INSTRUCTIONS FOR USE

Headrest

5. Edition / 2019 – 06

Swiss made

HAAG-STREIT
DIAGNOSTICS
INSTRUCTIONS FOR USE

Headrest

5. Edition / 2019 – 06

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

Purpose of use
The headrest is an accessory for Haag-Streit slit lamps. It serves to hold the patient’s head firmly in position.

Contraindications
There are no absolute contraindications known for examinations with this device. Appropriate professional assessment and caution are necessary.

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

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

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1. Safety

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

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

NOTE!
Important information: please read carefully.

1.1 Areas of application of the device

The device is intended to use in professional health care facility environment, like doctor’s practices, hospitals and optometrists and opticians premises, except near of HF surgical equipment and in 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 Ambient conditions

<table>
<thead>
<tr>
<th></th>
<th>Transport:</th>
<th>Storage:</th>
<th>Use:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>from −40°C to +70°C</td>
<td>from −10°C to +55°C</td>
<td>from +10°C to +35°C</td>
</tr>
<tr>
<td>Air pressure</td>
<td>from 500 hPa to 1060 hPa</td>
<td>from 700 hPa to 1060 hPa</td>
<td>from 800 hPa to 1060 hPa</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>from 10% to 95%</td>
<td>from 10% to 95%</td>
<td>from 30% to 90%</td>
</tr>
</tbody>
</table>

1.3 Shipment and unpacking

• Before you unpack the appliance, check whether the packaging shows traces of incorrect handling or damage. If this is the case, notify the transport company that has delivered the goods to you. Unpack the equipment together with a representative of the transport company.
• Make a report of any damaged parts. This report must be signed by you and by the representative of the transport company.
• Leave the device in the packaging for a few hours before unpacking it (condensation).
• Check the appliance for damage after it is unpacked.
• Return defective appliances in the appropriate packaging.

1.4 Installation warnings

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

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.

NOTE!
This equipment 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 "Purpose of use".

1.6 Disinfection

NOTE!
The device does not need to be disinfected. For more information on cleaning, please refer to the 'Maintenance' section.
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 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.
For USA only:
• This product is covered by a limited warranty granted by your seller.

1.8 Description of symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Icon" /></td>
<td>Read the instructions for use attentively</td>
</tr>
<tr>
<td><img src="image2.png" alt="Icon" /></td>
<td>Notes on disposal, see the ‘Disposal’ chapter</td>
</tr>
<tr>
<td><img src="image3.png" alt="Icon" /></td>
<td>Type B applied part</td>
</tr>
<tr>
<td><img src="image4.png" alt="Icon" /></td>
<td>European certificate of conformity</td>
</tr>
<tr>
<td><img src="image5.png" alt="Icon" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="image6.png" alt="Icon" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image7.png" alt="Icon" /></td>
<td>HS reference number</td>
</tr>
<tr>
<td><img src="image8.png" alt="Icon" /></td>
<td>Serial number</td>
</tr>
</tbody>
</table>

2. Introduction
The headrest comprises a chin rest and a forehead band, which make it possible to keep the patient’s head in a comfortable position. It also has two handles for the patient to hold on to. The chin rest is height adjustable, so heads of different sizes can be brought into the correct position for the examination. The correct eye level is indicated by a mark on the column. The optional fixation lamp can be used to fix the direction of sight of the eye not currently being examined. The round mark can be adjusted to suit the ametropia in the eye.

2.1 Overview
1. Lamp cable (optional)
2. Forehead band (applied part)
3. Height mark on headrest (patient eye)
4. Adjustable fixation lamp (optional)
5. Chin rest (applied part)
6. Height adjustment of chin rest
7. Handles (applied part)

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 Headrest
• The headrest is packaged fully assembled. Before first use the handles can be screwed into the threads provided.
• If you are installing the headrest on a table from another manufacturer, you will require special adapter plates, see "Accessories" section. The appropriate national standards also need to be taken into consideration.
3.2 Power supply

**NOTE!**
If the headrest is equipped with a lamp cable or a fixation lamp, please use a Haag-Streit power supply and follow the corresponding instructions for use. For further information, please consult your Haag-Streit representative.

4. Operation

4.1 Commissioning
Commissioning depends on the power supply you are using; please follow the corresponding instructions for use.

4.2 Operating the instrument
Use the turn screw (6) to adjust the chin rest (5) until the patient's eyes are at the same height as the black mark (3) on the sides of the head rest.

4.3 Adjustable fixation lamp (optional)
* The fixation lamp illuminates when the power supply is turned on, and the fixation mark (12) becomes visible.
* The fixation lamp can be moved in any direction using the bearer arm (9). This offers the examiner the possibility of moving into the required view direction during observation of the eye being examined through the microscope without any interruptions.
* Prerequisite for this is that the patient's eye is positioned exactly at the level of the black mark (11) on the head rest.
* It is possible to correct ametropia in the patient from +10 D to -10 D (10). This ensures safe immobilisation of the eyes, as accommodation and convergence are largely disengaged.

4.4 Eye cover (optional)
The eye cover is used to avoid distractions and in so doing ensure an optimal fixation of the patient's eye.

4.5 Preparing the patient
* In order to attain a solid basis for the forehead and chin to rest on, the table height should be selected such that the patient sits bent over forward.
* Clean the handles and the forehead band with alcohol and remove the top chin rest paper.

4.6 Decommissioning
The lamp must be switched off after every use. Decommissioning depends on the power supply you are using; please follow the corresponding instructions for use.

5. Technical data

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total height of headrest with base</td>
<td>720 mm</td>
</tr>
<tr>
<td>Total height of headrest without base</td>
<td>580 mm</td>
</tr>
<tr>
<td>Total width with handles</td>
<td>450 mm</td>
</tr>
<tr>
<td>Adjustable range of chin rest</td>
<td>90 mm</td>
</tr>
</tbody>
</table>

6. Maintenance

**WARNING!**
* Do not modify this equipment without authorization of the manufacturer. Installation and repairs may only be performed by trained specialists. Contact your Haag-Streit representative for installation, repairs and modification work on the system. The contact details are available at www.haag-streit.com.
* Only original Haag-Streit replacement parts may be used.

6.1 Device inspection
To check the correct functioning of the head rest, proceed as follows:
* Check head rest for tightness
* The chin rest has to be easy to move vertically by hand
* The knurled nut for the height adjustment must be able to be turned from the upper stop to the lower stop without jamming
6.2 Repairs
To ensure a long service life, the device should be cleaned weekly as described and covered with a dust cover when not in use. We recommend having the device inspected by an authorised service technician annually.

6.3 Cleaning and disinfection
The Haag-Streit slit lamps and their accessories can, if required, be carefully wiped down with ready-for-use disposable 70% ethanol disinfectant wipes. Surface-friendly disinfectants (containing or not containing aldehyde) are also permitted, such as Kohrsolin FF.

**WARNING!**
- Do not use sprays
- Observe the manufacturer’s safety instructions
- Do not use any cloths that might drip.
- Wring out any soaked cloths completely before use wherever necessary
- Ensure that no liquid penetrates into the device
- Comply with the stipulated exposure time

**NOTE!**
- IP code: IPX0 (device is not protected against liquids)

A. Appendix

A.1 Accessories / consumables / spare parts / upgrade

<table>
<thead>
<tr>
<th>Component</th>
<th>REF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pin for chin rest</td>
<td>1200713</td>
</tr>
<tr>
<td>Eye cover</td>
<td>1400113</td>
</tr>
<tr>
<td>Headrest base plate, small</td>
<td>7200163</td>
</tr>
<tr>
<td>Adapter for the headrest assembly RAL 9006</td>
<td>7220691</td>
</tr>
<tr>
<td>Adapter for the headrest assembly RAL 7035</td>
<td>7220692</td>
</tr>
<tr>
<td>Packet with chin rest paper</td>
<td>7220756</td>
</tr>
</tbody>
</table>

B. Legal regulations
- The Haag-Streit headrest has been designed and constructed according to EN 60601-1 and EN 60601-1-2 standards.
- The EN ISO 60601-1 standard must be observed when using different medical and/or non-medical electrical devices in combination.
- Compliance of the Haag-Streit headrest with the directive 93/42/EEC is confirmed by the CE marking.
- You can request a copy of the declaration of conformity for this instrument from Haag-Streit at any time.
- Statutory accident prevention regulations are to be observed.

**WARNING!**
The Haag-Streit head rest may only be used in an environment where the standard values as per EN 60601-1 are complied with.

C. Classification

- Standard EN 60601-1: Accessory for slit lamps
- Applied part: Type B
- Operating mode: Continuous operation
- CE Directive 93/42/EEC: Class I
- FDA: Accessory for slit lamps

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 60601-1-2
- EN ISO 10993-1
F. Information and manufacturer's declaration concerning electromagnetic compatibility (EMC)

The EMC tables in the instruction manuals for the main devices in question are relevant for head rests which contain a fixation lamp or main lamp cable.

**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.
Should you have any further questions, please contact your Haag-Streit representative at:
http://www.haag-streit.com/contact/contact-your-distributor.html