Bio-logic ABaer® Hearing Screener – Reference Bibliography

FDA 510(k) Indications for Use Statement – 1999

The Bio-logic Evoked Potential (EP) product family is indicated for use in the recording and analysis of human physiological data necessary for the diagnosis of auditory and hearing-related disorders. An auditory stimulus (click, tone, etc.) is presented to the patient's ear through an earphone or headphones, and the Brainstem Auditory Evoked Response from the patient is recorded using EEG electrodes placed on the scalp. Although this Brainstem Response is very low in amplitude (with respect to surrounding EEG "noise"), the stimulus-response cycle is repeated many times and the resulting responses are averaged from the time of the stimuli. The random noise averages to zero, but if the Brainstem Response signal is present, it's signal will be easily determined in the averaged signal.

The Bio-logic EP System can be used for patients of all ages, from children to adults, including infants and geriatric patients. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable, such as infants, young children, and cognitively impaired or uncooperative adults. The use of the Bio-logic EP family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

The feature modifications represented in this Special 51O(k) are for the use of a redesigned hardware package and a Windows based software program to control the hardware. The functions and electronic design of the hardware are substantially the same as those of the Predicate Device hardware. The software for control of this device is a simplified subset of the DOS-based Predicate Device software. Together, they implement the same infant hearing screening functions and perform the same intended use as the Predicate Device, but with improved ease-of-use. The POVR algorithm described in the Predicate Device is implemented in the new Windows software to generally assist in test data interpretation, and specifically assist in the assessment of signal-to-noise ratio and the quality of the Brainstem Auditory Evoked Response in infants. Based on this automatic assessment, the speed of testing may be reduced and/or the quality of the data recording may be improved, without compromising the quality of recorded data or limiting the control and flexibility of the health care professional administering the test.

Clinical Abstract Summary

Author(s)	Title	Summary	Journal	Year	Vol:Pages
Robert F. Burkard, Jos J. Eggermont, Manuel Don	**Automated Detection Algorithms for ABR Newborn Screening, from *Auditory Evoked Potentials: Basic Principles and Clinical Application***	Pp 262-268 Comprehensive description of POVR as a statistical response detection method and the standard methods of validation to be used for all screening devices.	***Publisher: Lippincott Williams & Wilkins***	**2007**	**Pp 262-268**

Author(s)	Title	Summary	Journal	Year	Vol:Pages
Yvonne Sininger, Martyn Hyde, Ping Luo	**Methods of automated detection of auditory evoked potentials: Point Optimized Variance Ratio and Time-domain Cumulative Sequential Hotelling T2.**	Two algorithms were developed for automated detection of auditory evoked potentials based on statistical properties of the noise properties and the expected waveforms of the EP. One algorithm is a point optimized variance ratio (POVR). Like Fsp, the POVR uses a single or small integer value point variance in the ratio denominator as an estimate of noise. The numerator of POVR is a subset of points selected to maximize the non-centrality parameter of the test statistic when the target response is present. This is accomplished by utilizing information about the morphology of a target EP waveform so as to maximize the statistical power of the detection test. The second algorithm employs a cumulative, sequential Hotelling T2 statistic. The T2 takes into account any pattern of correlation (covariance) among the data points thus avoiding any need to estimate or assume degrees of freedom. The two algorithms have been applied to the detection of the ABR elicited in human infants with low-level (30-35 dB nHL) click stimuli. 12 healthy newborns were evaluated at the Infant Auditory Research Laboratory of Los Angeles County + University of Southern California Medical Center, Women's and Children's Hospital using standard ABR technique and 30 dB nHL click stimuli. In each condition, 10,000 individual sweeps of 20 ms duration were stored off-line for analysis. ABRs were used to create a grand-average target waveform. Ten points were selected for the POVR numerator, based on sequential addition of points from the 200 point target that maximized variance and met the conditions of being separated by a minimum of 1 ms and the variance not falling below 20% of the variance of two points at waveform extremes. Test efficiency, relative to the number of averaged sweeps needed to reach an alpha of 0.01 on Fsp, was determined using infant electrophysiologic data for the POVR with four and ten selected points and for the Hotelling T2. Significant improvement in test efficiency was found for both POVR and Hotelling T2 for the sample of 12 infants. Results of performance of the POVR algorithm in an evaluation of 200 infants will also be discussed.	***Association for Research in Otolaryngology***	**2000**	**Abstract #5750**
Raviv G, Sininger Y, Murphy K	**ABaer™ Automated Brainstem Auditory Evoked Response System An Innovative Approach to Infant Hearing Screening**	White paper outlining the details of the F ratio and POVR statistical detection as applied in ABaer with reported sensitivity/specificity within a strict research paradigm and reports from two clinical sites on 280 infants screened using this approach. Graphs depicting POVR critical values vs. sweeps and template illustrations are provided.	***Bio-logic Systems Corp.***	**2000**	**White Paper**

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Abbey L. Berg, PhD, Jaclyn B. Spitzer, PhD, Helen M. Towers, MD, Christine Bartosiewicz, BA and Beverly E. Diamond, DSW	**Newborn Hearing Screening in the NICU: Profile of Failed Auditory Brainstem Response/Passed Otoacoustic Emission**	Distortion product otoacoustic emissions (DPOAE) and automated auditory brainstem response (AABR) screening were conducted in infants at a distant hospital using remote computing. Eighteen males and twelve females ranging in age from 11–45 days were tested. Both DPOAE and AABR data were recorded using an integrated test system which was connected to the computer network at the Utah Valley Regional Medical Center. Using a broadband Internet connection, an examiner at Utah State University, 200 km away, could control the DPOAE and the ABR equipment. Identical hearing screening results were obtained for face-to-face and telemedicine trials with all infants. The DPOAE means for face-to-face and telemedicine trials were not significantly different at any frequency. In an analysis of variance, there was no significant difference for the test method ($F = 0.8$, $P > 0.05$). These results indicate that remote computing is a feasible telemedicine method for providing DPOAE and ABR hearing screening services to infants in rural communities.	***Pediatrics***	**2005**	**116- 4: 933-938**
Mark Krumm, Todd Huffman, Kelly Dick and Richard Klich	**Telemedicine for audiology screening of infants**	Distortion product otoacoustic emissions (DPOAE) and automated auditory brainstem response (AABR) screening were conducted in infants at a distant hospital using remote computing. Eighteen males and twelve females ranging in age from 11–45 days were tested. Both DPOAE and AABR data were recorded using an integrated test system which was connected to the computer network at the Utah Valley Regional Medical Center. Using a broadband Internet connection, an examiner at Utah State University, 200 km away, could control the DPOAE and the ABR equipment. Identical hearing screening results were obtained for face-to-face and telemedicine trials with all infants. The DPOAE means for face-to-face and telemedicine trials were not significantly different at any frequency. In an analysis of variance, there was no significant difference for the test method ($F = 0.8$, $P > 0.05$). These results indicate that remote computing is a feasible telemedicine method for providing DPOAE and ABR hearing screening services to infants in rural communities.	***Telemed Telecare, Royal Society of Medicine Press***	**2008**	**14:102-104**

Author(s)	Title	Summary	Journal	Year	Vol:Pages
TADA HIROSHI, ARAI HIROKO	**Research on effective mass screening, followup, and family support for hearing loss of newborn infants. Effective screening for hearing loss of newborn infants for all newborns. Hearing test for newborns: results of simultaneous testing of DPOAE and automatic ABR using newborn hearing screener "ABaer".**	Various experiments are going on in the field of hearing tests for newborns. Major screening techniques include automated auditory brainstem response (automatic ABR) and otoacoustic emissions (OAE). We evaluated the utility of "ABaer", a device that can perform both automatic ABR and OAE.	***Kosei Rodo Kagaku Kenkyu (Kodomo Katei Sogo Kenkyu Jigyo) Hokokusho Heisei 14 Nendo Dai2/11***	**2003**	**13**

Author(s)	Title	Summary	Journal	Year	Vol:Pages
Pedersen L, Møller TR, Wetke R, Ovesen T	**Neonatal hearing screening. A comparison of automatic auditory brainstem audiometry and otoacoustic emissions**	The annual birth rate in Denmark is 65,000. Approximately 100 of these children have a congenital bilateral hearing loss which requires treatment. Furthermore, it is expected that yet another 150 newborns have a unilateral hearing loss. Treatment of the hearing loss within the first six months is fundamental in order to ensure optimal use of speech and language, as well as normal social adaptation. The purpose of this study is to compare the two screening methods for hearing loss in newborns as recommended in Denmark--ie. Transient-Evoked Oto-Acoustic Emission (TEOAE) and Automatic Auditory Brainstem Response (AABR). MATERIALS AND METHODS: During a period of six months, 1627 children were bilaterally screened with both AABR and TEOAE. The equipment used was Bio-logic's ABaer hearing screening system. Time usage and the number of refers was recorded. RESULTS: Of the 1627 children, 67 (4%) were referred on one or both ears when using AABR, compared to 177 (11%) when using TEOAE, which is a statistically significant difference (p = 2.43 x 10-16). Re-screening and further examinations in the Department of Audiology identified five children as suffering from a hearing loss. The average time used to perform AABR was 6.6 min.s compared to 3.8 min.s for TEOAE. CONCLUSION: AABR is well chosen as primary screening method. The time usage and equipment costs related to AABR exceed those of TEOAE, but this seems acceptable considering the larger number of re-screenings and further examinations in the Department of Audiology when using TEOAE.	***Ugeskr Laeger***	**2008**	**170(8): 642-6**