Using the Integrity within an Early Hearing Detection and Intervention Program

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CAA Breakfast Symposium
October 19, 2018
Niagara Falls, ON

Topics

1. Overview of the Ontario Infant Hearing Program
2. ABR assessment protocol for infant hearing loss identification
3. Development & application of nHL to eHL corrections

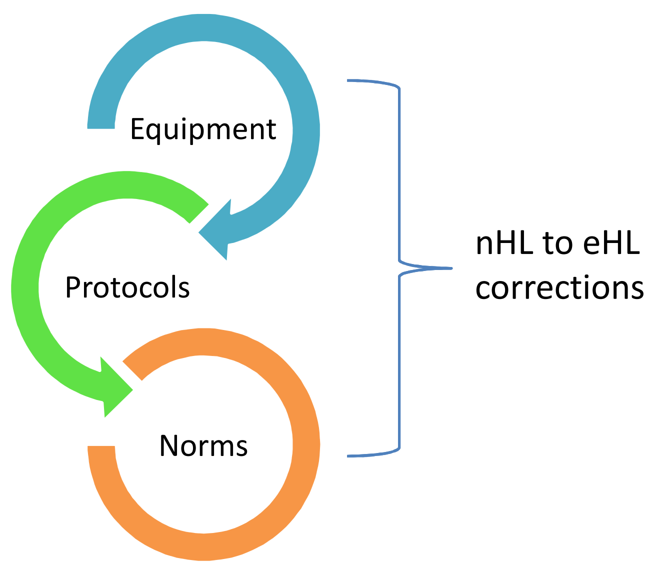
Rationale & Evidence Standard

Why did we need to do this work?

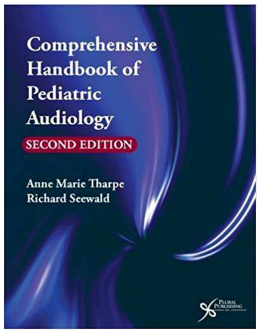
1. Rationale for correcting from nHL to eHL for the purposes of threshold estimation in infants prior to hearing aid fitting;
2. Review of research in the area of nHL to eHL corrections including current issues in this area; and
3. New data on the validity and application of corrections within our program; clinical protocols.

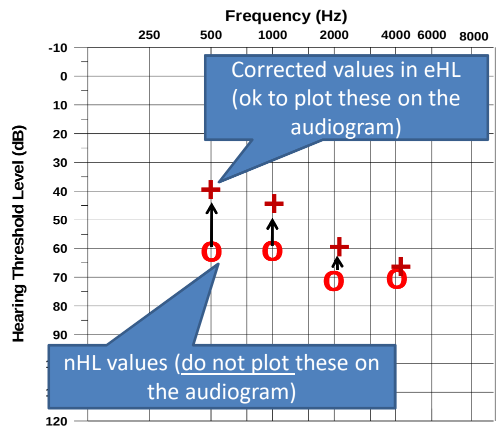
EHDI programs support early identification of hearing loss, often for the purposes of supporting intervention.

What do we need?



The clinical impact of nHL to eHL corrections: the hearing thresholds will be too high if not corrected.





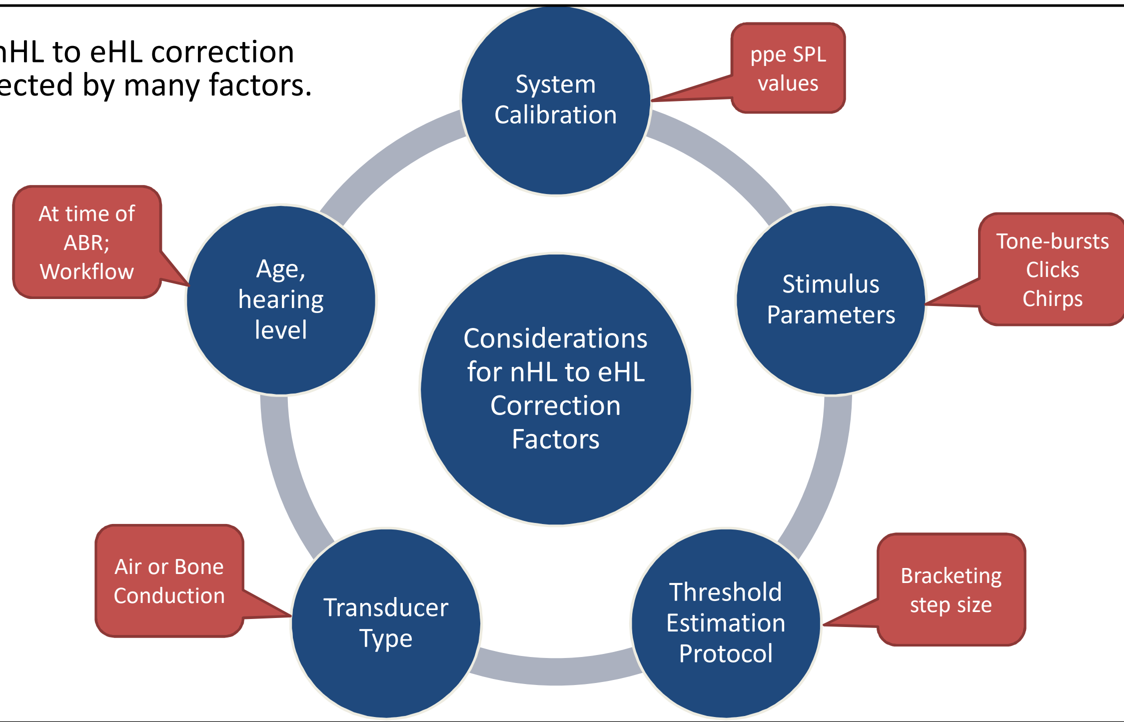
Chapter 25, figures 25-3

What is an nHL to eHL correction anyway?

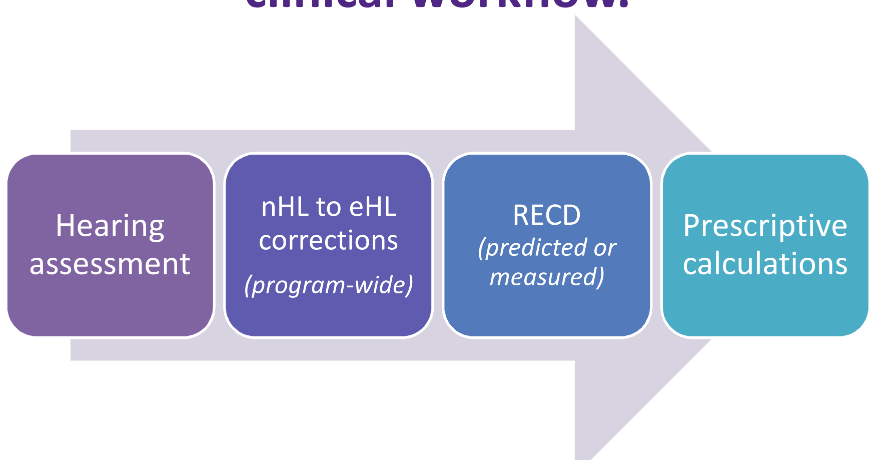
- Audiometric pure tones are calibrated in dB HL
- Frequency-specific ABR is calibrated in dB nHL
  - Various systems to define "normal" nHL levels exist & we'll review these.
- HL and nHL are not the same. nHL is typically higher than HL.
  - We can apply **corrections** to nHL to predict HL levels. The predicted units are designated with "eHL" for "estimated" HL so that record-keeping can distinguish between eHL and later HL audiograms from behavioural audiometry.

Bagatto et al 2005; 2010; Gorga et al 1993; McCreery et al 2015; Stapells et al 2005; Stapells 2000

The nHL to eHL correction is affected by many factors.



We apply nHL to eHL corrections in a systematic clinical workflow.



Ontario Infant Hearing Program 2016; 2016;
American Academy of Audiology 2013

In our Ontario IHP, this has been our plan for using nHL to eHL corrections for many years.

- The **assessing audiologist** applies the correction before plotting results on an audiogram. All results are discussed in eHL (not nHL) to better link to later assessment.
  - We have program-level corrections that are used at all sites. These are specific to our equipment and calibration.
- The **amplification audiologist** is trained that the corrections should already be done (so that it doesn't happen twice!).
- **Designated training centres** are available for consultation in difficult or ambiguous cases.

NEW STANDARDS NOW EXIST FOR SHORT TERM TONE BURST STIMULI

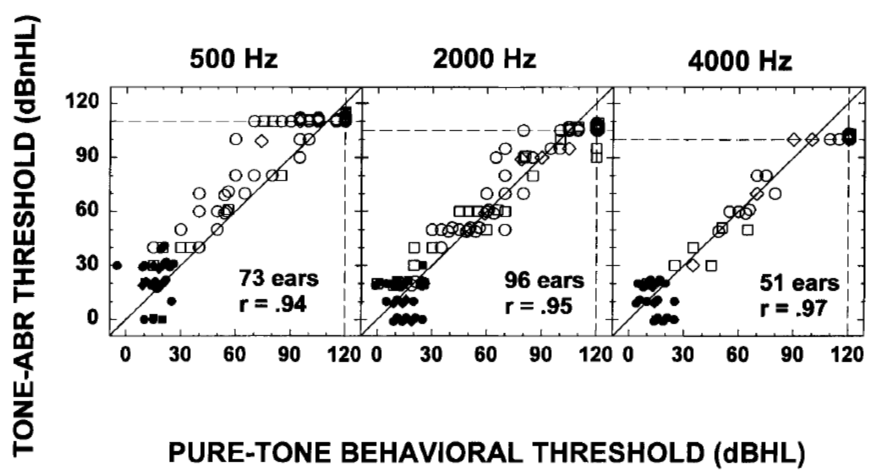
Volume 35, issue 4, 2014: audiometric calibration
Volume 36, issue 1, 2015: short tone calibration

IEC (2007) 60645-6

Even though standards are now available for some protocols with short stimuli, we need to consider whether these are universal. After a systematic literature review that included equipment factors, we can summarize:

- *nHL to eHL corrections may be specific to infant age & hearing loss equipment type, stimulus type, filter settings, window settings, repetition rate, type of averaging, and stopping rules.*

Early work defined one relationship between ABR and behavioural thresholds.



Stapells, Gravel, & Martin, 1995

A meta-analysis by Stapells et al (2000) revealed that normal hearing and hearing impaired eHL corrections may differ. (32 studies)

Table 5. Summary of Mean Thresholds, Standard Errors, and 95% Confidence Intervals for Tone-ABR Thresholds (in dB nHL) in Participants With Normal Hearing as a Function of Frequency.

	500 Hz	1000 Hz	2000 Hz	4000 Hz
Adults				
Mean Threshold (dB nHL)	20.4	16.2	13.4	11.8
Standard Error (dB)	0.8	0.6	0.5	0.5
95% Confidence Interval (dB nHL)	18.8 - 21.9	14.9 - 17.4	12.3 - 14.4	10.7 - 12.8
Number of Participants	271	271	216	258
Infants and Young Children				
Mean Threshold (dB nHL)	19.6	17.4	13.6	15.5
Standard Error (dB)	0.5	0.7	0.9	0.7
95% Confidence Interval (dB nHL)	18.8 - 20.5	16.0 - 18.7	11.8 - 15.5	14.1 - 16.8
Number of Participants	369	78	65	209

Table 6. Summary of Mean Difference Scores, Standard Errors, and 95% Confidence Intervals for Tone-ABR Estimation of Pure-Tone Behavioural Threshold in Participants With Sensorineural Hearing Loss as a Function of Frequency.

	500 Hz	1000 Hz	2000 Hz	4000 Hz
Adults				
Mean Threshold (dB nHL)	+13.4	+10.3	+8.4	+5.2
Standard Error (dB)	1.2	0.9	1.0	1.4
95% Confidence Interval (dB nHL)	11.0 - 15.8	8.4 - 12.1	6.3 - 10.3	2.4 - 8.0
Number of Participants	85	167	100	84
Infants and Young Children				
Mean Threshold (dB nHL)	+5.5	+4.9	+0.6	-8.1
Standard Error (dB)	1.3	1.3	1.1	2.0
95% Confidence Interval (dB nHL)	3.0 - 8.0	2.4 - 7.3	-1.6 - +2.7	-12.1 - -4.1
Number of Participants	125	118	110	35

Note. *Difference score = Tone-ABR threshold (in dB nHL) minus Pure-Tone Behavioural Threshold (in dB HL).*

Since then…

9 - adults with NH

5 - adults with HL

11 - children with NH

8 - children with HL

*studies including multiple groups have been counted repeatedly

A recent study found that degree of hearing loss degree impacts the eHL correction. Impact?

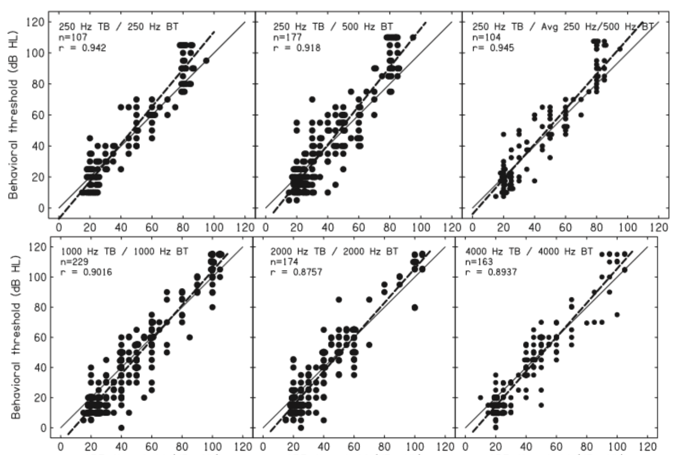


Fig. 2. Behavioral thresholds (BT) as a function of auditory brainstem response (ABR) thresholds for 1000 Hz (left), 2000 Hz (middle), and 4000 Hz (right). The number of observations (*n*) and the correlations are provided within each panel. The solid thin line is provided as a reference and has a slope of one. The dashed line represents a best-fit line to the data in each panel, and has a slope greater than one.

(McCreery et al., 2015)

Two approaches for nhL to eHL correction:

I. <u>Constant</u>

- Same for all degrees of hearing loss

AIR CONDUCTION				
Frequency (Hz)	0.5k	1k	2k	4k
Minimum Level (dB Dial)	35	35	30	25
Correction Factor (dB)*	-10	-10	-5	0

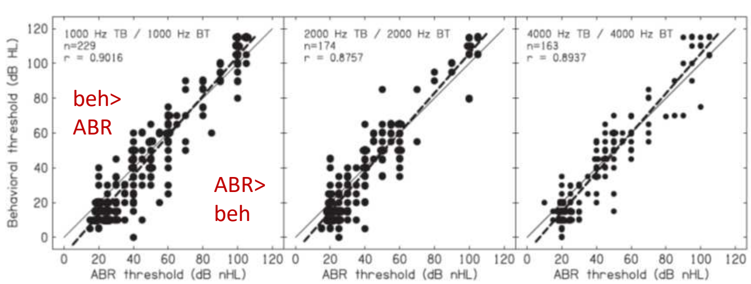
*CF to be added to ABR threshold in nHL

Appendix I (Ontario Infant Hearing Program ABRA Protocol, 2016)

Two approaches for nHL to eHL correction:

II. <u>Level-dependent</u>

- Different depending on degree of hearing loss



eHL (1000 Hz)=-0.13(ABR threshold at 1000 Hz) + 8.32

TABLE 4. Linear regression equations and correction factors for each test frequency

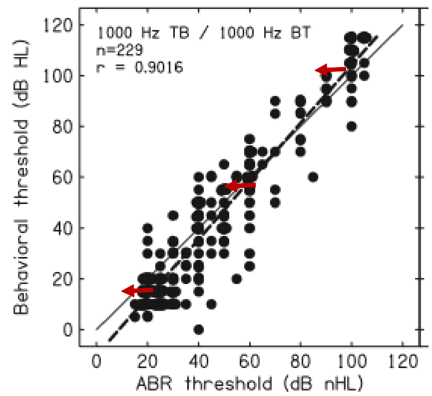
		Examples of Corrections for Specific ABR Thresholds			
	Equation	20 dB nHL	40 dB nHL	60 dB nHL	80 dB nHL
500 Hz	y = –0.22x + 5.90	5	–3	–7	–12
1000 Hz	y = –0.13x + 8.32	5	3	0	–2
2000 Hz	y = –0.14x + 7.31	5	2	–1	–4
4000 Hz	y = –0.16x + 9.32	6	3	0	–3

Correction factors to be subtracted from auditory brainstem response threshold to predict behavioral threshold.

(McCreery et al., 2015)

Impact of difference in correction approaches

- Possible "overcorrection" and therefore underestimation of eHL with constant correction.
- But, this is not replicated in many datasets.
- Importantly, the nHL to eHL relationship for our new equipment was not known last April.
  - Good norms for normal hearing infants, less info for SNHL.



What evidence do we require to support province-wide implementation?

- Historically, we have adopted Stapells' recommendation that any system should have normative nHL to HL data for this following factors before it is used to make clinical decisions for babies:
  - Per stimulus
  - For air and bone conduction
  - For infants and adults
  - For those with normal hearing and hearing loss.
- How to proceed?

Our program purchased new equipment last year:

- We deferred clinical decision-making for any individual infant with the new equipment until we had determined an nHL to eHL correction.
- We used a rapid method to develop the new correction:
  - Retrospective chart review to confirm nHL to eHL performance from onset of the ABRA 2016 protocol – this gives us a program baseline.
  - Side by side testing with Biologic & Vivosonic to determine nHL to nHL differences.
  - Protocol adjustments as needed once side by side data became available.

Estimating Audiograms from the ABR for Infant Hearing Aid Fittings: Data from the Ontario Infant Hearing Program

Marlene Bagatto, Rana El-Naji, David Purcell, Susan Scollie

Acknowledgements

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- Marie Pigeon, Children's Hospital of Eastern Ontario, Ottawa, Canada
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- Kristen Wheeler, ErinoakKids Children's Treatment Centre, Mississauga, Canada
- Jill Witt, Humber River Hospital, Toronto, Canada

- Ontario Ministry of Children and Youth Services
- Vivosonic, Inc.

Current Work: Rationale

Ontario Early Hearing Detection and Intervention (EHDI) program has adopted several ABR correction factors over the years

- Equipment updates
- Calibration changes
- Improved ABR threshold estimation skills

1) Assess accuracy of current ABR corrections
2) Evaluate ABR system new to the Ontario program
3) Inform future protocols

Ontario ABR Assessment Protocol

- AC ABR toneburst thresholds at 500, 2000, and 4000 Hz
  - also at 1000 Hz when indicated
- BC ABR toneburst thresholds at 500 and 2000 Hz
  - when indicated
- Click ABR to assess cochleo-neural status (as needed)
- Diagnostic DPOAE for cross check and neuropathy
- Tympanometry with 1000 Hz probe
- Ipsilateral reflexes at 1 kHz with a 1000 Hz probe

Bracketing Step Size:
No larger than 10
5 dB if ≥ 70 dB eHL

Ontario Ministry of Children and Youth Services 2008; 2016

Frequency-Specific Corrections (Ontario, 2016)

	AIR CONDUCTION				BONE CONDUCTION	
Frequency (Hz)	0.5k	1k	2k	4k	0.5k	2k
Minimum Level (dBnHL)	35	35	30	25	25 <1 yr 30 ≥1 yr	30
Correction Factor	-10	-10	-5	0	0	-5

Correction factors are applied to ABR nHL values to obtain estimates of behavioural thresholds (eHL)

https://www.mountsinai.on.ca/care/infant-hearing-program/documents/protocol-for-auditory-brainstem-response-2013-based-audiological-assessement-abra

Ontario Ministry of Children and Youth Services 2016

Research Question - 1

How well do the current Ontario ABR corrections predict behavioural thresholds?

Procedure - 1

Clinical File Review

- 4 Ontario IHP sites provided retrospective data from a total of 43 infants (84 ears)
- Age range: 1 to 21 months
- For each infant:
  - ABR threshold estimations (10 then 5 dB step sizes)
  - Behavioural (VRA) thresholds (10 then 5 dB step sizes)
  - Insert earphones coupled to foam eartips
  - Varying degrees of SNHL

Conclusions - 1

- Current Ontario ABR corrections provide good predictions of behavioural thresholds
  - Largest VRA-ABR difference = 2.26 dB at 2000 Hz
- Step size matters
  - No need for level-dependent corrections
- Application of ear canal acoustics improves prediction of behavioural thresholds from the ABR
  - Important for individualizing hearing aid prescription

Research Question - 2

What is the impact of infant ABR collection parameters on correction factors?

Procedure - 2

Evaluation of ABR collection parameters and their impact on current corrections

- 7 Ontario IHP sites (10 Audiologists) provided data from a total of 82 infants (101 ears)
- Parameters evaluated:
  - Participant age
  - Hearing level
  - System type

Ontario IHP purchased new ABR equipment. Required evaluation for infants with hearing loss.

Procedure - 2

- Clinical sites executed Ontario ABR Assessment Protocol (2016) with current equipment (Biologic NavPro) during a clinical appointment
- When time and test conditions permitted, used new IHP system (Vivosonic Integrity) to estimate ABR thresholds with same infant
  - Weighting of recordings (versus unweighted averaging) main parameter difference

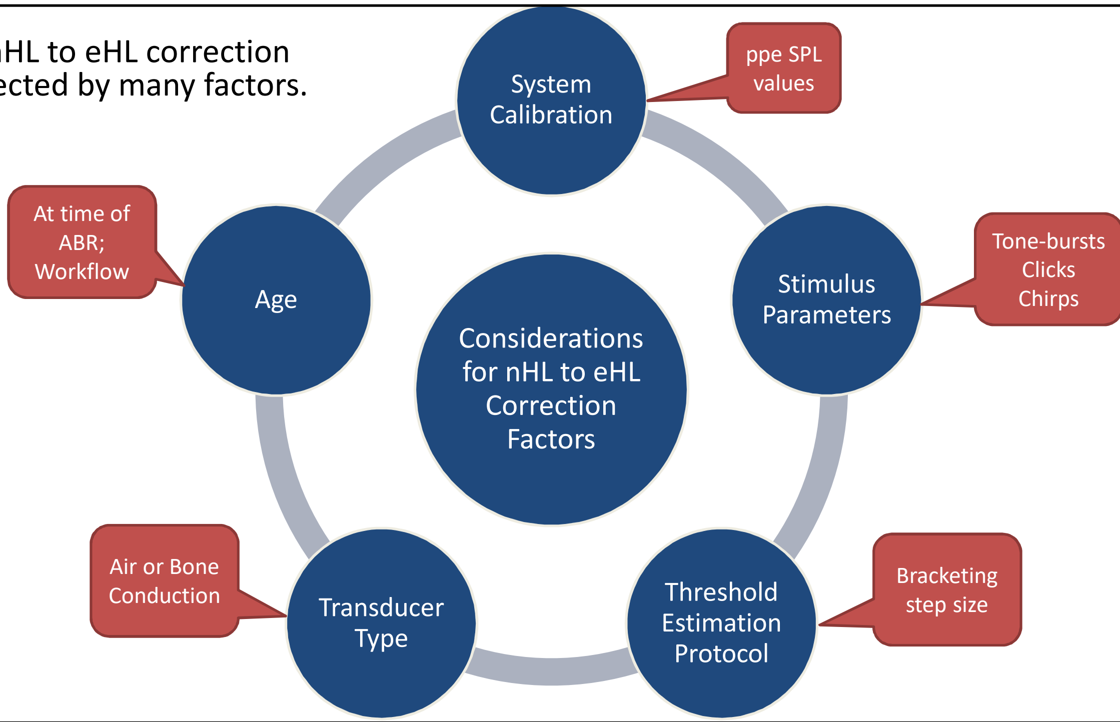
Conclusions - 2

- When ABR assessment parameters are closely matched to Ontario 2016 protocol, Vivosonic Integrity predicts ABR thresholds in infants similar to Biologic NavPro
  - Largest Bio-Viv difference = 4.24 dB at 2000 Hz
- Need more sampling of infants with hearing losses >70 dB nHL
- Minor changes to Ontario ABRA protocol to account for system differences prior to provincial implementation

Clinical Implications

- Corrections to ABR threshold estimates used in Ontario predict behavioural thresholds well
  - Variation in step sizes at high levels supports frequency-dependent correction only
- Application of RECD to assessment information is still necessary for individualizing hearing aid fittings in infants
- Using an alternative ABR system with current Ontario protocol has little impact on accuracy of threshold estimation in infants with hearing loss

The nHL to eHL correction is affected by many factors.



Transition to the Integrity

Practical Tips for New Users

Rana El-Naji

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Overview

- Differences between the systems
  - Hardware (wireless transmission)
  - Appearance of waveforms (aspect ratio)
  - Artifact rejection and Kalman-Weighted Averaging
  - The Use of A and B buffers (concurrent versus sequential collections)
- Recommendations
- Ontario IHP ABRA Protocol Parameters

Hardware

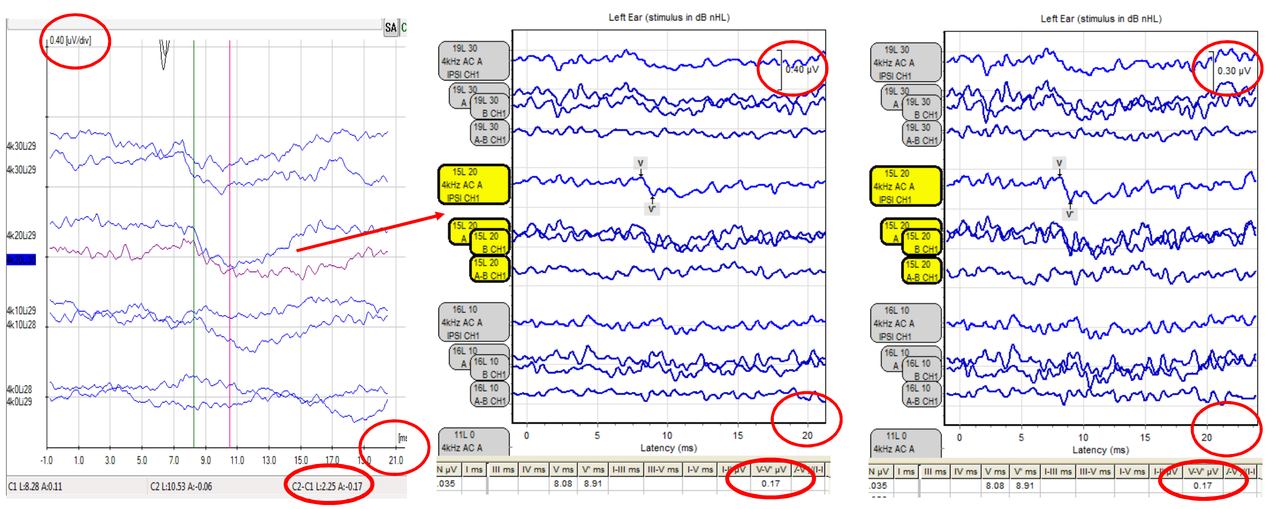
- Wireless feature
  - Integrity system connects through Bluetooth
  - Wireless connection must be established to perform tests
  - Bluetooth on cellphones should be turned off

www.vivosonic.com

Appearance of waveforms

- The waveforms appeared smaller although the amplitude is the same
  - The visual appearance of waveform amplitude is influenced by aspect ratios
  - We standardized two display parameters:
    - Grid: 0.3 µV/division
    - Horizontal axis: 25 milliseconds

Side by Side Comparison



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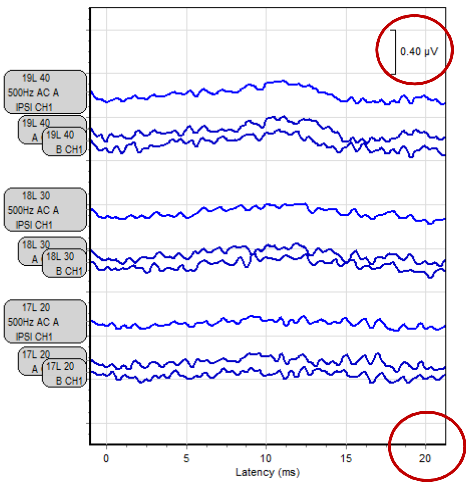
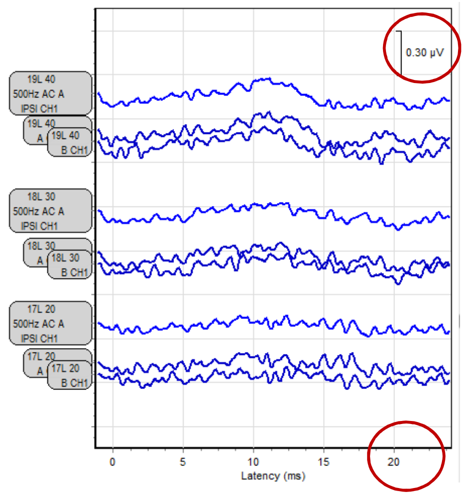


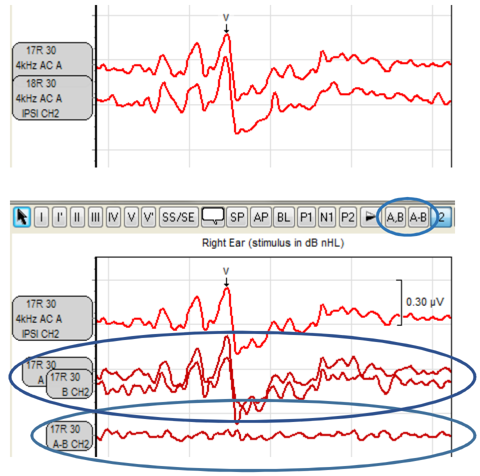


Artifact Rejection and Weighted Averaging

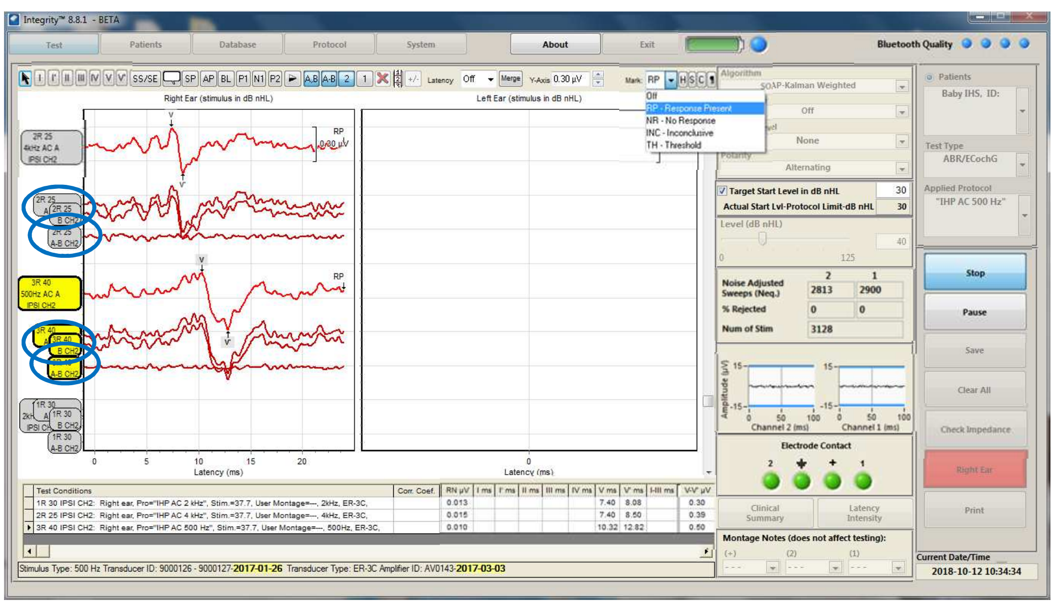
- Kalman-Weighted Averaging versus Unweighted Averaging
  - Averaging: 0 or 100% (all or nothing)
  - Weighted averaging: between 0-100%
- Noisy sweeps weighted less but not rejected
- Use of the pause button is less important
  - Only recommended if EEG very noisy and continued intervention is required

A and B buffers

- Sequential sorting (min: 2000 x2)
  - Collecting one waveform, stop, repeat
- Concurrent collections (min: 4000 x1)
  - While the collection is running, it is actually generating two waveforms, dividing the sweeps simultaneously into an A buffer and a B buffer
  - Time efficient, convenient
  - Baby state is the same across A & B



Test Screen



Recommendations

- Impedance should still be under 5 kOhms and within 1 kOhm of each other
- Vivolink battery should be fully charged or at least more than 50% to avoid any connection issues
- Collect at least 4000 noise-adjusted sweeps combined (2000 in each buffer) for No Response and Threshold judgements
  - If Inconclusive, do another run
  - If at screening level, 2000 combined sweeps might be enough
- Residual noise under 25 nV, or 0.025 µV
  - How does the A-B tracing look? (quiet/flat?)
- Use clinical sort feature available for pattern recognition
- Use the waveform labels provided in the software to create a record of your session with interpretation
  - Remote desktop and anonymized soft files help with between-clinic communication.

Protocol Parameters

FILTERS	
HIGH-PASS ('LOW')	Tonepip thresholds 30 Hz All click recordings 150 Hz
LOW-PASS ('HIGH')	Tonepip thresholds 1500 Hz All click recordings 2000 Hz
NOTCH FILTER	Off, except as a last resort when 60 Hz artifact is severe.
ARTIFACT REJECT	Off
AMPLIFIER GAIN	150,000 (not adjustable)
AVERAGING	2000-4000 adjusted sweeps per combined tracing, 1 to 3 combined tracings per condition.
EPOCH LENGTH	25 ms
GRID	0.3 µV
RESIDUAL NOISE TARGET	≤ 0.025 µV, recommended for Response-Negative judgment.
INTENSITY LEVELS	Starting at 0, 5 dB intervals until max level
STIMULI	
TONEPIPS	Linear ramp (Trapezoidal envelope), 2-1-2 cycle rise/plateau/fall times. Alternating polarity. Repetition rate 37.7/s.
CLICKS	100 µs drive voltage pulse duration Alternating, condensation, rarefaction polarity as specified. Repetition rate 21.5/s
MASKING	Ipsilateral: None. Contralateral: discretional 60 dB broad-band noise.
STIMULUS TRANSDUCER CALIBRATION OFFSETS	`See Appendix D for IHP Integrity Stimulus Transducer Calibration. See Appendix E for IHP Integrity Protocols.

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