



NEWBORN AABR/OAE SCREENER



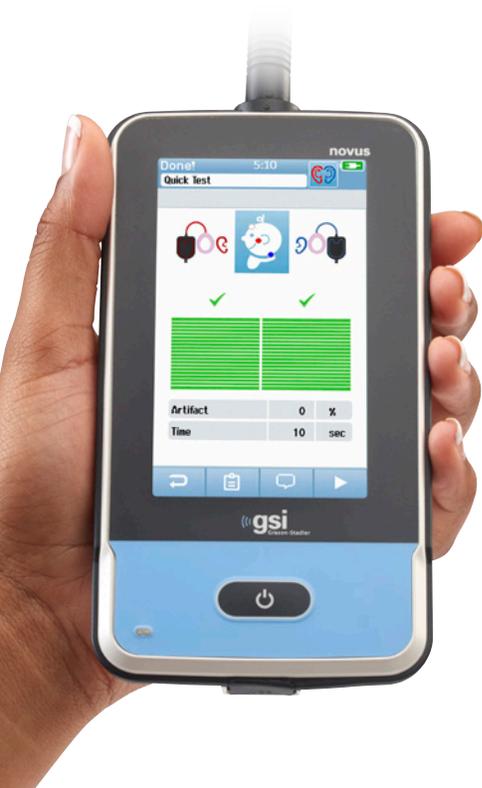
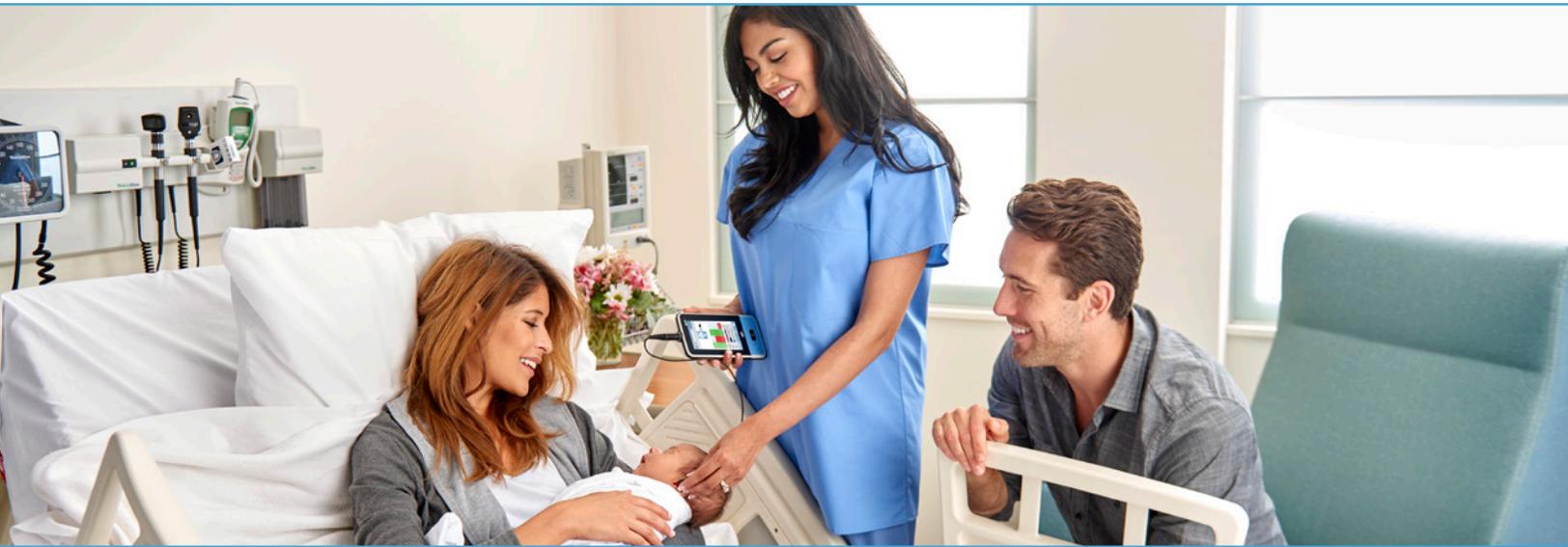
— NOVUS —

AABR TESTING

HAS NEVER BEEN EASIER

GSI NOVUS OBJECTIVE AND ACCURATE

The GSI Novus™ is a sleek, handheld, 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.

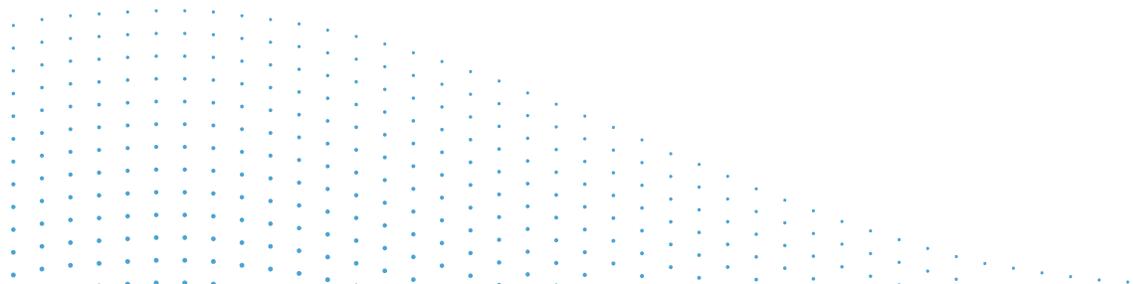


MANAGE YOUR DATA WITH HEARSIM

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 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.

TEST BOTH EARS AT THE SAME TIME

The Novus offers two methods for simultaneous testing of AABR by using IP30 insert phones with ear tips or ear cups. Testing both ears at the same time offers significant time saving benefits.



KEY DEVICE FEATURES

COMBINED AABR/OAE TESTING

The Novus can combine AABR and OAE capabilities into one device. Reduce training time and screen infants in well-baby and NICU nurseries with one device.

CE-CHIRP STIMULI FOR ABR

CE-Chirp ABR responses are twice as large as the traditional click stimulus. Larger responses result in faster test times.

QUICK TEST OPTION

Perform a test without entering demographic information. This is ideal when training new staff.

AUTOMATED PASS/REFER

Save time with automatic results as soon as pass/refer criteria are met. The Novus is optimized for the infant ear.

TOUCH SCREEN DISPLAY

Screening staff feels an instant comfort with the intuitive touch screen display and can navigate seamlessly through the testing screens.

WIRELESS CHARGING

A wireless charging dock is included with the Novus. Screening tests can be completed any time the battery is low and is placed on the dock. A fully charged Novus can last for approximately 50 ABR screens or 150 OAE screens.



3 KEY

BENEFITS



PORTABLE DESIGN

Compact design allows the Novus to be easily transported to the infant's bedside. The Novus is the perfect solution for a busy hospital that needs a screener that is reliable, maneuverable, and fast.



DEPENDABLE TESTING

The Novus is designed to withstand the constant, intense nature of hospital screening and is a device that you can rely on day in and day out.



EASY TO USE

The Novus has a straight forward and logical interface which hospital screeners can learn quickly and with confidence.

NEWBORN AABR/OAE SCREENER

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.

DIMENSIONS AND WEIGHT

W x D x H: 3.3 in x 6.2 in x 0.8 in (15.8 cm x 8.3 cm x 1.9 cm)

Display: 272 x 480 px / color

Weight: 0.6 lb (265 g)

GENERAL SPECIFICATIONS

User Interface: Resistive touch screen

User Feedback: Integrated speaker

Language Settings: English, default (15 options)

Memory: 1GB

Data Interfaces: USB, Bluetooth®

Start 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

INSTRUMENT SPECIFICATIONS – 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: 0.8 lb (360 g)

Paper: Thermal paper or labels (0.79 lb, 358 g)

ENVIRONMENTAL

Temperature and Humidity/Operating Range:

- **Operating:** +59° F (15° C) to +95° F (35° C)
- **Transport and Storage:** -4° F (-20° C) to +122° F (50° C)
- **Maximum Humidity:** 90% (operation, non-condensing)
- **Maximum Humidity:** 95% (storage, non-condensing)

QUALITY SYSTEM

Manufactured, designed, developed and marketed under ISO 13485 certified quality systems.

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, Type 2
- IEC 60645-7, Type 2