**Product Specifications**

(Generation 1)

**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
- **Amplitude©**: AEP Transducers
- **OEProbes**: P40-GP custom probe for general use (option)
- **AAE Probes**: P40-GP smaller probe suitable for newborns, infants (option)

**Software Modules:**
- **ABR**: Auditory Brainstem Response
- **ASSR**: Auditory Steady-State Response
- **DPOAE**: Distortion Product Otoacoustic Emissions
- **ECoG©**: Electrocochleography
- **TEOA**: 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 percent per second with 0.1/s step
Stimulus polarity: Condensation (C), Rarefaction (R), Alternating (C & R averaged), Alternating Split (C & R displayed separately)
Recording: Average (A-B), buffers A & B and difference (A-B)
Recording window: From 0 to 120 ms
Digital filters: Adjustable, High-pass 300-3000 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' 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: 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
Frequency rates:
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 (f2/1)
System noise & system DP:
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, SP/AP amplitude ratio

**TEOA – diagnostic & automated screening**
Stimuli: Click 80, 120 µs, 60-85 dB pe SPL, linear, non-linear
Measurable variables:
- Signal, noise, SNR in 1-kHz, 1, 1/2, 1/4, 1/6-oct bands
- Pass-referrer criteria: Multiple, flexible, user-selectable

**40 Hz ERP – threshold estimation**
Stimulation: Air-conduction (AC) and Supra-aural headphones
Stimulus: 0.105 dB nHL, Chirp stimul with center frequency 0.5, 1, 2, 4 kHz
Recording traces: Average (A-B), buffers A & B & difference (A-B)
Recording window: 125 ms
Measurable 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 Amplitude, 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
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

**Amplitude©**
Nominal gain: 7,500
Frequency band: 30-3000 Hz
Input impedance: 1.5 MΩ at 60Hz
Noise level: 8 nV/√Hz at 100 Hz
Common mode rejection ratio: >120 dB at 60 & 50 Hz (>135 dB typical)
Erectodes: 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-GU-J probe: General use and suitable for newborns and infants.

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

**Quality System**

**Regulatory Compliance**
- **Brazil:** ANVISA, INMETRO, ANATEL
- **Canada:** Health Canada Medical Device Licence 67609.
- **China:** CFDA
- **European Union:** CE Registration DE/CA09/0170/12071 to 1212A1, 3157
- **Japan:** Ministry of Health, Labour and Welfare.
- **Korea:** KDFA, KCC
- **Mexico:** COFEPRIS
- **United States:** FDA 510(k) K043396. ETL Listed 3087966. FCC Part 15, FCC ID TVZ-V50.

**Other countries:** Please enquire.

**Full-featured Integrity ABR/ECoG©**
Laptop computer, VivoLink, A61, ER-3A, B-71, ER3-28V electrode earip 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/ECoG© software, Integrity V500 User’s Manual (PDF), Integrity V500 Quick Reference. Optional: printer

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

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