From Eye to Insight

Leica
MICROSYSTEMS

MEDICAL DIVISION

GLOW800

User Manual

10 747 243 - Version 03

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.

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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.

Contents

1 Introduction

1.1 About this user manual

The GLOW800 is an accessory for Leica surgical microscopes.
In this user manual the functions of the GLOW800 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.

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 the Leica surgical microscope, 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 use

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

Contraindication

- 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.

2.2 Dangers of use

⚠ **WARNING**

Risk of infection due to insterile 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 Leica surgical microscope. Follow the instructions on parfocal setup.

⚠ **WARNING**

User selected with a programmed fluorescence function.

► Correct user is activated.
► Preparational check is performed.
► Microscope illumination lamp is within tolerances (see user manual of the Leica surgical microscope).

WARNING

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

- ► Only use fluorescence media approved for the planned application.

WARNING

Danger of injury to the patient due to excessive GLOW800 radiation.

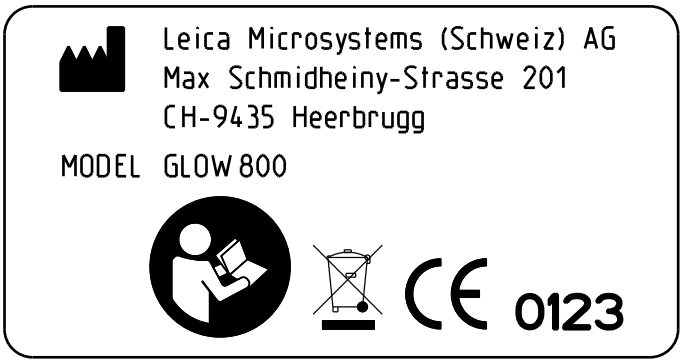
- ► Avoid extended and/or excessively frequent use of GLOW800 radiation.
- ► GLOW800 mode is disabled automatically no later than after 180 seconds to prevent excessive exposure of the patient to GLOW800 radiation.

2.3 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.

2.4 Signs and labels

Type label



3 Description

3.1 Function

The illumination for the GLOW800 is a xenon lamp and is located in the Leica surgical microscope. This lamp provides visible and near infrared light. The NIR light cannot be observed through the surgical microscope, but it is recorded using a special camera and visualized on the monitor mounted on the Leica surgical microscope.
Using the handles/buttons defined in the user settings you can switch between visible and GLOW800 light.

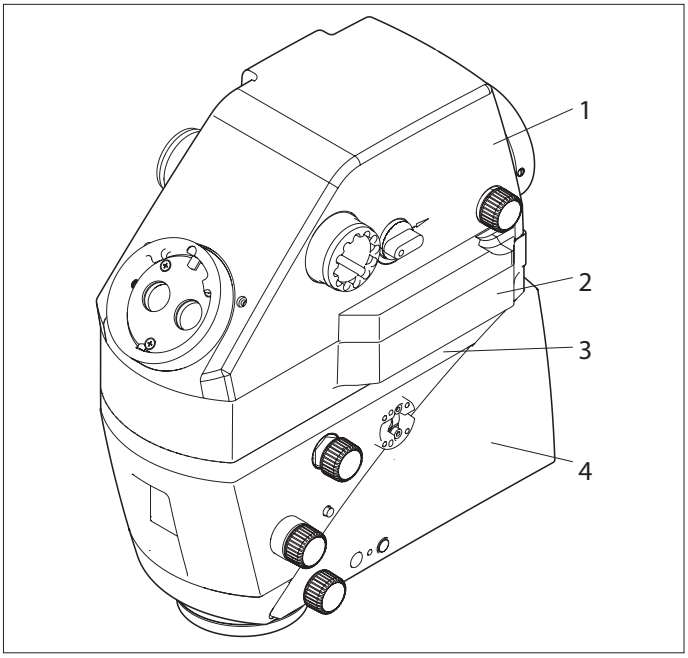
Please refer to the user manual of the corresponding Leica surgical microscope.

3.2 Design

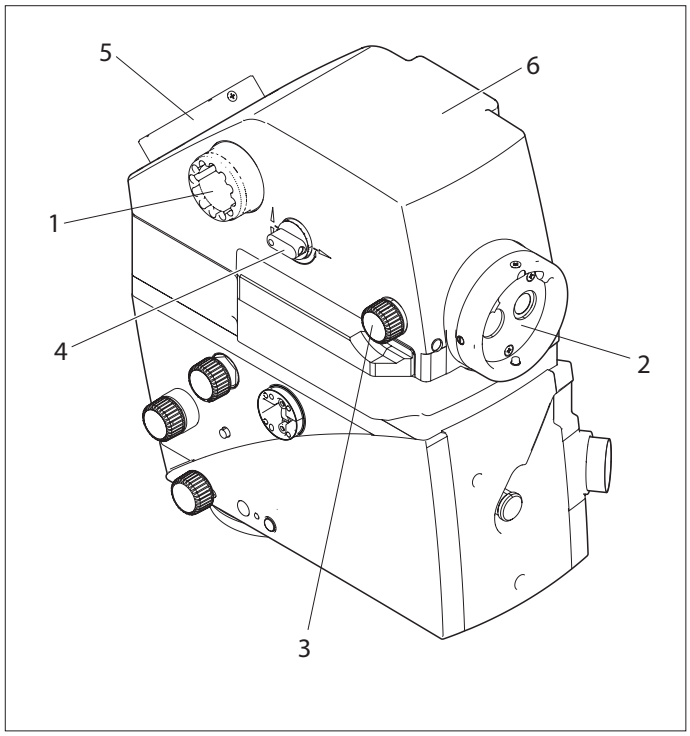
The GLOW800 is an accessory to a M530 optics carrier.

GLOW800 is composed of the following components:
A GLOW800 ULT, see chapter 3.2.1, position (1)
B GLOW800 VPU, see chapter 3.2.3, position (3)
C GLOW800 filters, see chapter 3.2.3, in position (4)

3.2.1 M530 optics carrier with GLOW800 ULT



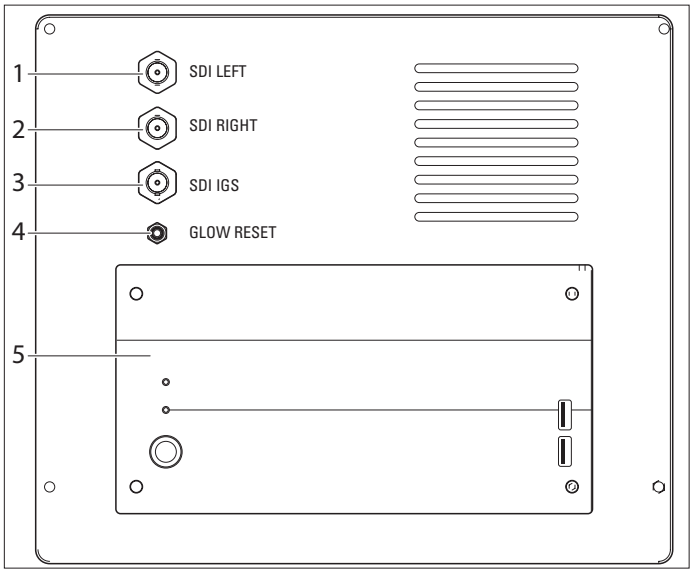
1 GLOW800 ULT
2 Image Injection module Leica CaptiView (optional)
3 Fluorescence module Leica FL400, FL560 or FL400/560 (optional)
4 M530 Optics Carrier



1 Interface for lateral left and right assistant
2 Interface for back/opposite assistant, 360° rotatable
3 Back assistant fine focus
4 Switch lateral or back assistant
5 Interface main surgeon, 360° rotatable
6 GLOW800 ULT

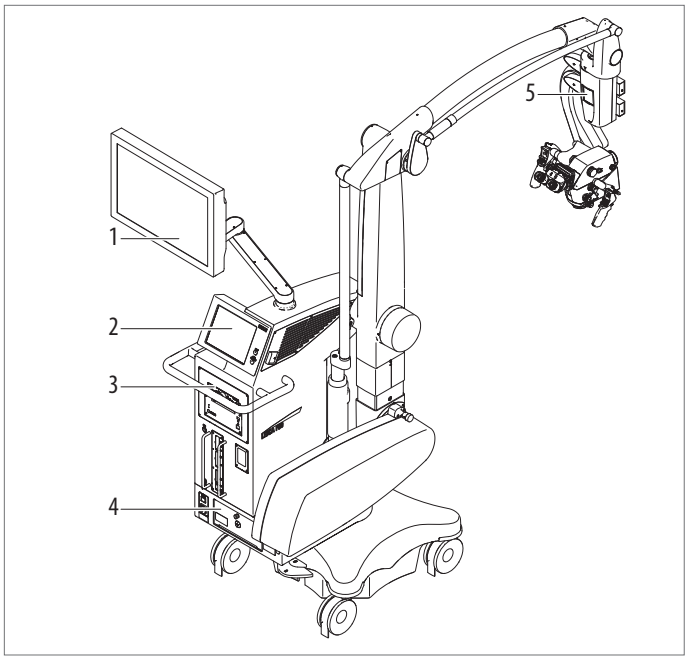
- GLOW800 is built into the housing of the ULT530
- Integrated cameras for visible light and for NIR light (fluorescence), one common remote controlled fine focus for both

3.2.2 GLOW800 VPU



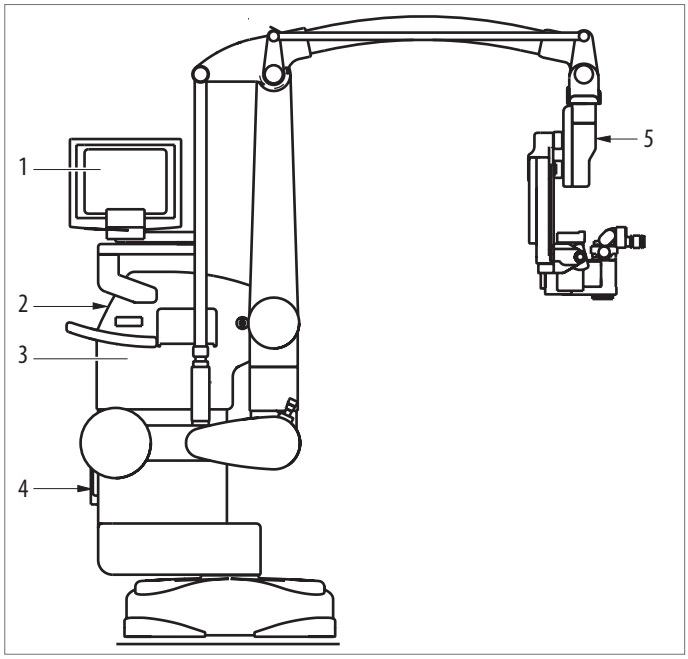
1 Video signal SDI left
2 Video signal SDI right
3 Video signal IGS
4 Reset button to reboot/reset of the system
5 Documentation system (optional)

3.2.3 Leica OHX surgical microscope with GLOW800 components



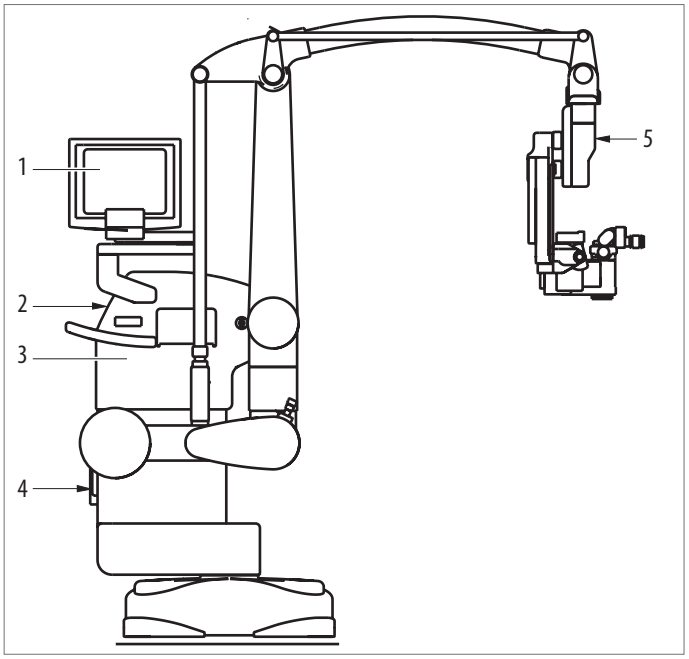
1 Monitor (optional)
2 GUI screen
3 GLOW800 VPU (see chapter 3.2.2)
4 Illumination unit with GLOW800 filters
5 Surgeon panel

3.2.4 Leica OH6 surgical microscope with GLOW800 components



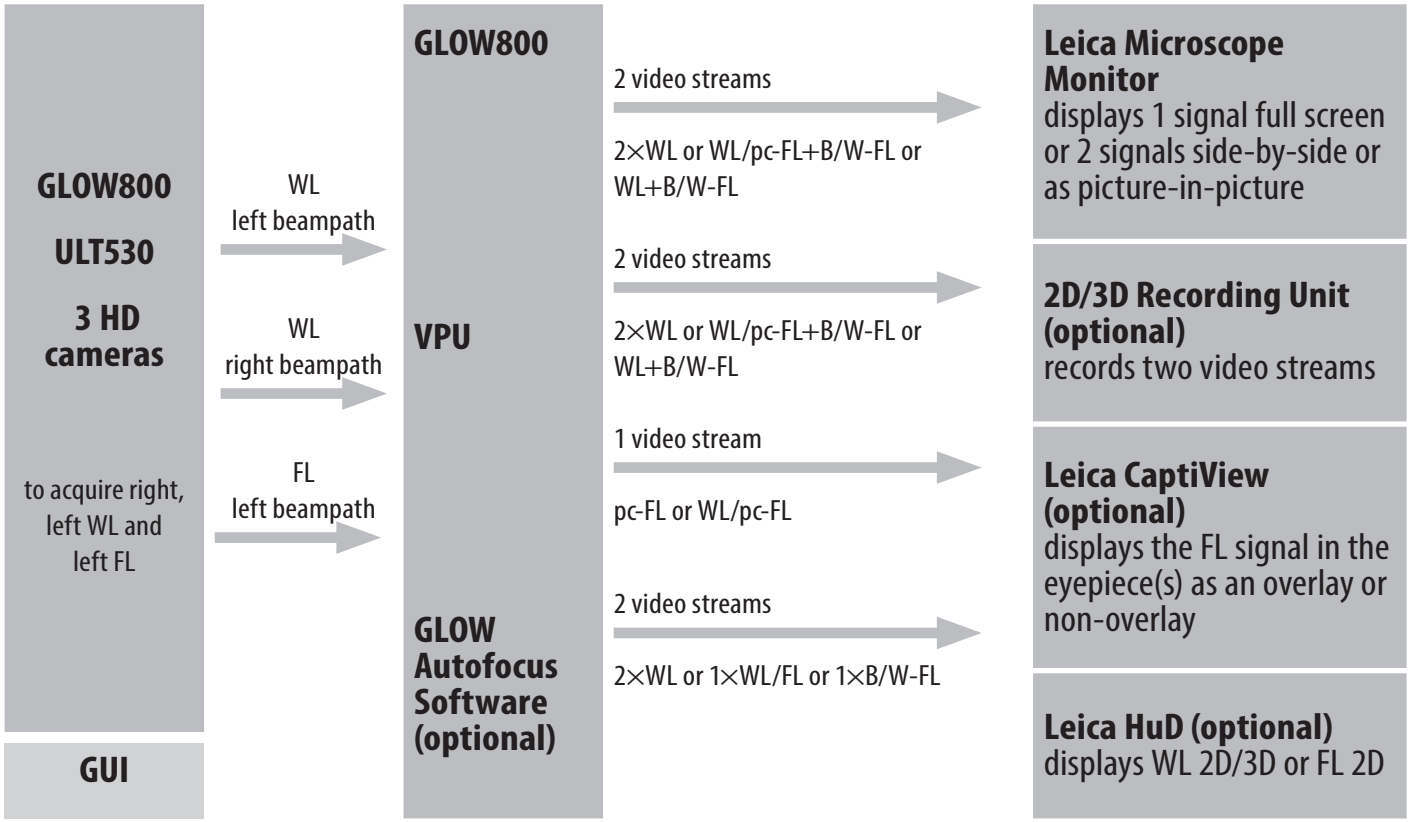
1 Monitor (optional)
2 GUI screen
3 GLOW800 VPU (see chapter 3.2.2)
4 Illumination unit
5 Status LED

3.2.5 ARveo surgical microscope with GLOW800 components



1 Monitor (optional)
2 GUI screen
3 GLOW800 VPU (see chapter 3.2.2)
4 Illumination unit
5 Status LED

4 GLOW800 System Components - Signal overview



Explanation:
pc-FL = pseudo color fluorescence
B/W-FL = black & white fluorescence
WL/pc-FL = White light object image & pseudo color fluorescence

! 3D visualization is only for teaching purposes not intended for heads-up surgery.

5 Description

5.1 Function

The optional accessory GLOW800 enables the surgeon to excite and observe Near Infrared (NIR) fluorescence (FL) of the fluorophore (ICG) with the surgical microscopes M530 OH6, M530 OHX or ARveo.

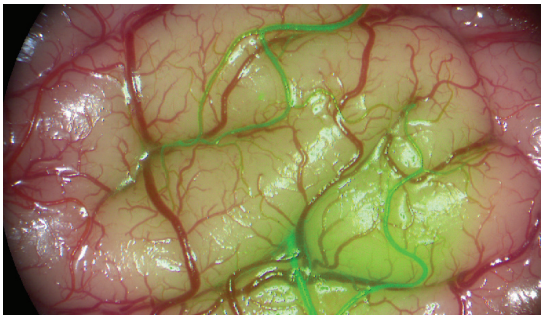
When activating the GLOW800 mode, the white light illumination of the Leica microscope stand (Leica OH6, Leica OHX or ARveo) is extended to InfraRed (IR) to excite the fluorophore (ICG).

The filtered NIR fluorescence signal of the fluorophore (ICG) is acquired by a NIR sensitive video camera in the GLOW800 ULT and processed in the GLOW800 VPU.

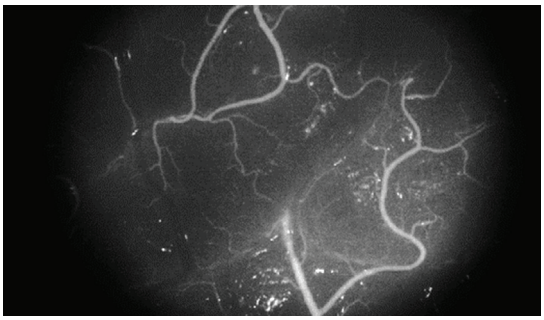
5.1.1 Fluorescence observation on the microscope video monitor

GLOW800 offers two different types to observe the fluorescence video signal on the optional microscope video monitor:

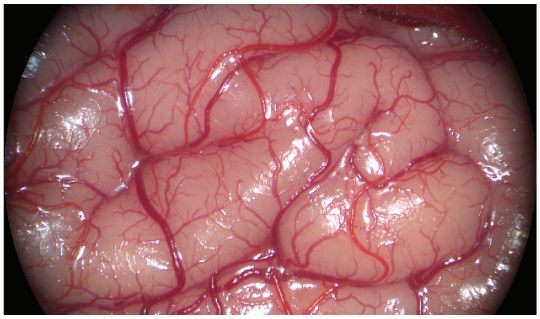
Type A: Pseudocolor mode (Pseudocolor ON)
White light object view with the embedded fluorescence signal in pseudocolor, Video #1A



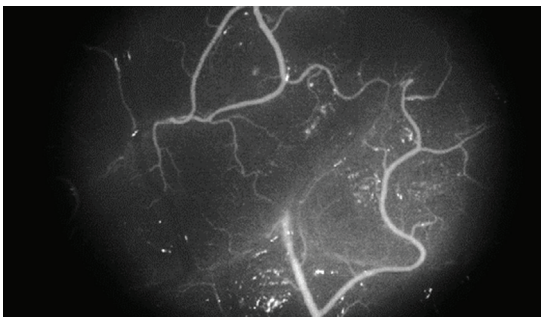
Black&White fluorescence view Video#2A



Type B: Black&White Mode (Pseudocolor OFF)
White light object view #1B

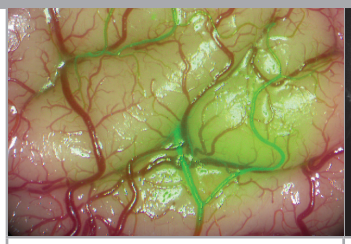
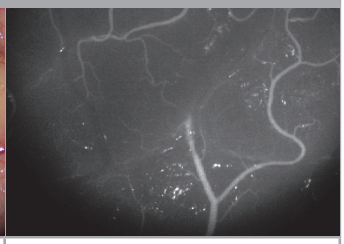
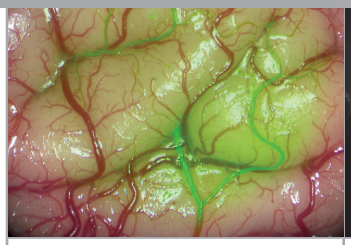
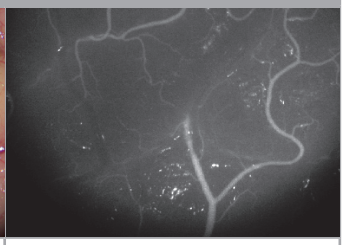
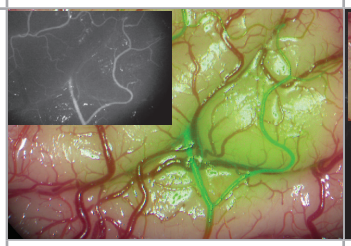
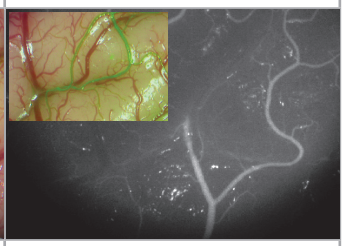
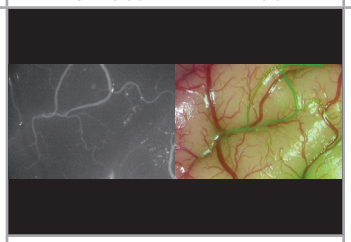


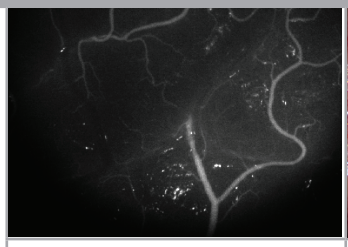
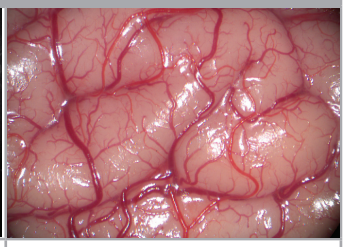
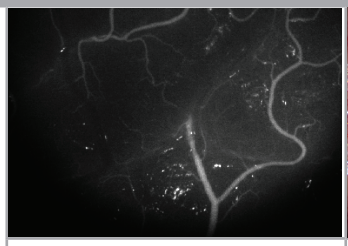
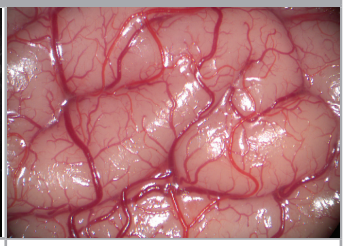
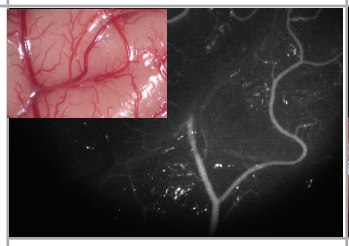
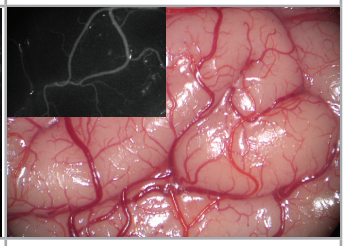
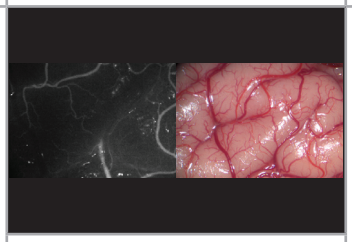
Black&White fluorescence view Video#2B



5.1.2 Fluorescence observation and recording with a documentation system

The GLOW800 VPU generates two videos which can be recorded by an optional documentation system, e. g. HDMD PRO, if integrated into the surgical microscope.
The following recording and visualization settings can be predefined on an optional documentation system. The records and displays are done in the following way:

<table>
<tr><th colspan="4">White light fluorescence type A: Pseudocolor mode (Pseudocolor On – WL/FL) and b/w fluorescence observation (B/W-FL)</th></tr>
<tr><td colspan="4">GLOW800 Image processing</td></tr>
<tr><td colspan="2">Two videos are provided for visualization and recording</td><td> 
Main video #1A</td><td> 
2nd video #2A</td></tr>
<tr><td colspan="4">Viewing and Recording</td></tr>
<tr><td>Setting 1</td><td>One video view on the video monitor, either the main or the 2nd video. Both videos are recorded</td><td> 
Main video #1A</td><td> 
2nd video #2A</td></tr>
<tr><td>Setting 2</td><td>Picture-in-Picture view on the video monitor, either the main or the 2nd video is at full screen. Both videos are recorded</td><td> 
Main video #1A= full screen,
2nd video #2A = window</td><td> 
Main video #2A= full screen,
2nd video #1A = window</td></tr>
<tr><td>Setting 3</td><td>Side-by-Side view on the video monitor. Both videos are recorded</td><td> 
Left = video #2A,
right = video #1A</td><td></td></tr>
</table>

<table>
<tr><th colspan="4">Black & White fluorescence type B: Black & White Mode (Pseudocolor OFF) (B/W-FL) and white light observation (WL)</th></tr>
<tr><td colspan="4">GLOW800 Image processing</td></tr>
<tr><td colspan="2" rowspan="2">Two videos are provided for visualization and recording</td><td>  </td><td>  </td></tr>
<tr><td>Main video #2B</td><td>2nd video #1B</td></tr>
<tr><td colspan="4">Viewing and Recording</td></tr>
<tr><td rowspan="2">Setting 1</td><td rowspan="2">One video view on the video monitor, either the main or the 2nd video. Both videos are recorded</td><td>  </td><td>  </td></tr>
<tr><td>Main video #2B</td><td>Video #1B</td></tr>
<tr><td rowspan="2">Setting 2</td><td rowspan="2">Picture-in-Picture view on the video monitor, either the main or the 2nd video is at full screen. Both videos are recorded</td><td>  </td><td>  </td></tr>
<tr><td>Main video #2B = full screen,
2nd video #1B = window</td><td>Main video #1B = full screen,
2nd video #2B = window</td></tr>
<tr><td rowspan="2">Setting 3</td><td rowspan="2">Side-by-Side view on the video monitor. Both videos are recorded</td><td>  </td><td rowspan="2"></td></tr>
<tr><td>Left = video #2B,
Right = video #1B</td></tr>
</table>

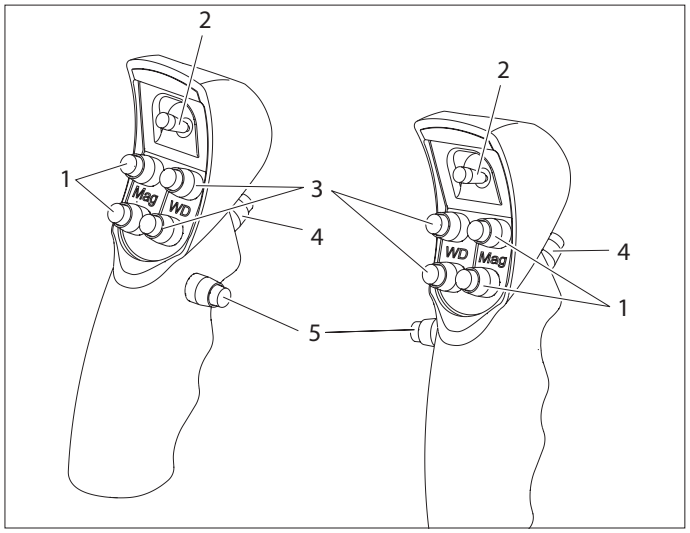
With the optional HDMD Pro recording system activating and deactivating the GLOW800 will automatically start and stop the recording of the two predefined video streams. If the recording of the white light mode is already running, the recording will switch to record the two predefined video streams ("Loop WL and "Loop NIR"). Several "Loop" recordings and WL recordings (segments) can be differentiated by an index in the video review page. If the GLOW800 mode is ended, both records will end as well.

Note If the white light record should proceed after the GLOW mode it has to be started again.

The play back function of the optional HDMD PRO documentation system allows to display again any of the "loops" on the screen, once or steadily, in normal, slow or frame-by-frame motion. The second recorded video can be selected for play back as well, either as the main video source or as a picture-in-picture (PiP) or side-by-side (SbS).
Please refer to the documentation device manuals for further information.

6 Controls

6.1 Handles

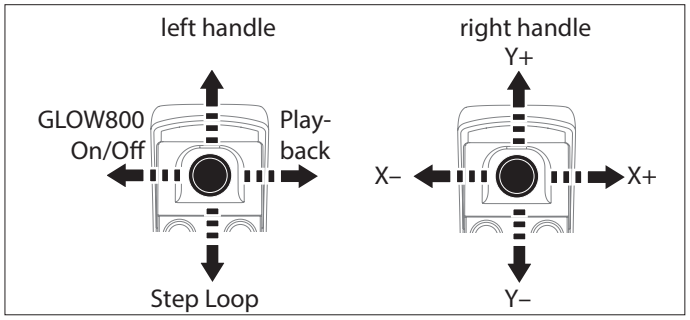


Assignment in the factory setting

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.

6.2 Status LEDs and Display

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:

6.2.1 Leica OH6 - Status LED

1 Status LED for fluorescence
2 Status LED for recording

The fluorescence status LED (1) indicates the fluorescence activity

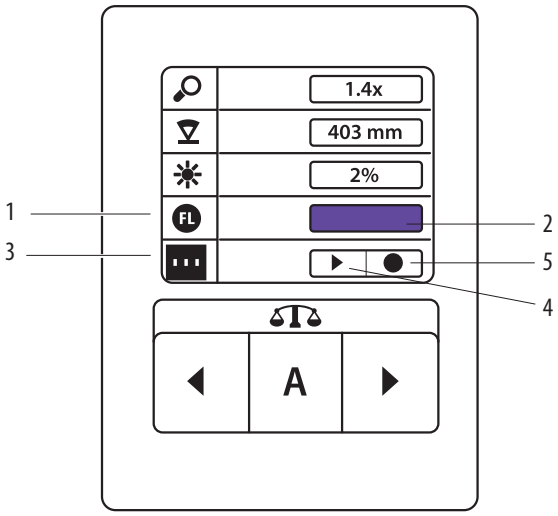
▢	white:	no fluorescence, white light mode
	blue :	FL400 is on
	cyan:	FL560 is on
	yellow:	FL800 is on
	magenta:	GLOW800 is on

The status LED for recording (2) light up in

	red:	GLOW800 loop recording in progress
	green:	GLOW800 replay mode

6.2.2 Leica OHX surgeon panel

The surgeon panel indicates the status of the fluorescence.



1 Fluorescence icon
2 Fluorescence status color bar
3 Documentation icon
4 Replay icon
5 Recording icon

The fluorescence status color bar (4) indicates the fluorescence activity.

	white light:	no fluorescence, white light mode
	blue:	FL400 is on
	cyan:	FL560 is on
	yellow:	FL800 is on
	magenta:	GLOW800 is on

- ► If the optional recording system is integrated into the microscope system, the recording icon (5) will change from black to red if the GLOW800 NIR video sequence (loop) is recorded.
- ► The replay icon (4) stays black.
- ► In replay mode the replay icon (4) becomes green and the recording icon (5) stays black (see below).

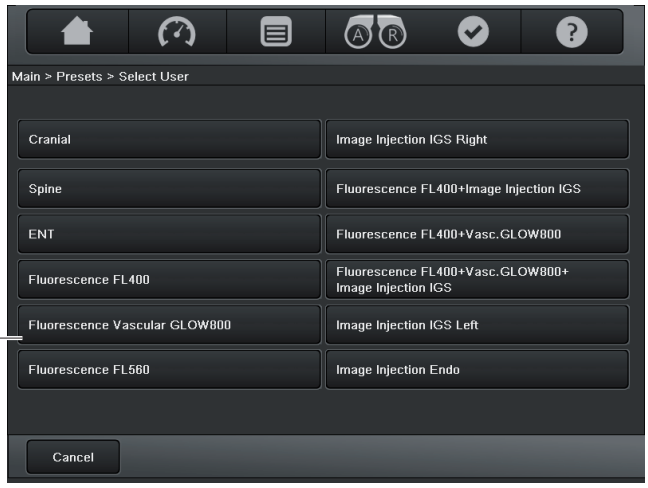
7 Preparation before surgery

7.1 Adjustments on the M530 control unit for GLOW800

Ensure that the GLOW800 accessories are enabled. Please contact your Leica representative for further assistance.

Using the "Fluorescence Vascular GLOW800" user preset

- ► In the Main menu click on the "Preset" button (1).
  The availbale presets are displayed.

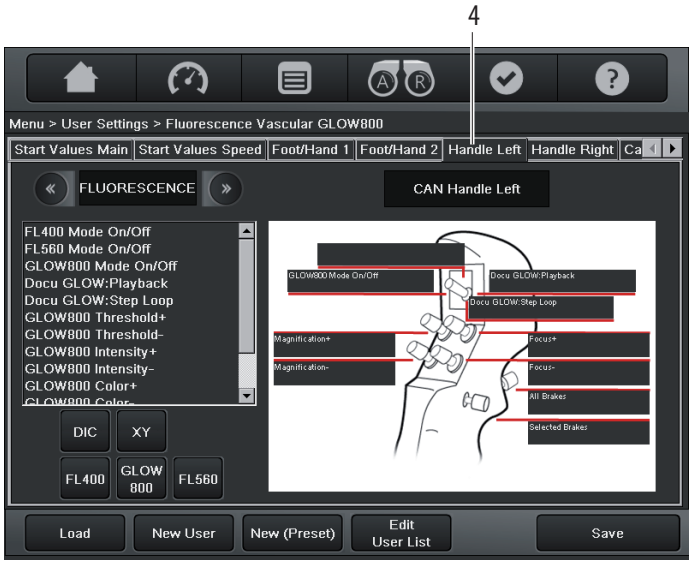


- ► Select the "Fluorescence Vascular GLOW800" user preset (2).
- ► Click on the "Select" button.
  The selected user preset is displayed in the status line.

Handle assignment

► In the Main menu click on the "Show Settings" button (3).

► Select the "Handle Left" or "Handle Right" tab (4).



You see an overview with which buttons of the left handle the GLOW800 functions can be operated.

Modifying the "Fluorescence Vascular GLOW800" user preset

> ! If you adjusted the settings of the "Fluorescence Vascular GLOW800" user preset to your needs during the application, you can adopt and save them under a new user name.

► In the "User settings" menu click on "Save" and then on "Save as".
► Select an empty position in the user list.
► Enter the desired user name via the keyboard.
► Click on the "Save" button to save your settings under the user name entered at the desired location.

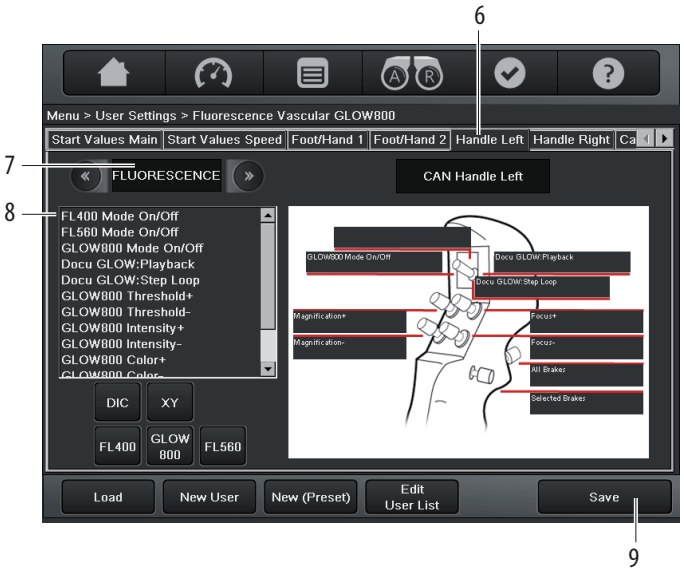
> ! These settings can later be edited at any time via the User Settings menu.

Creating your own GLOW800 user

► Click on the "Menu" quick access button (5).

► Select "User Settings".

► Select "New User".
► Open the "Handle Left" or "Handle Right" tab (6) to assign GLOW800 functions to the handle.



► In the left selection field, select the "Fluorescence" function group (7) by clicking on it.
► Assign the function "GLOW800 Mode On/Off" (8) to any button by selecting the desired function.
► Afterwards, click on the label field of the desired button to assign the desired function.
– or –
Press the desired button on the handle to be assigned.
► Repeat this process for all functions to be added.
► Click on "Save".
► Select an empty position in the user list.
► Enter the desired user name via the keyboard, e.g. "ICG Glow User".

► Click on the "Save" button (9) to save your settings under the user name entered at the desired location.

In the service menu, a value for the maximum duration of the GLOW800 mode from 10 to 180 seconds can be adjusted by service.

Note We recommend to put just the GLOW functions to the handle which are known thoroughly. Typical commands are "On/Off" and "Playback".

7.2 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.

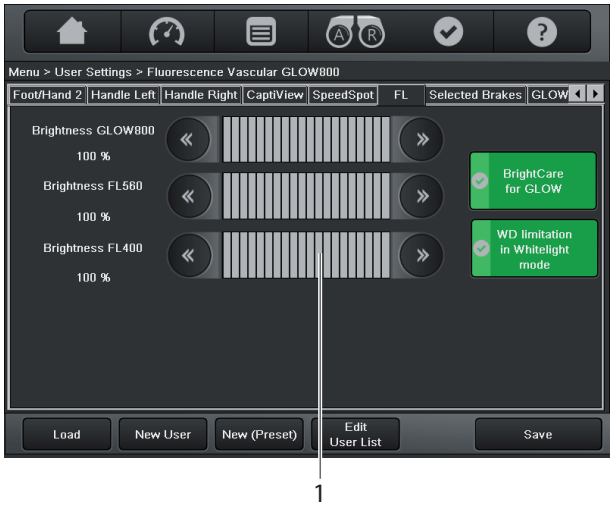
- Less excitation intensity “Brightness GLOW800” and/or a lower ICG dosage reduces the fluorescence visibility, especially at high magnification and/or long working distance. Less fluorescence visibility or fluorescence brightness might be observed already at a lower magnification and WDs.
- Higher excitation intensity “Brightness GLOW800” 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 life time reaches its end.

In this case a message is displayed on the graphical user interface (GUI) with a request to change the illumination bulb.

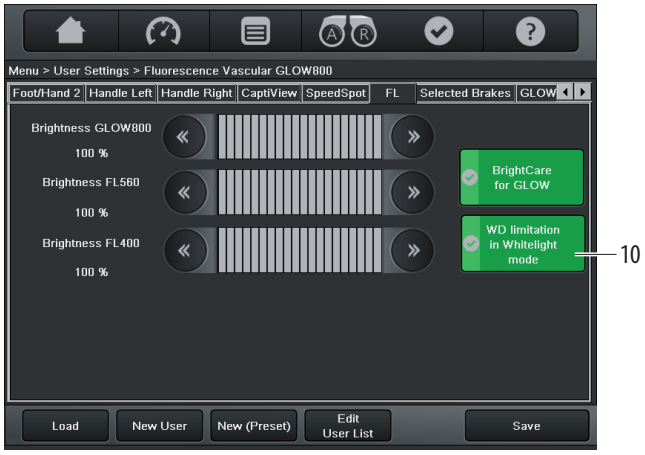
7.2.1 GLOW800 Brightness (Illumination/ Excitation intensity)

► Open the "FL" tab to set the GLOW800 brightness to the required level with bar (1).



Recommended Brightness settings
The default and recommended "Brightness GLOW800" setting is 100 % to achieve good fluorescence visibility in higher magnifications and working distances.

7.2.2 Working distance limitation

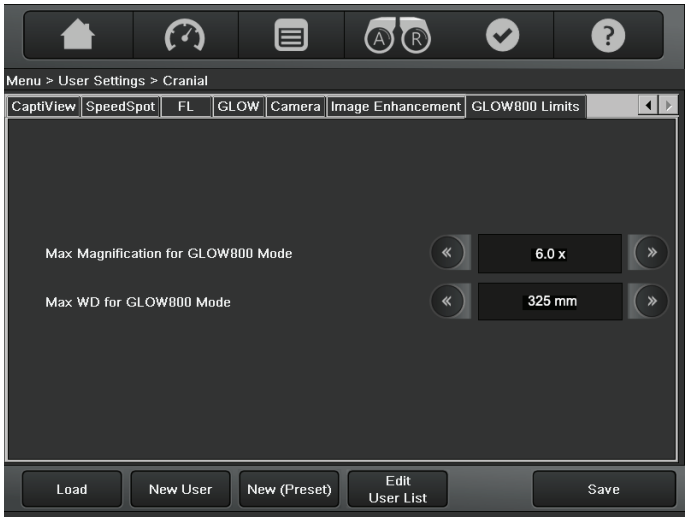


► Decide if the working distance limitation in white light mode should be switched on (default) or off (10).

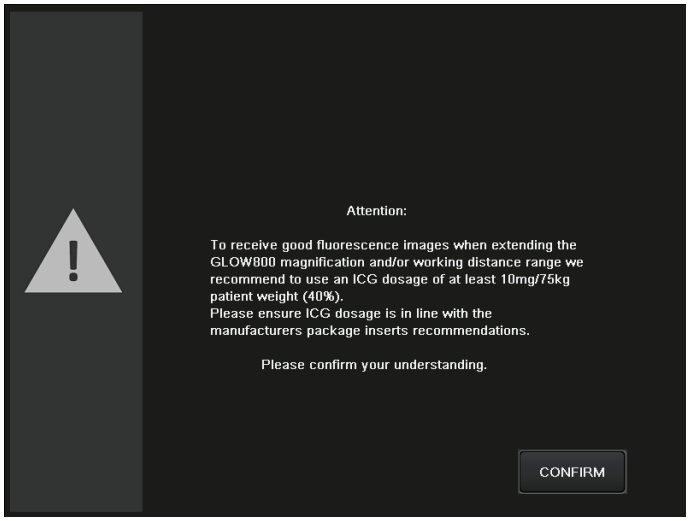
When the working distance limitation in white light mode is switched off and the working distance is above the limit when switching to GLOW800 mode, the working distance will be reduced and the picture will get out of focus.

7.2.3 GLOW800 Limits

The "GLOW800 Limits" define Magnification and Working Distance ranges for good fluorescence visibility.

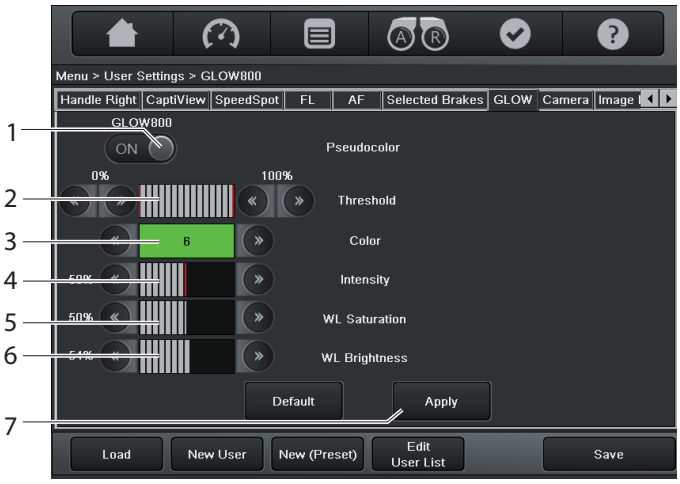


To extend the Magnification and/or Working Distance range(s) you have to confirm that you may have to adjust the ICG dosage to get optimal fluorescence visualization.



7.3 GLOW800 User Setting Menu

The tab offers specific GLOW800 settings for each user:

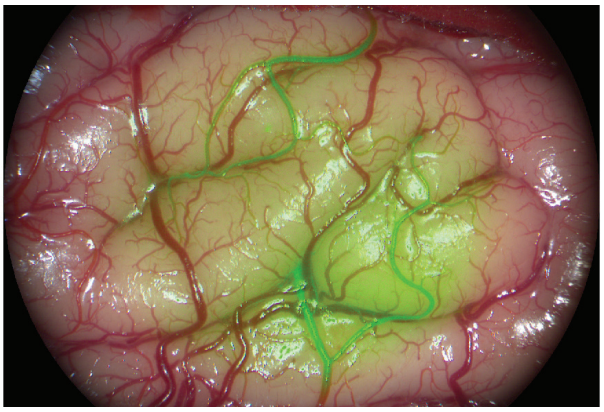


7.3.1 Pseudocolor

Pseudocolor defines one of two types of fluorescence observation.
Pseudocolor can be switched On or Off with button (1).
Default is on.

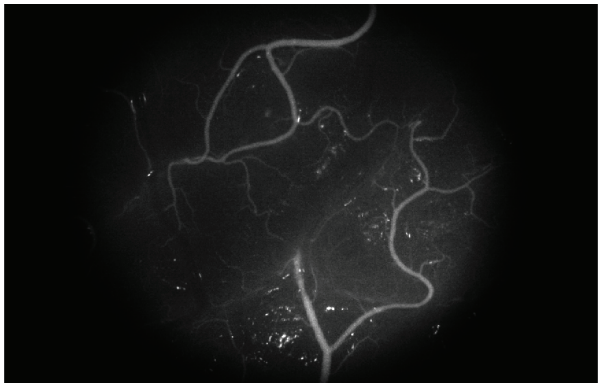
Pseudocolor on (Observation type A-1 to A-4)

- White light object view with the embedded fluorescence signal in pseudocolor (white light fluorescence observation = WL/FL)



Pseudocolor off (Observation type B-5)

- Standard Black & White fluorescence view = B/W-FL on the microscope monitor.

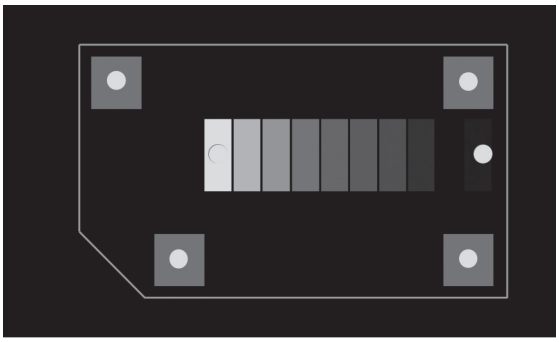


See as well Chapter 5.1.1.

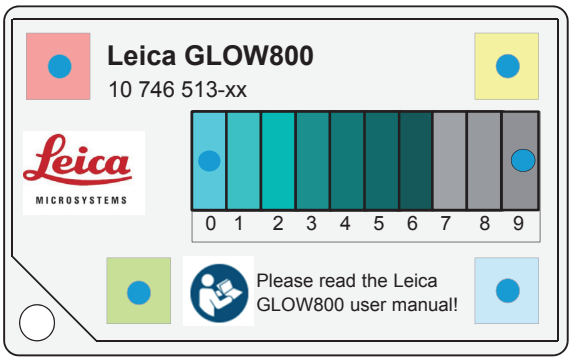
7.3.2 Threshold

With the «Threshold» bar (2, page 14) the fluorescence intensity range to be displayed in the white light fluorescence view can be defined. Low intensity signals (e. g. noise) and/or high intensity signals can be filtered out by defining a lower and an upper threshold with the two red bars.
The default value and recommended setting for the lower threshold is 0 %, for the upper threshold 100 % to observe the full range of fluorescence signals. Using the test card demonstrates how the «Threshold» function influences the fluorescence signal.

Lower Threshold at 0 % and and upper Threshold at 100 %- all fluorescence intensities are displayed

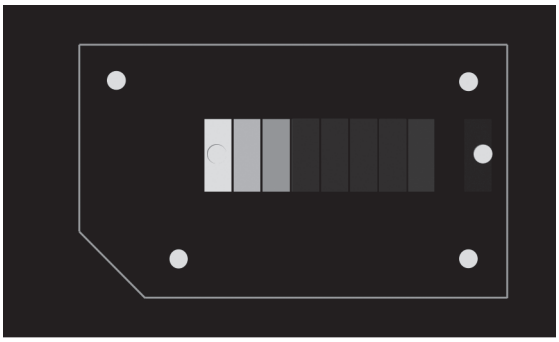


Black & White fluorescence observation
(Video monitor)

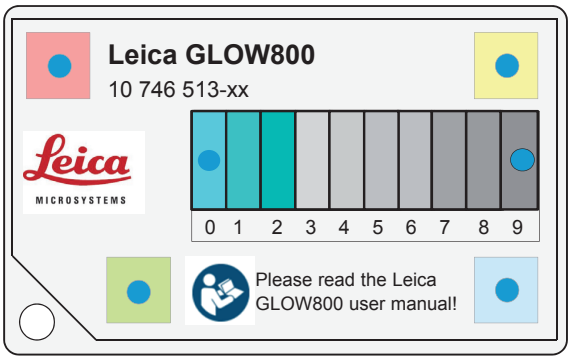


White light + fluorescence observation
(Video monitor)

Lower Threshold at 60 % and upper Threshold at 100 % - middle to high intensity is displayed only

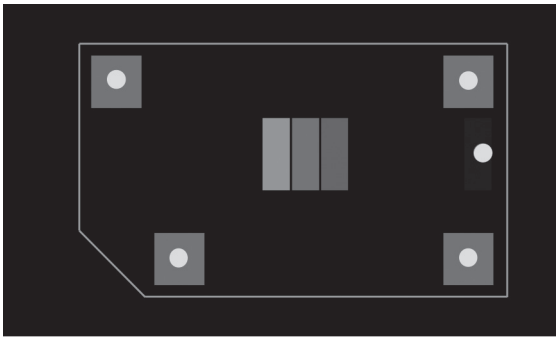


Black & White fluorescence observation
(Video monitor)

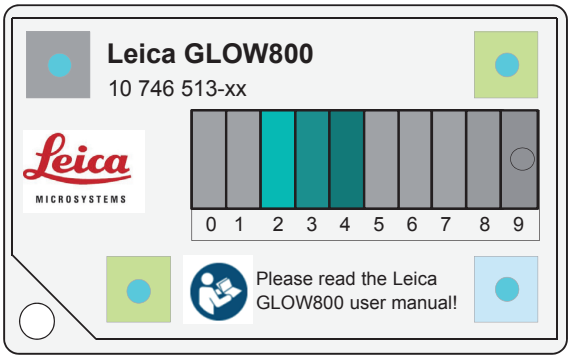


White light + fluorescence observation
(Video monitor)

LowerThreshold at 40 % and upper Treshold at 70 % - middle to high intensity is displayed only

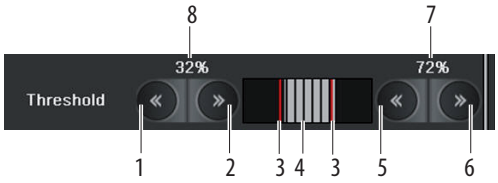


Black & White fluorescence observation
(Video monitor)



White light fluorescence observation
(Video monitor)

Threshold settings



Threshold defines the indicated fluorescence range by the lowest indicated fluorescence intensity (1= Down, 2=Up) and the highest fluorescence intensity (5= Down, 6=Up). The red bars (3) indicate the stored values, the grey bars (4) the displayed fluorescence range. The percentages of the lower and upper limit of the range are given by the values (7) and (8).

Default is the display of the full fluorescence range with a lower limit = 0 % and upper limit = 100 %.

In case of adaptation of the range by the buttons (1), (2), (5) and (6) the bar will indicate the adjusted range. The new range can be activated by the «Apply» button (7, page 14) to observe the results on the screen and eyepieces (with optional CaptiView). If the new range is saved the red bars will move to the appriate positions in the graphics; example: 32–72 % range.

7.3.3 Color

With «Color» button (3, page 14) the pseudocolor of the fluorescence signal can be chosen.
Selectable color values are from 1=magenta to 7=chartreuse, if the FL image is not injected into the eyepiece(s). The chosen color defines the appearance of the fluorescence on top of the white light image to optimize the color contrast between the colors of the object in white light and the fluorescence signal.

If the GLOW800 image is injected in the left or both eyepieces by use of the optional CaptiView module (chapter 7.7), the choice of colors is reduced to blue #3 and green #6.

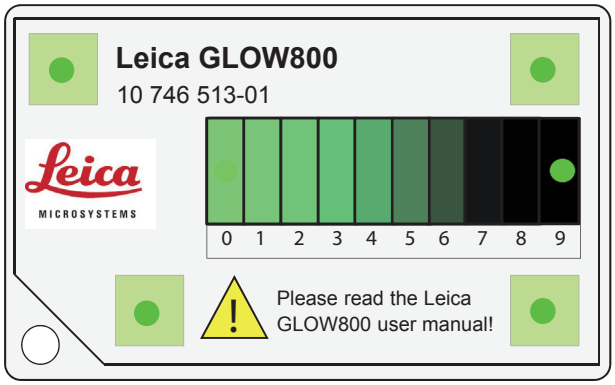
Without image injection

	color	color name	RGB value
1		magenta	255-000-255
2		violet	127-000-255
3		blue	000-000-255
4		azure	000-127-255
5		dark cyan	000-221-221
6		green	000-255-000
7		chartreuse	127-255-000

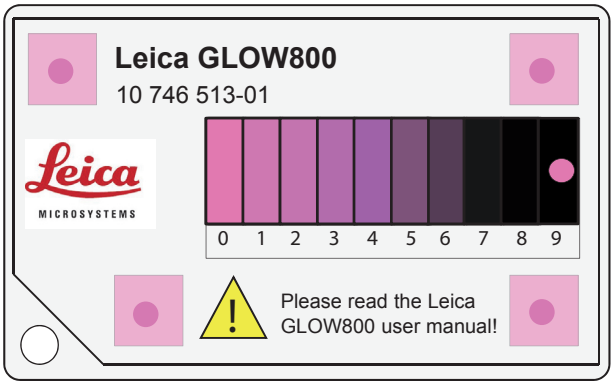
With image injection

	color
3	
6	

Displaying the fluorescence with color #6 Green in white light fluorescence observation. Color #6 is the default color in the GLOW800 preset (Video monitor)



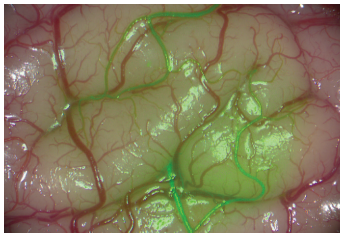
Displaying the fluorescence with color #1 – magenta in white light fluorescence observation (Video monitor)



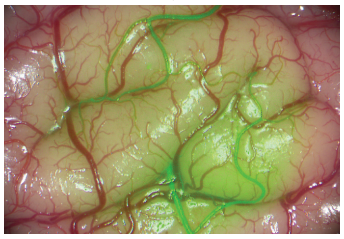
7.3.4 Intensity

«Intensity» bar (4, page 14) 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.
E.g. at 0 % intensity fluorescence is just visible with the object dominant, at 100 % intensity fluorescence is intensively visible and dominant.

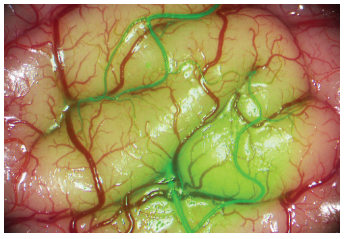
Minimum intensity setting – 0 %



Medium intensity setting – 50 %



Maximum intensity setting – 100 %



7.3.5 WL Saturation and WL Brightness

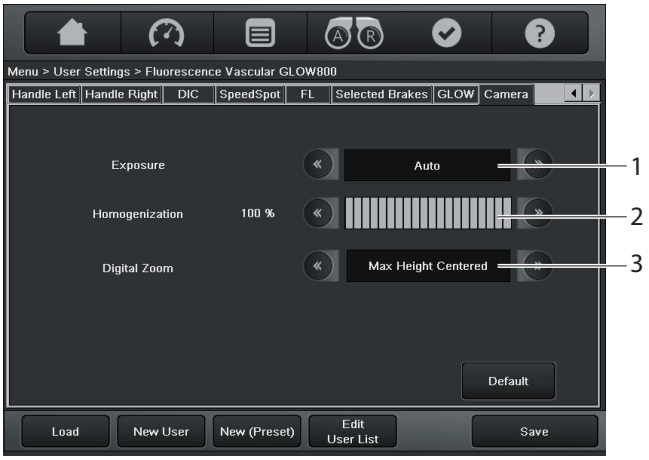
To increase the contrast of the fluorescence information in relation to the anatomical video image the characteristics of the white light anatomical image can be adapted by:

- Reduction of the white light anatomical image color saturation with the WL Saturation bar (5, page 14)
- Reduction of the white light anatomical image brightness with the WL Brightness bar (6, page 14)

7.3.6 Apply button

By pressing the "Apply" button (7, page 14) on the GLOW800 page of the user settings changes of one or more of the different GLOW800 settings become active in the GLOW800 system.
The result of the changed settings can be observed after a few seconds on the GLOW800 screen.

7.4 User settings camera

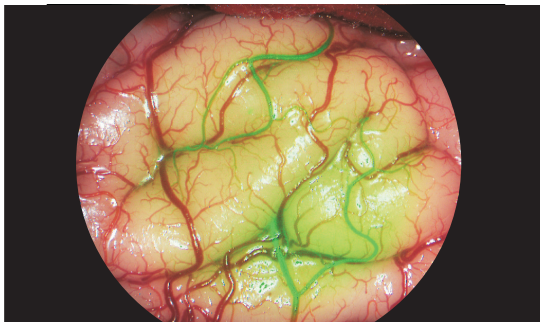


7.4.1 Digital zoom

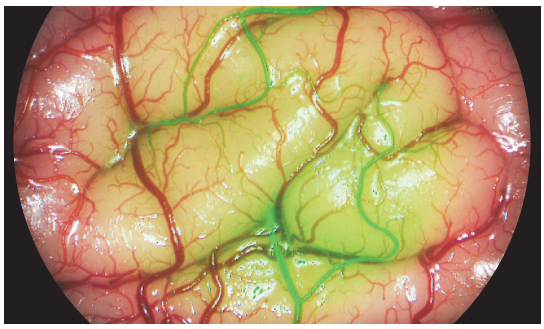
With «Digital Zoom» the display format is adjusted to the needs of each GLOW user. There are four formats available which can be changed with the Digital Zoom button (3).
Default setting is "Max. Height Centered".

Max. Height
Fits the maximum detected field of view in the centre of the screen of the documentation monitor.

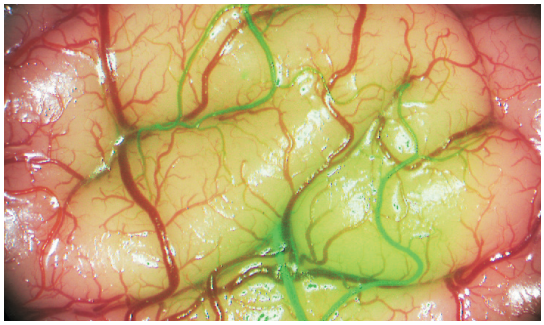
- Nearly round image format – full video resolution



Full width
Fits the full horizontal field of view on the screen of the documentation monitor
► format with rounded edges – full horizontal video resoltion



Full screen:
fits the diagonal of the field of view into the diagonal of the screen of the documentation monitor
► rectangular image format – reduced video resolution



GLOW Digital Zoom in combination with navigation systems
If the surgical microscope is connected to a navigation system and the navigation system is active/switched on, the choice of the four GLOW Digital Zoom options is automatically reduced to one. This remaining/activated setting is defined within the integration and calibration process of the navigation system.

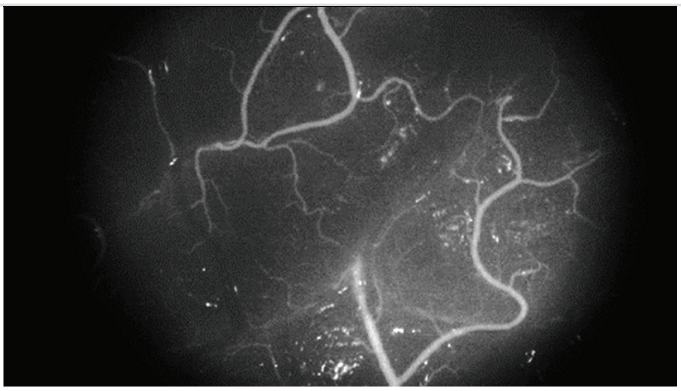
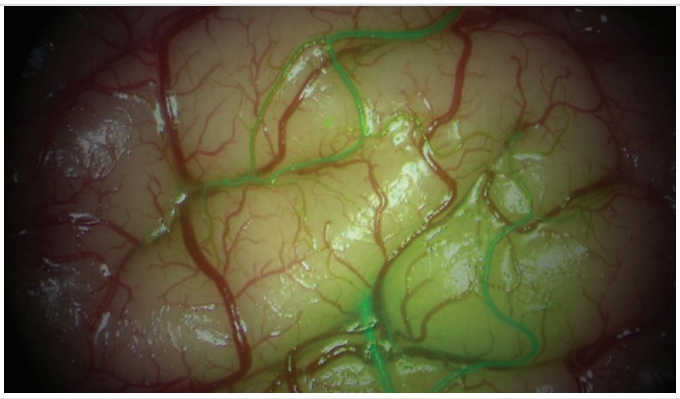
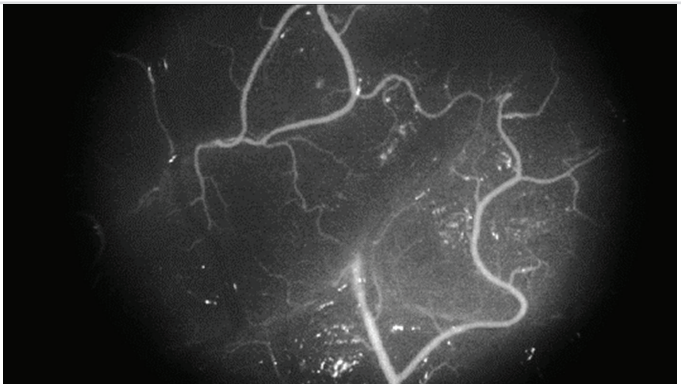
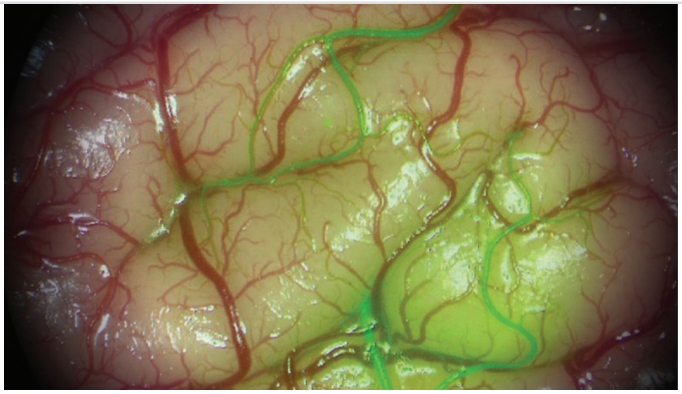
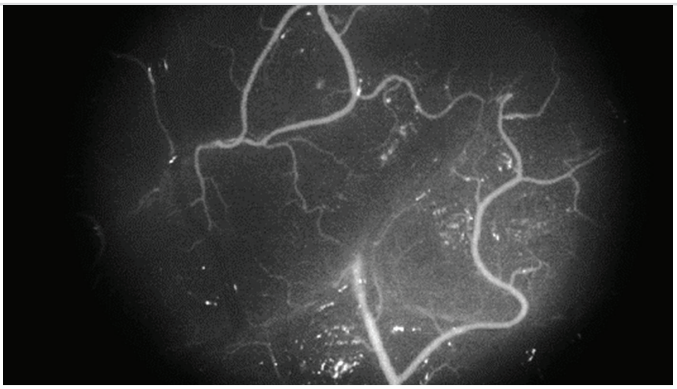
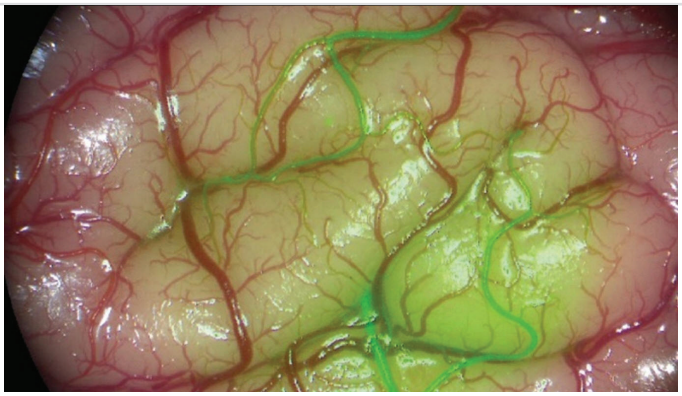
Disclaimer:
Views on monitor or in the eyepiece might slightly differ from the images shown in this manual.

7.4.2 Exposure

"Exposure" button (1, page 18) defines the shutter speed for the white light camera.
If set to "Auto" the shutter speed is selected automatically by the camera to receive best brightness and contrast of the image (default setting).
To enforce a specific shutter speed the setting can be changed from "Auto" to manually selectable shutter speed values, selectable in steps from 1/60 to 1/10000.

7.4.3 Homogenization (GLOW800)

With «homogenization» bar (2, page 18) the effect of center-weighted illumination can be compensated for the white light image and in GLOW mode for the white light part of the GLOW image. Neither the monochrome fluorescence image nor the fluorescence content of the GLOW image is homogenized.

Monochrome (pseudocolor ON)	**GLOW800 white light fluorescence image homogenization**
No homogenization	No homogenization
	
Medium homogenization – 50 %	Medium homogenization – 50 %
	
Maximum homogenization – 100 %	Maximum homogenization – 100 %
	

Homogenization is as well active in B/W mode (Pseudocolor = OFF).

7.5 Video settings

7.5.1 White light video settings

The default values for Brightness, Contrast and Gamma are defined to result in good differentiation of bright and dark image areas. Values below 50 % define a decrease, above 50 % an increase, the new values apply and will adapt the image immediately.
If adaptation is required, each value can be adjusted with the Image Balance bars (2–8) in the user settings.
Although the Default for Red, Green and Blue shall produce a neutral color video image with a natural color saturation, the color balance and the saturation of the video image can be adjusted in three different ways for each of the available modes: White light, GLOW800, FL400 and FL560 - by toggling from mode to mode with button (1):

- ► To re-activate the default/company reset values press the Default button (9).
- ► To re-adjust the Color Balance to a reference standard, place a white object below the microscope which covers the whole field of view, adjust the illumination intensity to the required level and press the Auto White Balance button (10).
- ► To adapt the Color Balance to specific needs, each color can be attenuated or intensified with the color bars (5, 6, 7; values below 50 % define a decrease, above 50 % an increase, the new values apply and will adapt the image immediately).

To check the color balance, the color areas on the front and back side of the GLOW800 testcard can be used by comparing the original optical image with the video display image.

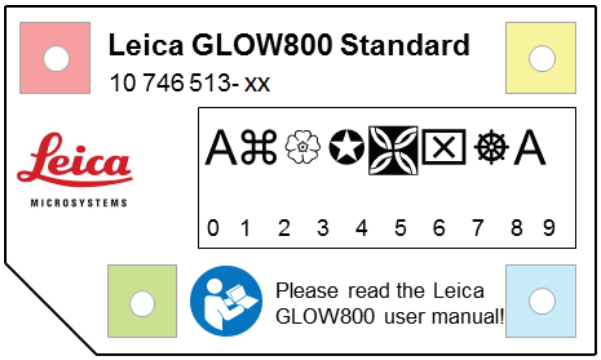


Image of GLOW800 test card – front

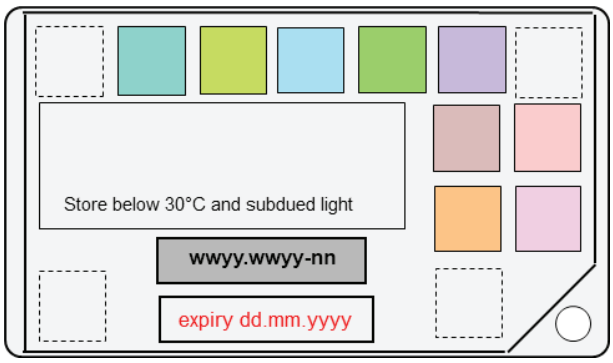


Image of GLOW800 test card – back

7.6 GLOW800 image injection

With the optional CaptiView image injection integrated into the surgical microscope M530 ARveo, OH6 and OHX, the GLOW800 fluorescence information can be observed in the right, left or both eyepieces, as an injected digital image or as an overlay, according to the selected fluorescence observation type and the CaptiView settings.
To decide about observation type A or B see chapter 7.3.1, to decide about observation types A-1 to A-4, means the CaptiView user settings see chapter 7.7.

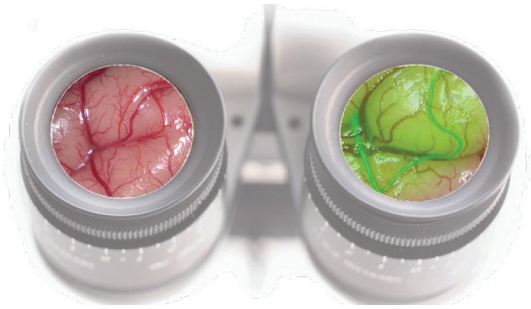
Observation Type A-1/WLFL

Digital white light image with embedded fluorescence in pseudocolor video in the right eyepiece and optical 2D image in the left eyepiece

Observation Type A-3/OVL

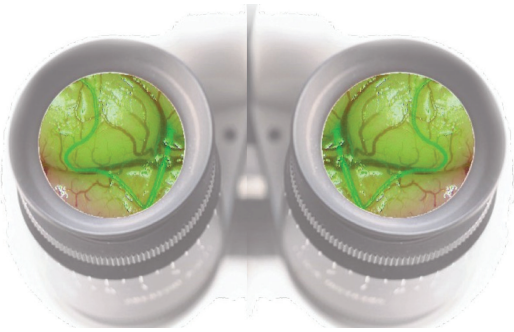
Digital pseudocolor fluorescence image overlay in the left eyepiece to the stereoscopic observation of the optical images in both eyepieces

Observation Type A-2/OVR



Digital pseudocolor fluorescence image overlay in the right eyepiece to the stereoscopic observation of the optical images in both eyepieces

Observation Type A-4/OVLR



Digital pseudocolor fluorescence image overlay in both eyepieces to the stereoscopic observation of the optical images in both eyepieces

! For correct fitting fluorescence overlays in the eyepiece(s) it is recommended to check the fluorescence image focus on the monitor.

! To avoid a double recorded or displayed fluorescence images on the monitor switch off the overlay in the left eyepiece.

7.7 Image injection of GLOW into the eyepiece(s) (User Settings)

The injection of the GLOW800 images can be defined for each user in the CaptiView tab with the setting "GLOW800" (1) and the following options:

- OFF = no injection
- Image injection right = Observation Type A-1
- Overlay right = Observation Type A-2
- Overlay left = Observation Type A-3
- Overlay left and right = Observation Type A-4

- Please refer to the user manual of the corresponding Leica image injection system (CaptiView).
- If the GLOW800 image is injected in one or both eyepieces, the choice of pseudocolors is reduced to blue #1 and green #6, see chapter 7.3.3.
- If Pseudo Color is switched off for GLOW800 in case of image injection the overlayed fluorescence image is done in b/w.
- If the GLOW800 image is injected in the left or both eyepieces, the monitor view and the recording might show a slight displacement of the the fluorescence signal for quick movements.
- In case of high magnification > 5.0× it is recommended to switch image injection off to avoid overlays with increased noise because of physical reasons.

7.8 Video Fine Focus

The GLOW800 ULT offers fine focusing and parfocality reset of the video focus.

The video focus can be adapted to your needs by pressing the focus button up (3) or/and down (1). This command can be given to the GUI and from the handle, if defined.

Focus adjustment operates in both directions with an endless circular movement.

The video fine focus can be re-adjusted to parfocality position by pressing the parfocality button (2). The video focal plane will then be aligned for all observers with zero diopters respectively with correct individual diopter settings. This command can be as well given on the GUI and from the handle, if defined.

8 Check the illumination and function and adjustment

8.1 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 the user manual of the Leica surgical microscope).

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 Leica surgical microscope refer to the corresponding user manual.

8.2 Test card

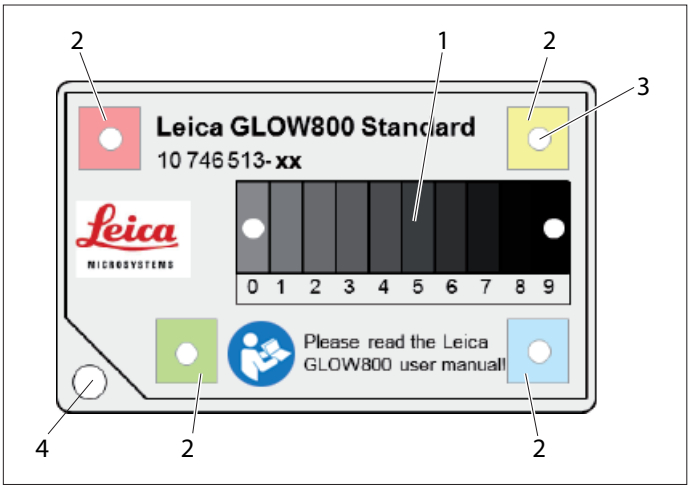
To check and test the GLOW800 function, to verify the proper adjustment of the white light and fluorescence image and to verify the illumination level the GLOW800 test card has to be used.

WARNING

Risk of infection due to insterile 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 Leica surgical microscope. Follow the instructions on parfocal setup.

Please prepare the test as follows:



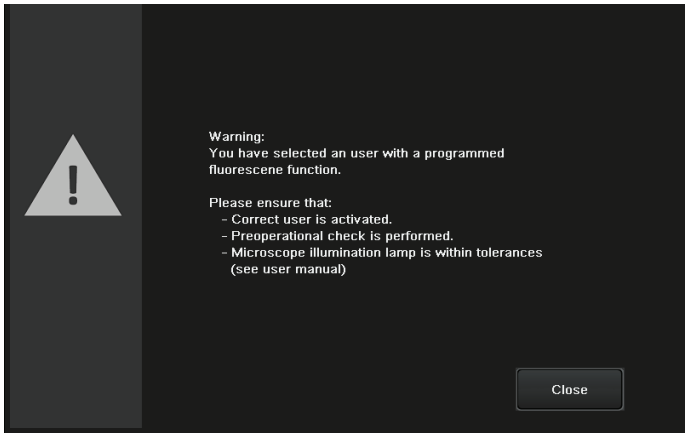
1 Stepwise decreasing NIR Intensity fields 0=bright to 9=dark
2 Low intensity NIR fluorescence area including 4 different white light color areas
3 Round spot high intensity NIR fluorescence signal
4 Hole to fix the card

8.3 Preparation

WARNING

User selected with a programmed fluorescence function.

- ► Correct user is activated.
- ► Preparational check is performed.
- ► Microscope illumination lamp is within tolerances (see user manual of the Leica surgical microscope).



Please prepare the test as follows:

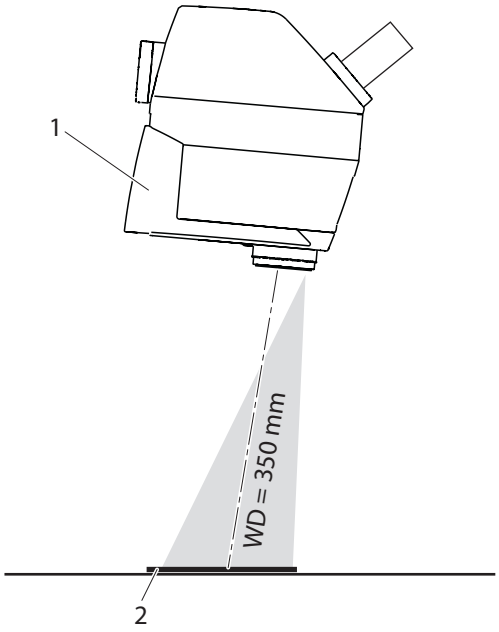
- ► For general tests please use the GLOW800 preset.
- ► Place the GLOW800 test card below the microscope.

WARNING

Risk of infection due to insterile 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 Leica surgical microscope. Follow the instructions on parfocal setup.

- ► Adjust the working distance (WD) to 350 mm.
- ► To avoid reflexes position the microscope in a small, but sufficient angle over the test card.
- ► Follow the instructions on parfocal setup.
- ► Get in focus by repositioning the microscope at highest magnification (Do not focus!).
- ► After positioning and focussing 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 On/Off button on the handle.
- ► Adjust the fluorescence illumination to 50 %.
- ► The GLOW800 test card can now be observed in the eyepiece in white light and on the optional monitor in white light fluorescence.



1 Microscope optics carrier
2 Test card

Eyepiece view:

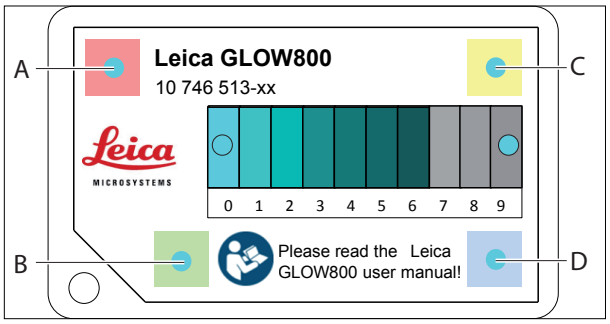
Appearance of the test card in white light observation:
Holes in the colors squares will allow to check the adjustment of the fluorescence and white light image.

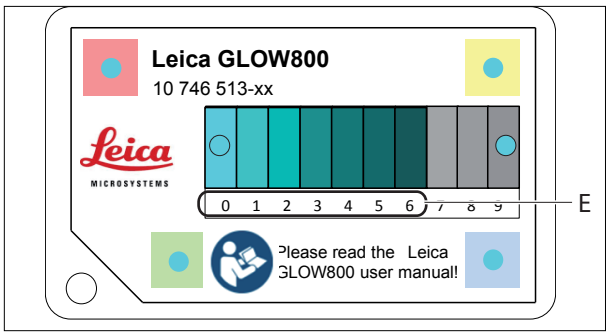
8.4 Test card functional areas

Tests in white light fluorescence observation mode

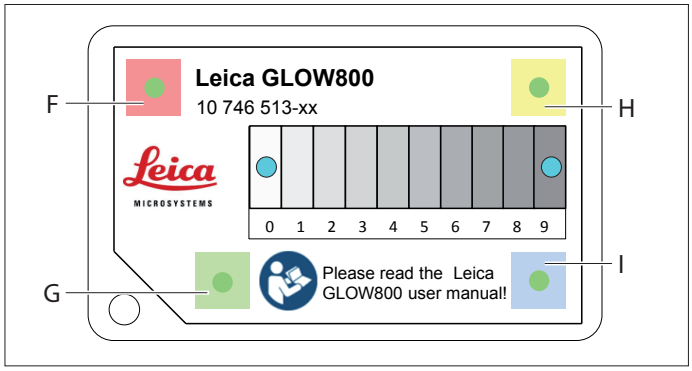
Check for the proper adjustment of the fluorescence image with the white light image.

1. All bright fluorescence dots have to fit precisely into the holes of the color squares (A-D).



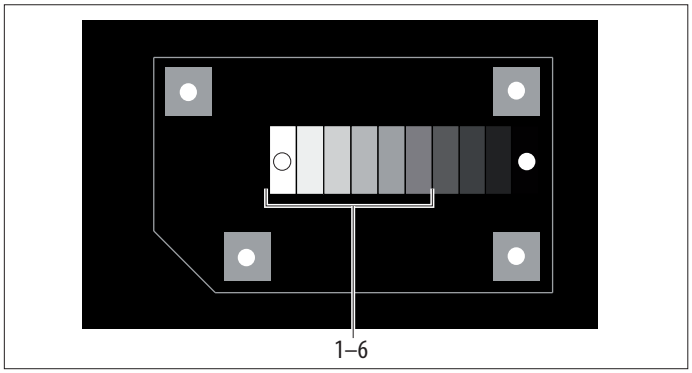


2. Check the fluorescence intensity (A–D).
   At the required WD = 350 mm,
   Magnification = 3.0× and
   Brightness GLOW800 = 50 %
   In GLOW800 fluorescence mode at least the fluorescence bars 1-6 have to be visible (E)!
3. Check if the fluorescence pseudocolor is the one you intend to have.



4. Check the colors (F–I) of the white lightimage 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 = 350 mm, Magnification = 3.0× and illumination = 50 % in GLOW800 fluorescence mode at least the fluorescence bars 1-6 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:
  - Luxmeter reading is ok
  - Bulb hours are within the range
  - Light guide is in proper shape

Contact the Leica service if more analysis is needed.

9 Operation

WARNING

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

- ► Only use fluorescence media approved for the planned application.

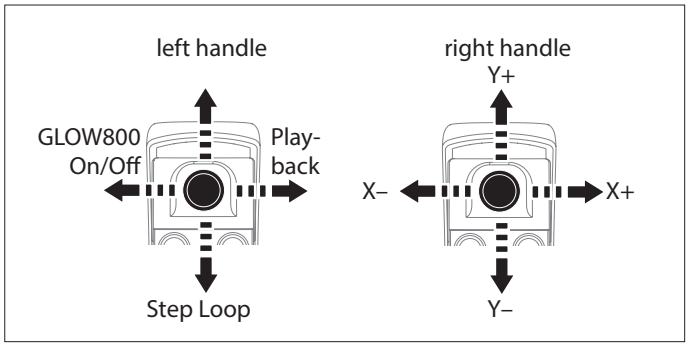
When using GLOW800 please ensure to have a Doppler Ultrasound or similar in place, in case of none or insufficient blood flow visualization out of the ICG/GLOW800 procedure is given.

9.1 Using the GLOW800

- ► Switch on the illumination of the Leica surgical microscope.
- ► Select a user: Select either the "Fluorescence Vascular GLOW800" user preset or an own GLOW800 user.

9.2 Controlling the GLOW800 functions

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



GLOW800 On/Off

The handle permits switching between white light mode (GLOW800 On/Off) and GLOW800 mode.

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

WARNING

Danger of injury to the patient due to excessive GLOW800 radiation.

- ► Avoid extended and/or excessively frequent use of GLOW800 radiation.

GLOW800 mode is disabled automatically no later than after 180 seconds (preset, the value can be changed) to prevent excessive exposure of the patient to GLOW800 radiation.

The "GLOW800 On/Off" function activates the GLOW800 illumination and the GLOW800 sensitive camera, connects the GLOW800 video signals to the system's video output, ports and the video is displayed on the monitor.
At the same time the recording of the GLOW800 video signals is started at the optional connected HDMD PRO recording unit.
When the "GLOW800 On/Off" button is pressed again, the system returns to white light mode and disables the GLOW800 functions and the GLOW800 recording is finished.

Replay

- ► If an optional HDMD PRO recording unit is provided, pressing the joystick to the right starts the replay of the last recorded loop on the recording unit.

Step loop

- ► If an optional HDMD PRO recording unit is provided, by repeatedly pressing the joystick downward, you can switch back to previously recorded GLOW800 loops.

10 GLOW Autofocus (optional)

10.1 Description

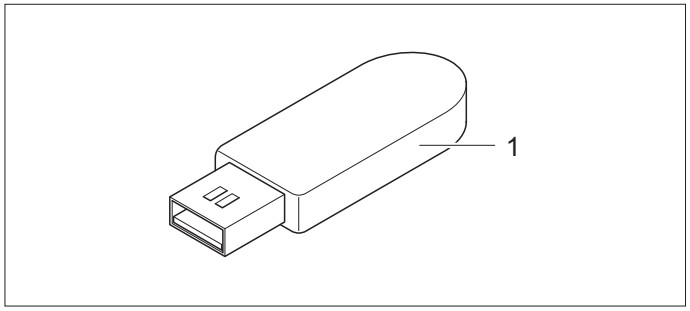
10.1.1 Function

The GLOW Autofocus function is used for the automatic focus adjustment for Leica surgical microscopes with Leica OH6, Leica OHX or ARveo control units.
In the default setting, the autofocus function is activated and automatic focussing is initiated each time when the brake is activated.
You can also start the automatic focussing via handle or foot switch.

Please refer to the user manual of the corresponding Leica surgical microscope.

10.2 Design

The GLOW Autofocus is an accessory to the Leica OH6, Leica OHX or ARveo control units.



1 GLOW Autofocus USB stick

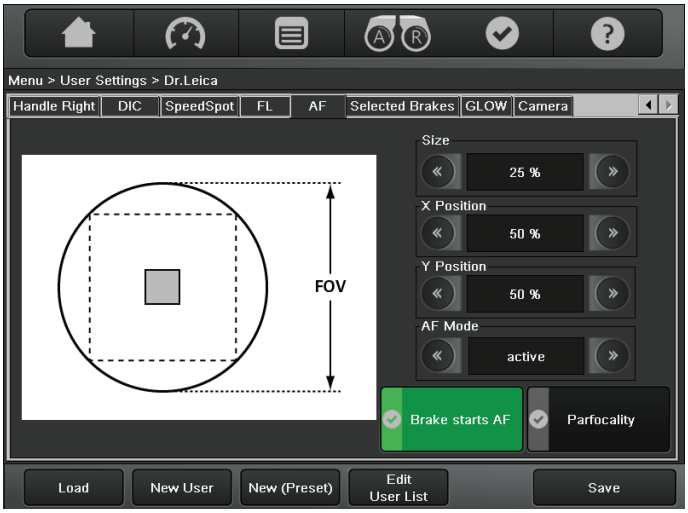
10.3 Installation

For the installation of the GLOW Autofocus please call a Leica service technician.

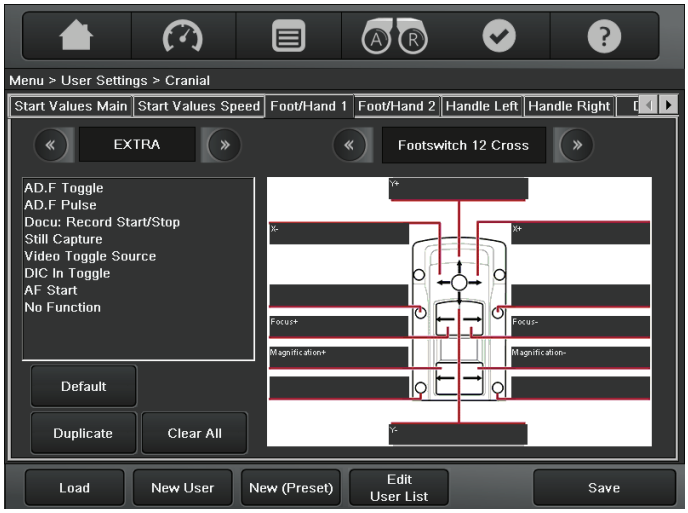
After installation of the GLOW Autofocus, the following is available in the menu:

- Autofocus button in the main menu

- Autofocus tab in the user settings



- Function "AF Start" available in the settings for foot/hand switches



In the default setting, the autofocus function is activated and automatic focussing is initiated each time when the brake is activated (Brake starts AF).

10.4 Working with the GLOW Autofocus system

To operate the Leica OH6, Leica OHX or ARveo control unit, read the user manuals of the corresponding surgical microscope systems.

The GLOW Autofocus system is controlled via the control unit of the Leica OH6, Leica OHX or ARveo. You can configure the following settings via the control unit:

- Activate/deactivate the Autofocus
- Activate/deactivate the parfocality function for diopter setting
- Change the size of the autofocus window
- Change the position of the autofocus window
- Assign a button on the footswitch/handswitch for starting the Autofocus
- Save the individual autofocus settings of the operating doctor

In the default setting after installation, the autofocus function is started each time the brakes are activated.

10.4.1 Activating/deactivating the GLOW Autofocus system

Via the Main menu

The Autofocus system is active, when the "Autofocus" button is highlighted in green.

Deactivating the GLOW Autofocus system

► Click the green "Autofocus" button.
A message is displayed and in the following the "Autofocus" button will be gray.

Activating the GLOW Autofocus system

► Click the gray "Autofocus" button.
A prompt is displayed if you really want to activate the autofocus system.
► Press "Confirm" to activate the autofocus system.

Via controls

If you do not want automatic focussing each time when the brake is activated, you can deactivate Autofocus and assign the function to a button on a handle or foot switch instead.

► Press the assigned button.
Automatic focussing is executed once.

10.4.2 Activating/deactivating the parfocality function for diopter setting

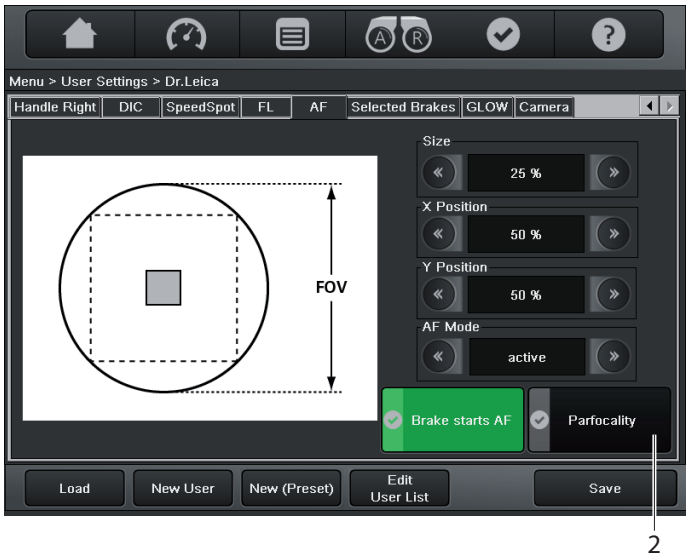
The parfocality function can be activated in addition to the Autofocus function.

With the Autofocus Parfocality function the adjustment of the user´s diopter setting is supported.

► Press the "Parfocal" button (1) on the GUI main page to get the GLOW800 fine focus in parfocal position.
► If "Parfocality" (2) is activated in your user settings and a button is assigned to "Autofocus" press this button.

The "Autofocus" function autofocuses on the preselected object area at highest magnification and will present a sharp video image at a medium magnification in parfocal position.
All observers can now adapt the diopters for each eyepiece to get the preselected object area in focus.

10.4.3 Autofocus settings



The small grey field in the middle represents the Autofocus window. The dotted line represents the maximum available Autofocus window.

Size

► Adjust the size of the Autofocus window.
Possible settings 10 % to 100 %
Default setting 25 % (recommended)

X Position / Y Position

► Adjust the X and Y position of the Autofocus window.
Possible settings 0 % to 100 %
Default setting 50 % each, so the Autofocus window is exactly in the middle (recommended)

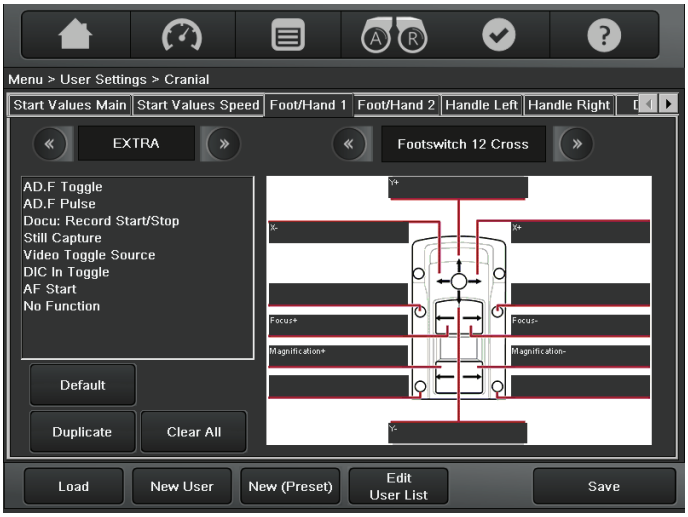
AF Mode

► Activate/deactivate AF Mode.

Brake starts AF

- When activated, releasing the break button starts the Autofocus function.
- When deactivated and AF Mode set to active, the Autofocus function can be started using another key defined in the user settings.

10.4.4 Assigning a button for starting the Autofocus function



► Select a user preset.
► Select the "Foot/Hand 1" or "Foot/Hand 2" tab.
In the list of available functions "AF Start" is displayed.
► Assign the "AF Start" function to a button.

For more details on assigning functions to the foot/hand switch and saving user settings refer to the user manuals of the corresponding surgical microscope system.

10.4.5 Autofocus Scan

If not otherwise specified in the Autofocus service menu, the Autofocus will scan up and down for the best focal plan in the WD range from 225 to 600 mm starting at the present position.

11 Care and maintenance

GLOW800 is an accessory for a Leica surgical microscope. For care and maintenance please refer to the user manual of the Leica surgical microscope.

12 Disposal

The respective applcable 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?

13.1 General

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

13.2 GLOW800

13.2.1 Calibration

Observation	Cause	Remedy
The GLOW800 injection in the eyepiece does not fit with the optical image.	The CaptiView calibration is lost	▶ The calibration has to be redone. ▶ Get in contact with Leica Service.
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. ▶ Get in contact with Leica Service.

13.2.2 VPU

Observation	Cause	Remedy
Incorrect information is shown for interpretation to the user	Device algorithm calibration failure	▶ Use reset button to reboot/reset the system.
	Improper pre-operational check	▶ Repeat pre-operational procedure. ▶ Get in contact with Leica Service.
The system is not booting up	Electronic failure	▶ Get in contact with Leica Service.
The video signal shows red cross /Red "X"	Camera signal lost	▶ Use reset button to reboot/reset of the system. ▶ Get in contact with Leica Service.
The system is frozen/ no reaction	Software initialization failure	▶ Use reset button to reboot/reset the system.

13.2.3 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 your receive a sharp GLOW800 image

Observation	Cause	Remedy
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.
Double fluorescence, one floating with latency on the monitor and in the record	When injecting the fluorescence in the left eyepiece the fluorecence image is recorded and displayed on the monitor twice	▶ To avoid the double fluorescence image the overlay in the left eyepiece has to be switched off.
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 dosis if possible. With an ICG dosage of 12.5 mg/75 kg the GLOW800 will generate fluorescence images with good visibilty 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 fibre light guide or illumination beam path)	▶ Check the illumination bulb life time and the illumination system. ▶ Call the Leica Service for professional investigation when needed.

13.2.4 Corrections by the user

Observation	Cause	Remedy
Neither a sharp GLOW800 nor a sharp White Light image on the monitor	The video fine focus is not adjusted correctly	▶ Press the parfocal button or adjust the fine focus manually by pressing the buttons (+) or (-).
	The diopter settings of the surgeon's eyepiece are incorrect and you work off parfocality	▶ Press the parfocal button, 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 %.

Observation	Cause	Remedy
Injected fluorescence image in the eyepiece is faint/pale although the signal on the monitor is good	The fluorescence signal is too low for a good overlay at higher magnifications and WDs	▶ Reduce the magnification and check the illumination/excitation settings to be at least 100 %.
	The brightness of the injected image is too low	▶ Increase the brightness of the CaptiView injection.
The GLOW800 image is not bright enough	In lower WDs and high magnification BrightCare Plus 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.
The flow signal in fine vessels is not visible in some cases, just strong FL is indicated	The GLOW “Lower Threshold” is set too high possibly by an unintended handle command	▶ To avoid unintended changes of the threshold check if GLOW “Lower Threshold” +” or “–“ function is set active on a handle button. If yes delete this function in the handle settings.
The flow signal to object contrast too low	The color “Saturation” of GLOW image is too high	▶ Reduce the GLOW “Saturation”.
The white light part of the GLOW image lacks in colors	The color “Saturation” of GLOW image is too low	▶ Increase the GLOW “Saturation”. **Note** Increased “Saturation” can reduce the contrast of the superimposed FL information on top of the WL object image.
The injected fluorescence image in the eyepiece is faint/pale although the signal on the monitor is good	The fluorescence signal is too low for a good overlay at higher magnifications and WDs	▶ Reduce the magnification and check the illumination/excitation settings to be at least 100 %.
	2) The brightness of the injected image is too low	▶ Increase the brightness of the Captiview injection.
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 %.

13.2.5 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 On/Off 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 disadjusted.	▶ Get in contact with 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 lightsource 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 3D monitors	A viewing position below and/or laterally off the monitor axis get the observed image darker	▶ Align the monitor axis to fit your observation direction.

13.2.6 HDMD

Observation	Cause	Remedy
Neither a GLOW fluorescence image on the monitor, nor injected, although it worked before	No more disc space on the HDMD PRO HDD.	▶ Check the capacity of the HDD: ▶ If the HDMD PRO HDD is full, save and delete not used user data to generate sufficient capacity.

13.3 GLOW Autofocus system

Malfunction	Cause	Remedy
The microscope does not find the focus	The focus is outside the configured value for the relative autofocus mode	▶ Have the value for the relative autofocus mode corrected by the service technician.
	The focus does not find a level image plane in the configure autofocus window	▶ Reduce the autofocus window.

14 Technical data

14.1 Technical data GLOW800

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

GLOW800 spectrums

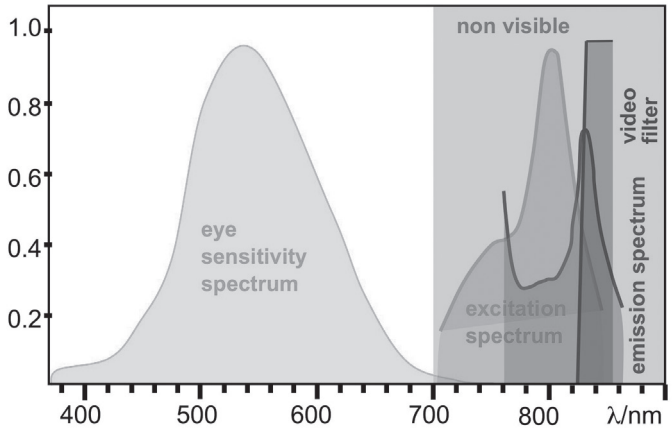
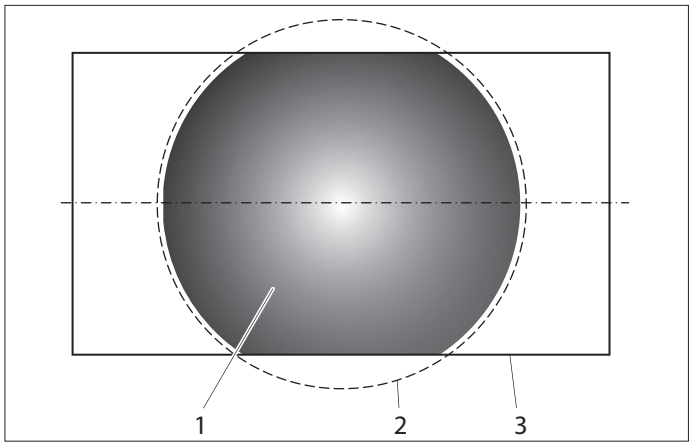


Image sensor	3× 1/1.2" inch
NIR camera	High sensitive, HD color camera

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

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 Compatability

Leica surgical microscopes	Leica M530 OH6 Leica M530 OHX ARveo

14.3 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

14.4 Standards fulfilled

CE conformity

- Medical Devices Directive 93/42/EEC including amendments.
- Classification: Class IIa, in compliance with Annex IX, Rule 1 and Rule 10 of the Medical Devices Directive.
- Medical electrical equipment, Part 1: Generally defined for the security in IEC 60601-1; EN 60601-1; UL 60601-1; CAN/CSA-C22.2 NO. 601.1-M90.
- Electromagnetic compatibility: IEC 60601-1-2; EN 60601-1-2.
- The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standards ISO 13485 relating to quality management, quality assurance and environmental management.

15 Manufacturer's declaration of electromagnetic compatibility (EMC)

The GLOW800 was tested in combination with Leica surgical microscopes. For the EMC declaration, please refer to the user manual of the Leica surgical microscope.

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