INSTRUCTIONS FOR USE
Imaging Module

IM 900
Accessory for the BQ 900 Slit Lamp

6. edition / 2019 – 06
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Introduction
Thank you for choosing a Haag-Streit device. Provided you comply carefully with the regulations in this instructions for use, we can guarantee the reliable and unproblematic use of our product.

Purpose of use
This device is an accessory for Haag-Streit slit lamps BQ 900, which can be used to produce digital photographs and videos for documentation of the eye.

Contraindication
There are no absolute contraindications known for examinations with this device. Appropriate professional assessment and caution are necessary.

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

NOTE!
Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.
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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 Areas of application of the device
The device is intended to use in professional health care facility environment, like doctor's practices, hospitals and optometrists and opticians premises, except near of HF surgical equipment and RF shielded rooms of ME-systems for magnetic resonance imaging. Some portable radio frequency equipment, like cell phones or RF telephone equipment including antennas may interference medical devices. Such equipment has to be kept in a distance of more than 30 cm (12 inches) from any part of the instrument. Inobservance of this precaution may lower the correct function of the instrument. The software may be stopped or needs to be restarted. If such unexpected disturbances of the software are observed, the cause could be a cell phone or RF telephone in the immediate vicinity to the instrument. Increase the distance to the unit, until the interference disappears. The communication between imaging module and PC may also be disturbed or interrupted, if the device is exposed to a mains power supply delivering excessively transient disturbances or short voltage interruptions. If this happens, the USB connector needs to be disconnected for a short time or the PC needs to be restarted.

1.2 Ambient conditions

<table>
<thead>
<tr>
<th>Use:</th>
<th>Temperature</th>
<th>from</th>
<th>to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use:</td>
<td>+10°C</td>
<td>+35°C</td>
<td></td>
</tr>
<tr>
<td>Air pressure</td>
<td>from</td>
<td>to</td>
<td></td>
</tr>
<tr>
<td>Air pressure</td>
<td>800 hPa</td>
<td>1060 hPa</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>from</td>
<td>to</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>30%</td>
<td>90%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Transport:</th>
<th>Temperature</th>
<th>from</th>
<th>to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport:</td>
<td>−40°C</td>
<td>+70°C</td>
<td></td>
</tr>
<tr>
<td>Air pressure</td>
<td>from</td>
<td>to</td>
<td></td>
</tr>
<tr>
<td>Air pressure</td>
<td>500 hPa</td>
<td>1060 hPa</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>from</td>
<td>to</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>10%</td>
<td>95%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage:</th>
<th>Temperature</th>
<th>from</th>
<th>to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage:</td>
<td>−10°C</td>
<td>+55°C</td>
<td></td>
</tr>
<tr>
<td>Air pressure</td>
<td>from</td>
<td>to</td>
<td></td>
</tr>
<tr>
<td>Air pressure</td>
<td>700 hPa</td>
<td>1060 hPa</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>from</td>
<td>to</td>
<td></td>
</tr>
<tr>
<td>Relative humidity</td>
<td>10%</td>
<td>95%</td>
<td></td>
</tr>
</tbody>
</table>

1.3 Shipment and unpacking

- Before you unpack the device, check whether the packaging shows traces of incorrect handling or damage. If this is the case, notify the transport company that has delivered the goods to you. Unpack the device together with a representative of the transport company. Prepare a report for any possible 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 possible returns or when moving.

1.4 Installation warnings

**WARNING!**
* Do not modify this equipment 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 (HS) replacement parts may be used.
* The device must not be stacked or placed in close proximity to other electronic devices.

**NOTE!**
The power supply unit's mains connector must be accessible in order to allow for disconnection from the mains at any time.

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!
* The imaging module 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 RM02 is affixed with strong magnets. Keep magnet-sensitive storage media (e.g. credit cards) away from the magnet.

NOTE!
This equipment 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 “Purpose of use”.

1.6 Disinfection
NOTE!
The device does not require disinfection. For more information on cleaning, please refer to the ‘Maintenance’ section.

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 Description of symbols
Follow instruction for use
Read the instructions for use attentively

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

2.4 Camera module CM03
6. Camera module CM03
7. Switch (rotating knob) beam splitter
8. Diaphragm selection knob
9. Operational control LED
10. Camera cable (CM03 to RM02)
11. Cable holder

2.5 Release module RM02
12. Release module RM02
13. Sticker left/right identification
14. Cable harness

2.6 Power supply
15. Power supply
16. Mains connector (country-dependent)
3. Device assembly / installation

WARNING!
* Do not modify this equipment 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 replacement parts may be used.

3.1 Placement of adhesive label for the automatic left/right detection
17. Protective film 19. Roller rail
18. Rest of the sticker 20. Gliding plate
* Remove rail cover (5) and place slit lamp aside. Clean surface of table.
* Remove protective film (17) from the back of the adhesive label. Carefully start at the corner opposite the black surface.
* Position the sticker against the right roller rail (19) and the gliding plate (20). Press firmly on the white/black surface, press away any air bubbles.
* Carefully tear off the remainder of the adhesive label (18) (the ‘positioning tool’) along the perforation.
* Reassemble the slit lamp and rail cover.

3.2 Connecting the CM03 in the beam path
21. Cover caps
22. Marking points
23. Arrow (lock)
* Disassemble the breath shield.
* Remove the black and white cover caps (21).
* Align the marking points (22) on the upper side of the parts to be connected.
* Turn the locking ring in the direction of the arrow shown (23) to tighten.

3.3 Weight compensation facility
24. 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 (24). To do so, please follow the instructions in the instruction manual for the slit lamp.
3.4 Cabling of the CM03 and the RM02 (diagram)

**WARNING!**
- Only use the supplied USB 3.0 cable (REF 1022373) for the connection to the PC. Only use medically approved PCs or operate via a medically approved isolating transformer.
- Auxiliary units on the PC (e.g. printer, monitor) must be operated through an isolating transformer.
- Ethernet may only be used through a galvanic isolation in accordance with EN 60601-1.
- The power supply unit's mains connector must be accessible in order to allow for disconnection from the electric mains at any time!

25. Power grid
26. Med. approved isolating transformer
27. Instrument table (IT)
28. Med. approved power supply
29. Printer
30. Screen
31. Personal computer
32. Local network
33. Galvanic isolation (EN 60601-1)
34. Headrest
35. Cable headrest / LED illumination / RM02
36. Release module RM02
37. LED illumination
38. Camera module CM03
39. Fastening screw
40. Two-pole connection plug

If the middle LED lights up red during operation, the two-pole connection plug (40) is connected incorrectly.
- Disconnect the device from the power grid.
- Remove the cover on the upper part of the illumination facility by loosening the fastening screw (39).
- Turn the two-pole connection plug (40) 180°.
- Fix the cover on the upper part of the illumination facility with the fastening screw (39).
- Connect the device to the power grid again.

**WARNING!**
- Keep magnet-sensitive storage media (e.g. credit cards) away from the magnets on the release module RM02!
- Only external medical power supplies approved by Haag-Streit that fulfill EN 60601-1 may be used.

### 3.4.1 Step-by-step cabling

- Place the release module RM02 over the slit lamp's cross slide. Four magnets are used for fixing.

**NOTE!**
- No external USB devices may be connected to USB ports (59) and (61).
- 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 RM02 is mounted.

- Insert the camera cable connector plug (50) in the socket (59).
- Press the camera cable into the cable holders (49).
- Computer cable USB 3.0 (47), power supply cable (46) and cable headrest / LED illumination / RM02 (45) must be fed through in the braided sleeving (44).
- Insert the connector plug of the power supply cable (46) in the socket (59).
- Insert the connector plug of the computer cable USB 3.0 (47) in the socket (60).
- Pull on the braided sleeving taught and mount a cable tie (43) on each end.
• Connect the headrest cable (42) with the counterpart (40) on the headrest.
• Mount the table top and place the slit lamp on the table.
• Connect the computer cable USB 3.0 (47) to the PC.
• Connect the electric power supply lead (15) to the power supply (14).
• Connect the power supply connector plug to the power grid.
• Plug the headrest cable (1) into the lamp head.

41. Connection plug headrest
42. Connector plug headrest / LED illumination / RM02
43. Cable tie
44. Braided sleeving
45. Cable headrest / LED illumination / RM02
46. Power supply cable
47. Computer cable USB 3.0
48. Camera (not shown)
49. Recess on the microscope arm
50. Connector plug camera cable
51. Release module RM02
52. RM02 operational control LED

53. On/Off key
54. Rotating knob, periphery or background illumination / RM02
55. Rotating knob, slit illumination
56. Selector key A
57. Selector key B
58. Release key RM02
59. Socket camera cable
60. Socket for power supply connector plug
61. Socket computer cable USB 3.0 micro B
62. Threaded bolt
63. Pin assignment
64. Cable cover

4. Startup

4.1 Switching on the device
• Connect the power supply to the power grid and press the On/Off key (53) on the release module RM02. The green operational control LED (52) illuminates when the device is switched on. The camera has no On/Off key and switches on automatically when the PC is switched on. The status is displayed by the indicator light (8).
• Turn the rotating knob on the slit illumination (55) to a position between ‘1’ and ‘10’.
5. 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 or BP 900.

5.1 Changing the image brightness
Select a diaphragm with the knob.
1 = Largest diaphragm (lowest depth of sharpness)
6 = Smallest diaphragm (highest depth of sharpness)
Select the exposure time on the Release Module RM02.
Image via trigger key on the Release Module RM02

5.2 Camera Module CM03
Set the switch (7) beam splitter to the camera symbol ⚫
* 70% of the light goes to the camera and
* 30% to the examiner
Switch (7) beam splitter to the top
* 100% of the light goes to the examiner (applies to both beam paths)

5.2 Camera Module CM03 30/70
Set the switch (7) beam splitter to the camera symbol ⚫
* 30% of the light goes to the camera and
* 70% to the examiner
Switch (7) beam splitter to the top
* 100% of the light goes to the examiner (applies to both beam paths)

5.3 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:

5.4 History trigger
• Press the release key (58) on the release module RM02
• Select the desired image via selector key (56) or (57)
• Press the release key (58) on the release module RM02 again – the image is saved

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

5.5.1 Slit lamp preparation
1. Turn on the slit lamp
2. Filter position ‘open’ (no filter)
3. Set magnification to 16 ×
4. Completely open the slit diaphragm
5. Connect the diffuser upstream
6. Position the Haag-Streit greycard in front of the slit lamp and use it for focusing
7. The brightness of the slit lamp’s illumination should be set in such a way that the greycard’s structure is clearly discernible.
5.5.2 Conducting a white balance
8. Start the ‘EyeSuite Imaging’ software
9. Activate the intensity auto mode
10. Open the ‘White balance’ application
11. 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 greycards REF 1021485

Image is blurry or overexposed
Structure is discernible

5.6 Software / Help menu / error messages
The 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.

5.7 LED display illumination head

<table>
<thead>
<tr>
<th>Operating status</th>
<th>Periphery or background illumination</th>
<th>Polarity</th>
<th>Slit lamp illumination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standby mode</td>
<td>Green, short flashes</td>
<td>⚫️</td>
<td>⚫️</td>
</tr>
<tr>
<td>Normal operation</td>
<td>Green</td>
<td>⚫️</td>
<td>Green</td>
</tr>
<tr>
<td>Slit and periphery or background illumination on</td>
<td>Green</td>
<td>⚫️</td>
<td>Green</td>
</tr>
<tr>
<td>Only slit illumination on</td>
<td>Green, short flashes</td>
<td>⚫️</td>
<td>Green</td>
</tr>
<tr>
<td>Only periphery or background illumination on</td>
<td>Green</td>
<td>⚫️</td>
<td>Green</td>
</tr>
<tr>
<td>Reduced periphery or background illumination operation</td>
<td>Green, flashing</td>
<td>⚫️</td>
<td>Green, flashing</td>
</tr>
<tr>
<td>High LED temperature, thus reducing periphery or background illumination operation</td>
<td>Green, flashing</td>
<td>⚫️</td>
<td>Green, flashing</td>
</tr>
</tbody>
</table>

5.8 LED display power supply
Normal operation: Green

5.9 LED display release module RM02
Normal operation: Green
LED illumination switched off: Green, pulsing
Establishing connection: Orange
5.10 LED display camera module CM03

<table>
<thead>
<tr>
<th>Normal operation</th>
<th>Green</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establishing connection</td>
<td>Orange</td>
</tr>
</tbody>
</table>

5.11 Error messages (illumination head)

<table>
<thead>
<tr>
<th>Error messages</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1 Incorrect supply polarisation</td>
<td>Contact your Haag-Streit representative.</td>
</tr>
<tr>
<td>E2 Illumination control not recognized</td>
<td>Connect illumination control or replace, if necessary.</td>
</tr>
<tr>
<td>E3 Temperature is too high</td>
<td>The light sources’ power will be reduced. Normal operation is ensured once the permissible temperature has been reached.</td>
</tr>
<tr>
<td>E4 No communication between power supply and illumination</td>
<td>Contact your Haag-Streit representative.</td>
</tr>
<tr>
<td>E6 General error</td>
<td>Send PS-LED to the appropriate service branch.</td>
</tr>
</tbody>
</table>

5.12 Error messages release module RM02

<table>
<thead>
<tr>
<th>Error messages</th>
<th>Measures</th>
<th>Operational control LED (75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>E14 No communication with LED illumination LI01 plus / LI02 plus</td>
<td>Contact your Haag-Streit representative.</td>
<td>Red, flashing 2 ×</td>
</tr>
<tr>
<td>E16 General error</td>
<td>Send device to the appropriate service branch.</td>
<td>Red, flashing 4 ×</td>
</tr>
</tbody>
</table>
5.13 Error messages camera module CM03

<table>
<thead>
<tr>
<th>Error</th>
<th>Message</th>
<th>Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>E18</td>
<td>No communication with LED illumination LI01 plus / LI02 plus</td>
<td>Contact your Haag-Streit representative.</td>
</tr>
</tbody>
</table>

6. Decommissioning

Press the On/Off key (53) on the release module RM02 briefly to switch off the LED illumination after the examination. This does not switch off the camera. This is signaled with pulsing green flashing. Pressing the key for approx. 3 sec. switches off the release module completely and the operational control LED (52) goes out. The camera has no separate On/Off switch. It switches off automatically when the PC is switched off.

**NOTE!** The On/Off key on the release module RM02 does not disconnect the device from the electric mains. Disconnect the power supply from the power grid by unplugging the mains connector if you do not intend to use it for an extended period of time.

7. Technical data

7.1 Power supply

<table>
<thead>
<tr>
<th>Type</th>
<th>ICCNEXERGY, ELPAC POWER SYSTEMS,</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>MWA030018B-10A REF 1022106</td>
</tr>
<tr>
<td>Mains voltage</td>
<td>100 – 240 V</td>
</tr>
<tr>
<td>Current consumption</td>
<td>0.8 A</td>
</tr>
<tr>
<td>Operating frequency</td>
<td>50 – 60 Hz</td>
</tr>
</tbody>
</table>

7.2 Dimensions

<table>
<thead>
<tr>
<th>Camera module CM03</th>
<th>Weight: 2.6 kg (incl. packaging)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions L x W x H:</td>
<td>190 x 127 x 76 mm</td>
</tr>
<tr>
<td>Packing L x W x H:</td>
<td>380 x 270 x 130 mm</td>
</tr>
</tbody>
</table>

7.3 Minimum PC requirements

<table>
<thead>
<tr>
<th>Processor type</th>
<th>Intel i5, 5th gen or higher with 4 cores.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Note:</td>
<td>6th gen is not recommended. 2 cores with hyperthreading are not recommended.</td>
</tr>
<tr>
<td>RAM</td>
<td>8 GB RAM if PC is exclusively used to operate the imaging module. 16 GB RAM if third-party applications such as patient administration software are to be used alongside EyeSuite. Use 2 RAM module.</td>
</tr>
<tr>
<td>Hard disk</td>
<td>At least 500 GB (NTFS data system).</td>
</tr>
<tr>
<td>Graphics</td>
<td>Graphics card with at least 2 GB memory (Nvidia or AMD chip set recommended). OpenGL 2.0</td>
</tr>
<tr>
<td>Monitor</td>
<td>At least 19&quot;, 1920 x 1080 pixel resolution.</td>
</tr>
<tr>
<td>Operating system</td>
<td>Windows 7, Windows 8.1, Windows 10. 64-bit system only.</td>
</tr>
<tr>
<td>PCI slot</td>
<td>PCI-Express 3.0</td>
</tr>
<tr>
<td>PCI Express card</td>
<td>Chip set by Renesas / NEC.</td>
</tr>
</tbody>
</table>

7.4 Camera

<table>
<thead>
<tr>
<th>Camera beam:</th>
<th>Beam path right (from the point of view of the doctor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interface:</td>
<td>USB 3.0</td>
</tr>
<tr>
<td>Frame rate:</td>
<td>30 fps (frames per second)</td>
</tr>
<tr>
<td>Power consumption:</td>
<td>5 V === / 420 mA</td>
</tr>
</tbody>
</table>

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8. Maintenance

**WARNING!**
- Do not modify this equipment 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 replacement parts may be used.

8.1 Device inspection
To check the correct function, proceed as follows:
- Insert the test piece in the radial movement bearing, while aligning the surface at a right-angle to the Microscope
- Set the slit length to 8 or 14mm
- Illumination intensity to 50%
- Set the magnification of the Microscope to max.
- Set the ocular so that the structure on the test piece is shown in focus. In doing so, turn the ocular from the (+) to the (-) side.
- Switch on camera
- For all magnifications, the structure of the test piece in the ocular and in the camera image must be sharply imaged
- Turn on the illumination of the 0.2mm diaphragm
- Turn on the crosshairs in EyeSuite, the cross must be inside the illuminated dot

8.2 Servicing
To ensure a long service life, the device should be cleaned weekly as described and covered with a dust cover when not in use. We recommend having the device inspected by an authorized service technician annually.

8.3 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
- 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)

A. Appendix

A.1 Accessories / consumables / spare parts / upgrade

<table>
<thead>
<tr>
<th>Components</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set white balance greycards</td>
<td>1021485</td>
</tr>
<tr>
<td>Power supply ICCNEXERGY</td>
<td>1022106</td>
</tr>
<tr>
<td>Computer cable USB 3.0</td>
<td>1022373</td>
</tr>
<tr>
<td>Release module RM02</td>
<td>7220546</td>
</tr>
</tbody>
</table>

B. Statutory requirements
- The imaging module IM 900 was designed and built 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 imaging module IM 900 with the Directive 93/42/EEC is confirmed by the CE-designation.
- You can request a copy of the declaration of conformity for this instrument from Haag-Streit at any time.
- Statutory accident regulations are to be observed.
WARNING!
The imaging module IM 900 may only be operated in an environment in which standard values pursuant to standard EN 60601-1 are observed.

C. Classification

<table>
<thead>
<tr>
<th>Standard EN 60601-1</th>
<th>Slit lamp accessories as per protection class I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating mode</td>
<td>Continuous operation</td>
</tr>
<tr>
<td>CE Directive 93/42/EEC</td>
<td>Class I</td>
</tr>
<tr>
<td>FDA</td>
<td>Accessory for slit lamps</td>
</tr>
</tbody>
</table>

D. Disposal

Electrical and electronic devices must be disposed of separately from household waste! This appliance 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.

E. Observed standards

<table>
<thead>
<tr>
<th>EN 60601-1</th>
<th>EN 60601-1-2</th>
</tr>
</thead>
</table>
F. Information and manufacturer’s declaration concerning electromagnetic compatibility (EMC)

F.1 General
The Imaging Module IM 900 system fulfills the requirements on electromagnetic compatibility according to EN 60601-1-2:2007 (IEC 3rd Edition) + EN 60601-1-2:2015 (IEC 4th Edition). The instrument 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 instrument itself is suitably immune to electromagnetic interference.

**WARNING!**
Avoid damages due to high electrostatic discharges (ESD). Electrostatic discharges with voltages exceeding 6 kV to some parts of the slit lamp like joystick or metallic parts on the instrument base may influence the instrument.

- The communication between Imaging Module and PC could be interrupted, which would require a restart of the EyeSuite software.

F.2 Emitted interference (standard table 1)

**Guidance and manufacturer’s declaration – electromagnetic emissions**
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.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class A</td>
<td>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.</td>
</tr>
<tr>
<td>Emission of harmonics according to EN 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
</tbody>
</table>
F.3 Immunity (standard table 2)
The information is based on the requirements of EN 60601-1-2:2007 (IEC 3rd edition).

Guidance and manufacturer’s declaration – electromagnetic immunity
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.

<table>
<thead>
<tr>
<th>Immunity test standard</th>
<th>EN 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD)</td>
<td>± 6 kV contact</td>
<td>± 6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>EN 61000-4-2</td>
<td>± 8 kV air</td>
<td>± 8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient / burst</td>
<td>± 2 kV for power supply lines</td>
<td>± 2 kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>EN 61000-4-4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>± 1 kV for symmetrical voltages</td>
<td>± 1 kV for symmetrical voltages</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>EN 61000-4-5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and voltage variations on power supply lines</td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for ½ cycle</td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for ½ cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued function even in the event of interruptions in the energy supply, this product should be powered from an uninterruptible power supply or a battery.</td>
</tr>
<tr>
<td>EN 61000-4-11</td>
<td>&lt; 40% Uₚ (&gt; 60% drop in Uₚ) for 5 cycles</td>
<td>&lt; 40% Uₚ (&gt; 60% drop in Uₚ) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 70% Uₚ (&gt; 30% drop in Uₚ) for 25 cycles</td>
<td>&lt; 70% Uₚ (&gt; 30% drop in Uₚ) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for 5 s</td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for 5 s</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for ½ cycle</td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for ½ cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 40% Uₚ (&gt; 60% drop in Uₚ) for 5 cycles</td>
<td>&lt; 40% Uₚ (&gt; 60% drop in Uₚ) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 70% Uₚ (&gt; 30% drop in Uₚ) for 25 cycles</td>
<td>&lt; 70% Uₚ (&gt; 30% drop in Uₚ) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for 5 s</td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for 5 s</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for ½ cycle</td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for ½ cycle</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 40% Uₚ (&gt; 60% drop in Uₚ) for 5 cycles</td>
<td>&lt; 40% Uₚ (&gt; 60% drop in Uₚ) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 70% Uₚ (&gt; 30% drop in Uₚ) for 25 cycles</td>
<td>&lt; 70% Uₚ (&gt; 30% drop in Uₚ) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for 5 s</td>
<td>&lt; 5% Uₚ (&gt; 95% drop in Uₚ) for 5 s</td>
<td></td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field</td>
<td>3 A/m</td>
<td>100 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>EN 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: \( Uₚ \) = the AC mains voltage prior to application of the test level.
F.4 Immunity for non-life support devices (standard table 4)
The information is based on the requirements of EN 60601-1-2:2007 (IEC 3rd edition).

Guidance and manufacturer's declaration – electromagnetic immunity
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.

Electromagnetic environment – guidance
Portable and mobile RF communications equipments 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.

<table>
<thead>
<tr>
<th>Immunity test standard</th>
<th>EN 60601 test level</th>
<th>Compliance level</th>
<th>Recommended distance&lt;sup&gt;b&lt;/sup&gt;:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF EN 61000-4-6</td>
<td>3 V&lt;sub&gt;rms&lt;/sub&gt; 150 kHz – 80 MHz</td>
<td>5 V&lt;sub&gt;rms&lt;/sub&gt;</td>
<td>( D = 0.7 \sqrt{P} )</td>
</tr>
<tr>
<td>Radiated RF EN 61000-4-3</td>
<td>3 V/m 80 MHz – 2.7 GHz</td>
<td>3 V/m 80 MHz – 2.7 GHz</td>
<td>( D = 1.2 \sqrt{P} 80 MHz – 800 MHz ) ( D = 2.3 \sqrt{P} 800 MHz – 2.7 GHz )</td>
</tr>
</tbody>
</table>

Where \( P \) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and \( D \) is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>a</sup>, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz the higher frequency applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. 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. 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 re-orienting or relocating this product.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 5 V<sub>eff</sub>.
c. Possible shorter distances outside the ISM bands do not contribute to improved application in this table.
F.5  Safe distances for non-life support devices (standard table 6)
The information is based on the requirements of EN 60601-1-2:2007 (IEC 3rd edition).

**Recommended safe distances between portable and mobile HF communication devices and this device.**
This product is designed to be operated in an electromagnetic environment in which radiated HF interference is controlled. The customer or user of this product can help to prevent electromagnetic interference by maintaining minimum distances between portable and mobile HF communication systems (transmitters) and this product, as recommended below in accordance with the maximum output of the communication system.

<table>
<thead>
<tr>
<th>Nominal output of the transmitter (W)</th>
<th>150 kHz – 80 MHz</th>
<th>80 MHz – 800 MHz</th>
<th>800 MHz – 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.07</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>0.1</td>
<td>0.22</td>
<td>0.38</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td>0.7</td>
<td>1.2</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td>2.2</td>
<td>3.8</td>
<td>7.3</td>
</tr>
<tr>
<td>100</td>
<td>7</td>
<td>12</td>
<td>23</td>
</tr>
</tbody>
</table>

For transmitters with a nominal output not listed in the table above, the distance $D$ can be calculated in meters (m) using the equation for the respective column, in which $P$ is the nominal output of the transmitter in watts (W) according to the specifications of the transmitter manufacturer.

**NOTE 1:** At 80 MHz and 800 MHz the higher frequency applies.

**NOTE 2:** To calculate the recommended safe distance of transmitters in the frequency range of 80 MHz to 2.5 GHz an additional factor of $10^2$ was used to reduce the probability of a mobile/portable communication device causing interference if inadvertently brought into the patient area.

**NOTE 3:** These guidelines may not apply in all situations. Electromagnetic wave propagation is influenced by absorption and reflection of buildings, objects and people.
Should you have any further questions, please contact your Haag-Streit representative at:
http://www.haag-streit.com/contact/contact-your-distributor.html

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