Automated Methods for ABR Detection in Neonatal Hearing Screening

Auditory Brainstem Response (ABR) detection is an accurate technique to assess proper function of the auditory system in newborns, especially in at-risk babies. It has been regarded as the gold standard for auditory evaluation during the first six months of life for more than 20 years [*Durieux-Smith A et al, 1985; Fria, 1985; Galambos R, Hicks GE, Wilson MJ , 1984; Hall JW et al, 1988; Hyde M et al, 1984; Jacobson JT, Jacobson CA, Spahr RC, 1990; Stein, 1984*].

ABR detection requires recognition of the presence of a specific click-evoked brainwave pattern, an involuntary electrophysiological response indicating neural synchrony (repeated simultaneous brain activity) in the brainstem. Absence or decrease of auditory neural synchrony is highly correlated with hearing impairment.

Rationale for Automated Detection

Universal newborn hearing screening for early detection of hearing loss has dramatically increased the number of infants tested prior to hospital discharge. Requirements to limit the number of experts in the staff have increased the interest in objective screening procedures with 'automated' results in order to allow existing staff and non-technical employees to operate screening equipment reliably and accurately.

During the past decade, techniques have been developed to automate ABR detection, including AccuScreen's binomial statistics for ABR detection, and several other analysis methods, such as cross-correlation analysis, signal-to-noise analysis, frequency analysis and template matching. These techniques are not identical and require knowledge of their individual features in order to evaluate their utility for newborn screening.

In conventional scalp recordings using sensors placed on the skin, the ABR is mixed with physiologic and environmental electrical activity, which completely obscures the response. The most common way to detect an ABR in this background noise is to use signal averaging, which decreases the non-synchronous noise with increased sampling, while the ABR remains constant. The amount of averaging required to detect the presence of an ABR depends on the amplitude of both the ABR and of the back-ground noise. The averaging process can also bring out non-ABR components, which may be related to unexpected physiologic signals, external sources or inappropriate use of the recording device.

When properly controlled, signal averaging permits trained professionals to identify the ABR and to estimate features such as latency and amplitude, which significantly contribute to diagnostic decisions.

Template weighted binomial statistics on ABR

The AccuScreen ABR detection algorithm is a fully 'automated' process, which uses binomial template matching techniques that presume that the new-born is hearing-impaired, until enough click responses have been evaluated to conclude on a very high probability level that the baby has satisfactory auditory neural synchrony. Because the statistics of a non-response condition is very well defined, this probability can be precisely controlled and has shown a clinical sensitivity of more than 99%, without requiring decisions or equipment adjustment by the user as described below. This technique can also distinguish between ABR and non-ABR signals, eliminating the need for waveform review or interpretation by clinicians.

The AccuScreen ABR was introduced in 2001, using the experience from the AccuScreen TEOAE algorithm which also uses binomial statistics. The handheld unit was designed to ensure reliable "hands-off" operation in the nursery environment.

Other Analysis Methods

Cross-correlation analysis compares two or more sets of measured click responses with each

other and attempts to identify the presence of a common synchronous signal which is assumed to be the ABR. An important drawback of this method is that ABR and non-ABR signals are not differentiated from one another which may lead to increased probability for passing a hearing-impaired baby (false passes or false- negatives). This may result in compromised sensitivity and specificity.

Signal-to-noise analysis quantifies the amount of noise remaining in the click response after averaging. This technique also lacks the ability to differentiate between ABR signals and those that do not look like an ABR. Variations of this technique are also known as SNR, Fsp, Fap or POVR, but they all share the same basic drawback with cross-correlation analysis, even though a theoretical sensitivity can be set very high with a presumed ABR signal. To correct for this drawback, ABR detection devices that employ either of these techniques (Bio-Logic *ABaer*, SLE *SABRe*, IHS *SmartScreener*) commonly display the resultant synchronous waveform on the screen, requiring trained professionals to perform the final interpre-tation and confirmation of the result indicated by the device. This could compromise the documented product sensitivity and specificity.

Frequency analysis searches for expected patterns of ABR in the frequency domain while template matching relies upon equivalent expected amplitude patterns in the time domain. Both of these pattern matching approaches derive their thresholds for detection from limited empirical data without the strict control of theoretical models and consequently without the ability to maintain detection performance.

Devices that employ either of these techniques (SonaMed *Clarity*, IHS *SmartScreener*) cannot guarantee statistical performance under all operating conditions and sometimes allow for the adjustment of threshold parameters, requiring trained professionals to maintain detection performance. This could compromise the documented product sensitivity and specificity.

Informed Choice and Quality Assurance

It is essential to understand that these differences in ABR detection methods mean that ABR hearing screeners cannot be considered as equivalent. The ability to adjust screening parameters and the requirement for waveform review or interpretation by trained professionals may have a significant impact on performance reliability, consistency and cost in Newborn Hearing Screening programs.

Unfortunately, these issues are often not addressed by manufacturers reporting clinical performance. Even more concerning is that strict product sensitivity & specificity are rarely provided in writing.

The advantages of the AccuScreen 's ABR detection technology is it's standardized, fully automated technology, which cannot be adjusted and which does not require interpretation, and has been tested and demonstrated for years now by independent clinical research

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