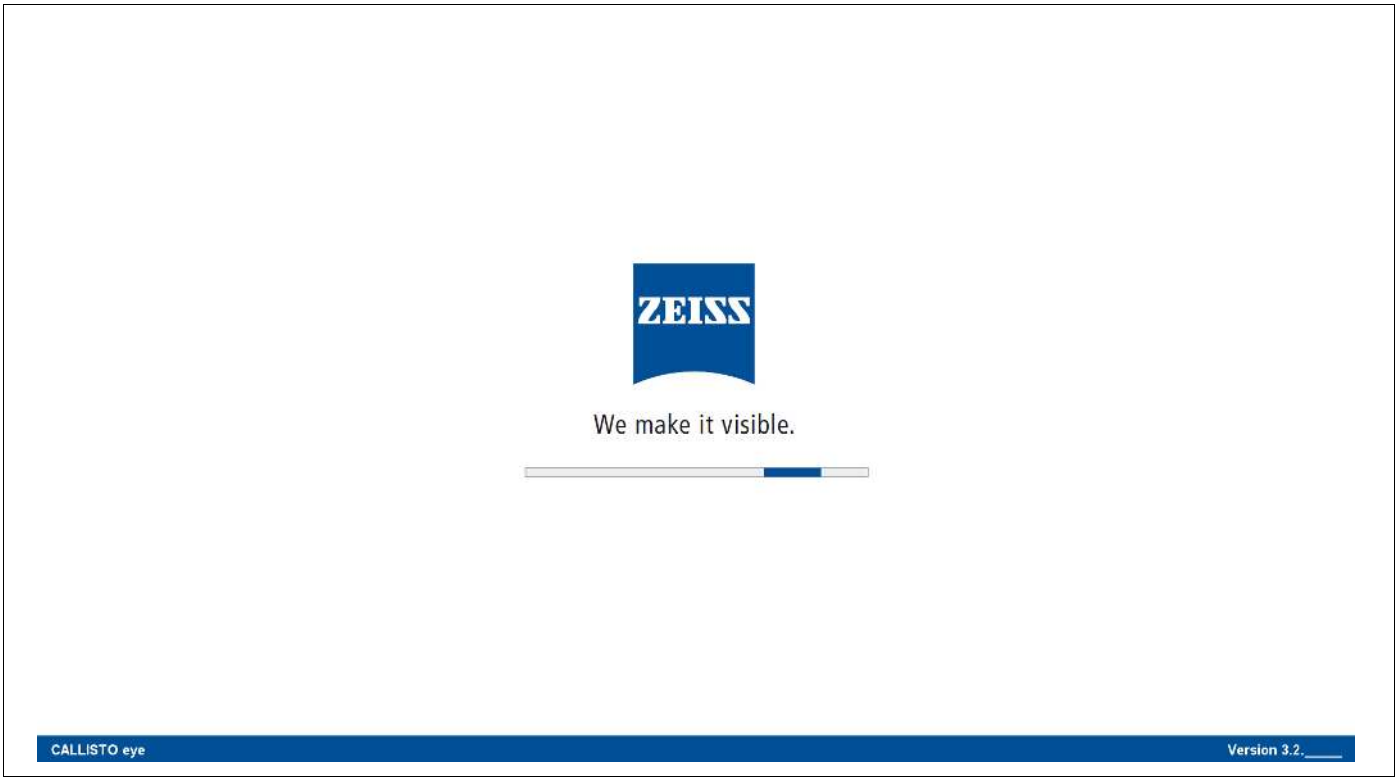
CALLISTO eye®

Software Version 3.2



Instructions for Use

G-30-1708-en

Version 8.0

21/06/2013

About these Instructions for Use

The Instructions for Use form part of the delivery package

- Please read them carefully before use.
- They should be kept at the location where the device is used.
- Retain these for the service life of the device.
- Please pass them on to any subsequent owner or user of the software.

Scope

These CALLISTO eye® Instructions for Use, Software-Version 3.2, apply to the following basic package:

CALLISTO eye® (Order Number: 301640-3000-320)

Orientation aids

– The section summary at the beginning of the Instructions for Use provides an overview of the topics covered.
– You will find a detailed table of contents at the beginning of each section.
– The keyword index in the appendix facilitates searching for terms.

Trademark

CALLISTO eye®

is the trademark of Carl Zeiss Meditec AG.

Information on the manufacturer

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Original language

These Instructions for Use were originally drafted and published in German.

Copyright

Subject to change

Modifications to models, scope of supply and further technical development are subject to change without notice. Printed in Germany.

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Description of CALLISTO eye

CALLISTO eye is an information, documentation, visualization and control system for eye surgeries in ophthalmo-surgical hospitals.

A CALLISTO eye system consists of the CALLISTO eye user terminal (touch-screen with integrated PC) and a stand (table stand, rolling stand or attachment via mounting to the OPMI LUMERA® 700), and the CALLISTO eye software.

CALLISTO eye is intended for video and photo documentation, display of video live images, control of a LUMERA 700 surgical microscope, display and importing of patient data, OCT camera control and the display of (intra-operative) OCT scans performed (OCT: Optical Coherence Tomography and the exporting of OR videos and photos after completion of the operation. Injection of parameter data into the IDIS (Integrated Data Injection System) of the OPMI LUMERA700.

A data base is installed on the integrated PC. All patient data are stored in this database.

CALLISTO eye can be integrated into a network.

Interfaces / Connection options

Additional devices can be connected to the CALLISTO eye:

- A LUMERA 700 surgical microscope: this can be operated remotely from CALLISTO eye.
- The video camera of the LUMERA 700 surgical microscope.
- A RESCAN 700 OCT camera.
- IDIS (Integrated Data Injection System).

You can also connect a USB memory medium to CALLISTO eye (USB stick or external hard disk). You can store treatment data on the memory medium or import patient data from the memory medium.

Functional Scope

CALLISTO eye is a user terminal (PC with touchscreen), with installed software to assist with and document eye surgeries, i.e. an information, documentation and control software for ophthalmo-surgical hospitals with the following basic functions:

- Information for the OR staff regarding the patients.
- The saving and indexing of video data created during OR procedures and other data regarding OR process.
- Exporting of this information onto USB medium.
- Control of devices in the OR, as far as these are designed for remote control. Remote control of devices comprises only those device functions which do not result in any change of position of the operator.

Areas of use are all ophthalmo-surgical hospitals with large numbers of patients, especially day clinics, as well as "mini-practices" and practices treating out-patients.

General software functions:

- User administration
- Patient administration
- OR (video) recording
- Live video
- Control of OCT camera and display of images
- Control Center
- Surgical microscope remote control
- Network link
- Exporting of OP data

Scope of delivery

- 21" panel PC with integrated touchscreen and pre-installed CALLISTO eye software
- Cover for connections on the underside of the touchscreen
- Power cord
- Instructions for Use in the available languages: German, English, French, Italian, Japanese and Spanish
- Instruction protocol
- Optionally available as accessories:
  - Sterile protective covers (drapes) as monitor cover
  - Stand for CALLISTO eye panel PC (table stand or trolley)
  - USB, HDD with 500 GB memory capacity (incl. USB cable)
  - USB stick with 32 GB memory capacity
  - LAN connection cable
  - Video cable (HD-SDI)

Please ask your ZEISS dealer for the order numbers of compatible and approved accessories.

In addition to the Instructions for Use for the CALLISTO eye, please also observe the Instructions for Use for accessories purchased.

CAUTION

Non-approved accessories have not been verified by Carl Zeiss Meditec AG, and may result in material damage or personal injuries.

Used icons

The following information icons are used in these Instructions for Use:

– Lists

✓ Precondition for an action

• Action prompt

→ Result of an action

The names of buttons and input fields are shown in angle brackets, e.g. <Save>.

The names of tabs or tab areas as well as those of menus and display fields are shown in inverted commas, e.g. "Patient", "User".

Additional information and tips.
These contain no warnings of hazards.

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Hazard symbols in these Instructions for Use

The following Safety advice is incorporated in these Instructions for Use. Please follow this safety advice and take particular care in these cases.

⚠ **WARNING**	Indicates a hazard which **can lead to death** or **severe injury** if it is not prevented.
⚠ **CAUTION**	Indicates a hazard which can cause **minor** and **medium injury** if it is not prevented.
NOTE	Indicates a hazard which may cause **material damage** if it is not prevented.

Warning and Information Signs on the device

Various warning and information signs are affixed to the back of the CALLISTO eye.

Should you find that one of these signs is missing from your device or has become illegible, please contact us or one of our authorized distributors. We will supply you with replacements.

- Please observe the warning and information signs.

The signs have the following meaning:

	Please observe the Instructions for Use.
	Please observe the Instructions for Use.

Country-specific contact details which should be used in the event of a service call.

Rating label

It includes the following information:

Symbol for "Manufacturer"	
Manufacturer (Company name)	Carl Zeiss Meditec AG
Address of manufacturer	Göschwitzer Str. 51–52 07745 Jena Germany
Serial Number (SN)	690912xxxx
Device name	CALLISTO eye
Reference number	REF 6909
Nominal voltage	100 V~ – 240 V~
Supply current	1.0 – 0.5 A
Power frequency range	50 Hz – 60 Hz
Protection rating according to IP code	IP20 Protected against solid foreign matter with a diameter of 12.5 mm or larger Not protected against water
	CE mark

Year of manufacture

	WEEE symbol Indicates that the device must be disposed of properly (see page 198). May not be disposed of in domestic waste/residual waste.

Further technical data about the user terminal can be found in section "Technical Data" at page 201.

Warning and Notice icons on the program user interface

The following warning and notice icons may be displayed:

	Additional information for the user
	Important information on the performed program function
	Negative notification if performance of a program function was not possible or was incomplete

	This key indicates that the loaded patient is not the active patient (See pages 112, 117 and 125).
	Red coloring of the menu button indicates a malfunction (see page 211).
	

CE Conformity

The device meets the essential requirements stipulated in Annex I to Directive 93/42/EEC governing medical devices. The device is labeled with:

CE 0297

Target group

These Instructions for Use are intended for doctors and professional medical staff, including the persons responsible for the organization and planning of ophthalmological surgeries, who will prepare and operate the system following suitable induction. It is the duty of the system owner/operator to train and brief the operating staff.

CALLISTO eye must only be used by properly trained medical experts.

Any service activities not described herein must only be performed by specialist staff trained by ZEISS.

Intended use / Normal use

Intended purpose

CALLISTO eye acts as an information and documentation system for eye surgery. The system enables the visualisation of the anterior and posterior segments of the eye and allows the connection and remote control of a surgical microscope using OCT Camera.

General system description

CALLISTO eye offers functions for the documentation of operations, e.g. video recording and temporary storage of the data gathered during this process. It supplies the OR team with relevant information and provides an interface for the control of surgical instruments in the OR (see page 10). The patient and operation data is saved, and can be exported to external systems after completion of the operation.

CALLISTO eye makes available to the surgeon in particular functions for displaying live OCT scans during the OR, together with their recording.

Image and video data are not intended for diagnostic purposes

CAUTION

To avoid unnecessary or incorrect treatments please observe the following:

- Do not use stored video or image data for diagnostic purposes.

CALLISTO eye is not an archiving system

CALLISTO eye is not intended for the permanent archiving of data.

CAUTION

To prevent data loss, please observe the following:

CALLISTO eye is not an archiving system. You may under some circumstances no longer be able to access your data due to a malfunction.

The next user can delete unsecured data or it can be deleted in the event of a repair.

- Secure your data using a suitable data backup procedure.

Every user is personally responsible for backing up his/her own data.

- Protect your data using a suitable data backup procedure or instruct your IT administrator to secure the patient, image and video data at regular intervals onto CD, DVD, USB sticks or other data carriers.

Section "Exporting treatment data" on page 98 describes how you can backup your data.

ZEISS will not be held liable for the loss of patient, image or video data or user-specific configuration data.

Prerequisites for the connection of additional devices

NOTE

Only the following medical devices may be used in combination with CALLISTO eye 3.2:

– OPMI LUMERA 700 (Version 3.0)

– RESCAN 700 OCT camera (Version 1.0)

• Please ensure that only these medical devices are connected to CALLISTO eye to prevent any hazard resulting from line-voltage carrying parts and to avoid material damage.

Please note: The system may only be set-up or commissioned by a ZEISS technician or suitably trained staff.

Additional devices connected to medical electrical devices must verifiably comply with their corresponding IEC or ISO Standards (e.g. IEC 60950 for data processing devices). Furthermore, all configurations must fulfill the normative requirements for medical systems (see IEC 60601-1-1 or Section 16 of 3rd Edition of IEC 60601-1). Any person connecting additional devices to medical electrical devices is a system configurer, and is thus responsible for compliance of the system with the normative requirements for systems.

Please note that local legislation takes priority over the above mentioned normative requirements. In case of questions please contact your local dealer or ZEISS-Service.

Data protection and information security

CAUTION

Function and safety testing of connected medical devices.

- Please ensure that function and safety tests of connected medical devices are performed in accordance with the Instructions for Use of the respective medical devices prior to initial operation to prevent hazards from live parts or material damage.

CAUTION

To prevent delays in the OR process, please observe the following:

Software viruses can result in malfunction of CALLISTO eye. The owner/operator of CALLISTO eye must ensure that the computer and system environment are and remain virus-free.

CALLISTO eye may only be operated in virus-protected networks. The operator is responsible for the security of the network. The consequences of virus attacks cannot be predicted.

It is the responsibility of the user to ensure that external memory media (e.g. USB sticks) used to exchange data are virus-free.

The user is advised to perform analysis and evaluation, and as required to take the necessary steps to control the risks. This must be repeated with every modification to the network or data communication network.

The owner/operator or his IT representative and every user have to ensure that the applicable legislation and requirements for data protection for the respective country are observed. The necessary technical and organizational preconditions for this must be implemented.

CAUTION

The user or IT representative must ensure

- That the data in his software is protected from misuse, i.e. that protected, personal data cannot be collected, processed or used without authorization.
- That personal data is protected; personal data is the individual details about personal or factual conditions relating to a specific or specifiable natural entity (marital status, type of occupation, religion, income, etc.), in other words, all the data that directly relates to a person (members of staff, customers, suppliers, etc.).
- That the data is protected during processing, i.e. during storage (collection, recording or retention), transmission (transferring to locations outside the company), modification (content changes, anonymization and alias allocation), deletion (rendering unrecognizable) and blocking (identification to restrict processing or use).
- That the data is also protected during other use (e.g. during internal transfer).
- Data sent to third parties, outside of the responsible body, are protected by the respective recipient.

Should a CALLISTO eye device require servicing, the device must be sent to ZEISS or to the national branch office in your country/state.

Delete all patient and treatment data from the defective unit for data protection reasons, as far as this is still possible.

Electromagnetic compatibility (EMC)

The device complies with the EMC requirements of IEC 60601-1-2.

⚠ **CAUTION**

To prevent personal injuries due to electric voltage (see "Interfaces / Connection options" on page 10) only connect approved cables and connectors.

⚠ **CAUTION**

- During device operation observe the precautionary measures listed below with respect to electromagnetic compatibility:
  - Use only ZEISS-approved spares for this device.
  - Do not use any portable or mobile HF communication equipment near the device, as the possibility that device function may be affected cannot be excluded.
  - Do not use any cell phones near the device. These represent a potential danger for the proper functioning of medical devices. Malfunctions may occur, depending on a variety of local factors. These are not foreseeable and cannot be assessed in any way.
- Please observe the EMC guidelines on pages 202ff.

NOTE

To prevent damage to this device and ensure proper operation, please observe the following:

- Operate CALLISTO eye within the specified voltage ranges (see page 201).
- Ensure that voltage fluctuations in the voltage supply are less than 10%.

Safety information for the hardware platform

CAUTION

Function and safety testing of connected medical devices.

- Please ensure that function and safety tests of connected medical devices are performed in accordance with the Instructions for Use of the respective medical devices prior to initial operation to prevent hazards from live parts or material damage.

CALLISTO eye

CAUTION

To prevent delays in the OR process, please observe the following:

– Perform a visual inspection

  - Ensure there is no obvious damage to or modification of the user terminal.

    Discolorations, deformations, scratches, kinked, broken or frayed cables indicate equipment damage, which could affect proper use.

– Ensure proper functioning

  - Only power up the user terminal once all cables have been connected, both on the user terminal and building side.
  - Check the proper functioning of the user terminal and equipment carrier before every use.

CAUTION

To prevent personal injury due to unexpected equipment behavior, perform function testing of the system prior to commencing treatment.

- Ensure the touchscreen is not dirty.
- Make sure the device is in a stable working position. Please ensure that the device is securely fastened to the table leg, so that the device cannot drop and either suffer or cause possible harm.
- Immediately unplug the power plug if you notice smoke, sparks or unusual noises from your device. Should this occur the device must not be used again before it has been repaired by our Service department.

- Ensure that no liquid can enter the device.
- Do not pull on the cable connections.
- Do not exert any force when plugging in electrical plug-in connections (connectors, jacks). If this is not possible, check that the connector and socket match. If you notice damage on the plug connection, have our Service department repair the damage.
- Do not shake, knock, overheat or scratch the CALLISTO eye.
- Only start up the machine if
  - The device is connected using the power cable intended for this purpose.
  - The power cable is inserted in a power outlet which has a fully functioning earth conductor.
  - All cables and plug-in connectors are in perfect condition.

NOTE

Improper installation, operation or use may cause unexpected behavior in the CALLISTO eye. This may result in data loss.

NOTE

Please observe the following in order to avoid malfunction of the CALLISTO eye:

- Only operate the device under the approved ambient conditions (see page 208).
- Please observe the Technical Data (see page 201).

Table stand, trolley

The table stand and trolley are only designed to carry the CALLISTO eye.

- Do not attach any other devices and do not use it for any other purpose.

Transporting the CALLISTO eye over long distances

⚠ **CAUTION**

To avoid personal injury due to electrical voltage or material damage resulting from transit damage, please observe the following:

CALLISTO eye and accessories may only be transported over long distances (e.g. in event of relocation, return shipment for repair purposes, etc.) in the original packaging or in a special shipping crate. Contact your dealer, national branch office or ZEISS-Service about this.

Recommendation: Retain the original packaging and observe the transportation conditions (see page 208).

Perform a visual inspection:

- Make certain there is no visible damage to or modifications of the user terminal, such as:
  - Discolorations, deformations, scratches
  - Kinked, broken, frayed cables
  - Dirty touchscreen

Safety information for use

⚠ **CAUTION**

To avoid data protection violations, please observe the following:

- Ensure that only authorized persons have access to the device.
- In the event of relocation, repairs or disposal, delete all patient and treatment data from the device, as far as this remains possible.

- Familiarize yourself thoroughly with the contents of the Instructions for Use prior to putting the product into operation. Also observe the Instructions for Use of other connected components.
- The device and software may only be operated by briefed and trained persons. Training and briefing of the operating personnel is the responsibility of the owner/operator.
- Ensure the Instructions for Use are always to hand for operating staff.

- Please observe the latest Release Notes for this medical product. These form part of the scope of delivery when delivered.
- Use the product only in accordance with the intended use (see page 21).
- Observe the legislative provisions for accident prevention and occupational safety applicable in your country.

CAUTION

- It is the responsibility of the user (IT representative) to ensure that no viruses are transferred to the software via the data network.

CAUTION

- It is the responsibility of the user to ensure that the data carriers used for the exchange of data (CD, DVD, USB sticks or other data carriers) are virus free.

- Operate the product using only the software packages contained in the scope of delivery. If you wish to use other software packages, verify in advance that Carl Zeiss or the manufacturer of the software package have demonstrated and confirmed the safety and usability of the software.
- Making modification to this device is prohibited. Any modification to the device not described in these Instructions for Use makes you the manufacturer of a medical device in the eyes of national legislation (the legal manufacturer).
- The manufacturer is not liable for damage resulting from unauthorized tampering with the product. Furthermore all warranty claims, together with the labeling required to operate this medical product, also become null and void as a result.
- The warranty and liability depends on the contractually specified conditions.

CAUTION

- Before every operation, check against other available sources of information the respective patient and OR data stored in the database to exclude mix-ups and incorrect treatments.

- If so required by regulations and directives in the country of use, connect the device to a special backup power supply.
- In the event of a fault that you cannot remedy by restarting the CALLISTO eye, label the unit as non-functional and notify our Service department.

- If power-operated, the devices included in the delivery package may not be operated:
  - in potentially explosive areas
  - within 25 cm of inflammable anesthetics or volatile solvents such as alcohol, benzine or similar

There is a potential equalization connector on the device. This enables connection of other active devices to the same earth potential or redundant connection with protective earth (PE).

- Do not touch the device if your body is electrostatically charged and the device is not earthed.
- Do not touch any live parts or signal interfaces during contact with the patient.

Sterility

During treatment the CALLISTO eye may only be operated by persons in sterile clothing when covered with a sterile cover (drape).

⚠ **CAUTION**

To prevent infection and personal injury resulting from erroneous data interpretation, use only the drapes approved exclusively for the device.

The sterile device drape should lie as flat as possible on the front of the CALLISTO eye so that you can see the device's user interface through the drape and are able to operate the touchscreen.

Order number of drapes: 301640/-0014-100

CALLISTO eye requirements

Data requirements

When data is to exported from the CALLISTO eye, the integrity of the planning data must be safeguarded. The data generated during the surgery, e.g. video recordings, are intended for medical case documentation, not for patient-related documentation.

Safety requirements

CALLISTO eye supports patient management and offers the surgeon functionality for device control in the OR. It does not directly take over any safety-critical function for operations. Treatments in the OR can at any time be performed without CALLISTO eye.

Product service life

CALLISTO eye is designed for a product service life of five years. I.e. you will receive support from the manufacturer, Carl Zeiss Meditec AG, for five years from date of purchase. A separate agreement with Carl Zeiss Meditec AG is required for any support beyond this time frame.

Installation

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Installation requirements

A series of prerequisites must be fulfilled to ensure trouble-free installation and commissioning.

Space requirements

There must be sufficient space available to operate the CALLISTO eye. The specified ambient conditions must be adhered to (see page 208).

Electrical requirements

The required supply voltage is (100 V~ - 240 V~) ± 10% at 50 Hz – 60 Hz. The expected power consumption of the user terminal is 1.0 to 0.5 A.

Voltage fluctuations in the voltage supply must be less than 10%.

NOTE

To prevent damage to this device and ensure proper operation, please observe the following:

- Operate CALLISTO eye within the specified voltage ranges (see page 201).
- Ensure that the voltage fluctuations in the voltage supply are less than 10%.

Line voltage carrying parts must be insulated as specified.

⚠ **WARNING**

If line voltage carrying parts are not insulated in accordance with regulations, the user may suffer an electric shock on coming into contact with these parts. This can result in paralysis of muscles, extremities and the heart, or death.

- Use only the plug-in connections and cables approved by the manufacturer.
- Do not use any multi-outlet power strips.

The power connection must have a fully functional earth conductor.

Inadequately earthed devices conducting supply voltage may flow increased leakage current when touched.

Data network requirements

If CALLISTO eye is to be operated in a network, then certain minimum requirements must be fulfilled:

– The network connection requires a RJ45 connection on the network side.

– The plug on the cable end towards the isolating equipment (network side) must be sufficiently protected from touch, e.g. made of plastic.

⚠ **CAUTION**

– The owner/operator of the network must ensure that the network environment and computer are virus-free.

⚠ **CAUTION**

• Only connect Cat-5e network cables EIA/TIA-568A-5, i.e. the newer values as per Class D in ISO/IEC 11801:2002 or EN 50173-1:2002) to the network.

NOTE

To prevent the loss of individual data records, please observe the following:

• Ensure your network has sufficient capacity.

The local data network must be designed for a minimum data transmission rate of 100 Mbits/s (Fast Ethernet).

Hardware and software installation

ZEISS-Service or a person authorized by Carl Zeiss will install the CALLISTO eye hardware and software on your premises and set the time zone on the CALLISTO eye.

Connecting external devices

The service technician will make all necessary connections and plug-ins (e.g. to a surgical microscope) and cover the connector panel with the cover provided for this.

NOTE

Do not remove the cover from the connector panel. Do not undo any plug-in connections or connect any cables yourself.

If you want to transfer the CALLISTO eye to a different location, do not detach the cables on the CALLISTO eye, but unplug them at the connected devices or unplug the cable from the power socket, then transport the device with the connected cables to the intended location.

⚠ **CAUTION**

To prevent personal injury resulting from electric voltage connect only approved connectors (see "Interfaces / Connection options" on page 10).

To import patient data or export treatment data, you can connect a USB memory medium (USB stick, external hard drive) to the CALLISTO eye. A corresponding interface is found on the right-hand side of the device.

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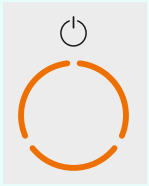
Operating Elements on the CALLISTO eye

Buttons and displays

On the lower edge of the CALLISTO eye monitor are mounted two buttons with integrated control displays.

Buttons and displays



<POWER> button:

- Press this button to switch the CALLISTO eye on/off.

  The LED on the ON/OFF switch can assume the following states:

  – Black / OFF: CALLISTO eye is not connected to the power supply (or the touch function is disabled).

  – Orange: CALLISTO eye is connected to the power supply.

  – Green: CALLISTO eye is switched on and ready for use.

Button <De-activate/Activate Touch Function>

The touch function can be de-activated to prevent unintended incorrect operation, such as when cleaning the touchscreen:

- Press the button illustrated here.

  → The button is illuminated more brightly than when the function is activated.

  → The <Power> button lighting goes off.

- To re-activate the touch function, hold the button down until the power button re-illuminates (approx. five seconds).

Touchscreen

The CALLISTO eye software is operated using a touch-sensitive screen (touch-screen). Using the touchscreen you can perform all the required operating steps, i.e. you can call up menus and tabs by pressing buttons, enter text and numbers, perform date settings or initiate actions.

The touch function can be deactivated to prevent unintentional operations (see page 41).

On the touchscreen you can also view saved images, videos and OCT images.

NOTE

The touchscreen can only be operated using fingers; it cannot be operated using a (sterile) stylus.

Never press on the touchscreen with pointed, hard items such as pencils, ballpoints, knives or other items made of wood, metal or plastic. This could damage or destroy the touchscreen.

Switching CALLISTO eye on/off

Switching-on CALLISTO eye

Prerequisite ✓ CALLISTO eye must be connected to the power supply. If this is the case, the <POWER> button is illuminated orange.

Procedure • Press the <POWER> button.

Result → The system starts up; the <POWER> button illuminates green.

→ The last active user is again active, or a password is requested.

Switching off CALLISTO eye

Procedure • Press the <POWER> button.

Result → CALLISTO eye is switched off.

→ The <POWER> button illuminates orange.

Configuring CALLISTO eye

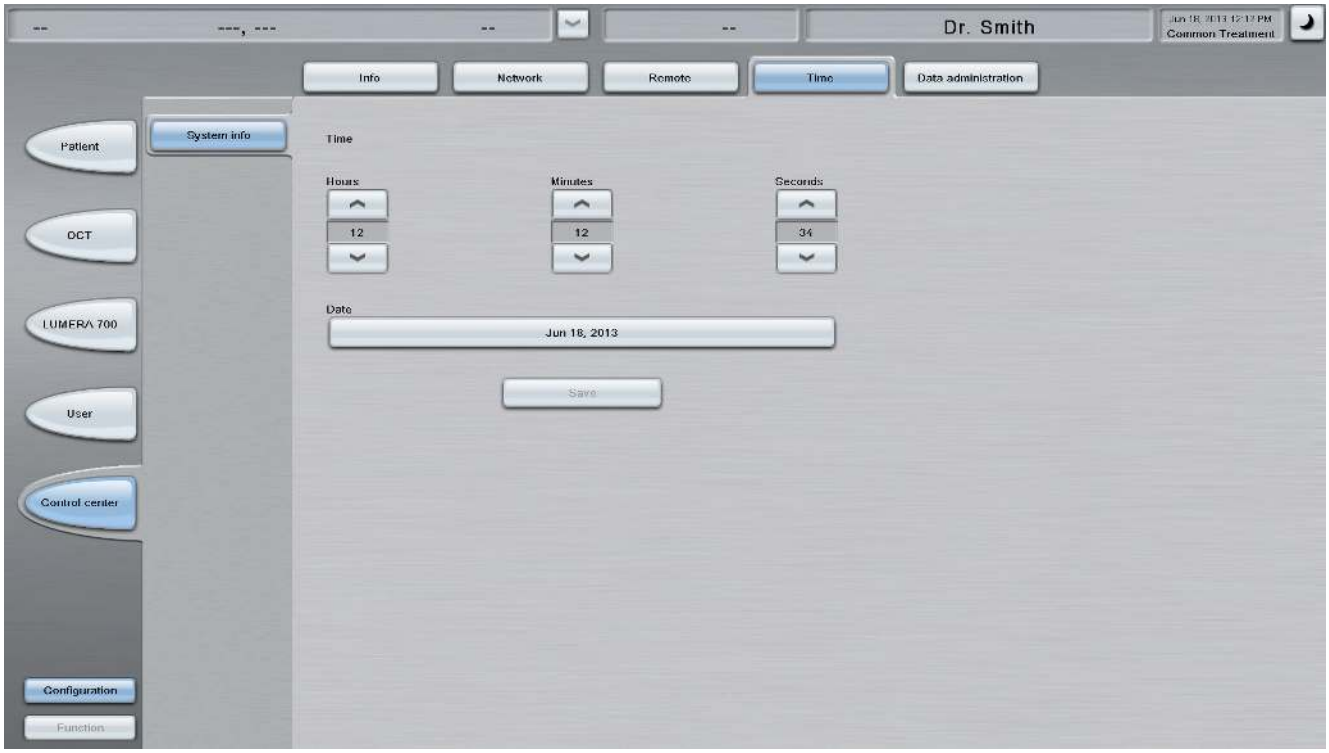
Setting the date and time

Procedure

- Press the <Control center> button.

  → The "System info" sub-menu opens.

- Select the "Time" tab.



- Set the required time and date.
- Press the <Save> button.

  → A message requests you to re-start CALLISTO eye.

- Confirm the request by pressing the <OK> button.

Result

→ The settings are saved. The changed date and time are displayed at the top right in the header.

Activating/Deactivating data protection

If data protection is activated, the user must log in with his/her password and only has the rights assigned to him/her. When data protection is de-activated, every user can log in without a password and has unlimited rights (about User Rights see page 177).

Default setting: Data protection is activated.

This setting must be made in agreement with your hospital's Data Protection Officer.

Prerequisite

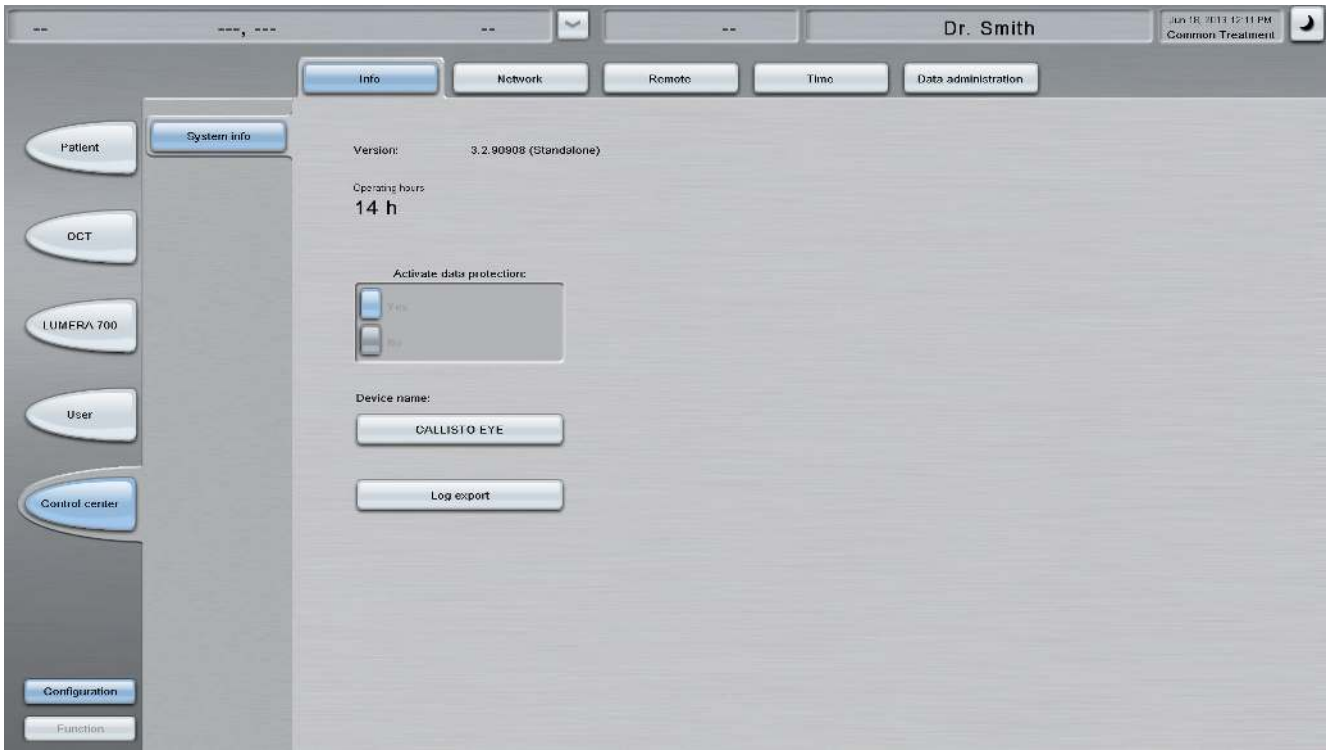
✓ The System administrator must be logged in as a user (only the System administrator can change the data protection setting).

Procedure

- Press the <Control center> button.

  → The "System info" sub-menu opens.

- Activate the "Info" tab.



- In the area "Activate data protection" press the required button (<Yes> or <No>).

Result

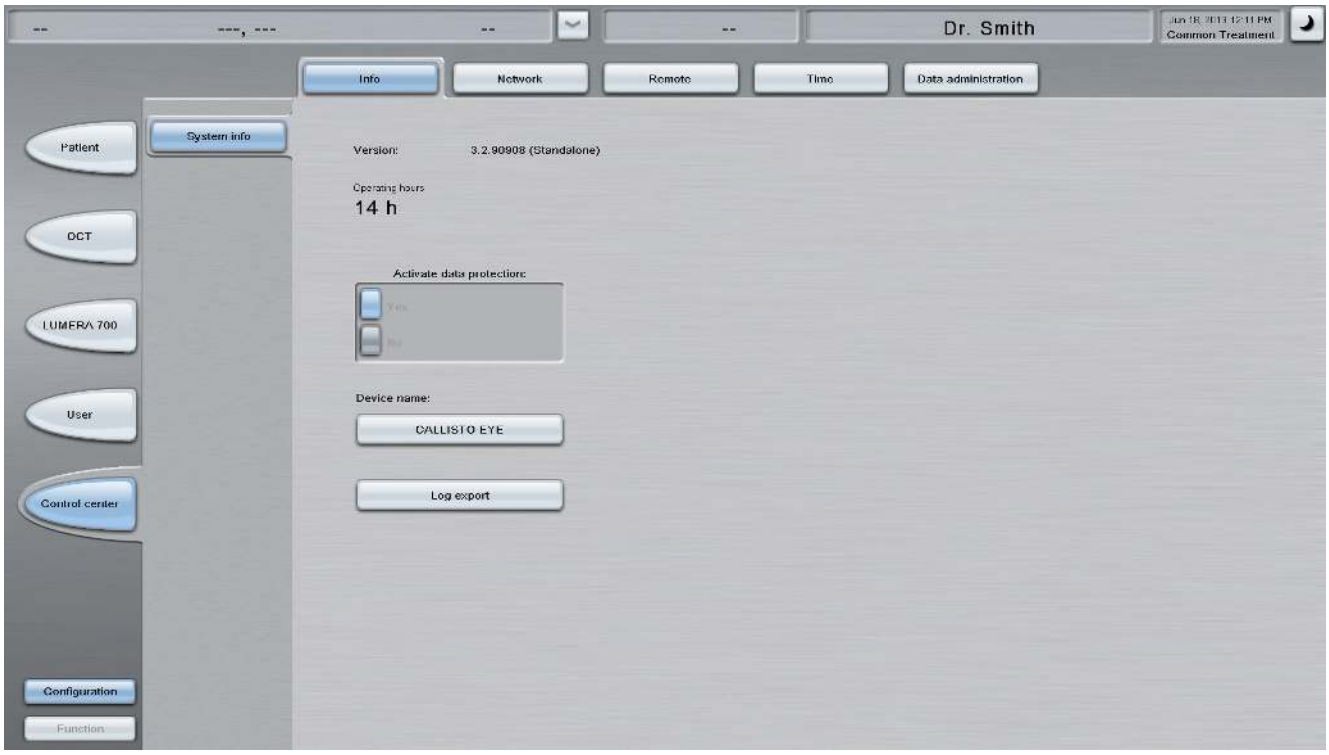
→ Data protection will be activated / deactivated depending on the selection.

Assigning a device name

You can assign a device name to the CALLISTO eye.

Procedure

- Press the <Control center> button.
  → The "System info" sub-menu opens.
- Activate the "Info" tab.



- Press the <Device name> button.
  → The keyboard for entering text appears.
- Enter the desired device name.

Result

→ The device name entered is displayed on the button.

Creating and configuring device settings

A device setting allows certain start-up settings to be pre-set for connected equipment (surgical microscope, hand grips, foot control panel) and allows saving of the configuration for data injection in the OPMI LUMERA 700 eyepiece and of OCT visualisation preferences (see Configuration Views of the "LUMERA 700" and "OCT" menus, page 167 or page 151).

Only those settings of the surgical microscope, hand grips and foot control panel made in the Configuration view of the "LUMERA 700" menu are saved in the device setting. Settings made in the Function view are lost when the device setting is changed.

Device settings are user-specific, i.e. they are saved in the user profile of the currently logged in user and can only be used by that user.

Changing the device setting can be done in several ways:

- in the "Patient" tab in the "Patient" menu (see page 69)
- in the "Selection" tab in the "User" menu (see page 71)
- in the "Workflow steps" tab of the "LUMERA 700" menu (see the Instructions for Use for the LUMERA 700 surgical microscope).
- by pivoting the RESIGHT 700® module
- by pressing an appropriately configured button on the foot control panel or hand grips (see the Instructions for Use for the LUMERA 700 surgical microscope)

The "Common Treatment" device setting is automatically created for every user when the user is created. It can be renamed, changed or deleted.

For the default user "OCT Default User" (see page 171) two device settings are specified: "Anterior" and "Posterior". These device settings hold preconfigured special settings for the OPMI LUMERA 700 which mean that OCT visualization is possible immediately the user logs on, (see also the Instructions for Use for the LUMERA 700 surgical microscope).
Both device settings can be changed if necessary.

Note: OCT visualization processes may also be performed if another user is logged on.

Prerequisite

✓ The user for whom you want to configure a device setting must be active (see "Switching user" on page 67).

The currently active user is displayed in the "User" field (in the header, third field from the left).

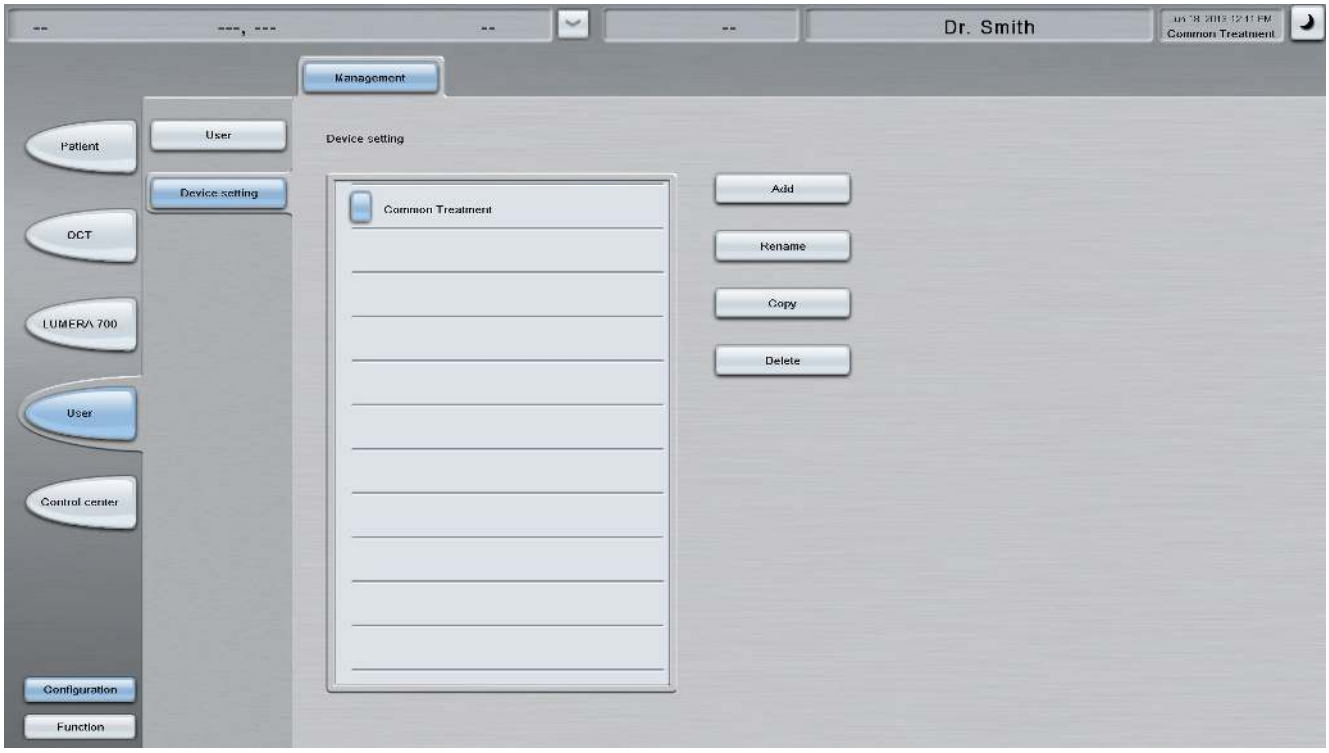
✓ The devices for which the settings are to be configured (LUMERA 700, hand grips, foot control panel), must be connected to CALLISTO eye or LUMERA 700 and be ready to operate.

Creating a new device setting

Procedure

- Press the buttons <User> <Configuration> <Device setting>.

  → The "Management" tab is displayed.



- Press the <Add> button.

  → The keyboard opens.

- Enter a name for the device setting.

  → The name appears in the "Device setting" list.

  → The currently active settings for the connected devices are initially stored under the new name. These can be changed as follows.

You can also copy or rename an existing device setting. This is useful if, for example, you already have a device setting configured that is very similar to the new setting you want to create.

Configuring a new device setting

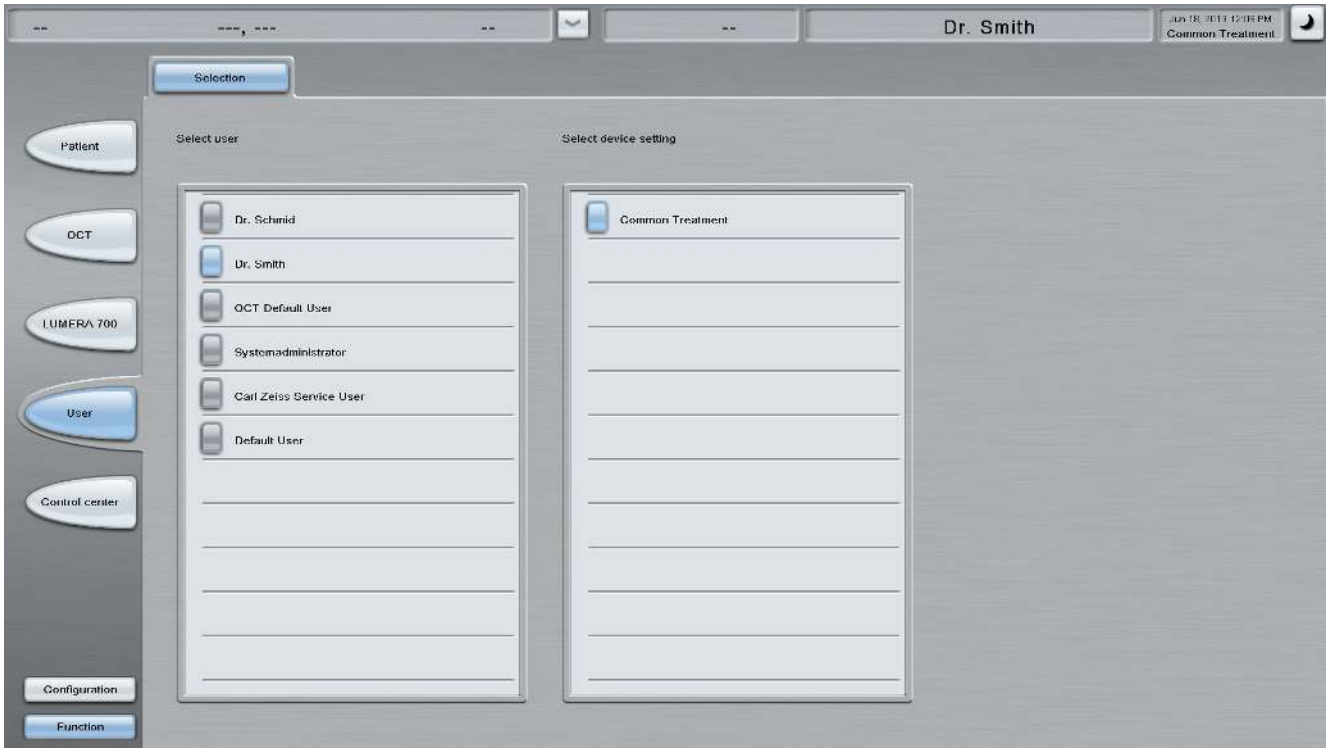
Prerequisite

✓ The "User" menu must be selected.

Procedure

- Press the <Function> button.

  → The "Selection" tab is displayed.



- Select the newly-created device setting.

  → The name of the device setting is displayed at the top on the right.

Configuring startup settings for connected devices

- Press the <LUMERA 700> button.

  → The menu for remote control of the surgical microscope and other devices (foot control panel, hand grips) appears. This offers a Function and a Configuration view.

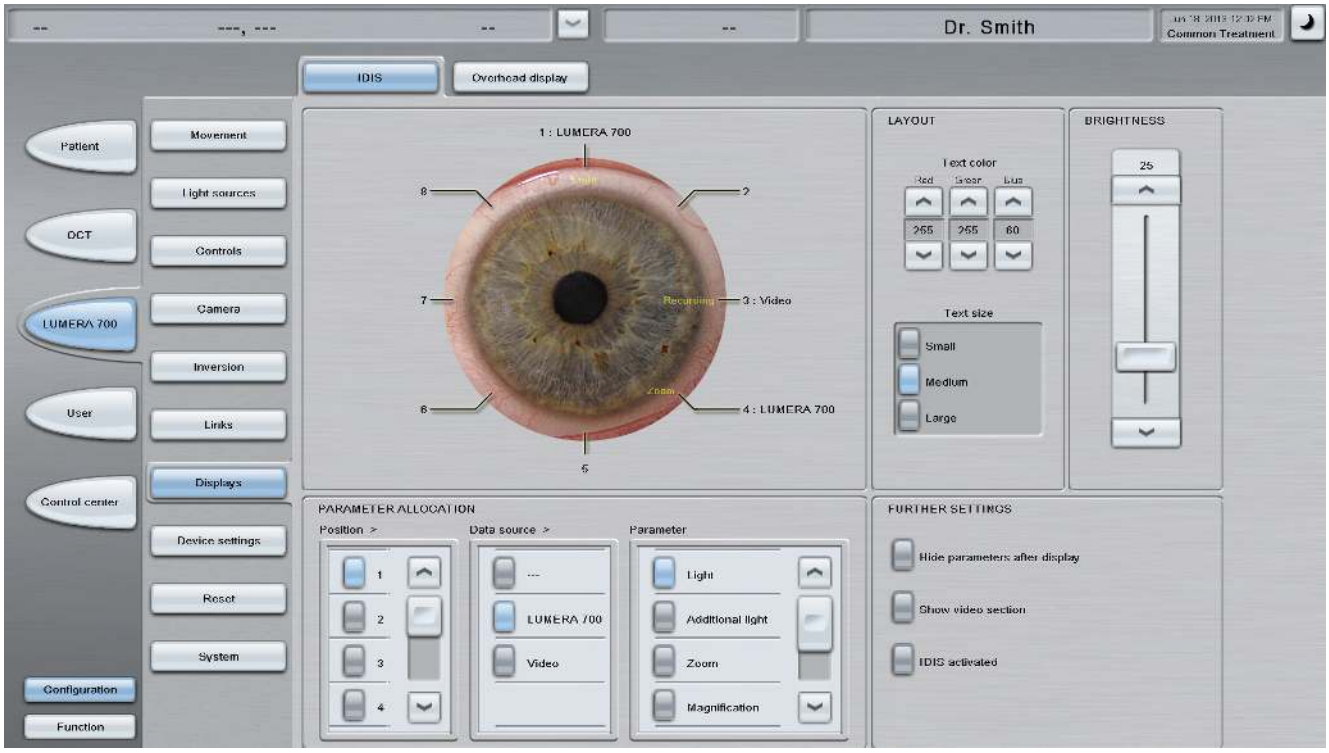
- Press the <Configuration> button
- Make the required settings.

Settings in the Function view are not saved in the device settings.

Configure data injection in the LUMERA 700

(Example of a configuration option for the LUMERA 700)

- Press the buttons <LUMERA 700> <Configuration> <Displays>.
- Select the "IDIS" tab.



- Configure data injection as desired.

Result

→ All settings made for the connected devices and data injection (IDIS) are automatically saved immediately upon input under the name of the current device setting.

→ If this device setting is loaded, all the settings defined in this are sent to the connected devices.

Changing a device setting

Procedure

- Press the buttons <User> <Function>.

  → The "Selection" tab is displayed.
- Select the device setting you want to change.
- Proceed as explained in section "Configuring a new device setting" (sections "Configuring startup settings for connected devices" on page 50 and "Configure data injection in the LUMERA 700" on page 51).

Result

→ All the changes are immediately saved automatically upon entry under the name of the device setting.

→ If this device setting is loaded, all the settings defined in this are sent to the connected devices.

Renaming a device setting

Procedure

- Press the buttons <User> <Configuration> <Device setting>.

  → The "Management" tab is displayed.
- Select the device setting you want to rename.
- Press the <Rename> button.

  → The keyboard opens.
- Enter a new name for the device setting.

Result

→ The new name appears in the "Device setting" list.

Copying a device setting

Procedure

- Press the buttons <User> <Configuration> <Device setting>.

  → The "Management" tab is displayed.
- Select the device setting you want to copy.
- Press the <Copy> button.

Result

→ A new entry for the copied device setting appears in the list.

→ The copied device setting can be renamed or changed.

Deleting a device setting

Procedure

- Press the buttons <User> <Configuration> <Device setting>.
  → The "Management" tab is displayed.
- Select the device setting you want to delete.
- Press the <Delete> button.

Result

→ The selected device setting is deleted after the confirming the prompt.

Activating / deactivating automatic video recording

The following description applies to automatic live video recording of the surgical microscope. The activation/deactivation of automatic OCT video recording is described under page 55.

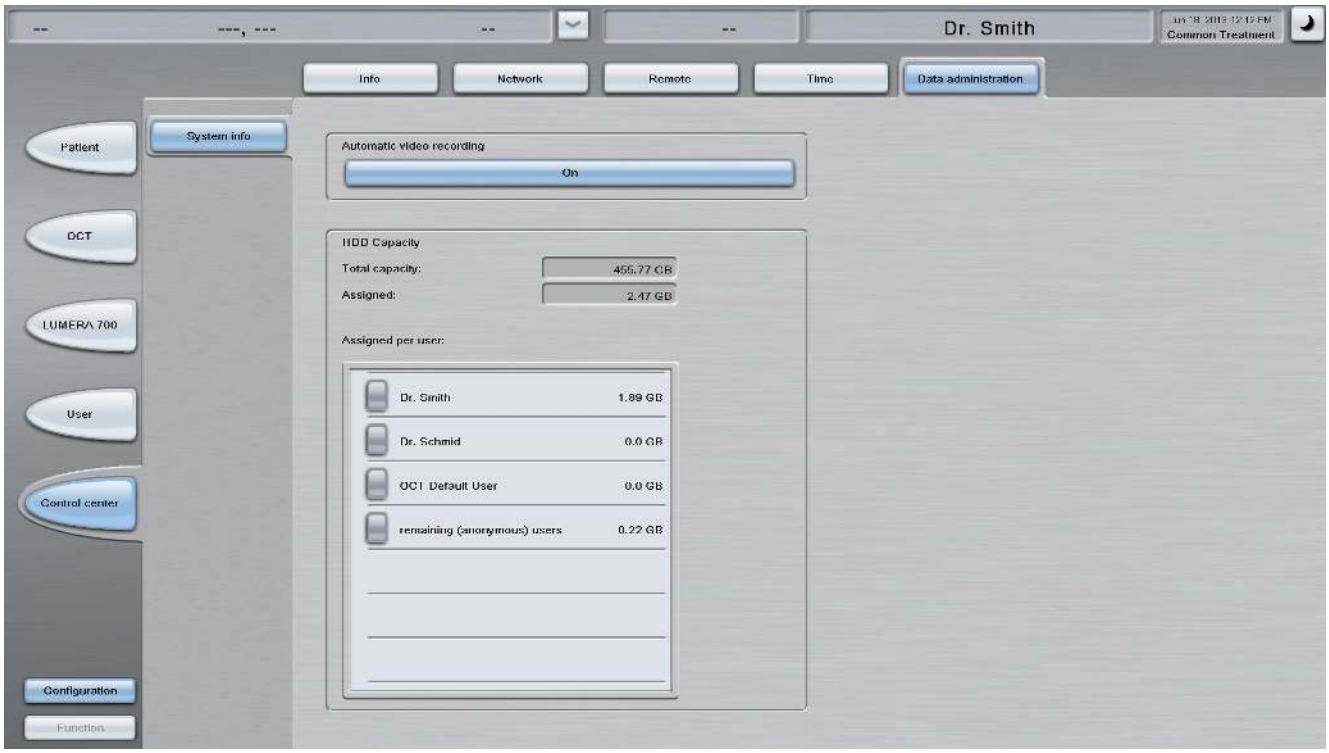
If a patient has "active" status (see page 112), a video can be recorded. CALLISTO eye can be configured such that video recording starts automatically when a patient is activated, or that video recording must be started manually.

Procedure

- Press the <Control center> button.

  → The "System info" sub-menu opens.

- Select the "Data administration" tab.



- Press the button <Automatic video recording> to switch the function on or off.

Result

→ When the function is activated, video recording commences automatically when a patient is activated. If the function is de-activated, video recording must be started manually.

Activating / deactivating automatic OCT video recording

If a patient has "active" status (see page 112), video of an OCT visualization can be recorded. (OCT Video). CALLISTO eye can be configured such that OCT visualization recording starts automatically at the start of a live scan, or that video recording must be started manually.

Please note: A running OCT video recording ends automatically when you switch off the OCT live scan (button <OCT On/Off> in the "Live" tab; see page 145), if you press the <Capture> button (in the "Live" tab; see page 147), or if you change to any other tab.

Procedure

- Press the buttons <OCT> <Configuration> <Live Settings>.

- Under "Auto OCT Recording" press the <On> or <Off> button to switch automatic OCT video recording on or off.

Result → If the function is activated OCT video recording starts automatically when the Live OCT Scan is started. Live OCT Scan is started in one of the following ways:

- The "Live" tab (in the Function view of the "OCT" menu) is opened.
- The Live Scan is reactivated after deactivation using the "Live" tab (button <OCT On/Off>).
- Automatically after interruption of a live scan after pressing the <Capture> button (in the "Live" tab).

If the function is de-activated, video recording must be started manually.

Configure presettings for OCT visualization

For OCT visualization (OCT: Optical Coherence Tomography) you can set a series of presettings. These settings are user-specific and are activated if you log in as a user on CALLISTO eye.

Preset options include settings for live scans, for OCT images (capture scans), LUMERA 700 shutter settings, and for displaying OCT images.

Configure settings for live scans

Procedure

- Press the buttons <OCT> <Configuration> <Live Settings>.

  → The "Live Settings" tab is displayed.

- Set the settings for live scan type, resolution, scan size, X/Y increment, line spacing, the OCT assignment of the foot control panel and automatic OCT video recording as desired (the settings options are described in detail from page 152 and page 158).

The settings for scan size and line spacing also apply for OCT images (see page 58).

Result

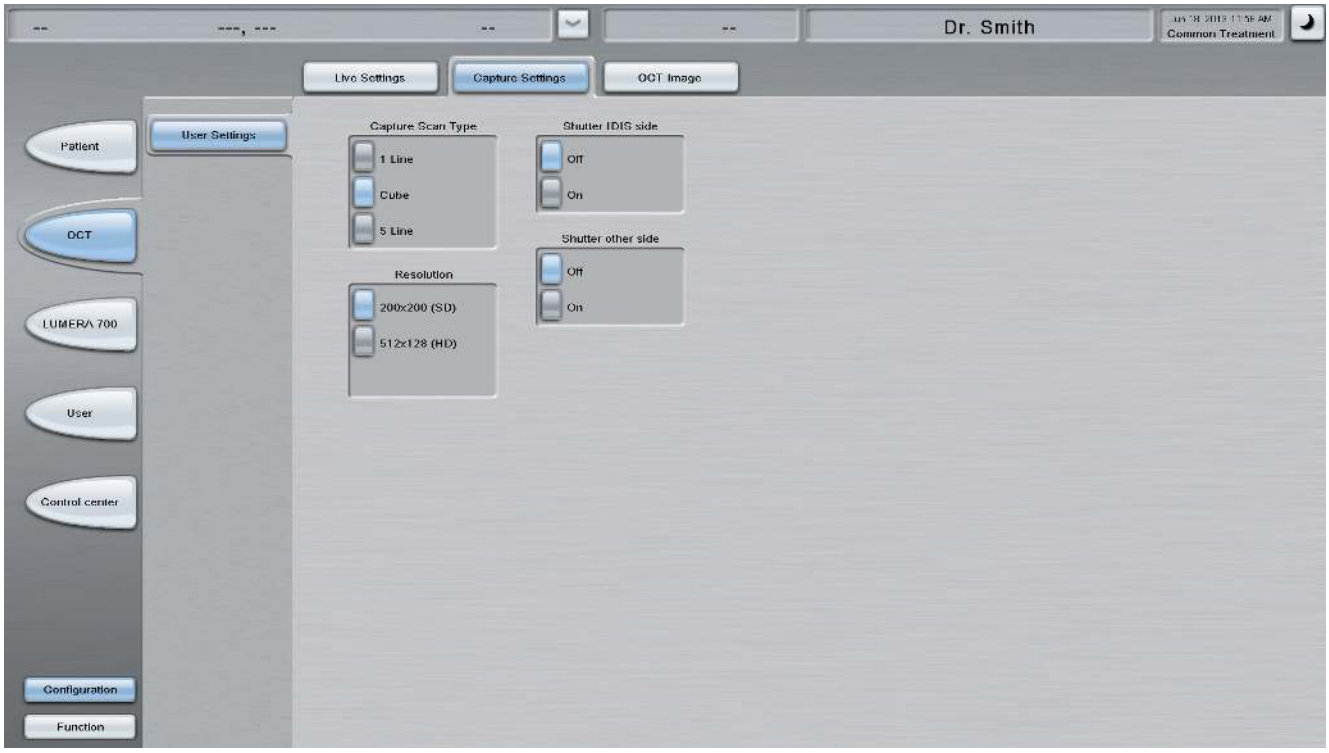
→ The chosen settings are preset if you log in as a user on CALLISTO eye.

Configure settings for OCT images (Capture)

Procedure

- Press the buttons <OCT> <Configuration> <Capture Settings>.

  → The "Capture Settings" tab is displayed.



- Make the settings as necessary for the image scan type (capture scan type), resolution and shutter settings (the settings options are described in detail from page 155).

Please note: The same settings apply for the scan size and the line spacing for OCT images (capture scans) as for live scans ("Live Settings" tab, see page 57).

Shutter settings apply only for the review of an OCT image ("Review" tab).

Result

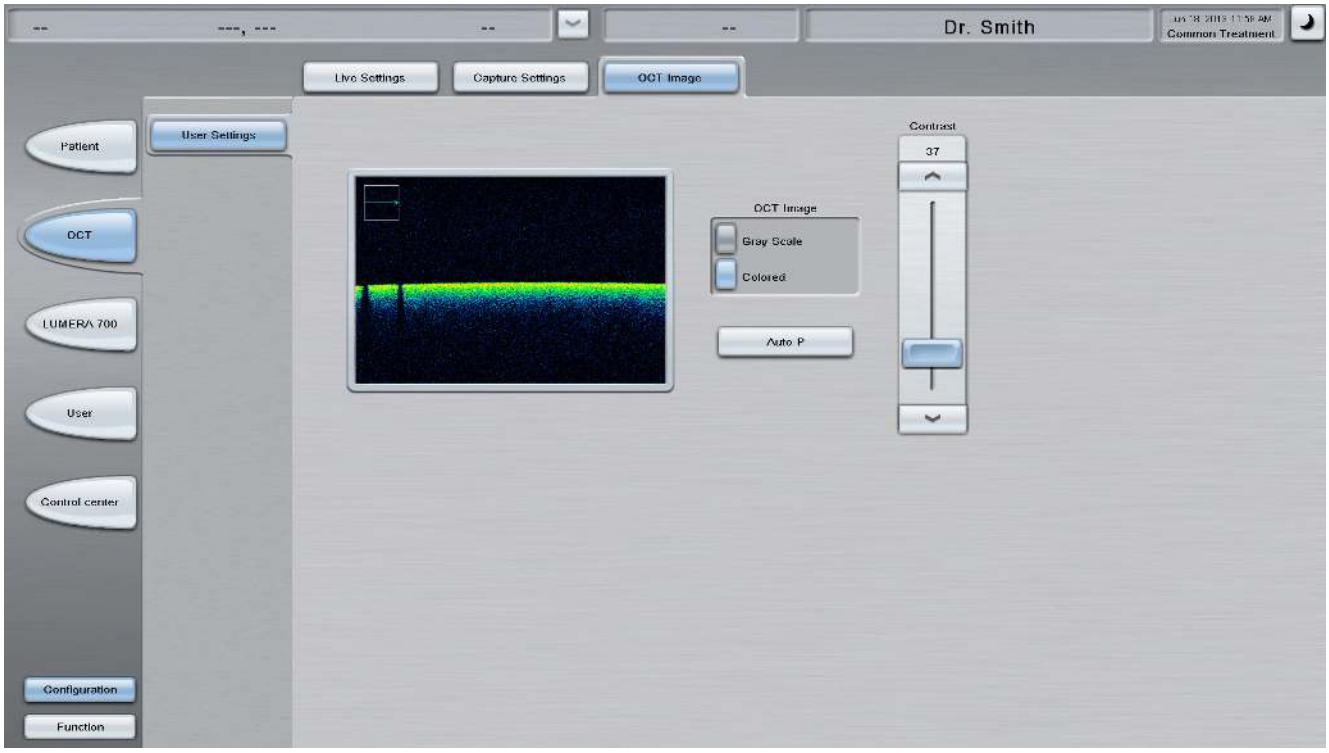
→ The chosen settings are preset if you log in as a user on CALLISTO eye.

Configure settings for OCT images

Procedure

- Press the buttons <OCT> <Configuration> <OCT image>.

  → The "OCT image" tab is displayed.



- Select the presentation mode for OCT images (grey scale or color) and adjust the contrast (color images only).

Result

→ The selected setting is preset when you log in as a user on CALLISTO eye.

→ OCT images are displayed and also saved in the "Live" tab in the Function view of the "OCT" menu in the selected presentation.

Setting up and testing a network connection

Settings are usually configured during installation of CALLISTO eye by ZEISS-Service or your network administrator.

Only change these settings if changes affecting the CALLISTO eye network link were made post-installation in your network.

Prerequisite

✓ CALLISTO eye is connected to the network.

Procedure

- Press the <Control center> button.

  → The "System info" sub-menu opens.

- Select the "Network" tab.

- Enter the network parameters.

The setting and detail requirements will depend on the network in which you intend to operate your CALLISTO eye. Please consult ZEISS-Service and your in-house network administrator on this.

The second network card is used to connect CALLISTO eye to the computer for the OCT function. The settings are preconfigured in the factory and cannot be changed.

- Enter the IP address of a computer within the network and press the button <IP test> to test the link between your CALLISTO eye and the network.

  → A message will appear advising you whether the test was successful.

- Press the <Save> button.

  → A message requests you to re-start the CALLISTO eye.

- Confirm the request by pressing the <OK> button.

Result → The current settings are adopted: CALLISTO eye is integrated into the network.

Obtaining information about CALLISTO eye

You can obtain information on the software version installed on the CALLISTO eye and the number of operating hours.

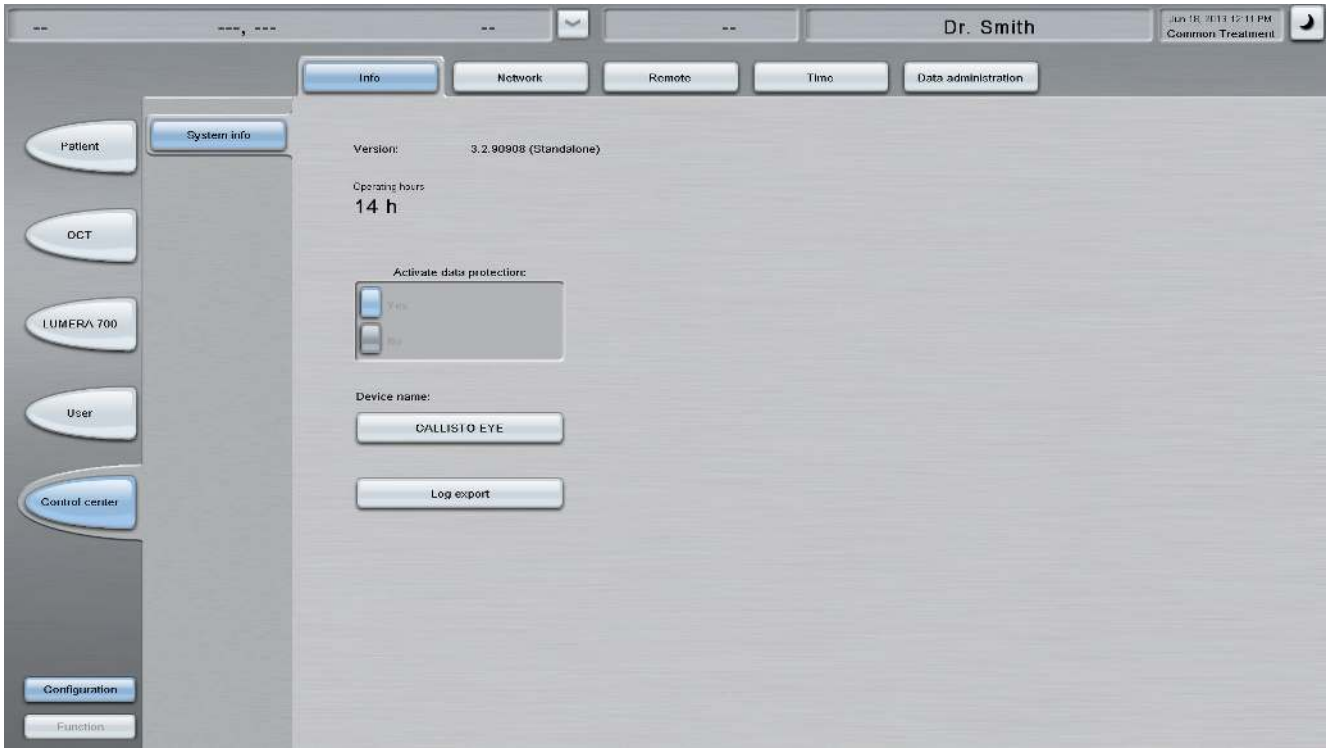
Querying the software version and number of operating hours

Procedure

- Press the <Control center> button.

  → The "System info" sub-menu opens.

- Activate the "Info" tab.



Result

→ The installed software version and number of operating hours are displayed.

Operation

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Introduction

This section describes the most important functions of the CALLISTO eye and how you perform them step by step. The prerequisite for this is that you have basic knowledge of the user interface and operation of the software (see page 103 and following). It also requires that CALLISTO eye be ready to operate and that all the necessary configuration steps have already been completed (see page 44 and following).

A detailed description of all CALLISTO eye functions can be found in the section entitled Software description (starting on page 101). All the tabs in the software are described in detail there.

How CALLISTO eye is switched on/off is described on page 43 .

Managing users

Creating new users

Prerequisite

✓ The active user has the relevant rights (see "User rights" and "View patient data" on page 177) or data protection is de-activated (see page 45).

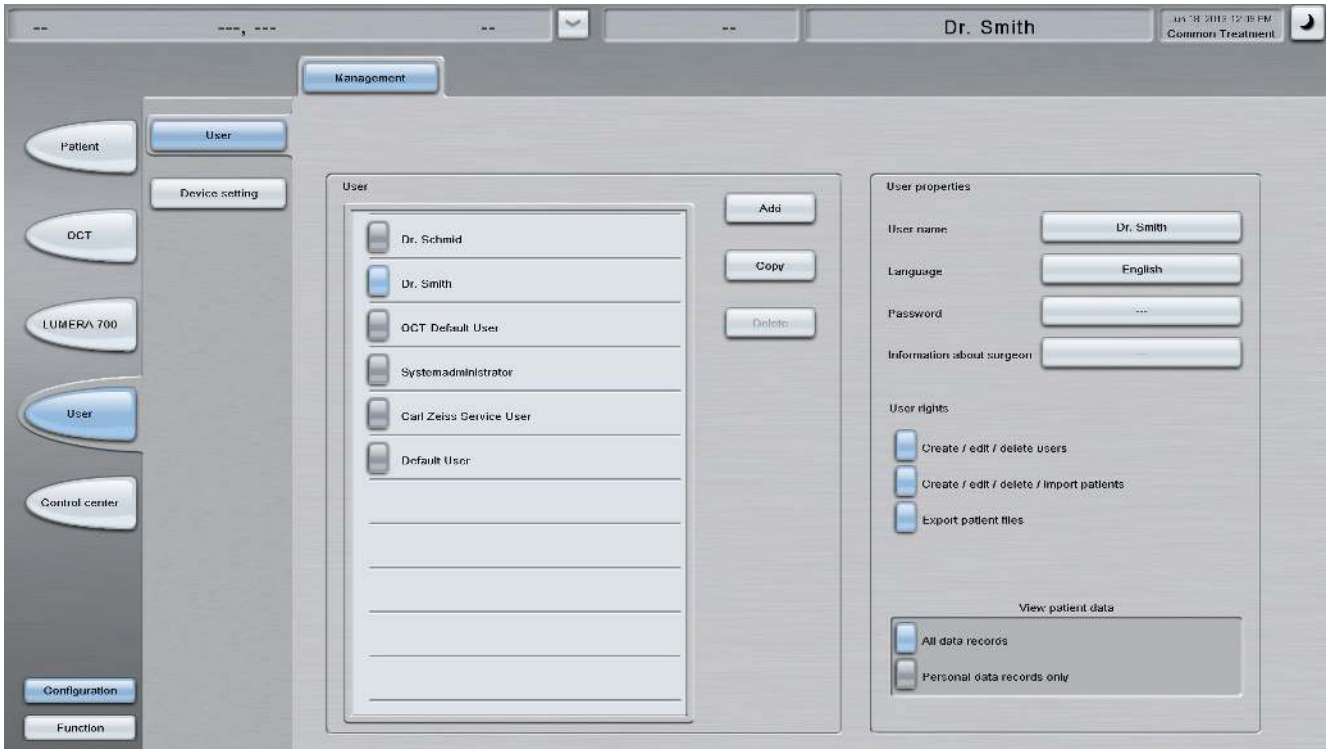
The user who is currently active is displayed in the field "User" (in the header).

Procedure

- Press the <User> button.

  → User Administration opens.

- Press the <Configuration> button.
- Select the sub-menu "User".



- Press the <Add> button.

  → The keyboard opens.

- Enter the name of the new user.

  → The new user appears in the "User" list, and is created using the following settings:

  – Language: English

  – no password

  – no information regarding surgeon

  – Rights to create/edit/delete patients, to export patient data and to view personal data records; no right to create users.

- Select the new user.

- If necessary, edit the settings for the new user in the "User properties" area.

Result → The new user is created. The user appears in the "Selection" tab of User administration (Functions view) and can be activated there.

Switching user

The currently active user is displayed in the "User" field (in the header).

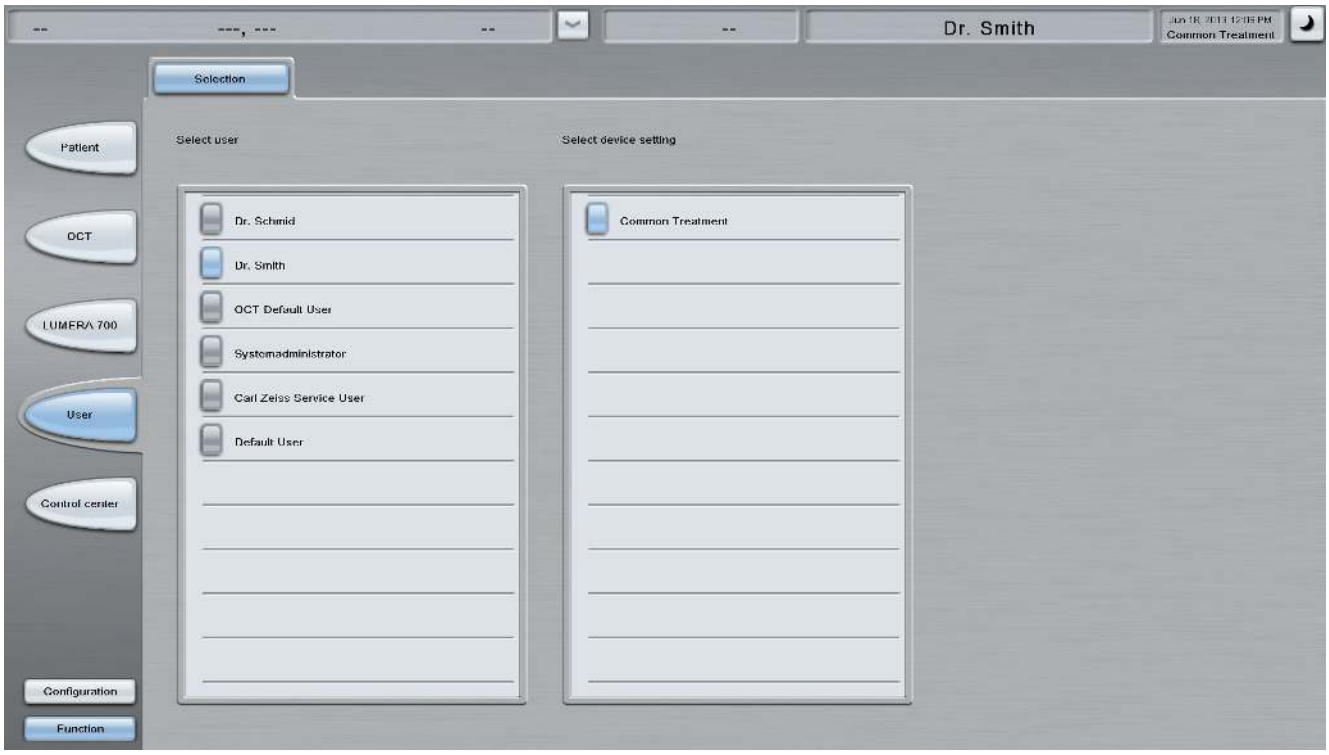
The user cannot be switched if a patient currently has "active" status. (Status "active": see page 112).

Procedure

- Press the <User> button.

  → User Administration opens.

- Press the <Function> button.



- Select the desired user.

  → If a password was saved in the user data, this will be requested.

- Enter the password, where applicable.

Result

→ All saved configurations for the activated user will be loaded (language setting for User interface, rights, device settings, OCT presets).

→ The "User" field in the header bar will be labeled with the name of the active user.

→ Only those patients will be displayed in the patient list for whom the user has the right to view the data (see page 113; see Rights see page 177).

Switching a device setting

Device settings are user-specific settings.

The currently active user appears in the "User" field; the currently active device setting is displayed below the date in the header.

Changing the device setting can be done in several ways:

- in the "Patient" tab in the "Patient" menu (see page 69)
- in the "Selection" tab in the "User" menu (see page 71)
- in the "Workflow steps" tab of the "LUMERA 700" menu (see the Instructions for Use for the LUMERA 700 surgical microscope).
- by pivoting the RESIGHT 700® module
- by pressing an appropriately configured button on the foot control panel or hand grips (see the Instructions for Use for the LUMERA 700 surgical microscope)

Please note: The selected device setting will not be saved with the currently open or active patient.

Prerequisite

- ✓ The user for whom the device setting is to be switched, must be active (see page 67).
- ✓ Device settings must be configured for the user for whom the device setting is to be switched (only settings created under the name of the logged-in user can be loaded; see page 47).

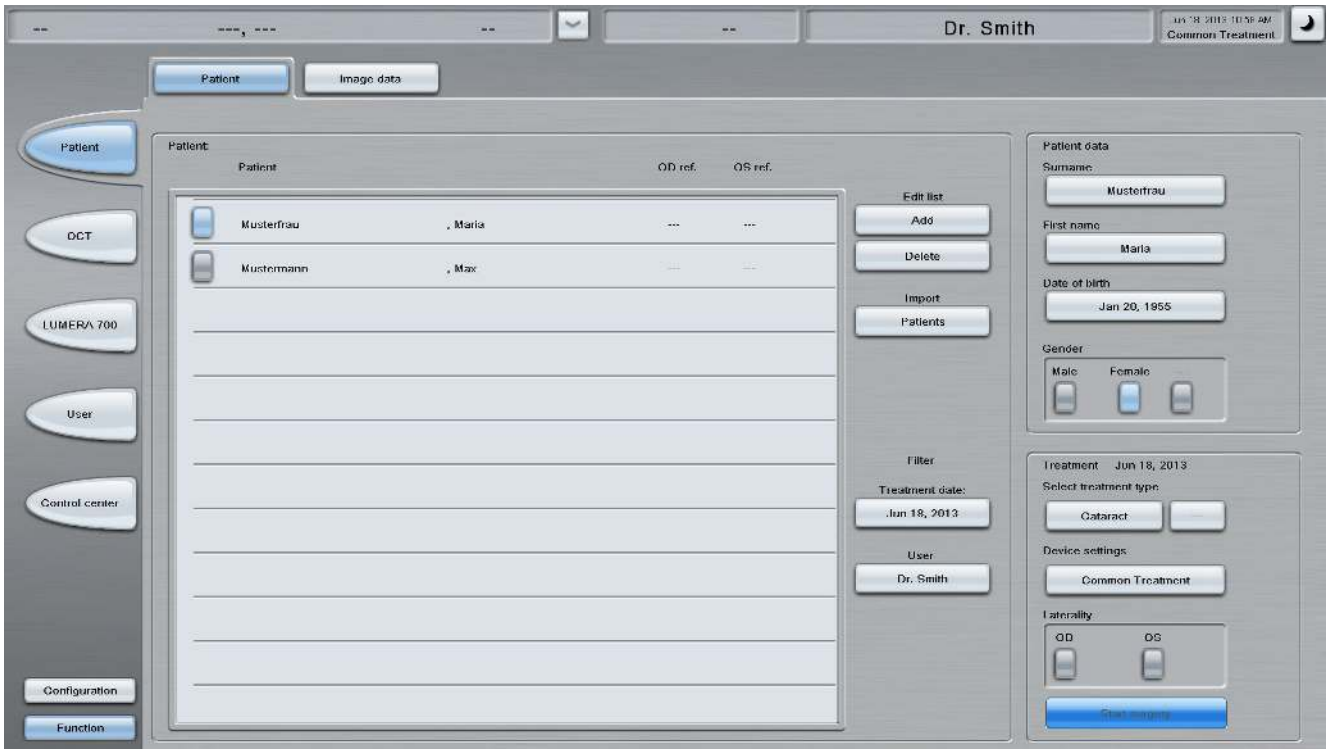
Switching a device setting in patient administration

Procedure

- Press the <Patient> button.

  → Patient administration opens.
- Press the <Function> button.
- Activate the "Patient" tab.
- Select a patient.

The chosen device setting is not saved under the patient. In order to be able to select a device setting, a patient must be selected (or activated).



- Press the <Device settings> button in the "Treatment" area.

  → A selection list opens containing device settings created for the logged-in user
- Select the desired device setting.

Result

→ The selected device setting is activated, i.e. the last settings made under this name (see page 47) are sent to the connected devices.

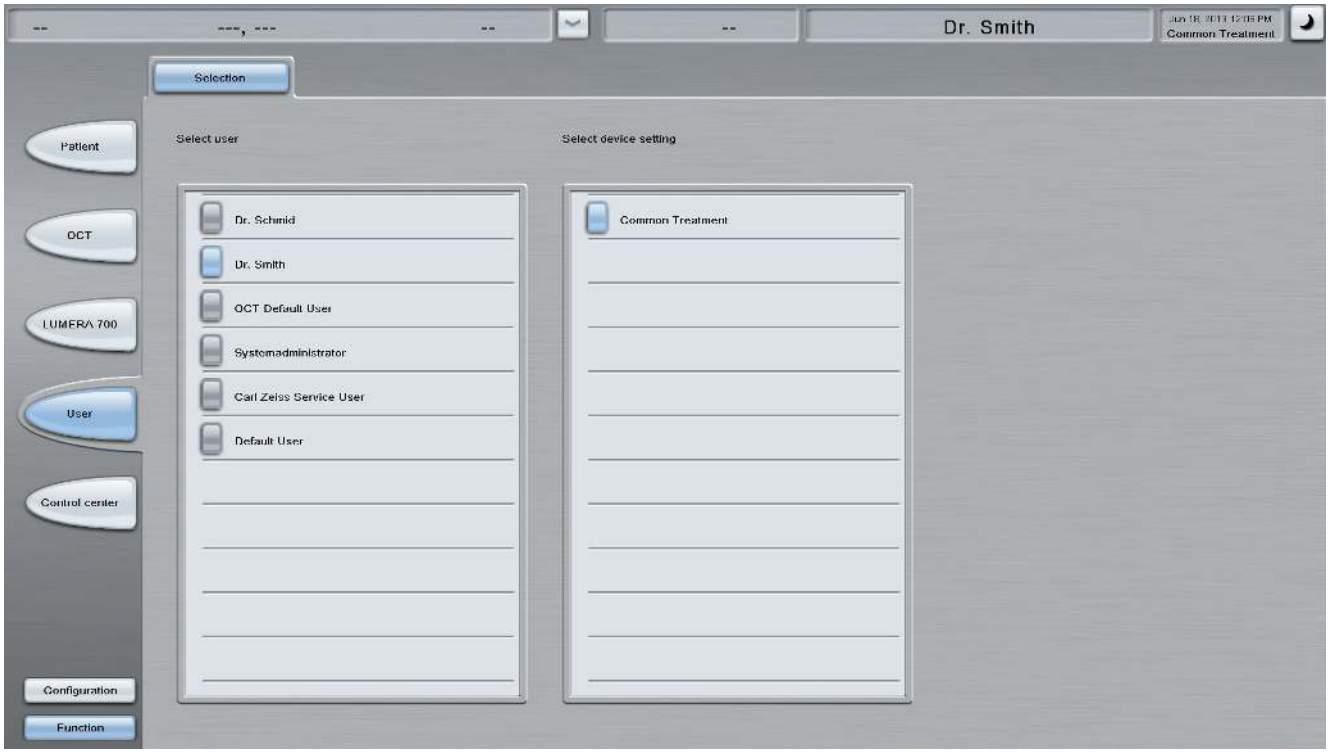
Switching a device setting in user administration

Procedure

- Press the <User> button.

  → User Administration opens.

- Press the <Function> button.



- Select the desired device setting.

Result

→ The selected device setting is activated, i.e. the last settings made under this name (see page 47) are sent to the connected devices.

Patient administration

Creating a new patient or new treatment

You can only create one treatment at a time for each patient. After completion of the treatment or recording of the operation you can however amend the data (e.g. different treatment type, different eye) and re-start recording of the operation. Every started operation is saved as a separate treatment.

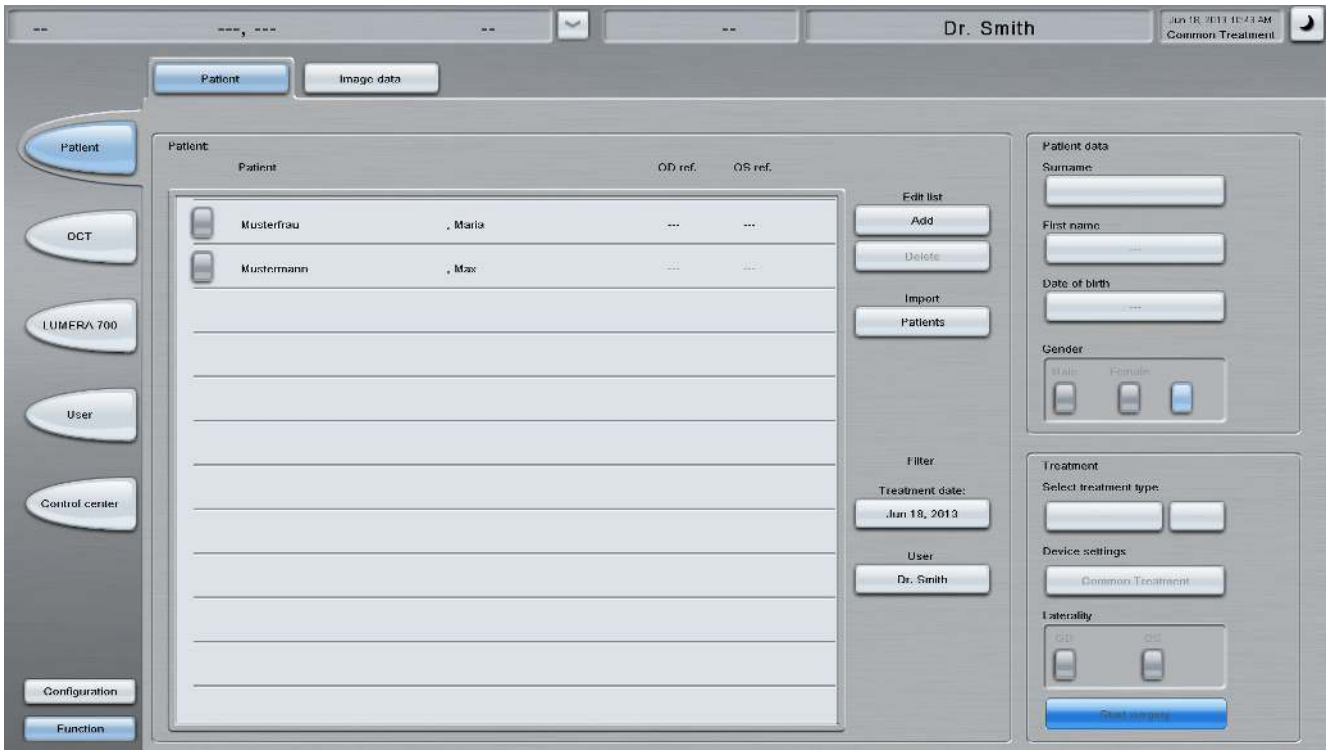
Prerequisite

✓ The active user has the relevant rights (see "User rights" and "View patient data" on page 177) or data protection is de-activated.

Procedure

- Press the <Patient> button.

  → Patient administration opens.
- Press the <Function> button.
- Activate the "Patient" tab.



- Press the <Add> button.

  → A new blank line is added to the patient list. The line is selected automatically.

- Enter the data for the new patient in the "Patient data" area.

  → The name of the new patient appears under Patient.

  → The current date is entered into the "Treatment" area.

- Enter a treatment type.

  – A desired treatment type is entered using the keyboard. Open the keyboard by pressing the button ....

  – You can open a list from which to select a treatment type by pressing the left button.

  The list then only contains entries if the logged-in user has already entered the treatment types using the keyboard and has also started these treatments (see page 118).

CAUTION

To prevent treatment errors, please observe the following:

- When entering or editing treatment data, please ensure that the correct patient data record is being displayed.
- Before every treatment, verify the patient and treatment data using sources of information outside of CALLISTO eye.

- Select a device setting, if desired (see page 47).
- Define the laterality.

  → The button <Start surgery> becomes active.

Result

→ The new patient or new treatment are created.

→ The patient can be activated by pressing the <Start surgery> button, i.e. live video recording of the treatment can be started and photos and OCT videos and recordings can be saved (see page 80, page 84 and page 92). (If the <Start surgery> button is pressed, CALLISTO eye automatically switches to the "LUMERA 700" menu).

Please note: Treatment type, device setting and laterality are not saved with the patient. Entry of this data is only of importance if you activate the patient immediately after entering this data.

Import patient data

CALLISTO eye gives you the option of importing patient data. To do this the patient data must be saved in a CSV file. The file can contain surname, first name, date of birth and the gender of the patient. How to create an importable CSV file is described on page 117.

CALLISTO eye treats imported patient data as the personal data records of the user who was logged in during the importing process. This means they can only be viewed by other users if they have the right to see all data records.

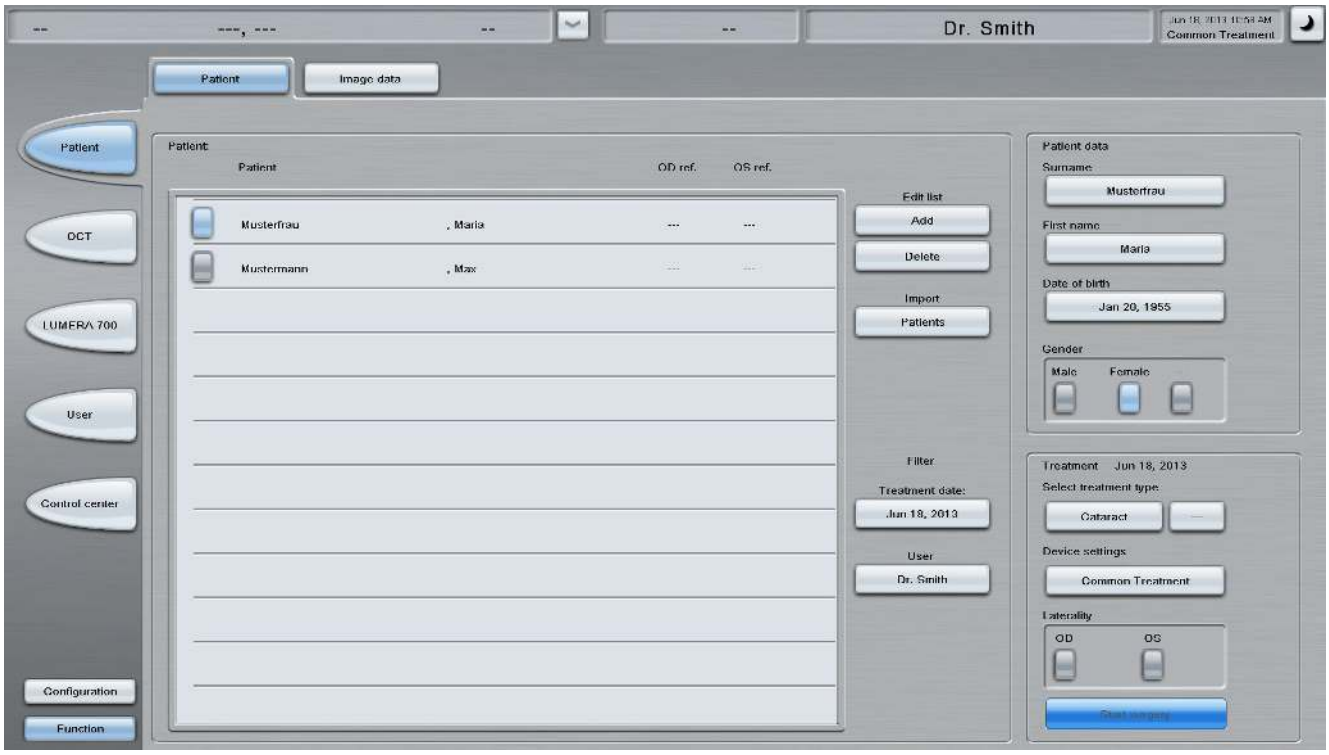
Prerequisite

- ✓ The data to be imported are located on a USB memory medium, e.g. a USB stick.
- ✓ The active user has the rights to import patient data (see "User rights" on page 177) or data protection is de-activated.

Procedure

- Connect the memory medium containing the data to be imported to one of the CALLISTO eye USB connections (see page 37).
- Press the <Patient> button.

  → Patient administration opens.
- Press the <Function> button, if applicable.
- Activate the "Patient" tab.



- Press the <Patients> button.

  → A window opens in which to select the file to import.

- Select the file to be imported and press the <OK> button.

  → A message with statistical data appears (number of imported patients, number of non-imported patients).

All the patients contained in the file will be imported. A file may contain a maximum of 500 patient data records.

Result → The imported patients are saved in CALLISTO eye as personal data of the logged-in user and are displayed in the list under Patient.

Changing patient or treatment data

Prerequisite

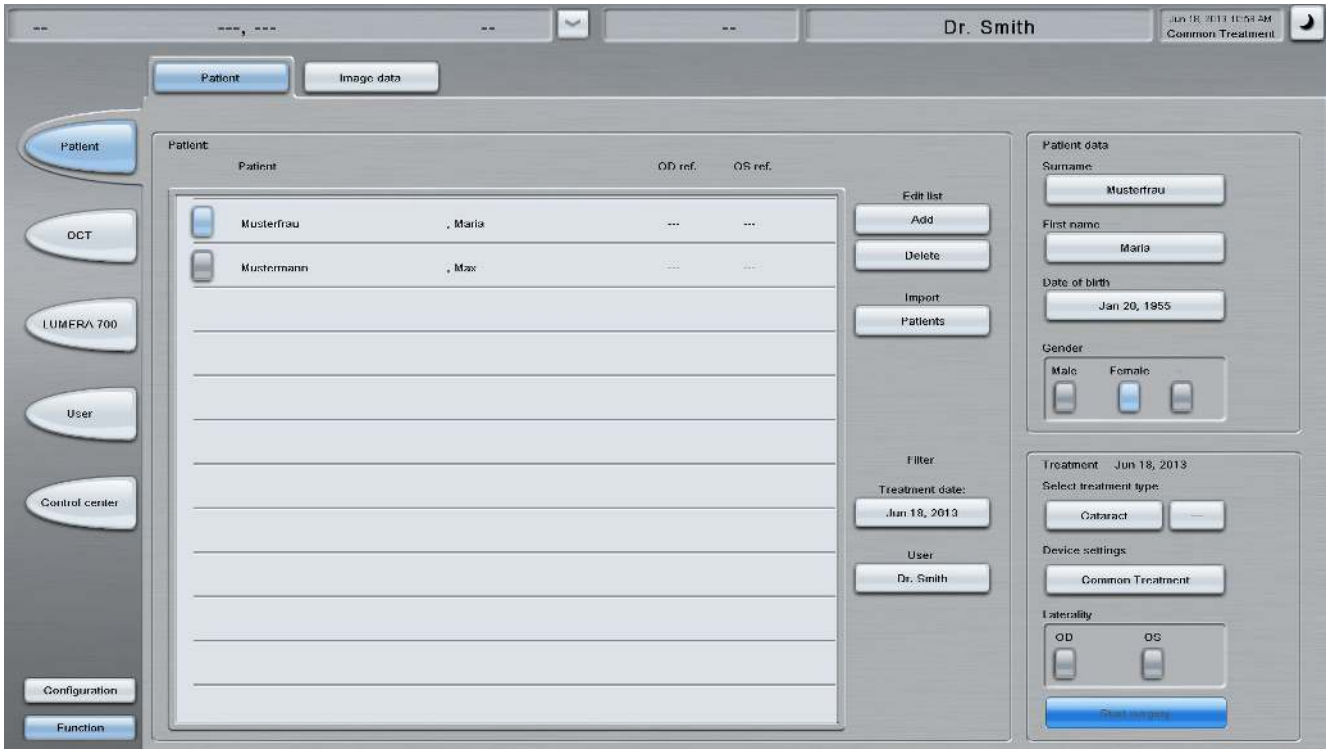
✓ The active user has the relevant rights (see "User rights" and "View patient data" on page 177) or data protection is de-activated.

Procedure

- Press the <Patient> button.

  → Patient administration opens.

- Press the <Function> button.
- Activate the "Patient" tab.



- Set the filters <Treatment date> and <User> so that the desired patient appears in the Patient list.
- Select the desired patient in the list.

  → The data held in the system for the selected patient is displayed in the "Patient data" and "Treatment" areas.

CAUTION

To prevent treatment errors, please observe the following:

- When entering or editing treatment data, please ensure that the correct patient data record is being displayed.
- Before every treatment, verify the patient and treatment data using sources of information outside of CALLISTO eye.

- Change the data as required.

Result → The amended data will be saved immediately after entry.

Display live microscope image

The live video image from the LUMERA 700 surgical microscope can be displayed in large format on CALLISTO eye. The tabs "Illumination", "Position" and "Workflow steps" can be displayed in the function view of the "LUMERA 700" menu. The display is identical in all three tabs.

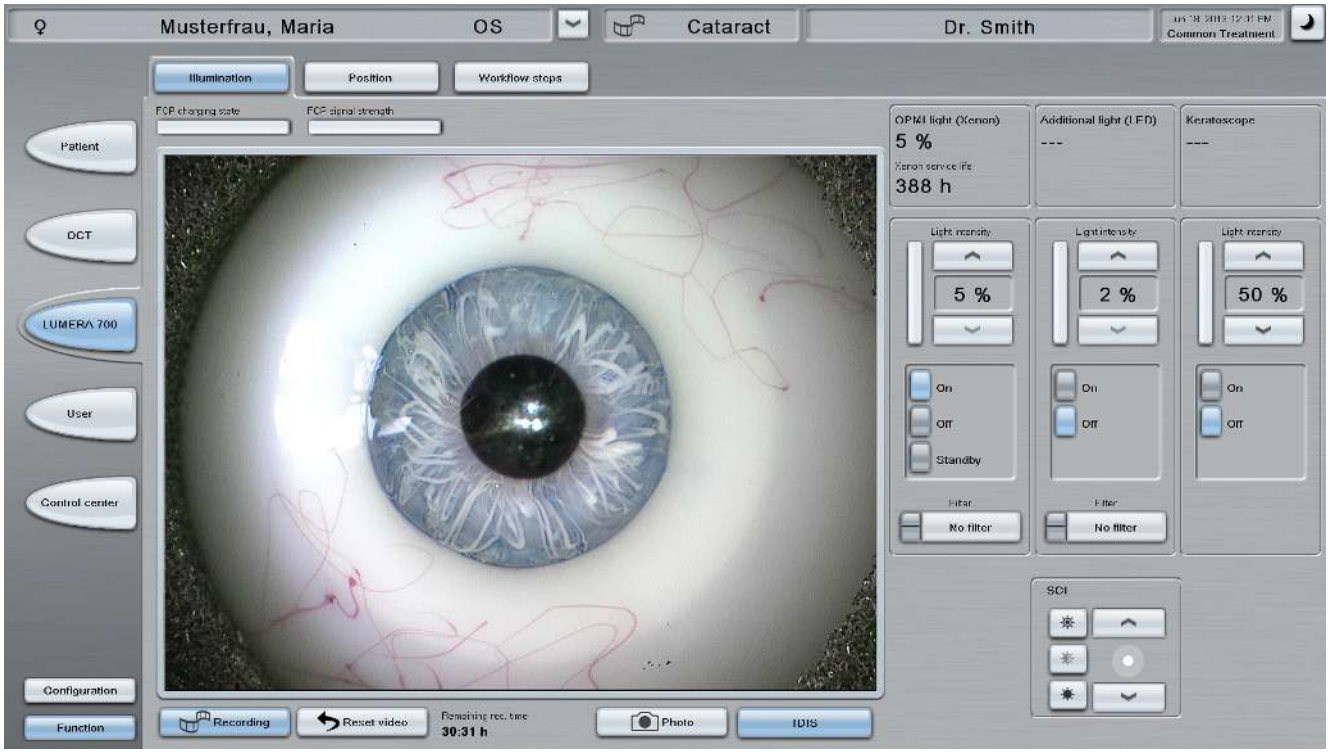
If a patient has status "active", you can start, pause, discard or end a video recording in these tabs and can also save image stills (see page 80).

Prerequisite

✓ The LUMERA 700 surgical microscope must be connected to CALLISTO eye and be ready to operate.

Procedure

- Press the <LUMERA 700> button.
- Press the <Function> button.



Result → The CALLISTO eye screen shows one of the three tabs "Illumination", "Position" or "Workflow steps" displaying the live image from the surgical microscope.

The tab shown is the one the user last activated. If the user has not opened any of the three tabs since logging on, the "Illumination" tab is displayed.

Touching the video image switches CALLISTO eye to a full format display of the video image. To return to the normal view you press the button displayed in the full format display  .

Full picture mode is automatically unavailable if a fault occurs or there is a change in the device setting.

Pressing the <IDIS> button allows data injection to be switched on or off in the OPMI LUMERA 700 eyepiece.

Data injection is displayed when the <IDIS> button is blue. For configuration of data injection see page 167.

Recording a video of an operation

You can record two different types of videos with CALLISTO eye: A video of the live image from the surgical microscope, and an OCT video that in addition to the live image from the surgical microscope also contains OCT images. The following description refers to video recording of the live image from the surgical microscope. Recording of an OCT video is described at page 93.

The patient must be activated in CALLISTO eye to be able to record a video of a live operation. Depending on the configuration of CALLISTO eye (see page 54), video recording starts automatically after the patient is activated, or must be started manually.

The video picture from a surgical microscope connected to CALLISTO eye is displayed in the "Illumination", "Position" and "Workflow steps" tabs of the Function view of the "LUMERA 700" menu (see page 78). The display is identical in all three tabs.

As long as a patient has an "active" status you can save photos (digital images) (see page 84). You can interrupt a video recording while it is being done, then resume again (see page 83) and can also discard a video recording in progress and re-start (see page 84). The patient retains the status of "active" throughout.

Activate patient and start video recording

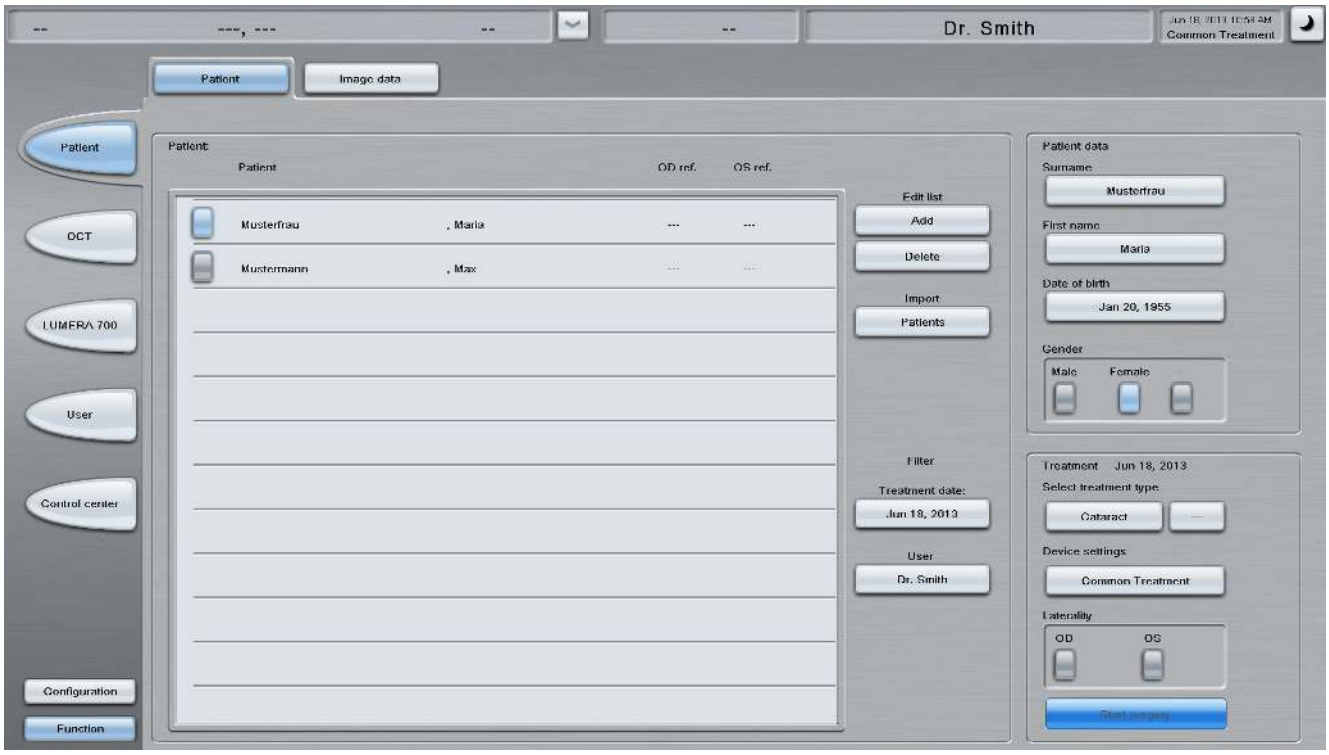
Prerequisite

- ✓ The LUMERA 700 surgical microscope must be connected to CALLISTO eye and be ready to operate.
- ✓ The patient for whom the video recording is to be created must exist in the system.

Procedure

- Press the <Patient> button.

  → Patient administration opens.
- Press the <Function> button.
- Selected the "Patient" tab.



- Change the filter settings if the desired patient cannot be displayed.
- Select the desired patient in the Patient list.

  → The indicator field in front of the patient's name appears blue.

⚠ **CAUTION**

To prevent treatment errors, please observe the following:

- When entering or editing treatment data, please ensure that the correct patient data record is being displayed.
- Before every treatment, verify the patient and treatment data using sources of information outside of CALLISTO eye.

- Select laterality (OD or OS).
- Press the <Start surgery> button.

  → The selected patient will be activated.

  → A black triangle appears in the patient list before the patient's name.

  → If neither first name nor surname were entered when creating the patient file, the patient is automatically assigned the designation "Pat_YYYYMMDD_HHMM" (YearMonthDay_Time).

  → The starting time for the treatment is set to the current system time.

  → The <Start surgery> button is replaced by the <End surgery> button.

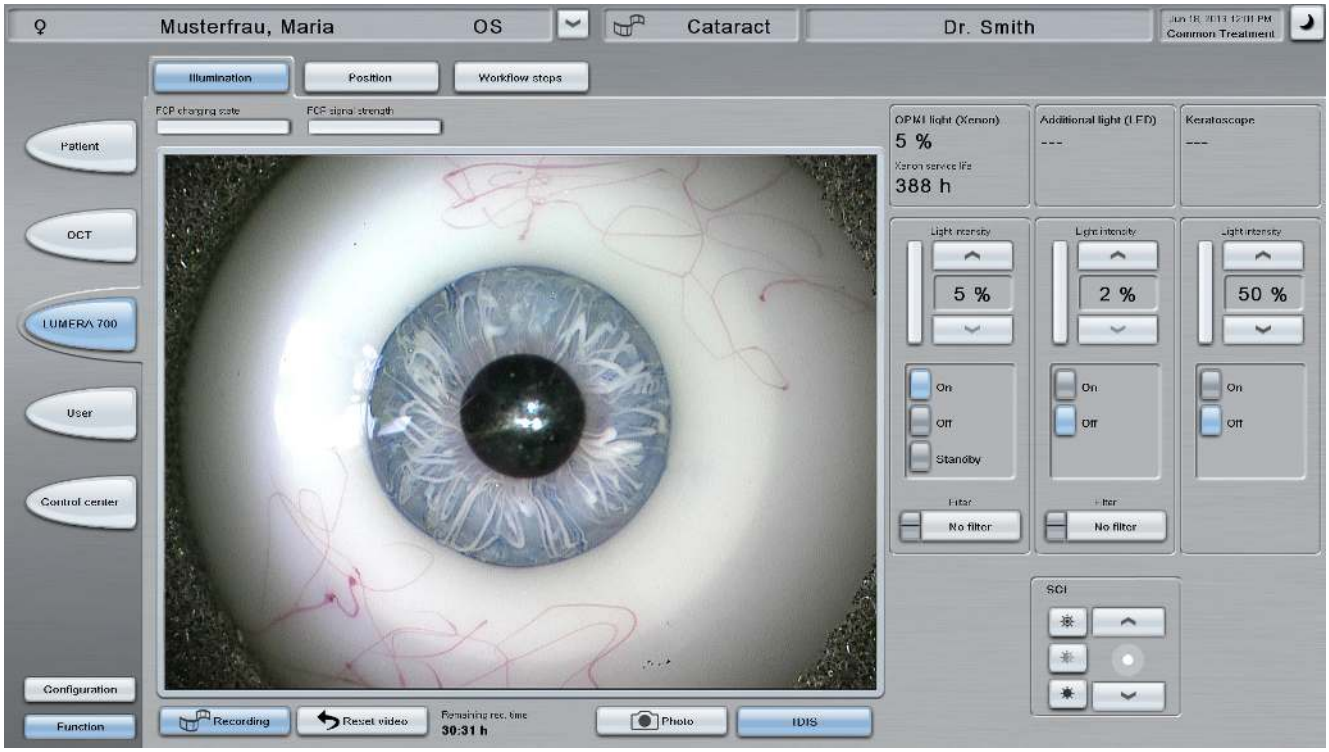
→ The "Patient" field in the header bar will be labeled with the name of the activated patient.

→ The button to the right of the "Patient" field becomes activated. Pressing this button opens a window in which the most important patient data is displayed in large format (see page 106).

→ The treatment type entered in the "Treatment" area is displayed in the second field from the left.

→ CALLISTO eye changes automatically to the Function view of the "LUMERA 700" menu. The current live image is displayed in one of the three tabs "Illumination", "Position" or "Workflow steps".

The tab shown is the one the user last activated. If the user has not opened any of the three tabs since logging on, the "Illumination" tab is displayed.



→ With the appropriate configuration (see page 54), video recording starts automatically. The <Recording> button turns blue.

If during configuration it was specified that video recording should not start automatically (see page 54), the <Recording> button is gray. The recording can then be started manually.

- If the video recording does not start automatically: Press the <Recording> button.

Result

→ Video recording operates. This is indicated by the icon  in the "Treatment" field in the header.

→ The video recording can be interrupted, continued, discarded and restarted (see page 83 or page 84).

→ Freeze frames can be saved (see page 84).

Interrupting active video recordings

Procedure

- Press the <Recording> button.

Result

→ The video recording is interrupted. The patient remains activated.

→ The video recording made up to this point is saved; a start and end image are created for the video and saved with the date and time of its generation.

The video, start and end images can be viewed in Patient administration in the "Image data" tab.

→ The <Recording> button is then gray.

→ The <Reset video> button is disabled.

Continuing video recording

Procedure

- Press the <Recording> button.

Result

→ Video recording is continued; a new video file is generated.

→ The <Recording> button turns blue.

→ The <Reset video> button is activated.

Discarding running video recordings

Procedure

- Press the <Reset video> button.

Result

→ The previous video recording is terminated and discarded (not saved). **No safety prompt** is given. The patient remains activated.

→ The starting time for the treatment is set to the current system time.

→ A new video recording starts.

Saving still images

Procedure

- Press the button 

.

Result

→ The image is saved. This can be viewed in the Patient Administration Function view, "Image data" tab.

Terminating a video recording (Deactivating patient)

Procedure

- Press the <Patient> button.

  → Patient administration opens.
- Press the <Function> button.
- Activate the "Patient" tab.
- Press the <End surgery> button.

Result

→ The video recording will be terminated. The video will be saved, start and end images will be created and also saved.

→ The icon  in the "Treatment" field in the header bar is no longer displayed.

→ The selected patient will be de-activated.

→ The black triangle before the patient's name is removed in the patient list.

→ The laterality shown in the "Treatment" area is deleted.

→ The patient name is removed from the "Patient" field in the header.

→ The button to the right of the "Patient" field will be de-activated.

Operating the surgical microscope remotely

Many functions and settings on the LUMERA 700 surgical microscope as well as the foot control panel and the hand grips can be remotely controlled from the CALLISTO eye using the optional remote control functions in the "LUMERA 700" menu.

Please note: All changes made in Configuration view tabs in the "LUMERA 700" menu are automatically saved under the name of the active device setting (exception: if the currently active user is one of "Systemadministrator", "ZEISS Service User" or "Default User"). This means that existing device settings will be overwritten. If you don't want to overwrite the current settings, you should then start by first creating a new device setting (see page 47 or page 69).

Changes made in Function view tabs will not be saved.

CAUTION

To prevent personal injuries due to unexpected equipment behavior, please observe the following:

- When changing settings, please ensure that the correct user and correct device setting are activated.

The active user and active device settings are displayed in the header on the user interface (third and fourth field from the left).

Controllable functions for the OPMI LUMERA 700 are described in the microscope's Instructions for Use. Familiarize yourself with the operating functions before performing any settings on CALLISTO eye.

Prerequisite

✓ The surgical microscope must be connected to the CALLISTO eye and be ready to operate.

Procedure

- Press the <LUMERA 700> button.

  → The "LUMERA 700" menu is opened.

- Make the required settings (see the OPMI LUMERA 700 Instructions for Use for details).

Result → The settings are transferred to the surgical microscope or foot control panel.

Please note: For OCT function control, CALLISTO eye offers a special button configuration for the foot control panel (see page 158). This configuration is automatically activated when the "OCT" Menu is opened. The foot control panel OCT configuration is preconfigured in the factory and cannot be changed (with the exception of the rocker switch).

→ Changes made in the Configuration view tabs are automatically saved under the name of the active device setting.

Perform OCT visualization

Using the CALLISTO eye OCT functions you can perform Optical Coherence Tomography visualization. The results can be viewed live on the CALLISTO eye screen. You can save as many OCT images/recordings as you like for a patient. You can switch at any time between the Live Scan display and saved recordings display. You can therefore compare OCT scans of different areas of the patient eye or cross-compare scans produced with different parameters. Saved OCT images can be viewed on the CALLISTO eye screen and in the eyepiece of the LUMERA 700 surgical microscope.

You can also control some OCT functions using the foot control panel (see page 158).

You can configure presets for some OCT functions (Configuration view of the "OCT" menu, see page 151). Your presets are always activated when you log on as a user.

If during visualization you change in the Function view ("Live" tab) a parameter set by a preset, the changed settings apply until you change them again or until another user logs in to CALLISTO eye.

General Information

CAUTION

The OCT functions may only be used with the video camera built into the LUMERA 700 surgical microscope.

CAUTION

- To prevent personal injury due to unexpected equipment behavior, perform function testing of the system prior to commencing treatment.
- To prevent infection and personal injury resulting from erroneous data interpretation, use only the drapes approved exclusively for the device.
- Before commencing the operation, check adjustment of the surgical microscope and data injection (IDIS).

Perform live OCT visualization

Prerequisite

✓ The LUMERA 700 surgical microscope including the OCT camera must be connected to CALLISTO eye and ready to operate.

✓ The patient to be treated must be in the system and activated (see page 80) if OCT photos, vidoes or recordings are to be saved.

⚠ **CAUTION**

To prevent treatment errors, please observe the following:

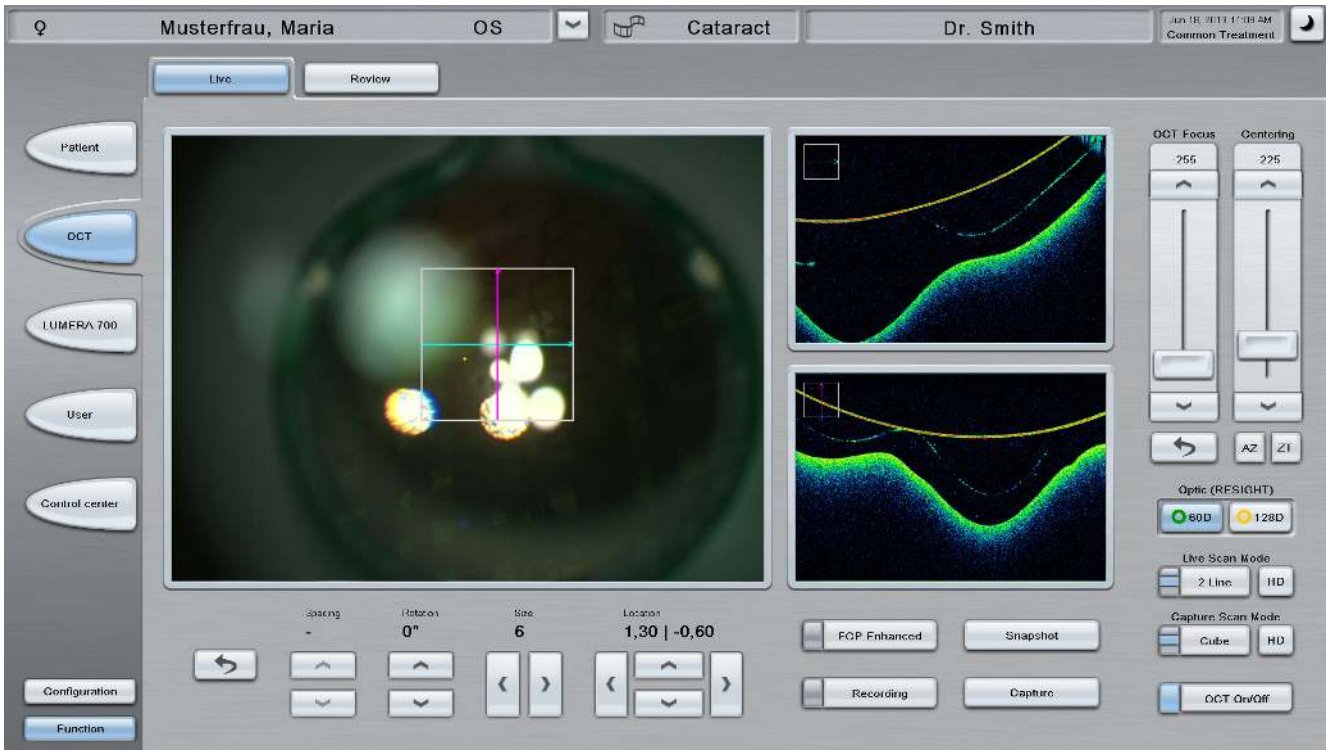
- Please make sure that the correct patient was activated.
- Before every treatment, verify the patient and treatment data using sources of information outside of CALLISTO eye.

Procedure

- If necessary for visualization, pivot the RESIGHT 700 add-on module on the microscope.
- Using the microscope controls ("LUMERA 700" menu or directly on the microscope) zoom in on the area of the eye you want to examine and fine-tune the microscope image.
- Press the <OCT> <Function> buttons onscreen or bottom-right button on the foot control panel.

  → The foot control button configuration switches to the OCT configuration (see page 158).

  → The "Live" tab is displayed.



→ When using the RESIGHT 700 module in the "Posterior" device setting, setting of the OCT Focus and scan level occurs automatically (Slider "OCT Focus" and "Centering" in the "Live" tab); the software then switches to automatic guidance of the centering process, (Z-tracking, indicated by blue coloring of the <ZT> button).

Z-tracking means that centering is automatically corrected when the level to be examined shifts (e.g. because structures move in the z direction due to the doctor's actions).
As long as Z-tracking is switched on, centering can only be readjusted using the "Centering" arrow keys and not using the slider.

For recordings without the RESIGHT 700 fundus viewing system, the z-plane of the OCT is parfocal to the focal plane of the microscope.

→ The live microscope image is displayed on the left.

→ The Scan Location Marker is shown superimposed in the microscope image (depending on the live scan type setting, one, two mutually perpendicular lines or five parallel lines).

You can preconfigure the live scan type setting (see page 152), and also in the "Live" tab.

→ Depending on the live scan type setting, one, two or five images, are displayed on the right next to the microscope image. Depending on the presetting the images are in grayscale or color (see page 157).

→ Touching the video image or an OCT image switches CALLISTO eye to a full format display of the video image or OCT image. To return to normal view press the button appearing in the full format display  .

Full picture mode is automatically unavailable if a fault occurs or there is a change in the device setting.

→ If the RESIGHT 700 module is in a pivoted position the "Optic (RESIGHT)" buttons are displayed, otherwise the "Optic" buttons appear.

- Select the correct optics setting:
  - If the RESIGHT 700 module is in a pivoted position, press the button corresponding to the selected magnifier <60D> or <128D).
    → Blue coloring of one of the two buttons shows the corresponding setting is selected.
  - If the RESIGHT 700 module is not pivoted:

    Press button  if you are using a flat contact lens for the vitrectomy[1], otherwise button  .

    → Blue coloring of one of the two buttons shows the corresponding setting is selected.
- If necessary select the desired Live Scan Type.
  → The corresponding Scan Location Marker is displayed in the microscope video image.
  → Next to the video image, one, two or five OCT images are displayed, depending on the scan type selected.
- Set the desired resolution by pressing the <HD> button.
  → If the <HD> button is blue this means that high resolution (HD, 1024Px) is selected. If the button is gray, lower resolution has been selected (SD, 512 Px).

1. tested using a "DORC 1284.DD flat vitrectomy lens"

- Position the Scan Location Marker at the desired location using the <Rotation> and <Location> arrow keys.

You can change the increment for changing the position in the "Live Settings" tab of the Configuration view (see page 152).

- Set the size and (if scan type "5 Line" is selected) the line spacing.
- If necessary optimize the OCT Focus and centering.

CAUTION

- Make certain that there are no instruments or other items within the field of view of the live image that will partly or fully obscure the area to be examined.
- Also ensure that no unwanted reflections are produced as these affect the result.
- Check the displayed data for accuracy.

Result

→ The result of the OCT scan is displayed on the right next to the video image.

→ You are free to change the scan parameters at any time. The OCT scan images show the result immediately after change to the parameters.

→ You can save the results of OCT visualization if a patient has an "active" status:

- You can start and stop the recording of an OCT video (<Recording> button). This contains the microscope image and OCT image(s).
- You can save a digital image (<Snapshot> button). This contains the microscope image and OCT image(s) in an image file.
- You can save an OCT recording (<Capture> button). This contains the microscope image and OCT image(s) in their own respective image files.

All saved OCT recordings can be viewed in the "Image data" tab of the "Patient" menu (see page 122). Saved OCT recordings can also be viewed in the "Review" tab as long as the patient has "active" status (see page 95).

Manually starting an OCT video recording

You can specify that the OCT video recording starts automatically when the "Live" tab is opened (see page 55). In this case of course you do not have to start the recording manually.

Press the <Recording> button.

→ The video recording starts.

→ The blue color of the indicator field in front of the <Recording> button shows that the OCT Video Recording is running.

Ending running video recordings

Procedure

- Press the <Recording> button.

Result

→ The OCT video recording is terminated. The patient remains activated.

→ The OCT video recorded up to this point is saved. It can be viewed in Patient Administration, tab "Image data".

→ The indicator field in front of the <Recording> button is gray.

→ The OCT video recording can be restarted by pressing the <Recording> button.

Video recording automatically stops when scanning finishes. Scanning is not only terminated when you press the <Recording> button, but also when you press the <Capture> button or <OCT On/Off> button, or you switch to a different tab.

Save Snapshot

Procedure

- Press the <Snapshot> button.

Result

→ The snapshot is saved. This can be viewed in the Patient Administration Function view, "Image data" tab.

Save OCT image (Capture)

Procedure

- Select the desired Capture scan type ("1 Line", "Cube" or "5 Line") and the desired scan resolution.

  → Blue color of the <HD> button shows that high resolution is selected (HD or 512 x 128).

  If the <HD> button is gray, lower resolution has been selected (SD, or 200 x 200).

Please note: You can select the Capture scan type and Capture resolution independently of the live scan type and its resolution. The settings for line spacing and scan size apply to live scans and capture scans.

- Press the <Capture> button.

To achieve a good result, the eye should be kept still during recording.

Result

→ The recording is saved.

→ The recording can be viewed in the "Review" tab as long as the patient has the "active" status (see page 95).

During display of a recording in the "Review" tab, the OCT images are also shown in the eyepiece of the OPMI LUMERA 700.

→ Immediately after saving and also after the patient has been deactivated, the recording can be viewed in the Function View of Patient administration in the "Image data" tab (see page 122 and page 131).

View saved OCT visualization (Review)

You can view saved OCT recordings for the currently active patient in the "Review" tab of the "OCT" menu. This allows you to switch between the live view ("Live" tab) and the saved recordings view ("Review" tab) at the press of a button. During treatment you can therefore cross-compare the results of OCT visualization, e.g. of different areas of the eye or with different parameter settings.

All saved OCT recordings can be viewed in the "Image data" tab of the "Patient" menu at any time. (see page 122).

Please note: Any running OCT video recording is automatically ended when you change from the "Live" tab to a different tab.

Prerequisite

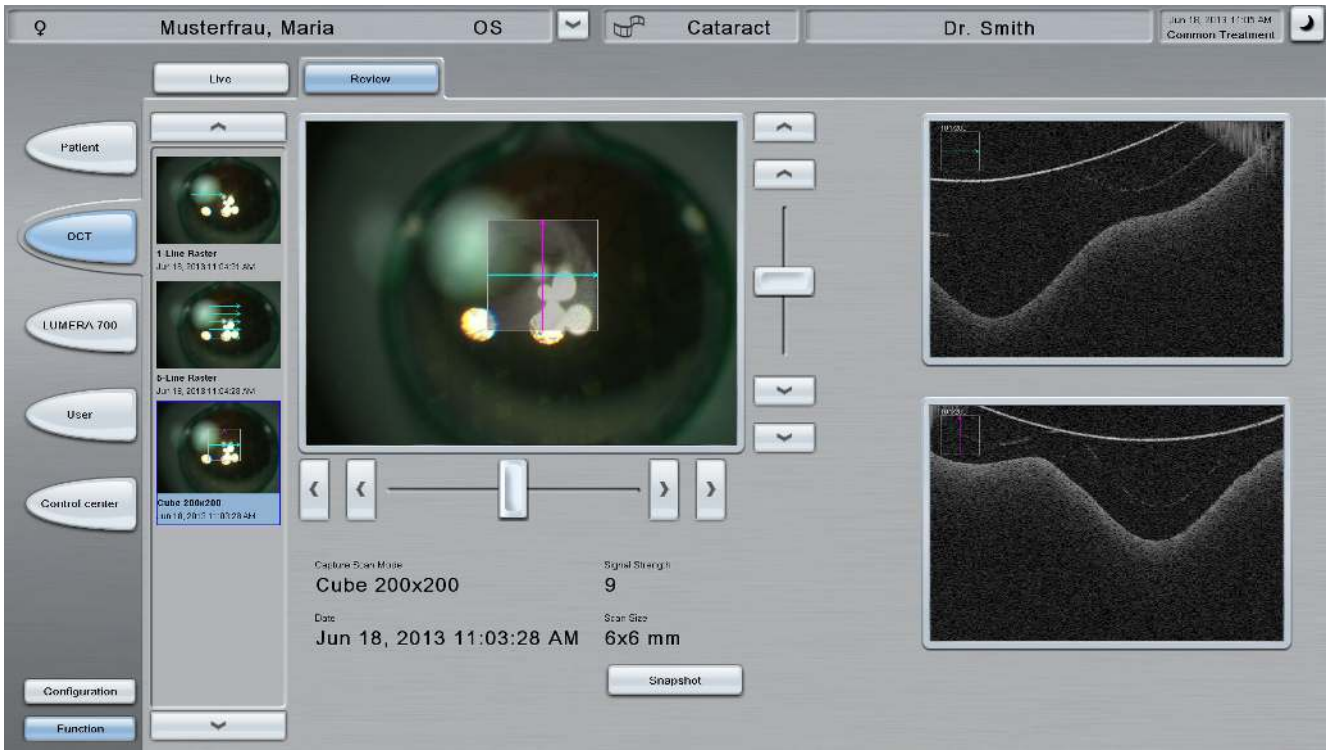
- ✓ You must have saved at least one OCT recording for the currently active patient.
- ✓ The patient must not have been deactivated since the recording was saved: In the "Review" tab, recordings for the patient are displayed until he is deactivated.

Procedure

- Press the <OCT> <Function> <Review> buttons onscreen or the top-right button on the foot control panel.

  → The "Review" tab is displayed.

  → The last saved recording is selected and displayed.



- Select from the thumbnail selection list the visualization you wish to display.

  → The selected visualization has a blue background.

Result

→ Depending on the capture scan type of the selected recording, one, two or five OCT scan images are displayed next to the saved microscope image.

If a "Cube" OCT visualization is selected, arrow keys and a slider also appear with which you can scroll through the recording:

- Use the outer arrow keys to start and stop automatic scrolling.
- Use the inner arrow keys to scroll through the recording in increments.
- Use the sliders to scroll quickly through the recording.

→ Various recording parameters are shown below the microscope image: Capture Scan type, Signal Strength, Scan Size and Recording date/Time.

The signal strength is determined by the OCT Camera for each recording. Value can be between 0 and 10. Optimum signal strengths are between 5 and 10. If a recording has a lower signal strength than 5, you should optimize focusing and repeat the recording.

→ Using the <Snapshot> key you can save a digital image. This contains the microscope image and, depending on the selected scan type, one, two or five OCT images.

Snapshots (photos) can be viewed in the Patient Administration Function view, "Image data" tab (see page 128).

Exporting treatment data

CAUTION

To prevent data loss, please observe the following:

CALLISTO eye is not an archiving system. You may under some circumstances no longer be able to access your data due to a malfunction.

The next user can delete unsecured data or it can be deleted in the event of a repair.

- Secure your data using a suitable data backup procedure.

Every user is personally responsible for backing up his/her own data.

As video recordings of surgeries in particular require a lot of memory space, and the memory capacity of the internal hard disk is limited, it is necessary to regularly backup any treatment data that is no longer needed and then to delete it (see page 140).

Data that are to be backed up or archived must be exported on an external USB memory medium.

Only completed treatments can be exported. This means treatments must have been started by pressing the button <Start surgery> and ended by pressing the button <End surgery> (see page 80).

The export of a treatment contains all documents saved for a particular patient with respect to the exported treatment on CALLISTO eye.

Exported data cannot be re-imported into CALLISTO eye.

CAUTION

It is the responsibility of the user to ensure that external memory media (e.g. USB sticks) used to exchange data are virus-free.

CAUTION

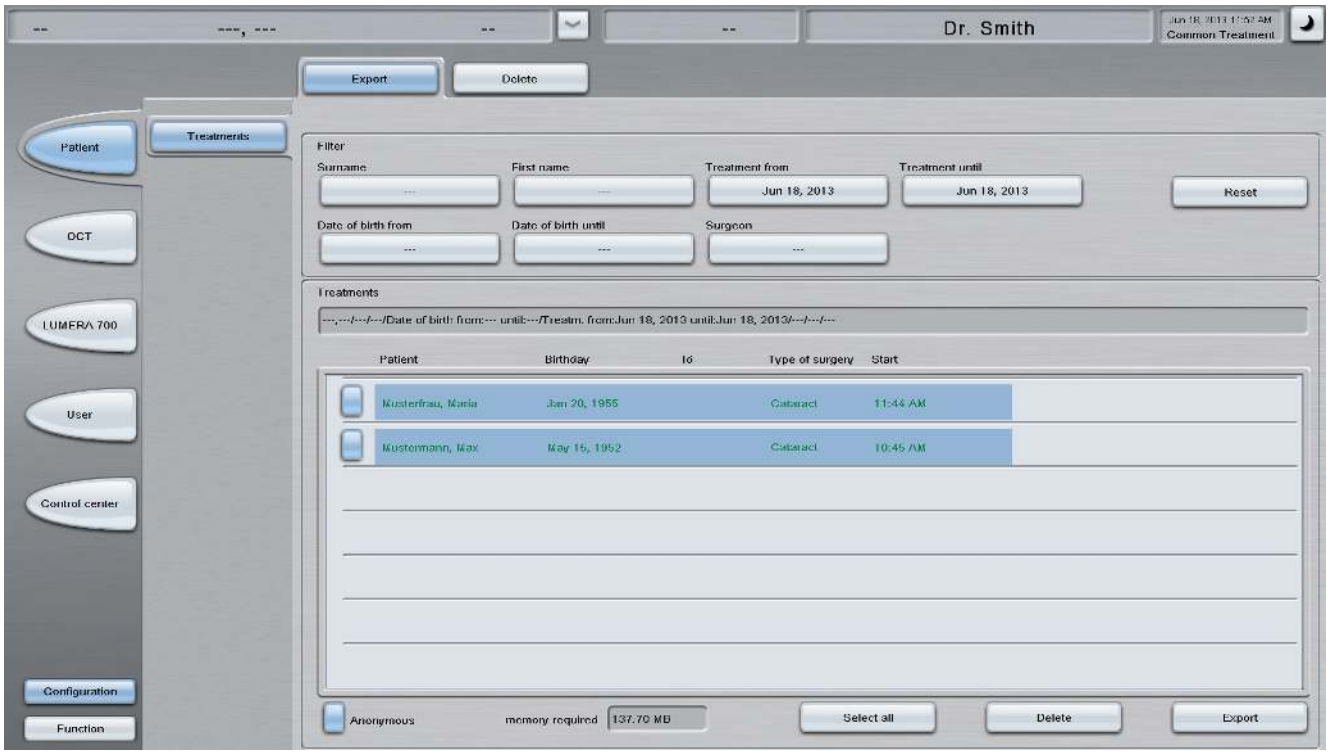
To avoid data protection violations, please observe the following:

- Export the data onto a medium that is protected against external access.

Procedure

- Connect a USB medium (stick, hard disk) to one of the USB connections on the CALLISTO eye.
- Press the <Patient> <Configuration> buttons.
- Select the "Export" tab.

  → All treatments corresponding to the current filter criteria are listed in the "Treatments" area.



- Change the filter criteria in such a way that at least all the treatments you want to export are displayed (you can make a more detailed selection later).
- De-activate the <Anonymous> button, if the export should not be anonymous.

  The button is colored blue when active, i.e. the export will be made anonymously (pre-set).

  With anonymous exports, treatment data is exported without patient data, i.e. the exported data can no longer be assigned to a patient.
- Select all the treatments to be exported from the list.

  → The required memory space is displayed in the field "memory required". Make certain there is sufficient space on the connected memory medium.

- Press the <Export> button.

  → A window appears in which the target directory for the export can be selected.

The button <Anonymous export> in this window is the same as the button <Anonymous> on the "Export" tab.

- Select the required target directory.

Please note: Opening the folder can take a few seconds.

Result:

→ The selected treatments are saved on the external USB memory medium. For data structure and file names, see page 138.

→ A window appears containing statistical data on the export.

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Introduction

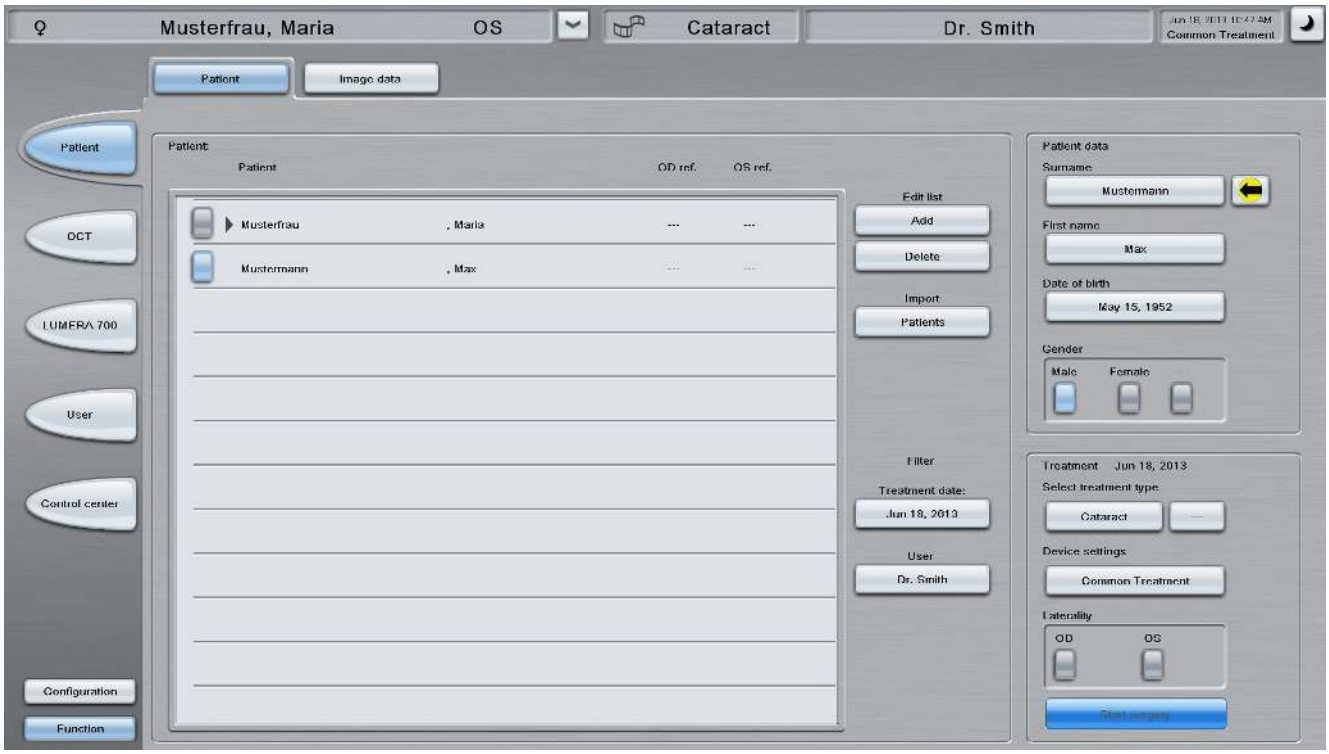
The graphical user interface on the touch panel represents the interface between the user and the system.

The software is subdivided into the following basic functions:

- Patient administration and operation recording
- Live Video (integrated into the OPMI LUMERA 700 remote control)
- Optical Coherence Tomography (OCT).
- Remote control of a surgical microscope LUMERA 700
- User administration
- Control center

Excepting the Control center, basic functions feature a Function view and a Configuration view. These views can be switched between at any time. The normal user interface is the Function view. The Configuration view can be used to perform fundamental and partially user-specific settings, and to access information about the system.

CALLISTO eye software user interface



The CALLISTO eye software user interface is divided into four areas:

– Header with display fields and a button.
  The fields are labeled with current selections and/or settings (active patient, active treatment, active user, date/time/active device setting).

– Menu buttons on the left
  (Patient, OCT, OPMI resp. LUMERA 700, User, Control center).
  Some menus additionally contain sub-menus which appear between menu bar and tabs after the menu is opened.

– Buttons to switch between Configuration view and Function view (lower left).

– Tabs with display, input and control fields (buttons).
  Each tab has a flag (button) at the top, used to call up the respective tab.

Buttons are special fields on the user interface: Pressing a button triggers a specific function or selects an option. Buttons can also serve as display fields.

The currently active menu item, currently active tab, and currently active selections and/or buttons are highlighted in blue.

Header bar

Patient	Displays the active patient: "[Gender] [Surname], [First name] [Laterality]". If no active patient is active, "-- --- , --- --" is displayed Active patient: see page 112.
	Displays the most important data of the active patient in large-size format in a separate window (see page 106).
Treatment	Displays the current treatment of the active patient. If the treatment is currently being videoed, the left side of this field will display an icon 
User name	Displays the user currently logged-in on the system (see page 172).
Date/time, device setting	Displays the current date and current time (setting see page 44). Displays the currently active device setting (activation see page 172).
	Switches between day and night mode. → The display is dimmed in night mode.

Displaying patient data in large-size format

If a patient has "active" status, pressing button ⌄ in the header to the right of the "Patient" field displays important patient data in large-size format.

Button

Close	Closes the large-size display of the patient data.

Menus

Buttons on the menu bar on the left side are used to open CALLISTO eye software functions or to control devices which can be connected to CALLISTO eye and operated remotely.

Menu bar

Patient	Opens Patient administration	see page 111
OCT	Activates the OCT function (Optical Coherence Tomography)	see page 141

OPMI or LUMERA 700	– Activates remote control of the LUMERA 700 surgical microscope – Activates the live video function. This allows treatment on the CALLISTO eye to be followed. If the connected surgical microscope is ready for operation its designation is displayed, otherwise "OPMI" appears.	see page 162 see page 164
User	Opens user administration (creation, deletion, switching users; viewing and editing user data, entry and changing of device settings).	see page 170
Control center	Opens system information with various display and setting options, e.g. – Setting date and time – Display current software version – Connection of CALLISTO eye to a network	see page 180

Function/Configuration

All menus except the Control center feature a Function view and Configuration view. These views can be switched between at any time.

Function	The Function view is the normal user interface.
Configuration	The Configuration view can be used to carry out fundamental, mostly user-specific settings, and to access system information.

Tabs

Each menu contains at least one tab, usually more. There is a flag at the top of each tab. Press the flag to open the respective tab.

A tab can contain various types of buttons and fields.

Alphanumeric entries can be made via a keyboard (see page 109). The keyboard opens when an appropriate button is pressed. For date entry a calendar opens from which the desired date can be selected (see following table). The decimal separator used for presentation and entry of decimal numbers is the dot (".").

All changes are saved immediately after completion of the entry.

Input button	Pressing an input button (e.g. surname) opens the keyboard (see page 109).  → After you have made your entries and closed the keyboard with <OK>, your entry is saved and displayed on the button. Input buttons without assigned text are labeled with "---".
Date button	Pressing a date button opens a calendar. A date can be selected from this calendar.  Pressing the <Delete> button deletes the selected date. → After the calender is closed with <OK>, the selected date appears on the button. If the <Cancel> button is pressed , "---" is displayed.
Selection field	A selection field contains several buttons that offer different options for an item (e.g. the patient gender). Press the appropriate button to select one of these options.  → The selected button is highlighted in blue.
	Extensive tabs are subdivided into several areas. Pressing this button opens up the areas not currently shown.

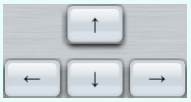
Keyboard

After pressing a button that requires entry of texts and/or numbers, a keyboard appears onscreen.

This is operated by pressing the buttons on the touchscreen.

The decimal separator used for entry of decimal numbers is the dot (".").

Function keys

	Enter an individual upper-case letter; the following letters are lowercased.
	Enter several upper-case letters in succession. The key remains active until pressed again.
	Tabulator key (tabulator steps are ignored in displays on buttons or in fields).
	Delete one character to the left of the cursor.
	Delete the entire text.
	Move the cursor.
	Enter special characters.
	Finalize input; your entries are transferred to the field in question and displayed.
	Cancel your entry.
	No function assigned.
	No function assigned.

"Patient" menu: Patient administration

Overview

Patient administration can be used to

- Manage patient data:
  - Create new patients
  - Delete patients
  - Import patient data from USB storage medium.
  - Change the display in the patient list using the filter functions (display all patients, display only patients for a treatment date, display only patients of one user)
  - Enter patient data
  - Enter treatment type
  - Call up a device setting
  - Define laterality (OD, OS)
- Activate a patient (see page 112)
- View and manage documents (single images, videos, OCT images)
- Exporting treatment data

Depending on permission the logged-in user can view either all patient data records or only records for their own cases. The logged-in user must have the necessary rights to create, edit, delete and export patient data.

"Open" and "active" patient

There is a difference between an "opened" and an "active" patient:

– A patient is "opened" when he/she has been selected from the patient list of the "Patient" tab (see page 113).

  The data and documents pertaining to the treatments of a patient can be viewed and edited if this patient is "opened".

– A patient is "active" when he/she has been selected from the patient list on the "Patient" tab, and the "Start surgery" button in this tab is then pressed (see page 118).

  If a patient has status "active" then during treatment a video can be recorded and photos of the microscope images and OCT data (OCT videos, snapshots and OCT images) saved.

While a patient is "active" no other patient can be opened.

The "Patient" field in the header appears in different ways:

– after activation of a patient (as long as the patient has "active" status): "[Gender] [Surname], [First name] [Laterality]"

– if no patient currently has "active" status: "-- --- , --- ---"

The name of the "opened" patient does not appear in this display field.

Function and Configuration view

The Patient administration features a Function view and a Configuration view. The Function view has two tabs: "Patient" and "Image data". The Configuration view contains the "Treatments" sub-menu with "Export" and "Delete" tabs.

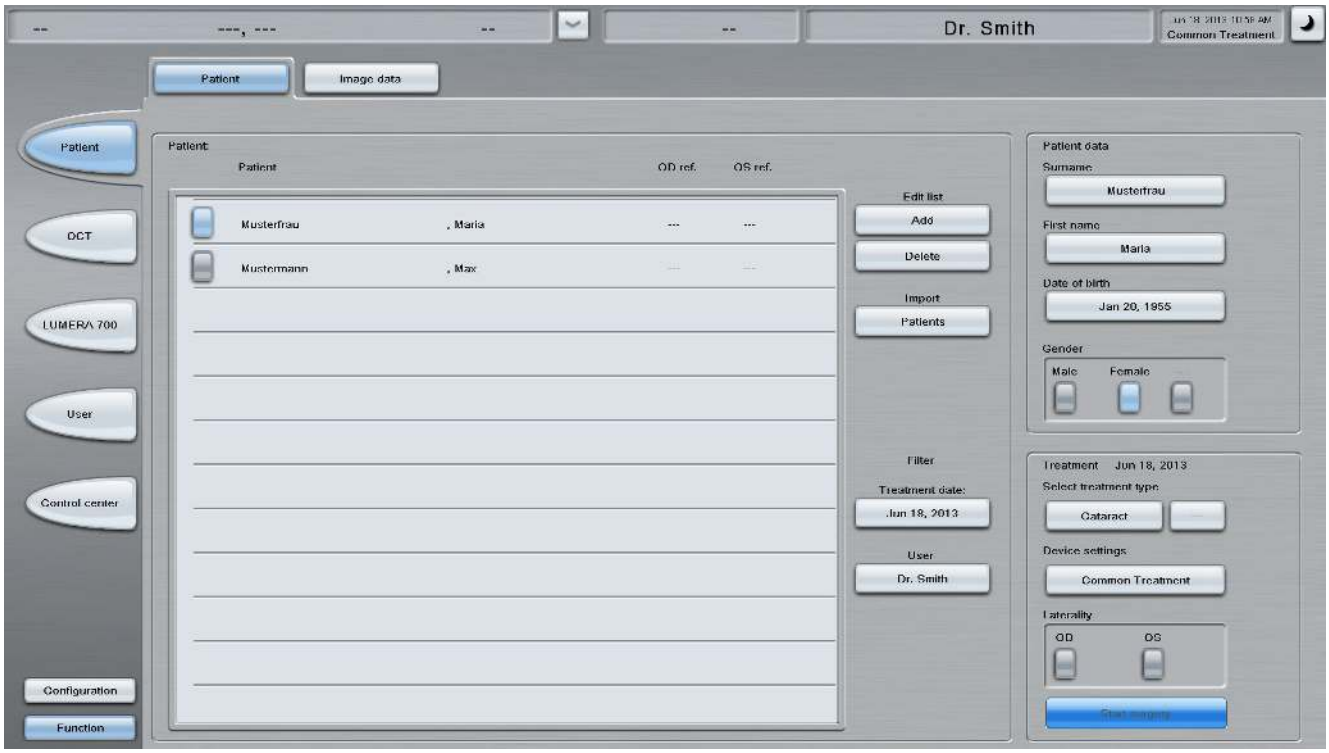
Function View

"Patient" tab

The "Patient" tab has three areas: "Patient", "Patient data" and "Treatment".

The "Patient" area contains an alphabetical list of all patients for whom data files are available in the system. The display can be limited to specific patients by entering filter criteria (treatment date, user). The "Patient data" area shows the personal data of the selected patient (i.e. opened) in the "Patient" area; this can be edited here. The "Treatment" area allows the entering of treatment type, selecting device setting, and specifying laterality, as well as starting and stopping video recording of an operation.

A patient is selected (opened) by pressing the corresponding line.



Area "Patient"

Patient	Patient's family name and first name
OD ref./OS ref.	Not used

Add	Adds a new patient to the list. → A new blank line is added to the patient list. The line is selected automatically. → Data for the new patient can be entered in the "Patient data" area.
Delete	Deletes the patient selected from the list. → After confirmation of the safety prompt, the patient is deleted together with all associated data including all images, videos and OCT images. The currently active patient cannot be deleted.
Patients	Imports patient data from a USB storage medium. 

	→ Pressing this button opens a window in which the files to be imported can be selected. First select the folder in which the import file is located and then the file. Using the  button you can move up one level in the USB medium's folder structure. Data to be imported must be in CSV format; structure as see page 117.  The file is always imported with all contained data records. If a patient of the same name already exists in the system another patient is created with this name, identified by a suffix.  CALLISTO eye treats imported patients as the personal data records of the user logged-in during the import.
Treatment date	Limits the list of patients displayed to a specific date. → Pressing this button opens a calendar. This calendar can be used to select a date or to delete a set filter. → The button displays either the selected date or "---". → If a date was selected, the following patients are listed: – Patients for whom a surgery was started on the selected day. – Patients for whom no surgery has yet been started. If the date filter is deleted, all patients are displayed (if the user logged in to CALISTO eye has permission to see all patient data).  Exception: A currently active patient is always displayed, irrespective of any filter settings.

User	Limits the list of patients displayed to a specific user (the attending surgeon).  Selecting "---" removes the filter. → The button displays the name of the selected user or "---". → If a user is selected, the following patients are listed: – Patients created by the selected user and patients imported by the selected user (so-called personal data). – Patients for whom surgery was started by the selected user. If the user filter is removed, all patients are displayed (if the user logged in to CALISTO eye has permission to see all patient data). Exception: A currently active patient is always displayed, irrespective of any filter settings.

Structure of a CSV file for importing patient data

A data record comprises the following fields:

Data field	Format
Family name	Text
First name	Text
Date of birth	YYYY-MM-DD
Gender	m/f (male/female)

The file must fulfill the following conditions:

- The data records start in the first line of the file.
- The maximum length of a data field is 50 characters.
- The separator to be used between fields is a comma.
- Data records are separated by a line break.
- All the fields may also be blank.
- Only ASCII characters may be used.
- Files may contain a maximum of 500 data records.

Example:

Mustermann,Max,1954-05-27,m
Musterfrau,Maria,1948-02-09,f
Schmid,,,

Files of this structure can for example be created in a text editor or a spreadsheet program.

"Patient data" area

Surname, First name, Date of birth, Gender	Display and entry of the relevant patient data.
	Opens the active patient. This button is displayed only if a patient is active, and the opened patient is not the active patient.

If no patient is opened or the "Patient" list is empty (e.g. because filters are applied and no patients meet the filter criteria), all fields are blank and disabled.

"Treatment" area

CAUTION

To prevent treatment errors, please observe the following:

- When entering or editing treatment data, please ensure that the correct patient data record is displayed.
- Before every treatment, verify the patient and treatment data using sources of information outside of CALLISTO eye.

[Date]	Displays the current date. → When a surgery is started, this date is saved as the treatment date.
Select treatment type	The treatment type can either be entered via the keyboard or selected from a list. The selection list contains treatment types entered by the logged-in user via the keyboard and that have been started at least once. I.e. The selection list is user-specific.
Left button	Selects and displays the treatment type.

Pressing the <Delete> button deletes the selected treatment type from the list **without confirmation**.

	→ After closing the selection window with <OK>, the selected treatment appears on the button.
	Opens the keyboard for entry of a treatment type. → The treatment type is displayed in the field on the left. If no treatment type is to be displayed: Open the keyboard by pressing the button, delete the treatment type, and close the keyboard with <OK>.
Device settings	Selection of a device setting.  → The selected device setting appears on the button. → The corresponding settings are transmitted to the connected devices. The device settings are created in the User administration (see page 178; for configuration, see page 47). If no device settings have been created, the only option available is "Common Treatment". The device setting can also be selected in the "Selection" tab of the "User" menu (see page 172).

Laterality	Selection of laterality (OD, OS).
Start surgery End surgery	Starts and stops recording of the surgery. The button text changes depending on current status. The <Start surgery> button is enabled only if laterality has been selected. The <End surgery> button is active only if the active patient is also the opened patient. If a different patient was opened after starting the surgery, the surgery can only be stopped after the active patient has been re-opened. Staring surgery recording triggers the following actions: → The status "active" is assigned to the selected patient. → A black triangle appears in the patient list before the patient's name. → If no surname was entered when creating the patient, the patient is automatically assigned designation "Pat_YYYYMMDD_HHMM" (YearMonthDay_Time). → The <Start surgery> button is replaced by the<End surgery> button. → The "Patient" field in the header displays "[Gender] [Surname], [First name] [Laterality]". → The start time of the now active treatment is set to the current system time. → The header displays the treatment type in the second field from the left. → CALLISTO eye automatically shows one of the tabs "Illumination", "Position" or "Workflow Steps" (Functions View of the "LUMERA 700" menu). The current live picture is shown in all three tabs. The tab that was last activated by the user before activating the patient is shown. → If configured accordingly (see page 54), video recording starts automatically. The <Recording> button turns blue. If during configuration it was specified that video recording should not start automatically, the <Recording> button is grey. Recording can be started manually.

→ Pressing the button in the header will display important patient data in large-size format (see page 106).

Stopping surgery recording (by pressing the <End surgery> button) triggers the following actions:

→ Video recording of the current active treatment is stopped. Initial and final images of the recorded video are generated.

→ The patient is deactivated. The "Patient" field in the header displays "-- --- , --- --".

→ The button to the header row right of the "Patient" field is de-activated.

→ The laterality shown in the "Treatment" area is deleted.

→ The black triangle before the patient's name is removed in the patient list.

→ The <Start surgery> button reappears.

Pressing the <Start surgery> button again (after again selecting laterality) continues surgery recording. This generates a new video.

"Image data" tab

The "Image data" tab contains the "Selection" and "View" areas. Opening this tab automatically displays the "Selection" area.

In the "Selection" area, you can select and open documents (videos, digital images OCT videos, OCT images and OCT snapshots) of a specific patient (i.e. display them in the "View" area), or delete or export them to a connected USB storage medium. The patient is selected from the list in the "Patient" tab (see page 113).

The "View" area shows the image data. The respective viewer is activated depending on the selected document type (video, digital image or OCT image).

Videos of the microscope image and OCT videos can be generated automatically or manually, depending on configuration, while a patient is active (see pages 54 and 80 or pages 142 and 155).

Digital images (snapshots) of the microscope image can be generated in the "Illumination", "Position" or "Workflow steps" tabs while a patient is active (Function view of the "LUMERA 700" menu, <Foto> button; see page 164, or subsequently from a stored video (see page 129).

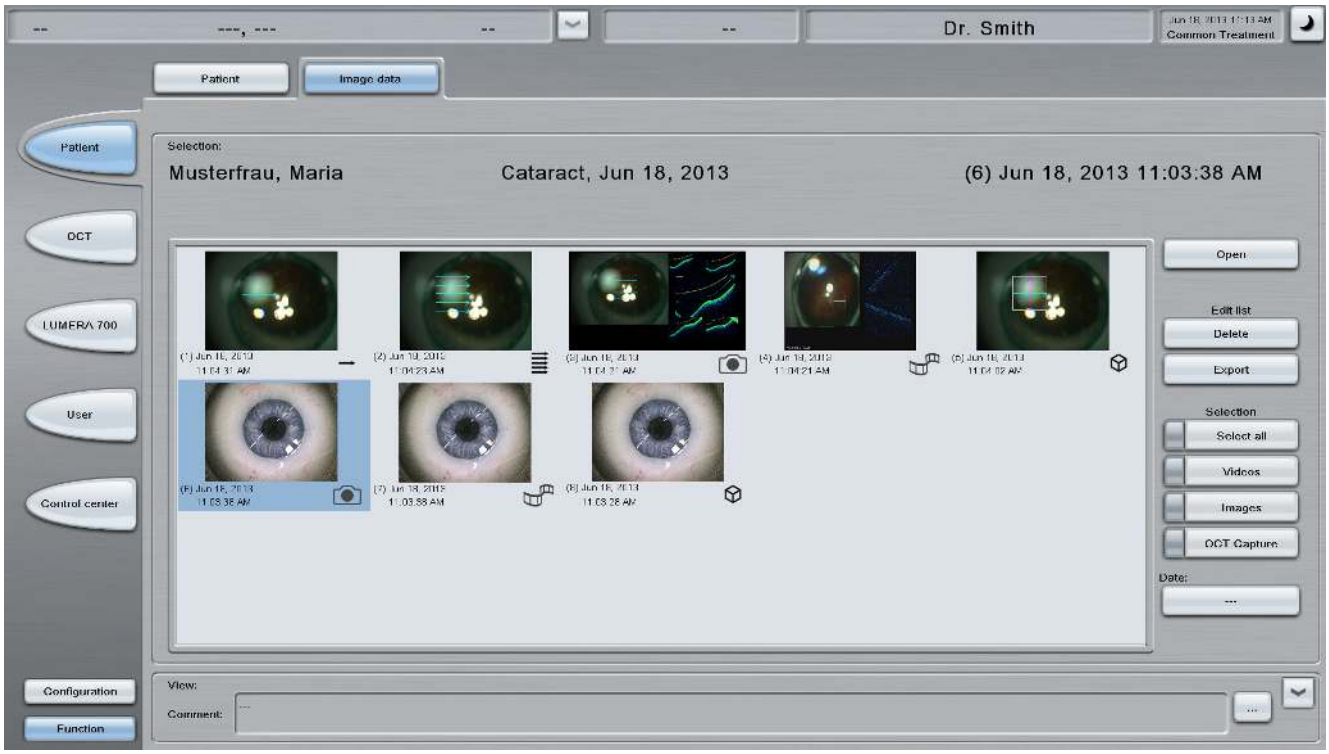
OCT digital images (snapshots) can be generated in the "Live" or "Review" tabs (Function view of the "OCT" menu, <Snapshot> button; see page 142 or page 148), while a patient is active or generated subsequently from a stored OCT video (see page 129).

OCT images can be generated in the "Live" tab (in the Function view of the "OCT" menu, <Capture> button (see page 142).

⚠ **CAUTION**

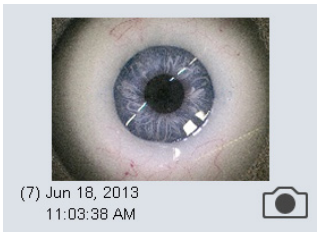
To avoid unnecessary or incorrect treatments please observe the following:

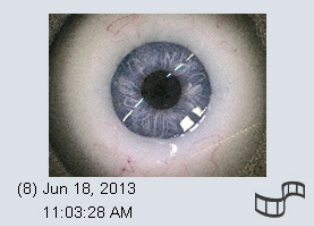
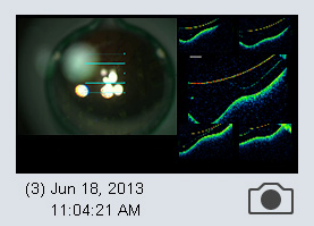
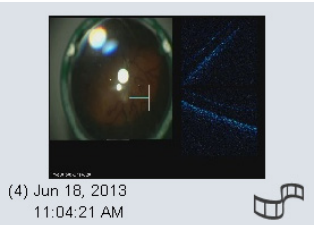
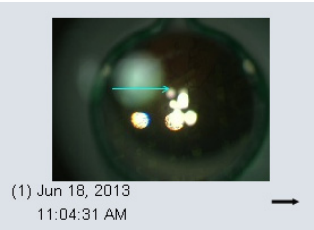
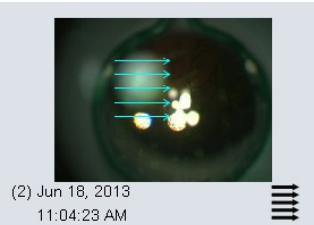
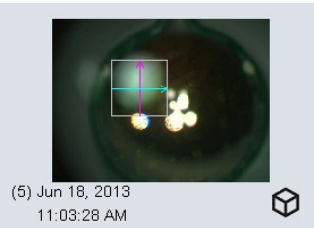
- Do not use stored video or image data for diagnostic purposes.



Area "Selection"

Documents are shown as a thumbnail Table of Contents (videos, digital images, OCT images), i.e. as small images (index images). These images are numbered consecutively (No. 1 is assigned to the most recent document) and labeled with the recording date and time. Videos are marked with a film symbol, digital images with a camera symbol, OCT images with an arrow, five arrows or a cube depending on the capture scan mode (see following overview).

Index image type	Document type
	Microscope image (snapshot)

Index image type	Document type
	Video of the microscope image
	OCT image (Snapshot): Digital image (snapshot); shows the microscope image with superimposed scan lines (Scan Location Marker) and - depending on the type of scan selected - two or five OCT images.
	Recording Shows the microscope image with superimposed scan lines (Scan Location Marker) and - depending on the type of scan selected - two or five OCT images.
  	OCT recording (Capture) Shows the microscope image with superimposed scan lines (Scan Location Marker) and - depending on the capture scan type selected - two or five OCT images. OCT images are displayed in the "View" area after selection and opening of the recording; they do not appear in the index image.

A document is selected by pressing the index image and is then highlighted in blue. It is also possible to select several documents. Documents are deselected by pressing the index image again.

The graphical Table of Contents presents the patient name, type and date of treatment as well as the number, recording date and time of the selected document. If no document is selected, "---" is displayed.

Buttons

	Open the active patient. This button is displayed only if a patient is active, and the opened patient is not the active patient.
Open	[Is displayed when not two or not only two OCT images of the "Cube" type are selected] Opens the document selected in the list. → The "View" area is opened and displays the selected document. If several or all documents are selected, the first selected document is shown. The  buttons in the "View" area can be used to navigate between the documents.
Compare	[Is displayed if two OCT images of type "Cube" and no other documents are selected] Compares the two OCT images selected in the list → The "View" area is opened. The two selected OCT images are displayed side by side.
Delete	Deletes the document selected from the list. → After confirmation of the safety prompt, the selected document is deleted.

Export	Exports the selected documents. → A window appears in which the target directory for the export can be selected.  It is only possible to select an existing directory, not create a new one. → Optionally, the image data can be exported anonymously. In this case images and videos can no longer be assigned to a patient. → After the target directory has been selected and the <OK> button pressed, a folder "CallistoEye_Surname_First name" is created. In anonymous export, the patient's surname and first name is replaced by "Anonymous". The selected documents are saved to this folder. If a folder with the same name already exists in the target directory, an extension is added to the name of the new folder. (…_1, …_2, …). → During export the message "Please wait" is displayed in the upper left area of the tab.

⚠ **CAUTION**	To avoid unnecessary or incorrect treatments please observe the following: • Do not use stored video or image data for diagnostic purposes.

⚠ **CAUTION**	To avoid data protection violations, please observe the following: • Export the data onto a medium that is protected against external access.

Selection	Select all	Selects all available documents for a patient. → All documents are highlighted in blue. Pressing the button again deselects the selection.
	Videos	Limiting the display in the thumbnail index to a specific type of document. Pressing the button again deselects the selection. If the display is enabled, the indicator field of the corresponding button is highlighted in color.
	Images	
	OCT Capture	
Date		Limits the list of the displayed documents to a specific date. Pressing this button opens a calendar. This calendar can be used to select a date or delete a set filter. → The selected date is displayed on the button. If no date has been selected, the entry "---" appears. → The display shows only documents recorded on the day selected.
		Shows the "View" area. → The "Selection" area is hidden. → The previously opened document is displayed. If no document has yet been opened, the display remains blank.

"View" area Viewing an image (photo)

The controls are the same for both types of images (microscope image/photo shown in the picture above and OCT snapshot).

Comment	Press button ... to add a comment to the digital image. → The comment entered is displayed in the "Comment" field.
	Deletes the digital image currently displayed. → The safety prompt must be confirmed to delete the image.
	Displays the digital image in large-size format. → The image is displayed in large-size format.
	(Button is displayed in the enlarged view). Displays the digital image in the original size.
	Displays the previous or next document. → The previous or next document is displayed; the corresponding viewer is opened if necessary.
	Shows the "Selection" area.

Viewing a video

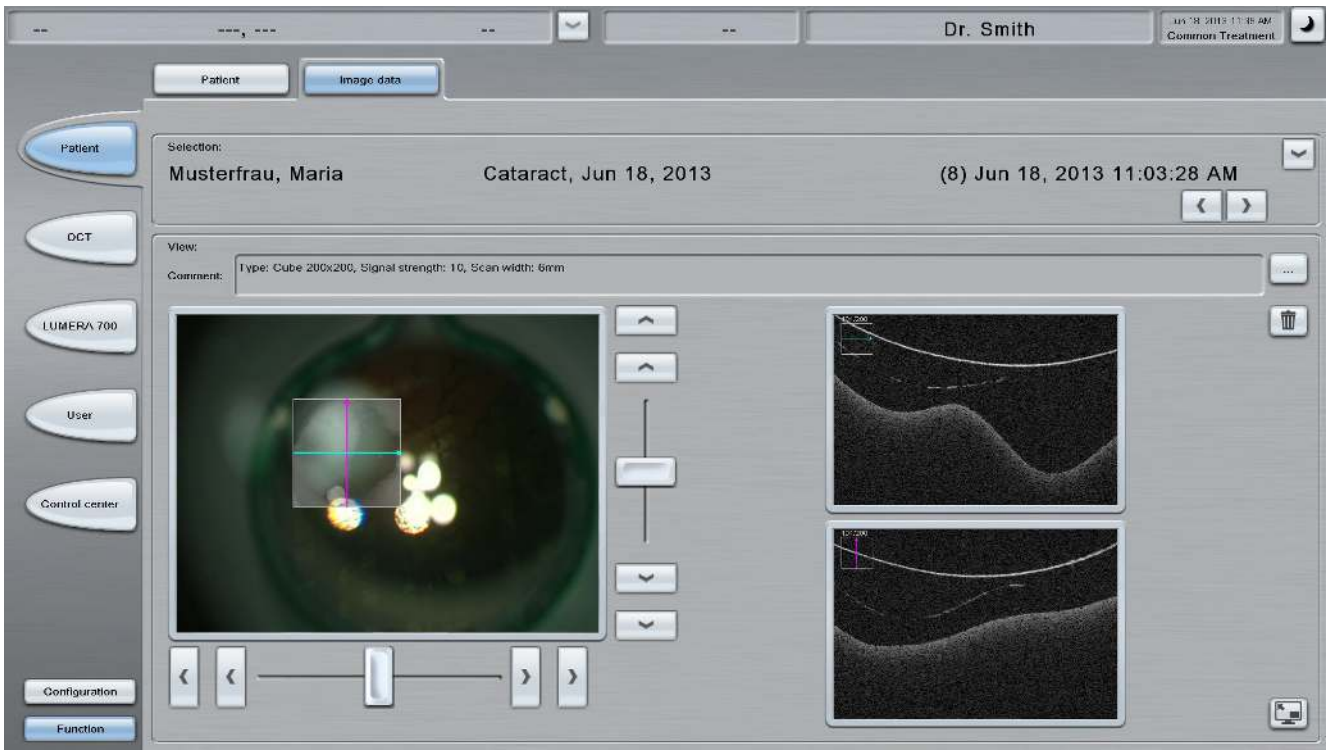
The controls are the same for both types of videos (Video of the microscope image and OCT video, shown in the picture above).

Fields, buttons and displays

Comment	Press the button ... to add a comment to the video recording. → The comment entered is displayed in the "Comment" field.
	Deletes the video currently displayed. → The confirmation prompt must be confirmed to delete the video.
	Displays the video in large-size format. → The video is displayed in large-size format.
	(Button is displayed in the enlarged view). Displays the video in the original size.
	Plays the video in fast reverse mode.

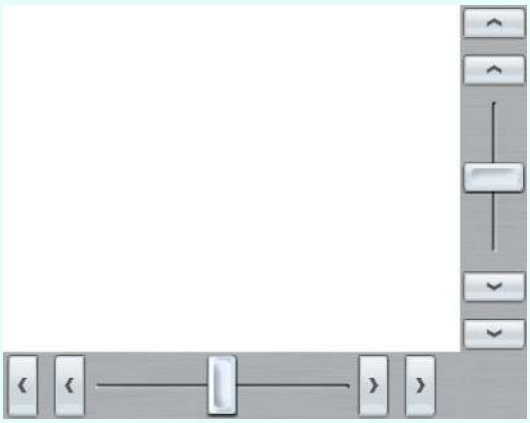
	Stops playback (pause). To resume playback, press one of the two playback buttons.
	Starts playback.
	Fast forwards the video.
	Creates a snapshot. → The snapshot is automatically saved as a digital image to the patient's documents. → The snapshot time is marked on the bar below the slide control.
	Slide control to set a specific playback position.
	Displays the time the snapshot was saved.
	Display the previous or next snapshot.
	Selects the previous or next document. → The previous or next document is displayed; the corresponding viewer is opened if necessary.
	Shows the "Selection" area.

View OCT images



The arrow keys and slider below and to the right of the microscope image are only shown for recordings of the "Cube" scan type. Other controls are the same for all types of capture scan types (1 Line, 2 Line, 5 Line).

Fields and buttons

Comment	Scan type, signal strength and scan size are shown. Press button [...] to change the entry.
Arrow keys, slider	 The arrow keys and slider are only shown for recordings of the "Cube" type. External arrow keys: Automatically scroll through the scan. → Pressing one of the external arrow keys starts automatic scrolling. → Pressing again stops automatic scrolling. Internal arrow keys: Scrolls through the scan in increments → Pressing one of the buttons displays the next or previous section respectively. Slider: Fast manual scrolling through the scan. → The selected section is shown.
	Delete the currently displayed OCT image. → After confirmation of the safety prompt, the OCT image is deleted.
	Displays the OCT image in large-size format. → The OCT image is displayed in large-size format (see next page).
	(Button is displayed in the enlarged view). Displays the video in the original size.
	Selects the previous or next document. → The previous or next document is displayed; the corresponding viewer is opened if necessary.
	Shows the "Selection" area.

Compare OCT images ("Cube" type only)

If two OCT images of "Cube" type are selected in the "Selection" area of the "Image data" tab (and no other documents) you can compare these in the "View" area.

Buttons

	Arrow keys: Scrolls through the scan in increments → Pressing one of the buttons displays the next or previous section respectively. Slider: Fast manual scrolling through the scan → The selected section is shown. In comparison view you can only scroll through the scan in one dimension.
LOCK	Synchronous scrolling through the images. → If this function is activated, the keys and slider for the left image are locked. Synchronous scrolling through both scans is possible using the buttons and slider in the right image. → The blue color of the indicator field in front of the button shows the function is enabled
	Selects the previous or next document. → The previous or next document is displayed; the corresponding viewer is opened if necessary.
	Shows the "Selection" area.

Configuration view

In the Patient administration Configuration view, treatment data can be exported and deleted.

Treatment data includes the documents you have saved for a patient.

Since surgery video recordings in particular require a lot of storage space and memory capacity of the internal hard disk is limited, patient data that is no longer required must be regularly deleted. Data to be archived should first be exported to an external storage medium.

The Configuration view contains the "Treatments" sub-menu with "Export" and "Delete" tabs.

"Treatments" sub-menu, "Export" tab

The "Export" tab can be used to export treatment data to an external USB medium and all data of selected treatments can be deleted.

Connect the USB medium (stick, hard disk) to one of the CALLISTO eye USB ports (see page 37).

CAUTION

It is the responsibility of the user to ensure that data carriers used for data backup are virus free.

The "Export" tab comprises the "Filter" and "Treatments" areas. The "Treatments" area contains a list of the treatments saved in the system. The treatments to be exported can be selected from this list. The list can be limited by entering filter criteria in the "Filter" area.

Exported documents can be viewed with corresponding viewers.

Only completed treatments can be exported. This means that the treatments must have been started using the <Start surgery> button and completed using the <End surgery> button ("Patient" tab, "Treatment" area, see page 118).

Exported data cannot be re-imported into CALLISTO eye.

CAUTION

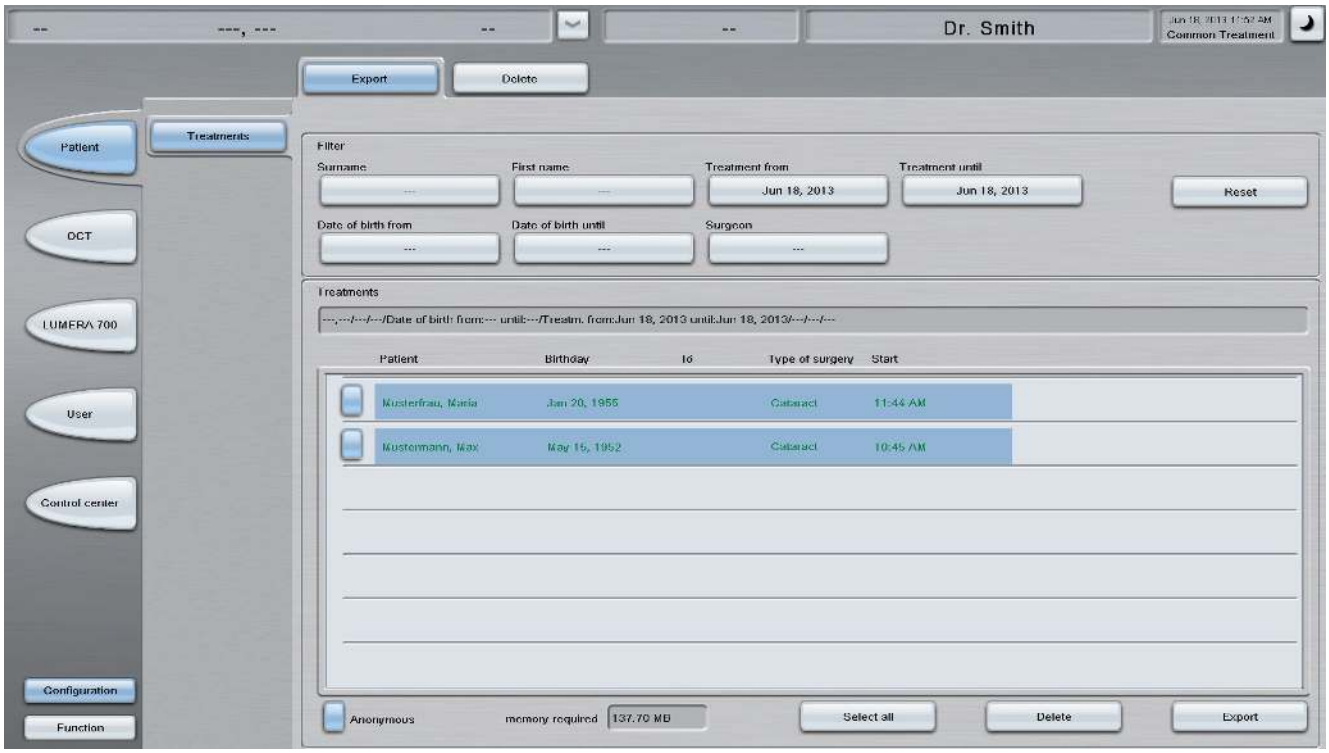
To avoid unnecessary or incorrect treatments please observe the following:

- Do not use the exported video sequences or images for diagnostic purposes.

CAUTION

To avoid data protection violations, please observe the following:

- Export the data onto a medium protected against third-party access.



Area "Filter"

Surname, First name, Date of birth from, Date of birth until, Surgeon	Filter criteria Entries can be made in individual fields, all fields or no fields. It is also possible to enter only parts of names (e.g. initials) in the Surname, First name and Surgeon fields (=User). → Depending on the button pressed, the keyboard, calendar or "Surgeon" selection list is opened for the entry or selection of the respective filter criterion.
Treatment from Treatment until	The "Treatment from" and "Treatment until" fields can be used to enter a time period from which treatments are to be exported. The current date is entered automatically. This date can be changed and deleted.
Reset	Deletes all filter criteria. → The "Treatments" area contains a list of all data records filed in the system.

"Treatments" area

The "Treatments" area shows a list of all data records that meet the filter criteria applied. The applied filter criteria are displayed at the top of this area (Surname/First name/ ...). Empty filter criteria are shown as "---".

In addition to the patient's name and date of birth, the list also includes the type of treatment (type of surgery) and the treatment start time (Id is not used).

A treatment is selected by pressing on a line. It is also possible to select several treatments. Press on the line again to undo the selection.

Anonymous	Deactivates or activates anonymous export. Default setting: anonymous export is activated. → If this button is activated, the data of a treatment is exported without patient data, i.e. the exported data can no longer be assigned to a patient.
memory required	Size of the data volume compiled for export.
Select all	Selects all treatments in the list for export. Press the button again to undo the selection.
Delete	Deletes selected treatments.  If all treatments of a patient are deleted, the patient itself is also deleted.

Export	Exports the data selected.

→ A window appears in which the target directory for the export can be selected.

It is only possible to select an existing directory, not create a new one.

The button <Anonymous export> in this window is synonymous with button <Anonymous> on the "Export" tab see page 137.

→ After selection of the target directory, for each treatment a folder is created named as "CallistoEye_Surname_First name".

If the image data is exported anonymously, the patient's surname and first name are replaced by "Anonymous". The documents of the selected treatments are saved in this folder.

If a folder with the same patient name already exists in the target directory or several treatments of a patient are exported, the new or following files are given an extension (…_1, …_2, …). Likewise, folders are numbered consecutively when several treatments are exported anonymously.

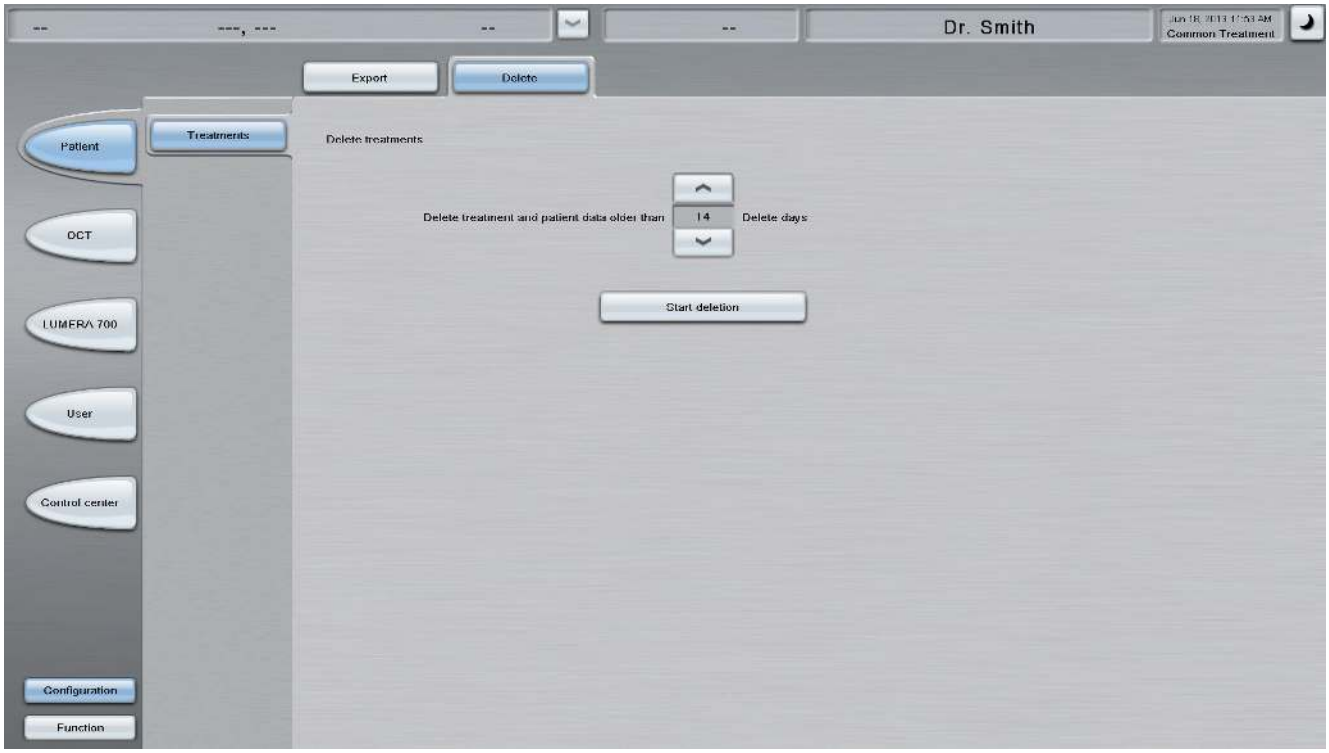
→ During export the message "Please wait" is displayed in the upper left area of the tab.

→ A window appears containing statistical data on the export.

"Treatments" sub-menu, "Delete" tab

In this tab, treatment, patient data and related data older than a freely selectable number of days can be deleted.

NOTE	Deleted data cannot be restored. • Save data that is still required to an external storage medium before deletion (see page 98).
⚠ **CAUTION**	Exported data cannot be re-imported into CALLISTO eye. • Do not delete any data that are still required in CALLISTO eye.



Delete treatment and patient data older than … days	Press the up/down buttons to set the number of preceding days for which all existing patient data should remain stored.
Start deletion	Deletes all patient data older than the set number of days. → After confirmation of a safety prompt, all data relating to these patients (videos, single images, OCT data, treatments, etc.) as well as the patients themselves are deleted from the system.

"OCT" menu (Optical Coherence Tomography)

The "OCT" menu is split into a Function and a Configuration view. The Function view has "Live" and "Review" tabs. The Configuration view contains the "Live Settings", "Capture settings" and "OCT image" tabs.

The OCT function can be used at any time i.e. even if no patient has "active" status. However images, videos and OCT images can only be saved if a patient has an "active" status.

⚠ **CAUTION**

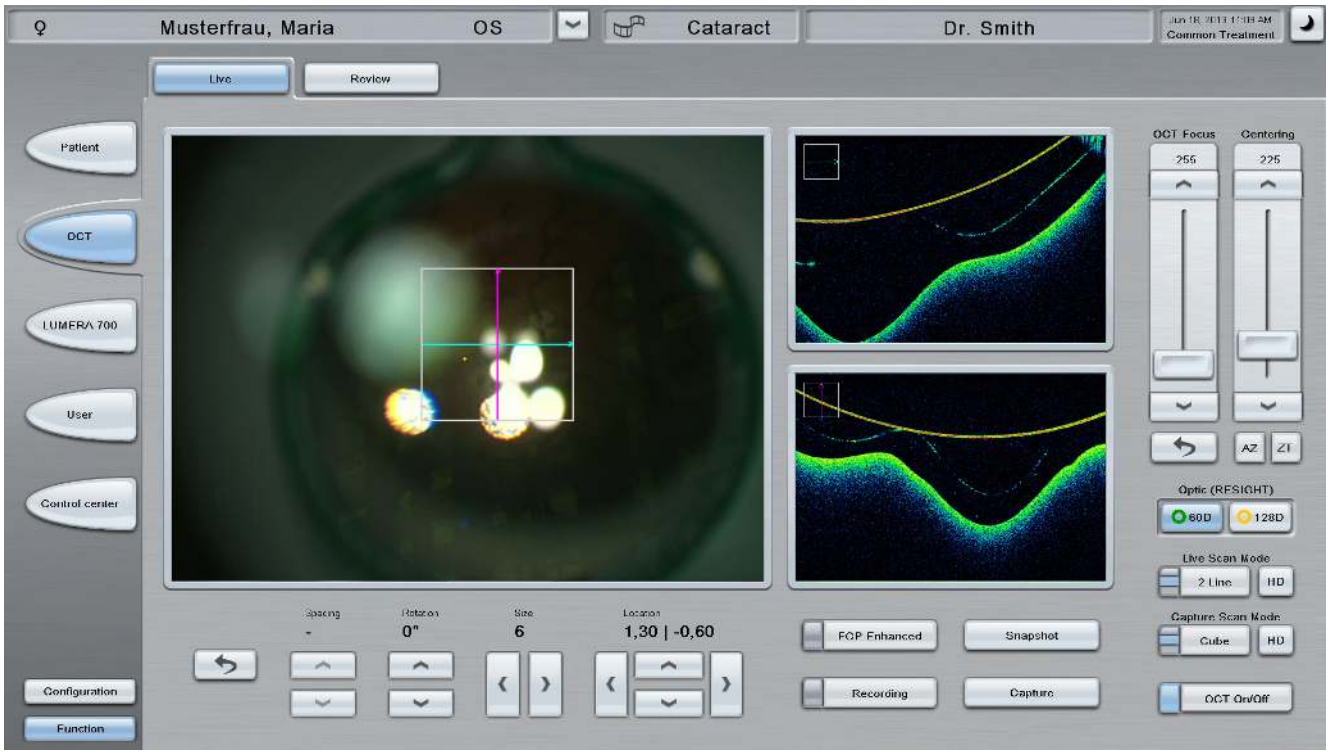
The OCT functions may only be used with the video camera built into the LUMERA 700 surgical microscope.

Function View

The Function view of the OCT menu has the two "Live" and "Review" tabs.

"Live" tab

You can switch the OCT scan on and off in this tab. You can configure settings for the scan, start and stop an OCT video recording and save digital images and OCT images.



On the left the live video image of the microscope is shown with the overlying scan lines (Scan Location Marker), and alongside on the right are two or five live OCT images depending on the scan type.

When using the RESIGHT 700 module in the "Posterior" device setting, automatic adjustment of the scan level (centering) occurs when the tab is opened. The software then switches to Z tracking (automatic guidance of the centering process), this being indicated by blue coloring of the <ZT> button.
For recordings without the RESIGHT 700 fundus viewing system, the z-plane of the OCT is parfocal to the focal plane of the microscope.

Pressing the video image or an OCT image switches CALLISTO eye to a full format display for the video image or the OCT image. To return to normal view press the button appearing in the full format display  .

Full picture mode is automatically unavailable if a fault occurs or there is a change in the device setting.

You can also control some of the functions offered in the "Live" tab using the foot control panel (see page 158).

Buttons on the right

OCT Focus	Adjust focus for the OCT scan.
Centering	Setting the Z position. → Changes are immediately visualized in the adjacent images. When automatic centering is activated (<ZT> button colored blue), the slider is locked. In this case centering can only be changed using the arrow keys.
	Reset → Resets the OCT focus setting.
AZ	Auto centering → After pressing the button CALLISTO eye automatically adjusts the centering function. → After successful auto centering, Z tracking is automatically activated.
ZT	Z-Tracking → If this function is activated (button colored blue) centering is automatically corrected when the level to be examined shifts (e.g. because structures move in the z direction due to the doctor's actions).
Optic (RESIGHT)	This is displayed when the RESIGHT 700 module is pivoted.
 	Selection of the magnifier pivoted on the RESIGHT 700.
	→ Blue coloring of one of the two buttons shows which magnification is selected.

Optic	This is displayed when the RESIGHT 700 module is not pivoted.	
		Standard setting
		If a contact lens is being used, the settings are automatically adjusted after pressing the button.
	→ Blue coloring of one of the two buttons shows which setting is enabled.	
Live Scan Mode	Selection of live scan type → Pressing the button cycles to the next live scan type. The button is labeled with the selected scan type. → Scan results are shown in the "Live" tab.	
	1 Line	Scan along a line
	2 Line	Scan along two mutually perpendicular lines
	5 Line	Scan along five lines in parallel
HD	Selection of Resolution (SD: 512Px, or HD: 1024Px; the button switches between these). → If HD is selected the button is blue.	
Capture Scan Mode	Selection of the recording (Capture) scan type → Pressing the button moves circularly to the next capture scan type. The button is labeled with the selected scan type. → Pressing the <Capture> button saves an OCT scan of the selected type.	
	1 Line	Scan along a line
	Cube	Scan along two mutually perpendicular lines (two dimensional scan)
	5 Line	Scan along five lines in parallel
HD	Selection of resolution (the button switches between these): – With Capture Scan type "1 Line" or "5 Line": Select either "Standard (SD)" or "Enhanced (HD)". – With the "Cube" Capture Scan type: Select either "200 × 200" or "512 × 128". → If the button is blue, "Enhanced (HD)" or "512 × 128" is selected.	

OCT On/Off	On	Standard setting when the "Live" tab is opened. → The indicator field on the left beside the button is colored blue. → One, two or five images, depending on scan type, are displayed on the right next to the microscope image. → If a patient has "active" status OCT video can be recorded and snapshots as well as OCT images (<Capture> button) can be saved.
	Off	→ The indicator field on the left beside the button is colored gray. → No OCT scan images are displayed. → Any video recording active before switching-off is ended. → No OCT video can be recorded and no snapshots or any OCT images can be saved.

Lower buttons

	Reset → The settings for the parameters "Spacing", "Rotation", "Size" and "Location" are reset to default values (see "Live Settings" tab on page 152).
Spacing	Adjust scan lines spacing (only active, if Live Scan Type "5 Line" is selected).
Rotation	Set rotation of the lines.
Size	Set the length of the lines.
Location	Set the Scan Location Marker position in the microscope image.  The increment for changes to position can be changed in the "Live Settings" tab (see page 152)
FCP Enhanced	Select foot control panel button assignment. → If the indicator field in front of the button is blue enhanced button assignment is activated, otherwise the standard button assignment applies (ENHANCED or STANDARD; see page 158).
Recording	Starts and stops video recording of the OCT visualization. The button is active only if a patient has status "active" and OCT is switched on (indicator field in front of button <OCT On/Off> is colored blue). An OCT visualization video contains the microscope image and, depending on the selected live scan type, one, two or five OCT images. → When video recording is running, the indicator field in front of the button is blue. If no video recording is underway, the indicator field in front of the button is gray.  You can change the scan type during video recording.

	Press the button while a video is being recorded: → The video recording stops (the patient continues to have "active" status)  The video recording automatically stops when scanning finishes. Scanning not only finishes when you press the <Recording> button, but also when you press the <Capture> button or the <OCT On/Off> button, or you switch to a different tab. Press the button again to resume video recording. This generates a new video
Snapshot	Generate a digital picture of the microscope image and OCT images The button is active only if a patient has status "active" and OCT is switched on (indicator field in front of button <OCT On/Off> is colored blue). → Pressing the button saves the current microscope image (with displayed scan lines) and the OCT scan image(s) as a digital photo. The date and time of generation is imprinted into the photo. This can be viewed in the "Image data" tab ("Patient" menu). The thumbnail index of the "Image data" tab shows the digital image denoted by a camera symbol
Capture	Save OCT image The button is active only if a patient has status "active" and OCT is switched on (indicator field in front of button <OCT On/Off> is colored blue). → Pressing the button saves an OCT scan of the type and resolution as selected respectively in "Capture scan mode". → The scan results can be viewed in the "Review" tab of the "OCT" menu (until the active patient is deactivated), or in the "Image data" tab of the "Patient" menu (even after the patient has been deactivated). → The thumbnail index in the "Image data" tabs shows a still from the microscope image with superimposed Scan Location Marker. The image is denoted with an icon (arrowhead, five arrows or cube; see page 124) corresponding to the Capture Scan type.

"Review" tab

You can view saved OCT images in this tab.

During the display of a recording in the "Review" tab, the OCT images are also shown in the eyepiece of the OPMI LUMERA 700.

The tab is divided into three areas:

– The Selection list on the left holds all the OCT images saved since activation of the patient (generated in the "Live" tab by pressing the <Capture> button. The thumbnail of the microscope image gives the Capture scan type and date and time of the recording.

  By pressing the thumbnail a visualization can be selected and then shown in the tab. The visualization selected has a blue background.

  If no patient has active status or no OCT images have been saved for the active patient since the activation, the whole tab is empty.

The recordings saved for a patient are not shown if the patient has meanwhile been deactivated. These can be viewed in the "Image data" tab ("Patient" menu).

– The center shows the microscope image of the recording with superimposed scan lines (Scan Location Marker). For the "Cube" capture scan type, also displayed are the arrow keys and slider that can be used to scroll through the scan.

  Below the microscope image are given the Capture Scan type and resolution, date of recording, signal strength and the scan size.

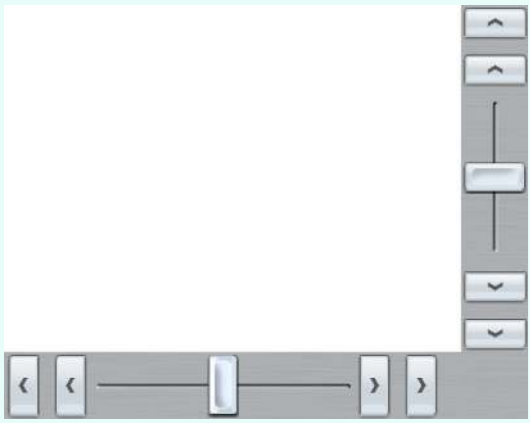
The signal strength is determined by the OCT Camera for each recording. Value can be between 0 and 10. Optimum signal strengths are between 5 and 10. If a recording has a lower signal strength than 5, you should optimize focusing and repeat the recording.

– The images on the right show the result of the OCT scan. Depending on the recording ("1 Line", "Cube" or "5 Line"), one, two or five images are shown here. The position of the scan line(s) are shown in the image(s).

For "5 Line" type recordings four of the 5 OCT images are shown at reduced size. Pressing on a small picture enlarges it. Pressing the picture again returns you to the original view.

With "Cube" images, the number of the displayed section is shown above the superimposed scan line (e.g. 85/200).

Buttons and controller

	Scroll through the picklist
Arrow keys, slider	 The arrow keys and sliders are only displayed for "Cube" type recordings. External arrow keys: Automatically scroll through the scan. → Pressing one of the external arrow keys starts automatic scrolling. → Pressing again stops automatic scrolling. Internal arrow keys: Scrolls through the scan in increments → Pressing one of the buttons displays the next or previous section respectively. Slider: Fast manual scrolling through the scan → The selected section is shown.
Snapshot	Generate a digital picture of the microscope image and OCT images → Pressing the button saves the current microscope image (with displayed scan lines) and the OCT scan image(s) as a digital photo. The date and time of production is imprinted on the digital image. This can be viewed in the "Image data" tab ("Patient" menu).

Configuration view

The Configuration view in the "OCT" menu contains a sub-menu "User Settings" with three tabs "Live Settings", "Capture Settings" and "OCT Image". You can define various presets for OCT visualization in these tabs.

The presets defined in the Configuration view are user specific, i.e. changes apply only to the user logged-in when the change is made.

The presets are always called up when you log on as a user. If during visualization you modify parameters in the Function view ("Live" tab, see page 142) that are determined by a preset, the changed settings continue to apply until you change them again or until another user logs in to CALLISTO eye.

"Live Settings" tab

Use this tab to configure different presets for the live representation of OCT visualization. The settings made here are provided as the default settings in the "Live" (see page 142) tab when you log on as a user.

The settings for scan size and line spacing also apply to OCT images (see page 155).

The "Live" tab can be used at any time to change all the settings except the X/Y increment.

Buttons

Live Scan Mode	Select the Live scan type preset.	
	1 Line	Scan along a line.
	2 Line	Scan along two mutually perpendicular lines.
	5 Line	Scan along five lines in parallel.
Scan Resolution	SD (512Px)	Select the resolution of the Live scan type.
	HD (1024Px)	
Scan size	Specify the standard setting for the length of the line.	
Spacing	for "5 Line" scan type: Specify the default setting for line spacing. for "1 Line" and "2 Line" scan types: irrelevant.	
X/Y Increment	Set the smallest increment by which the position of the Scan Location Marker may be changed. The increment is used to control the speed of the movement of the Scan Location Marker: The smaller the increment the more slowly the Scan Location Marker moves on pressing one of the position keys in the "Live" tab.	
Foot Control Panel	Select the OCT button assignment presets for the foot control panel (see page 158).	
	Standard	The foot control panel joystick has one function assigned.
	Enhanced	The foot control panel joystick has several functions assigned to it, that can be switched between using a button on the foot control panel.

Auto OCT recording	Select standard setting for automatic video recording of the OCT visualization.	
	On	OCT video recording starts automatically when Live OCT Scan is started. Live OCT Scan is started one of the following ways: – The "Live" tab (in the "OCT" menu Function view) is opened. – Live Scan is reactivated following deactivation (button <OCT On/Off> in the "Live" tab). – Automatically following interruption of the live scan after pressing the <Capture> button (in the "Live" tab).
	Off	The OCT video recording never starts automatically. It can be started manually in the "Live" tab.

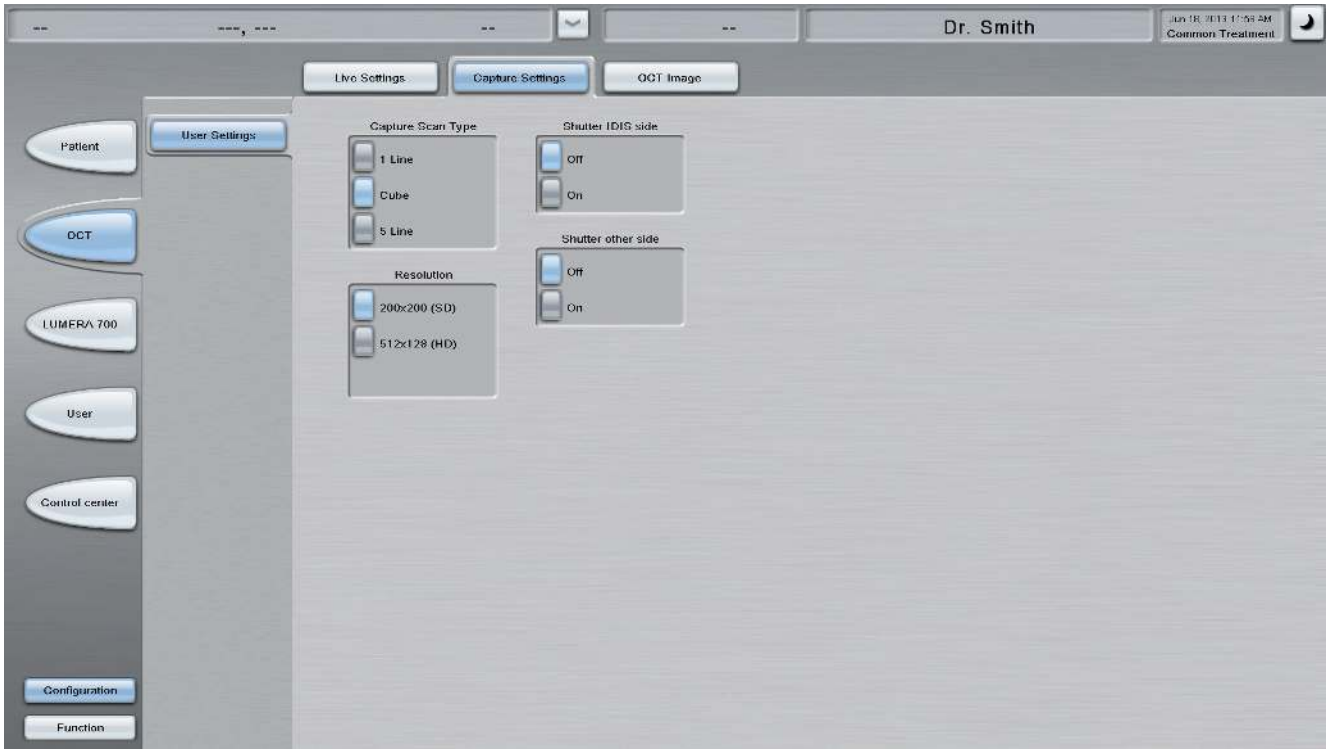
"Capture Settings" tab

Use this tab to configure different settings for recordings of OCT visualization and showing OCT images in the eyepiece of the OPMI LUMERA 700. An OCT visualization is termed a recording when you save it in the "Live" tab by pressing the <Capture> button.

The settings made here are provided as the default settings in the "Live" tab when you log on as a user.

You can temporarily change settings for the recording (Capture) scan type and the recording (Capture) resolution at any time in the "Live" tab.

Please note: The same settings for scan size and line spacing for OCT recordings (capture scans) apply as for live scans ("Live Settings" tab, see page 152).

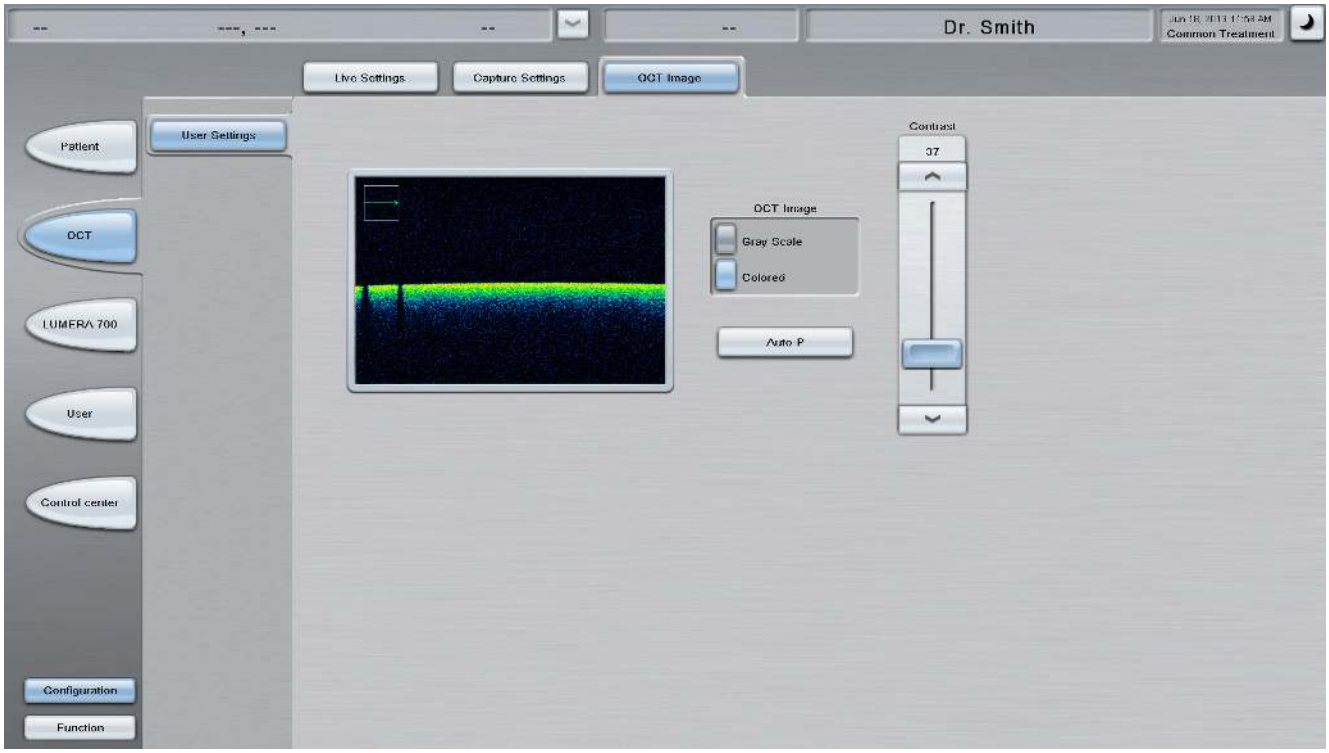


Buttons

Capture Scan Mode	Presetting of Recording (Capture) scan type.	
	1 Line	Scan along a line
	Cube	Two dimensional scan. The area is scanned by two mutually perpendicular lines.
	5 Line	Scan along five lines in parallel
Quality	Standard (SD)	Presetting of scan resolution for Capture scan types "1 Line" and "5 Line"
	Enhanced (HD)	
Resolution	200x200 (SD)	Default setting of scan resolution for the "Cube" Capture Scan Type
	512x128 (HD)	
Shutter IDIS side	If an OCT recording is viewed in the "Review" tab, the saved OCT scan image is also shown in the eyepiece of the OPMI LUMERA 700. Using the shutter the microscope image can be faded out for better visibility of the scan(s). The scans then appear against a black background.	
	On	The microscope image is not displayed.
	Off	The microscope image is displayed.
Shutter other side	(Works on the eyepiece in which the OCT images are not shown.) Using the shutter the microscope image can be faded out.	
	On	The microscope image is not displayed.
	Off	The microscope image is displayed.

"OCT image" tab

Use this tab to configure presentation of the OCT images.



Buttons

OCT Image	Gray Scale	Depending on the selection the OCT images are shown as gray scale images or in color. → The button of the selected presentation is blue.
	Colored	
Auto P		Automatic polarization
Contrast		Set the contrast for color representation. This control is shown only if the "Colored" option is selected.

OCT configuration of foot control panel

You can also control some OCT scan functions using the foot control panel. OCT configuration of the foot control panel is automatically activated if you display the "Live" tab (press the <OCT> <Function> <Live> buttons).

There are two variants of OCT configuration: In the STANDARD variant the buttons and joystick of the foot control panel all have a single assignment. In the "ENHANCED" version the joystick has several functions assigned that you can switch between with the touch of a button.

Both OCT configuration variants are preset and (with the exception of the rocker switch) cannot be configured by the user.

You can switch between STANDARD and ENHANCED versions by pressing the <FCP Enhanced> button in the "Live" tab (see page 142). The blue indicator field in front of the button shows that the "ENHANCED" version is enabled.

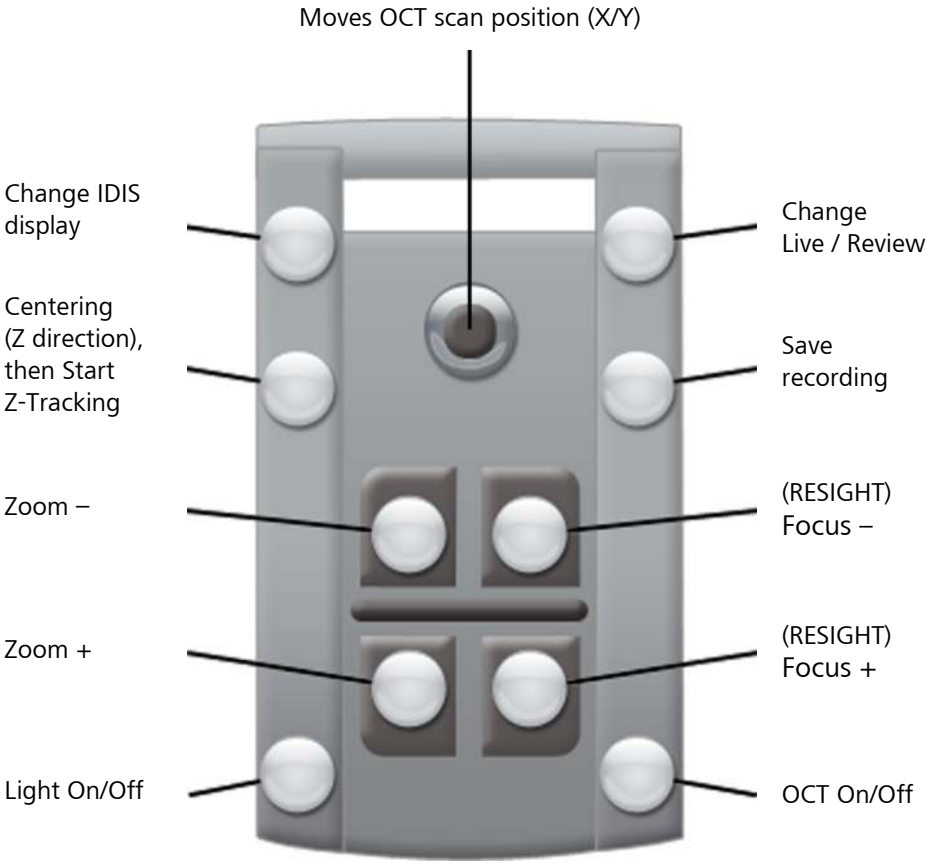
The following table gives an overview of the functions that can be controlled with the foot control panel and their equivalence in the CALLISTO eye software user interface (see also the illustration in the following pages).

Overview: OCT configuration of the foot control panel

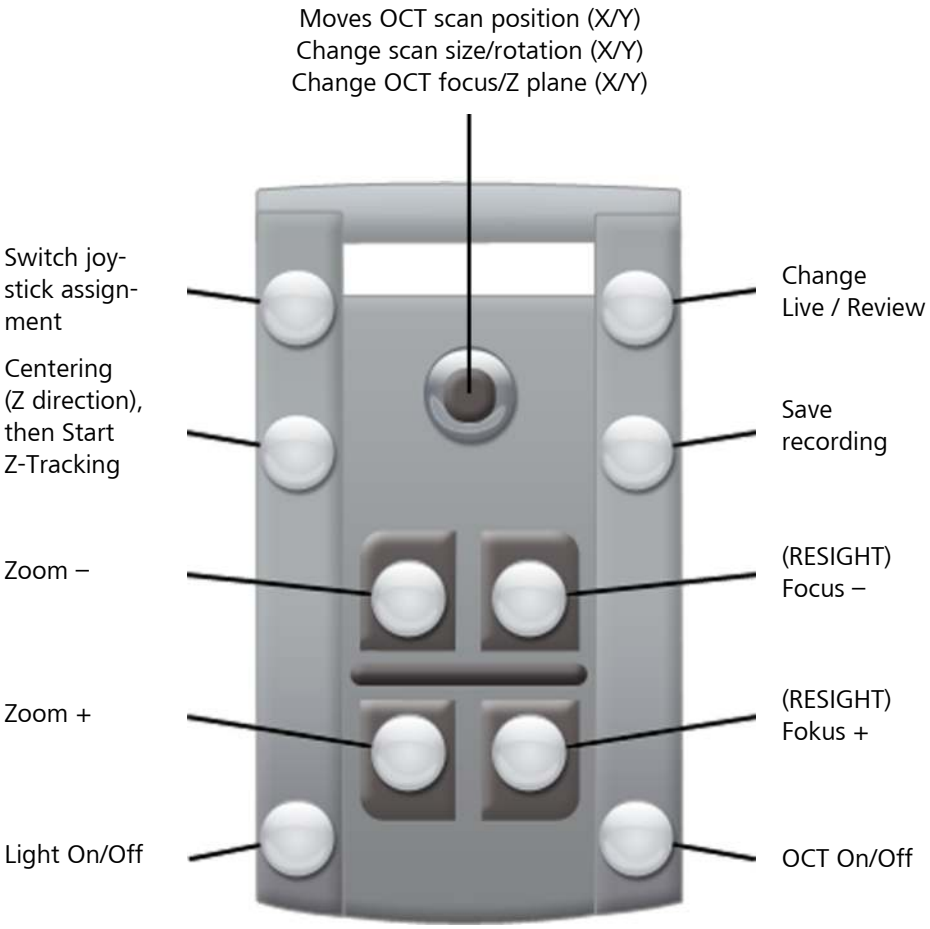
Position	Function	available in version		Equivalence in software (corresponding Function View in the menus)
		STD	EXP	
left top	Change IDIS representation	X	–	none
	Change Joystickconfiguration	–	X	none
left center	Centering (Z direction) + Start Z-Tracking / End Z-Tracking	X	X	"OCT" Menu, "Live" tab: Press Buttons <AZ> and the <ZT>
bottom left	Light On/Off	X	X	"LUMERA 700" menu, tab "Illumination"
right top	Switch Live / Review	X	X	"OCT" Menu: Select the "Live" tab or Select the "Review" tab
right center	Save recording	X	X	"OCT" Menu, "Live" tab: <Capture> button
right bottom	OCT On/Off	X	X	"OCT" Menu, open "Live" tab and start OCT. End OCT and switch to the previously opened menu.
Joystick	Moves the OCT scan position (X/Y)	X	X	"OCT" Menu, "Live" tab: Arrow key <Location>
	X direction: Change scan size	–	X	"OCT" Menu, "Live" tab: Arrow keys <Size>
	Y direction: Change rotation			"OCT" Menu, "Live" tab: Arrow keys <Rotation>
	X direction: Set the OCT Focus	–	X	"OCT" Menu, "Live" tab Arrow keys and slider <OCT Focus>
	Y direction: Setting the z-level			"OCT" Menu, "Live" tab: Arrow keys and slider <Centering>

The rocker switch has no fixed assignment. Its functions can be configured in the "LUMERA 700" menu, "Position" tab (for the standard assignment see the following illustrations)

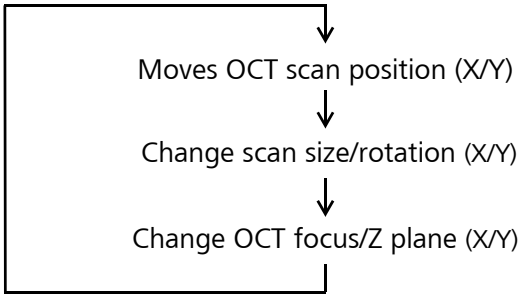
STANDARD variant



ENHANCED variant



Each press of the <Switch joystick assignment> button cycles to the next function:



"LUMERA 700" menu: Live image of the microscope and remote control of the surgical microscope

The LUMERA 700 surgical microscope can be connected to CALLISTO eye via the Ethernet port. You can then view the live microscope image in the CALLISTO eye "LUMERA 700" menu and make settings for the surgical microscope, foot control panel and hand grips.

The "LUMERA 700" menu features a function view and a Configuration view. The Function view contains three tabs, the Configuration view has ten submenus, each with one or more tabs.

A live video image of the LUMERA 700 can be displayed in all tabs of the Function view. The display is identical in all three tabs. If a patient has an "active" status you can start, pause, discard or end a video recording in these tabs and also save image stills (see page 164).

Pressing the video image switches CALLISTO eye to a full format display for the video image. To return to the normal view you press the button displayed in the full format display  .

Full picture mode is automatically unavailable if a fault occurs or there is a change in the device setting.

Video recording can be started, reset or stopped, and a photo saved, in all the Function view tabs if patient has "active" status (see page 112).

All changes in Configuration view tabs are automatically saved under the name of the active device setting (except where the current user is one of "Systemadministrator", "ZEISS Service User" or "Default User"). Different settings can be saved in various device settings which can then be transmitted to the device as required by selecting the respective device setting. These settings are user-specific, i.e. every user can save his/her own settings and load them as required (see page 178 and page 172).

Please note: Making changes in the Configuration view tabs will alter (overwrite) the currently active device setting. If you don't want to overwrite the current settings, you should start by first creating a new device setting (see page 47).
Changes in Function view tabs will not be saved.

CAUTION

To prevent personal injuries due to unexpected equipment behavior, please observe the following:

- When changing settings, please ensure that the correct user and correct device settings are activated.

The active user and active device settings are displayed in the header on the user interface (third and fourth field from the left).

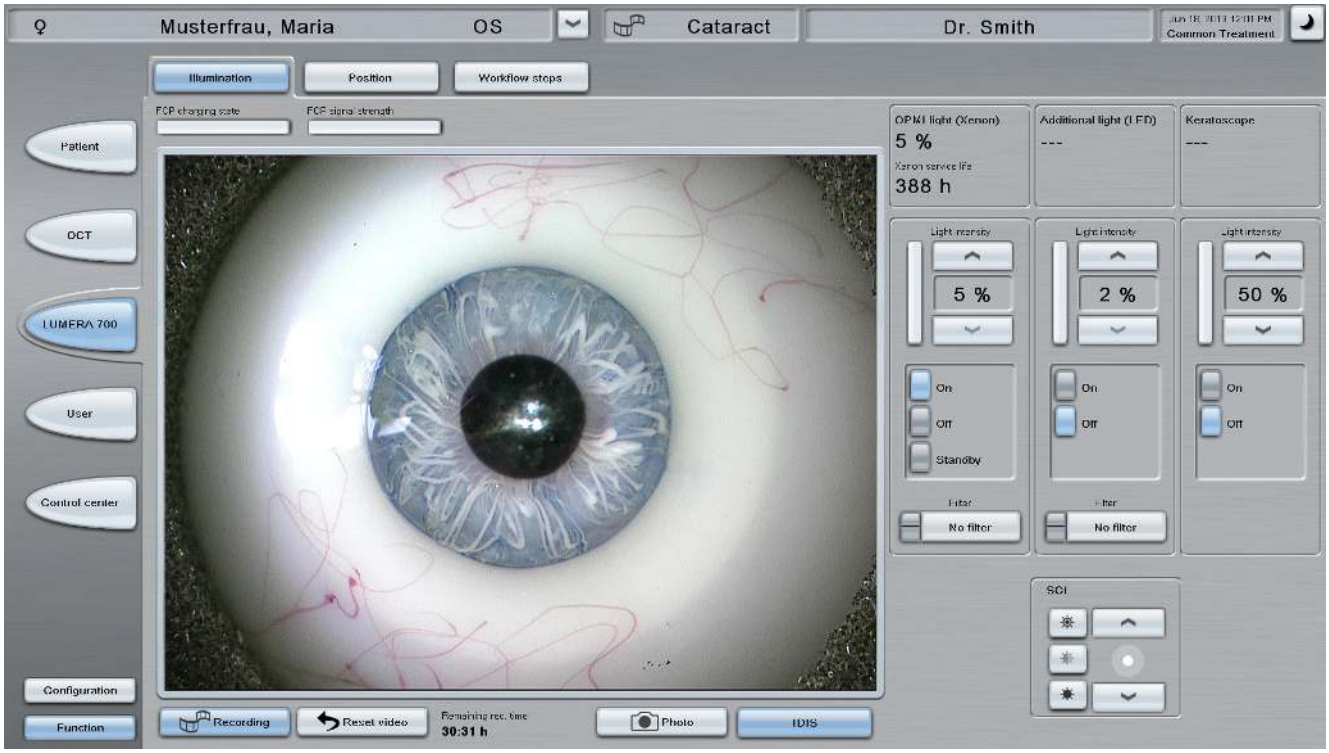
The controllable functions of the OPMI LUMERA 700, the foot control panel and the hand grips are described in the microscope's Instructions for Use. Familiarize yourself with the operating functions before making any settings on CALLISTO eye.

Function View

The Function View has three tabs; "Illumination", "Position" and "Workflow steps". Taking as an example the "Illumination" tab, the following describes the buttons and displays relating to video recording and photo saving. Please refer to the Instructions for Use for the surgical microscope for information about settings options for the microscope.

"Illumination" tab

Using this tab you can make settings for the microscope light and the keratoscope and display the image from the LUMERA 700 surgical microscope on the CALLISTO eye in large format. When a patient has "active" status, video of the treatment can be recorded and you can save a still image (digital image). You can interrupt and resume the video recording.



The <Recording>, <Reset video> and <Photo> buttons below the video image are only active if the patient has "active" status (see page 112). If there is no active patient, you can view the image of the connected microscope. However, it is not possible to record videos or to save still images.

Buttons and displays below the video image

Recording	Starts and stops the video recording of the current treatment. → When video recording is underway, the button is colored blue; in addition, the symbol  appears on the left in the header in the field "Treatment". If no video recording is underway, the button is gray. While video recording is underway: Pressing this button stops video recording of the current treatment. → The video recording is stopped (the patient continues to have "active" status). Initial and final images of the recorded video are generated. The video and initial/final images can be viewed in the "Image data" tab of the Patient administration ("Patient" menu). → The <Reset video> button is disabled. Press the button again to resume video recording of the surgery. This generates a new video and enables the <Reset video> button.
Reset video	Discards the current video recording. → Video recorded up to the point this button is pressed is discarded and not saved. **No safety prompt** is given.
Photo	Generates a still image. → Pressing this button saves the current image as a digital photo. After the patient has been de-activated the image can be viewed in the "Image data" tab of Patient administration ("Patient" menu) .

Remaining	Indicates the time left for recording videos (hours : Minutes).  The value given here is approximate since precise recording capacity is heavily dependent upon the actual video itself. → Should this time be insufficient for the recording of a scheduled treatment, data (patients, treatments or individual documents) must be deleted, where necessary after it has been exported to an external storage medium (see pages 114, 125 and 140).
IDIS	Activates and de-activates data injection into the surgical microscope eyepiece. Various microscope settings can be shown, and an indicator of whether a video is currently being recorded (parameter specification see page 167). → Injection is enabled if the button is blue.

Buttons and displays on the right

See the Instructions for Use for the LUMERA 700 surgical microscope.

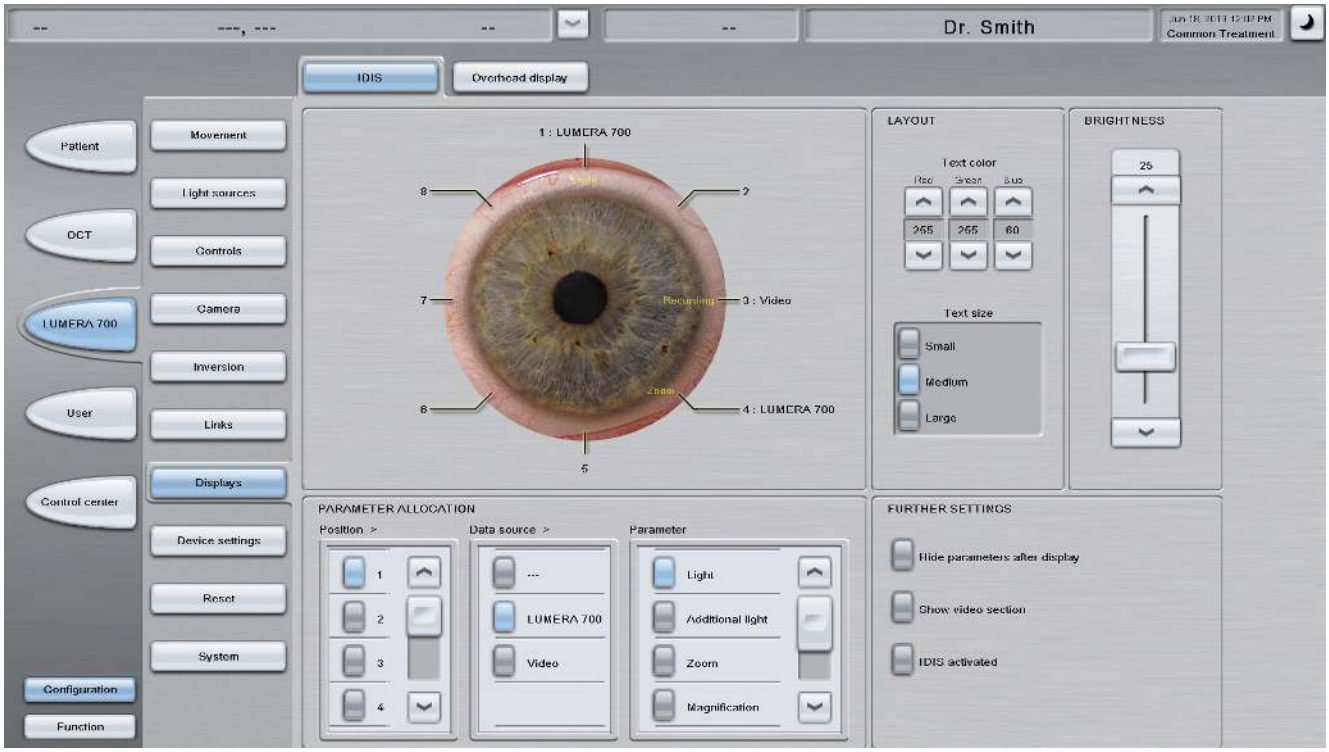
Configuration view

The Configuration view of the "LUMERA 700" menu has ten sub-menus, each with one or more tabs. Below by way of an example is a description of the configuration options for data injection into the eyepiece of the LUMERA 700 surgical microscope. For further setting options, please refer to the Instructions for use for the LUMERA 700.

"IDIS" tab

Use this tab to set-up injection into the surgical microscope's eyepiece.

The preview image of the tab displays the selected parameters and defined properties (color, font size, position).



Buttons and setting options

Position	Select the position in the live image at which the parameter selected under "Data source" and "Parameters" is to be inserted (e.g. 1: Center top; 6: bottom left; etc.)		
Data source, Parameter	Selection of parameter to be injected at the position selected:		
	---	No data source selected (default setting)	No injection
	LUMERA 700	Light	set brightness
		Additional light	set brightness
		Zoom	Gamma value (0.4 … 2.4)
		Magnification	Total magnification
		FCP charging state	Charge state of the battery of the foot control panel
		FCP Signal	Bluetooth signal strength when using the wireless foot control panel
	Video	Recording	Display indicating whether video recording is currently in progress
LAYOUT	Text color	Set the color and font size for display of the selected parameters in the live image. The set color and font size is also displayed in the preview image of the "IDIS" tab.	
	Text size		
BRIGHTNESS	Brightness of the injected/superimposed text		

FURTHER SETTINGS	Hide parameters after display	Before activating the function, you should switch off data injection (the <IDIS> button in one of the function view tabs of the "LUMERA 700" menu). If the function is activated, the parameters only appear in the LUMERA 700 eyepiece following a change, and then only briefly, if data injection is switched on by pressing the <IDIS> button in the Function view of the "LUMERA 700". → If the function is activated the button is blue. If the function is deactivated, the parameters are shown permanently.
	Show video section	→ In the preview image the area is indicated by a square, which will be visible on a video recording.
	IDIS activated	Presetting for data injection: On or Off. → If the function is activated the button is blue. The preset acts only on the injection of parameters configured in the "IDIS" tab. It has no effect on the injection of OCT images.

"User" menu (User administration)

CALLISTO eye software User administration can be used to set up a profile for every user and switch between users.

Many settings are user-specific, i.e. saved for a specific user (user interface language, user rights, password, device settings).

After the device has been started, the last logged-in user is automatically activated. If the last logged-in user was the System administrator, the default user (see below) is automatically activated. The name of the logged-in (active) user is displayed in the "User" field in the header (third field from the left).

The User administration Function view contains the "Selection" tab.

The User administration Configuration view contains the "User" and "Device setting" sub-menus, each with an "Management" tab.

There are three preset users:

- **Systemadministrator**
  User with full rights, English user interface, password protected.

  The Systemadministrator password is initially assigned by Carl Zeiss the software manufacturer. A Carl Zeiss employee will provide this password to the local system operator during training. The trained operator can then change the Systemadministrator password.

- **Carl Zeiss Service user**
  User exclusively for ZEISS-Service, password protected.

- **Default User**
  User with restricted rights, English language user interface, no password protection. The Default User is allowed to create, edit, delete, import and export patient data, but has no access to User administration and is only allowed to view personal patient data.

  The "Default user" should only be activated for test purposes.

These three users cannot be deleted. Changes made to settings while one of these three users is active are not saved, with one exception: System administrator password can be changed.

– **OCT Default User**
User with restricted rights, English language user interface, no password protection. The OCT Default user is allowed to create, edit, delete, import and export patient data, but has no access to User administration and is only allowed to view personal patient data.

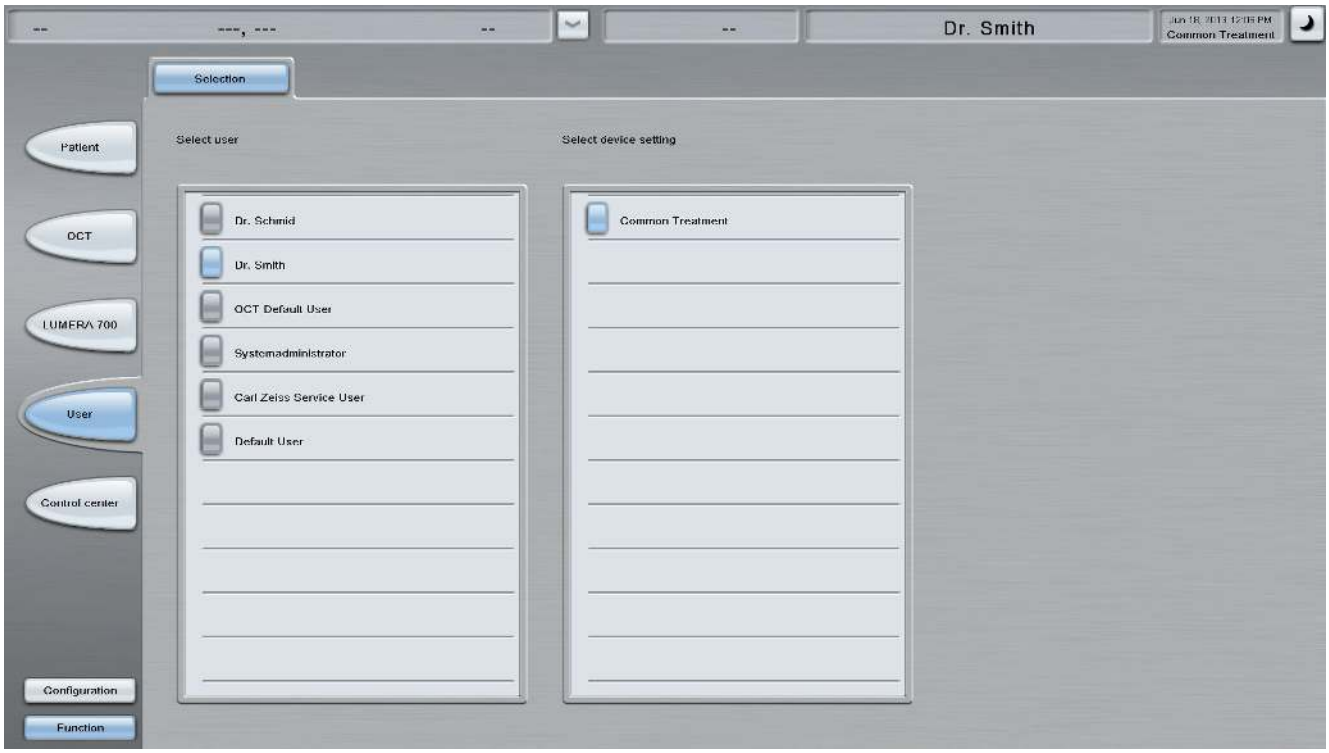
For the default user "OCT Default User" two device settings are preconfigured ("Anterior" and "Posterior"). These device settings hold preconfigured special settings for the OPMI LUMERA 700 (see also the Instructions for Use for the LUMERA 700 surgical microscope). This means that OCT visualization is possible immediately following log-on of the OCT default user. The device settings "Anterior" and "Posterior" can be changed.

Function View

"Selection" tab

Use this tab to change the active user and select a device setting (see page 178) for the active user.

Device settings are user-specific settings. This means that the "Select device setting" list (see figure below) always offers only those device settings created for the currently active user.



Lists

Select user	Selecting an entry activates the respective user. The user can only be changed while no patient is active. → If a password was saved in the user data, this will be requested.  After the password has been entered, the password request window reappears. The "Password" field now contains four asterisks (****) instead of "---". Press the <OK> button to confirm the password. If a user enters the wrong password three times, the system automatically asks for the System administrator password. After correct entry of the System administrator password, the user in question has to enter a new user password. → The language of the user interface is set to the language selected for the activated user. → All configurations saved for the activated user are loaded (rights, device settings, OCT presettings). → The "User" field in the header is labeled with the name of the activated user.
Select device setting	Selecting an entry selects the respective device setting. → All the settings saved under the name of the device setting selected will be sent to the connected devices. → The selected device setting is displayed in the header, i.e. in the upper right-hand corner below the date and time. → All changes made to the settings are automatically saved under the name of the selected device setting, i.e. the previously saved settings are overwritten.

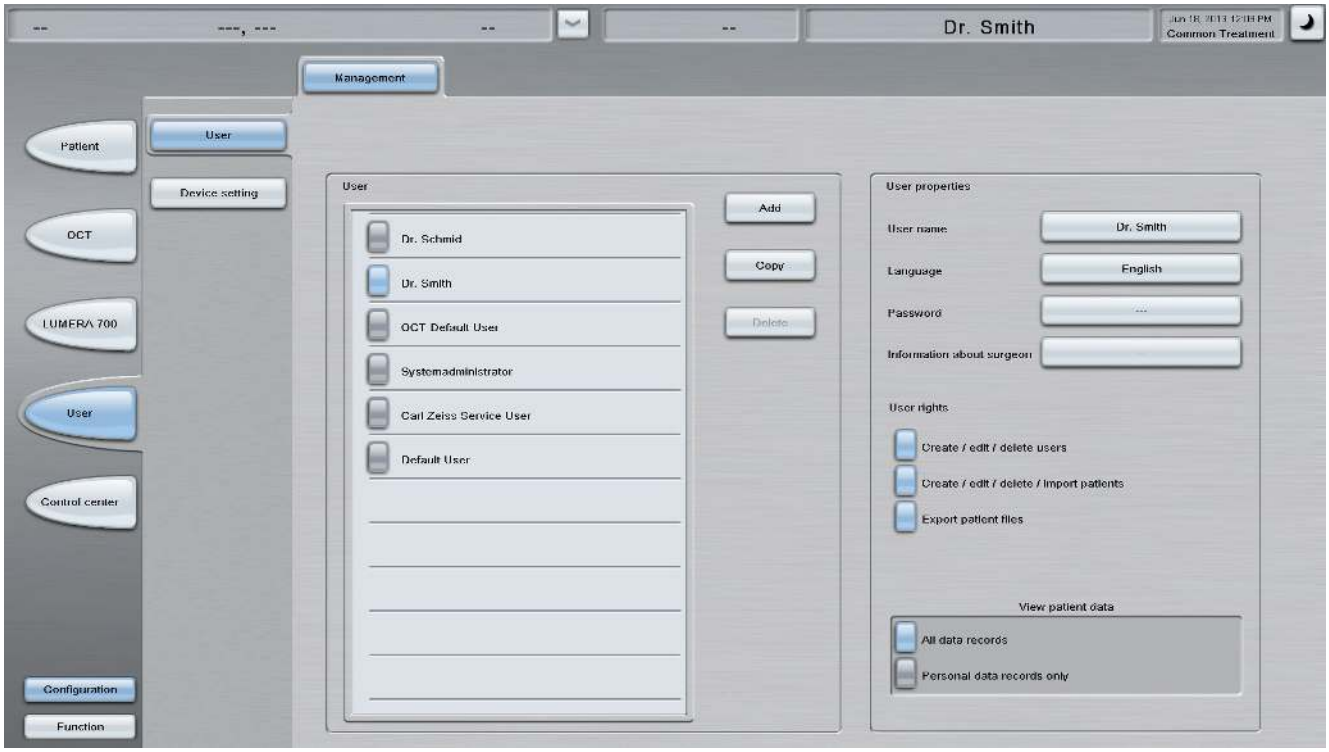
Configuration view

"User" sub-menu, "Management" tab

Use this tab to create new users, delete existing users and view or edit user data of all existing users. Depending on user rights, the user name can be changed, the user interface language customised, a login password stored or edited, a comment entered or edited, and user rights viewed and changed.

The active user must have the rights to edit user data in order to make changes in this tab. Without these rights, all buttons will be disabled (see "User rights" on page 177).

Unless a user has been created with the corresponding rights, users can be created and edited only by the Carl Zeiss Service User and the System administrator. In this case, the user interface language is English.



"User" area

"User" list	Lists all created users. A user is selected by pressing the corresponding button. → The selected user can be copied or deleted and the user data viewed and edited. Selecting the user does not make the user the "active" user. Users can only be activated in the "Selection" tab of the Function view (see page 172).
Add	Create a new user. A unique user name has to be entered. → The entered name appears in the user list. → The new user has the default settings – Language: English – no password – no information regarding surgeon – Rights to create/edit/delete patients, to export patient data and to view personal data records; no right to create users. These settings can be edited after the newly created user has been selected.
Copy	Copies the user selected in the list. → A new user is created with the data of the copied user. → The name assigned to the new user is that of the copied user with an extension.
Delete	Deletes the selected user. → After the confirmation of the safety prompt, the selected user is deleted from the list. Patient data created by the deleted user and the treatments that he performed (started) will not be deleted. The currently logged-in (active) user cannot be deleted.

"User properties" area

User name	Display and change user name: Pressing this button opens the keyboard. The user name can now be changed. → The button is labeled with the changed name. → The changed user name is listed in the user list of the "Selection" tab (Function view).
Language	Display and change the language of the graphical user interface:  → The language of the user interface is changed immediately after the confirmation of the selection with <OK>. → The setting is saved for the user, so that the language of the user interface is automatically set to the selected language every time this user is activated.
Password	Change the password saved for the user or create a new password: 
Old password	Entry of the old password if a password has already been filed.
New Password	Entry of the desired (new) password. The password is case-sensitive. The password must consist of at least two characters.

	Confirm password	Repetition of the entered password to prevent typing errors.
	OK	Confirmation of the new password. → The password is requested when the user is selected in the "Selection" tab of the Function view. The user is only activated after the correct password has been entered.
Information about surgeon	Option to store additional information about the user (e.g. special qualification).	
User rights	Shows the user rights of the selected user. Can be used to change the user rights of the selected user (only possible if editing rights have been assigned to the active user during setup).	
	Create / edit / delete users	The user may create new user accounts, edit his own user rights and the user rights of others, and delete user accounts. If this option is disabled, the user may only view his own rights.
	Create / edit / delete / import patients	The user may create new patient data records, edit and delete existing records, and import patient data records. If this option is disabled, the user can only select the created patients and view the patient data.
	Export patient files	The user is allowed to export patient data.
View patient data	All data records	The user may view all patient data contained in CALLISTO eye, i.e. both patient data entered by him/herself and patient data entered by other users, including related treatment data.
	Personal data records only	The user may view all data of the patients that s/he created.

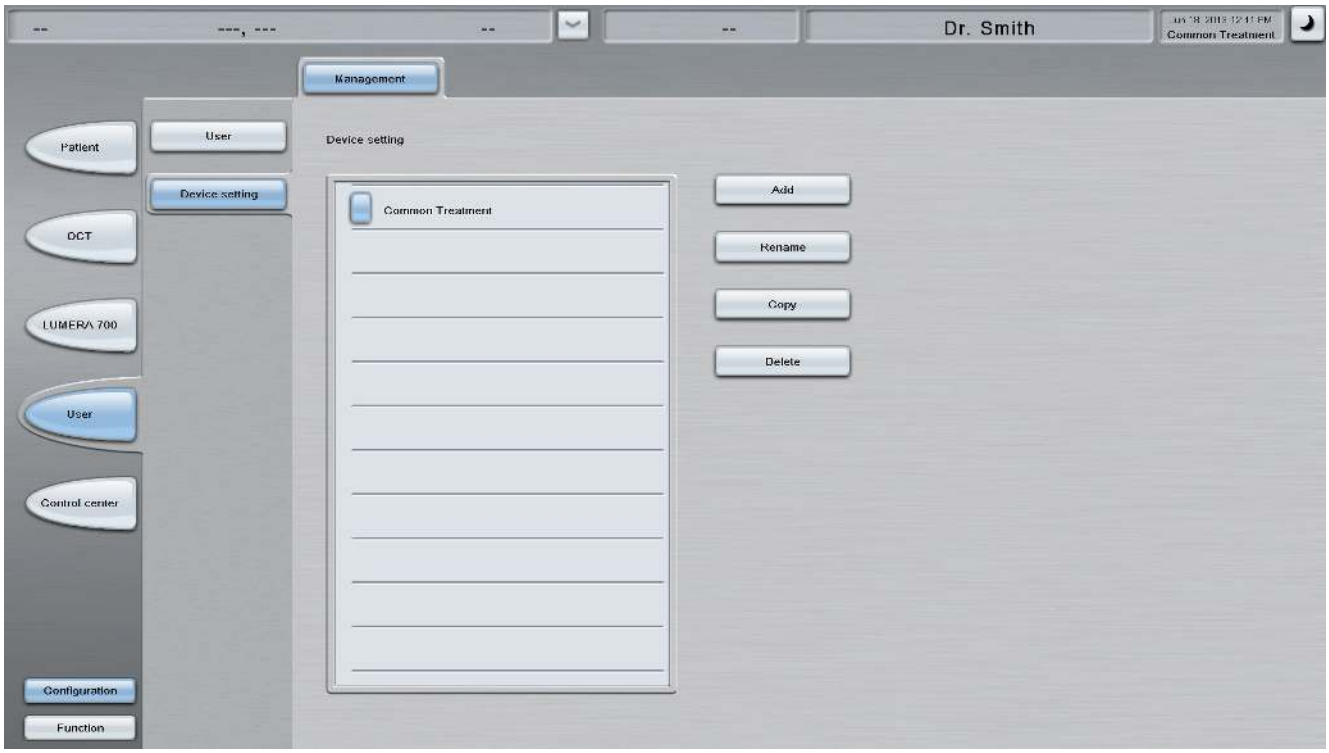
"Device setting" sub-menu, "Management" tab

Use the "Management" tab to enter device settings for the active user as well as to copy, delete and rename existing settings. Device settings are user-specific settings. They are available only to the user active during their entry.

Specific initial settings for connected devices (surgical microscope, hand grips, foot control panel) as well as settings for data injection in the OPMI LUMERA 700 eyepiece can be configured for each entered device setting. Configuration is carried out in the "LUMERA 700" menu (see page 162).

These settings are transmitted to the devices when a device setting is selected.

A device setting for the active user is selected (activated) in the Function view of the "User" menu in the "Selection" tab (see page 172) or in the Function view of the "Patient" menu in the "Patient" tab (see page 113).



Buttons

Add	Entering a new device setting. Pressing this button opens the keyboard. → After entry of the name of the device setting this name appears in the list. The device setting "Common Treatment" is the default setting for every user. This setting can be edited or deleted. If no other device setting is listed, the only enabled button is <Add>.
Rename	Edit the name of the selected device setting. Pressing this button opens the keyboard. → After entering the change the edited name appears in the list.
Copy	Copies the device setting selected in the list. → A new device setting is created. → The name of the copied device setting is assigned to the new device setting, followed by an extension.
Delete	Deletes the device setting selected. A device setting can only be deleted when it is not active.

"Control center" menu

Various system information can be viewed in the Control center:

- Software version
  ("Info" tab)
- System operating hours
  ("Info" tab)
- Device name (can be edited)
  ("Info" tab)
- Utilization of hard disk
  ("Data administration" tab)

In addition, various system settings can be made:

- Activate/deactivate data protection
  ("Info" tab)
- Network connection
  ("Network" tab)
- Remote control settings
  ("Remote" tab)
- Date and time
  ("Time" tab)
- Export system log
  ("Info" tab)
- Activate/de-activate automatic video recording when starting an operation
  ("Data administration" tab)

The Control center is opened by calling up the <Control center> menu button on the left margin. It comprises the Configuration view with the "System Info" sub-menu containing five tabs.

"Info" tab

This tab displays the installed software version and operating hours of CALLISTO eye. In addition, data protection can be de-activated, the device name edited, and a system log exported.

Version	Software version installed.
Operating hours	Number of operating hours of CALLISTO eye.
Activate data protection	Default setting: Yes Data protection can only be activated or deactivated by the System administrator. This setting must be coordinated with the Data Protection Officer of your hospital.
Yes	→ When the user is changed, a user with a stored password must enter his password before he will be activated. → If a user has only restricted user rights, s/he may only be able to view the data s/he has generated (see "User rights" on page 177).

	No	→ All users can log in without password, irrespective of the user rights assigned. → All users can view all data. → All users can create new users.
Device name	Assigning of a device name (default setting: CALLISTO EYE) → Pressing this button opens the keyboard for entry of a freely selectable name. → The button label will change accordingly.	
Log export	Save the system-generated log files to a connected USB drive. → The data are saved in encrypted form  In the event of failure, ZEISS-Service can obtain relevant information about internal program details from these log files.	

"Network" tab

Settings to connect CALLISTO eye to the network and database are made in this tab. It can also be used to check the proper functioning of the network connection.

Only change these settings if changes relating to the CALLISTO eye network link were made after installation in your network.

The type of settings and data that are required depends on the network in which you wish to operate your CALLISTO eye. Seek advice from ZEISS-Service or your in-house network administrator regarding these settings and data.

Buttons and fields

OR database …	Data for the connection of CALLISTO eye with the database. The settings are configured by ZEISS-Service during the installation of CALLISTO eye.
Computer name … MAC	Data for the connection of CALLISTO eye with the network.
IP test	Checks the proper functioning of the network connection. → A message will appear advising you whether the test was successful.
---	This button is used for entering an IP address for the IP test.
ORs	Operating room in which CALLISTO eye is used. Default setting: OP1. This setting cannot be changed.
Save	Save network settings → CALLISTO eye has to be restarted. The restart is initiated automatically after the corresponding message has been confirmed. → The current settings are stored. CALLISTO eye is integrated into the network.

The second network card is used to connect CALLISTO eye to the computer for the OCT function. The settings are preconfigured in the factory and cannot be changed.

"Remote" tab

Use this tab to make settings that will enable ZEISS-Service to perform remote maintenance measures.

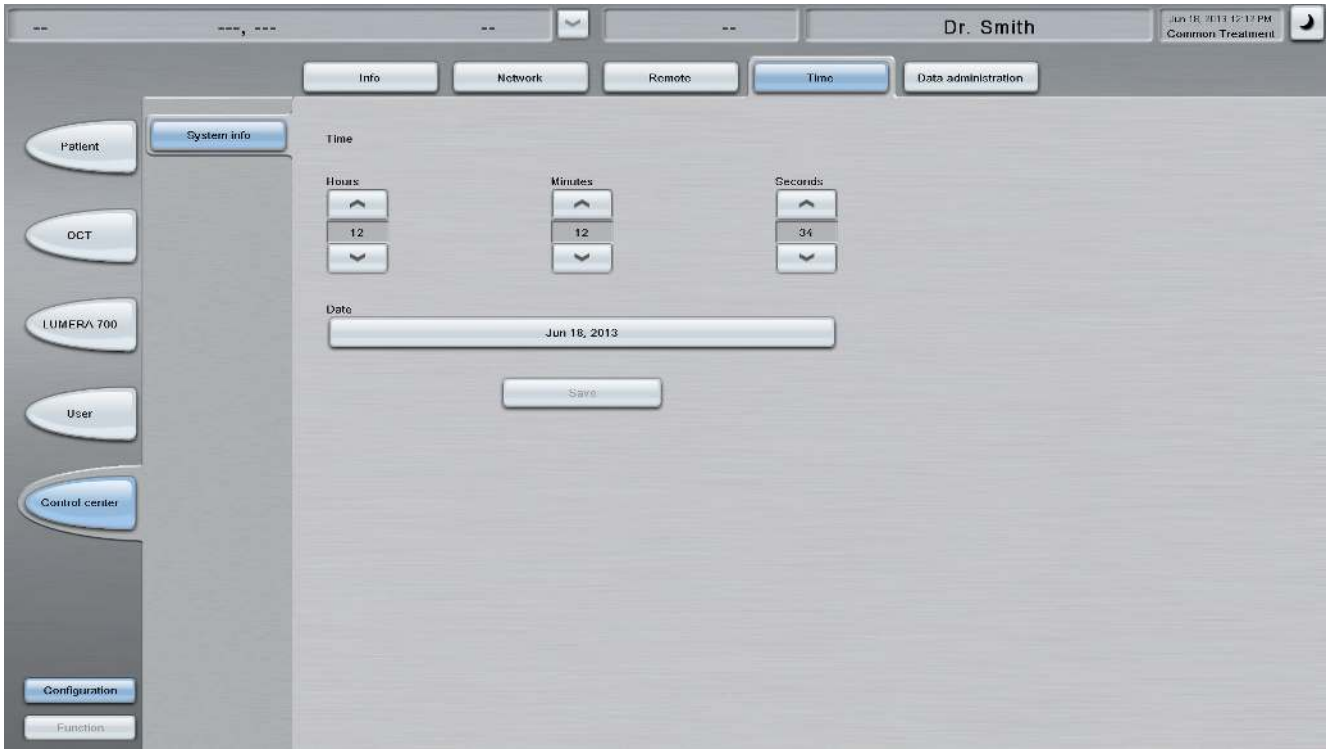
Remote maintenance requires that CALLISTO eye is connected to the Internet via a LAN.

Buttons and fields

Network	Data for the network connection.	
	IP address … Computer name	Data which describe the connection of CALLISTO eye to the network. This data cannot be edited here.
Remote	Data for the remote connection.	
	Session ID	The session ID can be obtained from ZEISS-Service.
	Proxy host name … Proxy password	Proxy configuration data. This data can be obtained from the system administrator responsible for your hospital network.
Start Remote	Starts remote operation.	
Use Proxy	Select whether remote connection should be made via a proxy server. → If blue, the button indicates that the function is on. The selection is made in co-ordination with ZEISS-Service.	

"Time" tab

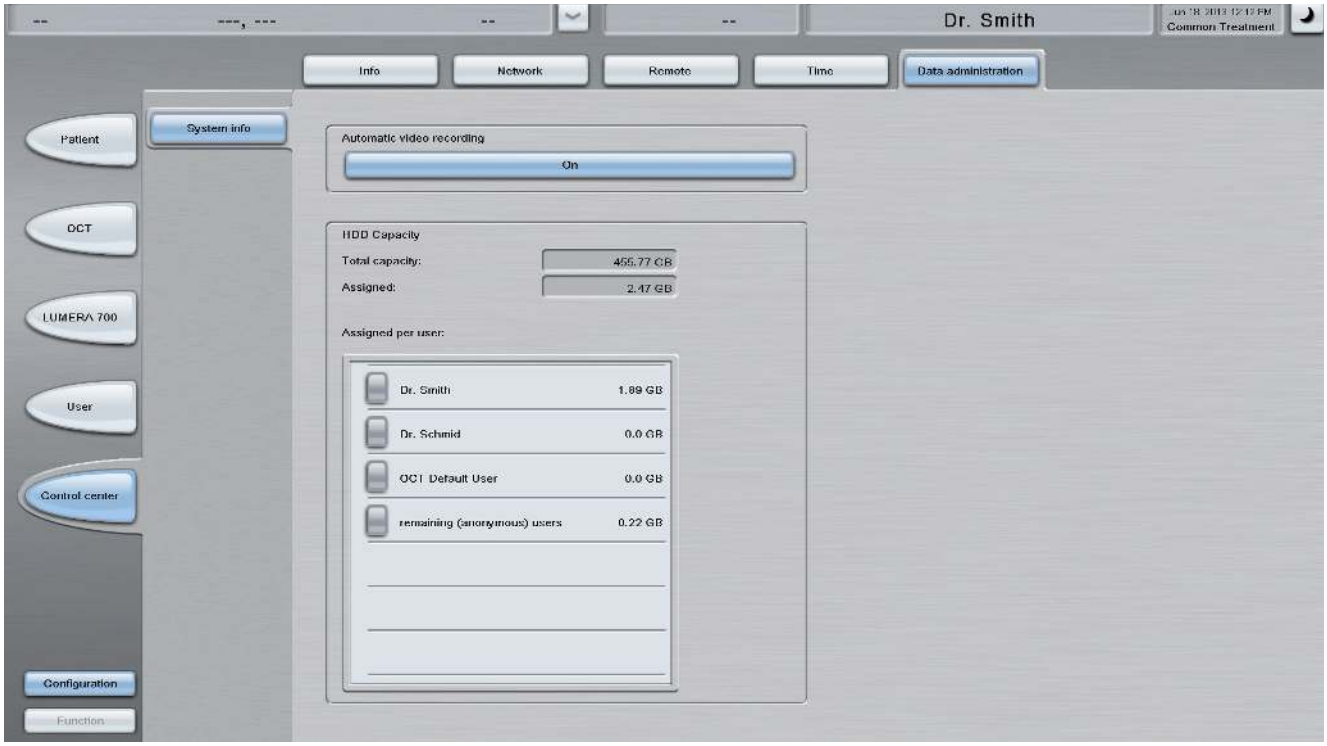
Use this tab to set the current date and the current time.



Time	Setting of the current time (system time) and current date (system date). → The system time and the system date are used as default settings in fields and displays in which a time/date is entered automatically.
Date	→ When the recording of a surgery video is started and stopped (video recording), the system time is saved as the start or stop time respectively, and the system date is saved as the surgery date.
Save	Saves the date and time settings. → CALLISTO eye has to be restarted. The restart is initiated automatically after the corresponding message has been confirmed. → The current settings are stored.

"Data administration" tab

This tab shows the capacity of the internal hard disk and the storage space currently assigned.



Automatic video recording

On	If an operation is started (see page 120), the video recording starts automatically.
Off	If an operation is started, the video recording does not start automatically. It can be started manually in one of the tabs of the Function view of the "LUMERA 700" menu.

HDD Capacity

Total capacity	Total storage space available on the internal hard disk.
Assigned	Total currently assigned storage space.
Assigned per user	Storage space assigned to each individual user. The three users defined by the system (Systemadministrator, Carl Zeiss Service User and Default User) are combined under "remaining (anonymous) users".

Maintenance

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Safety check

To prevent any impairment of system safety as a result of aging, wear, etc., the organization operating the system must ensure, in accordance with the applicable national regulations, that the regular technical safety checks defined for this device are performed on schedule and to the stipulated extent.

Safety checks must only be performed by the manufacturer or qualified personnel.

The user should additionally conduct at least the following safety checks at regular intervals:

- Check availability of the Instructions for Use.
- Visual inspection of the device and accessories for damage and legibility of labels.
- Function test of all switches, buttons, connectors and indicator lights on the device.
- Check of the electrical installation in accordance with DIN VDE 0751-1, DIN VDE 0701-0702 and BGV A3 or corresponding equivalent regulations in other countries.

The system does not normally require servicing. We do however recommend an annual maintenance checkup under a service contract.

Cleaning and disinfecting

The components of the CALLISTO eye must be carefully cleaned and disinfected prior to each treatment to protect patients and operating personnel against infections.

If you as a sterile user intend to operate CALLISTO eye yourself during a treatment, you must cover the system with a pre-sterilized, disposable drape (see page 31).

We recommend cleaning of CALLISTO eye and the table mount or trolley as immediately after use as possible. Soiling/contamination should not be allowed to dry on the objects as this makes cleaning and disinfection more difficult.

NOTE

To prevent data loss and damage to CALLISTO eye, please observe the following:

- Use only the cleaning agents and methods recommended in this section.
- Do not spray cleaning agents and disinfectants onto CALLISTO eye.
- Do not clean the mechanical surfaces with solvents or with caustic and abrasive cleaning agents and disinfectants.
- Only use a disinfectant which complies with the specifications on page 193.

NOTE

The cleaning tool must be only moist, not dripping wet.

Cleaning the housing and the table mount or trolley

- Clean with a soft non-abrasive cloth or gauze pad.

All mechanical surfaces can be wiped with a moist cloth.

- Ensure that no liquids enter the system.

Cleaning the touchscreen

- Deactivate the touch function to avoid unintended operating errors while cleaning the touchscreen:
  Push the <Activate/Deactivate touch function> button on the lower edge of the touchscreen.

  → Deactivating the touch function illuminates the button more brightly, the <Power> button is not illuminated.

- Clean the touchscreen with alcohol-free glass cleaner.
  Apply the cleaner to a soft, clean cloth (do not spray or pour directly onto the touchscreen) and wipe the touchscreen with the moist cloth.

Disinfecting the device

NOTE

To avoid damage to the device from unsuitable cleaning agents and disinfectants, use only the agents specified below.

- To avoid damage to the surfaces of the device use an aldehyde- or alcohol-based disinfectant.

  The addition of quaternary compounds is acceptable.

  The maximum allowed application concentrations are:

  – For alcohol (tested with 2-propanol): 60%

  – For aldehyde (tested with glutaraldehyde): 2%

  – For quaternary compounds (tested with DDAC): 0.2%

Remote operation

Remote operation enables ZEISS-Service to perform remote maintenance measures on CALLISTO eye.

Prerequisite

✓ Remote maintenance requires that CALLISTO eye be connected to the Internet via LAN.

✓ To facilitate communication between ZEISS-Service and the customer, a telephone connection is required for establishing and maintaining the remote connection.

Procedure

- Press the <Control center> button.
- Select the "Remote" tab.

- If Internet access is via proxy:
  - Ask the system administrator responsible for your hospital network to provide the proxy configuration data (host name, host port, host user name and password).
  - Enter this data in the corresponding fields of the "Remote" tab.
  - Activate the proxy connection using the <Use Proxy> button.
  - → The proxy connection is activated if the button is blue.
- Ask ZEISS-Service for a session ID.
- Enter the session ID in the corresponding field of the tab.
- Press the <Start Remote> button.

Result → The remote connection is established. The ZEISS-Service technician can now access the device via the Internet and perform the necessary maintenance work.

Shipping the device if service work is required

Should a CALLISTO eye device require servicing, the device must be sent to ZEISS or to the national branch office in your country/state.

NOTE

Service work may only be performed by authorized and trained service personnel of ZEISS-Service.

All data saved on the device will be deleted if repair work is needed. In the event of repairs by Carl Zeiss service staff, the recovery of patient, image, video and configuration data is no longer possible.

NOTE

Every user is personally responsible for backing up his/her own data.

- Prior to dispatching the device please be absolutely sure to back up all patient and treatment data to CD/DVD or a USB stick/external USB hard disk (as far as this is still possible).

CAUTION

To avoid data protection violations, please observe the following:

- Ensure that only authorized persons have access to the device.
- Should repair be necessary, delete all patient and treatment data from the device as far as this is still possible.

- Switch off the device and disconnect it from the external power supply and if applicable from the data network.

CAUTION

To avoid personal injury due to electrical voltage or material damage resulting from transit damage, please observe the following:

CALLISTO eye and accessories may only be transported over long distances (e.g. in event of relocation, return shipment for repair purposes, etc.) in the original packaging or in a special shipping crate. Contact your dealer, national branch office or ZEISS-Service about this.

Recommendation: Retain the original packaging and observe the transportation conditions (see page 208).

Perform a visual inspection:

- Make certain there is no visible damage to or modifications of the user terminal, such as:
  - Discolorations, deformations, scratches
  - kinked, broken, frayed cables
  - dirty touchscreen

Temporary shutdown

In the event of temporary shutdown of the device:

- Back up the data.
- Switch off the device and pull the power plug.
- Store the device in accordance with the operating and transport conditions.

Disposal

Correct disposal of this product helps to protect the environment and to prevent potential hazards to the environment and/or human health which may occur as a result of improper handling of the device to be disposed of.

For detailed information on disposal of the product, please contact your local dealer or the device manufacturer or its legal successor. Please also note the manufacturer's current information on the Internet. In the event of resale of the product or its components, the seller is required to inform the buyer that the product must be disposed of in accordance with the applicable national regulations currently in force.

CAUTION

To avoid data protection violations, please observe the following:

- If the device is disposed of, delete all patient and treatment data from the device as far as this is still possible.
- Please contact ZEISS-Service if it is not possible to delete patient and treatment data from the device.

Disposal in member states of the European Community

CALLISTO eye is subject to European Directive 2002/96/EC (WEEE) and the corresponding implementation in the law of EU member states. The WEEE symbol (see figure to the left) on the back of CALLISTO eye indicates that the device must be disposed of in accordance with this.

Under WEEE terminology, CALLISTO eye is a "device solely for commercial use". This means:

– The device must not end up in unsorted commercial waste.

– The device must not be handed over to municipal collection points (as would be acceptable for consumer goods).

At the end of its service life, the device can be returned to the supplier for proper disposal and recycling.

CAUTION

When disposing of the device, observe the legal provisions applicable in your country.

- Any parts replaced must also be disposed of in accordance with the relevant legal provisions, unless you also return these parts for disposal.

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Technical specifications

User terminal technical specifications

Weight	14.0 kg
Dimensions (W x H x D)	586 mm × 396 mm × 96 mm
Power connection	Only connect the device to power outlets equipped with a properly functioning ground conductor.
Input voltage	100 VAC to 240 VAC ±10%
Rated frequency	50 Hz – 60 Hz
Power consumption	1.0 to 0.5 A
Electrical design	Compliant with IEC 60601-1 / EN 60601-1 Protection class I, IP20
Product classification	In accordance with 93/42/EEC, Annex IX: Class IIa
EMC requirements	The device complies with the EMC requirements of IEC 60601-1-2. The device fulfils Class B (practices) RFI limit values.
CE mark	The device meets the essential requirements stipulated in Annex I to Directive 93/42/EEC governing medical devices. The device is labeled with: CE 0297
Display size	1920 × 1080 pixels
Video and image recording	HD video format: 1080i, 720p SD video format: PAL, NTSC Image resolution corresponds to 4:3 scaled video format.
HDD size	500 GB

EMC (electromagnetic compatibility)

The device complies with the EMC requirements of IEC 60601-1-2:2007.
When using the device, the EMC precautions set out below must be observed.

⚠ **CAUTION**

- During device operation observe the precautionary measures listed below with respect to electromagnetic compatibility:
  - Use only ZEISS-approved spares for this device.
  - Do not use any portable or mobile HF communication equipment near the device, as the possibility that device function may be affected cannot be excluded.
  - Do not use any cell phones near the device. These represent a potential risk to the proper functioning of medical devices. Malfunctions may occur, depending on a variety of local factors. These are not foreseeable and cannot be assessed in any way.

Terms

ME equipment: Medical electrical equipment

ME system: Network of electrical devices at least one of which is ME equipment.

Electromagnetic interference

Guidelines and manufacturer's declaration – electromagnetic emissions – for all ME equipment and ME systems

CALLISTO eye is intended for operation in an electromagnetic environment as specified below. The customer or user of CALLISTO eye is responsible for ensuring that it is operated in such an environment.

Emitted interference measurements	Compliance	Electromagnetic environment – guidelines
RF emissions as per CISPR11	Group 1	CALLISTO eye uses RF energy only for its internal functions. Consequently it has very low RF emissions that are unlikely to cause any interference in nearby electronic devices.
RF emissions as per CISPR11	Class B	CALLISTO eye is suitable for use in any type of facility, including locations in residential environments and similar, that are directly connected to the public power supply network which also supplies buildings used for residential purposes.
Harmonic emissions as per IEC 61000-3-2	Class A	
Emission of voltage fluctuations/ flicker as per IEC 61000-3-3	Compliant	

Electromagnetic immunity

Guidelines and manufacturer's declaration – electromagnetic immunity for ME equipment and ME systems

CALLISTO eye is intended for operation in an electromagnetic environment as specified below. The customer or user of CALLISTO eye is responsible for ensuring that it is operated in such an environment.

Immunity tests	Test level as per IEC 60601	Compliance level	Electromagnetic environment – Guidelines
Electrostatic discharge (ESD) as per IEC 61000-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be of wood or concrete or be covered with ceramic tiles. If the flooring contains synthetic materials, the relative humidity must be at least 30%.
Fast transient/ burst electrical immunity as per IEC 61000-4-4	± 2 kV For power lines ± 1 kV For input and output lines	± 2 kV For power lines ± 1 kV For input and output lines	Supply voltage quality should be that of a typical business or hospital environment.
Surges as per IEC 61000-4-5	±1 kV line-to-line voltage ±2 kV line-to-ground voltage	±1 kV line-to-line voltage ±2 kV line-to-ground voltage	Supply voltage quality should be that of a typical business or hospital environment.
Voltage drops, short interruptions and voltage fluctuations as per IEC 61000-4-11	< 5% U_T (> 95% dip of U_T) for 0.5 cycle 40% U_T (60% dip of U_T) for 5 cycles 70% U_T (30% dip of U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Supply voltage quality should be that of a typical business or hospital environment. If the user of CALLISTO eye also requires continued function in the event of power supply interruptions we recommend powering CALLISTO eye from an uninterruptible power supply.

Immunity tests	Test level as per IEC 60601-1-2	Compliance level	Electromagnetic environment – Guidelines
Power supply frequency (50/60 Hz) magnetic field as per IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels typical of business and hospital environments.

Note: U_T is the AC supply voltage prior to application of the test level.

Guidelines and manufacturer's declaration – electromagnetic immunity for non-life-supporting ME equipment and ME systems

CALLISTO eye is intended for operation in an electromagnetic environment as specified below. The customer or user of CALLISTO eye is responsible for ensuring that it is operated in such an environment.

Immunity tests	Test level as per IEC 60601-1-2	Compliance level	Electromagnetic environment – Guidelines
			Portable and mobile radio communication equipment should not be closer to CALLISTO eye, including its cables, than the recommended separation calculated using the equation applicable to the transmission frequency. **Recommended safety distance:**
Conducted RF disturbances as per IEC 61000-4-6	3 V 150 kHz to 80 MHz	10 V	$d = 0.35 \sqrt{P}$

Immunity tests	Test level as per IEC 60601-1-2	Compliance level	Electromagnetic environment – Guidelines
Emission of RF disturbances according to IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	10 V/m	d = 0.35 $\sqrt{P}$ for 80 MHz to 800 MHz d = 0.7 $\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d is the recommended separation distance in meters (m).[b)] Field strengths of stationary RF transmitters, as determined by a site survey[a)], should be less than the compliance level in all frequency ranges.[b)] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.

a) Theoretically, the field strengths of stationary transmitters such as base stations for mobile telephones and mobile land radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast transmitters cannot be predicted accurately. To assess the electromagnetic environment with respect to stationary RF transmitters, a site study of electromagnetic phenomena should be considered. If the measured field strength in the location where CALLISTO eye is to be used exceeds the compliance levels indicated above, CALLISTO eye should be monitored to verify normal operation. If abnormal performance characteristics are observed, additional measures may be necessary, such as re-orienting or relocating the ME equipment or ME system.

b) Field strengths over the frequency range 150 kHz to 80 MHz should be less than 10 V/m.

Recommended separation distances

Recommended separation distances between portable and mobile RF communication equipment and ME equipment and ME systems, for non-life-supporting ME equipment and ME systems.

Recommended separation distances between portable and mobile RF communication equipment and CALLISTO eye.

CALLISTO eye is intended for operation in an electromagnetic environment in which RF disturbances are controlled. The customer or user of CALLISTO eye can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and CALLISTO eye, depending on the output power of the communication equipment as specified below.

Rated maximum output of transmitter [W]	Separation distance depending on transmission frequency [m]		
	150 kHz to 80 MHz $d = 0.35 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.21
100	3.50	3.50	7.00

The recommended separation distance d in meters (m) for transmitters whose maximum rated output power is not specified in the above table can be determined according to the equation applicable to the frequency range of the transmitter. In this equation, P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer's specifications.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection by structures, objects and persons.

Ambient conditions for CALLISTO eye

For operation	Temperature	+10 °C … +35 °C +50 °F … +95 °F
	Rel. humidity	10% … 90% (without condensation)
	Air pressure	700 hPa … 1060 hPa
For transport and storage	Temperature	-10 °C … + 60 °C 14 °F to 140 °F
	Rel. humidity	5% … 90% (without condensation)
	Air pressure	700 hPa … 1060 hPa

Install the device only in a low-vibration environment.

Troubleshooting

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Error messages

Below are listed the error messages that may arise during use of the surgical microscope or OCT functions. Remedies are provided for each error.

Error messages arising for CALLISTO eye other than those mentioned are usually self-explanatory, i.e. the message will suggest how the error can be remedied.

Please contact ZEISS-Service should error messages arise that are neither self-explanatory nor described below.

Malfunction in connected surgical microscope

Error message	Remedy
 If the <LUMERA 700> menu button goes red, malfunction is indicated.	• Press the button. → A message will be displayed describing the fault, e.g.: "Defect in intensity setting of LED light source". • Confirm the message by pressing the <OK> key. • Correct the fault.

OCT function error messages

Error message	Remedy
 If the <OCT> menu button goes red, malfunction of the OCT camera is indicated.	• Press the button. → A message will be displayed describing the fault, e.g. "Controller board temperature outside permitted range". • Confirm the message by pressing the <OK> key. • Should the message recur, notify ZEISS-Service.

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