

From Eye to Insight



MEDICAL DIVISION

CaptiView

User Manual

10 746 768 - Version 01

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 so that you know and are able to utilize all the benefits of your Leica surgical microscope in an optimum way.

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 new Leica Microsystems surgical microscope.



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Legal disclaimer

All of the technical data is subject to change without notice.
The information provided in this manual relates directly to operation of the system.
Medical decisions remain 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. Please contact your local Leica representative if you need more detailed information.
You should never use a medical product of Leica Microsystems without the full understanding of the functions and operation of the product.

Liability

Please see our standard sales terms and conditions for information on liability.
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	2	8	What To Do If...?	20
1.1	About this document	2	8.1	Troubleshooting superimposed data	20
1.2	Optional product features	2	8.2	Troubleshooting the shutters	21
1.3	Product identification	2	8.3	Troubleshooting the display	21
1.4	Symbols in this user manual	2	9	Specifications	22
2	Safety Notes	3	9.1	Electrical data	22
2.1	Intended use	3	9.2	Optical data	22
2.2	Non-intended use	3	9.3	Physical data	22
2.3	Information for the person responsible for the instrument	3	9.4	Ambient conditions	22
2.4	Directions for the user of the instrument	3	9.5	Standards fulfilled	22
2.5	Dangers of use	3	9.6	Compatibility	22
3	Design and function	4			
3.1	CaptiView controls	4			
3.2	Design and function of the handles for Leica M530 OH6 / OHX	4			
4	Wiring	5			
4.1	Checking the wiring on the Leica OH6 / OHX	5			
5	Operation	6			
5.1	Operation of the instrument with handles for Leica M530 OH6 / OHX	6			
5.2	Operating the CaptiView on the control unit of the Leica M530 OH6 / OHX	6			
6	Settings for CaptiView	10			
6.1	Application 1 – FL800	10			
6.2	Application 2 – IGS	11			
6.3	Application 3 – Common	12			
6.4	Application 4 – IGS + FL800	13			
6.5	Application 5 – FL800 + Common	14			
6.6	Application 6a – IGS (1st) + Common (2nd)	15			
6.7	Application 6b – IGS (2nd) + Common (1st)	16			
6.8	Application 7a – FL800 (1st) + IGS (2nd) + Common (3rd)	17			
6.9	Application 7b – FL800 (1st) + IGS (3rd) + Common (2nd)	18			
7	Care and Maintenance	19			
7.1	Maintenance instructions	19			
7.2	Maintenance	19			
7.3	Service	19			
7.4	Disposal	19			

1 Introduction

1.1 About this document

This User Manual describes Assembly, Configuration and Operation of the CaptiView for the following systems:

- Leica M530 OH6
- Leica M530 OHX



This user manual contains important safety notes as well as information on using the instrument (see the Chapter "Safety notes").



Before setting up the product, carefully read through the user manual.

1.2 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.

1.3 Product identification

The model code and serial numbers of your product are located on the identification label on the CaptiView. Enter this data in your user manual and always refer to it when you contact us or the service workshop regarding any questions you may have.

Model:

Serial No.:

1.4 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

2.1 Intended use

- The CaptiView module is an optical instrument you can use to superimpose data or images. These overlays can be viewed superimposed over the microscopic image or on their own against a black background. Two users can observe the object under the microscope simultaneously at the optical outputs. In addition, you can connect a photo or video camera.
- ▶ Only use the connectors and cables included in the scope of delivery in order to connect the CaptiView. Use these connectors and cables when connecting it to an external device providing data as well.
- The CaptiView can only be adapted to the Leica M530 optics carrier.

2.2 Non-intended use

- Only use the CaptiView as described in this user manual. Failure to observe these instructions may result in property damage.

2.3 Information for the person responsible for the instrument

- Ensure that only instructed users use the CaptiView.
- Ensure that this User Manual is always available at the place where the instrument is used.
- Carry out regular inspections to make sure the users are complying with safety requirements.
- Brief the users thoroughly and explain the meaning of the warning signs and warning messages to them.
- Allocate responsibilities for preparing the instrument for work, for operating it and for maintaining it. Monitor compliance with these.
- Only use the CaptiView in proper condition.
- Inform your Leica Microsystems representative or Leica Microsystems (Schweiz) AG, Medical Division, 9435 Heerbrugg, Switzerland, immediately if you detect a product defect that could potentially cause injury or harm.
- Ensure that the usual precautionary measures for electromagnetic and other radiation are observed.
- Do not make any changes to this instrument.

- Connected units and all the configurations for the analog and digital interfaces (signal inputs and outputs) have to be certified in accordance with IEC 60601-1/EN 60601-1 for medical devices. It is the responsibility of the user to ensure that the limits of the above-mentioned standards are not exceeded. If in doubt, please contact the appropriate technical department or the representative responsible.
- The complete system does not conform to CE if the instrument is operated together with components that do not have CE certification.

2.4 Directions for the user of the instrument

- Follow the instructions given by your employer regarding the organization of work and safety at work.
- Follow the instructions given in this manual.
- The electrical system at the installation location must conform to IEC, CEC and NEC specifications as applicable.
- Do not sterilize the CaptiView.
- Observe the applicable statutory and country-specific regulations for accident prevention and environmental protection.
- Check the function of the CaptiView before surgery.

2.5 Dangers of use



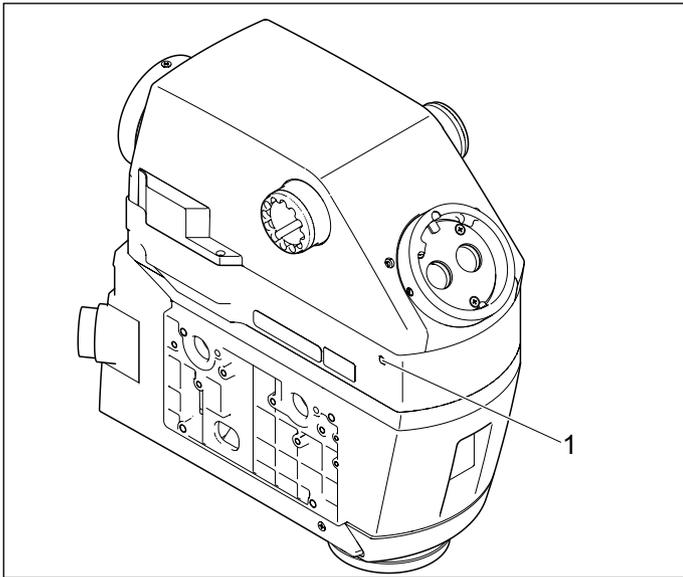
CAUTION

Danger of damage to the instrument due to improper storage!

- ▶ Protect the instrument from direct sunlight and heat.

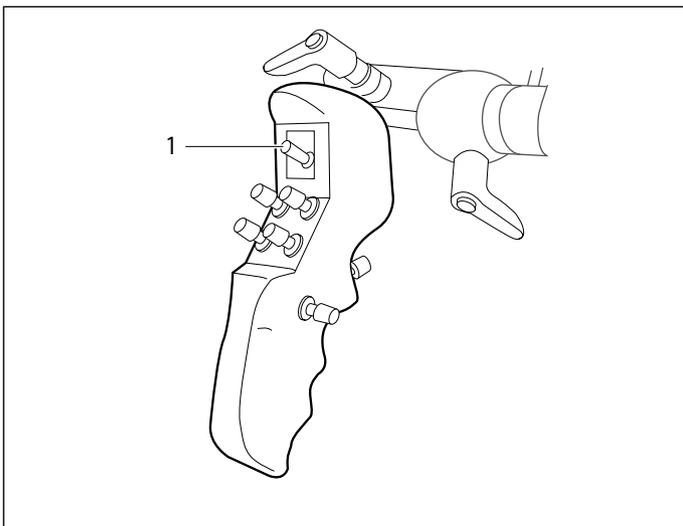
3 Design and function

3.1 CaptiView controls



1 Emergency stop switch

3.2 Design and function of the handles for Leica M530 OH6 / OHX



1 Joystick for menu navigation in the CaptiView

4 Wiring

4.1 Checking the wiring on the Leica OH6 / OHX

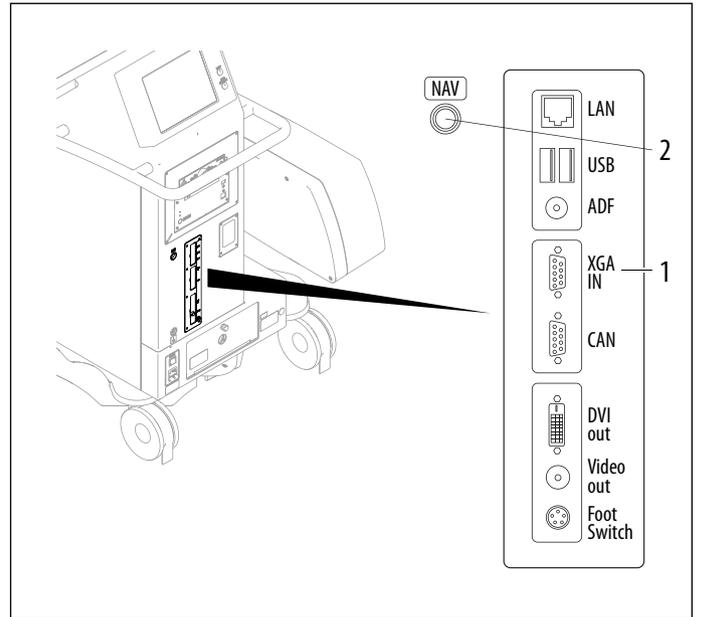
4.1.1 Leica OH6



► Ensure that sockets (1) to (4) are assigned only with the following connections:

- | | | |
|---|---------|--|
| 1 | XGA 3 | IGS |
| 2 | XGA 2 | FL800 |
| 3 | XGA 1 | General input (e.g. Endoscopic camera) |
| 4 | XGA Out | To the CaptiView |

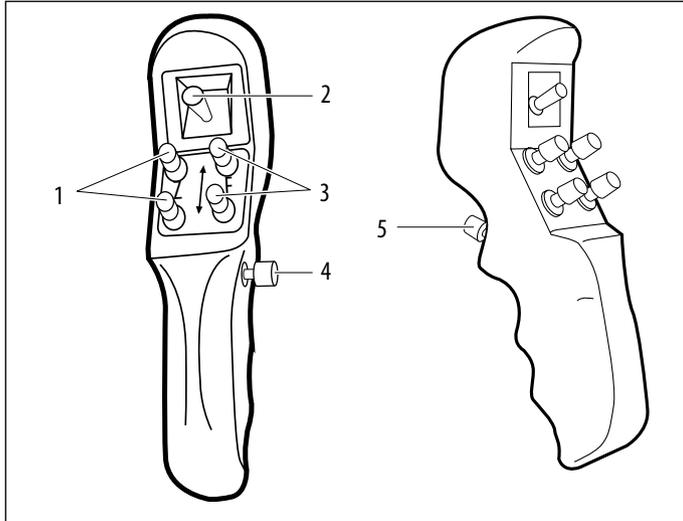
4.1.2 Leica OHX



- | | | |
|---|--------|--|
| 1 | XGA in | General input (e.g. Endoscopic camera) |
| 2 | NAV | IGS Connector |
| | | Note: FL800 connected internally |

5 Operation

5.1 Operation of the instrument with handles for Leica M530 OH6 / OHX



- 1 Mag up / down
- 2 Joystick (optionally for XY movements or for menu navigation in the CaptiView)
- 3 WD up / down
- 4 Selector button
- 5 ALL-FREE switch to release all brakes

CaptiView menu guidance

Moving the joystick in direction...

X+: Activate/deactivate imaging

X-: Individual control of the shutters with IGS workstation: Menu
ENTER

Y+: Increasing the brightness of the displayed image; with IGS
workstation Menu scroll up

Y-: Decreasing the brightness of the displayed image with IGS
workstation: Menu scroll down

The keys of the handles can be configured separately on the left and right handle.

! The joystick (2) can be configured for the X/Y-movement of the microscope or for menu control when using a CaptiView.

5.2 Operating the CaptiView on the control unit of the Leica M530 OH6 / OHX

5.2.1 Operating the control unit

If you are using a CaptiView, a "DIC" Quick Access Button is added to the static menu line.



Changing the current brightness of the image data:

- ▶ On the "DIC" page, press the or button.
- or
- ▶ Click the brightness adjustment bar directly.

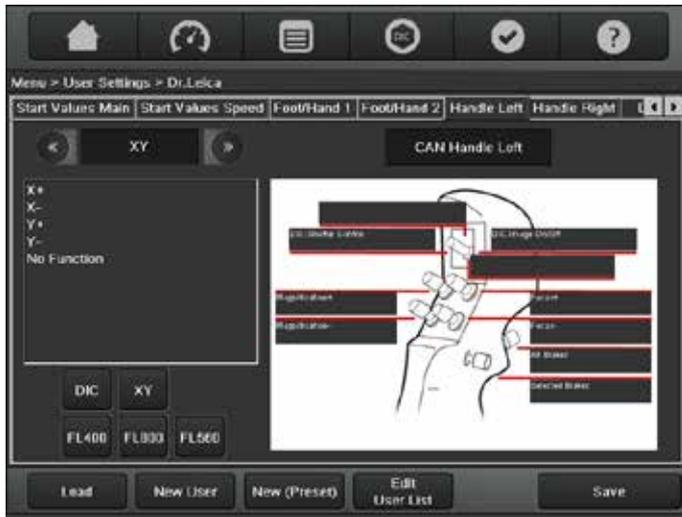
! Briefly clicking the or button changes the brightness value in increments of 10%.

! Use the "Image Off" button to disable the display in the CaptiView (brightness = 0%).

! You can also change the brightness of the image using the CAN handle/footswitch.

5.2.2 Operation on the handle/footswitch

The following functions can be assigned to your handle/footswitch to control your CaptiView:



"DIC: Image On/Off"

Switches the display with the superimposed data on/off manually. The shutters are switched as configured in the user settings.

- "DIC: Microscope Data On/Off" Activates or Deactivates the injection of the microscope data (see page 8 for details) immediately
- "DIC: Shutter Control"
Opens or closes the shutter manually as pre-configured in the user settings.
- "DIC: Brightness +"
Increases the brightness of the superimposed data.
- "DIC: Brightness -"
Decreases the brightness of the superimposed data.

5.2.3 User settings

You can configure the following settings for the user in the user settings:

- Default brightness for image of overlay and non-overlay data
- Overlay mode
- Image Injection Channel
- DIC In Assignment
- Microscope data
- Illumination linked Brightness

Setting the default brightness for the image of overlay data and non-overlay data:

- ▶ Press the or button or click directly on the bar for adjusting the brightness of the illumination.

Briefly clicking the or button changes the brightness value in increments of 1. Holding down the button with your finger changes the value in increments of five.

Shutter settings for manual operation:

These settings can be adjusted on an intraoperative basis via the CAN handle or the "DIC" screen of the control unit.

Overlay Mode

- Specify how data is to be displayed on your CaptiView in the "Overlay mode" options menu.

Overlay:

The displayed data is superimposed in the eyepiece over the surgical field.

All shutters are opened.



Non-Overlay:

The displayed data is displayed against a black background. The shutter on the overlay side is closed.



Image Injection Channel

It can be selected in which eye the image shall be injected (Left, Right, Left + Right).

Show Microscope Data

Microscope data can be injected. The injected data are:

- Working distance
- Magnification
- Illumination brightness
- Recording status

The selection criteria are:

- On - Off - Timeout
- Top - Bottom (of the field)

If "Timeout" is selected, the microscope data appears only when the brakes are released, WD, magnification or illumination brightness are changed or recording is started. The microscope data disappears automatically after 5 seconds.

Further, the color of the microscope data can be set (green, yellow, blue or red).

Illumination Linked Brightness

Links the display brightness to the illumination brightness of the system.

! If an IGS navigation system is connected, it automatically controls the shutter independently of this setting.

! In FL800 Mode the data is always displayed as Non-Overlay Data.

5.2.4 Settings for use with IGS workstation

A connected IGS workstation can supply various data for superimposition. The data can be correlated, superimposed data (for example, the IGS grid model) or various kinds of non-correlated and non-superimposed image data.

! If the CaptiView is connected to an IGS workstation, the workstation assumes control of the shutters. If correlated data (e.g. IGS grid model) is superimposed, all shutters remain open so that the data can be superimposed over the object image. If non-correlated data (such as CT, MRI or ultrasound) is displayed, the shutter settings stored in the control unit are activated.

! Consult the IGS/Navigation workstation user manual for specific functionality and workflow guidance.

! You do not need to configure any settings on the control unit.

5.2.5 Safety function of the CaptiView

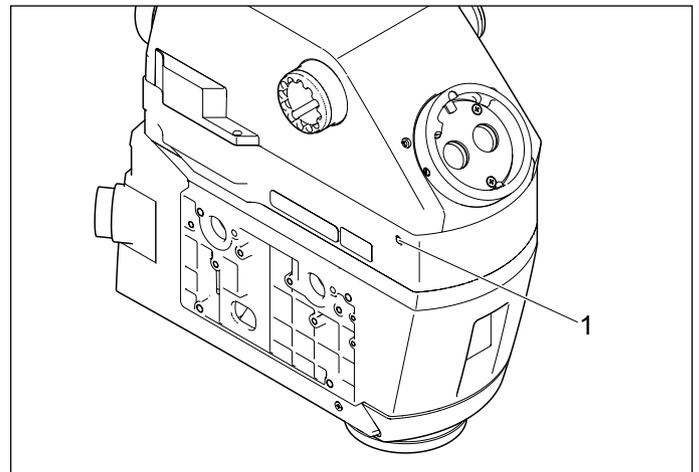
If, because of a malfunction, the shutters cannot be controlled or the display switches itself on and/or displays an incorrect video signal:

- ▶ Press the switch (1) for manually switching off the display and shutter release.

There is a red light in the push-button, signaling that the display is switched off and all shutters are open.

- ▶ Contact your Leica representative.

! The switch (1) for manually switching off the display and releasing all shutters should only be activated with a sterile, blunt object if a sterile cover is in place over the microscope and CaptiView.



In order to return the shutter control back to the control unit or to the IGS workstation:

- ▶ Press the switch for manually switching off the display and for releasing all shutters (1).

The red light on the switch for manually switching off the display and releasing all shutters (1) turns off.

6 Settings for CaptiView

In this chapter you can find detailed description of the XGA assignment.

6.1 Application 1 – FL800

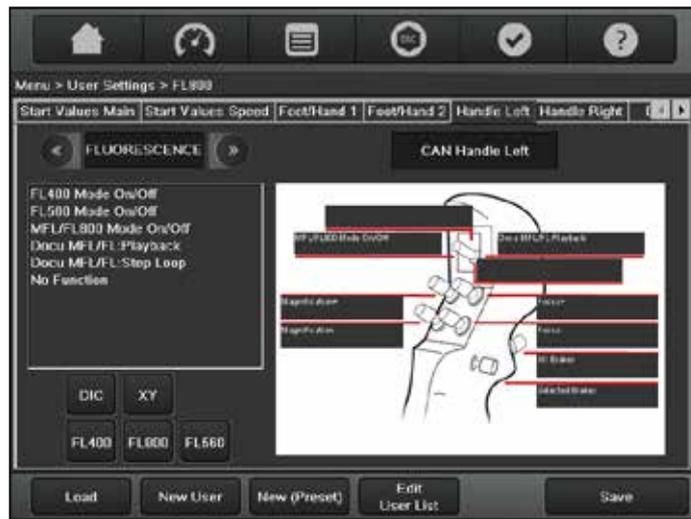
FL800 Input

To prepare the Leica operating microscope to display the signal of a Leica FL800 system for a specified user in the CaptiView.



User DIC settings

DIC In 1: No device
 DIC In 2: FL800
 DIC In 3: No device
 Default DIC In: DIC In 2



User handle settings

Handle left: Leica FL800 settings

6.2 Application 2 – IGS

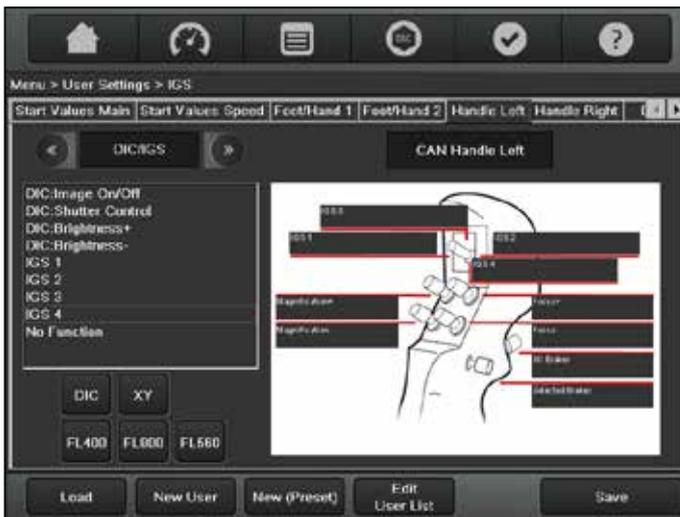
IGS Input

To prepare the Leica operating microscope to display the signal of an IGS system for a specified user in the CaptiView.



User DIC settings

DIC In 1: No device
 DIC In 2: No device
 DIC In 3: IGS
 Default DIC In: DIC In 3



User handle settings

Handle left: IGS1 to IGS4

6.3 Application 3 – Common

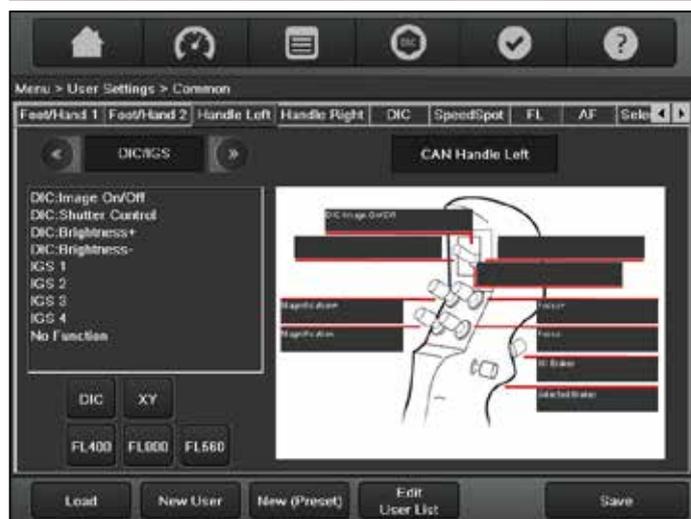
Common Input

To prepare the Leica operating microscope to display the signal of e.g. an endoscope for a specified user in the CaptiView.



User DIC settings

DIC In 1: Common
 DIC In 2: No device
 DIC In 3: No device
 Default DIC In: DIC In 1



User handle settings

Handle left: DIC Image On/Off

6.4 Application 4 – IGS + FL800

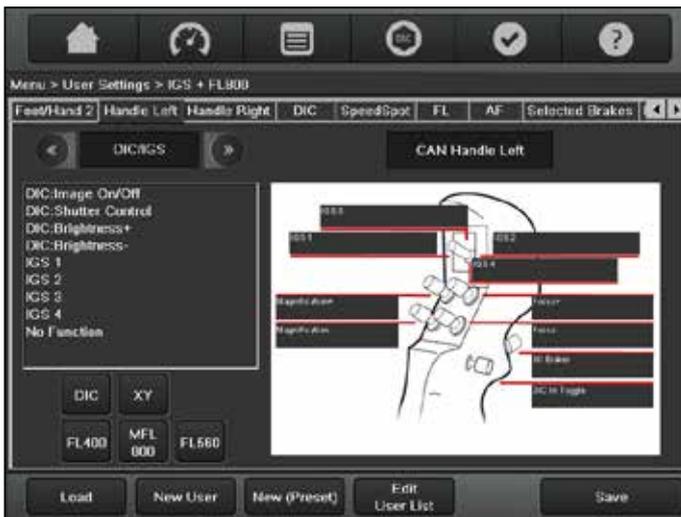
IGS + FL800 Input

To prepare the Leica operating microscope to display the signal of an IGS system and/or a Leica FL800 for a specified user in the CaptiView.



User DIC settings

DIC In 1: No device
 DIC In 2: FL800
 DIC In 3: IGS
 Default DIC In: DIC In 3



User handle settings

Handle left: IGS1 to IGS4
 DIC In toggle



Handle right: Leica FL800 settings

6.5 Application 5 – FL800 + Common

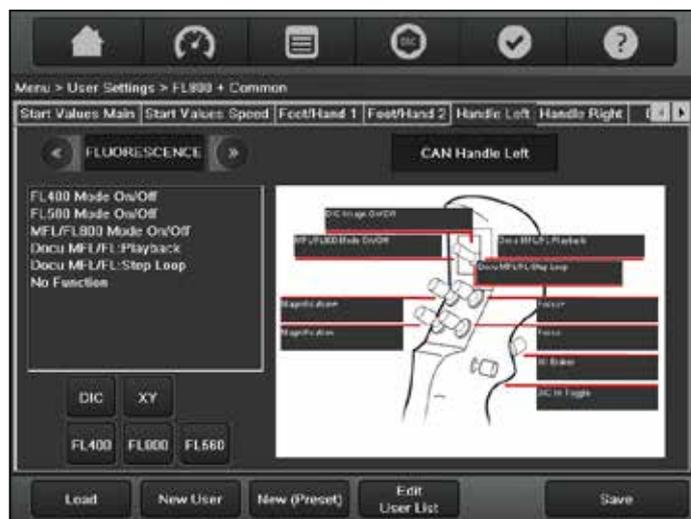
FL800 + Common Input

To prepare the Leica operating microscope to display the signal of a Leica FL800 and/or e.g. an endoscope for a specified user in the CaptiView.



User DIC settings

DIC In 1: Common
DIC In 2: FL800
DIC In 3: No device
Default DIC In: DIC In 1



User handle settings

Handle left: DIC Image On/Off
Leica FL800 settings
DIC In toggle (to switch from common to Leica FL800)

6.6 Application 6a – IGS (1st) + Common (2nd)

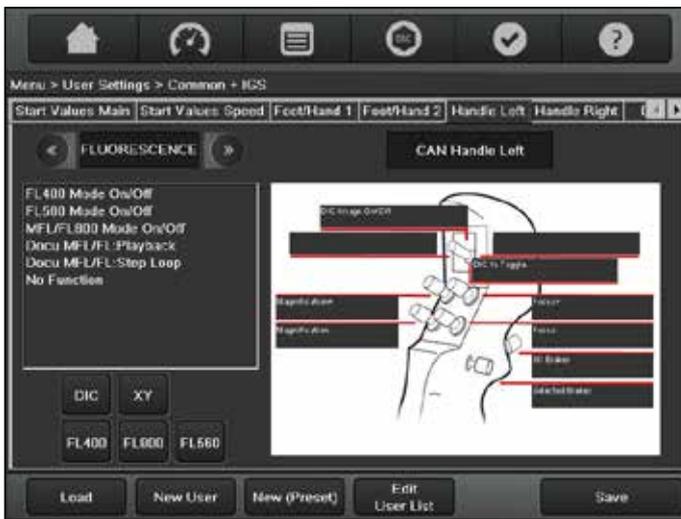
Common + IGS Input

To prepare the Leica operating microscope to display the signal of an IGS system (1st priority) and/or e.g. an endoscope (2nd priority) for a specified user in the CaptiView.



User DIC settings

DIC In 1: Common
 DIC In 2: No device
 DIC In 3: IGS
 Default DIC In: DIC In 3



User handle settings

Handle left: DIC Image On/Off
 DIC In toggle (to switch from IGS to common, if the IGS system takes the control of the CaptiView)



Handle right: IGS1 to IGS4

6.7 Application 6b – IGS (2nd) + Common (1st)

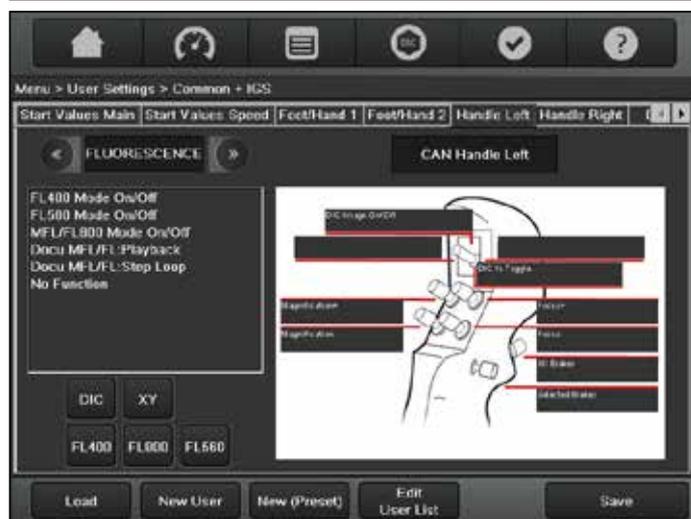
Common + IGS Input

To prepare the Leica operating microscope to display the signal of an IGS system (2nd priority) and/or e.g. an endoscope (1st priority) for a specified user in the CaptiView.



User DIC settings

DIC In 1: Common
 DIC In 2: No device
 DIC In 3: IGS
 Default DIC In: DIC In 1



User handle settings

Handle left: DIC Image On/Off
 DIC In toggle (to switch from IGS to common)



Handle right: IGS1 to IGS4

6.8 Application 7a – FL800 (1st) + IGS (2nd) + Common (3rd)

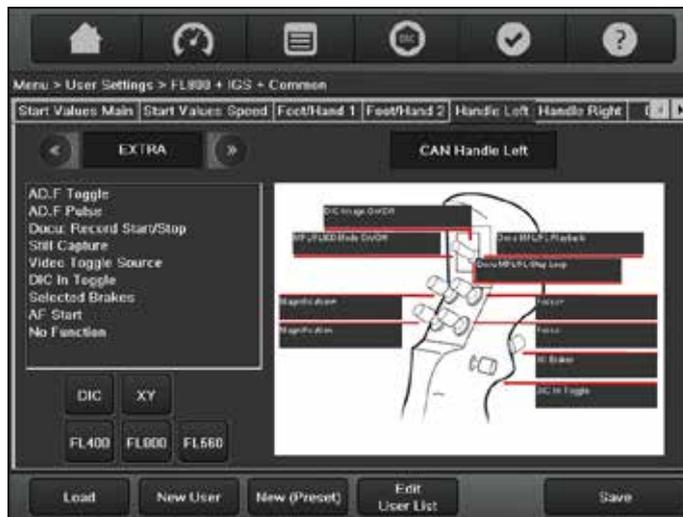
FL800 + Common + IGS Input

To prepare the Leica operating microscope to display the signal of a Leica FL800 (1st priority), an IGS system (2nd priority) and/or e.g. an endoscope (3rd priority) for a specified user in the CaptiView.



User DIC settings

DIC In 1: Common
 DIC In 2: FL800
 DIC In 3: IGS
 Default DIC In: DIC In 2



User handle settings

Handle left: DIC Image On/Off
 Leica FL800 settings
 DIC In toggle (to switch from IGS to common)



Handle right: IGS1 to IGS4

6.9 Application 7b – FL800 (1st) + IGS (3rd) + Common (2nd)

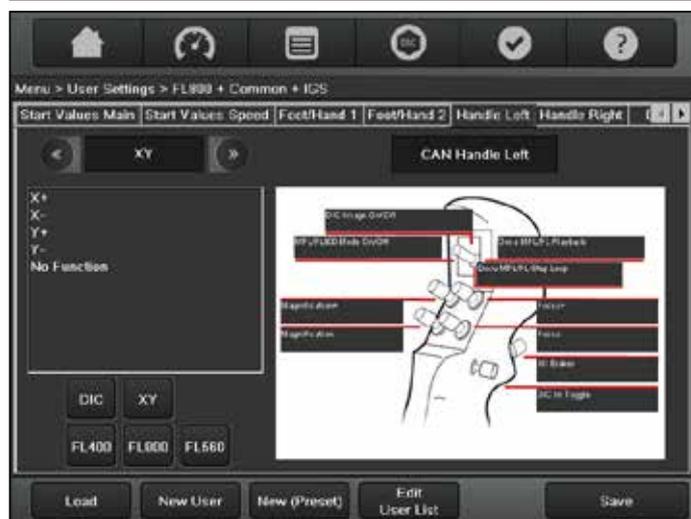
FL800 + Common + IGS Input

To prepare the Leica operating microscope to display the signal of a Leica FL800 (1st priority), an IGS system (3rd priority) and/or e.g. an endoscope (2nd priority) for a specified user in the CaptiView.



User DIC settings

DIC In 1: Common
 DIC In 2: FL800
 DIC In 3: IGS
 Default DIC In: DIC In 1



User handle settings

Handle left: DIC Image On/Off
 Leica FL800 settings
 DIC In toggle (to switch from common to IGS)



Handle right: IGS1 to IGS4

7 Care and Maintenance

7.1 Maintenance instructions



CAUTION

Danger of damage to the instrument due to improper storage!

- ▶ Store the CaptiView only with protective dust covers.
- ▶ Protect the instrument from direct sunlight and heat.

- ▶ Protect the CaptiView from improper operation.
- ▶ Clean the housing of the CaptiView using a moist towel and dry it using a soft, lint-free cloth.
- ▶ Protect the CaptiView from moisture, vapors, acids, alkalis, and corrosive substances.
- ▶ Do not store chemicals near the instrument.
- ▶ Protect the instrument from oil and grease. Never grease or oil mechanical parts or sliding surfaces.
- ▶ Do not sterilize the CaptiView and the handles.
- ▶ To disinfect the CaptiView, use compounds from the surface disinfectant group based on the following active ingredients:
 - aldehydes,
 - alcohols,
 - quaternary ammonium compounds.



Due to potential damage to the materials, never use products based on

- halogen-splitting compounds,
- strong organic acids,
- oxygen-splitting compounds.
- ▶ Follow the disinfectant manufacturer's instructions.

7.2 Maintenance

The CaptiView is maintenance-free. In order to maintain reliability, we recommend contacting the responsible Leica service organization.

Here you can arrange for periodic inspections and, if appropriate, purchase a maintenance contract.

7.3 Service

- Service work must only be performed by Leica Microsystems trained service technicians.
- Only original Leica Microsystems spare parts must be used.

7.4 Disposal

- Observe the relevant national regulations on disposing the unit. Suitable waste disposal companies are to be used. The unit packaging is to be recycled.

8 What To Do If...?

8.1 Troubleshooting superimposed data

Fault: No image superimposition

Cause 1: Data source does not transmit an image.
The connector of the XGA video cable or the XGA video cable is defective or connected incorrectly.

Fault remedy:

- ▶ Check whether the data source is sending an image.
- ▶ Check the cables between OH6 / OHX and CaptiView and the external cable source.
- ▶ If the XGA video cable is connected to the external data source correctly, contact your Leica representative.

Fault: The superimposed image does not have the correct color.

Cause 1: Defective plug connection.
The connector of the XGA video cable or the XGA video cable is defective or not inserted correctly.

Fault remedy:

- ▶ Check the connectors of the XGA video cable between the microscope and the external data source.
- If the XGA video cable is connected to the external data source correctly, contact your Leica representative.

Cause 2: The white balance of the video camera (endoscope) connected for the overlay is missing.
The lack of white balance for the video camera leads to color deviations.

Fault remedy:

- ▶ Carry out a white balance for the video camera (endoscope) connected for the overlay.
- ▶ If the external data source is a video camera, carry out a white balance.

Cause 3: Defective converter.
The converter processing the video signal returns an incorrect XGA signal.

Fault remedy:

- ▶ Check the converter.

Fault: A light glint is overlaid when dark objects are displayed

Cause: The connected workstation does not switch the module off.

Fault remedy:

- ▶ Check the IGS workstation and the program settings.

Fault: The superimposed image is sharp but can only be viewed with the utmost concentration

Cause: You are not viewing the image with your dominant eye.

Fault remedy:

- ▶ Switch the image to the other channel using the user settings (refer to Chapter "User settings", page CaptiView).
- You now see the image with your dominant eye.

Fault: When the image is changed over from the right to the left-hand beam path (or vice versa), correlated data is not adapted to the new perspective

Cause: The workstation does not receive the changeover signal or does not evaluate it.

Fault remedy:

- ▶ Check the workstation and the program settings.

Fault: A correlated contour is not precisely overlaid over the object.

Cause: The CaptiView is not calibrated with regard to the IGS software.

Fault remedy:

- ▶ Have the CaptiView calibrated by your IGS partner (see the manual of the IGS software).

Fault: The superimposed image is out of focus

Cause: Uncorrected refractive error.

Fault remedy:

- ▶ Correct the refractive error at the eyepieces (see the user manual of your microscope).

8.2 Troubleshooting the shutters

Fault: No microscope image when overlay is deactivated

Cause 1: The CaptiView receives incorrect commands from the IGS workstation. The shutters remain closed.

Fault remedy:

- ▶ Check the IGS workstation.
- If the IGS workstation does not function correctly:
- ▶ Press the switch for manually switching off the display and opening all shutters (18) (refer to Chapter "CaptiView controls", page CaptiView) and contact your IGS partner.

Cause 2: Defect in the CaptiView. The shutters remain closed.

Fault remedy:

- ▶ Check the IGS workstation.
- If the IGS workstation does not function correctly:
- ▶ Press the switch for manually switching off the display and opening all shutters (18) (refer to Chapter "CaptiView controls", page CaptiView) and contact your Leica representative

Fault: Shutters do not close/open as desiredCause: DIC settings set incorrectly.
The position of the shutters saved in the "DIC Settings" menu is incorrect.**Fault remedy:**

- ▶ Check the saved positions of the shutters in the "DIC" menu of the control unit (see page CaptiView) and set them as required.

8.3 Troubleshooting the display

Fault: The display shows a signal error

Cause 1: The display switches on by itself and/or shows an incorrect video signal.

Fault remedy:

- ▶ Press the switch for manually switching off the display and opening all shutters (18) (refer to Chapter "CaptiView controls", page CaptiView). Contact your Leica Microsystems representative.

9 Specifications

9.1 Electrical data

General classification

Safety type Type B

Power supply

Input voltage +24 V DC (via CAN connection)
Power consumption max. 10 W

Graphics interface

RGB signals 0.7V p-p / 75 Ohm
H sync and V sync TTL
Valid Resolutions
– 800(H) × 600(V) pixels at 60/72/75 Hz
– 1280(H) × 720(V) pixels at 60 Hz
– 1600(H) × 900(V) pixels at 60 Hz
– 1920(H) × 1080(V) pixels at 60 Hz

9.2 Optical data

Display features

Type 3 transmissive HTPS Panels
Resolution 1920 × 1080 Pixel
Contrast nom. 500:1 (native)
Color depth 24 bit

9.3 Physical data

Weight

CaptiView 1.2 kg

9.4 Ambient conditions

Transport –40 °C to +70 °C
–40 °F to +158 °F
Storage –10 °C to +55 °C
–14 °F to +131 °F
to 75 % relative humidity
Mode +10 °C to +40 °C
+50 °F to +104 °F
to 75 % relative humidity

9.5 Standards fulfilled

CE conformity

- Medical Devices Directive 93/42/EEC including amendments.
- Classification: Class I, in compliance with Annex IX, Rule 1 and Rule 12 of the Medical Devices Directive.
- Medical electrical equipment IEC 60601-1.
- Electromagnetic compatibility IEC 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.

9.6 Compatibility

Systems Leica M530 OH6
Leica M530 OHX

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.

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

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 9001, ISO 13485, and ISO 14001 relating to quality management, quality assurance and environmental management.



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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
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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
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· Shanghai	+86	21 6039 6000	+86	21 6387 6698
Japan · Tokyo	+81	3 6758 5670	+81	3515 54336
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