

General Description

The Integrity™ V500 is a medical device that is used as an auditory screening and diagnostic test tool, especially intended for subjects who cannot or will not properly test with standard behavioural audiometry and/or testing in adverse electrical challenging environments, such as the OR and NICU.

The main testing technologies are otoacoustic emissions (OAEs) and auditory evoked potentials (AEP), with emphasis on the auditory brainstem response (ABR), for both diagnostic and screening), electrocochleography (ECochG), the auditory steady-state response (ASSR), auditory evoked middle and late latency responses (MLR and LLR). In addition, it has vestibular evoked myogenic potentials (VEMP).

System Summary

Software Modules:

ABR	B	Auditory Brainstem Response, including basic ECochG, MLR, and LLR
ABR Screening	X	Auditory Brainstem Response Screening
ASSR	A	Auditory Steady-State Response
DPOAE	D	Distortion Product Otoacoustic Emissions
DPOAE Screening	W	Distortion Product Otoacoustic Emission Screening
TEOAE	T	Transient Evoked Otoacoustic Emissions
40 Hz ERP	F	40 Hertz Event-Related Potential
VEMP	V	Vestibular Evoked Myogenic Potential

Output from Software (reports)

- Report (customizable) for printing or save as a PDF; with or without patient name
- Export results directly to csv

Main Hardware Components:

Computer Interface	Windows 11 64-bit and Integrity V500 software.
VivoLink™	V500 Bluetooth wireless patient interface module (main unit)

Bio-Amplifiers and Transducers With Corresponding Test Modalities	ABR / ECochG / MLR	LLR	ABR Screening	ASSR	40 Hz ERP	DPOAE/DPOAE Screening	TEOAE	VEMP
	Bio-amplifiers							
Amplitrode®-in situ (A81 – 1 channel)	✓			✓	✓			
Amplitrode®-in situ (A82 – 2 channel)	✓			✓	✓			
VivoAmp™ (A90 – 1 & 2 channels)	✓		✓	✓	✓			
CV-Amp™ (A91 – 1 & 2 channels)		✓						✓
Insert Earphone								
ER-3A-800, ER-3C-800	✓	✓	✓	✓	✓			✓
IP30-800	✓	✓		✓				✓
ER-2-800 (up to 6 and 8 kHz)	✓	✓						
Supra-aural Headphone								
H-801 (TDH-39)	✓	✓		✓				✓
Circumaural Headphone								
VivoStim™ (ST-800) – pediatric, in development	✓	✓	✓					
Bone Conductor								
B71W	✓	✓						
B81	✓	✓		✓				✓
OAE Probes								
P81-GP (custom probe for general use)						✓	✓	
P81-UG (smaller probe for newborns, infants)						✓	✓	
P81-GX-A (custom probe with detachable nose)						✓	✓	

Algorithm Description

User Selectable Algorithms:

- SOAP/Kalman Weighted Averaging** weighs each accepted sweep in the averaged response based on the noise in the sweep
 - SOAP/Kalman Plus Weighted Averaging** weighs each accepted sweep in the average based on the noise in the specific frequency bands of the sweep
 - Traditional Averaging** Each accepted sweep is given equal weight
- User Selectable Artifact Rejection Level in ABR/MLR/LLR/ECochG/VEMP

AEP Repeatability Assessment

- Avoid need for running a second test
- Interleaving data collection in statistically independent A & B buffers
- Automatically calculated statistical measures: Correlation Coefficient, Residual Noise, SNR, and Fsp

Hardware Specifications

Computer Windows 11 on an Intel 64-bit iSeries processor with Bluetooth®, minimum 2 USB ports, 1366x768 resolution, 8 GM RAM; or equivalent.

VivoLink™

Sampling rate:	38,400 samples per second (sps)
A/D & D/A resolution:	24 bit
RF transmission *:	Radiofrequency, spread-spectrum wireless 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

Amplitrode®, VivoAmp™, CV-Amp™

Fixed nominal gain	7,600 (Amplitrode & VivoAmp; for ABR, MLR, & ASSR) 2,500 (CV-Amp; for LLR) Pre-filtering before amplification allows gain to be optimized. This avoids the need for gain adjustment due to signal saturation.
Frequency band:	30-3000 Hz (Amplitrode & VivoAmp; ABR, MLR, & ASSR) 1-1500 Hz (CV-Amp; for LLR)
Electrodes (snap):	Neuroline 72000-S, NeuroPlus Electrode A10040, NeuroPlus Electrode A10041
Electrodes (tab):	VivoTab™ (ABR Screening only)
Electrodes (gold cup):	CV-Amp; for LLR

OAE Probe Options

P81-GP probe:	General use. 2 microphones, 2 receivers, test cavity. No detachable parts; mini-brush & disinfecting wipes to clean
P81-UG probe:	General use and suitable for newborns and infants. 1 microphone, 2 receivers, test cavity.
P81-GX-A probe:	General use and suitable for newborns and infants. 1 microphone, 2 receivers, test cavity.

Warranty

One year warranty on system and 120-day warranty on battery packs.

Quality System

Meets the requirements of: EN ISO 13485:2016; FDA 21 CFR Part 820, Medical Device Regulation 2017/745 (CE marking approval); MDSAP

Regulatory Compliance

Canada: Health Canada Medical Device Licence 67609. TÜV SÜD 81763. Industry Canada ID: 8976C-SPBT302; SOR/98-282 - Canadian Medical Devices Regulations.

European Union: CE Registration: 228620202728

United States: FDA Device Listing: D006566. FDA 510(k): K043396, K242954. TÜV SÜD 81763. FCC Part 15, Subpart B, Class B. FCC ID: S9NSPBT30DP2.

Other countries: Please enquire.
* For Reference Only

Test Module Specifications

ABR / ECOCHG / MLR / LLR –

DIAGNOSTIC & THRESHOLD ESTIMATION

Stimulation: Air-conduction (AC) in dB nHL or dB peSPL, Bone-conduction (BC) in dB nHL
 Stimulus Type: Click, Toneburst, Wideband and Frequency-specific Chirp based on IEC 60645-3(2020)

Stimulus range [dB nHL]

Stimulus	ER-3A-800 ER-3C-800 IP30-800	ER-2-800	H-801 (TDH-39)	B71W / B81	
Click	-20 to 99 ± 3	-30 to 75 ± 3	-20 to 102 ± 3	0 to 55 ± 4	
Tone burst	500 Hz	-20 to 105 ± 3	-12 to 88 ± 3	-20 to 113 ± 3	0 to 50 ± 4
	1000 Hz	-20 to 104 ± 3	-13 to 89 ± 3	-20 to 118 ± 3	5 to 60 ± 4
	2000 Hz	-20 to 99 ± 3	-18 to 87 ± 3	-20 to 110 ± 3	5 to 55 ± 4
	3000 Hz	-20 to 97 ± 3	-23 to 85 ± 3	-20 to 112 ± 3	5 to 60 ± 4
	4000 Hz	-20 to 95 ± 3	-25 to 86 ± 3	-20 to 109 ± 3	5 to 55 ± 4
	6000 Hz	n/a	-28 to 78 ± 5	-20 to 96 ± 5	n/a
	8000 Hz	n/a	-25 to 79 ± 5	-20 to 86 ± 5	n/a
Chirp	Wideband	-20 to 95 ± 3	n/a	n/a	n/a
	500 Hz	-20 to 89 ± 3	n/a	n/a	n/a
	1000 Hz	-20 to 91 ± 3	n/a	n/a	n/a
	2000 Hz	-20 to 84 ± 3	n/a	n/a	n/a
	4000 Hz	-20 to 80 ± 3	n/a	n/a	n/a

RETSPL conversion files: Vivo-G2, Vivo-ISO, Vivo-Legacy-G1
 Toneburst windowing: Blackman, Rectangular, Linear
 Stimulus rate: 0.3 to 99.0 per second
 Stimulus polarity: Condensation (C), Rarefaction (R), Alternating (C & R averaged), Alternating Split (C & R displayed separately)
 Masking: Contralateral, white noise, 0-90 dB SPL
 Recording traces: Average (A+B), buffers A & B, and difference (A-B)
 Recording window: Up to 1000 ms
 Software notch filters: 50 Hz, 60 Hz, or switched OFF
 ECOchG recording: Gold-foiled ABR electrode (TipTrode™)
 Digital filters standard: Adjustable, High-pass 30-300 Hz, Low-pass: 300-3000 Hz
 Digital filters CV-Amp: Adjustable, High-pass 1-24 Hz, Low-pass: 10-1500 Hz
 ABR Markers: Wave I, I', II, III, IV, V, V'
 ABR Calculations: I-III, III-V, I-V, Amplitude: $I - I'$, $V - V'$, $(V - V') / (I - I')$ ratio
 ECOchG Markers: SP, AP, BL (baseline)
 ECOchG Calculations: SP/AP% amplitude ratio
 MLR/LLR Markers: Pa, Na, Pb, Nb, P1, N1, P2
 MLR/LLR Calculations: Latency and amplitude: P1 - N1, N1 - P2
 Statistical Measures: Correlation Coefficient, Residual Noise, SNR, and Fsp
 Interaural Differences: Latency and amplitude; amplitude asymmetry calculations
 Post-facto adjustments: Four levels of smoothing, comments, flip waveforms
 Display of waveforms: Multiple stimulus types on one graph
 Sorting based on collection order or stimulus type and level
 Latency norms: Newborn to adults
 Maximum Traces: 50
 Automated Scheduling: Ability to schedule up to 7 protocols with user-defined stopping criteria

ABR SCREENING – AUTOMATED SCREENING

Stimulation: Air-conduction (AC)
 Stimuli: 30, 35, or 40 dB nHL 80 µs click
 Transducer: ER-3A-800, ER-3C-800
 Bio-Amplifier: VivoAmp with VivoTab electrodes
 Database: Export to HiTrack or Oz EHD1 Management Systems.
 ABR detection: Automated: Pass / Refer / Incomplete

40 HZ ERP – THRESHOLD ESTIMATION

Stimulation: Air-conduction (AC)
 Stimulus type: Band-limited 40 Hz family modulated chirp
 Stimulus frequency: 0.5, 1, 2, and 4 kHz center frequencies
 Stimulus levels: 0 to 90 ± 3 dB nHL
 Recording traces: Average (A+B), buffers A & B, and difference (A-B)
 Recording window: 125 ms
 Measured variable: interpeak latency (ms)

ASSR – THRESHOLD ESTIMATION

Stimulation: Air-conduction (AC) or Bone-conduction (BC)
 Stimulus frequencies: 0.5, 1, 2, and 4 kHz
 Stimulus levels: Set up to 4 simultaneous frequencies per ear. 0 to 110 ± 3 dB nHL (AC) 0 to 60 ± 4 dB nHL (BC)
 Modulation frequency: 40 Hz and 80/90 Hz families
 Modulation type: Band-limited chirp
 Transducer: ER-3A-800, ER-3C-800, IP30-800, H-801 (TDH), B81
 Bio-Amplifier: A90 VivoAmp, A81 or A82 Amplitrode
 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
 Masking: Contralateral, white noise, 0-100 dB SPL

DPOAE DIAGNOSTIC

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
 Stimulus levels: 30-75 dB SPL, independent for f2 and f1
 f2 / f1 ratio: 1.2 & 1.22 (note: f2 > f1)
 System noise limitations: ≤-10 dB SPL at 75/75 dB SPL stimulus
 Modes of operation: Diagnostic, Manual Screening
 Measured variables: Signal, noise, SNR at f2 frequencies. L1 & L2.
 OAE Probes: P81-GP, P81-GX-A, and P81-UG

DPOAE SCREENING

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
 (Max 5 frequencies selectable)
 Stimulus levels: 30-75 dB SPL, independent for f2 and f1
 f2 / f1 ratio: 1.2 & 1.22 (note: f2 > f1)
 System noise limitations: ≤-10 dB SPL at 75/75 dB SPL stimulus
 Measured variables: Signal, noise, SNR at f2 frequencies. L1 & L2
 Pass-refer criteria: SNR, DP & Repeatability over runs.
 OAE Probes: P81-GP, P81-GX-A, and P81-UG

TEOAE – DIAGNOSTIC & AUTOMATED SCREENING

Stimuli: Click 80, 120 µs; linear and non-linear modes
 Stimulus levels: 60 – 85 ± 3 dB pe SPL
 Modes of operation: Assessment, Manual & Automatic Screening
 Measured variables: Signal, noise, SNR in 1-kHz, 1/2, 1/4, 1/6-oct bands
 Pass-refer criteria: Whole wave reproducibility; Multi-band: SNR, signal

VEMP – DIAGNOSTIC

VEMP Type: cVEMP and oVEMP
 Stimulation: Air-conduction (AC) or Bone-conduction (BC)
 Stimulus Type: Click and Toneburst (500 Hz, 750 Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz, 4 kHz) based on based on IEC 60645-3(2020)
 Toneburst windowing: As per ABR
 Stimulus rate: 0.3 to 9.9 per second
 Stimulus polarity: As per ABR
 Recording Window: -20 to 80 ms
 Digital filters CV-Amp: Adjustable, High-pass 1-24 Hz, Low-pass: 10-1500 Hz
 Stimulus range: As per ABR
 VEMP Markers: P1, N1, P2
 VEMP Calculations: P1-N1, N1-P2
 Statistical Measures: Correlation Coefficient, Residual Noise, Average Prestimulus RMS, and SNR
 Interaural Differences: Latency and amplitude; amplitude asymmetry calculations
 Asymmetry Ratio: For Regular and Normalized Waveforms
 Post-facto adjustments: Comments, flip waveforms
 Display of waveforms: As per ABR
 Biofeedback: EMG Monitor; Optional Patient View (Second Monitor)
 Graphs: Amplitude-Frequency
 Maximum Traces: 50