

From Eye to Insight



MEDICAL DIVISION

Leica FL560 for M530

User Manual

10 747 212– Version 02



Thank you for purchasing a Leica surgical microscope accessory.
In developing our systems, we have placed great emphasis on simple, self-explanatory operation. Nevertheless, we suggest studying this user manual in detail in order to utilize all the benefits of your new surgical microscope. For valuable information about Leica Microsystems products and services, and the address of your nearest Leica representative, please visit our website:

www.leica-microsystems.com

Thank you for choosing our products. We hope that you will enjoy the quality and performance of your Leica Microsystems surgical microscope.



Leica Microsystems (Schweiz) AG Medical Division
Max-Schmidheiny-Strasse 201 CH-9435 Heerbrugg
Phone: +41 71 726 3333

Legal disclaimer

All specifications are subject to change without notice.
The information provided by this manual is directly related to the operation of the equipment. Medical decision remains the responsibility of the clinician. Leica Microsystems has made every effort to provide a complete and clear user manual highlighting the key areas of product use. Should additional information regarding the use of the product be required, please contact your local Leica representative.
You should never use a medical product of Leica Microsystems without the full understanding of the use and the performance of the product.

Liability

For our liability, please see our standard sales terms and conditions. Nothing in this disclaimer will limit any of our liabilities in any way that is not permitted under applicable law, or exclude any of our liabilities that may not be excluded under applicable law.


Contents

		10.4 Common troubleshooting steps	30
1	Introduction	2	11
1.1	About this user manual	2	Technical data
1.2	Symbols in this user manual	2	11.1 Leica FL560 characteristics
1.3	Optional product features	2	11.2 Compatibility
			11.3 Ambient conditions
2	Product identification	2	12
3	Safety notes	3	Manufacturer's declaration of electromagnetic compatibility (EMC)
3.1	Intended Purpose	3	32
3.2	Indication for use	3	
3.3	Intended User	3	
3.4	Intended Target Population	3	
3.5	Signs and labels	3	
4	Description	4	
4.1	Function	4	
4.2	Design	4	
4.3	Controls	5	
5	Preparation before surgery (PROVIDO, OHX, OH6, ARveo)	6	
5.1	Using the "Fluorescence FL560" user preset	6	
5.2	Modifying the FL560 user	9	
5.3	Get current settings	10	
5.4	Creating your own FL560 user	11	
5.5	Example "Handle left" assignment	12	
5.6	Example "FL" settings	13	
5.7	Save user settings	14	
6	Preparation before surgery (ARveo 8)	15	
6.1	Selecting a profile with FL560 settings	15	
6.2	Creating a new surgeon profile	15	
7	Modifying the Leica FL560 settings (ARveo 8)	22	
7.1	Excitation intensity	22	
8	Operation	23	
8.1	Operating Range Limits for FL560	23	
8.2	Pre-operation checklist	23	
8.3	FL560 test card functional areas	23	
8.4	FL560 test card pre-operational check	25	
9	Care and maintenance	26	
10	What to do, if...	27	
10.1	General	27	
10.2	Status messages	27	
10.3	Electrical	29	


1 Introduction

1.1 About this user manual

The Leica FL560 for M530 is an accessory for Leica surgical microscope systems.
In this user manual the functions of the Leica FL560 for M530 are described. For information and description of the Leica surgical microscope, please refer to the user manual of the particular surgical microscope.







In addition to notes on the use of the instruments this user manual gives important safety information (see chapter "Safety notes")



► Read this user manual carefully before operating the product.

1.2 Symbols in this user manual

The symbols used in this user manual have the following meaning:

Symbol	Warning word	Meaning
	Warning	Indicates a potentially hazardous situation or improper use that could result in serious personal injuries or death.
	Caution	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in minor or moderate injury.
	Note	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in appreciable material, financial and environmental damage.
		Information about use that helps the user to employ the product in a technically correct and efficient way.
		Action required; this symbol indicates that you need to perform a specific action or series of actions.

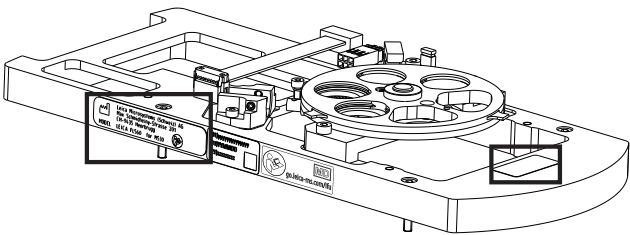
1.3 Optional product features

Different product features and accessories are optionally available. The availability varies from country to country and is subject to local regulatory requirements. Please contact your local representative for availability.

2 Product identification

The model and serial numbers of your product is located on the side and top of the Leica FL560 for M530 filter module.

- Enter this data in your user manual and always refer to it when you contact us or the service workshop regarding any questions you may have.



Type	Serial no.
...	...

3 Safety notes

A Leica surgical microscope with Leica FL560 for M530 is state-of-the-art technology. Nevertheless, hazards can arise during operation.

- Always follow the instructions in this user manual and in the user manual of the Leica surgical microscopes, and in particular the safety notes.

NOTE

Appearance of GUI screenshots

The graphical user interface (GUI) screenshots are for reference only and can vary in function of the configured options and different surgical microscopes. However, the functionality of the Leica FL560 is addressed.

3.1 Intended Purpose

The Leica FL560 is a surgical microscope accessory used in viewing fluorescence of fluorophores with an excitation peak between ~460 nm and ~500 nm (blue) and the fluorescence emission observation comprising the green, yellow and red spectrum in a spectral band above ~510 nm.

The Leica FL560 is intended to be used in conjunction with the Leica FL560 procedure kit. Please refer to the FL560 procedure kit for Sodium Fluorescein dosing and administration.



WARNING

Leica FL560 should only be used with fluorophores approved for use within the specified spectral ranges.



WARNING

Leica FL560 is not a standalone diagnostic device.



CAUTION

Federal Law restricts this device to sale by or on the order of a licensed medical practitioner.

3.2 Indication for use

The Leica FL560 is a surgical microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area.

3.3 Intended User

Leica FL560 is intended for professional use only. The user must have corresponding technical qualification and have been trained in the use of the instrument.

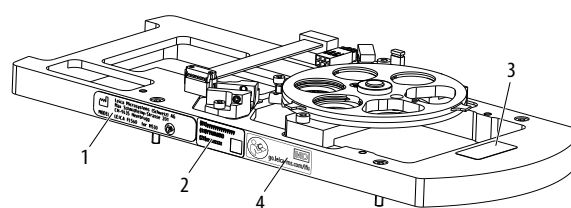
3.4 Intended Target Population

The intended target population are patients undergoing a surgical procedure as defined within the intended purpose and indications for use.

Contraindication

The medical contraindications applicable to the use of Leica surgical microscope accessories with Leica FL560 for M530 in combination with a fluorescence medium are those to be taken into account when using suitable brand substances. Medical decision remains the responsibility of the clinician.

3.5 Signs and labels



The type label is located on the side of the Leica FL560 for M530 filter module.

1		Type label
		Federal Law restricts this device to sale by or on the order of a licensed medical practitioner. (USA Only)
	CE label	
2	UDI Label	
3		Fabrication label a Reference number b Serial number
4		Mandatory label - read the user manual carefully before operating the product. Web address for electronic version of the user manual.
		Medical device

4 Description

4.1 Function

The illumination of the Leica M530 surgical microscope is a xenon lamp located in the stand.

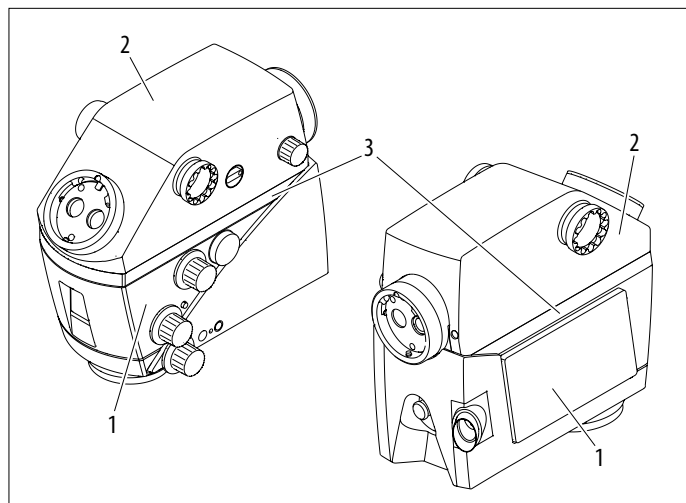
The Leica FL560 illumination filter module can provide visible and fluorescence excitation light.

To switch between visible (white) light and fluorescence mode illumination, a handle and/or foot paddle button has to be defined in the user settings for each Leica FL560 user/surgeon profile.

4.2 Design

The Leica FL560 for M530 is an accessory for the Leica M530 surgical microscope.

4.2.1 Optics carrier with Leica FL560 for M530

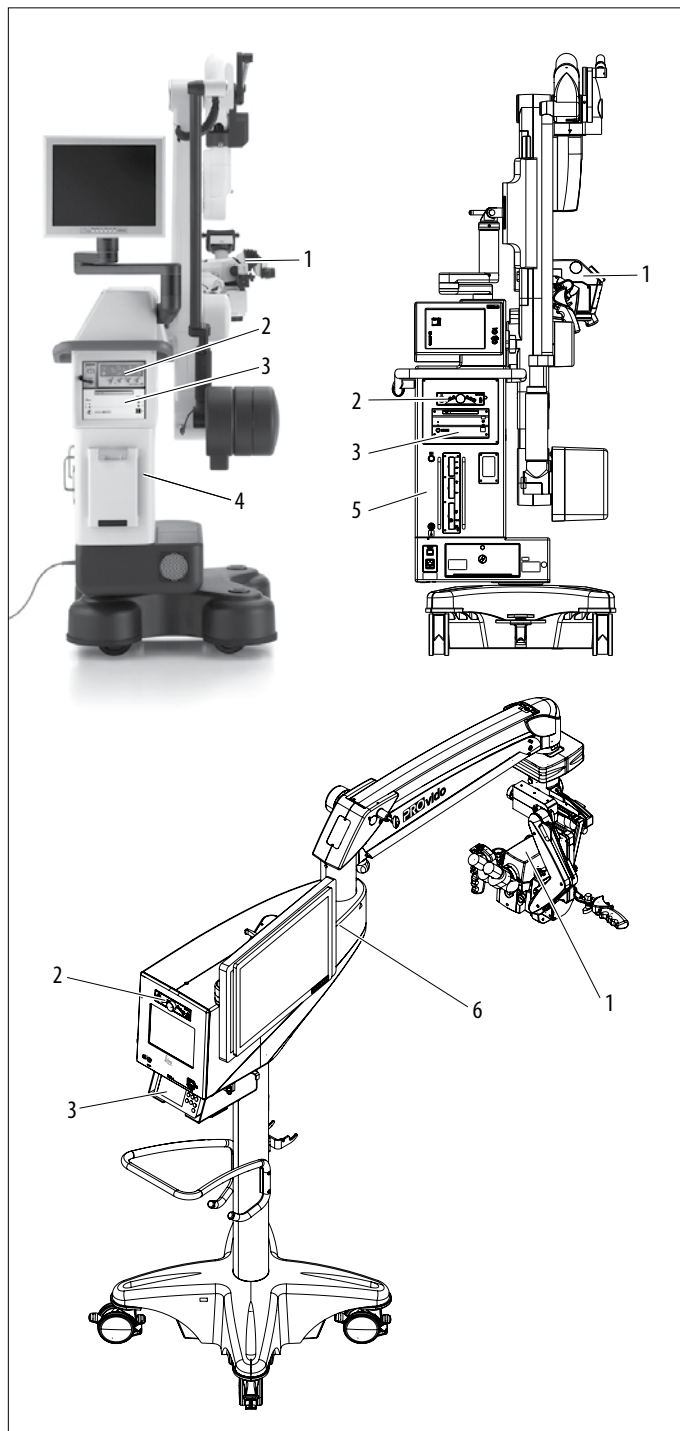


- 1 Leica M530 optics carrier
- 2 Leica ULT module
- 3 Leica FL560 for M530

- Optics carrier with integrated camera for visible light (optional).
- Interface for assistants, either to the left and right side or to the back.
- Main surgeon and back assistant interface, 360° rotatable both
- Back assistant interface with fine focus knob.
- Fluorescence observation filter module (Leica FL560 for M530).
- Leica ULT system components built into the common housing of the ULT.

4.2.2 Stand

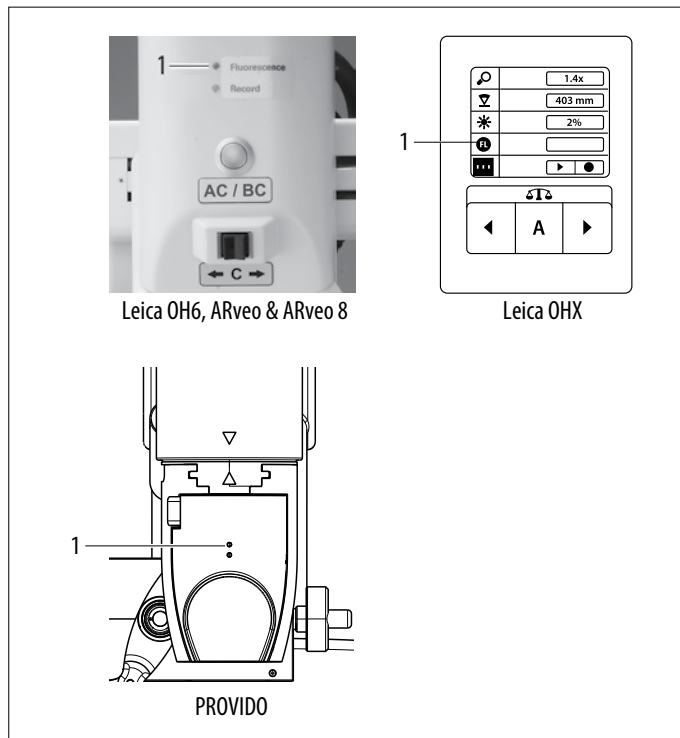
The following is an example of a Leica surgical microscope.



- 1 Leica M530 optics carrier
- 2 Camera control unit (optional)
- 3 Documentation system control unit (optional)
- 4 Leica M530 OH6, ARveo, ARveo 8 surgical microscopes
- 5 Leica M530 OHX surgical microscope
- 6 PROVIDO surgical microscope

4.3 Controls

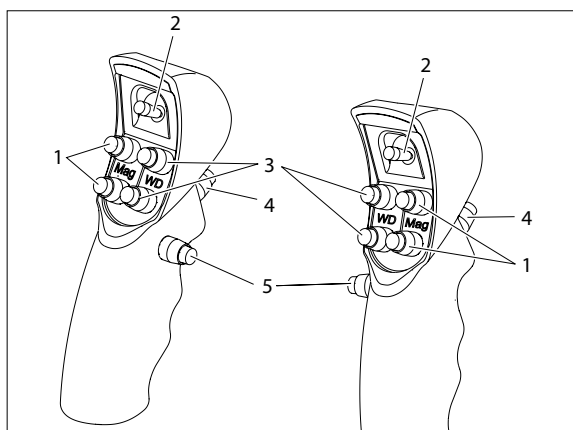
4.3.1 Status LEDs



The following LEDs on the swing arm are significant for the Leica FL560 for M530 application:

- 1 Status LED for fluorescence
 - LED lights up in cyan = Leica FL560 mode
 - LED lights up in white = White light mode (PROVIDO and M530 OHX only. On M530 OH6, ARveo and ARveo 8 the LED is simply off in white light mode)

4.3.2 Handles



Assignment in the factory setting

- 1 Magnification
- 2 4-function joystick
- 3 Working distance

- 4 Release all brakes
- 5 Release preselected brakes

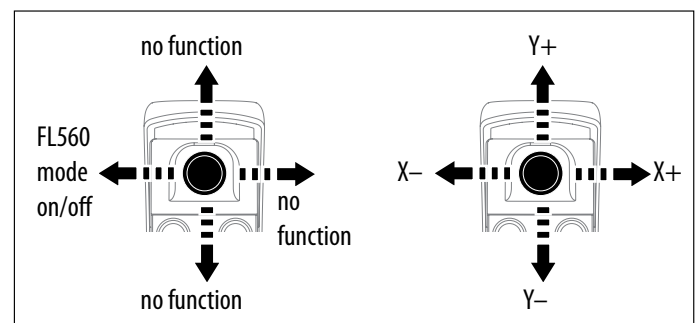


You can assign switches 1, 2, 3 and 5 of the handles individually for each user/ surgeon profile in the configuration menu.

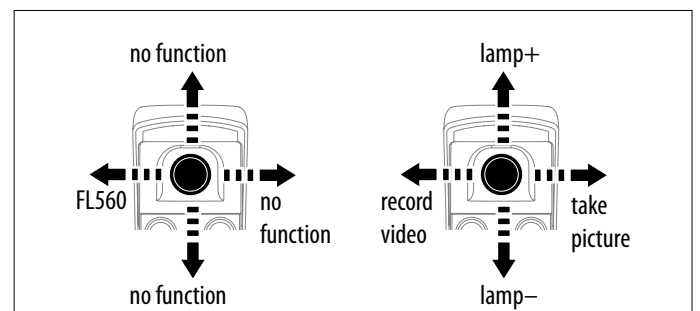
In all presets, key (4) releases all brakes. This key cannot be configured. For the joystick and the other keys presets are available according to your task.

Handle presets for Fluorescence FL560

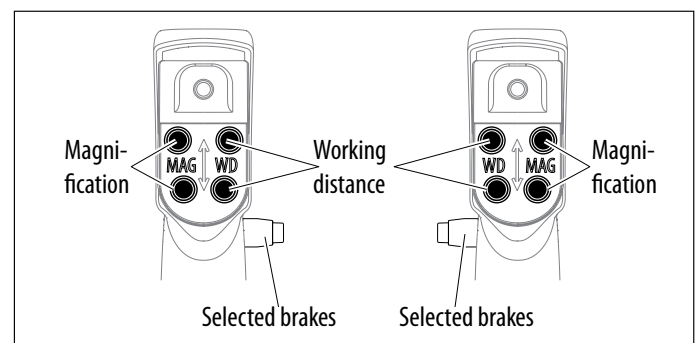
PROVIDO M530 OHX / M530 OH6 / ARveo



ARveo 8



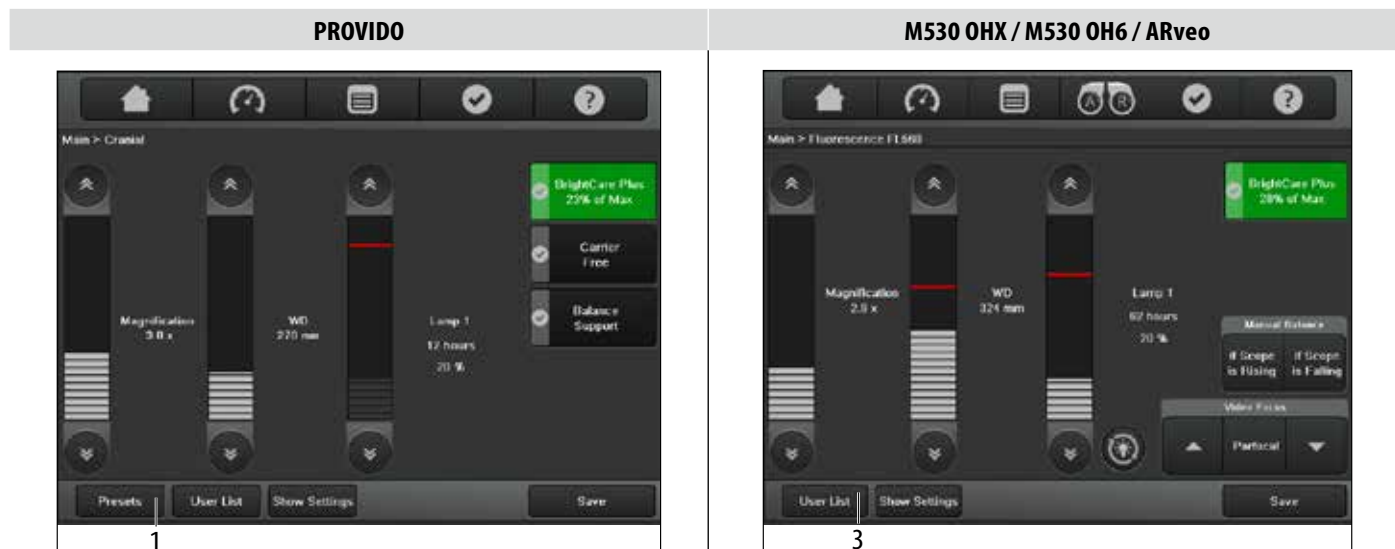
All microscopes



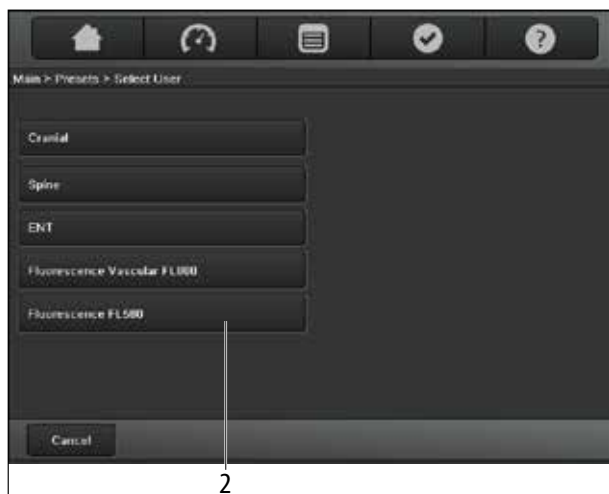
5 Preparation before surgery (PROVIDO, OHX, OH6, ARveo)

5.1 Using the "Fluorescence FL560" user preset

The current settings for the active user are displayed on the main page:



- ▶ Tap the "Presets" button (1).
The available presets for the microscope are displayed:



- ▶ Select the "Fluorescence FL560" user preset button (2).

- ▶ Tap on the "User List" button (3).
The available user list for the microscope is displayed:



- ▶ Tap the "Presets" button (4).
The available presets for the microscope are displayed:



- ▶ Select the "Fluorescence FL560" user preset button (5).

NOTE

The FL560 user are only available if the FL560 accessory is enabled in the accessory list of your Leica Surgical Microscope. If not, please get in contact with your local Leica Service.

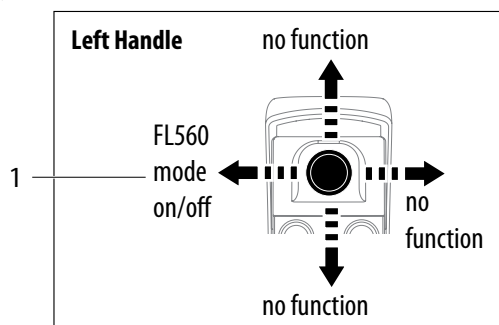
After you have selected the "Fluorescence FL560" preset you will be asked to confirm the change of the user preset.



- Select the "Confirm" button (1).
The main page for "Fluorescence FL560" with the actual settings in **white light mode** is displayed:

White light mode (PROVIDO)**White light mode (M530 OHX / M530 OH6 / ARveo)**

Switch the Fluorescence FL560 mode "ON" by using the predefined "ON/OFF button (1)" on the left handle.



► Press the joystick to the left:

The main page for "Fluorescence FL560" with the actual settings in **Fluorescence FL560 mode** are displayed:



NOTE

In FL560 mode, limitation of working distance and magnification is always active.

- To switch back to the white light mode press the joystick of the left handle to the left side once again.
The main menu "Fluorescence FL560" with the actual settings in white light mode are displayed.

5.2 Modifying the FL560 user



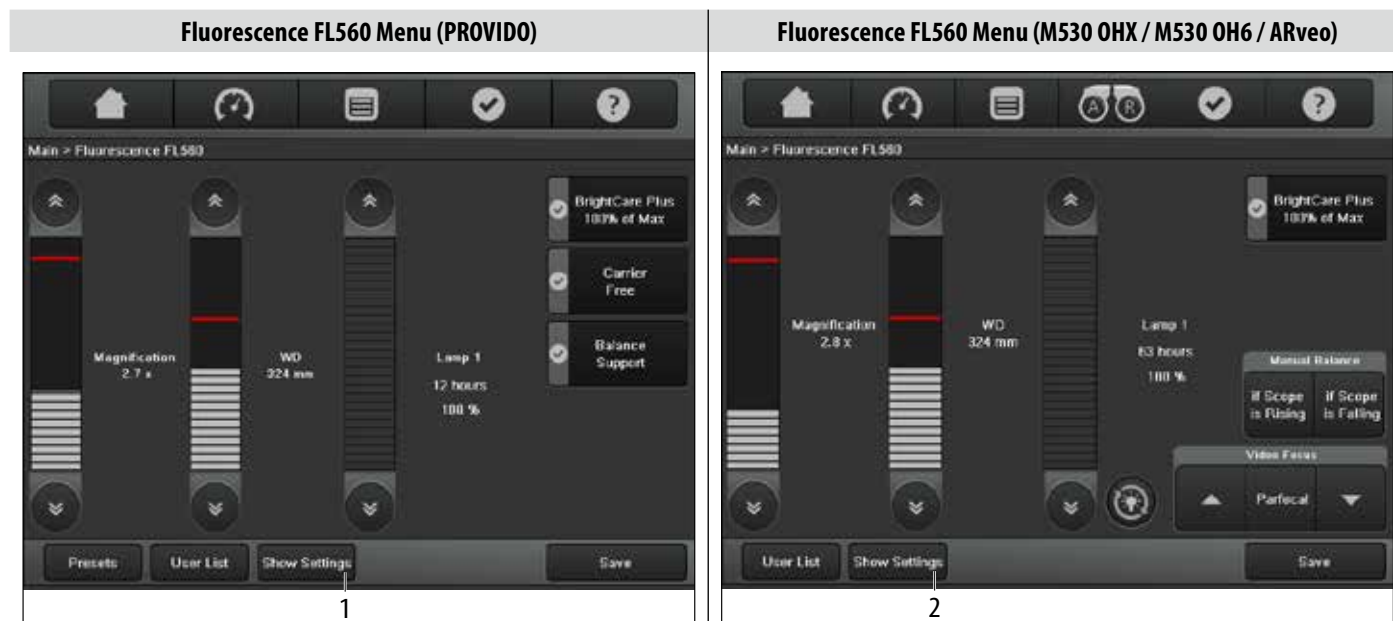
The factory FL560 user settings cannot be overwritten, however if you adjusted the settings to your needs, you can adopt and save them under a new user name. Please see chapter „5.4 Creating your own FL560 user“

NOTE

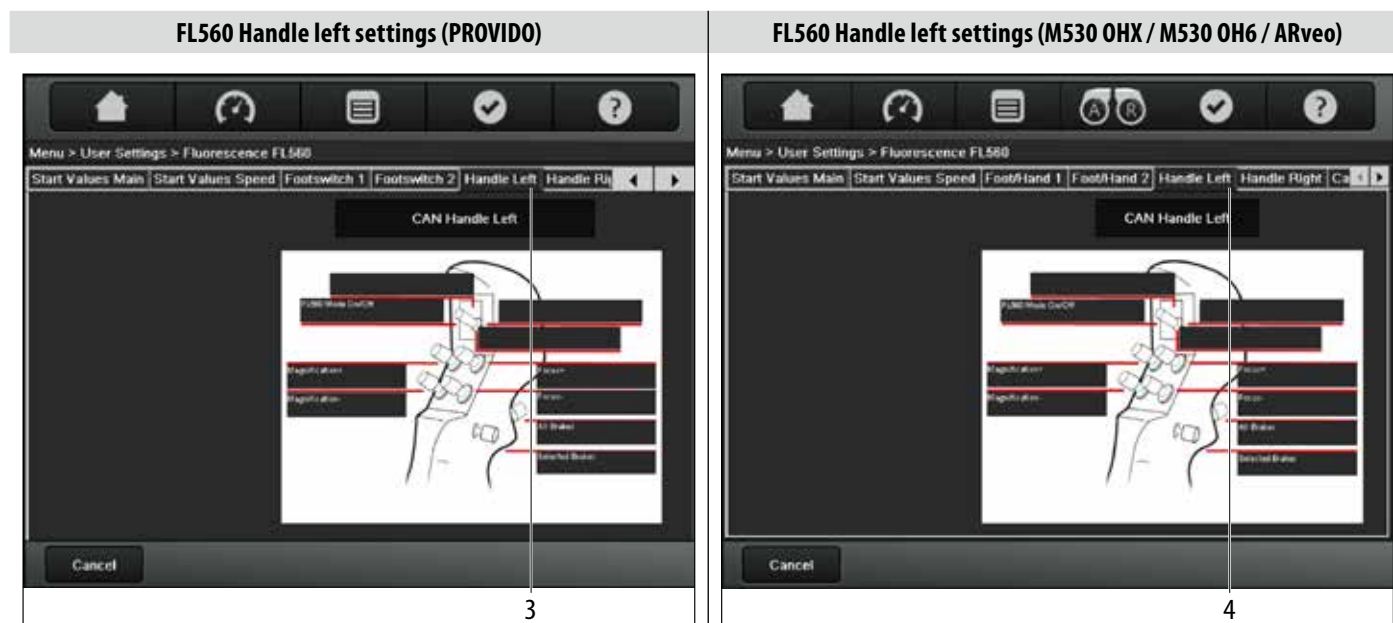
Do not change the settings or edit the user list when the microscope is in direct use on a patient. The FL560 mode is automatically stopped when modifying the settings.

5.3 Get current settings

On the page “Main > Fluorescence FL560” for both white light and FL560 modes, a “Show Settings” button can be found.



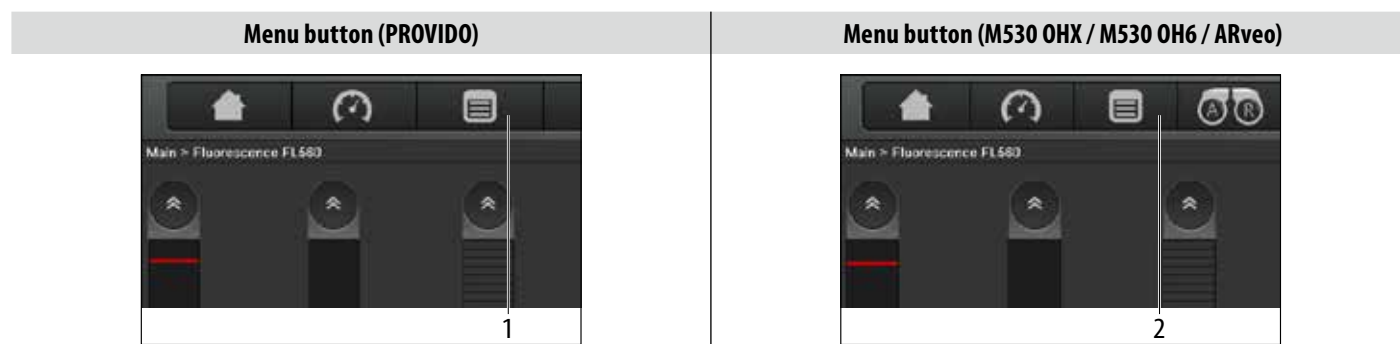
- ▶ Tap the “Show Settings” button ((1) or (2) depending on your microscope).
The “User Settings > Fluorescence FL560” page is displayed. On this page you can find several tabs with information on the current settings of the Leica surgical microscope system.
- ▶ Tap the “Handle Left” tab ((3) or (4) depending on your microscope).
This shows an overview of the buttons on the “Handle Left” including the button with which the FL560 functions (ON/OFF) can be operated:



5.4 Creating your own FL560 user

You can create and save your own FL560 settings according to your preferences.

- Before creating your own FL560 user follow the steps in chapter 5.1.
- Tap the quick access "Menu" button ((1) or (2) depending on your microscope) once you are on the main page for FL560:



After pressing the button the following screen is displayed:

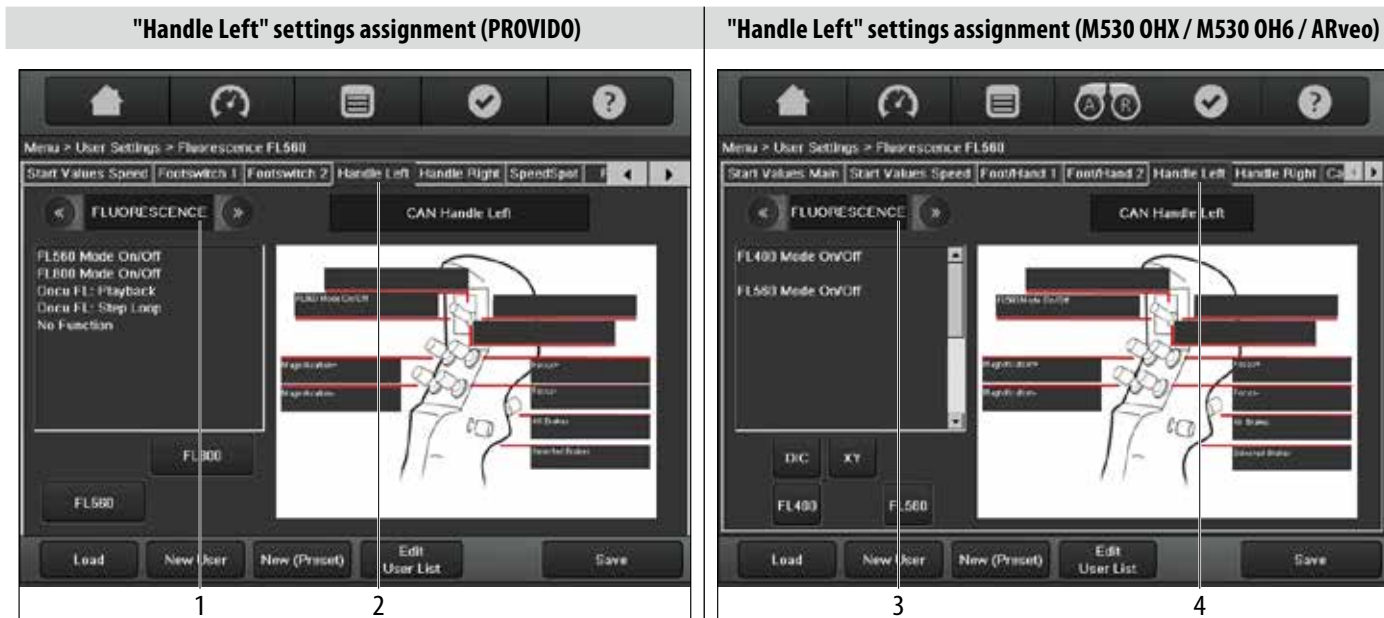


- Tap the "User Settings" button (3).
In each of the displayed tabs you can change the predefined user settings.



5.5 Example "Handle left" assignment

- ▶ Tap the "Handle left" tab ((2) or (4) depending on your microscope).
- This displays the user settings page for the left handle. On the handle left assignment screen you can assign up to nine functions of your choice:



Example: Assigning the "Fluorescence FL560" button for activating and de-activating the FL560 mode.

- ▶ In the left selection field ((1) or (3)) scroll to the function group "Fluorescence" by using the arrowheads (5).

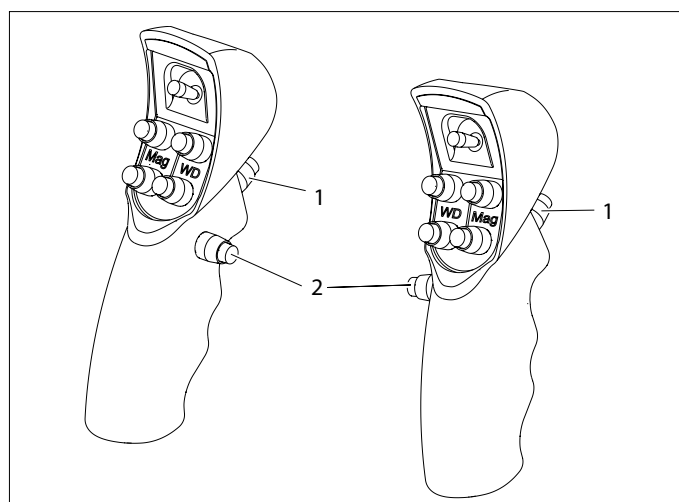


- ▶ Select the desired "Fluorescence FL560" function you wish to assign. In this example it would be: "FL560 Mode On/Off".
- ▶ Click on a free or assigned caption of the desired button on the handle to assign the selected function to it.

NOTE

The "All Brakes" function is always assigned to the rear switch (1) for both handles and can neither be overwritten nor deleted.

The inner switch (2) to which "Selected Brakes" is pre-assigned but can be freely assigned to your wishes.



5.6 Example "FL" settings

- ▶ Tap the "Menu" button in the header.
- ▶ Select "User Settings".
- ▶ Select the "FL" tab to set the brightness in FL560 mode to an adequate level.
Recommended and default brightness level is 100%.



- ▶ Scroll to the brightness level you like to use by using the arrowheads.
- ▶ Decide if the working distance (WD) limitation in White light mode should be switched ON (default) or OFF^{1,2}.

NOTE

¹⁾ Please note that a factory limitation is applied to the working distance (see „7.1 Excitation intensity“) as soon as the FL560 mode is activated. Hence, if working distance (WD) limitation in White light mode **is switched off** and the working distance is above this limit (see „7.1 Excitation intensity“) when switching to FL560 mode, the working distance will be reduced and the picture will get out of focus.

²⁾ This limitation can be activated within the FL560 mode settings menu [see graphics above]. This setting will enable or disable the WD limitation during white light mode. While using the WD limitation, the microscope might need to be repositioned (meeting the WD limitation value or getting closer than the WD limitation value) to get into focus.

The WD and Mag limitation values can be redefined to higher or smaller values generally for all users by Leica service personnel in the service menu to fit the needs of the surgical workflow.

NOTE

There is a default limitation to the WD and Mag when using the FL560 mode. If the WD and Mag are above this limit before switching to FL560 mode, the WD and Mag will be reduced upon switching to FL560 mode and the picture will get out of focus.

These limitations can be adjusted by the Leica service or product specialists if needed and the influence to signal intensity is understood.

NOTE

While using the WD limitation, the microscope might need to be repositioned (meeting the WD limitation value or getting closer than the WD limitation value) to get into focus.

The WD and Mag limitation values can be redefined to higher or smaller values generally for all users by Leica service personnel in the service menu to fit the needs of the surgical workflow.

5.7 Save user settings

After adapting the user settings, you can save your changes under a new username.



- In the "User settings" menu tap on "Save" (1) and then on "Save as New" buttons.

A editable list of users is displayed:



- Select an available location in the user list at which you want to store your settings.



- Enter the desired username using the on-screen keyboard.
- Tap the "OK" button to save the user settings at the desired location under the name you have entered.

NOTE

User setting protection

To avoid unauthorized or accidental changes of user settings, each user setting can be protected by a password/PIN. This keeps the working parameters identical each time you load a protected user setting. Changes can be done during the application but will not be stored unless saved by pressing "Save" and choosing either the "Save as current" or "Save as new" option, using the correct password/PIN or by creating a new user and password/PIN combination respectively.

Please refer to the user settings chapter in the manual of your respective surgical microscope for detailed instructions on how to set or change passwords.

6 Preparation before surgery (ARveo 8)

6.1 Selecting a profile with FL560 settings

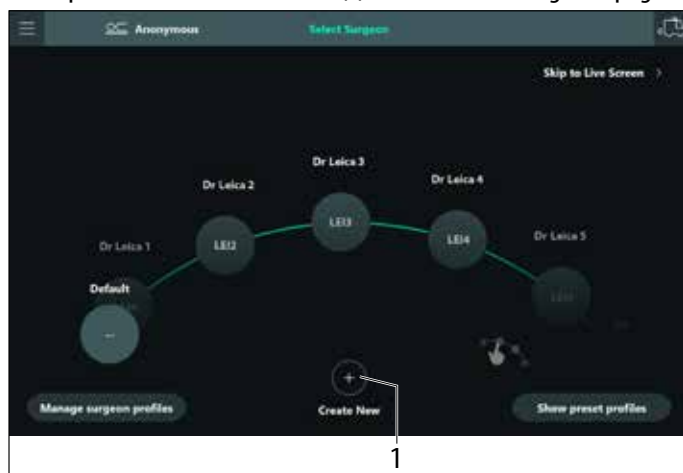


- Select a surgeon profile for which the FL560 profile has been already been defined at the "Select surgeon" page: If not, you have to create a new surgeon profile.

6.2 Creating a new surgeon profile

6.2.1 Register the new profile details

- Tap the "Create New" button (1) on the "Select surgeon" page:

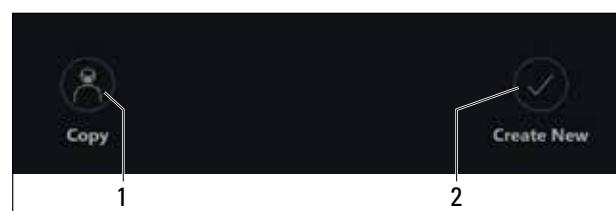


The "Create New Surgeon Profile" page is displayed



- Please fill in at least the mandatory data for a surgeon profile, i.e. first name and a unique three-letter acronym. Fields marked with a * are mandatory.

! You can enter your last name and a "passcode" to secure your settings. This is recommended to avoid unintended changes by other surgeons or personnel. Please note that the "passcode" has to be typed twice to confirm it.



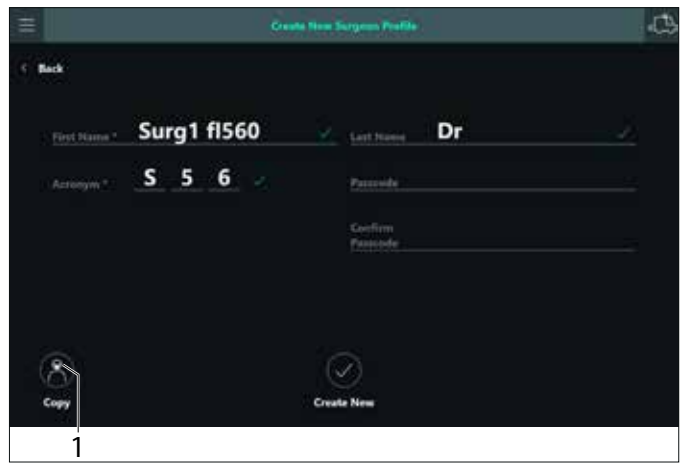
You can either press "Copy" (1) or "Create New" (2) .

- The "Copy" function (see section „6.2.2 Copying settings from the FL560 Preset or existing surgeon profile“) allows to copy settings from a preset or an existing surgeon profile which can then be adapted to your needs.
- The "Create New" function (see section „6.2.3 Creating a brand new profile“) allows to start from blank list of user input settings which you can configure.

6.2.2 Copying settings from the FL560 Preset or existing surgeon profile


This section describes how you can copy existing settings into your newly created surgeon profile using either an existing surgeon's profile or using the factory FL560 preset.

- ▶ Tap the "Copy" button (1) on the "Create New Surgeon Profile" page.



The list of existing profiles and presets is displayed on screen:

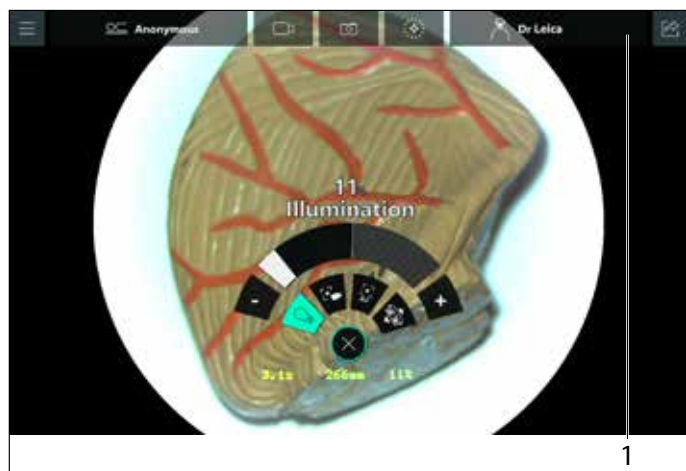


 The factory preset profiles are displayed at the top and are generally prefixed with an underscore (i.e. _FL560)

You have now two options:

Copy the predefined FL560 preset	Copy settings from an existing surgeon profile
<ul style="list-style-type: none">▶ Click on the _FL560 profile (1) and confirm with "OK" (2) The dialog box is closed and the FL560 profile is now copied into the surgeon's profile and allows for activation of the FL560 mode by pushing the joystick of the left handle to towards the left.▶ Press the "Create New" button to register the new surgeon profile.	<ul style="list-style-type: none">▶ Click on the surgeon profile you want to copy and confirm with "OK" (2). The dialog box is closed and the selected surgeon's profile and function mappings are now copied into the new surgeon profile you just created.▶ Press the "Create New" button to register the new surgeon profile.

In both cases (copying FL560 preset or copying an existing surgeon profile), after pressing "Create New", the live screen is displayed. You can see the surgeon profile's name on the top right corner of the screen (1):



- You can now follow the steps described in 6.2.4 to configure the user input settings.

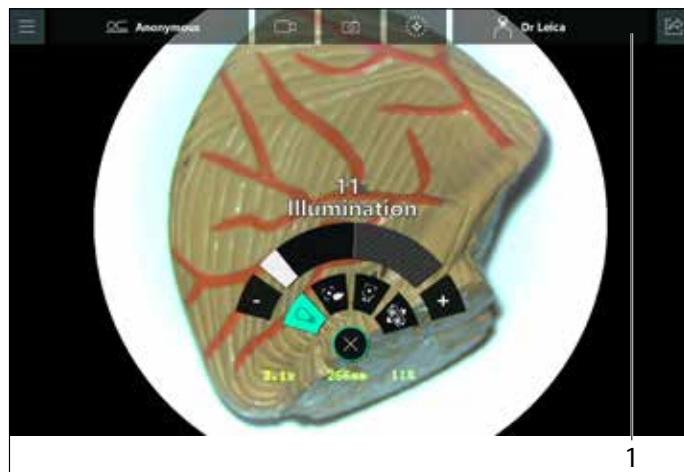
6.2.3 Creating a brand new profile

To create a new profile, you must first follow the steps described in 6.2.1.

- After having entered the new surgeon data, instead of pressing "Copy", press the "Create New" button in order to register the new profile.

This will register the new surgeon profile with a blank list of settings which are ready for you to configure.

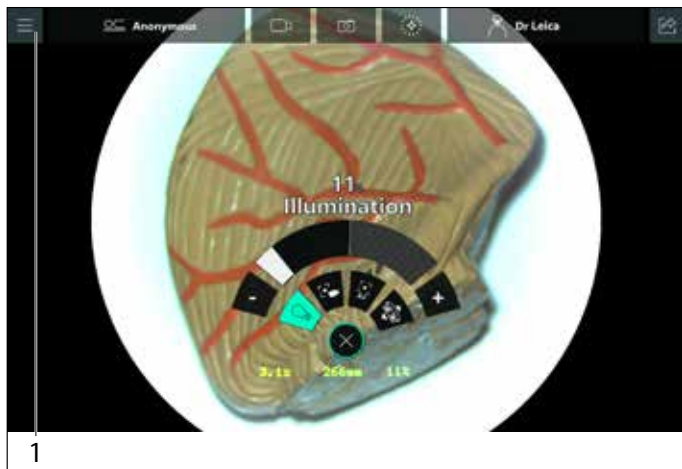
The live screen is displayed on which you can see the surgeon profile's name on the top right hand corner of the screen (1):



- You can now follow the steps described in 6.2.4 to configure the user input settings.

6.2.4 Configuring the user inputs on the handles

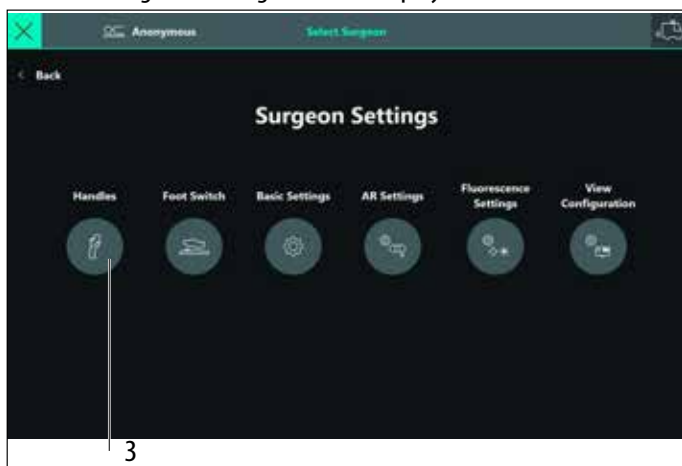
Make sure you are on the live screen for the selected or newly created surgeon profile:



- Press the menu button (1) on the top left hand corner of the screen to show the list of options.
The options screen is displayed:



- Tap on the "Surgeon Settings" button (2) to open the "Surgeon Settings" menu.
The ""Surgeon Settings" menu is displayed:



- Tap "Handles" button (3) to show the "Left Handle" settings.

The Left Handle configuration screen is displayed:



You can now view or edit the handle settings for the selected surgeon profile.

NOTE

- Click on "Right" if you want to configure the right handle.



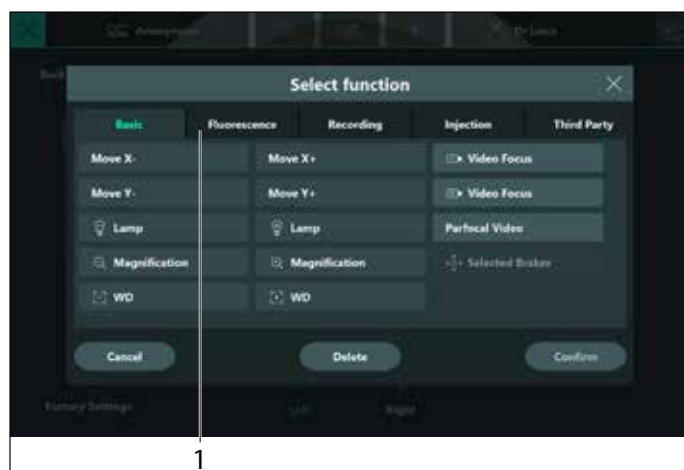
6.2.5 Example of how to assign the FL560 function

The following example shows how you can assign the FL560 ON/OFF function to a button on the left handle.

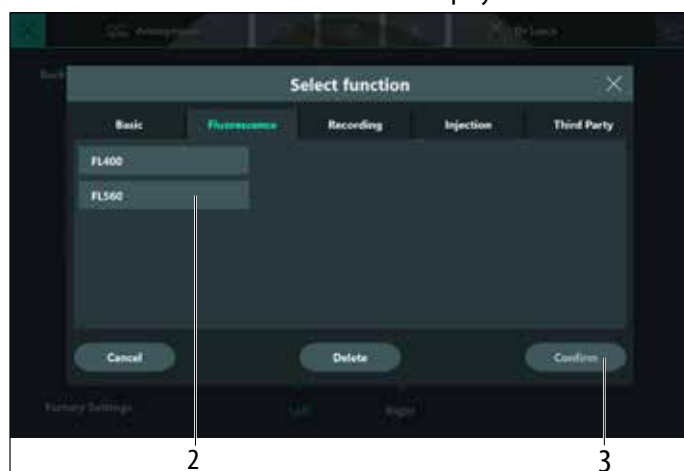
NOTE

This process can also be used for any of the buttons to which you wish to assign any other function.

- ▶ When you are on the handle configuration page, click the button you want to assign for the activation of the FL560 mode. This will display the "Select function" popup window for the selected button:



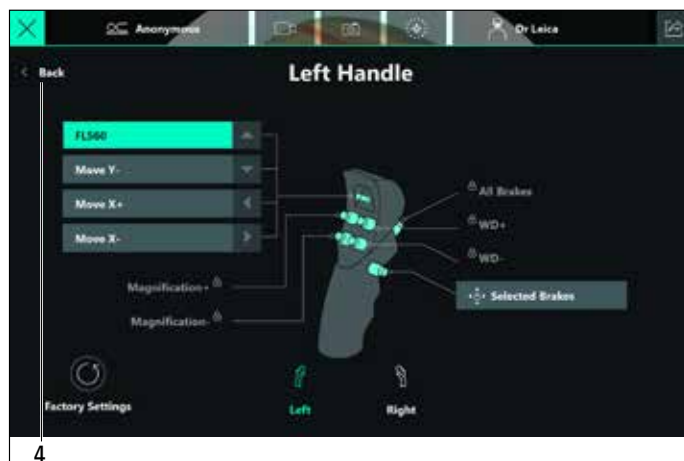
- ▶ Select the "Fluorescence" tab (1). A list of available FL functions will be displayed:



- ▶ Select the FL560 function (2) and tap "Confirm" (3) to store the settings.

! Press "Delete" to go back and "Cancel" if you want to select another function.

A functional overview of the left handle will be displayed:

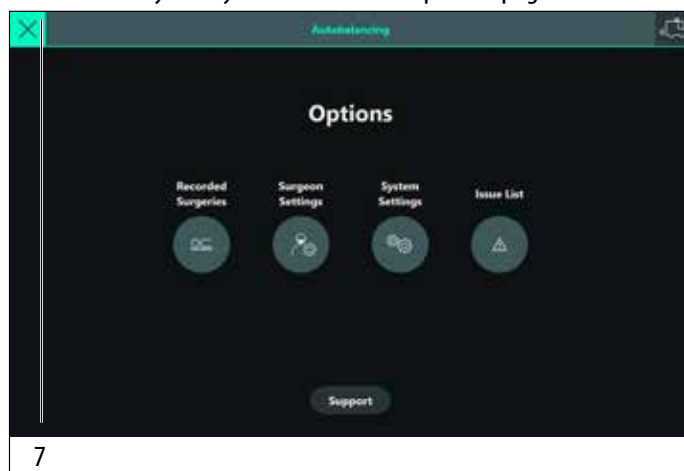


- ▶ Tap the "Back" button (4) once you have finished adapting your settings.

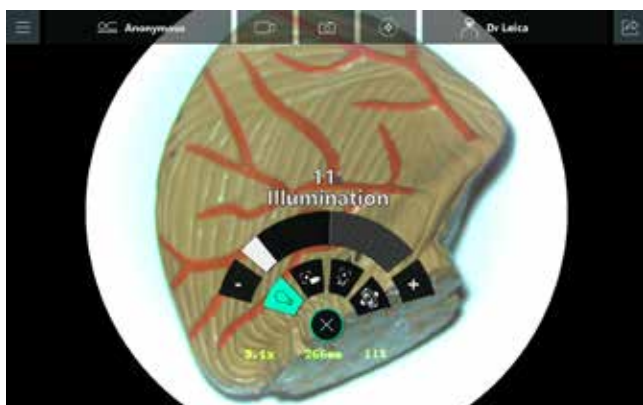
The "Save Surgeon Settings" window will be displayed:



- ▶ Save and store the settings by pressing "Yes, change in profile" (6). If you do not wish to store the settings, please press "No, only use now" (5).
- ▶ Move back in the menu hierarchy by pressing "Back" successively until you return to the "Options" page:



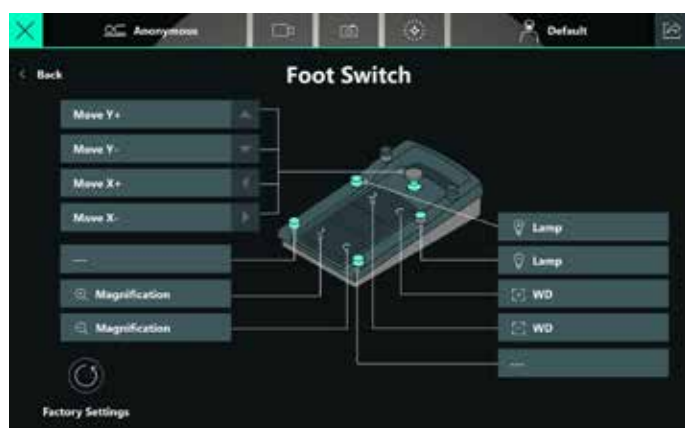
- ▶ Press "X" (7) to go back to the live screen. The live screen is displayed:



6.2.6 Configuring the foot switch

You can configure the foot switch similarly to the handles.

- Ensure you have loaded the surgeon profile you wish to edit (see chapter 6.2.7 "Selecting the FL560 Preset").
- Open the "Foot Switch" settings page in the "Options" -> "Surgeon Settings" page.
- Tap the selection field of the desired key on the foot switch.



The following selection menu opens:



- Select the desired function (1) and apply with Confirm (2). The selected function is displayed in the selection field.

The selections are identical to those for the handles with the exception of the brakes. **Example of foot switch with Leica FL560 assignment**



6.2.7 Selecting the FL560 Preset

NOTE

The preset can be used to quickly enable the FL560 ON/OFF functionality on the microscope.

This preset profile can be used and modified but any changes to the profile settings will not be stored, therefore with each new start up, the default profile settings will be restored.

Moving the joystick on the left handle to the left activates, resp. de-activates the FL560 mode.

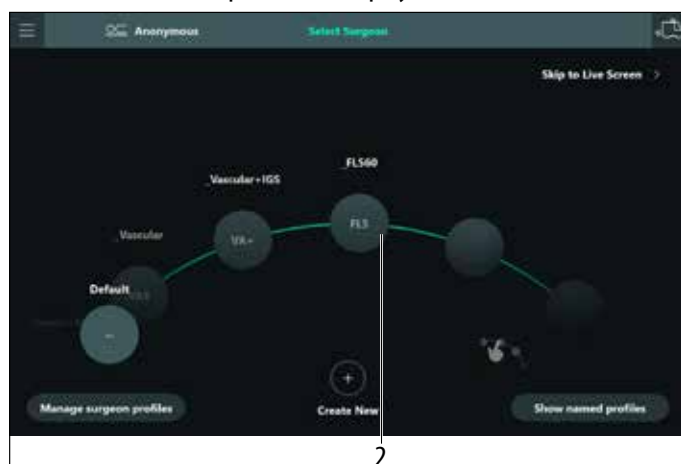
This preset can also be used as a starting point when creating a new surgeon profile (see „6.2.2 Copying settings from the FL560 Preset or existing surgeon profile“).

Because the modifications to this preset cannot be saved, it is highly recommended to create a new surgeon profile for a full workflow.



- While on the "Select Surgeon" menu tap the "Show preset profiles" button (1) to receive a list of preset profiles, dependent on the installed licenses.

The list of "Preset profiles" is displayed:



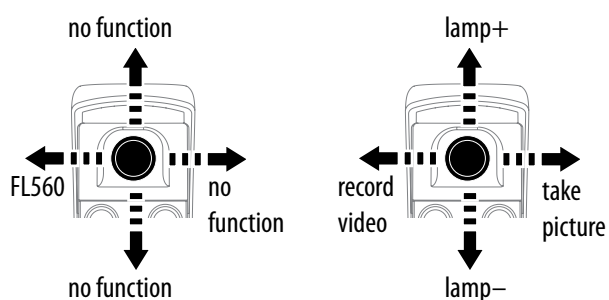
► Select the _FL560 preset (2).

When choosing this preset profile, a popup will appear to notify the user about the profile limitations.



It is highly recommended to change an existing or add a new surgeon profile to integrate the FL560 function in a full workflow.

The following functions are assigned when selecting the FL560 preset:

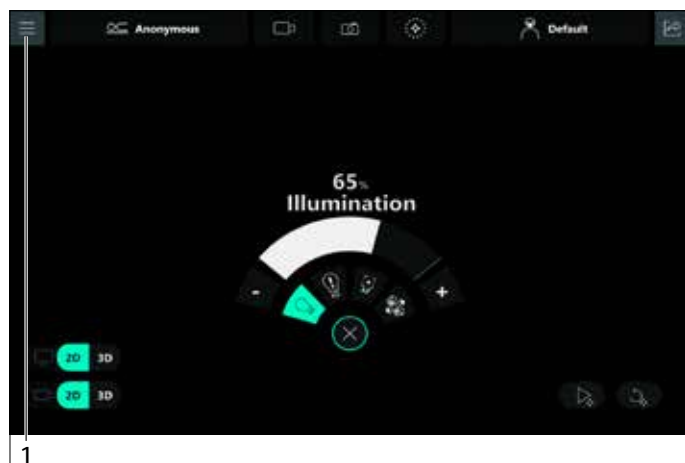


You can switch back to white light mode by pushing the joystick of the left handle towards the left again.

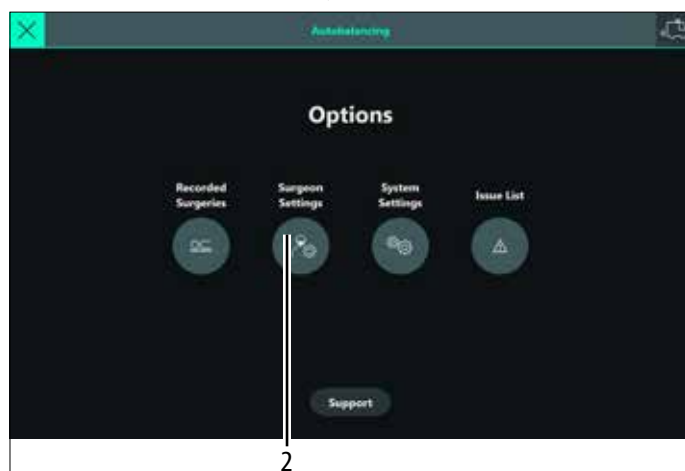
7 Modifying the Leica FL560 settings (ARveo 8)

7.1 Excitation intensity

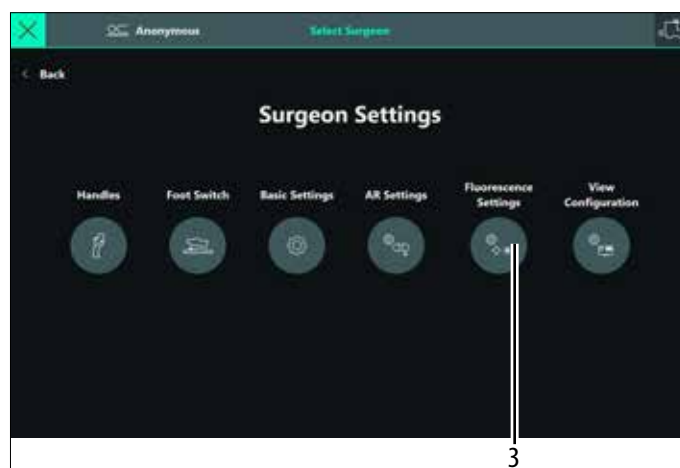
Per default the excitation value is set to 100% (see recommended excitation settings).



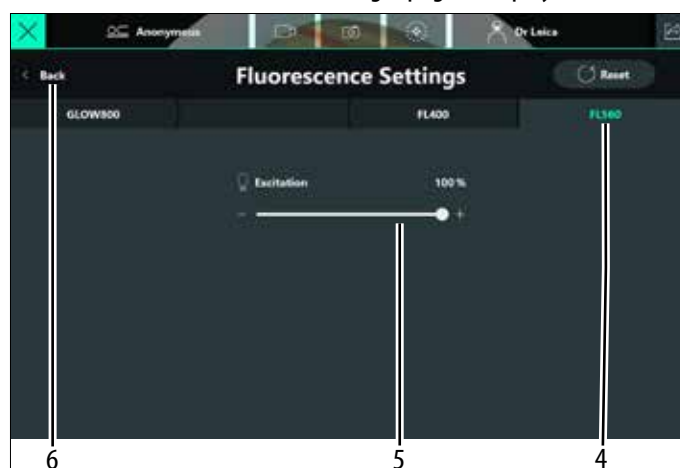
- ▶ Tap the menu icon (1) in the upper left corner of the "Live Screen" page.
The "Options" page is displayed:



- ▶ Tap the "Surgeon Settings" icon (2).
The "Surgeon Settings" page is displayed:



- ▶ Tap the "Fluorescence Settings" (3) icon and then tap the Leica FL560 tab (4).
Leica FL560 "Fluorescence Settings" page is displayed:



Recommended Excitation settings

To achieve good fluorescence visibility in higher magnifications and working distances the default and recommended "Excitation" setting (5) is 100%.

- ▶ Adapt the "Excitation" setting using the slider (5).
- ▶ Press "Back" (6).

If the excitation setting was modified, the "Save Surgeon Setting" is displayed:



- ▶ Select the desired option to save the setting to the profile or choose to use it only once, after which the change will be discarded.

8 Operation

8.1 Operating Range Limits for FL560

- Working Distance: 225 to 400 mm
- Magnification: 2.0× to 8.0×
- Brightness: 100 %

NOTE

Recommended settings for best image quality

To observe Leica FL560 fluorescence images in best quality and brightness, it is recommended to work in a working distance (WD) below 350 mm and a total magnification (MAG) less than 6.0 x in FL560 mode.

8.2 Pre-operation checklist

Cleaning optical accessories

- Check optical accessories for cleanliness.
- Remove dust and dirt.

FL560 application

- When using FL560 please ensure to have a Doppler Ultrasound or similar device in place, in case of none or insufficient blood flow visualization out of the FL560 procedure.

Balancing

- Balance the microscope after refitting (see the user manual of the Leica surgical microscope).

! Before using Leica FL560 in combination with other accessories please follow the instruction in the accessory Manual regarding Leica FL560.

! Before using Leica FL560 with the Leica Surgical Microscope please follow the instruction in the Leica Surgical Microscope Manual regarding Leica FL560.

! Do not change the configuration when performing Leica FL560 surgery.

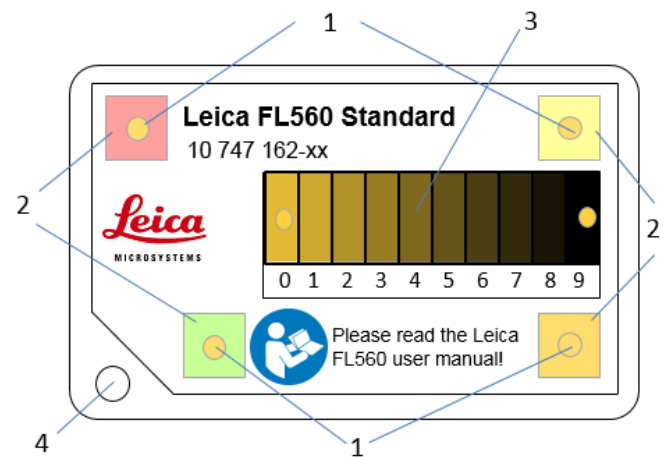
Operational check

- Switch on the microscope.
- Switch on the illumination.
- Check the FL560 illumination.
- Select an FL560 user/surgeon profile.
- Check visually whether the microscope illumination has switched from white to cyan light.

! For more information about the pre-operational check of the surgical microscope, refer to the Surgical Microscope user manual.

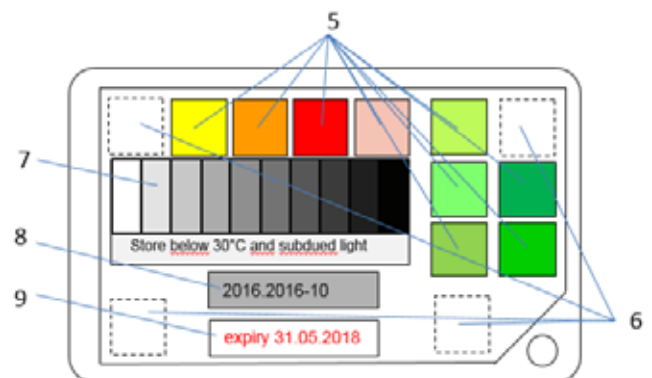
8.3 FL560 test card functional areas

FL560 Test card functional areas description (front side)



- 1 Round spot high intensity FL560 fluorescence signal
- 2 Low intensity FL560 fluorescence area including 4 different white light color areas
- 3 Stepwise decreasing FS Intensity fields 0=bright to 9=dark
- 4 Hole to fix the card

FL560 Test card functional areas description (back side)



- 5 Color samples (9) for Leica FL560 mode and white light color balancing
- 6 High intensity FS fluorescence samples
- 7 Grey scale for Leica FL560 mode anatomy illumination check. Stepwise decreasing FS Intensity fields 0=bright to 9=dark
- 8 Production lot
- 9 Expiry date of the test card

NOTE

The FL560 test card is also available as a Spare part (10747162)

- Please get in contact with your local Leica Service.

8.3.1 Assessment of FL560 functionality

FL560 Test Card (front side / white light mode)



The picture below shows the fluorescence intensity signal seen through the eyepieces with following settings:

- Working distance: 350 mm
- Magnification: 3.0 x
- FL560 Illumination brightness: 100%

FL560 Test Card (front side / FL560 mode) with good fluorescence feedback



Assessment criteria for Leica FL560 functionality check:

- In FL560 mode the intensity fields between 0 and 6 should be visible.

NOTE

If the fluorescence emission of intensity fluorescence fields 0 to 6 cannot be observed you need to check the FL560 functionality:

- ▶ "FL" brightness setting might not be 100%
- ▶ Xenon illumination lamp #1 is not activated or not efficient (e.g. end of life).

Refer to chapter "6.2 Status messages" in this document.

! If you do not observe any fluorescence emission at all please refer to chapter 10.4 in this user manual or get in contact with your local Leica Customer Service.

mode can be checked and optimized with the test card by adjusting the camera settings to accomplish identical colors of the color patterns on the monitor as in the eyepiece.

9 color samples allow to adjust proper color settings if needed.

FL560 Test Card (back side / white light mode)



FL560 Test Card (back side / FL560 mode)



! If you do not observe good color reproduction refer to chapter 10.4 in this user manual or get in contact with your local Leica Customer Service.

8.3.2 Check camera settings

The camera settings in white light and Leica FL560 fluorescence

8.4 FL560 test card pre-operational check

Use the FL560 test card to verify proper functionality of the FL560 module as well as the surgical microscope system.



WARNING

User selected with a programmed fluorescence function.

- ▶ Perform the Pre-operational check of the surgical microscope before surgery.
- ▶ Microscope illumination lamp is within tolerances (see user manual of the Leica surgical microscope).
- ▶ For PROVIDO illumination only: Check if the microscope illumination lamp #1 and #2 is within tolerances.



WARNING

Risk of infection due to unsterile FL560 test card.

- ▶ Do not use the Leica FL560 for M530 test card in the sterile field (of surgical procedure).

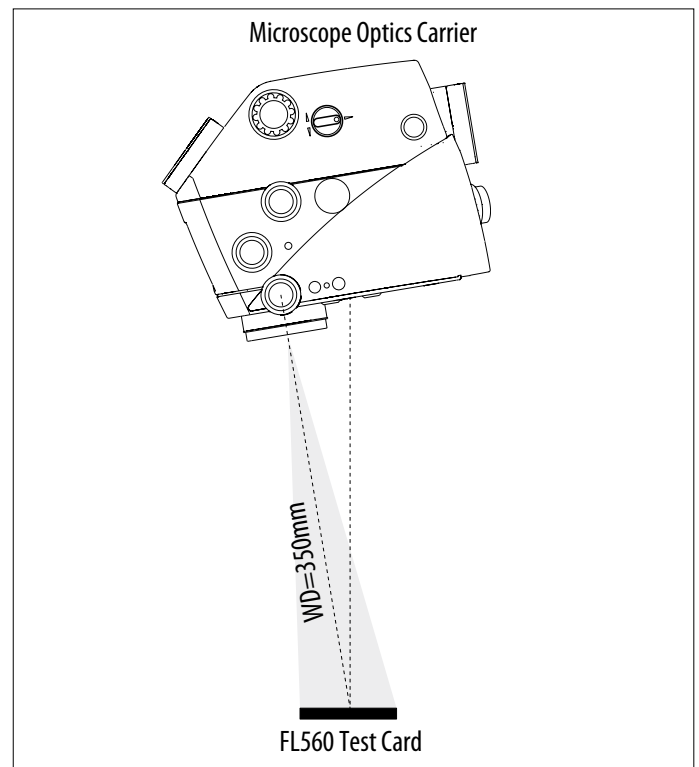


Do not use the Leica FL560 for M530 test card if it is expired.

Please prepare the FL560 functionality test as follows:

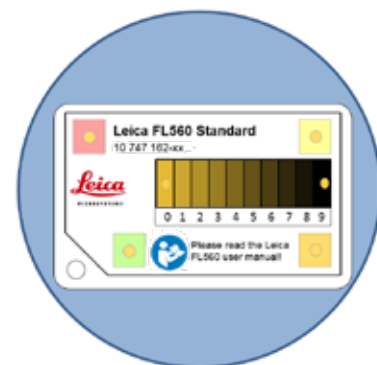
- ▶ Place the FL560 Test Card on a suitable base under the Leica Surgical Microscope.
- ▶ Adjust the working distance (WD) to 350 mm and get into focus by repositioning the microscope optics carrier.
- ▶ Adjust the magnification to 3.0 x.
- ▶ Move the FL560 Test Card into the center of the field of view.
- ▶ To avoid reflections please place the optical axis in a smaller angle than perpendicular towards the FL560 Test Card.

- ▶ Move the test card into the center of the field of view.



- ▶ Switch to FL560 mode by pressing the FL560 On/Off button on the handle.
- ▶ Adjust the fluorescence illumination to 100 %. (if its not done by system per default).
- ▶ The Leica FL560 test card can now be used to check the FL560 performance (see „8.3.1 Assessment of FL560 functionality“)
- ▶ The FL560 test card can now be observed in the eyepiece or/and on the optional monitor.

Eyepiece view



Appearance of the test card front side in white light observation.

8.4.1 Using the Leica FL560 for M530

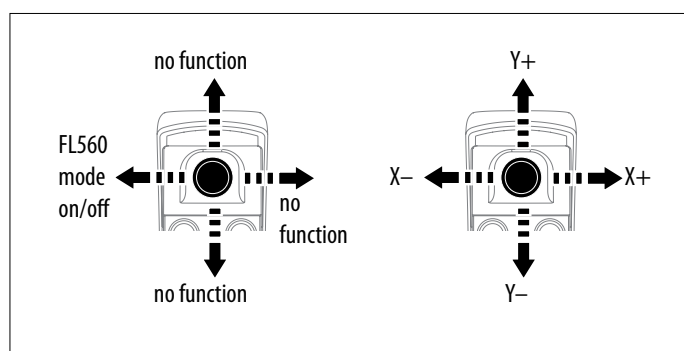
- Switch on the illumination of the particular surgical microscope.
- Select either the "Fluorescence FL560" preset user/surgeon profile or your own FL560 user/surgeon profile.

The status LED on the swing arm of the particular surgical microscope is illuminated in cyan if the FL560 mode is active (on all surgical microscopes), and white if switched back to white-light mode (PROVIDO and OHX only. On OH6 and ARveo and ARveo 8, the LED is simply off in white light mode).

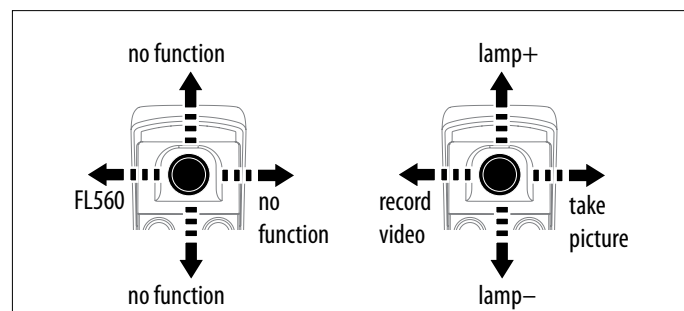
- ! If the illumination fails in the white-light or FL560 mode, change to the back up light bulb of the illumination source of the illumination unit.

Controlling the FL560 functions:

PROVIDO M530 OHX / M530 OH6 / ARveo



ARveo 8



- Activate Leica FL560 by pressing the joystick of the left handel outward. You can revert back to white-light and FL560 mode by pressing the joystick of the left Leica M530 handle outward. If another control has been selected, FL560 mode/white light is activated accordingly.

9 Care and maintenance

- ! It is recommended to conclude a service contract with Leica Service for the whole Leica Surgical microscope (annual maintenance).


- ! The Leica FL560 for M530 is cleaned together with the Surgical Microscope. Please refer to the user manual of the particular surgical microscope.

- ! Please do not dispose waste electrical and electronic equipment in household trash.

- ! For care and maintenance of the Leica FL560 for M530, please refer to the user manual of the particular surgical microscope.

10 What to do, if...


10.1 General

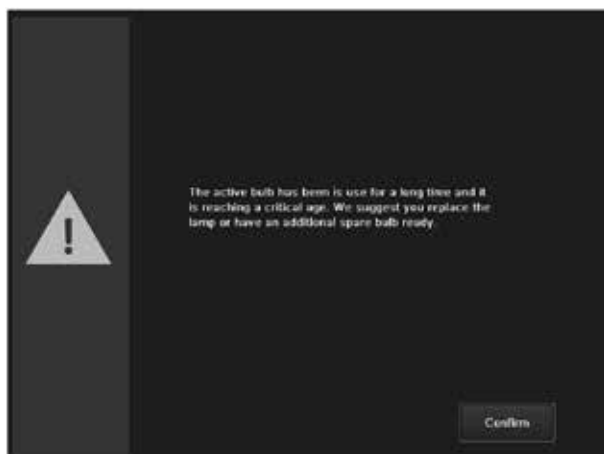
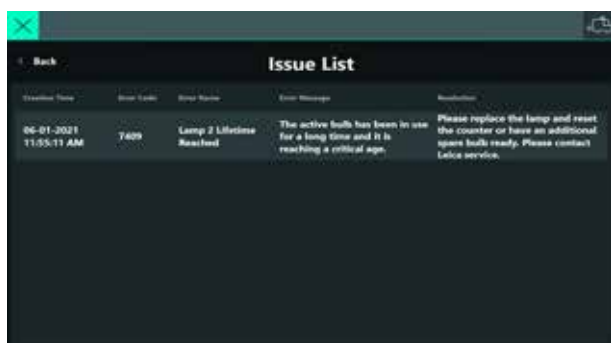
 For malfunctions regarding the Leica Surgical Microscope refer to the user manual of the particular surgical microscope.

10.2 Status messages

The Leica surgical microscopes OH6, ARveo, ARveo 8, OHX and PROVIDO monitor several parameters and check if these are still in the defined working range.

10.2.1 Lifetime of bulb

 **WARNING**
If the active bulb is used over a long time and its reaching a critical age you receive the recommendation to exchange the bulb(s):

Timestamp	Error Code	Error Name	Error Message	Resolution
06-01-2021 11:55:11 AM	7409	Lamp 2 Lifetime Reached	The active bulb has been in use for a long time and it is reaching a critical age.	Please replace the lamp and reset the counter or have an additional spare bulb ready. Please contact Leica service.

- ▶ Check the life time of the bulb(s) and replace the bulb(s) if the efficiency is too low.
- ▶ (please check with the FL560 Card as described in chapter 8.3.1 in this document)

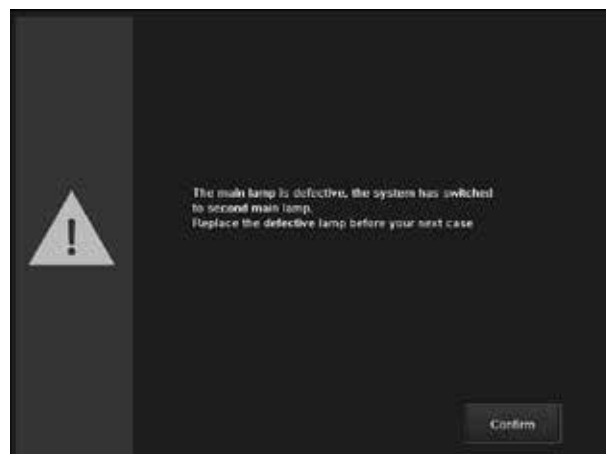
10.2.2 Defective main lamp



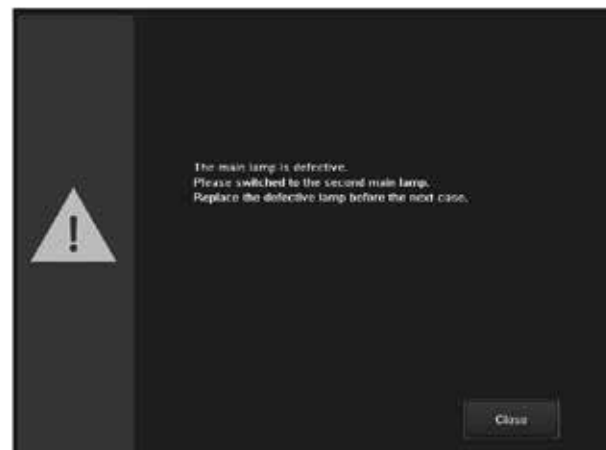
WARNING

In case the main lamp is defective you receive the information that the system has switched to the second main lamp (OH6, ARveo, ARveo 8 and OHX only) or you must switch to the second lamp manually (PROVIDO):

M530 OHX / M530 OH6 / ARveo - defective main lamp alert

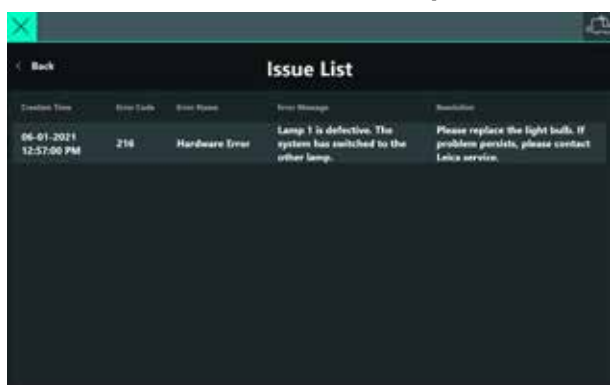


PROVIDO - defective main lamp alert





ARveo 8 - defective main lamp alert



- Exchange the defective bulb with a new one before your next case.

10.2.3 Defective lamp 2 (ARveo 8)



WARNING

In case the lamp 2 is defective you receive information that the system has switched to the other lamp.

ARveo 8 - defective lamp 2 alert



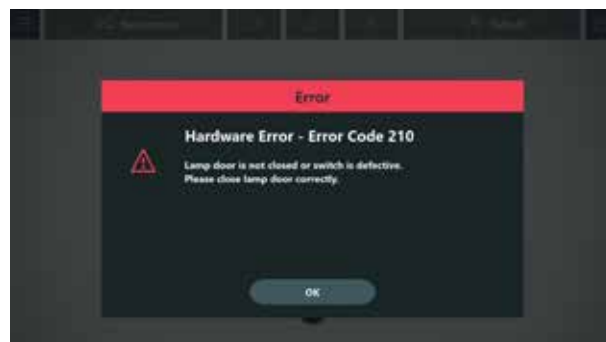
- Exchange the defective bulb with a new one before your next case.

10.2.4 Lamp door error (ARveo 8)



WARNING

Lamp door is open or the switch is defective.



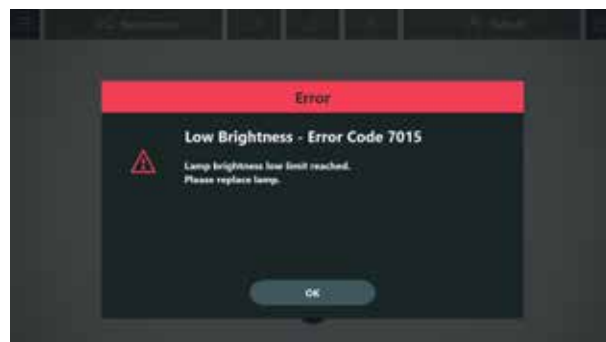
- Close the lamp door.

10.2.5 Low brightness limit (ARveo 8)



WARNING

Lamp brightness low limit reached.



- Replace the lamp.

10.2.6 PROVIDO / Lamp change messages FL560

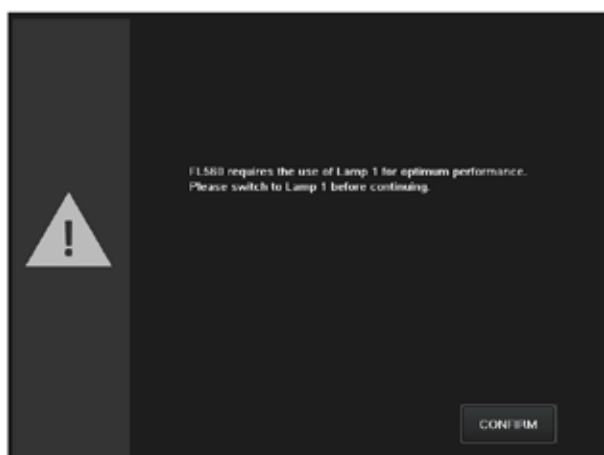


WARNING

In case the main lamp #2 of the PROVIDO illumination is in place you will get following messages:

- When system has booted up and the active user profile has the "FL560 mode on/off" programmed to any of the CAN handle buttons. PROVIDO will beep 3 times and the "Lamp Change" reminder will pop up.
- When a different user profile is loaded and this user profile has the "FL560 mode on/off" programmed to any of the CAN handle buttons. PROVIDO will beep 3 times and the "Lamp Change" reminder will pop up.
- During activation of the FL560 PROVIDO will beep 3 times and the "Lamp Change" reminder will pop up.

PROVIDO Lamp Change reminder message



- Switch to lamp #1 and confirm this message.

10.3 Electrical



If electrically operated functions do not work properly, always check these points first:

- Is the power switch switched on?
- Are the power cables attached correctly?
- Are all connecting cables attached correctly?

10.4 Common troubleshooting steps

Malfunction	Possible causes	Remedy
No FL visible in-vivo or with the test card FL, neither in the eyepiece, nor on the monitor	FL560 is not active	<ul style="list-style-type: none"> ▶ Check if FL560 is activated: <ul style="list-style-type: none"> • the status LED shines cyan • the illumination light is cyan • the observation light is reduced to green/yellow/red ▶ Check installation status with Leica service to assure FL560 function
	FL560 user/surgeon profile is not selected	<ul style="list-style-type: none"> ▶ Choose correct FL560 user/surgeon profile
No blue light in FL560 mode	FL560 mode is not active	<ul style="list-style-type: none"> ▶ Check that the fluorescence LED and the control unit display the FL560 mode. ▶ Check whether the FL560 On/Off function is assigned to a button of handle.
Dark in-vivo FL or lower number of active/visible FL areas on the test card, in the eyepiece and on the monitor	Insufficient illumination intensity	<ul style="list-style-type: none"> ▶ Check the illumination intensity: <ul style="list-style-type: none"> • verify that the "Brightness FL560" is set to 100% - see „5.6 Example "FL" settings“ • bulb life indicator time ▶ If the intensity value is still too low, call the Leica service
	Bulb usage is above time limit	<ul style="list-style-type: none"> ▶ Replace the bulb
False FL colors on the monitor	Incorrect monitor settings	<ul style="list-style-type: none"> ▶ Check monitor settings and correct if necessary
	Incorrect camera settings	<ul style="list-style-type: none"> ▶ Check if the camera switches to FL560 camera settings: <ul style="list-style-type: none"> • HD C100 (PROVIDO/OHX/OH6/ARveo): scene file indicator (see HD C100 manual) • GLOW800 (OHX/OH6/ARveo): see the GLOW800 manual • ARveo 8: see ARveo 8 manual ▶ With persisting false FL colors, correct monitor settings and correct switching to the FL560 camera settings, adjust the camera settings for the FL560 mode: <ul style="list-style-type: none"> • HD C100 FL560 scene file settings: check with Leica Service • GLOW800 (OHX/OH6/ARveo) image enhancement in video settings for FL560 mode: check with Leica Service • ARveo 8 FL560 camera settings: see ARveo 8 manual

11 Technical data

11.1 Leica FL560 characteristics

Fluorescence excitation	460–500 nm \pm 5 % (blue)
Fluorescence observation	\geq 510 nm

11.2 Compatibility

Leica surgical microscopes	Leica M530 OH6
	Leica M530 OHX
	ARveo
	ARveo 8
	PROVIDO

11.3 Ambient conditions

In use	+10 °C to +40 °C +50 °F to +104 °F 30 % to 95 % rel. humidity 800 mbar to 1060 mbar atmospheric pressure
Storage	–30 °C to +70 °C –86 °F to +158 °F 10 % to 100 % rel. humidity 500 mbar to 1060 mbar atmospheric pressure
Transport	–30 °C to +70 °C –86 °F to +158 °F 10 % to 100 % rel. humidity 500 mbar to 1060 mbar atmospheric pressure



Test cards only allow a maximum temperature of 30°C for storage and transport.

12 Manufacturer's declaration of electromagnetic compatibility (EMC)



For the EMC declaration of the Leica FL560 for M530, please refer to the user manual of the particular surgical microscope.



10 747 212en/02 • Copyright © by Leica Microsystems (Schweiz) AG, Medical Division, CH-9435 Heerbrugg, 2023 • 02.2023 -- • LEICA and the Leica Logo are registered trademarks of Leica Microsystems IR GmbH.

Leica Microsystems (Schweiz) AG Max Schmidheiny Strasse 201 CH-9435 Heerbrugg

T +41 71 726 3333

www.leica-microsystems.com

CONNECT
WITH US!

