



INSTRUCTIONS FOR USE
Biometer

Lenstar LS 900[®]

15. Edition / 2022 – 09



INSTRUCTIONS FOR USE

Biometer

Lenstar LS 900®

15. Edition / 2022 – 09

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	• 2 Intended purpose / intended use	9
◦ 1.1 Comments on these instructions for use	4	◦ 2.1 Device description	9
◦ 1.2 Ambient conditions	4	▪ 2.1.1 Intended users	10
◦ 1.3 Shipment and unpacking	4	◦ 2.2 Medical purpose	10
◦ 1.4 Installation warnings	4	▪ 2.2.1 Indications	10
◦ 1.5 Operation, environment	5	▪ 2.2.2 Part of the body	10
◦ 1.6 Plausibility of the measurements	6	▪ 2.2.3 Patient population	10
◦ 1.7 IOL calculation	7	▪ 2.2.4 Contraindications	10
▪ 1.7.1 References	7	◦ 2.3 Principles of operation	10
◦ 1.8 IOL constants	7	▪ 2.3.1 Operating environment	10
▪ 1.8.1 IOL constants derived using data from an immersion ultrasound biometer	8	◦ 2.4 Clinical benefit	10
▪ 1.8.2 IOL constants derived from data from a contact ultrasound biometer	8	• 3 Introduction	11
◦ 1.9 Optical radiation	8	◦ 3.1 Basic construction	11
◦ 1.10 Disinfection	8	◦ 3.2 Examination components	11
◦ 1.11 Warranty and product liability	8	◦ 3.3 Control component (PC)	12
◦ 1.12 Reporting obligation	8	◦ 3.4 Instrument table (option)	12
◦ 1.13 Description of symbols	9		

• 4 Device assembly / installation	12
◦ 4.1 Computer connection	12
◦ 4.2 Installing a short forehead band when using the optional T-Cone	12
• 5 Operation	13
◦ 5.1 Position of patient during measurement	13
◦ 5.2 Measuring with Lenstar APS (optional)	13
◦ 5.3 Optional T-Cone	13
▪ 5.3.1 Fitting the optional T-Cone	13
▪ 5.3.2 Measuring with the optional T-Cone	14
▪ 5.3.3 Removing the optional T-Cone	14
◦ 5.4 Fixation	14
◦ 5.5 Measured variables	15
▪ 5.5.1 A-Scan	15
▪ 5.5.2 Keratometry	15
▪ 5.5.3 White-to-white distance	15
▪ 5.5.4 Pupilometry & visual axis	15
• 6 Commissioning	16
◦ 6.1 Switching on the device	16
◦ 6.2 Switching off the device	16
• 7 Technical data	16
◦ 7.1 Weight	16
◦ 7.2 Power supply	16
▪ 7.2.1 Primary side	16
▪ 7.2.2 Secondary side	16
◦ 7.3 Illumination modalities	17
▪ 7.3.1 Eye length measurement (A-Scan) and central fixation	17
▪ 7.3.2 Keratometry	17
▪ 7.3.3 Illumination	17
▪ 7.3.4 Positioning aid (from serial number 2000)	17
◦ 7.4 Measured variables Lenstar LS 900	17
▪ 7.4.1 Central corneal thickness (CCT)	17
▪ 7.4.2 Anterior chamber depth (ACD)	17
▪ 7.4.3 Lens thickness (LT)	17
▪ 7.4.4 Axial length (AL)	17
▪ 7.4.5 Keratometry (R)	17
▪ 7.4.6 White-to-white distance (WTW)	17
▪ 7.4.7 Pupilometry	18
▪ 7.4.8 Study design	18
◦ 7.5 Technical data of T-Cone (option)	19
▪ 7.5.1 Normative considerations	19
▪ 7.5.2 Measuring accuracy	19
▪ 7.5.3 Reproducibility	19
• 8 Software / Help menu / Error messages	19
• 9 Maintenance	20
◦ 9.1 Function check / nullification	20
◦ 9.2 Cleaning and disinfection	20
▪ 9.2.1 Device in general	20

▪ 9.2.2 Applied parts	20
▪ 9.2.3 Tools	20
◦ 9.3 Dust cover	20
• 10 Appendix	21
◦ 10.1 Accessories / consumables / spare parts / upgrade	21
◦ 10.2 Legal regulations	21
◦ 10.3 Classification	21
▪ 10.3.1 Lenstar LS 900	21
▪ 10.3.2 T-Cone (option)	21
◦ 10.4 Disposal	22
◦ 10.5 Observed standards	22
◦ 10.6 Information and manufacturer's declaration concerning electromagnetic compatibility (EMC) (EMC-Tabellen angepasst gemäss Testbericht.)	22
▪ 10.6.1 General	22
▪ 10.6.2 Emitted interference	23
▪ 10.6.3 Electromagnetic immunity environment tested (part 1)	24
▪ 10.6.4 Electromagnetic immunity environment tested (part 2)	25
▪ 10.6.5 Recommended separation distances between portable and mobile RF communications equipment and this product	27

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.
- Only use the original packaging material for moving the device.

1.4 Installation warnings



WARNING!

- Only use a Haag-Streit approved external medical power supply (EN 60601-1).
- The plug, cable and socket must function perfectly.
- Before carrying out maintenance or cleaning and disinfection work, the device must always be disconnected from the mains by unplugging the power supply or plug.
- Computers and further ancillary devices (printers, etc.) must comply with the EN 60601-1 standard, or be connected with galvanic isolation to external networks (isolating transformer, galvanic Ethernet isolator, etc.).
- For connection to PC, use only the supplied USB cable (2 m).
- The power supply must be positioned in such a way that proper heat dispersion is guaranteed.
- The device should be set up in such a way that the plug is always easily accessible and the device can easily be disconnected from the mains.
- 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.

cluding cables specified by Haag-Streit. Otherwise, degradation of the performance of this device could result.

1.5 Operation, environment



DANGER!

- It is not permitted to make modifications to the measuring device.
- It is expressly forbidden to open the device.
- Never use the device in potentially explosive environments where volatile solvents (alcohol, petrol, etc.) and flammable anaesthetics are in use.



WARNING!

- 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.
- Only staff trained and experienced in the assessment of measuring data and calculations and the manual entry, editing and deletion of data may examine patients, operate the device and interpret results.
- 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.
- Measurements can be carried out with dilated or undilated pupils. Dilatation of the pupil only influences measurement of the pupil diameter (pupillometry).
- We recommend checking the calibration of the optional T-Cone when fitting it and repeating this if necessary (see chapter 'Function check').
- 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, in-



NOTE!

- This device may only be used in accordance with the instructions in the 'Intended purpose / intended use' chapter.
- Installation only by trained specialists.
- The PC on which the EyeSuite software is installed may not contain any other software which could restrict the correct operation of EyeSuite.
- Please switch the computer off if it is not to be used for a long time.
- The device may not be transported, stored, handled or operated outside the specified ambient conditions (see chapter 'Ambient conditions').
- The device is to be used in a room in the medical area with attenuated light.
- If the device or accessories to it are exposed to the effects of an external force (e.g., by being accidentally knocked or dropped), this sensitive measuring device must be promptly checked according to chapter 'Function check' and, if necessary, returned to the factory for repair.
- If the device is moved/transported, a functional check must be performed in accordance with chapter 'Function check'.
- Perform a nullification and function check when prompted by the software.
- The selected measuring mode must be checked before every measurement.
- 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.
- The manufacturer of the device is not liable for loss or damage due to unauthorised handling of the same. All warranty claims arising in this case are null and void.
- Always remove the dust cover before switching the device on. The device may otherwise become damaged due to overheating. Like-

wise, make sure that the device is switched off before attaching the dust cover.

- Repairs may only be conducted by suitably trained and authorised specialist personnel. Incorrect repairs can pose considerable risks for operating staff and patients.
- Only original spare parts and original accessories may be used for repairs.
- The software must be installed by trained personnel.
- The optional T-Cone may only be used with the Lenstar.
- The optional T-Cone may only be used with Lenstar devices with a serial number of ≥ 2000 or Lenstar devices converted to white light illumination.
- The optional T-Cone must be checked for damage before use.
- The optional T-Cone must not be exposed to strong direct sunlight.
- If unexpected disturbances are observed which manifest themselves as communication problems between LS 900 and EyeSuite software, the cause could be a cell phone or radio frequency telephone in the immediate vicinity to the LS 900 or its power supply. Increase the distance to the device until the interference disappears.
- The communication between LS 900 and PC may be interrupted, if the device is exposed to a mains power supply delivering excessively transient disturbances or short voltage interruptions. If this happens, the PC needs to be restarted and the measurement has to be repeated.

1.6 Plausibility of the measurements



WARNING!

- Users must check measurement readings for plausibility. This includes the checking of the A-scan and the cursors, which automatically adjust to the signal, the keratometry values, the white-to-white distance and the pupillometry, whenever one of the measurements displays an unusually high standard deviation. The operator must also take into account the type (e.g., posterior subcapsular cataract) and density of the cataract when evaluating plausibility.

- Prior to the measurement, the user must verify that the patient is not wearing contact lenses. Wearing contact lenses will result in erroneous measuring results.
- It may not be possible, under certain circumstances, to carry out measurements on persons with fixation problems.
- In cases of thick cataracts and uncertain measurement of the axial length, ultrasound biometry should be performed as a control examination.
- Dense lenticular opacities may make it impossible to measure the axial eye length and lens thickness.
- Pronounced opacities of the central cornea can likewise make it impossible to measure corneal thickness, anterior chamber depth, lens thickness or axial eye length.
- Blood in the vitreous may make it impossible to measure the axial eye length.
- Keratometry may be erroneous in eyes that have undergone keratorefractive surgery because such eyes may significantly deviate from spherical surfaces.
- The user should make a visual check when carrying out the measurement procedure, to ensure that all light spots are present.
- If the device repeatedly generates error messages, stop using it and contact the customer service.
- You are recommended always to examine both of the patient's eyes five times. The user should subject the measurement readings to extra scrutiny if there is a notable difference between the right and left eye. The following are classed as notable differences:
 - More than 1 D with respect to central corneal refractive power $\Rightarrow$ 0.18 mm difference with respect to the corneal curvature radius
 - More than 0.3 mm with respect to axial eye length
 - More than 1 D with respect to emmetropic IOL refractive power
- The user must check the A-Scan when measuring anterior chamber depth in pseudophakic mode. If only one IOL signal is visible, it is not clear whether this signal relates to the front or back of the IOL. Uncertainty in this case can lead to the displayed reading for anterior

or chamber depth being inaccurate by the thickness of the IOL (approx. ± 1 mm).

- The measured corneal thickness is not intended as a basis for the correction of intraocular pressure readings for diagnosing glaucoma.
- An excessively tilted or decentered IOL may make it impossible to measure the anterior chamber depth, lens thickness and aqueous depth.
- Measurement readings obtained from patients with a non-intact cornea (e.g., due to a corneal transplant, corneal opacity or corneal scarring, etc.) may possibly be inaccurate (this applies to keratometry in particular), and the user should check the data for plausibility.
- Ambient light has an impact on pupil-diameter measurement readings. The user is responsible for ensuring the correct level of ambient light when carrying out pupillometry. The device does not monitor ambient light, so do not use pupillometry as the decisive factor when considering kerato-refractive surgery.
- Keratometry may not be accurate in eyes with keratoconus, and so the user must verify its plausibility.
- The user must verify that the eye assignment (OD, OS) is correct for the measured eye.
- The white-to-white distance reading is merely an indirect measurement of the inner lateral dimensions of the anterior ocular section. It therefore provides only approximate indications of the actual inner lateral dimensions of the anterior ocular section and of the size of the implant used.
- The measured results of patients with asteroid hyalosis may not be accurate (in particular the axial length measurement) and must therefore be verified by the user in terms of their plausibility.
- If the optional T-Cone is used, the user should verify the even illumination of the cone.

1.7 IOL calculation

The measurements taken with the LS 900 are a central element of every IOL calculation. A further important parameter in calculating the lens to be implanted is the IOL constant. When using the Lenstar LS 900, only IOL constants optimised for op-

tical biometers should be used. Please contact your IOL manufacturer for information on optimised IOL constants for optical biometry. An alternative source of information for IOL constants optimised for optical biometry is the website of the 'User Group for Laser Interference Biometry' (ULIB) at the University of Wuerzburg, Germany. Even though the constants published there have been optimised for a different optical biometer, published data [1, 2, 3] indicate that these IOL constants can also be used for calculating IOL power with the Lenstar. Downloadable IOL Constants files for the Lenstar, featuring the ULIB IOL-Constants for the Haigis, Hoffer Q, Halladay I, SRK/T and SRK II - Formulae as well as IOL Constants for the use with the Olsen Formula are available in the Key-User section of the Haag-Streit homepage.

To further improve the clinical result, Haag-Streit recommends that every surgeon creates personally optimised IOL constants based on pre-operative measurement data generated with the Lenstar and reliable postoperative data (e.g., 3 months after the operation).

1.7.1 References

- [1] Buckhurst P J, Wolffsohn J S, Shah S, Naroo S A, Davies L N, Berrow E J, 'A new optical low coherence reflectometry device for ocular biometry in cataract patients', British Journal of Ophthalmology 2009;93:949-953
- [2] Holzer M P, Mamusa M, Auffarth G U, 'Accuracy of a new partial coherence interferometry analyser for biometric measurements', British Journal of Ophthalmology 2009;93:807-810
- [3] Rohrer K, Frueh B E, Wälti R, Clemetson I A, Tappeiner C, Goldblum D, 'Comparison and Evaluation of Ocular Biometry Using a New Noncontact Optical Low-Coherence Reflectometer', Ophthalmology 2009, 116:2087-2092

1.8 IOL constants

Haag-Streit recommends using personalised IOL constants to achieve maximum prediction accuracy of the IOL calculation. Using personalised IOL constants minimises the effects of individual surgical techniques, individual measurement and surgical equipment and individual physiological differences in the patient cohort under treatment on the IOL calculation.



WARNING:

It is the user's responsibility to use correct values of personalised IOL constants.

1.8.1 IOL constants derived using data from an immersion ultrasound biometer

If there are optimised IOL constants available from an immersion ultrasound biometer, they may be used as a starting point for further optimisation of IOL calculation with the Lenstar. Differences in IOL calculation may still occur, as the keratometry data are collected in different ways. The 'User Group for Laser Interference Biometry' (ULIB) at the University of Würzburg, Germany has published on its website a manual explaining how to correct the effect of keratometry on the IOL constants. Still, the IOL constants acquired in this way should only be used as a starting point for further optimisation/personalisation.

1.8.2 IOL constants derived from data from a contact ultrasound biometer

If there are optimised IOL constants available based on data from a contact ultrasound biometer, they must be stringently recalculated for use with the Lenstar. The 'User Group for Laser Interference Biometry' (ULIB) at the University of Würzburg, Germany has published on its website a manual explaining how to correct the effect of ultrasound biometry and keratometry on the IOL constants. Constants acquired in such a way should only be used as a starting point for further optimisation/personalisation.

1.9 Optical radiation



WARNING:

The light emitted from this device is potentially hazardous. The greater the number of examinations, the greater is the risk of ocular damage. Exposure to light from this device may exceed the recommended maximum exposure (RME) of 2.2 J/cm², if more than 100 individual measurements are performed per day and per patient's eye.



NOTE!

In accordance with EN 60825-1, the limiting values for class 1 lasers are respected when the device is used in the defined manner. The device complies with the limit values for risk group 1 in accordance with EN 62471 insofar as no more than 100 individual measurements are performed per day and per patient's eye with dilated pupil. If this limit value

of 100 individual measurements is exceeded, the patient's eye may be damaged by the white illumination. (Radiance 1800 Wm⁻² sr⁻¹)

1.10 Disinfection



NOTE!

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

1.11 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.
- The optional T-Cone must be stored in its original dust cover and protected from direct sunlight.
- For USA only: This product is covered by a limited warranty, which may be reviewed at www.haag-streit-usa.com.

1.12 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.

1.13 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



Alternating current



Direct current

IP20

Housing protection

2 Intended purpose / intended use

The LENSTAR LS 900 is a non-invasive, non-contact OLCR (optical low-coherence reflectometry) biometer used for obtaining ocular measurements and performing calculations to assist in the determination of the appropriate power and type of IOL (intraocular lens) for implantation after removal of the natural crystalline lens. The LS 900 measures:

- Axial eye length
- Corneal thickness
- Anterior chamber depth
- Aqueous depth
- Lens thickness
- Corneal curvature
- Radii for flat and steep meridian
- Axis of the flat meridian
- White-to-white distance
- Pupil diameter

2.1 Device description

The Lenstar LS 900 is a non-contact device for measurement of biometrical parameters of the eye, aimed to assist the calculation of intraocular lenses (IOLs) before intraocular lens implantation. The most common application is the preparation of cataract surgery.

This device uses OLCR (optical low-coherence reflectometry), an interferometric method to measure intraocular axial distances. Furthermore, it uses digital photography of the anterior section of the eye to measure pupil size and location and the white-to-white distance of the eye. In conjunction with a specific illumination pattern, the same photographic unit is used to measure the corneal curvature – this measurement is known as keratometry.

A supplementary measurement mode is available with the T-cone configuration, which allows measuring corneal curvature data on more locations than otherwise possible. This corneal topography measurement mode uses a Placido cone, a cone-shaped attachment to illuminate the cornea with a modified (ring-shaped) light pattern and provides adapted analysis functionality in the device software. An optional automated positioning system (APS) is available for Lenstar LS 900, providing hybrid positioning of the measurement head.

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 biometry 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 purpose:

- Investigation of the anatomy of the eye.

2.2.1 Indications

The use of this device is indicated for the following medical conditions:

- Cataracts
- Corneal irregularities
- Refractive errors

2.2.2 Part of the body

This device is intended for the examination 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 biometer 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.

2.2.4 Contraindications

There are no known contraindications.

2.3 Principles of operation

- The device uses contact-less measurement technologies: OLCR interferometry to measure biometry data along the visual axis (A-scan) and an integrated camera with dedicated illumination for keratometry, iris and pupil measurements.
- The optional T-cone illuminates the patient's eye with placido rings to measure anterior corneal topography. It is designed as a non-electrical part and uses the camera illumination source.

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.

2.4 Clinical benefit

Anatomical measurements of the eyes serve as basis of information for any medical condition related to the divergence of these measurements from known standards. Such measurements are well known to be paramount for intra-ocular lens (IOL) power calculations to achieve optimal postoperative outcomes. Both cataract and refractive surgery patients benefit from the refined IOL calculations.

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

3 Introduction

3.1 Basic construction

The system is divided into two parts: one concerned with examination (LS 900) and the other with control (Notebook, PC). The examination part communicates via a USB connection with the external PC. The LS 900 is operated using the 'EyeSuite' software installed on the PC. Integral, automatic error recognition for measurements guarantees reliable examination results.

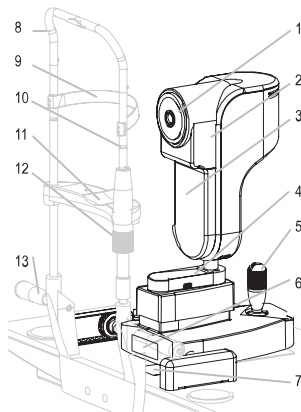
3.2 Examination components

Overview

1. Front ring
2. Housing
3. Service cover
4. Cable cover
5. Control lever
6. Type plate
7. Side identification sticker

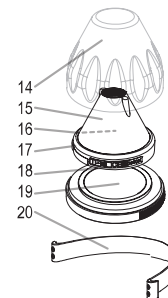
Headrest (option)

8. Headrest
9. Head band
10. Mark for optimum eye height
11. Chin rest
12. Chin rest height adjustment
13. Hand grips for patient



T-Cone (option)

14. Dust cover for storage packaging
15. T-Cone topography add-on
16. 'Top' – shows which side of the T-Cone is up
17. Locking/release clip
18. Type plate
19. Base plate for storage packaging
20. Short forehead band with four Phillips screws

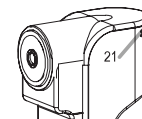


Device state

The device state indicator allows device monitoring without PC software:

21. State indicator

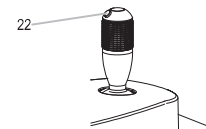
Dark	Off
Orange	Standby
Green	On
Blue	Light source on
RED	ERROR



Control lever

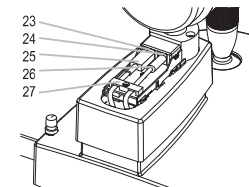
The joystick is used to position the device in relation to the patient's eye.

22. Trigger



Connections

23. USB-device connection
24. DC-device connection
25. USB 2.0 cable
26. DC cable
27. Cable tension compensator



3.3 Control component (PC)

A commercial PC is used as the control component for the biometer. (See chapter 'Installation Warnings').



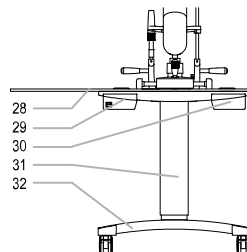
WARNING!

The software must be installed by trained personnel in accordance with the separate installation instructions. For further information, please contact your Haag-Streit representative.

3.4 Instrument table (option)

An adjustable instrument table (option) allows the height of the device to be set at a comfortable height for the individual patient.

- 28. Table top
- 29. Left-hand drawer (for external medical power supply) / Switch box SB01
- 30. Right-hand drawer (empty)
- 31. Elevator column (mechanical with spring)
- 32. Stand base with castors



4 Device assembly / installation



WARNING!

The device must be installed by trained personnel in accordance with the installation instructions provided in the separate service manual.

4.1 Computer connection



WARNING!

For connection to PC, only use the supplied USB cable (2 m)

- Connect the electric power supply cable. Integral mains components work with the voltages specified in section 'Technical data' under chapter 'Primary side'. It is not necessary to select the voltage on the device.

- If an instrument table HSM 901 (option) has been supplied, the power supply of the LS 900 can be connected to the Switchbox SB01 (left drawer). Use the instructions for use enclosed with the switchbox and the instrument table.

4.2 Installing a short forehead band when using the optional T-Cone

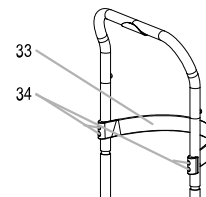


NOTE!

- If the Lenstar LS 900 biometer with the optional T-Cone topography add-on is used on an instrument table with a Haag-Streit headrest, the short forehead band delivered with the optional T-Cone must be used on the headrest for better measurability.
- If the Lenstar is operated without the optional T-Cone, the short forehead band does not need to be replaced with the long one.

- 33. Forehead band
- 34. Phillips screws

- Detach the forehead band by removing the four Phillips screws (34) using a size 1 Phillips screwdriver.
- Remove the forehead band (33).
- Insert the short forehead band (REF: 1021653) into the headrest and align the holes with the holes in the headrest.
- Attach the short forehead band using the four Phillips screws supplied.



5 Operation

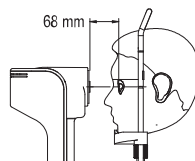
5.1 Position of patient during measurement



NOTE!

Prior to the measurement procedure, clean and disinfect the headrest (forehead band, chin rest shell and both handles) as described in the 'Maintenance' chapter.

Positioning of the device is done manually by the user. The patient must be positioned in such a way that the distance from the measuring head to the eye is approx. 68 mm. A steady head position is promoted by resting the patient's head in good contact with the chin rest and forehead band, and by the patient holding on to the handles supplied. This can positively influence adjustment time and measuring accuracy. The patient should sit up as straight as possible.



NOTE!

In order to get the best possible results, the patient should be requested to keep the eye as wide open as possible during the measurement and to focus on the measuring beam. Blinking is permitted, but should be kept to a minimum.

5.2 Measuring with Lenstar APS (optional)



WARNING!

The Lenstar APS (Automated Positioning System) device moves autonomously during the automated measurement process. To avoid trapping fingers, do not touch any moving parts during the measurement.



NOTE!

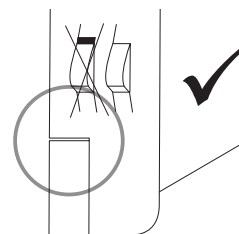
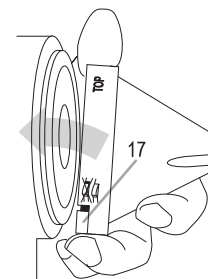
- Make sure that the Lenstar APS is free to move in any direction for optimum performance of the automated measurement process.

- Before using the Lenstar APS, ensure that the cross slide fixation screw is unlocked.

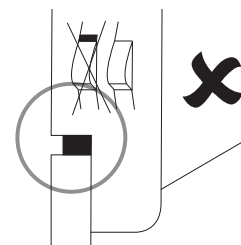
5.3 Optional T-Cone

5.3.1 Fitting the optional T-Cone

- Remove the dust cover from the storage packaging.
- Hold the T-Cone with the locking clip (17) pressed down next to the metal ring and fit it on the front ring of the Lenstar as shown on the illustration.
- Keep the locking clip depressed so that the T-Cone lies flush with the front ring. Make sure that 'TOP' on the metal ring of the T-Cone is at the top. The T-Cone is held in place on the front ring of the Lenstar LS 900 biometer by strong magnets.
- Ensure that the red safety mark is no longer visible on the locking clip. If the red safety mark is still visible, remove the T-Cone and fit it again.



The T-Cone is fitted correctly. The red safety mark is not visible.



The T-Cone is not fitted correctly. The red safety mark is visible. Please remove the T-Cone and fit it again.

**WARNING!**

- The T-Cone can only be used with the Lenstar with which it was calibrated. To use the T-Cone on another Lenstar or to use another T-Cone on a Lenstar with an already saved T-Cone calibration, the calibration must be performed again.
- The measuring distance from the T-Cone to the eye (apex) is approx. 6mm. Depending on the anatomy of the patient, the tip of the T-Cone may touch the eyelid or bridge of the nose. To avoid injuries, care must always be taken when moving the Lenstar with fitted T-Cone towards the patient.

**NOTE!**

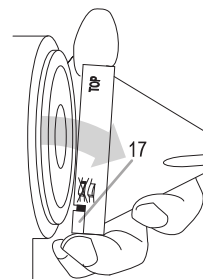
- When you use the T-Cone for the first time with the Lenstar LS 900 biometer, the software will prompt you to calibrate the T-Cone with the Lenstar LS 900 biometer. To do so, follow the software wizard and read the software operating instructions (F1 key).
- We recommend performing a test measurement every time the T-Cone is fitted and removed. The test measurement can be invoked in the software's biometry menu. To do so, follow the software wizard and read the software operating instructions (F1 key).

**NOTE!**

Ensure that the Lenstar / T-Cone is in the position furthest away from the patient before switching from the first eye to the second eye. This ensures that the T-Cone will not touch with the bridge of the patient's nose.

5.3.3 Removing the optional T-Cone

- Hold the T-Cone by the metal ring and press the locking clip (17). Now remove the T-Cone by tilting it off the front ring of the Lenstar as shown in the image.
- Place the T-Cone on the base plate of the storage packaging (19).
- Place the dust cover (14) on the base plate of the storage packaging (19) to protect the T-Cone from dust and dirt.



5.3.2 Measuring with the optional T-Cone

- Fit the T-Cone as described in chapter 'Fitting the optional T-Cone'.
- Prior to every measurement with a new patient, the tip of the T-Cone should be disinfected (see chapter 'Cleaning and disinfection'). Make sure the T-Cone is dry before measuring.
- Retract the Lenstar / T-Cone completely before positioning the patient in the headrest. Always start the measuring procedure with the Lenstar / T-Cone in the position furthest away from the patient.
- Explain to the patient that he should focus on the red, flashing light (measuring beam) in the centre of the T-Cone. The second eye (the one not being measured) can be covered with the eye patch on the optional headrest.
- Start the measuring procedure by pressing the button on the joystick and following the instructions on your PC screen. Detailed information on the measuring procedure can be found in the operating instructions for the software (F1 key).

5.4 Fixation

To obtain usable results, the patient must stare at the red fixation light in the measuring lens during measurement. If the patient has difficulty seeing the fixation light with the eye being measured, this can be remedied by fixing a remote object with the other eye.

5.5 Measured variables

5.5.1 A-Scan

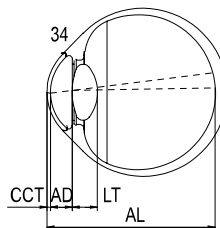
Depending on the patient's gaze at the fixation light, the optical path length of the visual axis is measured (34).

CCT: Central corneal thickness

AD: Aqueous depth (back of cornea to front of lens).

LT: Lens thickness

AL: Axial eye length (front of cornea to the inner limiting membrane).



NOTE!

Since the device measures up to the retinal pigmented epithelium, the reading displayed is adjusted to the internal limiting membrane, either automatically, as a function of axial length, or manually, according to the mode selected. (Manual correction is not available in the USA)

5.5.2 Keratometry

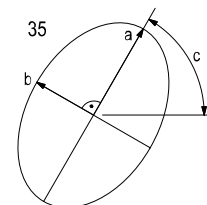
Keratometry is calculated through the position of 32 projected light reflections. Two rings, with sixteen measuring points on each eye are arranged in two rings with the following diameters:

(standard eye R=7.8 mm)	Outer measuring points:	2.3 mm
	Inner measuring points:	1.65 mm

For each measuring point, the equivalent of an ideal sphere is calculated.

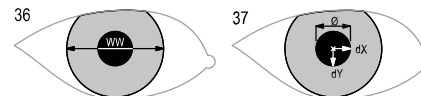
The values displayed (flat radius, steep radius) correspond to the radii of an ellipsoid that fits into the array of points. The axis of its rotation is measured counter-clockwise from the horizontal to the flat radius (35).

- a: Flat radius
- b: Steep radius
- c: Axis of rotation



5.5.3 White-to-white distance

The white-to-white distance (WTW) is determined using the image of the iris and the eye radii obtained from keratometry. The value displayed corresponds to the diameter of an ideal circle (36).



5.5.4 Pupillometry & visual axis

Pupil diameter ($\emptyset$) corresponds to the diameter of an ideal circle, with the smallest error perpendicular to the established pupil border. At the same time, the shift of visual axis towards the centre of the pupil is provided. The calculated dimensions are located on the theoretically derived level of the iris. The image enlargement achieved by the refraction of the eye is disregarded (37).

6 Commissioning

Power for the Lenstar LS 900 is supplied by a medical grade power supply which is provided with the device. Only use the power supply provided with the device.

6.1 Switching on the device

- Connect the power supply plug to the mains.
- Switch on the PC.
- Start the software on the PC.

6.2 Switching off the device

- Exit the software on the PC.
- Switch off the PC.
- Disconnect the power supply plug from the mains if you do not intend to use the device for an extended period of time.

7 Technical data

Type designation:	LS 900
Dimensions (W × D × H):	310 × 260 × 420 mm

7.1 Weight

Lenstar:	6.2 kg
Lenstar APS	6.6 kg

7.2 Power supply

Lenstar	FRIWO FW7401M/12:	REF: 1020392
	Globtek GTM96180-1117:	REF: 1023299
Lenstar APS	ICCN EXERGY, ELPAC POWER SYSTEMS,	
	Model: MWA030018B:	REF: 1022106

7.2.1 Primary side

Voltage:	100 – 240 V / 50 – 60 Hz
Current Lenstar FRIWO FW7401M/12:	310 mA
Current Lenstar Globtek GTM96180-1117:	600 mA
Current Lenstar APS:	800 mA

7.2.2 Secondary side

Lenstar	Voltage:	12 V ±5% ===
	Current:	1 A
Lenstar APS	Voltage:	18 V ±5% ===
	Current:	1.7 A

7.3 Illumination modalities

7.3.1 Eye length measurement (A-Scan) and central fixation

Light source:	Superluminescent diode
Wavelength:	820 nm
Power on patient's eye:	< 0.6 mW

7.3.2 Keratometry

Light source:	LED
Wavelength:	950 nm

7.3.3 Illumination

	Serial number of the system	
	Up to 1999*	From 2000
Light source:	LED	LED
Light colour:	Green	White

* Devices with a serial number < 1999 can be subsequently converted to white light illumination

7.3.4 Positioning aid (from serial number 2000)

Light source:	LED
Wavelength:	940 nm

7.4 Measured variables Lenstar LS 900

Measurement ranges are based on the 'Phakic' measurement mode.

7.4.1 Central corneal thickness (CCT)

Measurement range:	300 – 800 µm
Display resolution:	1 µm
In vivo repeatability (1 σ):	± 2.3 µm

7.4.2 Anterior chamber depth (ACD)

Measurement range:	1.5 – 6.5 mm
Display resolution:	0.01 mm
In vivo repeatability (1 σ):	± 0.04 mm

7.4.3 Lens thickness (LT)

Measurement range:	0.5 – 6.5 mm
Display resolution:	0.01 mm
In vivo repeatability (1 σ):	± 0.08 mm

7.4.4 Axial length (AL)

Measurement range:	14 – 32 mm
Display resolution:	0.01 mm
In vivo repeatability (1 σ):	± 0.035 mm

7.4.5 Keratometry (R)

Measurement range radius:	5 – 10.5 mm
Display resolution:	0.01 mm
In vivo repeatability (1 σ):	± 0.03 mm
Measuring area of axial angle:	0 – 180°
Display resolution:	1°
In vivo repeatability (1 σ):	$\pm 11^\circ$

7.4.6 White-to-white distance (WTW)

Measurement range:	7 – 16 mm
Display resolution:	0.01 mm
In vivo repeatability (1 σ):	± 0.04 mm

7.4.7 Pupillometry

Measurement range: 2 – 13 mm

Display resolution: 0.01 mm

The above mentioned measurement ranges correspond to the default setting for the automatic analysis.

The in vivo reproducibility was evaluated in a clinical study of cataract patients (see table 'All eyes' and table 'Special eyes')

1 σ = One standard deviation

7.4.8 Study design

- The clinical trial for deriving in vivo reproducibility was approved by the local ethics committee. The study was planned and conducted as a prospective, non-randomised comparative study.
- Two phases were scheduled in the approved study protocol. In the first phase, measurements of axial length (AL), central corneal thickness (CCT), anterior chamber depth (ACD), central lens thickness (LT), median corneal radius (R) and the axis position of the flat meridian (axis) were taken.
- The white-to-white distance (WTW) was measured in the second phase.
- A total of 144 eyes in 80 subjects were included in study phase 1 and a total of 40 eyes in 20 subjects in study phase 2.
- Subjects with different conditions of the anterior and posterior segment of the eye (cataract in different stages, pseudophakia with different IOLs, aphakia, silicone-oil fill) and subjects with healthy eyes were included in this clinical study. Data were analyzed for all eyes (see table 'All eyes') and for a subgroup of eyes with special health conditions (see table 'Special eyes'), with a complete set of 5 repeat measurements on both eyes of each subject.
- The special eyes group included eyes with one or more of the following conditions: pseudophakia, aphakia and silicone-oil fill.

Tab. 1: All eyes

[unit]	n	Mean _{grand}	SD _{repeat}	CV
AL [mm]	45 / 90	23.973	0.035	0.00145
CCT [μ m]	53 / 106	557.1	2.3	0.00407
ACD [mm]	34 / 68	3.19	0.04	0.01220

LT [mm]	27 / 54	4.56	0.08	0.01784
R [mm]	34 / 68	7.67	0.03	0.00396
Axis [°]	27 / 54	72	11	0.14191
WTW [mm]	9 / 18	12.27	0.04	0.00337

Tab. 2: Special eyes

[unit]	n	Mean _{grand}	SD _{repeat}	CV
AL [mm]	10 / 20	24.087	0.056	0.00234
CCT [μ m]	11 / 22	564.4	2.8	0.00496
ACD [mm]	5 / 10	7.75	0.03	0.00333
Axis [°]	3 / 6	80	13	0.16092

Abbreviations

n	Number of subjects / number of eyes
Mean _{grand}	Overall mean of results on all eyes
SD _{repeat}	Repeatability standard deviation
CV	Coefficient of variation
SD	Standard deviation
LT	Lens thickness
AL	Axial length
R	Corneal radius of curvature
CCT	Central corneal thickness
Axis	Axis of flat meridian
ACD	Anterior chamber depth
WTW	White-to-white distance

7.5 Technical data of T-Cone (option)

Type designation:	T-Cone
Weight:	0.2 kg
Diameter:	ø 84 mm
Placido rings:	11
Length:	63.5 mm
Covered optical zone:	≤ 6 mm

7.5.1 Normative considerations

- The T-Cone complies for the central and medial measuring zones with the standard EN ISO 19980 for corneal topography systems, type B. The T-Cone does not cover the peripheral measuring zone.
- The T-Cone complies for the central and medial measuring zones with the standard ANSI Z80.23 for corneal topography systems, type B. The T-Cone does not cover the peripheral measuring zone.

7.5.2 Measuring accuracy

Test surface (axial curvature difference in mm / elevation difference in µm)

	Central zone (Diameter ≤ 3 mm)			Middle zone (3 < Diameter ≤ 6 mm)		
	Mean value Curvature diff.	2 σ Curvature diff.	2 σ Elevation diff.	Mean value Curvature diff.	2 σ Curvature diff.	2 σ Elevation diff.
Toric (mm) R ₁ =7.987 R ₂ =7.584	0.006	0.065	0.66	0.004	0.044	0.33
Ellipsoid (mm) R=7.79 k=-0.255	0.001	0.083	0.78	0.020	0.038	1.51
Sphere 1 (mm) R=6.448	0.013	0.037	0.61	0.012	0.025	1.12
Sphere 2 (mm) R=7.804	-0.008	0.034	0.33	-0.008	0.026	0.75

Sphere 3 (mm) R=8.844	-0.017	0.056	0.46	-0.024	0.038	1.61
Sphere 4 (mm) R=10.501	-0.040	0.082	0.48	-0.069	0.044	0.58

2 σ = Two standard deviations

Sphere 1: ø11.5 mm

Toric, ellipsoid, sphere 2,3,4: ø14 mm

All surfaces: Precision ± <1 µm

Test surfaces were centred within ± 0.1 mm and their symmetry axes aligned within ± 0.5° with regard to their measuring axis.

7.5.3 Reproducibility

Human cornea (axial curvature difference, D / elevation difference, µm)

Central zone (Diameter ≤ 3 mm)			Middle zone (3 < Diameter ≤ 6 mm)		
Mean value	1 σ	2 σ	Mean value	1 σ	2 σ
-0.001 / -	0.38 / 0.66	0.76 / 1.31	-0.020 / -	0.36 / 3.22	0.72 / 6.45

n = 42 eyes

1 σ = One standard deviation

2 σ = Two standard deviations

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 the separate installation instructions.

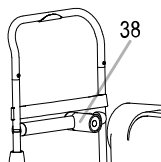
9 Maintenance

The LS 900 is practically maintenance-free and requires only minimum care to work for as long as possible to your complete satisfaction. However, we recommend instructing a service engineer to inspect the biometer periodically. Haag-Streit or your local agent will be happy to provide further information.

9.1 Function check / nullification

The inspection gauge (38) supplied with the device will assist the user in checking the proper functioning of the unit. The type plate with the serial number can be found on the rear of the gauge.

This check takes place for the first time when the device is commissioned. Subsequent test intervals (1 week) will be specified by the software (message displayed). For exact procedure see software instructions for use. Should the test be outside the tolerance limits, a software message appears and the unit must be taken out of use. Notify your Haag-Streit customer support centre.



9.2 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.
- The T-Cone must never be immersed in cleaning fluid or disinfectant.

9.2.1 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).

9.2.2 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 measurement with a new patient.

- Headrest (forehead band, chin rest shell and both handles)
- T-Cone

9.2.3 Tools

Use the following tools for cleaning and disinfection operations:

- Cleaning/disinfecting towel: Commercially available soft and lint-free cleaning towel
- 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.

9.3 Dust cover

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



WARNING!

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

10 Appendix

10.1 Accessories / consumables / spare parts / upgrade

Components	REF
Dust cover, small	1001395
Phillips screws for forehead band (4 pcs)	1005072 1023406
Checking gauge (replacement)	1021124
Short forehead band	1021653
Dust cover for storage packaging of T cone	1021665
Base plate for storage packaging of T-Cone	1021666
Eye patch	1400113
Base Plate small with Pivot	7200162
Base Plate small for headrest 7220477	7200163
T-Cone (without Toric Planner) only for use with the Eyesuite IOL Toric Planner installed	7220384
EyeSuite IOL Toric Planner	7220396
T-Cone Toric Platform	7220397
Headrest (LS 900)	7220477
Set of table fittings LS 900 APS	7220750
Pad of chin rest papers	7220756
Mains cable EU	7220760
Mains cable USA	7220761
Mains cable UK	7220762
Upgrade Kit LS 900	7225044
Headrest	Please refer to the instructions for use of headrest

10.2 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 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.

10.3 Classification

10.3.1 Lenstar LS 900

EN 60601-1	Continuous operation
EN 60825-1	Laser class I
EN 60529	Enclosure protection IP20
EN 62471	Risk group 1
EN ISO 15004-2	Group 2
EU 2017/745 (Medical Device Regulation)	Class IIa
FDA	Class II

10.3.2 T-Cone (option)

EN ISO 19980	Corneal topograph, type B
ANSI Z80.23	Corneal topograph, type B
EU 2017/745 (Medical Device Regulation)	Class IIa
FDA	Class II

10.4 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.



10.5 Observed standards

EN 60601-1	EN ISO 15004-1
EN 60601-1-2	EN ISO 15004-2
EN 62471	EN ISO 10343
EN 60825-1	EN ISO 22665
EN 60529	EN ISO 19980
ANSI Z80.23	ANSI Z80.36

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

10.6.1 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 electro-

magnetic 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 system like joystick or metallic parts on the instrument base may influence the device.
- The communication between the Lenstar 900 and the PC could be interrupted; this requires a restart of the EyeSuite software and a repetition of the investigation.

10.6.2 Emitted interference

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

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

P_{st} : Power short term flicker

P_{lt} : Power long term flicker

10.6.3 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
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV, 100kHz for power supply lines * ± 1 kV, 100 kHz for input/output lines *	± 2 kV, 100kHz for power supply lines * ± 0.5, ± 1 kV, 100 kHz for input/output lines *	Mains power quality should be that of a typical commercial or hospital environment. * Not applicable for DC and I/O if cable < 3 m.
Surge IEC 61000-4-5	± 0.5, ± 1 kV line(s) to line(s) * ± 0.5, ± 1, ± 2 kV line(s) to earth *	± 1 kV line(s) to line(s) * ± 0.5, ± 1, ± 2 kV line(s) to earth *	Mains power quality should be that of a typical commercial or hospital environment. * Not applicable for DC and I/O if cable < 3 m.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT: 1 cycle at 0° 0% UT: 250/300 cycles at 0° 70% UT: 25/30 cycles at 0°	0% UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT: 1 cycle at 0° 0% UT: 250/300 cycles at 0° 70% UT: 25/30 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or battery. UT is the a.c. mains voltage (100 – 240 V) prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

10.6.4 Electromagnetic immunity environment tested (part 2)

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

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

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

28 V/m
2400 – 2570 MHz
50% PM 217 Hz
9 V/m
5100 – 5800 MHz
50% PM 217 Hz

28 V/m
2400 – 2570 MHz
50% PM 217 Hz
9 V/m
5100 – 5800 MHz
50% PM 217 Hz

GSM 1800/1900: max 2 W
CDMA 1900: max 2 W
DECT: max 2 W
LTE Band 1, 3, 4, 25: max 2 W
UMTS: max 2 W
Bluetooth: max 2 W
WLAN 802.11b/g/n: max 2 W
RFID 2450: max 2 W
LTE Band 7: max 2 W
WLAN 802.11 a/n: max 0.2 W

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



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

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

10.6.5 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.

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

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

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

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

** Formulas coming from Edition 3 of the IEC 60601-1-2.

Should you have any further questions, please contact your Haag-Streit representative at:
www.haag-streit.com/haag-streit-group/contact/haag-streit-distributors/distributors



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