



GSI NOVUS™

AABR/OAE SCREENER



Setting The Clinical Standard



novus™

AABR/OAE Screener

The GSI Novus™ is a sleek, hand-held, comprehensive newborn hearing screening instrument. The Novus features a touch screen display and intuitive software in a compact hardware design. The Novus may be configured with any combination of AABR, TEOAE, and DPOAE which allows for seamless two stage infant screening.



Objective and Accurate

Automated Auditory Brainstem Response (AABR) testing has never been easier. The Novus uses a fast rate ABR algorithm with the CE-Chirp stimulus. Paired with a powerful response detection algorithm, the Novus quickly assigns a pass or refer result. Distortion Product Otoacoustic Emissions (DPOAE) and Transient Evoked Otoacoustic Emissions (TEOAE) protocols provide the flexibility required for efficiency in newborn screening. OAE testing will automatically stop as soon as the pass criteria is met ensuring fast test times.

Features

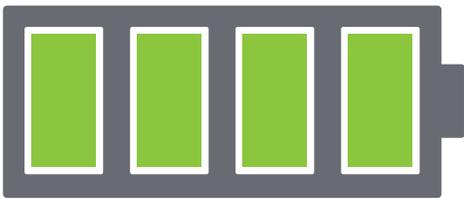
- Combined AABR and OAE in a single handheld unit
- Binaural simultaneous AABR testing option
- Stores up to 250 patients with up to 50 tests per patient
- Wireless charging
- Customized carrying case
- Flexible risk factor management
- Optional screener security
- HearSIM Data Management Software
- Compatible with tracking systems such as Hi-Track

Quick Test

It is possible to perform a screening evaluation without entering patient information by using the Quick Test option. This is ideal for sites that are testing and immediately printing or recording the results into the patient record. After testing, it is possible to assign patient information to a Quick Test for transfer to the HearSIM data management software.



50 ABR



150 OAE
Screens

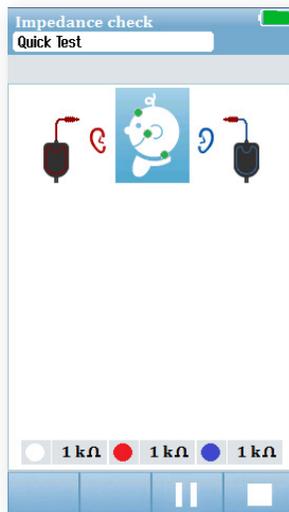


The Novus can handle a heavy test workload. A fully charged Novus will last for approximately 50 ABR screens and 150 OAE screens depending on test times. The Novus allows for testing when in the charging cradle for times when the battery is low, ensuring no missed screenings.

AABR Testing

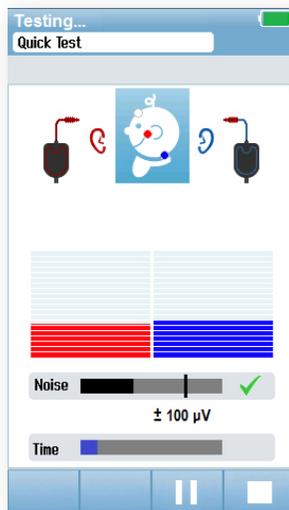
Patient Preparation

The Novus guides the user through every step of the screening process. When AABR is selected, an icon indicates which calibrated transducer is attached. After the patient is prepped, the Novus will perform an impedance check to ensure optimal testing. When impedances are within acceptable limits, the AABR test will begin automatically.



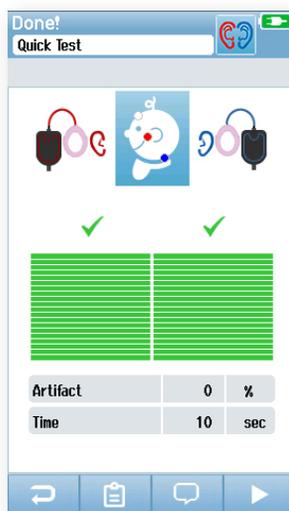
Optimized Testing

The Novus displays a number of visual indicators to allow the screener to monitor test progress. The bar graph displays progress up toward a "Pass" while the noise bar monitors interference from electric or biologic sources. The time bar tracks the test time. It is possible to pause or abort the test at any time.

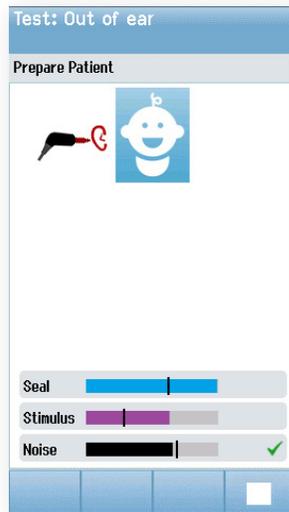


Results

When the test is completed, a passing result will be indicated with a green check mark. An amber X indicates a refer result. Other benchmarks such as test time and artifact will be displayed.

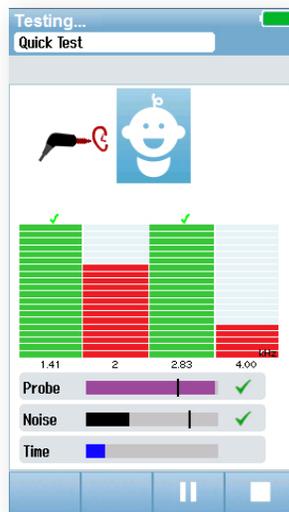


OAE Testing



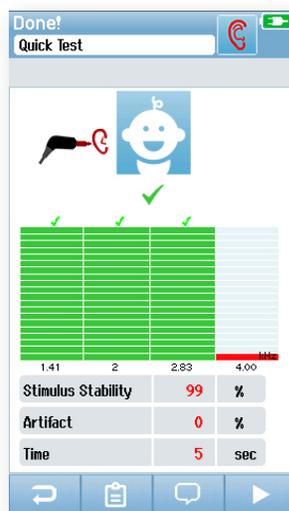
Probe Check

When the probe has been placed in the ear, a single screen press will initiate the testing process. Before the test begins, the Novus will perform a probe check to ensure proper seal in the ear. Visual representations of seal, stimulus level and noise level are displayed on the screen. If levels are not within acceptable limits, the screener has the opportunity to modify the patient setup or environment.



Fast Testing

The Novus displays visual indicators to help monitor test progress. The bar graph displays progress up toward a "Pass" at each frequency in both DP and TE modes. As soon as the pass criteria is met, the test will conclude.



Results

A green check mark indicates a passing result. An amber X indicates a refer result. Additional information such as artifact and test time will be displayed.

CE-Chirp®

Wave V

Ideal Stimulus for Newborn Screening

The Novus uses the CE-Chirp® stimulus and a fast rate ABR algorithm for newborn hearing screening. The CE-Chirp has been proven to produce Wave V responses that are 1.5 to 2 times larger than traditional ABR testing which makes CE-Chirp ideal for ABR. With larger responses, test times are reduced and more babies may be screened every day.

Test Both Ears at the Same Time

The GSI Novus offers two methods for simultaneous testing of ABR when using IP30 insert phones with ear tips or Ear Cups. The Novus differentiates ears by using alternative stimulation rates. Testing both ears at the same time offers significant time saving benefits.



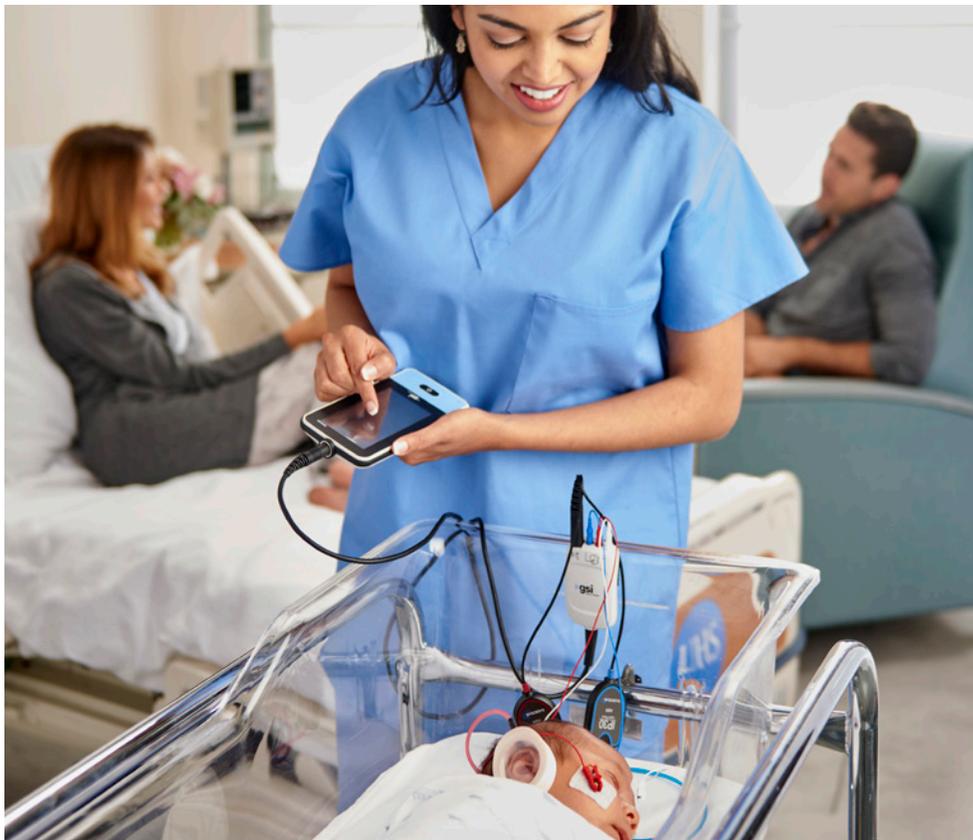
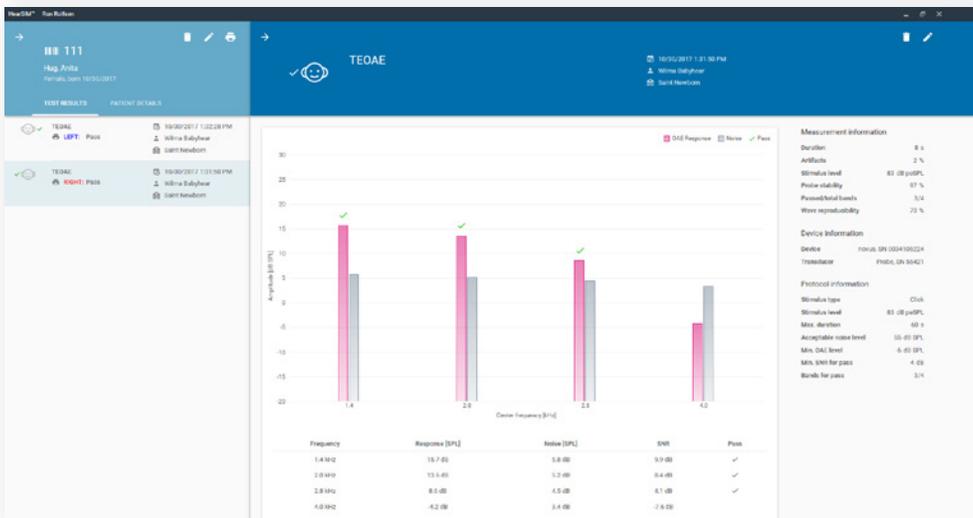
HearSIM™

HearSIM™ Patients

Displaying 8 of 8 patients

ALL EAR(S) DID NOT PASS EAR(S) NOT TESTED FLAGGED

Name	Patient id	Birthdate	Last update	TEOAE	DPOAE	ABR	Flagged
Rodriguez, Camilla	88456	♀ 3/8/2017	3/23/2017	✓	⊖	⊖	
O'Toole, Joseph	887456	♂ 3/14/2017	3/23/2017	✓	⊖	⊖	
Murphy, Baby	88756	♀ 3/1/2017	3/23/2017	✓	⊖	⊖	
Thompson, Hannah	77645	♀ 3/20/2017	3/23/2017	✓	⊖	⊖	
Pawl, John	55669	♂ 3/23/2017	3/23/2017	✓	⊖	⊖	
Anderson, Baby	8744	♂ 3/21/2017	3/23/2017	✓	⊖	⊖	
Johnson, Phillip	2324	♂ 3/22/2017	3/23/2017	✓	⊖	⊖	
Jones, Jessica	1234	♀ 3/14/2017	3/23/2017	✓	⊖	⊖	



HearSIM data management software offers everything you need to manage your newborn hearing screening program. Load patient names into the Novus or quickly determine which patients need additional testing with the intuitive database view. In addition to viewing, storing and printing test results, it is possible to export data to Hi-Track or save in other formats such as XML. Device settings such as screener names, security, and risk factors may be configured from HearSIM.



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Technical Specifications

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.

General Specifications

Environmental Conditions:

- › + 15 °C... + 35 °C / + 59 °F... + 95 °F (operation)
- › - 20 °C... + 50 °C / - 4 °F... + 122 °F (transport and storage)
- › Maximum humidity 90 % (operation, non-condensing)
- › Maximum humidity 95 % (storage, non-condensing)

Weight: 265 grams (with battery)

Dimensions: 158 mm x 83 mm x 19mm

Display: 95 mm x 56 mm, color, 272 x 480 resolution

User Interface: Resistive touch screen

User Feedback: Integrated speaker

Language Settings: English, default. (15 options)

Memory: 1GB

Data Interfaces: USB, Bluetooth®

Boot Up Time: <5 sec

Battery: Li-ion battery 44794; Capacity: 3.7V/3850 mAh

Warm Up Time: No warm-up time necessary after boot

Instrument Specifications – AABR

Test Signals: CE-Chirp®

Stimulus Rate: 88/sec left ear, 92.5/sec right ear

Stimulus Level: 35 dB nHL (default protocol)

Data Collection: 22 kHz sample rate, 24 bit

Preamplifier

EEG Filter: 0.5 Hz – 5.0 kHz

Gain: 72 dB

CMRR: >100 dB at 100Hz

Sample Rate: 22.05 kHz

Instrument Specification – OAE

DPOAE

Stimulus Frequencies: 2000, 3000, 4000, 5000 Hz

Stimulus Frequency Range: 1500-6000 Hz

Nominal Frequency, F2/F1 Ratio: F2, 1.22

Level L1/L2: 65/55 dB SPL

TEOAE

Stimulus Type: Non-Linear Click (according to IEC 60645-3)

Stimulus Frequency Range: 1000 – 4000 Hz

Stimulus Level: 83 dB peSPL, peak to peak calibrated, AGC controlled

Cradle

ELECTRICAL ISOLATION

DC Power In: 5V/1.6A

Power Supply: AC 100 – 240 V, ~ 50/60 Hz, 400mA

Transducers

Radioear IP30 Insert Earphones

Probe for OAE and AABR testing

Printer (optional)

Type: Thermal

Connection: Bluetooth®

Battery: Lithium Ion, DC 7.4V, 1500 mAh

Charger: AC 100-250V, ~ 50/60 Hz, 1.0 A

Weight: 360 g / 12.7 oz

Paper: Thermal paper or labels

Standards Compliance

Standards:

- › IEC 60601-1, Class II, Type BF
- › IEC 60601-1-2
- › IEC 60601-2-40
- › ISO 389-2
- › ISO 389-6
- › IEC 60645-3
- › IEC 60645-6 (2009), Type 2
- › IEC 60645-7, Type 2