

Integrity™ Technology: Making ABR Practical

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Abstract

Integrity™, the world's first and only Bluetooth® wireless ABR system, extensible to TEOAE, DPOAE, ASSR, largely eliminates noises and artifacts which often make conventional equipment difficult or impossible to use in many clinical environments. The focus of this paper are the newest ABR-recording technologies: in-situ amplification and filtering, wireless communications and Kalman-weighted averaging. Employed in the Integrity™, these technologies allow non-conventional ABR testing: in non-shielded rooms and with non-relaxed patients. Bluetooth® wireless, simple user interface, integrated database, portability, and many other features make it convenient and easy to use in hospitals and private practices.

Key words: Auditory Brainstem Response (ABR), Bluetooth® wireless communications, in-situ pre-amplification, physiological artifacts, electro-magnetic interferences, digital signal processing.

ABR Measurement

ABR response

ABR is a short, transient response elicited by short-duration stimuli, wide-band *click* or frequency-specific *tone burst*. Normal ABR has a very characteristic wave morphology, with its prominent waves I-V appearing within 1-10 seconds after stimulus, of which wave V has the largest amplitude (Fig. 1).

ABR is a combined synchronized response of ON-neurons of the VIIIth nerve and brainstem, and presents valuable information on their function. It is widely used in the diagnostics of cochlear vs. retro-cochlear pathology, particularly Auditory Neuropathy/Auditory Dys-Synchrony, and intra-operative monitoring [1, 2, 3]. In infants and young children, it is widely used for hearing screening, diagnostics, and predicting hearing thresholds [1, 2, 4].

The latencies of waves I, III, and V; inter-peak intervals I-III, III-V, and I-V; and the ratio of amplitudes of waves V and I (V/I ratio) are used in diagnostics, while identification of wave V is used in screening and threshold prediction. Hence, clear recording of waveforms is essential for the use of ABR: the clearer the response, the better the wave morphology, the easier it is to identify and label the waves and define their latencies.

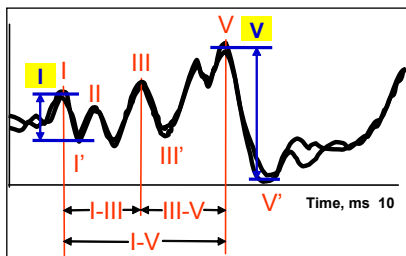


Figure 1. Typical normal ABR response waveform elicited by clicks at high (diagnostic) stimulus level (75-80 dB nHL). It is shown with two repetitions, as required to ensure repeatability of results.

ABR amplitude is very small, only 0.1-1 microvolt (μV), i.e. less than a millionth of a Volt. The frequency range of ABR is 50-3,000 Hz [1]. Recording such a faint signal requires significant signal *amplification* and *filtering*. Moreover, *digital signal processing* (DSP) is needed to synchronously collect a large number of responses (*sweeps*) to numerous stimuli in order to uncover the response from the background noise, which noise we will discuss below in detail. This is achieved with specialized equipment – ABR recording system.

ABR recording system

ABR is recorded with a system that contains patient-mounted electrodes, a differential amplifier, and a computer (Fig. 2).

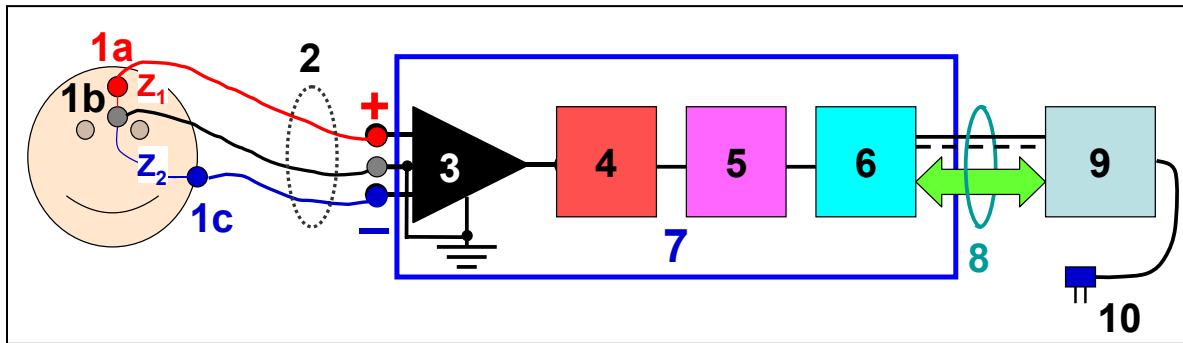


Figure 2. Conventional ABR recording system: 1a – non-inverting (+) electrode (shown placed on higher forehead, Fpz), 1b – ground electrode (shown placed on lower forehead, Fz), 1c – inverting electrode (shown placed on the left ear lobe, A1), 2 – electrode lead wires (leads), 3 – differential preamplifier, 4 – band-pass filter (typically 30-3000 Hz for ABR), 5 – power amplifier, 6 – analog-to-digital (A/D) converter, 7 – interface module, 8 – interface cable, 9 – personal computer (typically notebook), 10 – power cord.

Electrodes (1) are mounted on the patient's skin. Two of the electrodes are signal electrodes: *non-inverting* (1a) also called positive (+), *inverting* (1b) also called negative (-), and one electrode is neutral also called *ground* (1c). There is always certain electrical impedance of the skin and subcutaneous tissues between the non-inverting and ground electrodes (Z_1), and between the inverting and ground electrodes (Z_2). The difference between Z_1 and Z_2 is *inter-electrode impedance mismatch* (EIM):

$$\Delta Z = Z_1 - Z_2.$$

Conventionally, electrodes are connected to the *differential preamplifier* (3) inputs via lead wires (2), also called *leads*. The length of each lead is typically in excess of 3 ft (1 m), and they are not shielded in most conventional systems. The non-inverting (+) and inverting (-) inputs of the differential preamplifier cancel a substantial amount of noise due to the opposite polarity of the inputs. This effect is called *common mode rejection* (CMR), and the level of CMR is called *common mode rejection rate* (CMRR).

CMRR depends significantly on ΔZ : The better the non-inverting and inverting inputs of the differential amplifier are balanced and the lower is ΔZ , the higher CMRR and the less electromagnetic interference. This is why monitoring ΔZ is important not only prior to, but also during ABR testing. CMRR decreases with frequency and becomes very low at frequencies above 20 kHz [5] which is why high-frequency, particularly radio-frequency (RF), interferences may easily enter the system.

ABR frequencies range from 50-3000 Hz. Frequencies below and above this range are “noises” for ABR recording, and therefore, have to be filtered out by a band-pass filter, typically with 30-3000 Hz range. In conventional systems, the band-pass filter (4) is placed between differential preamplifier and *power amplifier* (5). The total gain for ABR recording is typically around 10,000, but it is distributed unequally between the differential preamplifier and the power amplifier: Typically 1000 and 10 respectively in conventional systems.

For the computer to process a signal, it has to be converted from *analog* to *digital* form which is performed by an *analog-to-digital (A/D) converter* (6). The maximum amplitude and dynamic range of A/D conversion is limited by the number of bits composing the digital output of the A/D converter called *A/D resolution*. The higher the A/D resolution, which is typically 16 bit in conventional systems, the larger the A/D dynamic range. The high-frequency limit of the signal's digital representation depends on the number of samples per second presented in digital form called *sampling rate*: the higher the rate, the higher the maximum frequency that can be represented in digital form.

Noises and artifacts in ABR recording

Physiological artifacts

Electrodes pick up not only ABR, but any *physiological* potentials from multiple sources:

- The brain - Electroencephalogram (EEG).
- The eyes - Electrooculogram (EOG) and Electronystagmogram (ENG).
- The heart - Electrocardiogram (ECG).
- Skeletal muscles - Electromyogram (EMG).

Electroencephalogram (EEG), reflecting the electrical activity of the brain, has the amplitude when awake under 70-100 μV and the frequency range within 3-40 Hz. In light sleep though, the amplitude may rise up to 400 μV in a narrower frequency range centered around 10 Hz, and may saturate ABR preamplifier.

The eye houses an electric potential field that can be described as a fixed *dipole* with a positive pole at the cornea and a negative pole at the retina. The magnitude of this corneoretinal potential is in the range 400-1,000 μV in the frequency range of 0.5-10 Hz. When the eye rotates, this potential generates a signal measured at a pair of periorbital surface electrodes known as the *electro-oculogram* (EOG), or *electronystagmogram* (ENG) when generated by the eye rotation in response to vestibular stimulation. Useful in other areas, EOG and ENG are very strong and harmful artifacts for ABR, as they may saturate the preamplifier. This is why conventional ABR systems require the patient's eyes to be closed and not rotating.

Electrocardiogram (ECG) spectrum in adults spans 1-50 Hz with the amplitude up to 500 μV . In infants, it may reach higher frequencies due to their twofold heart-beat rates, and have larger amplitude due to closer proximity of the heart to the head (and electrodes), and more central position of the heart.

Muscular activity (EMG) generates very strong artifacts up to 200 μV , with the strongest artifacts for ABR coming from the facial and neck muscles. They are always present in non-relaxed patients and normally disappear in sleep, particularly under *sedation*. Yet, some muscles in relaxed and even sedated patients may move and generate artifacts, while in some patients such artifacts may be present even without visible body movements. Very importantly, EMG frequencies range 30-500 Hz, i.e. well within the ABR frequency range. This is why they pass the ABR band-pass filter, and in conventional systems their effect can be reduced only by *artifact rejection* in digital signal processing (see below).

Extraneous noises

Multiple *extraneous* noises appear at the differential preamplifier input: *conducted electric*, *electromagnetic field-induced*, and *radio-frequency (RF)* noises.

Conducted noises come from AC *power lines* (60 Hz and its numerous harmonics) through the power cord (10 in Fig. 2), as well as from computer (9) through the interface cable (8).

Electric and *magnetic fields* exist in any clinical environment. Especially strong electromagnetic fields are found in *non-shielded* rooms: operating rooms (OR), intensive care units (ICU), neonatal intensive care units (NICU), hospital wards, and doctor's offices. They come from surrounding electrical wiring and various equipment and introduce electro-magnetic *interferences* (EMI) in conventional ABR systems. EMI may be so strong that they can make ABR testing very difficult or impossible.

Electric fields come from building wiring and electrical equipment, and generate *voltage* in leads (2). The amount of contamination from the electric field increases with the length of the leads and the inter-electrode impedance mismatch ΔZ (Fig. 3).

Magnetic fields induce *currents* in the three loops of lead wires: between non-inverting and ground, inverting and ground, and non-inverting and inverting electrodes (Fig. 4). They are quite strong in clinical environments in North America, as can be seen from Table 1 [6]. The amount of contamination from magnetic fields is proportional to the *area* of the three loops formed by the leads [7].

Table 1. Magnetic field strength in various clinical environments generated by various sources.

Intensive care unit	0.1 - 220	Measured at nurse's chest
Post-anesthesia care unit	0.1 - 24	
Magnetic resonance imaging (MRI)	0.5 - 280	Measured at technician's work locations
Desk work locations	0.1 - 7	Peaks due to laser printers
Desks near power center	18 - 50	
Power cables in floor	15 - 170	
Computer center	0.4 - 6.6	
Can opener	3000	Appliance fields measured 6 in. away
Desktop cooling fan	1000	
Other office appliances	10 - 200	
Building power supplies	25 - 1800	

Magnetic fields also introduce so called *motion artifacts*. These are the electric currents induced in the lead wires when they move through a magnetic field which happens if the patient moves, and lead wires move with the patient [8].

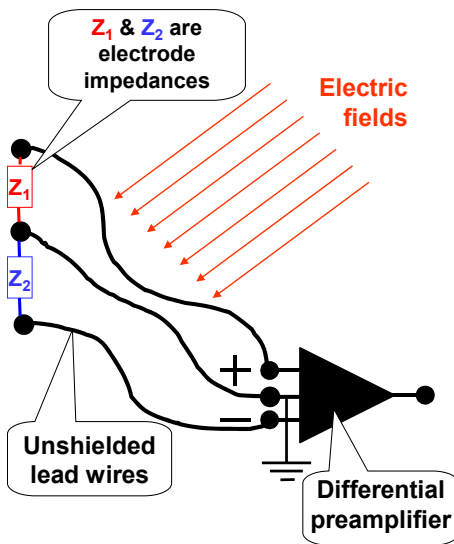


Figure 3. Electric fields generate *voltages* in electrode lead wires of conventional ABR systems.

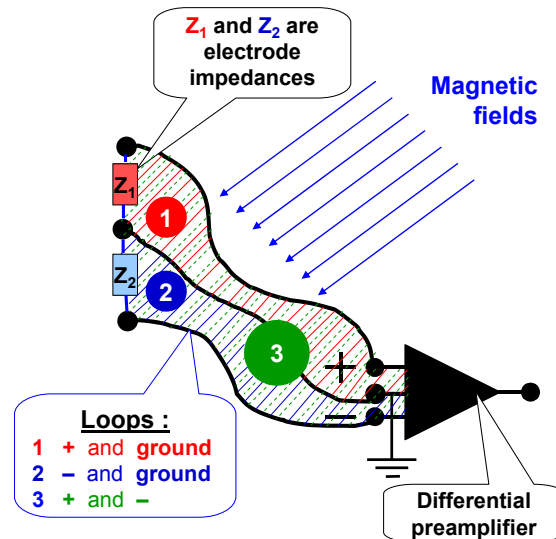


Figure 4. Magnetic fields induce electric *currents* in the loops created by electrode lead wires.

Radio-frequency (RF) field-induced noises are introduced in the differential preamplifier due to its *non-linearity* through a phenomenon called *rectification*, even though RF signals have manifold higher frequencies than ABR - in the Megahertz (MHz) and Gigahertz (GHz) ranges. Common-mode rejection is ineffective above 20 kHz and thus, does not protect against RF interferences. Moreover, if RF interferences rectify into the ABR frequency range, they cannot be filtered out by the band-pass filter, and will pass A/D conversion and complicate digital signal processing.

ABR signals and noises combined

Figure 5 summarizes graphically the signals and noises and artifacts in ABR recording: ABR signal is literally “buried” in noises. This makes ABR recording quite challenging in many clinical environments: 84% of clinics in the U.S. ranked noise frustration #1 [9].

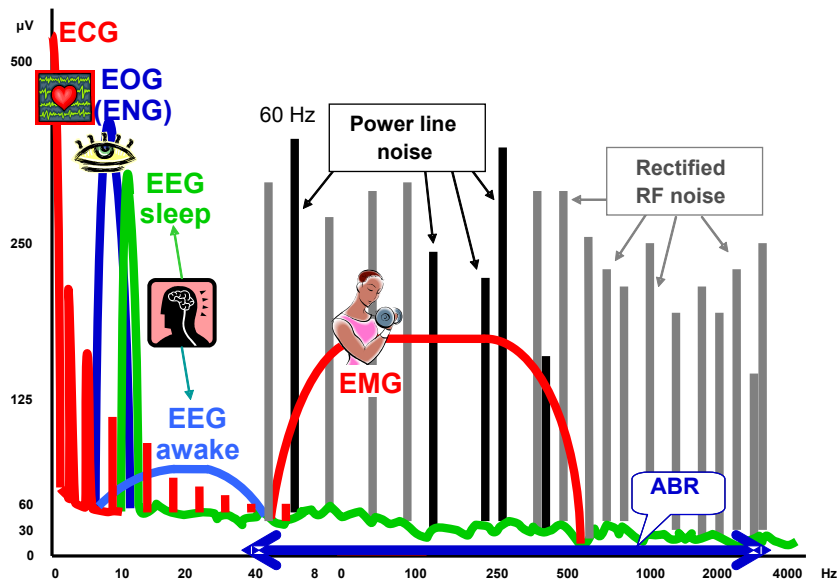


Figure 5. Spectrum of signals in ABR system: ABR signal is literally “buried” in noises.

Integrity™ approach to ABR recording

Vivosonic took a different approach to combat noises and artifacts in ABR recording:

- Signal pre-amplification *in-situ*, i.e. directly on the ground electrode.
- Analog band-pass filtering *prior* to pre-amplification.
- Bluetooth® *wireless* communication between the interface module and personal computer.
- Digital signal processing employing *Kalman-weighted* averaging.
- *24-Bit* A/D resolution.
- Monitoring electrode impedance mismatch ΔZ in real time.

In-situ amplification

An alternative arrangement that reduces the effects of electric and magnetic fields on AEP measurements is the Amplitrode™ (Fig. 6).

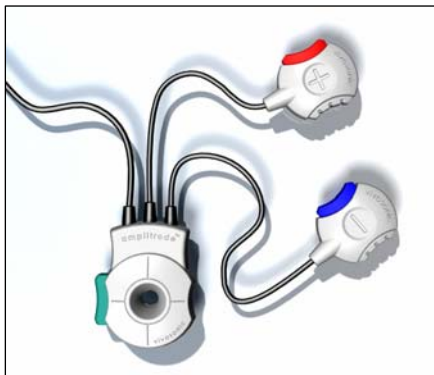


Figure 6. Amplitrode™ is an AEP differential preamplifier which is contained in a miniature housing with attached electrode clips. The Amplitrode™ circuitry is encapsulated in an air-tight plastic mold and electrically shielded. The leads from the Amplitrode™ to the Clips, which are mounted on the inverting and non-inverting electrodes, are short, electrically shielded, and grounded. This protects the Amplitrode™ from extraneous electrical fields and significantly reduces electric and magnetic field-induced noises.

The Amplitrode™ integrates an ABR preamplifier and electrode clips that snap directly onto the ground electrode. This arrangement *eliminates* the ground lead wire completely [10]. As a result, AEP signals are amplified *in-situ*, which means “on the site” in Latin, i.e. where they appear on the skin. Furthermore, since the preamplifier is mounted directly on the patient's head (Fig. 7), the lengths of the inverting and non-inverting leads and corresponding loop areas are minimized. Finally, the short leads between the Amplitrode™ and the clips are electrically shielded.

The effect of *in-situ* amplification, i.e. eliminating the ground lead wire and shortening and shielding the other leads is shown in Figure 8 on the example of electro-magnetic field-induced noises.

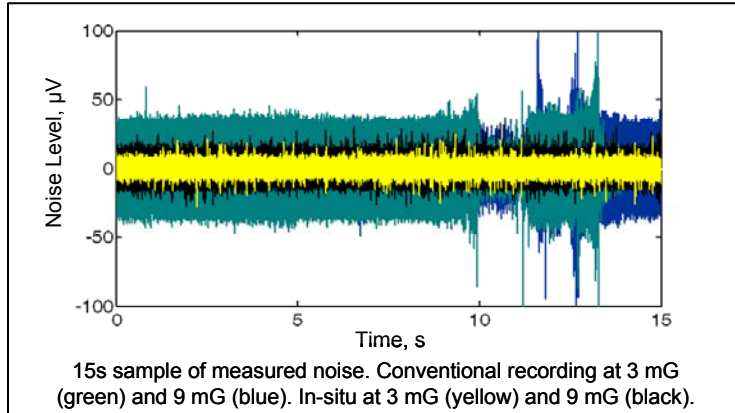


Figure 7. Magnetic field-induced noise at the Amplitrode™ output. It is shown with and without standard lead wires coupled to the Amplitrode™ in a 15-second sample. These noises were measured at the Amplitrode™ output with and without standard 3-ft (1 m) long lead wires taken from a conventional ABR system and connected to the Amplitrode and its clips, and mounted on the same electrodes in Fpz-A1-Fz montage.

The Amplitrode™ has two user-selectable gain and band-pass filter settings: 15,000 gain and 30-3,000 Hz filter are optimized for ABR, while 150,000 and 70-300 Hz are optimized for Auditory Steady State Response (ASSR).

Amplitrode™ convenience

The Amplitrode™ and both non-inverting (+) and inverting (-) clips have color-coded *electrode-release buttons* - red in the non-inverting clip and blue in the inverting clip (see Fig. 6). The buttons activate springs electrically connected to the Amplitrode™ ground and shielded cables of the clips: When the buttons are activated they release the springs, and the Amplitrode™ and its clips can be easily placed on or removed from the electrodes - effortlessly, without disturbing the patient. When the buttons are released, the springs clamp tightly on the nipples of the electrodes and establish reliable electrical contact.



Figure 8. Amplitrode™ placement. The Amplitrode™ is placed directly on the ground clip-type electrode. It is shown on the lower forehead of a one-month old infant, but can be placed in any position used for ground electrodes.

Filtering *prior* to pre-amplification

ABR signal is inevitably accompanied with physiological noises from numerous sources, particularly very low-frequency physiological signals coming from the ocular activity (EOG), brain activity (EEG), and cardiac activity (ECG) (see Fig. 5). Therefore, recording ABR requires filtering of the signal that comes to the input of the differential amplifier - in order to remove unwanted noises by passing the signal through a high-pass filter, which for ABR typically has the cutoff frequency of 30 Hz, and a low-pass filter which has the cutoff frequency of 3,000 Hz. Together, high-pass and low-pass filters compose a *band-pass* filter 30-3,000 Hz.

In the conventional differential preamplifier, ABR filtering is performed *after* pre-amplification. In such arrangement, the preamplifier is designed to amplify a broad-spectrum signal. This is why preamplifier is open not only to ABR signals, but also to EEG, EOG (ENG), and ECG.

Since EEG and EOG/ENG can be more than 100 times the magnitude of ABR [11], great care must be taken to ensure that the preamplifier gain is optimized: To maximize common-mode rejection and reduce field-induced noises, the preamplifier gain has to be large, but EEG and EOG/ENG would be also amplified with the same gain and may saturate the preamplifier. Subsequent analog (hardware) filtering cannot remove the created distortion [5]. Moreover, the operator may not even recognize such signal distortion, as the so-called “*on-going EEG*” found on the screen of any ABR system may display no significant artifacts, and sweeps with such distortion would not be rejected by artifact rejection, as they would not exceed the artifact-rejection threshold.

Saturation in the preamplifier can be avoided by reducing the preamplifier gain, but this arrangement has a significant disadvantage in its reduced common mode rejection ratio (CMRR) and, because of that, increased susceptibility to electro-magnetic field-induced noise [12]. Therefore, both too high and too low gain in a conventional preamplifier will result in higher noise contamination of the ABR signal.

The conventional arrangement of filtering *after* pre-amplification may also result in signal contamination due to radio-frequency (RF) interferences coming from cellular phones, wireless networks, personal digital assistants (PDA), and other high-frequency equipment [13]. As discussed above, conventional ABR amplifiers will demodulate (rectify) such high-frequency broad-band signals due to their non-linearity, causing an effective frequency shift of the RF-noise into the frequency range of ABR. Once this occurs, no amount of analog or digital low-pass filtering at the amplifier’s output can remove the error. Moreover, common mode rejection, which is the major purpose of differential ABR amplifiers, is typically ineffective for frequencies above 20 kHz [14].

A novel approach employed in the Amplitrode™ is to filter the input signal *prior* to its pre-amplification. Particularly, the Amplitrode™ applies a 30-Hz high-pass and a 2-MHz low-pass filtering. This technique eliminates contamination of the ABR signal by unwanted noises: Low-frequency physiological signals such as ECG, EOG/ENG, and most EEG noises are reduced by the high-pass filter. This, in turn, makes it possible to optimize the gains of both preamplifier and power amplifier for ABR, while preventing saturation and distortion in the preamplifier. Yet, RF interferences, which would be introduced in a conventional system by rectification, are prevented from entering the preamplifier.

Digital Kalman-weighted averaging (filtering)

Conventional ABR recording requires the patient to be “quiet”, i.e. is lying down, relaxed, asleep, or even sedated, in order to reduce muscular artifacts (EMG), as it dramatically contaminates the ABR signal. This is happening because EMG artifacts are in the frequency range of 50-500 Hz, i.e. within ABR frequencies (50-3,000 Hz) and thus, cannot be removed by band-pass filtering (30-3,000 Hz), while EMG amplitude (over 100 µV RMS) is manifold greater than ABR amplitude (0.1-1 µV).

The most commonly used DSP technique of reducing EMG artifacts in ABR recording is *averaging* numerous sweeps, typically 1.5-2 thousand. The sweeps containing artifacts greater than a certain pre-set value, called *artifact-rejection threshold* (ART), are excluded from averaging. This technique does not produce clear responses in the presence of muscular artifacts, and is time-consuming because many sweeps are rejected and it takes time to collect sweeps with amplitudes below ART.

To reduce the effect of EMG artifacts in conventional ABR systems, some clinicians utilize the “Pause/Resume” buttons of the user interface: During the test, they carefully watch the “On-going EEG” display, and press the “Pause” button when the noise is high, and “Resume” when the noise goes lower. However, this technique is as time-consuming as it is tiresome for the clinician.

A more effective technique for reducing the effects of EMG artifacts on ABR recordings is *weighted averaging*. Using this technique, recording periods that contain more artifactual noise are weighted less in the overall average than periods of relative quiet [15].

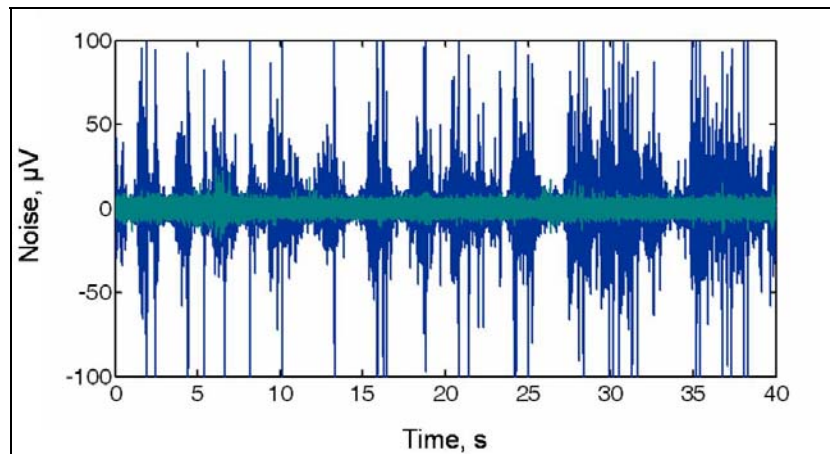


Figure 9. EMG artifacts in ABR recording. A 40-second sample of EEG experimentally obtained while an adult, male, 40-year old subject was resting (green) and eating (blue). In relaxation, EEG noise was within approximately $\pm 2\text{-}5\ \mu\text{V}$, while during facial muscular activity (eating) EMG contamination increased the noise amplitude to over $\pm 100\ \mu\text{V}$.

In the Integrity™, the relative weighting of recording periods is optimized based on a signal-processing method known as the *Linear Minimum Mean-Square Error Filter*, or *Kalman Filter* [16, 17, 18]. This technique estimates the error in each individual sweep based on the measurement *signal variance*, and continuously updates this estimate. Using this information, the Kalman filter produces an estimate of the ABR signal, in which the probability of error in the amplitude estimate at each latency is minimized.

By reducing the effects of intermittent EMG noise, the Kalman filtering technique allows ABR to be recorded accurately during substantial muscular activity of the patient, for example while the patient is moving, eating, or talking, or an infant is sucking - despite strong EMG artifacts that may be in excess of $100\ \mu\text{V}$ RMS (Root-Mean Square) [19]. Clinically, this means that any of the aforementioned patient muscular activity will not force the clinician to cancel, postpone, or prematurely terminate the scheduled ABR test.

Bluetooth® wireless recording

In ABR systems, there is an *interface module* that contains a differential amplifier, amplifiers for the stimulating transducers (insert phones and bone conductor), analog-to-digital (A/D) and digital-to-analog (D/A) converters (see Fig. 2). The interface module is connected to a personal computer (PC) which performs signal processing and controls the test. In a conventional ABR system, such connection is arranged via an *interface cable* connected to a serial or USB port. This connection may introduce significant electrically conducted noises into the preamplifier from the computer and the power line.

In the Integrity™, communication between the interface module and computer is performed through a *wireless* interface module, the VivoLink™ employing Bluetooth® wireless communications (Fig. 10, 11). Wireless communications between the interface module and computer completely eliminates *electrical path* between the computer and AEP amplifier, and as a result eliminates the introduction of electrically conducted noises from the computer and power line.

Bluetooth® is a wireless communications protocol employing a very low-energy (hence its limited range), broad-band digital signal in Gigahertz range which does not introduce RF interferences. It is encoded and therefore secure for transmitting medical information [20].

Wireless interface completely eliminates conducted noises from the power line and computer. This benefit is essential for ABR clear recording. Yet, it allows for very convenient ABR testing from a distance within the Bluetooth® range of about 30 feet (10 meters). For example, when testing infants, the VivoLink™ can be placed in an infant's crib, bassinet, incubator, stroller, or car seat, while the test-controlling computer can be placed anywhere within a 30-foot (10-meter) radius.



Figure 10. VivoLink™ has no cables connecting it to a computer – it communicates via Bluetooth® wireless communications. The glowing blue LED indicator informs that Bluetooth® is on.

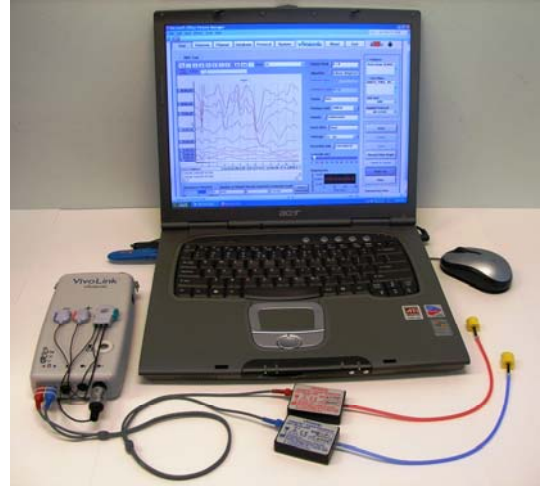


Figure 10. Integrity™ is a portable wireless ABR system extensible to TEOAE, DPOAE, ASSR.

In the Operating Room, the VivoLink™ can be placed near the patient, while the operator performing the ABR test, for example intra-operative monitoring, can be seated away from the operating table, even in another room, and without interfering the crew performing the operation [21].

The result is clear ABR in harsh environments and with non-relaxed patients

As the sources of noises and artifacts are numerous, only a combination of these technologies put together allows the Integrity™ to record exceptionally clear ABR responses in practically any clinical and non-clinical environment. Fig. 6 illustrates responses recorded in a general, non-shielded office from a non-relaxed subject.

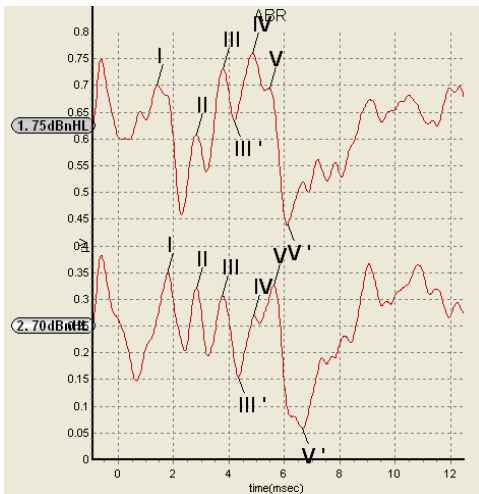


Figure 11. Example of Integrity™ ABR. Responses were recorded from the right ear of a normal-hearing, male, 50-year old subject in a general office, non-shielded environment. During the test, the subject's eyes were wide open, and the subject was moving, chewing, and talking. ABR were recorded ipsilaterally, in response to 70 and 75 dB nHL click stimuli, using Kalman-weighted averaging. The responses exhibit clear, easily recognizable ABR wave morphology.

Conclusions and clinical importance

The Integrity™, through its new technologies, is resistant to physiological artifacts, conducted noises, and electro-magnetic interferences. It allows for significant reduction or elimination of noises and artifacts in ABR recording: EMI - by *in-situ* amplification; EEG, EOG/ENG, ECG, RF - by filtering *prior* to amplification; conducted noise from AC power line and computer - by *wireless* communication; and EMG - by *Kalman-weighted* filtering.

Noise reduction enables recording clear ABR in *harsh electro-magnetic environments* where intensive electro-magnetic interferences are present, such as operating rooms (OR), NICU, ICU, doctor's offices, schools, etc., and with *non-relaxed* patients, i.e. with open eyes and active muscles. This makes ABR *practical* for testing patients of all ages in both hospitals and private practices, and can significantly enhance *clinical efficiency* – clinically and economically.

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About authors



Yuri Sokolov, Ph.D., MBA is President and Chief Executive Officer at Vivosonic. Yuri proposed the concept of the Integrity™ as a modular Bluetooth® wireless electrophysiological system.



Isaac Kurtz, M.H.Sc, B.Sc., P.Eng. is Director of Engineering and Research at Vivosonic. Isaac proposed the concepts of *in-situ* amplification, filtering prior to pre-amplification, and employing the Kalman Filter in ABR recording, and overall Integrity™ design.



Aaron Steinman, Ph.D., P.Eng. is Research Engineer at Vivosonic. Aaron conducted numerous experiments with characterizing EMG noises, ABR signal processing techniques, and optimized the Kalman Filter for ABR recording.



George Long, M.Sc. is Hardware Engineer and Team Leader at Vivosonic. George developed most of the Integrity™'s hardware, Amplitrode™ and VivoLink™, and implemented the Kalman Filter in Vivosonic's earlier ABR-recording algorithms.



Olena Sokolova, PhD, is Clinical Applications Specialist at Vivosonic. Olena developed clinical requirements to the Integrity™ and conducted numerous clinical ABR recordings with the Integrity™ within Vivosonic's rigorous program of internal clinical product testing. She also provides clinical application support to Vivosonic's customers.

Reviewed by **Jasna Szwagiel**, BA, and prepared for publication by **Donna-Maria Lakshman**.

Standards and regulatory approvals

Integrity™ has been developed and produced under Vivosonic Quality System certified to ISO 13485.

Integrity™ has the following regulatory approvals:

U.S.: FDA 510(k) # K043396.
Canada: Health Canada Licence 67609.
E.U.: CE Mark.

Standards applied in the design of Integrity™:

IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4,
EN 980:2003, EN 55011:1998, ISO 13485:1996, ISO 14971:2000.

Intellectual property

Integrity™ technologies and designs are protected by the following patents and patent applications:

U.S. Patents 6,463,411; 6,778,955.
U.S. Patent Applications 10/265,640; 60/556,881.
PCT Patent Application PCT/CA99/0155.
Canadian Patent Application 2,362,357.
European Patent Application 99953492.8.

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