ABR Evaluations:

Difficult Populations in Difficult Environments

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The History - 2003

- Infant Hearing and Screening Program
  - Improve standard of care for hospitalized infants
    - Add diagnostics and intervention to inpatient protocol
    - Adherence to EHDI/1-3-6 timeline
    - Carefully monitor children at risk for late onset and progressive loss (inpatient and outpatient basis)
  - Reduce LTF (Inpatient and Outpatient)
  - Compassion based care and counseling for families

The Good Times and the Bad

There's Got To Be A Better Way - 2011

Comparison of Auditory Brainstem Response Systems in the NICU Population

David K. Brown, Lisa L. Hunter, Kelly Baroch, Edie Eads

ABSTRACT

Completing auditory electrophysiologic recordings in preterm infants while in a NICU environment is a challenging procedure. Completion of a QI project can assist in determining whether investment in new technology is cost-effective. This project revealed that the Vivosonic Integrity obtained lower threshold levels in this noisy environment, and was comparable to the Bio-logic NavigatorPRO in classifying type and degree of hearing status.

INTRODUCTION

The Neonatal Intensive Care Unit (NICU) is an electrically hostile environment, with electrical signals in the frequency range of the Auditory Brainstem Response (ABR), which is much lower in amplitude than these extraneous noise sources. The NICU is also acoustically hostile, and the infant produces myogenic activity as well as respiration and vascular noise, which all can interfere with ABR recordings , particularly at low stimulus intensities.

Priorities for effective and efficient ABR Systems in the NICU include:

- **Ability to manage electrical artifact**
- **Ability to filter patient movement**
- **Ability to easily achieve acceptable impedance on infants with poor skin integrity**
- **Ease and efficiency of testing (i.e. data collection screens, protocol set up, data analysis, printing)**

- **NICU ABR challenge: Acoustic noise (low signal) + EMI (high noise) = low SNR → poor detection → false outcomes**

- **The Vivosonic Integrity™ system (Toronto, ON) aims to reduce electrical, ECG and EOG interference through an in-situ amplifier (Amplitrode™) mounted on the ground electrode, and to reduce myogenic artifacts through weighted averaging known as Kalman weighted averaging, through optimized signal buffering, and a Signal to Noise-adaptive filter.**

AIMS

1. Assess effectiveness of the Vivosonic Integrity™ system head to head with the Bio-logic NavigatorPro ABR system for click and toneburst ABR recordings.

2. Compare thresholds obtained for both systems to determine if responses could be improved using the Bluetooth amplifier, Kalman weighting and other features of the Vivosonic system.

METHODS

Participants:

- 28 infants tested in NICU with one or both instruments
- 20 ears provided click thresholds for both instruments
- 8 ears provided tone burst thresholds for both instruments at 1, 2 or 4 kHz

Hearing Status Categories (n=ears):

Normal = 11
Mild = 6
Mild to Moderate = 2
Profound = 2 (excluded from comparison)
Neural = 2 (excluded from comparison)

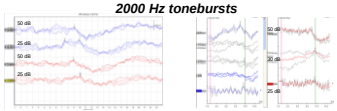
Procedures:

All tests were performed by an audiologist with over 10 years of experience assessing infants in the NICU with threshold ABR. Thresholds were independently verified by a second investigator. ABR protocol for the two systems is as follows:

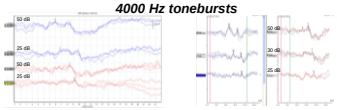
Vivosonic Integrity	***Bio-logic NavigatorPro***
• Clicks Alternating: 37.1/s • Response filter: 100-3000 Hz	• Clicks Alternating: 37.1/s • Response filter: 100-3000 Hz
• Tones Alternating: 37.1/s • Response Filter: 30-1500	• Tones Alternating: 37.1/s • Response Filter: 70-1500

Clicks

2000 Hz tonebursts



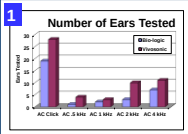
4000 Hz tonebursts



Individual click and tone burst responses from a single subject

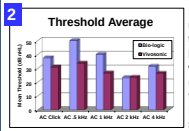
RESULTS

1



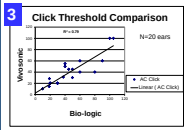
This figure shows the number of ears in which testing was completed for each unit by stimulus type.

2



For infants tested with both units, thresholds obtained with the Vivosonic were equal to or lower than the Bio-logic. Clicks were significantly different ($p=0.04$) and a similar trend for tone bursts was shown, but Ns were to small to show a significant difference.

3



The click thresholds were shown to be highly correlated between the two units.

Inter-Test Agreement for Bio-logic and Vivosonic:

- Within 10 dB = 15/20 (75%)
- >10 dB, less than 20 dB = 5/20 (25%)
- >20 dB = 0

Qualitative Advantages of Vivosonic compared to Bio-logic

- Reduction of electrical artifact
- Ease of achieving acceptable impedances
- Waveform integrity maintained with infant movement
- Ability to test in lighter sleep states/quiet alert states
- Ability to mark waves while testing and view both absolute and interpeak intervals in the test screen

Qualitative Disadvantages of Vivosonic Compared to Bio-logic

- Inability to switch between ears during testing
- Lack of split screen option
- Need a better neonatal electrode – smaller with flexible material
- Need more options on protocol settings – starting intensity, polarity
- Saving waveforms after 20 runs interrupts testing
- Cannot delete selected blocks of waves while testing
- Intensity selection – both in protocol screen and test screen
- Lengthy software initialization

SUMMARY

- The number of thresholds obtained for Bio-logic and Vivosonic were equivalent for clicks and tone bursts.
- Threshold averages were significantly better for the clicks using Vivosonic compared to Bio-logic. Similar trends were shown for tone bursts but Ns were to small to show a difference.
- Correlation between Bio-logic and Vivosonic thresholds for clicks was high ($R^2 = .79$).
- Majority of hearing status conclusions were within 10 dB (75%).
- 10-20 dB threshold differences occurred in 25% of ears.
- In 4/5 cases, Vivosonic showed lower (better) thresholds.

Limitations:

- Infants were in an NICU environment and thus limited time was available for full head to head comparison at all frequencies.
- Time and electrical artifact often precluded a full test with both instruments, therefore, head-head data on the same infant is limited.
- Bone conduction testing was lower priority due to environment and critical status.

CONCLUSION

1) The number of thresholds responses obtained for the two instruments was similar.
2) Wave V threshold level for the Vivosonic instrument was significantly better for clicks.
3) Clinical decisions about hearing status were the same or better in 95% of ears with Vivosonic.
4) Vivosonic was preferred for ease of obtaining results in noisy and awake infants.
5) Bio-logic was preferred for ease of software use .

REFERENCES

1. Leski,JM. Robust weighted averaging. (2002) IEEE Transactions on Biomedical Engineering, 49:796-804.

ACKNOWLEDGEMENTS

Thank you to the staff and families in the CCHMC NICU for their support throughout this project. Funding provided by the Division of Audiology, Cincinnati Children's Hospital Medical Center.

There's Got To Be A Better Way - 2011

- Head to head testing in NICU with standard signal averaging vs Integrity system (Kahlman weighting, Blue tooth technology, amplitrode)
- Thresholds were similar or better for clicks with Integrity
- Could obtain toneburst data with Integrity
- Excellent in electrically hostile environment with noisy infants
- Preferred old system for some "user issues" like printing waves

2011 Outpatient Quality Review

The Effects of Inconclusive Diagnostic ABR Results on Loss To Follow Up Rates

Kelly A. Baroch, Sara Kallini, Patricia Pauley, Lisa L. Hunter

Cincinnati Children's

Introduction

The Joint Committee on Infant Hearing (JCIH 2007) recommends newborn hearing screening by one month of age, diagnosis of hearing loss by three months of age, and access to intervention services by six months of age in order to maximize communication and educational capabilities.

Loss to follow-up (LTF) rates from newborn hearing screening (NHS) programs continue to be a challenge with only 45% of infants receiving a complete diagnostic evaluation by 3 months of age (CDC 2009).

Aim

The purpose of this quality improvement retrospective chart review was to:

1) determine what percentage of the time a complete ABR was obtained at the initial test session
2) identify LTF trends for infants requiring more than one ABR
3) determine the median age of definitive diagnosis for infants requiring more than one ABR evaluation
4) determine appropriate interventions to reduce LTF rates at this facility based on study findings

Method

- The authors hypothesized that infants requiring more than one ABR appointment have higher than average LTF rates and receive a definitive diagnosis at greater than 3 months of age
- A chart review was completed for 764 infants who were referred to a large children's hospital audiology clinic due to abnormal NHS results
- Infants received ABR evaluations between May 2010 and May 2011
- ABRs were completed by audiologists experienced in evoked potentials evaluations utilizing Biologic Navigator Pro ABR systems

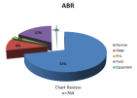
Method (cont.)

- Charts were divided into the following categories:
  - normal hearing after initial ABR
  - permanent hearing loss after initial ABR
  - infants who required more than one ABR due to the following: poor sleep state, middle ear pathology, and technical difficulties or equipment malfunction
- LTF rates were analyzed for each group requiring more than one evaluation.
- Age of definitive diagnosis was analyzed for all infants

Results

After initial ABR evaluation:

- 72% of infants were found to have normal hearing
- 17% had suspected middle ear pathology with incomplete/inconclusive ABR results
- 9% of infants could not be evaluated due to poor sleep state
- 4% were identified with permanent hearing loss
- <1% had incomplete results due to equipment malfunction



Infants Requiring >1 ABR

- **LTF = 48%**

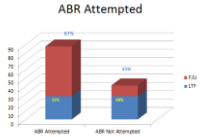
Infants with poor sleep state (9%)

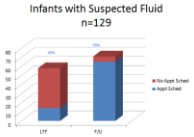
- 63% LTF rate for infants who did not sleep at first ABR
- Scheduling a follow-up appointment before the family left the audiology clinic significantly reduced the LTF rate

Results(cont.)

Infants with middle ear pathology (17%)

- 45% LTF rate
- LTF rates were higher, 68%, if the ABR was not attempted due to suspected middle ear pathology (flat tympanograms) compared to 32% LTF when ABR was attempted
- LTF rates were significantly reduced when a follow-up appointment was scheduled before the family left the audiology clinic





Technical Difficulties or Equipment Malfunction (<1%)

- LTF = 50%

Age of Definitive Diagnosis

- **Infants requiring more than one ABR**
  - >3mo at age of diagnosis = 41%
  - Median age = 6 months
  - Mean age = 4.3 months
  - Range = 2 to 13 months
- **Infants with complete evaluation at initial ABR**
  - >3mo at age of diagnosis = 8%
  - Median age =1 month
  - Mean age = 1.4 months
  - Range = 2 weeks to 4 months

Quality Improvement

Interventions:

- Audiologists educated regarding LTF rates for infants with incomplete ABR evaluations at first appointment
- Follow-up appointments scheduled before the family leaves the clinic for all infants who do not sleep for first ABR
- ABR attempted for all infants at first visit regardless of tympanometry results and middle ear status
- Bone conduction ABR or a statement as to why it could not be completed included for all abnormal ABRs
- Parents receive written results and recommendations for all incomplete/abnormal ABRs

Follow-up Data

Chart review completed for infants receiving ABR evaluations following QI Interventions (n=70)

- 91% of infants normal at first evaluation
- 4% with definitive diagnosis of SNHL or CHL at initial ABR
- 3% Undetermined type of HL (follow-up scheduled)
- 1% ABR not attempted due to poor sleep state (LTF at this time)

Conclusions

The results of this study indicate the following:

- LTF rates for infants requiring more than one ABR test session are higher than the national average (48% vs 45%).
- 41% of infants in this group are greater than 3 months of age at diagnosis.
- Scheduling a follow-up appointment for the family before they leave the audiology clinic reduces loss to follow-up rates
- Attempting an ABR even when middle ear pathology is present improves LTF rates
- QI studies can be effectively utilized to identify and ameliorate weaknesses in clinic procedures that contribute to increased LTF rates.

References

1. American Academy of Pediatrics, Joint Committee on Infant Hearing Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs Pediatrics, 120(2007),p898-921.
2. CDC 2009 data retrieved from http://www.cdc.gov/ncbddd/hearingloss/2009-Data/2009_EHDI_HSFS_Summary_508_OK.pdf

Acknowledgements

We would like to acknowledge Dora Murphy and the audiologists at CCHMC for their assistance and support of this project.

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2011 Outpatient Quality Review

The Effects of Inconclusive ABR Results on Loss To Follow Up

- ABRs at six outpatient centers (n=764)
- 9% did not achieve adequate sleep state (standard signal averaging) (n=71)
- 63% of those were lost to follow up
- 17% had suspected fluid with incomplete ABR due to inability to complete BC ABR
- 45% of these were lost to follow-up
- For infants needing more than one, ABR average age of ID for PHL was 4.3 months

2014 Outpatient Quality Review

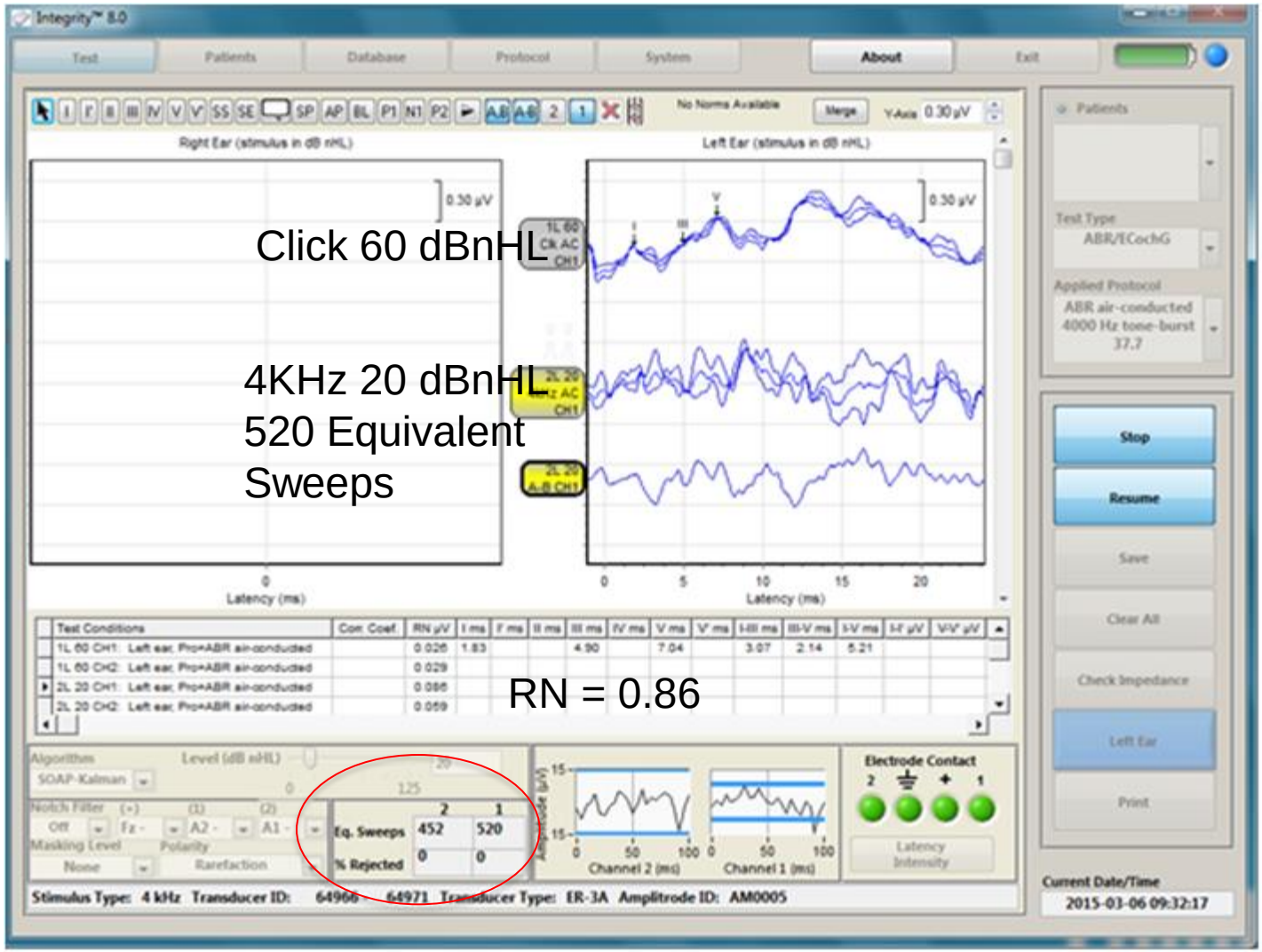
- 3 Outpatient Centers utilizing standard signal averaging
- 3 Outpatient Centers utilizing Vivosonic Integrity
- n=274
- Standard Signal Averaging
  - 11% incomplete due to sleep or no BC
- Vivosonic
  - 2% incomplete due to infant state

Case Studies

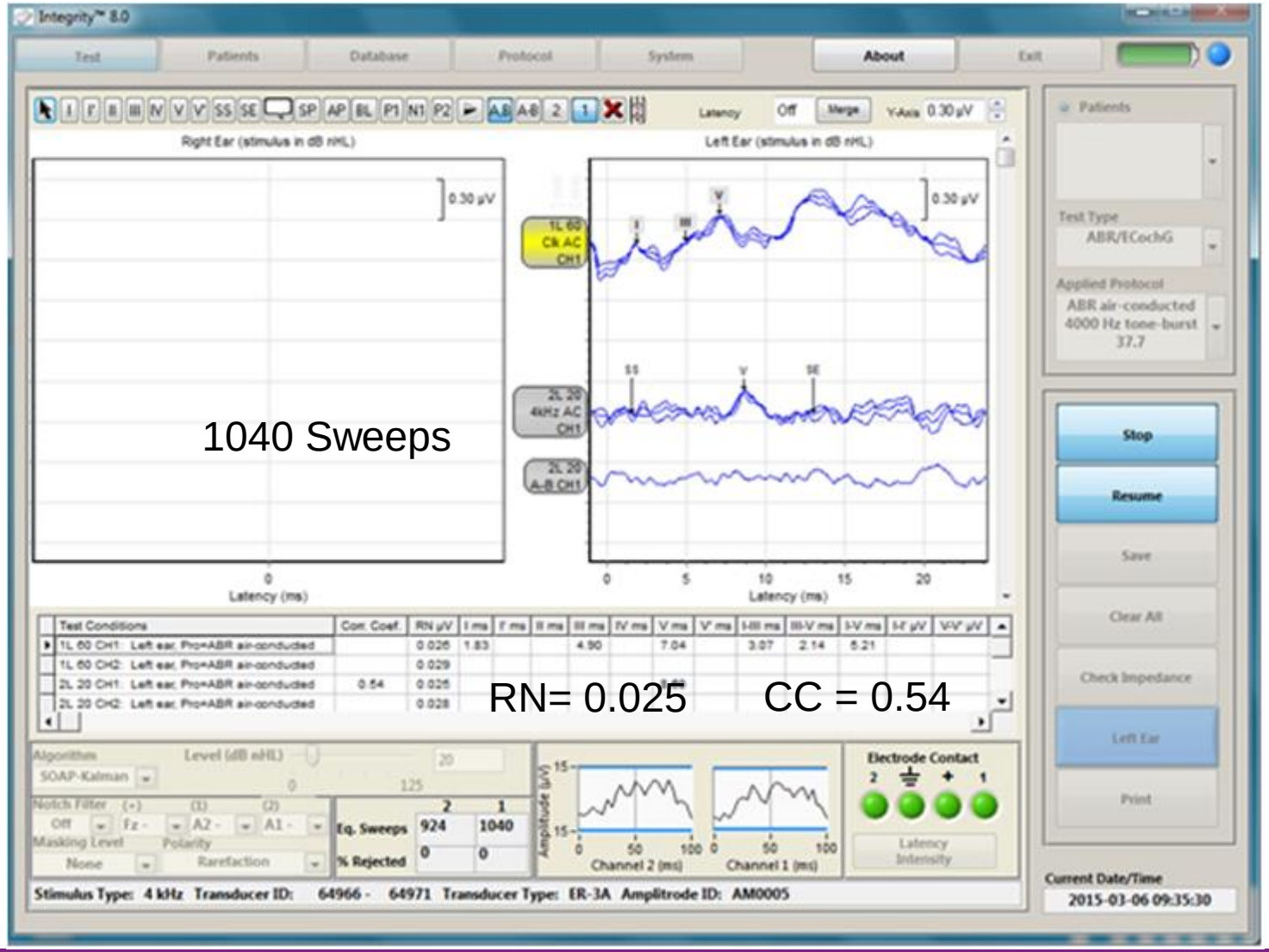
Case #1: Multiple Risk Factors

- Infant Boy born at 35 weeks gestation
- Congenital Diaphragmatic Hernia (CDH)
- ECMO (7 day cannulation)
- Congenital CMV
- Pulmonary hypertension
- Multiple courses of gentamicin, lasix, and valgancyclovir
- Tested at 48 weeks AA / 3 months CA

Case #1:


Integrity™ 8.0
Test
Patients
Database
Protocol
System
About
Exit
Right Ear (stimulus in dB nHL)
Left Ear (stimulus in dB nHL)
Click 60 dBnHL
4KHz 20 dBnHL
520 Equivalent
Sweeps
RN = 0.86
Latency (ms)
Test Conditions
Eq. Sweeps
% Rejected
Electrode Contact
Stop
Resume
Save
Clear All
Check Impedance
Left Ear
Print
Current Date/Time
2015-03-06 09:32:17
Stimulus Type: 4 kHz Transducer ID: 64966 64971 Transducer Type: ER-3A Amplitrode ID: AM0005

Case #1



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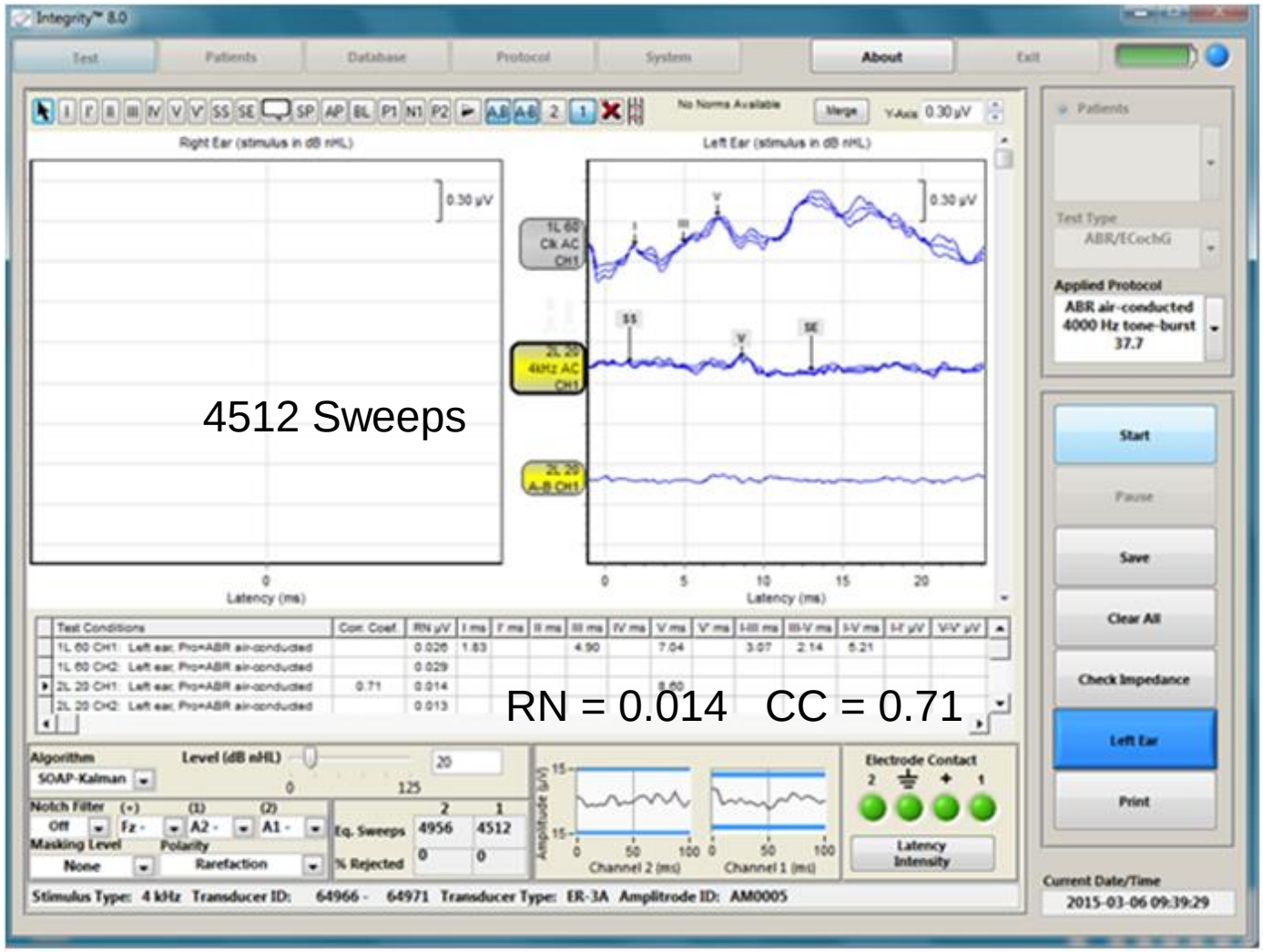
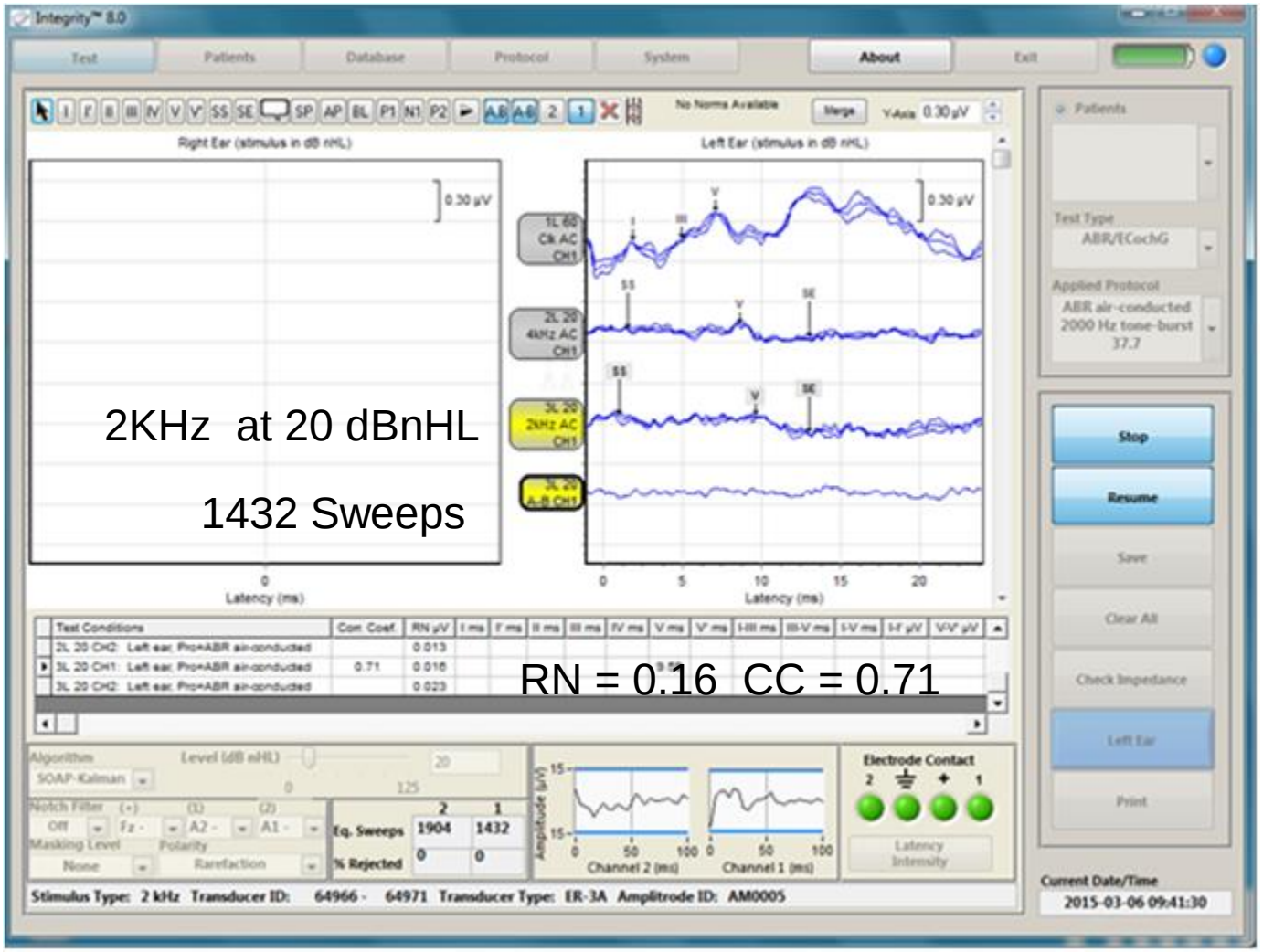
Case #1


Integrity™ 8.0
Test
Patients
Database
Protocol
System
About
Exit
No Norms Available
Merge
Y-Axis 0.30 µV
Right Ear (stimulus in dB nHL)
Left Ear (stimulus in dB nHL)
0.30 µV
4512 Sweeps
Latency (ms)
Patients
Test Type
ABR/ECochG
Applied Protocol
ABR air-conducted 4000 Hz tone-burst 37.7
Start
Pause
Save
Clear All
Check Impedance
Left Ear
Print
Test Conditions
Corr. Coef.
RN µV
1L 60 CH1: Left ear, Pro=ABR air-conducted 0.026
1L 60 CH2: Left ear, Pro=ABR air-conducted 0.029
2L 20 CH1: Left ear, Pro=ABR air-conducted 0.71 0.014
2L 20 CH2: Left ear, Pro=ABR air-conducted 0.013
RN = 0.014 CC = 0.71
Algorithm
SOAP-Kalman
Level (dB nHL)
Notch Filter
Masking Level
None
Polarity
Rarefaction
Eq. Sweeps 4956 4512
% Rejected 0 0
Channel 2 (ms)
Channel 1 (ms)
Electrode Contact
Latency Intensity
Current Date/Time
2015-03-06 09:39:29
Stimulus Type: 4 kHz Transducer ID: 64966 - 64971 Transducer Type: ER-3A Amplitrode ID: AM0005

Case #1:



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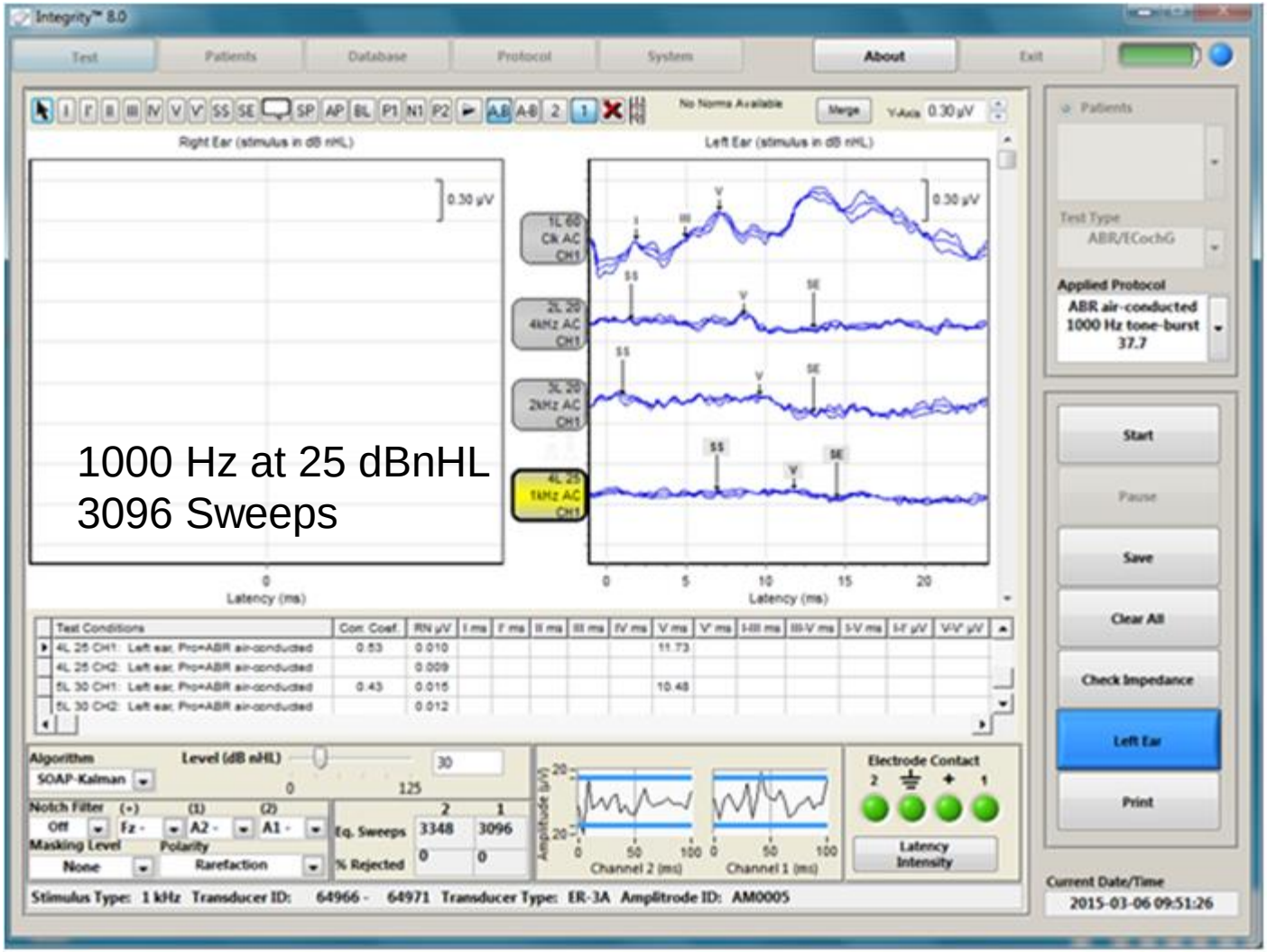
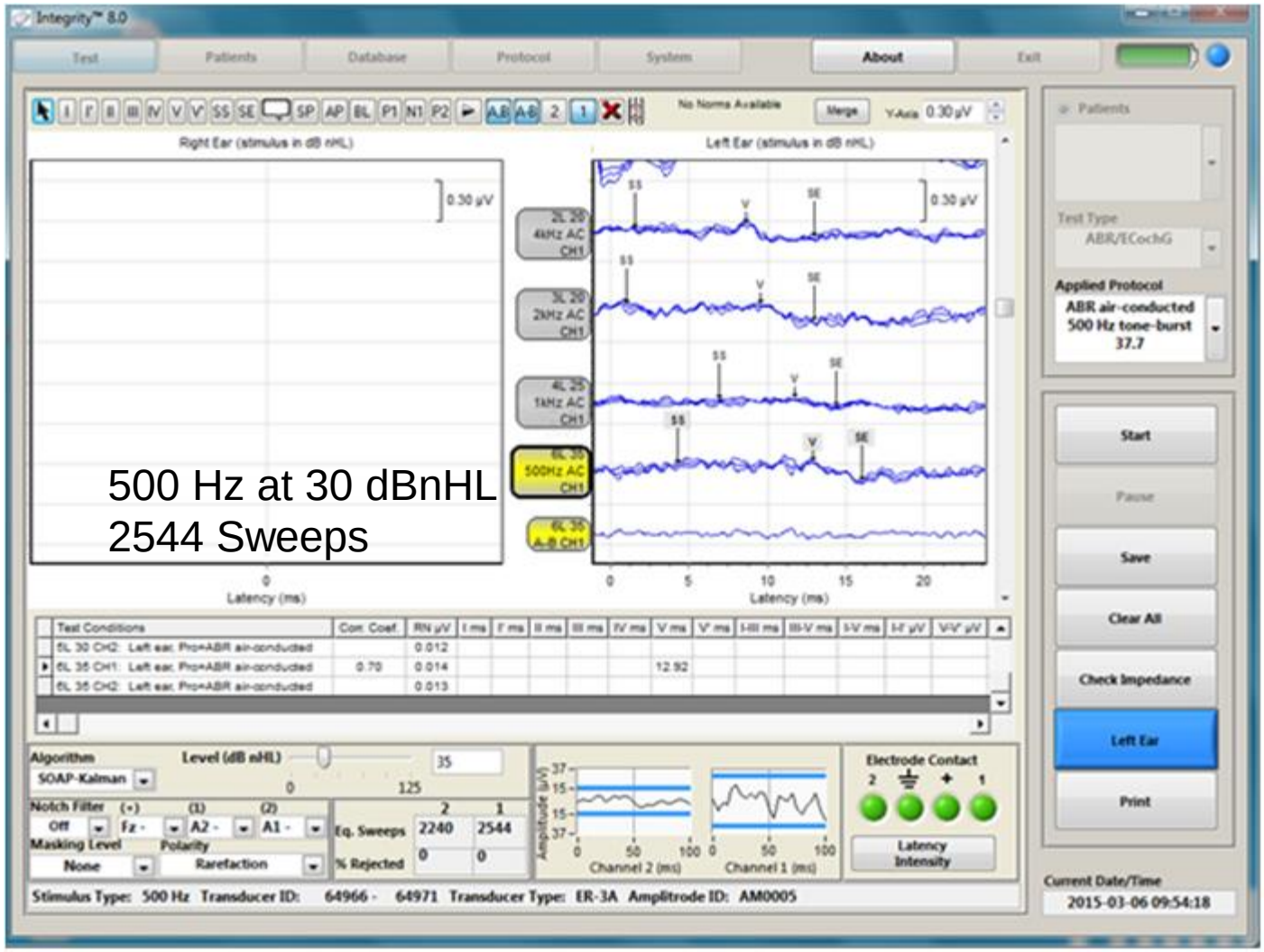

Integrity™ 8.0
Test
Patients
Database
Protocol
System
About
Exit
Right Ear (stimulus in dB nHL)
Left Ear (stimulus in dB nHL)
0.30 µV
1000 Hz at 25 dBnHL
3096 Sweeps
Latency (ms)
Test Type
ABR/ECochG
Applied Protocol
ABR air-conducted
1000 Hz tone-burst
37.7
Start
Pause
Save
Clear All
Check Impedance
Left Ear
Print
Test Conditions
Algorithm
SOAP-Kalman
Level (dB nHL)
Notch Filter
Masking Level
None
Polarity
Rarefaction
Eq. Sweeps
% Rejected
Electrode Contact
Latency Intensity
Channel 2 (ms)
Channel 1 (ms)
Stimulus Type: 1 kHz Transducer ID: 64966 - 64971 Transducer Type: ER-3A Amplitrode ID: AM0005
Current Date/Time
2015-03-06 09:51:26

Case #1:



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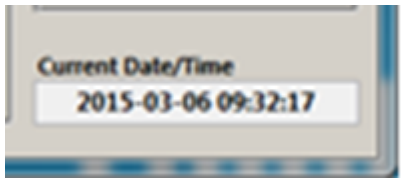
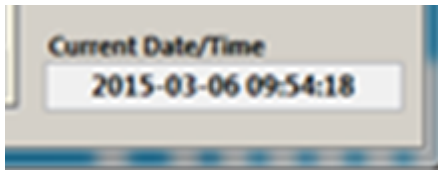
Case #1:

Time Study

- Awake but quiet, calm baby
- Click and 4 frequencies
- Screen shots
- 24 minutes

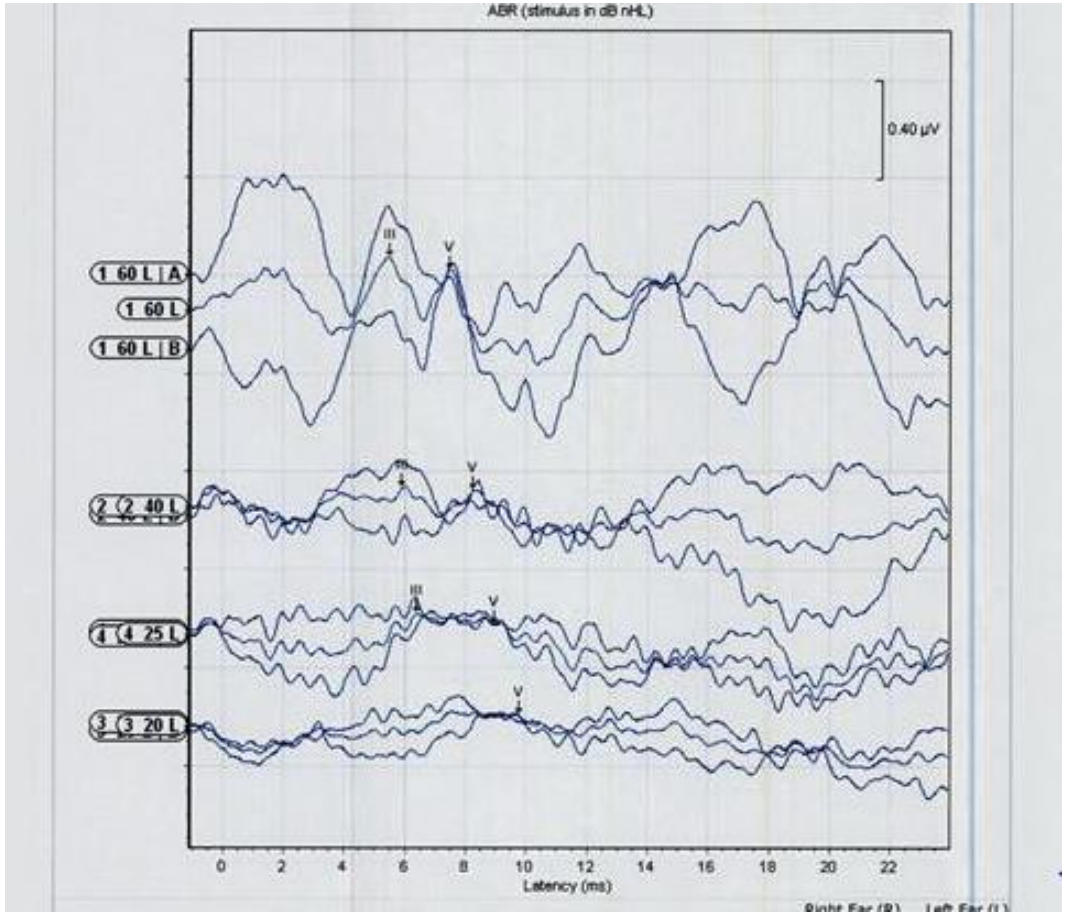




Case #1: The Baby Who Won't Sleep

- A sleeping baby is **ALWAYS** best!
- Patience!! Avoid the temptation to accept noisy waveforms.
- Longer averaging and longer test time
- Utilize residual noise measurement and correlation coefficient to verify visual identification of waveform
- Look at the EEG not the baby!!!

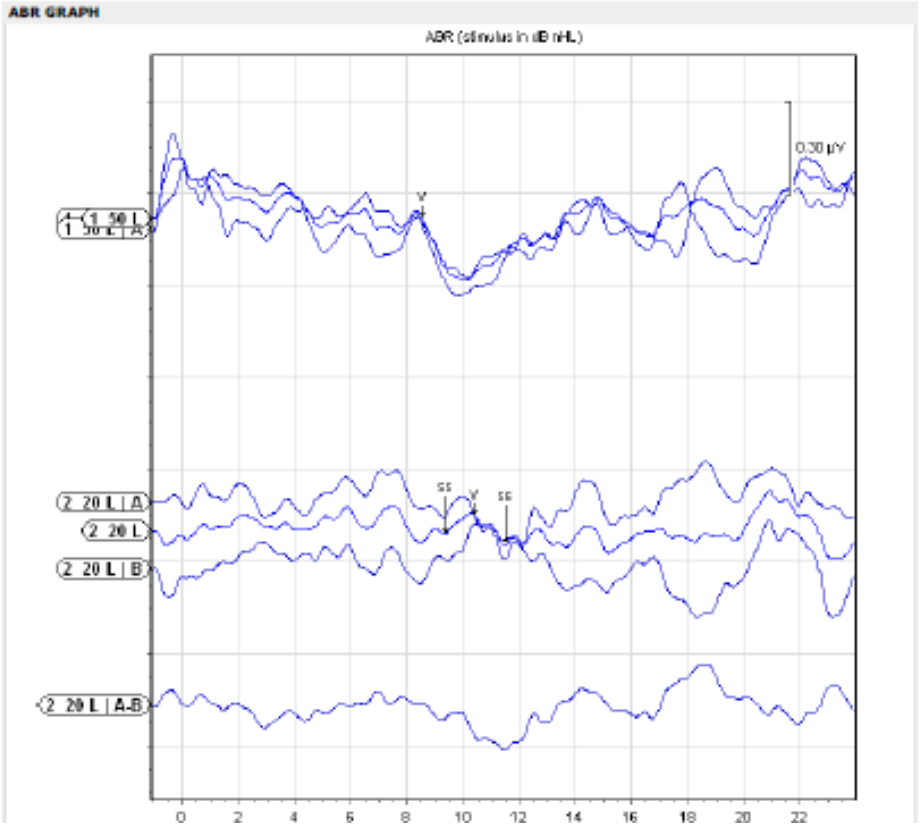
Case #1: The Baby Who Won't Sleep



Please, please, please don't take garbage!!

Use all of the tools available: latency norms, residual noise, correlation coefficient!!!

Case #1: The Baby Who Won't Sleep



Please, please, please
Don't try to cheat
the correlations!!

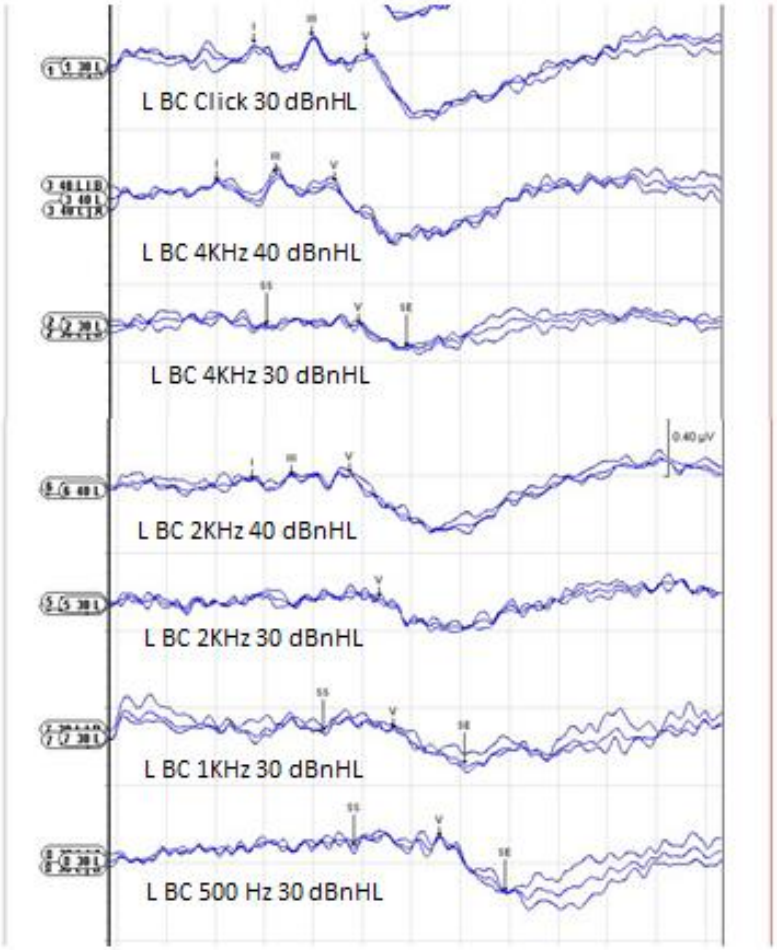
Case #2: Bone Conduction ABR

- Infant Girl
- Born at 36 weeks GA
- Treacher Collins Syndrome
- Micrognathia
- Bilateral aural atresia
- Tested at 37 weeks GA

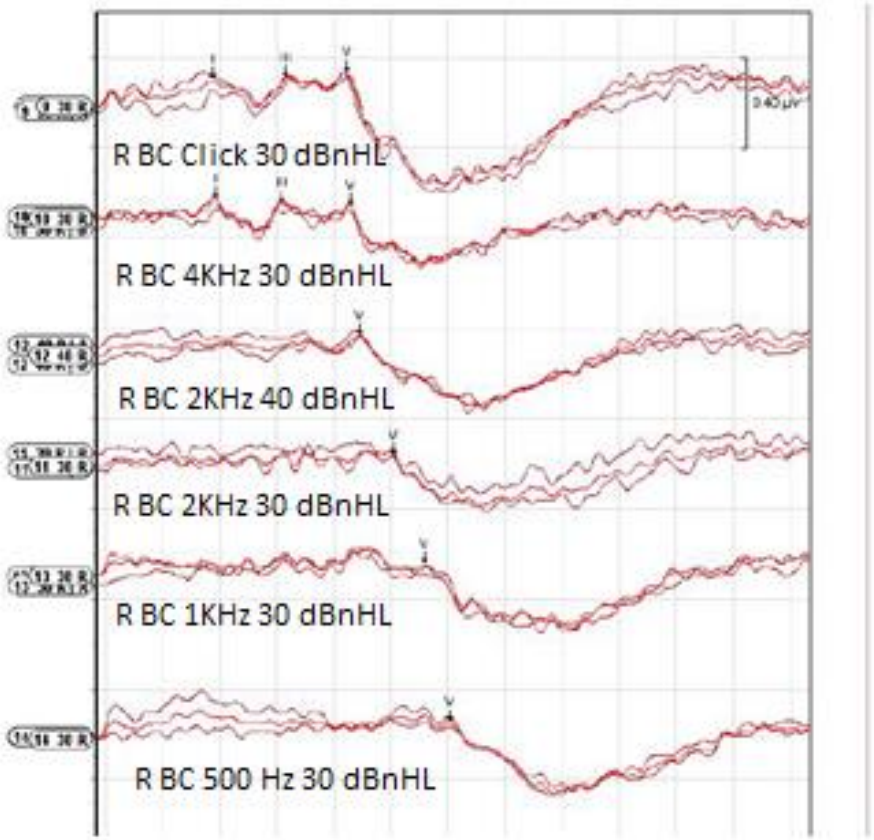
Case #2: Bone Conduction ABR

- CT scan of IAC
- **Bilateral Enlarged Vestibular Aqueducts**

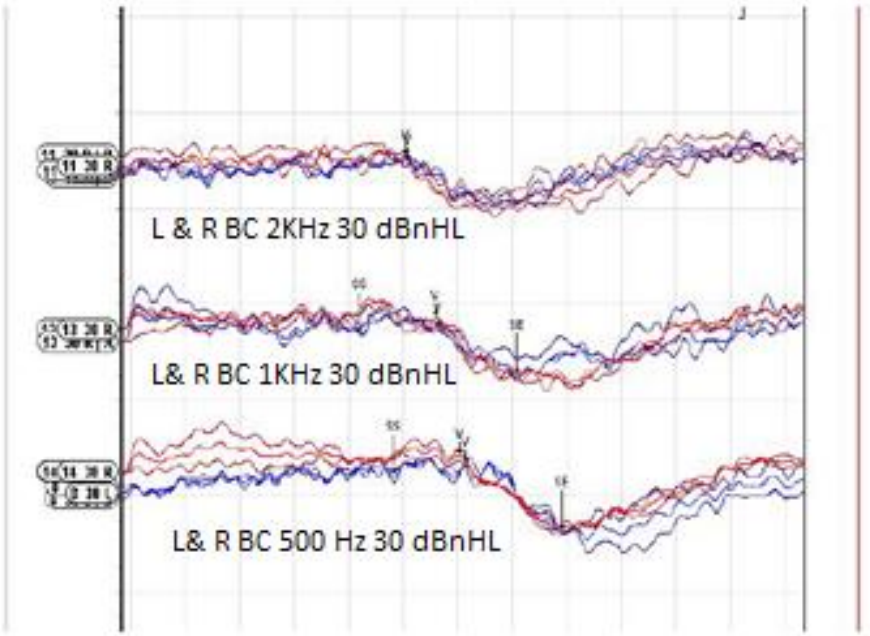
Case #2: Bone Conduction ABR



Case #2: Bone Conduction ABR

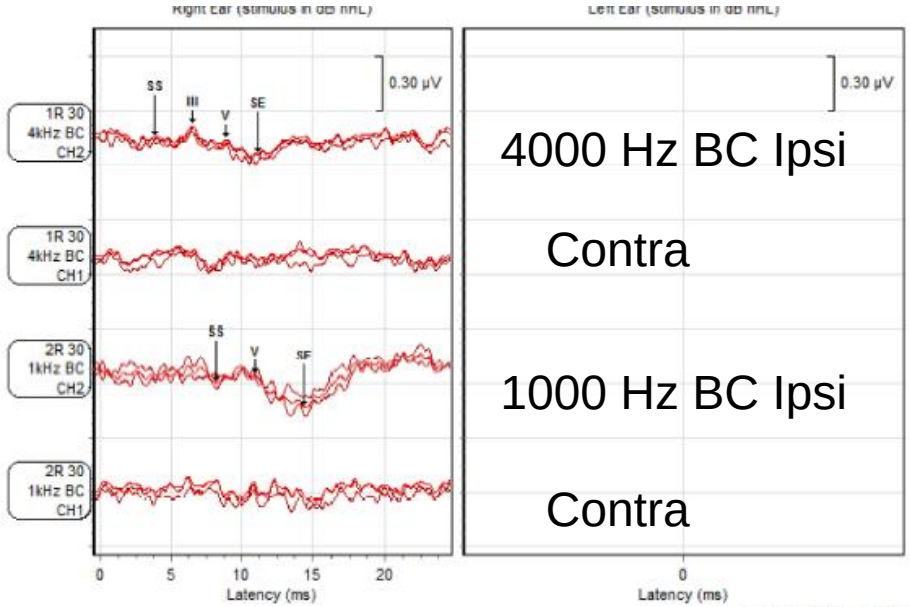


Case #2: Bone Conduction ABR



Because the latencies and amplitudes are the same, you can be sure that both are ipsilateral recordings.

Case #2: Bone Conduction ABR



Right Ear (R) Left Ear (L)

ABR WAVEFORM DATA

		Corr. Coef.	RN µV	Time (ms) I	I'	II	III	IV	V	V'	I-III	III-V	I-V	Amp (µV) I-I'	V-V'	Ratio [V-V']/[I-I']	SS	SE
1	R 30 1	—	0.018	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
1	R 30 2	0.77	0.015	—	—	—	6.54	—	8.88	—	—	2.34	—	—	—	—	3.88	11.17
2	R 30 1	—	0.021	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
2	R 30 2	0.77	0.021	—	—	—	—	—	10.96	—	—	—	—	—	—	—	8.15	14.45

Corr. Coef. = Correlation Coefficent, RN = Residual Noise

TEST CONDITIONS

		Stimulus Level	Stimulus Type	Stimulus Rate (/sec)	Polarity	Rec. Side	Electrodes +	Electrodes -	Mask Level (dB HL)	Notch Filter (Hz)	Algorithm	# Eq. Sweep	% Rej.	# of Stimuli
1	R 30 1	30 dB nHL	4000 Hz	37.7	Alt.	Contra.	Fz	A1	—	—	SOAP-Kalman	2192	0	3785
		ABR bone conducted 4000 Hz tone-burst 37.7												
1	R 30 2	30 dB nHL	4000 Hz	37.7	Alt.	Ipsi.	Fz	A2	—	—	SOAP-Kalman	1900	0	3785
		ABR bone conducted 4000 Hz tone-burst 37.7												
2	R 30 1	30 dB nHL	1000 Hz	37.7	Alt.	Contra.	Fz	A1	—	—	SOAP-Kalman	1308	0	1753
		ABR bone conducted 1000 Hz tone-burst 37.7												

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Case #2: Bone Conduction ABR

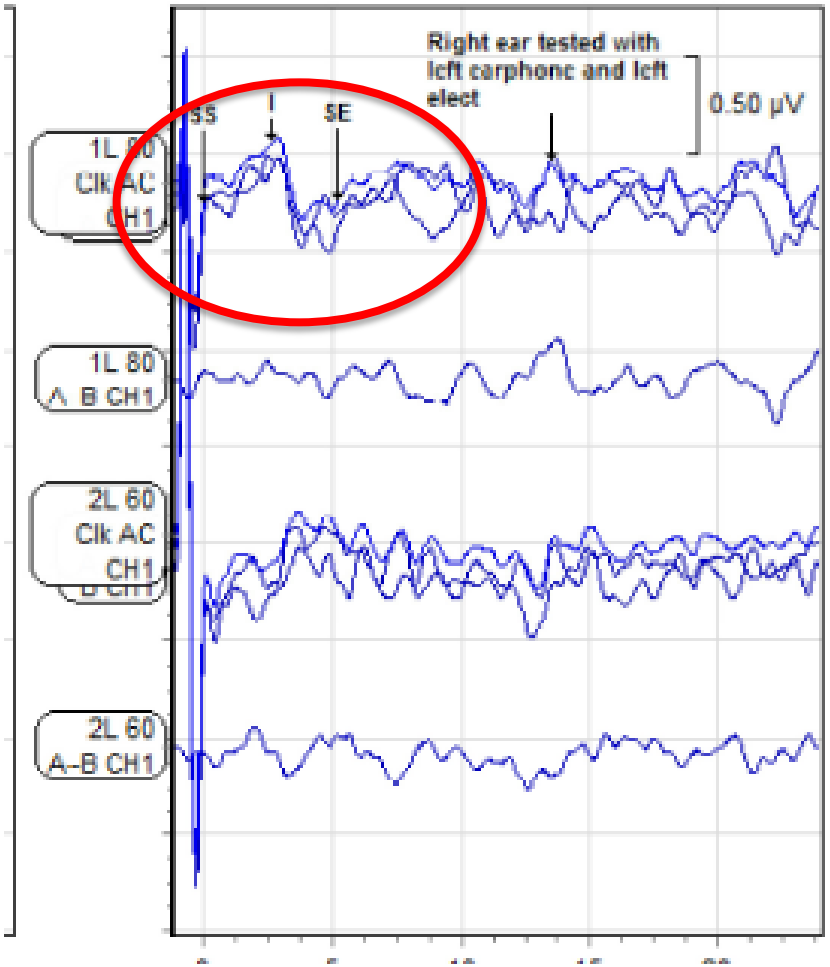
- Superior posterior placement
- Alternating polarity
- Mask, utilize second channel, or obtain a wave I to know response is from the ipsilateral side

Case #3: Brainstem Dysfunction

- Infant Boy
- Born at 33 weeks GA
- Dandy Walker Malformation
- Severe brainstem and cerebellar hypoplasia
- Lissencephaly
  - "Smooth brain"

- Neurosurgery requested a brainstem study
- Infant intubated and on bili lights
- No gag reflex or purposeful movement

Case #3: Brainstem Dysfunction



Case #3: Brainstem Dysfunction

- Utilized a 7.6 click rate
- Delayed wave I in left ear only at 80dBnHL
- Flat tympanograms bilaterally
- Absent DPOAEs bilaterally
- Severe brainstem dysfunction and possible cochlear hearing loss

Case #3: Brainstem Dysfunction

- Don’t waste time chasing tone burst thresholds on infants with brainstem dysfunction!!!
- Always assess neural transmission in NICU infants. Especially infants with myelomeningocele, hydrocephalus, IVH and VP shunts!!!
- Don’t forget to slow down the click rate
- OAEs will be critical in these cases
- If neural component is going to resolve, will typically see normalized ABR about 8 weeks post shunt.
- This is not ANSD!!!

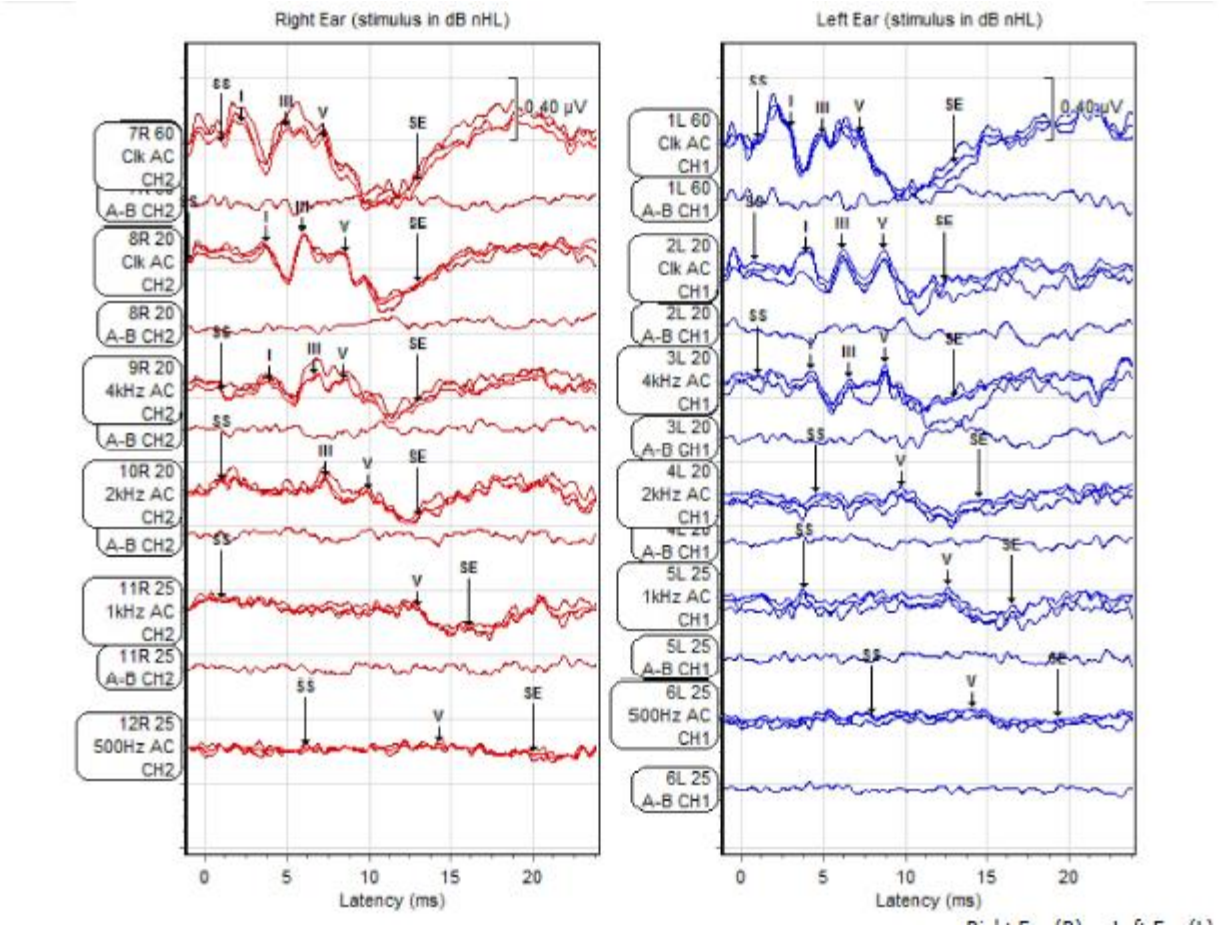
Case #4: Monitoring of Older Infants

- Infant Boy
- Born at 36 weeks gestation
- Presented to ED in January 2015
- Low grade fever x 4 days
- Poor weight gain
- Neuromuscular weakness, respiratory distress
- Imaging revealed multiple brain tumors
- Diagnosed as CNS Atypical teratoid/rhabdoid tumor

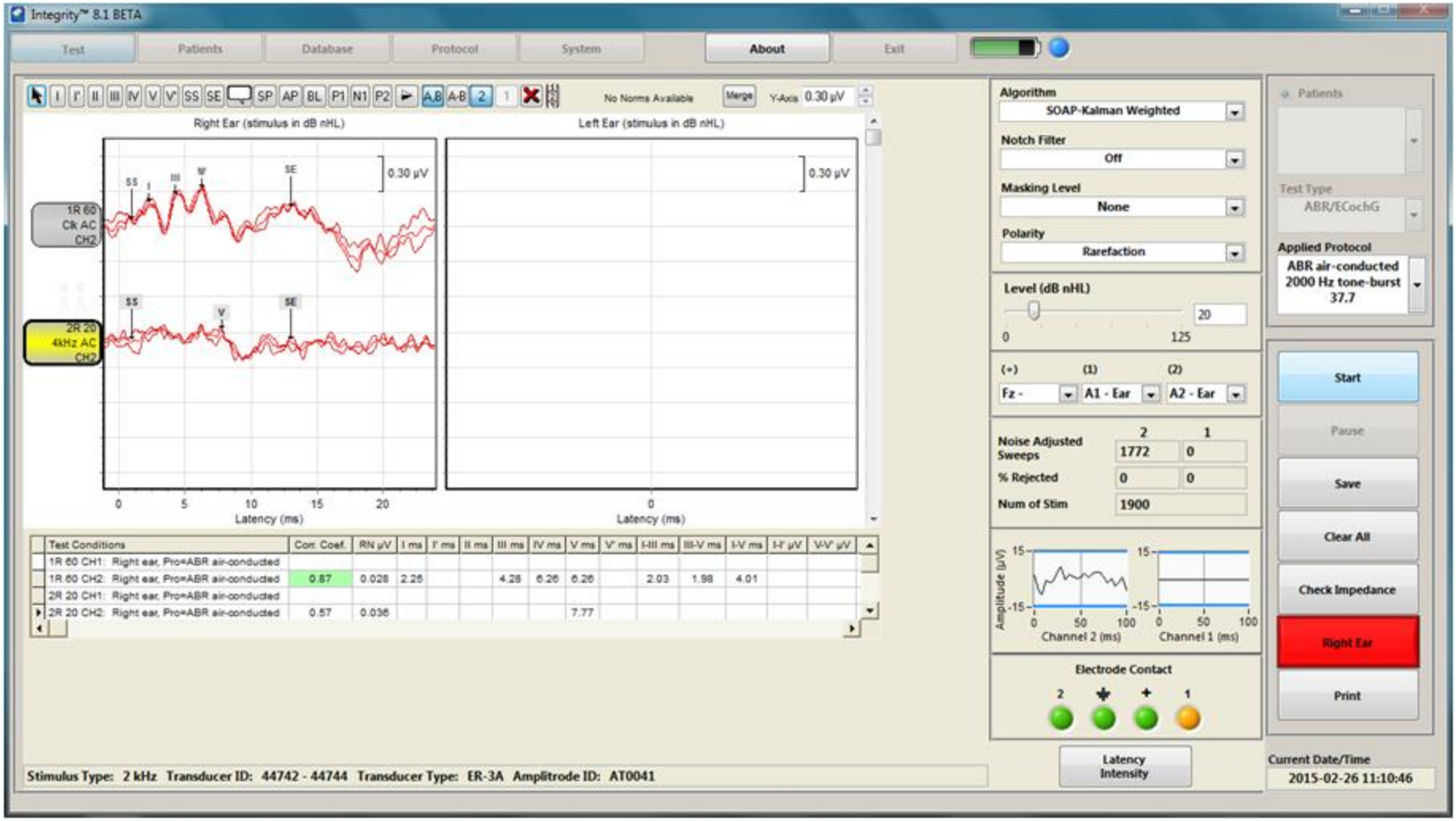
Case #4: Monitoring of Older Infants

- ATRT is a rare aggressive brain tumor occurring most often in children under age 3
- Tumor resection followed by chemotherapy

Case #4: Monitoring of Older Infants



Cincinnati Children's



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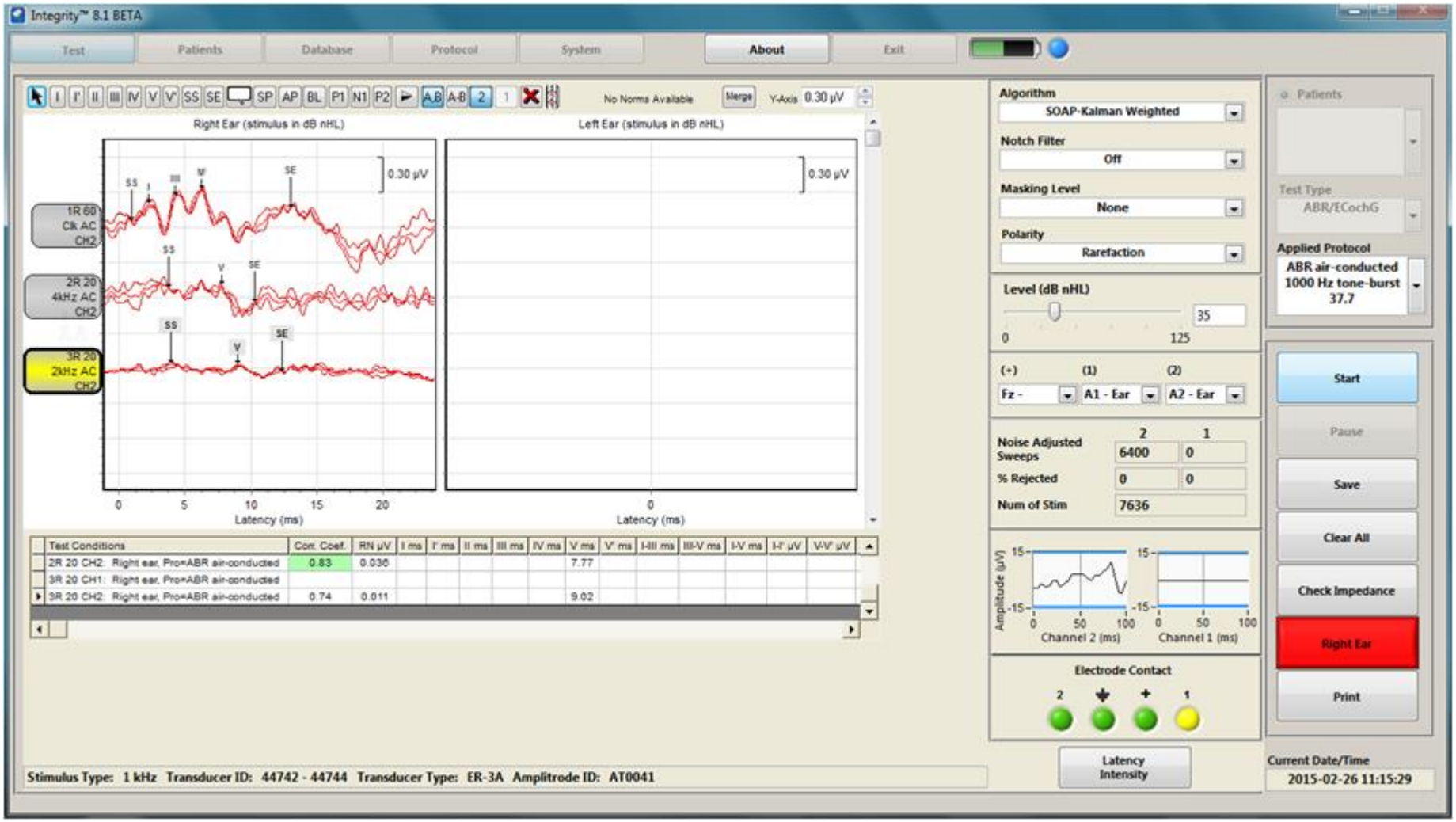

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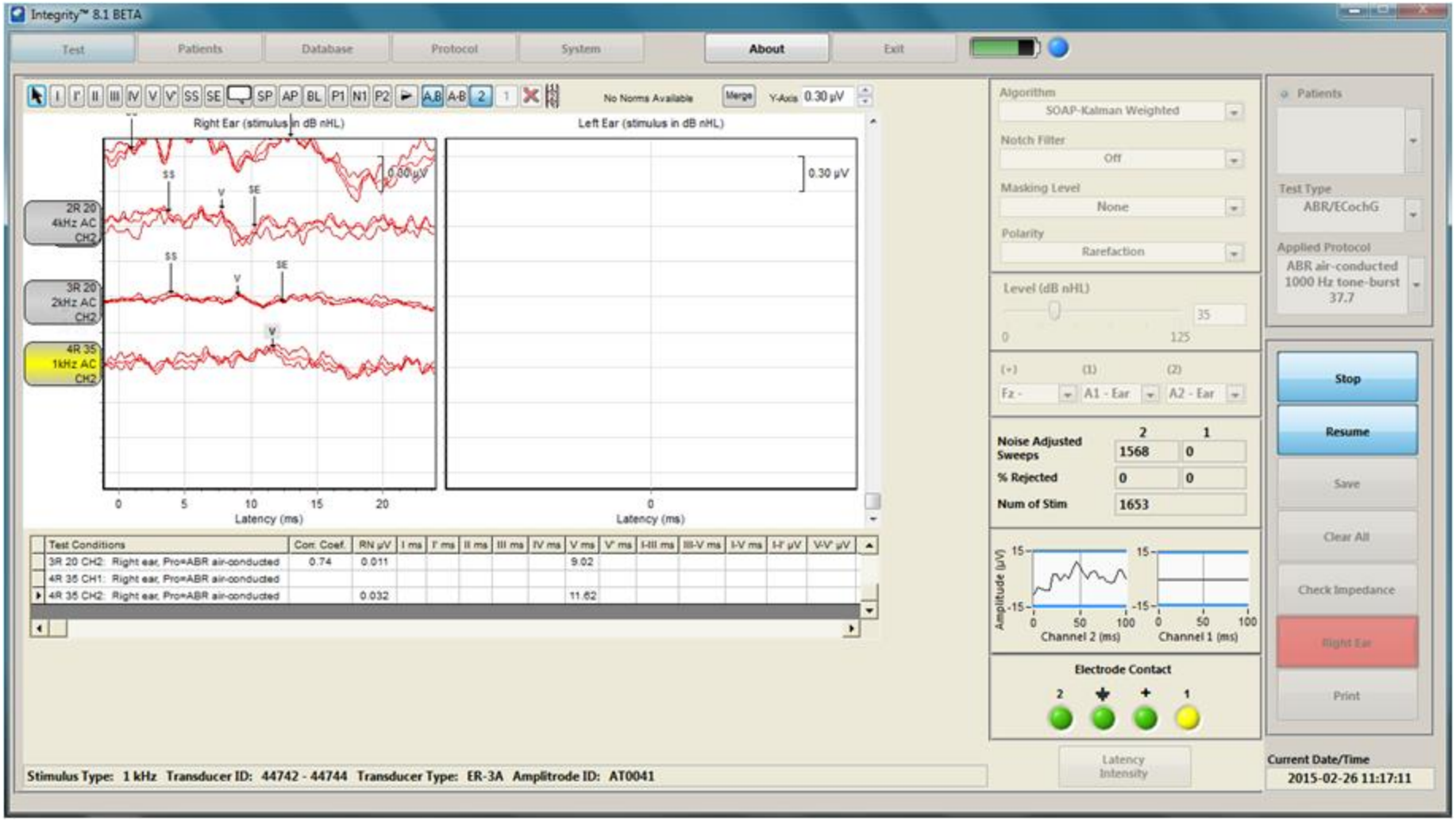

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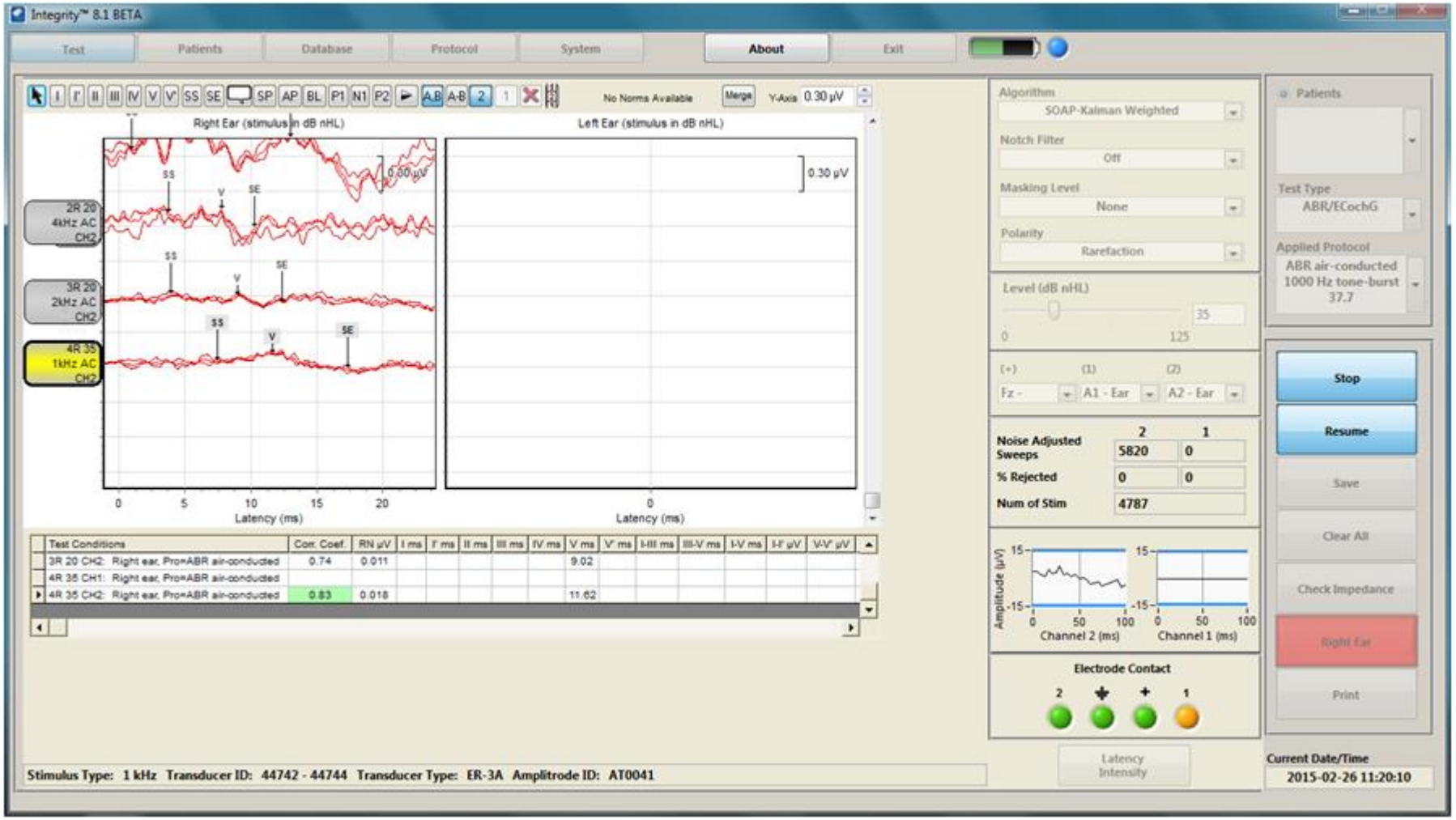

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Case #4: Monitoring of Older Infants

- Always worth it to attempt natural sleep with older children who can't/won't complete behavioral testing.
- Always risks with anesthesia
- Careful counseling with parents. Everyone must be on the same page.
- Will not always be successful.
- Distractors critical (iPad, quiet toys, books, pictures, games on cell phone).

Take-home Message

- ABRs must be accurate!!
- Don’t be tempted to take garbage!!
- Utilize all available tools for cross check of thresholds
- Don’t over manipulate the correlations!!
- Not all children will be able to be tested without sedation/anesthesia, but it should be utilized as an absolute last resort!!

Lessons Learned

- Audiologists don’t like change in general
- Have to utilize technology that provides the best outcomes for patients vs what is comfortable
- Training is KEY
- Need manufacturers that will work with us