Science **made** smarter

Instructions for Use - US

Sera™



8503349 / D-0113323-E – 2020/08

Interacoustics

Table of contents

1 Introduction 1
1.1. About this manual 1
1.2. Intended use 1
1.3. Contraindications 1
1.4. Product description 2
1.5 Clinical benefit 3
1.6 Warnings 3
1.7 Safety features and complaint handling 4
1.7.1 Complaints/safety reporting 4

2 Safety precautions 5
General 5
2.1 Cautions - general 5
2.2 Environmental factors 6
2.3 Electrical and electrostatic safety 6
2.4 Electromagnetic compatibility (EMC) 6
2.5 Explosion hazards 6
2.6 Use in home healthcare environment 6
2.7 Measuring security and clinical benefit 7
2.8 Miscellaneous 7
2.9 Use of equipment after transport and storage 7

3 Unpacking and installation 9
3.5 Unpacking and inspection 9
3.6 Markings 10
3.7 Installing the cradle 12
3.8 Installing the HM-E200 label printer (optional) 13
3.8.1 Battery charging 13
3.8.2 Installing label paper in the printer 13
3.8.3 Turning the printer on and off 13
3.8.4 Connecting the wireless printer to the Sera™ 14
3.8.5 Printer offline 14
3.9 The Sera™ hardware 15
3.10 Connecting the probe cable to the Sera™ 16
3.11 Connecting transducers to the preamplifier 16
3.12 Connecting the electrode cables to the preamplifier 16
3.13 Use of the IP30 transducer with ear tips or EarCups (ABRIS only) 17
3.14 Connecting to the optional pass-checker 17
3.15 Transducers and calibration 18
3.16 Charging and powering Sera™ 19
3.16.1 The battery 19
3.16.2 Battery lifetime and charging time 19
3.16.3 Indication lights on Sera™ 20
3.17 HearSIM™ software bundle 21
3.18 Licenses 21
3.18.1 Adding a new license to Sera™ 21
3.19 Updating the firmware 21

4 Operating instructions 23
4.5 General precautions 23
4.6 Switching the Sera™ on and off 24
4.7 Testing during charging 24
4.8 Battery charge status indicator 24
4.9 Sera™ operation and button overview 25
4.9.1 The Sera™ screen format 25

4.9.2 Common function buttons 26
4.9.3 Keyboards (special characters) 26
4.9.4 Home screen 28
4.9.5 Adding a new patient 28
4.9.6 Patient ID conflict 29
4.9.7 Selecting from the patient list 30
4.10 General test information 31
4.10.1 Patient preparation – Automated ABR testing 31
4.10.2 Patient preparation – OAE testing 31
4.10.3 Handling and selection of ear tips 31
4.10.4 Use of EarCups 32
4.10.5 Starting a test 32
4.10.6 Select test type 33
4.10.7 Test-related field entry 33
4.10.8 Screening result symbols 34
4.10.9 Stop reason for incomplete test 34
4.10.10 Printing after testing 35
4.11 Automated ABR testing 36
4.11.1 Automated ABR initial test screen 36
4.11.2 Impedance check screen 37
4.11.3 Automated ABR measurement screen 38
4.11.3.1 Noise bar 38
4.11.3.1 Time bar 39
4.11.3.2 Test done screen 39
4.12 OAE testing 41
4.12.1 OAE initial test screen 41
4.12.2 Probe check screen 42
4.12.3 OAE measurement screen 44
4.12.3.1 Probe stability bar 45
4.12.3.2 Noise bar 45
4.12.3.3 Time bar 46
4.12.4 Test done screen 46
4.12.4.1 Probe stability % (DPOAE only) 49
4.12.4.2 Stimulus stability % (TEOAE only) 49
4.12.4.3 Artifact % 49
4.12.4.4 Time 49
4.13 Quick test 50
4.13.1 General 50
4.13.2 Saving a quick test 50
4.14 Printing 51
4.14.1 Ways of printing 51
4.14.2 Label print format 51
4.15 Reviewing patients and saved sessions 52
4.15.1 Select patient 52
4.15.2 Search for a patient 52
4.15.3 Test button 52
4.15.4 View saved tests 52
4.15.4.1 Printing a saved test 53
4.15.5 Reviewing a saved test 53
4.16 User management on device 54
4.16.1 General 54
4.16.2 Selecting the user (optional) 54
4.16.3 Entering the password 54
4.16.4 Incorrect password 55
4.17 Setup 56
4.17.1 Language screen 56
4.17.2 Device 56
4.17.3 Sound 57
4.17.4 Printer 57

4.17.5 About 58

5 Equipment (integrity) checks 59
5.5 General 59
5.6 Pass-checker for automated ABR (optional) 59
5.7 Probe integrity test for TEOAE 61
5.8 Probe integrity test for DPOAE 62

6 Maintenance 63
6.5 General maintenance procedures 63
6.6 General maintenance procedures 63
6.7 Cleaning the Sera™ 64
6.7.1 Touch screen 64
6.7.2 Case, cradle and cables 64
6.7.3 Disposables 64
6.8 Cleaning the OWA probe tip 65
6.9 Cleaning the SnapPROBE™ 67
6.10 Accessories/replacement parts 67
6.11 Repair 68
6.12 Warranty 68

7 General technical specification 69
7.1 Sera™ instrument – technical specifications 69
7.2 Specification of input/output connections 73
7.3 Calibration reference values for the CE-Chirp® stimulus 74
7.4 Calibration reference values for the click stimulus 74
7.5 Coupler types used for calibration 74
7.6 General information about specifications 75
7.7 Appendix A: Stimulus 75
7.8 Appendix B: Electromagnetic Compatibility (EMC) 76

Introduction

1.1. About this manual

This manual is valid for Sera™ version 1.2. This product is manufactured by:

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
Denmark
Tel.: +45 6371 3555
Fax: +45 6371 3522
E-mail: info@interacoustics.com
Web: www.interacoustics.com

Instructions for Use/Additional information:
'Instructions for use' contains all the information required to operate this system in a safe and effective manner but the **'Additional information'** guide is also available to the interested reader. The operator can refer to these manuals on the manufacture's official website.

1.2. Intended use

The Sera™ with DPOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Sera™ with DPOAE includes all ages.

The Sera™ with TEOAE is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Sera™ with TEOAE includes all ages.

The Sera™ with ABRIS is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for Sera™ with ABRIS is newborns.

The Sera™ System is to be used by trained personnel only, such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted. The Sera™ is intended in a hospital, clinic, healthcare facility or other suitable quiet environment.

1.3. Contraindications

Contraindications to testing include outer ear surgery, recent stapedectomy, a discharging ear, acute external auditory canal trauma, discomfort (e.g, severe otitis externa) or occlusion of the external auditory canal or wounds. Testing should not be performed on patients with such symptoms without a medical doctor's approval.

For US only: Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a licensed medical practitioner.

1.4. Product description

The Sera™ is a multifunctional handheld screening device that can perform and record the following test types depending on the licenses installed:

- Distortion Product Otoacoustic Emissions (DPOAE)
- Transient Evoked Otoacoustic Emissions (TEOAE)
- Automated Auditory Brainstem Responses (ABRIS)

Available configurations are:

- Sera™ with ABRIS
- Sera™ with ABRIS and Transient Evoked Otoacoustic Emissions (TEOAE)
- Sera™ with ABRIS and Distortion Product Otoacoustic Emissions (DPOAE)
- Sera™ with ABRIS, Transient Evoked Otoacoustic Emissions (TEOAE) and Distortion Product Otoacoustic Emissions (DPOAE)

License configurations can be added even after the device has been purchased and taken into use. Refer to section 3.14 Licenses for more information.

The Sera™ operates with different transducers and cable configurations. The table below shows which transducers and cable configurations are possible for use with the Sera™.

TRANSDUCER / CABLE CONFIGURATION	DPOAE	TEOAE	ABRIS
SnapPROBE™ directly connected to Sera™	Yes	Yes	No
OWA Probe directly connected to Sera™	Yes	Yes	No
SnapPROBE™ and OWA Probe directly connected to Preamplifier cable	Yes	Yes	Yes
IP30 directly connected to Preamplifier cable	No	No	Yes

The system consists of the following included and optional parts:

Standard Components, General	Configurations	
	ABRIS	ABRIS + OAE
Sera™ handheld device	•	•
Sera™ cradle	•	•
Cradle power supply	•	•
Preamplifier[1]	•	•
USB Type A-B Micro cable	•	•
Carrying case	•	•
Infant ear simulator	n/a	•
Pinch clip cables for snap electrodes[1]	•	•
Instructions for Use	•	•
HearSIM™ software bundle	•	•
Sera™ Probe Tip Kit	Optional	•
Sera™ ADI Screening Eartip Kit	•	•
Sera™ Probe Cleaning Kit	•	•
IP/Probe Accessory Kit[1]	•	•
EarCup Accessory Kit[1]	Optional	Optional
Stylus Pen	•	•
Cleaning cloth for touchscreen	•	•

[1] Applied part according to IEC 60601-1

Neckstrap for preamplifier[1]	•	•
Transducers		
SnapPROBE™[1]	Optional	•
OWA Probe 500 mm[1]	Optional	Optional
OWA Probe 1200 mm[1]	Optional	Optional
IP 30 (50 Ω) insert earphone with Eartip adapters Kit[1]	•	•
IP 30 (50 Ω) insert earphone with EarCup adapters Kit[1]	Optional	Optional
Optional Accessories		
Sera™ ABRIS Pass Checker	Optional	Optional
Label Printer HM-E200 Kit (includes printer, power supply and 2 rolls of thermal label paper)	Optional	Optional
Disposables		
Assortment of Ear Tips	Optional	•
Infant earcups	Optional	-
Snap Electrodes	•	-
Gauze swaps	Optional	-
Conductivity gel	Optional	-
Alcohol pads	•	Optional
Printer label paper	Optional	Optional
Probe tip kit	•	•

Disposables are single use only! Reuse of disposables can impact test results and the patient's safety. Refer to sections 2.7 Safety precautions. All disposable supplies included with Sera™ are supplied by Sanibel Supply®. The system has only been tested using disposables manufactured by Sanibel Supply®. Use of other brand disposables could alter the behavior and results obtained with the device and is not recommended.

1.5. Clinical benefit

Undiagnosed hearing loss in infants can impact many developmental areas, including language acquisition, social interactions, emotions, cognitive ability, academic performance and vocational skills. This may negatively impact the patient's quality of life. The diagnosis of hearing loss can therefore have significant benefit for the individuals as well as relatives.

1.6. Warnings

Throughout this manual, the following meanings of warnings, cautions and notices apply:



The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.



The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.

NOTICE

NOTICE is used to address practices not related to personal injury.

1.7. Safety features and complaint handling

Complaints/safety reporting



Please contact your local distributor in case of any incident related to product defects (hardware defects or software bugs) or adverse events (which do not necessarily have a causal association to the product). It is recommended for a user to report all the known facts about the incident. Upon receipt of any serious incident with a serious health impact for the patient or user (serious adverse events), Interacoustics shall ensure that the regulatory authority in the patient's home country is informed according to the vigilance requirements. Interacoustics shall handle all the product complaints and adverse events as per the internal procedure.

2 Safety precautions

General

The following safety precautions must always be observed. General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

Interacoustics is aware that safety rules within individual organizations vary. If a conflict exists between the instructions in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.

The Sera™ is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists), nurses or technicians who have been trained in the proper use of the device.

2.1 Cautions - general



If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with Interacoustics' specifications.
Do not drop or in any other way cause undue impact to this device. If the instrument is damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Interacoustics.

Equipment is not user repairable. Repairs must be performed by an authorized service representative only. No modifications of the equipment are allowed by anyone other than a qualified Interacoustics representative. Modification of the equipment could be hazardous.

Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibrations instructions, or other information that will assist authorized service personnel to repair those parts of this instrument that are designated by Interacoustics as repairable by service personnel.

No parts of the equipment can be serviced or maintained while in use with the patient.

Only connect accessories purchased from Interacoustics to the Sera™. Only accessories which have been stated by Interacoustics to be compatible may be connected to the device or cradle.

2.2 Environmental factors





Use and store the instrument indoors only. It is recommended to operate the instrument within an ambient temperature range of 5 °C / 41 °F to 40 °C / 104 °F and in a relative humidity between 15 % and 93 % (non-condensing).

For transport and storage conditions, please refer to section 6.

Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorized service technician.

2.3 Electrical and electrostatic safety





Before performing any service to the insert earphones, you must uncouple the Sera™ transducers and electrodes from the patient.

Do not touch the contacts on the bottom of the instrument and the patient at the same time. The consequence could be a too high leakage current to the patient.

Do not open the case of the instrument. Refer servicing to qualified personnel.

2.4 Electromagnetic compatibility (EMC)



Although the instrument fulfills the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears. Please also refer to the appendix regarding EMC.

2.5 Explosion hazards



Risk of explosion.

Do not use in the presence of flammable anesthetics or other gases.

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device near flammable anesthetic gases.

Do NOT use the Sera™ in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

2.6 Use in home healthcare environment

The instrument is suited for use in home healthcare environments when protected with the enclosed carrying case during transport

2.7 Measuring security and clinical benefit

To guarantee that the Sera™ works properly, the instrument should be checked and calibrated at least once a year.

The service and calibration must be performed by an authorized service technician. If these checks are not performed, Medical Device Regulations may be violated, and warranties may be void.

The use of non-calibrated devices can lead to incorrect test results and is not advisable. Incorrect test results can lead to inappropriate treatment of patients.

2.8 Miscellaneous

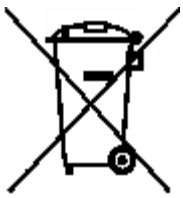
Please note:

DO NOT connect the Sera™ hardware to the computer before the software has been installed!

Storage in temperatures below 0°C /32°F and above 50°C /122°F may cause permanent damage to the instrument and its accessories.

Do not place the instrument next to a heat source of any kind.

Great care should be exercised when handling transducers, as rough handling, for example dropping onto a hard surface, may break or damage the parts.



Within the European Union it is illegal to dispose of electrical and electronic waste as unsorted municipal waste. Electrical and electronic waste may contain hazardous substances and therefore must be disposed of separately. Such products will be marked with the crossed-out wheelie-bin image shown to the left. User cooperation is important in order to ensure a high level of reuse and recycling of electrical and electronic waste. Failure to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

Outside the European Union, local regulations should be followed when disposing of the product after its end of life.

2.9 Use of equipment after transport and storage

Please make sure that the instrument is functioning correctly before use. If the instrument has been stored in a cold environment (even for short period of time), please allow the instrument to become acclimatized. This can take a long time depending on the conditions (such as environmental humidity). You can reduce the condensation by storing the instrument in its original packaging. If the instrument is stored under warmer conditions than the actual use conditions no special precaution is required before use. Always ensure proper operation of the instrument by following routine check procedures for audiometric equipment

.

3 Unpacking and installation

3.1 Unpacking and inspection

Check box and contents for damage
When the instrument is received please check the shipping box for rough handling and damage. If the box is damaged, it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty, please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment
Sera™ comes in its own shipping carton, which is specially designed for the Sera™. Please keep this carton. It will be needed if the instrument has to be returned for service.
If service is required, please contact your local distributor.

Reporting Imperfections
Inspect before connection
Prior to connecting the product, it should once more be inspected for damage. The cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults
Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a "Return Report" where you can describe the problem.

Please use the "Return Report"
Use of the return report provides the service engineer with the relevant information to investigate the reported issue. Without this information, there may be difficulty in determining the fault and repairing the device. Please always return the device with a completed Return Report in order to guarantee that correction of the problem will be to your satisfaction.

Home Health Care Transport
Use the carrying bag that is provided with the delivery of your Sera™.

3.2 Markings

The following markings can be found on the instrument:

Symbol	Explanation
	Type B applied parts. According to IEC 60601-1. Patient applied parts that are not conductive and can be immediately released from the patient.
	Applied part is Type BF according to the international standard IEC60601-1.
	Caution.
	Refer to instructions for use.
	Follow Instructions for Use.
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. Failing to do so may endanger the environment.
 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Medical Device.
	Serial number.
	Date of manufacture.
	Manufacturer.
	Reference number.

	Do not re-use. Ear-tips and similar are for single use only.
	Keep dry.
	Transport and storage humidity range.
	Transport and storage temperature range.
Interacoustics	Logo.
	Turns the instrument on or off. Long press to turn off. Short press to wake the device from sleep mode (display off).
	Do not reuse.
IP20	Degree of protection provided by the enclosure against ingress of objects. Effective against objects greater than 12.5 mm.
IP02	Degree of protection provided by the enclosure against ingress of liquid. Effective against dripping water when case is tilted at 15°.
	Reference to Sera™ Additional Information.

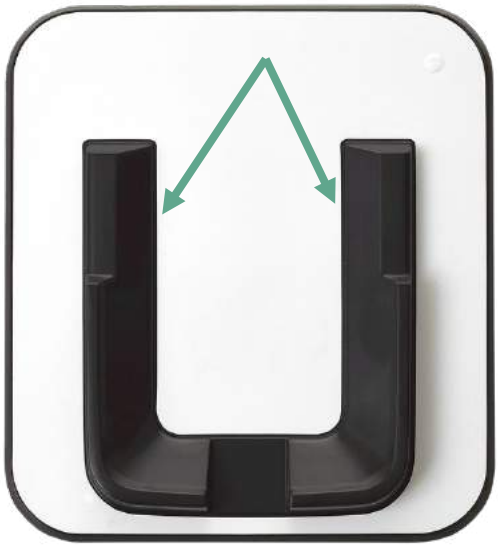
3.3 Installing the cradle



Connect the Type A-B Micro USB plug of the power supply to the rear of the cradle (1).

USE ONLY UE08WCP- 050160SPA- POWER SUPPLY.

Do not attempt to use any other power supply. It can cause risk of fire or electrical shock to operator or patient.



Place the cradle upright on your desk. There are two insertion guides to place the instrument properly into the cradle.



Place the Sera™ into the cradle so that it sits within the U-shaped placement guides. Proper placement in the cradle is needed to ensure charging of the battery.

Grasp the upper portion of the Sera™ above the cradle placement guides and lift it out of the cradle.

3.4 Installing the HM-E200 label printer (optional)

The connection of the Sera™ and the HM-E200 label printer is made via wireless pairing. Only use the recommended printer from Interacoustics.

NOTICE: Only printers purchased through Interacoustics distributors or Sanibel Supply® are compatible with the Sera™.

3.4.1 Battery charging



The printer is powered by a Lithium-ion battery.

In order to charge the battery, you must insert the plug of the charger into the laterally placed socket and plug the power supply into a power outlet or connect the printer to a PC. Alternatively, the printer can be placed in its cradle while the cradle is connected to a power outlet. The green light on the front side of the printer will flash to indicate charging is occurring. Should the battery be fully charged, the green light will be constant.

3.4.2 Installing label paper in the printer



To insert a new label roll into the label printer, open the printer by sliding the button on the left side of the printer downwards.



Insert the label roll into the printer with the paper end placed facing the printer display.



Once the label roll is in place, close the cover.

Turn the printer on and press the feed button on the left side so that the printer can properly align the labels with the print head.

Optionally, thermal paper can be used with the HM-E200 thermal printer. Refer to the HM-E200 printer user manual for setup instructions.

3.4.3 Turning the printer on and off

Push the POWER BUTTON for two seconds to power ON or OFF.
The Green Power Indicator is lit while the printer is on. Once the printer goes into standby, the green Power Indicator will flash, while the display turns black. Push the power button shortly to get the printer out of standby mode.

3.4.4 Connecting the wireless printer to the Sera™

Pairing the printer to the Sera™ is necessary before wireless printing is possible.

Follow these instructions to pair the printer:

1. Turn the printer on by holding down the power button for 2 seconds
2. On the Sera™ hand-held unit, go to **Setup | Printer** and press **Search**
3. Let the instrument search for wireless devices. This may take up to 1 minute
4. A device called HM-E200 should appear in the list of devices
5. Press **Select** to finish pairing

Please note: Do not power off the Sera™ during printing.

It is possible to share one printer with multiple Sera™ devices. However, only one device can be paired with the printer at a time. This means that only one Sera™ can be turned on in range of the printer and the printer must be powered off after use with one Sera™ to then successfully connect to the other Sera™ device.

If you want to print measured results on the connected printer, it is recommended to switch on the printer before doing the measurements. This will allow the printer enough time to connect and be ready for printing when measurements are completed.

3.4.5 Printer offline



An attempt to print when the wireless printer is powered off or is out of range to the Sera™ will result in the appearance of an error message.

Dismiss the message by selecting the check button in the bottom control bar. Try again after turning on the printer or moving into range.

3.5 The Sera™ hardware

The Sera™ handheld unit consists of a resistive touch screen, which responds to the pressure of touching icons.



Viewing your Sera™ from the front side, you will see the touch screen display (1) and the On/Off/Home button (2), and a charging light indicator (LED) (3).



On the top of the device, an ABR preamp/OAE probe cable connector (1) is placed.



At the base of the device, there is a micro-USB connector (1) and the built-in slot for attaching a neck lanyard (2) for transport of the device.

3.6 Connecting the probe cable to the Sera™

The probe used with Sera™ is called the SnapPROBE™. The SnapPROBE™ can be connected in two ways to the device:

1) Directly connected to the device (for OAE only)
2) Via the preamplifier cable (for OAE & Automated ABR)





Ensure that the Sera™ is switched off before attaching or detaching the probe or the preamplifier cable from the Sera™.

Align the raised dot on the probe plug/preamplifier cable plug with the one on the front of the socket at the top of the Sera™. Insert the plug and push it securely into place. The Sera™ is designed to guide the probe plug/preamplifier into the correct position.

3.7 Connecting transducers to the preamplifier

The preamplifier cable is required for Automated ABR testing and can also be used with all other modules.





Align the probe/insert phone/EarCup cable plug with the socket at the top of the preamplifier cable marked with the graphic. Insert the plug and push it securely into place. The Sera™ is designed to guide the probe plug/preamplifier into the correct position.

3.8 Connecting the electrode cables to the preamplifier



Connect the three electrode lead cables securely into the electrode jacks on top of the preamplifier, matching the color of the cable with the jack. Make sure they are fully inserted into the jack.

3.9 Use of the IP30 transducer with ear tips or EarCups (ABRIS only)

There are two versions of the IP30 transducer for use with the ABRIS module.

IP30 stereo ID earphone



The IP30 stereo ID earphones are for use with ear tips via an adaptor. The transducer is labeled “Calibrated for use with inserts”.

IP30 stereo ID EarCups



The IP30 stereo ID EarCups transducer is for use with disposable EarCups via an adaptor. The transducer is labeled “Calibrated for use with EarCups”.

Even though the transducers appear to be the same, ensure that you are using the transducer with the disposable (ear tips or EarCups) it is calibrated for. Misuse may lead to incorrect results due to differences in the calibration.

3.10 Connecting to the optional pass-checker



The ABRIS pass-checker can be used for assessing the integrity of the hardware, electrode leads and transducer.

IP30 Stereo ID earphone – place a blue flanged ear tip onto the end of the ear tip adaptor and insert into the holes of the pass-checker.

IP30 stereo ID EarCups – insert the black EarCup adapters directly into the holes of the pass-checker.

(The Pass-Checker is not required for patient testing.)

3.11 Transducers and calibration

The transducers used with Sera™ use a special omnetics plug that allows the calibration data to be stored within the cable/plug (also known as an ID transducer). Transducers (probes, insert phones etc) can be swapped between devices without requiring recalibration to a specific Sera™ device. Sera™ will automatically detect the transducer type and read the calibration data from the ID transducer.

3.12 Charging and powering Sera™

3.12.1 The battery

The instrument is powered by a rechargeable Lithium-ion (Li-ion) battery. The battery is charged by placing the instrument in the AC powered cradle.
The battery can also be charged by:

- Connecting the instrument to a powered PC using the supplied USB cable. Charging this way will be slower than charging with the cradle.
- Connecting the device to mains using the power supply from the cradle directly plugged into the micro USB port of the Sera™.



This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative. If the instrument is connected to a PC (IT equipment forming a system), ensure not to touch the patient while operating the PC.

If the instrument is connected to a PC (IT equipment forming a system) assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601.
Note! The USB connection on the instrument has insulation protections to the patient connections.
The consequence of not following this precaution could be a too high leakage current to the patient.

IMPORTANT NOTE: The internal battery should only be replaced by an authorized service representative. Damage to the electronics resulting from an attempt to change the battery by someone other than an authorized representative will not qualify for repair under the product warranty.

3.12.2 Battery lifetime and charging time

Please note: Please observe the following precautions:
The battery can only be maintained by service personnel.

- Keep the battery fully charged
- Do not place the battery in a fire or apply heat to the battery
- Do not damage the battery or use a damaged battery
- Do not expose the battery to water
- Do not short circuit the battery or reverse the polarity
- The battery automatically starts charging when the Sera™ is placed properly into the AC-powered cradle or when connected via USB to the PC
- Use only the charger provided with the Sera™
- The Sera™ will shut down automatically when the battery charge is too low to support continued operation.

When fully charged, the Sera™ battery will last for a full day of testing under normal test conditions when the default power save and power off is enabled.

Table 1 gives an estimate of the battery charging time (ct) in hours. Values below assume that the device is switched off during charging.

Table 1: Estimated time of charging the Sera™ in hours.

	ct through cradle up to 90%	ct through USB (PC) up to 90%	ct through USB (PC) and cradle up to 90%
Off	6	9	3.5

3.12.3 Indication lights on Sera™

The table below summarizes the LED indicator light colors displayed on Sera™ under varying conditions (see Table 32).

Table 2: LED Status on Sera™ and Cradle.

Instrument status:	**OFF**		**ON**		**Power Save (Standby)**	
Battery status:	**Battery charging**	**Battery not charging / full**	**Battery not full**	**Battery Full**	**Battery charging**	**Battery not charging**
USB charge	Blue solid	Green solid	Off	Off	Blue blink	Green blink
Cradle charge	Blue solid	Green solid	Off	Off	Blue blink	Green blink
Not charging	Off	Off	Off	Off	N/A	Green blink
Battery fault	Green+blue solid	Green+blue solid	Off	Off	Green+blue blink	Green+blue blink

3.13 HearSIM™ software bundle

The Sera™ can be connected to a PC via a USB cable for use in conjunction with HearSIM™. The HearSIM™ software allows the user to customize Sera™ device settings, manage screening data and export it into other database systems.

Please refer to the HearSIM™ manual for further information.

Using operating systems where Microsoft have discontinued software and security support will increase the risk for viruses and malware, which may result in breakdowns, data loss and data theft and misuse. Interacoustics A/S cannot be held liable for your data. Some Interacoustics A/S products support or may work with operating systems unsupported by Microsoft. Interacoustics A/S recommends you to always use Microsoft supported operating systems that are kept fully security updated.

3.14 Licenses

When you receive the Sera™, it already contains the license(s) for the modules you have purchased. If you would like to add another test type to the device (e.g., DPOAE or TEOAE), please contact your dealer to purchase a new license.

3.14.1 Adding a new license to Sera™

To add a new license:

1. Ensure you have the last released version of the Sera™ software bundle.
2. Connect the Sera™ device to the PC via the supplied USB cable.
3. Run the FirmwareUpgradeSera.exe file located in the “Tools” folder on the Sera™ USB stick.
4. Press Upgrade and follow the onscreen instructions. This will ensure your device is running the latest firmware version. Failure to do may lead to use of an older version of the newly licensed test type.
5. Run the ErisLicenseManager.exe file located in the Sera Tools folder on the Sera™ USB stick.
6. Enter the new license key provided and press the Set license button
7. The firmware is now up to date and the new test type should now be available on your Sera™ device.

3.15 Updating the firmware

Interacoustics will periodically release new firmware for the Sera™ device. The device should always contain the latest available firmware to ensure that the device is working optimally.

To check the firmware version:
From the Home Screen, press the Setup button 

1. Press About
2. The device’s firmware version number is displayed along with the MCU and DSP compile dates.

To update the firmware on your device:

1. Ensure you have the last released version of the Sera™ software bundle.
2. Connect the Sera™ device to the PC via the supplied USB cable.
3. Run the FirmwareUpgradeSera.exe file located in the “Tools” folder on the Sera™ USB stick.
4. Press Upgrade and follow the onscreen instructions.

4 Operating instructions

4.1 General precautions

When operating the instrument, please observe the following general precautions:



1. Use this device only as described in this manual.
2. Use only the disposable Sanibel™ ear tips designed for use with this instrument.
3. Always use a new ear tip, foam insert or EarCup for each patient to avoid cross-contamination. The ear tips, foam inserts or EarCups are not designed for reuse.
4. Never insert the probe tip into the ear canal without affixing an ear tip as this may damage the patient's ear canal.
5. Keep the box of ear tips outside the reach of the patient.
6. Be sure to insert the probe tip in a way which will ensure a tight fit without causing any harm to the patient. Use of a correct and clean ear tip is mandatory.
7. Be sure to use only stimulation intensities acceptable to the patient.
8. It is recommended to conduct an Integrity Check at the beginning of each day to ensure that the transducers, the probe and/or cable is functioning correctly for Automated ABR, TEOAE and DPOAE measurements.
9. Clean the probe tip regularly to ensure wax or other debris stuck in the probe tip does not affect the measurement.

Please note:

1. Careful handling of the instrument whenever in contact with a patient should be given high priority. Calm and stable positioning while testing is preferred for optimal accuracy.
2. The Sera™ should be operated in a quiet environment, so that measurements are not influenced by outside acoustic noises. This may be determined by an appropriately skilled person trained in acoustics. ISO 8253 Section 11 defines a quiet room for audiometric hearing testing in its guideline.
3. Never clean the transducer housing with water or insert non-specified instruments into the transducer.
4. Do not drop and avoid other undue impact to this device. If the instrument is dropped or in any other way damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.



See the Sera™ Additional Information for symptoms, possible causes and suggested troubleshooting.

4.2 Switching the Sera™ on and off

Switch the Sera™ on by pressing the home key. To switch the Sera™ off, hold down home key for approx. 2 seconds. The Sera™ will always start on the **Home** screen.

Please note: The Sera™ takes approximately 5 seconds to boot up.

Please also refer to section 2.3.10 when the instrument is used just after transport.

Important information or reminders may be displayed during the boot up process. This could include:

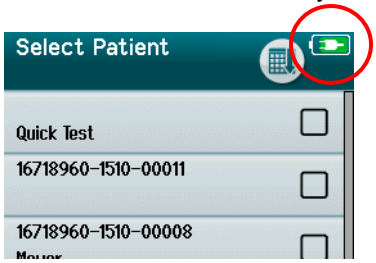
- Calibration expiration reminder
- Low battery charge warning

4.3 Testing during charging

Testing can be performed while Sera™ is charging in the cradle once the charge is sufficient to support testing.
Testing can also be performed when Sera™ is connected to the powered PC via the USB cable or with the power supply plugged directly into the device. However, electrical interference may introduce noise into the recording prolonging the test time and increasing the chances of a refer result. Therefore, testing while the device is connected to a PC or to mains power is not recommended.

4.4 Battery charge status indicator

When the Sera™ battery's power capacity becomes low, the first indication you will see is the battery symbol in the top right-hand corner of the hand-held unit change color. When the battery's power level becomes so low that measurements can no longer be performed, a warning will appear on screen, the measurement will be stopped, and all recorded data will be stored. You will have to place the Sera™ in the cradle or connect it to a PC via USB cable to be able to continue testing. Upon restarting the Sera™, the previously measured data will be recovered, and you can continue with your measurements without retesting.



The charge status of the battery is represented graphically in the status bar at the top of the Sera™ touchscreen when it is powered on.

The explanation of the charge status symbols is given in Table 1.

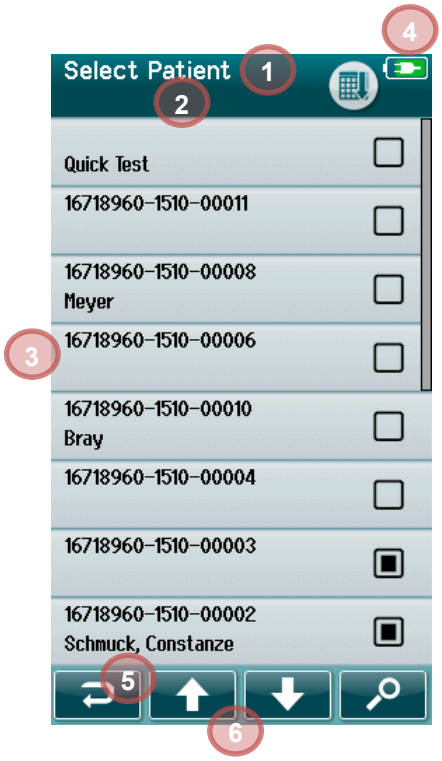
Table 1: Explanation of charge status symbols.

Symbol	Charge status
	Charging
	100%
	75 %
	50 %
	25 %
	10% (Approx. 30 minutes of active test time remaining)
	5% (Testing cannot be performed; recharge ASAP)
	3% (Automatic shutdown)

4.5 Sera™ operation and button overview

4.5.1 The Sera™ screen format

The general Sera™ screen format includes:



1. Screen title
2. Status/sub-header
3. Main screen
4. Battery indicator
5. Function button
6. Control bar with function buttons

4.5.2 Common function buttons

The common function buttons are explained in Table 2.

Table 2: Common function buttons.

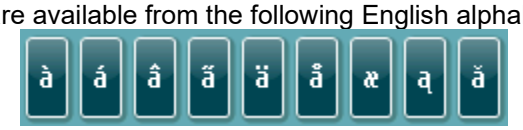
	OK (accept/save)		Go Back (previous screen)		Cancel
	Print		Search		Add comment
	Page up		Page down		Show test list
	View test fields		Proceed to test/start test		Pause (test)
	Stop (test)		Resume (test)		Quick add of new patient
	Both ears (test)		Right ear		Left ear
	Sort order (alphabetical)		Sort order (chronological)		Change screener

4.5.3 Keyboards (special characters)

The default keyboard uses the English language character set. To access special characters from other languages, tap and hold down the most similar letter to the special character you are trying to insert. Available alternative characters will be displayed for selection.

Special characters are available from the following English alphabet characters:

A



C



D



E



G



I



L



N



O



R



S



T



U



Z



4.5.4 Home screen



Usually, the Sera™ starts on the **Home** screen. The Home Screen displays the buttons controlling entry into the major functions of the Sera™.

The following information can be viewed on the screen:

- Select **New Patient** to enter demographics for a new patient. After entry of the patient's information you can save the name to the database for testing later or immediately proceed with the testing.
- **Select Patient** to review the list of patients saved on the device. Select a patient to review detailed demographic and test information for this patient or to begin a test.
- Select **Quick Test** to proceed immediately to perform a test without entry of patient information. Quick tests are saved temporarily under the patient name of Quick Test. If you want to save a Quick Test session to a specific patient after testing, you can save it by editing the Patient Information.
- The **Change User** control will be unavailable for selection if user login is disabled. Select **Change User** to log out of the current user and display the User list for selection of a new user.
- Select **Setup** to access a list of the device settings that can be changed directly on Sera™. Some settings can only be changed using HearSIM™.

4.5.5 Adding a new patient





Patient information can be entered manually into the Sera™ via the New Patient screen. Select the New Patient button on the Home screen.

In the New Patient screen, select a field for data entry by touching the desired field. The appropriate data entry control such as the keyboard, calendar or drop-down list will open. Enter the patient's data for the desired fields:

- Patient ID (mandatory field)
- Last name
- First name
- Date of birth
- Gender
- Risk factors
- Other risk factor

Select and enter data until all desired fields are completed.

The Patient ID field must be completed in order to save the data or proceed to a test.



It is possible to configure the device to input an automatic ID number into this field so that you do not have to enter an ID. The format of the automatic ID will include the device serial number followed by the year and month in YYMM format and a sequential number from 1 to 65550. This ID can be overwritten when entering the patient data.

Configuring Sera™ to use an automatically entered ID number is accomplished via HearSIM™.

When you have completed entry of data, you can proceed immediately to test the patient or press the 'quick add' button .

4.5.6 Patient ID conflict



The Patient ID must be unique. If you attempt to enter a duplicate patient ID into the database, an ID conflict message will display. After dismissing the message by selecting the **Checkmark** in the bottom control bar, change the ID to a different unique number.

4.5.7 Selecting from the patient list

A patient can be selected from the Patient list. Select the **Select Patient** button on the Home screen.



You can find the desired patient in the list in several ways:

- Use the **Search** button to open a screen in which you can enter all or part of the patient's ID, last or first name to search for matching patients. The patient list will be shortened to include only matching entries
- Page down or up using the arrow keys to find the desired patient name
- Select the patient of interest to open the Patient information screen

After selecting the patient, you can proceed to:

- **Review** the patient's test history
- **Test** the patient

In the Select Patient list, a square is present on the right-hand side of the patient's name/ID. The appearance of the square reflects the test status (Table 3).

Table 3: Test Status of patient.

	No tests are saved in the device for this patient.
	Tests are saved in the device (between 1 and 49 tests).
	The maximum number of tests are saved (50). No additional tests can be performed for this patient.

4.6 General test information

It is important to secure the consent of the patient, or in case of the patient being underage, the patient's parents or custodian. It is furthermore recommended to give the patient and attending patient's relations a general outline of the test procedure, what to expect and how to interpret the test result.

4.6.1 Patient preparation – Automated ABR testing

During Automated ABR testing, electrical signals from the neurologic pathway between the cochlea and the brainstem are collected via electrodes which are placed on the baby. As these signals are very small and can be disturbed by myogenic signals, it is recommended that the baby is asleep or in a very calm state for testing. The baby can stay in its crib, be placed on an examination table or be held by the parent.

Preparing the skin helps to achieve good contact (i.e. low impedance) between the skin and the electrode. After cleaning, remove any residue of the skin prep product so that the skin is dry. This will help to ensure good adhesion of the disposable electrode to the skin.



The electrodes used by Sera™ with ABRIS are intended for use on intact, external skin around the ears and on the scalp. They should not be used if the skin is not intact of the baby has a contagious dermatological condition.



Please refer to the Sera™ Additional Information for further instructions on how to prepare the patient and which electrode montage to use.



Risk of strangulation.
Keep cables away from baby's neck.



Avoid contact between the unused electrodes and any other conductive parts.

4.6.2 Patient preparation – OAE testing

OAE responses are very small, and it is recommended that the baby be asleep or in a very calm state for testing. The baby can stay in its crib, be placed on an examination table or be held by the parent during testing.



Please refer to the Sera™ Additional Information for further instructions on how to prepare the patient for testing.

4.6.3 Handling and selection of ear tips

The Sanibel™ ear tips are single use only and should not be reused. Reuse of ear tips can lead to the spread of infection from patient to patient.

The probe and insert phones must be fitted with an ear tip of a suitable type and size before testing. Your choice will depend on the size and shape of the ear canal and ear. Your choice may also depend on personal preference and the way you perform your test.



Make sure that the ear tip inserts completely into the ear canal before starting a test. The SnapPROBE™ ear tips, flanged and mushroom shaped ear tips allow you to obtain a good fit in the ear canal in order to test 'hands free' (not holding the probe or insert phone in place). Hands-free testing reduces the chance of contact noise disturbing the measurement.

Please note: All disposable supplies included with Sera™ are manufactured by Sanibel Supply®. The system has only been tested using disposables manufactured by Sanibel Supply®. Use of other brand disposables could alter the behavior and results obtained with the device and is not recommended. Sanibel™ disposables are latex, DEHP and BPA free and comply to current bio-compatibility standards.

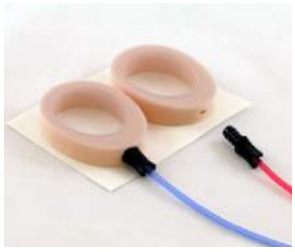
Refer to the "Selecting the Correct Ear Tip" Quick Guide included in the Sera™ Additional Information for an overview of ear tip sizes and selection.

Risk of choking.
Always keep ear tips and similar small pieces out of reach of the baby.

4.6.4 Use of EarCups

The Sanibel™ Infant EarCups™ are single use only and should not be reused. Reuse of EarCups can lead to the spread of infection from patient to patient and potentially affect the delivery of the correct stimulus level to the patient's ear.

Ensure that the EarCup is correctly fitted to the EarCup adaptor attached to the headphone tubes before testing. Removal of the EarCup is best achieved using an alcohol wipe or water to reduce irritation to the baby's skin.



Ensure that the EarCup adaptor is completely inserted into the disposable EarCup before testing. Incorrect insertion can lead to an incorrect stimulus level being presented to the patient's ear which may affect test results.

Please note: All disposable supplies included with Sera™ are produced by Sanibel Supply®. The system has only been tested using disposables supplied by Sanibel Supply®. Use of other brand disposables could alter the behavior and results obtained with the device and is not recommended. Sanibel™ disposables are latex, DEHP and BPA free and comply to current bio-compatibility standards.

4.6.5 Starting a test

A test can be started in several ways:



1. After entering **New Patient** information.



2. From the Patient Information screen after you have chosen a patient from the **Select Patient** list.

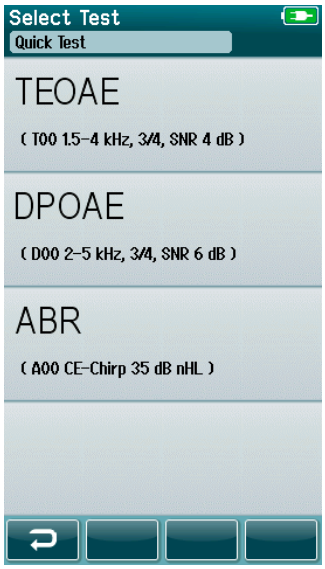


3. **Quick Test** (on the Home screen).
   Quick test functionality can be enabled/disabled by an Administrator via HearSIM™. If Quick Test is disabled on your device, then the **Quick Test** button will not appear on the Home screen.

The following processes are the same regardless of the type of testing (Automated ABR or OAE) you perform.

Selection of the **Test** button starts the process toward testing. Depending on the configuration of your device, some screens may appear before the actual test screen is displayed.

4.6.6 Select test type



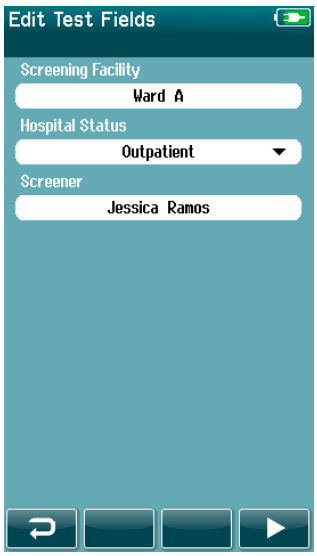
If your device has both Automated ABR and OAE functionality or more than one protocol of the same test type exists on the device, then a Select Test screen may appear for you to select which test you wish to perform.

Underneath the test type (e.g., TEOAE), the name of the protocol is listed.

Displayed tests are also dependent on the connected transducer. For example, if only the probe is connected to Sera™, then Automated ABR tests will not show in the list. The preamplifier must be connected with an appropriate transducer to see Automated ABR tests.

Please refer to the Sera™ Additional Information for further information about the protocols.

4.6.7 Test-related field entry



Your Sera™ can be configured via HearSIM™ to save information with each test regarding:

- Screening facility name
- Hospital status

When this function is enabled, a Test field entry screen will appear so you can complete these fields correctly for the current patient. Since these fields are often the same from patient to patient, your selection will be recalled so that you only need to confirm the entry by proceeding with selection of the **Test** button if the current items displayed in the fields are correct.

If you have logged into the device upon boot up, then your name will also be saved with the test and the Test field entry screen displays your name in read-only format.

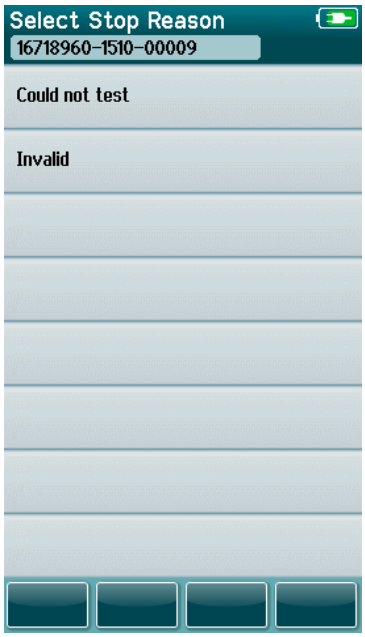
4.6.8 Screening result symbols

An explanation of the screening result symbols is provided in Table 3.

Table 3: Screening Result Symbols.

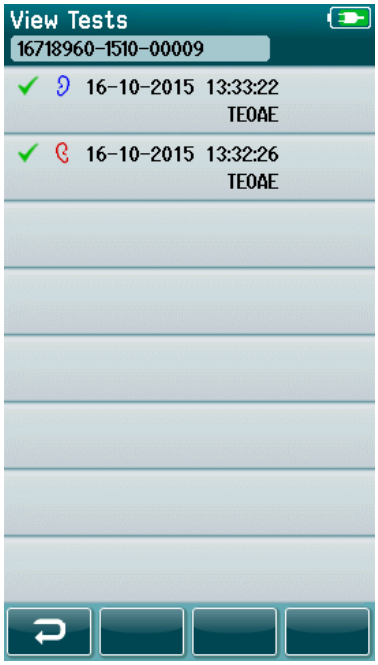
Symbol	Screening result
✓	Pass
✖	Refer
?	Incomplete

4.6.9 Stop reason for incomplete test



The administrator can enable a feature in Sera™ via HearSIM™ for automatically displaying a Select Stop Reason screen when a test is manually stopped. This information is saved with the test record.

4.6.10 Printing after testing



Printing of test results on the label printer can be performed at the Test Done screen by selecting the **Test List** button in the bottom control bar. The full list of tests performed for this patient will appear in reverse chronological order.

For your convenience, the most recently performed right and left ear test result in the current session will be pre-selected for printing as reflected by a small green checkmark appearing on a printer icon at the right side of the row. You can deselect a test by touching the symbol. You can select other tests in the list for printing according to your preferences.

If only one right and one left ear test result is selected for printing in the list, then both ears' results will print out on a single label. When more than 2 tests are selected for an ear, then each test result will print out on a separate label.

Please note: The print icons will not appear on Sera™ under the following conditions.

1. If label printing or wireless communication is disabled on the device via HearSIM™ or
2. If a label printer has not been paired to the Sera™.

4.7 Automated ABR testing

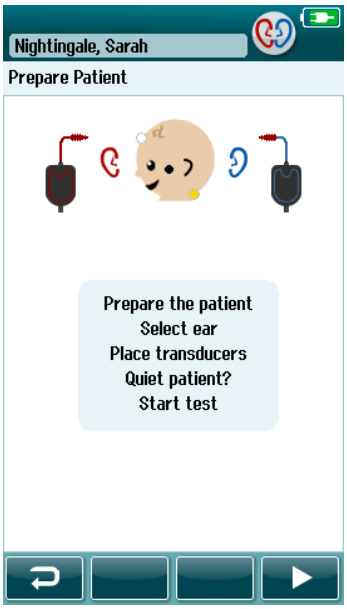
During Automated ABR testing, the screens will change to reflect the processes taking place and the options available to the screener.

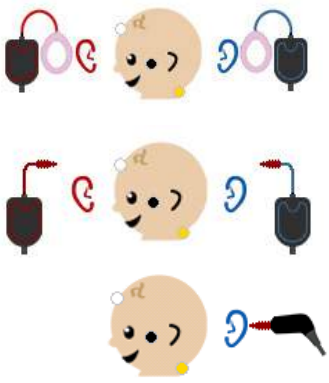
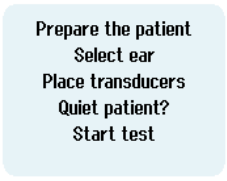
Please refer to the Sera™ Additional Information for further information about Automated ABR and the protocols.

4.7.1 Automated ABR initial test screen

The initial Automated ABR screen displays the following information and instructions (Table 4).

Table 4: Initial Automated ABR screen.

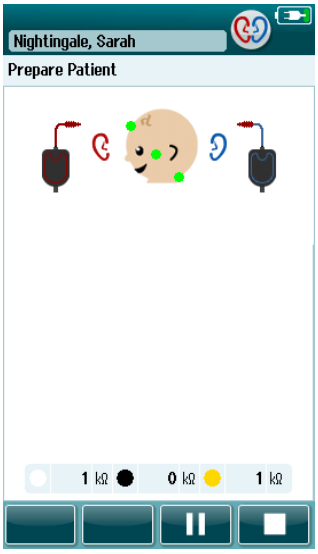


Displayed graphic	Function name	Description
	Patient information.	Displays the selected patient name.
	Ear selection button.	Toggle to select the test ear.
	Transducer type.	The transducer image displayed next to the baby head reflects the connected transducer (EarCups, inserts or probe).
	User instruction.	Test instruction information is displayed.
	Start button.	Starts the impedance check.
	Back button.	Returns to the previous screen.

4.7.2 Impedance check screen

During the impedance check, the electrode symbols on the graphic of the baby's head will display in green or amber with the kΩ impedance value shown toward the bottom of the screen (Table 5). Once the impedance values at all locations remain "green" (<50 kOhms) for a few consecutive seconds, the impedance check terminates, and the response detection phase begins automatically.

Table 5: Automated ABR impedance check screen.



Displayed graphic	Function name	Description
	Test status information.	Indicates device is in impedance check mode.
	Patient information.	Displays the selected patient name.
	Impedance check feedback.	Provides feedback about the impedance values: Green = good impedance. Amber = poor impedance. Impedance values in kOhms are displayed.
	Stop button.	Stops the impedance check.
	Pause/continue button.	Pause/Continue the impedance check.

If any impedance indicator remains "amber", improve the impedance at this electrode position by:

- Making sure that the electrode is placed properly on the prepared skin site
- If poor impedance persists, it may be necessary to remove the electrode and use the skin preparation product to clean the skin again or use a conductive gel. It may be possible to reapply the same electrode, but if the adhesion is insufficient then a new electrode may be required

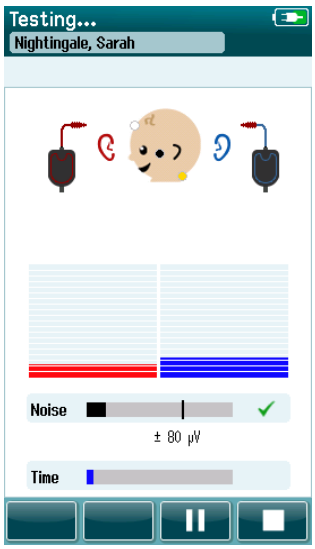
If impedance remains poor, an impedance timeout message will appear after approximately 60 seconds of impedance checking. Upon dismissing the message, the initial test screen will appear again.

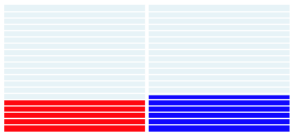
4.7.3 Automated ABR measurement screen

During the Automated ABR measurement, a bar graph shows the progress toward a Pass result (Table 6). A red bar reflects the test progress for the right ear. A blue bar reflects the test progress for the left ear.

At the conclusion of the test, the screening result symbol appears at the top of the bar graph.

Table 6: Automated ABR measurement screen.



Displayed graphic	Function name	Description
	Test status information.	Indicates device is in testing mode.
	Patient information.	Displays the selected patient name.
	Test progress bars.	Provides feedback about the test progress for reaching a Pass result.
	Noise bar with checkmark if noise is acceptable.	Indicates the quality of the incoming EEG.
	Time bar.	Elapsed test time.
	Stop button.	Stops the test; assigns an Incomplete result.
	Pause/continue button.	Pause/Continue the measurement.

4.7.3.1 Noise bar

During testing, the **Noise bar** will display the amplitude of the incoming EEG samples. A checkmark will appear to the right-hand side of the bar when the incoming signals are quiet enough to be accepted and processed by the response detection algorithm. If the incoming EEG samples contain high noise due to myogenic or electrical noise, the checkmark will disappear, and the noise bar will reflect noise exceeding the rejection level.
If this occurs, you should Pause the test and attend to the noise by calming the baby or managing other sources of noise (electrical).

4.7.3.2 Time bar

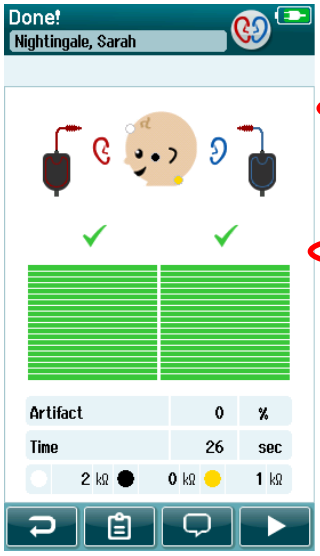
During testing, the **Time or progress bar** will fill up, as good samples of data are obtained. When 180 seconds (3 minutes) of acceptable EEG samples have been acquired, the bar will be completely filled, and the test will terminate automatically.

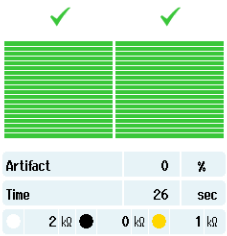
4.7.3.3 Test done screen

At the conclusion of a test, the result of the most recently completed test will continue to be visible (Table 7). The ear selection control becomes active again so that the user can select the other ear for testing or can repeat a test measure on the same ear.

The ear selection control can also be used to toggle between the last Automated ABR test performed on the right and left ear during the session.

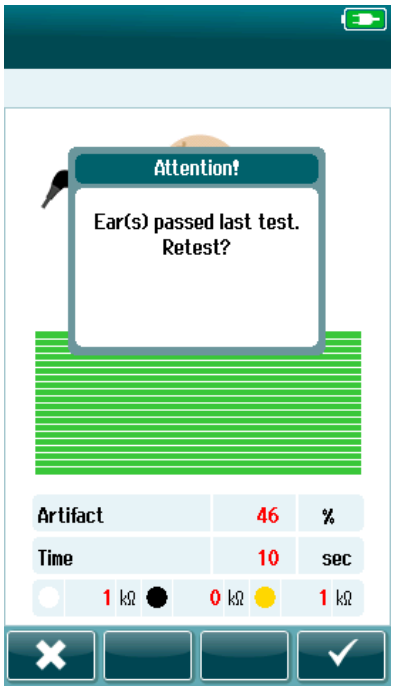
Table 7: Automated ABR Test done screen.



Displayed graphic	Function name	Description
	Test status information.	Indicates test is done.
	Patient information.	Displays the selected patient name.
	Ear selection button.	Toggle to select test ear.
	Test result bars, result symbols and additional test information.	Provides feedback about the result(s) of the most recent test performed per ear.
	Start button.	Begins an impedance check for a new test.
	Show test list button.	Opens up list of all tests performed in this session. Printing available if printer is setup.

	Add comment button.	Select to add a comment about the test just performed.
	Back button.	Returns to previous screen (Select test type or Prepare patient screen).

If the user starts another test on the same ear that just passed, the following screen will display:



This message alerts the user that the ear test has just passed and asks for confirmation of a desire to retest the same ear again.

Users can select the checkmark to proceed with a retest or can select the cancel button to cancel the retest and return to the Test Done screen.

4.8 OAE testing

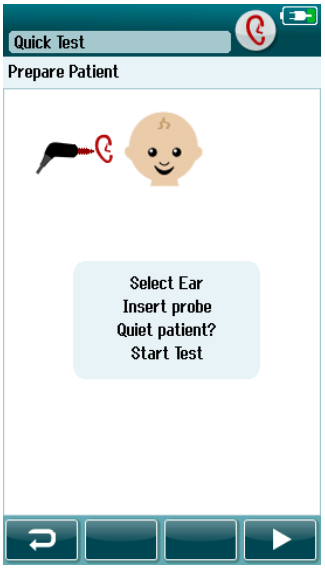
During OAE testing, the screens will change to reflect the processes taking place and the options available to the screener.

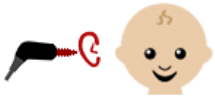
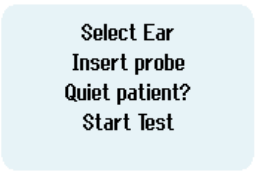
Please refer to the Sera™ Additional Information for further information about TEOAE and DPOAE and the protocols.

4.8.1 OAE initial test screen

The initial OAE screen displays the following information and instructions (Table 8).

Table 8: OAE initial test screen.

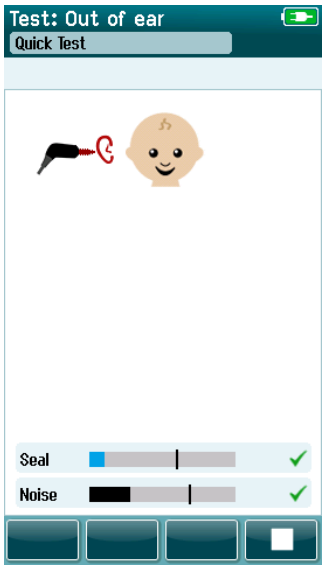


Displayed graphic	Function name	Description
	Patient information.	Displays the selected patient name.
	Ear selection button.	Toggle to select the test ear.
	Transducer.	The transducer image displayed next to the baby head reflects the connected transducer.
	User instruction.	Test instruction information is displayed.
	Start button.	Starts the probe check.
	Back button.	Returns to the previous screen.

4.8.2 Probe check screen

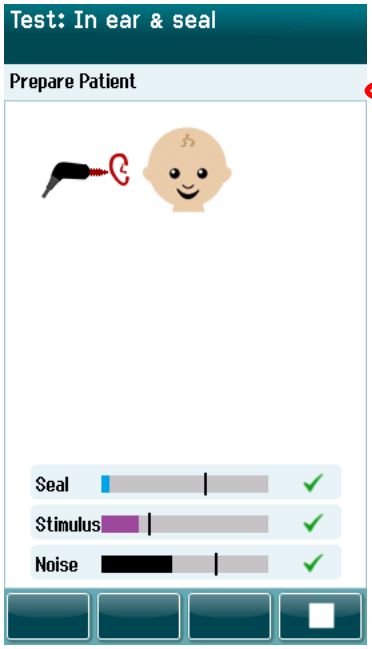
During the probe check, information is displayed regarding the quality of the fit of the probe in the ear canal. (DPOAE in Table 9 and TEOAE in Table 10). Once the probe fit is good, the probe check terminates and the OAE measurement phase begins automatically.

Table 9: DPOAE Probe check screen.



Displayed graphic	Function name	Description
	Probe check status.	Displays the probe check status – in ear, out of ear or blocked.
	Patient information.	Displays the selected patient name.
	Status bars.	Displays the status of the probe in the ear. All criteria must be met before a test will start.
	Stop button.	Stops the probe check.
	Pause/continue button.	Pause/Continue the probe check.

Table 10: TEOAE Probe check screen.



Displayed graphic	Function name	Description
	Probe check status.	Displays the probe check status – in ear, out of ear or blocked.
	Patient information	Displays the selected patient name.
	Status bars.	Displays the status of the probe in the ear. All criteria must be met before a test will start.
	Stop button.	Stops the probe check.

If the probe fit is not acceptable you need to improve the situation before testing will begin:

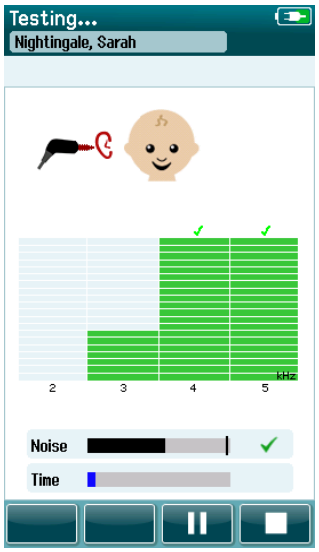
- Make sure the probe tip is inserted securely into the ear canal.
- Ensure the baby is relaxed and quiet or sleeping and/or attend to any acoustical noise in the test environment.

4.8.3 OAE measurement screen

During the OAE measurement, a bar graph for each of the frequencies in the test protocol reflects the progress toward a pass (Table 11). The bar will fill up completely in color and a checkmark will appear above the bar when the criteria for a pass is achieved at the specific frequency.

Additionally, horizontal bars for probe stability, noise and test progress appear. When noise and probe stability are acceptable, a checkmark appears next to the horizontal bar.

Table 11: DPOAE measurement screen.



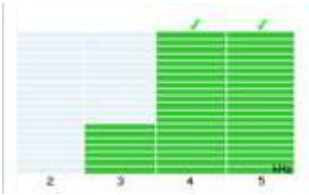
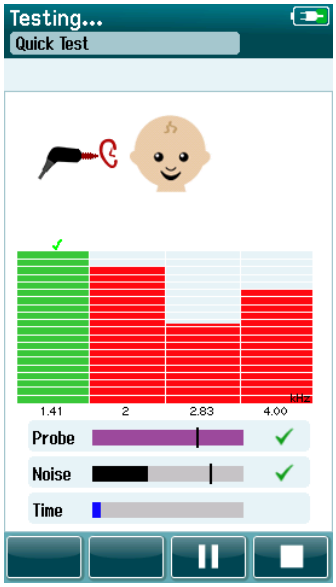
Screen area/graphic	Function name	Description
	Test status information.	Indicates device is in testing mode.
	Patient information.	Displays the selected patient name.
	Test progress bars.	Provides feedback about the test progress for reaching a Pass result.
	Noise bar with checkmark if noise is acceptable.	Indicates acceptable noise rejection level and status.
	Time bar.	Elapsed test time.
	Stop button.	Stops the test; assigns an Incomplete result.
	Pause/continue screening button.	Pause/Continue the measurement.

Table 12: TEOAE measurement screen.



Screen area/graphic	Function name	Description
	Test status information.	Indicates device is in testing mode.
	Patient information.	Displays the selected patient name.
	Test progress bars.	Provides feedback about the test progress for reaching a Pass result.
	Probe.	Indicates the probe fit status.
	Noise bar with checkmark if noise is acceptable.	Indicates acceptable noise rejection level and status.
	Time bar.	Elapsed test time.
	Stop button.	Stops the test; assigns an Incomplete result.
	Pause/continue screening button.	Pause/Continue the measurement.

4.8.3.1 Probe stability bar

During testing, the **Probe stability bar** will reflect the status of the probe in the ear canal. A checkmark will appear to the right-hand side of the bar when the probe stability is acceptable. If the probe stability drops below an acceptable level, this suggests that the probe is falling out of the ear, and checkmark will disappear. If this happens, you should check the fit of the probe in the ear.

4.8.3.2 Noise bar

During testing, the **Noise bar** will display the amplitude of the incoming acoustic noise. A checkmark will appear to the right-hand side of the bar when the incoming signals are quiet enough to be accepted and processed by the response detection algorithm. If the incoming data sample contains high noise, the checkmark will disappear, and the noise bar will reflect noise exceeding the rejection level.

If this occurs, you should Pause the test and attend to the noise by calming the baby or managing other sources of ambient noise. The fit of the probe should also be checked.

4.8.3.3 Time bar

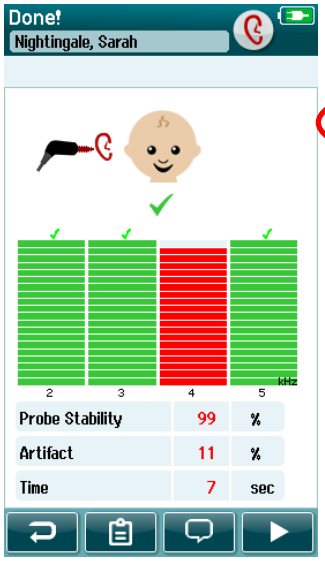
During testing, the **Time or progress bar** will fill up as good samples of data are processed. When the maximum test time has been reached, the bar will be filled in completely and the test will terminate automatically.

Test done screen

At the conclusion of a screening, the result of the most recently completed screening will continue to be visible. The ear selection control will return so that the user can select the other ear for testing or can repeat a screening measure on the same ear.

The ear selection control can also be used to toggle between the last OAE test performed on the right and left ears during the session.

Table 13: DPOAE Test done screen.



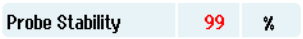
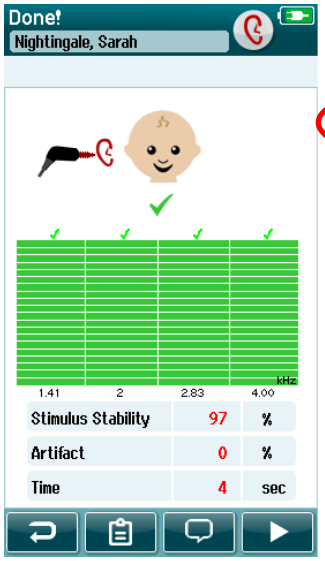
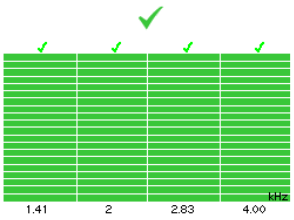
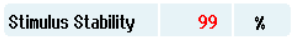
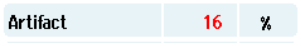
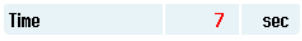
Screen area/graphic	Function name	Description
	Patient information and "Test Done" status.	Shows current patient.
	Ear selection buttons return after test is done.	Choose ear to test; or toggle to view the results for the opposite ear tested in this session.
	Test result bars and symbols and additional information about the test.	Feedback about the result(s) of the most recent screening performed in this test session. Overall result appears at the top. Results for individual frequencies appear above ear bar.
	Probe stability %.	Indicates the quality of the probe fit throughout the test.
	Artifact %.	Indicates the percentage of artifacts measured during the test.
	Time.	Total test time.
	Start button.	Begins OAE probe fit check.
	Test list view.	Opens up list of all tests performed in this session; can print from here if printer is setup.
	Back button.	Returns to prior screen (before initial test screen).
	Comment.	Select to open up a screen for inserting a comment about the test just performed

Table 14: TEOAE Test done screen.



Screen area/graphic	Function name	Description
	Patient information and “Test Done” status.	Shows current patient.
	Ear selection buttons return after test is done.	Choose ear to test; or toggle to view the results for the opposite ear tested in this session.
	Test result bars and symbols and additional information about the test.	Feedback about the result(s) of the most recent screening performed in this test session. Overall result appears at the top. Results for individual frequencies appear above ear bar.
	Stimulus stability %.	Indicates the stability of the stimulus throughout the test.
	Artifact %.	Indicates the percentage of artifacts measured during the test.
	Time.	Total test time.
	Start button.	Begins OAE probe fit check.
	Test list view.	Opens up list of all tests performed in this session; can print from here if printer is setup.
	Back button.	Returns to prior screen (before initial test screen).
	Comment.	Select to open up a screen for inserting a comment about the test just performed

4.8.3.4 Probe stability % (DPOAE only)

When the measurement is finished, the **Probe stability %** provides an indication of how stable the probe placement was throughout the entire test. A low probe stability % indicates that the probe was moving during testing.

4.8.3.5 Stimulus stability % (TEOAE only)

When the measurement is finished, the **Stimulus stability %** provides an indication of how stable the stimulus level was throughout the measurement. A low stability value usually indicates that the probe was moving during testing.

4.8.3.6 Artifact %

When the measurement is finished, the total amount of artifact measured during the test will be shown.

4.8.3.7 Time

When the measurement is finished, the total test time will be presented here.

4.9 Quick test

General



Selection of **Quick Test** from the Home screen bypasses entry of patient information or selection of a patient from the database.

The process of a **Quick Test** is identical to that of a standard test.

Quick tests can be printed immediately after the test is completed, but no identifying information will appear on the print-out.

Only the last Quick Test session is saved temporarily in the Sera™ until the next time that the Quick Test button is selected on the Home screen. When Quick Test is selected, the previous Quick Test session is immediately and permanently deleted from Sera™.

Please note: Quick test functionality can be enabled/disabled by an Administrator via HearSIM™. If Quick Test is disabled on your device, then the **Quick Test** button will not appear on the Home screen.

Saving a quick test

If it is your standard practice to save screening tests, it is highly recommended that you first enter the patient information or select an existing patient in the database **before** performing the screening.
However, if you want to save a Quick Test session (all tests) immediately after it was performed, follow these steps:

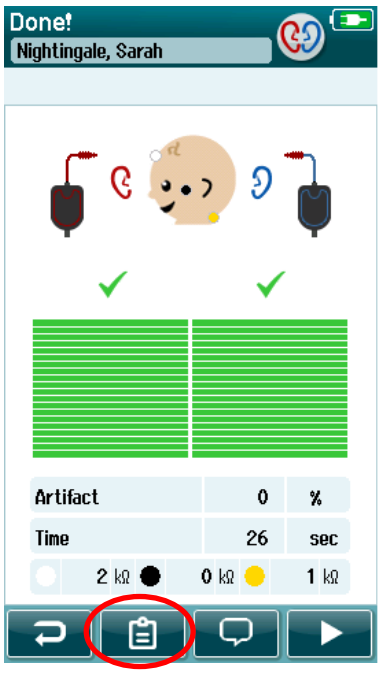
1. At the Home screen, choose **Select Patient**
2. Select the "**Quick Test**" patient
3. Edit the patient's data in the Patient Information screen
4. Select the Checkmark in the bottom control bar

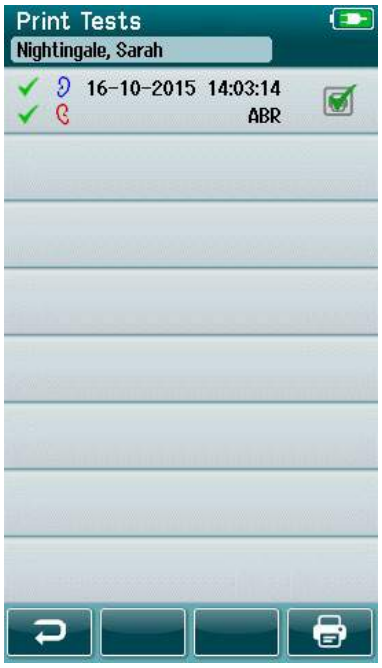
The Quick Test session is now saved under the patient ID and name you entered.

4.10 Printing

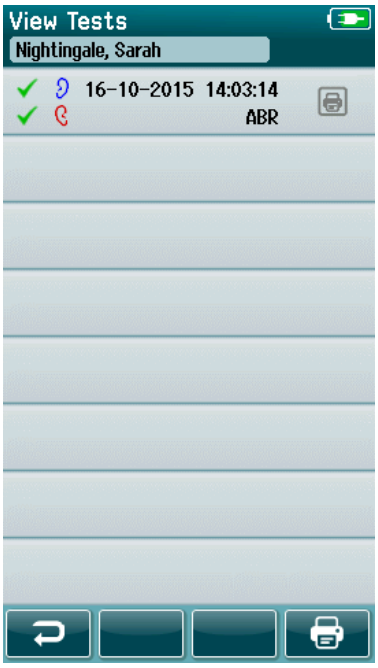
Ways of printing

Printing of screening results on the label printer can be accomplished from within the Test List screen that can be accessed from either the Test Done! screen or from the Patient Information screen.





Print from the Test Done! screen



Print from the Patient Information Screen

Label print format

The label printout displays the following information:

- First Name
- Last Name
- ID
- Gender
- Birthdate
- Result of left ear, date and time
- Result of right ear, date and time

4.11 Reviewing patients and saved sessions

The following section describes the steps for searching for a patient stored on the device, editing patient information, viewing tests (saved sessions), selecting a session to print and viewing test information.

Select patient



Select the **Select Patient** button on the Home screen to view the list of names of patients contained in the device database. The list can be sorted alphabetically by last name or by test date in reverse chronological order using the sort icon at the top right corner.



Use the **UP** and **Down** arrow keys in the bottom control bar to page through the list.

Search for a patient

You can use the **Search** button in the control bar to open a keyboard screen. Type in all or a portion of the patient's last name or ID number and select Search again to return to a shortened list containing only matching patients. Select the desired patient in the list to proceed to the Patient Information screen showing this patient's details.

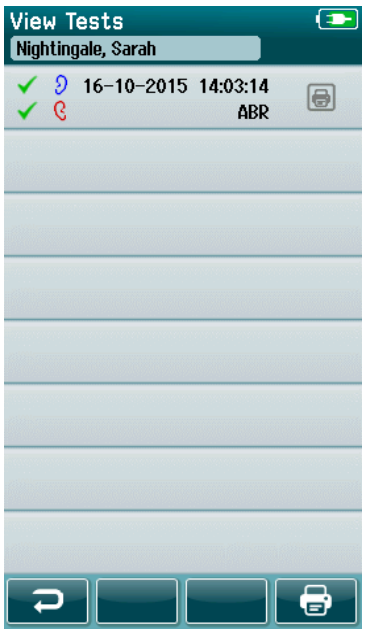
When you have selected a patient from the list, that patient's details will be displayed for review.

Test button

Select the **Test** button from the control bar to proceed with testing this patient.

View saved tests

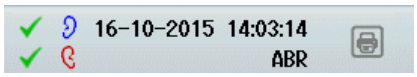
Select the **Test List** button from the control bar of the Patient Information screen to see a list of tests performed on this patient.



The test list is sorted chronologically with the most recent test at the top. Each row represents one test.

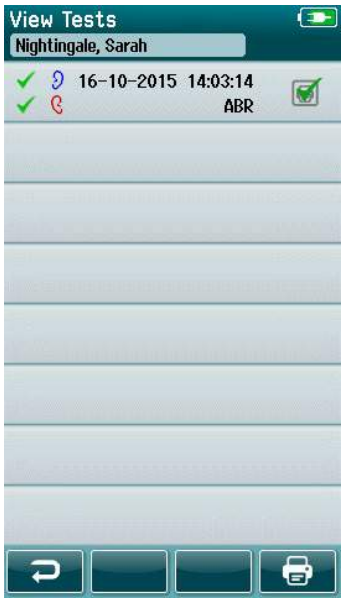
If more than 8 tests are saved, use the **Up** and **Down** arrow buttons in the bottom control bar to scroll through the list.

Each row in the Test List shows the following information:



- Result symbol for Pass, Refer or Incomplete
- Test ear symbol for Right, Left or Both ears
- Test date & time
- Test type (Automated ABR, DPOAE or TEOAE)

4.11.1.1 Printing a saved test



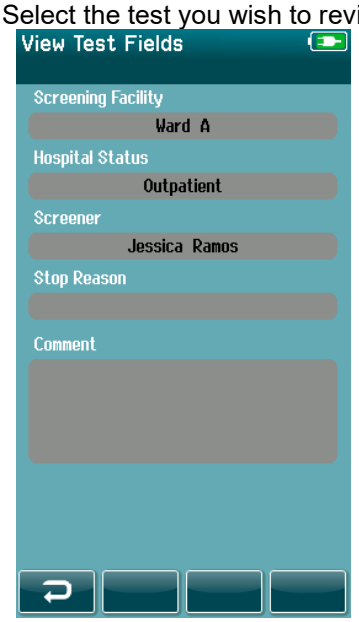
Push the Printer box to the right of the test to select the test for printing. When selected, the print icon box will contain a green checkmark. Select as many tests as you want to print. Then select the **Print** button in the control bar.

Each test will print out on a separate label except in the case where you have selected only one right and one left ear test of the same test type. In this case, both tests will print on a single label.

Please note: Printer boxes and the **Print** button only appear on the screen if your Sera™ has the wireless and Printer settings enabled via HearSIM™ and if an HM-E200 printer has been paired with the device. Otherwise, these controls are hidden from view.

Reviewing a saved test

Select the test you wish to review to see the **test results** and the **test field** information.



Select the **View Test Fields** button in the control panel to view Test-related Field information. This screen will only be available if the Test Fields option is enabled on the device via HearSIM™.

The Test-related fields cannot be edited on the Sera™. If edits are needed, the test data must be first transferred to the HearSIM™ and edited from there.

4.12 User management on device

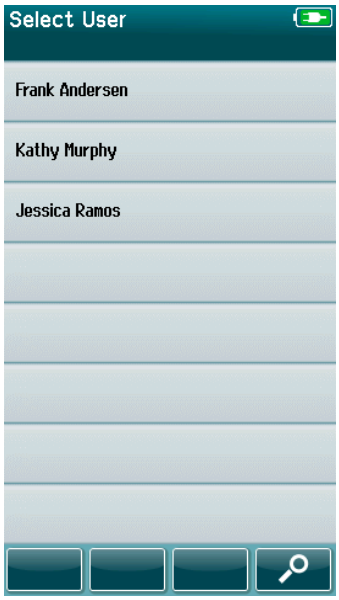
General

The Sera™ can be set up to require user login on the device via HearSIM™. This is disabled by default.



As soon as login is enabled, a button to change the user can be found on the home screen.

Selecting the user (optional)



The Sera™ can be setup to require user login on the device via HearSIM™. This is disabled by default.

When user login is enabled, a User List screen that you created in HearSIM™ and transferred to the Sera™ will display after the device boots up.

Select your username from the list to proceed to the password entry screen. **Up** and **down** arrows in the control bar allow you to move through pages of names if there are more than 8 users in the list.

Select the **Search button** in the control bar in order to type in characters of your username using the on-screen keyboard. Then select the **checkmark** in the control bar to return to view a shortened user list.

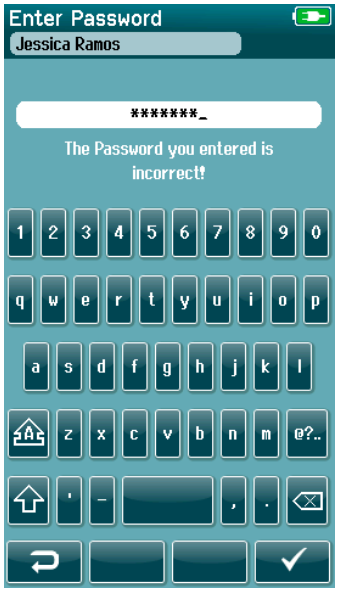
Entering the password



Enter your password in the password entry screen using the on-screen keyboard and select the **Checkmark** button in the control bar.

If the password is correct, the **Home** screen will display.

Incorrect password



If an incorrect password is entered, a message will appear indicating that the password you entered was incorrect.

The message will display for several seconds and then it will disappear, clearing the entry field so that you can try to re-enter the password again.

4.13 Setup



Select the **Setup** button in the control bar of the **Home** screen to access a list of the settings that can be made directly on the Sera™.

Language screen



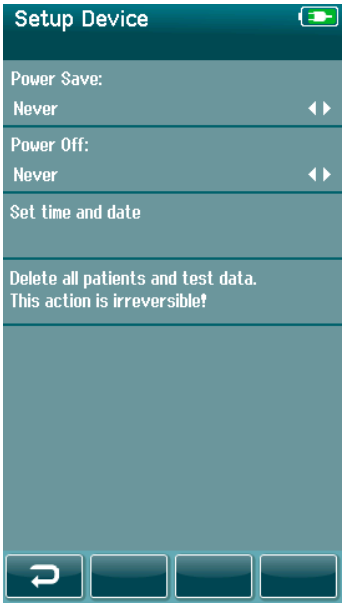
Use the **Up** and **Down** arrows to scroll through the list of languages.

Select the desired language so that a checkmark appears in the checkbox next to the language.

To confirm the selection and exit the Language screen, select the **checkmark** button in the control bar.

Available languages are English, German, Spanish, French, Italian, Portuguese, Dutch, Polish, Finnish, Russian, Chinese, Korean, Norwegian Turkish and Japanese.

Device



Set your time preference for **Power Save** and **Power Off** features.

- **Power Save** (Standby) can be set to Never, 1-5 minutes or 10 minutes
- **Power Off** can be set to Never or 1, 5, 10, 15 or 30 minutes

Select the **Checkmark** button in the control bar to confirm the settings and close the Device Setup screen.

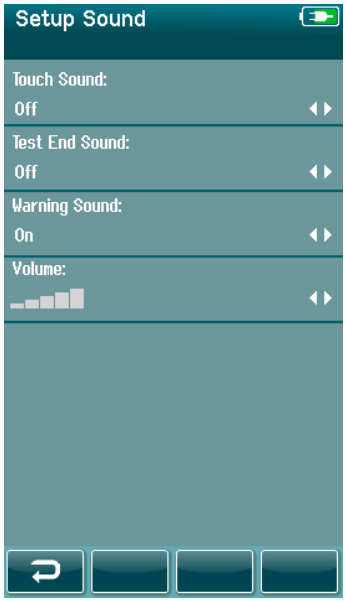
Set your preferences for **time and date**.

- Adjust time and date setting
- Choose between 24-hour clock or 12-hour clock mode

Option to **delete all patients and test data** from device.

- Deleting data is irreversible. A warning notification will be displayed before deletion is completed

Sound

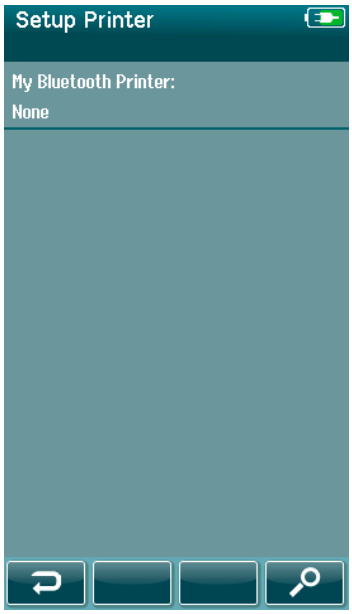


Set up your preferences for the presentation of a sound as feedback under various conditions. The volume level can also be set here. Conditions for which you can choose to present a sound are:

- **Touch sound** – a sound is presented for all button presses on the device
- **Test end sound** – a sound is presented when a test is completed
- **Warning sound** – a warning sound is presented when an electrode becomes detached during Automated ABR testing or when the battery charge is low

Select the **Checkmark** button in the control bar to confirm the settings and close the Sound Setup screen.

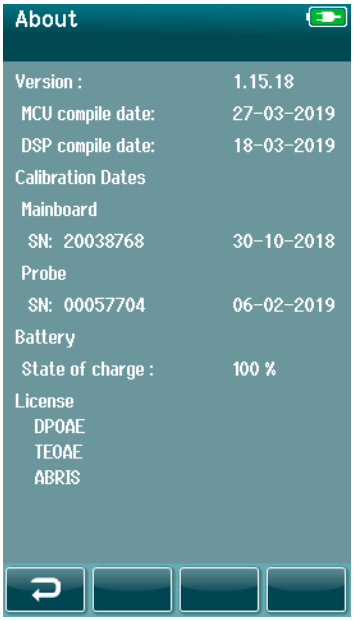
Printer



To pair to the optional HM-E200 wireless printer, select the **Search** button in the control bar. Be sure that the printer is powered on. The name “HM-E200” will display when the printer is successfully paired to the Sera™.

Select the **Checkmark** button in the control bar to confirm the settings and close the Printer Setup screen.

About



Select the **About** item to view information about the Sera™ including:

- Firmware versions
- Serial numbers and calibration dates
- Battery information
- Licenses

5 Equipment (integrity) checks

5.1 General

The performance of the probe and the electrode cables are crucial to the test results. We recommend that you conduct an equipment check at the beginning of each day before starting to test on patients to ensure that the equipment is functioning correctly.

- Before conducting the integrity test, ensure that the probe tip or ear tip adapter is clean and free of wax and/or debris
- Always conduct the equipment check in a quiet test environment
- Only use the recommend Pass-Checker or cavity for testing. Using a different type of device or cavity may not detect equipment or transducer faults

5.2 Pass-checker for automated ABR (optional)

The optional Sera™ ABRIS Pass-Checker accessory can be used to perform an integrity check of the electrode cables and transducer used for Automated ABR testing with Sera™. An integrity check can be done on a regular basis or can be performed if you suspect a problem with the Sera™ hardware, electrode cables or transducer. The Pass-Checker can be purchased from your Interacoustics representative.



1. Verify that the electrode cables and the insert earphones/EarCups/Probe are connected to the Sera™ preamplifier cable and that the preamplifier cable is attached to the Sera™.

2. Connect the 3 colored electrode cables to their respective metal buttons on the Pass-Checker – ensure that the colors of the cables match to the ring around the metal buttons).



3. For an EarCups transducer, insert the black EarCup adaptors completely into the holes on each side.



When using insert phones, ensure the ear tip adaptor is connected to a disposable ear tip (9mm green recommended). Insert the ear tips into the holes until the outer edge of the mushroom sits flush with the outer edge of the hole. Do not push the ear tip in too far or it can get lodged inside.

If using the probe, ensure a disposable ear tip is connected (blue recommended) before inserting it into the hole. Block the other hole of the Pass-Checker before conducting the test.

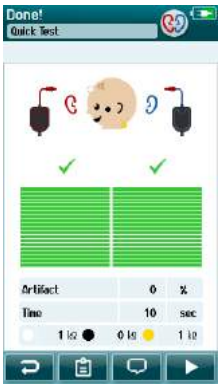


4. Switch on the Pass-Checker by pressing the power button. The amber LED lights up when the Pass-Checker is turned on.

   The Pass-Checker has an auto-off function. If you perform repeated tests during troubleshooting, make sure that the Pass-Checker is still switched on during your tests.



5. Perform a standard binaural or monaural (for probe) Automated ABR test.



6. The test should proceed quickly through the impedance and measurement phases ending in a Pass result for both ears (one if probe used). If the test does not Pass or the test cannot go further than the Impedance check, there is a potential issue with the system.

See the Sera™ Additional Information for symptoms, possible causes and suggested troubleshooting.

Please note: The Pass-Checker battery should only be replaced by an authorized Interacoustics representative. Damage to the Pass-Checker electronics resulting from an attempt to change the battery by someone other than an authorized representative will not qualify for repair under the product warranty.

If no Pass-checker is available to perform the Automated ABR integrity check, you can perform the testing on yourself.

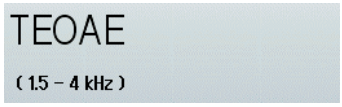
5.3 Probe integrity test for TEOAE

A test cavity called the Infant Ear Simulator is provided with Sera™ for conducting a probe integrity test for the OAE modules.

The probe integrity test ensures that system distortions are not being generated by the probe or hardware. The probe tip should be inspected for wax or debris prior to conducting the test. And testing should be conducted in a quiet environment



1. Insert the OWA-probe with the 3mm red flanged ear tip or the SnapPROBE™ with either ear tip attached into the Infant Ear Simulator provided with the Sera™.



2. Select the quick test option on the main screen and run a standard TEOAE test. Let the test run until it stops automatically. Do not stop the test manually.



3. If the probe is functioning correctly (no TE bands get a checkmark), it is possible to continue with daily testing.



4. If error messages appear during testing or if one or more of the TE bands has a checkmark above it at the end of the test, the probe integrity test has failed. Check and clean the probe tip for wax or debris and redo the test. If the probe test fails a second time, the Sera™ **must not be used to test on patients. Contact your local distributor for assistance**.



See the Sera™ Additional Information for symptoms, possible causes and suggested troubleshooting.

Please note: If a probe is handled roughly (e.g., dropped onto a hard surface), it might need to be calibrated again. Calibration values of the probe are stored in the probe plug. Therefore, probes can always be exchanged.

5.4 Probe integrity test for DPOAE

A test cavity called the Infant Ear Simulator is provided with Sera™ for conducting a probe integrity test for the OAE modules.

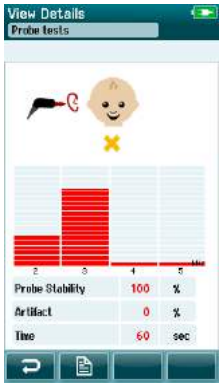
The probe integrity test ensures that system distortions are not being generated by the probe or hardware. The probe tip should be inspected for wax or debris prior to conducting the test. And testing should be conducted in a quiet environment



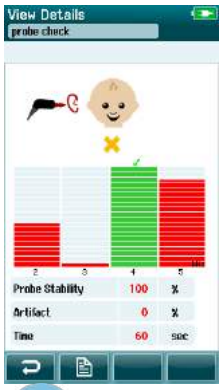
1. Insert the OWA-probe with the 3mm red flanged ear tip or the SnapPROBE™ with either ear tip attached into the Infant Ear Simulator provided with the Sera™.



2. Select the quick test option on the main screen and run a standard TEOAE test. Let the test run until it stops automatically. Do not stop the test manually.



3. If the probe is functioning correctly (no DP frequency points get a checkmark), it is possible to continue with daily testing.



4. If error messages appear during testing or if one or more of the DP frequency points has a checkmark above it at the end of the test, the probe integrity test has failed. Check and clean the probe tip for wax or debris and redo the test. If the probe test fails a second time, the Sera™ **must not be used to test on patients. Contact your local distributor for assistance**.

See the Sera™ Additional Information for symptoms, possible causes and suggested troubleshooting.

Please note: If a probe is handled roughly (e.g., dropped onto a hard surface), it might need to be calibrated again. Calibration values of the probe are stored in the probe plug. Therefore, probes can always be exchanged .

6 Maintenance

6.1 General maintenance procedures

The performance and safety of the instrument will be maintained if the following recommendations for care and maintenance are observed:

1. It is recommended that the instrument go through at least one annual service, to ensure that the acoustical, electrical and mechanical properties are correct. This should be carried out by an authorized repairer in order to guarantee proper service and repair.
2. Observe that no damage is present to the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load that could involve damage.
3. To ensure that the reliability of the instrument is maintained, we recommend that the operator at short intervals, for instance once a day, performs a test on a person with known data. This person could be the operator. For OAE testing, a daily probe integrity test is recommended to confirm the probe is functioning properly before testing on patients.
4. If the surface of the instrument or parts of it is contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and detergent or similar. Always disconnect the mains power adaptor during the cleaning process and be careful that no fluid enters the inside of the instrument or accessories.
5. After each patient examination, ensure that there has been no contamination to the parts touching the patient. General precautions must be observed in order to avoid cross-contamination of disease from one patient to another. Water should be used for frequent cleaning, but in the case of severe contamination it may be necessary to use a disinfectant.



Please refer to the Sera™ Additional Information for further information about cleaning and maintenance of the equipment and accessories.

6.2 General maintenance procedures



- Before cleaning always switch off and disconnect from the power supply
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the metal parts inside the earphones/headphones
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use components

Recommended cleaning and disinfection solutions:

- Warm water with mild, non-abrasive cleaning solution (soap)
- 70% isopropyl alcohol only on hard cover surfaces

6.3 Cleaning the Sera™

Touch screen

Clean the instrument by wiping the outer case with a lint free cloth lightly dampened with cleaning solution. Use a lens cleaning or microfiber cloth to clean the Sera™ touch screen.

Case, cradle and cables



Use caution while cleaning.

- Before cleaning, remove the Sera™ from the cradle and unplug the cradle from mains power.
- Use a soft cloth moistened with a mild solution of water and detergent to clean the plastic parts of the Sera™ and cradle.
- If disinfection is required, use a disinfectant wipe rather than a spray product. Make sure that excess liquid from the wipe does not seep into any sensitive areas such as connectors and seams where plastic pieces connect such as under the rubber rim around the Sera™.

Follow the instructions on the disinfection product.

Disposables

Use only the Sanibel™ disposable supplies that are supplied with your Sera™. Ear tips, EarCups and adhesive electrodes are intended for single use only. These should be discarded after use. They cannot be disinfected.



In the event of re-use of the single-use disposables, you enhance the risk of cross contamination!

6.4 Cleaning the OWA probe tip

In order to secure correct measurements, it is important to make sure that the probe system is always kept clean. Therefore, please follow the below illustrated instructions on how to remove e.g. cerumen from the small acoustic channels of probe tip.



Use the Thornton Bridge & Implant Floss or the Thornton 3 in 1 Floss for cleaning.

Discard used floss after use.

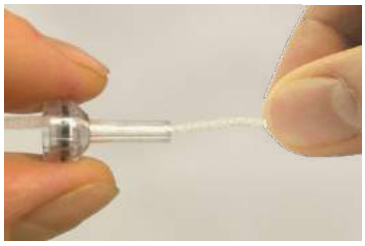


Never clean the probe tip while the tip is still attached to the probe body.

Unscrew the probe cap by turning it in a counterclockwise direction and remove the probe tip from the probe body.



Thread the cleaning floss into one of the channels from the base of the probe tip.



Pull the cleaning floss completely through the probe tip channel. Repeat for each channel if required.



To clean the larger channel, it is advisable to double the floss to effectively clean all corners.



To access and clean the larger channel, it is necessary to remove the gasket from inside the probe tip. You can do this using a fine pin. Push the gasket back into place after cleaning.





Reattach the probe tip to the probe and screw the gasket into place.



DO NOT try to clean the probe tip while it is mounted on the probe.

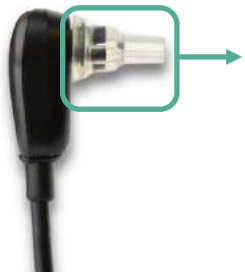
Only insert the cleaning floss or wire into the base of the probe to ensure wax/debris is pushed out of the probe tip instead of into it. This also protects the gasket from being damaged. Never use tools to affix the probe cap!

Please refer to the Sera™ Additional Information for further information about Cleaning of the probe.

6.5 Cleaning the SnapPROBE™

The ear tips for the SnapPROBE™ are designed to maintain distance between the sensitive components of the probe and an infant ear canal. The elongated shape will typically collect most of the ear wax, which is disposed along with the ear tip after use, thereby limiting how often the filters in the probe need to be replaced. It is important that the probe tip is clean and free of wax or other debris before conducting a test. Wax or debris in the probe tip can cause incorrect presentation of the stimulus or recording. A visual inspection of the probe and its filters should therefore be made prior to every measurement.

If any traces of ear wax, debris or the like are present, the filters of the probe need to be replaced.



Remove the ear tip from the probe in order to access the SnapPROBE™'s three filters.



The filters can be removed using a replacement filter tool from the replacement filter kit.



Use the empty slot of the replacement filter kit to remove a filter from the probe.



Insert the new filter provided on the tool in the empty filter slot. Dispose of the old filter immediately to avoid mixing it up with new replacement filters.

6.6 Accessories/replacement parts

Some reusable components are subject to wear with use over time. We recommend that you keep these replacement parts available (as appropriate for your Sera™ device configuration).

6.7 Repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

1. Assembly operations, extensions, readjustments, modifications or repairs are carried out by authorized persons
2. A 1-year service interval is maintained
3. The electrical installation of the relevant room complies with the appropriate requirements, and
4. The equipment is used by authorized personnel in accordance with the documentation supplied by Interacoustics.

The customer shall reach out to the local distributor to determine the service/repair possibilities including onsite service/repair. It is important that the customer (through local distributor) fills out the **RETURN REPORT** every time when the component/product is sent for service/repair to Interacoustics.

6.8 Warranty

Interacoustics guarantees that:

- The Sera™ is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service center to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.

The expected service life of the instrument is 7 years.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative;
- altered in any way so as, in Interacoustics opinion, to affect its stability or reliability;
- subject to misuse or negligence or accident, or that has had the serial or lot number altered; defaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions provided by Interacoustics.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics. Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

7 General technical specification

7.1 Sera™ instrument – technical specifications

Medical CE-mark CE 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no0123 The Sera™ is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.	
Standards	**Safety:**	IEC 60601-1:2012, Internally powered, Type B and BF applied parts
	EMC:	IEC 60601-1-2:2014 IEC 60601-2-40:2016
	Calibration:	ISO 389-2:1994 ISO 389-6:2007
	Test Signal:	IEC 60645-3:2007
	OAE:	IEC 60645-6:2009, Type 2
	ABR:	IEC 60645-7:2009, Type 2
Cradle	**Safety:** **Power** **Mains voltages and frequencies:** **Output:**	IEC 60601-1:2012, Class II UE08WCP-050160SPA Item number 8029254 100 – 240 V~, 50/60 Hz, 400 mA 5.0V DC, 1.6A MAX
Operation environment 	**Temperature:** **Relative Humidity:** **Ambient Pressure:** **Boot-up time:** **Warm-up Time:**	5 – 40°C, + 41°F... + 104°F 15 – 93% (non-condensing) 98 kPa – 104 kPa < 5 sec Nil
Transport & Storage environment	**Storage Temperature:** **Transport Temperature:** **Storage and Transport rel. Humidity:**	0°C – 50°C, - 4°F... + 122°F -25 – 70°C, - 13°F... + 158°F Max 93% (non-condensing)
Altitude rating	**Max. operating altitude:**	2000 m / 6561 ft above sea level
Markings **IP02** **IP20**	IP marking is an ingress protection marking. The marking specifies the protection provided against ingress of particle matter and liquids. This instrument has different IP marking with the follow impact: IP02: To protect the instrument against rain and water always use the carrying bag during transport. IP20: This marking can be found on the instrument parts meaning that the parts are not protected against water NOTE: The charger, power supply and cradle are not to be used in home healthcare environments.	

General		
Dimensions Sera™		15.8 x 8.3 x 1,9 cm / 6.2 x 6.2 x 0.7 inches
Sera™ Weight		265 g / 0.5 lbs
User Interface:		Resistive Touch Screen
Display Size:		9.5 x 5.6 cm, color, 272 x 480 resolution
Data Interfaces:		Wireless Transmit frequency: 2400 – 2483.5 MHz Modulation types: GFSK, π/4-DQPSK and 8DPSK Radiated power: 2.5 mW (Class 2)
User Feedback:		Integrated speaker
Language Settings:		English, German, Spanish, French, Italian, Portuguese, Dutch, Polish, Finnish, Romanian, Russian, Chinese, Korean, Turkish, Norwegian, Japanese.
Battery	**Type:**	Li-ion battery 44794; Capacity: 3.7V/3850 mAh
	Expected life time:	Depending on use – typically more than 3 years
Memory		1 GB (max. 250 Patient can be stored with 50 tests each)
Connector		Omnetics 12-pin connector
Preamplifier weight		85 g / 0.19 lbs
Preamplifier dimensions		8.5 x 0.5 x 2.5 cm / 3.4 x 0.2 x 0.9 inches

Printer		
Thermal printer (Optional)	**Type:**	HM-E200
	Connection:	Wireless
	Battery:	Rechargeable Li-polymer, DC 7.4 V, 1300 mAh
	Charger:	AC 100 – 240 V, ~50/60 Hz, 1.0 A
	Weight:	234 g / 8.3 oz
	Paper:	Thermal paper Thermal labels (103 per roll)
	Paper width:	58 mm (width) on thermal printer 56 mm x 60 mm (width x length) on label printer
	Printing time:	Max. 100mm/s. Printing time depends on the size of the used protocol.

ABRIS		
Preamplifier	**One Channel:**	3 electrodes, 51 cm, 20”
	Gain:	65 dB (72 dB nom.)
	Frequency response:	0,5 - 5000 Hz
	Noise:	<25 nV/√Hz
	CMR Ratio:	> 100 dB at 100 Hz
	Sample rate:	22.05 kHz
	Max input offset voltage:	2.5 V
	Input impedance:	10 MΩ/ 250 pF
	Power from main unit:	Isolated power supply
Electrical Impedance measurement	**Measurement frequency:**	33 Hz
	Waveform:	Rectangular
	Measurement current:	11.25 µA
	Range:	0.5 kΩ – 50 kΩ ± 10 %
Stimulus	**Stimuli:**	CE-Chirp® (200 Hz – 11 kHz), Click (200 Hz – 11 kHz)
	Stimulus rate:	90 Hz
	Transducers:	IP30 insert phone

	(Calibrated to Standards)	IP30 EarCup OWA Probe SnapPROBE™
	Level:	30, 35, 40, 45 dB nHL
	Bandwidth:	22.05 kHz
Recording	**Analysis time:**	3 minutes
	A/D resolution:	24 bit
	Artifact reject system:	Rejection level (Peak, Min RMS, Max RMS) & Clipping (Saturation)
Display		Transducer, test result bars, result symbols (pass/refer/incomplete), test time, artifact, electrode impedances.
Accuracy of Measurement	**Algorithmic Sensitivity (default protocol):**	≥ 99.6 % Please refer to the Sera™ Additional Information for further information about available test protocols, test protocol settings and sensitivity and specificity.

DPOAE		
Stimulus	**Frequency range:**	1500 to 6000 Hz
	Nominal frequency:	f2
	f2/f1 ratio:	1.22
	Level:	50 – 65 dB SPL
	Transducer:	SnapPROBE™ auto detection, auto calibrated Replaceable probe tip OWA Probe auto detection, auto calibrated Replaceable probe tip
Recording	**Analysis time:**	60 seconds
	A/D Resolution:	24 bit, 5.38 Hz resolution
	Artifact (noise) rejection system:	30 dB SPL
	Residual noise:	An RMS average measurement in the DP-bin frequency area (26 bins at frequencies < 2500 Hz & 60 bins ≥ 2500 Hz).
	Test Pressure:	Ambient
Display		Transducer, test result bars, result symbols (pass/refer/incomplete), probe stability, test time, artifact.
Accuracy of Measurement:	**Algorithmic Sensitivity (default protocol):**	≥ 99.6 % Please refer to the Sera™ Additional Information for further information about available test protocols, test protocol settings and sensitivity and specificity.

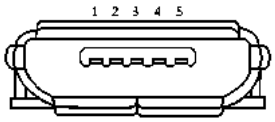
The Sera™ with DPOAE uses an improved method of stimuli level control, which more accurately delivers the specified intensity in the full range of ear canals, from infants to adults. The applicability of the IEC 60645-6 standard is currently limited to adult ears. Therefore, in order to better serve a market with a product that provides more accurate stimulus levels to a wide range of ear canal volumes (specifically infants), we have elected to utilize a more comprehensive calibration procedure for DPOAEs that is outside the scope of IEC 60645-6 for some protocols.
All protocols that include IEC in the name use the specified IEC calibration method.

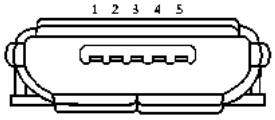
TEOAE		
Stimulus	**Frequency range:**	1500 to 4000 Hz
	Stimulus type:	Non-Linear (according to IEC 60645-3:2007)
	Level:	60 – 83 dBpe SPL, peak to peak calibrated, AGC controlled
	Click rate:	71/second
	Transducer:	SnapPROBE™ auto detection, auto calibrated Replaceable probe tip OWA Probe auto detection, auto calibrated Replaceable probe tip
Recording	**Analysis time:**	60 seconds
	Recording window:	2.5 – 14.1 ms
	A/D Resolution:	24 bit
	Artifact (noise) rejection system:	55 dB SPL
	Test pressure:	Ambient
	Residual noise:	A RMS value for each octave band, based on the Bayesian weighted average for the defined OAE time window.
Accuracy of Measurement	**Algorithmic Sensitivity (default protocol):**	≥ 99.6 % Please refer to the Sera™ Additional Information for further information about available test protocols, test protocol settings and sensitivity and specificity.
Display		Transducer, test result bars, result symbols (pass/refer/incomplete), stimulus stability, test time, artifact.

7.2 Specification of input/output connections

	Sera™ ABR/OAE Connector for Probe, Preamplifier	**Preamplifier, Probe, Transducer connector**
Pin	Description	Description
1	CH1 out	CH1 out
2	CH1 GND	CH1 GND
3	DGND	DGND
4	GND A / GND Microphone	GND A / GND Microphone
5	Microphone – input / Analog balanced in	Microphone – input / Analog balanced in
6	Microphone + input / Analog balanced in	Microphone + input / Analog balanced in
7	Power supply +3/+5V	Power supply +3/+5V
8	CH2 out	CH2 out
9	CH2 GND	CH2 GND
10	I2C CLK	I2C CLK
11	I2C DATA	I2C DATA
12	I2C Interrupt	I2C Interrupt

Data input/output	
USB type A-B micro	USB port for communication

CRADLE CONNECTOR	**CONNECTOR**
MAINS	 **MICRO USB 5V/1.6A**

SERA™ CONNECTOR			
		MICRO USB (IN)	
	1		1. +5 VDC 2. NC 3. NC 4. NC 5. Ground

Calibration properties

Accuracy	
ABRIS	±2 dB for all stimulus types

DPOAE	±1.5 dB for 1000 to 4000Hz and ±3 dB outside range
TEOAE	±2 dB for click stimulus

7.3 Calibration reference values for the CE-Chirp® stimulus

Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance to IEC 60318-4.

Transducer	peRETSPL [dB re. 20 µPa]
RadioEar IP30 with ear tips	31.5 dB SPL
RadioEar IP30 with EarCups	58.5 dB SPL
OWA probe	35 dB SPL
SnapPROBE™	xx dB SPL

Reference values for the CE-Chirp® stimulus are Interacoustics standard values.

7.4 Calibration reference values for the click stimulus

Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance to IEC 60318-4.

Transducer	peRETSPL [dB re. 20 µPa]
RadioEar IP30 with ear tips	35 dB SPL
RadioEar IP30 with EarCups	61.5 dB SPL
OWA probe	33.5 dB SPL
SnapPROBE™	xx dB SPL

7.5 Coupler types used for calibration

ABRIS:
Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance to IEC 60318-4.
DPOAE:
Probe stimuli L1 and L2 are calibrated individually in SPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.
TEOAE:
Probe stimuli are calibrated in peSPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.

7.6 General information about specifications

Interacoustics continuously strives to improve its products and their performance. Therefore, the specifications can be subject to change without notice.
The performance and specifications of the instrument can only be guaranteed if it is subject to technical maintenance at least once per year. This should be carried out by a workshop authorized by Interacoustics.

Interacoustics puts diagrams and service manuals at the disposal of authorized service companies.

Enquiries about representatives and products may be sent to:

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
Denmark
Tel.: +45 6371 3555
Fax: +45 6371 3522
E-mail: info@interacoustics.com
Web: www.interacoustics.com

7.7 Appendix A: Stimulus

Another stimulus than specified in the standard IEC 60645-3 is used for some Automated ABR protocols. This CE-Chirp® stimulus has the same linear magnitude frequency response as the Click stimulus specified in the standard. However, it is designed as a sum of cosine functions in the frequency domain. The frequencies of the cosines are multiples of the stimulus repetition rate. With equal intensity for each frequency, to achieve the same linear magnitude frequency response. However, the phase of the cosine components is delayed according to the cochlear delay of the according frequency in order to achieve a more effective stimulus design. The frequency range of the stimulus is from 200 Hz up to 11 kHz.

7.8 Appendix B: Electromagnetic Compatibility (EMC)

This equipment is suitable in hospital and clinical environments except for near-active HF surgical equipment and RF-shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

NOTICE: ESSENTIAL PERFORMANCE for this equipment is defined by the manufacturer as:
This equipment does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk.
Final diagnosis shall always be based on clinical knowledge.

Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories and cables can be found in this section.

Portable RF 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 this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

This equipment complies with IEC60601-1-2:2014, emission class B group 1.

NOTICE: There are no deviations from the collateral standard and allowances uses.

NOTICE: All necessary instructions for maintenance comply with EMC and can be found in the general maintenance section in this instruction. No further steps required.
To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories as applicable:

Item	Manufacturer	Model
Preamplifier	Interacoustics	-
OWA Probe	RadioEar	-
Snap Probe	RadioEar	-
IP30 50Ohm stereo ID earphone	RadioEar	IP30
IP30 50Ohm earcup stereo ID headset	RadioEar	IP30

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length (meter)	Screened (Yes/No)
Power Supply	1,5	N
Wireless charger/cradle	-	-
Audiometric Insert-Headsets (IP30)	0,25	Y
Ear Probes (OWA / Snap)	0,50	Partial
Preamplifier	1,15	Partial
Electrode cables	0,51	N

The use of the accessories, transducers and cables with medical equipment/system other than this equipment may result in increased emissions or decreased immunity of the medical equipment/system.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *Sera™* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Sera™* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***Sera™*** 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	The ***Sera™*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the *Sera™*.

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

Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated 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.

Note 1 At 80 MHz and 800 MHZ, the higher frequency range applies.

Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ***Sera™*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Sera™*** should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***Sera™*** requires continued operation during power mains interruptions, it is recommended that the ***Sera™*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***Sera™*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Sera™*** should assure that it is used in such an environment,			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***Sera™***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz w $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***Sera™*** is used exceeds the applicable RF compliance level above, the ***Sera™*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***Sera™***. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Return Report – Form 001

Interacoustics

Opr. dato:	af:	Rev. dato:	af:	Rev. nr.:	
2014-03-07	EC		MSt	4	

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone
(+1) 800 947 6334

Fax
(+1) 952 903 4200

E-mail
rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

_____

_____

_____

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods: _____

☐ **The above mentioned item is reported to be dangerous to patient or user** [1]

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

[1] EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.