novus™

AABR/OAE Screener

New Combination AABR/OAE Screener

The new GSI Novus™ is a hand-held comprehensive newborn hearing screening instrument. The Novus features a touch screen display and user-friendly software in a compact hardware design. Novus may be configured with AABR, OAE or both which allows for seamless two stage infant screening.

Product Features

- Combined AABR and OAE into one
- Touch screen display
- Customized risk factor management
- Compatible with tracking systems such as Hi-Track
- Wireless charging
- Data management software

AABR

The Novus uses fast rate Automated Auditory Brainstem Response (AABR) technology for newborn screening. A powerful response detection algorithm will quickly assign a pass or refer result.

OAE

Distortion Product (DPOAE) and Transient Otoacoustic Emissions (TEOAE) protocols assess the stimulus integrity and noise levels providing visual feedback to the screener through every step of the screening test.

Data Management

HearSIM™ software is a dynamic tool that has everything you need to manage your newborn hearing screening program. Store, view and print test results. Export patient and testing information. Customize the Novus settings including screener names, risk factors and device security.

Setting The Clinical Standard **www.grason-stadler.com**

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GSI NOVUS™

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.

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 x19mm
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

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