



# 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.

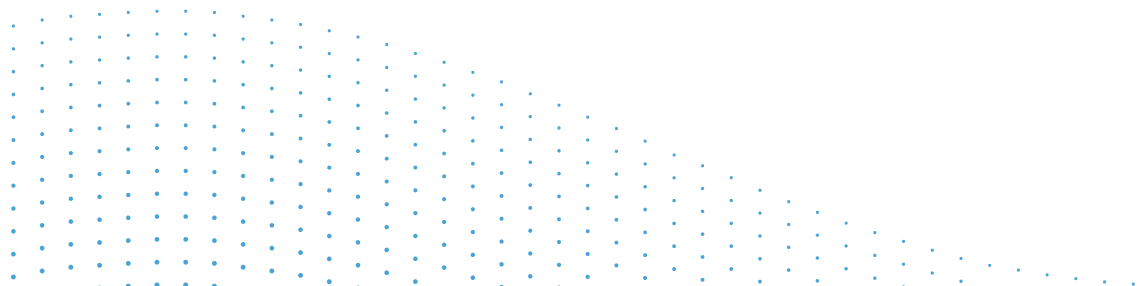


## MANAGE YOUR DATA WITH HEARSIM

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 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.

## **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 straightforward and logical interface which hospital screeners can learn quickly and with confidence.

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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.

### 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