

***Audiologic Guidelines for the Assessment of Hearing in Infants and
Young Children***

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Committee Members

Mona M. Dworsack-Dodge, Au.D.

Senior Audiologist
Research and Development
GN Otometrics A/S
Denmark

Judith Gravel, Ph.D.¹

Alison M. Grimes, AuD

Clinical Manager, Audiology, UCLA
Medical Center
Assistant Clinical Professor, Head and
Neck Surgery
David Geffen School of Medicine at
UCLA
Los Angeles, CA

Lisa Hunter, Ph.D.

Associate Professor and Senior
Director
Division of Audiology
Cincinnati Children's Medical Center
University of Cincinnati
Cincinnati, OH

Karen Johnson, Ph.D.

Clinical Research Coordinator
Children's Auditory Research and
Evaluation Center
House Research Institute
Los Angeles, CA

Marilyn Neault, Ph.D.

Director, Habilitative Audiology Program
Children's Hospital Boston
Waltham, MA

Jack Roush, Ph.D

Professor and Director
Division of Speech and Hearing
Sciences
University of North Carolina School of
Medicine
Chapel Hill, NC

Yvonne Sininger, Ph.D.

Professor, Head & Neck Surgery
University of California Los Angeles
Los Angeles, CA

Anne Marie Tharpe, Ph.D.

Professor and Chair
Vanderbilt Bill Wilkerson Center
Department of Hearing & Speech
Sciences
Vanderbilt University School of Medicine
Nashville, TN.

Wende Yellin, Ph.D., Chair

Associate Professor
Department of Communication Sciences
and Disorders
Northern Arizona University
Flagstaff, AZ

¹ Dr. Gravel served on this committee until her death in December of 2008. She contributed substantially to this document and her work is greatly appreciated.

Introduction

The American Academy of Audiology supports early identification, assessment, and intervention for all types of hearing loss in infants and young children to minimize deleterious effects on speech, language, education, and social/psychological development. These *Clinical Practice Guidelines* describe recommended practices for the assessment of auditory function in children. The most appropriate protocol will be individualized for each child based on his or her developmental and/or chronological age and other relevant factors. Thus, test procedures needed to address this population are diverse. The scope-of-practice and responsibility of the audiologist is to determine the appropriate test procedures to use for each child.

The purpose of this document is to describe recommended practices for the assessment of auditory function in children. The Pediatric Hearing Assessment Task Force has delineated the following areas that make up the pediatric audiologic assessment test battery:

- Behavioral observation
- Visual Reinforcement Audiometry (VRA)
- Conditioned Play Audiometry (CPA)
 - Frequency-specific stimuli
 - Speech Audiometry
- Physiologic Assessments, including
 - Acoustic Immittance, including tympanometry and acoustic reflex testing
 - Otoacoustic Emission (OAE) testing
- Electrophysiologic Audiometry including
 - Auditory Brainstem Response (ABR)
 - Auditory Steady State Response (ASSR) audiometry

The Test Battery Approach

When evaluating auditory function in infants and young children, a variety of techniques must be incorporated. The use of a test battery approach to determine a child's auditory profile is described as the cross-check principle (Jerger and Hayes, 1976). Current practice of pediatric audiology dictates that both behavioral and physiologic, and in some cases, electrophysiologic assessments should be incorporated into a complete evaluation to confirm results across various procedures. While the use of various techniques may require more than one test session over a period of time before accurate and reliable results are obtained, it is imperative that the diagnostic process be accomplished as quickly as possible. The 2007 Joint Committee on Infant Hearing 1-3-6 guidelines recommend diagnosis of hearing loss by 3 months of age and intervention by 6 months of age. Of course, earlier diagnosis and intervention would be acceptable and is preferred. For any infant under the age of 3 years for whom hearing aids and/or cochlear implant(s) are to be fitted or recommended, at least one electrophysiological measure of threshold prediction should be completed (JCIH, 2007).

The gold standard of hearing measurement is behavioral assessment. The goal of behavioral testing is to establish hearing thresholds across the speech frequencies for each ear, and to assess, when possible, speech perception at a supra-threshold level. This information is necessary when making decisions regarding amplification, aural habilitation, and educational strategies. Appropriate behavioral procedures will depend upon the child's developmental, cognitive and linguistic level, visual and motor development, and ability to respond appropriately. As children mature, more specific behavioral information can be obtained. In this document, auditory behavioral procedures that change with developmental level, including behavioral observation, Visual Reinforcement Audiometry (VRA), and Conditioned Play Audiometry (CPA), are described in detail.

The use of a team testing approach for Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA) may be helpful in some circumstances, such as when testing children who have developmental delays. The use of an appropriately trained student and/or test assistant may help to maintain the child's attention and proper placement of the transducers.

Physiologic and electrophysiologic tests are used to assess specific auditory function as well as estimate or infer auditory thresholds or sensitivity without requiring an overt behavioral response from the child. In this document, physiological and electrophysiological procedures, including acoustic immittance (tympanometry and acoustic reflex threshold tests), otoacoustic emission (OAE) tests, and auditory brainstem response (ABR) audiometry, also contribute to audiologic diagnosis.

For final determination of type and degree of hearing loss, results from behavioral, physiologic and electrophysiologic testing should be combined. Any discrepancies among these procedures should be investigated and explained. For infants, very young children, and some children with severe developmental disabilities, participation in behavioral measures may not be possible. Because electrophysiologic testing can be performed at earlier ages than behavioral measures, electrophysiological results may need to stand alone for a period of time. However, as soon as the child is able to participate, behavioral threshold measures should be obtained and used to cross-check prior results.

General Procedures

Regardless of which tests are included in a specific test battery, the following should be included in all pediatric audiologic assessments:

- Case History
- Otoscopy

Case History

A complete case history should be obtained from the infant's/child's parent or primary care giver. The case history should address:

- Relevant medical and developmental history, including prenatal and perinatal history;

- Newborn hearing screening results, if known;
- Risk factors for infant hearing loss and progressive/late onset hearing loss (JCIH, 2007);
- Development of motor, cognitive and vision skills;
- Emerging communication milestones, including receptive and expressive speech and language;
- Parent/caregiver's judgments regarding responsiveness to sound in real-world environments, including behaviors observed when sounds are presented.

Care must be taken to utilize language interpreters whenever necessary to obtain and give accurate information.

Otoscopy

Before testing begins, examination of the outer ear as well as otoscopy should be performed on each ear.

When examining the outer ear:

- Take note of any malformations in and around the pinna. Malformations can include skin tags, otic pits, etc.
- Note if the pinnae are protruding, low set, positioned awkwardly on the head, or if any portion of the pinna is missing.
- Look for any lesions or cysts on the pinna and note any delicate skin condition.

When performing otoscopy:

- Determine the size and direction of the ear canal to help in the selection and placement of probes or inserts used during testing.
- Determine if any obstruction of the external auditory canal, such as excessive wax, tumor, or foreign body, is present. In newborns, examine for the presence of vernix, which can affect test results.
- Determine and note if there is any evidence of abnormality or disorder of the external auditory canal.
- Determine if the external auditory canals collapse when pressure is applied. Collapsing canals can induce a transient conductive component to the hearing sensitivity, and can be avoided with the appropriate transducer.
- Note the appearance of the tympanic membrane including light reflex and any abnormalities such as perforation, ventilation tubes, or retraction.

Infection Control

All local and hospital infection control procedures should be followed including:

- Washing hands;
- Cleaning and disinfecting any equipment or items that come into contact with patient;
- Use of appropriate disposable supplies when possible.

Decontamination, cleaning, disinfection, and sterilization of multiple-use equipment before re-use must be carried out according to facility-specific infection control policies

and procedures and according to manufacturer's instructions (Centers for Disease Control, 2011).

Comprehensive Reporting

It is important to document and interpret test results in a comprehensive report and to distribute the report to the family and all associated medical, rehabilitation and educational professionals. The Health Information Technology for Economic and Clinical Health (HITECH) Act and the Health Insurance Portability and Accountability Act (HIPAA) regulations are to be followed and parental consents obtained (HIPAA, 1996). A report must include:

- Appropriate demographic information, name, medical record number, birth date, date of test, and place of test. (etc.)
- Adequate detail of test procedures (see protocols)
- Original graphics of test results when possible (tympanometry, ABR)
- Audiologic Diagnosis
- Summary and Conclusions
- Follow-up Plan
- Signature, contact information and credentials of the audiologist in charge.

All test results should be explained to the family or caregiver in person in a timely manner with an opportunity for the family to ask questions. As with the case history, information should be provided in a language that is understandable to the family; a language interpreter should be utilized whenever requested by the family or when a question of understanding arises.

When a child under 3 years of age is identified with hearing loss, the Individuals with Disabilities Education Act (IDEA) Part C provider must be notified within 48 hours (2004). In addition, written information provided in language accessible to the family/caregiver, and written at no greater than an eighth-grade reading level², should be given to the family/caregiver to explain the test results, implications, and next steps in diagnosis and treatment. Information regarding all communication modes should be presented to the family/caregiver in a non-biased fashion. The family should also receive referrals to peer-support groups and educational programs as deemed appropriate.

Sedation

For some pediatric audiologic procedures in some groups of children (see protocols) it may be necessary for a child to be sedated to obtain accurate test results. Each facility should develop protocols that follow their institution's guidelines regarding sedation or anesthesia. The American Academy of Pediatrics Guidelines for Monitoring and Management of Pediatric Patients during and after Sedation for Diagnostics Procedures (see reference and link) should be consulted in development of local guidelines when sedation is necessary.

² The average reading level of adults in the United States is eighth grade (Kirsch, Jungeblut, Jenkins, Kolstad., 1993).

Equipment and Calibration

Audiometric equipment must be well maintained and meet federal and state standards for safety and efficacy. Equipment must be calibrated regularly by appropriately trained personnel according to manufacturers' recommendations. (See individual protocols for specific needs.)

Billing Codes

The billing codes for the procedures describe in this guideline may be found at the following sites:

- AAA Super Bill:
http://www.audiology.org/practice/coding/Documents/2012_EncounterForm.pdf
- Centers for Medicare and Medicaid Services (CMS):
https://www.cms.gov/PhysicianFeeSched/50_Audiology.asp
https://www.cms.gov/TherapyServices/Downloads/Audiology_Codes.pdf
- American Medical Association:
<http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page>

References

- American Academy of Pediatrics, American Academy of Pediatric Dentists. (2006). Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures: An Update. *Pediatrics* **118:6** 2587-2602.
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- Jerger, J.F., and Hayes, D. (1976). The cross-check principle in pediatric audiology. *Archives of Otolaryngology* **102**, 614-620.
- Joint Committee on Infant Hearing. (2007). Year 2007 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs. *Pediatrics* **120**, 898-921
- Kirsch IS, Jungeblut A, Jenkins L, Kolstad A. Adult Literacy in America. National Center for Education Statistics, U.S. Department of Education, September, 1993, Washington, D.C.
- Centers for Disease Control (2011, August). High-Impact HIV Prevention CDC's Approach to Reducing HIV Infections in the United States .
http://www.cdc.gov/hiv/strategy/dhap/pdf/nhas_booklet.pdf
- U.S. Department of Health and Human Services Office for Civil Rights. Health Insurance Portability and Accountability Act (HIPAA) of 1996. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.

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Audiology Protocol – Behavioral Observation

1. Test Name: The term “audiometry” should be reserved for tests of hearing ability. Because this procedure does not result in the determination of hearing thresholds, the term *Behavioral Observation Audiometry* or *BOA* is not appropriate, and the preferred term is *Behavioral Observation*.
2. Purposes: To assist in the determination of global auditory skill development. This method is inappropriate for hearing screening or estimating auditory thresholds, or for selecting, modifying or verifying amplification.
3. Populations Intended: Newborns and infants under approximately six-months developmental age or others unable to participate in behavioral audiometry.
4. Expected Outcome: Observation of behavioral responses to auditory stimuli may contribute to the global assessment of auditory skill development.
5. Normative Data: none
6. Practice Guidelines (method):
 - A. Test area: Observations should be carried out in a quiet room.
 - B. Otoscopy – not a prerequisite; examine external ear for deformities, and abnormalities
 - C. Patient preparation – Preferably in quiet state or light state of sleep (rapid eye movement [REM]), seated in car seat, baby tote, or other resting pillow (i.e., not in parent’s lap, if possible). If baby is placed in parent’s lap, parent masking should be considered. Parents should be cautioned not to cue their children when a stimulus is presented.
 - D. Recommended stimulus – complex acoustic stimuli (e.g., speech, speech-shaped noise) presented between 60 and 90 dB HL. Duration of stimuli should be between 3-4 seconds as the alerting and response time is longer in younger than older babies (Sonksen 1983).
 - E. “No sound” or “catch trials” should be inserted to avoid misinterpretation of random child activity (Diefendorf & Gravel, 2001)
 - F. Only 2-3 stimulus presentations may be possible prior to infant habituation
 - G. Real World Behavioral Observation: Use of functional auditory assessment tools completed by parents/caregivers and reviewed with audiologist (e.g., Early Listening Function; Anderson, 2000) is

recommended to provide a more in-depth assessment of behavioral responses to sound than a single observational session.

7. Test Interpretation: Startle reflexes might be observed when peripheral hearing is normal in response to auditory stimuli presented between 60 and 90 dB HL. Startle reflexes are highly influenced by physiological states such as infant hunger and fatigue. Therefore, the absence of a startle reflex should be interpreted cautiously and in conjunction with other observations and test results. Other changes in behavior that are time-locked to the stimulus presentation should be noted only as “present” or “absent” and not interpreted as a threshold or minimum response level.
8. Equipment specifications: Audiometer with soundfield capability.
9. Supplies: none
10. Reporting Requirements: The intended recipients should be considered in report writing (e.g., physicians, educators). The results should be characterized as observational and not intended as predictive of auditory thresholds.

References:

- American National Standards Institute (1999). American National Standard Criteria for Permissible Ambient Noise During Audiometric Testing (ANSI S3.1-1991). New York: ANSI.
- Anderson, K.L. (2000). Early Listening Function (ELF). www.hear2learn.com.
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- Joint Committee on Infant Hearing. (2007). Year 2007 position statement: Principles and guidelines for early hearing detection and intervention programs. *Pediatrics*, 102, 893–921.
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- Hicks CB, Tharpe AM, Ashmead DH. Behavioral auditory assessment of young infants: methodological limitations or natural lack of auditory responsiveness? *Am J Audiol.* 2000 Dec;9(2):124-30.
- Weber, B. A. (1969). Validation of observer judgments in behavior observation audiometry. *Journal of Speech and Hearing Disorders*, 34, 350–354.

Wilson, W. R., & Thompson, G. (1984). Behavioral audiometry. In J. Jerger (Ed.), *Pediatric audiology* (pp. 1–44). San Diego, CA: College-Hill Press.

Links:

UK Newborn Hearing Screening Program www.nhsp.info

www.nhsp.info/cms Behavioral Observation Audiometry Protocol

www.phonak.com Early Listening Function (ELF; Karen Anderson)

Audiology Protocol – Visual Reinforcement Audiometry

1. Test Name: Visual Reinforcement Audiometry (VRA)
2. Purposes: Used to estimate frequency- and ear-specific hearing sensitivity and hearing loss type using a conditioned response procedure.
3. Populations Intended: Infants between approximately 5 and 24 months developmental age
4. Expected Outcome: Estimation of hearing thresholds based on minimum response levels (MRLs) that have a close relationship with perceptual thresholds
5. Normative Data: Available for TDH-39 earphones at a limited number of frequencies (Nozza & Wilson 1984; Sabo et al. 2003) and for sound field stimuli (Gravel & Wallace 2000), and for insert phones (Parry, Hacking, & Bamford, 2003).
6. Practice Guidelines (method):
 - A. Test area – Sound-treated booth
 - B. Calibration – Standard speaker calibration (ANSI S3.6, 1996), sound booth meeting ANSI S3.1 (1999) ears not covered (500-8000Hz) specifications, and appropriate earphone calibration (TDH-series and insert-type)
 - C. Otoscopy – Otoscopy should be performed prior to testing to ensure clear external auditory canals and to determine the insert ear tip size to be used for testing
 - D. Patient preparation – Seated in highchair or, when preferred, in caregiver's lap. If child is placed in parent's lap, parent masking should be considered. Parents should be cautioned not to cue their children when a stimulus is presented.
 - E. Procedure -
 - i. Transducers: Insert earphones coupled with ear tip or child's personal earmold, bone conduction vibrator, or sound field speaker(s) as determined by specific circumstances or test needs
 - ii. Conditioning: Most children will provide a clear spontaneous head turn within 2-3 seconds upon the presentation of the first stimulus without classical conditioning (i.e., pairing the stimulus and reinforcer). Others, especially those with developmental delays,

might require classical conditioning. The preferred response with a VRA task is a 90 degree head turn. This response is less ambiguous for an audiologist to observe as compared to a 45 degree head turn.

If a response to the auditory stimulus alone is not elicited, the transducer should be changed to a bone vibrator and a low frequency signal (e.g., 250 Hz) or speech should be presented at a level known to provide tactile stimulation (e.g., 50 dB HL).

If the child does not respond to the stimulus/reinforcer combination or to the vibrotactile stimulus alone, it is likely that the task is not developmentally appropriate for the child (usually at the younger end of the age range) or that the task is not sufficiently interesting to the child (usually at the older end of the age range). In such circumstances, alternative hearing assessment procedures (i.e., physiological) should be considered.

- iii. Threshold search: Testing should begin after two consecutive correct responses have been obtained. A systematic bracketing protocol with pre-determined start level, and step-sizes is recommended (Tharpe & Ashmead, 1993; Widen et al., 2000; Widen et al., 2005).
- iv. Order of Presentation: Minimum response levels (MRLs) should be obtained for speech stimuli (e.g., monosyllables, individual speech sounds, child's name) first, followed by tonal stimuli with center frequencies of 0.5, 1.0, 2.0, and 4.0 kHz; order of stimulus presentation will depend on focus of the evaluation. For example, starting with high frequencies first has the advantage of making an early determination of the need for amplification in case the child cannot participate for testing of all test frequencies. If insert earphones can be utilized, consideration should be given to alternating ears between stimuli in order to obtain partial or complete data on both ears. For example, obtain MRL for speech in right ear, then in left ear; MRL for 2.0 kHz tone in right ear, then in left ear, and so on.

See Appendix A for tips on conducting successful VRA. Appendix B provides references for different VRA protocols.
- v. Midline Distractor: Following the child's head turn towards the reinforcer, an assistant (e.g., student, parent, audiologist) in the test booth can serve the function of returning the child's attention and gaze to midline.

7. Test Interpretation: Thresholds or minimum response levels consistent with normal hearing sensitivity vary depending upon age of the child and are available in the literature (Sabo et al., 2003; Widen et al., 2005).
8. Equipment specifications: Audiometer with sound field capability; visual reinforcers (e.g., multiple animated toys individually housed in dark Plexiglass boxes; illuminated and/or activated remotely) or video reinforcement system located 90-degrees to one side or both sides of the child at eye level (reinforcers positioned at a 45-degree angle are generally insufficient for eliciting an observable head turn); earphone masking system for mid-line distracter and parent
9. Supplies: Disposable child-sized foam insert eartips; quiet toys for mid-line distraction

References:

- American National Standards Institute (1996). Specifications for audiometers (ANSI S3.6-1996). New York: Author.
- American National Standards Institute (1999). Maximum permissible ambient noise levels for audiometric test rooms (ANSI S3.1-1999). New York: Author.
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Schmida MJ, Peterson HJ, Tharpe AM. Visual reinforcement audiometry using digital video disc and conventional reinforcers. 2003. *Am J Audiol*. 12(1); 35-40.

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Widen JE, Folsom RC, Cone-Wesson B, Carty L, Dunnell JJ, Koebse K, et al. Identification of neonatal hearing impairment: hearing status at 8 to 12 months corrected age using a visual reinforcement audiometry protocol. *Ear Hear*. 2000;21:471-87.

Widen JE, Johnson JL, White KR, Gravel JS, Vohr BR, James M, et al. A multisite study to examine the efficacy of the otoacoustic emission/automated auditory brainstem response newborn hearing screening protocol: results of visual reinforcement audiometry. *Am J Audiol*. 2005;14:S200-16.

Links:

www.nhsp.info/cms Visual Reinforcement Audiometry Protocol

Appendix A. Tips for VRA testing

Room set up	<ul style="list-style-type: none"> • Room should be devoid of distracting elements upon the child's entrance; toys to be used as distracters should not be available to child during history taking so child will not tire of them before testing begins. • VRA relies on continued cooperation of the child, in particular their ability to stay seated. To avoid delay/disruptions in the procedure, ensure that all required equipment is available and checked in advance (e.g., audiometer is set for immediate implementation of test, talk-over equipment is working, distraction toys are available).
Reinforcement	<ul style="list-style-type: none"> • What is rewarding to one child may not be rewarding to another. That is, some children like visual reinforcement while others prefer social reinforcement. One tip is to hold some reinforcement "in reserve" for when you need it. For example, the midline distracter may want to interact minimally with the child as long as the visual reinforcer is keeping him/her on task. As soon as the child appears to start habituating or appears disinterested in the reinforcer, the midline distracter can start providing social reinforcement (clapping, cheering) to prolong cooperation. • Some children may be upset by certain animated toys. If so, reward through simple illumination rather than animation or switch to alternative toys. • Towards the end of the test procedure, return to the first frequency tested and present at MRL (or 5 dB above that dial level) - does the child still respond? This information will help the tester judge validity of later responses.
Earphone placement	<p>Experience indicates that many infants between 6 and 15+ months are fairly easy to test using insert earphones as long as you get them in their ears quickly and your midline distracter keeps the infant occupied.</p>
Midline distraction	<p>Midline distracter should be cautioned not to cue the child that an auditory stimulus has occurred. Masking earphones that play background noise or music can be useful and should allow for a "talk over" option for the tester to communicate.</p>

Appendix B. VRA protocols.

Day J, Green R, Munro K, Parry G, Shaw P, Wood S, Brown E, Sutton G (2008). Visual reinforcement audiometry testing of infants: A recommended test protocol. National Health Service. Retrieved 6-20-09 from <http://hearing.screening.nhs.uk/getdata.php?id=10490>.

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Audiology Protocol – Conditioned Play Audiometry

1. Test Name: Conditioned Play Audiometry (CPA)
2. Purposes: To determine ear-specific and frequency-specific hearing sensitivity.
3. Populations Intended: Children between approximately two and five years developmental age
4. Expected Outcome: Quantifies the degree, type and configuration of hearing status
5. Practice Guidelines (method):
 - A. Test area – Sound-treated booth
 - B. Calibration – Sound booth meeting ANSI S3.1 (1999) ears not covered (500-8000Hz) specifications, and earphone calibration (ANSI, 1996);
 - C. Case history – To include risk factors for infant hearing loss and progressive/late onset hearing loss (JCIH, 2007), and to include the parent/caregiver’s judgments regarding responsiveness to sound in real-world environments. Case history also includes infant/child’s auditory developmental status, including emerging communication milestones, among others
 - D. Otoscopy – Should be performed prior to testing to ensure clear external auditory canals and to determine the earphone size to be used for testing
 - E. Patient preparation – Optimally, seated at a child-sized table in an appropriately-sized chair. Conditioning phase includes review of play task (motor response) with sufficient number of trials to ensure child understands instructions. When verbal instructions are not appropriate (because of language age or severity of hearing loss), other methods of ensuring response reliability are required (such as use of a vibro-tactile stimulus during conditioning phase).
 - F. Recommended stimuli – Tonal stimuli with center frequencies of .5, 1.0, 2.0, and 4.0 kHz for frequency-specific testing. Speech thresholds (e.g., spondees or individual speech sounds depending on nature of task) should be obtained.
 - G. Procedures – Frequency-specific stimuli
 1. Use of insert earphones coupled to foam eartips or child’s personal earmolds, supra-aural earphones, bone vibrator, or

sound field testing as determined by specific circumstances or test needs.

2. A brief initial training session (i.e., conditioning) should be conducted to ensure that child understands task. Child should reliably provide two consecutive, unprompted correct responses to the presence of a stimulus before starting the threshold testing. The loudness level of the conditioning tone should be easily audible to the child and determined by the level of the SAT or SRT. There are at least two possible explanations for a child's inability to provide conditioned responses to air-conducted stimuli. First, the auditory stimuli might not be audible. In this situation, a bone vibrator should be used for conditioning purposes (either placed on the head or held in child's hand). If child conditions with the bone vibrator, bone conduction thresholds to pure tones should be obtained and examiner should re-attempt conditioning with air-conduction stimuli.

Second, if the child does not condition with the bone vibrator, the task might not be developmentally appropriate or appealing, and visual reinforcement audiometry should be utilized.

3. Appropriate play tasks for obtaining thresholds include placing a peg in a pegboard, tossing a block in a box, stacking blocks, or other game-type activities in response to an auditory stimulus (speech or frequency-specific). Tangible reinforcement operant conditioning audiometry (TROCA) and Visual Reinforced Operant Conditioning Audiometry (VROCA) are also acceptable options.
4. A systematic bracketing protocol with audible starting level, and pre-determined step-sizes is recommended; for children of this age, this typically means a down 10, up 5 dB step size but might require larger step sizes (down 20, up 10 dB) if speed is required;
5. Thresholds to tonal stimuli of .5, 1.0, 2.0, and 4.0 kHz should be obtained next; order of stimulus presentation will depend on focus of the evaluation. For example, starting with high frequencies first has the advantage of making an early determination of the need for amplification in case the child cannot maintain attention for testing of all test frequencies. That is, if a high frequency hearing loss is identified, even if lower frequencies are not yet assessed, initial steps toward hearing aid fitting can be made (e.g., referral for funding source, scheduling for hearing aid selection) before completion of all audiometric testing. Additional frequencies might be appropriate under different circumstances (e.g., addition of 3.0 kHz when fitting amplification). For very young children (i.e., 2-3

years developmental age), consideration should be given to alternating ears between stimuli in order to obtain partial or complete data on both ears. For example, obtain a SRT in right ear, then in left ear; threshold for 2.0 kHz tone in right ear, then in left ear; and so on.

6. Equipment specifications: audiometer with air and bone conduction, supra-aural and insert-type earphones, soundfield capabilities, Tangible Reinforcement Operant Conditioning Audiometry system (optional)
7. Supplies: disposable child-sized foam insert eartips; toys (e.g., blocks, pegs) consistent with need for repeatable, volitional motor acts in response to auditory stimuli; open- and closed-set speech perception tests; spondee picture cards
8. Infection Control Procedures: All procedures must adhere to universal health precautions (e.g., prevention of bodily injury and transmission of infectious disease). Decontamination, cleaning, disinfection, and sterilization of multiple-use equipment before re-use must be carried out according to facility-specific infection control policies and procedures and according to manufacturer's instructions (Centers for Disease Control, 1988).
9. Reporting Requirements: Reports of CPA should be written in lay language appropriate for parents, physicians, educators, and other interventionists. Reports should include interpretation of results, additional recommended referrals, and a plan (with time line) for follow up.

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Audiology Protocol – Speech Audiometry

1. Test names: Speech perception, speech audiometry
2. Purpose: To determine ability to perceive speech or speech-like stimuli; to aid in determination of pure tone threshold reliability; includes speech awareness, speech discrimination, and speech recognition determinations
3. Population Intended: children at and above approximately 6 months developmental age
4. Expected Outcome: quantification of speech perception ability bilaterally
5. Practice Guidelines:
 - A. Test area: Testing should be carried out in a quiet area. A clinical test booth is not required as long as ambient and environmental noise is maintained at a low level.
 - B. Calibration – Sound booth meeting ANSI S3.1 (1999) ears not covered (500-8000Hz) specifications, and earphone calibration (ANSI, 1996);
 - C. Procedures -
 1. Use of insert earphones coupled to foam eartips or child's personal earmolds, supra-aural earphones, bone vibrator, or sound field testing as determined by specific circumstances or test needs.
 2. Prior to obtaining thresholds to frequency-specific stimuli, a threshold for speech should be obtained. Speech reception thresholds (SRT) are typically obtained using developmentally-appropriate spondee words. Responses can be made orally or by picture pointing. Picture pointing should be used if the child's speech production abilities are compromised. If picture cards are used, examiner should have child point to each picture upon request prior to starting the test. If the child is unable to point to the pictures, the examiner should consider modifying the protocol (e.g., point to body parts). If procedure is still unsuccessful, speech awareness threshold (SAT) should be obtained.
 3. A systematic bracketing protocol with audible starting level, and pre-determined step-sizes is recommended when speech thresholds are being obtained; step sizes and start/stop rules should be consistent with those used for obtaining pure tone thresholds for children of the same age;

4. Supra-threshold speech perception testing is routinely conducted with closed-set (e.g., picture pointing) tasks or open-set (e.g., word or sentence repetition), as appropriate. Receptive language ability should be considered when selecting age-appropriate tests. In addition, if speech production abilities are limited or likely to interfere with intelligibility, picture-pointing tasks can be utilized. When appropriate, and when children cannot participate for recognition testing, consideration should be given to assessment of pattern perception abilities (e.g., discrimination tasks).
6. Reporting: Reports of speech perception should be written in lay language appropriate for parents, physicians, educators, and other interventionists. Reports should include interpretation of results, additional recommended referrals, and a plan (with time line) for follow up.

Audiology Protocol – Pediatric Immittance Testing

1. Test names: Tympanometry and Acoustic Reflex Measures
2. Purpose: To assess middle ear function and auditory pathway integrity; to evaluate for otitis media and other middle ear abnormalities.
3. Population intended: Infants and young children. Immittance assessment should occur routinely as a component of the hearing evaluation, and more frequently for children at increased risk for middle ear disease or for those with known sensorineural hearing loss, or at risk for auditory neuropathy.
4. Probe tone frequency and developmental effects: Because 226-Hz tympanometry and acoustic reflex results can be spurious in the neonatal population, a higher probe tone frequency such as 1000-Hz has been advocated for infants below 6 months of age (JCIH, 2007) and there is evidence that it is more sensitive in the identification of middle ear disease (Baldwin, 2006; Mazlan et al. 2009).
4. Expected outcome: Accurate prediction of middle ear status; abnormal patterns, in conjunction with other audiologic test procedures may help to determine etiology.
5. Normative data: See appendix.
6. Practice guidelines:
 - A. Test area: Testing should be carried out in a quiet area. A clinical test booth is not required as long as ambient and environmental noise is maintained at a low level.
 - B. Sedation: Sedation is not typically necessary as tympanograms and acoustic reflexes are rapidly recorded. Infants and young children should be resting quietly during the test. Older children may sit quietly or be distracted by pictures or video.
 - C. Equipment and Supplies: Acoustic immittance instruments are commercially available for tympanometry and acoustic reflex measures. Most employ a low frequency (e.g. 226 Hz) probe tone but some are capable of performing tympanometry with higher frequency probe tones (e.g. 678 Hz or 1000 Hz). Some diagnostic instruments also allow multicomponent tympanometry (e.g., susceptance and conductance). Supplies include disposable or reusable tips required to seal the probe assembly in the external ear canal. Equipment should be calibrated according to ANSI, 1987 (R2007).
 - D. Stimuli: Commercially available tympanometers vary considerably with

regard to pump speed, pressure sweep, and automatic calculation of admittance and gradient or width (depending on method for subtracting admittance of ear canal). Thus, it is important to consider these variables when applying normative data. Probe tone frequency is the most important examiner-controlled variable. A probe tone frequency of 226 Hz is optimal for routine tympanometry and acoustic reflexes except for infants under the age of 6 months. For neonates and young infants, a higher frequency probe tone (678 Hz or 1000 Hz) is needed to obtain an accurate assessment of middle ear status. Normative data are available for 1000 Hz for these populations (Margolis et al 2003; Kei et al., 2003; Calandruccio et al., 2005; Maslin et al., 2009).

- E. Calibration: Acoustic immittance instruments must be calibrated annually according to ANSI standards (ANSI, 1987) and daily volume calibrations should be performed using a calibration cavity supplied by the manufacturer.
- F. Otoscopy: Otoscopy should be performed prior to testing to determine if the external auditory canal is occluded by cerumen or other debris and to determine probe size for immittance measures. Newborn infant ear canals may be occluded by vernix or prone to ear canal collapse, which may affect measurements. It is important to document ear canal status and implications for test interpretation purposes.
- G. Patient preparation and infection control: A clean flexible probe tip is sealed in the external auditory canal and testing is initiated once the probe seal is adequate (i.e. pressurization is achieved).
- H. Procedure
 - i. A probe tip of sufficient size to achieve a hermetic seal without discomfort is selected and attached to the probe assembly.
 - ii. The probe tip and probe assembly are stabilized in the ear canal; a series of measures are performed that typically include: tympanometric peak pressure, static admittance, equivalent volume, and tympanometric 'shape,' based on a calculation of tympanometric width.
 - iii. Ipsilateral acoustic reflex is performed using the same probe tone selected for tympanometry at the peak pressure determined by tympanometry. The addition of contralateral acoustic reflex is useful for assessment of auditory pathway integrity.
 - iv. Reflexes should be performed at 1000 Hz, and other stimulus frequencies as desired, or for broadband noise. A repeatable, observable decrease in admittance timed with the stimulus should occur; the lowest intensity with a repeatable admittance decrease is

defined as the acoustic reflex threshold.

- v. The probe is then removed from the ear and the resulting measures recorded or printed.

I. Interpretation

- i. Tympanometry is considered normal if:
 - a. An identifiable tympanometric peak is observed at or near atmospheric pressure with admittance and tympanometric width values typical for the patient's age (refer to normative data).
- ii. Tympanometry is considered abnormal if:
 - a. There is no identifiable pressure peak
 - b. A pressure peak is observed but with static admittance values indicative of hypo-or hyper-mobility of the middle ear (refer to normative data).
 - c. A peak is observed but the tympanometric width is abnormally increased or gradient is abnormally reduced (refer to normative data).
 - d. A peak is observed but with markedly reduced negative ear pressure (e.g., < -200 daPa).
Note: Negative peak pressure is associated with Eustachian tube dysfunction; however there is no evidence that it is predictive of middle ear effusion
- iii. Acoustic reflexes are considered abnormal if:
 - a. The acoustic reflex threshold is > 95 dB HL for 500 and 4000 Hz; or > 100 dB HL for 1000 and 2000 Hz.
Note: maximum stimulus level should not exceed 105 dB HL due to the possibility of noise-induced hearing loss caused by the reflex stimulus (Hunter et al., 1999).
- iv. The acoustic reflex is most reliable as a predictor of middle ear status when coupled with tympanometric measurements including static admittance (Casselbrant et al., 1985; Marchant et al., 1986) and gradient (Nozza et al., 1992). The acoustic reflex alone may not be the best predictor of middle ear effusion. Nozza et al. (1992) reported that, coupled with tympanometric gradient of less than 0.1 mmho, the absence of the acoustic reflex is a powerful indicator of middle ear

effusion.

- v. Acoustic reflexes are helpful in investigating the possibility of auditory neuropathy, when combined with otoacoustic emission assessment and/or other clinical findings, as the acoustic reflex is nearly always absent or elevated in confirmed cases of auditory neuropathy (Berlin et al., 2005).

7. Reporting: In general, tympanometric results may be reported as follows:

- i. When tympanometric findings are within normal limits they may be reported as consistent with normal middle ear function
- ii. When there is no pressure peak (i.e. a 'flat' tympanogram)
 - a. In the presence of normal equivalent volume, the results may be reported as consistent with middle ear effusion.
 - b. In the presence of abnormally large equivalent volume the results may be reported as consistent with a patent tympanostomy tube or dry perforation of the tympanic membrane.
- iii. When the tympanogram has an identifiable peak at a pressure interval outside the normal range, it may be reported as consistent with abnormally negative (or positive) middle ear pressure.
- iv. When the tympanogram has an identifiable peak with abnormally low admittance or broad width, it may be reported as consistent with reduced middle ear mobility (this may be due to otitis media, ossicular fixation, or other abnormalities of middle ear function).
- v. When the tympanogram has an identifiable peak with abnormally high admittance, it may be reported as consistent with abnormally increased middle ear mobility (this may be due to ossicular interruption or abnormalities of the tympanic membrane)

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Table 1. Normative data for ages 0 to 30 Months: Tympanometry using 226-Hz and 1000-Hz probe tones.

Authors	Age	Probe Frequency (Hz)	Static Admittance 5% to 95%tiles (mmho)	Tympanometric Width (daPa)	Pump Speed/ Direction
Margolis, et al., 2003	Birth - 4 weeks CA	1 k Hz	.60 to 4.3 -400 tail to peak	na	+200 to -400 (600 daPa/sec @ tails, 200 daPa/sec @ peaks)
Kei, et al., 2003	1 to 6 days	1 k Hz	<u>Right ears</u> +200 tail to peak .39 to 2.28	<u>Right ears</u> 56.6 to 154	+200 to -200 @ 50 daPa/sec
“”	1 to 6 days	1 k Hz	<u>Left ears</u> +200 tail to peak .39 to 1.95	<u>Left ears</u> 46.1 to 144.2	+200 to -200 @ 50 daPa/sec
Baldwin, 2006.	2-21 weeks	226 Hz	Mean = .68 (± .32)	NA	+200 to -400 (600 daPa/sec @ tails, 200 daPa/sec @ peaks)
Roush, et al., 1995	6-12 mo	226 Hz	.20 to .50 +200 tail to peak	102 to 234 Ytm>=.3mm ho	+200 to -300
“”	12-18 mo	226 Hz	.20 to .60 +200 tail to peak	102 to 204 Ytm>=.3mm ho	+200 to -300
“”	18-24 mo	226 Hz	.30 to .70 +200 tail to peak	102 to 204 Ytm>=.3mm ho	+200 to -300
	24-30 mo	226 Hz	.30 to .80 +200 tail to peak	96 to 192 Ytm>=.3mm ho	+200 to -300

Table 2. Normative data for ages 0 to 12 Months: Acoustic Reflex Thresholds (ART) at various probe tone frequencies

Study	Ages	Probe Frequency	Test Frequencies	Presentation Levels	Normative Values
(Kankkunen & Lidén, 1984)	Newborns and children	660 Hz	500, 1000, 2000, 4000 Hz and broadband noise – ipsilateral presentation	Up to limits of equipment: 90 dB HL at 500 and 4000 Hz, 100 dB HL at 2000 Hz, and 110 dB HL at 1000 Hz.	Upper limit ART: 500 Hz = 95, 1000 Hz = 101, 2000 Hz = 102, 4000 Hz = 96 dB HL
Mazlan, Kei & Hickson, 2009)	Healthy newborns	1000 Hz	Broadband noise and 2000 Hz		BBN = 65 dB HL; 2000 Hz = 76 dB HL.
(McMillan, Marchant, & Shurin, 1985)	2 wks to 12 mos	220 and 660 Hz	500, 1000, and 2000, 4000 Hz ipsilateral presentation	70 dB HL raised in 5 dB steps to the limits of the equipment.	Median ipsilateral reflex thresholds = 80 to 85 dB HL for all conditions.

Audiology Protocol - Otoacoustic Emissions

1. Test name: Otoacoustic Emissions (OAEs). Currently, two types of evoked OAEs are used for clinical assessment: transient-evoked OAEs (TEOAEs), elicited using an acoustic click or other short transient, and distortion product OAEs (DPOAEs), elicited by the simultaneous presentation of two pure tones.
2. Purpose: To assess cochlear/outer hair cell function. Although not a direct measure of hearing, OAEs provide information about the status of the auditory periphery and, in the absence of middle ear disorder, the likelihood of sensory hearing loss. OAEs can be used as a screening procedure for hearing loss in neonates and infants, a cross-check verification of behavioral testing when indicated, and/or to establish some aspects of cochlear function in children with neural hearing loss. OAEs can also be used to monitor cochlear function in children undergoing potentially ototoxic treatments (e.g., chemotherapy, aminoglycoside antibiotic therapy), although currently there are no universally established criteria for the degree of change in OAEs considered to be clinically significant.
3. Population intended: Infants and children of all ages.
4. Testing Frequency: OAEs should be assessed routinely as part of the pediatric assessment battery whenever the goal is to establish or predict auditory sensitivity, to confirm type and degree of hearing loss, and/or to identify the site of auditory disorder. In view of the ease and speed of its administration, OAEs can also be used as often as deemed medically necessary to screen or monitor preneural auditory function (e.g. following courses of ototoxic therapies and interventions), or whenever a physiologic crosscheck of behavioral testing is desired.
5. Normative Data: Expected OAE amplitudes and spectra from normal hearing infants and children are markedly different than those from normal hearing adults. Response amplitudes and spectral characteristics should be compared with normative values reported in large-scale studies in children of comparable age. For information on normal TEOAE amplitude and reproducibility in infants and children see Harrison & Norton (1999); Norton et al. (2000a), Prieve et al. (1993, 1997a, 2009). For normative data on DPOAE amplitude in infants and children see Abdala et al. (2008), Gorga et al. (2000), Prieve et al. (1997b).
6. Practice guidelines:
 - A. Testing area: Testing should be conducted in a quiet area. A clinical test booth is optimal but not required as long as noise from environmental sources is kept to a minimum. Continuous background noise in excess of approximately 50 to 55 dB A should be avoided, as it is likely to reduce OAE signal-to-noise ratio and reproducibility (Rhoades et al, 1998).
 - B. Equipment and Supplies: OAE equipment is available from most audiometric equipment manufacturers. Options include test type (DPOAE and/or TEOAE)

and screening and diagnostic protocols. Stimuli are presented and ear canal responses are monitored via a probe assembly that is fit to the ear with individual, disposable ear tips. A variety of ear tip sizes is needed to ensure proper fitting across the range of ear canal sizes found in infants and children.

- C. Stimuli: Stimuli used for OAE measurements include transients (TEOAEs) and pure tones (DPOAEs). Stimulus level for TEOAEs should be 80 dB peak–equivalent SPL \pm 3 dB (approximately 77 to 83 dB peSPL), as measured in the ear canal. Stimuli within this range have been shown to be sensitive to hearing losses $>$ 20 dB HL in the 1000 to 4000 Hz region (Harrison & Norton, 1999; Lichtenstein & Stapells, 1996; Prieve et al, 1993). Higher click levels (84 to 86 dB pe SPL) appear to be sensitive to hearing losses $>$ 30 dB HL. The stimulus spectrum measured in the ear canal should be broad and flat, with approximately equal energy through 6000 Hz.

DPOAE measures use pairs of pure tones where f_1 = the lower frequency primary tone and f_2 = the higher frequency primary tone. Target stimulus levels are generally $L_1 = 65$ dB SPL (the level of the lower frequency tone, f_1) and $L_2 = 50$ or 55 dB SPL (the level of the higher frequency tone, f_2). These moderate stimulus levels, with a 10 to 15 dB difference between L_1 and L_2 ($L_1 > L_2$), have been shown to be optimal for separating ears with normal hearing from ears with hearing loss in the 20 to 30 dB HL range (Gaskill & Brown, 1990; Brook et al, 2001; Stover et al, 1996; Whitehead et al, 1995b; Gorga et al, 1997). In current clinical practice, stimulus levels of $L_1=65$ and $L_2=55$ typically are used (e.g., Abdala, 2008; Gorga et al, 2005; Shera & Abdala, In Press).

- D. Calibration: Currently, there are no uniform standards for the calibration of stimulus levels used to evoke OAEs. (For a discussion of calibration of click or short duration tones in general see the Electrophysiologic Test Protocol). Nevertheless, most clinical OAE systems incorporate self-calibration protocols to ensure that the instrumentation is functioning properly and not producing artifactual signals that could be mistaken for true OAEs. OAE equipment should be calibrated routinely according to the schedule and procedures recommended by the manufacturer. Most clinical systems also provide feedback regarding stimulus levels and spectra as recorded by the probe microphone in the ear canal of the individual being assessed. Prior to testing, stimulus levels should be verified and adjusted, if necessary, to achieve desired SPL levels. If appropriate stimulus levels or spectra cannot be achieved, the probe should be inspected and the adequacy of its fit (size of ear tip, depth of insertion) evaluated.
- E. Patient Preparation: The most common source of noise in OAE recordings is physiologic noise from the child or infant (e.g., crying, sucking, breathing, movement). Newborns and infants must be resting or sitting quietly to record OAEs, so it may be optimal to test soon after eating or around their typical

naptime. Older children may sit quietly or be quietly distracted. Sedation is typically not necessary as OAEs are rapidly recorded.

F. Procedures:

- i. Otoscopy: Otoscopy should be performed prior to testing to assess the status of the external auditory canal and determine the size probe tip to be used for testing. The presence of vernix, cerumen or debris that could impede the ability to obtain a good test, through blockage of the probe ports or occlusion of the ear canal, should be noted.
- ii. General Probe Fit: The probe should be coupled to the ear with an appropriate size ear tip inserted deep into the ear canal using care to avoid debris in the ear that could block the ports in the probe. If adequate stimulus levels or spectra are not observed prior to testing, the probe should be removed, inspected, cleaned if necessary, and reinserted.
- iii. TEOAEs: Stimulus stability should be monitored in the ear canal during recording and should be 70% or higher for adequate measurements. This assures that the probe is firmly situated in the canal throughout testing. A recording time base of 20 ms following click onset is recommended. A shorter time base of 10 or 12.5 ms can be used for newborns to reduce low-frequency physiologic noise and accelerate testing (Kemp & Ryan, 1993; Whitehead et al, 1995a). The number of sweeps that should be acquired is variable and depends upon the response strength and amplitude, as well as the recording conditions. Once TEOAEs have reached a clear response level that remains stable, testing may be terminated (see interpretation). Alternatively, if the recording conditions are excessively noisy or TEOAE amplitude is small, the number of stimuli may be increased to improve the SNR.
- iv. DPOAEs: Stimuli intensity should be within +/- 3 dB of target levels. Other testing parameters, including the frequency range, number of points per octave, and stopping criteria should be selected based on the purpose of the evaluation, the population to be assessed, and the test conditions. A total of six to eight frequencies are typically tested in the mid- to high-frequency range (two to three points per octave), although fewer points may be used. In neonates and young infants, it may not be possible to measure a response with an f2 below 1500 Hz in due to high levels of physiologic noise (Gorga et al, 2000). Thus, when testing this population the frequency range should be restricted to f2s at 2000 Hz and above to maintain an acceptable noise floor and speed of testing. Recordings that show do not show unequivocal OAE presence or absence should be repeated to ensure reliability.
- v. In the event that OAE responses are absent, reduced in amplitude, or observed within a restricted frequency band, the audiologist should assure

that the OAE recordings were not compromised by environmental or patient-generated noise, inadequate stimulus levels or spectra due to occlusion of the ear canal, cerumen or debris within the probe assembly, or poor probe fit in the ear canal.

7. Test Interpretation and Reporting:

A. TEOAEs:

- i. TEOAEs are considered to be **present and normal** if: a response is observed with SNR > 3 to 6 dB in the majority of frequency bands assessed (Harrison & Norton, 1999; Norton et al, 2000a; Prieve et al. 2000; Spivak et al, 2000), the overall (wave) reproducibility is > 70% (Hurley & Musiek, 1994; Prieve et al, 1993), **and** the overall response amplitude is within the range typical for normal hearing children of comparable age (see 5. Normative Data above).
- ii. TEOAEs are considered to be **present, but not normal** if: a response is observed, but at fewer than 75% of frequency bands tested, the overall (wave) reproducibility is < 50% (even though a response is observed in isolated frequency bands; Kemp, et al, 1986), **or** the overall response amplitude is significantly lower than age-appropriate values.
- iii. TEOAEs are considered to be **absent** if: a response is not observed with a SNR of \geq 3 to 6 dB in more than one frequency band (i.e. nearly all data points are imbedded in noise) **and** the overall response reproducibility is less than 50% (Kemp, et al, 1986; Stevens & Ip, 1988).
- iv. TEOAEs are most effective in separating normal ears from non-normal ears in the region of 2000 to 4000 Hz, with slightly poorer separation at 1000 Hz.
- v. For hit and false alarm rates associated with various TEOAE stimulus levels, recording parameters, response criteria, and definitions of hearing loss, see: Harrison & Norton, 1999; Hussain et al, 1998; Prieve et al, 1993.

B. DPOAEs:

- i. DPOAEs are considered to be **present and normal** if: DPs are observed at a signal-to-noise ratios (SNR) > 3 to 6 dB at the majority of frequency bands assessed (Avan & Bonfils 1993; Lonsbury-Martin et al., 1990; Moulin et al., 1994; Smurzynski 1994) **and** the overall response is within the range typical for normal hearing children of comparable age (see 5. Normative Data above).

- ii. DPOAEs are considered to be **present but abnormal** if: DPs are observed at fewer than 75% of frequency bands assessed **or** the overall response amplitude is significantly lower than age-appropriate values.
 - iii. DPOAEs are considered **absent** if a response is not observed with a ≥ 3 to 6 dB SNR for more than one f2 frequency.
 - iv. DPOAEs are most effective in separating normal from non-normal ears in the region of 1500 to 6000 Hz (Gorga et al, 1997, 2005; Kim et al, 1996). Slightly poorer identification is achieved at ≤ 1000 Hz and at 8000 Hz.
 - v. For hit and false alarm rates associated with various DPOAE stimulus levels, recording parameters, response and hearing loss criteria, see: Gorga et al, 1997; 2005).
- C. For diagnostic purposes, OAE results should be interpreted within the context of a test battery, including acoustic immittance measures, electrophysiologic measures, and/or behavioral testing. A copy of the OAE data should be included with the audiometric report. When administered as part of such a battery, results may be reported in general as follows:
- i. When OAEs are present at normal amplitudes throughout the majority of frequency bands assessed, results may be reported as consistent with functional integrity of the outer hair cell system. In the absence of auditory neural dysfunction, normal amplitude OAEs are consistent with auditory sensitivity better than approximately 25 to 30 dB HL within the frequency regions of the evoking stimuli. This result, however, is not synonymous with “normal hearing”, in that OAEs do not reflect the integrity of the auditory system beyond the level of the cochlea.
 - ii. When normal middle ear function can be confirmed and recording conditions are judged to be adequate: a) the absence of OAEs suggests dysfunction involving the outer hair cell system and a sensory hearing loss of approximately 30 to 40 dB HL or greater; b) the presence of OAEs at reduced amplitudes or within a restricted range of frequencies may be an indicator of early or sub-clinical outer hair cell dysfunction and/or mild hearing loss and further assessment and/or follow-up is indicated (Shera & Abdala, In press).
- D. Because there are no universally established criteria for the degree of change in OAEs considered to clinically significant for the purpose of monitoring cochlear function (e.g., in children undergoing potentially ototoxic treatments), each facility should establish its own criteria based on the test-retest characteristics of the stimuli and protocols used.
- E. Due to inter-individual variability, caution should be used when attempting to predict auditory sensitivity based on OAEs.

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Appendix A: Helpful Hints for OAE testing

<p>Probe fit</p>	<p>A good probe fit is essential in OAE testing in order to ensure adequate signal delivery and minimize interference from ambient noise. Probe fit should be evaluated prior to data collection and the probe re-seated in the ear canal if necessary. A poorly fitting probe can result in failed stimulus calibration, an unstable stimulus, prolonged testing time, or failure of the test to run altogether.</p> <ul style="list-style-type: none"> • Although an air tight seal is not required, the probe should be seated deeply within the ear canal rather than sitting flush with ear canal opening. It is important to use the correct probe tip size for the ear canal and that the tip is fitted snugly on the probe. The tip should not be damaged or torn. • The procedure for seating the probe is the same as that for fitting insert earphones. To open and straighten the ear canal, gently pull the pinna upwards and back. The signal delivery and response collection ports of the probe should be facing the tympanum and not partially blocked by the probe tip or the canal wall. • Occasionally insertion of the probe tip will result in collection of debris from the ear canal within the probe tubes. If no stimulus or inadequate stimulus intensity levels are observed prior to testing, remove the probe, inspect for debris, and clean out the probe tubes, if necessary, prior to reinsertion. • Probe fit can be assessed as part of the stimulus calibration conducted prior to testing. For TEOAEs, the stimulus spectrum should be broad and fairly flat from approximately 1 to 5 kHz. Excessive high frequency “ringing” in the stimulus may indicate that the probe is partially blocked by the tip, ear canal wall or debris. For both TEOAEs and DPOAEs the stimulus level should be +/- 3 dB of the target SPL. If target stimulus levels cannot be achieved, the probe may not be seated deeply enough within the ear canal or may be failing out.
<p>Noise management</p>	<p>Noise, whether from internal (physiologic) or external (environmental) sources, may interfere with the ability to test, prolong testing time, and adversely impact signal-to-noise ratios. Noise levels should be monitored prior to and throughout testing. When excessive noise is noted, efforts should be made to identify the noise source, reduce the noise, and minimize its contribution to the OAE recording.</p> <ul style="list-style-type: none"> • Physiologic noise: The most common source of noise in OAE recordings in young children is physiologic noise (e.g., crying, sucking, breathing, movement). The following suggestions may help to calm the child and reduce physiologic noise that can interfere with testing: <ul style="list-style-type: none"> ▪ Newborns and infants: Schedule testing after feeding or when the baby is likely to be sleeping. Swaddling newborns and infants up to 3 to 4

months of age often serves to soothe them and encourage sleep. Placing a hand on infant's shoulder, head, or back may further serve to calm the baby. Avoid patting, however, as this may keep the baby aroused.

- Toddlers and older children: If possible, schedule testing for toddlers during their naptime. Older infants and toddlers often can be quietly distracted by the examiner or a test assistant or by playing a video with the sound turned off. Allowing the older child watch the OAE monitor while the instrumentation is in the data collection mode (i.e., "makes a picture") also may provide sufficient distraction for the length of time it takes to perform the test.
- In all cases, position and stabilize the probe cable away from child's body to prevent noise contamination from movement.
- Environmental Noise: Noise from external sources is more likely to be problematic when testing in locations other than a sound-treated booth.
 - Common sources of ambient noise include: ventilators or fans, running water (from sinks), equipment or computer noise (including OAE equipment), hallway noise or other "traffic" nearby, and conversations conducted near the testing area. If the environmental noise cannot be controlled it's source, schedule testing for a time when there is likely to be less noise or move infant or child to a quieter location for testing.
 - Poor probe fit may allow an excessive noise in the recording, especially if the testing is not conducted in a sound treated room. Make sure that the probe is seated appropriately within the ear canal and has not fallen, or in the process of falling, from the ear. If the noise problem persists for no apparent reason, check the calibration of the instrumentation.
- Noise levels should be monitored throughout the recording session and artifact rejection used to eliminate excessive contamination from myogenic, electrical, and environmental sources. Testing in continuous background noise in excess of approximately 50 to 55 dB A should be avoided. Increasing the number of averages can also improve the signal-to-noise ratio under noisy conditions.

Test Administration and Interpretation:	<ul style="list-style-type: none">• Acoustic immittance measures should be conducted prior to OAE testing to assess the status of middle ear system.• In ears with normal cochlear function, the spectrum of the TEOAE response will mirror the spectrum of the stimulus the ear canal. Thus, a TEOAE should not be interpreted as reduced or absent within frequency bands in which the stimulus was not adequately represented.• In DPOAE measurement, the complex interaction among recording parameters, emission source components, and individual ear anatomy can produce summations and cancellations within the ear canal, resulting in peaks and troughs within the OAE response, especially in normal ears. These idiosyncratic variations in amplitude at discrete frequencies within the overall response should not be over-interpreted as “islands” of hearing or hearing loss if adjoining frequency bands are not similarly affected.• Similarly, interpretation should not be based on the “combining” the several runs, in which a DP is “present” at a single frequency in one test run and “present” at another (different) frequency in second run (although absent in the first test run).
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Audiology Protocol - Electrophysiologic (EP) Evaluation

1. Test names: Tone-burst (TB)-Auditory Brainstem Response (ABR) and Auditory Steady-State Response (ASSR).
2. Purpose: To determine presence and type of hearing loss, and to estimate hearing levels for individual frequencies in each ear.
3. Population intended: Newborns and infants; a child of any age who is incapable of providing accurate information for behavioral tests or who has yielded behavioral test results that are not reliable or are incomplete.
4. Testing Frequency: These tests require the patient to be sleeping or sedated. They require long appointment times and significant patient preparation. After the initial full assessment is obtained, these tests should be repeated only if necessary and with caution when sedation is required.
5. Normative data: For ABR, see (Stapells 2000, Sininger et al. 1997, Hall 1992, Gorga et al. 1998). For ASSR, See Cone-Wesson, et al., 2002; Dimitrijevic et al., 2002; Johnson & Brown, 2005; Luts, et al., 2004; Perez-Abalo, et al., 2001; Ahn et al., 2007, Rance & Tomlin, 2006
6. Practice Guidelines
 - a. Test Environment and Patient Preparation
 - i) Testing area: Either ABR and/or ASSR should be performed in a quiet room or sound treated booth. When the procedures are performed with sedation/anesthesia, the surgery center, a procedure room or operating room are permissible. The space and power supply must be free of excessive electrical noise. The space should include a crib or secure area for infant.
 - ii) Equipment and Supplies: FDA-approved, auditory evoked potential computer with insert earphones and bone oscillator. Two-channel capability is advisable but not necessary. Supplies include electrodes, either disposable or those that can be disinfected, skin preparation gels, alcohol prep pads, electrode conduction cream/paste, surgical tape, gauze squares, variety of sizes of single-use or disinfectible earphone tips, an otoscope and specula.
 - iii) Stimuli and Calibration:
 - (1) **ABR**: Short duration tones of 6 ms or less (tone bursts or pips) consisting of at least at least 3 cycles of the frequencies specified are used (Sininger et al., 1996). Stimuli with nominal octave frequencies from 250 or 500 to 4000 Hz are used. The stimulus must be ramped on and off with an appropriate windowing function (Blackmann or linear ramps are appropriate). Alternating the polarity of the tone bursts will help to distinguish portions of the response that are neural and those that are

cochlear such as the cochlear microphonic (CM). The pre-neural cochlear response (CM) will change polarity along with the stimulus while the neural response (ABR) does not. However, the down side of alternating stimulus polarity is that this can induce some slight jitter in the neural response and slight latency differences will be found in response to rarefaction and condensation stimuli. While clicks do not provide frequency specific information and should not be substituted for tone bursts for diagnostic audiometric purposes, click ABR is used in the diagnosis of auditory neuropathy spectrum disorder (see section on auditory neuropathy).

- (2) **ASSR:** stimuli may be presented as individual carrier frequencies or multiple stimuli can be presented simultaneously. Each pure-tone carrier is amplitude modulated (AM), generally 100%, and may also be frequency modulated (FM) (Dimitrijevic, et al., 2002) or exponentially modulated.

Transducers: The transducer of choice is an insert earphone for air-conduction testing, and a standard clinical bone oscillator for bone conduction testing. For testing of children with ear canal stenosis or atresia, supra-aural earphones will be necessary. The bone oscillator is best placed on the mastoid posterior to the pinna of the test ear. When testing bone conduction in infants, crossover may be reduced relative to what is seen in older children and adults due to significant differences in the structure of infant and adult skulls. However, contralateral masking is still recommended to insure that the non-test ear is isolated for bone conduction testing. Forehead placement should be avoided for clinical testing because it yields smaller response amplitudes and higher thresholds than mastoid and temporal placement, which yield equivalent thresholds in pre-term infants (Small et al., 2007). Supra-aural headphones may be required in cases of ear canal stenosis and/or atresia as a supplement to obtaining bone-conducted thresholds.

Calibration:

(1) ABR stimuli: Initially 0 dB nHL (normalized Hearing Level) should be determined for each stimulus and transducer. This involves presenting the stimulus at the rate used for presentation in short bursts (1 second) in a sound treated environment. These stimuli are used to determine the threshold for each stimulus in a group of subjects with normal-hearing ears. At this time, either ear can be used to calibrate and the values will be acceptable as clinical calibration in either ear. The average threshold determined in this way is considered 0 dB nHL and ABR thresholds are referenced to this number. A recent standard, ISO 389-6, provides peak-equivalent, reference equivalent threshold in SPL (peRETSPL) data for threshold level click stimuli only. These are only appropriate for click stimuli. A peRETSPL can be determined for any short duration stimulus, such as a tone burst, in the manner described by (Richter & Fedtke 2005). Once the peRETSPL is determined for the 0 dB nHL for tone bursts, this

value can be used for subsequent checking of physical output levels without the need for subjective judgments.

(2) ASSR stimuli: ASSR tonal stimuli should be calibrated in dB HL according to the ANSI standard for pure-tones (ANSI, 1996), or in dB nHL using a small group of normative subjects (Rance et al., 2006).

Sedation and Patient Preparation

More than any other audiologic test, it is imperative that children sleep soundly for a prolonged period of time, to obtain clean, low-noise electrophysiologic recordings. Natural sleep is best but when this cannot be assured, sedation is necessary. (See introduction regarding sedation protocols.) Patients must be managed appropriately prior to their appointments to facilitate a quietly sleeping child. When testing children in natural sleep it is important to develop a protocol for parents that includes depriving the child of sleep prior to the test (including time in transit) and often involves bringing children to the appointment hungry and asking the parent to feed the child after electrode preparation to help induce sleep. It is not uncommon for a complete electrophysiologic evaluation to be conducted in two or more test sessions. It is advisable to prepare the parents for that possibility when scheduling the initial appointment.

Electrode Preparation: To prepare skin for electrode application with electrode prep cream; carefully clean and mildly abrade skin. Disposable electrodes are recommended for infection control. Electrode placement is as follows: the electrode connected to the positive (non-inverting) connection on the amplifier should be at midline, preferably vertex (C_z) or high forehead (F_{pz}). The negative (inverting) electrode should be applied to the mastoid, earlobe or to the nape of neck at the midline. Earlobe or nape electrodes will minimize interference when testing by bone-conduction. The ground electrode on opposite ear is convenient but it can be elsewhere on head. Two channel recordings are recommended for ABR if possible. The second channel can include the vertex or high forehead (+) to the nape of the neck or to the contralateral mastoid or earlobe (-). Electrode impedance should be no more than 5 kOhms between any electrode pair and should be matched across pairs within 1 kOhms. Once electrodes are in place, insure that child is comfortable (dry, fed) and attempt to induce sleep. Infants or children who are unable to sleep for adequate time may need sedation. Once asleep, place the child in a secure area for testing and observation.

B. Procedure **ABR**

- i. Recording bandwidth: High-pass filter should be 30-50 Hz if possible or 100 Hz only if noise does not permit use of a lower frequency. High pass filters settings above 100 Hz are not recommended. Low-pass filter should be in the region of 1000 to

1500 Hz (Sininger 1995). Filter slopes should be no more than 12 dB per octave. The data analysis window should be a minimum of 20 ms.

- ii. Amplifier settings and Artifact Rejection: The amplifier is generally set to 100,000 X amplification. Artifact rejection is generally a user-adjustable parameter. The level of artifact rejection should be set so that a very quiet patient would produce about 5-10% rejection. It is reasonable to raise the reject level for moderately noisy patients but if the standard rejection level is producing 40-50% rejection or more, the noise must be reduced in ways other than raising the rejection level (reduce electrode impedance, soothe the patient or wait for sleep.)
- iii. Recommended stimulus rate is 27-39/s. The protocol should be set by default to at least 6000 sweeps and stopped manually when a clear response is detected. A minimum of 1000 sweeps are always needed to insure a stable response. Reliability can be evaluated by repeating an average at least once or by the use of valid response detection criteria such as F_{sp} (Don 1989, Sininger 1993). At threshold, or if child is noisy, more sweeps (4000 to 6000 or more) may be necessary to achieve a quality response in which the waveform is clear. Under sedation, fewer sweeps should be necessary in general. Given time limitations, response repetition can be used only as necessary to clarify presence/absence of response. When automated response detection facilities are available they should be utilized to determine number of sweeps needed and reliability of response presence/absence.
- iv. Standard threshold search procedures should be employed, starting at 50 or 60 dB nHL. If clear response is seen, decrease intensity in 20 dB steps, using an up 10 dB, down 20 dB bracketing procedure to determine threshold. Threshold determination below 15-20 dB HL is generally not necessary. It is also reasonable for experienced clinicians to begin testing at screening levels (35-40 dB) in order to quickly identify normal and near normal thresholds. If a response is not clearly observable, increase intensity by 20 dB steps until clearly observed, and continue the bracketing procedure. Unless otherwise indicated, testing should start with a high frequency (for example 2000 Hz) in one, and then the opposite ear, followed by a low frequency (500 Hz). It is valuable to alternate ears if possible to have information on both if the child wakes up before the test is complete. Bone conduction assessment at 500 Hz, followed by 2000 Hz, with contralateral masking as necessary, should immediately follow unless the air conduction thresholds are unequivocally normal. Time permitting, additional frequencies (for example, 4000 Hz followed by 1000 Hz) should be assessed.

C. Procedure **ASSR**

- i. ASSR Recording Bandwidth: High-pass should be 1-65 Hz. Low-pass should be 250-300 Hz. Artifact Rejection: Monitoring residual noise and response amplitude or artifact level will be critical in determination of response presence or absence and in making judgments about when to change intensities. Some commercially available systems monitor residual noise estimates automatically by using adaptive modeling techniques that estimate the response and noise while adjusting the estimates of amplitude and phase over a series of sweeps (Vander Werff, 2009). Response amplitudes are smaller at lower stimulus intensities and will likely require longer test time. Response amplitudes are smaller in newborns than older infants and children, so lower noise levels are required. Less recording time is typically required for quiet, sleeping, or sedated patients.
- ii. ASSR in infants should be elicited using modulation rates between 75 and 110 Hz (Rickards et al. 1994).
- iii. Some commercially available systems allow for simultaneous testing of multiple frequencies in both ears (unique modulation rates should be employed for each individual frequency). If simultaneous testing is not possible, testing should begin with a high-frequency (for example 2000 Hz) in first one, and then the opposite ear, followed by a low frequency (500 Hz). Time permitting, additional frequencies (for example, 4000 Hz followed by 1000 Hz) should be assessed.
- iv. Standard threshold search procedures should be employed, starting at a moderate intensity, using a bracketing technique. It is also reasonable for experienced clinicians to begin testing at screening levels (35-40 dB) in order to quickly identify normal and near normal thresholds. If a response is not clearly observable, increase intensity by 20 dB steps until clearly observed and continue the bracketing procedure. If multiple frequencies are being presented, bracketing may need to be modified somewhat, according to the system being used, particularly if there is any slope to the patient's hearing loss. In cases of sloping hearing loss or disparate thresholds between ears, it may be advisable to switch to a single-frequency test modality to simplify the bracketing process.
- v. It is not advisable to attempt to measure bone conduction thresholds with ASSR because of the increased risk of detecting stimulus artifact with the automated analysis techniques. It may be possible to obtain accurate bone conduction threshold estimates if the responses are within normal limits but artifactual responses have been detected at moderate to severe hearing levels making interpretation difficult when significant hearing loss exists (Small & Stapells 2004, Swanepoel et al. 2008). While alternating stimulus polarity and the use of additional anti-

aliasing filters can reduce artifactual response detection, the risk of errors in estimating bone conduction thresholds using ASSR outweighs any potential advantages. Infants with more than a mild hearing loss should have bone conduction thresholds measured using tonal ABR. Any disparities between air conducted ASSR and bone conducted tonal ABR thresholds should be cross-checked with air conducted tonal ABR.

- D. Special Populations: Auditory Neuropathy Spectrum Disorder (ANSD): If there is no ABR response to 2000 Hz by air conduction at the limits of the equipment, or if all ASSR thresholds are not within normal limits, an assessment for ANSD should be initiated. Using a high-level (80 dB nHL) click stimulus in each of the two single polarities (rarefaction, condensation), record ABR, and plot two responses on top of each other, inspecting the waveform for cochlear microphonic (Starr et al. 2001). Repeat in opposite ear. If CM is present, and the ABR waveform is poorly developed or absent, results may indicate ANSD, and further threshold measures with ABR or ASSR should be discontinued. To distinguish CM from stimulus artifact, conduct one additional average with the earphone tubing clamped or disconnected. The CM should disappear. If not, it is probably stimulus artifact. If not done previously, conduct an OAE assessment.

All infants with elevated EP thresholds should have thresholds measured by bone conduction using tonal ABR. If the baby is to be fitted with hearing aids, bone conduction thresholds must be determined in order to establish appropriate gain and output targets. If the baby has ear canal atresia, bone conduction must be tested. If atresia is unilateral, air conduction testing should be conducted in the open ear and bone conduction should be performed on the side of the atretic ear, utilizing appropriate contra-lateral masking.

7. Test Interpretation and Reporting requirements. When possible, obtain tympanogram, acoustic reflex thresholds and otoacoustic emissions prior to recording. This information will be necessary for test interpretation. Note that presence of middle ear effusion is not a contraindication to testing, and EP testing should not be delayed until effusion has cleared.

ABR: Individual clinics may decide to apply correction factors to EP thresholds to predict behavioral thresholds. To predict the behavioral air conduction threshold from the ABR threshold, for example, a frequency-specific correction factor would be subtracted. VanderWerff et al. (2009) found that correction factors of 5 dB, 0 dB and -10 dB for 500, 2000 and 4000 Hz respectively (as suggested by Stapells, 2000) produced an excellent prediction of behavioral threshold from ABR thresholds in infants.

In contrast to air conduction thresholds, no correction should be applied to ABR 500 or 2000 Hz ABR bone conduction thresholds for infants. In fact, an air-bone gap of about 15 dB is expected for uncorrected 500 Hz ABRs in an infant without middle ear involvement (Vander Werff et al. 2009). Therefore, at 500 Hz, only

air-bone gaps that exceed 15-20 dB should be considered clinically significant for middle ear involvement in infants. Air-bone gaps at 2000 Hz can be interpreted as usual.

ASSR: Correction factors are typically applied to ASSR thresholds in order to estimate behavioral hearing levels. A 10 dB correction is widely used but some have found the difference between behavioral thresholds and ASSR to vary by carrier frequency and by test duration (see Dimitrijevic et al. (2002) and Small and Stapells (2006) for more information on air and bone conduction correction factors for ASSR).

The professional training of the target audience should be considered in report-writing (e.g., medical, educational personnel). Raw ABR data (waveforms and/or ASSR data e.g. response criterion, response amplitude) should be included along with narrative report. A clear definition of the limitations of ABR and/or ASSR as a tool to predict "hearing threshold" should be included. The clinician should indicate any correction factors utilized. A statement of interpretation of results, in terms of speech-language and auditory development, and proposed treatment plan, should be included.

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<http://aappolicy.aappublications.org/>

British Columbia Infant Diagnostic Protocols

<http://www.phsa.ca/NR/rdonlyres/EAD072EA-0C0E-40C6-830A-557357C14DA5/32441/DAAGProtocols1.pdf>

ABR/ASSR Clinical Tips

<http://www.courses.audiospeech.ubc.ca/haplab/clinic.htm>

Appendix A: Helpful Hints for electrophysiological testing.

As with most things, concentration on the basics is important to obtaining good EP recordings from infants and toddlers. These are some principles to keep in mind:

<p>Electrodes</p>	<ul style="list-style-type: none"> • When beginning the evaluation, insuring that electrodes are secure and have low impedance will pay off throughout the evaluation. Low, balanced electrode impedance will help ensure that the common mode rejection on your amplifier will be able to reduce the overall noise in recordings. (Noise is enemy #1.) Be diligent in cleaning the skin. Slightly rough gauze pads with some electrode prep gel work well. The skin may get pink and parents should be told that some irritation is normal. Do not worry if the baby cries, this is normal. One trick is to take some conducting gel or electrode cream and rub it into the cleaned area. As the cream sinks into the skin, it can create a conducting bridge between the skin and the electrode. You can put some of the same electrode cream on the inside surface of the electrode even if it is pre-gelled. Mixing conducting media won't hurt. Use tape if necessary to secure the electrodes so that they do not come off during testing. Sometimes it takes a minute or so for the electrode impedance to come down so wait to see if it does. If impedance remains high, do not hesitate to take off the offending electrode and scrub again. Periodically re-check electrode impedance during testing, especially if the recording becomes noisy, as electrodes can dislodge. • If you are re-using electrodes after proper disinfecting, check to ensure that they are functional by shorting them together to observe 0 Ohm resistance! • Manage electrode leads well. Another trick is to place electrodes so that the leads are pointing toward the back and top of the head. Then draw them all back like a pony-tail and secure them together at the top of the head. Braid the remaining wires together or connect them with tape and lead the bundle off to the amplifier or head box. This procedure helps to ensure that all the wires will experience the same noise (better common mode rejection) and that the baby will be less likely to grab one and pull it off. Ensure that the leads are far away from any stimulus cables.
<p>Physical Setup</p>	<ul style="list-style-type: none"> • Avoid having the parent hold the baby. Holding the baby may be good to get the baby to sleep but it is not a good way to insure a long, quiet recording session. The parent gets tired, fidgety and hot. The parent also obstructs the view of the earphones and electrodes. Try a basinet like the one used in the hospital nursery. Wrap the baby securely in a swaddling blanket. Let the baby cry if necessary while comforting with gentle pats or a hand on the back. If you are comfortable with this, the parent will be as well. • Ensure that you can see the earphone at all times during testing, as it is not uncommon that the earphone tip works its way out of the ear canal.

Test Order	<ul style="list-style-type: none">• Prioritize test stimulus order to maximize information; hearing aids can be fitted based on a single low frequency (500 Hz) and a single high frequency (2000 Hz) threshold. Bone conduction thresholds should be obtained as early as possible in the diagnostic session, when elevated thresholds are measured for any frequency, prior to pursuing other frequencies by air conduction.
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