

CLARUS 500

Instructions for Use



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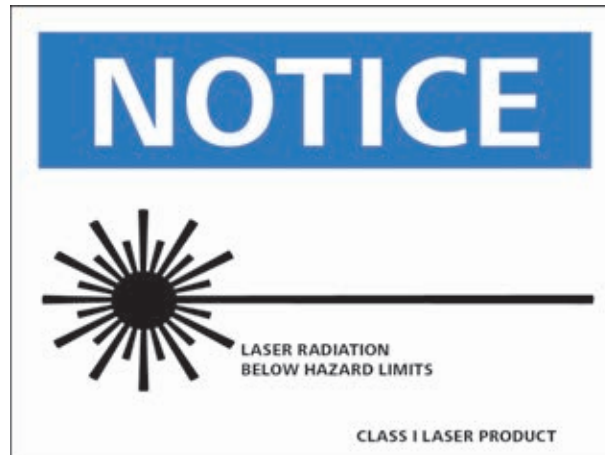
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1 Safety and Certifications

1.1 Compliance

CLARUS™ 500 from ZEISS is compliant with ISO 10940:2009 and ISO 15004-1:2006.

1.1.1 Laser Safety and Compliance



Complies with 21 CFR
Subchapter J

1.1.2 Optical Safety

CLARUS 500 is compliant with the following optical safety standards:

- IEC 60825-1
- ANSI Z80.36
- ISO 15004-2
- **Classification:** Group 1 Instrument - Per ANSI Z80.36 and ISO 15004-2

Group 1 instruments are ophthalmic instruments for which no potential light hazard exists.

- Class 1 Laser Product – Per IEC 60825-1.













1.1.3 RoHS Compliance











The product is RoHS-compliant according to Directive 2011/65/EU.

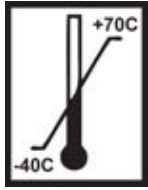
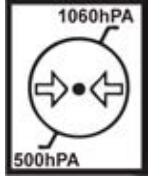
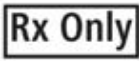
1.1.4 Electrical Safety

Electrical Safety Class I Equipment - Protection against electrical shock (per IEC 60601-1).

1.2 Symbols and Labels

Symbol	Meaning
	Warning
	Caution
	Note
	Electricity
	Must follow Instructions for Use
	Power On (computer)
	Power Off (computer)
	Protective Earth
	Fuse
	Direct Current
	Type B Applied Parts
	Manufacturer

Symbol	Meaning
	Authorized European Community Representative
	Serial Number
	Catalog Number/Part Number
	Model Number
LR 96697  C US	Certification mark of CSA – Nationally Recognized Testing Laboratory for US and Canada
	Disposal of the Product within the E.U. Do not dispose via domestic waste disposal system or communal waste disposal facility.
	Fragile
	Keep Dry
	This End Up
	Transport conditions: humidity (10% to 95%)

Symbol	Meaning
	Transport conditions: temperature (-40°C to 70°C)
	Transport conditions: atmospheric pressure (500 hPa to 1060 hPa)
	Caution: Federal law (or United States) restricts this device to sale by or on the order of a licensed healthcare practitioner

1.3 Warnings, Cautions, and Notes

1.3.1 Definitions

Warnings and cautions are defined as follows:

WARNING!

Indicates hazards that, if not avoided, could cause severe injury or death.

- ▶ These are actions that can be taken to prevent the hazard.

CAUTION!

Indicates hazards that, if not avoided, could cause minor or moderate injury.

- ▶ These are actions that can be taken to prevent the hazard.

1.3.2 Warnings

WARNING!

Opening the device covers

may result in injury.

- ▶ Only ZEISS authorized service technicians may remove device covers.

WARNING!

Tipping the device

may result in injury.

- ▶ Do not allow the patient to lean on the table or use it as a support to stand up.

 **WARNING!**

Modifying this device

may increase risks and decrease the service life of the device.

- ▶ Do not use in the presence of flammable gasses.
- ▶ Do not use in oxygen rich environments.

 **WARNING!**

Using this device in the presence of flammable gases

may cause ignition and result in a fire hazard.

- ▶ Do not use this device in the presence of flammable anesthetics or oxidizers such as pure oxygen or nitrous oxide.

 **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!**

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.

- ▶ Use only the accessories, transducers, and cables specified or provided by ZEISS.

 **WARNING!**

Adding peripheral equipment or replacing parts

may result in noncompliance with the safety requirements of IEC 60601-1.

- ▶ You are responsible for ensuring that the system meets the safety requirements of IEC 60601-1.
- ▶ Only approved equipment to their respective IEC/ISO standards such as IEC 60601-1 or IEC 60950 are allowed to be connected to the Signal Input/Output parts (SIP/SOPs).
- ▶ Place any AC-powered, non-medical device peripherals at least 1.5 m away from the instrument and connect them to a separation device, unless an isolation transformer is used.

 **WARNING!**

Unplugging the power cord is the means of disconnecting from the power supply.

Blocking access to the plug may result in an electrical hazard.

- ▶ Set up the instrument so that it can be unplugged easily.

 **WARNING!**

Using parts that are not authorized by ZEISS

may compromise device safety during operation.

- ▶ Use only accessories authorized by ZEISS.
- ▶ In the U.S., call 800-341-6968. Outside the U.S., contact your local Zeiss distributor. You can find the ZEISS contact partner for your country on our website: www.zeiss.com.

 **WARNING!**

Class 3B laser radiation

when open.

- ▶ Avoid exposure to beam.

 **WARNING!**

Contact with the patient and a peripheral device

may cause an electric shock.

- ▶ Do not touch the patient and a peripheral device at the same time.

 **WARNING!**

Device produces visual stimuli, including flickering light and flashing patterns, between 5 and 65 Hz

may adversely affect certain patients, although this effect is yet unproven.

- ▶ Medical professionals need to determine whether this device should be used for patients who may be photosensitive, including those with epilepsy.

 **WARNING!**

Unqualified personnel

may injure themselves or cause damage to the instrument.

- ▶ Only trained, qualified personnel may use this device.
- ▶ This device may be used only for its intended purpose.
- ▶ Only ZEISS authorized personnel may perform maintenance or repair procedures not described in this manual.

 **WARNING!**

Use of the acquisition device, a printer, or the power table with an extension cord or a power strip (multiple portable socket outlet)

could cause electrical shock to the patient or operator.

- ▶ Do not use extension cords with the instrument.
- ▶ Do not use power strips with the instrument.
- ▶ Do not plug in any other equipment into the same wall outlet as the instrument.
- ▶ To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

1.3.3 Cautions

 **CAUTION!**

Use of controls or adjustments or performance of procedures other than those specified herein

may result in hazardous optical radiation exposure.

 **CAUTION!**

Attempting to carry out activities not specifically endorsed by ZEISS

may void your warranty and could result in damage to the instrument.

- ▶ Read the user documentation.
- ▶ Follow directions carefully.
- ▶ Do not make upgrades, or carry out repairs or modifications, without specific guidance and instruction from ZEISS or an authorized ZEISS representative.

 **CAUTION!**

Improper cleaning

may result in inadequately disinfected equipment.

- ▶ Refer to the cleaning instructions in this Instructions for Use and local and national disinfecting regulations.

 **CAUTION!**

Internet connection of the CLARUS 500

increases its vulnerability to serious security risks, including viruses and worms that could disable your system or adversely affect its performance and may void the instrument warranty.

- ▶ Transfer data through internal networks.
- ▶ Ensure that all firewalls and internet security applications are up-to-date and running.
- ▶ Connecting the device to the internet or transferring data via USB devices may result in compromised patient privacy and expose the network to malware.

 **CAUTION!**

Installing or putting the device into service without regard to EMC information provided

may void your Device warranty, result in damage to the instrument and/or compromise safety for patients and operators.

- ▶ The CLARUS 500 has special EMC precaution requirements and needs to be installed and put into service according to the EMC information provided herein.

 **CAUTION!**

Using this instrument with patients who are light-sensitive, including epileptics

may cause nausea or harm to the patient.

 **CAUTION!**

Attempting to decommission your system

may result in damaged equipment and danger to personnel.

- ▶ Never attempt to decommission a ZEISS system or instrument. Only ZEISS approved representatives are qualified to safely decommission your system.
- ▶ Contact your ZEISS approved representatives to set up an appointment for system or instrument decommissioning.

 **CAUTION!**

Packaging and transport by non-ZEISS personnel

could result in damage, loss, or non-compliance within the country of transit.

- ▶ Allow only change to Zeiss approved representative to prepare the instrument and associated components for transport.
- ▶ Allow only ZEISS-approved personnel to transport the instrument and associated components.

⚠ CAUTION!

Do not lift or carry the instrument using the patient support.

The patient support could break if used as a carrying handle.

- ▶ Make sure you support the instrument from the base whenever you carry the instrument.

⚠ CAUTION!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas)

should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.

- ▶ Otherwise, degradation of the performance of this equipment could result.

⚠ CAUTION!

The CLARUS 500 is intended for use in a professional healthcare facility environment.

Using the instrument in any other environment may void the warranty and compromises the safety of the patient and/or operator.

⚠ CAUTION!

Image Degradation

If image quality is degraded or image is absent from display, please contact Zeiss customer service.

- ▶ The physician must decide whether the image is appropriate for diagnosis

1.3.4 Notes

NOTE

Transferring data via USB devices

may result in compromised patient privacy and expose the network to malware.

- ▶ Use access controls to ensure that only authorized personnel use the device.

NOTE

Connecting the device to a network that includes other equipment

may result in previously unidentified risks.

- ▶ You are responsible for analyzing and controlling these risks.
- ▶ You must reassess these risks when you make any changes to the network, including connecting, disconnecting, or upgrading equipment.

NOTE

Unprotected devices

may be at risk from unauthorized individuals.

- ▶ Select and set the Password strength setting in the User management screen.

1.4 Report Serious Accidents

Report any serious incident related to this instrument, the operator, patient, or anyone else:

- To the instrument manufacturer or distributor.
- (European Union only) To the competent authority in the state where the instrument operator is established.

1.5 Essential Performance

The main clinical performance of the CLARUS 500 is to capture, display and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina, ocular surface and visible adnexa. Since there is no surgical or treatment decisions made solely on data obtained by the instrument, it was determined that the CLARUS 500 has no "essential performance" as defined in IEC 60601-1 standard.

1.6 Electromagnetic Compatibility (EMC)

WARNING!

Installing or putting the device into service without regard to EMC information provided

may void your Device warranty, result in damage to the instrument and/or compromise safety for patients and operators.

- ▶ CLARUS 500 has special EMC precaution requirements and needs to be installed and put into service according to the EMC information provided herein.

NOTE

The emissions characteristics of this equipment

make it suitable for use in industrial areas and hospitals (CISPR 11 Class A).

- ▶ If it is used in a residential environment, this equipment might not offer adequate protection to radio-frequency communication services.
- ▶ The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic Emissions [▶ 19] and Electromagnetic Immunity [▶ 19] are required per IEC 60601-1-2:2007.

1.6.1 Electromagnetic Emissions

The CLARUS 500 complies with the following emission requirements:

Phenomenon	Standard
Conducted and radiated RF emissions	Group 1 CISPR 11 Class A
Harmonic distortion	IEC 61000-3-2
Voltage fluctuations and flicker	IEC 61000-3-3 Class A

Table 1: Electromagnetic Emissions

1.6.2 Electromagnetic Immunity

The CLARUS 500 complies with the following immunity requirements:

Phenomenon	Basic EMC standard or test method	Immunity test levels
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Wireless Communications [▶ 20]
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Phenomenon	Basic EMC standard or test method	Immunity test levels
Voltage dips, short interruptions, and voltage variations on power supply input lines	IEC 61000-4-11	0 % UT ¹ ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT ¹ ; 1 cycle and 70 % UT ¹ ; 25/30 cycles Single phase: at 0°
Voltage Interruptions	IEC 61000-4-11	0 % UT ¹ ; 250/300 cycle

Table 2: Electromagnetic Immunity

¹UT is the a.c. mains voltage prior to application of the test level.

1.7 Wireless Communications

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TERTRA 400	Pulse 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse 217 Hz	0.2	0.3	9

Table 3: Test specifications for enclosure port immunity to RF wireless communications equipment.

2 Introduction

2.1 Scope

2.1.1 Intended Use / Indications for Use

The CLARUS ophthalmic camera is intended to capture, display, annotate and store images to aid in the diagnosis and monitoring of diseases and disorders occurring in the retina, ocular surface and visible adnexa, as well as manual measurement of the retina. It provides true color, infrared reflectance and autofluorescence imaging modes for stereo, widefield, ultra-widefield, and montage fields of view.

2.2 Usage

The CLARUS 500 is designed for continuous use in a professional healthcare facility environment.

The mode of operation for the table is 2 minutes on and 20 minutes off.

2.3 Intended Audience

CLARUS 500 users have a *role*, which is assigned when an **Administrator** creates their username and password. These roles are:

- **Operator**
- **Doctor**
- **Administrator**

For more information, refer to: About User Roles [▶ 58].

2.3.1 Patient Profile

This device may be used on any patient who is able to sit upright with his or her face in the instrument's chin and forehead rest, independently or with assistance.

2.3.2 Operator Profile

2.3.2.1 Intended Demographic

This device is intended for use by the following trained professionals:

- Opticians
- Ophthalmic Photographers
- Optometrists
- Ophthalmologists

- Medical Assistants
- Clinical Researchers

2.3.2.2 Required Skills

Operators are expected to have the following skills:

- Knowledge of how to capture fundus images
- Experience managing patients
- Experience with the Microsoft Windows operating system and applications based on it

2.3.3 Doctor Profile

2.3.3.1 Intended Demographic

Doctors are ophthalmologists, optometrists, or other health care professionals with training in interpretation of fundus images.

2.3.3.2 Required Skills

Doctors are expected to know how to evaluate fundus images.

2.3.4 Administrator Profile

2.3.4.1 Intended Demographic

Administrators maintain the facility's computers, instruments, and networks.

2.3.4.2 Required Skills

Administrators are expected to know:

- Windows administration principles
- Networking principles
- Data management principles
- Permissions and user assignment principles
- The site or facility systems, including:
 - Network(s)
 - Computers and connections
 - Medical record system connections
 - Instrument connections

2.4 User Documentation

2.4.1 Purpose

The user documentation that comes with your device is provided to ensure that all users operate and maintain it safely and successfully.

- Read all user documentation before starting and using the device
- Keep all user documentation where it is accessible at all times for all users
- Pass the user documentation on to the next owner of the device

2.4.2 Access

User documentation for your device is provided on the USB drive that came with the device as part of the Instrument Accessory Kit.

2.4.3 Conventions Used in This Document

Certain types of information are specially marked in this document for better recognition.

- This is a list.
 - This is a second level list.

This is a cross-reference: Questions and comments [▶ 23].

This is `software code or program text`.

The name of software windows are Capitalized. For example: "Patient Screen"

Names of menus, and buttons or other selectable items, are shown in **Bold**.

- **View** menu.
- **File > Save as**
- **My documents > Documents**

2.5 Questions and Comments

If you have questions or comments about this user documentation or the device, contact your ZEISS representative.

2.6 System Overview

2.6.1 System Description

CLARUS 500 is a non-contact, high-resolution imaging device for in vivo imaging of the human eye. Imaging modes include:

- True color reflectance imaging
- Infrared reflectance imaging (IR)
- Fundus autofluorescence with green or blue excitation (FAF-G and FAF-B)
- Stereo imaging
- External eye imaging

2.6.1.1 Principles of Operation

Using a monochromatic camera, a broad line of illumination scans across the retina.

Red, green and blue Light Emitting Diodes (LEDs) sequentially illuminate to generate true color images. The broad bandwidth of LEDs gives a true color rendering. Blue and green LED illumination enables Fundus AutoFlourescence (FAF) imaging.

By illuminating only a narrow strip of the retina at a time, the illumination stays out of the viewing path, keeping haze and fluorescence of the anterior segment out of the retinal image and allowing a clear view of much more of the retina than the annular-ring illumination used in traditional fundus cameras. The design allows a single exposure to image an area of the retina previously covered by the 7-fields in the Early Rreatment of Diabetic Retinopathy Study (ETDRS).

2.6.1.2 Key Features

Scan Type Options:

- True color
- Infrared reflectance (IR)
- Fundus autofluorescence with green excitation
- Fundus autofluorescence with blue excitation
- Stereo imaging
- External eye imaging

Field of View Options:

- **Widefield:** A single image with a 133° FOV when measured from the center of the eye.
(90° when measured as described in ISO 10940).
- **Ultra-widefield:** Two images stitched together into a montage with a 200° FOV when measured from the center of the eye.
(135° when measured as described in ISO 10940).
- **AutoMontage:** a 4-scan montage using preset fixation targets.
- **Montage:** 2-6 widefield images stitched into a single, combined retina image.

2.6.2 Hardware Overview

The CLARUS 500 is connected to the All-in-One PC using cables mounted under the table. The operator controls the instrument and software using the instrument joystick, the All-in-One PC touch-screen, wireless keyboard and touchpad.

2.6.2.1 System Hardware



Figure 1: System Hardware

1	CLARUS 500 Acquisition Head	2	All-in-One PC
3	Keyboard Tray	4	Touchpad
5	Keyboard	6	Joystick

2.6.2.1.1 USB Locations

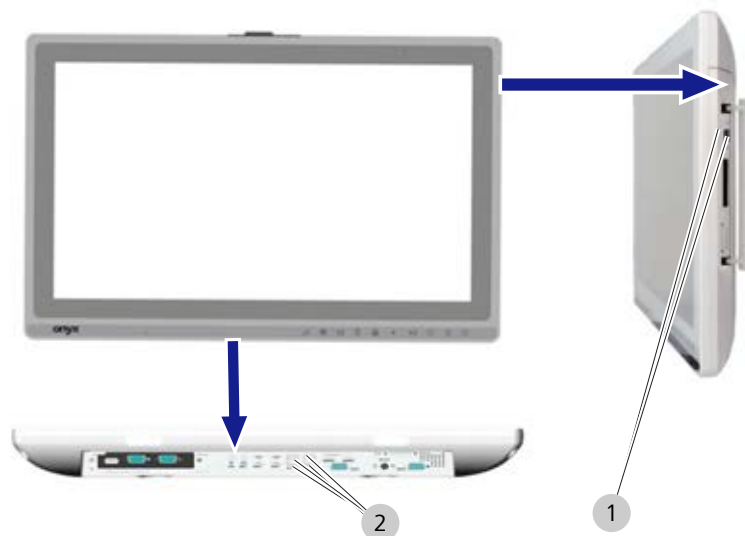


Figure 2: USB Port Locations (6 total)

Number	Type	Quantity	Location
1	USB 2.0	2	Side
2	USB 3.0	4	Bottom

2.6.2.2 Patient View



Figure 3: Patient View

1	Forehead rest	Helps keep the patient's head steady and in place
2	Front lens	Aperture for image acquisition
3	Chin rest	Positions the patient's head at the correct height
4	Chin rest adjuster	Manually raises and lowers the chin rest

2.6.2.3 Operator Controls



Figure 4: Operator Controls

1	Focus knob	Manually adjusts the focus
2	Friction knob	Tightens or loosens the swivel movement of the acquisition head
3	Joystick	Moves the acquisition head side-to-side and forward and back (The joystick button triggers image capture)
4	Cross-table lock	Locks the lateral movement of the acquisition head

2.6.2.4 External Fixation Target



Figure 5: Installing the External Fixation Target

1	External Fixation Target	Used when patient cannot see the internal fixation target
2	External Fixation Target Mount	Mount for the external fixation target
3	Patient Support	Support for the headrest and chinrest

2.6.3 Software Overview

The CLARUS 500 software includes three distinct areas: **Patient**, **Acquire**, and **Analyze** windows. All windows use the same top toolbar.

2.6.3.1 Main Toolbar



Figure 6: Main Toolbar

Pos.	Symbol	Explanation
1	Patient > Acquire	Indicates your current screen: <ul style="list-style-type: none"> ■ Patient ■ Patient > Acquire ■ Patient > Analyze
2		Quickly hides the screen for patient privacy

Pos.	Symbol	Explanation
3		Opens notification volume control
4		Opens the Settings to configure the instrument and set your preferences
5		Minimizes the application on the computer's desktop
6		Allows you to log off or shut down

2.6.3.2 Patient Window

Use the **Patient** window to find, edit, and add patient records.

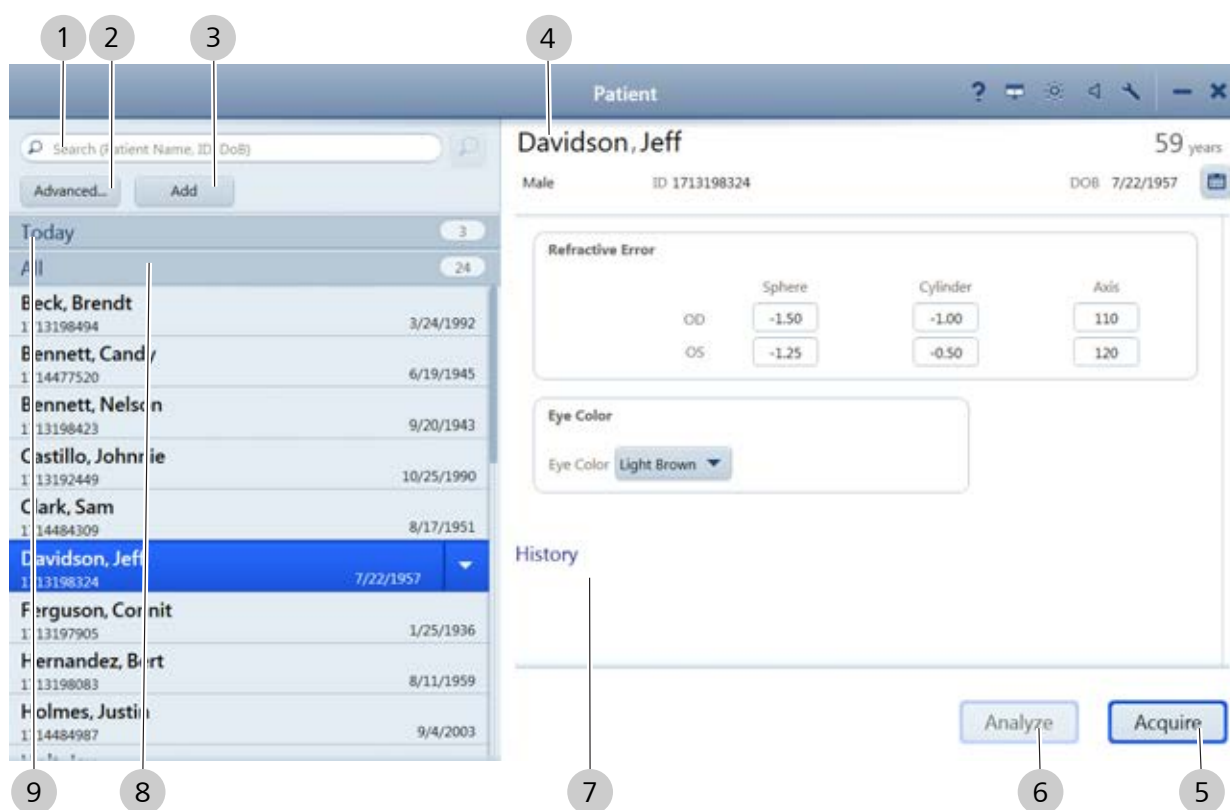


Figure 7: Patient Window

Pos.	Name	Explanation
1	Search field	Searches for a patient record by patient name, ID, or date of birth
2	Advanced	Opens the Advanced search, which allows a more detailed search
3	Add	Allows you to create a new patient record
4	Patient data	Displays data about the selected patient
5	Acquire	Opens the Acquire window allowing you to acquire new scans for the selected patient

Pos.	Name	Explanation
6	Analyze	Opens the Analyze window allowing you to analyze scans and prepare reports
7	History	Lists the selected patient's scans from prior visits
8	All	Lists patient records available on the local database
9	Today	Lists patient records for the patients scheduled today

2.6.3.3 Acquire Window

Use the **Acquire** window to set image capture options and capture images.



Figure 8: Acquire Window

Pos.	Name	Explanation
1	Patient data	Information about the currently selected patient
2	Laterality	Indicates which eye is being captured
3	Alignment preview	A visual aid for aligning the instrument to the patient's pupil
4	Live preview	Displays a real-time preview image prior to capture and a quality check image following capture
5	Thumbnail filters	Filters the capture bin by laterality or scan type

Pos.	Name	Explanation
6	Capture bin	Displays thumbnails of images that have already been captured, along with the capture settings
7	Analyze	Opens the Analyze window
8	Focus	Displays the current focus and allows for manual focus adjustments. Auto determines the best focus setting automatically.
9	Blink internal fixation target	Blinks the internal fixation target for a configurable amount of time
10	Capture	Captures the image
11	Scan Type	Sets the type of scan
12	Pupil Size	Toggles between mydriatic and non-mydriatic acquisition modes
13	Fixation Type	Toggles between internal fixation and external fixation targets
14	Patients	Returns to the Patients window

2.6.3.4 Analyze Window - Proof

The **Analyze** window has two screens:

- **Proof** to view and select images
- **Review** to compare and edit images

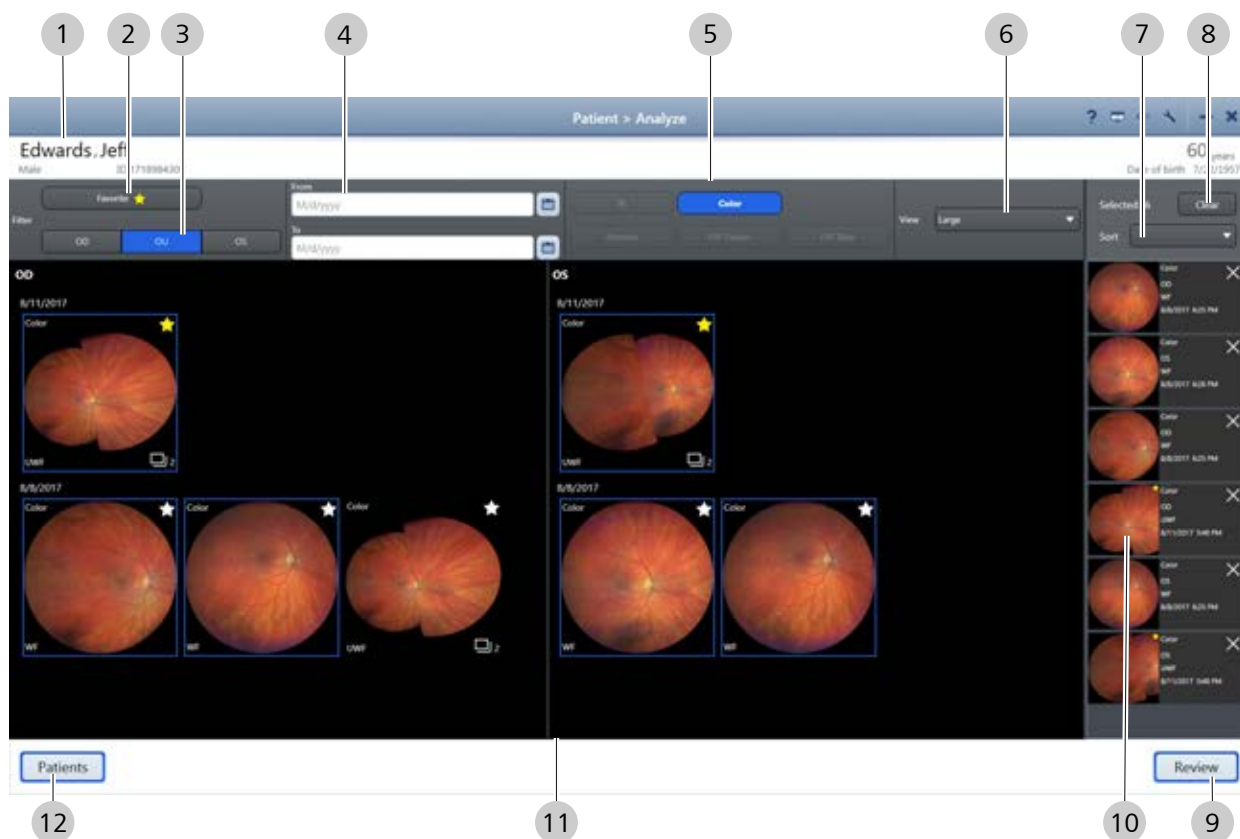


Figure 9: Analyze Window - Proof

Pos.	Name	Explanation
1	Patient data	Displays information about the currently selected patient
2	Favorite	Flags selected thumbnails with a yellow star for easy identification
3	Laterality filter	Allows you to filter the thumbnails to show one or both eyes
4	Date filters	Allows you to filter the thumbnails to show only those taken between the start date and end date you set
5	Scan type filter	Allows you to select which type(s) of scans to show
6	View	Allows you to select what size to display the thumbnails in preview
7	Sort	Allows you to group the thumbnails by scan type or laterality or show thumbnails in the order they were taken (Date/Time)
8	Clear	Remove all thumbnails from the Selection bin
9	Review	Opens the Review screen for viewing and editing the images in the Selection bin
10	Selection bin	Displays thumbnails of selected images
11	Preview	Displays available thumbnails as filtered
12	Patients	Returns to the Patient window

2.6.3.5 Analyze Window - Review

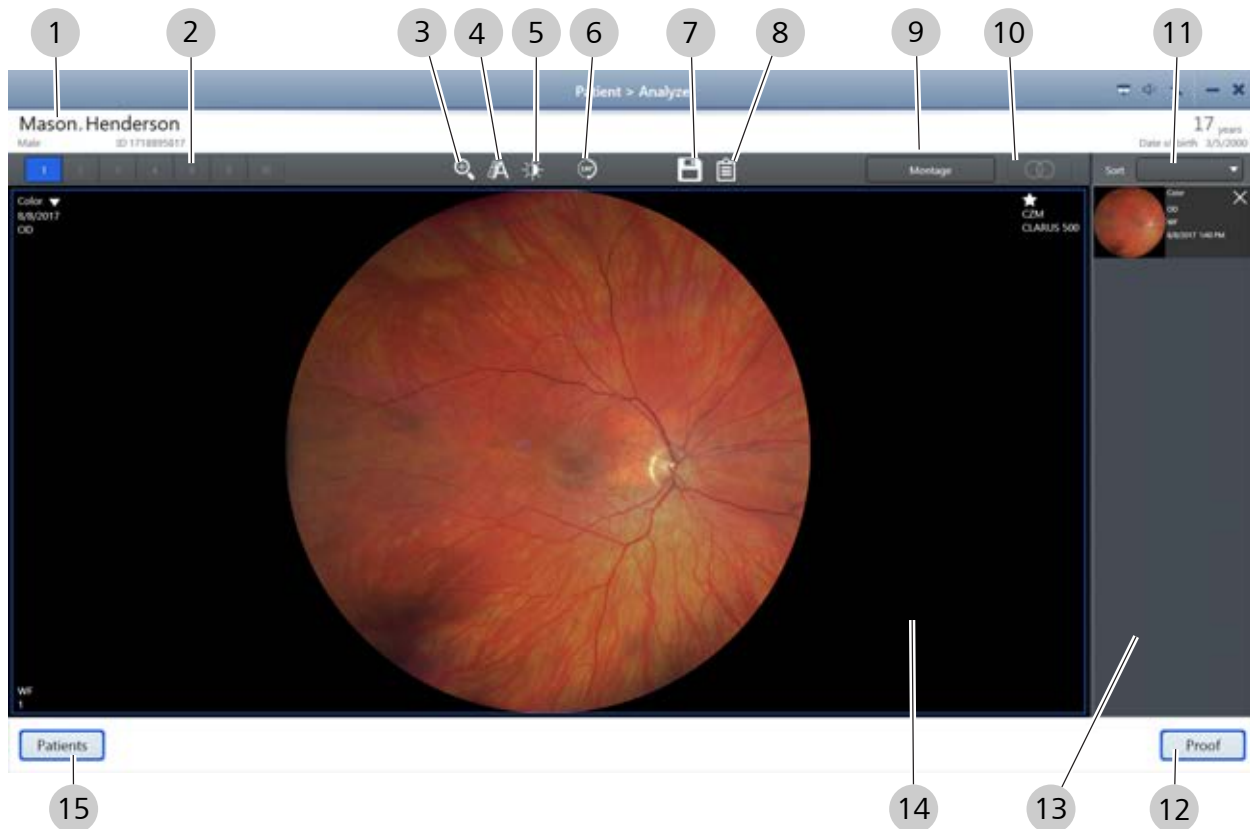


Figure 10: Analyze Window - Review

Pos.	Name	Explanation
1	Patient data	Provides information about the selected patient
2	Number of viewports	Controls how many viewports are in the main display area
3	Zoom	Opens the zoom slider
4	Annotate	Opens the annotation tool panel
5	Adjust image	Opens the brightness, contrast, saturation, and sharpness sliders
6	Rotate	Rotates the image 180°
7	Save	Saves the edited image
8	Print Report	Opens a preview of the report to print
9	Montage	Allows you to select and create a montage
10	Stereo	Displays linked, side-by-side view of stereo image pairs
11	Sort Selection	Allows you to select the way to sort the selected scans
12	Proof	Returns to the Proofsheet
13	Selection bin	Displays thumbnails of the selected images
14	Viewport	Allows you to see the selected images.

Pos.	Name	Explanation
15	Patients	Returns to the Patient window

2.6.4 Networking Overview

CLARUS 500 can run as a standalone instrument storing patient and exam data locally, or it can be connected to a network server or EMR system to share data and worklists in a central location.

WARNING!

Adding peripheral equipment

may result in noncompliance with the safety requirements of IEC 60601-1.

- ▶ You are responsible for ensuring that the system meets the safety requirements of IEC60601-1.
- ▶ Place any AC-powered, non-medical device peripherals at least 1.5 m away from the device and connect them to a separation device, or else use an isolation transformer.

WARNING!

Connection to It-Networks including other equipment

could result in previously unidentified risks related to patients, operators or third parties.

Changes to the IT networks could introduce new risks that require additional analysis.

Changes to the IT networks include:

- ▶ Changes to network configurations
 - ▶ Connections of additional items
 - ▶ Disconnection of items
 - ▶ Update of equipment
 - ▶ Upgrade of equipment
- ✓ The Responsible Organization should identify, analyze, evaluate and control these risks.

Empty page, for your notes

3 Installation

Hardware Installation

- 3.1** Your instrument will be installed by qualified ZEISS representatives. Do not attempt to install the instrument yourself.

WARNING!

Unauthorized Installation

Unauthorized installation could lead to the injury of patients and operators, as well as to property damage.

- ▶ Only ZEISS authorized personnel may install Zeiss products.

WARNING!

Powering peripherals directly through a wall socket

could result in electrical shock to the patient and/or examiner.

- ▶ When using a printer in the USB configuration, always power the printer through an isolation transformer. Some ZEISS equipment comes with an isolation transformer that may be used by plugging into a special power strip provided with the equipment. Talk to your ZEISS Service Representative to determine if this is true for your equipment.
- ▶ If you are not sure, plug all peripherals (such as a printer), into an isolation transformer. This requires a special power cable. In North America, the required cable has an IEC-320-14 connector on one end and a NEMA 5-15R connector on the other end. This cable is included in the accessory kit shipped with the instrument.

CAUTION!

Do not lift or carry the instrument using the patient support.

The patient support could break if used as a carrying handle.

- ▶ Make sure you support the instrument from the base whenever you carry the instrument.

3.1.1 Preparing to Install

Install the CLARUS 500 instrument in an environment that meets the following requirements:

- no direct sunlight
- properly grounded, dedicated 15 A power source that meets all local electrical codes
- not connected to a power strip
- the device's ventilation openings are not blocked
- the device is not exposed to water or other liquids

Do not modify the instrument or use cables not provided by ZEISS.

The CLARUS 500 instrument arrives on a pallet with three boxes that contain all parts and accessories needed to assemble the instrument and table.

3.2 Software Installation

The CLARUS 500 system ships with software installed on your instrument. From time to time you will be notified to upgrade system software (Upgrading Instrument and Review Software [▶ 41]).

You can install review software on any compatible laptop or computer that clinicians use to review scanned images (Installing Review Software [▶ 38]).

3.2.1 Installing Review Software

You can install review software on computers that clinicians use to compare, analyze, annotate and save scans acquired on CLARUS 500.

NOTE

If you need to uninstall review software, use the Windows control panel for adding and removing programs.

The computer must meet the following minimum requirements:

- Runs on:
 - Windows 7
 - Windows 8
 - Windows 10
 - Windows 2008 Server R2
 - Windows 2012 Server R2
- Has an Intel processor with a Passmark benchmark score of at least 5675
- Has at least 8 GB of memory
- Has a monitor with resolution set to at least 1024 x 768

NOTE

Review software does not support: adding, editing, or deleting a patient record.

Adding, editing, or deleting a patient record

Deleting a scan

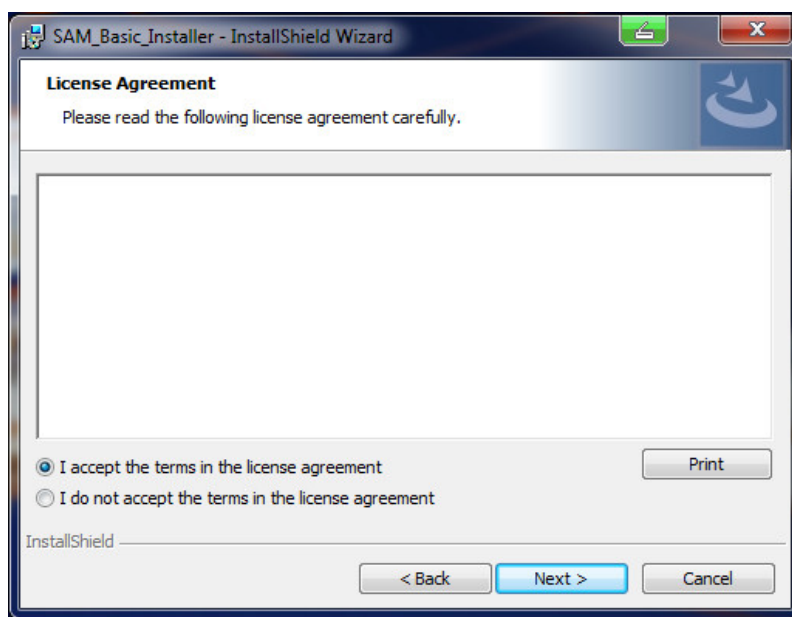
Adding users or user accounts

Adding, editing, or deleting the Institution data

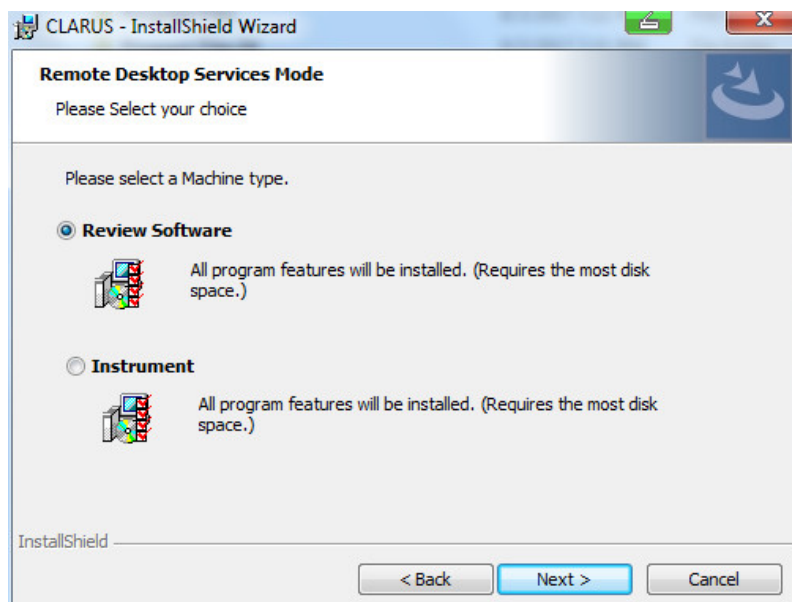
To install review software:

- The computer and monitor meet the minimum requirements listed above.

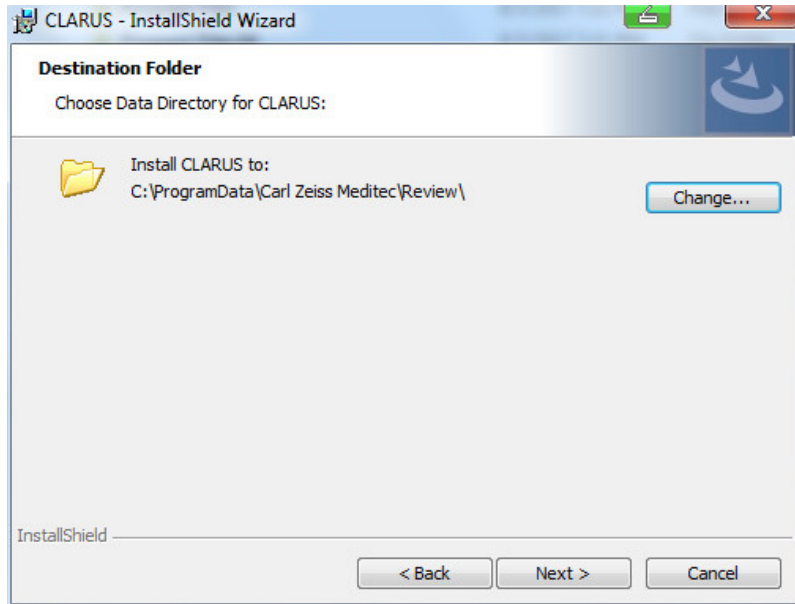
1. Insert the software media into the review station computer's USB drive.
2. In the CLARUS 500 software folder, double-click on `setup.exe`.
⇒ A confirmation opens.
3. Click **Next**.
4. Accept the license agreement, then click **Next**.



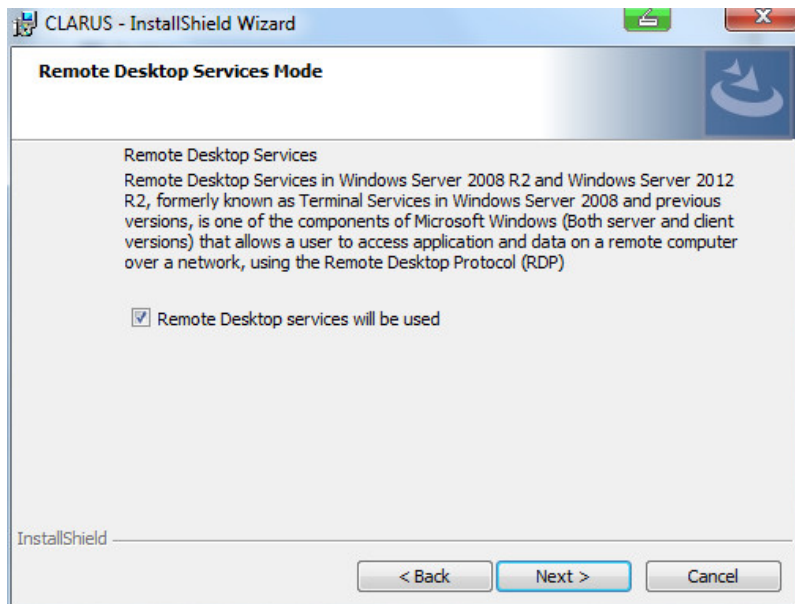
5. Type the user name and organization name and click **Next**.
6. Select **Review Software**, then click **Next**.



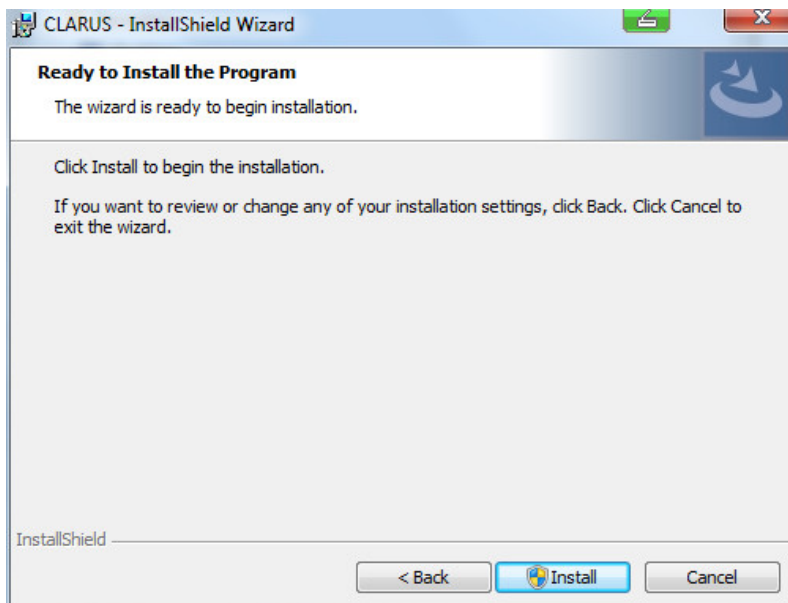
7. If you want to choose a different destination folder for the review software, click **Change...** and browse to the desired folder.



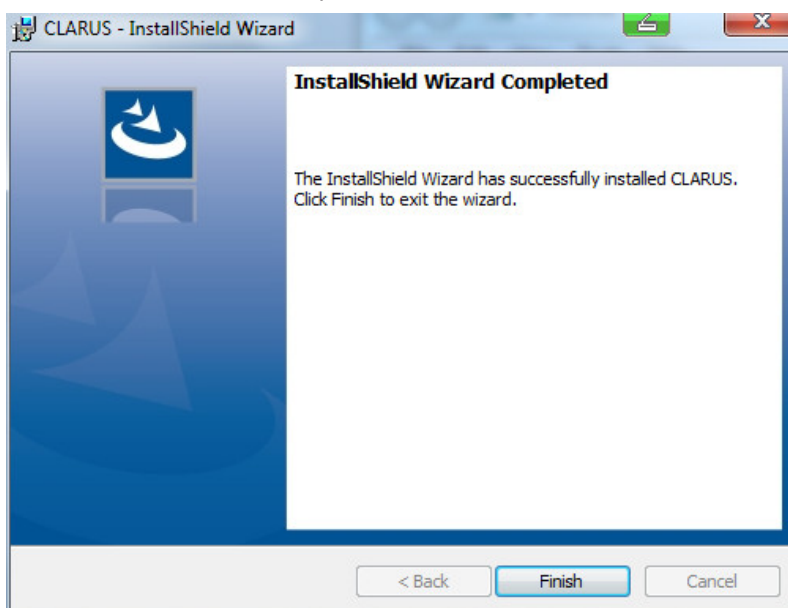
8. Click **Next**.
9. If this review software will use Remote Desktop Services, check **Remote Desktop services will be used**.



10. Click **Next**.



11. Click **Install**.
12. If your system prompts you to confirm changes on the computer, click **Yes**.
 - ⇒ Review software installation begins. Installation takes several minutes to complete.
13. When installation is complete, click **Finish**.



Result

- ✓ Installation completes and the configuration wizard opens. For more information about the configuration wizard, refer to: Setting All Options [▶ 46].

3.2.2 Upgrading Instrument and Review Software

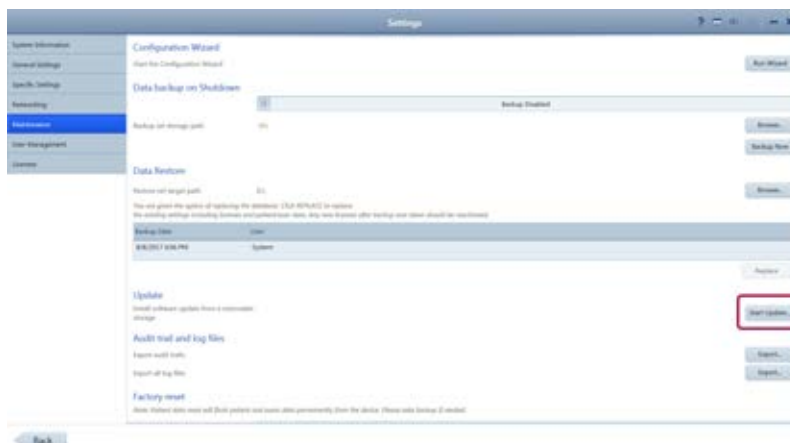
Prerequisite

- Settings are open (Opening Settings [▶ 45]).

Action

1. Select the **Maintenance** tab.

2. Under **Update**, click **Start Update...**



⇒ A confirmation opens.

3. Click **Yes**.

✓ The software installs and the system reboots.

Result

When you upgrade instrument or review software, CLARUS 500 retains stored information including:

- Logins and Passwords
- Patient Data
- Exam Data

4 Daily Startup

4.1 Turn on the Instrument

⚠ CAUTION!

Do not unplug the instrument during startup

or instrument may not start up successfully.

- ▶ Make sure the instrument has completed its system checks before you unplug or remove power.

Each time you turn on the CLARUS 500, system diagnostics checks that the system initialized correctly and is running properly. If the diagnostic check detects any problems, an error or alert message displays. For more information about startup errors and alerts, refer to: Troubleshooting [▶ 145].

NOTE

If a critical system test fails

take the device out of service.

- ▶ Contact your ZEISS representative.
- ▶ If a non-critical test fails or a warning appears, the device can still be used. Contact your ZEISS representative. (See Maintenance [▶ 143].)

To turn on the instrument:



Action

1. Turn on the instrument (green switch).
2. When the system test sequence completes, click **Continue**.
3. Log in (Logging In [▶ 44]).
 - ⇒ The **Patient** window displays.

4.2 Logging In

After the system boots up and runs a series of system checks, the login screen opens. The login screen also appears when a user logs out.


NOTE

Passwords are case-sensitive.

An Administrator must add a user's name and password before that user can log in. (Adding a New User [▶ 58])

Action

To log in:

1. Double-click on the CLARUS 500 application icon. 
⇒ The login screen opens.
2. Select your user name.
3. Type your password.

5 Configuration

5.1 Opening Settings

The **Settings** icon is on the top toolbar of all application windows. You can open settings from any screen in the application.

Setting options allows you to configure the application the way you want to use it. Different types of users can set different options. For more information about settings permissions, refer to: About User Roles [▶ 58].

Setting	Description
System Information	Instrument and software information
General Settings	<ul style="list-style-type: none"> ■ Your institution information ■ Duration for displaying alerts ■ Local date, time, and language ■ Teleservice ■ On-screen keyboard ■ Patient ID creation ■ Printer and reports
Specific Settings	Acquisition settings <ul style="list-style-type: none"> ■ Capture preview duration ■ Fixation target blink duration ■ Scan type presets Import and Export Settings (DICOM and FORUM)
Networking	Network connection settings
Maintenance	<ul style="list-style-type: none"> ■ Record backup and restore ■ Application update ■ Log files ■ Factory reset
User Management	<ul style="list-style-type: none"> ■ Create, edit, and delete users ■ Change password
Licenses	<ul style="list-style-type: none"> ■ View, activate, repair, and return licensed features

Table 4: Settings



Action

Result

To open settings:

1. Click on the **Settings** icon on the toolbar.
 - ✓ The **Settings** window opens.

5.2 Setting All Options

CLARUS 500 has an initial settings wizard that you can also use for checking or resetting options.

NOTE

Only Administrators can complete this task.

Prerequisite

Action

To set all options using the wizard:

- Settings are open (Opening Settings [▶ 45]).
- 1. Select **Maintenance** and click **Run Wizard**.



⇒ The initial settings wizard opens and steps you through settings.

5.3 Managing Data

5.3.1 Manage Patient Records

When patient records are imported from an EMR, they are reconciled with local records as follows:

- Same ID and Issuer of ID, different name, date of birth, or gender: The local record is updated to match the EMR record.
- Different ID or Issuer of ID: A new patient record is generated.

Some EMR systems allow records that are missing key identifying information. The CLARUS 500 automatically adds the default "Unknown" if the name is missing, but rejects records that do not have a Patient ID or date of birth.

5.3.1.1 Adding a Patient

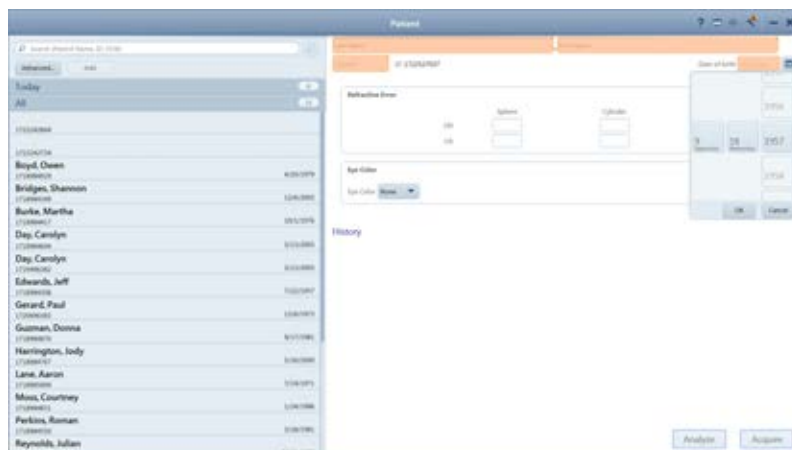
Adding the patient's name and date of birth are both required.

To add a patient:

- The **Patient** window is open.
- 1. Click **Add**.

Prerequisite

Action



2. Type the patient's first and last name.
3. Select the patient's gender.
4. Select the patient's date of birth.
5. (Optional) Type the patient's **Refractive Error** information.
6. (Optional) Select the patient's **Eye Color** (optional).
7. To acquire a scan, click **Acquire**.

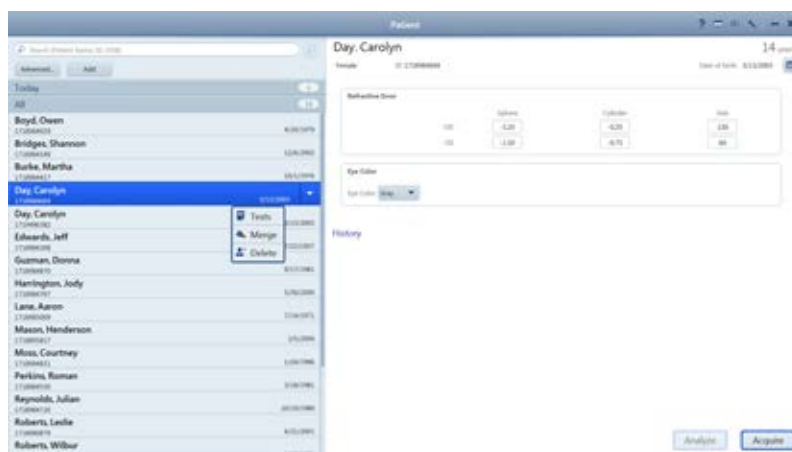
5.3.1.2 Merging Patient Records

If two records are inadvertently created for the same patient, they can be merged to store all the patient data in one record.

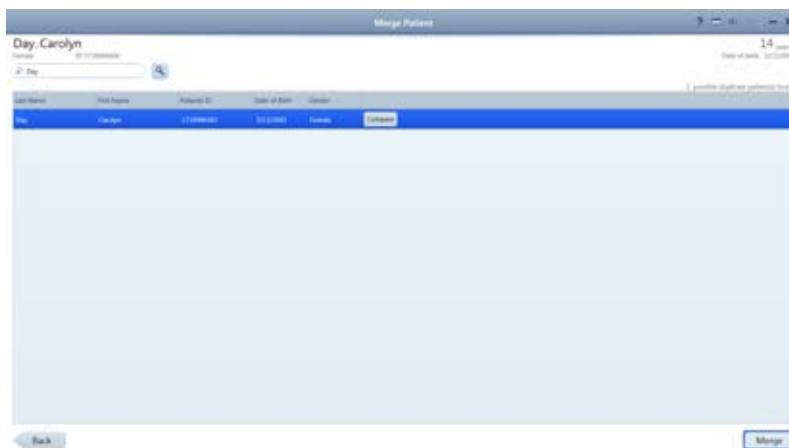
To merge patient records:

Action

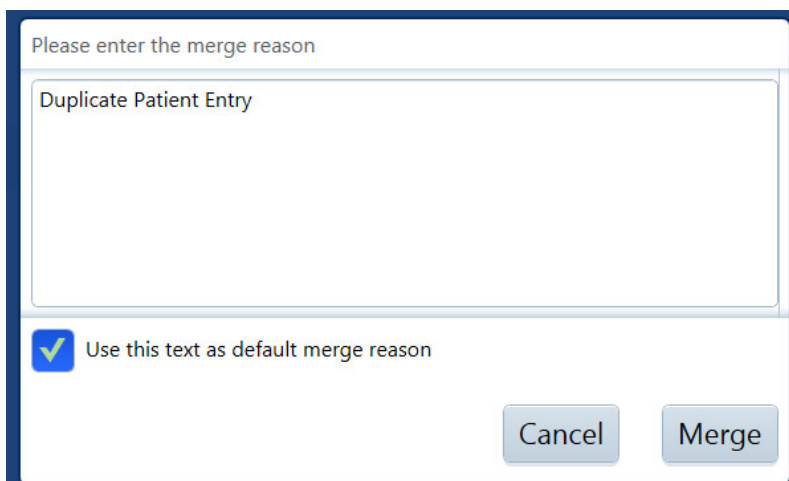
1. In the **Patient** window, select the patient name and click on the down arrow.



2. Select **Merge**.
3. Type the name or ID for the duplicate patient record in the search field and click **Search**.



4. Select the duplicate patient record(s). You can merge up to 20 patient records.
5. To see the details of selected patient records side by side with the original record, select **Compare**.
6. Select **Merge**.



7. Enter a reason for the merge, then select **Merge** again.
⇒ The exam data from the duplicate patient record is added to the original patient record.

5.3.1.3 Reassigning Image Scan

If you inadvertently select the wrong patient record at the beginning of an exam, you can reassign the data to the correct patient record.

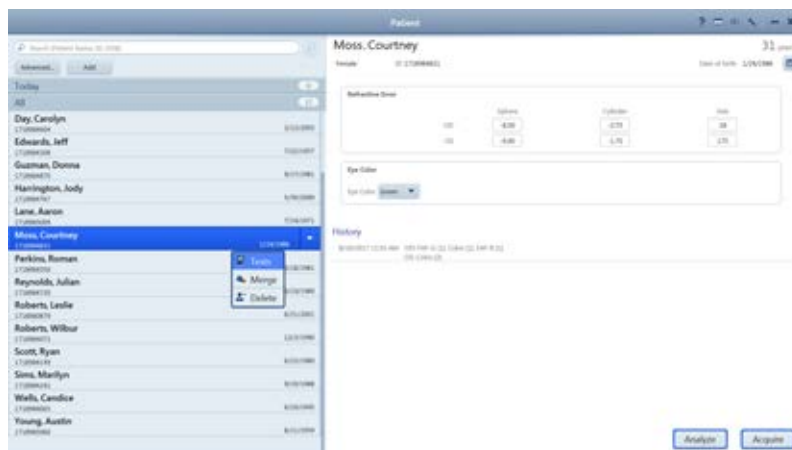
To reassign test data:

Prerequisite

- Settings are open (Opening Settings [▶ 45]).
- The patient with incorrect test data is selected Search for a Patient Record.

Action

1. Click the down arrow for the patient with test data that you want to reassign.



2. Select **Tests**.

⇒ A list of the tests assigned to the patient opens.

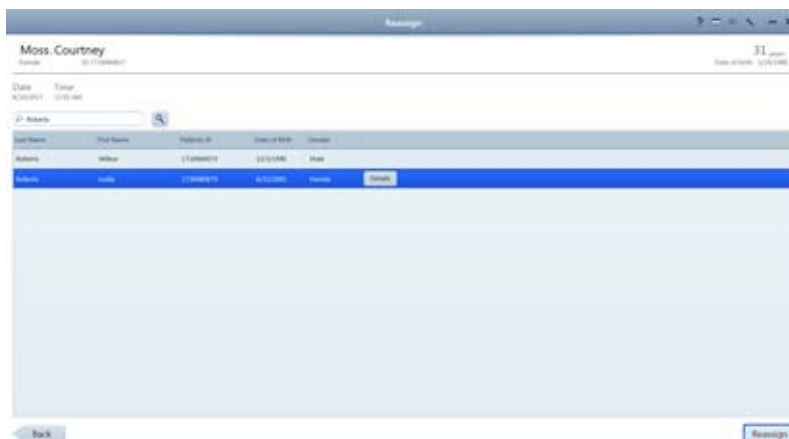


3. Select the incorrectly saved test and click **Reassign**.

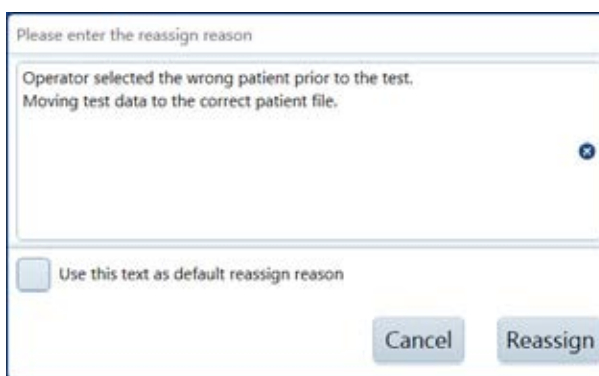
⇒ The **Reassign** page opens.



4. In the search field, type the name, ID number, or DOB of the patient the test data belongs to and click the search icon.



5. Select the correct patient and click 2660021167882 Rev. A.pdf.
⇒ A confirmation opens.



6. Type a reason for reassigning the test.
7. Click **Reassign**.

5.3.1.4 Deleting a Patient Record

NOTE

Only Administrators can complete this task.

Patients deleted on the instrument are not deleted from the EMR system.

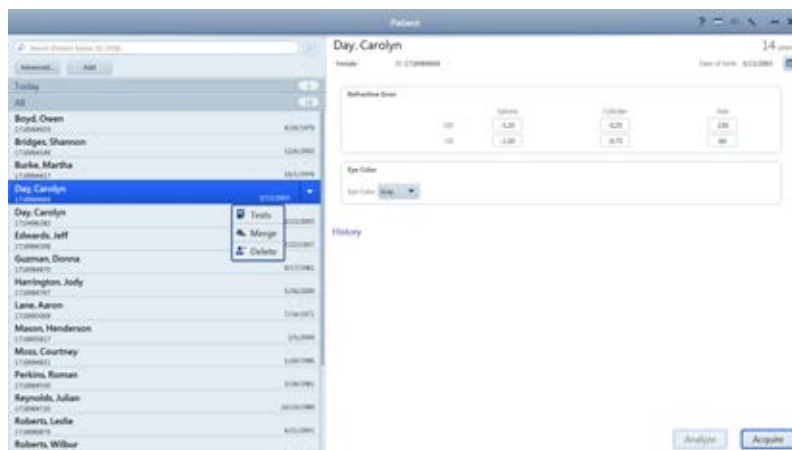
To delete a patient record:

- The instrument is not connected to FORUM or any other EMR system.

Prerequisite

Action

1. In the **Patient** window, select the patient name and click on the down arrow and select **Delete**.



⇒ A confirmation opens.

2. Click **Delete**.

5.3.1.5 Manually Correcting Laterality

You can change the laterality of an image after it is saved using the **Review** or **Proof** screen.

Laterality change feature does not work under the following conditions:

- After the data is exported
- In connected mode (FORUM)
- On imported data

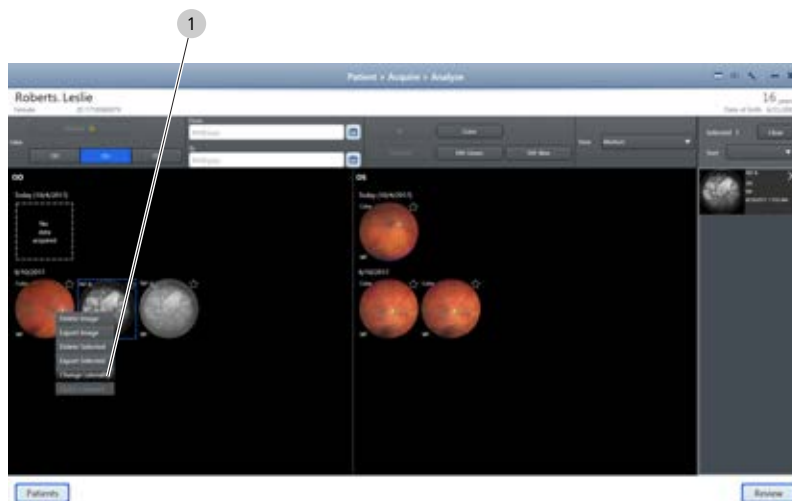
To correct laterality manually in Proof:

Proof Sheet is open.

1. Right-click on the image you want to change.

Prerequisite

Action



2. Select **Change Laterality**.

⇒ A confirmation opens.

3. Click **OK**.

Result

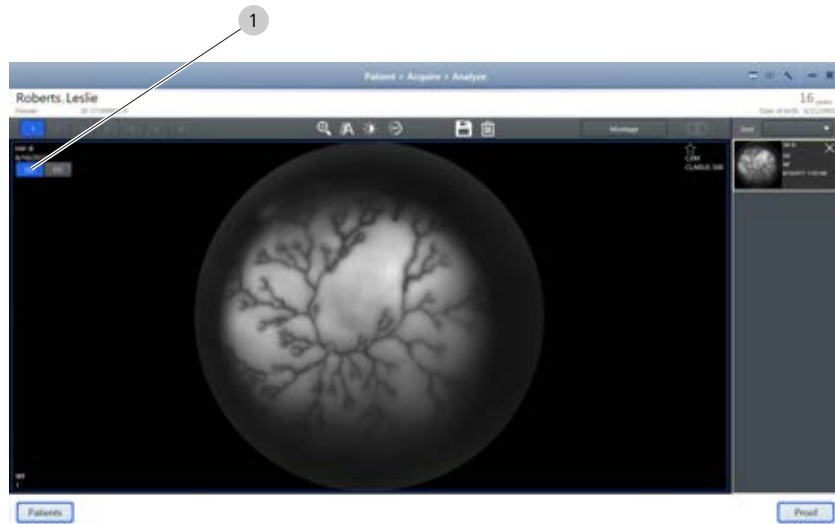
✓ The thumbnail changes laterality.

To correct laterality manually in Review:

Prerequisite

Review is open.

4. Select the image you want to change.
5. Click on the current laterality indicator in the preview panel.
⇒ The other laterality appears for selection.



6. Click the desired laterality.
⇒ The laterality indicator changes.
7. Click **Save**.

5.3.1.6 Importing Data

You can import data in the following individual exams or multiple exams (bulk import).

You can import the following file formats:

- JPG
- TIFF
- PNG
- JPEG2000
- DICOM
- ZIP (compressed)

To import data:

Prerequisite

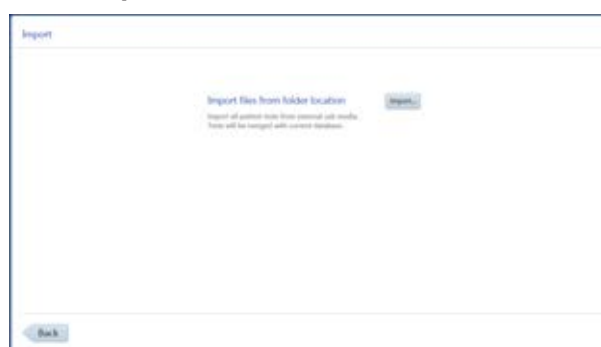
Settings are open (Opening Settings [▶ 45]).

Action

1. Insert the removable media into the USB port.
2. Click **Specific Settings**.
⇒ The **Specific Settings** window opens.



3. Click **Import**.



4. Click **Import...** and navigate to the file stored on the external removable media device.

5. Click **Select**.

⇒ A confirmation informs you when the import completes.

6. Click **OK**.

5.3.1.6.1 Data Integrity of Imported Records

For all imported patient records, it is possible to import new scan data and update patient data, including obscured patient records. If during import the device encounters information associated with a patient that was already imported, the device does the following:

- imports all scan data (exams) not previously imported, but never deletes nor overwrites any scan data already imported
- updates patient data only if it was created on a later date than the data already imported. This prevents overwriting of newer patient data with older patient data

5.3.1.7 Exporting Data

You can export data in multiple ways:

- In the **Proof** or **Review** screen, select an image and right-click.
- In the **Proof** screen, select multiple images and right-click.

- Export all of a patient's data; select **Settings > Specific Settings > Export**.
- Set automatic export (Configuring Import and Export)

To export data:

Prerequisite

- Settings are open (Opening Settings [▶ 45]).

Action

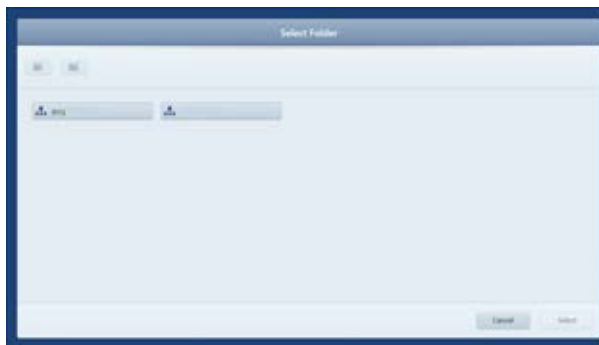
1. If you are exporting to removable media, insert the media into the USB port.
2. Click **Specific Settings**.
⇒ The **Specific Settings** window opens.



3. Click **Export**.
⇒ A list of all patients opens.



4. Check the patients you want to export and click **Export**.



5. Navigate to the folder you want to use for export and click **Select**.
 - ⇒ A progress bar appears until export is complete.
6. Click **OK**.
 - ⇒ The data exports and a confirmation opens.
7. Click **OK**.

5.3.1.8 Configuring Import Settings

You can choose automatic import of images and data from a folder.

NOTE

If you use an EMR system, make sure you complete the networking settings

to ensure that automatic export can connect to your EMR server.

Prerequisite

Action

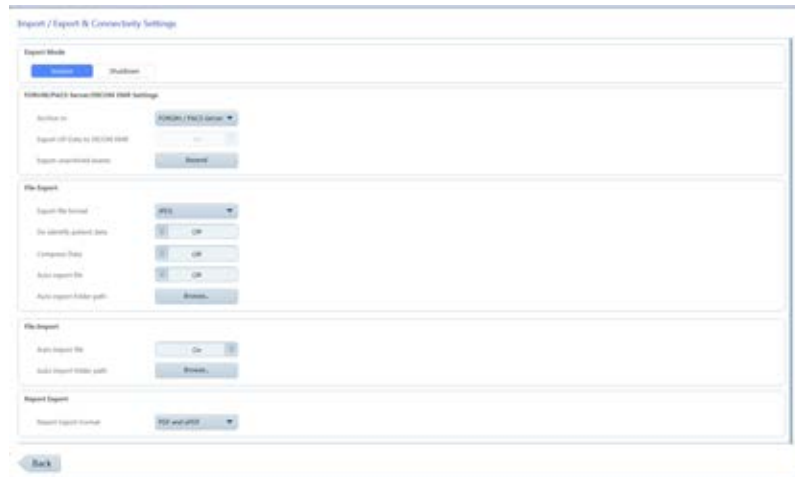
To configure import settings:

- Settings are open (Opening Settings [▶ 45]).
- A folder for automatic imports is created and you know the path to it.

1. Select **Specific Settings**.



2. Click **Import Export Settings**.



3. Under **File import**, set **Auto import files** to **On**.
4. Click **Browse...** and navigate to the folder to use for automatic importing.
5. Click **Select**.
 - ✓ The folder path appears next to the **Browse...** button and files stored in that location will be automatically imported.

Result

5.3.1.9 Configuring Export Settings

You can choose automatic exporting of images and data settings, including:

- How often to automatically export images and patient data whenever a user either:
- What type of EMR server to send the exported images and data and the server path
- What image format to use for export
- What report format to use for export
- Whether to compress files on export
- Whether to removes patient demographic information from exported exam data

NOTE

If you use an EMR system, make sure you complete the networking settings

to ensure that automatic export can connect to your EMR server.

To configure export settings:

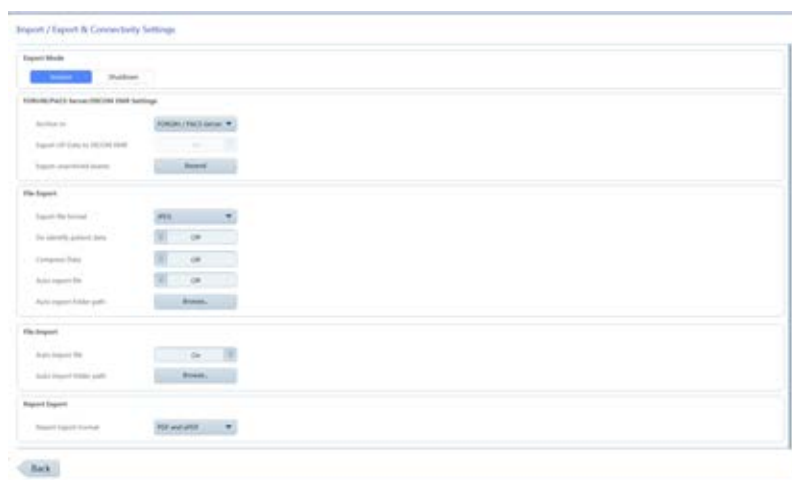
- ☑ Settings are open (Opening Settings [▶ 45]).
- 1. Select **Specific Settings**.

Prerequisite

Action



2. Click **Import Export Settings**.



3. Set the frequency of automatic exports:
To set automatic export when a user logs off, click **Session**.
To set automatic export when a user shuts down the ZEISS application, click **Shutdown**.
4. If you use and EMR system, select the type (FORUM/PACS or DICOM).
5. Under **File Export**, select the file format for images (DICOM, JPEG, PNG, TIFF, JPEG2000).
6. To automatically removes patient demographic information from exported exam data, set **De-identify** patient data to **On**.
7. To automatically compress data on export, set **Compress Data** to **On**.
8. For **Report Export**, select whether to use PDF, ePDF or both formats.

5.3.2 Manage Users



Do not use Bitlocker Passkeys with this instrument or review software.

NOTE

Unsecured Logins

may result in unauthorized access or inaccurate record-keeping.

- ▶ Create individual user accounts for each staff member.
- ▶ Staff members should log out after every use.

5.3.2.1 About User Roles

Not all users have access to all features. The table below list some of the key differences for different types of users.

	Operator	Doctor	Adminis- trator
Acquire scans	X	X	
Review scans	X	X	
Select, edit and annotate scans	X	X	
Use review software installed on a separate computer	X	X	
Reset your own password	X	X	X
Delete a local patient record	X	X	X
Save and print reports	X	X	X
Import and export data	X	X	X
Configure import and export settings	X	X	X
Configure general settings		X	X
Configure network settings			X
Configure data backup			X
Restore data from a backup			X
Perform system maintenance			X
Manage licenses			X
Reset other user's passwords			X
Add or delete users			X
Export log files			X

Table 5: Permissions Levels

5.3.2.2 Adding a New User

NOTE

Only Administrators can complete this task.

For valid password format, see: Password Requirements [▶ 61].

To add a new user:

Prerequisite

- Settings are open (Opening Settings [▶ 45]).

Action

1. Click **Settings > User Management**.



2. Click **Add User**.



3. Type the information for the new user and select the user's role.
4. Click **Add User**.

Result

- ✓ The new user can now log in.

5.3.2.3 Deleting a User

NOTE

Only Administrators can complete this task.

To delete a user:

Prerequisite

- Settings are open (Opening Settings [▶ 45]).

Action

1. Click **Settings > User Management**.



2. Select the **Login name** for the user you want to delete.

3. Click **Delete User**.
✓ The user's Login is now disabled.

Result

5.3.2.4 Changing a User's Password

NOTE

Only Administrators can complete this task.

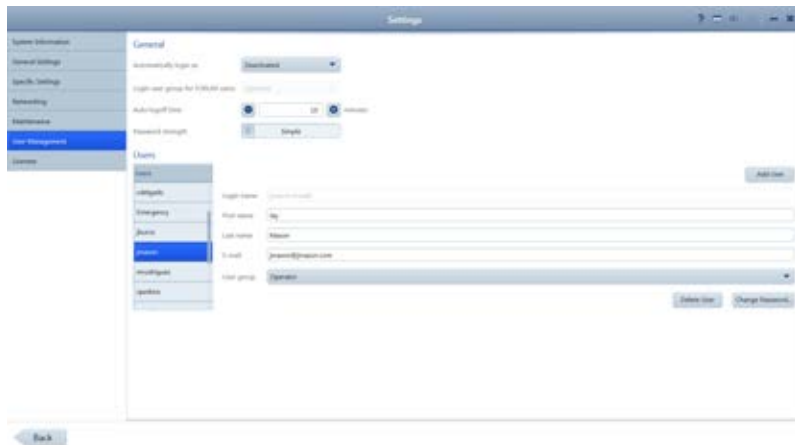
For valid password format, see: (Password Requirements [▶ 61])

To change a user's password:

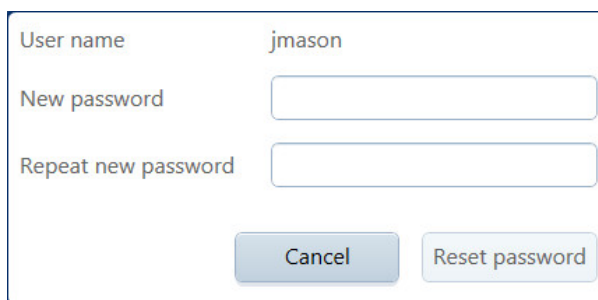
- ✓ Settings are open (Opening Settings [▶ 45]).
1. Select **User Management**.
 2. Select the **Login name** for the user who needs a new password and click **Change Password ...**

Prerequisite

Action



⇒ The password reset panel opens.

A screenshot of a password reset dialog box. It contains three input fields: 'User name' with the value 'jason', 'New password', and 'Repeat new password'. At the bottom, there are two buttons: 'Cancel' and 'Reset password'.

3. For **New password**, type a new password for the user.
4. For **Repeat new password**, retype the new password.
✓ The new password for the user is now active.

Result

5.3.2.5 Changing Your Own Password

For valid password format, see: (Password Requirements [▶ 61])

To change your password:

- ✓ Settings are open (Opening Settings [▶ 45]).

Prerequisite

Action

1. Click **Settings > User Management**.



2. Click **Change Password**



3. For **Old password**, type your existing password.
4. For **New password**, type a new password.
5. For **Repeat new password**, retype the new password.
✓ Your password is now changed to the new password.

Result

5.3.2.6 Password Requirements

CLARUS 500 users' passwords expire every 60 days. All passwords must follow these rules:

- Must be at least seven characters long.
- Must contain at least three of the following:
 - English uppercase characters (A through Z)
 - English lowercase characters (a through z)
 - Numbers (0 through 9)
 - Non-alphabetic characters (for example: !, \$, #, %)
- Must not contain the user's account name.
- Must not contain two consecutive letters of the user's name.

5.3.3 Manage Backups

On the CLARUS 500, you can enable data backup each time the system shuts down (Configuring Automatic Backups [▶ 62]). You can also back up data manually at any time (Backing Up Data Manually [▶ 62]).

5.3.3.1 Configuring Automatic Backups

You can save a backup copy of selected data at any time. You can save this data on removable media for import into other applications.

To configure automatic backups:

- Settings are open (Opening Settings [▶ 45]).
- 1. Insert the removable media into the USB port.
- 2. Click **Settings > Maintenance**.
 - ⇒ The **Maintenance** window opens.

Prerequisite

Action



- 3. Slide **Data backup on Shutdown** to **Backup Enabled**.
- 4. Click **Browse**.



- 5. Navigate to the folder where you want to store the backups and click **Select**.

Result

- Each time the system shuts down a backup will be saved in the selected folder.

5.3.3.2 Backing Up Data Manually

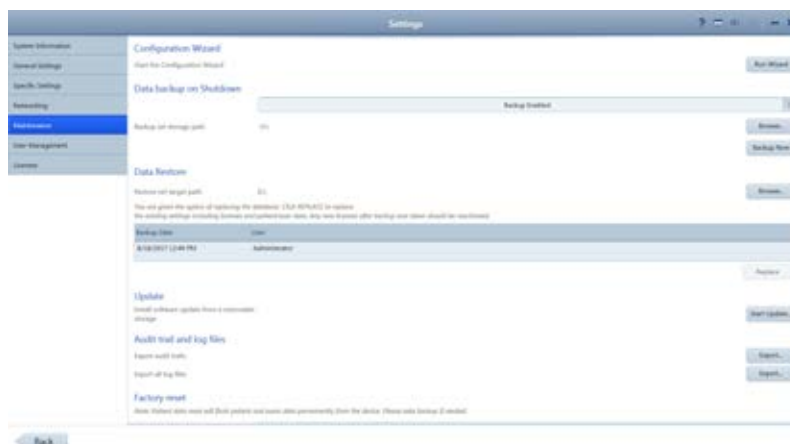
To back up data manually:

- Settings are open (Opening Settings [▶ 45]).

Prerequisite

Action

1. Insert the removable media into the USB port.
2. Click **Settings > Maintenance**.
⇒ The **Maintenance** window opens.



3. Click **Backup Now**.
⇒ A progress bar opens.
⇒ When the backup completes, a confirmation opens.
4. Click **OK**.

Result

- ✓ A new data backup is stored in the folder you configured to store automatic backups. (See Configuring Automatic Backups [▶ 62].)

5.3.3.3 Restoring Data from a Backup

NOTE

Only Administrators can complete this task.

If the CLARUS 500 has automatic backups enabled or if there is a saved manual backup, you can restore the system with the data from the backup file.

After you restore data, you must restart the instrument.

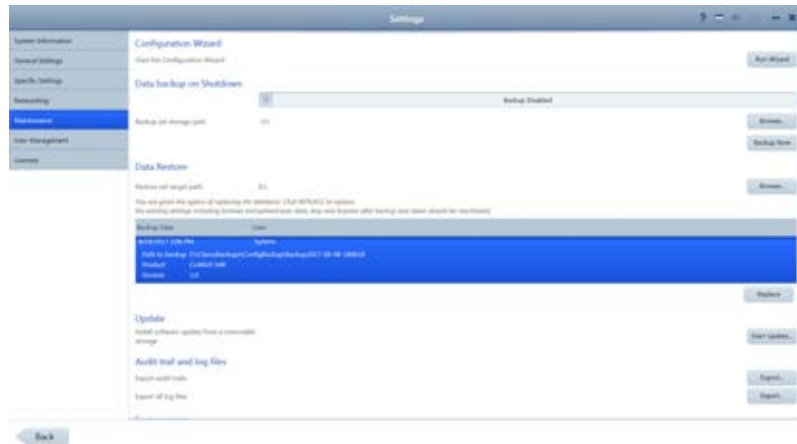
To restore data from a backup:

- Settings are open (Opening Settings [▶ 45]).

Prerequisite

Action

1. Select **Maintenance**.



2. Under **Data Restore**, select the backup you want to install.
3. Click **Replace**.
⇒ A confirmation opens.
4. Click **Replace**.
⇒ A progress bar opens. When restoration is complete, a restart confirmation opens.
5. Click **Restart**.
✓ The system restarts with the data that existed in the backup.

Result

5.3.4 Log Files

CLARUS 500 records the following events and identifies them by date, time, and User ID:

- Log on/log off
- Create, modify, delete data
- Import/export data from removable media
- Receipt/transmit data from/to the network
- Remote service activity

A new file is created when the application starts. Events are automatically recorded in 1-5 audit files of 10 Mb each.

The instrument retains up to 100 of the latest log files. When file size limit is reached, the device overwrites existing files (starting with the oldest file).

The default folder for the audit log files is C:\ProgramData\Carl Zeiss Meditec\...\Logs.

NOTE

Save (export) audit log files regularly

to ensure events of consequence can be tracked should you encounter a data error.

- ▶ Log on as Administrator.
- ▶ Click **Tools > Export Audit Log File**.
- ▶ In the Browse folder, browse to the export location.
- ▶ Click **Save**.

⇒ The log is exported as a .zip file with the format:
AuditLog_dd_mm_yyyy_hh_mm.

5.3.5 Data Storage

The CLARUS 500 includes a some storage space on its PC. If you need additional data storage capacity, add external networked storage devices as required.

5.4 Managing Connections

5.4.1 Connecting to a Wireless Printer

NOTE

Connect only to wireless printers recommended).

NOTE

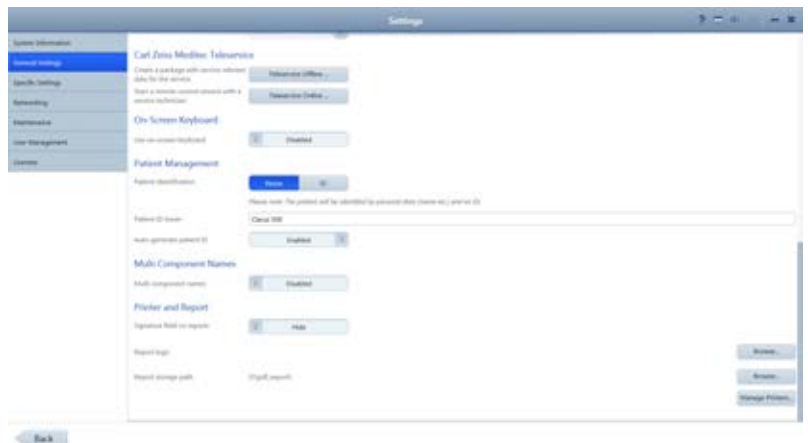
Only Administrators and Doctors can complete this task.

Prerequisite

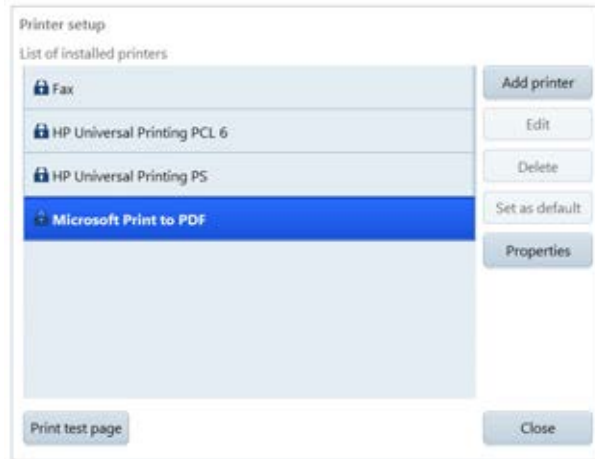
Action

To connect to a wireless printer:

- The CLARUS 500 and printer are on.
 - The printer is configured correctly.
 - Settings are open (Opening Settings ▶ 45)].
1. Select **General Settings** and scroll to the bottom.
 2. Under **Printer and Report**, click **Manage Printers**.



3. Select the printer you want to connect and click **Add Printer**.



4. To print a test page, select the printer and click **Print test page**.
5. To view the properties of the printer, click **Properties**.

5.4.2 Mapping Networked Drives

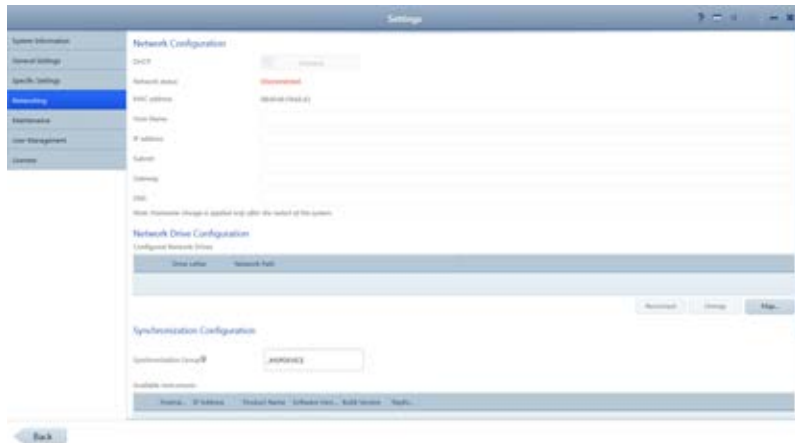
To map a networked drive:

Prerequisite

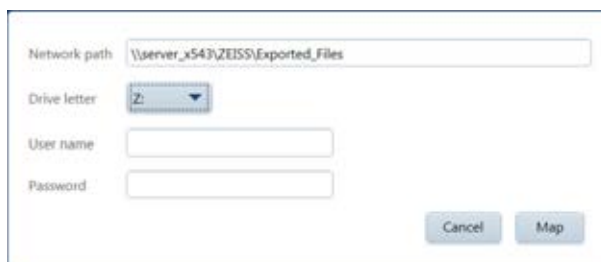
- Settings are open (Opening Settings [▶ 45]).
- You know the path of the drive you want to map in the format: \\<servername>\<foldername>\<subfoldername>. For example: \\Server_x543\ZEISS\Exported_Files

Action

1. Select **Networking**.



2. Under **Network Drive Configuration**, click **Map...**



3. Type the path and select the **Drive letter**.
4. To save the login credentials, type a **User name** and **Password** for the server.
5. Click **Map**.

Result

✓ The drive is now mapped.

5.4.3 Connecting to a LAN

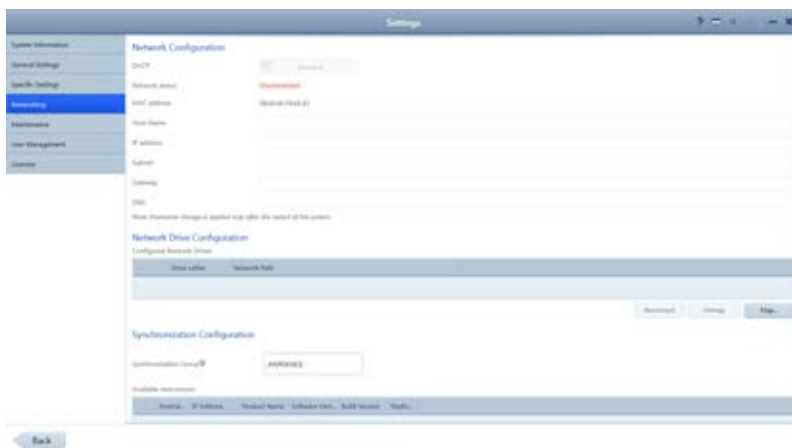
To connect to a LAN:

Prerequisite

- ☑ The CLARUS 500 must be connected to the local network using a network cable. Be gentle with the connector when plugging it into the CLARUS 500 ethernet port.
- ☑ Settings are open (Opening Settings [▶ 45]).

Action

1. Select **Networking**.



2. To automatically assign an IP address to the instrument, set **DHCP** to **Enabled**. For a network with static IP addresses, set **DHCP** to **Disabled** and enter the relevant network information.
3. Under **Network Drive Configuration**, select **Map....**
4. Enter the network path for the shared folder you'd like to connect to. The shared folder must be a root directory or a subdirectory of a root directory.
5. Select an unused drive letter.
6. If a password is required for access to the shared folder, enter the username and password. Otherwise, leave these fields blank.
7. Select **Map**.
 - ⇒ Successfully mapped drives are indicated with a check mark in a green circle. To disconnect a network drive, select the drive, then click **Unmap**.

5.5 Configuring Local Settings

Local settings include information about your clinic such as address, local language and local time zone.

To configure local settings:

Settings are open (Opening Settings [▶ 45]).

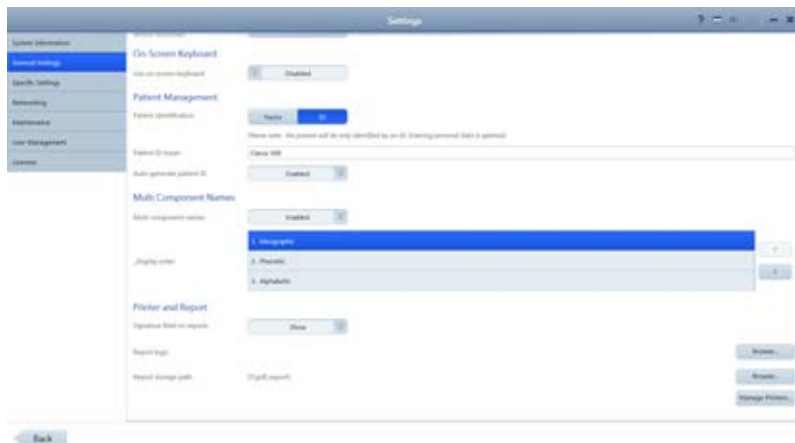
1. Select **General Settings**.
2. For **Institution Information**, complete the form for your clinic.

Prerequisite

Action



3. For **Alert display time**, select the number of seconds you want system or instrument alerts to display.
4. For **Locale Settings**, select the language and date formats.
5. Scroll to set additional general settings.
6. For **System Date and Time**, select the appropriate settings.



7. To display the onscreen keyboard, slide **On-Screen Keyboard** to **Enabled**.
8. For **Patient Management**, select **Name** or **ID** as patient data identifier.
9. Select the method for patient ID assignment. If you select CLARUS 500, the instrument will assign unique IDs for patients.

10. If your language requires **Multi-Component Names**, **Enable** Multi component names and select the appropriate type.

5.6 Configuring Report Settings

You can add your logo and a signature field to reports. You can also set the path for storing reports and manage printers.

To configure the report settings for automatic export, refer to: Configuring Export Settings [▶ 56].

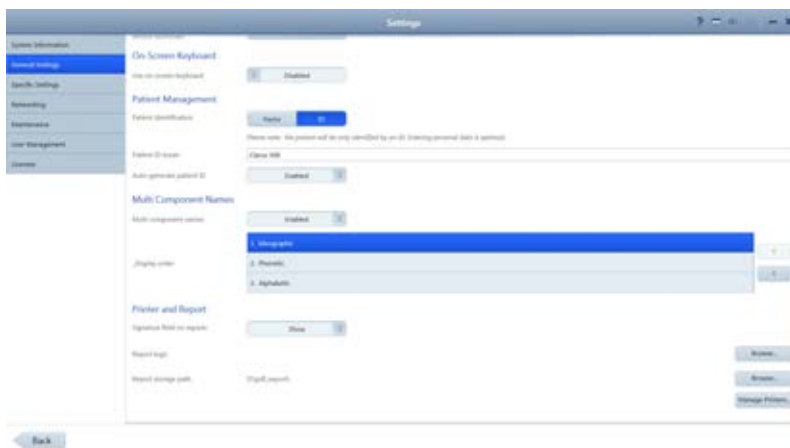
To configure report settings:

- Settings are open (Opening Settings [▶ 45]).

Prerequisite

Action

1. Select **General Settings**.
2. Scroll to the bottom of the **General Settings** panel.



3. To enable a signature field on reports, slide **Signature field on reports** to **Show**.
4. To add a logo to reports, click **Browse...** next to **Report logo** and navigate to the logo file and select it.
5. To set a path to store reports, click **Browse...** next to **Report storage path**.

5.7 Configuring Acquisition Settings

You can add your logo and a signature field to reports. You can also set the path for storing reports and manage printers.

To configure acquisition settings:

- Settings are open (Opening Settings [▶ 45]).

Prerequisite

Action

1. Select **Specific Settings**.



2. Click **Acquisition**.



5.8 Clearing Alert History

Prerequisite
Action

To clear alert history:

Settings are open (Opening Settings [▶ 45]).

1. Select **System Information**.



2. Under **Alert History**, click **Clear**.

⇒ The alerts are removed.

5.9 System Administration

NOTE

Only Administrators can complete this task.

This section contains detailed configuration information for system administrators. Only system administrators should make changes to these settings.

5.9.1 Windows Patches and Updates

Automatic Windows updates are disabled. Windows patches and updates are distributed with CLARUS 500 software after they are tested and approved for use.

5.9.2 Data Safety

5.9.2.1 Auto-lock

After 15 minutes of inactivity, the CLARUS 500 screen locks and the user must log in again.

5.9.2.2 Anti-Malware

When configuring anti-malware applications, ensure that updates and full system scans do not occur when data acquisition could be in progress. Refer to the software release notes for a list of approved anti-malware software.

5.9.2.3 User Names and Passwords

NOTE

Passwords for Tech Support users are unique for each system.

Zeiss instruments initially have three user names and passwords. Initial passwords are shown in the table below. Change these passwords before using the instrument.

User Name	Type	Password	Purpose
Zeiss	Administrator	November171846	Instrument User
ZeissAdmin	Administrator	November171846	Instrument Administration
Technical Support	Administrator	<unique>	Zeiss Technical Support

Table 6: Initial User Names and Passwords

5.9.3 Networking

5.9.3.1 Network Controllers and IP Addressing

NOTE

The CLARUS 500 is not compatible with networks using IPv4 addressing in the range of 192.168.111.0 to 192.168.111.254.

The CLARUS 500 contains two network controllers; Internal Network and External Network.

5.9.3.1.1 Internal Network Ports

NOTE

Do not rename the Internal Network.

Internal Network is for instrument use only with the following assignments:

- Static IPv4 address: 192.168.111.2
- Subnet mask: 255.255.255.0

5.9.3.1.2 External Network Ports

The **External Network** is for CLARUS 500 connectivity and automatically picks up an IP address.

5.9.3.2 Required Network Ports

The network ports listed in this section are required for proper operation of the CLARUS 500.

5.9.3.2.1 Required Internal Network Ports

- Internal Communication Port: TCP 80
- Internal Communication Port: TCP 22

5.9.3.2.2 Required External Network Ports

Service	TCP	UDP
Database inbound	18081	
Database outbound	18082	
Database inbound/outbound (open port visible externally)	3346	
Peer to Peer broadcast inbound/outbound		54183
Distributed Data Service inbound/outbound	54187	

Table 7: External Network Ports

5.9.3.2.3 Required External Network Ports for EMR and FORUM

Service	TCP	UDP
DICOM outbound	11119	
FORUM outbound	8080	

Service	TCP	UDP
DICOM inbound	11112	
FORUM inbound The first available port in this range will be used.	8081 ~ 8101	
DNS (AutoConnect for instruments outbound)		5353

Table 8: External Network Ports for EMR / FORUM

5.9.3.3 Additional Network Ports

The following network ports are not required to operate the instrument. These ports facilitate instrument configuration and maintenance.

Service	TCP	UDP
Remote service (outbound)	80	
DHCP		67 - 68
TCP/IP MS Networking	445	
NTP		123
NETBIOS Name Service (UDP open port visible externally)	137	137
NETBIOS Datagram Service	138	138
NETBIOS Session Service	139	139

Table 9: Additional Network Ports

5.9.4 Configuring Enhanced Security

Enhanced security settings are not required to operate the instrument properly. You can change these settings individually to match your Windows installation.

To remove Enhanced Security, log in as ZeissAdmin and run the "Remove Enhanced Security.CMD" script located on the desktop.

5.9.4.1 Disabling Enhanced Security Settings

When you received the CLARUS 500, enhanced security settings are turned on. These settings are not required for the instrument to operate properly.

You can change individual settings per your institution's requires or you can disable all of these settings using the *Remove Enhanced Security* command on the desktop.

Enhanced security settings are listed in the following sections:

- Enhanced Security Windows Firewall Rules [▶ 74]
- Enhanced Security Services [▶ 75]
- Enhanced Security Group Policy [▶ 76]

NOTE

Only Administrators can complete this task.

Prerequisite

Action

To disable enhanced security settings:

- The CLARUS 500 application is minimized (Main Toolbar [▶ 29])
1. Location the following command on the Windows desktop:
`Remove Enhanced Security.CMD`.
 2. Double-click `Remove Enhanced Security.CMD`.
 - ⇒ All enhanced security settings are reset to the Windows default settings.

5.9.4.2 Enabling Enhanced Security Settings

When you received the CLARUS 500, enhanced security settings are turned on. These settings are not required for the instrument to operate properly.

If there were changes to individual settings or if all enhanced security settings were disabled () you can re-enable all of these settings using the *Install Enhanced Security* command on the desktop.

Enhanced security settings are listed in the following sections:

- Enhanced Security Windows Firewall Rules [▶ 74]
- Enhanced Security Services [▶ 75]
- Enhanced Security Group Policy [▶ 76]

NOTE

Only Administrators can complete this task.

Prerequisite

Action

To enable enhanced security settings:

- The CLARUS 500 application is minimized (Main Toolbar [▶ 29])
1. Location the following command on the Windows desktop:
`Apply Enhanced Security.CMD`.
 2. Double-click `Apply Enhanced Security.CMD`.
 - ⇒ All enhanced security settings are enabled.

5.9.4.3 Enhanced Security Windows Firewall Rules

Enhanced security disables the following Windows firewall rules:

Disabled Firewall Rules
AllJoyn Router (TCP-In)
AllJoyn Router (TCP-Out)
AllJoyn Router (UDP-In)
AllJoyn Router (UDP-Out)
Cast to Device functionality (qWave-TCP-In)
Cast to Device functionality (qWave-TCP-Out)
Cast to Device functionality (qWave-UDP-In)
Cast to Device functionality (qWave-UDP-Out)
Cast to Device SSDP Discovery (UDP-In)
Cast to Device streaming server (HTTP-Streaming-In)
Cast to Device streaming server (RTCP-Streaming-In)
Cast to Device streaming server (RTP-Streaming-Out)
Cast to Device streaming server (RTSP-Streaming-In)
Cast to Device UPnP Events (TCP-In)
Cortana
Delivery Optimization (TCP-In)
Delivery Optimization (UDP-In)
DIAL protocol server (HTTP-In)
Microsoft.AccountsControl
Microsoft.LockApp
Microsoft.Windows.ContentDeliveryManager
Microsoft.Windows.ParentalControls
Microsoft.Windows.Apprep
Network Discovery (WSD Events-In)
Proximity sharing over TCP (TCP sharing-In)
Proximity sharing over TCP (TCP sharing-Out)
Remote Assistance (DCOM-In)
Remote Assistance (PNRP-In)
Remote Assistance (RA Server TCP-In)
Remote Assistance (SSDP TCP-In)
Remote Assistance (SSDP UDP-In)
Remote Assistance (TCP-In)
SmartScreen
Windows.ShellExperience
Windows Spotlight
Wireless Display (TCP-In)
Wireless Display (TCP-Out)
Wireless Display (UDP-Out)
Wireless Display Infrastructure Back Channel (TCP-In)

5.9.4.4 Enhanced Security Services

Enhanced security disables the following services:

Disabled Security Services
AllJoyn Router Service
Application Layer Gateway Service
Bluetooth Handsfree Service
Bluetooth Support Service
BranchCache
Connected Devices Platform Service
Connected User Experiences and Telenetry
Downloaded Maps Manager
Fax
Function Discovery Resource Publication
Geolocation Service
HomeGroup Listener
HomeGroup Provider
Infrared Monitor Service
Internet Connection Sharing (ICS)
Microsoft iSCSI Initiator Service
Microsoft Storage Spaces SMP
Microsoft Windows SMS Router Service
Network Connection Broker
Phone Service
Program Compatibility Assistant Service
Quality Windows Audio Video Experience
Retail Demo Service
Shell Hardware Detection
Telephony
Touch Keyboard and Handwriting Panel Service
Windows Camera Frame Server
Windows Event Collector
Windows Image Acquisition (WIA)
Windows Insider Service
Windows Media Player Network Sharing Service
Windows Mobile Hotspot Service
Work Folders Xbox Live Auth Manager Xbox Live Game Save Xbox Live Networking Service

5.9.4.5 Enhanced Security Group Policy

Policy	Setting
Access Credential Manager as a trusted caller	No One
Access this computer from the network	Administrators
Account lockout duration)	60 minute(s
Account lockout threshold	30 invalid logon attempt(s)
Accounts: Administrator account status	Enabled
Accounts: Guest account status	Disabled
Accounts: Limit local account use of blank passwords to console logon only	Enabled

Policy	Setting
Accounts: Rename administrator account	ZeissAdmin
Accounts: Rename guest account	Not Used
Act as part of the operating system	No One
Adjust memory quotas for a process	Administrators, Local Service, Network Service
Allow all trusted apps to install	Disabled
Allow Basic authentication	Disabled
Allow Cortana	Disabled
Allow indexing of encrypted files	Disabled
Allow log on locally	Administrators, Users
Allow Microsoft accounts to be optional	Enabled
Allow Telemetry 0 - Off (Enterprise Only)	Enabled
Allow unencrypted traffic	Disabled
Allow user control over installs	Disabled
Allow users to connect remotely by using Remote Desktop Services	Disabled
Allow Windows to automatically connect to suggested open hotspots, to networks shared by contacts, and to hotspots offering paid services	Disabled
Always install with elevated privileges	Disabled
Always prompt for password upon connection	Enabled
Apply UAC restrictions to local accounts on network logons	Enabled
Audit Policy: Account Logon: Credential Validation	Success and Failure
Audit Policy: Account Management: Other Account Management Events	Success and Failure
Audit Policy: Account Management: Security Group Management	Success and Failure
Audit Policy: Account Management: User Account Management	Success and Failure
Audit Policy: Detailed Tracking: Process Creation	Success
Audit Policy: Logon-Logoff: Account Lockout	Success
Audit Policy: Logon-Logoff: Logoff	Success

Policy	Setting
Audit Policy: Logon-Logoff: Logon	Success and Failure
Audit Policy: Logon-Logoff: Special Logon	Success
Audit Policy: Object Access: Removable Storage	Success and Failure
Audit Policy: Policy Change: Audit Policy Change	Success and Failure
Audit Policy: Policy Change: Authentication Policy Change	Success
Audit Policy: Privilege Use: Sensitive Privilege Use	Success and Failure
Audit Policy: System: IPsec Driver	Success and Failure
Audit Policy: System: Other System Events	Success and Failure
Audit Policy: System: Security State Change	Success
Audit Policy: System: Security System Extension	Success and Failure
Audit Policy: System: System Integrity	Success and Failure
Audit: Audit the access of global system objects	Disabled
Audit: Audit the use of Backup and Restore privilege	Enabled
Audit: Force audit policy subcategory settings (Windows Vista or later) to override audit policy category settings	Enabled
Audit: Shut down system immediately if unable to log security audits	Disabled
Back up files and directories	Administrators
Boot-Start Driver Initialization Policy Choose the boot-start drivers that can be initialized	Enabled Good, unknown and bad but critical
Change the system time	LOCAL SERVICE, Administrators
Configure Automatic Updates	Disabled
Configure Offer Remote Assistance	Disabled
Configure registry policy processing Do not apply during periodic background processing Process even if the Group Policy objects have not changed	Enabled TRUE TRUE

Policy	Setting
Configure Solicited Remote Assistance Maximum ticket time (units) Maximum ticket time (value) Method for sending email invitations Permit remote control of this computer	Enabled Hours 1 Simple MAPI Allow helpers to remotely control the computer Enabled
Configure Windows SmartScreen	Disabled
Create a pagefile	Administrators
Create a token object	No One
Create global objects	Administrators, SERVICE, LOCAL SERVICE, NETWORK SERVICE
Create permanent shared objects	No One
Create symbolic links	Administrators
Debug programs	Administrators
Deny access to this computer from the network	NT AUTHORITY \Local Account, GUESTS
Deny log on locally	Guests
Deny log on through Remote Desktop Services	NT AUTHORITY \Local Account, GUESTS
Detect compatibility issues for applications and drivers	Enabled
Devices: Allow undock without having to log on	Enabled
Disallow Autoplay for non-volume devices	Enabled
Disallow Digest authentication	Enabled
Disallow WinRM from storing RunAs credentials	Enabled
Do not allow drive redirection	Enabled
Do not allow passwords to be saved	Enabled
Do not display network selection UI	Enabled
Do not enumerate connected users on domain-joined computers	Enabled
Do not preserve zone information in file attachments	Disabled
Domain member: Digitally encrypt or sign secure channel data (always)	Enabled

Policy	Setting
Domain member: Digitally encrypt secure channel data (when possible)	Enabled
Domain member: Digitally sign secure channel data (when possible)	Enabled
Domain member: Disable machine account password changes	Disabled
Domain member: Maximum machine account password age	30 day(s)
Domain member: Require strong (Windows 2000 or later) session key	Enabled
Don't allow SmartScreen Filter warning overrides	Disabled
Enable computer and user accounts to be trusted for delegation	No One
Enable insecure guest logons	Disabled
Enable local admin password management	Enabled
Enable RPC Endpoint Mapper Client Authentication	Enabled
Enable screen saver	Enabled
Enforce password history	24 password(s)
Enumerate administrator accounts on elevation	Disabled
Enumerate local users on domain-joined computers	Disabled
Force shutdown from a remote system	Administrators
Generate security audits	Local Service, Network Service
Hardened UNC Paths Hardened UNC Paths: Hardened UNC Paths: = *\NETLOGON" RequireMutualAuthentication = 1 RequireIntegrity = 1	Enabled
Impersonate a client after authentication	Administrators, SERVICE, Local Service, Network Service
Include command line in process creation events	Enabled
Increase scheduling priority	Administrators
Interactive logon: Machine account lockout threshold	10 invalid logon attempts
Interactive logon: Machine inactivity limit	900 seconds
Interactive logon: Number of previous logons to cache (in case domain controller is not available)	10 logon(s)
Interactive logon: Prompt user to change password before expiration	5 day(s)

Policy	Setting
Interactive logon: Require Domain Controller authentication to unlock workstation	Disabled
Interactive logon: Require smart card	Disabled
Interactive logon: Smart card removal behavior	No Action
Load and unload device drivers	Administrators
Lock pages in memory	No One
Manage auditing and security log Administrators Maximum password age	60 days
Microsoft network client: Digitally sign communications (always)	Disabled
Microsoft network client: Digitally sign communications (if server agrees)	Enabled
Microsoft network client: Send unencrypted password to third-party SMB servers	Disabled
Microsoft network server: Amount of idle time required before suspending session	15 minute(s)
Microsoft network server: Digitally sign communications (if client agrees)	Enabled
Microsoft network server: Server SPN target name validation level	Accept if provided by client
Minimize the number of simultaneous connections to the Internet or a Windows Domain	Enabled
Minimum password age	1 day(s)
Minimum password length	7 character(s)
Minimum PIN length Minimum PIN length	Enabled 6
Modify an object label	No one
Modify firmware environment values	Administrators
MSS: (AutoAdminLogon) Enable Automatic Logon (not recommended)	Disabled
MSS: (DisableIPSourceRouting IPv6) IP source routing protection level (protects against packet spoofing) DisableIPSourceRoutingIPv6	Enabled Highest protection, source routing is completely disabled
MSS: (DisableIPSourceRouting) IP source routing protection level (protects against packet spoofing) DisableIPSourceRouting	Enabled Highest protection, source routing is completely disabled

Policy	Setting
MSS: (EnableICMPRedirect) Allow ICMP redirects to override OSPF generated routes	Disabled
MSS: (NoNameReleaseOnDemand) Allow the computer to ignore NetBIOS name release requests except from WINS servers	Enabled
Network access: Allow anonymous SID/Name translation	Disabled
Network access: Do not allow anonymous enumeration of SAM accounts	Enabled
Network access: Do not allow anonymous enumeration of SAM accounts and shares	Enabled
Network access: Do not allow storage of passwords and credentials for network authentication	Enabled
Network access: Let Everyone permissions apply to anonymous users	Disabled
Network access: Restrict anonymous access to Named Pipes and Shares	Enabled
Network access: Sharing and security model for local accounts	Classic - local users authenticate as themselves
Network security: Allow Local System to use computer identity for NTLM	Enabled
Network security: Allow LocalSystem NULL session fallback	Disabled
Network Security: Allow PKU2U authentication requests to this computer to use online identities	Disabled
Network Security: Configure encryption types allowed for Kerberos	RC4\AES128\AES256\Future types
Network security: LAN Manager authentication level	Send NTLMv2 response only. Refuse LM & NTLM
Network security: Do not store LAN Manager hash value on next password change	Enabled
Network security: Force logoff when logon hours expire	Disabled
Network security: LDAP client signing requirements	Negotiate signing
Network security: Minimum session security for NTLM SSP based (including secure RPC) clients	Require NTLMv2 session security, Require 128-bit encryption

Policy	Setting
Network security: Minimum session security for NTLM SSP based (including secure RPC) servers	Require NTLMv2 session security, Require 128-bit encryption
No auto-restart with logged on users for scheduled automatic updates installations	Enabled
Notify antivirus programs when opening attachments	Enabled
Password must meet complexity requirements	Enabled
Password protect the screen saver	Enabled
Perform volume maintenance tasks	Administrators
Prevent enabling lock screen camera	Enabled
Prevent enabling lock screen slide show	Disabled
Prevent the usage of OneDrive for file storage	Enabled
Profile single process	Administrators
Prohibit connection to non-domain networks when connected to domain authenticated network	Enabled
Recovery console: Allow automatic administrative logon	Disabled
Recovery console: Allow floppy copy and access to all drives and all folders	Disabled
Replace a process level token Local Service, Network Service Require a Password When a Computer Wakes (On Battery)	Enabled
Require a Password When a Computer Wakes (Plugged In)	Enabled
Require secure RPC communication	Enabled
Reset account lockout counter after	60 minute(s)
Restrict Unauthenticated RPC clients RPC Runtime Unauthenticated Client Restriction to Apply:	Enabled Authenticated
Restore files and directories	Administrators
Screen saver timeout Seconds	Enabled 900
Set client connection encryption level Encryption Level	Enabled High Level
Set the default behavior for AutoRun Default AutoRun Behavior	Enabled Do not execute any autorun commands
Shutdown: Allow system to be shut down without having to log on	Enabled

Policy	Setting
Shutdown: Clear virtual memory pagefile	Disabled
Sign-in last interactive user automatically after a system-initiated restart	Disabled
Specify the maximum log file size (KB) (Application Log) Maximum Log Size (KB)	Enabled 32768
Specify the maximum log file size (KB) (Security Log) Maximum Log Size (KB)	Enabled 196608
Specify the maximum log file size (KB) (System Log) Maximum Log Size (KB)	Enabled 32768
Store passwords using reversible encryption	Disabled
System cryptography: Use FIPS compliant algorithms for encryption, hashing, and signing	Disabled
System objects: Require case insensitivity for non-Windows subsystems	Enabled
System objects: Strengthen default permissions of internal system objects (e.g. Symbolic Links)	Enabled
System settings: Use Certificate Rules on Windows Executables for Software Restriction Policies	Disabled
Take ownership of files or other objects	Administrators
Turn off access to the Store	Enabled
Turn off app notifications on the lock screen	Enabled
Turn off Automatic Download and Install of updates	Enabled
Turn off Autoplay Turn off Autoplay on	Enabled All drives
Turn off Data Execution Prevention for Explorer	Disabled
Turn off downloading of print drivers over HTTP	Disabled
Turn off heap termination on corruption	Disabled
Turn off Internet download for Web publishing and online ordering wizards	Enabled
Turn off Microsoft consumer experiences	Enabled
Turn off Password Manager	Disabled
Turn off printing over HTTP	Disabled
Turn off the offer to update to the latest version of Windows	Enabled
Turn off the SmartScreen Filter	Enabled
Turn off toast notifications on the lock screen	Enabled
Turn off Windows Update device driver searching	Enabled

Policy	Setting
Turn on convenience PIN sign-in	Disabled
Turn on PowerShell Script Block Logging Log script block invocation start / stop events:	Enabled TRUE
Untrusted Font Blocking Mitigation Options	Enabled Block untrusted fonts and log events
Use a hardware security device	Enabled
Use enhanced anti-spoofing when available	Enabled
User Account Control: Admin Approval Mode for the Built-in Administrator account	Enabled
User Account Control: Allow UIAccess applications to prompt for elevation without using the secure desktop	Disabled
User Account Control: Behavior of the elevation prompt for administrators in Admin Approval Mode	Prompt for consent on the secure desktop
User Account Control: Behavior of the elevation prompt for standard users	Prompt for credentials
User Account Control: Detect application installations and prompt for elevation	Enabled
User Account Control: Only elevate executables that are signed and validated	Disabled
User Account Control: Only elevate UIAccess applications that are installed in secure locations	Enabled
User Account Control: Run all administrators in Admin Approval Mode	Enabled
User Account Control: Switch to the secure desktop when prompting for elevation	Enabled
User Account Control: Virtualize file and registry write failures to per-user locations	Enabled
WDigest Authentication (disabling may require KB2871997)	Disabled
Windows Firewall: Domain: Display a notification	No
Windows Firewall: Domain: Inbound connections Inbound Connections	Enabled Block
Windows Firewall: Domain: Logging: Log dropped packets	Yes
Windows Firewall: Domain: Logging: Log successful connections	Yes

Policy	Setting
Windows Firewall: Domain: Logging: Name	%SYSTEMROOT%\System32\logfiles\firewall\domainfw.log
Windows Firewall: Domain: Logging: Size limit (KB)	16384 KB
Windows Firewall: Domain: Outbound connections	Allow
Windows Firewall: Private: Display a notification	No
Windows Firewall: Private: Inbound connections Inbound Connections	Enabled Block
Windows Firewall: Private: Logging: Log dropped packets	Yes
Windows Firewall: Private: Logging: Log successful connections	Yes
Windows Firewall: Private: Logging: Name	%SYSTEMROOT%\System32\logfiles\firewall\privatefw.log
Windows Firewall: Private: Logging: Size limit (KB)	16384 KB
Windows Firewall: Private: Outbound connections	Allow
Windows Firewall: Public: Apply local connection security rules	No
Windows Firewall: Public: Apply local firewall rules	No
Windows Firewall: Public: Display a notification	No
Windows Firewall: Public: Inbound connections Inbound Connections	Enabled Block
Windows Firewall: Public: Logging: Log dropped packets	Yes
Windows Firewall: Public: Logging: Log successful connections	Yes
Windows Firewall: Public: Logging: Name	%SYSTEMROOT%\System32\logfiles\firewall\publicfw.log
Windows Firewall: Public: Logging: Size limit (KB)	16384 KB
Windows Firewall: Public: Outbound connections	Allow

Table 10: Table Title

6 Operation

6.1 Safety During Operation

CAUTION!

Improper operator training

could lead to poor scan quality, damage to system components, or inadvertent patient safety compromise.

- ▶ Train all operators fully.
- ▶ Ensure all personnel are familiar with the information contained in Safety and Certifications [▶ 9].
- ▶ Ensure that routine maintenance has been properly carried out in conformance with the Maintenance Schedules described in the chapter Maintenance [▶ 143].

For lens cleaning instructions, refer to: Cleaning the Front Lens [▶ 137].

6.2 Preparing the Device

Action

To prepare the device:

1. Wipe the chin rest and forehead rest with an alcohol pad, and allow the assembly to dry. (See Cleaning the Chinrest and Forehead Support [▶ 141].)
2. Carefully read and understand any instructions provided by the officiating physician or researcher.

6.2.1 Finding a Patient

Action

To find a patient:

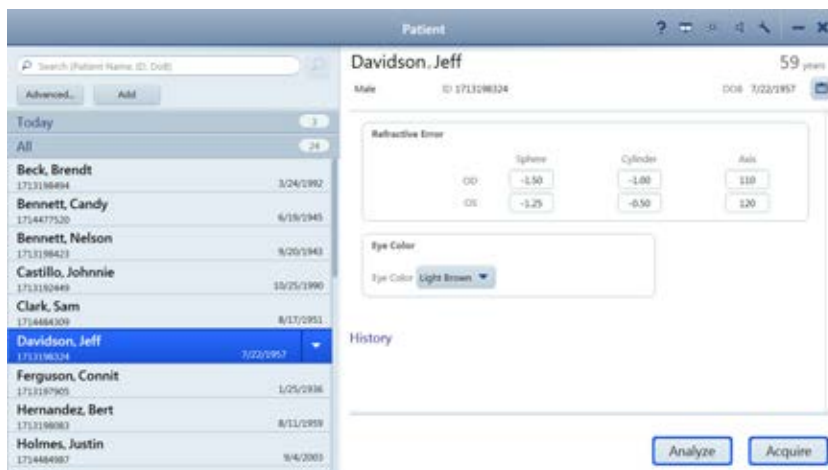
1. In the **Search** bar, type the first name, last name, patient ID, or a scan date of the person you want to find.
2. Click the **Search** icon.
3. To refine your search criteria, use **Advanced Search**.

6.2.2 Selecting the Patient

Finding a patient's name can vary depending on the systems you use.

- If you use an EMR system:
 - The patient's name might be listed under **Today**
 - If the patient is not listed under **Today**, search for their name or ID (See Finding a Patient [▶ 87]).

- If the patient is not in the database, add the patient's information. (See Adding a Patient [▶ 46]).
- If you do not use an EMR system:
 - Search for the patient's name or ID **Search** (See Finding a Patient [▶ 87]).
 - If the patient is not in the database, add the patient's information. (See Adding a Patient [▶ 46]).



To select a patient:

Action

1. Find the patient's name using the list or search and select the patient's name.
2. Click **Acquire**.

6.3 Preparing the Patient

NOTE

Keep the front of the lens clean.

The quality of image capture is affected by the cleanliness of the front lens.

- ▶ Avoid touching the lens with anything but approved cleaning equipment.
- ▶ Use the protective cover to keep dust off the lens when the device is not in use.

For complete instructions on cleaning the lens, refer to: Cleaning and Disinfection [▶ 137]

6.3.1 Dilating the Patient's Eyes (Optional)

The minimum pupil size for the CLARUS 500 is 2.5 mm, which is typically achieved without dilation.

6.3.2 Lifting the Patient's Eyelid (Optional)

Because the patient's eye is very close to the acquisition head, you might need to re-position the computer screen or reach around the instrument to lift a patient's eyelid.

The option you use can also depend on whether you are scanning the patient's right or left eye.

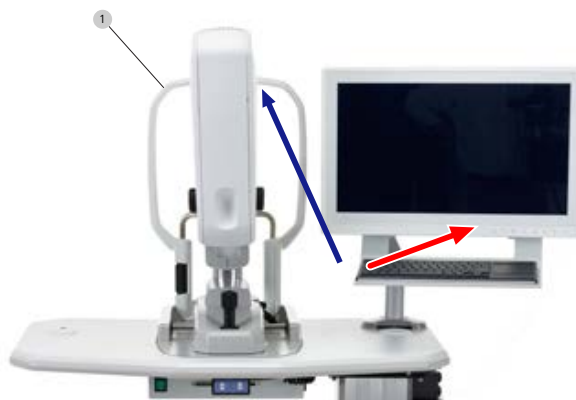
6.3.2.1 Option 1: Reach Between

This method works better if the operator cannot comfortably reach around the acquisition head. However, with the computer screen moved to provide access, the operator has a more limited view of the screen.

To lift the eyelid by reaching between:

Action

1. Swing the computer aside to allow access the patient's eye.



2. Reach between the acquisition head and the computer to access the back of the patient support.
3. Rest your hand against the back of the forehead rest and lift the patient's eyelid.

6.3.2.2 Option 2: Reach Around

This method provides the operator a consistent view of the computer screen. However, some operators may not be able to comfortably reach the patient's eyelid.

To left the eyelid by reaching around:

Action

1. Reach around the acquisition head to access the back of the patient support.



2. Rest your hand against the back of the forehead rest and lift the patient's eyelid.

6.3.3 Positioning the Patient

CAUTION!

Pinch hazard for hands and fingers.

- ▶ Keep operator and patient hands and fingers away from crosstable during alignment and image capture.

To position the patient:

Action

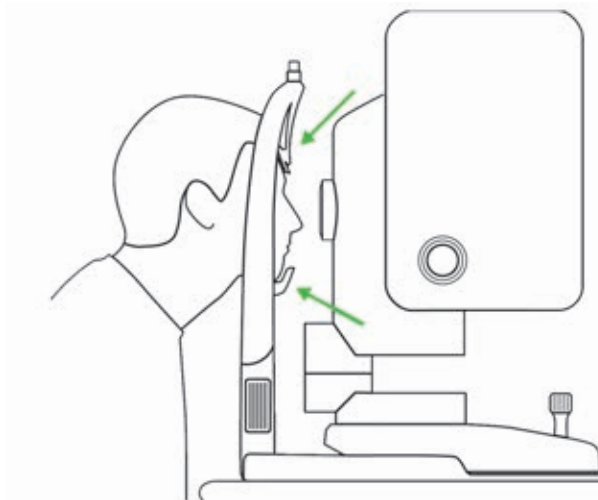
1. Adjust the table (and patient chair, if needed) until the patient can comfortably reach the headrest and chin rest.



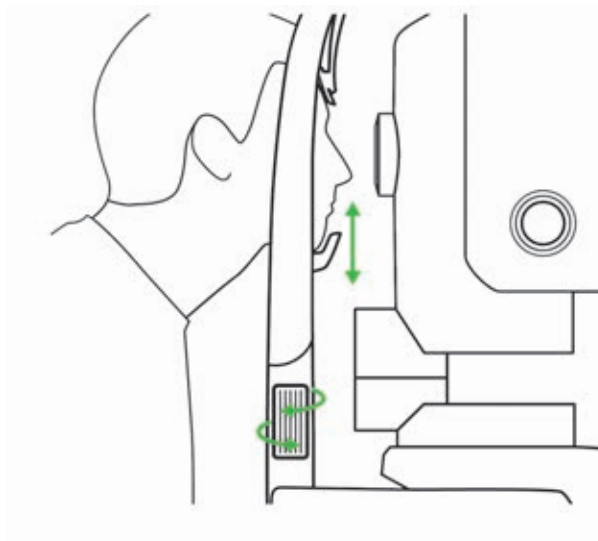
2. To move the table up, press and hold the up arrow (1).
3. To move the table down, press and hold the down arrow (2).
4. Ask the patient to:

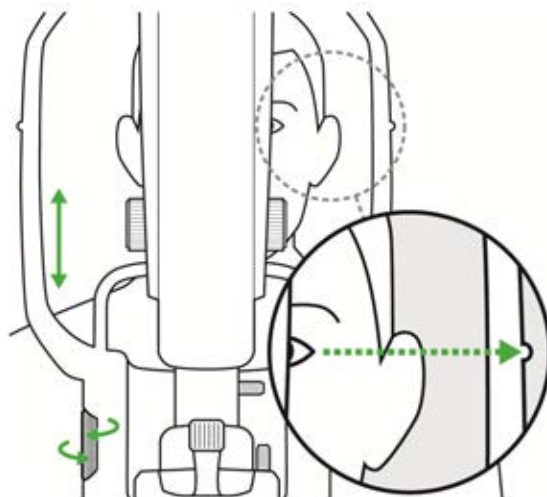
⇒ Sit comfortably with feet flat on the ground.

- ⇒ Lean forward slightly, grasping the table handles if needed for stability.
- ⇒ Rest their chin in the chin rest.
- ⇒ Rest their forehead against the forehead rest.

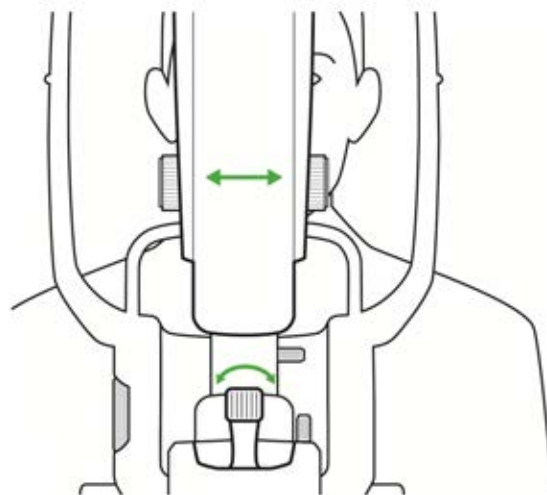


5. Adjust the chin rest up or down as needed until align the patient's canthus to the canthus marker on the patient support.





6. Swing the acquisition head left to align with the patient's right eye or right to align with the patient's left eye.



6.3.4 Aligning and Focusing on the Patient's Eye

In addition to the preview image, two images of the iris help to align the eye.



Figure 11: Acquire Screen

The top iris image is used for vertical alignment. The height of the band is the minimum pupil size required. If the pupil is smaller than the transparent band, you can change the pupil setting to **Non-Myd**, or dilate the patient's pupils.

Action

To align and focus on the patient's eye:

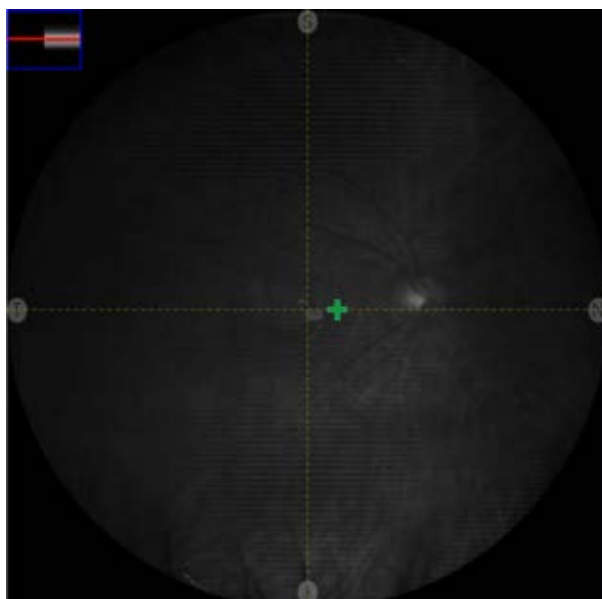
1. Push the acquisition head closer to the patient.
2. Twist the joystick to move the acquisition head up or down until the patient's pupil is aligned with the band.



3. If the patient's pupil is smaller than the transparent band, change the setting to **Non-Myd** or dilate the patient's pupil (Dilating the Patient's Eyes (Optional) [▶ 88]).
4. Slide the instrument front to back and side-to-side until the patient's pupil is centered on the yellow cross hairs on the bottom iris image.



⇒ When the pupil is aligned, a live view of the fundus appears in the live IR preview window.



5. Ensure that the image is in focus. If needed, manually focus the image (Manually Focusing the Image [▶ 110]).
6. Make fine adjustments as needed to eliminate any shadows showing in the IR preview window.
7. If either alignment is not centered, repeat these steps until they are centered.

NOTE

If the acquisition head drifts after you align it, you can set the lock to secure it in place.





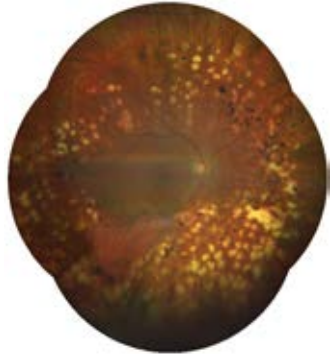

6.4 Acquire Images

6.4.1 About Acquisition Options

6.4.1.1 Field of View Options



Pos.	Description	Example
1	Widefield (WF) Single image, 133° wide by 133° high	

Pos.	Description	Example
2	Ultra-widefield (UWF) Two image montage, 200° wide by 133° high	
3	Auto Montage Four image montage, 200° wide by 200° high	
4	Montage Up to six images montaged in an operator-selected configuration	

6.4.1.2 Scan Types




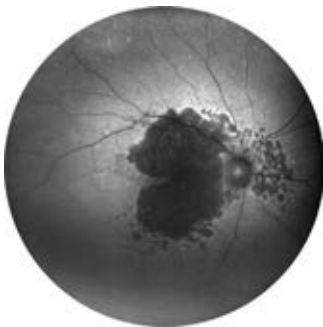
NOTE

Example images shown below are taken from scans acquired from multiple subjects.



Figure 12: Scan Types

Pos.	Description	Explanation	Example
1	Color	<p>Color</p> <p>High resolution, color images of the fundus appear similar in color to direct observation (ophthalmoscopy).</p> <p>You can also view a monochrome image of each composite color (red, green, and blue).</p>	
		<p>Blue Channel</p> <p>Blue channel images increase visibility of the anterior retinal layers.</p>	
		<p>Red Channel</p> <p>Red channel images reveal the choroid in more detail.</p>	

Pos.	Description	Explanation	Example
		Green Channel Green channel images provide excellent contrast of the retina, especially of vasculature and hemorrhages.	
2	IR	Infrared reflectance Infrared light is used to capture these images, with the unique property of increased penetration through tissue, providing improved visualization of choroidal structures. A monochrome image is generated.	
3	FAF-Green	Fundus autofluorescence with green excitation. The eye is illuminated with light at a wavelength that stimulates the natural fluorescence of lipofuscin. A monochrome image is generated.	
4	FAF-Blue	Fundus autofluorescence with blue excitation. The eye is illuminated with light at a wavelength that stimulates the natural fluorescence of lipofuscin. A monochrome image is generated.	

6.4.1.3 Internal Fixation Targets

The internal fixation target set positions include 9 fixed points to steer a patient's gaze:

- Central
- Temporal
- Nasal



Figure 13: Fixed Targets

- Superior
- Inferior
- Superotemporal
- Superonasal
- Inferonasal
- Inferotemporal

You can override the preset fixation targets and choose any location within the patient's field of view (See Manually Positioning the Internal Fixation Target [▶ 111].)

If the patient is unable to see the fixation target, you can blink the fixation target to help the patient to see it. (See Blinking the Fixation Target [▶ 109].)

Internal fixation targets adjust to any point within the 90 degree circular FOV.

6.4.1.3.1 Internal Fixation Target Preset Positions




Scan Type	Location(s)	Description
Widefield (WF)		Central
Ultra widefield		Temporal Nasal
AutoMontage		Temporal Superior Nasal Inferior

Table 11: Preset Internal Fixation Targets for Scans

6.4.1.3.2 Tips to Help Patients Find Fixation Targets

Some patients have difficulty seeing the internal fixation target. When the target is on the side (nasal / temporal), it can appear as though the internal fixation target is outside the acquisition head. When a patient cannot see the fixation target, you can help them locate it using the tips below.

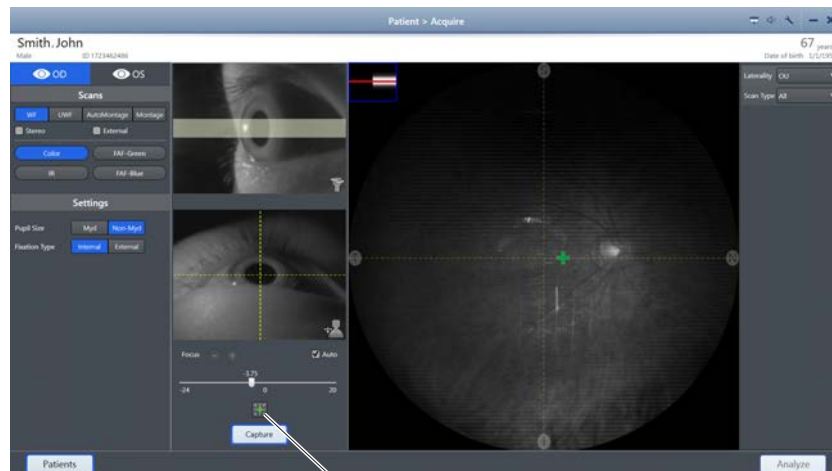
Tips

1. Describe the target (a green star pattern).



2. Pull acquisition head towards you and realign the instrument (Aligning and Focusing on the Patient's Eye [▶ 93]).

3. Blink the **fixation target (1)** (Blinking the Fixation Target [▶ 109]).



4. For temporal fixation targets, swivel the acquisition head slightly towards the center.
5. Increase the duration of fixation target blinks (Configuring Acquisition Settings [▶ 69]).
6. Have the patient follow the fixation target from the center position to the side:
 - Manually position the **fixation target (1)** towards the center (Manually Positioning the Internal Fixation Target [▶ 111]).
 - When the patient sees the centered target, ask them to follow the target as you manually reposition it to the side.



7. If the patient still cannot see the internal fixation target, use the external fixation target (Using the External Fixation Target [▶ 112]).

6.4.2 Capturing a Widefield Image



Figure 14: Widefield Fixation Target

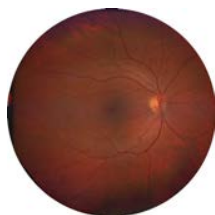


Figure 15: WF Image Example

When you capture a widefield (**WF**) image, CLARUS 500 takes one image and with a fixation target preset near the center.

If the patient cannot see the fixation target, you can:

- Blink the fixation target: Blinking the Fixation Target [▶ 109]
- Change the fixation target: Manually Positioning the Internal Fixation Target [▶ 111]
- Use the external fixation target: Using the External Fixation Target [▶ 112]

To capture a WF image:

- The device is prepared. (See Preparing the Device [▶ 87].)
- The patient is prepared. (See Preparing the Patient [▶ 88].)

Prerequisite

Action

1. Under **Scans**, select **WF**.
2. Select the Scan Type (**Color**, **IR**, **FAF-Green**, or **FAF-Blue**). For more information, refer to: Scan Types [▶ 97].
3. Under **Settings**, select **Myd** if the patient's pupil is dilated and **Non Myd** if the patient's pupil is not dilated.
4. Instruct the patient to look inside the lens, focus on the green fixation target and blink naturally.

NOTE

If the patient cannot see the fixation target, refer to: Tips to Help Patients Find Fixation Targets [▶ 100].

5. The instrument automatically focuses the image. To manually adjust focus, refer to: Manually Focusing the Image [▶ 110].
6. Instruct the patient to blink and then open their eyes wide.
7. Click the joystick button or click **Capture**.
 - ⇒ A preview of the captured image appears for several seconds and is added to the selection bin.
8. Repeat adjustments and scans as needed until all scans are acquired.

6.4.3 Capturing an Ultra-widefield Image (2-Image Montage)



Figure 16: UWF Fixation Targets



Figure 17: UWF Image Example

When you capture an ultra-widefield (UWF) image, CLARUS 500 takes two widefield images and stitches them together for a wider view of the retina. The fixation targets for these images are preset at temporal and nasal.

Prerequisite

Action

To capture an UWF image:

- The device is prepared. (See Preparing the Device [▶ 87].)
 - The patient is prepared. (See Preparing the Patient [▶ 88].)
1. Under **Scans**, select **UWF**.
 2. Select the Scan Type (**Color**, **IR**, **FAF-Green**, or **FAF-Blue**). For more information about Scan Types, refer to: Scan Types [▶ 97].
 3. For **Pupil Size**, select **Myd** if the patient's pupil is dilated and **Non-Myd** if the patient's pupil is not dilated.
 4. Instruct the patient to look inside the imaging aperture, focus on the green fixation target and blink naturally.

NOTE

If the patient cannot see the fixation target, refer to: Tips to Help Patients Find Fixation Targets [▶ 100].

5. The instrument automatically focuses the image. To manually adjust focus, refer to: Manually Focusing the Image [▶ 110].
6. Instruct the patient to blink and then open their eyes wide.
7. Click the joystick button or click **Capture**.
 - ⇒ A preview of the captured image appears for several seconds and is added to the selection bin.
 - ⇒ The internal fixation target advances to the next position in the sequence.
8. Recheck adjustments and focus for the second scan in the series, and click **Capture**.
 - ⇒ A preview of the captured image appears for several seconds and is added to the capture bin.
 - ⇒ If the images montage successfully, each thumbnail displays a green checkmark.
 - ⇒ If an image did not montage successfully, the thumbnail displays a yellow exclamation point.
9. To delete and retake the image, refer to: Deleting or Replacing an Image [▶ 113].

6.4.4 Capturing an AutoMontage Image (4-Image Montage)

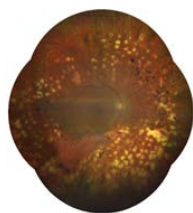


Figure 18: AutoMontage Example

When you capture an AutoMontage image, CLARUS 500 takes four widefield images and stitches them together for a wider view of the retina. The fixation targets for these images are preset at



If you do not complete all four scans, CLARUS 500 saves the completed scans as individual wide field scans.

Prerequisite

To capture an AutoMontage image:

- The device is prepared. (See Preparing the Device [▶ 87].)
- The patient is prepared. (See Preparing the Patient [▶ 88].)

Action

1. Under **Scans**, select **AutoMontage**.
2. Select the Scan Type (**Color**, **IR**, **FAF-Green**, or **FAF-Blue**). For more information about Scan Types, refer to: Scan Types [▶ 97].
3. For **Pupil Size**, select **Myd** if the patient's pupil is dilated and **Non-Myd** if the patient's pupil is not dilated.
4. Instruct the patient to look inside the imaging aperture, focus on the green fixation target and blink naturally.

NOTE

If the patient cannot see the fixation target, refer to: Tips to Help Patients Find Fixation Targets [▶ 100].

5. The instrument automatically focuses the image. To manually adjust focus, refer to: Manually Focusing the Image [▶ 110].
6. Instruct the patient to blink and then open their eyes wide.
7. Click the joystick button or click **Capture**.
 - ⇒ A preview of the captured image appears for several seconds and is added to the selection bin.
8. Ask the patient to relax while the you review the scan.
 - ⇒ The internal fixation target advances to the next position in the sequence.
9. **Next Scan:** confirm alignment and focus for the next scan in the series, and click **Capture**.
 - ⇒ A preview of the captured image appears for several seconds and is added to the capture bin.

- ⇒ The internal fixation target advances to the next position in the sequence.
- 10. Repeat **Next scan** steps until all four scans are complete.
 - ⇒ If the images montage successfully, each thumbnail displays a green checkmark.
 - ⇒ If an image did not montage successfully, the thumbnail displays a yellow exclamation point.
- 11. To delete and retake the image, refer to: Deleting or Replacing an Image [▶ 113].

6.4.5 Capturing a Montage Image (2-6 Image Custom Montage)

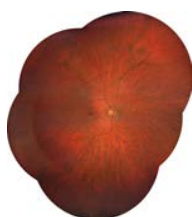


Figure 19: Custom Montage Example

When you capture a custom **Montage** image, CLARUS 500 takes a series of widefield images and stitches them together. You can decide how many images to include in the montage. For each image, you can choose any internal fixation target location or have the patient focus on the external fixation target (Using the External Fixation Target [▶ 112]).

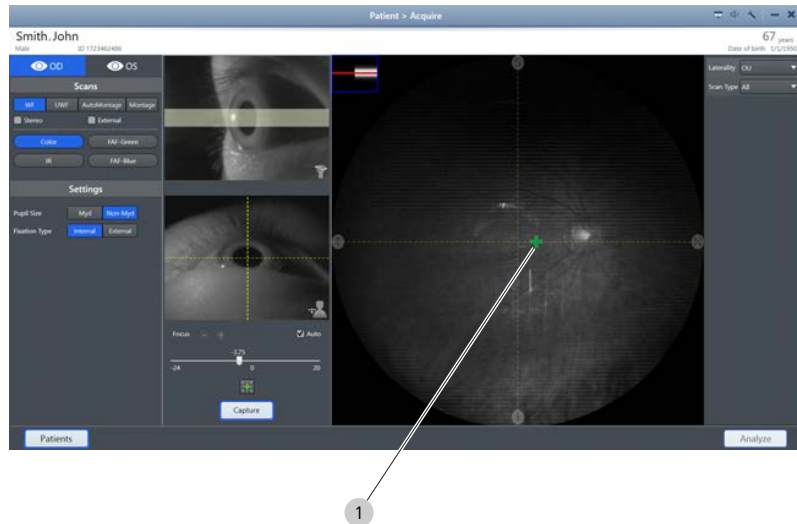
To capture a Montage image:

Prerequisite

- The device is prepared. (See Preparing the Device [▶ 87].)
- The patient is prepared. (See Preparing the Patient [▶ 88].)

Action

1. Under **Scans**, select **UWF**.
2. Select the Scan Type (**Color**, **IR**, **FAF-Green**, or **FAF-Blue**). For more information about Scan Types, refer to: Scan Types [▶ 97].
3. Under **Settings**, select **Myd** if the patient's pupil is dilated and **Non Myd** if the patient's pupil is not dilated.
4. Using the touchscreen or mouse, select a fixation target (1) in the **Preview** panel.



5. Instruct the patient to look inside the imaging aperture, focus on the green fixation target and blink naturally.

NOTE

If the patient cannot see the fixation target, refer to: Tips to Help Patients Find Fixation Targets [▶ 100].

6. The instrument automatically focuses the image. To manually adjust focus, refer to: Manually Focusing the Image [▶ 110].
7. Instruct the patient to blink and then open their eyes wide.
8. Click the joystick button or click **Capture**.
 - ⇒ A preview of the captured image appears for several seconds and is added to the selection bin.
9. **Next Scan:** confirm alignment and focus for the next scan in the series, and click **Capture**.
 - ⇒ A preview of the captured image appears for several seconds and is added to the selection bin.
10. Repeat **Next scan** steps for each scan in the series (2-6 total).
11. When you are finished taking scans, click **End Montage**.
 - ⇒ If the images montage successfully, each thumbnail displays a green checkmark.
 - ⇒ If an image did not montage successfully, the thumbnail displays a yellow exclamation point.
12. To delete and retake the image, refer to: Deleting or Replacing an Image [▶ 113].

6.4.6 Capturing a Stereo Image

A stereo image is comprised of two separate images of the same eye, offset to produce a stereoscopic pair.

A pair of images of the same eye created as a stereo pair are stored the pair using *Stereometric Relationship* IOD in DICOM. In the **Review** screen, stereoscopic pairs display as linked viewports for simultaneous pan and zoom.

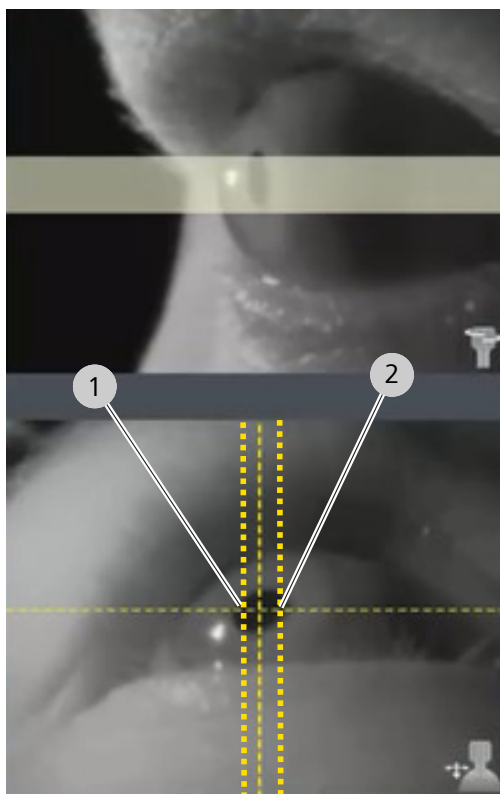
To capture a stereo image:

Prerequisite

- The device is prepared. (See Preparing the Device [▶ 87].)
- The patient is prepared. (See Preparing the Patient [▶ 88].)

Action

1. Under **Scans**, check **Stereo**.
2. Select the Scan Type (**Color**, **IR**, **FAF-Green**, or **FAF-Blue**). For more information about Scan Types, refer to: Scan Types [▶ 97].
3. Under **Settings**, select **Myd** if the patient's pupil is dilated and **Non Myd** if the patient's pupil is not dilated.
4. Adjust the alignment for the first stereo image (1) (offset to one side of the pupil).



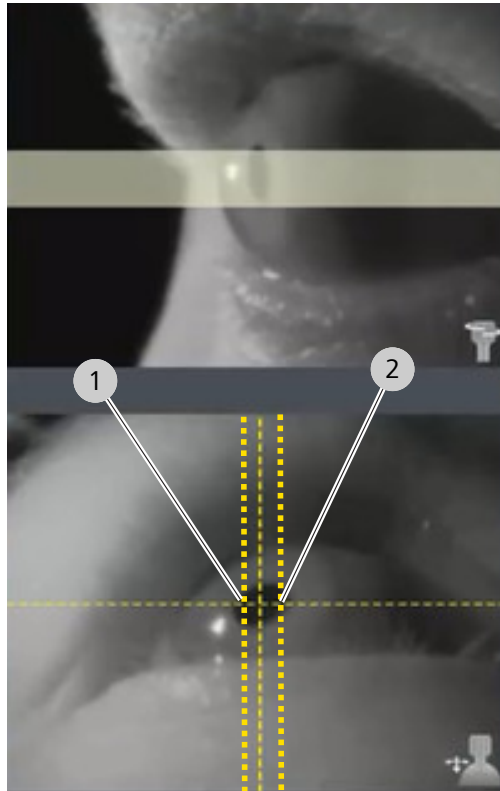
5. Instruct the patient to look inside the imaging aperture, focus on the green fixation target and blink naturally.

NOTE

If the patient cannot see the fixation target, refer to: Tips to Help Patients Find Fixation Targets [▶ 100].

6. The instrument automatically focuses the image. To manually adjust focus, refer to: Manually Focusing the Image [▶ 110].
7. Instruct the patient to blink and then open their eyes wide.

8. Click the joystick button or click **Capture**.
⇒ A preview of the captured image appears for several seconds and is added to the selection bin.
9. Adjust the alignment for the second stereo image (2) (offset to the other side of the pupil).



⇒ A preview of the captured image appears for several seconds and is added to the selection bin.

10. Ask the patient to relax while the you review the scan.

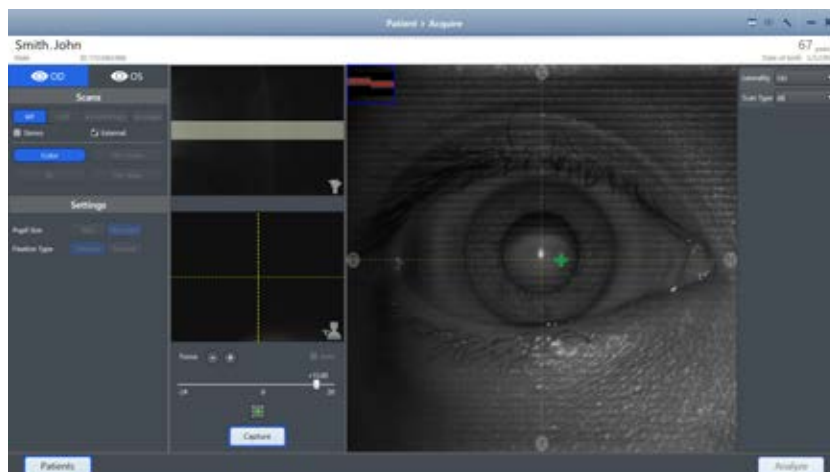
6.4.7 Capturing an External Eye Image

Capturing external eye images allows you to store a photograph of the eye along with the retinal images. Each external image is stored as an individual scan.

To capture an external eye image:

Prerequisite

- The device is prepared. (See Preparing the Device [▶ 87].)
- The patient is prepared. (See Preparing the Patient [▶ 88].)



Action

1. Under **Scans**, check **External**.
2. Straighten the acquisition head until the eye is directly in front of it.
3. Move the instrument all the way back.
4. Slowly move the instrument forward until the patient's eye appears in the **Preview** screen as you want it to appear in the image.
5. Use the joystick to manually focus the image.
6. Instruct the patient to look straight ahead. The fixation target may not be visible and it is not necessary for the patient to focus on the fixation target for this scan.
7. Instruct the patient to blink.
8. Click the joystick button or click **Capture**.
9. Repeat adjustments and scans as needed until all scans are acquired.

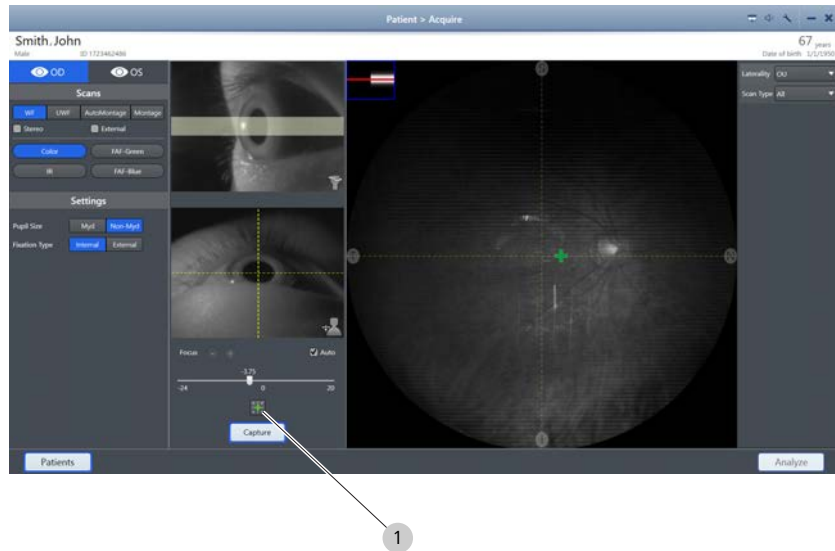
6.4.8 Blinking the Fixation Target

If the patient is having trouble seeing the internal fixation target, you can blink the target to make it easier for them to see. To change the blink settings, refer to: Configure Capture Settings.

To blink the fixation target:

Prerequisite

- A patient is being prepared for **Scan Acquisition** and cannot see the fixation target.



Action
Result

1. Click the blink button (1).
✓ The internal fixation target blinks several times.

6.4.9 Manually Focusing the Image

To focus the image manually:

Prerequisite

- You reached the focus step in a **Scan Acquisition** task.
- You want to manually focus the image.

Action

1. Uncheck **Auto**.
2. Turn the focus knob on the acquisition head (1) or use (+ and -) (2) or the focus slider (3) on the screen to manually adjust focus.





- Use the focusing guides (4) in the upper left corner of the **IR Preview** panel, to aid in focus.

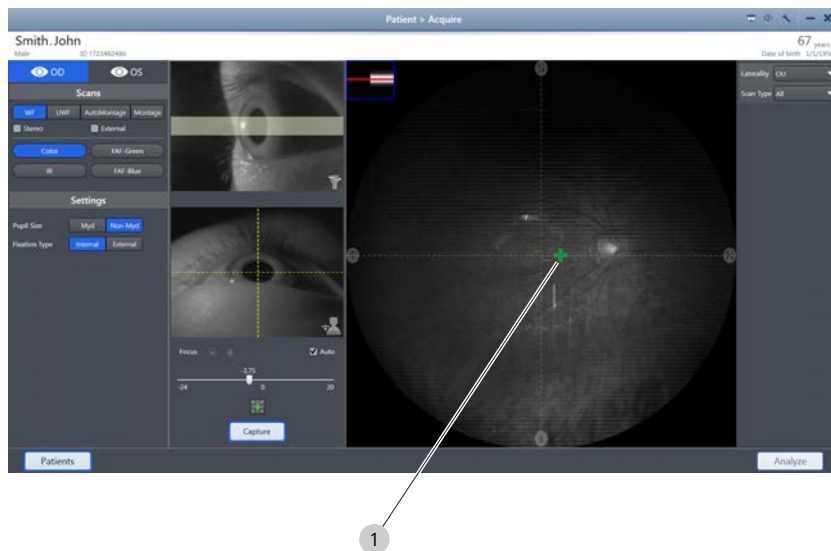
6.4.10 Manually Positioning the Internal Fixation Target

You can place the internal fixation target anywhere on the screen using the touchscreen or the mouse.

To manually position the internal fixation target:

Prerequisite

- A patient is being prepared for **Scan Acquisition** and you want to change or set the internal fixation target.



Action

- In the **IR Preview** panel, double-click (or press the touchscreen and hold) to select a position for the internal fixation target (1).

Result

- ✓ The internal fixation target moves to your selected location in both the **Preview** panel and the patient's FOV.

6.4.11 Using the External Fixation Target

The external fixation target is a light you can position to guide the patient's gaze. The external fixation target is in the accessory kit. Use this target when the patient cannot see the internal fixation target.

To install the external fixation target:

Action

1. Remove the external fixation target from the accessory kit.



2. Install the external fixation target (1) onto mount (2) on the patient support (3).



3. Position the target where you want the patient to focus.

6.4.12 Checking Scan Quality

Once data acquisition is complete, scans must be reviewed for acceptance prior to being released for analysis.

Review all scans carefully. If possible, retake scans that do not pass the acceptance criteria (Deleting or Replacing an Image [▶ 113]).

To check scan quality:

Action

1. Check that the focus is sharp and clear.
2. Ensure that the image is illuminated uniformly.
3. Ensure that there are few to no artifacts that cast shadows on the image.

Result

- ✓ If image quality is degraded, contact ZEISS customer service (<https://www.zeiss.com/>).

6.4.13 Deleting or Replacing an Image

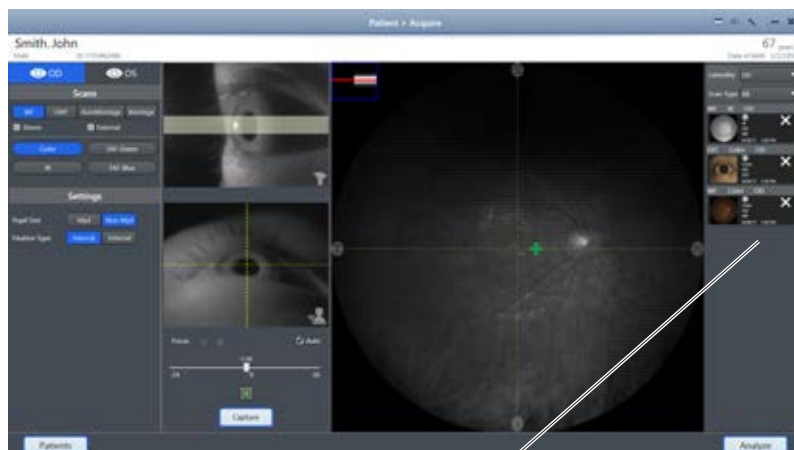
To delete or replace an image:

Prerequisite

- You reached the image check step in a **Scan Acquisition** task.
- You want to delete or replace an image.

Action

1. In the selection bin, locate the image you want to recapture.



2. Click on the X (1) to delete the image.
⇒ A confirmation opens.
3. To delete and recapture the image, click **Delete & Recapture**.
4. To delete the image, click **Delete**.

6.5 Analyze Images

There are two **Analyze** modes: **Proof** and **Review**.

Proof allows you to sort and select images.

Review allows you to view, compare, and annotate images. .

6.5.1 Proof

Proof shows an overview of all images for the patient. Using the Proof Sheet, you can filter images by scan type, date of acquisition, laterality and favorite status.

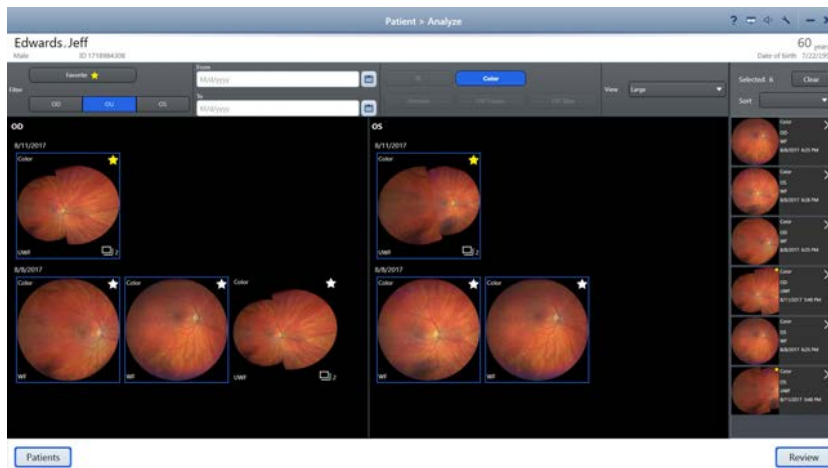


Figure 20: **Analyze > Proof** Screen

6.5.2 Review

Review shows the images selected in Proof. **Review** allows you to annotate and edit scans, save them and print a report.

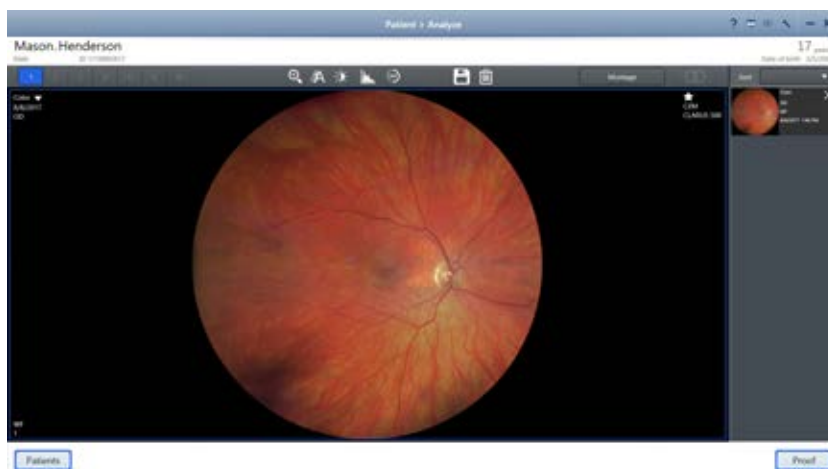


Figure 21: **Analyze > Review** Screen

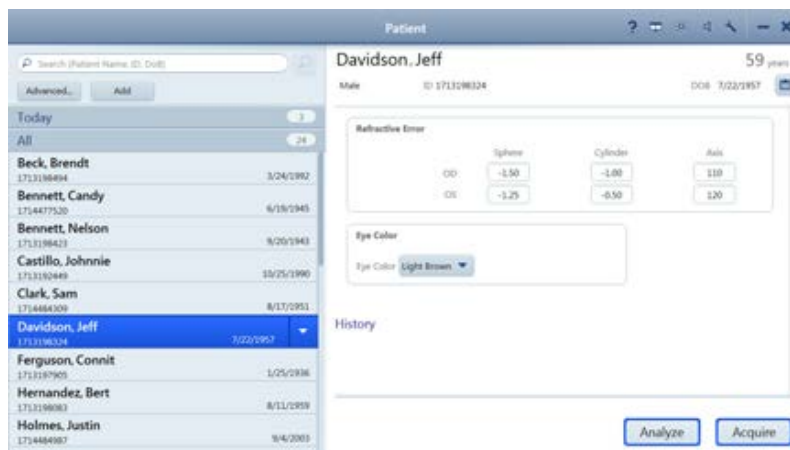
6.5.3 Opening the Analyze Window

You can analyze that patient's images by clicking **Analyze**.

To open the Analyze window:

1. Select the patient (Selecting the Patient [▶ 87]).

Action



2. Click **Analyze**.

6.5.4 Sorting and Selecting Images

Proof allows you to find and select images you want to include in **Review**.

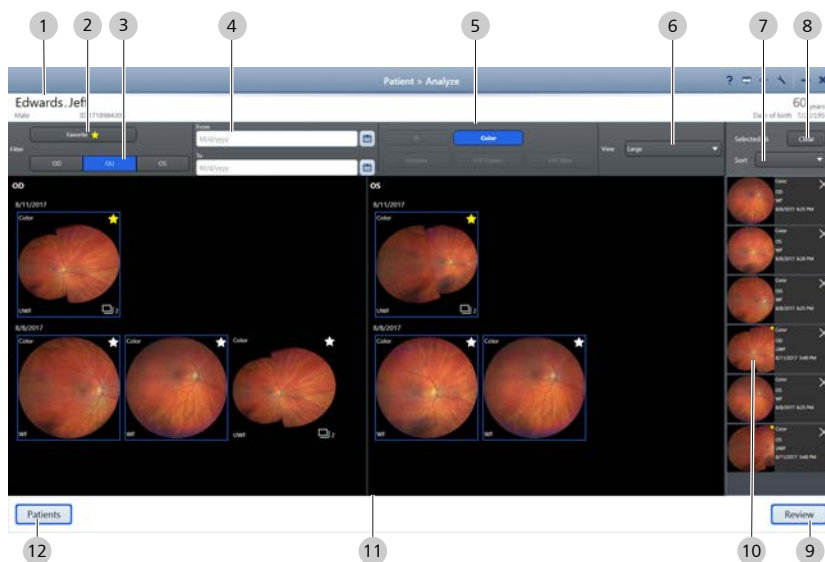
To find the images to include in the **Review**, you can sort and filter in the following ways:

- Laterality
- Scan type
- Date and time acquired

To sort and select images:

- The selected patient has saved scans
- The **Review** screen is open.

Prerequisite



Action

1. In the View panel (11), click on the image(s) you want to include in review. Use the sorting and filtering options to help locate the images.

- ⇒ Thumbnails of the selected image(s) appear in the selection bin (10).
- 2. To mark an image as a favorite, click on the image's star in the view panel.
 - ⇒ The star turns yellow.
- 3. To view only images marked as favorites, click **Favorites** (2).
- 4. To view scans acquired within a certain date range, choose a **From** and **To** date (4).
- 5. To filter scans by laterality, click on **OD**, **OU** or **OS** (3).
- 6. To filter scans by scan type, click on a scan type (5).
- 7. To sort selected scans by date, choose **Sort > Date/ Time** (7).
- 8. To sort selected scans by laterality, choose **Sort > Laterality** (7).
- 9. To sort selected scans by scan type, choose **Sort > Scan Type** (7).
- 10. Once all scans for review are in the selection bin (10), click **Review** (9).

6.5.5 Editing Scanned Images

To edit images, select one or more images in the viewport and use the editing toolbar.

To apply the same edits to multiple images, select multiple images before you begin to edit.

6.5.5.1 Choosing How Many Images to View

You can scroll through the selected images one at a time. You can also scroll through selected images with multiple images in the viewport (2, 3, 4, 8, 9, or 16 at a time).



Use the viewport numbers to decide how many of the images from the selection bin to include in the view panel.]

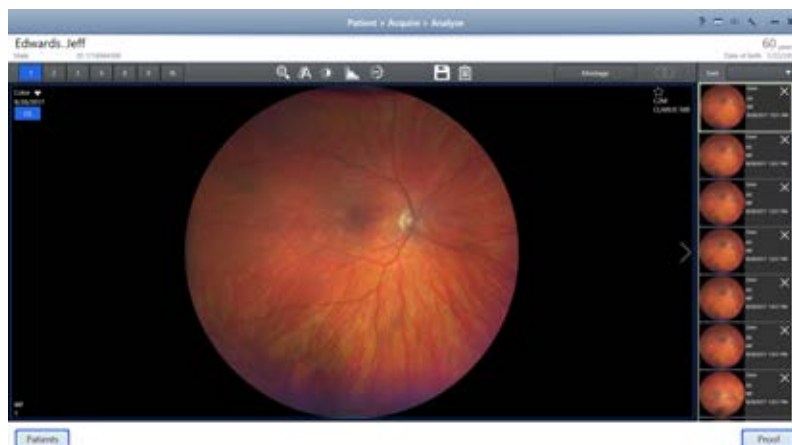
To choose how many images to view:

Prerequisite

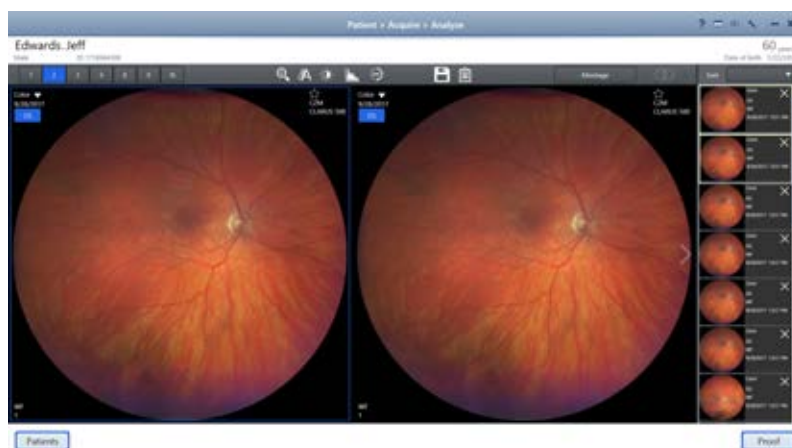
- Multiple images are selected (Sorting and Selecting Images [▶ 115]).
- The **Analyze > Review** window is open (Opening the Analyze Window [▶ 114]).

Action

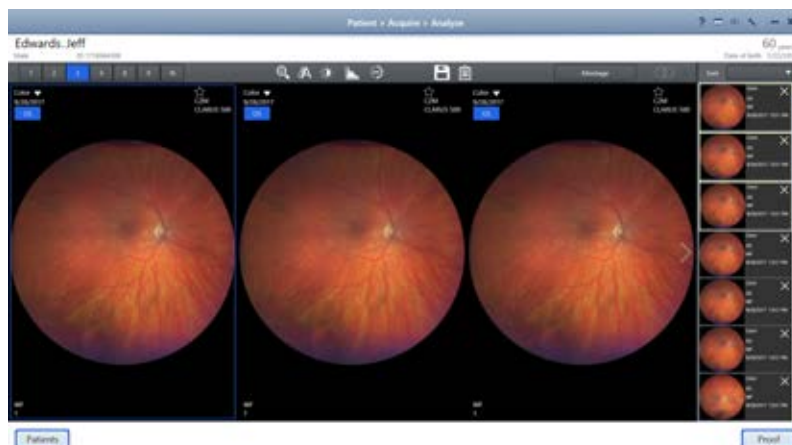
1. To view 1 image at a time in the view panel, click viewport **1**.



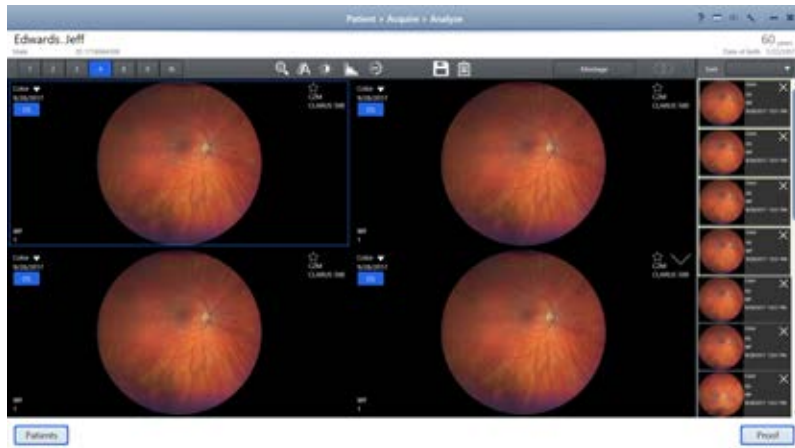
2. To view 2 images at a time in the view panel, click viewport 2.



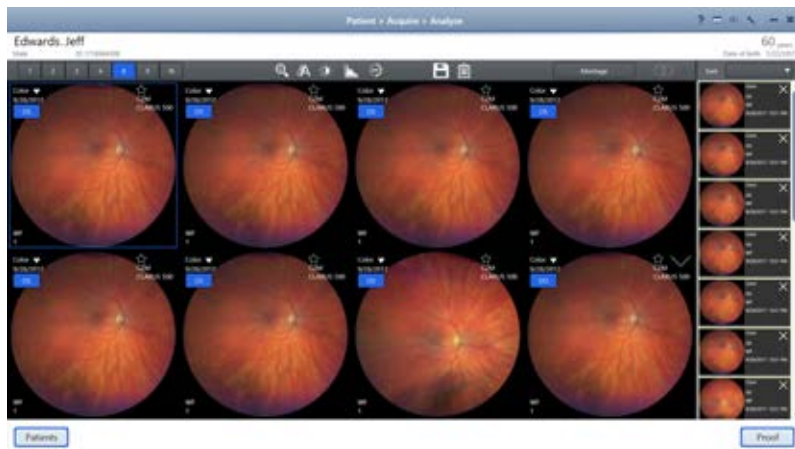
3. To view 3 images at a time in the view panel, click viewport 3.



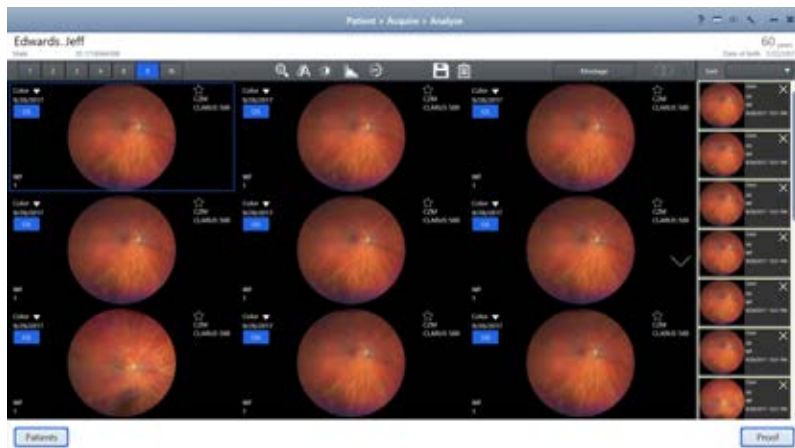
4. To view 4 images at a time in the view panel, click viewport 4.



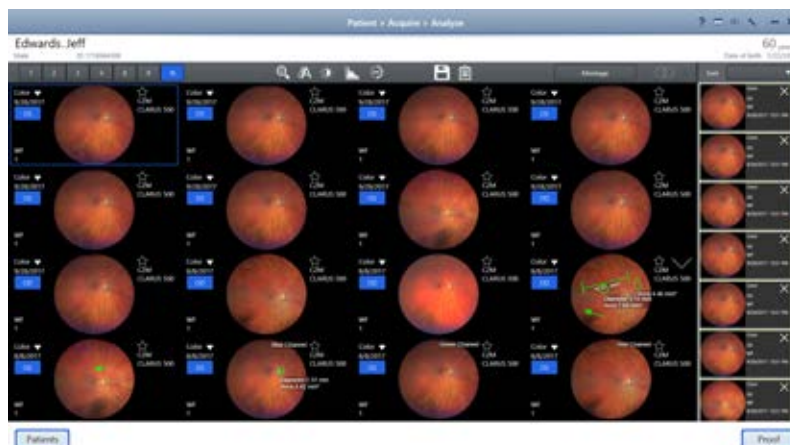
5. To view 8 images at a time in the view panel, click viewport **8**.



6. To view 9 images at a time in the view panel, click viewport **9**.



7. To view 16 images at a time in the view panel, click viewport **16**.



To scroll through the next set of images, click the scroll icon



6.5.5.2 Viewing Separate Color Channels of a Full Color Image

When analyzing a true color image, you can also view each color channel individually. You can select:

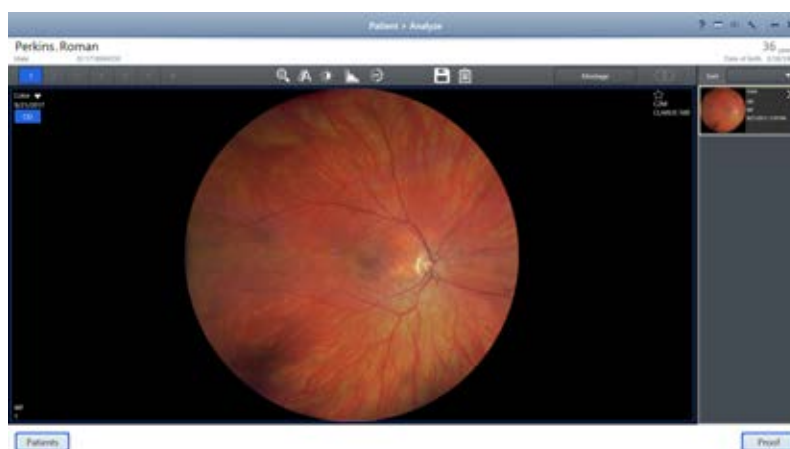
- Color
- Red
- Green
- Blue

Prerequisite

- True color image(s) exist in the patient record (Scan Types [▶ 97])
- True color image(s) are selected for review (Sorting and Selecting Images [▶ 115])
- The **Analyze > Review** window is open (Opening the Analyze Window [▶ 114]).

Action

1. Click on a true color thumbnail image in the selection bin.
⇒ A larger view of the image appears in the preview.



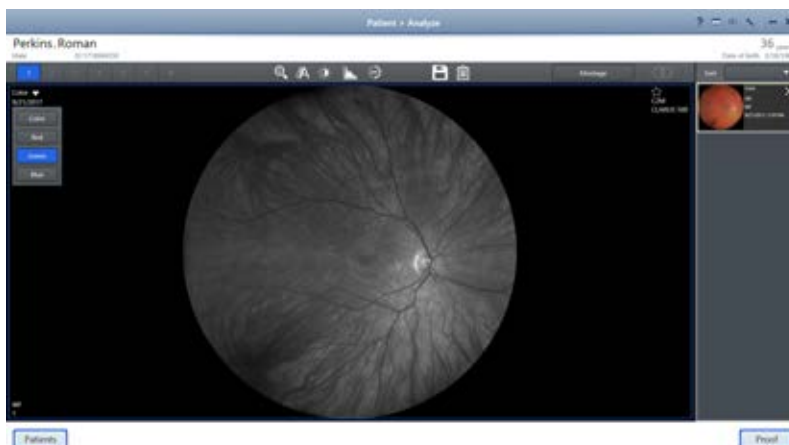
2. To view the red channel image, click **Color > Red**.

⇒ The red channel image opens.



3. To view the green channel image, click **Color > Green**.

⇒ The green channel image opens.



4. To view the blue channel image, click **Color > Blue**.



⇒ The blue channel image opens.

6.5.5.3 Zooming In or Out

To zoom in or out:

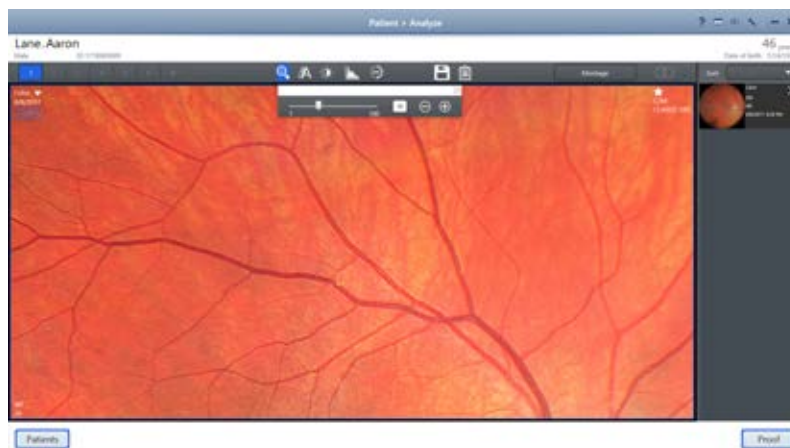
Prerequisite



Action

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).

1. Select the image you want to adjust.
 - ⇒ The selected image is outlined in blue.
2. Click the zoom adjustment icon.
 - ⇒ The zoom adjustment panel opens.



3. Zoom and pan the image until you see the area of the image you want to save.
4. Close the zoom adjustment panel.

6.5.5.4 Annotating Images

Most annotations must be inside the image or field of view to save them on an image. The caliper tool for indicating measurement can stretch beyond the image borders.

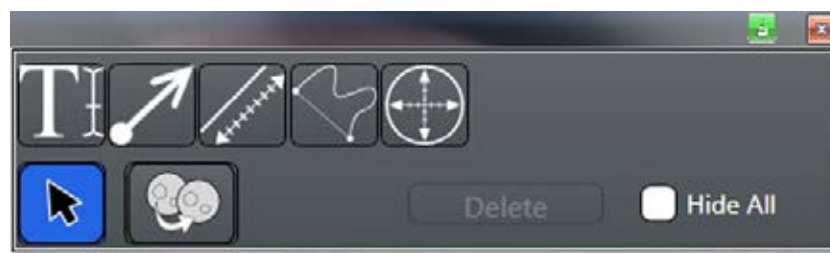









Figure 22:

Symbol	Name	Explanation
	Text	Adds text annotations to the image
	Arrow	Draws an arrow on the image

Symbol	Name	Explanation
	Caliper	Draws a line and adds the measurement (in mm or μm) to the image
	Freehand	Draws a freehand shape and adds the area enclosed by the shape (in mm^2) to the image
	Circle	Adds a circle and its area (in mm^2) or diameter (in mm) to the image
	Select	Selects an annotation so that it can be moved, edited, or deleted
	Copy	Copies annotations from one image onto another image
	Delete	Removes the selected annotation(s)
	Hide All	Hides all annotations

6.5.5.4.1 Selecting the Annotation Tool

You can draw any length arrow or multiple arrows on the image to identify something specific on the image. You can add text to arrows to label what you are identifying on the image. After you place arrows on the image, you can resize, move or delete them.

To select the Annotation tool:

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- 1. Select the **Annotations** tool.
 - ⇒ The annotations tools panel opens.

Prerequisite



Action

6.5.5.4.2 Adding Text to Images

You can add text labels to an image to identify findings. After you place text labels on an image, you can edit, move, or delete them.

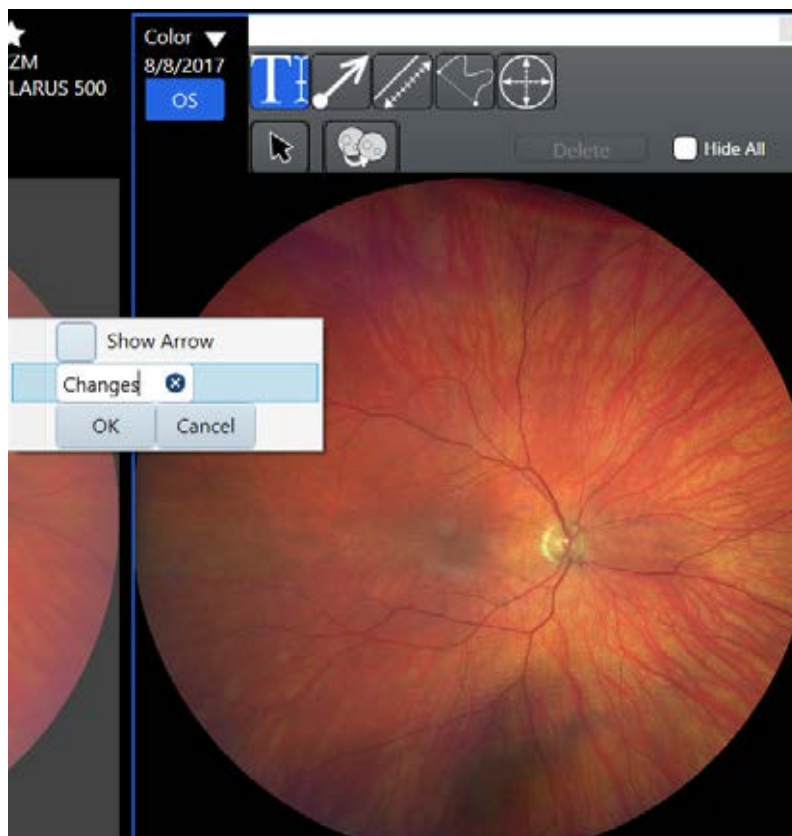
To add text to images:

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).
- 1. Select the **Text** tool.
- 2. Touch or click on the starting point for the text.
 - ⇒ The text insert tool opens.

Prerequisite



Action



3. Type your text annotation.
4. If you want an arrow to appear with the text, click **Show Arrow**.
5. Click **OK**.
6. Close the annotations panel.
 - ✓ The text annotation appears on the image.

Result

6.5.5.4.3 Adding Arrows to Images

You can draw any length arrow or multiple arrows on the image to identify something specific on the image. You can add text to arrows to label what you are identifying on the image. After you place arrows on the image, you can resize, move or delete them.

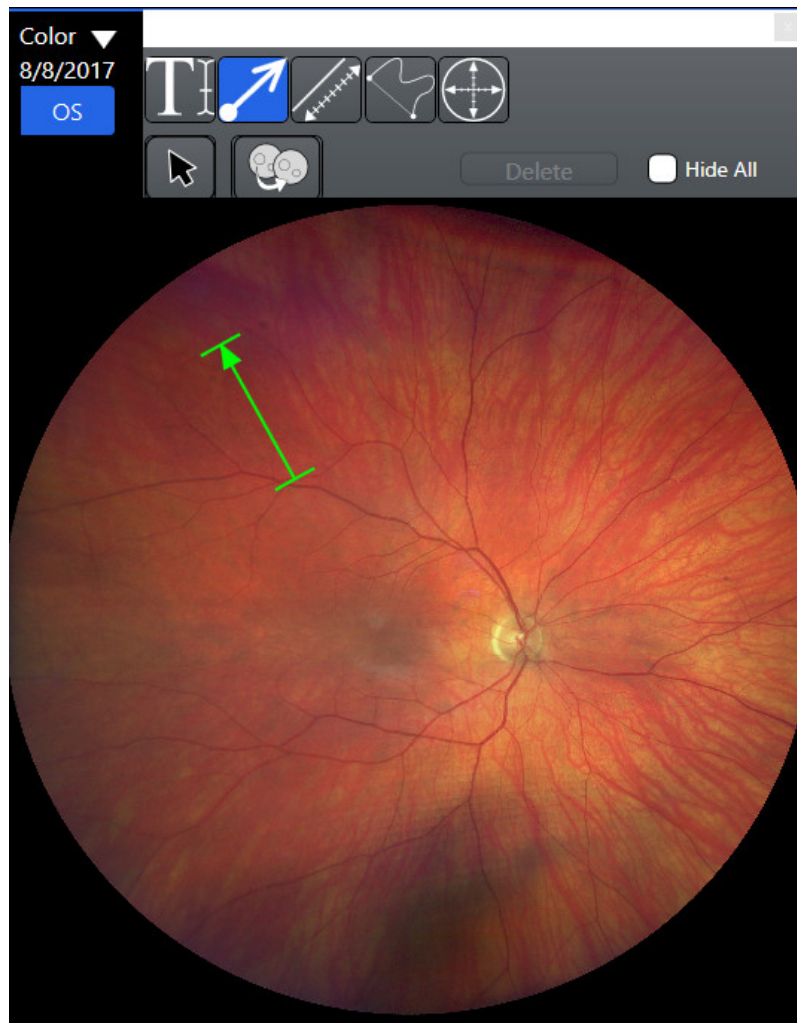
To add arrows to images:

- ☑ The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
 - ☑ The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).
1. Select the **Arrow** tool.
 2. Point to the location in the image where you want to begin to draw the line with an arrow.

Prerequisite



Action



3. Touch or click on the appropriate starting point and drag to the area you want the arrow to point.
4. Close the annotations panel.
 - ✓ The arrow appears on the image.

Result

6.5.5.4.4 Adding Measurements to Images

When you draw caliper lines on an image, the review software calculates the measurement. After you draw caliper lines, you can edit, move or delete them.

To add measurements to images:

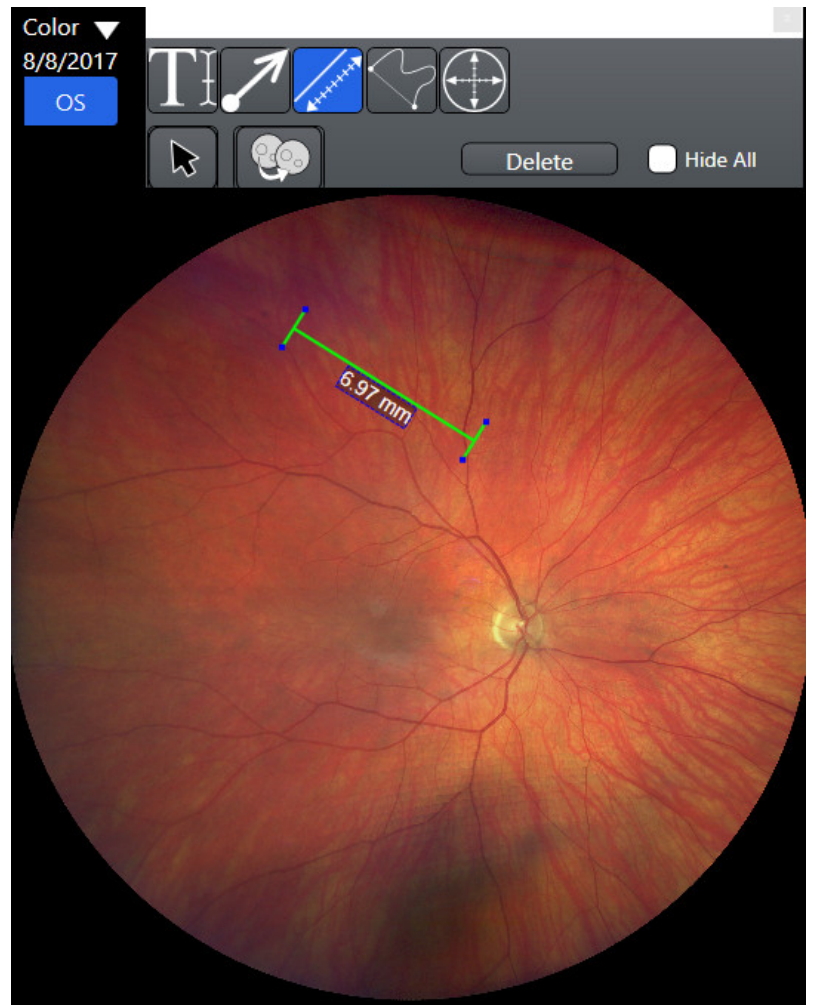
Prerequisite

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).



Action

1. Select the **Caliper** tool.
2. Touch or click on the appropriate starting point on the image and drag to the appropriate end point.



Result

3. Close the annotations panel.
 - ✓ When you finish drawing the caliper line, the review software calculates its length.

6.5.5.4.5 Circling an Area of an Image

Prerequisite

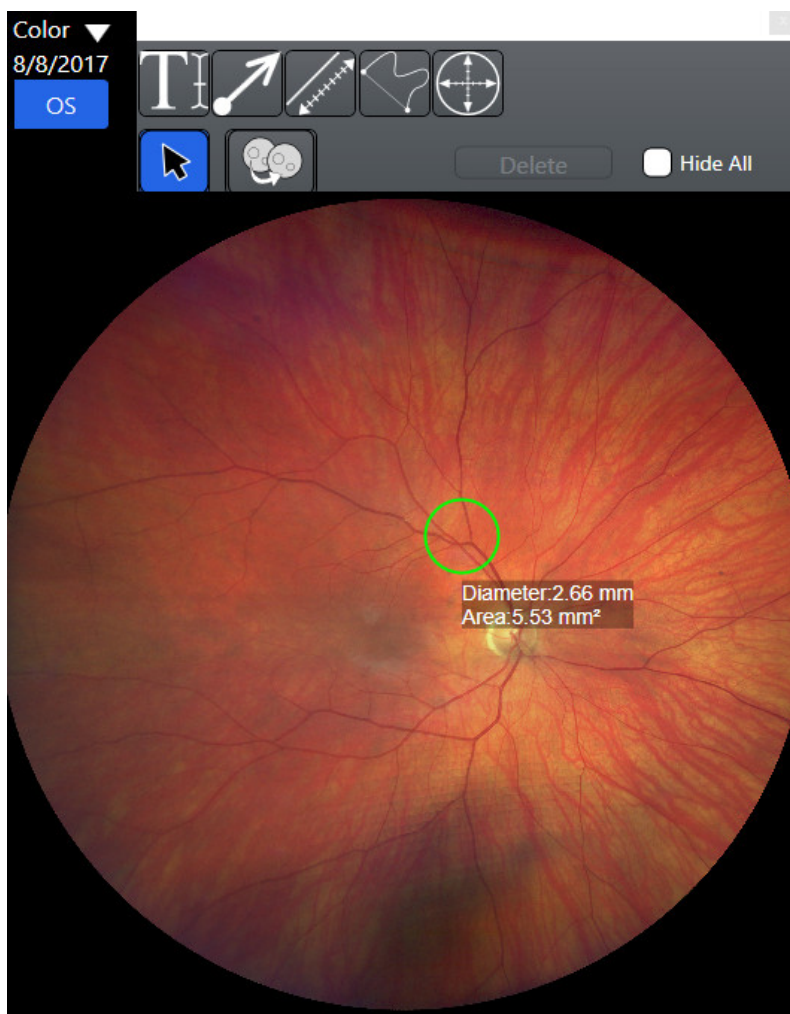
To circle an area of an image:

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).



Action

1. Select the **Circle** tool.
2. Touch or click on the appropriate starting point and drag around the area of the image you want to emphasize.



Result

3. Close the annotations panel.
 - ✓ When you finish drawing the circle, the review software calculates the area.

6.5.5.4.6 Drawing a Freehand Shape in an Image

The **Freehand** tool allows you to draw any shapes around findings you want to emphasize. After you place shapes on the image, you can move or delete them.

Prerequisite

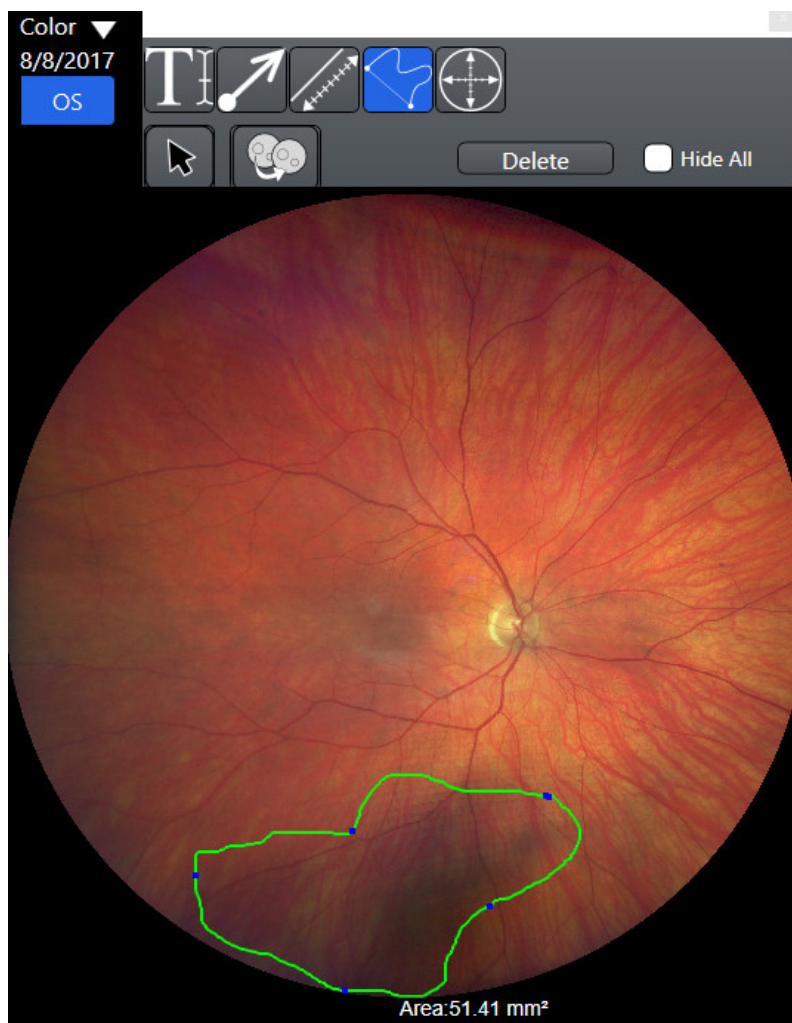
To draw a freehand shape:

- ✓ The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- ✓ The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).



Action

1. Select the **Freehand** tool.
2. Touch or click on the appropriate starting point on the image and draw around the area of interest.



⇒ When you connect to the starting point, the review software calculates the area of your shape.

3. Close the annotations panel.

6.5.5.4.7 Copying and Pasting Annotations

NOTE

Copy Annotation registers the images to each other in order to copy to the appropriate location. This process will only work well for good quality images where the images are of the same eye over the same portion of the eye.

If the registration between images is poor, the annotations may be copied to the wrong part of the image.

- ▶ You can select the annotation and move it to the correct location.

To copy and paste annotations:

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).

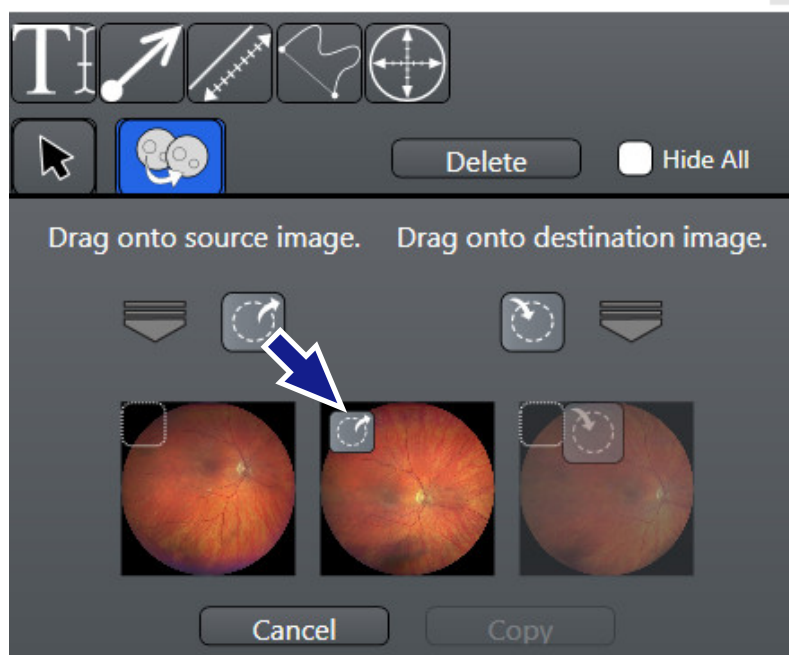
Prerequisite



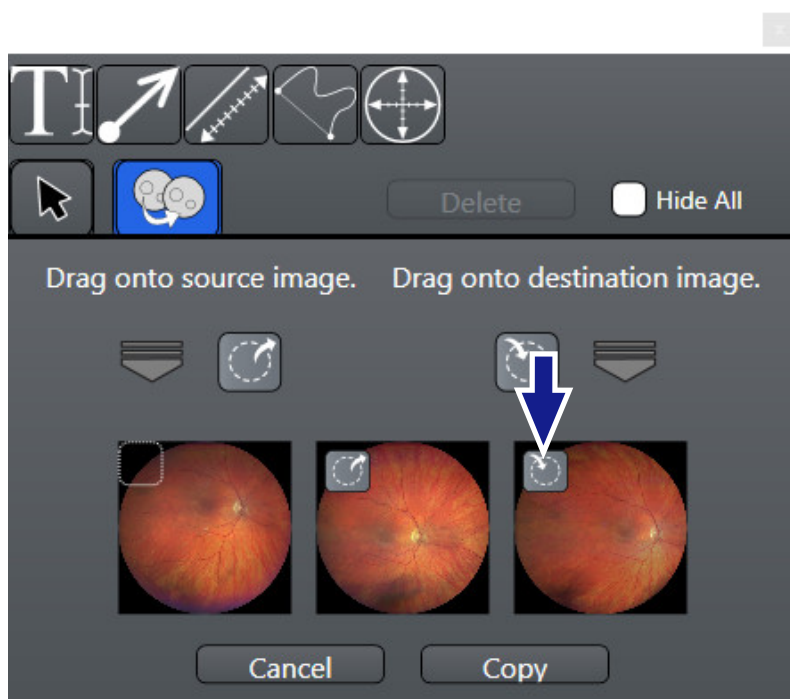
Action

The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).

1. Click on the copy icon.
⇒ The copy & paste annotations panel opens showing thumbnails of the selected images. The thumbnails in the panel are in the same configuration as the larger images in **Preview**.
2. Inside the copy & paste panel, click on the source icon and drag it to the thumbnail that represents the image with annotations to copy.

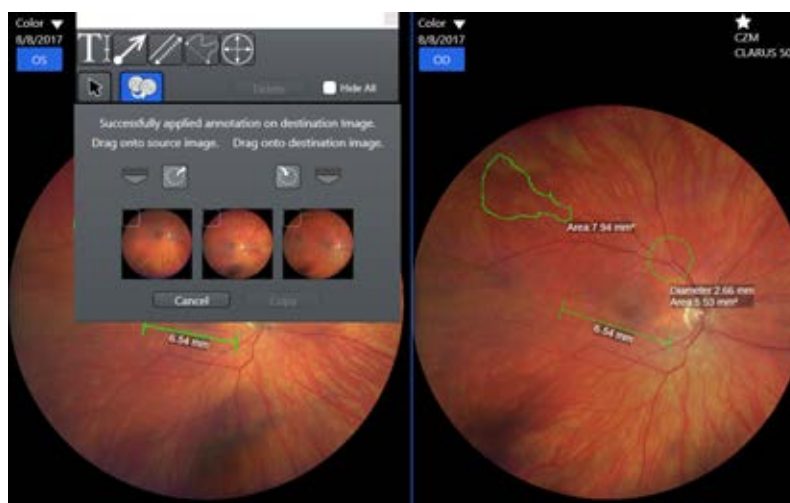


3. Inside the copy & paste panel, click on the destination icon and drag it to the thumbnail that represents the image to paste annotations onto.



4. Click **Copy**.

⇒ The annotations appear on both images.



5. Close the annotations panel.

6.5.5.4.8 Hiding Annotations in an Image

Hide All temporarily hides all annotations on the image allowing you to see the original image only.

To hide annotations:

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).

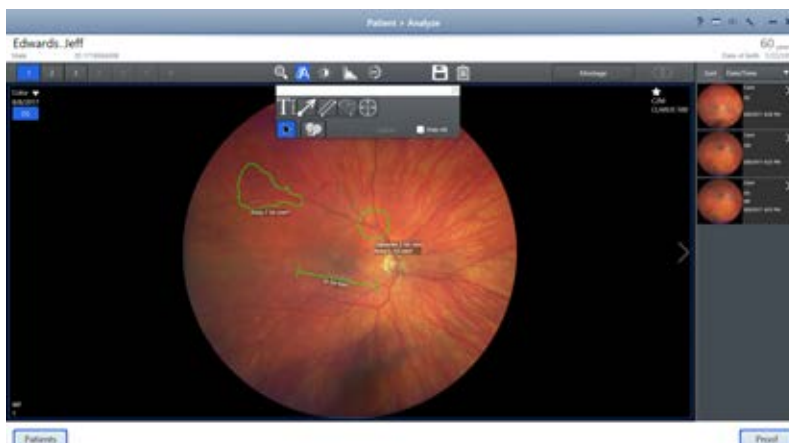
1. Select the image you want to view without annotations.

Prerequisite



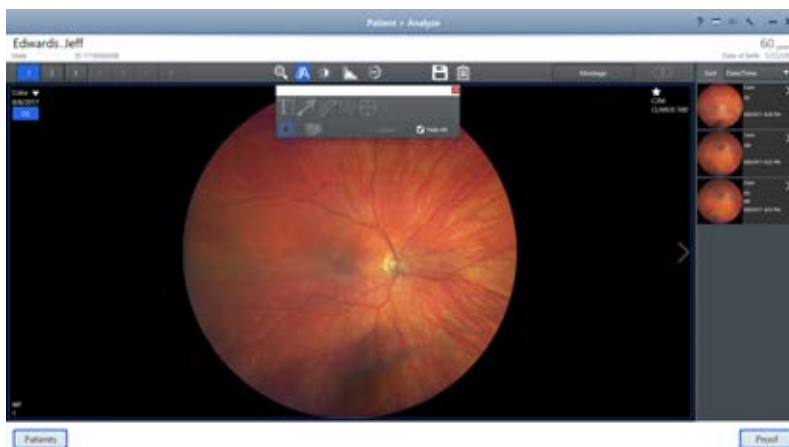
Action

⇒ The selected image is outlined in blue.



2. Check **Hide All**.

⇒ Annotations are temporarily hidden from view.



3. To view the annotations again, uncheck **Hide All**.

4. Close the annotations panel.

6.5.5.4.9 Deleting Annotations

You can select any annotation from the image or select multiple annotations and delete them together.

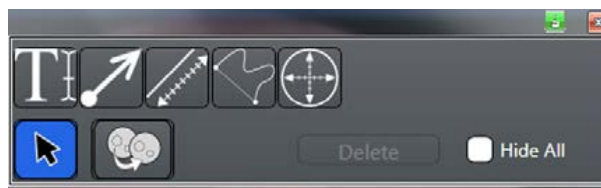
To delete an annotations:

Prerequisite

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- The **Annotation** tool is selected (Selecting the Annotation Tool [▶ 122]).

Action

1. Click on the selection tool.
2. Select annotations to delete.
3. Click **Delete**.



6.5.5.5 Adjusting Image Brightness

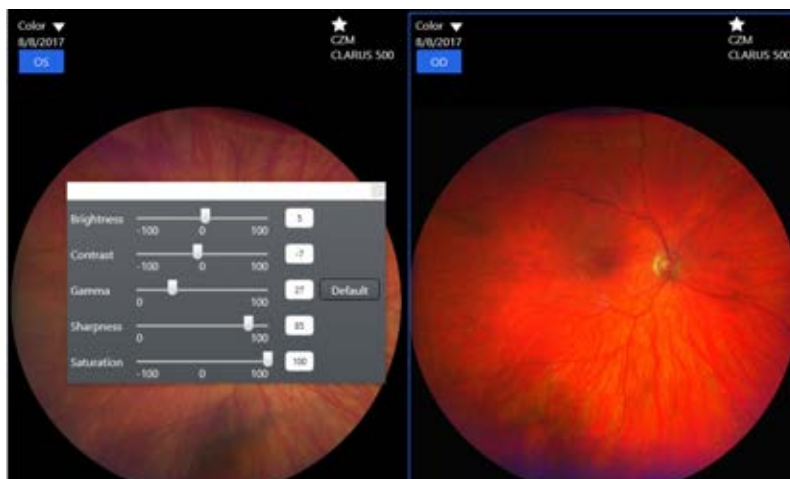
Prerequisite



Action

To adjust image brightness:

- The **Analyze** window is open (Opening the Analyze Window [▶ 114]).
- Image(s) are selected (Sorting and Selecting Images [▶ 115])
 1. Select the image you want to adjust.
 - ⇒ The selected image is outlined in blue.
 2. Click the brightness adjustment icon.
 - ⇒ The brightness adjustment panel opens.



3. Adjust the settings until the image enhanced as you want to save it.
4. Close the brightness adjustment panel.

6.5.5.6 Rotating Images

Each time you click the rotate image icon, the image rotates 180°.

To rotate an image:

Prerequisite

Action

- The annotation tool is open.
 1. Click on the selection tool.
 2. Select the image you want to rotate.
 3. Click on the rotate icon.



6.5.6 Manually Creating a Montage

You can select from two to six images of the same eye to create a montage image.

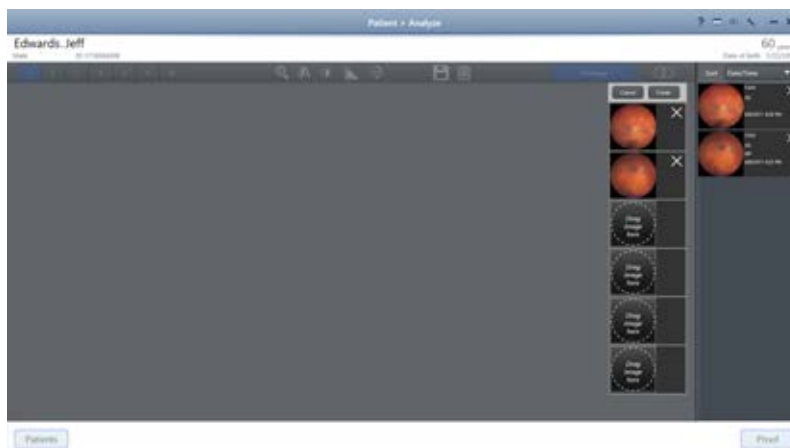
To create a montage manually:

Prerequisite

- The **Analyze > Review** screen is open.
- Two to six images of the same eye are selected (Sorting and Selecting Images [▶ 115]).

Action

1. Click **Montage**.
 - ⇒ The montage bin opens.



2. Drag each thumbnail image want to include in the montage into a slot in the Montage bin.
3. Click **Create**.
 - ⇒ A progress bar appears as the montage image forms.
4. When the montage image completes, click **Save**.

6.5.7 Viewing Stereo Images



Stereo image pairs can be viewed in stereo mode. When you view image pairs in stereo mode, viewports are linked, so that pan and zoom apply to both images.

When Stereo Mode is selected, all non-stereo images are filtered out of the selection bin and only 2-up and 4-up viewing options are available for viewing the selected Stereo pairs.

To view stereo images:

- The **Review** screen is open.
- 1. Click the **Stereo** icon.
 - ✓ Only stereo image pairs appear in the selection bin.

Prerequisite

Action

Result

6.5.8 Saving Edited Images

You can save the original image with the edits and annotations you made or you can save a copy of the edited image. The thumbnail identifies images that were edited.

If you did not make any changes to an image you select to save, no changes or copies of the image are made.

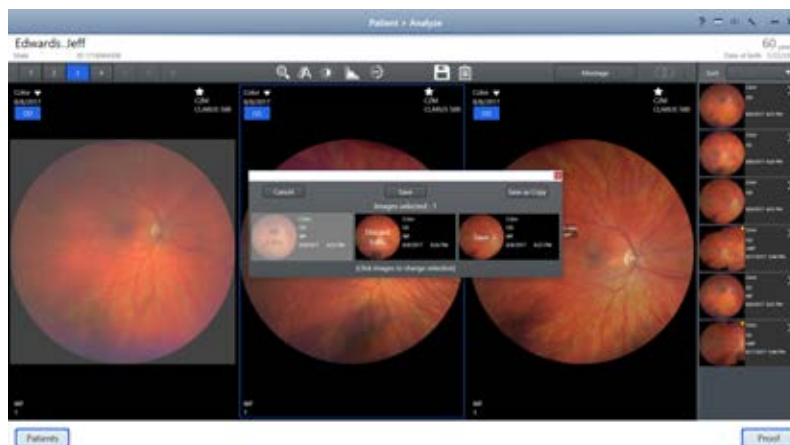


To save an edited image:

- Analyze - Review window is open.
- Editing and annotations were made (as required) on image(s).
- 1. Click the **Save** icon.

Prerequisite

Action



- ⇒ Images that you edited or annotated are automatically selected and identified to **Save**.
- 2. To deselect an image, click on its thumbnail.
 - ⇒ **Save** changes to **Discard Edits**.
- 3. To save the original image(s) with your editing and annotations, click **Save**.

4. To save a copy of the image with the editing and annotations, click **Save as Copy**.
⇒ The new copy appears in the selection bin.

6.5.9 Creating a Report

For information about configuring reports, refer to: Configure Reports

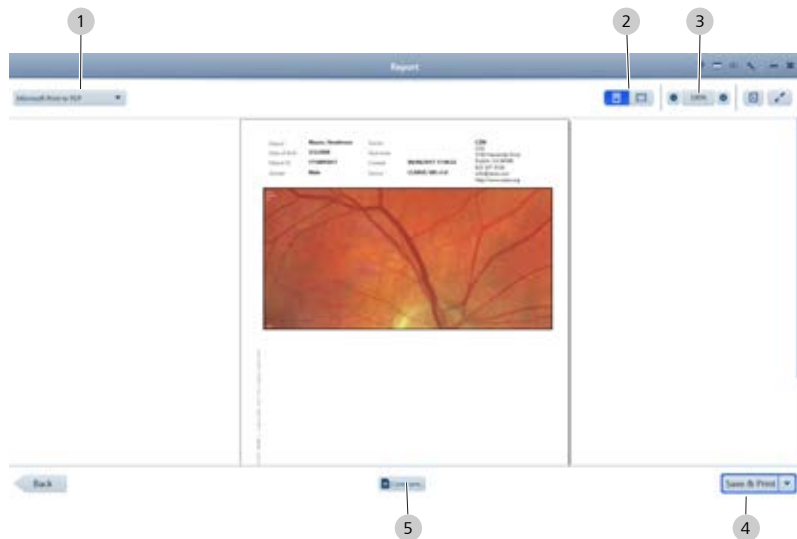


Prerequisite

Action

To create a report:

- The review screen is open.
1. Click the **Reports** icon.
⇒ A report preview opens.



2. Select the type of document for the report (1).
3. Select landscape or portrait orientation (2).
4. If you want to change the image size, zoom in or zoom out (3).
5. To add a comment to the report:
Click **Comment** (5).
Type your comments and click **Add Comment**.
6. Select **Print**, **Save**, or **Save & Print** (4).

6.6 Shutdown

The windows password must be updated every 60 days.

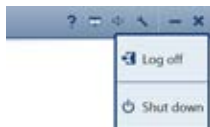
Shut down and restart the instrument regularly. On startup, the instrument prompts you when it is time to update the windows password.

6.6.1 Logging Off

Action

To log off:

1. Select the X in the upper right corner.



2. Select **Log off**.

6.6.2 Shutting Down

CAUTION!

Do not use the power switch to shut down the system

or you could interrupt automatic archiving or interrupt operating system updates.

Each time you shut down the system, all shutdown activity completes (if set) and CLARUS 500 retains a log of the actions completed. Activities that can be set to run each time the system shuts down include:

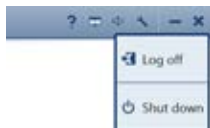
- Export images and patient data to DICOM (Configuring Export Settings [▶ 56])
- Automatic backups (Configuring Automatic Backups [▶ 62])

Do not switch off the power until the CLARUS 500 application and Windows have both shut down completely.

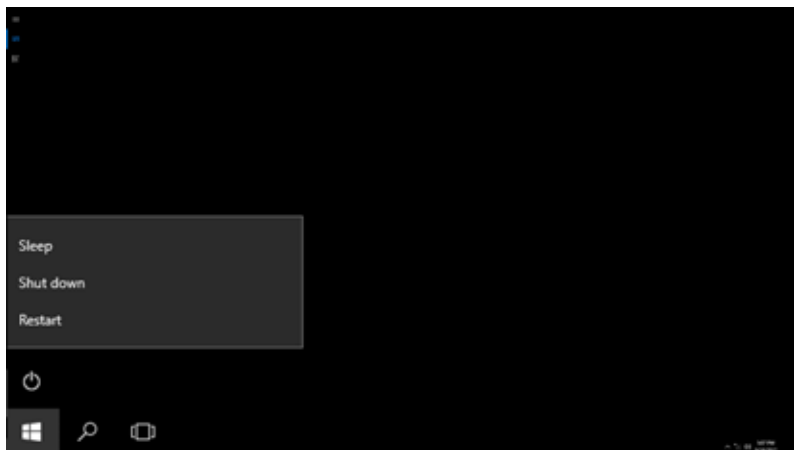
To shut down the system:

Action

1. To exit the application, click on the X in the upper right corner.



2. Select **Shut down**.
⇒ The application closes and automatic shutdown tasks run.
3. When application shutdown is complete, click the Windows icon on the desktop (lower left corner) and select **Shut down**.



⇒ Shutdown also turns off the CLARUS 500 acquisition head.



4. Turn off the power switch (1).

7 Cleaning and Disinfection

7.1 Safety During Cleaning

CAUTION!

Cleaning lenses too frequently

can damage optic surfaces.

- ▶ Clean optics only when necessary.
- ▶ Keep the protective cover on the instrument when not in use.

7.2 Cleaning Agents

Cleaning Agent	Use
Distilled water, 70% isopropyl alcohol in water, mild, ammonia-free glass cleaner, or alcohol wipes	instrument covers, chinrest, and forehead rest
Volk LensPen® cleaning pen	front lens
Optical cleaning set, Safebuds, or cotton ball sticks	front lens
Microfiber cloth	front lens

7.3 Cleaning the Front Lens

NOTE

Using harsh cleaning agents

may damage the device.

- ▶ Use only the recommended cleaning materials.

7.3.1 Removing Fluid Splashes

The most common cause of minor fluid contamination is from the patient's tears splashing onto the lens when the patient blinks. These drops show up in images as light spots.

Action

1. Start in the center of the lens surface and wipe in widening circles with the felt end of the LensPen, applying gentle pressure.
2. If the bright spots remain after repeated wiping, refer to Removing Severe Contamination [▶ 138].

7.3.2 Removing Minor Dust Accumulation

Action

1. Use the brush side of the LensPen or the brush provided in the cleaning set to quickly remove dust or other loose particles.

2. If dust remains, start in the center of the lens surface and wipe in widening circles with the felt end of the LensPen, applying gentle pressure.
3. After using the felt tip, replace the protective cap and rotate it three or four times.

7.3.3 Removing Severe Contamination

More serious contamination may result from patients sneezing or touching the lens with their nose or fingers. This causes distinct bright areas on the image.

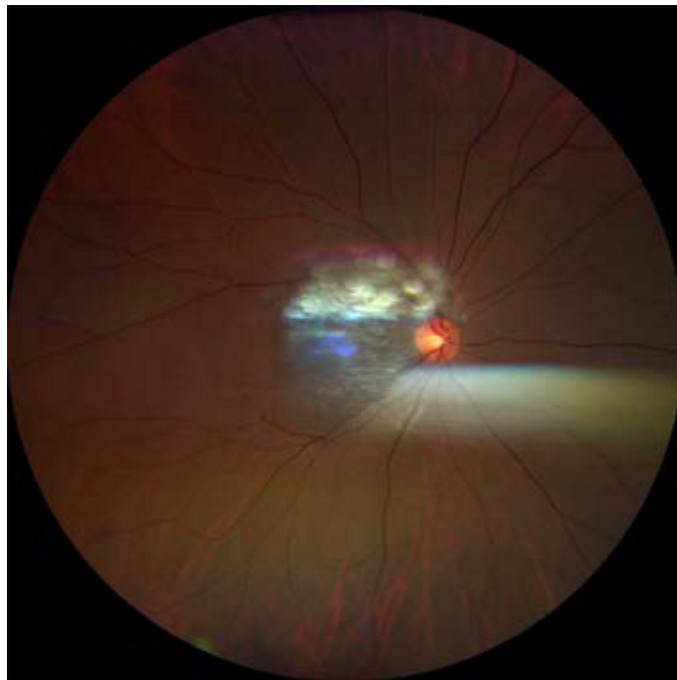


Figure 23: Fundus Image with Fingerprint Contamination

Action

1. Using moist disposable cloths or microfiber cloths, cotton ball sticks, or Safebuds sprayed with cleaning fluid, start in the center of the lens surface and wipe in widening circles. Do not allow your fingers to touch the lens surface as you clean.
2. Repeat as needed, using a clean portion of the cloth each time.
3. Verify that smudges and streaks have been removed by breathing on the lens.
4. Use the felt end of the LensPen to remove any remaining residue.
5. To verify that cleaning has been successful, take a photograph in a darkened room. Check the resulting image for bright spots.

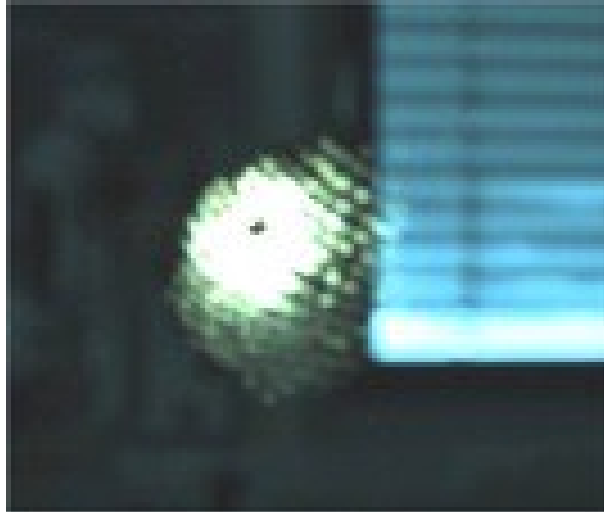


Figure 24: Residual Bright Spots after Cleaning

7.4 Cleaning the Front Window Lens

7.4.1 Cleaning Heavy Contamination

Fingerprints, oil, or water spots should be cleaned immediately. Skin acids attack coatings and glass, and can leave permanent stains. Cleaning with solvents alone tends to redistribute grime. These contaminants must be lifted from an optical surface with soap or other wetting agent. The optic is then rinsed in water and the water removed with alcohol. Acetone helps speed drying and helps eliminate streaks from forming.

Action

1. Blow off dust.
2. Using a soap-saturated lens tissue placed around a swab, wipe the optic gently in a figure-eight motion.
3. Repeat as necessary.
4. Repeat this procedure with distilled water.
5. Repeat again with alcohol.
6. Repeat once more with acetone.

7.4.2 Brush Cleaning Method

This technique is ideal for cleaning smaller optics, including lenses, and involves holding a folded lens tissue with a hemostat to brush the surface clean.

NOTE

Edges on mounted optics

are often hard to reach.

- ▶ Wrap a lens tissue around a swab.
- ▶ Soak the covered swab in acetone.
- ▶ Brush around the edge of the lens and then across the middle using a continuous figure-eight stroke.
- ▶ Repeat if necessary.

Action

1. Fold a lens tissue so as not to touch the part of the tissue that will make contact with the optic. The fold should be about as wide as the optic.
2. Hold the tissue with hemostats parallel to and near the fold.
3. While holding the optic, using tweezers if necessary, blow off any dust.
4. Soak the tissue with acetone.
5. Brush the fold in the tissue across the surface of the optic using light pressure.
6. Repeat as necessary until the optic is clean, making sure new lens tissue is exposed with each wipe.

7.4.3 Wipe Cleaning Method

For heavier cleaning of lenses and mirrors, this method involves wiping an optic with a lens tissue by hand.

Action

1. Blow off dust.
2. Fold a lens tissue as with the brush method.
3. Apply acetone to the tissue.
4. Holding the lens tissue in your hand with the fold near the tip of your fingers, apply uniform pressure while gently wiping across the surface of the optic.
5. Repeat as necessary until the optic is clean, making sure new lens tissue is exposed with each wipe.

7.4.4 Dust Cleaning

Dust on optics can be very tightly bound by static electricity. Blowing removes some dirt; the remainder can be collected by the surface tension of a wet alcohol swab. Acetone helps promote rapid drying of the optic to eliminate streaks.

Action

1. Blow off dust.
2. If any dust remains, twist lens tissue around a swab, soak in alcohol, and wipe the optic in one direction with a gentle figure-eight motion.
3. Repeat as necessary.
4. Repeat the steps above, using acetone.

7.5 Cleaning the Chinrest and Forehead Support

NOTE

Do not spray cleaner directly on the chin rest or forehead support.

Action

- ▶ Before each use, wipe the chinrest and forehead support with a non-acetone based spray or disinfectant wipe.

7.6 Peripherals and Table

NOTE

Do not spray cleaner directly on the peripherals or instrument table.

Action

1. Regularly dust or wipe down the instrument table.

7.7 Cleaning the PC Screen

NOTE

Do not spray cleaner directly on the touch screen.

Action

1. Turn OFF the instrument before cleaning the touch screen.
2. Wipe gently with a cloth that has been sprayed with a mild glass cleaner containing no ammonia.

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8 Maintenance

8.1 Safety During Maintenance

WARNING!

Unqualified personnel

may injure themselves or cause damage to the instrument.

- ▶ Only trained, qualified personnel may use this device.
- ▶ This device may be used only for its intended purpose.
- ▶ Only ZEISS authorized personnel may perform maintenance or repair procedures not described in this manual.

CAUTION!

Do not service instrument while in use with patient.

Servicing instrument while in use with patient may cause injury.

- ▶ Complete patient exam with instrument before starting service.

8.2 Maintenance Schedule

Periodically inspect the CLARUS 500 to ensure that the instrument is free of dust and the optics are cleaned as instructed. Frequency of inspections depends on the frequency of use and the environmental conditions.

Component	Task	Interval
External fixation lamp diode	Replace	As needed
Illumination source	Check brightness	As needed

8.3 Offline Teleservice

If an internet connection is not available, you can use offline Teleservice to create a file with information and screen shots related to the problem, which you can then send to ZEISS service.

Action

1. On the **General Settings** tab of the **Settings** window, under **Carl Zeiss Meditec Teleservice**, select the **Teleservice Offline...** button.
2. The offline **Teleservice** window opens.
3. Enter contact information and a description of the problem.
4. If you would like to include a screenshot of the problem, click **Add Screenshot**.
5. Select **Yes** to agree to sending screenshots.
6. Select **Screenshot** to take a screenshot of your screen.

7. Repeat as needed to generate additional screenshots, then select **Continue**.
8. Select the network drive or USB flash drive to export the file to, then select **Continue**.
9. A confirmation is displayed and the file "ServicePackage.svp" is saved to the selected drive. Send the file to ZEISS service for further assistance.

8.4 Data Storage - Backup

All data stored on the hard disk and any external media are the Purchaser's records, and it is his or her responsibility to preserve the integrity of these files.

Carl Zeiss Meditec is not responsible for the loss of patient files stored on the hard disk or external media.

The Purchaser assumes the responsibility for the installation, use, and results obtained from the instrument and programs.

8.5 Replacing the External Fixation Diode

Action

- ▶ To replace the flashing diode at the end of the external fixation lamp, unscrew it from the holder and replace it with a new diode.

9 Troubleshooting

9.1 Safety During Troubleshooting

CAUTION!

Reconfiguring system components on the table, or adding non-system devices or components to the table, or replacing original system components with substitutes not approved by ZEISS

could result in failure of the table height adjustment mechanism, instability of the table, tipping and damage to the instrument, and injury to operator and patient.

- ▶ Do not reconfigure system components on the table, nor add non-system devices or components to the table, nor replace original system components with substitutes not approved by ZEISS.

CAUTION!

Attempting to carry out activities not specifically endorsed by ZEISS

may void your warranty and could result in damage to the instrument.

- ▶ Read the user documentation.
- ▶ Follow directions carefully.
- ▶ Do not make upgrades, or carry out repairs or modifications, without specific guidance and instruction from ZEISS or an authorized ZEISS representative.

CAUTION!

Using a non-approved or incorrectly connected device

could invalidate the system safety approval.

- ▶ Follow all indications in this user document to ensure that all connections are approved and correctly configured.

WARNING!

Unqualified personnel

may injure themselves or cause damage to the instrument.

- ▶ Only trained, qualified personnel may use this device.
- ▶ This device may be used only for its intended purpose.
- ▶ Only ZEISS authorized personnel may perform maintenance or repair procedures not described in this manual.

9.2 Error Messages

Message / Fault	Cause	Solutions
Component error occurred while importing exam data.	System Malfunction	Call for Service
Connectivity exception occurred while exporting the exam.	System Malfunction	Call for Service
Connectivity exception occurred while exporting the exam.	System Malfunction	Call for Service
Database error occurred while importing exam data.	System Malfunction	Call for Service
Error occurred while importing exam data.	System Malfunction	Call for Service
Export process is stopped due to Incorrect IOD data.	System Malfunction	Call for Service
Imager Initialization Failed	System Malfunction	Call for Service
The system has encountered an error and must be rebooted before acquiring additional scans. All work has been saved. If this problem persists, please contact ZEISS customer support. Continue in review mode or Reboot.	System Malfunction	Call for Service
Mapper not found error occurred while importing exam data.	System Malfunction	Call for Service
Montage could not be created with selected images.	System Malfunction	Call for Service
Network data validation exception occurred while exporting the exam.	System Malfunction	Call for Service
Network error occurred while importing exam data.	System Malfunction	Call for Service
Network exception occurred while exporting the exam.	System Malfunction	Call for Service
Number of exams that failed to be exported.	System Malfunction	Call for Service
Path : '{0}' does not contain dcm files.	System Malfunction	Call for Service
There is not enough space for Montage, please remove some images from Montage Bin.	System Malfunction	Call for Service

Message / Fault	Cause	Solutions
You have exceeded the maximum thumbnails limit of {0} in selection bin. Please remove existing thumbnails from selection bin to add new thumbnails.	System Malfunction	Call for Service

9.3 Information Messages

Message / Fault	Cause	Solutions
Amount of time for export (hh:mm:ss:ms).	Provides estimate of time it takes to export file.	N/A
Amount of time for import (hh:mm:ss:ms).	Provides estimate of time it takes to import file.	N/A
Are you sure you want to delete the selected thumbnail?	Confirms that you want to delete the selected thumbnail.	<ul style="list-style-type: none"> ■ Click Yes to delete the selected image. ■ Click No to return without deleting the image.
Click images to change selection.	Suggests optional action.	N/A
Click images to save or discard edits.	Suggests optional action	N/A
De-identify patient data.	Confirms to hide patient information such as name, date of birth, ID.	Click OK .
Delete context menu item in proof-sheet.	Confirms that you want to remove an item from the proof sheet.	Click OK .
Delete selected annotations?	Confirms that you want to delete the annotations.	<ul style="list-style-type: none"> ■ Click Yes to delete the selected annotations. ■ Click No to return without deleting the annotations.
Failed to save the log file.	Indicates that the log file did not save successfully	Re-save the log file.
Exporting exams in progress...	Indicates the progress of an exported exam.	N/A
Imager Initialization Succeeded	Indicates completion of successful startup.	N/A
Images that are part of a UWF or montage image cannot be deleted.	Informs you that an individual image you are trying to delete is part of a montage, so it cannot be delete.	Click OK .
Import all patient tests from external usb media.	Confirms that you want to import all tests stored on the USB stick.	Click YES to import or NO to cancel import.

Message / Fault	Cause	Solutions
Importing exams in progress...	Indicates the progress of an imported exam.	N/A
Log file saved successfully.	Indicates that the log file saved successfully	Click OK .
Number of exams selected for export.	Indicates the number of exams selected for export.	N/A
Number of exams successfully exported.	Indicates the number of exams exported.	N/A
Please select 4 thumbnails.	Prompts you to select the appropriate number of thumbnail images from the stack.	Click OK .
Select auto import folder path.	Prompts you to select the folder for imported images.	Browse to the folder you want to use for imported images.
Select what you would like to do with this thumbnail:	Message requires decision about thumbnail.	Select Delete , Cancel/Delete , or Replace
Set the export mode.	Message requires that the export mode be set.	Set the export mode either Session, Daily, or other choice.
Source and destination images are both required in order to copy annotations.	When copying annotations, informs you when either or both a source and destination for the annotations is missing.	Click OK and select a source image and a destination image for copying annotations.
Tests will be merged with current database.	Confirms that you want to save the scans in the database.	Click OK .
Transfer Completed	Informs you that your files transferred successfully.	Click OK .
You are about to delete all edits made to image.	Confirms that you want to delete your edits.	Click OK .
You have created a montage image. Do you wish to save or discard this image?	When attempting to select something else, informs that you created a montage image, but did not save it.	Click Save or Discard .
You have unsaved edits.	Informs that you created a montage image, but did not save it.	Click OK
You have unsaved edits which will be discarded if you leave this screen. Discard before exit ?	Confirms that you want to exit without saving.	Click OK

Message / Fault	Cause	Solutions
Quick Compare	Shows all scans of same laterality and scan type as the right-clicked image.	N/A

Table 12: Information Messages

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10 Specifications

10.1 Electrical Specifications

Parameter	Value
External Power Supply	100 - 240 V~, 50 / 60 Hz, 4 A max
Fuse	T 4.0 A, L 250 V
Electrical Class per IEC 60601-1	Class I

10.2 Instrument Specifications

Parameter	Value
Imaging Modes	<ul style="list-style-type: none"> ■ Reflectance images (true color, IR) ■ Live IR preview image ■ Fundus autofluorescence with blue or green excitation (FAF-B, FAF-G) ■ Stereo images ■ External eye images
Mode of Operation	Continuous
Working Distance	25 mm, cornea to glass
Device Group (ANSI Z80.36, ISO 15004-2)	Group 1
Service Life	7 years

10.2.1 At-Instrument Computer Specifications

Parameter	Value
Data Ports	2 network, 4 USB3 (2 USB2) Display Port v HDMI 2 RS232
RAM	≥ 8 GB
Storage	≥ 1 TB
Screen Resolution	1920 x 1080
Gigabit LAN port	RJ45, bandwidth ≥ 125 MB/s
Touchscreen	PCAP

10.3 Dimensions and Weight

Parameters	Value
Dimensions (W x D x H)	362 mm by 546 mm by 676 mm
Instrument Table Dimensions (W x D x H)	916 mm by 615 mm by 711 - 925 mm
Acquisition Device Weight	20.9 kg
At-Instrument Computer Weight	8.5 kg
Instrument Table Weight	38 kg

10.4 Ambient Requirements for Operation

Parameter	Value
Temperature	10°C to 35°C
Relative Humidity	30% to 90%, non-condensing
Atmospheric Pressure	800 hPa to 1060 hPa

10.5 Ambient Requirements for Storage

Parameter	Value
Temperature	-10°C to 55°C
Relative Humidity	10% to 95%, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa

10.6 Ambient Requirements for Transport

Parameter	Value
Temperature	-40°C to 70°C
Relative Humidity	10% to 95%, non-condensing
Atmospheric Pressure	500 hPa to 1060 hPa

10.7 Fundus Camera Specifications

Parameter	Value
Field of view <ul style="list-style-type: none"> ■ Widefield ■ Ultra-widefield 	<ul style="list-style-type: none"> ■ 90° ■ 135°
Ametropia Compensation	+20 D to -24 D
Pixel Pitch on the Fundus	7.3 µm/pixel

Parameter	Value
Resolution (zones defined in ISO 10940): <ul style="list-style-type: none">■ Center■ Middle■ Periphery	<ul style="list-style-type: none">■ 60 lp/mm at central field (0°)■ 40 lp/mm at 23° FOV■ 25 lp/mm at 45° FOV
Sensor: <ul style="list-style-type: none">■ Color Imaging■ Fluorescence Imaging	<ul style="list-style-type: none">■ 3 x 12 megapixels■ 12 megapixels monochrome

10.8 Laser Classification

Class 1 laser product

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11 Legal Notices

11.1 Software Copyright

The software program ("Software") included with your CLARUS™ 500 is a proprietary product of Zeiss and in certain instances contains material proprietary to Microsoft Corporation and other third party licensors, suppliers and vendors. These proprietary products are protected by copyright laws and international treaty. You must treat the Software like any other copyrighted material. Copyright ©2017 Carl Zeiss Meditec, Inc. All rights reserved.

11.2 End User Software License Agreement

Upon initial configuration of your CLARUS™ 500, you will be presented with an End User Software License Agreement (the "EULA"), which you must accept in order to use the Software. The EULA is a legal contract between You and Carl Zeiss Meditec, Inc., which governs Your use of the Software. If you do not agree with the terms and conditions of the EULA and do not agree to be bound by the EULA, do not use the Software. If You have any questions concerning the EULA, contact Carl Zeiss Meditec, Inc., Attention: Customer Service, 5160 Hacienda Drive, Dublin, CA 94568. Telephone 800-341-6968.

11.3 Acknowledgment

You acknowledge that you have read all the provisions in this Chapter, including End User Software License Agreement, understand them, and agree to be bound by their terms and conditions.

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12 Accessories and User Replaceable Spare Parts

This section contains parts lists for this instrument, instructions for ordering parts and instructions for returning defective parts.

WARNING!

Using parts that are not authorized by ZEISS

may compromise device safety during operation.

- ▶ Use only accessories authorized by ZEISS.
- ▶ In the U.S., call 800-341-6968. Outside the U.S., contact your local Zeiss distributor. You can find the ZEISS contact partner for your country on our website: www.zeiss.com.

NOTE

The procedure for returning defective parts from International operations differs somewhat from that for U.S. domestic operations

These differences are noted in the instructions.

- ▶ Please follow the instructions carefully.

NOTE

Part numbers are subject to change

- ▶ When ordering, confirm all part numbers with your ZEISS Representative.

12.1 Parts Orders

12.1.1 U.S. Domestic Parts Ordering

Spare parts may be ordered as needed following established parts ordering procedures. Parts needed overnight may be ordered by phone from the Parts Department. The cost of shipping parts for next day delivery is very high and should be used only in emergencies. The Parts Department phone number is:

- 1-800-341-6968 (domestic toll-free)
- 1-925-557-4843 (domestic)
- 1-925-557-4652 (domestic fax)

12.1.2 International Service Operations

Customers are billed for shipping charges, including any customs fees required.

For International Service Operations, please use the ordering procedures that have been established for your area of operations, and which meet the requirements of the Carl Zeiss Meditec International Parts Department.

12.2 Accessory Kit Parts List (Replaceable Parts)















Image	Part Number	Quantity	Description
	2660021166733	1	DUST COVER CLARUS
	2660100007672	1	LENS CLEANER
	2660100007673	1	LENS WIPES
	2660021121819	1	CABLE NETWORK CAT5E SNAGLESS BOOT
	2660021165915	2	SCR M6X1 X16 THUMB
	2660021167011	1	BRACKET ACCESSORY BAG
	2660100022511	1	POWER CORD 120V

Image	Part Number	Quantity	Description
	2660021147390	1	WIRELESS MOUSE

12.3 Additional Replaceable Parts

Image	Part Number	Description
	2660021167501	Accessory bag
	2660021167244 3197519005000	Fixation Device (External) Occluding Sleeve for Fixation Device
	3013509052000	Fixation Lamp (Red)
	2660021165748	Ocular Lens Cover
	2660021158754	Ethernet CAT5E Shielded 1.5 m/59 in
	2660021140192	USB Display Port Cable 2 m/79 in

12.4 Returning Defective Parts

Receiving returned parts helps us to:

- Evaluate defects and analyze root cause.
- Rebuild and return servicable parts to stock.

12.4.1 Equipment Return Authorization

Authorization must be obtained from Carl Zeiss Meditec before equipment is returned for repair. A Return Material Authorization (RMA) number is required on each return shipment to Carl Zeiss Meditec.

The procedure for obtaining an RMA number varies, depending on your area of operation. Use the procedure that has been established by Carl Zeiss Meditec for your area of operations.

12.4.2 Packing for Shipment

Defective instrument subassemblies/parts should be packed in the shipping container received with the replacement subassembly or part. If necessary, contact the Carl Zeiss Meditec Parts Department for a replacement shipping container.

Shipping containers are not available for assemblies that are supplied by a separate vendor (i.e., monitor, printer, keyboard, computer) so it is important to preserve those shipping containers when the instrument is first received by the customer.

13 Decommissioning

13.1 Safety During Decommissioning

 CAUTION!**Attempting to decommission your system**

may result in damaged equipment and danger to personnel.

- ▶ Never attempt to decommission a ZEISS system or device. Only ZEISS approved field service representatives are qualified to safely decommission your system.
 - ▶ Contact your ZEISS Representative to set up an appointment for system/device decommissioning.
-

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14 Packaging and Transport

14.1 Safety During Transport

CAUTION!

Packaging and transport by non-ZEISS personnel

could result in damage, loss, or non-compliance within the country of transit.

- ▶ Allow only change to Zeiss approved representative to prepare the instrument and associated components for transport.
- ▶ Allow only ZEISS-approved personnel to transport the instrument and associated components.

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15 Disposal

15.1 Packaging Disposal

- Keep instrument packing material in the event of a relocation or repair.
- If you want to dispose of the packing material: Dispose of packing material by sending it for recycling through an acknowledged collection system.

15.2 Instrument Disposal

The device contains electronic components with integrated batteries.

- ▶ Dispose of the device and integrated batteries correctly, in accordance with national legislation.



The device specified on the delivery note must not be disposed off via household waste or communal disposal companies according to the applicable EU guidelines valid at the time the device was placed on the market.

- ▶ For more information about the disposal of the device, please contact the ZEISS contact partner in your country.
- ▶ If you want to sell on the device or its components: Inform the purchaser that they must dispose of the device according to the regulations valid at that time.

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Glossary

DHCP

a client/server protocol that automatically provides an Internet Protocol (IP) host with its IP address and other related configuration information such as the subnet mask and default gateway.

DICOM

DICOM (Digital Imaging and Communications in Medicine) is an open standard for the archiving and exchange of information within medical image management.

DNS

a hierarchical decentralized naming system for computers, services, or other resources connected to the Internet or a private network. (The Internet's equivalent of a phone book.)

EMR

Any electronic medical records system, including FORUM, whether DICOM-compatible or not

ePDF

a DSC-conforming PostScript document with additional restrictions intended to be usable as a graphics file format.

ETDRS

aids in evaluating the changes in vision in patients with diabetic retinopathy.

FAF

Fundus Autofluorescence. A type of fundus imaging in which the eye is illuminated with light at a wavelength that stimulates the natural fluorescence of lipofuscin.

FAF-Blue

Fundus autofluorescence with blue excitation

FAF-Green

Fundus autofluorescence with green excitation

FORUM

A software product for managing, archiving, and viewing patient data, images, and reports from computerized diagnostic instruments or documentation systems.

FOV

Field of View. The measure that indicates how much of the eye can be imaged in a capture. Field of view can be measured from the pupil, as described in ISO 10940, or it can be measured from the center of the eye.

IOD

Information Object Definitions

IR

is a non-invasive en face imaging technique capable of visualizing sub-retinal pathology

JPEG

a commonly used method of lossy compression for digital images, particularly for those images produced by digital photography.

JPEG2000

an image compression standard and coding system created by the Joint Photographic Experts Group committee in 2000 with the intention of superseding their original discrete cosine transform-based JPEG standard (created in 1992) with a newly designed, wavelet-based method.

LEDs

a two-lead semiconductor light source.

NETBIOS

a program that allows applications on different computers to communicate within a local area network (LAN).

NTP

a networking protocol for clock synchronization between computer systems over packet-switched, variable-latency data networks.

PACS

a medical imaging technology used for storing, retrieving, presenting and sharing images produced by various medical hardware modalities, such as X-ray, CT scan, MRI and ultrasound machines.

PDF

a file format that provides an electronic image of text or text and graphics that looks like a printed document and can be viewed, printed, and electronically transmitted.

PNG

a raster graphics file format that supports lossless data compression.

Proof

A screen that presents thumbnails of all images associated with a patient record.

Selection bin

The list of thumbnails of the images that have been selected from the Proofsheets.

Stereo image

An image that simulates a three-dimensional image by placing two images side-by-side that were taken from slightly different angles.

TCP/IP

a suite of communication protocols used to interconnect network devices on the internet.

TIFF

a computer file format for storing raster graphics images, popular among graphic artists, the publishing industry, and photographers. TIFF is widely supported by scanning, faxing, word processing, optical character recognition, image manipulation, desktop publishing, and page-layout applications.

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