Integrity V500 Specifications

**Intended Use:** Integrity V500 is intended for audiological, medical and non-medical applications requiring non-invasive assessment and objective testing of the auditory system. It is designed to serve as an essential tool for otologists, pediatricians, neurologists, audiologists, and other medical professionals.

**Software Specifications:**
- **ABR:** Auditory Brainstem Response (Differential or broadband)
- **ASSR:** Auditory Steady-State Response (Differential or broadband)
- **ECochG:** Electrocochleography
- **DPOAE:** Distortion Product Otoacoustic Emissions
- **TEOAE:** Tone-Evoked Otoacoustic Emissions

**Application Example:**
- **Non-Sedated ABR, OAEs & ECochG:**
- **Diagnostic System:**
- **Non-Invasive ECochG Diagnostic System**
- **Specifications:**
- **Gain:** User-selectable, 0, 10, 20 & 40 dB (post-Amplitrode)
- **Sampling rate:** 300,000 per second
- **A/D & D/A resolution:** 24 bit
- **Built-in:** 1-cc Cavity for OAE Probe, 3 snaps for parking Amplitrode, power switch, 3 LED indicators for power ON, impedance match & wireless ON
- **Notch Filters:** User-selectable 50 Hz, 60 Hz, or OFF
- **Lightening:** Non-invasive

**Hardware Specifications:**
- **Vivosonic Interface Module:**
  - Cam-USB, 1010, VMS-USB, VMS-USB-4, VMS-USB-8 (post-Amplitrode)
- **Sampling Rate:** 300,000 per second
- **AXD & DMS connectors:** 24 pin
- **Screen:** 14” color LCD, 1024 x 768 resolution
- **Input:** 100-240VAC, 50/60Hz, 2 Amps
- **Environment:** 0°C to 40°C, 10% to 90% non-condensing

**Integrity V500 Features:**
- **High definition display:** 14” color LCD, 1024 x 768 resolution
- **Stimuli:**
  - Click: 5-20 ms, 30-300 ms, 50-500 ms
  - Toneburst: 30 ms, 50-500 ms, 200-2000 ms
  - Clicks at 0.5, 1, 2, 3 & 4 kHz
  - Levels 40-75 dB SPL; f2/f1 ratio 1.2 & 1.22 (f2> f1)
- **Latency norms:** Newborn to adults (UCLA, Vanderbilt & Boys Town) Masking: White noise, 0-90 dB HL
- **Measured variables:** Signal, noise & SNR in 1-kHz, 1, 1/2, 1/4, 1/6-oct bands

**Regulatory Clearances:**
- **Canada Health Canada Medical Device License: 67609. Industry Canada IC 6273A-V50 (Toronto, ON) 383.00-383.89 Disorders of the middle ear 383.90-383.99 Other disorders of the external ear 384.00-384.99 Other disorders of the tympanic membrane 385.00-385.99 Other disorders of the middle ear 386.00-386.99 Other disorders of the ossicles 387.00-387.99 Other disorders of the inner ear 388.00-388.89 Other disorders of the ear 389.00-389.89 Hearing loss 780.40-780.49 Dizziness & giddiness
- **United States:**
  - **CPT Coding:**
    - 92584 Electrococleography
    - 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

**About Vivosonic:**
- Sales & Service Centers:
  - Canada: sales@vivosonic.com www.vivosonic.com
- Regulatory clearances:
  - Australia: Australian Therapeutic Goods Administration (TGA)
  - Canada: Health Canada Medical Device License 67609. Industry Canada IC 6273A-V50 (Toronto, ON) 383.00-383.89 Disorders of the middle ear 383.90-383.99 Other disorders of the external ear 384.00-384.99 Other disorders of the tympanic membrane 385.00-385.99 Other disorders of the middle ear 386.00-386.99 Other disorders of the ossicles 387.00-387.99 Other disorders of the inner ear 388.00-388.89 Other disorders of the ear 389.00-389.89 Hearing loss 780.40-780.49 Dizziness & giddiness
- **Software architecture (Graphic User Interface, GUI):**
  - SQL-based, secured, password-protected, spreadsheet-style data sorting & analysis
  - Database: SQL-based, for running tests & on-line viewing results
  - Protocol: Password-protected, for setting protocol parameters
  - System: SQL-based, for setting up and running tests & on-line viewing results
  - Software: Distributed, for running tests & on-line viewing results
  - Diagnosis: SQL-based, secured, password-protected, spreadsheet-style data sorting & analysis
  - Testing: SQL-based, secured, password-protected, spreadsheet-style data sorting & analysis
  - Patient: SQL-based, secured, password-protected, spreadsheet-style data sorting & analysis
  - Stimulation: Air (AC) & bone conduction (BC), ipsi- & contralateral
  - Stimuli: Click 100 μs, 60-85 dB pe SPL, linear & non-linear
  - Calibration: dB pe SPL & dB nHL for AC, dB pe FL & dB nHL for BC
  - Tone-burst windowing: Blackman, rectangular & Hamming
  - Recording: Gold-foiled ABR electrode (TipTrode™)
- **Diagnostic System:**
  - **Vivosonic’s patented algorithm (Kalman Weighted Averaging):**
    - Normal Gain: 15,000
    - Frequency band: 30-3000 Hz
    - Input impedance: 1.5 MΩ
  - **Distortion Product Otoacoustic Emissions:**
    - dB SPL: 100-120 dB SPL
    - Levels: 40-75 dB SPL; f2/f1 ratio 1.2 & 1.22 (f2> f1)
    - Electrodes: Snap type, NNL 703-065
  - **OAE Probe:**
    - Design: For DPOAE & TEOAE, 2 microphones, 3 electrodes
    - Datalink: DirectLink, wireless series, for two or three ports.

**CPT Coding:**
- **92584 Electrococleography**
- **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**

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**Vivosonic’s patented algorithm (Kalman Weighted Averaging):**
- Optimizes digital signal processing and dramatically reduces artifacts from muscular and ocular electrical activity.

**It is ideal for testing patients without sedation - from a nursing infant, to a child playing quietly, to an adult requiring an objective hearing assessment.**

**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 demonstration.**
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 Averaging, the Integrity is able to generate reliable 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 ECochG, 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 a 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.

**Integrity**

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 backpack.

**2. 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 dismounting of the Amplitrode from the snap electrodes.

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

**4. 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.

**5. 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.