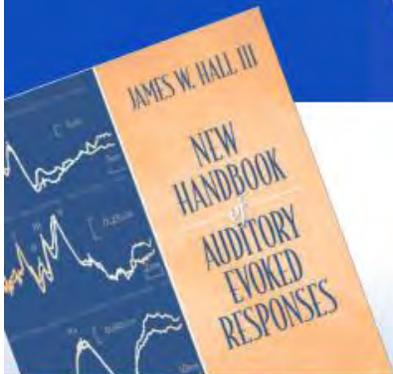




Manufacturer Supplement eHANDBOOK of AUDITORY EVOKED RESPONSES

James W. Hall III, Ph.D.



“After researching the internet for the newest technology in newborn and early child ABR diagnosis, we found Vivosonic and the possibility of having an accurate test without sedation and with a baby that is awake...” - Letter from a parent [\[Read Full Letter\]](#)

Sections

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I. Quality ABR Measurement

Good clinical practice combined with the advantages of technology go hand-in-hand to facilitate quality ABR measurements.

What Would You Want from an Ideal ABR System?

Challenges in ABR Measurement

Costs, risks and caregiver anxiety associated with sedation/anesthesia, in addition to associated wait times.

Significant difficulty obtaining reliable results in the presence of muscular artifact leading to incomplete or prolonged assessments, rescheduling issues, multiple appointments, and delayed diagnosis.

Electrically noisy environments such as the NICU and OR.

The Ideal ABR System

Non-sedated ABR measurement.

Ability to record ABR in the presence of myogenic activity.

Built-in noise immunity. System automatically adapts to electrical noise in the environment.

Restricted patient movement and positioning due to wired connections.

Lengthy measurement time to obtain estimated auditory threshold.

Wireless connection between computer and patient interface module.

Tools help determine when sufficient repeatability has been achieved.



3-year old boy and 1-year old girl with Down syndrome have a non-sedated ABR test while engaged in quiet activity.

[\[View Video-1\]](#)



Young patient with bilateral hearing loss has an ABR assessment with Integrity™ V500 System to adjust her hearing aids.

[\[View Video-2\]](#)

II. Solutions to Manage Common Challenges in ABR Measurement

“Problems previously encountered using traditional ABR systems were largely solved by the wireless technology and superior noise reduction technology. Data collected were cleaner and obtained much faster than with other ABR systems.”

- Dr. J. Sullivan, AuD, MS, CCC-A; Director, Newborn Hearing Screening Program

integrity™
V500
Auditory Diagnostic System



Reliable ABR without Sedation

Clinics in over 55 countries experience the practical benefits of the [Integrity™ V500 System](#) for auditory evoked potentials (AEP) and otoacoustic emissions (OAE)

measurements. The unique advantages of the Integrity™ V500 System, with one or two channel functionality, have made it the “go to” ABR system for clinics specializing in pediatric audiology, and more recently is providing equally valuable benefits for clinics serving the general population, [special needs adults](#), [cases of non-compliance](#), and geriatric patients.

Customers and leading experts report that the Vivosonic Integrity™ V500 System enables reliable ABR measurement in more clinical situations. [[Read about it](#)]

“...there are many children and infants that I am now able to assess without the use of sedation.”

“Prior to using the Integrity, it was not uncommon to have to move an infant to a separate area of the NICU...”

“It makes it possible to test some difficult-to-manage patients.”

“The wireless interface with the computer is innovative!”

Newborn hearing screening programs confirm the important benefits of incorporating Integrity™ V500 System in their standard procedures to meet the early hearing detection and intervention “1-3-6 EHD Plan.” The benefits include significant reductions in the need for sedation (and related parent anxiety), improved efficiencies in scheduling, timelier completion of ABR assessments, reduced wait time for outpatient assessments, and the ability to assess more infants prior to discharge leading to immediate intervention.¹

The Integrity™ V500 System is further being used successfully in telehealth programs which provide audiological services to rural and underserved populations via teleaudiology. The portability of the Integrity system means it is ideal to share and transport between locations, and its ease of use ensures remote assistants are easily trained. The advanced noise handling capabilities offer service providers the flexibility to conduct testing almost anywhere it is needed, without the need for sedation or shielding.



Clinical Significance of Advanced ABR Technology for Newborn Hearing Screening Programs [\[Read Article\]](#)



Advantages of the Vivosonic Integrity™ V500 System [\[View Video-3\]](#)

Summary of the unique technology behind the Integrity™ V500 System:

1. [Convenient Wireless Recording Technology](#). Wireless freedom of movement enables caregivers to comfort, hold and stroll with infants during testing.
2. [Patented Amplitrode®](#). The world's first *in-situ* bio-amplifier is a combination of pre-amplifier and electrode located at the recording site to provide maximum noise reduction.
3. [SOAP™ Adaptive Processing](#). A patented noise-reducing algorithm, based on Kalman Weighted Averaging, cleans electrophysiological signals and ensures exceptional response detection.
4. [Time-saving Tools](#). Concurrent display of two statistically independent waveforms and built-in statistical tools help to quickly evaluate waveform repeatability and residual noise. Alternating-split polarity enables the real-time display of cochlear microphonic.

The combination of wireless capabilities, along with new signal processing technologies and improved amplifier design, makes it possible to conduct ABR testing without sedation or anesthesia, test when an infant is awake, and obtain accurate results in places with high electromagnetic interference such as the neonatal intensive care unit (NICU) and operating rooms (OR).

For further details, please refer to the section, “III. Progressive Technologies for Efficient and Reliable Evoked Response Detection.”

The Integrity™ V500 System supports these test modalities: Awake/Non-sedated ABR, non-invasive ECoChG, DPOAE, TEOAE, automated ASSR, 40 Hz ERP and VEMP*.

(* VEMP is currently not FDA cleared on AEP equipment in the United States).

aurix™
Newborn Hearing Screening System



Easy Automated ABR

The choice of [newborn hearing screening equipment](#) is critical for accurate, efficient, and cost-effective screening outcomes. Vivosonic’s [advanced technologies](#) enable newborn hearing screening programs to screen and diagnose more infants with hearing loss before three months of age conveniently and quickly.

Aurix™, an advanced hearing screening system with fully [automated ABR](#), reliably screens awake newborns and high-risk infants in environments with high electromagnetic interference such as the neonatal intensive care unit (NICU). Wireless technology provides the needed flexibility to safely screen infants in incubators or while comforted in their mothers' arms.



Quality Product Initiative in
Newborn Hearing Screening
[\[Read Article\]](#)

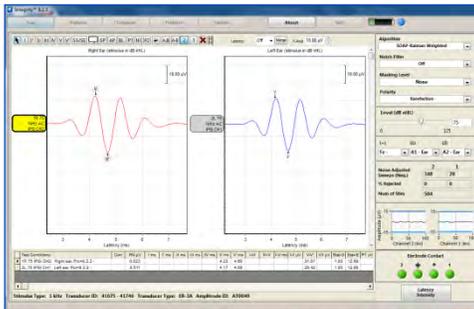


Aurix™ Newborn Hearing Screening System
See it. Try it. Believe it.
[\[View Video-4\]](#)

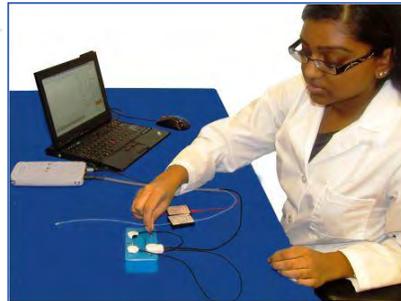


Optimize your Integrity™ Experience

Have you ever wondered whether your system is recording accurately and your patient has true hearing loss? The [VivoCheck™](#) is a portable, quick and easy-to-use tool to check the performance of the Integrity™ V500 System. This practical device is a complete acoustic and electrical loopback system that verifies Integrity™ is performing optimally. In addition, it is designed to give an indication of the electromagnetic interference in the environment from a clinical perspective (i.e. environmental noise that can contaminate the traces). The VivoCheck™ is also a useful classroom tool that demonstrates various aspects of the acoustic stimuli used for AEP, the effects of physiological noise and electromagnetic interference on AEP measurements, as well as the effects of various test parameters on signal processing and waveform analysis.



Typical tone-burst stimulus waveforms with markers indicating peak-to-peak amplitudes.



The VivoCheck™ is used with the Integrity™ V500 System.

[\[View Video-5\]](#)

III. Progressive Technologies for Efficient and Reliable Evoked Response Detection

Every Vivosonic product is engineered with powerful and patented core technologies that enhance auditory evoked response detection and provide significant clinical benefits.

Vivosonic technologies that have proven advantages:

1. [Convenient VivoLink™ Wireless Technology.](#)

2. [Patented Amplitrode®](#).
3. [SOAP™ Adaptive Processing](#).
4. [Time-saving Tools](#).

It is the combination of these unique technologies that effectively minimizes artifact due to patient movement and electromagnetic interference in the environment in the evoked response waveform, and simplifies the analysis and interpretation of the data. The significance of these technologies is evident in the Integrity™ V500 System and Aurix™ Newborn Hearing Screening System as discussed in the following sections and supported by clinical evidence in “*IV. Clinical Evidence Confirms the Benefits of Vivosonic Technology.*”

1. Convenient VivoLink™ Wireless Technology

Technology that can provide complete wireless communication between the recording platform and the electrodes has valuable benefits. As a battery-powered unit, the VivoLink™ is immune to line noise. Furthermore, elimination of wires reduces susceptibility to electromagnetic interference in the recording environment. Overall, this means there is less noise to manage which translates to very clean waveforms in very little time. Wireless recording also makes it possible to collect data while a baby is held, strolled, or nursed – untethered to equipment. In the case of high-risk babies in the NICU, the VivoLink™ enables babies to be tested inside an incubator while the recording platform remains outside. The incubator may even be closed shut while testing is in progress, with the recording platform up to 30 feet (10 meters) away. This technology also permits children and adults the freedom to move and be tested in comfort.²

Clinical Benefits

- * Freedom of movement
- * Patient comfort
- * Clinical flexibility and convenience
- * Reduced impact of power line interference
- * Testing in incubators or isolation rooms
- * Wireless recording up to a distance of 30 feet (10 meters)
- * Wearable configurations for children and adults

[\[View Video-6\]](#)



VivoLink™ wireless recording technology provides freedom of movement.
[\[View Video-7\]](#)

2. The Patented Amplitrode®

This patented technology provides two distinct innovations:

filtering of the ABR before amplification, along with amplification of the signal directly at the recording electrode site. By pre-filtering the signal, the effects of EOG, ECG, motion artifact, and RF are almost completely eliminated. Gain adjustments are no longer needed, and the risk of signal saturation is reduced. Furthermore, by amplifying the signal “in situ” (at the recording site), sources of noise from the recording environment are reduced and the result is the recording of a more robust ABR signal. In contrast, the lack of in-situ amplification in conventional systems means that amplification occurs after

the signal has had to travel from the electrode, along a cable, all the way to a preamplifier. With the cables acting as an antenna, there is a great deal of opportunity for noise to be introduced from sources present in the recording environment. Line noise and additional wires also contribute to contamination of the signal. Now, when the signal reaches the preamplifier, it is contaminated with all sorts of noise which is subsequently amplified. The patented Amplitrode® eliminates many of the problems related to extraneous noise by pre-filtering and amplifying immediately at the site of data

Clinical Benefits

- * Cleaner EEG signals in the NICU, ICU, OR, offices, and environments with high electromagnetic noise
- * Eliminates the need to adjust gain
- * No signal saturation and clipping
- * Spring release buttons for safe and easy mounting on snap electrodes

[\[View Video-8\]](#)

acquisition, before the signal has had a chance to pick up undesirable noise.²



The two-channel Amplitrode® is patented technology that combines an amplifier with an electrode.



Amplitrode® with built-in pre-filtering and amplification at the recording site.

3. SOAP™ Adaptive Processing (based on Kalman Weighted Averaging)

SOAP™ (Signal-to-Noise Optimized Adaptive Processing) is a combination of patented and proprietary technologies that adaptively reduce the myogenic and electromagnetic noise in ABR. It is an evolution of signal processing algorithms that use Kalman Weighted Averaging. Together with the VivoLink™ wireless technology and the Amplitrode®, SOAP™ provides superior response detection under non-ideal conditions and facilitates non-sedated ABR measurement. As with Kalman Weighted Averaging techniques, there is no artifact rejection. Instead,

Clinical Benefits

- * Clear waveforms in less time
- * Better handling of myogenic artifacts
- * Eliminates the need to adjust gain
- * No signal clipping or signal saturation
- * No rejection artifact setting

all sweeps are included in the main waveform and assigned a weighting based on their noise content. Groups of sweeps with less noise are assigned a much greater weighting than sweeps with higher amplitude noise. Thus, noisy responses have less of an impact on the waveform morphology relative to quieter responses. By including all sweeps, and by weighting them according to the noise content, one can actually obtain a much clearer ABR waveform in less time. In addition to Kalman Weighted Averaging, other SNR Adaptive Processing methods are used throughout the measurement in order to reduce noise and optimize the generation of the underlying AEP waveform. The system recalculates all weightings according to the noise content and the relationship between

sweeps (covariance). This very active and unique dynamic weighting system provides much cleaner waveforms in much less time.²

In addition to the main waveform, the SOAP™ algorithm also concurrently generates two waveforms, “A” and “B”, each with half the sweeps of the main waveform. These two waveforms have the same statistical independence as if they were obtained sequentially and allow the clinician to compare the A and B waveforms without having to repeat the test. The A and B buffering is based on a statistical distribution of the estimated noise between the two concurrently generated waveforms.



Noise Reduction to Achieve Quality ABR Measurement
[\[Read Article\]](#)

“Most audiologists would agree that noise is the foremost frustration with clinical auditory brainstem response (ABR) measurements. In this context, noise refers to interference from electromagnetic and myogenic sources which make it challenging to recognize and detect the true response in ABR waveforms. Whether employing ABR for neurodiagnostics, for estimating hearing ability, or for screening, noise is a common and persistent issue.”²
- A. Marcoux, Ph.D. & I. Kurtz, MSc, PEng.

4. Time-saving Tools

The following features help to reduce the overall test time and allow you to test more patients in a day.

a) Real-time repeatability

The repeatability of AEP responses can be readily visualized in real-time with the help of the concurrent display of two statistically independent waveforms (A and B) generated from different sets of sweeps obtained during data collection. These two independent waveforms enable the visual inspection of the response without repeating the collection protocol. In addition, objective statistical measures such as correlation coefficients are calculated between the A and B waveforms to further enhance confidence in waveform interpretation. Together, visual inspection and statistical repeatability help to reduce test

time, especially in cases where reproducibility is quickly evident. Once repeatability has been determined in real-time, there is no need for post-facto collection of more sweeps.

b) Noise estimation

An “A-B” (A minus B) trace is the difference between the two independent waveforms and represents a real-time visual noise estimate. The corresponding statistical estimate, the Residual Noise (RN) is calculated from the “A-B” trace. Both the visual trace and statistical residual noise estimates help the clinician determine the amount of noise in the waveform and when to stop data collection when no response is present.

c) Alternating-Split polarity

Alternating-Split polarity is a combination of the alternating stimulus with the real-time dual-buffering with all of the condensation sweeps averaged in one buffer and all of the rarefaction sweeps averaged into the other buffer. The difference between these buffers (the “A-B” trace) is not only a noise estimate, but also displays the cochlear microphonic in real-time. This can facilitate the clinical diagnosis of auditory neuropathy spectrum disorder and Ménière’s disease.



Statistical tools for evaluating waveform repeatability.

[\[View Video-9\]](#)

IV. Clinical Evidence Confirms the Benefits of Vivosonic Technology

“Availability of the Vivosonic Integrity reduces the need for sedation...reduces the wait time for ABR assessment... useful in the objective assessment of adult patients...”³

- J.W. Hall III, Ph.D. & T. Sauter, M.S., CCC-A

Clinical evidence from independent [research studies and leading experts](#) in the field of audiology validates Vivosonic technology and demonstrates the practical advantages of the Integrity™ V500 System over conventional AEP equipment.

Benefits of Vivosonic Technology	Clinical Evidence
Integrity reduces the need for sedation	By 66-92% ^{3,4}
Integrity reduces healthcare costs	By at least 85%. ³ By up to \$5000 USD per patient. ^{5,6}
Integrity reduces wait times for ABR assessment	From > 2 months to < 3 weeks. ^{1,3} From 5-6 months to 1 week. ⁴
Integrity has significant impact on Universal Newborn Hearing Screening referrals	Increased ability to complete diagnostic testing while a baby is an inpatient. ¹ Reduced need for follow-up appointments. Ability to test older awake babies. ⁴
Integrity is less susceptible to physiological noise compared to conventional AEP systems	Significant advantage at 50-60 dB peSPL (~15-25 dB nHL) in steady-state motor noise condition with 30-44% greater probability of obtaining a response. Possible to initiate test while infant is awake and obtain wave V at 20 or 30 dB nHL. ⁵ Thresholds in (physiologic) noise at 4 kHz were significantly more reliable – fewer “No Responses” – than a competing product. ⁷ In the “Active” condition, significantly more subjects had normal Wave V thresholds with Vivosonic than a conventional machine. ⁸
Integrity is less susceptible to electrical artifact	In 4/5 cases, Integrity showed lower (better) thresholds in the NICU than a conventional AEP system. ⁹ Effective in managing electrical and muscular artifacts for NICU ABR testing. The environment did not have to be altered to perform newborn hearing screenings. ¹⁰
Integrity obtains estimated auditory threshold more efficiently	Average time for ABR assessment reduced to 1 hour 20 minutes. No longer need to reserve 3 hours for an outpatient visit. ¹ Measure AC and BC thresholds in both ears at multiple

	frequencies in lightly sleeping or awake infants in less than 1.5 hour, including time for other activities. ¹¹
Integrity accurately measures hearing thresholds and provides information that contributes to clinical decisions	Contributed to management decision in over 90% non-sedated cases. ³ Clinical decisions were same or better in 95% of ears tested. ⁹ AC and TB ABR threshold responses were similar to published findings of conventional equipment that measured accuracy. ¹¹
Integrity is effective for testing difficult-to-test populations	Effective screening device for children who are difficult to test by behavioral methods. Significantly increased completed screening from 57% (behavioural only) to 81% (behavioral and ABR screening). ¹² High success rates using clicks and 500 Hz TB stimuli (without sedation) with patients with cerebral palsy. ¹³ Subjects with true noise-induced hearing loss can be distinguished from those who are malingering. With other ABR systems, patients who are malingering are able to delay a response indefinitely, elevating their thresholds to levels that entitle them to receive insurance benefits. ¹⁴



Clinical Experience with New Technology
for Recording Un-Sedated ABRs
[\[Read Article\]](#)

Integrity™ V500 System presented at NCHAM Workshop
with James W. Hall III, Ph.D.
[\[View Video-10\]](#)

V. Why do Customers Choose Vivosonic?

“...almost as important as the equipment itself is the customer service a company provides. Vivosonic has always provided excellent service and support.”

- Dr. F. Cunningham, AuD, CCC-A, ABA

The top reasons customers choose Vivosonic:

- The important clinical benefits of more reliable ABR;
- The company’s commitment to exceptional customer service;
- The team’s dedication to the continuous improvement of their products and services;
- The ongoing investment in R&D to develop innovative solutions to hearing healthcare challenges.

About Vivosonic

Vivosonic Inc. is a leader in the development of innovative technologies that enhance auditory evoked response detection. The company develops, manufactures and markets the [Integrity™ V500 System](#) for auditory diagnostic measurement and the [Aurix™ Newborn Hearing Screening System](#), and is ISO 13485 certified. Vivosonic products are designed to help busy professionals improve clinical efficiency and patient care. Portable and easy to use, with convenient [wireless capabilities](#), superior handling of myogenic artifact, and immunity to electromagnetic interference, Vivosonic products enable reliable ABR measurement, without sedation, when and where you need it.

Vivosonic invests heavily in R&D, and is recognized in the industry for developing [unique solutions](#) to the everyday challenges faced by hearing healthcare professionals. The company holds patents on proprietary [SOAP™-Kalman algorithm](#) techniques for advanced signal processing of evoked potentials, as well as the award-winning [Amplitrode®](#) technology, a combination electrode and amplifier. Together with the VivoLink™ wireless capabilities, these technological advancements make it possible to obtain an earlier diagnosis, and test more patients, in more places, with a significant reduction in the need for sedation. Visit www.vivosonic.com for more information.

VI. Vivosonic Would Love to Hear from You!

Thank you for taking the time to learn about Vivosonic and the advantages of its technology and products. To request additional information or to book a product demonstration, please contact info@vivosonic.com.

E-mail: info@vivosonic.com

Telephone: 1.416.231.9997

Website: www.vivosonic.com

“Since our son’s diagnosis, we have met numerous families of newborn babies that were going through the same frustrations and were having a difficult time getting results. They were either referred for a sedated ABR or further regular sleep ABR, both forcing them further into the future and thus losing precious hearing time for the babies. It would just be so easy and comfortable if these families would have access to Vivosonic testing for their infants.” - Letter from a parent [\[Read More Success Stories\]](#)

VII. Selected Articles & Presentations

Abstracts, full articles, and additional references are available at www.vivosonic.com.

1. Walker B (2012). Clinical Significance of Advanced ABR Technology for Newborn Hearing Screening Programs.
2. Marcoux A, Kurtz I (2013). Noise Reduction to Achieve Quality ABR Measurement.
3. Hall JW III, Sauter T (2010). Clinical Experience with New Technology For Recording Un-Sedated ABRs.
4. Sebzda JM (2010). Pediatric ABR testing without sedation? Is it possible?
5. Cone B, Norrix LW. University of Arizona. "Measuring the Advantage of Kalman-Weighted Averaging for Auditory Brainstem Response Hearing Evaluation in Infants". American Journal of Audiology, Newly Published on May 22, 2015. doi:10.1044/2015_AJA-14-0021, 2015.
6. Cone B, Dean J, Norrix L, Velenovsky D (2013). Innovations in the Electrophysiologic Assessment of Infant Hearing: Cost Model.
7. Wheeler JK (2011). The Effect of Kalman Weighted Filtering and In-situ Pre-amplification on the Accuracy and Efficiency of ABR Threshold Estimation.
8. Meyer D, Moskop J, Winston A, Schupbach J (2011). ABR Results in Quiet and Active Subjects.
9. Brown DK, Hunter LL, Baroch K, Eads E (2011). Comparison of Auditory Brainstem Response Systems in the NICU Population.
10. Johnson K (2012). Universal Newborn Hearing Screening in the NICU Population Using New Features of the Vivosonic Integrity ABR Unit: Assessing the Correlation Coefficient as a Function of the Number of Sweeps Collected.
11. Elsayed AM, Hunter LL, Keefe DH, Feeney MP, Brown DK, Meinzen-Derr JK, Baroch K, Sullivan-Mahoney M, Francis K, Schaid LG. Cincinnati Children's Hospital Medical Center. "Air and Bone Conduction Click and Tone-Burst Auditory Brainstem Thresholds Using Kalman Adaptive Processing in Nonsedated Normal-Hearing Infants." Ear and Hearing, Published Ahead-of-Print doi: 10.1097/AUD.000000000000155, 2015.
12. Wieggers JS, Bielefeld EC, Whitelaw GM. The Ohio State University. "Utility of the Vivosonic Integrity™ auditory brainstem response system as a hearing screening device for difficult-to-test children". International Journal of Audiology, April 2015, Vol. 54, No. 4, Pages 282-288.
13. van der Westhuizen C (2010). The Clinical Utility of the Vivosonic Integrity Auditory Brainstem Response System in Children with Cerebral Palsy.
14. Steinman A, Holdstein Y (2013). Use of the Vivosonic Integrity V500 System to Identify False Indications of Noise Induced Hearing Loss.
15. Wilson U, Kaf W (2013). Accuracy of TB-ABR and 40-Hz Automated & Sinusoidal ASSR Thresholds in Normal-Hearing Adult Females using Kalman-Weighted Filtering.