

From Eye to Insight



MEDICAL DIVISION

# Leica FL800 ULT

**User Manual**

10 744 763 - Version 06



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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](http://www.leica-microsystems.com)

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



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### **Legal disclaimer**

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

### **Liability**

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

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# 1 Introduction

## 1.1 About this user manual

The Leica FL800 ULT is an accessory for Leica surgical microscopes. In this user manual the functions of the Leica FL800 ULT 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
	<b>Warning</b>	Indicates a potentially hazardous situation or improper use that could result in serious personal injuries or death.
	<b>Caution</b>	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in minor or moderate injury.
	<b>Note</b>	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in appreciable material, financial and environmental damage
		Information about use that helps the user to employ the product in a technically correct and efficient way.
►		Action required; this symbol indicates that you need to perform a specific action or series of actions.

## 1.3 Optional product features

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

The subsequent screenshots are reference only and not representative for all models. However the functionality of the Leica FL800 ULT is addressed.

## 2 Safety notes

A Leica surgical microscope with Leica FL800 ULT 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.

### 2.1 Intended use

- The Leica FL800 ULT is a surgical microscope accessory used in viewing intra-operative blood flow in the cerebral vascular area, blood flow of the coronary vascular 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 Leica FL800 ULT 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 Leica FL800 ULT in ophthalmology.

### 2.2 Dangers of use



#### WARNING

**Risk of infection due to insterile Leica FL800 ULT test patterns.**

- ▶ Check the Leica FL800 ULT 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 Leica FL800 radiation**

- ▶ Avoid extended and/or excessively frequent use of Leica FL800 radiation.
- ▶ Leica FL800 mode is disabled automatically no later than after 180 seconds to prevent excessive exposure of the patient to Leica FL800 radiation.

### 2.3 Information for the person responsible for the instrument

- ▶ When using Leica FL800 ULT please ensure to have a Doppler Ultrasound or similar in place, in case of none or insufficient blood flow visualization out of the ICG/Leica FL800 ULT procedure is given.

### 2.4 Signs and labels

#### Type label



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

MODEL LEICA FL800 ULT



CE 0123

## 3 Description

### 3.1 Function

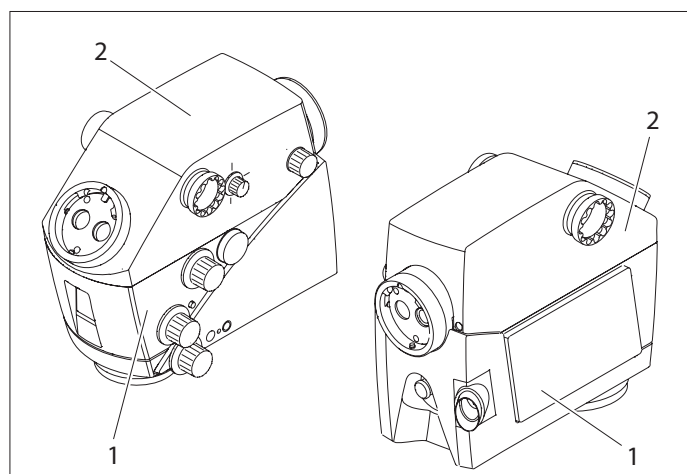
The illumination of the Leica FL800 ULT is a xenon lamp and is located in the Leica surgical microscope. This lamp provides visible light and the Leica FL800 spectrum. This image cannot be observed through the surgical microscope, but it is recorded using a special camera and visualized on the monitor.

Using the handles or via user settings you can switch between visible and Leica FL800 light.

### 3.2 Design

The Leica FL800 ULT is an accessory to a Leica surgical microscope.

#### 3.2.1 Optics carrier and Leica FL800 ULT

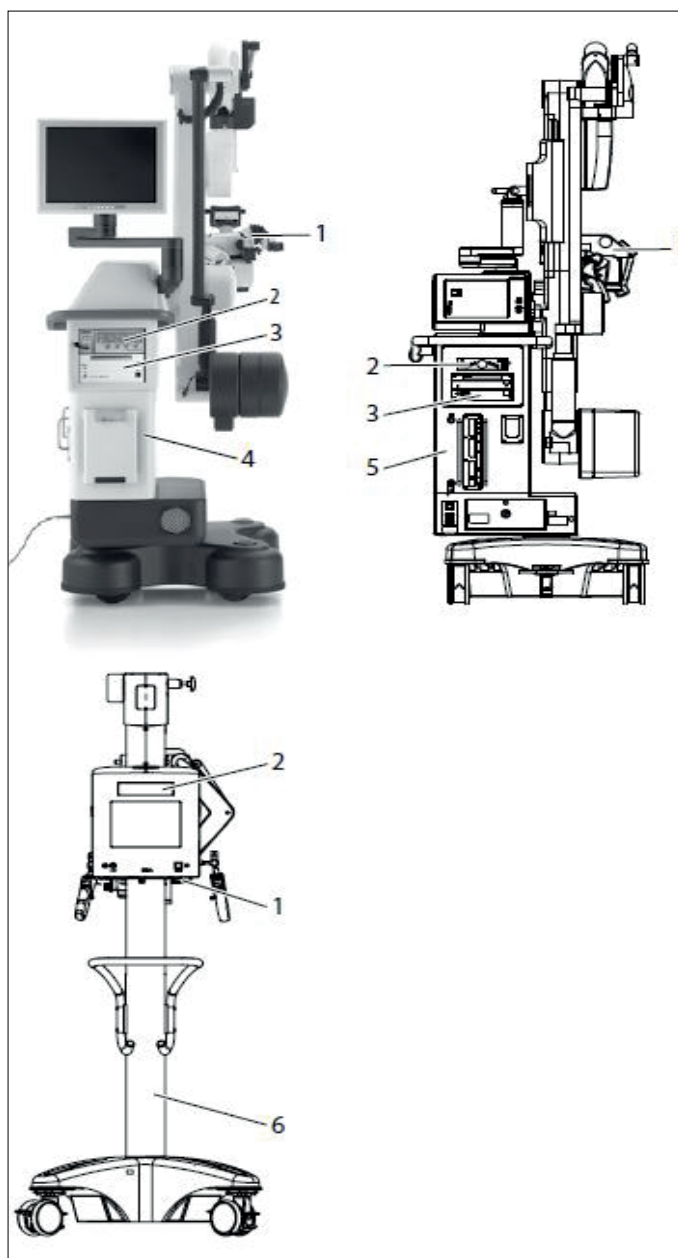


- 1 Leica Optics carrier
- 2 Leica FL800 ULT

- Leica FL800 ULT system components built into the common housing of the ULT
- Optics carrier with integrated camera for visible light Leica HD C100 (optional)
- Interface for assistants, either to the left or right side or to the back
- Main surgeon and back assistant interface, 360° rotatable both
- Back assistant interface with fine focus knob

#### 3.2.2 Stand

The following is an example of a Leica surgical microscope.



- 1 Leica M530 Optics Carrier
- 1 Camera control unit (optional)
- 2 Documentation system control unit (optional)
- 3 Leica M530 OH6 and ARveo surgical microscope
- 4 Leica M530 OHX surgical microscope
- 5 PROVIDO Stand
- 6 PROVIDO Stand

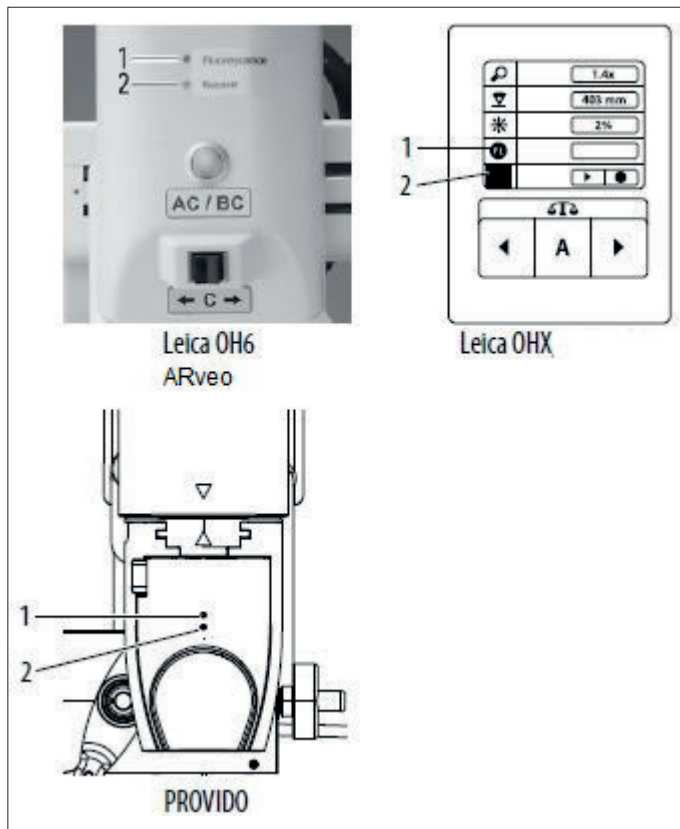
### 3.3 Controls

#### 3.3.2 Handles

Description

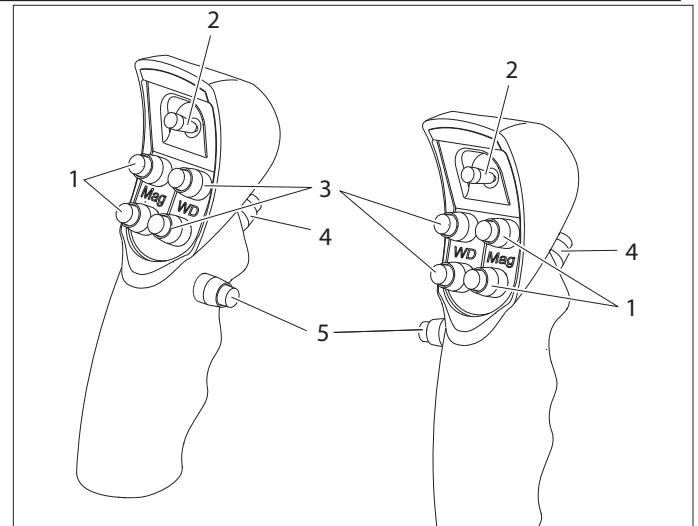
##### 3.3.1 Status LEDs (optional)

**!** Status-LEDs are not available on all Leica surgical microscopes.



If provided, on the swing arm the following LEDs are significant for the Leica FL800 ULT application:

- 1 Status LED for fluorescence
  - LED lights up in yellow = Leica FL800 mode
  - LED lights up in green = Leica FL800 playback mode
- 2 Status LED for recording  
LED lights up red = recording in progress

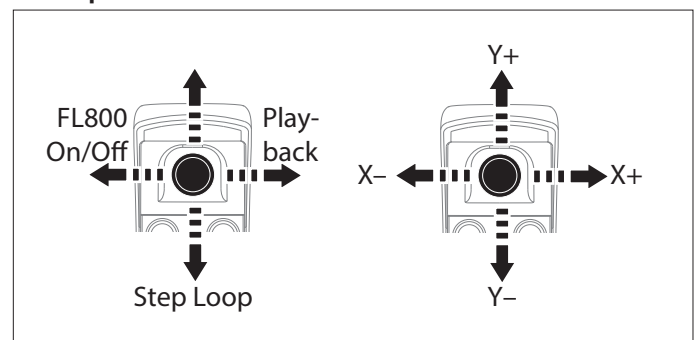


##### Assignment in the factory setting

- 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 Leica FL800



##### 3.3.3 Recording system unit (optional)

**!** Please refer to the user manual of the corresponding recording system unit.

## 4 Preparation before surgery

### 4.1 Adjustments

Adjustments on the Leica Surgical Microscope control unit for Leica FL800 ULT

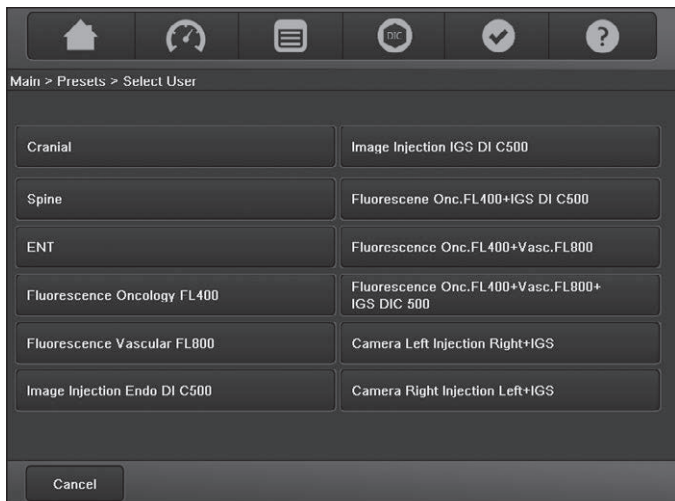
**!** Ensure that the Leica FL800 ULT accessories are enabled in the accessory list in the service menu of your Leica surgical microscope.

Afterwards, the respective current mode is displayed on the right of the status line of the control unit and indicated by the LEDs on the swing arm.

#### Using the "Fluorescence Vascular FL800" user preset

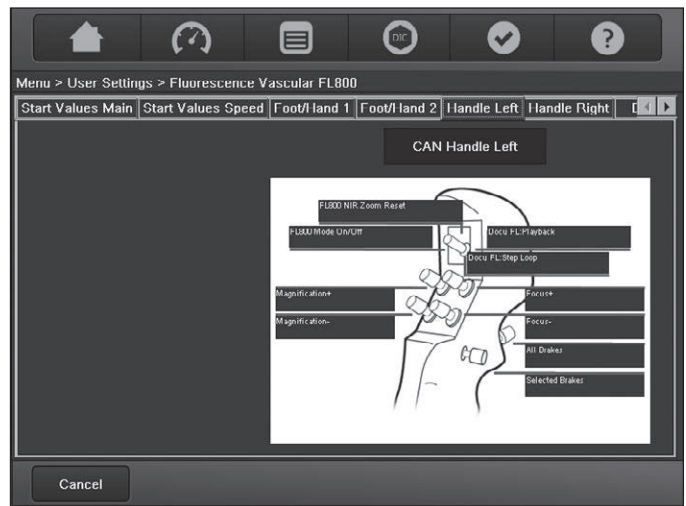


- ▶ In the Main menu click on the "Presets" button. The available presets are displayed.



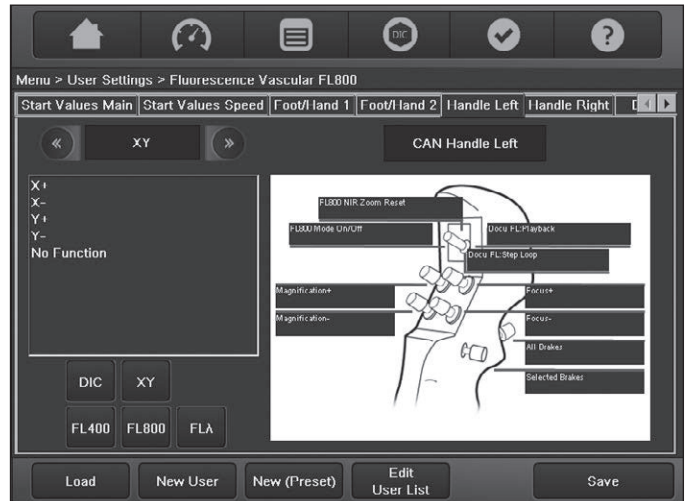
- ▶ Select the "Fluorescence Vascular FL800" user preset.
- ▶ Click on the "Select" button.

The selected user preset is displayed in the top line.



#### Handle assignment

- ▶ 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 Leica FL800 functions can be operated.



## Modifying the "Fluorescence Vascular FL800" user preset

**!** If you adjusted the settings of the "Fluorescence Vascular FL800" 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.

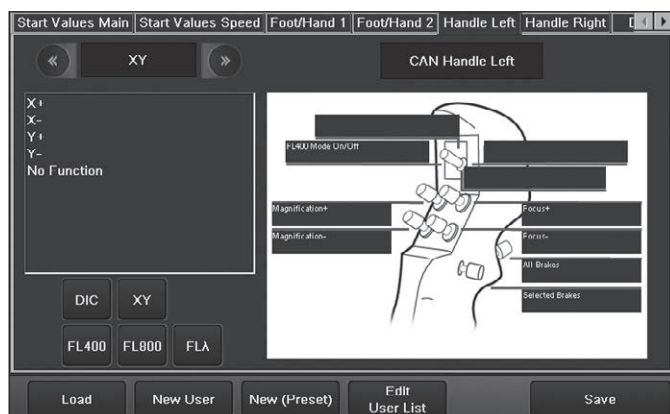
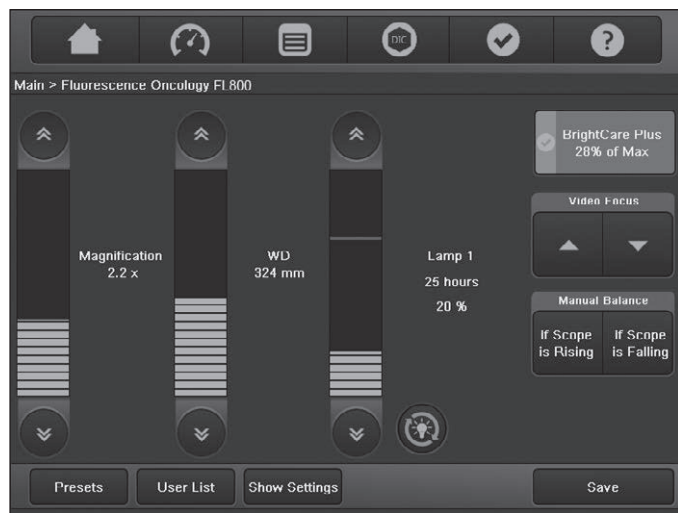
**!** These settings can later be edited at any time via the User Settings menu.

## Creating your own FL800 user

- ▶ Click on the "Menu" quick access button and select "User Settings".



- ▶ Select "New User".
- ▶ Open the "Handle Left" or "Handle Right" tab to assign FL800 functions to the handle.



- ▶ In the left selection field, select the "Fluorescence" function group by Press the "left symbol" or "right symbol", where symbols are actual GUI TIF used.
- ▶ Assign the function "FL800 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.
- ▶ 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.

**!** In the service menu, you can adjust a value for the maximum duration of the Leica FL800 mode from 10 to 180 seconds.

## Brightness

- ▶ Open the "FL" tab to set the brightness in FL800 mode to an adequate level.



### Video Fine Focus

The Leica FL800 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.

## 4.2 Checking the Leica FL800 ULT illumination



### WARNING

**Risk of infection due to insterile Leica FL800 ULT test patterns.**

- ▶ Check the Leica FL800 ULT illumination in non-sterile environment only.

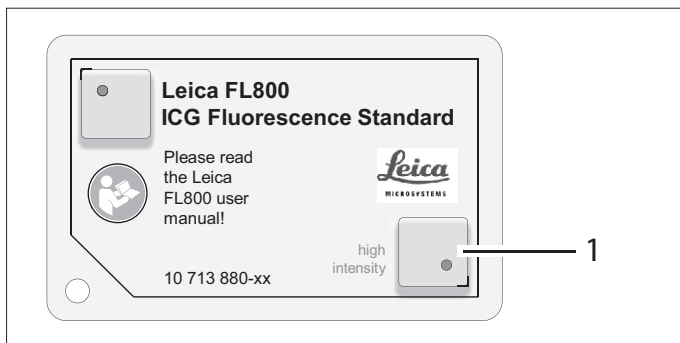
- ▶ Place the Leica FL800 test pattern under the microscope.
- ▶ Focus the microscope at a low magnification.  
The Leica FL800 test pattern will be visible in the microscope in white-light mode.

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

- ▶ Activate Leica FL800 mode with the handle.  
A connected monitor will display the Leica FL800 image of the ICG test pattern.

### Leica FL800 test pattern in white-light mode

- Front side



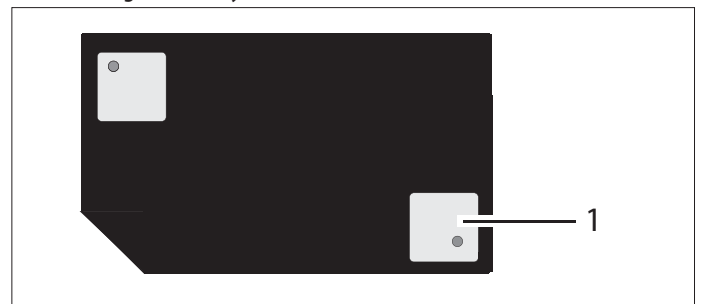
1 ICG test pattern

- Back side

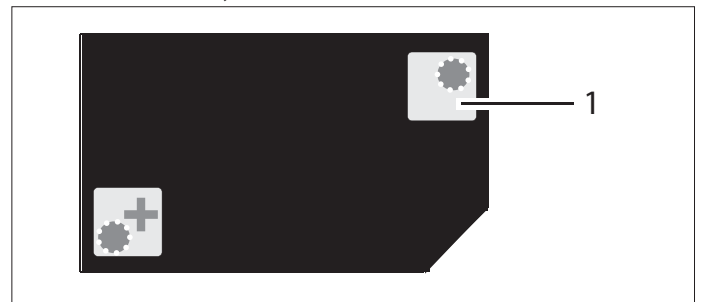


### Leica FL800 test pattern in FL800 mode

- With high intensity, use the front side



- With low intensity, use the back side



1 ICG test pattern

### 4.3 Pre-operation checklist (Leica FL800 ULT)

#### **Cleaning optical accessories**

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

#### **Leica FL800 ULT application**

- ▶ When using Leica FL800 ULT please ensure to have a Doppler Ultrasound or similar in place, in case of none or insufficient blood flow visualization out of the ICG/Leica FL800 ULT 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 Leica FL800 ULT illumination according to section 4.2.



See also Quick Reference Guide Leica FL800 ULT.

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#### **Sterility**

- ▶ Apply the sterile drape.



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

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# 5 Operation



**WARNING**

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

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



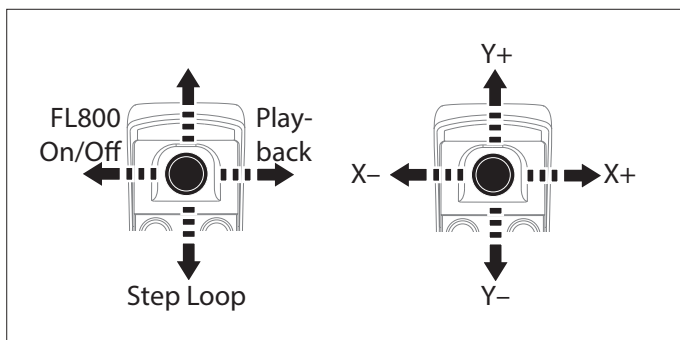
When using Leica FL800 ULT please ensure to have a Doppler Ultrasound or similar in place, in case of none or insufficient blood flow visualization out of the ICG/Leica FL800 ULT procedure is given.

## 5.1 Using the Leica FL800 ULT

- ▶ Switch on the illumination of the Leica surgical microscope.
- ▶ Select a user: Select either the "Fluorescence Vascular FL800" user preset or an own Leica FL800 user.

## 5.2 Controlling the Leica FL800 functions

**Controlling the Leica FL800 functions, e.g., on the microscope's left handle**



**Leica FL800 On/Off**

The handle permits switching between white-light mode (Leica FL800 Off) and Leica FL800 mode.

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



**WARNING**

**Danger of injury to the patient due to excessive Leica FL800 radiation**

- ▶ Avoid extended and/or excessively frequent use of Leica FL800 radiation.



Leica FL800 mode is disabled automatically no later than after 180 seconds (preset, the value can be changed) to prevent excessive exposure of the patient to Leica FL800 radiation.



The "Leica FL800 On" function activates the Leica FL800 ULT illumination and the Leica FL800 ULT sensitive camera, and switches the Leica FL800 video signal to the system's video output.

At the same time, recording of the Leica FL800 video signal on a connected, optional recording unit is started and the correctly scaled video signal is displayed.

The "Leica FL800 Off" function returns the system to white-light mode and disables the Leica FL800 functions and the Leica FL800 recording is finished.

**Playback**

- ▶ If an optional recording unit is provided, pressing the joystick to the right starts the playback 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 Leica FL800 loops.

## 6 Care and maintenance

**!** Leica FL800 ULT is an accessory for a Leica surgical microscope. For care and maintenance please refer to the user manual of the Leica surgical microscope.

## 7 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?

### 7.1 General

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

### 7.2 Leica FL800 ULT

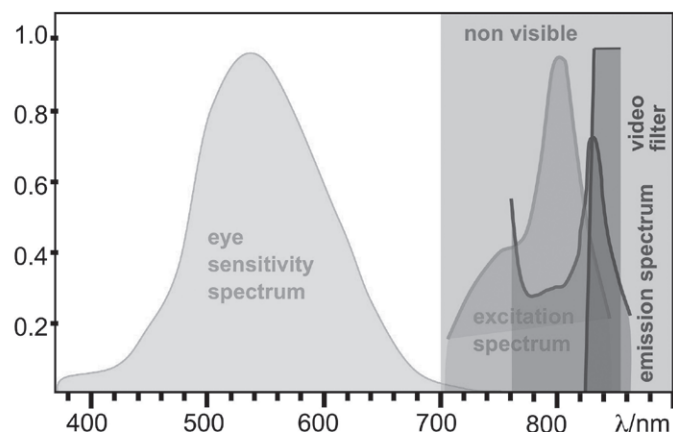
Malfunction	Cause	Remedy
No NIR image displayed	FL800 mode is not active	<ul style="list-style-type: none"> <li>▶ Check that the fluorescence LED and the control unit display the FL800 mode.</li> <li>▶ Check whether the FL800 On/Off function is assigned to a button of handle.</li> </ul>
No sharp FL800 image on the monitor	You are working in an excessive magnification range.	<ul style="list-style-type: none"> <li>▶ Initiate the "FL800 NIR Zoom Reset" function for optimizing the Leica FL800 setting on the handle to quickly and correctly position the microscope.</li> </ul>
FL800 image is incorrectly aligned	FL800 camera is not correctly positioned on the FL800 dual video adapter.	<ul style="list-style-type: none"> <li>▶ Use the FL800 test pattern to align the FL800 camera.</li> </ul>
FL800 image is not bright enough	IR emitting sources nearby	<ul style="list-style-type: none"> <li>▶ Switch off / remove IR emitting sources.</li> </ul>
	BrightCare Plus active for Leica FL800	<ul style="list-style-type: none"> <li>▶ Deactivate BrightCare Plus to get more FL800 light.</li> </ul>

## 8 Technical data

### 8.1 Technical data Leica FL800 ULT

Protection class	2
Fluorescence excitation	790 nm (Leica FL800 ULT)
Fluorescence signal	835 nm (Leica FL800 ULT)

#### Leica FL800 spectrums



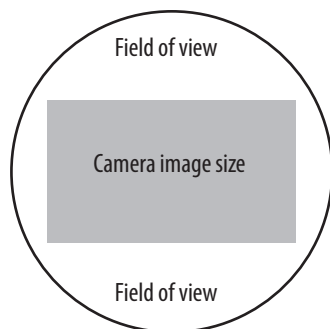
#### Leica FL800 ULT

Image sensor	1/2" CCD
NIR camera	High sensitive, built-in NIR video 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

Leica FL800 ULT NIR camera



**!** The figure shows the camera image size with respect to the field of view for the visual video camera and the Leica FL800 ULT NIR camera. Please be aware that the field of view is not fully covered by the documentation system.

### 8.2 Compatibility

Leica surgical microscopes	Leica M530 OH6 Leica M530 OHX ARveo PROVIDO
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### 8.3 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

### 8.4 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 standard ISO 13485 relating to quality management, quality assurance and environmental management.

## 9 Manufacturer's declaration of electromagnetic compatibility (EMC)



The Leica FL800 ULT 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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