Pediatric ABR testing without sedation? Is it possible?

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Don’t become a dinosaur
Change to:

Pediatric ABR testing without sedation? It is possible.
Background

- SENTAC – Society for Ear, Nose and Throat Advances in Children Milwaukee December 2007
- APNP – Did you see the new wireless ABR system that allows testing without sedation? “Yeah, right.” “Really, go see it.”
- Vivosonic, completed ABR while talking
- Asked to demo unit in clinic
- Used for 1 month in clinic
- Missed daily when returned
- Loss claim 😊
- SBARR
- Purchased first Vivosonic Integrity in November 2008
- 2nd system now at New Berlin Clinic
- Grant with Wisconsin Sound Beginnings
  3rd unit will travel to neighborhood CSG clinics
Special Thank You

- Vivosonic for supplying slides and system for demonstration
- Not a sales pitch, not a representative
- Share CHW experience
- Audiologists (12) convinced it works
- Very easy to learn
- Huge impact on sedation in the clinic
- Huge impact on UNHS program
NOISE AND LOW DEFINITION ARE THE BIGGEST PROBLEM IN CLINICAL ABR:
Artifacts, interferences, and low resolution reduce the accuracy of wave recognition and latency measurement, and thus, the screening and diagnostic value of ABR
Clinicians experience significant frustrations with ABR

ABR is often difficult to administer for many clinicians, particularly in harsh clinical environments such as NICU, hospital floor, doctor’s office, and Operating Room (OR):

Noise is reported by 84% of U.S. clinics as their FRUSTRATION # 1*)

Noise artifacts lead to unclear results and long test times – up to 90-120 min, typically 45-60 min per test

Long test time results in use of valuable OR time and difficulty of intra-operative monitoring

Risks associated with sedation

Sedation protocols – very complicated (JCAHO)

Abrading the skin, to reduce impedance, increases the risk of infection **) 

The above factors result in higher risks of misdiagnosis, infection, and operating costs, and reduce diagnostic value of ABR, particularly in medium and small clinics and private practices that do not have shielded rooms and sedation facilities

Physiological artifacts and extraneous interferences contaminate ABR signal

Physiological artifacts – from the patient
- Brain (EEG)
- Eyes (EOG)
  - Electric dipole movements (ENG) – very large
  - Ocular muscles (EMG)
- Skeletal muscles (EMG)
- Heart (mostly in infants) (ECG or EKG)

Extraneous interferences – from outside the patient
- Electric and magnetic field-induced interferences
  - Electric field-induced noise (EF)
  - Magnetic field-induced noise (MF)
- Radio-frequency interferences (RF)
- Conducted power-line noise: 50 or 60 Hz and their harmonics
PHYSIOLOGICAL ARTIFACTS

are coming from the patient, independent from the environment, and thus cannot be “shielded”
ABR and ASSR signals are contaminated with physiological artifacts.
EXTRANEOUS NOISES

are coming from the environment (EM interferences) and testing equipment (system noise)
Lead wires and cables introduce large electric and magnetic field-induced noises in a conventional AEP amplifier.

Amp – amplifier (Preamp + BPF + Power Amp)
A/D – analog-to-digital conversion
DSP – digital signal processing
RF noise may strongly interfere with EP recording

Radio-frequency (RF) noise comes from various sources:
- Cell phones, pagers, Blackberry, wireless intercom
- FM-systems, FM-radio
- Wireless computer networks used in many hospitals
- PDAs (Personal Digital Assistants), Palmtops
- Medical equipment (ICUs, operating rooms, general offices)
- Office equipment: copiers, fax-machines, computers

Introduce electro-magnetic noise

Interferes at EP (low) frequencies despite the fact that RF frequencies are much higher – in MHz and GHz ranges – through rectification because of amplifier non-linearity

There is no common-mode rejection (CMR) at frequencies ≥ 20 kHz

Amplitude: up to 10 mV

Conducted noises come from AC power line through power cord and from AEP system computer through the cable.

**Sources**
- **Power line** – low frequency
- **PC** – low and high frequency

**Interferes** with AEP at a *number* of frequencies – mostly 50 Hz (60 Hz) & its harmonics – within the frequency range of ABR and ASSR:

- **60 Hz AC**: 60, 120, 180, 240, 300, 360 Hz …
- **50 Hz AC**: 50, 100, 150, 200, 250, 300 Hz …

… hence, 50/60 Hz **Notch Filter** may *not* help

**Amplitude** can be large: up to 1-10 mV
Conventional AEP system provides little protection to ABR signal from physiological artifacts and extraneous noises.

1 – Electrodes placed on the scalp:
   1a – non-inverting (+) with impedance $Z_1$
   1b – inverting (–) with impedance $Z_2$
   1c – neutral (ground)

2 – Electrode lead wires typically 3 ft (1 m) & cable, typically 6 ft (2 m)

3 – *Differential* preamplifier (typical gain $\times 1000$) – for Common Mode Rejection

4 – Band-pass filter (typical range 30 – 3000 Hz)

5 – Power amplifier (typical gain $\times 10$)

6 – Analog-to-digital (A/D) converter (typically 16 bit)

7 – Interface module (brand-name “box” containing electronics)

8 – Interface cable between the module and PC (power and signals)

9 – Personal computer (PC)

10 – Power cord
ABR tests in pediatric patients often require sedation or anesthesia which need special monitoring and management.
AAP Guidelines: Sedation and anesthesia impose serious risks on the child

Sedation of pediatric patients has serious associated risks, such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment. These adverse responses during and after sedation for a diagnostic or therapeutic procedure may be minimized, but not completely eliminated, by a careful preprocedure review of the patient’s underlying medical conditions and consideration of how the sedation process might affect or be affected by these conditions. Appropriate drug selection for the intended procedure as well as the presence of an individual with the skills needed to rescue a patient from an adverse response are essential. Appropriate physiologic monitoring and continuous observation by personnel not directly involved with the procedure allow for accurate and rapid diagnosis of complications and initiation of appropriate rescue interventions.
CHW Sedation Protocol

- 17 page document
- Physician
  - moderate sedation privileges
  - available during procedure and recovery
  - complete and bill for airway assessment
- Nurse
  - administers chloral hydrate
  - monitors vital signs
  - bill every 15 minutes after 1st 30 minutes
- Audiologist
  - bill for ABR/DPOAE’s/tympanogram
- High risk or over 30lbs go to Day Surgery for general anesthesia
  - bill for hospital procedure room charge
  - bill for Anesthesiologist
- Currently 3 levels of sedation – clinic, radiology suite, OR/Day surgery
- Costly but necessary testing
NEW VIVOSONIC ABR TECHNIQUES:
Recording in virtually any patient, any environment, and with high definition
Integrity™ is the world’s first and only Bluetooth® wireless analyzer for Auditory Electrophysiology

VivoLink™
Bluetooth® Wireless Interface Module

Amplitrode®
In-situ AEP amplifier

Integrity™ has been developed and is produced with a Quality System certified to ISO 13485:2003

Integrity™ regulatory clearances
U.S.: FDA 510(k) K043396
Canada: Health Canada Licence 67609
E.U.: CE Mark

Cleared modalities: ABR, ASABR (Automated Screening ABR), ECochG, TEOAE, DPOAE, ASSR

Integrity and VivoLink are trade marks of Vivosonic Inc.
Amplitrode is a registered trade mark of Vivosonic Inc.
A combination of new techniques was employed to eliminate interferences and artifacts in ABR.

**In-situ amplification** – on the ground electrode – protects from EMI.

- **High-resolution A/D conversion** increases the accuracy of ABR.
- **Kalman-weighted filtering in DSP** removes EMG artifacts.
- **Wireless interface** eliminates conducted power noises and AC isolation transformer.

**In-situ band-pass filtering** eliminates EOG, ECG, and EEG artifacts, and RF interference.

Battery operation provides “clean power”.

**Bluetooth®, a registered trade mark of Special Interest Group (SIG)**
In-situ amplification mostly eliminates electric (EF) and largely reduces magnetic (MF) field-induced noises.

In-situ, electrode-mounted pre-amplifier, the Amplitrode™, eliminates the ground lead, with the other leads very short and shielded.

This significantly reduces electric and magnetic field-induced interferences and enables a clearer EP signal at the amplifier output.
Wireless communication eliminates *conducted* interference from power lines and enables the ultimate electrical safety

**Bluetooth® wireless protocol**

- Radio-frequency (RF) signal at 79 randomly hopping carrier frequencies in 2.40-2.48 GHz (billions of Hertz) range, less than 0.4 second at each frequency
- Low energy – no RF interference – certified EMI Class B – can be used at home
- Encoded transmission – secure for medical information
- Allows testing from a distance 30 feet (10m) – ideal for Operating Room monitoring and other testing situations where close proximity to the patient is not desired – ultimate patient mobility

**VivoLink™ RF data**

- Bluetooth Spread Spectrum Transmission 2,402-2,480 MHz (2.40-2.48 GHz)
- Emitted RF Power 1.02 mW maximum

**VivoLink Bluetooth® RF regulatory clearances**

- U.S. FCC Part 15 Spread Spectrum Transmission # TVZ-V50
- Canada IC 6273A-V50
Kalman filter estimates ABR signal by extracting the signal from each sweep – with no rejection

**Model of System Process**

- **Error associated with the Model of System Process**
- **Covariance error matrix**
  - (noise associated with predicted ABR signal)

**Prediction Stage**

- \( X_p = G \hat{X}^- \)
- \( P_p = G \hat{P}^- G + Q \)

**Measurement Update (Estimation) Stage**

- **Kalman gain (weight)**
- **Covariance error matrix**
  - (noise associated with estimated ABR signal)
- **Error associated with Measured ABR signal**
  - (how noisy is the sweep)

- **Measured ABR signal**
  - (Buried in EEG)

- **Predicted ABR signal**
- **Estimated ABR signal**
- **Displayed ABR trace**
  - (waveform)

U.S. Pat. 6,463,411, 6,778,955. Other U.S. and European patents pending.
Kalman filter rejects no artifacts, but weights each sweep according to signal variance within recording window.

Kalman filter would consider this sweep “quieter” with higher weight contributing to a clearer ABR trace, while averaging with 20 µV ART would reject it and thus “miss” a “good” sweep.

Kalman filter would consider this sweep “noisier” with lower weight avoiding noise contamination, but averaging with 20 µV ART would accept it resulting in a noisier ABR trace.

R - Error associated with measured ABR signal: “Quieter” sweeps have lower R.
24-bit A/D resolution and high 38,400-sps sampling rate result in high resolution – High Definition ABR™

High-definition ABR is illustrated by an example of visual image resolution*)

<table>
<thead>
<tr>
<th>1</th>
<th>4</th>
<th>25</th>
<th>100 pixels</th>
<th>400</th>
<th>2,500</th>
<th>10,000</th>
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Image illustrating conventional ABR resolution with 16-bit A/D and low sampling rate 25 pixels

Image illustrating Integrity™ ABR resolution with 24-bit AD and high sampling rate 10,000 pixels

High-definition ABR™ enables clear determination of diagnostically valuable ABR waves

Click-ABR waveform, recorded from RE of a normal-hearing subject at 80 dB nHL, shows clear morphology with precisely measurable wave latencies.
Integrity™ ABR

Freedom in Audiology
Freedom from Sedation
test “most” children at any age
Freedom from wires

- VivoLink™, uses Bluetooth technology, no wires connecting patient to PC
- Test up to 30 feet away
- Run on battery, no power cord
- Portable, lap top PC – carry between clinics
- HUGE benefit
Freedom from interference

- Electrical
  - Computers, MRI, ect.

- Patient
  - Awake, eating, drinking, nursing, playing and watching DVD’s
Integrity™ allows recording clear ABR in the NICU and other settings with electromagnetically harsh conditions.

Non-sedated, premature 10-week-old infant girl, in a large hospital NICU, suckling on her pacifier. Conventional ABR results unattainable. Integrity™ allowed recording clear ABR to 35-90 dB nHL clicks.
PRACTICAL APPROACHES TO NON-SEDATED ABR TEST:

With the artifacts and interferences not being an issue, practical approaches still need to be taken

- Screen patient referrals – tolerate insert earphones
- Review test process with family in detail, bring food, toys, movies
- Schedule 2 hours
- Set appropriate expectations, unsuccessful, need sedation
- Better position the system and the child.

- Keep the child from removing electrodes and inserts.
- Keep the child from continuous crying which would acoustically mask the stimuli and elevate thresholds.

... And here’s how it can be done
Testing NICU infants is convenient right in the incubator, without taking the infant out, and no cables around.

When testing in an NICU, VivoLink™ is placed in or on the incubator, and the test is administered from an up to 30-foot (10 meter) distance.

Shown: ABR administered in a premature, 10-days old (gestational 31 weeks) female patient in the NICU incubator.
Testing newborns and infants is very patient- and parent-friendly

When testing newborns and infants, VivoLink™ is placed in the crib or a car seat, or held by the caregiver. The caregiver can comfort the child during the test, while the child can be bottle-feeding or even breast-feeding.
When testing toddlers/kids, the best “comforter” is being with the caring parents.

VivoLink™ back-mounted on 2- and 3-year-old male patients.
A bottle is often the solution, with facial muscle artifacts being not a problem.
A good way to keep the child “quiet” is to occupy the child with toys, watching a cartoon, drawing etc.

VivoLink™ attracted the 3-year-old female patient and allowed for a faster test.
Integrity™ provides unprecedented convenience in Evoked Potential testing.

In adults and teenagers, VivoLink™ is conveniently placed on the lanyard.
CHW Slide Show
That’s all!
Hearing health care benefits: Integrity™ extends reliable, precise, practical ABR to all clinical settings and beyond

**High diagnostic value**
- Precise ABR latencies for neuro-diagnostics
- Precise hearing thresholds for hearing aid fitting
- Non-invasive ECoG for Meniere’s disease diagnostics

**Patients with physiological artifacts**
- Children of all ages – with no sedation or anesthesia
- Patients that cannot be sedated or anesthetized – due to health risks or because anesthesia is unavailable.
- Restless, anxious adult patients: sleep apnea, anxiety, patients with pacemakers.
- Mentally and physically challenged patients: Autism, Cerebral Palsy etc.

**Environments with strong electro-magnetic interferences**
- Neonatal intensive care units (NICU)
- Intensive-care units (ICU) and Emergency Rooms.
- Operating rooms (OR).
- “Conventional” clinical settings – with no electro-magnetic shielding.

**Testing at the patient’s home**
- Portability.
- Certified EMI-Class B rating.

**Testing in motion**
- Automobiles, aircraft, space crafts
- Centrifuges, etc.
Business Rationale used by Masters Family Speech and Hearing Center

- Contingency funds, not budgeted
- SBARR
  - Situation, Background, Assessment, Recommendations, and Response
- Focused on safety and sedation delay
SBARR

Situation: The situation is two fold. First, we have a wait period of 3-4 months for all ABR testing in the clinic and Day Surgery. Second, the new CHW sedation protocol, based on the recommendations during our last JCAHO review, has complicated our process in both the clinic and Day Surgery.

Background: CHW is the primary referral source for Western Wisconsin, Northern Illinois, the Upper Peninsula of Michigan and parts of Iowa and Ohio for sedated ABR testing in children. We have 8 appointments per month in the clinic for sedated testing using chloral hydrate and 6 in Day Surgery using general anesthesia for our high risk patients. Additionally, we complete testing in the OR with physicians. Our current wait time for an ABR test is 12 weeks for the clinic and 15 weeks for Day Surgery. This is a long time for families to wait for confirmation of hearing abilities. Frequently families first come to the clinic to attempt behavioral testing and we are unsuccessful for various reasons. The child’s ears could be free of fluid on that particular day. By the time we are able to schedule ABR testing, they often arrive with middle ear fluid which results in the testing being cancelled and rescheduled. This further prolongs confirmation of hearing abilities. Additionally, the new CHW sedation protocol has impacted our clinic and Day Surgery ABR’s. Chloral Hydrate sedations in the clinic now require 1) Physician monitoring the procedure must be granted moderate sedation privileges, 2) Same physician must complete the H&P the same day of the test and we can no longer accept referring physician H&P’s, 3) Same physician must remain on site from time sedation is administered until patient is cleared to go home, which can be up to 4 hours, 4) Nurse must monitor vital signs and bill every 15 minutes and 5) Monitoring time for children under 6 months has increased to 3 hours after waking up (this has increased costs billed to families). In Day Surgery patients must now be seen in the pre-op clinic in the hospital within 5 days of test and bring an H&P from the referring physician. This appointment cannot happen the same day of the test and therefore leads to an overnight stay for some families, which increases the expense.

Assessment: We demoed an ABR system, the Vivosonic Integrity, in March which uses blue tooth, wireless technology and different collection parameters that allows testing children without sedation. We were very impressed that we were able to successfully complete ABR testing on a children while eating, drinking, nursing, playing or watching videos. This system would allow us to potentially test children on the day of the first appointment or schedule them to come back for testing without the risk of sedation. This has the potential to 1) improve patient safety by eliminating the risks associated with sedation, 2) improve parent satisfaction by making testing safer for their children, 3) increase staff productivity by not having to schedule additional visits thereby having those appointments open for additional families, 4) increase revenue by adding additional ABR appointments to our schedules, 5) increase physician satisfaction by completing the testing in the clinic 2-3 weeks following PE tubes so that we do not have to take up 1 hour of their valuable OR time allowing them to schedule more surgeries and 6) others not yet identified.

Recommendation: Purchase a Vivosonic Integrity system using contingency funds. Although the system has been budgeted for 2009, we are currently experiencing a long wait period for ABR testing and a solution is needed quickly.

Response: I await your response. Please contact me for any further information or clarification.
Results to date

- Used 124 times
- Successful 110 or 92%
- Unsuccessful 14 times
  - 3 too noisy
  - 11 crying, would not tolerate
- Location
  - 106 in clinic, 5 in NICU, 8 on floor, 5 in OR
- Avoided 110 possible sedations
- 54 involved initial failed UNHS
- Eliminated the need for FU appointments
- Parents obtained information same day of appointment
Impact on Sedation Scheduling

- Time to sedated ABR in clinic
  - Reduced from 5 months (20 weeks) to 1 week
  - Releasing time for other appts
- Time to Day Surgery ABR
  - Reduced from 6 months (24 weeks) to 1 week
- Time to Vivosonic ABR
  - TTNA is 1 week
  - Very popular
  - 2nd unit at our new location, New Berlin Clinic, audiologist in training, open 4-6 non-sedated per month, possibly 4 sedated (meetings scheduled)
  - Releasing time for other appts
UNHS Protocol

- Automated ABR if asleep and <6 months
  - Algo, 35dBNHL click
- Awake or over 6 months
  - 80dBNHL alternating split
  - 35dBNHL rarefaction click
- Pass or refer for diagnostic ABR
- Ear verification by APNP – very important step
- Less referrals for sedated ABR’s as we can complete screening
- Do refer to specialty clinics even if pass to monitor hearing
  - DSC, CLP, VCF
Things we love!

- NO Sedation!!
- NO Sedation!!
- Improved safety
- Improved parent satisfaction
- Wireless freedom – is hugely empowering
- Ease of use – train staff in 2-3 patients
- Impact on scheduling, significant reduction in time to next appointment (TTNA)
- Impact on UNHS – did not expect such an impact with many babies arriving awake, can test, not reschedule, results immediate 10-15 minutes, information about possible fluid, schedule diagnostic immediately
- Use in NICU and on floor – wireless allows only Vivolink to be in room, use with older, awake babies, huge with contact isolation patients – MRSA, Transplant, Oncology
- Use in OR – NO electrical interference, was taken because Nav Pro would not function

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Things we do not like

- Single channel – learned to switch between ears as needed
- Storage – file holds 20 runs, test RE and save, test LE and save
  - Would prefer one large file
- No circumaural earphones – atresia kiddos, in design
- No ASSR – CI referrals – in design
- Printing – possible but difficult, avoid
Case Studies

- 5 month old failed UNHS
- 3 year old Down Syndrome
- ANSD – bilateral
- 3 year old late identification
- UNHS in NICU
5 month old failed UNHS

- Did not pass either ear
- Arrived awake
- Tested sucking on pacifier
- No return appointment needed
Right ear
Left ear
3-year-old Down Syndrome

- Passed UNHS
- Behavioral testing – mild sensitivity loss
- Bilateral PE tubes
- Vivosonic testing completed sitting on Dad’s lap playing with toys
2000Hz
4000Hz
500Hz
ANSD - Bilateral

- Born 7-22-08 with twin-to-twin transfusion disorder, she was donor
- 8-19-08-Twins seen for UNHS as inpatients, she failed, sister passed
- 9-2-08-readmitted, failed second UNHS
- 9-26-08-Diagnostic ABR/DPOAE, natural sleep, consistent with ANSD
- 11-08-fit with loaner BTE’s
- 2-25-09-Repeat ABR, fluid, test cancelled
- 6-15-09-Repeat with Vivosonic, consistent with ANSD
- Has been inconsistent hearing aid use
- Family convinced she “hears”, have discussed all aspects of hearing vs. hearing well enough to develop speech/language
- Behavioral testing
DPOAE

The graph above shows the relationship between dB and kHz for DP-Gram and F2 Frequency.
ANSD – Vivosonic Integrity
Behavioral Audiogram
3 year old- late ID

- Referred due to parental concerns of hearing difficulties and speech/language delay
- Born full-term, reportedly passed UNHS
- History of high bilirubin-light treatment
- Family history of hearing loss
  - Maternal grandmother has 2 deaf cousins
  - Paternal aunt had acquired hearing loss - virus
Vivosonic ABR
RE - Click
RE – 2000Hz
2nd behavioral audiogram
UNHS in NICU

- 6month 3wk, former 25 week premie
- Adjusted age 12 weeks
- Referred on initial UNHS at birth hospital
- Meningitis, sepsis
- Ototoxic drugs
- Sleeps on back, easy stimulated
- Repeat Algo, referring on both ears, noisy
- Rescheduled screening using Vivosonic to be able to observe the waveforms
- Passed both ears
- Normative data
UNHS in NICU
Impact for Audiology

- **IMPROVED SAFETY!**
  - Prematurity
  - Liver/Kidney disease, metabolic issues
  - Sedation failure or difficulty
  - Other high risk issues
- Complete testing the same day
- Reduce, but not eliminate, the number of sedated ABRs
  - Clinic, OR and Day surgery
  - Children with cognitive delays, sensory issues
- Reduce 2\textsuperscript{nd} appointments
  - Unable to condition for behavioral testing
  - Failed UNHS, awake, ears clear
- Reduce time to next appointment
  - Fewer ABRs means sooner return appointment
  - Meet TJC recommendations for identification
- Improved productivity
- Improved patient/family satisfaction
- Test at off site clinics where sedation not possible
- Portability – moved to various sites
- Telehealth - crossloop.com, Audiologist can remote onto desktop
- Additional ?
Contact

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