MADSEN AccuScreen®

AccuScreen
OAE & ABR Screener

Test Methods

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1.1 About Otoacoustic Emissions

Congenital hearing impairment has serious consequences for speech and language acquisition as well as emotional and intellectual development. Recent research has confirmed that this can be minimised, when identification and intervention occur, before the hearing-impaired child reaches 6 months of age. In addition, technological advances have made automated screening of infants' hearing possible by a wide range of caregivers. One such automated screening method makes use of the presence of otoacoustic emissions to determine its outcome.

Otoacoustic emissions (OAEs) are sounds found in the ear canal that originate from activity in the cochlea. These sounds are small, but potentially audible, sometimes amounting to as much as 30 dB SPL. They are created by motion of the eardrum driven by vibrations in the cochlea, which are transmitted through the middle ear chain. Consequently, they can be detected only when the middle ear is operating normally. OAEs are generated only when the Organ of Corti is in normal or near normal condition. They can emerge spontaneously, but more commonly follow acoustic stimulation.

Note that otoacoustic emissions do not contribute to hearing, but are *by-products* of an active process in the cochlea, in which motility of the outer hair cells tunes the basilar membrane and amplifies weak sounds. They are clinically significant in the sense that they provide an indication of the integrity of the cochlear amplifier/outer hair cells.

1.1.1 Recording OAEs

In general, the recording of all OAEs requires that a sensitive, low noise microphone be sealed in the external ear canal. Recording of emissions elicited by an acoustic stimulus also requires that there is one (for TEOAE) or two receivers (for DPOAE) to deliver the stimuli. The microphone records the sound present in the external ear canal in response to the acoustic stimulus. The type of signal analysis used depends on the type of emissions to be recorded.

1.1.2 Types of OAEs

Spontaneous otoacoustic emissions (SOAE)
SOAEs are low level, tonal signals, which are measured in the ear canal in the absence of any known stimulus. They are usually inaudible to the persons from whose ears they are detected.

SOAEs are of limited use clinically because they cannot be measured in all ears, and appear at discrete and unpredictable frequencies. However, the presence of an SOAE indicates that hearing is within normal limits near the frequency at which it appears. In addition, it may influence behavioural testing, as well as measurements of other types of OAEs.

Transiently evoked otoacoustic emissions (TEOAEs)
This type of emission is elicited by brief stimuli such as clicks or tone bursts. They can be recorded in nearly all persons with normal hearing. When a click is used to elicit the response, the resultant waveform is, like a fingerprint, idiosyncratic.

TEOAEs are extremely non-linear. Their pattern of growth is consistent with the operation of the cochlear amplifier, which provides most gain for low level inputs, and lends support to the notion that OAEs arise from outer hair cell activity.

TEOAEs do not correlate with behavioural audiometric thresholds. Consequently, it is not possible to predict hearing thresholds based on TEOAE thresholds. However, since the presence of TEOAEs correlates strongly with normal hearing, the most common clinical application involves click stimulation at moderate intensity levels for the purpose of hearing screening or differential diagnosis.

Distortion Product Otoacoustic Emissions (DPOAE)
As with other OAEs, DPOAEs are thought to be generated by the active cochlear process, which is responsible for enhancing the basilar membrane motion.

DPOAEs are tones produced by the ear in response to two simultaneous pure-tone stimuli known as primary tones. They are "distorted" in the sense that they are not present in the eliciting pure-tone stimuli. The lower frequency pure-tone stimulus is called the f1 primary, and the higher frequency stimulus is called the f2 primary.

The most frequently measured distortion product is at the frequency 2f1-f2, although the cochlea also produces distortion products at other frequencies. The 2f1-f2-distortion product is the largest distortion product, and is the only one utilised for clinical purposes at present.

1.1.3 Applications of OAEs

Identification of hearing loss

The presence of TEOAEs strongly indicates that a portion of the audiogram has hearing threshold levels better than 25 dB HL, and correlates best with good hearing in the mid-frequency range. It is not possible to rely on the TEOAE spectrum to predict threshold levels by frequency. TEOAEs are well suited and widely accepted for the purpose of screening hearing.

It has been hoped that DPOAEs would allow clinicians to predict behavioural thresholds, but this is not yet the case. However, there is correspondence between DP-gram configurations and audiogram configurations (i.e. in ears with sensory hearing loss, DPOAEs are reduced or eliminated only for the stimulus frequency regions, which coincide with the impaired region). Accordingly, DPOAEs can give a better frequency specific impression of cochlear integrity than TEOAEs, and are well suited to monitoring of cochlear function.

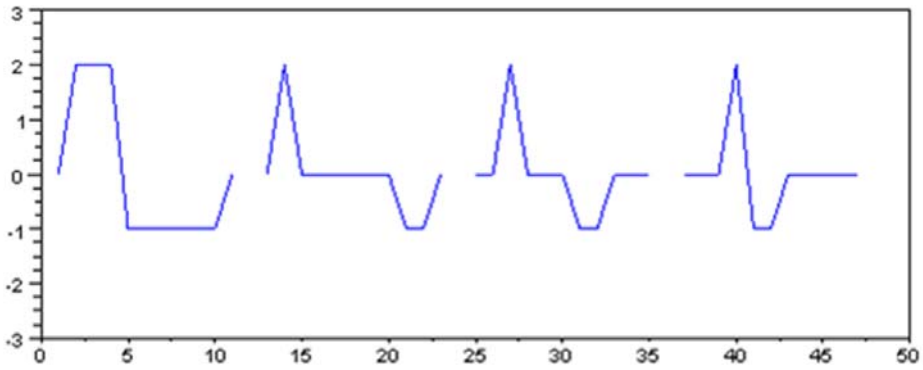
Differential diagnosis

While OAEs have not proven good predictors of auditory nerve tumors, they nevertheless provide the opportunity to document normal or near-normal cochlear function. This makes them helpful in pinpointing sites of lesion, as well as in making management decisions.

1.1.4 How AccuScreen determines a *PASS* in TEOAE testing

AccuScreen uses a weighted averaging test to give either a *PASS* or a *REFER* result. Most TEOAE instruments use the signal-averaging technique with two buffers. In contrast, AccuScreen calculates the statistical probability that an emission has been recorded at a succession of sampling points ranging from 5 to 12 ms after the end of the stimulus.

The Stimulus sequence is composed of 4 broadband, transient, DC-free clicks that are composed so that the sum of the last 3 clicks is equal to the first click. The instrument, when recording sound, will substract the 3 last frames from the 1st in each sequence, resulting in the suppression of linear stimulus artifacts, such as ringing.



Each recorded sweep is weighted with a factor according to its amplitude. The statistical analysis is carried out continuously, and the test result will be a *PASS* if the criterion for this outcome is met. A *PASS* is indicated by the presence of 8 data points at which a time-locked signal has been detected.

The expected amplitude of the weighted-averaged signal can be determined by keeping track of the energy of all single, weighted frames that have been averaged. A significant data point means that the expected value is exceeded by a factor of at least 3. The probability of this happening is less than 0.3% (for a single sample).

The advantage of this system over the usual averaging techniques is that the tests are more robust with regard to noise and the test duration can be reduced. Also, the statistical criterion reduces the probability of a false negative result (which means detecting 8 significant signal peaks with alternating sign) down to less than 0.1%.

Artifact is defined in AccuScreen as a sweep which, based on its relatively large amplitude, is likely to be influenced mostly by noise. Thus, including it in the analysis would lower the signal-to-noise ratio and prolong test time. The automatic identification and exclusion of artifact results in a dramatic shortening of the test duration, especially in the case of restless infants. An artifact rate, which exceeds 20%, indicates that conditions are too noisy to carry out reliable tests.

The Stimulus Stability indicates the proportion of recorded sweeps in which the tested stimulus level deviates significantly from the calibrated level. Low stimulus stability indicates that the probe has moved during testing.

1.1.5 How AccuScreen determines a *PASS* in DPOAE

Distortion Products are the result of cochlear activity, which originates from processing a two-tone signal. The two tones are called "primaries", and their frequencies are designated as f_1 and f_2, and the levels are termed L_1 and L_2.

The challenge of DPOAE evaluation is to discriminate environment sounds - the "noise" - from the cochlear sound response, the Distortion Product (DP). This cannot be achieved with absolute certainty. However, by applying an appropriate statistical algorithm, the chances of wrongly classifying noise as a cochlear signal can be reduced to a known probability - in AccuScreen the probability of erroneously identifying noise as a DP is 0.3% for each frequency applied.

Conventional criteria used commonly in DP screening devices are based on algorithms which attempt to estimate the "noise floor" by averaging the amplitude of the response at frequencies adjacent to the DP frequency. This value is then compared to the amplitude of the response at the DP frequency, and the difference is taken to be the Signal-to-Noise Ration (SNR). Such methods show a false *PASS* rate that is considerably higher than the AccuScreen method. In fact, the false *PASS* rate can be up to 10% for the commonly used criteria of 6 dB SNR.

The statistical method used by AccuScreen makes it possible to evaluate the spectrum specifically at the frequency of the expected DP. Thus, no comparison with adjacent spectral lines is necessary.

During a specified time the acoustic activity at the expected DP frequency $F_{DP}=2F_1-F_2$ is analyzed by calculating the complex Fourier transform value for this frequency. This complex number, as a phase vector, is weighted with the inverse noise level of the raw data frame. These vectors can be added by using the laws of vector addition in the polar coordinate system.

The evaluation is based upon the laws of statistical distributions: it can be shown mathematically that the vector sum of *n* randomly distributed unit vectors will not exceed a certain value with a probability 99.7%. Spectral components of random noise with phases that are independent of the primary tones behave like that. A DP with fixed phase relative to the phases of the primaries will add a constant value to the vector sum. Therefore, if the vector sum exceeds this limit, the presence of an emission can be claimed on a 99.7% confidence level.

The test criterion, which is configurable, is by default set up for each of four frequencies applied: 2, 3, 4 and 5 kHz.

An overall *PASS* result requires 3 passes out of 4 frequencies.

1.2 About Auditory Brainstem Response (ABR)

Sounds are processed by the different parts of the ear and transformed by the auditory sensory cells to a series of action potentials, which are transmitted to the brain by neural conduction. On their way to the auditory cortex the action potentials pass a number of regions called nuclei, where the coded acoustic information is filtered, processed, compared to other information, and distributed to different pathways.

These nuclei are the origin of „bursts" of synchronous multiple cell discharges, which cause electro-magnetic „far-field potentials", which can be tested via scalp electrodes. The potentials picked up by the electrodes are called Auditory Evoked Potentials (AEP) or auditory responses.

There are different AEP-producing regions between the cochlea and the primary auditory cortex. However, the responses of the brainstem (ABRs) are particularly well suited for hearing tests in new-borns, infants and children. Reasons for this include:

- The responses are not influenced by state, and can thus be tested during sleep. This is the ideal state to test ABRs because it minimises influence of potentials from muscular activity, which could make a good measurement difficult.
- Many investigations have shown that the behavioural hearing threshold correlates strongly with the response threshold of the brainstem. In other words: If an ABR can be tested as a response to an acoustic stimulus, it is nearly certain that the individual can hear this stimulus. It would only be in rare cases of damage to the midbrain or auditory cortex that this would not hold true.

Care must be taken during testing and evaluation in order to avoid false results. The amplitude of the electric response to a 30 or 40 dB stimulus is frequently below 100 nV and therefore considerably lower than the scalp electroencephalogram (EEG) and electromyogram (EMG).

1.2.1 How AccuScreen determines a *PASS* in ABR testing

The Auditory Brainstem Response (ABR) is a low-amplitude signal usually buried in the electric brain and muscle activity (EEG and EMG). It can only be extracted by applying special filtering techniques. "Averaging" is the procedure most commonly used to make it visible: the stimulus is presented repeatedly - up to several thousand times - and the signal from the electrodes, which follow the stimulus, is summed continuously until the response can be detected. Visual detection and interpretation of such a signal requires a great deal of expertise.

For screening purposes, the decision to pass or refer must be performed quickly and automatically. As a consequence, a different evaluation approach must be used for screening. A statistical approach determines the ABR PASS criterion.

The procedure involves the application of a template and weighted averaging. Each recorded sweep of raw EEG data is first cross-correlated with the template that represents a typical newborn ABR response. The resulting sweep is then weighted with a factor according to its amplitude. Since raw data is dominated by EEG and EMG noise, the amplitude of a raw sweep can be considered as a noise measure. Sweeps with high amplitude are weighted low, and sweeps with low amplitude are weighted high.

The resulting, averaged waveform is shown continuously, and statistical analysis is done periodically to issue a PASS or REFER result. The statistics involve calculating the amplitude of the waveform in the region that corresponds to the typical latency of a newborn ABR. This amplitude is then compared to an expected value for a no-response recording. The region where the amplitude is analyzed is shown as a box in the waveform display.

The waveform, because it has been processed with the template, does not feature a typical ABR pattern anymore. Instead, for a stable recording, it will show one major peak, that corresponds to the correlation function.

Because the shape of the ABR response waveform changes with age, the detection algorithm is optimised accordingly by pre-filtering the recorded signals with a typical pattern for infants up to one year old. Although this does not preclude testing older children and adults with AccuScreen, the sub-optimal fit may result in longer test times for these patients.

1.2.2 Advantages of combined OAE/ABR-Screening

AccuScreen provides a feature for setting the stimulus level at either 35, 40 or 45 dB nHL. This means that it is either 35, 40 or 45 dB above the normal hearing threshold of a healthy individual.

The spectrum of the stimulus includes all frequencies between 500 and 4000 Hz, but due to filtering in the ear canal and other influences, the main region tested is between 2000 and 4000 Hz. Most significant hearing losses can be found in this region.

As compared to the testing of otoacoustic emissions, the ABR discriminates more precisely between mild and moderate hearing losses. Consequently, its specificity for detecting moderate losses is higher. However, the test requires more time for preparation and testing than an OAE test. Automated ABR tests are therefore ideal as a second step following an OAE screening test with a *REFER* result, as well as screening children who are at greater risk for retrocochlear hearing loss.

1.2.3 How AccuScreen performs simultaneous binaural ABR tests

Because the electrodes are placed on the forehead and nape, they record ABR signals regardless of which ear is being stimulated. However, the brain generates a huge amount of other signals at the same time, which act as noise in the ABR recording, because they are not synchronized with the acoustic stimulus.

The same mechanism can be used for a simultaneous recording of ABR on both ears: If both ears are stimulated at different stimulus rates, the opposite ear's ABR response can be treated as an uncorrelated signal and will disappear during averaging.

The AccuScreen uses a so-called jitter to randomize the stimulus rates when recording ABR anyway. For simultaneous recording, this randomization is done independently for both ears, and ABR is recorded in synchronization with each stimulus sequence independently.

The statistical evaluation for both ears is identical to the one that is used for testing only one ear, therefore the performance in sensitivity is equal. The overall gain in test time will, however, not be the ideal factor of two, because usually the two ears will need a different number of averages to pass due to statistical distribution. The simultaneous test has to wait for the "slower" ear, making the gain in test time somewhat lower, but still significant.

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