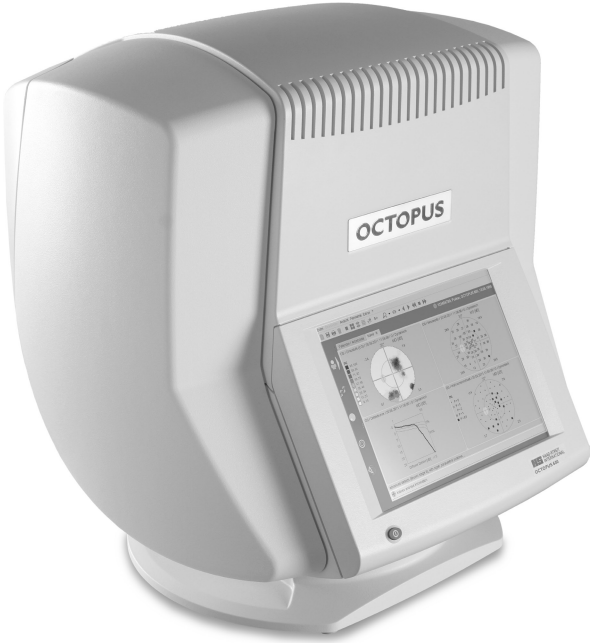


Swiss made

INSTRUCTIONS FOR USE
Perimeter

OCTOPUS® 600

11. Edition / 2022 – 10

HAAG-STREIT DIAGNOSTICS

INSTRUCTIONS FOR USE
Perimeter

OCTOPUS® 600

11. Edition / 2022 – 10

Preface

Thank you for choosing a Haag-Streit device. Provided you comply carefully with the regulations in these instructions for use, we can guarantee reliable and trouble-free use of our product.

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

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

Contents

1 Safety

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

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

NOTE!
Important information, please read carefully.

1.1 Comments on these instructions for use

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

1.2 Ambient conditions

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

1.3 Shipment and unpacking

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

1.4 Installation warnings

WARNING!
- Do not modify this device without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists.
- Any third-party device must be connected in compliance with the EN 60601-1 standard.
- Only original Haag-Streit spare parts may be used.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Grounding reliability can only be achieved when unit is connected to a hospital grade receptacle. (Not valid for EU countries).

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.

1.5 Operation, environment

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

WARNING!

- 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.
- 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 device is only connected to power supplies as defined on the type plate. The device must be disconnected from the mains by pulling out the plug before any maintenance and cleaning/ disinfecting 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, galvanic Ethernet isolator, etc.)
- 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 with regard to the safety instructions contained therein.
- This device must not be operated near of high frequency surgical equipment and the radio frequency shielded room of a medical electrical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by Haag-Streit. Otherwise, degradation of the performance of this device could result.
- If unexpected disturbances of the software are observed – the software may be stopped or needs to be restarted – the cause could be a cell phone or radio frequency telephone in the immediate vicinity to the device. Increase the distance to the device until the interference disappears.

NOTE!

- This device must only be operated by qualified personnel. The owner is responsible for their training.
- This device may only be used in accordance with the instructions in the 'Intended purpose / intended use' chapter.
- Keep these instructions for use in a place where they are accessible at all times to those working with the device. Warranty claims can only be made if the instructions for use have been complied with.
- Always remove the dust cover before switching the device on. The device may otherwise become damaged due to overheating. Likewise, make sure that the device 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 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.

1.6 Disinfection

NOTE!
The applied parts of the device should be disinfected prior to every examination with a new patient. For more information, please refer to the 'Maintenance' chapter.

1.7 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 damaged product 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.

1.8 Reporting obligation

NOTE!
Any serious incident that has occurred in relation to the device must be reported to Haag-Streit and the competent authority of the Member State in your country.

1.9 Description of symbols

	Follow instruction for use		Read the instructions for use attentively
	General warning, read the accompanying documentation		European certificate of conformity
	Date of manufacture		Manufacturer
	Haag-Streit reference number		Serial number
	Trademark of the manufacturer Haag-Streit AG		Notes on disposal, see the 'Disposal' chapter
	Listed European Authorized Representative		Medical Device
	Testsymbol of TÜV Rheinland with approval for INMETRO Brasil		MET Listed Mark with approval for USA and Canada
	Type B applied part		Protective earth (ground)

2 Intended purpose / intended 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.

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.

2.1.1 Intended users

Users are qualified medical professionals such as ophthalmologists, optometrists, opticians, nurses and researchers or other qualified specialists as permitted by local legislation. The interpretation of measurement data is restricted to professionals with the appropriate educational background as permitted by local legislation.

2.2 Medical purpose

This device has the following medical purposes:

- Diagnosis and monitoring of pathologies affecting the visual pathways
- Diagnosis and monitoring of visual field losses
- Investigation of the physiological state of the visual pathway

2.2.1 Indications

The use of this device's standard perimetry feature is indicated for the following medical conditions:

1. Localisation of pathology affecting the afferent visual pathways
    - Anterior segment pathology
    - Retinal pathology
    - Optic nerve pathology
    - Chiasmal pathology
    - Retrochiasmal pathology
2. Quantitation of pathological involvement

2.2.2 Part of the body

This device is intended for the examination of the visual field of the human eye.

2.2.3 Patient population

This device is intended for use on human patients with the physical ability to sit in front of a perimetry device with their head resting against the headrest in a steady position and the mental ability to follow instructions. Patients must be at least 6 years old.

2.2.3.1 Contraindications

There are no known contraindications to perimetry. However, it should be noted that the testing procedure is lengthy and arduous to the patient.

2.3 Principles of operation

Perimetry, in general, presents the patients with visual clues of varying intensity at different locations in their visual fields and examines the patients response (or lack thereof). Following methods have been implemented:

Static Perimetry

The patient sits at the device facing the projection screen, fixating onto a target in the middle of the screen. Dots of light are projected onto the screen. If the patient registers them he may register this by pressing a button. If the patient fails to register a cue, the same cue appears again in a higher light intensity. Should the patient not see the cue again, this is noted by the device and the program continues at a different location.

Pulsar

Pulsar is a flicker contrast test used for glaucoma detection. The stimulus consists of two images, the phase and counterphase images that alternate with a frequency of 10 Hz over 500 ms. When flicker-sensitivity is reduced, the phase and counterphase images result in an overlapped image that is no longer visible. The Pulsar method tests flicker and contrast sensitivity that are affected in glaucoma.

2.3.1 Operating environment

This device is intended to be used in professional health care facilities such as hospitals, physician's, optometrist's and optician's practices. For optimal use of the device, the ambient lighting should be attenuated. The headrest and the patient response button should be disinfected between patients.

2.4 Clinical benefit

The clinical benefits of perimetry are the detection of functional losses caused by pathologies of the visual pathways; differential diagnostic purposes for identification and localisation of a visual deficits; monitoring of acute and chronic disease processes; and evaluation the efficacy of treatments in order to preserve the patient's visual function.

The clinical benefits of the product outweigh the remaining residual risks to the patient.

3 Introduction

3.1 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.

3.2 System components

- The Octopus 600 comprises the following components:
- Octopus 600
- Patient response button (Type B application part)
- Keyboard/mouse (optional)

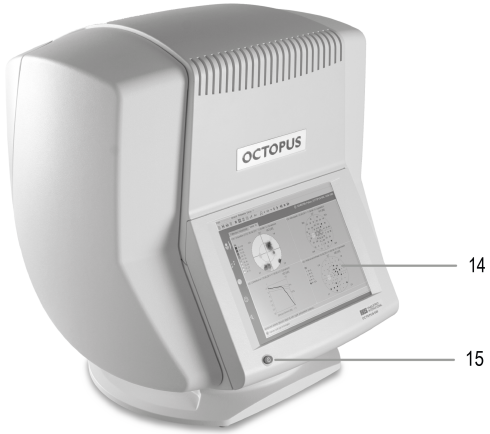
3.3 Device overview

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



3.4 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.

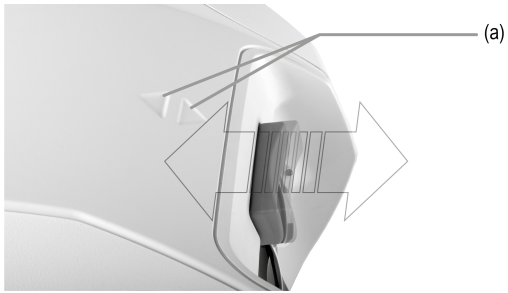
3.5 Housing

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

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

3.6 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).



3.7 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.

3.8 Near correction lens

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

3.9 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.

3.10 Corrective lenses

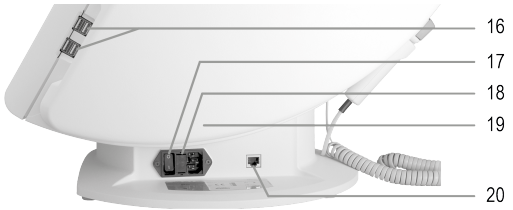
Patients' ametropia can be corrected with the supplied corrective lenses. A corrective lens set is composed of 12 spherical corrective lenses (9) from –8 dpt to +4 dpt.

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.

3.11 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



3.11.1 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.

3.11.2 Mains connection

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

3.11.3 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.

3.12 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.

3.13 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).

3.14 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.

4 Device assembly / installation

4.1 Transporting the device

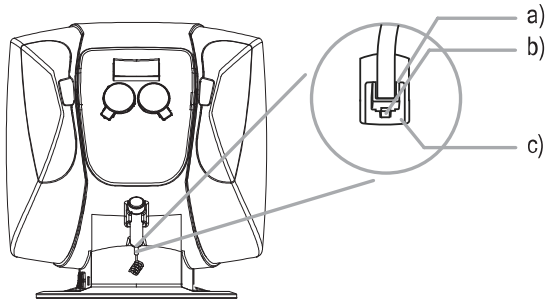
- Transport the device over larger distances in its original packaging.
- For short distances, grasp the device with two hands holding the side shells on the left and right and lift it.
- Unplug the power source before moving the device.

4.2 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.



4.3 Connecting the electric power supply cable

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

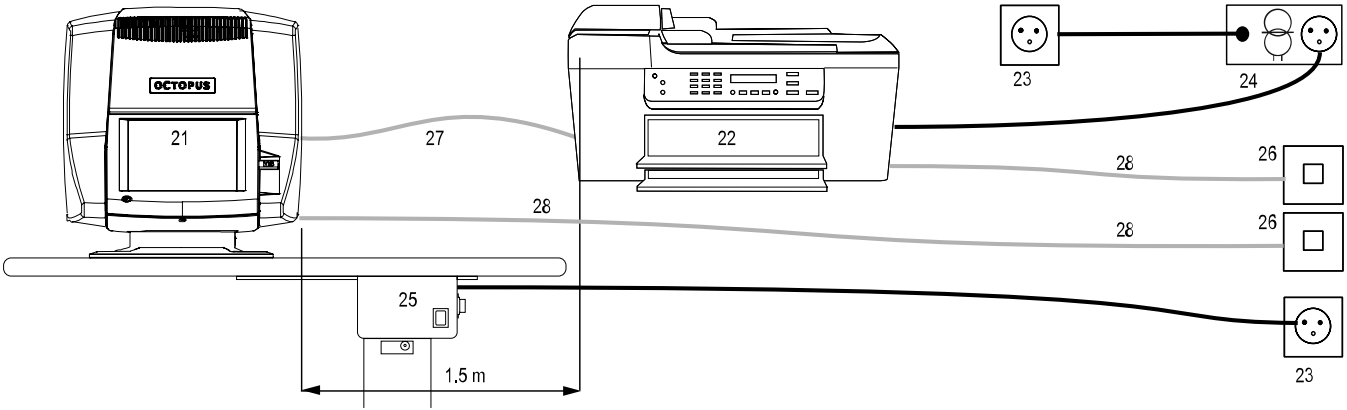
5 Safe system configuration in accordance with EN 60601

5.1 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.

6 Commissioning

6.1 Switching on the device

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.

6.2 Switching off the device

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.

7 Operation

7.1 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.

8 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.

9 Technical data

9.1 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

9.2 Infrared illumination

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

9.3 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

9.4 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°

10 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.

10.1 Repairs

To ensure long-term safe and error-free functioning, we recommend having an authorised professional check the device 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.

10.2 Cleaning and disinfection

WARNING!

- Before carrying out cleaning and disinfection work, the device must always be disconnected from the mains by pulling out the plug.
- The efficacy of the disinfectants are determined by the disinfection manufacturers.
- The efficacy of the disinfectants mentioned was not tested on their correct disinfection effect on the applied parts.
- The efficacy of the disinfectants must be validated by means of the user's disinfection process.
- Comply with the stipulated exposure time.
- Observe the manufacturer's safety instructions.
- Too strong or aggressive disinfectants or cleaning liquids e.g. hydrogen peroxide will damage the finish and coating of the device.
- Do not use sprays.
- Do not use any towels that drip.
- Wring out any soaked towels before use when necessary.
- Ensure that no liquid penetrates the device.

10.2.1 Device in general

Regular dusting of the device is sufficient. More stubborn dirt can be removed using a cleaning towel dampened with water or alcohol at maximum 70%. The cleaning intervals for cleaning the complete device shall be performed within reasonable time (e.g. once a week).

10.2.2 Touch screen

Fingerprints and dust on the touch screen can be removed using a display towel.

10.2.3 Applied parts

NOTE!
In order to comply with general hygiene requirements and to prevent the transmission of infections, the applied parts should be disinfected prior to every examination with a new patient.

- Forehead rest and optional chin rest
- Patient response button
- Eye patch
- Corrective lenses
- Patient side cover

10.2.4 Tools

Use the following tools for cleaning and disinfection operations:

- Cleaning/disinfecting towel: Commercially available soft and lint-free cleaning towel
- Display towel: Commercially available wipes for cleaning screens
- Cleaning/disinfecting liquid: Use e.g. 70% isopropyl alcohol, or ready-for-use disposable 70% ethanol disinfectant wipes. Surface-friendly disinfectants (containing aldehyde or aldehyde-free) are also permitted, such as Kohrsolin FF.

NOTE!
The corrective lenses can also be cleaned in an ultrasound bath.

10.3 Dust cover

A dust cover is delivered with the device. Cover the device when the room is being cleaned or if it is not used for longer periods of time. Always remove the dust cover before switching on the power.

WARNING!
The device must not be switched on when covered (Heat build-up, fire hazard).

11 Appendix

11.1 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 VLAN 110 VLAN
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

* See separate instructions for use

11.2 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 chapter 'Observed standards'.
- This is a Class IIa device in accordance with Appendix Appendix VIII of EU 2017/745 (Medical Device Regulation). 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 this device from Haag-Streit at any time.
- This device fulfils the European Directive 2011/65/EC.

11.3 Classification

Standard EN 60601-1	Protection class I
Applied part	Type B
Operating mode	Continuous operation
EU 2017/745 (Medical Device Regulation)	Class IIa
Standard EN 62471	Exempt group
Standard EN ISO 15004-2	Group 1

11.4 Disposal

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

11.5 Observed 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	

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

11.6.1 General

This device fulfills the requirements on electromagnetic compatibility according to IEC 60601-1-2:2014 (4th Edition). The device is built so that the generation and emission of electromagnetic interference is limited to the extent that other devices are not disturbed in their use in accordance with the regulations and so that the device itself is suitably immune to electromagnetic interference.

WARNING!

- Electrical medical devices and systems are subject to special EMC measures and must be installed in accordance with the EMC instructions contained in this accompanying document.
- Use of accessories, transducers and cables other than those specified or provided by Haag-Streit could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

- Third-party devices may only be connected in compliance with the IEC 60601-1 standard.

WARNING!

Avoid damages due to high electrostatic discharges (ESD). Electrostatic discharges with voltages exceeding 6 kV to USB ports may influence the device.

- The firmware of the device 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 device.

11.6.2 Emitted interference

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

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	P_{st} = 1.0 P_{lt} = 0.65	

P_{st}: Power short term flicker

P_{lt}: Power long term flicker

11.6.3 Electromagnetic immunity environment tested (part 1)

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV, 100kHz for power supply lines * ± 1 kV, 100 kHz for input/output lines *	± 2 kV, 100kHz for power supply lines * ± 0.5, ± 1 kV, 100 kHz for input/output lines *	Mains power quality should be that of a typical commercial or hospital environment. * Not applicable for DC and I/O if cable < 3 m.
Surge IEC 61000-4-5	± 0.5, ± 1 kV line(s) to line(s) * ± 0.5, ± 1, ± 2 kV line(s) to earth *	± 1 kV line(s) to line(s) * ± 0.5, ± 1, ± 2 kV line(s) to earth *	Mains power quality should be that of a typical commercial or hospital environment. * Not applicable for DC and I/O if cable < 3 m.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T: 1 cycle at 0° 0% U_T: 250/300 cycles at 0° 70% U_T: 25/30 cycles at 0°	0% U_T: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T: 1 cycle at 0° 0% U_T: 250/300 cycles at 0° 70% U_T: 25/30 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or battery. U_T is the a.c. mains voltage (100 – 240 V) prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

11.6.4 Electromagnetic immunity environment tested (part 2)

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

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz – 80 MHz outside ISM bands and radio amateur band * 6 V_{rms} 150 kHz – 80 MHz in ISM bands and radio amateur band *	3 V_{rms} 150 kHz – 80 MHz outside ISM bands and radio amateur band * 6 V_{rms} 150 kHz – 80 MHz in ISM bands and radio amateur band *	If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this product. Minimum separation distance shall be calculated by following equation: $E = \frac{6}{d}\sqrt{P}$ E is the immunity test level in [V/m] d is the minimum separation in [m] P is the maximum power in [W] **RF wireless equipment maximum output power and separation distance tested (at 30 cm):** TETRA 400: max 1.8 W GMRS 460, FRS 460: max 2 W LTE Band 13 and 17: max 0.2 W GSM 800/900: max 2 W TETRA 800: max 2 W iDEN 820: max 2 W CDMA 850: max 2 W LTE Band 5: max 2 W
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM 1 kHz	5 V/m 80 MHz – 2.7 GHz 80% AM 1 kHz	
Proximity field from RF wireless communication equipment IEC 61000-4-3	27 V/m 380 – 390 MHz 50% PM 18 Hz 28 V/m 430 – 470 MHz FM ± 5 kHz deviation, 1kHz sine 9 V/m 704 – 787 MHz 50% PM 217 Hz 28 V/m 800 – 960 MHz 50% PM 18 Hz 28 V/m 1700 – 1990 MHz 50% PM 217 Hz	27 V/m 380 – 390 MHz 50% PM 18 Hz 28 V/m 430 – 470 MHz FM ± 5 kHz deviation, 1kHz sine 9 V/m 704 – 787 MHz 50% PM 217 Hz 28 V/m 800 – 960 MHz 50% PM 18 Hz 28 V/m 1700 – 1990 MHz 50% PM 217 Hz	

28 V/m 2400 – 2570 MHz 50% PM 217 Hz 9 V/m 5100 – 5800 MHz 50% PM 217 Hz	28 V/m 2400 – 2570 MHz 50% PM 217 Hz 9 V/m 5100 – 5800 MHz 50% PM 217 Hz	GSM 1800/1900: max 2 W CDMA 1900: max 2 W DECT: max 2 W LTE Band 1, 3, 4, 25: max 2 W UMTS: max 2 W Bluethooth: max 2 W WLAN 802.11b/g/n: max 2 W RFID 2450: max 2 W LTE Band 7: max 2 W WLAN 802.11 a/n: max 0.2 W

Interference may occur in the vicinity of equipment marked with the following symbol:

***** The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are: 6.765 – 6.795 MHz, 13.553 – 13.567 MHz, 26.957 – 27.283 MHz, 40.66 – 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are: 1.8 MHz – 2 MHz, 3.5 – 4.0 MHz, 5.3 – 5.4 MHz, 7 – 7.3 MHz, 10.1 – 10.15 MHz, 14 – 14.2 MHz, 18.07 – 18.17 MHz, 21.0 – 21.4 MHz, 24.89 – 24.99 MHz, 28.0 – 29.7 MHz, 50.0 – 54.0 MHz.

If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this product.

11.6.5 Recommended separation distances between portable and mobile RF communications equipment and this product

This product is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communication equipment.

	Separation distance according to frequency of transmitter [m]		
Rated maximum output power of transmitter [W]	**150 kHz – 80 MHz outside ISM and radio amateur bands *** d = 1.2 √P **	**150 kHz – 80 MHz in ISM and radio amateur bands *** d = 2.0 √P	**80 MHz – 6 GHz (for define RF Wireless transmitters see table before)** d = 1.2 √P
0.01	0.12	0.20	0.12
0.1	0.38	0.63	0.38
1	1.2	2.0	1.2
10	3.8	6.3	3.8
100	12	20	12

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres [m] can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

$$E = \frac{6}{d}\sqrt{P}$$

* The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are: 6.765 – 6.795 MHz, 13.553 – 13.567 MHz, 26.957 – 27.283 MHz, 40.66 – 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are: 1.8 MHz – 2 MHz, 3.5 – 4.0 MHz, 5.3 – 5.4 MHz, 7 – 7.3 MHz, 10.1 – 10.15 MHz, 14 – 14.2 MHz, 18.07 – 18.17 MHz, 21.0 – 21.4 MHz, 24.89 – 24.99 MHz, 28.0 – 29.7 MHz, 50.0 – 54.0 MHz.
** Formulas coming from Edition 3 of the IEC 60601-1-2.

Should you have any further questions, please contact your Haag-Streit representative at:

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