

## Intended Use

Integrity™ V500 System is intended to aid in detecting hearing loss and lesions in the auditory pathway. It is a prescription device with labelling, instructions and user operations designed for trained professionals.

## System Summary

Main Hardware Components:

**Computer Interface** Portable laptop with Windows 7/10 64-bit and Integrity V500 software.

**VivoLink™** Wireless interface module

**Amplitude® and** A81 1-channel in-situ differential bio-amplifier

**VivoAmp™** A82 2-channel in-situ differential bio-amplifier

A90 1 and 2-channel differential bio-amplifier

**AEP Transducers** ER-3A-800 insert earphones

ER-3C-800 insert earphones

ER-2-800 insert earphones

B71W bone-conductor

H-800/H-801 EP Headphones

**OAE Probes** P81-GP custom probe for general use

P81-UG smaller probe suitable for newborns, infants

Software Modules:

**ABR** B Auditory Brainstem Response

**ABR Screening** X Auditory Brainstem Response Screening

**ASSR** A Auditory Steady-State Response

**DPOAE** D Distortion Product Otoacoustic Emissions

**ECochG** C Electrocochleography

**TEOAE** T Transient Evoked Otoacoustic Emissions

**40 Hz ERP** F 40 Hertz Event-Related Potential

Output from Software (reports):

Customizable PDF, file export

## Test Module Specifications

### ABR – diagnostic & threshold estimation

Stimulation: Air-conduction (AC), Bone-conduction (BC)

Stimuli: Click 100 µs, Toneburst 0.5, 1, 2, 3, 4 kHz, Broadband chirp

Calibration: AC: dB pe SPL, dB nHL

BC: dB pe FL, dB nHL

Toneburst windowing: Blackman, Rectangular, Linear

Stimulus intensity: Click: 0-99 dB nHL

Toneburst: 0.5 kHz: 0-105, 1 kHz: 0-104, 2 kHz: 0-99,

3 kHz: 0-97, 4 kHz: 0-95 dB nHL

Chirp: 0-111 dB nHL

Stimulus rate: 1.0 to 99.0 per second with 0.1/s step

Stimulus polarity: Condensation (C), Rarefaction (R), Alternating (C & R averaged), Alternating Split (C & R displayed separately)

Recording traces: Average (A+B), buffers A & B and difference (A-B)

Recording window: From 0 to 120 ms

Digital filters: Adjustable, High-pass 30-300 Hz, Low-pass: 300-3000 Hz

Measured variables: Real-time Wave: I, II, III, IV, V latencies

Interpeak intervals: I-III, III-V, I-V

Amplitudes: Wave I & V, V/I amplitude ratio

Latency-specific Correlation Coefficient

Latency norms: Newborn to adults

Masking: White noise, 0-90 dB HL

### ABR Screening – automated screening

Stimulation: Air-conduction (AC)

Stimuli: 30 or 35 dB nHL click 100 µs

ABR detection: Automated

Report: Pass / Refer

### ASSR – threshold estimation

Stimulation: Air-conduction (AC)

Stimulus frequencies: 0.5, 1, 2, 4 kHz

Set up to 4 simultaneous frequencies per ear.

Stimulus intensity: 0 to 95 dB nHL

Set maximum, minimum and initial levels.

Modulation frequency rates: 40 Hz and 80 Hz families

Modulation type: Modified chirp

Threshold search method: Automated method using two user-definable search resolution steps. Users can monitor and adjust settings.

Maximum search time: User-definable

ASSR detection: Automated

Conversion factors: User-definable conversion from ASSR to behavioral

Report: Estimated audiogram, ASSR gram

### DPOAE – diagnostic & automated screening

Stimuli: f2 frequencies: 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.2, 3.5, 4, 4.5, 5,

5.5, 6, 7, 8 kHz

levels: 40-75 dB SPL

f2/f1 ratio: 1.2 & 1.22 (f2 > f1)

System noise & <math>\leq 10</math> dB SPL at 75/75 dB SPL stimulus

system DP:

Measured variables: Signal, noise, SNR at f2 frequencies

Pass-refer criteria: Multiple, flexible, user-selectable

### ECochG – diagnostic

Stimulation: Air-conduction (AC)

Stimuli: Click 100 µs, 0-99 dB nHL

Recording: Gold-foiled ABR electrode (TipTrod™)

Measured variables: Baseline, SP & AP latencies & amplitudes, SP/AP amplitude ratio

### TEOAE – diagnostic & automated screening

Stimuli: Click 80, 120 µs, 60-85 dB pe SPL, linear, non-linear

Measured variables: Signal, noise, SNR in 1-kHz, 1, 1/2, 1/4, 1/6-oct bands

Pass-refer criteria: Multiple, flexible, user-selectable

### 40 Hz ERP – threshold estimation

Stimulation: Air-conduction (AC) and Supra-aural headphones

Stimuli: 0-105 dB nHL, Chirp stimuli with center frequency

0.5, 1, 2, 4 kHz

Recording traces: Average (A+B), buffers A & B & difference (A-B)

Recording window: 125 ms

Measured variable: interpeak latency (ms)

## Hardware Specifications

### Computer

iSeries laptop with built-in Bluetooth® adapter, minimum 3 USB ports, 1366x768 resolution; or equivalent.

### VivoLink™

Sampling rate: 38,400 samples per second (sps)

A/D & D/A resolution: 24 bit

Built-in: 4 snaps for parking Amplitude, power switch, 3 LED

indicators for power level, impedance match and wireless ON

Software notch filters: 50 Hz, 60 Hz, or switched OFF

Patient isolation: Radio-frequency, spread-spectrum wireless

RF transmission: hopping, 2,402 to 2,480 MHz, emitted power < 3 dBm,

connection range 30 feet (10 meters)

Dimensions: L 7.1" (18cm) x W 3.6" (9.1cm) x H 1.2" (3.2cm)

Weight: 0.8 lb (363g) with battery pack

Batteries: Vivosonic rechargeable battery pack

### Amplitude® and VivoAmp™

Nominal gain: 7,600

Frequency band: 30-3000 Hz

Input impedance: 1.5 MΩ at 60Hz

Noise level: 15 nV/root (Hz) at 100 Hz

Common mode rejection ratio: >120 dB at 60 & 50 Hz (>130 dB typical)

Electrodes: Snap type, Neuroline 72000-S, NeuroPlus Electrode A10040,

NeuroPlus Electrode A10041, VivoTab™ (ABR Screening

### OAE Probe Options

P81-GP probe: General use. 2 microphones, 2 receivers. No detachable

parts. Easy to clean with mini-brush and disinfecting wipes.

P81-UG probe: General use and suitable for newborns and infants.

1 microphone, 2 receivers, test cavity.

### Warranty

One year warranty on system and 120-day warranty on battery packs.

### Quality System

Meets the requirements of ISO 13485, FDA 21 CFR Part 820, Medical Devices

Directive 93/42/EEC (CE marking approval).

### Regulatory Compliance

**Canada:** Health Canada Medical Device Licence 67609.

TÜV SÜD 81763. Industry Canada ID 1520A-LMX9838.

CE Registration DE/CA09/0170/1207Å1 to 1212Å1, 3157

ETSI EN 300 328 V1.8.1.

**United States:** FDA 510(k) K043396. TÜV SÜD 81763. FCC Part 15, FCC

ID ED9LMX9838.

**Other countries:** Please enquire.

### Configurations

**Full-featured** Laptop computer, VivoLink, A90, ER-3C-800, B71W, ER3-60

**Integrity** electrode eartip cable with connector, tip adapters, battery

**ABR/ECochG:** pack charging kit, carrying case, shoulder straps, starter kit of

disposables and consumables, Integrity V500 ABR/ECochG

software, Integrity V500 User's Manual (PDF), Integrity V500

Quick Reference.

Optional: ABR Screening module, ASSR module,

DPOAE/TEOAE module with OAE Probe and test cavity, 40

Hz ERP, ER-2-800, H-800/H-801 EP Headphones, and

printer.