Product Specifications - Summary
(Generation 2)

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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 the standard AEP capabilities to enable vestibular evoked myogenic potentials (VEMP); VEMP has not been approved for use by the FDA.

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
TEOAE	T	Transient Evoked Otoacoustic Emissions
40 Hz ERP	F	40 Hertz Event-Related 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 10 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**	**TEOAE**
Bio-amplifiers							
Amplitrode®-*in situ* (A81 – 1 channel)	✓			✓	✓		
Amplitrode®-*in situ* (A82 – 2 channels)	✓			✓	✓		
VivoAmp™ (A90 – 1 & 2 channels)	✓		✓	✓	✓		
CV-Amp™ (A91 – 1 & 2 channels)		✓					
Insert Earphone							
ER-3A-800, ER-3C-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-GT (custom probe for general use)						✓	✓
P81-UG (smaller probe for newborns, infants)						✓	✓
P81-GX (improved probe for all) in development						✓	✓

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

ABR 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 10 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.

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 Devices Directive 93/42/EEC (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 DE/CA09/0170/V07/006-03CE Registration DE/CA09/0170/V07/007-04

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

Other countries: Please enquire.

***** For Reference Only

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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 or dB peFL
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	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

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 EHDI Management Systems.
ABR detection:	Automated: Pass / Refer / Incomplete

ASSR – THRESHOLD ESTIMATION

Stimulation:	Air-conduction (AC)
Stimulus frequencies:	0.5, 1, 2, and 4 kHz Set up to 4 simultaneous frequencies per ear.
Stimulus levels:	0 to 95 ± 3 dB nHL Set maximum, minimum, and initial levels.
Modulation frequency:	40 Hz and 80/90 Hz families
Modulation type:	Band-limited chirp
Transducer:	ER-3A-800, ER-3C-800
Bio-Amplifier:	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

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)

DPOAE – DIAGNOSTIC & AUTOMATED 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
Stimulus levels:	40-75 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:	Assessment, Manual & Automatic Screening
Measured variables:	Signal, noise, SNR at f2 frequencies
Pass-refer criteria:	SNR, selectable frequencies for DP level and Noise level
OAE Probes:	P81-GT 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, 1/2, 1/4, 1/6-oct bands
Pass-refer criteria:	Whole wave reproducibility; Multi-band: SNR, signal

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