From Eye to Insight

Leica
MICROSYSTEMS

MEDICAL DIVISION

GLOW800

User Manual

10 747 241 - Version 00

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
Fax: +41 71 726 3334

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 in the cerebral vascular area and bypass grafts during coronary artery bypass (CABG) surgery, as well as blood flow during plastic and reconstructive surgery.

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 MFL800 test card.

- ► Do not use the MFL800 test card in the sterile field.
- ► Use only in non-sterile environment.

WARNING

User selected with a programmed fluorescence function.

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

WARNING

Risk of infection due to insterile MFL800 test card.

- ► Check the microscope illumination in non-sterile environment only.

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.

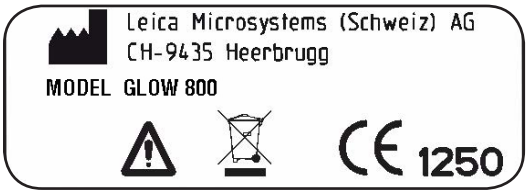
- ► Avoid extended and/or excessively frequent use of GLOW800 radiation.
- ► GLOW800 mode is disabled automatically no later than after 180 seconds to prevent excessive exposure of the patient to GLOW800 radiation.

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. This 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 or via user settings you can switch between visible and GLOW800 light.

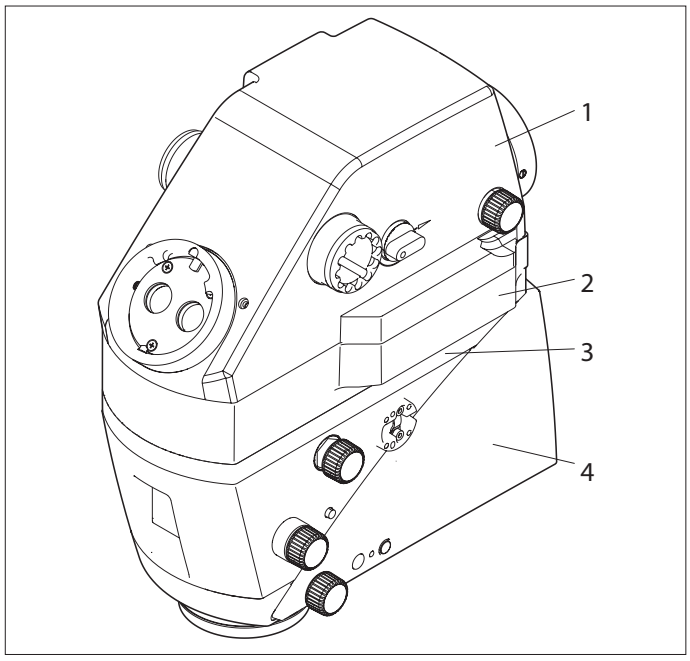
> **!** Please refer to the user manual of the corresponding Leica surgical microscope.

3.2 Design

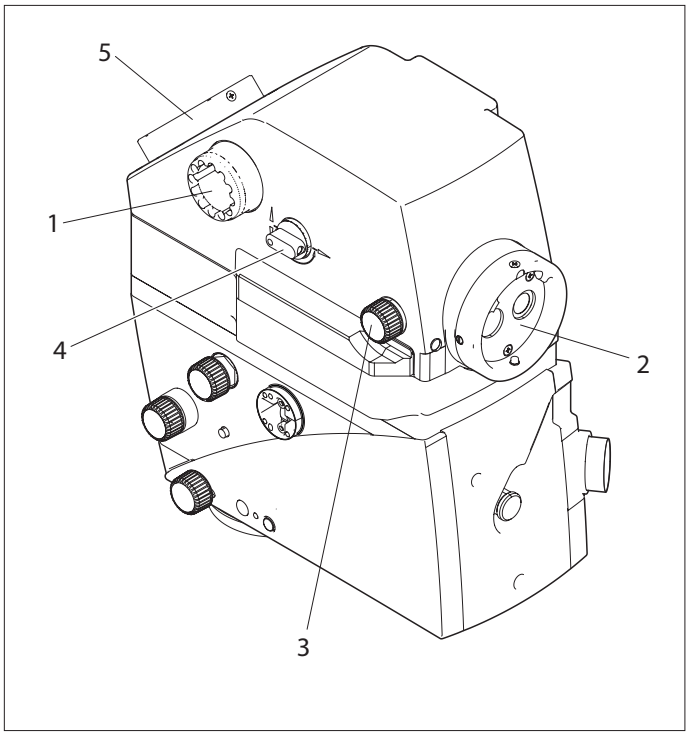
GLOW800 is an accessory to the Surgical Operating Microscope and is incorporated into the M530 optics carrier.

GLOW800 is composed of the following components:
A GLOW800 ULT, see chapter 3.2.1, position (1)
B GLOW800 VPU, see chapter 3.2.2, position (3)
C GLOW800 filters, see chapter 3.2.2, in position (4)

3.2.1 M530 optics carrier with GLOW800



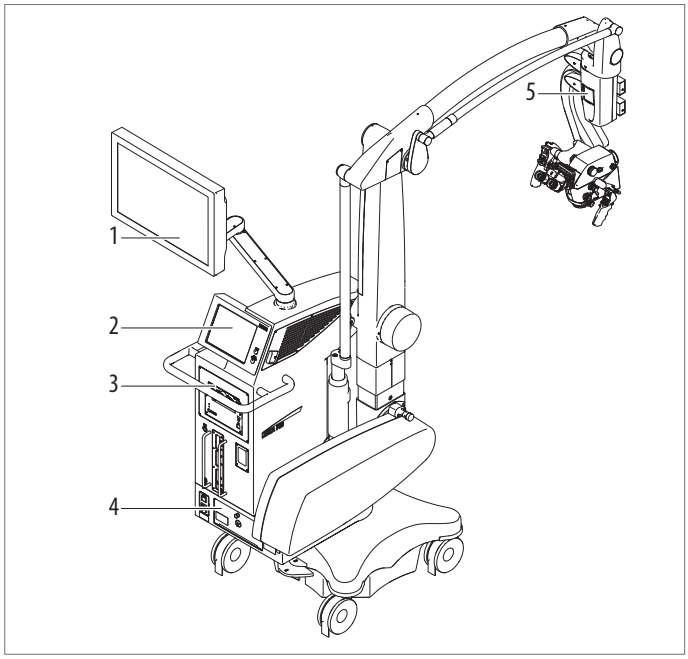
1 GLOW800 ULT
2 Image Injection module Leica CaptiView (optional)
3 Fluorescence module Leica FL400, FL560 or FL400/560 (optional)
4 M530 Optics Carrier



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

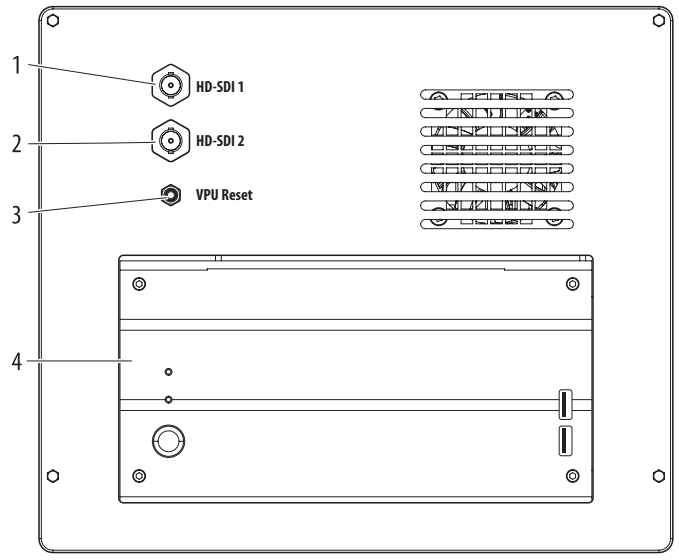
- GLOW800 is built into the housing of the ULT530
- Integrated cameras for visible light and for NIR light (fluorescence), one common remote controlled fine focus for both

3.2.2 Leica OHX surgical microscope with GLOW800 components



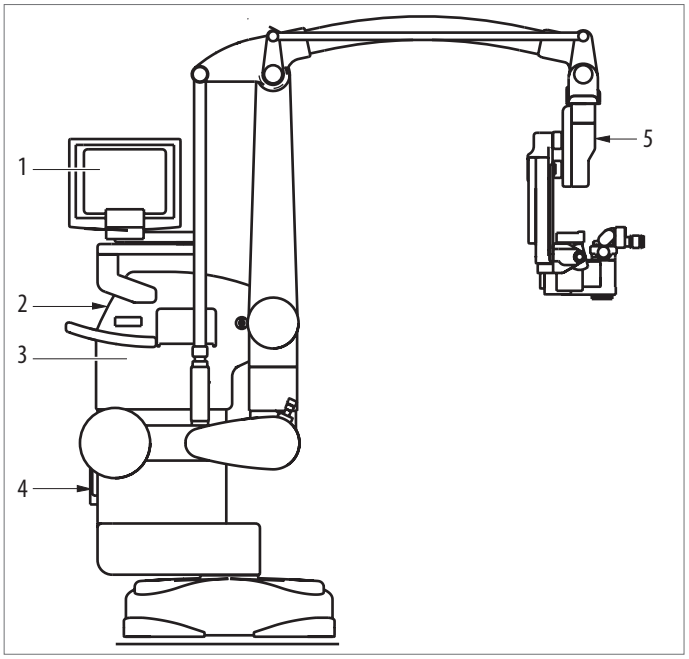
1 Monitor (optional)
2 GUI screen
3 GLOW800 VPU (see chapter 3.2.3)
4 Illumination unit with GLOW800 filters
5 Surgeon panel

3.2.3 GLOW800 VPU



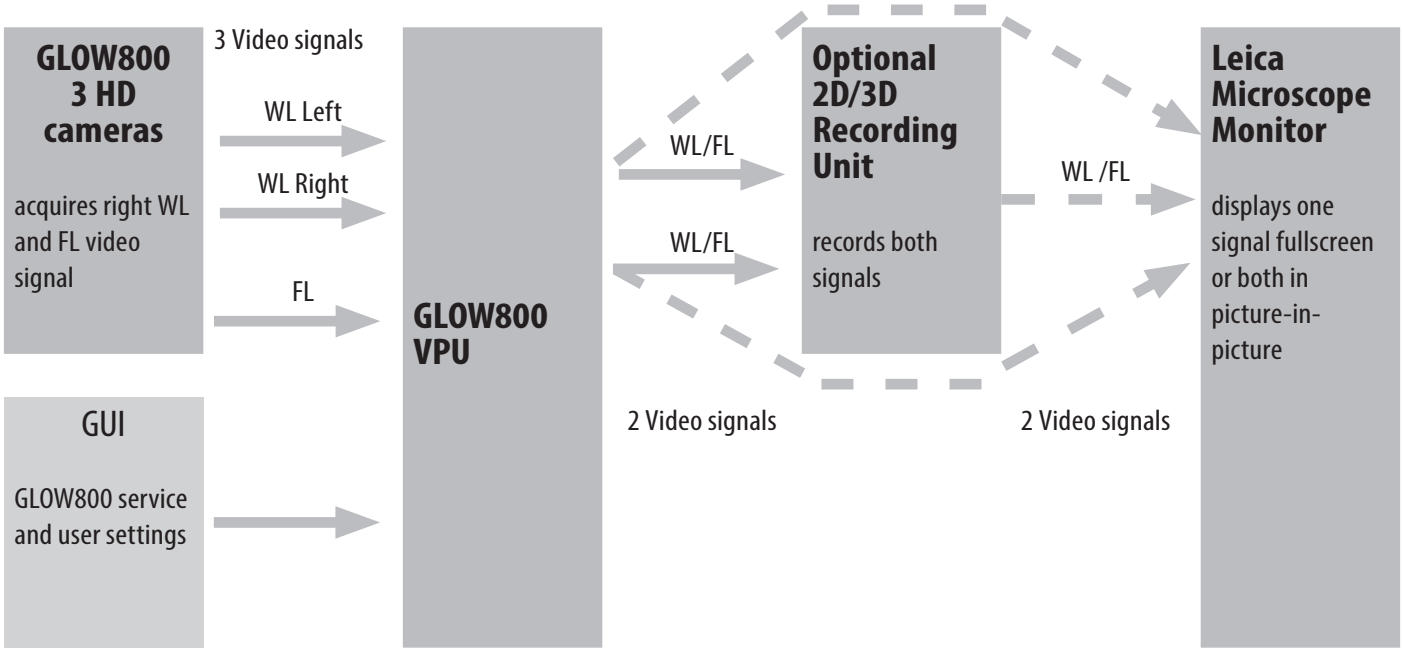
1 Video signal output 1
2 Video signal output 2
3 Reset button to reboot/reset of the system
4 Documentation system (optional)

3.2.4 Leica OH6 surgical microscope with GLOW800 components



1 Monitor (optional)
2 GUI screen
3 GLOW800 VPU (see chapter 3.2.3)
4 Illumination unit
5 Status LED

4 GLOW800 System Components - Signal overview



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

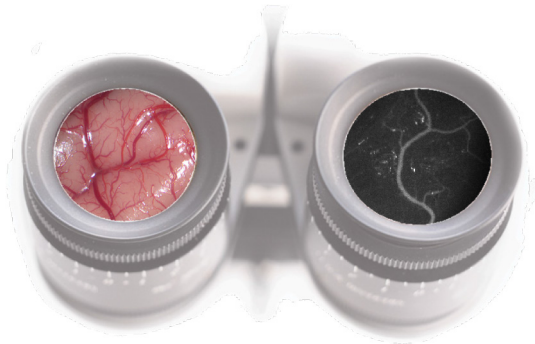
5 GLOW800 image injection

If an optional CaptiView image injection system is integrated into the surgical microscope M530 OH6 and M530 OHX, the fluorescence information can be observed in the right eyepiece, according to the selected fluorescence observation type.

(Observation Type A)

White light image with embedded fluorescence in pseudo color video*

(Observation Type B)



Black & White fluorescence video*

Please refer to the user manual of the corresponding Leica image injection system (CaptiView).

* Disclaimer: Representative pictures.

6 Description

6.1 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 and M530 OHX.

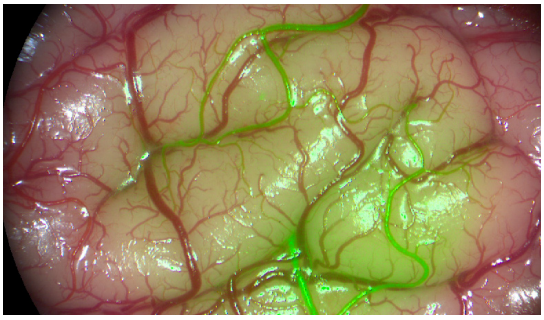
When activating the GLOW800 mode, the white light illumination of the Leica microscope stand (Leica OH6 or OHX) is extended to InfraRed (IR), to excite the fluorophore (ICG).

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.

6.1.1 Fluorescence observation on the microscope video monitor

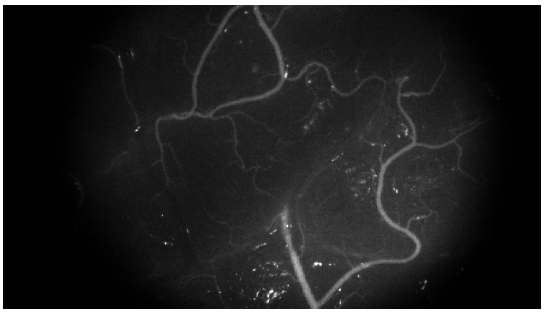
GLOW800 offers two different types to observe the fluorescence video signal on an attached Leica surgical microscope video monitor (optional):

White light object view with the embedded fluorescence signal in pseudo color:



White light fluorescence observation (WL/FL) Standard

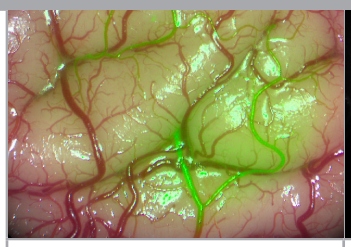
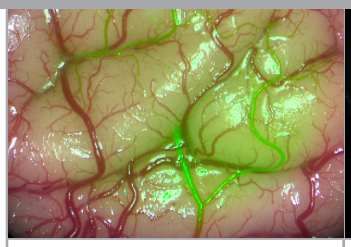
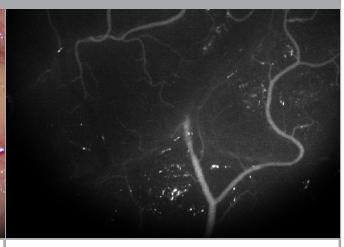
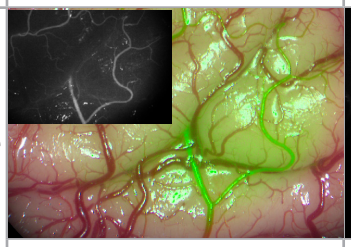
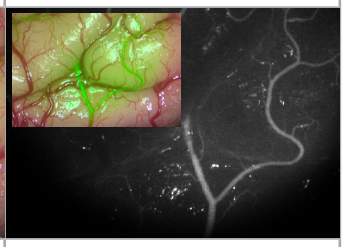
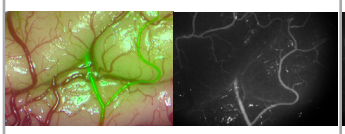
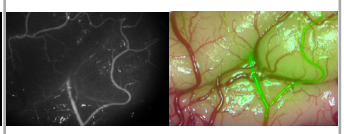
Black & White (B & W) fluorescence view e.g. with GLOW800:



Black & White fluorescence observation (B & W/FL)

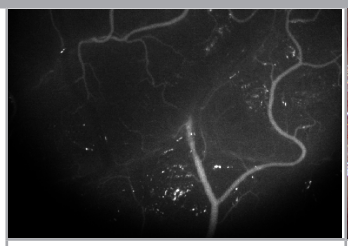
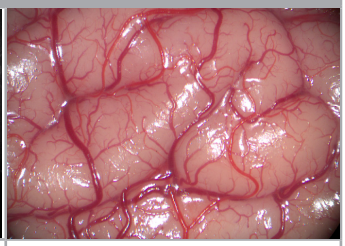
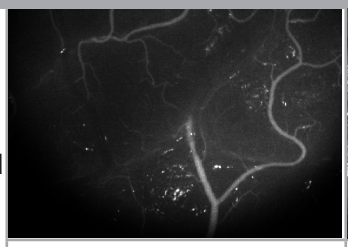
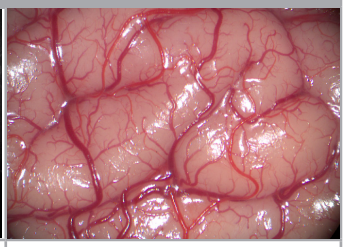
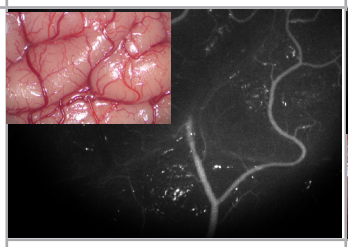
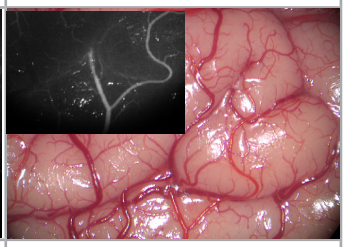
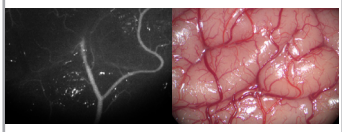
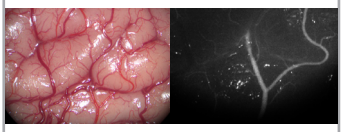
6.1.2 Fluorescence observation and recording with a documentation system

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 display are done in the following way:

<table>
<tr><th colspan="4">White light fluorescence observation (WL/FL) with Black & White fluorescence observation (B & W/FL)</th></tr>
<tr><td colspan="4">GLOW800 Image processing</td></tr>
<tr><td colspan="2" rowspan="2">Two provided videos for visualization and recording</td><td>  </td><td>  </td></tr>
<tr><td>Main video 1</td><td>2nd video</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, both videos are recorded</td><td>  </td><td>  </td></tr>
<tr><td>Main video 1</td><td>2nd video</td></tr>
<tr><td rowspan="2">Setting 2</td><td rowspan="2">Picture-in-Picture view on the video monitor, both videos are recorded</td><td>  </td><td>  </td></tr>
<tr><td>Main video 1 = full screen, 2nd video = window</td><td>2nd video = full screen, main video 1 = 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>  </td></tr>
<tr><td>Left = video 1, right = 2nd video</td><td>Left = 2nd video video 1, right = video 1</td></tr>
</table>

The GLOW800 VPU generates two videos which can be recorded by an optional documentation system if integrated into the surgical microscope.

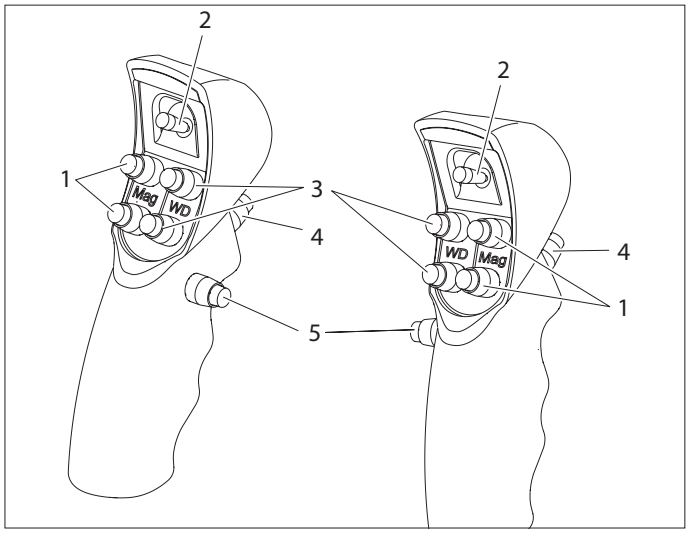
The records and visualization are done is the following way:

<table>
<tr><th colspan="4">Black & White fluorescence observation (B & W/FL) with white light fluorescence observation (WL/FL)</th></tr>
<tr><td colspan="4">GLOW800 Image processing</td></tr>
<tr><td colspan="2" rowspan="2">Two provided videos for visualization and recording</td><td>  </td><td>  </td></tr>
<tr><td>Main video 1</td><td>2nd video</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, both videos are recorded</td><td>  </td><td>  </td></tr>
<tr><td>Main video 1</td><td>2nd video</td></tr>
<tr><td rowspan="2">Setting 2</td><td rowspan="2">Picture-in-Picture view on the video monitor, both videos are recorded</td><td>  </td><td>  </td></tr>
<tr><td>Main video 1 = full screen,
2nd video = window</td><td>2nd video = full screen,
main video 1 = 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>  </td></tr>
<tr><td>Left = video 1,
right = 2nd video</td><td>Left = 2nd video video 1,
right = video 1</td></tr>
</table>

The documentation system replay function allows to observe the fluorescence video once or steadily in the same way as it was displayed before or during the record (first video). Additionally, the second recorded video can be selected for observation, either as 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.

7 Controls

7.1 Handles

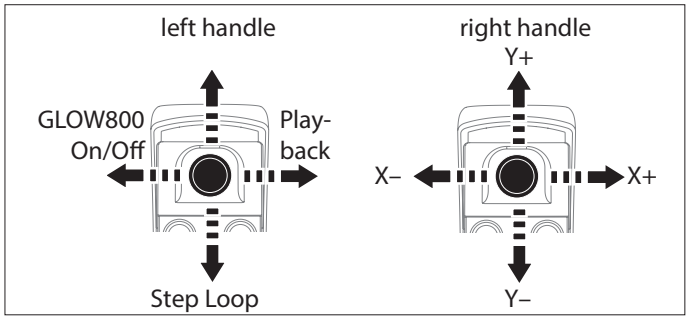


Assignment in the factory setting

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

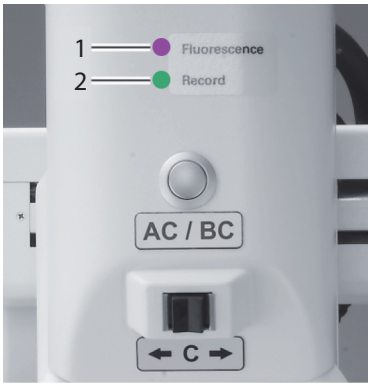


It is recommended to use the 4-function joystick (2) to control the GLOW800 as it is defined in the GLOW800 preset, although you can assign the switches 1, 2, 3 and 5 of the handles individually in the configuration menu to fit the needs of each user.
In all presets, switch (4) releases all brakes. This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

7.2 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:

7.2.1 Leica OH6 - Status LED



1 Status LED for fluorescence
2 Status LED for recording

The fluorescence status LED (1) indicates the fluorescence mode selection.

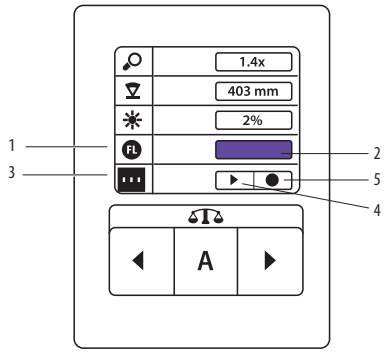
▢	white:	no fluorescence, white light mode
	blue :	FL400 mode active
	cyan:	FL560 mode active
	yellow:	FL800 mode active
	magenta:	GLOW800 mode active

The status LED for recording (2) light up in

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

7.2.2 Leica OHX surgeon panel

The surgeon panel indicates the fluorescence mode selected and on/off status.



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

The fluorescence status color bar (4) indicates the fluorescence mode selection.

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

- ► 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).

8 Preparation before surgery

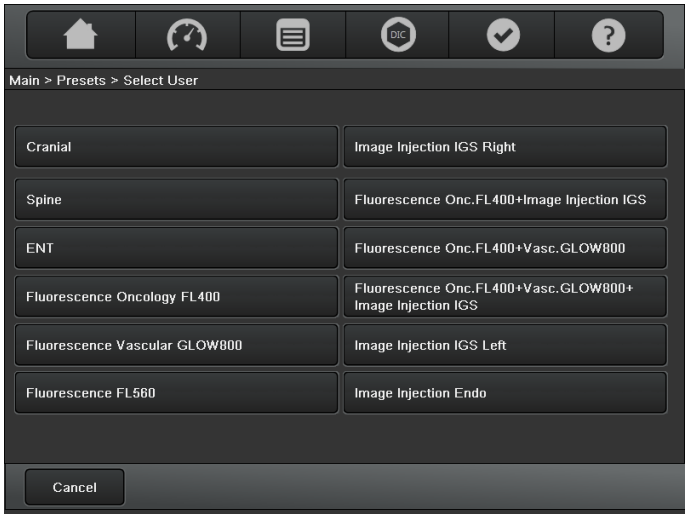
8.1 Adjustments

8.1.1 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.
The availbale presets are displayed.



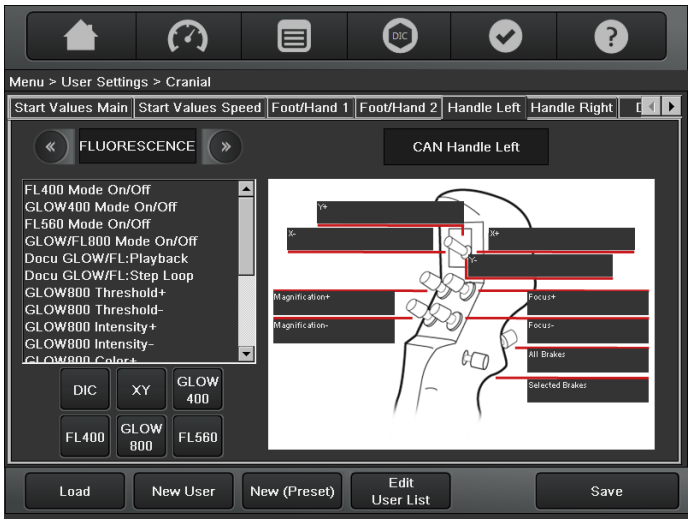
Select the "Fluorescence Vascular GLOW800" user preset.

► 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.

► Select the "Handle Left" or "Handle Right" tab.



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.

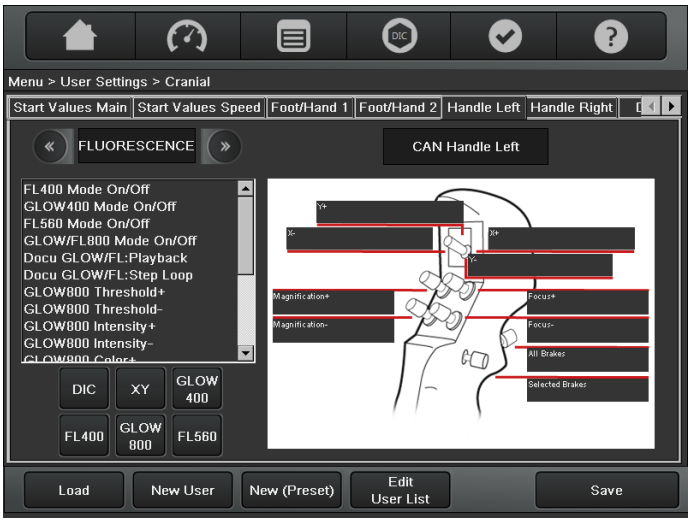
These settings can later be edited at any time via the User Settings menu.

Creating your own GLOW800 user

- ► Click on the "Menu" quick access button (1).

- ► Select "User Settings".

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



- ► In the left selection field, select the "Fluorescence" function group by clicking on it.
- ► Assign the function "GLOW800 Mode On/Off" 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 the function "docu FL: playback".
- ► Click on "Save".
- ► Select an empty position in the user list.
- ► Enter the desired user name via the keyboard, e.g. "ICG User".
- ► Click on the "Save" button to save your settings under the user name entered at the desired location.

Brightness

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

► Open the "FL" tab to set the brightness in GLOW800 mode to an adequate level.

Note We recommend to set the brightness to 100 % (Default).

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

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.

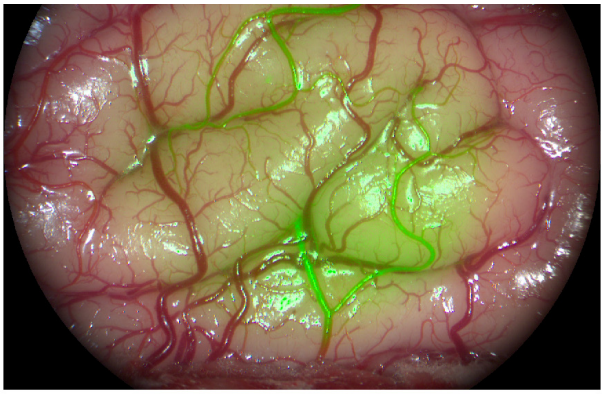
8.2 GLOW800 User settings menu

The tab offers specific GLOW800 settings for each user:

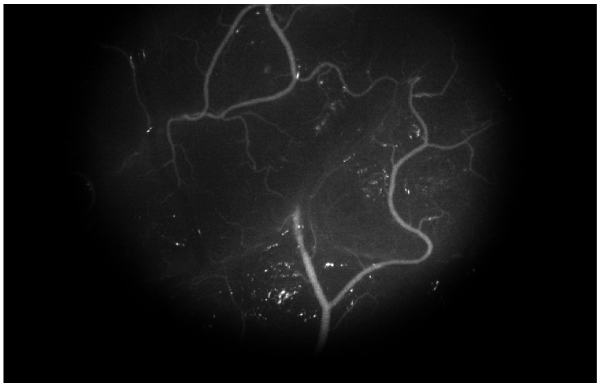
8.2.1 Output mode

With «output mode» one of two types of fluorescence observation can be chosen:

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



- Standard Black & White fluorescence view (Black & White fluorescence observation = B & W/FL)



See as well Chapter 6.1.1, page 7

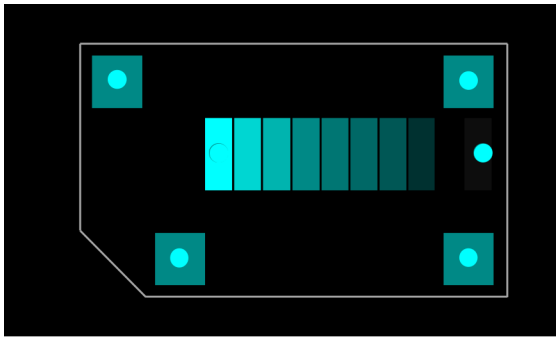
8.2.2 Threshold

With «threshold» the fluorescence intensity level can be chosen from which on the fluorescence signal is displayed in the white light fluorescence and Black & White fluorescence view.

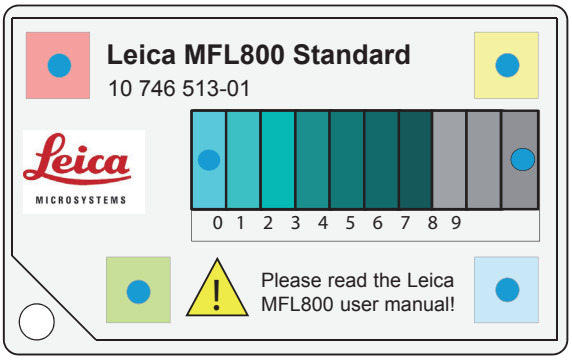
Selectable threshold values range from:
0 % = display of the full range of low to high intensity fluorescence signals to 100 % = just high intensity fluorescence signals.

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

Threshold at 0 % - all fluorescence intensities are displayed

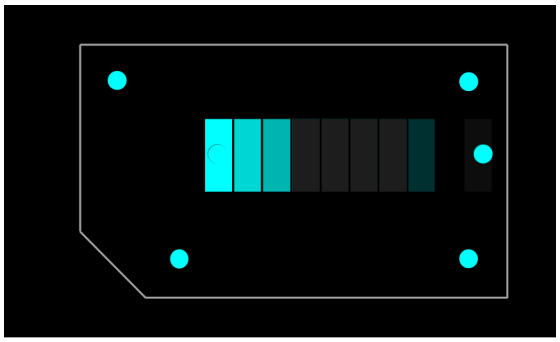


Black & White fluorescence observation
(Video monitor)

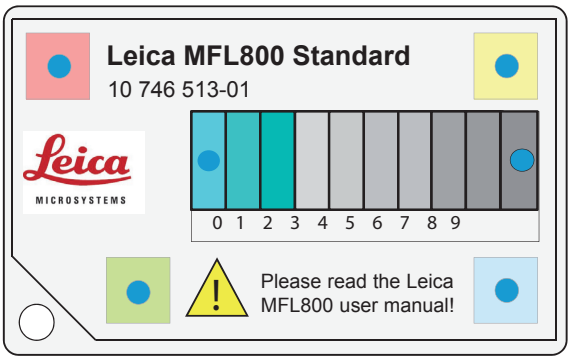


White light fluorescence observation
(Video monitor)

Threshold at 100 % - middle to high intensity is displayed only



Black & White fluorescence observation
(Video monitor)



White light fluorescence observation
(Video monitor)

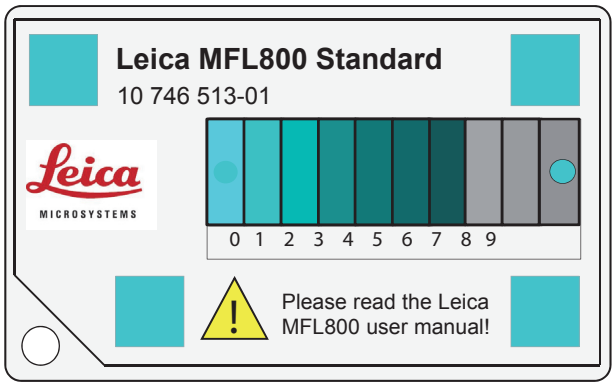
Reference section 9 for test card details.

8.2.3 Color

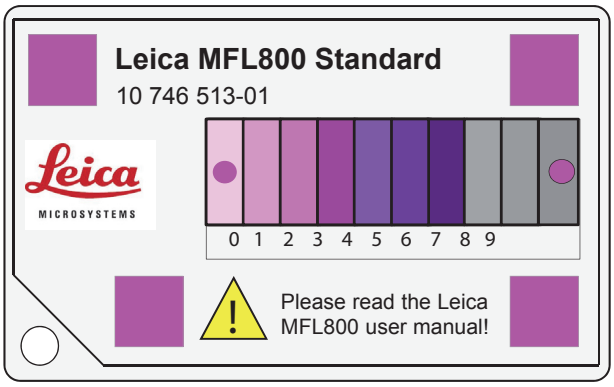
With «color» the pseudo color of the fluorescence signal can be chosen.
Selectable color values are from 1=magenta to 7=chartreuse. The chosen color defines the appearance of the fluorescence on top of the white light image to optimize the color contrast between the colors of the object in white light and the fluorescence signal.

	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
8			
9			

Displaying the fluorescence with color #5 - dark cyan in white light fluorescence observation #5 is the default color in the GLOW800 preset (Video monitor)



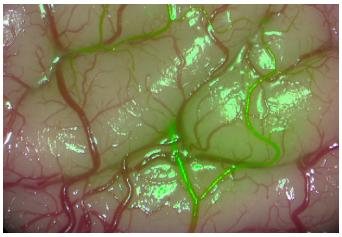
Displaying the fluorescence with color #1 – magenta in white light fluorescence observation (Video monitor)



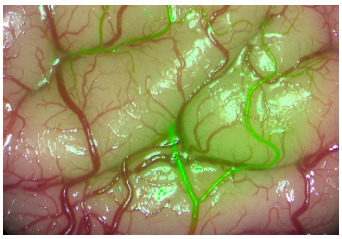
8.2.4 Intensity

«Intensity» adjusts the fluorescence contrast, brightness and transparency in relation to the object details.
The intensity values range from 0 % to 100 %. 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.

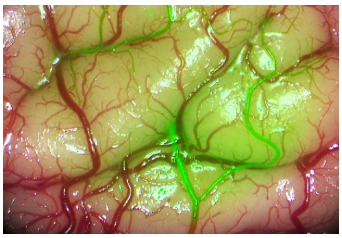
Minimum intensity setting – 0 %



Medium intensity setting – 50 %



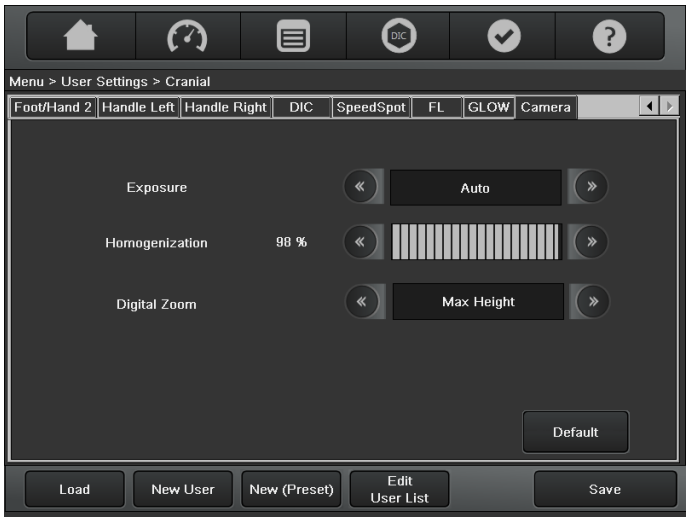
Maximum intensity setting – 100 %



8.2.5 Apply button

By pressing the "Apply" button 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.

8.3 User settings camera

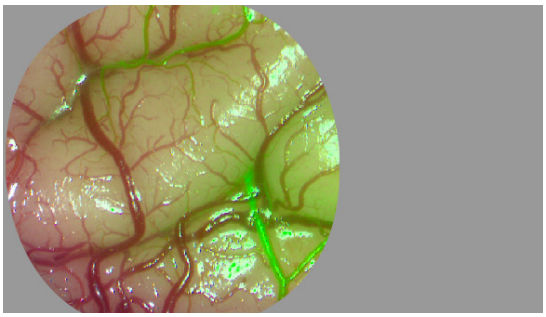


8.3.1 Digital zoom

With «digital zoom» the display format is adjusted to the needs of each GLOW800 user. There are three formats available:

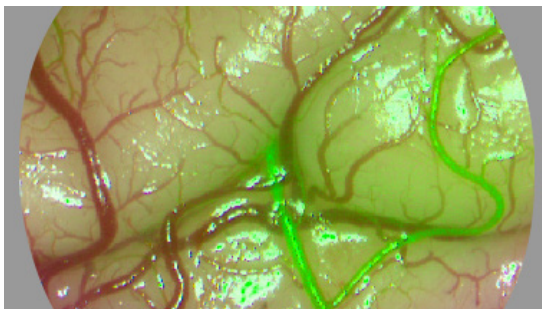
Max. Height:
fits the maximum detected field of view on the screen of the documentation monitor

► nearly round image format – full video resolution



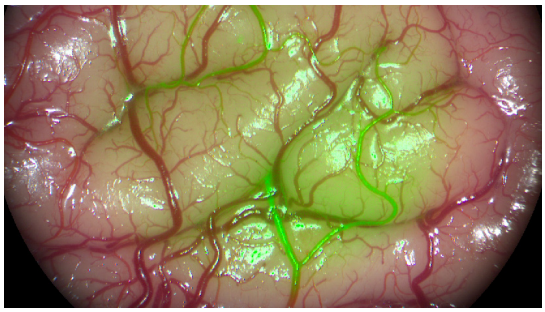
Full width
fits the full horizontal field of view on the screen of the documentation monitor

► 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

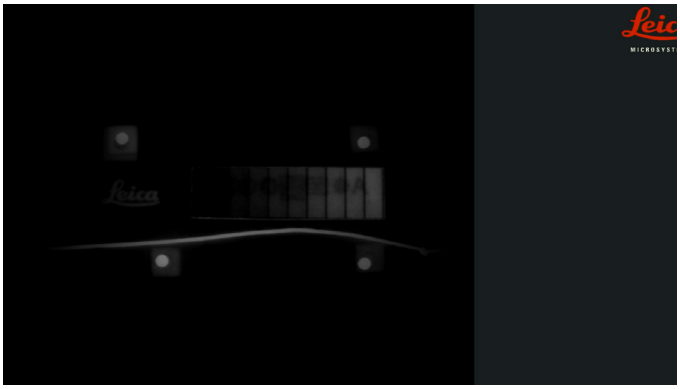
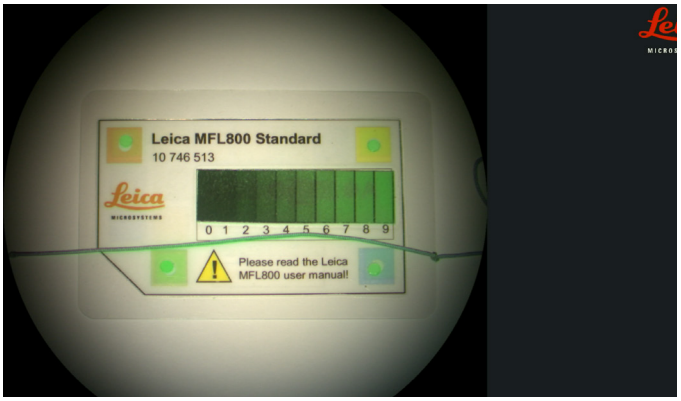
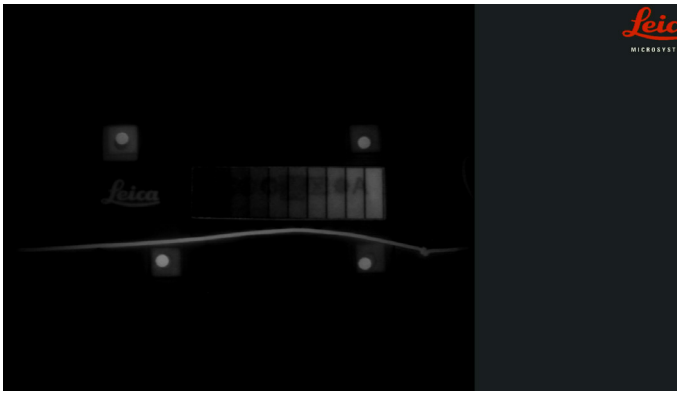
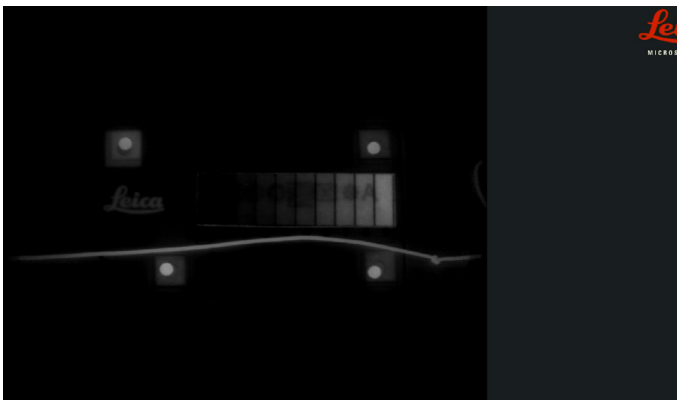
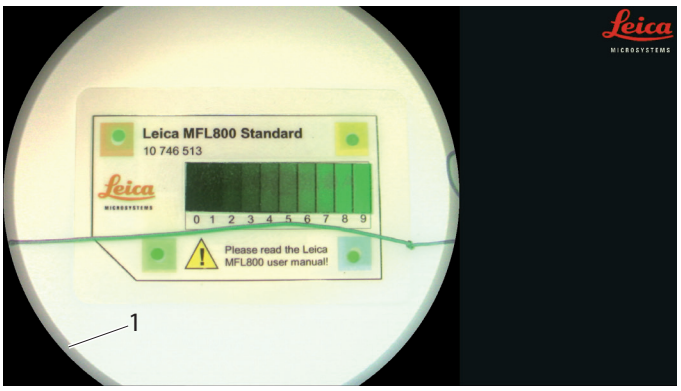


8.3.2 Exposure

"Exposure" 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.

8.3.3 Homogenization

With «homogenization» the effect of center-weighted illumination can be compensated. The homogenization takes place for the GLOW800 fluorescence and the white light image.
The homogenization values range from 0 % (no homogenization) to 100 % (maximum homogenization).

Black & White light fluorescence image homogenization	**GLOW800 white light fluorescence image homogenization**
No homogenization – 0 %	No homogenization – 0 %
	
Medium homogenization – 50 %	Medium homogenization – 50 %
	
Maximum homogenization – 100 %	Maximum homogenization – 100 %
	

The area at the periphery which cannot be homogenized is marked with a transparent grey overlay (1).

9 Check the illumination and function & adjustement

9.1 Test card

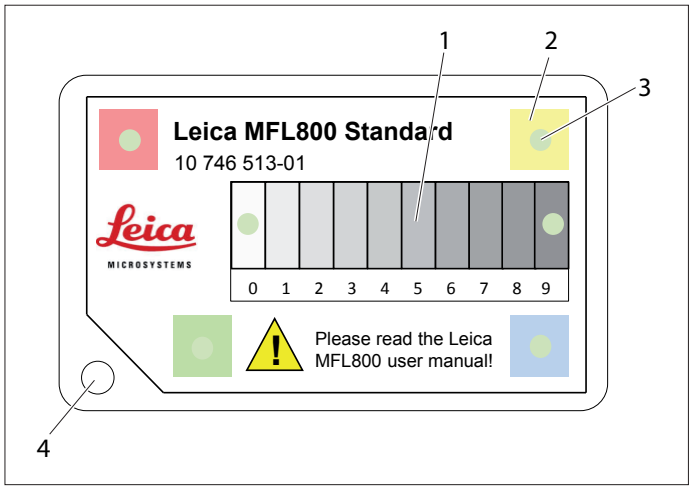
To check and test the GLOW800 function, to verify the proper adjustment of the white light and fluorescence image and to verify the illumination level the MFL800 test card has to be used.

WARNING

Risk of infection due to insterile MFL800 test card.

- ► Do not use the MFL800 test card in the sterile field.
- ► Use only in non-sterile environment.

Please prepare the test as follows:



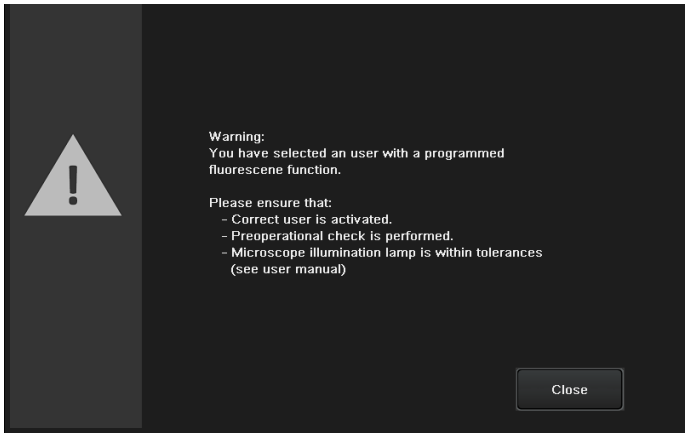
1 Stepwise decreasing NIR Intensity fields 0=bright to 9=dark
2 Low intensity NIR fluorescence area including 4 different white light color areas
3 Round spot high intensity NIR fluorescence signal
4 Hole to fix the card

9.2 Preparation

WARNING

User selected with a programmed fluorescence function.

- ► Correct user is activated.
- ► Preperational 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 MFL800 test card below the microscope.

WARNING

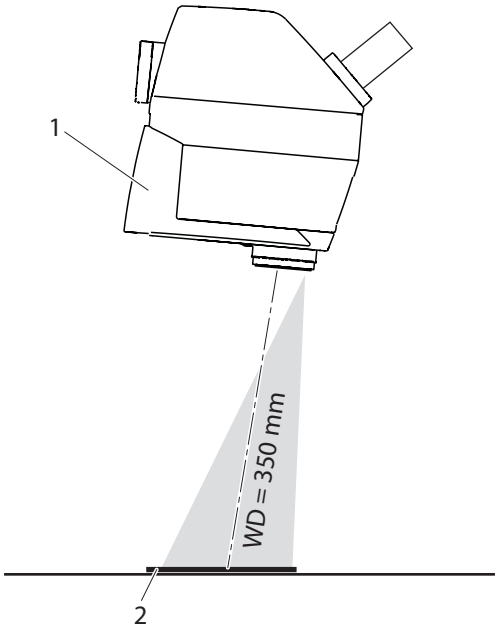
Risk of infection due to insterile MFL800 test card.

- ► Check the microscope illumination in non-sterile environment only.

- ► Adjust the working distance (WD) to 350 mm.
- ► To avoid reflexes position the microscope in a small, but sufficient angle over the test card.

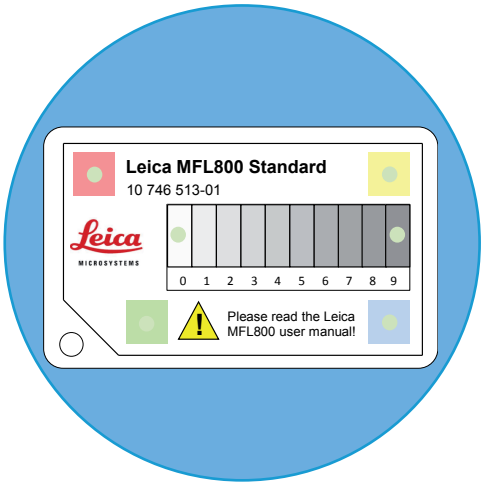
Take care to ensure the precise parfocal setting of the Leica surgical microscope. Follow the instructions on parfocal setup.

- ► Follow the instructions on parfocal setup.
- ► Get in focus by repositioning the microscope at highest magnification.
- ► 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 MFL800 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.

9.3 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

Sterility

- ► Apply the sterile drape.

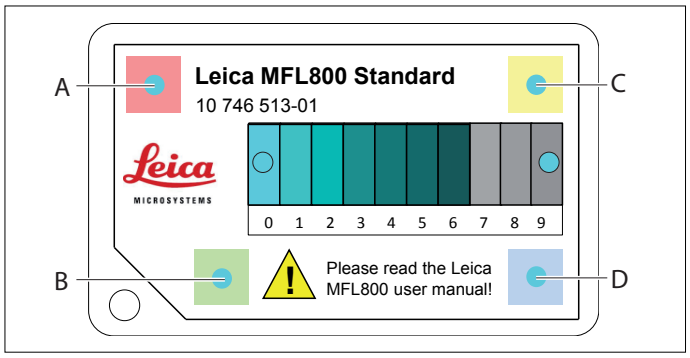
For sterilizable components of the Leica surgical microscope refer to the corresponding user manual.

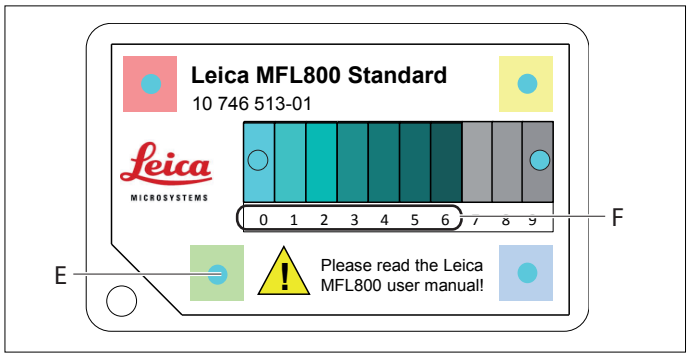
9.4 Test card functional areas

Tests in white light fluorescence observation mode

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

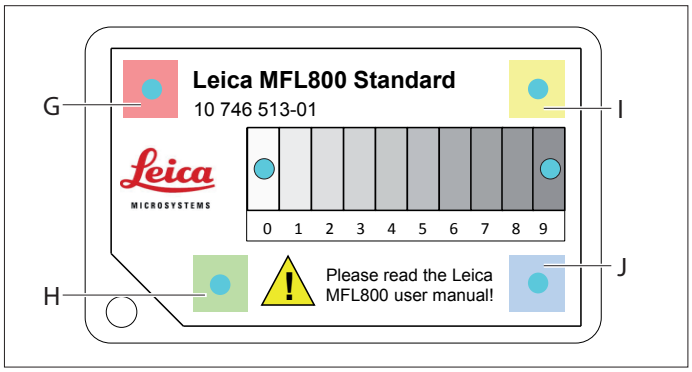
1. All bright fluorescence dots have to fit precisely into the holes of the color squares (A-D).





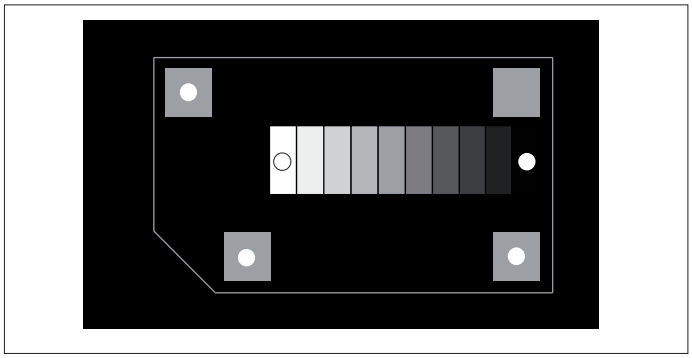
2. Check the fluorescence intensity (E).
   At the required WD = 350mm,
   Magnification = 3.0× and
   illumination = 50 % in GLOW800
   fluorescence mode: the fluorescence bars 1-6
   have to be visible (F) !

3. Check if the fluorescence pseudo color is the one you intend to have.



4. Check the colors (G-J) 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



5. Check the fluorescence intensity.
   At the required WD = 350mm,
   Magnification = 3.0× and
   illumination = 50 % in GLOW800
   fluorescence mode: the fluorescence bars 1-6
   have to be visible !

10 Operation

WARNING

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

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

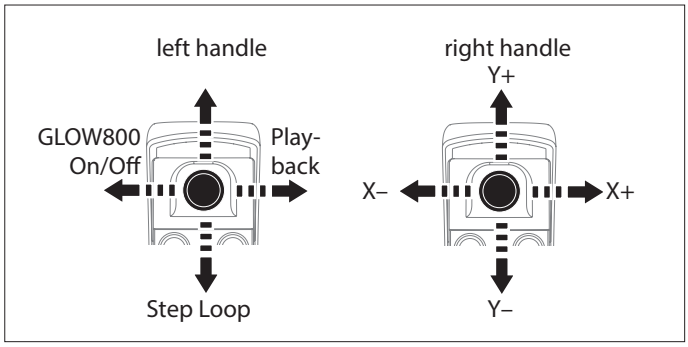
When using GLOW800 please ensure to have a Doppler Ultrasound or similar in place, in case of none or insufficient blood flow visualization out of the ICG/GLOW800 procedure is given.

10.1 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.

10.2 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 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" function activates the GLOW800 illumination and the GLOW800 sensitive camera, and switches the GLOW800 video signal to the system's video output.
At the same time, recording of the GLOW800 video signal on a connected, optional recording unit is started and the correctly scaled video signal is displayed.
The "GLOW800 Off" function returns the system to white light mode and disables the GLOW800 functions and the GLOW800 recording is finished.

Optimizing the GLOW800 settings

- ► Press the joystick upward to optimize the GLOW800 settings of the microscope.
  The microscope magnification is set to around 2/5 of the maximum magnification if the currently selected value is higher.

The overview, resolution and sharpness of the video display in GLOW800 mode are thus optimized.

Replay

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

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 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?

13.1 General

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

13.2 GLOW800

Malfunction	Cause	Remedy
Incorrect information shown for interpretation to the user	Device algorithm calibration failure	▶ Use reset button to reboot/reset of the system (see chapter 3.2.3).
	Improper pre-operational check	▶ Repeat pre-operational procedure. ▶ Get in contact with Leica Service.
System fails to boot up	Electronic failure	▶ Get in contact with Leica Service.
Video signal shows red cross /Red "X"	Camera signal lost	▶ Check there is no loose connection. ▶ Use reset button to reboot/reset the system (see chapter 3.2.3). ▶ Get in contact with Leica Service.
System freezes	Software initialization failure	▶ Use reset button to reboot/reset the system (see chapter 3.2.3).
No NIR image 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 a button of handle.

Malfunction	Cause	Remedy
No sharp GLOW800 image on the monitor	Excessive magnification range.	▶ Use handle controls to quickly and correctly position the microscope for optimizing the GLOW800 setting.
GLOW800 image is incorrectly aligned	GLOW800 camera is not correctly aligned/ positioned. Mechanical distortion.	▶ Get in contact with Leica Service.
The overlay is not correctly embedded to the object	The XY parameter for the GLOW800 in the controls of the optional documentation system have been altered.	▶ Fix the XY parameter for the GLOW800 in the controls of the optional documentation system.
GLOW800 image is not bright enough	IR emitting sources nearby	▶ Switch off / remove IR emitting sources.
	BrightCare Plus active for GLOW800	▶ Deactivate BrightCare Plus to get more GLOW800 light.
The image remains unfocused	System not in parfocal condition	▶ Check eyepiece view with proper diopter settings.
	Camera out of focus range	▶ Use video fine focus settings.

14 Technical data

14.1 Technical data GLOW800

Protection class	2
Fluorescence excitation	790 nm (GLOW800)
Fluorescence signal	835 nm (GLOW800)

GLOW800 spectrums

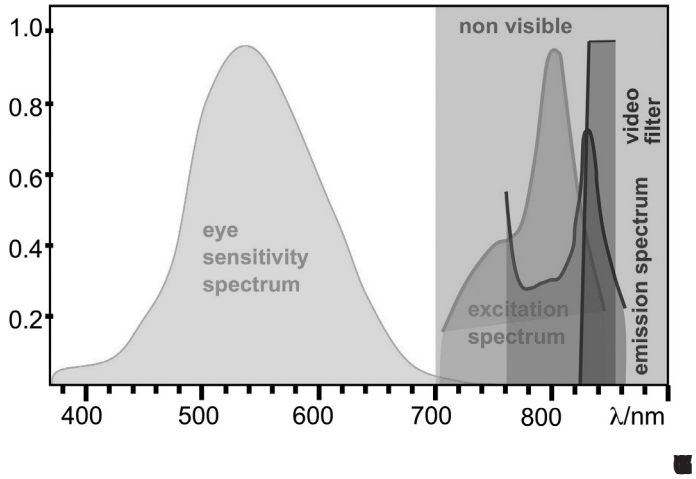
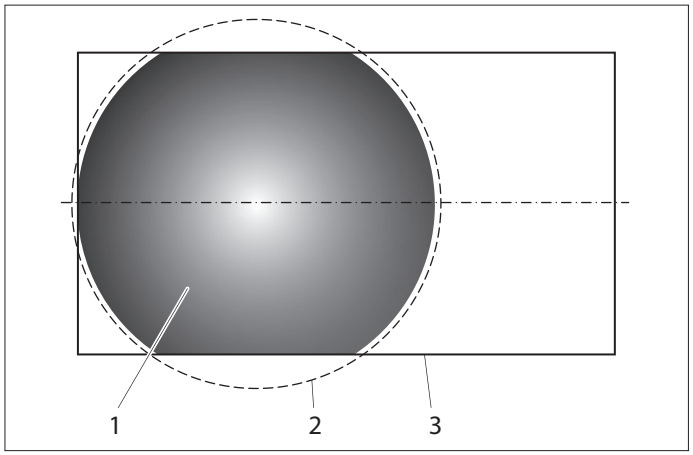


Image sensor	3× 1/1.2" inch
NIR camera	High sensitive, HD color camera

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	M530 OH6 M530 OHX

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 and ISO 14001 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.

www.leica-microsystems.com

MICROSYSTEMS

The fruitful collaboration "with the user, for the user" has always been the foundation of Leica Microsystems' innovative strength. On this basis, we have developed our five corporate values: Pioneering, High-end Quality, Team Spirit, Dedication to Science, and Continuous Improvement.

MEDICAL DIVISION

What does a surgeon expect from an outstanding surgical microscope? Sharp, clear images, and a modular system aligned with the surgeon and OR staff needs.

Innovations for your practice

From the first surgical microscope with widefield optics in the 1980s to the first microscopes with Horizontal Optics and with LED illumination, Leica Microsystems has been at the forefront of innovation in the development of surgical microscopes.

HD video, fluorescence and retinal viewing systems also demonstrate the continued innovative nature of the Leica team. We strive to provide the surgeon with leading edge technology to enhance performance, surgeon comfort, and patient outcomes.

The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standards ISO 13485 and ISO 14001 relating to quality management, quality assurance and environmental management.

CE 1250

Leica Microsystems – an international company with a strong network of worldwide customer services:

Active worldwide	Tel.		Fax	
USA · Buffalo Grove/Illinois	+1	800 248 0123	+1	847 405 0164
Canada · Concord/Ontario	+1	800 248 0123	+1	847 405 0164
Australia · North Ryde/NSW	+61	2 8870 3500	+61	2 9878 1055
Austria · Vienna	+43	1 486 80 50 0	+43	1 486 80 50 30
Belgium · Diegem	+32	2 790 98 50	+32	2 790 98 68
Denmark · Ballerup	+45	4454 0101	+45	4454 0111
France · Nanterre Cedex	+33	811 000 664	+33	1 56 05 23 23
Germany · Wetzlar	+49	64 41 29 40 00	+49	64 41 29 41 55
Italy · Milan	+39	02 574 861	+39	02 574 03392
Netherlands · Rijswijk	+31	70 4132 100	+31	70 4132 109
Portugal · Lisbon	+351	21 388 9112	+351	21 385 4668
Spain · Barcelona	+34	900 210 992	+34	93 494 95 40
Sweden · Kista	+46	8 625 45 45	+46	8 625 45 10
Switzerland · Heerbrugg	+41	71 726 34 34	+41	71 726 34 44
United Kingdom · Milton Keynes	+44	800 298 2344	+44	1908 246 312
China · Hong Kong	+852	2 564 6699	+852	2 564 4163
· Shanghai	+86	21 6039 6000	+86	21 6387 6698
Japan · Tokyo	+81	3 5421 2800	+81	3 5421 2896
Korea · Seoul	+82	2 514 65 43	+82	2 514 65 48
Singapore	+65	6550 5999	+65	6564 5955