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**INSTRUCTIONS FOR USE**
**Perimeter**

# OCTOPUS 900®

## EyeSuite Perimetry

11. Edition / 2022 – 10

HAAG-STREIT DIAGNOSTICS

# INSTRUCTIONS FOR USE
## Perimeter

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## EyeSuite Perimetry

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## 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** ..... 4
  - 1.1 Comments on these instructions for use ..... 4
  - 1.2 Ambient conditions ..... 4
  - 1.3 Shipment and unpacking ..... 4
  - 1.4 Installation warnings ..... 4
  - 1.5 Operation, environment ..... 5
  - 1.6 Disinfection ..... 5
  - 1.7 Warranty and product liability ..... 5
  - 1.8 Reporting obligation ..... 6
  - 1.9 Description of symbols ..... 6
- **2 Intended purpose / intended use** ..... 6
  - 2.1 Device description ..... 6
    - 2.1.1 Intended users ..... 6
  - 2.2 Medical purpose ..... 6
    - 2.2.1 Indications ..... 6
    - 2.2.2 Part of the body ..... 7
    - 2.2.3 Patient population ..... 7
      - 2.2.3.1 Contraindications ..... 7
  - 2.3 Principles of operation ..... 7
    - 2.3.1 Operating environment ..... 7
  - 2.4 Clinical benefit ..... 7
- **3 Introduction** ..... 8
  - 3.1 Device description ..... 8
  - 3.2 System components ..... 8
  - 3.3 Device overview ..... 8
  - 3.4 LCD display ..... 9
  - 3.5 Control panel ..... 9
  - 3.6 Connections ..... 9
  - 3.7 Housing ..... 9
  - 3.8 Cupola ..... 10
  - 3.9 Forehead rest ..... 10
  - 3.10 Chin rest ..... 10
  - 3.11 Swing arm ..... 10
  - 3.12 Refractive lens holder ..... 10
  - 3.13 Patient-response button ..... 10
  - 3.14 Network connection ..... 10
  - 3.15 Light sources ..... 10
  - 3.16 Light intensities ..... 10
  - 3.17 Stimulus ..... 11
  - 3.18 Periphery or background illumination ..... 11
  - 3.19 Fixation marks ..... 11
  - 3.20 Fixation control ..... 11
  - 3.21 Examination data ..... 11
- **4 Device assembly / installation** ..... 11
  - 4.1 Transporting the device ..... 11
  - 4.2 Connecting the patient response button ..... 12
  - 4.3 Connect the network cable ..... 12
  - 4.4 Connect the electric power supply cable ..... 12
- **5 Safe system configuration in accordance with EN 60601** ..... 13
- **6 Commissioning** ..... 14
  - 6.1 Switching on the device ..... 14
  - 6.2 Switching off the device ..... 14
- **7 Operation** ..... 14
  - 7.1 Setting up the patient ..... 14
- **8 Software / Help menu / Error messages** ..... 14
- **9 Technical data** ..... 14
  - 9.1 Octopus 900 ..... 14
  - 9.2 Infrared illumination ..... 15
  - 9.3 Field of sight ..... 15
  - 9.4 Octopus 900 control unit / PC ..... 15
- **10 Maintenance** ..... 15
  - 10.1 Repairs ..... 15
  - 10.2 Cleaning and disinfection ..... 15
    - 10.2.1 Device in general ..... 16
    - 10.2.2 Display, control panel ..... 16
    - 10.2.3 Cupola ..... 16
    - 10.2.4 Applied parts ..... 16
    - 10.2.5 Tools ..... 16
  - 10.3 Light sources ..... 16
  - 10.4 Dust cover ..... 16
- **11 Appendix** ..... 17
  - 11.1 Accessories / consumables / spare parts / upgrade ..... 17
  - 11.2 Legal regulations ..... 17
  - 11.3 Classification ..... 17
  - 11.4 Disposal ..... 17
  - 11.5 Observed standards ..... 17
  - 11.6 Information and manufacturer's declaration concerning electromagnetic compatibility (EMC) . 18
    - 11.6.1 General ..... 18
    - 11.6.2 Emitted interference ..... 19
    - 11.6.3 Electromagnetic immunity environment tested (part 1) ..... 20
    - 11.6.4 Electromagnetic immunity environment tested (part 2) ..... 21
    - 11.6.5 Recommended separation distances between portable and mobile RF communications equipment and this product ..... 23

# 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 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.

## 1.5 Operation, environment

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

**WARNING!**
- 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.
- 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.

**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.
- 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 those listed may result in higher emissions or lower interference immunity of the Octopus 900 system.

## 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 |  | Do not push! The device may tilt if pushed on the side. |

## 2 Intended purpose / intended 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.

### 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 Octopus 900 is operated using the Eye-Suite Perimetry software installed on the PC. The examination unit communicates with the external PC via an Ethernet connection. Integrated patient 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

The use of this device's Goldmann kinetic perimetry feature is indicated when unable to perform static perimetry due to difficulties particular to the patient or for the following medical conditions:

1. Non organic disorders
2. Peripheral visual field defects

### 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).

**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.

**Kinetic Perimetry**

In kinetic perimetry the target moves into the visual field following a user-defined vector. The patient may register his awareness of the target by pressing the button. The response or lack thereof is registered by the device and other vectors are presented.

### 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 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 device, 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.

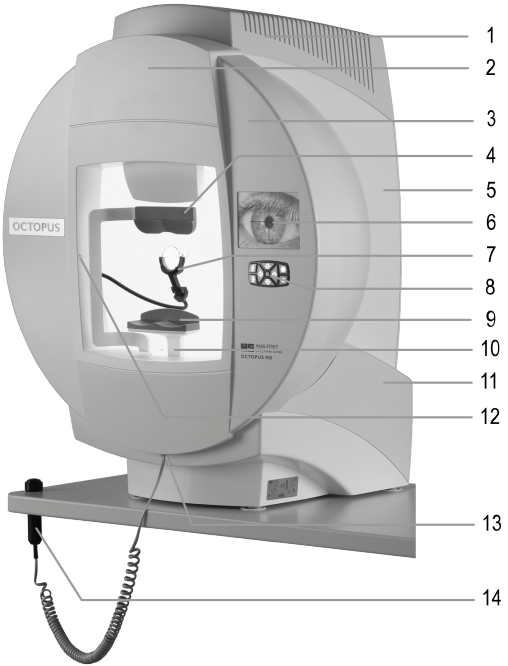
## 3.2 System components

The Octopus 900 system comprises the following components:

- Octopus 900
- Patient response button

## 3.3 Device overview

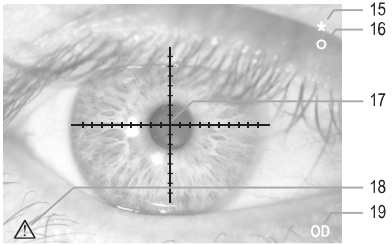
1. Top cover for stimulus projector
2. Front cover
3. Housing / cupola
4. Forehead rest (application part)
5. Rear panel
6. TFT display
7. Refractive lens holder with IR illumination
8. Control panel
9. Chin cup with integrated sensors for detecting the head position
10. Chin rest (application part)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



## 3.4 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:

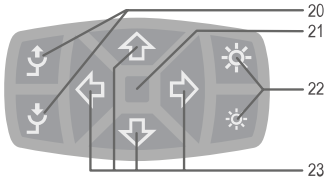
15. Display of a '★' during the stimulus presentation
16. Display of a 'O' if the patient response button is pressed.
17. The crosshairs help to centre the eye, scale = 1 mm interval
18. Warning or error message
19. Display of left (OS) or right eye (OD)




## 3.5 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.

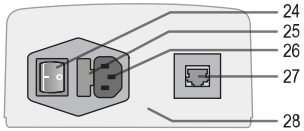
20. Turn the refractive lens holder in and out
21. Start examination
22. Display brightness setting
23. Position chin rest left, right, up, down



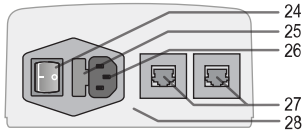

## 3.6 Connections

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

24. Mains switch
25. Fuse holder with two fuses T3.15 AH / 250 V
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)

## 3.7 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 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.

## 3.8 Cupola

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

## 3.9 Forehead rest

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

## 3.10 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 (see chapter 'Appendix').

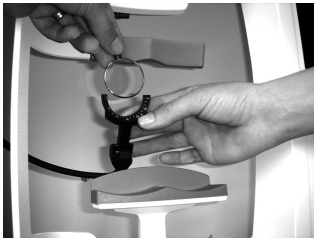
## 3.11 Swing arm

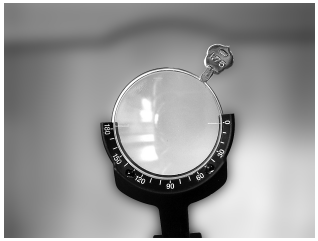
An automatic swing arm allows the refractive lens holder to be turned in and out during the examination without changing the position of the patient. This swing arm can be operated with the computer mouse at either the control panel or on the control unit. Once the refractive lens holder has been swung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

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

## 3.12 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.





## 3.13 Patient-response button

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

## 3.14 Network connection

The Ethernet port is located at the back of the device. 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.

## 3.15 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.

## 3.16 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.

### 3.17 Stimulus

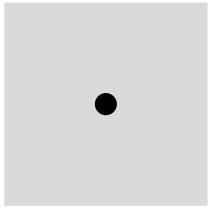
The stimulus light is projected indirectly into the cupola via a mirror unit. Five different diaphragm diameters can be selected in the user-defined programs. The attenuation of the stimulus intensity is infinitely adjustable via an electronic control unit. Stimulus presentations of 100-500 ms are permitted. 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.

### 3.18 Periphery or background illumination

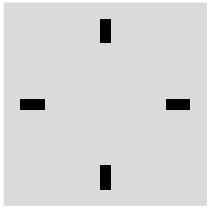
The white background brightness amounts to 31.4 or 4 asb for W/W perimetry. You can also select a yellow background with 314 asb for B/Y perimetry. The background brightness consists of two light sources, each equipped with several LEDs. The background LEDs have a service life of >30,000 h and are thus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

### 3.19 Fixation marks

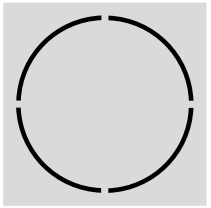
Three different fixation marks can be selected and their brightness changed electronically in 10 steps. A green LED, which is maintenance-free and has a service life of >30,000 h, serves as light source.



(Centre point)



(Cross markers)



(Circle)

### 3.20 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.

### 3.21 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.

## 4 Device assembly / installation

**WARNING!**

- Do not modify this device 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 spare parts may be used.

### 4.1 Transporting the device

Transporting or moving the device (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 device with one hand on the front cover and with the other hand on the back cover, then take a firm hold and lift the device (Figure 7-2, Figure 7-3).

Figure 7-1

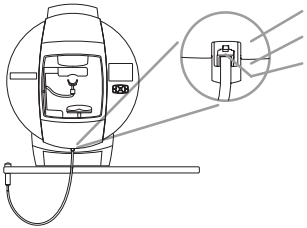
Figure 7-2

Figure 7-3

## 4.2 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.

## 4.3 Connect the network cable

**Version A: an Ethernet port** (see 'Connections' chapter)
Connect the Octopus 900 and the laptop/PC with two Ethernet cables via the network switch (10/100 MB) provided with the device. A computer network can also be connected via the network switch.

**Version B: two Ethernet ports with integrated switch** (see 'Connections' chapter)
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 chapter 'Safe system configuration in accordance with EN 60601-1'.

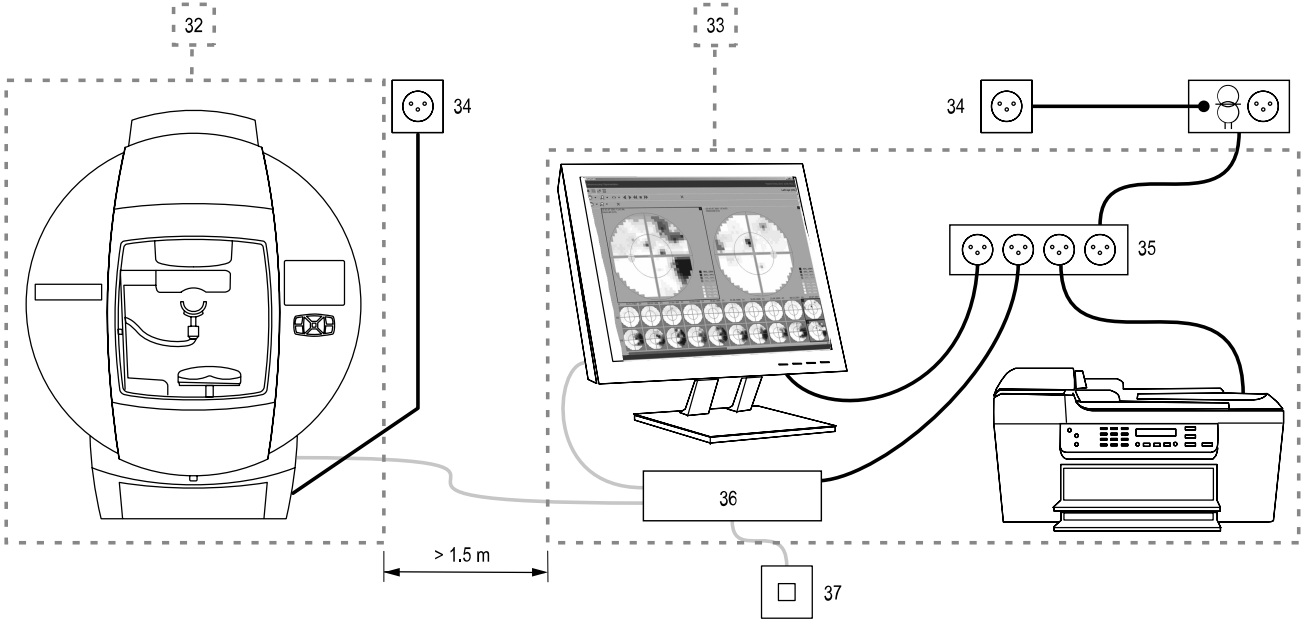
## 4.4 Connect the electric power supply cable

The built-in mains power units operate with the voltages specified in the 'Technical data' chapter. It is not necessary to select the voltage on the device. 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.

## 5 Safe system configuration in accordance with EN 60601

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.




32. Medical devices
33. Non medical devices
34. Mains connection
35. Power supply socket
36. Network switch
37. LAN connection

# 6 Commissioning

## 6.1 Switching on the device

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.

## 6.2 Switching off the device

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

# 7 Operation

## 7.1 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.

# 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.

# 9 Technical data

## 9.1 Octopus 900

| Type designation | Octopus 900 |
|---|---|
| Ambient temperature: | See chapter 'Ambient conditions' |
| 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 'Ambient conditions' |
| 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 |

## 9.2 Infrared illumination

| **Cupola emission:** | | **Refractive lens holder emission** | |
|---|---|---|---|
| Light sources: | LED | Light sources: | LED |
| Wavelength: | 875 nm | Wavelength:: | 880 nm |
| Angle of radiation: | ±8.5° | Angle of radiation: | ±20° |

## 9.3 Field of sight

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

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

## 9.4 Octopus 900 control unit / PC

A standard PC can be used as control unit for the Perimeter. The control unit software runs on Windows 8.1, Windows 10, Windows 11.

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

# 10 Maintenance

**WARNING!**
- The housing components of the Perimeter device 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 device is unplugged from the mains power socket.
- Do not modify this device 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.
- Warranty claims can be made only if the instructions in these instructions for use have been complied with.

## 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 Display, control panel

Fingerprints and dust can be removed using a display towel or a cleaning/disinfecting towel respectively.

### 10.2.3 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.

### 10.2.4 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 chin rest
- Patient response button
- Eye patch

### 10.2.5 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.

## 10.3 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.

## 10.4 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 |
|---|---|---|---|
| Instrument table * | HSM 600 | 7220621<br>7220622<br>7220623<br>7220624 | 230 V<br>110 V<br>230 V LAN<br>110 V LAN |
| Patient response button | Octopus 900 | 1802032 | 1x |
| Dust cover | | 1803061 | 1x |
| Eye patch set | | 1802349 | 2x / set |
| Chin rest adapter for children | | 1820075 | 1x |

* 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.

## 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 |

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

## 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 some parts of the device, like patient answer button or display, may influence the device.

- The firmware of the device 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 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<br>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<br>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<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions<br>IEC 61000-3-3 | $P_{st}$ = 1.0<br>$P_{lt}$ = 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<br>± 2, ± 4, ± 8, ± 15 kV air | ± 8 kV contact<br>± 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<br>IEC 61000-4-4 | ± 2 kV, 100kHz for power supply lines *<br>± 1 kV, 100 kHz for input/output lines * | ± 2 kV, 100kHz for power supply lines *<br>± 0.5, ± 1 kV, 100 kHz for input/output lines * | Mains power quality should be that of a typical commercial or hospital environment.<br>* Not applicable for DC and I/O if cable < 3 m. |
| Surge<br>IEC 61000-4-5 | ± 0.5, ± 1 kV line(s) to line(s) *<br>± 0.5, ± 1, ± 2 kV line(s) to earth * | ± 1 kV line(s) to line(s) *<br>± 0.5, ± 1, ± 2 kV line(s) to earth * | Mains power quality should be that of a typical commercial or hospital environment.<br>* Not applicable for DC and I/O if cable < 3 m. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | 0% $U_T$: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$: 1 cycle at 0°<br>0% $U_T$: 250/300 cycles at 0°<br>70% $U_T$: 25/30 cycles at 0° | 0% $U_T$: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$: 1 cycle at 0°<br>0% $U_T$: 250/300 cycles at 0°<br>70% $U_T$: 25/30 cycles at 0° | Mains power quality should be that of a typical commercial or hospital environment.<br>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.<br>$U_T$ is the a.c. mains voltage (100 – 240 V) prior to application of the test level. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50/60 Hz | 100 A/m<br>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<br>IEC 61000-4-6 | 3 $V_{rms}$<br>150 kHz – 80 MHz outside ISM bands and radio amateur band *<br><br>6 $V_{rms}$<br>150 kHz – 80 MHz in ISM bands and radio amateur band * | 10 $V_{rms}$<br>150 kHz – 80 MHz outside ISM bands and radio amateur band *<br><br>10 $V_{rms}$<br>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.<br><br>Minimum separation distance shall be calculated by following equation:<br>$E = \frac{6}{d}\sqrt{P}$<br><br>E is the immunity test level in [V/m]<br>d is the minimum separation in [m]<br>P is the maximum power in [W]<br><br>**RF wireless equipment maximum output power and separation distance tested (at 30 cm):**<br><br>TETRA 400: max 1.8 W<br>GMRS 460, FRS 460: max 2 W<br>LTE Band 13 and 17: max 0.2 W<br>GSM 800/900: max 2 W<br>TETRA 800: max 2 W<br>iDEN 820: max 2 W<br>CDMA 850: max 2 W<br>LTE Band 5: max 2 W |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz – 2.7 GHz<br>80% AM 1 kHz | 3 V/m<br>80 MHz – 2.7 GHz<br>80% AM 1 kHz | |
| Proximity field from RF wireless communication equipment<br>IEC 61000-4-3 | 27 V/m<br>380 – 390 MHz<br>50% PM 18 Hz<br><br>28 V/m<br>430 – 470 MHz<br>FM ± 5 kHz deviation, 1kHz sine<br><br>9 V/m<br>704 – 787 MHz<br>50% PM 217 Hz<br><br>28 V/m<br>800 – 960 MHz<br>50% PM 18 Hz<br><br>28 V/m<br>1700 – 1990 MHz<br>50% PM 217 Hz | 27 V/m<br>380 – 390 MHz<br>50% PM 18 Hz<br><br>28 V/m<br>430 – 470 MHz<br>FM ± 5 kHz deviation, 1kHz sine<br><br>9 V/m<br>704 – 787 MHz<br>50% PM 217 Hz<br><br>28 V/m<br>800 – 960 MHz<br>50% PM 18 Hz<br><br>28 V/m<br>1700 – 1990 MHz<br>50% PM 217 Hz | |

| | | |
|---|---|---|
| 28 V/m<br>2400 – 2570 MHz<br>50% PM 217 Hz<br>9 V/m<br>5100 – 5800 MHz<br>50% PM 217 Hz | 28 V/m<br>2400 – 2570 MHz<br>50% PM 217 Hz<br>9 V/m<br>5100 – 5800 MHz<br>50% PM 217 Hz | GSM 1800/1900: max 2 W<br>CDMA 1900: max 2 W<br>DECT: max 2 W<br>LTE Band 1, 3, 4, 25: max 2 W<br>UMTS: max 2 W<br>Bluethooth: max 2 W<br>WLAN 802.11b/g/n: max 2 W<br>RFID 2450: max 2 W<br>LTE Band 7: max 2 W<br>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 = 0.35 √P ** | **150 kHz – 80 MHz in ISM and radio amateur bands *** d = 1.2 √P | **80 MHz – 6 GHz (for define RF Wireless transmitters see table before)** d = 2.0 √P |
| 0.01 | 0.04 | 0.12 | 0.20 |
| 0.1 | 0.13 | 0.38 | 0.63 |
| 1 | 0.40 | 1.2 | 2.0 |
| 10 | 1.3 | 3.8 | 6.3 |
| 100 | 4.0 | 12 | 20 |

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:

**www.haag-streit.com/haag-streit-group/contact/haag-streit-distributors/distributors**

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