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Additional Information

Sera™

D-0114042-I 2024-11

Interacoustics

Table of contents

1 ABOUT THE ADDITIONAL INFORMATION MANUAL 1
1.1 Warnings 1
2 LIST OF ABBREVIATIONS 2
3 BATTERY LIFE 3
4 DISPOSABLES 4
4.1 Ear tips 4
4.2 Tips for use of the Sanibel disposable tab and snap electrodes 5
5 SENSITIVITY AND SPECIFICITY 6
5.1 What is sensitivity and specificity? 6
6 PREPARING FOR THE SCREENING TEST 7
6.1 Acoustical noise 7
6.2 Electrical noise & Automated ABR 7
6.3 OAE probe test 8
6.4 Automated ABR patient preparation 8
6.4.1 General information 8
6.4.2 Skin preparation 8
6.4.3 Electrode preparation sites for the nape montage 9
6.4.4 Electrode placement for the nape montage 9
6.4.5 Preamplifier cable connections 10
6.4.6 Place transducers 10
6.4.7 Insert earphones with EarCups 11
6.4.8 Insert earphones with ear tips 12
6.4.9 Probe 13
6.5 OAE patient preparation 14
6.5.1 General information 14
6.5.2 Place transducer 15
7 ABRIS 16
7.1 About the ABRIS module 16
7.2 Automated ABR testing 16
7.3 Automated ABR with Sera™ 16
7.4 Electrode impedance measurement technique 17
7.5 Electrode impedance check with Sera™ 18
7.6 Transducer information area in Sera™ 18
7.7 Automated ABR protocols 19
7.8 Explanation of protocol parameters 19
8 DPOAE 21
8.1 About the DPOAE module 21
8.2 DPOAE testing 21
8.3 Automated DPOAE with Sera™ 21
8.4 DPOAE protocols 22
8.5 Explanation of protocol parameters 25
9 TEOAE 26
9.1 About the TEOAE module 26
9.2 TEOAE testing 26
9.3 Automated TEOAE with Sera™ 26
9.4 TEOAE protocols 27
9.5 Explanation of protocol parameters 29
10 HEARSIM™ SOFTWARE APPLICATION 30
11 CLEANING AND DISINFECTION 31
11.1 General information about cleaning and disinfection 31
11.2 Caution during cleaning and disinfection 31
11.3 Sera™ hardware device 31
11.3.1 Cleaning the touch screen 32
11.4 Cradle 32
11.5 Preamplifier and electrode lead wires 32

11.6 Insert phone cable 33
11.7 EarCup and ear tip adapters 33
11.8 Probe 33
11.8.1 Cleaning the OWA probe tip 34
11.8.2 Cleaning the SnapPROBE™ 36
11.9 Disposables 37
11.10 Accessories/replacement parts 37
11.11 Sera™ ABRIS Pass-Checker (optional) 37
12 FAQ/TROUBLESHOOTING 38
12.1 Hardware 38
12.2 Firmware 39
12.3 Optional Sera™ ABRIS pass-checker 43
13 STATEMENT REGARDING TEOAE STIMULUS 44

1 About the Additional Information manual

The Additional Information manual provides a more detailed overview of the product features, measurement parameters, and helpful hints about test preparation which are not contained in the Instructions for Use manual.

The Instructions for Use guides you to the Additional Information with this icon, where more detailed information is available about a particular topic.

1.1 Warnings

Throughout this manual the following meanings of cautions apply:

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

2 List of abbreviations

ABR	Auditory Brainstem Response.
ABRIS	Auditory Brainstem Response Infant Screening.
DPOAE	Distortion Product Otoacoustic Emissions.
TEOAE	Transient evoked Otoacoustic Emissions.
EEG	Electroencephalogram

3 Battery life

Estimated Battery Life for Automated ABR Screening = >50
Estimated Battery Life for OAE Screening = >150

*Test duration affects battery life. Test duration depends on the state of the baby and test technique issues that can vary widely. Therefore, the number of screens per battery charge may vary significantly in your facility.

**The device should be placed in the charging cradle when not in use so that it does not become fully discharged. Habitually allowing the battery to fully discharge between charges will shorten the overall life of the battery.

4 Disposables

4.1 Ear tips

Selecting the correct size ear tip takes practice. In general, flanged, or mushroom shaped ear tips are recommended for use when measuring DPOAEs, TEOAEs or Automated ABRs.

The table below can be used as a guide to help you select an appropriate ear tip size when using IP30 insert earphones, the OWA probe or the SnapPROBE™.

Age (years)	Ear tips inserted into the ear canal			
Up to 0.5		Ear tip 4 mm at tip, 9 mm at base elongated		Ear tip 4 mm at tip, 9 mm at base, conical
0.5		Ear tip, Preemie		Ear tip 3-5 mm, flanged
		Ear tip 4-7 mm, flanged		Ear tip 5-8 mm, flanged
		Ear tip 7 mm, mushroom		Ear tip 8 mm, mushroom
4		Ear tip 9 mm, mushroom		Ear tip 10 mm, mushroom
10		Ear tip 11 mm, mushroom		Ear tip 12 mm, mushroom
Adult		Ear tip 13 mm, mushroom		Ear tip 14 mm, mushroom
		Ear tip 15 mm, mushroom		Ear tip 19 mm, mushroom

4.2 Tips for use of the Sanibel disposable tab and snap electrodes

Figure 1: Tab electrodes

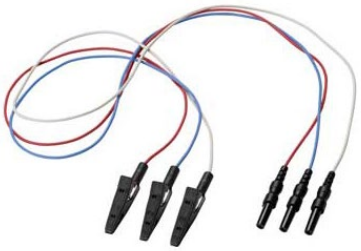

Figure 2: Alligator cables

Figure 3: Snap electrodes

Figure 4: Pinch cables

To ensure the optimal use of your Sanibel disposable tab or snap electrodes, please observe the following:

- Ensure that the skin is clean and dry before placing the electrode
    - *It is recommended to clean the new-borns skin, especially if the skin is greasy or oily, prior to placing the electrodes*
- Use a small amount of conductive electrode gel to improve impedances, if required
- When applying electrodes to the skin, press down firmly on the entire electrode surface to improve adhesion
- Use pinch cables for snap electrodes and alligator cables for tab electrodes
- Electrode adhesion time is limited to a maximum of 1 hour
- Store unused electrodes in unopened pouches at temperatures 5°-27° C / 40°-80° F
- Use before the expiry date printed on the pouch

5 Sensitivity and specificity

5.1 What is sensitivity and specificity?

Sensitivity and specificity are common words used when discussing newborn hearing screening given the importance of detecting those children with a potential hearing loss who require further diagnostic assessment and treatment.

In a medical diagnosis:

Sensitivity refers to the probability that a test will be positive when the disease is present (true positive).
Specificity refers to the probability that a test will be negative when the disease is not present (true negative).

These terms can often be confusing in the field of hearing screening. This may be due to the fact that hearing screening instruments label the outcome of a test where “normal” hearing was detected as a “pass” whereas the definition above refers to labelling a test that detects a disease as “positive” and non-diseased or normal as “negative”.

Essentially, hearing screening products should have a high sensitivity, meaning they should be good in detecting patients with a disease (a potential hearing loss) and labelling the result as a REFER. They also need to have a high specificity, ensuring patients without the disease (normal hearing) are not unnecessarily sent on for further diagnostic testing when it was not required.

Sensitivity is principally determined by the instrument implementation (algorithms and hardware). Poor sensitivity leads to unwanted false passes and can have very serious consequences for the child, as they would not receive timely and adequate treatment or amplification, leading to potential language development and social issues.

Specificity is also a measure of instrument implementation; however, it is also heavily influenced by the test environment, the tester and the test procedure. Therefore, the specificity quoted by one screening program with highly trained screeners who screen babies in a quiet room 12-24 hours after the child’s birth, may differ from another screening program where staff have limited training, babies are tested in noisy test environments or within hours of being born. Poor specificity (or false refers) can lead to an increased cost to screening programs requiring babies to be rescreened numerous times or being sent for unnecessary costly diagnostic assessments. It also leads to increased anxiety for parents or caregivers.

6 Preparing for the screening test

The ideal environment for hearing screening is one that is acoustically quiet with minimal potential for electrical interference (especially important for Automated ABR testing). This may not be easily achieved in a hospital, where most newborns are screened.

Nevertheless, the screener should be aware of how the environment can impact the testing process and results and should attempt to control the environment to the extent that it is possible.

If possible, check the external ear canal for wax with an otoscope. Excessive wax should be removed by a trained professional prior to testing to prevent the probe tip opening from clogging, which will inhibit testing.

6.1 Acoustical noise

Acoustical noise in the screening environment can be so loud that the low-level stimulus delivered by the hearing screening system is overwhelmed by the background noise.

Acoustical noise can also awaken the baby causing less than optimal recording conditions and artifacts that prolong the test time.

Acoustical noise can lead to a Refer result even for a baby with normal hearing.

What can the screener do to reduce acoustical noise?

- Find a location for the screening that is as quiet as possible, such as an unoccupied patient or procedure room
- Close the door to the test room to reduce the noise from others walking in the hallway who may be talking or pushing equipment that is noisy
- Be aware of “hidden” sources of acoustical noise, such as air conditioner vents, motors from devices or other medical equipment. Try to avoid them by moving as far away as possible
- Ask others in the test room to suspend talking, talk in a quieter voice, and mute or turn off radios or TVs while the test is being performed
- Ask parents to take young visitors out of the room during the test

6.2 Electrical noise & Automated ABR

Electrical noise in the screening environment can cause high artifact levels and generally noisy EEG, prolonging Automated ABR test times and increasing the chance of a refer result. Electrical noise issues can be very difficult to troubleshoot and avoid in a hospital environment.

What possible sources of electrical noise should the screener be aware of?

- Other electrical equipment in the test room, especially devices attached to the baby such as other monitoring equipment
- Nearby cell phones, tablets, computers, walkie-talkies
- MRI or other radiographic equipment located in the vicinity of the nursery, even on the floor above or below

If the screener notices high levels of electrical artifact during testing or an increase in refer rates, these sources of electrical interference should be considered and eliminated if possible. The screener may need help from the infant’s nurse or physician to troubleshoot electrical interference issues if it involves other types of monitoring equipment attached to the baby that are critical to the child’s care.

6.3 OAE probe test

Probe performance is crucial to OAE test results. We recommend that you conduct a probe test at the beginning of each day before starting to test on patients to ensure that the probe is functioning correctly.

Daily probe test

It is common practice to conduct a probe test at the beginning of each day before starting to test on patients to ensure that the probe is functioning correctly.

- Before conducting the probe test, ensure that the probe tip (OWA probe) and filters (SnapPROBE™) is clean and free of wax and/or debris
- Always conduct the probe test in a quiet test environment
- Only use the recommend cavity for testing. Using a different type of cavity may not detect probe faults

Refer to the Instructions for Use for further information about how to perform this daily probe test.

6.4 Automated ABR patient preparation

6.4.1 General information

The Sera™ with ABRIS (automated ABR) collects electrical signals from the brain via electrodes which are placed on the baby. As these signals are very small, 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.

Ideally, show the electrodes and transducer to be used to the parent before testing and explain the following:

- The aim of the test is to screen the hearing organ for its functionality
- The skin will be prepared before placing three electrodes
- A transducer (probe, insert headphones or EarCups) will be used to deliver the sound to the ear
- A soft clicking sound will be heard during the test
- The baby is not required to do anything during the test as it is automated
- Crying, sucking and movement may result in a longer test time

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 supplies could alter the behavior and results obtained with the device and are not recommended. Sanibel disposables are latex, DEHP and BPA free and have been tested for bio-compatibility. Data sheets are available upon request.

6.4.2 Skin preparation

The skin should be clean and free of lotions or oils. If any greasy skin care products have been used where the electrodes are to be placed, the lotion/oil should be carefully removed prior to placing the electrodes. This removal procedure should be discussed with a qualified nurse or doctor.

The electrode sites can be prepared and cleaned in order to obtain lower skin impedances. For this purpose, a large variety of skin preparation pastes/gels can be purchased. Please note that two different types of electrode pastes/gels exist: One which is an abrasive gel (such as NuPrep) to abrade the skin and another which is an electrically conductive paste.

Typically, if the baby's skin is clean and free of lotions/oils, you will not need to perform any skin preparation. However, to lower the skin impedances, follow these instructions:

- Clean the skin where the electrodes will be placed
- Put some of the skin preparation gel (NuPrep) onto a piece of gauze or swab and rub the skin gently several times. Neonates generally do not require excessive abrasion and in some cases, it may make impedances worse
- Remove any excessive abrasive gel and ensure the skin is dry before placing the electrodes
- If the baby's skin is dry or you are obtaining high impedances, applying a small amount of conductive gel/paste to the baby's skin prior to connecting the surface electrode will help to rehydrate the skin and to lower impedances

6.4.3 Electrode preparation sites for the nape montage

Clean each of the electrode sites as per the illustration below prior to placing the electrodes on the skin.

High forehead (centered) near the hairline

Cheek (or shoulder)

Nape (just below the hairline)

6.4.4 Electrode placement for the nape montage

Place the electrodes on the prepared electrode sites on the skin as illustrated below.

Note: All three electrodes must be positioned in order to perform testing.

High forehead (centered) near the hairline

Cheek (or shoulder)

Nape (just below the hairline)

Please note: The disposable electrodes supplied with the unit are single use only. If reusable electrodes are to be used, cleaning and disinfecting procedures should be clarified with your hospital's infection control department.

6.4.5 Preamplifier cable connections

After preparing the skin and placing the three electrodes on the baby, connect the electrode cables to the electrodes.

Figure 5

Ensure that the electrode cables are securely connected into the correct electrode jack on the top of the preamplifier, matching the color of the cable with the jack. The graphic near the electrode jacks on the preamplifier illustrates proper placement of electrodes for the nape montage (Figure 5).

Connect the cables to the electrodes as follows:

Electrode lead color	**Electrode location (nape montage)**
White	High forehead (centered) near the hairline
Black	Cheek (either side) or shoulder
Yellow	Nape (just below the hairline)

6.4.6 Place transducers

Different transducers can be used with the Sera™ for Automated ABR testing. At the time of purchase, you choose your preferred style of acoustic transducer – probe, insert earphones with ear tips or insert phones with EarCups. All use single-use disposable supplies.

Re-use of single-use disposables enhances the risk of cross contamination!

6.4.7 Insert earphones with EarCups

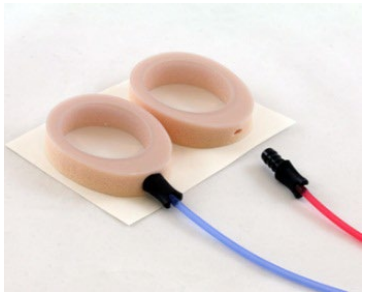

Figure 6: EarCup setup

The EarCup is an around-the-ear coupler that connects to the tubing of the insert earphones using the EarCup adapter. The EarCups adheres to the skin around the baby's ear.

Insert the EarCup adapter at the end of each of the insert earphone tubes into the hole in the foam at the top of the EarCup (Figure 6) so that it is fully inserted (Figure 6.1).

Figure 7: Baby with EarCups

Peel the EarCup attached to the red tubing from the backing card. Place it around the baby's right ear with the adapter and tubing pointing toward the top of the head. Press around the entire circumference of the EarCup to ensure adhesion to the baby's skin.

Peel the EarCup attached to the blue tubing from the backing card. Place it around the baby's left ear with the adapter and tubing pointing toward the top of the head. Press around the entire circumference of the EarCup to ensure adhesion to the baby's skin.

Place the insert earphone transducer boxes above or to the side of the baby's head away from electrode leads to reduce electrical interference.

6.4.8 Insert earphones with ear tips

The ear tip is a small silicone tip that is placed on the infant ear tip adapter that is attached to the tubing of the insert earphones. The ear tip is inserted into the baby's ear canal.

Do not insert the ear tip adapter into the baby's ear without an ear tip attached.

Please note: When using insert earphones, you cannot use the same transducer for testing both ears. Only use the red colored transducer for the right ear and the blue transducer for the left ear.
Choose the appropriate size of ear tip based on your inspection of the size of the baby's ear canals (Figure 8). The Sanibel green ear tip fits most newborn ears. Other sizes are available for larger ear canals.

Place the ear tips onto the ear tip adapters at the end of the insert earphone tubing.

Figure 8: Insert earphone ear tip adapter with ear tip

Figure 9: Insert earphone in baby's ear

Insert the ear tip attached to the red tubing into the baby's right ear. Do this by pulling gently down and out on the baby's ear lobe to open up the ear canal. Hold the adapter, aim and gently twist the ear tip into the ear canal. The fit of the ear tip should be secure; not superficial. Release the earlobe. Repeat this procedure for inserting the ear tip attached to the blue tubing into the baby's left ear

If you find that it is difficult to keep both ear tips secure in the baby's ear canals at the same time, you can choose to test one ear at a time. It is important that you use the transducer with the red tubing for the right ear and the transducer with the blue tubing for the left ear.

Place the insert earphone transducer boxes above or to the side of the baby's head to reduce electrical interference (Figure 9).

6.4.9 Probe

Do not insert the probe tip into the patient's ear canal without a disposable ear tip attached.

Choose the appropriate size of ear tip based on your inspection of the size of the baby's ear canals (Figure 10). The Sanibel green Preemie and the red flanged ear tip or the SnapPROBE™ ear tips fit most newborn ears. Other sizes are available for larger ear canals.

Place the ear tip onto the probe tip.

Figure 10: OWA-probe with ear tip

Figure 11: SnapPROBE™ with ear tip

Figure 112: Automated ABR using the probe

Insert the probe with ear tip attached into the baby's first test ear. Do this by pulling gently down and out on the baby's ear lobe to open up the ear canal. Hold the probe, aim and gently twist the ear tip into the ear canal.The fit of the ear tip should be secure; not superficial. Release the earlobe. You should not hold the probe during the measurement as this can produce excessive noise in the recording, prolonging the test time.

6.5 OAE patient preparation

6.5.1 General information

The Sera™ with DPOAE and TEOAE records otoacoustic emissions emitted by the outer hair cells, located in the cochlea. As these signals are very small, 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.

Ideally, show the probe to the parent before testing and explain the following:

- The aim of the test is to screen the hearing organ for its functionality
- A transducer (probe) will be used to deliver the sound to the ear
- A soft clicking sound will be heard during the test
- The baby is not required to do anything during the test as it is automated
- Crying, sucking and movement may result in a longer test time

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 supplies could alter the behavior and results obtained with the device and is not recommended. Sanibel disposables are latex, DEHP and BPA free and have been tested for bio-compatibility. Data sheets are available upon request.

6.5.2 Place transducer

Do not insert the probe tip into the patient's ear canal without a disposable ear tip attached.

Choose the appropriate size of ear tip based on your inspection of the size of the baby's ear canals (Figure 10). The Sanibel green Preemie and the red flanged ear tip or the SnapPROBE™ ear tips fit most newborn ears. Other sizes are available for larger ear canals.

Figure 123: OWA-probe with ear tip

Place the ear tip onto the probe tip.

Figure 134: SnapPROBE™ with ear tip

Insert the probe with ear tip attached into the baby's first test ear. Do this by pulling gently down and out on the baby's ear lobe to open up the ear canal. Hold the probe, aim and gently twist the ear tip into the ear canal. The fit of the ear tip should be secure; not superficial. Release the earlobe. You should not hold the probe during the measurement as this can produce noise in the recording.

OAE tests should not be performed while holding the probe in the patient's ear as this increases noise levels and the chance of incorrect delivery of the stimulus.

Figure 15: Probe being inserted in baby's ear

Figure 15.1: SnapPROBE™ inserted in baby's ear

7 ABRIS

7.1 About the ABRIS module

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 ABRIS is to be used by trained personnel only, such as audiologists, ENT surgeons and 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.

7.2 Automated ABR testing

Automated ABR testing is commonly used for infant hearing screenings as it tests the entire auditory system up to the brainstem.

Automated ABR technology uses a broadband stimulus such as a click or CE-Chirp® to stimulate the ear using a fast stimulus rate. Electrodes are placed on the baby and record the brain activity (EEG) that is evoked during presentation of the stimulus. Advanced algorithms are used to determine if there is a response to the stimulus in the recorded EEG.

It is ideal for testing newborns and infants as the patient does not need to be awake or respond in any way to the test stimulus. Responses from the brainstem are detected from electrodes that are attached to the head of the neonatal patient. Results are automatically analyzed and displayed as either PASS or REFER.

7.3 Automated ABR with Sera™

The ABRIS module with Sera™ performs Automated ABR by stimulating the ear with a click or CE-Chirp® at a fast stimulus rate (90Hz).

The algorithm is a multiple q-sample test with a critical test value set to a sensitivity of 99.9% and was developed by Stürzebecher et al. (1999[1]) and later improved by Mario Cebulla and colleagues (2006[2]). The algorithm assesses the incoming EEG in the frequency domain assessing amplitude and phase at a range of harmonics of the response to the periodic stimulus. By measuring many EEG-responses, and performing a frequency analysis on the data, it is possible to calculate a test value, which gives an indication of the phase stability for the frequencies equal to the stimulus rate and the first 8 harmonics. Comparing the phase stability with a mathematically found critical test value, it is possible to determine if there is a response to the stimulus in the EEGs. The calculation is performed everyone and a half second, and if the test value is greater than or equal to the critical test value the algorithm returns a “PASS”. If the test value has not reached the critical test value before the maximum test time (180 seconds), the algorithm returns a “REFER”.

The critical test value for PASS/REFER cannot be modified.

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[1] *Stürzebecher, E., Cebulla, M., & Wernecke, K.D. (1999). Objective response detection in the frequency domain: Comparison of several q-sample tests. Audiol Neurootol, 4, 2-11.*

[2] *Cebulla, M., Stürzebecher, E., Elberling, C. (2006). Objective detection of auditory steady-state responses: Comparison of one-sample and q-sample tests. J Am Acad Audiol, 17(2), 93-103.*

7.4 Electrode impedance measurement technique

When measuring electrode impedances, the numerical value that describes the impedance of each electrode depends on the application of the surface electrode and the method of impedance measurement. Application factors include the size of the electrode, preparation of the skin prior to electrode adhesion, application of pressure of the electrode and the electrode placement site.

The frequency used to measure the impedance also significantly affects the value. As a general rule, electrode impedances are low when measured using a high frequency and high when measured using a low frequency (Rosell et al., 1988[3]).

The Sera™ Preamplifier, like most clinical devices uses a 33Hz square wave frequency for determining electrode impedances. Therefore, electrode impedances seen with the Sera™ will be higher than those seen on many other newborn hearing screening instruments (that are using a 1000Hz frequency for measurement). While the numerical value may differ (between equipment) due to the measurement technique used, the actual impedance (the resistance of the skin between two electrodes) is actually the same.

For example, on other newborn hearing screening devices (using a 1000Hz measurement frequency), you will typically see electrode impedance values between 0-50kΩ whereas typical impedance values for the Sera™ are between 15-25kΩ. These value differences do not affect the test.

[3] *Rosell, J., Colominas, J., Rui, P., Pallas-Areny, R., & Webster, J. G. (1988). Skin impedance from 1 Hz to 1 MHz, IEEE Trans Biomed Eng, 35(8), 649-5.1*

7.5 Electrode impedance check with Sera™

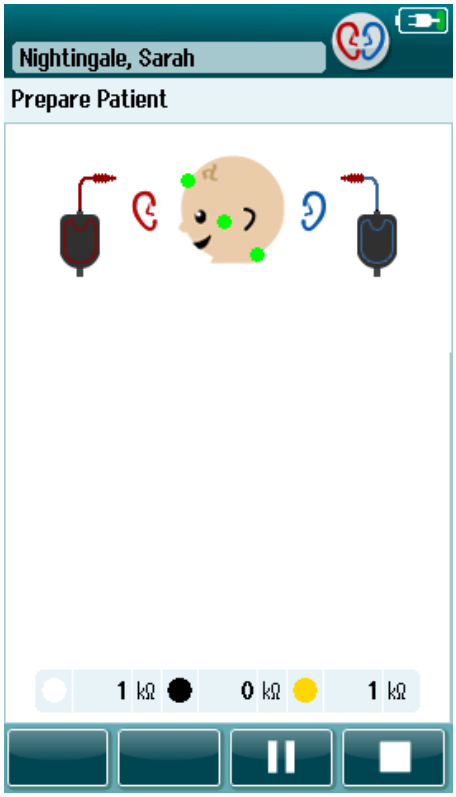

Figure 146: Impedance check

After attaching the electrodes and cables to the baby, it is essential to check if the impedances are acceptable for testing. Typically, the impedance of each electrode site should be as low as possible, however testing is still possible with higher impedances.

After pressing start, the system will automatically detect the electrode impedance and an indication of the impedance acceptability will be displayed on the infant picture in either green or amber (Figure 14). A green dot indicates an impedance between 0 and 50kΩ (Acceptable). An amber dot indicates the impedance is above 50kΩ (Poor).

Electrode impedance is monitored only before and after testing. Therefore, during testing only the cable color indicators are shown on the infant picture. Just before a recording stops the electrode impedance is measured and saved with the session. Historic sessions show these saved electrode impedances.

If an electrode falls off or becomes disconnected during testing, the Preamp will detect an abnormal input and a message will be displayed to ask the user to “Reconnect electrode”. A warning tone can also be heard when an electrode is disconnected.

Please note that when it is not possible to get low enough impedances (> 50kΩ), the software will **not** allow you to start a measurement.

7.6 Transducer information area in Sera™

On the preparation screen of Sera™, the type of transducer to be used is displayed next to the baby’s head.

The transducer is automatically detected when connected to the preamplifier. Because the transducer contains its own calibration data it can be freely connected to any Sera™ device.

The following transducers can be used for Automated ABR testing:

- IP30 insert earphones with ear tips
- IP30 insert earphones with EarCups
- OWA probe
- SnapPROBE™

7.7 Automated ABR protocols

The Sera™ device is delivered with one default Automated ABR protocol (A00 CE-Chirp 35 dB nHL). The protocol on the device can be changed and additional protocols can be added to Sera™ through the HearSIM™ software.

The available protocols are:

Protocol name	Stimulus type	Stimulus intensity	Rejection level	Max test time	Algorithmic Sensitivity
A00 CE-Chirp 35 dB nHL	CE-Chirp®	35 dB nHL	100 µV	3 minutes	> 99.99%
A01 CE-Chirp 30 dB nHL	CE-Chirp®	30 dB nHL	100 µV	3 minutes	> 99.99%
A02 CE-Chirp 40 dB nHL	CE-Chirp®	40 dB nHL	100 µV	3 minutes	> 99.99%
A03 CE-Chirp 45 dB nHL	CE-Chirp®	45 dB nHL	100 µV	3 minutes	> 99.99%
A04 Click 35 dB nHL	Click	35 dB nHL	100 µV	3 minutes	> 99.99%
A05 Click 30 dB nHL	Click	30 dB nHL	100 µV	3 minutes	> 99.99%
A06 Click 40 dB nHL	Click	40 dB nHL	100 µV	3 minutes	> 99.99%
A07 Click 45 dB nHL	Click	45 dB nHL	100 µV	3 minutes	> 99.99%
A08 CE-Chirp 25dB nHL	CE-Chirp®	25 dB nHL	100 µV	3 minutes	> 99.99%
A09 Click 25 dB nHL	Click	25 dB nHL	100 µV	3 minutes	> 99.99%

7.8 Explanation of protocol parameters

Stimulus type
Two stimulus types are available on Sera™, a broadband click and a broadband CE-Chirp®.

The **Click** stimulus is a broadband stimulus comprised of many frequencies that has been used in newborn hearing screening for many years.

The **CE-Chirp®** stimulus is also a broadband stimulus that compensates for travel time in the cochlea. The CE-Chirp® uses the same frequency characteristics as a traditional click, however by sending the lower frequencies a little earlier and the highest frequencies a little later into the cochlea, all frequencies activate their corresponding positions on the basilar membrane at the same time. As a result the ABR response of a CE-Chirp® is bigger and is much easier to detect compared to traditional click measurements. Screening with the CE-Chirp® will in general take less time and have a higher chance of reaching a pass in difficult testing circumstances. More information about the CE-Chirp is available on the Interacoustics website.

Stimulus intensity
The stimulus intensity is the level at which the stimulus is presented to the ear. The levels available are 25, 30, 35, 40 and 45 dB nHL.

Rejection level
The **rejection level** sets the EEG artifact rejection level that will be used by the preamplifier. When EEG levels exceed the set rejection level, the test is automatically paused, and no data is collected until EEG levels fall below the rejection level again.

Maximum test time
The **max test time** is how long the test will continue for if no response can be detected before it automatically stops testing and displays a REFER result. The test time on Sera™ equals the nett time used for testing. In other words, it does not include time elapsed when measurements are being rejected. For a test to reach a REFER, 3 minutes of good data must be collected before the test will automatically stop.

Test times using the same detection algorithm and CE-Chirp® stimulus are typically less than 30 seconds[4][5][6].

Electrode montage
All Sera™ protocols are designed to be use with a nape montage. The electrode montage indicates where electrodes should be placed for testing and the baby picture displayed on the test screen and on the preamplifier guides the user where to place the electrodes. The predefined nape electrode montage tells the system which is the active, reference and ground electrode. Use of an alternative montage (such as a mastoid montage) may increase test times or produce more refer results.

Result
All protocols will indicate a **Pass/Refer** result for the test or, if the measurement is stopped before completion of the test, **Incomplete** will appear.

Symbol	Screening result
	**Pass**
	**Refer**
	**Incomplete**

[4] Almeida, M.G., Sena-Yoshinaga, T.A., Côrtes-Andrade, I.F., Sousa, M.N.C., & Lewis, D.R. (2014). Automated auditory brainstem responses with CE-Chirp® at different intensity levels. Audiol Commun Res, 19(2), 117-123

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[5] Sena-Yoshinaga, T.A., Almeida, M G., Côrtes-Andrade, I. F., & Lewis, D. R. (2014). Neonatal hearing screening with automated auditory brainstem response: using different technologies. Audiol Commun Res, 19(1), 19-24.

[6] Sena, T.A., Ramos, N., Rodrigues, G.R.I., & Lewis, D.R. (2013). Testing time comparison between two procedures with new technologies of Automated Auditory Brainstem Response. CoDAS, 25(1), 34-38.

8 DPOAE

8.1 About the DPOAE module

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 DPOAE is to be used by trained personnel only, such as audiologists, ENT surgeons and 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.

8.2 DPOAE testing

Distortion Product Otoacoustic Emissions (DPOAEs) are commonly used for infant hearing screening and in diagnostic testing as they screen patients for cochlear hearing loss.

DPOAE technology uses pairs of pure tones presented in sequence to assess the status of the outer hair cells within the cochlea. Responses from the outer hair cells to the stimulus are predictable and therefore can be measured via a sensitive microphone placed in the patient's ear canal.

It is ideal for testing newborns and infants as the patient does not need to be awake or respond in any way to the test stimulus. Responses from the cochlea (outer hair cells) are recorded and results are automatically analyzed and displayed as either PASS or REFER.

8.3 Automated DPOAE with Sera™

The DPOAE module with Sera™ uses a predefined protocol together with a detection algorithm to assess the presence or absence of an OAE response. Prior to the start of the measurement, the stimulus level is adjusted with reference to the ear canal volume to ensure the correct stimulus level is presented to the test ear. Various frequencies are then tested by simultaneous presentation of two pure tones (also known as primaries) and the corresponding distortion product at the frequency mathematically expressed by $2f_1 - f_2$ is recorded. The recorded response is averaged using an averaging technique called Bayesian weighting in order to obtain a sufficient signal to noise ratio (SNR). For every test frequency, a minimum of 3 seconds of data is collected. Data epochs which exceed the noise threshold are excluded from this total of 3 seconds of data. After this time the decision algorithm assesses whether the SNR of the DP meets the protocol SNR criteria as well as whether the signal level is more than 2.3 standard deviations above the mean noise level before it is flagged as being detected. Once the test frequency meets the protocol requirements for detected, this test frequency is not revisited. This allows the data collection phase of the algorithm to concentrate on trying to obtain a good quality signal at those test frequencies which have not yet established the presence of a DP. When the minimum number of frequencies required for the test to pass (as defined by the protocol) have been detected, the test automatically stops, and the test result is labelled a PASS. If the minimum number of frequencies required for a PASS is not met during the maximum test time, the test ends with a REFER result. If the test is stopped before a PASS is detected or before the maximum test time is exceeded, the test is labelled as INCOMPLETE.

8.4 DPOAE protocols

The Sera™ device is delivered with one default DPOAE protocol (D00 2-5kHz, 3_4, SNR 6 dB). The protocol on the device can be changed and additional protocols can be added to Sera™ through the HearSIM™ software.

The available protocols are:

Protocol name	**Parameters**		**Algorithmic sensitivity**
D00 2-5kHz, 3_4, SNR 6 dB	Test frequencies(f_2): Stimulus level (L_1/L_2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min DP level: SNR: DP reliability: DP stability: # frequencies for a pass:	2, 3, 4, 5 kHz 65/55 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -5 dB SPL 6 dB 98.3% ±2 dB 3 / 4	> 99.6%
D01 1.5-4kHz, 3_4, SNR 6 dB	Test frequencies(f_2): Stimulus level (L1/L2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min DP level: SNR: DP reliability: DP stability: # frequencies for a pass:	1.5, 2, 3, 4 kHz 65/55 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -5 dB SPL 6 dB 98.3% ±2 dB 3 / 4	> 99.6%
D02 1.5-6kHz, 3_5, SNR 6 dB	Test frequencies(f_2): Stimulus level (L1/L2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min DP level: SNR: DP reliability: DP stability: # frequencies for a pass:	1.5, 2, 3, 4, 6 kHz 65/55 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -5 dB SPL 6 dB 98.3% ±2 dB 3 / 5	> 99.6%

Protocol name	Parameters		Algorithmic sensitivity
D03 2-5 kHz, 65_55 dB SPL, IEC[7]	Test frequencies(f_2): Stimulus level (L1/L2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min DP level: SNR: DP reliability: DP stability: # frequencies for a pass:	2, 3, 4, 5 kHz 65/55 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -5 dB SPL 6 dB 98.3% ±2 dB 3 / 4	> 99.6%
D04 2-5 kHz, 60_50 dB SPL, IEC[7]	Test frequencies(f_2): Stimulus level (L1/L2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min DP level: SNR: DP reliability: DP stability: # frequencies for a pass:	2, 3, 4, 5 kHz 60/50 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -5 dB SPL 6 dB 98.3% ±2 dB 3 / 4	> 99.6%
D05 1.5-6kHz, 3_6, SNR 7 dB	Test frequencies(f_2): Stimulus level (L1/L2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min DP level: SNR: DP reliability: DP stability: # frequencies for a pass:	1.5, 2, 3, 4, 5, 6 kHz 65/55 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -5 dB SPL 7 dB 98.3% ±2 dB 3 / 6	> 99.6%

[7] *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 DPOAE protocols that include IEC in the name use the specified IEC calibration method.

Protocol name	Parameters		Algorithmic sensitivity
D06 2-5kHz, 3_4, SNR 8 dB	Test frequencies(f_2): Stimulus level (L1/L2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min. DP level: SNR: DP reliability: DP stability: # frequencies for a pass:	2, 3, 4, 5kHz 65/55 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -25 dB SPL 8 dB 98.3% ±2 dB 3 / 4	> 99.6%
D07 1.5-6kHz, 4_6, SNR 6 dB	Test frequencies(f_2): Stimulus level (L1/L2): Stimulus tolerance: Ratio f_2/f_1: Noise rejection level: Max test time: <u>DP detection criteria</u> Min DP level: SNR: DP reliability: DP stability: # frequencies for a pass: All frequencies require min. 1 sample for pass	1.5, 2, 3, 4, 5, 6kHz 65/55 dB SPL ±7 dB 1.22 30 dB SPL 60 seconds -5 dB SPL 6 dB 98.3% ±2 dB 4 / 6	> 99.6%

8.5 Explanation of protocol parameters

Test frequencies (f_2) list the test frequencies in kHz. The two pure tone stimuli used in testing are also referred to as primary tones. The f_1 primary is the lower frequency pure tone, while the f_2 primary is the higher pure tone. The f_2 primary is the one mentioned when describing the protocol's test frequencies.

Stimulus level (L_1/L_2) refers to the stimulus levels of the two pure tones (primaries). L_1 refers to the stimulus level for the f_1 primary and L_2 refers to the stimulus level of the f_2 primary.

Stimulus tolerance defines the range in which the presented intensity of the stimuli are still acceptable. The number indicates the allowed difference in both positive and negative direction from the stimulus level setting.

The **Ratio f_2/ f_1** indicates the ratio relationship between the two primaries f_1 and f_2.

The **Noise rejection level** is the level in dB SPL above which recordings are considered to be too noisy. No DPOAE data is collected during rejection.

The **Maximum test time** is how long the test will continue for if no DPOAE can be detected before it automatically stops testing and displays a REFER result. The test time on Sera™ equals the nett time used for testing. In other words, it does not include time elapsed when measurements are being rejected. For a test to reach a REFER, 60 seconds of good data must be collected before the test will automatically stop.

Run descending means that testing will begin with the highest frequency and then proceed testing to the lower frequencies.

Minimum DP level is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the detection criteria.

SNR is the minimum signal to noise ratio that must be reached to meet the detection criteria. The signal to noise ratio (in dB) is the difference between the DPOAE level and the noise level.

DP reliability % is the minimum DP reliability % that must be reached to meet the detection criteria. Basically, the OAE is compared to the noise surrounding it and the calculated reliability % represents the chance that the OAE is indeed not part of the noise. For this comparison, it is assumed that the noise is normally distributed.

DP stability defines how stable the OAE level must be over time in order for it to meet the detection criteria.

 # frequencies required for a pass indicates the number of frequencies that must be detected before the test will stop and be labelled with a PASS result.

9 TEOAE

9.1 About the TEOAE module

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 TEOAE is to be used by trained personnel only, such as audiologists, ENT surgeons and 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.

9.2 TEOAE testing

Transient Evoked Otoacoustic Emissions (TEOAEs) are commonly used for infant hearing screening and in diagnostic testing as they screen patients for cochlear hearing loss.

TEOAE technology uses a broadband click stimulus to assess the status of the outer hair cells within the cochlea. Responses from the outer hair cells to the stimulus are predictable and therefore can be measured via a sensitive microphone placed in the patient's ear canal.

It is ideal for testing newborns and infants as the patient does not need to be awake or respond in any way to the test stimulus. Responses from the cochlea (outer hair cells) are recorded and results are automatically analyzed and displayed as either PASS or REFER.

9.3 Automated TEOAE with Sera™

The TEOAE module with Sera™ uses a predefined protocol together with a detection algorithm to assess the presence or absence of an OAE response within various frequency bands. Prior to the start of the measurement, the stimulus level is adjusted with reference to the ear canal volume to ensure the correct stimulus level is presented to the test ear. Testing occurs by delivery of a sub-group of 4 broadband click stimuli (8 subgroups = 1 sweep) multiple times and performing a sequence of signal processing operations to optimally extract any TEOAE signal that is present in the responses to these stimuli. A time domain averaging technique together with noise rejection and Bayesian weighting is used to obtain a sufficient signal to noise ratio (SNR). The time-averaged responses (waveform) are stored in two memory buffers, labelled A and B. If the patient has a normal OAE, it is these two responses which improve in signal quality (i.e. increasing signal to noise ratio) as the data collection and averaging process progresses. These two responses are then analyzed to assess whether an OAE is present and whether to stop further data collection. Once a minimum amount of data is recorded (50 sweeps), the detection algorithm can then label each of the frequency bands as detected or not. The fundamental identifying factor is the presence of sufficient SNR in a half octave frequency band. However, there are several qualifying factors that are included into the decision process such as the stability of the stimulus throughout the test, the level of noise, and features in the response waveform that indicate a risk of a false response. When the minimum number of frequencies bands required for the test to pass (as defined by the protocol) have been detected, the test automatically stops, and the test result is labelled a PASS. If the minimum number of frequencies bands required for a PASS is not met during the maximum test time, the test ends with a REFER result. If the test is stopped before a PASS is detected or before the maximum test time is exceeded, the test is labelled as INCOMPLETE.

9.4 TEOAE protocols

The Sera™ device is delivered with one default TEOAE protocol (T00 1.5-4kHz, 3_4, SNR 4 dB). The protocol on the device can be changed and additional protocols can be added to Sera™ through the HearSIM™ software.

The available protocols are:

Protocol name	Parameters		Algorithmic sensitivity
T00 1.5-4 kHz, 3_4, SNR 4 dB	Center frequency bands: Stimulus type: Stimulus level: Stimulus tolerance: Noise rejection level: Max test time: <u>TE detection criteria</u> Min TE level: SNR: Min total OAE: # bands for a pass:	1.4, 2, 2.8, 4 kHz Non-linear click 83 dB peSPL ±3 dB 55 dB SPL 60 seconds -5 dB SPL 4 dB 0 dB 3 / 4	> 99.6%
T01 1.5-4 kHz, 2_4, SNR 6 dB	Center frequency bands: Stimulus type: Stimulus level: Stimulus tolerance: Noise rejection level: Max test time: <u>TE detection criteria</u> Min TE level: SNR: Min total OAE: # bands for a pass:	1.4, 2, 2.8, 4 kHz Non-linear click 83 dB peSPL ±3 dB 55 dB SPL 60 seconds -5 dB SPL 4 dB 0 dB 2 / 4	> 99.6%
T02 1.5-4 kHz, 3_4, 80 dB SPL	Center frequency bands: Stimulus type: Stimulus intensity: Stimulus tolerance: Noise rejection level: Max test time: <u>TE detection criteria</u> Min TE level: SNR: Min total OAE: # bands for a pass:	1.4, 2, 2.8, 4 kHz Non-linear click 80 dB peSPL ±3 dB 55 dB SPL 60 seconds -5 dB SPL 4 dB 0 dB 3 / 4	> 99.6%

Protocol name	Parameters		Algorithmic sensitivity
T03 1.5-4 kHz, 60 dB SPL, IEC[8]	Center frequency bands: Stimulus type: Stimulus level: Stimulus tolerance: Noise rejection level: Max test time: <u>TE detection criteria</u> Min TE level: SNR: Min total OAE: # bands for a pass:	1.4, 2, 2.8, 4 kHz Non-linear click 60 dB peSPL ±3 dB 55 dB SPL 60 seconds -5 dB SPL 4 dB 0 dB 3 / 4	> 99.6%
T04 1.5-4 kHz, 70 dB SPL, IEC[8]	Center frequency bands: Stimulus type: Stimulus intensity: Stimulus tolerance: Noise rejection level: Max test time: <u>TE detection criteria</u> Min TE level: SNR: Min total OAE: # bands for a pass:	1.4, 2, 2.8, 4 kHz Non-linear click 70 dB peSPL ±3 dB 55 dB SPL 60 seconds -5 dB SPL 4 dB 0 dB 3 / 4	> 99.6%

[8] *These TEOAE protocols have been provided to meet the IEC60645-6 Standard. Stimulus levels and test sensitivity may not be appropriate for newborn hearing screening purposes.*

9.5 Explanation of protocol parameters

Center frequency bands lists the center frequency of the ½ octave test frequency bands.

The **stimulus type** defines the stimulus type used for testing. The stimulus is a bipolar non-linear click, which is typically used in both screening and diagnostic OAE testing.

The **stimulus level** indicates the stimulus intensity level in dB peSPL at which the test is conducted.

The stimulus tolerance defines the range in which the presented stimulus is still acceptable. The number (in dB) indicates the allowed difference in both a positive and negative direction from the stimulus level. When the level tolerance exceeds the limit set, the test is paused until the stimulus goes back into the acceptable range.

The **Noise rejection level** is the level in dB SPL above which recordings are too noisy. No TEOAE data is collected during rejection.

The **Maximum test time** is how long the test will continue for if no TEOAE can be detected before it automatically stops testing and displays a REFER result. The test time on Sera™ equals the net time used for testing. In other words, it does not include time elapsed when measurements are being rejected. For a test to reach a REFER, 60 seconds of good data must be collected before the test will automatically stop.

SNR is the minimum signal to noise ratio that must be reached to meet the detection criteria. The signal to noise ratio (in dB) is the difference between the TEOAE level and the noise level.

Minimum TE level is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the detection criteria.

Min total OAE, is the minimum total OAE (in dB SPL) that must be detected before the test can meet the stop criteria.

 # bands for a pass indicates the number of center frequency bands that must be detected before the test will stop and be labelled with a PASS result.

10 HearSIM™ software application

The Sera™ can be connected to a PC via a USB cable for use in conjunction with the HearSIM™ database and software application.

HearSIM™ is an accessory software tool that allows you to:

- Store, view and manage patient information
- Store, view and manage patient information in OtoAccess
- Store, view and manage test data transferred from a supported device
- Transfer names of patients requiring testing to a supported device
- Add and remove test protocols to a supported device
- Print test results on a standard PC-compatible printer
- Export patient and test data (HiTrack, OZ, CSV, XML format supported)
- Customize the device settings to your preferences
- Manage device users
- Manage device custom lists (e.g. Screening facility names, risk factors)
- Manage HearSIM™ user accounts
- Backup and restore the HearSIM™ patient database and custom lists

Note: Please refer to the HearSIM™ manual for further information.

11 Cleaning and disinfection

11.1 General information about cleaning and disinfection

Individual manufacturer's instructions should be followed when using their disinfecting agent to ensure an appropriate level of disinfection.

The cleaning instruction below is in accordance with ISO 17664.

Please note: Recommendations for cleaning and disinfection of the Sera™ presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

Non-disposable parts of the system, including the preamplifier, electrode wires and insert phone tubes with either EarCup or ear tip adapters attached, which are in direct contact with the patient, should be cleaned between patients.

11.2 Caution during cleaning and disinfection

The Sera™ and any of its components or accessories cannot withstand washer-disinfector process or autoclaving. The device will be damaged, and the warranty will become void.

Non-disposable parts of the system that meet the patient should be cleaned and disinfected after use to prevent cross-contamination.

Water should be used for frequent cleaning, but in the case of severe contamination it may be necessary to use a disinfectant. Do not spray liquid cleaning or disinfection products directly onto any components of the device. Instead, use a damp cloth/disinfectant wipe. It is recommended to use a soft cloth moistened with a mild solution of water and detergent or similar. If disinfection is necessary, use of non-alcohol based disinfectant may be used on hard cover surfaces only. Non-alcohol based products contain the active ingredient referred to as quaternary ammonia compound. Make sure that excess liquid from the cloth/wipe does not drip into any sensitive areas such as connectors and seams where plastic pieces connect such as the battery compartment or edges around the touch screen.

Ensure that the components/accessories are completely dry of residual cleaning solution/disinfectant before using the device and before reassembling the components after the cleaning process.

11.3 Sera™ hardware device

To avoid contamination of the Sera™ device and reduce the need for cleaning/disinfection, do not set the device on the patient's bedding or hold it in contaminated hands during testing. Instead, set the device on a trolley that is used for transport or on a clean surface near the patient. Use a stylus or pen for operation of the device, thereby eliminating the need to touch it with your hands after contact with the patient.

- If the Sera™ device has become contaminated, it can be wiped down with a damp cloth and/or a disinfectant wipe
- Before cleaning/disinfecting, remove the Sera™ from the cradle
- Always switch off the device during cleaning
- Make sure no liquid enters the connectors of the Sera™ or drips into any seams or gaps in the plastic
- Make sure that the Sera™ is completely dry before using the device

11.3.1 Cleaning the touch screen

Use a lens cleaning or microfiber cloth to clean the Sera™ touchscreen.

11.4 Cradle

The cradle is not required for performing a screening. To avoid contamination of the cradle and reduce the need for cleaning/disinfection, we suggest that you do not bring it into the patient care area. If you need to have the cradle near the patient care area, do not set it on the patient's bedding or hold it in contaminated hands for testing. Instead, set the cradle on a trolley that is used for transport or on a clean surface near the patient.

If the cradle becomes contaminated, it can be wiped down with a damp cloth and/or a disinfectant wipe.

Before disinfection, remove the Sera™ from the cradle and unplug the cradle from AC power.

Be careful that no fluid enters sensitive components of the cradle such as the USB/power connector.

Make sure that the cradle is completely dry before reconnecting the power cable and reinserting the Sera™.

11.5 Preamplifier and electrode lead wires

The preamplifier and electrode lead wires can be wiped down with a damp cloth or a disinfectant wipe if necessary.

Be careful that no fluid enters sensitive areas of the preamplifier or electrode lead wire connector.

The preamplifier and electrode lead wires should be completely dry before re-use.

11.6 Insert phone cable

The insert earphones including the transducer boxes, cables, tubes and adapters can be wiped down with a damp cloth and a disinfectant wipe after use. Be careful that no fluid enters sensitive areas such as the cable connections to the transducers or the connector plug.

The insert earphone components should be completely dry before re-use.

- The insert earphone tubes should be examined periodically for any cracks in the tubing
- The tubes and adapters can be replaced if necessary

11.7 EarCup and ear tip adapters

The insert earphone adapters can be wiped down with a damp cloth or a disinfectant wipe after use if necessary. Be careful that no fluid enters inside the adapters.

If an ear tip adapter is contaminated with earwax or debris on the inside of the adapter, use the ear tip adapter cleaning brush to clean the debris out of the adapter, then clean in an ultrasonic bath. Alternatively, replace the adapter with a new one.

Do not insert the insert earphone ear tip adapter into the patient's ear canal without a disposable ear tip installed on it.

Do not insert the insert earphone EarCup adapter into the patient's ear canal. It must be inserted into an EarCup which is then placed around the patient's ear for testing.

11.8 Probe

The probe body and cable can be wiped down with a damp cloth or a disinfectant wipe after use if necessary. Be careful that no fluid enters sensitive areas such as the cable connections or probe body.

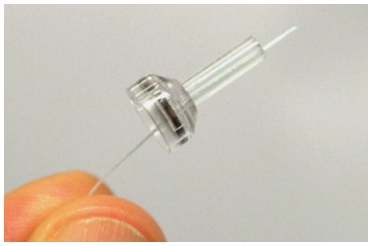
The probe and cable should be completely dry before re-use.

11.8.1 Cleaning the OWA probe tip

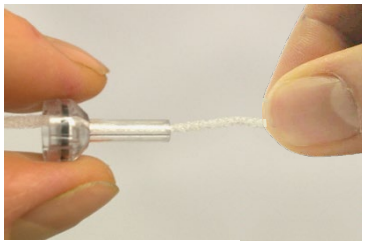
After each use, visually inspect the probe tip for signs of debris in any of the channels. It is important that the probe tip is clean and free of wax or other debris before conducting a test. Wax or debris in the probe tip can cause incorrect presentation of the stimulus or recording.

Clean the probe tip regularly: To avoid earwax clogging the channels of the ear tip and affecting measurements performed with Sera™, it is recommended to clean the probe tip regularly.

If the probe tip becomes contaminated with earwax or debris, you must remove it from the probe body before cleaning. Unscrew the probe cap by turning it counter-clockwise and detach it from the probe body. Remove the clear probe tip by pulling it straight out from the probe body.



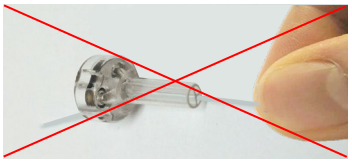
Thread the cleaning floss into one of the channels from the base of the probe tip.



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.



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 tip 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!

After cleaning the different components, put the probe tip and the probe cap into an ultrasonic bath to guarantee a proper cleaning.

Remove ear tip from ultrasonic bath after cleaning is completed. The probe tip should not remain in the bath for longer than 30 minutes.

The probe tip should be replaced with a new one when contaminated, completely blocked, or cracked.

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

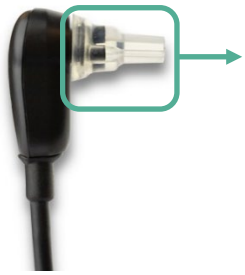
If damage occurs to the sealing gasket, the probe must be serviced by an authorized Interacoustics representative.

Do not insert the probe tip into the patient's ear canal without a disposable ear tip attached.

11.8.2 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 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.

11.9 Disposables

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

EarCups, ear tips and disposable electrodes are intended to be used for a single-patient and should be discarded after use. In case of re-use of the single-use disposables, you enhance the risk of cross contamination!

11.10 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).

11.11 Sera™ ABRIS Pass-Checker (optional)

The Pass-Checker is not required for performing a patient screening. To avoid contamination of the Pass-Checker and the need to disinfect it, connect only clean Sera™ components to it. If the Pass-Checker has become contaminated, it can be wiped down with a damp cloth or disinfectant wipe. Before cleaning, make sure the Pass-Checker is powered off by pressing and holding the power button or allow it to turn off automatically.

Be careful that no fluid enters sensitive components of the Pass-Checker, such as the gaps around electrode connection posts, the power switch, or the cavities for the acoustic connections.

Make sure that the Pass-Checker is completely dry before re-use.

12 FAQ/Troubleshooting

In the event you don’t find an answer to your question listed here in the troubleshooting section, please contact an authorized representative for further assistance.

12.1 Hardware

Problem	Explanation	Solution
Sera™ will not switch on when placed in the cradle.	If a battery is run completely empty, it is possible that even after starting to recharge it, the power is not yet sufficient to support the tasks needed in Sera™. In this event, Sera™ will not allow itself to start up.	Check power supply to the cradle Check if the cradle light is solid green, indicating that Sera™ is placed correctly and is charging
Device states that no probe is connected while there is a probe attached.	When the battery in Sera™ is nearly empty it shuts off power to the probe.	Charge the Sera™ battery
	Probe cable is not completely inserted into the connector.	Detach and re-attach the probe ensuring it is firmly attached to the connector.
No printer found when printing from Sera™ to a wireless printer.	After the wireless printer is switched on it typically takes 10 to 30 seconds to restore the connection.	Wait until connection is restored or; Switch the wireless printer on before starting the measurement so connection is available when measurement has been completed.

12.2 Firmware

Problem	Explanation	Solution
Sera™ shows an error code on the screen.	Although Sera™ is thoroughly tested, you could have encountered an unknown firmware problem.	After a firmware error code appears, it is advised to switch Sera™ off and on again. If a problem persists, Interacoustics would very much appreciate it if you report the problem and the situation causing it to occur.
Cannot pass impedance for one or more electrodes (Automated ABR testing).	Insufficient skin preparation.	Remove electrode and use NuPrep or another skin preparation product to prepare the skin.
	Electrode has lost contact with the skin.	Check contact of electrodes to the skin at the prepared sites.
	Electrode lead wire is not fully attached to the preamplifier.	Check connections to the preamplifier and try again.
	Electrode lead wire has a short in the wire which may lead to intermittent contact.	Replace the electrode lead wire with a new one (you may need to replace more than one of the electrode wires).
	Connection of preamplifier cable to the Sera™ transducer connector is not secure.	Check the connection of the preamplifier cable to the Sera™; remove it and re-insert it verifying that it is securely attached.
“Reconnect Electrode” message during Automated ABR testing.	Electrode is not in contact with the skin.	Reapply the electrode to prepared skin site.
“Check Cables“ message during Automated ABR screening.	Electrode contact may be poor.	Check electrode contact to skin.
“Mains noise” message during ABR testing.	There is mains noise (50 Hz) in the environment.	Move away from the current test environment that is contaminated with mains noise interference.
“Too Noisy” message during OAE test.	High acoustic noise is present during OAE test.	Quiet the baby or the environment.
“Out of ear” message during OAE test.	The probe is coming out of the ear or has fallen out completely.	It is recommended to stop the test and start again since reinsertion of probe in ear needs a new in-ear calibration process before testing.

“Off Levels” message during OAE test.	Probe is coming out of baby’s ear or placement of probe has otherwise changed during the test so that stimulus levels are outside of the acceptable range.	Check the fit of probe in the baby’s ear. It may be necessary to stop the test and start again after securing the probe in the baby’s ear canal.

Problem	Explanation	Solution
Touchscreen is non-responsive to touch.	Software is frozen in a process.	Hold the Sera™ power button down for 10 seconds to force a power off and then reboot the system.
Sera™ battery is not charging when device is in the cradle.	Poor connection to the power supply; wrong power supply.	Verify that you are using the correct power supply for the Sera™ and it is properly connected.
“Out of ear” message during OAE test.	The probe is coming out of the ear or has fallen out completely.	It is recommended to stop the test and start again since reinsertion of probe in ear needs a new in-ear calibration process before testing.
Excessive artifacts are observed during the Automated ABR measurement.	Baby is too active, moving, sucking, crying, muscle tension, etc.	Pause the recording and calm the baby. Swaddle the baby in a blanket. Resume recording only when the baby is quiet.
	Electrode has lost contact with the skin.	Check contact of electrodes to the skin at the prepared sites.
	Electrode lead wire has a short in the wire which may lead to intermittent contact.	Replace the electrode lead wire with a new one (you may need to replace more than one of the electrode wires).
	Electrical interference is interfering due to AC connection.	If Sera™ is being used in the cradle with the AC plugged in, unplug the cradle power supply from the outlet and run on battery only.
	Electromagnetic interference is present from other electronic devices in the environment.	Shut down all unnecessary devices near the test area including cell phones, tablets, lights, TVs, etc. Move as far away as possible from devices that cannot be powered off. Ask the baby’s doctor or nurse to assist with troubleshooting if the baby is connected to monitoring devices to determine if they can be powered off temporarily for troubleshooting. RFID devices used for security that are attached to or near the baby may cause interference. Ask the nurse or doctor if they can be temporarily removed. Try testing is a different location.

Problem	Explanation	Solution
High refer rate.	Screening babies when they are too active.	Perform a screening only when the baby is quiet - preferably sleeping, comfortable, and recently fed. Screen just after feeding when the mother is still holding the baby.
	Screening babies within a few hours after birth when the ear canals are still wet and possibly occluded with vernix.	Wait to screen until at least 12 hours after birth when it is more likely that the ear canals are clear.
	Environment is too acoustically noisy.	Switch off all sources of noise such as TVs, radios. Ask others in the environment to stop talking. Ask parents to remove noisy siblings from the test room. Close the door to reduce noise coming from the hallway or nearby rooms. Move away from noise sources such as air conditioning vents or devices that have motors that turn on and off.
	EarCup is not attached, or ear tip is not placed in the ear properly.	Make sure that the EarCup is surrounding the ear and that there are no big gaps between the foam and baby's skin. For ear tips, make sure that the ear tip is securely inserted into the baby's ear canal.
	Stimulus is not coming through the insert earphones or probe.	Check the connection of the insert earphone cable or probe into the preamplifier; remove it and re-insert it verifying that it is securely attached.
		Check the connection of the cable to the Sera™ transducer connector.
		Check the connection of the insert earphone cable to the red and blue transducer boxes.
		Check the insert earphone adapter to see if it is cracked or occluded. The insert earphone clear adapter may need to be cleaned with the adapter cleaning kit.
		Make sure the insert earphone tubes are free of any crimping or compression; replace the tube with a new one if damaged.
		Replace the insert earphone cable with a new one.
		Check the probe tip to ensure it is clear of any wax or debris in the channels. Clean it or replace it as needed.

12.3 Optional Sera™ ABRIS pass-checker

Problem	Explanation	Solution
Cannot pass impedance for one or more electrodes.	Electrode lead wire is not fully attached to the preamplifier or to the Pass-Checker.	Check cable connections at the preamplifier cable jack and on the Pass-Checker and try again.
	Electrode lead wire has a short in the wire which may lead to intermittent contact.	Replace the electrode lead wire with a new one (you may need to replace more than one of the electrode wires).
	Connection of preamplifier cable to the Sera™ transducer connector is not secure.	Check the connection of the preamplifier cable to the Sera™; remove it and re-insert it verifying that it is securely attached.
Excessive artifacts are observed during the measurement.	Electrode lead wire has a short in the wire which may lead to intermittent contact.	Replace the electrode lead wire with a new one (you may need to replace more than one of the electrode wires).
Test does not pass in one or both ears.	Connection of insert earphone cable into the preamplifier cable jack is not secure.	Check the connection of the insert earphone connector into the preamplifier; remove it and re-insert it verifying that it is securely attached.
	Insert earphone cable is not securely attached to the transducer box.	Check the connection of the insert earphone cable to the red and blue transducer boxes.
	Insert earphone adapter is occluded with debris or is cracked; more likely to occur with the clear Ear tip adapter.	Clean the adapter using the Infant Ear Tip Cleaning kit brush. Or replace the adapter with a new one.
	Tubing of insert earphone is crimped shut or has a tear in the tube.	Make sure the tubes are free of any crimping or compression; replace the tube with a new one if damaged.
	Insert earphone cable has a short in the cable.	Replace the insert earphone cable with a new one.
	Low battery on the Pass-Checker? Is the LED flickering?	Contact an authorized technician to arrange to change the battery on the Pass-Checker. We recommend annual battery change at the time of calibration of your Sera™ device.

13 Statement regarding TEOAE stimulus

The IEC60645-6 standard allows the use of manufacturer specific stimuli waveform shapes. However, the current 60645-6 standard refers to the IEC60645-3 standard on the specific topic of a reference stimulus characteristic for TEOAE measurements (i.e. the use of short duration stimuli).

The IEC60645-3 standard documents the electrical characteristics of a reference short duration stimulus which is a rectangular, unipolar signal of 100 microsecond duration (with a tolerance of 10 microseconds, and specified rise and fall times). Note that this reference pulse is an ‘electrical signal’ that is used to generate an acoustic stimuli and as such is heavily modified by the electro-acoustic nature of the probe transducer, the acoustic design of the probe, and the ear simulator or other cavity that it used during acoustic calibration of the equipment.

The Sera utilises an optimised TEOAE stimulus that avoids the inherent difficulties that arise during TEOAE measurements when using a simple unipolar rectangular pulse such as the 60645-3 specified reference pulse. This optimised stimulus is bipolar so that it contains no DC component. DC and low frequency energy (i.e. below 400Hz or so) increase the risk of contamination of the TEOAE response with residual stimulus energy – this typically occurs up to 4mS after the electrical pulse is applied. It is possible to reduce this risk of contamination by only measuring the TEOAE response after say 5mS has elapsed. However, the high frequency components of the TEOAE (which originate at the basal end of the cochlea) will then be considerably diminished and the test will take longer and be less effective. Furthermore, the optimised stimulus concentrates the energy of the pulse in the frequency region that is most relevant to infant hearing screening.

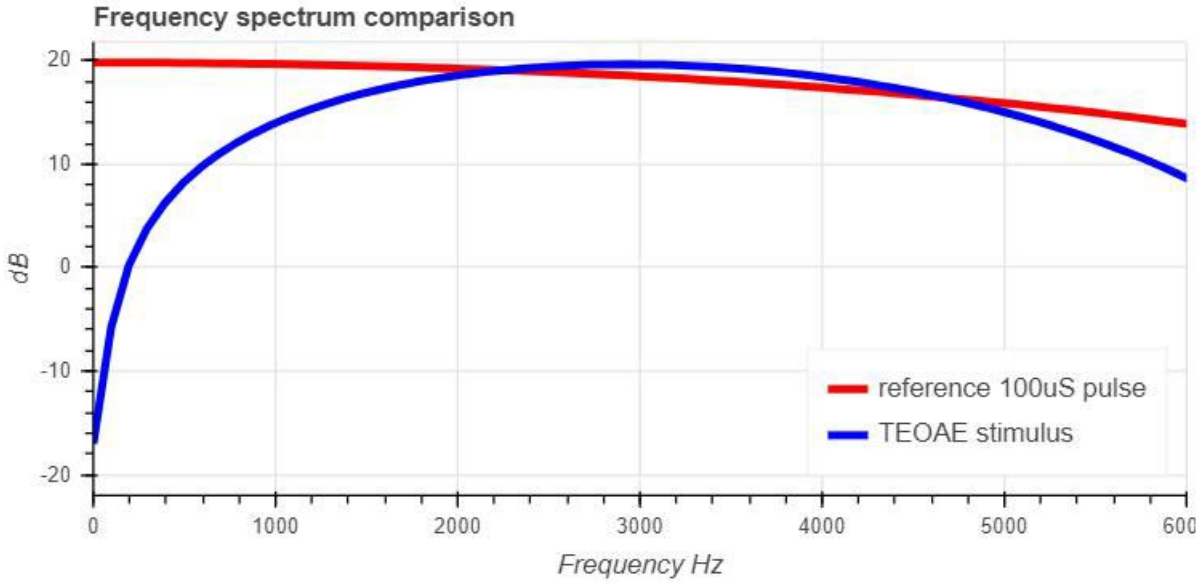
In order to permit comparisons of electrical calibration between the Sera and the IEC60645-3 reference stimulus, this document provides a comparison of the energy contained within the electrical characteristics of both the reference and the optimised stimulus. This was calculated using an ‘area under the curve’ method, in other words a simple integral of voltage over time for each of the stimuli shapes. Please note that a pure rectangular electrical pulse is rarely measurable at any accessible point on OAE equipment since there will usually be filtering applied to the signal once it has been generated by the DAC long before it reaches the OAE probe. Fast edged signals contain considerable high frequency energy and cause problems with no benefits at all in OAE measurements. Furthermore, sometimes this filtering is included in the DAC internal circuitry making the original signal unavailable outside of the integrated circuit.

The comparison of the reference pulse and our bipolar optimised stimulus requires careful attention to the use of ‘peak’ and ‘peak to peak’ measurements since one is a unipolar signal and the other is bipolar. Although this is the case at the exact source of electrical generation, both signals will be bipolar when delivered acoustically due to the inherent high-pass filtering of the transducers and any high-pass filtering present in the signal chain. This document provides comparison using both methods of measurement. In practice, an acoustic comparison will fall somewhere between these two extremes due to the filtering.

Using a ‘peak’ measurement: I.e. the rectangular pulse has a height equivalent to only the positive excursion of the optimised bipolar pulse, the optimised stimulus used in the Sera delivers 5.18dB additional energy for equivalent peak voltages.

Using a ‘peak to peak’ measurement: I.e. the rectangular pulse has a height equivalent to the full positive to negative excursion of the optimised bipolar pulse, the optimised stimulus used in the Sera delivers -0.84dB energy relative to the reference rectangular pulse.

Finally, the graph below shows a comparison of the frequency response of the reference pulse and the optimised stimulus. The relative levels of the two pulse types has been adjusted to reflect the typical resulting levels when acoustic calibration is performed (i.e. peak to peak acoustic levels in an adult ear simulator). The graph clearly illustrates the severe reduction of low frequency and DC components and the slight enhancement in the required OAE screening frequency region.


Frequency spectrum comparison
20
10
0
-10
-20
dB
0
1000
2000
3000
4000
5000
600
Frequency Hz
reference 100uS pulse
TEOAE stimulus