Swiss made

INSTRUCTIONS FOR USE

Imaging Module 910

3. Edition / 2024 – 04

HAAG-STREIT DIAGNOSTICS

INSTRUCTIONS FOR USE

Imaging Module 910

3. Edition / 2024 – 04

Preface

Thank you for choosing a Haag-Streit device. Provided you comply carefully with the regulations in these instructions for use, we can guarantee reliable and trouble-free use of our product.

WARNING!
Read the instruction manual carefully before commissioning this product. It contains important information regarding the safety of the user and patient.

NOTE!
For USA only: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

Contents

1 Safety

DANGER!
Failure to comply with these instructions may result in material damage or pose a danger to patients or users.

WARNING!
These warnings must absolutely be complied with to guarantee safe operation of the product and to avoid any danger to users and to patients.

NOTE!
Important information, please read carefully.

1.1 Comments on these instructions for use

NOTE!
In these instructions for use the point is used as decimal separator.

1.2 Ambient conditions

Transport	Temperature	−40 °C	...	+70 °C
	Air pressure	500 hPa	...	1060 hPa
	Relative humidity	10 %	...	95 %
Storage	Temperature	−10 °C	...	+55 °C
	Air pressure	700 hPa	...	1060 hPa
	Relative humidity	10 %	...	95 %
Use	Temperature	+10 °C	...	+35 °C
	Air pressure	800 hPa	...	1060 hPa
	Relative humidity	30 %	...	90 %

1.3 Shipment and unpacking

- Before unpacking the device, check whether the packaging shows traces of improper handling or damage. If this is the case, notify the transport company that delivered the goods to you.
- Unpack the device together with a representative of the transport company. Make a report of any damaged parts. This report must be signed by you and by the representative of the transport company.
- Leave the device in the packaging for a few hours before unpacking it (condensation).
- Check the device for damage after it is unpacked.
- Return defective devices in the appropriate packaging.
- Store packaging material carefully so that it can be used for potential returns or when moving.

1.4 Installation warnings

WARNING!
- Do not modify this device without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists.
- Any third-party device must be connected in compliance with the EN 60601-1 standard.
- Only original Haag-Streit spare parts may be used.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- The device should be set up in such a way that the plug is always easily accessible and the device can easily be disconnected from the mains.

1.5 Operation, environment

DANGER!
Never use the device in potentially explosive environments where volatile solvents (alcohol, petrol, etc.) and flammable anaesthetics are in use.

WARNING!
- This device must not be operated near of high frequency surgical equipment and the radio frequency shielded room of a medical electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by Haag-Streit. Otherwise, degradation of the performance of this device could result.
- The Imaging Module 910 (IM 910) is intended for documentation purposes. The ocular image is critical for diagnosing a patient.
- Before every examination, check that the automatic left to right detection works correctly from the release module.
- The release module is affixed with strong magnets. Keep magnet-sensitive storage media (e.g. credit cards) away from the magnet.

NOTE!
- This device must only be operated by qualified personnel. The owner is responsible for their training.
- This device may only be used in accordance with the instructions in the 'Intended purpose / intended use' chapter.

1.6 Disinfection

NOTE!
The device can, but does not need to be disinfected. For more information, please refer to the 'Maintenance' chapter.

1.7 Warranty and product liability

- Haag-Streit products must be used only for the purposes and in the manner described in the documents distributed with the product.
- The product must be treated as described in the 'Safety' chapter. Improper handling can damage the product. This would void all guarantee claims.
- Continued use of a product damaged by incorrect handling may lead to personal injury. In such a case, the manufacturer will not accept any liability.
- Haag-Streit does not grant any warranties, either expressed or implied, including implied warranties of merchantability or fitness for a particular use.
- Haag-Streit expressly disclaims liability for incidental or consequential damage resulting from the use of the product.
- This product is covered by a limited warranty granted by your seller.
- For USA only: This product is covered by a limited warranty, which may be reviewed at www.haag-streit-usa.com.

1.8 Reporting obligation

NOTE!
Any serious incident that has occurred in relation to the device must be reported to Haag-Streit and the competent authority of the Member State in your country.

1.9 Description of symbols

	Follow instruction for use		Read the instructions for use attentively
	General warning, read the accompanying documentation		European certificate of conformity
	Date of manufacture		Manufacturer
	Haag-Streit reference number		Serial number
	Trademark of the manufacturer Haag-Streit AG		Notes on disposal, see the 'Disposal' chapter

EC REP	Listed European Authorized Representative	MD	Medical Device
	Rotating knob on camera symbol = 70 % of the light goes to the camera		Diaphragm selection knob
	Slit illumination		Background illumination
	Strong permanent magnets		On (Power)
MET	MET Listed Mark with approval for USA and Canada		

2 Intended purpose / intended use

The Imaging Module 910 was developed exclusively for the Haag-Streit slit lamp BQ 900, which can be used to produce digital photographs and videos (optionally available in 3D) for documentation of the eye.

3 Introduction

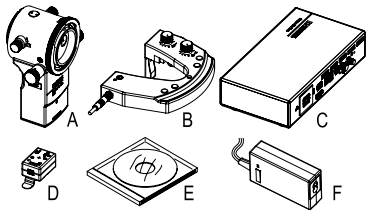
3.1 Description of the device

The system allows for creation of digital images and videos. An optional licence enables processing of digital pictures and videos in 3D (stereo). Without a licence processing is in 2D (mono). The divider mirror can be switched off with a switch (rotating knob) so that 100% of the light reaches the eyepiece. With the release module, it is possible to release images or videos and to change the camera's exposure time without letting go of the joystick. The connector box enables viewing a live stream on a connected monitor without EyeSuite. The position sensor is an optional accessory for automatically switching the system on/off depending on the table position.

3.2 System components

The Imaging Module 910 is a system made up of the following main components:

A. Camera module CM04
B. Release module RM03
C. Connector box CB01
D. Position sensor PoS01[1)]
E. EyeSuite software[2)]
F. Power supply



1) Optional accessory
2) EyeSuite Imaging extension can be optionally activated for a surcharge

3.3 LED illumination (prerequisite)

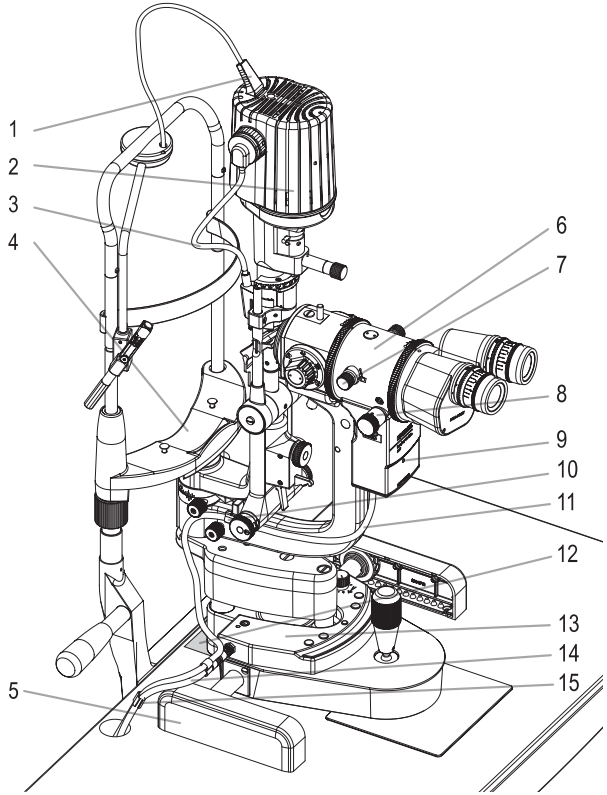
1. Lamp cable with special connection plug for LI01 plus / LI02 plus
2. LED illumination head with background illumination (see separate instructions for use)
3. Fiber optic line for background illumination
4. Headrest (see separate instructions for use)
5. Rail cover

3.4 Camera module CM04

6. Camera module CM04
7. Beam splitter switch (rotating knob)
8. Diaphragm selection (rotating knob)
9. Operational control LED
10. Cable clamp
11. Cable CXP (CM04 to CB01)

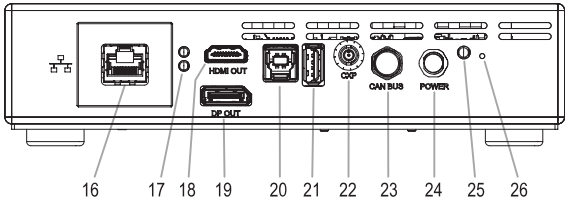
3.5 Release module RM03

12. Sticker left/right identification
13. Release module RM03
14. Cable distributor
15. Cable clip



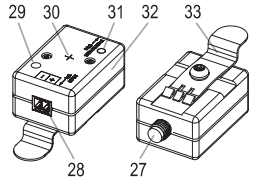
3.6 Connector box CB01

16. Ethernet socket
17. Indicator LED for ethernet
18. HDMI socket
19. Displayport socket
20. USB 3.0 socket
21. USB 2.0 socket
22. CoaXPress socket (CXP)
23. CAN bus socket
24. Power socket
25. Indicator LED of CB01
26. Reset button



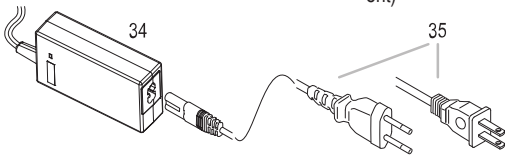
3.7 Position sensor PoS01

27. CAN bus socket
28. Control input
29. Dip switches
30. Magnetic switch zone
31. Indicator LED
32. Terminal block
33. DIN rail clip



3.8 Power supply

34. Power supply
35. Mains connector (country-dependent)



4 Device assembly / installation

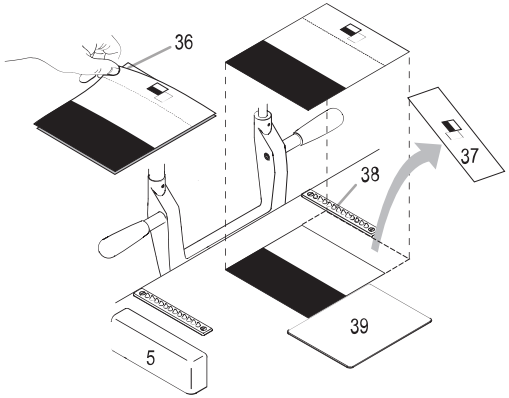
WARNING!

- Do not modify this device without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists.
- Contact your Haag-Streit representative for installation, repairs and modification work on the system. The contact details are available at www.haag-streit.com.
- Only original Haag-Streit spare parts may be used.

4.1 Placement of adhesive label for the automatic left/right detection

36. Protective film
37. Rest of the sticker
38. Roller rail
39. Gliding plate

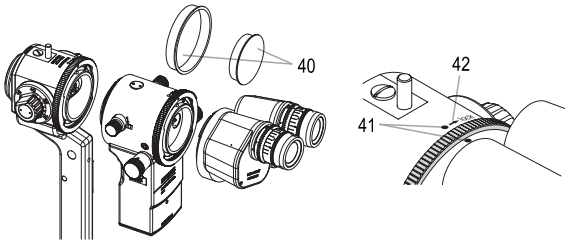
- Remove rail cover (5) and place slit lamp aside. Clean surface of table.
- Remove protective film (36) from the back of the adhesive label. Carefully start at the corner opposite the black surface.
- Position the sticker against the right roller rail (38) and the gliding plate (39). Press firmly on the white/black surface, press away any air bubbles.
- Carefully tear off the remainder of the adhesive label (37) (the 'positioning tool') along the perforation.
- Reassemble the slit lamp and rail cover.



4.2 Connecting the CM04 in the beam path

40. Cover caps
41. Marking points
42. Arrow (lock)

- Disassemble the breath shield.
- Remove the black and white cover caps (40).
- Align the marking points (41) on the upper side of the parts to be connected.
- Turn the locking ring in the direction of the arrow shown (42) to tighten.



4.3 Weight compensation facility

43. Setting screws weight compensation facility

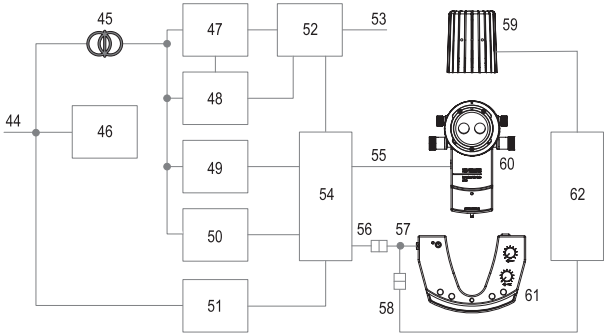
The slit lamp's crosstree carriage offers the option of balancing the weight of the accessory so that the height adjustment on the joystick remains smooth (43). To do so, please follow the instructions in the instruction manual for the slit lamp.

4.4 Cabling of the CM04 and the RM03 (diagram)

WARNING!

- Only use medically approved PCs or operate via a medically approved isolating transformer.
- Auxiliary units on the connector box CB01 (e.g. monitor HDMI, monitor Displayport) must be operated through an isolating transformer.
- The power supply unit's mains connector must be accessible in order to allow for disconnection from the mains at any time.

44. Mains
45. Medical approved isolating transformer
46. Instrument table (IT)
47. Printer
48. Personal computer
49. Monitor HDMI
50. Monitor Displayport
51. Medical approved power supply
52. Ethernet switch
53. Local network
54. Connector box
55. Cable CXP (camera cable)
56. Cable M8 (CAN-BUS)
57. Cable distributor
58. Cable headrest
59. LED illumination LI02 plus
60. Camera module CM04
61. Release module RM03
62. Headrest

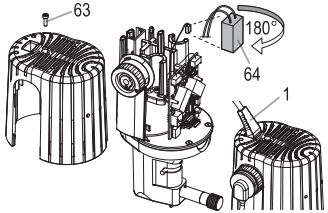


NOTE!

- To ensure that the system works correctly, Haag-Streit recommends not using laptops and using a high-quality desktop computer instead.
- The release module RM03 only works properly with a LED illumination LI02 plus. The functions with older versions of LED illumination cannot be guaranteed.
- Do not cover the connector box CB01, as the box can overheat and shut down.

63. Fastening screw
64. Two-pole connection plug

If the middle LED lights up red during operation, the two-pole connection plug (64) is connected incorrectly.



- Disconnect the device from the mains.
- Remove the cover on the upper part of the illumination facility by loosening the fastening screw (63).
- Turn the two-pole connection plug (64) 180°.
- Fix the cover on the upper part of the illumination facility with the fastening screw (63).
- Connect the device to the mains again.

WARNING!
- Keep magnet-sensitive storage media (e.g. credit cards) away from the magnets on the release module RM03.
- Only external medical power supplies approved by Haag-Streit that fulfill EN 60601-1 may be used.

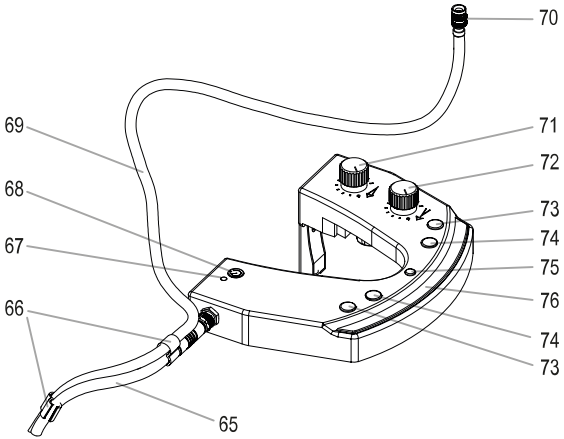
4.4.1 Step-by-step cabling

- Place the release module RM03 over the slit lamp's cross slide. Four magnets are used for fixing.

NOTE!
- No external USB devices may be connected to USB ports (20) and (21).
- With BQ 900 slit lamps with a date of manufacture before 1998, the cover plate is fixed on the crosstree carriage with screws. The two screws at the back must be removed before the RM03 is mounted.

- Insert the CXP plug of the camera cable (70) in the socket on the camera module CM04.
- Press the camera cable (69) into the cable clamp (10).
- Connect the cable distributor (65) with the release module RM03.
- Cable distributor and camera cable can be fixed with cable clips (66).
- Connect the cable M8 (CAN-BUS) with the cable distributor (65).
- Connect the headrest plug of cable distributor (65) with the counterpart on the headrest.
- Mount the table top and place the slit lamp on the table.
- Plug the headrest cable (1) into the lamp head.

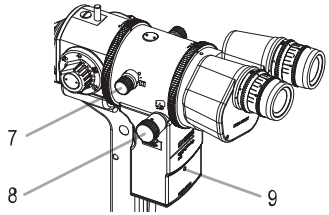
65. Cable distributor
66. Cable clips
67. RM03 operational control LED
68. On/Off key
69. Camera cable
70. Camera cable CPX plug
71. Rotating knob, background illumination
72. Rotating knob, slit illumination
73. Outer key
74. Inner key
75. Menu key
76. Release key RM03



5 Commissioning

5.1 Switching on the device

- Connect the power supply to the mains and press the On/Off key (68) on the release module RM03. The green operational control LED (67) lights up when the device is switched on. The camera has no On/Off key and switches on automatically when the connector box CB01 is switched on. The status is displayed by the indicator light (9).
- Turn the rotating knob on the slit illumination (72) to a position between '1' and '10'.



6 Operation

NOTE!
The slit lamp's eyepieces must be adjusted in accordance with the refraction of the examiner. See instructions for use for the slit lamp BQ 900.

6.1 Changing the depth of sharpness

- Select a diaphragm with the rotating knob (8).
  1 = Largest diaphragm (lowest depth of sharpness)
  5 = Smallest diaphragm (highest depth of sharpness)
- Select the the target illumination on the release module RM03.
- Capture an image via release key on the release module RM03

6.2 Camera module CM04

Set the beam splitter switch (7) to the camera symbol

- 70% of the light goes to the camera
- 30% of the light goes to the examiner

Set the beam splitter switch (7) to the top

- 100% of the light goes to the examiner (applies to both beam paths)

6.3 Camera module CM04 30/70

Set the beam splitter switch (7) to the camera symbol

- 30% of the light goes to the camera
- 70% of the light goes to the examiner

Set the beam splitter switch (7) to the top

- 100% of the light goes to the examiner (applies to both beam paths)

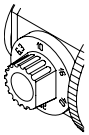
6.4 Field of view

WARNING!
The images and videos should only be used for documentation purposes. Only the image in the eyepiece may be used for diagnosis.

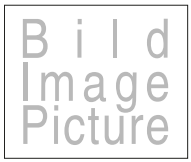
Field of view of the object, see table

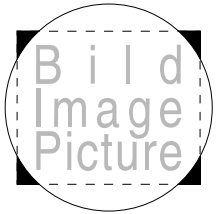
Circle: The field of view of the object observed through the microscope's eyepiece.

Rectangle: Surface area of the sensor:



	Object image section in the eyepiece (mm)	Object image section in the camera
	12.5 ×	**Recording mode 5:4**
6.3 ×	ø 33	24.4 × 29.2
10 ×	ø 20	15.4 × 18.4
16 ×	ø 12.7	9.7 × 11.7
25 ×	ø 8	6.1 × 7.4
40 ×	ø 5.1	3.9 × 4.7





6.5 Image & video capture mode

- When setting the beam splitter switch (7) to the camera symbol the camera will automatically start and the live-stream image of the camera (mounted in the right optical path) will be displayed.
- Image capture: By pressing the release key (76) an image will be captured.
- Video capture: A long press on the release key (76) starts video capturing. Pressing the menu button (75) will stop the recording function. During video capturing images can still be taken by pressing the release key (76).
- By resetting the beam splitter switch (7) the option to end the current examination or continue with the existing examination appears if 'End Examination Mode' is enabled.

6.5.1 Exposure mode

By default the system operates in auto exposure mode thus the exposure is selected by the system. If you want to change the exposure manually, you have the following options:

- Brighter: By pressing the outer key (73) of the release module RM03 the image brightness level will be increased.
- Darker: By pressing the inner key (74) of the release module RM03 the image brightness level will be decreased.
- Restore auto exposure mode: By pressing the inner key (74) and outer key (73) simultaneously the mode will switch to auto exposure mode.

6.5.2 Aperture priority mode

- When an aperture is selected manually the camera will operate in the aperture priority mode. Exposure and gain will continue to operate automatically but the aperture is fixed.

6.6 Image review mode

- By pressing the menu key (75) you can switch from capture to review mode and vice-versa.
- In the review mode all captured images and videos of the session are listed in chronologic order. With the inner key (74) and outer key (73) of the release module RM03 you can scroll through the list. Please note that the images saved on the connector box CB01 will be deleted after 7 days.
- Deleting images and videos: In the image review mode selected images and videos can be deleted by pressing the trigger key (76).

6.7 Menu

- By pressing the menu key (75) for two seconds you enter the menu. In the menu you can initiate a white balancing, enter the settings and find the 'About' dialogue by selecting the keys (73), (74) and (76).
- Under 'Settings' you'll find 'Audio', 'Capture Mode', 'Aperture Mode', 'Focus Mode' and 'End Examination Mode'.
  - 'Audio' – Determines if an acoustic confirmation of the key buttons of the RM03 is provided.
    - 'Audio ON' – Acoustic confirmation is activated.
    - 'Audio OFF' – Acoustic confirmation is deactivated.
  - 'Capture Mode' – Defines how the images are selected during the capturing process.
    - 'Best Image' – Selects the best image of the last 30 frames for you. This increases the overall success rate of good pictures, however, in certain situations it may theoretically happen that a picture is selected that you would have discarded.
    - 'Newest Image' – Selects the most recent image at the exact moment the release key (76) is pressed.
  - 'Aperture Mode' – Determines which mode is set as default at the start of the examination.
    - 'Aperture Auto' – Sets auto aperture control as default at the start of the examination.
    - 'Aperture Manual' – Sets manual aperture control as default at the start of the examination.
  - 'Focus Mode' – Hides the user interface in the image capturing screen.
    - 'Focus Mode Direct Capture' – Hides the user interface by maintaining the regular workflow.
    - 'Focus Mode Freeze Capture' – Hides the user interface and displays a freeze preview of the captured image (video recording is disabled when 'Focus Mode Freeze Capture' is selected).
    - 'Focus Mode OFF' – Enables the user interface in the image capturing screen.
  - 'End Examination Mode' – Offers the possibility of summarizing recordings to examinations, initiated by switching the beam splitter switch and confirming the end of the current examination.
    - 'End Examination Mode ON' – Activates the mode. When enabled, an 'End of Examination' prompt appears when the beam splitter switch is operated. When confirmed, the system will store all images and videos taken during the examination in a corresponding folder on the connector box CB01. Simultaneously it will start a new examination session. (The 'End of Examination?' prompt can also be initiated by pressing the inner key (74) and outer key (73) simultaneously when you are in the preview mode).
    - 'End Examination Mode OFF' – Deactivates the mode.

6.8 White balance

- The Haag-Streit Imaging Module 910 is optimized for maximum image quality with the Haag-Streit slit lamp BQ 900. The image quality is dependent, among other things, on the correct calibration of the color tones to the respective slit illumination. We recommend performing a white balance in order to improve the image quality and achieve a realistic color reproduction.

6.8.1 Conducting a white balance (IM 910 software)

- Follow the instruction displayed on the screen.
  1. Turn the slit lamp on.
  2. Select a 16 × magnification.
  3. Place an 18% grey card in front of the slit lamp (use Haag-Streit white balancing grey card).
  4. Adjust brightness in order to have a homogeneous illumination of the grey card.
  5. Set illumination level to 100%.
  6. The texture of the grey card can be clearly recognized.
- Press release button to start the white balancing.

6.8.2 Conducting a white balance (EyeSuite)

1. Start the 'EyeSuite Imaging' software
2. Activate the intensity auto mode
3. Open the 'White balance' application
4. Start the 'White balance' by activating the 'Calibration' function

WARNING!
To achieve an optimal result during the white balance, the image must be homogeneously illuminated.

Set white balance greycard (*REF 1021485*)

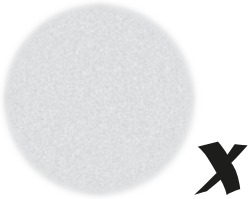
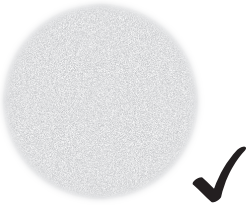


Image is blurry or overexposed



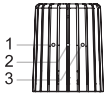
Structure is discernible

6.9 Software / Help menu / error messages

The EyeSuite software's help section contains instructions and guidance for performing an examination as well as descriptions of the error messages. Help can be opened by pressing the F1 key or by going to the [?] - [Help] menu.

WARNING!
The software must be installed by trained personnel in accordance with separate installation instructions.

6.10 LED indicator illumination head



	1) Background illumination	2) Polarity reversal	3) Slit illumination
Operating state	● ○ ○	○ ● ○	○ ○ ●
Standby mode	Green, pulsing	x	Green, pulsing
Normal operation Slit and background illumination on	Green	x	Green
Only slit illumination on	Green, pulsing	x	Green
Only background illumination on	Green	x	Green, pulsing
Reduced background illumination operation High LED temperature, thus reducing background illumination operation	Green, flashing	x	Green, flashing

6.11 LED indicator power supply

Normal operation	Green

6.12 LED indicator release module RM03

Normal operation	Green
LED illumination switched off	Green, pulsing
Establishing connection	Orange
LED illumination not connected	Green, flashing

6.13 LED indicator camera module CM04

Normal operation	Green
Firmware update is ongoing	Blue, flashing

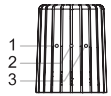
6.14 LED indicator connector box CB01

Normal operation	Green
Firmware update is ongoing	Blue, flashing
Reboot connector box CB01 by pressing the reset button for > 5 seconds	White
Configuration reset by pressing the reset button for > 15 seconds.	Orange

6.15 LED indicator position sensor PoS01

Normal operation	Green
Establishing connection	Orange

6.16 Error messages (illumination head)



ERROR	Error messages	Measures	1) Background illumination ● ○ ○	2) Polarity reversal ○ ● ○	3) Slit illumination ○ ○ ●
E1	Incorrect supply polarisation	Contact your Haag-Streit representative.	x	Red ▬	x
E2	Illumination control not recognized	Connect illumination control or replace, if necessary.	Red ▬	x	Red ▬
E3	Temperature is too high	The light sources' power will be reduced. Normal operation is ensured once the permissible temperature has been reached.	Red, flashing ▮▮▮▮▮▮▮▮▮	x	Red, flashing ▮▮▮▮▮▮▮▮▮
E4	No communication between power supply and illumination	Contact your Haag-Streit representative.	Red, flashing 2 × ▮▮ ▮▮ ▮▮	x	Red, flashing 2 × ▮▮ ▮▮ ▮▮
E6	General error	Send PS-LED to the appropriate service branch.	Red, flashing 4 × ▮▮▮▮ ▮▮▮▮	x	Red, flashing 4 × ▮▮▮▮ ▮▮▮▮

6.17 Error messages release module RM03

ERROR	Error messages	Measures	Operational control LED (67)
E10	General error	Send device to the appropriate service branch.	Red ▬
E12	Communication error	Contact your Haag-Streit representative.	Red, flashing 2 × ▮▮ ▮▮ ▮▮
E14	Hardware version error	Contact your Haag-Streit representative.	Red, flashing 4 × ▮▮▮▮ ▮▮▮▮

6.18 Error messages camera module CM04

ERROR	Error messages	Measures	Operational control LED (9)
E18	No communication with connector box CB01	Contact your Haag-Streit representative.	Red, flashing 2 × 
E20	Firmware update failed	Send device to the appropriate service branch.	Red 
E22	Temperature is too high	The power of the camera module CM04 will be reduced. Operation is only possible again when the permissible temperature has been reached and the connector box CB01 has been restarted.	Red, flashing 

6.19 Error messages connector box CB01

ERROR	Error messages	Measures	Operational control LED (25)
E24	General error	Contact your Haag-Streit representative.	Red 
E26	Temperature is too high	The power of the connector box CB01 will be reduced. Operation is only possible again when the permissible temperature has been reached and the connector box CB01 has been restarted.	Red, flashing 

7 Decommissioning

Press the On/Off key (68) on the release module RM03 briefly to switch off the LED illumination after the examination. This does not switch off the camera. This is signaled with green pulsing. Pressing the key for approx. 3 sec. switches off the release module completely and the operational control LED (67) goes out. The camera has no separate On/Off switch. It switches off automatically when the connector box CB01 is switched off.

NOTE!
The On/Off key on the release module RM03 does not disconnect the device from the electric mains. Disconnect the power supply from the mains by unplugging the mains connector if you do not intend to use it for an extended period of time.

8 Technical data

8.1 Power supply

Type	EDACPOWER Electronics Co
Model	EM10682H
Mains voltage	100 – 240 VAC
Current consumption	2.0 - 1.0 A
Operating frequency	50 – 60 Hz

8.2 Dimensions

IM 910 set	
Weight	4.5 kg (incl. packaging)
Dimensions CM04 (L × W × H)	173 × 127 × 82 mm
Packaging (L × W × H)	380 × 270 × 130 mm

8.3 Minimum network requirement for operation with EyeSuite

Ethernet interface (for PC and switch)	1000BASE-T (1 Gbit/s)

NOTE!
Minimum requirements for PCs can be found in the EyeSuite instructions for use.

8.4 Allowed monitor resolutions for standalone operation

1920 x 1080 pixel resolution (FHD)
2560 x 1440 pixel resolution (QHD)
3840 x 2160 pixel resolution (4K UHD)[1)]

1) Limited to 30 frames per second

8.5 Camera

Camera beam mono	Beam path right (from the point of view of the doctor)
Camera beam stereo	Beam path left and right
Interface	CoaXPress CXP
Frame rate	30 fps (frames per second)
Image file format	jpg
Video file format	mp4
Power consumption	24 VDC ⎓ / 420 mA

8.6 Connector box CB01

Storage size		256 GB
Interface		HDMI, DisplayPort (DP), LAN
Power consumption	Input Output Output	24 VDC / ±5% / 2 A 24 VDC / 1 A (CAN-BUS) 24 VDC / 700 mA (CXP)

9 Maintenance

WARNING!
- Do not modify this device without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists.
- Contact your Haag-Streit representative for installation, repairs and modification work on the system. The contact details are available at www.haag-streit.com.
- Only original Haag-Streit spare parts may be used.

9.1 Device inspection

To check the correct function, proceed as follows:

- Insert the test rod into the radial movement bearing, whilst at the same time aligning the surface to the microscope at a right angle.
- Set the slit length to 8 or 14 mm.
- Set the illumination intensity to 50%.
- Set the magnification in the microscope to max.
- Set the eyepieces in such a way that the test rod is in sharp focus. In doing so, turn the ocular from the (+) to the (-) side.
- Switch on the camera.
- For all magnifications, the structure of the test rod in the ocular and in the camera image must be shown in sharp focus.
- Turn on the illumination of the 0.2 mm diaphragm.
- Turn on the crosshairs in EyeSuite; the cross must be inside the illuminated dot.

9.2 Servicing

To guarantee a long service life, the device must be cleaned weekly as described and protected with the dust cover when not in use. We recommend having the device inspected once a year by an authorized service technician.

9.3 Cleaning and disinfection

The Haag-Streit slit lamps and their accessories can, if required, be carefully wiped down with ready-for-use disposable 70% ethanol disinfectant wipes. Surface-friendly disinfectants (containing aldehyde or aldehyde-free) are also permitted, such as Kohrsolin FF.

WARNING!
- The preparation instructions provided do not apply to tonometer measuring prisms.
- Tonometer measuring prisms must be prepared in accordance with a different manual
- Too strong or aggressive disinfectants or cleaning liquids e.g. hydrogen peroxide will damage the finish and coating of the device.
- Do not use sprays
- Observe the manufacturer's safety instructions
- Do not use any cloths that drip
- Wring out any soaked cloths before use when necessary
- Ensure that no liquid penetrates the device
- Comply with the stipulated exposure time
- Clean optical surfaces after disinfection with a very soft cloth

NOTE!
IP code: IPX0 (device is not protected against liquids)

10 Appendix

10.1 Accessories / functionals parts / detachable parts / consumables

Components	*REF*
Position sensor PoS01	*7221014*
Cable distributor	*1023636*
Cable Ethernet Cat. 6e (3m)	*1820489*
Cable HDMI 3m	*1024083S*
Cable set long (6m)	*7221024*
Cable set short (3m)	*7221023*
Set white balance grey card	*1021485*

10.2 Legal regulations

- This device was developed and designed taking the EN 60601-1 and EN 60601-1-2 standards into account.
- The EN 60601-1 standard must be observed when using different medical and/or non-medical electrical devices in combination.
- Compliance of the device with the EU 2017/745 (Medical Device Regulation) is confirmed by the CE-designation.
- You can request a copy of the declaration of conformity for this device from Haag-Streit at any time.
- Statutory accident regulations are to be observed.

WARNING!
The device may only be operated in an environment in which standard values pursuant to standard EN 60601-1 are observed.

10.3 Classification

Standard EN 60601-1	Protection class I
Operating mode	Continuous operation
EU 2017/745 (Medical Device Regulation)	Class I
FDA	Class II

10.4 Disposal

Electrical and electronic devices must be disposed of separately from household waste! This device was made available for sale after the 13th August 2005. For correct disposal, please contact your Haag-Streit representative. This will guarantee that no hazardous substances enter the environment and that valuable raw materials are recycled.

10.5 Observed standards

EN 60601-1
EN 60601-1-2

10.6 Information and manufacturer's declaration concerning electromagnetic compatibility (EMC)

10.6.1 General

This device fulfills the requirements on electromagnetic compatibility according to IEC 60601-1-2:2014+A1:2020 (Edition 4.1). The device is built so that the generation and emission of electromagnetic interference is limited to the extent that other devices are not disturbed in their use in accordance with the regulations and so that the device itself is suitably immune to electromagnetic interference.

WARNING!

- Electrical medical devices and systems are subject to special EMC measures and must be installed in accordance with the EMC instructions contained in this accompanying document.
- Use of accessories, transducers and cables other than those specified or provided by Haag-Streit could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Third-party devices may only be connected in compliance with the IEC 60601-1 standard.

10.6.2 Emitted interference

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 32	Class B	
Harmonics emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

10.6.3 Electromagnetic immunity environment tested (part 1)

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV, 100kHz for power supply lines * ± 1 kV, 100 kHz for input/output lines *	± 2 kV, 100kHz for power supply lines * ± 0.5, ± 1 kV, 100 kHz for input/output lines *	Mains power quality should be that of a typical commercial or hospital environment. * Not applicable for DC and I/O if cable < 3 m.
Surge IEC 61000-4-5	± 0.5, ± 1 kV line(s) to line(s) * ± 0.5, ± 1, ± 2 kV line(s) to earth *	± 1 kV line(s) to line(s) * ± 0.5, ± 1, ± 2 kV line(s) to earth *	Mains power quality should be that of a typical commercial or hospital environment. * Not applicable for DC and I/O if cable < 3 m.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T: 1 cycle at 0° 0% U_T: 250/300 cycles at 0° 70% U_T: 25/30 cycles at 0°	0% U_T: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T: 1 cycle at 0° 0% U_T: 250/300 cycles at 0° 70% U_T: 25/30 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or battery. U_T is the a.c. mains voltage (100 – 240 V) prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m 50/60 Hz	60 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

10.6.4 Electromagnetic immunity environment tested (part 2)

Portable and mobile RF communications equipment should be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz – 80 MHz outside ISM bands and radio amateur band *	10 V_{rms} 150 kHz – 80 MHz outside ISM bands and radio amateur band *	If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this product. Minimum separation distance shall be calculated by following equation: $E = \frac{6}{d}\sqrt{P}$ E is the immunity test level in [V/m] d is the minimum separation in [m] P is the maximum power in [W] **RF wireless equipment maximum output power and separation distance tested (at 30 cm):** TETRA 400: max 1.8 W GMRS 460, FRS 460: max 2 W LTE Band 13 and 17: max 0.2 W GSM 800/900: max 2 W TETRA 800: max 2 W iDEN 820: max 2 W CDMA 850: max 2 W LTE Band 5: max 2 W
	6 V_{rms} 150 kHz – 80 MHz in ISM bands and radio amateur band *	10 V_{rms} 150 kHz – 80 MHz in ISM bands and radio amateur band *	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 6 GHz 80% AM 1 kHz	10 V/m 80 MHz – 6 GHz 80% AM 1 kHz	
Proximity field from RF wireless communication equipment IEC 61000-4-3	27 V/m 380 – 390 MHz 50% PM 18 Hz	27 V/m 380 – 390 MHz 50% PM 18 Hz	
	28 V/m 430 – 470 MHz FM ± 5 kHz deviation, 1kHz sine	28 V/m 430 – 470 MHz FM ± 5 kHz deviation, 1kHz sine	
	9 V/m 704 – 787 MHz 50% PM 217 Hz	9 V/m 704 – 787 MHz 50% PM 217 Hz	
	28 V/m 800 – 960 MHz 50% PM 18 Hz	28 V/m 800 – 960 MHz 50% PM 18 Hz	
	28 V/m 1700 – 1990 MHz	28 V/m 1700 – 1990 MHz	

	50% PM 217 Hz 28 V/m 2400 – 2570 MHz 50% PM 217 Hz 9 V/m 5100 – 5800 MHz 50% PM 217 Hz	50% PM 217 Hz 28 V/m 2400 – 2570 MHz 50% PM 217 Hz 9 V/m 5100 – 5800 MHz 50% PM 217 Hz	GSM 1800/1900: max 2 W CDMA 1900: max 2 W DECT: max 2 W LTE Band 1, 3, 4, 25: max 2 W UMTS: max 2 W Bluethooth: max 2 W WLAN 802.11b/g/n: max 2 W RFID 2450: max 2 W LTE Band 7: max 2 W WLAN 802.11 a/n: max 0.2 W
Radiated fields in close proximity IEC 61000-4-39	8 A/m 30 kHz 65 A/m 134.2 kHz 7.5 A/m 13.56 MHz	8 A/m 30 kHz 65 A/m 134.2 kHz ** 7.5 A/m 13.56 MHz	Interference may occur in the vicinity of equipment marked with the following symbol:

* The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are: 6.765 – 6.795 MHz, 13.553 – 13.567 MHz, 26.957 – 27.283 MHz, 40.66 – 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are: 1.8 MHz – 2 MHz, 3.5 – 4.0 MHz, 5.3 – 5.4 MHz, 7 – 7.3 MHz, 10.1 – 10.15 MHz, 14 – 14.2 MHz, 18.07 – 18.17 MHz, 21.0 – 21.4 MHz, 24.89 – 24.99 MHz, 28.0 – 29.7 MHz, 50.0 – 54.0 MHz.
** In the event of a severe 134.2 kHz interference, communication to the illumination head may be lost. It may be necessary to restart the device manually.

If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this product.

10.6.5 Recommended separation distances between portable and mobile RF communications equipment and this product

This product is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communication equipment.

	Separation distance according to frequency of transmitter [m]		
Rated maximum output power of transmitter [W]	**150 kHz – 80 MHz outside ISM and radio amateur bands *** d = 0.35 √P **	**150 kHz – 80 MHz in ISM and radio amateur bands *** d = 1.2 √P	**800 MHz – 6 GHz (for define RF Wireless transmitters see table before)** d = 0.60 √P
0.01	0.04	0.12	0.06
0.1	0.13	0.38	0.19
1	0.40	1.2	0.60
10	1.3	3.8	1.9
100	4.0	12	6.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres [m] can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

$$E = \frac{6}{d}\sqrt{P}$$

* The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are: 6.765 – 6.795 MHz, 13.553 – 13.567 MHz, 26.957 – 27.283 MHz, 40.66 – 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are: 1.8 MHz – 2 MHz, 3.5 – 4.0 MHz, 5.3 – 5.4 MHz, 7 – 7.3 MHz, 10.1 – 10.15 MHz, 14 – 14.2 MHz, 18.07 – 18.17 MHz, 21.0 – 21.4 MHz, 24.89 – 24.99 MHz, 28.0 – 29.7 MHz, 50.0 – 54.0 MHz.
** Formulas coming from Edition 3 of the IEC 60601-1-2.

Should you have any further questions, please contact your Haag-Streit representative at:
www.haag-streit.com/en/contact/distributors

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