Swiss made

INSTRUCTIONS FOR USE
LED illumination set

LI 900®

12. Edition / 2023– 01

HAAG-STREIT DIAGNOSTICS

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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.

Contents

1 Safety

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

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

NOTE!
Important information, please read carefully.

1.1 Comments on these instructions for use

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

1.2 Ambient conditions

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

1.3 Shipment and unpacking

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

1.4 Installation warnings

WARNING!
- Do not modify this device without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists.
- Any third-party device must be connected in compliance with the EN 60601-1 standard.
- Only original Haag-Streit spare parts may be used.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- 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.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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 'Purpose of use' chapter.

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-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 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.

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	CE	European certificate of conformity
	Date of manufacture		Manufacturer
REF	Haag-Streit reference number	SN	Serial number
HS	Trademark of the manufacturer Haag-Streit AG		Notes on disposal, see the 'Disposal' chapter
EC REP	Listed European Authorized Representative	MD	Medical Device
Segurança	Testsymbol of TÜV Rheinland with approval for INMETRO Brasil	MET	MET Listed Mark with approval for USA and Canada
	Earth (ground)		Disconnect the plug before opening the device
	Slit lamp illumination		Background illumination
	Illumination control of an external supplier		On (Power)

2 Purpose of use

The illumination set LI 900 was developed exclusively for Haag-Streit slit lamps BQ 900, BP 900 and BM 900. The intensities of the slit and background illumination can be set via the illumination controls.

3 Introduction

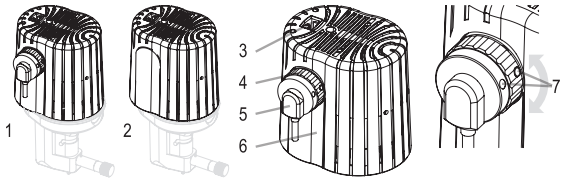
3.1 Device description

- The illumination set LI 900 consists of an LED illumination unit, a power supply PS-LED and an illumination control. A light conductor set is also required for the version with background illumination. Slit lamps with LED lighting may only be used with the intended PS-LED or RM02 power supply.
- Both the supply current for the LED and the signals for communication between the power supply and illumination are conducted by the two-pole connection cable.
- The light intensity of slit and background illumination can be controlled continuously with the illumination controls. The illumination controls can be connected to the power supply PL-LED with a longer connection cable.

NOTE!
The instruction manual for the slit lamp must be complied with.

3.2 Overview

1. LED illumination LI02 plus with background illumination
2. LED illumination LI01 without background illumination
3. Plug connection for headrest
4. Filter wheel for blue filter
5. Background illumination connection
6. Lid



3.3 LED illumination LI02 plus

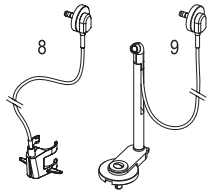
3.3.1 Blue filter

7. 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.

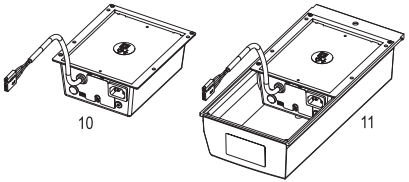
8. Background illumination fixed
9. Background illumination pivoting



3.4 Power supply PS-LED

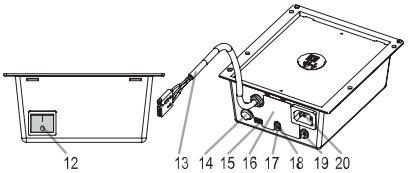
3.4.1 Versions

10. Power supply PS-LED, for installation on third-party tables and units
11. Power supply PS-LED HSM 901 insert, for the instrument table HSM 901



3.4.2 Description

12. Rocker switch
    Switch in position 0 = 'OFF': Power supply device is deenergized.
    Switch in position 1 = 'ON': Pilot lamp lights up green.
13. Main and fixing lamp connection
14. Connection illumination control from an third-party supplier (Power Jack 2.1 mm)
15. Connection Haag-Streit illumination control IC01x (USB mini B)
16. Type plate (on housing)
17. S1, button
18. L1, LED indicator (green / red)
19. Connection function ground (M3)
20. 3-pole mains connection



WARNING!
No other USB device may be connected to port 15 (USB mini-B), which is exclusively reserved for the Haag-Streit IC01x lighting control

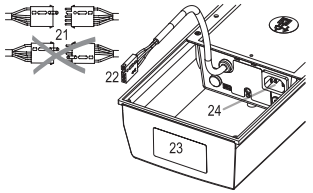
4 Device assembly / installation

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 Power supply for instrument table HSM 901

NOTE!
Haag-Streit recommends connecting the aluminum tray to the protective conductor connection of the power supply.

21. Plug alignment
22. Main and fixing lamp connection
23. Type plate on housing
24. Mains connection



NOTE!
The instruction manual 'Instrument table HSM 901' must be complied with.

4.2 Power supply on HSM 600 and third-party tables

- Connect all cables, relieve the mains cable with a cable tie if necessary.
- Fix the power supply PS-LED in place with 4 screws.
- Connect the multi-pole jump lead connection between the head holder and the instrument table.
- Connect the main lamp cable (27) on the upper part of the illumination unit.

WARNING!

- When mounting the guide rail and the head holder, it is important to ensure that there is no electrical connection to any metal part of the table. Otherwise, a grounding wire must be mounted on the head holder.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Cables must not be trapped as this can cause a short circuit!
- Work on cables or device components, which are in contact with the power supply, may only be carried out by qualified personnel.

4.3 Guidelines for assembly on HSM 600 and third-party tables

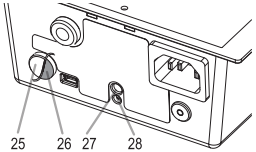
If a power supply is installed on a third-party table, then it will be necessary to observe Directive 93/42 EEC in conjunction with the standards EN 60601-1 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance” and EN 60601-1-2 “Electromagnetic compatibility.”

4.4 Installation on HSM 600 and on third-party tables

An illumination control of an third-party supplier can be connected via connection (25) on the power supply PS-LED.

- It must first be calibrated for the relevant potentiometer value.
- Controls between 5 and 50 kΩ can be calibrated.

25. Protective cap
26. Connection
27. LED L1
28. Button S1



4.4.1 Calibrating illumination controls of an third-party supplier

- Remove the protective cap for access to the connection (25).
- Connect the third-party illumination control (Power Jack 2.1 mm) and set to maximum illumination (knob to the right stop).
- Switch on the power supply PS-LED.
- Press the button S1 > 1 sec. The device switches to calibration mode. The orange LED (27) signals that the illumination control is being calibrated.
- The calibration process is complete after approx. 1 to 3 seconds (depending on the illumination control). This is indicated by the green LED (27) flashing briefly twice.

4.5 Converting tungsten to LED illumination

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.

Slit lamps with tungsten illumination can be converted to LED illumination by technicians trained by Haag-Streit. If an LED upper part of the illumination unit with background illumination is used, there is no need to use an additional cold light source.

5 Commissioning

5.1 Switching on the device

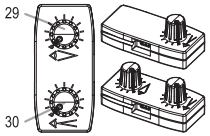
- Connect the power supply to the mains and press the rocker switch. When the device is switched on, the green lamp lights up in the rocker switch.
- Set the knob of the illumination control to a position between ’1’ and ’10’.

6 Operation

The light sources are switched on if the knob of the illumination control IC01 is in a position between ’1’ and ’10’. In the 0 position, the light sources are switched off. (Standby).

- Slit and background illumination can be set separately with the potentiometers.
- The blue dial on the illumination head can be used to switch the background illumination between white and blue light.

29. Background illumination knob
30. Slit illumination knob

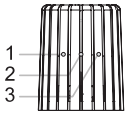


WARNING!
Illumination control cables can only be used for connecting an illumination control IC01 and a power supply PS-LED. Only connect illumination controls to suitable devices!

6.1 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.

6.2 LED indicator Illumination head

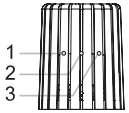


	1) Background illumination	2) Polarity reversal	3) Slit lamp illumination
Operating state	● ○ ○	○ ● ○	○ ○ ●
Standby mode	Green, pulsing	x	Green, pulsing
Normal operation Slit and background illumination on	Green	x	Green
Only slit illumination on	Green, pulsing	x	Green
Only background illumination on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

6.3 LED indicator (PS-LED power supply)

Normal operation	Green

6.4 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 the illumination control or replace if necessary.	Red ▬	x	Red ▬
E3	Temperature is too high	The output of the light sources is reduced. Normal operation is guaranteed again when the permissible temperature is 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 × ▮▮▮▮ ▮▮▮▮

6.5 Error messages (PS-LED power supply)

ERROR	Error messages	Measures	LED indicator L1 (27)
E12	Illumination control not recognized	Connect the illumination control or replace if necessary.	Red ▬
E14	No communication with LED illumination LI02	Contact your Haag-Streit representative.	Red, flashing 2 × ▮▮ ▮▮ ▮▮
E16	General error	Send device to the appropriate service branch.	Red, flashing 4 × ▮▮▮▮ ▮▮▮▮

7 Decommissioning

The LED illumination can be switched off with the illumination controls. The power supply remains switched on during this process and the switch lights up green. To switch off the system completely, the rocker switch must be moved to position 0 = 'OFF'. This creates a two-pole isolation 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.

8 Technical data

8.1 LI01 / LI02 plus

NOTE!
- Observe the respective Haag-Streit instructions for use. For further information, please contact your Haag-Streit representative.
- This device must only be operated with PS-LED and PS-LED HSM 901 Haag-Streit power supplies and the RM02 release module.

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

8.2 Power supply PS-LED / PS-LED HSM 901

Mains voltage:	100 - 240 V
Power consumption:	60 VA
Operating frequency:	50-60 Hz

8.3 Dimensions

PS-LED	
Length:	164 mm
With:	140 mm
Height:	60 mm
Weight:	450 mm

PS-LED HSM 901	
Length:	316 mm
With:	146 mm
Height:	69 mm
Weight:	750 mm

Illumination control IC01	
Length:	75 mm
With:	35 mm
Height:	33 mm
Weight:	32 mm

Illumination control IC01 T	
Length:	90 mm
With:	51 mm
Height:	33 mm
Weight:	32 mm

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 Servicing

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

9.2 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!
- 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.

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

10 Appendix

10.1 Accessories / functionals parts / detachable parts / consumables

NOTE!
An asterisk (*) indicates that you should contact your Haag-Streit representative for further information. Two asterisks (**) indicate a need to refer to the separate instructions for use.

Components	*REF*
Background illumination fixed FI01f	*1020886*
Background illumination pivoting FI01p	*1020887*
Illumination control cable USB 2000 mm	*1020940*
Illumination control cable USB 5000 mm	*1020956*
Illumination control IC01 (double, slit and background 'on table')**	*1020883*
Illumination control IC01-1 (single, slit only 'on table')**	*1021020*
Illumination control IC01T (double, slit and background 'in table')**	*1021022*
Illumination control IC01T-1 (single, slit only 'in table')**	*1021024*
Mains cable CH, length: 2500 mm	*1001319*
Mains cable US, length: 3100 mm	*1001316*
Mains cable US, length: 760 mm	*1002147*
Power supply PS-LED	*1020881*
Power supply PS-LED HSM901**	*1020882*
Release module RM02 (with power supply see 7220546)	*1022052*

10.2 Legal regulations

- This device was developed and designed taking the EN 60601-1, EN ISO 10939, EN 60601-1-2 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.
- Statutory accident regulations are to be observed.

10.3 Classification

Standard EN 60601-1	As equipment safety class I
Operating mode:	Continuous operation

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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Fulfilled	

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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Wiki Revision ID: 135140