

Integrity™ V500 Data Sheet



Freedom

- from sedation
- from interferences
- of mobility
- in Audiology

Product Overview

Integrity™

Vivosonic Integrity™ V500 is the world's only Wireless System for Auditory Electrophysiological Assessment and Hearing Screening. Constellation of new patented technologies makes clear ABR results attainable in virtually any patient of any age, and virtually any environment. These award-winning technologies include: in-situ amplification with the patented Amplitrode®, wireless communication with the VivoLink™, and digital Kalman-weighted filtering.

Amplitrode®

Amplitrode® is the world's only patented in-situ bio-amplifier mounted directly on the electrode. In-situ amplification, i.e. "at the source," reduces electric, magnetic, and RF field-induced noises. The result is a clean EEG signal in virtually any environment, including NICU, ICU, OR, doctors' offices. To provide comfort and safety, Amplitrode® and its Clips have springs and release buttons for easy mounting and dismounting from the snap electrodes.

VivoLink™

VivoLink™ is the world's only wireless platform for Auditory Electrophysiological Assessment and Screening. It is battery-powered and controlled from a remote computer via wireless communication. Built-in microprocessor generates stimuli and analyzes responses. To ensure precision of stimuli generation and signal acquisition, VivoLink™ employs very high A/D and D/A

resolution and sampling rates. VivoLink™ is very convenient and comfortable to use with newborns, infants, young children, and adults. It can be secured on the adult's chest with a lanyard; placed next to the baby in a crib, car seat, or stroller; worn by the baby's caregiver; secured to the bed or incubator in the NICU; or conveniently placed in a toddler's toy back-pack. Mobility makes testing comfortable and easy for both the patient and the clinician.

Kalman-weighted Filtering

Vivosonic's patented algorithms (Kalman Filtering) optimize digital signal processing to dramatically reduce artifacts coming from muscular and ocular electrical activity, yielding clear responses in virtually any patient. It is ideal for testing non-sedated, non-sleeping, non-relaxed, and even active patients like feeding infants and playing children.

Clinical benefits

Integrity™ obviates sedation, with the associated risks and costs. Integrity™ makes it possible to test patients who are not candidates for sedation and to provide them with the care they need. This way, Integrity™ sets a new standard of patient care.



Award-winning technology

integrity™
Freedom in Audiology

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Specifications

Intended use

Integrity™ V500 is indicated for auditory evoked response testing as an aid in detecting hearing loss and lesions in the auditory pathway. Integrity™ V500 is a prescription device. The labeling, instructions and user operations are designed for trained professionals.

System

Portable PC-based, consisting of hardware and computer software, and configured in a carrying case.

Software specifications

Modules (test modalities)

ABR	B	Auditory Brainstem Response (diagnostic and threshold)
ASABR	A	Automated Screening ABR (Summer 2007)
ECochG	C	Electrocochleography
DPOAE	D	Distortion Product Otoacoustic Emission
TEOAE	T	Transient Evoked Otoacoustic Emission
ASSR	S	Auditory Steady State Response (late 2007)

Computer software architecture (Graphic User Interface, GUI)

Seven tab-selectable, common for all software modules (test modalities), user-friendly, and easy-to-navigate functional screens:

Patients	spreadsheet-style data entry, for patient demographic information
Planner	spreadsheet-style data entry, for scheduling appointments
Protocol	password-protected, for setting protocol parameters
Test	SQL-based, for running tests and on-line viewing results
System	for system settings and fully secure data backup, restore, and merging from multiple Integrity™ units
Database	SQL-based, secured, password-protected, spreadsheet-style data sorting and query, viewing and off-line analysis of test results, typing reports, printing results and reports, and exporting data to statistical software
About	Software identification and Customer Support information

Module-specific specifications

ABR – diagnostic and threshold estimation

Stimulation: Air (AC) and bone conduction (BC), ipsi- and contralateral
Stimuli: Click 100 μ s and tone bursts 0.5, 1, 2, 3, and 4 kHz
Calibration: dB pe SPL and dB nHL for AC, dB pe FL and dB nHL for BC
Tone-burst windowing: Blackman, rectangular, and linear
Stimulus rate: 7.1 to 95.0 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 and B, and difference (A-B)
Recording window: From -1 to 0-30 ms
Digital filters: Adjustable, high-pass 30-300 Hz and low-pass 1000-3000 Hz
Measured variables: Real-time Wave I, II, III, IV, V latencies, I-III, III-V, I-V interpeak intervals, Wave I and V amplitudes, V/I amplitude ratio, and latency-specific Correlation Coefficient
Latency norms: Newborn to adults (UCLA, Vanderbilt, and Boys Town)

ASABR – automated screening ABR (Summer 2007)

Stimulus: Air-conducted click 100 μ s, 35 dB nHL, rate 37.7 per second
Screening criteria: Statistic-based (variance ratio), not template-based

ECochG

Stimuli: Click 100 μ s, 80-100 dB nHL (135 dB pe SPL)
Recording: Gold-foiled ABR electrode (TipTrobe™)
Measured variables: Baseline, SP, and AP latencies and amplitudes, and SP/AP amplitude ratio

TEOAE – diagnostic and automated screening

Stimuli: Click 80 and 120 μ s, 60-85 dB pe SPL, linear and non-linear
Measured variables: Signal, noise, and SNR in 1-kHz, 1, 1/2, 1/4, 1/6-oct bands
Pass-refer criteria: Multiple, flexible, user-selectable

DPOAE – diagnostic and automated screening

Stimuli: f_2 frequencies 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 3.2, 3.5, 4, 4.5, 5, 5.5, 6, 7, and 8 kHz; levels 40-75 dB SPL; f_2/f_1 ratio 1.2 and 1.22 ($f_2 > f_1$)
System Noise and System DP: \leq 10 dB SPL at 75/75 dB SPL stimulus
Measured variables: Signal, noise, and SNR at f_2 frequencies
Pass-refer criteria: Multiple, flexible, user-selectable

ASSR (late 2007)

Stimuli: AM, FM, mixed AM and FM, single-ear and simultaneous R&L ears, single-frequency and multiple frequency modes, carrier frequencies 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 4.5, 6, and 8 kHz

Hardware specifications

VivoLink™ – wireless interface module

Gain: User-selectable, 0, 10, 20, and 40 dB (post-Amplitude®)
Sampling rate: 38,400 samples per second (sps)
A/D and D/A resolution: 24 bit
Built-in: 1-cc Cavity for OAE Probe, 3 snaps for parking Amplitude®, power switch, 3 LED indicators for power ON, impedance match, and wireless ON
Notch filters: User-selectable 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 <1.02 mW, connection range 30 feet (10 meters)
Connectors: ER3-A (R&L) insert earphones, B-71 bone conductor, OAE Probe, Amplitude®
Physical: 0.8 lb (350g) weight, 7.2" (18cm) L x 3.65" (9.1cm) W x 1.2" (3cm) H
Batteries: 4 AA NiMH (rechargeable) or Alkaline (non-rechargeable)

Amplitude® – electrode-mounted in-situ differential bio-amplifier

Gain: 15,000
Frequency band: 30-3000 Hz
Input impedance: 1.5 M Ω at 60Hz
Noise level: 8 nV/root (Hz) at 100 Hz
Common Mode
Rejection Rate: \geq 115 dB at 60 and 50 Hz
Electrodes: Snap type, Neuroline 720 00-S or equivalent

OAE Probe

Design: Common for DPOAE and TEOAE, 2 microphones, 2 receivers
Easy cleaning: Mini-brush, disinfecting wipes. No detachable parts.

Configurations

AEP Kit: Notebook computer with Integrity™ software, VivoLink™, Amplitude®, ER-3A-ABR insert phones (10 Ω), B-71 bone conductor with calibration on CD-ROM, ER3-06 Eartip Adapter, starter ear tip set, starter Neuroline 720 00-S electrode set, disinfecting wipes, prep gel or pads, Bluetooth® dongle, ER-28S Cables and gold-foiled ear tips, Charger and 8 AA NiMH batteries, User's Manual, carrying case

OAE Kit: Notebook computer with Integrity™ software, VivoLink™, Probe with calibration on built-in EEPROM, Starter Ear Tip Set, disinfecting wipes, software, Bluetooth® dongle, Charger and 8 AA NiMH batteries, User's Manual, carrying case

Notebook computer: 15" screen, 1024x768 resolution, min 3 USB ports

Optional devices: Printer, cart

Warranty

One year warranty on parts and labor. Extended warranty available

Intellectual property

U.S. Patent Nos. 6,463,411 and 6,778,955. Other patents pending in the US and other countries. Integrity and VivoLink are trademarks, and Amplitude is a registered trade mark of Vivosonic Inc. Bluetooth is a registered trade mark of Bluetooth SIG

Regulatory clearances

Canada: Health Canada Medical Device Licence 67609. Industry Canada IC 6273A-V50

United States: FDA 510(k) K043396. FCC Part 15 Product ID TVZ-V50

European Union: CE Registration DE/CA09/0170/1207 to 1212, ETSI EN 300 328 V1.6.1 (2004-07)

Reimbursement (US)

CPT Coding:

92584	Electrocochleography
92585	Auditory evoked potentials for evoked response audiometry
92586	Limited auditory evoked potentials
92587	Evoked otoacoustic emissions; limited
92588	Evoked otoacoustic emissions, comprehensive or diagnostic evaluation

ICD-9 Diagnoses Codes:

380.00-380.89	Disorders of the external ear
381.00-381.89	Nonsuppurative otitis media and Eustachian tube disorders
382.00-382.9	Suppurative and unspecified otitis media
383.00-383.9	Mastoiditis and related conditions
384.00-384.9	Other disorders of tympanic membrane
385.00-385.9	Other disorders of middle ear and mastoid
386.00-386.9	Vertiginous syndromes and other disorders of vestibular system
387.0-387.9	Otosclerosis
388.00-388.8	Other disorders of the ear
389.00-389.8	Hearing loss
780.4	Dizziness and giddiness



Integrity™ is designed and produced through a state-of-the-art Quality Management System certified to ISO 13485: 2003.

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