INSTRUCTIONS FOR USE
Slit lamp

BM 900®

16. Edition / 2018 – 04

HAAG-STREIT
DIAGNOSTICS

INSTRUCTIONS FOR USE
Slit lamp

BM 900®

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Introduction

Thank you for choosing a HAAG-STREIT device. Provided you comply carefully with the regulations in this instructions for use, we can guarantee the reliable and unproblematic use of our product.

Purpose of use

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.

Contraindication

There is no absolute contraindication for tests with this device. Appropriate professional judgement 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.

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.

Contents

1. Safety

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

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

NOTE!
Important information: please read carefully.

1.1 Areas of application of the device

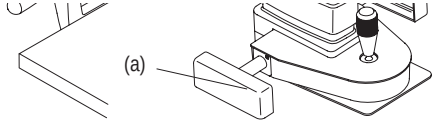
The device is intended to use in professional health care facility environment, like doctor's practices, hospitals and optometrists and opticians premises, except near of HF surgical equipment and in RF shielded rooms of ME-systems for magnetic resonance imaging. Some portable radio frequency equipment, like cell phones or RF telephone equipment including antennas may interference medical devices. Such equipment has to be kept in a distance of more than 30 cm (12 inches) from any part of the instrument. Inobservance of this precaution may lower the correct function of the instrument.

1.2 Ambient conditions

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

1.3 Shipment and unpacking

- Before you unpack the appliance, 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 equipment 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 appliance for damage after it is unpacked. Return defective appliances in the appropriate packaging.
- Store packaging material carefully so that it can be used for potential returns or when moving.
- The slit lamp and head rest must be installed on an electrically insulated, fireproof table top.
- The rail covers (a) prevent the slit lamp from tilting.
- Are the connection parts of the accessories in the correct position (screw connections, quick-release fasteners)?



1.4 Installation warnings

WARNING!
- Do not modify this equipment without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists.
- Any third-party device must be connected in compliance with the EN 60601-1 standard.
- Only original HS replacement parts may be used.
- The device must not be stacked or placed in close proximity to other electronic devices.

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.

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

1.6 Light toxicity

WARNING!
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 750nm. 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 accordingly. 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. The light from this instrument may be dangerous. The risk of eye damage increases with the exposure time. An exposure time with this instrument at maximum intensity of longer than 143 seconds exceeds the guideline value for a risk.

1.7 Disinfection

NOTE!
The device does not need to be disinfected. For more information on cleaning, please refer to the 'Maintenance' section.

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 Description of symbols

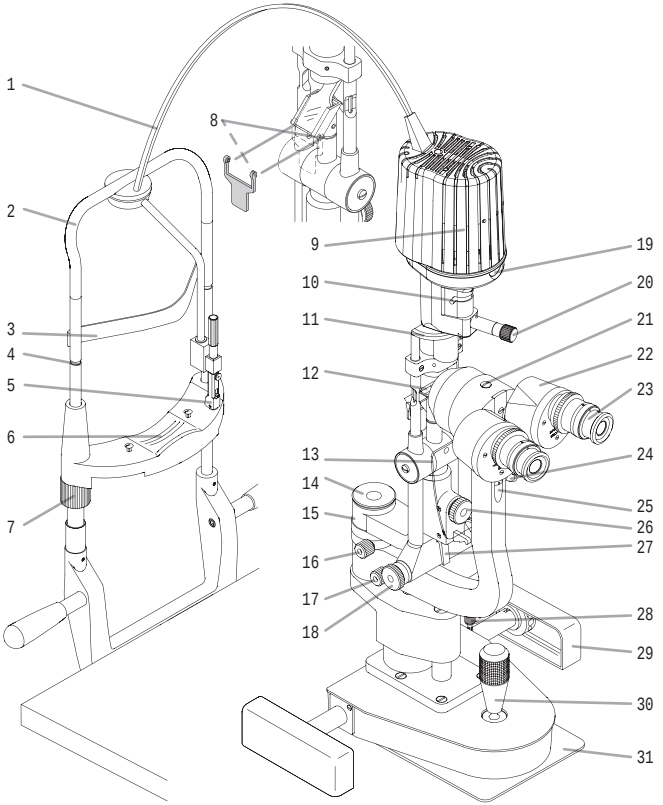
Follow instruction for use	Read the instructions for use attentively
Notes on disposal, see the 'Disposal' chapter	Date of manufacture
Manufacturer	SN Serial number
REF HS reference number	European certificate of conformity
ETL Listed Mark with approval for USA and Canada	Testsymbol of TÜV Rheinland with approval for INMETRO Brasil
Test symbol of CSA with approval for USA	

2. Introduction

The slit lamp comprises an illumination and a binocular microscope. The entire device can be moved in front of the eyes using the instrument base. The illumination offers a range of setting possibilities for making the practically invisible areas of 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.

2.1 Overview

1. Lamp cable
2. Head rest
3. Headband
4. Height mark on head rest (patient eye)
5. Adjustable fixation lamp
6. Chin rest
7. Height adjustment of chin rest
8. Diffusor
9. Illumination head LED LI 900 (see separate instructions)
10. Lever to change filter
11. Scale for angled position of the slit image (5° increments)
12. Illumination mirror
13. Breath shield (option)
14. Protective cover
15. Illumination unit / microscope angle scale
16. Illumination arm locking screw
17. Microscope arm locking screw
18. Slit width setting screw
19. Slit length / diaphragm scale
20. Slit length, slit rotation, blue filter and fixation star control
21. Cap screw for accessories base
22. Stereo microscope with eyepieces
23. Eyepieces
24. Lens-changing lever
25. Mounting screw for the stereo microscope
26. Centring screw
27. Inclination angle latch 0°-20°
28. Joy stick base locking screw
29. Rail cover
30. Control lever
31. Slide plate



3. Appliance 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 Microscope and illumination

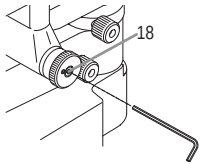
The slit lamp is packaged and shipped fully assembled. The transport safety devices must be removed before commissioning.

3.2 Power supply

NOTE!
- Observe the respective HAAG-STREIT instructions for use. (For further information, please contact your HAAG-STREIT dealer).
- This device must only be operated with PS-LED and PS-LED HSM 901 HS power supplies and the RM02 release module.

3.3 Regulating the clearance of the slit width control

The small screw in the centre of the right control knob (18) 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. Commissioning

The device can be switched on and off using the mains power switch on the device power supply. The green light on the rocker switch illuminates when the device is switched on.

4.1 Switching on the device

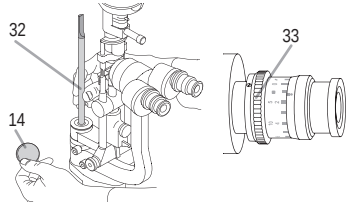
- Connect the power supply up to the mains and press the rocker switch. The green light on the rocker switch illuminates when the device is switched on.
- Turn the rotating knob on the illumination control to a position between '1' and '10'.

5. Operation

5.1 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 provided focus test rod (32) in place of the protective cover (14) and turn its black projection surface at a right angle to the microscope axis. Return the illumination and microscope to the central position (0°).

14. Protective cover
32. Test rod
33. Knurled ocular refraction ring with dioptre scale



- Each eyepiece should be set individually by turning the knurled ocular refraction ring with dioptre scale (33) such that the projected slit can be seen in focus. The setting is performed from the (+) to the (−) side at low magnification.
- The pupil distance should then be set on the microscope.

5.2 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.
- Parts which come into contact with the patient should be cleaned with a dry cloth prior to every use.
- The lamp must be switched off after every examination.

5.3 Operating the instrument

WARNING!
The device must be switched off after every use. Otherwise there is a risk of overheating when a protective dust cover is employed.

- Use the turn screw (7) to set the chin rest (6) in such a way that the patient's eyes are at the same height as the black mark (4) on the sides of the head rest.

- Adjust the eyepieces (23) 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 luminous aigrette is at eye level.
- The rigid control lever (30) gently inclined towards the examiner can be used to push the entire instrument 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, which is easily controlled at the top end, while observing via the stereo microscope (22).
- The slit width is set left or right with the rotating knob (17), as is the angle between the stereo microscope and illumination.
- The slit image can be set vertically, horizontally or as diagonally as required by turning the illumination facility on the control knob (20) (locking points at 45°, 90° and 135°; stops at 0° and 180°; scale in 5° increments).
- To ensure that unimpeded binocular fundus examination in the optical section is also possible at lateral angles of between 3° and 10°, a short mirror (12) is used, the illumination turned 90° using the locking screw (20) and tilted in 5° steps using the latch (27), and the illumination and microscope turned to the central position (0°).
- The magnification of the stereo microscope can be changed on the slit lamp BM 900 by changing the lenses using the lever (24) or exchanging the eyepieces.
- Front-lens glasses and contact glasses are used to examine the ocular fundus.

Diffuse illumination:

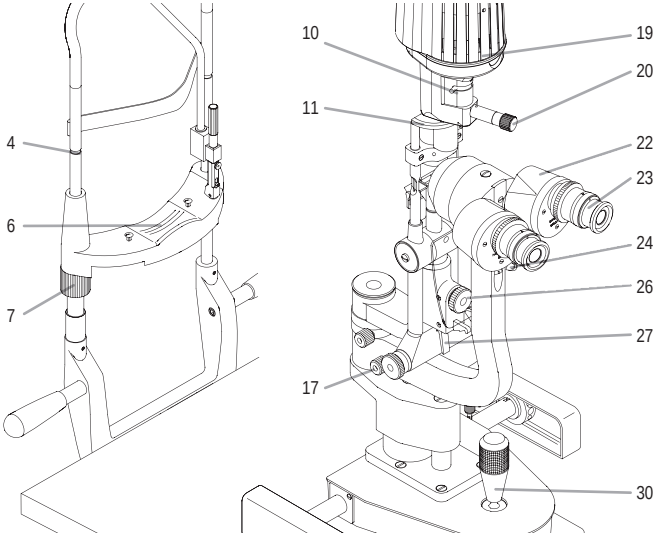
- A diffuse illumination is achieved by positioning the diffusor (8) upstream. This enables overview monitoring and can be used for taking overview images with the Imaging Module.

Indirect illumination:

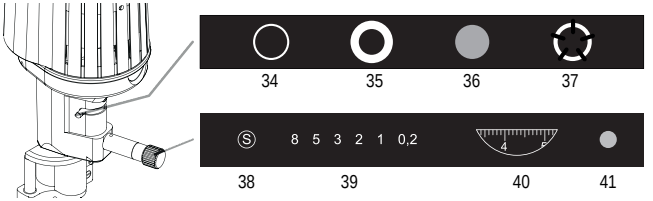
- For observation in regredient light (indirect illumination), the centering screw (26) is loosened in order to move the slit image out of the center of the visual field. Tightening the screw centers the slit image again.

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 glasses (fundus and gonioscopy) and magnifying glasses.



5.4 Setting the filters & diaphragms



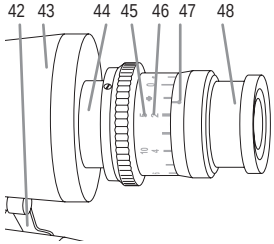
34. Open
35. Grey filter (10%)
36. Red removal filter
37. Reserve opening for filter Ø 15mm (0 / -0.2), thickness 2.5mm
38. Fixation star
39. Apertures of 8, 5, 3, 2, 1 and 0.2 mm in ø
40. Display of slit length in 1 to 8 mm
41. Blue filter

5.5 Fixation star

- Turning the diaphragm disc to the left stop switches on the fixation star and the 'S' symbol appears in the viewing 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 center hole of the star. This shows the examiner the point where the patient's vision is most focused.
- A typical use of the fixation star is close to the macula during laser treatment. The projection of the fixation star can also be used to identify microstrabismus. The fixation star is usually used with upstream red removal filter.

5.6 Microscope and eyepiece

The magnification of the microscope can be altered by changing the lens mounted in a revolving turret piece or by exchanging the eyepieces. Only the lever (48) is to be adjusted, from 1x to 1.6x, when changing the lens. In this instance, the examination need not be interrupted; nor is a new adjustment of the microscope needed. This change will alter the overall magnification from 10x to 16x (on the 10x eyepiece) and from 25x to 40x (on the 25x eyepiece) respectively.



42. Magnification changing lever
43. Prism housing
44. Eyepiece mounting
45. Dioptre scale for 16x eyepieces for setting the refraction of the examiner (± 8 D)
46. Dioptre scale for 10x eyepieces for setting the refraction of the examiner (± 8 D)
47. Index (white point)
48. 10x or 25x eyepiece

6. Decommissioning

The LED illumination can be switched off with the illumination control. The device power supply remains switched on and the switch illuminates green. To switch the system off completely, the rocker switch must be set to the 0 = 'OFF' position. This results in double pole disconnection from the mains.

NOTE!
Disconnect the power supply from the mains if you do not intend to use it for an extended period of time.

7. Technical data

7.1 Slit illumination

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

Spectral range slit illumination	400 to 750 nm
Spectral range background illumination	400 to 750 nm
Slit image width	0-8 mm continuous
Slit image length	1-8 mm continuous
Illumination field circle	8 / 5 / 3 / 2 / 1 / 0.2 mm in ø
Test mark	with fixation star
Slit image rotatability	0-90°
Inclination of slit illumination to microscope axis	Horizontal ± 90°, vertical 0-20°
Filters	Blue, red removal (green), grey (10%)

NOTE!
Further information is available in the LED illumination LI 900 instructions for use.

7.2 Stereo microscope

Stereo angle	13°
Magnification changer	1x and 1.6x
Magnif. with 10x eyepiece	10x and 16x (standard)
Magnif. with 25x eyepiece	25x and 40x
Range of adjusting eye-pieces	+8 to -8 dioptres
Pupil distance	54 – 94 mm
Lens	1x / 1.6x / 1x / 1.6x
Eyepiece	10x / 10x / 25x / 25x

Total magnification	10x / 16x / 25x / 40x
Object field diameter	18 mm / 11.3 mm / 8 mm / 5 mm

7.3 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)

7.4 Dimensions

Weight:	11.4 kg (without power supply, head rest and options)
Dimensions L x W x H:	290 x 332 x 700 mm
Packaging L x W x H:	420 x 510 x 780 mm

8. Maintenance

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

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

8.1 Device inspection

In order to correctly check the slit lamp, proceed as follows:
- Insert test rod into the radial movement bearing, whilst at the same time aligning the surface to the microscope at a right angle
- Set slit length to 8 mm
- Set llumination strength to 50%
- Set magnification to max. in the microscope.
- Set the eyepieces in such a way that the test rod is in sharp focus. Turn the eyepiece from the (+) to the (-) side.
- The structure of the test rod must be in sharp focus in all magnifications.
- Close slit edges to approx. 0.5 mm. The borders must be in sharp focus here.
- Completely open slit edges and turn the test rod by 45°, the sharp area must be in the centre of the test rod.

8.2 Repair

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.
In order to guarantee optimal operational integrity, the device must undergo periodic maintenance. The length of the maintenance interval depends on use, but may not exceed 3 years.

8.3 Cleaning and disinfection

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

WARNING!
- The preparation instructions provided do not apply to tonometer measuring prisms!
- Tonometer measuring prisms must be prepared in accordance with a different manual
- Do not use sprays
- Observe the manufacturer's safety instructions
- Do not use any cloths that drip.
- Wring out any soaked cloths before use when necessary
- Ensure that no liquid penetrates the device
- Comply with the stipulated exposure time
- Clean optical surfaces after disinfection with a very soft cloth

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

8.4 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.

8.5 Dust cover

We recommend protecting the slit lamp with a dust cover (53) when not in use.

A. Appendix

A.1 Accessories / spare parts

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.

NOTE!

An asterisk (*) shows that you should contact your HAAG-STREIT representative for further information.

Component	HS art. no.
10x eyepiece	*7020023*
25x eyepiece	*7020034*
25x eyepiece McIntyre	*7020025*
Allen key 5 mm	*1001602*
Block of paper slips for chin rest	*1001309*
Diffusor	*7200660*
Dust cover, large (for several instruments)	*1001434*
Dust cover, small (for slit lamp)	*1001395*
Dusting brush	*1001398*
Illumination control, simple, 'in table'	*1021024*
Illumination control, simple, 'on table'	*1021020*
Instrument table HSM 901	*
Long mirror	*1001590*
Pin for chin rest	*1200713*
Pivot	*1022449*
Power supply for LED illumination, HSM 901	*1020882*
Power supply for LED illumination, tables from other manufacturers	*1020881*
Short mirror	*1001591*
Test rod	*1021656*
USB illumination cable 2000 mm	*1020940*
USB illumination cable 5000 mm	*1020956*

B. Legal regulations

- The BM 900 slit lamp 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 BM 900 slit lamp with the Directive 93/42/EEC is confirmed by the CE-designation.
- The BM 900 slit lamp 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.
- Statutory accident regulations are to be observed.

C. Classification

Standard EN 60601-1	Slit lamp BM 900 acc. to protection class I
Operating mode:	Continuous operation
CE Directive 93/42/EEC	Class I
FDA	Class II

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. Standards

EN ISO 10939	EN 60601-1
EN 60601-1-2	EN ISO 15004-2

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

F.1 General

The BM 900 slit lamp system fulfills the requirements on electromagnetic compatibility according to EN 60601-1-2:2007 (IEC 3. Edition) + EN 60601-1-2:2015 (IEC 4. Edition). The instrument is built so that the generation and emission of electromagnetic interference is limited to the extent that other devices are not disturbed in their use in accordance with the regulations and so that the instrument itself is suitably immune to electromagnetic interference.

WARNING!
- 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.
- 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)

The information is based on the requirements of EN 60601-1-2:2007 (IEC 3rd edition) and EN 60601-1-2:2015 (IEC 4th edition).

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 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.
Emission of harmonics according to EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to EN 61000-3-3	Fulfilled	

F.3 Immunity (standard table 2)

The information is based on the requirements of EN 60601-1-2:2007 (IEC 3rd edition).

Guidance and manufacturer's declaration – electromagnetic immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.			
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	± 1 kV for symmetrical voltages ± 2 kV for asymmetrical voltages	± 1 kV for symmetrical voltages ± 2 kV for asymmetrical voltages	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_T= the AC mains voltage prior to application of the test level.			

F.4 Immunity for non-life support devices (standard table 4)

The information is based on the requirements of EN 60601-1-2:2007 (IEC 3rd edition).

Guidance and manufacturer's declaration – electromagnetic immunity

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

Electromagnetic environment – guidance

Portable and mobile RF communications equipments 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[c]:
Conducted RF EN 61000-4-6	3 V_{rms} 150 kHz – 80 MHz	10 V_{rms}	$D = 0.35\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz – 2.7 GHz	5 V/m 80 MHz – 2.7 GHz	$D = 0.7\sqrt{P}$ 80 MHz – 800 MHz $D = 1.4\sqrt{P}$ 800 MHz – 2.7 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 10 V/m.
c. Possible shorter distances outside the ISM bands do not contribute to improved application in this table.

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

The information is based on the requirements of EN 60601-1-2:2007 (IEC 3rd edition).

Recommended safe distances between portable and mobile HF communication devices and this device.

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

	Safe distance according to transmission frequency (m)		
Nominal output of the transmitter (W)	150 kHz – 80 MHz $D = 0.35\sqrt{P}$	80 MHz – 800 MHz $D = 0.7\sqrt{P}$	800 MHz – 2.7 GHz $D = 1.4\sqrt{P}$
0.01	0.035	0.07	0.14
0.1	0.1	0.2	0.44
1	0.35	0.7	1.4
10	1.1	2.2	4.4
100	3.5	7	14

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 2.7 GHz an additional factor of $^{10}/_{3}$ was used to reduce the probability of a mobile/portable communication device causing interference if inadvertently brought into the patient area.
NOTE 3:	These guidelines may not apply in all situations. Electromagnetic wave propagation is influenced by absorption and reflection of buildings, objects and people.

Should you have any further questions, please contact your HAAG-STREIT dealer at:

http://www.haag-streit.com/contact/contact-your-distributor.html

HAAG-STREIT DIAGNOSTICS

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