INSTRUCTIONS FOR USE
LED illumination set
LI 900®

Swiss made

HAAG-STREIT DIAGNOSTICS
INSTRUCTIONS FOR USE
LED illumination set
LI 900®


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
The LED 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.

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

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

NOTE!
Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

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** ................................................................. 4  
   1.1 Areas of application of the device ........................................ 4  
   1.2 Ambient conditions ..................................................... 4  
   1.3 Shipment and unpacking .................................................. 4  
   1.4 Installation warnings ..................................................... 4  
   1.5 Operation, environment .................................................. 4  
   1.6 Light toxicity .............................................................. 5  
   1.7 Disinfection ............................................................... 5  
   1.8 Warranty and product liability .......................................... 5  
   1.9 Description of symbols .................................................. 5  

2. **Introduction** ....................................................... 5  
   2.1 Device description ........................................................ 5  
   2.2 Overview ............................................................... 6  
   2.3 LED illumination LI02 plus .............................................. 6  
   2.4 Blue filter ............................................................... 6  
   2.5 Background illumination ................................................ 6  
   2.6 Power supply PS-LED ................................................... 6  
   2.6.1 Versions ............................................................... 6  
   2.6.2 Description ............................................................ 6  

3. **Equipment assembly / installation** ............................... 6  
   3.1 Power supply for instrument table HSM 901 ........................ 6  
   3.2 Power supply on HSM 600 and third-party tables ............... 7  
   3.3 Guidelines for assembly on HSM 600 and third-party tables .... 7  
   3.4 Installation on HSM 600 and on third-party tables ............... 7  
   3.4.1 Calibrating illumination controls of an third-party supplier .. 7  
   3.5 Converting tungsten to LED illumination ............................ 7  

4. **Commissioning** ................................................... 7  
   4.1 Switching on the appliance ............................................. 7  

5. **Operation** ............................................................ 8  
   5.1 Reduced operation ...................................................... 8  
   5.2 LED indicator Illumination head ....................................... 8  
   5.3 LED indicator (PS-LED power supply) .............................. 8  
   5.4 Error messages (Illumination head) ................................... 8  
   5.5 Error messages (PS-LED power supply) ............................ 9  

6. **Decommissioning** ................................................ 9  

7. **Technical data** ..................................................... 9  
   7.1 LI01 / LI02 plus .......................................................... 9  
   7.2 Power supply PS-LED / PS-LED HSM 901 ....................... 10  
   7.3 Dimensions .............................................................. 10  

8. **Maintenance** ....................................................... 10  
   8.1 Repair .................................................................. 10  
   8.2 Cleaning and disinfection .............................................. 10  

9. **Appendix** ............................................................ 10  
   A. Accessories / consumables / spare parts / upgrade .............. 10  

10. **Legal regulations** ................................................ 11  

11. **Classification** ..................................................... 11  

12. **Disposal** ............................................................ 11  

13. **Standards** .......................................................... 11  

14. **Information and manufacturer's declaration**  
    concerning electromagnetic compatibility (EMC) .................. 12  

F.1 General ................................................................. 12  
F.2 Emitted interference (standard table 1) ............................. 12  
F.3 Immunity (standard table 2) ............................................. 13  
F.4 Immunity for non-life support devices (standard table 4) ....... 14  
F.5 Safe distances for non-life support devices (standard table 6) .. 15

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 possible returns or when moving.

1.4 Installation warnings

**WARNING!**
- Installation and repairs may only be performed by trained specialists.
- Any third-party device must be connected in compliance with the EN 60601-1 standard.
- Only original Haag-Streit (HS) replacement parts may be used.
- The device must not be stacked or placed in close proximity to other electronic devices.
- Grounding reliability can only be achieved when unit is connected to a hospital grade receptacle. (Not valid for EU countries).

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.

**WARNING!**
To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

**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 131 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' 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 Description of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Symbol]</td>
<td>Read the instructions for use attentively</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Follow instruction for use</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Notes on disposal, see the 'Disposal' chapter</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>European certificate of conformity</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Date of manufacture</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Disconnect the plug before opening the device</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Serial number</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>HS reference number</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Silt lamp illumination</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Background illumination</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Illumination control of an external supplier</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>ETL Listed Mark with approval for USA and Canada</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>MET Listed Mark with approval for USA and Canada</td>
</tr>
</tbody>
</table>

2. Introduction

2.1 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.
2.2 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

2.3 LED illumination LI02 plus

2.4 Blue filter
7. The blue filter can be swiveled in using the rotary knob. Marking points at the same height = blue filter on.

2.5 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

2.6 Power supply PS-LED

2.6.1 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

2.6.2 Description
12. Rocker switch switch in position 0 = 'OFF' power supply device is deenergized.
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.

3. Equipment assembly / installation

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

3.1 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.

3.2 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.

3.3 Guidelines for assembly on HSM 600 and third-party tables
If a device 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.”

3.4 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

3.4.1 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.

3.5 Converting tungsten to LED illumination

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

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.

4. Commissioning
4.1 Switching on the appliance
* 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’. 
5. 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!

5.1 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.

5.2 LED indicator

Illumination head

<table>
<thead>
<tr>
<th>Operating state</th>
<th>a)</th>
<th>b)</th>
<th>c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standby mode</td>
<td>![Green flashing briefly]</td>
<td>×</td>
<td>![Green flashing briefly]</td>
</tr>
<tr>
<td>Normal mode</td>
<td>![Green]</td>
<td>×</td>
<td>![Green]</td>
</tr>
<tr>
<td>Reduced operation of the background illumination</td>
<td>![Green flashing briefly]</td>
<td>×</td>
<td>![Green flashing briefly]</td>
</tr>
<tr>
<td>Normal mode</td>
<td>![Green]</td>
<td></td>
<td>![Green]</td>
</tr>
</tbody>
</table>

5.3 LED indicator (PS-LED power supply)

Normal mode

green

5.4 Error messages (illumination head)
5.5 Error messages (PS-LED power supply)

<table>
<thead>
<tr>
<th>ERROR</th>
<th>Error messages</th>
<th>Measures</th>
<th>LED indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>E12</td>
<td>Illumination control not recognized</td>
<td>Connect the illumination control or replace if necessary.</td>
<td>Red</td>
</tr>
<tr>
<td>E14</td>
<td>No communication with LED illumination LI02</td>
<td>Contact your Haag-Streit representative.</td>
<td>Red flashing 2x</td>
</tr>
<tr>
<td>E16</td>
<td>General error</td>
<td>Send the device to the relevant service branch.</td>
<td>Red flashing 4x</td>
</tr>
</tbody>
</table>

6. Decommissioning

The LED illumination can be switched off with the illumination controls. The power supply remains switched on and the switch lights up green. To switch off the system completely, the rocker switch must be moved to position 0 = 'OFF'. There is then 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.

7. Technical data

**NOTE!**

Detailed information regarding the radiation can be provided on request.
7.2 Power supply PS-LED / PS-LED HSM 901

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

7.3 Dimensions

<table>
<thead>
<tr>
<th>PS-LED</th>
<th>PS-LED HSM 901</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length: 164 mm</td>
<td>Length: 316 mm</td>
</tr>
<tr>
<td>Width: 140 mm</td>
<td>Width: 146 mm</td>
</tr>
<tr>
<td>Height: 60 mm</td>
<td>Height: 69 mm</td>
</tr>
<tr>
<td>Weight: 450 g</td>
<td>Weight: 750 g</td>
</tr>
</tbody>
</table>

**Illumination control IC01**

| Length: 75 mm | Length: 90 mm |
| Width: 35 mm | Width: 51 mm |
| Height: 33 mm | Height: 33 mm |
| Weight: 32 g | Weight: 32 g |

8 Maintenance

**WARNING!**

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

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

8.1 Repair

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

8.2 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 or not containing aldehyde) are also permitted, such as Kohrsolin FF.

**WARNING!**

- Do not use sprays
- Observe the manufacturer's safety instructions
- Do not use any cloths that might drip.
- Wring out any soaked cloths completely before use wherever necessary
- Ensure that no liquid penetrates into the device
- Comply with the stipulated exposure time

**NOTE!**

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

A. Appendix

A.1 Accessories / consumables / spare parts / upgrade

**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.

<table>
<thead>
<tr>
<th>Components</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA power supply lead, length: 3100 mm</td>
<td>1001316</td>
</tr>
<tr>
<td>CH power supply lead, length: 2500 mm</td>
<td>1001319</td>
</tr>
<tr>
<td>USA power supply lead, length: 760 mm</td>
<td>1002147</td>
</tr>
<tr>
<td>USB illumination cable 2000 mm</td>
<td>1020940</td>
</tr>
<tr>
<td>USB illumination cable 5000 mm</td>
<td>1020956</td>
</tr>
<tr>
<td>Cover T-0 for recess in table</td>
<td>1021085</td>
</tr>
<tr>
<td>Release module RM02 with power supply</td>
<td>7220546</td>
</tr>
<tr>
<td>Power supply for LED illumination for third-party tables</td>
<td>7220741</td>
</tr>
<tr>
<td>Power supply for LED illumination, HSM 901**</td>
<td>7220742</td>
</tr>
<tr>
<td>Illumination control, double slit and background 'on table'**</td>
<td>7220743</td>
</tr>
<tr>
<td>Background illumination F1 01f</td>
<td>7220744</td>
</tr>
<tr>
<td>Illumination control, simple, 'on table'**</td>
<td>7220745</td>
</tr>
<tr>
<td>Illumination control, double slit and background 'in table'**</td>
<td>7220746</td>
</tr>
<tr>
<td>Illumination control, simple, 'in table'**</td>
<td>7220747</td>
</tr>
<tr>
<td>Background illumination, swivelling</td>
<td>7220765</td>
</tr>
</tbody>
</table>
B. Legal regulations

- The illumination set LI 900 was designed taking the standards EN 60601-1, EN ISO 10939, EN 60601-1-2, and EN ISO 15004-2 into account.
- Compliance of the LI 900 illumination set with the Directive 93/42/EEC is confirmed by the CE marking.
- The EN 60601-1 standard must be observed when using different medical and/or non-medical electrical equipment in combination.
- You can request a copy of the declaration of conformity for this instrument from Haag-Streit at any time.
- The statutory accident regulations must be observed.

C. Classification

<table>
<thead>
<tr>
<th>Standard EN 60601-1</th>
<th>As equipment safety class I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating mode:</td>
<td>Continuous operation</td>
</tr>
<tr>
<td>CE directive 93/42 / EEC</td>
<td>Class I</td>
</tr>
<tr>
<td>FDA</td>
<td>Class II</td>
</tr>
</tbody>
</table>

D. Disposal

Electrical and electronic devices must be disposed of separately from household waste! This appliance was made available for sale after the 13th August 2005. For correct disposal, please contact your Haag-Streit representative. This will guarantee that no hazardous substances enter the environment and that valuable raw materials are recycled.

E. Standards

<table>
<thead>
<tr>
<th>EN 60601-1</th>
<th>EN ISO 10939</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 60601-1-2</td>
<td>EN ISO 15004-2</td>
</tr>
</tbody>
</table>
F. Information and manufacturer's declaration concerning electromagnetic compatibility (EMC)

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

WARNING!
• 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)

Guidance and manufacturer's declaration – electromagnetic emissions
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment:

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment - guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Emission of harmonics according to EN 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions according to EN 61000-3-3</td>
<td>Fulfilled</td>
<td></td>
</tr>
</tbody>
</table>
### F.3 Immunity (standard table 2)

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

**Guidance and manufacturer’s declaration – electromagnetic immunity**

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

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

NOTE: $U_m$ = the AC mains voltage prior to application of the test level.

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

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

Guidance and manufacturer’s declaration – electromagnetic immunity

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

Electromagnetic environment – guidance

Portable and mobile RF communications equipments should be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

<table>
<thead>
<tr>
<th>Immunity test standard</th>
<th>EN 60601 test level</th>
<th>Compliance level</th>
<th>Recommended distance (m):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF EN 61000-4-6</td>
<td>3 Vrms 150 kHz – 80 MHz</td>
<td>10 Vrms</td>
<td>$D = 0.35\sqrt{P}$</td>
</tr>
</tbody>
</table>
| 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 the transmitter in watts (W) according to the transmitter manufacturer and $D$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 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.

<table>
<thead>
<tr>
<th>Nominal output of the transmitter (W)</th>
<th>150 kHz – 80 MHz</th>
<th>80 MHz – 800 MHz</th>
<th>800 MHz – 2.7 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( D = 0.35 \sqrt{P} )</td>
<td>( D = 0.7 \sqrt{P} )</td>
<td>( D = 1.4 \sqrt{P} )</td>
</tr>
<tr>
<td>0.01</td>
<td>0.035</td>
<td>0.07</td>
<td>0.14</td>
</tr>
<tr>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>0.44</td>
</tr>
<tr>
<td>1</td>
<td>0.35</td>
<td>0.7</td>
<td>1.4</td>
</tr>
<tr>
<td>10</td>
<td>1.1</td>
<td>2.2</td>
<td>4.4</td>
</tr>
<tr>
<td>100</td>
<td>3.5</td>
<td>7</td>
<td>14</td>
</tr>
</tbody>
</table>

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

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

**NOTE 2:** To calculate the recommended safe distance of transmitters in the frequency range of 80 MHz to 2.7 GHz an additional factor of \( \frac{10}{3} \) 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 representative at:
http://www.haag-streit.com/contact/contact-your-distributor.html