confidence that lasts 10 year limited warranty

INSTRUCTIONS FOR USE
Slit lamp

BI 900®

7. Edition / 2023– 01

Swiss made

HAAG-STREIT DIAGNOSTICS

INSTRUCTIONS FOR USE
Slit Lamp

BI 900®

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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.

WARNING!
This device is equipped with high intensity light emitting diodes. Excessive exposure of patients in treatment with certain medication may lead to phototoxic adverse reactions, due to higher photosensitivity.

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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 Comments on these instructions for use

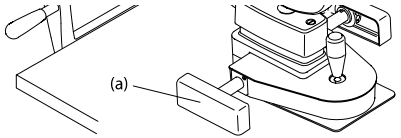
NOTE!
In these instructions for use the point is used as decimal separator.

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.
- The slit lamp and headrest must be installed on an electrically insulated, fireproof table top.
- The rail covers (a) prevent the slit lamp from tilting.
- Check that the connection parts of the accessories are in the correct position (screw connections, quick-release fasteners).



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.
- Grounding reliability can only be achieved when unit is connected to a hospital grade receptacle. (Not valid for EU countries).
- 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!
- The device must be switched off after every use. Otherwise there is a risk of overheating when a protective dust cover is used.
- 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.

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.
- If unexpected disturbances are observed which manifest themselves as communication problems between the imaging module and the EyeSuite software, the cause could be a cell phone or a radio frequency telephone in the immediate vicinity to the slit lamp or power supply. 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.

1.6 Light toxicity

WARNING!
- The light emitted from this device is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this device when operated at maximum intensity will exceed the safety guideline after 131 seconds. (EN ISO 15004-2)
- For USA only: The light emitted from this device is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this device when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2 J/cm² after 28 seconds. Caution is generally advised when exposing a patient to light radiation. However, because of a significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 131 seconds. (ANSI Z80.36)
- For USA only: The emissions of this device can exceed the specified limits for "weighted retinal visible and infrared radiation thermal irradiance" ($E_{VIR\text{-}R}$) defined in ANSI Z80.36. The device operates within the defined limits when the slit width is kept under 2 mm.
- As extended, intensive illumination can damage the retina, the use of the device in the examination of the eye should not be prolonged unnecessarily. The illumination of this slit lamp emits a radiation in the range between 400 and 750 nm. Detailed information on the radiation can be provided on request.
- The retinal dose for a photochemical risk is composed of the product of the radiance and the exposure time. If the radiance is halved, the time until the exposure time limit value is reached will double ac-

cordingly. To date, no acute, optical radiation hazard has been detected in slit lamps. Nevertheless, we recommend keeping the intensity of the light reaching the patient's retina to the minimum possible for the respective diagnosis. Children, people with aphakia and people suffering from eye conditions are most at risk. An increased risk may also occur if the retina is exposed to the same or a similar device with a visible light source within 24 hours. This applies, in particular, if the retina has been photographed with a flashbulb in advance.

1.7 Disinfection

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

1.8 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.

1.9 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.

1.10 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
	Listed European Authorized Representative		Medical Device
	Testsymbol of TÜV Rheinland with approval for INMETRO Brasil		MET Listed Mark with approval for USA and Canada
	Plug socket USB 3.0 micro B on RM02 for computer		Plug socket USB 3.0 on RM02 for camera
	Strong permanent magnets		Plug socket on RM02 for power supply
	Slit lamp illumination		Background illumination
	On (Power)		

2 Intended purpose / intended use

A slit lamp biomicroscope is intended for use in eye examination. It is used to aid in the diagnosis and documentation of diseases or trauma which affect the structural properties of the eye.

2.1 Device description

The devices of the slit lamp are made up of:

- Stereo biomicroscope
- Slit illumination
- Instrument base
- Headrest and chin rest

The illumination system and a biomicroscope are mounted to an instrument base operated by joystick. The single joystick allows horizontal and vertical displacement of the slit lamp across the examination table. Both elements, the illumination system and the biomicroscope, can be swiveled progressively across the pivot, independently of one another.

A sturdy headrest is attached to the table. Both the table and the chin rest are adjustable in height to provide a comfortable, yet sturdy examination position to the patient, outside of the device's range of motion. As this device operates non-invasively it only comes into contact with the patient at the chin rest and forehead band.

2.1.1 Intended users

Users are qualified medical professionals such as ophthalmologists, optometrists, opticians, nurses and researchers or other qualified specialists as permitted by local legislation.

2.2 Medical purpose

This device has the following medical purpose:

- Diagnosis and monitoring of diseases of the anterior segment of the eye
- Diagnosis and monitoring of injuries of the anterior segment of the eye
- Investigation of the anatomy and physiological or pathological state of the anterior segment of the eye

2.2.1 Indications

The use of the slit lamp is indicated for the following medical conditions:

- Local and systemic diseases affecting the eye
- Lesions and defects of the anterior segment
- Acute infections and inflammations
- Presence of intraocular foreign bodies
- Other traumata of the eye

2.2.2 Part of the body

The slit lamp is intended for the examination of the human eye, specifically the anterior segment of the eye (i.e., lids, lashes, conjunctiva, cornea, anterior chamber, iris, and lens).

2.2.3 Patient population

This device is intended for use on human patients with the physical ability to sit in front of a slit lamp with their head resting against the headrest in a steady position and the mental ability to follow instructions.

2.2.4 Contraindications

There are no known contraindications.

2.3 Principles of operation

- The slit lamp implements the principle of focal illumination: The focal point of the microscope and the illumination coincide.
- The microscope arm and the illumination arm are mounted on an instrument base: Both can be swivelled independently around the same vertical axis.
- The instrument base can be moved in all three axes.
- When illuminating transparent media with a narrow, sharp slit, an 'optical section' can be magnified and viewed through the microscope.
- The patient's head is fixed to a height-adjustable headrest holder so that the examination can be carried out quickly and as comfortably as possible for both doctor and patient.

2.3.1 Operating environment

The slit lamp is intended to be used in professional health care facilities such as hospitals, physician's, optometrist's and optician's practices. For optimal use of the slit lamp, the ambient lighting should be attenuated to improve image contrast. In case of transillumination of the iris or for viewing details at great magnification at a narrow slit, it may be necessary to completely darken the room.

2.4 Clinical benefit

The use of the slit lamp allows for the systematic examination of the eye under magnification, thus permitting the diagnoses of pathologies that may have otherwise remained unidentified and could have lead to blindness if left untreated.

The clinical benefits of the product outweigh the remaining residual risks to the patient.

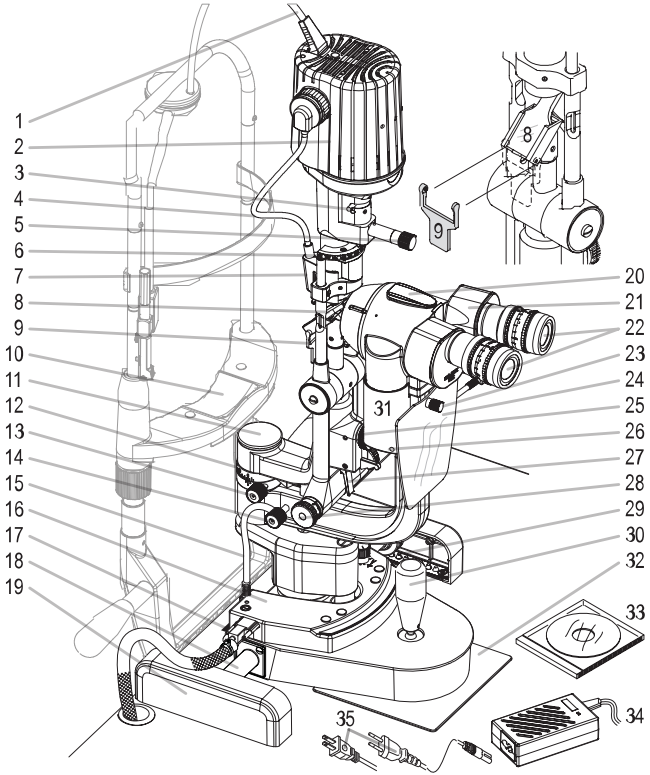
3 Introduction

The slit lamp consists of an illumination and a binocular microscope. The instrument base can be used to move the entire device in front of the eyes. The illumination offers a large number of setting options to make the practically invisible areas in the eye visible. There is also a range of accessories available for the slit lamp to allow special diagnosis possibilities in addition to the general examinations.

NOTE!
The BI 900 slit lamp can be optionally equipped with the imaging set (*REF 7220535*).

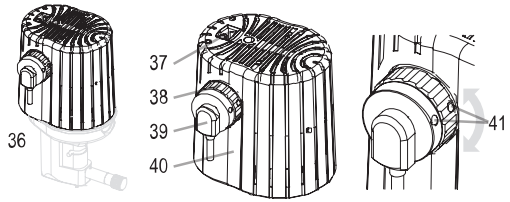
3.1 Overview

1. Lamp cable
2. LED illumination LI 900
3. Filter lever
4. Optical light guide for background illumination (option)
5. Slit length, slit rotation, blue filter and fixation star control, knob for rotating the slit
6. Scale for angled position of the slit image (5° increments)
7. Background illumination FI01f (option)
8. Illumination mirror
9. Diffusing lens
10. Headrest (see separate instructions)
11. Protective cover
12. Illumination unit / microscope angle scale
13. Illumination arm locking screw
14. Microscope arm locking screw
15. Camera cable (option)
16. Release module RM02
17. Sticker left/right identification
18. Axle
19. Rail cover
20. Cover cap for the accessories base
21. Stereo microscope
22. Eyepieces
23. Mounting screw for breath shield (option)
24. Breath shield (option)
25. Centring screw for illumination
26. Camera operational control LED (option)
27. Inclination angle latch 0 – 20°
28. Slit width controls
29. Roller rail
30. Control lever
31. Camera (option)
32. Slide plate
33. EyeSuite Imaging software (option)
34. Power supply
35. Electric power supply lead (country dependent)



3.2 Overview LED illumination

36. LED illumination LI02 plus with background illumination
37. Plug connection
38. Filter wheel for blue filter
39. Connection background illumination
40. Cover



3.3 LED illumination LI02 plus

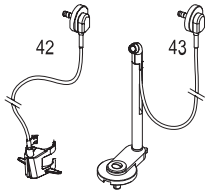
3.3.1 Blue filter

41. The rotating wheel is used to pivot the blue filter for the background illumination. Marking points at the same height = blue filter is on.

3.3.2 Background illumination

The background illumination can only be used in conjunction with an LED illumination LI02 plus.

42. Background illumination fixed
43. Background illumination pivoting (option)



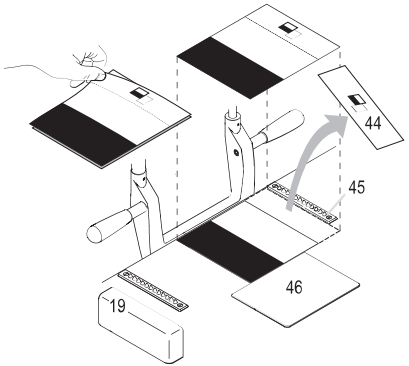
4 Device assembly / installation

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

- Remove rail cover (19) and place slit lamp aside. Clean surface of table.
- Remove protective film from the back of the adhesive label. Carefully start at the corner opposite the black surface.
- Position the sticker against the right roller rail (45) and the gliding plate (46). Press firmly on the white/black surface, press away any air bubbles.
- Carefully tear off the remainder of the adhesive label (44) along the perforation.
- Reassemble the slit lamp and rail cover.

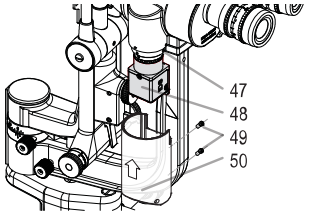
44. Rest of the sticker
45. Roller rail
46. Gliding plate



4.2 Camera assembly

- Remove the cover caps from the camera and adapter.
- Screw the camera (48) onto the adapter.
- Position the image upright setting on the monitor: Slightly loosen the 3 retaining screws (47), turn the camera around its vertical axis until the position is correct; reaffix the camera. Through the software, the image can be displayed horizontally or vertically.
- Mount the camera casing (50) and fix in place with screws (49)

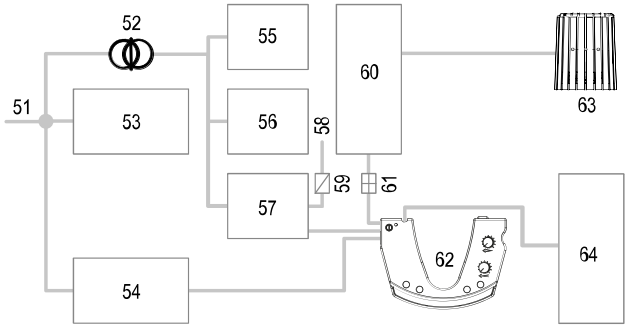
47. Retaining screws
48. Camera
49. Fastening screws
50. Camera casing



4.3 Cabling of 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.

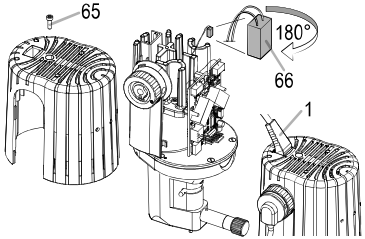
51. Mains
52. Medical approved isolating transformer
53. Instrument table
54. Medical approved power supply
55. Printer
56. Screen
57. Personal computer
58. Local network
59. Galvanic isolation (EN 60601-1)
60. Headrest
61. Cable headrest / LED illumination / RM02
62. Release module RM02
63. LED illumination
64. Camera



NOTE!
To ensure that the system works correctly, Haag-Streit recommends not using laptops and using a high-quality desktop computer instead.

65. Fastening screw
66. Two-pole connection plug

If the middle LED lights up red during operation, the two-pole connection plug (66) is connected incorrectly.



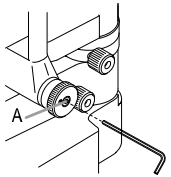
- Disconnect the device from the mains.
- Remove the cover on the upper part of the illumination facility by loosening the fastening screw (65).
- Turn the two-pole connection plug (66) 180°.
- Fix the cover on the upper part of the illumination facility with the fastening screw (65).
- Connect the device to the mains again.

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

4.4 Microscope and illumination

- The slit lamp is packaged and delivered fully assembled. The transport safety devices must be removed prior to commissioning.
- Fix the breath shield (24) in place by fastening the mounting screw (23) on the inside of the bearer arm.

The small screw in the centre of the right control knob (A) allows you to regulate the friction of the turning movement of these adjusting knobs. Turning it slightly to the right (in) makes it harder, turning it left (out) makes it easier. It should at least be set so hard that the slit cannot close on its own.

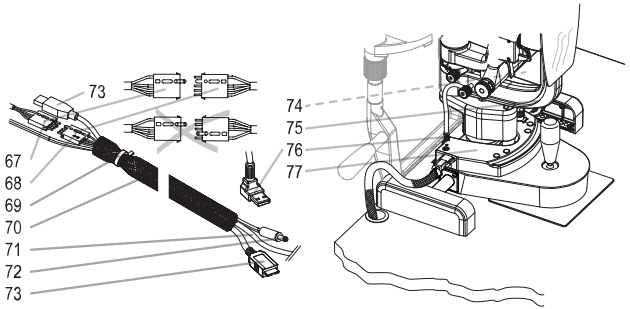


4.5 Step-by-step cabling

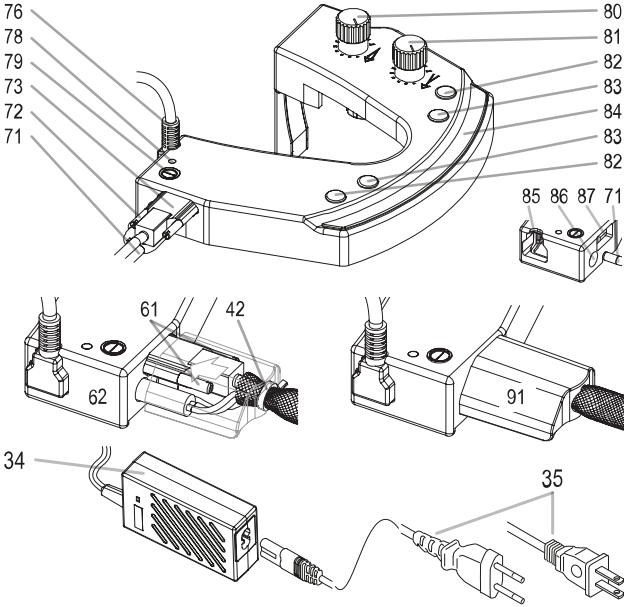
- Place the release module RM02 (73) over the slit lamp's cross slide. Four magnets are used for fixing.

NOTE!
No external USB devices may be connected to USB ports (85) and (87).

- Insert the camera cable's connector plug (76) into the socket (85).
- Press the cable into the recess on the microscope arm (75).
- Feed computer cable USB 3.0 (73), power supply cable (72), and cable headrest / LED illumination / RM02 (71) through the braided sleeving (70).
- Insert the connector plug of the power supply cable (72) into the socket (86).
- Insert the connector plug of the computer cable USB 3.0 (73) into the (87).
- Pull on the braided sleeving until taut and mount a cable tie (69) on each end.
- Mount a cable cover (91) on the threaded bolts (88) or mount the USB connector screws.
- Connect the headrest cable (68) with its counterpart (67) on the headrest.
- Mount the table board and place the slit lamp on the table.
- Connect the computer cable USB 3.0 (73) to the PC.
- Connect the electric power supply lead (35) to the power supply (34).
- Connect the power supply connector plug to the mains.
- Plug the headrest cable (1) into the lamp head.



67. Connection plug headrest
68. Connector plug headrest / LED illumination / RM02
69. Cable tie
70. Braided sleeving
71. Cable headrest / LED illumination / RM02
72. Power supply cable
73. Computer cable USB 3.0
74. Camera (not shown)
75. Recess on the microscope arm
76. Connector plug camera cable
77. Release module RM02
78. RM02 operational control LED
79. On/Off key
80. Rotating knob, background illumination
81. Rotating knob, slit illumination
82. Selector key A
83. Selector key B
84. Release key RM02
85. Socket camera cable
86. Socket for power supply connector plug
87. Socket computer cable USB 3.0 micro B
88. Threaded bolt
89. Pin assignment without imaging set
90. Pin assignment with imaging set
91. Cable cover



5 Commissioning

5.1 Switching on the device

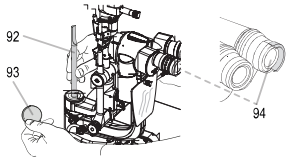
- Connect the power supply to the mains and press the On/Off key (79) on the release module RM02. The green operational control LED (78) lights up when the device is switched on. The camera has no On/Off key and switches on automatically when the PC is switched on.
- Turn the rotating knob on the slit illumination (81) to a position between '1' and '10'.

6 Operation

6.1 Setting the eyepieces

NOTE!
The eyepieces must be individually set prior to the first examination in accordance with the refraction of the examiner. Insert the adjusting pin (92) provided in place of the protective cover (93) and turn its black projection surface at a right angle to the microscope axis. Return the illumination and microscope to the central position (0°).

92. Adjusting pin
93. Protective cover
94. Sliding occluders



- Each eyepiece should be set individually by turning the knurled ocular refraction ring with dioptre scale until the projected slit can be seen in focus. The setting is performed from the (+) to the (-) side at low magnification.
- The sliding occluders (94) are used to set the correct working distance for the examiner from the eyepiece.
- Examiners who do not wear glasses: Pull the occluders out as far as they will go.
- Examiners who do wear glasses: Push the occluders in as far as they will go.

6.2 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:

	Object image section in the eyepiece (mm)	Object image section in the camera (mm)
1 ×	ø 18	24 × 32
1.6 ×	ø 11.25	15 × 20

6.3 White balance

The image quality is dependent 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.

6.3.1 Slit lamp preparation

1. Turn the slit lamp on.
2. Filter position 'open' (no filter).
3. Select a 16 × magnification.
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.

6.3.2 Conducting a white balance

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

NOTE!
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

6.4 Software / Help menu / Error messages

The software is described in the EyeSuite Imaging instruction for use.

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

6.5 Preparing the patient

- In order to attain a solid basis for the forehead and chin to rest on, the table height should be selected such that the patient sits bent over forward.
- To ensure that only the part of the eye being examined is illuminated, the slit height should be set accordingly in order to avoid distracting streaking of light.
- Applied parts which come into contact with the patient (headrest) should be disinfected prior to every use (see instructions for use 'Headrest').
- After each examination, the LED illumination must be switched off via the release module. See chapter "Decommissioning".

6.6 Operating the device

WARNING!
- Before every examination, check that the automatic left to right detection works correctly from the release module!
- The device must be switched off after every use. Otherwise there is a risk of overheating when a protective dust cover is used.

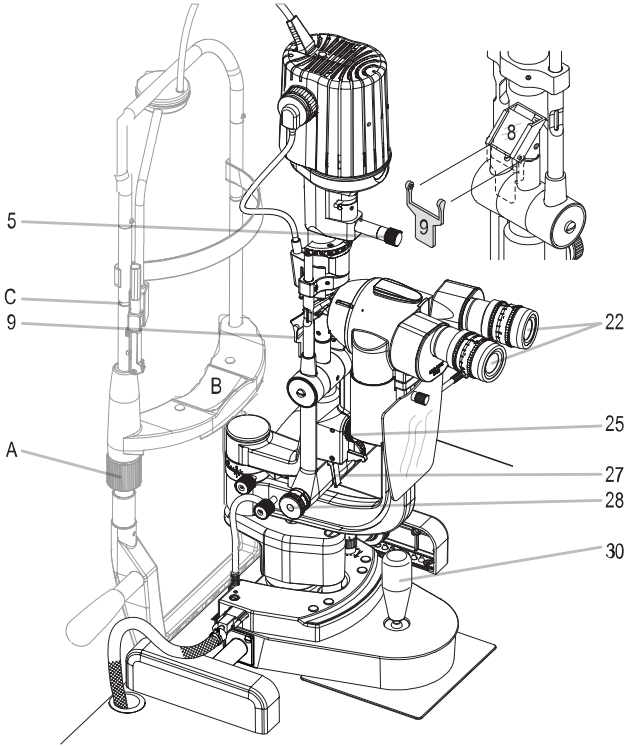
- Use the turn screw (A) to set the chin rest (B) so that the patient's eyes are at the same height as the black mark (C) on the sides of the headrest.
- Set the eyepieces (22) in accordance with the examiner's refraction by turning the knurled rings and set the eye distance.
- Switch on the illumination by turning the switch on the power supply.
- Adjust the height of the slit lamp by turning the control lever (30) until the light beam and microscope axis are at eye level.
- The magnification of the stereo microscope is changed using the magnification changer (100).
- The rigid control lever (30) gently inclined towards the examiner can be used to push the entire device until the slit appears approximately focused on the cornea. This initial setting is verified with the naked eye. Fine tuning is performed by tilting the control lever while observing via the stereo microscope (21).

- The slit width is set left or right with the rotating knob (28), as is the angle between the stereo microscope and illumination.
- The slit image can be set vertically, horizontally or diagonally as required by turning the illumination facility on the handle (5) (locking points at 45°, 90° and 135°; stops at 0° and 180°; scale in 5° increments).
- To ensure that unimpeded binocular fundus examination is also possible at lateral angles of between 3° and 10°, a short mirror (8) is used, the illumination turned 90° using the setting screw (5) and tilted in 5° steps using the latch (27), and the illumination and microscope turned to the central position (0°).
- Front lenses and contact lenses are used to examine the ocular fundus.

Diffuse illumination:
Connecting the diffusor (9) upstream creates diffused illumination. This allows monitoring of the overview and can be used to capture the overview with an imaging module.

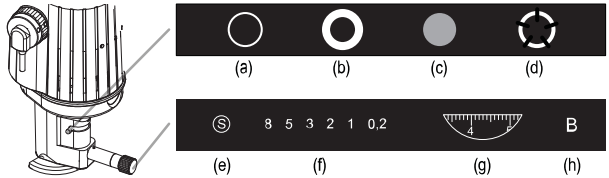
Indirect illumination:
For observation in regredient light (indirect illumination), the centring screw (25) is loosened in order to move the slit image out of the centre of the visual field. Tightening the screw centres the slit image again.

Slit tilting:
The latch (27) can be used to tilt the illumination in 5° steps. This creates an angled light beam during horizontal slit orientation. Tilting the slit enables reflex-free examination with contact lenses (fundus and gonioscopy) and magnifying lenses.



6.7 Setting the filters & diaphragms

a. Open
b. Grey filter (10%)
c. Red removal filter
d. Reserve opening for filter of choice ø 15 mm (0 / –0.2), thickness 2.5 mm
e. Fixation star (predominantly used for fixation examination of cross-eyed children with amblyopia)
f. Apertures of ø 8, 5, 3, 2, 1 and 0.2 mm
g. Display of slit length adjustment from 1 to 14 mm
h. Blue filter

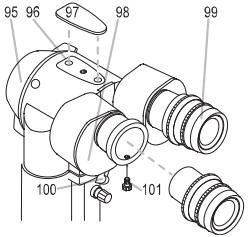


6.8 Fixation star

- Turning the diaphragm disc as far as it will go to the left switches on the fixation star and the symbol 'S' appears in the window. In some examinations of the fundus, this star is projected onto the ocular fundus and is also visible to the patient, who is asked to focus on the centre hole of the star. This allows the examiner to see where the patient's vision is most focused.
- A typical use of the fixation star is close to the macula during laser treatment. Similarly, it is also possible to identify microstrabismus with the projection of the fixation star. The fixation star is usually used with an upstream red removal filter.

6.9 Microscope and eyepiece

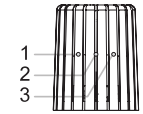
95. Two objective-lens pairs
96. Lever for yellow filter
97. Cover cap for the accessories base
98. Serial number microscope
99. 10 × or 25 × eyepiece
100. Lever magnification changer
101. Eyepiece retaining screw



6.10 Reduced operation

To guarantee a long service life of the light sources, the output of the background illumination is reduced slightly once the maximum operating temperature is reached. After a short cooling time, the full output can be used again. This operating state is only achieved if both light sources remain switched on together for a prolonged period and are therefore outside the specified temperature range.

6.11 LED indicator illumination head



	1) Background illumination	2) Polarity reversal	3) Slit lamp 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

6.12 LED indicator power supply

Normal operation	Green

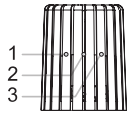
6.13 LED indicator release module RM02

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

6.14 LED indicator camera

Normal operation	Green
Establishing connection	Orange

6.15 Error messages (illumination head)



ERROR	Error messages	Measures	1) Background illumination ● ○ ○	2) Polarity reversal ○ ● ○	3) Slit lamp 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 RM02 to the appropriate service branch.	Red, flashing 4 × ▮▮▮▮ ▮▮▮▮	x	Red, flashing 4 × ▮▮▮▮ ▮▮▮▮

6.16 Error messages release module RM02

ERROR	Error messages	Measures	Operational control LED (78)
E14	No communication with LED illumination LI02 plus	Contact your Haag-Streit representative.	Red, flashing 2 × ▮▮ ▮▮ ▮▮
E16	General error	Send device to the appropriate service branch.	Red, flashing 4 × ▮▮▮▮ ▮▮▮▮

6.17 Error messages camera

ERROR	Error messages	Measures	Operational control LED (26)
E18	No communication with LED illumination LI02 plus	Contact your Haag-Streit representative.	Red ▬

6.18 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.

7 Decommissioning

Press the On/Off key (79) 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 green pulsing. Pressing the key for approx. 3 sec. switches off the release module completely and the operational control LED (78) 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 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 Slit illumination

NOTE!
Detailed information regarding the radiation can be provided on request.

Spectral range slit illumination	400 – 750 nm
Spectral range background illumination	400 – 750 nm
Slit image width (continuous)	0 – 14 mm
Slit image length (fixed diaphragms)	1 – 14 mm
Illumination field circle	ø 8 / 5 / 3 / 2 / 1 / 0.2 mm
Test mark	with fixation star
Slit image radial range	±90°
Radial (swiveling) movement of the slit illumination to microscope axis	Horizontal ± 90°, vertical 0 – 20°
Filters	Blue, red removal (green), grey (10%).

8.2 Power supply

Type	ICCNEXERGY, ELPAC POWER SYSTEMS
Model	MWA030018B-10A REF 1022106
Mains voltage	100 − 240 V
Current consumption	0.8 A
Operating frequency	50 − 60 Hz

8.3 Stereo microscope

Stereo angle	13°			
Magnification changer	1 × and 1.6 ×			
Eyepiece magnification	10 × (standard)			
Magnification changer	10 × / 16 ×, with eyepiece 25 ×: 25 × / 40 ×			
Range of adjusting eyepieces	+6 to −6 dioptres			
Pupil distance	54 − 94 mm			
Filters	Contrast enhancing (yellow)			
Lens	1 ×	1.6 ×	1 ×	1.6 ×
Eyepiece	10 ×	10 ×	25 ×	25 ×
Total magnification	10 ×	16 ×	25 ×	40 ×
Object field diameter	18 mm	11.3 mm	8 mm	5 mm

8.4 Instrument base

Operation:	Single-handed operation of control lever in three dimensions
Adjustment of instrument base:	100 mm (length), 100 mm (side), 30 mm (height)

8.5 Dimensions

Weight:	12 kg (without power supply, headrest and options)
Dimensions L × W × H:	310 × 332 × 700 mm
Packaging L × W × H:	420 × 510 × 780 mm

8.6 Camera

Camera beam	Beam path left (from the point of view of the doctor)
Sensor type	CMOS
Interface	USB 3.0
Frame rate	30 fps (frames per second)
Power consumption	5 V ⎓ / 600 mA

8.7 Minimum PC requirements

Processor type	Intel i5, 5th gen or higher with 4 cores. **NOTE!** • 6th gen is not recommended. • 2 cores with hyperthreading are not recommended.
RAM	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.
Hard disk	At least 500 GB (NTFS data system).
Graphics	Graphics card with at least 2 GB memory (Nvidia or AMD chip set recommended). OpenGL 2.0
Monitor	At least 19", 1920 × 1080 pixel resolution.
Operating system	Windows 10, Windows 11. 64-bit system only.
PCI slot	PCI-Express 3.0
PCI Express card	Chip set by Renesas / NEC.

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.

The LED illumination can be operated maintenance-free for its entire service life.

9.1 Device inspection

In order to correctly check the slit lamp, 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.
- For all magnifications, the structure of the test rod must be shown in sharp focus.
- Close the slit edges to approx. 0.5 mm. The edges must be shown in sharp focus.
- Open the slit edges completely and turn the test rod by 45°, the sharp area must be in the centre of the test rod.

9.2 Service

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)

9.4 Replacing the illumination mirror

The mirror can be most easily accessed if the microscope is turned away from the illumination and the illumination inclined two points.

WARNING!
Only use mirrors with a LOT number.

9.5 Dust cover

We recommend protecting the slit lamp with a dust cover when not in use.

10 Appendix

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.

10.1 Accessories / functionals parts / detachable parts / consumables

Components	*REF*
Eyepiece 10 × for estimating length (BI 900)	*1002602*
Eyepiece 10 × with crosshair-reticule	*1003022*
Eyepiece 25 × (BI 900)	*1200987*
Fixationbase with screw for BD / BI 900	*1022334*
Imaging set BI 900	*7220535*
Short mirror	*1001591*
Breath shield (slit lamp BQ/BM/BP)	*1007129*
Protection shield large (for BI 900)	*7221003*
Fine brush for cleaning the optics	*1001398*

Diagnostic contact lenses	Please refer to the instructions for use Contact lenses, Goldmann/Diagnostics/Laser
Applanation Tonometer	Please refer to the instructions for use AT 900® / AT 870 and Applanation tonometer AT 900® D
Headrest	Please refer to the instructions for use Headrest

10.2 Legal regulations

- This device was developed and designed taking the EN 60601-1, EN ISO 10939 and EN ISO 15004-2 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.
- The device satisfies the electromagnetic compatibility requirements of EN 60601-1-2. The device has been designed to maintain the emissions of electromagnetic interference at a level which does not exceed the statutory guidelines and which does not affect other devices in its vicinity.
- The device also has the immunity stipulated by the standard.
- 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.

10.3 Classification

Standard EN 60601-1	Protection class II
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
EN ISO 10939
EN ISO 15004-2
ANSI Z80.36

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.
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	30 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 * 6 V_{rms} 150 kHz – 80 MHz in ISM bands and radio amateur band *	3 V_{rms} 150 kHz – 80 MHz outside ISM bands and radio amateur band * 6 V_{rms} 150 kHz – 80 MHz in 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
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM 1 kHz	3 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 28 V/m 430 – 470 MHz FM ± 5 kHz deviation, 1kHz sine 9 V/m 704 – 787 MHz 50% PM 217 Hz 28 V/m 800 – 960 MHz 50% PM 18 Hz 28 V/m 1700 – 1990 MHz 50% PM 217 Hz	27 V/m 380 – 390 MHz 50% PM 18 Hz 28 V/m 430 – 470 MHz FM ± 5 kHz deviation, 1kHz sine 9 V/m 704 – 787 MHz 50% PM 217 Hz 28 V/m 800 – 960 MHz 50% PM 18 Hz 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	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 Interference may occur in the vicinity of equipment marked with the following symbol: 
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	

* 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 = 1.2 √P **	**150 kHz – 80 MHz in ISM and radio amateur bands *** d = 2.0 √P	**800 MHz – 6 GHz (for define RF Wireless transmitters see table before)** d = 2.0 √P
0.01	0.12	0.20	0.20
0.1	0.38	0.63	0.63
1	1.2	2.0	2.0
10	3.8	6.3	6.3
100	12	20	20

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:

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