central raster single scan view.

- Both eyes

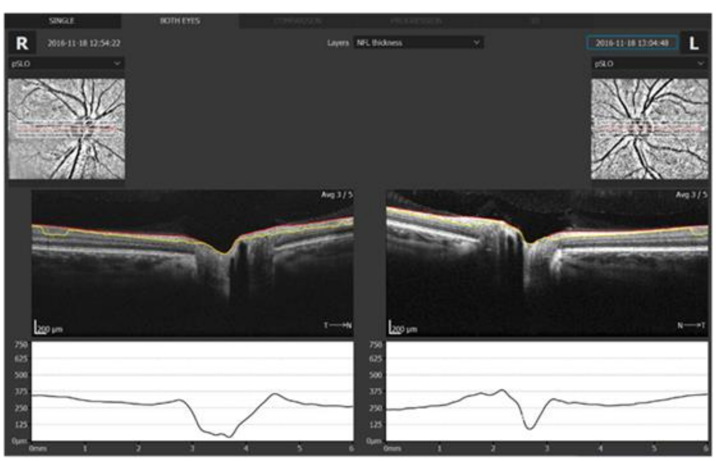


Figure 123. Raster both eyes view

- Comparison

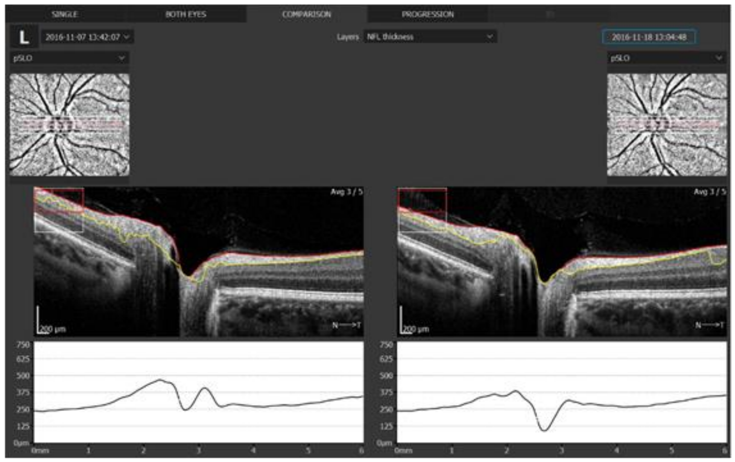


Figure 124. Raster scan comparison.

- Progression

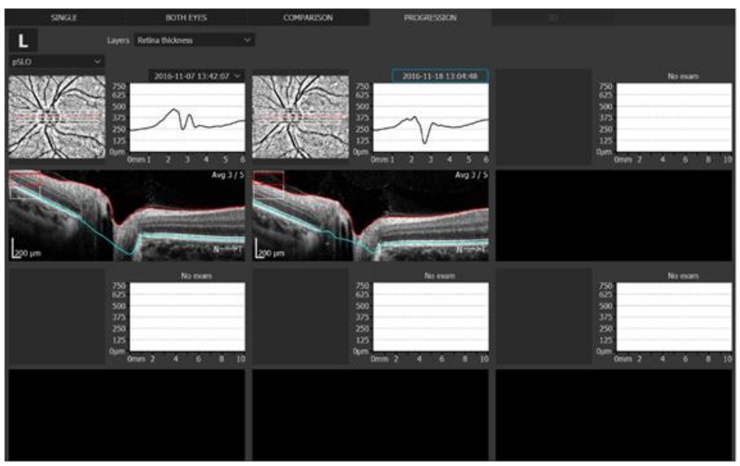
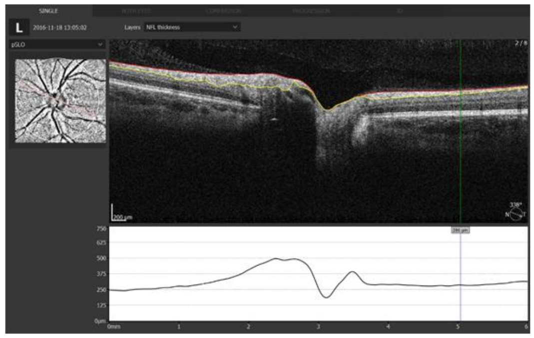


Figure 125. Raster progression view.

10.6.3 *Radial examination results review.*

Radial examination result provides asterisk scan images (number of B-scans taken here can be adjusted). Single B scan is displayed and by clicking on fundus preview it is possible to select different B-scan. Tomograms are displayed depending on scanned region. Below example of single view:



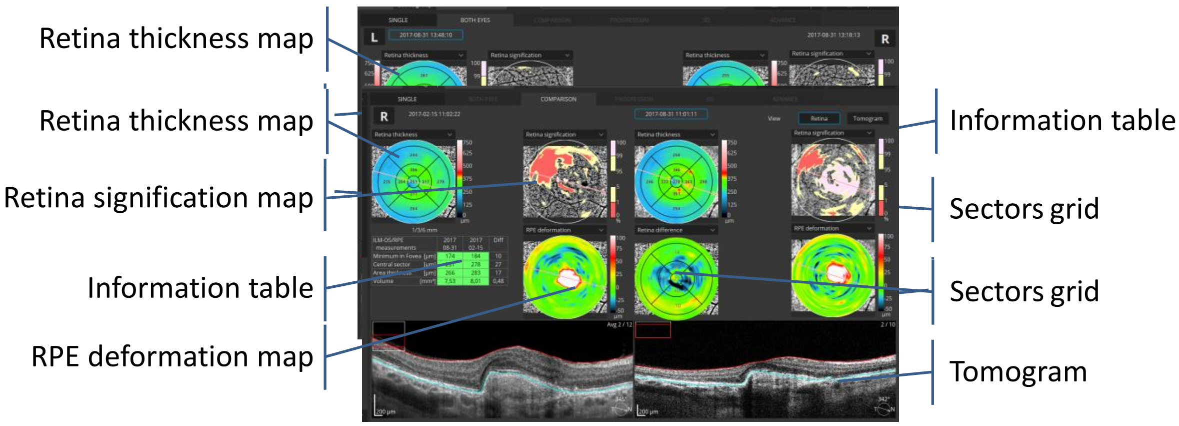


Figure 127. Radial examination both view.

Figure 128. Radial examination comparison view.

Progression displays are adequate to previously presented examples.

10.6.4 *Cross examination results review.*

Cross examination result provides image similar to Single B-scan. 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). Below example of single view:

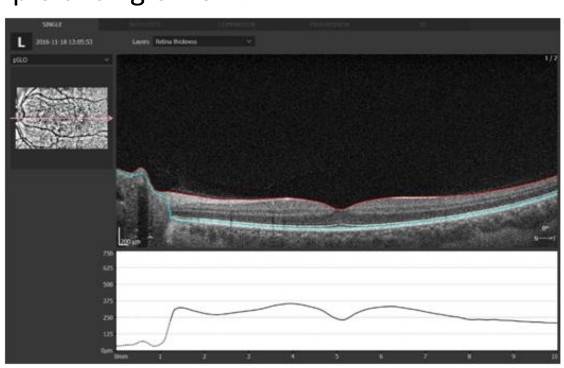


Figure 129. Cross scan horizontal B-scan view.

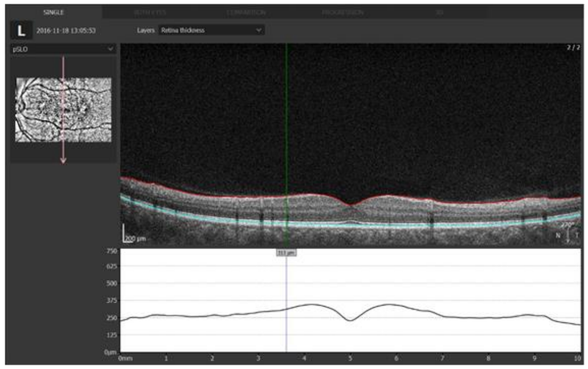


Figure 130. Cross scan vertical B-scan view.

Both eyes, Comparison, Progression displays are adequate to previously presented examples.

10.7 3D visualization

3D visualization tab is enabled only for posterior scans which have been taken using 3D and Angio scanning program. The window shows the 3D reconstruction of the retina structure. Software has the possibility of two 3D visualization modes: Solid and Volume.

10.7.1 *Manipulation of the 3D cube*

The following describes an example of how to operate the 3D view

- Rotating: Drag the 3D tomogram image in any direction. 3D reconstruction can be rotated by 360 degrees around the vertical axis and from -90 to +90 around horizontal axis.
- Slicing - In order to slice reconstruction, press right mouse button, gray balls appear. Direction of cutting is chosen by balls placed on proper axis. Click one of six balls to make one active (clicked ball changes from grey to red) and then user can slice tomograms by dragging the ball along the axis line or use scroll button to slice tomograms.
- Moving: Right Drag the 3D tomogram image in any direction with the shift key held down.
- Resizing: The ctrl keyboard button held down button and turn the mouse wheel.
- Restoring the 3D tomogram image to its original state. Press the [Reset] button.

10.7.2 *Selection of displayed layers*

Selection of layer that is shown

[Visible]: Shows selected layers in the 3D tomogram image. Uncheck ‘Visible’ checkbox to hide selected retina layer.

[Peeling]: Marked layers will be peeled during movement of red ball over tomograms. Operator can separately peel each layer. Easiest way to restore view is to use [Reset] button.

[Select All]: Mark this item to select all layers.

10.7.3 *Operation panel*

10.7.3.1 Mask tab

On the mask tab it is possible to change the item overlay on the surface of the cube.

[Enface] – it displays enface image of displayed layer.

[Map] – it displays thickness map of retina or selected layer.

[Surface] – It display non-transparent color-coded layers on the surface of each retina layer.

[Fundus photo] – Option enabled only whenever a fundus image has been imported to the examination. Option shows common part of the imported image fundus image on the surface of retina.

10.7.3.2 Shifting mask tab

Shifting mas tab is available for Solid view.

On the mask tab it is possible to shift position of specific layers and change brightness and contrast level.

[Shifting] – Separate position of layers. 0 – layers together.

[Brightness] – change Brightness level

[Contrast] – change Contrast level

10.7.3.3 Tuning tab

Tuning tab is available for Volume view.

On the mask tab it is possible to shift position of specific layers and change brightness and contrast level.

[Brightness] – Change Brightness level

[Contrast] – Change Contrast level

[Opacity] – Change Opacity level

[Threshold] – Change threshold of displayed points in retina

[Vitreous] – Change threshold of displayed points in vitreous

10.7.3.4 Display tab

The display options allow the user to change the visualization of the 3D.

B-scan alignment: Aligns B-scans displayed on the 3D visualization, in order to facilitate the view in the 3D reconstruction.

Thickness marker: Displayed boards with Retina, RNFL and RPE thicknesses for a selected point. In order to display thickness double, click on any point on the surface of the retina. A board will appear with values from selected point. All the values are expressed in microns. The software allows to show up to 4 measurements.

Color: Displays the 3D reconstruction in color or black and white.

Inverse: Inverses the color of tomograms.

White background: Changes the background color.

Flattening: It flats scanned cube base on RPE layer

Display details: Displays detailed tomogram on the front surface of the cube.

Fundus: Option enabled only whenever a fundus camera photo has been added to the examination. It displays fundus image on the bottom of scanned cube. It is possible to drag this image to desired position.

[Reset] – This button resets all parameters of the displayed image (angle of rotation, scale, displayed maps, tuning settings) to default settings.

[Play/Stop button] – Enables slicing tomogram automatically. After clicking this button control elements appear on the screen. Choose one direction to start animation slicing. It is possible to rotate reconstruction during slicing. To finish click [Stop] button which appears instead of play.

[Save as] – Saves currently displayed picture in JPEG format.

10.7.4 *[Solid] View*

Shows the surface, layers of the retina and choroid as non-transparent images.

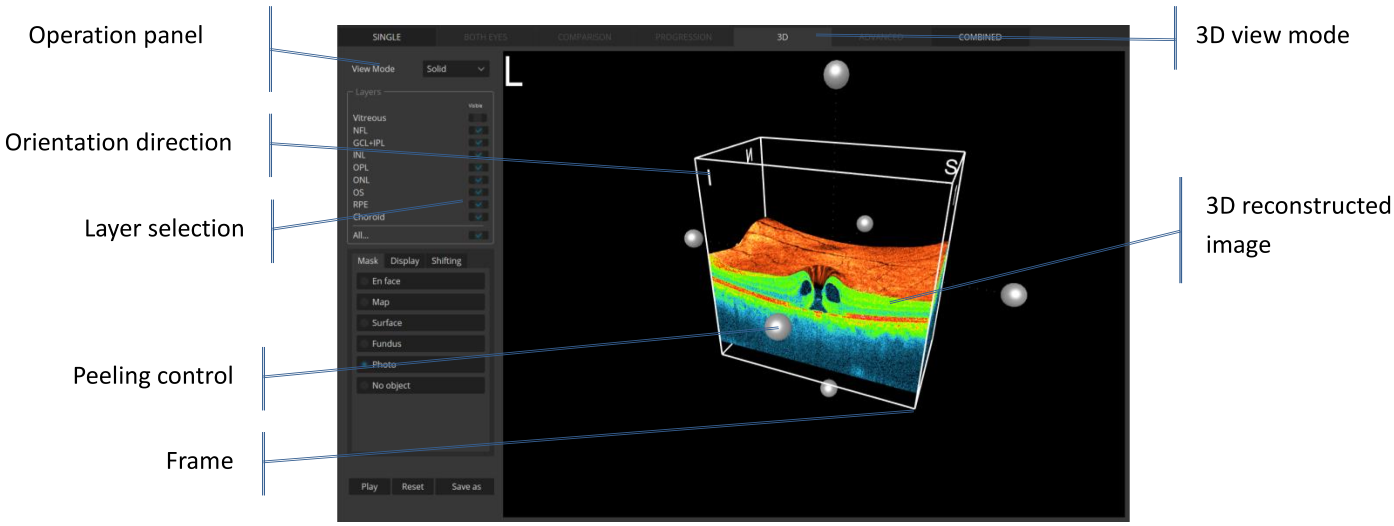


Figure 131. 3D Solid view

1. 3D tomogram image

This 3D image is constructed from B-scan tomograms.

2. Orientation direction

Letters 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], [Cross-Section] view only.

6. Selection of layer that is shown

[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

Display operation table allows user to modify the initial view.

10.7.5 *[Volume view]*

Shows the surface, layers of the retina and choroid as semi-transparent images.

Tunning 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.

[Brightness] - Change Brightness level

[Contrast] - Change Contrast level

[Vitreous Threshold] - Change threshold of displayed points in vitreous

[Vitreous Gamma] - Change gamma of displayed points in vitreous

[Retina Gamma] - Change gamma of displayed points in retina

[Frame Refresh] - Change the number of times in a second the view is being updated

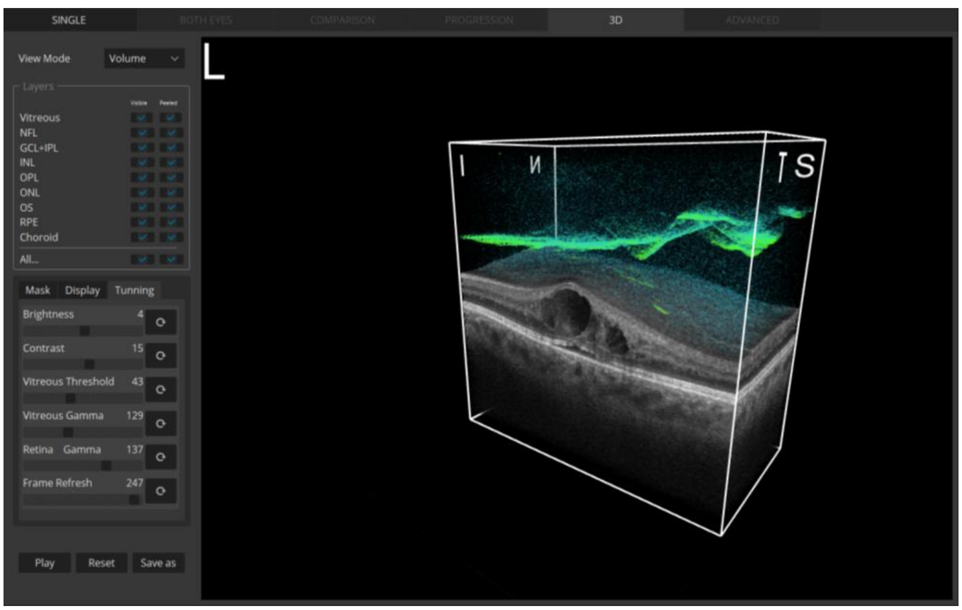


Figure 132. Volume view

11 ANTERIOR SEGMENT ANALYSIS

The SOCT was designed to posterior and anterior imaging. To obtain corneal and anterior segment images use Anterior Scan programs.

Anterior scans for 3-5 mm width do not require anterior lens.

Except for the REVO FC device, 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.

During analysis the System classifies recognized structures on the image and classifies 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,

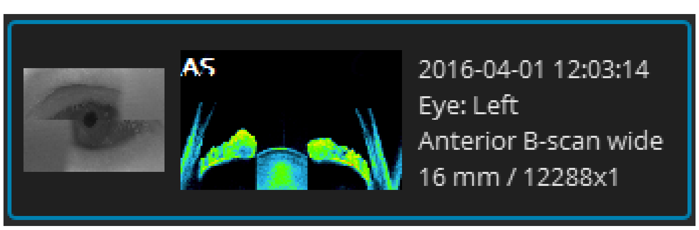
Lens,

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.



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. The system changes the type of the structure and reanalyzes the examination using a different algorithm.

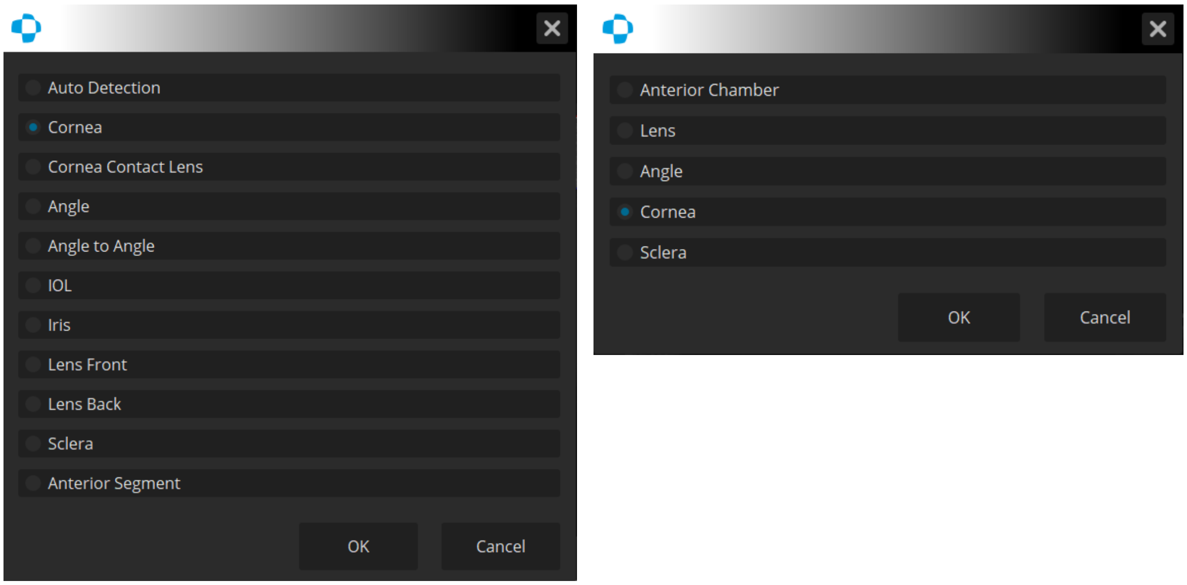


Figure 133. Structure classification menu for Anterior (on the right) and Full Range (on the right)

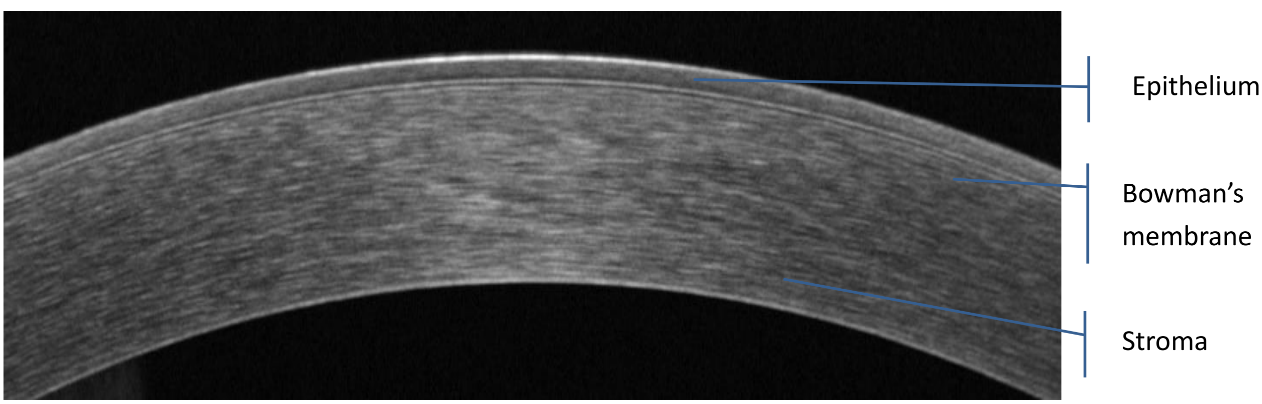


Figure 134. Short cornea scan

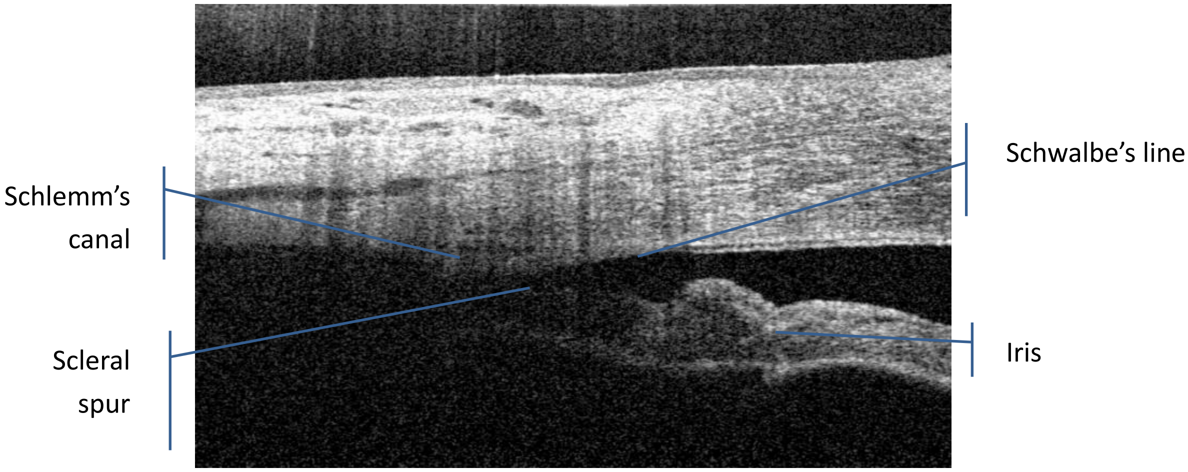


Figure 135. Short Anterior Angle scan

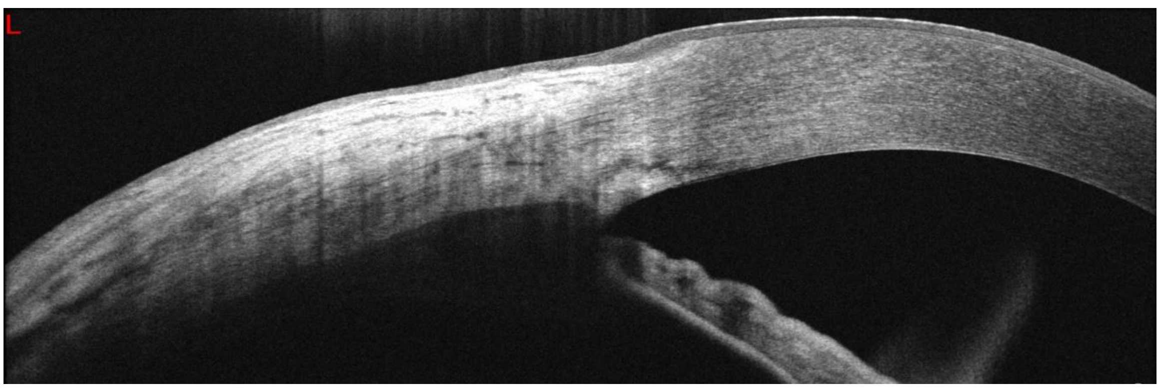


Figure 136. Sclera and Cornea Wide Anterior 11 mm scan

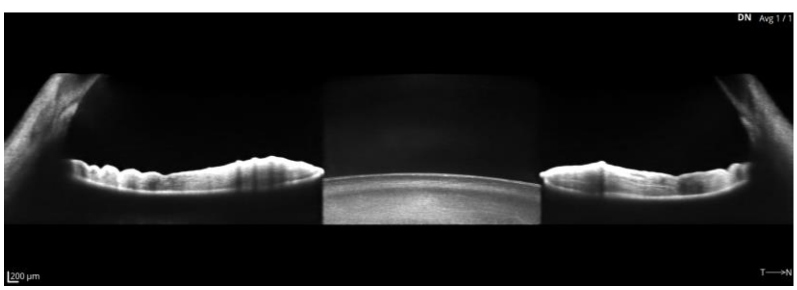


Figure 137. Angle to Angle view. Sample of wide anterior B-scan

11.1 **Anterior Radial**

The corneal thickness analysis is performed on the basis of the recognized structure of OCT images of the anterior segment captured in [Anterior Radial] and [Wide Anterior Radial] mode.

The analysis results are shown on maps, corneal grids and tables. These analysis results can be shown on the [Single], [Both Eyes], [Comparison], and [Progression] tab screens.

NOTE: Quantitative analysis is available only if the system classifies the scanned structure as Cornea.

11.1.1 *[Single] tab screen*

This screen shows the analysis results of one eye.

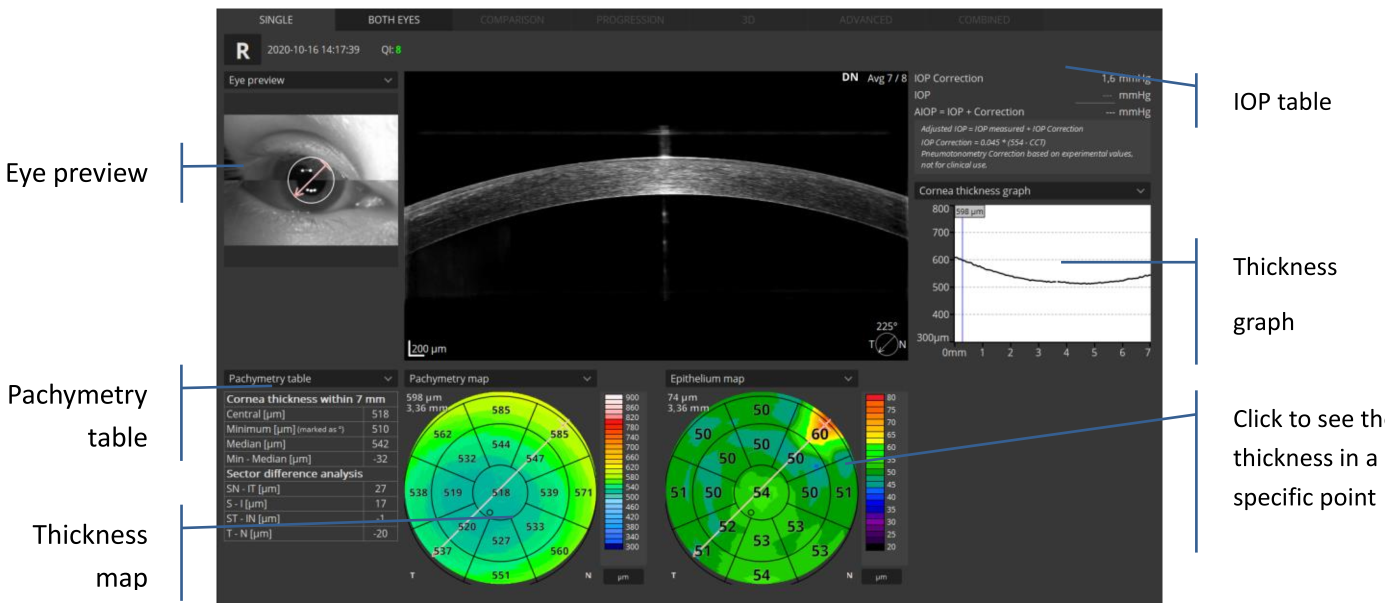


Figure 138. Single Anterior Radial

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 thickness color coded. Overlaid values correspond to displayed settings.

Changing display settings:

Right click to open the menu.

- B-scan reference enable on/off
- Select the grid option from the list:

  2 / 5 / 7 [mm]

  Grid - the whole map will be covered by grid of numbers. Each number represents thickness at a selected square.

  None.
- Values: average, maximum or minimum
- White background on/off

Color scales - to change the scale click one of the scale descriptions in the bottom corner of the map. The scale settings widow shows up. The user can change the scale type and units.

Color scales are available for the Pachymetry map: OScale, American and RevoScale.

Color scales are available for the Epithelium map: OScale and RevoScale.

For more information on scales go to chapter 20.6 Color scale – Standards.

IOP formula

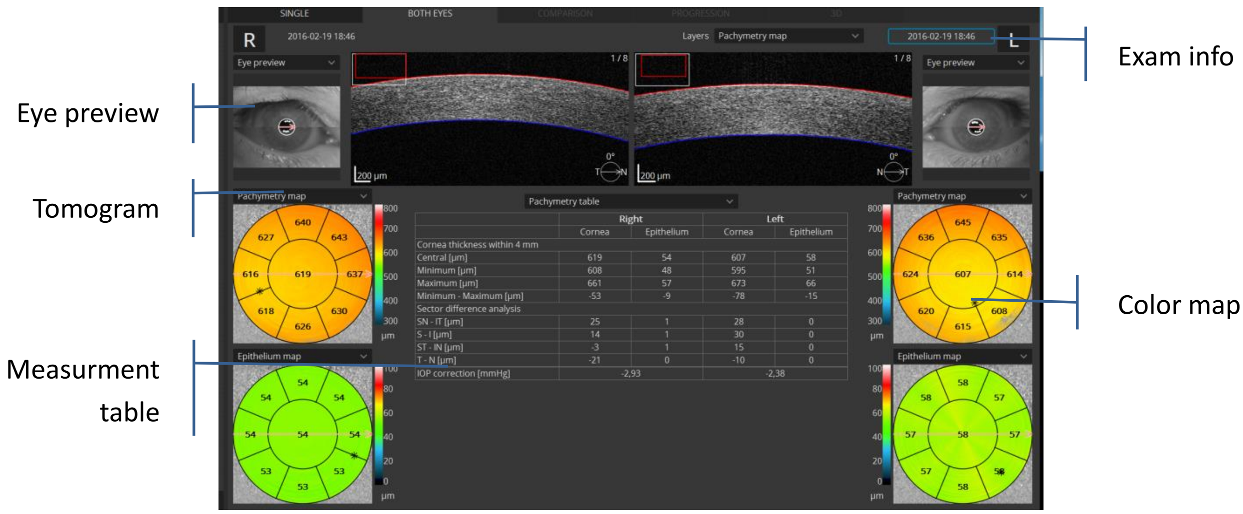
Displays IOP correction. Enter the patient's IOP into the form to see the adjusted IOP. The SOCT software can calculate the correction of IOP (Intraocular Pressure) reading from pneumo-tonometer on the basis of the cornea thickness. After obtaining a complete tonometry value the program calculates the level of correction (Correction) and the corrected IOP value (Adjusted IOP) for the examined eye. The calculation formula is predefined.

NOTE: In case of a later detection failure, 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.

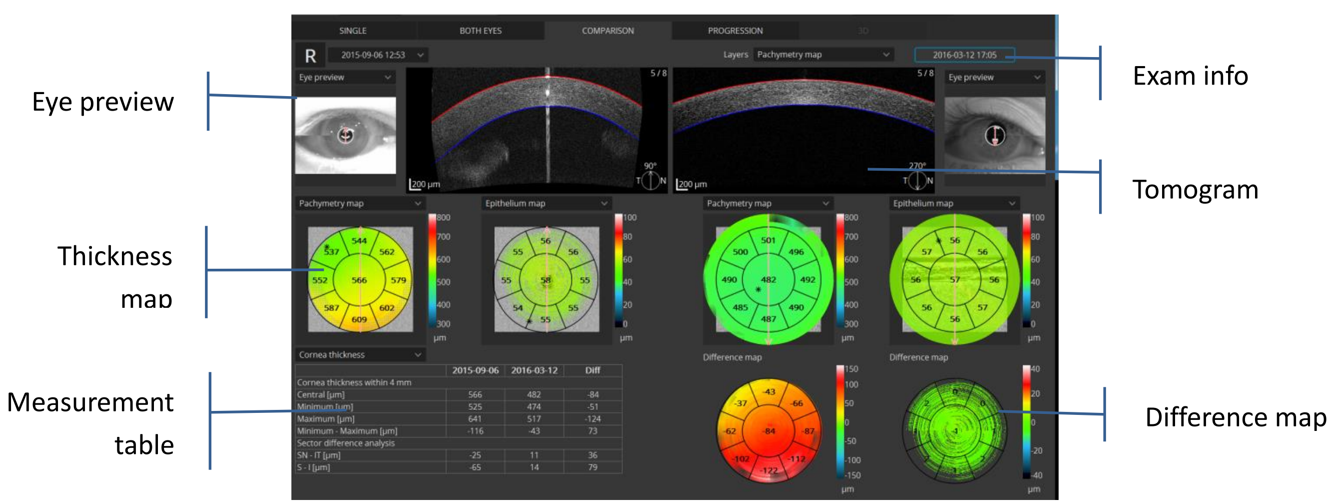
11.1.2 *[Both Eyes] tab screen*



This screen shows the analysis results comparing examinations of both eyes in the same scan mode on the same date.

11.1.3 *[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.



1. Eye preview

2. Thickness map

3. Corneal thickness (µm)

The items are the same as on the [Single] tab screen. This table shows the values for each examination. The rightmost column is the difference between the two examinations.

4. Tomogram

Same as [Single] tab screen.

5. 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.

11.1.4 *[Progression] tab screen*

This screen shows the analysis results comparing six examinations arranged in time sequence of eyes on the same side in the same scan mode, and same size of scanning area.

11.1.4.1 Maps view

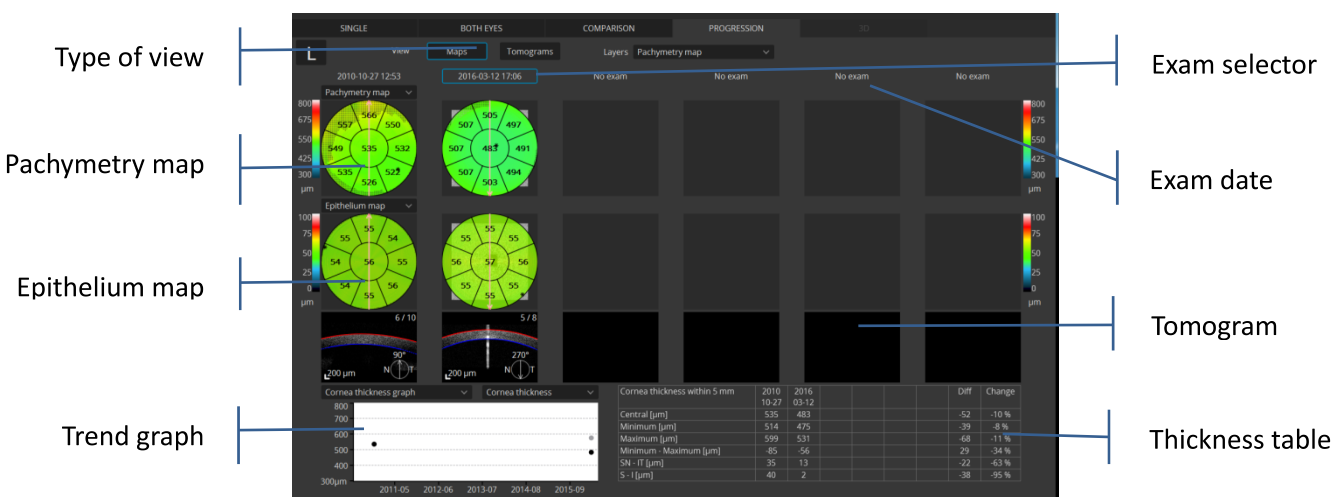


Figure 139. Progression Anterior radial maps view

1. Type of view:

Available views:

- Maps allow to evaluate quantitatively.
- Tomograms allow to evaluate 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 five examinations.

4. Trend graph

This graph plots all examinations performed for the same patient to show changes in the corneal thickness over time. Plots display results of all examinations. The selected examinations are displayed on the reports are indicated in black and other examinations not displayed on the report are indicated in grey.

You can select what is shown from the list box.

- Cornea thickness graph
- Epithelium thickness graph

5. Thickness table

This table shows the values for each examination. The rightmost column is the rate of change.

[Central Corneal Thickness]: Central corneal thickness

[Minimum Thickness]: Minimum corneal thickness

[Maximum Thickness]: Maximum corneal thickness

[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

11.1.4.2 Tomogram view

Tomogram view allows to analyze morphology of the anterior structure.

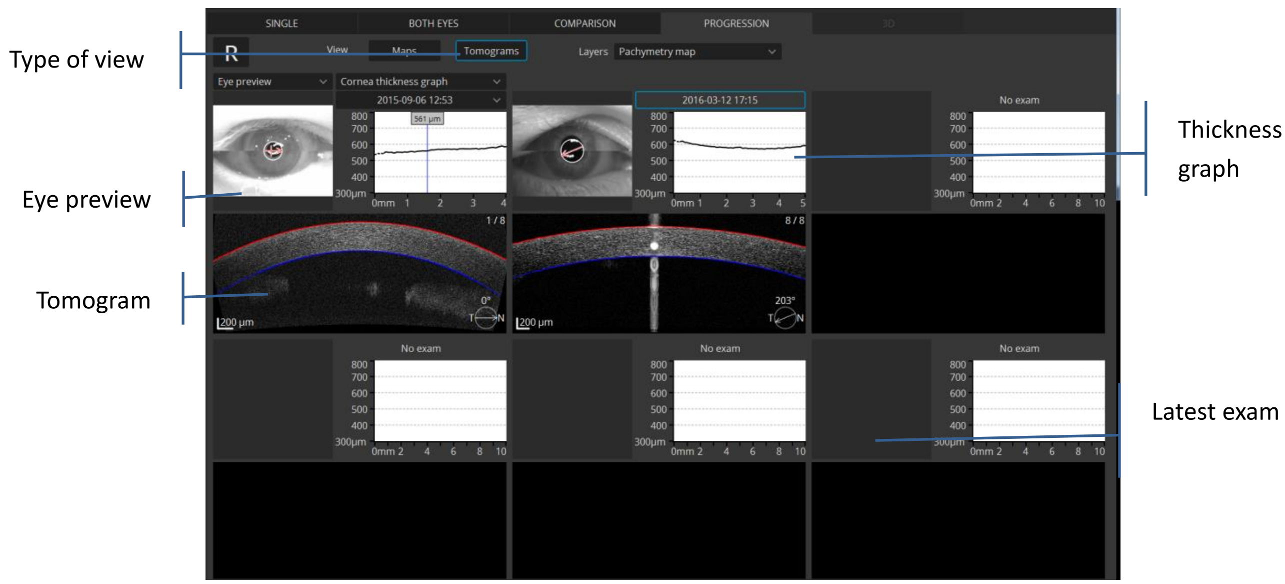


Figure 140. Anterior Progression Tomogram view

NOTE: When layers detection has failed, modify boundary of layers manually.

NOTE: Cornea analysis tab is available only when the system classifies the scanned object as Cornea scan. To change scan type, go to Examination list -> Right-Click -> Tomogram tab-> Menu -> Change Analysis type. Anterior Analysis type window will appear. Select [Cornea] type.

11.1.5 *Edit anterior surface.*

SOCT 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 in “optical distance space” to “physical distance space” The algorithm requires properly recognized boundary between the Air and Anterior structure of the eye.

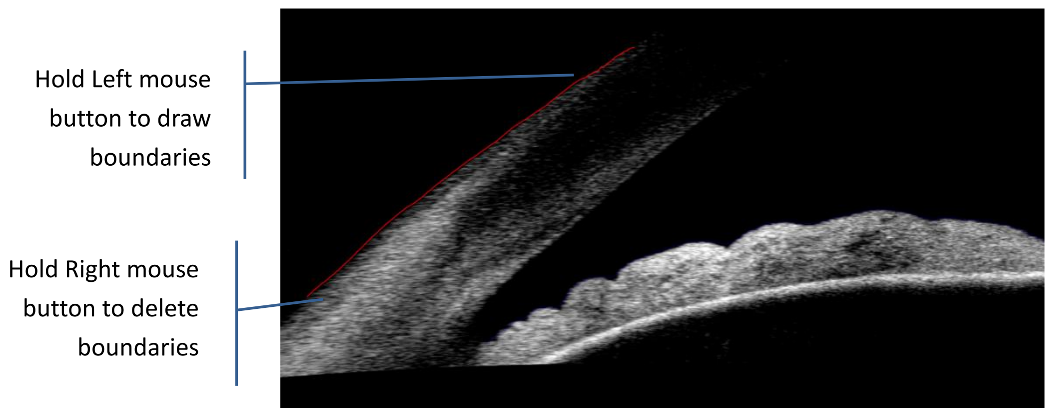
In some cases, the corneal surface lines clearly do not fit the corneal contours, due to anomalies in the scan image, such as may be caused by the interference of eyelids or eyelashes.

To edit the surface boundary lines so they fit better, double click on the Tomogram window. Press [Edit layers] button and select desired boundary. Then draw correct shape of anterior structure.

11.1.5.1 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 141. Edit Anterior layer



11.1.6 *AOD measurement*

Measurement tools is available only from the full scan window.

This tool enables to evaluate the angle opening. In order to use this tool, click  *'AOD'* button, position mouse cursor over Sclera Spure and press the left mouse button. In order to replace the apex of the tool move the cursor over them, press and hold the left button and point at the right places. You can replace the position of the information table in the same way.

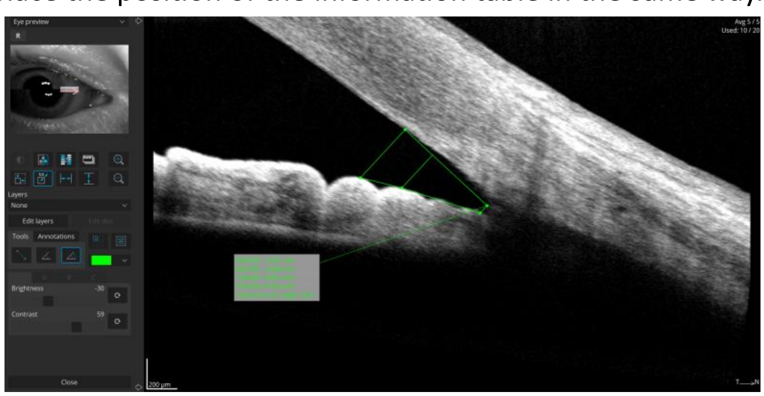


Figure 142. Example of an AOD measurement

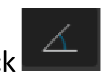
AOD500: Angle Opening Distance of 500 micron measured between two upper points along the posterior cornea surface. One of this point shall be located on sclera spur, the second one on the cornea surface away from sclera spur. Another point has to be located on Iris.

AOD750: Angle Opening Distance of 750 micron.

TISA: Trabecular Iris Segment Area.

NOTE: Only when border air-anterior surface is correct are AOD and TISA measurements accurate. Verify recognition correction before judging the Anterior Angle morphology.

11.1.7 *Angle measurement tool*

This tool enables to measure an angle. Click  '*Angle measurement*' button, put mouse cursor over the place where you want the apex of the angle and click left-mouse button. Now click in the place where you want to set one of the arms, place cursor of the angle to the desired position and click for the second time. Information about 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 2 points of measurement. The measurement checkbox will affect also the angle visibility in the tomogram window, so select or deselect this in order to show or hide the angle measurement.

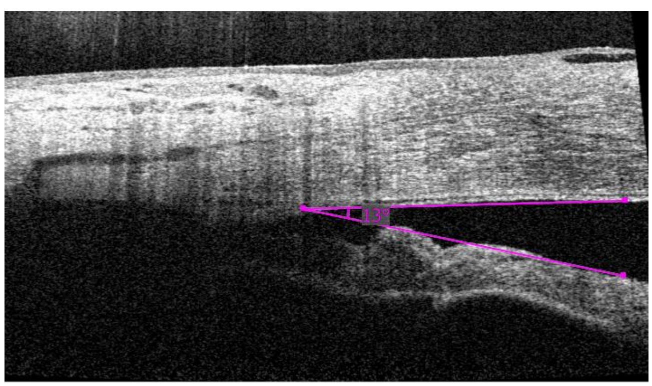


Figure 143. Example of an angle measurement

NOTE: Only when border air-anterior surface is correct Angle measurement is accurate. Verify recognition correction before judging the Anterior Angle morphology.

11.1.8 *Caliper tool*

Caliper tool is used to measure the length of various structures within the anterior chamber. To activate the tool, click the  button. Next, click and hold the left mouse button in the place on the image where you want to start the measurement and extend it by moving the mouse to the point you want the measurement to end at.

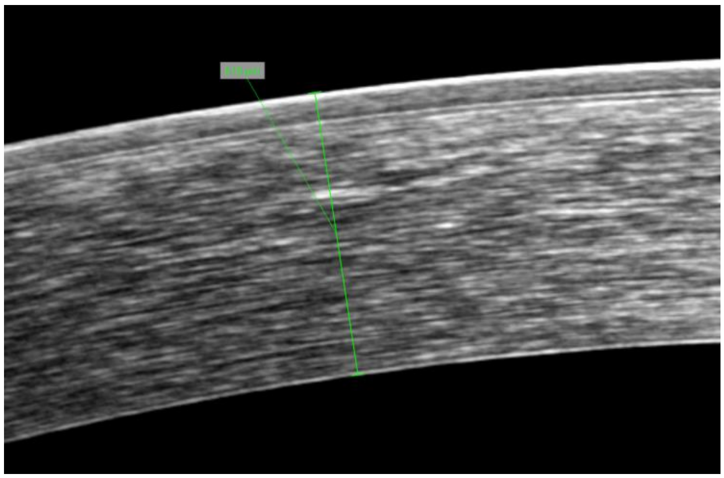
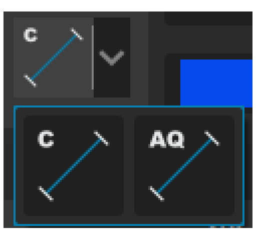


Figure 144. Example of a caliper measurement

Each of the three variants of the tool is optimized for measuring a specific structure type. To pick a variant click the  button and choose the desired option.



C – Caliper toll for measuring the thickness of cornea

AQ – Caliper tool for measuring distances within the anterior chamber

11.1.9 *Tomogram review analysis*

This shows the tomogram image and the defined thickness of the specified part. The compatible scan modes are [Raster], [B-scan], [Cross] and [Radial]. The tomogram images can be averaged.

12 FULL SCREEN WINDOW

To open Full screen tomogram window double click on the tomogram window. Full screen window enables operator to browse all the stored examination results. It contains all tools for editing of the layers, manual measurements and putting comments or descriptions in the tomogram.

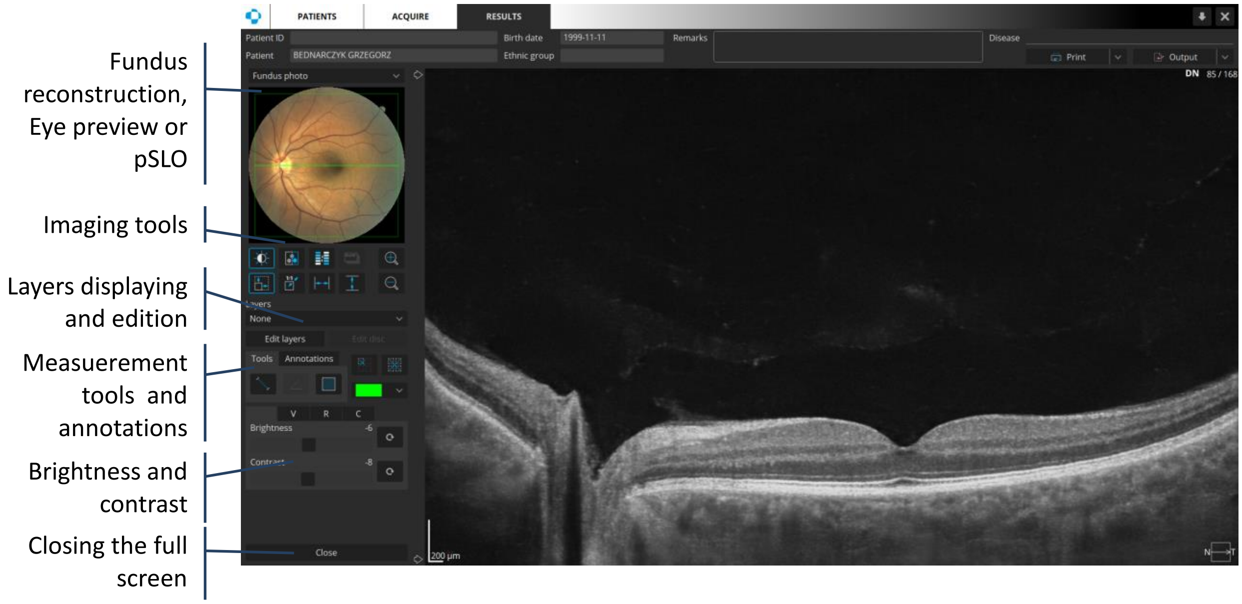


Figure 145. Full screen tomogram

12.1 Fundus reconstruction, eye preview or pSLO

Drop-down list box allows to toggle between fundus reconstruction, eye preview, pSLO or fundus photo.

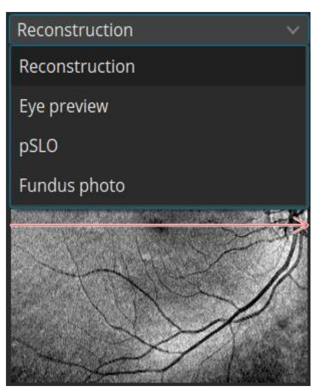
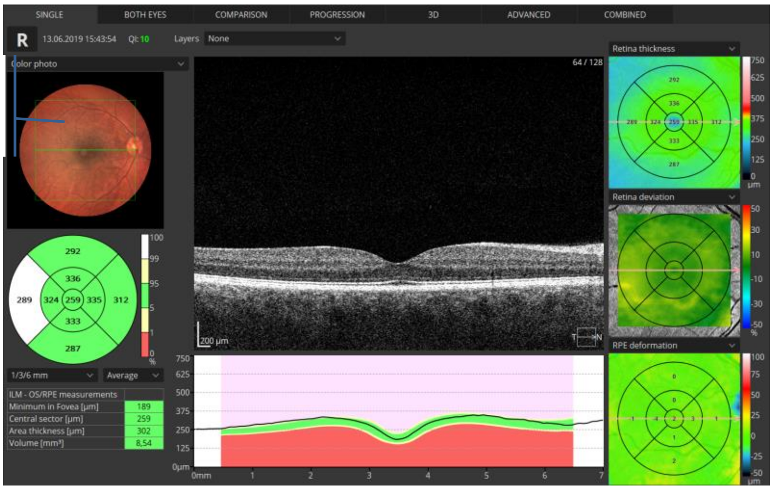


Figure 146. Eye preview type selection.

The fundus photo is set as default.

Color fundus photo



Single eye view with a fundus photo

12.2 **Imaging tools**

Imaging tools – module including tools for change color and tomogram proportions.

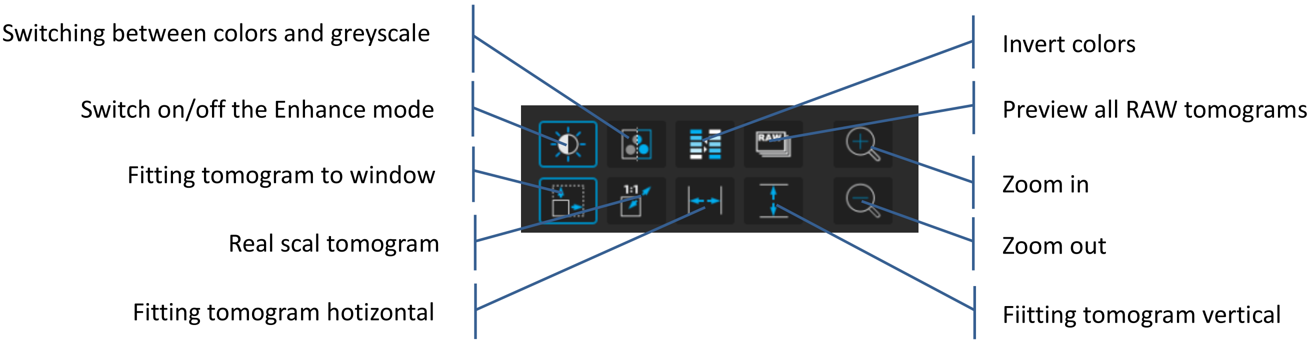


Figure 147. Imaging tools

Preview all RAW tomograms as default is unmarked.

This function is active only when examination contains averaged tomograms. When it is unmarked 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 for that averaged tomogram is displayed, until the next averaged tomogram is reached, after which the corresponding series of RAW will be displayed for that next averaged tomogram. Scroll down to go to the next tomograms and up to go to the previous ones.

12.3 **Measurement tools and annotations**

On the fundus reconstruction object and on the tomogram it is possible to use measurement tools. It is possible to make measurement of area and make measurement of the distance between two points or the angle between two sections.

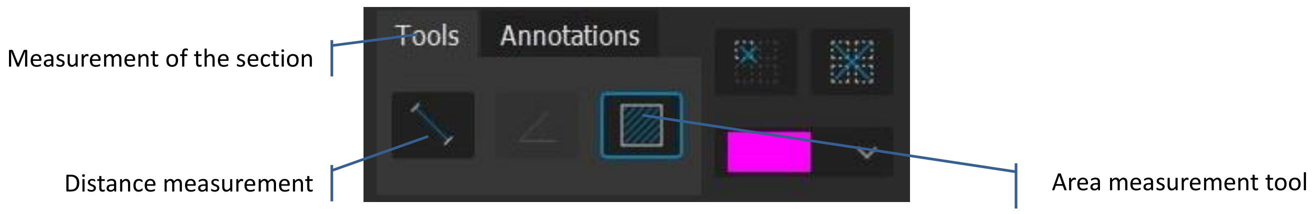


Figure 148. Measurement tools

Annotation tab makes possible inputting text field with operator comments as well as arrow symbol pointing exactly to the place which the comment concerns. Operator can also choose the color in which the particular marking will be displayed on tomogram. Additional two buttons allows to delete single marking or all markings on particular tomogram.

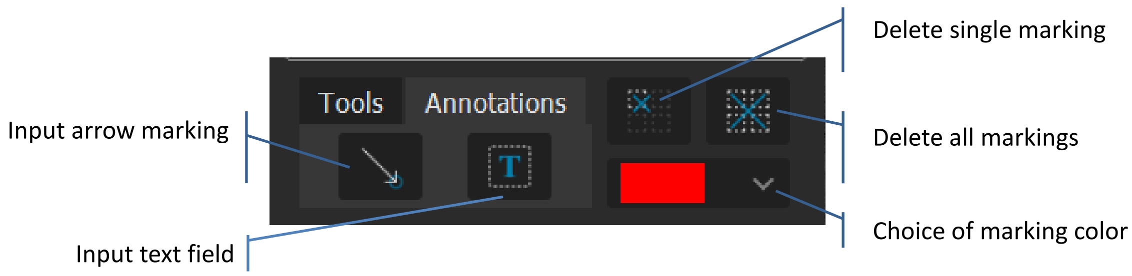


Figure 149. Tab of tomogram annotations

The above tools and annotations remain enabled and are able to continuously insert additional measurements and markings until disabled by clicking on them again.

12.4 **Brightness and contrast adjustment**

Brightness and contrast adjustment is 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.

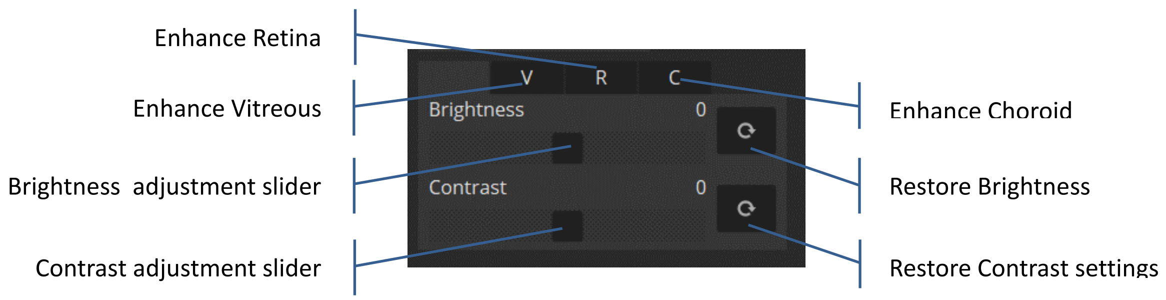


Figure 150. Brightness and contrast manipulation

Recommended tool to adjust Brightness and contrast is to move the cursor over the tomogram or angiogram window and drag the cursor up/down or right/left.

Dragging up and down: Adjusts the brightness. Dragging right and left: Adjusts the contrast.

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 the mode it is possible to adjust the brightness and contrast in one of three zones: Vitreous, Retina and Choroid. The vitreous mode adjusts brightness and contrast above the ILM layer. Retina mode adjusts brightness and contrast between the RPE/BM and ILM layers. Choroid mode adjusts brightness and contrast below the RPE/BM layer.

12.5 **Full screen mode exit**

Full screen mode exit – the button makes possible full screen mode exit and going to exam analysis. The same result is achieved by double clicking on tomogram.

12.6 **Tomogram window manipulation**

Right Click (long press using touch screen) over the tomogram preview opens 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.

Auto fit function has been modified.

Auto fit – it fits tomogram horizontally.

Note that the proportion of the scan may be different between examinations.

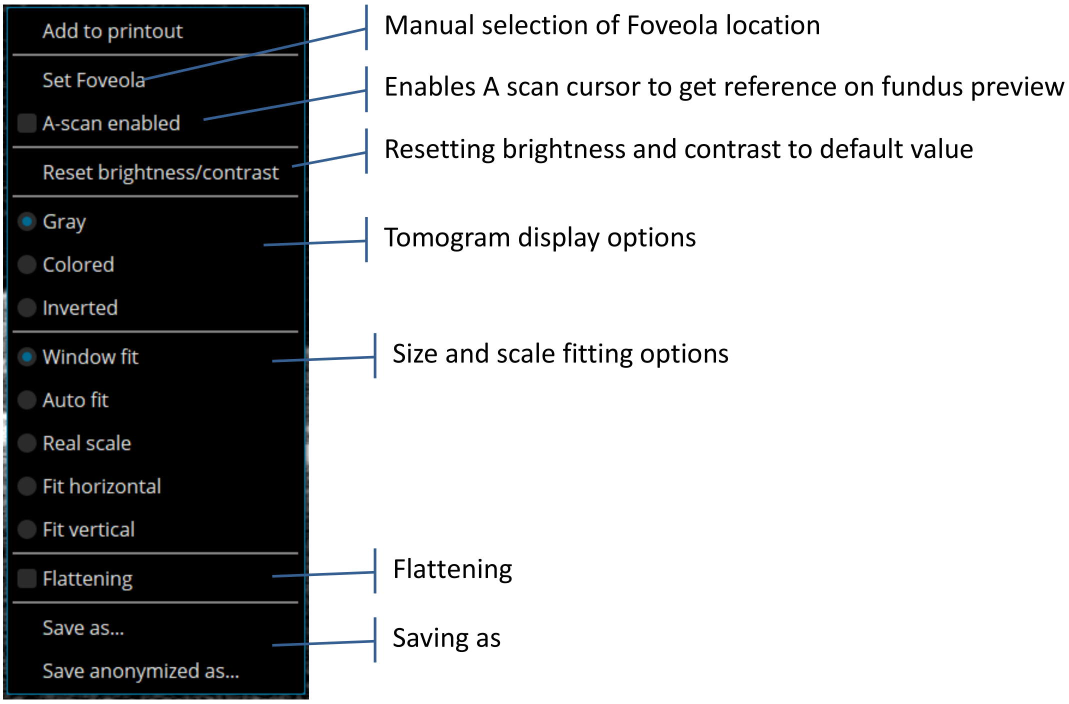


Figure 151. Tomogram display options window.

Double click on the tomogram preview switches the view to full screen and allows to edit layers recognition in the same way as in the Retina examination viewing tab.

12.7 Edition of recognized layers

System automatically recognizes layers. Whenever you find out that the recognition of layers is incorrect, you can manually correct them. This feature is especially useful in cases where the retina has structural anomalies or pathology that may cause the algorithms to incorrectly trace the actual boundaries.

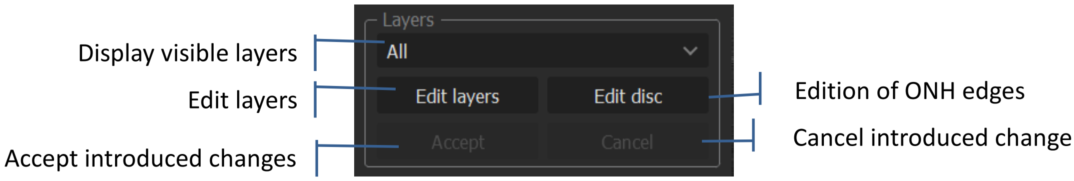


Figure 152. Selection and edition of layers

In order to correct recognized layers press the [Edit layers] button. In order to correct recognition of layers, choose the layer from the list and draw its outline on the tomogram. After correction of tomogram/s press [Accept] option. The software will automatically recalculate all the data, on the basis of the user modifications. 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 looking at examinations.

[Reanalyze] function is used to recover default recognition of layers. It is recommended to make reanalysis of examinations taken with previous software versions.

ILM	- Inner Limited Membrane - surface of the retina
RNFL/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
MZ/EZ	- Junction of Myoid and Ellipsoid zones
OS/RPE	- Junction of photoreceptors 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
IS	Photoreceptor Inner Segment
OS	Photoreceptor Outer Segment
RPE	Retinal Pigment Epithelium
BM	Bruch’s Membrane

12.8 **Manual disc contour edition**

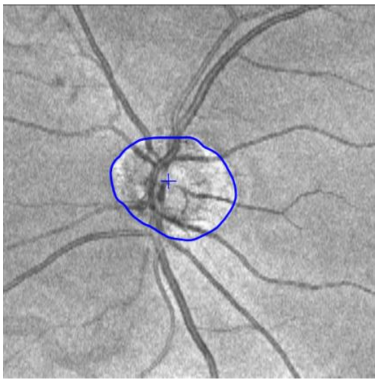
For Disc examination it is possible to edit position of recognized end of BM membrane which defines the disc shape. Press [Edit disc] button to correct the markers.

On the tomogram preview windows white markers points will appear on left and right edge of BM on actual scan (if actual scan crosses disc). If necessary, marker points can be moved by clicking and dragging them on tomogram image area (changes in single scan will occur on shape of disc and cup and will take effect in all analysis) to proper location. Yellow line shows Cup Offset Line (parallel to purple disc which represents disc surface). Distance between Cup Offset Line and disc surface line may be changed by editing the value on Cup Offset Panel or moving the cup offset line. To reset cup offset values double click on the cup offset line on the tomogram window.

After disc analyzing, operator can manually edit position of end of RPE markers. In order to replace markers which identify the edge of RPE click white marker, hold the button and drag to proper location in the disc profile (for each scan). It is possible to change position of edge by drawing shape of the disc in *Manual disc contour option.*

Changing the Cup Offset will move cup closer or further from disc, this will be also visible in cup shape on fundus reconstruction. All ONH data are automatically recalculated if Cup Offset or RPE edge factors change. It is possible to restore default analysis by using [Reanalyze] option. Right Click on the preview exam.

[Edit shape] – Opens "Manual disc contour edition" window which allows the physician to draw manually the shape of the disc.



This window allows the user to redefine shape of disc and its position.

[Apply] – applies the changes of the disc and closes the window.

[Cancel] – exits the window without changes.

[Reset] – resets a disc shape to condition which was before opening the window.

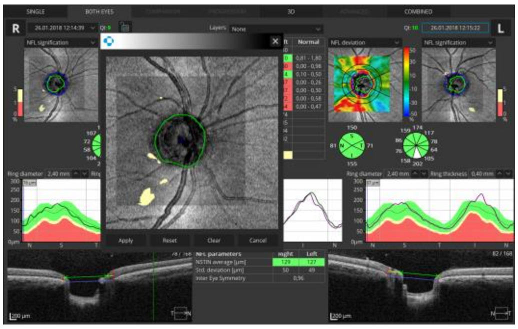
[Clear] – clears the disc's factors. New shape of disc should be drawn manually.

There are two ways to correct shape of disc.

One is to remove contour of disc by using [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 a disc. Recognition of the disc will be automatically circled between selected points around disc center. All other points will be automatically added after [Apply] button is used. If operator decides to draw disc contour more accurately (with non-elliptic shape) it's possible to add more disc points manually by clicking on the image

The other way is to redraw existing shape.

The disc shape adjustment window can be opened by double clicking on the NFL signification map in either the SINGLE or BOTH EYES view.



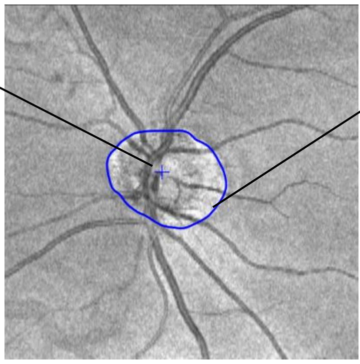
12.8.1 *Redraw the disc contour*

Operator can redraw disc contour position in two ways:

Click and hold left mouse button and draw desired shape.

Put the cursor over the blue point to activate it. Point will highlight. To move active point to new position click left mouse button and move mouse. To delete active point click right mouse button on it – the point will disappear and white disc contour line will be updated to connect two neighboring points.

Click and move the centre point



End of the blue tracking line points mouse cursor position. Click the left mouse button to move the active (highlighted) point from its position to the position of the mouse cursor. Click right mouse button to delete active point.

Disc contour lines are always restricted to image margins.

Whenever the manual analysis is still not helpful to perfectly draw the shape of the disc, the user can still fix the manual analysis, by means of 2 white markers in the tomogram preview of the main disc analysis window, as explained in Tomogram preview chapter 7.10 Live OCT preview.

DISCLAIMER: OPTOPOL Technology is not offering and does not offer advice, instruction in the diagnosis and interpretation of SOCT images. It is the clinician's responsibility to make diagnosis and interpretation of OCT scans.

13 PRINT

13.1 Posterior segment examination reports/outputs

13.1.1 *Retina 3D*

Press the [Print] button to print the displayed report.

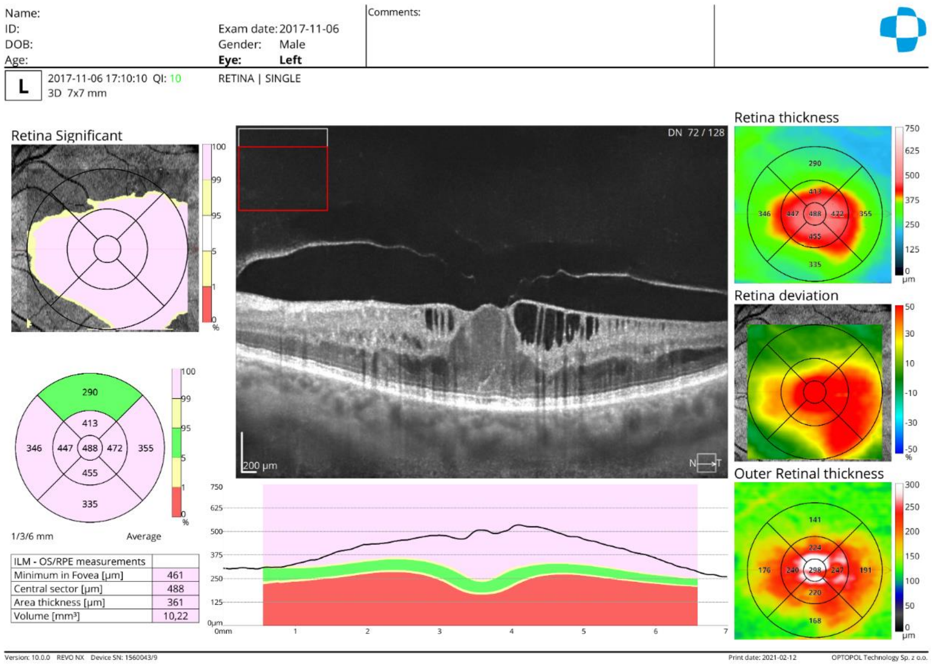


Figure 153. Examination report for Retina 3D Single output

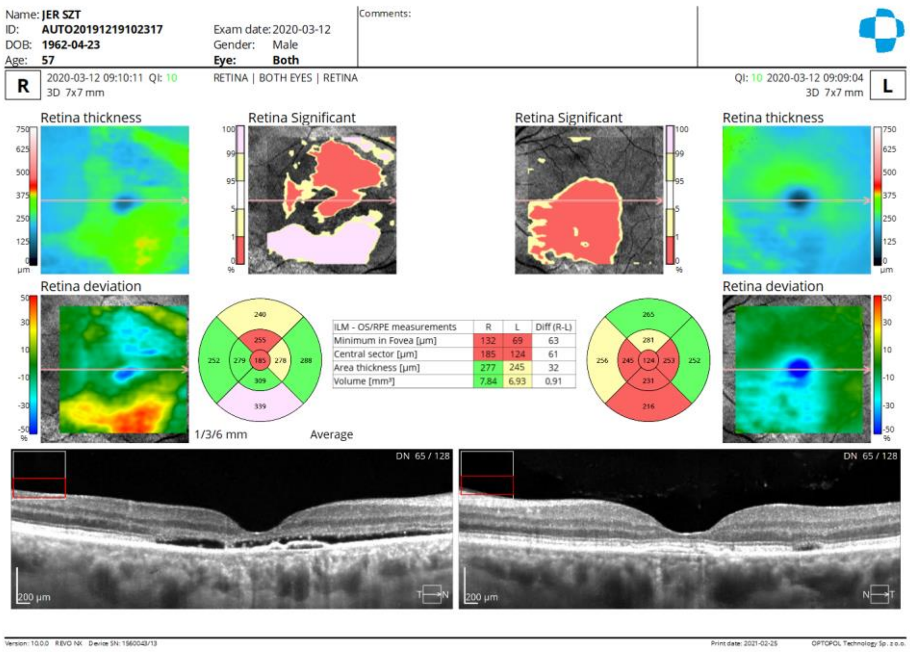


Figure 154. Examination report for Retina 3D both output

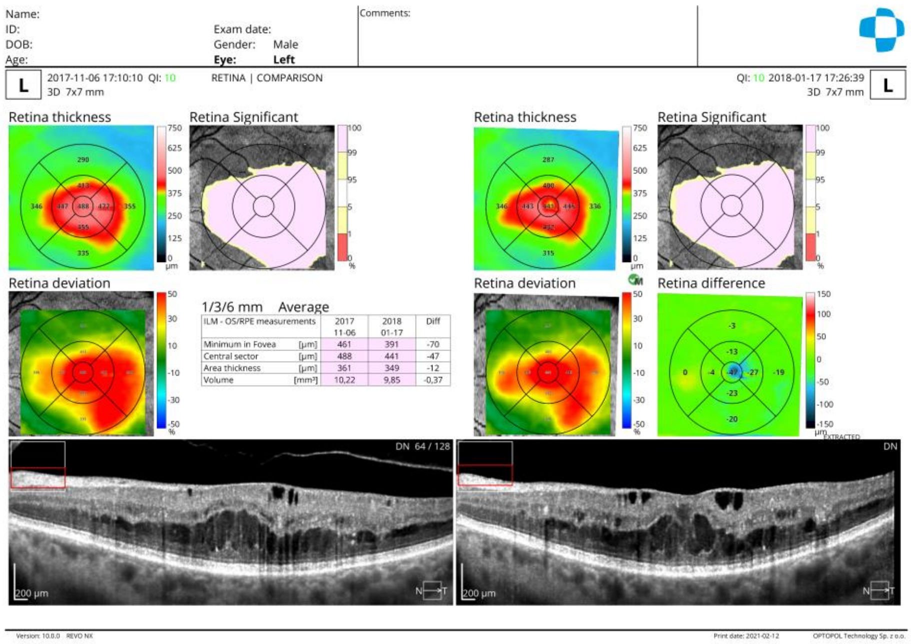


Figure 155. Examination report for Retina Comparison single view

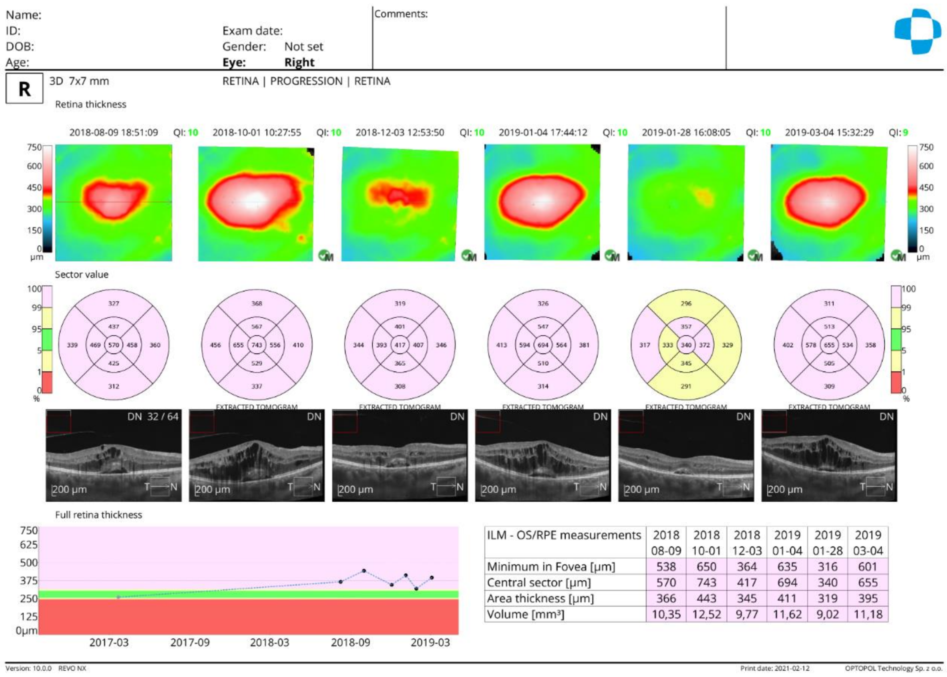


Figure 156. Examination report for Retina Progression single view

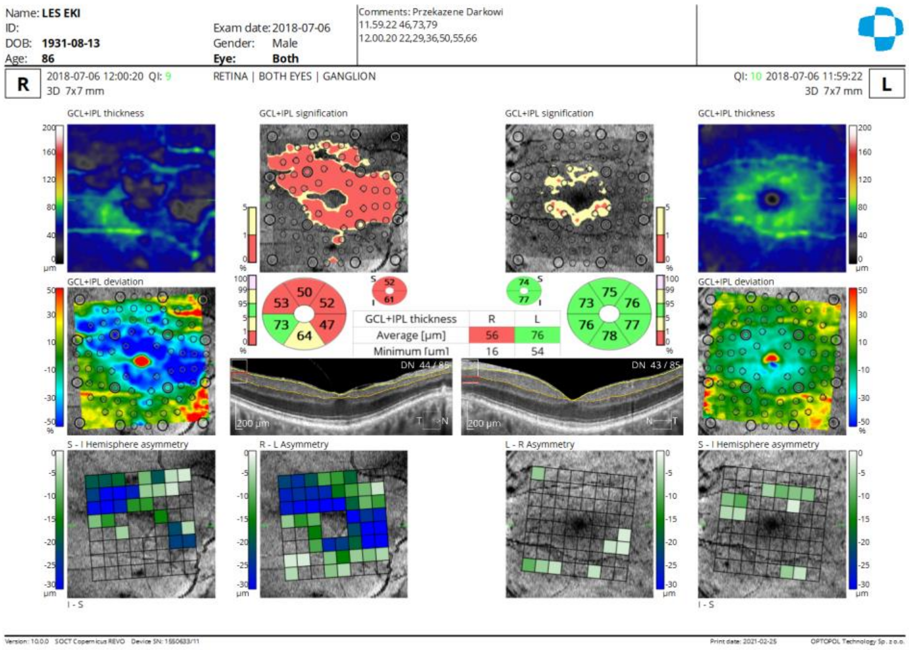


Figure 157. Examination report for Retina Ganglion both view

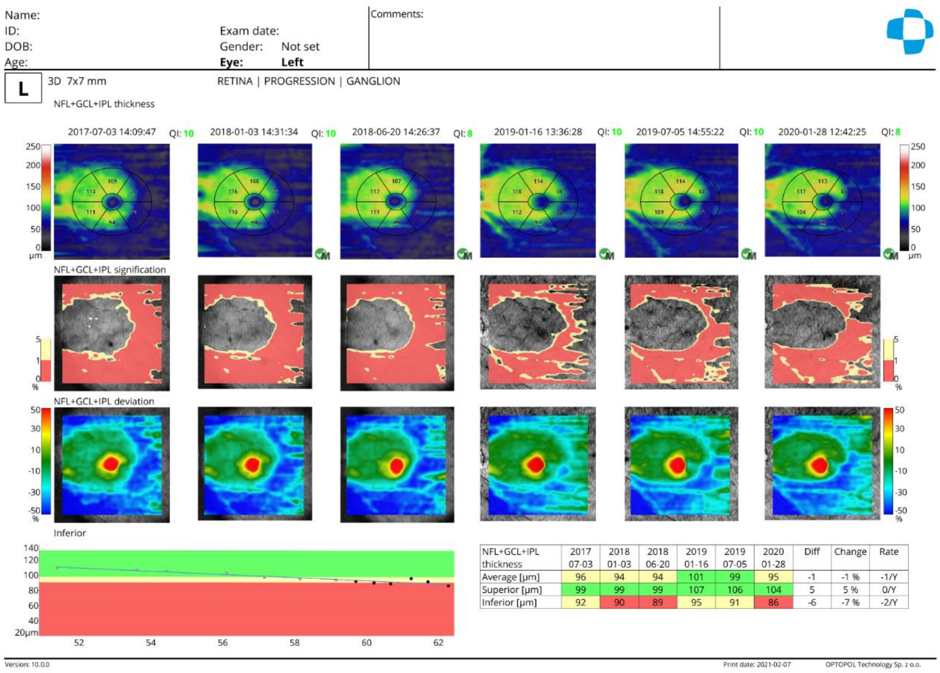


Figure 158. Examination report for Retina Progression Ganglion single view

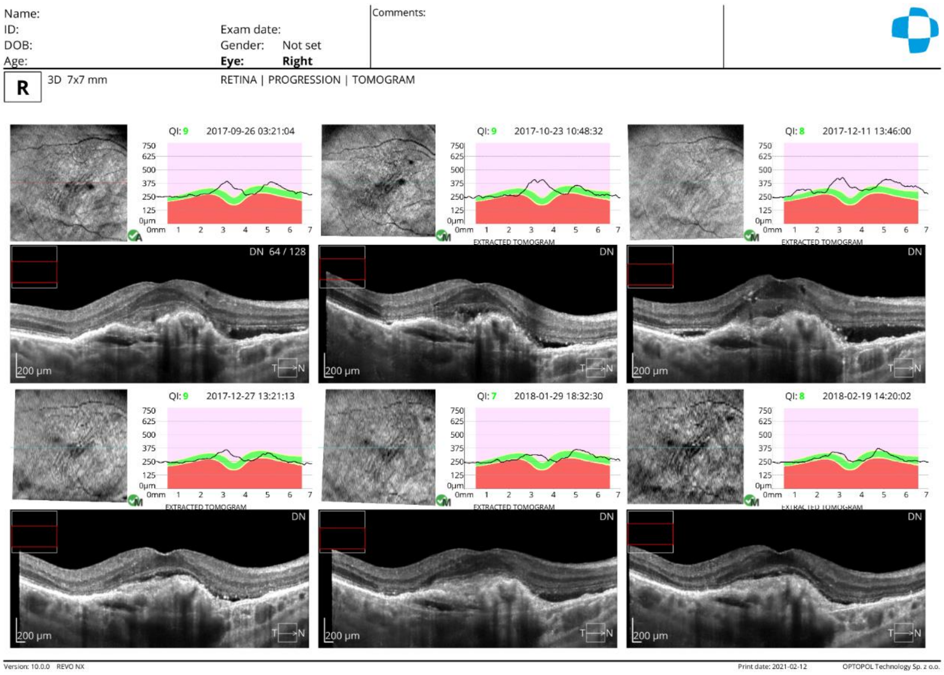


Figure 159. Examination report for Retina Progression Tomogram Morphology view

13.1.2*Disc 3D*

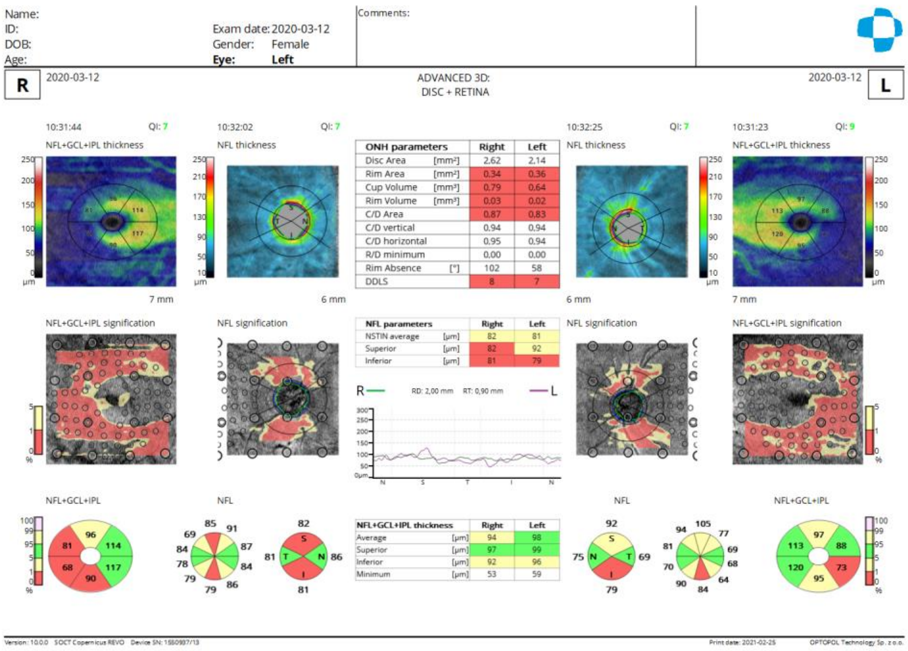


Figure 160. Examination report for Retina + Disc Advanced both view

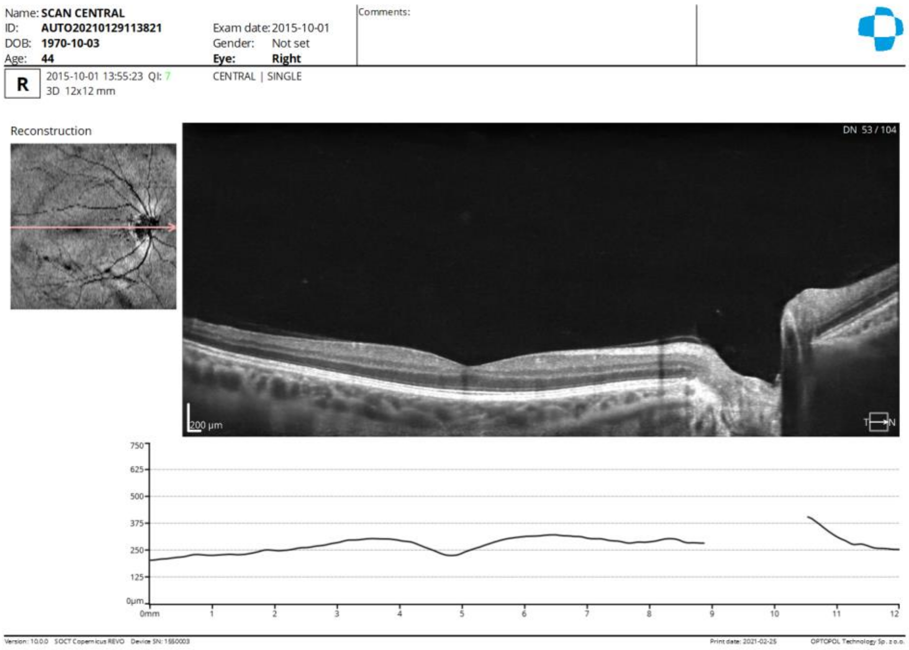


Figure 161. Examination report for Retina Central view

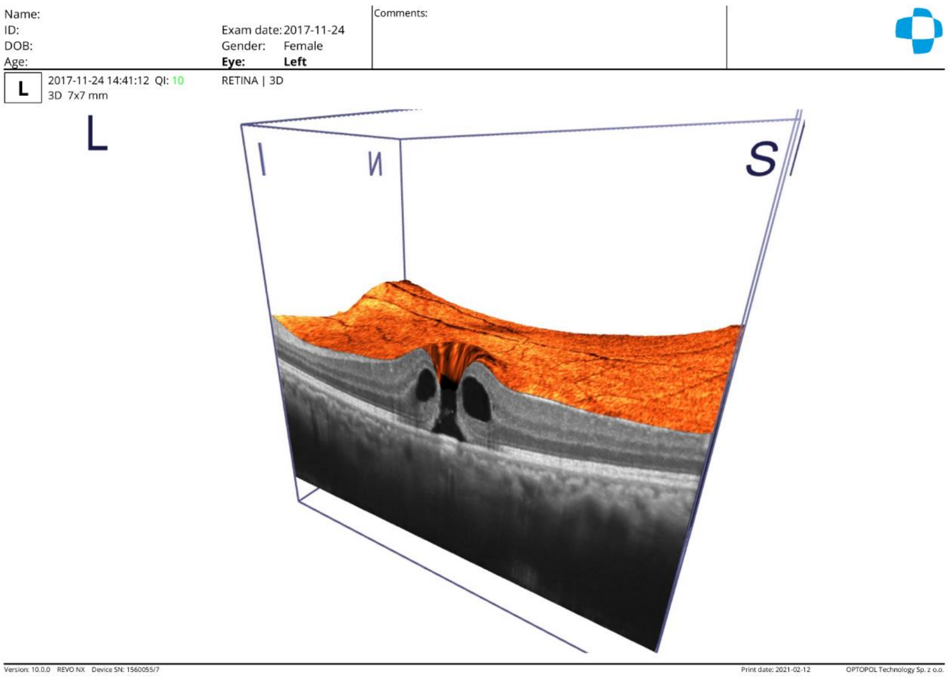


Figure 162. Examination report for 3D Retina single view

13.1.3 *Optic nerve head analysis reports*

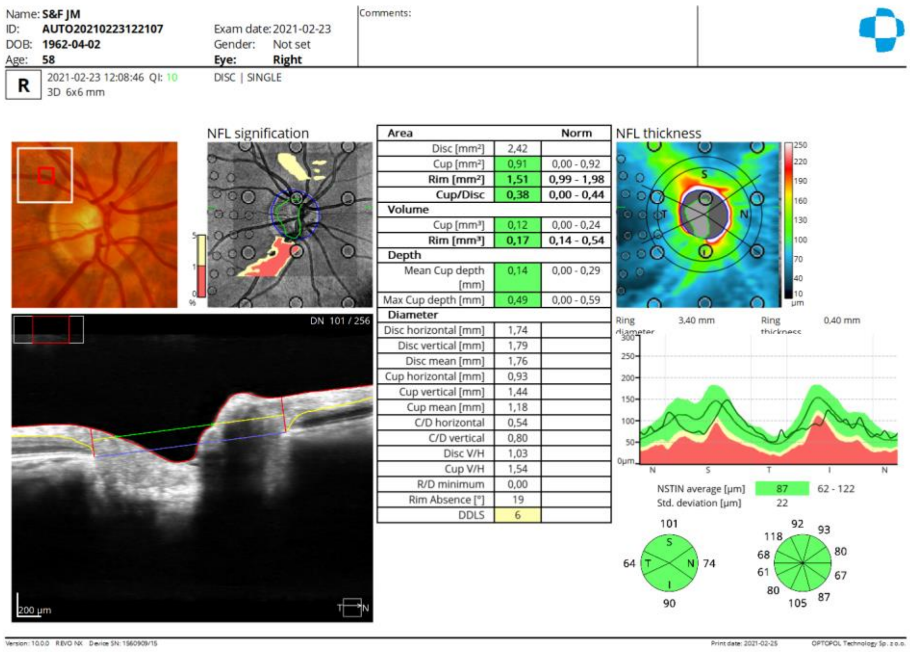


Figure 163. Examination report for single disc view

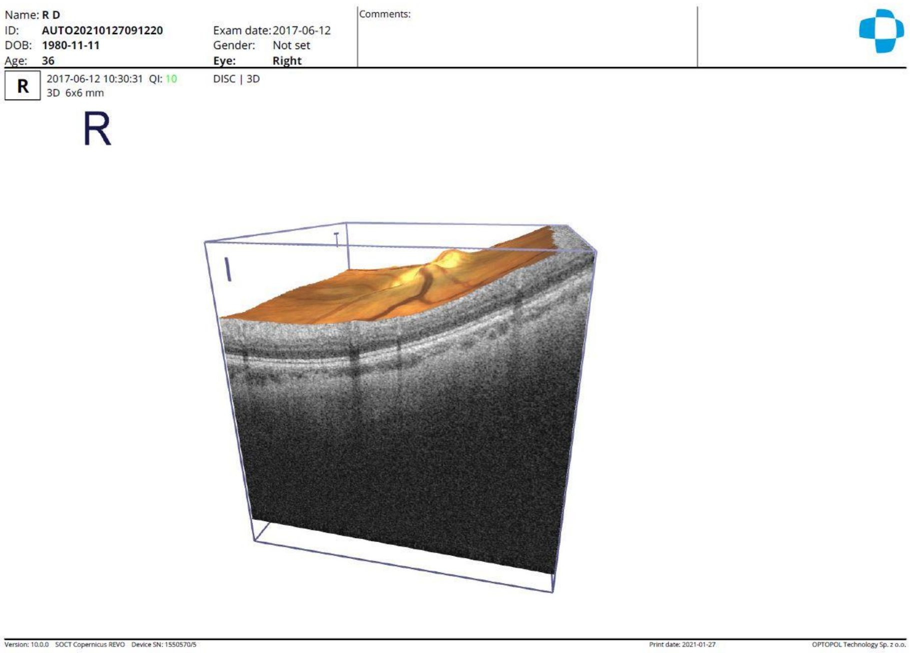


Figure 164. Examination report for 3D single disc view

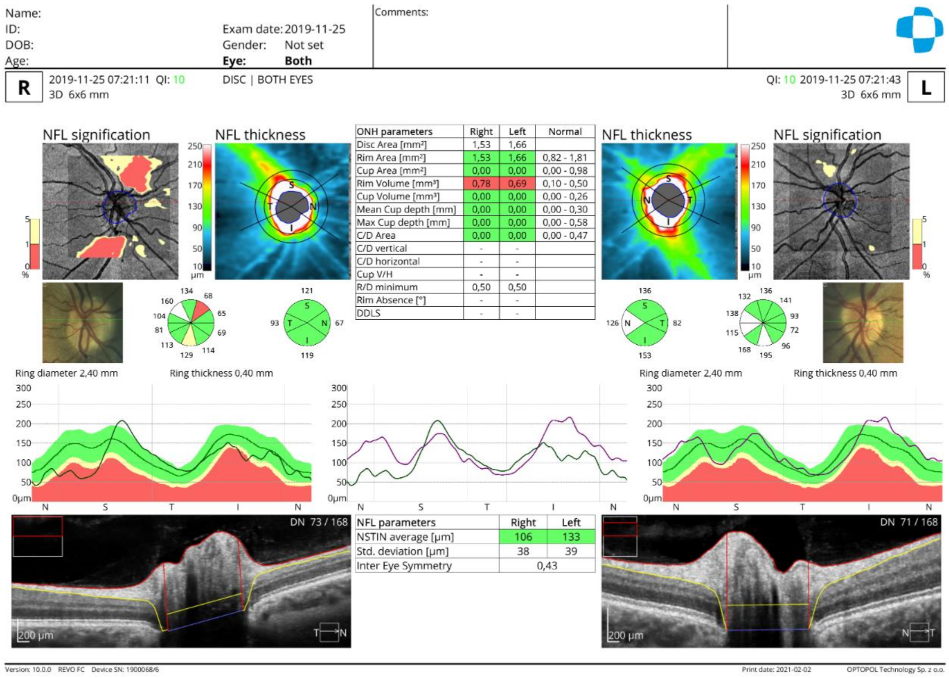


Figure 165. Examination report for both disc view

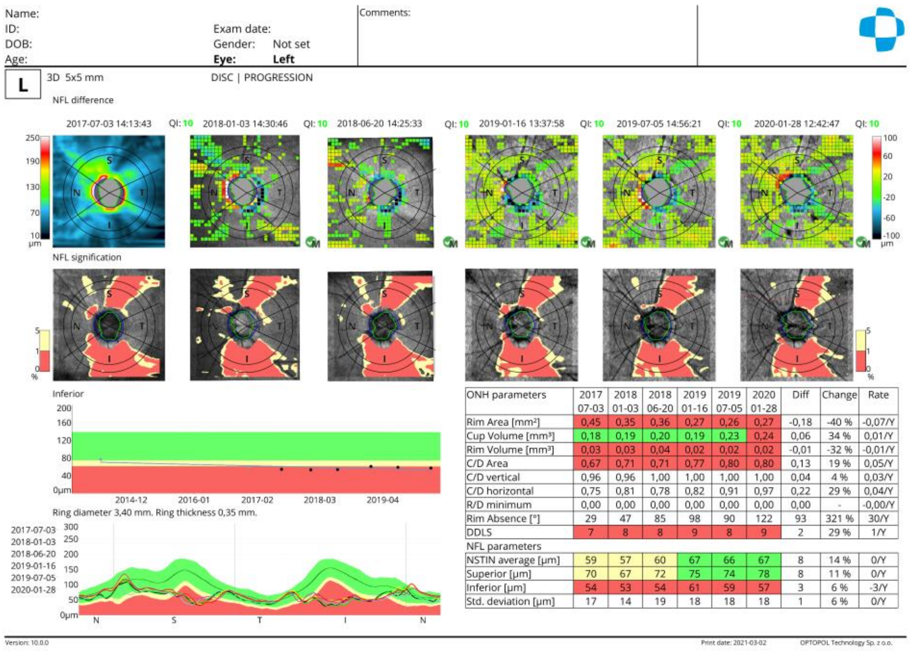


Figure 166. Examination report for single disc progression view

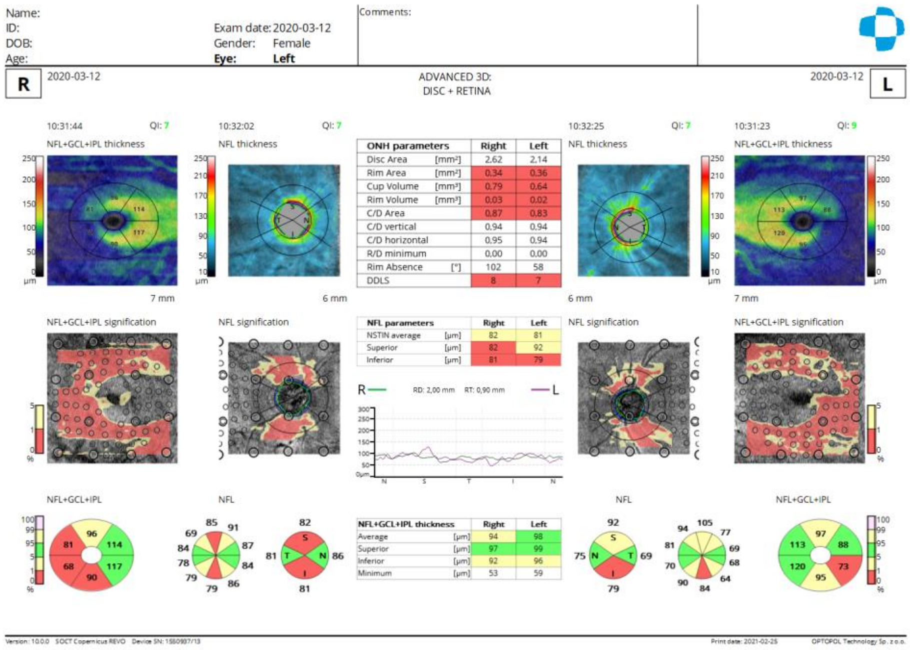


Figure 167. Examination report for Disc + Retina advanced both view Anterior segment examination reports

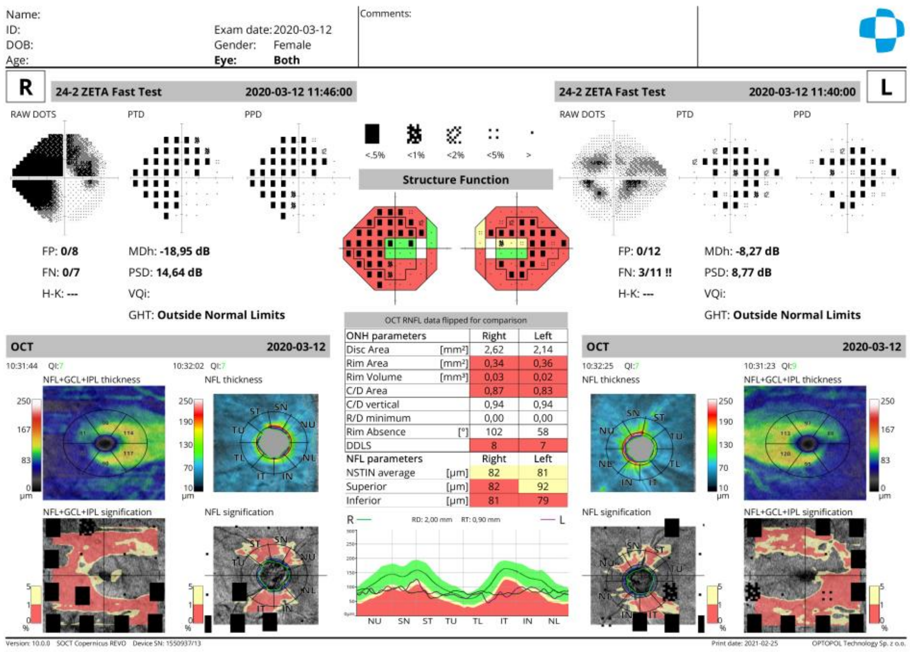


Figure 168. Structure and function examination report

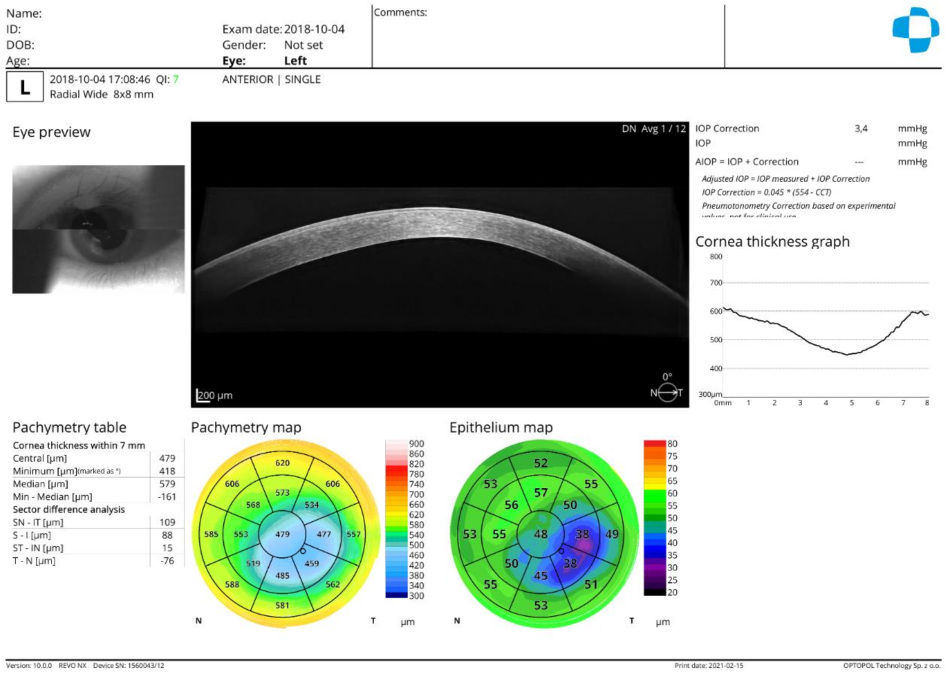


Figure 169 Examination report for Anterior segment single view

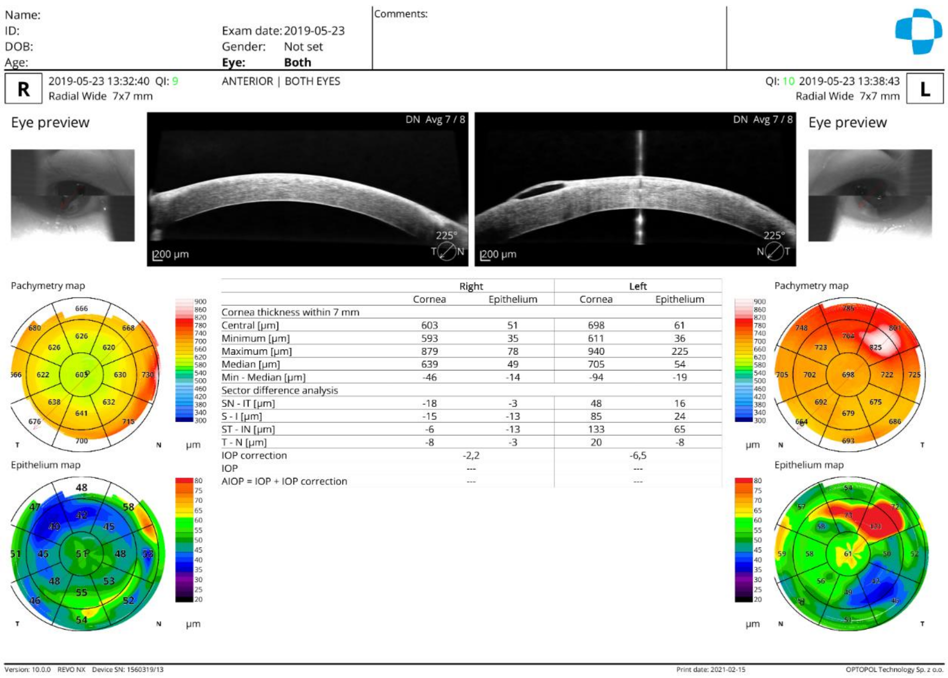


Figure 170. Examination report for Anterior segment both view

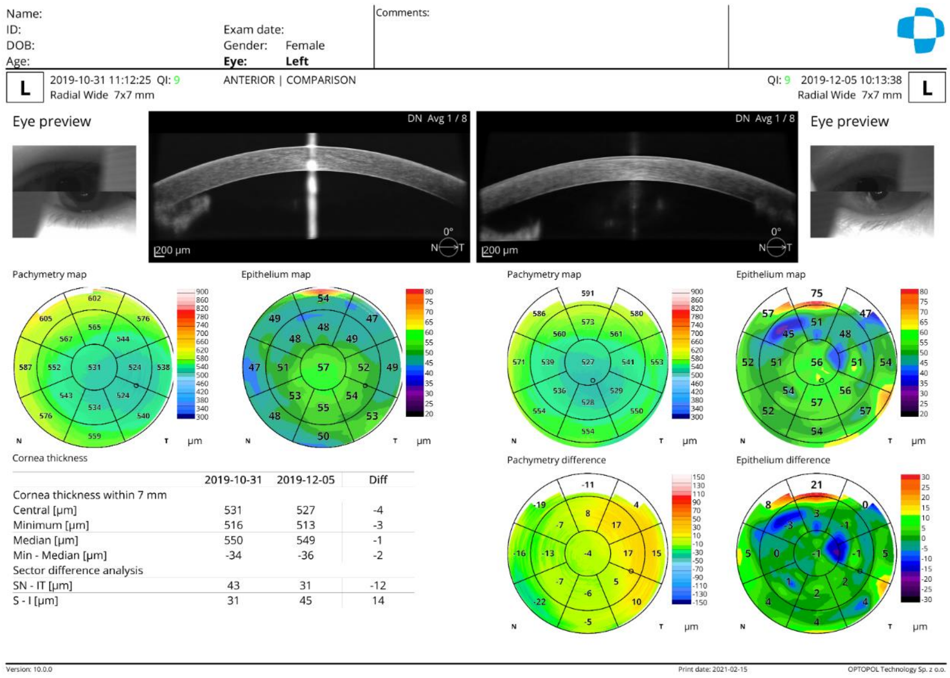


Figure 171. Examination report for Anterior segment comparison view

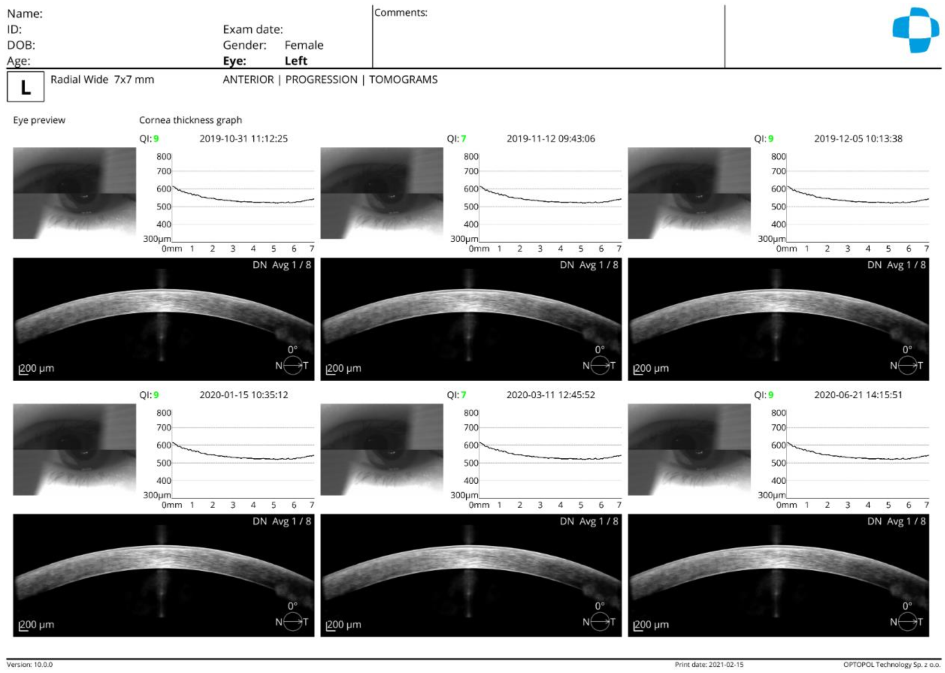


Figure 172. Examination report for Anterior segment progression view

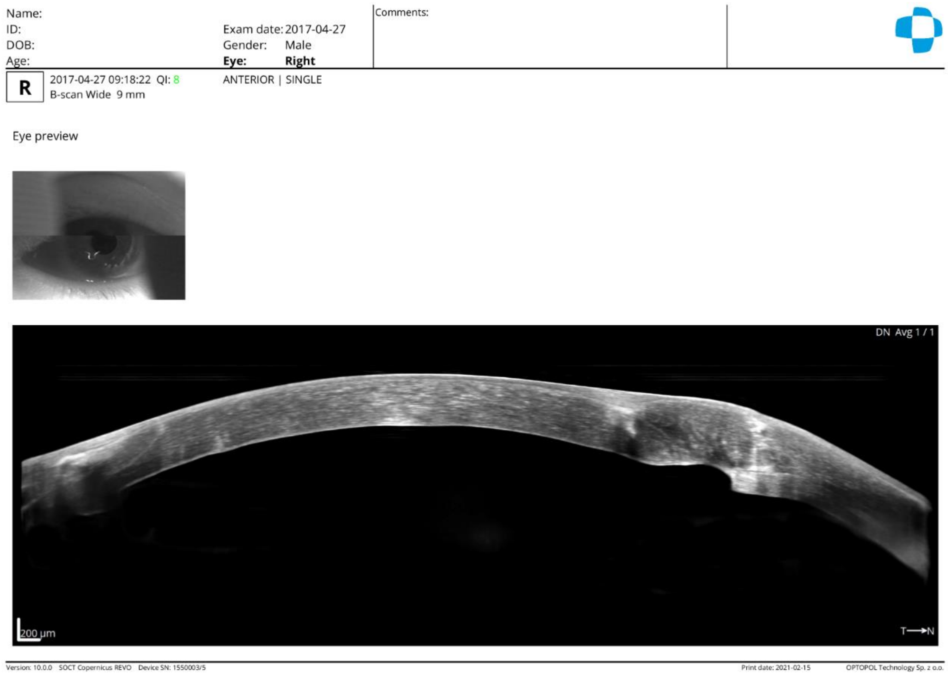


Figure 173. Examination report for Wide Anterior B-scan single view

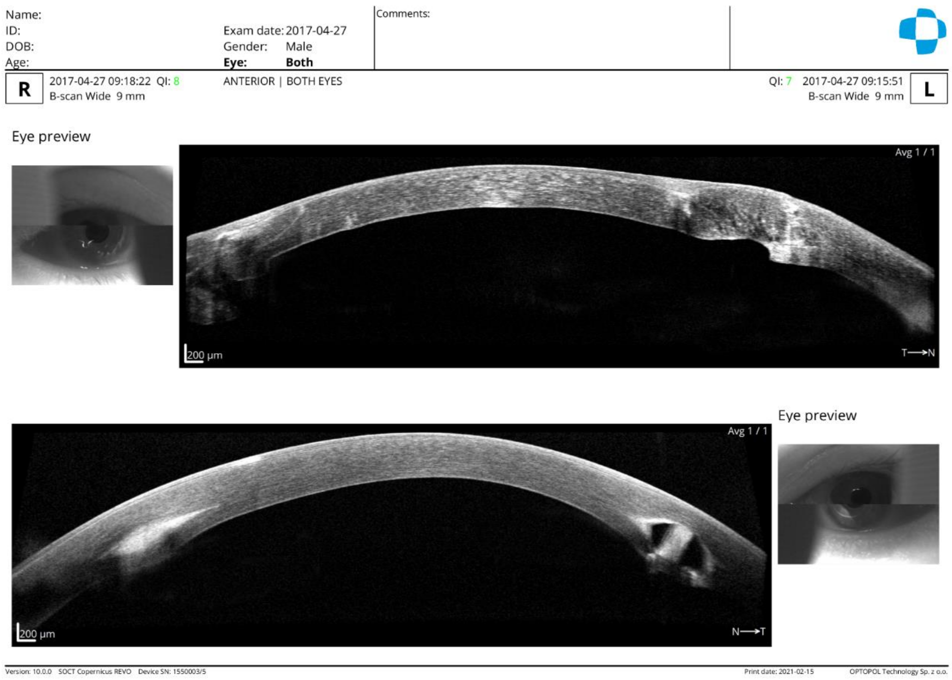


Figure 174. Examination report for Wide Anterior B-scan both view

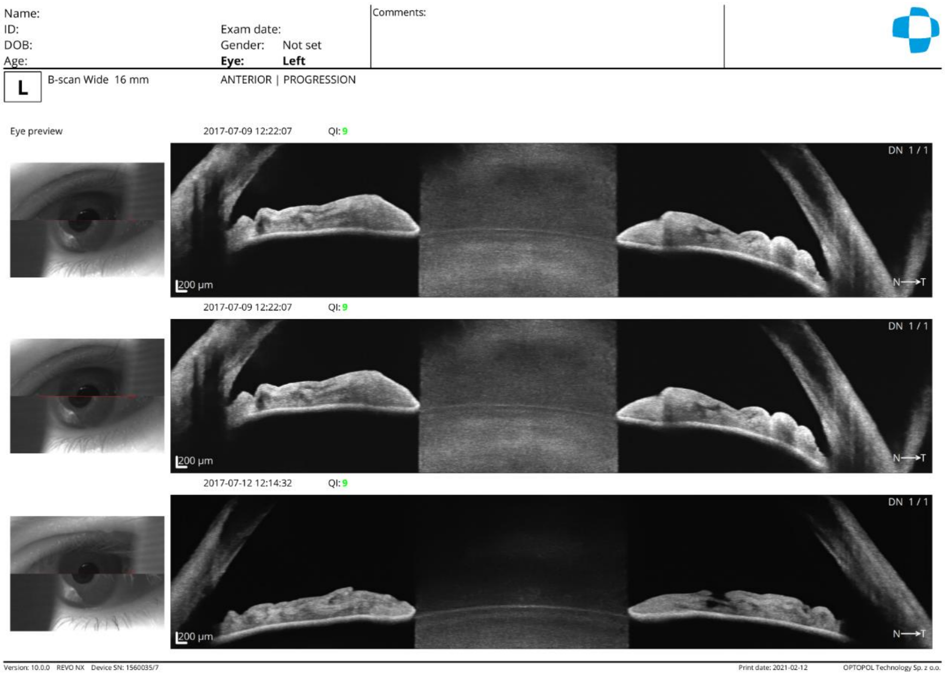


Figure 175. Examination report for Wide Anterior segment progression B-scan view

13.1.4 *Topography examination reports*

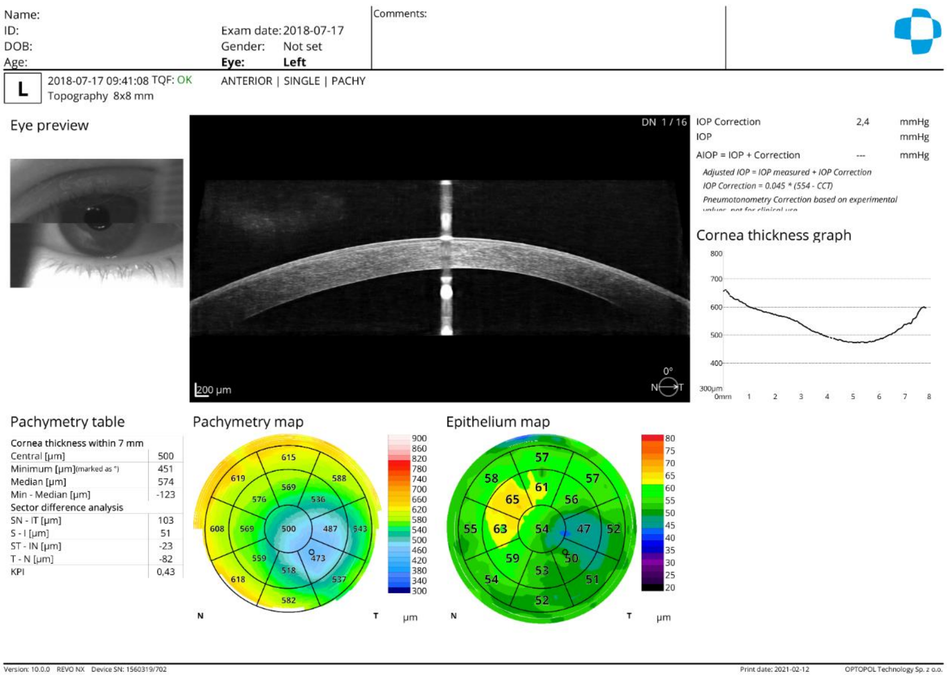


Figure 176. Examination report for Topography pachymetry single view

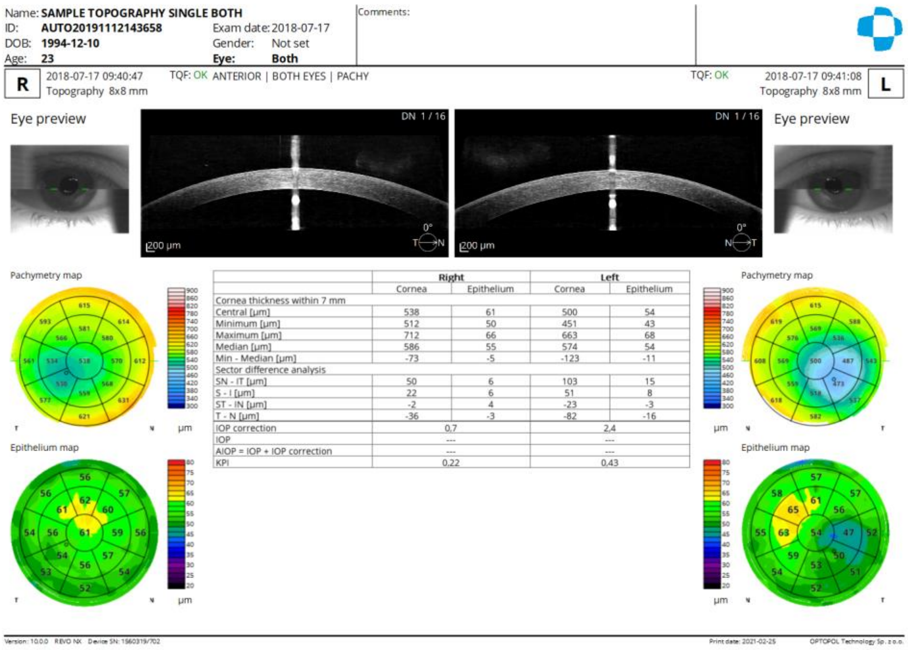


Figure 177. Examination report for Topography pachymetry both view

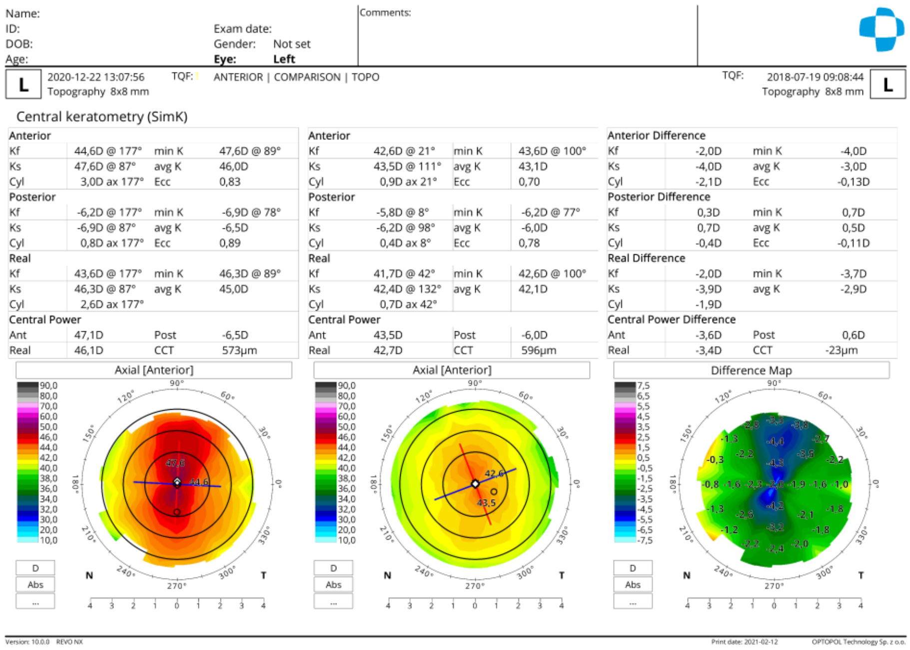


Figure 178. Examination report for Topography comparison view

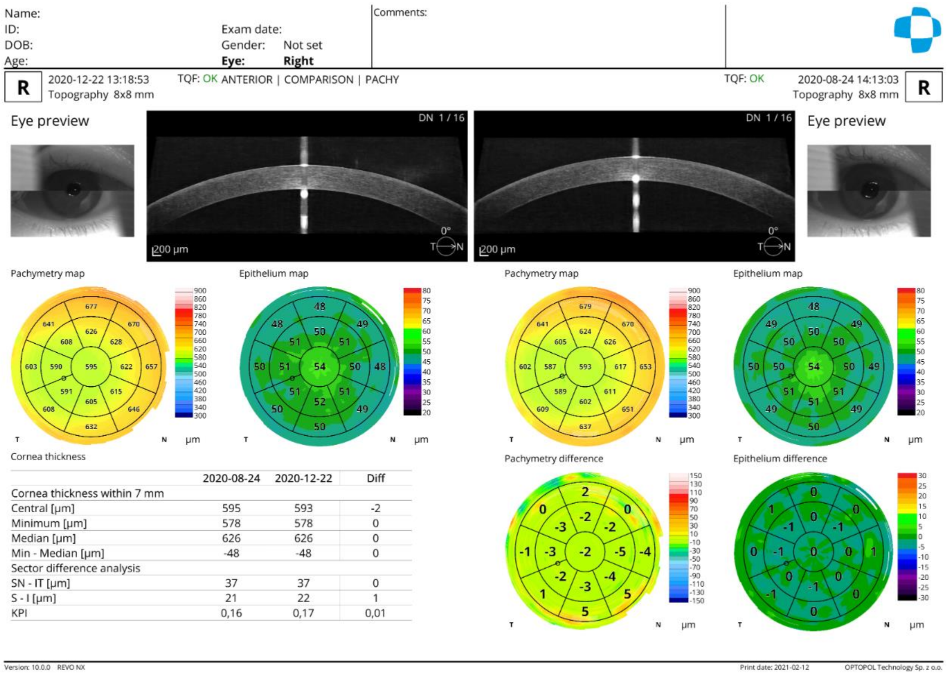


Figure 179. Examination report for Topography comparison pachymetry view

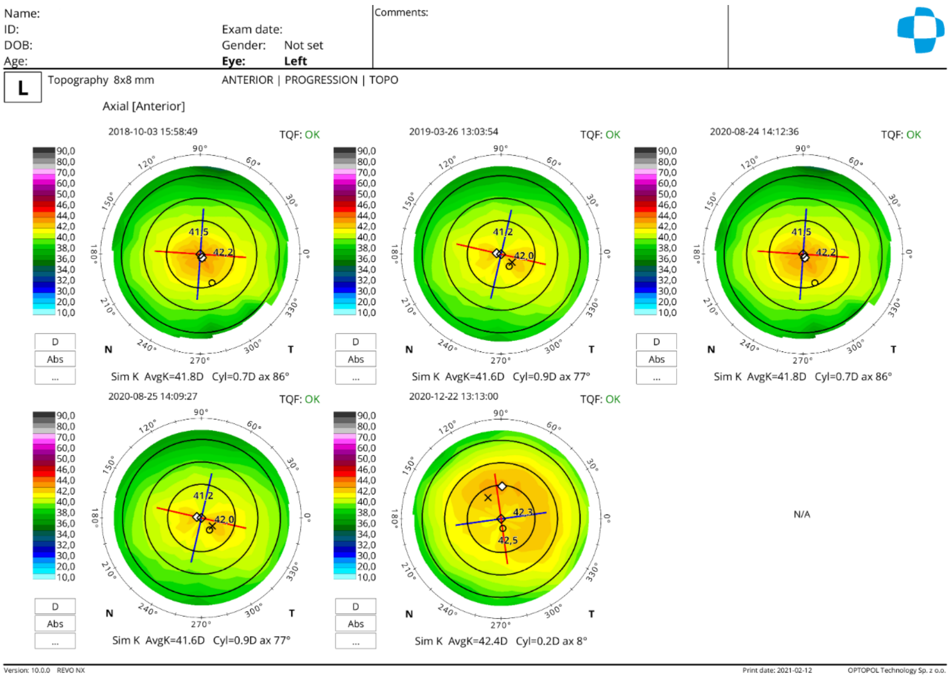


Figure 180. Examination report for Topography progression view

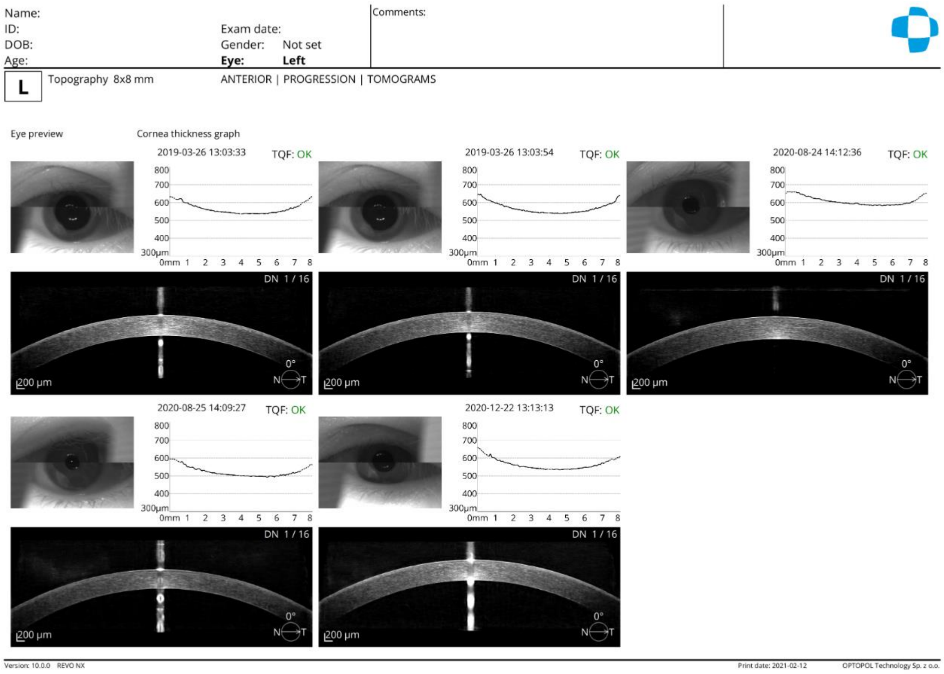
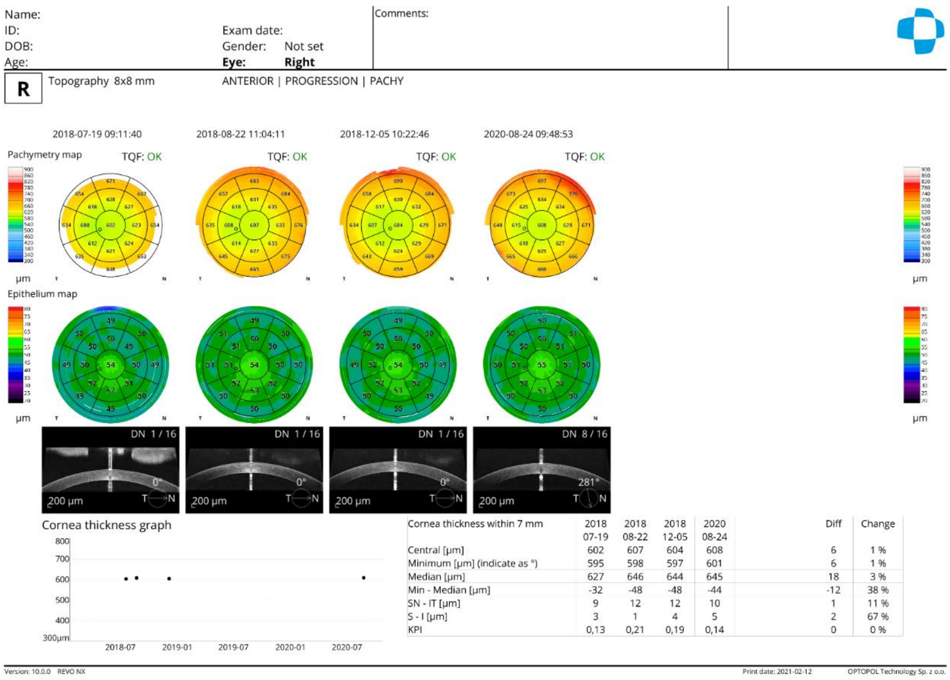


Figure 181. Examination report for Topography progression, tomograms view



Cornea thickness within 7 mm	2018 07-19	2018 08-22	2018 12-05	2020 08-24	Diff	Change
Central [µm]	602	607	604	608	6	1 %
Minimum [µm] (indicate as °)	595	598	597	601	6	1 %
Median [µm]	627	646	644	645	18	3 %
Min - Median [µm]	-32	-48	-48	-44	-12	38 %
SN - IT [µm]	9	12	12	10	1	11 %
S - I [µm]	3	1	4	5	2	67 %
KPI	0,13	0,21	0,19	0,14	0	0 %

Figure 182. Examination report for Topography progression pachymetry view

13.2 Fundus examination reports

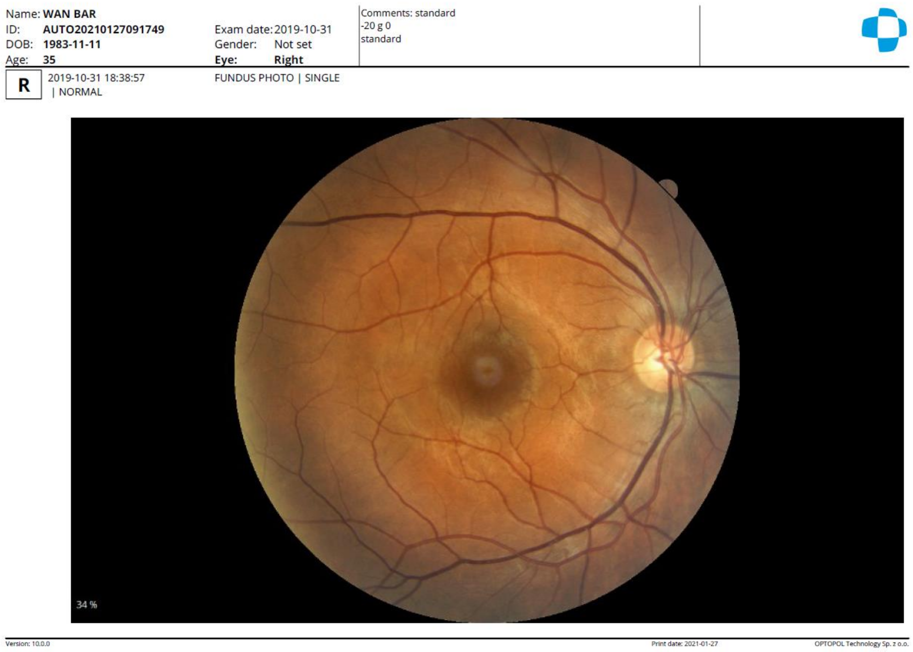


Figure 183. Examination report for Fundus single view

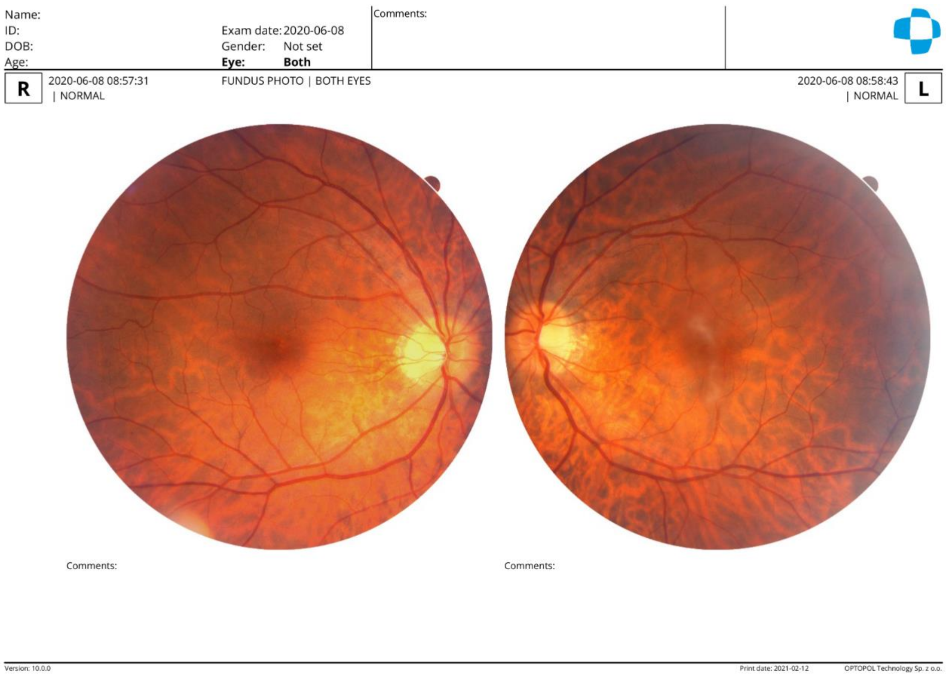


Figure 184. Examination report for Fundus both view

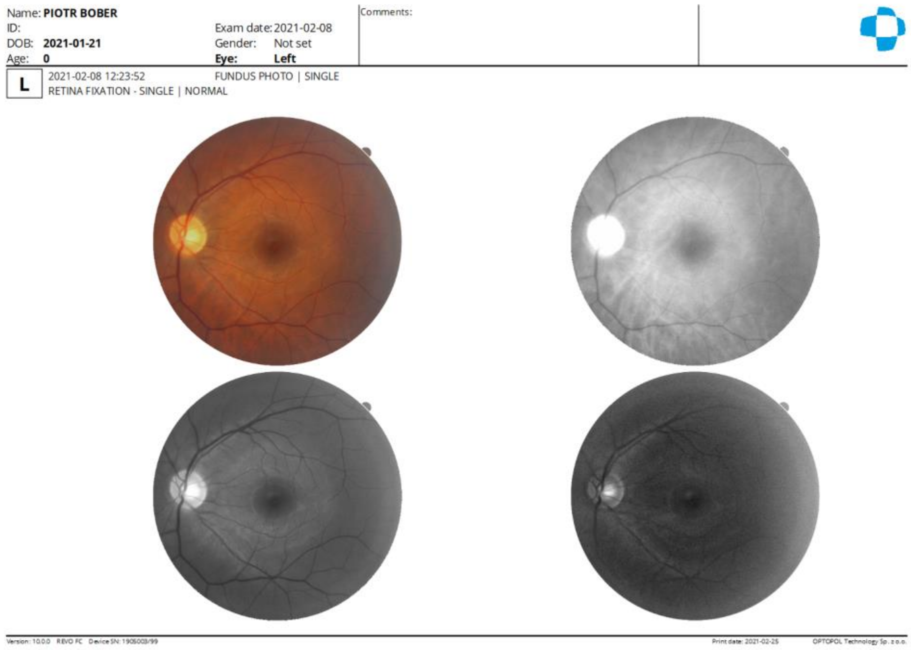


Figure 185. Examination report for Fundus single view x4

Figure 186. Examination report for Fundus comparison view

13.3 **Angiography examination reports**

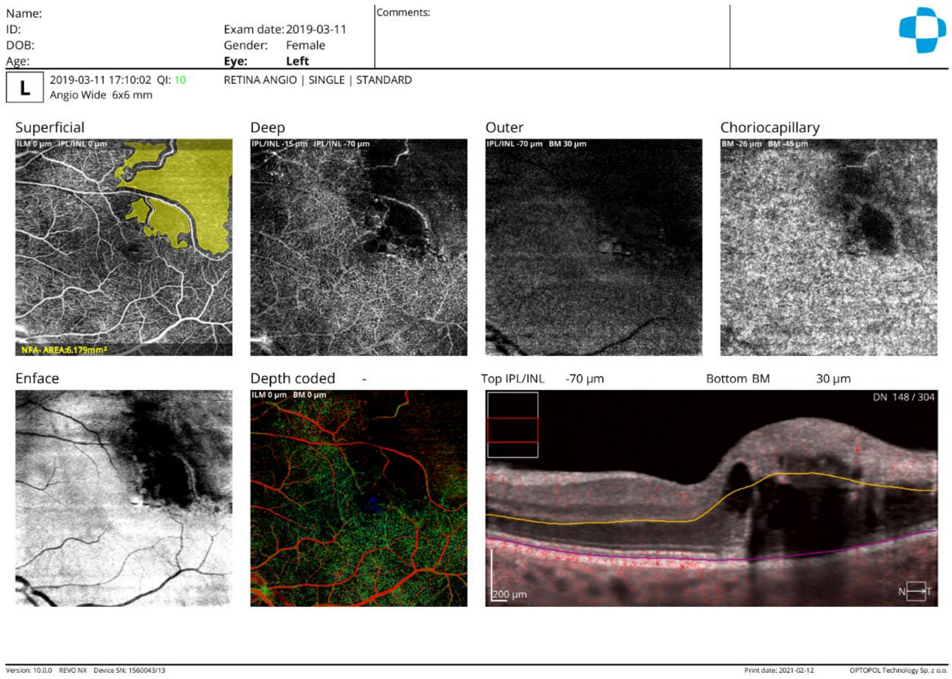


Figure 187. Examination report for Angiography standard single view

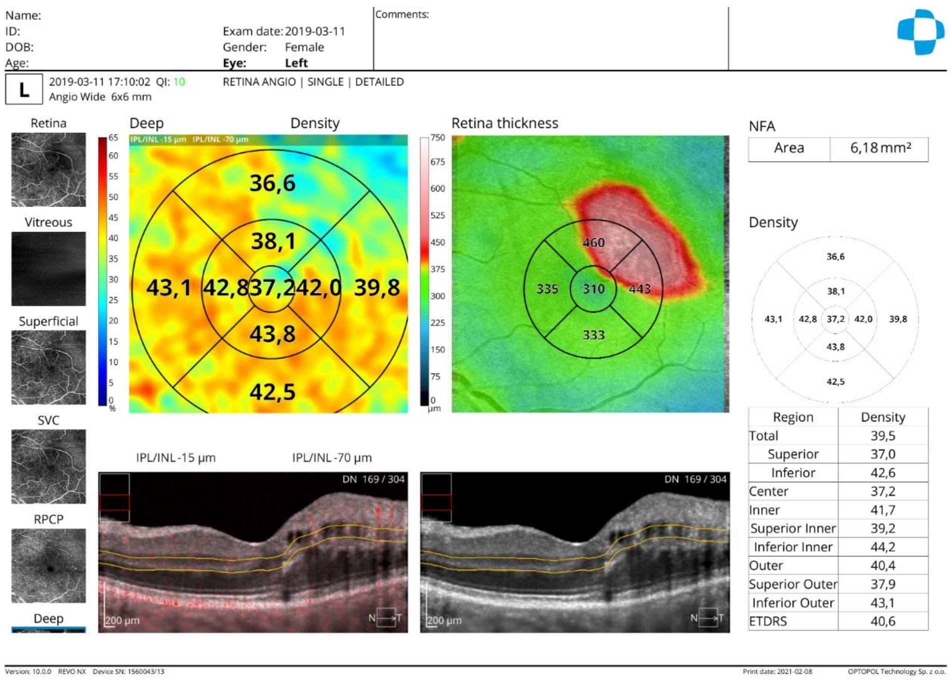


Figure 188. Examination report for Angiography detailed single view

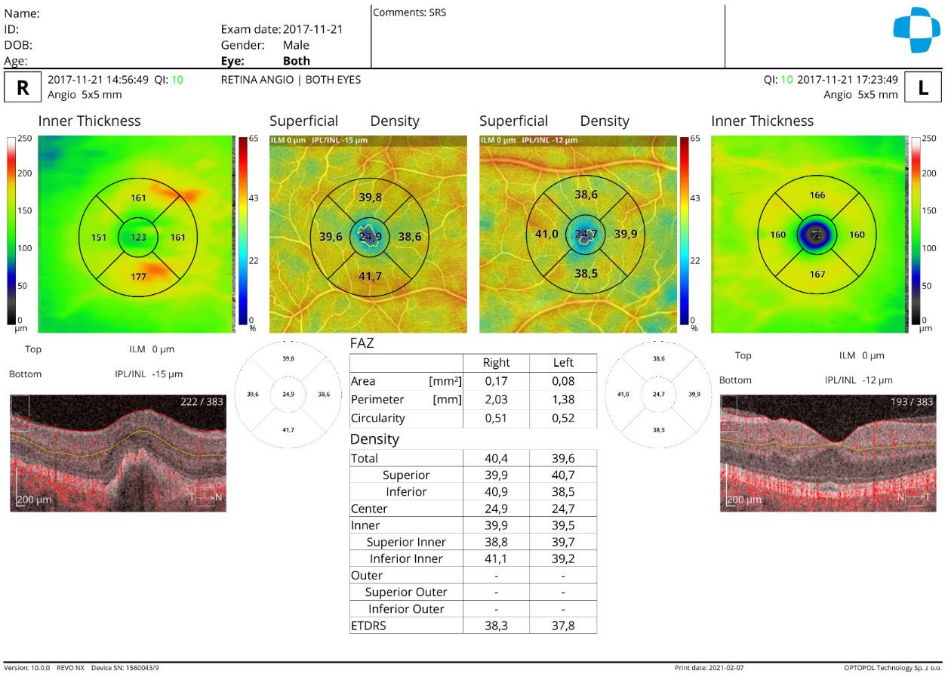


Figure 189. Examination report for Angiography both view

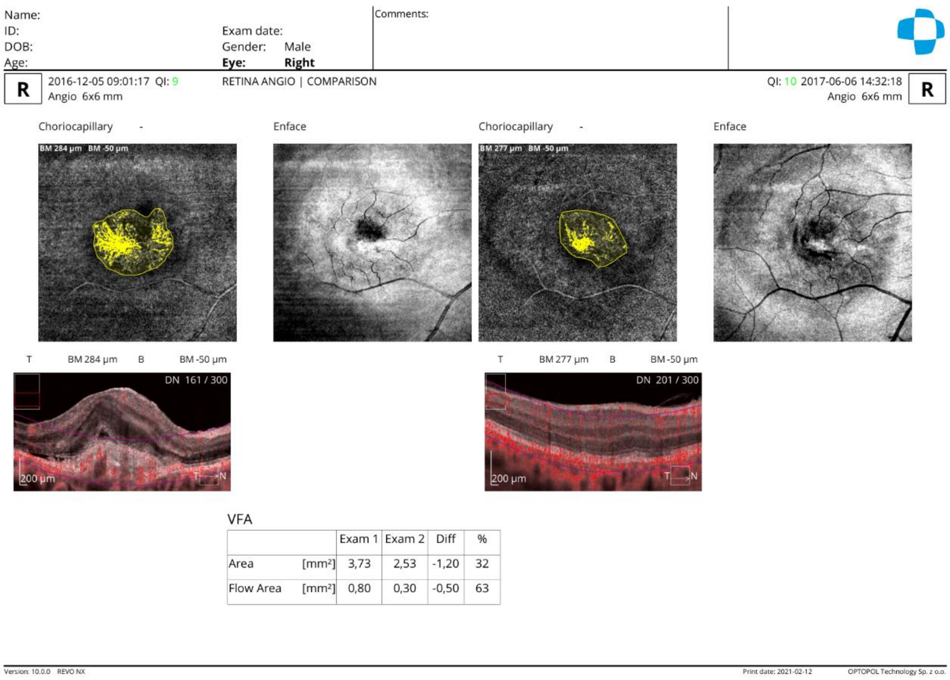


Figure 190. Examination report for Angiography comparison view

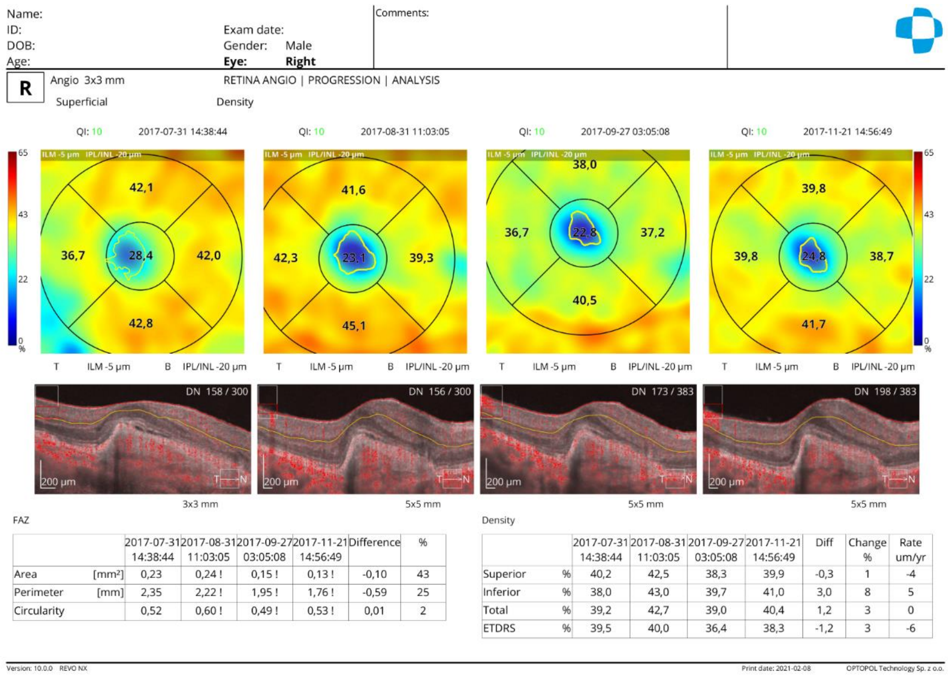


Figure 191. Examination report for Angiography progression analysis view

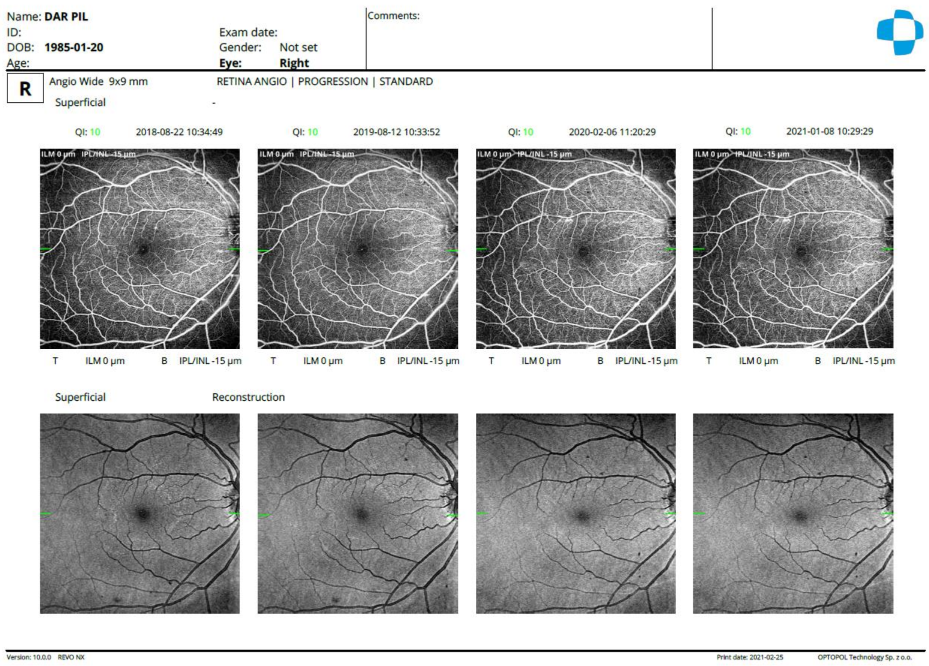


Figure 192. Examination report for Angiography progression standard view

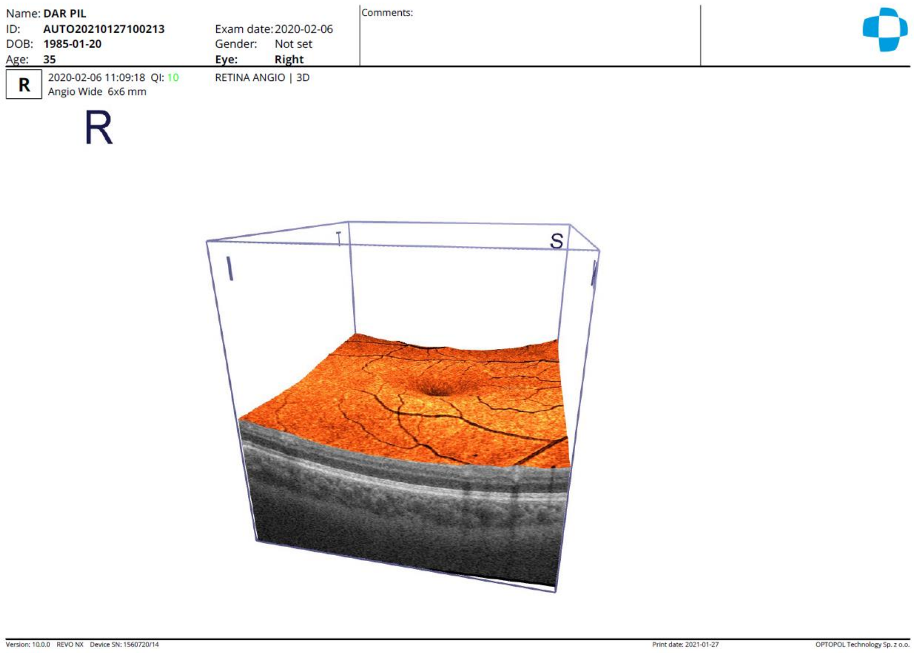


Figure 193. Examination report for Angiography 3D view

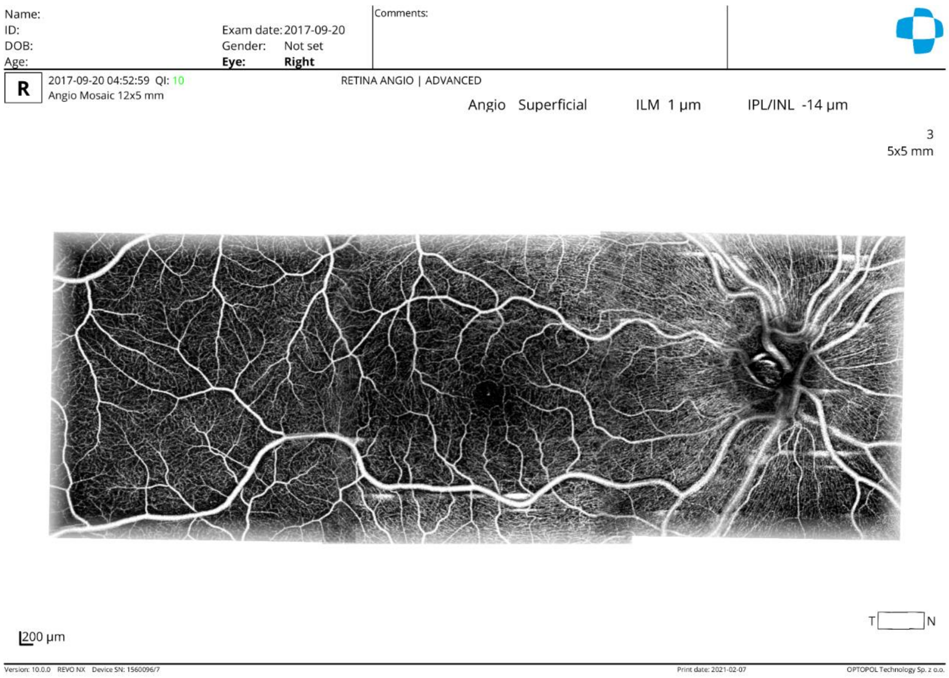


Figure 194. Examination report for Angiography advanced view

13.4 Disc OCT-A examination reports

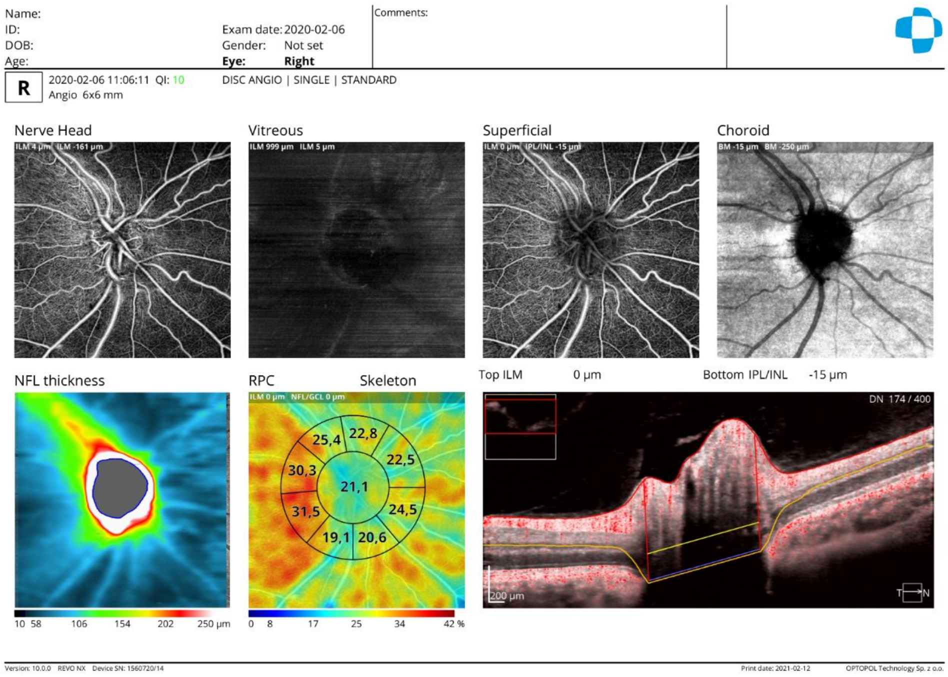


Figure 195. Examination report for Disc OCT-A standard single view

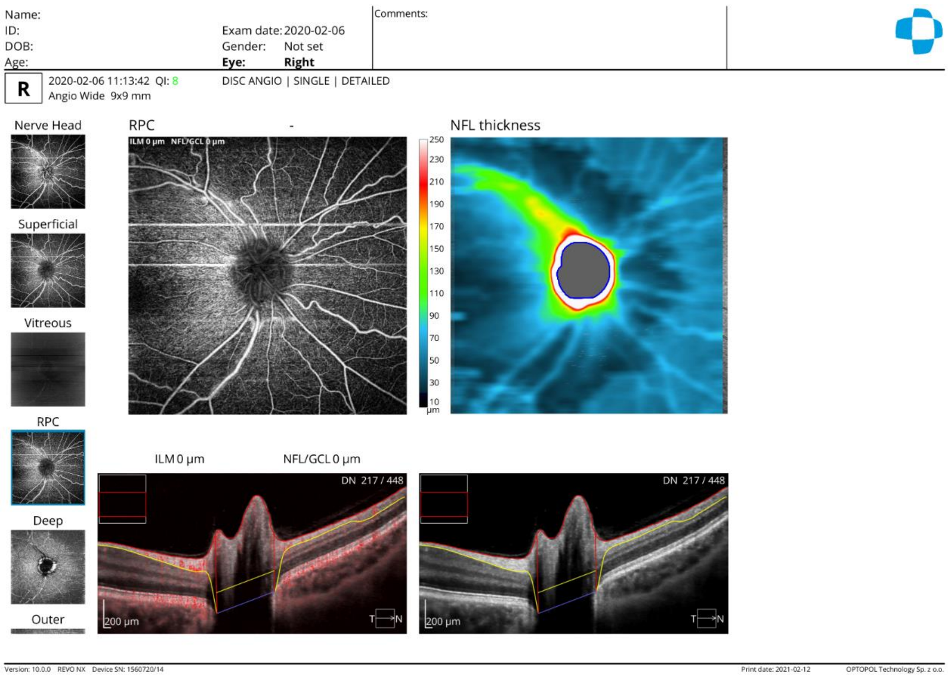


Figure 196. Examination report for Disc OCT-A detailed single view

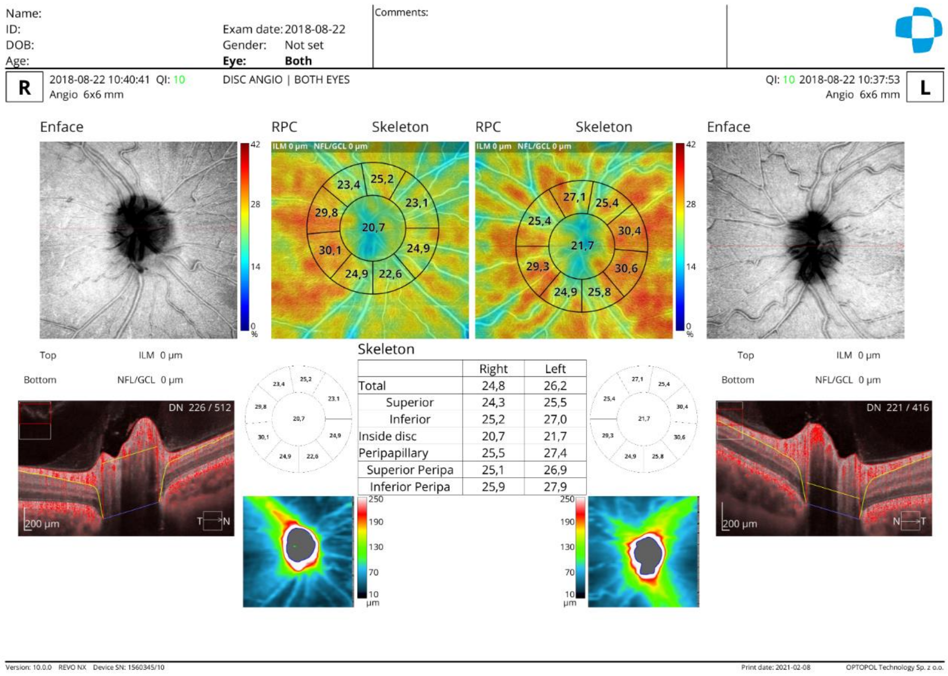


Figure 197. Examination report for Disc OCT-A both view

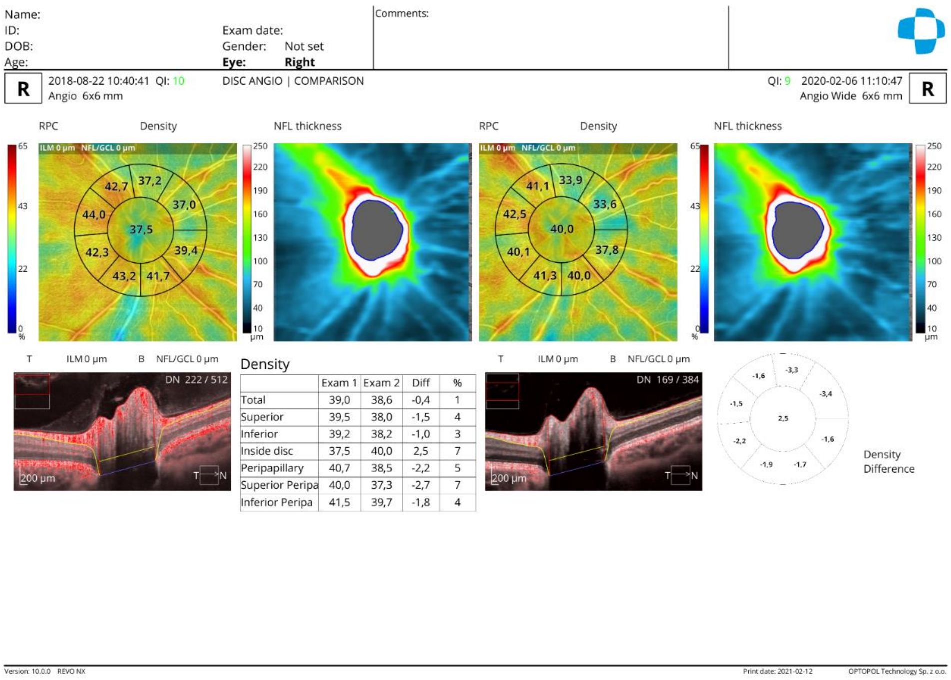
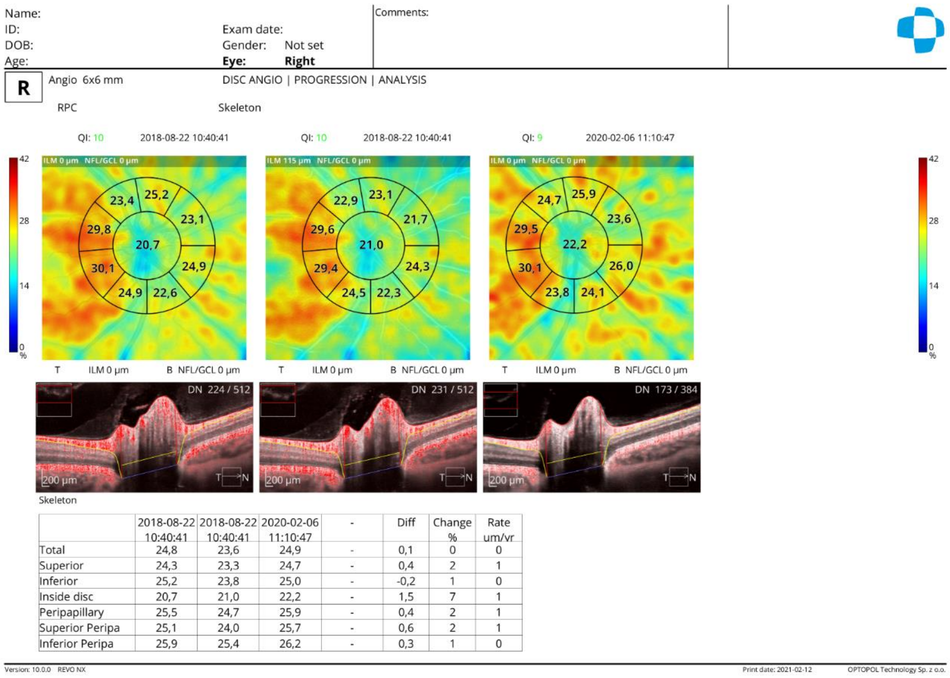


Figure 198. Examination report for Disc OCT-A comparison view



	2018-08-22 10:40:41	2018-08-22 10:40:41	2020-02-06 11:10:47	-	Diff	Change %	Rate um/yr
Total	24,8	23,6	24,9	-	0,1	0	0
Superior	24,3	23,3	24,7	-	0,4	2	1
Inferior	25,2	23,8	25,0	-	-0,2	1	0
Inside disc	20,7	21,0	22,2	-	1,5	7	1
Peripapillary	25,5	24,7	25,9	-	0,4	2	1
Superior Peripa	25,1	24,0	25,7	-	0,6	2	1
Inferior Peripa	25,9	25,4	26,2	-	0,3	1	0

Figure 199. Examination report for Disc OCT-A progression analysis view

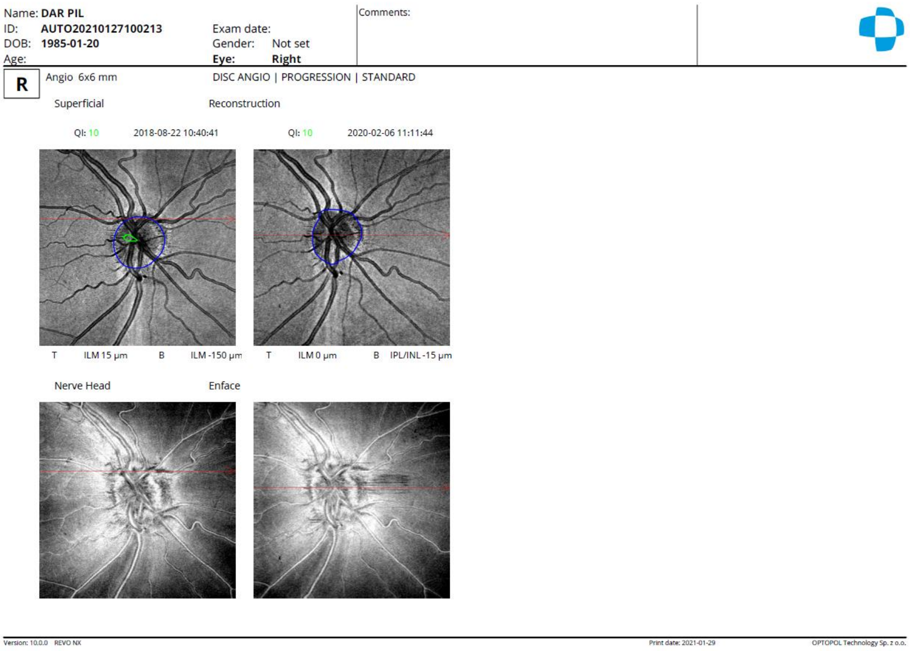


Figure 200. Examination report for Disc OCT-A progression standard view

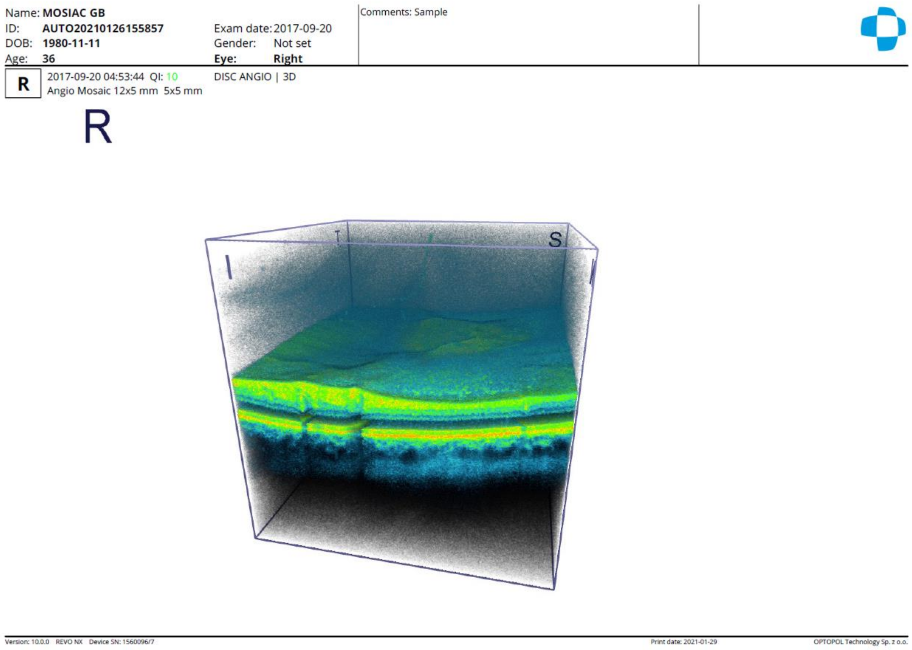
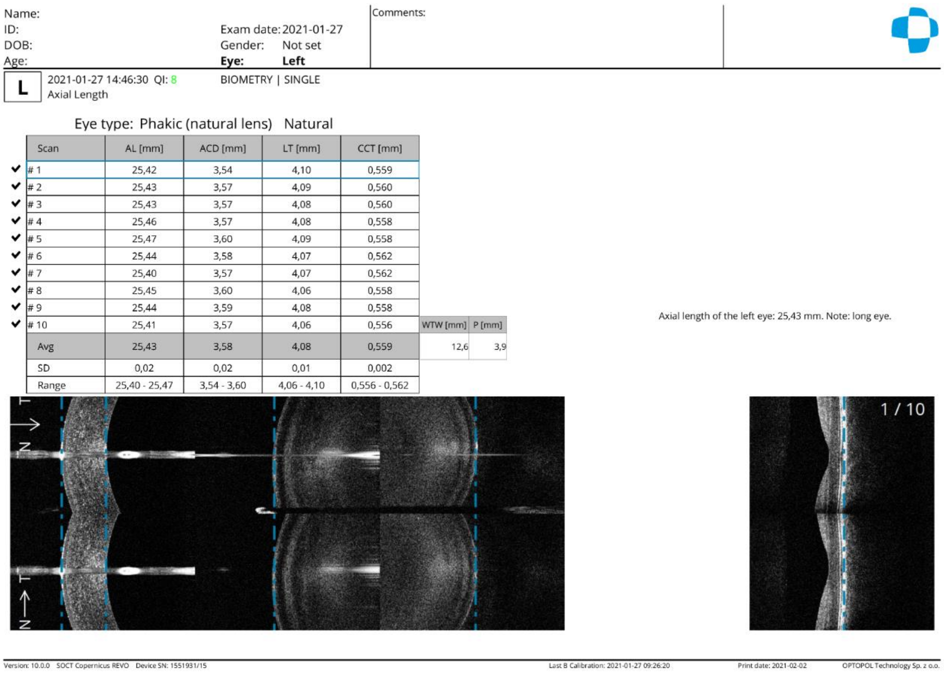


Figure 201. Examination report for Disc OCT-A 3D volume view

13.5 Biometry examination reports



Name:
ID:
DOB:
Age:

Exam date: 2021-01-27
Gender: Not set
Eye: **Left**

Comments:

L 2021-01-27 14:46:30 QI: 8
Axial Length

BIOMETRY | SINGLE

Eye type: Phakic (natural lens) Natural

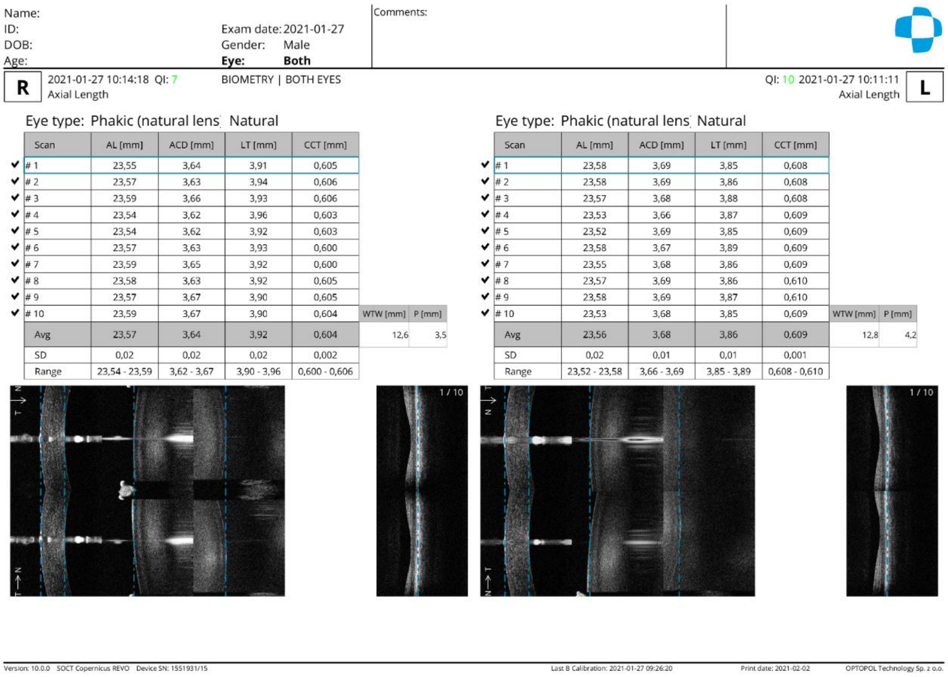
	Scan	AL [mm]	ACD [mm]	LT [mm]	CCT [mm]
✔	# 1	25,42	3,54	4,10	0,559
✔	# 2	25,43	3,57	4,09	0,560
✔	# 3	25,43	3,57	4,08	0,560
✔	# 4	25,46	3,57	4,08	0,558
✔	# 5	25,47	3,60	4,09	0,558
✔	# 6	25,44	3,58	4,07	0,562
✔	# 7	25,40	3,57	4,07	0,562
✔	# 8	25,45	3,60	4,06	0,558
✔	# 9	25,44	3,59	4,08	0,558
✔	# 10	25,41	3,57	4,06	0,556
	Avg	25,43	3,58	4,08	0,559
	SD	0,02	0,02	0,01	0,002
	Range	25,40 - 25,47	3,54 - 3,60	4,06 - 4,10	0,556 - 0,562

WTW [mm]	P [mm]
12,6	3,9

Axial length of the left eye: 25,43 mm. Note: long eye.

Version: 10.0.0 SOCT Copernicus REVO Device SN: 1551931/15 Last B Calibration: 2021-01-27 09:26:20 Print date: 2021-02-02 OPTOPOL Technology Sp. z o.o.

Figure 202. Examination report for Biometry single view



Name:
ID:
DOB:
Age:

Exam date: 2021-01-27
Gender: Male
Eye: **Both**

Comments:

R 2021-01-27 10:14:18 QI: 7
Axial Length

BIOMETRY | BOTH EYES

QI: 10 2021-01-27 10:11:11 L
Axial Length

Eye type: Phakic (natural lens Natural

	Scan	AL [mm]	ACD [mm]	LT [mm]	CCT [mm]
✔	# 1	23,55	3,64	3,91	0,605
✔	# 2	23,57	3,63	3,94	0,606
✔	# 3	23,59	3,66	3,93	0,606
✔	# 4	23,54	3,62	3,96	0,603
✔	# 5	23,54	3,62	3,92	0,603
✔	# 6	23,57	3,63	3,93	0,600
✔	# 7	23,59	3,65	3,92	0,600
✔	# 8	23,58	3,63	3,92	0,605
✔	# 9	23,57	3,67	3,90	0,605
✔	# 10	23,59	3,67	3,90	0,604
	Avg	23,57	3,64	3,92	0,604
	SD	0,02	0,02	0,02	0,002
	Range	23,54 - 23,59	3,62 - 3,67	3,90 - 3,96	0,600 - 0,606

WTW [mm]	P [mm]
12,6	3,5

Eye type: Phakic (natural lens Natural

	Scan	AL [mm]	ACD [mm]	LT [mm]	CCT [mm]
✔	# 1	23,58	3,69	3,85	0,608
✔	# 2	23,58	3,69	3,86	0,608
✔	# 3	23,57	3,68	3,88	0,608
✔	# 4	23,53	3,66	3,87	0,609
✔	# 5	23,52	3,69	3,85	0,609
✔	# 6	23,58	3,67	3,89	0,609
✔	# 7	23,55	3,68	3,86	0,609
✔	# 8	23,57	3,69	3,86	0,610
✔	# 9	23,58	3,69	3,87	0,610
✔	# 10	23,53	3,68	3,85	0,609
	Avg	23,56	3,68	3,86	0,609
	SD	0,02	0,01	0,01	0,001
	Range	23,52 - 23,58	3,66 - 3,69	3,85 - 3,89	0,608 - 0,610

WTW [mm]	P [mm]
12,8	4,2

Version: 10.0.0 SOCT Copernicus REVO Device SN: 1551931/15 Last B Calibration: 2021-01-27 09:26:20 Print date: 2021-02-02 OPTOPOL Technology Sp. z o.o.

Figure 203. Examination report for Biometry both view

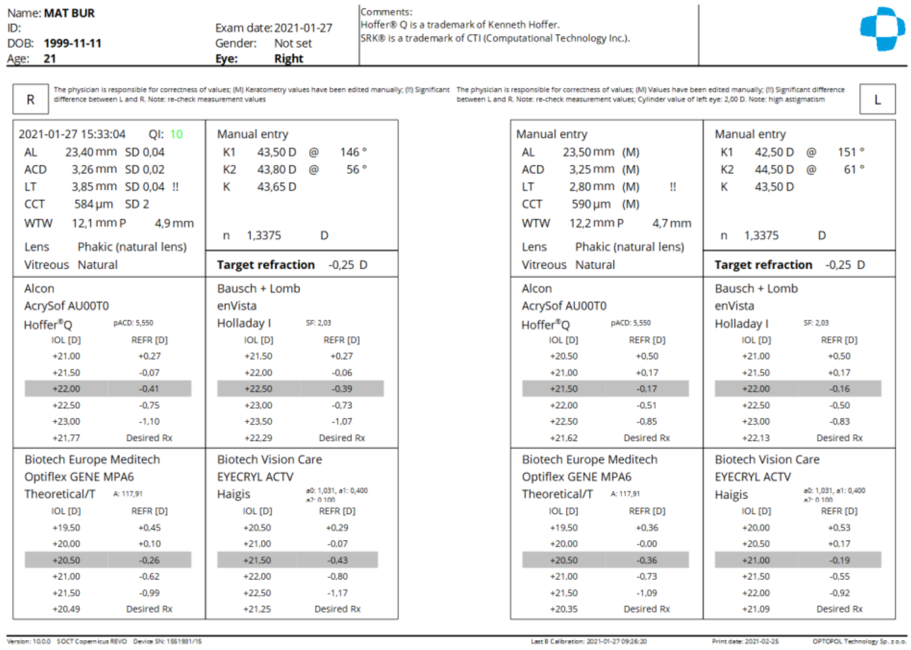


Figure 204. Examination report for IOL Calculation

13.6 Multi B-scan report

Multi B-scan procedure allows to print 4 tomograms on one printout. Press v on the [Print] button and select Multi B-scan from menu. System places 4 tomograms on printout. Tomograms can be automatically selected by system or selected by users.

New Multi B-scan acceptance window allows to verify, save, output and print Multi B-scan reports. The Multi B-scan acceptance window appears after selecting the Multi B-scan from the menu.

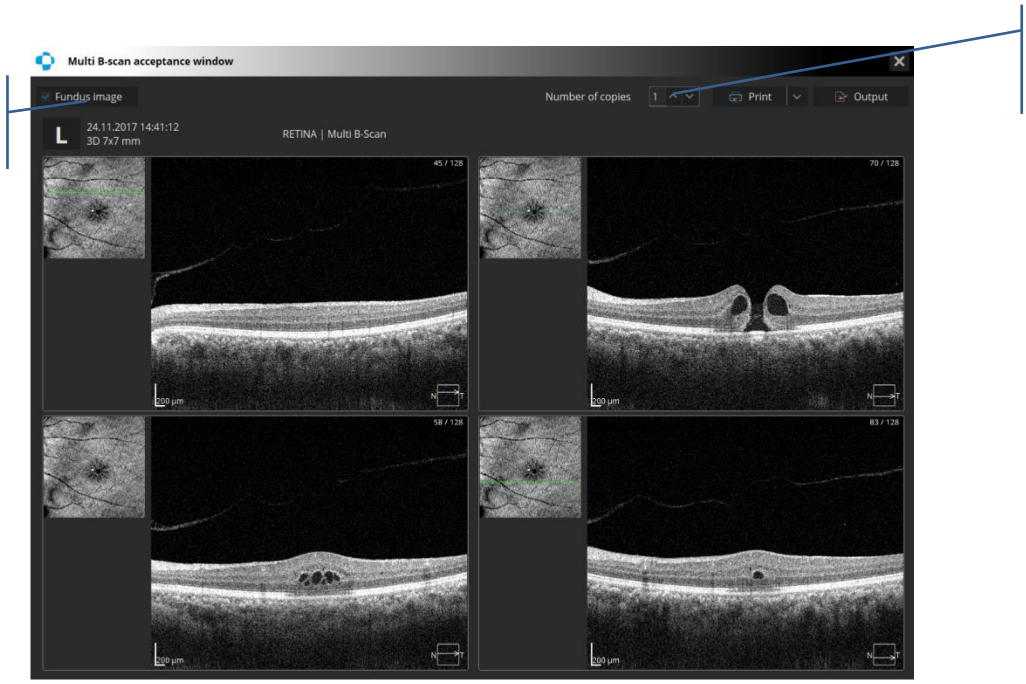


Figure 205. Multi B-scan acceptance window.

13.6.1 *Manually select tomograms*

It is possible to select tomograms individually to the Multi B-scan report. To select desired tomogram to Multi B-scan printout press Right Click and select ‘Add to printout’ from menu or hold [ctrl] button and Left-click anywhere in a printout preview. On the tomogram in the right-top corner the letter P will appear. When you select more than 4 tomograms last selected tomogram replaces the first selected. Press P letter on the tomogram to unselect tomogram from the Multi B-scan printout.

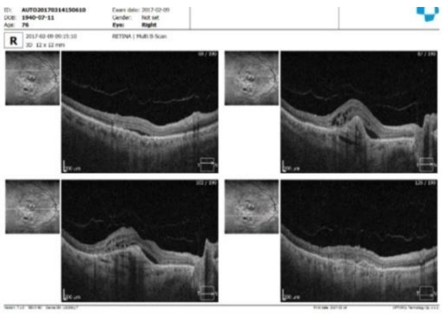


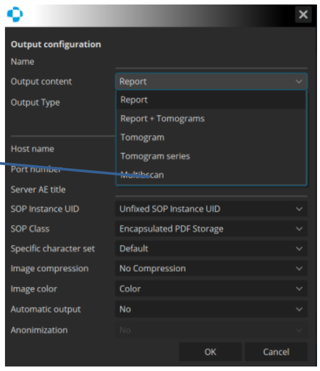
Figure 206. Multi B-scan report

13.6.2*Multi B-scan report for Both and Comparison view.*

Figure 207. Multi B-scan report for Both Eyes and Comparison view

The Multi B-scan report output settings is available in the SETUP/Preference/Output settings window.

Multi b scan output content



13.7 **Single tomogram report**

In order to print one tomogram on the whole page. Go to full screen view (double click on the tomogram window) and press Print button.

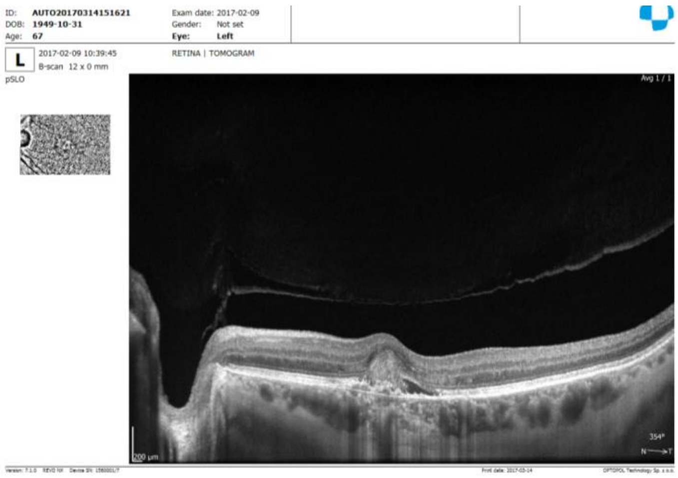
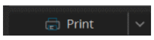


Figure 208. Single tomogram printout

13.8 **Select desired printer**

It is possible to select desired printer before printing. Press “v” on the  button and select [Select printer and Print] option from the list. Choose desired printer and press OK button.

14 OUTPUT

Output function allows to save examination results. When the output set is not created, system saves report to the file. When set is created, output window appears after pressing. User can select desired set(s) and then press [OK]. When the set is marked then output examination data are displayed on the right. If the option „When printing" is selected the system outputs data in the moment when user presses [Print] button.

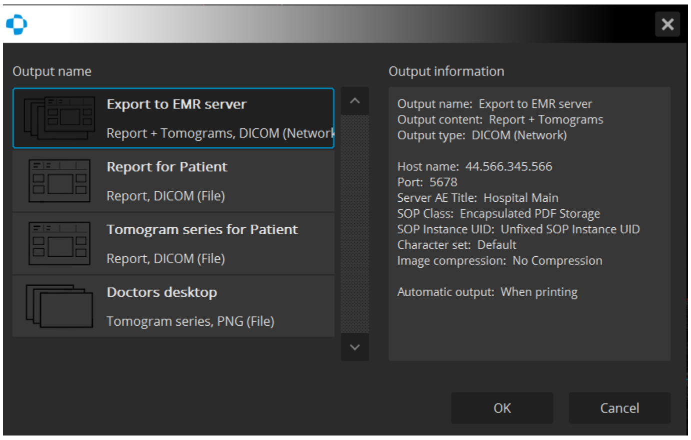


Figure 209. Output screen

User can define the output sets. In the set it is possible to specify 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 22 Setup Window.

15 SELECTING FUNDUS PHOTO

Fundus images captured by another device such as SLO or retinal camera, can be imported and shown instead of fundus reconstruction images. Retinal image can be added to the posterior scans.

Allowed image formats are .png, .tiff, .jpeg, .gif, .bmp and .jpg. When a retinal image is imported image is added to the visit as separate exam or can be displayed for reference image instead of fundus reconstruction.

The right-click context menu is available in the following views:

- Retina 3D Single
- Retina Raster Single
- Retina B-scan Single
- Retina Cross Single
- Retina Radial Single
- Retina Angio Single
- Disc Radial Single
- Disc Raster Single
- Disc Angio Single
- Central 3D Single
- Central Raster Single
- Central B-Scan Single

15.1 Adding fundus photo to the examination.

1 Right-click on the fundus reconstruction image and select [Import Fundus photo...] from the context menu.

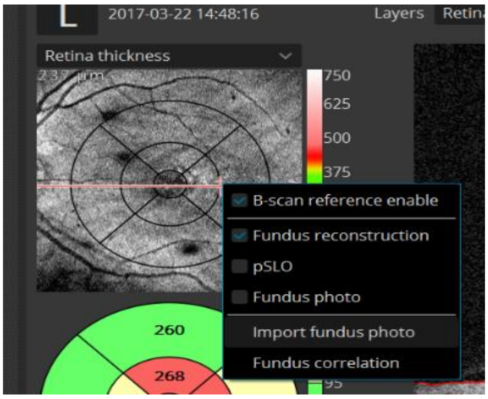


Figure 210 Context Menu

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 smaller or larger. See below.

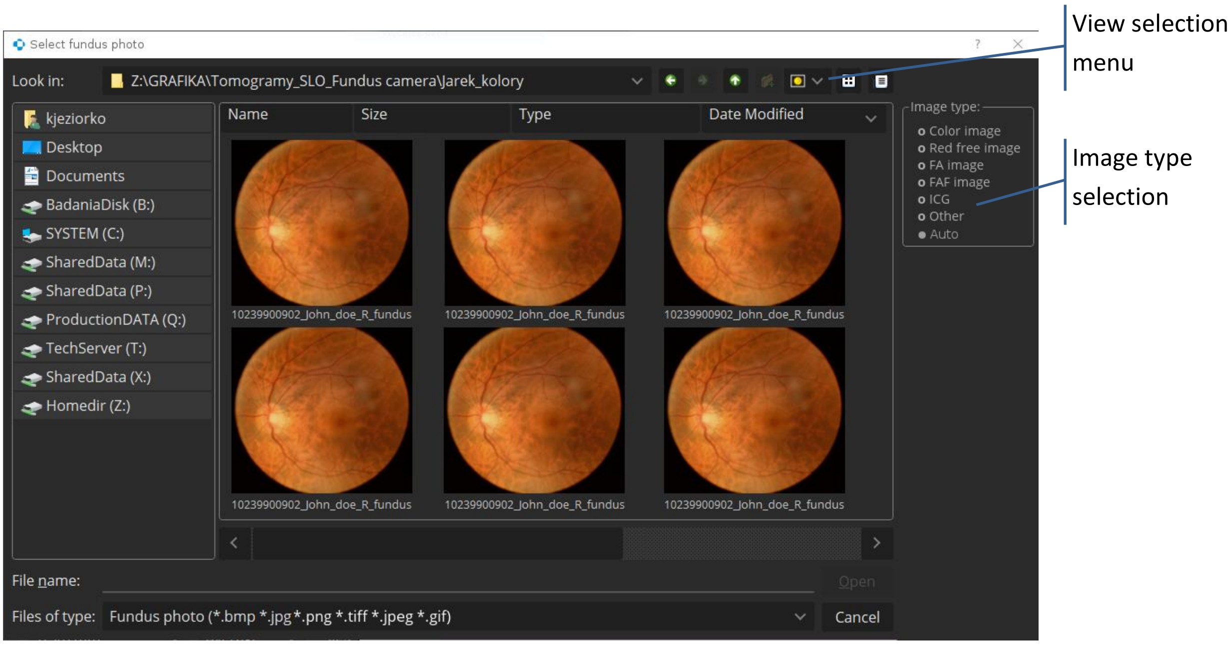


Figure 211 Fundus Import Selection

3 The user can indicate the type of the fundus photo which 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 correlation algorithm.

4 Once the desired file has been selected, click [Open]. A Fundus and OCT correlation window will now open. At this point, 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.

Figure 212 Fundus Correlation Blank and Marked

4 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 discard any

changes. Registration between the imported fundus image and retinal preview may be reviewed by changing transparency over result review window (3). Clicking [OK] will save the correlation 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. as long as selected in the top left window.

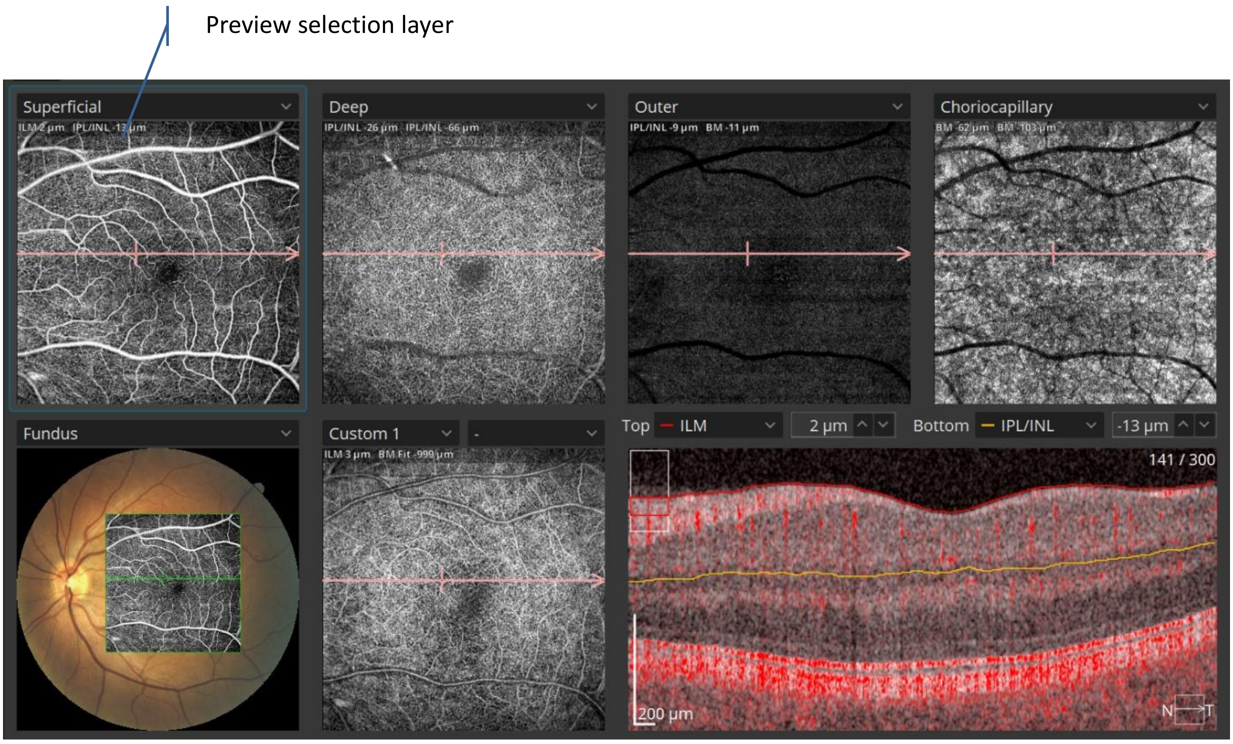


Figure 213 Vascular layer previews

15.2 **Fundus image registration correction**

Right-click on the fundus reconstruction window. From the context menu, select [Fundus correlation] option.

A ‘Fundus correlation screen’ will open. To correct the position, proceed as described in chapter 15.1 Adding fundus photo to the examination.

15.3 **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 shots per eye.
To link a photo to an exam click the right mouse button on the reconstruction image to open the context menu shown below. Choose [Link examination].

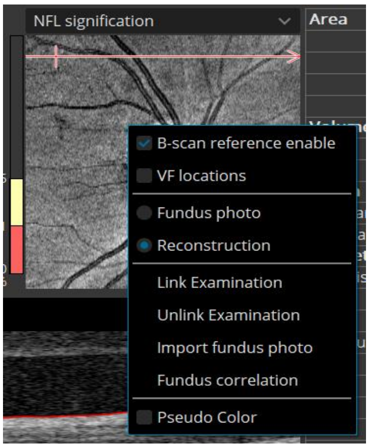


Figure 214. Context menu

A list of photos available 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 correlation window double click on a selected image.

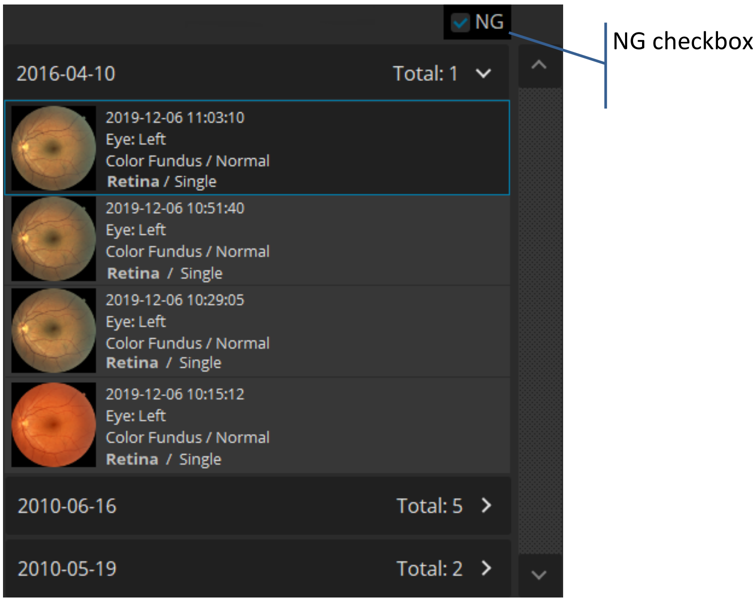


Figure 215. Fundus photo selection for linking with an examination

16 EXAMINATIONS CORRELATION

16.1 **OCT-OCT Registration**

The SOCT software automatically correlates examinations thanks to recognized shape of the blood vessels. If operator uses examinations free from eye movement artifacts for analysis, then the dense scanning provides enough data for precise overlaying which eliminates X, Y and rotation shifts between compared examinations. When above conditions are met, then this function serves as post processing tracking.

Exams with artefact can be marked by operator as not correct – NG examination status appears on the scan. Exams with NG status are not chosen automatically to any analysis (e.g. comparison, progression, etc.).

16.1.1 *Automatic correlation*

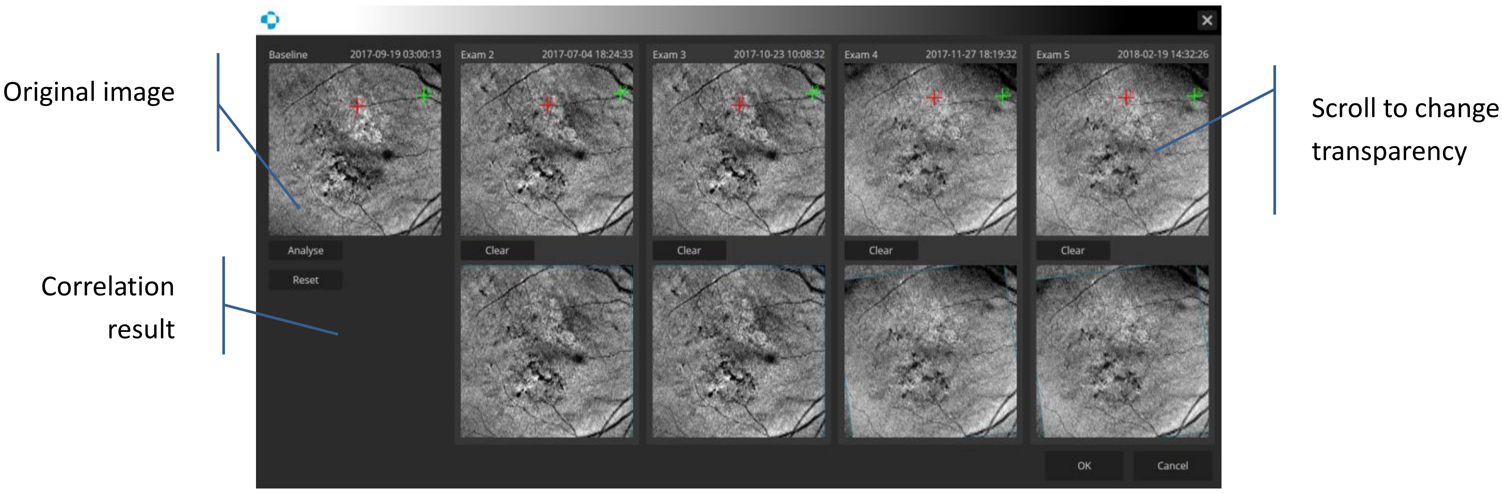


Figure 216. The result of OCT correlation – registration

System displays correlation status (A - Automatically correlated, M - manual correlated,  - Manual registration required). If automatic correlation is not possible, the system displays status Correlation failed. To verify automatic correlation or to correlate exams manually Press [Correlation] button, results are displayed on a pop-up screen, as shown above screen.

In this screen, images in top row are the original fundus reconstruction images. The bottom images are result images. The reconstruction images from each examination that has been registered are overlaid on the baseline exam.

Registration between the exams and baseline can be verified. Place the mouse cursor over one of the result images and scroll the mouse wheel to change the transparency.

16.1.2 *Manual registration*

If examinations have not been correlated automatically, the user can correlate them manually. Place each point markers on any characteristic points of 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 baseline image and compared examination image by using the mouse click.

Use the mouse scroll as needed, to change the transparency to see more of Exam Image or Baseline Image. By moving the scroll back and forth, you can see if blood vessels or other features from one image align with the identical features in the other image.

To return the registration to the original setting, press the [Reset] button.

If you are not satisfied with the positioning of the points, to delete selected point right Click over desired marker. To delete all markers, press [Clear] and then make new point selections.

It is possible to correct marker position. Press and hold the left mouse button and drag the point to desired position. Corresponding marker/s on other images highlight during dragging.

To call automatic correlation press [Analyze].

To see the final registered image, change the transparency slider over to result object. When you are satisfied with the resulting overlay, select [OK]. To reset the values to the original registration, click [Cancel].

16.2 **Fundus Correletion**

The SOCT software can automatically correlate fundus photographs with OCT examinations by recognizing patterns in the shape of vessels. To open the Fundus and OCT Correlation window click the right mouse button on a reconstruction image or a fundus photo and choose *Fundus correlation* from the drop-down menu.

16.2.1 *Automatic correlation*

To perform automatic correlation, choose the type of the image in the *Image type section* and click [Analyze]. The result of the correlation will be shown in the correlation preview. If automatic correlation is not possible the system displays the  symbol meaning that manual correlation is required. If the Image type is set to Auto and the result of the correlation 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 correlation is still not acceptable, the user can perform manual correlation. The procedure is described in section 16.2.2 Manual correlation.

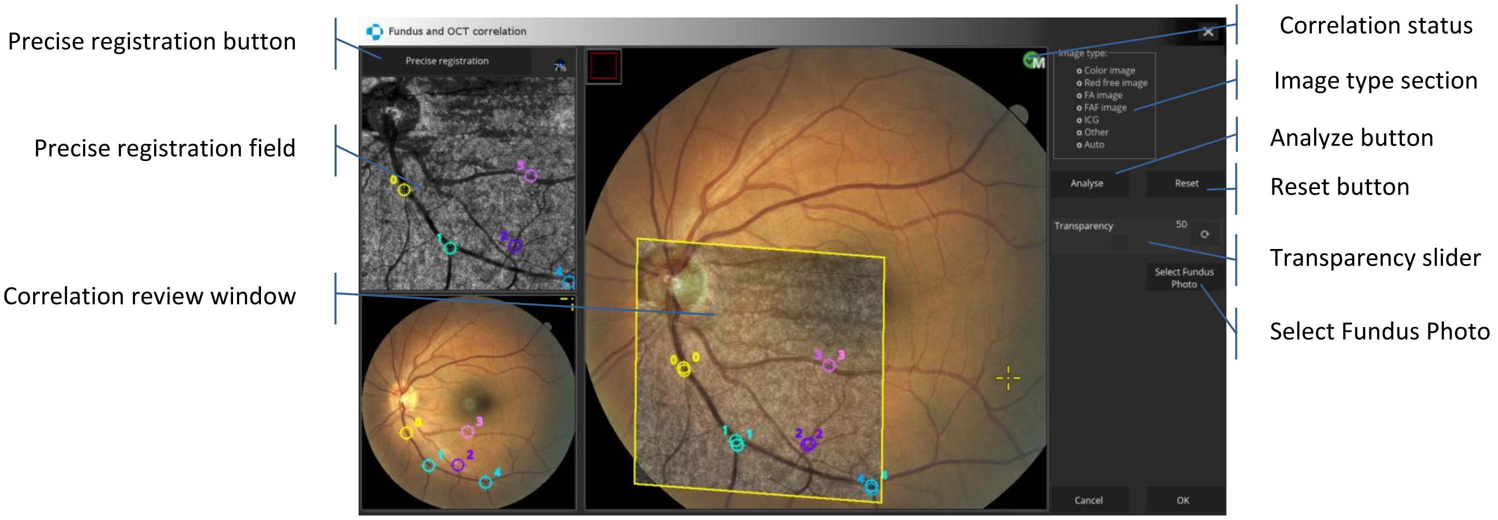


Figure 217. Fundus and OCT correlation window

Precise registration field In this field you can manually correlate the fundus photo with the OCT image. To do that place markers on any characteristic points of the retina such as blood vessels on both the fundus (1) and the OCT image. Right-click anywhere to view more options.

Correlation review window Shows the result of automatic correlation and allows the user to correct it manually. The OCT image is overlaid over the fundus image with 50% transparency. The level of transparency can be changed with the *Transparency slider*.

Correlation Status Indicates the status of automatic correlation:

 Automatic correlation

 Manual correlation (quick or precise)

 No automatic correlation

Image type Allows the user to indicate the type of the imported image to optimize the performance of the correlation algorithm.

Analyze Runs the correlation algorithm for analysis. The algorithm is optimized for the image type selected in the *Image type* field.

Reset Rejects all actions performed by the operator and restores the initial state of the correlation window.

Transparency slider Allows the user to adjust the level of transparency of the OCT image overlaid over the fundus photo from 0% to 100%. Transparency can also be adjusted by scrolling over the result preview section.

Select Fundus Photo	**Allows the user to select a fundus photo for correlation**
OK	Clicking *OK* closes the window and saves the result of the correlation with changes introduced by the user.
Cancel	Clicking Cancel closes the window without saving changes.

Additional options

For more options click your right mouse button over the *Precise registration* field or *Correlation preview* to open the following context menu:

Remove points	Removes all markers form the *Precise registration* field and *Correlation preview*
Reset zoom	Restores the original zoom
Reset all	Removes all markers and restores the original zoom
Reset brightness/contrast	Reset brightness ands contrast to default levels

16.2.2*Manual correlation*

If you are not satisfied with the result of automatic correlation, you can correct it manually. 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 correlation. Continue adding markers until good correlation is achieved. The result 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 moving the scroll back and forth, you can see if blood vessels or other features from one image align with identical features in the other image.

To return the registration to the original setting, press [Reset all] in the context menu.

If you are not satisfied with the positioning of the points, to delete a selected point right click over the desired marker. To delete all markers, choose [Clear all markers] from the context menu.

16.2.2.1 Fast manual correlation

If the user needs a quick, "on the spot" correlation result, they can manually stretch, move and rotate the OCT image over the fundus photo until a visual correlation of the structures is achieved. In order to stretch the OCT image, place the mouse cursor over any of the edges of the image. 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 stretch 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 and rotate the image.

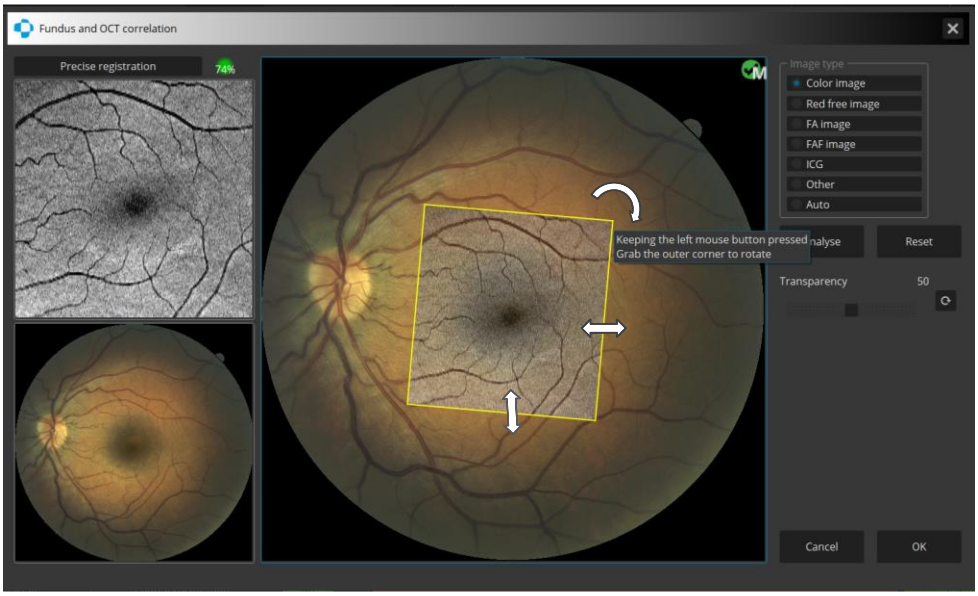


Figure 218. Correlation screen with arrows indicating the direction of the manipulation of the image

16.2.3 *Moving the overlaid OCT image*

<u>Dragging the image</u>

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.

<u>Rotating the image</u>

You can rotate the image in relation to its center. To do that 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.

16.2.4 *Closing Fundus and OCT Correlation window*

To exit the window and save correlation results click [OK]. Clicking [Cancel] rejects any changes to the images and closes the window without saving the results of the correlation.

16.3 **Extracting tomograms from a 3D exam**

The function makes it possible to display a follow-up tomogram that is tied-in location wise to the reference tomogram so that all tomograms always present the equivalent location of the patient's retina for precise comparison or tracking of disease progression. To reach the correct alignment of all tomograms, the software compensates the images for differences in scan positioning and rotation which occurred during acquisition.
Before the function can be used, examinations must be correlated automatically or manually. Correlation of examinations is explained in the chapter 16 Examinations Correlation.
An extracted tomogram is created by extracting A-scans of the follow-up tomogram on the basis of the correlation with the reference tomogram.

To display an extracted tomogram, go to Comparison or Progression tab. Make sure the examinations have been correlated. Click the arrow next to the lock button to unfold 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 causes both of them to act in sync, always presenting the same location of the patient's retina.

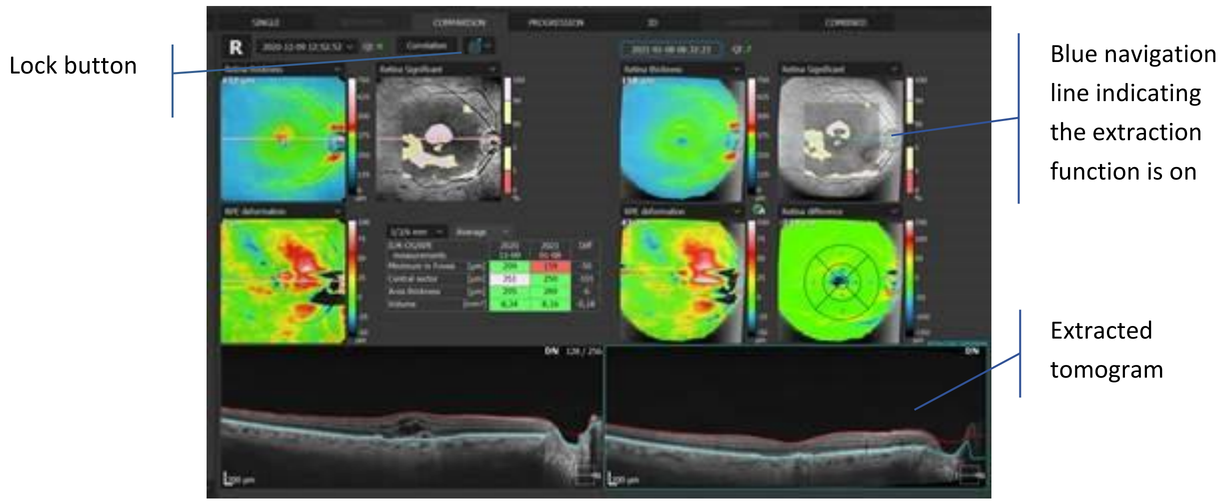
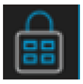


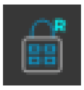
Figure 219. Comparison tab with an extracted tomogram displayed in the bottom right-hand corner

Different options in the lock button drop down menu indicate the following:

Lock is off, no correlation



Lock is on, no correlation



Extracted tomogram function is on

16.4 **FUNDUS CAMERA – RESULT REVIEW**

This functionality is available for Fundus camera photography acquisition by REVO FC or imported to the SOCT application from an external device.

16.4.1*Color fundus photo [Single] view x 1*

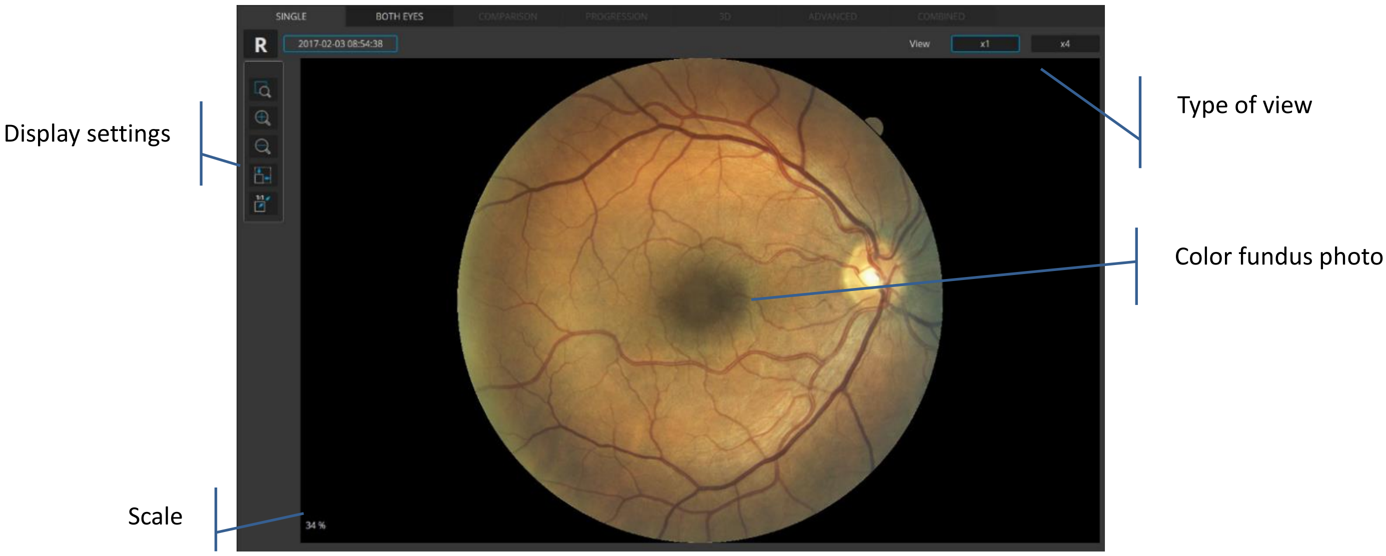


Figure 220. Single eye color fundus photo x1 view

16.4.2 *Color fundus photo [Single] view x 4*

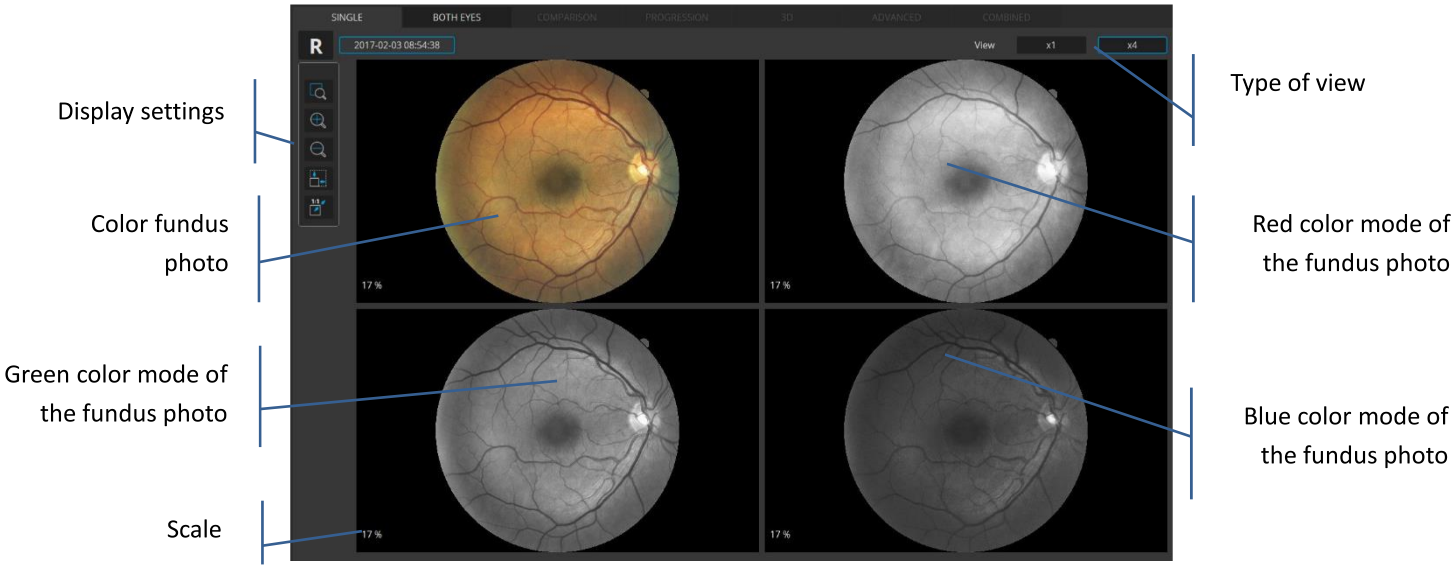


Figure 221. Single eye color fundus photo x4 view

16.4.3 *Color fundus photo Full screen view*

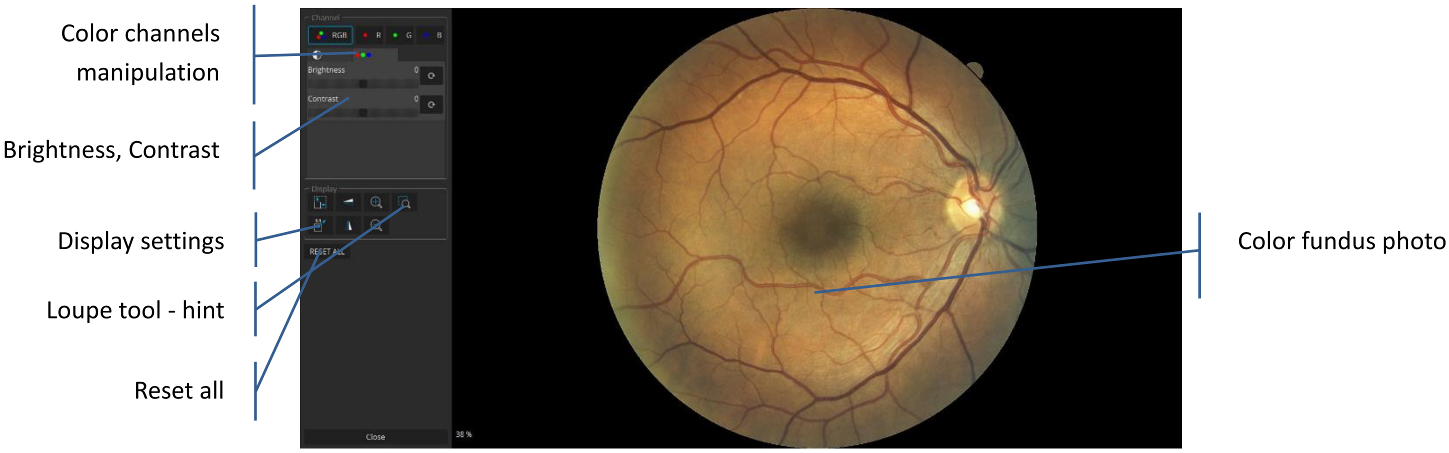


Figure 222. Single eye color fundus photo full screen view

The user can choose all channels tab (RGB) or a single channel (R, G or B).

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 3 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 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 display closes the previously chosen channel. Displaying multiple channels simultaneously is not possible. Deactivating all of the channels results in displaying the image in gray scale. 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).

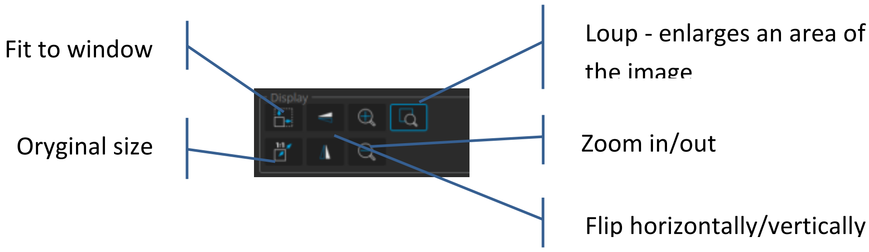


Figure 223. Display settings in single eye color fundus photo full screen view

16.4.4 *Color fundus photo [Both] view*

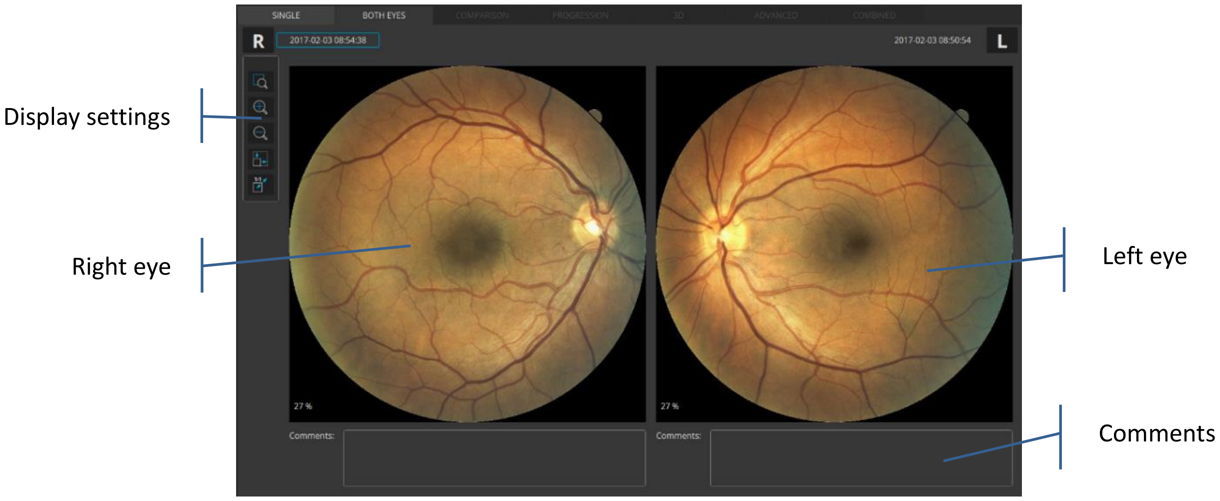


Figure 224. Both eyes color fundus photo view

16.4.5 *Color fundus photo [Comparison] view*

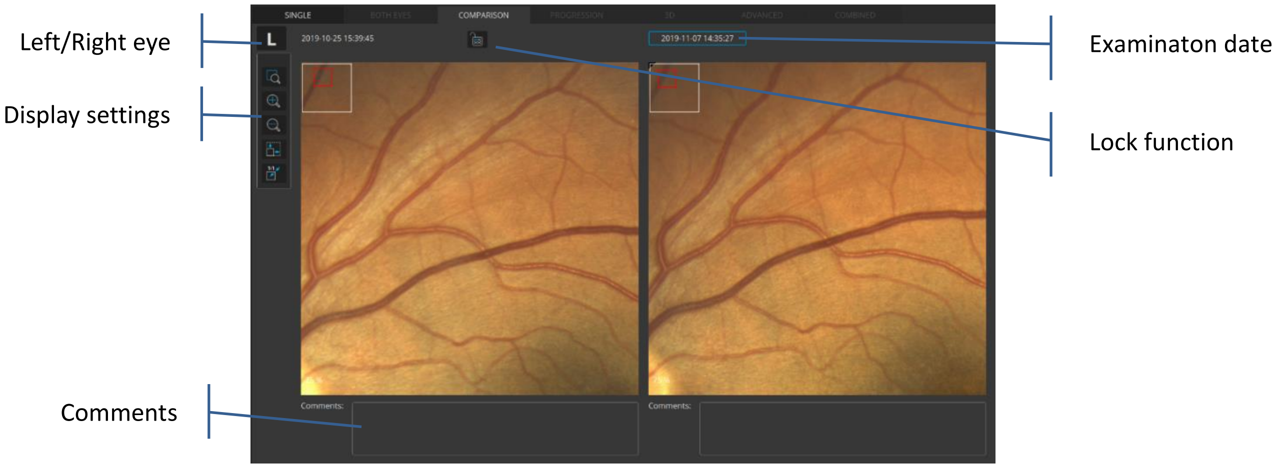


Figure 225. Comparison color fundus photo view

17 ANGIOGRAPHY OCT

17.1 RETINA OCT-A

Prepare the patient as explained in chapter 8.1 Preparation for examination.

For details on acquisition procedure consult chapter 7. EXAMINATION ACQUISITION TAB

Angio OCT module is available as an upgrade to the SOCT system.

Angio 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 Angio scan protocol create a 3D scan data set, that combines the results of repeated B-scans. The Angio mode graphically represents the results giving by OCT images that contrast areas of flow and static tissue. The Angio scan which constructs angiography OCTA data is acquired by 230 A-scans and 230 B-scans as default for REVO. In REVO nx operator can modify scanning protocol with maximum resolution 512 A-scan and 512 B-scan. The Angio scan which constructs angiography OCTA data is acquired by 320 A-scans and 320 B-scans as default for REVO FC.

17.1.1 *[Single] view – Standard*

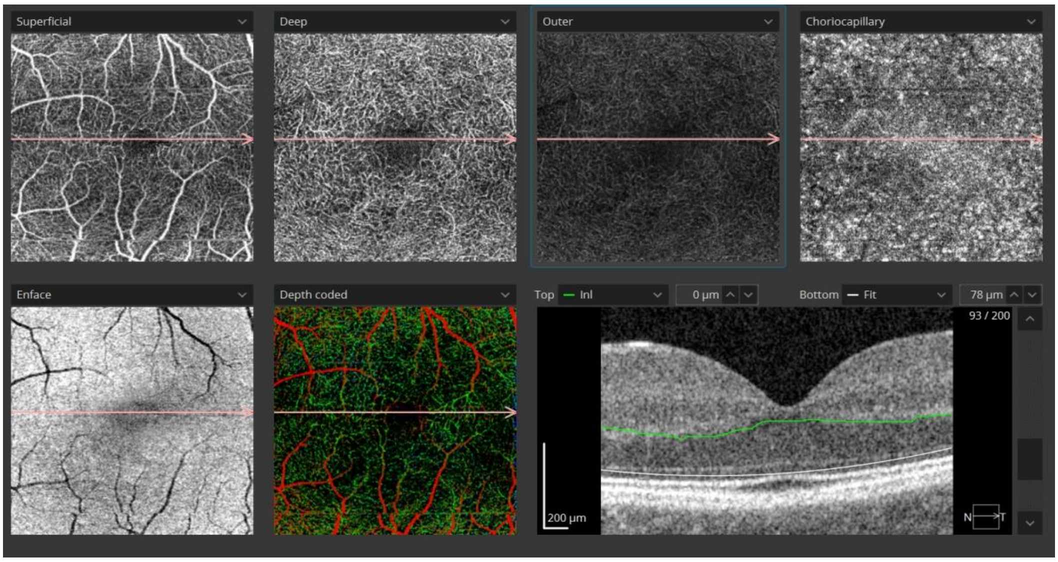


Figure 226. Single - Standard view

The Single Standard Angiography view includes:

The upper row features four angiogram windows of different predefined retina layers depths.

On the bottom left there is an OCT enface image, next is a depth coded color map, and at the bottom right there is a B-scan image. Each angiogram has red (horizontal) lines that indicate the current B-scan location. You can drag these lines to display tomogram from desired location.

It is possible to show only one retina layer in one angiogram window. You cannot show the same retina layer in two different angiogram windows.

The user can customize the layer boundaries and offsets. The Customized recognition is saved with the examination. The reanalyze function deletes, among other things, the customized data. Thanks to that the user can evaluate the customized angiograms.

It is possible to import fundus images for the enface object. Right click on the enface object and choose import fundus photo from the context menu.

17.1.2 *[Single] view - Detailed*

Detailed view allows to see large objects and quantify results.

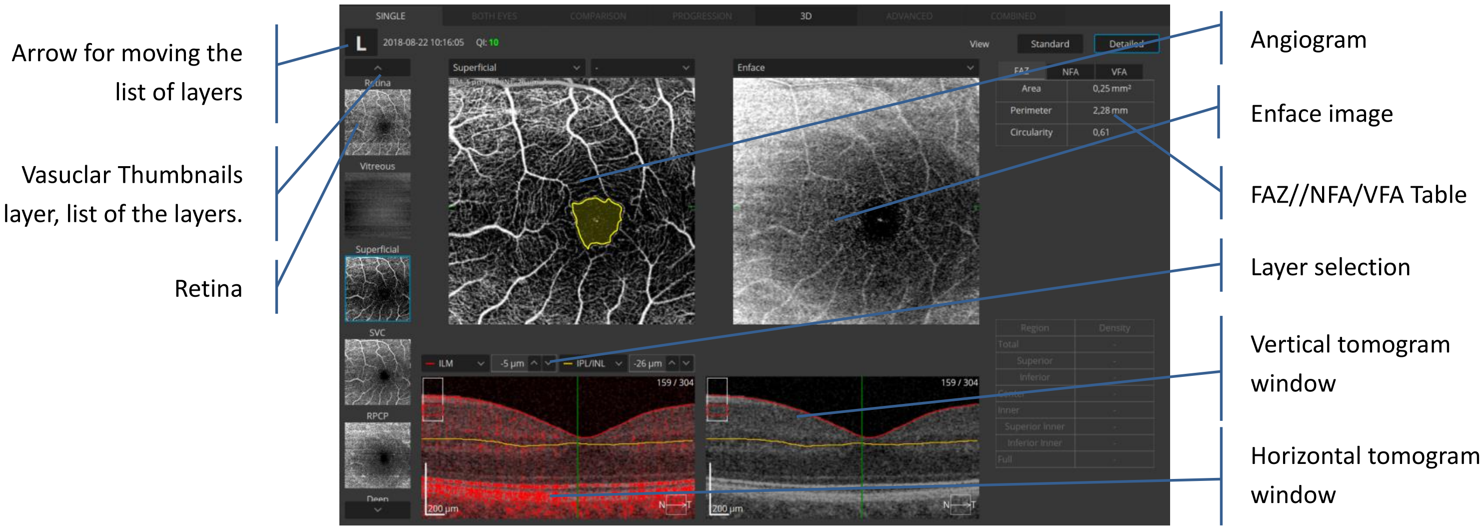


Figure 227. Single detailed Retina Angio view

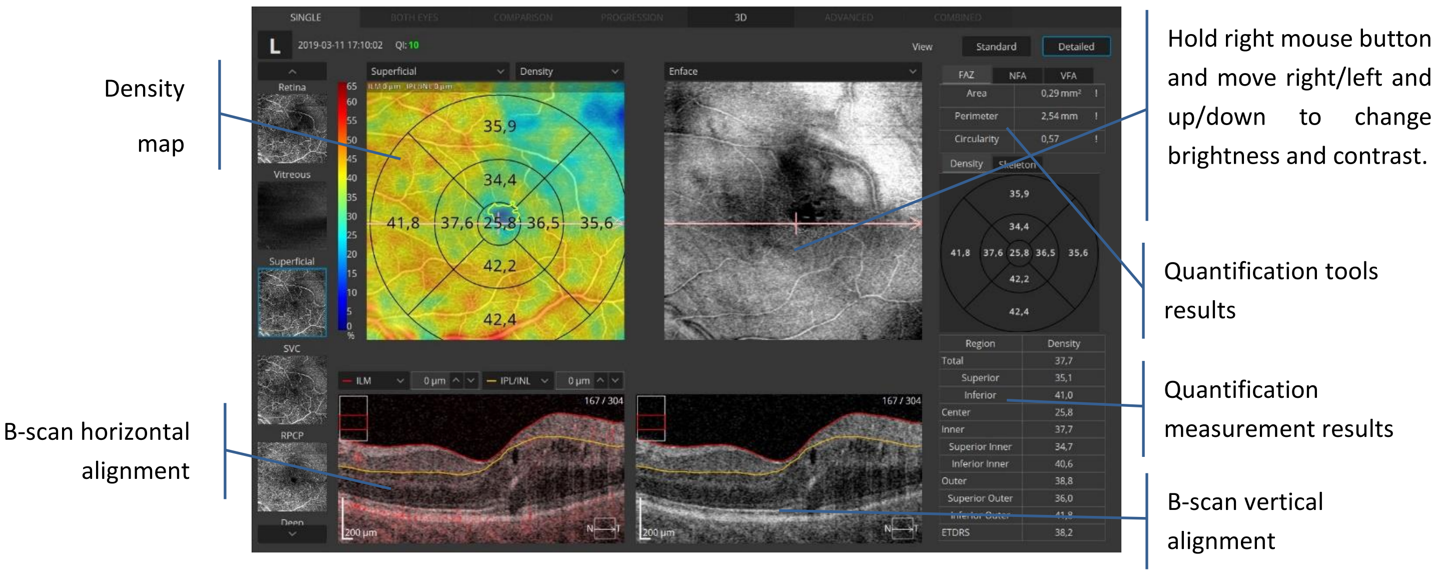


Figure 228. Single - Detail view – vertical and horizontal alignment

Thumbnails of vascular 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. You 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.

Enface image displays an image generated between the boundaries of the active angiogram window.

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. You can type in the offset over the tomogram window or grab and move it. The offset is expressed in microns from the original position of the recognized retinal layer. The 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 decorrelation mask on the B-scan. Press simultaneously the ctrl button 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.

Context menu initiated with a mouse right-click:

Angiogram context menu offers:

- Reset brightness/contrast - restore brightness/contrast default
- B-scan reference enable – enable/disable the reference B-scan on the angiogram
- Save as…/Save anonymized as… - save angiogram
- Projection removal - enable/disable the projection Artefact removal algorithm

Enface Image context menu offers:

- Reset brightness/contrast - restore brightness/contrast default
- B-scan reference enable enable/disable the reference B-scan on the angiogram
- Invert - invert the colors of the enface image
- Save as…/Save anonymized as… - save enface image

17.1.3 *Angio OCT Analysis.*

17.1.3.1 Angiogram object

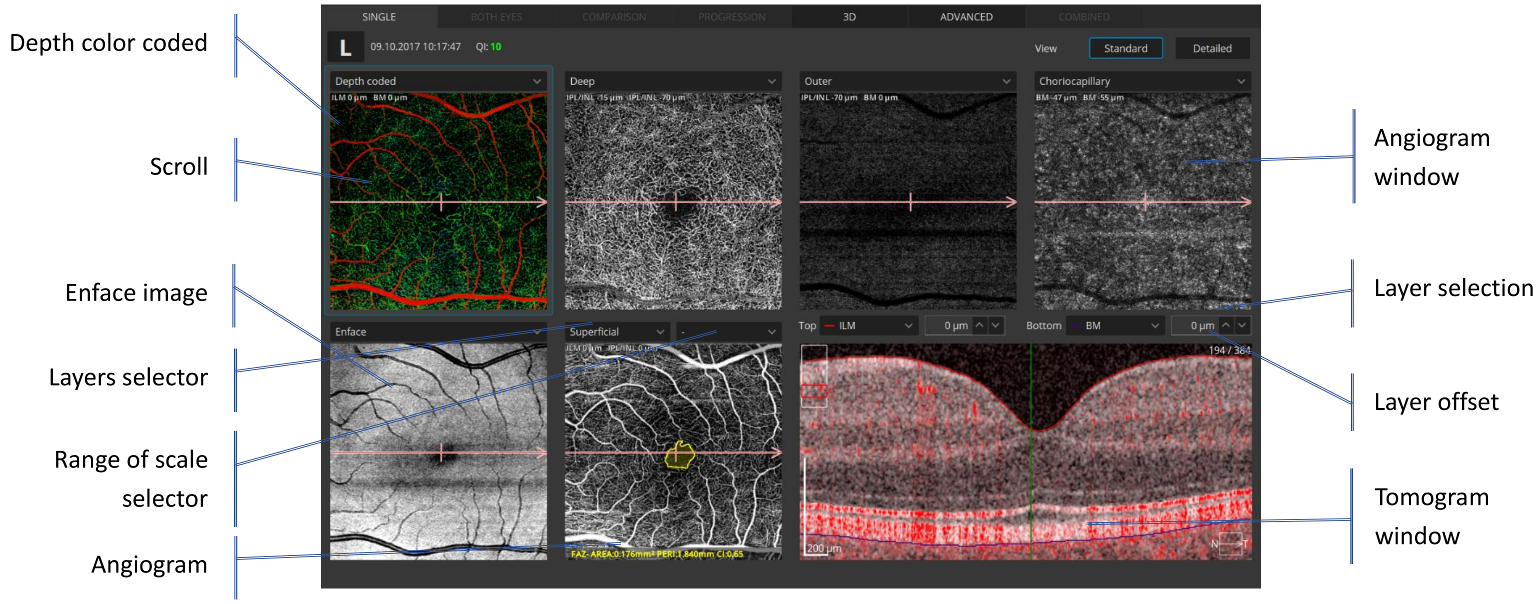


Figure 229. Single - Standard view – B-scan vertical alignment

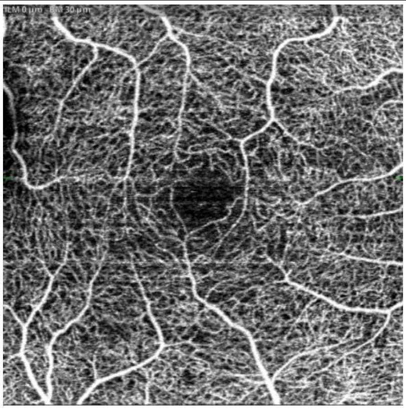
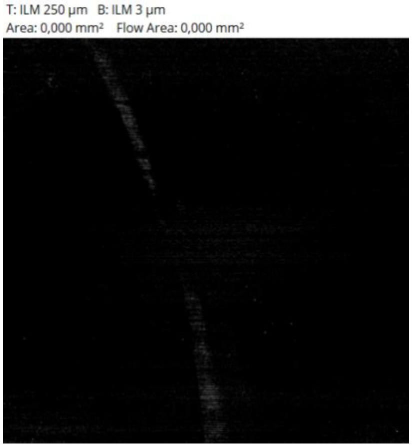
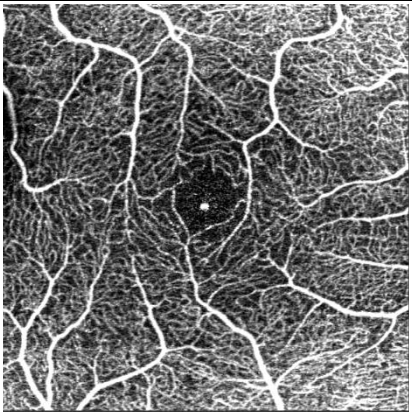
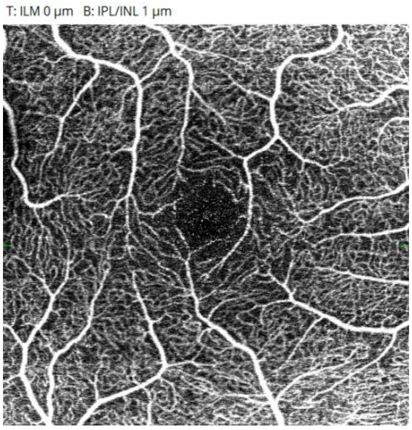
Right click on the tomogram window opens the context menu and allows to turn on/off the Angio flow on the tomogram.

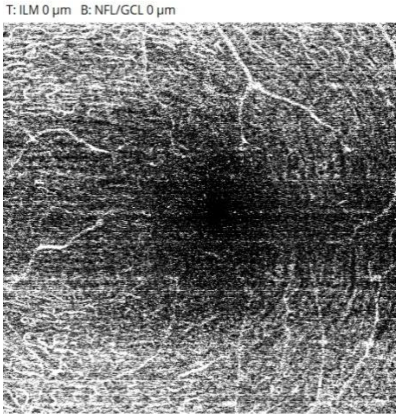
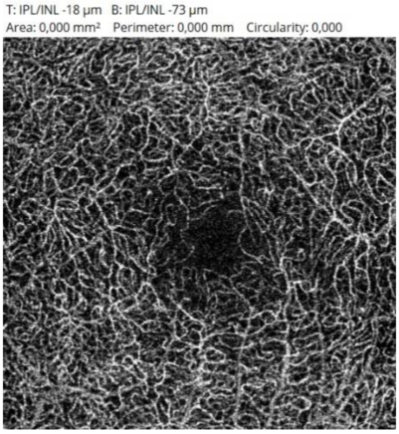
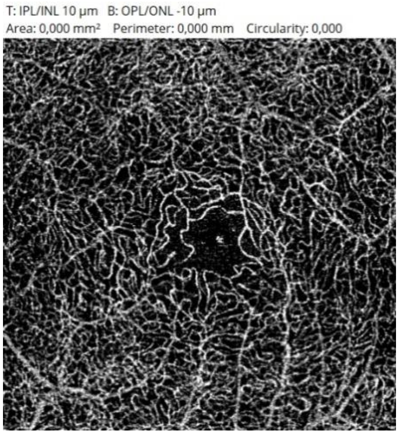
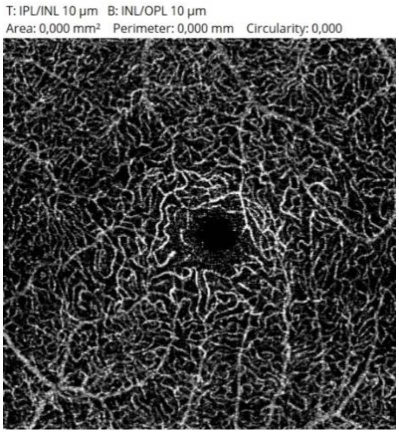
The SOCT algorithm calculates the decorrelation value for each pixel in the B-scan by comparing the OCT signal intensity variations across the B-scans in each set. Static tissue locations, without flow, exhibit little variation in OCT signal intensity over the repeated B-scans; therefore, the decorrelation values would be low.

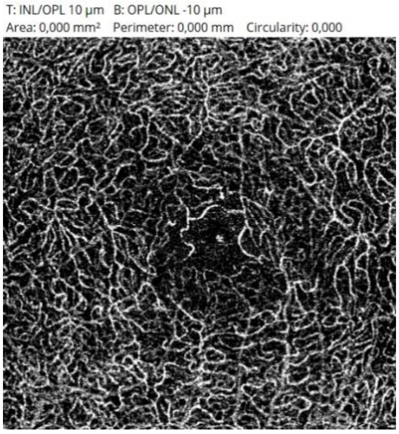
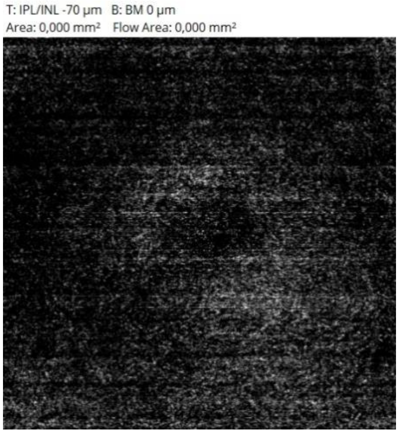
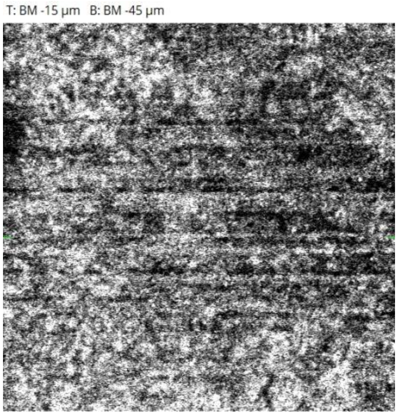
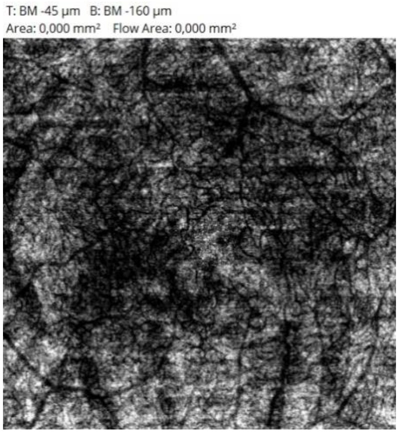
Tissue locations with flow (for example inside a flowing vessel), show large variations in OCT signal intensity over the repeated B-scans. At these pixel locations, the decorrelation values would be high, indicating the presence of flow. The Angiogram image is a graphical representation of the calculated decorrelation values, with high decorrelation values indicating flow and low decorrelation values indicating static tissue.

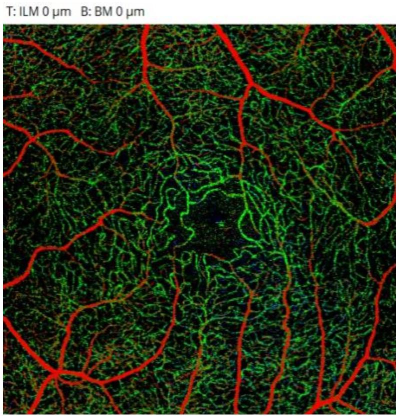
Information displayed on the angiogram object is extracted from the space limited by position of the top (selected retina layer and their offset) boundary and bottom (retina layer and their offset) boundary.

At 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 list box of available layers:

Vascular layer	Slab preview	Description of layer	Offset
Retina		Retinal vasculature angiogram	ILM 0µm, BM -30µm
Vitreous		Vitreous structure (above ILM layer)	ILM 250µm, ILM 3µm
Superficial		Superficial Capillary Plexus	ILM 0µm, IPL/INL -15µm
SVC		Superficial Vascular Plexus	ILM 0µm, IPL/INL 10µm

RPCP		Radial Peripapillary Capillary Plexus	ILM 0µm, NFL/GCL 0µm
Deep		Deep Capillary Plexus	IPL/INL -15µm, IPL/INL -70µm
DVC		Deep Vascular Plexus	IPL/INL 10µm, OPL/ONL -10µm
ICP		Intermediate Capillary Plexus	IPL/INL 10µm, INL/OPL 10µm

DCP		Deep Capillary Plexus	INL/OPL 10µm, OPL/ONL -10µm
Outer		Outer retina layers (avascular zone)	IPL/INL -70µm, BM 0µm
Choriocapillaris		Choroidal Capillary	BM -15µm, BM -45µm
Choroid		Choroidal Vessels	BM -45µm, BM -160µm

Depth Coded		Color coded Retinal vasculature angiogram	ILM 0µm, BM 0µm

Exact information about boundaries used to generate angiogram for active object is displayed in the upper part of the tomogram window.

NOTE: In an OCT image, the intensity of the section under a blood vessel will be changed by the blood flow. The intensity will affect the visualization of the highly reflective layers such as IS/OS or RPE. Therefore, the angiogram images including IS/OS or RPE layer appear to be similar to the angiogram of blood vessel structure of the inner retina. This effect is called Projection Artifact. In a healthy eye there are no blood vessels in the outer retina.

17.1.3.2 Operation on the angiogram object

Enlarge - Double click on the angiogram image.

Brightness and Contrast modification - press and hold the right mouse button and move it up/down and left/right to adjusts the brightness and contrast of the Angiogram image.

Modify boundary position – the user can modify the depth position of the top and bottom boundaries simultaneously. Scroll mouse wheel to go deeper or up from the initial position.

Save as – click the right mouse button and select 'Save as...' from the menu to save the Angiogram image.

Zoom in / Zoom out - press [ctrl] button and scroll over the angiogram window.

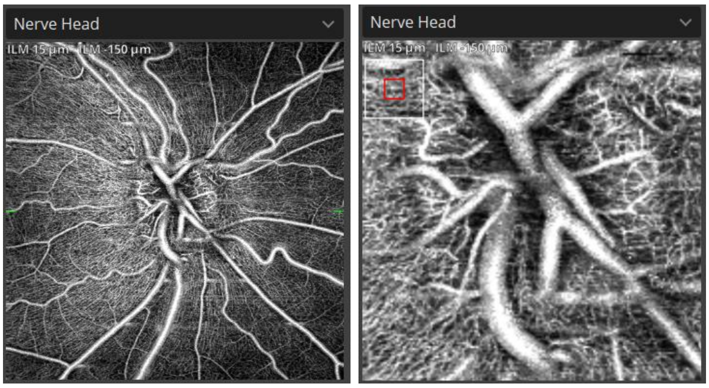


Figure 230. Zoom out/in over the angiogram window

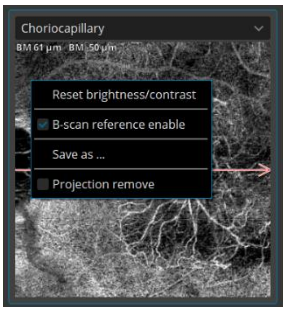
Angiogram context menu offers:

- Reset brightness/contrast - restore brightness/contrast default
- B-scan reference enable – enable/disable the reference B-scan on the angiogram
- Save as… - save angiogram
- Projection removal - enable/disable the projection Artefact removal algorithm

Left Click to desired position to see the tomogram from specific location. Hold left mouse button and move to smoothly change the position.

Projection Artefact Removal algorithm.

Angio OCT techniques are based on the principle of motion contrast. Visualization of the deeper vascular layers is affected by flow projection artefacts form fluctuating shadows of the flowing blood cells in the more superficial blood vessels that create “false flow” in the deeper layers. This phenomenon is called “projection artefacts”. On cross-sectional Angio OCT projection artefacts are seen as elongated signal tail. On enface OCTA images the higher layer blood vessels network gets duplicated on the deeper slabs.



You can turn on/off the projection Artefact removal by right-clicking in the context menu over the angiogram. As default PAR is activate for Outer, Choriocapillaris, Choroid and Deep layer.

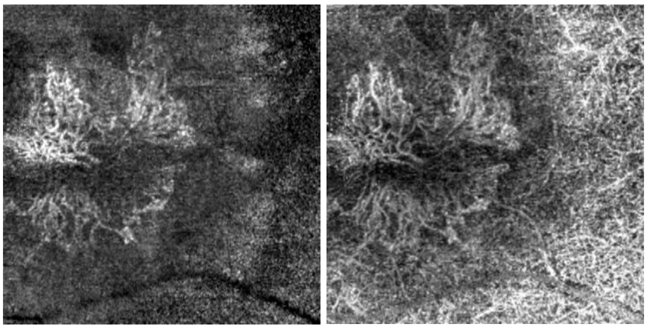


Figure 231. Projection artefact removal algorithm OFF / ON

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 retina layer recognition boundaries and layers offsets before evaluating angiogram of vascular layer.

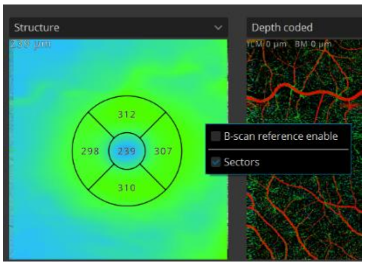
NOTE: Due to projection artifacts of the retinal flow signal onto deeper layers, such as the retinal pigment epithelium and choroid carefully evaluate the signal deeper vascular layer especially RPE and choriocapillaris.

17.1.3.3 Enface window

Enface window. The object displayed can be selected from the list box.

Enface	– it displays an enface image generated between the boundaries from the active angiogram window.
Fundus	– it displays color photo fundus image
Structure	– it shows color coded thickness map of the retina. Sector dimension on the map is 1/3mm in diameter.
Retina thickness	– it displays Retina thickness map
Inner Thickness	– it displays Inner Retina thickness map

When the Structure map is selected it is possible to hide thickness sectors. To hide the sector, position the mouse cursor over the Structure map, press the right button and uncheck the 'Sectors'.



Enface Image context menu offers:

- Reset brightness/contrast - restore brightness/contrast default
- B-scan reference enable - enable/disable the reference B-scan on the angiogram
- Invert - invert the colors of the enface image
- Save as… - save enface image

Invert – It inverts the gray scale in the images. When the invert function is used for choroid it allows to see shadows from choroidal blood vessels which are usually black as white/gray color which more correspondence to choroid image from ICG.

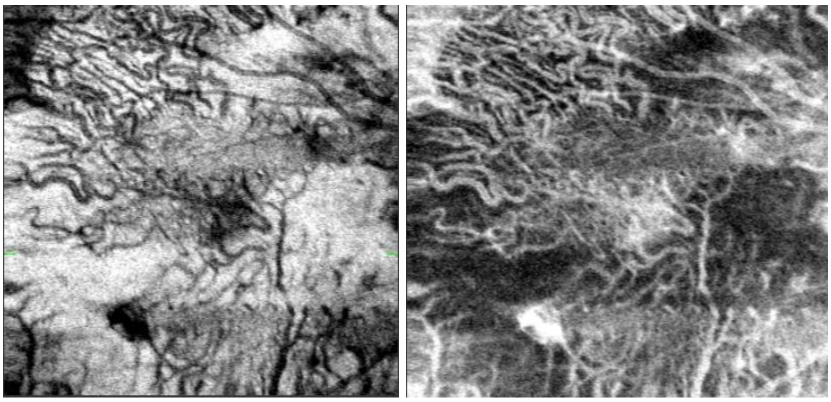


Figure 232. Enface image for the Choroid layer - invert OFF / ON

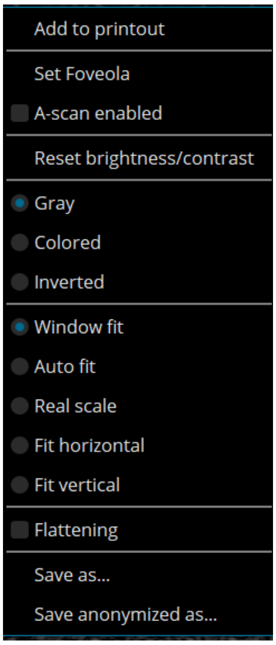
17.1.3.4 Tomogram window

It shows the selected tomogram overlaid with layers boundaries from the active angiogram window. On the tomogram a semitransparent, red decorrelation mask is overlaid. It is possible to change the position of the desired layer. You can type in the offset over the tomogram window or grab and move the selected layer. Offset is expressed as microns from the original position of the recognized retinal layer. The negative offset value describes the position below the original position.

17.1.3.4.1 *Operation on the tomogram object*

Standard manipulation of the tomogram window is described in chapter 12.6 Tomogram window manipulation. Additionally, it is possible to modify the position of boundary layers which 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



- Add to print
- Set Foveola
- A-scan enabled
- Reset brightness/contrast
- Angio Flow
- Gray
- Colored
- Inverted
- Window fit
- Auto fit
- Real scale
- Fit horizontal
- Fit vertical
- Flattening
- Vertical scan
- Save as…
- Save anonymized as…

When vertical scan is marked:

- the system displays a composed vertical tomogram (created from B-scans) with layers boundaries

- on the enface and angiogram object additional green vertical reference line appears
- B-scan alignment function is turned on (the same function as used in 3D)
- scrolling vertical tomograms is not synchronized with the horizontal tomogram
- additionally, 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 –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 contract adjustments.

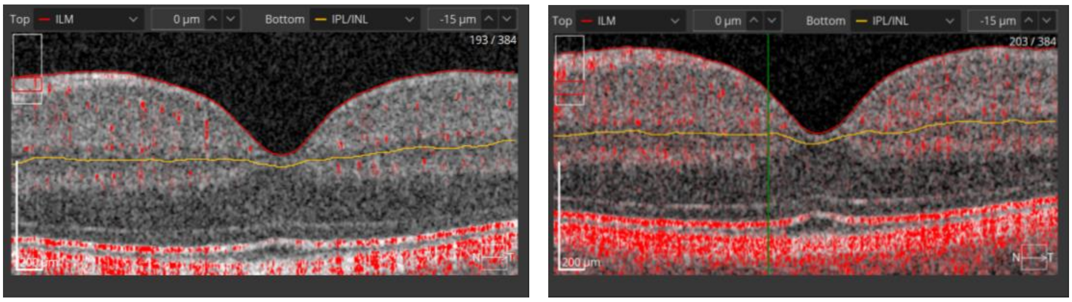


Figure 233. Angio flow tool

17.2 **Quantification tools: FAZ, VFA, NFA**

17.2.1 *FAZ tool*

In angiographic analysis of the retina, the center of the macula is generally capillary-free, this area being named the foveal avascular zone (FAZ).

Foveal avascular zone (FAZ) measurements are based on Angio Retina scans and are available only on the superficial, SVC, deep, DVC, ICP, DCP layers. Only one measurement per scan is possible.

FAZ – Foveal Avascular Zone tool is available with the angiography module. It can be open by double click on the Angiogram object. FAZ is not available on enface view and depth coded map...

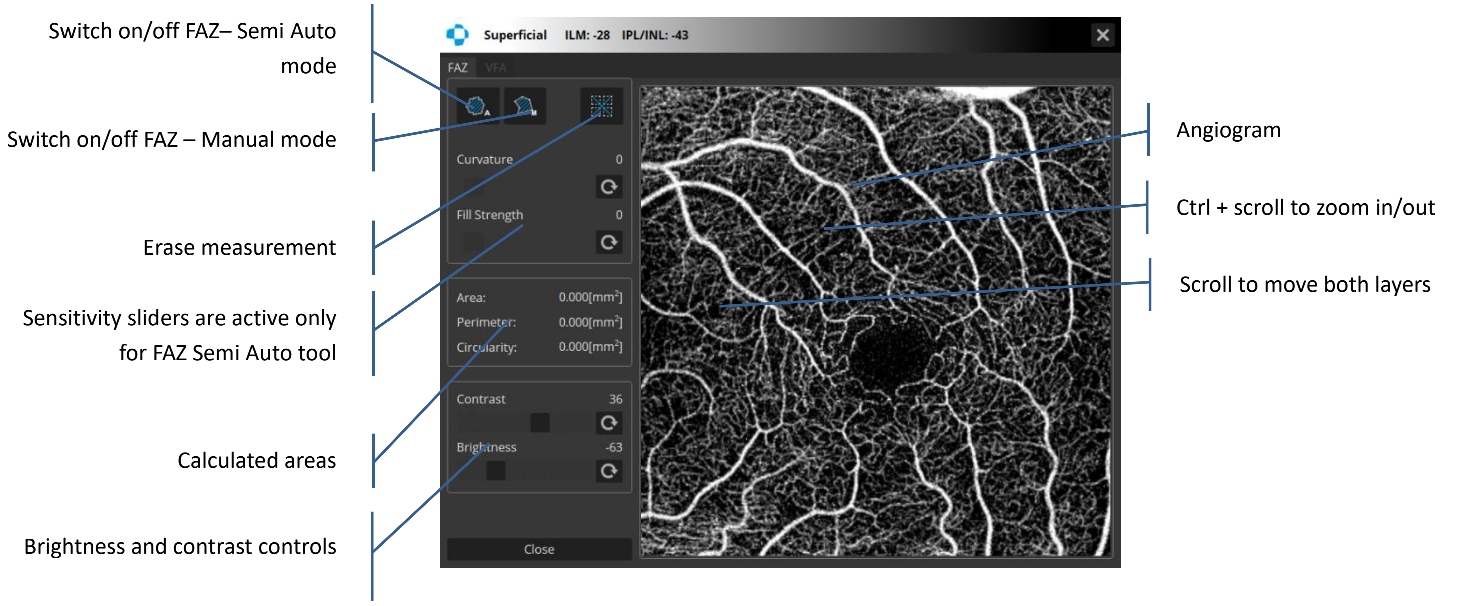


Figure 234. Foveal Avascular Zone tool

Erase measurements – clear all measurements.

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.

Brightness and contrast adjustment – two sliders for brightness and contrast adjustment.

Erase measurements – clear all measurements.

17.2.1.1.1 *Foveal Avascular Zone – Semi Auto*

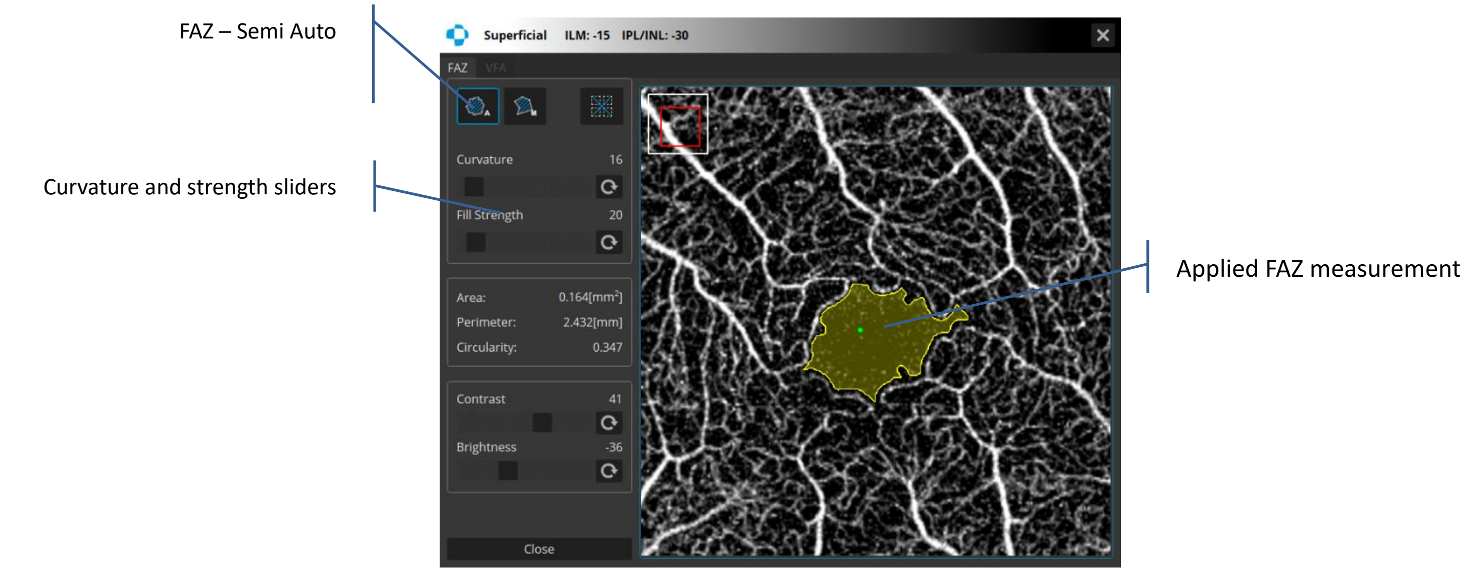


Figure 235. Foveal Avascular Zone tool – Semi Auto

Curvature and 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 are.

Brightness and contrast adjustment – two sliders for brightness and contrast adjustment.

17.2.1.1.2 *Foveal Avascular Zone – Manual*

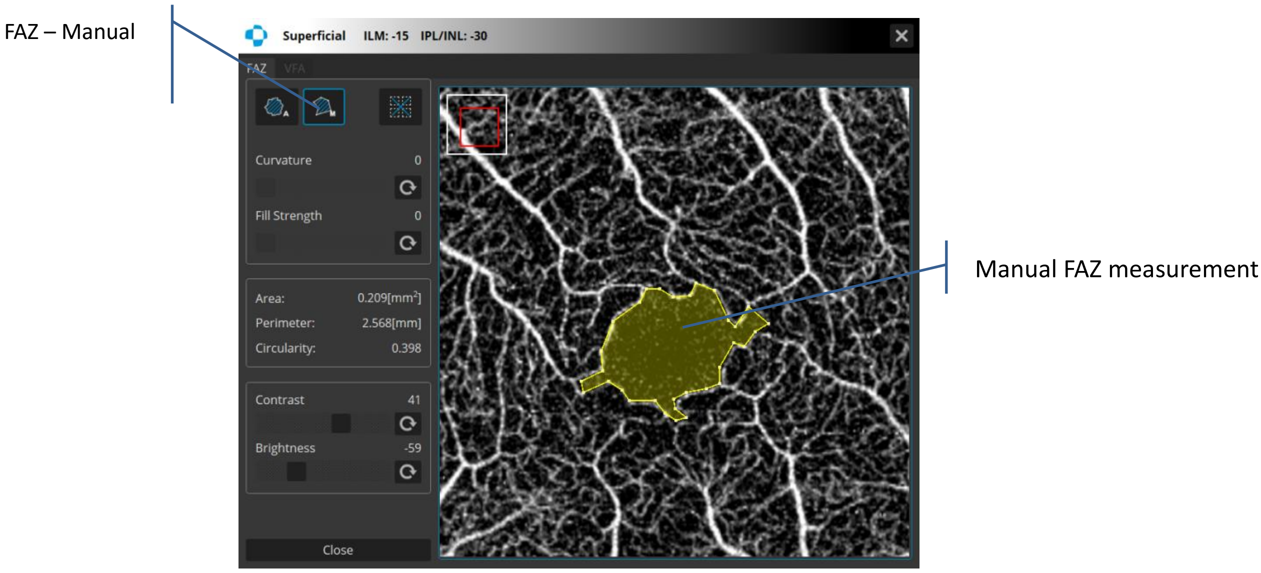


Figure 236. Foveal Avascular Zone tool – Manual

FAZ – Manual – Click where you want the first node and click again where you want to put the next one to begin. Continue clicking to create further nodes. CTRL + z keys combination removes the last seed.

Close the selection border by doing either of the following:

Position the pointer over the starting point and click. The mouse pointer changes to a hand icon when you are over the starting point.

If the pointer is not over the starting point click the right mouse button.

After closing to polygon, the user can correct the position of each node by grabbing and moving it. You may also grab and move the polygon. Over the node the mouse pointer 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 right adjustment of the brightness, contrast and sensitivity to highlight only the proper structure of the changes. OPTOPOL Technology Sp. z o.o. cannot be held responsible for misdiagnosis of results.

17.2.2 *VFA tool*

Vascular Flow Area measurement is based on Angio scans detecting the white vessels which usually run in the pre-defined layers. To use VFA (Vascular Flow Area tool) 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 and 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].

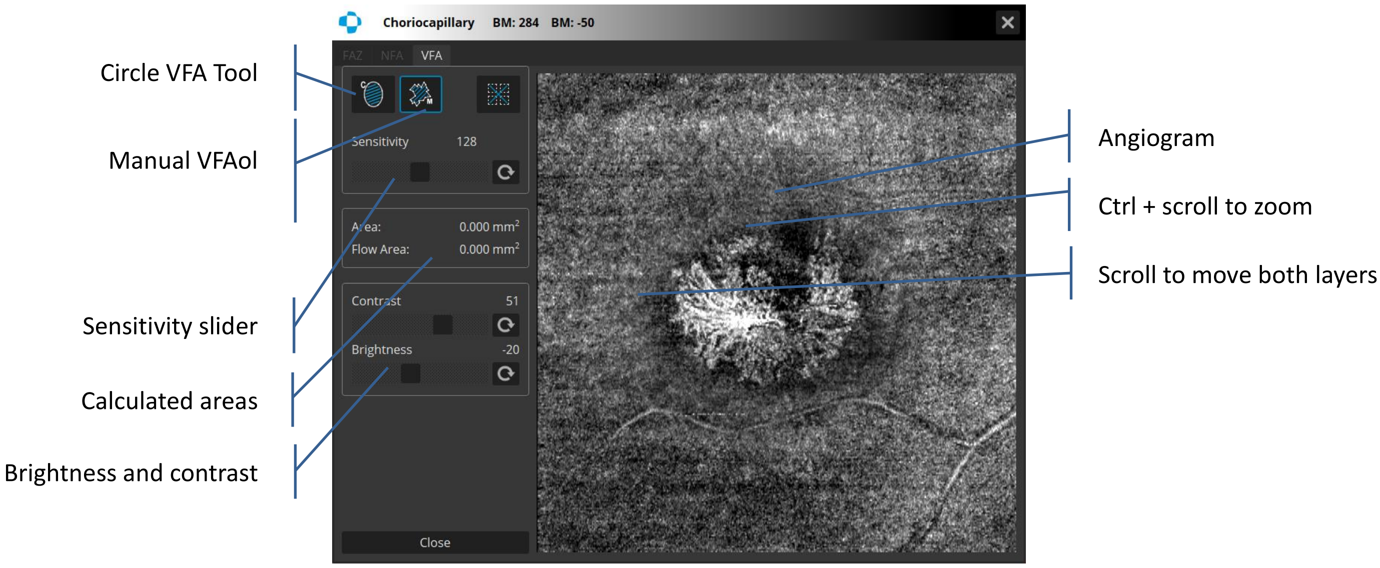


Figure 237. Vascular Flow Area tool

17.2.2.1.1 *VFA tool – Circle Area Tool*

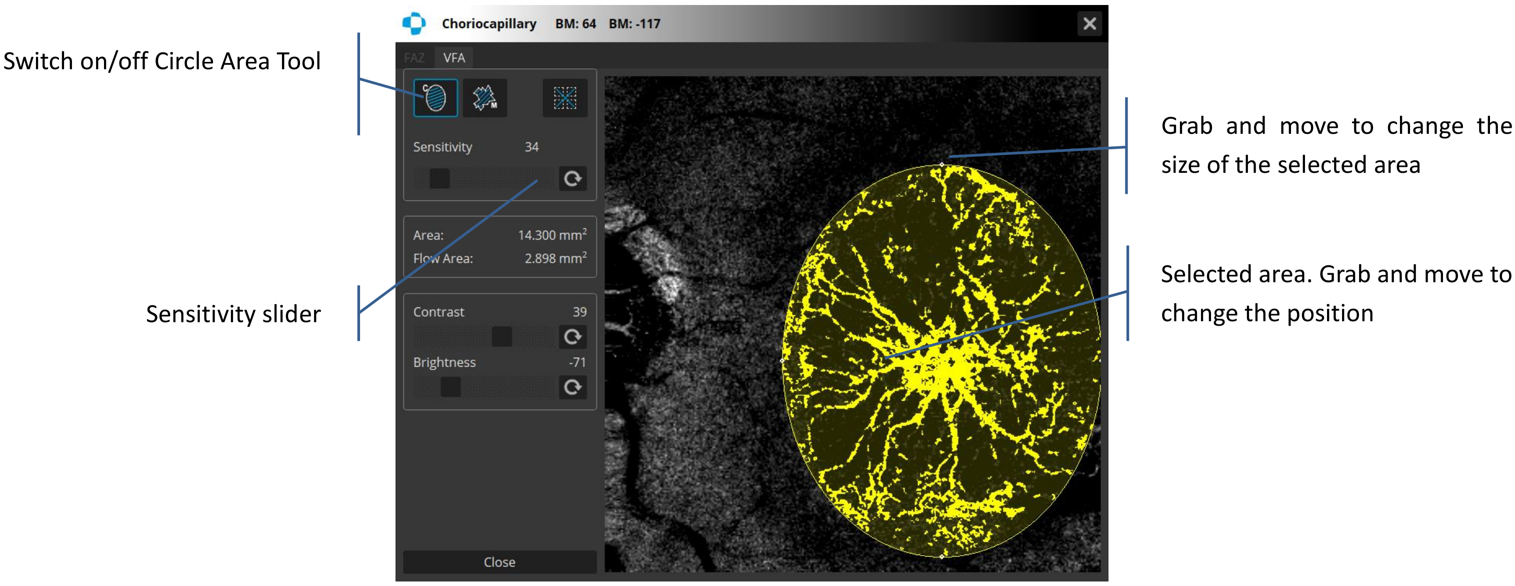


Figure 238. Vascular Flow Area tool – Circle Area Tool

Circle Area Tool. To draw an oval selection simply click at the point where you want 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 your mouse button to complete the selection. You may correct the selection by grabbing the oval and moving it to the proper position. You may also change the shape and size of the selected area by grabbing and moving individual nodes.

Sensitivity slider changes the tolerance of the tool.

17.2.2.1.2 *VFA tool – Manual Pointer Area Tool*

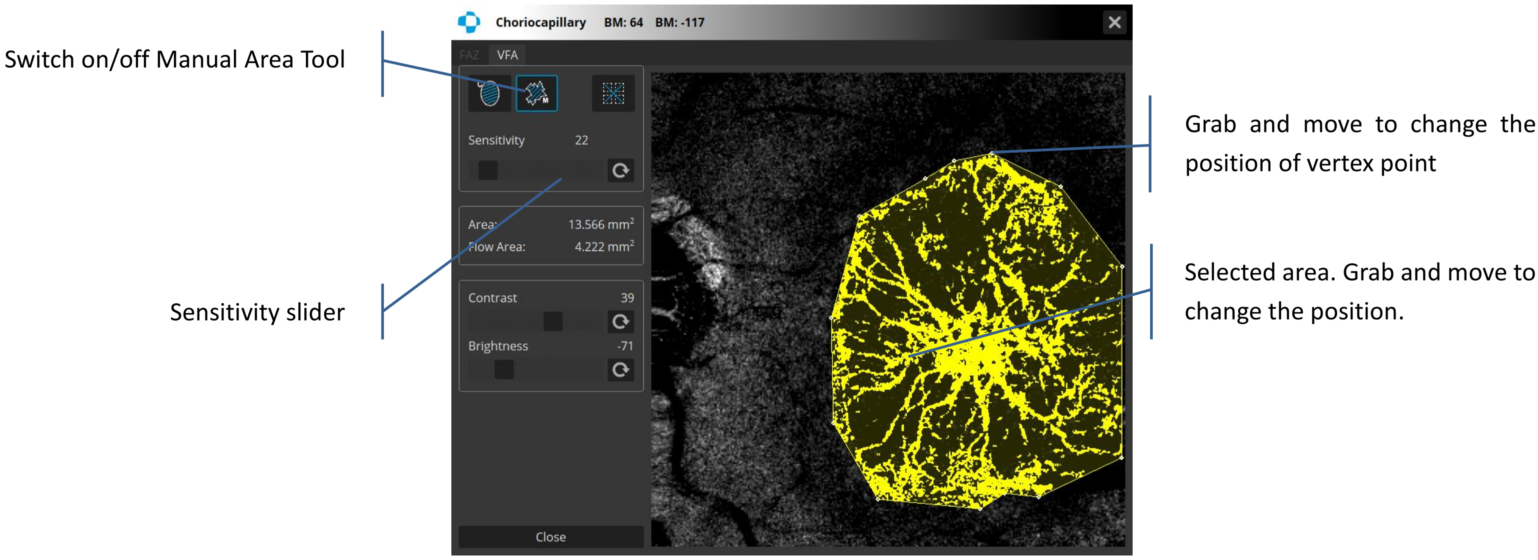


Figure 239. Vascular Flow Area tool – Manual Pointer Area Tool

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 setting seed.

To move a vertex, point just grab and move the chosen point. To delate the vertex point, click the right mouse button and chose one of two option: 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 users are responsible for the right adjustment of the brightness, contrast and sensitivity adjustments to highlight only the proper structure of the changes. OPTOPOL Technology Sp. z o.o. cannot be held responsible for misdiagnosis of results.

17.2.3 *NFA tool*

Non-Flow Area measurement allows to quantify the Non-flow Area on the OCT Angio examination. To use NFA (Non-Flow Area tool) double click on the Angiogram object. The tool is available only for Superficial, SVC, Deep, DVC, ICP and DCP layers. The nonflow detection can be performed either by using the Semi Auto tool or the manual pointer. For the selected space the area of the nonflow area will be provided [mm^2].

Provides:

- Non-Flow Area provides Area of as a sum of all marked spots
- Up to 30 spots can be analyzed.

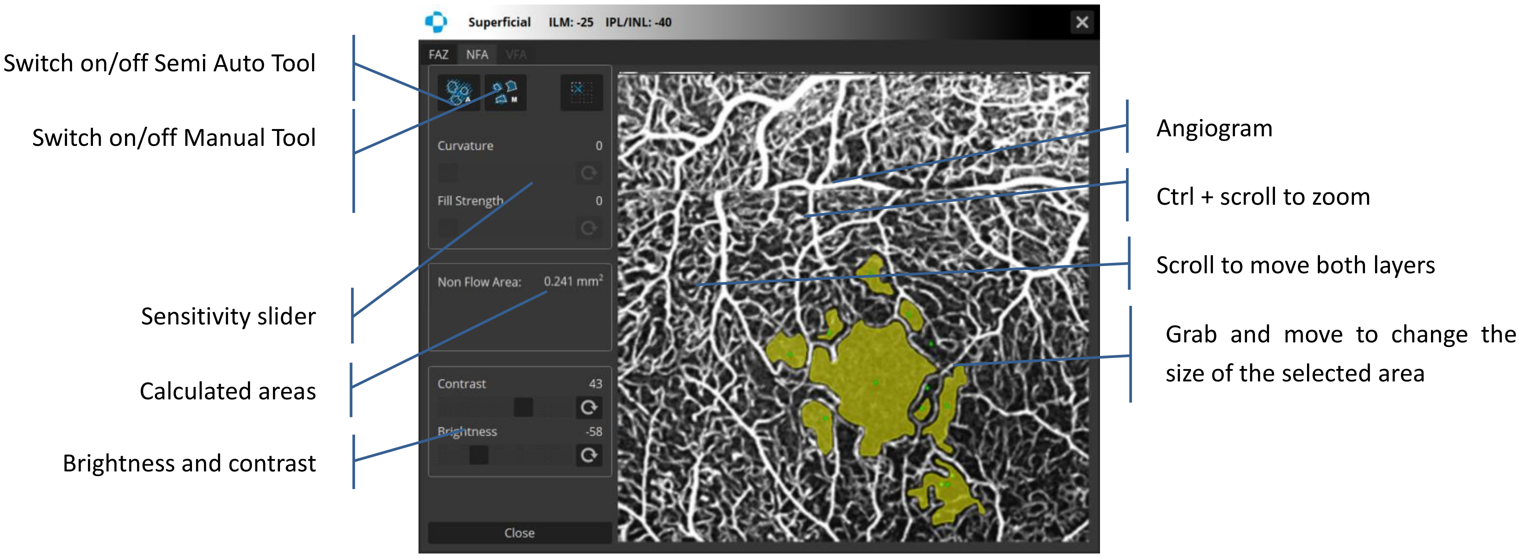


Figure 240. Non-Flow Area tool

17.2.3.1.1 *NFA tool - Semi Auto*

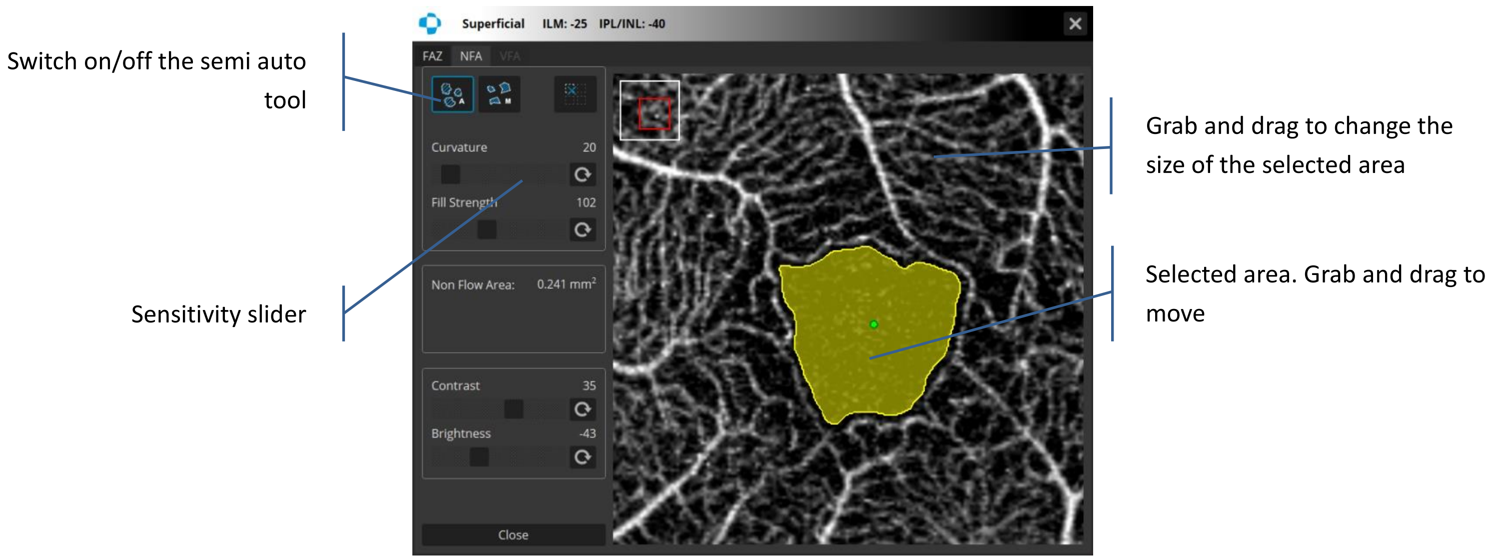


Figure 241. NFA tool – semi auto

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.

17.2.3.1.2 *NFA tool – Manual*

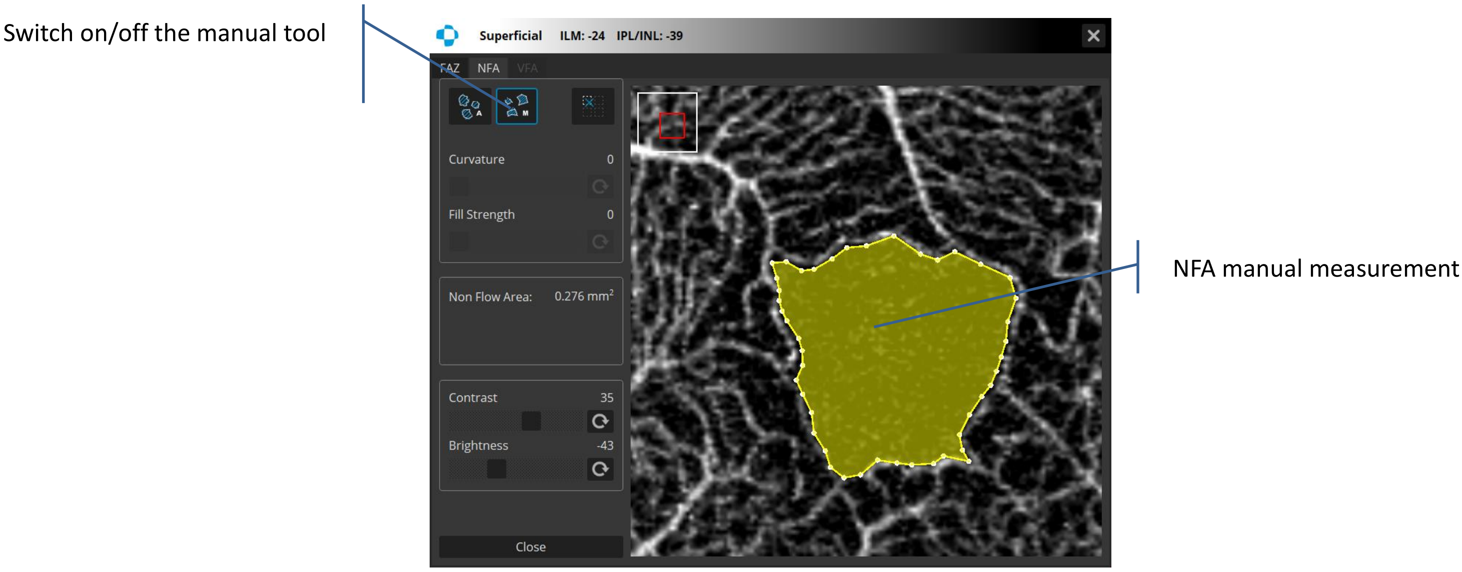


Figure 242. NFA tool - manual

Click where you want to position the first node. Then move the mouse to the spot where you want to place the next node and click again. Continue in this fashion to create further nodes. The CTRL + z combination cancels the last move.

17.2.4 *Quantification Maps [Density and Skeleton]*

Quantification provides the quantification of vasculature in specific sectors and heat map corresponding to the vasculature.

Density display - Vessel Area Density (VAD) - it 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 1 (fully perfused) (mm^2/mm^2).

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 1 (mm^2/mm^2).

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

Quantification is available for Retina Angio

- Superficial

- Deep and Disc Angio
- RPC

Analysis is available to all previously acquired examinations.

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.

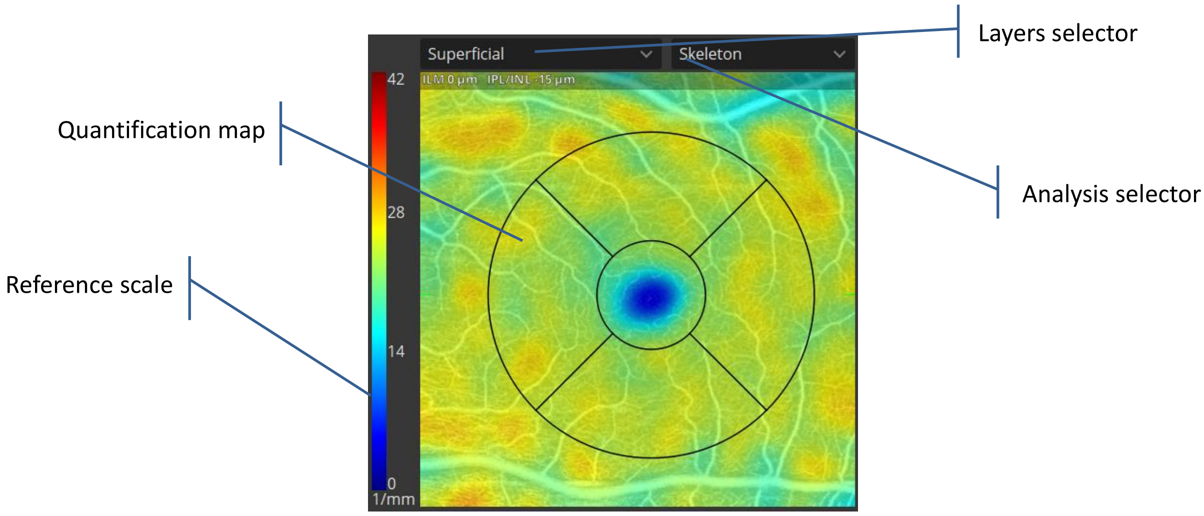
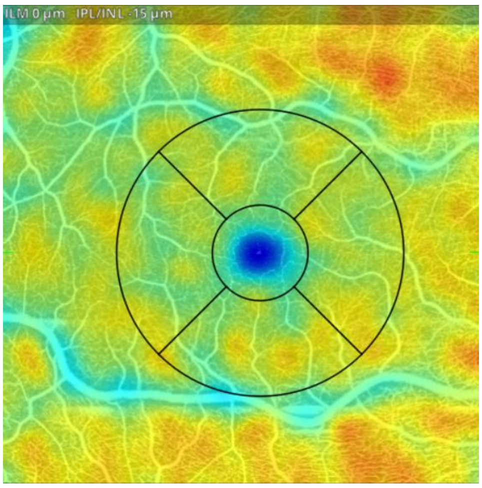
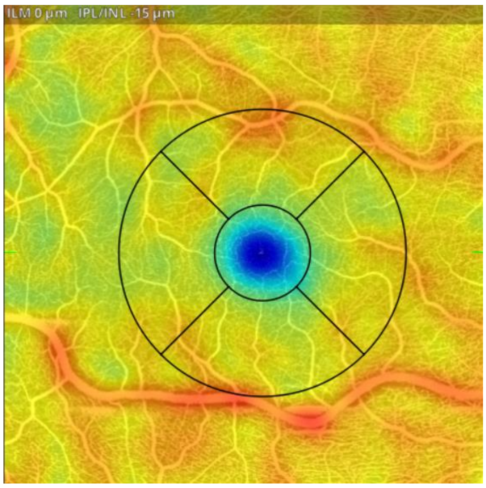


Figure 243. Quantification data field in Angio [SINGLE] Standard and Detail View



Skeleton Density map



Vessel Density Map

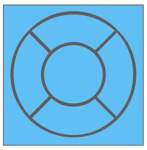
Layers selector – allows to select the layer. The quantification is not available for all layers.

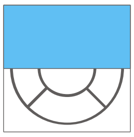
Analysis selector – Three types of scales are available. In the Single and Detailed view, the Density and Skeleton scales are available. The comparison and progression views offer the choice of Density, Skeleton, Reference scales.

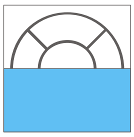
Quantification heat map - the results of the Quantification are displayed in the form of a mask over the analyzed area, with values according to the selection.
The results can be presented as values in the table acquired in the specific folder

Quantification table – presents the results of the quantification. The Comparison and Progression table 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.
In order to change the transparency of the quantification mask scroll over the quantification map.

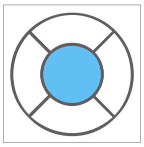
Measurement Zones for Retina from 3 to 5 mm scan

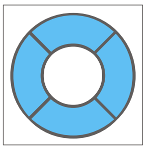

Total

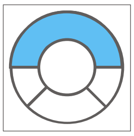

Superior

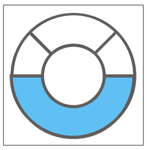

Inferior

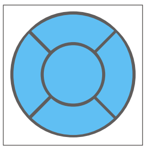
Region	**Density**
Total	56.1
Superior	56.2
Inferior	56.3
Central	56.4
Inner	56.5
Superior Inner	56.6
Inferior Inner	56.5
Full	56.6


Central

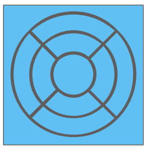

Inner

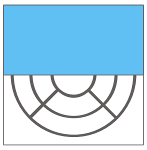

Superior Inner

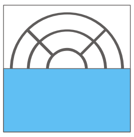

Inferior Inner

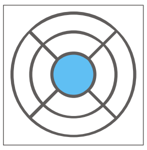

Full

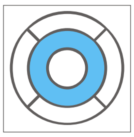
Measurement Zones for 6 mm width Retina scans

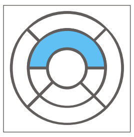

Total

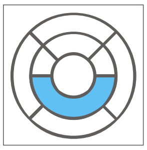

Superior


Inferior

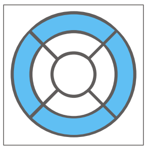

Center


Inner

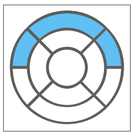

Superior Inner



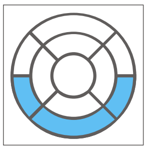
Inferior Inner



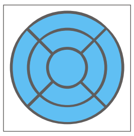
Outer



Superior Outer



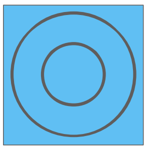
Inferior Outer



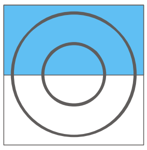
ETDRS

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

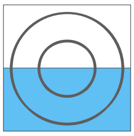
Measurement Zones for Disc



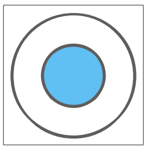
Total



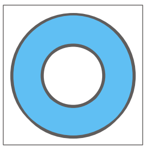
Superior



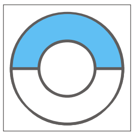
Inferior



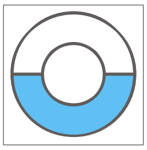
Inside Disc



Peripapillary



Superior Peripapillary

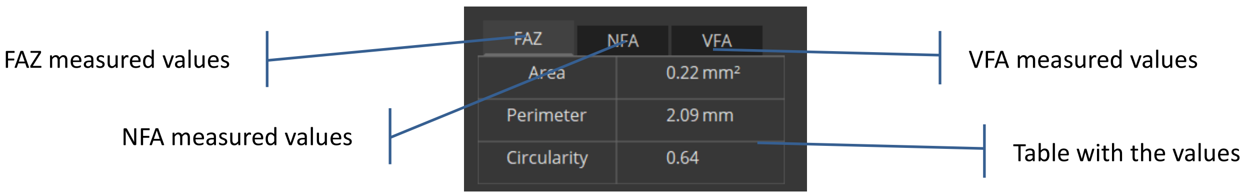


Inferior Peripapillary

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

17.2.5 *Angio OCT Analysis Table*

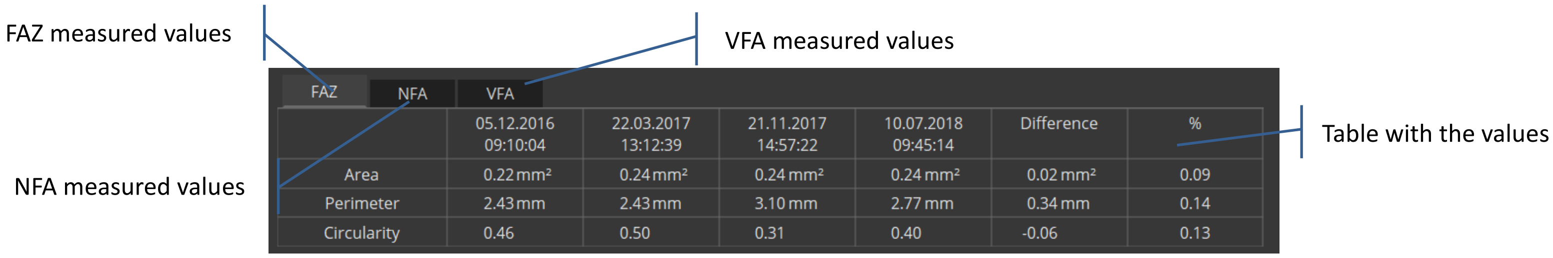
<u>Single view</u>



Area	0.22 mm²
Perimeter	2.09 mm
Circularity	0.64

Figure 244. Angio OCT Analysis Table for Single View

<u>Comparison view</u>



	05.12.2016 09:10:04	22.03.2017 13:12:39	21.11.2017 14:57:22	10.07.2018 09:45:14	Difference	%
Area	0.22 mm²	0.24 mm²	0.24 mm²	0.24 mm²	0.02 mm²	0.09
Perimeter	2.43 mm	2.43 mm	3.10 mm	2.77 mm	0.34 mm	0.14
Circularity	0.46	0.50	0.31	0.40	-0.06	0.13

Figure 245. Angio OCT Analysis Table for Comparison View

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. Difference is calculated as: newer scan - baseline scan. The percentage value is a percentage change compared to the baseline (change/baseline)*100%

If the operator uses only one analysis tool the tab with the measurements results is activate.

17.2.6 *[Both] view.*

In the „Both eyes" tab it is possible to make a comparison of both eyes' analysis, 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 angio retina examinations from the same visit.

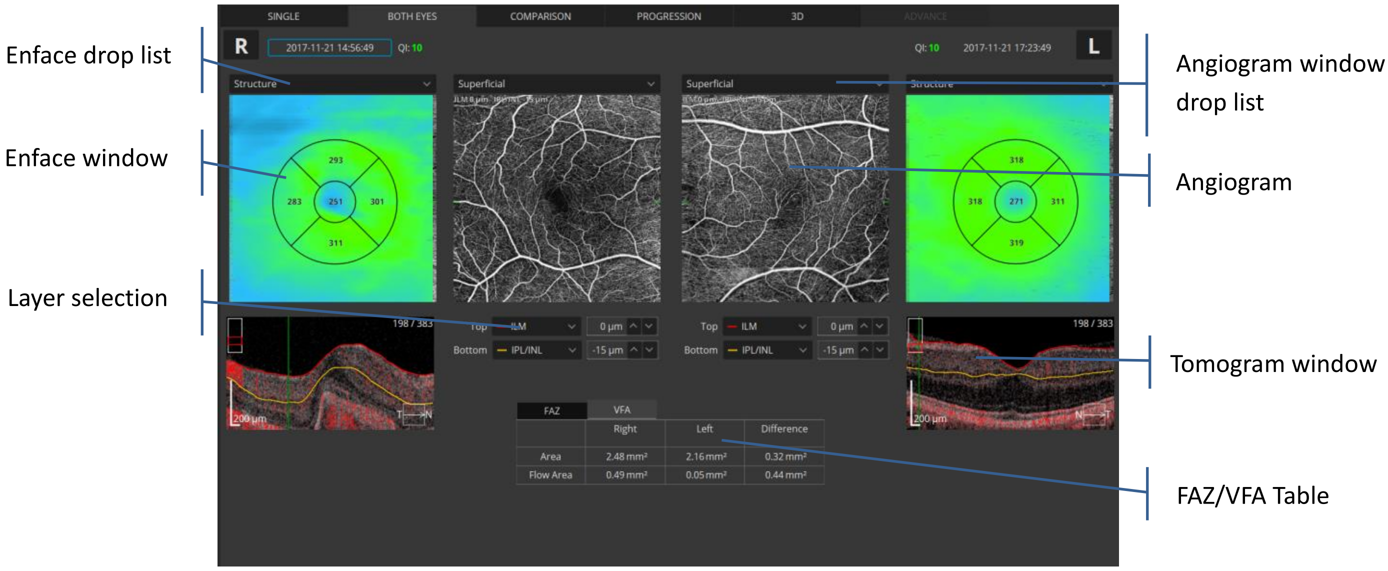


Figure 246. Both eyes Retina Angio view

Enface window: object displayed can be selected from the enface drop list.

- Enface - displays an enface image generated between the boundaries from the active angiogram window.
- Structure - shows a color-coded thickness map of the retina. Sector dimension on the map is 1/3mm in diameter.
- pSLO - shows the location of Angio scan on 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 recognized retina layer. The vascular layer can be selected from the angiogram drop list box:

- Retina - Retinal vasculature angiogram
- Depth Coded - Color coded Retinal vasculature angiogram
- Superficial - Superficial capillary plexus
- Deep - Deep capillary plexus
- Outer - Outer retina layers (avascular zone)
- Custom view - User defines top and bottom boundaries to generate angiogram
- Vitreous - Structure above ILM layer
- Choriocapillaris - Choroid choriocapillaris visualization
- Choroid - Choroid visualization.

Tomogram window shows the selected tomogram overlaid with the boundaries of layers from the active angiogram window. On the tomogram, semitransparent, red colored decorrelation mask is overlaid. It is possible to change the position of a layer. You can type in the offset over the tomogram window or grab and move it to the selected layer. Offset is expressed in microns from the original position of the recognized retinal layer. The negative offset value describes the position below the original position.

FAZ/VFA Table shows difference between eyes.

Changing the type of vascular layer on one object affects both eyes and both objects (angiogram and enface). FAZ tool can be used only on the superficial, deep, icp, dcp layers. VFA tool is available only for Outer retina and Choricapillary, vitreous layer and Choroid.

17.2.7 *[Comparison] 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.

Comparison view is used to observe follow up changes in the eye structure. The software automatically selects outermost examinations (the oldest and the newest) in order to compare them. The user can manually choose examinations from the list depending on the chosen comparison protocols that are highlighted.

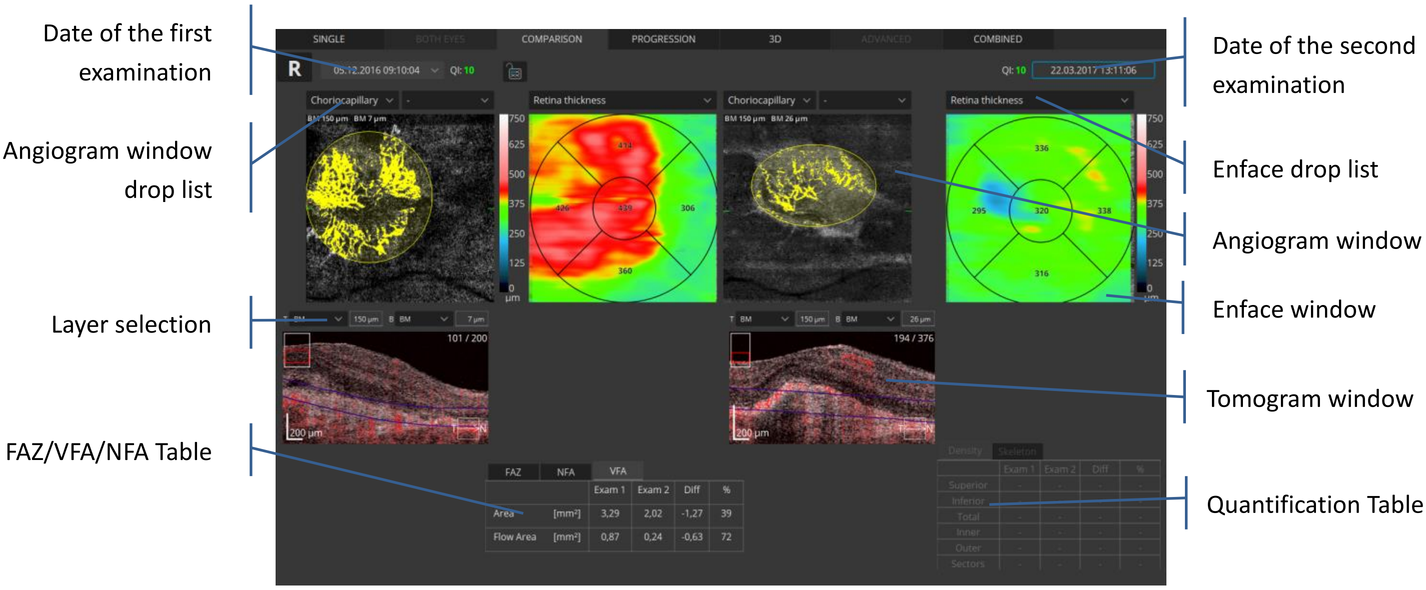


Figure 247. Comparison Retina Angio view

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 user can also change the dimension of the measurement rings. There are two options available:

- rings: 1; 3 and 6 mm (standardized ETDRS testing),
- rings: 0,6; 2,22 and 3,45 mm.

Tomogram window shows the selected tomogram overlaid with the boundaries of layers from the active angiogram window.

17.2.8 *[Progression] view*

This screen shows the analysis results comparing four examinations, done on the same side in the same scan mode, and on the same size of scanning area, arranged in a time sequence.

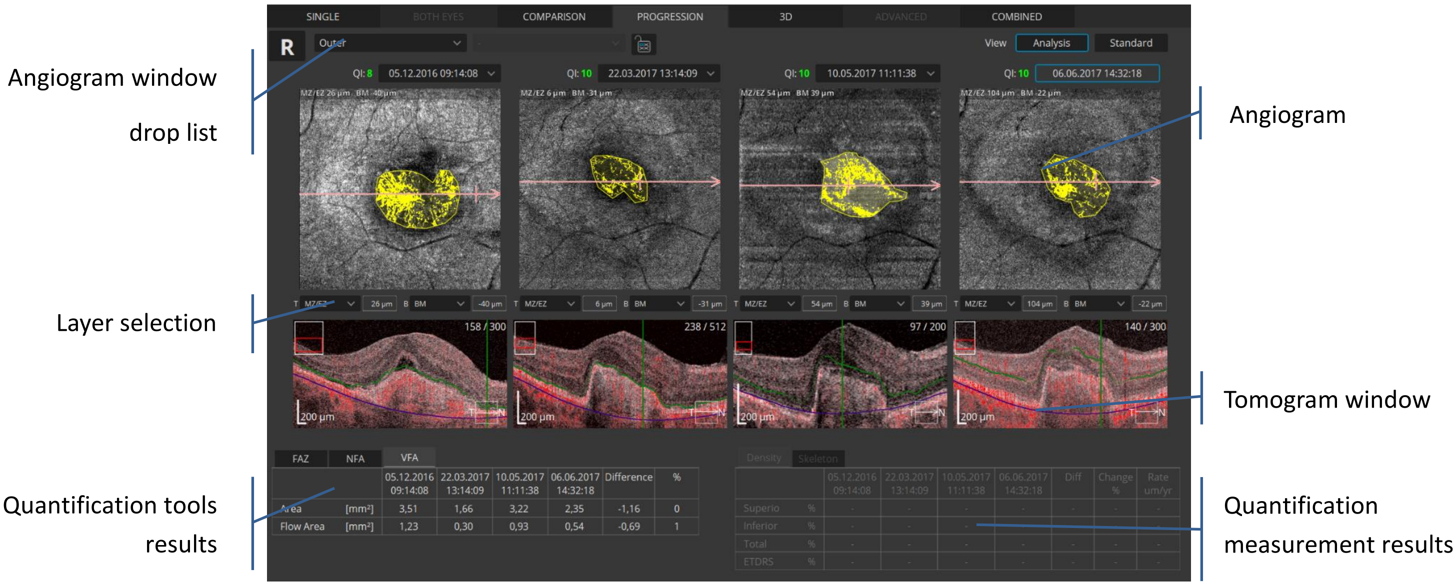


Figure 248. Progression Retina Angio Analysis view

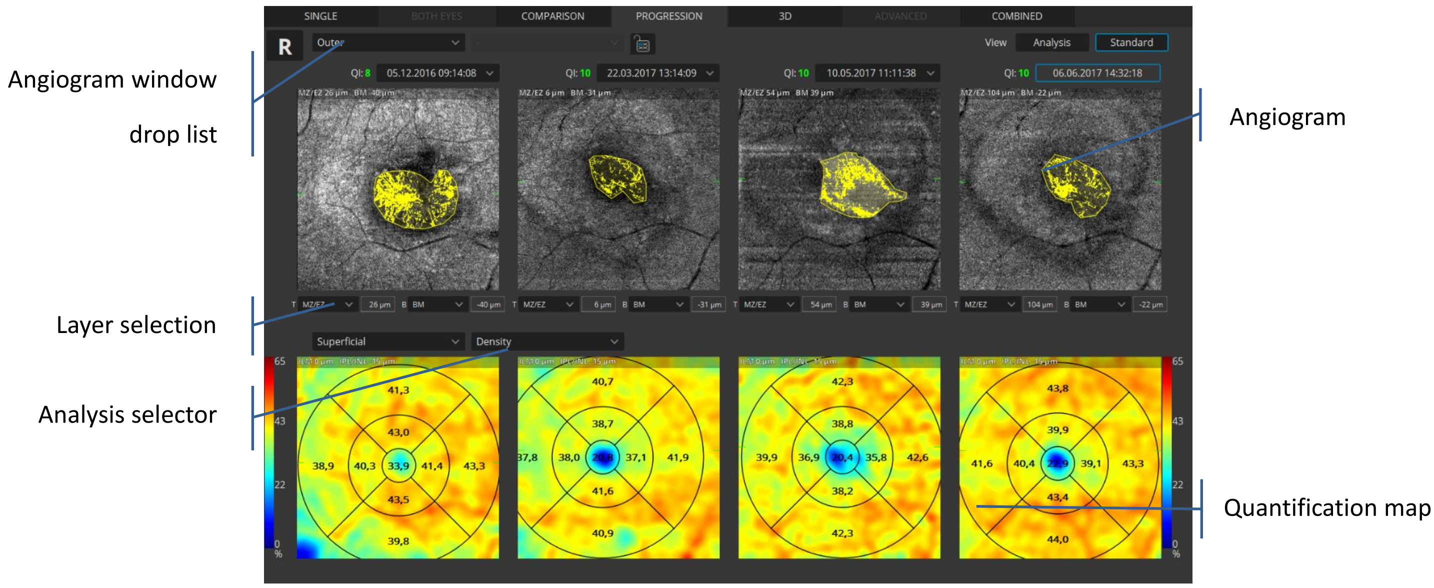


Figure 249. Progression Retina Angio Standard view

In the angiogram window the user can select one of the predefined vasculature layers based on the position of the recognized retina layer. Vascular layer can be selected from the 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

Tomogram window - it shows selected tomogram overlaid with the boundaries of layers from the active angiogram window. On the tomogram, semitransparent, red color decorrelation mask is overlaid. It is possible to change the position of a layer. You can type in the offset over the tomogram window or grab and move it to the selected layer. Offset is expressed in microns from the original position of the recognized retinal layer. The negative offset value describes the position below the original position.

FAZ/VFA/NFA Table shows difference between eyes.

17.3 **Motion Correction**

Motion correction algorithm is implemented to eliminate or minimize eye movement artifacts on Angio OCT and 3D exams. The algorithm allows to create an artifact-free exam from one or more scans.

The MC algorithm can be used on the number of examinations ranging from one to six. It is recommended to use at least 2 examination of the same area.

A single exam needs to provide sufficient data. If there is enough data the algorithm will generate correct result.

Mark the desired examinations on the Exam List in Results view (hold the ctrl button and click on each exam), press the right mouse button and select “Motion correction” from the Menu. The system will generate a new exam free of or with reduced motion artifacts.

If you use the Repeat function you can choose the Motion Correction function from the menu without selecting exams. The system will use all repeated examinations from the specified location.

The user can run the MC automatically by right-clicking on the chosen exam and selecting “Motion correction” from the context menu. The software generates the results from 1 up to 6 examinations depending on the number of identical exams available.

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 the affected area repeats exactly in the same position on all scans, the system will not be able to eliminate the artifact from this area.

Note: The right amount of data and the quality of the examination are necessary for correct motion artifacts reduction.

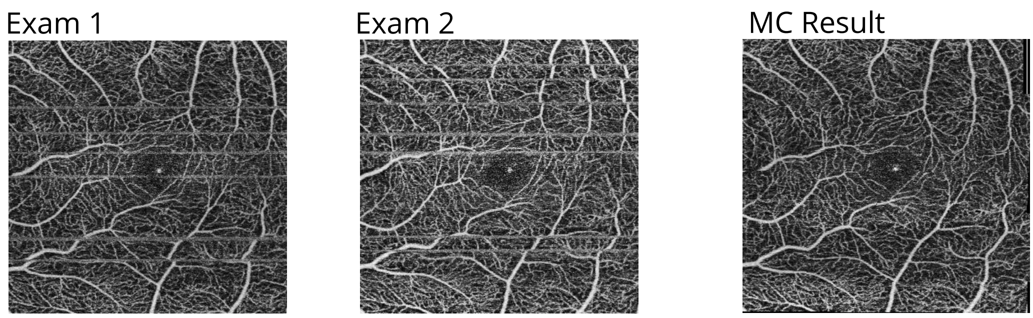


Figure 250. Example of Motion Corrected examination

17.3.1 *Motion Correction in 3D Examinations*

See chapter 7.11.1 Acceptance window for a 3D scan.

17.4 **DISC OCT-A**

17.4.1 *[Single] view.*

17.4.1.1 Standard

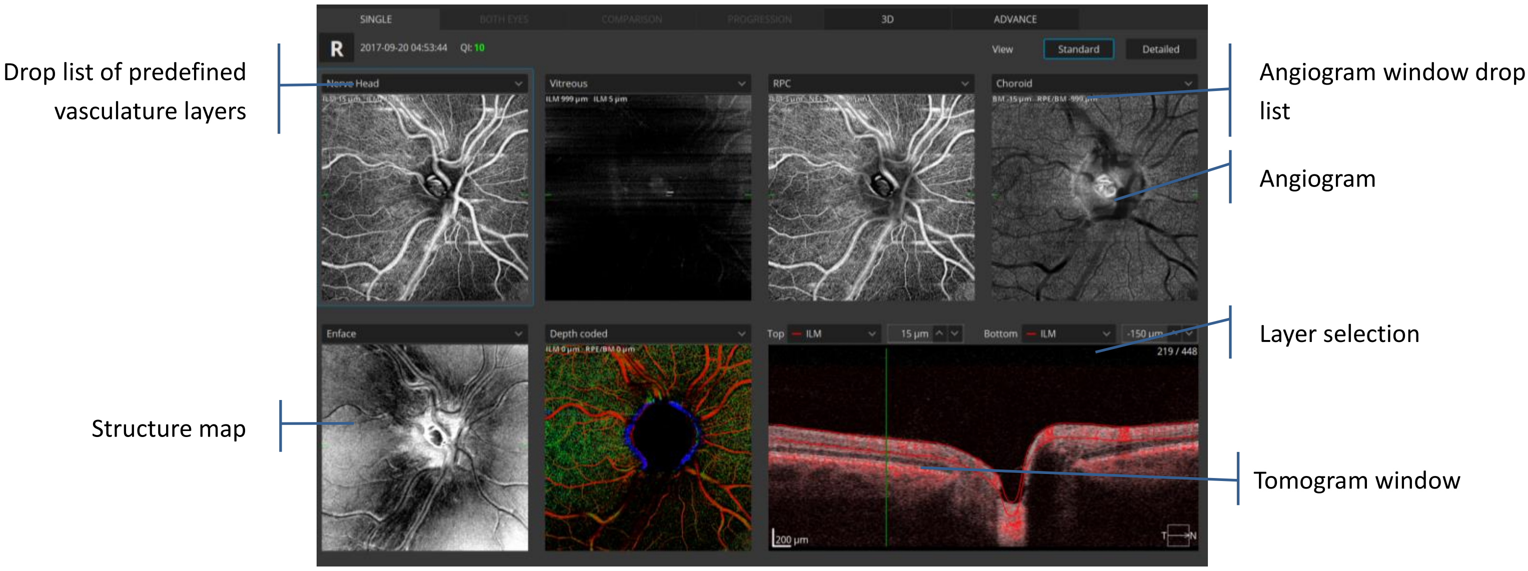


Figure 251. Single Standard Disc Angio view

In the angiogram window for Optic nerve head 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
Retina	Retinal vasculature angiogram	ILM 0µm, BM -30µm
Vitreous	Vitreous Structure (above ILM layer)	ILM 250µm, ILM 3µm
Superficial	Superficial Capillary Plexus	ILM 0µm, IPL/INL -15µm
SVC	Superficial Vascular Plexus	ILM 0µm, IPL/INL 10µm
RPCP	Radial Peripapillary Capillary Plexus	ILM 0µm, NFL/GCL 0µm
Deep	Deep Capillary Plexus	IPL/INL -15µm, IPL/INL -70µm
DVC	Deep Vascular Plexus	IPL/INL 10µm, OPL/ONL -10µm
ICP	Intermediate Capillary Plexus	IPL/INL 10µm, INL/OPL 10µm
DCP	Deep Capillary Plexus	INL/OPL 10µm, OPL/ONL -10µm
Outer	Outer retina layers (avascular zone)	IPL/INL -70µm, BM 0µm
Choriocapillaris	Choroidal Capillary	BM -15µm, BM -45µm
Choroid	Choroidal Vessels	BM -45µm, BM -160µm
Depth Coded	Color coded Retinal vasculature angiogram	ILM 0µm, BM 0µm
Custom view	User defined top and bottom boundaries to generate angiogram	

17.4.1.2 Detailed

Detailed view allows to view large objects and quantify results.

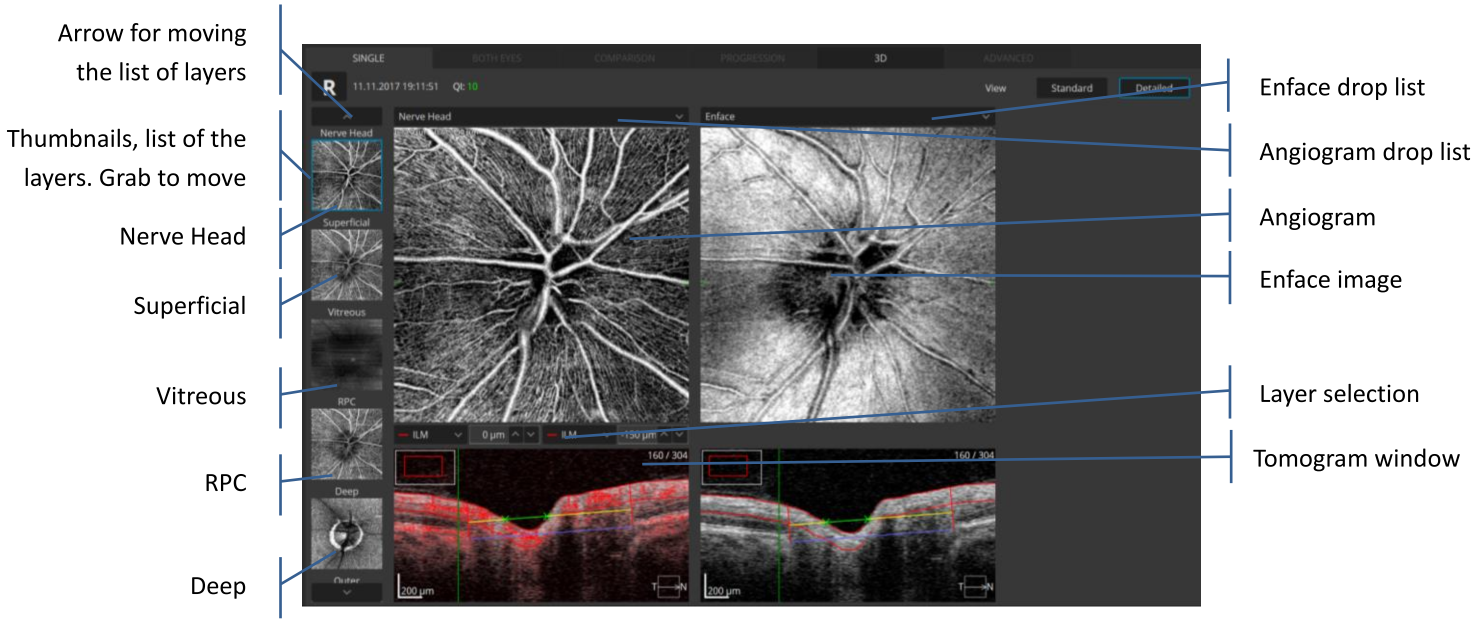


Figure 252. Single Detailed Disc Angio view

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. You may also change the thumbnails order by grabbing and moving them.

Angiogram and enface images respond to manipulations and changes in offset and layers.

Enface image displays the enface image generated between the boundaries from the active angiogram window.

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. You can type in the offset over the tomogram window or grab and move it to the selected layer. Offset is expressed in microns from the original position of the recognized retinal layer. The negative offset value describes the position below the original position.

17.4.2 *[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.

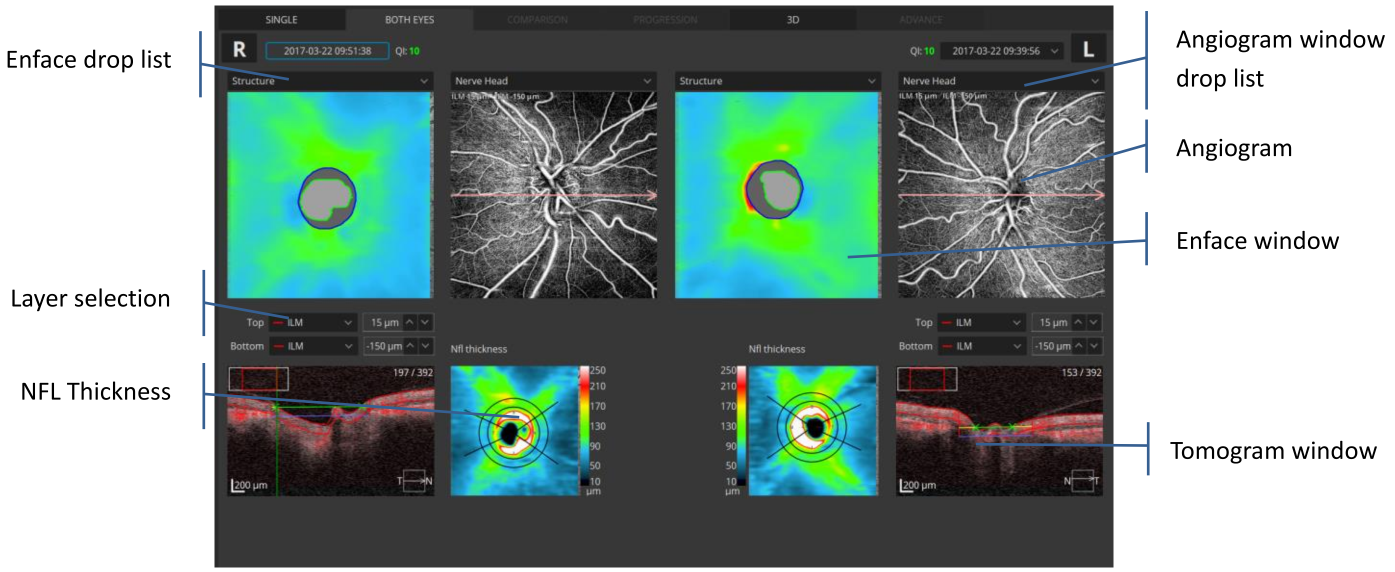


Figure 253. Both Discs Angio view

Enface window: to display an object, select it from the enface drop down menu.

- Enface- displays an enface image generated between the boundaries from the active angiogram window.
- Structure - shows a color-coded thickness map of the retina. Sector dimension on the map is 1/3 mm in diameter.
- pSLO - shows the location of the Angio 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.

- Nerve Head
- Superficial
- Vitreous
- RPC
- Deep
- Outer
- Choroid
- Depth Coded
- Custom view

Tomogram window shows the selected tomogram overlaid with the boundaries of layers from the active angiogram window. On the tomogram, a semitransparent, red decorrelation mask is overlaid. It is possible to change the position of the desired layer. You can type in the offset over the tomogram window or grab and move it to the selected layer. Offset is expressed in microns from the original position of the recognized retinal layer. The 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 layer on the scanned area.

To change the transparency level, turn the mouse wheel over the object.

17.4.3 *Angio Disc Comparison view*

This screen shows the analysis results comparing two examinations of one eye on the same side in the same scan mode, from different dates.

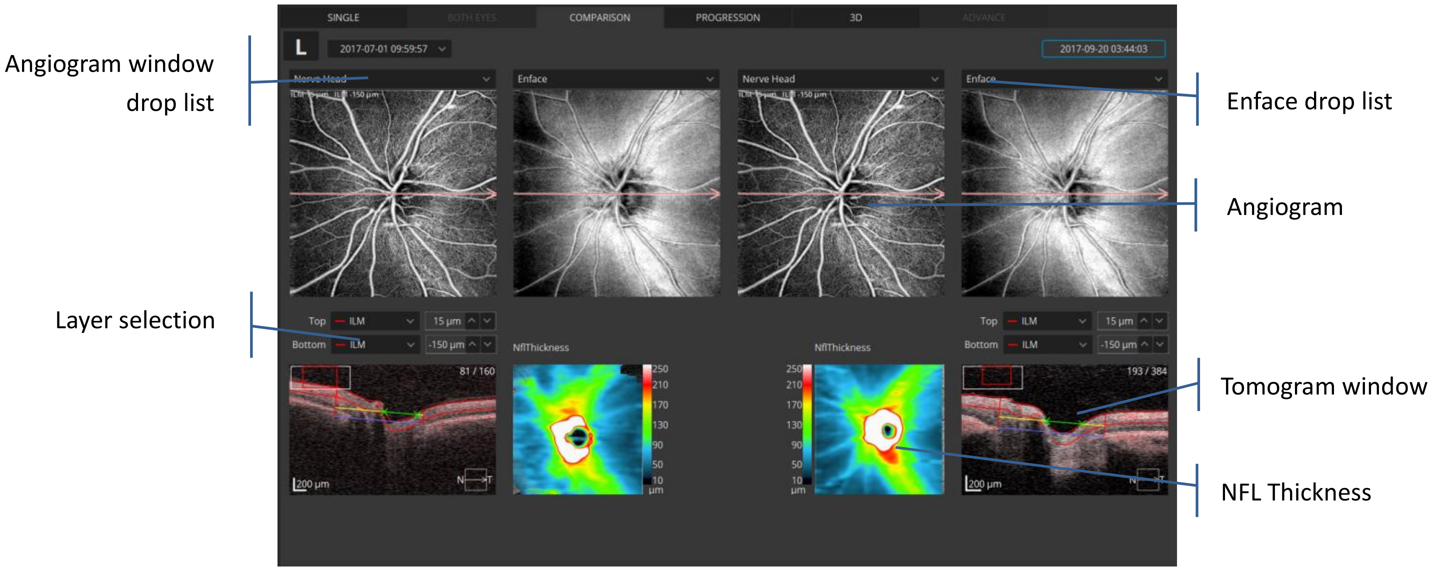


Figure 254. Comparison Disc Angio view

NFL thickness map shows the thickness of the NFL layer on the scanned area. A map to be overlaid on the fundus reconstruction can be selected from the list box:

- NFL+GCL+IPL thickness
- GCL+IPL thickness
- NFL thickness

To change the transparency level, turn the mouse wheel over the object.

17.4.4 *[Progression] view*

This screen shows the analysis results comparing four examinations done on the same side in the same scan mode, and the same size of scanning area, arranged in a time sequence.

Figure 255. Progression Disc Angio 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 layer can be selected from the drop list box.

Tomogram window - it shows the selected tomogram overlaid with the boundaries of layers from the active angiogram window. On the tomogram, a semitransparent, red decorrelation mask is overlaid. It is possible to change the position of the desired layer. You can type in the offset over the tomogram window or grab and move it to the selected layer. Offset is expressed in microns from the original position of the recognized retinal layer. The 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).

17.5 **Mosaic**

Angio mosaic feature can be used to present wider field of view with that same level of details. The algorithm uses examination from predefined sets of data of at least 2 examinations to superimpose the mosaic image. The Angio Mosaic can be created from 2 up to 12 images. Open the Advance tab to see superimpose images. User can modify initial position of images.

The SOCT allows to create mosaic from the examinations included from predefined set, 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.

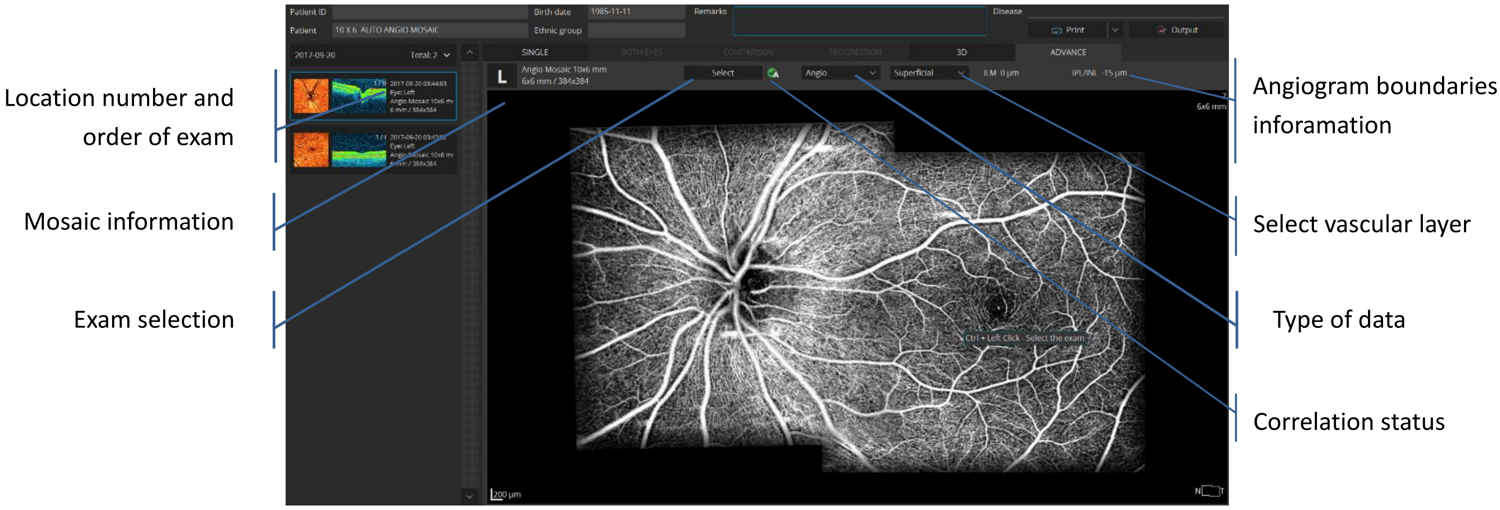


Figure 256. Advance tab – Angio mosaic.

At the mosaic window user can select one of predefined vasculature layers which base on position of recognized retina layer. Vascular layer can be selected from the list box:

Vitreous	- Structure above 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.

Type of displayed data can be selected from the list box. User can select 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
RNFL thickness	- RNFL thickness map

17.5.1 *Correlation status*

It informs about the method of superimposition.


Automatically superimpose


Manually superimposed (by the operator)

17.5.2 *Select screen*

On the select screen you can change, remove or add exams used in mosaic composition.

Once you select or unselect the exams [Analyze] button becomes active. Press [Analyze] to start automatic superimpose process.

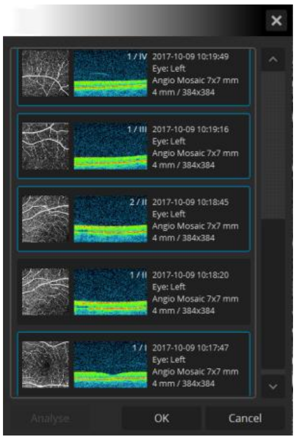


Figure 257. Select screen.

17.5.3 *Operation on the mosaic*

17.5.3.1 Operation on the whole mosaic

Zoom in/out	Press [ctrl] button and mouse scroll.
Move zoomed image	Hold left mouse button and move to smoothly change the position.
Brightness and Contrast	Press and hold the right mouse button and move the mouse up/down and left/right to adjusts the brightness and contrast of the Angiogram image.
Transparency	When Enface view or thickness map is selected mouse scroll change transparency level.

User can modify depth position of the top and bottom boundaries at once. Scroll mouse wheel to go deeper or upper from the initial position.

Right mouse menu

Inverse Inverses the color of tomograms.

Save as	Click Right mouse button and select ‘Save as...’ from menu to save mosaic image.

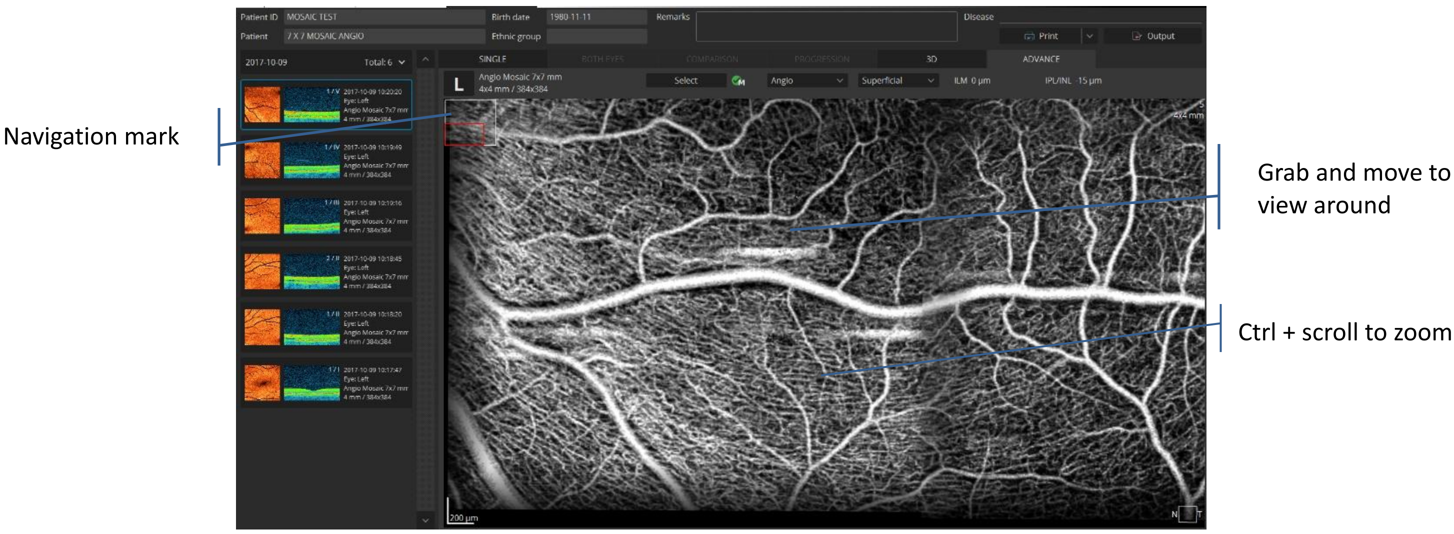


Figure 258. Advance tab – Manipulation of whole mosaic.

17.5.3.2 Operation on a single exam

Operator can modify the original position of superimpose images. Only selected exam/s can be manipulated.

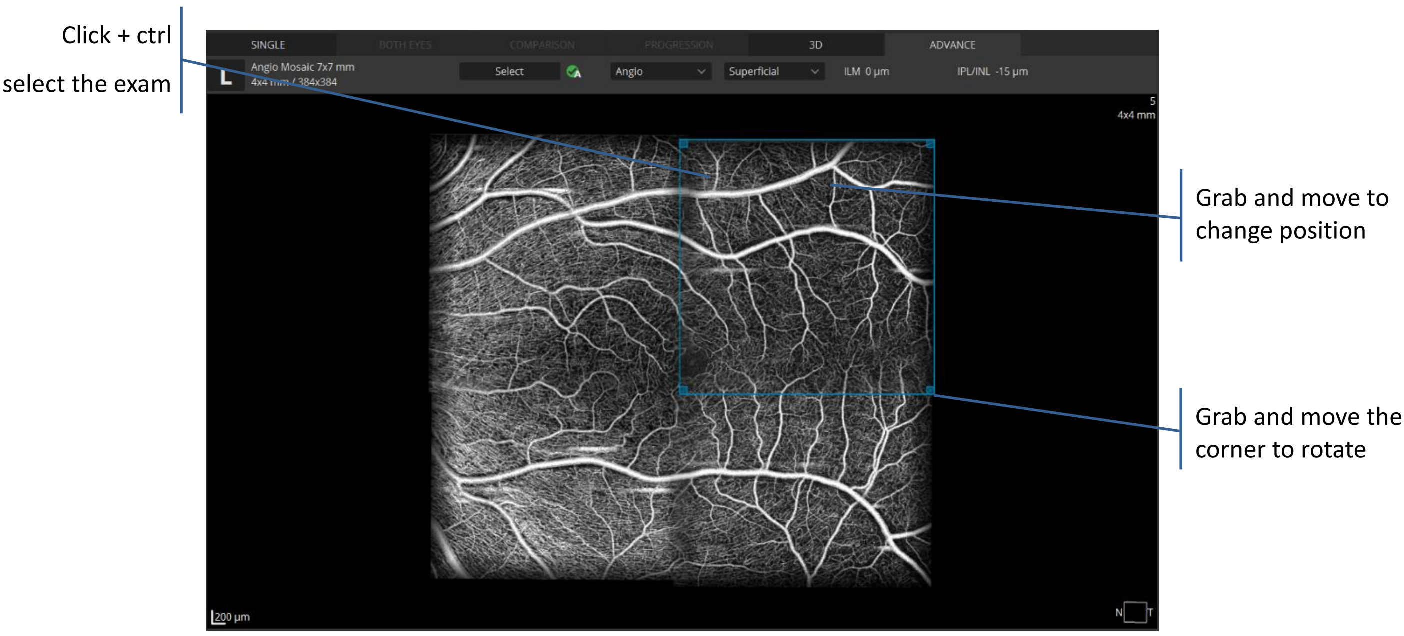


Figure 259. Advance tab – Manipulation of single image.

Select	In order to select/s exam [ctrl] keyboard and click on desired image/s. It is possible to select more than one examination.

Move	Grab and move to desired position. For precise alignment use [up]/[down]

	[right]/[left] arrows on the keyboard
Order	Use [page up] and [pg down] keyboards to changing angiogram layer order to front of layers and to back of layers.
Rotate	Grab and move the corner to rotate.

18 BIOMETRY OCT

NOTE: *Biometry OCT is optional software modules. If you do not have this feature and want to purchase it, contact Optopol's local distributor.*

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.

The software 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.

Axial length (AL) is the distance from the corneal apex to the fovea or more specifically, to the RPE (Retnal Pigment Epithelium). The calculation is performed as the sum of the thicknesses of the cornea, aqueous humor, lens, and vitreous humor and neurosensory retina.

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 (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.

WTW is the distance from limbus to limbus of the eye.

Pupil diameter –is measured horizontally through the center of the pupil

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.

WARNING!
Users must check measurement readings for plausibility. This includes the checking of the detected position boundaries on 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 take into account the type (e.g., posterior subcapsular cataract) and density of the cataract when evaluating plausibility.

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

NOTE It may not be possible, under certain circumstances, to carry out measurements on persons 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 likewise make it impossible to measure corneal thickness, anterior chamber depth, lens thickness or axial eye length.

NOTE Blood in the vitreous in cases of extremely dense cataract may make it impossible to measure the axial eye length.

NOTE Prior to the measurement, the user must verify that the patient is not wearing contact lenses. Wearing contact lenses will result in erroneous measuring results.

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

NOTE You are recommended always to examine both of the patient’s 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:

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

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

NOTE Users should check the OCT images to determine that the eye is not excessively tilted or decentered which may result in inaccurate or implausible values for measurement.

NOTE Users should verify detection on all scanned images.

NOTE Depending 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.

18.1 **Biometry Acquisition Mode**

Before a biometry examination can be carried out the operator is required to perform the initial calibration of the device. The calibration procedure is described in chapter 21 Calibration.

Prepare the patient as explained in chapter 8.1 Preparation for examination.

Ask the patient to look at the center of the green spot and blink freely if the sound support is Mute or disabled. If required, use the large fixation target. See chapter 7.8 Fixation target change.

Select biometric scan program. SOCT provides biometric scan program in Anterior tab group.

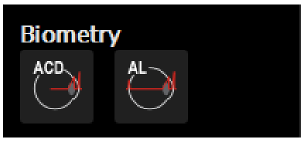
Measurement window to collect and automatically process the biometric data allows to take exams of one or both eyes of the patient. Measurement is done in two steps. First step is finding and optimizing the signal from retina, cornea and intraocular lens. In second step system acquires automatically series of tomograms. Each series contains 4 tomograms at prepared earlier positions. A single measurement can perform acquisition of 5, 10 or 15 series. Acquisition time of 5 series is around 3 seconds.

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

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

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

Biometry scan programs are available in Anterior scan list.



AL – scan provides: AL, CCT, ACD, LT

ACD – scan program provides CCT, ACD

Once scan program is selected operator has to confirm type of scanned eye.

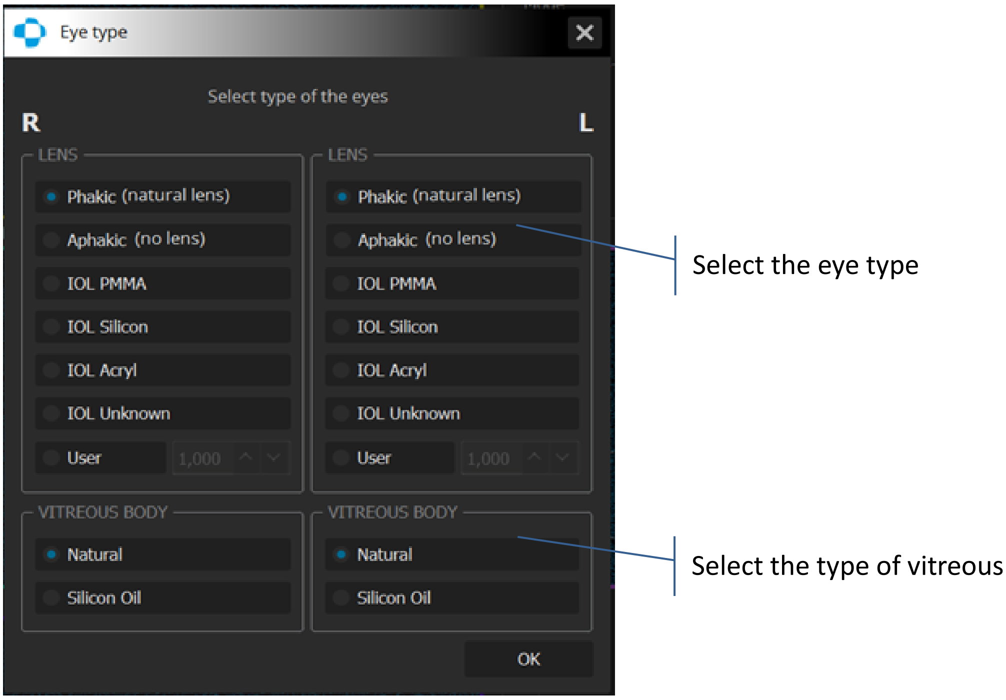


Figure 260. Type of eye selection window.

For each eye, select the type of crystalline currently present:

Phakic (natural lens) the patient has a natural crystalline lens.

Aphakic (no lens) the patient does not have any crystalline lens from birth or as a result of surgery.

Pseudophakic eye where the patient has an IOL (intra ocular lens) substituting the crystalline. In this case, it is very important to determine the type of material used by the surgeon and select one of the following option

IOL PMMA

IOL Acrylate

IOL Silicon

IOL Unknown

IOL User The user has to determine and enter the refraction index of the patient's IOL.

For the vitreous humor you can choose between:

Natural: The vitreous body has never been operated or treated such as to alter its composition.

Silicon Oil The vitreous body has been filled, even only partly, with silicon oil.

The measured axial eye length depends on the measuring mode selected. Depending on the measuring mode selected, SOCT corrects the measurement with a constant defined as follows.

SOCT takes into consideration two conditions of the eye that can alter the measurement of axial length:

- Vitreous body filled of silicone oil
- Implant of IOL intra ocular lens

The difference of 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

Phakic (natural lens)	0
Aphakic (no lens)	0.21
IOL PMMA	0.11
IOL Silicone	0.12
IOL Acrylic	0.1
IOL Unknown material	0.11

The correction values (in mm) of the vitreous body filled by Silicon Oil

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

18.1.1 *Full Auto mode*

Select the desired biometry scanning program. If required, change the number of repeats.

1. Mark the AutoAcquire checkbox and Press the START button

3. Press START button. Wait until the system finishes two phases of the examination. Patient will be voice guided by the software.

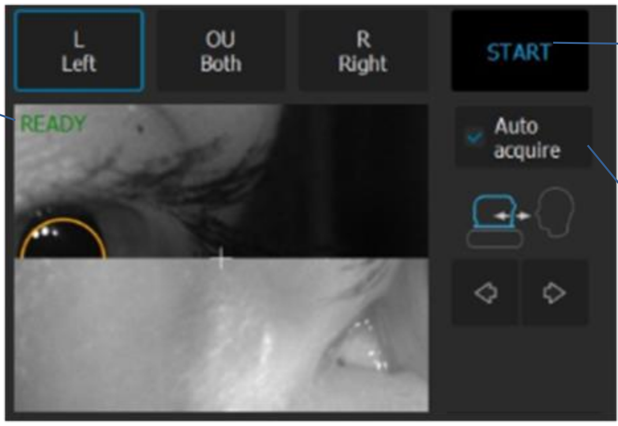


Figure 261. Full auto examination.

NOTE: There are a number of conditions in which auto functions processes could fail. For example: dense media opacities, eyelashes or eyelid which block the beam of light, inability of subjects to maintain fixation, strong nystagmus. When adverse condition occurs optimize the OCT signal manually.

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

NOTE: In case the system is not able to keep proper position of the retina (e.g. patient is shaking) operator has to switch off tracking and make examination manually.

18.1.2 *Semi Auto mode*

In nontypical and dense cataract cases it will be required for the operator to optimize signal manually. The operator is guided along the examination by text messages displayed in the tomogram preview window.

1. Uncheck [Auto Acquire]

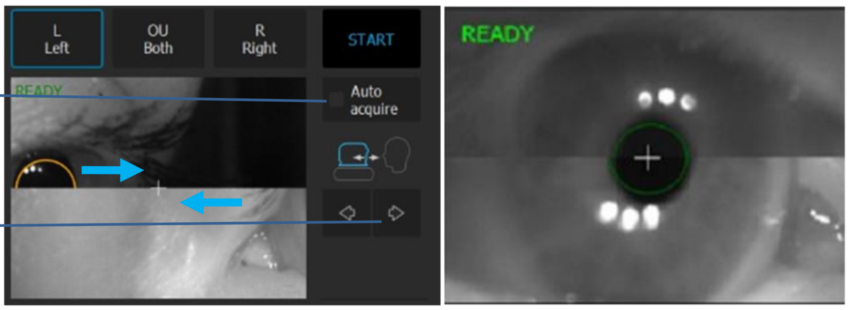


Figure 262. Manual examination mode.

2. 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. If you cannot find adjust the patient refraction value and try to find the signal one more time.
3. Some refracting correction may be needed to obtain the best quality of tomogram. Observe the QI bar in order to obtain the best signal while changing [FOCUS] bar position.
4. Verify 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.
5. Once the retina position is aligned press NEXT button.

NOTE: In dense cataract patient we can achieve only weak signal of retina. It will be enough

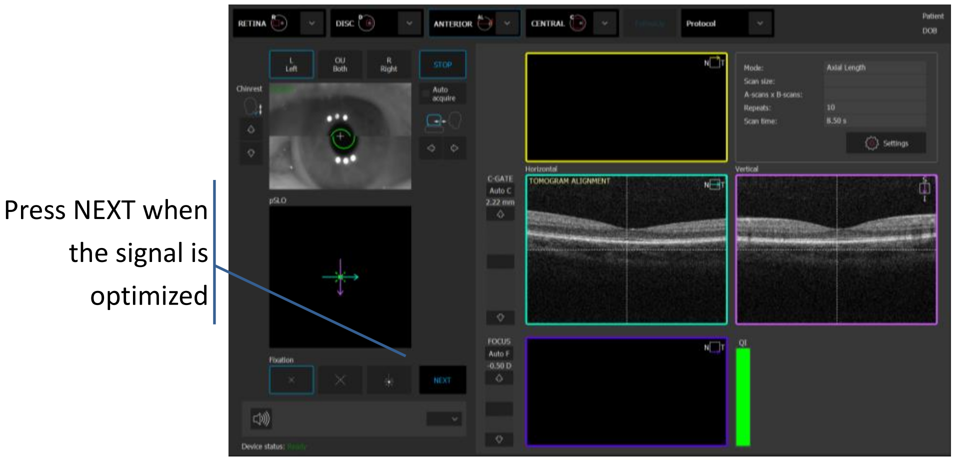


Figure 263. Manual examination process.

6. System will move to align the cornea signal. Operator can press [Start] button for automatic cornea alignment or align and optimize cornea manually as explained in chapter [8.3.6 Anterior measurement](#). Once cornea OCT image is optimized press the NEXT button.

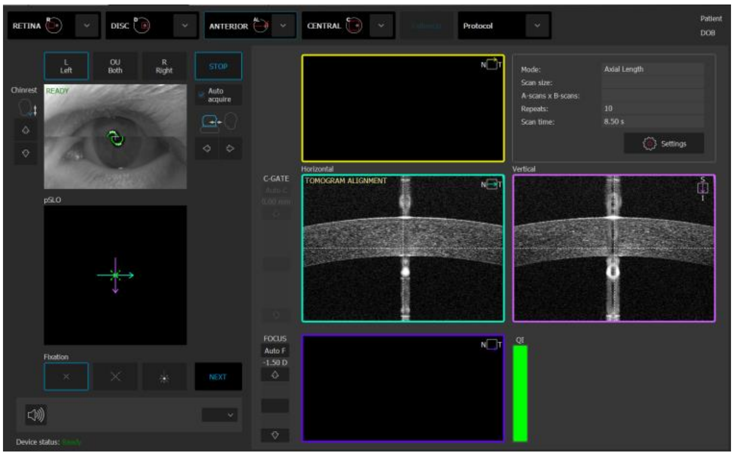


Figure 264. Proper position of the cornea.

6. System will move to align the intraocular lens or IOL if selected. Operator can press [Start] button for automatic lens alignment or align and optimize lens position manually as explained in chapter [8.3.6 Anterior measurement](#).

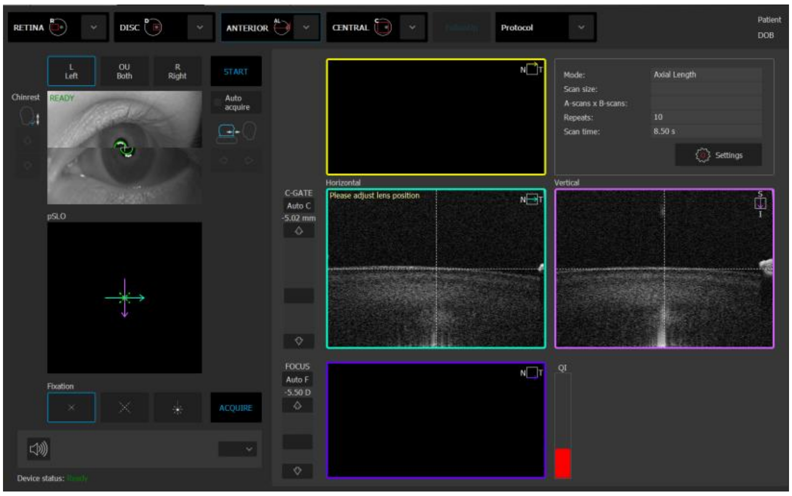


Figure 265. Proper position of the intraocular lens

7. Once Lens image is optimized ask the patient to blink and start final biometry acquisition. Click twice on the tomogram or press [Acquire] button. Device will initialize measurement immediately and then full scan will be performed.

   During biometry series acquisition patient can blink. System will reject improper measurements from calculation.

8. After examination is over the system will display acceptance window.

18.1.3 *Acceptance screen*

After capturing biometry examination system displays Acceptance window. Operator has to verify if the desired ocular structure has been scanned.

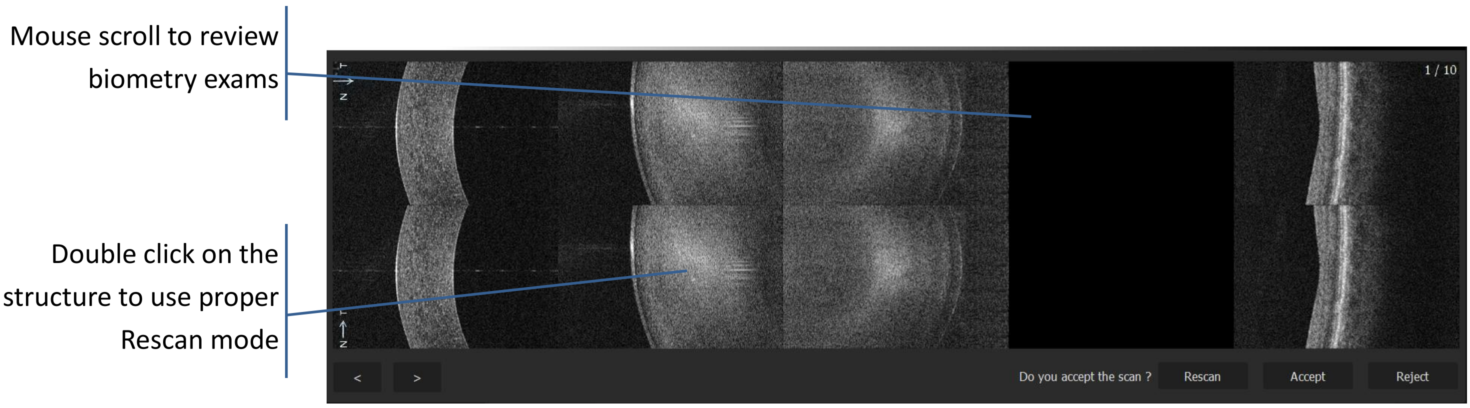


Figure 266. Biometry acceptance window

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

NOTE: When in the Acceptance window specific boundary repeat exam according to the below procedure:

The retina image is not properly visible on all tomograms Use repeat function or double click on the retina image.

- The cornea image is incorrect double click on the cornea tomogram. System repeats measurement in simplified biometry mode. It will start procedure from the cornea and will use retina data from previous scan. After adjusting the Cornea press [Next] button to align the lens.
- The front or back of the lens is not correctly visible double click on the lens tomogram. System repeats measurement in simplified biometry mode. It will start procedure from the cornea and will use retina data from previous scan. After adjusting the Cornea press [Next] button and manually align the lens position. Use C-gate slider or scroll on the tomogram window until lens image appears on the scan window. It may be required to use focus to optimize the strength of signal. In cases of very long lenses place image of front of the lens higher than on originally dashed lines and lower for shorter lenses. System behaves differently for natural and intra ocular lenses.
- the half of series you cannot see requested boundaries use [Repeat] function to repeat the series.

[<] [>]	Press arrow button to change displayed image.
Rescan	Come back to the Acquisition of scan. Examination is saved in database.
Accept	Save examination
Reject	Come back to Acquisition window. Examination is not stored.

18.1.4 *White to White*

White to White (WTW) is a measurement of the distance from limbus to limbus. The measurement yields two values:

1. White to White – the distance form limbus to limbus measured horizontally through the center of the pupil.
2. 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.

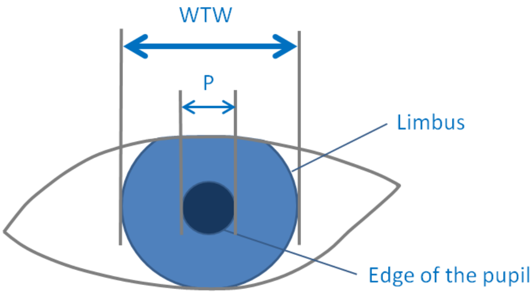


Figure 267. WTW and P measurement ranges

CAUTION The white-to-white 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 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 268. WTW and P measurement result table

The user can make adjustments to WTW and P results. After the circular WTW and P indicators are modified manually, they change color to blue and the results in the WTW and P table are marked by the * symbol.

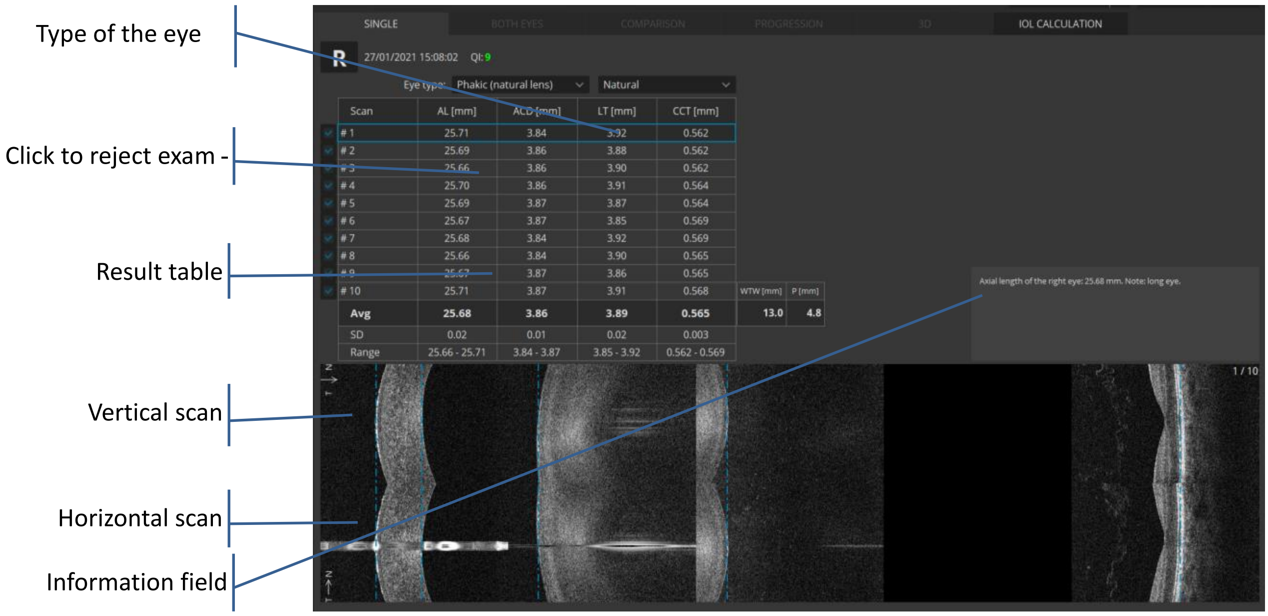
Editing WTW and P parameters is described in section 18.1.4. White to White

18.2 **Result review**

In order to be 100% sure of the validity of the results, it is recommended to review all series of measurements and their values with the corresponding boundary detection of the signal on the tomograms. In order to make manual correction of boundaries open Full screen by double click on tomogram from the Single or Both view.

18.2.1 *Single view*

Figure 269. Biometry Single view



<u>Type of the eye</u>

Depending the type of eye results may vary.

<u>Table</u>

Shows a table with the number of acquisitions in rows. Table containing Biometric results of each biometry series, the standard deviation and the average value.

<u>Checkbox</u>

Uncheck to exclude biometric exam from series. Excluded results are rejected from AVG and SD analysis.

<u>Horizontal/Vertical tomograms</u>

Operation similar to standard tomogram window. Zoom in/out, Brightness & Contrast manipulation, color display mode, Right click menus are available as on the standard tomogram window.

Reset Brightness/contrast

Gray

Colored

Inverse

Save as… Saves the composed image

18.2.1.1 Table

In the table system displays result of each measurement.

In the rows data from examination series are displayed.

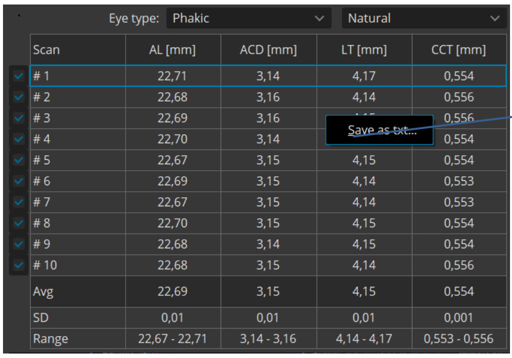
In the column there are results of specific parameters.

AVG – calculated averaged value for specific parameters. Only highlighted examinations are included for calculation.

SD – Standard deviation from calculated for highlighted data

In the table system marks measurement.

(!) 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 Topography and Biometry table enables exporting the data as a .txt file.



Scan	AL [mm]	ACD [mm]	LT [mm]	CCT [mm]
# 1	22,71	3,14	4,17	0,554
# 2	22,68	3,16	4,14	0,556
# 3	22,69	3,16	[illegible]	0,556
# 4	22,70	3,14	[illegible]	0,554
# 5	22,67	3,15	4,15	0,554
# 6	22,69	3,15	4,14	0,553
# 7	22,67	3,15	4,14	0,553
# 8	22,70	3,15	4,15	0,554
# 9	22,68	3,14	4,15	0,554
# 10	22,68	3,15	4,14	0,556
Avg	22,69	3,15	4,15	0,554
SD	0,01	0,01	0,01	0,001
Range	22,67 - 22,71	3,14 - 3,16	4,14 - 4,17	0,553 - 0,556

Right click on the Biometry results shows [Save as txt…]

18.2.2 *Both view*

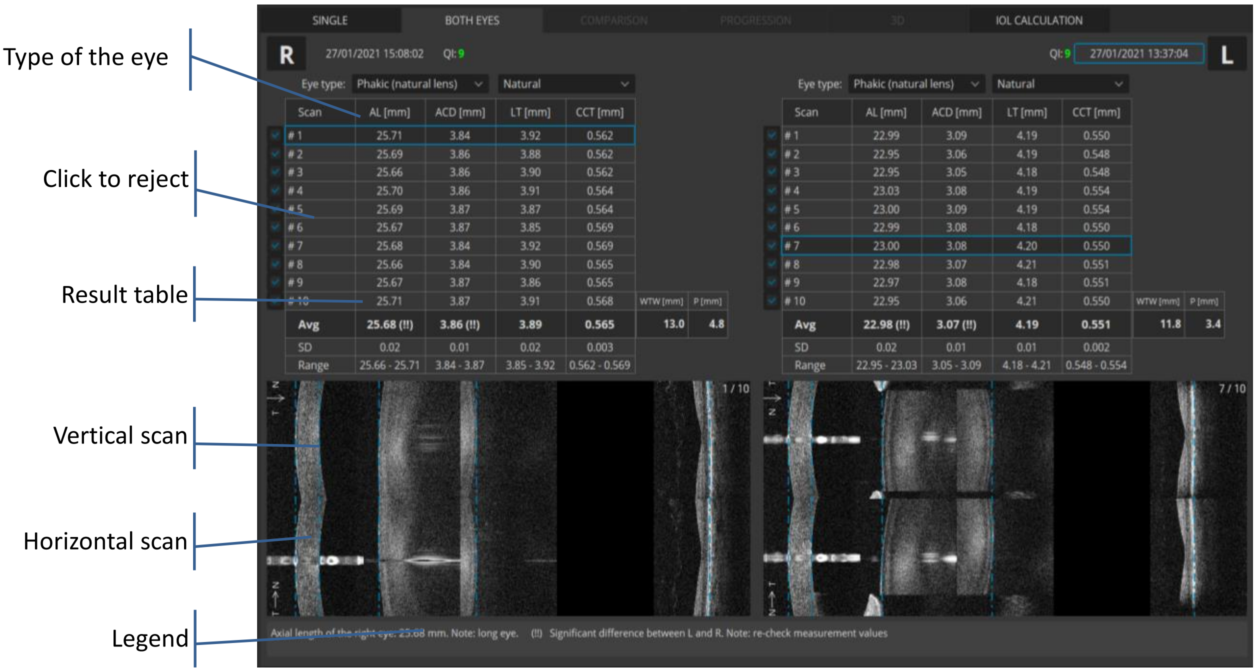


Figure 270. Biometry Both view

18.2.3*Full screen*

SOCT provides Full screen window to manually edit the values obtained. There may be instances of detecting the wrong boundaries, especially in the posterior of the lens as well as the retinal position. User can visually adjust the value by positioning the line-markers on the tomogram image and signal graph. Signal graph shows the value marked by horizontal line.

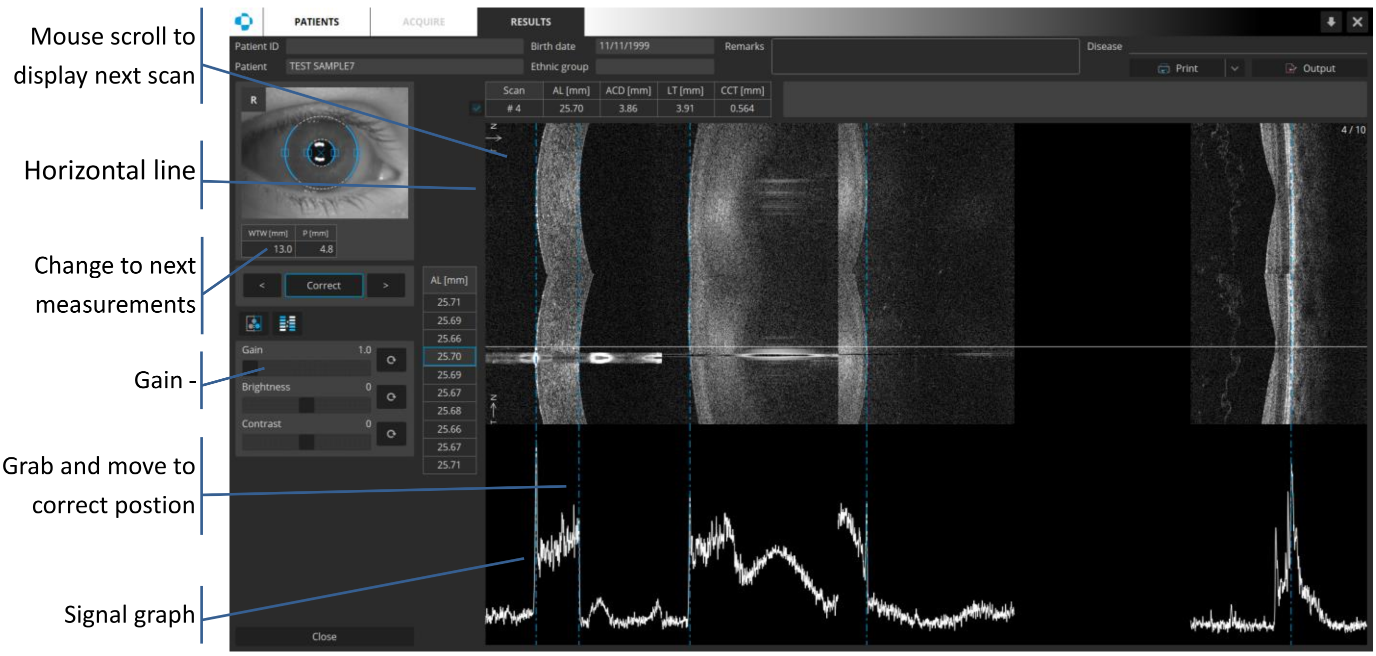


Figure 271. Biometry Full screen window

18.2.3.1 Editing distances

[<] [>] Press the arrow button to change displayed image.

Gain Amplify strength of intensity signal graph

Signal graph Display intensity of A-scans along composed tomogram. It displays result identify by horizontal line.

The operator can edit the distance by dragging the line markers to the desired location determined to be adequate.

Moving the line-markers automatically adjusts the values for distance calculation for all the related parameters and their SD and average value. Adjusted parameters will be shown with a caution (*) notation. In order to provide more control to the operator, a zoom-in & zoom is available.

Editing WTW and P

Double click on the Eye preview window to open editor. If required grab and move holder to desired position.

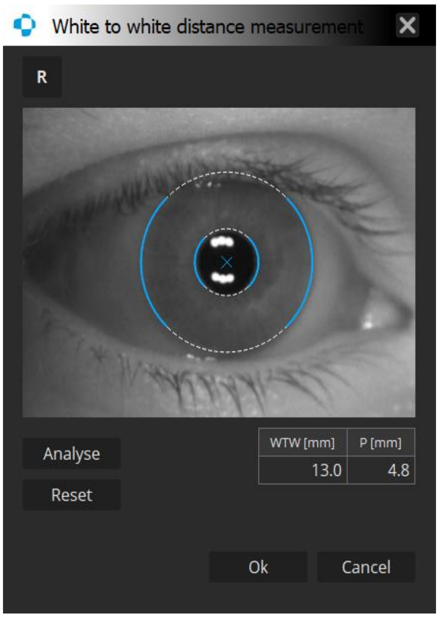


Figure 272. White to white distance measurement window

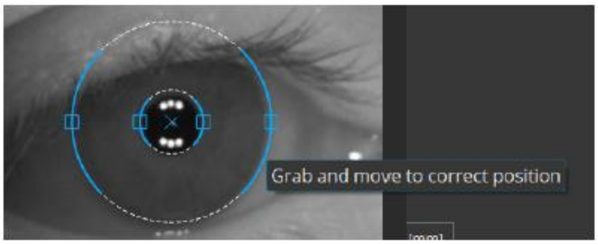


Figure 273. Editing WTW and P results – eye preview

To edit WTW and P grab any of the blue squares and move it to increase or decrease the diameter of the circles. You can zoom in and out the eye preview with the Ctrl key + scroll combination.

19 IOL CALCULATION TAB

IOL Calculation Tab allows the user to calculate the lens power of a selected IOL model on the basis of the patient's morphological data (AL, K's, ACD) and a IOL formula selected by the user.

Before staring work with the calculation tool, the user needs to enter IOL lens data in section 19.3 IOL Editor.

Running IOL calculations requires an active 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 Section 21.3 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 at all times. 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! 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, pupilometry and the white-to-white distance values. Performing a plausibility check is especially important if any of the measurements shows an unusually high standard deviation. Also, the characteristics of the cataract such as the type (for example posterior subcapsular cataract) and density must be taken into account.

WARNING! The measurements taken with REVO 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 devices only IOL constants optimised for optical biometers should be used. Please contact your IOL manufacturer for information on optimised IOL constants for optical biometry.

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

WARNING! Using data from acoustic instruments also requires the constant of every IOL to be optimized for those kinds of instrument. At present, it is more common to find online only databases of lenses optimized for optical interferometry instruments.

Note: Only biometry exam with valid calibration allows to open IOL Calculation tab.

Biometry results with an NG status are not available in the IOL Calculation Tab.

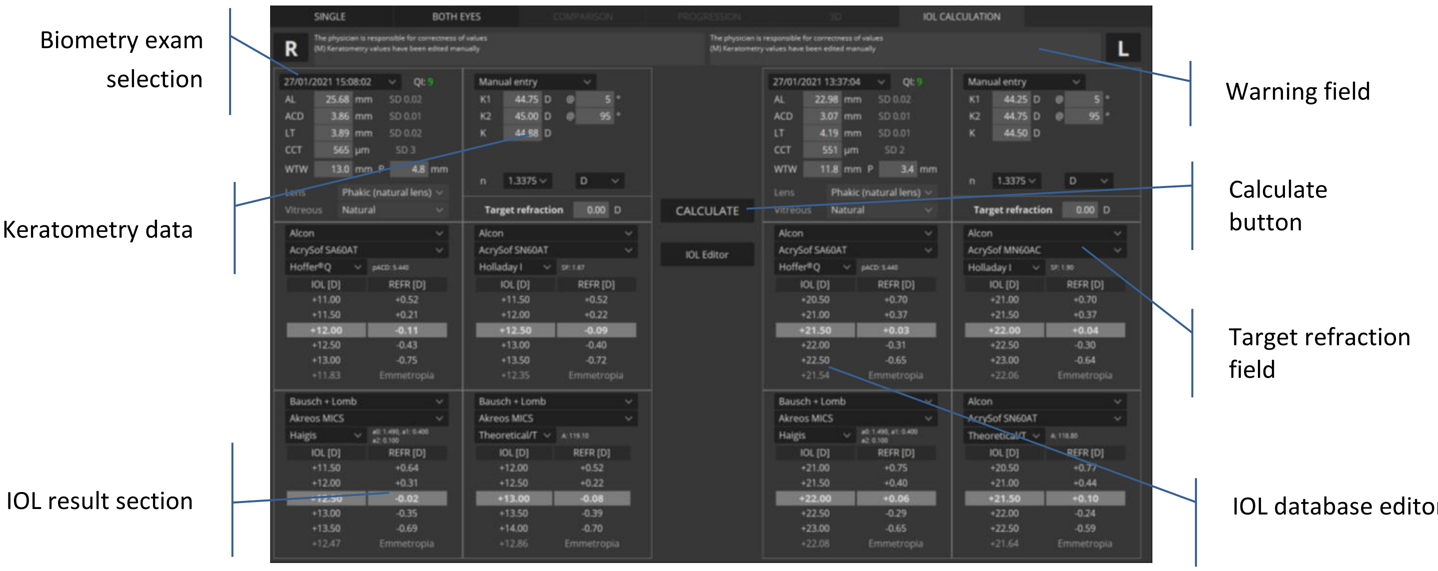


Figure 274. IOL Calculation Tab

19.1 **Performing IOL calculation**

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 keratometric data. To calculate IOL parameters it is also necessary to provide the target refraction value after the IOL exchange procedure. Click on the target refraction value field and enter the target value.

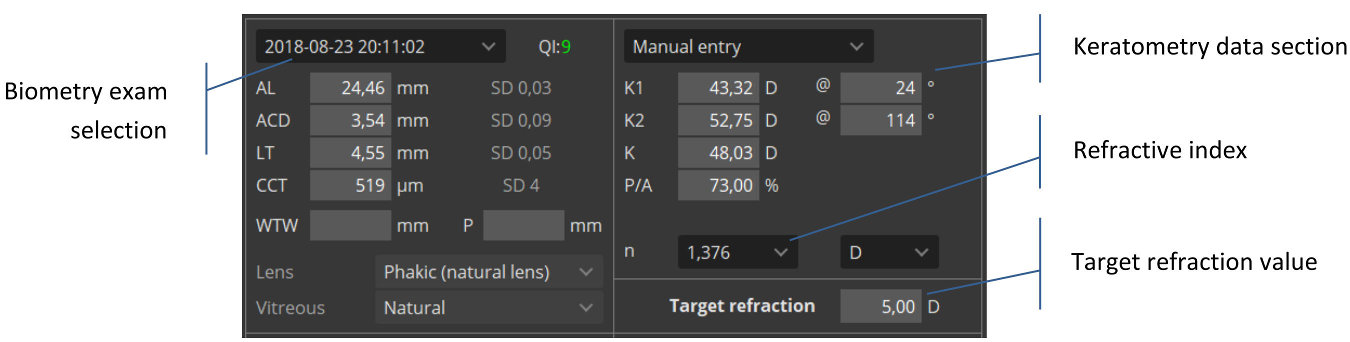


Figure 275. Entering biometry and keratometry data

Choose the IOL manufacturer and model by clicking on the drop-down menus as shown below. Similarly, specify the calculation formula.

You can choose from the following IOL power calculation formulas:

- **Hoffer®Q**[13]
- **Holladay I**[14]
- **Haigis**[15]
- **Theoretical/T**[16]
- **Regression II**[17]

For each eye, the user can choose even 4 formulas at the same time. Next click [Calculate] in the center of the Calculation Tab. The result of the calculation will be displayed in the results table in 6 lines. The third line presents the value closest to the target refraction. The two lines above and below the third line show lower and higher values respectively. The line at the bottom presents the value of Emmetropia.

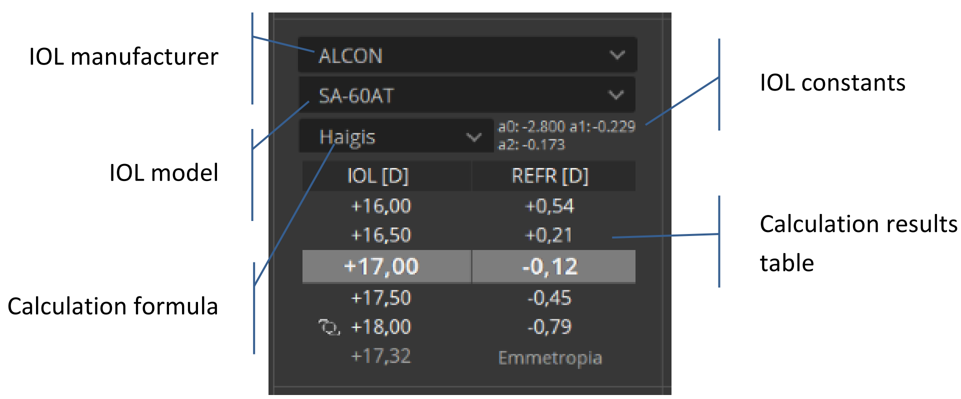


Figure 276. IOL Calculation results table

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[13] 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.

[14] 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.

[15] Haigis W. The Haigis formula. In: Shammas HJ ed. Intraocular Lens Power Calculations. Thorofare, NJ: Slack, Inc.; 2004:41–57.

[16] Based on the idea of the Development of the Theoretical intraocular lens implant power calculation.

[17] Second generation IOL formula which is now expired.

WARNING! The user chooses calculation parameters at their own discretion. The responsibility for the chosen parameters and the interpretation of results lies on the user.

CAUTION To ensure plausibility of 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.

19.2 Marking implemented lenses

You can mark two lenses, one for each eye. To do that click the right mouse button on the value you wish to mark to unfold a drop-down menu and choose *Select IOL*. Clicking *Remove IOL Selector* reverses the operation. The marked lens is identified by the sign which is also present on printout.

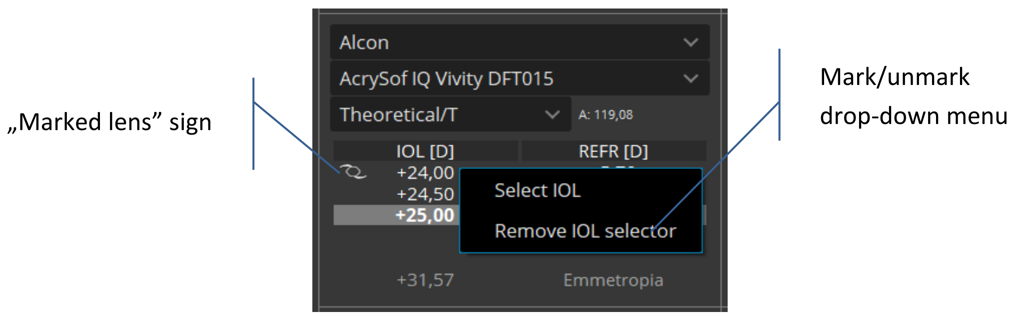


Figure 277. Marking lenses

19.3 IOL Editor

The IOL Editor window is where the user can import and export IOL data or edit data already present in the system. To go to the window, click the “IOL Editor” button in the center of the IOL Tab. Lenses tree on the left side of the window lists all available lenses sorted by manufacturer. The right-hand side of the window is the IOL constants editing section.

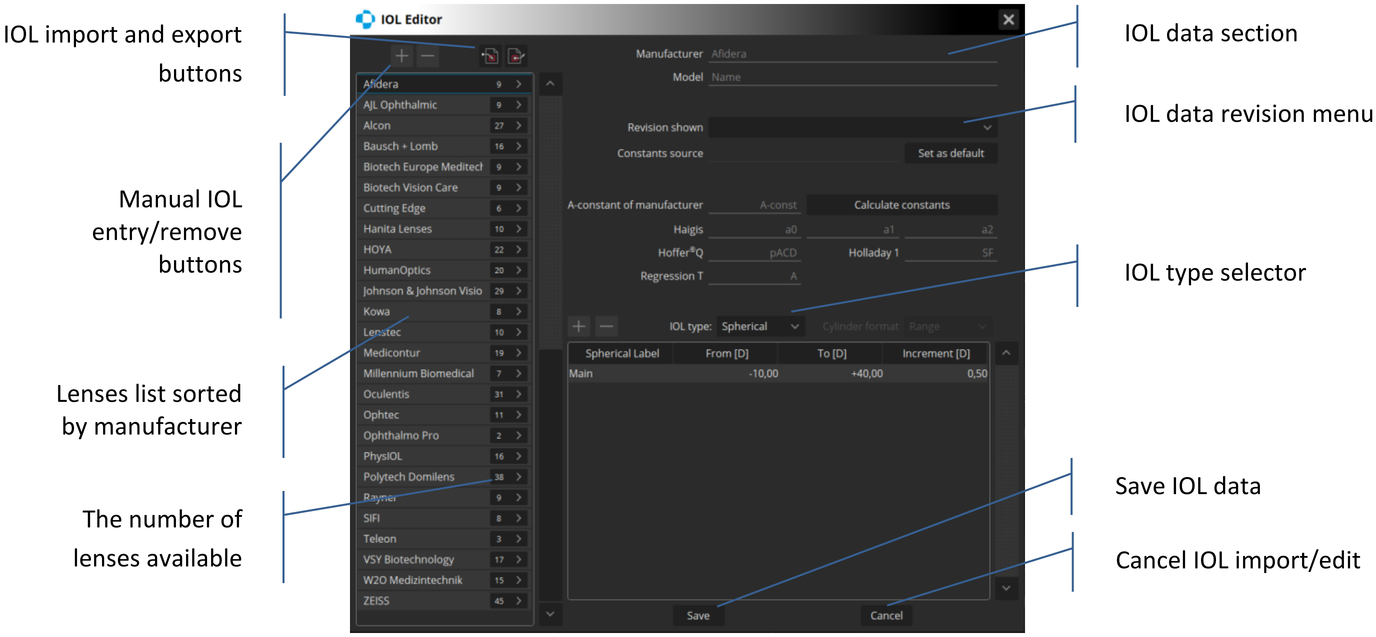


Figure 278. IOL Editor window

19.3.1 *Importing IOL data*

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

CAUTION The measurements taken with REVO 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 devices 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 data in the .mdb (ULIB), .xml (IOLcon) or .odb (Optolpol Database) format click the import button  and choose the data file to be imported.

19.3.2 *Exporting IOL data*

To export the full database or a single lens in the .odb (Optopol Database) format click the export button .

19.3.3 *Adding lenses manually*

In order 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.

19.3.4 *Deleting lenses manually*

If you want 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.

19.3.5 *Viewing the list of lenses*

In order to unfold the list of lenses by a chosen manufacturer double click the manufacturer's name. The list unfolds showing available lenses together with their type information. 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.

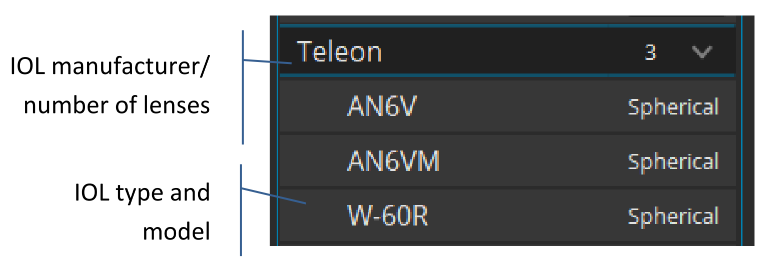
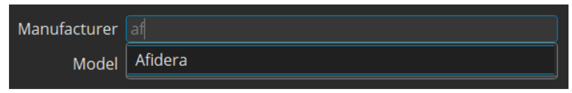


Figure 279. List of lenses in the IOL Editor window

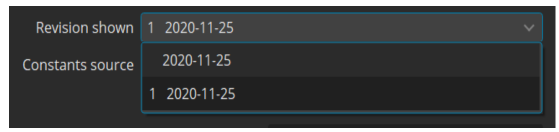
19.3.6 *Editing IOL data*

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.

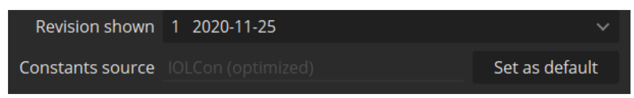


Revision shown drop-down menu allows the user to choose the revision of IOL data they wish to use for calculation. A new revision is created whenever the user introduces changes to the data and saves them by clicking [Save] at the bottom of the window. Consecutive IOL revisions are indicated by a number 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 manufacturer enter the A-constant value in the *A-const* field and click [Calculate constants].

CAUTION Remember that the A-constant is an estimate and should only be used for reference if no better constants are available. Use only IOL constants optimized for optical biometers.

CAUTION The software for taking measurements and performing calculations must be operated only be appropriately trained and experienced staff with knowledge suitable for interpreting the results. All members of the stuff must read this user manual thoroughly, paying special attention to the safety related points and instructions.

NOTE The user should always seek to ever 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 3 months after the surgery.

19.3.7 *Adding additional power ranges and increments*

The default power range in the IOL Editor window is -10 to +40 dioptres with the increment of 0.5 dioptres. It is also 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 you wish to modify and enter a new value. To remove a power range, click on it to highlight it and then click .

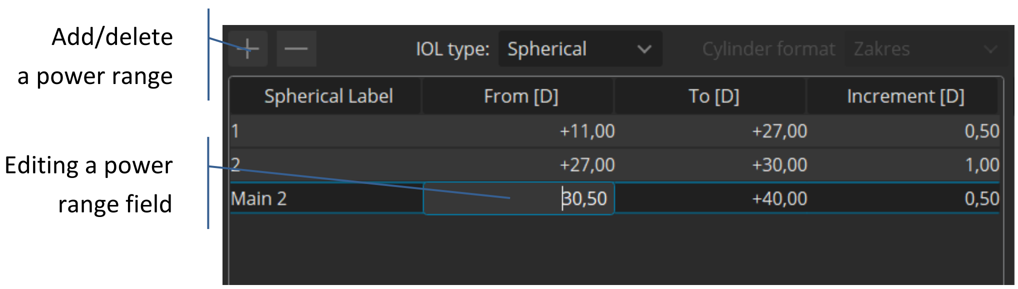


Figure 280. Adding additional power ranges and increments

Using a toric IOL requires the user to provide both the corneal astigmatism range and the cylinder power.

20 TOPOGRAPHY OCT[18]

NOTE: Biometry and Topography are optional software modules. If you do not have this feature and want to purchase it, contact Optopol's local distributor.

Topography module provides the analysis of both surfaces based on Corneal Curvature, Dioptric power, Elevation and Real power analysis based on both surfaces and local cornea thickness (Ray tracing).

Topography scan program is available in Anterior scan list. It has fixed scan parameters: 16 B scans, 8 mm width. Scan time: 0.17 sec. (0.3 for REVO 60).

20.1 Topography - Safety Notes

⚠ **NOTE**: Allow only well-trained operators to use the topography module

⚠ **NOTE**: Layers recognition is used for tracing.

⚠ **NOTE**: Fully examine the measured data for layer recognition results. In particular, if the difference between the 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 tracing and/or reliability on the check screen. If the measurement result is not conclusive, review the inspection result by performing another measurement or inspection.

⚠ **NOTE**: When using data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking measurements multiple times and/or conducting other examinations.

⚠ **NOTE**: When using the data taken by this instrument to select intraocular lenses, thoroughly determine the selection by also examining cataract surgery methods and other inspections. 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, thoroughly determine the selection by also examining surgery methods and other inspections. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or severe complication such as keratectasia.

[18] OCT Topography is an optional feature. It is available as an upgrade purchased separately.

NOTE: Since simultaneous use of multiple devices can cause misdiagnosis or result in a hazardous situation, exercise caution when using this instrument

NOTE: Fully examine the measured data for tracing results. In particular, if the difference between measurement values for the left and right eyes is significant or any problem is found on the anterior chamber during the preliminary examination, check the tracing and/or reliability on the check screen. If the measurement result is not conclusive, review the inspection result by performing measurement again or performing another inspection.

NOTE: It may be difficult to trace the border when capturing an image of an eye with opacity or malformation such as corneal disease, shallow anterior chamber, aphakic eye, pseudophakic eye or dense cataract eye.

NOTE: The following artifact may appear on the OCT image, but this does not indicate any failure.

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

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

NOTE: When using the data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking measurements multiple times and/or conducting other examinations.

NOTE: When using this instrument to select intraocular lenses, thoroughly determine the selection by also examining cataract surgery methods and performing other inspections. 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, thoroughly determine the selection by also examining surgery methods and performing other inspections. Refractive correction surgery conducted according to incorrect measurements or analysis results may result in further surgery or severe complication such as keratectasia.

NOTE: When using the anterior adapter, do not move the head too fast and monitor the proximity to the patient in order to avoid hitting the patient’s eye incidentally with the Anterior adapter lens surface.

NOTE: Ensure that the scanning head is in maximum backward position and the patient will not incidentally hit the anterior adapter.

CAUTION: Be careful when mounting the anterior adapter in order not to scratch the objective lens.

NOTE: When using the anterior adapter, do not move the head too fast and monitor proximity to the patient in order to avoid hitting the patient's eye incidentally with the Anterior adapter lens surface.

NOTE: Ensure that scanning head is in maximum backward position and the patient will not incidentally hit the anterior adapter.

CAUTION: Be careful when mounting the anterior adapter in order not to scratch the objective lens.

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

20.2 **Topography Acquisition Mode**

1. Prepare the patient as explained in chapter [8.1 Preparation for examination](#).
2. Ask the patient to look at the center of the green spot and blink freely if the sound support is Mute or disabled. If required, use the large fixation target. See chapter [7.8 Fixation target change](#).
3. Select the Topography scan program.

Once the scan program is selected the topography acquire window is available.

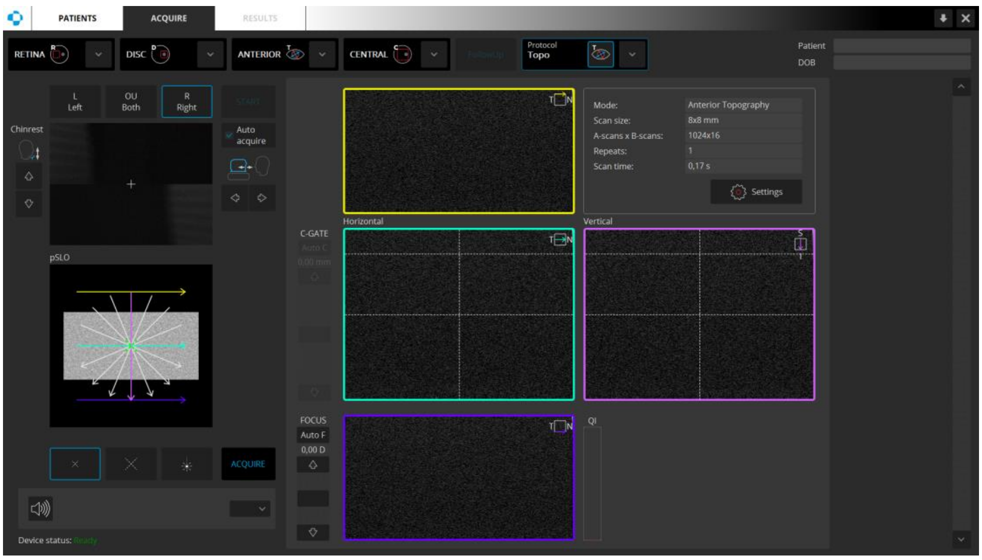


Figure 281. Topography acquire window

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.

Operator should make sure that the lids of the eye are not blocking or shadowing a significant portion of the image in vertical meridians.

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.

4. After the result is acquired, it is displayed in the Acceptance window. The operator should verify the measurement reliability indexes. A measurement with poor measurement reliability indicates an increased risk of measurement variability. Measurements with poor reliability should be replaced.
5. Follow the procedure depending on the Acquisition mode.

20.2.1 *Full Auto mode*

1. Mark AutoAcquire checkbox and Press the START button
2. Wait until the system finishes the examination. The patient will be voice guided by the software.

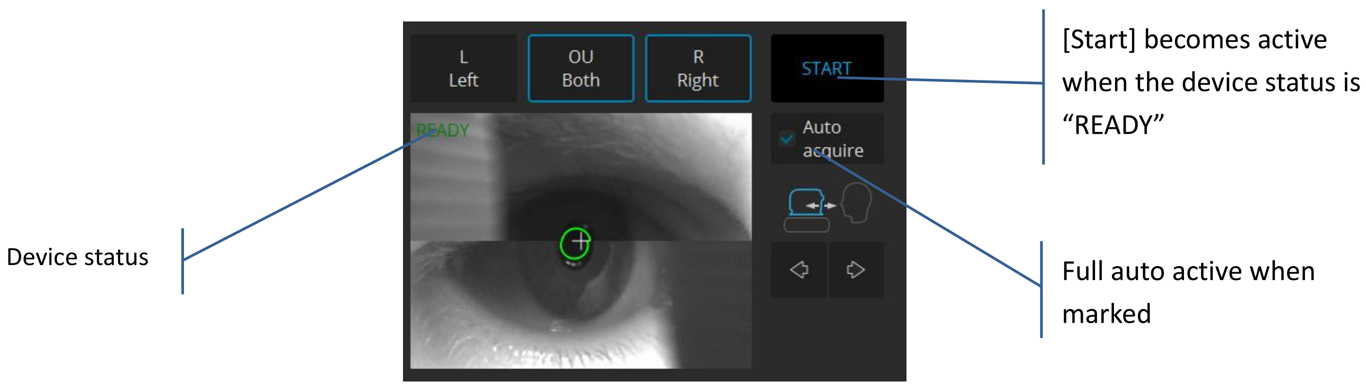


Figure 282. Full auto examination

NOTE: There are a number of conditions in which auto functions processes could fail. For example: dense media opacities, eyelashes or eyelids blocking the beam of light, inability of subjects to maintain fixation, strong nystagmus. When an adverse condition occurs optimize the OCT signal manually.

NOTE: If the system does not detect the pupil, the user has to adjust the center of the patient's pupil manually. In order to set the working position properly, align the center of the pupil on a proper height.

NOTE: In case the system is not able to keep the proper position of the retina (e.g. the patient is shaking) the operator needs to switch off tracking and do the examination manually.

20.2.2 *Semi Auto mode*

1. Uncheck [Auto Acquire]

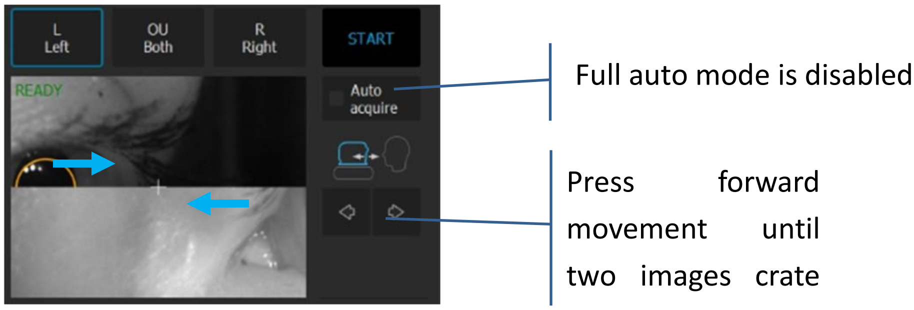


Figure 283. Manual examination mode

2. 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 you cannot find cornea OCT signal adjust the patient refraction value and try to find the signal once more.
3. Some refracting correction may be needed to obtain the best tomogram quality. Observe the QI bar in order 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 whenever possible.
5. Once the cornea position is aligned ask the patient to blink and start the final topography acquisition. Click twice on the tomogram or press the [Acquire] button. The device will initialize the measurement immediately to perform a full scan.

Figure 284. Manual examination process

6. After the examination is over the system will display an acceptance screen.

20.2.3 *Acceptance screen*

After capturing a topography examination the system checks if all measurement parameters are on an acceptable level. If any of them is not, the system displays an Acceptance window.

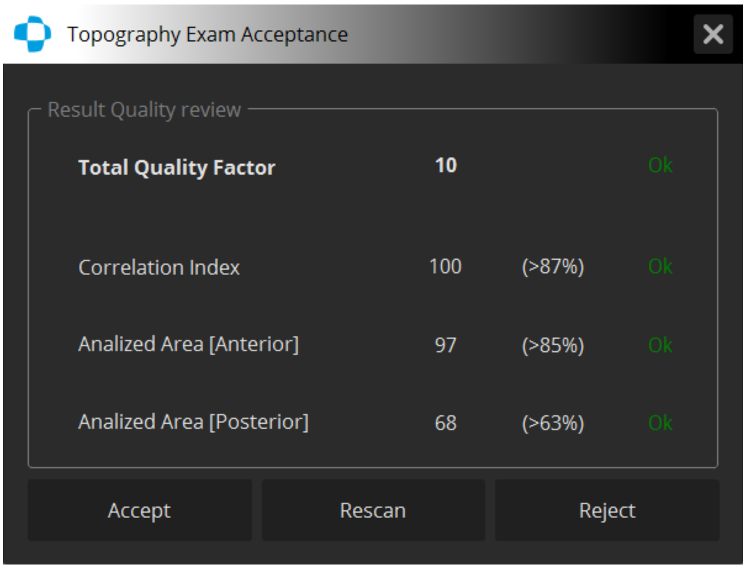


Figure 285. Topography Exam Acceptance window

[Rescan] – the examination is saved with the NG information. The system is ready to repeat the examination.

[Accept] - the examination is saved.

[Reject] - the examination is rejected 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 Auto Acquire check is selected the system automatically acquires a scan.

20.2.4 *Total Quality Factor*

Total Quality Factor – a summary factor that determines whether the operator can trust the measurement. The total 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 condition to the recognized area in the anterior and posterior. It is expressed in %

A AA – [Anterior Analyzed Area] –

OK	[Accepted]	>85 %	
!	[Borderline]	84> to >65%	
NG	[Not correlated]	Not correlated to	<64%

P AA – [Posterior Analyzed Area]

OK	[Accepted]	>63 %	
!	[Borderline]	63> to >41%	
NG	[Not correlated]	Not correlated to	<40%

Artifact– this warning appears when on 3 consecutive scans the system detects places where the recognition algorithm has uncertainty sections. This problem makes it possible to to detect artefacts relate to the close Eyelid, ghost signal from the iris, lack of signal due to long eyelashes or decreasing the signal due opacity in the cornea.

Results for the Topography scan are not displayed for scans with poor quality in which an algorithm failed. In this case, the scan should be repeated.

For clinical use, it is recommended for the user to take at least three corneal power scans and calculate mean corneal power for further measurement variability reduction.

20.3 **Result review**

20.3.1*[Single] view*

The overview display is a compilation of several evaluation representations which gives a quick overview of the anterior eye segment being measured.

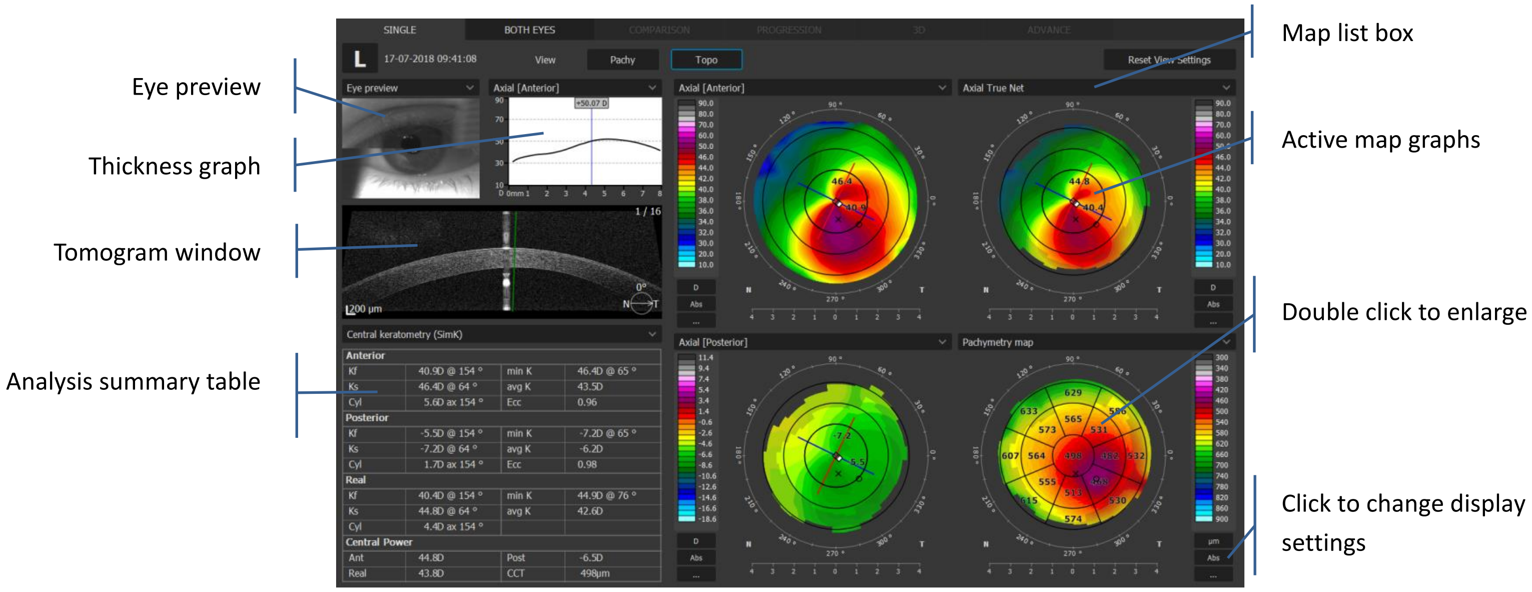


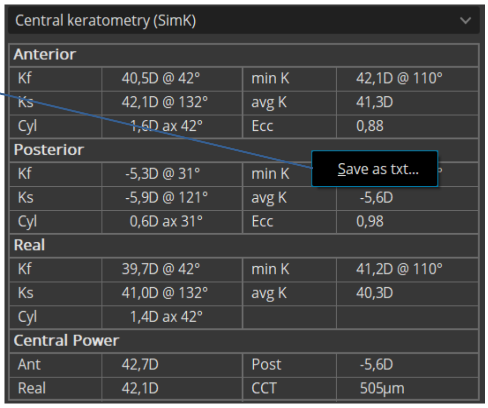
Figure 286. Single Topography view

At the topography window the user can select one of the predefined maps from the list box:

- Axial [Anterior]
- Axial [Posterior]
- Refractive Power map [Kerato]
- Refractive Power map [Anterior]
- Refractive Power map [Posterior]
- Refractive Power map [Total]
- Tangential map [Anterior]
- Tangential map [Posterior]
- Net Map
- Axial True Net
- Equivalent Keratometer
- Elevation Map [Anterior]
- Elevation Map [Posterior]
- Height map
- Pachymetry
- Epithelium

Clicking the right mouse button on the results Topography and Biometry table enables exporting the data as a .txt file.

Right click on the Topography results shows [Save as txt...]



Central keratometry (SimK)

Anterior			
Kf	40,5D @ 42°	min K	42,1D @ 110°
Ks	42,1D @ 132°	avg K	41,3D
Cyl	1,6D ax 42°	Ecc	0,88
Posterior			
Kf	-5,3D @ 31°	min K	
Ks	-5,9D @ 121°	avg K	-5,6D
Cyl	0,6D ax 31°	Ecc	0,98
Real			
Kf	39,7D @ 42°	min K	41,2D @ 110°
Ks	41,0D @ 132°	avg K	40,3D
Cyl	1,4D ax 42°		
Central Power			
Ant	42,7D	Post	-5,6D
Real	42,1D	CCT	505µm

20.3.1.1 Enlarged detailed map view

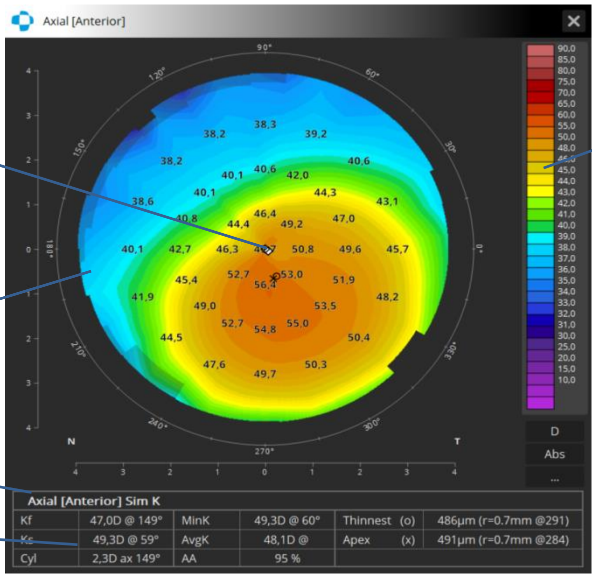
Double click on the active map for a new window with an enlarged detailed map.

The tip of the cornea

Click in any point to display the value

Map type

Analysis summary table



Scale

Figure 287. Enlarged detailed Topography map view

20.3.2 *[Both] view*

This screen shows the analysis results comparing examinations of both eyes performed in the same scan mode and on the same date.

Active map graphs

Analysis summary table:

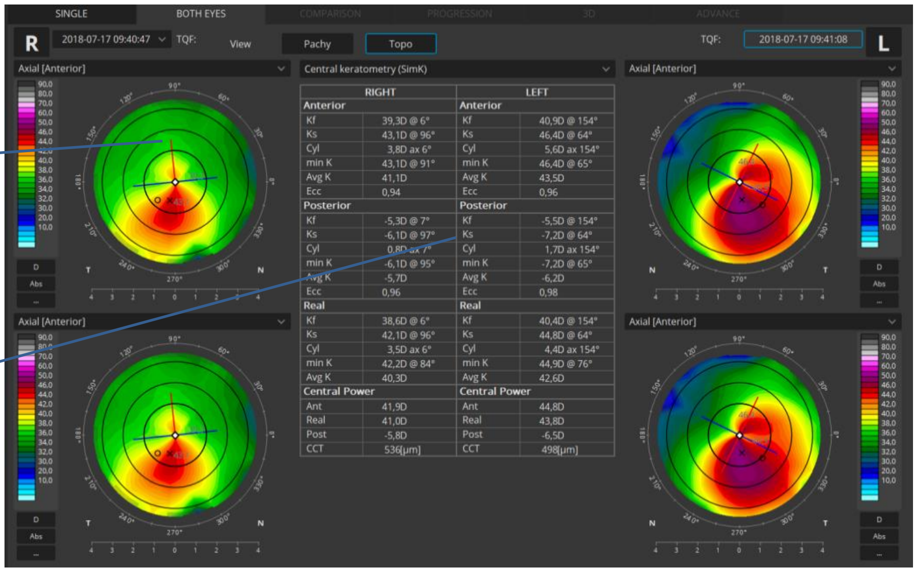


Figure 288. Both Topography view

20.3.3 *[Comparison] 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.

Analysis summary table

Active map graphs

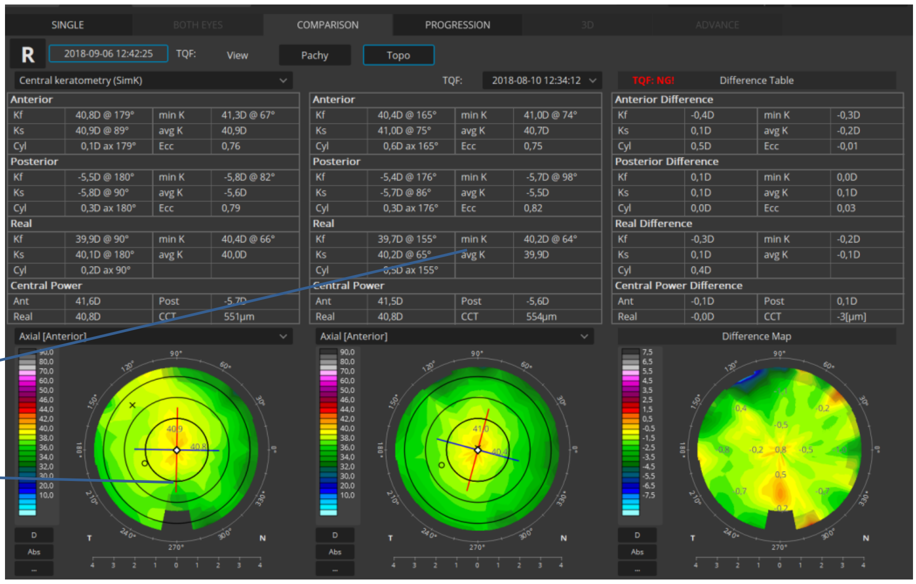


Figure 289. Comparison Topography view

20.3.4 *[Progression] 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.

Active map graphs

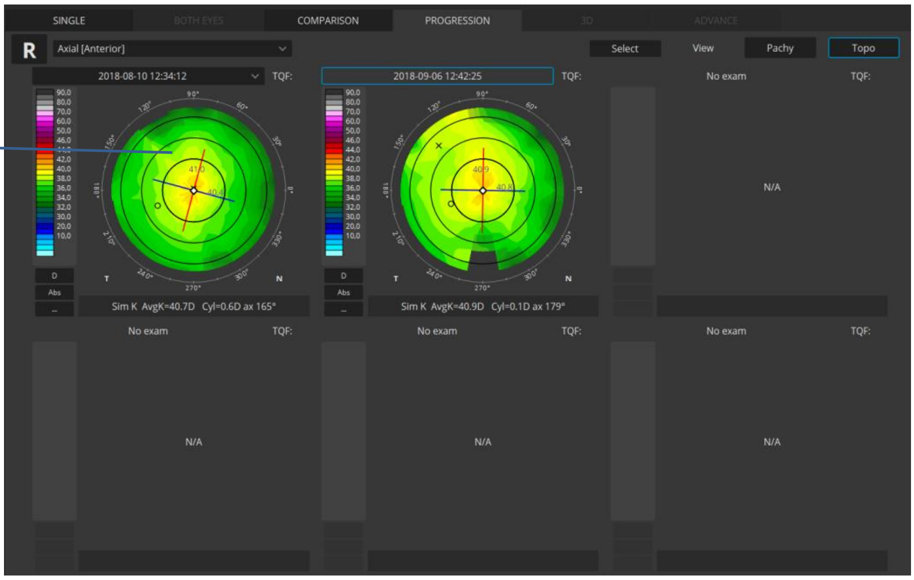


Figure 290. Progression Topography view

20.4 **Analysis**

20.4.1 *Central Keratometry – SimK*

It displays the Simulated Keratometry values from the central area bases on Axial map.

Central keratometry (SimK)

Anterior			
Kf	41,3D @ 144°	min K	41,8D @ 56°
Ks	41,8D @ 54°	avg K	41,5D
Cyl	0,5D ax 144°	Ecc	0,69
Posterior			
Kf	-5,6D @ 10°	min K	-5,9D @ 98°
Ks	-5,9D @ 100°	avg K	-5,7D
Cyl	0,2D ax 10°	Ecc	0,69
Real			
Kf	40,4D @ 144°	min K	41,0D @ 31°
Ks	40,9D @ 54°	avg K	40,7D
Cyl	0,5D ax 144°		
Central Power			
Ant	42,7D	Post	-5,7D
Real	42,0D	CCT	601µm

20.4.2 *Keratometry (Meridian)*

It calculates Astigmatism base on the mean diameter in each zone. Steep Axis is read as 90^0 shift from flat axis. Calculation bases on Axial map.

Keratometry (Meridian)		
Ø 3mm	**Anterior**	**Posterior**
Kf	42,3D @ 178°	-5,6D @ 10°
Ks	42,9D @ 88°	-5,8D @ 100°
Cyl	0,6D ax 178°	0,2D ax 10°
Avg	42,6D	-5,7D
Ø 5mm	**Anterior**	**Posterior**
Kf	40,6D @ 144°	-5,7D @ 10°
Ks	40,9D @ 54°	-5,9D @ 100°
Cyl	0,3D ax 144°	0,2D ax 10°
Avg	40,8D	-5,8D
Ø 7mm	**Anterior**	**Posterior**
Kf	39,7D @ 89°	-5,6D @ 10°
Ks	40,0D @ 179°	-5,8D @ 100°
Cyl	0,3D ax 89°	0,2D ax 10°
Avg	39,8D	-5,7D

20.4.3 *Keratometry (SemiMeridian)*

It calculates irregular Astigmatism base on the mean radius in each zone. Calculation bases on Axial map.

Keratometry (SemiMeridian)		
Ø 3mm	**Anterior**	**Posterior**
Kf	42,1D @ 260°	-5,6D @ 188°
Ks	44,0D @ 97°	-5,9D @ 98°
Kf	41,5D @ 315°	-5,6D @ 10°
Ks	43,0D @ 189°	-5,8D @ 293°
Ø 5mm	**Anterior**	**Posterior**
Kf	8,3D @ 247°	7,1D @ 212°
Ks	41,6D @ 99°	-6,0D @ 99°
Kf	40,0D @ 314°	-5,7D @ 10°
Ks	41,1D @ 189°	-5,8D @ 270°
Ø 7mm	**Anterior**	**Posterior**
Kf	39,5D @ 91°	-5,6D @ 213°
Ks	40,8D @ 133°	-6,0D @ 110°
Kf	39,3D @ 89°	-5,5D @ 9°
Ks	40,4D @ 181°	-5,7D @ 247°

20.4.4 *Keratoconus screening*

KPI Value

Values of indices

Keratoconus indication

Keratoconus screening	
Keratoconus screening	
KPI Keratoconus Prediction Index	0,17
Keratoconus:	**Non Keratoconus**
SAI Surface Asymmetry Index	0,79
DSI Differential Sector Index	1,47
OSI Opposite Sector Index	1,28
CSI Central/Surrounding Index	1,54
IAI Irregular Astigmatism Index	0,20

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.

20.4.4.1 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 291 Keratoconus screening classification.

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 below.

Caution: KPI bases on a publication by Naoyuki Maeda and can only be treated as supplementary information and cannot be treated as disease confirmation. Use for reference only.

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

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.

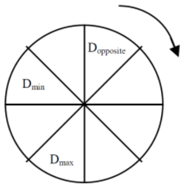
20.4.4.2 Definition of Quantitative Indices

DSI (Differential Sector Index) – the greatest difference in average power between any two (out of eight) sectors

OSI (Opposite Sector Index) – the greatest difference of the average power in opposite sectors

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 (see picture below).

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}).



$OSI = D_{max} - D_{opposite}$

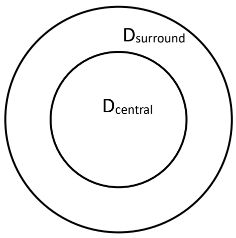
$DSI = D_{max} - D_{min}$

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

CSI (Central/Surrounding Index) – difference in the average area-corrected corneal power between the central area and an annulus surrounding the central area (see picture below)



$CSI = D_{central} – D_{surround}$

SAI (Surface Asymmetry Index) – difference in corneal powers at every ring (except for 180^{o}) over the entire cornea surface

K1 (Keratometry K1) – average maximum radius in 3 mm zone

K2 (Keratometry K2) – average minimum radius in 3 mm zone

IAI (Irregular Astigmatism Index) – average summation of inter ring area corrected power variations along every semi meridian for the entire analyzed surface, normalized by the average corneal power and number of data points

$$IAI = B * \ln \left[\frac{C * \sum_{i=1,\,256}^{j=2,\,30} \{\Delta A * [P_{i,\,j} - (P_{i,\,j+1} + P_{i,\,j-1})/2]\}}{\sum_{i=1,\,256}^{j=2,\,30} \Delta A} - D \right]$$

i – semi meridional position

j – ring number

$P_{i,j}$ – corneal power of the point (i, j)

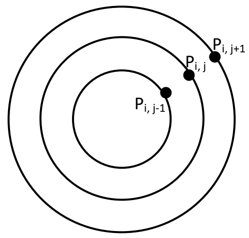
ΔA – area which corresponds to power $P_{i,j}$

B – normalization by power

C – normalization by number of points

D – scaling constant

Corneal power of the appropriate points: $P_{i,j-1}$, $P_{i,j}$, $P_{i,j+1}$:



AA (Analyzed Area) – analyzed area of the examined cornea.

Classification of keratoconus screening is performed according to the following graph:

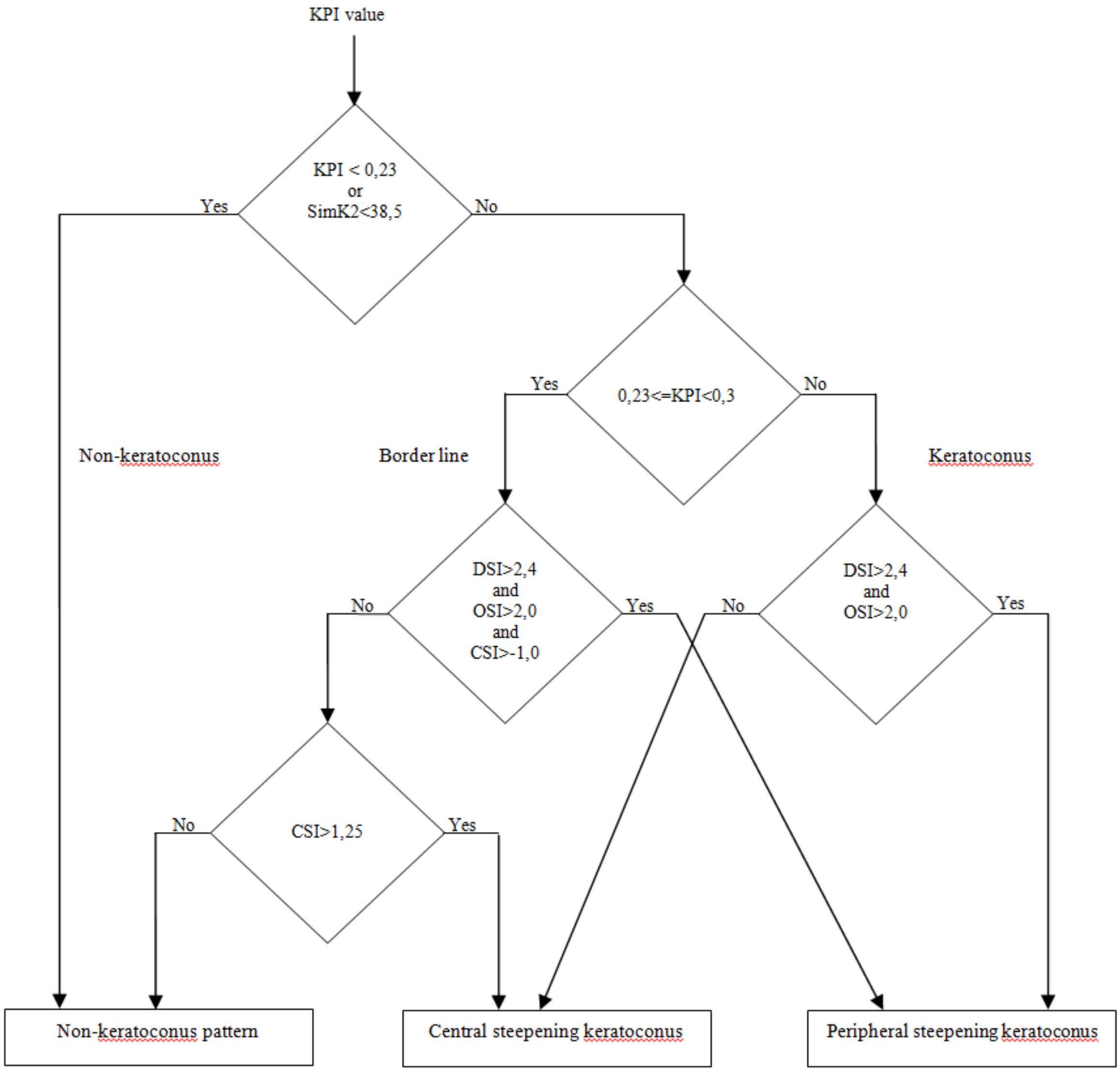


Figure 291 Keratoconus screening classification

20.4.5 *Pachymetry*

The table displays a summary of pachymetry data.

Pachymetry

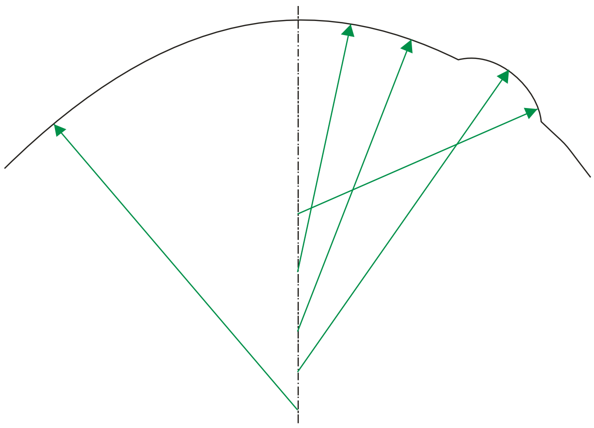
Pachymetry		
Cornea thickness - 7 mm	Cornea [µm]	Epithelium [µm]
Central Thickness	601	56
Minimum (indicate as °)	592	50
Median	625	55
Min - Max	-107	-8
Min - Median	-33	-5
Sector difference analysis:		
SN - IT	6	0
S - I	-8	1
ST - IN	-18	0
T - N	-17	0
KPI	0,17	

20.5 **Map Types**

The formula for converting geometrical radius [mm] values into optical power values in Diopters [D]. Diopter: D=[(Ref index-1)*1000]/Rmm

Axial maps - Axial Power 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 is 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 radius different at each point. The alternative name of the sagittal map is axial map.



Axial [Anterior] - an axial power map of the anterior surface. Refractive index: 1.3375.

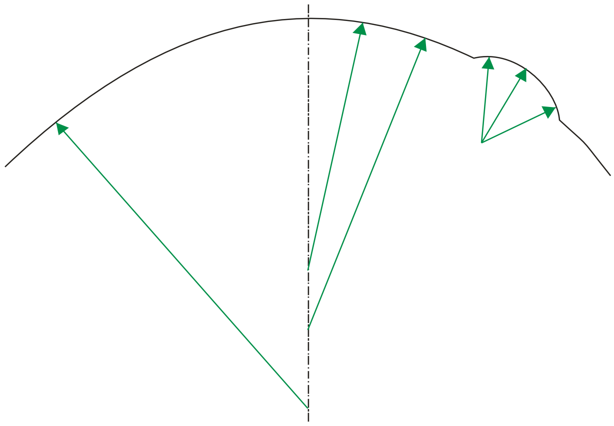
Axial [Posterior] - an axial power map of the posterior surface. Refractive index: 1.376.

Tangential maps clearly define 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.

Tangential map is calculated on the basis of digitally recognized ring pattern reflected from the surface of the cornea. It calculates the local curvature radius which gives 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 place and not on the axis.

From this point the cornea should be treated as an infinite set of small spherical lenses, where each of them has a different radius length and origin.

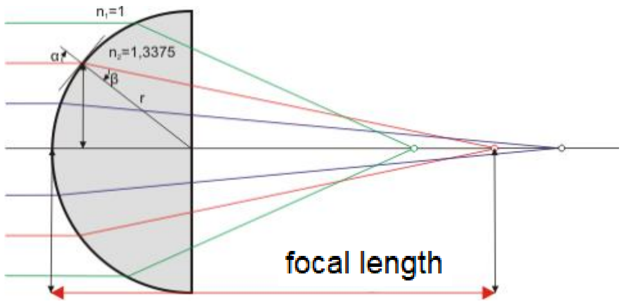
The picture below shows the calculation of tangential map graphically.



Tangential map [Anterior] - a tangential power map of the anterior surface. Refractive index: 1.3375

Tangential map [Posterior]- a tangential power map of the posterior surface Refractive index: 1.376.

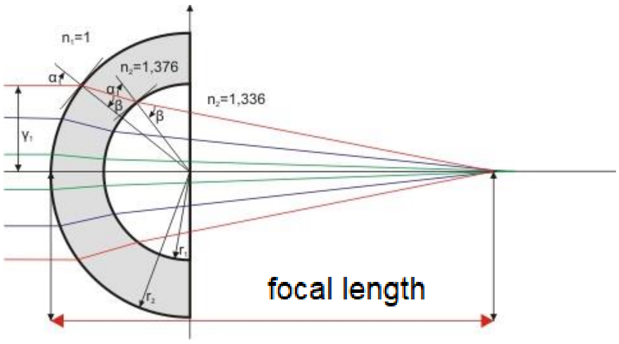
Refractive Power map [Kerato] calculates the focal length from Snell's law and the corneal refractive power. This map uses only values from the anterior surface, but it also takes refractive effect into account. It calculates corneal power according to Snell's law of refraction assuming a refractive index of 1.3375 to convert curvature into refractive power.



Refractive Power map [Anterior] - Refractive index of the cornea: 1.376. Calculate base on the Snell's law.

Refractive Power map [Posterior] – is calculated as difference between Refraction equivalent power map and 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 takes into account 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 differing principal planes due to corneal thickness. In this way the map takes the refractive effect , inclusion Anterior/Posterior surface and the location of the principle 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 humour: 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- Cornea 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 surface. 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 condsiders effects 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 humour 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 6 mm radius with 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

Elevation Map [Anterior] An axial power map of the anterior surface. The map is drawn based on the center of the anterior surface of the cornea.

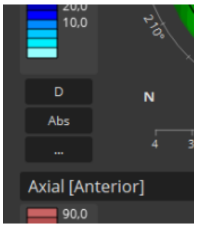
Elevation Map [Posterior] An axial power map of the posterior surface.

Height map is a difference from tangent surface to highest point of the cornea.

Pachymetry map of the corneal thickness with 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 thickness map shows the corneal epithelium thickness map for examination. It provides information for refractive lasik and Keratoconus patients.

20.6 Color scale - Standards

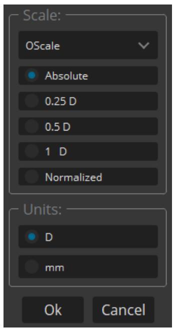


Switching the scale - to change the scale click one of the scale descriptions in the bottom corner of the map. Scale settings widow shows up. User can change the scale type, step and units. Only steps available for the chosen scale will show up. The system remembers maps chosen on each view position. After closing the examination the setting are saved and used for other 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
	0,25 mm	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
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

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 [Kerato], 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

21 CALIBRATION

To ensure system stability over time, before the first examination the topography module automatically prompts for a daily validation test. The validation test is performed with the 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 it is exceeded, the software will not allow the acquisition of topography scans. A warning message with instructions for further actions is displayed on the screen.

21.1 Calibration procedure preparation

Before the calibration you have to install the Calibration tool.

Figure 292. Calibration tool.

Take the tool from the box and open as it is shown on the following images.

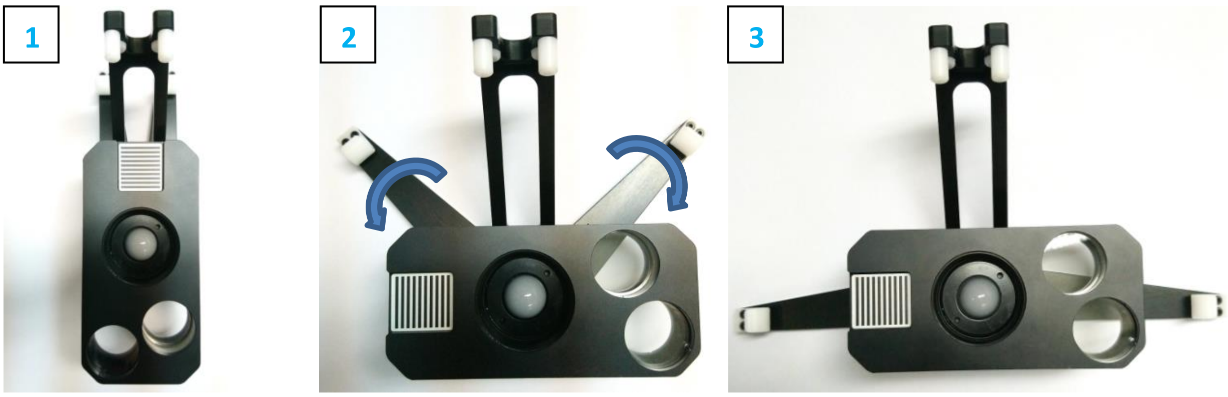


Figure 293. Opening the calibration tool.

Put the opened calibration tool on the forehead frame as shown on the following image. Mount the upper hooks first. Then push the lower hooks to the frame. Make sure there is no free space between the frame and the calibration tool.

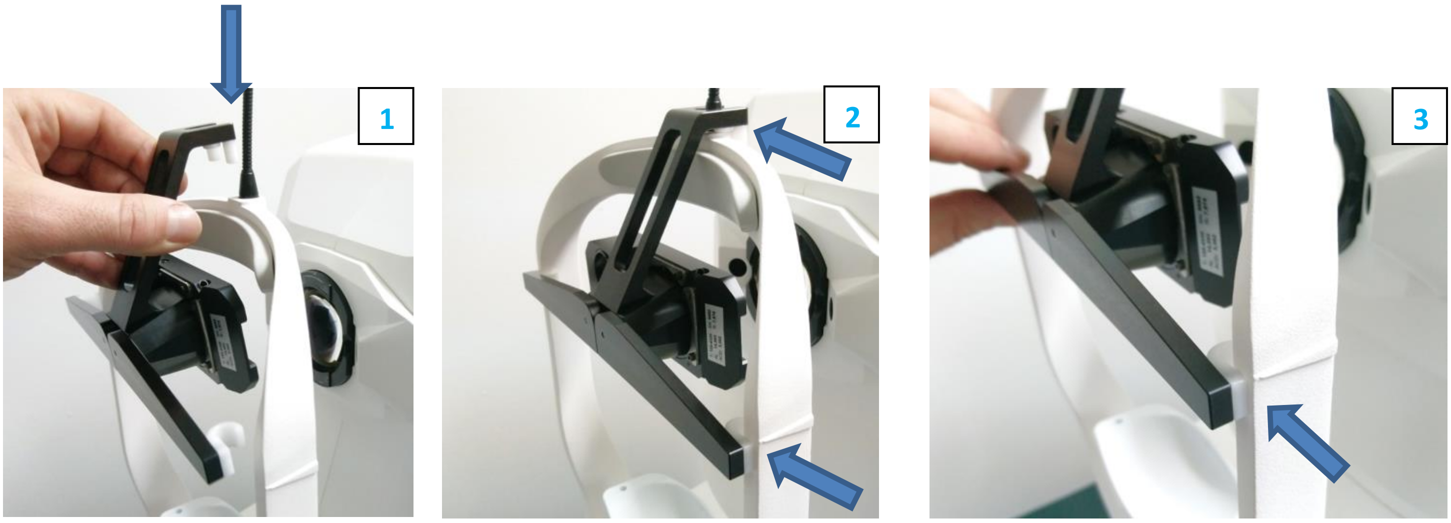
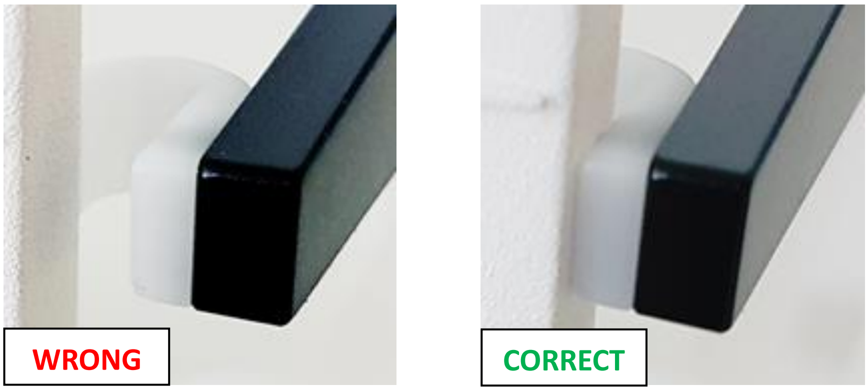


Figure 294. Mounting the calibration tool.

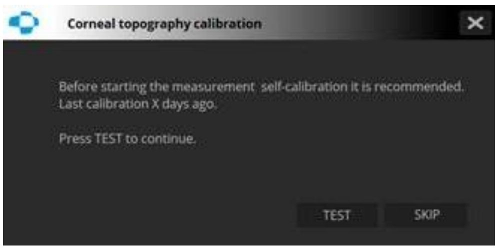
NOTE: Make sure the calibration tool is well fitted to the frame.



21.2 **Topography calibration**

21.2.1 *Intitial 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 technical support

[TEST] – starts the calibration process

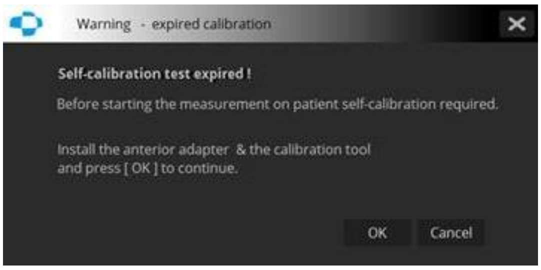
[SKIP] – skips the calibration and closes the information window

If the device has gone through the initial calibration successfully, the system starts to display the information as for standard calibration.

Note: the initial calibration is usually longer and it make take a while. If the calibration ends in failure, verify if: the Anterior adapter is installed, the tool is properly installed, the testing surface inside the calibration tool is free from pollution, no strong light is reflected from testing surface.

21.2.2 *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:



[OK] – starts the calibration process

[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 in one go. The common calibration procedure is described in section 21.3.5 Common calibration.

Before the examination the system checks when the device was calibrated for the last time and display the following information:

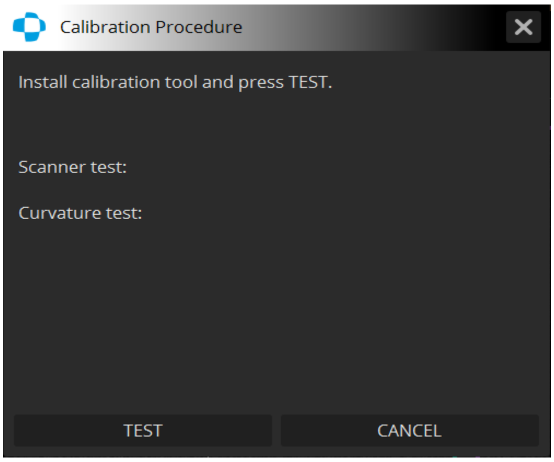
"Last calibration X days ago. Before starting a measurement on a patient self-calibration is recommended. Press OK to continue".

[Skip] – goes to Acquire window

[OK] – starts the calibration process

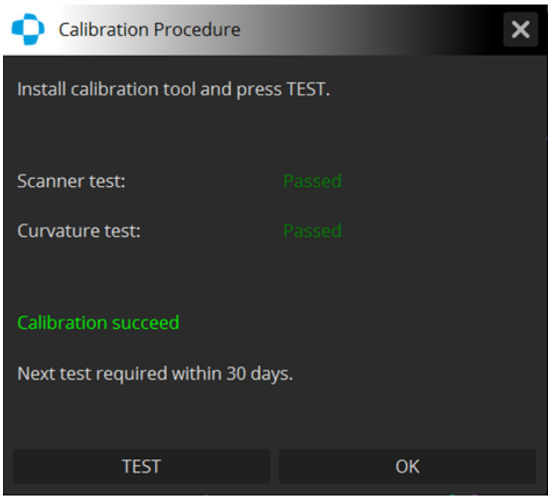
21.2.3 *Calibration process*

At the start of the calibration process the user will be asked to "Install the calibration tool on the chinrest and press Test"



[TEST] – starts an automatic calibration process

After calibration the system displays a calibration summary:



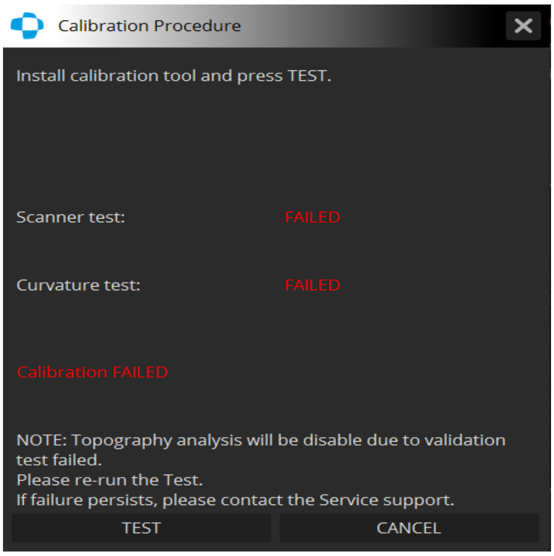
If the system passes calibration, the following message is displayed in the calibration window:

*“**Calibration successful**. Next test required within 7 days”*

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.”



[Cancel] – close the window

[Test] – repeat calibration

If the device does not pass the software calibration, it is impossible to test and analyze in the topography mode.

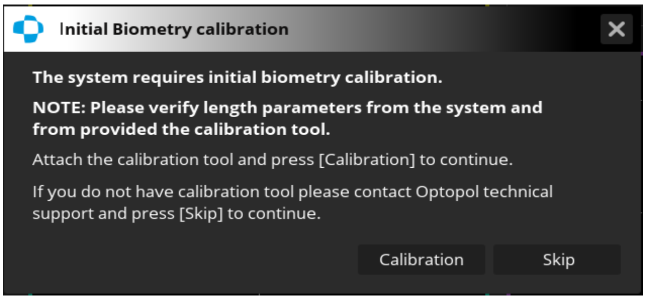
If both the Topography and Biometry modules have been activated in the system, the user can calibrate them in one go. This procedure is described section 21.3.5 Common calibration.

21.3 **Axial length (biometry) calibration**

Performing calibration of the Biometry module ensures high precision of measurements.

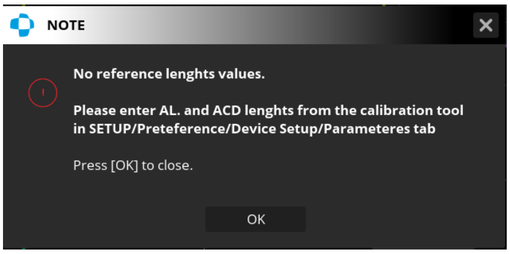
21.3.1 *Biometry calibration with the IOL Calculation tab unactivated*

Once the Biometry module is opened for the first time the system prompts the user to perform the initial calibration. After a year since the initial calibration the user will be prompted to repeat the calibration procedure.



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 calibration tool have not been entered, the system prompts the user to do that, as shown below.

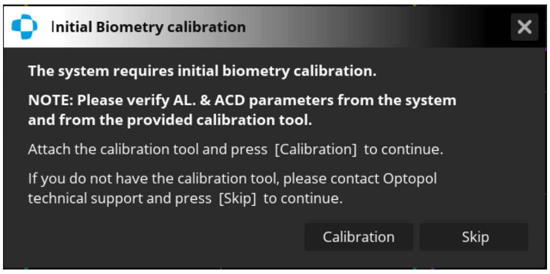


To close the window, click [OK].

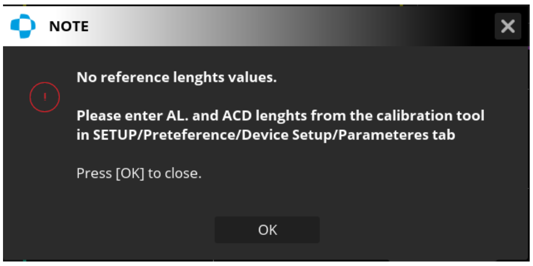
When the calibration process starts, the system displays the calibration procedure window.

21.3.2 *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 carry out 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 a 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 section 21.3.4 Entering biometry calibration parameters.



21.3.3 *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.

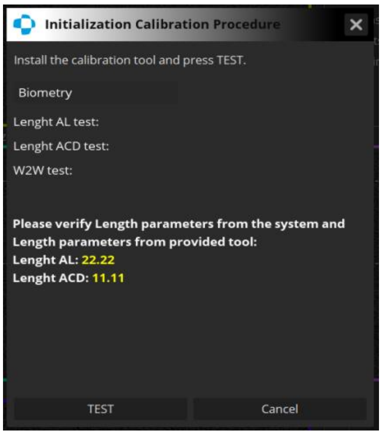


Figure 295. Calibration procedure window

The user is asked to install the calibration tool (the installation procedure is described in section 21.1 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.

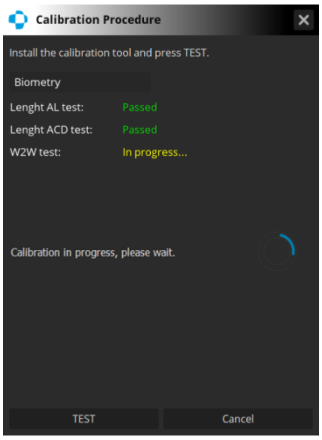


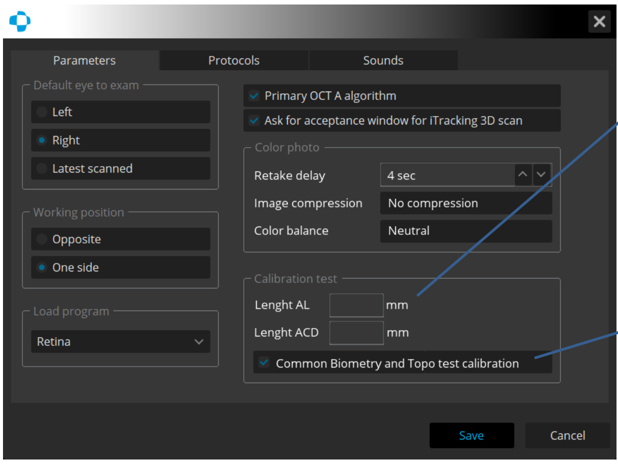
Figure 296. Calibration procedure in progress

A successful calibration is indicated by *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 if the IOL Calculator tab is activated in the system.

21.3.4 *Entering biometry calibration parameters*

Before you start calibration, it is necessary to enter calibration parameters provided with the calibration tool. To do that go to SETUP/Preferences/Device Setup/Parameters.



Calibration parameters section (available only if the biometry module is activated)

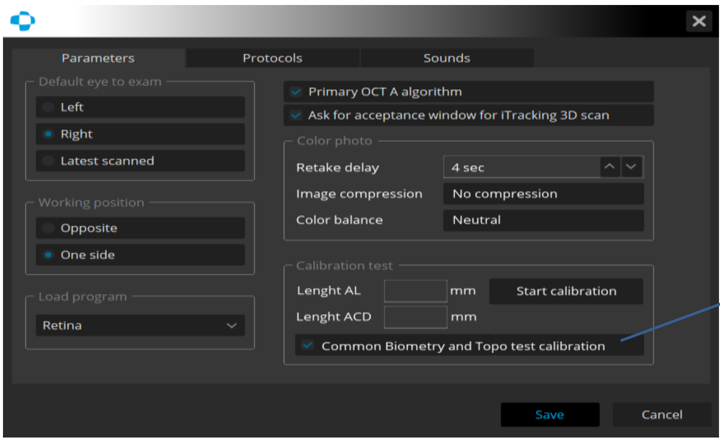
Common Biometry and Topography calibration checkbox

Figure 297. 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. If you want to perform a common calibration for both the Biometry and Topography module, select the *Common Biometry and Topography calibration* checkbox. If you leave the checkbox deselected, the system will perform two separate calibration tests, each for the individual module. To learn more about common calibration, go to section 21.3.5 Common calibration.

21.3.5 *Common calibration*

Common calibration allows the user to perform Biometry, Topography and WTW calibration all in one go. To enable common calibration, go to SETUP/Preferences/Device Setup/Parameters and select the *Common Biometry and Topography calibration* checkbox as shown below. If you leave the checkbox deselected, the common calibration function is off.



Common Biometry and Topography calibration checkbox

With common calibration enabled in the Preferences tab, each time a calibration is required, the system displays the common calibration window presented below.

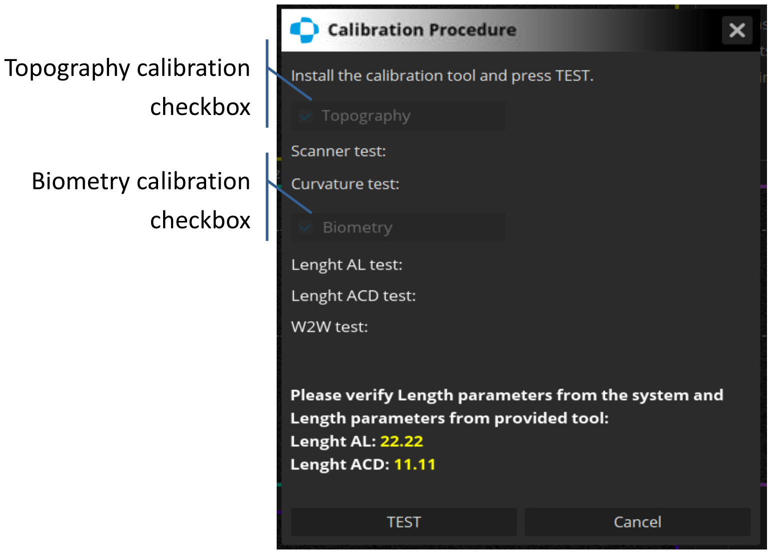
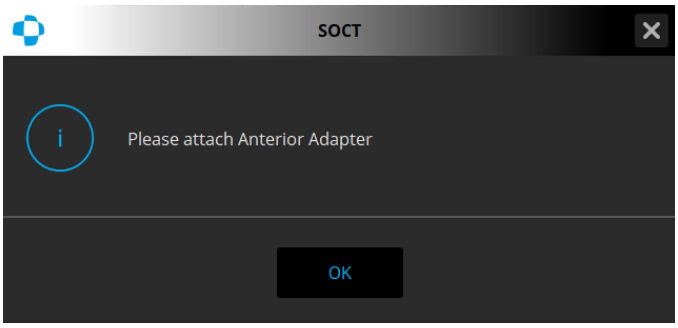


Figure 298. Common calibration window

To calibrate the Topography and Biometry modules simultaneously, make sure that their respective checkboxes are selected. If you want to exclude either of the modules from calibration, deselect its checkbox. The system will then perform calibration of the module which remains selected.

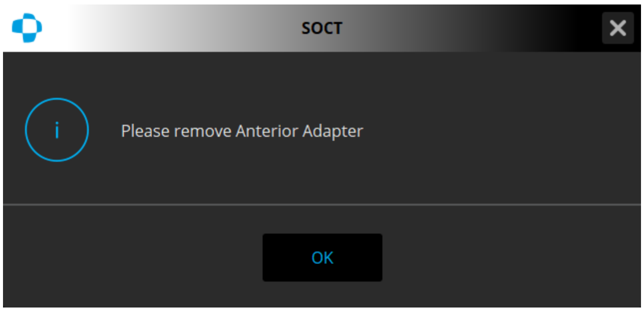
The window presents the calibration tool parameters. The user is asked to install the calibration tool and verify the correctness of the tool parameters with the values provided displayed in the window. If the values are correct, the user can start calibration by clicking the [TEST] button. To cancel calibration and close the window click [Cancel].

If the Topography checkbox is selected, after clicking [Test], 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 [Next] to continue. To cancel the process and close the window click [x].

You can follow the progress of the calibration in the common calibration window. To stop the process at any time, click [Cancel].

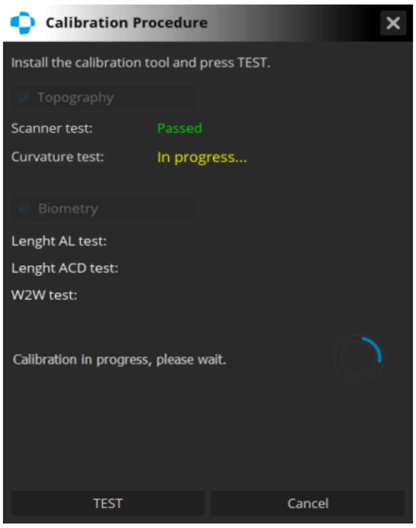


Figure 299. Common calibration in progress

The result of the calibration is presented in the common calibration result window.

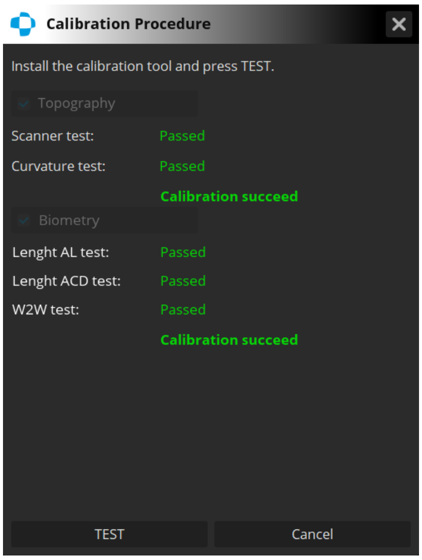


Figure 300. Common calibration result window

A successful calibration is indicated by *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 SETUP WINDOW

Setup window is used to set various parameters of SOCT system. In order to enter it, type in a user and password and select [Setup] button. If you use the software for the first-time new user should be created in USERS tab.

Figure 301. Entering device settings tab.

22.1 General

This tab allows the user to enter clinic details, change language or software skin layout.

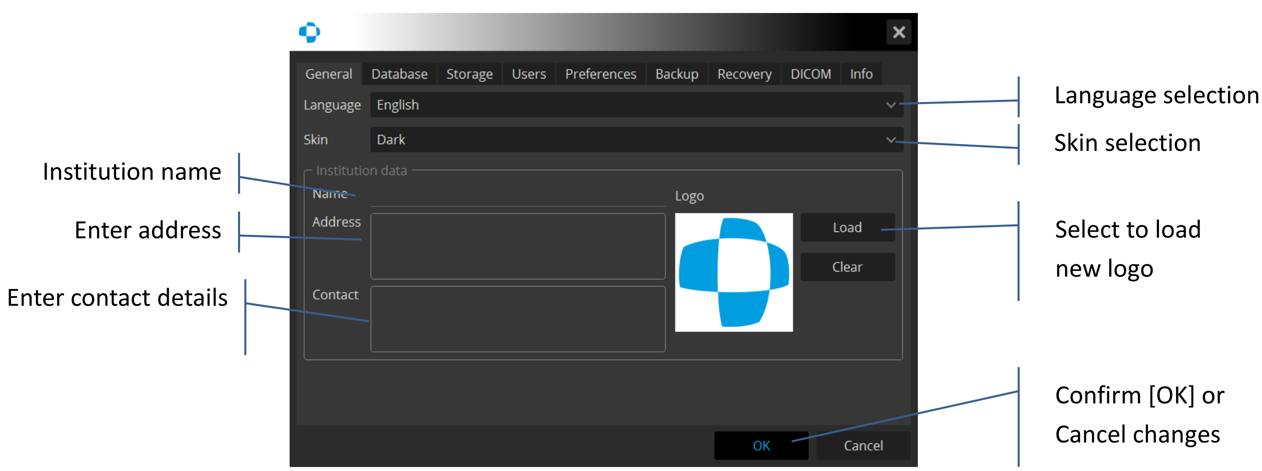


Figure 302.General setup window.

On this tab select desired language, select application skin (layout) and type the practice details and add practice logo. Practice details and logo will be visible on the printout header.

22.2 Database

Select 'Database' tab to be able to access all the tools needed to handle database and set networking parameters. This is a path to the folder containing database tables (Copernicus.db file). It can be typed manually or selected using the [Select] button. Connection with remote database can be tested. Storage of examination data is described below.

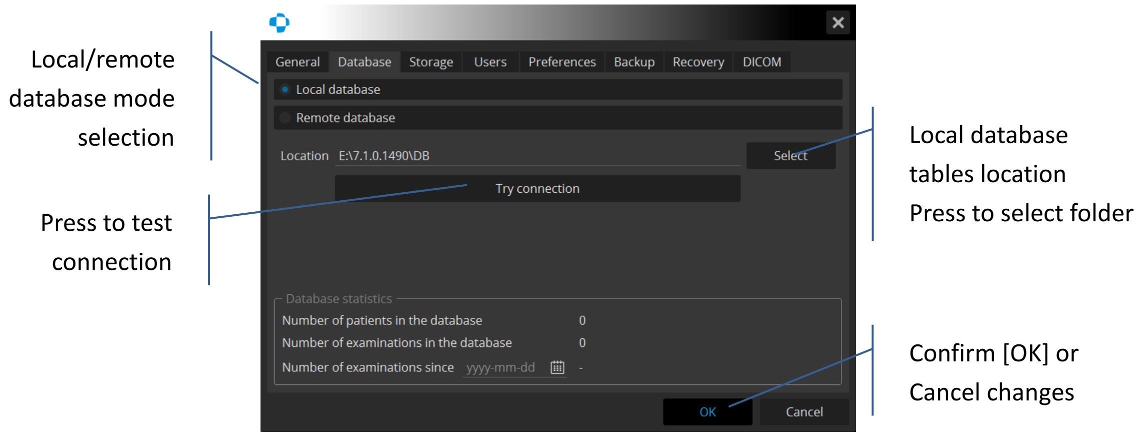


Figure 303. Database tab.

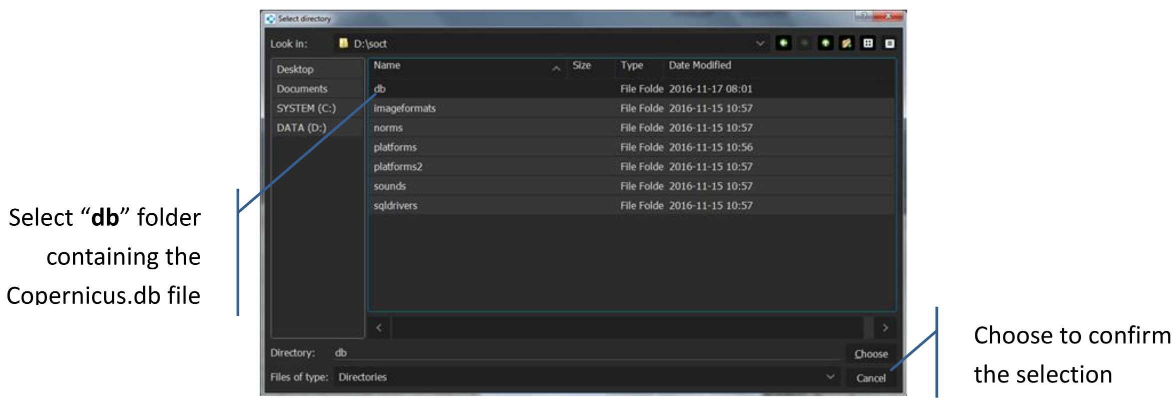


Figure 304. Selecting database table location.

Information appears in case "db" folder is not present in indicated directory. Make sure you are selecting right folder. Don't mark SOCT folder location only.

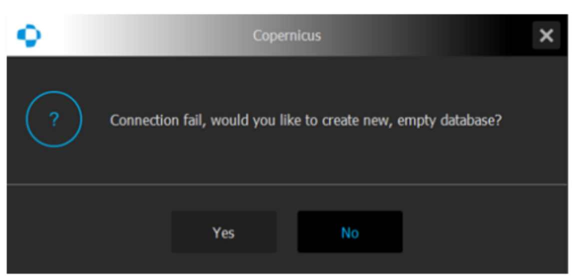


Figure 305. Example of connection error.

This message appears in case of wrong path indication or mistake in folder name

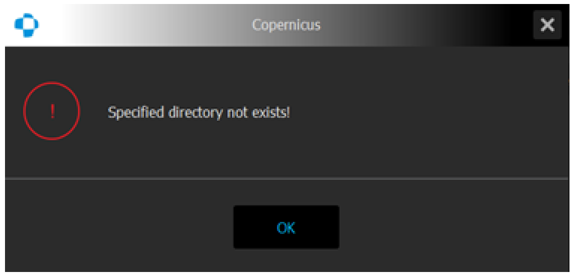


Figure 306. Lack of directory error.

Confirmation of proper connection with database tables file.

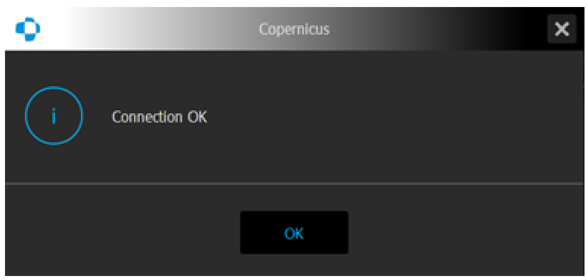


Figure 307. Confirmation of proper connection.

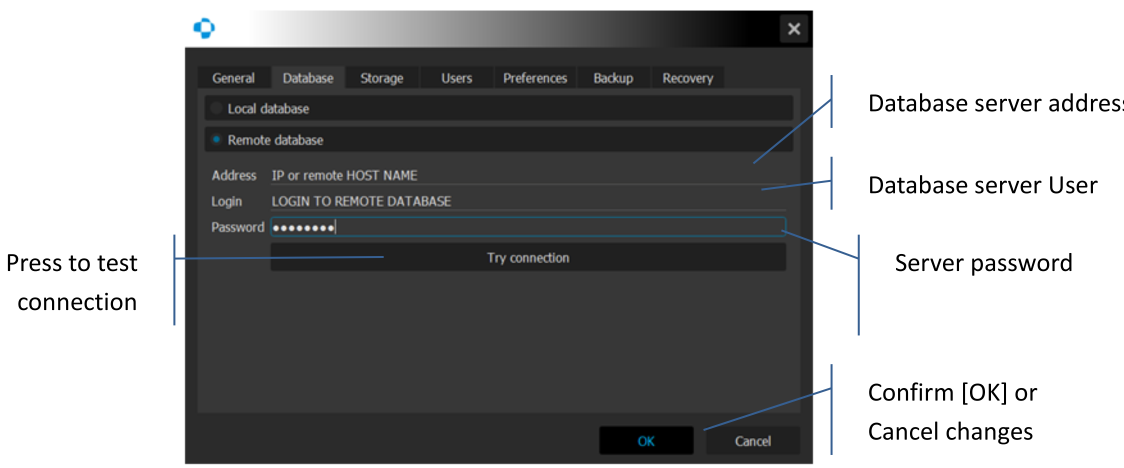


Figure 308. Remote server connection settings.

Local database – this mode should be selected in case database tables (Copernicus.db) file is located on SOCT device PC. Storage of examination data can be in different location(HDD or network location folder).

Remote database – mode used when connecting viewing stations to 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 remote database. In that case **all software applications** also SOCT PC should have the same settings of host and login to server application.

It is obligatory to enter **login** and **password** of the database server software we are connected to. For more details see chapter 24.1.1 SOCT network.

Simultaneously viewing station PC should have access to Storage locations containing examination data (all folders should be shared and visible to all users)

22.3 Storage

SOCT software allows to locate the database in various combined folders. It is possible to add more space for data storage if required and just indicate additional folder.

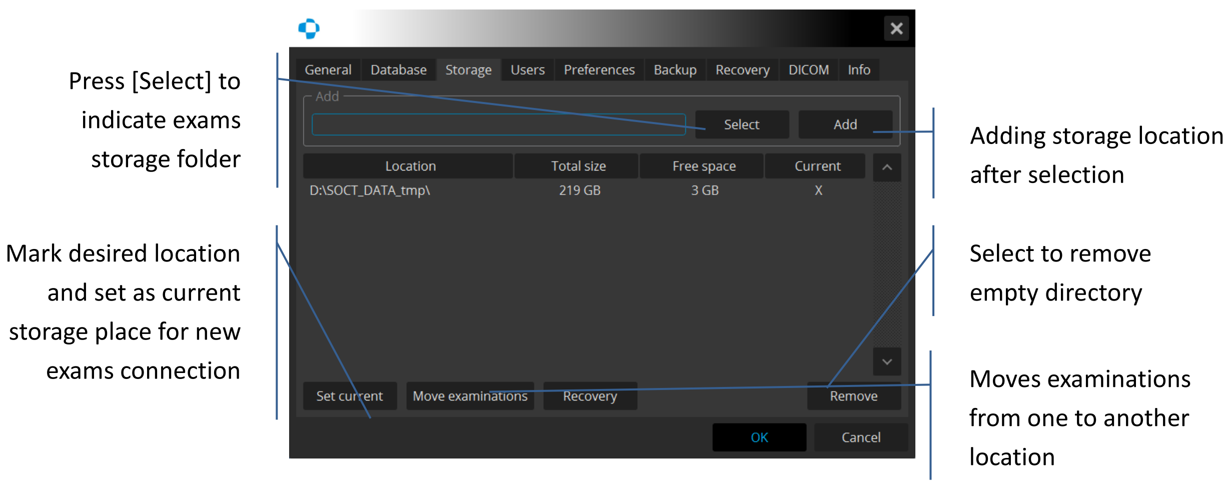


Figure 309. Storage administration tab.

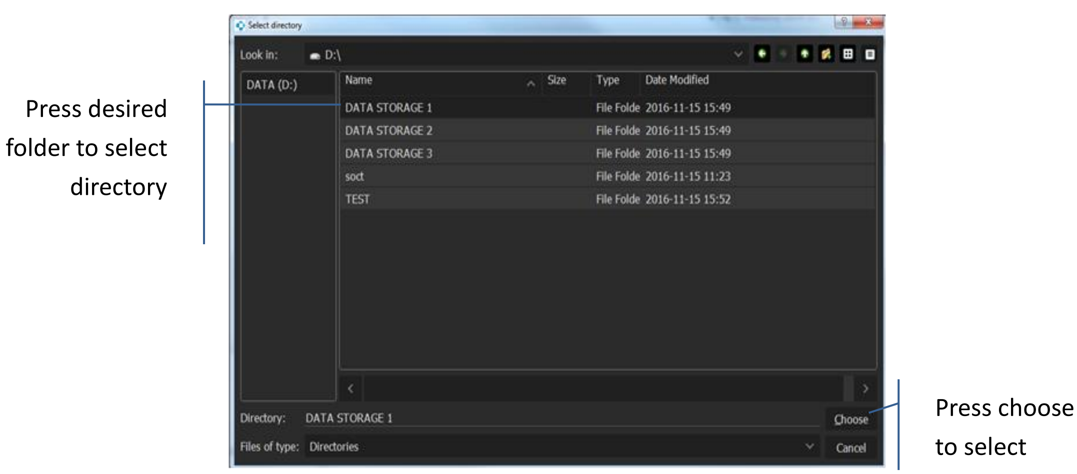


Figure 310. Selection of additional storage folder.

SOCT software will display all examinations from indicated folders. Folder marked as “Current” will be a storage for new examinations taken by the device.

[Move examinations] It allows to move examinations from one location to another. It allows to moves latest examinations from main HDD to another location and keep high performance of the system. Click to open a new window and select destination folder to move examinations.

[Recover] It allows to connect the examinations from the existing folder (.opt files) to current database. Use [Add] storage function to add a new location to existing database.

Note: This function does not copy data from recovered location! Do not remove folder after recover.

In case of viewing station connections storage locations should be shared in the network. For details see chapter 24 Network Configuration.

22.4 Users accounts

It is possible to login into the system by different operators. This tab allows to manage all SOCT software users. Here you can add, remove and edit users. It is mandatory to create at least one user to use the software. 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** the only way to open the software is to enter this information. In case of problems please contact your local distributor.

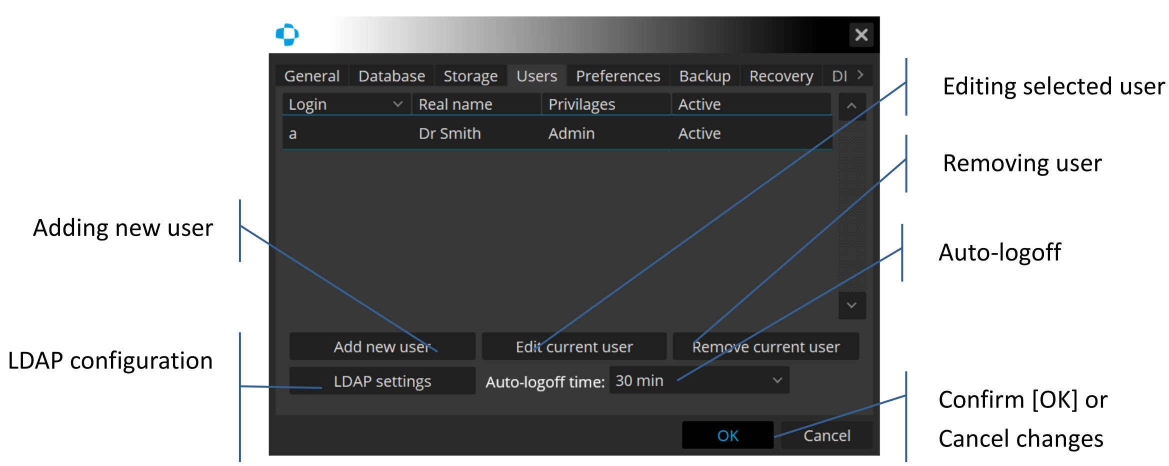


Figure 311.Users tab.

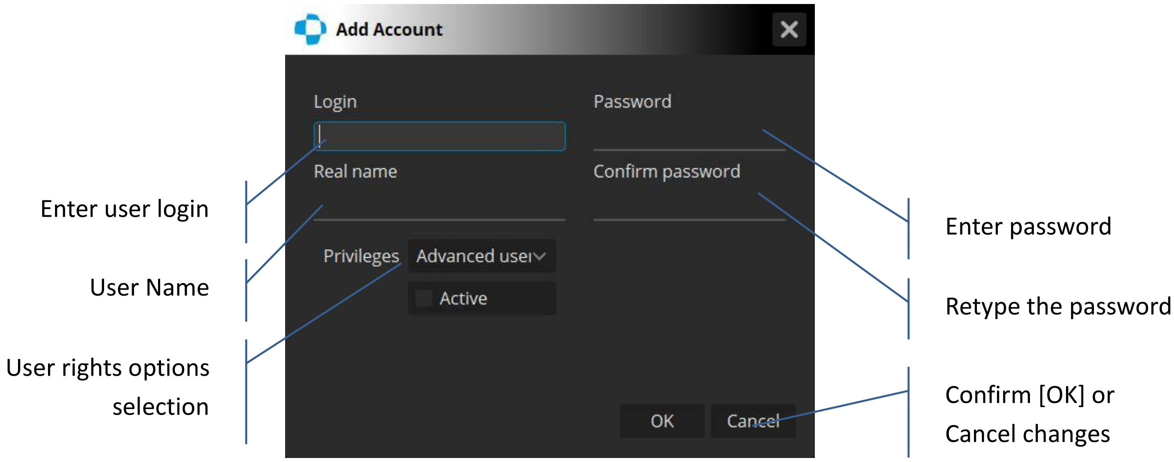


Figure 312. Users tab. Creating new user.

22.4.1 *Creating user accounts*

In order to create a new user account, press add new user and the window [Add Account] will pop up. The required fields in order to successfully create a user are Login, Password, Confirm Password and Privileges. 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. Privileges drop-down list allows to set the user rights. It is then possible to search for patient records by association with users. Software automatically and permanently associates saved scans with the current user when saving. Each operator can have own default scan parameters and printouts styles.

- Admin – entitles the user to perform, review and analyze all results. Also, this user is able to remove and/or edit patient data. It also allows the creation of additional modified user accounts and management of the application global setup
- Advanced user – entitles the user to perform, review and analyze all results with the option to export and import examinations
- 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 patients' exams, modify patients' 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 in order to disable specific user accounts for any reason.

22.4.2 *LDAP Settings*

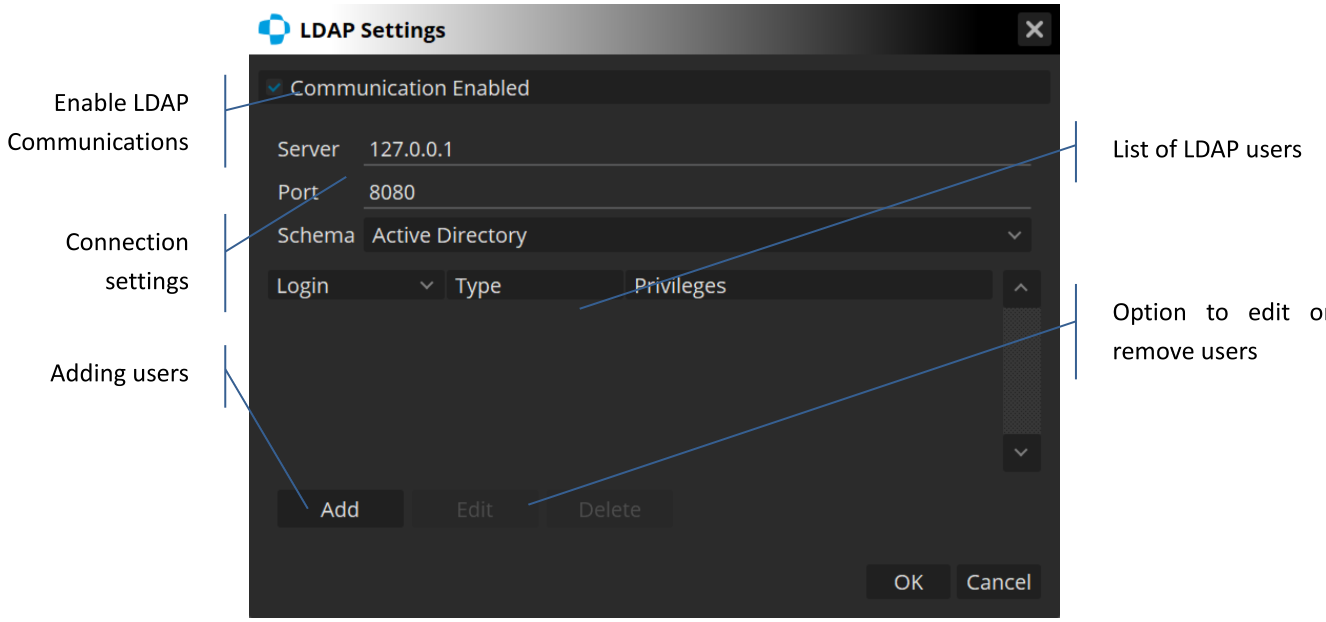


Figure 313 LDAP Settings

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 when necessary and to set a password difficulty requirement.

[Server] – correctly configured host server address/domain

[Port] – host server port

[Schema] – protocol to be used with a choice of active directory, Apache directory or custom.

In order to correctly setup LDAP, a server address with port must be entered. Logins and passwords must already be entered within the server in order 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 login if their account exists on the host server.

22.5 **Preferences**

The preferences tab allows to customize the device and software settings.

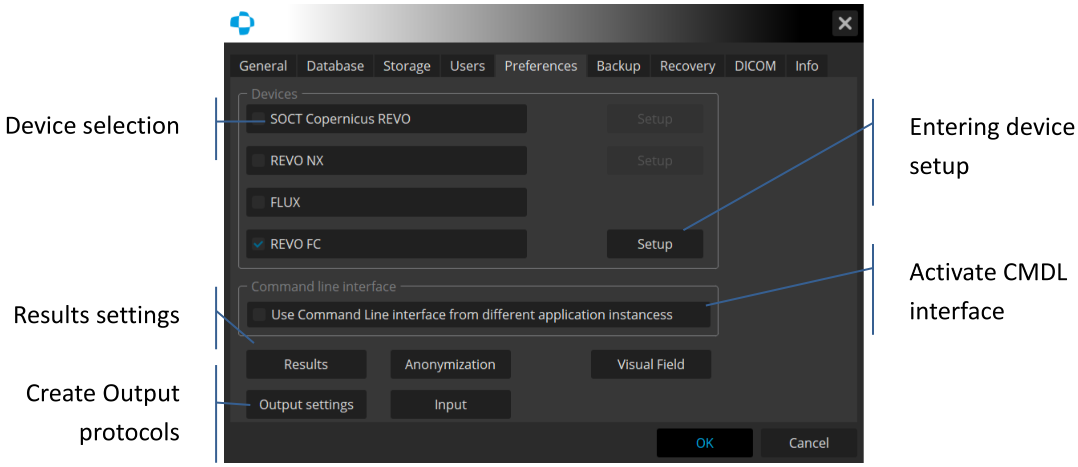


Figure 314. Preferences tab.

Devices

Select the type of the OCT device connected to PC. When the device is selected the device, Setup is available. If no checkbox is selected the device stays in Offline mode and works as a review station.

22.5.1 *CMDL interface*

This application was designed as an independent system to operate the device and to manage examination and patient data.

Use Command Line Interface from different instances – active CMDL communication. It features data exchange interfaces with external applications and the EMR systems.

When CMDL checkbox system creates Output Set – ‘Export to EMR’. The ‘Export to EMR’ protocol can be customized but the name cannot be changed. Find more details how to customize out protocol in chapter 22.7.1 Output set window.

The application can be ordered to run various orders (tasks) by external EMR system. All tasks are queued in the list of Work List when the application operates. The following tasks can be performed, based on data collected from the data exchange interface:

- Adding patient to one day Worklist
- Registering patients in a local database
- Displaying the examination results belonging to a patient

- Preparing to acquire examination or protocols according to received order from EMR
- Exporting output as report or tomogram file to a predefined directory for examination

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 to your Electronic Medical Record provider to implement communication protocol. Please contact your local Optopol Technology representative to receive the communication interface document.

22.5.2 *Devices setup*

When the device checkbox is marked [Setup] button is available. Press to open device configuration tabs.

22.5.2.1 Protocols tab

In order to change protocol settings press [Setup] button in Preferences tab. New window screen will appear. Select Protocol tab. In Protocol tab you can create, edit and delete a set of examinations. Up to 12 protocols can be registered. Up to 7 scan modes can be registered in a single protocol set. 6 protocols have been registered in the SOCT by default. These examination sets can be edited and deleted, but they cannot be returned to their default once they are edited and deleted.

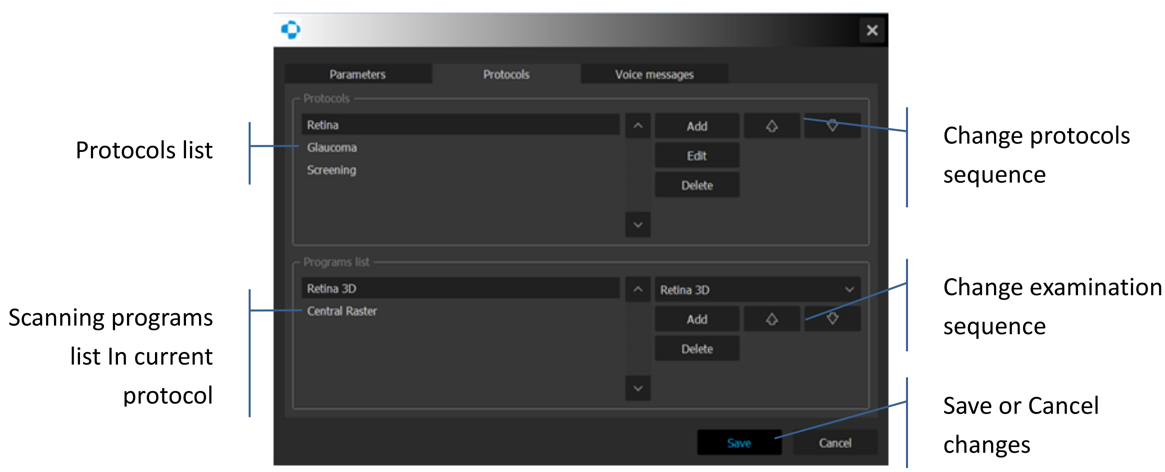


Figure 315. Protocol editor tab.

[Add protocol] – add new protocol to the list.

[Edit protocol] – allows to edit existing protocol

[Delete protocol] – remove protocol from the list

[Up and down arrow] - Move the position of selected protocol down or up on the list.

Each protocol contains set of examinations. Operator can add or remove examination on the list. It is possible to change sequence of scan program. Note: Anterior wide scans are always on the bottom of program list.

[Add] – Add new exam for selected protocol.

[Delete] – Remove examination from protocol.

[Save] – Save changes in protocol

Exam setting parameters (scan width, No. of A-scan, No of B-scan) are the same as settings in Acquire window.

There is a possibility to add Fundus Image to the protocols.

22.5.2.2 Creating New Protocol

1. Click [Add Protocol], a new window appears, type a protocol name there.
2. Input the name of the protocol and press [OK] button 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 as described in point 3.

To change the display order of protocols or tomogram on the list, select desired item and then click [Up arrow] or [Down arrow].

Note: Scan programs with Anterior Adapter are always on the bottom position of the Program list.

When operator acquires tomogram using the Protocol in Full Auto mode the system executes all programs from the protocol one by one automatically.

22.5.2.3 Editing a Protocol

Use the Protocol management screen to edit the Protocol, add and delete a scan program, or change the order of scan modes to be executed.

1. Select a Protocol, and then click [Edit] to change the name.

2. On the Program list you can add scan program by selecting desired scan program from the list box and pressing [Add] button.

3. To delete the scan program from the protocol: select Protocol, on the Programs list select the scan program you want to remove and click [Delete].

4. To delete the protocol, select desired Protocol from the Protocol list and click [Delete Protocol].

5. To change the display order of Protocols or scan program, select desired item on the list, and then click [Up arrow] or [Down arrow].

22.5.3 *Parameters tab*

In order to change parameters, press [Setup] button in Preferences tab.

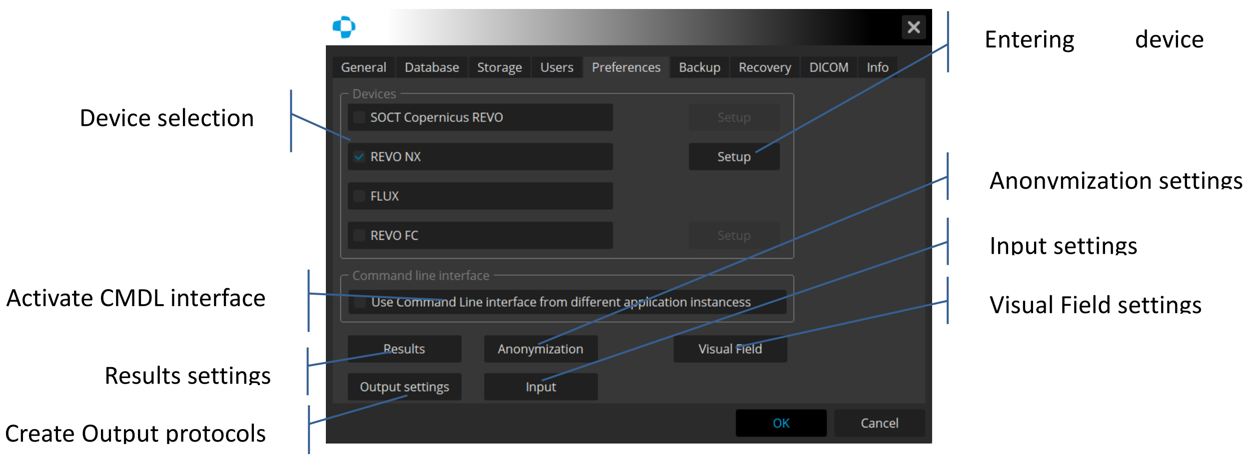


Figure 316. Preference tab.

'Default eye to exam' – set the initial position of the scanning head. The scanning head moves to the eye which will be examined for new patient. When Latest scanned is selected unit does not move from previous examination position.

'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.

'Load program' – allows to select first loaded scan program when opening Acquire tab. When 'Protocol' is selected, the first protocol from the list is loaded.

'Primary OCT Angiography' - allows to use an original when checked or enhances the Angio algorithms when unchecked.

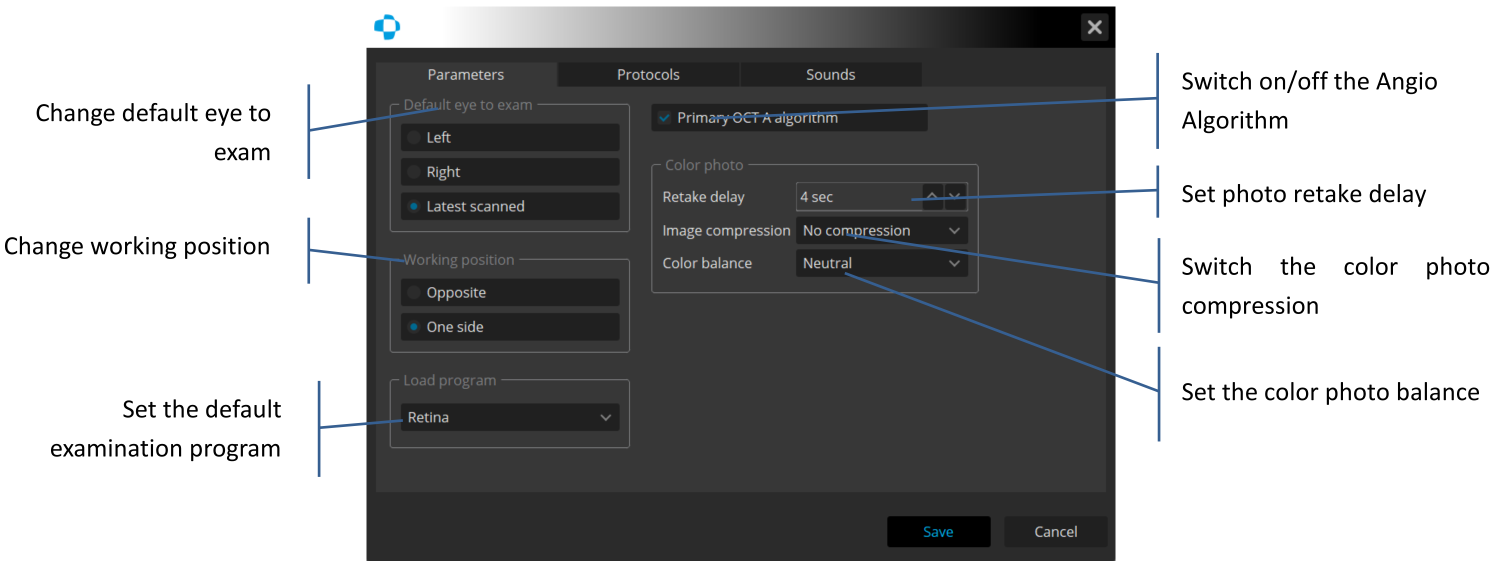


Figure 317. Parameters tab.

22.5.4 *Voice messages.*

In order to change voice settings press [Setup] button in Preferences tab.

'Voice message' tab contains options enabling customization of voice guide support or disabling it.

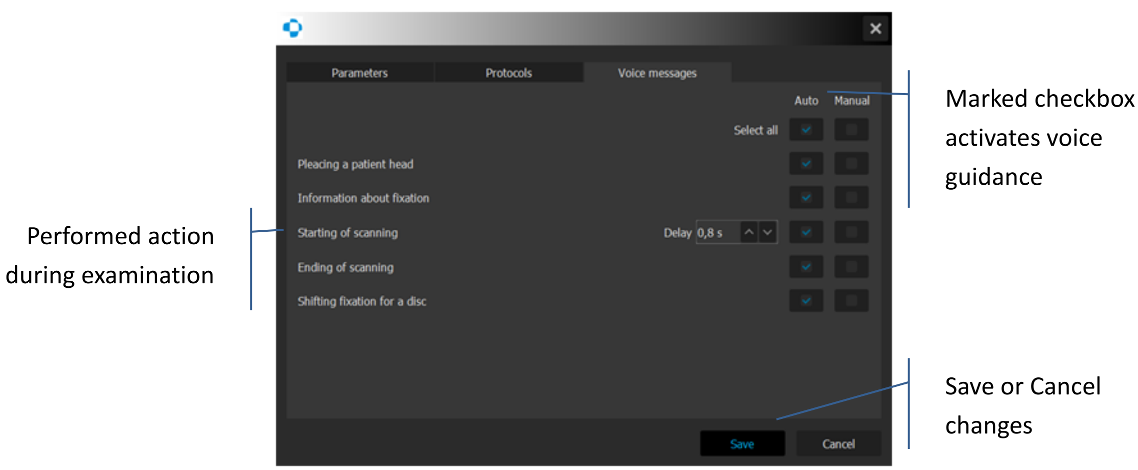


Figure 318. Voice messages settings

The system uses synthesized sentences to assist the patient during alignment and acquiring examination process. User can decide to customize the playing sound when device is working on fully auto mode (alignment with automatic acquiring data) or when operator decides to press [START] to optimize the signal and acquire examination by pressing [Acquire] button.

Auto – When 'Auto Acquire' function is checked.

Manual – When 'Auto Acquire' in unchecked.

Uncheck field to disable playing sound in situations described below. The system plays the following sentences:

Placing a patient head Sound “Please, place the head on the chinrest and blink freely” when Acquire tab is open. Sound plays once per Acquire session.

Informing about fixation Sound “Please look at the center of the green cross and blink freely.” – when operator presses the [Start] button and objective lens is coming on the front of the eye. Sound plays once for selected eye.

Start of scanning Sound “Please blink than keep your eyes open“ plays before starting acquisition of examination.

Delay The time period counted from the end of playing the sound to the start of acquisition of examination. When it has negative value scanning starts before end of message.

Ending of scanning “Thank you, you can blink freely” – when system finishes acquiring examination.

Shifting fixation for a disc Sound “Follow the green cross” – when system is changing fixation target during disc examination.

Note: Language of voice guide can be changed on the Acquire tab.

22.5.5 *Results settings*

In order to change results display settings press [Results] button in Preferences tab.

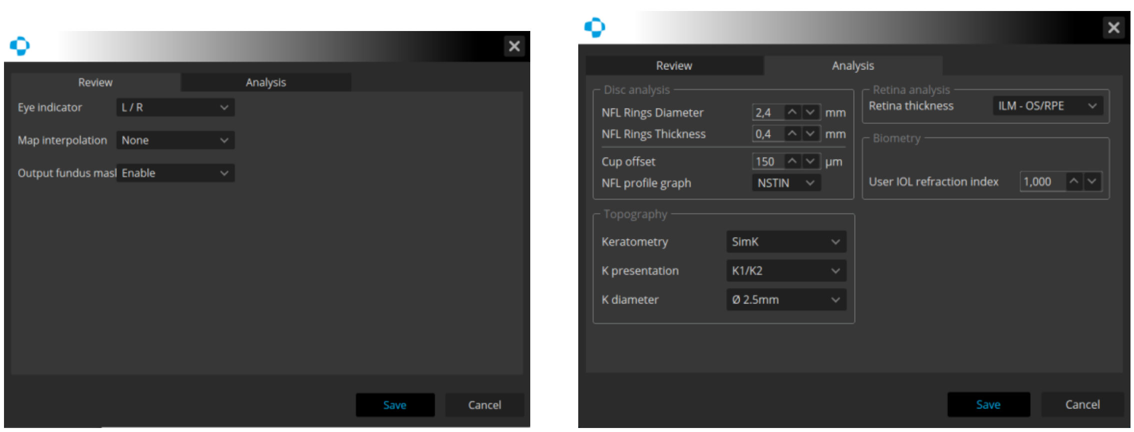


Figure 319. Results review settings tabs.

<u>Review tab</u>

Eye identifier – R/L or OS/OD can be selected

Map interpolation – it selects method of how interpolated areas are presented on the maps. Semitransparent, dashed, regular or none can be selected

Output fundus mask – allows the operator to enable or disable fundus mask display.

Analysis tab

NFL Ring diameter – It sets default ring diameter on RNFL map to calculate TSNIT plot

NFL Ring thickness - It sets default ring thickness on RNFL map to calculate TSNIT plot

Cup offset - It defines default value to calculate cup and rim parameters.

User IOL refraction index – Type refraction index of used IOL lens. The parameters will be used to IOL lens thickness calculation.

Retina thickness – define measured retina thickness definition. Select the one from available retina thickness measurement definition.

Select the RNFL thickness profile graph - TSNIT or NSTIN methods are available.

Topography

Keratometry - It sets the default topography summary table (SimK; Meridians; Semimeridians)

K presentation - It sets the default method of displaying values in the tables (K1/K2 or K steep/K flat)

K diameter - It defines the diameter values for SimK calculation (ø center of ring 2.5mm +/-0,5 mm thick ring or center ø3.0 thick ring mm)

22.5.6 *Anonymization*

In order 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. You can set the anonymization function for personal data and the items to be anonymized while printing, exporting data, saving images or text files.

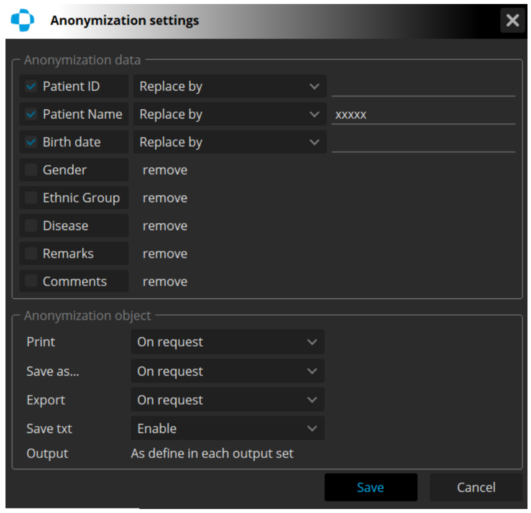


Figure 320. Anonymization settings window.

The Annonymization 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 grout – removed when checked
- Disease – removed when checked
- Remarks – removed when checked

Anonymization methods:

- Replace by - replaces the information with a specified text string typed in the type box. The text field is active. The user can enter the text string in the field.
- Encrypt - information is always coded in same way (using only letters and numbers).
- Random - information is converted randomly (using only letters and numbers).
- Replace by YYYY-MM-01' - only the day of birth is changed to 01.

- Remove when checked - information is removed

The user can select anonymization action for Print, Save as..., Export, Save txt.

Print

- Disable
- Enable data on the printout header anonymized as defined in anonymization data
- On request - displays a new position on the list box

Anonymization affects Print and multi B-scan print.

Save as..

- Disable
- Enable
- 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:

- Disable
- Enable
- On request - displays "Export anonymized" in RMB context menu below “Export in all menus” when export is available

Save as..

- Disable
- Enable

- On request - displays ""save anonymized as.."" in 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 (saving numerical data from Topography Table, Biometry Table, and in the future also form maps and as an output).

- Disable
- Enable

Output.

Each output can have the anonymization function enabled or disabled. By default it is disabled (unchecked). The settings for 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 'Anonymization data' group.

For more details go to chapter 22.7.2 Creating an Output set.

22.5.7 *Visual Field*

The configuration with the PTS 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 data transfer between the PTS software and SOCT.

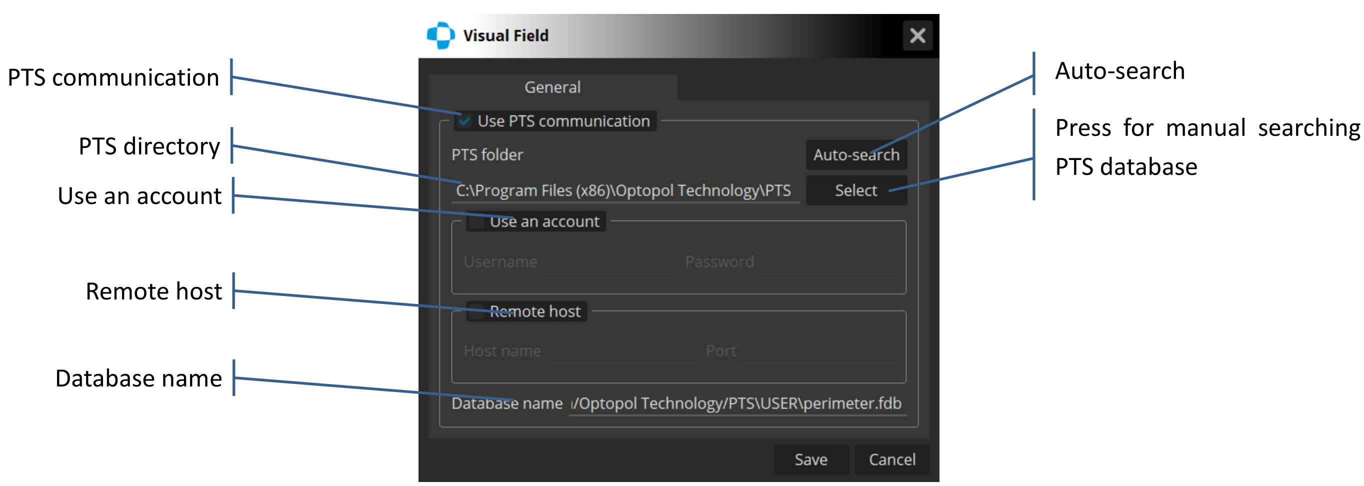


Figure 321 Visual Field settings window

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 - on clicking this field the application searches the system registry for an instance of the PTS software. If it is found, the field [PTS folder] is filled automatically and the [Database name] is derived from the 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 PTS user account. Checking the field is necessary if the PTS software is configured with user accounts. Otherwise the access to the PTS result database will not be granted. If that 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.

22.5.8 *Input settings window*

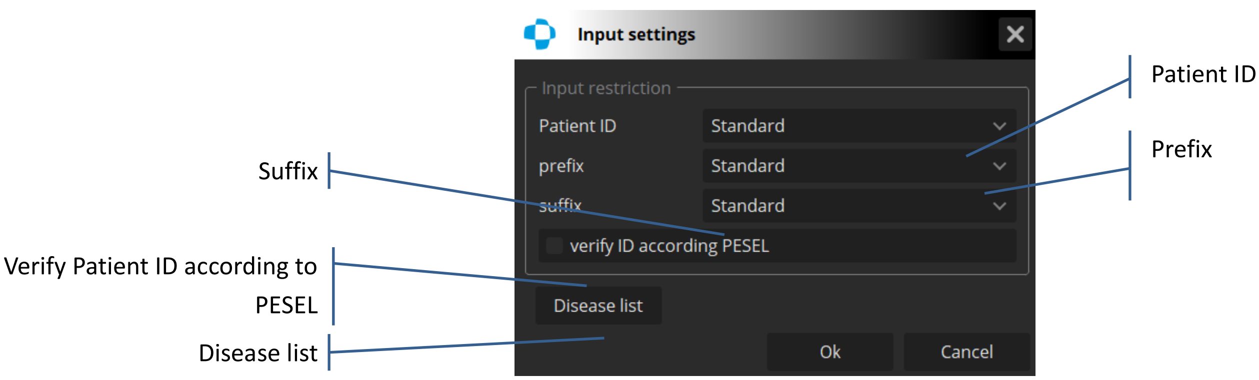


Figure 322 Input settings window

Patient ID - mandatory, standard or disable

Suffix - standard or disable

Prefix - standard or disable

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.

Disease list - allows to create a diseases list. The user can set and manage the disease list. The disease list can be enabled on the patient registering screen. The user can select a disease from the examination list.

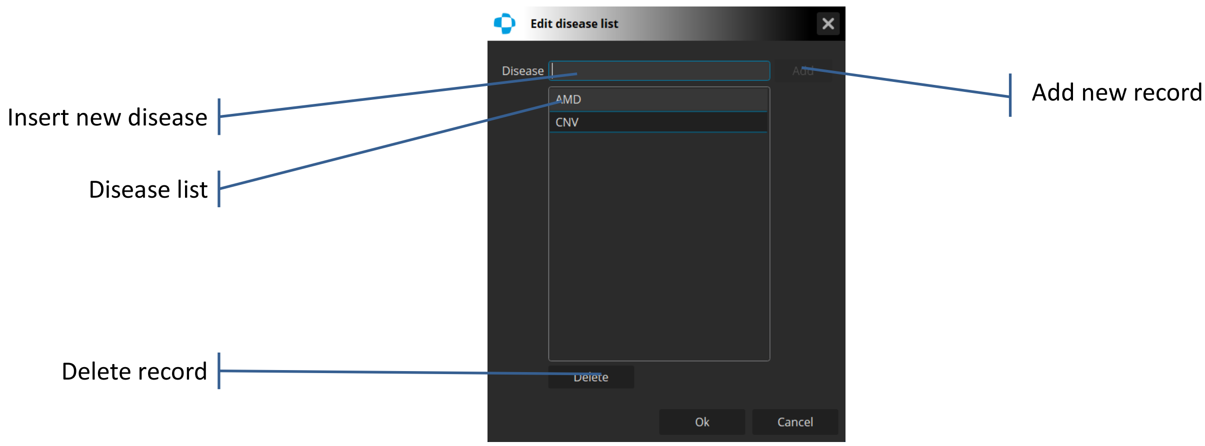


Figure 323. Disease list window

22.6 **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.

22.7 **Output settings**

22.7.1 *Output set window*

This section describes how to create, modify and remove sets of outputted data.

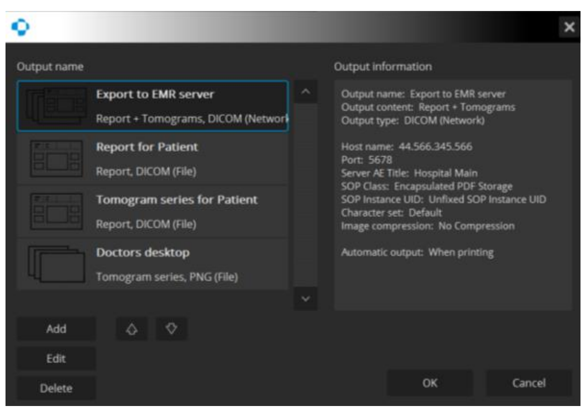


Figure 324 Output set window

[Add] – Press to create a new output set

[Edit] – Press to Edit currently existing set

[Delete] – Remove existing set

[Up and down arrow] - Move the position of selected output set down or up on the list.

Arrows - Change sequence position of desired set on the list

i. *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* if you wish 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).

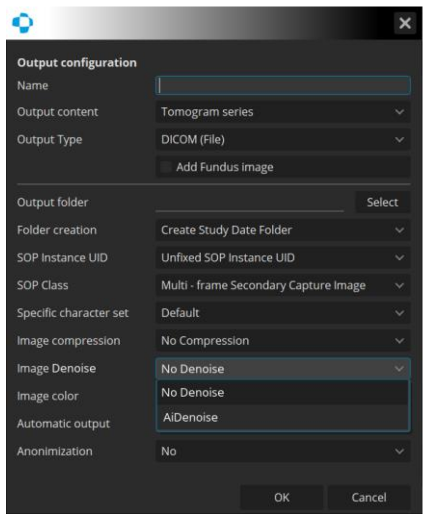


Figure 325. AI DeNoise export settings

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 such tomograms always make sure the exported denoised images are identical with the original unprocessed images

22.7.2 *Creating an Output set*

Output configuration window has two views. One view for DICOM storage configuration and the other for different file types.

22.7.3 *Graphic file standard*

Outputted data can be viewed in standard graphic file.

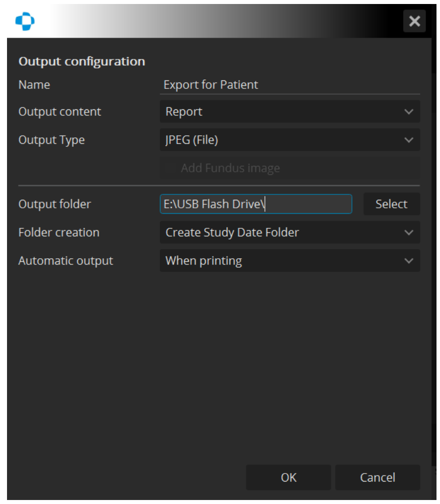


Figure 326. Output configuration screen.

Name	Input the Output set name
Output content	Tomogram, Series of tomogram and Report is available
Output type	Select from one of graphic standard file .jpg, .png, .bmp, .pdf and .avi for tomograms series.
Add fundus image	Reference fundus reconstruction image will be added on the side of tomogram object.
Output folder	location to save data. It can be local or network location.
Folder creation	Saved files can be placed automatically in the folder. Folder name is a date of preparing report (Output Date folder) or examination date (Study Date folder).
Automatic output	Select the moment when system data can be output.

When printing	System output data when operator initiate printing the report.
After capture	This option is available for tomogram/s only.

The output destinations are used to send DICOM with network or write result to DICOM/JPEG/BMP/PDF/Movie in a specified location (local or network).

Anonymization – by default it is disabled. Anonymization can be enabled or disabled for each output file.

22.7.4 *DICOM C-storage output set*

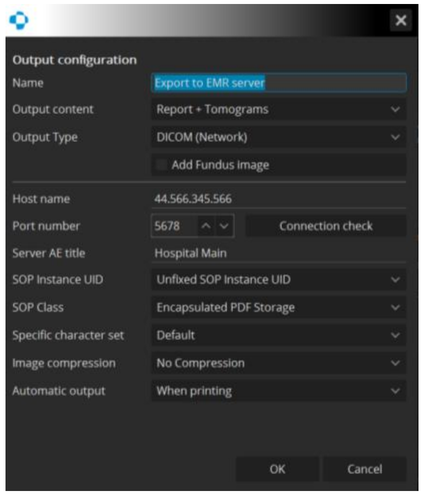


Figure 327. DICOM output configuration screen.

Name — Input the Output set name.

Output content — Tomogram, Report + tomogram, Series of tomograms and Report, Series of tomograms + Fundus photography examinations, Fundus photo, tomograms from – are available

Output type — DICOM file – it can be saved in any location

DICOM Network.

Add fundus image — On the side of tomograms reference fundus reconstruction

Image will be added.

Host Name — Enter the host name or the IP address (IPv4).

Port Number — Enter the port number.

Server AE Title — Enter the server AE title. Be sure to input the value.

SOP Instance UID — Fixed or Unfixed SOP Instance UID is available.

SOP class — Select an SOP class for the model to be configured.

Secondary Capture Encapsulated PDF Storage,

Multiframe True Color Secondary Capture Image Storage,

Multiframe Gray Scale 8bit Secondary Capture Image Storage,

Ophthalmic Tomography Image Storage, Fundus Image Storage

Specific Character Set — Select the specific character set. Default Unicode.

Image Compression — No compression is available.

Automatic output — Select the moment when system data can be output.

When printing System output data when operator initiates printing the report.

No User must press Output and select desired set.

[Connection check] Check the connection with DICOM server.

Anonymization Disabled by default. Anonymization can be enabled or disabled for each specific output file

22.8 Backup

Database and examinations backup can be performed on external HDD or in network server location.

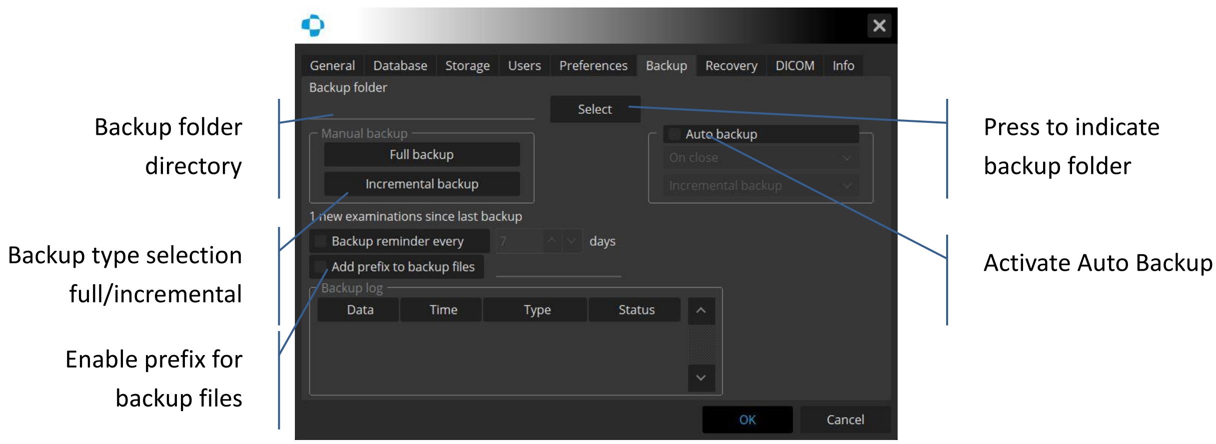


Figure 328. Backup tab.

<u>Manual backup options</u>:

Full backup - complete database will be saved as a spare copy.

Incremental - only new exams are added to previously archived with this method.

<u>Automatic backup options</u>:

Auto Backup – Activates automatic backup process.

- On close or on start – it decides when the SOCT application starts backup.
- Incremental or full backup – types of backup.

Backup reminder – When backup is not performed, the system displays backup reminder after specified period of time.

Add prefix to backup files – When 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 HDD/remote folder before performing backup process.

In case this window appears please select backup folder location. Or check external HDD connection.

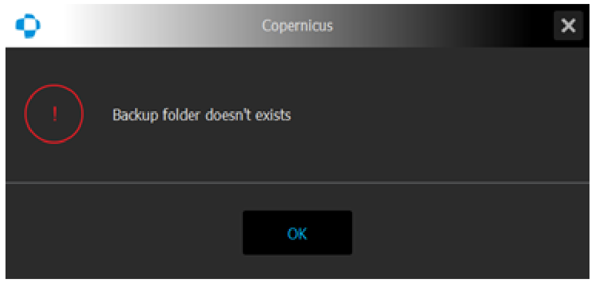


Figure 329. Backup error example.

22.9 **Recovery**

The SOCT provides an option for a data recovery from the internal and external storage.

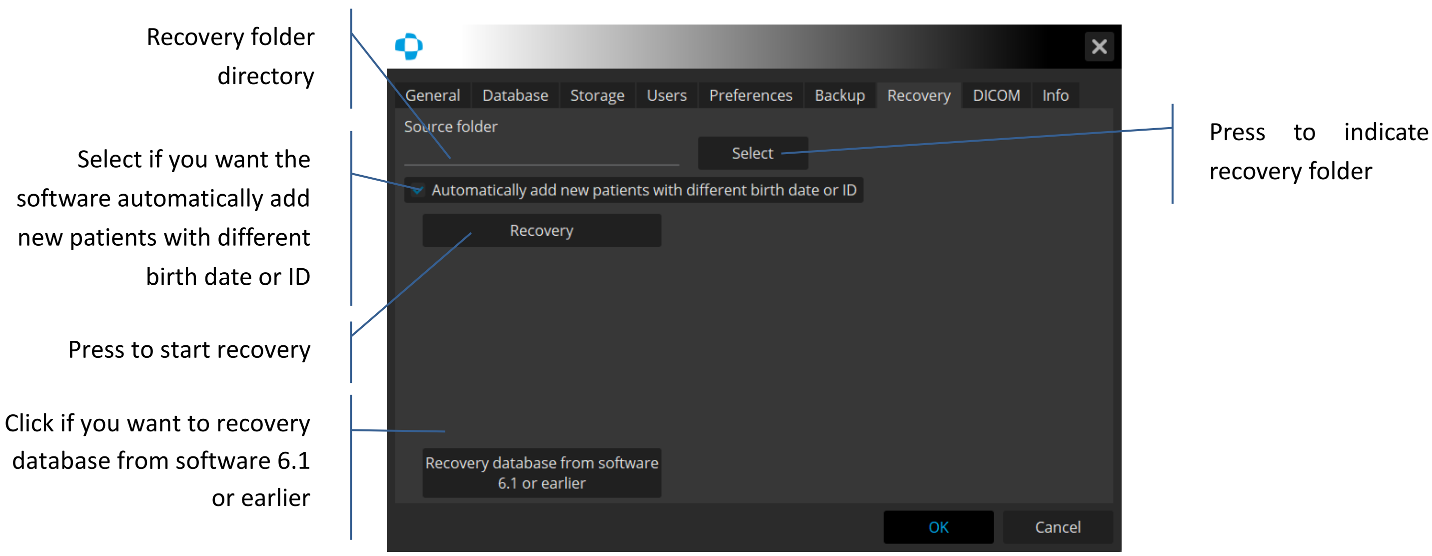


Figure 330. DICOM tab.

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 it 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 ale examinations to the database.

22.10 **DICOM**

DICOM Interface consists of two client modules (SCU):

- Result Storage (Reports, Tomograms)

- 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 unique ID (AE Title) and TCP/ID address. AE Title and TCP/ID address should be saved in the application settings and in all SCP

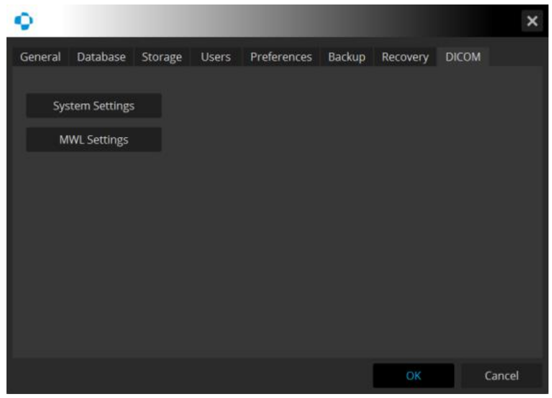


Figure 331. DICOM tab.

22.10.1 *System settings*

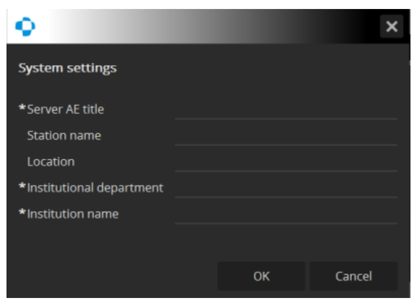


Figure 332. System settings window.

AE title	Enter the server AE title. This is obligatory value
Station Name	Input the station name.
Location	Input the location.
Institutional Department Name	Input the institutional department name. This is obligatory value
Institution Name	Input the institution name. This is an obligatory value

22.10.2 *MWL settings*

The module communicates with the Modality Work List whose ID (AE Title) and TCP/IP address can be configured in 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.

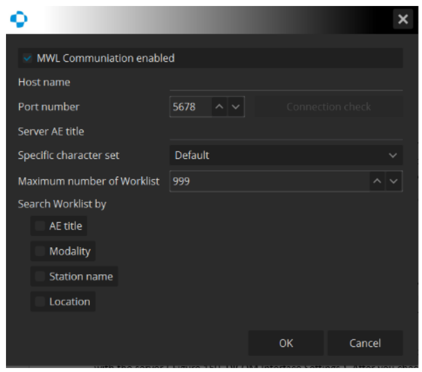


Figure 333. MWL Interface Settings.

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.

Host Name Enter the Host name

Port Number Enter the port number.

Server AE Title Enter the server AE title. Be sure to input the value.

Specific Character Set Select the specific character set.

Maximum number of worklist Maximum length of worklist.

Search Worklist by Retrieve the records from the Worklist sort by AE Title, Modality, Station name, Location.

[Connection check] Check the connection with DICOM server. . After you check the communication and compatibility of the settings, you will see a message indicating successful completion of the order, or a list of errors

NOTE: Make sure that the SCP host delivering patients' demographic data for tests is correctly configured and active. Otherwise data collecting will fail.

22.10.3 *C-storage*

Examination results can be sent to DICOM network or DICOM file.

SOCT saves files in standard: Encapsulated PDF Storage, Multiframe True Color Secondary Capture Image Storage, Multiframe Gray Scale 8bit Secondary Capture Image Storage, Ophthalmic Tomography Image Storage

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 in file "SOCT DICOM Conformance Statement.pdf"

Detailed explanation how to configure DICOM storage can be found in chapter 22.7.4 DICOM C-storage output set.

22.11 **Info tab**

Information label

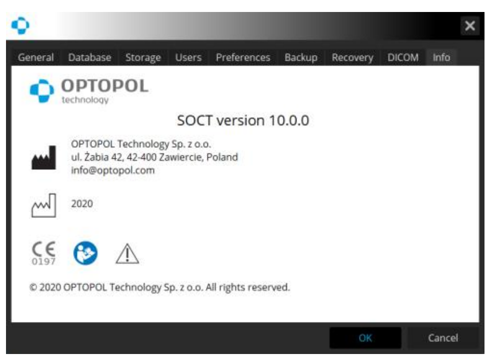


Figure 334. Information label

22.12 **Patient record change traceability and LogReader software**

The LogReader.exe is located in the 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 distributor.

23 MAINTENANCE AND CLEANING PROCEDURE

WARNING: All maintenance activities can only be made 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 authorized service staff.

WARNING: The main lens of the device should not contact the patient's eye or face.

NOTE: It is not allowed to make any modifications of the SOCT.

During the whole period of use, SOCT does not need any special maintenance procedures. The outside surfaces of 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.

23.1 Routine Cleaning

a) Cleaning of the device casing and equipment of the ME System (PC, monitor LCD, printer, keyboard and mouse PC)

Clean the casing with soft cloth. Use only cleaners dedicated for cleaning of electronic equipment. Clean periodically or when needed.

b) Cleaning of the applied parts (forehead and chinrest support)

The applied parts should be disinfected after examination of each and every patient. Use soft cloth, wet with 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 longer period of no use.

c) Cleaning of the lens

The lens should be cleaned sporadically, when contamination of lens surface is observable. For lens cleaning, use only cleaners applied in optics, that do not cause scratching of the lens. Clean the lens softly with little force. It comes with a lens cap to cover it when not in use. You should clean it to remove dust and oily smudges sporadically to ensure true tomogram images are obtained. You may use an alcohol prep swab or cotton swab dipped in isopropyl alcohol. Wipe dry with a soft, non-lining cloth or tissue.

d) **Dust Prevention**: When not using the SOCT, make sure the cloth dust cover is placed over the unit.

NOTE: Periodically one has to check if there are no mechanical damages to the device, damages to any of the cables and fuses.

23.2 Software maintenance activities

To keep software in good condition user should perform below activities as minimum:

1. Windows automatic updates should be checked periodically at least once a month. In order to do the update: Enable automatic updates, wait until system finishes the update process. During the process do not acquire 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), system administrator should manually keep operating system updated. System administrator should check regularly for new updates at least once a month.
3. Installed antivirus software should be updated at least once a week.
4. For OPTOPOL's software upgrades and patches OPTOPOL will inform users through its distributors.

23.3 Hard Disk Defragmentation

Defragmentation of the OCT PC hard disk becomes necessary when you delete, analyze old scans 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 you defragment the hard disk regularly.

NOTE: Since hard disk defragmentation usually requires several hours to complete, we recommend that you start defragmentation 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.

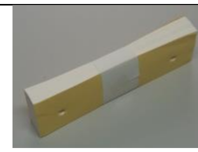
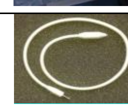
To defragment the hard drive, follow these steps:

1. Close the 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.

23.4 **Ordering consumables**

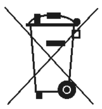
When ordering consumables and spare parts, contact your local dealer and tell them the article name, article code and quantity.

Article name:	Article code:	Description:
Single use chinrest labels	R C003P	
Fuses (applicable to REVO FC models)	R B006P	2 x F 4 A H 250V
Fuses	R018	2 x F 3,15 A L 250 V
Dust cover	R C005P R C005 FC	
External fixation with LED (interchangeable)	R024F	
USB 3.0 cable	R035	
Lens cover	R037	
Anterior Adapter (interchangeable)	R036	
USB Flash drive with the SOCT software, drivers and the User manual	R042	

23.5 Fuse

23.5.1 *Blown fuses exchange*

If the device does not work when the power is on, the possible reason is a blown fuse.



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

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

The fuses are located in the power supply socket at the back of the device. In order to replace the fuses, unplug the power supply cable, press the small plastic lever and pull the fuses casing.

24 NETWORK CONFIGURATION

Networking configuration procedure is described in the Installation Manual provided on the USB Installation Disc.

24.1 **Network connection configuration**

24.1.1 *SOCT network*

SOCT software allows to locate examination data on external network locations or HDD. Besides that, it is possible to share the database table from SOCT device PC. There is unlimited number of PCs connected to the same LAN which have access to *SOCT database.* All applications connected to server database should have the same settings in setup database tab (SOCT device software, viewing stations). Efficiency of work is limited by network structure and PC performance (OS Windows required). It is recommended to use minimum 1000 Mbps network structure. There is no additional synchronization button, this mechanism is done in the background.

Server application (e.g. MySQL, firebird) can also be installed on SOCT PC, in that case it will have to be on to share the database with viewing stations.

NOTE: Database tables storage has to be done with a use of server software e.g. MySQL.

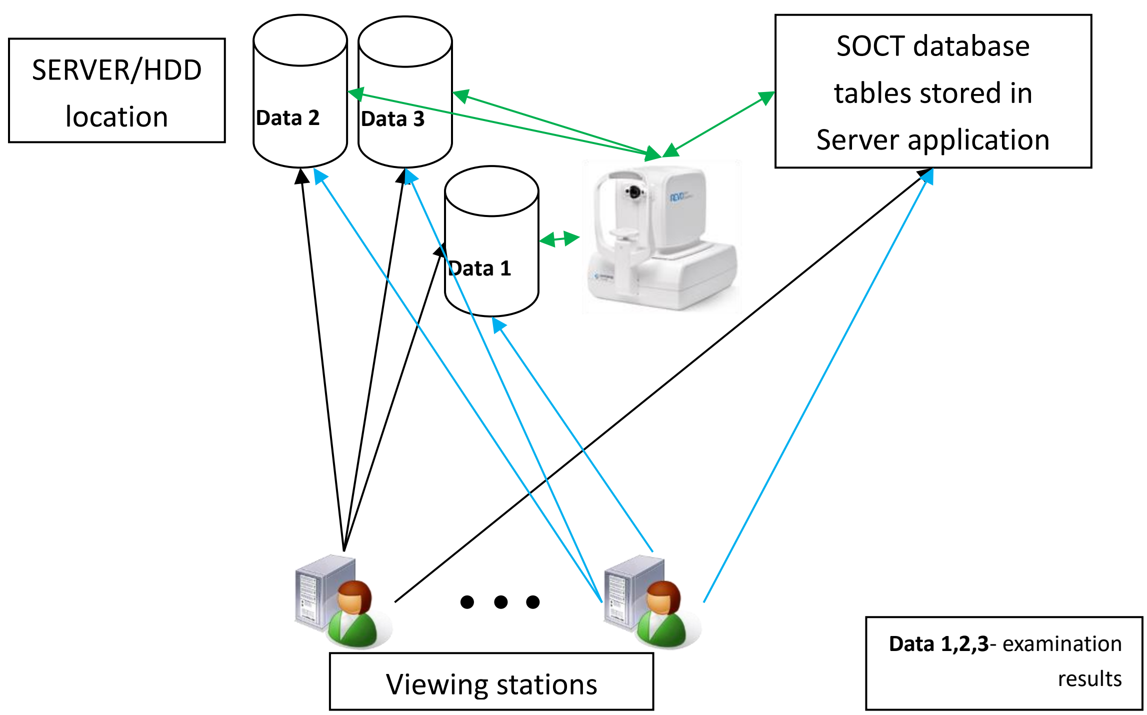


Figure 335. Networking possibilities scheme.

Networking functionality restrictions

When software is configured as Client, there are some limitations applied to its functionality:

- Only client connected to OCT device can perform new examinations.
- In case specific patient's file is used on any PC connected to 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.
- Users' accounts modification and settings can be changed from any software application connected to database on Server.
- All viewing stations need to have access to examination data folders (sharing enabled)

NOTE: Internal network settings should be adjusted by IT personnel to provide free access and communication between folders. Be aware of firewall exceptions for SOCT software

NOTE: When sharing database with viewing stations it is mandatory to share data folders in the network and allow other users read/write rights.

24.1.2 *SOCT software - viewing station configuration*

1. In order to configure database client, you need to install SOCT Software on each PC you want to use as a viewing station. You can find SOCT Software on the installation disc. To install it, run setup.exe and follow instruction on the screen.
2. Go to **Start/Control Panel/Network and Internet/Network and Sharing Centre/Advance sharing settings** and select:
    - Turn on network discovery
    - Turn on file and printer sharing

Accept and **Save Changes.**

3. Verify the type of database engine you want to use.
4. Before starting the software

For Firebird copy "fbclient.dll" file from C:\Program Files\Firebird\Firebird_3_0 and paste it to SOCT installation folder: C:\Program Files\Optopol\SOCT 7.1.0.

In Case of using MySQL copy 'libmysql.dll' from folder where MySQL is installed C:\Program files\MySQL

5. On the review station run SOCT software. Press LOGIN without entering any user details. Go to below window and select Connect to existing database.

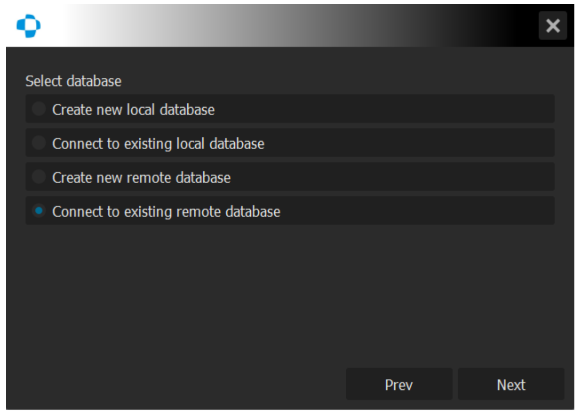


Figure 336. Window after login to new system.

6. Type name of the computer in the network group or IP address. Enter login and password for MySQL database.

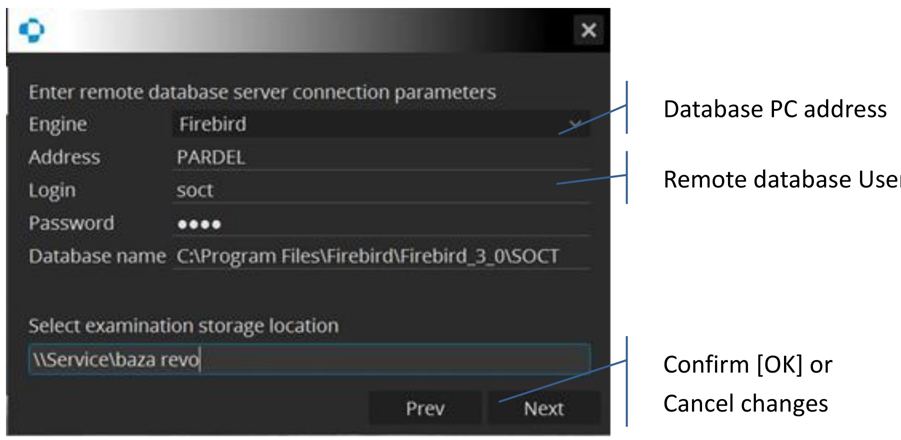


Figure 337.Remote database configuration.

Engine – *Select type of the database engine (MySQL or Firebird)*

Address - here enter IP number or Host name of remote server application that is used as a storage for database tables.

Login – enter username of the remote server software (e.g. MySQL)

Password – enter password to remote database software

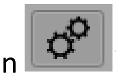
NOTE: Server application location has to be active to share the database.

7. Restart SOCT Software.
8. The next time you start the software, the system will connect to remote database.

25 REMOTE CONNECTION

25.1 PTS application for Structure & Function report

To configure the PTS application for remote communication with the application database, follow these steps:

- On the computer with the remote database (the host) run the PTS application, go to the settings page by clicking on the settings button (the cogwheel button ) and choose the Users tab.
- Add a user in the Users Manager window. To do that click the Add new user button, fill the User name and Password fields and add the Administrator privileges in the Role field.
- Click the Save button to save the changes.

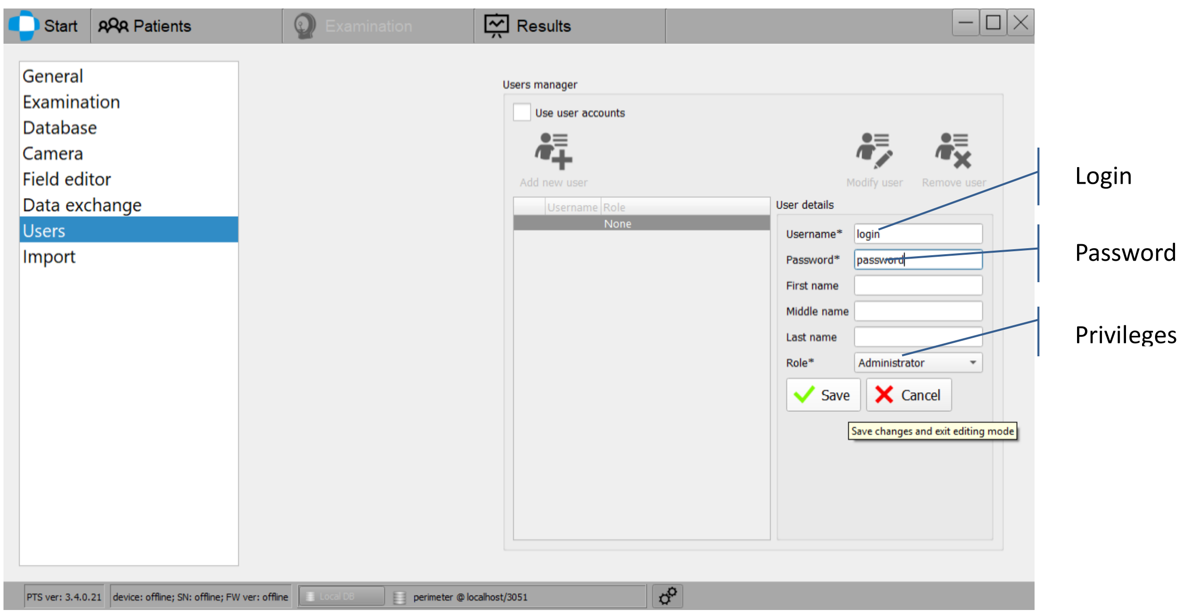


Figure 338.Users tab in PTS application.

- On the computer with the SOCT application run the PTS application, go to the Database tab. In the Database settings window mark the Remote database option and fill the Host name field by entering the name or the IP address of the remote server, the Port field by entering the port of the remote server, the Username and Password fields, and the path for the Database in the Database path field.
- Click the Save button to save the changes.

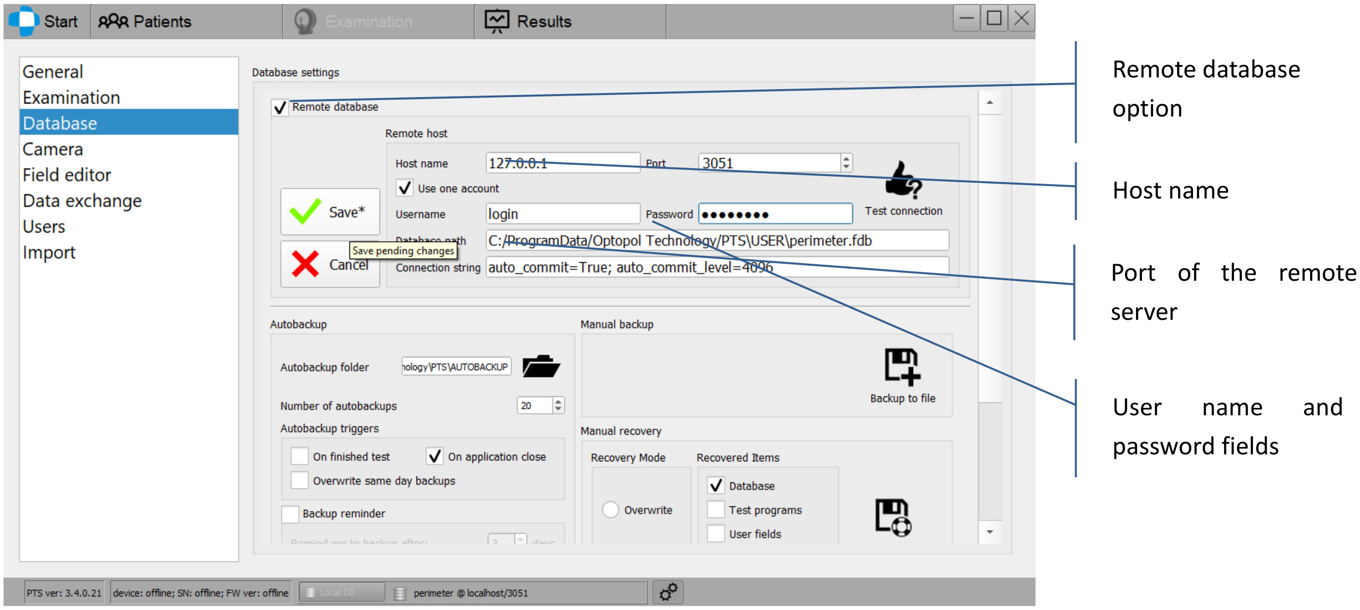


Figure 339.Database tab in PTS application.

On the computer with the remote database (the host) and on the computer with the SOCT application (the client) it is necessary to enable ports 3051 and 8100 by entering the following commands in the command line:

netsh advfirewall firewall add rule name="Perimeter Firebird 3051 in" dir=in action=allow protocol=TCP localport=3051

netsh advfirewall firewall add rule name="Perimeter Firebird 3051 out" dir=out action=allow protocol=TCP localport=3051

netsh advfirewall firewall add rule name="Perimeter Firebird 8100 in" dir=in action=allow protocol=TCP localport=8100

netsh advfirewall firewall add rule name="Perimeter Firebird 8100 out" dir=out action=allow protocol=TCP localport=8100

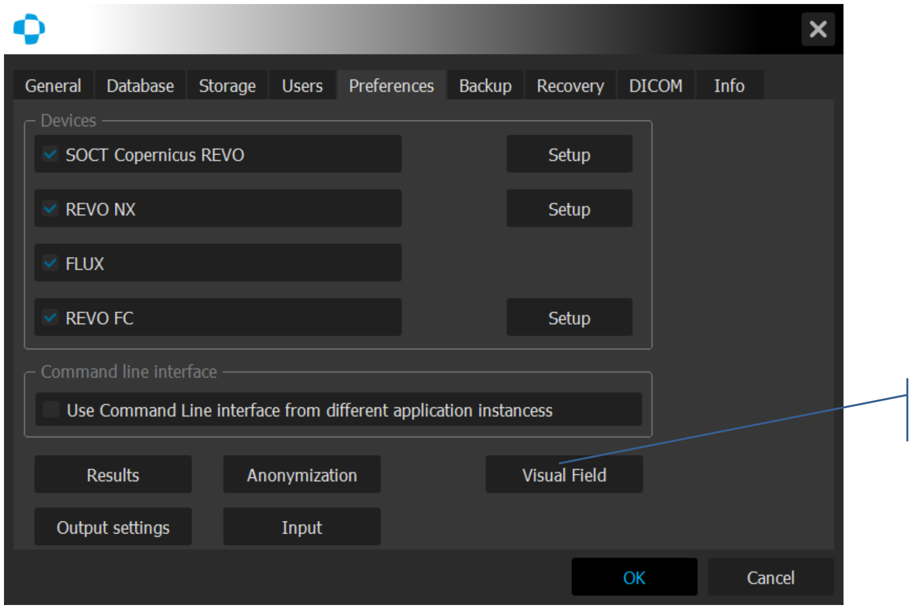
If a Firewall and/or antivirus program is installed, it may be necessary to manually unblock ports 3051 and 8100 in these programs.

Configuration of a remote connection with the database in the SOCT application

In order to configure the SOCT application for a remote connection with the PTS software database, follow these steps:

- Run the SOCT application, enter the login data and go to the application configuration option by clicking the Setup button.

- Go to the Preferences tab (the default tab) and click the Visual field button.



Visual field button

Figure 340.Preferemce tab in SETUP SOCT application.

- In the Visual field window check the Use PTS communication option and click the Auto-search button. An installation of the PTS application version 3.4.0 or higher is required. The PTS folder and Database text boxes should now be updated. If this does not happen, it is possible to fill these fields manually by choosing the path for the PTS installation folder (the folder with the PTS.exe file) in the PTS folder text box by clicking the Select button.
- Check the Use an account option and enter the user name and the password for the PTS application database in the Username and Password fields.
- In the case of a remote connection, check the Remote host option and enter the IP of the database server and the port in the Host name and Port fields.
- Click the Save button to save the changes.

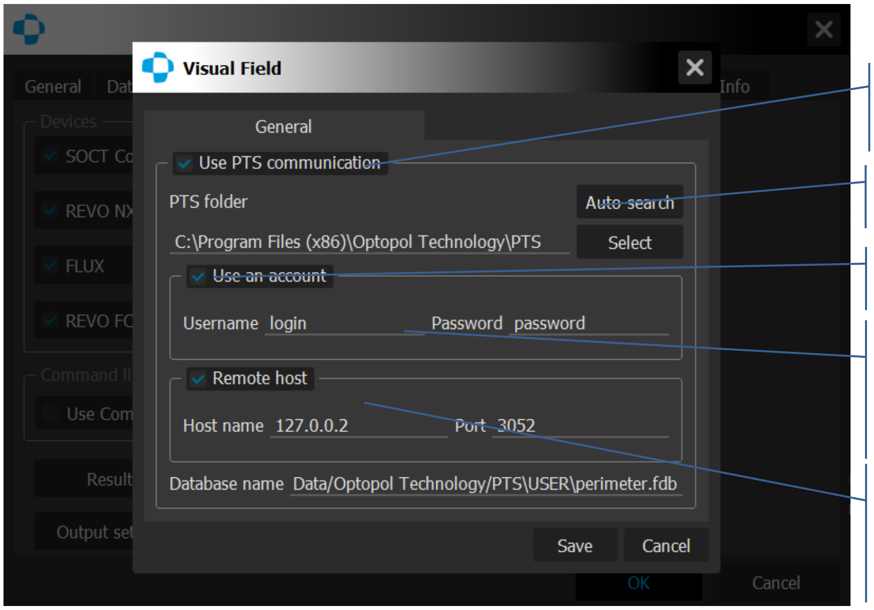


Figure 341. Visual field window in SOCT application.

26 ENVIRONMENTAL CONDITIONS

ENVIRONMENTAL CONDITIONS OF USE:

CRITERION	ENVIRONMENTAL CONDITIONS
Temperature	+ 10 °C to + 35 °C
Relative humidity	30 % to 75 %
Atmospheric pressure	800 hPa to 1060 hPa
Dust on the air	No visible particles

STORAGE CONDITIONS:

CRITERION	ENVIRONMENTAL CONDITIONS
Temperature	-10 °C to + 55 °C
Relative humidity	10 % to 95 %
Atmospheric pressure	700 hPa to 1060 hPa

TRANSPORT CONDITIONS:

CRITERION	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 where 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 SOCT with the optional power table requires an area at least (1,5 m by 2,4 m) for installation and patient comfort during use.

Measurement Units

All units on the SOCT are measured in the SI format. Unless otherwise noted, measurements are made in micrometers.

27 WARRANTY AND SERVICE

In case of problems contact your local distributor:

On request the supplier will 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.

Service life

The service life of this product is ten years if specified inspections and maintenance are performed.

About repairs

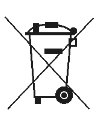
If a problem cannot be solved even after taking the measures indicated in "Chapter 29 TROUBLESHOOTING" contact OPTOPOL distributor for repairs.

When requesting repair, please provide the following information:

Full Name of the device and Serial Number: number on the rating label.

Description of malfunction: Report as much detail as possible.

28 UTILIZATION

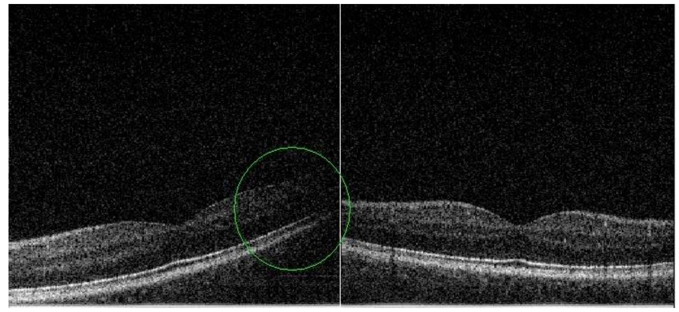


After usage period is over, contact your distributor for utilization instructions.

Maximum lifetime of device – 10 years since date of manufacture.

29 TROUBLESHOOTING

Q1: The tomogram images have good quality, but there is a shadow at horizontal tomogram image (left image) on the left or right edge and the image is diagonal.

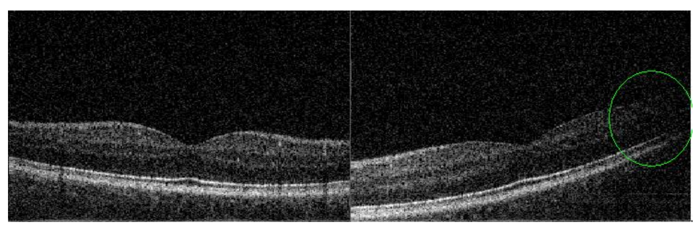


A1: The scanning beam is not centered on the pupil in the horizontal direction. This effect is observed mostly for very small pupils and wide scanning ranges. Grab and move the tomogram to left or right to obtain the best image quality.

Q2: The tomogram images have good quality, but the horizontal retina cross section image is diagonal.

A2: See A1

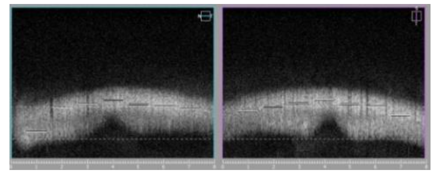
Q3: The tomogram images have good quality, but there is shadow at vertical tomogram image (right image) on the left or right edge and image is diagonal.



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 move slightly tomogram (in this case in right direction) on 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 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 software communication errors are displayed.

A6: Make sure that the scanning head finished self-test before you run the application.

Q7: Software displays massage “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: 1. Check cleanliness of the objective lens. Clean it if necessary. If it is not changed go to point 2. Make sure that system calibrates itself before the first examination.

Q9. The SOCT application is connected with the device but I get error messages when I open the Acquire tab or during work in Acquire tab.

A9. If Fast Speed USB 3.0 Connection is not available in the system, Aviva camera is not able to work in required mode. Verify points below:

1. Make sure that SOCT USB cable is connected to 3.0 USB port
2. Verify if the USB cable is protected from any unintentional tension, movement or push. Protect physically USB plug from any loose.

3. Unplug and plug again the USB cable. Make sure there is no play (slack) on the port. Wait a while 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.

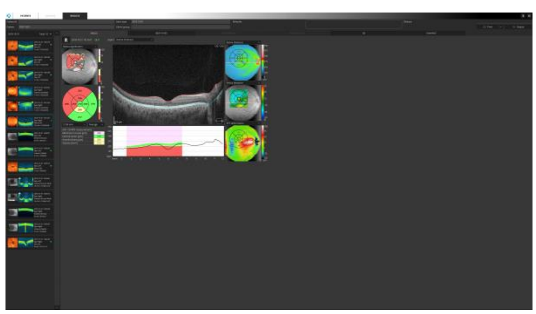
Q10: During Acquisition of tomograms OCT live windows become black.

A10: See the status of the device in left bottom corner of the OCT image. In case of error restart application. If the problems occur again see A9.

Q11: I have no connection to remote database.

A11: Verify procedure of connection according to user manual again. Make sure network settings are proper. Verify if Host name /IP is properly entered in all software applications connected to server.

Q12: The analyze window is displayed only in a quarter of the screen.



A12: Verify the screen and Windows resolution. Go to Control Panel=>Appearance and Personalization=>Display and select “*Larger – 150%*”

30 LIST OF FIGURES

31 PRODUCT COMPLIANCE

31.1 Radio Interference

The REVO nx has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with this user manual, may cause interference to radio communications. Operation of this equipment in a residential area is likely to cause interference, in which case users will be required to correct the interference at their own expense.

31.2 Canadian Regulations

The REVO nx does not exceed the Class A limits for radio noise emissions from digital apparatus as set out in the radio interference regulations of the Canadian Department of Communications.

31.3 EMC information

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The SOCT is intended for use in the electromagnetic environment specified below. The customer or the user of the SOCT should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The SOCT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The SOCT 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:
Note: The emissions characteristic of this equipment makes it suitable for use in industrial areas and hospitals (CISPR 11 class A). If the SOCT is used in a residential environment (for which CISPR 11 class B is normally used) this equipment might not offer adequate protection to radio-frequency communication service. The</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

		user might need to take mitigation measures such relocating or re-orienting equipment.

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The SOCT intended for use in the electromagnetic environment specified below. The customer or the user of the SOCT should assure that it is used in such an environment.</td></tr>
<tr><th>IMMUNITY test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Electrostatic discharge (ESD)
IEC 61000-4-2</td><td>± 8 kV contact
± 2,4,8,15 kV air</td><td>± 8 kV contact
± 2,4,8,15 kV air</td><td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.</td></tr>
<tr><td>Electrical fast transient/burst
IEC 61000-4-4</td><td>± 2 kV for power supply lines</td><td>± 2 kV for power supply lines</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge
IEC 61000-4-5</td><td>± 0,5; 1kV line(s) to line(s)
± 0,5; 1; 2 kV line(s) to earth</td><td>± 0,5; 1kV line(s) to line(s)
± 0,5; 1; 2 kV line(s) to earth</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Voltage dips, short interruptions and voltage variations on power supply input lines
IEC 61000-4-11</td><td>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°</td><td>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°</td><td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the SOCT requires mains interruptions, it is recommended that the SOCT be powered from an uninterruptible power supply or a battery.</td></tr>
</table>

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 a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The SOCT is intended for use in the electromagnetic environment specified below. The customer or the user of the SOCT should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the SOCT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	**Recommended separation distance** $d = [1{,}17]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = [1{,}17]\sqrt{P}$ 80 MHz to 800 MHz $d = [2{,}33]\sqrt{P}$ 800 MHz to 2,5 GHz

			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] 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 with the SOCT is used exceeds the applicable RF compliance level above, the SOCT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SOCT. [b] 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 SOCT			
The SOCT is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SOCT can help prevent electromagnetic interference			

by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SOCT 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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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 because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally