



Automated ABR screening in the NICU with zero Re-tests

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Remembering Prof. Poul Madsen (1923-1997)

Collaboration with Poul Madsen, then an Adjunct Professor at the *Institute of Biomedical Engineering*, University of Toronto, in 1996-1997, led to the development of our technologies.

November 14th, 2007, marked 10 years since Prof. Madsen passed away.

We will always remember his enormous contribution to the field of diagnostic Audiology – Madsen Electronics, Clinical Impedance Bridge, and ABR.



Presentation outline

- **Year 2007 JCIH Position Statement endorsement of AABR screening in the NICU**
- **The problem of noises in AABR: Physiological Artifacts and Extraneous noises**
- **New techniques helping clinicians obtain correct AABR outcomes**
- **Conclusions**
- **Questions and answers**

The Joint Committee on Infant Hearing (JCIH) released the new, *Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs* in October 2007

American Academy
of Pediatrics



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POLICY STATEMENT

Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs

Joint Committee on Infant Hearing

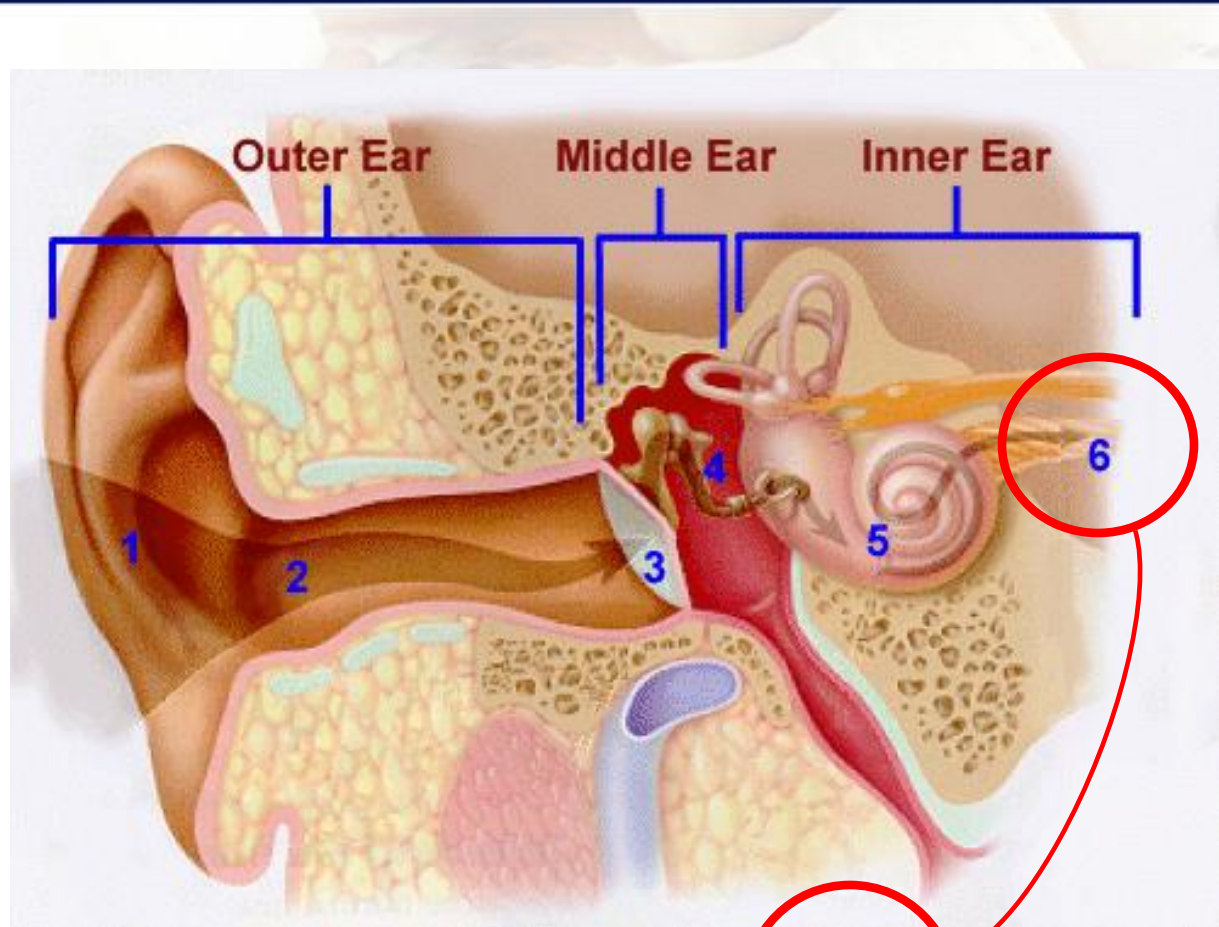
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<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;120/4/898.pdf>

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clinical efficiency through innovation

Year 2007 JCIH Position Statement expands the definition of *targeted* hearing loss to include *neural* hearing loss

Definition of hearing loss expanded from congenital permanent bilateral, unilateral sensory, or permanent conductive hearing loss to include **neural hearing loss** (e.g. “auditory neuropathy/dyssynchrony) in infants admitted to the neonatal intensive care unit (NICU).



HEARING LOSS:
SITE:

Conductive	Sensory	Neural	Mixed
2, 3, 4	5	6	

Year 2007 JCIH Position Statement endorses *separate* protocols for NICU and well-baby nurseries. AABR prevails

- **Well-infant Nursery babies** can be screened with either **OAE** or **AABR**, which will detect HL of 40 dB or greater.
 - If both OAE and AABR are used (two-stage), **AABR outcome prevails**:
 - » OAE “fail” and **AABR “pass”** is considered screening “pass”
 - » OAE “pass” and **AABR “fail”** is considered screening “fail”,
- **NICU babies** admitted for >5 days are to have **ABR** included in their screening so that **neural HL** is not missed.
 - Infants who do not pass AABR in NICU are to be referred to an audiologist for rescreening and, when indicated, comprehensive evaluation including ABR.
- **For rescreening**, screening on both ears is recommended, even if only one ear failed.
- **For readmissions** in the 1st month of life for all infants (NICU or well-baby) when there are conditions associated with potential HL, a repeat hearing screening is recommended before discharge.

AABR screening in the NICU is the **only** technique to detect Neural Hearing Loss, but is often challenging



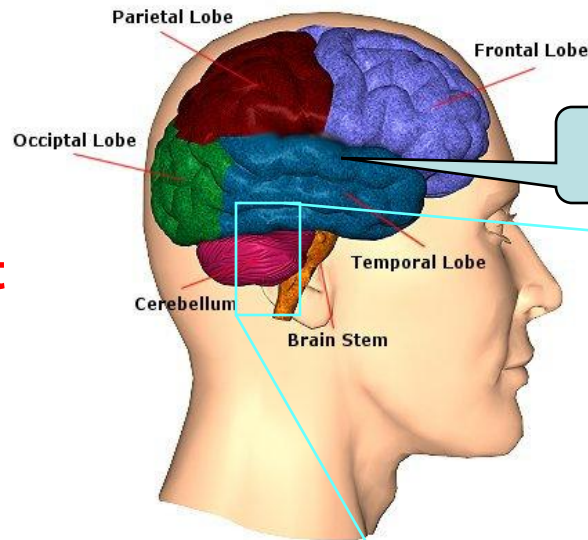
ABR originates from the Auditory Neural System

Auditory Evoked Potentials (AEPs)

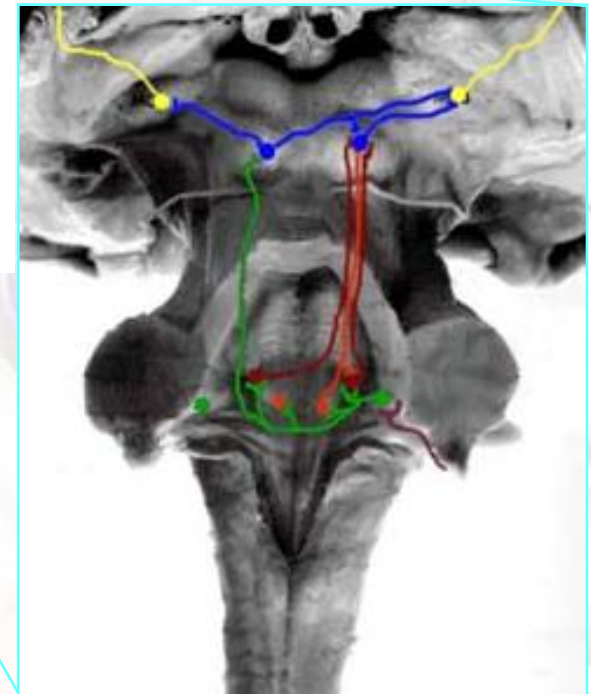
Any electrical potential that is produced by the auditory system and that can be recorded *in vivo*, mostly from the scalp.

Auditory Brainstem Response (ABR)

Generated by the Auditory Nerve (CN VIII) and ascending auditory pathways of the brainstem.

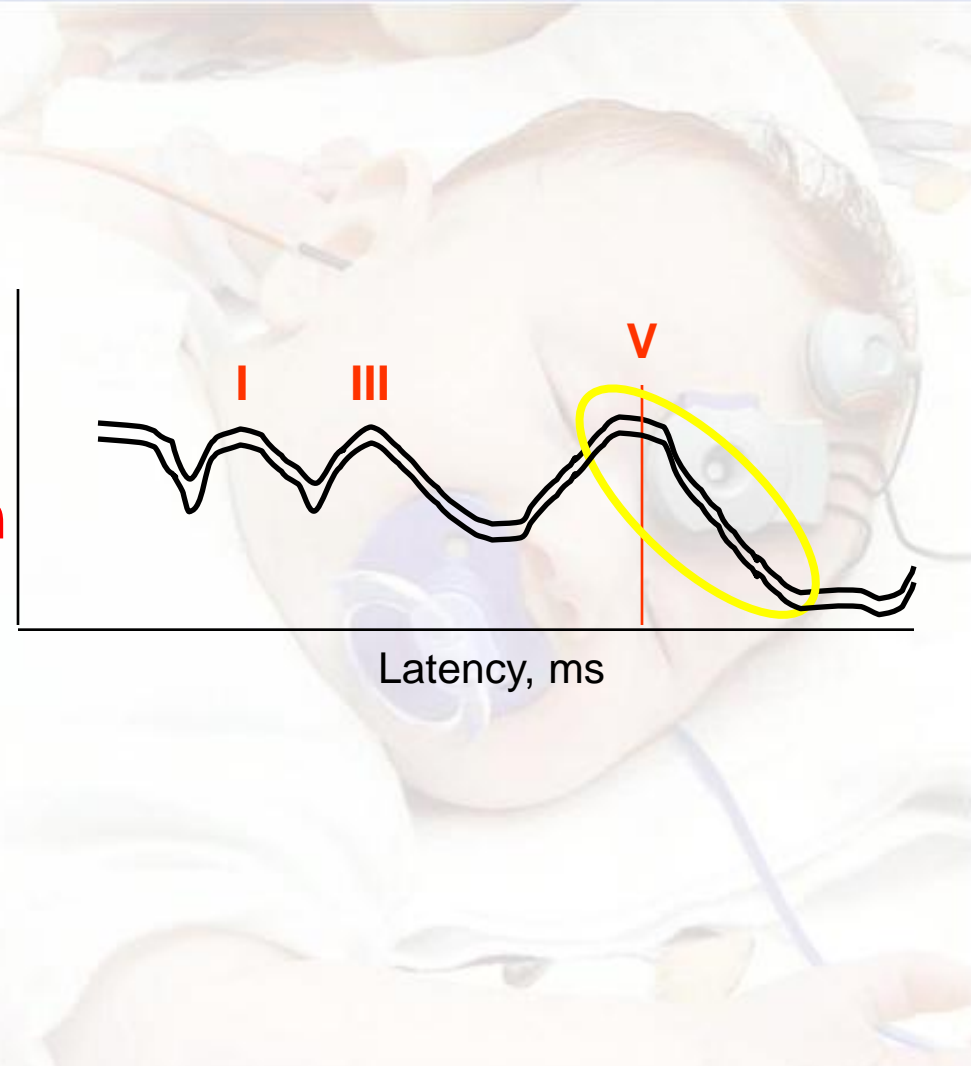


Auditory cortex



ABR screening is based on detecting Wave V at a set stimulus level, typically 35 dB nHL

- The only method to detect *neural* HL
- Absence of ABR to 30 or 35 dB nHL, 100 μ s clicks reveals mild and more severe hearing loss
- Absence of response to 45-50 dB nHL clicks reveals moderate and more severe hearing loss
- Screening parameter: **detection of Wave V**
- Automated detection of ABR – ***Automated ABR (AABR)***
 - Statistical technique based universal – non age-specific
 - Template-based are age-specific, typically 0-2 months of age

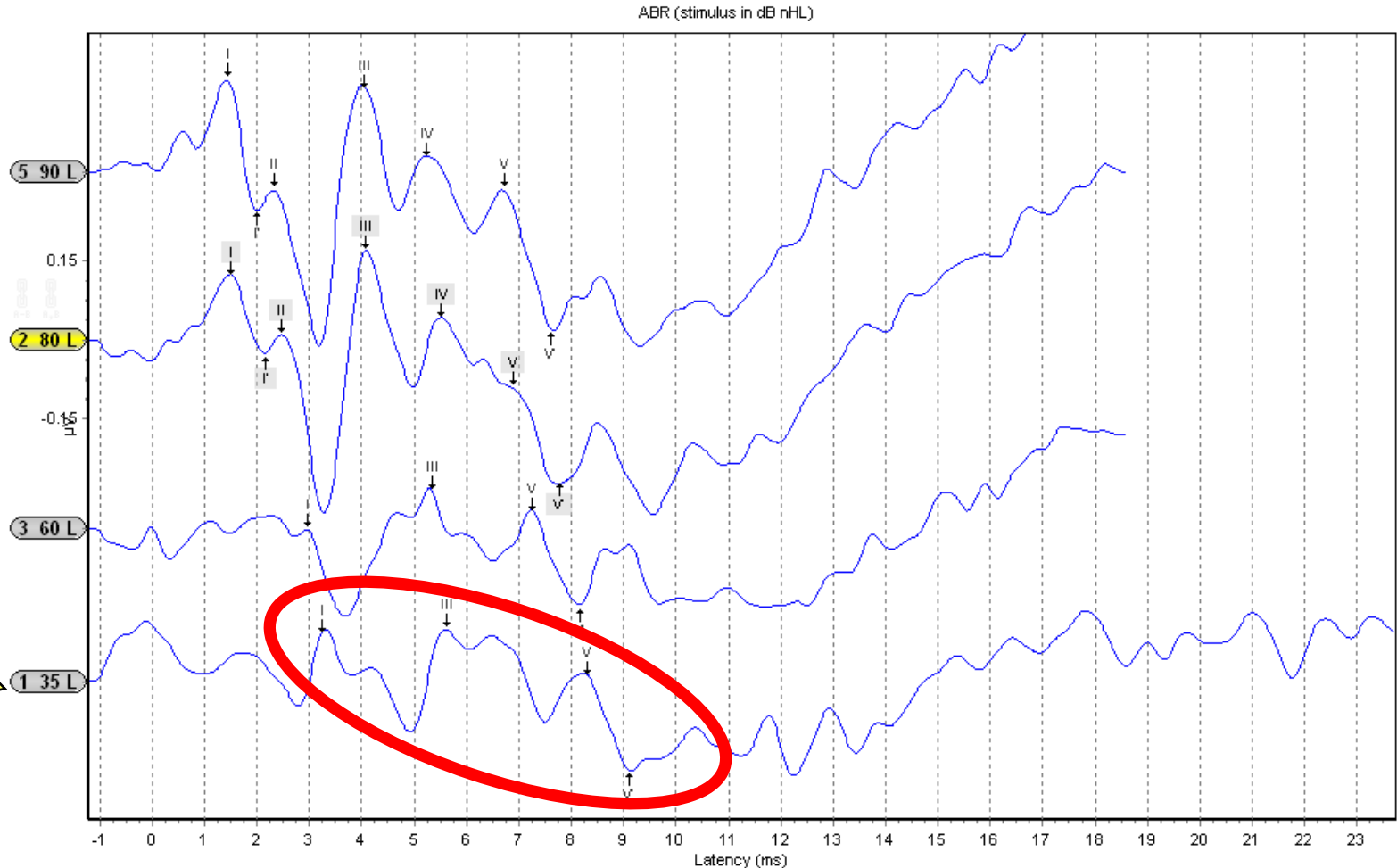


Any screening outcomes, PASS or REFER, can be true or false, and the *false* ones must be *minimized*

		Hearing	
		NORMAL	LOSS
Screening outcome	PASS	<p>True Negative - GOOD:</p> <ul style="list-style-type: none"> - No parent anxiety - NHS purpose fulfilled 	<p>False Negative - VERY BAD:</p> <ul style="list-style-type: none"> - Parents assured - HL detection and intervention delayed - NHS purpose defeated
	REFER	<p>False Positive - BAD:</p> <ul style="list-style-type: none"> - Parent anxiety - Unnecessary follow up - Unnecessary NHS system overload & excessive cost 	<p>True Positive - GOOD:</p> <ul style="list-style-type: none"> - HL detected - Timely follow up - NHS purpose fulfilled

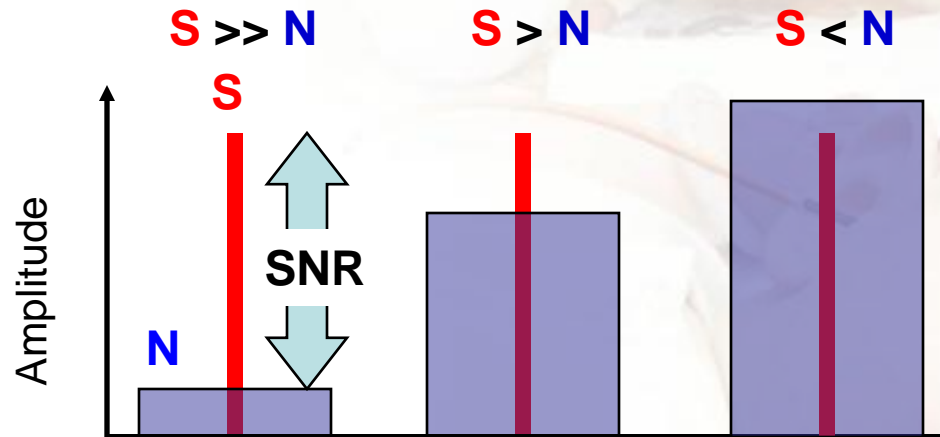
AABR screening is based on automatically detecting ABR signal in noise at a certain stimulus level, typically 35 dB nHL

Sample ABR in a normal-hearing, premature 10-week-old female infant



35 dB nHL
– typical
ABR
screening
level

Signal detection depends on the signal, noise, and signal-to-noise ratio – all affected in the NICU



The same **signal (S)** may or may not be recorded depending on **noise (N)** and **signal-to-noise ratio (SNR)**

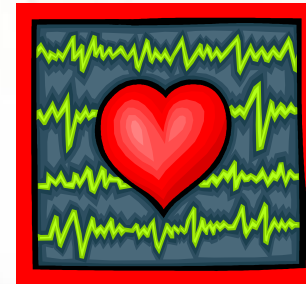
ABR detection factors:

- **Electrical ABR Signal** – will be reduced by acoustic masking of ambient noise
- **Electrical Noise** – physiological artifacts and environmental interferences
- **Residual Signal-to-Noise Ratio (SNR) after averaging:**
 - $S \gg N$, $SNR \gg 0$ – detection is very easy (low false outcomes)
 - $S > N$, $SNR > 0$ – possible, but more difficult (many false outcomes)
 - $S < N$, $SNR < 0$ – impossible (all outcomes may be false)

Physiological artifacts and extraneous contaminate ABR signal

Physiological *artifacts*

- **Brain (EEG)**
- **Eyes (EOG)**
 - Electric dipole movements (ENG) – very large
 - Ocular muscles (EMG)
- **Skeletal muscles (EMG)**
- **Heart (very high in infants) (ECG or EKG)**
 - Heart is relatively big vs. body size
 - Heart is close to the electrodes
 - Heart rate is 2-3 times higher vs. adults



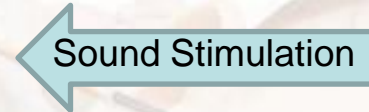
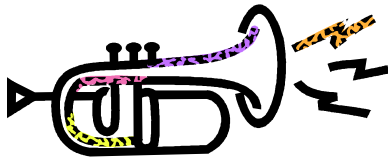
Extraneous *interferences*

- **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**

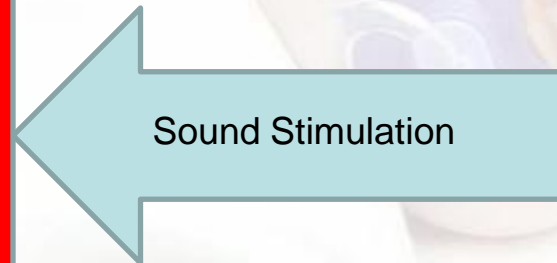
NICU AABR challenge: Acoustic noise (low signal) + EMI (high noise) = low SNR → poor detection → false outcomes



ABR signal can be reduced by ambient acoustic noise and/or ear-canal obstructions

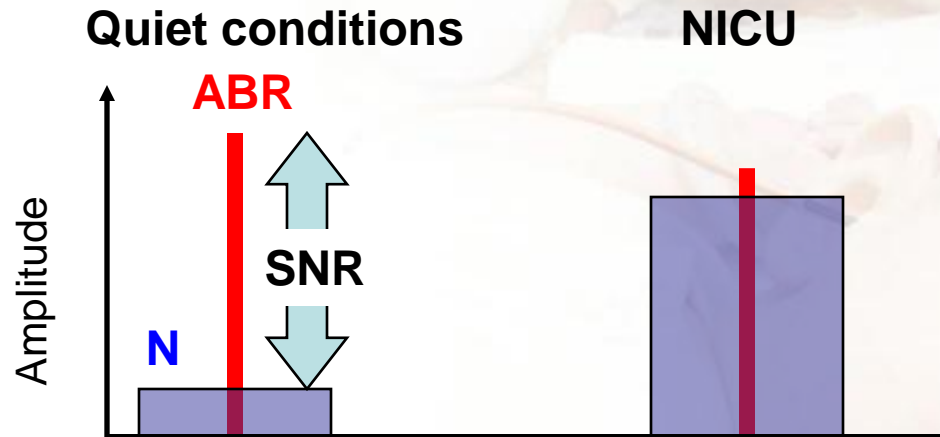


Stimulus is masked by acoustic noise – patient generated or externally generated



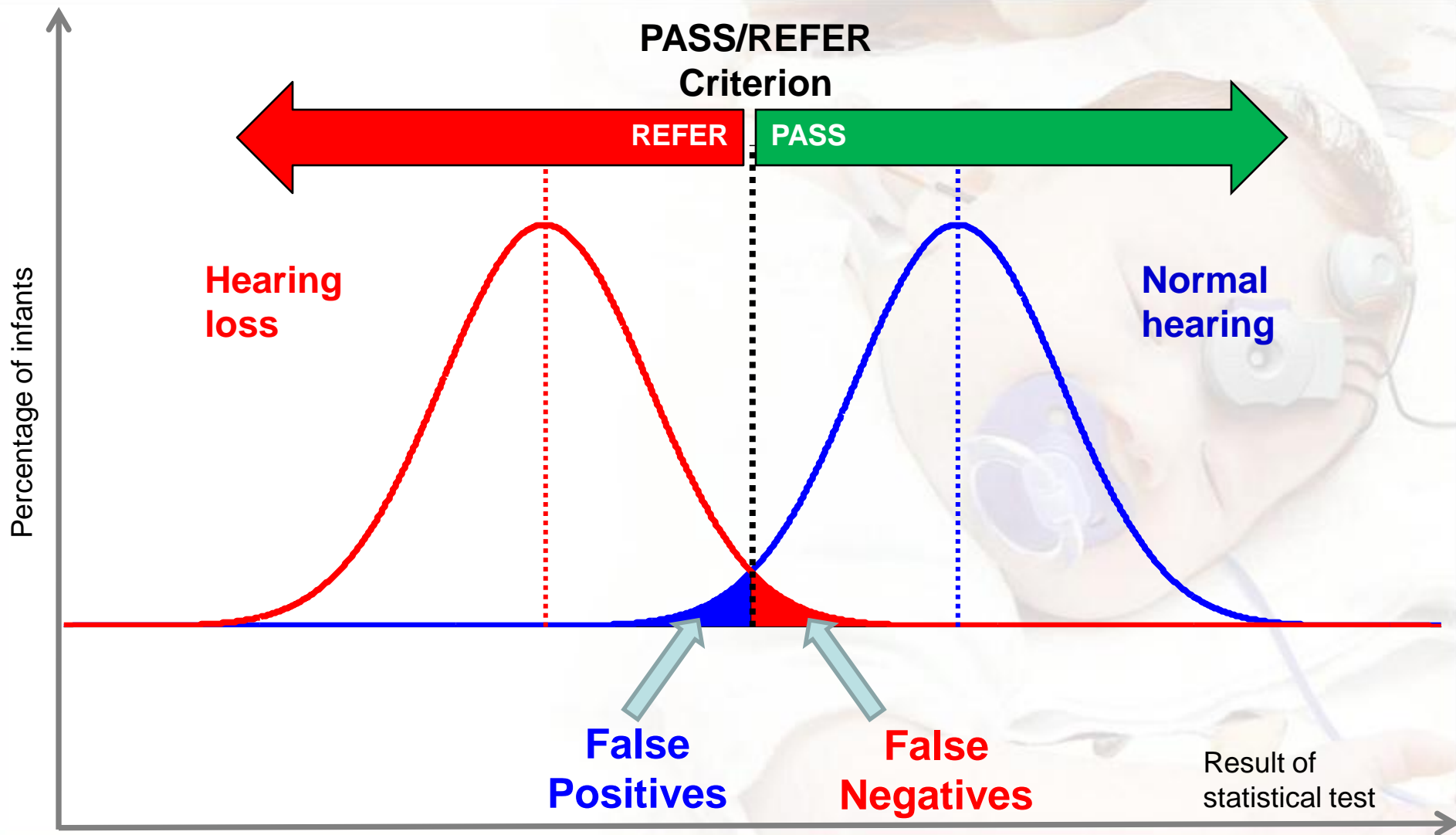
Stimulus does not reach the ear drum due to obstruction or ear-canal collapse invisible to the screening person

In the NICU, ABR signal is smaller, electrical noise higher, SNR lower – making ABR signal detection more difficult

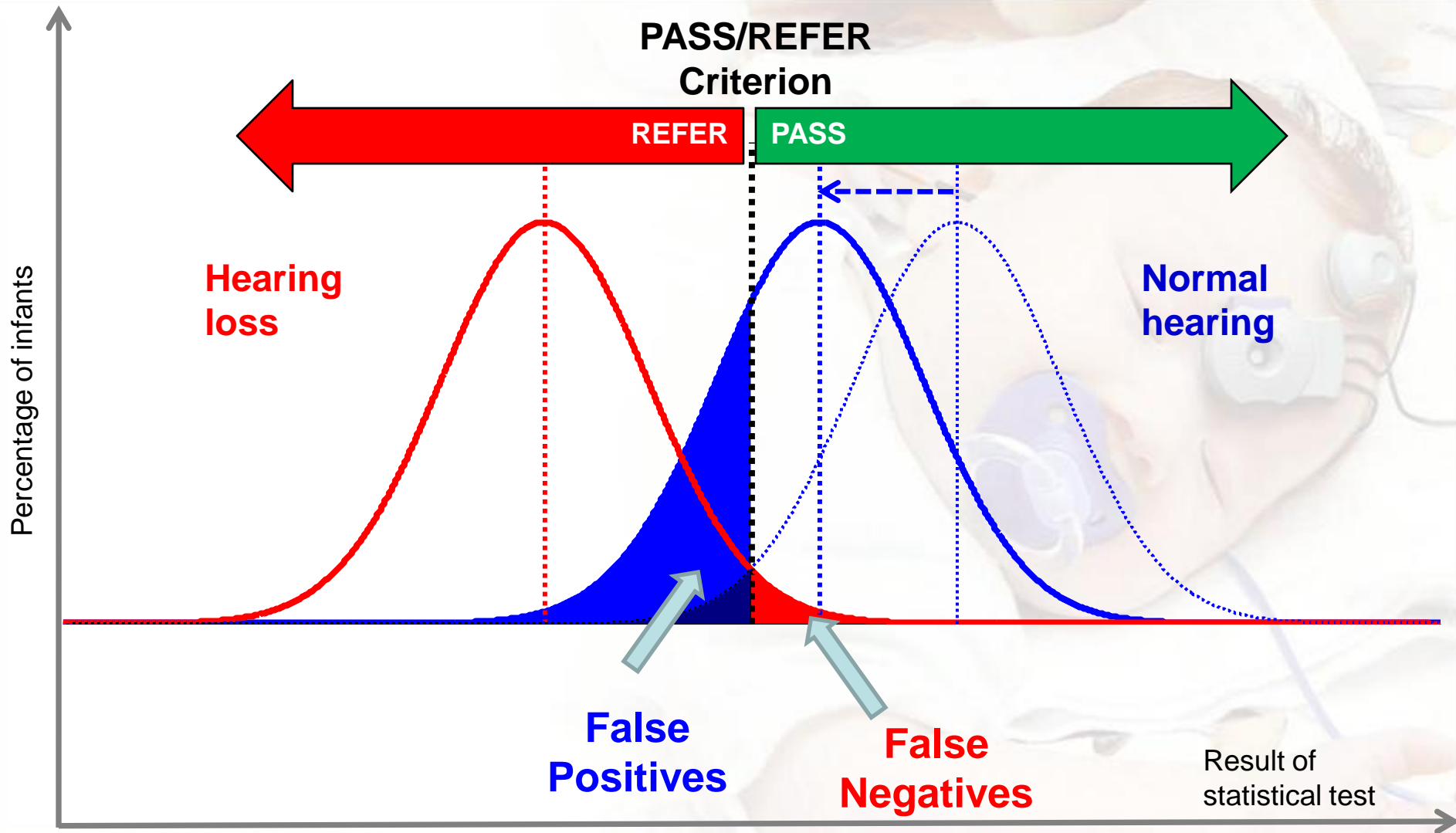


- **Electrical ABR Signal in the NICU is reduced by:**
 - Acoustic masking with ambient noise
 - Acoustic leakage of stimulus through poor seal of the ear couplers
 - Ear canal obstruction – invisible to the screening person due to the small size of the ear and poor visibility
- **Electrical Noise is increased by:**
 - Physiological artifacts – from the infant
 - Environmental interferences – electromagnetic and conducted

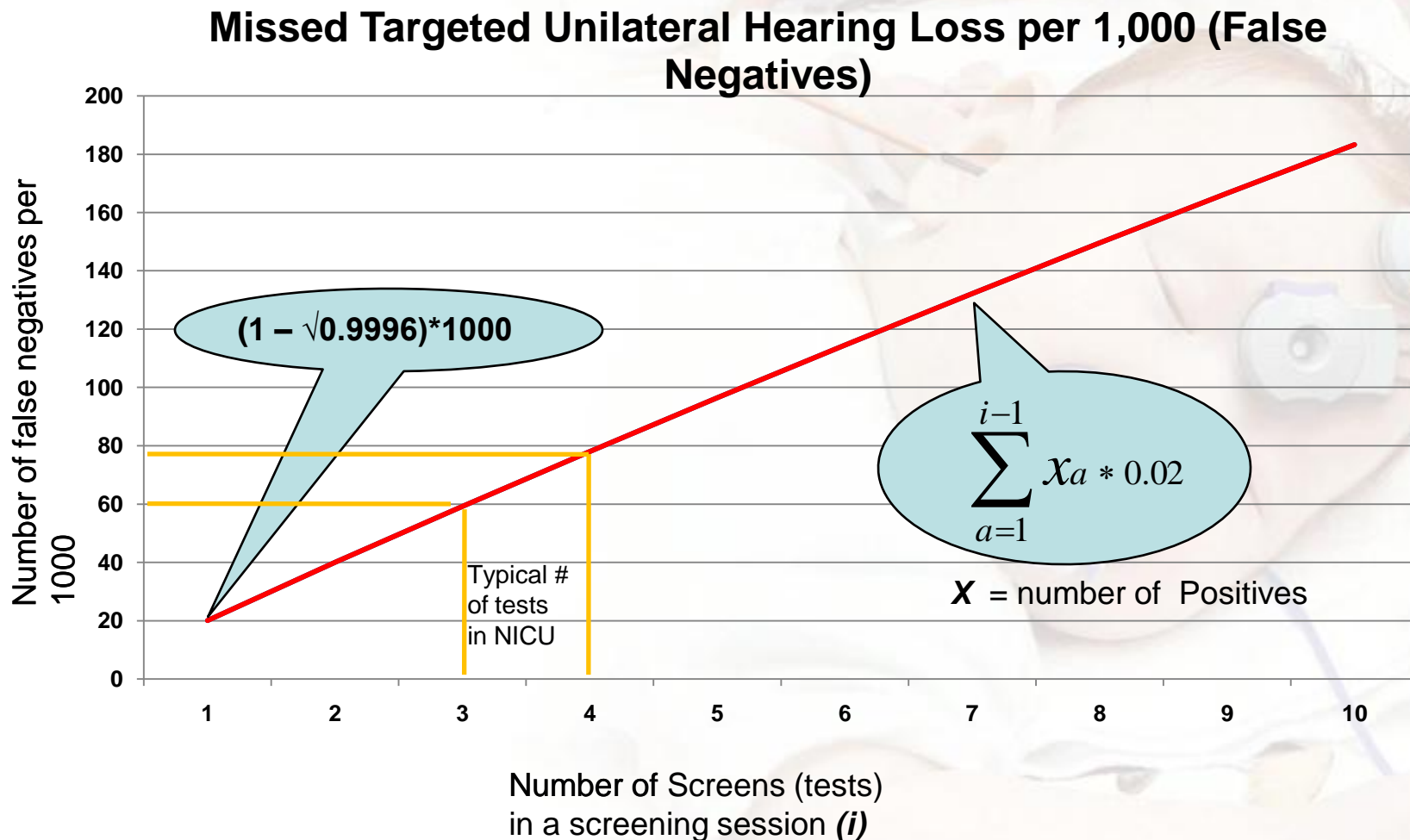
In a “Quiet” case, with high SNR, false positives and false negatives are minimal



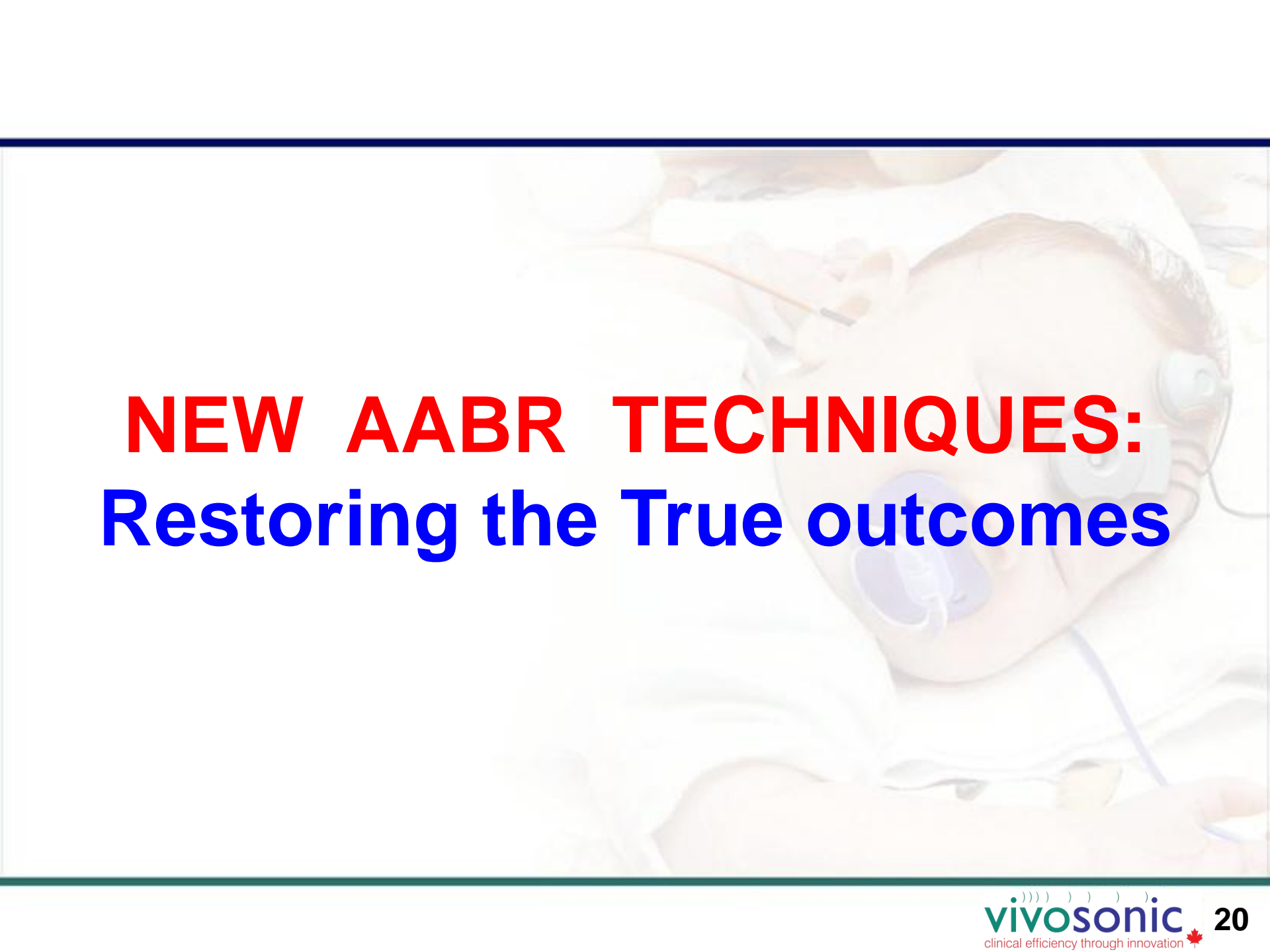
When acoustic or electrical noise is high, or the ear is obstructed, false positives increase



“Refer” outcomes and targeted Refer rates (4%) force re-screening, which increases the probability of False Negatives

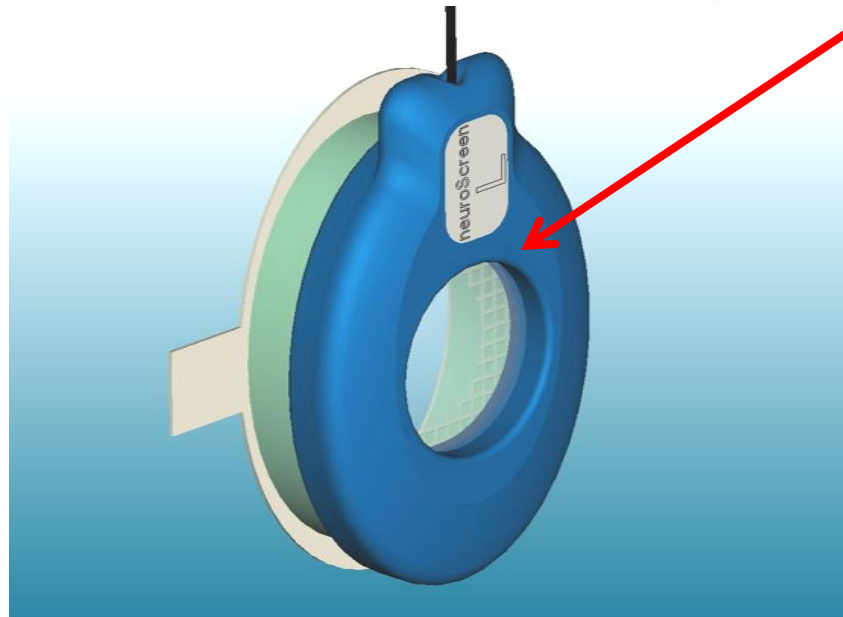


Note: Published sensitivity of AABR screening to bi-lateral HL = 99.96%

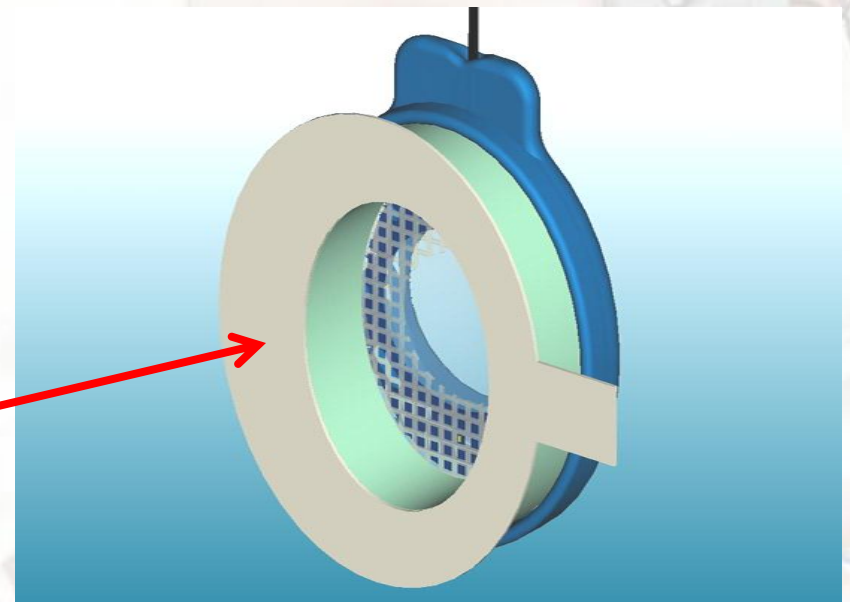


NEW AABR TECHNIQUES:
Restoring the True outcomes

Start with protecting the ear from ambient ACOUSTIC noise

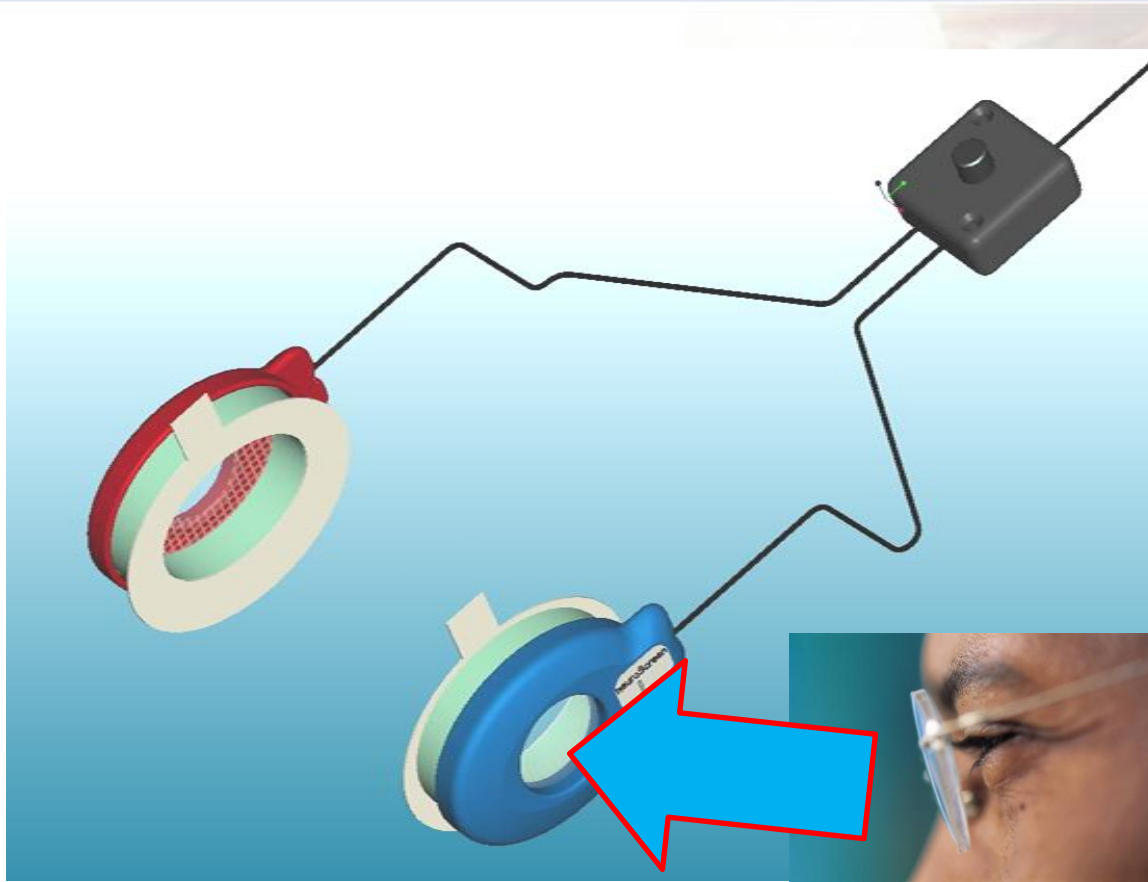


**Extra thick
sound insulation
to keep sounds
from masking
the stimulus**



**Extra wide flexible
seal ensures no
external sound
comes in**

Viewing the magnified and illuminated ear canal reduces the risk of undetected ear-canal obstruction and False Positives



Switch on light to illuminate the ear canal

View the magnified ear canal to detect obstructions



In-situ recording and optimized signal processing removes electrical noise, restores SNR – yielding True results

Signal acquisition and processing techniques

***In-situ*
Amplification
& Pre-filter**

Removes EMI, ECG,
EOG, RF

**Kalman-
Weighted
Averaging**

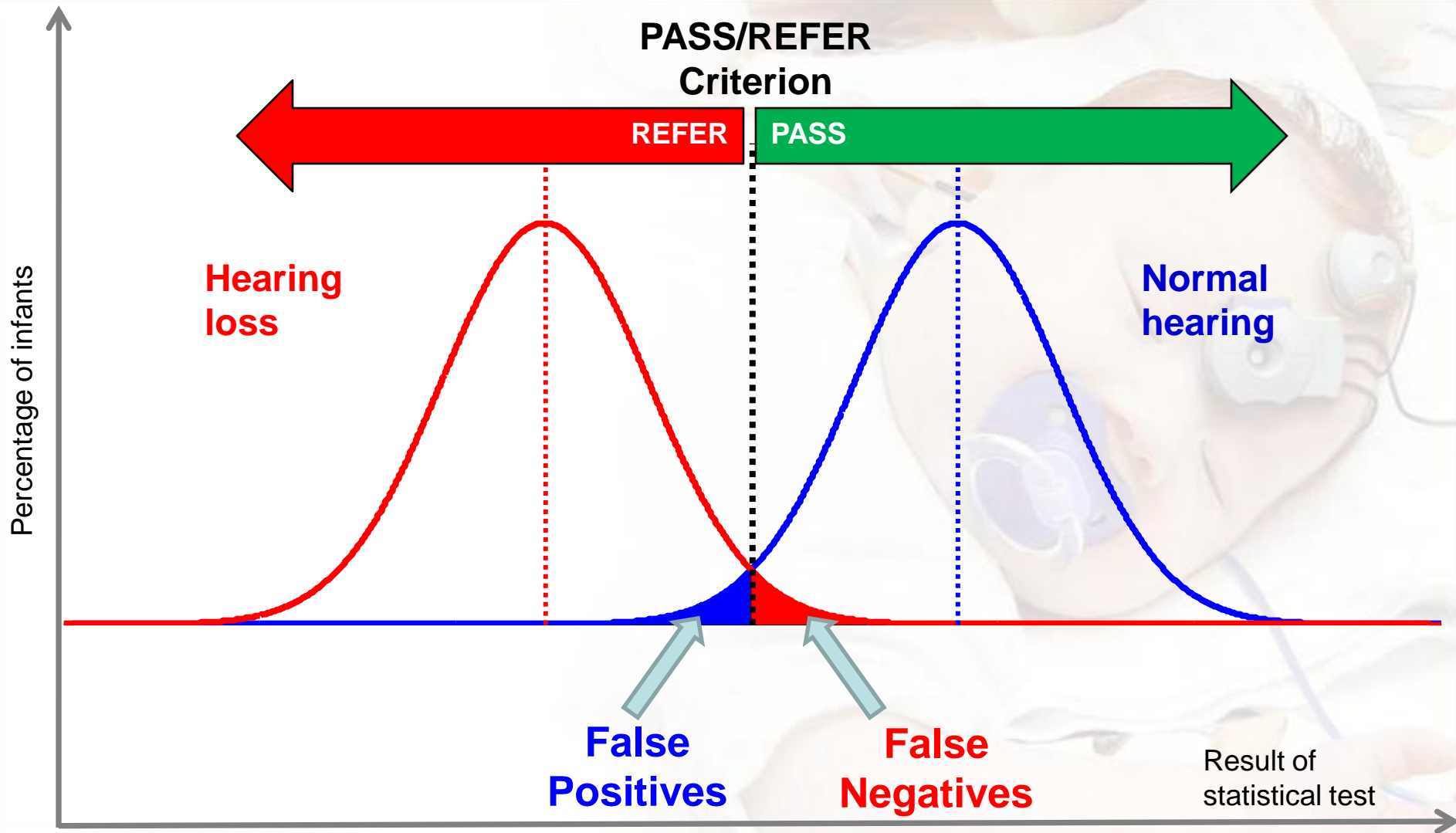
Removes
intermittent EMG
(occasional
movements like
heart beat and
suckling)

**Optimized
buffering**

Remove continuous EMG (tense muscles,
continuous movements facial grimace, cry)

**SNR-adaptive
filter**

New AABR techniques restore screening outcomes in the NICU to a “Quiet” case



Conclusions: New techniques aim to enable Zero Re-test and make AABR screening effective

- **Reduced risk of False positives**
 - **From Ear Canal Obstruction**
 - Novel View-Phone™ helps preventing ear-canal collapse
 - New Ear Domes™ protect from ambient noise
 - **From Patient-related muscular, ocular, and cardio artifacts**
 - Removed by new signal-acquisition and signal-processing techniques
- **Reduced risk of False Negatives**
 - Single test reduces the risk of False PASS due to chance alone
- **Reliable outcomes in the NICU**
- **Lower screening cost**
 - Lower-cost Ear Domes™
 - No re-tests saves multiple sets of disposables and tester's time

Questions?

Thank you
for your interest and

Best wishes
from
vivosonic