

From Eye to Insight



MEDICAL DIVISION

Leica FL400 for M530

User Manual

10 747 452– Version 03

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.



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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.


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1 Introduction

1.1 About this user manual

The Leica FL400 for M530 is an accessory for Leica surgical microscope systems.
In this user manual the functions of the Leica FL400 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.

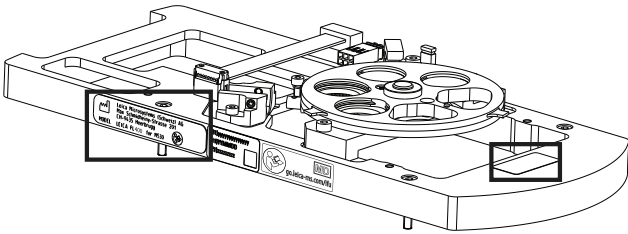
1.3 Optional product features

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 FL400 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 FL400 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 FL400 is addressed.

3.1 Intended use

Leica FL400 for M530 is a Leica surgical microscope accessory for viewing fluorescence of fluorophores with an excitation peak between 380 nm and 430 nm and an observation comprising the long-wave blue, green, yellow and red spectrum in the spectral band greater than 444 nm.



WARNING

Leica FL400 should only be used with fluorophores approved for use within the specified spectral ranges.

3.2 Indications for use

Leica FL400 is a Leica surgical microscope accessory used in fluorescent visualization of suspected grade III or IV gliomas during neurosurgery.



WARNING

Leica FL400 is not a standalone diagnostic device.

3.3 Intended User

Leica FL400 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 FL400 for M530 in combination with a fluorescence medium are those to be taken into account when using suitable brand substances.

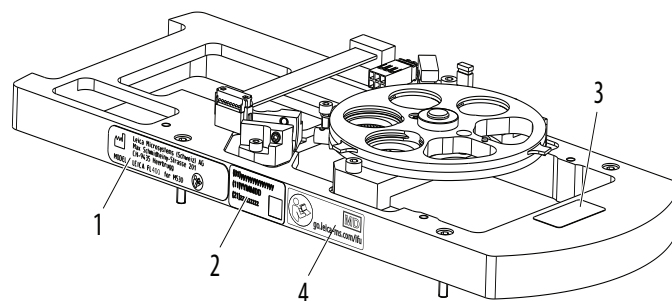
3.5 Dangers of use

NOTE

Mechanical interference.

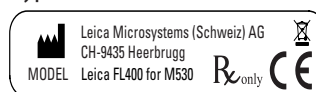
- ▶ Ensure, that the instrument did not suffer any mechanical interference since it was last used. A pre-operational check should be carried out prior to each new application.

3.6 Signs and labels



The type label is located on the side of the Leica FL400 for M530 filter module.

1 Typ label



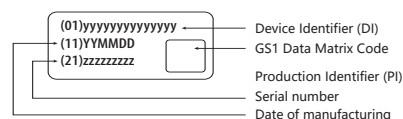
Rx only

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

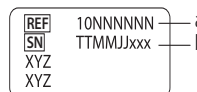


CE label

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.

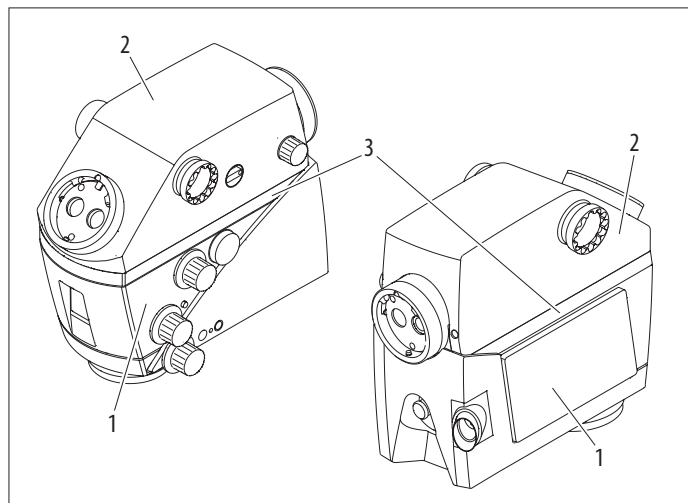
The Leica FL400 illumination filter module can provide visible and fluorescence excitation light.

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 FL400 user/ surgeon profile.

4.2 Design

The Leica FL400 for M530 is an accessory for the Leica M530 surgical microscope.

4.2.1 Optics carrier with Leica FL400 for M530

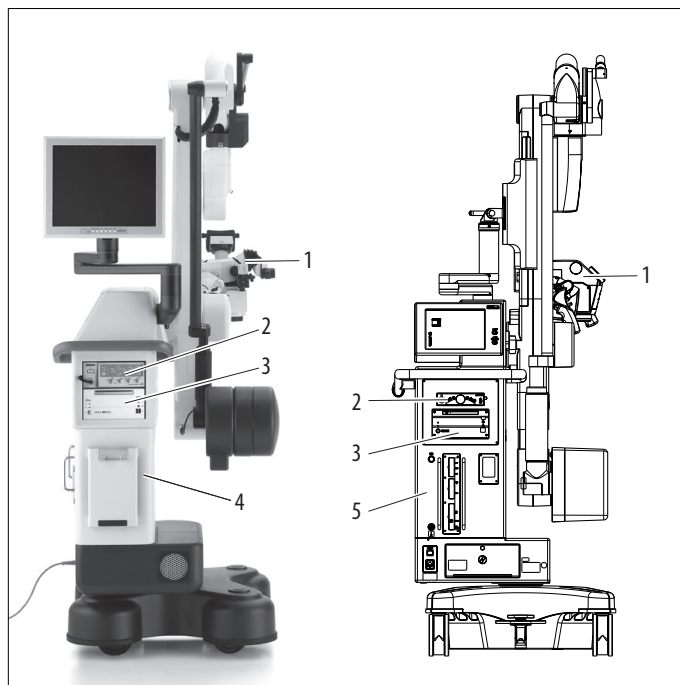


- 1 Leica M530 optics carrier
- 2 Leica ULT module
- 3 Leica FL400 for M530

- 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 FL400 for M530).
- Leica ULT system components built into the common housing of the ULT.

4.2.2 Stand

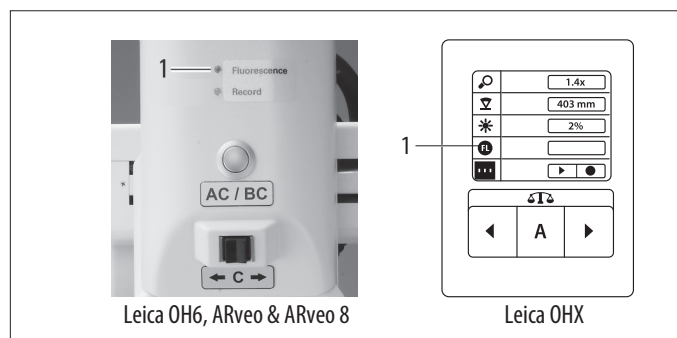
The following are examples of Leica surgical microscopes.



- 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

4.3 Controls

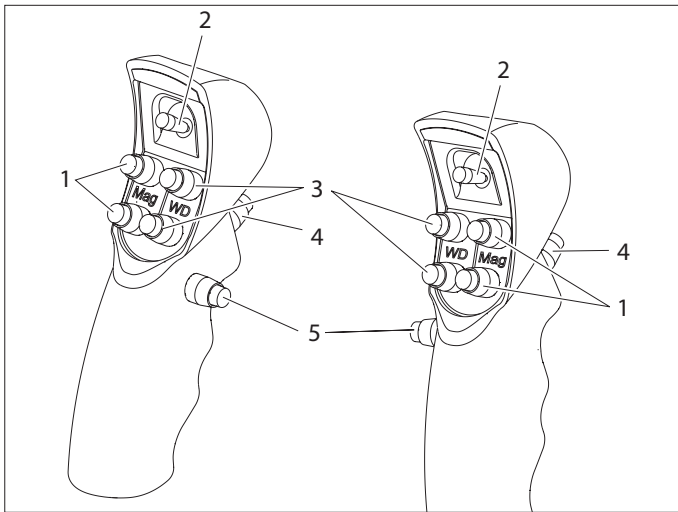
4.3.1 Status LEDs



The following LEDs on the swing arm are significant for the Leica FL400 for M530 application:

- 1 Status LED for fluorescence
 - LED lights up in blue = Leica FL400 mode
 - LED lights up in white = White light mode (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

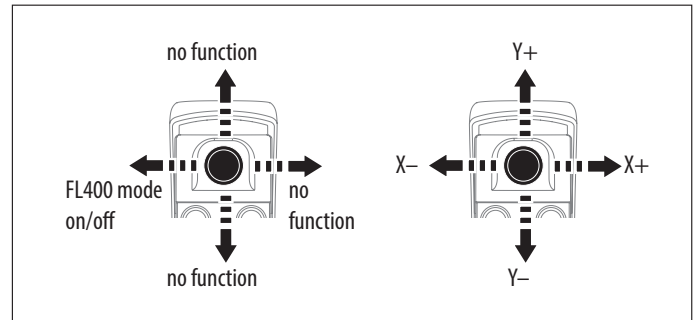
- 1 Magnification
- 2 4-function joystick
- 3 Working distance
- 4 Release all brakes
- 5 Release preselected brakes



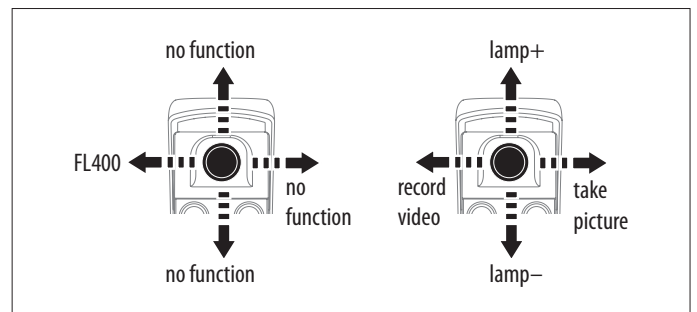
You can assign switches 1, 2, 3 and 5 of the handles individually for each user in the configuration menu. In all presets, key (4) releases all brakes. This key cannot be configured. For the joystick and the other keys presets are available according to your task.

Handle presets for Fluorescence FL400

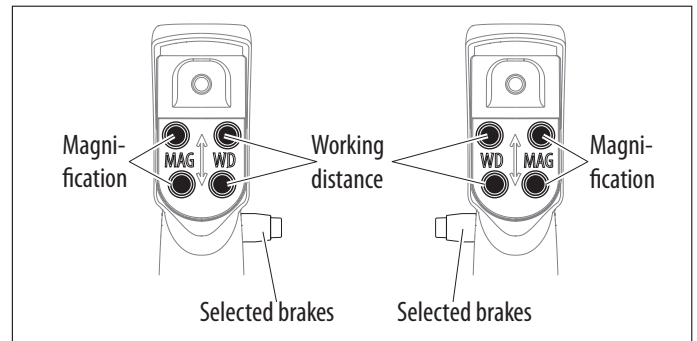
M530 OHX / M530 OH6 / ARveo



ARveo 8



All microscopes



5 Preparation before surgery (M530 OHX, M530 OH6, ARveo)

5.1 Using the "Fluorescence FL400" user preset

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



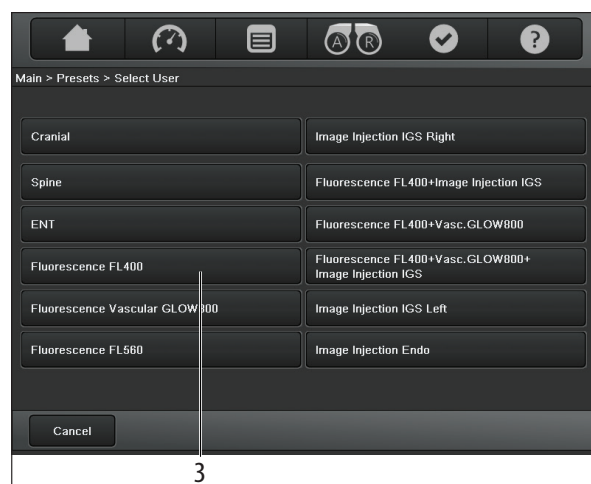
- ▶ Tap on the "User List" button (1).

The available user list for the microscope is displayed:



- ▶ Tap the "Presets" button (2).

The available presets for the microscope are displayed:

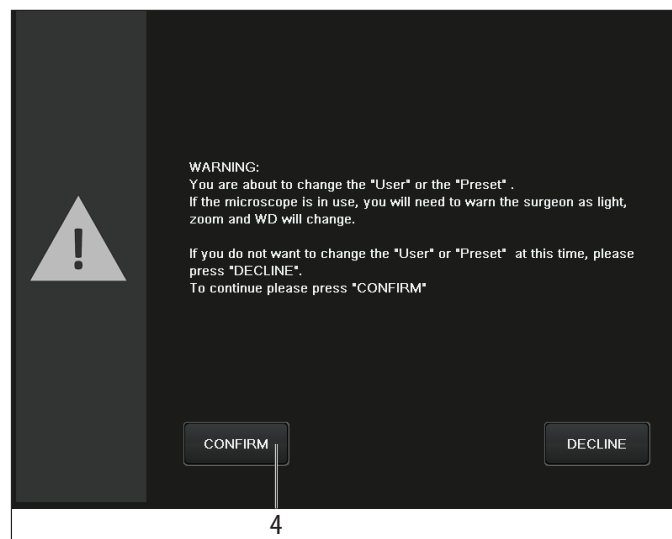


- ▶ Select the "Fluorescence FL400" user preset button (3).

NOTE

The FL400 user presets are only available if the FL400 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 FL400" preset you will be asked to confirm the change of the user preset.

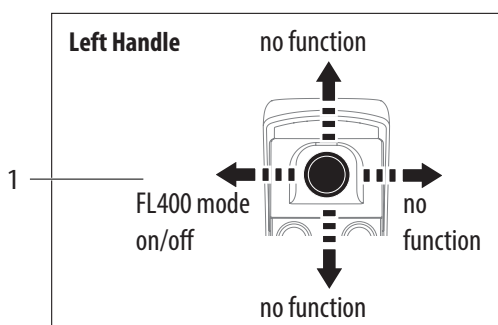


- ▶ Select the "Confirm" button (4).

The main page for "Fluorescence FL400" with the actual settings in **white light mode** is displayed:



Switch the Fluorescence FL400 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 FL400” with the actual settings in **Fluorescence FL400 mode** are displayed:



NOTE

In FL400 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 FL400” with the actual settings in white light mode are displayed.

5.2 Modifying the FL400 user preset



The factory FL400 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 5.7

NOTE

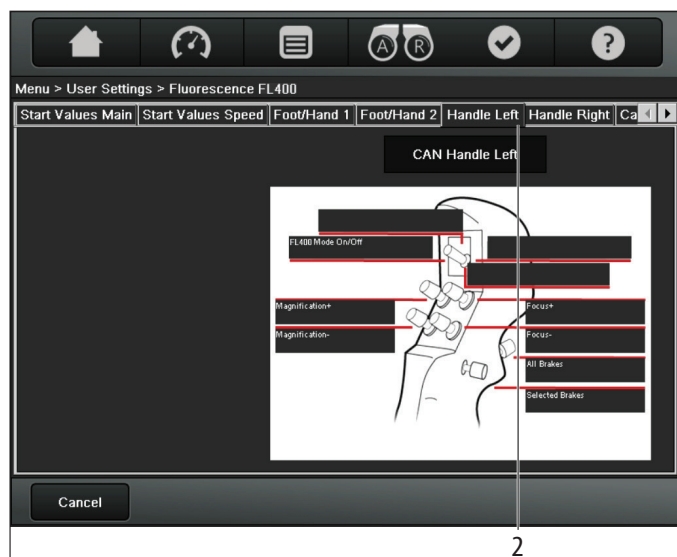
Do not change the settings or edit the user list when the microscope is in direct use on a patient. The FL400 mode is automatically stopped when modifying the settings.

5.3 Get current settings

On the page "Main > Fluorescence FL400" for both white light and FL400 modes, a "Show Settings" button can be found.



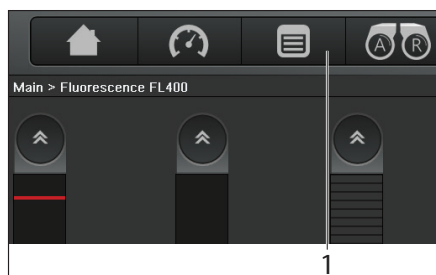
- ▶ Tap the "Show Settings" button (1).
The "User Settings > Fluorescence FL400" page is displayed. On this page you can find several tabs with information on the current settings of the Leica surgical microscope system.
- ▶ Tap the "Handle Left" tab (2).
This shows an overview of the buttons on the "Handle Left" including the button with which the FL400 functions (ON/OFF) can be operated:



5.4 Creating your own FL400 user

You can create and save your own FL400 settings according to your preferences.

- ▶ Before creating your own FL400 user follow the steps in chapter 5.1.
- ▶ Tap the quick access "Menu" button (1) once you are on the main page for FL400:



After pressing the button the following screen is displayed:

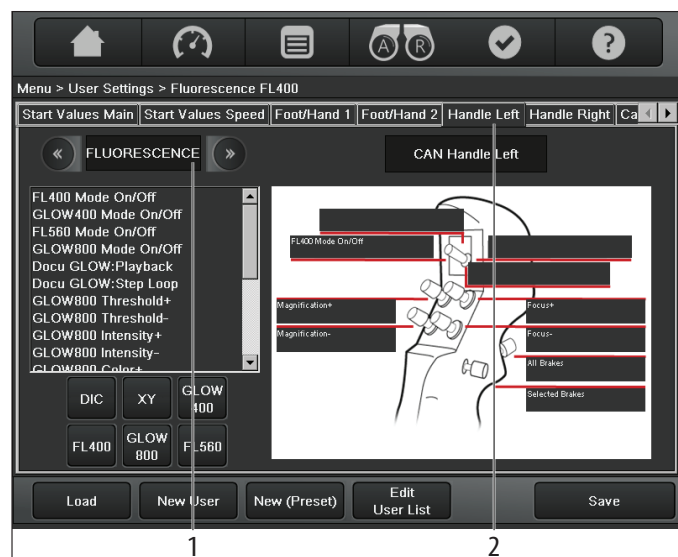


- ▶ Tap the "User Settings" button (2).
In each of the displayed tabs you can change the predefined user settings.



5.5 Example "Handle left" assignment

- ▶ Tap the "Handle left" tab (2).
- 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 button for activating and de-activating the FL400 mode.

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

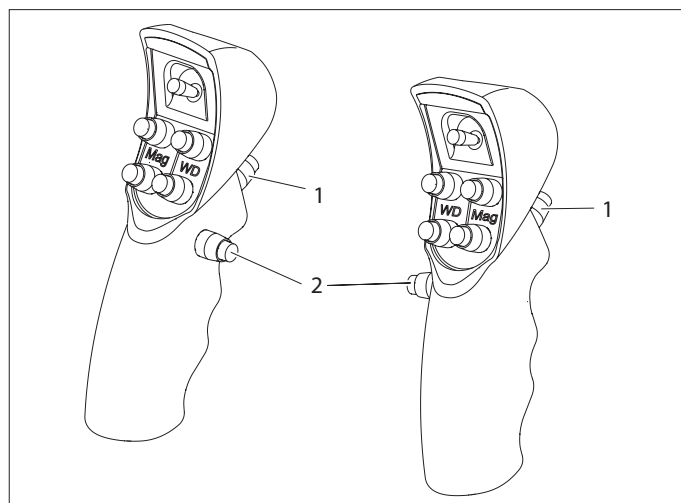


- ▶ Select the desired function you wish to assign. In this example it would be: "FL400 Mode On/Off".
- ▶ Click on a free or assigned caption of the desired button on the handle to assign the selected function to it.

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 FL400 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 8.1) as soon as the FL400 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 8.1) when switching to FL400 mode, the working distance will be reduced and the picture will get out of focus.

²⁾ This limitation can be activated within the FL400 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.

5.7 Save user settings

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

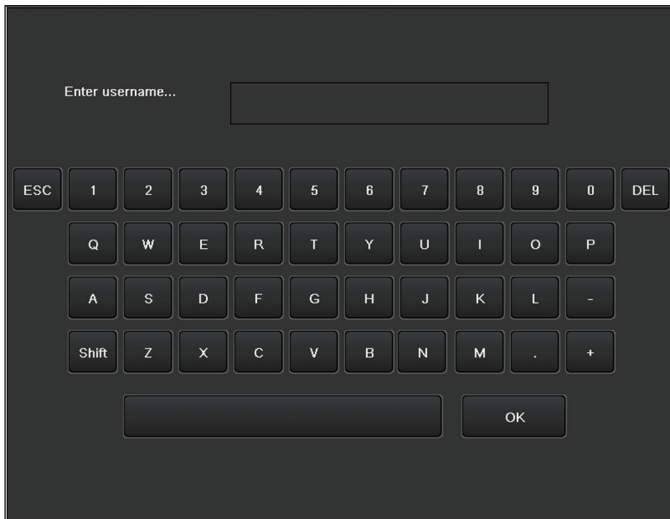


- ▶ In the "User settings" menu tap on "Save" (1) and then on "Save as New" buttons.

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.

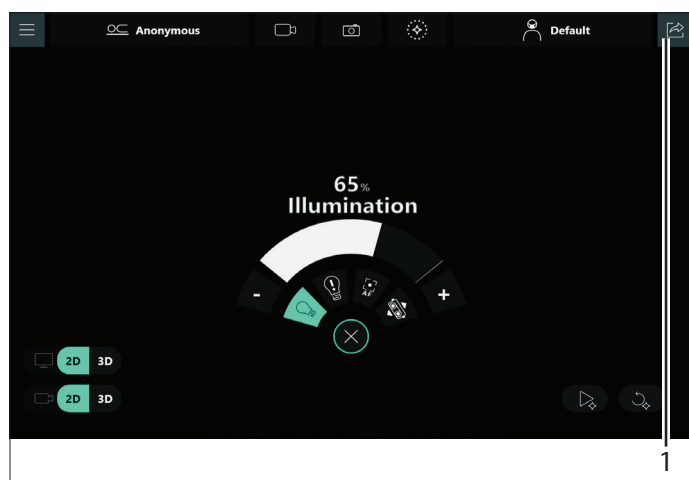
Please refer to the user settings chapter in the manual of your respective surgical microscope for detailed instructions on how to set or change passwords.

6 Preparation before surgery (ARveo 8)

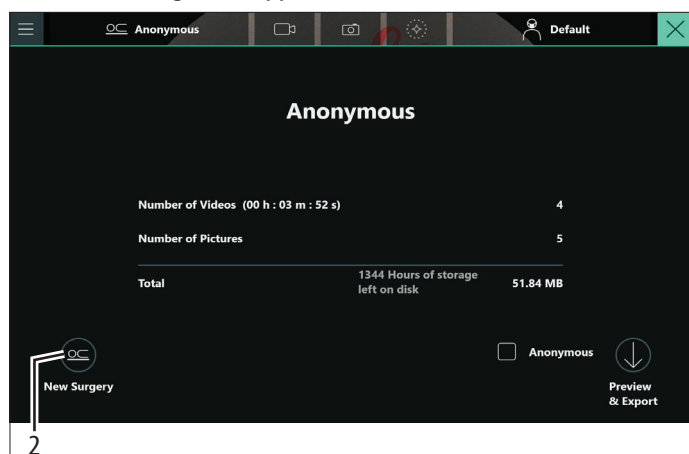
! For more information about preparation before surgery, refer to the user manual of ARveo 8.

6.1 Creating a surgeon profile

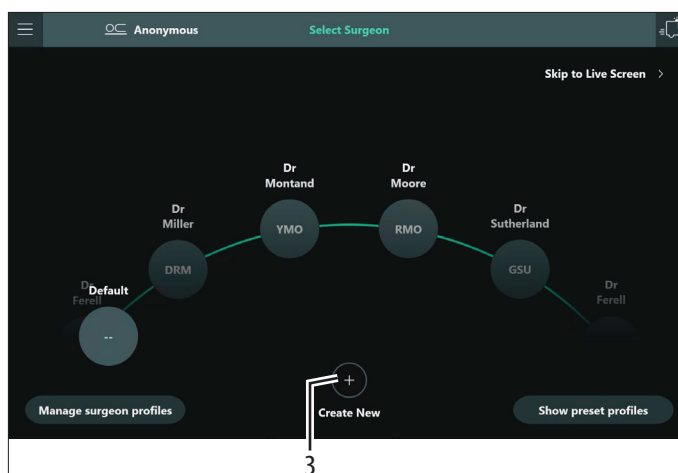
6.1.1 Creating a new surgeon profile with factory default settings



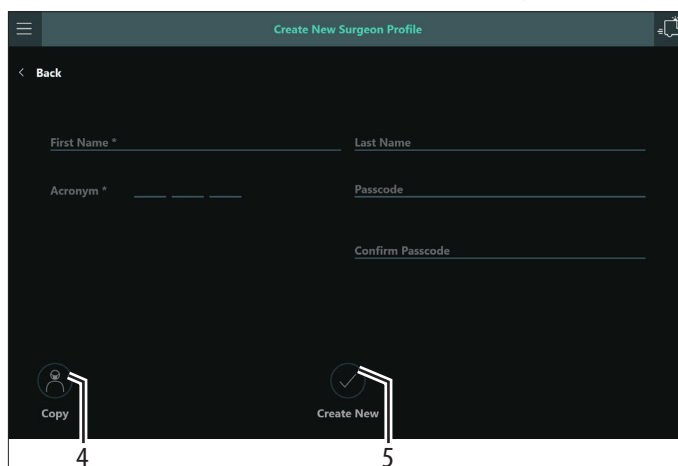
► Tap the "Data review" (1) icon on the GUI "Live Screen" page. The following menu appears:



► Press "New Surgery" (2). The "Select Surgeon" page appears.



► Tap the "Create New" button (3). The "Create New Surgeon Profile" page is displayed:



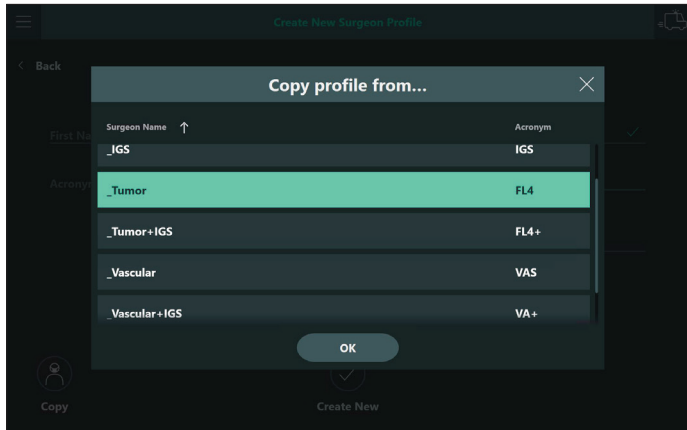
► Fill in at least the mandatory data for a surgeon profile, i.e. first name and a unique three-letter acronym. Fields marked with an * are mandatory.

! 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 and can contain maximum ten (10) characters.

► Press either "Copy" (4) or "Create New" (5). The "Create New" function allows to start from default factory settings. The "Copy" function (see chapter 6.1.2 "Creating a new surgeon profile from an existing surgeon profile or preset") allows to copy settings from a preset or an existing surgeon profile which can then be adapted to your needs.

6.1.2 Creating a new surgeon profile from an existing surgeon profile or preset

When the "Copy" function is used (see chapter 6.1.1 "Creating a new surgeon profile with factory default settings"), the list of existing surgeon profiles and presets is displayed.



The Leica FL400 user can choose a surgeon profile for which the Leica FL400 profile has already been defined or choose the FL400 preset profiles `_Tumor` or `_Tumor+IGS`.

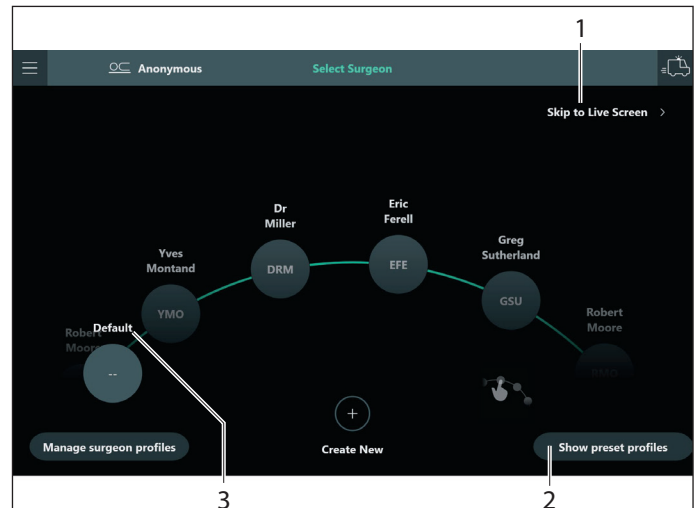


The factory preset profiles are displayed at the top and are generally prefixed with an underscore (i.e. `_Tumor`).

- ▶ Select the desired preset or surgeon profile to copy.
- ▶ Press "OK".
In both cases (copying preset or copying an existing surgeon profile), after pressing OK, the name of a surgeon profile specified on the "Create New Surgeon Profile" page (see chapter „6.1.1 Creating a new surgeon profile with factory default settings“) appears on the "Live Screen" on the top right with the copied settings.
- ▶ Configure the user input settings (see chapter 6.4.1 "Example of how to assign the Leica FL400 function to a handle button").

6.2 Select an existing surgeon profile

- ▶ Open "Select surgeon" page (see chapter „6.1.1 Creating a new surgeon profile with factory default settings“).
- ▶ Choose between different surgeon profiles from the "wheel".



If more than 5 profiles have been defined, the user can rotate through all defined and activated profiles by dragging with their finger. Profiles are alphabetically sorted by first name. The list is "infinite", i.e. after the last item in the list, the first item will appear as the next one. If there are less than 4 profiles, there is no need or option to drag.

Tapping on one of the surgeon profiles opens the "Live Screen" page and the name of a chosen surgeon profile appears on the top right.

When the user taps "Default" (3) or "Skip to Live Screen" (1), the default surgeon profile is chosen. Any changes to the default settings are applied immediately, but will not be stored. i.e., the next surgery using this default profile will start with the original factory settings again.

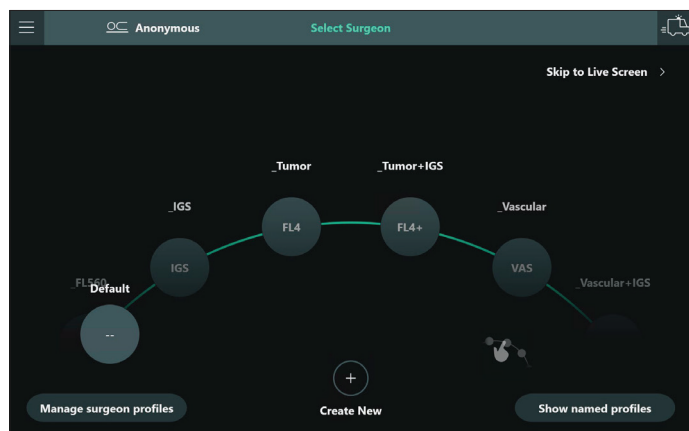
When the user taps "Show preset profiles" (2), a list of preset profiles appears, depending on the installed licenses.

6.3 How to use preset profiles

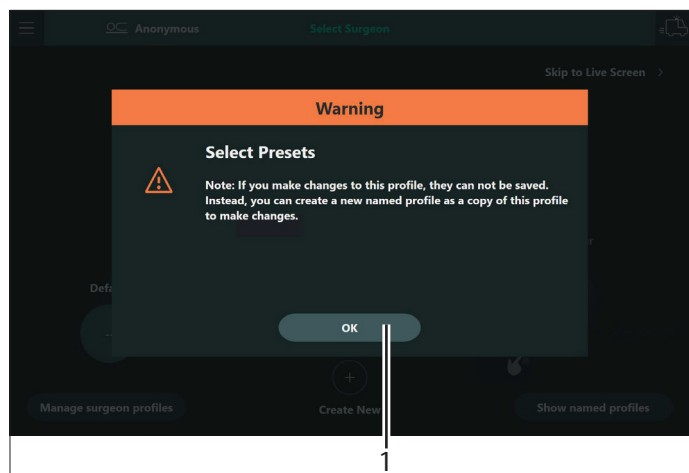
- ▶ Open "Select Surgeon" page (see chapter 6.1.1 "Creating a new surgeon profile with factory default settings").
- ▶ Tap "Show preset profiles".
The following page appears:



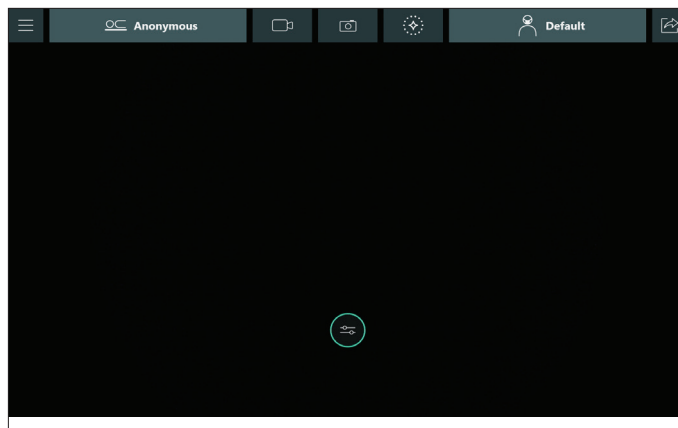
For more information about preset profiles, see the ARveo 8 user manual.



- ▶ Select the desired default profile. For Leica FL400 users select "_Tumor" or "_Tumor+IGS".
The following warning screen appears:



- ▶ Press "OK" (1).
The selected profile is shown on the "Live Screen" page.



- ▶ Configure the user input settings (see chapter 6.4.1 "Example of how to assign the Leica FL400 function to a handle button").

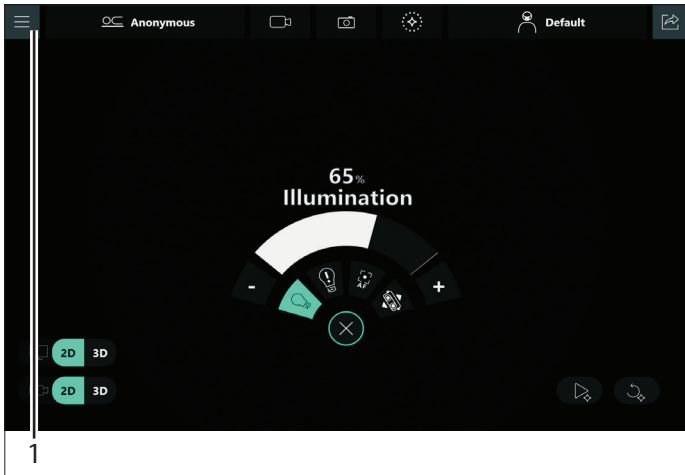


The preset profile can be used and modified, but any changes to the profile settings will not be saved. Therefore, with each new start-up, the default profile settings will be restored.

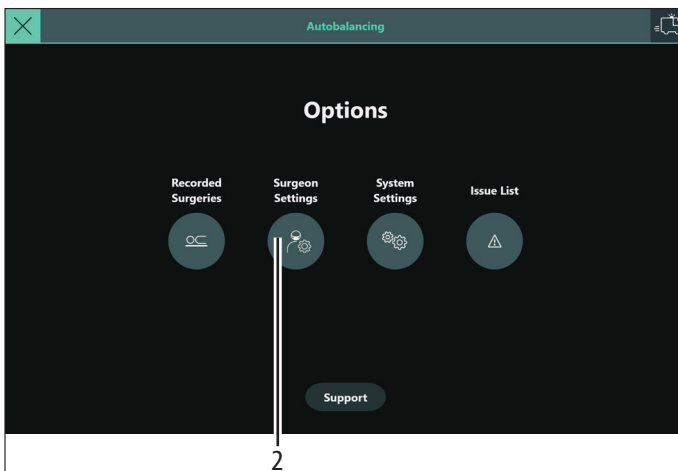
Since the modifications to the preset cannot be saved, it is highly recommended to create a new surgeon profile for a full workflow where a preset can be used as a starting point.

6.4 Configuring the user inputs on the handles and foot switches

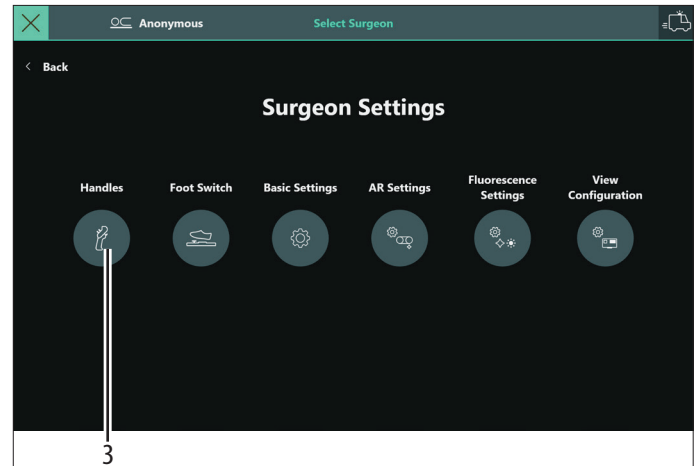
- Make sure you are on the "Live Screen" page for the selected or newly created surgeon profile.



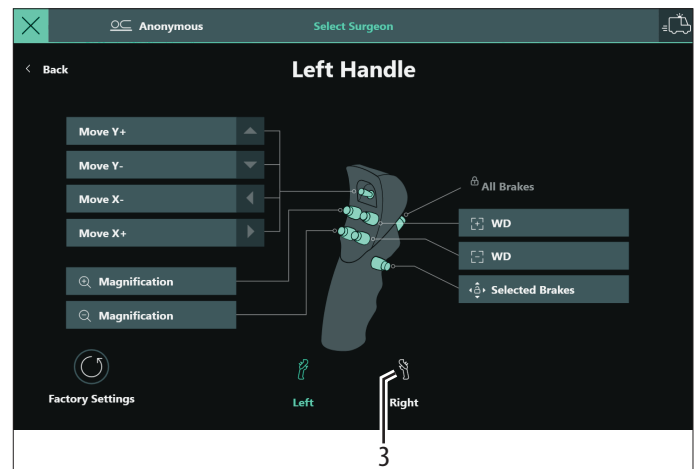
- Tap the menu icon in the upper left corner (1). The "Options" page is displayed:



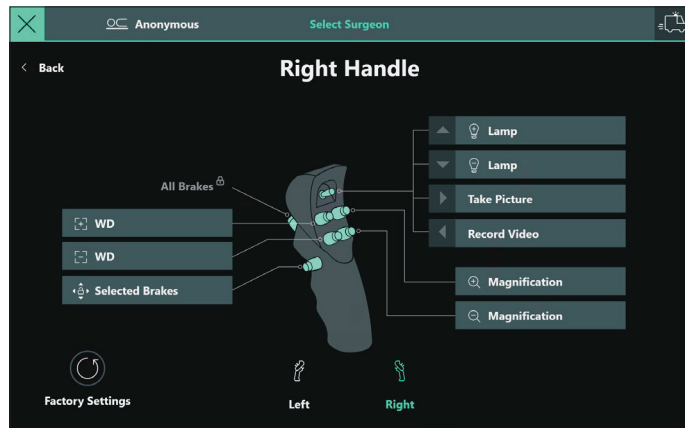
- Tap the "Surgeon Settings" icon (2). The "Surgeon Settings" page is displayed:



- Tap "Handles" button (3) to show the "Left Handle" settings. Depending on the surgeon profile that is set ("new surgeon profile with factory default settings" or "new surgeon profile from an existing surgeon profile or preset") the left and right handle display will differ. If using "new surgeon profile with factory default settings", the predefined factory settings of the left handle are displayed:



- Press on "Right" for the right handle configuration screen. Predefined factory settings of the right handle are displayed:



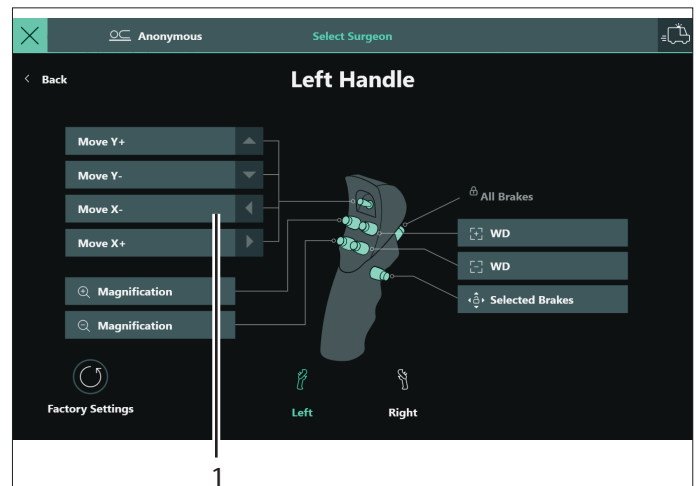
Now the handle settings can be viewed or edited for the selected surgeon profile.

6.4.1 Example of how to assign the Leica FL400 function to a handle button

FL400 mode activation is a prerequisite to enable Leica FL400 functionality on the microscope. The following steps show how the Leica FL400 function can be assigned to a button i.e., on the left handle.

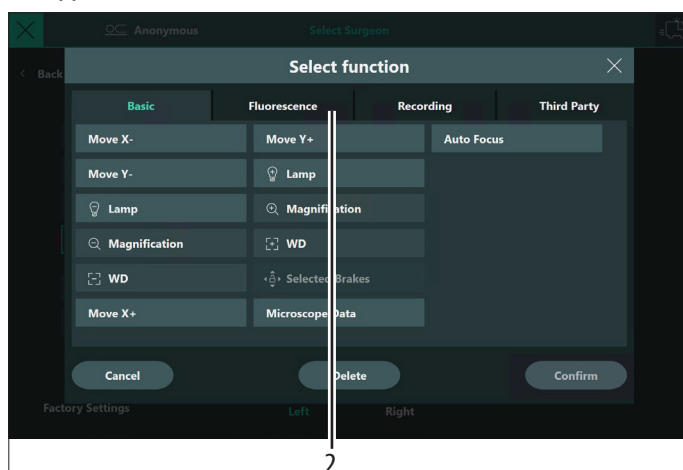
The preset for FL400 can be used to quickly assign the FL400 functionality to a predefined handle button (see chapter 6.1.2 "Creating a new surgeon profile from an existing surgeon profile or preset"), but this can be done also manually choosing any of the available buttons.

- Open the settings page for the handle you wish to configure (in this example the "Left Handle" settings page) as described in chapter 6.4 after having switched to the particular surgeon profile you wish to edit (see chapter 6.2):

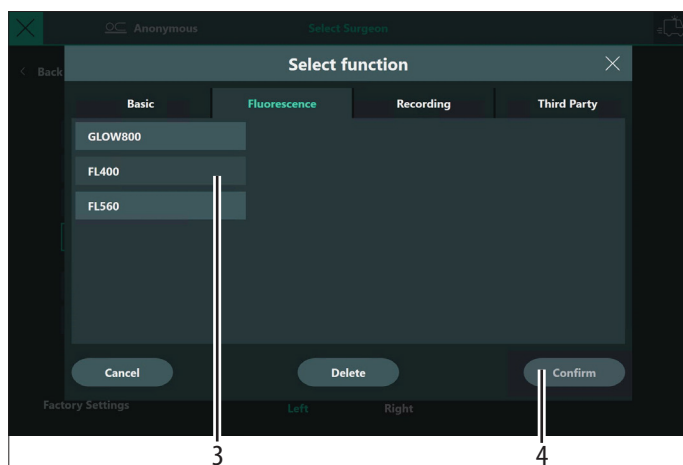


- When you are on the handle configuration page, press the button you want to assign for the activation of the Leica FL400. In this example we select the left button of the joystick (1).

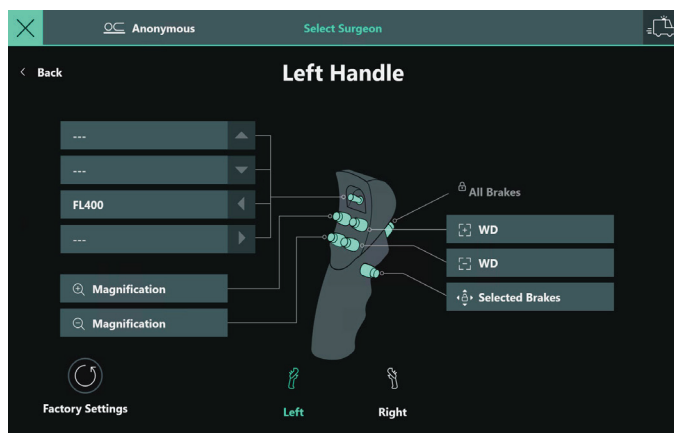
The "Select function" popup window for the selected button appears:



- Select the "Fluorescence" tab (2).
A list of available FL functions appears.

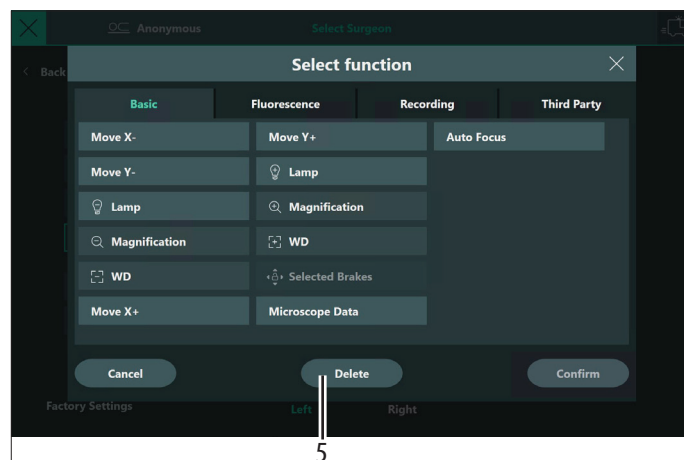


- Select the Leica FL400 function (3) and press "Confirm" (4) to save the settings.
The Leica FL400 function is assigned to the selected button as displayed:

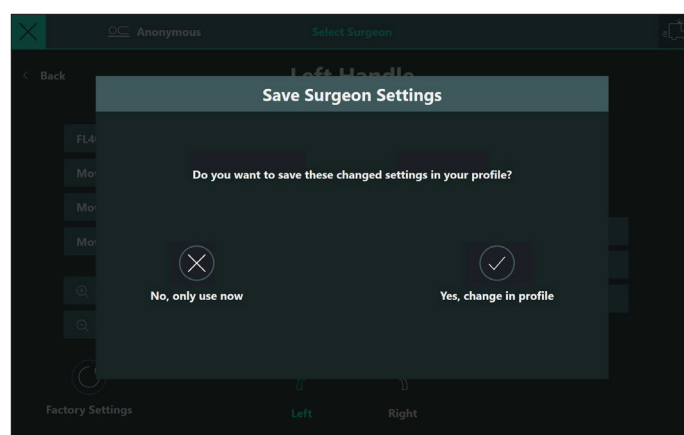


Deleting a function assignment

- In case the selected function needs to be deleted, press the function button on the handle configuration page.
The "Select function" popup window for the selected button appears:



- Press the "Delete" button (5).
The selected function disappears from settings of the handle configuration page.
- Press the "Back" button of the handle configuration page.
The "Save Surgeon Settings" dialog appears.



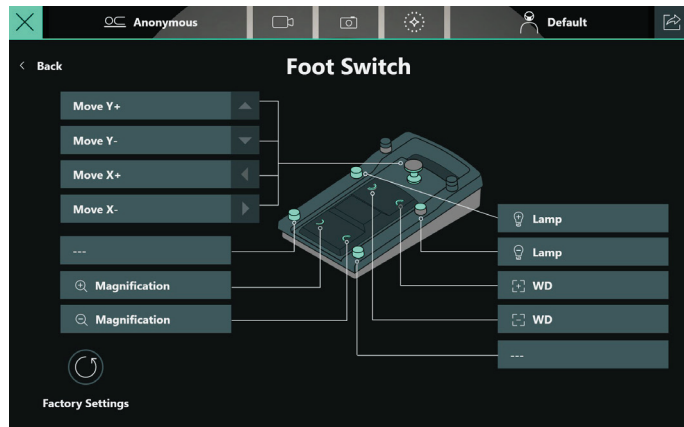
- Press desired option.
The "Surgeon Settings" appear.
- Press "Back" to return to the "Options" page.

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

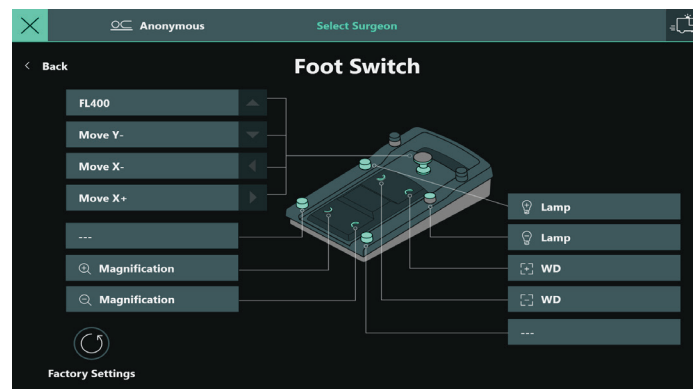
6.4.2 Configuring the foot switch

You can configure the foot switch similarly to the handles.

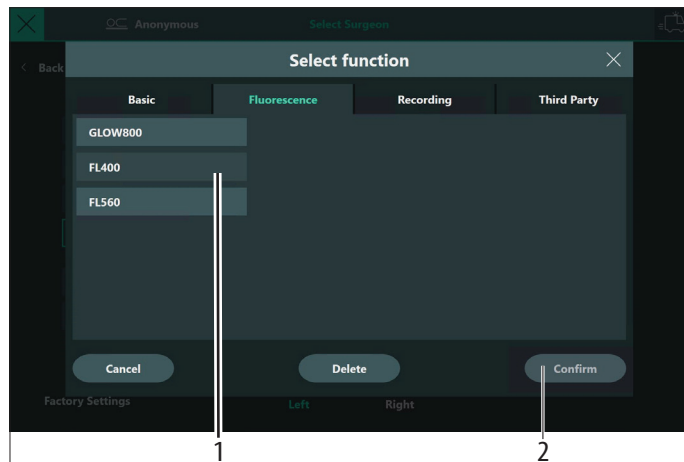
- Ensure you have loaded the surgeon profile you wish to edit (see chapter 6.2).
- Open the "Foot Switch" settings page in the "Options" -> "Surgeon Settings" page.
- Tap the selection field of the desired key on the foot switch.



Example of foot switch with Leica FL400 assignment



The following selection menu opens:

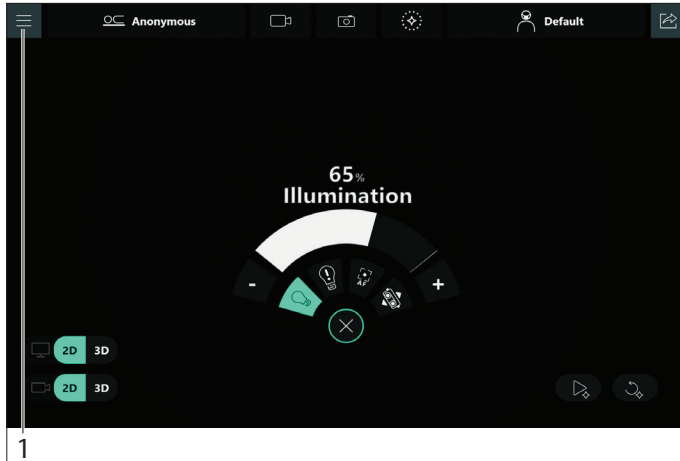


- Select the desired function (1) and apply with Confirm (2). The selected function is displayed in the selection field. The selections are identical to those for the handles with the exception of the brakes.

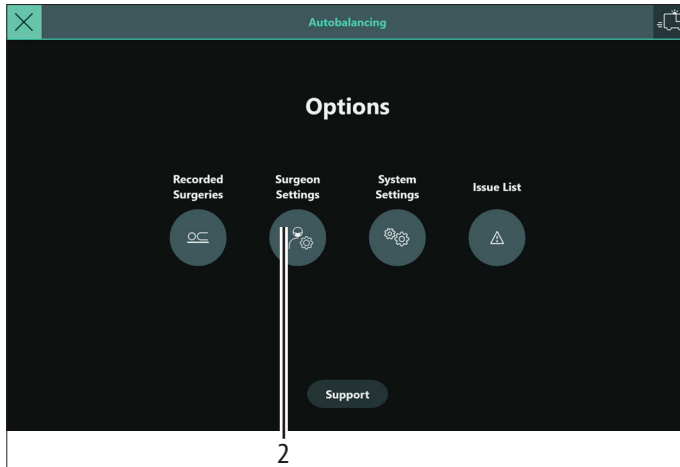
7 Modifying the FL400 settings (ARveo 8)

7.1 Excitation intensity

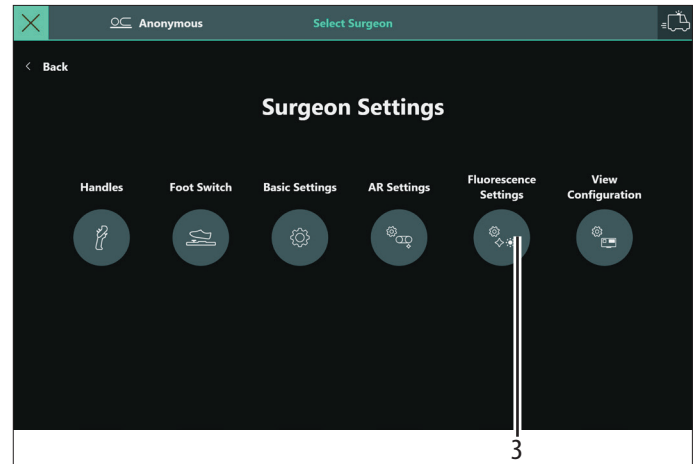
Per default the excitation value is set to 100% (see recommended excitation settings).



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

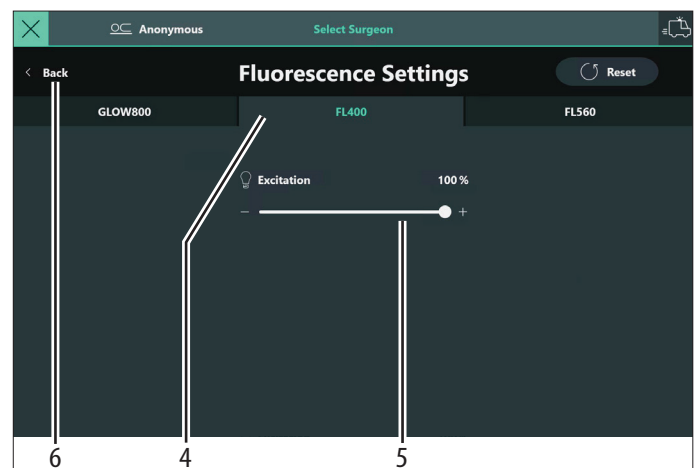


- ▶ Tap the "Surgeon Settings" icon (2).
The "Surgeon Settings" page is displayed:



- ▶ Tap the "Fluorescence Settings" (3) icon and then tap the FL400 tab (4).

The FL400 "Fluorescence Settings" page is displayed:

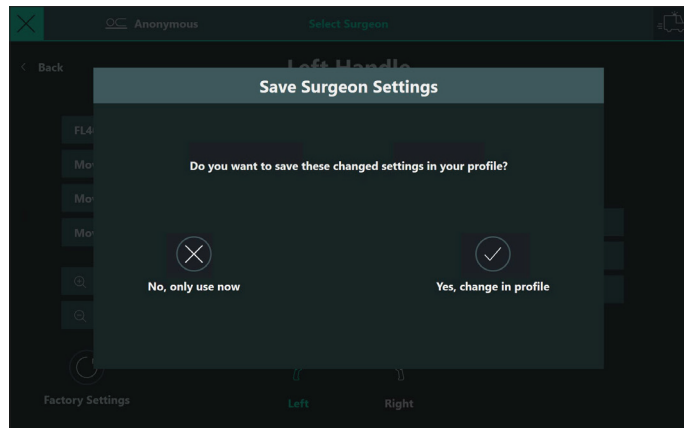


Recommended Excitation settings

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.

7.2 Fluorescence visibility

The Leica FL400 function automatically optimizes the fluorescence visibility to receive the best possible image for a broad working range of microscope parameters. However, these parameters still have an impact to the fluorescence visibility as the following description explains for further optimizations.

Less excitation intensity reduces the fluorescence visibility, especially at high magnification and/or long working distance. Less fluorescence visibility or fluorescence brightness might be observed already at lower magnifications and working distances (see chapter 8.1 "Operating range limits for Leica FL400").

Higher excitation intensity increases the fluorescence visibility, especially at high magnification and/or long working distance and can compensate the reduction of these two optical parameters.



The fluorescence visibility can decrease even with standard conditions if the efficiency of the illumination system is reduced or the xenon bulb lifetime reaches its end.

8 Operation

8.1 Operating Range Limits for FL400

- Working Distance (WD): 225 to 350 mm
- Magnification (MAG): 2.0× to 7.0×
- Illuminance: Min. 550kLux (at 225mm WD in the center of object field in white light mode)

Recommended settings for best image quality:


To observe Leica FL400 in best quality and brightness, it is recommended to work in a WD below 350 mm and a total MAG less than 7.0 x.


8.2 Preoperative checklist

- ▶ Switch on the surgical microscope.
- ▶ Ensure that the binocular tubes are installed on the optics carrier


 Do not change the configuration when performing FL400 surgery.

- ▶ Balance the microscope.
- ▶ Check if required accessories are properly connected.

 Before using Leica FL400 in combination with other accessories please follow the instruction in the accessory Manual regarding Leica FL400.

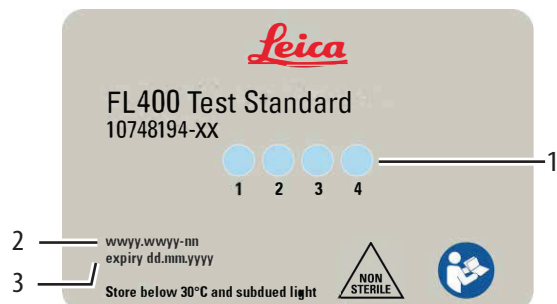
 Before using Leica FL400 with the Leica Surgical Microscope please follow the instruction in the Leica Surgical Microscope Manual regarding Leica FL400.

- ▶ Select user/ surgeon profile as described in the user manual
- ▶ Check the handle/foot switch assignment of FL400 mode and FL400 activation/deactivation functions for the selected user/ surgeon profile.
- ▶ Switch on the illumination used for FL400.
- ▶ Activate FL400.
- ▶ Check the FL400 functionality with the test standard as described in chapter 8.4.

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

8.3 Test Standard

Test Standard functional areas description (front side)



- 1 Round spots emitting different levels of fluorescence intensity.
- 2 Production lot
- 3 Expiry date of the Test Standard

The Test Standard offers four fluorescent spots. The fluorescence emission of the spots will provide the end user with a visual assessment of the Leica FL400 functionality during the preoperative check.

! Contact the local Leica representative to order a new Test Standard (article number 10748194).

8.4 Test Standard preoperative check

Use the Test Standard to verify the proper functionality of the Leica FL400 as well as the surgical microscope system.

! Check the expiration date on the Test Standard and replace the Test Standard before expiration

! Expired, defective or destroyed cards must not be used further and must be disposed of in the household waste.

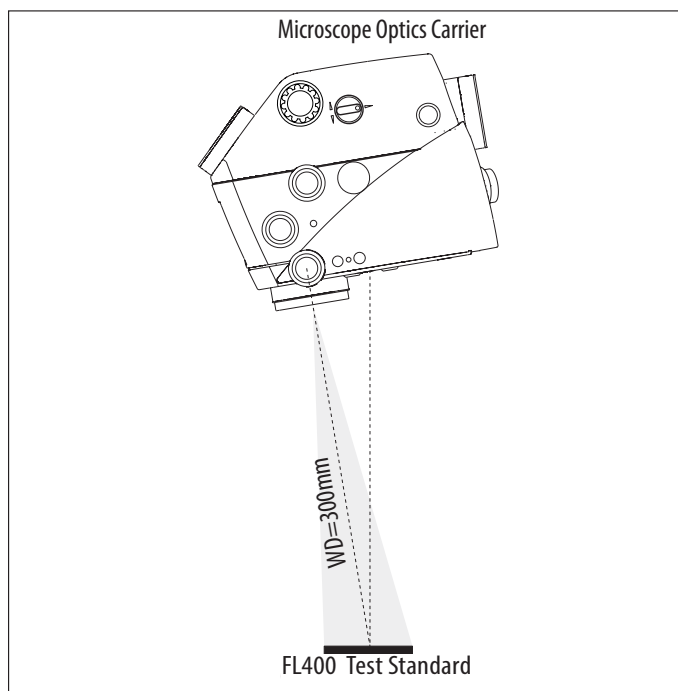
WARNING

Risk of infection

- Do not use the FL400 Test Standard in the sterile field.

Prepare the FL400 functionality test as follows:

- Place the test standard on a suitable base under the Leica surgical microscope.
- Adjust the working distance (WD) to 300 mm and get into focus by repositioning the microscope optics carrier.
- Adjust the magnification to 3.0 x.
- To avoid reflections do not place the optical axis fully perpendicular to the Test Standard.
- Minor adjustments may be needed until all reflections are eliminated.
- Move the Test Standard into the center of the field of view.



- Switch to FL400 mode by pressing the FL400 activation/deactivation button on the handle.
- Ensure that blue light excitation is visible in the binoculars.

! ► If there is no illumination switch to the second lamp as described in the Leica surgical microscope user manual.
 ► If blue light is not observed do not use and contact the local Leica Microsystems representative.

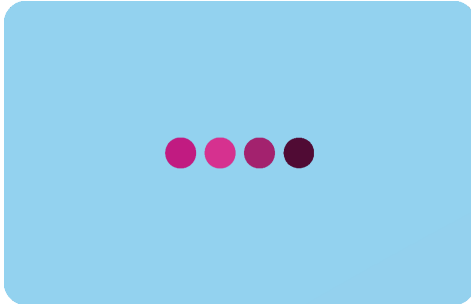
- Adjust the fluorescence excitation to 100 % (if it has been defined differently in the user/ surgeon profile).
- The test standard can now be used to check the Leica FL400 performance.

► **Assessment of Leica FL400 functionality**

The pictures below show the fluorescence intensity signal with the following settings:

- Working distance: 300 mm
- Magnification: 3.0 x
- Excitation: 100%

Test Standard functional areas description (front side), Leica FL400 mode with good fluorescence feedback



Active round fluorescence areas with (1) high, (2) high/middle, (3) middle/low and (4) low intensity Leica FL400 fluorescence signals.

Assessment criteria for FL400 functionality check:

- When activating FL400 all 4 intensity spots 1-4 should be visible.
- If the fluorescence emission intensity of the fluorescence spots 1 to 4 seems weak based on the observer's subjective opinion, check Leica FL400 functionality (see chapter Common troubleshooting steps"):
 - Fluorescence excitation setting might not be 100%.
 - Xenon illumination lamp #1 might not be activated or efficient (e.g. end of life).



- If the fluorescence emission intensity still appears weak, please call the local Leica representative.



- Make sure to use the correct Test Standard 10748194. Check the expiration date on the Test Standard and replace the Test Standard before expiration.

8.5 Using the Leica FL400 for M530

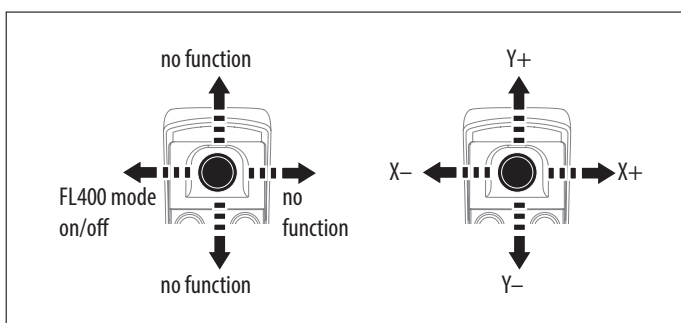
- Switch on the illumination of the particular surgical microscope.
- Select either the "Fluorescence FL400" preset user/ surgeon profile or your own FL400 user/ surgeon profile.

The status LED on the swing arm of the particular surgical microscope is illuminated in blue if the FL400 mode is active (on all surgical microscopes), and white if switched back to white-light mode (M530 OHX only. On M530 OH6, ARveo, ARveo 8 the LED is simply off in white light mode).

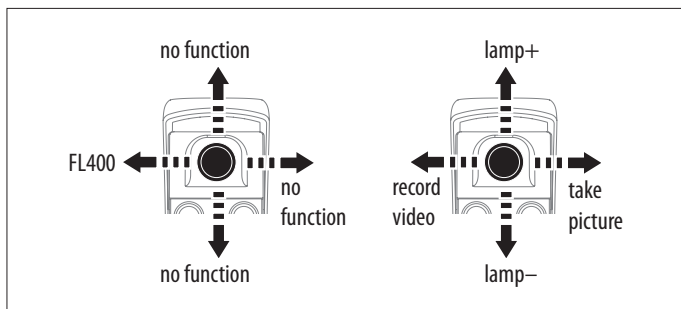
! If the illumination fails in the white-light or FL400 mode, change to the back up light bulb of the illumination source of the illumination unit.

Controlling the FL400 functions:

M530 OHX / M530 OH6 / ARveo



ARveo 8



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 FL400 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 FL400 for M530, please refer to the user manual of the particular surgical microscope.

10 What to do, if...

10.1 General

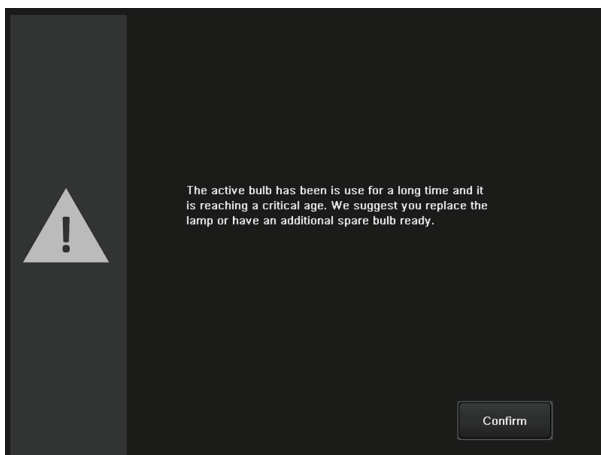
 For malfunctions regarding the Leica Surgical Microscope refer to the user manual of the particular surgical microscope.

10.2 Status messages

The Leica surgical microscopes OH6, OHX, ARveo and ARveo 8 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):



Issue List				
Creation Time	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.

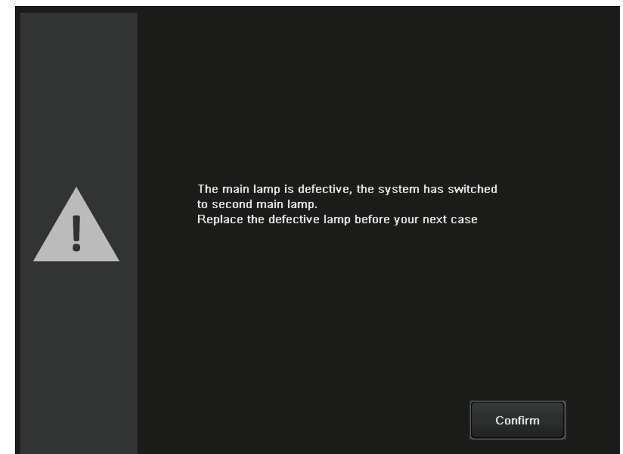
10.2.2 Defective main lamp



WARNING

In case the main lamp is defective you receive the information that the system has switched to the second main lamp:

Defective main lamp alert





ARveo 8 - defective main lamp alert

Issue List				
Creation Time	Error Code	Error Name	Error Message	Resolution
06-01-2021 12:57:00 PM	216	Hardware Error	Lamp 1 is defective. The system has switched to the other lamp.	Please replace the light bulb. If problem persists, please contact Leica service.

- 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

Issue List				
Creation Time	Error Code	Error Name	Error Message	Resolution
06-01-2021 11:59:52 AM	217	Hardware Error	Lamp 2 is defective. The system has switched to the other lamp.	Please replace the light bulb. If problem persists, please contact Leica service.

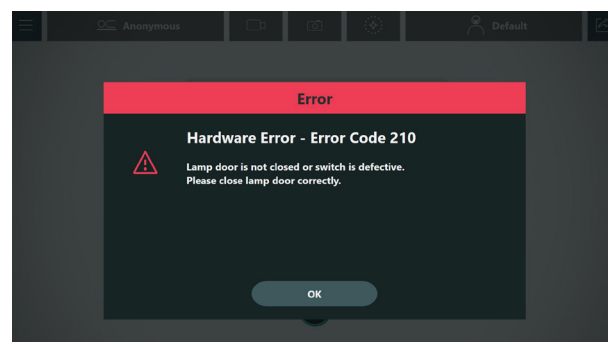
- Exchange the defective bulb with a new one before your next case.

10.2.4 Lamp door error (ARveo 8)



WARNING

Lamp door is open or the switch is defective.



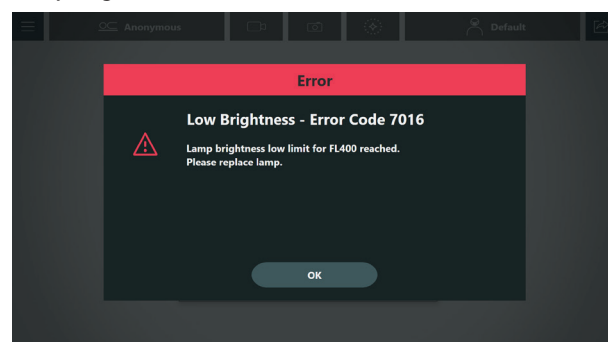
- Close the lamp door.

10.2.5 Low brightness limit (ARveo 8)



WARNING

Lamp brightness low limit reached.



- Replace the lamp.

10.3 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 neither in the eyepiece, nor on the monitor	FL400 is not active	<ul style="list-style-type: none"> ▶ Check if FL400 is activated: <ul style="list-style-type: none"> • the status LED shines blue • the illumination light is blue ▶ Check installation status with Leica service to assure FL400 function ▶ Check whether the FL400 mode function is assigned to a button of a handle.
	FL400 user/surgeon profile is not selected	<ul style="list-style-type: none"> ▶ Choose correct FL400 user/ surgeon profile
No blue light in FL400 mode	FL400 mode is not active	<ul style="list-style-type: none"> ▶ Check installation status with Leica service to assure FL400 function. ▶ Check that the fluorescence LED and the control unit display the FL400 mode. ▶ Check whether the FL400 On/Off function is assigned to a button of handle.
Dark in-vivo FL 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 FL400/ Excitation " is set to 100% - see chapter 5.6 and chapter 6.3 • 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 ▶ Reset the monitor settings to default.
	Incorrect camera settings	<ul style="list-style-type: none"> ▶ Check if the camera switches to FL400 camera settings: <ul style="list-style-type: none"> • HD C100: scene file indicator (see HD C100 manual) • GLOW800: see the GLOW800 manual • ARveo 8: see ARveo 8 manual. • etc. ▶ With persisting false FL colors, correct monitor settings and correct switching to the FL400 camera settings, adjust the camera settings for the FL400 mode: <ul style="list-style-type: none"> • HD C100 FL400 scene file settings: check with Leica Service • GLOW800 image enhancement in video settings for FL400 mode: check with Leica Service • ARveo 8 FL400 camera settings: see ARveo 8 manual.

11 Technical data

11.1 Leica FL400 characteristics

Fluorescence excitation	405 nm (blue light)
Fluorescence signal	635 nm (red)




For technical data related to the Leica surgical microscope refer to the Leica Surgical microscope user manual.

11.2 Compatibility

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

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 FL400 for M530, please refer to the user manual of the particular surgical microscope.

