

Natus Flexicoupler® Ear Couplers: Background and Rationale for this Sound Solution for Newborn Hearing Screening

UNHS TECHNOLOGY

Designing and implementing high quality universal newborn hearing screening (UNHS) programs is the critical foundation upon which Early Hearing Detection and Intervention (EHDI) is built. Among the decisions that must be made is the screening technology to be used, and the validity of the specific device (JCIH 2007). Automated Auditory Brainstem Response (ABR), an objective physiologic measure regarded as the “gold standard” for infant assessment, screens the entire auditory pathway from the ear to the brainstem and is the only screening technology capable of detecting neural hearing impairment. For this reason, “JCIH recommends ABR technology as the only appropriate screening technique for use in the NICU” (JCIH 2007). In the well-baby nursery, automated ABR is also used either as the single screening technology or in combination with otoacoustic emissions (OAE), the physiologic measure limited to the peripheral portion of the hearing system and, therefore, unable to detect neural hearing impairment.

Measuring the ABR response for purposes of newborn hearing screening requires the application of sensors on the skin and the delivery of a single intensity (35dBnHL) click stimulus to the ear at a rapid rate. Resulting changes in the EEG are collected and analyzed automatically for predictable characteristics that are compared to normative criteria. Achievement of a fixed high statistical confidence level generates a pass result without the need for clinical interpretation of raw, averaged EEG data. The development of automated ABR proved to be the turning point for advocacy of universal newborn hearing screening since it provided a feasible opportunity to rely upon a validated “gold standard” measure in the newborn nursery using available personnel taught to operate the device rather than requiring clinicians highly trained in pediatric audiology.

Early in the history of newborn hearing screening, the challenge of eliciting a reliable ABR response using the most suitable coupler to deliver the click stimulus was identified (Herrmann, Thornton, Joseph, 1995). The standard earphones and cushions commonly used for adults and older children proved problematic when screening newborns due to:

1. Weight collapsing infant ear canals and blocking transmission of the click stimulus
2. Difficulties in positioning earphones in proper alignment with the ear canal
3. Inability to achieve a complete seal that would not allow the click stimulus to leak out, thereby reducing the stimulus below the desired 35dBnHL
4. Arousal of the newborn and head movement causing variability in screening results as earphones shifted

Each of these factors contributes to excessive false refer results that not only increase program costs through repeat screening but also cause unnecessary parental anxiety. High refer rates overburden diagnostic resources to the extent that loss to follow-up and delays in diagnosis may occur. Additionally, infection control measures required cleaning standard earphones between each use, a practice that could be overlooked or inadequately completed in a busy hospital nursery.

An effective solution to these issues was the development of infant sized, self-adhesive, circumaural ear couplers with a clear plastic upper surface first introduced in 1985 (Herrmann, Thornton, Joseph, 1995). They offered significant advantages, including:

- Appropriate design with size, shape, and weight specific to the newborn population to avoid canal collapse as well as infant arousal associated with discomfort caused by standard earphones
- Easy, precise application and stability of placement due to adhesive seal
- Ability to directly visualize the ear canal to ensure optimal delivery of the click stimulus
- Attenuation of ambient noise allowing screening in any environment
- Superior infection control and elimination of the need to clean supplies
- Prevention of cross contamination by disposal after single use
- Improvement in the safety and efficiency necessary for universal newborn hearing screening to meet its objectives using non-audiologist personnel

ANOTHER OPTION

For more than twenty years, insert earphones have been offered as an alternative to standard earphones and to self-adhesive ear couplers in ABR screening. They are typically intended for disposal after single use and comply with infection control standards. While insert earphones are less likely to allow collapsed canals and leaks of the acoustic click stimulus than standard headphones, they do require careful and precise placement in tiny infant ear canals and may become dislodged without detection during screening. Their use has been promoted to overcome issues associated with headphones, but it is important to note that the “advantages” cited apply to standard earphones and cushions that often require handheld application by personnel rather than comparing

insert earphones to self-adhesive circumaural ear couplers designed specifically for newborns (Hall, 2007). Further, there is no acknowledgement that insertion of the earphone may collect vernix and debris commonly present in newborns resulting in partial or full ear canal blockage that compromises the reliability of screening results.

AN IMPORTANT DISTINCTION

Apart from ease of application and use factors, the most important distinction between circumaural infant ear couplers and insert earphones is the critical issue of stimulus intensity and its stability.

Coupling and Calibration

The intensity of a stimulus in ABR screening is the product of sound pressure level generated by the acoustic transducer/earphone assembly delivering the stimulus and the characteristics of the ear coupled to the earphone. The size, shape, and resonance characteristics of the infant ear differ considerably from the adult ear and from the standard hard-walled coupler used to calibrate audiometric equipment and amplification devices. The assumption that a simple sound pressure output per volt input calibration is sufficient has been questioned since it does not account for the difference between infant and adult ear/coupler interactions.

Sound pressure levels for all types of earphones depend upon the characteristics of the earphone and the characteristics of the ear. Moreover, the specific differences depend upon the reference location in the ear where the pressure is measured. Published clinical literature demonstrates that the sound pressure level generated by all types of earphones differs when comparing infant ears and adult ears and that the infant differences are not the same for all earphone types (Voss and Herrmann, 2005).

Evidence for Coupler Use

Specific comparison of the Natus Flexicoupler® to a currently available insert earphone reveals that the sound pressure level at the infant eardrum are within 2-3 dB of pressures at the adult eardrum for frequencies below 2000 Hz. At frequencies above 2000 Hz, sound pressure at the infant eardrum was smaller by up to 7dB when compared to those at the adult eardrum. This reduction of sound pressure level indicated that the circumaural Flexicoupler exhibits changes in the direction of increased sensitivity causing more infants with borderline hearing levels to refer instead of pass. The insert earphone, on the other hand, was found to produce sound pressure levels in the infant ear larger than those in an adult ear by as much as 5-8dB at most frequencies which could decrease sensitivity (Voss & Herrmann, 2005).

This analysis further supports an earlier study using a previous version of the circumaural Flexicoupler. In their 1998 report, Clark, Dybala, & Moushegian examined sound pressure levels using alternative earphones and concluded that the air volume under the Flexicoupler was essential to ensure calibration and intended performance of the Natus newborn hearing screener. Clark et al. affirmed that the importance of using the proper, manufacturer recommended coupler “could not be overemphasized” (Clark, et al., 1998). Similarly, the Voss & Herrmann study (2005) confirms that the volume of air within the circumaural Flexicoupler dominates the acoustic performance of this earphone generating smaller sound pressure differences between infant and adult ears than those created by insert earphones. They declare that it is “absolutely essential” that couplers be used as designed since “the calibration process relies on the coupling mechanisms.”

RATIONALE AND RECOMMENDATION

Since its founding in 1989, Natus Medical Incorporated has consistently recommended single use circumaural Flexicouplers for screening ABR. While ease of use, infection control, and practical advantages of these proprietary ear couplers are apparent, the acoustic significance of the Flexicoupler in achieving and maintaining appropriate calibration is the important underlying rationale that deserves greater attention. Quality universal newborn hearing screening that offers every infant the opportunity for detection and intervention demands technology that not only controls variables threatening efficient and effective performance, but also technology that delivers results with clinically proven reliability. Flexicoupler earphones play a crucial role in achieving this.

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