gsi Grason-Stadler

NEWBORN AABR/OAE SCREENER

NOVUS

USER MANUAL

Title: GSI Novus™ Newborn Hearing Screening System
User Manual

Manufacturer

Grason-Stadler, Inc.
10395 West 70th Street
Eden Prairie, MN 55344
USA

Compliance

The CE 0123 mark identifies compliance with the Medical Device Directive 93/42/EEC. Grason-Stadler is an ISO 13485 certified corporation.

EC REP

European Authority Representative
Grason-Stadler
c/o DGS Diagnostics A/S
Audiometer Alle 1
5500 Middelfart
Denmark

CE

0123

Caution: US Federal law restricts this device to sale by or on the order of a physician or licensed hearing care professional.

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PREFACE

This user manual provides information about the GSI Novus Newborn Hearing Screening System. This manual is intended for technically qualified personnel.

Please note: This operating manual is not intended as a training manual for newborn hearing screening. The reader should consult standard audiology texts for the theory and application of the screening tests provided by this instrument.
This operating manual contains information pertinent to the use of the Novus system including safety information as well as maintenance and cleaning recommendations.

It is highly recommended that users read the manual in its entirety prior to use of the Novus device on a patient.

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

MANUAL CONVENTIONS

Throughout this manual, the following meaning of warnings, cautions and notices are used.

WARNING

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

CAUTION

The CAUTION Symbol identifies conditions or practices that could result in damage to the equipment

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NOTE: Notes help you identify areas of possible confusion and avoid potential problems during system operation.

REGULATORY SYMBOLS

Symbol	Description
CE	Conforms to European Medical Device Directive 93/42/EEC.
SN	Symbol for "SERIAL NUMBER."
REF	GSI Part Number.
MD	Indicates that the device is a Medical Device
	Return to Authorized Representative, Special disposal required.
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.
EC REP	Symbol for “European Representative.”
	Symbol for “Manufacturer.”
	Symbol for “Date of Manufacture.”
	On/Off
7d www.grason-stadler.com	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.

Symbol	Description
	Consult the operating instructions/directions for use. A copy of the operating manual is available on this website: www.grason-stadler.com A printed copy of the operating instructions can be ordered from Grason-Stadler for shipment within 7 days; or you can contact your local representative.

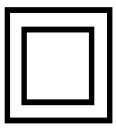
DEVICE SYMBOLS

The following symbols appear on the instrument, the instrument cradle or the mains adapter:

Definition: Refer to instruction manual (mandatory).

Definition: Type BF applied part – IEC 60601-1 uses the term applied part to refer to the part of the medical device which come into physical contact with the patient for the device to carry out its intended function. Type BF is used for devices that have conductive contact with the patient or having medium or long-term contact with the patient. The GSI Novus is Type BF according to the international standard IEC60601-1. The applied parts are the ear tips, ear cups and the electrodes.

Definition: The output from the mains AC adapter is Direct Current.



Definition: Class II equipment – equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

Definition: Industry-standard Type-B USB connection to a computer.

Warnings and Cautions

Important Safety Instructions

The following safety precautions must be observed always. 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 instrument must only be used by hearing health care professional qualified to perform newborn hearing screening tests such as an audiologist, otolaryngologist, researcher or a technician under the direct supervision by the specialist. Users should use their professional skills when interpreting the results and this should be done in conjunction with other testing as deemed appropriate given their professional skills. Incorrect use could lead to wrong results. It is intended for transient use as a screening tool; however, no surgical or medical procedure should be undertaken solely based on results obtained from the instrument.

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

Safety Precautions

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 snug and 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 GSI.

To comply with the standards IEC 60601-1 for safety and IEC 60601-1-2 for EMC the instrument is designed to be used only with the medically approved mains adapter supplied, which is specified as part of the equipment. **Do not use any other type of mains adapter with this instrument.**

In case of emergency, disconnect the instrument from the supply mains by pulling the plug out of the power USB socket.

Before the first use of the instrument each day, or if suspect or inconsistent results are apparent, the checks specified in the Performing Daily Checks section should be carried out. 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 Grason-Stadler published specifications.

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

Never insert the probe into a patient's ear canal without a suitable ear tip fitted to the probe.

Use only the recommended disposable ear tips/cups. These are for single use only - that is, each ear tip is intended to be used once only for a single ear for a single patient. Do not reuse ear tips/cups as this will pose the risk of ear-to-ear or patient-to-patient cross infection.

Latex is not used anywhere in the manufacturing process. The base material for the ear tips is made from silicone rubber.

The device is not intended to be used in environments exposed to fluid spills. No means is specified for fluid protection (not IP classed). Do not use the device in the presence of fluid that can contact 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. Do not immerse the unit in any fluids. See the Routine Maintenance Section of this manual for the proper cleaning procedure for the instrument and its accessories and the function of single-use parts.

Do not drop or otherwise impact this instrument. If the instrument is dropped or damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

Do not attempt to open, modify or service the instrument. Return the instrument to the manufacturer or distributor for all repair and servicing requirements. Opening the instrument will void the warranty.

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. The USB connection has a built-in galvanic insulation.

EXPLOSION

This system is not explosion proof.

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 Novus in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

NOTE: This instrument contains a rechargeable Lithium ion (Li-ion) battery-pack. The battery is not intended to be replaced by the user. The 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. Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures. Do not short-circuit.

ENVIRONMENTAL FACTORS

Use and store the instrument indoors only. It is recommended that the instrument be operated within an ambient temperature range of 15 °C / 59 °F to 35 °C / 95 °F and in relative humidity between 30 % and 90 % (non-condensing).

Transport the instrument in temperature between 20 °C / -4 °F to +50 °C / +122 °F and store the instrument in temperature between 0 °C / 32 °F to 50 °C / 122 °F.

ELECTROMAGNETIC COMPATIBILITY (EMC) CONSIDERATIONS

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the Appendix. 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. This appendix provides guidance on the electromagnetic environment in which to operate the instrument.

Portable and mobile radiofrequency (RF) communications equipment can affect medical electrical equipment. The instrument should not be used adjacent to or stacked with other equipment; if this is unavoidable, the instrument should be observed to verify normal operation and that no mutual disturbance appears.

INTRODUCTION

Thank you for purchasing the GSI Novus automated hearing screening system.

INDICATIONS FOR USE

The GSI Novus is intended to be used for the measurement and automated analysis of auditory evoked responses (auditory brainstem responses, ABR) and/or otoacoustic emissions (distortion product, DPOAE and transient evoked, TEOAE). These measures are useful in the screening evaluation, identification, documentation and diagnosis of auditory and hearing related disorders.

The auditory evoked response (ABR) measurement is intended for newborns and infants up to 6 months of age. The otoacoustic emissions (DPOAE and/or TEOAE) measurement is intended for use in patients of all ages.

The GSI Novus is intended to be used by a healthcare professional such as an ENT doctor, nurse or audiologist or by a trained technician under the supervision of a professional. The device is intended to be used in a hospital, clinic, or other facility with a suitable quiet testing environment.

CONTRAINDICATIONS

Contraindications to testing with GSI Novus include a discharging ear, acute external auditory canal trauma, or occlusion of the external auditory canal. Testing should not be performed on patients with such symptoms without a medical doctor's approval.

FEATURES

The GSI Novus features a touchscreen display and user-friendly software in a compact hardware design. Novus may be purchased with various licenses allowing you to perform different hearing screening tests.

ABR

Novus uses fast rate auditory brainstem response (ABR) technology to screen patients for hearing loss. A modified click stimulus, the CE-Chirp® of 35 dB nHL is delivered into the patient's ear while electrodes placed on the patient's head measure EEG activity.

The EEG is processed and analyzed automatically using the Novus's powerful, response detection algorithm. When a response is detected, the screening is stopped automatically, and a Pass result is assigned to the test ear. When no response is detected after 3 minutes of EEG activity has been processed, a Refer result is assigned.

NOTE: More information about the ABR screening and response detection method may be found in the following publication:
Sturzebecher E, Cebulla M, Werneke, KD. Objective response detection in the frequency domain: comparison of several q-sample tests. Audiol Neurootol. 1999;4(1):2-11

DPOAE

Distortion product otoacoustic emissions (DPOAE) technology uses pairs of pure tones presented in sequence to screen patients for cochlear hearing loss. Responses to the stimulus are predictable and therefore can be measured via a microphone placed in the patient's ear canal.

TEOAE

Transient otoacoustic emissions (TEOAE) technology uses a click stimulus to screen patients for cochlear hearing loss. Responses to the stimulus are predictable and therefore can be measured via a microphone placed in the patient's ear canal. The response is divided into frequency bands for assessment.

NOVUS CRADLE

The Novus cradle allows you to:

- Charge the Novus battery
- Perform screenings when the Novus battery charge is too low to support testing

NOVUS PC SOFTWARE PROGRAM OPTION - HEARSIM™

The Novus PC software allows you to:

- Store, view and manage patient information
- Store, view and manage test data transferred from the Novus
- Transfer names of patients requiring testing to the Novus
- Print test results on a standard PC-compatible printer
- Export patient and test data (HiTrack, OZ and ASCII formats)
- Configure various Novus device settings
- Manage Novus users
- Manage Novus custom lists (e.g. Screening facility names)

PRINTING OPTIONS

Printing test results from the Novus is accomplished in a variety of ways:

- Print directly from Novus using the optional wireless label printer that is available from GSI.
- Transfer Novus test data into a PC using the HearSIM software and print results using your standard printer attached to the PC.

UNPACKING THE SYSTEM

- ✓ It is recommended that you unpack your Novus carefully making sure that all components are removed from the packing materials.
- ✓ Verify that all components are included as shown on the packing slip included with your shipment.
- ✓ If any component is missing, contact your distributor immediately to report the shortage.
- ✓ If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.
- ✓ Please check that all accessories listed below have been received in good condition.
- ✓ All standard components are part of the medical device (incl. power supply) and suitable for operation in a patient environment.

If any of your purchased parts are missing, contact your distributor or GSI.

SAVE ALL THE ORIGINAL PACKING MATERIAL AND THE SHIPPING CONTAINER SO THE INSTRUMENT CAN BE PROPERLY PACKED IF IT NEEDS TO BE RETURNED FOR SERVICE OR CALIBRATION.

Notify the carrier immediately if any mechanical damage is noted. This will ensure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or GSI when the adjuster has completed the inspection.

STANDARD COMPONENTS - GENERAL

- Novus device
- Novus cradle
- Cradle power supply
- USB cable
- Carrying bag
- Operating Instructions (on USB drive)
- Cleaning cloth for touchscreen
- Stylus Pen
- Neck strap

ABR-RELATED COMPONENTS

- Preamplifier
- Electrode lead wires
- NuPrep™ skin preparation gel
- Hardware Pass-Checker

TRANSDUCERS (INCLUDED AS SELECTED AT TIME OF PURCHASE)

- IP 30 (50 Ω) insert earphone with Eartip adapters Kit
- IP 30 (50 Ω) insert earphone with EarCup adapters Kit
- OAE probe

DISPOSABLES SUPPLIED WITH INSERT EARPHONES WITH EARCUPS

- Sanibel Infant EarCup kit with snap electrodes (1 box; 20 screenings)
- ABR EarCup Accessory Kit

DISPOSABLES SUPPLIED WITH INSERT EARPHONES WITH EARTIPS

- Disposable snap electrodes (60 pcs; 20 screenings)
- Novus Eartip Starter Kit

DISPOSABLES SUPPLIED WITH OAE PROBE

- Eartip Starter Kit

OPTIONAL ACCESSORIES

- Label Printer HM-E200 Kit (includes printer, power supply and 1 roll of thermal label paper)
- Novus PC software HearSIM (software on USB drive)

APPLIED PARTS

The following items are considered applied parts according to IEC60601-1.

- Preamplifier cable
- Insert earphones
- OAE ear probe
- Electrode lead wires
- Disposable snap electrodes
- Probe ear tips
- EarCups

STORAGE

When the Novus is not in use, store it in the carry case or in a location where it will be safe from damage to the touchscreen or other sensitive components such as the acoustic transducers and cables. Store according to the recommended temperature conditions described in the specifications.

NOVUS OVERVIEW

COMPONENTS

DISPLAY

The display on the Novus is a resistive touch screen. It responds to the pressure of touching the icons. This can be accomplished with a finger or a stylus. Care should be taken not to scratch the surface of the touch screen.

PREAMP CABLE (FOR ABR ONLY)

The preamplifier cable connects to the top of the Novus. The electrode lead wires, and the acoustic transducer connect to the jacks at the top of the preamplifier box for performing ABR screenings.

INSERT EARPHONE CABLE (FOR ABR ONLY)

The insert earphone cable connects to the jack on the top edge of the preamplifier box. For testing using EarCups, the insert earphone EarCup adapters at the end of the red and blue tubes are inserted into the foam edge of the EarCups. If Eartips are used, disposable eartips are attached to the clear eartip adapters at the end of the tubes.

EAR PROBE (FOR OAE AND ABR)

The OAE ear probe is used for OAE screening. It may also be used as the transducer to deliver the acoustic stimulus for ABR screening as well by connecting to the preamplifier box. For testing, connect a disposable eartip of the proper size for the patient's ear onto the probe tip.

ELECTRODE LEAD WIRES (FOR ABR ONLY)

Electrode lead wires are provided with the system purchase when ABR is included. The color-coded plugs connect to the jacks on the top of the preamplifier box. The electrode lead wires connect to the disposable snap electrodes.

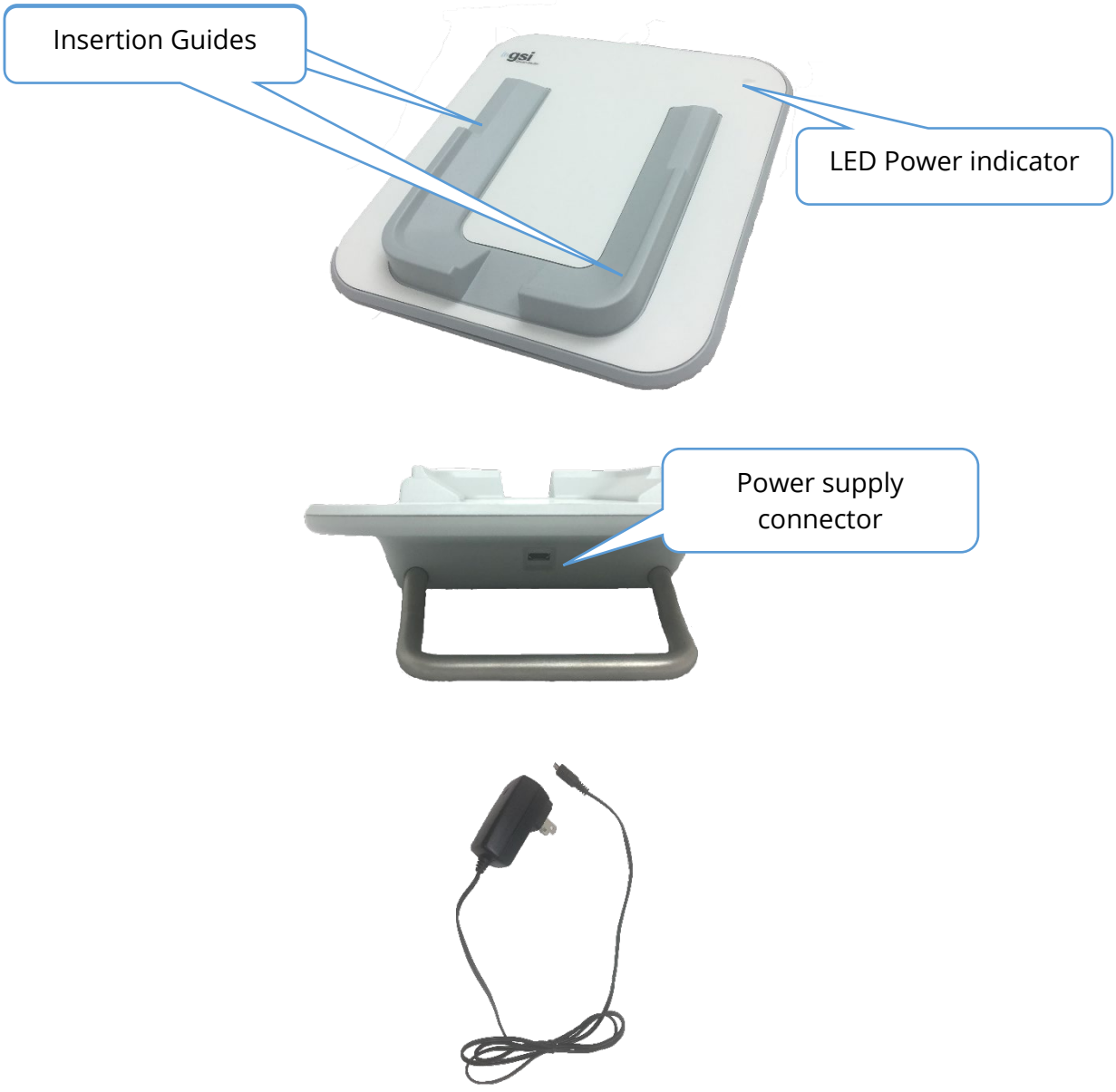
CARRY CASE

The carry case provides a means for storing, protecting and transporting the Novus and all its components.

LABEL PRINTER (OPTIONAL)

The optional Thermal Printer HM-E200 allows the direct printing of labels from the Novus.

CRADLE



The USB plug is used to safely disconnect the mains from the cradle. Do not position the cradle in a manner that would make it difficult to disconnect it from AC power.

Only use the UES12LCP-050160SPA Power Supply that is included with the system.

SYSTEM ASSEMBLY

The Novus will require some assembly before use. Depending on the screening test types purchased, the system assembly may include:

- Connecting the preamp cable (ABR license)
- Connecting the insert earphone cable (ABR license)
- Connecting the OAE probe (DPOAE or TEOAE or ABR license)
- Connecting the electrode lead wires (ABR license)
- Connecting (pairing) the Novus to the MLP 2 printer (optional)

CONNECTING THE PREAMP CABLE OR OAE PROBE TO THE DEVICE

Align the dot at the end of the preamplifier cable or OAE Probe (for OAE only systems) with the dot on the preamplifier connector socket at the top of the Novus. Insert the plug and push it securely into place.

IMPORTANT NOTE: The plug contains a series of small metal pins that insert into corresponding jacks in the socket. Be careful that the plug and socket are properly aligned so that the pins are not bent or broken during insertion. Do not twist the connector in the socket.

CONNECTING THE INSERT EARPHONE CABLE OR OAE PROBE TO THE PREAMP

Align the plug at the end of the insert earphone cable or OAE probe with the socket at the top of the preamplifier cable marked with the graphic. Insert the plug and push it securely into place.

IMPORTANT NOTE: The plug contains a series of small metal pins that insert into corresponding jacks in the socket. Be careful that the plug and socket are properly aligned so that the pins are not bent or broken during insertion. Do not twist the connector in the socket.

CONNECTING THE ELECTRODE LEAD WIRES

Connect the three electrode lead wires securely into the electrode jacks on top of the preamplifier, matching the color of the lead wire with the jack. Be sure they are fully inserted into the jack.

CHARGING NOVUS

The Novus is powered by a rechargeable Lithium-ion (Li-ion) battery. The battery is charged by placing the Novus in the AC powered cradle.

The cradle is powered by plugging the power supply into the micro USB connector on the back of the cradle and plugging the other end into an AC outlet using the appropriate adapter for your region. Use only the power supply delivered by GSI for powering the cradle.

Place the Novus into the cradle so that it sets within the U-shaped placement guides. Proper placement in the cradle is needed to ensure charging of the battery. Magnets in the cradle and the device form a connection to reduce the chance that the Novus will fall out of the cradle. The battery automatically starts charging when the Novus is placed properly into the AC-powered cradle.

An LED on the front of the Novus will light differently depending on the charging status.

LED Status	Novus Status
Solid Blue	Novus Off – Battery Charging
Solid Green	Novus Off – Battery Not Charging/Full
Blinking Blue	Novus Standby (power save) – Battery Charging
Blinking Green	Novus Standby (power save) – Battery Not Charging
Off	Novus On
Solid Green + Blue	Battery Fault

The battery may also be charged by connecting the Novus to a PC using a USB cable. Charging this way will be slower than charging with the cradle.

- Keep the battery fully charged
- In the cradle, the charging time is 5 hours if the device is fully discharged
- Charging via USB only, the charging time is 6-8 hours

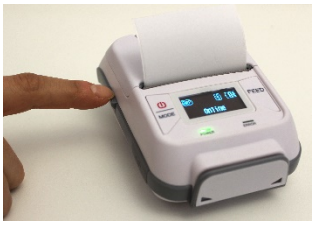
USING THE OPTIONAL LABEL PRINTER

POWERING THE LABEL PRINTER

The label printer is powered by a Lithium-ion battery. In order to charge the battery, you must insert the plug of the charger into the DC socket on the printer and plug the power supply into an outlet.

INSERT LABEL ROLLS INTO THE LABEL PRINTER

The printer indicates that it has run out of paper by displaying the message "Out of paper" on the screen and the blue LED (ERROR) flashes.



To insert a new label roll into the label printer, open the printer by pressing the small latch button

Insert the label roll into the printer with the paper end placed towards the open cover. Hold the paper end in place and 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.

CONNECTING THE LABEL PRINTER TO NOVUS

The connection of the Novus and the label printer is made via Bluetooth pairing (See the Setup, Printer section of this manual).

Getting Started with Novus

Power On

The Novus can be operated in or out of the cradle. Briefly press the *Home* button on the front of the Novus to turn on the device. The boot up process will take a few seconds. During this time the display will show the splash screen. Important information or reminders may be displayed during the boot up process. This could include:

- Calibration expiration reminder
- Low battery charge warning

Power-saving mode and power-off

When the Novus is inactive for some time, as specified in the device settings, the device will go into Power Save mode (standby) or Power Off automatically. In the power save mode the display will turn off and the LED will blink green. Pressing the *Home* button briefly will awaken the device. Upon awakening from standby, the screen will display as it was when it went into standby mode. If a User Login is enabled, you will need to enter your password again when the device awakens from standby. The time periods for power save and power off may be set in the Device Settings.

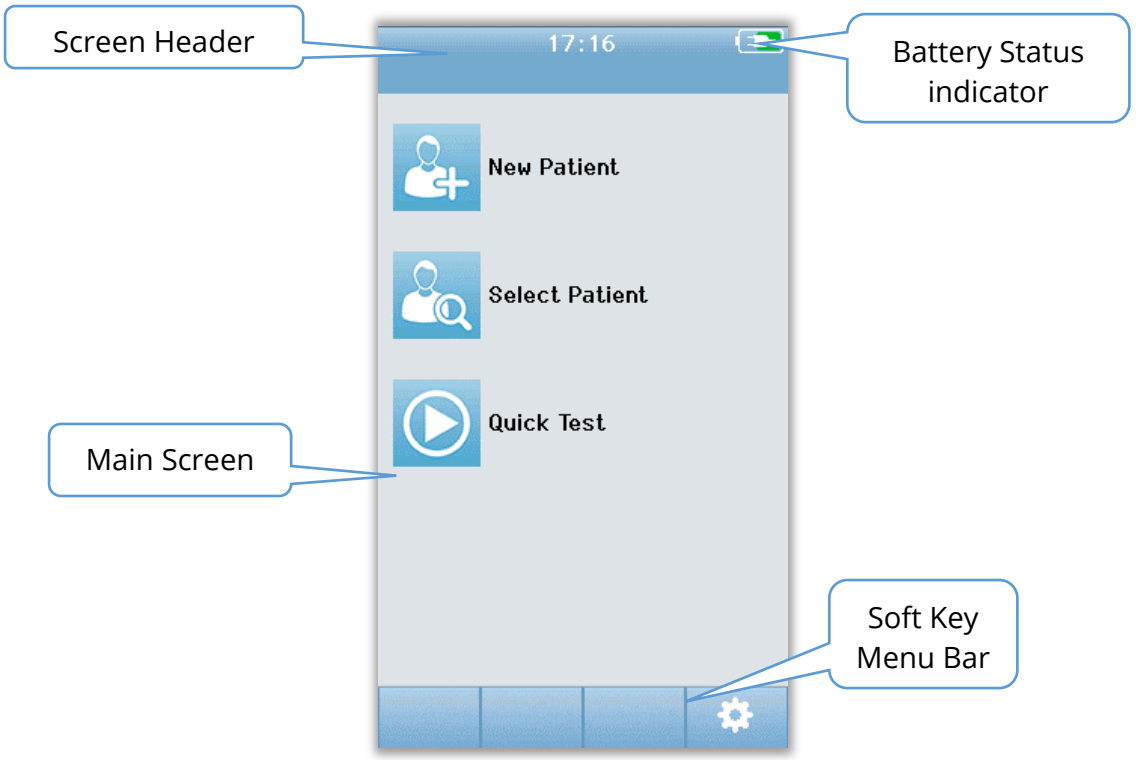
To turn off the device, press the *Home* button from the main screen. A confirmation dialog will be presented and then select the **check mark** to confirm or the **X** to cancel. Alternatively, to manually power off Novus, press and hold the *Home* button for more than 5 seconds.

Home button

In addition to turning the device On and Off, the *Home* button also functions to return to the **Home** screen when pressed from any other screen.

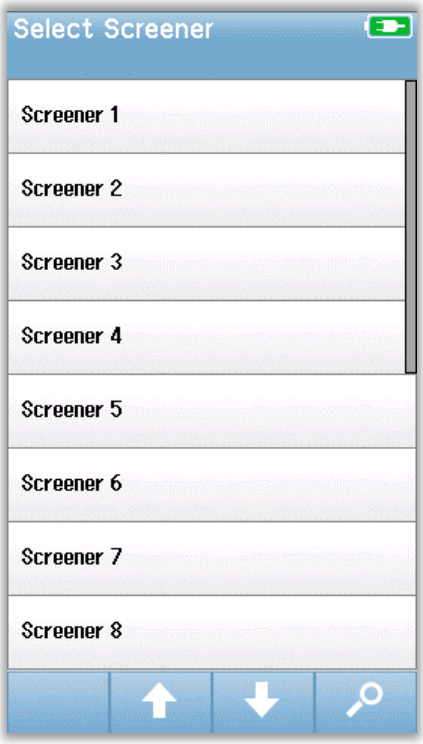
HOME SCREEN

After the system completes the boot up process the **Home** screen is presented. The **Home** screen displays the buttons controlling entry into the major functions of Novus.



The screen contents may vary depending on the options enabled for the configuration of the device. The PC Application HearSIM is used to define the configuration of the device. The Quick Test is a configurable item which is enabled by default. One of the options that may be configured is to require a User Login. If a User Login is required, the **Home** screen is not presented until after a successful login by the user. The User Login is not enabled by default.

USER LOGIN (OPTIONAL)

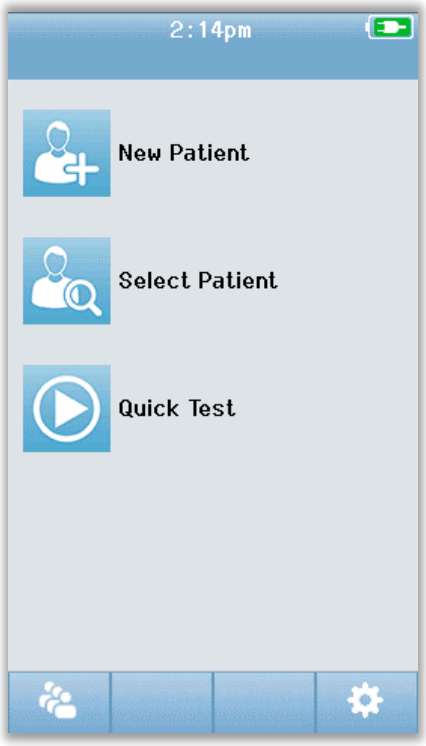


When the user login is enabled, a Select Screener List is presented after the device boots up. The list of screeners is created in the HearSIM PC program and transferred into Novus. If there are more than 8 screeners in the list, **Up** and **Down** arrow controls in the bottom control bar allow you to move through pages of names. Alternatively, you may select the **Search** button in the bottom control bar to type in characters of the screener name using the on-screen keyboard. After entering the name of the screener, select the **Search** button again to obtain a list of matching entries. Select the screener name from the list to proceed to the password entry screen.

When a screener is selected, the password entry screen is presented. Enter the password in the password entry screen using the on-screen keyboard and select the **Check** button in the bottom control bar. If an incorrect password is entered, a message will appear indicating that the password entered was incorrect. The message will display for several seconds and then disappears, clearing the entry field so that you can try again to enter the password.

Once the password has been entered correctly the **Home** screen is displayed.

HOME SCREEN FUNCTIONS



BATTERY STATUS

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

Symbol	Charge status
	Charging
	Remaining charge % is indicated
	10% (Approx. 30 minutes of active test time remaining)
	5% (Testing cannot be performed; recharge)
	3% (Automatic shutdown)

NOTE: The Novus will shut down automatically when the battery charge is too low to support continued operation. It should be charged by placing it in the cradle. Screening can be performed while the Novus is in the cradle.

NEW PATIENT

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 screening later or immediately proceed with the screening.

SELECT PATIENT

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 screening.

QUICK 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. Later if you want to save a Quick Test session you can save it by editing the Patient Information.

CHANGE USER

The **Change User** control will be not be shown if the user login is disabled. If the User Login is enabled, select **Change User** to log out the current user and display the Screener list for selection of a new user.

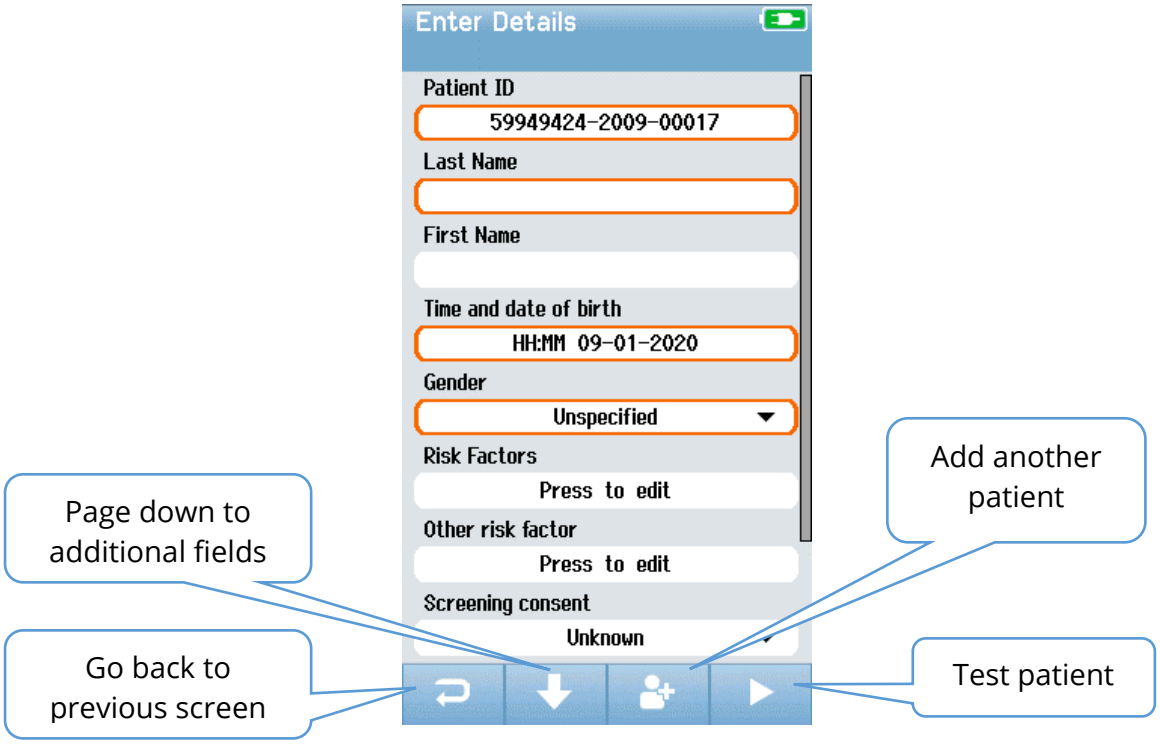
SETUP

Select **Setup** to access a list of the device settings that can be made directly on Novus. Some settings can only be made via use of the HearSIM PC application.

ENTERING OR CHOOSING A PATIENT FOR TESTING

ADDING A NEW PATIENT

Select the New Patient button from the Home screen to enter patient information.



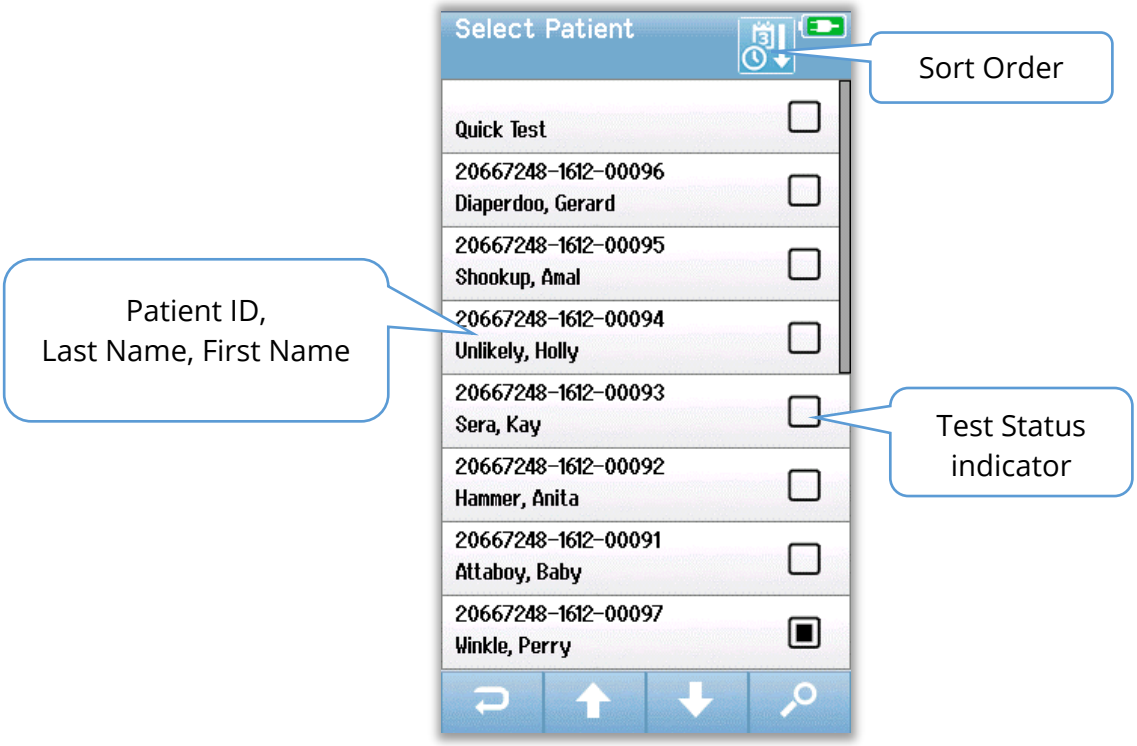
In the New Patient screen, select a field for data entry by touching the desired field. The appropriate data entry control such as the keyboard, calendar or drop-down list will open. Enter the patient's data for the field. Select another field and enter the data until all desired fields are completed. Required fields are outlined in orange.

NOTE: The Novus Risk Factors and required fields are customized using the HearSIM program and transferred from the PC to the device with other settings as described in the Novus PC Application, HearSIM, section in this manual and the HearSIM manual.

The Patient ID field and other required fields must be completed to save the data or proceed to a screening. 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. This ID can be overwritten when entering the patient data. Configuring Novus to use an automatically entered ID number is accomplished via the HearSIM PC application. 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 **Check** in the bottom control bar, edit the ID to a different number. Or if this number is correct, then this patient's information may already be present on the device. Return to the Home screen and select the **Select Patient** button to search the device for this patient's name/ID. When you have completed the entry of data, you can proceed immediately to screen the patient, add another patent or return to the Home screen using the options in the bottom menu bar.

SELECTING FROM THE PATIENT LIST

Choose the **Select Patient** button on the Home screen to present the Patient list.

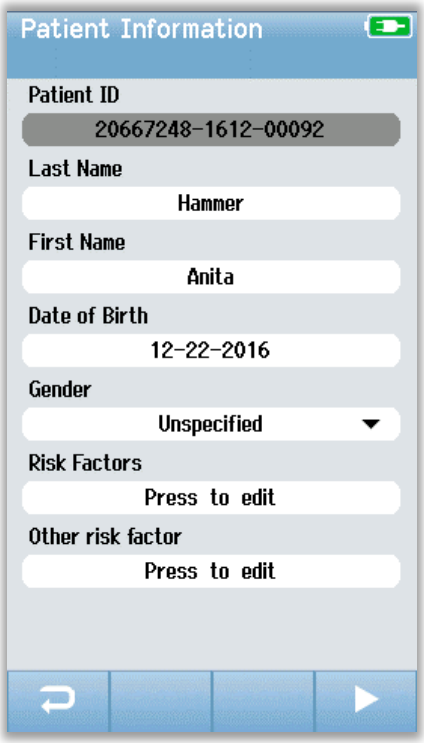


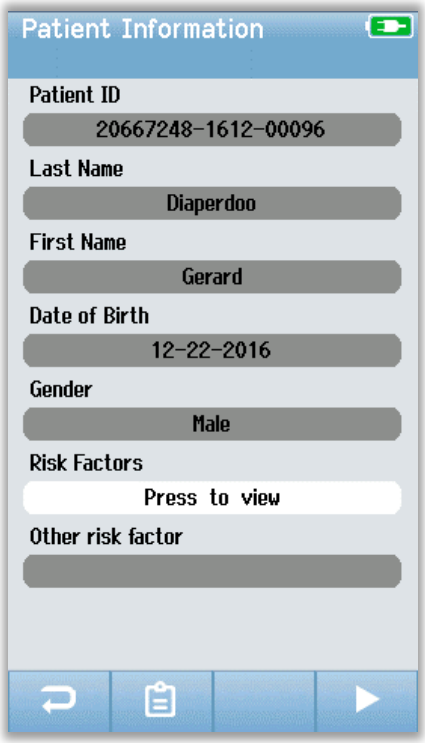
If there are more than 7 patients in the list, **Up** and **Down** arrow controls in the bottom control bar allow you to move through pages of names. Alternatively, you may select the **Search** button in the bottom control bar to open a screen in which you can enter all or part of the patient's ID, last or first name to search for matching patients. After entering the information, select the **Search** button again to obtain a list of matching entries. An icon in the screen header allows you to sort the entries chronologically or alphabetically. On the right side of each row in the Select Patient list, the square reflects the test status for the patient.

Symbol	Test Status
☐	No tests are saved in the device for this patient
▣	Tests are saved in the device for this patient (1 to 49 tests)
☒	The maximum number of tests are saved (50). No additional tests can be performed for this patient

Select the patient from the list to proceed to open the Patient Information screen.

The Patient Information screen shows the details of the patient that were entered from the Add Patient data entry. If the patient has not yet been tested, you may edit the details. If there is test data from the patient on the device, the data for the patient may not be edited and the fields will appear with a grey background.





From the Patient Information screen, you can **Review** the patient's test history (if test data exists for the patient), **Test** the patient or go back to the previous screen from selections in the bottom Menu bar.

FUNCTION BUTTONS

 Go Back One Screen	 Start Test	 OK Save
 View Test List	 Stop Test	 Cancel
 Add New Patient	 Pause Test	 Page Up
 Search	 Resume Test	 Page Down
 Switch User	 Add Comment	 Print
 Settings	 Select Ear Right	 Sort by Date/Time
 View Test Fields	 Select Ear Left	 Sort Alphabetical
	 Select Ear Both	

PREPARING FOR TESTING

PREPARING THE TEST ENVIRONMENT

GENERAL

The ideal environment for hearing screening is one that is acoustically quiet with minimal potential for electrical interference. This is not 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 this is possible.

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.

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. 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 mother’s room during the test

ELECTRICAL NOISE

Electrical noise in the screening environment can cause high artifact levels and generally noisy EEG, prolonging 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.

Possible sources of electrical noise:

- 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 near the nursery, even on the floor above or below.
- RFID tracking devices especially if attached to the baby or Mom holding the baby

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.

PREPARING THE PATIENT

GENERAL

It is recommended that screening should be performed when the newborn is medically stable and is at least 32 weeks postmenstrual age in the case of preterm infants. Infants who have risk factors for hearing loss should be referred for follow up and periodic re-screening of hearing even if the result of the hearing screening is a Pass.

Hearing screening is most successfully and efficiently performed on a quiet, sleeping baby. If the baby is awake but quiet or sucking intermittently, testing is possible though the test time may be affected. If the baby is crying, moving or sucking vigorously and constantly then the test will be prolonged and the chance of a refer result will be increased. In this case it would be best to terminate the screening attempt and return when the baby is sleeping.

Screening can be performed when the baby is lying in a crib, in a car seat or is being held by the screener or parent. The key is to make the baby comfortable and quiet for the screening. Swaddling the baby in a blanket with the arms wrapped inside is recommended. This will calm the baby and keep the baby from inadvertently grabbing the electrode lead wires or insert earphone tubes during the screening.

NOTE: All disposable supplies included with Novus 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 biocompatibility. Data sheets are available upon request.

PLACING ELECTRODES FOR ABR TESTING

ABR recording requires placement of 3 electrodes. The ideal electrode positions are:

- Center of the forehead at the hairline
- Shoulder or Cheek (either side)
- Nape (of the neck)

An alternate electrode montage may be used as indicated below. However, the screening time for the right ear may be prolonged when using this montage.

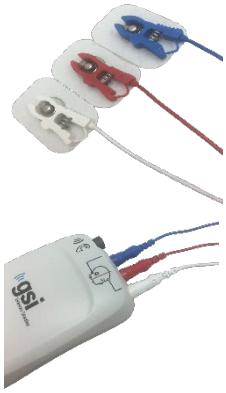
- Center of the forehead at the hairline

- Right mastoid
- Left mastoid

Regardless of the electrode placement you choose, the skin at the electrode locations must be cleaned with an electrode skin preparation product. Rub the product gently, but briskly on the skin at each position.

NOTE: Skin preparation products vary in terms of abrasiveness. Be sure to follow the instructions on the product to avoid damage to the skin

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.



Connect the white, red and blue pinch clip electrode lead wires to a snap electrode. Connect the jack end of the electrode cable to the preamplifier following the color scheme on the preamplifier.

Peel the electrodes from the backing card and place them on the baby at the desired electrode montage. A graphic near the electrode jacks on the preamplifier illustrates proper placement for the Nape montage as a reminder. Press gently around the entire surface of each electrode to help secure its adhesive to the skin.

	Nape Montage (recommended)	**Mastoid Montage (alternate)**
White	Forehead	Forehead
Red	Cheek or shoulder	Right mastoid
Blue	Nape of the neck	Left mastoid

FITTING THE EAR COUPLERS FOR ABR

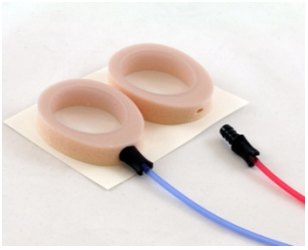
At the time of purchase, you chose your preferred style of acoustic transducer. If insert earphones were selected you also chose your preferred ear coupling method, the EarCup or the Ear tip.

ABR ear couplers use single-use disposable supplies. There is an enhanced risk of cross contamination if the single-use disposables are re-used!

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

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

EARCUPS (WITH INSERT EARPHONES)



Insert the EarCup adapter at the end of each of the insert earphone tube into the hole in the foam at the top of the EarCup so that it is fully inserted.

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.

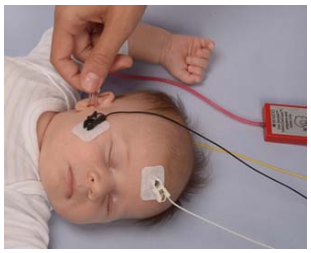
Place the insert earphone transducer boxes above or to the side of the baby's head.

EAR TIPS (WITH INSERT EARPHONES)

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

Choose the proper size of eartips based on your inspection of the size of the baby's ear canals. The Sanibel red flanged eartip fits most newborn ears. Other sizes are available for larger ear

canals. Apply the eartips onto the eartip adapters at the end of the insert earphone tubing.



Insert the eartip 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 the ear canal. Hold the adapter and aim and twist (gently) the eartip into the ear canal. The fit of the eartip should be secure; not superficial. Release the earlobe. Repeat this procedure inserting the eartip attached to the blue tubing into the baby's left ear

If you find that it is difficult to keep both eartips securely 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 on the right ear and the transducer with the blue tubing on the left ear.

Place the insert earphone transducer boxes above or to the side of the baby's head.

EARTIPS (WITH OAE PROBE)

Do not insert the OAE probe tip into the baby's ear without an ear tip installed. Always use a new eartip with each patient. The eartip is not reusable.

Choose the proper size of eartip based on your inspection of the size of the baby's ear canals. Apply the eartip onto the OAE probe.

Insert the eartip into the baby's first test ear. Do this by pulling gently down and out on the baby's ear lobe to open the ear canal. Hold the probe and aim and twist (gently) the eartip into the ear canal. The fit of the eartip should be secure and not superficial. Release the earlobe. You should **not** hold the OAE probe during the measurement since this can cause noise.

TESTING

GENERAL INFORMATION

A screening may be initiated in several ways:

- **Quick Test** (in Home screen)
- After entering **New Patient** information
- From the Patient Information screen after you have chosen a patient from the **Select Patient** list.

The following processes are the same regardless of the type of screening you perform.

QUICK TEST BUTTON

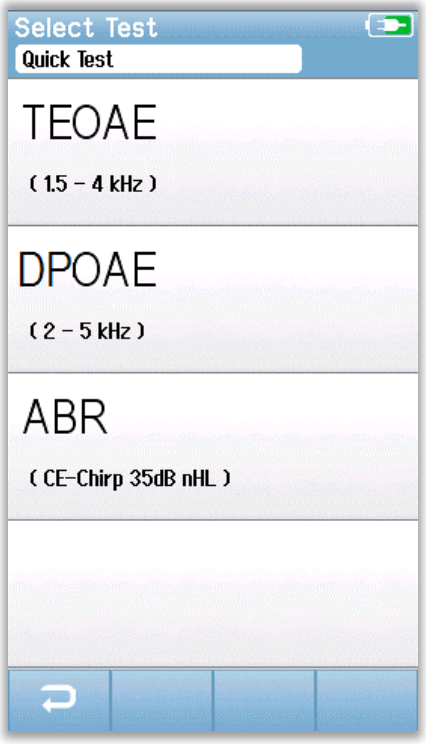
Quick test functionality can be enabled/disabled by an Administrator using the Novus PC application HearSIM. If the Quick Test is disabled on your device, then the **Quick Test** button will not appear on the Home screen.

SELECT THE "START" BUTTON

Selection of the **Start** button begins the screening testing.

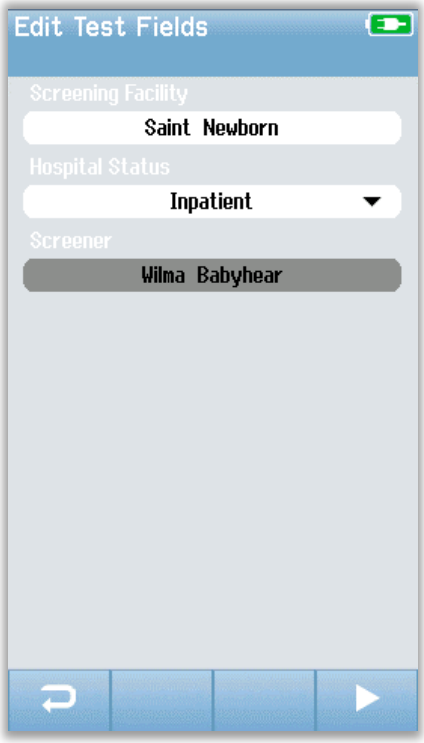
Depending on the configuration of your device, some screens may appear before the actual test screen is displayed.

SELECT TEST TYPE



If your device has both ABR and OAE functionality (DP, TE or both), then a Select Test screen may appear for you to select which type of screening you wish to perform. This screen will only appear if the cables attached to your Novus are appropriate for use with either type of test. If the detected cables only support one test type, then this screen will not appear.

ADDITIONAL TEST FIELDS



Using the Novus PC application HearSIM, your Novus may be configured to require the entry of the Facility Name and Hospital Status information with each test.

When this function is enabled, a Test field entry screen will appear, so you can complete these fields for the 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 **Start** button if the current items displayed in the fields are correct.

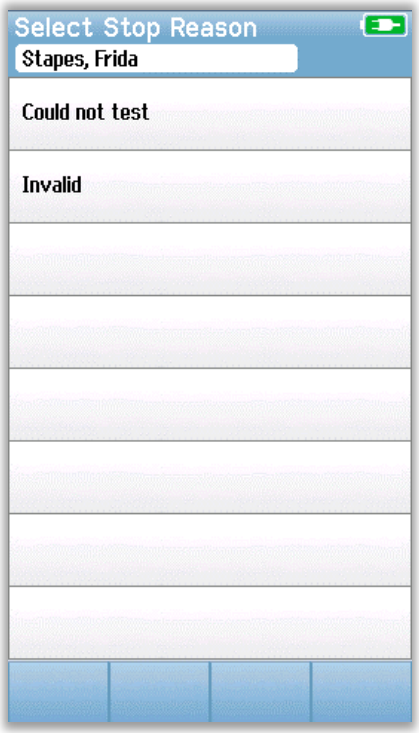
If you have logged into the device upon boot up, then your name will also be saved with the test. The Test field entry screen displays your name in read-only format.

SCREENING RESULT SYMBOLS

Symbol	Screening result
✓	Pass
✗	Refer
?	Incomplete

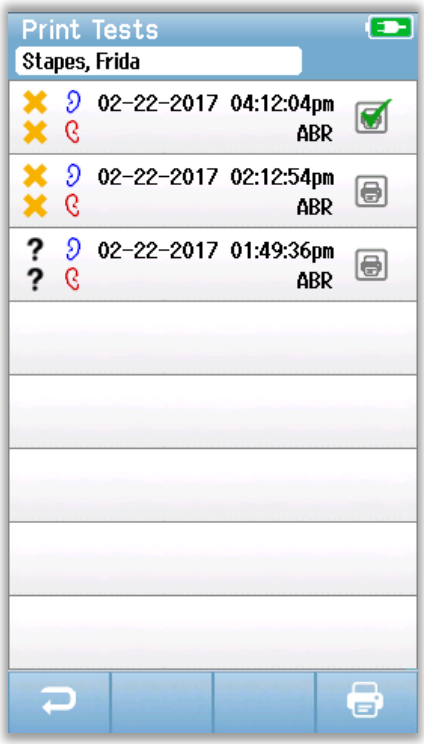
The screening test may result in one of three outcomes; Pass, Refer or Incomplete. These results are displayed graphically using the symbols in the table below.

REASON FOR INCOMPLETE TEST



Using the Novus PC application HearSIM, an administrator can configure your Novus to require the entry of the Stop Reason when a test is manually stopped. This stop reason information is saved with the test record.

PRINTING AFTER SCREENING



Printing of test results on the label printer can be performed at the completion of the screen by selecting the **Test List** button in the bottom control bar. The full list of screening tests performed for this patient will appear in reverse chronological order. The most recently performed right and left ear screening 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 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 screening 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 screening will print out on a separate label.

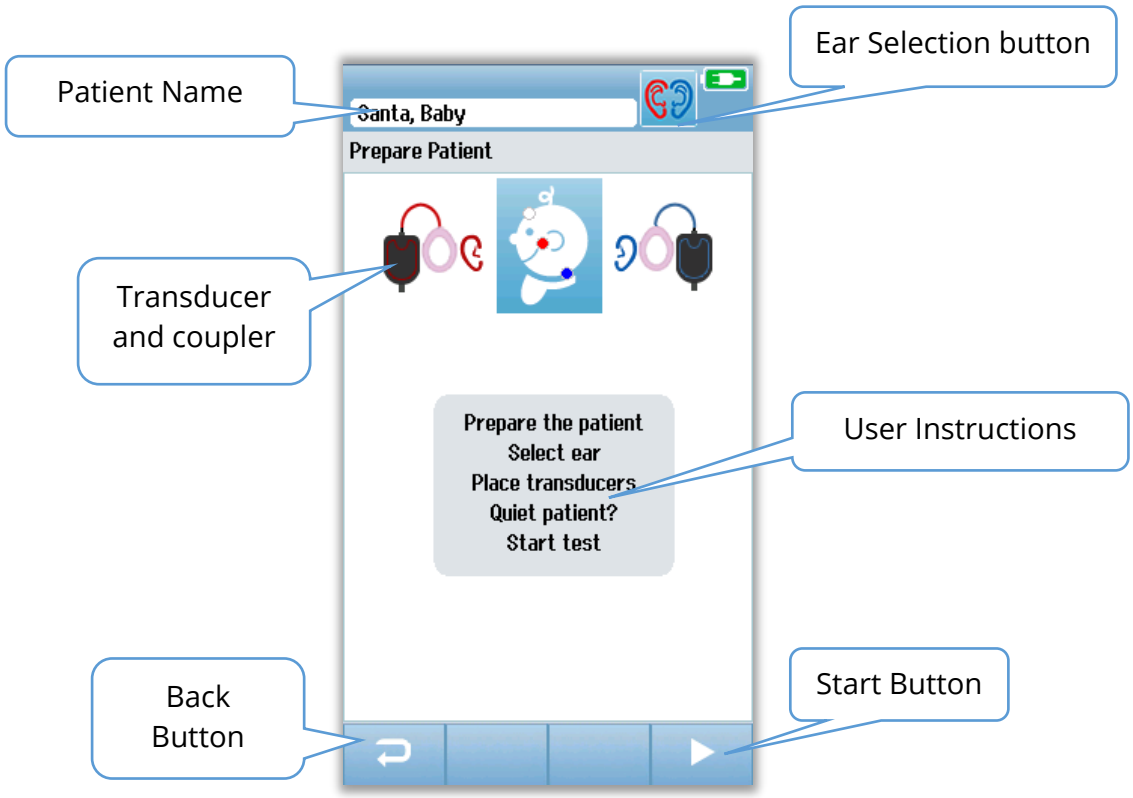
ABR TEST

During the ABR testing process the screens will change to reflect the processes taking place and the options available to the screener. There are 4 screens that are part of the ABR test:

- Patient Preparation
- Impedance Check
- Testing
- Test Complete

PREPARE PATIENT SCREEN

The initial ABR screen displays setup instructions.



The **Ear Selection Button** toggles to change the ear being tested. The transducer and coupler displayed by the baby head is based on the transducer that is attached to the Novus and the coupler that has been calibrated for the transducer.

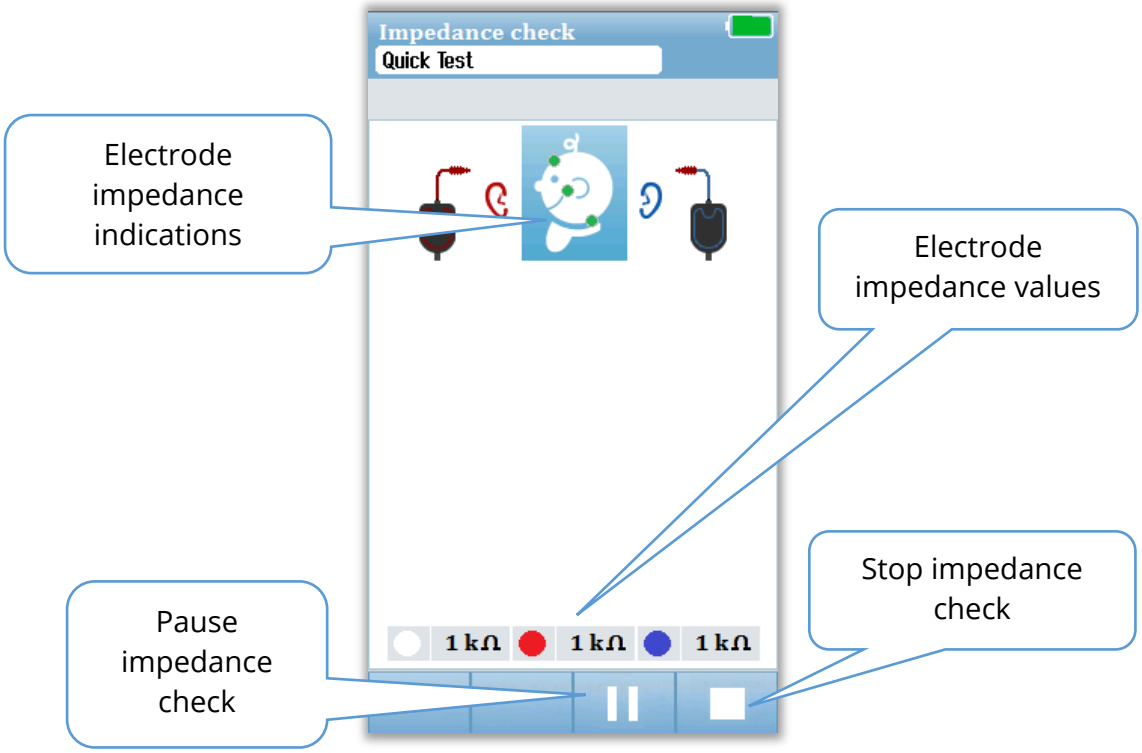
Insert earphone with ear cup

Insert earphone with ear tip

Probe with ear tip

IMPEDANCE CHECK SCREEN

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



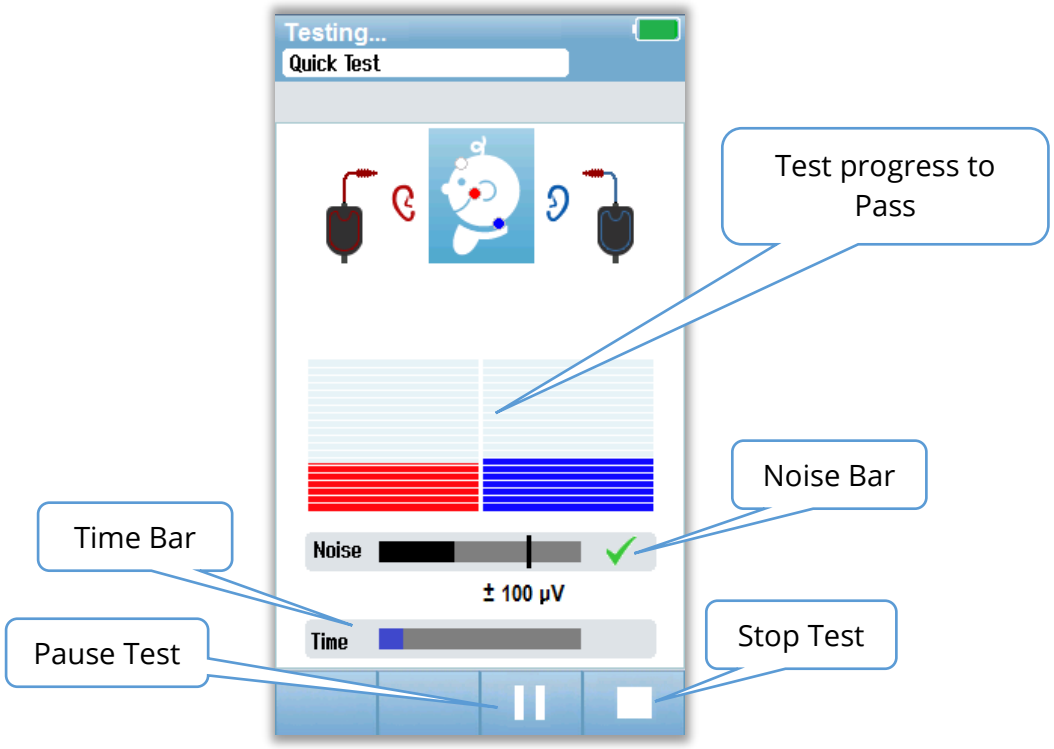
The color of the circles (electrode impedance indications) on the baby's head indicate if the impedances are within acceptable limits. Green is used to indicate a good impedance. An orange color indicates a poor impedance.

If any impedance indicator remains "orange", the impedance must be improved at this electrode position. Make 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 a skin preparation product to clean the skin again. It may be possible to reapply the same electrode but if the adhesion is insufficient then a new electrode may be required.

After approximately 60 seconds of impedance checking, an Impedance time out message will appear. Upon dismissing the message by pressing the check mark, the initial test screen will appear again.

ABR TESTING SCREEN

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



Noise bar

During measurement, a Noise bar will display the amplitude of the incoming EEG samples. A check will appear at the right side of the bar when the incoming signals are quiet enough to be accepted and processed in the response detection algorithm. If the incoming EEG samples contain high noise due to myogenic or electrical noise, the check will disappear, and the noise bar will reflect noise exceeding the threshold for rejection of those samples.

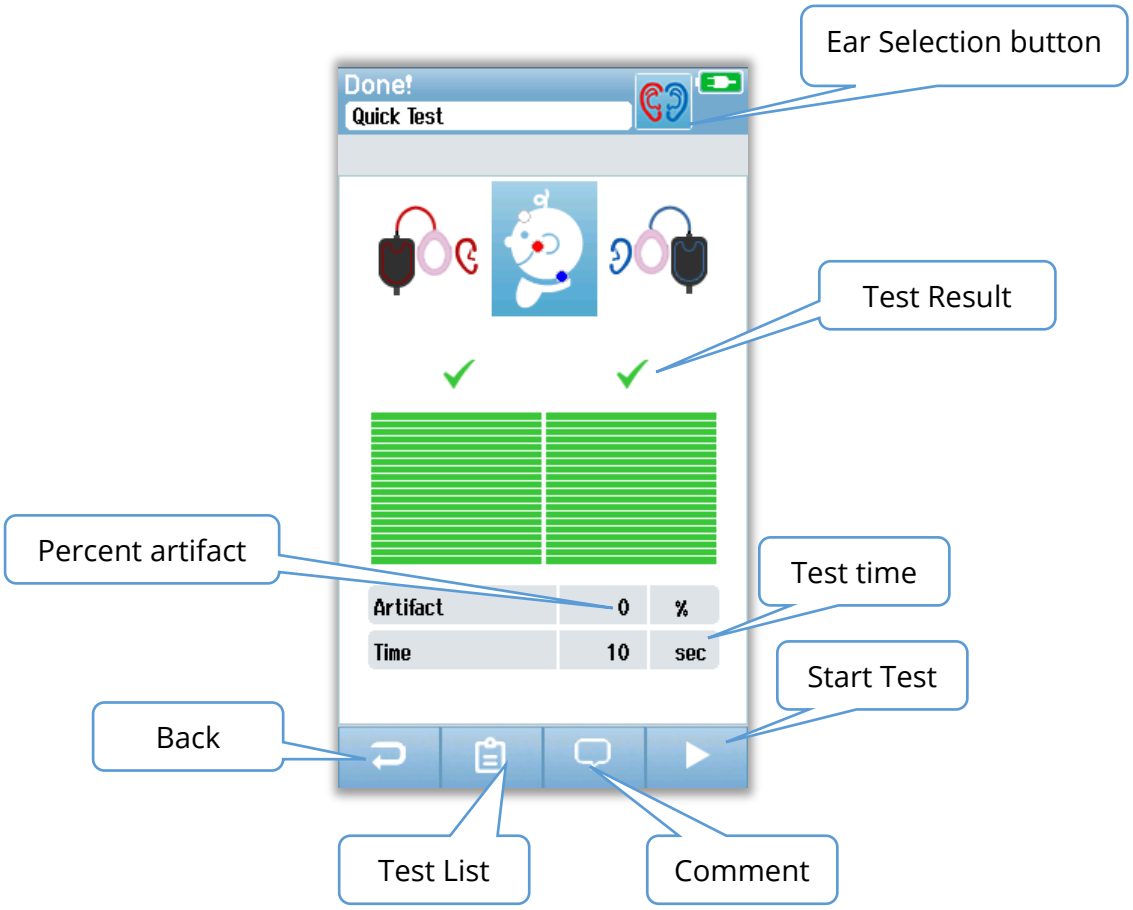
Time bar

During measurement, a Time or progress bar will fill in as good sample of data are processed. When 180 seconds of acceptable EEG samples have been acquired, the bar will be filled in completely and the test will terminate automatically.

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

TEST DONE SCREEN

At the end of a screening, the result of the will be displayed. 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 ABR test performed on the right and left ear during the session.



The **Back** button returns to prior screen (before initial test screen). The **Test List** button opens a list of all tests performed in this session. The **Comment** button opens a screen for inserting a comment about the test just performed. The **Start** button begins an impedance check for a new screening. If the user starts another screening test on the same ear that just passed, a message alerts the user that the ear just passed the screening and asks for confirmation to retest the same ear again.

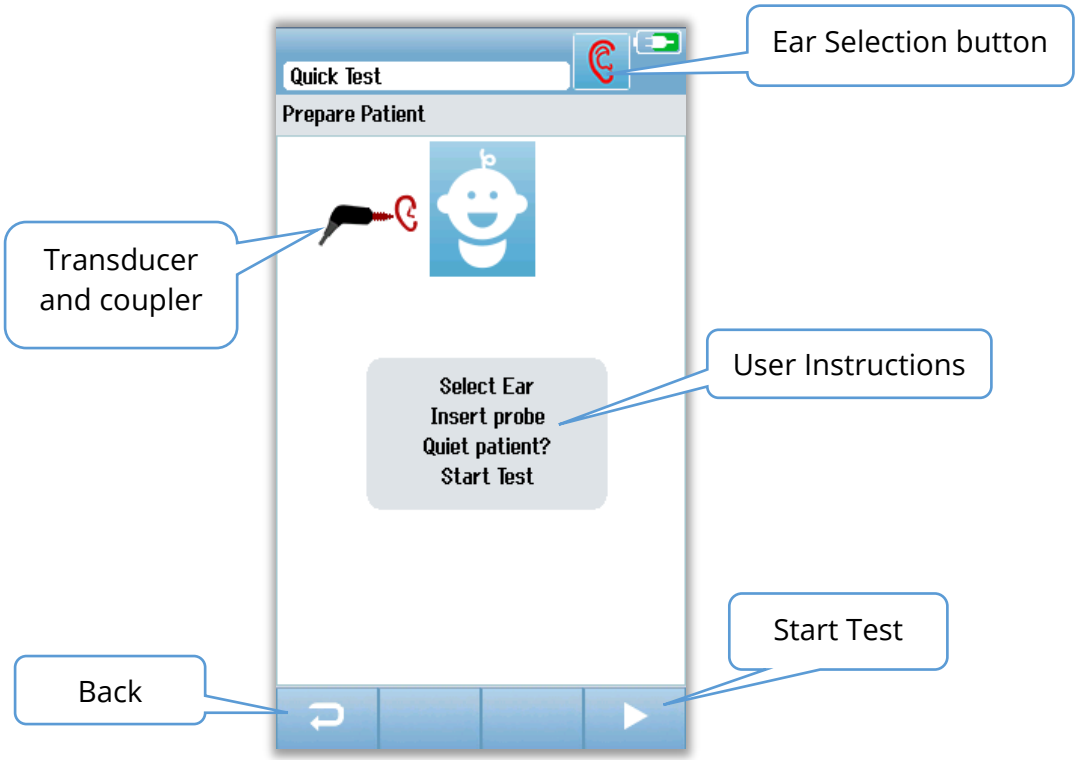
OAE Test Screens

During the OAE process the screens will change to reflect the processes taking place and the options available to the screener. There are 4 screens that are part of the OAE test:

- Patient Preparation
- Probe Check
- Testing
- Test Complete

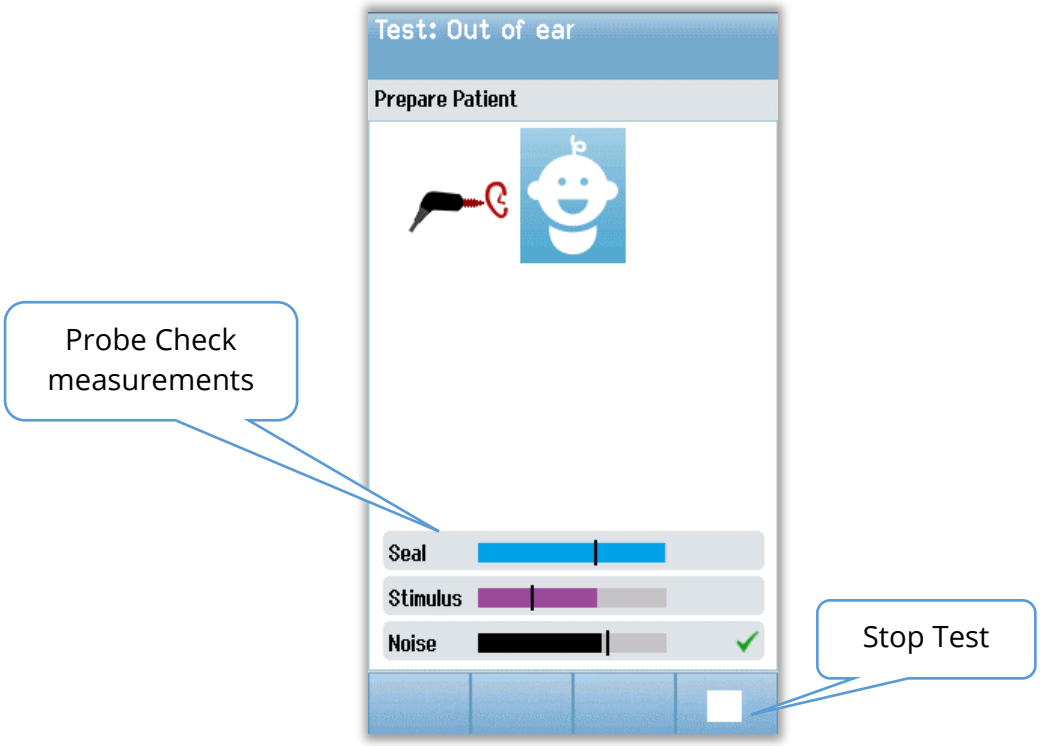
PREPARE PATIENT SCREEN

The initial OAE screen displays setup instructions.



PROBE CHECK SCREEN

During the probe check, information is displayed regarding the quality of the fit of the probe in the ear canal. Once the probe fit is good the probe check terminates and the OAE measurement begins automatically.



Seal

The seal parameter is a measure of how well the probe is seated in the ear canal. The tip should be secure in the ear canal and not moving. The line on the bar indicates the maximum acceptable level.

Stimulus

The stimulus parameter is a measure of how well the OAE stimulus is being delivered to the ear.

Noise

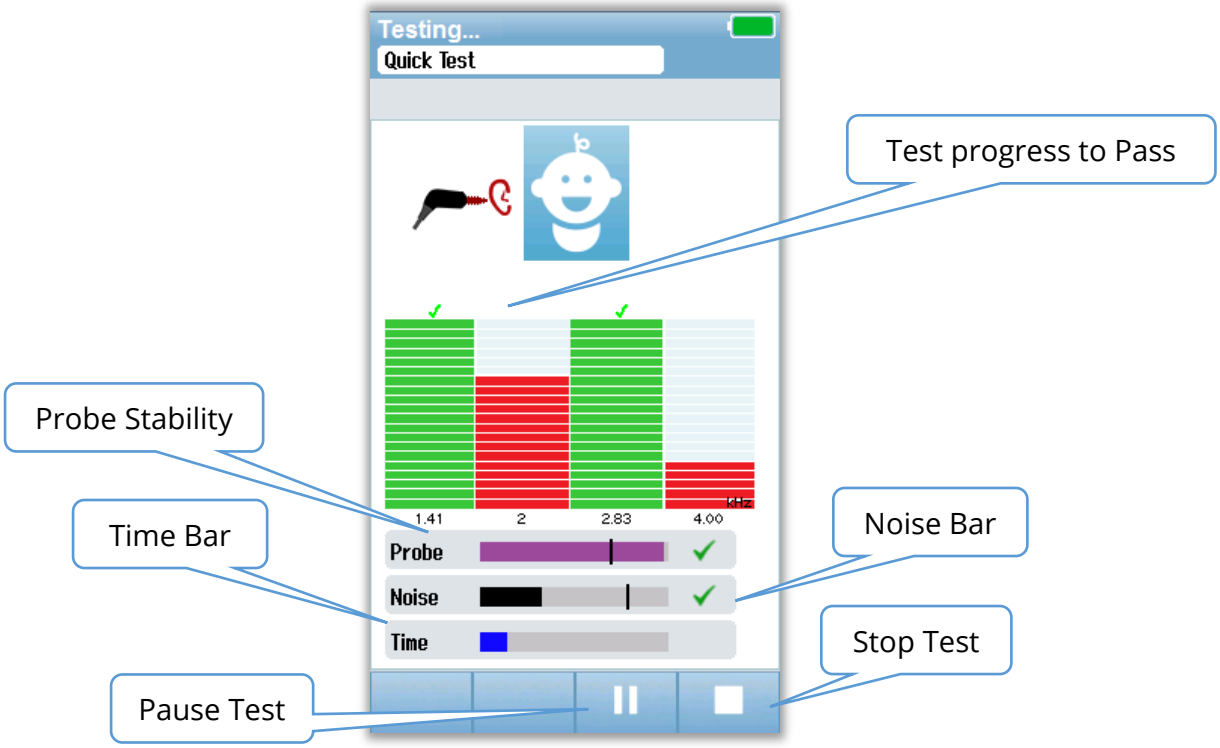
The noise parameter is an indication of the external noise in the testing environment.

A checkmark for the parameter indicates that the fit quality is acceptable. If the probe fit is not acceptable you need to improve the situation before the screening will begin:

- Make sure the probe tip is inserted securely into the ear canal.
- Quiet the baby or attend to any acoustic noise in the test environment.

OAE TESTING SCREEN

During the OAE measurement, a bar graph for each of the frequencies in the test protocol reflects the progress toward a pass. The bar will fill in completely with green color and a checkmark will appear above the bar when the criteria for a pass is achieved at that frequency. Test conditions are displayed as horizontal bars for probe stability, noise and test progress. When the probe stability and noise are acceptable, a checkmark appears next to the horizontal bar.



Probe stability (TEOAE only)

The Probe Stability bar reflects the status of the probe in the ear canal. A check will appear at the back of the bar when the probe stability is adequate. If the probe stability drops below an acceptable level suggesting that the probe is falling out of the ear, the check will disappear. If this happens you should check the fit of the probe in the ear.

Noise bar

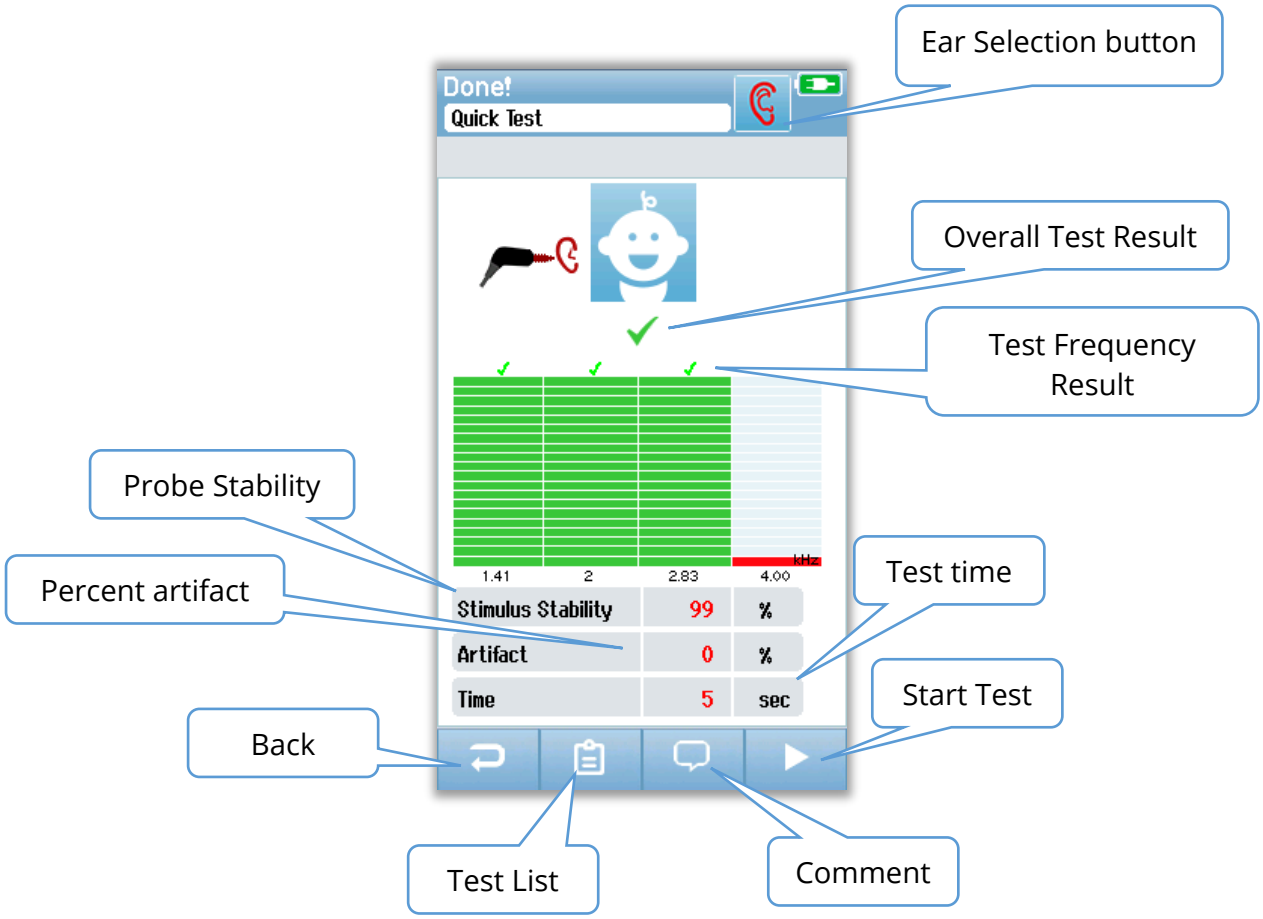
The Noise bar displays the amplitude of the incoming acoustic noise. A check will appear at the back of the bar when the environment is quiet enough. If the environment contains high noise, the check will disappear, and those samples are rejected. If this occurs, you should Pause the test and attend to the noise by calming the baby or managing other sources of ambient noise. The fit of the probe should also be checked.

Time bar

The Time or progress bar will fill in 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

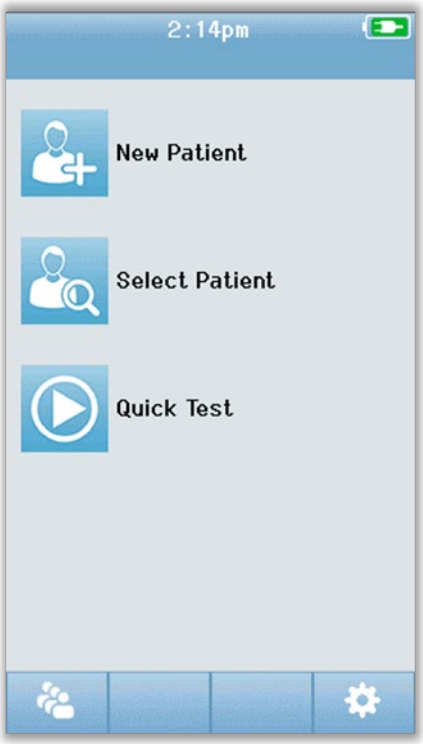
At the end of a screening, the result of the most recently completed screening will continue to be visible. The ear selection control will return so that the user can select the other ear for testing or can repeat a screening measure on the same ear. The ear selection control can also be used to toggle between the last OAE test performed on the right and left ear during the session.



The **Back** button returns to prior screen (before initial test screen). The **Test List** button opens a list of all tests performed in this session. The **Comment** button opens a screen for inserting a comment about the test just performed. The **Start** button begins a probe check for a new screening. If the user starts another screening test on the same ear that just passed, a message alerts the user that the ear just passed the screening and asks for confirmation to retest the same ear again.

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

One Quick Test session is saved temporarily in the Novus 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 Novus.

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. Enter 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.

PRINTING

LABEL PRINTER

Use only the recommended label printer from GSI. Pairing of the Bluetooth printer and the Novus is accomplished in the in the Setup/Printer screen. It is possible share one printer with multiple Novus devices. However, the device can be paired with only one printer at a time.

NOTE: Do not power off the Novus during printing. Thermal paper printouts fade with exposure to light or heat. Photocopying the test results will ensure a more permanent record.t

WAYS OF PRINTING

Printing of screening results on the label printer can be selected from within the 'Test List' screen. The 'Test List' screen can be accessed from either the 'Test Done' screen or from the 'Patient Information' screen.

An attempt to print when the label printer is powered off or is out of range to the Novus 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.

LABEL PRINT FORMAT

The label printout displays the following information:

Hearing Screening Report

ID: ***ID Number***
Last Name: *Last name*
First Name: *First name*
Birth Date: *00-00-0000*
Gender: *Gender*

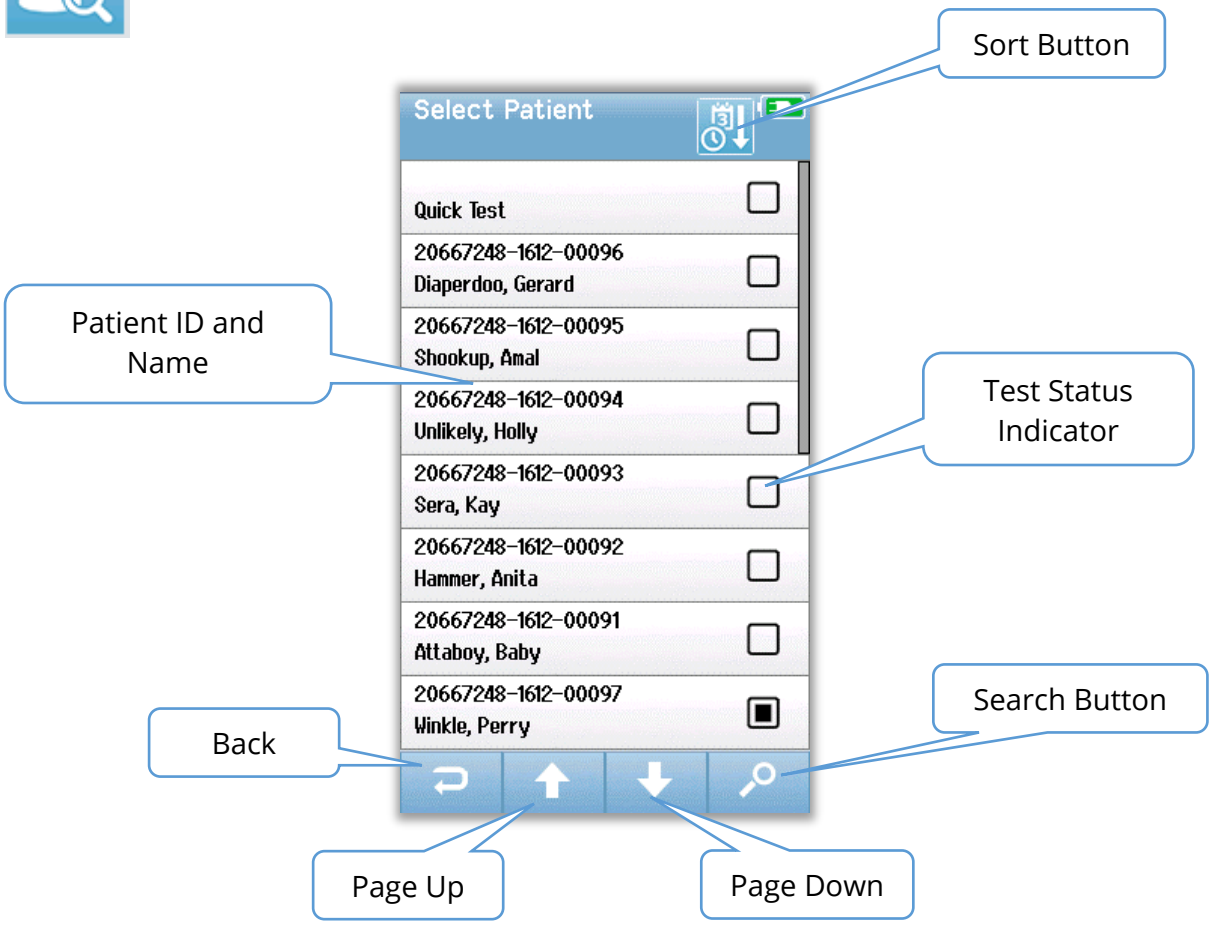
Right ABR 35 dB nHL – *Result*
Date & Time
Screener: *Screener*

Left ABR 35 dB nHL – *Result*
Date & Time
Screener: *Screener*

Reviewing Patients & Tests

Select Patient

The **Select Patient** button on the Home screen presents the list of names of patients contained in the device database.

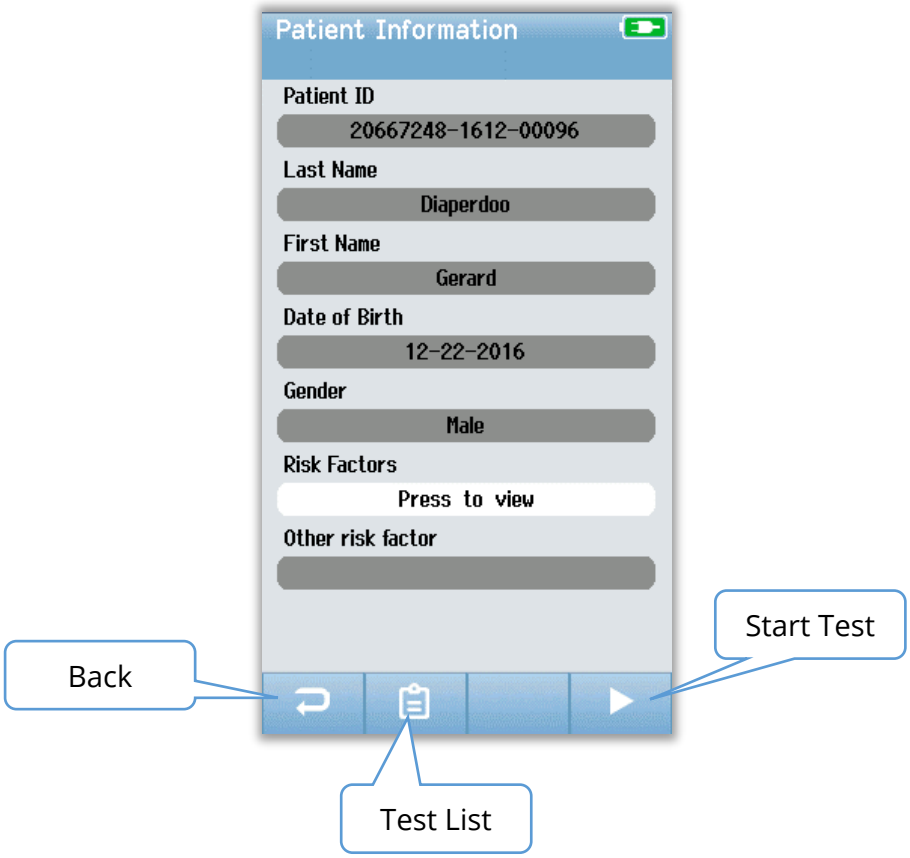


The list may be sorted alphabetically by last name or by test date in reverse chronological order using the sort icon at the top right corner. In both sort modes, the "Quick Test" patient appears at the top of the list if one is present.

Use the **UP** and **Down** arrow keys in the bottom control bar to page through the list. You can use the **Search** button in the bottom 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 on the list to proceed to the Patient Information screen showing this patient's details.

PATIENT INFORMATION

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



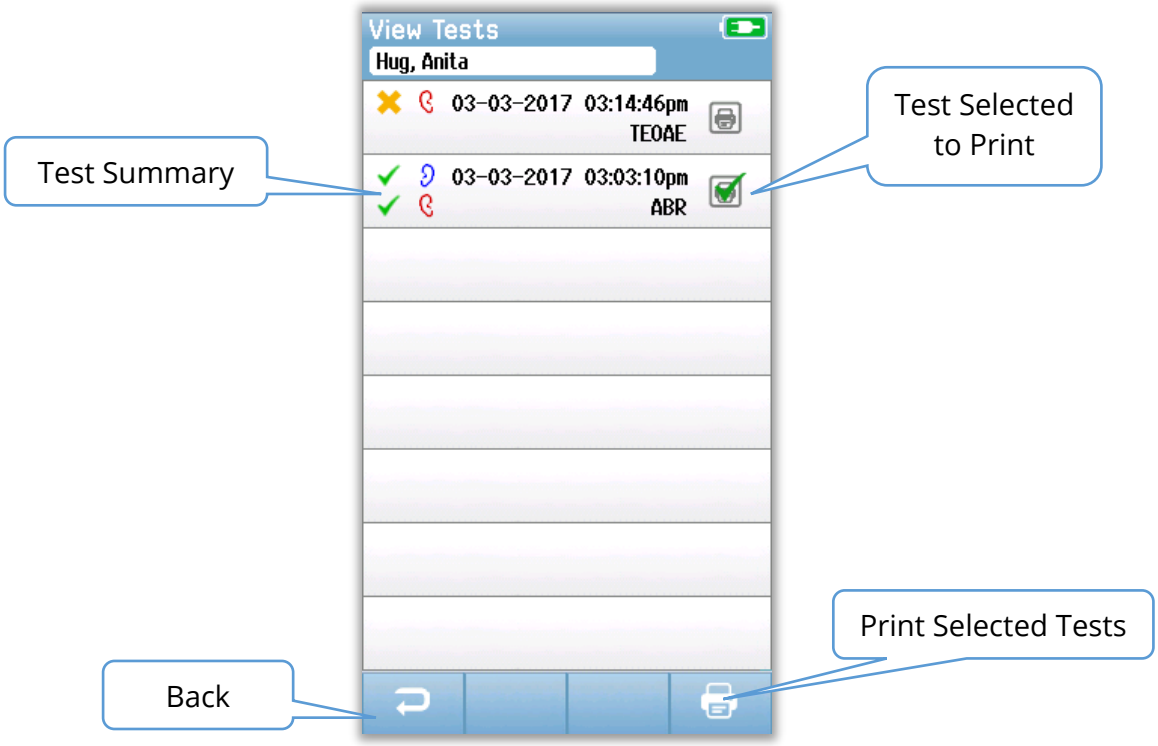
Editing of patient information on the Novus will be possible if the Administrator has enabled editing on the device using the HearSIM PC application. Patient information transferred from the HearSIM PC database to the device cannot be edited on the device. Editing of this patient information must be performed within the HearSIM PC database.

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

Select the **Start** button in the bottom control bar to proceed with testing this patient.

TEST LIST

The test list is sorted chronologically with the most recent test at the top. Each row represents one test. If more than eight (8) tests are saved, the **Up** and **Down** arrow buttons will be in the bottom control bar can be used to page through the list.



Each row in the Test List shows a summary of the test with the following information:

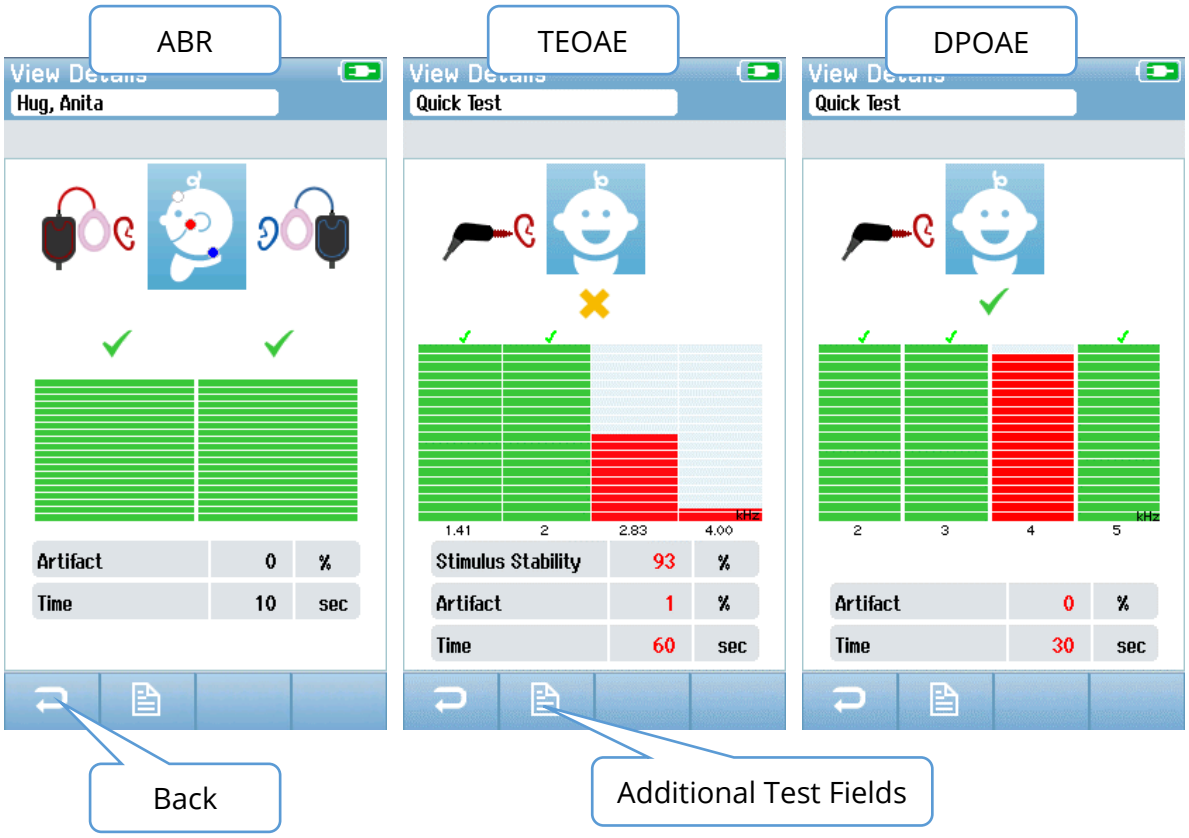
- Result symbol for Pass, Refer or Incomplete
- Test ear symbol for Right, Left or Both ears
- Test date & time
- Technology type (ABR, DPOAE or TEOAE)
- Printer Icon

The Printer icon to the right of the test summary is a button to select the test for printing. When selected the Printer icon in the test row will contain a green checkmark. Select as many tests as you want to print. Then select the **Print** button in the bottom control bar to print. 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 technology type. In that case, both tests will print on a single label.

Note: The Printer icons and the **Print** button only appear on the screen if your Novus has the Printer settings enabled via the HearSIM PC application and if a printer has been paired with the device. Otherwise these controls are hidden from view.

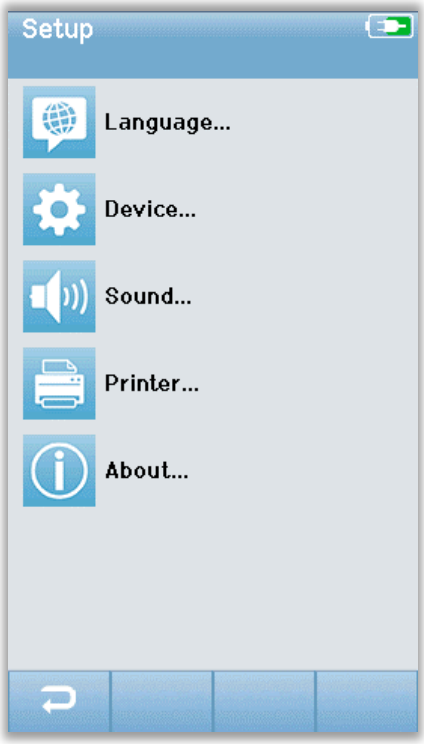
Test Details

Select one of the tests in the Test List to view the details of the test. The test details screen will be like the test complete screen and the content depends on the Test Type.



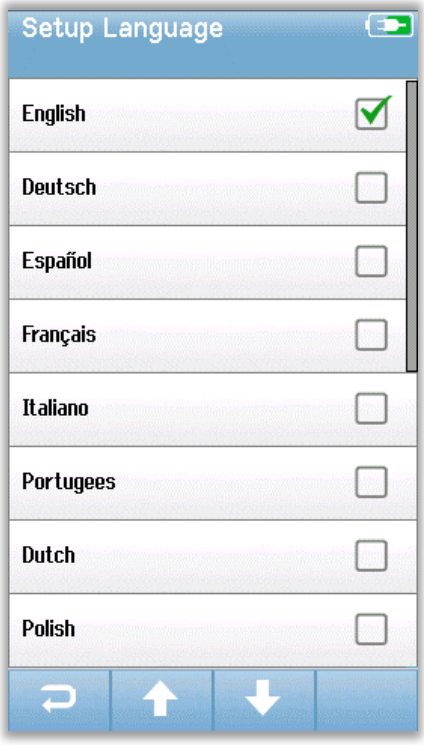
The **Additional Test Fields** button in bottom of the Test Details screen to view the Test-related Fields. This screen will be available only if the Test Fields option is enabled on the device via the HearSIM PC application. The Test-related fields cannot be edited on the Novus. If edits are needed, the test data must be transferred into the HearSIM PC application and the edits can be made in the HearSIM PC database.

SETUP



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

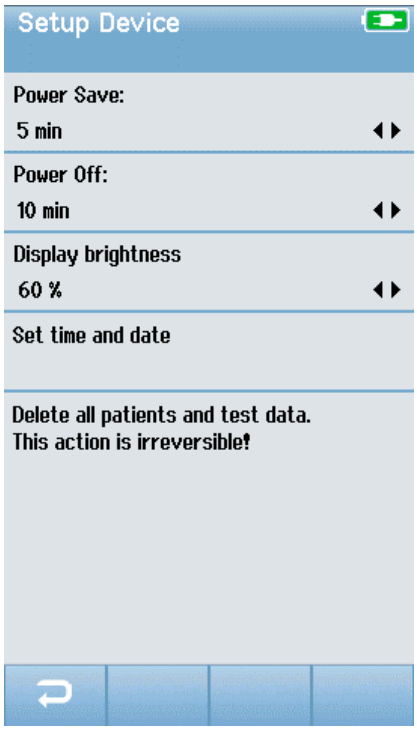
LANGUAGE



Select **Language** to display a list of available languages. Use the Up and Down arrow controls in the bottom bar to page through the list.

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 **Back** button in the bottom control bar.

DEVICE

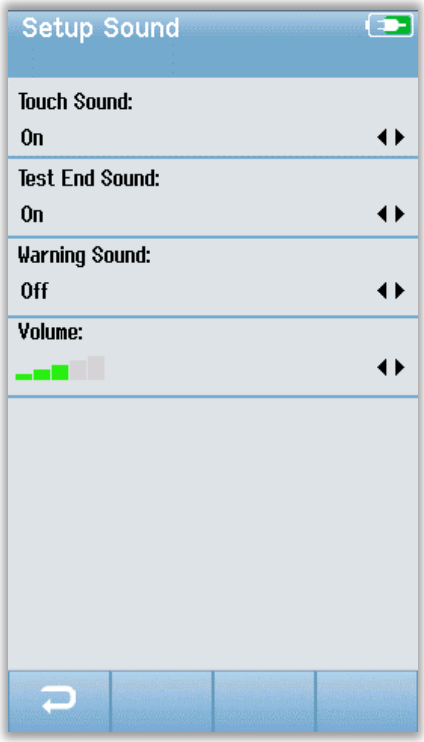


Select **Device** to set your preference for Power Save, Power Off, set the time and date, and to delete data from the device.

- 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.
- Display brightness controls the screen brightness.
- Set time and date allows you to set the time and date, including the hour format (12/24), and the date format. When complete select the check button to return to the Device Setup.
- Delete all patients and test data erases all the patient and test information from the device. A confirmation is required before the data is deleted.

To confirm the selection and exit the Device screen, select the **Back** button in the bottom control bar.

SOUND

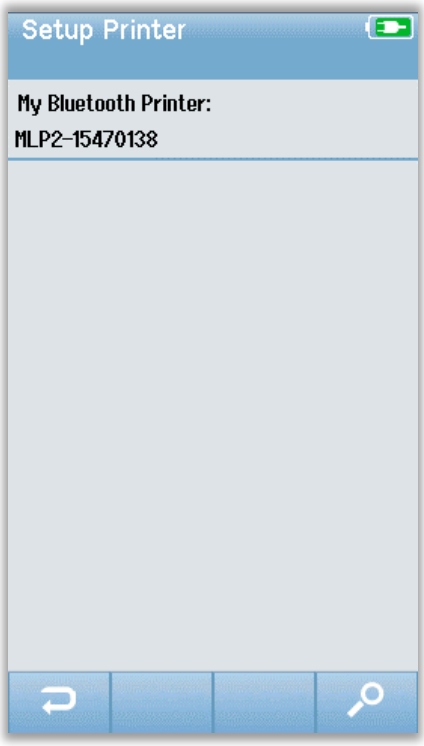


Select **Sound** to set your preferences for the presentation of a sound as feedback and the setting of the volume. Conditions for which you can choose to present a sound are:

- Touching a button or key (function button or keyboard key).
- Test end – plays a sound when a test is completed.
- Warning – plays a sound when an electrode becomes detached during ABR.

To confirm the selection and exit the Sound screen, select the **Back** button in the bottom control bar.

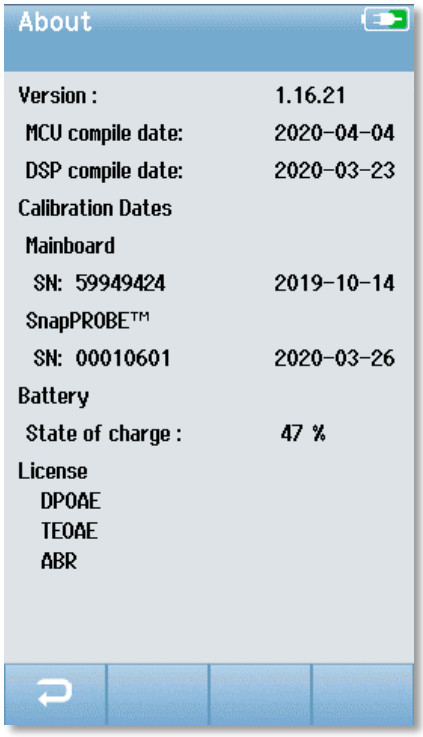
PRINTER



Select **Printer** to pair to the optional Bluetooth printer. Select the Search button in the bottom control bar to find matching printers. Be sure that the printer is powered on. The name HM-E200 or MLP2 and the serial number will display when the printer is successfully found. Then select the printer to pair to the Novus.

To confirm the selection and exit the Sound screen, select the **Back** button in the bottom control bar.

ABOUT



Select **About** to view information about the Novus including:

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

To exit the About screen, select the **Back** button in the bottom control bar.

CLEANING AND MAINTENANCE

CLEANING THE NOVUS

TOUCH SCREEN

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

CASE, CRADLE AND CABLES

Use caution while cleaning.

• Before cleaning, remove the Novus from the cradle and unplug the cradle from AC power.

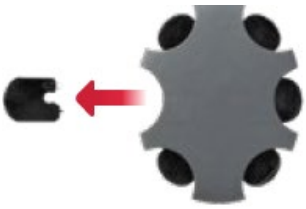
- Use a soft cloth moistened with a mild solution of water and detergent to clean the plastic parts of the Novus and cradle.
- If disinfection is required, use a disinfectant wipe rather than a spray product. Make sure that excess liquid from the wipe does not seep into any sensitive areas such as connectors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

PROBE

Patient contact parts should be cleaned prior to each use. The probe and insert earphones may be wiped with a slightly damp cloth containing soap and water, ammonia-based cleaners or bleach-based cleaners. Gently wipe the items with the slightly damp cloth taking care not to get moisture in the speaker portion of the probe or insert earphones.

The SnapPROBE™ uses a special Sanibel™ eartip that couples the probe to the ear and provides 3 separate acoustic channels. Each acoustic channel is protected with a wax guard. The wax guard prevents earwax from entering the probe body. The wax guards must be regularly checked for earwax in the openings. If you see earwax in the wax guard, you should replace it.

Remove the eartip from the probe by simply snapping it off the probe. Discard the disposable eartip. It is for single use only.



Remove the tool from the shell dispenser. The tool has two pins, one empty for removal and one with the new wax filter.

Empty pin (1): Push this pin in the wax guard and pull the wax guard straight out of the probe body.

Pin with new wax guard (2): Press the new wax guard into this hole and pull the tool out again. Verify that the new wax guard is set into the probe body. Discard the tool. Repeat for the other wax guards, as needed.

Never clean inside the probe itself.

If the inside of the probe, beyond the wax guards, becomes clogged or damaged, contact your authorized local distributor.

CLEANING & DISINFECTION

Non-disposable parts of the system, including the preamplifier, electrode wires and insert phone tubes with EarCup or insert phone adapter which are in direct contact with the patient need to be disinfected between patients.

This includes physically wiping down the equipment which contacts the patient using a disinfectant approved by your facility. Use of a non-alcohol-based disinfectant is recommended. Non-alcohol-based products contain the active ingredient referred to as quaternary ammonia compound or a hydrogen peroxide-based cleaner may be used. The quaternary ammonia compound and hydrogen peroxide are specifically designed to disinfect rubber, plastic, silicone and acrylic products which are commonly used in hearing evaluation instruments. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriate level of disinfection. Remove disposable EarCups, eartips or electrodes prior to disinfection.

To avoid person-to-person cross contamination of communicable diseases, all disposable items such as EarCups or eartips and disposable electrodes are intended for single-patient use only and need to be discarded after the screening.

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 switch off the device, disconnect the mains power adapter and be careful that no fluid enters the inside of the instrument or accessories.

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

DISPOSABLES

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

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

DEVICE CONTROL

The user of the instrument should perform a subjective instrument check of the acoustic stimulus at least once per week. The GSI Pass-Checker device may be purchased to perform a more objective test of system integrity.

CALIBRATION

To guarantee that the Novus works properly, the instrument should be checked and calibrated at least once per year. Have an authorized service technician perform electrical safety checks on the unit to maintain continued compliance to IEC and UL 60601-1.

The service and calibration must be performed by an authorized service center. If these checks are not done, EU Medical Device Directive (MDD) and other 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.

TROUBLESHOOTING

In case of problems, consult the table below for symptoms, possible causes and suggested troubleshooting.

Symptom	Possible cause	Suggested troubleshooting
Cannot pass ABR impedance for one or more electrodes.	Ineffective skin preparation	Remove electrode and use NuPrep or other skin prep 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 preamp	Check connections at the preamp cable jack and try again
	Electrode lead wire has a short in the wire	Replace the electrode lead wire with a new one (may need to replace more than one of the electrode wires)
	Connection of preamplifier cable to the Novus ABR/OAE connector is not secure	Check the connection of the preamp cable to the Novus; remove it and re-insert it verifying that it is securely attached
Excessive artifacts are observed during the 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 (ABR) is losing contact with the skin	Check electrode contact to skin making sure it is adhering to the prepared skin
	Electrode lead wire (ABR) has a short in the wire which may lead to intermittent contact	Replace the electrode lead wire with a new one (may need to replace more than one of the electrodes)
	Electrical interference is interfering due to AC connection	If Novus is being used in the cradle with AC attached, unplug the cradle power supply from

Symptom	Possible cause	Suggested troubleshooting
		the outlet to 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 in a different location.
High refer rate	Screening babies when they are too active	Perform screenings only when the baby is quiet - preferably sleeping, comfortable, and recently fed. Screen just after feeding when Mom 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

Symptom	Possible cause	Suggested troubleshooting
		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, devices that have motors that turn on and off.
	EarCup (ABR) or eartip is not on the ear properly	Make sure that the EarCup is surrounding the ear and that there are not big gaps between the foam and baby's skin. For eartips make sure that the ear tip is securely inserted into the baby's ear canal.
	Stimulus is not coming through the insert earphones (ABR) or OAE probe	Check the connection of the insert earphone cable or OAE probe into the preamplifier; remove it and re-insert it verifying that it is securely attached.
		Check the connection of the cable to the Novus ABR/OAE connector.
		Check the connection of the insert earphone cable to the red and blue transducers (ABR)
		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. (ABR)
		Make sure the insert earphone tubes are free of any crimping or compression; replace the tube with a new one. (ABR)

Symptom	Possible cause	Suggested troubleshooting
		Replace the insert earphone cable with a new one (ABR)
		Check the OAE probe tip to be sure it is clear of any wax or debris in any of the holes. Clean it or replace it as needed.
ABR Data collection is stalled in Electrode Off-Paused message	Electrostatic discharge event	Stop the measurement and start again
"Electrode Off – Paused" message during ABR testing	Electrode is not contacting skin	Reapply electrode to prepared skin site.
"Check Cables" message during ABR screening	Electrode contact may be poor	Check electrode contact to skin
"Too Noisy" message during OAE test	High acoustic noise is present during OAE test	Quiet baby or environment
"Out of ear" message during OAE test	OAE probe is coming out of the ear or has fallen out completely.	Recommend to stop the screening and start again since reinsertion of probe in ear needs a new in-ear calibration process before the screening.
"Off Levels" message during OAE test	Probe is coming out of baby's ear or placement of OAE probe has otherwise changed during the test so that calibration values are off	Check fit of probe in baby's ear. May be necessary to stop the screening and start again after securing the probe in the baby's ear canal.
Touchscreen is non-responsive to touch	Software is frozen in a process	Hold the Novus power button for 10 seconds to force a power off and then reboot the system
Novus battery is not charging when device is in the cradle	Poor connection of power supply; wrong power supply	Verify that you are using the correct power supply for the Novus and it is fully connected.

PASS-CHECKER

The Pass-Checker accessory may be used to perform a quality check of the Novus that has the ABR option. This can be done on a regular basis or may be performed if you suspect a problem with the Novus hardware. The Pass-Checker may be purchased from your GSI representative.

1. Verify that the electrode lead wires, and the insert earphones are connected to the Novus preamplifier cable and that the preamplifier cable is attached to the Novus.
2. Connect the 3 electrode lead wires to the posts on the Pass-Checker matching the colors of the wires to the ring around the posts.
3. Insert the insert earphone adapters securely into the holes on either side of the Pass-Checker.
    a. If the black EarCup adapters are used with your system these will fit into the hole directly.
    b. If the clear Ear Tip adapters are used with your system you will need to place a disposable eartip onto the adapters before inserting them into the Pass-Checker holes.
4. Switch on the Pass-Checker by pressing the power button. The amber LED lights up when the Pass-Checker is turned on.
    a. 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 both ears ABR test with the Pass Checker attached in this way.
6. The test should proceed quickly through the impedance and measurement phases ending in a Pass result for both ears.

Pass checker symptoms, possible causes and suggested troubleshooting.

Symptom	Possible cause	Suggested troubleshooting
Cannot pass impedance for one or more electrodes.	Electrode lead wire is not fully attached to the preamp or to the Pass-Checker	Check connections at the preamp cable jack and on the Pass-Checker and try again
	Electrode lead wire has a short in the wire	Replace the electrode lead wire with a new one (may need to replace more than one of the electrode wires)
	Connection of preamplifier cable to the Novus jack is not secure	Check the connection of the preamp cable to the Novus; 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 (may need to replace more than one of the electrodes)
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 cable; 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 transducers
	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 rip in the tube	Make sure the tubes are free of any crimping or compression; replace the tube with a new one
	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 service center regarding change of battery on the Pass-Checker. We recommend annual battery change at the time of calibration of your Novus device.

If these troubleshooting suggestions do not resolve the problem you are experiencing with your Novus device, allowing you to pass a screening using the Pass-Checker, contact your local GSI representative for assistance.

NOTE: The Pass-Checker battery should only be replaced by an authorized GSI 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.

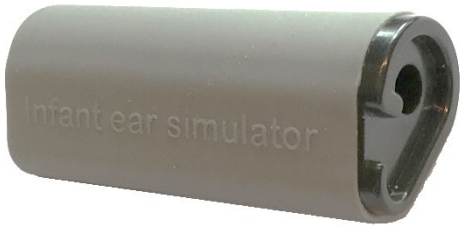
ACCESSORIES/REPLACEMENT PARTS

Some reusable components are subject to wear with use over time. We recommend that you keep theses replacement parts available (as appropriate for your Novus device configuration). Also, it is recommended that you keep replacement cables and accessories for your Novus available to perform these troubleshooting procedures.

REORDER NUMBER	DESCRIPTION
8100577	Insert earphone tubes and adapters for EarCups (around the ear)
8100590	Insert earphone tubes and adapters for eartip (in-the-ear)
8500390	Electrode lead wires (red, white, blue)
8517514	Preamplifier

INFANT EAR SIMULATOR

The Infant Ear-Simulator accessory may be used to perform a quality check of the Novus that has the OAE option. This can be done on a regular basis or may be performed if you suspect a problem with the Novus hardware or OAE probe.



The Infant Ear Simulator is a cavity specifically designed to mimic the acoustic absorbance properties of a real infant ear including the ear canal and middle ear. Other methods to assess probe performance use a hard-walled cavity. It is well known that a hard-walled cavity does not reflect the properties of an infant ear. Testing this way can produce false responses due to the resonance characteristics of the hard-walled cavity, making it difficult to assess how accurately the probe will perform in a real infant ear. Using the Infant Ear Simulator, it is possible to perform an OAE probe quality check in a realistic test cavity.

1. Attach a clean disposable eartip of the smallest size to your OAE probe.
2. Insert the probe with eartip into the Infant Ear Simulator.
3. Perform a standard OAE screening.
4. The screening outcome should be a Refer.

If the screening outcome is a Pass, contact your distributor to replace or repair your probe.

NOVUS PC APPLICATION – HEARSIM

The Novus may be connected to a PC using a USB cable. When connected to a PC, it can communicate with the Novus PC application, HearSIM. Minimum computer specifications for compatibility with the Novus PC application are found in the HearSIM User Manual.

The HearSIM application supports the following functions:

CONFIGURE DEVICE SETTINGS

The HearSIM application allows the administrator to enable or disable the following device features:

- User login – determines whether a user must login upon device boot up or after waking from standby mode
- Quick Test – ability to perform a test without first entering patient information
- Test fields – whether test-related fields of Screening Facility, Hospital Status, Screener and Comment are displayed for information entry when a test is performed
- Stop Reason – requires the user to enter the reason a test was stopped (Could not test, Invalid)
- Auto ID – automatically assigns a patient ID
- Print – enables printing using the Bluetooth label printer
- Comments – allows the user to enter a comment on the test results
- Protocols – allows the user to send screening protocols to the device

CUSTOMIZE DEVICE LISTS

The HearSIM application allows the administrator to customize the lists that display on the device. The customizable lists are:

- User names (with passwords)
- Screening facility
- Risk Factors

TRANSFER DATA TO PC

The HearSIM application allows authorized users to transfer patient information and screening data from the device to the PC for storage, viewing, export and printing of results.

TRANSFER PATIENT INFORMATION TO DEVICE

The HearSIM application allows authorized users to transfer patient information into the Novus device so that these patients can be selected from the device for testing.

Supplies and Accessories

Use only the recommended disposable ear tips/cups. These are for single use only - that is, each ear tip is intended to be used once only for a single ear for a single patient. Do not reuse ear tips/cups as this will pose the risk of ear-to-ear or patient-to-patient cross infection.

Part Number	Description
8519706	HM-E200 Bluetooth Printer Kit
8519836	Thermal Labels for HM-E200 printer (1 roll ~100 labels)
8049700	EarCups with snap electrodes (1 box; 20 sets)
8109096	Disposable snap electrodes (60 pcs, 20 screens)
8500390	Pinch clip cables for snap electrodes
8107449	Cleaning cloth
8100577	Insert earphone tubes and adapters for EarCups (around the ear)
8100590	Insert earphone tubes and adapters for eartip (in-the-ear)
	Sanibel Ear Tips (Single Use) & Waxguards
8522758	SnapPROBE™ Ear tip Infant A style, bag of 100pcs
8522759	SnapPROBE™ Ear tip Infant A style, bag of 25pcs
8522760	SnapPROBE™ Ear tip Infant C style, bag of 100pcs
8522761	SnapPROBE™ Ear tip Infant C style, bag of 25pcs
8516436	Probe Waxguard
8517889	Probe Waxguard Set (10)

APPENDIX A - TECHNICAL DATA

The Novus is an active, diagnostic medical product. The device is classified as a class IIa device according to the EU medical directive 93/42/EEC and a class II device according to the US FDA.

STANDARDS COMPLIANCE	
Safety and Electromagnetic compatibility (EMC)	IEC 60601-1, Type B and BF applied parts IEC 60601-1-2 IEC 60601-2-40
Calibration and Test Signal	ISO 389-2 ISO 389-6 IEC 60645-3
OAE	IEC 60645-6: 2009, Type 2 **Note**: An alternate stimulus level control procedure and stimulation intensities beyond the range required by the standard are used by Novus
ABR	IEC 60645-7: 2009, Type 2
Markings **IP02** **IP20**	IP marking is an ingress protection marking. The marking specifies the protection provided against ingress of particle matter and liquids. This device has different IP marking with the follow impact: IP02: To protect the device against rain and water always use the carrying bag during transport. IP20: This marking can be found on the device 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 SPECIFICATIONS	
ENVIRONMENTAL	
Transport and Handling 	Transport package shall be kept away from rain and in dry conditions
Temperature 	Operation: + 15° C to + 35° C (+ 59° F to + 95° F) Transport:- 20° C to + 50° C (- 4° F to + 122° F) Storage: 0° C to + 50° C (+32° F to + 122° F)
Humidity 	Operation: Maximum relative humidity 90 %, non-condensing Transport and Storage: Maximum relative humidity 93 %, non-condensing
Ambient air pressure	98 kPa – 104 kPa
Altitude	Maximum altitude: 2000 m (6561 feet) above sea level

PHYSICAL	
Weight	Device: 265 grams (with battery) ABR Preamplifier: 85 grams
Dimensions	Device: 158 mm x 83 mm x19mm ABR Preamplifier: 85 mmx 5 mm x 25 mm
Display	95 mm x 56 mm, color, 272 x 480 resolution
Battery	Li-ion battery 44794; Capacity: 3.7V/3850 mAh ABR Screening - > 50 ABR screens OAE Screening - >150 OAE screens Test duration effects 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.
Battery - Expected lifetime	Depending on use – typically more than 3 years
FUNCTIONAL	
User Interface	Resistive Touch screen
User Feedback	Integrated speaker
Language Settings	English default (select from 15 options)
Memory	1 GB (25,000 records: 250 patients with 100 tests each)
Data interfaces	Wireless (Bluetooth®) Transmit frequency: 2400 – 2483.5 MHz Modulation types: GFSK, π/4-DQPSK and 8DPSK Radiated power: 2.5 mW (Class 2) USB
Boot up time	<5 sec
Warm up time	< 1 minute
Expected Service Life	7 years
CRADLE	
Safety	IEC 60601-1, Class II
Power Supply Model Number	UES12LCP-050160SPA, Item no. 8515473
Power supply output	5V DC, 1.6A max
Mains power supply	100 – 240 V AC, 50/60 Hz, 0.5A
TRANSDUCERS	
RadioEar IP30 Insert Earphones	50 Ohms, with Ear Tip or EarCup adapter
OAE Probe	ABR, TEOAE and DPOAE capable
Cable	Calibration values and date saved in connector

PRINTER	
Type/Model	Thermal printer MLP2, HM-E200
Connection	Wireless Bluetooth®
Battery	Lithium Ion, DC 7.4V, 1500 mAh
Charger	100-250V AC, 50/60 Hz, 1.0 A
Weight	360 grams (12.7 oz.)
Paper	Thermal paper: 57.5 mm ± 0.5 mm (width)r Labels: 57.5 mm ± 0.5 mm x 60 mm (width x length)
TEST SPECIFICATIONS	
ABR	
Test signals	CE-Chirp® (default) or Click, Frequency range (200 Hz – 11 kHz), alternating polarity
Stimulus rate	88/sec left ear, 92.5/sec right ear
Stimulus level	35 dB nHL (default protocol), Range: 30-45 dB nHL
EEG filter	0.5 Hz – 5.0 kHz
Preamplifier Gain	72 dB
Input impedance	10 MΩ / 170 pF
Noise	<25 nV/$\sqrt{Hz}$
CMR Ratio	>100 dB at 100 Hz
Sample rate	22.05 kHz
A/D resolution	24 bit
Electrical impedance measurement	Before and during testing < 40 kΩ required for testing
Maximum test time	180 seconds (artifact free data samples)
DPOAE	
Stimulus frequencies	2000, 3000, 4000, 5000 Hz (default protocol) 1500-6000 Hz range
Nominal frequency, F2/F1 ratio	F2, 1.22
Level L1/L2 (tolerance)	65/55 dB SPL (± 1.5 dB) – in ear calibration
A/D resolution	24 bit, 5.38 Hz resolution
SNR criteria minimum	6 dB (default protocol)
Response amplitude minimum	-5 dB (default protocol)
Bands for Pass criteria	3 out of 4 (default protocol)
Analysis	Minimum 2 seconds to maximum 60 seconds
TEOAE	
Center frequencies	1400, 2000, 2800, 4000 Hz (default protocol) 1000-4000 Hz range
Stimulus	Non-Linear click (IEC 60645-3) rate 71/sec

Stimulus level	83 dB peSPL, peak to peak calibrated, AGC controlled (± 2 dB)
A/D resolution	24 bit
SNR criteria minimum	4 dB (default protocol)
Response amplitude minimum	-5 dB (default protocol)
Bands for Pass criteria	3 out of 4 (default protocol)
Maximum test time	60 seconds

Appendix B: Pass/Refer Criteria, Sensitivity and Specificity

Default Protocols

The criteria used for the Pass/Refer results are contained in the protocols supplied with the Novus. The specifications of these protocols are listed in the Test Specification in Appendix A. The default protocols supplied with the Novus were used to determine the sensitivity and specificity.

ABR PASS CRITERIA

- The Automatic Response Detection Algorithm uses fast Chirp stimulation (90 stim/s) at a level of 35 dB nHL
- The Amplitude and Phase of each of the first eight harmonic frequencies (multiples of 90 Hz) are used by a Modified Q-sample test to calculate a statistical test variable
- Pass criteria: statistical test variable compared to the detection criteria (selected for theoretical 99.9% sensitivity) and if greater than the detection criteria result is a PASS

TEOAE PASS CRITERIA

- Signal to noise ration minimum: 4 dB
- Minimum response amplitude: -5 dB
- Pass criteria: 3 of the 4 bands (1400, 2000, 2800, 4000 Hz) must meet the criteria for an overall pass

DPOAE PASS CRITERIA

- Signal to noise ration minimum: 6 dB
- Minimum response amplitude: -5 dB
- Pass criteria: 3 of the 4 bands (2000, 3000, 4000, 5000 Hz) must meet the criteria for an overall pass

Sensitivity and Specificity Testing Method

It is widely acknowledged that sensitivity testing requires an artificial test environment that simulates severe hearing impairment. For OAE sensitivity assessment, an acoustic test cavity is selected to provide an appropriate acoustic test load to the probe. For ABR sensitivity assessment the electrodes are normally attached to a resistive load approximately equivalent to the typical electrode impedance experienced in the clinical situation.

However, a more thorough assessment requires the inclusion of clinically equivalent noise into the measurement. To achieve this, a 'head simulator' was designed and built that provides the combination of:

- an infant sized ear canal acoustic impedance,
- electrode attachment points connected to a 2kΩ star configured set of resistors,
- 2 different fully controllable noise generators (one pink and the other being a long recording of acoustic noise typical in a clinic)

For each of the TEOAE, DPOAE and ABR modalities the Novus was controlled from the PC so that many repeat tests could be automatically performed. The PC was used to control the level of noise, from the simulator, injected into the instrument so that it experienced the full range of noise present in a typical clinical environment.

RESULTS

ABR mode: 525 tests were performed, no false ABR results occurred, the resulting sensitivity has been assessed to be better than or equal to 99.6%

TEOAE mode: 137 tests were performed, no false OAE results occurred, the resulting sensitivity has been assessed to be better than or equal to 99.6%

DPOAE mode: 370 tests were performed, no false OAE results occurred, the resulting sensitivity has been assessed to be better than or equal to 99.6%

APPENDIX C: ABR AND TEOAE STIMULUS

ABR STIMULUS

A stimulus other than that specified in the standard IEC 60645-3 is used. 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.

CALIBRATION VALUES FOR CE-CHIRP AND CLICK STIMULUS

Coupler IEC 60711

Transducer	**CE-Chirp peRETSPL [dB re. 20 µPa]**	**Click peRETSPL [dB re. 20 µPa]**
RadioEar IP30 with eartips	32	35
RadioEar IP30 with EarCups	58.5	61.5
OAE Probe	35	33.5
SnapPROBE™	34.1	37.4

Calibration values for E-A-RTONE™ 3A with eartips according to PTB report from 2008-05-19, in compliance to the calibration procedure defined in standard DIN EN 60645-3. Correction values for EarCup and OAE probe calibration values are defined as GSI standard. RadioEar IP30 insert earphones are equivalent to the E-A-RTONE™ 3A.

NOTE: The reference levels (RETSPL) for calibration of the ABR CE Chirp or click stimulus are based on normal adult ears as per the ISO 389-6, 2007 standard. A baby has a much smaller ear canal. When using any in-the-ear transducer for ABR screening, such as insert earphones with eartips or an OAE probe, the sound level at the tympanic membrane in the infant is approximately 10 dB higher compared to the same stimulus delivered to an adult ear**.** The actual difference will vary with the intersubject variability in the ear canal size and placement of the eartip in the canal.

Screening protocols using a stimulus level of 25 dB rather than the typical 35 dB nHL are available to transfer to your device in the event that you are testing infants with an in-the-ear transducer and want to compensate for the increased effective intensity due to small ear canal size. In so doing, you will detect milder degrees of possible hearing loss but also will have a higher refer rate.

TEOAE STIMULUS

The IEC 60645-6 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 IEC 60645-3 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 GSI Novus 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 GSI Novus and the IEC 60645-3 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.

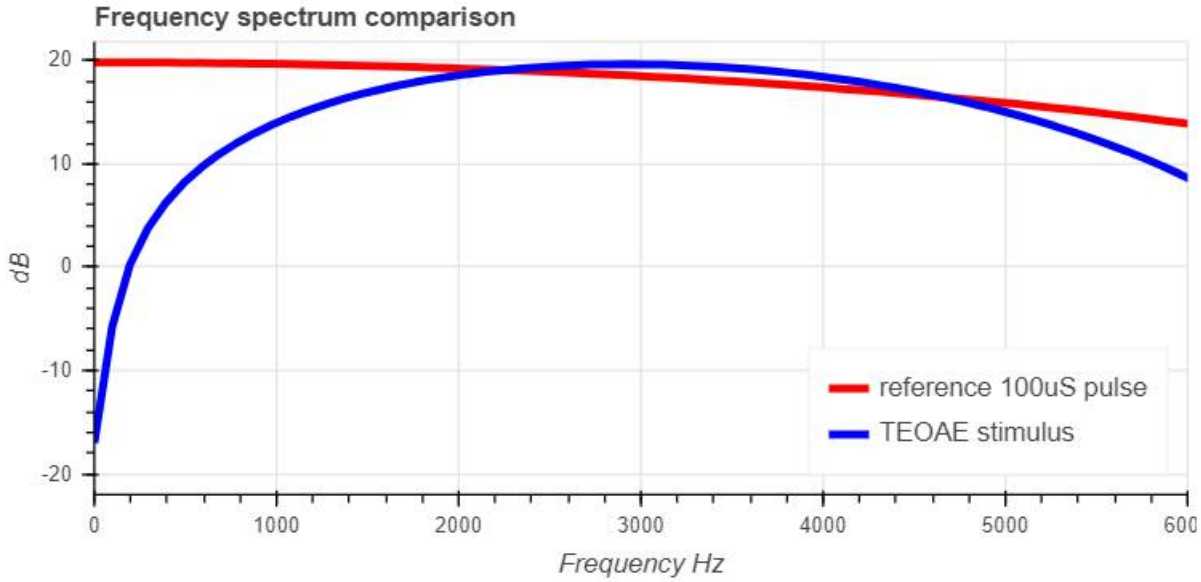
The comparison of the reference pulse and our bipolar optimised stimulus requires careful attention to the use of 'peak' and 'peak to peak' measurements since one is a unipolar signal and the other is bipolar. Although this is the case at the exact source of electrical generation, both signals will be 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 GSI Novus 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 GSI Novus 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.

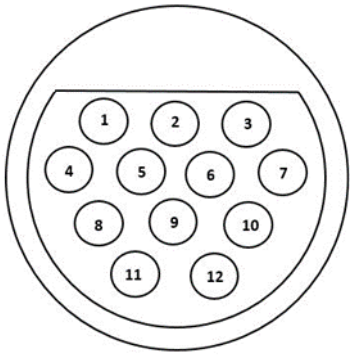


APPENDIX D: SPECIFICATION OF INPUT/OUTPUT CONNECTIONS

NOVUS ABR/OAE CONNECTOR FOR ABR PREAMPLIFIER

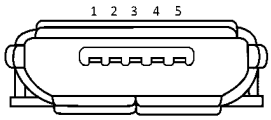
PREAMPLIFIER PROBE/TRANSDUCER CONNECTOR

Pin	Description
1	CH1 out
2	CH1 GND
3	DGND
4	GND A / GND Microphone
5	Microphone – input / Analog balanced in
6	Microphone + input / Analog balanced in
7	Power supply +3/+5V
8	CH2 out
9	CH2 GND
10	I2C CLK
11	I2C DATA
12	I2C Interrupt



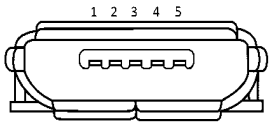
NOVUS MICRO USB CONNECTOR

Pin	Description
1	+ 5 V DC
2	Data
3	Data
4	ID
5	Ground



NOVUS CRADLE CONNECTOR

Pin	Description
1	VBUS from external host system
2	Ground connection – external supply
3	External power supply, 5V/1.5A DC
4	ID
5	Ground connection – external supply



APPENDIX E: AVAILABLE PROTOCOLS

If your NHS program requires different screening parameters than those supplied as the default protocols in Novus, additional protocols are available through the HearSIM™ application. You may choose the protocols in HearSIM and transfer them to your Novus. Instructions for reviewing the available protocols and transferring them to your Novus are found in the HearSIM™ Instructions for Use found on the HearSIM™ software USB.

Protocol name	**Parameters**	**Sensitivity**
ABR		
A00 CE-Chirp 35 dB nHL	CE-Chirp® stimulus of 35 dB nHL (default)	≥99.6%
A01 CE-Chirp 30 dB nHL	CE-Chirp® stimulus of 30 dB nHL	≥99.6%
A02 CE-Chirp 40 dB nHL	CE-Chirp® stimulus of 40 dB nHL	≥99.6%
A03 CE-Chirp 45 dB nHL	CE-Chirp® stimulus of 45 dB nHL	≥99.6%
A04 Click 35 dB nHL	Click stimulus of 35 dB nHL	≥99.6%
A05 Click 30 dB nHL	Click stimulus of 30 dB nHL	≥99.6%
A06 Click 40 dB nHL	Click stimulus of 40 dB nHL	≥99.6%
A07 Click 45 dB nHL	Click stimulus of 45 dB nHL	≥99.6%
DPOAE	**Parameters**	**Sensitivity**
D00 2-5 kHz, 3_4, SNR 6 dB	F2 Frequencies: 5k, 4k, 3k, 2kHz (default) Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s # Freq. for pass: 3 / 4 Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	≥99.6%
D01 1.5-4 kHz, 3_4, SNR 6 dB	F2 Frequencies: 4k, 3k, 2k, 1.5k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s Number Freq. for pass: 3 / 4 Pass criteria for each frequency:	≥99.6%

	Min OAE level: -5 dB SPL Min SNR: 6 dB Artifact rejection level: 30 dB SPL	
D02 1.5-6 kHz, 3_5, SNR 6 dB	F2 Frequencies: 6k, 4k, 3k, 2k, 1.5k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s Number Freq. for pass: 3 / 5 Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Max residual noise: -20 dB SPL	≥99.6%
D05 1.5-6 kHz, 3_6, SNR 7 dB	F2 Frequencies: 6k, 5k, 4k, 3k, 2k, 1.5k Hz Level (L1/L2): 65/55 dB SPL F2/F1 Ratio: 1.22 Max. test time: 60 s Number Freq. for pass: 3 / 6 Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 7 dB Artifact rejection level: 30 dB SPL	≥99.6%
TEOAE	**Parameters**	**Sensitivity**
T00 1.5-4 kHz, 3_4, SNR 4 dB	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz (default) Stimulus type: Click (non-linear) Level: 83 dB peSPL Max. test time: 60 s Number Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency band: Min SNR: 4 dB Band mandatory for Pass: None	≥99.6%
T01 1.5-4 kHz, 2_4 SNR 6 dB	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 83 dB peSPL Max. test time: 60 s Number Freq. for pass: 2 / 4 Min OAE level: 0 dB SPL Pass criteria for each frequency band: Min SNR: 6 dB Band mandatory for Pass: None	≥99.6%
T02 1.5-4 kHz, 3_4, 80 dB SPL	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 80 dB peSPL	≥99.6%

	Max. test time: 60 s Number Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency: Min SNR: 4 dB Band mandatory for Pass: None	

IEC 60645-6 PROTOCOLS

The following table lists the IEC 60645-6 compliant OAE protocols that are available. These OAE protocol are compliant with the IEC standard. Refer to the detailed explanation provided on PDF file contained in the "IEC protocols" folder on the HearSIM software USB.

Protocol name	Parameters	Sensitivity
DPOAE		
D03 2-5 kHz, 65_55 dB SPL, IEC	F2 Frequencies: 5k, 4k, 3k, 2kHz Level (L1/L2): 65/55 dB SPL F2/F1 ratio: 1.22 Max. test time: 60 s Number Freq. for pass: 3 / 4 Mic correction: disabled to comply with standard Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Max residual noise: -20 dB SPL	NA
D04 2-5 kHz, 60_50 dB SPL, IEC	F2 Frequencies: 5k, 4k, 3k, 2kHz (same as default) Level (L1/L2): 60/50 dB SPL F2/F1 ratio: 1.22 Max. test time: 60 s Number Freq. for pass: 3 / 4 Mic correction: disabled to comply with standard Pass criteria for each frequency: Min OAE level: -5 dB SPL Min SNR: 6 dB Max residual noise: -20 dB SPL	NA

TEOAE	Parameters	Sensitivity
T03 1.5-4 kHz, 60 dB SPL, IEC	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 60 dB peSPL Max. test time: 60 s Number Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency: Min SNR: 4 dB Band mandatory for Pass: None	NA
T04 1.5-4 kHz, 70 dB SPL, IEC	Center Frequencies: 1.4k, 2k, 2.8k, 4k Hz Stimulus type: Click (non-linear) Level: 70 dB peSPL Max. test time: 60 s Number Freq. for pass: 3 / 4 Min OAE level: -5 dB SPL Pass criteria for each frequency: Min SNR: 4 dB Band mandatory for Pass: None	NA

APPENDIX F - WARRANTY AND REPAIR

We, Grason-Stadler, warrant that this product is free from defects in material and workmanship and, when properly installed and used, will perform in accordance with applicable specifications. This warranty is extended to the original purchaser of the instrument by GSI through the distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser. If within one year after original shipment, it is found not to meet this standard; it will be repaired, or at our option, replaced at no charge except for transportation costs, when returned to an authorized Grason-Stadler facility. If field service is requested, there will be no charge for labor or material; however, there will be a charge for travel expense at the service center's current rate.

NOTE: Opening the instrument case or changes to the product not approved in writing by Grason-Stadler shall void this warranty. Grason-Stadler shall not be responsible for any indirect, special or consequential damages, even if notice has been given in advance of the possibility of such damages. The transducers may go out of calibration due to rough handling or impact (dropping). The lifetime of probe, probe seals and eartips is dependent upon conditions of use. These parts are only guaranteed against faulty materials or manufacture.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

We advise you against attempting to rectify any faults by yourself or commissioning non-experts to do so. 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 GSI representative. Modification of the equipment could be hazardous. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

To ensure that your instrument works properly, the GSI Novus should be checked and calibrated at least once per year. This check must be carried out by your dealer or authorized GSI service facility.

When returning the instrument for repairs or calibration it is essential to send the acoustic transducers with the device. Send the device to an authorized service center only. Please include a detailed description of faults. To prevent damage in transit, please use the original packing if possible when returning the instrument.

APPENDIX G - RECYCLING / DISPOSAL

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment and related waste including batteries, printed circuit boards, electronic components, wiring and other elements of electronic devices. Follow all local laws and regulations for the proper disposal of batteries and any other parts of this system.

Below is the contact address for proper return or disposal of electronic wastes relating to Grason-Stadler products in Europe and other localities. The contact information for the WEEE in Europe:

Grason-Stadler
c/o DGS Diagnostics A/S
Audiometer Alle 1
5500 Middelfart
Denmark

APPENDIX H: ELECTROMAGNETIC COMPATIBILITY (EMC)

Portable and mobile RF communications equipment can affect the Novus. Install and operate the Novus according to the EMC information presented in this chapter.

The Novus has been tested for EMC emissions and immunity as a stand-alone device. Do not use the Novus adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, except for servicing parts sold by GSI as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

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

CAUTIONS REGARDING EMC

This instrument is suitable in hospital 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.

Essential performance for this instrument is defined by the manufacturer as:

To generate and present stimulus signals in the audio range as specified in the applicable IEC 60645 series or ANSI standards in normal condition.

Absence of these performance features can lead to failure in diagnosis.

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

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 instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The GSI Novus is intended for use in the electromagnetic environment specified below. The customer or the user of the Instrument should assure that it is used in such an environment.

GUIDANCE AND MANUFACTURER'S DECLARATION
ELECTROMAGNETIC EMISSIONS

Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Novus 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 Novus is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT

The Novus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Novus can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Novus 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 Outside ISM bands $d = [3.5/V_1]\sqrt{P}$	**150 kHz to 80 MHz (ISM bands)** $d=[12/V_2]\sqrt{P}$	**80 MHz to 800 MHz** $d = [12/E_1]\sqrt{P}$	**800 MHz to 2.7 GHz** $d = [23/E_1]\sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.37	0.63	0.38	0.73
1	1.17	2.00	1.20	2.30
10	3.69	6.32	3.79	7.27
100	11.67	20.00	12.00	23.00

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 transmitters, 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

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	Not applicable ±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	Not applicable	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	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the *Novus* requires continued operation during power mains interruptions, it is recommended that the *Novus* be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 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.			

Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the Novus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = [3.5/V1]√P (150 kHz to 80 MHz) d=[12/V2]√P (ISM 150 kHz to 80 MHz) Radiated RF d = [12/E1]√P 80 MHz to 800 MHz d = [23/E1]√P 800 MHz to 2.7 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: 
NOTE 1 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 Novus is used exceeds the applicable RF compliance level above, the Novus should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Novus.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

NOTICE: All necessary instruction for maintaining compliance regarding EMC can be found in the general maintenance section in this instruction. No further steps required.

Use of accessories, transducers 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. To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

Item	Manufacturer	Item #
Novus Preamplifier	Grason-Stadler	8517514
SnapPROBE™	Grason-Stadler	8522679
IP30 insert earphone (50 Ohm) EarTip	RadioEar	8503722
IP30 insert earphone (50 Ohm) EarCup	RadioEar	8503723

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	Screened/Unscreened
Novus Preamplifier	1 m	partial
SnapPROBE™	1.20 m	partial
IP30 insert earphone (50 Ohm)	0.25 m	screened
Power supply	1.5 m	unscreened
Electrode cable	0.5 m	unscreened

NOTICE: 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.

Test Specifications for Enclosure Port Immunity to RF wireless communications equipment						
Test frequency (MHz)	**Band a (MHz)**	**Service a**	**Modulation b**	**Maximum power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 –390	TETRA 400	Pulse modulation b	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM c ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b 217 Hz	0.2	0.3	9
810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,	Pulse modulation b 18 Hz	2	0.3	28
1 720 1 845 1 970	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25;	Pulse modulation b 217 Hz	2	0.3	28
2 450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b 217 Hz	2	0.3	28
5 240 5 500 5 785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation b 217 Hz	0.2	0.3	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.