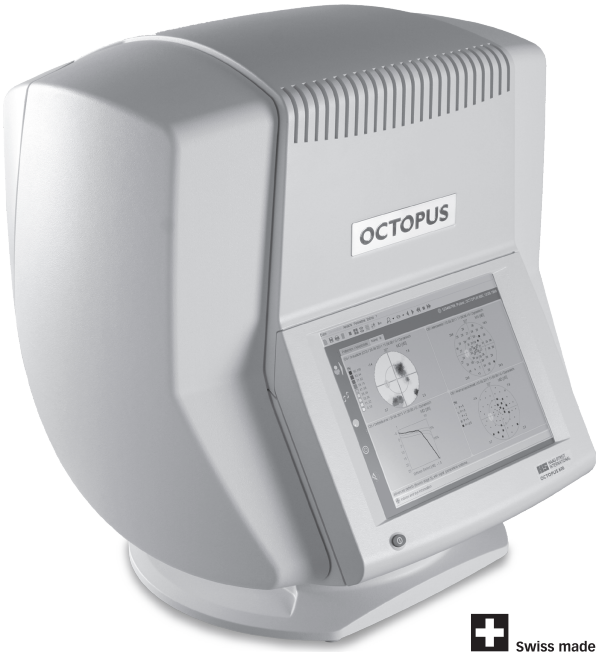

INSTRUCTIONS FOR USE
Perimeter

OCTOPUS® 600

10. Edition / 2020 – 02

HAAG-STREIT DIAGNOSTICS

INSTRUCTIONS FOR USE
Perimeter

OCTOPUS® 600

10. Edition / 2020 – 02

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 Octopus 600 perimeter is designed for the examination, analysis and documentation of the field of sight, especially the light difference sensitivity and other functions of the human eye.

Contraindication

WARNING!
Certain light stimuli with a high contrast and certain frequencies as presented in the Octopus 600 with the pulsar method can trigger episodes of photosensitive epilepsy or consciousness disturbances in isolated cases. This can also occur in patients who have not previously displayed any signs of epilepsy or similar conditions. Should the patient feel unwell during the examination or if there is any indication of a consciousness disturbance, the examination must be interrupted immediately. A standard white/white (SAP) examination can be performed as an alternative.

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.

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1. Safety

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

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

NOTE!
Important information: please read carefully.

1.1 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 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. The software may be stopped or needs to be restarted. If such unexpected disturbances of the software are observed, the cause could be a cell phone or RF telephone in the immediate vicinity to the instrument. Increase the distance to the unit, until the interference disappears.

1.2 Patient population

The patient must be capable of sitting up straight and keeping his head still. He/she must be physically and mentally able to cooperate well and is mentally capable of following the examination. Patients must be at least 6 years old.

1.3 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%

Application height < 2,000 m above sea level

1.4 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 (risk of 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.

1.5 Installation warnings

DANGER!
Never use the device in potentially explosive environments where volatile solvents (alcohol, benzine, etc.) and combustible anaesthetics are in use.

WARNING!
- Do not modify this equipment without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists.
- Any third-party device must be connected in compliance with the EN 60601-1 standard.
- Only original 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).

NOTE!
- The device must be set up in a medical room in such a way that no direct light falls on it from any side.
- The use of accessories other than than those listed may result in higher emissions or lower interference immunity of the Octopus 600.
- The software must be installed by trained personnel.

1.6 Operation and environment

WARNING!
- To avoid the risk of suffering an electric shock, this device may only be connected up to the mains with a ground connection.
- The plug, cable and ground connection of the socket must be functioning perfectly.
- Make sure that the appliance is only connected to power supplies as defined on the type plate. The appliance must be disconnected from the mains by pulling out the plug before any maintenance and cleaning work is performed.
- Computers and further ancillary devices (printers, etc.) must comply with the EN 60601-1 standard or be connected through galvanic isolation to external networks (safety isolating transformer).
- The doctor or the operator is obliged to inform the patient about the safety instructions concerning him and to ensure that these instructions are complied with.
- The examination of the patient, the use of the device and the interpretation of the results may only be conducted by trained and experienced individuals.
- Turning off the eye monitoring functions is not recommended. In all other cases, the user must monitor the eye personally during the examination.
- All users must be appropriately trained and familiarised with the contents of the instructions for use, especially in regard to the safety information contained therein.

NOTE!
- This appliance must only be operated by qualified and trained personnel. The owner is responsible for their training.
- This appliance may only be used for the purpose described in these instructions for use.
- Keep these instructions for use in a place where they are accessible to those working with the device at all times. Warranty claims can only be made if the instructions in these instructions for use are complied with.
- Always remove the dust cover before switching the appliance on. The device may otherwise become damaged due to overheating. Likewise, make sure that the appliance is switched off before attaching the dust cover.
- Only original spare parts and original accessories may be used for repairs. The use of accessories other than than those listed may result in higher emissions or lower interference immunity of the Octopus 600.
- Turn the device off if it will not be used for an extended period of time.
- Do not expose the device to direct sunlight.
- Protect the device with the dust cover when not in use.

1.7 Disinfection

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

1.8 Warranty and product liability

- Haag-Streit products must be used only for the purposes and in the manner described in the documents distributed with the product.
- The product must be treated as described in the ‘Safety’ chapter. Improper handling can damage the product. This would void all guarantee claims.
- Continued use of a product damaged by incorrect handling may lead to personal injury. In such a case, the manufacturer will not accept any liability.
- Haag-Streit does not grant any warranties, either expressed or implied, including implied warranties of merchantability or fitness for a particular use.
- Haag-Streit expressly disclaims liability for incidental or consequential damage resulting from the use of the product.
- This product is covered by a limited warranty granted by your seller.

For USA only:
- This product is covered by a limited warranty, which may be reviewed at www.haag-streit-usa.com.

1.9 Description of symbols

Follow instruction for use	Read the instructions for use attentively
General warning: Read the accompanying documentation	Type B applied part
Notes on disposal, see the 'Disposal' chapter	Protective earth (ground)
European certificate of conformity	Manufacturer
Date of manufacture	Serial number
HS reference number	MET Listed Mark with approval for USA and Canada
Testsymbol of TÜV Rheinland with approval for INMETRO Brasil	ETL Listed Mark with approval for USA and Canada

2. Introduction

2.1 Device description

- The Octopus 600 is a screen perimeter for examining the central field of sight (30°). The device can be employed autonomously, i.e., the examination and control components are integrated in the device.
- Integrated, automatic fixation monitoring increases the reliability of the examination results.
- The Octopus 600 is employed by clinical users and for research purposes.

2.2 System components

The Octopus 600 comprises the following components:

- Octopus 600
- Patient response button (Type B application part)
- Keyboard/mouse (optional)

2.3 Device overview

Overview of patient side

1. Upper part of housing
2. Right shell
3. Capacitive button for operating the forehead rest
4. Left shell
5. Forehead rest with integrated sensor for detecting the head position
6. Infrared eye illumination
7. Near correction lens +3.25 dpt
8. Patient-side cover
9. Corrective lenses
10. Corrective lens compartment
11. Automatically closing cover
12. Patient response button
13. Patient response button connection

Overview of user side

14. User interface with touch screen
15. Power on/off button

2.4 User interface (14)

- A high-contrast display allows operation of the Octopus 600 at a large angle of view.
- The user interface is optimised for use on a touch screen and guarantees rapid and reliable operation of the device.
- The high resolution of the display allows the accurate reproduction of examination results.

Keyboard/mouse (optional)

- If required, a keyboard and a mouse can be connected via a USB port for control purposes.
- We recommend choosing a wireless connection.

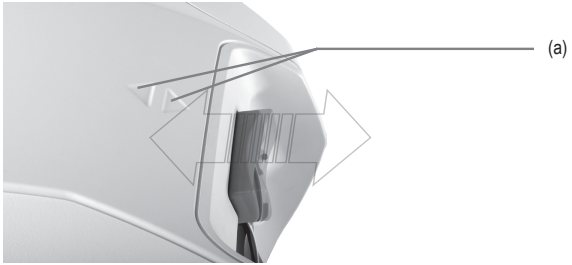
2.5 Housing

- The optical components and electronics are protected from light and soiling by housing covers.
- For servicing, see Section 'Maintenance'.

WARNING!
Always disconnect the appliance from the mains power supply by pulling out the mains cable before opening the appliance. Housing components may be removed only by correspondingly trained and authorised skilled personnel.

2.6 Forehead rest

A wide, ergonomically designed forehead rest (5) allows the patient to maintain a comfortable posture during the examination. The forehead rest can be moved forwards and backwards by pressing the triangular buttons (a).



2.7 Chin rest (optional)

The optional chin rest can be used to stabilize the patient. The height can be freely adjusted using the rotating knobs on the side.

2.8 Near correction lens

The near correction lenses (7) integrated in the device also make it possible to accommodate older patients on the examination screen.

2.9 Patient-side cover

The cover on the patient side (8) can be equipped with two corrective lenses. The magnetic holder on the corrective lenses allows simple, quick positioning.

2.10 Corrective lenses

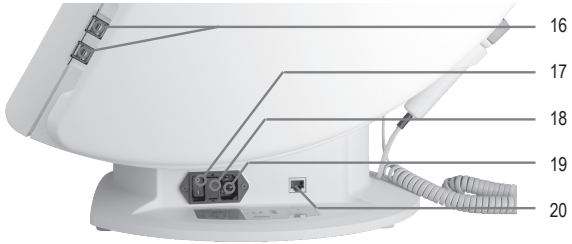
Patients' ametropia can be corrected with the supplied corrective lenses. A corrective lens set is composed of 12 spherical corrective lenses (9) from –8 dpt to +4 dpt.

NOTE!

- In cases of cylindrical ametropia > 1 dpt, we recommend that patients wear their own glasses or contact lenses for the examination insofar as this is possible and the field of sight is not restricted.
- To protect the lenses from soiling and damage, they should be put back in the compartment provided for right after use.

2.11 Connections

16. 2 × USB 3.0 connection (top), 2 × USB 2.0 connection (bottom)
17. Mains switch
18. Fuse holder with two fuses 3.15 AH / 250 V
19. Mains connection
20. Ethernet port



2.11.1 USB ports

There are a total of 4 USB ports (16) available. They can be used to connect USB components such as keyboards, mice, USB sticks, USB hard disks or printers.

WARNING!
This connection is not galvanically isolated. Devices such as printers can only be connected via USB if they are equipped with a safety isolating transformer as per EN 60601-1 or operated with a medically approved power supply.

2.11.2 Mains connection

The power cable must correspond to the nationally applicable safety requirements.

2.11.3 Ethernet port

There is an Ethernet port on the side of the device. Always use a shielded cable of category 5e permitting transmissions of up to 1 GHz without interference. This Ethernet port is electrically isolated and has a dielectric strength of 4 kV according to EN 60601-1.

2.12 LED background lighting

In the Octopus 600, LEDs are used as light sources for the periphery and stimulus. The light intensity of the background lighting is measured with two independent light sensors and adjusted to the preset nominal values each time the perimeter is switched on. These nominal values are defined in the factory by Haag-Streit. The LED background lighting of the examination display is set via an adjustable power source. The intensity of the display can also be varied via grey stages.

2.13 Fixation control

The examined eye of the patient is illuminated with infrared LEDs (6), photographed by a CMOS camera and displayed on the user monitor. The built-in automatic fixation control function increases the reliability of the examination results. Precise positioning of the examined eye is performed by motorised fine adjustment of the forehead rest (5).

2.14 Examination data

The examination data are stored on the integrated solid-state drive (SSD) or in an external database via the Ethernet port. It is also possible to export the examination data to a USB storage device via a USB port.

3. Appliance assembly / installation

3.1 Transporting the appliance

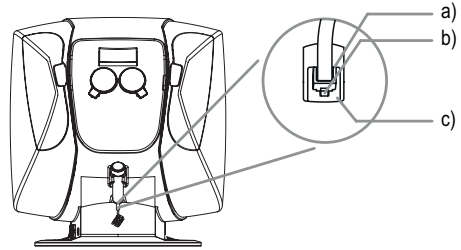
- Transport the appliance over larger distances in its original packaging.
- For short distances, grasp the device with two hands holding the side shells on the left and right and lift it.
- Unplug the power source before moving the device.

3.2 Connecting the patient response button

The connection socket for the patient response button is below the holder. The retaining bar on the connection plug is oriented towards the patient side.

DANGER!
Apart from the patient response button, no other cables may be connected to the RJ12 socket

- Push the connection plug (a) into the connection socket (c) until you hear the retaining bar click into place.
- To remove the patient response button, press the retaining catch (b) towards the plug (a) and pull the cable away downwards.



3.3 Connecting the electric power supply cable

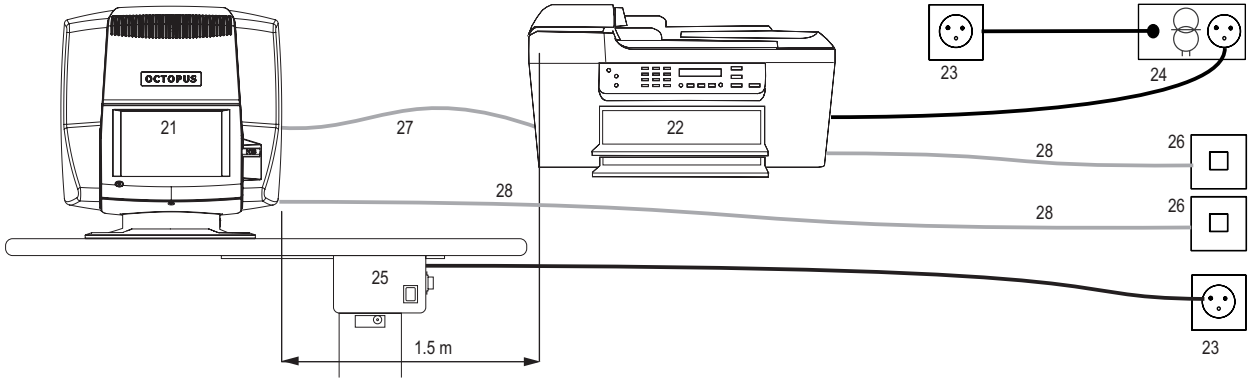
- The power unit for the Octopus 600 is designed for the voltages specified on the type plate.

4. Safe system configuration in accordance with EN 60601

4.1 System versions, Octopus 600 with printer

WARNING!
Printers connected via the USB port (27) must be connected to a safety isolating transformer as shown in the diagram below, in accordance with EN 60601-1.

NOTE!
For version II: If the distance from the Octopus 600 (21) to the printer (22) is larger than 1.5.m, the safety isolating transformer (24) may be dispensed with as shown in the diagram below, in accordance with EN 60601-1.



Version I: Printer connected via USB port (27)
Version II: Printer connected via Ethernet port (28)

21. Octopus 600
22. Printer
23. Mains connection
24. Safety isolating transformer
25. Support stand
26. LAN connection
27. Printer connection via USB port.
28. Printer connection via Ethernet port. This Ethernet port is electrically isolated in the Octopus 600 and has a dielectric strength of 4 kV according to EN 60601-1.

5. Commissioning

5.1 Switching on the appliance

Before connecting the Octopus 600 to a suitable power socket, it must be ensured that the mains switch (0/I) (17) is set to OFF (0). The mains switch is on the right of the base of the device viewed from the user's side. Then set the mains switch (0/I) to ON (I). The device is now in standby mode. The device can be switched on with the Power On/Off button (15). The operating system and then the application are started automatically. The device is ready for use after approximately one minute.

5.2 Switching off the appliance

Once the Power On/Off button (15) is pressed, a confirmation prompt appears. As an alternative to the Power On/Off button, the device can also be switched off via the software menu [File] - [Exit]. After approximately 15 seconds, the LED display on the Power On/Off button goes out and the device enters standby mode.

WARNING!
To avoid losing data, always switch the device off with the Power On/Off button (15) first and then the mains switch.
The Power On/Off button does not disconnect the device from the power supply. When servicing, always use the mains switch (17) and disconnect the device from the power supply.

NOTE!
If the mains switch is still switched on, the device is in standby mode and consumes little power.

6. Operation

6.1 Setting up the patient

- The corrective lenses are selected so that the patient sees the fixation mark on the examination screen clearly. The patient's glasses can be used as an aid for this.

- The patient sits comfortably in front of the device and places his forehead on the forehead rest. The forehead rest (and optional chin rest) can be set to the correct position. The user chooses the eye to be examined (OS or OD). Then the video image for fixation control appears. This is equipped with a rectangle which defines the relevant area of the pupil position.

7. Software / Help menu / Error messages

The software's help section contains instructions and help for performing an examination and descriptions of the error messages. The help can be opened via the F1 key or in the [?] - [Help] menu.

WARNING!
The software must be installed by trained personnel in accordance with separate installation instructions. It is strongly recommended to make a backup before running a software update.

8. Technical data

8.1 Octopus 600

Type designation	Octopus 600
Mains voltage:	100 – 240 VAC
Power consumption:	100 VA
Power consumption in standby:	3W
Operating frequency:	50 / 60 Hz
Fuses:	2 × T 3.15 AH 250 V
Functional principle:	Binocular screen perimeter
Examination principle:	Subjective test using bracketing procedure
Patient positioning:	Adjustable forehead rest
Fixation control:	Permanent video-based fixation control
Eccentricity:	30°
Dynamic range:	0 – 35 dB / src
Stimulus intensity:	0.015 – 150 cd/m²
Stimulus colour:	White
USB port:	USB 2.0 / USB 3.0 - standard
Ethernet port:	1000 Base-T (1Gbit)
Internal memory SSD:	32 GByte

8.2 Infrared illumination

Light source:	LED
Wavelength:	940 nm
Angle of radiation:	±22°

8.3 Dimensions

Dimensions (W × D × H):	467 × 508 × 500 mm
Weight:	12.7 kg
Shipping dimensions (W × D × H):	600 × 800 × 1030 mm
Shipping weight:	26 kg

8.4 Field of sight

On the screen of the Octopus 600 it is possible to examine up to the following eccentricity:

- Monocular field of sight horizontally 30°
- Monocular field of sight vertically 27°

9. Maintenance

WARNING!
- Housing parts may be removed and repairs performed only by appropriately trained and authorised skilled personnel. Incorrect repairs can pose considerable risks for operating staff and patients.
- The Power On/Off button (15) does not disconnect the device from the power supply. When servicing, always use the mains switch (17) and disconnect the device from the power supply by pulling out the plug.
- If components have to be replaced, only original spare parts from Haag-Streit or its representative may be installed.

9.1 Repairs

To ensure long-term safe and error-free functioning, we recommend having an authorised professional check the Octopus 600 every two years. Further information and the corresponding technical documentation for this are available from Haag-Streit or your local representative.

NOTE!
Calibration of the device will only be carried out by the manufacturer.

9.2 Cleaning

Occasional dusting with a soft cloth is sufficient. Stubborn dirt particles can be removed with a soft cloth dampened with water or alcohol. Fingerprints and dust on the user screen can be removed using a soft, moist cloth.

NOTE!
Do not allow the appliance to become wet and do not use solvents or abrasive cleaning products under any circumstances.

A dust cover is delivered with the Octopus 600 as an accessory. Cover the appliance when the room is being cleaned or if it is not used for longer periods.

NOTE!
The appliance must not be switched on when covered (heat build-up, fire hazard).

9.3 Applied parts

Applied parts such as the eye patch, patient response button and forehead and chin rest (optional) as well as other parts such as the corrective lenses and the patient-side cover are made of easy-to-clean plastics.

NOTE!
- These applied parts should be disinfected prior to every examination (e.g., with 70% isopropyl alcohol) in order to comply with general hygiene requirements and prevent the transmission of infections..
- The corrective lenses can also be cleaned in an ultrasound bath.

A. Appendix

A.1 Accessories / consumables / spare parts / upgrade

Component	Type	*REF*	Note
Chin rest	-	*7220636*	1x
Instrument table	HSM 600	*7220625* *7220626* *7220627* *7220628*	230 V 110 V 230 V LAN 110 V LAN See separate IFU*:
Corrective lens set	RL basic set	*1806170*	Set comprising 12 corrective lens
Corrective lens	+4 dpt	*1806184S*	1x
Corrective lens	+3 dpt	*1806183S*	1x
Corrective lens	+2 dpt	*1806182S*	1x
Corrective lens	+1 dpt	*1806181S*	1x
Corrective lens	-1 dpt	*1806191S*	1x
Corrective lens	-2 dpt	*1806192S*	1x
Corrective lens	-3 dpt	*1806193S*	1x
Corrective lens	-4 dpt	*1806194S*	1x
Corrective lens	-5 dpt	*1806195S*	1x
Corrective lens	-6 dpt	*1806196S*	1x
Corrective lens	-7 dpt	*1806197S*	1x
Corrective lens	-8 dpt	*1806198S*	1x
Patient response button	Octopus 600	*1806150*	1x
Dust cover		1802304	1x
Eye patch set		1802349	2x / set

*IFU = Instructions for use

B. Legal regulations

- Haag-Streit maintains a quality management system in accordance with EN ISO 13485. The device was developed and designed in accordance with all the standards listed in section 'EMC'.
- The Octopus 600 is a Class IIa device in accordance with Appendix IX of Directive 93/42/EEC. By affixing the CE mark we confirm that our device complies with the applicable standards and directives.
- You can request a copy of the declaration of conformity for the appliance from Haag-Streit at any time.
- This appliance fulfils the European Directive 2011/65/EC.

C. Classification

Standard EN 60601-1	Perimeter Octopus 600 acc. to protection class I
Applied part:	Type B
Operating mode:	Continuous operation
CE Directive 93/42/EEC	Class IIa
Standard EN 62471	Exempt group
Standard EN ISO 15004-2	Group 1

D. Disposal

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

E. Standards

EN 60601-1	ISO 9022
EN 60601-1-2	EN ISO 10993
EN ISO 15004-1, -2	EN 1041
EN ISO 12866	EN 15223-1
EN 62471	

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

F.1 General

The Octopus 600 fulfils 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.

WARNING!
Avoid damages due to high electrostatic discharges (ESD). Electrostatic discharges with voltages exceeding 6 kV to USB ports may influence the instrument.
- The firmware of the instrument may be disturbed. This requires a software restart and a repetition of the investigation.
- Furthermore it cannot be excluded that ESD with higher voltages may destroy internal electronic components of the instrument.

F.2 Emission (Standard table 1)

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

Guidance and manufacturer's declaration – electromagnetic emissions		
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Emission of harmonics according to EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to EN 61000-3-3	Fulfilled	

F.3 Immunity (Standard table 2)

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

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

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

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

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

Electromagnetic environment – guidance

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

Immunity test standard	EN 60601 test level	Compliance level	Recommended distance[c]:
Conducted RF EN 61000-4-6	3 V_{rms} 150 kHz – 80 MHz	3 V_{rms}	$D = 1.2\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz – 2.7 GHz	5 V/m 80 MHz – 2.7 GHz	$D = 0.7\sqrt{P}$ 80 MHz – 800 MHz $D = 1.4\sqrt{P}$ 800 MHz – 2.7 GHz

Where ***P*** is the maximum output power rating of the transmitter in watts **(W)** according to the transmitter manufacturer and ***D*** is the recommended separation distance in meters **(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_{eff}.
c. Possible shorter distances outside the ISM bands do not contribute to improved application in this table.

F.5 Recommended safe distances for non-life-support devices (Standard table 6)

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

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

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

	Safe distance according to transmission frequency (m)		
Nominal output of the transmitter (W)	150 kHz – 80 MHz $D = 1.2\sqrt{P}$	80 MHz – 800 MHz $D = 0.7\sqrt{P}$	800 MHz – 2.5 GHz $D = 1.4\sqrt{P}$
0.01	0.1	0.07	0.1
0.1	0.4	0.2	0.4
1	1.2	0.7	1.4
10	3.8	2.2	4.4
100	12	7	14

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

NOTE 1:	At 80 MHz and 800 MHz the higher frequency applies.
NOTE 2:	To calculate the recommended safe distance of transmitters in the frequency range of 80 MHz to 2.5 GHz an additional factor of $^{10}/_{3}$ was used to reduce the probability of a mobile/portable communication device causing interference if inadvertently brought into the patient area.
NOTE 3:	These guidelines may not apply in all situations. Electromagnetic wave propagation is influenced by absorption and reflection of buildings, objects and people.

For further questions please contact your Haag-Streit representative at:

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