INSTRUCTIONS FOR USE
Perimeter

OCTOPUS 900®

EyeSuite Perimetry

10. Edition / 2020 – 02

HAAG-STREIT DIAGNOSTICS

INSTRUCTIONS FOR USE
Perimeter

OCTOPUS 900®

EyeSuite Perimetry

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 900 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

No contraindications are known for perimetric examinations. For this reason, it is not necessary to take any measures here.

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.

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 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.

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 improper handling or damage. If it does, notify the transport company that delivered the goods to you. Unpack the equipment together with a representative of the transport company. Compile a report on any potentially 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 the packaging material carefully so that it can be used for possible returns or when moving.

1.5 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 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 Octopus 900 must be placed in a completely darkened room.
- The use of accessories other than than those listed may result in higher emissions or lower interference immunity of the Octopus 900 system.
- The software must be installed by trained personnel.

1.6 Operation and environment

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

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, galvanic Ethernet isolator, etc.)
- The doctor or operator is obliged to inform the patient of the safety instructions which concern the patient 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.
- All users must be appropriately trained and familiarised with the contents of the instructions for use, especially with regard to the safety information contained therein.

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".
- 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 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.
- Turn the system off if it will not be used for an extended period of time.

- 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 900 system.

1.7 Disinfection

NOTE!

The device does not need to be disinfected. For more information on cleaning, please refer to the 'Maintenance' 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	MET Listed Mark with approval for USA and Canada
European certificate of conformity	Do not push! The appliance may tilt if pushed on the side.

Date of manufacture	Manufacturer
REF HS reference number	SN Serial number
ETL Listed Mark with approval for USA and Canada	Testsymbol of TÜV Rheinland with approval for INMETRO Brasil

2. Introduction

2.1 Device description

- The Octopus 900 is an automatic projection Perimeter for the examination of the entire field of sight (90°).
- The system is divided into the examination unit (Octopus 900) and control unit (notebook, PC). The examination unit communicates with the external PC via an Ethernet connection. The Octopus 900 is operated using the software installed on the PC. The Perimeter may be operated from a bright side room if necessary.
- Integrated patient monitoring increases the reliability of the examination results.
- The Octopus 900 is used by clinical users and for research purposes, since its flexibility is practically unlimited.
- The Octopus 900 tests the entire field of sight up to 90° eccentricity because of its spherical cupola geometry by Goldmann. Thanks to the flexibility of this instrument, all perimetric questions can be answered – in both the 30° and 90° range, with kinetic perimetry, static perimetry or flicker perimetry.
- New PC and perimetry software can be downloaded and updated by going to www.Haag-Streit.com.

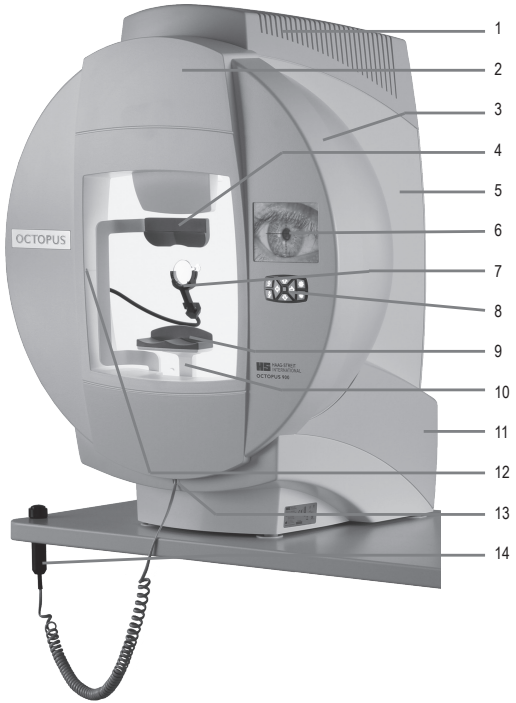
2.2 System components

The Octopus 900 system comprises the following components:

- Octopus 900
- Patient response button

2.3 Device overview

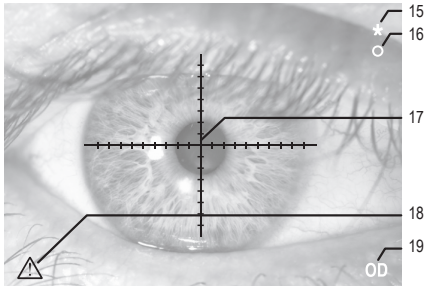
1. Top cover for stimulus projector
2. Front cover
3. Housing / cupola
4. Forehead rest (application part)
5. Rear panel
6. TFT display
7. Refractive lens holder with IR illumination
8. Control panel
9. Chin cup with integrated sensors for detecting the head position
10. Chin rest (application part)
11. IR cover
12. Mark for optimum eye height
13. Connection point for
14. patient response button (application part)



2.4 LCD display

The high-contrast TFT colour display enables the video image to be observed under a large angle of view. The following messages are shown on the display:

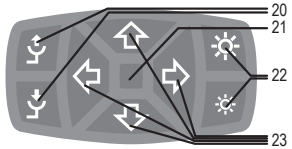
15. Display of a '★' during the stimulus presentation
16. Display of a 'O' if the patient response button is pressed.
17. The crosshairs help to centre the eye, scale = 1 mm interval
18. Warning or error message
19. Display of left (OS) or right eye (OD)



2.5 Control panel

The control panel is made of a comfortable and hard-wearing rubber material. All buttons are backlit with white light to make navigation easy in a darkened room. The light sources can be switched off if required, except for the display brightness setting.

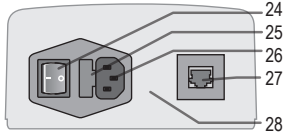
20. Turn the refractive lens holder in and out
21. Start examination
22. Display brightness setting
23. Position chin rest left, right, up, down



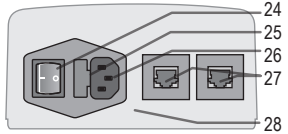
2.6 Connections

WARNING!
All externally connected devices must comply with the standards relevant to safety.

24. Mains switch
25. Fuse holder for two fuses T3.15 AH 250V
26. Mains connection
27. Ethernet port
28. Plug-in mains power unit



Version A (up to serial number 5999)



Version B (from serial number 6000)

2.7 Housing

The optical components and electronics are protected from light and dust by five housing covers. They can be removed for servicing with just a few actions. Once the four screws in the back panel have been removed, the panel, hood and both IR covers can be lifted out. The optical unit and electronic components of the Octopus 900 are now accessible

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.

2.8 Cupola

The cupola of the Octopus 900 has a diameter of 600 mm and thus conforms to the Goldmann standard.

2.9 Forehead rest

A wide, ergonomically designed forehead rest allows the patient to maintain a comfortable posture during the examination.

2.10 Chin rest

The chin rest (and thus the position of the patient's head) is adjusted with the four buttons. Fine adjustment can also be performed at the control unit (PC) using the mouse. Sensors in the chin rest detect the correct position of the patient's head. There is an optional attachment for the chin rest for examining children. (*REF 1820075*)

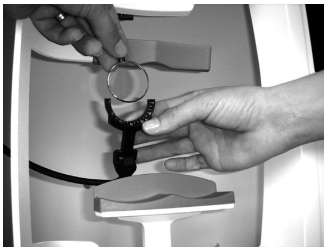
2.11 Swing arm

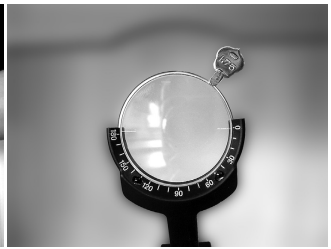
An automatic swing arm allows the refractive lens holder to be turned in and out during the examination without changing the position of the patient. This swing arm can be operated with the computer mouse at either the control panel or on the control unit. Once the refractive lens holder has been swung in, it can be finely adjusted to the correct distance from the eye being examined.

NOTE!
Always use the control panel buttons on the appliance or PC to swing the refractive lens holder in or out. Do not attempt to move the refractive lens holder manually.

2.12 Refractive lens holder

Refractive lenses can be used during examinations with 30° eccentricity. The corresponding lenses are inserted before the examination. The refractive lens holder can be tilted forward by about 25° to make it easier to change the refractive lenses.





2.13 Patient-response button

The patient-response button is connected to the bottom of the forehead rest holder (RJ11 plug connection).

2.14 Network connection

The Ethernet port is located at the back of the appliance. Always use a shielded category 5e cable which enables transmissions of 100 MHz without interference. This network connection is electrically isolated and has a dielectric strength of 4 kV according to EN 60601-1.

2.15 Light sources

LEDs are installed for periphery or background illumination, fixation assistance and stimulus. LEDs emit very low amounts of heat, so active cooling is not required.

2.16 Light intensities

The light intensity of stimulus and periphery is measured with independent light sensors and adjusted to the preset nominal values each time the Perimeter is switched on.

2.17 Stimulus

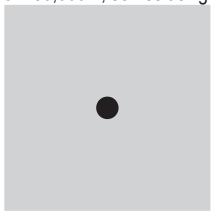
The stimulus light is projected indirectly into the cupola via a mirror unit. Five different diaphragm diameters can be selected in the user-defined programs. The attenuation of the stimulus intensity is infinitely adjustable via an electronic control unit. Stimulus presentations of 100-500 ms are permitted. A mechanical lock and optical damping elements are no longer required.
White stimulus for W/W perimetry and optionally blue and red stimulus for B/Y and R/W are possible. The stimulus intensity is detected using a light sensor, which also serves as reference point for the system of coordinates of the test zones. The stimulus LED has a service life of >30,000 h and is thus maintenance-free.

2.18 Periphery or background illumination

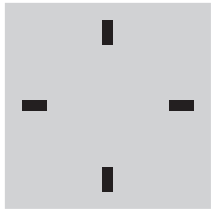
The white background brightness amounts to 31.4 or 4 asb for W/W perimetry. You can also select a yellow background with 314 asb for B/Y perimetry. The background brightness consists of two light sources, each equipped with several LEDs. The background LEDs have a service life of >30,000 h and are thus maintenance-free. The background brightness is measured by a separate light sensor.

2.19 Fixation marks

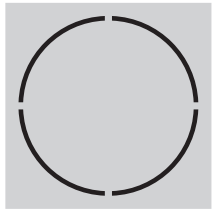
Three different fixation marks can be selected and their brightness changed electronically in 10 steps. A green LED, which is maintenance-free and has a service life of >30,000 h, serves as light source.



(Centre point)



(Cross markers)



(Circle)

2.20 Fixation control

The examined eye of the patient is illuminated with IR LEDs, photographed by a CMOS camera and displayed on the LCD display. 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 chin rest.

2.21 Examination data

All examination data are transmitted via the Ethernet interface to the control unit (PC / laptop), where they are saved and managed in a database. It is possible to export data to a server. Examination data can also be printed out on a printer connected to the control unit.

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 Haag-Streit replacement parts may be used.

3.1 Transporting the appliance

Transporting or moving the appliance (only short distances):

a) Unplug the power source before moving the device.

b_1) Stand in front of the device, grasp the cupola with both hands and lift the device (Figure 7-1), or

b_2) Stand to one side of the appliance with one hand on the front cover and with the other hand on the back cover, then take a firm hold and lift the appliance (Figure 7-2, Figure 7-3).

Figure 7-1

Figure 7-2

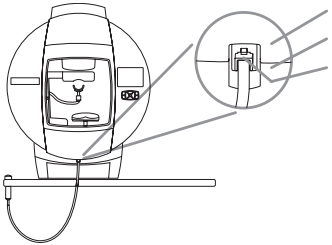
Figure 7-3

3.2 Connecting the patient response button

The connection socket for the response button is located at the bottom of the front cover. The retaining catch on the connection plug of the response button faces forwards.

DANGER!

No other cable may be connected to the RJ11 socket other than the patient response button!



29. Front cover
30. Cupola housing
31. Connection plug with retaining catch

- Push the connection plug into the connection socket until your hear the retaining catch click into place. To remove the response button, push the retaining catch towards the headrest and pull the cable downwards.

3.3 Connect the network cable

Version A: an Ethernet port (see chapter 2.6 "Connections")

Connect the Octopus 900 and the laptop/PC with two Ethernet cables via the network switch (10/100 MB) provided with the instrument. A computer network can also be connected via the network switch.

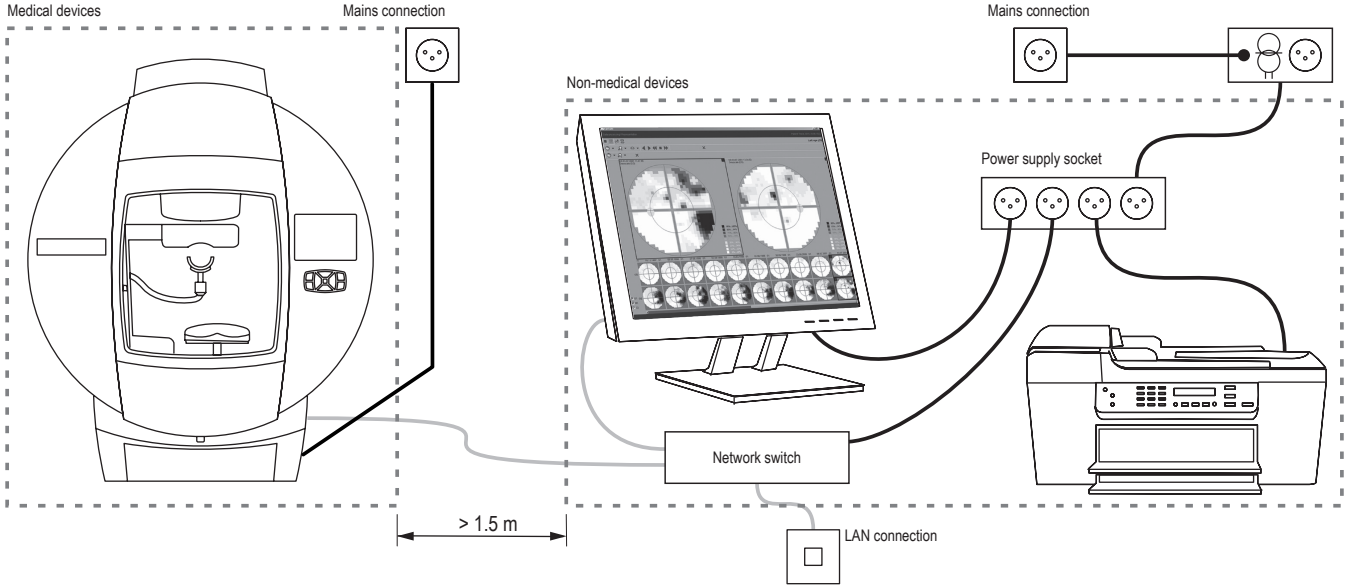
Version B: two Ethernet ports with integrated switch (see chapter 2.6 "Connections")
Connect the Octopus 900 and the laptop/PC directly via an Ethernet cable. A computer network can also be connected via the network switch installed in the Octopus 900. However, the switch is only active when the Octopus 900 is turned on. You will find further information in section 4 'Safe system configuration in accordance with EN 60601-1'.

3.4 Connect the electric power supply cable

The built-in mains power units operate with the voltages specified in the Technical Data section. It is not necessary to select the voltage on the appliance. If a support stand was also supplied, the Octopus 900 can be connected to the power socket in the support stand's electrical connection box.

4. Safe system configuration in accordance with EN 60601-1

If a medically approved control unit or a control unit with medically approved power supply unit is in operation with a non-medical device (e.g. printer), it is recommended for safety reasons that a safe distance of > 1.5 m from the Octopus 900 is maintained. Otherwise all non-medical devices must be operated through a safety isolating transformer.
Neither a safety isolating transformer nor a distance of > 1.5 m from the Octopus 900 is required if a medically approved control unit or a control unit with medically approved power supply unit without printer and without optional LAN connection is in being operated. For safety reasons, it is recommended to maintain a distance of > 1.5 m if at all possible.



5. Commissioning

5.1 Switching on the appliance

Before connecting the Octopus 900 to a suitable power socket, it must be ensured that the mains switch (24) is set to OFF '0'. The power socket is on the rear of the base of the device. Then set the mains switch to ON 'I'. The device will be ready for use after a couple of seconds.

5.2 Switching off the appliance

Set the network switch (24) to OFF '0'. There is no special shutdown procedure.

6. Operation

6.1 Setting up the patient

The patient sits comfortably in front of the device and places his/her chin on the chin rest. The forehead rest can be set to the correct 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.

8. Technical data

8.1 Octopus 900

Type designation	**Octopus 900**
Ambient temperature:	See chapter 1.3
Background colour I:	White (LED)
Background colour II:	Yellow (LED white with OG530 filter)
Background intensity I:	4 asb (1.27 cd/m²), 31.4 asb (10 cd/m²)
Background intensity II:	314 asb (100 cd/m²)
Dimensions (W × D × H):	648 mm × 519 mm × 796 mm
Display:	Colour TFT display (320 × 240 pixels)
Eccentricity:	90°
Ethernet port:	Ethernet T100
Fixation control:	Permanent video-based fixation control
Functional principle:	projection cupola perimeter
Fuses:	2 × T3.15 AH 250V
Humidity:	See chapter 1.3
Mains voltage:	100 – 120 VAC, 220 – 240 VAC
Maximum stimulus intensity:	3185 cd/m² (10000 asb)
Measurement accuracy:	0.5 dB
Measurement principle:	Bracketing procedure
Measurement range:	0 ... 47 dB
Operating frequency:	50 / 60 Hz
Patient positioning:	Adjustable headrest
Power consumption:	145 VA, 165 VA
Shipping dimensions (W × D × H):	800 mm × 600 mm × 900 mm
Shipping weight:	40 kg
Stimulus colour I:	White (LED)
Stimulus colour II:	Blue (LED white with 440 nm filter)
Stimulus colour III:	Red (LED white with 610 nm filter)
Stimulus duration (ms):	100, 200, 500, 1000, freely selectable
Stimulus interval:	Adaptive, fix 1.5 ... 4 sec
Stimulus size:	Goldmann I, II, III, IV and V
Weight:	25 kg

8.2 Infrared illumination

Cupola emission:

Light sources:	LED
Wavelength:	875 nm
Angle of radiation:	±8.5°

Refractive lens holder emission

Light sources:	LED
Wavelength:	880 nm
Angle of radiation:	±20°

8.3 Field of sight

The Octopus 900 makes it possible to examine up to the following eccentricity:

- Nasal 89°
- Temporal 89°
- Superior 60°
- Inferior 70°

8.4 Octopus 900 control unit / PC

A standard PC can be used as control unit for the Perimeter. The control unit software runs on WINDOWS VISTA SP2, WINDOWS 7, WINDOWS 8 and WINDOWS 10

NOTE!
The minimum requirements for PCs can be found in the EyeSuite instructions for use.

9. Maintenance

WARNING!
- The housing components of the Perimeter appliance may only be removed by suitably qualified service personnel.
- The ON/OFF switch does not isolate the Perimeter from the mains. Before removing the housing components, ensure that the appliance is unplugged from the mains power socket.
- This device must not be modified without the manufacturer's approval. 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.
- Warranty claims can be made only if the instructions in these instructions for use have been complied with.

9.1 Repairs

We recommend having an authorised professional check the Octopus 900 every two years to ensure long-term and trouble-free functioning. 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

Regular dusting of the device with a soft cloth is sufficient. More stubborn dirt can be removed using a soft, lint-free cloth dampened with water or alcohol at maximum 70%.

NOTE!
Do not allow the appliance to become wet and do not use other solvents of any kind.

A dust cover is included in the accessories of the Octopus 900. Cover the appliance when the room is being cleaned or if it is not used for longer periods. Always remove the dust cover before switching on the power.

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

9.2.1 Cupola

The inner surface of the cupola is coated with a special paint finish designed to ensure optimum results in perimetric examinations. It is not necessary to clean this inner surface in normal cases. Should dust be visible in the cupola, you can remove it by gently wiping with a soft, dry and fluff-free cloth. A soft cloth dampened slightly with mild soapsuds may only be used for local cleaning in emergencies, such as if spots have appeared due to patients' sneezing.

9.2.2 Response button, chin and forehead rest, eye occluder

These components are all made of easy-to-clean plastic materials. Disinfect them after every patient to keep them hygienically clean.

NOTE!
These application 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.

9.2.3 Display, control panel

Fingerprints and dust can be removed using a soft, moist cloth.

9.3 Light sources

In contrast to other perimetric devices, LEDs are used in the Octopus 900 as light sources for background and stimulus. These have a service life of >30,000h. If any of the LEDs still has to be replaced, please contact your representative's customer service department.

A. Appendix

A.1 Accessories / consumables / spare parts / upgrade

Component	Type	*REF*	Note
Instrument table	HSM 600	7220621	230V
		7220622	110V
		7220623	230V LAN
		7220624	110V LAN
			See separate IFU*:
Patient response button	Octopus 900	1802032	1x

Dust cover	1803061	1x
Eye patch set	1802349	2x / set

*IU = 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 E, 'Standards'.
- The Octopus 900 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.

C. Classification

Standard EN 60601-1	Perimeter Octopus 900 acc. to protection class I
Application part:	Type B
Operating mode:	Continuous operation
CE Directive 93/42/EEC	Class IIa
Standard EN 62471	Exempt group

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	EN ISO 15004-1	EN 62471	ISO 9022
EN 60601-1-2	EN ISO 12866	EN ISO 10993-1	

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

F.1 General

The Octopus 900 fulfils the requirements on electromagnetic compatibility according to EN 60601-1-2:2007 (IEC 3. Edition) + EN 60601-1-2:2015 (IEC 4. 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!
Avoid damages due to high electrostatic discharges (ESD). Electrostatic discharges with voltages exceeding 6 kV to some parts of the instrument, like patient answer button or display, may influence the instrument.

- The firmware of the instrument may be disturbed, such that the IR illumination for eye tracking turns off. 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.

WARNING!

- Electrical medical devices and systems are subject to special EMC measures and must be installed in accordance with the EMC instructions contained in this accompanying document.
- The operation of other lines or equipment than those listed may lead to higher emissions or may reduce the device's resistance to interference.
- Third-party devices may only be connected in compliance with the EN 60601-1 standard.

F.2 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	5 V_{rms}	$D = 0.7\sqrt{P}$
Radiated RF EN 61000-4-3	3 V/m 80 MHz – 2.7 GHz	3 V/m 80 MHz – 2.7 GHz	$D = 1.2\sqrt{P}$ 80 MHz – 800 MHz $D = 2.3\sqrt{P}$ 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 5 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 $D = 0.35\sqrt{P}$	80 MHz – 800 MHz $D = 0.7\sqrt{P}$	800 MHz – 2.7 GHz $D = 1.4\sqrt{P}$
0.01	0.035	0.07	0.14
0.1	0.1	0.2	0.44
1	0.35	0.7	1.4
10	1.1	2.2	4.4
100	3.5	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 2.7 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:

http://www.haag-streit.com/contact/contact-your-distributor.html

HAAG-STREIT DIAGNOSTICS

CE 0297

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