

Everyone has a secret weapon.  
Ours is named Kalman.

Vivosonic's patented algorithm (Kalman Weighted Filtering) optimizes digital signal processing and dramatically reduces artifacts coming from muscular and ocular electrical activity, allowing you to test virtually any patient.

It is ideal for testing non-sedated, non-relaxed, awake, and even active patients like feeding or nursing infants and playing children.

**Kalman is what makes Integrity non-sedated ABRs possible.**

If you'd like to know more about the Integrity System and what it can do for your clinic, contact us today to arrange a demo.

**1.877.255.7685**  
**www.vivosonic.com**



## Integrity V500 Specifications

### Intended Use:

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

### System:

Portable PC-based, consisting of hardware & computer software. Includes carrying case.

### Software Specifications:

#### Modules (test modalities):

<b>ABR</b>	B	Auditory Brainstem Response (diagnostic & threshold)
<b>ECochG</b>	C	Electrocochleography
<b>DPOAE</b>	D	Distortion Product Otoacoustic Emissions
<b>TEOAE</b>	T	Transient Evoked Otoacoustic Emissions

### Software architecture (Graphic User Interface, GUI):

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

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

### Output from software:

Print (Customizable), PDF or file export.

### Module-specific specifications:

#### ABR – diagnostic & threshold estimation

Stimulation: Air (AC) & bone conduction (BC), ipsi- & contralateral  
Stimuli: Click 100 µs & toneburst 0.5, 1, 2, 3 & 4 kHz  
Calibration: dB pe SPL & dB nHL for AC, dB pe FL & dB nHL for BC  
Tone-burst windowing: Blackman, rectangular & 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 & B & difference (A-B)  
Recording window: From -1 to 30 ms  
Digital filters: Adjustable, high-pass 30-300 Hz & 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 & V amplitudes, V/I amplitude ratio & latency-specific Correlation Coefficient  
Latency norms: Newborn to adults (UCLA, Vanderbilt & Boys Town)  
Masking: White noise, 0-90 dB HL

#### ECochG

Stimuli: Click 100 µs, 65-100 dB nHL (135 dB pe SPL)  
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

#### 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

### Hardware specifications:

#### VivoLink – wireless interface module

Gain: User-selectable, 0, 10, 20 & 40 dB (post-Amplirode)  
Sampling rate: 38,400 samples per second (sps)  
A/D & D/A resolution: 24 bit  
Built-in: 1-cc Cavity for OAE Probe, 3 snaps for parking Amplirode, power switch, 3 LED indicators for power ON, impedance match & 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, Amplirode  
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)

#### Amplirode – electrode-mounted in-situ differential bio-amplifier

Gain: 15,000  
Frequency band: 30-3000 Hz  
Input impedance: 1.5 MΩ at 60Hz  
Noise level: 8 nV/root (Hz) at 100 Hz  
Common Mode Rejection Rate: >120 dB at 60 & 50 Hz (>135 dB typical)  
Electrodes: Snap type, Neuroline 720 00-5

#### OAE Probe

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

### Configurations:

**All Integrity V500 Systems:** V51 Vivolink Wireless Interface Module Ver. 4.5 with V51-PS & V51-GS, Notebook Computer, Carrying Case, Peltor ear muffs, Battery Charger, 8 NiMH AA rechargeable batteries, Integrity V500 Software Installation CD-ROM, Integrity V500 User's Manual, Database Software Module.

**Pediatric ABR Modules:** A51 Amplirode® in-situ Pre-amplifier, 1 Set ER3-A-ABR Insert Earphones, B-71 Bone Conductor, Calibration CD-ROM. Includes Disposables Starter Set for 100 Patients.

**General Practice Modules:** A51 Amplirode® in-situ Pre-amplifier, 1 Set ER3-A-ABR Insert Earphones, B-71 Bone Conductor, Calibration CD-ROM, ECochG ER3-28V Electrode Eartip Cable with Clip-Snap and Starter Gold-foiled Eartip Set - 20 pcs. ER3-26A (13 mm) and 20 pcs. ER3-26B (10 mm), Spectra 360 Electrode Gel. Includes Disposables Starter Set for 100 Patients.

**TEOAE & DPOAE Modules:** P40 General-Use OAE Probe, Probe Cleaning Tool Set, Starter Single-Use Eartip Set - 156 pcs. in clear box, DPOAE Software License and/or TEOAE Software License.

**Disposables Starter Set for 100 Patients:** Foam Eartip Set for ER3-A-ABR Insert Earphone - 100 pcs. ER3-14A (13 mm) - 100 pcs. ER3-14B (10 mm), PVC Eartips - 20 ER3-14E 4.0 mm & 20 ER3-14D 3.5 mm, Starter Single-Use Eartip Set - 156 pcs. in clear box, 2 Impedance Tip Adapters, 1 Abrasive Skin Prepping Gel Tube, 100 pcs. PDI Electrode Prep Pads, 300 pcs. Single-use Neuroline® Electrodes (12 packs x 25/pack), ECochG Starter Gold-foiled Eartip Set - 20 pcs.\* ER3-26A (13 mm) & 20 pcs.\* ER3-26B (10 mm)\*, Spectra 360 Electrode Gel\*. \*Not included in Pediatric Module.

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

#### Optional devices:

Printer

#### Warranty:

One year warranty on parts & labor. Extended warranty available

#### 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 & Eustachian tube disorders
382.00-382.9	Suppurative & unspecified otitis media
383.00-383.9	Mastoiditis & related conditions
384.00-384.9	Other disorders of tympanic membrane
385.00-385.9	Other disorders of middle ear & mastoid
386.00-386.9	Vertiginous syndromes & 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 & giddiness



**integrity™**

**Non-Sedated ABR, OAEs  
Non-Invasive ECochG  
Diagnostic System**

**vivosonic**

120-5525 Eglinton Ave. W.  
Toronto, ON M9C 5K5

**Toll Free: 1.877.255.7685 Fax: 416.231.2289 E-mail: sales@vivosonic.com Online: www.vivosonic.com**

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sales@vivosonic.com

www.vivosonic.com

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# integrity™

Integrity's patented and award winning technologies reduce or eliminate many of the frustrations hampering today's Audiologists performing ABR tests by allowing for superior overall performance in clinical results, patient care and economic efficiency.

## High-Definition ABR Without Sedation

Using Kalman Weighted Filtering, the Integrity is able to generate superior diagnostic results without sedation. This is particularly suitable to pediatric patients, who can now feed, speak, play or wake up while being tested. It is also an invaluable tool for-hard-to test patients from the general population.

## Flexible Options to Suit Your Situational Needs

With variable options that can include Non-Sedated ABR, OAE and Non-Invasive ECoG, Vivosonic's innovative Integrity enables clinicians to perform Auditory Electrophysiological or Otoacoustic Emission assessment, on almost any patient, from newborns to seniors.

## Test Wirelessly, In Virtually Any Situation

The first system to possess wireless capabilities, Integrity is a revolution in portable diagnostics, fitting unobtrusively on an alert child's back who is playing quietly during testing, or into the OR. In addition, the Amplitrode (a miniature electrode mounted bio-amplifier) protects against electromagnetic noise, delivering clear results in places with electric and magnetic interferences such as Neonatal Intensive Care Units (NICU), hospitals, military medical centers, Operating Rooms (OR) and other clinical settings. Integrity is also valuable in the rare instances where anesthesia is necessary and can be used for intra-operative monitoring.

## Improved Patient Care and Economics

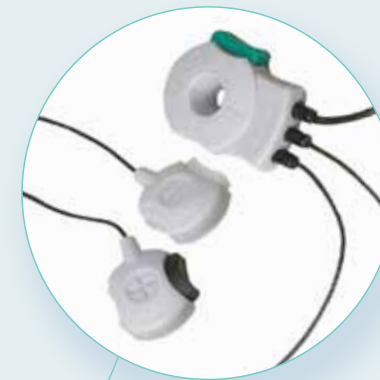
Hospitals will eliminate patient risk associated with anesthesia and shorten the test-to-service timeliness. In addition, they will also be helping to reduce the burden of anesthesia costs on the national healthcare system.

Integrity will enable private clinics to lessen patient referrals out and increase their patient population, ensuring quality hearing healthcare within their communities.

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## Integrity V500 System and Components



### Amplitrode®

Amplitrode is the world's first patented in-situ bio-amplifier. Mounted directly on the electrode, 'in-situ amplification' (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. Spring release buttons allow for easy and safe mounting and dismantling of the Amplitrode from the snap electrodes.



### OAE Probe

The OAE packages include a general-use probe (vented and serviceable) that consists of the smallest Knowles microphones and powerful mid-size receivers (speakers), a dual-microphone design which provides an additional 3 dB of signal-to-noise ratio (SNR) and an ultra-soft, 2m (6.7 ft) long cable with clothing clip. The probe fits comfortably into the ears of almost any adult or child when fitted with included ear tips and can be used with ear muffs for noise reduction.



### Non-Invasive ECoG

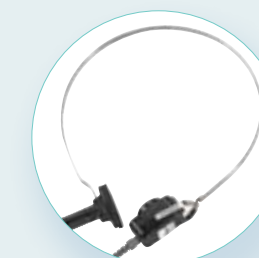
For those adults requiring additional tests for ailments such as Ménière's Disease, Integrity is one of the most patient-centric ECoG systems on the market. Unlike other systems Integrity is capable of achieving clear ECoG results using gold foiled ear tips, allowing for successful test results without touching or perforating the tympanic membrane.



### Vivolink™

VivoLink is the world's only wireless combined platform for Auditory Electrophysiological and Otoacoustic Emission assessment, as well as hearing screening. The included batteries provide clean power for better results.

A built-in microprocessor generates stimuli and analyzes responses. To ensure stimuli precision generation and signal acquisition, VivoLink employs very high A/D and D/A resolution and sampling rates. It is convenient and comfortable to use and can be secured on an adult with a lanyard, placed next to the baby in a NICU incubator, car seat, stroller, or worn by the baby's caregiver or child as a back-pack.



### Bone Conductor

In cases of conductive hearing loss, bone conduction ABR tests may be required. For this reason, a bone conductor is used with minimal artifacts due to Integrity technologies.

