

# INSTRUCTIONS FOR USE Slit Lamp

BQ 900®

18. Edition / 2016 – 02



**ENGLISH** 

Slit Lamp

BQ 900®

18. Edition / 2016 - 02

INSTRUCTIONS FOR USE

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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.

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## 1. Safety



#### DANGER!

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



#### WARNING!

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



#### NOTE!

Important information: please read carefully.

## 1.1 Areas of application of the device

The device is intended for use in doctor's practices, hospitals and optometrists' and opticians' premises.

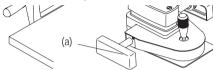
#### 1.2 Ambient conditions

Transport:	Temperature	from	-40°C	to	+70°C
	Air pressure	from	500 hPa	to	1060 hPa
	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 FN 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 and trained personnel. The owner is responsible for their training. This device may only be used in accordance with the instructions in "Purpose of use".

## 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 in accordance with EN ISO 15004-2

#### 17 Disinfection



#### NOTE!

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

## Warranty and product liability

- Haaq-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.

## **Symbols**



Read the instructions for use attentively



General warning: Read the accompanying documentation



Notes on disposal, see the 'Disposal' chapter



This appliance fulfills the European Directive 2011/65/EU (RoHS)



Year of production



Manufacturer



European certificate of Conformity



Earth (ground)



**DC** Direct current



Not protected from foreign



Serial number



HS reference number



Plug socket on RM 02 for power supply



✓ Slit lamp illumination



◆ Background illumination



Test symbol of CSA with approval for USA

## Introduction

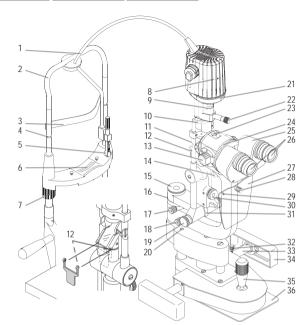
The slit lamp consists of an illumination and a binocular microscope. The instrument base can be used to move the entire device in front of the eyes. The illumination offers a large number of setting options to make the practically invisible areas in the eye visible. A wide range of accessories is available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

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#### 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. LED illumination LI 900, see separate manual
- 9. Lever for filters
- Scale for angled position of the slit image (5° increments)
- 11. Illumination mirror
- 12. Diffusor
- 13. Magnification changer
- Mounting screw for the stereo microscope
- 15. Protective cover
- 16. Illumination unit/microscope angle scale
- 17. Illumination arm locking screw
- 18. Microscope arm locking screw
- 19. Slit width setting screw
- 20. Weight compensation screws
- 21. Slit length/diaphragm scale
- 22. Setting screw for adjusting the slit length, blue filter and fixation star, handle for turning the slit
- 23. Cover screw for accessories pin
- 24. Quick-release fastener for accessories
- 25. Stereo microscope with eyepieces
- 26. Eyepieces
- 27. Breath shield
- 28. Mounting screw for breath shield

- 29. Thread for fixing (right-hand side) the tonometer AT 900 model BQ or AT 900 D model BQ
- 30. Centering screw
- 31. Inclination angle latch 0° 20°
- 32. Joy stick base locking screw
- 33. Axle
- 34. Rail cover
- 35. Control lever
- 36. 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 delivered fully assembled. The transport lock must be removed prior to commissioning. Fix the breath shield (27) in place by fastening the knurled screw (28) on the inside of the bearer arm.

## 3.2 Power supply



#### NOTE!

Observe the respective HAAG-STREIT instructions for use. (For further information, please contact your HAAG-STREIT dealer).

Dieses Gerät darf nur mit HS Gerätenetzteilen PS-LED, PS-LED HSM901 und dem Release Modul RM02 betrieben werden.

## 3.3 Instrument base with weight compensation facility

The weight of additional accessories mounted on the microscope can be compensated using counterbalance springs. This keeps the height adjustment of the slit lamp easy.

## 3.4 Setting the weight compensation facility

Turn the control lever (35) to its lowest position and then loosen it slightly a quarter turn. Turn the microscope and illumination to the side. Apply 1 – 3 springs depending on the accessory.

## 3.5 Switching on the weight compensation facility

Turn anticlockwise until the screws (20) are completely released.

## 3.6 Switching off the weight compensation facility

Turn clockwise until you meet resistance. Verify whether the microscope arm springs back downwards if you push it upwards with your hand. This will only happen if the load is already at maximum. Generally, as many counterbalance springs should be deactivated as necessary until this spring action occurs. The weight compensation facility is set correctly once the illumination and microscope with the mounted accessories weigh slightly more than the counterbalance springs.

## 3.7 Regulating the clearance of the slit width control

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



## Commissioning

The device can be switched on and off with a mains isolator on the power supply. The green lamp in the rocker switch lights up when the device is switched on.

## 4.1 Switching on the appliance

- Connect the power supply to the mains and press the rocker switch. The green lamp in the rocker switch lights up when the appliance is switched on.
- Set the knob on the illumination control to a position between '1' and '10'.

## 5. Operation

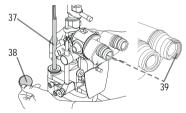
## 5.1 Setting the eyepieces



#### 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 (37) in place of the protective cover (38) and turn its black projection surface at a right angle to the microscope axis. Return the illumination and microscope to the central position (0°).

- 37. Test rod
- 38. Protective cover
- 39. Sliding occluder



- Each eyepiece should be set individually by turning the knurled ocular refraction ring with diopter scale such that the projected slit can be seen in focus. The setting is performed from the (+) to the (-) side at low magnification.
- The sliding occluders (39) are used to set the correct working distance for the examiner from the eyepiece.
- Examiners who do not wear glasses: Pull the occluders out as far as they will go.
- Examiners who do wear glasses: Push the occluders in as far as they will go.

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## 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 set so that the patient sits bent over forward.
- To ensure that only the part of the eye being examined is illuminated, the slit height should be set accordingly in order to avoid distracting streaking of light.
- 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 each use. The risk of overheating increases if a dust cover is used.

- Use the turn screw (7) to set the chin rest (6) so that the patient's eyes are at the same height as the black mark (4) on the sides of the head rest.
- Set the eyepieces (26) in accordance with the examiner's refraction by turning the knurled rings and set the eye distance.
- Adjust the height of the slit lamp by turning the control lever until the light beam is at eye level.
- Switch on the illumination by turning the switch on the power supply.
- The magnification of the stereo microscope is changed using the magnification changer (13).
- The rigid control lever (35) gently inclined towards the examiner can be used to
  push the entire device until the slit appears approximately focused on the cornea.
   This initial setting is verified with the naked eye. Fine tuning is performed by tilting
  the control lever while observing via the stereo microscope (25).
- The slit width is set left or right with the rotating knob (19), as is the angle between the stereo microscope and illumination. The slit image can be set vertically, horizontally or diagonally as required by turning the illumination facility on the handle (23) (locking points at 45°, 90° and 135°; stops at 0° and 180°; scale in 5° increments).
- To ensure that unimpeded binocular fundus examination is also possible at lateral
  angles of between 3° and 10°, a short mirror (11) is used, the illumination turned
  90° using the locking screw (23) and tilted in 5° steps using the latch (31), and
  the illumination and microscope turned to the central position (0°).
- Front-lens glasses and contact glasses are used to examine the ocular fundus.

#### Diffuse illumination:

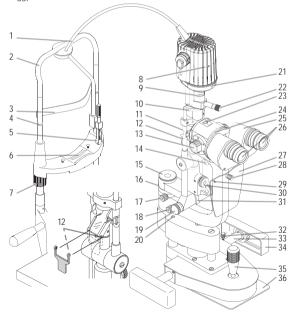
A diffuse illumination is achieved by positioning the diffusor (12) upstream. This
enables overview monitoring and can be used for taking overview images with the
Imaging Module.

#### Indirect illumination:

For observation in regredient light (indirect illumination), the centering screw (30) 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.

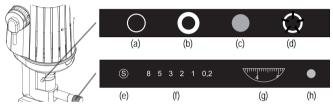
## Slit tilting:

The latch (31) 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

- a. Open
- Grey filter (10%)
- c. Red removal filter
- d. Reserve opening for filter of choice ø15 mm (0 / -0.2), thickness 2.5 mm
- Exaction star (predominantly used for fixation examination of cross-eyed children with amblyopia)
- f. Apertures of 8, 5, 3, 2, 1 and 0.2 mm ø
- g. Display of slit length adjustment from 1 to 14 mm
- h. Blue filter



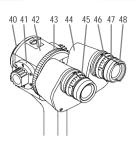
#### 5.5 Fixation star

- 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

- 40. Front lens
- 41. Rotary knob displaying the set magnification
- 42. 5-level magnification changer (Galilei system)
- 43. Knurled ring bayonet joint
- 44. Binocular tube with convergent insight, pupil distance adjustable 52 78 mm
- 45. Eyepiece 12.5x / field of vision ø 16 mm
- 46. Index (white point)
- 47. Knurled ring with diopter scale for setting the refraction of the examiner ( $\pm$  7 D)
- 48. Sliding occluder (for people who wear glasses)



## 6. 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 set 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.

## 7 Technical data

#### 7.1 Slit illumination



#### NOTE!

Detailed information regarding the radiation can be provided on request.

Slit image width	0 – 14 mm continuous
Slit image length	1 – 14 mm continuous
Illumination field circle	ø8/5/3/2/1/0.2 mm
Test mark	With fixation star
Slit image rotatability	± 90°

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Swiveling of the slit illumination to Horizontal ± 90°, vertical 0 – 20° the microscope axis

Filters Blue, red removal (green), gray (10%).

UV and thermal-protection filters are installed fixed



#### NOTE!

(Further information available in the LED illumination LI 900 instructions for use)

## Stereo microscope

13° Stereo angle: 6.3x / 10x / 16x / 25x / 40x Magnification changer: Ocular magnification: 12.5x Range of adjusting eye-pieces: +7 to -7 diopters Pupil distance: 52 - 78 mmTotal magnification: 6.3x / 10x / 16x / 25x / 40x Object field ø in mm: 32.0 / 20.0 / 12.7 / 8.0 / 5.1

## Instrument base

Single-handed operation of control lever in 3 dimensions Operation:

Adjustment of instru-100 mm (length) ment base: 100 mm (side)

30 mm (height)

#### Net weight

12.7 kg (without power supply, head rest and options)

## 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.

#### Device inspection 8.1

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 or 14 mm.
- Set Ilumination 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.

## 8.3 Cleaning

- Only clean the housing with a dry cloth.
- Do not use any liquids, alcohol or corrosive substances.
- The exposed glass surfaces can be dusted with a dusting brush. Lens brush HAAG-STREIT number 1001398



## 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 (49) when not in use.

Dust cover, small (for slit lamp) HS no. 1001395

Dust cover, large (for several instruments) HS no. 1001434



## 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.
 Only original HS replacement parts may be used.



#### NOTE!

An asterisk (\*) shows that you should contact your HAAG-STREIT dealer for further information. Two asterisks (\*\*) indicate that you should consult the separate instructions for use.

Component	HS art. no.
Locating pin	3000332
LED illumination, black without background illumination**	1020884
LED illumination with background illumination light gray RAL7035**	1021178
LED illumination, background illumination ready black RAL9005**	1020885
Illumination control double slit and background 'in table'**	1021022
Illumination control double slit and background 'on table'**	1020883
Illumination control single 'in table'**	1021024
Illumination control single 'on table'**	1021020
Split image eyepiece 12.5x	1400300
Cover T-0 for table opening**	1021085
Plug-in mirror short	1001591
Plug-in mirror long	1001590
Photo adapter DC 01 for digital cameras	1004665
Power supply for LED illumination on third-party tables**	1020882
Power supply for LED illumination HSM 901**	1020881
Imaging Module IM 900 complete (Camera Module CM03 + Release	7220550
Module RM02 + Software)	
Instrument table HSM 901	*
Instrument table HSM 901 Imaging	*
Instrument table HSM 901 Workstation	*

Cable channel without table top table channel ø 12 mm	7200086
Cable channel without table top table channel ø 20 mm	1001575
Contrast enhancer filter (yellow)	1400306
Measuring eyepiece 12.5x	1400302
Observer tube, short (without eyepiece)	1400301
Observer tube, long (without eyepiece)	1400034
Eyepiece 12.5x with diopter ring	1400303
Eyepiece 12.5x with McIntyre reticle	1400304
Eyepiece with double cross hair 12.5x	3000470
Check rod	1001051
Dust cover, large (for several instruments)	1001434
Dust cover, small (for slit lamp)	1001395
Stereo variator	7200109
Beam splitter 50/50	1400308
Beam splitter 70/30	1001600
Diffusor	1007085
Background illumination fixed**	1020886
Background illumination with swivel holder**	1020887
USB illumination cable 2000 mm**	1020940
USB illumination cable 5000 mm**	1020956
Video adapter with lens tube f56 1/3 (C-Mount)	1007780
Video adapter with lens tube f60 (3-chip, ½ inch)	1400321
Video adapter with lens tube f60 (mini camera)	1400320
Video adapter with lens tube f75 (C-mount)	1400319
Prescription glass, moving, -58.6 diopters, according to Hruby	1400223
Prescription glass carriage with rail (with guide plate)	1001219
Zoom module for slit lamp BQ 900	1400013
Connecting piece for angled view 20°	1400305

## B. Legal regulations

- The BQ 900 slit lamp was developed and designed in observance of the standards EN 60601-1, EN ISO 10939 and EN ISO 15004-2. Production, testing, setup, maintenance and repairs are performed in observance of international standards.
- The EN 60601-1 standard must be observed when using different medical and/or non-medical electrical appliances in combination.

- The CE marking confirms that the BQ 900 slit lamp is in compliance with Directive 93/42/EEC.
- The slit lamp BQ 900 fulfills the electromagnetic compatibility requirements of EN 60601-1-2. The device was designed to maintain the emission of electromagnetic interference at a certain level which does not exceed the statutory directives and does not affect other devices in its vicinity.
- The instrument also boasts the immunity stipulated by the standard.
- The statutory accident regulations must be observed.

## C. Classification

Standard EN 60601-1 BQ 900 slit lamp as per 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.



## F. Standards

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

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

## F.1 General

The BQ 900 slit lamp system fulfills the requirements on electromagnetic compatibility according to EN 60601-1-2. 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.
- Portable and mobile HF communication systems may interfere with electrical medical devices.
- The operation of other lines or equipment than those listed may lead to higher emissions or may reduce the device's resistance to interference.
- Third-party devices may only be connected in compliance with the EN 60601-1 standard.

## F.2 Emitted interference (standard table 1)

Guidance and manufacturer's declaration - electromagnetic emissions

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

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

## Immunity (standard table 2)

Guidance and manufacturer's declaration – electromagnetic immunity

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

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Immunity test standard	EN 60601 test level	Compliance level	Electromagnetic environment – guidance	
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered withs ynthetic material, the relative humidity should be at least 30%.	
Electrical fast transient / burst EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.	
Surge EN 61000-4-5	<ul><li>± 1 kV for symmetrical voltages</li><li>± 2 kV for asymmetrical voltages</li></ul>	<ul><li>± 1 kV for symmetrical voltages</li><li>± 2 kV for asymmetrical voltages</li></ul>	Mains power quality should be that of a typical commercial or hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply lines EN 61000-4-11	$ \begin{array}{l} <5\% \ \ U_{_{T}}(>95\% \ drop \ in \ U_{_{T}}) \\ for \ \% \ 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 \end{array} $	$ < 5\% \ U_{_{T}} \ (> 95\% \ drop \ in \ U_{_{T}}) $ for $1\% \ cycle$ $ < 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 char- acteristic of a typical location in a typical commercial or hos- pital environment.	
NOTE: $U_T$ = the AC mains voltage prior to application of the test level.				

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

Guidance and manufacturer's declaration - electromagnetic immunity

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

#### Electromagnetic environment – guidance

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

Immunity test standard	EN 60601 test level	Compliance level	Recommended distance <sup>(c)</sup> :
Conducted RF EN 61000-4-6	3 V <sub>rms</sub> 150 kHz – 80 MHz	10 Vrms	D = 1.2 $\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz – 2.5 GHz	00.1411 0.7.011	D = 1.2 $\sqrt{P}$ 80 MHz - 800 MHz D = 2.3 $\sqrt{P}$ 800 MHz - 2.5 GHz

Where P is the maximum output power rating of thet ransmitter in watts (W) according to the transmitter manufacturer and D is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol:



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

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

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
- c. Possible shorter distances outside the ISM bands do not contribute to improved application in this table.

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

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

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

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

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

- NOTE 1: At 80 MHz and 800 MHz the higher frequency applies.
- NOTE 2: To calculate the recommended safe distance of transmitters in the frequency range of 80 MHz to 2.5 GHz an additional factor of  $^{10}l_3$  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.

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







Reg. Nr. 11956





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