

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