Non-sedated ABR techniques

Yuri Sokolov, Isaac Kurtz, Aaron Steinman, Olena Sokolova

Vivosonic Inc., Toronto, Canada

EHDI Conference, Dallas, TX, March 9-10, 2009

vivosonic

integrity™

Presentation outline

- **Brief review of ABR role in pediatric hearing assessment**
- **The need for Non-sedated ABR**
- **Non-sedated ABR techniques**
  - **Technological**
  - **Protocols**
  - **Test administration**
- **Conclusions**

Year 2007 JCIH Position Statement endorsed ABR as a major tool for post-screening audiological assessment

Audiological assessment from birth to 6 months of age should include:

- **Frequency-specific ABR** with **air-conducted** and **bone-conducted tone bursts** – to determine the degree and configuration of HL in each ear for fitting of amplification devices.
- **Click-evoked ABR** with **condensation** and **rarefaction** polarity stimulus if there are indicators of neural HL – to determine if a cochlear microphonic is present, and all infants who demonstrate “no response” on tone-burst ABR.

For subsequent testing of infants and toddlers at 6 – 36 months of age the confirmatory test battery should include:

- **ABR** if responses to behavioral audiometry are not reliable or if ABR testing has not been performed in the past.

ABR is widely recommended and used in audiological assessment of infants and young children

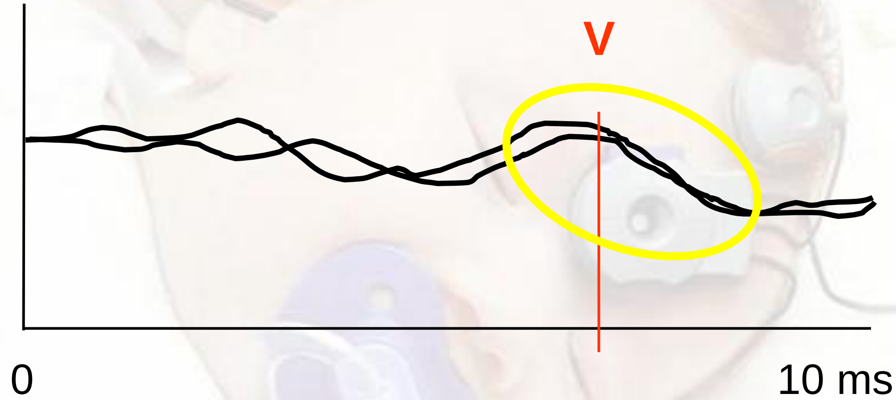
Extensive literature exists on pediatric ABR, e.g.:

- Berlin, C.
- Cone-Wesson, B.
- Don, M.
- Gorga, M.
- Hall, J.
- Hood, L.
- Hyde, M.
- Picton, T.
- Shallop, J.
- Sininger, Y.
- Stapells, D.

PEDIATRICS Volume 120, Number 4, October 2007

Hearing threshold estimation is the most common use of ABR in post-screening audiological assessment

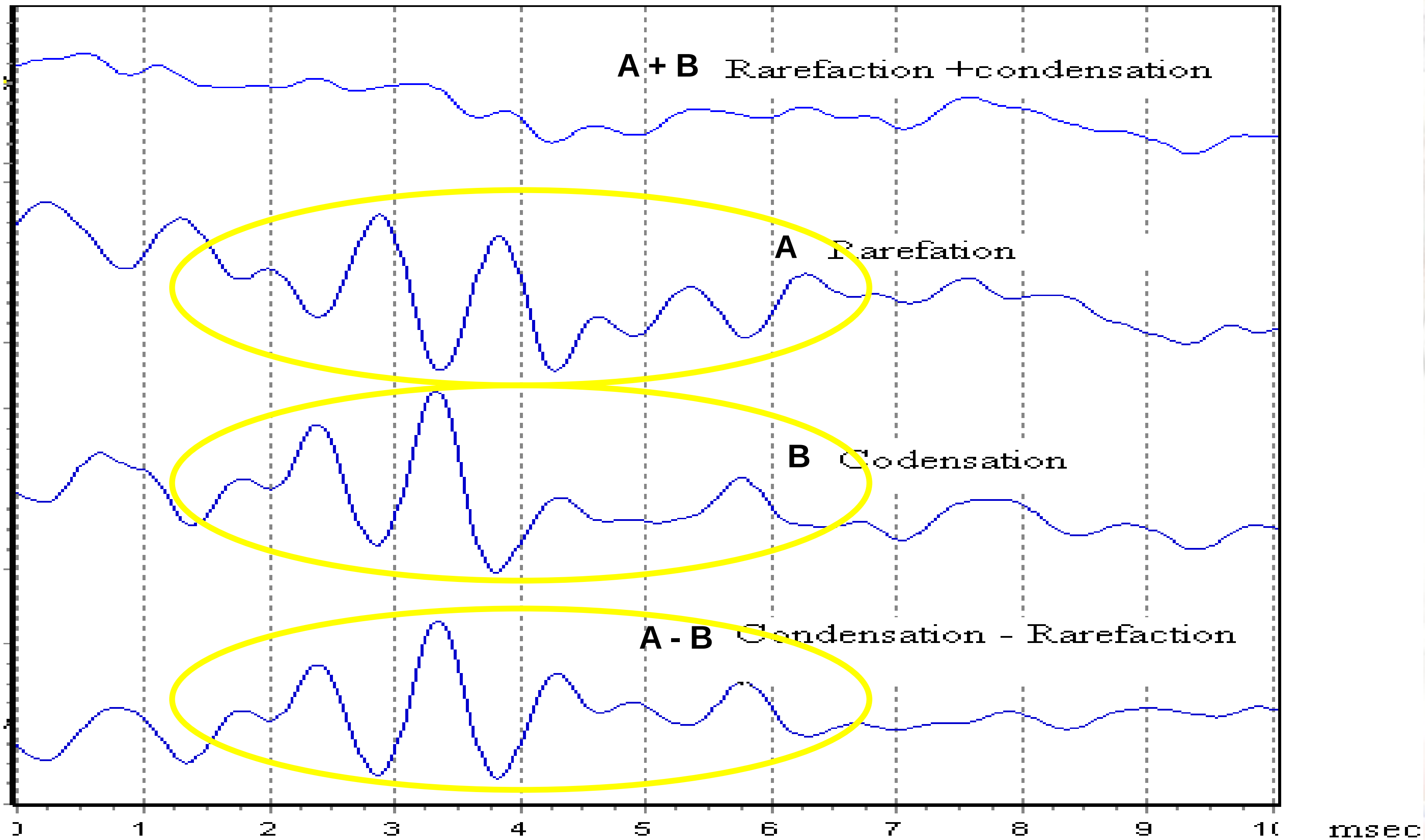
- **Frequency-specific**
- **Stimuli are tone bursts: 500, 1000, 2000, 4000 Hz, as needed for HA fitting**
- **Challenges:**
  - **Very small signal at threshold, difficult to recognize**
  - **Response at threshold can be masked acoustically in noisy test environments**
  - **Inter-subject response variability**
  - **Inter-tester response interpretation variability**
  - **Wave V is not always well expressed, especially at 500 Hz**
  - **No latency norms, as for click-ABR**
  - **If retro-cochlear pathways are involved, Wave V may be absent and thus cannot be used for threshold estimation.**



Multiple publications by Jay Hall III, Yvonne Sininger, David Stapells, and others.

Condensation and rarefaction click ABR – an essential tool for detecting Cochlear Microphonic for AN/AD

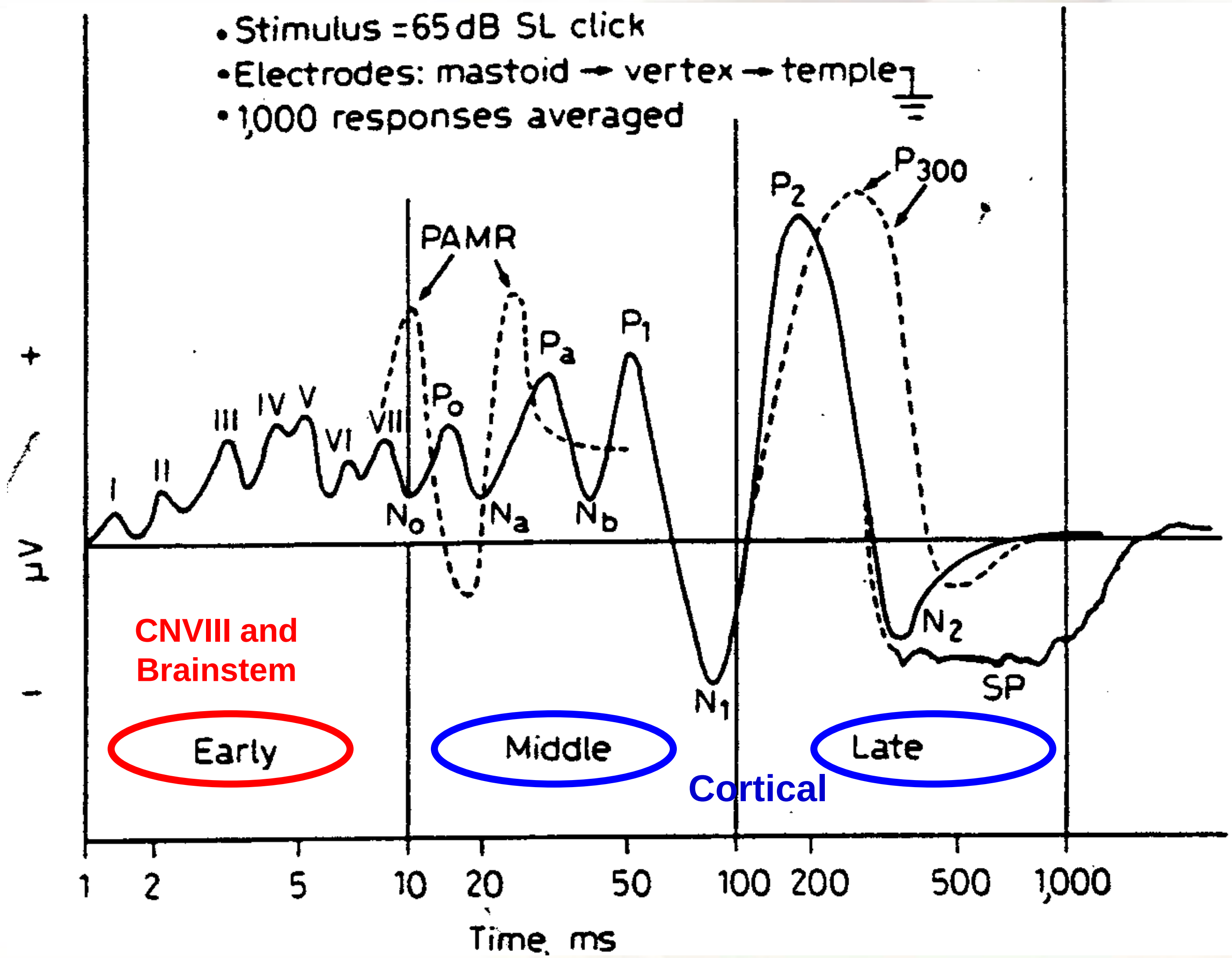
Example of CM in AN/AD



From: Talaat et al. (2009). *Prevalence of Auditory Neuropathy (AN) among infants and young children with severe to profound hearing loss* (in press).

vivosonic clinical efficiency through innovation

ABR is the smallest transient Auditory Evoked Potential – 0.1-0.5 microvolt amplitude – easily masked by artifacts & interferences

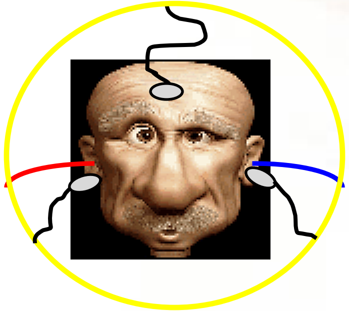


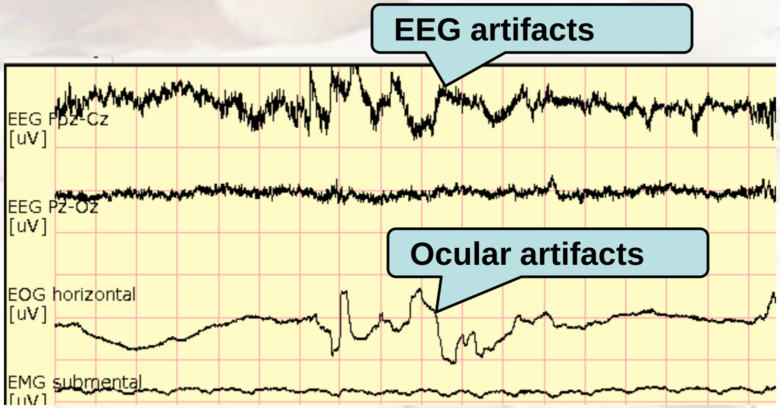
Jon Shallop (1983). *Electric Response Audiometry: The Morphology of Normal Responses*.

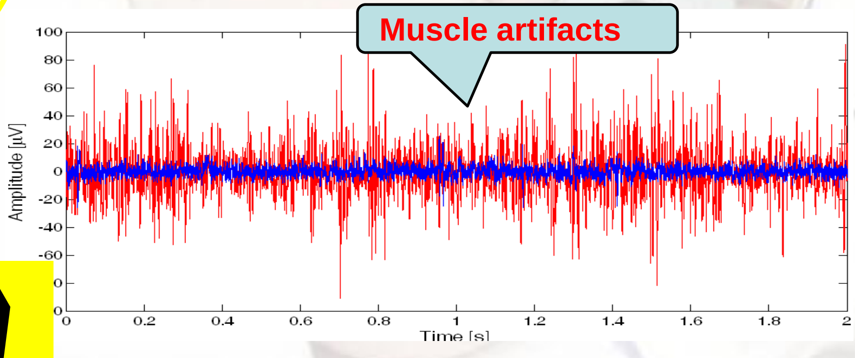
Physiological artifacts and extraneous interferences contaminate ABR signal, particularly at threshold

Physiological *artifacts* – from the patient

- ***Brain***
- ***Eyes***
- ***Skeletal* muscles**
- ***Heart (in infants)***



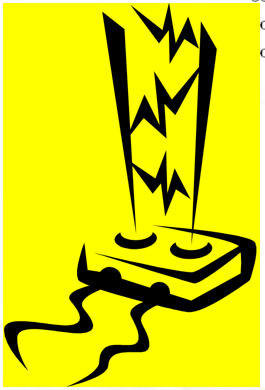


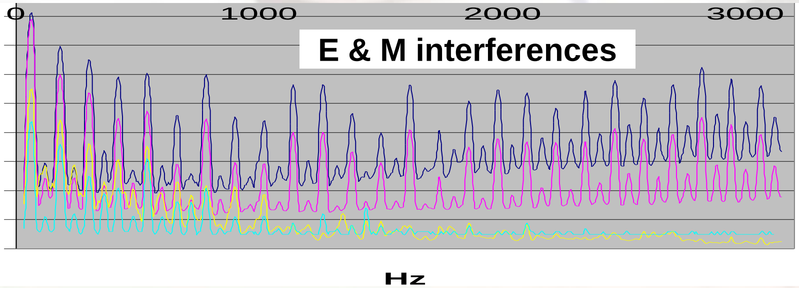


Non-physiological from the patient – pacemakers (adults)

Extraneous *interferences* – from the environment

- ***Electric and magnetic fields***
- ***Radio-frequency transmissions***
- ***Conducted power-line***
  50 / 60 Hz & harmonics





Due to physiological artifacts, ABR tests in pediatric patients with conventional technology often require sedation or general anesthesia

2006 AAP & AAPD Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update

American Academy of Pediatrics, American Academy of Pediatric Dentistry, Charles J. Coté, Stephen Wilson and the Work Group on Sedation

Pediatrics 2006;118;2587-2602
DOI: 10.1542/peds.2006-2780

This information is current as of January 4, 2007

PEDIATRICS Volume 118, Number 6, December 2006

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://www.pediatrics.org/cgi/content/full/118/6/2587

http://aappolicy.aappublications.org/cgi/reprint/pediatrics;118/6/2587.pdf

The AAP & AAPD Guidelines: Sedation imposes serious risks on the child. Monitoring & rapid intervention readiness required.

Sedation of pediatric patients has serious associated risks, such as hypoventilation, apnea, airway obstruction, laryngospasm, and cardiopulmonary impairment.[2,6,22,45,46,54,60–69] 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.[54] 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.[46,51,54]

PEDIATRICS Volume 118, Number 6, December 2006

ABR under anesthesia is administered in the OR, involves Audiologists and Anesthetists, is costly, unavailable in many clinics, and may affect the timeliness of diagnostics and intervention (reaching the 1-3-6 targets)

Photo: Courtesy of Dr. Jay Hall, III, Ph.D., University of Florida, Gainesville, FL

vivosonic
clinical efficiency through innovation

Moreover, recent findings suggest general anesthesia may affect child development. More studies required

- **Early research suggests a possible link between exposure to general anesthesia in infancy and early childhood and behavioral and developmental disorders later on.**
- **Children in the study exposed to general anesthesia were twice as likely as unexposed children to be diagnosed with such disorders.**
- **After adjusting for factors associated with behavioral and developmental disorders, including low birth weight and gender, the researchers concluded that children with a history of exposure to general anesthesia were nearly twice as likely to have a recognized developmental or behavioral disorder as children with no exposure.**
- **The findings are preliminary and must be confirmed.**

These findings were presented at the 2008 Annual Meeting of the American Society of Anesthesiologists in Orlando, FL by Dr. Lena S. Sun, MD, Columbia University, NYC.

Source: ***Advance for Speech-Language pathologists and Audiologists*, November 24, 2008**

The risks and costs of sedation and anesthesia evoke the need of the new, non-sedated ABR techniques and the goal of their development

Both sedation and general anesthesia may present health or developmental risks to children.

Significant additional costs to health care system:

- **Sedation:** **$500-800 / case**
- **Non-complicated anesthesia:** **$4,000-5,000 / case**
- **Complicated anesthesia (10% cases):** **$10,000-20,000 / case**

Therefore, administering ABR without sedation and anesthesia is needed from both patient-care and healthcare cost perspectives.

Avoiding the risks associated with sedation and anesthesia, in as many cases as possible, is the *goal* of the new ABR techniques.

ABR is particularly challenging in the NICU due to large EMIs from life-support equipment

Extensive electric wiring, CRT monitors, respiratory-equipment pumps, heaters, etc. emit significant EMI's.

However, being *life-support*, this equipment cannot be switched off for ABR!

The goal of non-sedated ABR is achieved by combining *technological* advancements with *clinical* protocols and *test-administering* practices

Technological advancements

- **In-situ pre-amplification and pre-filtering**
- **Wireless recording**
- **Kalman-weighted averaging**
- **Real-time noise estimate with A, B, and A-B traces, and meaningful correlation coefficient**

Clinical protocols

- **Increased number of equivalent / accepted sweeps**
- **Increased stimulus rate – higher than 11-21 / sec**
- **Stimulus rate close to 40/sec to utilize 40-Hz response in AWAKE children**
- **Wide recording latency window – especially for low-frequency tone bursts (500 Hz)**
- **Low high-pass filter setting – from 30 Hz**

Test-administering practices

- **Positioning the child in a (perceived by the child) safe & friendly environment**
- **Comforting by caregivers**
- **Pacifying infants – breast-feeding, bottle, pacifier**
- **Occupying toddlers & older children – games, videos, drawing**

Technological advancements for ABR recording in non-sedated patients

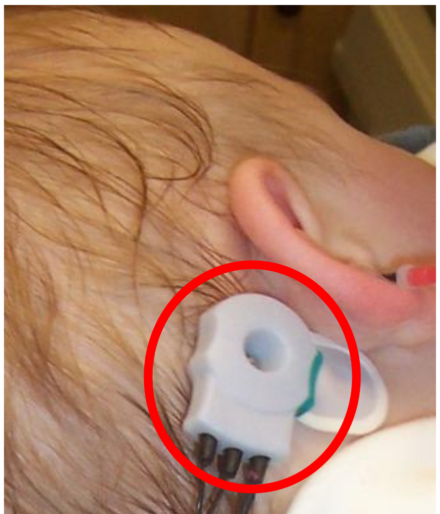
Technological advancements reduce physiological artifacts & environmental interferences enabling non-sedated ABR

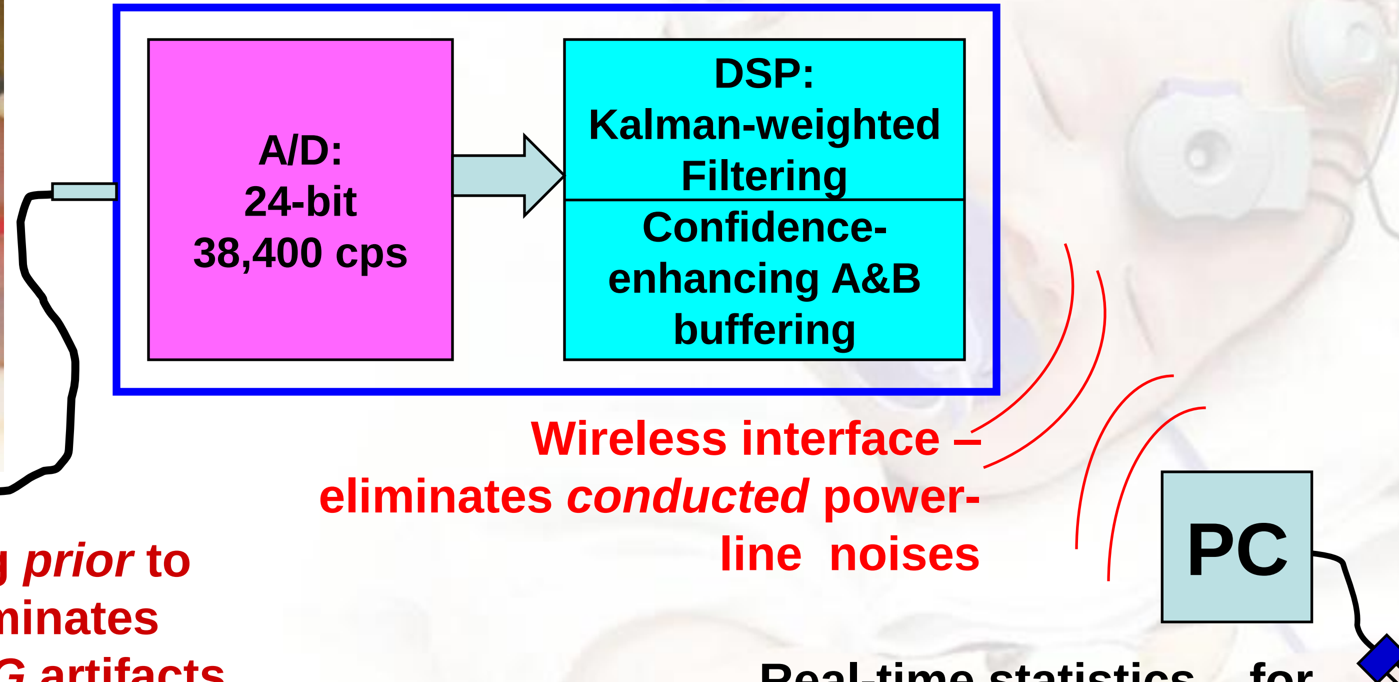
In-situ* amplification – on the ground electrode – protects from *EMI

High-resolution A/D conversion – increases the accuracy of ABR

Kalman-weighted filtering in DSP – removes *EMG* artifacts.

Confidence-enhancing A & B buffering – enhances confidence of ABR trace repeatability & correlation



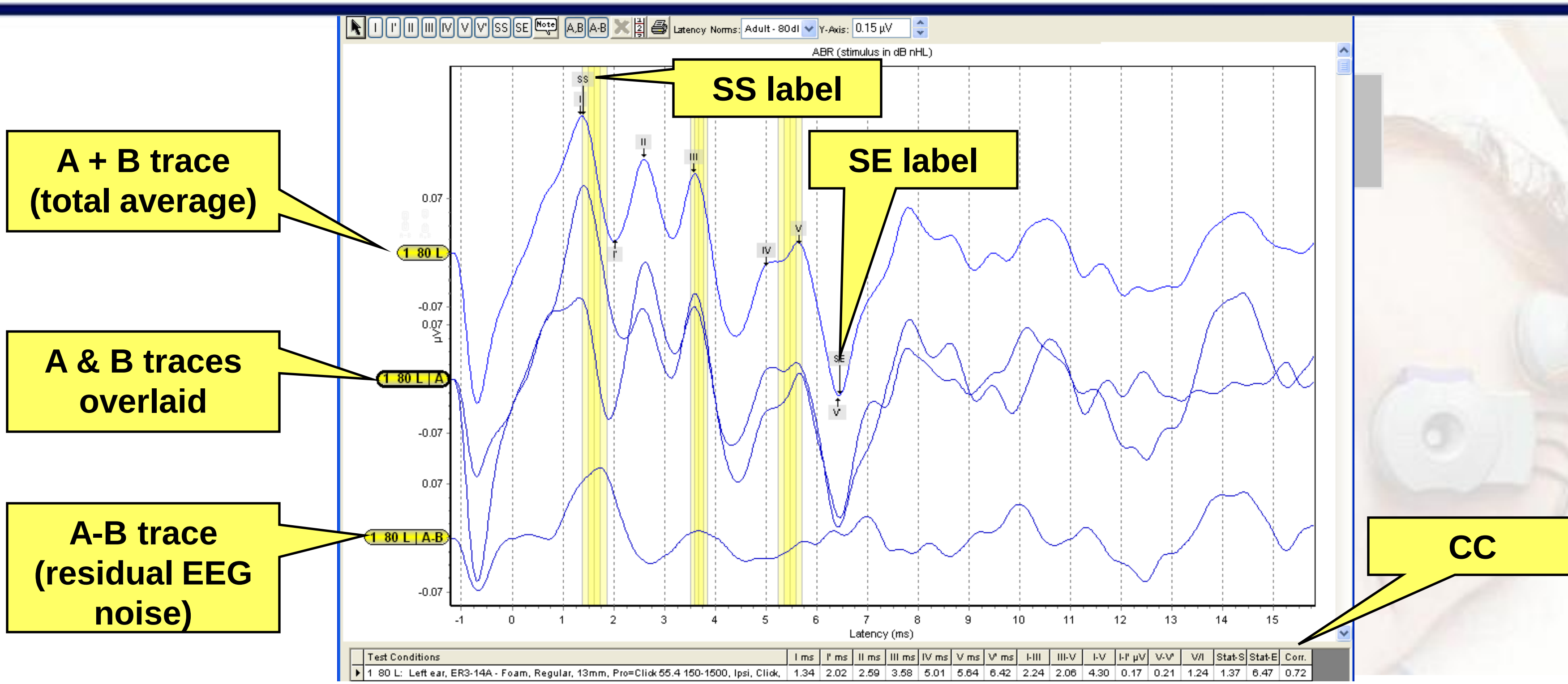


Wireless interface – eliminates *conducted* power-line noises

Band-pass filtering *prior* to amplification – eliminates *EOG, ECG and EEG* artifacts, and *RF* interference

Real-time statistics – for repeatability confidence

Statistical techniques enhance confidence in response repeatability



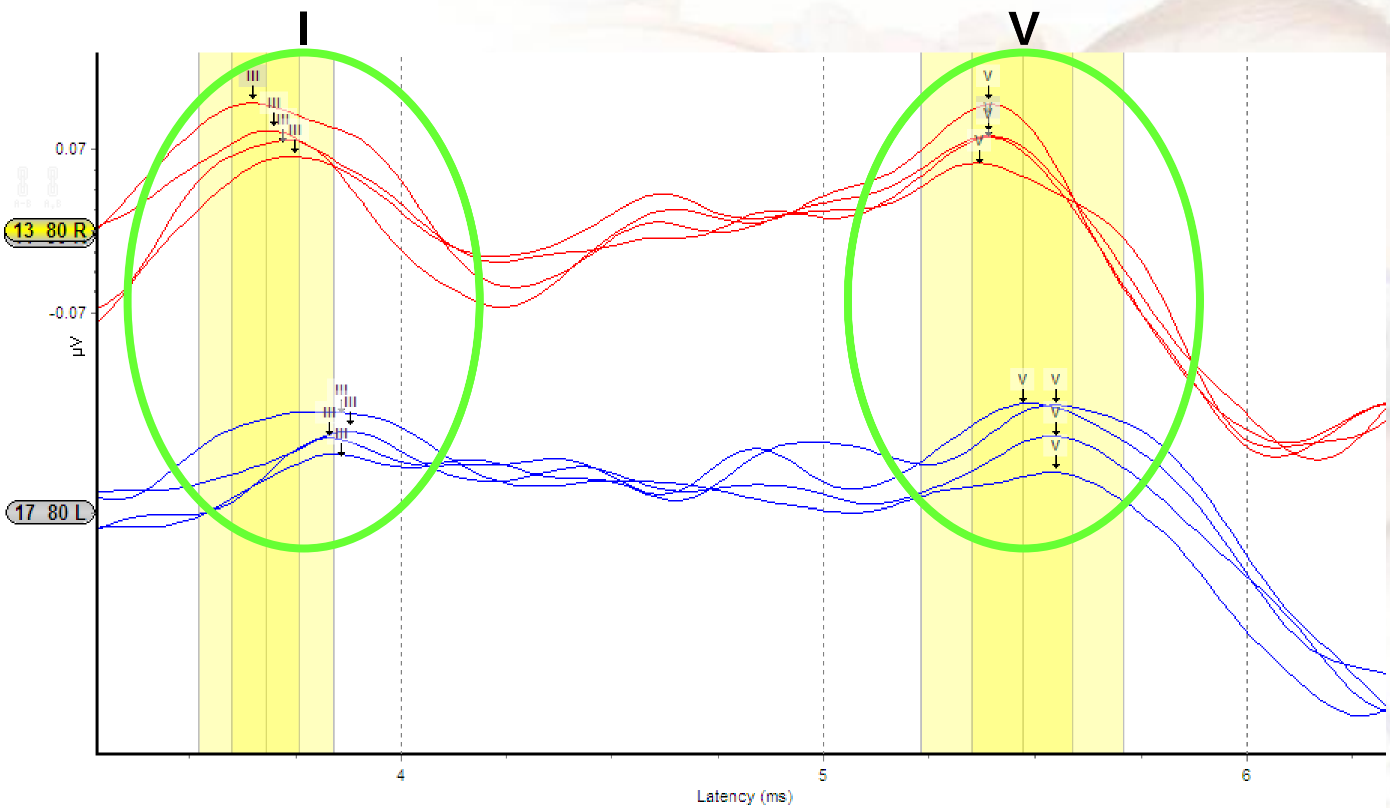
A (even sweeps) & **B** (odd sweeps) buffers show response repeatability within each test run – instead of repeating each test – and saves test time.

A-B (the difference between A and B) shows EEG noise floor – helps identify the response.

Correlation coefficient (**CC**) between **Statistics Start** (**SS**) and **Statistics End** (**SE**) labels – helps detecting response objectively.

High-definition ABR enables detecting very small inter-aural differences of ABR wave latencies

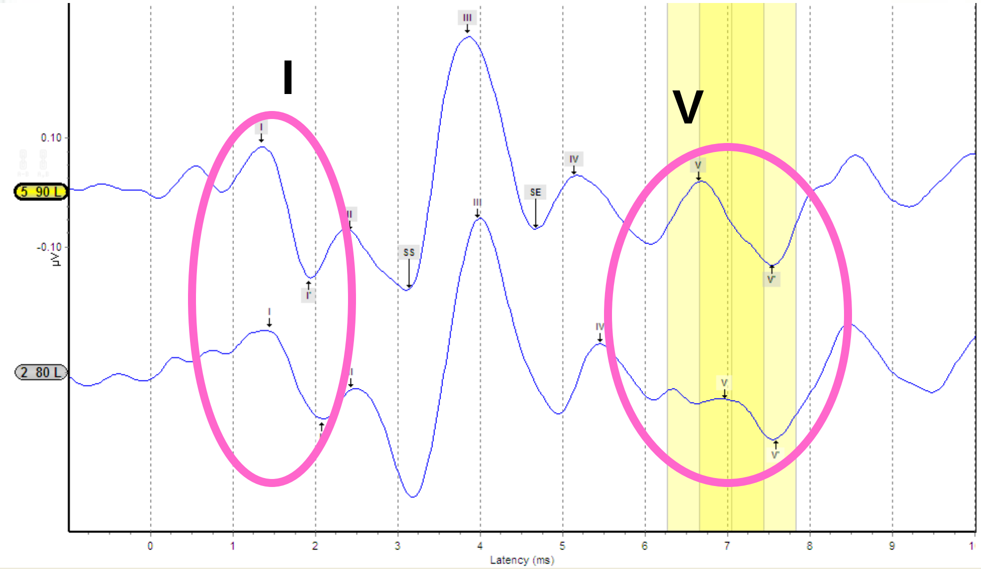
ABR waveforms recorded from a 79-year-old patient with moderate SNHL, showing clear inter-aural differences in Waves III and V



Test Conditions	I ms	I' ms	II ms	III ms	IV ms	V ms	V' ms	I-III	III-V	I-V	I-I' μV	V-V'	V/I	Stat-S	Stat-E	Com
14 80 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=Neurologic 150 -2400, Contra,	1.67			3.83		5.55		2.16	1.72	3.88						
15 80 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=Neurologic 150 -2400, Contra,	1.77			3.88		5.55		2.11	1.67	3.78						
16 80 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=Neurologic 150 -2400, Contra,	1.64			3.86		5.47		2.22	1.61	3.83						
17 80 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=Neurologic 150 -2400, Contra,	1.64			3.86		5.55		2.22	1.69	3.91						
18 80 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=Neurologic 150 -2400, Contra,																

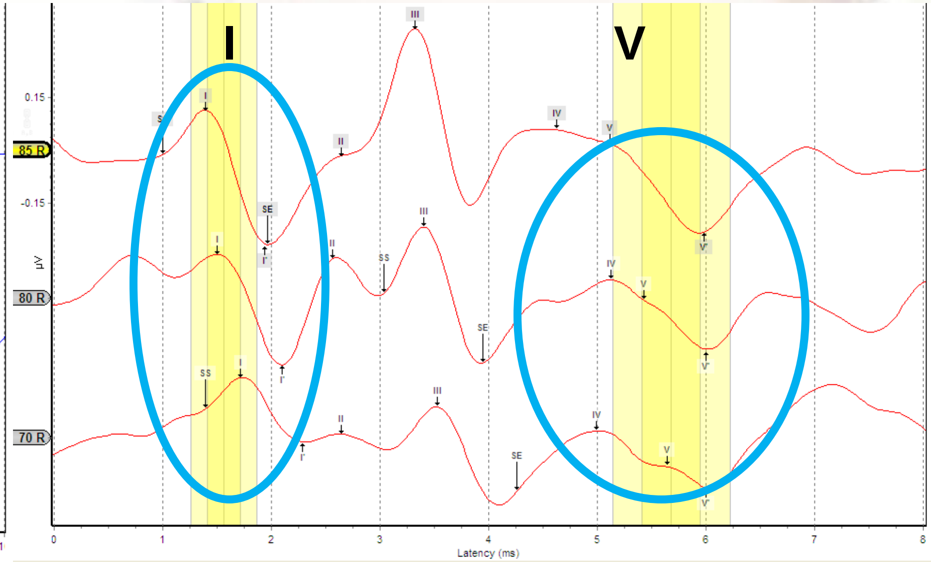
High-definition ABR helps identifying subtle variances that may increase the diagnostic value of ABR

ABRs from LE of a 5-week-old, 8-week-premature, non-sedated, female NICU infant
80 and 90 dB nHL
(shown are age norms for 80 dB nHL)



	Test Conditions	I ms	I' ms	II ms	III ms	IV ms	V ms	V' ms	I-III	III-V	I-V	I-I' μV	V-V'	V/I	Stat-S	Stat-E	Corr.
	4 60 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=Click 17.7 150-1500 0-97, Ipsi,						7.17										
▶	5 90 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=Click 17.7 150-1500 0-97, Ipsi,	1.34	1.91	2.41	3.84	5.14	6.65	7.54	2.50	2.81	5.31	0.25	0.15	0.60	3.16	4.65	0.98

ABRs from RE of a 3.5-year-old, non-sedated male patient with Cerebral Palsy
70, 80, 85 dB nHL
(shown are age norms for 80 dB nHL)



st Conditions	I ms	I' ms	II ms	III ms	IV ms	V ms	V' ms	I-III	III-V	I-V	I-I' μV	V-V'	V/I	Stat-S	Stat-E	Corr.
80 R: Right ear, ER3-14A - Foam, Regular, 13mm, Pro=Click 17.7 150-1500 0-97, Ipsi,	1.50	2.10	2.56	3.40	5.12	5.43	6.00	1.90	2.03	3.93	0.31	0.14	0.46	3.01	3.92	0.87
85 R: Right ear, ER3-14A - Foam, Regular, 13mm, Pro=Click 17.7 150-1500 0-97, Ipsi,	1.39	1.94	2.64	3.32	4.62	5.12	5.98	1.93	1.80	3.73	0.38	0.25	0.65	0.98	1.99	0.92
70 R: Right ear, ER3-14A - Foam, Regular, 13mm, Pro=Click 17.7 150-1500 0-97, Ipsi,	1.71	2.28	2.64	3.53	4.99	5.64	6.00	1.82	2.11	3.93	0.18	0.06	0.33	1.37	4.28	0.36

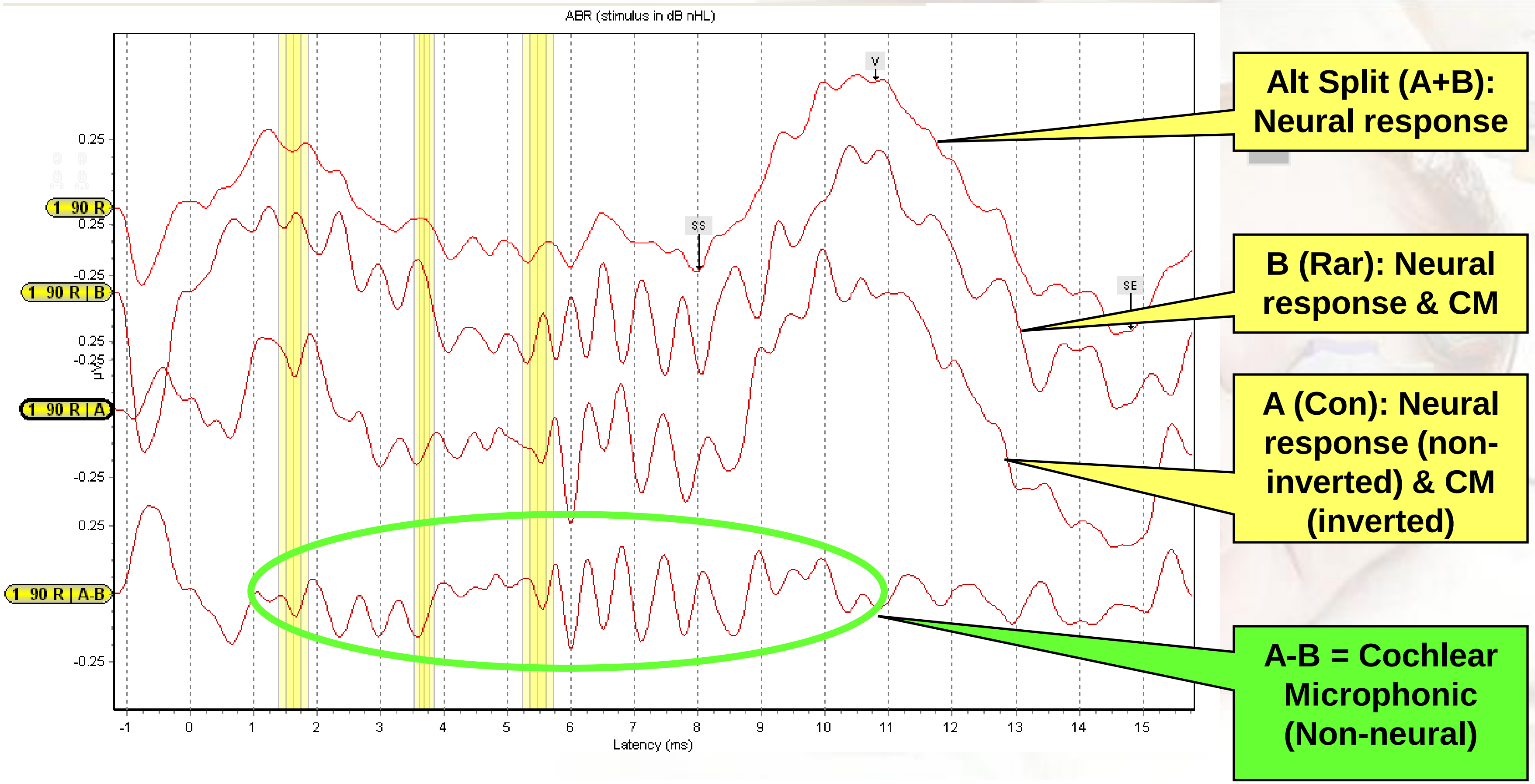
ABR indicates similarity of Wave V/I Ratio in premature and 3.5-yaer-old CP patient

New statistical techniques provide the clinician with good stop criteria to obtain meaningful results

The clinician can stop the test based on the following Integrity™ criteria:

- **A** and **B** traces are **visually** repeatable
- **A-B** trace, which represents the residual **noise**, is **visually** flatter than the **A+B** (total average) trace
- **Correlation Coefficient** in the latency range of interest is larger than 0.5 (50%), which indicates a non-random response, preferably larger than 0.75 (75%)

Alternating Split stimulus automatically administers Condensation (A) and Rarefaction (B) polarity clicks for CM identification in *neural* HL

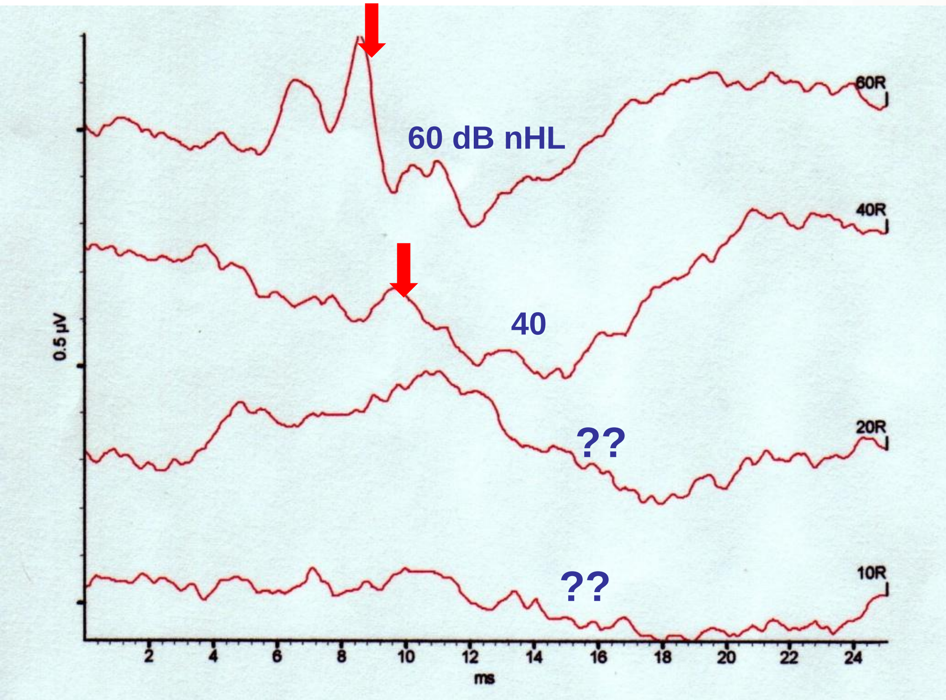


Right Ear of a 4-year-old boy with Auditory Neuropathy/Auditory Dys-synchrony. Left Ear with Cochlear Implant (CI). Candidate for a second CI for the Right Ear. 90 dB nHL click: A – Con, B – Rar, A+B – Neural, A-B – Non-neural (Cochlear Microphonic, CM)

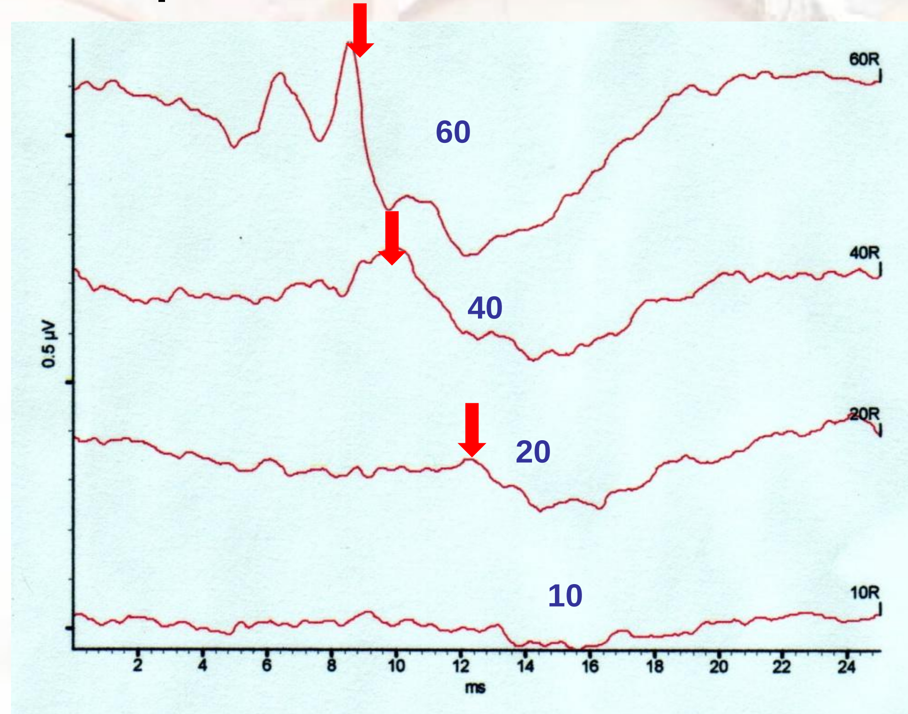
Clinical approaches to ABR recording in AWAKE pediatric patients

Using larger numbers of stimuli (sweeps) *near threshold* improves response clarity and helps ABR detection

Examples of click-ABR under the same conditions recorded with different number of accepted sweeps



2,000 sweeps

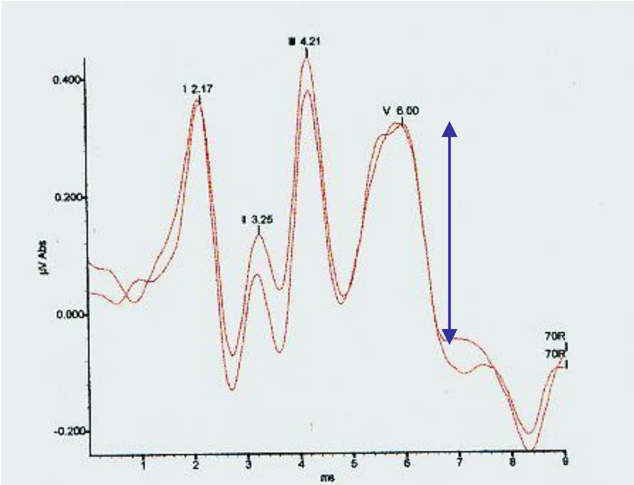


5,000 sweeps

Run *as many sweeps as necessary* to obtain a clear response, not a “standard” 2000, particularly at near-threshold stimulus levels.

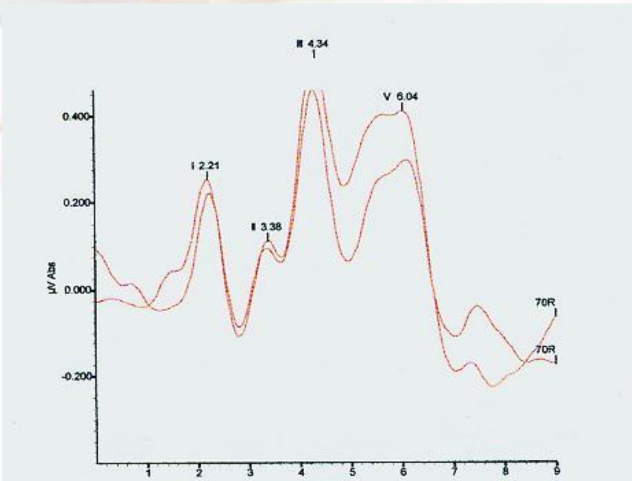
From: Dr. Todd Sauter, U. of Massachussetts Medical Centre, 2006

Stimulus rate affects wave morphology, but not Wave V amplitude. High stimulus rates save testing time



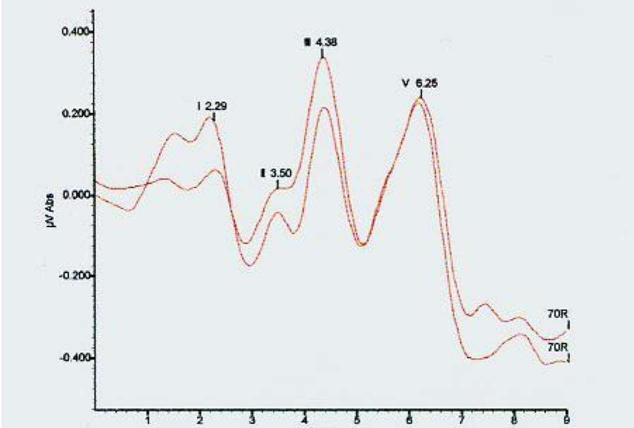
11.1/sec

Time for 4000 sweeps – 6 minutes



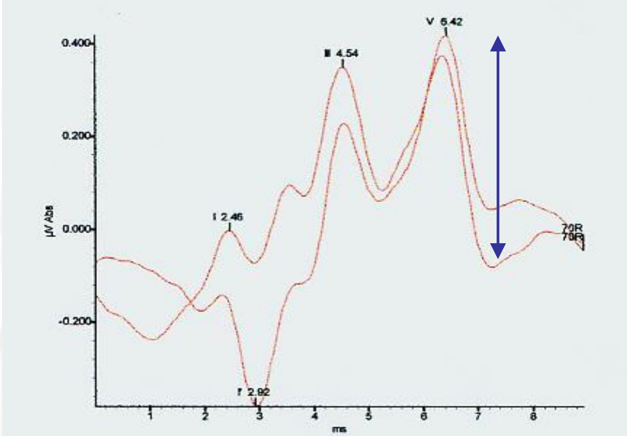
21.1/sec

Time for 4000 sweeps – 3 minutes



39.1/sec

Time for 4000 sweeps – 1 minute, 42 sec



55.9/sec

Time for 4000 sweeps – 1 minute, 10 sec

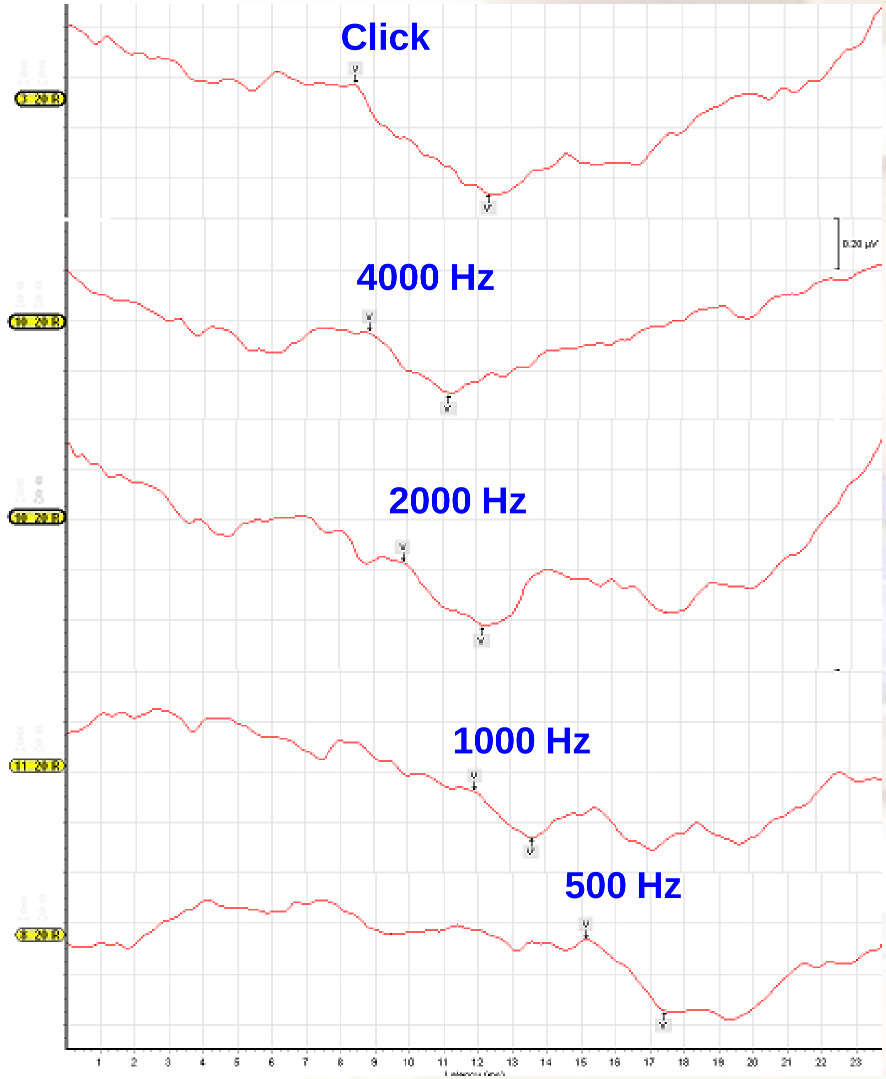
Dr. Todd Sauter, University of Massachussetts Medical Centre, 2006

vivosonic
clinical efficiency through innovation

Use window long enough to include full negative deflection following Wave V (Wave V' or SN10), particularly for low frequency stimuli

Example of ABR to various stimuli at 20 dB nHL.

Adult Subject.

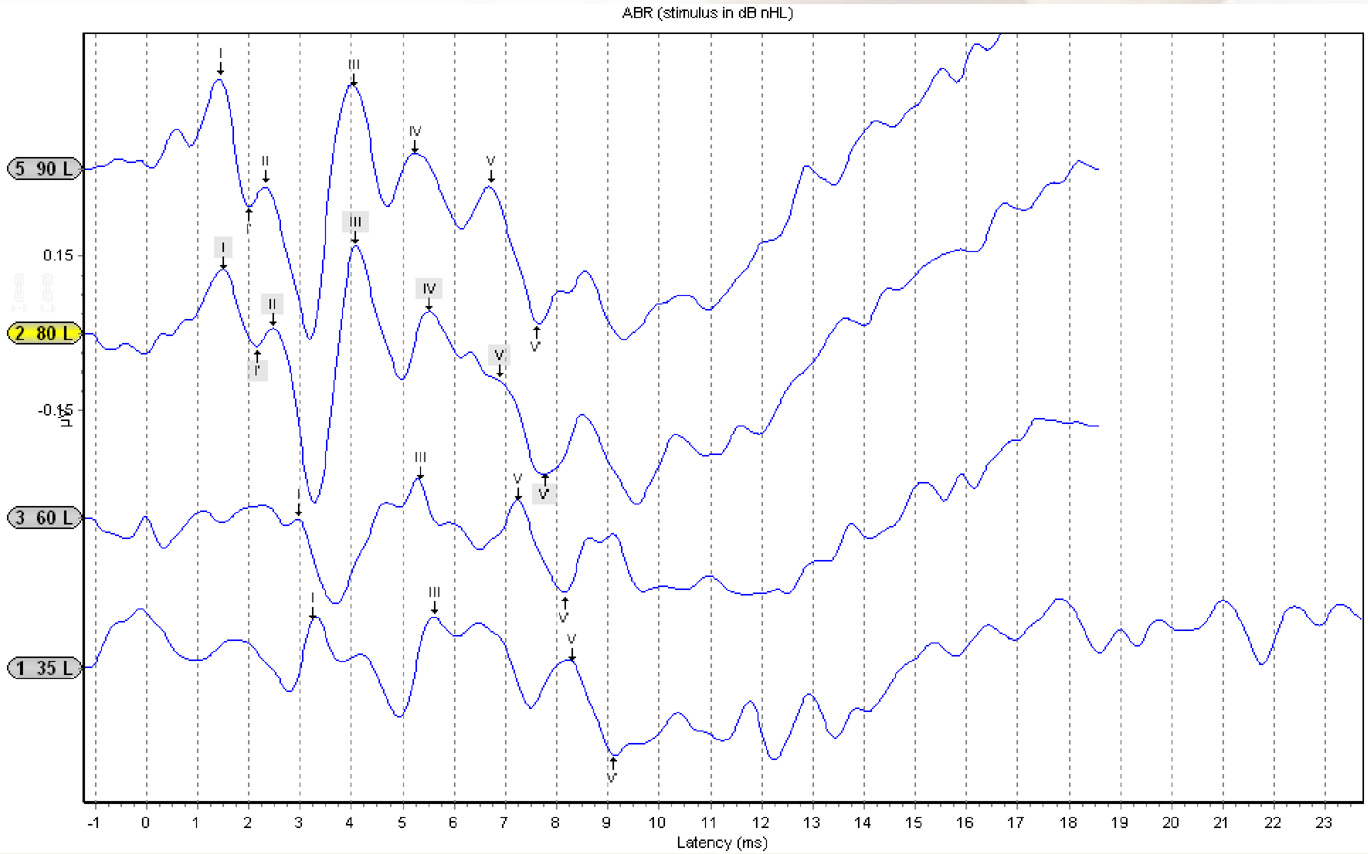


Test NICU babies in their incubators – this will eliminate the disturbance of moving out of the incubator and sound-proof from the NICU noise

When testing in an NICU or Step Down Unit, the wireless interface unit is placed in or on the incubator, and the test is administered from an up to 30-foot (10 meter) distance.

Shown: Administering ABR in a premature, 10-days old (gestational 31 weeks) female patient in the NICU incubator

Allow NICU babies for suckling on their pacifiers, remain in their natural position, and minimize other disturbances



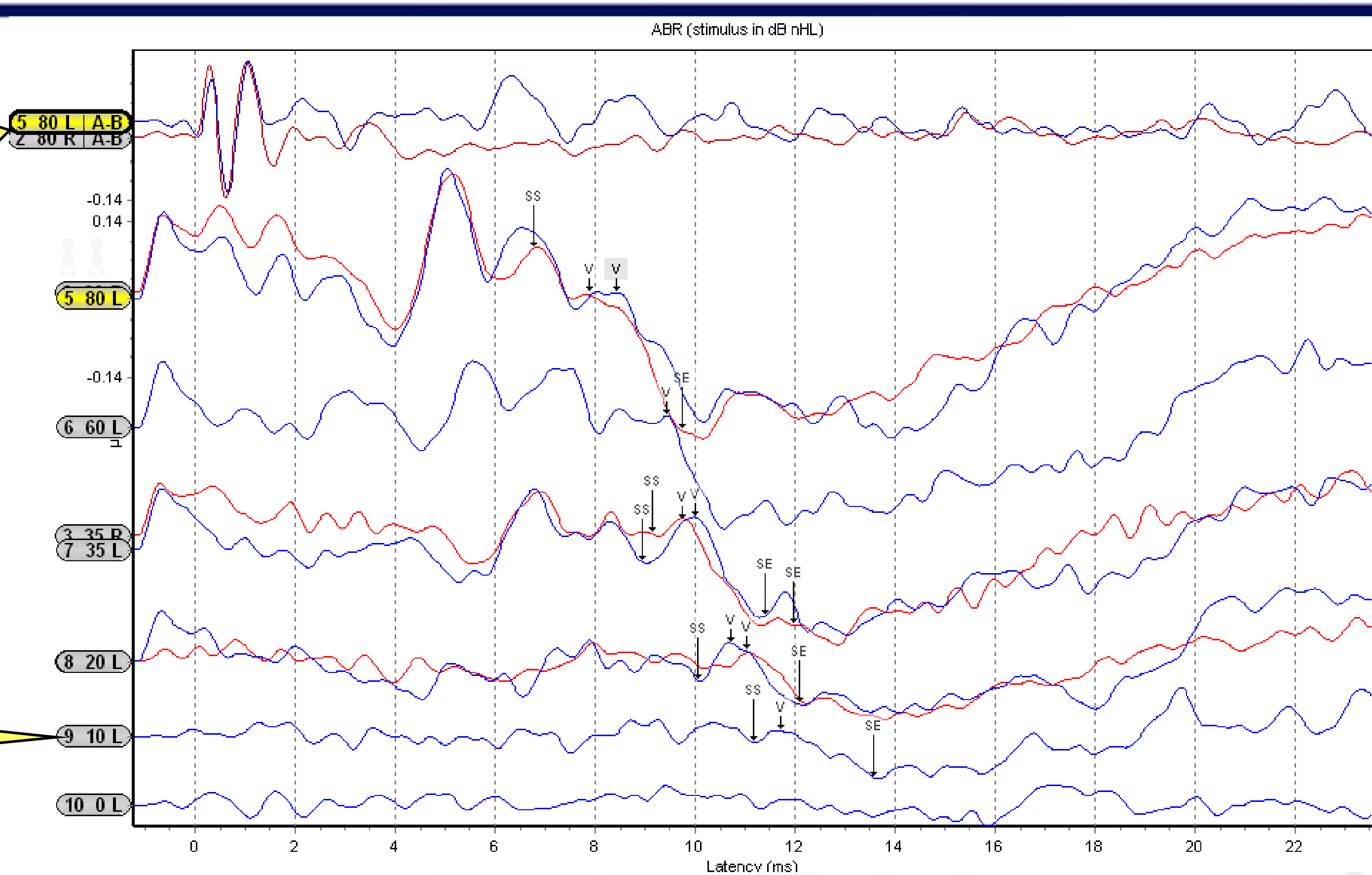
Non-sedated, premature 10-week-old infant girl, in a **NICU**, suckling on her pacifier. Conventional ABR results unattainable. New techniques enabled recording clear ABR to 35-90 dB nHL clicks.

New techniques enable the recording of clear ABR and CM in non-sedated NICU infants

CM in the A-B traces

R & L ears at 80 dB nHL

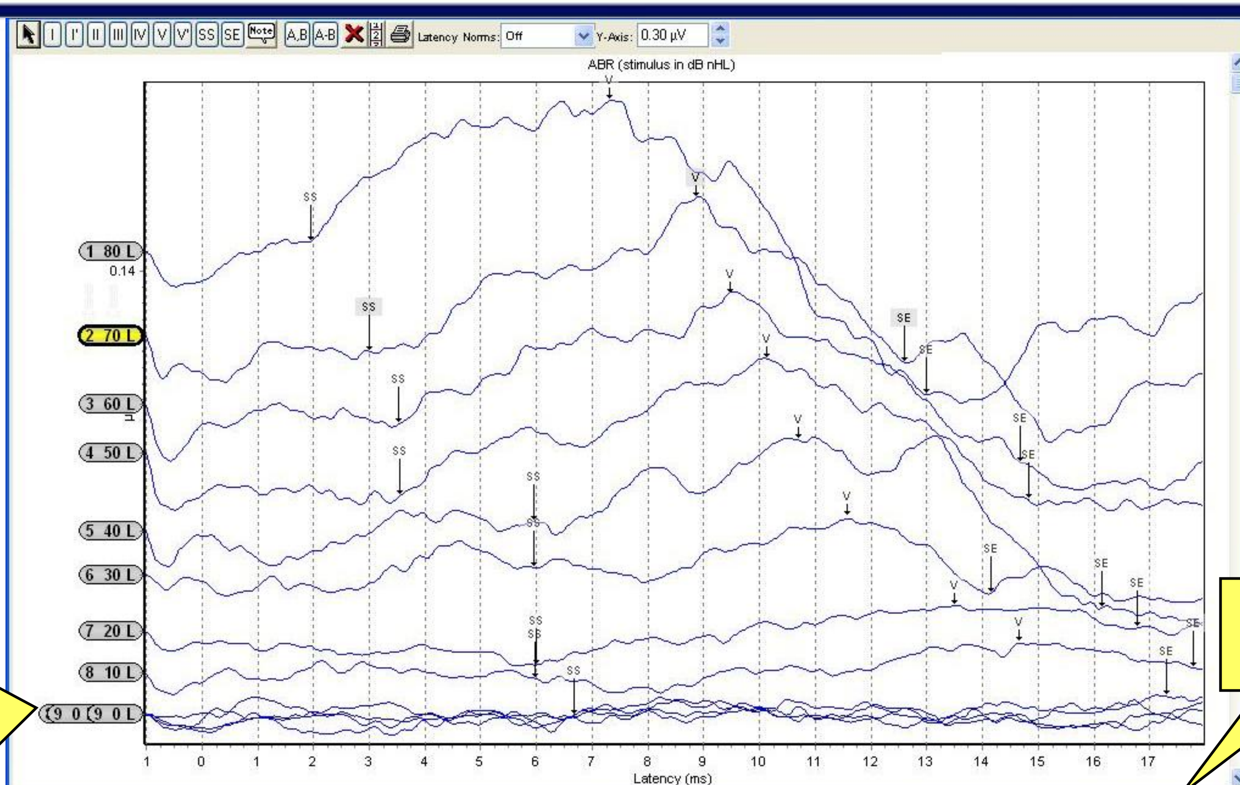
10 dB nHL



10-days old, premature (31-week gestational) infant girl, was impossible to test with a conventional ABR device due to very large artifacts. Clear response: clickABR to 0-80 dB nHL, R (red) & L (blue) ears.

Wide high-pass filtering (30-1500 Hz) utilize not only Wave V, but also 40-Hz response in AWAKE patients

A-B traces at all stimulus levels match the 0 dB nHL (no stimulus) trace, i.e. EEG noise



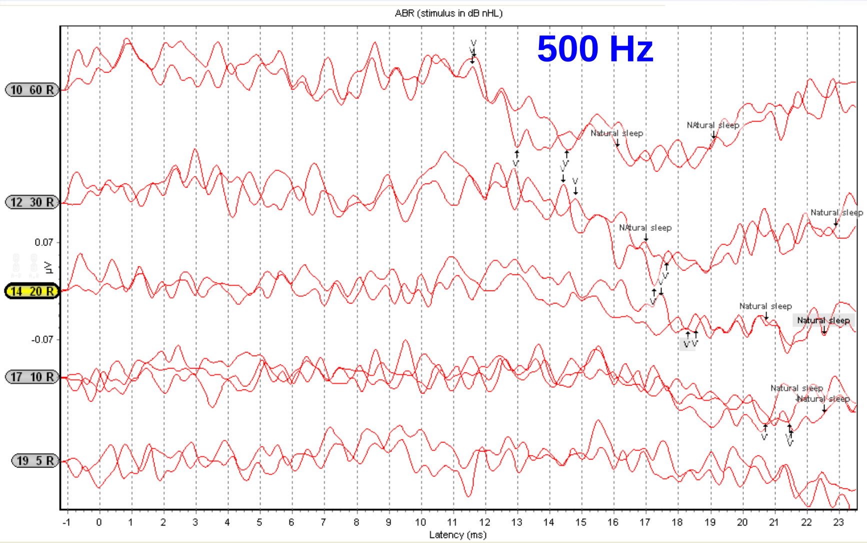
"Running" CC

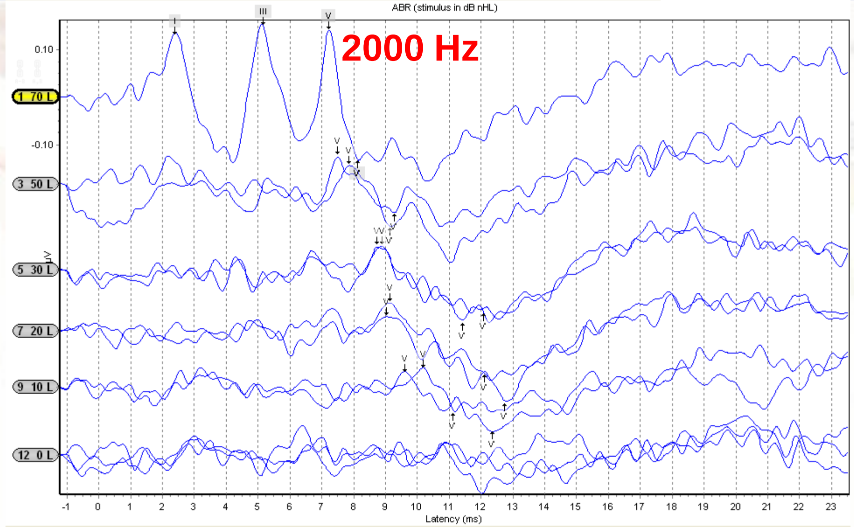
	Test Conditions	I ms	I' ms	II ms	III ms	IV ms	V ms	V' ms	I-III	III-V	I-V	I-I' µV	V-V'	V/I	Stat-S	Stat-E	Corr.
	1 80 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=500 49.8 41k, Ipsi, 500Hz,						7.31								1.94	12.96	0.93
▸	2 70 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=500 49.8 41k, Ipsi, 500Hz,						8.87								3.01	12.57	0.79
	3 60 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=500 49.8 41k, Ipsi, 500Hz,						9.47								3.53	14.65	0.83
	4 50 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=500 49.8 41k, Ipsi, 500Hz,						10.12								3.56	14.83	0.83
	5 40 L: Left ear, ER3-14A - Foam, Regular, 13mm, Pro=500 49.8 41k, Ipsi, 500Hz,						10.69								5.95	16.11	0.95

The user runs a test until A-B "flattens out" to below 0.03-0.05 µV.

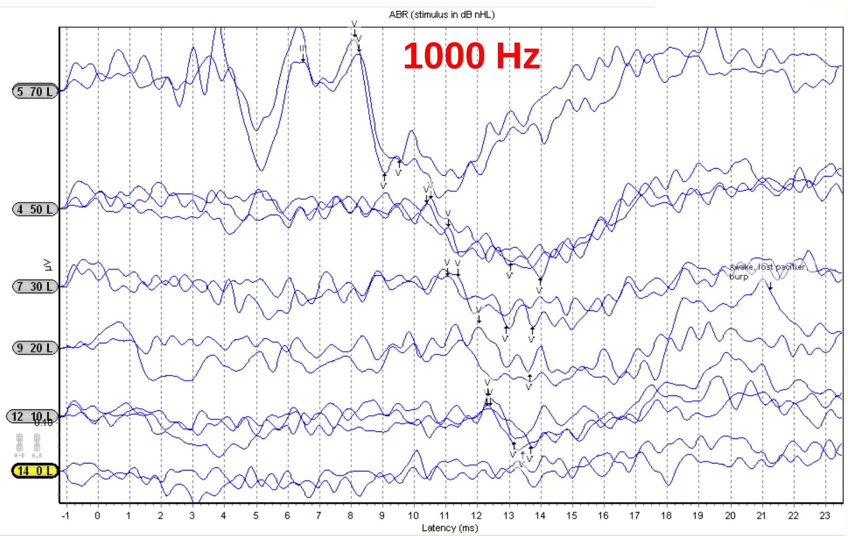
"Running" CC value is continuously updated, and CC > 0.5 indicates the presence of response, as in this sample **500 Hz** tone-burst ABR clearly identifiable to 10 dB nHL.

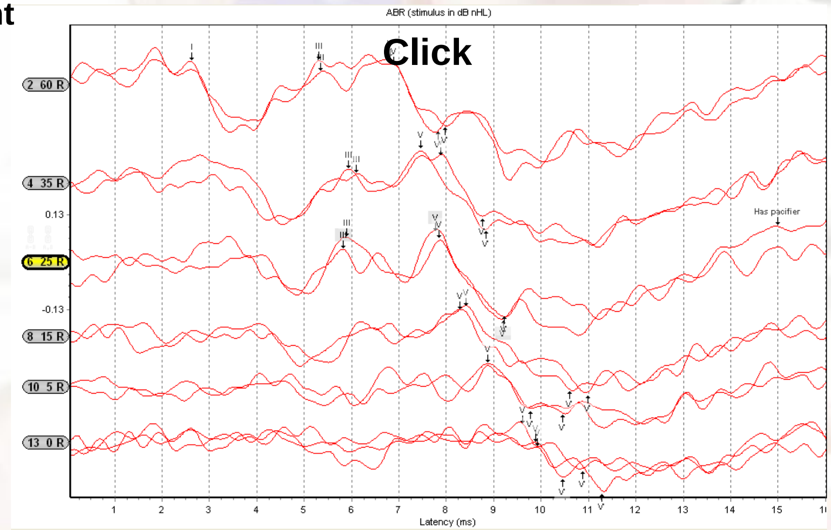
ABR can be recorded in non-sedated infants down to 0-10 dB nHL (nHL stimulus levels calibrated for adults)





4-wks old boy, intermittent sleep, pacifier

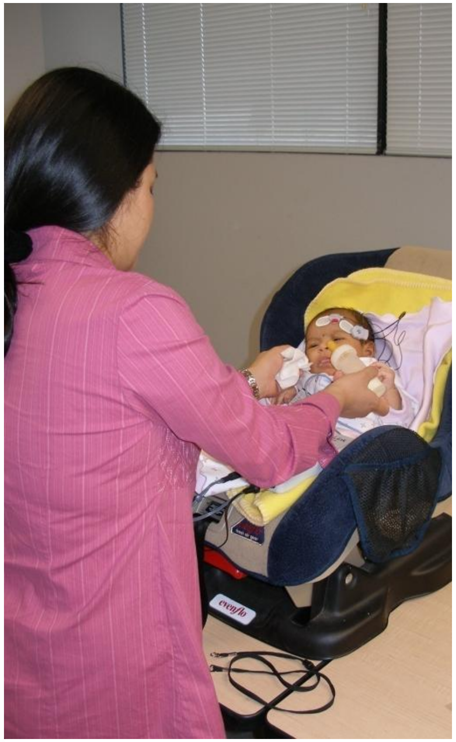


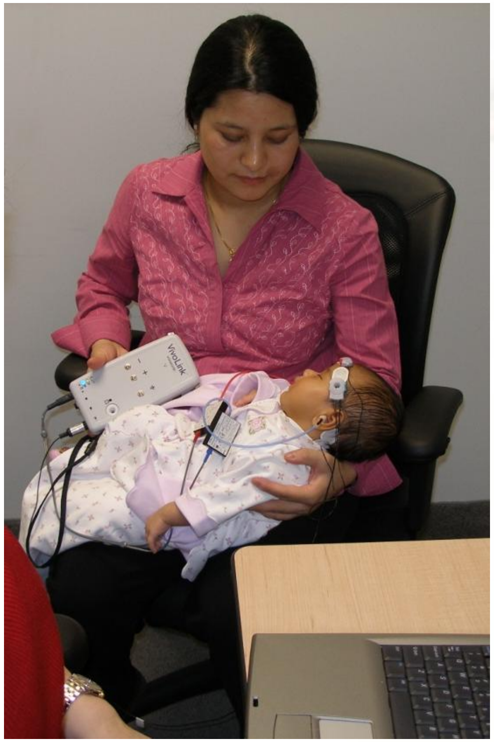


Bottle- or breastfeeding & known environment, like the child's car seat or stroller, help keeping awake infants quiet

Comforting infants by the parent or care-giver is helps keeping the infant quiet

Testing newborns and infants is very patient- and parent-friendly in comforting hands of the parent or care-giver





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.

Feeding on the bottle helps not only in infants, but in many toddlers

A position where the child feels *safe* may work better than sedation in some cases

A 2-year-old female toddler was given **5** cc of Chloral Hydrate, then another **2** cc – with no sedative effect. ABR could not be completed with a conventional ABR system.

Then she found safety on her father's shoulders where she was successfully ABR-tested with new techniques.

Tests conducted at a private Otolaryngology clinic, Cairo, Egypt

Photos: Courtesy of Dr. Sameh Farheed

Holding the child's hands in a safe position doesn't allow her to use the hands for removing the electrodes and inserts

Positioning the wireless unit as a "backpack" makes it invisible to the child and reduce the child's fear of the procedure

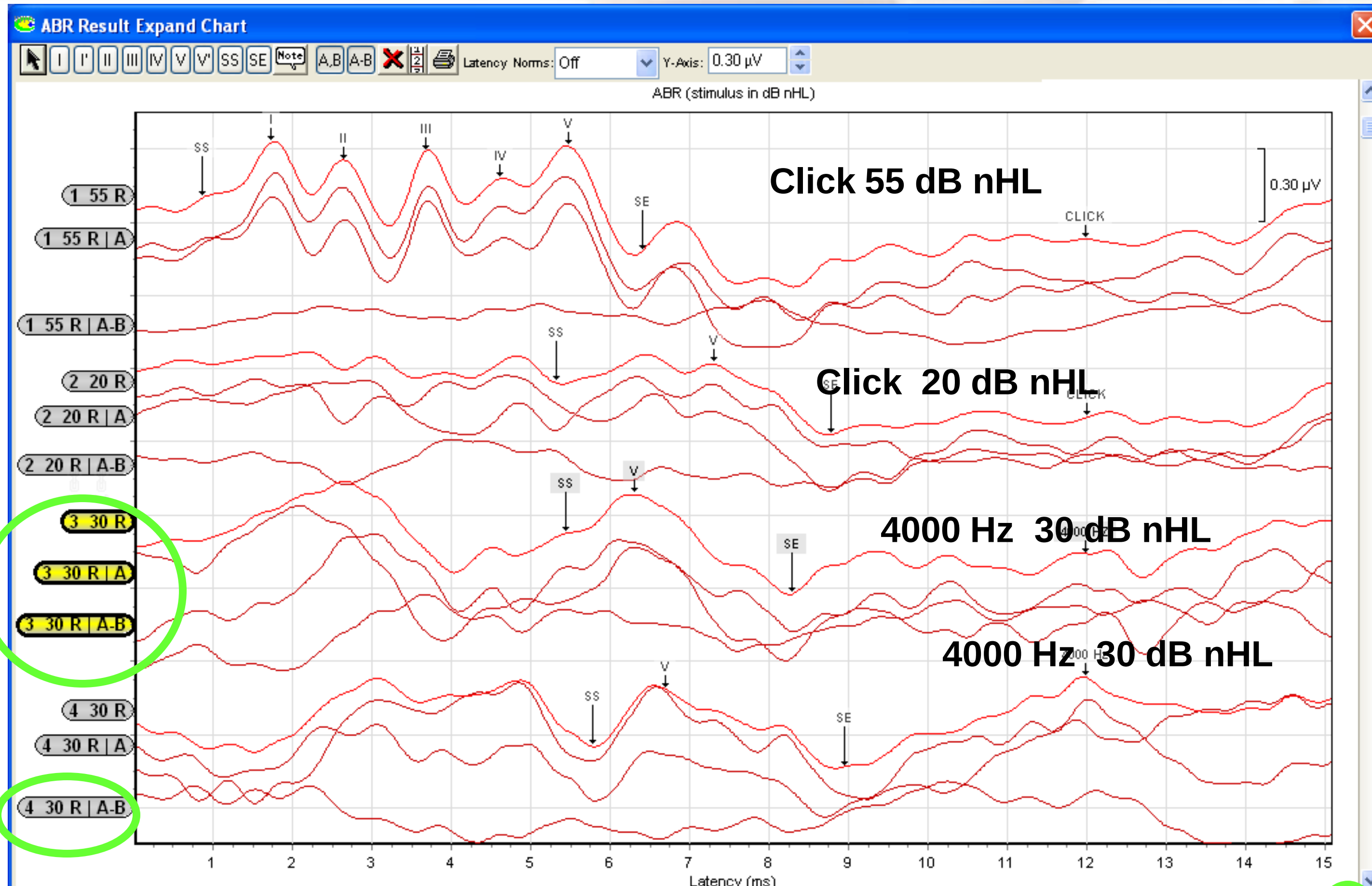
A good way to keep an older child “quiet” is to occupy the child with watching a cartoon, toys, drawing, games

VivoLink™ attracted the 3-year-old female patient and allowed for a faster test.

Using real-time split-traces A & B, A-B noise-estimation trace, and Correlation Coefficient speeds up threshold detection

Example of ABR to click & 4000 Hz tone burst.

4-year-old girl, drawing during the test.



	Test Conditions	I ms	III ms	V ms	-II	-\	-I	//	Stat-S	Stat-E	Corr.
	2 20 R: Right ear, Pro=4.50 - ABR air-conducted click 37.7, Stim.=37.7, Ipsi, Click, ER-3A, Pol=Rare, Alg=Kal, Sta=Awake, N=4720, 0%, Neq=2607			7.30					5.32	8.78	0.81
▸	3 30 R: Right ear, Pro=4.50 - ABR air-conducted click 37.7, Stim.=37.7, Ipsi, Click, ER-3A, Pol=Rare, Alg=Kal, Sta=Awake, N=2336, 0%, Neq=1321			6.31					5.45	8.29	0.84
	4 30 R: Right ear, Pro=4.50 - ABR air-conducted 4000 Hz tone-burst 37.7, Stim.=37.7, Ipsi, 4kHz, ER-3A, Pol=Rare, Alg=Kal, Sta=Awake, N=2960, 0%,			6.70					5.79	8.96	0.93
	5 20 R: Right ear, Pro=4.50 - ABR air-conducted 4000 Hz tone-burst 37.7, Stim.=37.7, Ipsi, 4kHz, ER-3A, Pol=Rare, Alg=Kal, Sta=Awake, N=4976, 0%,										

Non-sedated capability is particularly helpful in developing countries with limited anesthesia facilities

ABR tests conducted in non-sedated infants and young children at the University of Pretoria, South Africa.

Photos: Courtesy of Dr. Jay Hall, III, Ph.D., and Dr. De Wet Swanepoel, Ph.D., does not mean their endorsement of the new techniques.

Very important is to keep *acoustically quiet* during a threshold ABR test, as background acoustic noise elevates thresholds by masking!

- **Test in a quiet room in the clinic, but not necessarily booth**
- **Switch off devices that can produce acoustic noise – fans, ventilators, etc.**
- **Instruct parents and caregivers, and other staff to restrain from talking and producing noises otherwise near the patient**
- **Ensure good occlusion and appropriate insertion of the inserts**

Survey of Audiologists using new ABR technology found the quality of non-sedated ABR largely at par with sedated conventional ABR

Respondents who are using the new techniques on more than half of cases requiring an ABR have found:

It had positive overall impact on patient during diagnostic tests	48%
Chose the new technology for the quality of diagnostic tests	90%
The test quality was on par with Sedated ABR's	61%
New technology helps to test a wider range of patients	70%

Helmer, E. (2009) *Survey of Integrity™ users* (unpublished).

vivosonic
clinical efficiency through innovation

Conclusions

- New techniques enable practical ABR evaluation in most non-sedated pediatric patients.
- The quality of Non-sedated ABR obtained with the new techniques is largely at par with sedated ABR using conventional equipment.
- New techniques can be effectively used in electro-magnetically challenging environments like Neonatal Intensive Care Units (NICU) and enable timely delivery of audiological assessment to the NICU population.
- By eliminating the need of sedation and anesthesia in most cases, new techniques can reduce the associated risks, shorten the test-to-service delivery timeline, reduce the age of identification, help achieving the 1-3-6 EHDI goals.
- The healthcare system can save the costs of sedation and anesthesia for ABR.

Acknowledgements

The authors are very grateful to the many researchers, clinicians, and AuD students who pioneered, clinically use, and provided invaluable feedback and shared their experiences with the use of new ABR techniques in non-sedated pediatric patients:

Drs. Jay Hall, Todd Sauter, De Wet Swanepoel, Roger Ruth, Dianne Meyers, Lynn Spivak, Sharon Fujikawa Brooks, Thierry Morlet, Yehuda, Holdstein, Ben Sierra

Audiologists Leslie Wexler, Michelle Dubé, Scott Hanson, Hannah Alexander, Friedel Cunningham, Stella Gershkovich,

Thank you
for your interest

Best wishes
from
vivosonic

Questions?