**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
- **AmpliTed®**: A/B1 electrode-mounted in-situ differential bio-amplifier
- **AEP Transducers**: ER3-A-800 insert earphones (with ABR)
- **Stimuli**: B/7W bone-conductor (included with ABR)
- **H-900 EP Headphones (option)**
- **OAE Probes**: P81-GP custom probe for general use (option)
- **Recording traces**: P81-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
- **ECoG**: C Electrocochleography
- **TEOAE**: T Transient Evoked Otoacoustic Emissions
- **40 Hz ERP**: F 40 Hertz Event-Related Potential

**Product Specifications (Generation 2)**

**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 SPL, dB nHL
- **Toneburst window**: 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 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 30-3000 Hz, Low-pass: 300-3000 Hz
- **Measured variables**: Real-time Wave: I, II, III, IV, V latencies
- **Interpeak intervals**: I-II, III-V, I-V
- **Amplitudes**: Wave I & V, V/I amplitude ratio
- **Latency-specific Correlation Coefficient**: Customizable PDF, file export

**ASSR – threshold estimation**
- **Stimulation**: Air-conduction (AC) and Supra-aural headphones
- **Stimulus**: 0.5, 1, 2, 4 kHz
- **frequencies**: Set up to 4 simultaneous frequencies per ear.
- **Stimulus intensity**: 0 to 95 dB nHL
- **Set maximum, minimum and initial levels.
- **Modulation**: 40 Hz and 80 Hz families
- **Modulation frequency rates**: Fixed
- **Modulation method**: Modified chirp
- **Threshold search**: Automated method using two user-definable search resolution steps. Users can monitor and adjust settings.
- **Maximal search time**: User-definable
- **ASSR detection**: Automated
- **Conversion factors**: User-definable conversion from ASSR to behavioral

**DPOAE – diagnostic & automated screening**
- **Stimuli**: f1 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

**ECoG – 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, SPA/P-AP amplitude ratio

**TEOAE – diagnostic & automated screening**
- **Stimuli**: Click 80, 120 μs, 60-85 dB pe SPL, linear, non-linear
- **Recording**: Average (A+B), buffers A & B & difference (A-B)
- **Recording window**: 125 ms
- **Measured variable**: Interpeak latency (ms)

**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**: 4 snaps for parking Amplitrode, 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

**AmpliTed®**
- **Nominal gain**: 7,600
- **Frequency band**: 30-3000 Hz
- **Input impedance**: 1.5 MΩ at 60Hz
- **Noise level**: 15 nV/√Hz at 100 Hz
- **Common mode**: >120 dB at 60 & 50 Hz (>130 dB typical)
- **rejection ratio**: Electrodes: Snap type, Neuroline 72000-S, NeuroPlus Electrode
- **A10040, NeuroPlus Electrode A10041**

**OAE Probe Options**
- **P81-GP probe**: General use, 2 microphones, 2 receivers. No detachable parts. Easy to clean with mini-brush and disinfecting wipes. General use and suitable for newborns and infants.
- **P81-UG probe**: 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**
- **Canada**: Health Canada Medical Device Licence 67609.
- **European Union**: CE Registration DE/CA09/0170/1207Λ1 to 1212Λ1, 3157 ΛΕ9 LMX9838
- **United States**: FDA 510(k) K043396, TÜV SÜD 81763; FCC Part 15, FCC ID ED9LMX9838
- **Other countries**: Please enquire.

**Other countries**
- **Configurations**
- **Full-featured Integrity**
- **ABR/ECoGh**: Laptop computer, VivoLink, A81, A82, ER-3A-800, B7/1W, ER3-60 electrode earp cable with connector, tip adapters, battery pack charging kit, carrying case, shoulder straps, starter kit of disposables and consumables, Integrity V500 ABR/ECoGh software, Integrity V500 User’s Manual (PDF), Integrity V500 Quick Reference. Optional: printer
- **Option**: ASSR module, DPOAE/TEOAE module with OAE Probe and test cavity, 40 Hz ERP, supra-aural headphones.