

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 7/8 64-bit and Integrity V500 software.
VivoLink™	Wireless interface module
Amplitrode®	A61 electrode-mounted in-situ differential bio-amplifier
AEP Transducers	ER-3A insert earphones (included with ABR) B-71 bone-conductor (included with ABR)
OAE Probes	P40-GP custom probe for general use (option) P40-UG smaller probe suitable for newborns, infants (option)

Software Modules:

ABR	B	Auditory Brainstem Response
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), and Supra-aural headphones
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

ASSR – threshold estimation

Stimulation:	Air-conduction (AC) and Supra-aural headphones
Stimulus frequencies:	0.5, 1, 2, 4 kHz
Stimulus intensity:	Set up to 4 simultaneous frequencies per ear. 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 & system DP:	≤-10 dB SPL at 75/75 dB SPL stimulus
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 (TipTrode™)
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

Dual-core laptop with built-in Bluetooth® adapter, minimum 3 USB ports, 15" color, 1366x768 resolution; or equivalent.

VivoLink™

Sampling rate: 38,400 samples per second (sps) for windows <30ms
A/D & D/A resolution: 24 bit
Built-in: 3 snaps for parking Amplitrode, power switch, 3 LED indicators for power ON, impedance match and wireless ON

Software notch filters:

50 Hz, 60 Hz, or switched OFF
Patient isolation: Radio-frequency, spread-spectrum wireless hopping, 2.402 to 2.480 MHz, emitted power < 3 dBm, connection range 30 feet (10 meters)
RF transmission: L 7.1" (18cm) x W 3.6" (9.1cm) x H 1.2" (3.2cm)
0.8 lb (363g) with battery pack
Vivosonic rechargeable battery pack

Dimensions:

Weight: 0.8 lb (363g) with battery pack
Batteries: Vivosonic rechargeable battery pack

Amplitrode®

Nominal gain: 7,500
Frequency band: 30-3000 Hz
Input impedance: 1.5 MΩ at 60Hz
Noise level: 8 nV/root (Hz) at 100 Hz
Common mode rejection ratio: >120 dB at 60 & 50 Hz (>135 dB typical)
Electrodes: Snap type, Neuroline 720-00-S, NeuroPlus Electrode A10041-60

OAE Probe Options

P40-GP probe: General use. 2 microphones, 2 receivers. No detachable parts. Easy to clean with mini-brush and disinfecting wipes.
P40-UG probe: General use and suitable for newborns and infants. 1 microphone, 2 receivers, test cavity.

Warranty

One year warranty on most new parts and labor (excluding mishandling or misuse).
Amplitrode - 180 days. Battery packs – 120 days.

Quality System

Meets the requirements of ISO 13485, FDA 21 CFR Part 820, Medical Devices Directive 93/42/EEC (CE marking approval).

Regulatory Compliance

Brazil:	ANVISA, INMETRO, ANATEL.
Canada:	Health Canada Medical Device Licence 67609. ETL Listed 3087966. Industry Canada IC 6273A-V50.
China:	CFDA
European Union:	CE Registration DE/CA09/0170/1207A1 to 1212A1, 3157 ETSI EN 300 328 V1.8.1. Ministry of Health, Labour and Welfare.
Japan:	KFDA, KCC
Korea:	COFEPRIS
Mexico:	FDA 510(k) K043396. ETL Listed 3087966. FCC Part 15, FCC ID TVZ-V50.
United States:	Please enquire.

Other countries:

Configurations

Full-featured Integrity ABR/ECochG: Laptop computer, VivoLink, A61, ER-3A, B-71, ER3-28V electrode eartip cable with connector, tip adapters, battery pack charging kit, carrying case, shoulder straps, starter kit of disposables and consumables, calibration CD-ROM, Integrity V500 ABR/ECochG software, Integrity V500 User's Manual (PDF), Integrity V500 Quick Reference. Optional: printer

Optional: ASSR module, DPOAE/TEOAE module with OAE Probe and test cavity, 40 Hz ERP, supra-aural headphones.