SVENSKA NEDERLANDS PORTUGUÊS ESPAÑOL ITALIANO FRANÇAIS DEUTSCH ENGLISH



# INSTRUCTION MANUAL Imaging Module

# **IM 900**

Accessory for the BQ 900 Slit Lamp

2. edition / 2016 – 08



01-IFU\_IM900-7220551-04020\_eng.indd 1 02.08.2016 14:39:15

ENGLISH DEUTSCH FRANÇAIS ITALIANO ESPAÑOL PORTUGUÊS NEDERLANDS SVENSKA

INSTRUCTION MANUAL Imaging Module

**IM 900** 

Accessory for the BQ 900 Slit Lamp

2. edition / 2016 - 08

### 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 or BP 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.

01-IFU\_IM900-722051-04020\_eng.indd 2 02.08.2016 14:39:15

**ESPAÑOL** 

ITALIANC

FRANÇAIS

UTSCH ENGLIS

# Contents

1. 1.1 1.2 1.3 1.4 1.5 1.6 1.7 1.8	Safety  Areas of application of the device  Ambient conditions.  Shipment and unpacking Installation warnings Operation, environment Disinfection  Warranty and product liability Symbols	
2. 2.1 2.2 2.3 2.4 2.5 2.6	Introduction  Description of the device.  System components  LED illumination (prerequisite).  Camera module CM03  Release module RM02  Power supply.	(
3. 3.1 3.2 3.3 3.4 3.4.1	Device assembly / installation  Placement of adhesive label for the automatic left/right detection  Connecting the CM03 in the beam path  Weight compensation facility  Cabling of the CM03 and the RM02 (diagram)  Step-by-step cabling	
<b>4.</b> 4.1	Startup	
5. 5.1 5.2 5.3 5.4 5.4.1 5.4.2 5.5 5.6 5.7 5.8 5.9	Operation Beam splitter 70/30. Field of view History trigger White balance Slit lamp preparation Conducting a white balance Software / Help menu / error messages. LED display illumination head LED display power supply LED display release module RM02. LED display camera module CM03	10 10 10 10 11 11

5.10	Error messages (illumination head)	
5.11	Error messages release module RM02	
5.12	Error messages camera module CM03	13
6.	Decommissioning	13
7	Technical data	13
7.1	Power supply	
7.2	Dimensions	13
7.3	Minimum PC requirements	
7.4	Camera	13
8.	Maintenance	14
8.1	Servicing	14
8.2	Cleaning	14
A.	Appendix	14
A.1	Accessories	
B.	Statutory requirements	14
C.	Classification	14
D.	Disposal	14
E.	Observed standards	14
F.	Information and manufacturer's declaration	15
	concerning electromagnetic compatibility (EMC)	15
F.1	General	
F.2	Emitted interference (standard table 1)	15
F.3	Interference immunity (standard table 2)	
F.4	Interference immunity for non-life-supporting devices (standard table 4)	
F.5	Safe distances for non-life-supporting devices (standard table 6)	18

© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

# 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 device 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 for use in doctor's practices, hospitals and optometrists' and opticians' premises.

#### 1.2 Ambient conditions

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

#### 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



#### VARNING!

- 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 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 magnets!



#### NOTE!

This equipment must only be operated by qualified and trained personnel. The owner is responsible for their training. This device may only be used in accordance with the instructions in "Purpose of use".

© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

01-IFU IM900-7220551-04020 eng.indd 4

02.08.2016 14:39:16

The device does not require disinfection. For more information on

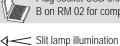
SN Serial number



Plug socket USB 3.0 micro



Plug socket on RM 02 for power supply



B on RM 02 for computer

**REF** HS reference number



∢ ➤ Background illumination



Rotating knob on camera symbol = 70 % of the light goes to the camera

# Warranty and product liability

1.6 Disinfection

NOTE!

· Haaq-Streit products must be used only for the purposes and in the manner described in the documents distributed with the product.

cleaning, please refer to the 'Maintenance' section.

- 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 **Symbols**



Read the instructions for use attentively

Notes on disposal, see the



General warning: Read the accompanying documentation



This appliance fulfills the Euro-



pean Directive 2011/65/EU (RoHS)



Year of production

'Disposal' chapter



Manufacturer



European certificate of conformity



Earth (ground)



Direct current



Not protected from foreign **bodies** 

#### 2. Introduction

#### 2.1 Description of the device

The system allows for creation of digital images and videos that can be viewed in the right beam path of the microscope: 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.

#### System components

The imaging module IM 900 is a system made up of the following main components:

- A. Camera module CM03
- B. Release module RM02
- C. EyeSuite software
- D. Power supply









© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

01-IFU\_IM900-7220551-04020\_eng.indd 5 02.08.2016 14:39:20 ENGLISH DEUTSCH FRANÇAIS ITALIANO ESPAÑOL PORTUGUÊS NEDERLANDS SVENSKA

# 2.3 LED illumination (prerequisite)

- 1. Lamp cable with special connection plug for LI01 plus / LI02 plus
- 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

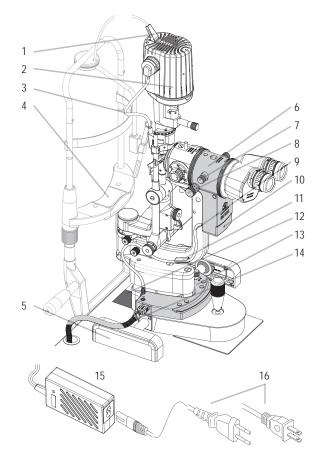
- 12. Release module RM02
- 13. Sticker left/right identification
- 14. Cable harness

# 2.6 Power supply

15. Power supply

6

16. Mains connector (country-dependent)



© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

01-IFU\_IM900-7220551-04020\_eng.indd 6 02.08.2016 14:39:22

FRANÇAIS

UTSCH ENG

# 3. Device assembly / installation

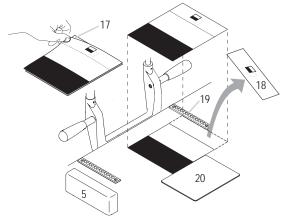


WARNING

- 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 HS replacement parts may be used.

# 3.1 Placement of adhesive label for the automatic left/right detection

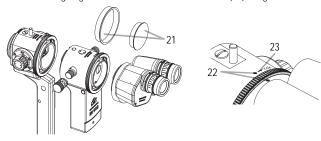
- 17. Protective film
- 19. Roller rail
- 18. Rest of the sticker
- 20. Gliding plate
- Remove rail cover (5) and place slit lamp aside. Clean surface of table.
- Remove protective film (17) from the back of the adhesive label. Carefully start at the corner opposite the black surface.
- Position the 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.



© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

### 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.



7

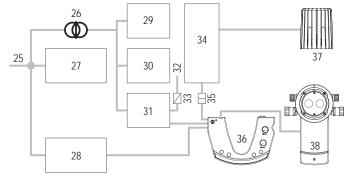
01-IFU\_IM900-722051-04020\_eng.indd 7 02.08.2016 14:39:23

# Cabling of the CM03 and the RM02 (diagram)



#### WARNING!

- Only use the supplied USB 3.0 cable (3m long, HS art. no. 1022373) for the connection to the PC.
- With lengths of over 3m, the cable with active signal amplification (HS art. no. 1022441) must be used.
- · 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 33. Galvanic isolation (EN 60601-1)
- 27. Instrument table (IT)
- 28. Med. approved power supply
- 29. Printer
- 30. Screen
- 31. Personal computer
- 32. Local network
- 34. Headrest
- 35. Cable headrest / LED illumination / RM02
- 36. Release module RM02
- 37. LED illumination
- 38. Camera module CM03





To ensure that the system works correctly, HAAG-STREIT recommends not using laptops and using a high-quality desktop computer instead.

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
- · 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!

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).

© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

01-IFU IM900-7220551-04020 eng.indd 8

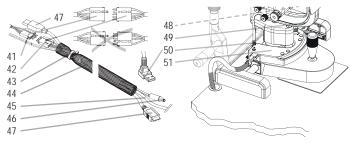
8

02.08.2016 14:39:25

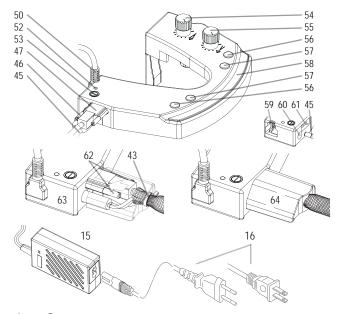
9

- 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
- nation / RM02
- 43. Cable tie
- 44. Braided sleeving
- 45. Cable headrest / LED illumination /
- 46. Power supply cable
- 47. Computer cable USB 3.0 (3m long)
- 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
- 42. Connector plug headrest / LED illumi-54. Rotating knob, periphery or background illumination
  - 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



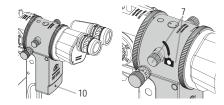
© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08



# Startup

### 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.
- Turn the rotating knob on the slit illumination (55) to a position between '1' and



01-IFU\_IM900-7220551-04020\_eng.indd 9 02.08.2016 14:39:28

# 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 Beam splitter 70/30

Set the switch (rotating knob) beam splitter to the camera symbol

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

Switch (rotating knob) beam splitter to the top

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

#### 5.2 Field of view



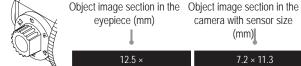
### WARNING!

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:



	12.5 ×	7.2 × 11.3
6.3 ×	ø 32	33.8 × 53.0
10 ×	ø 20	21.3 × 33.5
16 ×	ø 12.7	13.5 × 21.2
25 ×	ø 8	8.5 × 13.3
40 ×	ø 5.1	5.4 × 8.5





# 5.3 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

#### 5.4 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.

#### 5.4.1 Slit lamp preparation

- 1. Turn on the slit lamp
- 2. Filter position (open) (no filter)
- 3. Set magnification to 16x
- 4. Completely open the slit diaphragm
- 5. Connect the diffuser upstream
- Position the HAAG-STREIT greycard in front of the slit lamp and use it for focusing
- The brightness of the slit lamp's illumination should be set in such a way that the greycard's structure is clearly discernible.

#### 5.4.2 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.

© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

10

01-IFU\_IM900-7220551-04020\_eng.indd 10 02.08.2016 14:39:29



White balance greycard HS No.: 1021483



Image is blurry or overexposed

Structure is discernible

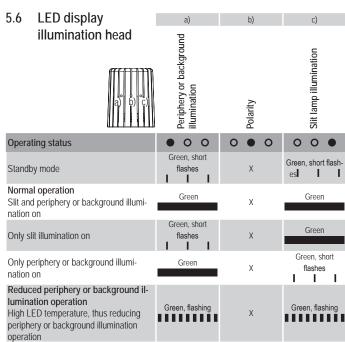
### 5.5 Software / Help menu / error messages

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 power supply

Normal operation	Green
Normal operation	

### 5.8 LED display release module RM02

Normal operation	Green
LED illumination switched off	Green, pulsing
Establishing connection	Orange

© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

11

01-IFU\_IM900-7220551-04020\_eng.indd 11 02.08.2016 14:39:33

ENGLISH	DEUTSCH	FRANÇAIS	ITALIANO	ESPAÑOL	PORTUGUÊS	NEDERLANDS	SVENSKA

# 5.9 LED display camera module CM03

Normal operation	Green
Establishing connection	Orange

# 5.10 Error messages (illumination head)

Ο.	5.10 Error messages (mumination nead)						
				a)	b)	c)	
	ERROR			Periphery or back- ground illumination	Polarity	Slit lamp illumination	
	ERI	Error messages	Measures	• 0 0	0 • 0	0 0 •	
	E1	Incorrect supply polarisation	Contact your HAAG-STREIT representative.	Χ	Red	X	
	E2	Illumination control not recognized	Connect illumination control or replace, if necessary.	Red	Х	Red	
Е	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	Х	Red, flashing	
	E4	No communication between power supply and illumination	Contact your HAAG-STREIT representative.	Red, flashing 2x	Х	Red, flashing 2x	
	E6	General error	Send PS-LED to the appropriate service branch.	Red, flashing 4x	Χ	Red, flashing 4x	

# 5.11 Error messages release module RM02

ERROR	Error messages	Measures	Operational control LED (75)
E14	No communication with LED illumination LI01 plus / LI02 plus	Contact your HAAG-STREIT representative.	Red, flashing 2x
E16	General error	Send device to the appropriate service branch.	Red, flashing 4x

© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

01-IFU\_IM900-7220551-04020\_eng.indd 12 02.08.2016 14:39:34

ERROR	Error messages	Measures	Operational control LED (26)
E18	No communication with LED illumination LI01 plus / LI02 plus	Contact your HAAG-STREIT representative.	Red

# 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. 2 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.



01-IFU\_IM900-7220551-04020\_eng.indd 13

#### 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

Туре	ICCNEXERGY, ELPAC POWER S	YSTEMS,
Model	MWA030018B-10A	HS no.: 1022106
Mains voltage	100 – 240 V	
Current consumption	0.8 A	
Operating frequency	50 - 60 Hz	

#### 7.2 Dimensions

Camera module CM03

Weight: 2.6 kg (incl. packaging)

Dimensions L x W x H: 190 x 127 x 76 mm

Packaging L x W x H: 380 x 270 x 130 mm

# 7.3 Minimum PC requirements

7.0	7.0 minimani o roquiromonio			
Processor type	Intel i5 (or better)			
RAM	4 GB (or more with a 64 bit operating system)			
Hard disk	At least 500 GB (NTFS data system)			
Graphics	Intel HD Graphics 4000 (or better)			
Optical drive	DVD-ROM			
Monitor	19" with at least 1280 x 800 pixel resolution			
Interface	USB 3.0			
Operating system	Windows Vista, SP2 (32 and 64 bit), Windows 7, SP1 (32 and 64 bit), Windows 8 / 8.1 (32 and 64 bit)			
Sound	Ideally, it is possible to work with sound			

#### 7.4 Camera

Camera beam:	Beam path right (from the point of view of the doctor)
Interface:	USB 3.0
Frame rate:	30 fps (frames per second)
Power consumption:	5 V / 420 mA

© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

02.08.2016 14:39:35

#### 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 HS replacement parts may be used.

#### 8.1 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.

#### 8.2 Cleaning

- The housing should only be cleaned with a slightly damp cloth.
- Do not use any liquids, alcohol or corrosive substances.
- Sterilization or disinfection of the device is not required.



#### WARNING!

Avoid making the device wet and use only the items listed above. Do not use solvents or abrasive agents under any circumstances.

# A. Appendix

# A.1 Accessories



#### NOTE!

Order numbers (HS No.) are written in italics

Components	HS Art. No.
Release module RM02	1022052
Set white balance greycards	1021485
Computer cable USB 3.0 (3m long)	1022373
Power supply ICCNEXERGY	1022106

# B. Statutory requirements

- The imaging module IM 900 was designed and built taking the EN 60601-1 and EN ISO 10939 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

Standard EN 60601-1	Slit lamp accessories as per protection class I
Operating mode	Continuous operation
CE Directive 93/42/EEC	Class I
FDA	Accessory for slit lamps

# 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

EN 60601-1	EN ISO 15004-1,-2
EN 60601-1-2	EN 1041
EN ISO 15223-1	EN ISO 10939
ISO 9022	•

© HAAG-STREIT AG, 3098 Koeniz, Switzerland - HS Doc. No. 1500.7220551.04020 - 2016 - 08

01-IFU\_IM900-7220551-04020\_eng.indd 14 02.08.2016 14:39:36

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

#### F.1 General

The imaging module IM 900 system satisfies the requirements on electromagnetic compatibility according to EN 60601-1-2. The device is built in such a manner that the generation and emission of electromagnetic interference is limited to the extent that other devices are not disturbed when used in accordance with their intended

purpose, and the device itself has appropriate immunity 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.
- Portable and mobile HF communication systems may interfere with electrical medical devices.
- The operation of other lines or equipment than those listed may lead to higher emissions or may reduce the device's resistance to interference
- Third-party devices may only be connected in compliance with the EN 60601-1 standard.

## 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.

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 A	This product is suitable for use in all establishments, including domestic establishments and those directly connected to
Emission of harmonics according to EN 61000-3-2	Class A	the public low-voltage power supply network that supplies buildings used for domestic purposes.

© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

15

01-IFU\_IM900-7220551-04020\_eng.indd 15 02.08.2016 14:39:36

ENGLISH	DEUTSCH	FRANÇAIS	ITALIANO	ESPAÑOL	PORTUGUÊS	NEDERLANDS	SVENSKA

# F.3 Interference immunity (standard table 2)

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.

Immunity test standard	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered withs ynthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	<ul><li>± 1 kV for symmetrical voltages</li><li>± 2 kV for asymmetrical voltages</li></ul>	<ul><li>± 1 kV for symmetrical voltages</li><li>± 2 kV for asymmetrical voltages</li></ul>	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines EN 61000-4-11	$ < 5\% \ U_{_{T}} \ (> 95\% \ drop \ in \ U_{_{T}}) $ for ½ cycle $ < 40\% \ U_{_{T}} \ (> 60\% \ drop \ in \ U_{_{T}}) $ for 5 cycles $ < 70\% \ U_{_{T}} \ (> 30\% \ drop \ in \ U_{_{T}}) $ for 25 cycles $ < 5\% \ U_{_{T}} \ (> 95\% \ drop \ in \ U_{_{T}}) $ for 5 s	$ < 5\% \ U_{_{T}} \ (> 95\% \ drop \ in \ U_{_{T}}) $ for ½ cycle $ < 40\% \ U_{_{T}} \ (> 60\% \ drop \ in \ U_{_{T}}) $ for 5 cycles $ < 70\% \ U_{_{T}} \ (> 30\% \ drop \ in \ U_{_{T}}) $ for 25 cycles $ < 5\% \ U_{_{T}} \ (> 95\% \ drop \ in \ U_{_{T}}) $ for 5 s	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.
Power frequency (50/60Hz) magnetic field EN 61000-4-8	3 A/m	100 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U<sub>T</sub>= the AC mains voltage prior to application of the test level.

© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

01-IFU\_IM900-7220551-04020\_eng.indd 16 02.08.2016 14:39:37

## F.4 Interference immunity for non-life-supporting devices (standard table 4)

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 hould 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.

Immunity test standard	EN 60601 test level	Compliance level	Recommended distance <sup>(c)</sup> :
Conducted RF EN 61000-4-6	3 V <sub>rms</sub> 150 kHz – 80 MHz	3 V <sub>rms</sub>	D = 1.2 $\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz – 2.5 GHz		D = 1.2 $\sqrt{P}$ 80 MHz - 800 MHz D = 2.3 $\sqrt{P}$ 800 MHz - 2.5 GHz

Where P is the maximum output power rating of thet ransmitter 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 a, should be less than the compliance level in each frequency range b 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 3 V/m.
- c. Possible shorter distances outside the ISM bands do not contribute to improved application in this table.

© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

17

02.08.2016 14:39:37

01-IFU IM900-7220551-04020 eng.indd 17

ENGLISH	DEUTSCH	FRANÇAIS	ITALIANO	ESPAÑOL	PORTUGUÊS	NEDERLANDS	SVENSKA

## F.5 Safe distances for non-life-supporting devices (standard table 6)

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.

	Safe distance according to transmission	n frequency (m)	
	150 kHz – 80 MHz	800 MHz – 2.5 GHz	
Nominal output of the transmitter (W)	$D = 1.2 \sqrt{P}$	D = 1.2 √ <b>P</b>	$D = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

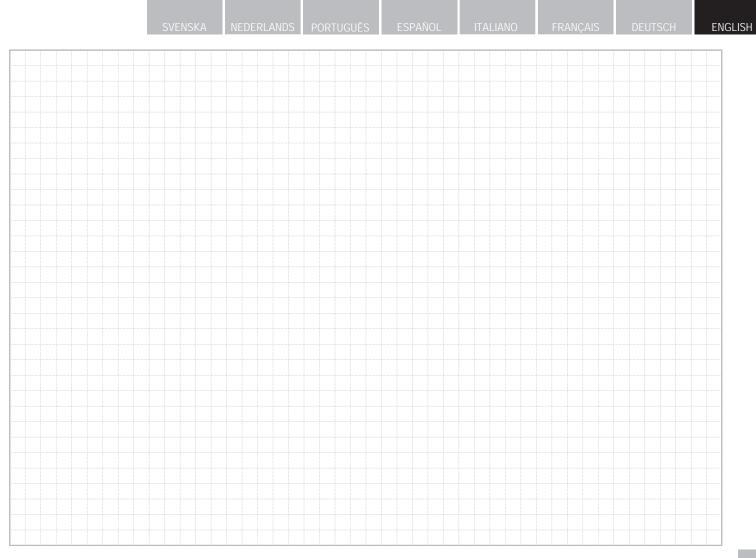
NOTE 1: At 80 MHz and 800 MHz the higher frequency applies.

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 <sup>10</sup>/<sub>3</sub> 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.

© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

01-IFU\_IM900-7220551-04020\_eng.indd 18 02.08.2016 14:39:37



© HAAG-STREIT AG, 3098 Koeniz, Switzerland – HS Doc. No. 1500.7220551.04020 – 2016 – 08

01-IFU\_IM900-7220551-04020\_eng.indd 19 02.08.2016 14:39:38

FNGLISH	DEUTSCH	FRANCAIS	ITAI IANO	FSPAÑOL	PORTUGUÊS	NEDERI ANDS	SVENSKA

Should you have any further questions, please contact your HAAG-STREIT dealer at: http://www.haag-streit.com/contact/contact-your-distributor.html



Certified Quality Management System



Reg. Nr. 11956



Phone

Phone Fax eMail Internet HAAG-STREIT AG Gartenstadtstrasse 10 3098 Koeniz, Switzerland +41 31 978 01 11 +41 31 978 02 82 info@haag-streit.com www.haag-streit.com

01-IFU\_IM900-7220551-04020\_eng.indd 20 02.08.2016 14:39:38