From Eye to Insight

Leica
MICROSYSTEMS

MEDICAL DIVISION

GLOW800

User Manual

10 748 652 - Version 01

CE 0123

Thank you for purchasing a Leica surgical microscope system.
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.

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Contents

1 Introduction 4
1.1 About this user manual 4
1.2 Symbols in this user manual 4

2 Safety notes 4
2.1 Intended purpose 4
2.2 Indications for use 4
2.3 Patient target group 4
2.4 Intended user 4
2.5 Dangers of use 5
2.6 Information for the person responsible for the instrument 5
2.7 Signs and labels 5

3 Description 6
3.1 Function 6
3.2 Design 6

4 Controls 7
4.1 Handles 7
4.2 Foot switch 7
4.3 Status LEDs 8
4.4 GUI Activation 8

5 Overview 9
5.1 2D and 3D view 9
5.2 Fluorescence observation modes 10
5.3 Fluorescence display layout 10

6 Modify the GLOW800 settings 12
6.1 Fluorescence settings 13
6.2 Intensity 15
6.3 BrightCare 16
6.4 Pseudocolor selection 16

7 Recording 18
7.1 Initiate recording / save picture 18
7.2 Playback 18

8 Preparation before surgery (ARveo 8) 19
8.1 Selecting a profile with GLOW800 settings 19
8.2 Creating a new surgeon profile 19

9 Check and adjust the illumination and functions 25
9.1 Pre-operation checklist (GLOW800) 25
9.2 Test card 26
9.3 Preparation 26
9.4 Test card functional areas 27

10 Operation 28
10.1 Using the GLOW800 28
10.2 Controlling the GLOW800 functions 28

11 Care and maintenance 29

12 Disposal 29

13 What to do if...? 30
13.1 Calibration 30
13.2 Control Unit 30
13.3 Limitation 30
13.4 Corrections by the user 31
13.5 Malfunction 32
13.6 In-built recording 32

14 Technical data 33
14.1 Technical data GLOW800 33
14.2 Compatibility 33
14.3 Ambient conditions 33

15 Manufacturer's declaration of electromagnetic compatibility (EMC) 34

1 Introduction

1.1 About this user manual

This user manual describes the function of GLOW800 in combination with ARveo 8 (10449157). For information and description of ARveo 8 (10449157), refer to the corresponding user manual.

In addition to notes on the use of the instruments, this user manual gives important safety information (see chapter 2 "Safety notes", page 4).

► 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.

2 Safety notes

A Leica surgical microscope with GLOW800 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 ARveo 8, and in particular the safety notes.
- ► Federal Law restricts this device to sale by or on the order of a licensed medical practitioner.

2.1 Intended purpose

GLOW800 is used in viewing fluorescence of fluorophores with an excitation peak between ~750 nm and ~800 nm and the resulting fluorescence emission observation in a spectral band above ~800 nm.

2.2 Indications for use

The GLOW800 is a Leica surgical microscope accessory used in viewing intra-operative blood flow in the cerebral vascular region and bypass grafts during coronary artery bypass (CABG) surgery, as well as blood flow during plastic and reconstructive surgery.

Contraindications

The medical contraindications applicable to the use of the Leica surgical microscope with GLOW800 in combination with a fluorescence medium are those to be taken into account when using suitable brand substances and state-of-the-art examination techniques.

⚠ **WARNING**

Danger of injury to the eyes.

- ► Do not use GLOW800 in ophthalmology.

2.3 Patient target group

The intended target population are patients undergoing a procedure as defined within the intended purpose.

2.4 Intended user

The GLOW800 is intended for professional use only. The user must have corresponding technical qualification and have been trained in the use of the instrument.

2.5 Dangers of use

WARNING

Risk of infection due to unsterile GLOW800 test card

- ► Do not use the GLOW800 test card in the sterile field.
- ► Use only in non-sterile environment.
- ► Check the microscope illumination in non-sterile environment only.
- ► Take care to ensure the precise parfocal setting of the ARveo 8. Follow the instructions on parfocal setup.

WARNING

Surgeon profile without a programmed fluorescence function

- ► Select the correct surgeon profile.
- ► Perform a pre-operative check.
- ► Check if the microscope illumination lamp is within tolerances (see user manual of ARveo 8).

WARNING

Danger of injury to the patient due to not approved fluorescence media

- ► Only use fluorescence media approved for the planned application, for example Indocyanine Green (ICG).

CAUTION

Danger of injury to the patient due to excessive GLOW800 radiation

GLOW800 mode is disabled automatically after 180 seconds. However, extended and/or excessively frequent use of GLOW800 damages the patient's skin and tissue.

- ► Avoid excessive exposure of the patient to GLOW800 radiation.

CAUTION

Caution to the user.

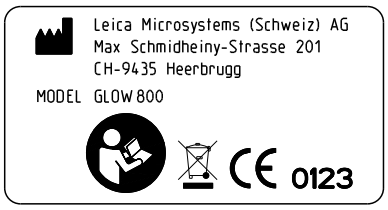
- ► Check the perception of the 3D view prior to surgery. If you do not feel confident with the 3D view, switch to 2D view.

2.6 Information for the person responsible for the instrument

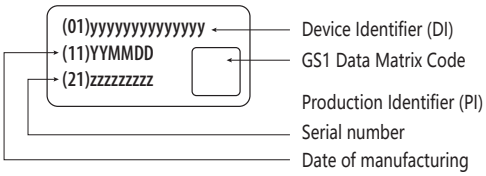
- ► When using GLOW800 please ensure to have a Doppler Ultrasound or similar in place, in case of none or insufficient blood flow visualization out of the ICG/GLOW800 procedure is given.

2.7 Signs and labels

Type label



UDI Label



Mandatory label

Read the user manual carefully before operating the product. Web address for electronic version of the user manual.

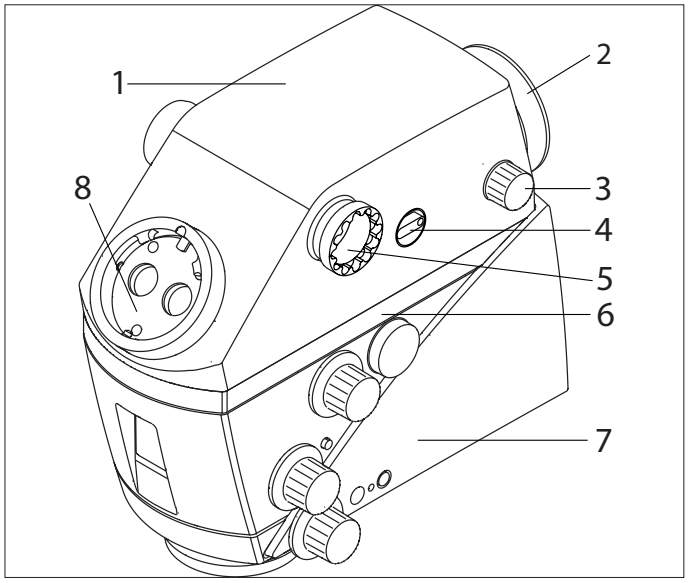
3 Description

3.1 Function

GLOW800 is an optional accessory for ARveo 8 that enables the user to excite and observe Near Infrared (NIR) fluorescence (FL) of the fluorophore (ICG). The filtered NIR fluorescence signal of the fluorophore (ICG) is acquired by NIR sensitive video cameras in the GLOW800 and processed in the microscope computing unit. The NIR light cannot be observed through the surgical microscope, but it is recorded and displayed on the monitor.

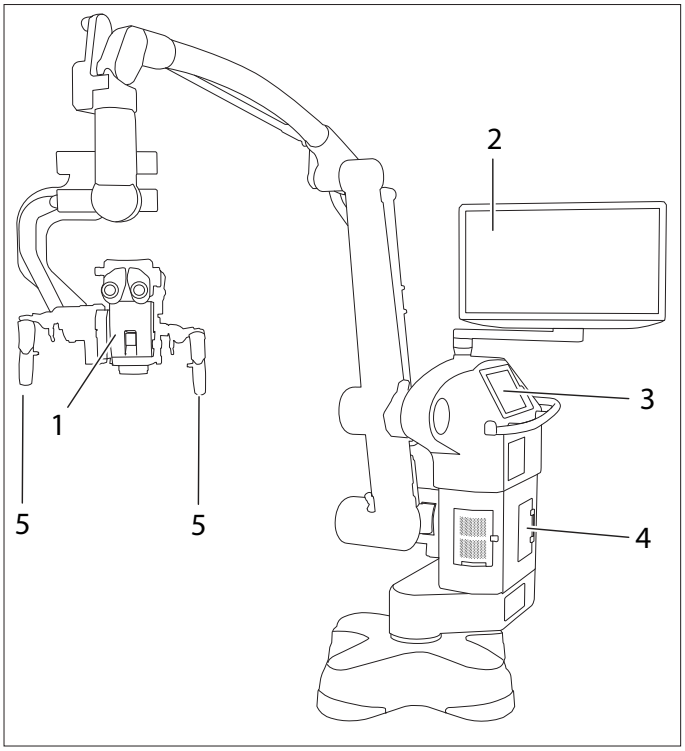
3.2 Design

3.2.1 M530 optics carrier with GLOW800



1 GLOW800
2 Interface for back/opposite assistant, 360° rotatable
3 Back assistant fine focus
4 Switch lateral or back assistant
5 Interface for lateral left and right assistant
6 Fluorescence module (optional)
7 M530 Optics Carrier
8 Interface main surgeon, 360° rotatable

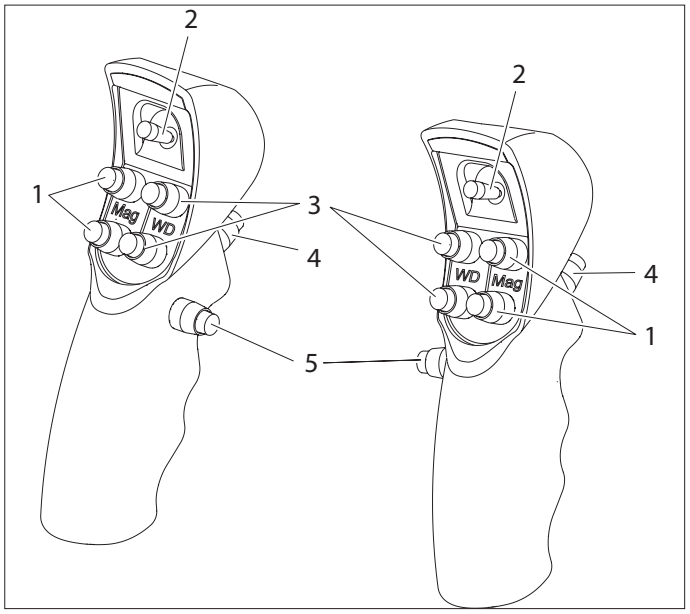
3.2.2 Leica ARveo 8 surgical microscope with GLOW800 components



1 M530 Optics Carrier
2 Video monitor
3 Control unit with touch panel
4 Illumination unit with GLOW800 filters
5 Handles

4 Controls

4.1 Handles

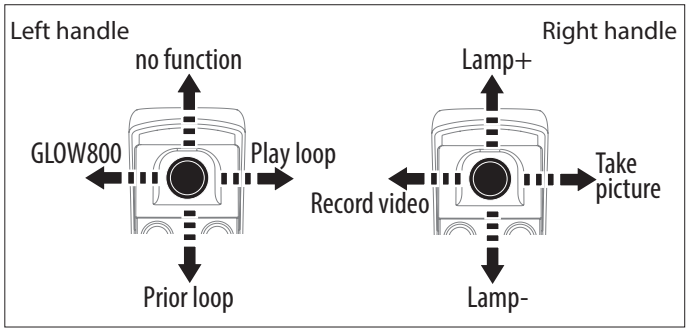


Assignment in the factory setting

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.

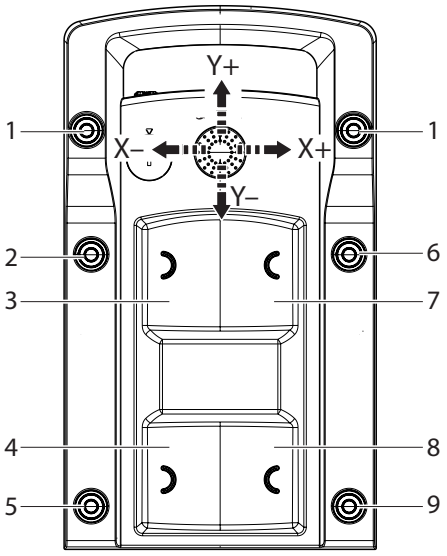
Handle presets for GLOW800



It is recommended to use the 4-function joystick (2) to control the GLOW800 as it is defined in the GLOW800 preset, although you can assign the switches (1), (2), (3) and (5) of the handles individually in the configuration menu to fit the needs of each user.
In all presets, switch (4) releases all brakes. This switch cannot be configured differently.

4.2 Foot switch

Foot switch, 12 functions (Individually assignable)



1 No function
2 Lamp +
3 Working distance –
4 Magnification +
5 not assigned
6 Lamp –
7 Working distance +
8 Magnification –
9 not assigned

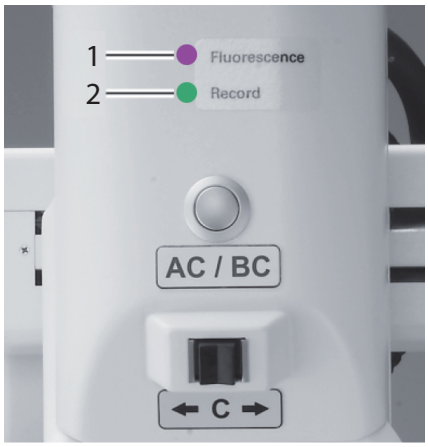
The foot switch can be assigned individually for each user in the configuration menu (see chapter 8.2.6 "Configuring the foot switch", page 24).

For information about how to assign GLOW800 functions to the handles (see chapter 8.2.5 "Example of how to assign the GLOW800 function to a handle button", page 22).

4.3 Status LEDs

The LEDs located on the C-arm of the stand are in the near sight of the surgeon and inform about the fluorescence and recording status of the microscope:

4.3.1 ARveo 8 Status LED



1 Status LED for fluorescence
2 Status LED for recording

The fluorescence status LED (1) indicates the fluorescence activity

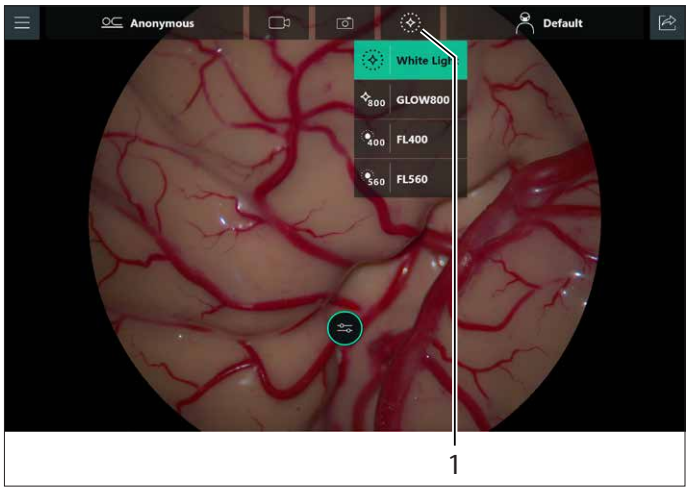
☐	Off:	no fluorescence, white light mode
■	Blue :	FL400 is activated
■	Cyan:	FL560 is activated
■	Magenta:	GLOW800 is activated

The status LED for recording (2) light up in

■	Red:	GLOW800 loop recording in progress
■	Green:	GLOW800 playback mode

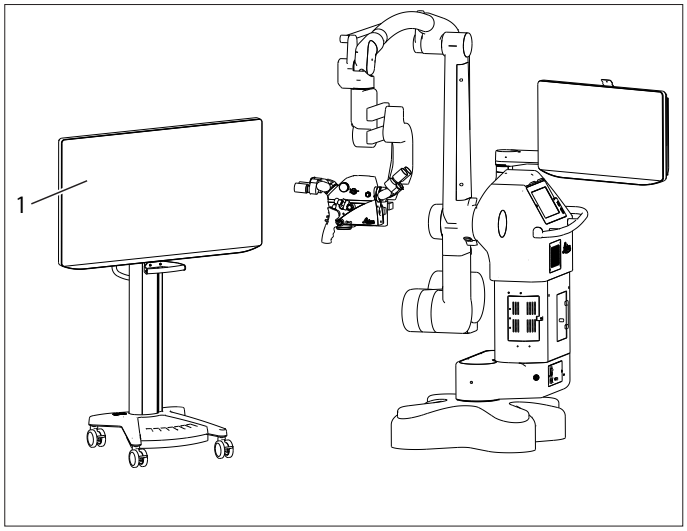
4.4 GUI Activation

In addition to the handle button, GLOW800 can also be activated and deactivated from the touch screen panel. Tapping the mode icon (1) a menu of available fluorescence modes is presented. When tapped, the selected mode becomes immediately active. Tapping "White Light" sets the system back to white light mode.



5 Overview

5.1 2D and 3D view



The optional Heads-up Microsurgery accessory for ARveo 8 Leica surgical microscope system displays the surgical field in 2D or 3D (stereoscopic) on a visualization device.

The technology provides ergonomic advantages as the user can maintain an upright posture while observing the surgical field. The Heads-up Microsurgery accessory contains a cart-mounted monitor which can be flexibly positioned to achieve optimal viewing positions. See user manual of Heads-up Microsurgery for more information.

The external monitor on cart (5) can display a stereoscopic 3D image when used in conjunction with 3D glasses.

The stand monitor (2) can be supplied as 2D or 3D capable only depending on your selected configuration.

The 3D capable monitors automatically switch between 2D and 3D mode when required by the visualization. For further details please refer to the Heads-Up Microsurgery user manual.

3D glasses
With the external 3D Video Monitor on cart and the 3D stand monitor, the below 3D glasses are provided

Leica Microsystems supplied glasses 10747283

Plastic frame glasses
Clip-on goggles

CAUTION

Caution to the user.

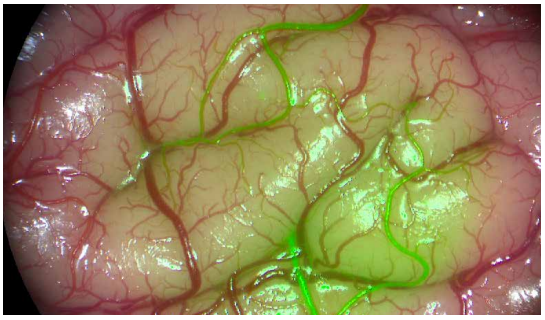
- Check the perception of the 3D view prior to surgery. If you do not feel confident with the 3D view, switch to 2D view.

5.2 Fluorescence observation modes

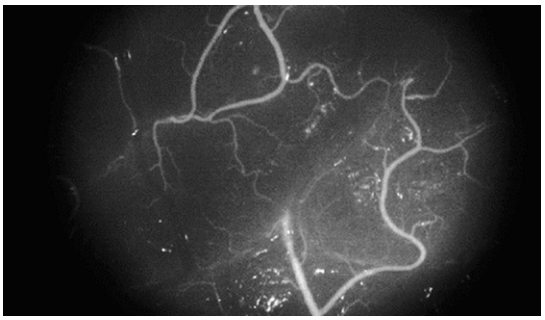
GLOW800 offers two different modes to observe the fluorescence video signal:

5.2.1 Type A: Pseudocolor mode (Pseudocolor ON)

White light object view with the embedded fluorescence signal in pseudocolor, Video #1A

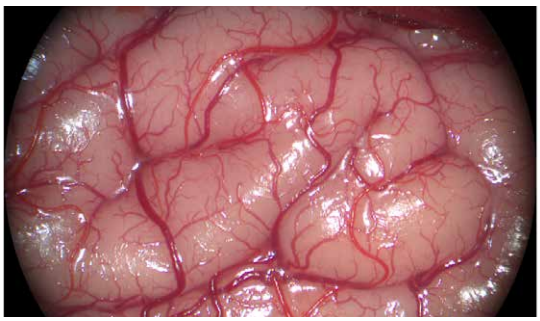


Black&White (monochrome) fluorescence view Video#2A

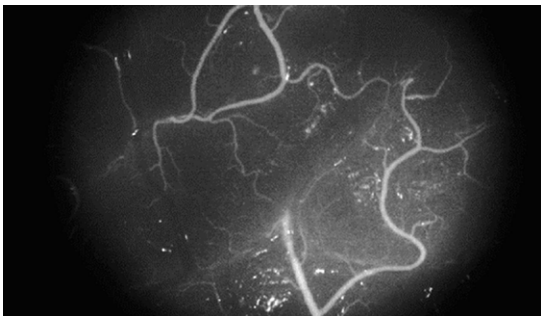


5.2.2 Type B: Black&White (monochrome) Mode (Pseudocolor OFF)

White light object view #1B



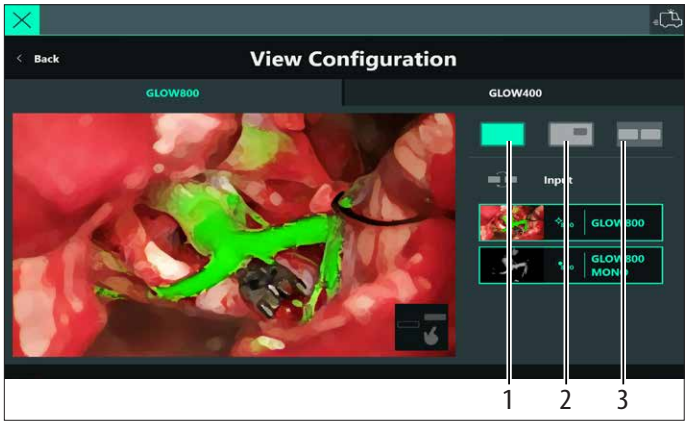
Black&White (monochrome) fluorescence view Video#2B



5.3 Fluorescence display layout

The following visualization settings can be predefined in the "View Configuration" page under the "Surgeon Settings" section. For each of the given view options you can decide where to display the monochrome and/or pseudocolor image on the monitor. You can do this by dragging the desired image and dropping it into the intended display zone.

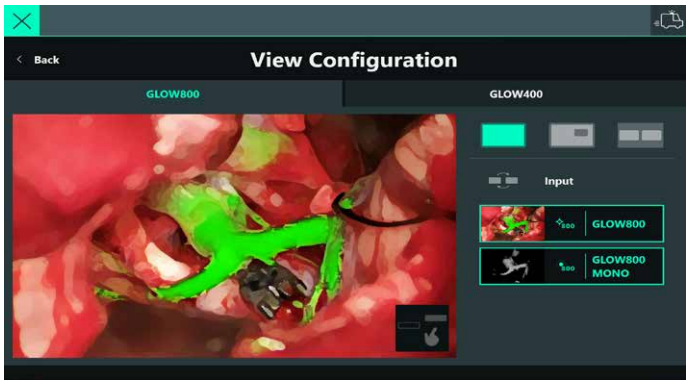
- ► Open the "Surgeon Settings" (see chapter 6 "Modify the GLOW800 settings", page 12).
- ► Tap the "View Configuration" button.
  The "View Configuration" page opens, giving you 3 different options to configure the view on the monitor: Single content (1), Picture-in-Picture (2), Side-by-Side (3).

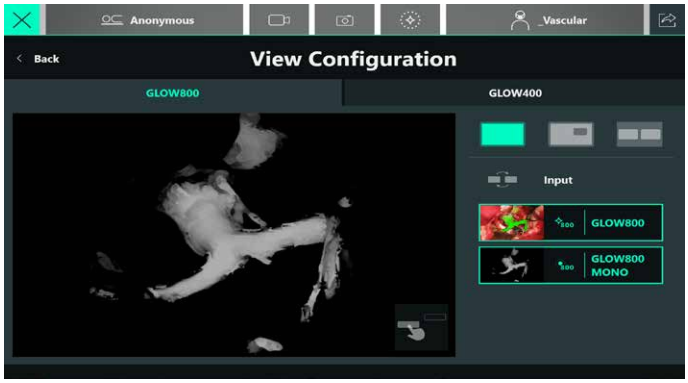


5.3.1 Single content view

Single video view on the monitor. Either the pseudocolor or the monochrome.

- ► Tap the Single content view option (1).
- ► Use the drag and drop feature on the touch panel to configure either the pseudocolor video recording view or the monochrome video recording view on the stand monitor.

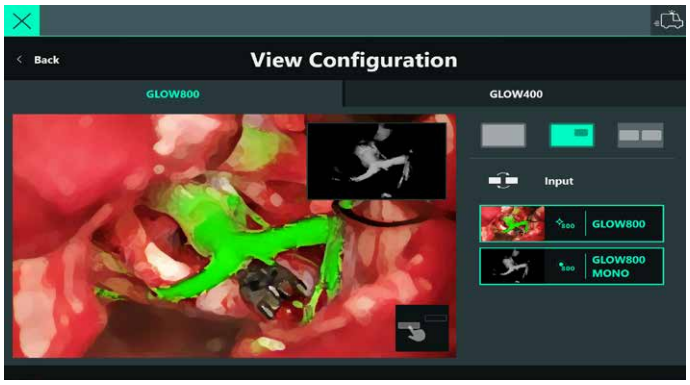




5.3.2 Picture-in-picture

Picture in Picture view of the pseudocolor and the monochrome video on the monitor.

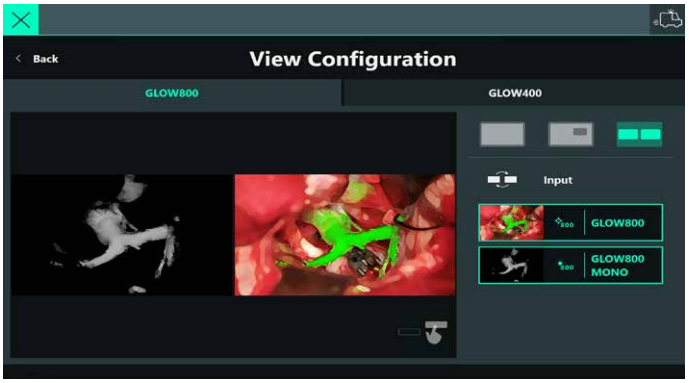
- ► Tap the Picture-in-Picture view option (2).
- ► Use the drag and drop feature on the touch panel to configure either the pseudocolor video recording view or the monochrome video recording view on the stand monitor in larger or smaller portion.

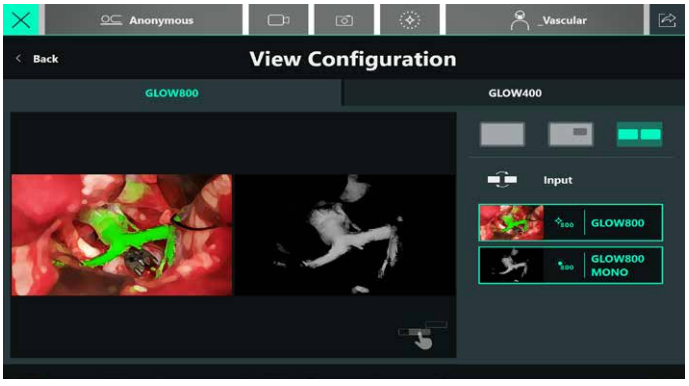


5.3.3 Side-by-side

Side-by-Side view of the pseudocolor and the monochrome video on the monitor.

- ► Tap the Side-by-Side view option (3).
- ► Use the drag and drop feature on the touch panel to configure either the pseudocolor video recording view or the monochrome video recording view on the left or right side of the stand monitor.





The pseudocolor picture on the "View Configuration" page is for illustration purpose only.
Independent if the selected pseudocolor is "GREEN" or "BLUE", the pseudocolor picture on the "View Configuration" will always be displayed in "GREEN", however the monitor will display the user selected pseudocolor.

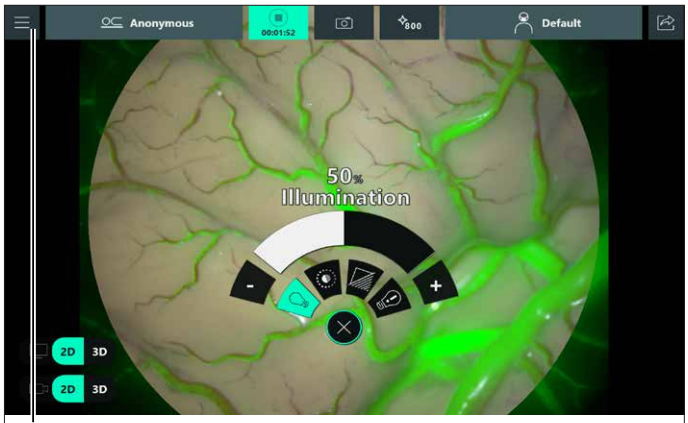
5.3.4 Fluorescence video recording

The GLOW800 video recording generates two videos:

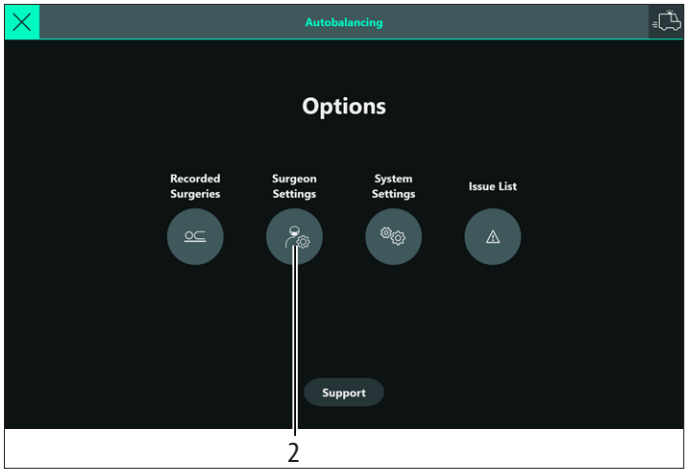
1. The first is always the monochrome video stream.
2. The second stream records what has been defined in the "AR Settings" (see chapter 6.4 "Pseudocolor selection", page 16).
   - if "Pseudocolor" is off
     - White light object video only
   - if "Pseudocolor" is on
     - Combined white light object image with overlaid pseudocolor fluorescence information

If a valid 3D license is installed on the ARveo 8 and 3D recording is activated, the GLOW800 video recording generates 4 videos: a set of 2 videos as described above for each channel (left and right). See the ARveo 8 user manual for further information on 3D recording..

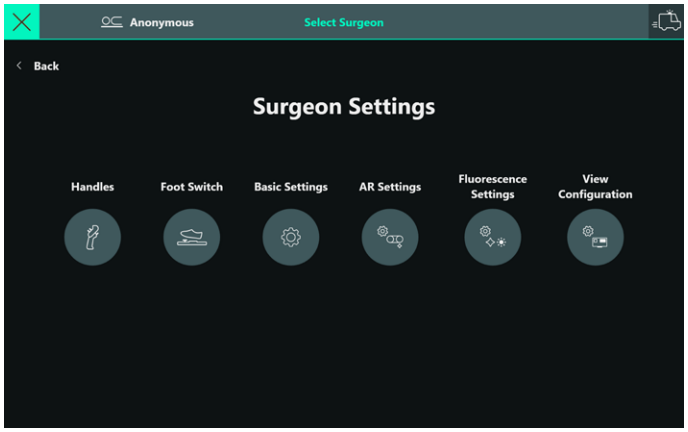
6 Modify the GLOW800 settings



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



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

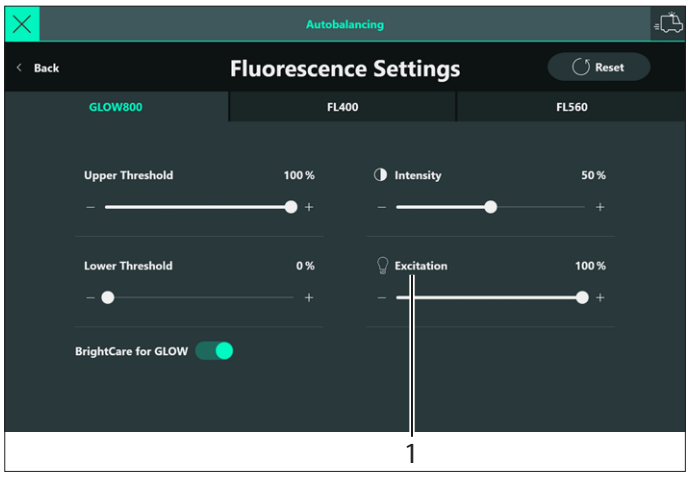


6.1 Fluorescence settings

- ► Open the "Surgeon Settings" page.
- ► Tap the "Fluorescence Settings" icon.
  The "Fluorescence Settings" page is displayed:

6.1.1 GLOW800 Brightness (Excitation intensity)

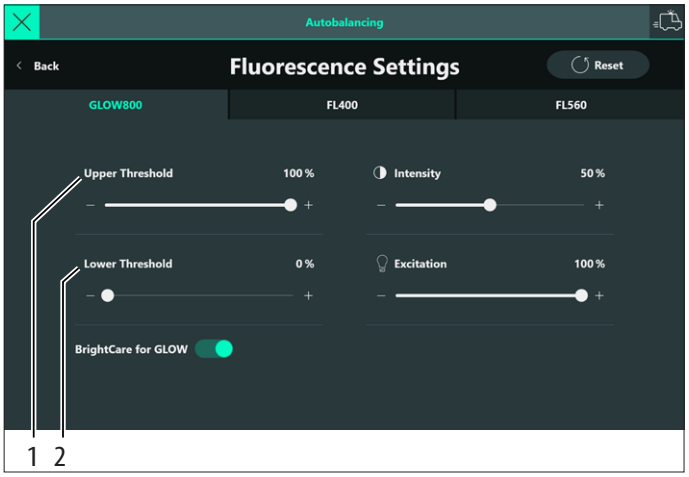
Recommended excitation settings
The default and recommended "Excitation" setting (1) is 100 % to achieve good fluorescence visibility in higher magnifications and working distances.



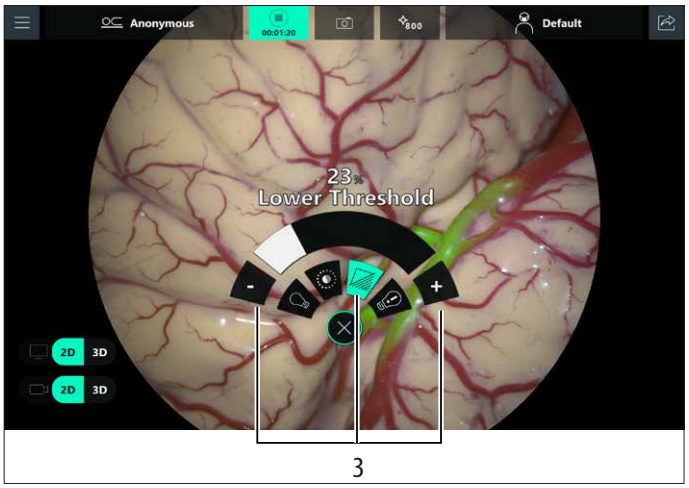
- ► Adapt the "Excitation" setting (1) using the slider.
- ► Press "Back" successively until you return to the "Options" page.
  You may be prompted to save the settings.
- ► Save the settings to the profile or choose to only use them once, after which the changes will be discarded.
- ► Press "X".
  The Live Screen is displayed.

6.1.2 Threshold

With the "Lower Threshold" and the "Upper Threshold", the fluorescence intensity range to be displayed in the white light fluorescence view can be defined. Low intensity signals (i.e. noise) and/or high intensity signals can be filtered out by defining a lower and an upper threshold with the two sliders. The default values for the lower and upper thresholds are 0 % and 100 % respectively, to observe the full range of fluorescence signals.

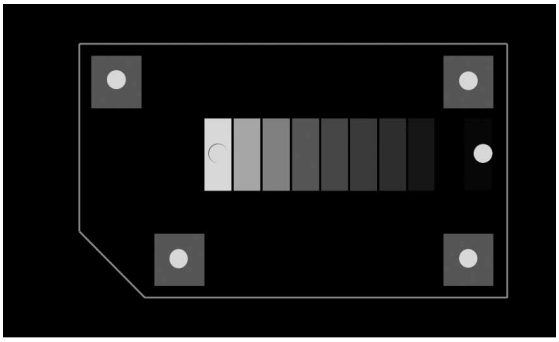
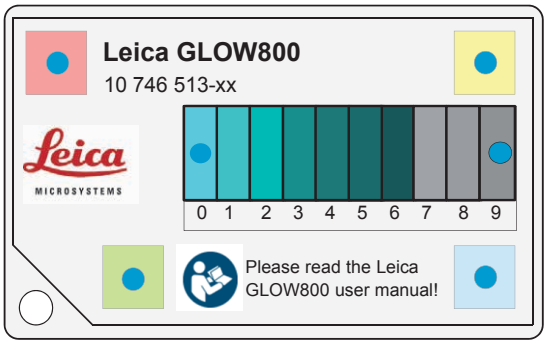
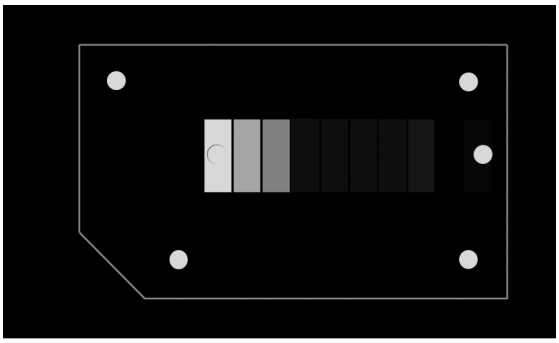
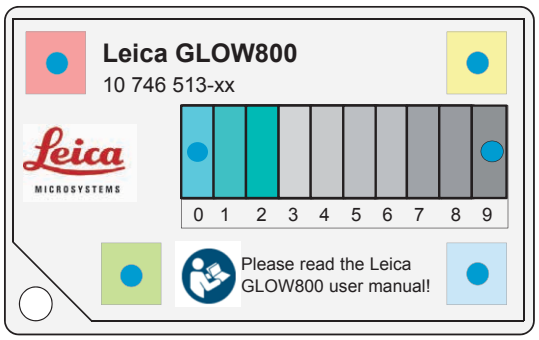
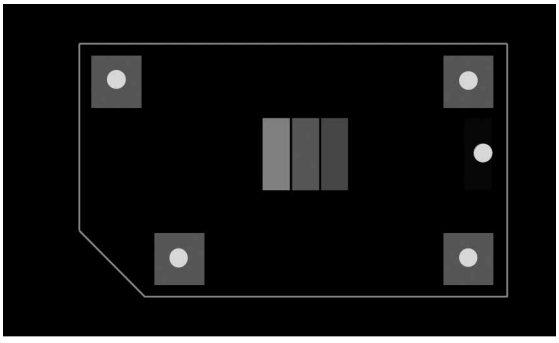
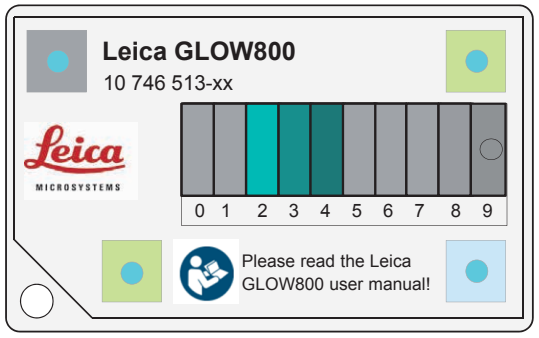


- ► Increase or decrease the "Upper Threshold" (1) and "Lower Threshold" (2) using the slider bars.



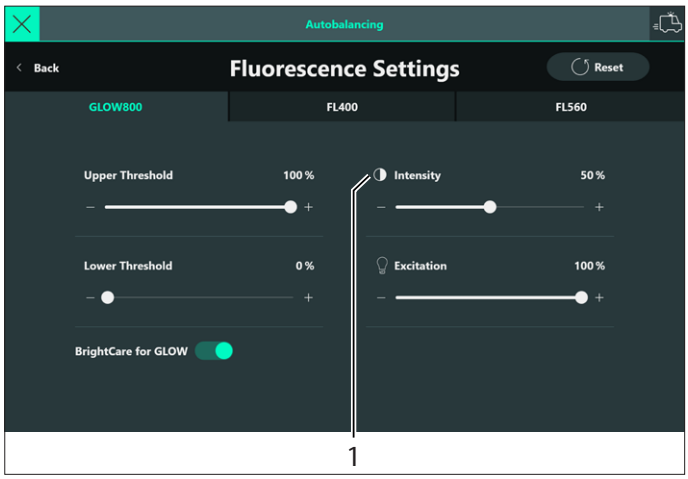
- ► Adjust the "Lower Threshold" values from the live screen using the rotary menu (3).
  There is always a difference of 10 % maintained between the upper and lower threshold values.

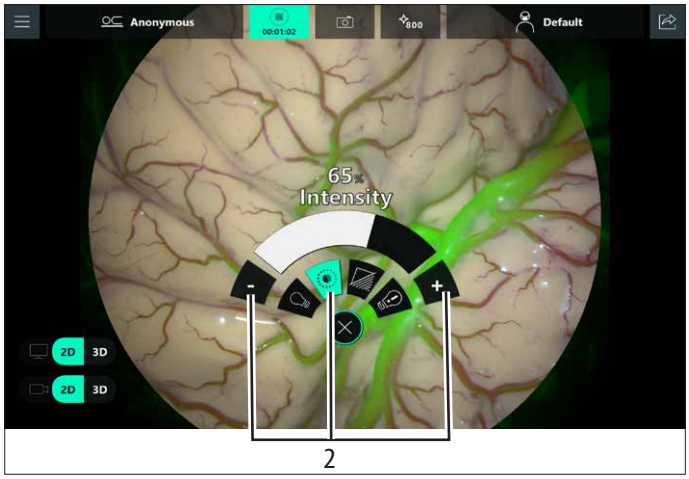
Using the test card demonstrates how the «Threshold» function influences the fluorescence signal.

<table>
<tr><td colspan="2">Lower Threshold at 0 % and upper Threshold at 100 %- all fluorescence intensities are displayed</td></tr>
<tr><td>  </td><td> 
</td></tr>
<tr><td>Black & White fluorescence observation
(Video monitor)</td><td>White light + fluorescence observation
(Video monitor)</td></tr>
<tr><td colspan="2">Lower Threshold at 60 % and upper Threshold at 100 % - middle to high intensity is displayed only</td></tr>
<tr><td>  </td><td> 
</td></tr>
<tr><td>Black & White fluorescence observation
(Video monitor)</td><td>White light + fluorescence observation
(Video monitor)</td></tr>
<tr><td colspan="2">Lower Threshold at 40 % and upper Threshold at 70 % - middle to high intensity is displayed only</td></tr>
<tr><td>  </td><td> 
</td></tr>
<tr><td>Black & White fluorescence observation
(Video monitor)</td><td>White light + fluorescence observation
(Video monitor)</td></tr>
</table>

6.2 Intensity

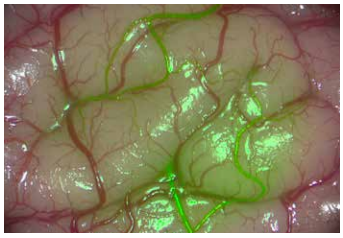
"Intensity" (1) slider bar adjusts the fluorescence contrast, brightness and transparency in relation to the object details. The intensity values range from 0 % to 100 %, default is 50 %. Fluorescence is visible across the full percentage range. For example, at 0 % intensity the fluorescence is only just visible with the white light content being more dominant and at 100 % intensity the fluorescence is much more intense and dominant.



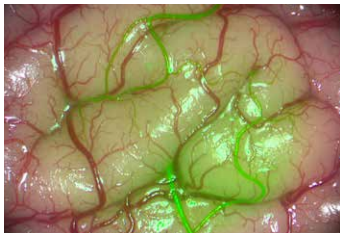


► Adjust the "Intensity" values from the live screen using the rotary menu (2).

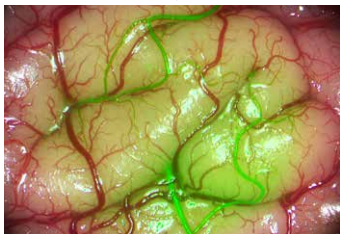
Minimum intensity setting – 0 %



Medium intensity setting – 50 %



Maximum intensity setting – 100 %



6.3 BrightCare

Due to technical reasons, in case of high magnifications at low working distances the fluorescence intensity suffers. The limitation of excitation intensity by BrightCare for GLOW800 can be switched off for better excitation and fluorescence intensity.

CAUTION

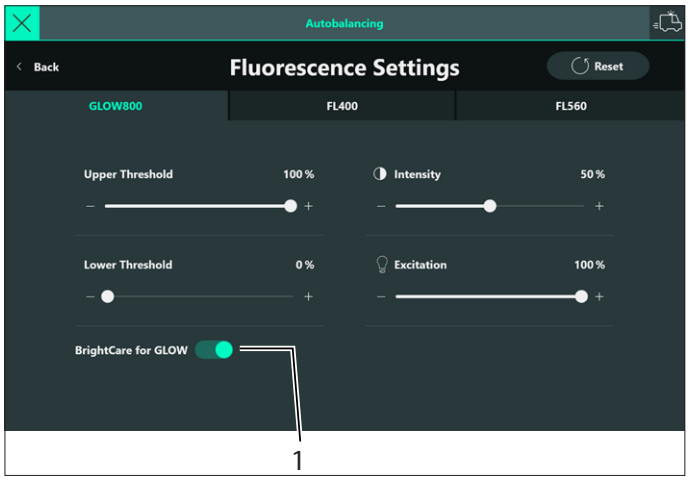
Danger of injury to the patient due to excessive GLOW800 radiation

GLOW800 mode is disabled automatically after 180 seconds. However, extended and/or excessively frequent use of GLOW800 damages the patient's skin and tissue.

► Avoid excessive exposure of the patient to GLOW800 radiation.

► Deactivate BrightCare for GLOW800 (1) in the GLOW800 tab of the "Fluorescence Settings".

If not saved, BrightCare for GLOW800 remains deactivated in the surgeon profile only until the end of the session.



For more information about the BrightCare function, refer to the user manual of ARveo 8.

Fluorescence visibility

The GLOW800 function optimizes automatically the fluorescence visibility to receive the best possible image for a broad working range of microscope parameters and ICG dosage.
However, these parameters still have an impact to the fluorescence visibility as the following description explains for further optimizations.

$$\text{FL Visibility} = \frac{\text{Illumination} \times \text{Dosage}}{\text{Mag}^2 \times \text{WD}^2}$$

FL Visibility:	Fluorescence brightness/perceptibility on the screen
Illumination:	Microscope Excitation intensity
Dosage:	Injected ICG amount in mg/kg
Mag.:	Magnification
WD:	Working Distance

The ICG Dosage is the anesthetist's and/or surgeon's decision.

- Less excitation intensity "Excitation" and/or a lower ICG dosage reduces the fluorescence visibility, especially at high magnification and/or long working distance. Less fluorescence visibility or fluorescence brightness might be observed already at a lower magnification and WDs.
- Higher excitation intensity "Excitation" and/or a higher ICG dosage 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.

There is a default limitation to the WD and Mag when using the GLOW800 mode. If the WD and Mag are above this limit before switching to GLOW800 mode, the WD and Mag will be reduced upon switching to GLOW800 mode and the picture will get out of focus.
In order to bring the picture back into focus, reposition the microscope (meeting the WD limitation value or getting closer than the WD limitation value).
Contact Leica service to adjust WD and Mag limitations.

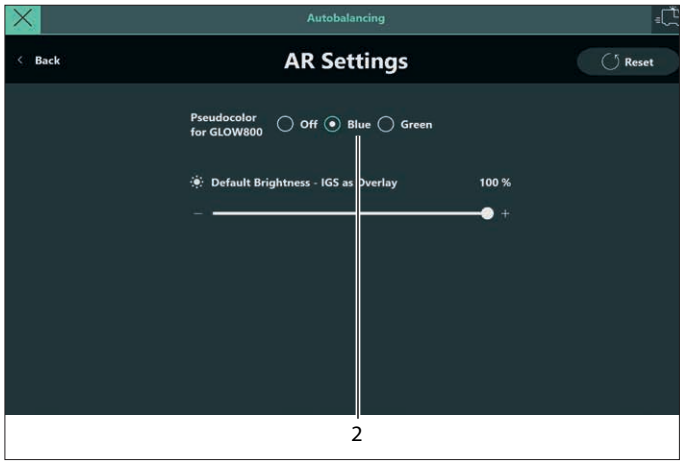
6.4 Pseudocolor selection

► Navigate to the "Surgeon Settings" page (see chapter 6 "Modify the GLOW800 settings", page 12).
► Tap the "AR Settings" icon.
The "AR Settings" page opens:
The pseudocolor can be defined for the monitor view through the "AR Settings" page.

With Pseudocolor set to "GREEN" or "BLUE"

You can choose the "Pseudocolor" to be "Green" (1) or "Blue" (2) for the fluorescence signal on the monitor. The color is indicated on the "AR Settings" page.

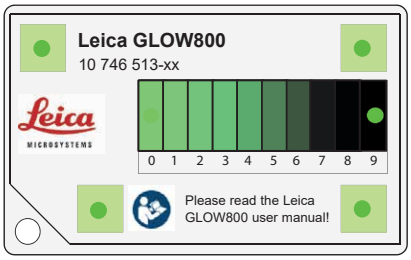
1



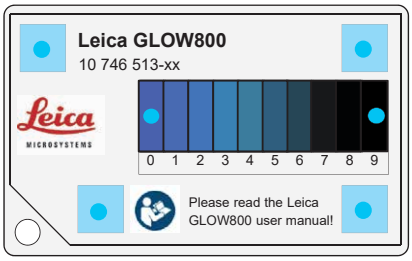
2

When using the test card, the fluorescence pseudocolor results on the monitor image should look as follows:

"GREEN"



"BLUE"



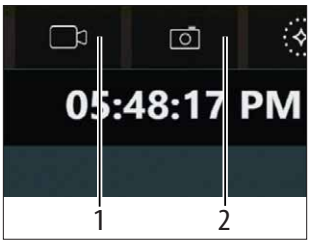
Disabling the "Pseudocolor" will display on the monitor:

- the monochrome fluorescence image in "Single image" mode or
- the monochrome fluorescence image and the digital white light image in Picture-in-picture or Side-by-side mode depending on the settings on the "Viewing Configuration" page (see chapter 5.3 "Fluorescence display layout", page 10).
- Pseudocolor: Color display in GLOW mode.

7 Recording

7.1 Initiate recording / save picture

Activating/deactivating GLOW800 mode (using assigned buttons on handle and/or foot switch) automatically starts/stops the recording. After 3 minutes the mode and recording will be stopped automatically and return to white light mode. Additionally you can take GLOW800 pictures via an assigned handle and/or foot switch button or the camera (2) icon on the touch panel.



Refer to the user manual of ARveo 8 for detailed instructions on how to use the built-in recording system.

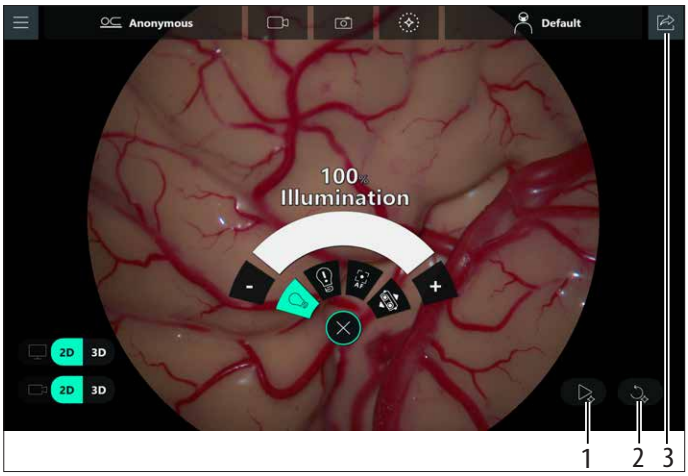
7.2 Playback

7.2.1 Via the handles

- ► Play back the last recorded GLOW800 loop by pressing the assigned "Play Loop" button on the microscope handle.
  The playback is shown on the monitor only, indicated by a yellow frame around the video display.
- ► Stop the playback by pressing the "Play Loop" button again.
- ► Toggle through previous GLOW800 loops within the same session by pressing the assigned "Prior Loop" button on the microscope handle.
- ► Refer to the ARveo 8 user manual for a full list of the assignable functions.

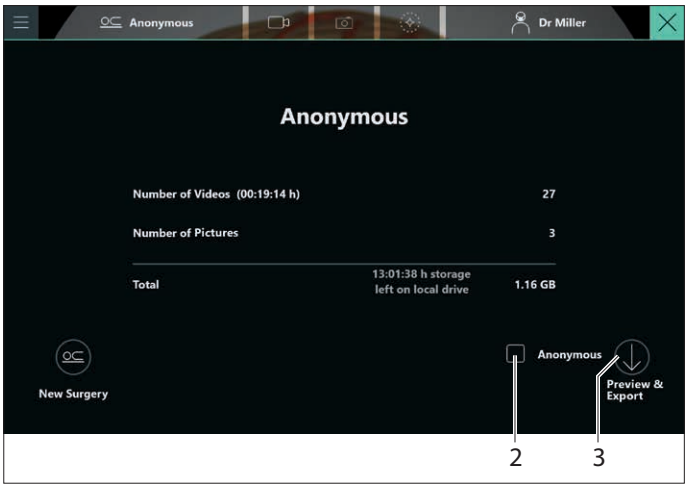
7.2.2 Via the touch panel

In addition, Play Loop (1) and Prior Loop (2) functions can also be activated from the GUI.



- ► Tap the "Data review" icon (3) to list the recordings for viewing and exporting.

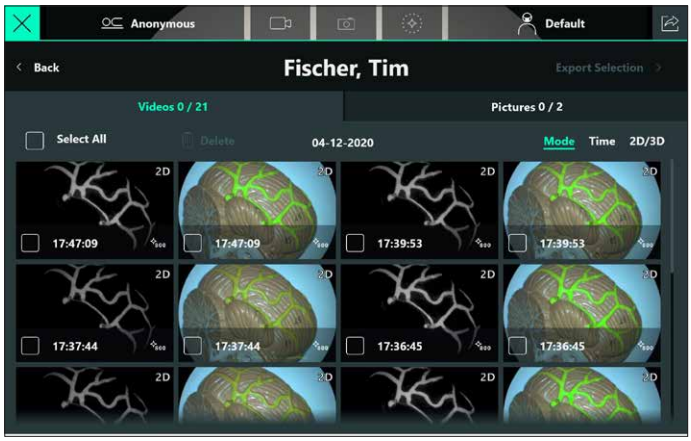
The following menu appears:



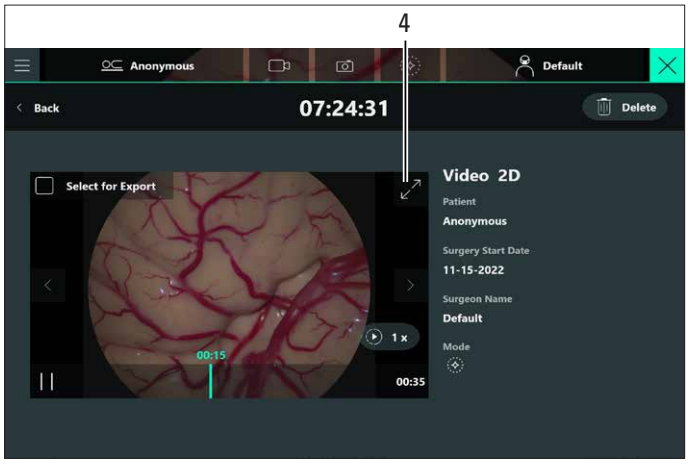
- ► Tap the "Anonymous" check box (2).

If you want to name the current patient, see the respective chapter in the ARveo 8 user manual.

- ► Tap the "Preview & Export" (3) button.
  The list of recordings and saved images is displayed:



► To review any of the videos or the pictures, tap on its thumbnail. This brings up a detailed view of the video or picture on the touch panel.



The video player allows to scroll through the timeline. Tapping the extension icon (4) displays the playback on the monitor and on the touch panel.

8 Preparation before surgery (ARveo 8)

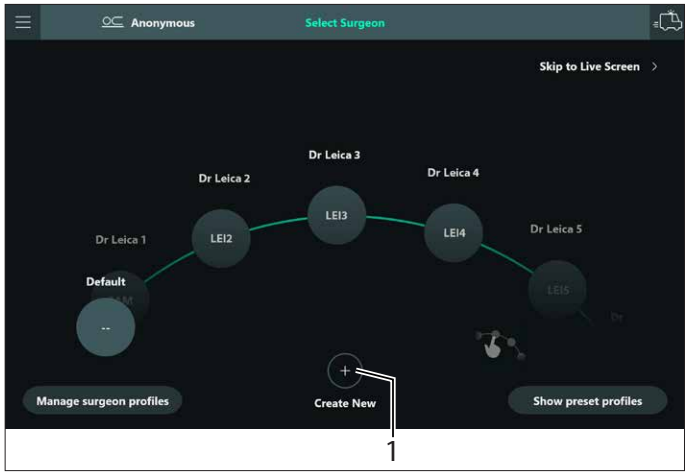
8.1 Selecting a profile with GLOW800 settings

► Select a surgeon profile for which the GLOW800 profile has already been defined at the "Select surgeon" page:
► Create a new surgeon profile if a surgeon profile has not been defined yet.

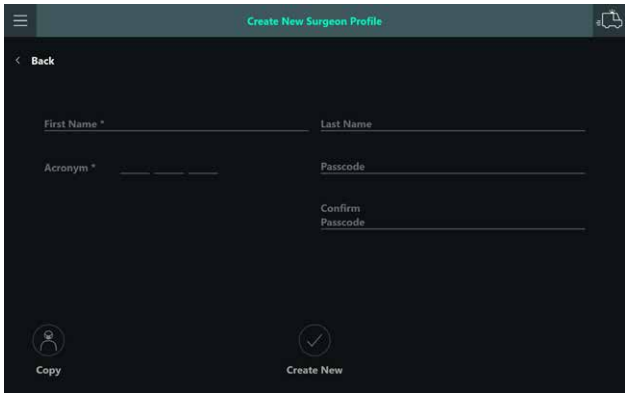
8.2 Creating a new surgeon profile

8.2.1 Register the new profile details

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

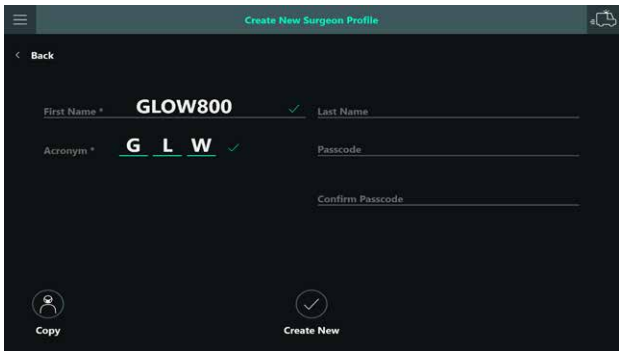


The "Create New Surgeon Profile" page is displayed



► 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.



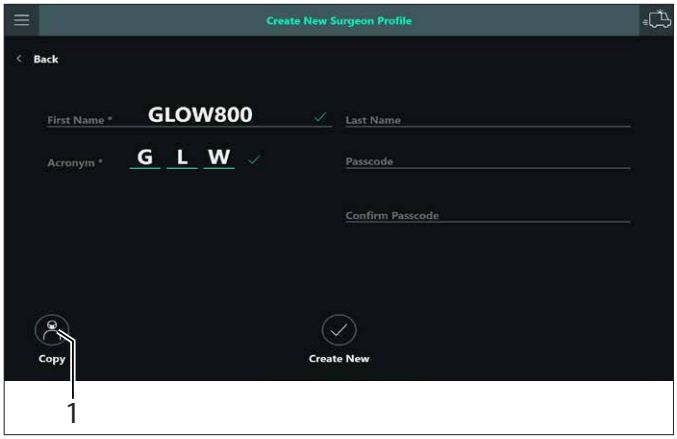
You can either press "Copy" (1) or "Create New" (2) .

- The "Copy" function (see chapter 8.2.2 "Copying settings from the GLOW800 "_Vascular" or "_Vascular+IGS" preset or existing surgeon profile", page 20) 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 chapter 8.2.3 "Creating a new profile", page 21) allows to start from blank list of user input settings which you can configure.

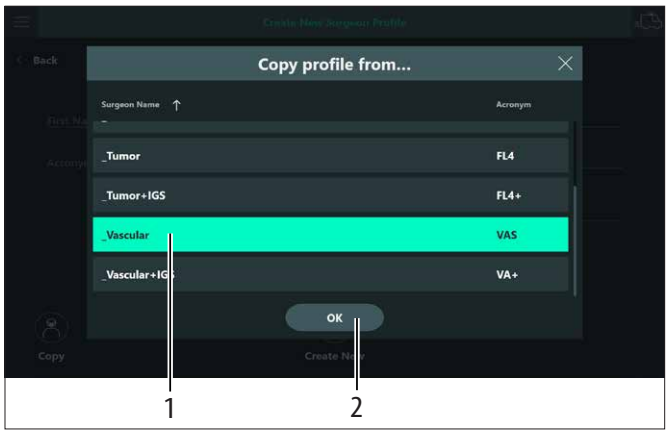
8.2.2 Copying settings from the GLOW800 "_Vascular" or "_Vascular+IGS" preset or existing surgeon profile

This section describes how you can copy existing settings into your newly created surgeon profile using either an existing surgeon profile or the factory GLOW800 "_Vascular" or "_Vascular+IGS" preset.

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



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

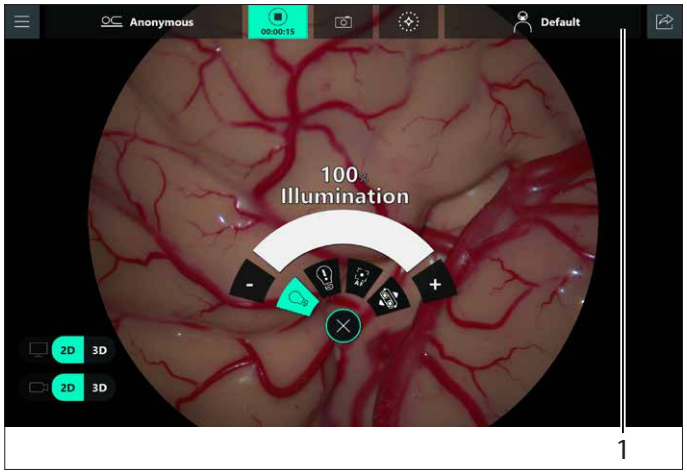


The factory preset profiles are displayed at the top and are generally prefixed with an underscore (i.e. "_Vascular" or "_Vascular+IGS").

You have now 2 options:

Copy the GLOW800 "_Vascular" or "_Vascular+IGS" preset	Copy settings from an existing surgeon profile
► Click on the "_Vascular" or "_Vascular+IGS" profile (1) and confirm with "OK" (2) The dialog box is closed and the selected profile is copied into the surgeon profile and allows for activation of the GLOW800 mode by pushing the joystick of the left handle to towards the left. ► Press the "Create New" button to register the new surgeon profile.	► 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.

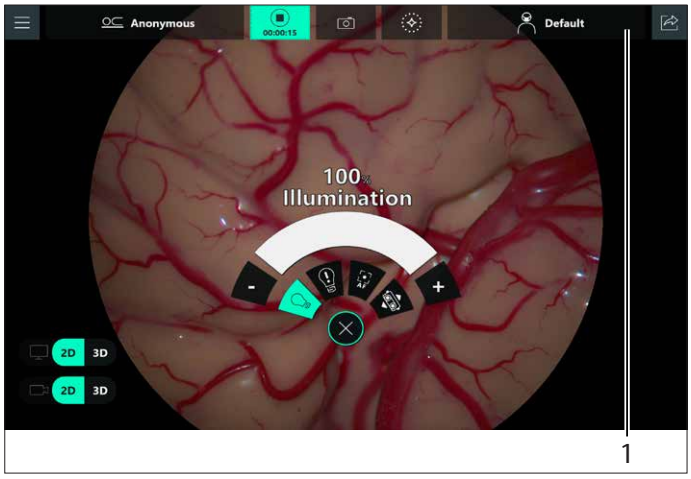
In both cases (copying the "_Vascular" or "_Vascular+IGS" preset or copying an existing surgeon profile), after pressing "Create New", the live screen is displayed. You can see the surgeon profile's name on the top right corner of the screen (1):



► Follow the steps to configure the user input settings (see chapter 8.2.4 "Configuring the user inputs on the handles", page 22).

8.2.3 Creating a new profile

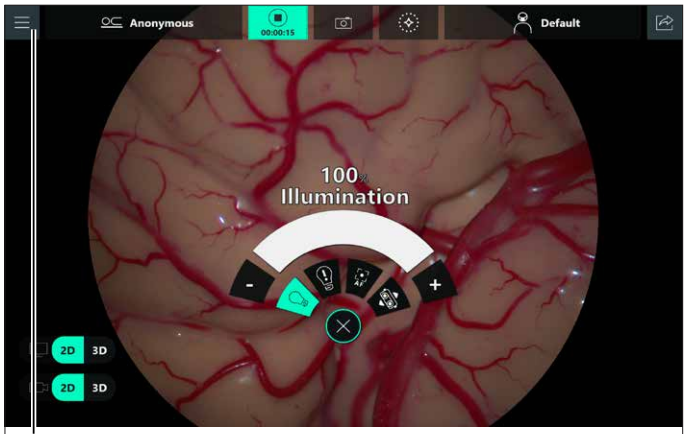
► Create a new profile (see chapter 8.2.1 "Register the new profile details", page 19).
► After having entered the new surgeon data, instead of pressing "Copy", press the "Create New" button in order to register the new profile.
This will register the new surgeon profile with a blank list of settings 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):



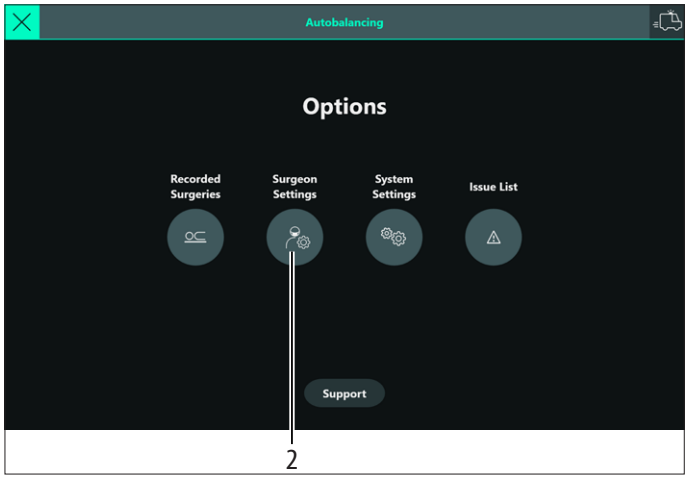
► Follow the steps to configure the user input settings (see chapter 8.2.4 "Configuring the user inputs on the handles", page 22).

8.2.4 Configuring the user inputs on the handles

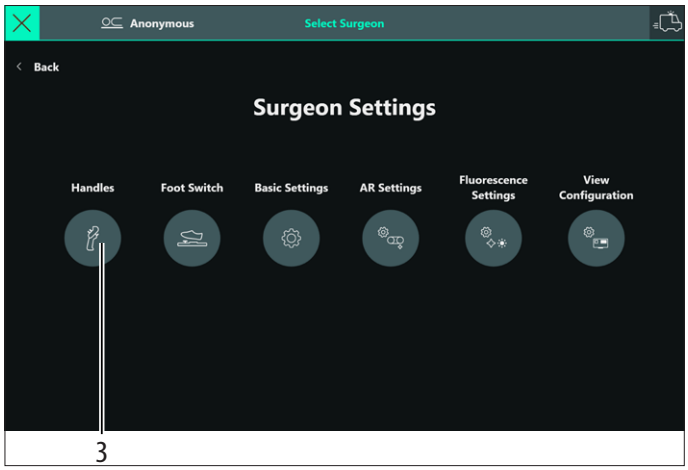
Make sure you are on the live screen for the selected or newly created surgeon profile:



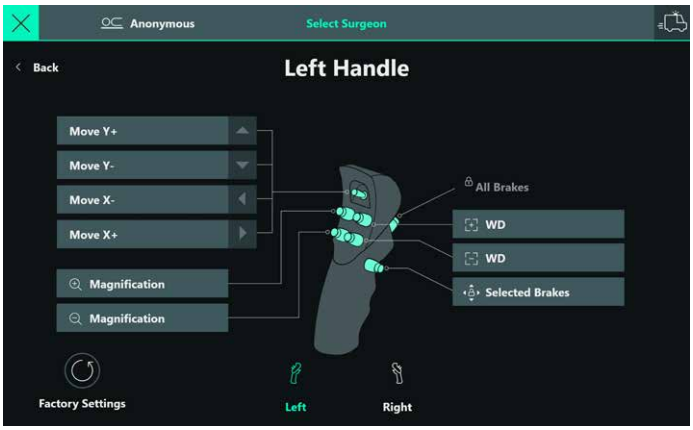
► Press the menu button (1) on the top left-hand corner of the screen to show the list of options.
The options screen is displayed:



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

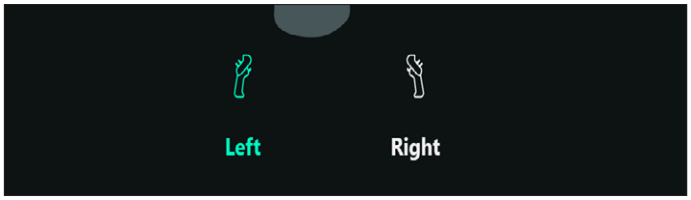


► Tap "Handles" button (3) to show the "Left Handle" settings.
The Left Handle configuration screen is displayed:



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

Note

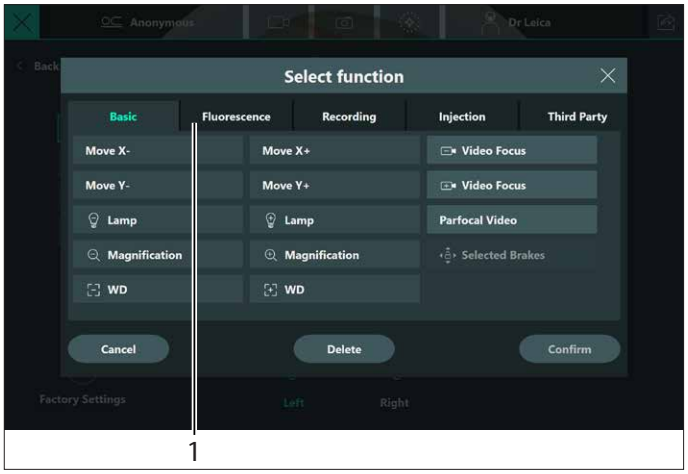


► Select "Right" if you want to configure the right handle.

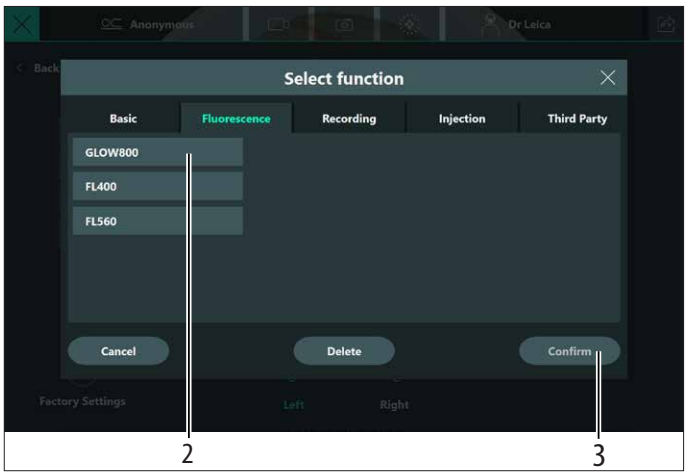
8.2.5 Example of how to assign the GLOW800 function to a handle button

The following example shows how you can assign the GLOW800 function to a button on the left handle. 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 GLOW800 mode.
This will display the "Select function" popup window for the selected button:

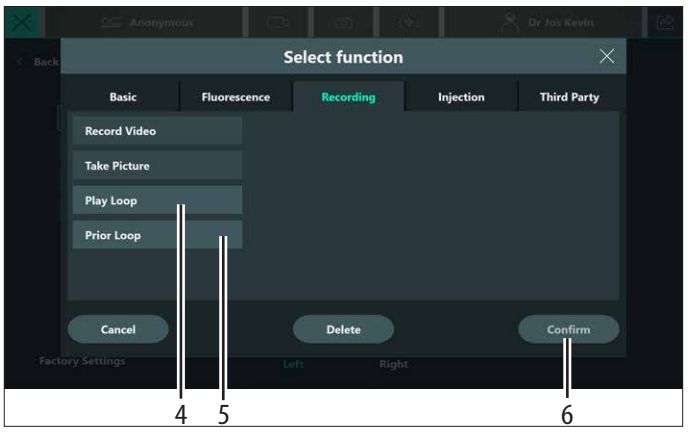


► Select the "Fluorescence" tab (1).
A list of available FL functions will be displayed:

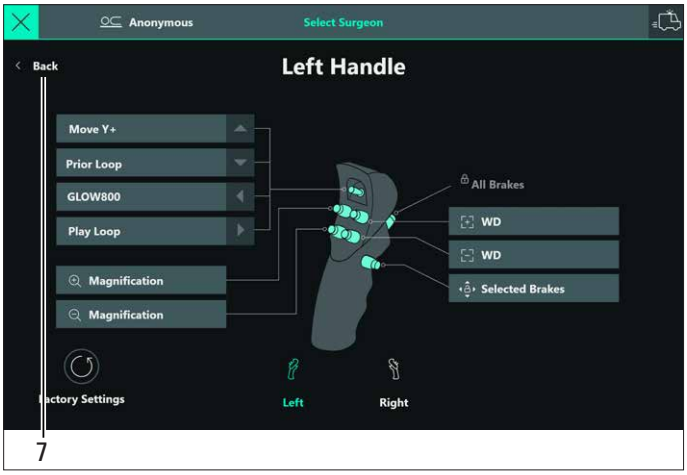


► Select the GLOW800 function (2) and tap "Confirm" (3) to store the settings.

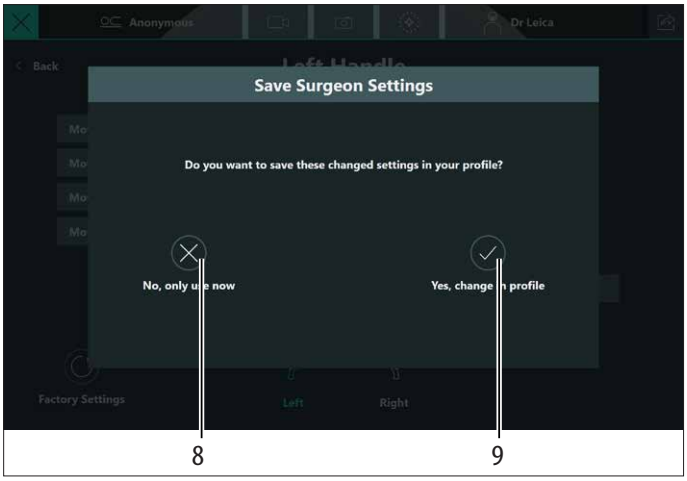
Press "Delete" to go back and "Cancel" if you want to select another function.



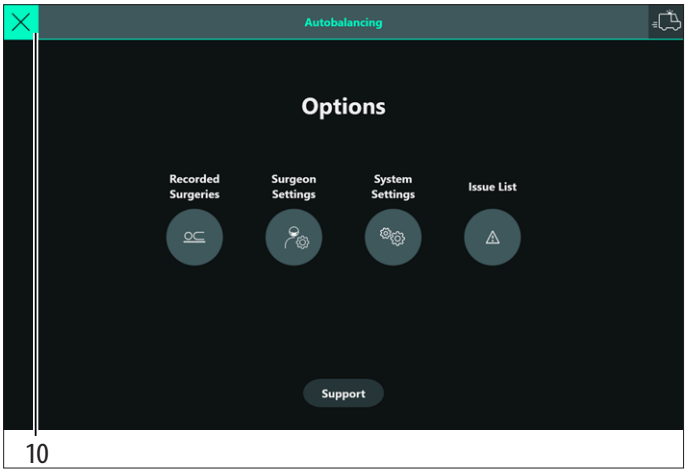
► Select the "Play Loop" (4) and/or "Prior Loop" (5) function and tap "Confirm" (6) to store the settings.
A functional overview of the left handle will be displayed:



► Tap the "Back" button (7) 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" (9). If you do not wish to store the settings, please press "No, only use now" (8).
► Move back in the menu hierarchy by pressing "Back" successively until you return to the "Options" page:

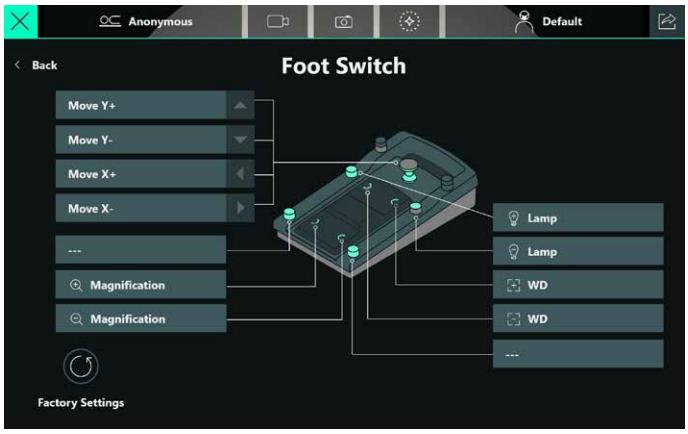


► Press "X" (10) to go back to the live screen.
The live screen is displayed:

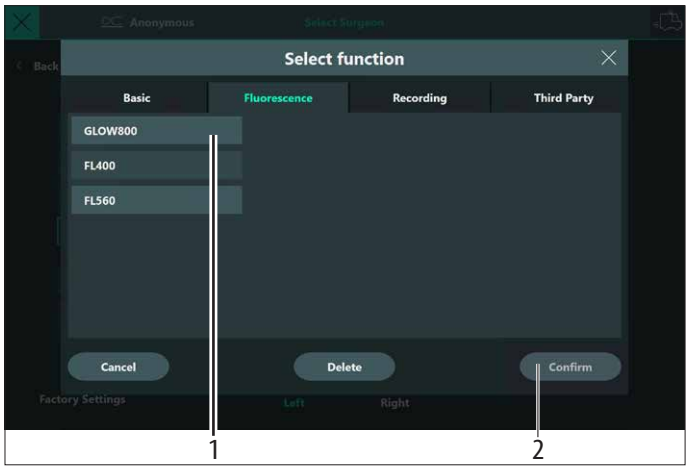
8.2.6 Configuring the foot switch

You can configure the foot switch similarly to the handles.

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

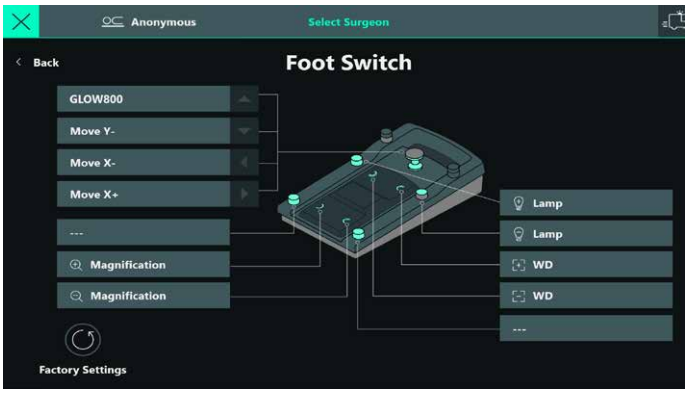


The following selection menu opens:



- ► 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 GLOW800 assignment



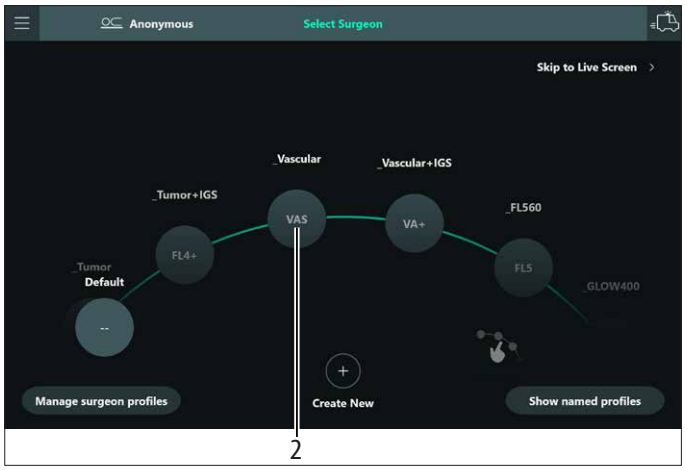
8.2.7 Selecting the GLOW800 Preset

The preset can be used to quickly enable the GLOW800 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 restart, the default profile settings will be restored.

Moving the joystick on the left handle to the left activates or deactivates the GLOW800 mode. This preset can also be used as a starting point when creating a new surgeon profile (see chapter 8.2.2 "Copying settings from the GLOW800 "_Vascular" or "_Vascular+IGS" preset or existing surgeon profile", page 20).

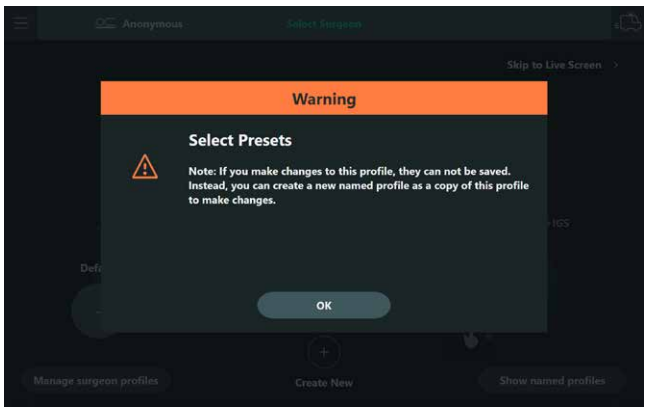
> Since the modifications to this preset cannot be saved, it is highly recommended to create a new surgeon profile for a full workflow.

- ► 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:



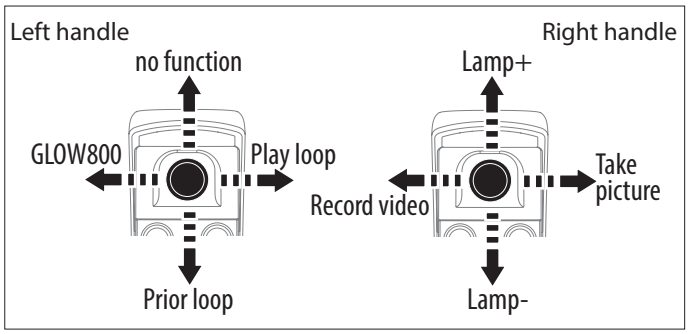
► Select the "_Vascular" or "_Vascular+IGS" preset (2).

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 surgeon profile or add a new surgeon profile to integrate the GLOW800 function in a full workflow.

The following functions are assigned when selecting the GLOW800 preset:



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

9 Check and adjust the illumination and functions

9.1 Pre-operation checklist (GLOW800)

Cleaning optical accessories

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

GLOW800 application

► When using GLOW800 please ensure to have a Doppler Ultrasound or similar device in place, in case of none or insufficient blood flow visualization out of the ICG/GLOW800 procedure is given.

Balancing

► Balance the microscope after refitting (see user manual of ARveo 8).

If you plan to use stereoscopic visualization, ensure that a suitable visualization device is available. Ensure that the specific precautions for stereoscopic visualization are taken care of.

Operational check

► Switch on the microscope.
► Switch on the illumination.
► Check the microscope illumination.
► Test the GLOW800 with the test card.

Sterility

► Apply the sterile drape.

For sterilizable components of the ARveo 8, refer to the corresponding user manual.

9.2 Test card

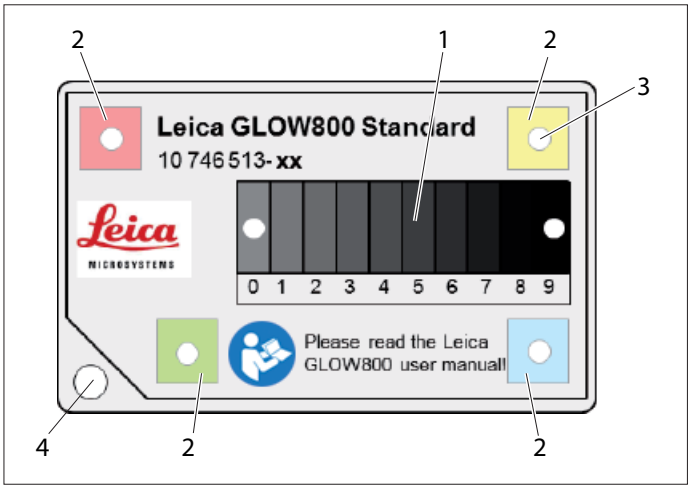
To check and test the GLOW800 function, to verify the proper adjustment of the white light and fluorescence image and to verify the illumination level the GLOW800 test card has to be used.

WARNING

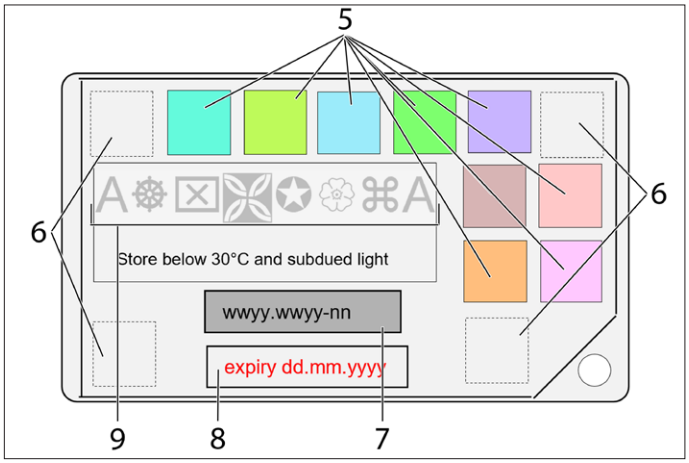
Risk of infection due to unsterile GLOW800 test card

- ► Do not use the GLOW800 test card in the sterile field.
- ► Use only in non-sterile environment.
- ► Check the microscope illumination in non-sterile environment only.
- ► Take care to ensure the precise parfocal setting of the ARveo 8. Follow the instructions on parfocal setup.

Please prepare the test as follows:



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



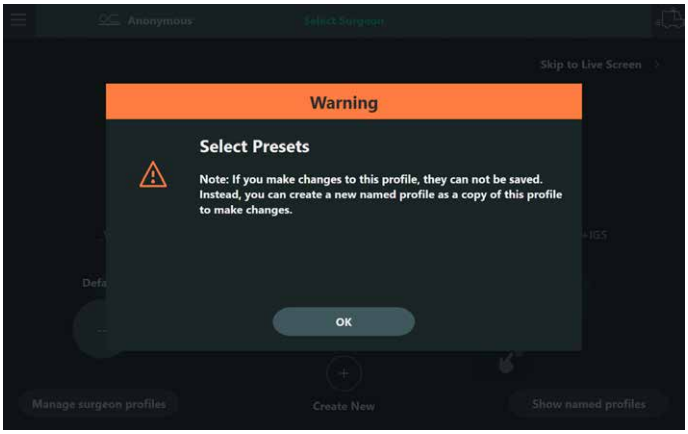
5 Color samples for GLOW800 mode and white light color balancing
6 High intensity fluorescence samples
7 Production lot
8 Expiry date of the test card
9 Symbols visible only in GLOW800 mode

9.3 Preparation

WARNING

Surgeon profile without a programmed fluorescence function

- ► Select the correct surgeon profile.
- ► Perform a pre-operative check.
- ► Check if microscope illumination lamp is within tolerances (see user manual of ARveo 8).



Please prepare the test as follows:

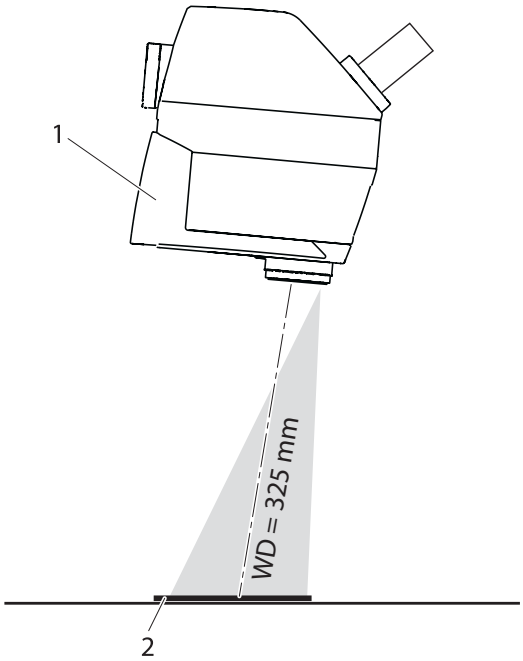
- ► For general tests use the GLOW800 "_Vascular" or "_Vascular+IGS" preset.
- ► Place the GLOW800 test card below the microscope.

WARNING

Risk of infection due to unsterile GLOW800 test card

- ► Do not use the GLOW800 test card in the sterile field.
- ► Use only in non-sterile environment.
- ► Check the microscope illumination in non-sterile environment only.
- ► Take care to ensure the precise parfocal setting of the ARveo 8. Follow the instructions on parfocal setup.

- ► Adjust the working distance (WD) to 325 mm.
- ► Position the microscope in a small but sufficient angle over the test card to avoid reflexes.
- ► Follow the instructions on parfocal setup.
- ► Get in focus by repositioning the microscope at highest magnification (Do not change the working distance setting).
- ► After positioning and focusing adjust the magnification to 3.0×.
- ► Move the test card into the center of the field of view.
- ► Switch to GLOW800 mode by pressing the GLOW800 button on the handle.
- ► Adjust the fluorescence excitation to 50 %.
- ► The GLOW800 test card can now be observed in the eyepiece or in white light fluorescence on the optional monitor.



1 Microscope optics carrier
2 Test card

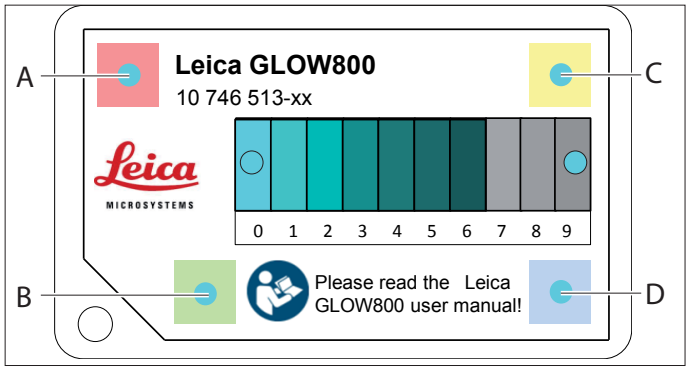
Eyepiece view

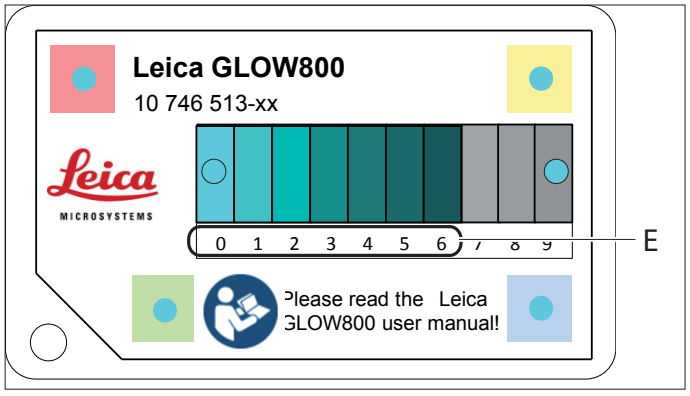
Appearance of the test card in white light observation:
Holes in the color squares will allow to check the adjustment of the fluorescence and white light image.

9.4 Test card functional areas

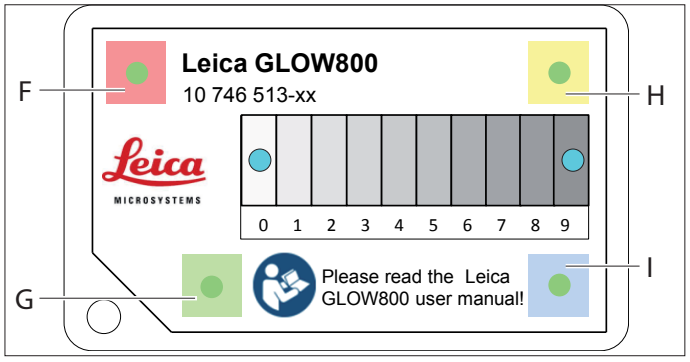
Tests in white light fluorescence observation mode

- ► Check for the proper adjustment of the fluorescence image with the white light image.
  All bright fluorescence dots have to fit precisely into the holes of the color squares (A–D).



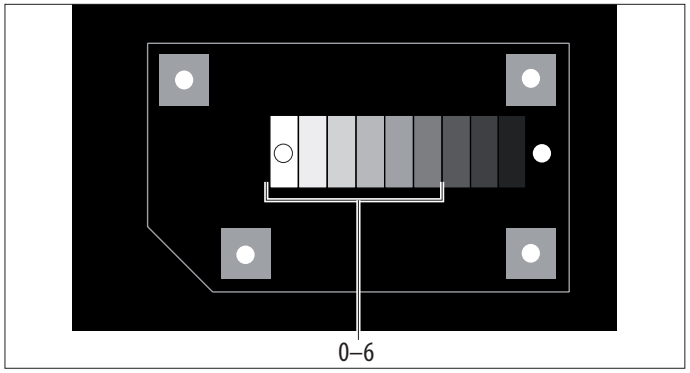


- ▶ Check the fluorescence intensity (A–D):
- At the required WD = 325 mm
- Magnification = 3.0×
- Excitation GLOW800 = 50 %
  In GLOW800 fluorescence mode at least the fluorescence bars 0–6 have to be visible (E).
- ▶ Check if the fluorescence pseudocolor is the one you intend to have.



- ▶ Check the colors (F–I) of the white light image in white light mode.
  The soft colors of the 4 color squares red, yellow, green and blue should be displayed in same color on the video monitor.

Tests in Black & White fluorescence observation mode



- ▶ Check the fluorescence intensity.
- At the required WD = 325 mm
- Magnification = 3.0×
- Excitation = 50 % in GLOW800 fluorescence mode
  At least the fluorescence bars 0–6 have to be visible.
- ▶ If there are less bars visible check if:
- The card is not expired
- The threshold is set to 0 % (lower) to 100 % (upper).
- The illumination systems performs as expected:
  - Bulb hours are within the range
  - Light guide is in proper condition
- ▶ Contact the Leica service for further assistance.

10 Operation

WARNING

Danger of injury to the patient due to not approved fluorescence media

- ▶ Only use fluorescence media approved for the planned application, for example Indocyanine Green (ICG).

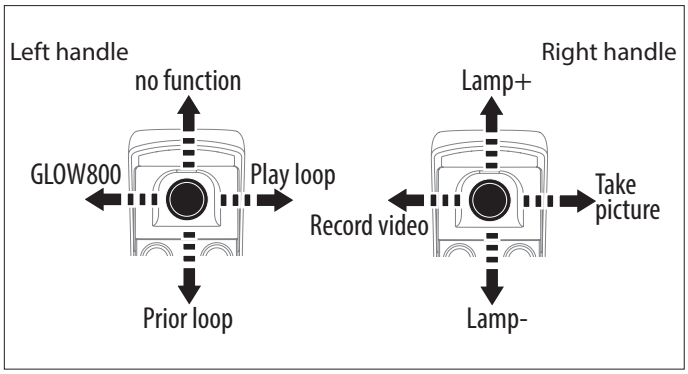
When using GLOW800 please ensure to have a Doppler Ultrasound or similar in place, in case of none or insufficient blood flow visualization out of the ICG/GLOW800 procedure is given.

10.1 Using the GLOW800

- ▶ Switch on the illumination of the ARveo 8.
- ▶ Select a surgeon profile: Select either the "_Vascular" or "_Vascular+IGS" preset or an own GLOW800 surgeon profile.

10.2 Controlling the GLOW800 functions

Controlling the GLOW800 functions, e.g., on the microscope's left handle



GLOW800
The handle permits switching between white light mode and GLOW800 mode.

- ▶ Press the joystick to the left to switch between the modes.

CAUTION

Danger of injury to the patient due to excessive GLOW800 radiation

GLOW800 mode is disabled automatically after 180 seconds. However, extended and/or excessively frequent use of GLOW800 damages the patient's skin and tissue.

► Avoid excessive exposure of the patient to GLOW800 radiation.

GLOW800 mode is disabled automatically no later than after 180 seconds to prevent excessive exposure of the patient to GLOW800 radiation.

Play loop

► Pressing the joystick to the right starts the replay of the last recorded loop on the recording unit.

Prior loop

► By repeatedly pressing the joystick downward, you can switch back to previously recorded GLOW800 loops.

11 Care and maintenance

GLOW800 is an accessory for ARveo 8. For care and maintenance, refer to the user manual of ARveo 8.

12 Disposal

The respective applicable national laws must be observed for disposal of the products, with the involvement of corresponding disposal companies. The unit packaging is to be recycled.

13 What to do if...?

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?
- Are all video cables attached correctly?

For malfunctions regarding the ARveo 8, refer to the corresponding user manual.

13.1 Calibration

Observation	Cause	Remedy
The GLOW800 fluorescence image is incorrectly aligned to the White Light image	The setting to fit both images are incorrect	▶ The settings have to be adapted to fit both images. ▶ Contact Leica Service.

13.2 Control Unit

Observation	Cause	Remedy
Incorrect information is shown for interpretation to the user	Device algorithm calibration failure	▶ Reboot the system.
	Improper pre-operational check	▶ Repeat pre-operational procedure. ▶ Contact Leica Service.
The system is not booting up	Electronic failure	▶ Contact Leica Service.
An error message "connection to camera lost" appears	Camera signal lost	▶ Reboot the system. ▶ Contact Leica Service.
The system is frozen/no reaction	Software initialization failure	▶ Reboot the system.

13.3 Limitation

Observation	Cause	Remedy
In high magnification the GLOW800 fluorescence is out of focus, although the White Light image is sharp	In high magnification the NIR focus can differ from the WL focus	▶ Reduce the magnification until you receive a sharp GLOW800 image
Some parts of the fluorescence image are sharp (region of interest), others are out of focus	The out of focus fluorescence does not cover the object, the fluorescence floats above the object	Even when the ROI is in focus, other fluorescent areas might be not and can produce disturbing, floating fluorescence. If not all fluorescent areas can be in focus, there is no way to avoid this effect.

Observation	Cause	Remedy
The flow signal is low/dark, invisible or noisy	The fluorescence signal is very low due to high magnification and/or the working distance	▶ Make sure the GLOW800 Illumination/ excitation is set to 100 %, reduce the magnification and/or increase the ICG dose if possible. With an ICG dosage of 12.5 mg/75 kg the GLOW800 will generate fluorescence images with good visibility even at higher magnifications or working distances.
	The illumination bulb efficiency is low and needs replacement or the illumination system is out of specification (low light transmission by the fiber light guide or illumination beam path)	▶ Check the illumination bulb lifetime and the illumination system. ▶ Call the Leica Service for professional investigation when needed.

13.4 Corrections by the user

Observation	Cause	Remedy
Neither a sharp GLOW800 nor a sharp White Light image on the monitor	The diopter settings of the surgeon's eyepiece are incorrect and you work off parfocality	▶ Adjust the WD to receive a sharp video image and adjust the diopters correctly.
The flow signal is overexposed	Fine vessels and perfusion show up too bright. Possibly the ICG concentration of the bolus is too high	▶ Reduce the ICG dosage to 12.5 mg/75 kg and/ or reduce GLOW Brightness (Illumination/ Excitation intensity) down to 50 %.
The flow signal is oversaturated or too dominant	There is no more transparency in the signal and the signal seems to be flat. The GLOW "intensity" is possibly too high	▶ Reduce the GLOW "Intensity" to the normal value of 50 % or less.
The flow signal is low	The fluorescence is faint, the flow in fine vessels is not indicated. The ICG concentration might be too low	▶ If possible increase the ICG dosage.
The flow signal is too pale	The GLOW "Intensity" is too low	▶ Increase the GLOW "Intensity", standard is 50 %.
The GLOW800 image is not bright enough	In lower WDs and high magnification BrightCare will reduce the illumination/excitation for GLOW800.	▶ Deactivate BrightCare Plus for GLOW800 to get maximum excitation intensity.
The GLOW800 image displays high intensive fluorescence only. Low intensity fluorescence and flow signal in fine vessels are missing	The lower threshold level is set too high	▶ Reduce the lower threshold level to ≤8 % to display the full range of fluorescence intensity.
Low fluorescence covers huge portions of the image	External NIR radiation is detected and displayed	▶ Switch the external light source off, which produces NIR radiation in the GLOW800 detected spectral range and/or increase the lower threshold to 8 %.
	A fluorescence signal is reflected by surrounding tissue	▶ Increase the lower threshold to 8 %–12 %.
	Remaining ICG shows low fluorescence	▶ Increase the lower threshold to 8 %–12 %.

13.5 Malfunction

Observation	Cause	Remedy
No GLOW image is displayed	GLOW800 mode is not active	▶ Check that the fluorescence LED and the control unit display the GLOW800 mode. ▶ Check whether the GLOW800 function is assigned to the intended button and handle. ▶ Use test card for proper testing. ▶ Call the Leica service if the issue persists.
No sharp GLOW800 image on the monitor in low magnification, but the White Light image is sharp, even in low magnifications	The fluorescence focal plane is misaligned.	▶ Contact Leica Service.
Disturbing fluorescence signals especially at the outer field of view	Ambient NIR light >800 nm is detected by the GLOW camera in outer FoV whereas the focus point is seated lower	▶ Switch the external light source off, which produces NIR radiation in the GLOW800 detected spectral range.
	The GLOW illumination touches the cavity border line and produces disturbing fluorescence artefacts	▶ Close the illumination iris to avoid the illumination of non-interesting areas.
GLOW fluorescence video image is imbued over the full field of view	Ambient NIR light of an OR light source or OR room illumination reaches the object field and is detected by the fluorescence camera over the whole FoV	▶ Switch external NIR light source off. ▶ For detection of this light source in the OR switch the microscope illumination off and focus the microscope in GLOW mode on a white paper. ▶ As long the false signal is present the ambient NIR light is active. Switch the OR light sources off one after the other until the issue is gone.
The flow signal appears dark on the visualization device.	A viewing position below and/or laterally off the visualization device axis get the observed image darker.	▶ Align the visualization device axis to fit your observation direction.

13.6 In-built recording

Observation	Cause	Remedy
No GLOW fluorescence image on the monitor although it worked before	No more disk space on the ARveo 8 recording unit.	▶ Check the capacity of the ARveo 8 recording unit: ▶ If the ARveo 8 recording unit disk space is full, save and delete unused user data to generate sufficient capacity.

14 Technical data

14.1 Technical data GLOW800

Fluorescence excitation	790 nm (GLOW800)
Fluorescence signal	835 nm (GLOW800)

GLOW800 spectrums

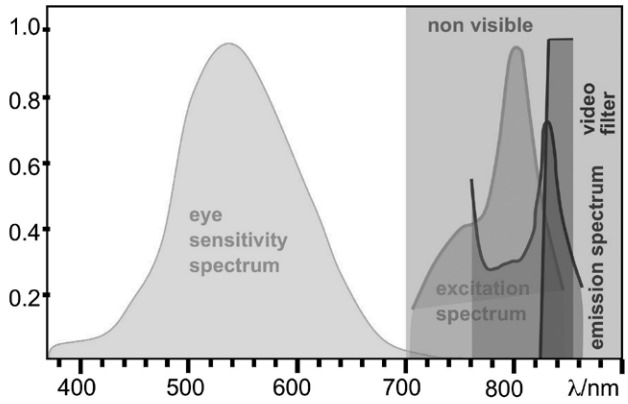
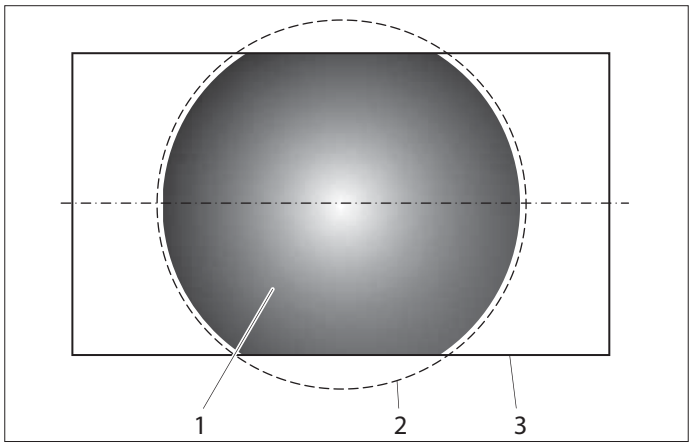


Image sensor	4× 1/1.2" inch
NIR camera	High sensitive, HD color camera

For technical data related to the ARveo 8, refer to the corresponding user manual.

Camera image size with respect to the field of view



1 Camera image size
2 Field of view
3 Screen size

The figure shows the camera image size with respect to the field of view for the visual video camera and the GLOW800 NIR camera. Please be aware that the field of view is not fully covered by the documentation system.

14.2 Compatibility

Leica surgical microscopes	ARveo 8 (10449157)

14.3 Ambient conditions

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

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

15 Manufacturer's declaration of electromagnetic compatibility (EMC)

The GLOW800 was tested in combination with ARveo 8. For the EMC declaration, refer to the corresponding user manual.

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

T +41 71 726 3333

www.leica-microsystems.com

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